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Clinical Study Report Errata List

Drug substance	Quetiapine fumarate
Study code	5077US/0049
Date	28 November 2005

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

Study dates:	First patient enrolled: 30 September 2002 Last patient completed: 17 September 2003
Phase of development:	Therapeutic confirmatory (IIIb)
International Coordinating Investigator:	Not applicable
Sponsor's Responsible Medical Officer:	Martin Brecher, MD, DMSc

5077US/0049 ERRATA LIST

Page	Section, location	Reads	Should read
2	Synopsis	**Phase of development** Therapeutic use (IV)	**Phase of development** Therapeutic confirmatory (IIIb)
28-30	Appendix 12.1.9, right-hand column of table	**Exclu**	**Exclude ITT**
		Decisi review	Decision on review

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Clinical Study Report

Drug substance:	Quetiapine fumarate
Study code:	5077US/0049
Date:	20 July 2005

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

Study dates:	First patient enrolled: 30 September 2002 Last patient completed: 17 September 2003
Phase of development:	Therapeutic confirmatory (IIIb)
Sponsor's Responsible Medical Officer:	Martin Brecher, MD, DMSc

This study was performed in compliance with Good Clinical Practice.

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Drug product:	SEROQUEL	**SYNOPSIS**	
Drug substance(s):	Quetiapine fumarate		
Study code:	5077US/0049		
Date:	20 July 2005		

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

Study centers

This study was conducted in 39 centers in the USA.

Publications

Calabrese JR, Keck PE Jr, Macfadden W, Minkwitz M, Ketter TA, Weisler RH, Cutler AJ, McCoy R, Wilson E, Mullen J. A randomised, double-blind, placebo-controlled trial of quetiapine in the treatment of bipolar I or II depression. Am J Psychiatry 2005; 162:1351-50.

Study dates		**Phase of development**
First patient enrolled	30 September 2002	Therapeutic use (IV)
Last patient completed	17 September 2003	

Objectives

Primary:

To evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

1. The change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score
2. the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment
3. the change from baseline to each assessment in the MADRS total score

4. the change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression – Severity (CGI-S)

5. the Clinical Global Impression – Improvement (CGI-I)

Secondary:

1. to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who meet the criteria for treatment-emergent mania on the Young Mania Rating Scale (YMRS) or report an adverse event of mania or hypomania

2. to evaluate the effect of quetiapine on anxiety compared to placebo by comparing

   – the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

   – the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

3. to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by comparing

   – the incidence and nature of all adverse events

   – the incidence and nature of drug-related adverse events

   – patient withdrawal due to adverse events during double-blind treatment

   – the number of patients having clinically significant changes in vital signs from baseline to end of treatment

   – the change in Simpson-Angus Scale (SAS) total score

   – the change in Barnes Akathisia Rating Scale (BARS)

   – the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Exploratory

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment.

Study design

This study was a randomized, multicenter, double-blind, placebo-controlled, double-dummy, parallel group, fixed-dose comparison of quetiapine vs placebo in the treatment of bipolar depression. Randomized treatment assignment was stratified in a 1:1:1 ratio for drug within bipolar diagnosis (bipolar I vs bipolar II).

Target subject population and sample size

Outpatients, aged 18 to 65 years, with a diagnosis of bipolar I or bipolar II disorder with a current major depressive episode of duration less than one year but greater than 4 weeks were enrolled in the trial. The patient's HAM-D (17-item scale) score had to be ≥20; the HAM-D item 1 (depressed mood) score had to be ≥2; the YMRS score had to be ≤12 at both Visit 1 and Visit 2 (randomization) for the patient to be eligible for entry into the trial. Approximately 530 patients were expected to be enrolled in the trial to obtain 504 evaluable patients.

Investigational product and comparator: dosage, mode of administration and batch numbers

Quetiapine fumarate was increased in a blinded manner to a total daily dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and to a total daily dose of 600 mg/day by Day 8 in the 600 mg/day treatment group. Thereafter, oral doses of the study drug were administered in a blinded fashion once daily at bedtime (qhs) in a dose of 300 or 600 mg/day. One-time dose reductions for intolerability of 100 mg/day in both the 300 mg/day and in the 600 mg/day treatment groups were allowed at the discretion of the investigator after Day 8. Placebo was administered once daily with tablets matching in number and appearance to blinded quetiapine dosing. Study treatment was given in tablets of the following doses (lot #): quetiapine 25 mg (7527F), quetiapine 100 mg (7513H), quetiapine 200 mg (7541F), placebo 25 mg match (7553F), placebo 100 mg match (7550F), placebo 200 mg match (1509C).

Duration of treatment

Patients received double-blind, double-dummy treatment for up to 8 weeks (56 days), following an initial washout period of between 7 to 28 days (depending on the medications involved) and came in to the clinic on Day 57 for final assessments.

Criteria for evaluation (main variables)

Efficacy

- Primary variable: Montgomery-Asberg Depression Rating Scale (MADRS) Total score change from baseline at last assessment

- Secondary variables: Percentage of patients with a ≥50% reduction from baseline to final MADRS Total score, MADRS Total score change from baseline at each assessment, Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, Clinical Global Impression Severity of Illness (CGI-S) score, Clinical Global Impression Improvement (CGI-I) score, Young Mania Rating Scale (YMRS) Total score, Hamilton Rating Scale for Anxiety (HAM-A), Pittsburgh Sleep Quality Index (PSQI), Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)

Safety

Safety assessments included: adverse events, patient withdrawal due to adverse events, adverse events of special interest (EPS, diabetes, mania/hypomania, suicidality), hematology and chemistry findings, vital signs, Simpson-Angus Scale (SAS), the Barnes Akathisia Rating Scale (BARS) and specific inquiries of relevant data for metabolic syndrome, cardiac function, neutropenia/agranulocytosis and thyroid function.

Statistical methods

All statistical tests were 2-sided. The primary analyses used last observation carried forward (LOCF) for the time period of interest. Analysis of Covariance (ANCOVA) was used for comparative analysis of continuous variables with the baseline score as the covariate and including treatment and diagnosis strata as fixed effects and center as a random effect in the model. The Simes-Himmel step up procedure was used to control for multiple comparisons with placebo for the MADRS change from baseline in order to preserve the overall experiment-wise error rate and conserve power. Cochran-Mantel-Haenszel Chi square tests (CMH) were used for categorical comparisons. Descriptive statistics were used for safety assessments except for SAS and BARS which were analyzed by CMH.

Subject population

Baseline subject characteristics are shown in Table S1.

Table S1 Patient population and disposition

		Treatment group		
		Quetiapine 300 mg (N=172)	**Quetiapine 600 mg (N=170)**	**Placebo (N=169)**
Demographic characteristics (ITT population)				
Sex (n and % of subjects)	Male	79 (45.9)	71 (41.8)	64 (37.9)
	Female	93 (54.1)	99 (58.2)	105 (62.1)
Age (years)	Mean (SD)	36.6 (11.2)	37.3 (11.4)	38.3 (11.08)
	Minimum	18	18	18
	Maximum	65	63	62

Table S1 Patient population and disposition

		Treatment group		
		Quetiapine 300 mg (N=172)	**Quetiapine 600 mg (N=170)**	**Placebo (N=169)**
Race (n and % of subjects)	Caucasian	141 (82.0)	144 (84.7)	129 (76.3)
	Black	23 (13.4)	18 (10.6)	26 (15.4)
	Oriental	0 (0)	1 (0.6)	2 (1.2)
	Hispanic	7 (4.1)	5 (2.9)	9 (5.3)
	Other	1 (0.6)	2 (1.2)	3 (1.8)
Baseline disease characteristics				
DSM-IV diagnosis [n and (%)]				
Bipolar I disorder		116 (67.4)	114 (67.1)	112 (66.3)
Bipolar II disorder		56 (32.6)	56 (32.9)	57 (33.7)
Baseline MADRS	Mean (SD)	30.3 (5.0)	30.3 (5.3)	30.6 (5.3)
Screening HAM-D	Mean (SD)	24.3 (3.1)	24.8 (3.6)	24.7 (3.4)
Screening YMRS	Mean (SD)	4.9 (2.8)	4.8 (3.2)	4.9 (3.2)
Baseline CGI-S	Mean (SD)	4.4 (0.5)	4.5 (0.6)	4.4 (0.6)
Baseline HAM-A	Mean (SD)	18.7 (7.3)	18.7 (7.3)	18.9 (7.2)
Disposition (all enrolled)				
N (%) of patients	Completed	121	98	107
	Discontinued	60	82	74
N safety[a]		179	180	180
N efficacy ITT[b]		172	170	169
N efficacy PP		152	147	154

a Number of subjects who received at least one dose of study drug
b Number of subjects who took at least 1 dose of study treatment and had at least 1 data point after dosing, excluding 2 patients who enrolled at 2 separate sites.
ITT=Intention to treat; N=Number; PP=Per-protocol

The three groups were well-matched as to number and demographic and baseline disease characteristics. Adverse events were the main reason for withdrawal in quetiapine-treated patients, while lack of efficacy was the main reason for withdrawal in placebo-treated patients.

Efficacy results

The comparison of change from baseline in total MADRS score supported the hypothesis that quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment of a

depressive episode in patients with bipolar disorder was superior to placebo in reducing the level of depressive symptoms. A treatment advantage for quetiapine over placebo was statistically significant by Day 8 and continued to be so through Day 57. Analysis of secondary outcome variables also supported the superiority of quetiapine over placebo in the treatment of depression in patients with bipolar disorder. For most secondary outcome variables the treatment advantage was apparent by Day 8 and continued through Day 57.

Table S2 Efficacy results at final assessment (LOCF, ITT population)

Outcome variable	Quetiapine 300 mg (N=172)		Quetiapine 600 mg (N=170)		Placebo (N=169)	
	Day 8	Day 57	Day 8	Day 57	Day 8	Day 57
MADRS LS mean change from baseline	-8.67[a]	-16.39[a]	-8.78[a]	-16.73[a]	-4.89	-10.26
Proportion with ≥50% MADRS response	17%	58%[a]	24%[a]	58%[a]	11%	36%
HAM-D LS Mean change from baseline	-8.01[a]	-13.38[a]	-7.95[a]	-13.84[a]	-4.64	-8.54
HAM-D Item 1 LS mean change from baseline	-0.73[b]	-1.65[a]	-0.73[b]	-1.68[a]	-0.47	-1.11
CGI-S LS mean change from baseline	-0.58[a]	-1.63[a]	-0.56[a]	-1.66[a]	-0.26	-0.95
Proportion improved on CGI-I	19%[c]	64%[a]	22%[b]	56%[a]	10%	34%

a $p<0.001$ comparison with placebo
b $p<0.01$ comparison with placebo
c $p<0.05$ comparison with placebo

Safety results

Both the 300 mg and 600 mg once-daily doses of quetiapine were generally well-tolerated. Analysis of adverse events indicated that nervous and gastrointestinal events predominated, with dry mouth, sedation, somnolence, dizziness and constipation occurring at higher rates with quetiapine compared to placebo. Most adverse events were mild to moderate. Sedation and somnolence were the adverse events most associated with discontinuation by quetiapine-treated patients, with higher rates of discontinuation in the quetiapine 600 mg group. SAEs were infrequent in all treatment groups. Treatment emergent mania and hypomania were low in incidence and did not differ across the treatment groups. An increase in the incidence of EPS events was noted for both groups of quetiapine-treated patients. The incidence of adverse events associated with suicidality for quetiapine-treated patients was no different than that for placebo-treated patients. No cases of neutropenia or agranulocytosis following quetiapine

treatment were reported. Increases in weight, triglycerides, total cholesterol and LDL, and decreases in HDL were consistent with the known safety profile for quetiapine.

Table S3 Adverse event overview (safety population)

Category of adverse event	Number (%) of subjects who had an adverse event in each category[a]					
	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
Any adverse events	166	(92.7)	165	(91.7)	148	(82.2)
Serious adverse events	6	(3.4)	9	(5.0)	16	(8.9)
Serious adverse events leading to death	0	(0)	0	(0)	0	(0)
Discontinuations of study treatment due to adverse events	29	(16.2)	47	(26.1)	15	(8.3)

[a] Subjects with multiple events in the same category are counted only once in that category. Subjects with events in more than 1 category are counted once in each of those categories.

Table S4 Adverse event incidence of at least 5% sorted by decreasing order within the quetiapine 300 mg group (safety population)

Preferred term	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
	n	(%)	n	(%)	n	(%)
Dry mouth	79	(44.1)	73	(40.6)	14	(7.8)
Sedation	53	(29.6)	58	(32.2)	11	(6.1)
Somnolence	49	(27.4)	44	(24.4)	15	(8.3)
Dizziness	30	(16.8)	41	(22.8)	15	(8.3)
Headache	22	(12.3)	18	(10.0)	36	(20.0)
Constipation	21	(11.7)	20	(11.1)	8	(4.4)
Fatigue	16	(8.9)	21	(11.7)	13	(7.2)
Nausea	14	(7.8)	16	(8.9)	23	(12.8)
Dyspepsia	12	(6.7)	17	(9.4)	10	(5.6)
Lethargy	11	(6.1)	16	(8.9)	3	(1.7)
Nasal congestion	10	(5.6)	12	(6.7)	3	(1.7)
Upper Respiratory Tract Infection NOS	9	(5.0)	13	(7.2)	18	(10.0)
Akathisia	9	(5.0)	9	(5.0)	2	(1.1)
Diarrhea NOS	8	(4.5)	11	(6.1)	15	(8.3)
Insomnia	8	(4.5)	7	(3.9)	9	(5.0)

Preferred term	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
	n	(%)	n	(%)	n	(%)
Appetite increase NOS	7	(3.9)	10	(5.6)	3	(1.7)
Vision blurred	5	(2.8)	13	(7.2)	3	(1.7)
Weight increased	3	(1.7)	11	(6.1)	1	(0.6)
Pain in extremity	2	(1.1)	9	(5.0)	4	(2.2)

Conclusions

- Quetiapine in doses of either 300 mg or 600 mg once-daily was superior to placebo in treating depression in patients with bipolar disorder.
- The antidepressant effect of quetiapine treatment was observed as early as 7 days after treatment initiation and was maintained throughout the 8-week treatment course.
- Quetiapine in doses of either 300 mg or 600 mg once-daily was superior to placebo in treating anxiety symptoms in patients with bipolar disorder who were experiencing a depressive episode.
- Quetiapine in doses of either 300 mg or 600 mg once-daily was superior to placebo in improving the quality of life for patients with bipolar disorder who were experiencing a depressive episode.
- Quetiapine in a dose of either 300 mg or 600 mg once-daily was generally safe and well-tolerated in patients with bipolar disorder who were experiencing a depressive episode. A higher rate of discontinuations due to sedation and dizziness was seen with the 600 mg once-daily dose. The most common adverse events associated with quetiapine treatment were dry mouth, somnolence, sedation, dizziness and constipation.
- Quetiapine in doses of either 300 mg or 600 mg once-daily was associated with low rates of treatment-emergent mania or hypomania similar to placebo.

Date of the report

20 July 2005

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

The following abbreviations and special terms are used in this study report.

Abbreviation or special term	Explanation
AE	Adverse event (see definition in Section 5.5.7.2).
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BID	twice daily
BMI	Body Mass Index
BPRS	Brief Psychiatric Rating Scale
BUN	Blood urea nitrogen
CGI-I	Clinical Global Impression Improvement scale
CGI-S	Clinical Global Impression Severity of Illness scale
CHM	Cochran-Mantel-Haenzel test
CRF	Case report form
CRO	Contract research organization
DSM-IV	Diagnostic and Statistical Manual of the American Psychiatric Association, ed. IV-TR
ECG	Electrocardiogram
EPS	Extrapyramidal symptoms
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D	Hamilton Rating Scale for Depression
HCG	Human Chorionic Gonadotropin
$HOMA_R$	Homeostatic Model Assessment of insulin resistance
ICH	International Conference on Harmonisation
ICI-D	Interactive Computer Interview for Depression
ICTI	Interactive Clinical Technologies, Inc.
IRB	Institutional Review Board
ITT	Intention to treat

Abbreviation or special term	Explanation
IVRS	Interactive voice recognition system
LLN	Lower limit of normal
LOCF	Last observation carried forward
LRA	Lineberry Research Associates
MADRS	Montgomery-Asberg Depression Rating Scale
MMRM	Mixed Model Repeated Measures
MedDRA	Medical Dictionary for Regulatory Affairs
NA	Not applicable
NOS	Not otherwise specified
OC	Observed cases
OFC	Olanzapine-fluoxetine combination
PP	Per-protocol
PR	P-R interval
PRO	Patient-reported outcomes
PSQI	Pittsburgh Sleep Quality Index
qd	once daily
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QUEST	Quetiapine Experience with Safety and Tolerability Trial
QUICKI	Quantitative Insulin Sensitivity Check Index
QRS	Q-R-S interval
QT	Q-T interval
QT_C	Q-T interval with Fridericia correction
RBC	Red blood cell count
SAE	Serious adverse event (see definition in Section 5.5.7.2)
SAS	Simpson-Angus Scale
SCID	Structured Clinical Interview for DSM-IV TR
T3RU	Triiodothyronine resin uptake
T4	Thyroxine
TSH	Thyroid stimulating hormone
ULN	Upper limit of normal
WBC	White blood cell count
YMRS	Young Mania Rating Scale

1. ETHICS

1.1 Ethics review

The study protocol, including Amendments 1 through 5, was approved by the Institutional Review Board (IRB) for each study site.

Names and addresses of each of the IRBs for each of the centers is provided in Appendix 12.1.3.

1.2 Ethical conduct of study

The study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with ICH/Good Clinical Practice and applicable regulatory requirements and the AstraZeneca policy on Bioethics.

1.3 Patient information and consent

Patients gave written, informed consent before screening. The master version of the consent form is included in Appendix 12.1.2.

2. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

2.1 Staff at investigational sites

Participating personnel at study sites are listed in Appendix 12.1.4.1.

2.2 AstraZeneca study personnel

Table 1 AstraZeneca study personnel

Name	Position	Role in study
Nadine Everett	Principal Statistical Programmer	Team SAS Programmer
James Gaddy, PhD	Medical Communication Scientist	Clinical Study Report Author
Robin McCoy, RN	Senior Clinical Research Scientist	Clinical Study Team Leader
Wayne Macfadden, MD	Director, Clinical Research	Team Physician
Margaret Minkwitz, PhD	Director, Biostatistics Project Team	Team Statistician
Jeris Minor	Clinical Data Analyst	Database Manager
Joy Russo	Senior Statistical Programmer	Statistical Programmer
Michele Gelman	Drug Safety Scientist	Drug Safety Representative
Ellis Wilson	Program Development Leader	Team Project Manager

2.3 Other participants

2.3.1 Non-sponsor organizations or individuals

Monitoring of study sites, clinical data base administration, and safety reporting services were provided by Lineberry Research Associates, Inc (LRA). A complete list of participating LRA personnel is included in Appendix 12.1.4.4.

ECG scoring and interpretation was performed by eResearch Technology, Inc. A complete list of participating eResearch Technology personnel is included in Appendix 12.1.4.4.

Quintiles Laboratories served as the central laboratory for this trial. A complete list of participating Quintiles Laboratories personnel is included in Appendix 12.1.4.4.

Concordant Raters, Inc. trained investigators in the administration of the Montgomery-Asberg Depression Rating Scale (MADRS), the Hamilton Rating scale for Depression (HAM-D), the Hamilton Rating scale for Anxiety (HAM-A) and the Young Mania Rating Scale (YMRS). Concordant Raters also supplied the ICI-D to selected study sites and monitored results of

testing (see Section 5.6.1). A complete list of participating Concordant Raters personnel is included in Appendix 12.1.4.4.

Randomization of treatment assignments was provided by Interactive Clinical Technologies, Inc. (ICTI). A complete list of participating ICTI personnel is included in Appendix 12.1.4.4.

2.3.2 Study committee(s)

No study committees were utilized for this trial.

3. INTRODUCTION

Quetiapine fumarate (SEROQUEL®, quetiapine) is a dibenzothiazepine derivative approved by the United States Food and Drug Administration (FDA) on 26 September 1997 following clinical development by AstraZeneca Pharmaceuticals LP (also referred to as the sponsor) for the treatment of subjects with schizophrenia. Quetiapine fumarate is designated chemically as bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl) piperazin-1-yl]ethoxy)ethanol] fumarate.

The bipolar disorders are psychiatric disorders in which a disturbance in mood is the predominant feature. Bipolar I disorder is characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes. Bipolar II disorder is characterized by one or more major depressive episodes accompanied by at least one hypomanic episode. Bipolar depression refers to the major depressive episodes that occur with bipolar I and II disorder.

The prevalence of bipolar disorder is estimated to be 1 to 3.5%, evenly divided between men and women. The length of time between onset and symptoms and proper diagnosis and treatment is approximately 10 years and it is estimated that only 60% of those suffering from a bipolar disorder are receiving appropriate pharmacotherapy.

Although there is extensive and emerging literature guiding the treatment of the manic phase of bipolar I disorder as well as many approved compounds for the treatment of unipolar depression, the treatment of bipolar depression has not been as widely studied. The use of currently available antidepressants for monotherapy for bipolar depression may require careful clinical monitoring as they may “switch” patients into hypomania or mania from depression, or increase cycle acceleration in patients with a rapid cycling course. The adjunctive use of mood stabilizing medications such as lithium carbonate ($LiCO_3$) is common and may decrease the likelihood of these complications.

Evidence indicates that medications with mood stabilizing properties which produced low levels of mania, hypomania, or cycle acceleration may be useful as monotherapy in the treatment of bipolar depression. The antiepileptic lamotrigine produced improvement in HAM-D and MADRS scores in a 7-week, double-blind, placebo controlled trial for the patients who completed this study (Calabrese 1999). The anti-manic agent divalproex demonstrated numerical improvement over placebo in the percentage of patients with bipolar depression having a 50% reduction in the HAM-D scores without mania in an 8 week trial

(Sachs 2001) but this difference was not statistically significant. Lithium carbonate, also approved for the treatment of mania, has been demonstrated to be effective in reducing the recurrence of bipolar depression (Baldessarini et al 2002).However, there are efficacy and tolerability limitations which may prohibit widespread use of divalproex, lamotrigine or lithium.

Currently there is only one product, a combination tablet of the antidepressant fluoxetine and the atypical antipsychotic olanzapine (OFC), that has been approved for marketing only in the US for the treatment of bipolar depression. The approval was based on two placebo controlled trials, in which OFC-treated patients (combined N=83) demonstrated significantly greater improvement in mean MADRS change than did patients treated with olanzapine monotherapy, or placebo. In these trials, patients treated with olanzapine alone (N=833) also demonstrated significant improvement in MADRS mean change, but without the addition of the antidepressant, the magnitude of effect was lower than that seen with the combination (Tohen et al 2003).

There is some evidence that medications with mood stabilizing properties may be useful as monotherapy in the treatment of bipolar depression. The potential efficacy of quetiapine in depressive symptoms is provided in data from the Quetiapine Experience with Safety and Tolerability Trial (QUEST) and from investigator-initiated trials in mood disorder patients. In an open-label trial evaluating the safety and tolerability of quetiapine over 700 subjects with schizophrenia and other psychotic disorders were randomized to treatment with quetiapine or risperidone (Sajatovic et al 2002). Quetiapine-treated patients experienced a greater improvement in depressive symptoms compared with risperidone-treated patients, with a mean difference of 1.3 points on the HAM-D after adjustment for baseline differences (P=0.028).

A trial of quetiapine in 20 neuroleptic-dependent patients with bipolar or schizoaffective disorder also suggested positive effects on the depressive and psychotic symptoms in these disorders (Sajatovic et al 2001). Overall, in 10 patients with bipolar disorder and 10 with schizoaffective disorder who received open-label quetiapine, significant improvement in Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), and HAM-D scores was noted.

In summary, the paucity of satisfactory treatments available signify an unmet medical need for the treatment of bipolar depression. There are signals of efficacy from clinical trials for the antidepressant properties of atypical antipsychotics such as quetiapine.

4. STUDY OBJECTIVES

4.1 Primary objectives

The primary objectives of the study were to evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks by comparing

1. the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

2. the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

3. the change from baseline to each assessment in the MADRS total score

4. the change from baseline to each assessment in the total Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S), and the Clinical Global Impression - Improvement (CGI-I).

4.2 Secondary objectives

The secondary objectives of the study were:

1. to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who meet the criteria for treatment-emergent mania on the Young Mania Rating Scale (YMRS) or report an adverse event of mania or hypomania

2. to evaluate the effect of quetiapine on anxiety compared to placebo by

   - the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

   - the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

3. to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by

   - the incidence and nature of overall adverse events

   - the incidence and nature of drug-related adverse events

   - subject withdrawal due to adverse events during double-blind treatment

   - the number of patients having clinically significant changes in vital signs from baseline to end of treatment

   - the change in Simpson-Angus Scale (SAS) total score

   - the change in the Barnes Akathisa Rating Scale (BARS) total score

   - the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Exploratory:

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in sleep quality using the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) from baseline to end of treatment

5. STUDY PLAN AND PROCEDURES

The overall study design and plan are presented and discussed in Section 5.1 and Section 5.2, respectively. The study population and its relationship to the intended target population are defined in Section 5.3. Study treatments and dosing regimens are described in Section 5.4.Study measurements and variables are described and justified in Section 5.5, and measures taken to ensure the quality of study data are described in Section 5.6.Statistical methods and presentation of the data are detailed in Section 5.7. Any changes to the planned conduct of the study, or planned statistical analyses, are presented in Section 5.8.

5.1 Overall study design

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial consisted of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects were to be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment of 8 patients per center (maximum 70). Subjects were required to have a HAM-D (17-item scale) score of ≥20 and a YMRS of ≤12 at screening baseline (Visit 1).

The trial comprised the following 2 periods:

- Washout period
  Subjects underwent HAM-D, SCID, YMRS, and safety evaluations at screen (Visit 1) and if they qualified to participate they commenced a washout of antidepressant, antipsychotic, and mood stabilizer medications. The number of days for washout depended upon the medication they were taking. These medications had to be discontinued for a period of at least 7 days prior to randomization (Day 1, Visit 2), with the exception of fluoxetine which had to be discontinued for a period of 14 days prior to randomization (Day 1, Visit 2) and depot injections of haloperidol decanoate or fluphenazine decanoate which required 28 days washout before randomization.

- 8-week double-blind randomized treatment period (Weeks 1 to 8)
  Eligible subjects were randomized on Day 1 (Visit 2) to 1 of 3 treatment groups: quetiapine 300 mg/day, quetiapine 600 mg/day, or placebo. The randomization was done using a stratification based on diagnosis. Treatment was administered once daily at bedtime for 8 weeks (Days 1 - 56). Subjects did not receive medication on Day 57 which was only for final assessments. Doses were titrated to achieve target doses of 300 mg/day within 4 days or 600 mg/day within 8 days. A dose reduction of 100 mg was allowed to improve patient tolerance in each treatment group. MADRS assessments (used to evaluate the primary efficacy variable) were performed at Days 1, 8, 15, 22, 29, 36, 43, 50, and 57.

Table 2 summarizes the study procedures and assessments conducted at each time point.

Table 2 Study plan

	Screen	Washout[a]	Double-blind treatment phase Weeks 1 through 8								
Days			**1**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**
Visits	**1**		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Informed consent	√										
Medical history	√										
Inclusion/Exclusion criteria	√		√								
Structured Clinical Interview for DSM-IV (SCID)	√										
Physical examination[d]	√										√
Urine toxicology screen	√										
Pregnancy tests (females)	√										
Vital signs, height, weight[c,e]	√		√	√	√	√	√	√	√	√	√
12-lead electrocardiogram	√		√[b]								√
Clinical chemistry and hematology	√		√[b]								√
Hamilton Rating Scale for Depression (17-item)	√		√	√	√	√	√	√	√	√	√
Montgomery-Asberg Depression Rating Scale			√	√	√	√	√	√	√	√	√
Young Mania Rating Scale	√		√	√	√	√	√	√	√	√	√
Hamilton Rating Scale for Anxiety			√	√	√	√	√	√	√	√	√
Clinical Global Impression - Severity	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression -Change				√	√	√	√	√	√	√	√
Barnes-Akathisia Rating Scale			√								√
Simpson-Angus Scale			√								√
Pittsburgh Sleep Quality Index			√				√				√
Quality of Life Enjoyment Satisfaction Questionnaire			√				√				√
Dispense study medication			√	√	√	√	√	√	√	√	
Adverse events	√	√	√	√	√	√	√	√	√	√	√

a Washout of antidepressants, antipsychotics, mood stabilizer for 7 to 28 days depending on the medications involved and a 14-day washout for fluoxetine
b Repeated laboratory tests and ECG only if results outside of normal range and clinically significant at Screening
c Height and weight on screen and weight on Day 57
d Physical exam included ophthalmoscopic exam on screen
e Blood pressure obtained in supine and standing positions

5.2 Rationale for study design, doses and control groups

This trial was designed as a double-blind placebo-controlled evaluation of quetiapine as monotherapy in bipolar depression. At the time of trial initiation there was no currently approved compound for use in bipolar depression; nor was there a clinically accepted "gold standard" monotherapy agent. Conventional antidepressants are not commonly used as monotherapy because of the need for close clinical monitoring to avoid the induction of manic symptoms. Due to the lack of a reasonable monotherapy alternative, and the high placebo rate in bipolar depression trials (approximately 30%), the use of a placebo treatment arm for comparison was clinically justified.

Trial treatment was administered as quetiapine monotherapy once daily at bedtime. The current label specifies twice daily (BID) but a double-blind crossover study in patients indicated that once daily (qd) was well tolerated and as effective as BID dosing (Chengappa et al 2003).

A period of 7 to 28 days is adequate for washout of most psychoactive medications including antidepressants, antipsychotics (including depot agents), and mood stabilizers to ensure that subjects are not experiencing residual psychotropic effects from any such medications they were taking before randomization. The double-blind treatment period of 8 weeks is consistent with the time period that is generally accepted to be required to see a clinically meaningful response in depressive symptoms.

The trial was designed as a fixed-dose evaluation due to the frequent failure of flexible dose regimens in other psychiatric disorders. The dosages are based on clinical trial data with quetiapine in patients with a mood disorder. In the QUEST trial, the average dose of quetiapine in patients with a primary mood disorder (N=316) was approximately 250 mg/day at 16 weeks (Sajatovic et al 2002). In 20 patients with bipolar or schizoaffective disorder treated with open-label quetiapine, the mean dose was approximately 200 mg/day (Sajatovic et al 2001). Based on these data, 300 mg/day administered as monotherapy is an appropriate low-dose treatment arm, and 600 mg/day is an appropriate high-dose treatment arm that should exhibit efficacy without a high rate of AEs or noncompliance.

The MADRS is a standardized, well-validated measure of depressive symptoms that is sensitive to treatment effects in depressed outpatients.

5.3 Selection of study population

5.3.1 Inclusion criteria

For inclusion in the study, patients had to fulfill all of the following criteria at Screening;

1. Documented ability to provide informed consent before beginning any study-specific procedures

2. Male and female patients between 18 and 65 years of age, inclusive

3. Females of childbearing potential, were to be using a reliable method of contraception. Reliable methods included hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

4. Women must have had a negative pregnancy test

5. Met DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x)

6. Outpatient status

7. HAM-D (17-item) total score of 20 or greater

8. HAM-D item 1 (depressed mood) score ≥2

9. YMRS total ≤12

Patients had to fulfill all of the following criteria at Randomization;

1. HAM-D (17-item) total score of 20 or greater

2. HAM-D item 1 (depressed mood) score ≥2

3. YMRS total ≤12

5.3.2 Exclusion criteria

Any of the following was regarded as a criterion for exclusion from the study:

1. Patients with a current Axis I disorder other than bipolar disorder within 6 months of screening

2. Patients whose current episode of depression exceeded 12 months or was less than 4 weeks

3. History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode

4. Patients who met DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening

5. Patients with a positive urine toxicology screen for illicit substances of abuse

6. Patients who were unable to discontinue all psychoactive medications (excluding prn benzodiazepines), including antidepressants, antipsychotics, and mood

stabilizer, at least 7 days prior to randomization and consistent with the pharmacokinetics of the drug

- Patients treated with fluoxetine who had not discontinued this medication for at least 14 days prior to randomization

- Patients treated with haloperidol decanoate or fluphenazine decanoate who had not discontinued these medications 28 days prior to randomization

7. Patients who had not discontinued the use of potent P450 inhibitors and inducers (See Section 5.4.5, Table 10)

8. Patients who in the investigators opinion would have required initiation of psychotherapy during the study period. Note: ongoing psychotherapy for a minimum of 3 months could continue

9. Patients who, in the investigator's judgment, posed a current serious suicidal or homicidal risk at Visit 1 (HAM-D Item 3 score of 3 or greater), or had made a suicide attempt within the past 6 months

10. Patients with a history of clinically significant cardiac, renal, neurologic, cerebrovascular, metabolic or pulmonary disease, or other disease or clinical finding that was unstable or that, in the opinion of the investigator, would have been negatively affected by study medication or that would have affected study medication

11. Patients who had had a myocardial infarction within 1 year before Visit 1

12. Patients with clinically significant abnormal laboratory findings at Visit 1

13. Patients with renal impairment (serum creatinine ≥1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal)

14. Patients whose TSH was ≥10% over the upper normal limit. Patients maintained on thyroid medication had to be euthyroid for a period of at least 3 months before Visit 1

15. Patients with clinically significant abnormalities on ECG

16. Women who had a positive human chorionic gonadotropin (HCG) pregnancy at Visit 1 or who were lactating or planning to become pregnant during the course of the study

17. Patients who had participated in a clinical trial of an investigational drug within the previous 3 months

18. Patients who, in the opinion of the investigator, would have been non-compliant with the visit schedule or study procedures

19. History of orthostatic hypotension or conditions that would have predisposed them to hypotension (eg dehydration, hypovolemia)

20. Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of Seroquel tablets, as judged by the investigator

5.3.3 Restrictions

Patients were required to adhere to the following special restrictions:

1. Use of any psychoactive drugs including antidepressants, hypnotics (with the exceptions noted in Section 5.4.5), mood stabilizing drugs, and antipsychotics was not permitted from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine was to be discontinued at least 14 days prior to randomization.

2. Use of cytochrome P450 3A4 inducers and potent inhibitors were not permitted from 14 days prior to randomization to end of study (see Table 10)

5.3.4 Discontinuation of subjects from treatment or assessment

5.3.4.1 Criteria for discontinuation

Subjects could be discontinued from study treatment and assessments at any time, at the discretion of the investigator. Specific reasons for discontinuing a subject from this study were:

1. Withdrawal of informed consent

2. Worsening psychiatric symptoms such that the symptoms constituted a danger to the patient or to others

3. Use of psychotropic medications at any time during the double-blind treatment period

4. Pregnancy at any time during the double-blind treatment period

5. A clinically significant or serious adverse event that would not be consistent with continuation in the study, as determined by the investigator, AstraZeneca, or the patient.

5.3.4.2 Voluntary discontinuation by a subject

Subjects were free to discontinue their participation in the study at any time, without prejudice to further treatment. Subjects who discontinued were asked about the reasons for their discontinuation and about the presence of any adverse events. If possible, they were seen and

assessed by an investigator. Adverse events were to be followed up, and any investigational products and study materials were to be returned by the subject.

5.3.4.3 Incorrectly enrolled or randomized subjects

Incorrectly enrolled were to be discontinued from further study treatment and assessments. If a patient was given an incorrect randomized treatment, the patient was to continue on that treatment.

5.3.4.4 Procedures for discontinuation

All study procedures required at Day 57 were to be conducted when a patient discontinued from the trial (See Table 2).

5.4 Treatments

5.4.1 Investigational products

The details of the investigational product and any study treatment are given in Table 3.

Table 3 Details of investigational product and any other study treatments

Investigational product or other treatment	Dosage form and strength	Manufacturer	Formulation number	Lot number
Quetiapine	tablet, 25 mg	AstraZeneca	F12804	7527F
Quetiapine	tablet, 100 mg	AstraZeneca	F12689	7513H
Quetiapine	tablet, 200 mg	AstraZeneca	F12690	7541F
Placebo	tablet, 25 mg	AstraZeneca	F12636	7553F
Placebo	tablet, 100 mg	AstraZeneca	F12637	7550F
Placebo	tablet, 200 mg	AstraZeneca	F12638	1509C

All investigational products were to be kept in a secure place under appropriate storage conditions.

5.4.2 Doses and treatment regimens

Quetiapine and placebo for each trial center were packaged in blister cards. The 8-week supply consisted of 8 double-blind blister cards that were packaged in subject-specific cartons.

Trial medication was provided for each subject in an 8-card carton that contained the following:

- 1-week titration double-blind treatment cards for Days 1-7

- Seven 1-week double-blind treatment cards for Days 8-56, with individual cards provided for treatment Days 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, and 50-56. Each one-week blister card included a 2-day treatment overage to accommodate visit schedules.

The Week 1 titration card consisted of 25 mg tablets, 100-mg tablets, and 200-mg tablets or matching placebo for each of the 300 mg/day and 600 mg/day treatment groups and placebo treatment group (Table 4, Table 6, Table 8).

Blister cards for Weeks 2 through 8, for each treatment group, consisted of 9 days of dosing with the same number of pills for each group (300-mg, 600-mg, and placebo) respectively. The cards for each treatment group consisted of 2 yellow tablets (quetiapine 100 mg or matching placebo) and 2 white tablets (quetiapine 200 mg or matching placebo) per day at bedtime (Table 5, Table 7, Table 9).

Quetiapine or placebo was administered once a day at bedtime with dose titration designed to reach a target dose of 300 mg/day by Day 4 in the 300 mg/day treatment group and 600 mg/day by Day 8 in the 600 mg/day group. Patients were instructed to take all the tablets in the row of the blister pack for the corresponding day of treatment.

Table 4 Week 1 blister pack for 300 mg/day quetiapine group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 5 Week 2-8 300 mg/day quetiapine blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
2	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
3	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
4	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 6 Week 1 600 mg/day quetiapine blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 7 Week 2-8 600 mg/day quetiapine blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
2	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
3	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
4	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 8 Week 1 blister pack for placebo group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg placebo	25-mg placebo		
2	100-mg placebo			
3	200-mg placebo			
4	100-mg placebo	200-mg placebo		
5	100-mg placebo	100-mg placebo	200-mg placebo	
6	100-mg placebo	100-mg placebo	200-mg placebo	
7	100-mg placebo	100-mg placebo	200-mg placebo	
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Table 9 Week 2-8 blister pack for placebo group

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
2	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
3	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
4	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
5	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
6	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
7	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Dose reduction

Dose reduction for intolerability was allowed after Day 8. Dose reductions of 100 mg/day were achieved by reducing the dose by one 100-mg tablet. Each column in the blister packs was numbered 1-4. By Day 6 Columns 1 and 2 of the blister packs each contained a 100-mg tablet or matching placebo (Table 5, Table 7, Table 9). Dose reductions were implemented by instructing the patient to not take the tablet in Column 1 of the blister pack

5.4.3 Method of assigning subjects to treatment groups

This trial utilized a non-center-specific labeling randomization which was stratified in a 1:1:1 ratio for treatment group within bipolar diagnosis (bipolar I vs bipolar II). Randomization to trial treatment was done via an Interactive Voice Response System (IVRS) at ICTI on Day 1 (Visit 2) in balanced blocks within each bipolar stratum in order to ensure relative balance in total number of subjects among treatment groups and strata. The randomization schedule was created under the auspices of AstraZeneca Quantitative Decision Sciences Group and allocated subject numbers to the treatment regimens. Clinical supplies contained a 4-digit kit number. A separate randomization assigned kits of packaged drugs to the sites. The IVRS system at ICTI allocated a kit number at the site for the treatment assigned through the stratified randomization.

5.4.4 Blinding and procedures for unblinding the study

5.4.4.1 Methods for ensuring blinding

All packaging of treatments was identical with placebo and active tablets identical in size and color. The number of tablets dispensed on each card was identical across all treatment arms.

The patient treatment assignment randomization was generated by an AstraZeneca randomization staff member not associated with the trial and was provided directly to the medication packaging group and to ICTI Clinical Supplies Management Group for incorporation into the IVRS system. No member of the study team in AstraZeneca, at investigational sites or the contract research organization handing data had access to the randomization scheme during the conduct of the study.

5.4.4.2 Methods for unblinding the study

Treatment codes, indicating the treatment randomization for each randomized subject, were available to the investigators or pharmacists at the study center. The treatment code was not to be broken except in medical emergencies when the appropriate management of the subject necessitated knowledge of the treatment randomization. The investigator was to document and report to AstraZeneca any breaking of the treatment code. AstraZeneca retained the right to break the code for serious adverse events that were causally related to treatment and potentially required expedited reporting to regulatory authorities and, in exceptional circumstances, for other safety reasons. Treatment codes were not to be broken for the planned analyses of data until all decisions on the availability of the data from each individual subject were made and documented.

5.4.5 Pre-study, concomitant, and post-study treatments

Nonpsychotropic medication, including over-the counter medications, taken by the subject before entry into the trial could be continued during the trial. Medications required to treat illnesses or complaints that occur during the trial could be used at the discretion of the investigator. Use of cytochrome P450 inducers and potent inhibitors was restricted (see Table 10, below).

Women who entered the trial with an intrauterine device in place, using oral contraceptives, or using injectable or implantable hormonal agents designed to prevent pregnancy could continue these treatments throughout the trial.

The use of psychoactive drugs other than those specifically allowed during the trial (ie, lorazepam and zolpidem tartrate) was restricted. Medications specifically prohibited or restricted, and those permitted during the trial are listed in Table 10.

Table 10 Permitted, restricted and prohibited medications

Use category	Type of medication
Permitted	Previous medications for medical, nonpsychiatric illnesses
	Oral contraceptives and contraceptive devices
Restricted	Zolpidem tartrate 5-10 mg at bedtime for insomnia
	Lorazepam 1-3 mg per day for severe anxiety
	These drugs could be prescribed during the first 3 weeks of the study as long as they did not interfere with any assessments
Prohibited	Potent cytochrome P450 3A4 inducers (including but not limited to barbiturates, carbamazepine, rifampin, and St John's Wort)
	Potent cytochrome P450 3A4 inhibitors (including but not limited to ketoconazole, itraconazoole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir, and saquinavir)
	Antipsychotic medications (including but not limited to phenothiazines, risperidone, olanzapine, ziprasidone, clozapine, loxapine, thiothixene, molindone)
	Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a period of 7 to 28 days depending on the medications involved (eg. 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study.
	Fluoxetine had to be discontinued at least 14 days prior to randomization.

Other medication considered necessary for the subject's safety and well being could be given at the discretion of the investigators. The administration of all medication (including investigational products) was recorded in case report forms (CRFs).

5.4.6 Treatment compliance

Compliance was assessed by returned tablet counts. Compliance was calculated as the number of tablets taken (dispensed - returned) divided by the prescribed number of tablets (number of days times number of tablets per day) expressed as a percent. Based on this calculation a subject with at least 75% compliance with study medication during study participation was classified as compliant.

If, in the opinion of the investigator, there were any significant irregularities in compliance the patient was to be withdrawn from the study.

5.5 Measurements of study variables and definitions of outcome variables

5.5.1 Primary variable

The primary outcome variable was the change from baseline to final assessment in the MADRS total score. This outcome variable was the basis for the sample size calculation (Section 5.7.5).

5.5.2 Screening and demographic measurements

The following data were collected at screening:

- date of birth, sex and race. Race was defined by the geographic origin of the patient's family. Caucasian was used for family origins in Europe, India, Pakistan, Afghanistan, Arabia, North Africa, Middle East countries, and Asia Minor. Black was used for Africa but not North Africa. Oriental was used from Asia (except for Asian countries classified as Caucasian) and for Greenland. Other was used for mixed races and for Aboriginal, Maori, Melanesian, Pygmean, and Tamil. Hispanic was not specifically defined in the CRF and was left to the discretion of the investigator.
- vital signs, height, weight
- supine and standing blood pressure and pulse
- significant medical history (including current adverse events)
- physical examination including ophthalmoscopic exam
- 12-lead electrocardiogram
- clinical chemistry and hematology
- pregnancy test (if female of childbearing potential)
- HAM-D assessment
- YMRS
- CGI-S
- DSM-IV diagnosis, based on SCID assessment

5.5.3 Efficacy measurements and variables

5.5.3.1 Summary of efficacy objectives and variables

Table 11 summarizes the efficacy variables of this study, and shows how they relate to the study objectives.

Table 11 Efficacy objectives, and outcome variables relating to each objective

Objective	Summary outcome variables for analysis (including timepoint and population)
Primary	**Primary outcome variable**
Evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks	Change from baseline to final assessment in the MADRS total score in the Intention-to-treat (ITT) population
	Secondary outcome variables
	Percentage of patients in the ITT population showing a ≥50% reduction from baseline in MADRS total score (responders) at each assessment and at final assessment
	Percentage of patients in the ITT population showing a MADRS total score ≤12 (remitters) at each assessment and at final assessment
	Change from baseline to each assessment for the MADRS total score in the ITT and PP populations
	Change from baseline to each assessment in the total HAM-D total score in the ITT population
	Change from baseline to each assessment in the HAM-D Item 1 score in the ITT population
	Change from baseline to each assessment and at final assessment for the CGI-S in the ITT population
	CGI-I score at each assessment and at final assessment in the ITT population
Secondary	**Secondary outcome variables**
Evaluate the effect of quetiapine compared to placebo on symptoms of anxiety	Change from baseline to each assessment and to final assessment in the HAM-A total score in the ITT population

The timings of the efficacy assessments are presented in the study plan in Section 5.1. The methods for collecting efficacy data are presented below.

5.5.3.2 Primary variable: MADRS total score change from baseline at last assessment

(a) Methods of assessment

The MADRS is a 10-item instrument that was used to rate the patient's depressive symptoms for the preceding week (Montgomery and Asberg 1979). Scoring for each of the items was made on a 0- to 6-point scale, with higher scores indicating more severe depression.

(b) Calculation or derivation of outcome variable

The MADRS total score was calculated by summing the scores from each of its 10 items. Change from baseline in the MADRS total score was calculated by subtracting the baseline total score from the visit score. Alleviation of depressive symptoms was thus indicated by a negative change score.

5.5.3.3 Secondary variable: MADRS response

(a) Methods of assessment

As specified in Section 5.5.3.2.

(b) Calculation or derivation of outcome variable

Response at a visit was defined as a decrease from baseline MADRS total score of ≥50% at the given visit.

5.5.3.4 Secondary variable: MADRS remission

(a) Methods of assessment

As specified in Section 5.5.3.2.

(b) Calculation or derivation of outcome variable

Remission at a visit was defined as a MADRS total score ≤12 at the given visit.

5.5.3.5 Secondary variable: MADRS total score change from baseline at each assessment

As specified in Section 5.5.3.2 for each visit.

5.5.3.6 Secondary variable: change from baseline in HAM-D total score

(a) Methods of assessment

The HAM-D is a 17-item instrument that was used to rate the patient's depressive symptoms for the preceding week (Hamilton 1960). The items are scored on a 0- to 2-, 0- to 3-, or 0- to 4-point scale, with higher scores indicating more severe depression. The maximum score is 53.

(b) Calculation or derivation of outcome variable

The HAM-D total score was calculated by summing the scores from each of its 17 items. Change from baseline in the HAM-D total score was calculated by subtracting the baseline total score from the visit score. Alleviation of depressive symptoms was thus indicated by a negative change score.

5.5.3.7 Secondary variable: change from baseline in HAM-D Item 1 score

(a) Methods of assessment

Item 1 of the HAM-D is a 0- to 4-point rating of depressed mood.

(b) Calculation or derivation of outcome variable

Change from baseline in the HAM-D Item 1 score was calculated by subtracting the baseline score from the visit score. Alleviation of depressed mood was thus indicated by a negative change score.

5.5.3.8 Secondary variables: change from baseline in CGI

The CGI is a three-item scale used to assess treatment response in psychiatric patients (Guy 1976). Only Items 1 and 2 were recorded on the CRF and evaluated in this study. They are: Severity of Illness (CGI-S) and Global Improvement (CGI-I)[1]. Item 1 is rated on a seven-point scale (1=normal to 7=extremely ill) and item 2, on a seven-point scale (1=very much improved to 7=very much worse).

(a) Methods of assessment – CGI-S

The Severity of Illness item requires the clinician to rate the severity of the patient's illness at the time of assessment, relative to the clinician's past experience with patients who have the same diagnosis. Considering total clinical experience, a patient is assessed on severity of mental illness at the time of rating according to: normal (not at all ill); borderline mentally ill; mildly ill; moderately ill; markedly ill; severely ill; or extremely ill.

(b) Calculation or derivation of outcome variable

Change from baseline of the CGI-S was calculated by subtracting the baseline score from the visit score. Alleviation of symptom severity was thus indicated by a negative change score.

(c) Methods of assessment – CGI-I

The Improvement item requires the clinician to rate how much the patient's illness has improved or worsened relative to a baseline state. Compared to condition at baseline, a

[1] The abbreviation for the CGI Global Improvement scale was changed from "CGI-C" as used in the protocol to "CGI-I" to be consistent with the clinical literature.

patient's illness is compared to change over time, and rated according to: very much improved; much improved; moderately improved; minimally improved; no change; minimally worse; moderately worse; much worse; or very much worse.

(d) Calculation or derivation of outcome variable

For the CGI-I, symptomatic improvement from status at entry into the trial was thus indicated by scores of 3 or less while symptomatic deterioration was indicated by scores of 5 or more.

5.5.3.9 Secondary variable: incidence of treatment-emergent mania -- YMRS

(a) Methods of assessment

The YMRS is an 11-item instrument that was used to rate the patient's mania symptoms for the preceding week (Young et al 1978). Scoring for the items was made on a 0- to 4-point scale for 7 of the items and on a 0- to 8-point scale for the remaining 4 items. Reports of investigator-diagnosed cases of treatment-emergent mania or hypomania were compiled from adverse events reports.

(b) Calculation or derivation of outcome variable

Treatment-emergent mania for a patient was scored if the patient's YMRS total score was ≥16 at any two consecutive visits or final visit or if they received an AE report of mania or hypomania from the investigator. Change from baseline in the YMRS score was calculated by subtracting the baseline score from the visit score. The primary variable, the change from baseline in YMRS, was defined as the YMRS total score at Day 57 or final assessment minus the YMRS total score at baseline (Visit 2; Day 1). An increase in mania or hypomania symptoms was thus indicated by a positive change score.

5.5.3.10 Secondary variable: change from baseline in HAM-A

(a) Methods of assessment

The HAM-A is a 14-item instrument that was used to rate the patient's anxiety symptoms for the preceding week (Hamilton 1959). Scoring for each of the items was made on a 0- to 4-point scale of increasing severity.

(b) Calculation or derivation of outcome variable

Change from baseline in the HAM-A score was calculated by subtracting the baseline score from the visit score. Alleviation of anxiety symptoms was thus indicated by a negative change score.

5.5.4 Patient-Reported Outcomes (PROs) measurements and variables

5.5.4.1 Summary of PRO objectives and variables

Table 12 shows how the efficacy outcome variables of this study relate to the study objectives.

Table 12 Quality of life objectives and outcome variables relating to each objective

Objective	Summary outcome variables for analysis (including time point and population)
Exploratory	**Exploratory measure**
evaluate the effect of quetiapine compared to placebo on the overall quality of life	Change from baseline to each assessment and final assessment in short form Q-LES-Q in the ITT population
evaluate the effect of quetiapine compared to placebo on quality of sleep	Change from baseline to each assessment and final assessment in PSQI in the ITT population

The methods of collecting quality of life data are described below.

5.5.4.2 Change from baseline in the Q-LES-Q

(a) Methods of assessment

The Q-LES-Q is a quality of life questionnaire assessing physical health, subjective feelings, leisure activities, social relationships, and medication and life satisfaction (Endicott et al 1993).Higher scores indicate better quality of life. The Q-LES-Q short form consisting of the 16-item "General Activities" scale of the Q-LES_Q long form was used. The items are scored on a 5-point scale.

(b) Calculation or derivation of outcome variable

The short form has 16 self-rated questions, and the first 14 were incorporated into percent of maximum score by converting the raw summary scores and expressing them as a percentage of the maximum possible score (100). The change from baseline was calculated at each assessment (observed cases) and final assessment in the Q-LES-Q by subtracting the baseline score from the visit score. Improvement in quality of life was thus indicated by a positive change score.

5.5.4.3 Change from baseline in the PSQI

(a) Methods of assessment

The PSQI is a 10-item questionnaire which the patient used to rate sleep quality for the previous month (Buysse et al 1989). Higher scores indicate more severe difficulties in sleep quality.

(b) Calculation or derivation of outcome variable

The first 9 questions were incorporated into 7 component scores which were added together to yield one total "global" score (see the Statistical Analysis Plan in Appendix 12.1.9). The

change from baseline was calculated at each assessment (observed cases) and at final assessment (LOCF) by subtracting the baseline score from the visit score. Improvement in sleep quality was thus indicated by a negative change score.

5.5.5 Health Economics measurements and variables

Not applicable.

5.5.6 Pharmacokinetic measurements and variables

Not applicable.

5.5.7 Safety measurements and variables

5.5.7.1 Summary of safety objectives and variables

Table 13 summarizes the safety variables assessed in this study, and shows how they relate to the study objectives.

Table 13 Safety objectives and outcome variables relating to each objective

Objective	Summary outcome variables for analysis (including time point and population)
Evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	Incidence and severity of adverse events during double-blind treatment Incidence of drug-related adverse events during double-blind treatment Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment
	Incidence of subject withdrawal due to adverse events
	Clinical laboratory assessments change from baseline to Day 57 in the safety population
	Incidence of potentially clinically important changes in clinical laboratory assessments
	Change in weight and body mass index (BMI) from baseline to Day 57 in the safety population
	Vital signs from baseline to Day 57 in the safety population
	Incidence of potentially clinically important changes in vital signs
	Electrocardiogram (ECG)
	Incidence of potentially clinically important changes in ECG
	Change in the SAS total score from baseline to final assessment

Table 13 Safety objectives and outcome variables relating to each objective

Objective	Summary outcome variables for analysis (including time point and population)
	Change in BARS Global Assessment score from baseline to final assessment
Evaluate the incidence of treatment-emergent mania in quetiapine-treated patients compared to placebo-treated patients	Proportion of patients exhibiting a YMRS total score ≥16 on two consecutive assessments or at final assessment or having an AE report of treatment-emergent mania or hypomania. Change from baseline to each assessment and to final assessment in the YMRS total score in the ITT population

The timings of the safety assessments are presented in the study plan in Section 5.1. The methods for collecting safety data are described below.

5.5.7.2 Adverse events

(a) Definitions

An adverse event was defined as the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. This definition included events in any screening period or during any follow-up period specified in the study protocol. An undesirable medical condition could be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver) or the abnormal results of an investigation (eg, laboratory findings, electrocardiogram).

A serious adverse event was defined as an AE occurring during any study phase (ie, run-in, treatment, washout, follow-up), and at any dose of the investigational product, comparator or placebo, that fulfilled one or more of the following criteria:

- resulted in death
- was immediately life-threatening
- required in-patient hospitalization or prolonged existing hospitalization
- resulted in persistent or significant disability or incapacity
- was a congenital abnormality or birth defect
- was an important medical event that might have jeopardized the subject or might have required medical intervention to prevent one of the outcomes listed above?

Study drug abuse was to be considered an SAE, even when there are no symptoms or additional AEs. Misuse of study drug was considered to be an AE but was not considered an SAE unless accompanied by serious sequelae.

All overdoses, with or without associated symptoms, were to be reported as AEs.

Suicide and attempted suicide, irrespective of the method, but occurring in connection with the use of study drug, was to be reported as AEs (serious or non-serious). The event was to be identified as suicide or attempted suicide, and the method of the suicide or attempt was to be provided. If an attempted suicide meets the criteria for an SAE, the event was to be reported as such.

(b) Recording of adverse events

All AEs that occur before, during treatment, or within 30 days following the cessation of treatment, whether or not related to the study drug, had to be recorded on the CRF provided by the sponsor.

A description of the event, its intensity, duration, action taken and outcome were to be recorded, along with the investigator's causality assessment of the relationship of the event to the study drug. If a diagnosis of the patient's condition was made, then the diagnosis was to be recorded as the AE. However, if a diagnosis of the patient's condition had not been made, or if the individual symptoms were not well-recognized, then the individual symptoms were to be recorded separately.

AEs were entered coded according to the MedDRA dictionary by AstraZeneca personnel.

In general, abnormal laboratory tests or vital signs were not to be reported as AEs unless they fulfilled the criteria for an SAE or lead to discontinuation. If an abnormal laboratory test result or vital sign was associated with clinical signs and symptoms, the sign or symptom was reported to be an AE, and the associated test result or vital sign was to be recorded on the CRF.

Any detrimental change in the patient's condition after the patient entered the study was to be discussed with the investigator. Where the detrimental change was considered by the investigator to constitute a progression or relapse of bipolar depression or a lack of efficacy, the change was not considered to be an AE event where hospitalization was necessitated or prolonged. If it was believed that study medication contributed to deterioration, it was recorded as an AE. If it was not believed that the study medication contributed to deterioration, it was recorded as lack of efficacy.

Signs & symptoms noted in patient reported outcome instruments (PSQI & Q-LES-Q) were not reported as AEs.

Pregnancy in itself was not regarded as an adverse event unless there was a suspicion that the investigational product under study may have interfered with the effectiveness of a

contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) was to be followed up and documented even if the subject was discontinued from the study. All reports of congenital abnormalities, birth defects and spontaneous miscarriages were to be recorded as SAEs. Elective abortions without complications were not to be considered as adverse events. All outcomes of pregnancy were to be reported to AstraZeneca on the pregnancy outcomes report form.

(c) Reporting of serious adverse events

All SAEs were to be reported, whether or not they were considered causally related to the investigational product. When an investigator became aware of an SAE during the course of the study, the SAE was to be reported to the local monitor or other AstraZeneca representative in accordance with the AstraZeneca study protocol. If any SAEs were recorded during the 30-day follow-up period, all concomitant medications taken during the 30-day follow-up were also to be recorded on the CRF.

5.5.7.3 Laboratory safety measurements and variables

Laboratory safety variables assessed in this study are summarized in Table 14.

Table 14 Laboratory safety variables

Type of assessment	Variables
Fasting hematology	Hemoglobin
	Hematocrit
	Red blood cell count (RBC)
	White blood cell count (WBC)
	Differential white blood cell count (% and absolute)
	Platelet count
Clinical chemistry	
Hepatic function	Alanine transaminase (ALT)
	Aspartate transaminase (AST)
	Alkaline phosphatase
	Total bilirubin
Renal function	Creatinine
Lipids	Total cholesterol
	low-density lipoprotein cholesterol
	high-density lipoprotein cholesterol
	triglycerides

Table 14 Laboratory safety variables

Type of assessment	Variables
Electrolytes	Sodium
	Potassium
	chloride
	bicarbonate
Thyroid function	Thyroid stimulating hormone (TSH)
	Triiodothyronine resin uptake (T3RU)
	Free thyroxine (T4)
Other	Insulin
	Glucose

Laboratory results were converted to standard units according to conversion factors listed in Table 11.3.7.1.1.1 and Table 11.3.7.1.2.1. Change from baseline (the final test value minus the screening test value) was derived for all subjects who had a screening laboratory test and a final laboratory test. Abnormal laboratory findings were identified as outside the normal range according to local laboratory criteria or as clinically important according to the criteria presented in Table 15, which presents criteria specified in the statistical analysis plan and the criteria that were adopted as the safety analysis proceeded. The criteria for clinically important changes were revised to reflect changes in medical standards and to insure consistency across the Seroquel programs as defined in 2005 and agreed with regulatory authorities.

Table 15 Definition of clinically important clinical laboratory values

Laboratory assessment	Units	Low	High
Hematology			
Hematocrit (males)	vol fraction	≤0.37	≥0.50
Hematocrit (females)	vol fraction	≤0.32	≥0.55
Hemoglobin (males)	g/dL	≤11.5	≥18.5
Hemoglobin (females)	g/dL	≤10.5	≥16.5
RBC	10^{12} cells/L	≤3	≥6
Platelet count	10^{9} cells/L	≤100	≥600
WBC	10^{9} cells/L	≤3.0	≥16.0
Neutrophils			

Table 15 Definition of clinically important clinical laboratory values

Laboratory assessment	Units	Low	High
proportion	%	None	None
Absolute (neutropenia)	10^9 cells/L	≤1.5[a]	≥10
Absolute (agranulocytosis)	10^9 cells/L	≤0.5[b]	NA
Eosinophils			
proportion	%	NA	None
absolute	10^6 cells/L	NA	≥1000
Basophils			
proportion	%	NA	None
absolute	10^9 cells/L	NA	≥0.5
Lymphocytes			
proportion	%	None	None
absolute	10^9 cells/L	≤0.5	≥6
Monocytes			
proportion	%	NA	None
absolute	10^9 cells/L	NA	≥1.4
Chemistry			
ALT	ULN	NA	≥3
AST	ULN	NA	≥3
Alkaline phosphatase	ULN	NA	≥3
Total bilirubin	ULN	NA	≥1.5
BUN	mg/dL	NA	≥30
Creatinine	mg/dL	NA	≥1.58
Sodium	mmol/L	≤132	≥152
Potassium	mmol/L	≤3.0	≥5.5
Bicarbonate (CO_2)	mmol/L	≤18	≥30
Chloride	mmol/L	≤90	≥120
Free T4	LLN/ULN	<0.8	>1.2
TSH	mIU/L	NA	>5

Table 15 Definition of clinically important clinical laboratory values

Laboratory assessment	Units	Low	High
Total cholesterol	mg/dL	NA	≥240
HDL	mg/dL	≤40	None
LDL	mg/dL	None	≥160
Triglycerides	mg/dL	NA	≥200
Glucose			
fasting	mg/dL	≤45	≥126
random	mg/dL	≤45	≥200

LLN Lower limit of normal
ULN Upper limit of normal
NA Not applicable
a Criterion for neutropenia
b Criterion for agranulocytosis

5.5.7.4 Vital signs measurement

Vital signs included supine and standing pulse, and systolic and diastolic blood pressure. Changes from baseline at each visit for each of these variables were calculated. Differences in supine and standing scores were also computed.

Vital signs assessed are shown in Table 16, along with criteria for potentially clinically important values.

Table 16 Definitions of potentially clinically important vital signs by FDA criteria

Vital sign	Criterion value	Change from baseline
Pulse	>120 bpm	increase ≥15 bpm
	<50 bpm	decrease ≥15 bpm
Systolic blood pressure	≥180 mm Hg	increase ≥20 mm Hg
	≤90 mm Hg	decrease ≥20 mm Hg
Diastolic blood pressure	≥105 mm Hg	increase ≥30 mm Hg
	≤50 mm Hg	decrease ≥20 mm Hg
Orthostatic changes		
Systolic blood pressure or	decrease ≥20 mm Hg from supine to standing after 1 min	
Diastolic blood pressure	decrease ≥20 mm Hg from supine to standing after 1 min	
Pulse	increase ≥20 bpm from supine to standing after 1 min	
Combined	Decrease ≥20 mm Hg in systolic BP and increase ≥20 bpm in pulse rate	

bpm beats per minute

5.5.7.5 ECG safety measurements and variables

Twelve-lead ECGs were performed at screening and on Day 57. ECGs for patients at all trial sites were acquired at the site using an approved unit and were transmitted to eResearch Technology. Quality assurance of the ECG waveform and patient demographics was conducted by a central laboratory operator at eResearch Technology. ECGs were processed through a computer interpretation program and then reviewed first by an ECG analyst and then by a board-certified cardiologist. QTc intervals were calculated using the Fridericia formula (Puddu 1988). ECG parameters are shown in Table 17 , along with criteria for potentially clinically important values.

Table 17 Definition of potentially clinically important electrocardiogram parameters

ECG parameter	Criterion value	Change from baseline
Heart rate	>120 bpm	increase ≥15 bpm
	<50 bpm	decrease ≥15 bpm
PR	≥210 msec	NA
QRS	≤50 msec	NA
	≥120 msec	NA
QT	≥500 msec	Increase ≥60 msec
	≤200 msec	NA
QT_C (Fridericia Correction)	≥450 msec	Increase ≥60 msec

NA Not applicable

5.5.7.6 Weight and Body Mass Index (BMI)

Patient weight data were also explored as change in BMI. Patients were stratified by BMI category to determine changes within and across categories.

Body mass index was calculated using the following formula:

BMI = weight in kilograms ÷ (height in meters)^2

For cross tabulation the following categorization was used:

Category	BMI (kg/m^2)
Underweight	Under 18.5
Normal weight	18.5 – 24.9
Overweight	25 – 29.9
Obese	30 – 39.9
Severely Obese	40 and over

Changes in body weight and BMI were computed as Day 57 (LOCF) measurement minus the baseline measurement. The key endpoint for weight change was whether a patient gained ≥7% over baseline. Weight loss of ≥7% has been presented as well.

5.5.7.7 Physical examination

New positive findings on last-visit physical examination were to be reported as adverse events.

5.5.7.8 Simpson-Angus Scale (SAS)

The SAS (Simpson and Angus 1970) is the sum of a 10-item scale that is used to rate the presence and intensity of extrapyramidal motor symptoms, with the score for each item ranging from 0 to 4. The investigator could also enter each item as "not ratable." Items rated as "not ratable" were scored as a "9" in the database and were treated as missing data and not included in the total score (See Statistical Analysis Plan, Appendix 12.1.9, for further detail). Increases from baseline in total score thus indicated an increase in extrapyramidal motor symptoms.

5.5.7.9 Barnes-Akathisia Rating Scale (BARS)

The BARS (Barnes 1989) has 4 items and is used to assess objective and subjective attributes of akathisia. Only one item of the BARS, the Global Assessment of Akathisia, with a score ranging from 0 to 5 was analyzed. Increases from baseline in the global assessment item score thus indicated an increase in akathisia.

5.6 Data management and quality assurance

The quality of study data was assured through monitoring of investigational sites, provision of appropriate training for study personnel, and use of data management procedures, as detailed below.

AstraZeneca's quality assurance and internal quality control procedures provide reassurance that the clinical study program was carried out in accordance with GCP guidelines. AstraZeneca undertakes a GCP audit program to ensure compliance with its procedures and to assess the adequacy of its quality control measures. Audits, by a Global Quality Assurance group operating independently of the study monitors and in accordance with documented policies and procedures, are directed towards all aspects of the clinical study process and its associated documentation.

5.6.1 Monitoring

An investigator's meeting was held before the start of the study. During the study, the LRA monitors had regular contact with the investigational sites; these contacts included visits to confirm that the facilities remained acceptable, that the investigational teams were adhering to the protocol, that data were being accurately recorded in the CRF and to provide information and support to the investigator. The monitor ensured that drug accountability was being carried out. Source data verification (a comparison of the data in the CRF with the hospital and other records at the investigational site) was also performed. The monitors or other LRA personnel were available between visits to provide any information or advice required by the investigator.

5.6.2 Training

Investigational personnel were trained and tested on the administration of the MADRS, the HAM-D, the HAM-A and the YMRS at an investigators meeting in San Diego in September 2002. Testing standards were set at ±2points for each test item. If trainees failed to meet this

standard for ≥3 items, or if their total test score was deviant by 4 points or more, they were required to repeat the test using a new test videotape. Training but no testing was also provided by Michael B First, MD, Columbia University for the SCID.

In addition, all site personnel were given a refresher course on study procedures by one of 5 WEBEX meetings in May of 2003. The refresher course also covered known points of difficulty based upon experience in the trial to date.

5.6.3 Data management

Case report forms were provided for recording of data. The forms were printed in triplicate on carbonless paper. Data were to be recorded directly and legibly onto the case report forms with black ink, preferably with black ball-point pen. If any data were not available, omissions were to be indicated on the case report forms. Corrections were to be made legibly and be initialed and dated by approved personnel; the reasons for significant changes had to be provided. Correction fluid or covering labels could not be used. The top 2 sheets were collected and returned to AstraZeneca Pharmaceuticals and the 3rd sheet was retained by the investigator.

Data from the completed CRFs were entered into a Microsoft ACCESS database version 97 at LRA and transferred to AstraZeneca as SAS datasets. The process was documented in the Data Management Plan and the Data Management Validation Guidelines and the validation performed under the direction of the responsible Data Manager. Centrally collected ECG data were sent from eResearch Technology in an electronic format to be loaded by batch process.

Clinical laboratory data were transferred to AstraZeneca from Quintiles Laboratories as SAS datasets.

Data management activities (i.e, cleaning of data) were performed using the ACCESS database version 97. Any data queries raised following validation were dealt with using data query sheets. The distribution of copies was as for the CRFs.

5.7 Statistical methods and determination of sample size

5.7.1 Statistical evaluation

The statistical evaluation of study data was performed by Margaret Minkwitz of the AstraZeneca Quantitative Decision Sciences group using SAS® Version 8.

5.7.2 Description of outcome variables in relation to objectives and hypotheses

Definitions of efficacy outcome variables are given in Section 5.5.3. Definitions of patient-reported outcome variables are given in Section 5.5.5. Definitions of safety outcome variables are given in Section 5.5.7.

Statistical comparisons of the primary outcome variable, the change from baseline at Day 57 (LOCF) in the MADRS total score, tested the hypothesis that treatment with quetiapine 300 mg once daily or with quetiapine 600 mg once daily would produce larger reductions than

would treatment with placebo. The same hypotheses were tested for the following secondary efficacy, exploratory efficacy and safety outcome variables:

- Change from baseline at each assessment of MADRS total score
- Change from baseline to each assessment in the total HAM-D total score
- Change from baseline to each assessment in the HAM-D Item 1 score
- Change from baseline to each assessment and at final assessment for the CGI-S score
- CGI-I score at each assessment and at final assessment
- Change from baseline to each assessment and at final assessment for the Q-LES-Q score
- Change from baseline to each assessment and at final assessment for the YMRS score
- Change from baseline at final assessment for the PSQI score
- Change from baseline at final assessment for the BARS score

Analysis of the secondary outcome variables of response to treatment (≥50% reduction in MADRS total score from baseline) and remission (achievement of MADRS total score ≤12) following treatment tested the hypotheses that treatment with quetiapine 300 mg once daily or with 600 mg once daily would produce a larger proportion of patients that met criteria within either of the treatment groups compared to the placebo group.

Analysis of the secondary outcome variables of change from baseline to each assessment and to final assessment in the HAM-A total score tested the hypotheses that treatment with quetiapine 300 mg once daily or with quetiapine 600 mg once daily would produce similar or larger reductions than would treatment with placebo.

5.7.3 Description of analysis sets

Data analysis was based on the following 3 patient populations:

- The safety population included all enrolled patients classified according to treatment actually received. Randomized patients who did not receive treatment were excluded.
- The intention-to-treat (ITT) population included all evaluable patients in the safety population, classified according to the assigned randomized treatment. It included all enrolled patients who took study medication and who had a baseline MADRS and at least 1 valid post baseline MADRS assessment. Two patients who had

enrolled at two separate sites and who were randomly assigned to placebo treatment at both sites were not regarded as evaluable. Their exclusion reduced the original placebo group by 4. The ITT population was used to assess the primary efficacy outcome variable.

- The per-protocol (PP) population excluded patients from the ITT population with protocol violations and deviations that were regarded as interfering with an accurate efficacy assessment (see Statistical Analysis Plan in Appendix 12.1.9 for further detail).

5.7.4 Methods of statistical analysis

5.7.4.1 General principles

All statistical tests were 2-sided. The primary analyses used last observation carried forward (LOCF) for the time period of interest.

This trial employed a central randomization with a stratification based on diagnosis (bipolar 1 and bipolar 2); therefore diagnosis (not center) was included as a stratification variable in the analysis models. Center was included in the ANCOVA model as a random effect.

For the primary analysis a Simes-Hommel step up procedure was used to adjust for the 2 comparisons of each quetiapine dose with placebo. The p-values obtained from the analysis were ordered as: $P(1) \leq P(2)$. The following rule was used to assess statistical significance for the primary analysis:

1. If $P(2) \leq 0.05$, then reject both null hypotheses associated with P(2) and P(1): else proceed

2. If $P(1) \leq 0.025$, the reject null hypothesis associated with P(1)

All secondary analyses were conducted at the nominal significance level of 0.05, with no adjustment for multiple comparisons.

The primary analysis of efficacy was performed on the ITT population. A PP analysis was also conducted for the primary efficacy variable to assess sensitivity of results.

Although the data were stratified by entry criteria for diagnosis, bipolar I or bipolar II, if a patient's diagnosis on the case report form differed from the stratification group, the patient was reclassified into the appropriate diagnostic group for analysis.

Patients who were randomized but subsequently were never dosed were excluded from both efficacy and safety analyses.

5.7.4.2 Testing of covariates

In general, the baseline value for a given score was included as a covariate in an analysis of change from baseline for that score. Because randomization was stratified by diagnosis, diagnosis stratum was also included as a covariate where appropriate.

Potential center effects were evaluated. It was not expected that all centers would contribute patients to all strata. Thus imbalances were expected both in terms of number randomized and in the distribution across the strata. The expectation was that approximately 1/3 would be bipolar II and 2/3 bipolar I. There was a limit of 70 patients in a center (13% of the randomized population) but the median was expected to be >12 patients/center.

Assumptions of the intended analysis were explored using blinded data (e.g., using probability plots when testing the assumption of normality and consistency of variance). If any of the assumptions were found to be violated, an appropriate transformation or a non-parametric technique was considered to validate the main results.

5.7.4.3 Efficacy analysis methods

Efficacy analysis methods are summarized below. Changes from the original statistical analysis plan are described in Section 5.8.2.

Primary analysis for MADRS

The primary analysis of change from baseline to final assessment (LOCF) in MADRS total scores tested the superiority of each dose level of quetiapine using an Analysis of Covariance (ANCOVA) with the baseline MADRS total score as the covariate and including treatment and diagnosis strata as fixed effects and center as a random effect in the model.

The significance of the pairwise comparisons of quetiapine dose groups to placebo were ordered and compared to the cut off values for the Simes-Himmel step up procedure to preserve the overall experiment-wise error rate and conserve power.

The primary analysis used the ITT population with a second analysis performed on the PP population to assess sensitivity of results to population.

A further analysis of the change from baseline in MADRS total score was performed using a repeated measures mixed effects model. The model included terms for treatment, bipolar diagnosis, treatment x bipolar diagnosis, baseline MADRS total score, visit (week), and treatment x visit effects. Several covariance structures were examined, including autoregressive, banded Toeplitz, compounded symmetry and unstructured. The best fitting covariance structure, the banded Toeplitz, was determined using the Bayesian information criterion.

Secondary efficacy analysis

All secondary analyses were made in order to yield supportive evidence that quetiapine was more effective than placebo. These analyses used the ITT population and mainly have been

presented as point estimates with associated 95% confidence intervals for the treatment effects and the difference between groups. The confidence levels and p-values displayed are nominal with no adjustment for multiplicity.

MADRS item analyses

Although item analysis for the MADRS was not initially described in the SAP, the items were analyzed using an ANCOVA model. Analysis was conducted for completeness to identify aspects of the scale where quetiapine treatment separated from placebo.

Response

Analysis of categorized MADRS response (at least a 50% reduction from baseline) tested the treatment and placebo difference at each visit and at final assessment (LOCF) using a Cochran-Mantel-Haenszel Chi square test across diagnosis strata. Summary statistics (number and % in each treatment group responding) have been presented along with the p-values and estimated log-odds ratio with 95% confidence interval. The model was fitted using the PROC FREQ procedure in SAS®.

Remission

Post-hoc analysis of categorized MADRS remission (total score ≤12) tested the treatment and placebo difference at each visit and at final assessment (LOCF) using a Cochran-Mantel-Haenszel Chi square test across diagnosis strata. Summary statistics (number and % in each treatment group responding) have been presented along with the p-values and estimated log-odds ratio with 95% confidence interval. The model was fitted using the PROC FREQ procedure in SAS®.

HAM-D

Descriptive statistics have been presented for HAM-D total score, HAM-D Item 1 score, change from baseline for HAM-D total score and change from baseline HAM-D Item 1 by visit and final assessment (LOCF). The ANCOVA model was used with baseline as a covariate and treatment and diagnosis strata as fixed effects.

CGI

Descriptive statistics have been presented for the CGI-S, CGI-I and change from baseline in CGI-S by visit and final assessment.

Two approaches to analysis were evaluated; one approach handled the data as if they were continuous and analyzed the change from baseline CGI-S and CGI-I using an ANCOVA model with baseline CGI-S as a covariate and treatment and diagnosis strata as fixed effects.

In the second approach, the CGI-I was dichotomized into a binomial response: improved (defined as rating of “much improved” or “very much improved”) or not improved (defined as any lesser rating than “much improved”). This was assessed in the same manner as MADRS response.

YMRS total score

Descriptive statistics have been presented for the YMRS total score and the change from baseline in YMRS total score by visit and at final assessment. The ANCOVA model was used with the MADRS baseline as a covariate and treatment and diagnosis strata as fixed effects.

HAM-A

Descriptive statistics have been presented for the HAM-A total score and the change from baseline in HAM-A total score by visit and at final assessment. The ANCOVA model was used with the MADRS baseline as a covariate and treatment and diagnosis strata as fixed effects.

PSQI

The PSQI score was calculated as described in Section 5.5.4.3. Descriptive statistics have been presented for the PSQI total score, change from baseline in PSQI total score and itemized response to each question by assessment visit and final assessment. The ANCOVA model was used for PSQI change from baseline to each assessment and final visit with the baseline PSQI total score as a covariate and treatment and diagnosis strata as fixed effects.

Q-LES-Q

Descriptive statistics of overall level of satisfaction with general activities have been presented for the Q-LES-Q raw total score, Q-LES-Q % maximum total score, change from baseline in Q-LES-Q raw total score, and change from baseline in % maximum total score by assessment visit and final assessment. The ANCOVA model was used for Q-LES-Q change from baseline for both raw total score and % maximum score to each assessment and final visit with the appropriate baseline Q-LES-Q total score as a covariate and treatment and diagnosis strata as fixed effects.

5.7.4.4 Safety analysis methods

All safety analysis were based on the safety population, but where change from baseline was the primary focus of the analysis, only patients with both baseline and post baseline data were included.

Adverse events incidence rates were tabulated and presented for the following categories: all adverse events, serious adverse events, drug related adverse events, adverse events leading to death, and adverse events leading to withdrawal of patients from the study. No formal statistical testing was performed for adverse events.

Safety areas of special interest defined for the Seroquel program included extrapyramidal syndrome (EPS), QT prolongation, neutropenia/agranulocytosis, weight changes, metabolic syndrome, diabetes and suicidality. For this trial, suicidality was defined on the basis of adverse events only. QT prolongation, neutropenia/agranulocytosis, weight changes, metabolic syndrome and diabetes were evaluated on the bases of both adverse event reports and clinical findings. EPS was examined by using adverse event and anticholinergic medication data along with SAS and BARS scores.

Laboratory, weight, vital signs and ECG data have been analyzed as descriptive statistics for change from baseline, as shifts from normal/abnormal values and as shifts from positive/negative potentially clinically important findings.

Glucose metabolism variables were evaluated for the general safety population and for the 3 subgroups of patients defined as 1) known to be diabetic, 2) regarded as at-risk for diabetes, and for those who were 3) neither diabetic nor at-risk for diabetes. Patients were considered as known to be diabetic if they had a history of diabetes or had a baseline fasting glucose assessment ≥126 mg/dL. Patients were considered to be at-risk for diabetes if they had a history of gestational diabetes, a BMI ≥35, or a baseline fasting glucose assessment ≥100 mg/dL but <126 mg/dL. Patients were considered to be neither diabetic nor at-risk for diabetes if they did not meet criteria for diabetes or diabetes risk. Diabetes and at-risk subgroups were also classified on the basis of criteria for random glucose sampling (≥200 mg/dL for diabetes; random criteria were not applied to classify the at-risk category) to explore the possibility of variable fasting status for blood sampling.

As insulin and glucose were measured in this study, post hoc analysis of their functional relationship considered insulin resistance ($HOMA_R$) and insulin sensitivity (QUICKI) as additional summary variables. $HOMA_R$ was computed using the formula:

$$HOMA_R = Insulin\ (\mu U/mL) \times glucose\ (mmol/L)/22.5$$

QUICKI was computed using the formula:

$$QUICKI = 1/\{\log_{10}[fasting\ insulin\ (\mu U/mL)] + \log_{10}[fasting\ glucose\ (mg/dL)]\}$$

A post-hoc evaluation of the glucose change from baseline and the insulin, $HOMA_R$, and QUICKI final assessment results were performed to determine the impact of treatment on those measures. ANCOVA models were applied, with treatment, diabetes risk group, baseline assessment results and study site (random variable) as explanatory variables.

Metabolic syndrome risk factors were evaluated by determining which patients had relevant medical history at baseline or who exhibited combinations of the following findings:

- BMI ≥30 kg/m^2
- Supine systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥85 mmHg averaged over the last 2 assessments
- Triglycerides ≥150 mg/dL
- HDL <40 mg/dL for men or <50 mg/dL for women
- Glucose ≥110 mg/dL or random glucose ≥140 mg/dL

Patients who met an aggregate of at least 3 metabolic syndrome risk factors were considered to be at risk for metabolic syndrome. Patients were classified as meeting or not meeting each individual criterion at baseline and at final assessment. The number and proportion of patients shifting from meeting 0, 1, or 2 criteria to meeting either fewer than 3 vs 3 or more criteria at final assessment were determined. The contribution of each criterion factor to the meeting of 3 or more criteria was evaluated within the population meeting aggregate risk criteria by determining the proportion of patients who shifted from not meeting to fulfilling each individual criterion. A more detailed presentation of the methods used for analyzing metabolic syndrome risk factors is included in Appendix 12.1.9.

The difference between treatment groups in the proportion of patients whose SAS scores and BARS scores were greater than baseline at the final assessment was tested using a logistic regression model. The odds ratio was calculated for each treatment arm compared to placebo, together with a 95% confidence interval, using results from PROC GENMOD and was used to compare treatments. Statistical tests were performed as 2-tailed, with a significance level of 0.05. The main analysis was the final assessment (LOCF) for the time period of interest.

5.7.4.5 Study medication compliance and exposure

To summarize patient dose in concordance with the intent-to-treat principle, the prescribed daily dose (number of tablets) was used to measure the daily dose. Investigators could reduce the dose by 1 tablet per day after day 8 if needed. The number and percentage of patients for whom dose reduction was initiated was tabulated by treatment group.

Individual patient compliance was assessed based on tablets taken and expected number based on the duration of study participation. The patient was then classified as fully compliant (≥80%), partially compliant (≥70% and ≤80%) or non-compliant (<70%).

Patients were classified by the nominal dose for the treatment group to which they were assigned. Descriptive statistics have been provided on the category of compliance by treatment group and diagnosis.

5.7.4.6 Sleep medication use

Number of days and percent of the first 21 days with lorazepam use or sleep medication use was calculated for each patient. If a patient withdrew early, the percent was calculated based on the number of days in the trial if less than 21. These data were summarized by treatment group and diagnosis strata using descriptive statistics.

5.7.4.7 Withdrawals

Differences between treatment groups in overall rate of withdrawal and category of withdrawal were tested using a CMH test stratified by diagnosis. Withdrawals on or before day 8 were examined as part of the consideration of balance between treatment groups due to early withdrawal.

For each visit (week of study) withdrawals were summarized in total and by reason for withdrawal using descriptive statistics.

5.7.5 Determination of sample size

As there were no data using the MADRS instrument in the assessment of quetiapine in treating bipolar subjects with depression, the sample size estimation was based on published data from bipolar depression trials with lamotrigine (Calabrese et al 1999) and olanzapine monotherapy (Tohen et al 2003). The percentage change in the HAM-D across these lamotrigine studies in bipolar depression is similar to that observed with quetiapine (Sajatovic, Mullen and Sweitzer 2002). MADRS scores correlate significantly with those of the HAM-D (Montgomery and Asberg 1979).

Sample size was estimated using an Bonferroni correction for the 2 comparisons with placebo. A clinically meaningful 3.6-unit difference between quetiapine treatment and placebo was used to estimate the effect size (with 3.1 units considered a minimally effective and detectable difference). The variability used for calculation was 10 units, the variability seen in the olanzapine study. A sample size of 168 subjects/arm (504 subjects total) would provide 85% power for 2-sided pair-wise comparisons with placebo at α=0.025 which provides an overall experiment wise type I error rate of 0.05. Therefore, 740 patients were planned for screening and approximately 530 for randomized assignment to treatment (allowing for a 5% early drop out rate), to insure 504 patients with post baseline data available for analysis (MITT analysis population). This sample size would provide 72% power to detect a 3.1 unit difference from placebo.

5.7.6 Interim analyses

There were no interim analyses for this study.

5.7.7 Data and safety monitoring board

There were no data or safety monitoring boards for this study.

5.8 Clinical study protocol amendments and other changes in the conduct of the study or planned analyses

5.8.1 Changes in the conduct of the study

Amendments to the study protocol are shown in Table 18, which also indicates when amendments came into force with respect to the recruitment of subjects.

Table 18 Protocol amendments

Number (date of internal approval)	Key details of amendment (Section of this report affected)	Reason for amendment	Persons who initiated amendment[a]
Amendments made before the start of subject recruitment			
Amendment 1 30 September 02	Inclusion/exclusion criteria adjusted (Section 5.3)	Criteria clarified and better specified	Study team

Table 18 Protocol amendments

Number (date of internal approval)	Key details of amendment (Section of this report affected)	Reason for amendment	Persons who initiated amendment[a]
	QOL and safety outcome variables removed from Days 8, 15, 22, 35 and 43 assessments (Section 5.1)	Assessments deemed unnecessary	Study team
Amendments made after the start of subject recruitment			
Amendment 2 4 December 02	Established administration of the ICI-D (Section 5.5.3.2)	Quality control for MADRS administration	Study team
Amendment 3 21 April 03	Procedure for reporting AEs and for follow-up of AES for 30 days after cessation of study treatment changed to 7 days. (Section 5.5.7.2)	Follow-up limited to no more than 5 half-lives of quetiapine	Study team
	Specification of washout period for psychoactive medications simplified. (Section 5.3.3)	Allowed for greater consistency throughout protocol	
Amendment 4 12 May 03	Minimum and maximum number of patients enrolled per site changed from 4 and 50 to none and 70, respectively (Section 5.1)	Allowed greater enrollment without loss of balance across sites	Study team
	Day 57 or discontinuation assessments of CGI-I, CGI-S and Q-LES-Q added; all psychiatric assessments dropped when patient has missed 72 hours of study drug before visit. (Section 5.1)	Quetiapine's half-life of 4 hours makes 72-hour post dose assessment of questionable value	
	Text added to specify that patient data would be given privacy protection with patient authorization. (Section 1)	Protocol made compliant with HIPAA.	
Amendment 5 14 July 03	Procedure for reporting AEs and for follow-up of AES for 7 days after cessation of study treatment changed to 30 days. (Section 5.5.7.2)	Restored FDA-requested procedures.	Study team

a All protocol amendments were approved within AstraZeneca before being implemented.

5.8.2 Changes to planned analyses

Changes to the planned analyses are shown in Table 19. This table indicates when any changes were made in relation to the unblinding of study data.

Table 19 Changes to planned analyses

Key details of change (Section of this report affected)	Reason for amendment	Persons who initiated amendment
Changes made before unblinding of study data		
Hypotheses for HAM-A outcome variable changed from protocol statement "quetiapine….will be similar or better than placebo in producing anxiety symptoms" to "similar or better than placebo in reducing anxiety symptoms"	Error correction	Study team
Outcome variable name for BARS assessment corrected from "total score" to "global assessment score"	Error correction	Study team
Criteria for treatment-emergent mania/hypomania redefined as YMRS ≥16 on two consecutive assessments or at final assessment or an adverse event of mania or hypomania	Clearer, more inclusive criteria	Study team
Analysis of change from baseline for Q-LES-Q and PSQI at all assessments specified	Clearer, more inclusive criteria	
Criteria for treatment compliance changed in SAP from that stated in protocol	Clearer, more precise definition	Study team
Changes made after unblinding of study data		
Item analysis for MADRS added	Additional interpretive material on efficacy obtained	Study team
Comparative analysis of the rates of remission for each treatment group, defined as the proportion of patients with MADRS scores ≤ 12 at any visit was added to the analysis plan	Additional interpretive material on efficacy obtained	Study team
Comparative analyses of changes from baseline in MADRS item scores for each treatment group added to the analysis plan	Additional interpretive material on efficacy obtained	Study team
Criteria for binomial categorization of CGI-I redefined from that given in SA.	Definition more in accord with accepted criteria in medical literature	Study team
Computation of $HOMA_R$ and QUICKI at each visit added to safety analysis	Additional interpretive material on safety obtained	Study team

Table 19 Changes to planned analyses

Key details of change (Section of this report affected)	Reason for amendment	Persons who initiated amendment
Thyroid function assessments specified as T3 resin uptake instead of triiodothyronine	Clinical laboratory notified study team that incorrect analysis was reported	Study team
Safety assessments of special interest expanded to include EPS, diabetes, QT prolongation, neutropenia/agranulocytosis, weight changes, and metabolic syndrome risk factors	Identified as areas of regulatory interest and necessary for program consistency	Study team
Clinically important criteria revised as specified in Table 15 through Table 17	Criteria adjusted to current standards and for program consistency	Study team

6. STUDY SUBJECTS

A summary of the subject population is given in Section 6.1. Thereafter, the following aspects of the study population are considered: disposition (Section 6.2), adherence to the study protocol (Section 6.3), populations analyzed (Section 6.4), demography and other baseline characteristics (Section 6.5), and treatment compliance and use of concomitant medication (Section 6.6). Conclusions on the suitability of the subject population with respect to the overall purpose of the study are given in Section 6.7.

6.1 Summary of subjects

In total, 838 patients were screened and 542 patients with either bipolar I disorder and bipolar II disorder exhibiting moderate to severe depression were randomly assigned to receive either quetiapine 300 mg daily, quetiapine 600 mg daily or placebo. Bipolar I patients made up 66.4% of the total and bipolar II patients, 33.6%. Approximately 21% of all patients had rapid cycling courses (≥4 mood episodes in past year). The first patient was enrolled on 30 September 2002 and the last patient completed the study on 17 September 2003. Of the 542 patients recruited, 539 received treatment and were included in the safety population, of whom 511 were analyzed for efficacy in an intention-to-treat analysis set and 453 in a per-protocol analysis set. The three groups were well-matched in number and demographic and baseline disease characteristics. The mean patient age was approximately 37 years, and approximately 58% of the patients were female. Approximately 75% to 85% of patients in each treatment group were Caucasian, and most of the remainder were Black. Within the safety population,

67% of quetiapine 300 mg patients, 54% of quetiapine 600 mg patients and 59% of placebo patients completed the protocol. Adverse events were the main reason for withdrawal in quetiapine-treated patients, while lack of efficacy was the main reason for withdrawal in placebo-treated patients.

Table 20 shows where the data supporting this section are presented.

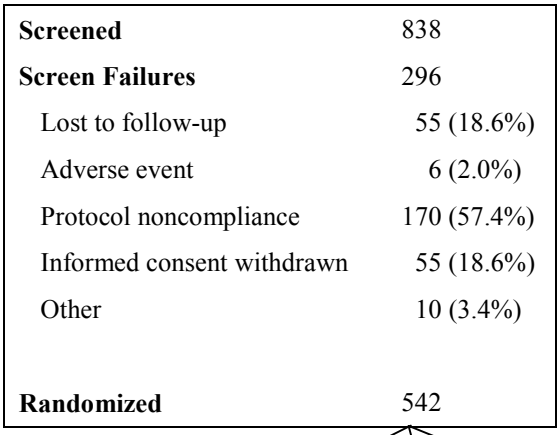
Table 20 Location of supporting data on study subjects

Data	Location	
	Summary tables (Section 11.1)	**Individual subject data (Appendix 12.2)**
Subject disposition	Table 11.1.1.1 to Table 11.1.4.5	Appendix 12.2.1.1 to Appendix 12.2.2
Discontinued subjects	Table 11.1.4.1 to Table 11.1.4.2 and Table 11.1.4.5	Appendix 12.2.1.2
Subjects completing the study	Table 11.1.4.3 to Table 11.1.4.5	Appendix 12.2.1.2
Subjects for whom the treatment code was prematurely broken	None	None
Protocol deviations	Table 11.1.3.1 and Table 11.1.3.2	Appendix 12.2.2
Subjects and data excluded from efficacy analyses	Table 11.1.3.1 and Table 11.1.3.2	Appendix 12.2.1.4
Demographic and baseline characteristics	Table 11.1.5.1.1 to Table 11.1.6.5	Appendix 12.2.4.1, to Appendix 12.2.4.4,
Prior medication use	Table 11.1.7.1 to Table 11.1.7.5	Appendix 12.2.10.6
Concomitant medication use	Table 11.1.7.6 to Table 11.1.7.10	Appendix 12.2.10.7
Treatment compliance	Table 11.3.1.4 to Table 11.3.1.6	Appendix 12.2.5

6.2 Disposition

The disposition of study subjects is summarized in Figure 1.

Figure 1 Subject disposition (completion or discontinuation)



	Quetiapine 300 mg	Quetiapine 600 mg	Placebo
Randomized	181	180	181
Not treated[a]	2	0	1
Received drug	179	180	180
Discontinued study treatment	60	82	74
Lost to follow-up	12	21	11
Adverse event	29	47	16
Protocol noncompliance	10	4	11
Informed consent withdrawn	5	6	12
Lack of efficacy	4	1	24
Other	0	3	0
Completed study	121	98	107

a Patients not treated are also included in the discontinued from study treatment population due to protocol noncompliance

Data derived from Table 11.1.1.1, Table 11.1.2.1 and Table 11.1.4.1

Rates of study completion were 68% for quetiapine 300 mg patients, 54% for quetiapine 600 mg patients and 59% for placebo-treated patients. However, the differences between active treatment groups and the placebo group were not statistically significant (quetiapine 300 mg vs placebo: p = 0.109; quetiapine 600 mg vs placebo: p = 0.343; see Table 11.1.4.5). Similar proportions of patients in the quetiapine 300 mg group (99.4%), the quetiapine 600 mg group (96.1%) and the placebo group (98.9%) participated in the study through the first 8 days of treatment (see Table 11.1.4.3) although some had discontinued study therapy during the first 8 days (see Table 21).

Among all patients assigned to treatment, lack of efficacy was cited as the reason for withdrawal of 2.2% of quetiapine 300 mg patients, 0.6% of quetiapine 600 mg patients and 13.3% of placebo patients (see Table 11.1.4.1). Patients treated with quetiapine 600 mg had higher rates of withdrawal than did quetiapine 300 mg patients and placebo-treated patients due to being lost to follow-up (11.7%, 6.6% and 6.1% respectively; see Table 11.1.4.1). Patients treated with placebo showed higher withdrawal rates due to withdrawal of informed consent than did either quetiapine treated group (placebo: 6.6%; quetiapine 600 mg: 3.3%; quetiapine 300 mg: 2.8%; see Table 11.1.4.1). Withdrawal due to adverse events was seen in 16.0% of quetiapine 300 mg patients, 26.1% of quetiapine 600 mg patients and 8.8% of placebo-treated patients in the randomly-assigned population (see Table 11.1.4.1). Of all patients randomly assigned to treatment, 55.3% of Bipolar I patients and 48.6% of Bipolar II patients completed the protocol (see Table 11.1.4.4).

6.3 Protocol violation and deviations leading to exclusion from the PP population

The number of subjects with protocol violations or deviations in each treatment group that lead to exclusion from the PP population are summarized in Table 21.

Table 21 Protocol violations and deviations leading to exclusion from the PP population

Protocol deviation or violation	Number (%) of ITT subjects		
	Quetiapine 300 mg N=172	Quetiapine 600 mg N=170	Placebo N=169
Protocol violators and deviators[a]	20 (11.6)	23 (13.5)	15 (8.9)
YMRS total score >12 at screen or baseline visit	0 (0)	1 (0.6)	0 (0)
Depression episode >12 months or <4 weeks	0 (0)	1 (0.6)	2 (1.2)
History of substance dependence	1 (0.6)	1 (0.6)	0 (0)
Use of psychoactive medications within 7-28 days prior to randomization[b]	3 (1.7)	4 (2.4)	4 (2.4)
TSH >10% over the ULN at screen/baseline	0 (0)	0 (0)	3 (1.8)

Table 21 Protocol violations and deviations leading to exclusion from the PP population

Protocol deviation or violation	Number (%) of ITT subjects		
	Quetiapine 300 mg N=172	Quetiapine 600 mg N=170	Placebo N=169
Zolpidem use >10 mg in first 3 weeks	1 (0.6)	0 (0)	0 (0)
Zolpidem or lorazepam use after Week 3	1 (0.6)	0 (0)	0 (0)
Potent P450 inhibitor use	0 (0)	1 (0.6)	0 (0)
Antipsychotic use during study	1 (0.6)	1 (0.6)	0 (0)
Antidepressants, hypnotics, mood stabilizers during study	1 (0.6)	3 (1.8)	2 (1.2)
Subjects who reduced study medication by more than 100 mg	0 (0.0)	4 (2.4)	0 (0.0)
Subjects who received any dose reduction before Day 8	3 (1.7)	3 (1.8)	2 (1.2)
Subjects who received less than 70% of prescribed doses	2 (1.2)	2 (1.2)	1 (0.6)
Subjects who received <=8 days of study therapy	15 (8.7)	16 (9.4)	7 (4.1)
MADRS assessment collected >4 days after last dose of study medication	6 (3.5)	6 (3.5)	1 (0.6)
Documented drug abuse during study	1 (0.6)	1 (0.6)	0 (0)
No post-baseline assessment after data exclusions	2 (1.2)	0 (0)	0 (0)

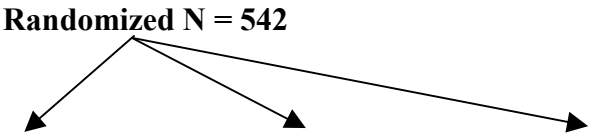
a Patients in this category may have multiple reasons listed below
b See Section 5.1 for drug washout requirements
Data derived from Table 11.1.3.2 and include only items with counts

Patients were excluded from the PP population in similar proportions and for similar causes among the 3 treatment groups overall. Exclusion for receiving less than 9 days of treatment was the most common reason for all treatment groups.

6.4 Subject populations analyzed (analysis sets)

The analysis sets and the number of subjects in each analysis set are summarized in Figure 2. Definitions of the analysis sets are given in Section 5.7.3.

Figure 2 Analysis sets



	Quetiapine 300 mg n = 181	Quetiapine 600 mg n = 180	Placebo n = 181
Excluded from safety population			
Not treated	2	0	1
Safety population	179	180	180
Excluded from ITT population	7	10	11
No valid baseline or post-baseline MADRS score	7	10	7
Multiple center participation	0	0	4
Intent-to-Treat Population	172	170	169
Excluded from PP population see Table 21 for reasons	20	23	15
PP population	152	147	154

Data derived from Table 11.1.2.1, Table 11.1.3.1 and Table 11.1.3.2.

All decisions on the inclusion or exclusion of patients from analyses were made while the data were masked.

Protocol deviations and violations leading to exclusion of quetiapine-treated patients from the ITT population were restricted to missing MADRS data that made computation of change from baseline impossible. Two placebo-treated patients were excluded for participating in the study at more than one site, resulting in a loss of 4 from the ITT population. Altogether, ten of the 180 patients treated with quetiapine 600 mg, 7 of the 179 patients treated with quetiapine 300 mg and 11 of the 180 patients treated with placebo were excluded from the ITT population (see Table 11.1.3.1). Exclusions from the PP population are described in Section 6.3.

6.5 Demographic and other patient characteristics

6.5.1 Sex, age, race and weight

The demographic and key baseline characteristics of study subjects in the ITT population are summarized in Table 22. Data for the safety population are presented in Table 11.1.5.1.1 and Table 11.1.5.2.1.

Table 22 Demographic and baseline characteristics of the ITT population

Demographic or baseline characteristic		Treatment group		
		Quetiapine 300 mg (N=172)	Quetiapine 600 mg (N=170)	Placebo (N=169)
Demographic characteristics				
Sex: n(%)	Male	79(45.9)	71 (41.8)	64 (37.9)
	Female	93(54.1)	99 (58.2)	105 (62.1)
Age (years)	Mean (SD)	36.6 (11.2)	37.3 (11.4)	38.3 (11.1)
	Minimum	18	18	18
	Maximum	65	63	62
Age distribution: n (%)	18-39 years	103 (59.9)	99 (58.2)	96 (56.8)
	40-65 years	69 (40.1)	71 (41.8)	73 (43.2)
Race: n(%)	Caucasian	141 (82.0)	144 (84.7)	129 (76.3)
	Black	23 (13.4)	18 (10.6)	26 (15.4)
	Oriental	0 (0)	1 (0.6)	2 (1.2)
	Hispanic	7 (4.1)	5 (2.9)	9 (5.3)
	Other	1 (0.6)	2 (1.2)	3 (1.8)
Baseline characteristics				
Weight (kg)	Mean (SD)	86.6 (20.9)	84.8 (21.6)	83.8 (21.8)
	Minimum	47	41	44
	Maximum	159	158	149
BMI: n (%)	<18.5 kg/m^2	0	2 (1.2)	2 (1.2)
	18.5 to <25 kg/m^2	47 (27.6)	47 (28.1)	53 (31.4)
	25 to <30 kg/m^2	57 (33.5)	63 (37.7)	51 (30.2)
	30 to <40 kg/m^2	49 (28.8)	40 (24.0)	47 (27.8)
	≥40 kg/m^2	17 (10.0)	15 (9.0)	16 (9.5)

Data derived from Table 11.1.5.1.2 and Table 11.1.5.2.2.

The safety and PP populations were similar to the ITT population in distribution of demographic and baseline characteristics. The treatment groups were well-matched in all analysis populations (see Tables 11.1.5.1.1, and 11.1.5.1.2 and Tables 11.1.5.2.1 and 11.1.5.2.2).

6.5.2 Baseline disease characteristics

Baseline disease characteristics for the ITT population are displayed in Table 23. Baseline disease characteristics for the safety population are presented in Table 11.1.6.1 and Table 11.1.6.2).

Table 23 Baseline disease characteristics (ITT population)

	Quetiapine 300 mg (N=172)		Quetiapine 600 mg (N=170)		Placebo (N=169)	
DSM-IV diagnosis: n (%)						
Bipolar I disorder	116	(67.4)	114	(67.1)	112	(66.3)
Bipolar II disorder	56	(32.6)	56	(32.9)	57	(33.7)
Baseline MADRS total score						
Mean (SD)	30.3	(5.0)	30.3	(5.3)	30.6	(5.3)
Minimum, maximum	13,	45	16,	48	20,	47
Screening HAM-D score						
Mean (SD)	24.3	(3.1)	24.8	(3.6)	24.7	(3.4)
Range – minimum, maximum	20,	35	20,	34	20,	35
Baseline HAM-A score						
Mean (SD)	18.7	(7.3)	18.7	(7.3)	18.9	(7.2)
Range – minimum, maximum	3,	41	0,	38	0,	37
Screening YMRS score						
Mean (SD)	4.9	(2.8)	4.8	(3.2)	4.9	(3.2)
Range – minimum, maximum	0,	12	0,	12	0,	12
Baseline CGI-S score						
Mean (SD)	4.4	(0.5)	4.5	(0.6)	4.4	(0.6)
Range – minimum, maximum	3,	6	3,	6	3,	6
Baseline Q-LES-Q score						
Mean (SD)	35.9	(8.3)	34.3	(9.0)	34.6	(7.8)
Range – minimum, maximum	17,	64	15,	55	14,	63
Years since first depressed episode						
Mean (SD)	18.3	(10.7)	18.4	(10.7)	18.6	(10.8)
Range – minimum, maximum	2,	47	2,	45	2,	55

Table 23 Baseline disease characteristics (ITT population)

	Quetiapine 300 mg (N=172)		Quetiapine 600 mg (N=170)		Placebo (N=169)	
Depressed episodes over lifetime						
Mean (SD)	14.3	(23.1)	17.4	(43.3)	15.5	(25.4)
Range – minimum, maximum	1,	199	0,	456	0,	200
Depressed episodes over past year						
Mean (SD)	1.3	(1.8)	1.3	(2.3)	1.4	(3.6)
Range – minimum, maximum	0,	12	0,	24	0,	36
Years since first manic or hypomanic episode						
Mean (SD)	14.6	(10.1)	15.6	(9.5)	15.2	(10.5)
Range – minimum, maximum	1,	44	2,	43	1,	54
Manic or hypomanic episodes over lifetime						
Mean (SD)	11.1	(15.0)	12.3	(18.9)	13.8	(19.5)
Range – minimum, maximum	1,	99	1,	99	1,	120
Manic or hypomanic episodes over past year						
Mean (SD)	1.3	(1.5)	1.4	(2.4)	1.6	(3.5)
Range – minimum, maximum	0,	8	0,	20	0,	36
Mood episodes over the past year: n (%)						
<4	130	75.6	139	81.8	134	79.3
≥4	42	24.4	31	18.2	35	20.7

Data derived from Table 11.1.6.1, Table 11.1.6.3, Table 11.2.1.1.1, Table 11.2.2.1.1, Table 11.2.3.1.1, Table 11.2.5.1.1, Table 11.2.6.1, Table 11.1.6.5, Table 11.3.8.1..7.1

MADRS total scores at baseline ranged from 13 to 48; the mean MADRS total score was between 30 and 31 in the 3 groups within the ITT population. The PP population was similar to the ITT population with respect to baseline MADRS scale scores (see Table 11.2.1.1.1 and Table 11.2.1.1.3). HAM-D total scores at screening ranged from 20 to 35; the mean HAM-D total score was between 24 and 25 in the 3 groups within the ITT population. CGI-S scores at screening ranged from 3 to 6 with means of 4.3 to 4.5 for the 3 groups.

Descriptive parameters for years since first depressed episode, for the number depressed episodes over lifetime and for the number of manic or hypomanic episodes over lifetime were similar for the 3 treatment groups (see Table 23).

The ITT population comprised two-thirds Bipolar I and one-third Bipolar II patients, with similar proportions for each treatment group (see Table 11.1.6.1). Both Bipolar I and Bipolar II patients exhibited baseline mean MADRS scores of 30 to 31 points and mean screening HAM-D scores of 24 to 25 points (see Table 11.2.1.1.2 and Table 11.2.2.1.1). CGI-S scores for the Bipolar I patients ranged from 4.4 to 4.5 for the 3 groups, while for the Bipolar II patients, from 4.2 to 4.4 (see Table 11.2.3.4.1). Patients with a rapid cycling course (≥4 mood episodes in the past year) made up 21% of patients in all three treatment groups (see Table 11.1.6.5).

6.6 Treatment compliance and use of concomitant medication

6.6.1 Treatment compliance

Compliance was uniform and high within the entire safety population for the 3 treatment groups. One hundred seventy six quetiapine 300 mg patients (98.3%), 177 quetiapine 600 mg patients (98.3%) and 178 placebo patients (98.9%) were classified as being compliant on the basis of tablet counts that were consistent with at least 80% consumption of doses (see Table 11.3.1.4).

6.6.2 Concomitant medication

6.6.2.1 Use of medication at study entry

The use of psychoactive medications at Visit 1 (screening) in the ITT population is summarized in Table 11.1.7.2. Approximately 16% to 17% of patients in the safety population were taking an antidepressant before Visit 1 (screening); 4% to 12% were taking an antipsychotic, and 3% to 8% were taking both an antipsychotic and an antidepressant (see Table 11.1.7.5). The treatment groups were well-matched with respect to recent medication history.

6.6.2.2 Use of concomitant medication after randomization

The use of psychoactive medications after study entry in the ITT population is summarized in Table 11.1.7.7. Lorazepam use was noted for 9.9% of quetiapine 300 mg patients, 5.3% of quetiapine 600 mg patients and 8.3% of placebo patients. Zolpidem use was noted for 4.1% of quetiapine 300 mg patients, 6.5% of quetiapine 600 mg patients and 7.7% of placebo patients. Deviations from the protocol list of excluded medications were recorded for a small number of patients in the safety population and were distributed across all three treatment groups. Most of these cases arose from hospitalizations for psychiatric AEs (see individual patient narratives in Section 11.3.5.3) or from prescriptions initiated at the close of a patient's participation in the study.

Anticholinergic use for any indication was low (<7% at any week) for all treatment groups (see Table 11.1.7.10). One patient (Patient 0014012; see Table 12.2.10.7) treated with 600 mg of quetiapine daily for 18 days was given diphenhydramine 10 mg for 2 days to treat akathisia.

6.7 Conclusions on study subjects

The 542 patients with either bipolar I disorder or bipolar II disorder exhibiting moderate to severe depression who participated in this study provided an adequate number to meet the design requirements to provide adequate statistical power. The patients were representative of the general patient population -- bipolar I patients made up 66.4% of the total, and 21.1% of all patients had rapid cycling courses. The three treatment groups were well-matched in number and demographic and baseline disease characteristics. The mean patient age was approximately 37 years, and approximately 58% of the patients were female. Approximately 75% to 85% of patients in each treatment group were Caucasian, and most of the remainder were Black. Within the safety population, 67% of quetiapine 300 mg patients, 54% of quetiapine 600 mg patients and 59% of placebo patients completed the study. Adverse events were the main reason for withdrawal in quetiapine-treated patients, while lack of efficacy was the main reason for withdrawal in placebo-treated patients.

7. EFFICACY RESULTS

A summary of the efficacy results is given in Section 7.1. Full results are given in following sections, and any issues potentially affecting these results are discussed in Section 7.6. Conclusions on efficacy are given in Section 7.7.

7.1 Summary of efficacy results

The comparison of change from baseline in total MADRS score supported the hypothesis that quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment of a depressive episode in patients with bipolar disorder was superior to placebo in reducing the level of depressive symptoms. Quetiapine treated groups also showed superiority to placebo at Day 57 for changes from baseline in HAM-D total score, HAM-D Item 1, CGI and the HAM-A, and for MADRS-defined response. A treatment advantage for quetiapine over placebo for the primary and most secondary outcome variables was statistically significant by Day 8 and continued to be so through Day 57. The proportion of patients showing ≥50% reduction in MADRS total score (responders) was statistically significantly higher for the quetiapine 600 mg group compared to the placebo group by Day 8 and for the quetiapine 300 mg group by Day 15.

Table 24 shows where the data supporting this section are presented.

Table 24 Location of supporting data on efficacy

Data	Location	
	Summary tables (Section 11.2)	**Individual subject data (Appendix 12.2.6)**
Primary variable		
MADRS total score	Table 11.2.1.1.1, to Table 11.2.1.2.8, Table 11.2.1.4.1 to Table 11.2.1.4.4, Table 11.2.1.7 to Table 11.2.1.9, Table 11.2.1.10.1, to Table 11.2.1.10.4 Table 11.2.1.11.1, to Table 11.2.1.11.10 Figure 11.2.1.3.1 to Figure 11.2.1.3.6, Figure 11.2.1.5.1 to Figure 11.2.1.5.2	Appendix 12.2.6.1
Secondary variables		
MADRS response	Table 11.2.1.12, Table 11.2.1.13.1 to Table 11.2.1.13.6, Table 11.2.1.15 Figure 11.2.1.14	Appendix 12.2.6.1
MADRS remission	Table 11.2.1.15, Table 11.2.1.16.1 Table 11.2.1.16.2 Figure 11.2.1.17	Appendix 12.2.6.1
HAM-D	Table 11.2.2.1.1 to Table 11.2.2.2.4, Table 11.2.2.4.1 to Table 11.2.2.5.2 Figure 11.2.2.3.1 to Figure 11.2.2.3.6	Appendix 12.2.6.2
HAM-D Item 1	Table 11.2.2.5.1 to Table 11.2.2.6.4	Appendix 12.2.6.2

Table 24 Location of supporting data on efficacy

Data	Location	
	Summary tables (Section 11.2)	**Individual subject data (Appendix 12.2.6)**
CGI-S	Table 11.2.3.1.1 to Table 11.2.3.2.4, Table 11.2.3.4.1 to Table 11.2.3.6 Figure 11.2.3.3.1 to Figure 11.2.3.3.3	Appendix 12.2.6.3
CGI-I	Table 11.2.4.1.1 ,to Table 11.2.4.2.6, Table 11.2.4.4.1, Table 11.2.4.4.2 Figure 11.2.4.3	Appendix 12.2.6.3
HAM-A	Table 11.2.5.1.1, to Table 11.2.5.2.4, Table 11.2.5.4.1, Table 11.2.5.4.2 Figure 11.2.5.3.1 to Figure 11.2.5.3.3	Appendix 12.2.6.5

7.2 Efficacy results

7.2.1 Primary variable: MADRS total score change from baseline at last assessment

Results of the analysis of Day 57 change from baseline in MADRS total score are shown in Table 25.

Table 25 MADRS total score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**Upper 95% Limit**	**p-value**
Quetiapine 300 mg	172	30.3 (5.03)	-16.39	-14.59	
Quetiapine 600 mg	170	30.3 (5.29)	-16.73	-14.92	
Placebo	169	30.6 (5.27)	-10.26	-8.45	
Quetiapine 300 mg vs placebo			-6.13	-3.94	<0.001
Quetiapine 600 mg vs placebo			-6.47	-4.26	<0.001

Data derived from Table 11.2.1.2.1

MADRS total scores decreased for both quetiapine and placebo-treated patients, but the decrease was significantly greater for the quetiapine-treated patients (see Table 25). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 6.13 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 6.47 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo:$p<0.001$; see Table 25). The same general magnitude of mean difference between treatments was also seen in the PP patients in the ITT population in which quetiapine 300 mg patients had a least square mean of 6.39 points lower score than did placebo-treated patients and quetiapine 600 mg patients had a least square mean of 7.14 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 11.2.1.2.3). The OC analysis of the ITT population, revealed that patients treated with quetiapine 300 mg had a least square mean of 5.67 points lower than placebo-treated patients and those treated with quetiapine 600 mg, had a least square mean of 7.74 points less than placebo-treated patients at Day 57 (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 300 mg vs placebo: $p<0.001$; see Table 11.2.1.2.2).

Analysis using the MMRM technique supported the primary analysis findings (see Table 11.2.1.2.7).

Change from baseline in MADRS total score is shown by bipolar diagnosis in Table 26.

Table 26 MADRS change from baseline at Day 57 by bipolar diagnosis (LOCF, ITT population)

	QTP 300		QTP 600		Placebo	
	N	Mean change	N	Mean change	N	Mean change
Bipolar I	116	-17.1	114	-18.2	112	-9.5
Bipolar II	56	-15.2	56	-13.9	57	-12.2

Data derived from Table 11.2.1.4.1

Bipolar I and bipolar II patients treated with either 300 mg or 600 mg of quetiapine showed greater improvements in MADRS total score compared to patients treated with placebo. Bipolar I patients exhibited larger differences from placebo at final assessment than did bipolar II patients. The less pronounced differential effect for Bipolar II patients was due to a smaller reduction in MADRS total score for each quetiapine treatment group and a greater reduction in score for Bipolar II placebo patients compared to Bipolar I placebo patients (see also Figure 11.2.1.5.1).

Descriptive statistics of MADRS data classified by race, age or sex did not reveal any notable differences between the treatment groups (see Table 11.2.1.7, Table 11.2.1.8 and Table 11.2.1.9).

Comparison of quetiapine treatment groups to the placebo treatment group for MADRS individual item changes from baseline at Day 57 is shown in Table 27.

Table 27 MADRS item comparisons at Day 57 (LOCF, ITT population)

	Quetiapine 300 mg		Quetiapine 600 mg	
MADRS item	**LS mean difference from placebo**	**p-value**	**LS mean difference from placebo**	**p-value**
1. Apparent sadness	-0.57	<0.001	-0.66	<0.001
2. Reported sadness	-0.67	<0.001	-0.80	<0.001
3. Inner tension	-0.49	0.002	-0.75	<0.001
4. Reduced sleep	-1.28	<0.001	-1.38	<0.001
5. Reduced appetite	-0.34	0.056	-0.29	0.107
6. Concentration difficulties	-0.61	<0.001	-0.51	0.005
7. Lassitude	-0.32	0.080	-0.40	0.028
8. Inability to feel	-0.59	<0.001	-0.55	0.002
9. Pessimistic thoughts	-0.81	<0.001	-0.71	<0.001
10. Suicidal thoughts	-0.43	<0.001	-0.41	0.001

Data derived from Table 11.2.1.11.1 through Table 11.2.1.11.10

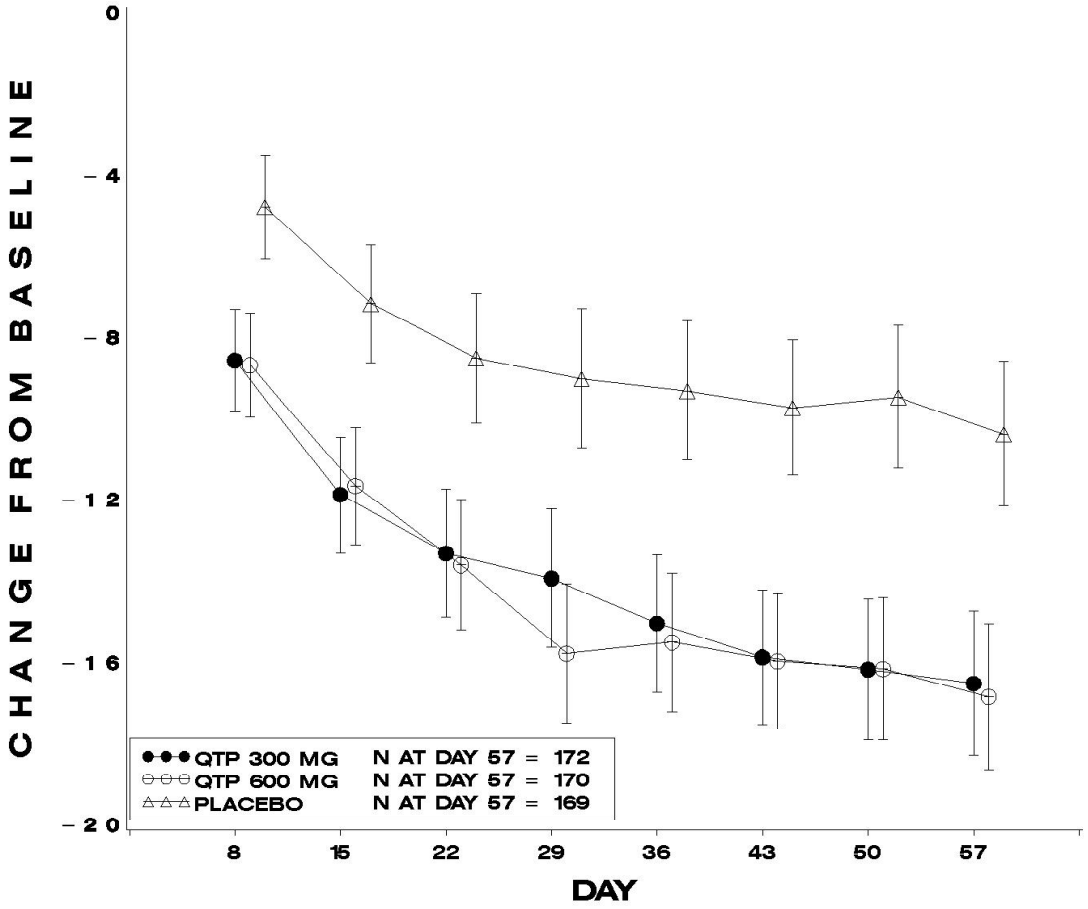
All of the ten individual MADRS item scores were reduced more by quetiapine treatment than by placebo treatment, with the largest treatment differences in Reduced Sleep and Reported Sadness items. The Reduced Appetite and Lassitude items were the only two that did not reach p-values <0.05 for both doses of quetiapine.

7.2.2 Secondary variables

7.2.2.1 Change from baseline to each assessment for the MADRS total score

Changes from baseline in the MADRS total score at each visit for ITT patients are shown in Figure 3.

Figure 3 **MADRS total score change from baseline -- LS mean (95% CI) (LOCF, ITT population)**

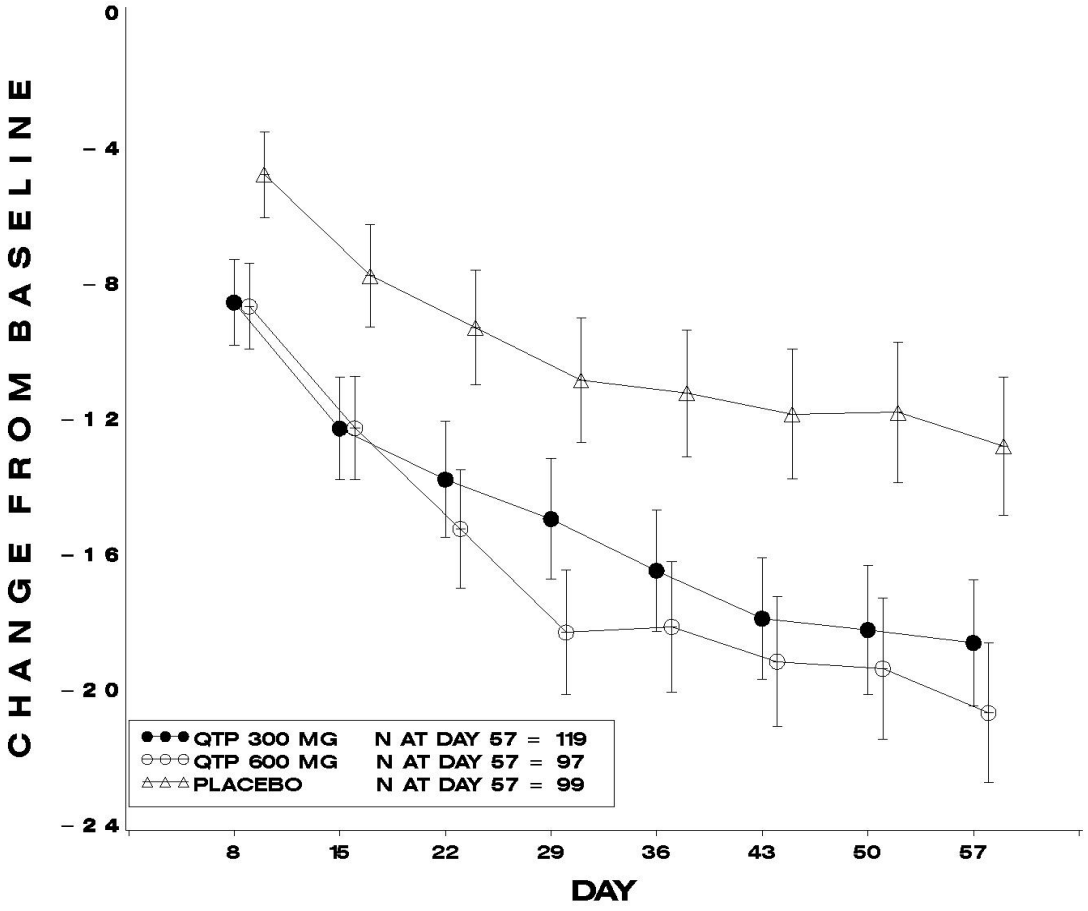


Replication of Figure 11.2.1.3.5

Baseline MADRS values were similar for the 3 groups. The change from baseline for both quetiapine treatment groups was significantly better than placebo at Day 8 (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$) and continued to be superior to placebo at all subsequent assessments (see Table 11.2.1.2.1).

Changes from baseline in the MADRS total score at each visit for observed cases in the ITT population are shown in Figure 4.

Figure 4 **MADRS total score change from baseline -- LS mean (95% CI) (OC, ITT population)**



Replication of Figure 11.2.1.3.6

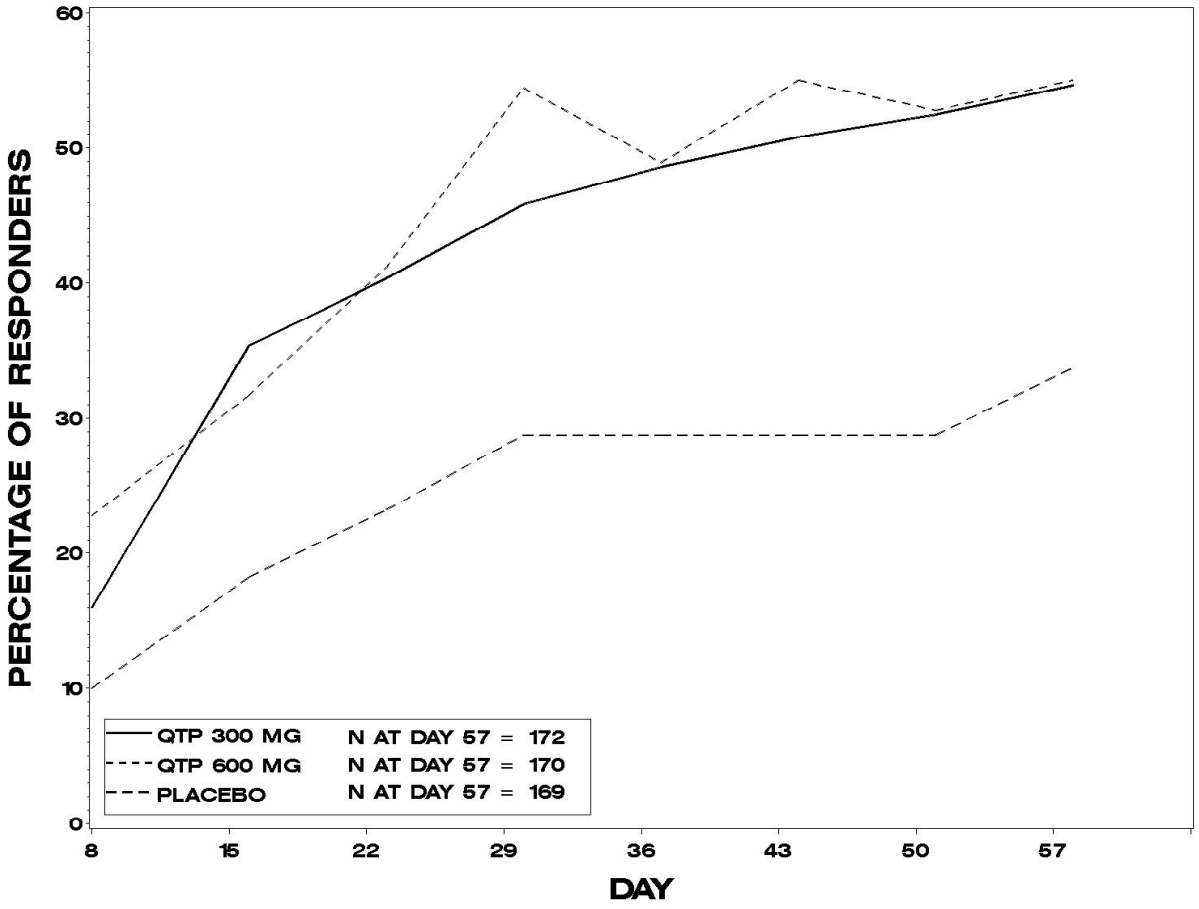
Changes from baseline in MADRS score for observed cases showed greater separation from placebo for the two quetiapine treatment groups at Day 8 and continued to be superior to placebo at all subsequent assessments. The OC analysis indicated that patients taking 600 mg of quetiapine showed greater improvement than did those taking 300 mg of quetiapine.

Throughout the course of treatment, OC data revealed that bipolar I and bipolar II patients treated with either 300 mg or 600 mg of quetiapine showed greater improvements in MADRS total score compared to patients treated with placebo (see Figure 11.2.1.5.1).

7.2.2.2 MADRS response

The percentage of patients showing a MADRS response, at least a 50% improvement from baseline in MADRS total score, is shown for each visit in Figure 5.

Figure 5 **MADRS response (≥50% score reduction) -- percent of patients responding by visit day (LOCF, ITT population)**



Replication of Figure 11.2.1.14

At final assessment, 58% of quetiapine 300 mg patients, 58% of quetiapine 600 mg patients and 36% of placebo patients had achieved a status of MADRS responder (quetiapine 300 mg vs placebo p<0.001; quetiapine 600 mg vs placebo p<0.001; see Table 11.2.1.13.1). The statistically significant differential between quetiapine and placebo groups was established by Day 15 for the quetiapine 300 mg group (p<0.001) and by Day 8 for the quetiapine 600 mg group (p<0.001) and continued to be superior to placebo at all subsequent assessments for both quetiapine groups (see Table 11.2.1.13.1). Similar comparisons of the three treatment groups were noted when criteria for response were varied from 30% to 70% (see Table 11.2.1.12).

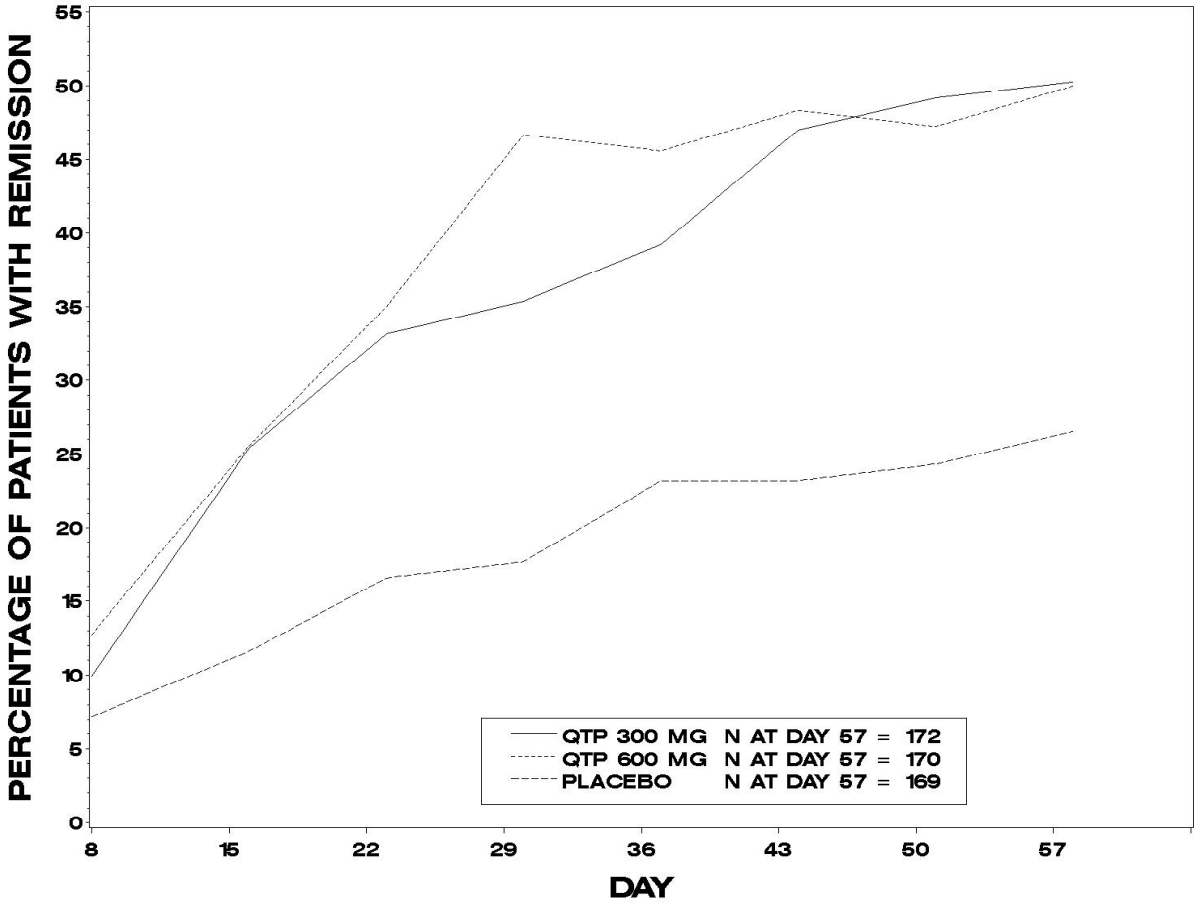
Among those who completed the study, 68% of patients treated with quetiapine 300 mg, 74% of patients treated with quetiapine 600 mg and 46% of patients treated with placebo met criteria for MADRS response (quetiapine 300 mg vs placebo p=0.002; quetiapine 600 mg vs placebo p<0.001; see Table 11.2.1.13.2).

Within the Bipolar I population at Day 57, 62% of quetiapine 300 mg patients, 64% of quetiapine 600 mg patients and 33% of placebo patients had achieved a status of MADRS responder. For Bipolar II patients, the response rates were 48% for quetiapine 300 mg patients, 46% for quetiapine 600 patients and 42% for placebo patients (see Table 11.2.1.13.1).

7.2.2.3 MADRS-defined remission

The percentage of patients showing a reduction in MADRS score to ≤12, is shown for each visit in Figure 6.

Figure 6 MADRS-defined remission (MADRS score ≤12) -- percent of patients by visit day (LOCF, ITT population)



Replication of Figure 11.2.1.17

At last assessment, 53% of quetiapine 300 mg patients, 53% of quetiapine 600 mg patients and 28% of placebo patients had achieved a MADRS score of ≤12 and were regarded as being in remission (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 11.2.1.16.1). The statistically significant difference between quetiapine and placebo

groups was established by Day 15 for both quetiapine-treated groups (p<0.001) and continued to be superior to placebo at all subsequent assessments (see Table 11.2.1.16.1).

7.2.2.4 Change from baseline to each assessment for the HAM-D total score

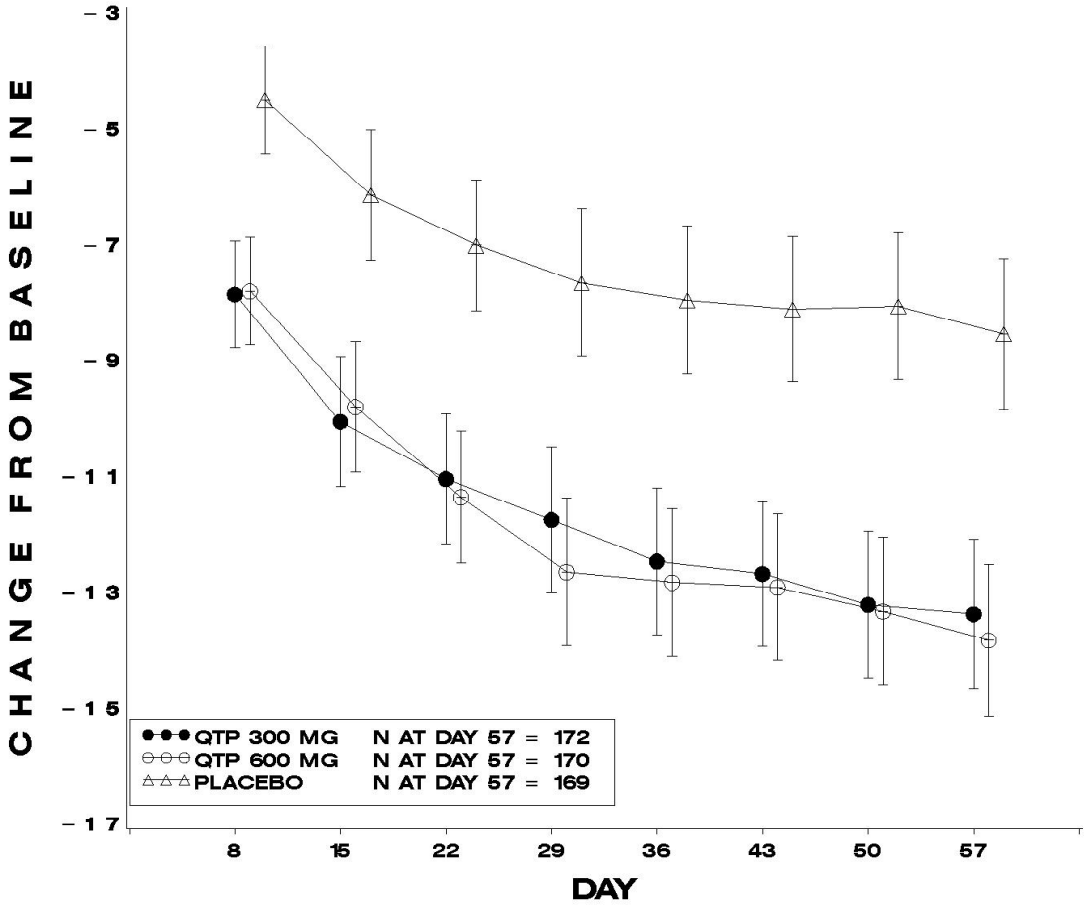
Results of the analysis of Day 57 change from baseline in HAM-D total score are shown in Table 28. Changes from baseline in the HAM-D total score at each visit for ITT patients are shown in Figure 7.

Table 28 HAM-D total score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**Upper 95% Limit**	**p-value**
Quetiapine 300 mg	172	24.5 (3.00)	-13.38	-12.07	
Quetiapine 600 mg	170	24.7 (3.51)	-13.84	-12.51	
Placebo	169	24.6 (3.29)	-8.54	-7.22	
Quetiapine 300 mg vs placebo			-4.84	-3.26	<0.001
Quetiapine 600 mg vs placebo			-5.29	-3.71	<0.001

Data derived from Table 11.2.2.2.1

Figure 7 **HAM-D total score change from baseline --LS mean (95% CI) (LOCF, ITT population)**



Replication of Figure 11.2.2.3.5

Baseline HAM-D values were similar for the 3 groups. The improvement for both quetiapine treatment groups was significantly better than placebo at Day 8 (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$) and continued to be superior to placebo at all subsequent assessments (see Table 11.2.2.2.1 and Figure 7). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 4.84 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 5.29 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 28).

Among patients who completed the study, quetiapine 300 mg patients in the ITT population had a least square mean of 4.46 points lower HAM-D total score at Day 57 than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 6.32 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 11.2.2.2.2).

Mean individual HAM-D item scores were lower for quetiapine-treated patients compared to those for placebo-treated patients, with the largest treatment differences in Depressed Mood, Anxiety Psychic, Work and Activities and the 3 insomnia items (see Table 11.2.2.5.1 and Table 11.2.2.5.2).

7.2.2.5 Change from baseline to each assessment for the HAM-D Item 1 (depressed mood) score

Results of the analysis of Day 57 change from baseline in HAM-D Item 1 (depressed mood) score are shown in Table 29.

Table 29 HAM-D Item 1 score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**Upper 95% Limit**	**p-value**
Quetiapine 300 mg	172	2.9 (0.46)	-1.65	-1.46	
Quetiapine 600 mg	170	2.9 (0.48)	-1.68	-1.49	
Placebo	169	2.9 (0.44)	-1.11	-0.92	
Quetiapine 300 mg vs placebo			-0.54	-0.30	<0.001
Quetiapine 600 mg vs placebo			-0.57	-0.33	<0.001

Data derived from Table 11.2.2.6.1

Baseline HAM-D Item 1 values were similar for the 3 groups. The improvement for both quetiapine treatment groups was significantly better than placebo at Day 8 (quetiapine 300 mg vs placebo: p=0.003; quetiapine 600 mg vs placebo: p=0.003) and continued to be superior to placebo at all visits (see Table 11.2.2.6.1). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 0.54 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.57 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo p<0.001; quetiapine 600 mg vs placebo p<0.001; see Table 29).

Among patients who completed the study, quetiapine 300 mg patients in the ITT population had a least square mean of 0.51 points lower HAM-D Item 1 score at Day 57 than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least

square mean of 0.64 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo p<0.001; quetiapine 600 mg vs placebo p<0.001; see Table 11.2.2.6.2).

7.2.2.6 Change from baseline to each assessment for the CGI-S score

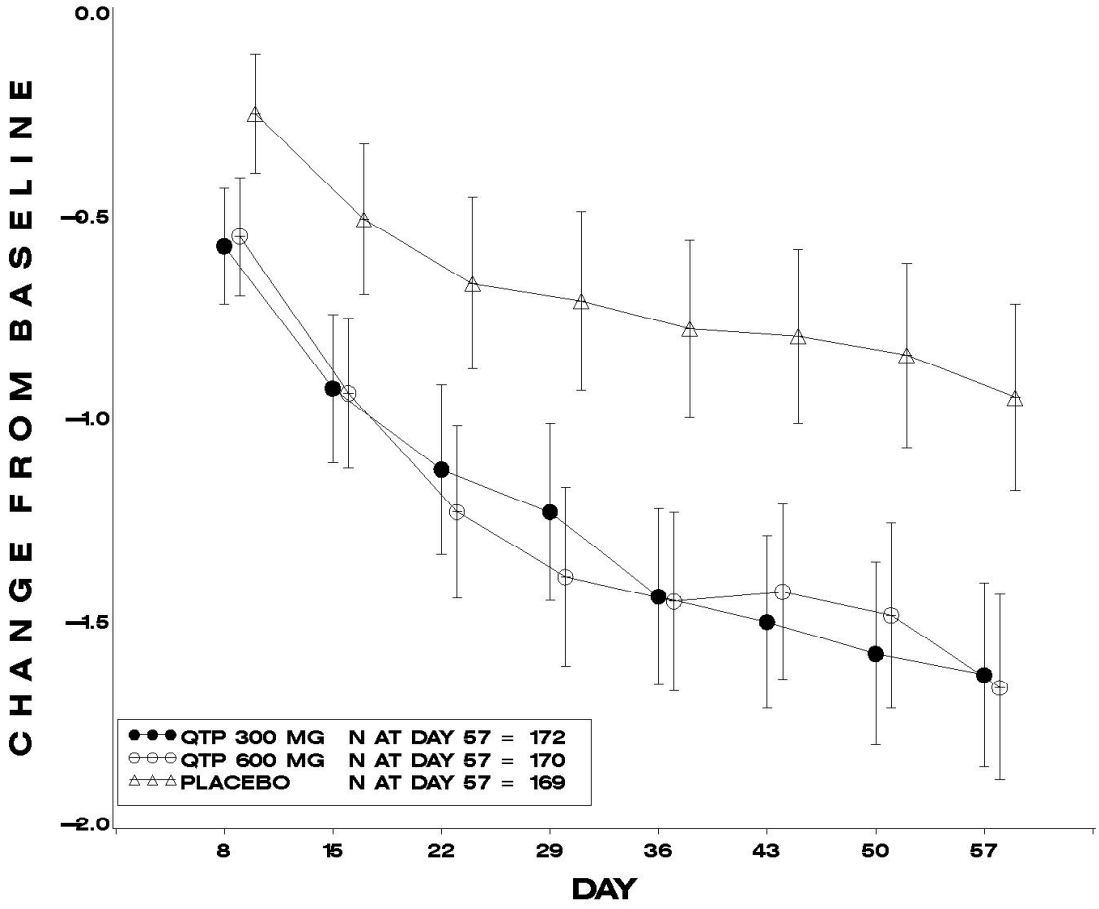
Results of the analysis of Day 57 change from baseline in CGI-S score are shown in Table 30. Changes from baseline in the CGI-S score at each visit for ITT patients are shown in Figure 8.

Table 30 CGI-S score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**Upper 95% Limit**	**p-value**
Quetiapine 300 mg	172	4.4 (0.52)	-1.63	-1.40	
Quetiapine 600 mg	170	4.5 (0.62)	-1.66	-1.43	
Placebo	169	4.4 (0.60)	-0.95	-0.71	
Quetiapine 300 mg vs placebo			-0.68	-0.42	<0.001
Quetiapine 600 mg vs placebo			-0.72	-0.45	<0.001

Data derived from Table 11.2.3.2.1

Figure 8 **CGI-S score change from baseline -- LS mean (95% CI) (LOCF, ITT population)**



Replication of Figure 11.2.3.3.3

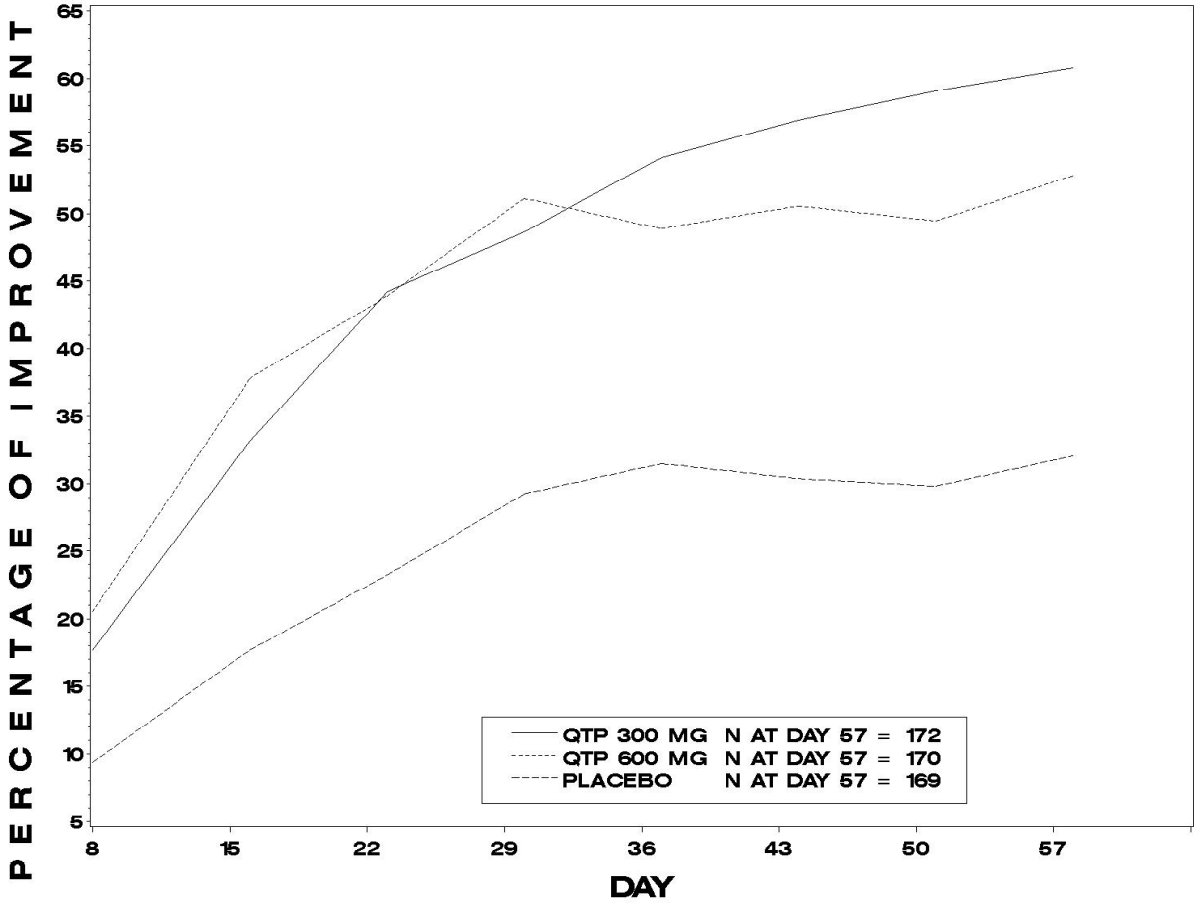
Baseline CGI-S values were similar for the 3 groups within the ITT population. The response for both quetiapine treatment groups was significantly better than placebo at Day 8 (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$) and continued to be superior to placebo at all visits (see Table 11.2.3.2.1 and Figure 8). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 0.68 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.72 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 30).

Among ITT patients who completed the study, on Day 57 quetiapine 300 mg patients in the ITT population had a least square mean of 0.62 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.98 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$; see Table 11.2.3.2.2).

7.2.2.7 CGI-I

The percent of patients rated as "much improved" or "very much improved" on the CGI-I at each visit is presented in Figure 9.

Figure 9 **CGI-I scale -- patients "much improved" or "very much improved" (LOCF, ITT population)**



Replicated from Figure 11.2.4.3

At last observation, 64% of quetiapine 300 mg patients, 56% of quetiapine 600 mg patients and 34% of placebo patients were rated as "much improved" or "very much improved" in the CGI-I (quetiapine 300 mg vs placebo: $p < 0.001$; quetiapine 600 mg vs placebo: $p < 0.001$; see Table 11.2.4.2.5). The differentiation between quetiapine and placebo treatment was apparent at earlier assessments and persisted to the final assessment. At Day 8, 19% of quetiapine 300 mg patients, 22% of quetiapine 600 mg patients and 10% of placebo patients had shown global improvement in the CGI-I (quetiapine 300 vs placebo: $p = 0.024$; quetiapine 600 mg vs placebo: $p = 0.003$; see Table 11.2.4.2.5).

Among patients who completed the study, at Day 57, 74% of quetiapine 300 mg patients, 77% of quetiapine 600 mg patients and 42% of placebo patients were rated as "much improved" or "very much improved" in the CGI-I (quetiapine 300 mg vs placebo: $p < 0.001$; quetiapine 600 mg vs placebo: $p = 0.001$; see Table 11.2.4.2.6).

Results of the ANCOVA of Day 57 CGI-I scores are shown in Table 31.

Table 31 CGI-I score at Day 57 (LOCF, ITT population)

		ANCOVA results		
	N	**CGI-I LS mean change or difference**	**Upper 95% limit**	**p-value**
Quetiapine 300 mg	172	2.27	2.49	
Quetiapine 600 mg	170	2.37	2.59	
Placebo	169	2.97	3.20	
Quetiapine 300 mg vs placebo		-0.71	-0.44	<0.001
Quetiapine 600 mg vs placebo		-0.60	-0.34	<0.001

Data derived from Table 11.2.4.2.1

The response for the CGI-I score for both quetiapine treatment groups was significantly better than placebo at Day 8 (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$) and continued to be superior to placebo at all visits (see Table 11.2.4.2.1). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a CGI-I least square mean of 0.71 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.60 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 31).

Among patients who completed the study, quetiapine 300 mg patients in the ITT population had a CGI-I least square mean of 0.68 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.83 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 11.2.4.2.2).

7.2.2.8 Change from baseline the HAM-A total score

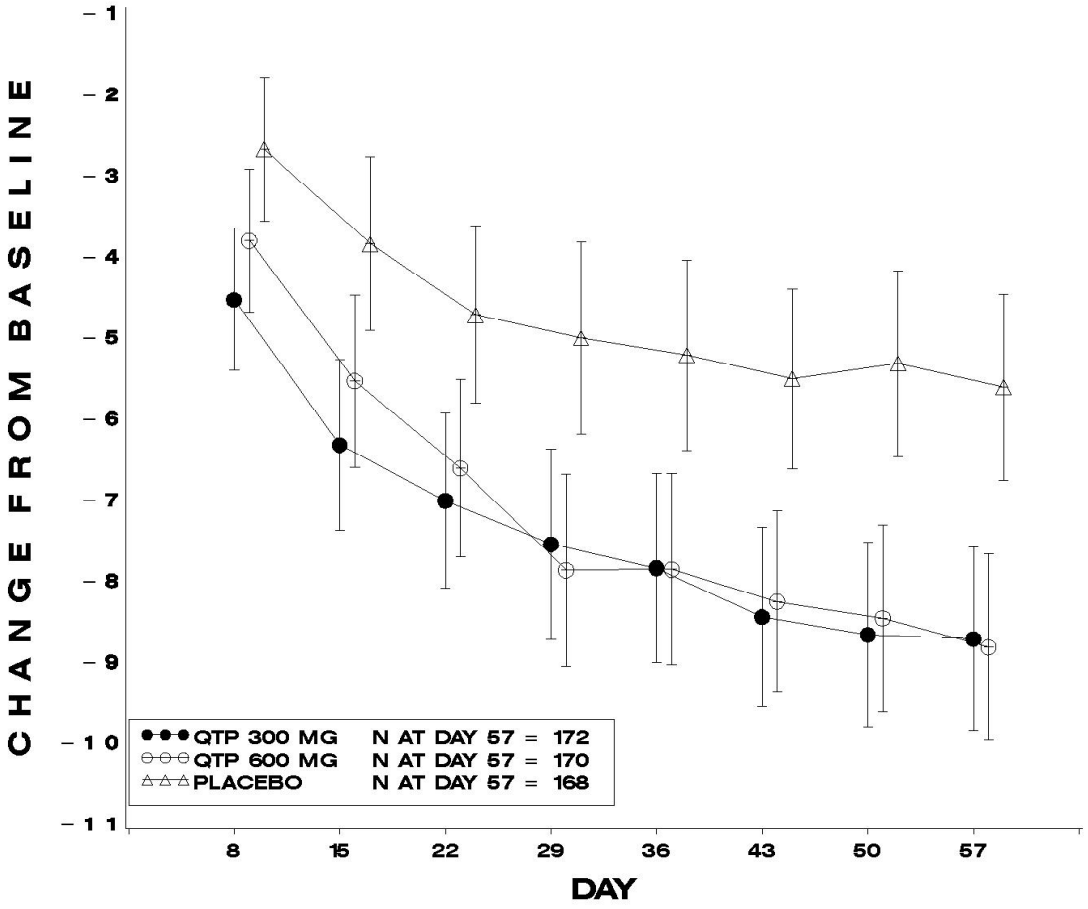
Results of the analysis of Day 57 change from baseline in HAM-A total score are shown in Table 32. Changes from baseline in the HAM-A score at each visit for ITT patients are shown in Figure 10.

Table 32 HAM-A score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline mean (SD)**	**LS mean change or difference**	**Upper 95% limit**	**p-value**
Quetiapine 300 mg	172	18.7 (7.28)	-8.64	-7.49	
Quetiapine 600 mg	170	18.7 (7.32)	-8.75	-7.59	
Placebo	168	18.9 (7.25)	-5.54	-4.38	
Quetiapine 300 mg vs placebo			-3.10	-1.61	<0.001
Quetiapine 600 mg vs placebo			-3.20	-1.71	<0.001

Data derived from Table 11.2.5.2.1

Figure 10 **HAM-A score change from baseline -- LS mean (95% CI) (LOCF, ITT population)**



Replication of Figure 11.2.5.3.3

The response for the HAM-A score for both quetiapine treatment groups was significantly better than placebo at Day 8 (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p=0.031$) and continued to be superior to placebo at all visits (see Table 11.2.5.2.1 and Figure 10). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a HAM-A least square mean of 3.10 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 3.20 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine: 600 mg vs placebo $p<0.001$; see Table 32).

Among patients who completed the study, at Day 57 quetiapine 300 mg patients in the ITT population had a HAM-A least square mean of 3.21 points lower score than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 4.37 points lower score than did placebo-treated patients (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine: 600 mg vs placebo $p<0.001$; see Table 11.2.5.2.2).

Individual items of the HAM-A that most differentiated quetiapine-treated patients from placebo patients were Anxious Mood, Depressed Mood, Insomnia, Genitourinary and Tension (see Table 11.2.5.4.1 and Table 11.2.5.4.2).

7.3 Patient Reported Outcomes

7.3.1 Summary of patient reported outcomes

Table 33 shows where the data supporting this section are presented.

Table 33 Location of supporting data on patient reported outcomes

Data	Location	
	Summary tables (Section 11.2)	**Individual subject data (Appendix 12.2.6)**
Q-LES-Q	Table 11.2.6.1 to Table 11.2.6.3	Table 12.2.6.7
PSQI	Table 11.2.7.1.1, to Table 11.2.7.3.2	Table 12.2.6.6

7.3.2 Patient reported outcomes results

7.3.2.1 Q-LES-Q

Results of the analysis of Day 57 change from baseline in Q-LES-Q total score are shown in Table 34.

Table 34 Q-LES-Q percent-of-maximum-score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**Lower 95% Limit**	**p-value**
Quetiapine 300 mg	156	39.5 (14.05)	19.27	16.33	
Quetiapine 600 mg	157	35.9 (14.65)	20.93	18.02	
Placebo	158	36.0 (13.24)	11.54	8.64	
Quetiapine 300 mg vs placebo			7.72	3.68	<0.001
Quetiapine 600 mg vs placebo			9.39	5.37	<0.001

Data derived from Table 11.2.6.2.3

The Q-LES-Q responses for both quetiapine treatment groups were significantly better than placebo at final assessment (quetiapine 300 mg vs. placebo: <0.001; quetiapine 600 mg vs. placebo: p<0.001; see Table 34). On Day 29, it was observed that the quetiapine 300 mg group had a change from baseline 6.09 points greater than the placebo group (p=0.001) and the quetiapine 600mg group had a change from baseline 8.52 points greater than the placebo group (p< 0.001). At end of treatment, the quetiapine 300 mg group showed a 7.72 point advantage over the placebo group and the quetiapine 600 mg group showed a 9.39 point advantage over placebo. The mean Q-LES-Q score at final assessment for both quetiapine 300 mg and 600 mg patients was 46.2 points, compared to 40.9 points for placebo patients (see Table 11.2.6.1). Among patients who completed the trial, quetiapine 300 mg patients exhibited a mean Q-LES-Q score of 47.7, quetiapine 600 mg patients, a score of 50.2, and placebo patients, a score of 43.4 (see Table 11.2.6.1).

7.3.2.2 PSQI

Results of the analysis of Day 57 change from baseline in PSQI total score are shown in Table 35.

Table 35 PSQI score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	Baseline Mean (SD)	LS mean change or difference	Upper 95% Limit	p-value
Quetiapine 300 mg	150	11.4 (3.82)	-5.16	-4.53	
Quetiapine 600 mg	152	11.6 (4.16)	-5.46	-4.83	
Placebo	150	11.7 (3.82)	-2.94	-2.31	
Quetiapine 300 mg vs placebo			-2.22	-1.36	<0.001
Quetiapine 600 mg vs placebo			-2.52	-1.66	<0.001

Data derived from Table 11.2.7.3.1

Baseline PSQI values were 11.4 to 11.7 for the 3 groups, indicating moderate to severe sleep difficulty. The improvement for both quetiapine treatment groups was significantly better than placebo at final assessment (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$; see Table 35). An observed cases analysis showed that on Day 29 the quetiapine 300 mg group had a change from baseline 2.48 points greater than the placebo group ($p<0.001$) and the quetiapine 600 mg group had a change from baseline 2.81 points greater than placebo ($p<0.001$). By Day 57 patients who completed the study showed a 1.72 point advantage over placebo for the quetiapine 300 mg group, and a 2.76 point advantage for the quetiapine 600 mg group (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$; see Table 11.2.7.3.1). The mean PSQI score at final assessment for quetiapine 300 mg patients was 6.4, for quetiapine 600 mg patients, 6.2 and for placebo patients, 8.8, all above the normative cut-off of 5.0 for non-disordered sleep (Buysse et al 1989; see Table 11.2.7.1.1).

7.4 Health Economics results

Not applicable.

7.5 Pharmacokinetic results

Not applicable.

7.6 Potential issues affecting efficacy results

No potential issues affecting efficacy results have been identified.

7.7 Conclusions on efficacy results

The linkage between these conclusions, the specific efficacy and pharmacokinetic objectives of the study, and the study variables selected to address each objective, is presented in Table 36.

Table 36 Efficacy objectives, variables, and conclusions

Objective	Variables	Conclusions
Primary	**Primary**	
Evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks	Change from baseline to final assessment in the MADRS total score in the Intention-to-treat (ITT) population	Quetiapine fumarate at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline on the MADRS total score.
	Secondary	
	Percentage of patients in the ITT population showing a ≥50% reduction from baseline in MADRS total score (responders) at each assessment and at final assessment	Quetiapine fumarate at a dose of either 300 mg daily or 600 mg daily in patients with bipolar depression was superior to placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score. Superiority was evident for both quetiapine treatment groups on Day 15 of treatment and was maintained at each assessment to Day 57 of treatment.
	Change from baseline to each assessment for the MADRS total score in the ITT population	Superiority of quetiapine at a dose of either 300 mg daily or 600 mg over placebo was evident in MADRS total score change from baseline on Day 8 of treatment in patients with bipolar depression and was maintained at each assessment to Day 57 of treatment.

Table 36 Efficacy objectives, variables, and conclusions

Objective	Variables	Conclusions
	Change from baseline to each assessment in the HAM-D total score in the ITT population	Quetiapine fumarate at a dose of either 300 mg daily or 600 mg daily in patients with bipolar depression was superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to up to 8 weeks of treatment on the HAM-D. Superiority of quetiapine at a dose of either 300 mg daily or 600 mg daily over placebo was evident in HAM-D total score change from baseline on Day 8 of treatment and was maintained at each assessment to Day 57 of treatment.
	Change from baseline to each assessment in the HAM-D Item 1 score in the ITT population	Quetiapine fumarate at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing the level of depressed mood as measured by the change from baseline on the HAM-D Item 1. Superiority of quetiapine at a dose of either 300 mg daily or 600 mg daily over placebo was evident in HAM-D Item 1 score change from baseline on Day 8 of treatment and was maintained at each assessment to Day 57 of treatment.
	Change from baseline to each assessment and at final assessment for the CGI-S in the ITT population	Quetiapine fumarate at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing the severity of illness as measured by the change from baseline on the CGI-S. Superiority of quetiapine at a dose of either 300 mg daily or 600 mg daily over placebo was evident in CGI-S score change from baseline on Day 8 of treatment and was maintained at each assessment to Day 57 of treatment.

Table 36 Efficacy objectives, variables, and conclusions

Objective	Variables	Conclusions
	Change from baseline to each assessment and at final assessment for the CGI-I in the ITT population	Quetiapine fumarate at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in improving the patient's clinical status as measured by the CGI-I. Superiority of quetiapine at a dose of either 300 mg daily or 600 mg daily over placebo was evident in CGI-I score on Day 8 of treatment and was maintained at each assessment to Day 57 of treatment.
Evaluate the effect of quetiapine compared to placebo on symptoms of anxiety	Change from baseline to each assessment and to final assessment in the HAM-A total score in the ITT population	Quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing anxiety symptoms as measured by change from baseline in the HAM-A total score. Superiority of quetiapine at a dose of either 300 mg daily or 600 mg daily over placebo was evident in HAM-A score on Day 8 of treatment and was maintained to Day 57 of treatment.
Exploratory		
Evaluate the effect of quetiapine compared to placebo on the overall quality of life	Change from baseline in the short form Q-LES-Q in the ITT population	Quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks for treatment in patients with bipolar depression was statistically superior to placebo in improving Quality of Life Enjoyment and Satisfaction, measured by the 14-item Q-LES-Q (Quality of Life Enjoyment and Satisfaction Questionnaire) short-form.
Evaluate the effect of quetiapine compared to placebo on quality of sleep	Change from baseline to final assessment in the PSQI total score in the ITT population	Quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in improving the quality of sleep, measured by the PSQI.

8. SAFETY RESULTS

Safety data in this report are presented under the following headings:

- Summary of safety (Section 8.1)
- Exposure (Section 8.2)
- Adverse events (Section 8.3)
- Deaths, serious adverse events, discontinuations due to adverse events, and other significant adverse events (Section 8.4)
- Clinical laboratory evaluation (Section 8.5)
- Vital signs, ECG, physical findings and other observations related to safety. (Section 8.6).

8.1 Summary of safety

Both the 300 mg and 600 mg once-daily doses of quetiapine were generally well-tolerated. Analysis of adverse events indicated that nervous and gastrointestinal events predominated, with dry mouth, sedation, somnolence, dizziness and constipation occurring at higher rates with quetiapine compared to placebo. Most adverse events were mild to moderate. Sedation and somnolence were the adverse events most associated with discontinuation by quetiapine-treated patients ,and a larger proportion of patients in the higher quetiapine dose group discontined than did patients in the lower dose group. SAEs were infrequent in all treatment groups. Treatment emergent mania and hypomania were low in incidence and did not differ across the treatment groups. An increase in the incidence of EPS events was noted for both groups of quetiapine-treated patients, but the mean change from baseline in SAS and BARS scores was generally in the direction of improvement for all three groups. The incidence of adverse events associated with suicidality for quetiapine-treated patients was no different than that for placebo-treated patients. No cases of neutropenia or agranulocytosis following quetiapine treatment were reported. Increases in weight, tryglycerides, total cholesterol and LDL were consistent with the known safety profile for quetiapine. The incidence of aggregate shifts of blood pressure, BMI, triglycerides, HDL and glucose to criteria for possible metabolic syndrome was higher for quetiapine-treated patients compared to placebo. Increases in weight, triglycerides, total cholesterol and LDL, and decreases in HDL were consistent with the known safety profile for quetiapine.

Table 37 identifies where the data that support this section can be found.

Table 37 Location of supporting data on safety

Data	Location	
	Summary tables (Section 11.3)	**Individual subject data (Appendix 12.2)**
Treatment compliance (extent of exposure)	Table 11.3.1.1 to Table 11.3.1.6	Appendix 12.2.5
Adverse events	Table 11.3.2.1 to Table 11.3.2.8	Appendix 12.2.7.1, Appendix 12.2.7.2, Appendix 12.2.7.3
Deaths	none	none
Serious adverse events, discontinuation due to adverse events, and other significant adverse events	Table 11.3.3.1 to Table 11.3.6.2	Table 11.3.4.2, Table 11.3.5.2, Table 11.3.6.2 Appendix 12.2.7.1
Treatment emergent mania	Table 11.3.8.1.7.1 to Table 11.3.8.1.7.6, Table 11.3.8.1.7.10 to Table 11.3.8.1.7.15 Figure 11.3.8.1.7.7 to Figure 11.3.8.1.7.9	Appendix 12.2.6.4, Appendix 12.2.7.1
Clinical laboratory evaluations	Table 11.3.7.1.1.1 to Table 11.3.7.1.1.3.4, Table 11.3.7.1.2.1 to Table 11.3.7.1.2.3.9, Table 11.3.7.2.1.1 to Table 11.3.7.2.2.6 Figure 11.3.7.1.1.4.1 to Figure 11.3.7.1.1.4.10, Figure 11.3.7.1.2.4.1 to Figure 11.3.7.1.2.4.12	Table 11.3.7.2.1.1 to Table 11.3.7.2.4.10, Table 11.3.7.2.1.1 to Table 11.3.7.2.2.7 Appendix 12.2.8.1 to Appendix 12.2.8.6
Weight, vital signs, ECG, physical findings and other observations related to safety	Table 11.3.8.1.1.1 to Table 11.3.8.1.2.1, Table 11.3.8.1.2.3 to Table 11.3.8.1.3.5 Figure 11.3.8.1.2.2, Figure 11.3.8.1.3.6	Appendix 12.2.9.1, Appendix 12.2.9.2 (vital signs), Appendix 12.2.9.3 to Appendix 12.2.10.2 (other safety data)
Metabolic syndrome	Table 11.3.8.1.4.1, Table 11.3.8.1.4.4	Appendix 12.2.10.3
SAS	Table 11.3.8.1.5.1 to Table 11.3.8.1.5.3 Figure 11.3.8.1.5.4	Appendix 12.2.10.4

Table 37 Location of supporting data on safety

Data	Location	
	Summary tables (Section 11.3)	**Individual subject data (Appendix 12.2)**
BARS	Table 11.3.8.1.6.1 to Table 11.3.8.1.6.3 Figure 11.3.8.1.6.4	Appendix 12.2.10.5

8.2 Extent of exposure

An overview of exposure, in terms of duration of treatment and doses received, is presented in Table 38. This table also provides supporting data on the numbers of subjects who completed or discontinued the study.

Table 38 Overview of exposure in the safety population

		Quetiapine 300 mg (N=179)	Quetiapine 600 mg (N=180)	Placebo (N=180)
Exposure by duration of treatment (days)	Mean	44.4	40.3	43.0
	Minimum	3	1	1
	Maximum	64	62	64
Mean daily dose (mg) over study[a]	Median	281	531	0.0
	Minimum	50	31	0
	Maximum	344	624	0
Cumulative dose (mg) over study	Mean	12145	21034	0
	Minimum	350	50	0
	Maximum	19250	33050	0
Subjects with dose reduction	n (%)	30 (16.8%)	40 (22.2%)	9 (5.0%)

Data derived from Table 11.3.1.1 and Table 11.3.1.3
a Median computed over days in study rather than days of dosing

8.3 Adverse events

This section gives an overview of the adverse events reported in the study.

8.3.1 Categories of adverse events

A summary of adverse events in each category is presented in Table 39.

Table 39 Subjects who had an adverse event in any category (safety population)

Category of adverse event	Number (%) of subjects who had an adverse event in each category[a]					
	Quetiapine 300 mg (n=179)		Quetiapine 600 mg (n=180)		Placebo (n=180)	
Any adverse events[a]	166	(92.7)	165	(91.7)	148	(82.2)
Serious adverse events	6	(3.4)	9	(5.0)	16	(8.9)
Serious adverse events leading to death	0	(0)	0	(0)	0	(0)
Study drug-related adverse events	152	(84.9)	156	(86.7)	85	(47.2)
Discontinuations of study treatment due to adverse events[b]	29	(16.2)	47	(26.1)	15	(8.3)

a Subjects with multiple events in the same category are counted only once in that category. Subjects with events in more than 1 category are counted once in each of those categories.
b Adverse events were regarded as associated with discontinuation if they were present at the discontinuation visit.
Data derived from Table 11.3.2.1.

Quetiapine-treated patients exhibited an overall adverse event rate of approximately 92% to 93%, 10 percentage points higher than the rate for the placebo group. In contrast, SAEs were more common (8.9%) in the placebo group than in either the quetiapine 600 mg (5.0%) or quetiapine 300 mg (3.4%) groups. Approximately 26% of quetiapine 600 mg patients, 16% of quetiapine 300 mg patients and 8% of placebo patients discontinued treatment due to adverse events.

Categories of adverse events are shown for bipolar I and bipolar II patients in Table 11.3.2.2.

8.3.2 Most common adverse events

The most common adverse events in the study, summarized by system organ class, are shown in Table 40.

Table 40 Adverse events by system organ class, sorted by decreasing order of incidence (safety population)

System organ class	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
	n	(%)	n	(%)	n	(%)
Nervous system	134	(74.9)	132	(73.3)	74	(41.1)
Gastrointestinal	108	(60.3)	109	(60.6)	63	(35.0)
General disorders and administration site conditions	41	(22.9)	59	(32.8)	31	(17.2)
Psychiatric	37	(20.7)	38	(21.1)	34	(18.9)
Respiratory, thoracic & mediastinal	34	(19.0)	31	(17.2)	24	(13.3)
Musculoskeletal & connective tissue	30	(16.8)	33	(18.3)	23	(12.8)
Infections & infestations	27	(15.1)	23	(12.8)	37	(20.6)
Vascular	14	(7.8)	15	(8.3)	9	(5.0)
Injury, poisoning and procedural complications	12	(6.7)	13	(7.2)	22	(12.2)
Cardiac	12	(6.7)	7	(3.9)	5	(2.8)
Eye	9	(5.0)	16	(8.9)	8	(4.4)
Metabolism & Nutrition	9	(5.0)	13	(7.2)	6	(3.3)
Skin & subcutaneous tissue	8	(4.5)	17	(9.4)	16	(8.9)
Renal & urinary	8	(4.5)	8	(4.4)	5	(2.8)
Reproductive system & breast	7	(3.9)	6	(3.3)	8	(4.4)
Ear & labyrinth	6	(3.4)	5	(2.8)	2	(1.1)
Investigations	3	(1.7)	13	(7.2)	2	(1.1)
Social circumstances	2	(1.1)	4	(2.2)	0	(0)
Immune system	2	(1.1)	0	(0)	1	(0.6)
Neoplasms, benign, malignant & unspecified (include cysts & polyps)	2	(1.1)	0	(0)	0	(0)
Blood & lymphatic	1	(0.6)	0	(0)	0	(0)
Surgical & medical procedures	1	(0.6)	0	(0)	0	(0)
Congenital, familial and genetic	0	(0)	1	(0.6)	0	(0)
Hepatobiliary	0	(0)	0	(0)	1	(0.6)
Pregnancy, puerperium & perinatal	0	(0)	0	(0)	1	(0.6)

Data derived from Table 11.3.2.3.
Note: Data are ordered by descending incidence in the quetiapine 300 mg group.

Quetiapine treatment was associated with a greater incidence of adverse events in the nervous and gastrointestinal systems. The quetiapine 300 mg and 600 mg groups showed similar rates of adverse events in these two systems, with a difference in incidence of 33.8 percentage points compared to the placebo group for the nervous system events and one of approximately 25.3 percentage points for the gastrointestinal system events. The incidence of adverse events in the general disorders classification was at least 5 percentage points higher for the quetiapine 600 mg group than for the quetiapine 300 mg group. The incidences of adverse events in the infections and in the injury classifications were higher for the placebo group than for either of the quetiapine groups.

The incidence of adverse events by system organ class is presented for bipolar I and bipolar II patients in Table 11.3.2.4.

The most common adverse events, as summarized by preferred term, are shown in Table 41.

Table 41 Subjects with commonly-reported adverse events, sorted by decreasing order of frequency (safety population)

Preferred term	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
	n	(%)	n	(%)	n	(%)
Dry mouth	79	(44.1)	73	(40.6)	14	(7.8)
Sedation	53	(29.6)	58	(32.2)	11	(6.1)
Somnolence	49	(27.4)	44	(24.4)	15	(8.3)
Dizziness	30	(16.8)	41	(22.8)	15	(8.3)
Headache	22	(12.3)	18	(10.0)	36	(20.0)
Constipation	21	(11.7)	20	(11.1)	8	(4.4)
Fatigue	16	(8.9)	21	(11.7)	13	(7.2)
Nausea	14	(7.8)	16	(8.9)	23	(12.8)
Dyspepsia	12	(6.7)	17	(9.4)	10	(5.6)
Lethargy	11	(6.1)	16	(8.9)	3	(1.7)
Nasal congestion	10	(5.6)	12	(6.7)	3	(1.7)
Upper Respiratory Tract Infection NOS	9	(5.0)	13	(7.2)	18	(10.0)
Akathisia	9	(5.0)	9	(5.0)	2	(1.1)
Diarrhea NOS	8	(4.5)	11	(6.1)	15	(8.3)
Insomnia	8	(4.5)	7	(3.9)	9	(5.0)
Appetite increase NOS	7	(3.9)	10	(5.6)	3	(1.7)
Vision blurred	5	(2.8)	13	(7.2)	3	(1.7)
Weight increased	3	(1.7)	11	(6.1)	1	(0.6)
Pain in extremity	2	(1.1)	9	(5.0)	4	(2.2)

Note: This table uses a cut-off of 5% in any group. Data are ordered by descending incidence in the quetiapine 300 mg group.
Data from Table 11.3.2.5

The most commonly reported AE for the quetiapine-treated groups was dry mouth. The onset of dry mouth in quetiapine-treated patients most often occurred in the first 8 days of treatment (see Table 11.3.2.7). Mild to moderate dry mouth was reported for 72 quetiapine 300 mg patients, 65 quetiapine 600 mg patients and 14 placebo patients. Severe dry mouth was reported for 7 quetiapine 300 mg patients, 8 quetiapine 600 mg patients and no placebo

patients (see Table 11.3.2.6). Study treatment-related dry mouth was judged in 78 quetiapine 300 mg patients, 72 quetiapine 600 mg patients and 12 placebo patients (see Table 11.3.2.8).

Sedation and somnolence was more often seen in the quetiapine treatment groups than in the placebo group. The onset of sedation and somnolence in quetiapine-treated patients most often occurred in the first 8 days of treatment (see Table 11.3.2.7), and sedation was the most often cited event in association with discontinuation (see Section 8.4.3). Mild to moderate sedation was reported for 48 quetiapine 300 mg patients, 49 quetiapine 600 mg patients and 9 placebo-treated patients (see Table 11.3.2.6). Five quetiapine 300 mg patients, 9 quetiapine 600 mg patients and 2 placebo-treated patients experienced severe sedation. Study treatment-related sedation was judged in 52 quetiapine 300 mg patients, 58 quetiapine 600 mg patients and 11 placebo patients (see Table 11.3.2.8). Mild to moderate somnolence was reported for 39 quetiapine 300 mg patients, 37 quetiapine 600 mg patients and 15 placebo patients. Ten quetiapine 300 mg patients, 7 quetiapine 600 mg patients and no placebo-treated patients experienced severe somnolence (see Table 11.3.2.6). Study treatment-related somnolence was judged in 49 quetiapine 300 mg patients, 44 quetiapine 600 mg patients and 12 placebo-treated patients (see Table 11.3.2.8).

Dizziness was more often seen in the quetiapine treatment groups than in the placebo group. Mild to moderate dizziness was reported for 28 quetiapine 300 mg patients, 32 quetiapine 600 mg patients and 13 placebo-treated patients. Two patients treated with quetiapine 300 mg, 9 patients treated with quetiapine 600 mg and 2 patients treated with placebo reported severe dizziness (see Table 11.3.2.6). The onset of dizziness in quetiapine-treated patients most often occurred in the first 8 days of treatment (see Table 11.3.2.7). Study treatment-related dizziness was judged in 28 quetiapine 300 mg patients, 37 quetiapine 600 mg patients and 8 placebo patients (see Table 11.3.2.8).

Headache was more often seem in the placebo treatment group than in the quetiapine treatment groups. The onset of headache in all three treatment groups most often occurred in the first 8 days of treatment (see Table 11.3.2.7). Mild to moderate headache was reported for 20 quetiapine 300 mg patients, 15 quetiapine 600 mg patients and 35 placebo patients. Severe headache was reported for 2 quetiapine 300 mg patients, 3 quetiapine 600 mg patients and 1 placebo patient. Study treatment-related headache was judged in 9 quetiapine 300 mg patients, 11 quetiapine 600 mg patients and 28 placebo patients (see Table 11.3.2.8).

Akathisia occurred with higher incidence (5.0%) in the quetiapine-treated groups than in the placebo-treated group (1.1%). Akathisia and EPS findings are discussed in detail in Section 8.4.4.1.

Other gastrointestinal system adverse events occurring frequently were constipation, dyspepsia, nausea and diarrhea. For all groups, most of these events were mild to moderate ones. No group experienced many severe digestive adverse events (see Table 11.3.2.6). Constipation was attributed to study medication for approximately 9% to 11% of quetiapine-treated patients and 3% of placebo-treated patients. Study treatment-related judgments for dyspepsia, nausea and diarrhea were similar for the 3 groups (see Table 11.3.2.8).

Mild to moderate weight increase was noted in 3 quetiapine 300 mg patients, 11 quetiapine 600 mg patients and 1 placebo patient. No patients experienced severe weight gain (see Table 11.3.2.6). Study treatment-related weight increase was judged in 3 of quetiapine 300 mg patients, 8 quetiapine 600 mg patients and no placebo patients (see Table 11.3.2.8).

8.3.3 Discussion of common adverse events

In general, the known adverse event profile for quetiapine was reported in patients with bipolar depression. Adverse events classified within the central nervous system and the gastrointestinal system were most common. The most common adverse events, dry mouth, sedation, somnolence, dizziness and constipation, are consistent with the established safety profile for quetiapine. Dry mouth, somnolence and sedation were most-often reported as mild to moderate.

8.4 Deaths, serious adverse events, discontinuation due to adverse events, and other significant adverse events

8.4.1 Deaths

No patient deaths were reported in this trial.

8.4.2 Serious adverse events other than deaths

Serious adverse events are summarized by system organ class and preferred term in Table 42. All subjects who had a serious adverse event other than death are listed in Table 43.

Table 42 SAE incidence by system organ class (safety population)

		Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
System organ class	**Preferred term**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Nervous system	Total	0	(0)	1	(0.6)	2	(1.1)
	Convulsions NOS	0	(0)	0	(0)	1	(0.6)
	Hemiparesis	0	(0)	0	(0)	1	(0.6)
	Migraine NOS	0	(0)	1	(0.6)	0	(0)
Gastrointestinal	Total	0	(0)	1	(0.6)	2	(1.1)
	Duodenal ulcer hemorrhage	0	(0)	0	(0)	1	(0.6)
	Intestinal obstruction NOS	0	(0)	1	(0.6)	0	(0)
	Pancreatitis NOS	0	(0)	0	(0)	1	(0.6)
General disorders and administration site conditions	Total	0	(0)	3	(1.7)	0	(0)
	Chest pain	0	(0)	1	(0.6)	0	(0)
	Hernia NOS	0	(0)	1	(0.6)	0	(0)

Table 42 SAE incidence by system organ class (safety population)

System organ class	Preferred term	Quetiapine 300 mg (N=179) n	(%)	Quetiapine 600 mg (N=180) n	(%)	Placebo (N=180) n	(%)
	Influenza-like illness	0	(0)	1	(0.6)	0	(0)
Psychiatric	Total	4	(2.2)	4	(2.2)	5[a]	(2.8)
	Acute psychosis	0	(0)	0	(0)	1	(0.6)
	Bipolar I disorder	0	(0)	1	(0.6)	0	(0)
	Conversion disorder	1	(0.6)	0	(0)	0	(0)
	Depression	0	(0)	1	(0.6)	0	(0)
	Hallucination, auditory	0	(0)	0	(0)	1	(0.6)
	Major depressive disorder NOS	0	(0)	0	(0)	1	(0.6)
	Mania	0	(0)	0	(0)	1	(0.6)
	Mental status changes	0	(0)	1	(0.6)	0	(0)
	Suicidal ideation	2	(1.1)	2	(1.1)	2	(1.1)
	Suicide attempt	1	(0.6)	1	(0.6)	0	(0)
Musculoskeletal & connective tissue	Total	0	(0)	0	(0)	1	(0.6)
	Intervertebral disk herniation	0	(0)	0	(0)	1	(0.6)
Respiratory, thoracic & mediastinal	Total	0	(0)	0	(0)	1	(0.6)
	Asthma NOS	0	(0)	0	(0)	1	(0.6)
Vascular	Total	0	(0)	1	(0.6)	1	(0.6)
	Deep vein thrombosis	0	(0)	1	(0.6)	1	(0.6)
Injury, poisoning and procedural complications	Total	1	(0.6)	1	(0.6)	2	(1.1)
	Hip fracture	0	(0)	0	(0)	1	(0.6)
	Injury	1	(0.6)	0	(0)	0	(0)
	Non-accidental overdose	0	(0)	1	(0.6)	1	(0.6)
	Spinal fracture NOS	0	(0)	0	(0)	1	(0.6)
Reproductive system & breast	Total	1	(0.6)	1	(0.6)	0	(0)
	Adnexa uteri pain	1	(0.6)	0	(0)	0	(0)
	Prostatitis	0	(0)	1	(0.6)	0	(0)
Immune system	Total	0	(0)	0	(0)	1	(0.6)
	Drug hypersensitivity	0	(0)	0	(0)	1	(0.6)
Hepatobiliary	Total	0	(0)	0	(0)	1	(0.6)

Table 42 SAE incidence by system organ class (safety population)

System organ class	Preferred term	Quetiapine 300 mg (N=179) n	(%)	Quetiapine 600 mg (N=180) n	(%)	Placebo (N=180) n	(%)
	Cholecystitis	0	(0)	0	(0)	1	(0.6)
Pregnancy, puerperium & perinatal	Total	0	(0)	0	(0)	1	(0.6)
	Ectopic pregnancy	0	(0)	0	(0)	1	(0.6)

a Includes 2 reports for same event in same patient reported by 2 different investigators because patient enrolled in study at two sites and was randomized to placebo treatment at both sites.

Data derived from Table 11.3.4.1.1

A total of 30 patients reported 40 SAEs. Six of the 30 patients with SAEs were treated with quetiapine 300 mg, 9 with quetiapine 600 mg and 15 with placebo. Serious psychiatric disorders were observed in 4 patients treated with quetiapine 300 mg, 4 patients treated with quetiapine 600 mg and 4 patients treated with placebo. One placebo-treated patient who enrolled at two different study sites, and thus received two enrollment numbers (E0026028 and E0028031), is shown in Table 42 and Table 43 as having psychotic symptoms described by each of the two investigators. Four of 7 SAEs for quetiapine 300 mg treatment, 3 of 14 SAEs for quetiapine 600 mg treatment and 10 of 19 SAEs for placebo treatment were associated with withdrawal from the trial.

Serious adverse events for bipolar I and bipolar II patients are described in Table 11.3.4.1.2.

Table 43 Patient listing of serious adverse events other than death (safety population)

Treatment, dose regimen and bipolar diagnosis	Subject code[a]	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Intensity[b]	Duration of AE (if resolved)	Action taken with respect to investigational product	Causality (as assessed by the investigator)
Quetiapine 300 mg daily Bipolar I	0020013	M	23	Suicide attempt	Suicide attempt	13	Sev	1 day	Permanently stopped	No
	0022022	F	23	Conversion disorder	Conversion disorder	42	Mod	38 days	None	No
	0022036	M	22	Suicidal ideation	Suicidal ideation	77	Mod	3 days	None[c]	No
	0023034	F	18	Adnexa uteri pain	Ovarian cyst pain	53	Sev	2 days	None	No
	0028045	M	46	Suicidal ideation	Suicidal ideation with acute psychosis	39	Sev	4 days	None	No
				Bipolar I disorder	Bipolar affective disorder mixed state with mood congruent psychosis	Unk	Sev	17 days	None	No
Quetiapine 300 mg daily Bipolar II	0031021	M	27	Injury	Stab wounds	36	Sev	21 days	None	No
Quetiapine 600 mg daily Bipolar I	0009001	F	36	Influenza like illness	Flu-like symptoms	49	Sev	Unk	None	No
	0010014	F	38	Hernia NOS	Recurrent bowel hernia	30	Sev	34 days	None	No
				Intestinal obstruction NOS	Strangulated bowel	63	Sev	1 day	None[c]	No
	0018007	F	42	Deep vein thrombosis	Recurrent deep vein thrombosis without pulmonary embolism	5	Sev	80 days	Permanently stopped	No
				Migraine NOS	Migraine headache	6	Sev	1 day	None	No
	0028007	F	22	Non-accidental overdose	Overdose of study medication (intentional)	39	Mod	1 day	None	No
	0028023	M	54	Suicide attempt	Suicide attempt	48	Sev	1 day	None	No

Table 43 Patient listing of serious adverse events other than death (safety population)

Treatment, dose regimen and bipolar diagnosis	Subject code[a]	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Intensity[b]	Duration of AE (if resolved)	Action taken with respect to investigational product	Causality (as assessed by the investigator)
	0039028	M	39	Chest pain	Chest pain (not cardiac related)	46	Mod	1 day	None	No
				Suicidal ideation	Suicidal ideation	47	Sev	8 days	Permanently stopped	No
				Depression	Worsening of depression	58	Sev	15 days	None[c]	No
Quetiapine 600 mg daily Bipolar II	0026003	M	46	Prostatitis	Acute prostatitis	57	Sev	6 days	None[c]	No
	0026023	M	20	Mental status changes	Altered mental status	59	Sev	2 days	None[c]	No
	0028032	M	36	Bipolar I disorder	Mixed episode with psychosis	55	Sev	11 days	None	No
				Suicidal ideation	Suicidal ideation	55	Sev	11 days	None	No
Placebo Bipolar I	0002016	F	56	Hemiparesis	Right sided weakness	22	Mod	7 days	None	No
	0004006	F	37	Drug hypersensi-tivity	Hypersensitivity reaction to Lamictal	74	Sev	8 days	None[c]	No
	0005019	F	22	Non-accidental overdose	Intentional overdose (over the counter sleeping pill)	2	Mod	1 day	Permanently stopped	No
	0007003	M	53	Duodenal ulcer hemorrhage	Bleeding ulcer duodenal	23	Sev	7 days	Permanently stopped	No
	0022011	M	28	Hip fracture	Hip fracture	2	Mil	97 days	Permanently stopped	No
				Spinal fracture NOS	Multiple vertebral fractures T11 – L4	2	Mil	97 days	Permanently stopped	No
				Deep vein thrombosis	Deep vein thrombosis left leg	6	Mil	168	Permanently stopped	No

Table 43 Patient listing of serious adverse events other than death (safety population)

Treatment, dose regimen and bipolar diagnosis	Subject code[a]	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Intensity[b]	Duration of AE (if resolved)	Action taken with respect to investigational product	Causality (as assessed by the investigator)
	0026028	M	35	Major depressive disorder NOS	Psychotic: depression	22	Sev	Unk	None	No
				Acute psychosis	Acute psychosis	26	Sev	4 days	Permanently stopped	No
	0028003	F	53	Cholecystitis NOS	Cholecystitis exacerbation	4	Sev	33 days	None	No
	0028031	M	35	Hallucination auditory	Self mutilating auditory hallucinations	17	Sev	5 days	None	No
	0033010	F	26	Ectopic pregnancy	Ectopic pregnancy	44	Sev	1 day	Permanently stopped	No
	0033014	M	53	Intervertebral disk herniation	Herniated spinal disc pain	31	Mod	Unk	None	No
	0035002	M	46	Suicidal ideation	Suicidal ideation	24	Mod	Unk	None	No
	0039030	F	52	Suicidal ideation	Suicidal ideation	75	Sev	3 days	None[c]	No
	0039038	F	40	Asthma NOS	Asthma attack	13	Sev	5 days	Temporarily stopped	No
	0041010	M	32	Mania	Manic episode	39	Sev	7 days	Permanently stopped	No
Placebo Bipolar II	0014001	F	25	Pancreatitis NOS	Pancreatitis	25	Sev	8 days	Temporarily stopped	No
	0026027	F	40	Convulsions NOS	Seizure	1	Sev	1 day	Permanently stopped	No

a Subject code includes study center number in left-most 4 digits and a subject number for that study center in the right-most 3 digits
b Mil=mild; Mod=moderate; Sev=severe; Unk=unknown
c During 30-day follow-up period after study treatment was completed
Data from Table 11.3.4.2

8.4.3 Discontinuations due to adverse events

Discontinuations due to adverse events are summarized by system organ class and preferred term in Table 44. All subjects who were discontinued from study treatment due to an adverse event are listed in Table 45.

Table 44 Incidence of discontinuations due to adverse events by system organ class (safety population)

		Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
System organ class	**Preferred term**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Nervous system	Total	20	(11.2)	31	(17.2)	2	(1.1)
	Akathisia	1	(0.6)	3	(1.7)	0	(0)
	Balance impaired NOS	3	(1.7)	0	(0)	0	(0)
	Convulsions NOS	0	(0)	0	(0)	1	(0.6)
	Coordination abnormal NOS	1	(0.6)	0	(0)	0	(0)
	Disturbance in attention	1	(0.6)	0	(0)	0	(0)
	Dizziness	1	(0.6)	6	(3.3)	0	(0)
	Dysarthria	1	(0.6)	1	(0.6)	0	(0)
	Dyskinesia	1	(0.6)	0	(0)	0	(0)
	Dystonia	0	(0)	1	(0.6)	0	(0)
	Extrapyramidal disorder	0	(0)	0	(0)	1	(0.6)
	Headache	0	(0)	1	(0.6)	0	(0)
	Paraesthesia	0	(0)	1	(0.6)	0	(0)
	Restless legs syndrome	1	(0.6)	2	(1.1)	0	(0)
	Sedation	10	(5.6)	17	(9.4)	0	(0)
	Somnolence	7	(3.9)	5	(2.8)	0	(0)
	Syncope	0	(0)	1	(0.6)	0	(0)
Gastrointestinal	Total	3	(1.7)	4	(2.2)	1	(0.6)
	Constipation	0	(0)	1	(0.6)	0	(0)
	Dry mouth	0	(0)	2	(1.1)	0	(0)
	Duodenal ulcer hemorrhage	0	(0)	0	(0)	1	(0.6)
	Dysphagia	0	(0)	1	(0.6)	0	(0)
	Nausea	3	(1.7)	0	(0)	0	(0)
	Tooth disorder NOS	0	(0)	1	(0.6)	0	(0)
	Vomiting NOS	1	(0.6)	0	(0)	0	(0)
General disorders and	Total	4	(2.2)	2	(1.1)	0	(0)

Table 44 Incidence of discontinuations due to adverse events by system organ class (safety population)

		Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
System organ class	**Preferred term**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
administration site conditions	Fatigue	0	(0)	1	(0.6)	0	(0)
	Feeling cold	0	(0)	1	(0.6)	0	(0)
	Lethargy	4	(2.2)	0	(0)	0	(0)
Psychiatric	Total	7	(3.9)	11	(6.1)	7	(3.9)
	Acute psychosis	0	(0)	0	(0)	1	(0.6)
	Anxiety	2	(1.1)	1	(0.6)	1	(0.6)
	Bruxism	0	(0)	1	(0.6)	0	(0)
	Confusional state	0	(0)	1	(0.6)	0	(0)
	Conversion disorder	1	(0.6)	0	(0)	0	(0)
	Delusion NOS	0	(0)	1	(0.6)	0	(0)
	Disorientation	1	(0.6)	0	(0)	0	(0)
	Dissociative disorder NOS	0	(0)	0	(0)	1	(0.6)
	Flat affect	0	(0)	1	(0.6)	0	(0)
	Hallucination, auditory	0	(0)	0	(0)	1	(0.6)
	Hypomania	0	(0)	1	(0.6)	0	(0)
	Insomnia	0	(0)	0	(0)	1	(0.6)
	Irritability	1	(0.6)	2	(1.1)	0	(0)
	Libido decreased	0	(0)	1	(0.6)	0	(0)
	Loss of libido	1	(0.6)	0	(0)	0	(0)
	Major depressive disorder NOS	0	(0)	0	(0)	1	(0.6)
	Mania	0	(0)	1	(0.6)	2	(1.1)
	Panic disorder NOS	1	(0.6)	0	(0)	0	(0)
	Paranoia	1	(0.6)	1	(0.6)	0	(0)
	Restlessness	1	(0.6)	0	(0)	0	(0)
	Suicidal ideation	1	(0.6)	1	(0.6)	0	(0)
	Suicide attempt	1	(0.6)	1	(0.6)	0	(0)
	Suspiciousness	1	(0.6)	0	(0)	0	(0)
Musculoskeletal & connective tissue	Total	0	(0)	3	(1.7)	1	(0.6)
	Back pain	0	(0)	0	(0)	1	(0.6)
	Joint stiffness	0	(0)	1	(0.6)	0	(0)

Table 44 Incidence of discontinuations due to adverse events by system organ class (safety population)

		Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
System organ class	**Preferred term**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
	Limb discomfort NOS	0	(0)	1	(0.6)	0	(0)
	Muscle cramp	0	(0)	1	(0.6)	0	(0)
	Muscle twitching	0	(0)	1	(0.6)	0	(0)
Respiratory, thoracic & mediastinal	Total	1	(0.6)	2	(1.1)	0	(0)
	Dyspnea	1	(0.6)	1	(0.6)	0	(0)
	Nasal congestion	0	(0)	1	(0.6)	0	(0)
Skin & subcutaneous tissue	Total	0	(0)	1	(0.6)	1	(0.6)
	Rash NOS	0	(0)	0	(0)	1	(0.6)
	Sweating increased	0	(0)	1	(0.6)	0	(0)
Eye	Total	0	(0)	1	(0.6)	0	(0)
	Vision blurred	0	(0)	1	(0.6)	0	(0)
Vascular	Total	1	(0.6)	3	(1.7)	1	(0.6)
	Deep vein thrombosis	0	(0)	1	(0.6)	1	(0.6)
	Orthostatic hypotension	1	(0.6)	2	(1.1)	0	(0)
Injury, poisoning and procedural complications	Total	0	(0)	0	(0)	2	(1.1)
	Hip fracture	0	(0)	0	(0)	1	(0.6)
	Non-accidental overdose	0	(0)	0	(0)	1	(0.6)
	Spinal fracture NOS	0	(0)	0	(0)	1	(0.6)
Renal & urinary	Total	0	(0)	1	(0.6)	0	(0)
	Urinary incontinence	0	(0)	1	(0.6)	0	(0)
Social circumstances	Total	0	(0)	2	(1.1)	0	(0)
	Drug abuser NOS	0	(0)	2	(1.1)	0	(0)
Neoplasms	Total	1	(0.6)	0	(0)	0	(0)
	Chronic lymphocytic leukemia NOS	1	(0.6)	0	(0)	0	(0)
Pregnancy, puerperium & perinatal	Total	0	(0)	0	(0)	1	(0.6)
	Ectopic pregnancy	0	(0)	0	(0)	1	(0.6)

Data derived from Table 11.3.5.1.1

Patients discontinuing from the study due to AEs totalled 29 (16.2%) of the quetiapine 300 mg group, 47 (26.1%) of the quetiapine 600 mg group, and 15 (8.3%) of the placebo group. Nervous system disorders constituted the largest portion of the DAEs, with a total of 20

(11.2%) patients in the quetiapine 300 mg group, 31 (17.2%) patients in the quetiapine 600 mg group and 2 (1.1%) in the placebo group. Sedation was noted as associated with discontinuation in 10 (5.6%) quetiapine 300 mg patients, 17 (9.4%) quetiapine 600 mg patients and no placebo patients. Somnolence was cited for 7 (3.9%) quetiapine 300 mg patients, 5 (2.8%) quetiapine 600 mg patients and no placebo patients. Dizziness was listed for 1 (0.6%) quetiapine 300 mg patients, 6 (3.3%) quetiapine 600 mg patients and no placebo patients (see Table 44.). Most of the nervous system DAEs occurred in the first 8 days of the trial during the titration period (see Table 45).

Adverse events leading to discontinuation are displayed by bipolar I and bipolar II diagnosis in Table 11.3.5.1.2.

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
Quetiapine 300 mg daily Bipolar I	0002018	M	48	Somnolence	Drowsiness	1	4	N	Y
	0004013	F	24	Sedation	AM sedation	2	24	N	Y
	0005004	F	36	Lethargy	Lethargy	2	UNK	N	Y
				Sedation	Sedation	2	UNK	N	Y
	0005013	F	43	Dizziness	Dizziness not related to orthostatic hypotension	1	5	N	Y
				Dyskinesia	Incoordination (dyskinesia)	1	7	N	Y
				Sedation	Sedation	1	7	N	Y
	0005027	M	41	Sedation	Sedation	2	20	N	Y
	0006018	M	57	Somnolence	Extreme sleepiness	1	5	N	Y
				Coordination abnormal NOS	Loss of coordination (not due to EPS)	3	3	N	Y
	0010032	F	38	Sedation	Sedativism	2	UNK	N	Y
				Nausea	Nausea	5	UNK	N	Y
				Orthostatic hypotension	Fainting feel (due to orthostatic hypotension)	5	UNK	N	Y
	0013007	M	49	Somnolence	Drowsiness	1	11	N	Y
	0019004	F	32	Irritability	Irritability	29	UNK	N	Y
	0020013	M	23	Suicide attempt	Suicide attempt	13	1	Y	N
	0022022	F	23	Conversion disorder	Conversion disorder	42	38	Y	N
	0022035	F	20	Somnolence	Somnolence	2	5	N	Y
	0023044	F	44	Restless legs syndrome	Restless legs (not due to EPS)	5	UNK	N	Y

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
	0026010	M	31	Nausea	Nausea	2	6	N	Y
				Vomiting NOS	Emesis	2	6	N	Y
	0028045	M	46	Suicidal ideation	Suicidal ideation with acute psychosis	39	4	Y	N
				Bipolar I disorder	Bipolar affective disorder mixed state with mood congruent psychosis	UNK	17	Y	N
	0034002	M	55	Somnolence	Daytime drowsiness	2	24	N	Y
Quetiapine 300 mg daily Bipolar II	0005036	F	40	Sedation	Sedation	1	8	N	Y
	0007008	F	42	Sedation	Sedation	1	8	N	Y
	0009009	F	23	Somnolence	Drowsiness	1	11	N	Y
	0015003	F	54	Sedation	Excessive sedation	1	10	N	Y
	0019014	M	24	Lethargy	Lethargy	2	UNK	N	Y
				Balance impaired NOS	Equilibrium problems (not due to orthostatic hypotension)	4	UNK	N	Y
	0019027	F	26	Balance impaired NOS	Problems with equilibrium	2	4	N	Y
				Dysarthria	Slurred speech	2	4	N	Y
				Sedation	Excessive sedation	2	4	N	Y
				Lethargy	Lethargy	2	7	N	Y
	0019039	M	35	Lethargy	Lethargy	1	4	N	Y
				Anxiety	Anxiety	3	2	N	Y
				Balance impaired NOS	Decreased equilibrium (not due to orthostatic hypotension)	3	2	N	Y

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
				Disorientation	Disorientation	3	2	N	N
				Disturbance in attention	Decreased concentration	3	2	N	Y
				Dyspnea	Shortness of breath	3	2	N	Y
				Panic disorder NOS	Panic disorder symptoms	3	2	N	Y
				Paranoia	Paranoia	3	2	N	Y
				Suspiciousness	Suspiciousness	3	2	N	Y
				Akathisia	Akathisia (not due to EPS)	3	34	N	Y
	0031020	M	44	Chronic lymphocytic leukemia NOS	Chronic lymphocytic leukemia	17	UNK	N	N
	0031029	M	24	Nausea	Nausea	4	17	N	Y
	0033006	M	38	Loss of libido	Loss of libido	3	UNK	N	Y
	0035013	F	28	Anxiety	Anxiety	5	5	N	Y
				Restlessness	Restlessness not due to EPS	5	5	N	Y
	0035015	F	33	Sedation	Extreme sedation	1	6	N	Y
	0039052	F	37	Somnolence	Drowsiness	4	UNK	N	Y
Quetiapine 600 mg daily Bipolar I	0003016	F	33	Irritability	Irritability	19	4	N	Y
	0004001	F	33	Sedation	Sedation	1	13	N	Y
				Dysarthria	Slurred speech in P.M.	22	12	N	Y
				Sedation	Sedation	22	12	N	Y
	0005009	M	24	Sedation	Sedation	1	6	N	Y

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
	0005022	M	25	Sedation	Sedation	7	29	N	Y
	0005025	F	40	Sedation	Sedation	2	15	N	Y
				Sedation	Sedation	17	22	N	Y
	0010002	M	46	Dizziness	Fainting feeling (not due to postural hypotension)	1	1	N	Y
				Feeling cold	Cold flash	1	1	N	Y
				Orthostatic hypotension	Lightheaded due to orthostatic hypotension	1	1	N	Y
	0010023	F	28	Paranoia	Paranoid thinking	4	9	N	Y
	0010027	M	32	Anxiety	Increased anxiety	13	6	N	Y
	0013006	F	28	Dystonia	Dystonia	8	1	N	Y
	0013014	M	48	Akathisia	Restlessness (akathisia)	22	1	N	Y
	0014007	F	22	Sedation	Sedation	3	17	N	Y
	0014012	F	55	Akathisia	Akathisia	3	28	N	Y
	0018007	F	42	Deep vein thrombosis	Recurrent deep vein thrombosis without pulmonary embolism	5	80	Y	N
	0022025	F	46	Restless legs syndrome	Restless legs syndrome (worsening) “not due to EPS”	2	8	N	N
	0022038	M	39	Somnolence	Somnolence	37	6	N	Y
	0022058	M	43	Somnolence	Somnolence	2	33	N	Y
	0022062	M	63	Somnolence	Somnolence	1	17	N	Y
	0028007	F	22	Drug abuser NOS	Drug abuse (methamphetamine)	38	1	N	N
	0028023	M	54	Suicide attempt	Suicide attempt	48	1	Y	N
	0028025	M	27	Libido decreased	Decreased libido	1	13	N	Y
				Flat affect	Flat affect	3	11	N	N

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
	0029008	F	22	Syncope	Fainting (not due to orthostatic hypotension)	4	1	N	Y
	0029012	F	39	Somnolence	Somnolence	4	35	N	Y
	0029015	F	45	Sedation	Sedation	2	14	N	Y
	0030024	F	30	Dry mouth	Dry mouth	3	4	N	Y
	0030025	F	63	Delusion NOS	Delusional thinking	36	UNK	N	N
	0036002	F	32	Mania	Mania	26	6	N	Y
	0036007	F	35	Urinary incontinence	Intermittent urinary incontinence secondary to sedation	9	4	N	Y
				Sedation	Sedation	12	2	N	Y
	0039028	M	39	Suicidal ideation	Suicidal ideation	47	8	Y	N
Quetiapine 600 mg daily Bipolar II	0001006	M	29	Muscle cramp	Muscle cramps not due to EPS	2	6	N	Y
				Muscle twitching	Muscle twitching not due to EPS	2	6	N	Y
				Fatigue	Fatigue	1	7	N	Y
				Muscle twitching	Lips twitching not due to EPS	2	UNK	N	Y
	0005033	F	33	Nasal congestion	Nasal congestion	5	25	N	Y
	0005038	F	31	Sedation	Sedation	1	UNK	N	Y
	0007009	F	29	Sedation	Sedation	3	6	N	Y
	0011020	M	33	Orthostatic hypotension	Dizziness secondary to postural hypotension	2	2	N	Y
	0018003	F	27	Sedation	Sedation	4	UNK	N	Y
	0018013	M	44	Akathisia	Akathisia	2	5	N	Y
	0019024	M	26	Confusional state	Confusion	2	7	N	Y

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
				Dizziness	Lightheaded (not due to orthostatic hypotension)	2	7	N	Y
				Dyspnea	Difficulty breathing	2	7	N	Y
				Dyspnea	Shortness of breath	2	7	N	Y
				Somnolence	Drowsy	2	7	N	Y
				Tooth disorder NOS	Weird feeling in teeth	2	7	N	Y
				Limb discomfort NOS	Uncomfortable feeling in legs and arms	3	6	N	Y
				Bruxism	Bruxism	6	3	N	Y
				Dizziness	Dizziness (not due to orthostatic hypotension)	6	3	N	Y
				Dysphagia	Difficulty swallowing	6	3	N	Y
	0019031	M	47	Sedation	Sedation	1	5	N	Y
				Joint stiffness	Tightness in joints (not due to EPS)	2	3	N	Y
				Paraesthesia	Tingling in arms	2	3	N	Y
				Paraesthesia	Tingling in legs	2	3	N	Y
	0019035	F	34	Sedation	Sedation	3	36	N	Y
				Restless legs syndrome	Restless legs at night not due to EPS	17	22	N	Y
				Hypomania	Hypomania	25	14	N	Y
	0019042	F	27	Irritability	Irritability	12	4	N	Y
	0023023	F	35	Dizziness	Dizzy not due to postural hypotension	2	4	N	Y
				Sedation	Sedation	2	4	N	Y

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
				Sweating increased	Sweating	2	4	N	Y
	0023029	F	46	Dizziness	Dizziness not due to postural hypotension	2	5	N	Y
				Dry mouth	Dry mouth	2	5	N	Y
				Sedation	Sedation	2	5	N	Y
	0026005	F	57	Sedation	Sedation	1	13	N	Y
	0026009	F	43	Dizziness	Dizzy (not due to postural hypotension)	3	3	N	Y
	0031010	F	37	Sedation	Daytime sedation	1	UNK	N	Y
	0031015	F	27	Constipation	Constipation	2	9	N	Y
				Dizziness	Lightheadedness not due to postural hypotension	4	7	N	Y
				Sedation	Daytime sedation	4	7	N	Y
				Vision blurred	Blurred vision	4	7	N	Y
	0033009	F	46	Headache	More severe headaches	2	UNK	N	Y
	0039043	M	20	Drug abuser NOS	Drug abuse with cocaine	25	UNK	N	N
Placebo Bipolar I	0002004	F	33	Depression	Anxiety related to depression	-7	UNK	N	N
	0005019	F	22	Non-accidental overdose	Intentional overdose (over the counter sleeping pills)	2	1	Y	N
	0007003	M	53	Duodenal ulcer hemorrhage	Bleeding ulcer (duodenal)	23	7	Y	N
	0007006	M	39	Rash NOS	Rash	18	10	N	Y
	0009012	M	28	Extrapyramidal disorder	EPS (involuntary movement of mouth – dystonia)	1	2	N	Y

Table 45 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
	0010028	F	32	Insomnia	Worsening of insomnia	17	23	N	Y
	0011008	M	23	Mania	Onset of manic symptoms	15	UNK	N	Y
	0014004	F	29	Back pain	Back pain – left side	2	22	N	Y
	0022011	M	28	Hip fracture	Hip fracture	2	97	Y	N
				Spinal fracture NOS	Multiple vertebral fractures T11 -- L4	2	97	Y	N
				Deep vein thrombosis	Thrombosis left leg	6	168	Y	N
	0026028	M	35	Major depressive disorder	Psychotic depression	22	UNK	Y	N
				Acute psychosis	Acute psychosis	26	4	Y	N
	0028031	M	35	Hallucination, auditory	Self-mutilating auditory hallucinations	17	5	Y	N
	0029039	F	30	Dissociative disorder	Dissociative episode	12	1	N	N
	0033010	F	26	Ectopic pregnancy	Ectopic pregnancy	44	1	Y	N
	0041010	M	32	Mania	Manic episode	39	7	Y	N
Placebo Bipolar II	0026027	F	40	Convulsions NOS	Seizure	1	1	Y	N
	0029038	M	61	Anxiety	Anxiety	2	7	N	Y

Data from Table 11.3.5.2

a Events of unknown duration were ongoing at the time of discontinuation.

8.4.4 Adverse events of special interest

8.4.4.1 Adverse events related to EPS

Adverse events related to EPS are summarized by system organ class and preferred term in Table 46.

Table 46 Adverse events coded to EPS (safety population)

	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
Preferred term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total[a]	21	(11.7)	23	(12.8)	8	(4.4)
Akathisia	9	(5.0)	9	(5.0)	2	(1.1)
Tremor	5	(2.8)	5	(2.8)	1	(0.6)
Dyskinesia	4	(2.2)	2	(1.1)	0	(0)
Dystonia	2	(1.1)	5	(2.8)	1	(0.6)
Restlessness	2	(1.1)	1	(0.6)	2	(1.1)
Extrapyramidal disorder	0	(0)	2	(1.1)	1	(0.6)
Muscle contractions involuntary	0	(0)	1	(0.6)	0	(0)
Psychomotor hyperactivity	0	(0)	1	(0.6)	0	(0)
Muscle rigidity	0	(0)	0	(0)	1	(0.6)

a Subjects with multiple events in the same category are counted only once in that category. Subjects with events in more than 1 category are counted once in each of those categories.

Data derived from Table 11.3.6.1.

MedDRA-encoded as EPS-related symptoms were reported for 11.7% of quetiapine 300 mg patients, 12.8% of quetiapine 600 mg patients and 4.4% of placebo patients. Akathisia was noted in quetiapine-treated patients with an incidence of 5.0% compared to one of 1.1% in placebo-treated patients. All EPS events were reported as mild to moderate for all groups.

If an AE was reported that coded to an EPS, the investigator was asked whether or not they judged this AE as being due to EPS. A summary of adverse events coded as extrapyramidal adverse events by MedDRA as shown in Table 46 with the exclusion of those considered by the investigators to not be extrapyramidal symptoms is shown in Table 47.

Table 47 Adverse events coded as EPS and not excluded as EPS by investigators (safety population)

	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
Preferred term	**n**	**(%)**	**n**	**%**	**n**	**%**
Total[a]	12	(6.7)	16	(8.9)	4	(2.2)
Akathisia	8	(4.4)	9	(5.0)	2	(1.1)
Dyskinesia	3	(1.7)	1	(0.6)	0	(0)
Dystonia	2	(1.1)	4	(2.2)	1	(0.6)
Extrapyramidal disorder	0	(0)	2	(1.1)	1	(0.6)
Psychomotor hyperactivity	0	(0)	1	(0.6)	0	(0)

a Subjects with multiple events in the same category are counted only once in that category. Subjects with events in more than 1 category are counted once in each of those categories.

Data derived from Table 11.3.6.2.

After EPS-coded adverse events specified by investigators as not being due to EPS were removed from those reported in Table 46, the remaining data (reported in Table 47) contained reports of extrapyramidal symptoms for 6.7% of patients in the quetiapine 300 mg group, 8.9% of patients in the quetiapine 600 mg group and 2.2% of patients in the placebo group.

8.4.4.2 Adverse events related to QT prolongation

No adverse events encoded to the MedDRA terms of "long QT syndrome," "electrocardiogram QT corrected interval prolonged," "electrocardiogram QT prolonged," "long QT syndrome congenital," "torsades de pointes," "cardiac arrest," "cardio-respiratory arrest," "cardiac death," "electromechanical dissociation" or "sinus arrest" were reported for patients in any of the three treatment groups.

8.4.4.3 Adverse events related to neutropenia and agranulocytosis

No adverse events encoded to the MedDRA terms of "band neutrophil count decreased," "band neutrophil percentage decreased," "febrile neutropenia," "neutropenia," "neutropenic infection," "neutropenic sepsis," "neutrophil count decreased," "neutrophil percentage decreased," "granulocyte count decreased," "granulocytopenia," "idiopathic neutropenia," "neutrophil count abnormal," "neutrophil percentage abnormal" or "agranulocytosis" were reported for patients in any of the three treatment groups.

8.4.4.4 Adverse events related to treatment-emergent mania and hypomania

Adverse events related to treatment-emergent mania and hypomania are summarized by system organ class and preferred term in Table 48.

Table 48 Treatment-emergent mania and hypomania (LOCF, safety population)

	Quetiapine 300 mg (N=179		Quetiapine 600 mg (N=180)		Placebo (N=180)	
Criteria	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
All[a]	7	(3.9)	4	(2.2)	7	(3.9)
YMRS alone[b]	4	(2.2)	4	(2.2)	6	(3.3)
Adverse events alone	3	(1.7)	2	(1.1)	2	(1.1)

Data derived from Table 11.3.8.1.7.14.
a Subjects with multiple events in the same category are counted only once in that category. Subjects with events in more than 1 category are counted once in each of those categories.
b YMRS >15 at two consecutive visits or at final visit

The rates of treatment-emergent mania were similar among the three treatment groups.

Both quetiapine-treated groups showed greater improvement in YMRS scores compared to placebo at end of treatment (quetiapine 300: p=0.002; quetiapine 600: p=0.012; see Table 11.3.8.1.7.3).

8.4.4.5 Adverse events related to diabetes

Four cases of adverse events possibly related to diabetes, all of which were "increased thirst," were identified. Two of the cases (patients E0006005 and E0027003) were treated with quetiapine 300 mg daily. The remaining two cases (patients E0014017 and E0028010) were treated with placebo. Review of these cases revealed no evidence of other signs or symptoms of diabetes.

8.4.4.6 Adverse events related to suicidality

Adverse events related to suicidality are summarized by system organ class and preferred term in Table 49.

Table 49 Adverse events related to suicidality incidence (safety population)

	Quetiapine 300 mg (N=179)		Quetiapine 600 mg (N=180)		Placebo (N=180)	
Preferred term	**n**	**%**	**n**	**%**	**n**	**%**
Total[a]	4	(2.2)	3	(1.7)	3	(1.7)
Suicidal ideation	3	(1.7)	3	(1.7)	3	(1.7)
Suicide attempt	1	(0.6)	1	(0.6)	0	(0)

a Subjects with multiple events in the same category are counted only once in that category. Subjects with events in more than 1 category are counted once in each of those categories.

Data derived from Table 11.3.6.1.

The incidence of adverse events related to suicidality in quetiapine-treated patients was similar to that of placebo patients. All three treatment groups exhibited an incidence of 2%.

8.4.5 Discussion of deaths, serious adverse events, discontinuation due to adverse events, and other significant adverse events

There were no deaths reported in this study, and serious adverse events were infrequent in all three treatment groups. More quetiapine-treated patients discontinued the study due to adverse events than did placebo-treated patients. Sedation and somnolence, most often occurring in the first 8 days of treatment, were the adverse events most-frequently associated with discontinuation after administration of quetiapine. The incidence of discontinuation in association with an adverse event may have been increased due to the requirement that the investigator regard any adverse event reported at the discontinuation visit as being associated with discontinuation.

Adverse events of special interest included EPS, diabetes, QT prolongation, neutropenia/agranulocytosis, treatment-emergent mania/hypomania and suicidality. Low rates of EPS-related adverse events were noted with most events being mild to moderate and not-often associated with discontinuation. The incidence of suicidality and treatment-emergent mania/hypomania were both similar to placebo for both quetiapine treatment groups. No cases of QT prolongation or neutropenia/agranulocytosis were reported.

8.5 Clinical laboratory evaluation

Clinical laboratory results are presented separately for hematology and clinical chemistry variables. Within each of these categories, results are examined in 3 ways: changes in mean values over time, changes in individual subjects over time, and individual clinically important abnormalities. The results for all clinical laboratory evaluations are discussed collectively in Section 8.5.3.

8.5.1 Hematology

8.5.1.1 Changes in mean values over time in hematology

Changes in hematology from baseline to Day 57 are shown in Table 50.

Table 50 Hematology changes from baseline (LOCF, safety population)

	Treatment								
	Quetiapine 300 mg N=179			Quetiapine 600 mg N=180			Placebo N=180		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Hematocrit (vol fraction)	155	-0.01	0.02	138	-0.01	0.03	149	-0.01	0.03
Hemoglobin (g/dL)	155	-0.24	0.78	141	-0.33	0.82	149	-0.20	1.08
Total RBC count (10^{12}/L)	155	-0.08	0.25	141	-0.10	0.30	149	-0.07	0.37
Platelet count (10^9/L)	154	-4.67	44.35	137	-6.68	41.76	146	-4.21	48.08
Total WBC count (10^9/L)	155	-0.28	1.59	141	-0.53	1.91	149	-0.33	1.82
Neutrophils (10^9/L)	155	-0.15	1.46	141	-0.44	1.80	149	-0.18	1.49
Eosinophils (10^9/L)	155	0.00	0.12	141	0.00	0.10	149	-0.02	0.13
Basophils (10^9/L)	155	-0.00	0.02	141	-0.00	0.03	149	-0.00	0.02
Lymphocytes (10^9/L)	155	-0.13	0.59	141	-0.09	0.45	149	-0.11	0.58
Monocytes (10^9/L)	155	-0.00	0.14	141	-0.02	0.15	149	-0.01	0.15

Data derived from Table 11.3.7.1.1.2.

There were no clinically relevant differences between treatment groups in mean change from baseline for any hematology assessments.

8.5.1.2 Changes in individual subjects over time in hematology

The number of patients within each treatment group with positive findings of categorical shifts to out-of-range hematology abnormalities are summarized in Table 51. Complete shift analyses for hematology assessments are presented in Table 11.3.7.1.1.3.1 (see also Figure 11.3.7.1.1.4.1 through Figure 11.3.7.1.1.4.10).

Table 51 Hematology shifts exceeding laboratory norms - incidence (safety population)

	Shift to low			Shift to high		
	Quetiapine 300 mg	Quetiapine 600 mg	Placebo	Quetiapine 300 mg	Quetiapine 600 mg	Placebo
Hematocrit	2.1	3.7	5.0	0.6	1.4	0.0
Hemoglobin	1.3	2.8	4.3	0.0	0.0	0.7
Total RBC count	0.7	1.4	4.9	0.0	0.0	0.0
Platelet count	0.7	0.0	0.7	1.3	0.0	0.0
Total WBC count	4.5	2.2	6.4	2.0	1.4	0.7
Neutrophils	0.7	0.7	3.5	3.3	1.5	0.7
Eosinophils	NA	NA	NA	2.0	2.9	2.1
Basophils	NA	NA	NA	0.0	0.0	0.0
Lymphocytes	3.9	2.2	2.0	0.7	0.7	2.9
Monocytes	7.3	8.1	7.6	5.4	6.1	8.5

Incidence (%) of cases with out-of-normal range findings at final visit in the population of patients who did not have out-of-normal range findings at baseline are noted in each cell. Normal ranges are shown in Table 11.3.7.1.1.1.
NA Not applicable
Data derived from Table 11.3.7.1.1.3.2

There were no clinically relevant differences between treatment groups in hematology shifts to out of normal range values.

8.5.1.3 Individual clinically important abnormalities in hematology

The number of patients within each treatment group with positive findings of categorical shifts to clinically important hematology abnormalities are summarized in Table 52. Complete shift analyses for clinically important hematology assessments are presented in Table 11.3.7.1.1.3.3 (see also Figure 11.3.7.1.1.4.1 through Figure 11.3.7.1.1.4.10).

Table 52 Hematology shifts to clinically important values - incidence (safety population)

	Shift to low			Shift to high		
	Quetiapine 300 mg	**Quetiapine 600 mg**	**Placebo**	**Quetiapine 300 mg**	**Quetiapine 600 mg**	**Placebo**
Hematocrit	0.7	0.0	2.7	0.0	0.0	0.0
Hemoglobin	0.7	0.0	2.0	0.0	0.0	0.0
Total RBC count	0.0	0.0	0.7	0.0	0.0	0.0
Platelet count	0.6	0.0	1.4	0.0	0.0	0.0
Total WBC count	0.0	0.0	0.7	0.0	0.0	0.0
Neutrophils	0.6	0.7	1.4	1.3	0.7	0.0
Neutrophils (agranulocytosis)	0.0	0.0	0.0	NA	NA	NA
Eosinophils	NA	NA	NA	0.0	0.7	0.0
Basophils	NA	NA	NA	0.0	0.0	0.0
Lymphocytes	0.0	0.0	0.7	0.0	0.0	0.0
Monocytes	NA	NA	NA	0.0	0.0	0.0

Incidence (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell. Clinically important criteria are shown in Table 15.
Data derived from Table 11.3.7.1.1.3.4

There were no clinically relevant differences between treatment groups in hematology shifts to clinically important abnormalities.

8.5.2 Clinical chemistry

8.5.2.1 Changes in mean values over time in clinical chemistry

Changes in chemistry assessments from baseline to Day 57 are shown in Table 53.

Table 53 Clinical chemistry changes from baseline (LOCF, safety population)

	Treatment								
	Quetiapine 300 mg N=179			Quetiapine 600 mg N=180			Placebo N=180		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
AST (U/L)	156	-0.65	10.04	147	1.35	9.19	152	0.32	15.38
ALT (U/L)	156	0.44	13.97	147	1.95	16.61	152	0.51	13.60
Alkaline phosphatase (U/L)	156	4.08	12.01	147	4.96	13.45	152	1.41	16.94
Total bilirubin (mg/dL)	156	-0.06	0.20	147	-0.06	0.26	152	-0.00	0.23
Creatinine (µmol/L)	156	0.01	0.12	147	0.03	0.12	152	0.01	0.12
Glucose (mg/dL)	156	3.19	13.47	147	5.90	17.17	152	3.80	25.60
Insulin (pmol/L)	156	43.54	191.69	143	94.07	257.71	151	11.27	183.96
Sodium (mmol/L)	156	0.25	2.89	146	-0.49	2.57	152	0.07	3.21
Potassium (mmol/L)	156	-0.01	0.46	146	-0.10	0.45	152	-0.02	0.46
Chloride (mEq/L)	156	1.02	3.13	146	0.42	2.93	152	0.70	3.16
Bicarbonate (mEq/L)	156	-0.50	3.42	147	-0.33	3.15	152	-0.28	3.12
Triglycerides (mg/dL)	156	35.17	98.89	147	21.61	78.45	152	6.47	140.59
Total cholesterol (mg/dL)	156	1.25	27.27	147	1.78	27.95	152	-1.11	32.28
HDL (mg/dL)	156	0.21	8.83	147	-1.50	10.02	152	-0.26	8.19
LDL (mg/dL)	156	-3.65	24.76	147	-1.01	26.35	152	-2.91	24.59
TSH (mU/L)	156	0.11	1.09	140	-0.07	0.91	152	0.08	1.22
Total T4 (nmol/L)	156	-9.63	18.41	147	-18.23	24.24	152	-0.84	17.86

Data derived from Table 11.3.7.1.2.2.

Kidney function and electrolyte test changes from baseline were similar for the three treatment groups. Liver function tests were similar for the three groups for AST and ALT but alkaline phosphatase exhibited a slight increase with quetiapine treatment.

Triglycerides and total cholesterol exhibited higher mean increases from baseline for the quetiapine-treated patients than for the placebo-treated patients. Triglyceride median changes from baseline were consistently lower than the corresponding means for all three treatment groups (quetiapine 300: 13.5 mg/dL; quetiapine 600: 12.0 mg/dL; placebo: 2.0 mg/dL; see Table 11.3.7.1.2.2) and the standard deviations for change from baseline were large compared

to the means. Triglyceride standard deviations for final assessment were larger than those for baseline assessments for all three treatment groups. LDL showed a mean decrease that was more pronounced for the quetiapine 300 mg group and the placebo group than for the quetiapine 600 mg group.

Quetiapine-treated patients exhibited a greater, apparently dose-related, mean decrease in total thyroxine than did the placebo-treated patients. Mean TSH concentrations were little-changed from baseline for all treatment groups.

While glucose was increased slightly for all three treatment groups, mean insulin levels increased in an apparent dose-response relationship with the most pronounced increase in the quetiapine 600 mg group. However, the data were highly variable, with the variability increasing as the mean increased. Median changes from baseline for glucose and insulin were generally lower than mean changes for all but placebo group insulin concentrations (Glucose -- quetiapine 300: 2.5 mg/dL; quetiapine 600: 3.0 mg/dL; placebo: 1.0 mg/dL; Insulin -- quetiapine 300: 6.9 pmol/L; quetiapine 600: 27.8 pmol/L; placebo: 13.9 pmol/L; see Table 11.3.7.1.2.2). Part of the variability of insulin concentration could be explained by the variation in blood sampling time of day; as many samples were collected past morning (>50%), and were probably not taken while patients were in the fasting state (see Figure 11.3.7.1.2.4.11 and Figure 11.3.7.1.2.4.12). For this reason, analyses of glucose findings have been presented using presumption of both fasting and random criteria. Separate examination of patients with pre-existing diabetes or risk for diabetes did not reveal changes in insulin or glucose concentrations that would indicate a deterioration of diabetic status when analyzed by either an LOCF or an OC method (see Table 11.3.7.1.2.3.5, Table 11.3.7.1.2.3.6, Table 11.3.7.1.2.3.7 and Table 11.3.7.1.2.3.8). Analysis using the ANCOVA method allowed examination of insulin final values (log_{10} transformed) to reveal significantly higher concentrations in patients treated with QTP 600 mg compared to either placebo (log_{10} difference = 0.24; p=0.007) or to QTP 300 mg (log_{10} difference = -0.17; p=0.046). No significant differences in final insulin concentration were noted for patients treated with QTP 300 mg compared to those treated with placebo. ANCOVA of change from baseline in glucose concentration did not demonstrate significant differences among the three treatment groups (see Table 11.3.7.1.2.3.9).

Changes from baseline in $HOMA_R$, an estimator of insulin resistance, and QUICKI, an estimator of insulin sensitivity, are shown in Table 54.

Table 54 Insulin resistance and sensitivity change from baseline (LOCF, safety population)

	Quetiapine 300 N=157			Quetiapine 600 N=147			Placebo N=152		
	n	Median change	Mean (SD) change	n	Median change	Mean (SD) change	n	Median change	Mean (SD) change
$HOMA_R$	144	0.4	1.72 (8.52)	138	1.1	4.26 (13.33)	144	0.3	0.06 (11.59)
QUICKI	144	-0.0075	-0.0106 (0.0426)	138	-0.0237	-0.0227 (0.0460)	144	-0.0131	-0.0158 (0.0496)

Data derived from Table 11.3.7.1.2.3.5
N Number of patients in dose group. n Number of patients in analysis subset.

The changes from baseline to final assessment in the $HOMA_R$ estimate of insulin resistance and the QUICKI estimate of insulin sensitivity were highly variable with relatively small deviations from no change. Patients who completed the study and thus received exposure to treatment for the full 8 weeks, showed similar patterns of response (see Table 11.3..7.1.2.3.6 and Table 11.3.7.1.2.3.8). Examination of data for quetiapine-treated and placebo-treated patients with diabetes or diabetes risk did not reveal systematic differences for $HOMA_R$ or QUICKI assessments (see Table 11.3.7.1.2.3.5 and Table 11.3.7.1.2.3.6). Analysis using the ANCOVA method allowed examination of $HOMA_R$ final values to reveal significantly higher concentrations in patients treated with QTP 600 mg compared to placebo (difference = 3.91; $p=0.002$) but not to those treated with QTP 300 mg (difference = -2.25; $p>0.05$). No significant differences for $HOMA_R$ final values were noted for patients treated with QTP 300 mg compared to those treated with placebo. ANCOVA of QUICKI final assessment values did not demonstrate significant differences among the three treatment groups (see Table 11.3.7.1.2.3.9).

8.5.2.2 Changes in individual subjects over time in clinical chemistry

The number of patients within each treatment group with findings of categorical shifts to out-of-range chemistry abnormalities are summarized in Table 55. Complete shift analyses for chemistry parameters are presented in Table 11.3.7.1.2.3.1 (see also Figure 11.3.7.1.2.4.1 through Figure 11.3.7.1.2.4.10).

Table 55 Clinical chemistry shifts exceeding laboratory norms - incidence (safety population)

Parameter	Shift to low			Shift to high		
	Quetiapine 300 mg	Quetiapine 600 mg	Placebo	Quetiapine 300 mg	Quetiapine 600 mg	Placebo
AST	0.0	0.7	0.7	3.4	5.1	2.1
ALT	0.0	1.4	0.0	7.2	10.4	1.4
Alkaline phosph.	0.0	0.0	0.0	6.0	2.8	2.1
Total bilirubin	1.3	2.7	3.3	0.0	2.1	1.3
Creatinine	0.0	0.0	0.0	0.0	0.0	0.7
Glucose	0.7	2.8	0.7	2.6	6.2	4.7
Insulin	2.0	1.4	0.7	26.0	30.8	23.7
Sodium	0.0	0.0	0.0	1.9	0.0	1.3
Potassium	0.0	0.0	0.0	1.9	0.7	0.0
Chloride	0.0	0.0	0.0	0.6	0.7	1.3
Bicarbonate	6.0	4.8	1.3	0.0	0.0	0.0
Triglycerides	0.0	2.1	2.7	15.7	6.2	6.2
Total cholesterol	1.3	3.5	1.4	12.5	18.5	10.5
HDL	17.4	14.3	11.5	1.4	0.0	1.4
LDL	NA	NA	NA	10.1	17.2	11.2
TSH	0.7	3.6	1.4	1.9	0.7	2.6
Total T4	1.3	4.8	0.7	0.0	1.4	0.7

Incidence (%) of cases with out-of-normal range findings at final visit in the population of patients who did not have out-of-normal range findings at baseline are noted in each cell. Normal ranges are shown in Table 11.3.7.1.2.1.
Data derived from Table 11.3.7.1.2.3.2

More quetiapine-treated patients with low or normal baseline liver function tests showed shifts to out-of-range high results after treatment compared to placebo-treated patients. However, the incidence across AST, ALT and alkaline phosphatase shifts was fewer than ten percentage points over placebo for either quetiapine group. Insulin showed a 24% to 31% incidence of shift to high concentrations for all three treatment groups. Triglycerides, total cholesterol and LDL concentrations shifted to out-of-normal-range concentrations for quetiapine-treated patients with incidences that were 2 to 10 percentage points higher compared to placebo-treated patients. HDL concentrations shifted to out-of-range lower concentrations for quetiapine-treated patients with incidences that were 3 to 6 percentage points lower compared to placebo-treated patients.

8.5.2.3 Individual clinically important abnormalities in clinical chemistry

The number of patients within each treatment group with positive findings of categorical shifts to potentially clinically important clinical chemistry abnormalities are summarized in Table 56. Complete shift analyses for potentially clinically important chemistry results are presented in Table 11.3.7.1.2.3.3 (see also Figure 11.3.7.1.2.4.1 through Figure 11.3.7.1.2.4.10).

Table 56 Clinical chemistry shifts to clinically important values - incidence (safety population)

	Shift to low			Shift to high		
	Quetiapine 300 mg	Quetiapine 600 mg	Placebo	Quetiapine 300 mg	Quetiapine 600 mg	Placebo
AST	NA	NA	NA	0.0	0.0	2.0
ALT	NA	NA	NA	0.0	0.7	0.7
Alkaline phosphatase	NA	NA	NA	0.0	0.0	0.0
Total bilirubin	NA	NA	NA	0.0	0.7	0.7
Creatinine	NA	NA	NA	0.0	0.0	0.0
Glucose (fasting)	0.0	0.0	0.0	2.6	4.1	3.4
Glucose (random)	0.0	0.0	0.0	0.0	0.0	0.7
Sodium	0.6	0.7	0.7	0.0	0.0	0.7
Potassium	0.0	0.0	0.0	2.6	0.7	0.7
Chloride	0.0	0.0	0.0	0.0	0.0	0.0
Bicarbonate	1.3	0.7	0.7	0.7	3.5	4.2
Triglycerides	NA	NA	NA	16.0	13.4	7.4
Total cholesterol	NA	NA	NA	9.6	6.5	6.1
HDL	16.2	14.9	13.3	0.0	0.0	0.0
LDL	NA	NA	NA	7.0	4.8	4.4
TSH	NA	NA	NA	3.3	0.7	2.6
Total T4	0.0	0.0	0.0	0.0	0.7	0.0

Incidence (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell Clinically important criteria are shown in Table 15.
Data derived from Table 11.3.7.1.2.3.4

Quetiapine 300 mg-treated patients showed a 8.6-percentage-point-higher incidence of clinically important elevated tryglyceride concentration than did placebo-treated patients. The incidence of clinically important low concentration of HDL was 2 to 3 percentage point higher for quetiapine-treated patients compared to placebo-treated patients.

8.5.2.4 Metabolic syndrome risk factors

Shifts in metabolic syndrome risk factors using criteria for fasting and random glucose elevations are presented in Table 57. An analysis of individual risk factors for shifting to meeting criteria for metabolic syndrome for patients who did not meet risk criteria and baseline is presented in Table 11.3.8.1.4.3. Shifts in metabolic syndrome risk factors using criteria for fasting and random glucose elevations are presented in Table 11.3.8.1.4.1 and Table 11.3.8.1.4.2 with proportions calculated as a percentage of all patients with baseline and post-baseline data.

Table 57 Metabolic syndrome risk factors, shift from baseline (safety population)

		QTP 300 (N=179)		QTP 600 (N=180)		PLA (N=180)	
Factor	**Shift criteria**	**N at risk**	**n (%) shifting**	**N at risk**	**n (%) shifting**	**N at risk**	**N (%) shifting**
Metabolic syndrome risk (fasting glucose criterion)	≥3 risk factors	145	18 (12.4)	146	20 (13.7)	140	4 (2.9)
Metabolic syndrome risk (random glucose criterion)	≥3 risk factors	145	16 (11.0)	147	19 (12.9)	141	4 (2.8)

Data derived from Table 11.3.8.1.4.1 and Table 11.3.8.1.4.2

Note: Patients classified as "at risk" in each treatment group did not meet criteria for the specific risk factor at baseline. The proportion (%) who shifted to meeting 3 or more risk factors is computed from the "at risk" population within each treatment group.

Quetiapine-treated patients showed an 8 to 10 percentage point higher rate of shift than did placebo patients to meeting criteria for an aggregate of 3 metabolic syndrome risk factors. The most pronounced differential shifts to meeting criteria among quetiapine-treated patients compared to placebo-treated patients were observed for increases in triglycerides, while the least pronounced were for increases in blood glucose (see Table 11.3.8.1.4.4).

The incidence of meeting aggregate metabolic syndrome risk factors after the criterion for triglyceride elevation has been removed is shown in Table 58.

Table 58 Metabolic syndrome risk factors without triglyceride criterion, shift from baseline (safety population)

Factor	Shift criteria	QTP 300 (N=179) N at risk	QTP 300 (N=179) n (%) shifting	QTP 600 (N=180) N at risk	QTP 600 (N=180) n (%) shifting	PLA (N=180) N at risk	PLA (N=180) N (%) shifting
Metabolic syndrome risk (fasting glucose criterion)	≥3 risk factors	161	11 (6.8)	163	11 (6.7)	157	4 (2.5)
Metabolic syndrome risk (random glucose criterion)	≥3 risk factors	162	7 (4.3)	163	10 (6.1)	159	3 (1.9)

Data derived from Table 11.3.8.1.4.4

Note: Patients classified as "at risk" in each treatment group did not meet criteria for the specific risk factor at baseline. The proportion (%) who shifted to meeting 3 or more risk factors is computed from the "at risk" population within each treatment group.

When the criteria for triglyceride elevation was ignored, quetiapine-treated patients showed a 2 to 4 percentage point higher rate of shift than did placebo-treated patients to meeting criteria for an aggregate of 3 metabolic syndrome risk factors.

8.5.3 Discussion of clinical laboratory results

In this study, the known clinical laboratory profile for quetiapine was reported in patients with bipolar depression. Decreases in the concentrations of thyroxine without accompanying increases in TSH, and increases in transaminases were seen in this population. These findings have been well-characterized in previous studies in patients treated with quetiapine for other disorders.

The increases in cholesterol and triglycerides seen in this study are also known effects of quetiapine, although the increase in triglycerides in this study may have been somewhat exaggerated by possible non-fasting assessments for some patients. The distribution of data for triglycerides, glucose and insulin were skewed and highly variable, with markedly higher concentrations detected for some patients but not for others. The distribution of blood sampling times-of-day suggests that many samples were likely drawn from non-fasting patients. Therefore, it is not possible to know to what degree increases in triglycerides, glucose and insulin are due to quetiapine versus recent food intake of indeterminate fat or carbohydrate content. Statistically significant differences in insulin concentration between the QTP 600 mg group and the other treatment groups could be interpreted as due to increased hunger or increased carbohydrate craving as easily as to differences in insulin sensitivity. The increase in appetite for patients whose depression was improving with treatment as shown by the MADRS item scores could also account for some differential effect for quetiapine in comparison with placebo.

Increases in levels of cholesterol, triglycerides, glucose and insulin led to exploration of possible decreased insulin sensitivity (increased insulin resistance). While quetiapine-treated patients exhibited numerically-higher-but-highly-variable $HOMA_R$ scores and numerically-lower-but-highly-variable QUICKI scores, those indexes were computed from insulin and glucose concentrations. To the degree that insulin and glucose data are spurious due to non-fasting conditions, so will the $HOMA_R$ and QUICKI estimates of insulin resistance and sensitivity be spurious, as both indexes assume fasting conditions. When shifts in metabolic syndrome risk factors were explored taking into account blood pressure, body mass index, and HDL concentrations as well as triglyceride and glucose concentrations, quetiapine-treated patients showed a higher proportion of patients shifting to meet aggregate criteria for risk for metabolic syndrome. However, the evidence for shifts to criterion levels for risk of metabolic syndrome were heavily influenced by elevated triglyceride concentrations that were of questionable validity.

Examination of clinical laboratory data for patients with pre-existing diabetes showed no clinically relevant findings to suggest that progression of diabetes had occurred. Examination of data for patients considered to be at-risk for diabetes showed no clinically relevant findings to suggest that diabetes was emergent in these patients. These data were in accord with the lack of adverse events that might suggest the development of diabetic symptoms.

Examination of hematology data did not reveal the development of neutropenia or agranulocytosis in any patients, and there were no adverse event reports of those conditions.

8.6 Vital signs, ECG, physical findings and other observations related to safety

Results for vital signs and ECG are grouped together. In the vital signs and ECG section, results are examined in 2 ways: trends or group changes over time and individual potentially clinically important abnormalities. The results for all vital signs, ECG and other physical findings are discussed collectively in Section 8.6.4.

8.6.1 Changes in vital signs and ECG over time

Changes in vital sign and ECG parameters from baseline to Day 57 are shown in Table 59. Tables 11.3.8.1.1.1 through 11.3.8.1.1.3 include presentation of standing blood pressure and orthostatic changes.

Table 59 Vital signs and ECG parameters change from baseline (LOCF, safety population)

	Treatment								
	Quetiapine 300 mg N=179			Quetiapine 600 mg N=180			Placebo N=180		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Vital signs									
Supine pulse (bpm)	174	3.4	10.9	171	4.7	12.5	175	1.1	9.5
Supine systolic BP (mmHg)	174	1.0	11.4	171	0.2	12.8	175	-0.5	11.8
Supine diastolic BP (mmHg)	174	0.8	9.8	171	1.3	10.1	175	-0.4	8.7
ECG									
Heart rate (bpm)	155	6.4	10.9	146	9.8	10.9	150	1.7	10.2
PR interval (msec)	155	-0.1	16.7	146	-0.5	15.8	150	0.6	15.6
QRS interval (msec)	155	-0.5	6.5	146	-0.4	6.2	150	-0.9	6.3
QT interval (msec)	155	-14.8	26.7	146	-19.2	26.4	150	-4.9	25.2
Fridericia corrected QTC interval (msec)	155	-3.7	21.1	146	-1.7	19.4	150	-2.1	19.3

Data derived from Table 11.3.8.1.1.3 and Table 11.3.8.1.2.1.

Small mean increases in heart rate were observed in quetiapine patients, suggesting a dose-related response. There was no indication of an increase in the QTC interval in any treatment group.

8.6.2 Individual clinically important abnormalities in vital signs and ECG

Patients within each treatment group with positive findings of categorical shifts to clinically important vital sign abnormalities are summarize in Table 60. Complete shift analyses for clinically important vital sign results are presented in Table 11.3.8.1.1.4 and Table 11.3.8.1.1.5 and for ECG results in Table 11.3.8.1.2.4 and Table 11.3.8.1.2.5 (also see Figure 11.3.8.1.2.2 and Table 11.3.8.1.2.3). A summary of clinically important of shifts in orthostatic changes is presented in Table 61.

Table 60 Vital signs and ECG shifts to potentially clinically important values - incidence (safety population)

Parameter	Shift to low			Shift to high		
	Quetiapine 300 mg %	Quetiapine 600 mg %	Placebo %	Quetiapine 300 mg %	Quetiapine 600 mg %	Placebo %
Vital signs						
Supine pulse	0	0	0	0	0	0
Supine systolic BP	1.2	1.2	2.9	0	0	0
Supine diastolic BP	0	0.6	0.6	0	1.2	1.7
ECG						
Heart rate	0.7	1.4	2.1	0	0	0
PR interval	NA	NA	NA	0.7	0	0
QRS interval	0	0	0	0	0	0
QT interval	0	0	0	0	0	0
Fridericia corrected QTC interval	NA	NA	NA	0	0	0

Incidence (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell
Data derived from Table 11.3.8.1.1.5 and Table 11.3.8.1.2.5

Table 61 Orthostatic change shifts to clinically important values - incidence (safety population)

Orthostatic change	Shift to positive findings		
	Quetiapine 300 mg %	Quetiapine 600 mg %	Placebo %
Pulse	3.6	6.9	1.2
Systolic BP	0.6	1.2	2.9
Diastolic BP	1.7	0.6	0
Combined pulse & SBP	0	0.6	0.6

Incidence (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell
Data derived from Table 11.3.8.1.1.6

While an apparent dose-response for an increased pulse rate change upon standing with quetiapine administration was noted, combined criteria for orthostatic changes did not show any differential effect of quetiapine administration compared to placebo.

Shifts in ECG assessments did not show any differential effect of quetiapine administration compared to placebo.

8.6.3 Physical findings and other observations related to safety

8.6.3.1 Physical examinations

Abnormal findings from physical examination were to be reported as adverse events.

8.6.3.2 Weight and BMI

At end of treatment, placebo patients showed a mean loss of 0.2 kg of body weight, quetiapine 300 mg patients showed a mean gain of 1.0 kg and quetiapine 600 mg patients showed a mean gain of 1.6 kg. (see Table 11.3.8.1.3.1.1). Among patients who completed the protocol, quetiapine 300 mg patients showed a gain of 1.1 kg; quetiapine 600 mg patients showed a gain of 2.0 kg; and placebo patients, a gain of 0.2 kg (see Table 11.3.8.1.3.1.2). Changes in body weight and BMI from baseline to final visit are shown in Table 62 for patients categorized by baseline BMI classification.

Table 62 Body weight (kg) and BMI (kg/m^2) change from baseline by BMI category (LOCF, safety population)

		Treatment								
		Quetiapine 300 mg N=			Quetiapine 600 mg N=			Placebo N=		
BMI category		N	Mean	SD	N	Mean	SD	N	Mean	SD
≤18.49										
	Weight	0	NA	NA	2	0.5	2.12	2	0.0	2.83
	BMI	0	NA	NA	2	0.2	0.85	2	0.0	1.06
18.5 to 24.9										
	Weight	44	1.6	3.55	40	1.9	2.92	48	-0.3	1.99
	BMI	44	0.6	1.15	40	0.6	0.95	48	-0.1	0.68
25 to 29.9										
	Weight	50	0.5	2.63	56	1.6	3.95	45	0.2	2.05
	BMI	50	0.2	0.93	56	0.6	1.31	45	0.1	0.79
30 to 39.9										
	Weight	47	1.3	3.02	34	1.6	4.82	45	0.0	2.37
	BMI	47	0.5	1.02	34	0.5	1.78	45	0.0	0.84
>40										

Table 62 Body weight (kg) and BMI (kg/m^2) change from baseline by BMI category (LOCF, safety population)

BMI category		Treatment								
		Quetiapine 300 mg N=			Quetiapine 600 mg N=			Placebo N=		
		N	Mean	SD	N	Mean	SD	N	Mean	SD
	Weight	14	0.4	3.76	11	1.2	4.21	13	2.1	3.17
	BMI	14	0.1	1.40	11	0.4	1.56	13	0.8	1.17

Data derived from Table 11.3.8.1.3.2.
Note: Due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from this table

No consistent pattern of differential weight gain dependent upon baseline BMI was noted. At end of treatment, 15 (9.7%) quetiapine 300 mg patients, 16 (11.2%) quetiapine 600 mg patients and 3 (2.0%) placebo patients showed a weight gain ≥7% (see Table 11.3.8.1.3.5).

8.6.3.3 SAS

At the end of treatment, quetiapine 300 mg patients showed a mean SAS total score of 0.3 (SD = 0.7), quetiapine 600 mg patients showed a mean total score of 0.6 (SD = 1.3) and placebo patients, a mean score of 0.3 (SD = 0.6). The three treatment groups were similar in mean change in the SAS total score at end of treatment (quetiapine 300 mg: -0.2 (SD = 1.1); quetiapine 600 mg: -0.1 (SD = 1.4); placebo: -0.3 (SD = 1.2); see Table 11.3.8.1.5.1).

The distribution of patients whose SAS score improved, worsened or stayed the same is shown in Table 63.

Table 63 SAS categorical change from baseline (LOCF, safety population)

	Quetiapine 300 N= 179		Quetiapine 600 N= 180		Placebo N= 180	
	n	%	n	%	n	%
Improved	33	21.9	29	20.1	34	22.8
No change	104	68.9	93	64.6	102	68.5
Worsened	14	9.3	22	15.3	13	8.7
Total	151	100.0	144	100.0	149	100.0

Data derived from Table 11.3.8.1.5.3
N Number of patients in dose group. n Number of patients in analysis subset.

There was no statistically significant difference between either quetiapine treatment group and placebo in the number of patients showing increases from baseline in SAS score (quetiapine

300 mg vs placebo: p=0.888; quetiapine 600 mg vs placebo: p=0.075; see Table 11.3.8.1.5.2).

8.6.3.4 BARS

At the end of treatment, quetiapine 300 mg patients showed a mean BARS Global Assessment score of 0.2 (SD = 0.6), quetiapine 600 mg patients showed a mean score of 0.3 (SD = 0.8) and placebo-treated patients, a mean score of 0.1 (SD = 0.4). The three treatment groups were similar in mean change in the BARS Global Assessment score at the end of treatment (quetiapine 300 mg: -0.1 (SD = 0.7); quetiapine 600 mg: -0.0 (SD = 0.8); placebo: -0.1 (SD = 0.6); see Table 11.3.8.1.6.1).

The distribution of patients whose BARS score improved, worsened or stayed the same is shown in Table 64.

Table 64 BARS Global Assessment categorical change from baseline (LOCF, safety population)

	Quetiapine 300 N= 179		Quetiapine 600 N = 180		Placebo N= 180	
	n	%	n	%	n	%
Improved	24	15.7	27	18.6	24	16.1
No change	115	75.2	100	69.0	112	75.2
Worsened	14	9.2	18	12.4	13	8.7
Total	153	100.0	145	100.0	149	100.0

Data derived from Table 11.3.8.1.6.3
BARS. Barnes Akathisia Rating Scale. N Number of patients in dose group. n Number of patients in analysis subset.

There was no statistically significant difference between either quetiapine treatment group and placebo in the number of patients showing increases from baseline in BARS score (quetiapine 300 mg vs placebo: p=0.888; quetiapine 600 mg vs placebo: p=0.306; see Table 11.3.8.1.6.2).

8.6.4 Discussion of vital signs, ECG, physical findings and other observations related to safety

The small increases in heart rate and body weight are consistent with known effects of quetiapine in other populations. SAS and BARS assessments were not statistically significantly different for quetiapine treated patients compared to placebo treated patients and this finding was inconsistent with the slight increase in EPS adverse events for quetiapine-treated patients.

8.7 Conclusions on safety results

Treatment of patients with a depressive episode in bipolar disorder with either quetiapine 300 mg or quetiapine 600 mg daily was generally safe and well tolerated. Most adverse events

and clinical findings seen in these patients have been previously identified in patients treated with quetiapine for other disorders. Sedation and somnolence were the adverse events most often associated with discontinuation in quetiapine-treated patients. The rate of discontinuation due to adverse events may have been over-estimated because investigators were required to attribute a discontinuation to an adverse event if the patient was experiencing an adverse event at the time of discontinuation.

The linkage between these conclusions, the specific safety objectives of the study, and the study variables selected to address these objectives, is presented in Table 65.

Table 65 Safety objectives, variables and conclusions

Objective	Variables	Conclusions
Evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	Incidence and severity of adverse events during double-blind treatment	The most common AEs associated with quetiapine administration were dry mouth, sedation, somnolence and constipation.
	Incidence of drug-related adverse events during double-blind treatment	AEs most-often attributed to quetiapine administration were dry mouth, sedation, somnolence and constipation.
	Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment.	Low rates of EPS were noted with most events being mild to moderate and not-often associated with discontinuation. The incidence of suicidality was similar to placebo for both quetiapine treatment groups.
	Incidence of subject withdrawal due to adverse events	Somnolence and sedation were the most common adverse events associated with discontinuation. Higher rates of withdrawal due to adverse events were associated with the quetiapine 600 mg dose than with the 300 mg dose.
	Clinical laboratory assessments change from baseline to Day 57 in the safety population	There were no clinically relevant hematology findings for quetiapine-treated patients in comparison with placebo-treated patients.
	Incidence of potentially clinically important changes in clinical laboratory assessments	Decreases in the concentrations of thyroxine (without increases in TSH) and increases in transaminases were consistent with those seen in other patient populations. Increases in tryglycerides and glucose, while confounded by probable non-fasting assessments were elevated and contributed to a higher estimate of shift to metabolic syndrome risk factors among quetiapine-treated patients.

Table 65 Safety objectives, variables and conclusions

Objective	Variables	Conclusions
	Change in weight and body mass index (BMI) from baseline to Day 57 in the safety population	Quetiapine-treated patients showed a slight increase in body weight consistent with findings in other patient populations.
	Vital signs from baseline to Day 57 in the safety population	Small mean increases in heart rate were observed in quetiapine patients.
	Incidence of clinically significant changes in vital signs	An apparent dose-response for an increased pulse rate change upon standing with quetiapine administration was noted, but combined criteria for orthostatic changes did not show any differential effect of quetiapine administration compared to placebo.
	Electrocardiogram (ECG)	ECG interval changes were consistent with an increase in heart rate in quetiapine-treated patients, with no indication of an increase in the QTC interval in any treatment group.
	Incidence of potentially clinically important changes in ECG	Shifts in ECG assessments did not show any differential effect of quetiapine administration compared to placebo.
	Change in the SAS total score from baseline to final assessment	Quetiapine-treated patients were similar to placebo-treated patients in final score, change from baseline and the number of patients showing increases in SAS score.
	Change in BARS Global Assessment score from baseline to final assessment	Quetiapine-treated patients were similar to placebo-treated patients in final score, change from baseline and the number of patients showing increases in BARS score.
Evaluate the efficacy of quetiapine compared to placebo in the incidence of treatment-emergent mania	Proportion of patients exhibiting a YMRS total score ≥16 on 2 consecutive assessments or on the final assessment or having an AE report of mania or hypomania.	Quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression indistinguishable from placebo in producing treatment-emergent manic of hypomanic symptoms as measured by change from baseline in the YMRS total score or an adverse event of mania.

9. DISCUSSION AND OVERALL CONCLUSIONS

9.1 Discussion

In total, 832 patients were screened and 542 patients with either bipolar I disorder or bipolar II disorder, with or without a rapid cycling course, exhibiting moderate to severe depression were randomly assigned to receive either quetiapine 300 mg daily, quetiapine 600 mg daily or placebo. Of the 542 patients recruited, 539 received treatment and were included in the safety population, of whom 511 were analyzed for efficacy in an intention-to-treat analysis set and 453 in a per-protocol analysis set. The three treatment groups were well-matched in number and demographic and baseline disease characteristics and were representative of the general population of patients with bipolar disorder.

The study was well-conducted and high levels of compliance with study drug administration were inferred from tablet counts. Study completion rates were within the expected ranges for depression studies. Within the safety population, 54% of quetiapine 600 mg patients, 68% of quetiapine 300 mg patients and 59% of placebo patients completed the study. Adverse events were the main reason for withdrawal in quetiapine-treated patients, while lack of efficacy was the main reason for withdrawal in placebo-treated patients.

The primary objective for this study was to evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder for up to 8 weeks. The comparison of change from baseline in total MADRS score supported the hypothesis that quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment of a depressive episode in patients with bipolar disorder was superior to placebo in reducing the level of depressive symptoms. A relatively small numerical advantage in treatment effect for MADRS change from baseline was seen for the quetiapine 600 mg group compared to the quetiapine 300 mg group, and that advantage was more pronounced for patients who completed the full 8 weeks of treatment. Treatment advantages for both quetiapine groups over placebo were statistically significant by Day 8 and continued to be so through Day 57. The superiority for both doses of quetiapine over placebo in MADRS total score was due to improvements across all ten of the MADRS items, each evaluating different symptoms of depression.

Analysis of secondary outcome variables also supported the superiority of quetiapine over placebo in the treatment of depression in patients with bipolar disorder. The proportion of patients showing ≥50% reduction in MADRS total score (responders) was statistically significantly higher for the quetiapine 600 mg group compared to the placebo group by Day 8 and for the quetiapine 300 mg group by Day 15, and continued through trial completion for both quetiapine groups. The changes from baseline in HAM-D total score, HAM-D Item 1 and CGI-S were statistically significantly greater for the quetiapine groups compared to the placebo groups by Day 8, with greater differential effect compared to placebo to Day 57. The CGI-I comparisons of quetiapine groups to placebo were also statistically significant by Day 8 and continued to be significant through Day 57. As with the MADRS change from baseline, secondary outcome variables exhibited a more pronounced numerical advantage for

quetiapine 600 mg compared to quetiapine 300 mg for patients who completed the full 8 weeks of treatment in the last-observation-carried-forward analysis.

Bipolar I and bipolar II patients showed greater improvement in MADRS change from baseline with either dose of quetiapine than with placebo. The change from baseline in MADRS score was greater for bipolar I patients than for bipolar II patients, but the study was under-powered for statistical comparison of bipolar I vs bipolar II subgroups or for either diagnostic subgroup vs placebo. Subgroups categorized by sex, race and age also showed a therapeutic advantage for quetiapine treatment. There was no diagnostic or demographic subgroup that did not exhibit an improvement with quetiapine treatment compared to placebo treatment.

The evaluation of the effect of quetiapine on anxiety in bipolar patients with depression was a secondary objective of the study. The comparison of change from baseline in total HAM-A score supported the hypothesis that quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment of a depressive episode in patients with bipolar disorder was superior to placebo in reducing the level of anxiety symptoms. Treatment advantages for both quetiapine groups over placebo were statistically significant by Day 8 and continued to be so through Day 57.

The evaluation of the safety and tolerability of quetiapine in the treatment of bipolar patients with depression was a secondary objective of the study. Analysis of adverse events indicated that nervous system and gastrointestinal events predominated, with dry mouth, sedation, somnolence, dizziness and constipation occurring at higher rates with quetiapine treatment compared to placebo treatment. Most adverse events were mild to moderate. Serious adverse events were reported for a greater proportion of patients given placebo than for those given quetiapine. Adverse events leading to discontinuation were more numerous for the quetiapine-treated groups than for the placebo-treated group and occurred at a higher rate in the quetiapine 600 mg group than in the quetiapine 300 mg group. Sedation and somnolence were the adverse events most associated with discontinuation by quetiapine-treated patients. Sedation and dizziness were associated with discontinuation in patients receiving the 600 mg dose more than in those receiving the 300 mg dose. As attribution of withdrawal as due to an adverse event was forced if any adverse event was present at withdrawal, the rate of withdrawal due to adverse events may be overestimated in this study compared to studies without such a definition.

The evaluation of treatment-emergent mania/hypomania was a secondary objective of the study. Treatment-emergent mania was not associated with quetiapine treatment -- it was noted in 7 patients treated with placebo, 7 patients treated with quetiapine 300 mg daily and 4 patients treated with 600 mg daily. Consistent with these findings, the decrease in YMRS scores at final assessment showed a statistically significant advantage for both groups of quetiapine treated patients compared to placebo.

Safety events of special interest included EPS, QT prolongation, neutropenia/agranulocytosis; weight changes, metabolic syndrome, diabetes and suicidality.

Akathisia was reported at higher rates with quetiapine treatment than with placebo treatment. This finding may be due to increased sensitivity in bipolar depression patients and will be assessed in future studies.

No cases of neutropenia or agranulocytosis following quetiapine treatment were reported. Increases in weight, triglycerides, total cholesterol and LDL were consistent with the known safety profile for quetiapine. Increases in glucose and insulin were observed but were confounded by probable non-fasted sampling. The incidence of aggregate shifts of blood pressure, BMI, triglycerides, HDL and glucose to criteria for risk of metabolic syndrome was higher for quetiapine-treated patients compared to placebo.

The incidence of adverse events associated with suicidality for quetiapine-treated patients was no different than that for placebo-treated patients.

Exploratory objectives included the evaluation of the Q-LES-Q change from baseline and the PSQI change from baseline, both of which are patient-reported outcomes. The improvements in Q-LES-Q score from baseline values were superior for quetiapine-treated patients compared to placebo-treated patients, indicating that quetiapine-treated patients judged that their quality of life had improved over placebo levels. Improvements in subjective sleep quality were also apparent following quetiapine treatment, with the PSQI change from baseline confirming that quetiapine-treated patients felt that they were sleeping better than did placebo-treated patients.

The efficacy results of this study suggest that quetiapine could be an important treatment for depressive episodes in bipolar disorder. The improvement in the entire range of depression symptoms assessed by the MADRS, the HAM-D and the HAM-A demonstrated that the core mood disturbance, the somatic symptoms and anxiety overlays were addressed by the treatment with the net subjective effect being an improvement in quality of life. The alleviation of the full range of depression symptoms was apparent by Day 8 of the study -- 7 days after the beginning of treatment, when both the quetiapine 300 mg and the quetiapine 600 mg groups demonstrated separation from placebo in most efficacy assessments. This is a relatively rapid onset of effect, given that most antidepressants do not show such separation until approximately 3 weeks after the start of treatment.

Evaluation of safety and tolerability in this study revealed a safety profile for quetiapine in patients with bipolar depression that is generally consistent with that seen in previous studies of inpatients with schizophrenia or mania. However, there was some indication that the outpatients in this study were less tolerant of the sedative, somnolent and dizziness effects of quetiapine, especially at the 600 mg daily dose. As these outpatients were functioning in their community, maintaining employment, driving and contributing to their families, somnolence and dizziness may have been more disruptive than to inpatients that were evaluated in previous studies. Nonetheless, these outpatients reported improvements in their quality of life, suggesting that the inconvenience of the adverse events was outweighed by the alleviation of depression, resulting in a positive benefit/risk assessment.

9.2 Overall conclusions

- Quetiapine in doses of either 300 mg or 600 mg once-daily was superior to placebo in treating depression in patients with bipolar disorder.

- The antidepressant effect of quetiapine treatment was observed as early as 7 days after treatment initiation and was maintained throughout the 8-week treatment course in patients with bipolar disorder who were experiencing a depressive episode.

- Quetiapine in doses of either 300 mg or 600 mg once-daily was superior to placebo in treating anxiety symptoms in patients with bipolar disorder who were experiencing a depressive episode.

- Quetiapine in doses of either 300 mg or 600 mg once-daily was superior to placebo in improving the quality of life for patients with bipolar disorder who were experiencing a depressive episode.

- Quetiapine in a dose of either 300 mg or 600 mg once-daily was generally safe and well-tolerated in patients with bipolar disorder who were experiencing a depressive episode. A higher rate of discontinuation due to sedation and dizziness was seen with the 600 mg daily dose. The most common adverse events associated with quetiapine treatment were dry mouth, somnolence, sedation, dizziness and constipation.

- Quetiapine in doses of either 300 mg or 600 mg once-daily was associated with low rates of treatment-emergent mania or hypomania similar to placebo in patients with bipolar disorder who were experiencing a depressive episode.

10. REFERENCE LIST

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11. TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

11.1 Demographic, baseline, concomitant medication and other subject-specific characteristics

11.2 Pharmacokinetic and pharmacodynamic data

11.3 Safety Data

Table 11.1.1.1 Disposition of Screened Patients

	N	%
TOTAL PATIENTS SCREENED	838	
PATIENTS RANDOMIZED	542	
SCREEN FAILURES	296	
--- LOST TO FOLLOW-UP	55	18.6
--- ADVERSE EVENT	6	2.0
--- PROTOCOL/NONCOMPLIANCE	170	57.4
--- INFORMED CONSENT WITHDRAWN	55	18.6
--- OTHER	10	3.4

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Table 11.1.1.2 Randomized Patients by Center

CENTER	TREATMENT						TOTAL	
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
	N	%	N	%	N	%	N	%
TOTAL	181	33.4	180	33.2	181	33.4	542	100.0
0001	1	33.3	1	33.3	1	33.3	3	0.6
0002	5	41.7	2	16.7	5	41.7	12	2.2
0003	5	41.7	6	50.0	1	8.3	12	2.2
0004	4	30.8	5	38.5	4	30.8	13	2.4
0005	10	31.3	13	40.6	9	28.1	32	5.9
0006	4	66.7	1	16.7	1	16.7	6	1.1
0007	2	18.2	3	27.3	6	54.5	11	2.0
0009	3	30.0	3	30.0	4	40.0	10	1.8
0010	5	29.4	9	52.9	3	17.6	17	3.1
0011	5	31.3	3	18.8	8	50.0	16	3.0
0013	2	20.0	3	30.0	5	50.0	10	1.8
0014	2	13.3	4	26.7	9	60.0	15	2.8
0015	1	20.0	2	40.0	2	40.0	5	0.9
0016	2	50.0	2	50.0	0	0	4	0.7
0017	0	0	0	0	1	100.0	1	0.2
0018	2	18.2	4	36.4	5	45.5	11	2.0

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Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.

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Table 11.1.1.2 Randomized Patients by Center

CENTER	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
0019	17	45.9	14	37.8	6	16.2	37	6.8
0020	5	33.3	6	40.0	4	26.7	15	2.8
0022	16	29.1	20	36.4	19	34.5	55	10.1
0023	14	35.9	15	38.5	10	25.6	39	7.2
0025	1	50.0	0	0	1	50.0	2	0.4
0026	9	37.5	8	33.3	7	29.2	24	4.4
0027	2	50.0	2	50.0	0	0	4	0.7
0028	12	40.0	10	33.3	8	26.7	30	5.5
0029	5	20.8	7	29.2	12	50.0	24	4.4
0030	5	38.5	4	30.8	4	30.8	13	2.4
0031	6	26.1	8	34.8	9	39.1	23	4.2
0033	4	28.6	2	14.3	8	57.1	14	2.6
0034	4	57.1	2	28.6	1	14.3	7	1.3
0035	8	42.1	3	15.8	8	42.1	19	3.5
0036	1	25.0	3	75.0	0	0	4	0.7
0037	3	37.5	3	37.5	2	25.0	8	1.5
0039	12	38.7	9	29.0	10	32.3	31	5.7

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Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.

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Table 11.1.1.2 Randomized Patients by Center

CENTER	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
0040	1	33.3	0	0	2	66.7	3	0.6
0041	2	20.0	2	20.0	6	60.0	10	1.8
0042	1	50.0	1	50.0	0	0	2	0.4

Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.

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Table 11.1.1.3 Randomized Patients by Center and Bipolar Diagnosis

CENTER	TREATMENT																	
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TOTAL	122	33.9	120	33.3	118	32.8	59	32.4	60	33.0	63	34.6	360	100.0	182	100.0
0001	0	0	0	0	0	0	1	33.3	1	33.3	1	33.3	0	0	3	1.6
0002	5	41.7	2	16.7	5	41.7	0	0	0	0	0	0	12	3.3	0	0
0003	4	40.0	5	50.0	1	10.0	1	50.0	1	50.0	0	0	10	2.8	2	1.1
0004	4	30.8	5	38.5	4	30.8	0	0	0	0	0	0	13	3.6	0	0
0005	7	30.4	10	43.5	6	26.1	3	33.3	3	33.3	3	33.3	23	6.4	9	4.9
0006	2	50.0	1	25.0	1	25.0	2	100.0	0	0	0	0	4	1.1	2	1.1
0007	1	16.7	2	33.3	3	50.0	1	20.0	1	20.0	3	60.0	6	1.7	5	2.7
0009	0	0	1	33.3	2	66.7	3	42.9	2	28.6	2	28.6	3	0.8	7	3.8
0010	4	26.7	8	53.3	3	20.0	1	50.0	1	50.0	0	0	15	4.2	2	1.1
0011	1	20.0	1	20.0	3	60.0	4	36.4	2	18.2	5	45.5	5	1.4	11	6.0
0013	2	22.2	3	33.3	4	44.4	0	0	0	0	1	100.0	9	2.5	1	0.5
0014	2	16.7	4	33.3	6	50.0	0	0	0	0	3	100.0	12	3.3	3	1.6
0015	0	0	2	66.7	1	33.3	1	50.0	0	0	1	50.0	3	0.8	2	1.1
0016	2	50.0	2	50.0	0	0	0	0	0	0	0	0	4	1.1	0	0
0017	0	0	0	0	1	100.0	0	0	0	0	0	0	1	0.3	0	0
0018	2	33.3	1	16.7	3	50.0	0	0	3	60.0	2	40.0	6	1.7	5	2.7
0019	5	71.4	2	28.6	0	0	12	40.0	12	40.0	6	20.0	7	1.9	30	16.5

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Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM202.SAS
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Table 11.1.1.3 Randomized Patients by Center and Bipolar Diagnosis

CENTER	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
0020	5	35.7	5	35.7	4	28.6	0	0	1	100.0	0	0	14	3.9	1	0.5
0022	13	27.1	19	39.6	16	33.3	3	42.9	1	14.3	3	42.9	48	13.3	7	3.8
0023	8	44.4	5	27.8	5	27.8	6	28.6	10	47.6	5	23.8	18	5.0	21	11.5
0025	1	50.0	0	0	1	50.0	0	0	0	0	0	0	2	0.6	0	0
0026	7	50.0	3	21.4	4	28.6	2	20.0	5	50.0	3	30.0	14	3.9	10	5.5
0027	1	100.0	0	0	0	0	1	33.3	2	66.7	0	0	1	0.3	3	1.6
0028	12	41.4	9	31.0	8	27.6	0	0	1	100.0	0	0	29	8.1	1	0.5
0029	1	8.3	5	41.7	6	50.0	4	33.3	2	16.7	6	50.0	12	3.3	12	6.6
0030	5	38.5	4	30.8	4	30.8	0	0	0	0	0	0	13	3.6	0	0
0031	2	25.0	2	25.0	4	50.0	4	26.7	6	40.0	5	33.3	8	2.2	15	8.2
0033	1	16.7	1	16.7	4	66.7	3	37.5	1	12.5	4	50.0	6	1.7	8	4.4
0034	4	80.0	1	20.0	0	0	0	0	1	50.0	1	50.0	5	1.4	2	1.1
0035	4	36.4	3	27.3	4	36.4	4	50.0	0	0	4	50.0	11	3.1	8	4.4
0036	1	25.0	3	75.0	0	0	0	0	0	0	0	0	4	1.1	0	0
0037	3	50.0	1	16.7	2	33.3	0	0	2	100.0	0	0	6	1.7	2	1.1
0039	10	38.5	7	26.9	9	34.6	2	40.0	2	40.0	1	20.0	26	7.2	5	2.7
0040	0	0	0	0	0	0	1	33.3	0	0	2	66.7	0	0	3	1.6
0041	2	25.0	2	25.0	4	50.0	0	0	0	0	2	100.0	8	2.2	2	1.1

(Continued)

Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM202.SAS
GENERATED: 12JUL2005 17:41:46 iceadmn3

Table 11.1.1.3 Randomized Patients by Center and Bipolar Diagnosis

CENTER	TREATMENT																	
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
0042	1	50.0	1	50.0	0	0	0	0	0	0	0	0	2	0.6	0	0

Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM202.SAS
GENERATED: 12JUL2005 17:41:46 iceadmn3

Table 11.1.2.1 Patient Population Summary

POPULATION	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
RANDOMIZED	181	100.0	180	100.0	181	100.0	542	100.0
--- RANDOMIZED NO DOSE	2	1.1	0	0.0	1	0.6	3	0.6
--- SAFETY	179	98.9	180	100.0	180	99.4	539	99.4
--- INTENT-TO-TREAT	172	95.0	170	94.4	169	93.4	511	94.3
--- PER-PROTOCOL	152	84.0	147	81.7	154	85.1	453	83.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM203.SAS
GENERATED: 12JUL2005 17:41:48 iceadmn3

Table 11.1.2.2 Patient Population Summary by Bipolar Diagnosis

POPULATION	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RANDOMIZED	122	100.0	120	100.0	118	100.0	59	100.0	60	100.0	63	100.0	360	100.0	182	100.0
--- RANDOMIZED NO DOSE	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	2	0.6	1	0.5
--- SAFETY	120	98.4	120	100.0	118	100.0	59	100.0	60	100.0	62	98.4	358	99.4	181	99.5
--- INTENT-TO-TREAT	116	95.1	114	95.0	112	94.9	56	94.9	56	93.3	57	90.5	342	95.0	169	92.9
--- PER-PROTOCOL	105	86.1	102	85.0	100	84.7	47	79.7	45	75.0	54	85.7	307	85.3	146	80.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM204.SAS
GENERATED: 12JUL2005 17:41:50 iceadmn3

Table 11.1.3.1 Missing Data Leading to Exclusion from The Intent-to-Treat Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=179		N=180		N=180			
	N	%	N	%	N	%	N	%
PROTOCOL VIOLATORS AND DEVIATORS *	7	3.9	10	5.6	11	6.1	28	5.2
--- NO BASELINE OR POST-BASELINE MADRS ASSESSMENT	7	3.9	10	5.6	7	3.9	24	4.5
--- MULTIPLE CENTER STUDY PARTICIPATION	0	0.0	0	0.0	4	2.2	4	0.7

*Patients in this category may have multiple reasons listed below.
Note: Percentage is the proportion of the safety population.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV200.SAS
GENERATED: 12JUL2005 17:46:36 iceadmn3

Table 11.1.3.2 Protocol Violations and Deviations Leading to Exclusion from The Per-Protocol Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
	N=172		N=170		N=169		TOTAL	
	N	%	N	%	N	%	N	%
PROTOCOL VIOLATORS AND DEVIATORS *	20	11.6	23	13.5	15	8.9	58	11.4
I01: NO DOCUMENTED ABILITY TO PROVIDE INFORMED CONSENT PRIOR TO START OF STUDY	0	0.0	0	0.0	0	0.0	0	0.0
I05: DOES NOT MEET DSM_IV CRITERIA FOR BIPOLAR DISORDER I OR II	0	0.0	0	0.0	0	0.0	0	0.0
I07: HAM-D (17-ITEM) TOTAL SCORE <20 AT SCREEN OR BASELINE VISIT	0	0.0	0	0.0	0	0.0	0	0.0
I08: HAM-D ITEM 1 (DEPRESSED MOOD) SCORE <2 AT SCREEN OR BASELINE VISIT	0	0.0	0	0.0	0	0.0	0	0.0
I09: YMRS TOTAL SCORE >12 AT SCREEN OR BASELINE VISIT	0	0.0	1	0.6	0	0.0	1	0.2
E02: DEPRESSION EPISODE >12 MONTHS OR <4 WEEKS	0	0.0	1	0.6	2	1.2	3	0.6
E03: HISTORY OF NON-RESPONSE TO AN ADEQUATE TRIAL OF >2 CLASSES OF ANTIDEPRESSANTS	0	0.0	0	0.0	0	0.0	0	0.0
E04: HISTORY OF SUBSTANCE DEPENDENCE	1	0.6	1	0.6	0	0.0	2	0.4
E06: USE OF PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION	3	1.7	4	2.4	4	2.4	11	2.2
E09: SUICIDAL RISK	0	0.0	0	0.0	0	0.0	0	0.0
E14: TSH >10% OVER THE ULN AT SCREEN/BASELINE	0	0.0	0	0.0	3	1.8	3	0.6
E17: MULTIPLE CENTER STUDY PARTICIPATION	0	0.0	0	0.0	0	0.0	0	0.0
D01: ZOLPIDEM USE >10 MG IN FIRST 3 WEEKS	1	0.6	0	0.0	0	0.0	1	0.2

(Continued)

*Patient in this category may have multiple reasons listed below.
Note: Percentage is the proportion of the intent-to-treat population.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV201.SAS
GENERATED: 12JUL2005 17:46:38 iceadmn3

Table 11.1.3.2 Protocol Violations and Deviations Leading to Exclusion from The Per-Protocol Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=172		N=170		N=169			
	N	%	N	%	N	%	N	%
D02: LORAZEPAM USE >3 MG IN FIRST 3 WEEKS	0	0.0	0	0.0	0	0.0	0	0.0
D03: ZOLPIDEM OR LORAZEPAM USE AFTER WEEK 3	1	0.6	0	0.0	0	0.0	1	0.2
D04: POTENT P450 INDUCER USE	0	0.0	0	0.0	0	0.0	0	0.0
D05: POTENT P450 INHIBITOR USE	0	0.0	1	0.6	0	0.0	1	0.2
D06: ANTIPSYCHOTIC USE DURING STUDY	1	0.6	1	0.6	0	0.0	2	0.4
D07: ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY	1	0.6	3	1.8	2	1.2	6	1.2
D08: SUBJECTS WHO REDUCE STUDY MEDICATION BY MORE THAN 100 MG	0	0.0	4	2.4	0	0.0	4	0.8
D09: SUBJECTS WHO RECEIVE ANY DOSE REDUCTION BEFORE DAY 8	3	1.7	3	1.8	2	1.2	8	1.6
D10: SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSES	2	1.2	2	1.2	1	0.6	5	1.0
D12: SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY	15	8.7	16	9.4	7	4.1	38	7.4
D14: SUBJECTS WHO RECEIVE INCORRECT RANDOMIZED STUDY MEDICATION	0	0.0	0	0.0	0	0.0	0	0.0
D17: MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION	6	3.5	6	3.5	1	0.6	13	2.5
D18: DOCUMENTED DRUG ABUSE DURING STUDY	1	0.6	1	0.6	0	0.0	2	0.4
D20: NO POST-BASELINE ASSESSMENT AFTER DATA EXCLUSIONS	2	1.2	0	0.0	0	0.0	2	0.4

*Patient in this category may have multiple reasons listed below.
Note: Percentage is the proportion of the intent-to-treat population.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV201.SAS
GENERATED: 12JUL2005 17:46:38 iceadmn3

Table 11.1.4.1 Withdrawals and Reason For Withdrawal

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
TOTAL NUMBER OF RANDOMIZED PATIENTS	181	100.0	180	100.0	181	100.0	542	100.0
COMPLETED PROTOCOL	121	66.9	98	54.4	107	59.1	326	60.1
WITHDRAWALS	60	33.1	82	45.6	74	40.9	216	39.9
--- LOST TO FOLLOW-UP	12	6.6	21	11.7	11	6.1	44	8.1
--- ADVERSE EVENT	29	16.0	47	26.1	16	8.8	92	17.0
--- PROTOCOL/NONCOMPLIANCE	10	5.5	4	2.2	11	6.1	25	4.6
--- INFORMED CONSENT WITHDRAWN	5	2.8	6	3.3	12	6.6	23	4.2
--- LACK OF EFFICACY	4	2.2	1	0.6	24	13.3	29	5.4
--- OTHER	0	0.0	3	1.7	0	0.0	3	0.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM205.SAS
GENERATED: 12JUL2005 17:41:52 iceadmn3

Table 11.1.4.2 Withdrawals and Reason For Withdrawal by Bipolar Diagnosis

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TOTAL NUMBER OF RANDOMIZED PATIENTS	122	100.0	120	100.0	118	100.0	59	100.0	60	100.0	63	100.0	360	100.0	182	100.0
COMPLETED PROTOCOL	85	69.7	68	56.7	65	55.1	36	61.0	30	50.0	42	66.7	218	60.6	108	59.3
WITHDRAWALS	37	30.3	52	43.3	53	44.9	23	39.0	30	50.0	21	33.3	142	39.4	74	40.7
--- LOST TO FOLLOW-UP	5	4.1	14	11.7	7	5.9	7	11.9	7	11.7	4	6.3	26	7.2	18	9.9
--- ADVERSE EVENT	16	13.1	28	23.3	14	11.9	13	22.0	19	31.7	2	3.2	58	16.1	34	18.7
--- PROTOCOL/NONCOMPLIANCE	9	7.4	1	0.8	6	5.1	1	1.7	3	5.0	5	7.9	16	4.4	9	4.9
--- INFORMED CONSENT WITHDRAWN	5	4.1	6	5.0	8	6.8	0	0.0	0	0.0	4	6.3	19	5.3	4	2.2
--- LACK OF EFFICACY	2	1.6	1	0.8	18	15.3	2	3.4	0	0.0	6	9.5	21	5.8	8	4.4
--- OTHER	0	0.0	2	1.7	0	0.0	0	0.0	1	1.7	0	0.0	2	0.6	1	0.5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM206.SAS
GENERATED: 12JUL2005 17:41:54 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=179		N=180		N=180		N=539	
	N	%	N	%	N	%	N	%
STUDY DAY								
1	179	100.0	180	100.0	180	100.0	539	100.0
2	179	100.0	179	99.4	180	100.0	538	99.8
3	179	100.0	177	98.3	180	100.0	536	99.4
4	179	100.0	177	98.3	180	100.0	536	99.4
5	179	100.0	177	98.3	180	100.0	536	99.4
6	179	100.0	177	98.3	180	100.0	536	99.4
7	179	100.0	177	98.3	180	100.0	536	99.4
8	178	99.4	173	96.1	178	98.9	529	98.1
9	171	95.5	164	91.1	176	97.8	511	94.8
10	168	93.9	164	91.1	174	96.7	506	93.9
11	167	93.3	164	91.1	173	96.1	504	93.5
12	167	93.3	162	90.0	172	95.6	501	92.9
13	166	92.7	160	88.9	171	95.0	497	92.2
14	165	92.2	159	88.3	171	95.0	495	91.8
15	164	91.6	157	87.2	169	93.9	490	90.9

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM207.SAS
GENERATED: 12JUL2005 17:41:56 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=179		N=180		N=180		N=539	
	N	%	N	%	N	%	N	%
STUDY DAY								
16	163	91.1	150	83.3	166	92.2	479	88.9
17	162	90.5	147	81.7	166	92.2	475	88.1
18	162	90.5	146	81.1	165	91.7	473	87.8
19	161	89.9	146	81.1	165	91.7	472	87.6
20	160	89.4	145	80.6	164	91.1	469	87.0
21	159	88.8	145	80.6	162	90.0	466	86.5
22	156	87.2	142	78.9	162	90.0	460	85.3
23	153	85.5	140	77.8	156	86.7	449	83.3
24	148	82.7	137	76.1	152	84.4	437	81.1
25	146	81.6	137	76.1	151	83.9	434	80.5
26	146	81.6	137	76.1	151	83.9	434	80.5
27	146	81.6	137	76.1	149	82.8	432	80.1
28	146	81.6	135	75.0	148	82.2	429	79.6
29	145	81.0	133	73.9	145	80.6	423	78.5
30	142	79.3	132	73.3	139	77.2	413	76.6

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM207.SAS
GENERATED: 12JUL2005 17:41:56 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=179		N=180		N=180		N=539	
	N	%	N	%	N	%	N	%
STUDY DAY								
31	142	79.3	132	73.3	138	76.7	412	76.4
32	142	79.3	131	72.8	138	76.7	411	76.3
33	142	79.3	130	72.2	136	75.6	408	75.7
34	142	79.3	128	71.1	134	74.4	404	75.0
35	142	79.3	128	71.1	131	72.8	401	74.4
36	142	79.3	127	70.6	128	71.1	397	73.7
37	140	78.2	125	69.4	127	70.6	392	72.7
38	140	78.2	124	68.9	127	70.6	391	72.5
39	139	77.7	123	68.3	125	69.4	387	71.8
40	138	77.1	123	68.3	124	68.9	385	71.4
41	138	77.1	122	67.8	124	68.9	384	71.2
42	138	77.1	122	67.8	124	68.9	384	71.2
43	138	77.1	120	66.7	123	68.3	381	70.7
44	135	75.4	117	65.0	121	67.2	373	69.2
45	134	74.9	117	65.0	120	66.7	371	68.8

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM207.SAS
GENERATED: 12JUL2005 17:41:56 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=179		N=180		N=180		N=539	
	N	%	N	%	N	%	N	%
STUDY DAY								
46	134	74.9	116	64.4	118	65.6	368	68.3
47	134	74.9	116	64.4	118	65.6	368	68.3
48	134	74.9	115	63.9	118	65.6	367	68.1
49	134	74.9	114	63.3	118	65.6	366	67.9
50	134	74.9	114	63.3	117	65.0	365	67.7
51	129	72.1	113	62.8	116	64.4	358	66.4
52	129	72.1	113	62.8	114	63.3	356	66.0
53	129	72.1	112	62.2	113	62.8	354	65.7
54	128	71.5	111	61.7	113	62.8	352	65.3
55	125	69.8	111	61.7	110	61.1	346	64.2
56	121	67.6	105	58.3	103	57.2	329	61.0
57	108	60.3	91	50.6	87	48.3	286	53.1
58+	55	30.7	46	25.6	47	26.1	148	27.5

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM207.SAS
GENERATED: 12JUL2005 17:41:56 iceadmn3

Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=120		N=120		N=118		N=59		N=60		N=62		N=358		N=181	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
1	120	100.0	120	100.0	118	100.0	59	100.0	60	100.0	62	100.0	358	100.0	181	100.0
2	120	100.0	119	99.2	118	100.0	59	100.0	60	100.0	62	100.0	357	99.7	181	100.0
3	120	100.0	118	98.3	118	100.0	59	100.0	59	98.3	62	100.0	356	99.4	180	99.4
4	120	100.0	118	98.3	118	100.0	59	100.0	59	98.3	62	100.0	356	99.4	180	99.4
5	120	100.0	118	98.3	118	100.0	59	100.0	59	98.3	62	100.0	356	99.4	180	99.4
6	120	100.0	118	98.3	118	100.0	59	100.0	59	98.3	62	100.0	356	99.4	180	99.4
7	120	100.0	118	98.3	118	100.0	59	100.0	59	98.3	62	100.0	356	99.4	180	99.4
8	120	100.0	118	98.3	116	98.3	58	98.3	55	91.7	62	100.0	354	98.9	175	96.7
9	118	98.3	113	94.2	115	97.5	53	89.8	51	85.0	61	98.4	346	96.6	165	91.2
10	116	96.7	113	94.2	113	95.8	52	88.1	51	85.0	61	98.4	342	95.5	164	90.6
11	115	95.8	113	94.2	112	94.9	52	88.1	51	85.0	61	98.4	340	95.0	164	90.6
12	115	95.8	111	92.5	111	94.1	52	88.1	51	85.0	61	98.4	337	94.1	164	90.6
13	114	95.0	110	91.7	110	93.2	52	88.1	50	83.3	61	98.4	334	93.3	163	90.1
14	114	95.0	110	91.7	110	93.2	51	86.4	49	81.7	61	98.4	334	93.3	161	89.0
15	114	95.0	108	90.0	109	92.4	50	84.7	49	81.7	60	96.8	331	92.5	159	87.8

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM208.SAS
GENERATED: 12JUL2005 17:42:00 iceadmn3

Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=120		N=120		N=118		N=59		N=60		N=62		N=358		N=181	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
16	113	94.2	103	85.8	108	91.5	50	84.7	47	78.3	58	93.5	324	90.5	155	85.6
17	112	93.3	101	84.2	108	91.5	50	84.7	46	76.7	58	93.5	321	89.7	154	85.1
18	112	93.3	101	84.2	107	90.7	50	84.7	45	75.0	58	93.5	320	89.4	153	84.5
19	112	93.3	101	84.2	107	90.7	49	83.1	45	75.0	58	93.5	320	89.4	152	84.0
20	111	92.5	100	83.3	106	89.8	49	83.1	45	75.0	58	93.5	317	88.5	152	84.0
21	110	91.7	100	83.3	105	89.0	49	83.1	45	75.0	57	91.9	315	88.0	151	83.4
22	109	90.8	99	82.5	105	89.0	47	79.7	43	71.7	57	91.9	313	87.4	147	81.2
23	108	90.0	97	80.8	100	84.7	45	76.3	43	71.7	56	90.3	305	85.2	144	79.6
24	104	86.7	95	79.2	97	82.2	44	74.6	42	70.0	55	88.7	296	82.7	141	77.9
25	102	85.0	95	79.2	96	81.4	44	74.6	42	70.0	55	88.7	293	81.8	141	77.9
26	102	85.0	95	79.2	96	81.4	44	74.6	42	70.0	55	88.7	293	81.8	141	77.9
27	102	85.0	95	79.2	95	80.5	44	74.6	42	70.0	54	87.1	292	81.6	140	77.3
28	102	85.0	94	78.3	94	79.7	44	74.6	41	68.3	54	87.1	290	81.0	139	76.8
29	101	84.2	92	76.7	91	77.1	44	74.6	41	68.3	54	87.1	284	79.3	139	76.8
30	99	82.5	91	75.8	86	72.9	43	72.9	41	68.3	53	85.5	276	77.1	137	75.7

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM208.SAS
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Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=120		N=120		N=118		N=59		N=60		N=62		N=358		N=181	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
31	99	82.5	91	75.8	85	72.0	43	72.9	41	68.3	53	85.5	275	76.8	137	75.7
32	99	82.5	90	75.0	85	72.0	43	72.9	41	68.3	53	85.5	274	76.5	137	75.7
33	99	82.5	89	74.2	85	72.0	43	72.9	41	68.3	51	82.3	273	76.3	135	74.6
34	99	82.5	88	73.3	83	70.3	43	72.9	40	66.7	51	82.3	270	75.4	134	74.0
35	99	82.5	88	73.3	81	68.6	43	72.9	40	66.7	50	80.6	268	74.9	133	73.5
36	99	82.5	88	73.3	79	66.9	43	72.9	39	65.0	49	79.0	266	74.3	131	72.4
37	99	82.5	86	71.7	79	66.9	41	69.5	39	65.0	48	77.4	264	73.7	128	70.7
38	99	82.5	85	70.8	79	66.9	41	69.5	39	65.0	48	77.4	263	73.5	128	70.7
39	99	82.5	85	70.8	77	65.3	40	67.8	38	63.3	48	77.4	261	72.9	126	69.6
40	98	81.7	85	70.8	77	65.3	40	67.8	38	63.3	47	75.8	260	72.6	125	69.1
41	98	81.7	84	70.0	77	65.3	40	67.8	38	63.3	47	75.8	259	72.3	125	69.1
42	98	81.7	84	70.0	77	65.3	40	67.8	38	63.3	47	75.8	259	72.3	125	69.1
43	98	81.7	82	68.3	76	64.4	40	67.8	38	63.3	47	75.8	256	71.5	125	69.1
44	95	79.2	81	67.5	75	63.6	40	67.8	36	60.0	46	74.2	251	70.1	122	67.4
45	94	78.3	81	67.5	74	62.7	40	67.8	36	60.0	46	74.2	249	69.6	122	67.4

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM208.SAS
GENERATED: 12JUL2005 17:42:00 iceadmn3

Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=120		N=120		N=118		N=59		N=60		N=62		N=358		N=181	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
46	94	78.3	80	66.7	73	61.9	40	67.8	36	60.0	45	72.6	247	69.0	121	66.9
47	94	78.3	80	66.7	73	61.9	40	67.8	36	60.0	45	72.6	247	69.0	121	66.9
48	94	78.3	79	65.8	73	61.9	40	67.8	36	60.0	45	72.6	246	68.7	121	66.9
49	94	78.3	79	65.8	73	61.9	40	67.8	35	58.3	45	72.6	246	68.7	120	66.3
50	94	78.3	79	65.8	73	61.9	40	67.8	35	58.3	44	71.0	246	68.7	119	65.7
51	91	75.8	78	65.0	73	61.9	38	64.4	35	58.3	43	69.4	242	67.6	116	64.1
52	91	75.8	78	65.0	72	61.0	38	64.4	35	58.3	42	67.7	241	67.3	115	63.5
53	91	75.8	78	65.0	71	60.2	38	64.4	34	56.7	42	67.7	240	67.0	114	63.0
54	90	75.0	77	64.2	71	60.2	38	64.4	34	56.7	42	67.7	238	66.5	114	63.0
55	87	72.5	77	64.2	68	57.6	38	64.4	34	56.7	42	67.7	232	64.8	114	63.0
56	85	70.8	73	60.8	64	54.2	36	61.0	32	53.3	39	62.9	222	62.0	107	59.1
57	77	64.2	63	52.5	58	49.2	31	52.5	28	46.7	29	46.8	198	55.3	88	48.6
58+	41	34.2	27	22.5	31	26.3	14	23.7	19	31.7	16	25.8	99	27.7	49	27.1

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM208.SAS
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Table 11.1.4.5 Withdrawal Analysis (CMH)
Safety Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
EVENT	STRATA													
TRIAL COMPLETION	BIPOLAR I	85	120	71	68	120	57	65	118	55	.	.	.	.
	BIPOLAR II	36	59	61	30	60	50	42	62	68	.	.	.	.
	ALL	121	179	68	98	180	54	107	180	59	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.109	1.14	0.97	1.33
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.343	0.92	0.76	1.10

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/DEM209.SAS
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Table 11.1.5.1.1 Age, Weight, and BMI at Study Entry by Sex - Descriptive Statistics
Safety Population

		TREATMENT									TOTAL		
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO					
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
AGE (YEARS)	N	83	96	179	77	103	180	71	109	180	231	308	539
	MEAN	37.83	35.15	36.39	38.34	35.98	36.99	39.21	37.65	38.27	38.42	36.31	37.22
	SD	11.11	11.23	11.22	12.26	10.58	11.36	11.74	10.56	11.04	11.66	10.79	11.21
	MEDIAN	39.0	35.0	36.0	39.0	34.0	35.0	39.0	36.0	37.0	39.0	35.0	36.0
	MIN	18	18	18	18	18	18	18	18	18	18	18	18
	MAX	65	60	65	63	63	63	61	62	62	65	63	65
WEIGHT (KG)	N	83	94	177	75	101	176	71	109	180	229	304	533
	MEAN	90.10	83.63	86.66	93.01	78.78	84.85	86.31	81.66	83.49	89.88	81.31	84.99
	SD	19.54	21.51	20.80	20.88	20.88	21.98	17.73	24.06	21.85	19.56	22.27	21.55
	MEDIAN	87.0	81.0	86.0	91.0	75.0	81.0	86.0	77.0	80.5	87.0	77.5	82.0
	MIN	60.0	47.0	47.0	54.0	41.0	41.0	55.0	44.0	44.0	54.0	41.0	41.0
	MAX	159.0	150.0	159.0	159.0	156.0	159.0	146.0	149.0	149.0	159.0	156.0	159.0
BMI (KG/M^2)	N	83	94	177	75	101	176	71	109	180	229	304	533
	MEAN	28.39	30.79	29.67	28.66	29.35	29.06	27.07	30.51	29.16	28.07	30.22	29.29
	SD	5.98	7.41	6.86	6.17	7.22	6.78	5.02	8.80	7.70	5.78	7.88	7.13
	MEDIAN	27.5	29.1	28.1	27.2	27.9	27.5	26.9	28.3	27.7	27.4	28.3	27.9
	MIN	19.4	19.6	19.4	18.7	17.1	17.1	17.7	17.6	17.6	17.7	17.1	17.1

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM210.SAS
GENERATED: 12JUL2005 17:42:03 iceadmn3

Table 11.1.5.1.1 Age, Weight, and BMI at Study Entry by Sex - Descriptive Statistics
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BMI (KG/M^2)	MAX	47.5	50.7	50.7	47.8	49.6	49.6	45.6	54.7	54.7	47.8	54.7	54.7

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM210.SAS
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Table 11.1.5.1.2 Age, Weight, and BMI at Study Entry by Sex - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT									TOTAL		
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO					
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
AGE (YEARS)	N	79	93	172	71	99	170	64	105	169	214	297	511
	MEAN	37.96	35.35	36.55	39.21	35.89	37.28	39.55	37.58	38.33	38.85	36.32	37.38
	SD	11.16	11.19	11.22	12.20	10.66	11.41	11.73	10.66	11.08	11.65	10.84	11.24
	MEDIAN	39.0	35.0	36.0	40.0	34.0	35.0	40.0	36.0	38.0	39.0	35.0	37.0
	MIN	18	18	18	18	18	18	18	18	18	18	18	18
	MAX	65	60	65	63	63	63	59	62	62	65	63	65
WEIGHT (KG)	N	79	91	170	70	97	167	64	105	169	213	293	506
	MEAN	90.46	83.22	86.58	92.89	78.93	84.78	86.61	82.01	83.75	90.10	81.37	85.04
	SD	19.62	21.47	20.88	19.77	21.09	21.62	16.98	24.20	21.81	18.99	22.36	21.43
	MEDIAN	87.0	81.0	86.0	92.0	75.0	81.0	86.0	77.0	81.0	88.0	77.0	82.0
	MIN	60.0	47.0	47.0	54.0	41.0	41.0	55.0	44.0	44.0	54.0	41.0	41.0
	MAX	159.0	150.0	159.0	158.0	156.0	158.0	146.0	149.0	149.0	159.0	156.0	159.0
BMI (KG/M^2)	N	79	91	170	70	97	167	64	105	169	213	293	506
	MEAN	28.48	30.64	29.63	28.66	29.41	29.10	27.03	30.60	29.24	28.10	30.22	29.33
	SD	6.02	7.36	6.84	6.04	7.29	6.79	4.58	8.87	7.72	5.65	7.91	7.12
	MEDIAN	27.5	28.7	28.1	27.6	27.9	27.8	26.9	28.3	27.5	27.4	28.3	27.9
	MIN	19.4	19.6	19.4	18.7	17.1	17.1	19.5	17.6	17.6	18.7	17.1	17.1

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM211.SAS
GENERATED: 12JUL2005 17:42:05 iceadmn3

Table 11.1.5.1.2 Age, Weight, and BMI at Study Entry by Sex - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BMI (KG/M^2)	MAX	47.5	50.7	50.7	47.8	49.6	49.6	45.6	54.7	54.7	47.8	54.7	54.7

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM211.SAS
GENERATED: 12JUL2005 17:42:05 iceadmn3

Table 11.1.5.1.3 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT											
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BIPOLAR I DISORDER	AGE (YEARS)	N	58	62	120	49	71	120	51	67	118	158	200	358
		MEAN	38.36	35.68	36.98	39.92	36.73	38.03	39.57	37.70	38.51	39.23	36.73	37.84
		SD	10.25	11.94	11.19	12.26	11.06	11.62	10.67	10.31	10.46	10.99	11.07	11.09
		MEDIAN	39.0	35.5	37.5	39.0	35.0	37.5	39.0	37.0	38.0	39.0	35.0	38.0
		MIN	20	18	18	19	18	18	22	18	18	19	18	18
		MAX	59	60	60	63	63	63	59	62	62	63	63	63
	WEIGHT (KG)	N	58	61	119	48	70	118	51	67	118	157	198	355
		MEAN	91.76	82.90	87.22	94.50	79.67	85.70	88.47	84.15	86.02	91.53	82.18	86.32
		SD	20.46	21.82	21.54	19.63	21.86	22.14	18.83	25.75	23.03	19.71	23.20	22.19
		MEDIAN	89.0	81.0	86.0	92.0	75.0	81.0	86.0	79.0	82.0	89.0	79.0	84.0
		MIN	60.0	47.0	47.0	64.0	41.0	41.0	55.0	44.0	44.0	55.0	41.0	41.0
		MAX	159.0	150.0	159.0	158.0	156.0	158.0	146.0	149.0	149.0	159.0	156.0	159.0
	BMI (KG/M^2)	N	58	61	119	48	70	118	51	67	118	157	198	355
		MEAN	28.97	30.59	29.80	29.28	29.41	29.36	27.67	31.51	29.85	28.64	30.48	29.67
		SD	6.34	7.50	6.98	6.28	6.87	6.61	5.25	9.53	8.16	5.99	8.05	7.26
		MEDIAN	27.8	29.4	28.1	28.1	28.2	28.2	27.8	28.3	28.1	27.8	28.5	28.1
		MIN	20.0	19.6	19.6	21.4	17.1	17.1	19.5	17.6	17.6	19.5	17.1	17.1

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM213.SAS
GENERATED: 12JUL2005 17:42:07 iceadmn3

Table 11.1.5.1.3 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT											
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BIPOLAR I DISORDER	BMI (KG/M^2)	MAX	47.5	50.7	50.7	47.8	49.6	49.6	45.6	54.7	54.7	47.8	54.7	54.7
BIPOLAR II DISORDER	AGE (YEARS)	N	25	34	59	28	32	60	20	42	62	73	108	181
		MEAN	36.60	34.18	35.20	35.57	34.31	34.90	38.30	37.57	37.81	36.67	35.54	35.99
		SD	13.02	9.91	11.29	11.99	9.37	10.60	14.39	11.08	12.13	12.89	10.27	11.38
		MEDIAN	35.0	33.0	33.0	36.5	33.5	34.0	39.0	34.5	35.5	37.0	34.0	34.0
		MIN	18	19	18	18	22	18	18	20	18	18	19	18
		MAX	65	58	65	62	57	62	61	62	62	65	62	65
	WEIGHT (KG)	N	25	33	58	27	31	58	20	42	62	72	106	178
		MEAN	86.24	84.97	85.52	90.37	76.77	83.10	80.80	77.69	78.69	86.28	79.69	82.35
		SD	16.96	21.19	19.33	23.10	18.66	21.76	13.43	20.78	18.67	18.86	20.44	20.03
		MEDIAN	86.0	82.0	83.0	88.0	75.0	79.0	82.5	70.0	73.5	86.0	75.0	79.0
		MIN	63.0	56.0	56.0	54.0	50.0	50.0	56.0	50.0	50.0	54.0	50.0	50.0
		MAX	135.0	136.0	136.0	159.0	127.0	159.0	103.0	118.0	118.0	159.0	136.0	159.0
	BMI (KG/M^2)	N	25	33	58	27	31	58	20	42	62	72	106	178
		MEAN	27.06	31.18	29.40	27.54	29.24	28.45	25.56	28.92	27.84	26.82	29.72	28.55
		SD	4.89	7.35	6.68	5.93	8.07	7.15	4.12	7.31	6.61	5.12	7.55	6.81
		MEDIAN	26.3	28.7	28.1	26.4	25.4	26.4	25.9	27.5	26.6	26.3	28.1	27.1

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM213.SAS
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Table 11.1.5.1.3 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT										TOTAL		
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO						
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BIPOLAR II DISORDER	BMI (KG/M^2)	MIN	19.4	20.3	19.4	18.7	20.4	18.7	17.7	19.6	17.7	17.7	19.6	17.7
		MAX	39.4	50.3	50.3	43.6	47.8	47.8	31.5	47.2	47.2	43.6	50.3	50.3

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM213.SAS
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Table 11.1.5.1.4 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT											
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BIPOLAR I DISORDER	AGE (YEARS)	N	56	60	116	45	69	114	47	65	112	148	194	342
		MEAN	38.66	35.85	37.21	40.87	36.91	38.47	40.09	37.83	38.78	39.78	36.89	38.14
		SD	10.13	11.88	11.11	12.19	11.16	11.68	10.93	10.44	10.66	11.01	11.12	11.15
		MEDIAN	39.0	35.5	37.5	42.0	35.0	38.0	40.0	38.0	39.0	39.5	36.0	38.0
		MIN	21	18	18	19	18	18	22	18	18	19	18	18
		MAX	59	60	60	63	63	63	59	62	62	63	63	63
	WEIGHT (KG)	N	56	59	115	45	68	113	47	65	112	148	192	340
		MEAN	92.05	82.81	87.31	95.38	79.38	85.75	87.85	84.00	85.62	91.73	82.00	86.24
		SD	20.43	22.02	21.67	19.94	22.10	22.59	18.44	26.08	23.17	19.76	23.47	22.43
		MEDIAN	89.0	81.0	86.0	95.0	74.5	81.0	86.0	79.0	81.0	89.0	78.5	83.0
		MIN	60.0	47.0	47.0	64.0	41.0	41.0	55.0	44.0	44.0	55.0	41.0	41.0
		MAX	159.0	150.0	159.0	158.0	156.0	158.0	146.0	149.0	149.0	159.0	156.0	159.0
	BMI (KG/M^2)	N	56	59	115	45	68	113	47	65	112	148	192	340
		MEAN	28.99	30.52	29.77	29.50	29.30	29.38	27.35	31.42	29.71	28.62	30.39	29.62
		SD	6.38	7.49	6.98	6.42	6.95	6.71	4.88	9.66	8.23	5.98	8.12	7.31
		MEDIAN	27.8	29.4	28.1	28.6	28.1	28.2	27.5	28.3	27.9	27.8	28.3	28.1
		MIN	20.0	19.6	19.6	21.4	17.1	17.1	19.5	17.6	17.6	19.5	17.1	17.1

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM214.SAS
GENERATED: 12JUL2005 17:42:09 iceadmn3

Table 11.1.5.1.4 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT											
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BIPOLAR I DISORDER	BMI (KG/M^2)	MAX	47.5	50.7	50.7	47.8	49.6	49.6	45.6	54.7	54.7	47.8	54.7	54.7
BIPOLAR II DISORDER	AGE (YEARS)	N	23	33	56	26	30	56	17	40	57	66	103	169
		MEAN	36.26	34.45	35.20	36.35	33.53	34.84	38.06	37.18	37.44	36.76	35.24	35.83
		SD	13.44	9.93	11.42	11.91	9.15	10.52	13.96	11.14	11.93	12.82	10.23	11.30
		MEDIAN	34.0	33.0	33.0	38.5	33.0	34.0	40.0	34.0	35.0	38.0	34.0	34.0
		MIN	18	19	18	18	22	18	18	20	18	18	19	18
		MAX	65	58	65	62	57	62	58	62	62	65	62	65
	WEIGHT (KG)	N	23	32	55	25	29	54	17	40	57	65	101	166
		MEAN	86.57	83.97	85.05	88.40	77.86	82.74	83.18	78.78	80.09	86.38	80.16	82.60
		SD	17.27	20.72	19.23	19.03	18.82	19.47	11.87	20.69	18.51	16.67	20.15	19.06
		MEDIAN	86.0	81.0	83.0	88.0	75.0	79.0	87.0	72.0	77.0	87.0	76.0	80.0
		MIN	63.0	56.0	56.0	54.0	50.0	50.0	65.0	50.0	50.0	54.0	50.0	50.0
		MAX	135.0	136.0	136.0	134.0	127.0	134.0	103.0	118.0	118.0	135.0	136.0	136.0
	BMI (KG/M^2)	N	23	32	55	25	29	54	17	40	57	65	101	166
		MEAN	27.24	30.85	29.34	27.15	29.67	28.50	26.14	29.26	28.33	26.92	29.88	28.72
		SD	4.95	7.23	6.57	5.06	8.17	6.96	3.63	7.33	6.58	4.64	7.51	6.68
		MEDIAN	26.3	28.7	27.7	26.4	26.9	26.7	26.3	28.2	26.9	26.3	28.4	27.2

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM214.SAS
GENERATED: 12JUL2005 17:42:09 iceadmn3

Table 11.1.5.1.4 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT										TOTAL		
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO						
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
BIPOLAR II DISORDER	BMI (KG/M^2)	MIN	19.4	20.3	19.4	18.7	20.4	18.7	20.1	19.6	19.6	18.7	19.6	18.7
		MAX	39.4	50.3	50.3	38.0	47.8	47.8	31.5	47.2	47.2	39.4	50.3	50.3

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM214.SAS
GENERATED: 12JUL2005 17:42:09 iceadmn3

Table 11.1.5.2.1 Sex, Race, Age and BMI Groups
Safety Population

		TREATMENT						TOTAL	
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
		N	%	N	%	N	%	N	%
SEX	TOTAL	179	100.0	180	100.0	180	100.0	539	100.0
	MALE	83	46.4	77	42.8	71	39.4	231	42.9
	FEMALE	96	53.6	103	57.2	109	60.6	308	57.1
RACE	TOTAL	179	100.0	180	100.0	180	100.0	539	100.0
	CAUCASIAN	147	82.1	152	84.4	139	77.2	438	81.3
	BLACK	24	13.4	19	10.6	26	14.4	69	12.8
	ORIENTAL	0	0	1	0.6	2	1.1	3	0.6
	HISPANIC	7	3.9	6	3.3	10	5.6	23	4.3
	OTHER	1	0.6	2	1.1	3	1.7	6	1.1
AGE (YEARS)	TOTAL	179	100.0	180	100.0	180	100.0	539	100.0
	18-39	107	59.8	107	59.4	104	57.8	318	59.0
	40-65	72	40.2	73	40.6	76	42.2	221	41.0
BMI (KG/M^2)	TOTAL	177	100.0	176	100.0	180	100.0	533	100.0
	0 - <18.5	0	0.0	2	1.1	3	1.7	5	0.9
	18.5 - <25	49	27.7	51	29.0	57	31.7	157	29.5
	25 - <30	59	33.3	65	36.9	53	29.4	177	33.2
	30 - <40	50	28.2	42	23.9	51	28.3	143	26.8

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM216.SAS
GENERATED: 12JUL2005 17:42:11 iceadmn3

Table 11.1.5.2.1 Sex, Race, Age and BMI Groups
Safety Population

		TREATMENT							
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
		N	%	N	%	N	%	N	%
BMI (KG/M^2)	>=40	19	10.7	16	9.1	16	8.9	51	9.6

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM216.SAS
GENERATED: 12JUL2005 17:42:11 iceadmn3

Table 11.1.5.2.2 Sex, Race, Age and BMI Groups
Intent-to-Treat Population

		TREATMENT							
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
		N	%	N	%	N	%	N	%
SEX	TOTAL	172	100.0	170	100.0	169	100.0	511	100.0
	MALE	79	45.9	71	41.8	64	37.9	214	41.9
	FEMALE	93	54.1	99	58.2	105	62.1	297	58.1
RACE	TOTAL	172	100.0	170	100.0	169	100.0	511	100.0
	CAUCASIAN	141	82.0	144	84.7	129	76.3	414	81.0
	BLACK	23	13.4	18	10.6	26	15.4	67	13.1
	ORIENTAL	0	0	1	0.6	2	1.2	3	0.6
	HISPANIC	7	4.1	5	2.9	9	5.3	21	4.1
	OTHER	1	0.6	2	1.2	3	1.8	6	1.2
AGE (YEARS)	TOTAL	172	100.0	170	100.0	169	100.0	511	100.0
	18-39	103	59.9	99	58.2	96	56.8	298	58.3
	40-65	69	40.1	71	41.8	73	43.2	213	41.7
BMI (KG/M^2)	TOTAL	170	100.0	167	100.0	169	100.0	506	100.0
	0 - <18.5	0	0.0	2	1.2	2	1.2	4	0.8
	18.5 - <25	47	27.6	47	28.1	53	31.4	147	29.1
	25 - <30	57	33.5	63	37.7	51	30.2	171	33.8
	30 - <40	49	28.8	40	24.0	47	27.8	136	26.9

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM217.SAS
GENERATED: 12JUL2005 17:42:13 iceadmn3

Table 11.1.5.2.2 Sex, Race, Age and BMI Groups
Intent-to-Treat Population

		TREATMENT							
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
		N	%	N	%	N	%	N	%
BMI (KG/M^2)	>=40	17	10.0	15	9.0	16	9.5	48	9.5

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM217.SAS
GENERATED: 12JUL2005 17:42:13 iceadmn3

Table 11.1.5.2.3 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT						TOTAL	
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
			N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	SEX	TOTAL	120	100.0	120	100.0	118	100.0	358	100.0
		MALE	58	48.3	49	40.8	51	43.2	158	44.1
		FEMALE	62	51.7	71	59.2	67	56.8	200	55.9
	RACE	TOTAL	120	100.0	120	100.0	118	100.0	358	100.0
		CAUCASIAN	101	84.2	97	80.8	91	77.1	289	80.7
		BLACK	15	12.5	16	13.3	16	13.6	47	13.1
		ORIENTAL	0	0	1	0.8	2	1.7	3	0.8
		HISPANIC	4	3.3	5	4.2	6	5.1	15	4.2
		OTHER	0	0	1	0.8	3	2.5	4	1.1
	AGE (YEARS)	TOTAL	120	100.0	120	100.0	118	100.0	358	100.0
		18-39	68	56.7	69	57.5	66	55.9	203	56.7
		40-65	52	43.3	51	42.5	52	44.1	155	43.3
	BMI (KG/M^2)	TOTAL	119	100.0	118	100.0	118	100.0	355	100.0
		0 - <18.5	0	0.0	2	1.7	2	1.7	4	1.1
		18.5 - <25	33	27.7	26	22.0	32	27.1	91	25.6
		25 - <30	38	31.9	49	41.5	39	33.1	126	35.5
		30 - <40	33	27.7	31	26.3	32	27.1	96	27.0

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM219.SAS
GENERATED: 12JUL2005 17:42:15 iceadmn3

Table 11.1.5.2.3 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT							
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
			N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	BMI (KG/M^2)	>=40	15	12.6	10	8.5	13	11.0	38	10.7

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM219.SAS
GENERATED: 12JUL2005 17:42:15 iceadmn3

Table 11.1.5.2.3 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT						TOTAL	
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
			N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	SEX	TOTAL	59	100.0	60	100.0	62	100.0	181	100.0
		MALE	25	42.4	28	46.7	20	32.3	73	40.3
		FEMALE	34	57.6	32	53.3	42	67.7	108	59.7
	RACE	TOTAL	59	100.0	60	100.0	62	100.0	181	100.0
		CAUCASIAN	46	78.0	55	91.7	48	77.4	149	82.3
		BLACK	9	15.3	3	5.0	10	16.1	22	12.2
		HISPANIC	3	5.1	1	1.7	4	6.5	8	4.4
		OTHER	1	1.7	1	1.7	0	0	2	1.1
	AGE (YEARS)	TOTAL	59	100.0	60	100.0	62	100.0	181	100.0
		18-39	39	66.1	38	63.3	38	61.3	115	63.5
		40-65	20	33.9	22	36.7	24	38.7	66	36.5
	BMI (KG/M^2)	TOTAL	58	100.0	58	100.0	62	100.0	178	100.0
		0 - <18.5	0	0.0	0	0	1	1.6	1	0.6
		18.5 - <25	16	27.6	25	43.1	25	40.3	66	37.1
		25 - <30	21	36.2	16	27.6	14	22.6	51	28.7
		30 - <40	17	29.3	11	19.0	19	30.6	47	26.4
		>=40	4	6.9	6	10.3	3	4.8	13	7.3

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM219.SAS
GENERATED: 12JUL2005 17:42:15 iceadmn3

Table 11.1.5.2.4 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT						TOTAL	
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
			N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	SEX	TOTAL	116	100.0	114	100.0	112	100.0	342	100.0
		MALE	56	48.3	45	39.5	47	42.0	148	43.3
		FEMALE	60	51.7	69	60.5	65	58.0	194	56.7
	RACE	TOTAL	116	100.0	114	100.0	112	100.0	342	100.0
		CAUCASIAN	97	83.6	92	80.7	85	75.9	274	80.1
		BLACK	15	12.9	15	13.2	16	14.3	46	13.5
		ORIENTAL	0	0	1	0.9	2	1.8	3	0.9
		HISPANIC	4	3.4	5	4.4	6	5.4	15	4.4
		OTHER	0	0	1	0.9	3	2.7	4	1.2
	AGE (YEARS)	TOTAL	116	100.0	114	100.0	112	100.0	342	100.0
		18-39	66	56.9	63	55.3	60	53.6	189	55.3
		40-65	50	43.1	51	44.7	52	46.4	153	44.7
	BMI (KG/M^2)	TOTAL	115	100.0	113	100.0	112	100.0	340	100.0
		0 - <18.5	0	0.0	2	1.8	2	1.8	4	1.2
		18.5 - <25	32	27.8	25	22.1	31	27.7	88	25.9
		25 - <30	37	32.2	47	41.6	38	33.9	122	35.9
		30 - <40	32	27.8	29	25.7	28	25.0	89	26.2

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM220.SAS
GENERATED: 12JUL2005 17:42:17 iceadmn3

Table 11.1.5.2.4 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT							
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
			N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	BMI (KG/M^2)	>=40	14	12.2	10	8.8	13	11.6	37	10.9

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM220.SAS
GENERATED: 12JUL2005 17:42:17 iceadmn3

Table 11.1.5.2.4 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT						TOTAL	
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
			N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	SEX	TOTAL	56	100.0	56	100.0	57	100.0	169	100.0
		MALE	23	41.1	26	46.4	17	29.8	66	39.1
		FEMALE	33	58.9	30	53.6	40	70.2	103	60.9
	RACE	TOTAL	56	100.0	56	100.0	57	100.0	169	100.0
		CAUCASIAN	44	78.6	52	92.9	44	77.2	140	82.8
		BLACK	8	14.3	3	5.4	10	17.5	21	12.4
		HISPANIC	3	5.4	0	0	3	5.3	6	3.6
		OTHER	1	1.8	1	1.8	0	0	2	1.2
	AGE (YEARS)	TOTAL	56	100.0	56	100.0	57	100.0	169	100.0
		18-39	37	66.1	36	64.3	36	63.2	109	64.5
		40-65	19	33.9	20	35.7	21	36.8	60	35.5
	BMI (KG/M^2)	TOTAL	55	100.0	54	100.0	57	100.0	166	100.0
		0 - <18.5	0	0.0	0	0	0	0	0	0.0
		18.5 - <25	15	27.3	22	40.7	22	38.6	59	35.5
		25 - <30	20	36.4	16	29.6	13	22.8	49	29.5
		30 - <40	17	30.9	11	20.4	19	33.3	47	28.3
		>=40	3	5.5	5	9.3	3	5.3	11	6.6

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM220.SAS
GENERATED: 12JUL2005 17:42:17 iceadmn3

Table 11.1.6.1 DSM-IV Diagnosis by Population

		TREATMENT							
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
		N	%	N	%	N	%	N	%
SAFETY	TOTAL	179	100.0	180	100.0	180	100.0	539	100.0
	DSM-IV DIAGNOSIS								
	BIPOLAR I DISORDER	120	67.0	120	66.7	118	65.6	358	66.4
	BIPOLAR II DISORDER	59	33.0	60	33.3	62	34.4	181	33.6
INTENT-TO-TREAT	TOTAL	172	100.0	170	100.0	169	100.0	511	100.0
	DSM-IV DIAGNOSIS								
	BIPOLAR I DISORDER	116	67.4	114	67.1	112	66.3	342	66.9
	BIPOLAR II DISORDER	56	32.6	56	32.9	57	33.7	169	33.1
PER-PROTOCOL	TOTAL	152	100.0	147	100.0	154	100.0	453	100.0
	DSM-IV DIAGNOSIS								
	BIPOLAR I DISORDER	105	69.1	102	69.4	100	64.9	307	67.8
	BIPOLAR II DISORDER	47	30.9	45	30.6	54	35.1	146	32.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM222.SAS
GENERATED: 12JUL2005 17:42:20 iceadmn3

Table 11.1.6.2 Psychiatric History - Descriptive Statistics
Safety Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST DEPRESSED EPISODE	N	178	180	178	536
	Mean	18.1	18.1	18.6	18.3
	Std	10.7	10.5	10.8	10.6
	Min	2	1	2	1
	Max	47	45	55	55
NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	140	134	140	414
	Mean	14.6	17.9	15.4	15.9
	Std	23.2	43.1	25.5	31.6
	Min	1	0	0	0
	Max	199	456	200	456
NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	177	178	175	530
	Mean	1.4	1.3	1.4	1.3
	Std	1.8	2.3	3.5	2.6
	Min	0	0	0	0
	Max	12	24	36	36
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	176	177	177	530
	Mean	14.5	15.3	15.2	15.0
	Std	10.0	9.4	10.6	10.0

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY202.SAS
GENERATED: 12JUL2005 17:44:14 iceadmn3

Table 11.1.6.2 Psychiatric History - Descriptive Statistics
Safety Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	Min	1	2	1	1
	Max	44	43	54	54
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	151	147	145	443
	Mean	12.1	12.3	14.4	12.9
	Std	20.2	18.6	21.1	20.0
	Min	1	1	1	1
	Max	180	99	123	180
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	174	178	175	527
	Mean	1.5	1.4	1.7	1.5
	Std	3.0	2.3	3.5	3.0
	Min	0	0	0	0
	Max	36	20	36	36

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY202.SAS
GENERATED: 12JUL2005 17:44:14 iceadmn3

Table 11.1.6.3 Psychiatric History - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST DEPRESSED EPISODE	N	171	170	167	508
	Mean	18.3	18.4	18.6	18.4
	Std	10.7	10.7	10.8	10.7
	Min	2	2	2	2
	Max	47	45	55	55
NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	134	128	131	393
	Mean	14.3	17.4	15.5	15.7
	Std	23.1	43.3	25.4	31.7
	Min	1	0	0	0
	Max	199	456	200	456
NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	170	169	164	503
	Mean	1.3	1.3	1.4	1.3
	Std	1.8	2.3	3.6	2.7
	Min	0	0	0	0
	Max	12	24	36	36
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	169	168	166	503
	Mean	14.6	15.6	15.2	15.1
	Std	10.1	9.5	10.5	10.1

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY200.SAS
GENERATED: 12JUL2005 17:44:10 iceadmn3

Table 11.1.6.3 Psychiatric History - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	Min	1	2	1	1
	Max	44	43	54	54
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	145	141	137	423
	Mean	11.1	12.3	13.8	12.4
	Std	15.0	18.9	19.5	17.9
	Min	1	1	1	1
	Max	99	99	120	120
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	167	169	165	501
	Mean	1.3	1.4	1.6	1.4
	Std	1.5	2.4	3.5	2.6
	Min	0	0	0	0
	Max	8	20	36	36

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY200.SAS
GENERATED: 12JUL2005 17:44:10 iceadmn3

Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR I	YEARS SINCE FIRST DEPRESSED EPISODE	N	116	114	110	340
		Mean	18.8	19.7	18.5	19.0
		Std	11.2	10.9	9.9	10.7
		Min	2	2	2	2
		Max	47	45	41	47
	NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	94	85	87	266
		Mean	11.0	14.2	15.4	13.5
		Std	13.4	17.8	26.0	19.7
		Min	1	0	0	0
		Max	74	99	200	200
	NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	116	113	110	339
		Mean	1.2	1.2	1.3	1.2
		Std	1.5	1.4	2.7	1.9
		Min	0	0	0	0
		Max	9	7	23	23
	YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	115	112	110	337
		Mean	14.8	17.0	15.5	15.8
		Std	10.5	10.1	10.5	10.4

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY201.SAS
GENERATED: 12JUL2005 17:44:12 iceadmn3

Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR I	YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	Min	1	2	1	1
		Max	44	43	54	54
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	99	96	93	288
		Mean	8.9	10.8	12.5	10.7
		Std	12.6	14.1	19.6	15.7
		Min	1	1	1	1
		Max	99	99	120	120
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	116	113	111	340
		Mean	1.3	1.2	1.4	1.3
		Std	1.5	1.5	2.6	1.9
		Min	0	0	0	0
		Max	8	10	24	24
BIPOLAR II	YEARS SINCE FIRST DEPRESSED EPISODE	N	55	56	57	168
		Mean	17.3	15.8	18.9	17.3
		Std	9.6	9.7	12.5	10.7
		Min	3	2	2	2
		Max	43	44	55	55

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY201.SAS
GENERATED: 12JUL2005 17:44:12 iceadmn3

Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR II	NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	40	43	44	127
		Mean	22.0	23.6	15.6	20.3
		Std	36.2	70.5	24.4	47.7
		Min	2	1	1	1
		Max	199	456	135	456
	NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	54	56	54	164
		Mean	1.6	1.5	1.6	1.6
		Std	2.3	3.5	5.1	3.8
		Min	0	0	0	0
		Max	12	24	36	36
	YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	54	56	56	166
		Mean	14.2	12.7	14.5	13.8
		Std	9.4	7.5	10.7	9.3
		Min	2	2	1	1
		Max	43	38	41	43
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	46	45	44	135
		Mean	15.9	15.6	16.6	16.0
		Std	18.5	26.3	19.3	21.5

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY201.SAS
GENERATED: 12JUL2005 17:44:12 iceadmn3

Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR II	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	Min	3	1	1	1
		Max	99	99	90	99
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	51	56	54	161
		Mean	1.4	1.8	2.1	1.8
		Std	1.5	3.6	4.9	3.6
		Min	0	0	0	0
		Max	6	20	36	36

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY201.SAS
GENERATED: 12JUL2005 17:44:12 iceadmn3

Table 11.1.6.5 Manic or Depressive Episodes Over the Past Year Summary
Intent-to-Treat Population

NUMBER MIXED/DEPRESSED EPISODES	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=172		N=170		N=169		N=511	
	N	%	N	%	N	%	N	%
<4	130	75.6	139	81.8	134	79.3	403	78.9
>=4	42	24.4	31	18.2	35	20.7	108	21.1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISPY203.SAS
GENERATED: 12JUL2005 17:44:16 iceadmn3

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		132	73.7	154	85.6	148	82.2
ALIMENTARY TRACT AND METABOLISM	TOTAL	53	29.6	53	29.4	53	29.4
	ANTACIDS	1	0.6	0	0	0	0
	ASCORBIC ACID	5	2.8	5	2.8	4	2.2
	ATROPINE SULFATE	1	0.6	0	0	0	0
	BISACODYL	0	0	0	0	1	0.6
	BISMUTH SUBSALICYLATE	2	1.1	1	0.6	0	0
	CALCIUM	4	2.2	4	2.2	6	3.3
	CALCIUM ASCORBATE	0	0	0	0	1	0.6
	CALCIUM CARBONATE	6	3.4	6	3.3	5	2.8
	CALCIUM CITRATE	0	0	0	0	1	0.6
	CIMETIDINE	0	0	3	1.7	0	0
	CLIDINIUM	1	0.6	0	0	0	0
	DEXAMFETAMINE SULFATE	0	0	1	0.6	2	1.1
	DICYCLOVERINE HYDROCHLORIDE	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DIHYDROXYALUMINUM SODIUM CARBONATE	3	1.7	1	0.6	1	0.6
	DOCUSATE SODIUM	2	1.1	1	0.6	0	0
	DOXYCYCLINE	0	0	1	0.6	1	0.6
	ENEMAS	1	0.6	0	0	0	0
	ERGOCALCIFEROL	18	10.1	19	10.6	20	11.1
	ESOMEPRAZOLE	5	2.8	2	1.1	2	1.1
	FAMOTIDINE	0	0	0	0	1	0.6
	FERROUS FUMARATE	0	0	0	0	1	0.6
	FERROUS SULFATE	0	0	1	0.6	0	0
	FIBRE, DIETARY	2	1.1	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.6
	GLIPIZIDE	0	0	0	0	1	0.6
	GLUCOSE MONOHYDRATE	1	0.6	0	0	0	0
	HYOSCYAMINE SULFATE	1	0.6	1	0.6	0	0
	INSULIN	1	0.6	0	0	0	0
	LACTOBACILLUS ACIDOPHILUS	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	LANSOPRAZOLE	3	1.7	2	1.1	3	1.7
	LOPERAMIDE	0	0	1	0.6	0	0
	LOPERAMIDE HYDROCHLORIDE	1	0.6	0	0	1	0.6
	MACROGOL	1	0.6	0	0	0	0
	MAGNESIUM HYDROXIDE	1	0.6	2	1.1	2	1.1
	METFORMIN	0	0	0	0	1	0.6
	METFORMIN HYDROCHLORIDE	4	2.2	0	0	1	0.6
	MINERAL SUPPLEMENTS	0	0	2	1.1	0	0
	MULTIVITAMINS WITH MINERALS	1	0.6	0	0	0	0
	MULTIVITAMINS, PLAIN	0	0	0	0	1	0.6
	OMEPRAZOLE	0	0	2	1.1	1	0.6
	PANCRELIPASE	1	0.6	0	0	0	0
	PANTOPRAZOLE SODIUM	1	0.6	2	1.1	3	1.7
	PHENTERMINE	0	0	0	0	1	0.6
	PHOSPHORIC ACID	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	POTASSIUM	1	0.6	0	0	1	0.6
	POTASSIUM CHLORIDE	1	0.6	1	0.6	1	0.6
	PRASTERONE	1	0.6	0	0	1	0.6
	PYRIDOXINE HYDROCHLORIDE	3	1.7	3	1.7	3	1.7
	RABEPRAZOLE SODIUM	1	0.6	1	0.6	0	0
	RANITIDINE HYDROCHLORIDE	5	2.8	2	1.1	4	2.2
	RETINOL	0	0	1	0.6	1	0.6
	ROSIGLITAZONE MALEATE	0	0	2	1.1	1	0.6
	SELENIUM	0	0	1	0.6	1	0.6
	TETRACYCLINE	0	0	1	0.6	1	0.6
	TILACTASE	1	0.6	0	0	0	0
	TOCOPHEROL	5	2.8	4	2.2	5	2.8
	VITAMINS	0	0	0	0	1	0.6
	VITAMINS NOS	0	0	1	0.6	4	2.2
	ZINC	0	0	1	0.6	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	4	2.2	8	4.4	6	3.3
	ACICLOVIR	1	0.6	1	0.6	0	0
	AMOXICILLIN TRIHYDRATE	0	0	0	0	1	0.6
	AZITHROMYCIN	1	0.6	1	0.6	0	0
	BENZYLPENICILLIN	1	0.6	2	1.1	1	0.6
	CEFALEXIN	0	0	1	0.6	0	0
	CLARITHROMYCIN	0	0	0	0	1	0.6
	LEVOFLOXACIN	0	0	1	0.6	0	0
	NITROFURANTOIN	0	0	0	0	2	1.1
	RITONAVIR	0	0	1	0.6	0	0
	VALACICLOVIR HYDROCHLORIDE	1	0.6	1	0.6	1	0.6
	ZIDOVUDINE	0	0	1	0.6	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	2	1.1
	ETANERCEPT	0	0	0	0	1	0.6
	METHOTREXATE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD AND BLOOD FORMING ORGANS	TOTAL	2	1.1	4	2.2	8	4.4
	CLOPIDOGREL SULFATE	0	0	0	0	1	0.6
	CYANOCOBALAMIN	1	0.6	3	1.7	0	0
	FERROUS SULFATE	0	0	0	0	2	1.1
	FOLIC ACID	1	0.6	0	0	0	0
	IRON	0	0	0	0	4	2.2
	LECITHIN	1	0.6	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.6	1	0.6
CARDIOVASCULAR SYSTEM	TOTAL	21	11.7	21	11.7	23	12.8
	AMLODIPINE BESILATE	2	1.1	0	0	1	0.6
	ATENOLOL	1	0.6	2	1.1	3	1.7
	ATORVASTATIN	6	3.4	4	2.2	2	1.1
	BENAZEPRIL HYDROCHLORIDE	1	0.6	0	0	0	0
	BUMETANIDE	0	0	0	0	1	0.6
	CARNITINE	1	0.6	0	0	0	0
	CLONIDINE	0	0	2	1.1	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	DOXAZOSIN MESILATE	1	0.6	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.6
	FISH OIL	2	1.1	1	0.6	2	1.1
	FLUVASTATIN SODIUM	0	0	1	0.6	0	0
	FOSINOPRIL SODIUM	1	0.6	0	0	0	0
	FUROSEMIDE	0	0	1	0.6	1	0.6
	GEMFIBROZIL	0	0	0	0	1	0.6
	HYDROCHLOROTHIAZIDE	5	2.8	6	3.3	8	4.4
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.6
	LABETALOL	0	0	1	0.6	0	0
	LISINOPRIL	0	0	4	2.2	4	2.2
	LOSARTAN POTASSIUM	1	0.6	0	0	0	0
	METOPROLOL	0	0	2	1.1	2	1.1
	METOPROLOL SUCCINATE	1	0.6	0	0	0	0
	MINOXIDIL	0	0	1	0.6	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.6	0	0
	NICOTINIC ACID	1	0.6	0	0	1	0.6
	NIFEDIPINE	0	0	0	0	1	0.6
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.6	2	1.1	0	0
	PRAVASTATIN SODIUM	0	0	0	0	2	1.1
	PROPRANOLOL	1	0.6	0	0	0	0
	PROPRANOLOL HYDROCHLORIDE	1	0.6	2	1.1	1	0.6
	SEROTONIN ANTAGONISTS	0	0	0	0	1	0.6
	SIMVASTATIN	2	1.1	1	0.6	2	1.1
	SPIRONOLACTONE	0	0	0	0	1	0.6
	TRIAMTERENE	0	0	0	0	2	1.1
	UBIDECARENONE	0	0	2	1.1	0	0
	VERAPAMIL	0	0	0	0	1	0.6
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.6	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	TOTAL	3	1.7	0	0	0	0
	CALCIPOTRIOL	1	0.6	0	0	0	0
	SMILAX ARISTOLOCHIIFOLIA ROOT	1	0.6	0	0	0	0
	TRIAMCINOLONE	1	0.6	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	19	10.6	21	11.7	18	10.0
	EQUISETUM ARVENSE	0	0	1	0.6	0	0
	ESTRADIOL	0	0	1	0.6	3	1.7
	ESTROGENS CONJUGATED	1	0.6	3	1.7	1	0.6
	ETHINYLESTRADIOL	12	6.7	6	3.3	9	5.0
	LEVONORGESTREL	0	0	1	0.6	0	0
	MEDROXYPROGESTERONE ACETATE	2	1.1	4	2.2	2	1.1
	MICONAZOLE NITRATE	0	0	0	0	1	0.6
	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	1	0.6
	NORETHISTERONE	1	0.6	0	0	1	0.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	NORETHISTERONE ACETATE	0	0	1	0.6	0	0
	OXYBUTYNIN	0	0	1	0.6	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.6	0	0
	PROGESTERONE	0	0	1	0.6	0	0
	RALOXIFENE HYDROCHLORIDE	1	0.6	0	0	0	0
	SERENOA REPENS	1	0.6	0	0	0	0
	SILDENAFIL CITRATE	0	0	1	0.6	0	0
	TAMSULOSIN HYDROCHLORIDE	0	0	2	1.1	0	0
	TESTOSTERONE	1	0.6	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.6	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	40	22.3	48	26.7	51	28.3
	ALENDRONATE SODIUM	0	0	2	1.1	0	0
	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	2	1.1

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	ASCORBIC ACID	0	0	2	1.1	0	0
	BOTULINUM TOXIN TYPE A	0	0	1	0.6	0	0
	CARISOPRODOL	0	0	0	0	3	1.7
	CELECOXIB	1	0.6	4	2.2	2	1.1
	CHONDROITIN SULFATE	1	0.6	0	0	2	1.1
	COLCHICINE	0	0	0	0	1	0.6
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.6	0	0	0	0
	GLUCOSAMINE	1	0.6	0	0	0	0
	IBUPROFEN	30	16.8	25	13.9	27	15.0
	INDOMETACIN	1	0.6	0	0	0	0
	KETOPROFEN	1	0.6	0	0	0	0
	METAXALONE	0	0	0	0	1	0.6
	METHOCARBAMOL	1	0.6	0	0	1	0.6
	NABUMETONE	0	0	1	0.6	0	0
	NAPROXEN	2	1.1	4	2.2	4	2.2
	NAPROXEN SODIUM	2	1.1	6	3.3	7	3.9

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	OXAPROZIN	0	0	1	0.6	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	1	0.6	1	0.6	2	1.1
	ROFECOXIB	1	0.6	1	0.6	3	1.7
	VALDECOXIB	1	0.6	3	1.7	1	0.6
NERVOUS SYSTEM	TOTAL	87	48.6	113	62.8	99	55.0
	ACETAZOLAMIDE	0	0	1	0.6	0	0
	ACETYLSALICYLIC ACID	16	8.9	15	8.3	20	11.1
	ALPRAZOLAM	3	1.7	3	1.7	7	3.9
	AMITRIPTYLINE	0	0	2	1.1	1	0.6
	AMITRIPTYLINE HYDROCHLORIDE	1	0.6	3	1.7	0	0
	ANTIDEPRESSANTS	1	0.6	0	0	0	0
	ARIPIPRAZOLE	2	1.1	1	0.6	0	0
	BUPROPION HYDROCHLORIDE	11	6.1	15	8.3	5	2.8
	BUSPIRONE HYDROCHLORIDE	1	0.6	1	0.6	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	BUTALBITAL	0	0	0	0	1	0.6
	BUTORPHANOL TARTRATE	0	0	1	0.6	1	0.6
	CARBAMAZEPINE	6	3.4	0	0	0	0
	CITALOPRAM	0	0	0	0	1	0.6
	CITALOPRAM HYDROBROMIDE	1	0.6	1	0.6	5	2.8
	CLONAZEPAM	2	1.1	6	3.3	2	1.1
	CODEINE PHOSPHATE	1	0.6	3	1.7	0	0
	CYCLOBENZAPRINE	1	0.6	0	0	0	0
	DIAZEPAM	1	0.6	1	0.6	3	1.7
	DIPHENHYDRAMINE	3	1.7	1	0.6	6	3.3
	DOXEPIN	1	0.6	0	0	0	0
	ESCITALOPRAM	4	2.2	2	1.1	1	0.6
	ETHANOL	0	0	1	0.6	0	0
	FLUOXETINE	1	0.6	0	0	0	0
	FLUOXETINE HYDROCHLORIDE	2	1.1	4	2.2	6	3.3

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	GABAPENTIN	5	2.8	4	2.2	4	2.2
	GINKGO BILOBA	0	0	1	0.6	0	0
	HYDROXYZINE	1	0.6	0	0	0	0
	HYDROXYZINE EMBONATE	0	0	2	1.1	0	0
	LAMOTRIGINE	3	1.7	8	4.4	2	1.1
	LEVETIRACETAM	0	0	1	0.6	0	0
	LEVODOPA	0	0	0	0	1	0.6
	LITHIUM	5	2.8	5	2.8	8	4.4
	LITHIUM CARBONATE	5	2.8	4	2.2	1	0.6
	LORAZEPAM	15	8.4	16	8.9	9	5.0
	METHYSERGIDE	0	0	0	0	1	0.6
	MIRTAZAPINE	5	2.8	3	1.7	0	0
	MODAFINIL	1	0.6	1	0.6	0	0
	NEFAZODONE HYDROCHLORIDE	0	0	4	2.2	0	0
	NICOTINE	0	0	1	0.6	1	0.6
	OLANZAPINE	13	7.3	4	2.2	7	3.9

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	OXCARBAZEPINE	2	1.1	6	3.3	0	0
	PARACETAMOL	22	12.3	34	18.9	24	13.3
	PAROXETINE HYDROCHLORIDE	6	3.4	16	8.9	9	5.0
	QUETIAPINE FUMARATE	1	0.6	0	0	0	0
	RISPERIDONE	3	1.7	5	2.8	3	1.7
	RIZATRIPTAN BENZOATE	1	0.6	0	0	0	0
	SERTRALINE HYDROCHLORIDE	6	3.4	5	2.8	5	2.8
	SUMATRIPTAN SUCCINATE	0	0	1	0.6	1	0.6
	TEMAZEPAM	1	0.6	0	0	1	0.6
	TIAGABINE HYDROCHLORIDE	2	1.1	0	0	0	0
	TOPIRAMATE	3	1.7	2	1.1	3	1.7
	TRAMADOL	0	0	0	0	1	0.6
	TRAZODONE	5	2.8	6	3.3	5	2.8
	TRAZODONE HYDROCHLORIDE	2	1.1	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	TRYPTOPHAN, L-	1	0.6	0	0	0	0
	VALPROATE SEMISODIUM	10	5.6	13	7.2	17	9.4
	VALPROIC ACID	1	0.6	0	0	0	0
	VENLAFAXINE	0	0	0	0	1	0.6
	VENLAFAXINE HYDROCHLORIDE	5	2.8	10	5.6	7	3.9
	ZALEPLON	0	0	3	1.7	3	1.7
	ZIPRASIDONE HYDROCHLORIDE	2	1.1	2	1.1	0	0
	ZOLMITRIPTAN	0	0	0	0	1	0.6
	ZOLPIDEM TARTRATE	7	3.9	10	5.6	9	5.0
RESPIRATORY SYSTEM	TOTAL	33	18.4	35	19.4	37	20.6
	ALLERGY MEDICATION	0	0	1	0.6	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	1	0.6	0	0
	BECLOMETASONE DIPROPIONATE	0	0	0	0	1	0.6
	BENZONATATE	0	0	1	0.6	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	BUDESONIDE	0	0	2	1.1	1	0.6
	CAMPHOR	0	0	1	0.6	0	0
	CETIRIZINE HYDROCHLORIDE	3	1.7	2	1.1	4	2.2
	CODEINE	0	0	0	0	1	0.6
	DESLORATADINE	1	0.6	0	0	2	1.1
	DIPHENHYDRAMINE	0	0	0	0	1	0.6
	DIPHENHYDRAMINE HYDROCHLORIDE	5	2.8	4	2.2	9	5.0
	DOXYLAMINE SUCCINATE	1	0.6	0	0	0	0
	EPINEPHRINE	0	0	1	0.6	0	0
	FEXOFENADINE HYDROCHLORIDE	3	1.7	4	2.2	2	1.1
	FLUTICASONE PROPIONATE	3	1.7	5	2.8	7	3.9
	GUAIFENESIN	0	0	2	1.1	1	0.6
	HYDROCODONE	0	0	0	0	2	1.1
	IPRATROPIUM BROMIDE	2	1.1	0	0	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	LORATADINE	2	1.1	3	1.7	3	1.7
	MECLOZINE	0	0	1	0.6	1	0.6
	MOMETASONE FUROATE	1	0.6	0	0	1	0.6
	MONTELUKAST SODIUM	0	0	0	0	1	0.6
	OXYMETAZOLINE HYDROCHLORIDE	0	0	1	0.6	0	0
	PIRBUTEROL ACETATE	0	0	0	0	1	0.6
	PROMETHAZINE	0	0	0	0	1	0.6
	PROMETHAZINE HYDROCHLORIDE	1	0.6	1	0.6	1	0.6
	PSEUDOEPHEDRINE	1	0.6	0	0	1	0.6
	PSEUDOEPHEDRINE HYDROCHLORIDE	5	2.8	4	2.2	3	1.7
	PSEUDOEPHEDRINE SULFATE	0	0	1	0.6	1	0.6
	SALBUTAMOL	13	7.3	9	5.0	8	4.4
	SALMETEROL XINAFOATE	0	0	1	0.6	1	0.6
	TRIAMCINOLONE ACETONIDE	2	1.1	4	2.2	1	0.6

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SENSORY ORGANS	TOTAL	1	0.6	1	0.6	1	0.6
	BIMATOPROST	1	0.6	0	0	0	0
	LATANOPROST	0	0	1	0.6	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.6
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	7	3.9	9	5.0	11	6.1
	ACTONEL	0	0	0	0	1	0.6
	CORTISONE	1	0.6	0	0	0	0
	LEVOTHYROXINE	0	0	1	0.6	0	0
	LEVOTHYROXINE SODIUM	6	3.4	7	3.9	9	5.0
	LIOTHYRONINE SODIUM	1	0.6	0	0	1	0.6
	MELATONIN	0	0	1	0.6	0	0
	THYROID	0	0	0	0	1	0.6
VARIOUS	TOTAL	8	4.5	6	3.3	9	5.0
	BORAGE OIL	0	0	0	0	1	0.6
	ECHINACEA EXTRACT	2	1.1	0	0	2	1.1
	GINGER	0	0	2	1.1	0	0

(Continued)

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	HERBAL EXTRACTS NOS	0	0	0	0	1	0.6
	HERBAL PREPARATION	3	1.7	4	2.2	2	1.1
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.6
	KAVA-KAVA RHIZOMA	1	0.6	0	0	0	0
	LINSEED OIL	2	1.1	0	0	1	0.6
	ST. JOHN'S WORT	2	1.1	0	0	1	0.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		127	73.8	148	87.1	140	82.8
ALIMENTARY TRACT AND METABOLISM	TOTAL	50	29.1	51	30.0	50	29.6
	ANTACIDS	1	0.6	0	0	0	0
	ASCORBIC ACID	4	2.3	5	2.9	4	2.4
	ATROPINE SULFATE	1	0.6	0	0	0	0
	BISACODYL	0	0	0	0	1	0.6
	BISMUTH SUBSALICYLATE	2	1.2	1	0.6	0	0
	CALCIUM	4	2.3	4	2.4	5	3.0
	CALCIUM ASCORBATE	0	0	0	0	1	0.6
	CALCIUM CARBONATE	6	3.5	6	3.5	5	3.0
	CALCIUM CITRATE	0	0	0	0	1	0.6
	CIMETIDINE	0	0	2	1.2	0	0
	CLIDINIUM	1	0.6	0	0	0	0
	DEXAMFETAMINE SULFATE	0	0	1	0.6	2	1.2
	DICYCLOVERINE HYDROCHLORIDE	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DIHYDROXYALUMINUM SODIUM CARBONATE	3	1.7	0	0	1	0.6
	DOCUSATE SODIUM	2	1.2	1	0.6	0	0
	DOXYCYCLINE	0	0	1	0.6	1	0.6
	ENEMAS	1	0.6	0	0	0	0
	ERGOCALCIFEROL	17	9.9	19	11.2	20	11.8
	ESOMEPRAZOLE	5	2.9	2	1.2	2	1.2
	FERROUS FUMARATE	0	0	0	0	1	0.6
	FERROUS SULFATE	0	0	1	0.6	0	0
	FIBRE, DIETARY	2	1.2	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.6
	GLIPIZIDE	0	0	0	0	1	0.6
	GLUCOSE MONOHYDRATE	1	0.6	0	0	0	0
	HYOSCYAMINE SULFATE	1	0.6	1	0.6	0	0
	INSULIN	1	0.6	0	0	0	0
	LACTOBACILLUS ACIDOPHILUS	1	0.6	0	0	0	0
	LANSOPRAZOLE	2	1.2	2	1.2	2	1.2

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	LOPERAMIDE	0	0	1	0.6	0	0
	LOPERAMIDE HYDROCHLORIDE	1	0.6	0	0	1	0.6
	MACROGOL	1	0.6	0	0	0	0
	MAGNESIUM HYDROXIDE	1	0.6	2	1.2	2	1.2
	METFORMIN	0	0	0	0	1	0.6
	METFORMIN HYDROCHLORIDE	4	2.3	0	0	1	0.6
	MINERAL SUPPLEMENTS	0	0	2	1.2	0	0
	MULTIVITAMINS WITH MINERALS	1	0.6	0	0	0	0
	MULTIVITAMINS, PLAIN	0	0	0	0	1	0.6
	OMEPRAZOLE	0	0	2	1.2	1	0.6
	PANCRELIPASE	1	0.6	0	0	0	0
	PANTOPRAZOLE SODIUM	1	0.6	2	1.2	1	0.6
	PHENTERMINE	0	0	0	0	1	0.6
	POTASSIUM	1	0.6	0	0	1	0.6
	POTASSIUM CHLORIDE	1	0.6	1	0.6	1	0.6

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	PRASTERONE	1	0.6	0	0	1	0.6
	PYRIDOXINE HYDROCHLORIDE	3	1.7	3	1.8	3	1.8
	RABEPRAZOLE SODIUM	1	0.6	1	0.6	0	0
	RANITIDINE HYDROCHLORIDE	5	2.9	2	1.2	4	2.4
	RETINOL	0	0	1	0.6	1	0.6
	ROSIGLITAZONE MALEATE	0	0	2	1.2	1	0.6
	SELENIUM	0	0	1	0.6	1	0.6
	TETRACYCLINE	0	0	0	0	1	0.6
	TILACTASE	1	0.6	0	0	0	0
	TOCOPHEROL	4	2.3	4	2.4	4	2.4
	VITAMINS	0	0	0	0	1	0.6
	VITAMINS NOS	0	0	1	0.6	4	2.4
	ZINC	0	0	1	0.6	1	0.6
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	4	2.3	8	4.7	5	3.0
	ACICLOVIR	1	0.6	1	0.6	0	0

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	AMOXICILLIN TRIHYDRATE	0	0	0	0	1	0.6
	AZITHROMYCIN	1	0.6	1	0.6	0	0
	BENZYLPENICILLIN	1	0.6	2	1.2	1	0.6
	CEFALEXIN	0	0	1	0.6	0	0
	LEVOFLOXACIN	0	0	1	0.6	0	0
	NITROFURANTOIN	0	0	0	0	2	1.2
	RITONAVIR	0	0	1	0.6	0	0
	VALACICLOVIR HYDROCHLORIDE	1	0.6	1	0.6	1	0.6
	ZIDOVUDINE	0	0	1	0.6	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	2	1.2
	ETANERCEPT	0	0	0	0	1	0.6
	METHOTREXATE	0	0	0	0	1	0.6
BLOOD AND BLOOD FORMING ORGANS	TOTAL	2	1.2	4	2.4	8	4.7
	CLOPIDOGREL SULFATE	0	0	0	0	1	0.6
	CYANOCOBALAMIN	1	0.6	3	1.8	0	0
	FERROUS SULFATE	0	0	0	0	2	1.2

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD AND BLOOD FORMING ORGANS	FOLIC ACID	1	0.6	0	0	0	0
	IRON	0	0	0	0	4	2.4
	LECITHIN	1	0.6	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.6	1	0.6
CARDIOVASCULAR SYSTEM	TOTAL	21	12.2	21	12.4	23	13.6
	AMLODIPINE BESILATE	2	1.2	0	0	1	0.6
	ATENOLOL	1	0.6	2	1.2	3	1.8
	ATORVASTATIN	6	3.5	4	2.4	2	1.2
	BENAZEPRIL HYDROCHLORIDE	1	0.6	0	0	0	0
	BUMETANIDE	0	0	0	0	1	0.6
	CARNITINE	1	0.6	0	0	0	0
	CLONIDINE	0	0	2	1.2	1	0.6
	DOXAZOSIN MESILATE	1	0.6	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.6
	FISH OIL	2	1.2	1	0.6	2	1.2
	FLUVASTATIN SODIUM	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	FOSINOPRIL SODIUM	1	0.6	0	0	0	0
	FUROSEMIDE	0	0	1	0.6	1	0.6
	GEMFIBROZIL	0	0	0	0	1	0.6
	HYDROCHLOROTHIAZIDE	5	2.9	6	3.5	8	4.7
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.6
	LABETALOL	0	0	1	0.6	0	0
	LISINOPRIL	0	0	4	2.4	4	2.4
	LOSARTAN POTASSIUM	1	0.6	0	0	0	0
	METOPROLOL	0	0	2	1.2	2	1.2
	METOPROLOL SUCCINATE	1	0.6	0	0	0	0
	MINOXIDIL	0	0	1	0.6	1	0.6
	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.6	0	0
	NICOTINIC ACID	1	0.6	0	0	1	0.6
	NIFEDIPINE	0	0	0	0	1	0.6
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.6	2	1.2	0	0

(Continued)

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	PRAVASTATIN SODIUM	0	0	0	0	2	1.2
	PROPRANOLOL	1	0.6	0	0	0	0
	PROPRANOLOL HYDROCHLORIDE	1	0.6	2	1.2	1	0.6
	SEROTONIN ANTAGONISTS	0	0	0	0	1	0.6
	SIMVASTATIN	2	1.2	1	0.6	2	1.2
	SPIRONOLACTONE	0	0	0	0	1	0.6
	TRIAMTERENE	0	0	0	0	2	1.2
	UBIDECARENONE	0	0	2	1.2	0	0
	VERAPAMIL	0	0	0	0	1	0.6
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.6	1	0.6
DERMATOLOGICALS	TOTAL	3	1.7	0	0	0	0
	CALCIPOTRIOL	1	0.6	0	0	0	0
	SMILAX ARISTOLOCHIIFOLIA ROOT	1	0.6	0	0	0	0
	TRIAMCINOLONE	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	18	10.5	21	12.4	18	10.7
	EQUISETUM ARVENSE	0	0	1	0.6	0	0
	ESTRADIOL	0	0	1	0.6	3	1.8
	ESTROGENS CONJUGATED	1	0.6	3	1.8	1	0.6
	ETHINYLESTRADIOL	11	6.4	6	3.5	9	5.3
	LEVONORGESTREL	0	0	1	0.6	0	0
	MEDROXYPROGESTERONE ACETATE	2	1.2	4	2.4	2	1.2
	MICONAZOLE NITRATE	0	0	0	0	1	0.6
	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	1	0.6
	NORETHISTERONE	1	0.6	0	0	1	0.6
	NORETHISTERONE ACETATE	0	0	1	0.6	0	0
	OXYBUTYNIN	0	0	1	0.6	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.6	0	0
	PROGESTERONE	0	0	1	0.6	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	RALOXIFENE HYDROCHLORIDE	1	0.6	0	0	0	0
	SERENOA REPENS	1	0.6	0	0	0	0
	SILDENAFIL CITRATE	0	0	1	0.6	0	0
	TAMSULOSIN HYDROCHLORIDE	0	0	2	1.2	0	0
	TESTOSTERONE	1	0.6	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.6	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	39	22.7	45	26.5	48	28.4
	ALENDRONATE SODIUM	0	0	2	1.2	0	0
	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	2	1.2
	ASCORBIC ACID	0	0	2	1.2	0	0
	BOTULINUM TOXIN TYPE A	0	0	1	0.6	0	0
	CARISOPRODOL	0	0	0	0	3	1.8
	CELECOXIB	1	0.6	3	1.8	2	1.2
	CHONDROITIN SULFATE	1	0.6	0	0	1	0.6

(Continued)

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	COLCHICINE	0	0	0	0	1	0.6
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.6	0	0	0	0
	GLUCOSAMINE	1	0.6	0	0	0	0
	IBUPROFEN	29	16.9	23	13.5	26	15.4
	INDOMETACIN	1	0.6	0	0	0	0
	KETOPROFEN	1	0.6	0	0	0	0
	METAXALONE	0	0	0	0	1	0.6
	METHOCARBAMOL	0	0	0	0	1	0.6
	NABUMETONE	0	0	1	0.6	0	0
	NAPROXEN	2	1.2	4	2.4	3	1.8
	NAPROXEN SODIUM	2	1.2	6	3.5	7	4.1
	OXAPROZIN	0	0	1	0.6	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	1	0.6	1	0.6	2	1.2
	ROFECOXIB	1	0.6	1	0.6	3	1.8
	VALDECOXIB	1	0.6	2	1.2	1	0.6
NERVOUS SYSTEM	TOTAL	84	48.8	109	64.1	94	55.6

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	ACETAZOLAMIDE	0	0	1	0.6	0	0
	ACETYLSALICYLIC ACID	16	9.3	13	7.6	19	11.2
	ALPRAZOLAM	2	1.2	3	1.8	6	3.6
	AMITRIPTYLINE	0	0	2	1.2	1	0.6
	AMITRIPTYLINE HYDROCHLORIDE	1	0.6	3	1.8	0	0
	ANTIDEPRESSANTS	1	0.6	0	0	0	0
	ARIPIPRAZOLE	2	1.2	1	0.6	0	0
	BUPROPION HYDROCHLORIDE	11	6.4	15	8.8	4	2.4
	BUSPIRONE HYDROCHLORIDE	1	0.6	1	0.6	1	0.6
	BUTALBITAL	0	0	0	0	1	0.6
	BUTORPHANOL TARTRATE	0	0	1	0.6	1	0.6
	CARBAMAZEPINE	6	3.5	0	0	0	0
	CITALOPRAM	0	0	0	0	1	0.6
	CITALOPRAM HYDROBROMIDE	1	0.6	1	0.6	5	3.0

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	CLONAZEPAM	2	1.2	6	3.5	1	0.6
	CODEINE PHOSPHATE	1	0.6	3	1.8	0	0
	CYCLOBENZAPRINE	1	0.6	0	0	0	0
	DIAZEPAM	1	0.6	1	0.6	2	1.2
	DIPHENHYDRAMINE	2	1.2	1	0.6	5	3.0
	DOXEPIN	1	0.6	0	0	0	0
	ESCITALOPRAM	4	2.3	2	1.2	1	0.6
	ETHANOL	0	0	1	0.6	0	0
	FLUOXETINE	1	0.6	0	0	0	0
	FLUOXETINE HYDROCHLORIDE	2	1.2	4	2.4	6	3.6
	GABAPENTIN	5	2.9	4	2.4	4	2.4
	GINKGO BILOBA	0	0	1	0.6	0	0
	HYDROXYZINE	1	0.6	0	0	0	0
	HYDROXYZINE EMBONATE	0	0	2	1.2	0	0
	LAMOTRIGINE	3	1.7	8	4.7	2	1.2
	LEVETIRACETAM	0	0	1	0.6	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	LEVODOPA	0	0	0	0	1	0.6
	LITHIUM	5	2.9	5	2.9	8	4.7
	LITHIUM CARBONATE	5	2.9	4	2.4	1	0.6
	LORAZEPAM	15	8.7	15	8.8	8	4.7
	METHYSERGIDE	0	0	0	0	1	0.6
	MIRTAZAPINE	5	2.9	3	1.8	0	0
	MODAFINIL	1	0.6	1	0.6	0	0
	NEFAZODONE HYDROCHLORIDE	0	0	4	2.4	0	0
	NICOTINE	0	0	1	0.6	1	0.6
	OLANZAPINE	13	7.6	4	2.4	6	3.6
	OXCARBAZEPINE	2	1.2	6	3.5	0	0
	PARACETAMOL	21	12.2	31	18.2	23	13.6
	PAROXETINE HYDROCHLORIDE	6	3.5	16	9.4	8	4.7
	QUETIAPINE FUMARATE	1	0.6	0	0	0	0
	RISPERIDONE	3	1.7	5	2.9	3	1.8

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	RIZATRIPTAN BENZOATE	1	0.6	0	0	0	0
	SERTRALINE HYDROCHLORIDE	6	3.5	5	2.9	5	3.0
	SUMATRIPTAN SUCCINATE	0	0	1	0.6	1	0.6
	TEMAZEPAM	1	0.6	0	0	1	0.6
	TIAGABINE HYDROCHLORIDE	2	1.2	0	0	0	0
	TOPIRAMATE	3	1.7	2	1.2	3	1.8
	TRAMADOL	0	0	0	0	1	0.6
	TRAZODONE	5	2.9	6	3.5	5	3.0
	TRAZODONE HYDROCHLORIDE	2	1.2	0	0	0	0
	TRYPTOPHAN, L-	1	0.6	0	0	0	0
	VALPROATE SEMISODIUM	10	5.8	13	7.6	16	9.5
	VALPROIC ACID	1	0.6	0	0	0	0
	VENLAFAXINE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	VENLAFAXINE HYDROCHLORIDE	5	2.9	10	5.9	7	4.1
	ZALEPLON	0	0	3	1.8	3	1.8
	ZIPRASIDONE HYDROCHLORIDE	2	1.2	2	1.2	0	0
	ZOLMITRIPTAN	0	0	0	0	1	0.6
	ZOLPIDEM TARTRATE	6	3.5	10	5.9	8	4.7
RESPIRATORY SYSTEM	TOTAL	32	18.6	34	20.0	34	20.1
	ALLERGY MEDICATION	0	0	1	0.6	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	1	0.6	0	0
	BENZONATATE	0	0	1	0.6	1	0.6
	BUDESONIDE	0	0	1	0.6	1	0.6
	CAMPHOR	0	0	1	0.6	0	0
	CETIRIZINE HYDROCHLORIDE	3	1.7	2	1.2	3	1.8
	CODEINE	0	0	0	0	1	0.6
	DESLORATADINE	1	0.6	0	0	2	1.2
	DIPHENHYDRAMINE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	DIPHENHYDRAMINE HYDROCHLORIDE	4	2.3	3	1.8	7	4.1
	DOXYLAMINE SUCCINATE	1	0.6	0	0	0	0
	EPINEPHRINE	0	0	1	0.6	0	0
	FEXOFENADINE HYDROCHLORIDE	2	1.2	3	1.8	2	1.2
	FLUTICASONE PROPIONATE	3	1.7	5	2.9	6	3.6
	GUAIFENESIN	0	0	2	1.2	1	0.6
	HYDROCODONE	0	0	0	0	2	1.2
	IPRATROPIUM BROMIDE	2	1.2	0	0	1	0.6
	LORATADINE	2	1.2	3	1.8	3	1.8
	MECLOZINE	0	0	1	0.6	1	0.6
	MOMETASONE FUROATE	0	0	0	0	1	0.6
	MONTELUKAST SODIUM	0	0	0	0	1	0.6
	PIRBUTEROL ACETATE	0	0	0	0	1	0.6
	PROMETHAZINE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	PROMETHAZINE HYDROCHLORIDE	0	0	1	0.6	1	0.6
	PSEUDOEPHEDRINE	1	0.6	0	0	1	0.6
	PSEUDOEPHEDRINE HYDROCHLORIDE	5	2.9	4	2.4	3	1.8
	PSEUDOEPHEDRINE SULFATE	0	0	1	0.6	1	0.6
	SALBUTAMOL	13	7.6	9	5.3	8	4.7
	SALMETEROL XINAFOATE	0	0	1	0.6	1	0.6
	TRIAMCINOLONE ACETONIDE	2	1.2	4	2.4	1	0.6
SENSORY ORGANS	TOTAL	1	0.6	1	0.6	1	0.6
	BIMATOPROST	1	0.6	0	0	0	0
	LATANOPROST	0	0	1	0.6	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.6
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	7	4.1	9	5.3	10	5.9
	CORTISONE	1	0.6	0	0	0	0
	LEVOTHYROXINE	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	LEVOTHYROXINE SODIUM	6	3.5	7	4.1	9	5.3
	LIOTHYRONINE SODIUM	1	0.6	0	0	1	0.6
	MELATONIN	0	0	1	0.6	0	0
	THYROID	0	0	0	0	1	0.6
VARIOUS	TOTAL	8	4.7	6	3.5	8	4.7
	BORAGE OIL	0	0	0	0	1	0.6
	ECHINACEA EXTRACT	2	1.2	0	0	2	1.2
	GINGER	0	0	2	1.2	0	0
	HERBAL EXTRACTS NOS	0	0	0	0	1	0.6
	HERBAL PREPARATION	3	1.7	4	2.4	2	1.2
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.6
	KAVA-KAVA RHIZOMA	1	0.6	0	0	0	0
	LINSEED OIL	2	1.2	0	0	1	0.6
	ST. JOHN'S WORT	2	1.2	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		91	75.8	102	85.0	99	83.9	41	69.5	52	86.7	49	79.0
ALIMENTARY TRACT AND METABOLISM	TOTAL	38	31.7	35	29.2	36	30.5	15	25.4	18	30.0	17	27.4
	ANTACIDS	1	0.8	0	0	0	0	0	0	0	0	0	0
	ASCORBIC ACID	2	1.7	3	2.5	2	1.7	3	5.1	2	3.3	2	3.2
	ATROPINE SULFATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	BISACODYL	0	0	0	0	1	0.8	0	0	0	0	0	0
	BISMUTH SUBSALICYLATE	2	1.7	0	0	0	0	0	0	1	1.7	0	0
	CALCIUM	2	1.7	3	2.5	4	3.4	2	3.4	1	1.7	2	3.2
	CALCIUM ASCORBATE	0	0	0	0	0	0	0	0	0	0	1	1.6
	CALCIUM CARBONATE	5	4.2	5	4.2	5	4.2	1	1.7	1	1.7	0	0
	CALCIUM CITRATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	CIMETIDINE	0	0	2	1.7	0	0	0	0	1	1.7	0	0
	CLIDINIUM	1	0.8	0	0	0	0	0	0	0	0	0	0
	DEXAMFETAMINE SULFATE	0	0	1	0.8	2	1.7	0	0	0	0	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DICYCLOVERINE HYDROCHLORIDE	1	0.8	0	0	0	0	0	0	0	0	0	0
	DIHYDROXYALUMINUM SODIUM CARBONATE	2	1.7	1	0.8	1	0.8	1	1.7	0	0	0	0
	DOCUSATE SODIUM	1	0.8	1	0.8	0	0	1	1.7	0	0	0	0
	DOXYCYCLINE	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	ENEMAS	1	0.8	0	0	0	0	0	0	0	0	0	0
	ERGOCALCIFEROL	12	10.0	15	12.5	10	8.5	6	10.2	4	6.7	10	16.1
	ESOMEPRAZOLE	5	4.2	1	0.8	1	0.8	0	0	1	1.7	1	1.6
	FAMOTIDINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	FERROUS FUMARATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	FERROUS SULFATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	FIBRE, DIETARY	2	1.7	0	0	0	0	0	0	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	GLIPIZIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	GLUCOSE MONOHYDRATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	HYOSCYAMINE SULFATE	1	0.8	0	0	0	0	0	0	1	1.7	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	INSULIN	0	0	0	0	0	0	1	1.7	0	0	0	0
	LACTOBACILLUS ACIDOPHILUS	1	0.8	0	0	0	0	0	0	0	0	0	0
	LANSOPRAZOLE	3	2.5	0	0	1	0.8	0	0	2	3.3	2	3.2
	LOPERAMIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	LOPERAMIDE HYDROCHLORIDE	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	MACROGOL	1	0.8	0	0	0	0	0	0	0	0	0	0
	MAGNESIUM HYDROXIDE	1	0.8	2	1.7	2	1.7	0	0	0	0	0	0
	METFORMIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	METFORMIN HYDROCHLORIDE	3	2.5	0	0	1	0.8	1	1.7	0	0	0	0
	MINERAL SUPPLEMENTS	0	0	2	1.7	0	0	0	0	0	0	0	0
	MULTIVITAMINS WITH MINERALS	1	0.8	0	0	0	0	0	0	0	0	0	0
	MULTIVITAMINS, PLAIN	0	0	0	0	0	0	0	0	0	0	1	1.6
	OMEPRAZOLE	0	0	2	1.7	1	0.8	0	0	0	0	0	0
	PANCRELIPASE	1	0.8	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	PANTOPRAZOLE SODIUM	1	0.8	1	0.8	2	1.7	0	0	1	1.7	1	1.6
	PHENTERMINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	PHOSPHORIC ACID	1	0.8	0	0	0	0	0	0	0	0	0	0
	POTASSIUM	0	0	0	0	0	0	1	1.7	0	0	1	1.6
	POTASSIUM CHLORIDE	1	0.8	0	0	1	0.8	0	0	1	1.7	0	0
	PRASTERONE	1	0.8	0	0	1	0.8	0	0	0	0	0	0
	PYRIDOXINE HYDROCHLORIDE	2	1.7	2	1.7	3	2.5	1	1.7	1	1.7	0	0
	RABEPRAZOLE SODIUM	0	0	0	0	0	0	1	1.7	1	1.7	0	0
	RANITIDINE HYDROCHLORIDE	5	4.2	1	0.8	4	3.4	0	0	1	1.7	0	0
	RETINOL	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	ROSIGLITAZONE MALEATE	0	0	2	1.7	1	0.8	0	0	0	0	0	0
	SELENIUM	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	TETRACYCLINE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	TILACTASE	1	0.8	0	0	0	0	0	0	0	0	0	0
	TOCOPHEROL	3	2.5	4	3.3	2	1.7	2	3.4	0	0	3	4.8

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	VITAMINS	0	0	0	0	1	0.8	0	0	0	0	0	0
	VITAMINS NOS	0	0	0	0	3	2.5	0	0	1	1.7	1	1.6
	ZINC	0	0	0	0	1	0.8	0	0	1	1.7	0	0
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	1	0.8	4	3.3	5	4.2	3	5.1	4	6.7	1	1.6
	ACICLOVIR	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	AMOXICILLIN TRIHYDRATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	AZITHROMYCIN	1	0.8	0	0	0	0	0	0	1	1.7	0	0
	BENZYLPENICILLIN	0	0	2	1.7	1	0.8	1	1.7	0	0	0	0
	CEFALEXIN	0	0	0	0	0	0	0	0	1	1.7	0	0
	CLARITHROMYCIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	LEVOFLOXACIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	NITROFURANTOIN	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	RITONAVIR	0	0	0	0	0	0	0	0	1	1.7	0	0
	VALACICLOVIR HYDROCHLORIDE	0	0	0	0	1	0.8	1	1.7	1	1.7	0	0
	ZIDOVUDINE	0	0	0	0	0	0	0	0	1	1.7	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	ETANERCEPT	0	0	0	0	1	0.8	0	0	0	0	0	0
	METHOTREXATE	0	0	0	0	0	0	0	0	0	0	1	1.6
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	0.8	4	3.3	5	4.2	1	1.7	0	0	3	4.8
	CLOPIDOGREL SULFATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	CYANOCOBALAMIN	0	0	3	2.5	0	0	1	1.7	0	0	0	0
	FERROUS SULFATE	0	0	0	0	0	0	0	0	0	0	2	3.2
	FOLIC ACID	0	0	0	0	0	0	1	1.7	0	0	0	0
	IRON	0	0	0	0	3	2.5	0	0	0	0	1	1.6
	LECITHIN	1	0.8	0	0	0	0	0	0	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.8	1	0.8	0	0	0	0	0	0
CARDIOVASCULAR SYSTEM	TOTAL	14	11.7	18	15.0	14	11.9	7	11.9	3	5.0	9	14.5
	AMLODIPINE BESILATE	2	1.7	0	0	1	0.8	0	0	0	0	0	0
	ATENOLOL	0	0	2	1.7	2	1.7	1	1.7	0	0	1	1.6
	ATORVASTATIN	4	3.3	4	3.3	2	1.7	2	3.4	0	0	0	0
	BENAZEPRIL HYDROCHLORIDE	1	0.8	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	BUMETANIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	CARNITINE	0	0	0	0	0	0	1	1.7	0	0	0	0
	CLONIDINE	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	DOXAZOSIN MESILATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	FISH OIL	1	0.8	1	0.8	0	0	1	1.7	0	0	2	3.2
	FLUVASTATIN SODIUM	0	0	1	0.8	0	0	0	0	0	0	0	0
	FOSINOPRIL SODIUM	1	0.8	0	0	0	0	0	0	0	0	0	0
	FUROSEMIDE	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	GEMFIBROZIL	0	0	0	0	1	0.8	0	0	0	0	0	0
	HYDROCHLOROTHIAZIDE	4	3.3	6	5.0	3	2.5	1	1.7	0	0	5	8.1
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	LABETALOL	0	0	1	0.8	0	0	0	0	0	0	0	0
	LISINOPRIL	0	0	3	2.5	3	2.5	0	0	1	1.7	1	1.6
	LOSARTAN POTASSIUM	1	0.8	0	0	0	0	0	0	0	0	0	0
	METOPROLOL	0	0	2	1.7	2	1.7	0	0	0	0	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	METOPROLOL SUCCINATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	MINOXIDIL	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	NICOTINIC ACID	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	NIFEDIPINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.8	1	0.8	0	0	0	0	1	1.7	0	0
	PRAVASTATIN SODIUM	0	0	0	0	2	1.7	0	0	0	0	0	0
	PROPRANOLOL	0	0	0	0	0	0	1	1.7	0	0	0	0
	PROPRANOLOL HYDROCHLORIDE	0	0	2	1.7	1	0.8	1	1.7	0	0	0	0
	SEROTONIN ANTAGONISTS	0	0	0	0	1	0.8	0	0	0	0	0	0
	SIMVASTATIN	2	1.7	0	0	2	1.7	0	0	1	1.7	0	0
	SPIRONOLACTONE	0	0	0	0	0	0	0	0	0	0	1	1.6
	TRIAMTERENE	0	0	0	0	2	1.7	0	0	0	0	0	0
	UBIDECARENONE	0	0	1	0.8	0	0	0	0	1	1.7	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	VERAPAMIL	0	0	0	0	0	0	0	0	0	0	1	1.6
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	1	1.6
DERMATOLOGICALS	TOTAL	2	1.7	0	0	0	0	1	1.7	0	0	0	0
	CALCIPOTRIOL	1	0.8	0	0	0	0	0	0	0	0	0	0
	SMILAX ARISTOLOCHIIFOLIA ROOT	1	0.8	0	0	0	0	0	0	0	0	0	0
	TRIAMCINOLONE	0	0	0	0	0	0	1	1.7	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	13	10.8	13	10.8	9	7.6	6	10.2	8	13.3	9	14.5
	EQUISETUM ARVENSE	0	0	0	0	0	0	0	0	1	1.7	0	0
	ESTRADIOL	0	0	1	0.8	2	1.7	0	0	0	0	1	1.6
	ESTROGENS CONJUGATED	1	0.8	3	2.5	1	0.8	0	0	0	0	0	0
	ETHINYLESTRADIOL	9	7.5	4	3.3	4	3.4	3	5.1	2	3.3	5	8.1
	LEVONORGESTREL	0	0	0	0	0	0	0	0	1	1.7	0	0
	MEDROXYPROGESTERONE ACETATE	2	1.7	3	2.5	1	0.8	0	0	1	1.7	1	1.6
	MICONAZOLE NITRATE	0	0	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	0	0	0	0	0	0	1	1.6
	NORETHISTERONE	1	0.8	0	0	0	0	0	0	0	0	1	1.6
	NORETHISTERONE ACETATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	OXYBUTYNIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	PROGESTERONE	0	0	1	0.8	0	0	0	0	0	0	0	0
	RALOXIFENE HYDROCHLORIDE	0	0	0	0	0	0	1	1.7	0	0	0	0
	SERENOA REPENS	0	0	0	0	0	0	1	1.7	0	0	0	0
	SILDENAFIL CITRATE	0	0	1	0.8	0	0	0	0	0	0	0	0
	TAMSULOSIN HYDROCHLORIDE	0	0	0	0	0	0	0	0	2	3.3	0	0
	TESTOSTERONE	0	0	0	0	0	0	1	1.7	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	TOTAL	27	22.5	33	27.5	35	29.7	13	22.0	15	25.0	16	25.8
	ALENDRONATE SODIUM	0	0	2	1.7	0	0	0	0	0	0	0	0
	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	ASCORBIC ACID	0	0	2	1.7	0	0	0	0	0	0	0	0
	BOTULINUM TOXIN TYPE A	0	0	1	0.8	0	0	0	0	0	0	0	0
	CARISOPRODOL	0	0	0	0	2	1.7	0	0	0	0	1	1.6
	CELECOXIB	1	0.8	4	3.3	2	1.7	0	0	0	0	0	0
	CHONDROITIN SULFATE	1	0.8	0	0	1	0.8	0	0	0	0	1	1.6
	COLCHICINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.8	0	0	0	0	0	0	0	0	0	0
	GLUCOSAMINE	1	0.8	0	0	0	0	0	0	0	0	0	0
	IBUPROFEN	21	17.5	18	15.0	18	15.3	9	15.3	7	11.7	9	14.5
	INDOMETACIN	0	0	0	0	0	0	1	1.7	0	0	0	0
	KETOPROFEN	0	0	0	0	0	0	1	1.7	0	0	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	METAXALONE	0	0	0	0	0	0	0	0	0	0	1	1.6
	METHOCARBAMOL	1	0.8	0	0	0	0	0	0	0	0	1	1.6
	NABUMETONE	0	0	0	0	0	0	0	0	1	1.7	0	0
	NAPROXEN	2	1.7	1	0.8	3	2.5	0	0	3	5.0	1	1.6
	NAPROXEN SODIUM	2	1.7	4	3.3	7	5.9	0	0	2	3.3	0	0
	OXAPROZIN	0	0	0	0	0	0	0	0	1	1.7	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	1	0.8	2	1.7	1	1.7	0	0	0	0
	ROFECOXIB	0	0	0	0	0	0	1	1.7	1	1.7	3	4.8
	VALDECOXIB	1	0.8	2	1.7	1	0.8	0	0	1	1.7	0	0
NERVOUS SYSTEM	TOTAL	59	49.2	73	60.8	67	56.8	28	47.5	40	66.7	32	51.6
	ACETAZOLAMIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	ACETYLSALICYLIC ACID	7	5.8	12	10.0	12	10.2	9	15.3	3	5.0	8	12.9
	ALPRAZOLAM	2	1.7	0	0	3	2.5	1	1.7	3	5.0	4	6.5
	AMITRIPTYLINE	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	AMITRIPTYLINE HYDROCHLORIDE	1	0.8	1	0.8	0	0	0	0	2	3.3	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	ANTIDEPRESSANTS	1	0.8	0	0	0	0	0	0	0	0	0	0
	ARIPIPRAZOLE	2	1.7	1	0.8	0	0	0	0	0	0	0	0
	BUPROPION HYDROCHLORIDE	7	5.8	8	6.7	5	4.2	4	6.8	7	11.7	0	0
	BUSPIRONE HYDROCHLORIDE	1	0.8	1	0.8	0	0	0	0	0	0	1	1.6
	BUTALBITAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	BUTORPHANOL TARTRATE	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	CARBAMAZEPINE	4	3.3	0	0	0	0	2	3.4	0	0	0	0
	CITALOPRAM	0	0	0	0	1	0.8	0	0	0	0	0	0
	CITALOPRAM HYDROBROMIDE	0	0	1	0.8	3	2.5	1	1.7	0	0	2	3.2
	CLONAZEPAM	2	1.7	6	5.0	2	1.7	0	0	0	0	0	0
	CODEINE PHOSPHATE	0	0	1	0.8	0	0	1	1.7	2	3.3	0	0
	CYCLOBENZAPRINE	0	0	0	0	0	0	1	1.7	0	0	0	0
	DIAZEPAM	1	0.8	0	0	1	0.8	0	0	1	1.7	2	3.2
	DIPHENHYDRAMINE	3	2.5	0	0	4	3.4	0	0	1	1.7	2	3.2

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	DOXEPIN	1	0.8	0	0	0	0	0	0	0	0	0	0
	ESCITALOPRAM	4	3.3	2	1.7	0	0	0	0	0	0	1	1.6
	ETHANOL	0	0	0	0	0	0	0	0	1	1.7	0	0
	FLUOXETINE	1	0.8	0	0	0	0	0	0	0	0	0	0
	FLUOXETINE HYDROCHLORIDE	2	1.7	2	1.7	6	5.1	0	0	2	3.3	0	0
	GABAPENTIN	2	1.7	2	1.7	2	1.7	3	5.1	2	3.3	2	3.2
	GINKGO BILOBA	0	0	0	0	0	0	0	0	1	1.7	0	0
	HYDROXYZINE	0	0	0	0	0	0	1	1.7	0	0	0	0
	HYDROXYZINE EMBONATE	0	0	1	0.8	0	0	0	0	1	1.7	0	0
	LAMOTRIGINE	3	2.5	5	4.2	1	0.8	0	0	3	5.0	1	1.6
	LEVETIRACETAM	0	0	0	0	0	0	0	0	1	1.7	0	0
	LEVODOPA	0	0	0	0	0	0	0	0	0	0	1	1.6
	LITHIUM	4	3.3	3	2.5	5	4.2	1	1.7	2	3.3	3	4.8
	LITHIUM CARBONATE	3	2.5	4	3.3	0	0	2	3.4	0	0	1	1.6
	LORAZEPAM	8	6.7	13	10.8	9	7.6	7	11.9	3	5.0	0	0

(Continued)

Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	METHYSERGIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	MIRTAZAPINE	4	3.3	2	1.7	0	0	1	1.7	1	1.7	0	0
	MODAFINIL	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	NEFAZODONE HYDROCHLORIDE	0	0	3	2.5	0	0	0	0	1	1.7	0	0
	NICOTINE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	OLANZAPINE	12	10.0	2	1.7	4	3.4	1	1.7	2	3.3	3	4.8
	OXCARBAZEPINE	2	1.7	3	2.5	0	0	0	0	3	5.0	0	0
	PARACETAMOL	15	12.5	24	20.0	14	11.9	7	11.9	10	16.7	10	16.1
	PAROXETINE HYDROCHLORIDE	4	3.3	7	5.8	6	5.1	2	3.4	9	15.0	3	4.8
	QUETIAPINE FUMARATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	RISPERIDONE	1	0.8	4	3.3	3	2.5	2	3.4	1	1.7	0	0
	RIZATRIPTAN BENZOATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	SERTRALINE HYDROCHLORIDE	4	3.3	3	2.5	2	1.7	2	3.4	2	3.3	3	4.8
	SUMATRIPTAN SUCCINATE	0	0	0	0	1	0.8	0	0	1	1.7	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	TEMAZEPAM	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	TIAGABINE HYDROCHLORIDE	1	0.8	0	0	0	0	1	1.7	0	0	0	0
	TOPIRAMATE	3	2.5	0	0	2	1.7	0	0	2	3.3	1	1.6
	TRAMADOL	0	0	0	0	1	0.8	0	0	0	0	0	0
	TRAZODONE	4	3.3	4	3.3	4	3.4	1	1.7	2	3.3	1	1.6
	TRAZODONE HYDROCHLORIDE	1	0.8	0	0	0	0	1	1.7	0	0	0	0
	TRYPTOPHAN, L-	1	0.8	0	0	0	0	0	0	0	0	0	0
	VALPROATE SEMISODIUM	7	5.8	11	9.2	14	11.9	3	5.1	2	3.3	3	4.8
	VALPROIC ACID	1	0.8	0	0	0	0	0	0	0	0	0	0
	VENLAFAXINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	VENLAFAXINE HYDROCHLORIDE	5	4.2	6	5.0	3	2.5	0	0	4	6.7	4	6.5
	ZALEPLON	0	0	2	1.7	2	1.7	0	0	1	1.7	1	1.6
	ZIPRASIDONE HYDROCHLORIDE	1	0.8	1	0.8	0	0	1	1.7	1	1.7	0	0
	ZOLMITRIPTAN	0	0	0	0	1	0.8	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	ZOLPIDEM TARTRATE	4	3.3	9	7.5	6	5.1	3	5.1	1	1.7	3	4.8
RESPIRATORY SYSTEM	TOTAL	21	17.5	20	16.7	23	19.5	12	20.3	15	25.0	14	22.6
	ALLERGY MEDICATION	0	0	0	0	0	0	0	0	1	1.7	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	0	0	0	0	0	0	1	1.7	0	0
	BECLOMETASONE DIPROPIONATE	0	0	0	0	0	0	0	0	0	0	1	1.6
	BENZONATATE	0	0	0	0	0	0	0	0	1	1.7	1	1.6
	BUDESONIDE	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	CAMPHOR	0	0	0	0	0	0	0	0	1	1.7	0	0
	CETIRIZINE HYDROCHLORIDE	2	1.7	1	0.8	1	0.8	1	1.7	1	1.7	3	4.8
	CODEINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	DESLORATADINE	1	0.8	0	0	0	0	0	0	0	0	2	3.2
	DIPHENHYDRAMINE	0	0	0	0	0	0	0	0	0	0	1	1.6
	DIPHENHYDRAMINE HYDROCHLORIDE	4	3.3	3	2.5	8	6.8	1	1.7	1	1.7	1	1.6
	DOXYLAMINE SUCCINATE	1	0.8	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	EPINEPHRINE	0	0	0	0	0	0	0	0	1	1.7	0	0
	FEXOFENADINE HYDROCHLORIDE	2	1.7	3	2.5	2	1.7	1	1.7	1	1.7	0	0
	FLUTICASONE PROPIONATE	2	1.7	2	1.7	2	1.7	1	1.7	3	5.0	5	8.1
	GUAIFENESIN	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	HYDROCODONE	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	IPRATROPIUM BROMIDE	1	0.8	0	0	1	0.8	1	1.7	0	0	0	0
	LORATADINE	2	1.7	1	0.8	2	1.7	0	0	2	3.3	1	1.6
	MECLOZINE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	MOMETASONE FUROATE	1	0.8	0	0	1	0.8	0	0	0	0	0	0
	MONTELUKAST SODIUM	0	0	0	0	0	0	0	0	0	0	1	1.6
	OXYMETAZOLINE HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	PIRBUTEROL ACETATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	PROMETHAZINE	0	0	0	0	0	0	0	0	0	0	1	1.6
	PROMETHAZINE HYDROCHLORIDE	1	0.8	1	0.8	1	0.8	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	PSEUDOEPHEDRINE	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	2	1.7	3	2.5	2	1.7	3	5.1	1	1.7	1	1.6
	PSEUDOEPHEDRINE SULFATE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	SALBUTAMOL	8	6.7	7	5.8	5	4.2	5	8.5	2	3.3	3	4.8
	SALMETEROL XINAFOATE	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	TRIAMCINOLONE ACETONIDE	2	1.7	4	3.3	1	0.8	0	0	0	0	0	0
SENSORY ORGANS	TOTAL	1	0.8	0	0	1	0.8	0	0	1	1.7	0	0
	BIMATOPROST	1	0.8	0	0	0	0	0	0	0	0	0	0
	LATANOPROST	0	0	0	0	0	0	0	0	1	1.7	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	4	3.3	7	5.8	6	5.1	3	5.1	2	3.3	5	8.1
	ACTONEL	0	0	0	0	0	0	0	0	0	0	1	1.6
	CORTISONE	1	0.8	0	0	0	0	0	0	0	0	0	0
	LEVOTHYROXINE	0	0	1	0.8	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	LEVOTHYROXINE SODIUM	3	2.5	5	4.2	6	5.1	3	5.1	2	3.3	3	4.8
	LIOTHYRONINE SODIUM	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	MELATONIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	THYROID	0	0	0	0	0	0	0	0	0	0	1	1.6
VARIOUS	TOTAL	5	4.2	1	0.8	5	4.2	3	5.1	5	8.3	4	6.5
	BORAGE OIL	0	0	0	0	0	0	0	0	0	0	1	1.6
	ECHINACEA EXTRACT	0	0	0	0	1	0.8	2	3.4	0	0	1	1.6
	GINGER	0	0	0	0	0	0	0	0	2	3.3	0	0
	HERBAL EXTRACTS NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	HERBAL PREPARATION	1	0.8	1	0.8	2	1.7	2	3.4	3	5.0	0	0
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.8	0	0	0	0	0	0
	KAVA-KAVA RHIZOMA	1	0.8	0	0	0	0	0	0	0	0	0	0
	LINSEED OIL	2	1.7	0	0	0	0	0	0	0	0	1	1.6
	ST. JOHN'S WORT	2	1.7	0	0	0	0	0	0	0	0	1	1.6

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		88	75.9	98	86.0	94	83.9	39	69.6	50	89.3	46	80.7
ALIMENTARY TRACT AND METABOLISM	TOTAL	36	31.0	33	28.9	34	30.4	14	25.0	18	32.1	16	28.1
	ANTACIDS	1	0.9	0	0	0	0	0	0	0	0	0	0
	ASCORBIC ACID	2	1.7	3	2.6	2	1.8	2	3.6	2	3.6	2	3.5
	ATROPINE SULFATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	BISACODYL	0	0	0	0	1	0.9	0	0	0	0	0	0
	BISMUTH SUBSALICYLATE	2	1.7	0	0	0	0	0	0	1	1.8	0	0
	CALCIUM	2	1.7	3	2.6	4	3.6	2	3.6	1	1.8	1	1.8
	CALCIUM ASCORBATE	0	0	0	0	0	0	0	0	0	0	1	1.8
	CALCIUM CARBONATE	5	4.3	5	4.4	5	4.5	1	1.8	1	1.8	0	0
	CALCIUM CITRATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	CIMETIDINE	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	CLIDINIUM	1	0.9	0	0	0	0	0	0	0	0	0	0
	DEXAMFETAMINE SULFATE	0	0	1	0.9	2	1.8	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DICYCLOVERINE HYDROCHLORIDE	1	0.9	0	0	0	0	0	0	0	0	0	0
	DIHYDROXYALUMINUM SODIUM CARBONATE	2	1.7	0	0	1	0.9	1	1.8	0	0	0	0
	DOCUSATE SODIUM	1	0.9	1	0.9	0	0	1	1.8	0	0	0	0
	DOXYCYCLINE	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	ENEMAS	1	0.9	0	0	0	0	0	0	0	0	0	0
	ERGOCALCIFEROL	11	9.5	15	13.2	10	8.9	6	10.7	4	7.1	10	17.5
	ESOMEPRAZOLE	5	4.3	1	0.9	1	0.9	0	0	1	1.8	1	1.8
	FERROUS FUMARATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	FERROUS SULFATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	FIBRE, DIETARY	2	1.7	0	0	0	0	0	0	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	GLIPIZIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	GLUCOSE MONOHYDRATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	HYOSCYAMINE SULFATE	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	INSULIN	0	0	0	0	0	0	1	1.8	0	0	0	0

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	LACTOBACILLUS ACIDOPHILUS	1	0.9	0	0	0	0	0	0	0	0	0	0
	LANSOPRAZOLE	2	1.7	0	0	1	0.9	0	0	2	3.6	1	1.8
	LOPERAMIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	LOPERAMIDE HYDROCHLORIDE	0	0	0	0	1	0.9	1	1.8	0	0	0	0
	MACROGOL	1	0.9	0	0	0	0	0	0	0	0	0	0
	MAGNESIUM HYDROXIDE	1	0.9	2	1.8	2	1.8	0	0	0	0	0	0
	METFORMIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	METFORMIN HYDROCHLORIDE	3	2.6	0	0	1	0.9	1	1.8	0	0	0	0
	MINERAL SUPPLEMENTS	0	0	2	1.8	0	0	0	0	0	0	0	0
	MULTIVITAMINS WITH MINERALS	1	0.9	0	0	0	0	0	0	0	0	0	0
	MULTIVITAMINS, PLAIN	0	0	0	0	0	0	0	0	0	0	1	1.8
	OMEPRAZOLE	0	0	2	1.8	1	0.9	0	0	0	0	0	0
	PANCRELIPASE	1	0.9	0	0	0	0	0	0	0	0	0	0
	PANTOPRAZOLE SODIUM	1	0.9	1	0.9	0	0	0	0	1	1.8	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	PHENTERMINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	POTASSIUM	0	0	0	0	0	0	1	1.8	0	0	1	1.8
	POTASSIUM CHLORIDE	1	0.9	0	0	1	0.9	0	0	1	1.8	0	0
	PRASTERONE	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	PYRIDOXINE HYDROCHLORIDE	2	1.7	2	1.8	3	2.7	1	1.8	1	1.8	0	0
	RABEPRAZOLE SODIUM	0	0	0	0	0	0	1	1.8	1	1.8	0	0
	RANITIDINE HYDROCHLORIDE	5	4.3	1	0.9	4	3.6	0	0	1	1.8	0	0
	RETINOL	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	ROSIGLITAZONE MALEATE	0	0	2	1.8	1	0.9	0	0	0	0	0	0
	SELENIUM	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	TETRACYCLINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	TILACTASE	1	0.9	0	0	0	0	0	0	0	0	0	0
	TOCOPHEROL	3	2.6	4	3.5	2	1.8	1	1.8	0	0	2	3.5
	VITAMINS	0	0	0	0	1	0.9	0	0	0	0	0	0
	VITAMINS NOS	0	0	0	0	3	2.7	0	0	1	1.8	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	ZINC	0	0	0	0	1	0.9	0	0	1	1.8	0	0
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	1	0.9	4	3.5	4	3.6	3	5.4	4	7.1	1	1.8
	ACICLOVIR	0	0	1	0.9	0	0	1	1.8	0	0	0	0
	AMOXICILLIN TRIHYDRATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	AZITHROMYCIN	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	BENZYLPENICILLIN	0	0	2	1.8	1	0.9	1	1.8	0	0	0	0
	CEFALEXIN	0	0	0	0	0	0	0	0	1	1.8	0	0
	LEVOFLOXACIN	0	0	1	0.9	0	0	0	0	0	0	0	0
	NITROFURANTOIN	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	RITONAVIR	0	0	0	0	0	0	0	0	1	1.8	0	0
	VALACICLOVIR HYDROCHLORIDE	0	0	0	0	1	0.9	1	1.8	1	1.8	0	0
	ZIDOVUDINE	0	0	0	0	0	0	0	0	1	1.8	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	ETANERCEPT	0	0	0	0	1	0.9	0	0	0	0	0	0
	METHOTREXATE	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	0.9	4	3.5	5	4.5	1	1.8	0	0	3	5.3
	CLOPIDOGREL SULFATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	CYANOCOBALAMIN	0	0	3	2.6	0	0	1	1.8	0	0	0	0
	FERROUS SULFATE	0	0	0	0	0	0	0	0	0	0	2	3.5
	FOLIC ACID	0	0	0	0	0	0	1	1.8	0	0	0	0
	IRON	0	0	0	0	3	2.7	0	0	0	0	1	1.8
	LECITHIN	1	0.9	0	0	0	0	0	0	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.9	1	0.9	0	0	0	0	0	0
CARDIOVASCULAR SYSTEM	TOTAL	14	12.1	18	15.8	14	12.5	7	12.5	3	5.4	9	15.8
	AMLODIPINE BESILATE	2	1.7	0	0	1	0.9	0	0	0	0	0	0
	ATENOLOL	0	0	2	1.8	2	1.8	1	1.8	0	0	1	1.8
	ATORVASTATIN	4	3.4	4	3.5	2	1.8	2	3.6	0	0	0	0
	BENAZEPRIL HYDROCHLORIDE	1	0.9	0	0	0	0	0	0	0	0	0	0
	BUMETANIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	CARNITINE	0	0	0	0	0	0	1	1.8	0	0	0	0
	CLONIDINE	0	0	1	0.9	1	0.9	0	0	1	1.8	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	DOXAZOSIN MESILATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	FISH OIL	1	0.9	1	0.9	0	0	1	1.8	0	0	2	3.5
	FLUVASTATIN SODIUM	0	0	1	0.9	0	0	0	0	0	0	0	0
	FOSINOPRIL SODIUM	1	0.9	0	0	0	0	0	0	0	0	0	0
	FUROSEMIDE	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	GEMFIBROZIL	0	0	0	0	1	0.9	0	0	0	0	0	0
	HYDROCHLOROTHIAZIDE	4	3.4	6	5.3	3	2.7	1	1.8	0	0	5	8.8
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	LABETALOL	0	0	1	0.9	0	0	0	0	0	0	0	0
	LISINOPRIL	0	0	3	2.6	3	2.7	0	0	1	1.8	1	1.8
	LOSARTAN POTASSIUM	1	0.9	0	0	0	0	0	0	0	0	0	0
	METOPROLOL	0	0	2	1.8	2	1.8	0	0	0	0	0	0
	METOPROLOL SUCCINATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	MINOXIDIL	0	0	1	0.9	1	0.9	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS203.SAS
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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	NICOTINIC ACID	0	0	0	0	1	0.9	1	1.8	0	0	0	0
	NIFEDIPINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.9	1	0.9	0	0	0	0	1	1.8	0	0
	PRAVASTATIN SODIUM	0	0	0	0	2	1.8	0	0	0	0	0	0
	PROPRANOLOL	0	0	0	0	0	0	1	1.8	0	0	0	0
	PROPRANOLOL HYDROCHLORIDE	0	0	2	1.8	1	0.9	1	1.8	0	0	0	0
	SEROTONIN ANTAGONISTS	0	0	0	0	1	0.9	0	0	0	0	0	0
	SIMVASTATIN	2	1.7	0	0	2	1.8	0	0	1	1.8	0	0
	SPIRONOLACTONE	0	0	0	0	0	0	0	0	0	0	1	1.8
	TRIAMTERENE	0	0	0	0	2	1.8	0	0	0	0	0	0
	UBIDECARENONE	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	VERAPAMIL	0	0	0	0	0	0	0	0	0	0	1	1.8
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	TOTAL	2	1.7	0	0	0	0	1	1.8	0	0	0	0
	CALCIPOTRIOL	1	0.9	0	0	0	0	0	0	0	0	0	0
	SMILAX ARISTOLOCHIIFOLIA ROOT	1	0.9	0	0	0	0	0	0	0	0	0	0
	TRIAMCINOLONE	0	0	0	0	0	0	1	1.8	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	12	10.3	13	11.4	9	8.0	6	10.7	8	14.3	9	15.8
	EQUISETUM ARVENSE	0	0	0	0	0	0	0	0	1	1.8	0	0
	ESTRADIOL	0	0	1	0.9	2	1.8	0	0	0	0	1	1.8
	ESTROGENS CONJUGATED	1	0.9	3	2.6	1	0.9	0	0	0	0	0	0
	ETHINYLESTRADIOL	8	6.9	4	3.5	4	3.6	3	5.4	2	3.6	5	8.8
	LEVONORGESTREL	0	0	0	0	0	0	0	0	1	1.8	0	0
	MEDROXYPROGESTERONE ACETATE	2	1.7	3	2.6	1	0.9	0	0	1	1.8	1	1.8
	MICONAZOLE NITRATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	NORETHISTERONE	1	0.9	0	0	0	0	0	0	0	0	1	1.8
	NORETHISTERONE ACETATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	OXYBUTYNIN	0	0	1	0.9	0	0	0	0	0	0	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	PROGESTERONE	0	0	1	0.9	0	0	0	0	0	0	0	0
	RALOXIFENE HYDROCHLORIDE	0	0	0	0	0	0	1	1.8	0	0	0	0
	SERENOA REPENS	0	0	0	0	0	0	1	1.8	0	0	0	0
	SILDENAFIL CITRATE	0	0	1	0.9	0	0	0	0	0	0	0	0
	TAMSULOSIN HYDROCHLORIDE	0	0	0	0	0	0	0	0	2	3.6	0	0
	TESTOSTERONE	0	0	0	0	0	0	1	1.8	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.9	0	0	0	0	0	0	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	26	22.4	30	26.3	33	29.5	13	23.2	15	26.8	15	26.3
	ALENDRONATE SODIUM	0	0	2	1.8	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	ASCORBIC ACID	0	0	2	1.8	0	0	0	0	0	0	0	0
	BOTULINUM TOXIN TYPE A	0	0	1	0.9	0	0	0	0	0	0	0	0
	CARISOPRODOL	0	0	0	0	2	1.8	0	0	0	0	1	1.8
	CELECOXIB	1	0.9	3	2.6	2	1.8	0	0	0	0	0	0
	CHONDROITIN SULFATE	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	COLCHICINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.9	0	0	0	0	0	0	0	0	0	0
	GLUCOSAMINE	1	0.9	0	0	0	0	0	0	0	0	0	0
	IBUPROFEN	20	17.2	16	14.0	17	15.2	9	16.1	7	12.5	9	15.8
	INDOMETACIN	0	0	0	0	0	0	1	1.8	0	0	0	0
	KETOPROFEN	0	0	0	0	0	0	1	1.8	0	0	0	0
	METAXALONE	0	0	0	0	0	0	0	0	0	0	1	1.8
	METHOCARBAMOL	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	NABUMETONE	0	0	0	0	0	0	0	0	1	1.8	0	0
	NAPROXEN	2	1.7	1	0.9	2	1.8	0	0	3	5.4	1	1.8
	NAPROXEN SODIUM	2	1.7	4	3.5	7	6.3	0	0	2	3.6	0	0
	OXAPROZIN	0	0	0	0	0	0	0	0	1	1.8	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	1	0.9	2	1.8	1	1.8	0	0	0	0
	ROFECOXIB	0	0	0	0	0	0	1	1.8	1	1.8	3	5.3
	VALDECOXIB	1	0.9	1	0.9	1	0.9	0	0	1	1.8	0	0
NERVOUS SYSTEM	TOTAL	57	49.1	71	62.3	64	57.1	27	48.2	38	67.9	30	52.6
	ACETAZOLAMIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	ACETYLSALICYLIC ACID	7	6.0	11	9.6	12	10.7	9	16.1	2	3.6	7	12.3
	ALPRAZOLAM	1	0.9	0	0	3	2.7	1	1.8	3	5.4	3	5.3
	AMITRIPTYLINE	0	0	1	0.9	1	0.9	0	0	1	1.8	0	0
	AMITRIPTYLINE HYDROCHLORIDE	1	0.9	1	0.9	0	0	0	0	2	3.6	0	0
	ANTIDEPRESSANTS	1	0.9	0	0	0	0	0	0	0	0	0	0
	ARIPIPRAZOLE	2	1.7	1	0.9	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	BUPROPION HYDROCHLORIDE	7	6.0	8	7.0	4	3.6	4	7.1	7	12.5	0	0
	BUSPIRONE HYDROCHLORIDE	1	0.9	1	0.9	0	0	0	0	0	0	1	1.8
	BUTALBITAL	0	0	0	0	1	0.9	0	0	0	0	0	0
	BUTORPHANOL TARTRATE	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	CARBAMAZEPINE	4	3.4	0	0	0	0	2	3.6	0	0	0	0
	CITALOPRAM	0	0	0	0	1	0.9	0	0	0	0	0	0
	CITALOPRAM HYDROBROMIDE	0	0	1	0.9	3	2.7	1	1.8	0	0	2	3.5
	CLONAZEPAM	2	1.7	6	5.3	1	0.9	0	0	0	0	0	0
	CODEINE PHOSPHATE	0	0	1	0.9	0	0	1	1.8	2	3.6	0	0
	CYCLOBENZAPRINE	0	0	0	0	0	0	1	1.8	0	0	0	0
	DIAZEPAM	1	0.9	0	0	1	0.9	0	0	1	1.8	1	1.8
	DIPHENHYDRAMINE	2	1.7	0	0	4	3.6	0	0	1	1.8	1	1.8
	DOXEPIN	1	0.9	0	0	0	0	0	0	0	0	0	0
	ESCITALOPRAM	4	3.4	2	1.8	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	ETHANOL	0	0	0	0	0	0	0	0	1	1.8	0	0
	FLUOXETINE	1	0.9	0	0	0	0	0	0	0	0	0	0
	FLUOXETINE HYDROCHLORIDE	2	1.7	2	1.8	6	5.4	0	0	2	3.6	0	0
	GABAPENTIN	2	1.7	2	1.8	2	1.8	3	5.4	2	3.6	2	3.5
	GINKGO BILOBA	0	0	0	0	0	0	0	0	1	1.8	0	0
	HYDROXYZINE	0	0	0	0	0	0	1	1.8	0	0	0	0
	HYDROXYZINE EMBONATE	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	LAMOTRIGINE	3	2.6	5	4.4	1	0.9	0	0	3	5.4	1	1.8
	LEVETIRACETAM	0	0	0	0	0	0	0	0	1	1.8	0	0
	LEVODOPA	0	0	0	0	0	0	0	0	0	0	1	1.8
	LITHIUM	4	3.4	3	2.6	5	4.5	1	1.8	2	3.6	3	5.3
	LITHIUM CARBONATE	3	2.6	4	3.5	0	0	2	3.6	0	0	1	1.8
	LORAZEPAM	8	6.9	13	11.4	8	7.1	7	12.5	2	3.6	0	0
	METHYSERGIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	MIRTAZAPINE	4	3.4	2	1.8	0	0	1	1.8	1	1.8	0	0

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	MODAFINIL	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	NEFAZODONE HYDROCHLORIDE	0	0	3	2.6	0	0	0	0	1	1.8	0	0
	NICOTINE	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	OLANZAPINE	12	10.3	2	1.8	3	2.7	1	1.8	2	3.6	3	5.3
	OXCARBAZEPINE	2	1.7	3	2.6	0	0	0	0	3	5.4	0	0
	PARACETAMOL	15	12.9	22	19.3	14	12.5	6	10.7	9	16.1	9	15.8
	PAROXETINE HYDROCHLORIDE	4	3.4	7	6.1	6	5.4	2	3.6	9	16.1	2	3.5
	QUETIAPINE FUMARATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	RISPERIDONE	1	0.9	4	3.5	3	2.7	2	3.6	1	1.8	0	0
	RIZATRIPTAN BENZOATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	SERTRALINE HYDROCHLORIDE	4	3.4	3	2.6	2	1.8	2	3.6	2	3.6	3	5.3
	SUMATRIPTAN SUCCINATE	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	TEMAZEPAM	0	0	0	0	1	0.9	1	1.8	0	0	0	0

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	TIAGABINE HYDROCHLORIDE	1	0.9	0	0	0	0	1	1.8	0	0	0	0
	TOPIRAMATE	3	2.6	0	0	2	1.8	0	0	2	3.6	1	1.8
	TRAMADOL	0	0	0	0	1	0.9	0	0	0	0	0	0
	TRAZODONE	4	3.4	4	3.5	4	3.6	1	1.8	2	3.6	1	1.8
	TRAZODONE HYDROCHLORIDE	1	0.9	0	0	0	0	1	1.8	0	0	0	0
	TRYPTOPHAN, L-	1	0.9	0	0	0	0	0	0	0	0	0	0
	VALPROATE SEMISODIUM	7	6.0	11	9.6	13	11.6	3	5.4	2	3.6	3	5.3
	VALPROIC ACID	1	0.9	0	0	0	0	0	0	0	0	0	0
	VENLAFAXINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	VENLAFAXINE HYDROCHLORIDE	5	4.3	6	5.3	3	2.7	0	0	4	7.1	4	7.0
	ZALEPLON	0	0	2	1.8	2	1.8	0	0	1	1.8	1	1.8
	ZIPRASIDONE HYDROCHLORIDE	1	0.9	1	0.9	0	0	1	1.8	1	1.8	0	0
	ZOLMITRIPTAN	0	0	0	0	1	0.9	0	0	0	0	0	0
	ZOLPIDEM TARTRATE	3	2.6	9	7.9	5	4.5	3	5.4	1	1.8	3	5.3

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	TOTAL	20	17.2	19	16.7	22	19.6	12	21.4	15	26.8	12	21.1
	ALLERGY MEDICATION	0	0	0	0	0	0	0	0	1	1.8	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	0	0	0	0	0	0	1	1.8	0	0
	BENZONATATE	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	BUDESONIDE	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	CAMPHOR	0	0	0	0	0	0	0	0	1	1.8	0	0
	CETIRIZINE HYDROCHLORIDE	2	1.7	1	0.9	1	0.9	1	1.8	1	1.8	2	3.5
	CODEINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	DESLORATADINE	1	0.9	0	0	0	0	0	0	0	0	2	3.5
	DIPHENHYDRAMINE	0	0	0	0	0	0	0	0	0	0	1	1.8
	DIPHENHYDRAMINE HYDROCHLORIDE	3	2.6	2	1.8	7	6.3	1	1.8	1	1.8	0	0
	DOXYLAMINE SUCCINATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	EPINEPHRINE	0	0	0	0	0	0	0	0	1	1.8	0	0
	FEXOFENADINE HYDROCHLORIDE	1	0.9	2	1.8	2	1.8	1	1.8	1	1.8	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS203.SAS
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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	FLUTICASONE PROPIONATE	2	1.7	2	1.8	2	1.8	1	1.8	3	5.4	4	7.0
	GUAIFENESIN	0	0	1	0.9	1	0.9	0	0	1	1.8	0	0
	HYDROCODONE	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	IPRATROPIUM BROMIDE	1	0.9	0	0	1	0.9	1	1.8	0	0	0	0
	LORATADINE	2	1.7	1	0.9	2	1.8	0	0	2	3.6	1	1.8
	MECLOZINE	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	MOMETASONE FUROATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	MONTELUKAST SODIUM	0	0	0	0	0	0	0	0	0	0	1	1.8
	PIRBUTEROL ACETATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	PROMETHAZINE	0	0	0	0	0	0	0	0	0	0	1	1.8
	PROMETHAZINE HYDROCHLORIDE	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	PSEUDOEPHEDRINE	0	0	0	0	1	0.9	1	1.8	0	0	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	2	1.7	3	2.6	2	1.8	3	5.4	1	1.8	1	1.8
	PSEUDOEPHEDRINE SULFATE	0	0	1	0.9	1	0.9	0	0	0	0	0	0

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	SALBUTAMOL	8	6.9	7	6.1	5	4.5	5	8.9	2	3.6	3	5.3
	SALMETEROL XINAFOATE	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	TRIAMCINOLONE ACETONIDE	2	1.7	4	3.5	1	0.9	0	0	0	0	0	0
SENSORY ORGANS	TOTAL	1	0.9	0	0	1	0.9	0	0	1	1.8	0	0
	BIMATOPROST	1	0.9	0	0	0	0	0	0	0	0	0	0
	LATANOPROST	0	0	0	0	0	0	0	0	1	1.8	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	4	3.4	7	6.1	6	5.4	3	5.4	2	3.6	4	7.0
	CORTISONE	1	0.9	0	0	0	0	0	0	0	0	0	0
	LEVOTHYROXINE	0	0	1	0.9	0	0	0	0	0	0	0	0
	LEVOTHYROXINE SODIUM	3	2.6	5	4.4	6	5.4	3	5.4	2	3.6	3	5.3
	LIOTHYRONINE SODIUM	0	0	0	0	1	0.9	1	1.8	0	0	0	0
	MELATONIN	0	0	1	0.9	0	0	0	0	0	0	0	0
	THYROID	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	TOTAL	5	4.3	1	0.9	5	4.5	3	5.4	5	8.9	3	5.3
	BORAGE OIL	0	0	0	0	0	0	0	0	0	0	1	1.8
	ECHINACEA EXTRACT	0	0	0	0	1	0.9	2	3.6	0	0	1	1.8
	GINGER	0	0	0	0	0	0	0	0	2	3.6	0	0
	HERBAL EXTRACTS NOS	0	0	0	0	1	0.9	0	0	0	0	0	0
	HERBAL PREPARATION	1	0.9	1	0.9	2	1.8	2	3.6	3	5.4	0	0
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.9	0	0	0	0	0	0
	KAVA-KAVA RHIZOMA	1	0.9	0	0	0	0	0	0	0	0	0	0
	LINSEED OIL	2	1.7	0	0	0	0	0	0	0	0	1	1.8
	ST. JOHN'S WORT	2	1.7	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.5 Prior Medications of Interest Per Patient
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIDEPRESSANT	0	136	76.0	124	68.9	140	77.8
	1	31	17.3	31	17.2	28	15.6
	2	6	3.4	14	7.8	9	5.0
	3	6	3.4	11	6.1	3	1.7
ANXIOLYTICS/HYPNOTICS	0	153	85.5	143	79.4	145	80.6
	1	16	8.9	25	13.9	28	15.6
	2	5	2.8	9	5.0	4	2.2
	3	5	2.8	3	1.7	3	1.7
MOOD STABILIZERS	0	150	83.8	149	82.8	148	82.2
	1	21	11.7	22	12.2	26	14.4
	2	4	2.2	3	1.7	2	1.1
	3	4	2.2	6	3.3	4	2.2
ANTIPSYCHOTIC	0	158	88.3	168	93.3	170	94.4
	1	21	11.7	10	5.6	8	4.4
	2	0	0.0	2	1.1	2	1.1
	3	0	0.0	0	0.0	0	0.0
COMBINATION OF ABOVE	0	165	92.2	173	96.1	175	97.2

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS208.SAS
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Table 11.1.7.5 Prior Medications of Interest Per Patient
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
COMBINATION OF ABOVE 4	14	7.8	7	3.9	5	2.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS208.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY CONCOMITANT MEDICATION		136	76.0	149	82.8	142	78.9
ALIMENTARY TRACT AND METABOLISM	TOTAL	62	34.6	68	37.8	60	33.3
	ANTACIDS	2	1.1	0	0	0	0
	ASCORBIC ACID	6	3.4	5	2.8	3	1.7
	ATROPINE SULFATE	1	0.6	0	0	0	0
	BISACODYL	1	0.6	0	0	2	1.1
	BISMUTH SUBSALICYLATE	3	1.7	1	0.6	2	1.1
	CALCIUM	4	2.2	5	2.8	6	3.3
	CALCIUM ASCORBATE	0	0	0	0	1	0.6
	CALCIUM CARBONATE	7	3.9	14	7.8	9	5.0
	CALCIUM CITRATE	0	0	0	0	1	0.6
	CHARCOAL, ACTIVATED	0	0	1	0.6	0	0
	CIMETIDINE	0	0	5	2.8	0	0
	DEXAMETHASONE	0	0	0	0	1	0.6
	DIHYDROXYALUMINUM SODIUM CARBONATE	5	2.8	2	1.1	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DOCUSATE CALCIUM	1	0.6	0	0	0	0
	DOCUSATE SODIUM	2	1.1	2	1.1	1	0.6
	DOLASETRON MESILATE	0	0	0	0	1	0.6
	DOXYCYCLINE	0	0	0	0	1	0.6
	ENEMAS	2	1.1	0	0	0	0
	ERGOCALCIFEROL	19	10.6	20	11.1	23	12.8
	ESOMEPRAZOLE	5	2.8	2	1.1	2	1.1
	FAMOTIDINE	0	0	3	1.7	3	1.7
	FERROUS FUMARATE	0	0	0	0	1	0.6
	FERROUS SULFATE	0	0	1	0.6	0	0
	FIBRE, DIETARY	2	1.1	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.6
	GLIPIZIDE	0	0	0	0	1	0.6
	GLUCOSE MONOHYDRATE	1	0.6	0	0	0	0
	HYOSCYAMINE	0	0	0	0	1	0.6
	HYOSCYAMINE SULFATE	1	0.6	1	0.6	0	0
	INSULIN	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	LACTOBACILLUS ACIDOPHILUS	1	0.6	0	0	0	0
	LANSOPRAZOLE	4	2.2	1	0.6	3	1.7
	LAXATIVES	0	0	1	0.6	0	0
	LOPERAMIDE	0	0	1	0.6	0	0
	LOPERAMIDE HYDROCHLORIDE	1	0.6	1	0.6	1	0.6
	MACROGOL	1	0.6	0	0	0	0
	MAGNESIUM	0	0	1	0.6	0	0
	MAGNESIUM HYDROXIDE	2	1.1	3	1.7	2	1.1
	MAGNESIUM SULFATE	0	0	0	0	1	0.6
	METFORMIN	0	0	0	0	1	0.6
	METFORMIN HYDROCHLORIDE	4	2.2	0	0	2	1.1
	METOCLOPRAMIDE	0	0	0	0	1	0.6
	MINERAL SUPPLEMENTS	0	0	1	0.6	0	0
	MULTIVITAMINS WITH MINERALS	1	0.6	0	0	0	0
	NPH INSULIN	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	NYSTATIN	0	0	0	0	1	0.6
	OMEPRAZOLE	0	0	3	1.7	1	0.6
	ONDANSETRON HYDROCHLORIDE	0	0	1	0.6	0	0
	PANCRELIPASE	1	0.6	0	0	0	0
	PANTOPRAZOLE SODIUM	1	0.6	3	1.7	4	2.2
	PHOSPHORIC ACID	1	0.6	0	0	0	0
	PIOGLITAZONE HYDROCHLORIDE	1	0.6	0	0	1	0.6
	POTASSIUM	1	0.6	1	0.6	2	1.1
	POTASSIUM CHLORIDE	1	0.6	2	1.1	0	0
	PRASTERONE	1	0.6	0	0	0	0
	PYRIDOXINE HYDROCHLORIDE	3	1.7	3	1.7	3	1.7
	RABEPRAZOLE SODIUM	1	0.6	2	1.1	0	0
	RANITIDINE	0	0	1	0.6	1	0.6
	RANITIDINE HYDROCHLORIDE	5	2.8	3	1.7	4	2.2
	RETINOL	0	0	1	0.6	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	ROSIGLITAZONE MALEATE	0	0	2	1.1	1	0.6
	SELENIUM	0	0	1	0.6	1	0.6
	SENNA	1	0.6	0	0	0	0
	SIMETICONE	1	0.6	0	0	0	0
	SODIUM BICARBONATE	0	0	1	0.6	0	0
	TEGASEROD	0	0	0	0	1	0.6
	TETRACYCLINE	0	0	0	0	1	0.6
	THIAMINE	0	0	0	0	1	0.6
	TILACTASE	1	0.6	0	0	0	0
	TOCOPHEROL	5	2.8	3	1.7	5	2.8
	VITAMINS	0	0	0	0	1	0.6
	VITAMINS NOS	0	0	1	0.6	4	2.2
	ZINC	0	0	1	0.6	1	0.6
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	12	6.7	12	6.7	18	10.0
	ACICLOVIR	1	0.6	1	0.6	0	0
	AMOXICILLIN	1	0.6	2	1.1	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	ANTIBIOTICS	1	0.6	0	0	1	0.6
	AZITHROMYCIN	2	1.1	3	1.7	4	2.2
	BENZYLPENICILLIN	1	0.6	1	0.6	0	0
	CEFALEXIN	0	0	1	0.6	1	0.6
	CEFALEXIN MONOHYDRATE	1	0.6	0	0	1	0.6
	CEFTRIAXONE SODIUM	0	0	1	0.6	0	0
	CLARITHROMYCIN	0	0	0	0	1	0.6
	CLAVULANATE POTASSIUM	2	1.1	1	0.6	3	1.7
	FLUCONAZOLE	1	0.6	0	0	1	0.6
	GATIFLOXACIN	0	0	0	0	1	0.6
	GENTAMICIN	0	0	0	0	1	0.6
	INFLUENZA VIRUS VACCINE POLYVALENT	0	0	0	0	1	0.6
	LEVOFLOXACIN	0	0	2	1.1	2	1.1
	NITROFURANTOIN	0	0	0	0	1	0.6
	RITONAVIR	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	SULFAMETHOXAZOLE	1	0.6	0	0	1	0.6
	VALACICLOVIR HYDROCHLORIDE	1	0.6	1	0.6	1	0.6
	ZIDOVUDINE	0	0	1	0.6	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	2	1.1
	ETANERCEPT	0	0	0	0	1	0.6
	METHOTREXATE	0	0	0	0	1	0.6
ANTIPARASITIC PRODUCTS,INSECTIC-IDES AND REPELLENTS	TOTAL	1	0.6	0	0	0	0
	PERMETHRIN	1	0.6	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	3	1.7	4	2.2	12	6.7
	CLOPIDOGREL SULFATE	0	0	0	0	2	1.1
	CYANOCOBALAMIN	1	0.6	3	1.7	0	0
	FERROUS SULFATE	0	0	0	0	3	1.7
	FOLIC ACID	1	0.6	0	0	1	0.6
	HEPARIN	0	0	0	0	2	1.1
	HEPARIN-FRACTION, SODIUM SALT	0	0	0	0	2	1.1

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD AND BLOOD FORMING ORGANS	I.V. SOLUTIONS	1	0.6	0	0	0	0
	IRON	0	0	0	0	3	1.7
	LACTATED RINGER'S INJECTION	0	0	0	0	1	0.6
	LECITHIN	1	0.6	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.6	2	1.1
CARDIOVASCULAR SYSTEM	TOTAL	21	11.7	23	12.8	25	13.9
	AMLODIPINE BESILATE	2	1.1	0	0	3	1.7
	ATENOLOL	1	0.6	2	1.1	4	2.2
	ATORVASTATIN	6	3.4	4	2.2	2	1.1
	BENAZEPRIL HYDROCHLORIDE	1	0.6	0	0	0	0
	CARNITINE	1	0.6	0	0	0	0
	CLONIDINE	0	0	2	1.1	1	0.6
	DOXAZOSIN MESILATE	1	0.6	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.6
	FISH OIL	3	1.7	1	0.6	2	1.1
	FLUVASTATIN SODIUM	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	FOSINOPRIL SODIUM	1	0.6	0	0	0	0
	FUROSEMIDE	0	0	2	1.1	1	0.6
	GEMFIBROZIL	0	0	0	0	1	0.6
	HYDROCHLOROTHIAZIDE	5	2.8	7	3.9	9	5.0
	IPRATROPIUM BROMIDE	0	0	0	0	1	0.6
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.6
	LABETALOL	0	0	1	0.6	0	0
	LISINOPRIL	0	0	4	2.2	4	2.2
	LOSARTAN POTASSIUM	1	0.6	0	0	0	0
	LOVASTATIN	0	0	0	0	1	0.6
	METOPROLOL	0	0	3	1.7	2	1.1
	METOPROLOL SUCCINATE	1	0.6	0	0	0	0
	MINOXIDIL	0	0	1	0.6	1	0.6
	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.6	0	0
	NICOTINIC ACID	1	0.6	0	0	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	NIFEDIPINE	0	0	0	0	1	0.6
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.6	2	1.1	0	0
	PRAVASTATIN SODIUM	0	0	0	0	2	1.1
	PROPRANOLOL	1	0.6	1	0.6	0	0
	PROPRANOLOL HYDROCHLORIDE	1	0.6	2	1.1	1	0.6
	RAMIPRIL	0	0	0	0	1	0.6
	SIMVASTATIN	1	0.6	1	0.6	2	1.1
	SPIRONOLACTONE	0	0	0	0	1	0.6
	TRIAMTERENE	0	0	0	0	2	1.1
	UBIDECARENONE	0	0	2	1.1	0	0
	VALSARTAN	0	0	1	0.6	0	0
	VERAPAMIL	0	0	0	0	2	1.1
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.6	1	0.6
DERMATOLOGICALS	TOTAL	3	1.7	3	1.7	2	1.1
	CALCIPOTRIOL	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	CLOBETASOL PROPIONATE	0	0	1	0.6	0	0
	COLECALCIFEROL	0	0	0	0	1	0.6
	DIPHENHYDRAMINE HYDROCHLORIDE	0	0	0	0	1	0.6
	GLYCEROL	0	0	1	0.6	0	0
	HYDROCORTISONE	0	0	2	1.1	0	0
	NEOMYCIN SULFATE	0	0	1	0.6	1	0.6
	PETROLATUM	1	0.6	0	0	0	0
	TRIAMCINOLONE	1	0.6	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	22	12.3	20	11.1	19	10.6
	CLINDAMYCIN	1	0.6	0	0	0	0
	EQUISETUM ARVENSE	0	0	1	0.6	0	0
	ESTRADIOL	0	0	1	0.6	3	1.7
	ESTROGENS CONJUGATED	1	0.6	3	1.7	1	0.6
	ETHINYLESTRADIOL	12	6.7	5	2.8	10	5.6
	LEVONORGESTREL	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	MEDROXYPROGESTERONE ACETATE	2	1.1	4	2.2	2	1.1
	MICONAZOLE NITRATE	0	0	0	0	1	0.6
	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	1	0.6
	NORETHISTERONE	1	0.6	0	0	1	0.6
	NORETHISTERONE ACETATE	0	0	1	0.6	0	0
	OXYBUTYNIN	0	0	1	0.6	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.6	0	0
	PHENAZOPYRIDINE HYDROCHLORIDE	1	0.6	0	0	0	0
	PROGESTERONE	0	0	1	0.6	0	0
	RALOXIFENE HYDROCHLORIDE	1	0.6	0	0	0	0
	SERENOA REPENS	1	0.6	0	0	0	0
	SILDENAFIL CITRATE	1	0.6	1	0.6	0	0
	TAMSULOSIN HYDROCHLORIDE	0	0	2	1.1	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	TESTOSTERONE	1	0.6	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.6	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	56	31.3	62	34.4	63	35.0
	ALENDRONATE SODIUM	0	0	2	1.1	0	0
	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	1	0.6
	ASCORBIC ACID	0	0	2	1.1	0	0
	CARISOPRODOL	0	0	1	0.6	1	0.6
	CELECOXIB	1	0.6	5	2.8	7	3.9
	CHONDROITIN SULFATE	1	0.6	0	0	1	0.6
	COLCHICINE	0	0	0	0	1	0.6
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.6	0	0	0	0
	GLUCOSAMINE	1	0.6	0	0	0	0
	IBUPROFEN	43	24.0	38	21.1	36	20.0
	KETOPROFEN	1	0.6	0	0	0	0
	METAXALONE	0	0	0	0	2	1.1

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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	NABUMETONE	0	0	1	0.6	0	0
	NAPROXEN	2	1.1	4	2.2	3	1.7
	NAPROXEN SODIUM	8	4.5	5	2.8	14	7.8
	ORPHENADRINE CITRATE	0	0	1	0.6	0	0
	OXAPROZIN	0	0	1	0.6	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	2	1.1	0	0	2	1.1
	ROFECOXIB	1	0.6	1	0.6	3	1.7
	TIZANIDINE HYDROCHLORIDE	1	0.6	0	0	1	0.6
	VALDECOXIB	1	0.6	5	2.8	1	0.6
NERVOUS SYSTEM	TOTAL	71	39.7	77	42.8	85	47.2
	ACETAZOLAMIDE	0	0	1	0.6	0	0
	ACETYLSALICYLIC ACID	27	15.1	26	14.4	33	18.3
	ALPRAZOLAM	0	0	0	0	1	0.6
	AMANTADINE	0	0	1	0.6	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	AMITRIPTYLINE HYDROCHLORIDE	0	0	1	0.6	0	0
	ANAESTHETICS, GENERAL	0	0	0	0	2	1.1
	ANAESTHETICS, LOCAL	0	0	1	0.6	0	0
	ANALGESICS	0	0	0	0	1	0.6
	ARIPIPRAZOLE	1	0.6	0	0	0	0
	BENZATROPINE MESILATE	2	1.1	1	0.6	1	0.6
	BUPROPION HYDROCHLORIDE	0	0	2	1.1	0	0
	BUTORPHANOL TARTRATE	0	0	0	0	1	0.6
	CITALOPRAM HYDROBROMIDE	0	0	0	0	1	0.6
	CLONAZEPAM	0	0	0	0	3	1.7
	CODEINE PHOSPHATE	0	0	0	0	2	1.1
	DIAZEPAM	0	0	0	0	2	1.1
	DIPHENHYDRAMINE	2	1.1	1	0.6	3	1.7
	DISULFIRAM	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	DOXEPIN HYDROCHLORIDE	0	0	1	0.6	0	0
	ESCITALOPRAM	1	0.6	0	0	1	0.6
	ETHANOL	1	0.6	0	0	5	2.8
	FENTANYL	0	0	1	0.6	0	0
	GABAPENTIN	0	0	1	0.6	2	1.1
	GINKGO BILOBA	0	0	1	0.6	0	0
	HYDROCODONE BITARTRATE	1	0.6	0	0	0	0
	HYDROMORPHONE HYDROCHLORIDE	0	0	0	0	2	1.1
	HYDROXYZINE EMBONATE	0	0	1	0.6	0	0
	LEVETIRACETAM	0	0	1	0.6	0	0
	LEVODOPA	0	0	0	0	1	0.6
	LITHIUM	0	0	1	0.6	1	0.6
	LITHIUM CARBONATE	1	0.6	0	0	0	0
	LORAZEPAM	17	9.5	10	5.6	15	8.3
	MEPYRAMINE MALEATE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	MIDAZOLAM HYDROCHLORIDE	0	0	0	0	1	0.6
	MORPHINE HYDROCHLORIDE	0	0	1	0.6	0	0
	MORPHINE SULFATE	1	0.6	0	0	1	0.6
	NICOTINE	1	0.6	1	0.6	0	0
	OXCARBAZEPINE	0	0	0	0	1	0.6
	OXYCODONE HYDROCHLORIDE	0	0	1	0.6	0	0
	PARACETAMOL	41	22.9	43	23.9	37	20.6
	PETHIDINE HYDROCHLORIDE	0	0	0	0	2	1.1
	PHENYTOIN SODIUM	0	0	0	0	1	0.6
	PROCAINE HYDROCHLORIDE	1	0.6	0	0	0	0
	QUETIAPINE FUMARATE	0	0	0	0	1	0.6
	RISPERIDONE	0	0	1	0.6	2	1.1
	RIZATRIPTAN BENZOATE	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	SERTRALINE HYDROCHLORIDE	0	0	1	0.6	0	0
	SUMATRIPTAN SUCCINATE	0	0	0	0	2	1.1
	TOPIRAMATE	0	0	1	0.6	0	0
	VALERIANA OFFICINALIS ROOT	0	0	1	0.6	0	0
	ZALEPLON	0	0	0	0	1	0.6
	ZOLMITRIPTAN	0	0	0	0	1	0.6
	ZOLPIDEM TARTRATE	8	4.5	12	6.7	15	8.3
RESPIRATORY SYSTEM	TOTAL	38	21.2	43	23.9	52	28.9
	ALLERGY MEDICATION	0	0	1	0.6	0	0
	ANTI-ASTHMATICS	0	0	1	0.6	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	1	0.6	0	0
	AZELASTINE HYDROCHLORIDE	0	0	0	0	1	0.6
	BECLOMETASONE DIPROPIONATE	0	0	0	0	1	0.6
	BENZONATATE	0	0	1	0.6	2	1.1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	BUDESONIDE	0	0	2	1.1	1	0.6
	CAMPHOR	1	0.6	1	0.6	0	0
	CETIRIZINE HYDROCHLORIDE	3	1.7	3	1.7	5	2.8
	CHLORPHENAMINE MALEATE	0	0	2	1.1	0	0
	CODEINE PHOSPHATE	0	0	1	0.6	1	0.6
	COUGH AND COLD PREPARATIONS	0	0	0	0	2	1.1
	DESLORATADINE	1	0.6	0	0	2	1.1
	DEXBROMPHENIRAMINE MALEATE	0	0	0	0	1	0.6
	DEXTROMETHORPHAN HYDROBROMIDE	0	0	0	0	2	1.1
	DIPHENHYDRAMINE	1	0.6	0	0	0	0
	DIPHENHYDRAMINE HYDROCHLORIDE	2	1.1	2	1.1	10	5.6
	EPINEPHRINE	0	0	1	0.6	0	0
	ETHANOL	1	0.6	0	0	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	FEXOFENADINE HYDROCHLORIDE	4	2.2	5	2.8	4	2.2
	FLUTICASONE PROPIONATE	4	2.2	7	3.9	9	5.0
	GARLIC	1	0.6	0	0	0	0
	GUAIFENESIN	5	2.8	3	1.7	7	3.9
	HYDROCODONE	1	0.6	0	0	1	0.6
	IPRATROPIUM BROMIDE	2	1.1	0	0	2	1.1
	LORATADINE	2	1.1	5	2.8	6	3.3
	MECLOZINE	0	0	1	0.6	1	0.6
	MECLOZINE HYDROCHLORIDE	0	0	0	0	1	0.6
	MEPYRAMINE MALEATE	0	0	1	0.6	0	0
	MOMETASONE FUROATE	1	0.6	0	0	1	0.6
	MONTELUKAST SODIUM	0	0	0	0	2	1.1
	NASAL DECONGESTANTS FOR SYSTEMIC USE	0	0	0	0	1	0.6
	OTHER COLD COMBINATION PREPARATIONS	1	0.6	1	0.6	0	0

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	OXYMETAZOLINE HYDROCHLORIDE	0	0	2	1.1	4	2.2
	PARACETAMOL	0	0	1	0.6	2	1.1
	PHENYLEPHRINE HYDROCHLORIDE	0	0	1	0.6	1	0.6
	PHENYLPROPANOLAMINE HYDROCHLORIDE	0	0	0	0	1	0.6
	PIRBUTEROL ACETATE	0	0	0	0	1	0.6
	PROMETHAZINE HYDROCHLORIDE	0	0	1	0.6	2	1.1
	PSEUDOEPHEDRINE	0	0	0	0	1	0.6
	PSEUDOEPHEDRINE HYDROCHLORIDE	6	3.4	4	2.2	8	4.4
	PSEUDOEPHEDRINE SULFATE	0	0	1	0.6	1	0.6
	SALBUTAMOL	13	7.3	12	6.7	10	5.6
	SALMETEROL XINAFOATE	0	0	1	0.6	1	0.6
	SODIUM CHLORIDE	0	0	0	0	1	0.6
	TERPIN HYDRATE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	TRIAMCINOLONE ACETONIDE	2	1.1	5	2.8	1	0.6
SENSORY ORGANS	TOTAL	4	2.2	3	1.7	2	1.1
	BIMATOPROST	1	0.6	0	0	0	0
	HYDROCORTISONE	1	0.6	0	0	1	0.6
	KETOROLAC TROMETHAMINE	1	0.6	2	1.1	0	0
	LATANOPROST	0	0	1	0.6	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.6
	TROPICAMIDE	1	0.6	0	0	0	0
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	7	3.9	10	5.6	16	8.9
	ACTONEL	0	0	0	0	1	0.6
	CORTISONE	1	0.6	1	0.6	1	0.6
	DEXAMETHASONE	0	0	0	0	1	0.6
	LEVOTHYROXINE	0	0	1	0.6	0	0
	LEVOTHYROXINE SODIUM	6	3.4	7	3.9	9	5.0
	LIOTHYRONINE SODIUM	1	0.6	0	0	1	0.6

(Continued)

Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	METHYLPREDNISOLONE	0	0	0	0	2	1.1
	PREDNISONE	0	0	1	0.6	2	1.1
	THYROID	0	0	0	0	2	1.1
VARIOUS	TOTAL	7	3.9	6	3.3	10	5.6
	BARIUM	0	0	1	0.6	0	0
	BORAGE OIL	0	0	0	0	1	0.6
	DIAGNOSTIC RADIOPHARMACEUTICA-LS	0	0	0	0	1	0.6
	ECHINACEA EXTRACT	2	1.1	0	0	4	2.2
	GINGER	0	0	1	0.6	0	0
	HERBAL EXTRACTS NOS	0	0	0	0	1	0.6
	HERBAL PREPARATION	3	1.7	3	1.7	3	1.7
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.6
	LINSEED OIL	2	1.1	0	0	1	0.6
	NALOXONE HYDROCHLORIDE	0	0	1	0.6	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY COMCOMITANT MEDICATION		133	77.3	144	84.7	135	79.9
ALIMENTARY TRACT AND METABOLISM	TOTAL	59	34.3	67	39.4	56	33.1
	ANTACIDS	2	1.2	0	0	0	0
	ASCORBIC ACID	5	2.9	5	2.9	3	1.8
	ATROPINE SULFATE	1	0.6	0	0	0	0
	BISACODYL	1	0.6	0	0	2	1.2
	BISMUTH SUBSALICYLATE	3	1.7	1	0.6	2	1.2
	CALCIUM	4	2.3	5	2.9	5	3.0
	CALCIUM ASCORBATE	0	0	0	0	1	0.6
	CALCIUM CARBONATE	7	4.1	14	8.2	9	5.3
	CALCIUM CITRATE	0	0	0	0	1	0.6
	CHARCOAL, ACTIVATED	0	0	1	0.6	0	0
	CIMETIDINE	0	0	4	2.4	0	0
	DEXAMETHASONE	0	0	0	0	1	0.6
	DIHYDROXYALUMINUM SODIUM CARBONATE	5	2.9	1	0.6	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DOCUSATE CALCIUM	1	0.6	0	0	0	0
	DOCUSATE SODIUM	2	1.2	2	1.2	0	0
	DOLASETRON MESILATE	0	0	0	0	1	0.6
	DOXYCYCLINE	0	0	0	0	1	0.6
	ENEMAS	2	1.2	0	0	0	0
	ERGOCALCIFEROL	18	10.5	20	11.8	23	13.6
	ESOMEPRAZOLE	5	2.9	2	1.2	2	1.2
	FAMOTIDINE	0	0	3	1.8	2	1.2
	FERROUS FUMARATE	0	0	0	0	1	0.6
	FERROUS SULFATE	0	0	1	0.6	0	0
	FIBRE, DIETARY	2	1.2	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.6
	GLIPIZIDE	0	0	0	0	1	0.6
	GLUCOSE MONOHYDRATE	1	0.6	0	0	0	0
	HYOSCYAMINE	0	0	0	0	1	0.6
	HYOSCYAMINE SULFATE	1	0.6	1	0.6	0	0
	INSULIN	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	LACTOBACILLUS ACIDOPHILUS	1	0.6	0	0	0	0
	LANSOPRAZOLE	3	1.7	1	0.6	2	1.2
	LAXATIVES	0	0	1	0.6	0	0
	LOPERAMIDE	0	0	1	0.6	0	0
	LOPERAMIDE HYDROCHLORIDE	1	0.6	1	0.6	1	0.6
	MACROGOL	1	0.6	0	0	0	0
	MAGNESIUM	0	0	1	0.6	0	0
	MAGNESIUM HYDROXIDE	2	1.2	3	1.8	2	1.2
	MAGNESIUM SULFATE	0	0	0	0	1	0.6
	METFORMIN	0	0	0	0	1	0.6
	METFORMIN HYDROCHLORIDE	4	2.3	0	0	2	1.2
	MINERAL SUPPLEMENTS	0	0	1	0.6	0	0
	MULTIVITAMINS WITH MINERALS	1	0.6	0	0	0	0
	NPH INSULIN	0	0	0	0	1	0.6
	NYSTATIN	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	OMEPRAZOLE	0	0	3	1.8	1	0.6
	ONDANSETRON HYDROCHLORIDE	0	0	1	0.6	0	0
	PANCRELIPASE	1	0.6	0	0	0	0
	PANTOPRAZOLE SODIUM	1	0.6	3	1.8	2	1.2
	PIOGLITAZONE HYDROCHLORIDE	1	0.6	0	0	1	0.6
	POTASSIUM	1	0.6	1	0.6	2	1.2
	POTASSIUM CHLORIDE	1	0.6	2	1.2	0	0
	PRASTERONE	1	0.6	0	0	0	0
	PYRIDOXINE HYDROCHLORIDE	3	1.7	3	1.8	3	1.8
	RABEPRAZOLE SODIUM	1	0.6	2	1.2	0	0
	RANITIDINE	0	0	1	0.6	1	0.6
	RANITIDINE HYDROCHLORIDE	5	2.9	3	1.8	4	2.4
	RETINOL	0	0	1	0.6	1	0.6
	ROSIGLITAZONE MALEATE	0	0	2	1.2	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	SELENIUM	0	0	1	0.6	1	0.6
	SENNA	1	0.6	0	0	0	0
	SIMETICONE	1	0.6	0	0	0	0
	SODIUM BICARBONATE	0	0	1	0.6	0	0
	TEGASEROD	0	0	0	0	1	0.6
	TETRACYCLINE	0	0	0	0	1	0.6
	THIAMINE	0	0	0	0	1	0.6
	TILACTASE	1	0.6	0	0	0	0
	TOCOPHEROL	4	2.3	3	1.8	4	2.4
	VITAMINS	0	0	0	0	1	0.6
	VITAMINS NOS	0	0	1	0.6	4	2.4
	ZINC	0	0	1	0.6	1	0.6
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	12	7.0	12	7.1	18	10.7
	ACICLOVIR	1	0.6	1	0.6	0	0
	AMOXICILLIN	1	0.6	2	1.2	1	0.6
	ANTIBIOTICS	1	0.6	0	0	1	0.6
	AZITHROMYCIN	2	1.2	3	1.8	4	2.4

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	BENZYLPENICILLIN	1	0.6	1	0.6	0	0
	CEFALEXIN	0	0	1	0.6	1	0.6
	CEFALEXIN MONOHYDRATE	1	0.6	0	0	1	0.6
	CEFTRIAXONE SODIUM	0	0	1	0.6	0	0
	CLARITHROMYCIN	0	0	0	0	1	0.6
	CLAVULANATE POTASSIUM	2	1.2	1	0.6	3	1.8
	FLUCONAZOLE	1	0.6	0	0	1	0.6
	GATIFLOXACIN	0	0	0	0	1	0.6
	GENTAMICIN	0	0	0	0	1	0.6
	INFLUENZA VIRUS VACCINE POLYVALENT	0	0	0	0	1	0.6
	LEVOFLOXACIN	0	0	2	1.2	2	1.2
	NITROFURANTOIN	0	0	0	0	1	0.6
	RITONAVIR	0	0	1	0.6	0	0
	SULFAMETHOXAZOLE	1	0.6	0	0	1	0.6
	VALACICLOVIR HYDROCHLORIDE	1	0.6	1	0.6	1	0.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS205.SAS
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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	ZIDOVUDINE	0	0	1	0.6	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	2	1.2
	ETANERCEPT	0	0	0	0	1	0.6
	METHOTREXATE	0	0	0	0	1	0.6
ANTIPARASITIC PRODUCTS,INSECTICIDES AND REPELLENTS	TOTAL	1	0.6	0	0	0	0
	PERMETHRIN	1	0.6	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	3	1.7	4	2.4	11	6.5
	CLOPIDOGREL SULFATE	0	0	0	0	2	1.2
	CYANOCOBALAMIN	1	0.6	3	1.8	0	0
	FERROUS SULFATE	0	0	0	0	3	1.8
	FOLIC ACID	1	0.6	0	0	1	0.6
	HEPARIN	0	0	0	0	2	1.2
	HEPARIN-FRACTION, SODIUM SALT	0	0	0	0	1	0.6
	I.V. SOLUTIONS	1	0.6	0	0	0	0
	IRON	0	0	0	0	3	1.8

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD AND BLOOD FORMING ORGANS	LECITHIN	1	0.6	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.6	1	0.6
CARDIOVASCULAR SYSTEM	TOTAL	21	12.2	23	13.5	24	14.2
	AMLODIPINE BESILATE	2	1.2	0	0	3	1.8
	ATENOLOL	1	0.6	2	1.2	3	1.8
	ATORVASTATIN	6	3.5	4	2.4	2	1.2
	BENAZEPRIL HYDROCHLORIDE	1	0.6	0	0	0	0
	CARNITINE	1	0.6	0	0	0	0
	CLONIDINE	0	0	2	1.2	1	0.6
	DOXAZOSIN MESILATE	1	0.6	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.6
	FISH OIL	3	1.7	1	0.6	2	1.2
	FLUVASTATIN SODIUM	0	0	1	0.6	0	0
	FOSINOPRIL SODIUM	1	0.6	0	0	0	0
	FUROSEMIDE	0	0	2	1.2	1	0.6
	GEMFIBROZIL	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	HYDROCHLOROTHIAZIDE	5	2.9	7	4.1	9	5.3
	IPRATROPIUM BROMIDE	0	0	0	0	1	0.6
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.6
	LABETALOL	0	0	1	0.6	0	0
	LISINOPRIL	0	0	4	2.4	4	2.4
	LOSARTAN POTASSIUM	1	0.6	0	0	0	0
	LOVASTATIN	0	0	0	0	1	0.6
	METOPROLOL	0	0	3	1.8	2	1.2
	METOPROLOL SUCCINATE	1	0.6	0	0	0	0
	MINOXIDIL	0	0	1	0.6	1	0.6
	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.6	0	0
	NICOTINIC ACID	1	0.6	0	0	1	0.6
	NIFEDIPINE	0	0	0	0	1	0.6
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.6	2	1.2	0	0
	PRAVASTATIN SODIUM	0	0	0	0	2	1.2

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	PROPRANOLOL	1	0.6	1	0.6	0	0
	PROPRANOLOL HYDROCHLORIDE	1	0.6	2	1.2	1	0.6
	SIMVASTATIN	1	0.6	1	0.6	2	1.2
	SPIRONOLACTONE	0	0	0	0	1	0.6
	TRIAMTERENE	0	0	0	0	2	1.2
	UBIDECARENONE	0	0	2	1.2	0	0
	VALSARTAN	0	0	1	0.6	0	0
	VERAPAMIL	0	0	0	0	2	1.2
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.6	1	0.6
DERMATOLOGICALS	TOTAL	3	1.7	3	1.8	2	1.2
	CALCIPOTRIOL	1	0.6	0	0	0	0
	CLOBETASOL PROPIONATE	0	0	1	0.6	0	0
	COLECALCIFEROL	0	0	0	0	1	0.6
	DIPHENHYDRAMINE HYDROCHLORIDE	0	0	0	0	1	0.6
	GLYCEROL	0	0	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS205.SAS
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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	HYDROCORTISONE	0	0	2	1.2	0	0
	NEOMYCIN SULFATE	0	0	1	0.6	1	0.6
	PETROLATUM	1	0.6	0	0	0	0
	TRIAMCINOLONE	1	0.6	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	21	12.2	20	11.8	19	11.2
	CLINDAMYCIN	1	0.6	0	0	0	0
	EQUISETUM ARVENSE	0	0	1	0.6	0	0
	ESTRADIOL	0	0	1	0.6	3	1.8
	ESTROGENS CONJUGATED	1	0.6	3	1.8	1	0.6
	ETHINYLESTRADIOL	11	6.4	5	2.9	10	5.9
	LEVONORGESTREL	0	0	1	0.6	0	0
	MEDROXYPROGESTERONE ACETATE	2	1.2	4	2.4	2	1.2
	MICONAZOLE NITRATE	0	0	0	0	1	0.6
	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	1	0.6
	NORETHISTERONE	1	0.6	0	0	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	NORETHISTERONE ACETATE	0	0	1	0.6	0	0
	OXYBUTYNIN	0	0	1	0.6	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.6	0	0
	PHENAZOPYRIDINE HYDROCHLORIDE	1	0.6	0	0	0	0
	PROGESTERONE	0	0	1	0.6	0	0
	RALOXIFENE HYDROCHLORIDE	1	0.6	0	0	0	0
	SERENOA REPENS	1	0.6	0	0	0	0
	SILDENAFIL CITRATE	1	0.6	1	0.6	0	0
	TAMSULOSIN HYDROCHLORIDE	0	0	2	1.2	0	0
	TESTOSTERONE	1	0.6	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.6	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	55	32.0	60	35.3	61	36.1
	ALENDRONATE SODIUM	0	0	2	1.2	0	0

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	1	0.6
	ASCORBIC ACID	0	0	2	1.2	0	0
	CARISOPRODOL	0	0	1	0.6	1	0.6
	CELECOXIB	1	0.6	5	2.9	7	4.1
	CHONDROITIN SULFATE	1	0.6	0	0	0	0
	COLCHICINE	0	0	0	0	1	0.6
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.6	0	0	0	0
	GLUCOSAMINE	1	0.6	0	0	0	0
	IBUPROFEN	42	24.4	37	21.8	35	20.7
	KETOPROFEN	1	0.6	0	0	0	0
	METAXALONE	0	0	0	0	2	1.2
	NABUMETONE	0	0	1	0.6	0	0
	NAPROXEN	2	1.2	4	2.4	3	1.8
	NAPROXEN SODIUM	8	4.7	5	2.9	14	8.3
	ORPHENADRINE CITRATE	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	OXAPROZIN	0	0	1	0.6	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	2	1.2	0	0	2	1.2
	ROFECOXIB	1	0.6	1	0.6	3	1.8
	TIZANIDINE HYDROCHLORIDE	1	0.6	0	0	1	0.6
	VALDECOXIB	1	0.6	4	2.4	1	0.6
NERVOUS SYSTEM	TOTAL	70	40.7	74	43.5	78	46.2
	ACETAZOLAMIDE	0	0	1	0.6	0	0
	ACETYLSALICYLIC ACID	27	15.7	25	14.7	31	18.3
	ALPRAZOLAM	0	0	0	0	1	0.6
	AMANTADINE	0	0	1	0.6	1	0.6
	AMITRIPTYLINE HYDROCHLORIDE	0	0	1	0.6	0	0
	ANAESTHETICS, GENERAL	0	0	0	0	2	1.2
	ANAESTHETICS, LOCAL	0	0	1	0.6	0	0
	ANALGESICS	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	ARIPIPRAZOLE	1	0.6	0	0	0	0
	BENZATROPINE MESILATE	2	1.2	1	0.6	0	0
	BUPROPION HYDROCHLORIDE	0	0	2	1.2	0	0
	BUTORPHANOL TARTRATE	0	0	0	0	1	0.6
	CITALOPRAM HYDROBROMIDE	0	0	0	0	1	0.6
	CLONAZEPAM	0	0	0	0	1	0.6
	CODEINE PHOSPHATE	0	0	0	0	2	1.2
	DIAZEPAM	0	0	0	0	1	0.6
	DIPHENHYDRAMINE	2	1.2	1	0.6	3	1.8
	DISULFIRAM	0	0	0	0	1	0.6
	DOXEPIN HYDROCHLORIDE	0	0	1	0.6	0	0
	ESCITALOPRAM	1	0.6	0	0	0	0
	ETHANOL	1	0.6	0	0	5	3.0
	FENTANYL	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	GABAPENTIN	0	0	1	0.6	0	0
	GINKGO BILOBA	0	0	1	0.6	0	0
	HYDROCODONE BITARTRATE	1	0.6	0	0	0	0
	HYDROMORPHONE HYDROCHLORIDE	0	0	0	0	1	0.6
	HYDROXYZINE EMBONATE	0	0	1	0.6	0	0
	LEVETIRACETAM	0	0	1	0.6	0	0
	LEVODOPA	0	0	0	0	1	0.6
	LITHIUM	0	0	1	0.6	0	0
	LITHIUM CARBONATE	1	0.6	0	0	0	0
	LORAZEPAM	17	9.9	9	5.3	14	8.3
	MEPYRAMINE MALEATE	0	0	0	0	1	0.6
	MORPHINE HYDROCHLORIDE	0	0	1	0.6	0	0
	MORPHINE SULFATE	1	0.6	0	0	0	0
	NICOTINE	1	0.6	1	0.6	0	0

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	OXYCODONE HYDROCHLORIDE	0	0	1	0.6	0	0
	PARACETAMOL	41	23.8	42	24.7	35	20.7
	PETHIDINE HYDROCHLORIDE	0	0	0	0	1	0.6
	PROCAINE HYDROCHLORIDE	1	0.6	0	0	0	0
	RISPERIDONE	0	0	1	0.6	0	0
	RIZATRIPTAN BENZOATE	1	0.6	0	0	0	0
	SERTRALINE HYDROCHLORIDE	0	0	1	0.6	0	0
	SUMATRIPTAN SUCCINATE	0	0	0	0	2	1.2
	TOPIRAMATE	0	0	1	0.6	0	0
	VALERIANA OFFICINALIS ROOT	0	0	1	0.6	0	0
	ZALEPLON	0	0	0	0	1	0.6
	ZOLMITRIPTAN	0	0	0	0	1	0.6
	ZOLPIDEM TARTRATE	7	4.1	11	6.5	13	7.7

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	TOTAL	37	21.5	42	24.7	49	29.0
	ALLERGY MEDICATION	0	0	1	0.6	0	0
	ANTI-ASTHMATICS	0	0	1	0.6	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	1	0.6	0	0
	AZELASTINE HYDROCHLORIDE	0	0	0	0	1	0.6
	BENZONATATE	0	0	1	0.6	2	1.2
	BUDESONIDE	0	0	1	0.6	1	0.6
	CAMPHOR	1	0.6	1	0.6	0	0
	CETIRIZINE HYDROCHLORIDE	3	1.7	3	1.8	4	2.4
	CHLORPHENAMINE MALEATE	0	0	2	1.2	0	0
	CODEINE PHOSPHATE	0	0	1	0.6	1	0.6
	COUGH AND COLD PREPARATIONS	0	0	0	0	2	1.2
	DESLORATADINE	1	0.6	0	0	2	1.2
	DEXBROMPHENIRAMINE MALEATE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	DEXTROMETHORPHAN HYDROBROMIDE	0	0	0	0	2	1.2
	DIPHENHYDRAMINE	1	0.6	0	0	0	0
	DIPHENHYDRAMINE HYDROCHLORIDE	2	1.2	2	1.2	8	4.7
	EPINEPHRINE	0	0	1	0.6	0	0
	ETHANOL	1	0.6	0	0	1	0.6
	FEXOFENADINE HYDROCHLORIDE	3	1.7	4	2.4	4	2.4
	FLUTICASONE PROPIONATE	4	2.3	7	4.1	9	5.3
	GARLIC	1	0.6	0	0	0	0
	GUAIFENESIN	5	2.9	3	1.8	7	4.1
	HYDROCODONE	1	0.6	0	0	1	0.6
	IPRATROPIUM BROMIDE	2	1.2	0	0	2	1.2
	LORATADINE	2	1.2	5	2.9	6	3.6
	MECLOZINE	0	0	1	0.6	1	0.6
	MECLOZINE HYDROCHLORIDE	0	0	0	0	1	0.6

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	MEPYRAMINE MALEATE	0	0	1	0.6	0	0
	MOMETASONE FUROATE	0	0	0	0	1	0.6
	MONTELUKAST SODIUM	0	0	0	0	2	1.2
	NASAL DECONGESTANTS FOR SYSTEMIC USE	0	0	0	0	1	0.6
	OTHER COLD COMBINATION PREPARATIONS	1	0.6	1	0.6	0	0
	OXYMETAZOLINE HYDROCHLORIDE	0	0	2	1.2	4	2.4
	PARACETAMOL	0	0	1	0.6	2	1.2
	PHENYLEPHRINE HYDROCHLORIDE	0	0	1	0.6	1	0.6
	PHENYLPROPANOLAMINE HYDROCHLORIDE	0	0	0	0	1	0.6
	PIRBUTEROL ACETATE	0	0	0	0	1	0.6
	PROMETHAZINE HYDROCHLORIDE	0	0	1	0.6	1	0.6
	PSEUDOEPHEDRINE	0	0	0	0	1	0.6
	PSEUDOEPHEDRINE HYDROCHLORIDE	6	3.5	4	2.4	8	4.7

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS205.SAS
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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	PSEUDOEPHEDRINE SULFATE	0	0	1	0.6	1	0.6
	SALBUTAMOL	13	7.6	12	7.1	10	5.9
	SALMETEROL XINAFOATE	0	0	1	0.6	1	0.6
	SODIUM CHLORIDE	0	0	0	0	1	0.6
	TERPIN HYDRATE	0	0	0	0	1	0.6
	TRIAMCINOLONE ACETONIDE	2	1.2	5	2.9	1	0.6
SENSORY ORGANS	TOTAL	4	2.3	3	1.8	2	1.2
	BIMATOPROST	1	0.6	0	0	0	0
	HYDROCORTISONE	1	0.6	0	0	1	0.6
	KETOROLAC TROMETHAMINE	1	0.6	2	1.2	0	0
	LATANOPROST	0	0	1	0.6	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.6
	TROPICAMIDE	1	0.6	0	0	0	0

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	7	4.1	10	5.9	15	8.9
	CORTISONE	1	0.6	1	0.6	1	0.6
	DEXAMETHASONE	0	0	0	0	1	0.6
	LEVOTHYROXINE	0	0	1	0.6	0	0
	LEVOTHYROXINE SODIUM	6	3.5	7	4.1	9	5.3
	LIOTHYRONINE SODIUM	1	0.6	0	0	1	0.6
	METHYLPREDNISOLONE	0	0	0	0	2	1.2
	PREDNISONE	0	0	1	0.6	2	1.2
	THYROID	0	0	0	0	2	1.2
VARIOUS	TOTAL	7	4.1	6	3.5	10	5.9
	BARIUM	0	0	1	0.6	0	0
	BORAGE OIL	0	0	0	0	1	0.6
	DIAGNOSTIC RADIOPHARMACEUTICALS	0	0	0	0	1	0.6
	ECHINACEA EXTRACT	2	1.2	0	0	4	2.4
	GINGER	0	0	1	0.6	0	0

(Continued)

Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	HERBAL EXTRACTS NOS	0	0	0	0	1	0.6
	HERBAL PREPARATION	3	1.7	3	1.8	3	1.8
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.6
	LINSEED OIL	2	1.2	0	0	1	0.6
	NALOXONE HYDROCHLORIDE	0	0	1	0.6	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY CONCOMITANT MEDICATION		90	75.0	98	81.7	95	80.5	46	78.0	51	85.0	47	75.8
ALIMENTARY TRACT AND METABOLISM	TOTAL	43	35.8	47	39.2	40	33.9	19	32.2	21	35.0	20	32.3
	ANTACIDS	2	1.7	0	0	0	0	0	0	0	0	0	0
	ASCORBIC ACID	3	2.5	3	2.5	2	1.7	3	5.1	2	3.3	1	1.6
	ATROPINE SULFATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	BISACODYL	0	0	0	0	1	0.8	1	1.7	0	0	1	1.6
	BISMUTH SUBSALICYLATE	2	1.7	0	0	2	1.7	1	1.7	1	1.7	0	0
	CALCIUM	2	1.7	4	3.3	4	3.4	2	3.4	1	1.7	2	3.2
	CALCIUM ASCORBATE	0	0	0	0	0	0	0	0	0	0	1	1.6
	CALCIUM CARBONATE	6	5.0	10	8.3	7	5.9	1	1.7	4	6.7	2	3.2
	CALCIUM CITRATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	CHARCOAL, ACTIVATED	0	0	1	0.8	0	0	0	0	0	0	0	0
	CIMETIDINE	0	0	2	1.7	0	0	0	0	3	5.0	0	0
	DEXAMETHASONE	0	0	0	0	1	0.8	0	0	0	0	0	0
	DIHYDROXYALUMINUM SODIUM CARBONATE	3	2.5	2	1.7	1	0.8	2	3.4	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS206.SAS
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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DOCUSATE CALCIUM	0	0	0	0	0	0	1	1.7	0	0	0	0
	DOCUSATE SODIUM	1	0.8	2	1.7	1	0.8	1	1.7	0	0	0	0
	DOLASETRON MESILATE	0	0	0	0	0	0	0	0	0	0	1	1.6
	DOXYCYCLINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	ENEMAS	2	1.7	0	0	0	0	0	0	0	0	0	0
	ERGOCALCIFEROL	13	10.8	16	13.3	13	11.0	6	10.2	4	6.7	10	16.1
	ESOMEPRAZOLE	5	4.2	1	0.8	1	0.8	0	0	1	1.7	1	1.6
	FAMOTIDINE	0	0	1	0.8	1	0.8	0	0	2	3.3	2	3.2
	FERROUS FUMARATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	FERROUS SULFATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	FIBRE, DIETARY	2	1.7	0	0	0	0	0	0	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	GLIPIZIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	GLUCOSE MONOHYDRATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	HYOSCYAMINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	HYOSCYAMINE SULFATE	1	0.8	0	0	0	0	0	0	1	1.7	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	INSULIN	0	0	0	0	0	0	1	1.7	0	0	0	0
	LACTOBACILLUS ACIDOPHILUS	1	0.8	0	0	0	0	0	0	0	0	0	0
	LANSOPRAZOLE	3	2.5	0	0	1	0.8	1	1.7	1	1.7	2	3.2
	LAXATIVES	0	0	1	0.8	0	0	0	0	0	0	0	0
	LOPERAMIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	LOPERAMIDE HYDROCHLORIDE	0	0	1	0.8	0	0	1	1.7	0	0	1	1.6
	MACROGOL	1	0.8	0	0	0	0	0	0	0	0	0	0
	MAGNESIUM	0	0	1	0.8	0	0	0	0	0	0	0	0
	MAGNESIUM HYDROXIDE	2	1.7	3	2.5	2	1.7	0	0	0	0	0	0
	MAGNESIUM SULFATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	METFORMIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	METFORMIN HYDROCHLORIDE	3	2.5	0	0	2	1.7	1	1.7	0	0	0	0
	METOCLOPRAMIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	MINERAL SUPPLEMENTS	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	MULTIVITAMINS WITH MINERALS	1	0.8	0	0	0	0	0	0	0	0	0	0
	NPH INSULIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	NYSTATIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	OMEPRAZOLE	0	0	2	1.7	1	0.8	0	0	1	1.7	0	0
	ONDANSETRON HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	PANCRELIPASE	1	0.8	0	0	0	0	0	0	0	0	0	0
	PANTOPRAZOLE SODIUM	1	0.8	1	0.8	3	2.5	0	0	2	3.3	1	1.6
	PHOSPHORIC ACID	1	0.8	0	0	0	0	0	0	0	0	0	0
	PIOGLITAZONE HYDROCHLORIDE	1	0.8	0	0	1	0.8	0	0	0	0	0	0
	POTASSIUM	0	0	1	0.8	1	0.8	1	1.7	0	0	1	1.6
	POTASSIUM CHLORIDE	1	0.8	1	0.8	0	0	0	0	1	1.7	0	0
	PRASTERONE	1	0.8	0	0	0	0	0	0	0	0	0	0
	PYRIDOXINE HYDROCHLORIDE	2	1.7	2	1.7	3	2.5	1	1.7	1	1.7	0	0
	RABEPRAZOLE SODIUM	0	0	1	0.8	0	0	1	1.7	1	1.7	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	RANITIDINE	0	0	0	0	0	0	0	0	1	1.7	1	1.6
	RANITIDINE HYDROCHLORIDE	5	4.2	2	1.7	4	3.4	0	0	1	1.7	0	0
	RETINOL	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	ROSIGLITAZONE MALEATE	0	0	2	1.7	1	0.8	0	0	0	0	0	0
	SELENIUM	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	SENNA	1	0.8	0	0	0	0	0	0	0	0	0	0
	SIMETICONE	1	0.8	0	0	0	0	0	0	0	0	0	0
	SODIUM BICARBONATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	TEGASEROD	0	0	0	0	1	0.8	0	0	0	0	0	0
	TETRACYCLINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	THIAMINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	TILACTASE	1	0.8	0	0	0	0	0	0	0	0	0	0
	TOCOPHEROL	3	2.5	3	2.5	2	1.7	2	3.4	0	0	3	4.8
	VITAMINS	0	0	0	0	1	0.8	0	0	0	0	0	0
	VITAMINS NOS	0	0	0	0	3	2.5	0	0	1	1.7	1	1.6

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	ZINC	0	0	0	0	1	0.8	0	0	1	1.7	0	0
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	6	5.0	6	5.0	13	11.0	6	10.2	6	10.0	5	8.1
	ACICLOVIR	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	AMOXICILLIN	1	0.8	2	1.7	1	0.8	0	0	0	0	0	0
	ANTIBIOTICS	1	0.8	0	0	0	0	0	0	0	0	1	1.6
	AZITHROMYCIN	1	0.8	0	0	3	2.5	1	1.7	3	5.0	1	1.6
	BENZYLPENICILLIN	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	CEFALEXIN	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	CEFALEXIN MONOHYDRATE	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	CEFTRIAXONE SODIUM	0	0	0	0	0	0	0	0	1	1.7	0	0
	CLARITHROMYCIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	CLAVULANATE POTASSIUM	1	0.8	0	0	2	1.7	1	1.7	1	1.7	1	1.6
	FLUCONAZOLE	1	0.8	0	0	0	0	0	0	0	0	1	1.6
	GATIFLOXACIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	GENTAMICIN	0	0	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	INFLUENZA VIRUS VACCINE POLYVALENT	0	0	0	0	1	0.8	0	0	0	0	0	0
	LEVOFLOXACIN	0	0	2	1.7	2	1.7	0	0	0	0	0	0
	NITROFURANTOIN	0	0	0	0	0	0	0	0	0	0	1	1.6
	RITONAVIR	0	0	0	0	0	0	0	0	1	1.7	0	0
	SULFAMETHOXAZOLE	0	0	0	0	0	0	1	1.7	0	0	1	1.6
	VALACICLOVIR HYDROCHLORIDE	0	0	0	0	1	0.8	1	1.7	1	1.7	0	0
	ZIDOVUDINE	0	0	0	0	0	0	0	0	1	1.7	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	ETANERCEPT	0	0	0	0	1	0.8	0	0	0	0	0	0
	METHOTREXATE	0	0	0	0	0	0	0	0	0	0	1	1.6
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	TOTAL	1	0.8	0	0	0	0	0	0	0	0	0	0
	PERMETHRIN	1	0.8	0	0	0	0	0	0	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	0.8	4	3.3	8	6.8	2	3.4	0	0	4	6.5
	CLOPIDOGREL SULFATE	0	0	0	0	2	1.7	0	0	0	0	0	0
	CYANOCOBALAMIN	0	0	3	2.5	0	0	1	1.7	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD AND BLOOD FORMING ORGANS	FERROUS SULFATE	0	0	0	0	1	0.8	0	0	0	0	2	3.2
	FOLIC ACID	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	HEPARIN	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	HEPARIN-FRACTION, SODIUM SALT	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	I.V. SOLUTIONS	0	0	0	0	0	0	1	1.7	0	0	0	0
	IRON	0	0	0	0	2	1.7	0	0	0	0	1	1.6
	LACTATED RINGER'S INJECTION	0	0	0	0	1	0.8	0	0	0	0	0	0
	LECITHIN	1	0.8	0	0	0	0	0	0	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.8	2	1.7	0	0	0	0	0	0
CARDIOVASCULAR SYSTEM	TOTAL	13	10.8	20	16.7	15	12.7	8	13.6	3	5.0	10	16.1
	AMLODIPINE BESILATE	2	1.7	0	0	3	2.5	0	0	0	0	0	0
	ATENOLOL	0	0	2	1.7	3	2.5	1	1.7	0	0	1	1.6
	ATORVASTATIN	4	3.3	4	3.3	2	1.7	2	3.4	0	0	0	0
	BENAZEPRIL HYDROCHLORIDE	1	0.8	0	0	0	0	0	0	0	0	0	0
	CARNITINE	0	0	0	0	0	0	1	1.7	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	CLONIDINE	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	DOXAZOSIN MESILATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	FISH OIL	1	0.8	1	0.8	0	0	2	3.4	0	0	2	3.2
	FLUVASTATIN SODIUM	0	0	1	0.8	0	0	0	0	0	0	0	0
	FOSINOPRIL SODIUM	1	0.8	0	0	0	0	0	0	0	0	0	0
	FUROSEMIDE	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	GEMFIBROZIL	0	0	0	0	1	0.8	0	0	0	0	0	0
	HYDROCHLOROTHIAZIDE	4	3.3	7	5.8	4	3.4	1	1.7	0	0	5	8.1
	IPRATROPIUM BROMIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	LABETALOL	0	0	1	0.8	0	0	0	0	0	0	0	0
	LISINOPRIL	0	0	3	2.5	3	2.5	0	0	1	1.7	1	1.6
	LOSARTAN POTASSIUM	1	0.8	0	0	0	0	0	0	0	0	0	0
	LOVASTATIN	0	0	0	0	0	0	0	0	0	0	1	1.6
	METOPROLOL	0	0	3	2.5	2	1.7	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	METOPROLOL SUCCINATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	MINOXIDIL	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	NICOTINIC ACID	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	NIFEDIPINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.8	1	0.8	0	0	0	0	1	1.7	0	0
	PRAVASTATIN SODIUM	0	0	0	0	2	1.7	0	0	0	0	0	0
	PROPRANOLOL	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	PROPRANOLOL HYDROCHLORIDE	0	0	2	1.7	1	0.8	1	1.7	0	0	0	0
	RAMIPRIL	0	0	0	0	1	0.8	0	0	0	0	0	0
	SIMVASTATIN	1	0.8	0	0	2	1.7	0	0	1	1.7	0	0
	SPIRONOLACTONE	0	0	0	0	0	0	0	0	0	0	1	1.6
	TRIAMTERENE	0	0	0	0	2	1.7	0	0	0	0	0	0
	UBIDECARENONE	0	0	1	0.8	0	0	0	0	1	1.7	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	VALSARTAN	0	0	1	0.8	0	0	0	0	0	0	0	0
	VERAPAMIL	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	1	1.6
DERMATOLOGICALS	TOTAL	1	0.8	2	1.7	1	0.8	2	3.4	1	1.7	1	1.6
	CALCIPOTRIOL	1	0.8	0	0	0	0	0	0	0	0	0	0
	CLOBETASOL PROPIONATE	0	0	1	0.8	0	0	0	0	0	0	0	0
	COLECALCIFEROL	0	0	0	0	1	0.8	0	0	0	0	0	0
	DIPHENHYDRAMINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	0	0	1	1.6
	GLYCEROL	0	0	0	0	0	0	0	0	1	1.7	0	0
	HYDROCORTISONE	0	0	1	0.8	0	0	0	0	1	1.7	0	0
	NEOMYCIN SULFATE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	PETROLATUM	0	0	0	0	0	0	1	1.7	0	0	0	0
	TRIAMCINOLONE	0	0	0	0	0	0	1	1.7	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	15	12.5	12	10.0	9	7.6	7	11.9	8	13.3	10	16.1
	CLINDAMYCIN	1	0.8	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	EQUISETUM ARVENSE	0	0	0	0	0	0	0	0	1	1.7	0	0
	ESTRADIOL	0	0	1	0.8	2	1.7	0	0	0	0	1	1.6
	ESTROGENS CONJUGATED	1	0.8	3	2.5	1	0.8	0	0	0	0	0	0
	ETHINYLESTRADIOL	9	7.5	3	2.5	4	3.4	3	5.1	2	3.3	6	9.7
	LEVONORGESTREL	0	0	0	0	0	0	0	0	1	1.7	0	0
	MEDROXYPROGESTERONE ACETATE	2	1.7	3	2.5	1	0.8	0	0	1	1.7	1	1.6
	MICONAZOLE NITRATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	0	0	0	0	0	0	1	1.6
	NORETHISTERONE	1	0.8	0	0	0	0	0	0	0	0	1	1.6
	NORETHISTERONE ACETATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	OXYBUTYNIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	PHENAZOPYRIDINE HYDROCHLORIDE	0	0	0	0	0	0	1	1.7	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	PROGESTERONE	0	0	1	0.8	0	0	0	0	0	0	0	0
	RALOXIFENE HYDROCHLORIDE	0	0	0	0	0	0	1	1.7	0	0	0	0
	SERENOA REPENS	0	0	0	0	0	0	1	1.7	0	0	0	0
	SILDENAFIL CITRATE	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	TAMSULOSIN HYDROCHLORIDE	0	0	0	0	0	0	0	0	2	3.3	0	0
	TESTOSTERONE	0	0	0	0	0	0	1	1.7	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.8	0	0	0	0	0	0	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	39	32.5	41	34.2	44	37.3	17	28.8	21	35.0	19	30.6
	ALENDRONATE SODIUM	0	0	2	1.7	0	0	0	0	0	0	0	0
	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	0	0	0	0	0	0	1	1.6
	ASCORBIC ACID	0	0	2	1.7	0	0	0	0	0	0	0	0
	CARISOPRODOL	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	CELECOXIB	0	0	3	2.5	4	3.4	1	1.7	2	3.3	3	4.8
	CHONDROITIN SULFATE	1	0.8	0	0	0	0	0	0	0	0	1	1.6

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	COLCHICINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.8	0	0	0	0	0	0	0	0	0	0
	GLUCOSAMINE	1	0.8	0	0	0	0	0	0	0	0	0	0
	IBUPROFEN	31	25.8	27	22.5	26	22.0	12	20.3	11	18.3	10	16.1
	KETOPROFEN	0	0	0	0	0	0	1	1.7	0	0	0	0
	METAXALONE	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	NABUMETONE	0	0	0	0	0	0	0	0	1	1.7	0	0
	NAPROXEN	2	1.7	1	0.8	2	1.7	0	0	3	5.0	1	1.6
	NAPROXEN SODIUM	7	5.8	4	3.3	13	11.0	1	1.7	1	1.7	1	1.6
	ORPHENADRINE CITRATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	OXAPROZIN	0	0	0	0	0	0	0	0	1	1.7	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	2	1.7	0	0	2	1.7	0	0	0	0	0	0
	ROFECOXIB	0	0	0	0	0	0	1	1.7	1	1.7	3	4.8
	TIZANIDINE HYDROCHLORIDE	0	0	0	0	0	0	1	1.7	0	0	1	1.6

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	VALDECOXIB	1	0.8	4	3.3	1	0.8	0	0	1	1.7	0	0
NERVOUS SYSTEM	TOTAL	48	40.0	53	44.2	59	50.0	23	39.0	24	40.0	26	41.9
	ACETAZOLAMIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	ACETYLSALICYLIC ACID	15	12.5	19	15.8	22	18.6	12	20.3	7	11.7	11	17.7
	ALPRAZOLAM	0	0	0	0	1	0.8	0	0	0	0	0	0
	AMANTADINE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	AMITRIPTYLINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	1	1.7	0	0
	ANAESTHETICS, GENERAL	0	0	0	0	2	1.7	0	0	0	0	0	0
	ANAESTHETICS, LOCAL	0	0	1	0.8	0	0	0	0	0	0	0	0
	ANALGESICS	0	0	0	0	1	0.8	0	0	0	0	0	0
	ARIPIPRAZOLE	1	0.8	0	0	0	0	0	0	0	0	0	0
	BENZATROPINE MESILATE	0	0	1	0.8	1	0.8	2	3.4	0	0	0	0
	BUPROPION HYDROCHLORIDE	0	0	0	0	0	0	0	0	2	3.3	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	BUTORPHANOL TARTRATE	0	0	0	0	0	0	0	0	0	0	1	1.6
	CITALOPRAM HYDROBROMIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	CLONAZEPAM	0	0	0	0	3	2.5	0	0	0	0	0	0
	CODEINE PHOSPHATE	0	0	0	0	2	1.7	0	0	0	0	0	0
	DIAZEPAM	0	0	0	0	2	1.7	0	0	0	0	0	0
	DIPHENHYDRAMINE	2	1.7	1	0.8	2	1.7	0	0	0	0	1	1.6
	DISULFIRAM	0	0	0	0	1	0.8	0	0	0	0	0	0
	DOXEPIN HYDROCHLORIDE	0	0	0	0	0	0	0	0	1	1.7	0	0
	ESCITALOPRAM	1	0.8	0	0	1	0.8	0	0	0	0	0	0
	ETHANOL	1	0.8	0	0	3	2.5	0	0	0	0	2	3.2
	FENTANYL	0	0	1	0.8	0	0	0	0	0	0	0	0
	GABAPENTIN	0	0	0	0	2	1.7	0	0	1	1.7	0	0
	GINKGO BILOBA	0	0	0	0	0	0	0	0	1	1.7	0	0
	HYDROCODONE BITARTRATE	1	0.8	0	0	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	HYDROMORPHONE HYDROCHLORIDE	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	HYDROXYZINE EMBONATE	0	0	1	0.8	0	0	0	0	0	0	0	0
	LEVETIRACETAM	0	0	0	0	0	0	0	0	1	1.7	0	0
	LEVODOPA	0	0	0	0	0	0	0	0	0	0	1	1.6
	LITHIUM	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	LITHIUM CARBONATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	LORAZEPAM	11	9.2	9	7.5	15	12.7	6	10.2	1	1.7	0	0
	MEPYRAMINE MALEATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	MIDAZOLAM HYDROCHLORIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	MORPHINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	1	1.7	0	0
	MORPHINE SULFATE	1	0.8	0	0	1	0.8	0	0	0	0	0	0
	NICOTINE	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	OXCARBAZEPINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	OXYCODONE HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	PARACETAMOL	30	25.0	28	23.3	24	20.3	11	18.6	15	25.0	13	21.0
	PETHIDINE HYDROCHLORIDE	0	0	0	0	2	1.7	0	0	0	0	0	0
	PHENYTOIN SODIUM	0	0	0	0	0	0	0	0	0	0	1	1.6
	PROCAINE HYDROCHLORIDE	0	0	0	0	0	0	1	1.7	0	0	0	0
	QUETIAPINE FUMARATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	RISPERIDONE	0	0	1	0.8	2	1.7	0	0	0	0	0	0
	RIZATRIPTAN BENZOATE	1	0.8	0	0	0	0	0	0	0	0	0	0
	SERTRALINE HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0
	SUMATRIPTAN SUCCINATE	0	0	0	0	2	1.7	0	0	0	0	0	0
	TOPIRAMATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	VALERIANA OFFICINALIS ROOT	0	0	1	0.8	0	0	0	0	0	0	0	0
	ZALEPLON	0	0	0	0	0	0	0	0	0	0	1	1.6
	ZOLMITRIPTAN	0	0	0	0	1	0.8	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	ZOLPIDEM TARTRATE	4	3.3	9	7.5	12	10.2	4	6.8	3	5.0	3	4.8
RESPIRATORY SYSTEM	TOTAL	27	22.5	23	19.2	35	29.7	11	18.6	20	33.3	17	27.4
	ALLERGY MEDICATION	0	0	0	0	0	0	0	0	1	1.7	0	0
	ANTI-ASTHMATICS	0	0	0	0	0	0	0	0	1	1.7	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	0	0	0	0	0	0	1	1.7	0	0
	AZELASTINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	0	0	1	1.6
	BECLOMETASONE DIPROPIONATE	0	0	0	0	0	0	0	0	0	0	1	1.6
	BENZONATATE	0	0	0	0	0	0	0	0	1	1.7	2	3.2
	BUDESONIDE	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	CAMPHOR	0	0	0	0	0	0	1	1.7	1	1.7	0	0
	CETIRIZINE HYDROCHLORIDE	2	1.7	1	0.8	2	1.7	1	1.7	2	3.3	3	4.8
	CHLORPHENAMINE MALEATE	0	0	1	0.8	0	0	0	0	1	1.7	0	0
	CODEINE PHOSPHATE	0	0	0	0	0	0	0	0	1	1.7	1	1.6

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	COUGH AND COLD PREPARATIONS	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	DESLORATADINE	1	0.8	0	0	0	0	0	0	0	0	2	3.2
	DEXBROMPHENIRAMINE MALEATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	DEXTROMETHORPHAN HYDROBROMIDE	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	DIPHENHYDRAMINE	1	0.8	0	0	0	0	0	0	0	0	0	0
	DIPHENHYDRAMINE HYDROCHLORIDE	2	1.7	2	1.7	8	6.8	0	0	0	0	2	3.2
	EPINEPHRINE	0	0	0	0	0	0	0	0	1	1.7	0	0
	ETHANOL	1	0.8	0	0	0	0	0	0	0	0	1	1.6
	FEXOFENADINE HYDROCHLORIDE	4	3.3	3	2.5	2	1.7	0	0	2	3.3	2	3.2
	FLUTICASONE PROPIONATE	2	1.7	3	2.5	4	3.4	2	3.4	4	6.7	5	8.1
	GARLIC	1	0.8	0	0	0	0	0	0	0	0	0	0
	GUAIFENESIN	4	3.3	1	0.8	5	4.2	1	1.7	2	3.3	2	3.2
	HYDROCODONE	1	0.8	0	0	0	0	0	0	0	0	1	1.6

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	IPRATROPIUM BROMIDE	1	0.8	0	0	1	0.8	1	1.7	0	0	1	1.6
	LORATADINE	2	1.7	2	1.7	5	4.2	0	0	3	5.0	1	1.6
	MECLOZINE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	MECLOZINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	0	0	1	1.6
	MEPYRAMINE MALEATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	MOMETASONE FUROATE	1	0.8	0	0	1	0.8	0	0	0	0	0	0
	MONTELUKAST SODIUM	0	0	0	0	0	0	0	0	0	0	2	3.2
	NASAL DECONGESTANTS FOR SYSTEMIC USE	0	0	0	0	0	0	0	0	0	0	1	1.6
	OTHER COLD COMBINATION PREPARATIONS	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	OXYMETAZOLINE HYDROCHLORIDE	0	0	1	0.8	4	3.4	0	0	1	1.7	0	0
	PARACETAMOL	0	0	1	0.8	2	1.7	0	0	0	0	0	0
	PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	PHENYLPROPANOLAMINE HYDROCHLORIDE	0	0	0	0	1	0.8	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	PIRBUTEROL ACETATE	0	0	0	0	1	0.8	0	0	0	0	0	0
	PROMETHAZINE HYDROCHLORIDE	0	0	0	0	1	0.8	0	0	1	1.7	1	1.6
	PSEUDOEPHEDRINE	0	0	0	0	1	0.8	0	0	0	0	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	3	2.5	2	1.7	7	5.9	3	5.1	2	3.3	1	1.6
	PSEUDOEPHEDRINE SULFATE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	SALBUTAMOL	8	6.7	9	7.5	7	5.9	5	8.5	3	5.0	3	4.8
	SALMETEROL XINAFOATE	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	SODIUM CHLORIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	TERPIN HYDRATE	0	0	0	0	0	0	0	0	0	0	1	1.6
	TRIAMCINOLONE ACETONIDE	2	1.7	4	3.3	1	0.8	0	0	1	1.7	0	0
SENSORY ORGANS	TOTAL	4	3.3	0	0	2	1.7	0	0	3	5.0	0	0
	BIMATOPROST	1	0.8	0	0	0	0	0	0	0	0	0	0
	HYDROCORTISONE	1	0.8	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SENSORY ORGANS	KETOROLAC TROMETHAMINE	1	0.8	0	0	0	0	0	0	2	3.3	0	0
	LATANOPROST	0	0	0	0	0	0	0	0	1	1.7	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.8	0	0	0	0	0	0
	TROPICAMIDE	1	0.8	0	0	0	0	0	0	0	0	0	0
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	4	3.3	6	5.0	9	7.6	3	5.1	4	6.7	7	11.3
	ACTONEL	0	0	0	0	0	0	0	0	0	0	1	1.6
	CORTISONE	1	0.8	0	0	1	0.8	0	0	1	1.7	0	0
	DEXAMETHASONE	0	0	0	0	0	0	0	0	0	0	1	1.6
	LEVOTHYROXINE	0	0	1	0.8	0	0	0	0	0	0	0	0
	LEVOTHYROXINE SODIUM	3	2.5	5	4.2	6	5.1	3	5.1	2	3.3	3	4.8
	LIOTHYRONINE SODIUM	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	METHYLPREDNISOLONE	0	0	0	0	1	0.8	0	0	0	0	1	1.6
	PREDNISONE	0	0	0	0	1	0.8	0	0	1	1.7	1	1.6
	THYROID	0	0	0	0	1	0.8	0	0	0	0	1	1.6
VARIOUS	TOTAL	4	3.3	3	2.5	7	5.9	3	5.1	3	5.0	3	4.8

(Continued)

Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	BARIUM	0	0	1	0.8	0	0	0	0	0	0	0	0
	BORAGE OIL	0	0	0	0	0	0	0	0	0	0	1	1.6
	DIAGNOSTIC RADIOPHARMACEUTICA-LS	0	0	0	0	1	0.8	0	0	0	0	0	0
	ECHINACEA EXTRACT	1	0.8	0	0	2	1.7	1	1.7	0	0	2	3.2
	GINGER	0	0	0	0	0	0	0	0	1	1.7	0	0
	HERBAL EXTRACTS NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	HERBAL PREPARATION	1	0.8	1	0.8	3	2.5	2	3.4	2	3.3	0	0
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.8	0	0	0	0	0	0
	LINSEED OIL	2	1.7	0	0	0	0	0	0	0	0	1	1.6
	NALOXONE HYDROCHLORIDE	0	0	1	0.8	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY CONCOMITANT MEDICATION		88	75.9	96	84.2	90	80.4	45	80.4	48	85.7	45	78.9
ALIMENTARY TRACT AND METABOLISM	TOTAL	41	35.3	46	40.4	37	33.0	18	32.1	21	37.5	19	33.3
	ANTACIDS	2	1.7	0	0	0	0	0	0	0	0	0	0
	ASCORBIC ACID	3	2.6	3	2.6	2	1.8	2	3.6	2	3.6	1	1.8
	ATROPINE SULFATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	BISACODYL	0	0	0	0	1	0.9	1	1.8	0	0	1	1.8
	BISMUTH SUBSALICYLATE	2	1.7	0	0	2	1.8	1	1.8	1	1.8	0	0
	CALCIUM	2	1.7	4	3.5	4	3.6	2	3.6	1	1.8	1	1.8
	CALCIUM ASCORBATE	0	0	0	0	0	0	0	0	0	0	1	1.8
	CALCIUM CARBONATE	6	5.2	10	8.8	7	6.3	1	1.8	4	7.1	2	3.5
	CALCIUM CITRATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	CHARCOAL, ACTIVATED	0	0	1	0.9	0	0	0	0	0	0	0	0
	CIMETIDINE	0	0	1	0.9	0	0	0	0	3	5.4	0	0
	DEXAMETHASONE	0	0	0	0	1	0.9	0	0	0	0	0	0
	DIHYDROXYALUMINUM SODIUM CARBONATE	3	2.6	1	0.9	1	0.9	2	3.6	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	DOCUSATE CALCIUM	0	0	0	0	0	0	1	1.8	0	0	0	0
	DOCUSATE SODIUM	1	0.9	2	1.8	0	0	1	1.8	0	0	0	0
	DOLASETRON MESILATE	0	0	0	0	0	0	0	0	0	0	1	1.8
	DOXYCYCLINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	ENEMAS	2	1.7	0	0	0	0	0	0	0	0	0	0
	ERGOCALCIFEROL	12	10.3	16	14.0	13	11.6	6	10.7	4	7.1	10	17.5
	ESOMEPRAZOLE	5	4.3	1	0.9	1	0.9	0	0	1	1.8	1	1.8
	FAMOTIDINE	0	0	1	0.9	0	0	0	0	2	3.6	2	3.5
	FERROUS FUMARATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	FERROUS SULFATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	FIBRE, DIETARY	2	1.7	0	0	0	0	0	0	0	0	0	0
	GLIMEPIRIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	GLIPIZIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	GLUCOSE MONOHYDRATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	HYOSCYAMINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	HYOSCYAMINE SULFATE	1	0.9	0	0	0	0	0	0	1	1.8	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	INSULIN	0	0	0	0	0	0	1	1.8	0	0	0	0
	LACTOBACILLUS ACIDOPHILUS	1	0.9	0	0	0	0	0	0	0	0	0	0
	LANSOPRAZOLE	2	1.7	0	0	1	0.9	1	1.8	1	1.8	1	1.8
	LAXATIVES	0	0	1	0.9	0	0	0	0	0	0	0	0
	LOPERAMIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	LOPERAMIDE HYDROCHLORIDE	0	0	1	0.9	0	0	1	1.8	0	0	1	1.8
	MACROGOL	1	0.9	0	0	0	0	0	0	0	0	0	0
	MAGNESIUM	0	0	1	0.9	0	0	0	0	0	0	0	0
	MAGNESIUM HYDROXIDE	2	1.7	3	2.6	2	1.8	0	0	0	0	0	0
	MAGNESIUM SULFATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	METFORMIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	METFORMIN HYDROCHLORIDE	3	2.6	0	0	2	1.8	1	1.8	0	0	0	0
	MINERAL SUPPLEMENTS	0	0	1	0.9	0	0	0	0	0	0	0	0
	MULTIVITAMINS WITH MINERALS	1	0.9	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	NPH INSULIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	NYSTATIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	OMEPRAZOLE	0	0	2	1.8	1	0.9	0	0	1	1.8	0	0
	ONDANSETRON HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	PANCRELIPASE	1	0.9	0	0	0	0	0	0	0	0	0	0
	PANTOPRAZOLE SODIUM	1	0.9	1	0.9	1	0.9	0	0	2	3.6	1	1.8
	PIOGLITAZONE HYDROCHLORIDE	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	POTASSIUM	0	0	1	0.9	1	0.9	1	1.8	0	0	1	1.8
	POTASSIUM CHLORIDE	1	0.9	1	0.9	0	0	0	0	1	1.8	0	0
	PRASTERONE	1	0.9	0	0	0	0	0	0	0	0	0	0
	PYRIDOXINE HYDROCHLORIDE	2	1.7	2	1.8	3	2.7	1	1.8	1	1.8	0	0
	RABEPRAZOLE SODIUM	0	0	1	0.9	0	0	1	1.8	1	1.8	0	0
	RANITIDINE	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	RANITIDINE HYDROCHLORIDE	5	4.3	2	1.8	4	3.6	0	0	1	1.8	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	RETINOL	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	ROSIGLITAZONE MALEATE	0	0	2	1.8	1	0.9	0	0	0	0	0	0
	SELENIUM	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	SENNA	1	0.9	0	0	0	0	0	0	0	0	0	0
	SIMETICONE	1	0.9	0	0	0	0	0	0	0	0	0	0
	SODIUM BICARBONATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	TEGASEROD	0	0	0	0	1	0.9	0	0	0	0	0	0
	TETRACYCLINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	THIAMINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	TILACTASE	1	0.9	0	0	0	0	0	0	0	0	0	0
	TOCOPHEROL	3	2.6	3	2.6	2	1.8	1	1.8	0	0	2	3.5
	VITAMINS	0	0	0	0	1	0.9	0	0	0	0	0	0
	VITAMINS NOS	0	0	0	0	3	2.7	0	0	1	1.8	1	1.8
	ZINC	0	0	0	0	1	0.9	0	0	1	1.8	0	0
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	6	5.2	6	5.3	13	11.6	6	10.7	6	10.7	5	8.8
	ACICLOVIR	0	0	1	0.9	0	0	1	1.8	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	AMOXICILLIN	1	0.9	2	1.8	1	0.9	0	0	0	0	0	0
	ANTIBIOTICS	1	0.9	0	0	0	0	0	0	0	0	1	1.8
	AZITHROMYCIN	1	0.9	0	0	3	2.7	1	1.8	3	5.4	1	1.8
	BENZYLPENICILLIN	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	CEFALEXIN	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	CEFALEXIN MONOHYDRATE	0	0	0	0	1	0.9	1	1.8	0	0	0	0
	CEFTRIAXONE SODIUM	0	0	0	0	0	0	0	0	1	1.8	0	0
	CLARITHROMYCIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	CLAVULANATE POTASSIUM	1	0.9	0	0	2	1.8	1	1.8	1	1.8	1	1.8
	FLUCONAZOLE	1	0.9	0	0	0	0	0	0	0	0	1	1.8
	GATIFLOXACIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	GENTAMICIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	INFLUENZA VIRUS VACCINE POLYVALENT	0	0	0	0	1	0.9	0	0	0	0	0	0
	LEVOFLOXACIN	0	0	2	1.8	2	1.8	0	0	0	0	0	0
	NITROFURANTOIN	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	RITONAVIR	0	0	0	0	0	0	0	0	1	1.8	0	0
	SULFAMETHOXAZOLE	0	0	0	0	0	0	1	1.8	0	0	1	1.8
	VALACICLOVIR HYDROCHLORIDE	0	0	0	0	1	0.9	1	1.8	1	1.8	0	0
	ZIDOVUDINE	0	0	0	0	0	0	0	0	1	1.8	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	ETANERCEPT	0	0	0	0	1	0.9	0	0	0	0	0	0
	METHOTREXATE	0	0	0	0	0	0	0	0	0	0	1	1.8
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	TOTAL	1	0.9	0	0	0	0	0	0	0	0	0	0
	PERMETHRIN	1	0.9	0	0	0	0	0	0	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	0.9	4	3.5	7	6.3	2	3.6	0	0	4	7.0
	CLOPIDOGREL SULFATE	0	0	0	0	2	1.8	0	0	0	0	0	0
	CYANOCOBALAMIN	0	0	3	2.6	0	0	1	1.8	0	0	0	0
	FERROUS SULFATE	0	0	0	0	1	0.9	0	0	0	0	2	3.5
	FOLIC ACID	0	0	0	0	1	0.9	1	1.8	0	0	0	0
	HEPARIN	0	0	0	0	1	0.9	0	0	0	0	1	1.8

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD AND BLOOD FORMING ORGANS	HEPARIN-FRACTION, SODIUM SALT	0	0	0	0	0	0	0	0	0	0	1	1.8
	I.V. SOLUTIONS	0	0	0	0	0	0	1	1.8	0	0	0	0
	IRON	0	0	0	0	2	1.8	0	0	0	0	1	1.8
	LECITHIN	1	0.9	0	0	0	0	0	0	0	0	0	0
	WARFARIN SODIUM	0	0	1	0.9	1	0.9	0	0	0	0	0	0
CARDIOVASCULAR SYSTEM	TOTAL	13	11.2	20	17.5	14	12.5	8	14.3	3	5.4	10	17.5
	AMLODIPINE BESILATE	2	1.7	0	0	3	2.7	0	0	0	0	0	0
	ATENOLOL	0	0	2	1.8	2	1.8	1	1.8	0	0	1	1.8
	ATORVASTATIN	4	3.4	4	3.5	2	1.8	2	3.6	0	0	0	0
	BENAZEPRIL HYDROCHLORIDE	1	0.9	0	0	0	0	0	0	0	0	0	0
	CARNITINE	0	0	0	0	0	0	1	1.8	0	0	0	0
	CLONIDINE	0	0	1	0.9	1	0.9	0	0	1	1.8	0	0
	DOXAZOSIN MESILATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	FELODIPINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	FISH OIL	1	0.9	1	0.9	0	0	2	3.6	0	0	2	3.5

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	FLUVASTATIN SODIUM	0	0	1	0.9	0	0	0	0	0	0	0	0
	FOSINOPRIL SODIUM	1	0.9	0	0	0	0	0	0	0	0	0	0
	FUROSEMIDE	0	0	1	0.9	1	0.9	0	0	1	1.8	0	0
	GEMFIBROZIL	0	0	0	0	1	0.9	0	0	0	0	0	0
	HYDROCHLOROTHIAZIDE	4	3.4	7	6.1	4	3.6	1	1.8	0	0	5	8.8
	IPRATROPIUM BROMIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	ISOSORBIDE MONONITRATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	LABETALOL	0	0	1	0.9	0	0	0	0	0	0	0	0
	LISINOPRIL	0	0	3	2.6	3	2.7	0	0	1	1.8	1	1.8
	LOSARTAN POTASSIUM	1	0.9	0	0	0	0	0	0	0	0	0	0
	LOVASTATIN	0	0	0	0	0	0	0	0	0	0	1	1.8
	METOPROLOL	0	0	3	2.6	2	1.8	0	0	0	0	0	0
	METOPROLOL SUCCINATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	MINOXIDIL	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	MOEXIPRIL HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	NICOTINIC ACID	0	0	0	0	1	0.9	1	1.8	0	0	0	0
	NIFEDIPINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	OMEGA-3 MARINE TRIGLYCERIDES	1	0.9	1	0.9	0	0	0	0	1	1.8	0	0
	PRAVASTATIN SODIUM	0	0	0	0	2	1.8	0	0	0	0	0	0
	PROPRANOLOL	0	0	1	0.9	0	0	1	1.8	0	0	0	0
	PROPRANOLOL HYDROCHLORIDE	0	0	2	1.8	1	0.9	1	1.8	0	0	0	0
	SIMVASTATIN	1	0.9	0	0	2	1.8	0	0	1	1.8	0	0
	SPIRONOLACTONE	0	0	0	0	0	0	0	0	0	0	1	1.8
	TRIAMTERENE	0	0	0	0	2	1.8	0	0	0	0	0	0
	UBIDECARENONE	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	VALSARTAN	0	0	1	0.9	0	0	0	0	0	0	0	0
	VERAPAMIL	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	VERAPAMIL HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	1	1.8
DERMATOLOGICALS	TOTAL	1	0.9	2	1.8	1	0.9	2	3.6	1	1.8	1	1.8
	CALCIPOTRIOL	1	0.9	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	CLOBETASOL PROPIONATE	0	0	1	0.9	0	0	0	0	0	0	0	0
	COLECALCIFEROL	0	0	0	0	1	0.9	0	0	0	0	0	0
	DIPHENHYDRAMINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	0	0	1	1.8
	GLYCEROL	0	0	0	0	0	0	0	0	1	1.8	0	0
	HYDROCORTISONE	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	NEOMYCIN SULFATE	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	PETROLATUM	0	0	0	0	0	0	1	1.8	0	0	0	0
	TRIAMCINOLONE	0	0	0	0	0	0	1	1.8	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	14	12.1	12	10.5	9	8.0	7	12.5	8	14.3	10	17.5
	CLINDAMYCIN	1	0.9	0	0	0	0	0	0	0	0	0	0
	EQUISETUM ARVENSE	0	0	0	0	0	0	0	0	1	1.8	0	0
	ESTRADIOL	0	0	1	0.9	2	1.8	0	0	0	0	1	1.8
	ESTROGENS CONJUGATED	1	0.9	3	2.6	1	0.9	0	0	0	0	0	0
	ETHINYLESTRADIOL	8	6.9	3	2.6	4	3.6	3	5.4	2	3.6	6	10.5
	LEVONORGESTREL	0	0	0	0	0	0	0	0	1	1.8	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	MEDROXYPROGESTERONE ACETATE	2	1.7	3	2.6	1	0.9	0	0	1	1.8	1	1.8
	MICONAZOLE NITRATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	0	0	0	0	0	0	0	0	0	1	1.8
	NORETHISTERONE	1	0.9	0	0	0	0	0	0	0	0	1	1.8
	NORETHISTERONE ACETATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	OXYBUTYNIN	0	0	1	0.9	0	0	0	0	0	0	0	0
	OXYBUTYNIN HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	PHENAZOPYRIDINE HYDROCHLORIDE	0	0	0	0	0	0	1	1.8	0	0	0	0
	PROGESTERONE	0	0	1	0.9	0	0	0	0	0	0	0	0
	RALOXIFENE HYDROCHLORIDE	0	0	0	0	0	0	1	1.8	0	0	0	0
	SERENOA REPENS	0	0	0	0	0	0	1	1.8	0	0	0	0
	SILDENAFIL CITRATE	1	0.9	1	0.9	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	TAMSULOSIN HYDROCHLORIDE	0	0	0	0	0	0	0	0	2	3.6	0	0
	TESTOSTERONE	0	0	0	0	0	0	1	1.8	0	0	0	0
	TOLTERODINE L-TARTRATE	0	0	1	0.9	0	0	0	0	0	0	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	38	32.8	39	34.2	43	38.4	17	30.4	21	37.5	18	31.6
	ALENDRONATE SODIUM	0	0	2	1.8	0	0	0	0	0	0	0	0
	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS	0	0	0	0	0	0	0	0	0	0	1	1.8
	ASCORBIC ACID	0	0	2	1.8	0	0	0	0	0	0	0	0
	CARISOPRODOL	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	CELECOXIB	0	0	3	2.6	4	3.6	1	1.8	2	3.6	3	5.3
	CHONDROITIN SULFATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	COLCHICINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	CYCLOBENZAPRINE HYDROCHLORIDE	1	0.9	0	0	0	0	0	0	0	0	0	0
	GLUCOSAMINE	1	0.9	0	0	0	0	0	0	0	0	0	0
	IBUPROFEN	30	25.9	26	22.8	25	22.3	12	21.4	11	19.6	10	17.5

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	KETOPROFEN	0	0	0	0	0	0	1	1.8	0	0	0	0
	METAXALONE	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	NABUMETONE	0	0	0	0	0	0	0	0	1	1.8	0	0
	NAPROXEN	2	1.7	1	0.9	2	1.8	0	0	3	5.4	1	1.8
	NAPROXEN SODIUM	7	6.0	4	3.5	13	11.6	1	1.8	1	1.8	1	1.8
	ORPHENADRINE CITRATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	OXAPROZIN	0	0	0	0	0	0	0	0	1	1.8	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	2	1.7	0	0	2	1.8	0	0	0	0	0	0
	ROFECOXIB	0	0	0	0	0	0	1	1.8	1	1.8	3	5.3
	TIZANIDINE HYDROCHLORIDE	0	0	0	0	0	0	1	1.8	0	0	1	1.8
	VALDECOXIB	1	0.9	3	2.6	1	0.9	0	0	1	1.8	0	0
NERVOUS SYSTEM	TOTAL	47	40.5	53	46.5	54	48.2	23	41.1	21	37.5	24	42.1
	ACETAZOLAMIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	ACETYLSALICYLIC ACID	15	12.9	19	16.7	21	18.8	12	21.4	6	10.7	10	17.5

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	ALPRAZOLAM	0	0	0	0	1	0.9	0	0	0	0	0	0
	AMANTADINE	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	AMITRIPTYLINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	1	1.8	0	0
	ANAESTHETICS, GENERAL	0	0	0	0	2	1.8	0	0	0	0	0	0
	ANAESTHETICS, LOCAL	0	0	1	0.9	0	0	0	0	0	0	0	0
	ANALGESICS	0	0	0	0	1	0.9	0	0	0	0	0	0
	ARIPIPRAZOLE	1	0.9	0	0	0	0	0	0	0	0	0	0
	BENZATROPINE MESILATE	0	0	1	0.9	0	0	2	3.6	0	0	0	0
	BUPROPION HYDROCHLORIDE	0	0	0	0	0	0	0	0	2	3.6	0	0
	BUTORPHANOL TARTRATE	0	0	0	0	0	0	0	0	0	0	1	1.8
	CITALOPRAM HYDROBROMIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	CLONAZEPAM	0	0	0	0	1	0.9	0	0	0	0	0	0
	CODEINE PHOSPHATE	0	0	0	0	2	1.8	0	0	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	DIAZEPAM	0	0	0	0	1	0.9	0	0	0	0	0	0
	DIPHENHYDRAMINE	2	1.7	1	0.9	2	1.8	0	0	0	0	1	1.8
	DISULFIRAM	0	0	0	0	1	0.9	0	0	0	0	0	0
	DOXEPIN HYDROCHLORIDE	0	0	0	0	0	0	0	0	1	1.8	0	0
	ESCITALOPRAM	1	0.9	0	0	0	0	0	0	0	0	0	0
	ETHANOL	1	0.9	0	0	3	2.7	0	0	0	0	2	3.5
	FENTANYL	0	0	1	0.9	0	0	0	0	0	0	0	0
	GABAPENTIN	0	0	0	0	0	0	0	0	1	1.8	0	0
	GINKGO BILOBA	0	0	0	0	0	0	0	0	1	1.8	0	0
	HYDROCODONE BITARTRATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	HYDROMORPHONE HYDROCHLORIDE	0	0	0	0	0	0	0	0	0	0	1	1.8
	HYDROXYZINE EMBONATE	0	0	1	0.9	0	0	0	0	0	0	0	0
	LEVETIRACETAM	0	0	0	0	0	0	0	0	1	1.8	0	0
	LEVODOPA	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	LITHIUM	0	0	1	0.9	0	0	0	0	0	0	0	0
	LITHIUM CARBONATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	LORAZEPAM	11	9.5	9	7.9	14	12.5	6	10.7	0	0	0	0
	MEPYRAMINE MALEATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	MORPHINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	1	1.8	0	0
	MORPHINE SULFATE	1	0.9	0	0	0	0	0	0	0	0	0	0
	NICOTINE	0	0	1	0.9	0	0	1	1.8	0	0	0	0
	OXYCODONE HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	PARACETAMOL	30	25.9	28	24.6	23	20.5	11	19.6	14	25.0	12	21.1
	PETHIDINE HYDROCHLORIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	PROCAINE HYDROCHLORIDE	0	0	0	0	0	0	1	1.8	0	0	0	0
	RISPERIDONE	0	0	1	0.9	0	0	0	0	0	0	0	0
	RIZATRIPTAN BENZOATE	1	0.9	0	0	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	SERTRALINE HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0
	SUMATRIPTAN SUCCINATE	0	0	0	0	2	1.8	0	0	0	0	0	0
	TOPIRAMATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	VALERIANA OFFICINALIS ROOT	0	0	1	0.9	0	0	0	0	0	0	0	0
	ZALEPLON	0	0	0	0	0	0	0	0	0	0	1	1.8
	ZOLMITRIPTAN	0	0	0	0	1	0.9	0	0	0	0	0	0
	ZOLPIDEM TARTRATE	3	2.6	9	7.9	10	8.9	4	7.1	2	3.6	3	5.3
RESPIRATORY SYSTEM	TOTAL	26	22.4	22	19.3	33	29.5	11	19.6	20	35.7	16	28.1
	ALLERGY MEDICATION	0	0	0	0	0	0	0	0	1	1.8	0	0
	ANTI-ASTHMATICS	0	0	0	0	0	0	0	0	1	1.8	0	0
	ANTIHISTAMINES FOR SYSTEMIC USE	0	0	0	0	0	0	0	0	1	1.8	0	0
	AZELASTINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	0	0	1	1.8
	BENZONATATE	0	0	0	0	0	0	0	0	1	1.8	2	3.5
	BUDESONIDE	0	0	0	0	1	0.9	0	0	1	1.8	0	0

(Continued)

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	CAMPHOR	0	0	0	0	0	0	1	1.8	1	1.8	0	0
	CETIRIZINE HYDROCHLORIDE	2	1.7	1	0.9	2	1.8	1	1.8	2	3.6	2	3.5
	CHLORPHENAMINE MALEATE	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	CODEINE PHOSPHATE	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	COUGH AND COLD PREPARATIONS	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	DESLORATADINE	1	0.9	0	0	0	0	0	0	0	0	2	3.5
	DEXBROMPHENIRAMINE MALEATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	DEXTROMETHORPHAN HYDROBROMIDE	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	DIPHENHYDRAMINE	1	0.9	0	0	0	0	0	0	0	0	0	0
	DIPHENHYDRAMINE HYDROCHLORIDE	2	1.7	2	1.8	7	6.3	0	0	0	0	1	1.8
	EPINEPHRINE	0	0	0	0	0	0	0	0	1	1.8	0	0
	ETHANOL	1	0.9	0	0	0	0	0	0	0	0	1	1.8
	FEXOFENADINE HYDROCHLORIDE	3	2.6	2	1.8	2	1.8	0	0	2	3.6	2	3.5

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	FLUTICASONE PROPIONATE	2	1.7	3	2.6	4	3.6	2	3.6	4	7.1	5	8.8
	GARLIC	1	0.9	0	0	0	0	0	0	0	0	0	0
	GUAIFENESIN	4	3.4	1	0.9	5	4.5	1	1.8	2	3.6	2	3.5
	HYDROCODONE	1	0.9	0	0	0	0	0	0	0	0	1	1.8
	IPRATROPIUM BROMIDE	1	0.9	0	0	1	0.9	1	1.8	0	0	1	1.8
	LORATADINE	2	1.7	2	1.8	5	4.5	0	0	3	5.4	1	1.8
	MECLOZINE	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	MECLOZINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	0	0	1	1.8
	MEPYRAMINE MALEATE	0	0	0	0	0	0	0	0	1	1.8	0	0
	MOMETASONE FUROATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	MONTELUKAST SODIUM	0	0	0	0	0	0	0	0	0	0	2	3.5
	NASAL DECONGESTANTS FOR SYSTEMIC USE	0	0	0	0	0	0	0	0	0	0	1	1.8
	OTHER COLD COMBINATION PREPARATIONS	1	0.9	1	0.9	0	0	0	0	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	OXYMETAZOLINE HYDROCHLORIDE	0	0	1	0.9	4	3.6	0	0	1	1.8	0	0
	PARACETAMOL	0	0	1	0.9	2	1.8	0	0	0	0	0	0
	PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	PHENYLPROPANOLAMINE HYDROCHLORIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	PIRBUTEROL ACETATE	0	0	0	0	1	0.9	0	0	0	0	0	0
	PROMETHAZINE HYDROCHLORIDE	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	PSEUDOEPHEDRINE	0	0	0	0	1	0.9	0	0	0	0	0	0
	PSEUDOEPHEDRINE HYDROCHLORIDE	3	2.6	2	1.8	7	6.3	3	5.4	2	3.6	1	1.8
	PSEUDOEPHEDRINE SULFATE	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	SALBUTAMOL	8	6.9	9	7.9	7	6.3	5	8.9	3	5.4	3	5.3
	SALMETEROL XINAFOATE	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	SODIUM CHLORIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	TERPIN HYDRATE	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	TRIAMCINOLONE ACETONIDE	2	1.7	4	3.5	1	0.9	0	0	1	1.8	0	0
SENSORY ORGANS	TOTAL	4	3.4	0	0	2	1.8	0	0	3	5.4	0	0
	BIMATOPROST	1	0.9	0	0	0	0	0	0	0	0	0	0
	HYDROCORTISONE	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	KETOROLAC TROMETHAMINE	1	0.9	0	0	0	0	0	0	2	3.6	0	0
	LATANOPROST	0	0	0	0	0	0	0	0	1	1.8	0	0
	TETRYZOLINE HYDROCHLORIDE	0	0	0	0	1	0.9	0	0	0	0	0	0
	TROPICAMIDE	1	0.9	0	0	0	0	0	0	0	0	0	0
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	TOTAL	4	3.4	6	5.3	9	8.0	3	5.4	4	7.1	6	10.5
	CORTISONE	1	0.9	0	0	1	0.9	0	0	1	1.8	0	0
	DEXAMETHASONE	0	0	0	0	0	0	0	0	0	0	1	1.8
	LEVOTHYROXINE	0	0	1	0.9	0	0	0	0	0	0	0	0
	LEVOTHYROXINE SODIUM	3	2.6	5	4.4	6	5.4	3	5.4	2	3.6	3	5.3
	LIOTHYRONINE SODIUM	0	0	0	0	1	0.9	1	1.8	0	0	0	0

(Continued)

Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=116		N=114		N=112		N=56		N=56		N=57	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	METHYLPREDNISOLONE	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	PREDNISONE	0	0	0	0	1	0.9	0	0	1	1.8	1	1.8
	THYROID	0	0	0	0	1	0.9	0	0	0	0	1	1.8
VARIOUS	TOTAL	4	3.4	3	2.6	7	6.3	3	5.4	3	5.4	3	5.3
	BARIUM	0	0	1	0.9	0	0	0	0	0	0	0	0
	BORAGE OIL	0	0	0	0	0	0	0	0	0	0	1	1.8
	DIAGNOSTIC RADIOPHARMACEUTICALS	0	0	0	0	1	0.9	0	0	0	0	0	0
	ECHINACEA EXTRACT	1	0.9	0	0	2	1.8	1	1.8	0	0	2	3.5
	GINGER	0	0	0	0	0	0	0	0	1	1.8	0	0
	HERBAL EXTRACTS NOS	0	0	0	0	1	0.9	0	0	0	0	0	0
	HERBAL PREPARATION	1	0.9	1	0.9	3	2.7	2	3.6	2	3.6	0	0
	HOMEOPATIC PREPARATION	0	0	0	0	1	0.9	0	0	0	0	0	0
	LINSEED OIL	2	1.7	0	0	0	0	0	0	0	0	1	1.8
	NALOXONE HYDROCHLORIDE	0	0	1	0.9	0	0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS207.SAS
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Table 11.1.7.10 Anticholinergic Medications During the Randomized Treatment Phase
Safety Population

Treatment Interval(Weeks since randomization)	TREATMENT								
	QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
	N=179			N=180			N=180		
	N*	n**	%	N*	n**	%	N*	n**	%
WEEK 1	179	5	2.8	180	1	0.6	180	6	3.3
WEEK 2	164	2	1.2	159	1	0.6	170	9	5.3
WEEK 3	151	3	2.0	140	2	1.4	159	10	6.3
WEEK 4	142	1	0.7	132	0	0.0	144	4	2.8
WEEK 5	135	1	0.7	124	0	0.0	129	4	3.1
WEEK 6	133	1	0.8	116	0	0.0	120	4	3.3
WEEK 7	130	1	0.8	109	1	0.9	116	4	3.4
WEEK 8	123	1	0.8	105	1	1.0	109	4	3.7

* Number of patients in the study at the start of the treatment interval.
** Number of patients receiving at least one dose of medication during the treatment interval.
Percentages are calculated as n**/N* x 100.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS209.SAS
GENERATED: 12JUL2005 17:45:36 iceadmn3

Table 11.2.1.1.1 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	172	30.3	5.03	30.0	13	45	170	30.3	5.29	30.0	16	48	169	30.6	5.27	31.0	20	47
	DAY 8	171	21.8	7.50	23.0	0	38	169	21.6	7.98	22.0	5	41	169	25.8	8.36	27.0	1	45
	DAY 15	172	18.4	8.68	19.0	0	40	170	18.6	8.61	18.5	0	42	169	23.3	9.16	24.0	2	46
	DAY 22	172	17.2	9.46	17.0	0	39	170	16.8	9.47	17.0	0	41	169	22.0	10.01	23.0	1	48
	DAY 29	172	16.5	9.25	16.0	0	38	170	14.6	9.90	13.0	0	37	169	21.5	10.59	21.0	1	48
	DAY 36	172	15.2	9.71	15.0	0	38	170	14.7	10.49	13.0	0	42	169	21.3	10.73	22.0	0	48
	DAY 43	172	14.4	9.76	13.0	0	38	170	14.3	10.58	11.5	0	38	169	20.8	10.85	21.0	0	48
	DAY 50	172	14.2	9.92	12.0	0	39	170	14.2	10.59	12.5	0	38	169	21.0	11.41	21.0	0	48
	DAY 57	172	13.9	10.46	12.0	0	39	170	13.6	10.66	12.0	0	38	169	20.2	11.55	20.0	0	48
CHG FROM BASELINE	DAY 8	171	-8.5	7.18	-8.0	-32	11	169	-8.7	7.76	-8.0	-29	8	169	-4.8	7.30	-3.0	-31	7
	DAY 15	172	-11.9	8.28	-11.5	-36	4	170	-11.8	9.29	-11.0	-35	7	169	-7.3	8.05	-6.0	-27	9
	DAY 22	172	-13.2	8.69	-13.0	-41	5	170	-13.5	10.22	-13.5	-40	10	169	-8.5	9.42	-8.0	-31	9
	DAY 29	172	-13.8	9.26	-14.5	-41	6	170	-15.7	10.37	-17.0	-36	6	169	-9.1	10.01	-9.0	-32	13
	DAY 36	172	-15.1	9.38	-15.5	-38	5	170	-15.6	11.03	-16.0	-41	11	169	-9.3	10.01	-9.0	-33	13
	DAY 43	172	-15.9	9.36	-16.0	-41	5	170	-16.0	11.14	-17.5	-39	9	169	-9.8	10.12	-10.0	-33	13
	DAY 50	172	-16.1	9.55	-17.5	-41	5	170	-16.2	11.21	-17.0	-41	9	169	-9.6	10.88	-9.0	-33	15

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS202.SAS
GENERATED: 12JUL2005 17:44:28 iceadmn3

Table 11.2.1.1.1 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	172	-16.5	9.88	-17.0	-41	10	170	-16.8	10.94	-18.0	-39	9	169	-10.4	10.77	-10.0	-35	13

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS202.SAS
GENERATED: 12JUL2005 17:44:28 iceadmn3

Table 11.2.1.1.2 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	172	30.3	5.03	30.0	13	45	170	30.3	5.29	30.0	16	48	169	30.6	5.27	31.0	20	47
	DAY 8	171	21.8	7.50	23.0	0	38	169	21.6	7.98	22.0	5	41	169	25.8	8.36	27.0	1	45
	DAY 15	148	18.0	8.61	18.0	0	40	148	18.0	8.57	18.0	0	42	149	22.5	8.73	23.0	2	46
	DAY 22	139	16.8	9.44	16.0	0	39	133	15.4	9.36	15.0	0	41	143	21.2	9.83	22.0	1	48
	DAY 29	133	15.5	8.73	15.0	0	38	127	12.2	8.90	11.0	0	37	126	19.5	10.08	19.5	1	42
	DAY 36	130	13.7	9.04	13.0	0	37	113	11.9	9.87	10.0	0	42	119	18.8	10.12	20.0	0	40
	DAY 43	123	12.1	8.61	11.0	0	37	107	10.8	9.31	8.0	0	37	107	18.0	10.29	19.0	0	43
	DAY 50	121	12.0	8.89	9.0	0	39	101	10.7	9.53	8.0	0	37	102	18.2	11.20	17.0	0	43
	DAY 57	119	11.9	9.60	10.0	0	39	97	9.6	9.18	7.0	0	36	99	17.5	11.14	15.0	0	43
CHG FROM BASELINE	DAY 8	171	-8.5	7.18	-8.0	-32	11	169	-8.7	7.76	-8.0	-29	8	169	-4.8	7.30	-3.0	-31	7
	DAY 15	148	-12.4	8.34	-13.0	-36	4	148	-12.4	9.36	-12.0	-35	7	149	-7.8	7.97	-6.0	-27	9
	DAY 22	139	-13.6	8.63	-13.0	-41	5	133	-15.2	9.93	-16.0	-40	10	143	-9.2	9.57	-8.0	-31	9
	DAY 29	133	-14.7	8.99	-16.0	-41	6	127	-18.3	9.56	-20.0	-36	6	126	-10.7	10.05	-10.5	-32	13
	DAY 36	130	-16.5	8.99	-18.0	-38	3	113	-18.2	10.51	-19.0	-41	11	119	-11.2	10.13	-11.0	-33	10
	DAY 43	123	-18.1	8.58	-19.0	-41	2	107	-19.1	10.41	-21.0	-39	9	107	-11.8	10.16	-12.0	-32	9
	DAY 50	121	-18.2	8.87	-19.0	-41	3	101	-19.3	10.67	-20.0	-41	7	102	-11.7	11.44	-12.0	-33	15

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS200.SAS
GENERATED: 12JUL2005 17:44:21 iceadmn3

Table 11.2.1.1.2 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	119	-18.6	9.19	-19.0	-41	10	97	-20.4	9.75	-21.0	-39	5	99	-12.7	11.06	-13.0	-35	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS200.SAS
GENERATED: 12JUL2005 17:44:21 iceadmn3

Table 11.2.1.1.3 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	152	30.5	4.87	30.0	19	45	147	30.4	5.39	30.0	16	48	154	30.6	5.31	31.0	20	47
	DAY 8	152	21.9	7.44	23.0	0	37	147	21.5	8.00	22.0	5	41	154	25.4	8.47	26.0	1	42
	DAY 15	152	18.2	8.68	19.0	0	40	147	17.8	8.41	18.0	0	42	154	22.8	9.12	23.0	2	46
	DAY 22	152	16.9	9.56	16.5	0	39	147	16.2	9.27	16.0	0	41	154	21.4	9.96	23.0	1	48
	DAY 29	152	16.2	9.32	15.0	0	38	147	13.7	9.63	11.0	0	37	154	21.2	10.50	21.0	1	48
	DAY 36	152	14.7	9.77	14.0	0	38	147	13.9	10.31	12.0	0	42	154	20.8	10.73	22.0	0	48
	DAY 43	152	13.8	9.77	12.0	0	38	147	13.5	10.37	11.0	0	38	154	20.2	10.83	21.0	0	48
	DAY 50	152	13.5	9.94	11.0	0	39	147	13.3	10.36	12.0	0	38	154	20.4	11.31	21.0	0	48
	DAY 57	152	13.1	10.37	11.0	0	38	147	12.3	10.23	10.0	0	38	154	19.5	11.49	18.5	0	48
CHG FROM BASELINE	DAY 8	152	-8.6	7.30	-8.0	-32	11	147	-8.9	7.73	-8.0	-29	8	154	-5.1	7.35	-4.0	-31	7
	DAY 15	152	-12.3	8.38	-13.0	-36	4	147	-12.6	9.09	-12.0	-35	7	154	-7.8	7.99	-6.0	-27	9
	DAY 22	152	-13.6	8.78	-13.0	-41	5	147	-14.2	9.92	-15.0	-40	10	154	-9.1	9.39	-8.0	-31	9
	DAY 29	152	-14.3	9.42	-15.0	-41	6	147	-16.7	10.02	-17.0	-36	6	154	-9.4	9.94	-9.0	-32	13
	DAY 36	152	-15.8	9.45	-17.0	-38	5	147	-16.4	10.77	-17.0	-34	11	154	-9.7	10.06	-10.0	-33	13
	DAY 43	152	-16.7	9.38	-18.0	-41	5	147	-16.9	10.89	-19.0	-39	9	154	-10.3	10.12	-10.0	-33	13
	DAY 50	152	-17.0	9.54	-18.0	-41	5	147	-17.0	10.95	-19.0	-40	9	154	-10.2	10.79	-9.5	-33	13

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS203.SAS
GENERATED: 12JUL2005 17:44:30 iceadmn3

Table 11.2.1.1.3 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	152	-17.4	9.78	-18.0	-41	10	147	-18.1	10.56	-19.0	-39	9	154	-11.1	10.72	-10.5	-35	13

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS203.SAS
GENERATED: 12JUL2005 17:44:30 iceadmn3

Table 11.2.1.1.4 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Per-Protocol Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	152	30.5	4.87	30.0	19	45	147	30.4	5.39	30.0	16	48	154	30.6	5.31	31.0	20	47
	DAY 8	152	21.9	7.44	23.0	0	37	147	21.5	8.00	22.0	5	41	154	25.4	8.47	26.0	1	42
	DAY 15	142	17.9	8.45	18.0	0	40	139	17.7	8.49	18.0	0	42	142	22.4	8.81	23.0	2	46
	DAY 22	136	16.7	9.48	16.0	0	39	126	15.5	9.32	15.0	0	41	134	20.8	9.79	22.0	1	48
	DAY 29	131	15.5	8.80	15.0	0	38	118	12.2	9.04	10.5	0	37	118	19.5	10.09	19.0	1	42
	DAY 36	128	13.6	9.08	13.0	0	37	107	12.1	10.00	10.0	0	42	110	18.7	10.23	20.0	0	40
	DAY 43	121	12.0	8.65	11.0	0	37	101	11.1	9.39	9.0	0	37	99	17.8	10.23	18.0	0	43
	DAY 50	119	11.9	8.91	9.0	0	39	99	10.9	9.54	8.0	0	37	95	17.7	11.01	17.0	0	43
	DAY 57	112	11.4	9.34	9.0	0	38	94	9.2	8.78	6.5	0	34	93	16.9	11.01	15.0	0	43
CHG FROM BASELINE	DAY 8	152	-8.6	7.30	-8.0	-32	11	147	-8.9	7.73	-8.0	-29	8	154	-5.1	7.35	-4.0	-31	7
	DAY 15	142	-12.5	8.31	-13.0	-36	4	139	-12.7	9.19	-12.0	-35	7	142	-8.0	7.92	-6.5	-27	9
	DAY 22	136	-13.7	8.63	-13.0	-41	5	126	-15.1	9.75	-15.5	-40	10	134	-9.6	9.54	-8.0	-31	9
	DAY 29	131	-14.7	9.06	-16.0	-41	6	118	-18.2	9.62	-20.0	-36	6	118	-10.7	10.06	-10.5	-32	13
	DAY 36	128	-16.6	9.02	-18.0	-38	3	107	-18.0	10.51	-19.0	-34	11	110	-11.5	10.20	-11.0	-33	7
	DAY 43	121	-18.1	8.64	-19.0	-41	2	101	-18.8	10.43	-20.0	-39	9	99	-12.3	9.96	-13.0	-32	9
	DAY 50	119	-18.3	8.88	-19.0	-41	3	99	-19.0	10.54	-20.0	-40	7	95	-12.4	11.15	-12.0	-33	9

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS201.SAS
GENERATED: 12JUL2005 17:44:24 iceadmn3

Table 11.2.1.1.4 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Per-Protocol Population

		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	112	-18.8	9.14	-19.0	-41	10	94	-20.6	9.54	-21.0	-39	-2	93	-13.4	10.83	-14.0	-35	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS201.SAS
GENERATED: 12JUL2005 17:44:24 iceadmn3

Table 11.2.1.2.1 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	30.4	5.00	-8.5	7.18	-8.67	0.647	-9.95	-7.39	.
	Q600MG	169	30.3	5.29	-8.7	7.76	-8.78	0.652	-10.07	-7.49	.
	P	169	30.6	5.27	-4.8	7.30	-4.89	0.649	-6.17	-3.60	.
	Q300MG VS P	.	.	.	.	.	-3.79	0.767	-5.29	-2.28	<.001
	Q600MG VS P	.	.	.	.	.	-3.89	0.772	-5.41	-2.38	<.001
DAY 15	Q300MG	172	30.3	5.03	-11.9	8.28	-11.92	0.735	-13.38	-10.46	.
	Q600MG	170	30.3	5.29	-11.8	9.29	-11.70	0.740	-13.17	-10.23	.
	P	169	30.6	5.27	-7.3	8.05	-7.21	0.738	-8.68	-5.75	.
	Q300MG VS P	.	.	.	.	.	-4.71	0.889	-6.46	-2.96	<.001
	Q600MG VS P	.	.	.	.	.	-4.49	0.894	-6.25	-2.73	<.001
DAY 22	Q300MG	172	30.3	5.03	-13.2	8.69	-13.26	0.808	-14.86	-11.66	.
	Q600MG	170	30.3	5.29	-13.5	10.22	-13.55	0.814	-15.16	-11.94	.
	P	169	30.6	5.27	-8.5	9.42	-8.46	0.811	-10.07	-6.85	.
	Q300MG VS P	.	.	.	.	.	-4.80	0.989	-6.74	-2.86	<.001
	Q600MG VS P	.	.	.	.	.	-5.09	0.994	-7.04	-3.14	<.001
DAY 29	Q300MG	172	30.3	5.03	-13.8	9.26	-13.87	0.870	-15.60	-12.15	.
	Q600MG	170	30.3	5.29	-15.7	10.37	-15.73	0.876	-17.47	-14.00	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223.SAS
GENERATED: 12JUL2005 17:29:31 iceadmn3

Table 11.2.1.2.1 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	30.6	5.27	-9.1	10.01	-8.96	0.874	-10.70	-7.22	.
	Q300MG VS P	.	.	.	.	.	-4.92	1.023	-6.93	-2.90	<.001
	Q600MG VS P	.	.	.	.	.	-6.78	1.029	-8.80	-4.75	<.001
DAY 36	Q300MG	172	30.3	5.03	-15.1	9.38	-14.93	0.866	-16.65	-13.22	.
	Q600MG	170	30.3	5.29	-15.6	11.03	-15.41	0.872	-17.14	-13.68	.
	P	169	30.6	5.27	-9.3	10.01	-9.21	0.870	-10.93	-7.48	.
	Q300MG VS P	.	.	.	.	.	-5.73	1.066	-7.82	-3.63	<.001
	Q600MG VS P	.	.	.	.	.	-6.20	1.071	-8.31	-4.10	<.001
DAY 43	Q300MG	172	30.3	5.03	-15.9	9.36	-15.71	0.848	-17.38	-14.03	.
	Q600MG	170	30.3	5.29	-16.0	11.14	-15.81	0.854	-17.50	-14.12	.
	P	169	30.6	5.27	-9.8	10.12	-9.57	0.851	-11.25	-7.89	.
	Q300MG VS P	.	.	.	.	.	-6.14	1.077	-8.25	-4.02	<.001
	Q600MG VS P	.	.	.	.	.	-6.24	1.082	-8.37	-4.12	<.001
DAY 50	Q300MG	172	30.3	5.03	-16.1	9.55	-16.05	0.891	-17.82	-14.29	.
	Q600MG	170	30.3	5.29	-16.2	11.21	-16.05	0.898	-17.83	-14.27	.
	P	169	30.6	5.27	-9.6	10.88	-9.36	0.895	-11.13	-7.59	.
	Q300MG VS P	.	.	.	.	.	-6.70	1.107	-8.87	-4.52	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223.SAS
GENERATED: 12JUL2005 17:29:31 iceadmn3

Table 11.2.1.2.1 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-6.69	1.113	-8.88	-4.51	<.001
DAY 57	Q300MG	172	30.3	5.03	-16.5	9.88	-16.39	0.906	-18.18	-14.59	.
	Q600MG	170	30.3	5.29	-16.8	10.94	-16.73	0.913	-18.53	-14.92	.
	P	169	30.6	5.27	-10.4	10.77	-10.26	0.910	-12.06	-8.45	.
	Q300MG VS P	.	.	.	.	.	-6.13	1.116	-8.32	-3.94	<.001
	Q600MG VS P	.	.	.	.	.	-6.47	1.122	-8.67	-4.26	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223.SAS
GENERATED: 12JUL2005 17:29:31 iceadmn3

Table 11.2.1.2.2 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	30.4	5.00	-8.5	7.18	-8.67	0.647	-9.95	-7.39	.
	Q600MG	169	30.3	5.29	-8.7	7.76	-8.78	0.652	-10.07	-7.49	.
	P	169	30.6	5.27	-4.8	7.30	-4.89	0.649	-6.17	-3.60	.
	Q300MG VS P	.	.	.	.	.	-3.79	0.767	-5.29	-2.28	<.001
	Q600MG VS P	.	.	.	.	.	-3.89	0.772	-5.41	-2.38	<.001
DAY 15	Q300MG	148	30.4	4.95	-12.4	8.34	-12.34	0.786	-13.90	-10.78	.
	Q600MG	148	30.4	5.39	-12.4	9.36	-12.34	0.789	-13.90	-10.77	.
	P	149	30.3	5.26	-7.8	7.97	-7.82	0.773	-9.35	-6.28	.
	Q300MG VS P	.	.	.	.	.	-4.53	0.946	-6.39	-2.67	<.001
	Q600MG VS P	.	.	.	.	.	-4.52	0.947	-6.38	-2.66	<.001
DAY 22	Q300MG	139	30.4	4.92	-13.6	8.63	-13.71	0.878	-15.45	-11.97	.
	Q600MG	133	30.6	5.63	-15.2	9.93	-15.17	0.899	-16.95	-13.39	.
	P	143	30.4	5.28	-9.2	9.57	-9.24	0.860	-10.95	-7.54	.
	Q300MG VS P	.	.	.	.	.	-4.47	1.074	-6.58	-2.36	<.001
	Q600MG VS P	.	.	.	.	.	-5.93	1.089	-8.07	-3.78	<.001
DAY 29	Q300MG	133	30.3	4.90	-14.7	8.99	-14.85	0.917	-16.67	-13.03	.
	Q600MG	127	30.4	5.47	-18.3	9.56	-18.20	0.939	-20.06	-16.34	.

(Continued)

Table 11.2.1.2.2 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	126	30.2	5.03	-10.7	10.05	-10.79	0.927	-12.63	-8.95	.
	Q300MG VS P	.	.	.	.	.	-4.06	1.108	-6.24	-1.88	<.001
	Q600MG VS P	.	.	.	.	.	-7.41	1.126	-9.62	-5.20	<.001
DAY 36	Q300MG	130	30.2	4.94	-16.5	8.99	-16.36	0.919	-18.19	-14.54	.
	Q600MG	113	30.1	5.28	-18.2	10.51	-18.02	0.986	-19.97	-16.06	.
	P	119	30.0	4.84	-11.2	10.13	-11.17	0.940	-13.04	-9.31	.
	Q300MG VS P	.	.	.	.	.	-5.19	1.196	-7.54	-2.84	<.001
	Q600MG VS P	.	.	.	.	.	-6.84	1.244	-9.29	-4.40	<.001
DAY 43	Q300MG	123	30.1	4.86	-18.1	8.58	-17.62	0.917	-19.44	-15.80	.
	Q600MG	107	29.9	5.24	-19.1	10.41	-18.88	0.978	-20.82	-16.95	.
	P	107	29.9	4.62	-11.8	10.16	-11.71	0.959	-13.61	-9.81	.
	Q300MG VS P	.	.	.	.	.	-5.91	1.214	-8.30	-3.52	<.001
	Q600MG VS P	.	.	.	.	.	-7.18	1.257	-9.65	-4.70	<.001
DAY 50	Q300MG	121	30.2	4.86	-18.2	8.87	-17.90	0.982	-19.84	-15.95	.
	Q600MG	101	30.0	5.37	-19.3	10.67	-19.09	1.061	-21.18	-16.99	.
	P	102	29.9	4.91	-11.7	11.44	-11.63	1.037	-13.69	-9.58	.
	Q300MG VS P	.	.	.	.	.	-6.26	1.300	-8.82	-3.70	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS229.SAS
GENERATED: 12JUL2005 17:29:49 iceadmn3

Table 11.2.1.2.2 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-7.45	1.360	-10.13	-4.78	<.001
DAY 57	Q300MG	119	30.5	5.08	-18.6	9.19	-18.39	0.958	-20.29	-16.49	.
	Q600MG	97	29.9	5.46	-20.4	9.75	-20.46	1.053	-22.54	-18.38	.
	P	99	30.1	4.72	-12.7	11.06	-12.72	1.018	-14.73	-10.70	.
	Q300MG VS P	.	.	.	.	.	-5.67	1.320	-8.27	-3.08	<.001
	Q600MG VS P	.	.	.	.	.	-7.74	1.386	-10.47	-5.02	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS229.SAS
GENERATED: 12JUL2005 17:29:49 iceadmn3

Table 11.2.1.2.3 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	152	30.5	4.87	-8.6	7.30	-8.70	0.673	-10.03	-7.37	.
	Q600MG	147	30.4	5.39	-8.9	7.73	-9.00	0.685	-10.35	-7.64	.
	P	154	30.6	5.31	-5.1	7.35	-5.20	0.661	-6.51	-3.89	.
	Q300MG VS P	.	.	.	.	.	-3.50	0.820	-5.11	-1.89	<.001
	Q600MG VS P	.	.	.	.	.	-3.80	0.830	-5.43	-2.17	<.001
DAY 15	Q300MG	152	30.5	4.87	-12.3	8.38	-12.29	0.785	-13.85	-10.73	.
	Q600MG	147	30.4	5.39	-12.6	9.09	-12.53	0.798	-14.11	-10.94	.
	P	154	30.6	5.31	-7.8	7.99	-7.66	0.772	-9.19	-6.12	.
	Q300MG VS P	.	.	.	.	.	-4.63	0.930	-6.46	-2.81	<.001
	Q600MG VS P	.	.	.	.	.	-4.87	0.942	-6.72	-3.02	<.001
DAY 22	Q300MG	152	30.5	4.87	-13.6	8.78	-13.62	0.849	-15.30	-11.94	.
	Q600MG	147	30.4	5.39	-14.2	9.92	-14.29	0.864	-16.00	-12.57	.
	P	154	30.6	5.31	-9.1	9.39	-8.96	0.834	-10.61	-7.30	.
	Q300MG VS P	.	.	.	.	.	-4.66	1.036	-6.70	-2.63	<.001
	Q600MG VS P	.	.	.	.	.	-5.33	1.049	-7.39	-3.27	<.001
DAY 29	Q300MG	152	30.5	4.87	-14.3	9.42	-14.43	0.917	-16.25	-12.60	.
	Q600MG	147	30.4	5.39	-16.7	10.02	-16.81	0.933	-18.67	-14.96	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS225.SAS
GENERATED: 12JUL2005 17:29:37 iceadmn3

Table 11.2.1.2.3 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	154	30.6	5.31	-9.4	9.94	-9.27	0.903	-11.07	-7.47	.
	Q300MG VS P	.	.	.	.	.	-5.16	1.069	-7.26	-3.05	<.001
	Q600MG VS P	.	.	.	.	.	-7.54	1.084	-9.67	-5.41	<.001
DAY 36	Q300MG	152	30.5	4.87	-15.8	9.45	-15.65	0.908	-17.45	-13.85	.
	Q600MG	147	30.4	5.39	-16.4	10.77	-16.28	0.924	-18.12	-14.45	.
	P	154	30.6	5.31	-9.7	10.06	-9.61	0.892	-11.38	-7.84	.
	Q300MG VS P	.	.	.	.	.	-6.04	1.121	-8.24	-3.84	<.001
	Q600MG VS P	.	.	.	.	.	-6.67	1.135	-8.90	-4.44	<.001
DAY 43	Q300MG	152	30.5	4.87	-16.7	9.38	-16.47	0.879	-18.21	-14.73	.
	Q600MG	147	30.4	5.39	-16.9	10.89	-16.73	0.896	-18.50	-14.96	.
	P	154	30.6	5.31	-10.3	10.12	-10.12	0.863	-11.82	-8.41	.
	Q300MG VS P	.	.	.	.	.	-6.35	1.131	-8.57	-4.13	<.001
	Q600MG VS P	.	.	.	.	.	-6.61	1.143	-8.86	-4.37	<.001
DAY 50	Q300MG	152	30.5	4.87	-17.0	9.54	-16.88	0.930	-18.72	-15.03	.
	Q600MG	147	30.4	5.39	-17.0	10.95	-16.96	0.947	-18.84	-15.09	.
	P	154	30.6	5.31	-10.2	10.79	-9.98	0.913	-11.79	-8.17	.
	Q300MG VS P	.	.	.	.	.	-6.90	1.158	-9.17	-4.62	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS225.SAS
GENERATED: 12JUL2005 17:29:37 iceadmn3

Table 11.2.1.2.3 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-6.98	1.172	-9.29	-4.68	<.001
DAY 57	Q300MG	152	30.5	4.87	-17.4	9.78	-17.37	0.941	-19.23	-15.51	.
	Q600MG	147	30.4	5.39	-18.1	10.56	-18.13	0.958	-20.02	-16.23	.
	P	154	30.6	5.31	-11.1	10.72	-10.98	0.924	-12.81	-9.15	.
	Q300MG VS P	.	.	.	.	.	-6.39	1.160	-8.67	-4.11	<.001
	Q600MG VS P	.	.	.	.	.	-7.14	1.174	-9.45	-4.84	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS225.SAS
GENERATED: 12JUL2005 17:29:37 iceadmn3

Table 11.2.1.2.4 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	152	30.5	4.87	-8.6	7.30	-8.70	0.673	-10.03	-7.37	.
	Q600MG	147	30.4	5.39	-8.9	7.73	-9.00	0.685	-10.35	-7.64	.
	P	154	30.6	5.31	-5.1	7.35	-5.20	0.661	-6.51	-3.89	.
	Q300MG VS P	.	.	.	.	.	-3.50	0.820	-5.11	-1.89	<.001
	Q600MG VS P	.	.	.	.	.	-3.80	0.830	-5.43	-2.17	<.001
DAY 15	Q300MG	142	30.4	4.94	-12.5	8.31	-12.49	0.806	-14.09	-10.90	.
	Q600MG	139	30.4	5.46	-12.7	9.19	-12.64	0.812	-14.25	-11.03	.
	P	142	30.4	5.28	-8.0	7.92	-7.94	0.789	-9.51	-6.37	.
	Q300MG VS P	.	.	.	.	.	-4.55	0.957	-6.43	-2.67	<.001
	Q600MG VS P	.	.	.	.	.	-4.70	0.963	-6.59	-2.81	<.001
DAY 22	Q300MG	136	30.3	4.95	-13.7	8.63	-13.74	0.903	-15.53	-11.95	.
	Q600MG	126	30.5	5.64	-15.1	9.75	-15.15	0.933	-17.00	-13.30	.
	P	134	30.4	5.23	-9.6	9.54	-9.57	0.893	-11.34	-7.80	.
	Q300MG VS P	.	.	.	.	.	-4.17	1.087	-6.30	-2.03	<.001
	Q600MG VS P	.	.	.	.	.	-5.58	1.110	-7.76	-3.40	<.001
DAY 29	Q300MG	131	30.2	4.92	-14.7	9.06	-14.87	0.940	-16.74	-13.00	.
	Q600MG	118	30.4	5.49	-18.2	9.62	-18.26	0.981	-20.20	-16.31	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS230.SAS
GENERATED: 12JUL2005 17:29:52 iceadmn3

Table 11.2.1.2.4 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	118	30.2	4.97	-10.7	10.06	-10.78	0.960	-12.68	-8.87	.
	Q300MG VS P	.	.	.	.	.	-4.10	1.139	-6.34	-1.86	<.001
	Q600MG VS P	.	.	.	.	.	-7.48	1.172	-9.79	-5.17	<.001
DAY 36	Q300MG	128	30.2	4.96	-16.6	9.02	-16.46	0.950	-18.35	-14.58	.
	Q600MG	107	30.1	5.31	-18.0	10.51	-17.88	1.032	-19.93	-15.84	.
	P	110	30.1	4.85	-11.5	10.20	-11.43	0.989	-13.39	-9.47	.
	Q300MG VS P	.	.	.	.	.	-5.03	1.232	-7.46	-2.61	<.001
	Q600MG VS P	.	.	.	.	.	-6.45	1.293	-9.00	-3.91	<.001
DAY 43	Q300MG	121	30.1	4.88	-18.1	8.64	-17.66	0.938	-19.52	-15.80	.
	Q600MG	101	29.9	5.27	-18.8	10.43	-18.62	1.012	-20.62	-16.62	.
	P	99	30.1	4.70	-12.3	9.96	-12.07	0.996	-14.05	-10.10	.
	Q300MG VS P	.	.	.	.	.	-5.58	1.239	-8.02	-3.15	<.001
	Q600MG VS P	.	.	.	.	.	-6.55	1.293	-9.09	-4.00	<.001
DAY 50	Q300MG	119	30.1	4.88	-18.3	8.88	-17.93	0.985	-19.88	-15.98	.
	Q600MG	99	29.9	5.31	-19.0	10.54	-18.79	1.063	-20.89	-16.69	.
	P	95	30.1	4.93	-12.4	11.15	-12.20	1.056	-14.29	-10.11	.
	Q300MG VS P	.	.	.	.	.	-5.73	1.318	-8.32	-3.13	<.001

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS230.SAS
GENERATED: 12JUL2005 17:29:52 iceadmn3

Table 11.2.1.2.4 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-6.59	1.376	-9.29	-3.88	<.001
DAY 57	Q300MG	112	30.2	4.95	-18.8	9.14	-18.67	0.955	-20.56	-16.78	.
	Q600MG	94	29.8	5.43	-20.6	9.54	-20.73	1.043	-22.79	-18.66	.
	P	93	30.3	4.76	-13.4	10.83	-13.26	1.016	-15.26	-11.25	.
	Q300MG VS P	.	.	.	.	.	-5.42	1.335	-8.04	-2.79	<.001
	Q600MG VS P	.	.	.	.	.	-7.47	1.395	-10.22	-4.73	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS230.SAS
GENERATED: 12JUL2005 17:29:52 iceadmn3

Table 11.2.1.2.5 MADRS Total Score Effect Size Change from Baseline
Last Observation Carried Forward
Intent-to-Treat Population

VISIT	TREATMENT	EFFECT SIZE	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER
DAY 8	Q300MG VS P	-0.52	-0.74	-0.31
	Q600MG VS P	-0.52	-0.73	-0.30
DAY 15	Q300MG VS P	-0.58	-0.79	-0.36
	Q600MG VS P	-0.52	-0.73	-0.30
DAY 22	Q300MG VS P	-0.53	-0.75	-0.31
	Q600MG VS P	-0.52	-0.73	-0.30
DAY 29	Q300MG VS P	-0.51	-0.73	-0.29
	Q600MG VS P	-0.66	-0.88	-0.45
DAY 36	Q300MG VS P	-0.59	-0.81	-0.37
	Q600MG VS P	-0.59	-0.81	-0.37
DAY 43	Q300MG VS P	-0.63	-0.85	-0.41
	Q600MG VS P	-0.59	-0.80	-0.37
DAY 50	Q300MG VS P	-0.65	-0.87	-0.44
	Q600MG VS P	-0.61	-0.82	-0.39
DAY 57	Q300MG VS P	-0.59	-0.81	-0.38
	Q600MG VS P	-0.60	-0.81	-0.38

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS224.SAS
GENERATED: 12JUL2005 17:29:34 iceadmn3

Table 11.2.1.2.6 MADRS Total Score Effect Size Change from Baseline
Observed Cases
Intent-to-Treat Population

VISIT	TREATMENT	EFFECT SIZE	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER
DAY 8	Q300MG VS P	-0.52	-0.74	-0.31
	Q600MG VS P	-0.52	-0.73	-0.30
DAY 15	Q300MG VS P	-0.56	-0.79	-0.32
	Q600MG VS P	-0.52	-0.75	-0.29
DAY 22	Q300MG VS P	-0.49	-0.73	-0.25
	Q600MG VS P	-0.61	-0.85	-0.37
DAY 29	Q300MG VS P	-0.43	-0.67	-0.18
	Q600MG VS P	-0.76	-1.01	-0.50
DAY 36	Q300MG VS P	-0.54	-0.80	-0.29
	Q600MG VS P	-0.66	-0.93	-0.40
DAY 43	Q300MG VS P	-0.63	-0.90	-0.37
	Q600MG VS P	-0.70	-0.97	-0.42
DAY 50	Q300MG VS P	-0.62	-0.89	-0.35
	Q600MG VS P	-0.67	-0.96	-0.39
DAY 57	Q300MG VS P	-0.56	-0.83	-0.29
	Q600MG VS P	-0.74	-1.03	-0.45

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS231.SAS
GENERATED: 12JUL2005 17:29:55 iceadmn3

Table 11.2.1.2.7 MADRS Total Score Change from Baseline (MMRM)
Repeated Measure: Visit (Week)
Intent-to-Treat Population

	LS Means			Quetiapine 300 mg vs Placebo			Quetiapine 600 mg vs Placebo		
	Placebo	300 mg	600 mg	Estimate	SE	P-value	Estimate	SE	P-Value
DAY 8	-4.7	-8.6	-8.7	-3.9	0.94	<.001	-4.0	0.95	<.001
DAY 15	-7.6	-12.5	-12.2	-4.9	0.98	<.001	-4.5	0.98	<.001
DAY 22	-9.1	-13.9	-14.6	-4.8	1.00	<.001	-5.5	1.00	<.001
DAY 29	-10.0	-14.9	-17.7	-4.9	1.02	<.001	-7.7	1.03	<.001
DAY 36	-10.7	-16.5	-17.6	-5.8	1.04	<.001	-6.9	1.07	<.001
DAY 43	-11.6	-17.7	-18.5	-6.1	1.08	<.001	-6.8	1.10	<.001
DAY 50	-11.3	-17.9	-18.7	-6.6	1.09	<.001	-7.4	1.13	<.001
DAY 57	-12.6	-18.5	-19.8	-6.0	1.11	<.001	-7.2	1.16	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS253.SAS
GENERATED: 12JUL2005 17:30:42 iceadmn3

Table 11.2.1.2.8 MADRS Total Score Effect Sizes (MMRM)
Repeated Measure: Visit (Week)
Intent-to-Treat Population

	Quetiapine 300 mg vs Placebo			Quetiapine 600 mg vs Placebo		
	Estimate	Std Dev	Effect Size	Estimate	Std Dev	Effect Size
DAY 8	-3.89	9.80	0.40	-3.98	9.80	0.41
DAY 15	-4.86	9.42	0.52	-4.52	9.42	0.48
DAY 22	-4.76	9.28	0.51	-5.49	9.28	0.59
DAY 29	-4.89	9.14	0.53	-7.71	9.14	0.84
DAY 36	-5.81	9.04	0.64	-6.91	9.04	0.76
DAY 43	-6.08	8.94	0.68	-6.84	8.94	0.77
DAY 50	-6.63	8.92	0.74	-7.39	8.92	0.83
DAY 57	-5.97	8.92	0.67	-7.24	8.92	0.81

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS254.SAS
GENERATED: 12JUL2005 17:31:49 iceadmn3

FIGURE 11.2.1.3.1 MADRS TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD- INTENT TO TREAT)

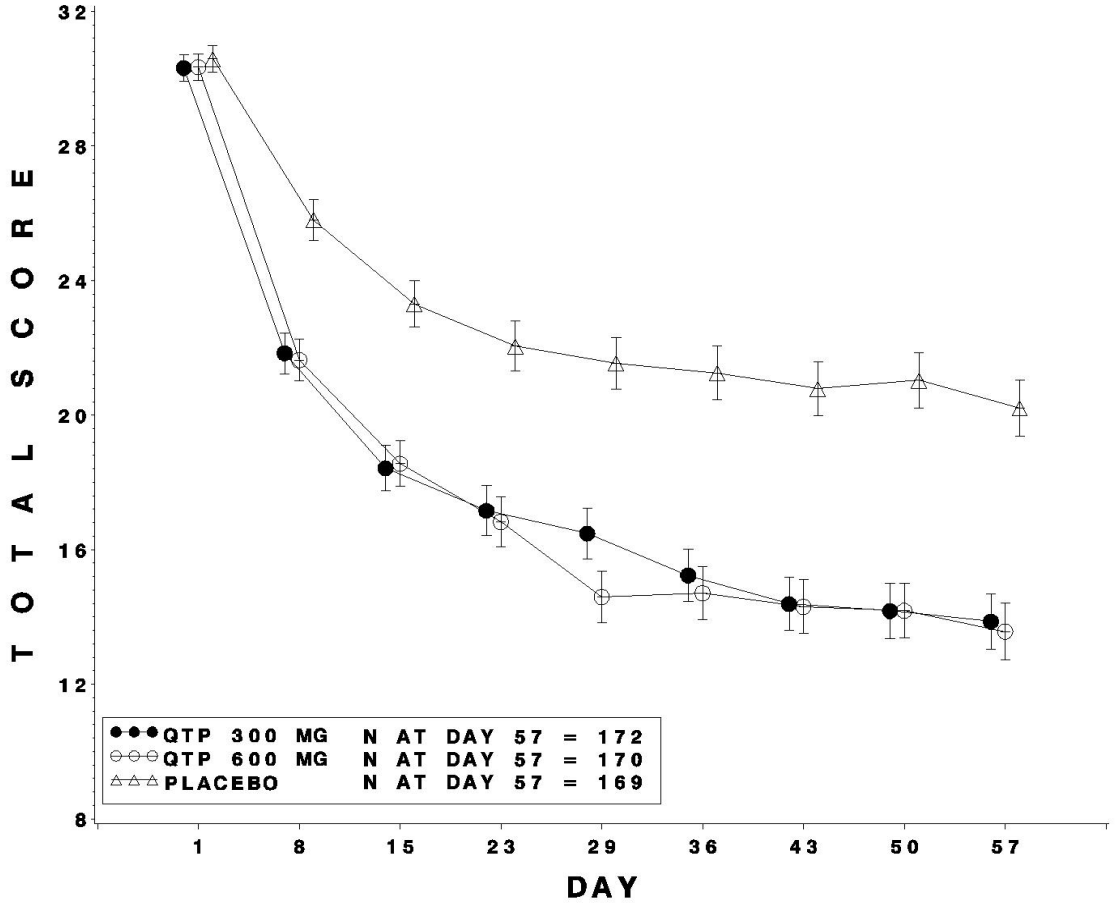

FIGURE 11.2.1.3.2 MADRS TOTAL SCORE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

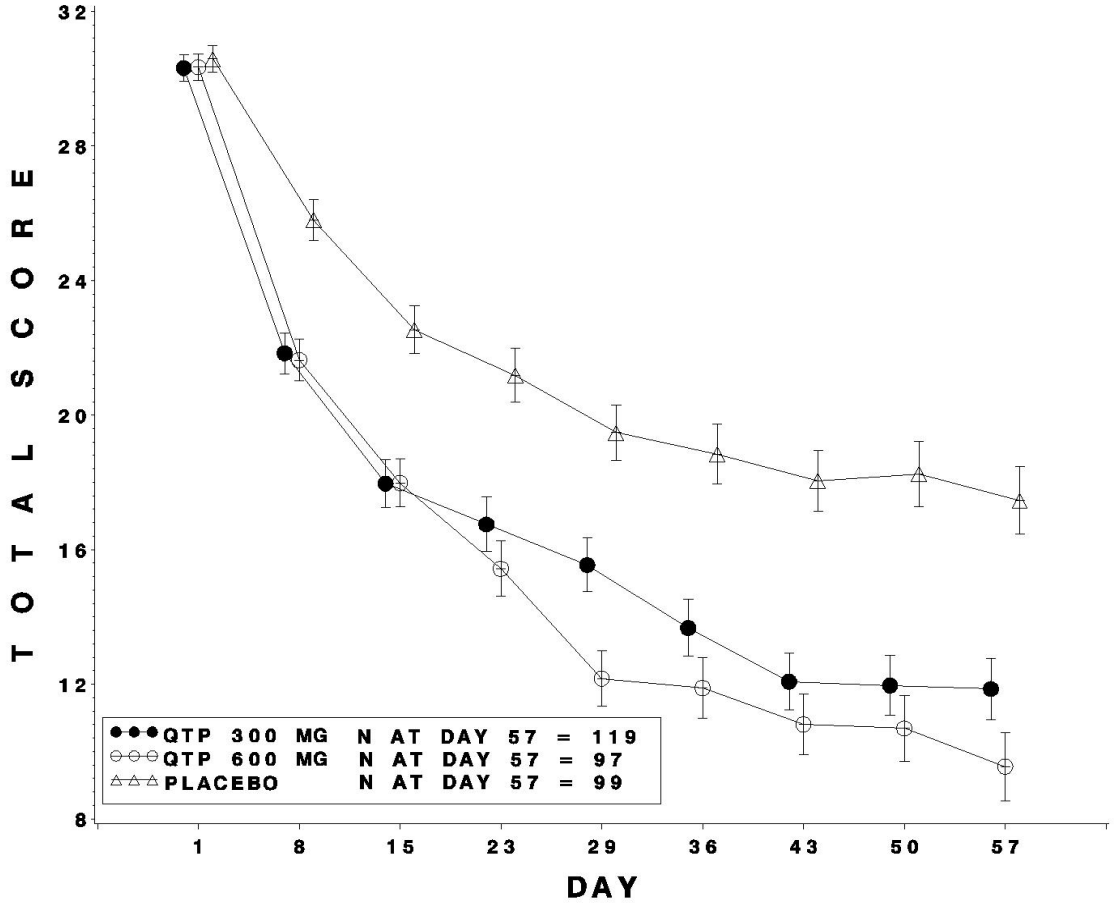

FIGURE 11.2.1.3.3 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

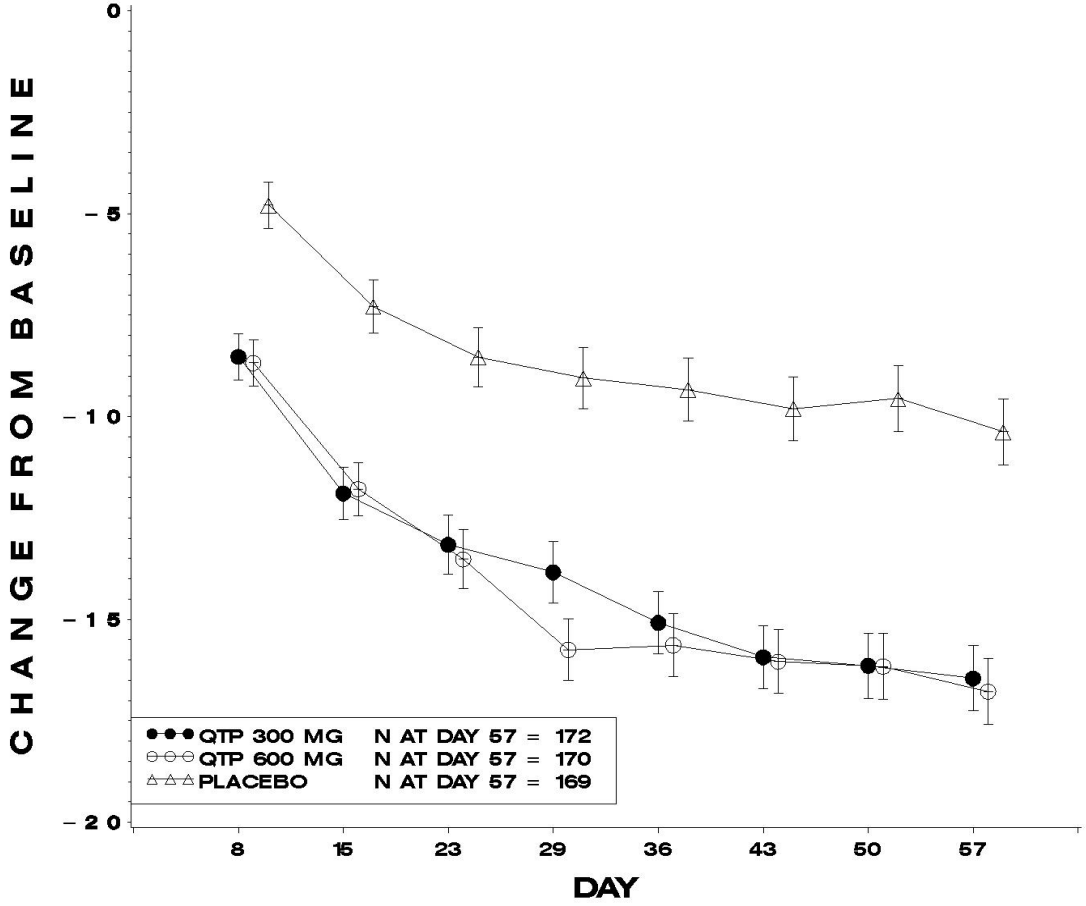

FIGURE 11.2.1.3.4 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

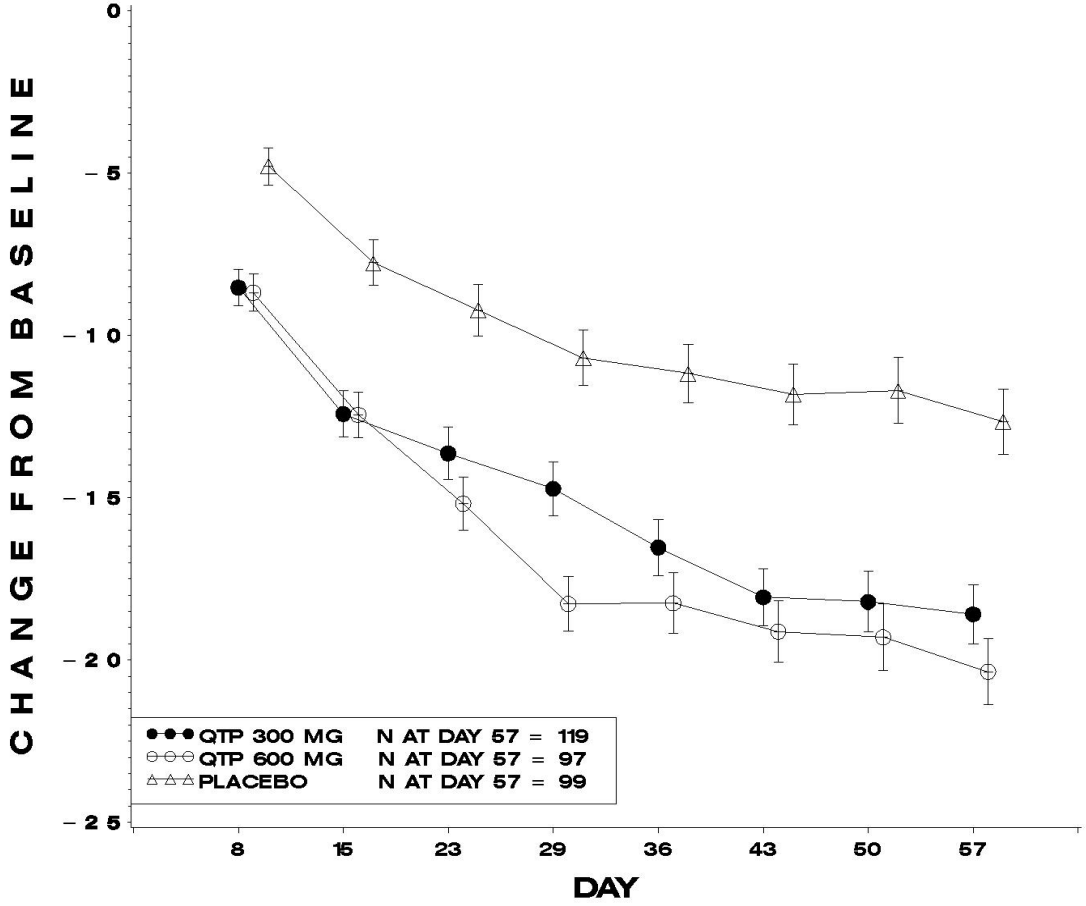

FIGURE 11.2.1.3.5 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

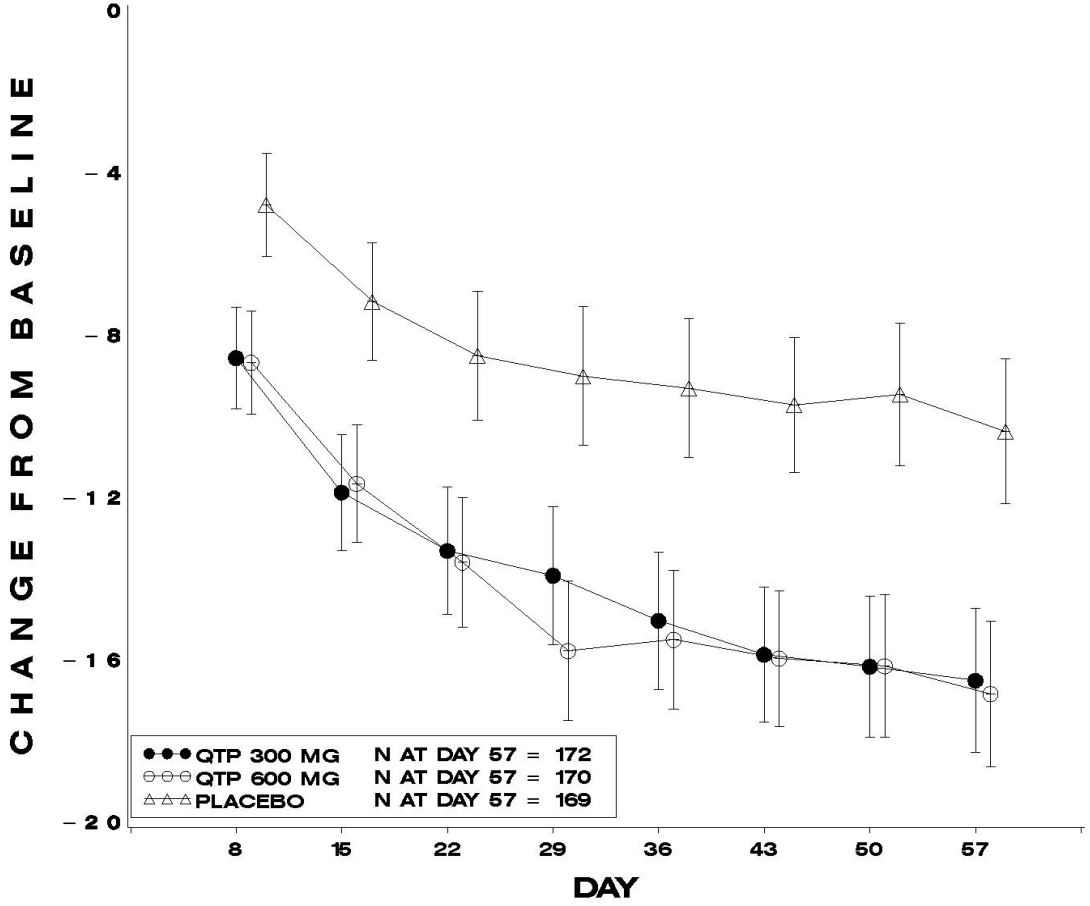

FIGURE 11.2.1.3.6 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(OBSERVED CASES - INTENT TO TREAT)

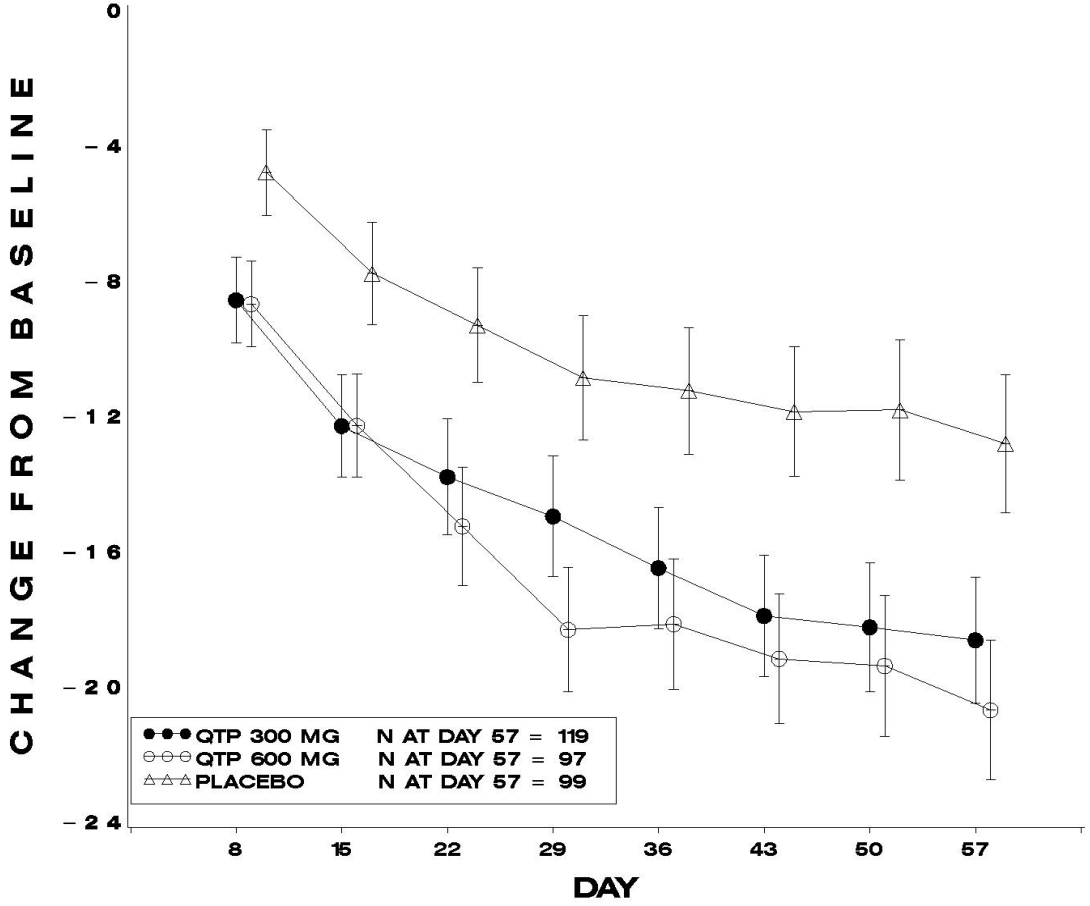

Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	116	30.0	5.07	30.0	13	44	114	30.6	5.41	30.0	16	48	112	31.0	5.52	31.0	20	47
	DAY 8	115	22.0	7.96	23.0	0	38	114	21.6	8.38	22.0	5	41	112	26.8	8.62	27.5	1	45
	DAY 15	116	18.2	8.89	18.0	0	38	114	18.4	9.09	18.0	0	42	112	24.0	9.32	25.0	2	46
	DAY 22	116	16.9	10.06	16.0	0	39	114	16.0	9.89	16.0	0	41	112	22.8	10.24	24.0	2	48
	DAY 29	116	16.4	9.86	16.0	0	38	114	13.8	10.19	11.0	0	37	112	22.3	10.69	23.0	1	48
	DAY 36	116	14.4	10.15	13.0	0	38	114	14.0	10.84	12.0	0	42	112	22.2	11.23	23.0	0	48
	DAY 43	116	13.8	10.05	12.0	0	38	114	13.3	10.83	10.0	0	38	112	21.6	11.14	23.0	0	48
	DAY 50	116	13.6	10.25	10.5	0	39	114	13.3	10.92	10.0	0	38	112	21.7	11.78	23.0	0	48
	DAY 57	116	13.0	10.62	9.5	0	39	114	12.4	10.73	10.0	0	38	112	21.5	11.59	24.0	0	48
CHG FROM BASELINE	DAY 8	115	-8.1	7.17	-8.0	-32	11	114	-9.0	8.24	-8.5	-29	8	112	-4.2	7.47	-2.0	-31	7
	DAY 15	116	-11.8	8.07	-12.0	-36	4	114	-12.2	9.55	-12.0	-35	5	112	-6.9	8.08	-5.0	-27	7
	DAY 22	116	-13.1	8.87	-13.0	-41	5	114	-14.6	10.71	-16.0	-40	10	112	-8.2	9.14	-7.0	-31	9
	DAY 29	116	-13.7	9.30	-14.5	-41	5	114	-16.9	10.57	-19.0	-36	6	112	-8.7	9.91	-8.5	-32	13
	DAY 36	116	-15.6	9.48	-17.0	-38	5	114	-16.6	11.25	-18.0	-34	11	112	-8.8	10.35	-8.5	-31	13
	DAY 43	116	-16.3	9.40	-18.0	-41	5	114	-17.4	11.05	-20.0	-38	9	112	-9.3	10.20	-9.0	-32	13
	DAY 50	116	-16.4	9.57	-18.0	-41	5	114	-17.3	11.34	-20.0	-40	9	112	-9.2	11.05	-8.5	-33	15

(Continued)

Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	116	-17.1	9.70	-18.0	-41	10	114	-18.2	11.04	-20.0	-39	9	112	-9.5	10.58	-8.0	-33	13

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS206.SAS
GENERATED: 12JUL2005 17:44:37 iceadmn3

Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO				
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	56	30.9	4.93	30.0	20	45	56	29.8	5.03	30.0	18	41	57	29.8	4.68	30.0	20	40
	DAY 8	56	21.5	6.51	22.0	6	37	55	21.7	7.16	22.0	8	36	57	23.9	7.53	25.0	7	38
	DAY 15	56	18.8	8.28	19.0	0	40	56	18.9	7.61	19.5	5	35	57	21.9	8.74	22.0	4	42
	DAY 22	56	17.7	8.13	17.5	2	37	56	18.6	8.38	18.0	2	36	57	20.5	9.43	23.0	1	38
	DAY 29	56	16.7	7.92	16.0	2	37	56	16.3	9.15	17.5	0	33	57	20.1	10.32	20.0	1	42
	DAY 36	56	16.9	8.58	17.0	2	37	56	16.1	9.68	15.5	0	37	57	19.4	9.48	19.0	2	40
	DAY 43	56	15.6	9.09	15.0	2	37	56	16.4	9.81	16.5	0	37	57	19.1	10.16	20.0	2	43
	DAY 50	56	15.4	9.19	14.5	2	37	56	16.0	9.72	15.0	0	36	57	19.6	10.61	18.0	2	43
	DAY 57	56	15.8	9.97	15.0	1	37	56	15.9	10.22	16.0	0	36	57	17.6	11.12	16.0	0	43
CHG FROM BASELINE	DAY 8	56	-9.4	7.17	-8.0	-30	4	55	-7.9	6.65	-7.0	-22	6	57	-5.9	6.88	-4.0	-26	3
	DAY 15	56	-12.1	8.76	-11.0	-32	4	56	-10.9	8.76	-10.0	-29	7	57	-7.9	8.02	-8.0	-27	9
	DAY 22	56	-13.2	8.38	-12.0	-31	3	56	-11.2	8.80	-10.5	-36	7	57	-9.3	10.00	-8.0	-31	9
	DAY 29	56	-14.2	9.24	-14.5	-34	6	56	-13.5	9.65	-14.0	-33	3	57	-9.7	10.27	-11.0	-32	9
	DAY 36	56	-14.0	9.16	-14.0	-33	3	56	-13.7	10.41	-13.5	-41	7	57	-10.4	9.30	-11.0	-33	7
	DAY 43	56	-15.3	9.34	-15.5	-33	3	56	-13.4	10.95	-13.0	-39	7	57	-10.7	9.99	-11.0	-33	9
	DAY 50	56	-15.5	9.55	-15.0	-35	3	56	-13.8	10.68	-13.5	-41	6	57	-10.2	10.60	-11.0	-33	9

(Continued)

Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	56	-15.2	10.21	-15.0	-34	6	56	-13.9	10.21	-14.5	-39	5	57	-12.2	11.01	-13.0	-35	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS206.SAS
GENERATED: 12JUL2005 17:44:37 iceadmn3

Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	116	30.0	5.07	30.0	13	44	114	30.6	5.41	30.0	16	48	112	31.0	5.52	31.0	20	47
	DAY 8	115	22.0	7.96	23.0	0	38	114	21.6	8.38	22.0	5	41	112	26.8	8.62	27.5	1	45
	DAY 15	103	17.9	8.67	17.0	1	38	105	18.0	8.93	18.0	0	42	96	22.8	8.68	23.0	2	46
	DAY 22	95	16.4	9.97	15.0	0	39	94	14.6	9.42	14.0	0	41	93	21.7	9.83	22.0	2	48
	DAY 29	93	15.2	9.11	15.0	0	38	91	11.7	9.02	10.0	0	37	79	19.5	9.56	21.0	1	39
	DAY 36	90	12.7	9.14	11.5	0	34	82	11.8	10.07	9.0	0	42	74	19.1	10.31	21.0	0	37
	DAY 43	87	11.4	8.40	10.0	0	35	77	10.3	9.37	8.0	0	37	67	17.8	10.08	19.0	0	35
	DAY 50	87	11.1	8.67	8.0	0	39	71	10.0	9.43	6.0	0	37	63	17.9	11.25	18.0	0	42
	DAY 57	83	10.8	9.09	8.0	0	39	68	8.6	8.47	6.0	0	34	58	18.5	10.61	17.0	0	35
CHG FROM BASELINE	DAY 8	115	-8.1	7.17	-8.0	-32	11	114	-9.0	8.24	-8.5	-29	8	112	-4.2	7.47	-2.0	-31	7
	DAY 15	103	-12.1	8.05	-13.0	-36	4	105	-12.6	9.53	-12.0	-35	5	96	-7.9	7.94	-6.0	-27	7
	DAY 22	95	-13.7	8.91	-14.0	-41	5	94	-16.3	10.04	-17.5	-40	10	93	-9.2	9.14	-8.0	-31	9
	DAY 29	93	-14.6	9.00	-17.0	-41	5	91	-19.0	9.42	-21.0	-36	6	79	-11.1	9.62	-10.0	-32	13
	DAY 36	90	-17.0	9.03	-19.0	-38	3	82	-18.5	10.41	-21.0	-34	11	74	-11.2	10.47	-10.5	-31	10
	DAY 43	87	-18.3	8.57	-19.0	-41	2	77	-19.7	10.00	-21.0	-38	9	67	-12.3	10.19	-12.0	-32	8
	DAY 50	87	-18.6	8.89	-19.0	-41	3	71	-20.0	10.27	-21.0	-40	7	63	-12.3	11.55	-12.0	-33	15

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS204.SAS
GENERATED: 12JUL2005 17:44:32 iceadmn3

Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	83	-19.3	8.77	-21.0	-41	10	68	-21.3	9.30	-21.5	-39	-2	58	-11.9	10.58	-9.5	-33	8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS204.SAS
GENERATED: 12JUL2005 17:44:32 iceadmn3

Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	56	30.9	4.93	30.0	20	45	56	29.8	5.03	30.0	18	41	57	29.8	4.68	30.0	20	40
	DAY 8	56	21.5	6.51	22.0	6	37	55	21.7	7.16	22.0	8	36	57	23.9	7.53	25.0	7	38
	DAY 15	45	18.1	8.57	19.0	0	40	43	18.0	7.72	18.0	5	35	53	22.1	8.90	22.0	4	42
	DAY 22	44	17.6	8.23	18.0	2	33	39	17.5	9.00	16.0	2	36	50	20.3	9.88	23.0	1	38
	DAY 29	40	16.3	7.83	15.5	2	34	36	13.4	8.60	11.0	0	30	47	19.5	11.01	19.0	1	42
	DAY 36	40	15.9	8.49	16.5	2	37	31	12.2	9.47	11.0	0	37	45	18.4	9.89	17.0	2	40
	DAY 43	36	13.8	8.97	11.5	2	37	30	12.2	9.16	10.5	0	31	40	18.5	10.75	19.5	2	43
	DAY 50	34	14.2	9.19	12.0	2	30	30	12.3	9.72	11.0	0	36	39	18.8	11.24	16.0	2	43
	DAY 57	36	14.4	10.36	12.0	1	35	29	11.7	10.49	7.0	0	36	41	16.0	11.81	14.0	0	43
CHG FROM BASELINE	DAY 8	56	-9.4	7.17	-8.0	-30	4	55	-7.9	6.65	-7.0	-22	6	57	-5.9	6.88	-4.0	-26	3
	DAY 15	45	-13.1	9.02	-14.0	-32	4	43	-12.0	9.03	-11.0	-29	7	53	-7.6	8.08	-7.0	-27	9
	DAY 22	44	-13.5	8.10	-12.0	-29	0	39	-12.5	9.24	-11.0	-36	7	50	-9.3	10.44	-8.5	-31	9
	DAY 29	40	-14.9	9.10	-14.5	-34	6	36	-16.4	9.79	-17.0	-33	3	47	-10.0	10.80	-11.0	-32	9
	DAY 36	40	-15.5	8.91	-14.5	-33	0	31	-17.5	10.91	-17.0	-41	7	45	-11.2	9.67	-12.0	-33	6
	DAY 43	36	-17.6	8.70	-18.5	-33	0	30	-17.6	11.44	-18.0	-39	6	40	-10.9	10.16	-12.5	-29	9
	DAY 50	34	-17.3	8.89	-18.0	-35	-2	30	-17.6	11.56	-18.0	-41	6	39	-10.8	11.35	-11.0	-33	9

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS204.SAS
GENERATED: 12JUL2005 17:44:32 iceadmn3

Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	36	-17.0	10.05	-16.0	-34	6	29	-18.1	10.58	-18.0	-39	5	41	-13.7	11.77	-15.0	-35	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS204.SAS
GENERATED: 12JUL2005 17:44:32 iceadmn3

Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	105	30.1	4.79	30.0	19	44	102	30.7	5.57	30.0	16	48	100	31.0	5.58	31.0	20	47
	DAY 8	105	22.0	7.78	23.0	0	37	102	21.4	8.27	21.5	5	41	100	26.3	8.79	27.0	1	42
	DAY 15	105	18.0	8.72	18.0	0	38	102	17.6	8.70	17.5	0	42	100	23.4	9.25	24.0	2	46
	DAY 22	105	16.6	9.99	16.0	0	39	102	15.3	9.51	15.5	0	41	100	22.1	10.19	23.0	2	48
	DAY 29	105	16.0	9.75	16.0	0	38	102	13.0	9.80	11.0	0	37	100	21.9	10.50	23.0	1	48
	DAY 36	105	13.9	9.98	13.0	0	38	102	13.5	10.56	10.5	0	42	100	21.8	11.24	22.5	0	48
	DAY 43	105	13.1	9.80	12.0	0	38	102	12.7	10.45	10.0	0	38	100	21.0	11.08	22.0	0	48
	DAY 50	105	13.0	10.03	9.0	0	39	102	12.7	10.59	10.0	0	38	100	21.0	11.64	22.0	0	48
	DAY 57	105	12.2	10.22	9.0	0	38	102	11.7	10.31	10.0	0	38	100	20.7	11.49	22.5	0	48
CHG FROM BASELINE	DAY 8	105	-8.1	7.25	-8.0	-32	11	102	-9.2	8.30	-8.5	-29	8	100	-4.7	7.59	-3.5	-31	7
	DAY 15	105	-12.1	8.15	-13.0	-36	4	102	-13.1	9.34	-12.5	-35	5	100	-7.6	8.03	-6.0	-27	7
	DAY 22	105	-13.4	8.92	-13.0	-41	5	102	-15.4	10.47	-16.0	-40	10	100	-8.9	9.09	-8.0	-31	9
	DAY 29	105	-14.1	9.41	-15.0	-41	5	102	-17.7	10.33	-20.0	-36	6	100	-9.1	9.76	-9.0	-32	13
	DAY 36	105	-16.2	9.49	-18.0	-38	5	102	-17.2	11.16	-19.0	-34	11	100	-9.2	10.44	-8.0	-31	13
	DAY 43	105	-17.0	9.35	-18.0	-41	5	102	-18.0	10.89	-20.0	-38	9	100	-9.9	10.19	-9.5	-32	13
	DAY 50	105	-17.1	9.52	-19.0	-41	5	102	-18.0	11.24	-20.0	-40	9	100	-10.0	10.93	-8.5	-33	13

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS207.SAS
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Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	105	-17.8	9.51	-19.0	-41	10	102	-19.0	10.84	-20.0	-39	9	100	-10.2	10.48	-8.0	-33	13

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS207.SAS
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Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	47	31.5	4.96	31.0	20	45	45	29.7	4.93	30.0	18	39	54	29.8	4.71	30.0	20	40
	DAY 8	47	21.9	6.71	23.0	6	37	45	21.6	7.44	22.0	8	36	54	23.8	7.66	25.0	7	38
	DAY 15	47	18.8	8.66	19.0	0	40	45	18.4	7.78	18.0	5	35	54	21.6	8.84	21.5	4	42
	DAY 22	47	17.6	8.59	17.0	2	37	45	18.2	8.49	17.0	2	36	54	20.2	9.49	22.5	1	38
	DAY 29	47	16.5	8.36	15.0	2	37	45	15.2	9.15	13.0	0	33	54	19.8	10.45	19.0	1	42
	DAY 36	47	16.6	9.09	16.0	2	37	45	14.9	9.77	14.0	0	37	54	19.0	9.56	18.5	2	40
	DAY 43	47	15.4	9.61	14.0	2	37	45	15.3	10.04	13.0	0	37	54	18.7	10.28	19.0	2	43
	DAY 50	47	14.9	9.69	12.0	2	37	45	14.7	9.80	13.0	0	36	54	19.2	10.69	17.0	2	43
	DAY 57	47	15.2	10.52	14.0	1	37	45	13.6	10.03	12.0	0	33	54	17.2	11.24	16.0	0	43
CHG FROM BASELINE	DAY 8	47	-9.6	7.38	-8.0	-30	4	45	-8.1	6.27	-8.0	-21	6	54	-6.0	6.89	-4.0	-26	3
	DAY 15	47	-12.7	8.96	-13.0	-32	4	45	-11.4	8.46	-10.0	-29	7	54	-8.2	7.98	-8.0	-27	9
	DAY 22	47	-13.8	8.57	-13.0	-31	3	45	-11.6	8.01	-11.0	-32	7	54	-9.6	10.00	-8.5	-31	9
	DAY 29	47	-15.0	9.53	-16.0	-34	6	45	-14.5	9.00	-15.0	-33	3	54	-10.0	10.32	-11.0	-32	9
	DAY 36	47	-14.8	9.41	-14.0	-33	3	45	-14.8	9.74	-15.0	-34	7	54	-10.8	9.31	-11.0	-33	7
	DAY 43	47	-16.1	9.54	-17.0	-33	3	45	-14.5	10.60	-15.0	-39	7	54	-11.0	10.05	-12.5	-33	9
	DAY 50	47	-16.6	9.67	-17.0	-35	3	45	-15.0	10.08	-15.0	-37	6	54	-10.5	10.60	-11.0	-33	9

(Continued)

Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	47	-16.3	10.38	-16.0	-34	6	45	-16.1	9.74	-16.0	-39	3	54	-12.6	11.10	-13.5	-35	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS207.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	105	30.1	4.79	30.0	19	44	102	30.7	5.57	30.0	16	48	100	31.0	5.58	31.0	20	47
	DAY 8	105	22.0	7.78	23.0	0	37	102	21.4	8.27	21.5	5	41	100	26.3	8.79	27.0	1	42
	DAY 15	99	17.8	8.49	17.0	1	38	98	17.5	8.78	17.5	0	42	90	22.7	8.79	23.0	2	46
	DAY 22	93	16.3	9.99	15.0	0	39	88	14.5	9.38	14.0	0	41	85	21.3	9.79	22.0	2	48
	DAY 29	92	15.2	9.16	15.0	0	38	85	11.6	9.20	10.0	0	37	72	19.6	9.53	20.5	1	39
	DAY 36	89	12.7	9.19	11.0	0	34	78	11.9	10.23	9.0	0	42	66	19.0	10.52	21.5	0	37
	DAY 43	86	11.3	8.40	10.0	0	35	72	10.5	9.49	8.0	0	37	60	17.5	9.95	18.0	0	34
	DAY 50	86	11.1	8.71	8.0	0	39	70	10.1	9.48	6.5	0	37	57	17.2	10.97	18.0	0	36
	DAY 57	78	10.4	8.78	8.0	0	38	67	8.7	8.53	6.0	0	34	53	17.9	10.36	16.0	0	35
CHG FROM BASELINE	DAY 8	105	-8.1	7.25	-8.0	-32	11	102	-9.2	8.30	-8.5	-29	8	100	-4.7	7.59	-3.5	-31	7
	DAY 15	99	-12.2	8.07	-13.0	-36	4	98	-13.2	9.35	-13.0	-35	5	90	-8.1	7.96	-6.0	-27	7
	DAY 22	93	-13.7	8.90	-14.0	-41	5	88	-16.5	9.96	-17.5	-40	10	85	-9.6	9.15	-8.0	-31	9
	DAY 29	92	-14.6	9.04	-16.5	-41	5	85	-19.2	9.53	-21.0	-36	6	72	-11.0	9.71	-10.0	-32	13
	DAY 36	89	-17.0	9.08	-19.0	-38	3	78	-18.4	10.61	-21.0	-34	11	66	-11.4	10.71	-10.5	-31	7
	DAY 43	86	-18.3	8.61	-19.5	-41	2	72	-19.5	10.21	-21.0	-38	9	60	-12.9	9.95	-13.0	-32	5
	DAY 50	86	-18.5	8.93	-19.0	-41	3	70	-20.0	10.34	-21.0	-40	7	57	-13.2	11.20	-12.0	-33	7

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS205.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	78	-19.3	8.80	-20.5	-41	10	67	-21.3	9.37	-21.0	-39	-2	53	-12.8	10.26	-11.0	-33	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS205.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	VISIT																		
	DAY 1	47	31.5	4.96	31.0	20	45	45	29.7	4.93	30.0	18	39	54	29.8	4.71	30.0	20	40
	DAY 8	47	21.9	6.71	23.0	6	37	45	21.6	7.44	22.0	8	36	54	23.8	7.66	25.0	7	38
	DAY 15	43	18.1	8.47	19.0	0	40	41	18.2	7.84	18.0	5	35	52	21.9	8.90	22.0	4	42
	DAY 22	43	17.5	8.30	17.0	2	33	38	17.8	8.88	16.0	2	36	49	20.1	9.83	23.0	1	38
	DAY 29	39	16.3	7.94	15.0	2	34	33	13.6	8.57	11.0	0	30	46	19.3	11.02	18.0	1	42
	DAY 36	39	15.7	8.56	16.0	2	37	29	12.6	9.51	11.0	0	37	44	18.2	9.87	16.0	2	40
	DAY 43	35	13.9	9.07	12.0	2	37	29	12.6	9.12	11.0	0	31	39	18.3	10.77	19.0	2	43
	DAY 50	33	14.0	9.23	12.0	2	30	29	12.7	9.61	12.0	0	36	38	18.5	11.18	16.0	2	43
	DAY 57	34	13.7	10.26	12.0	1	35	27	10.4	9.44	7.0	0	30	40	15.7	11.83	14.0	0	43
CHG FROM BASELINE	DAY 8	47	-9.6	7.38	-8.0	-30	4	45	-8.1	6.27	-8.0	-21	6	54	-6.0	6.89	-4.0	-26	3
	DAY 15	43	-13.2	8.91	-14.0	-32	4	41	-11.4	8.79	-10.0	-29	7	52	-7.8	7.93	-7.5	-27	9
	DAY 22	43	-13.7	8.13	-12.0	-29	0	38	-11.8	8.51	-11.0	-32	7	49	-9.6	10.27	-9.0	-31	9
	DAY 29	39	-15.0	9.21	-15.0	-34	6	33	-15.8	9.56	-17.0	-33	3	46	-10.3	10.69	-11.5	-32	9
	DAY 36	39	-15.6	8.95	-15.0	-33	0	29	-16.9	10.34	-17.0	-34	7	44	-11.5	9.50	-12.0	-33	6
	DAY 43	35	-17.5	8.82	-18.0	-33	0	29	-16.9	10.89	-18.0	-39	6	39	-11.3	10.03	-14.0	-29	9
	DAY 50	33	-17.6	8.83	-18.0	-35	-2	29	-16.8	10.87	-18.0	-37	6	38	-11.3	11.12	-11.0	-33	9

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS205.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	34	-17.7	9.92	-17.0	-34	6	27	-19.0	9.95	-18.0	-39	-2	40	-14.1	11.64	-15.0	-35	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS205.SAS
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FIGURE 11.2.1.5.1 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE) BY BIPOLAR DIAGNOSIS

(LAST OBSERVATION CARRIED FORWARD- INTENT TO TREAT)

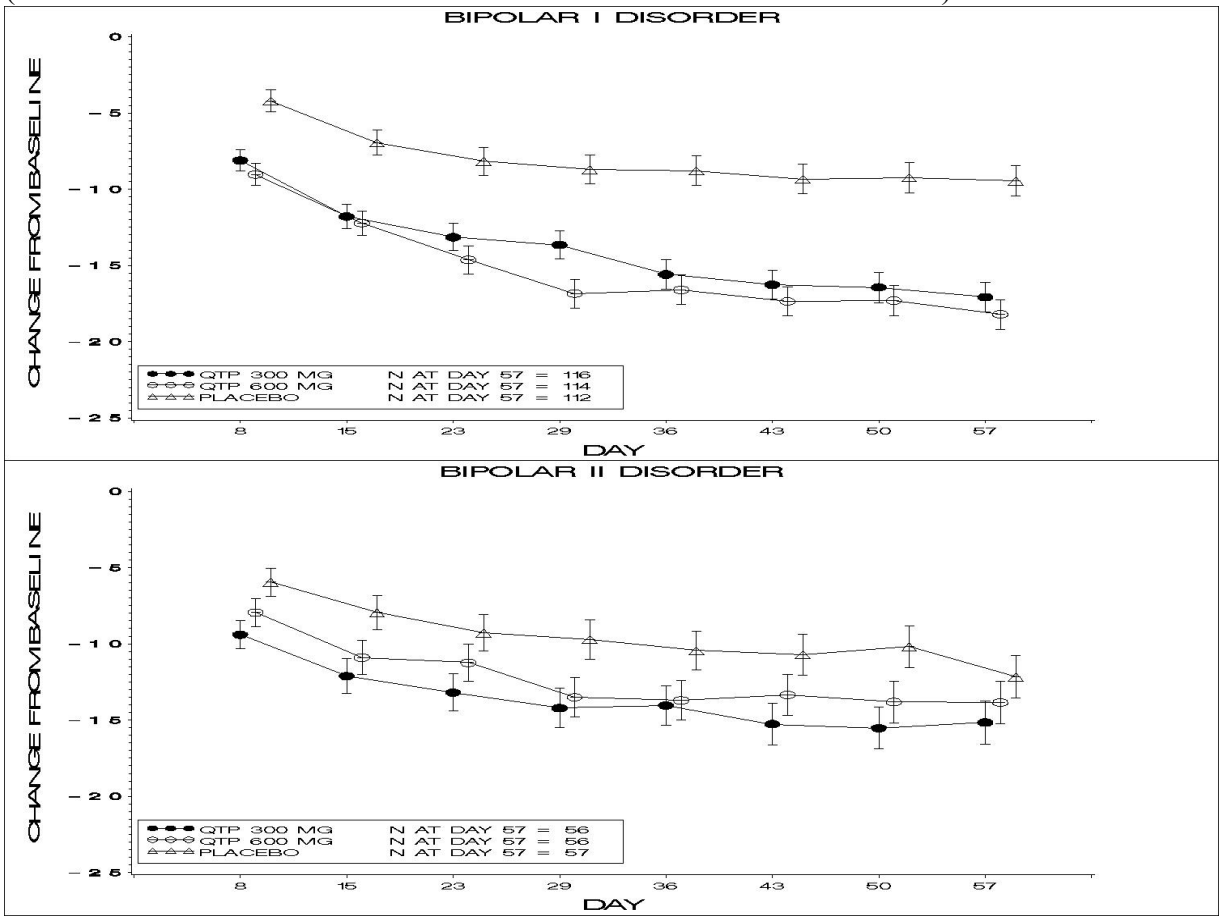

FIGURE 11.2.1.5.2 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE) BY BIPOLAR DIAGNOSIS

(OBSERVED CASES - INTENT TO TREAT)

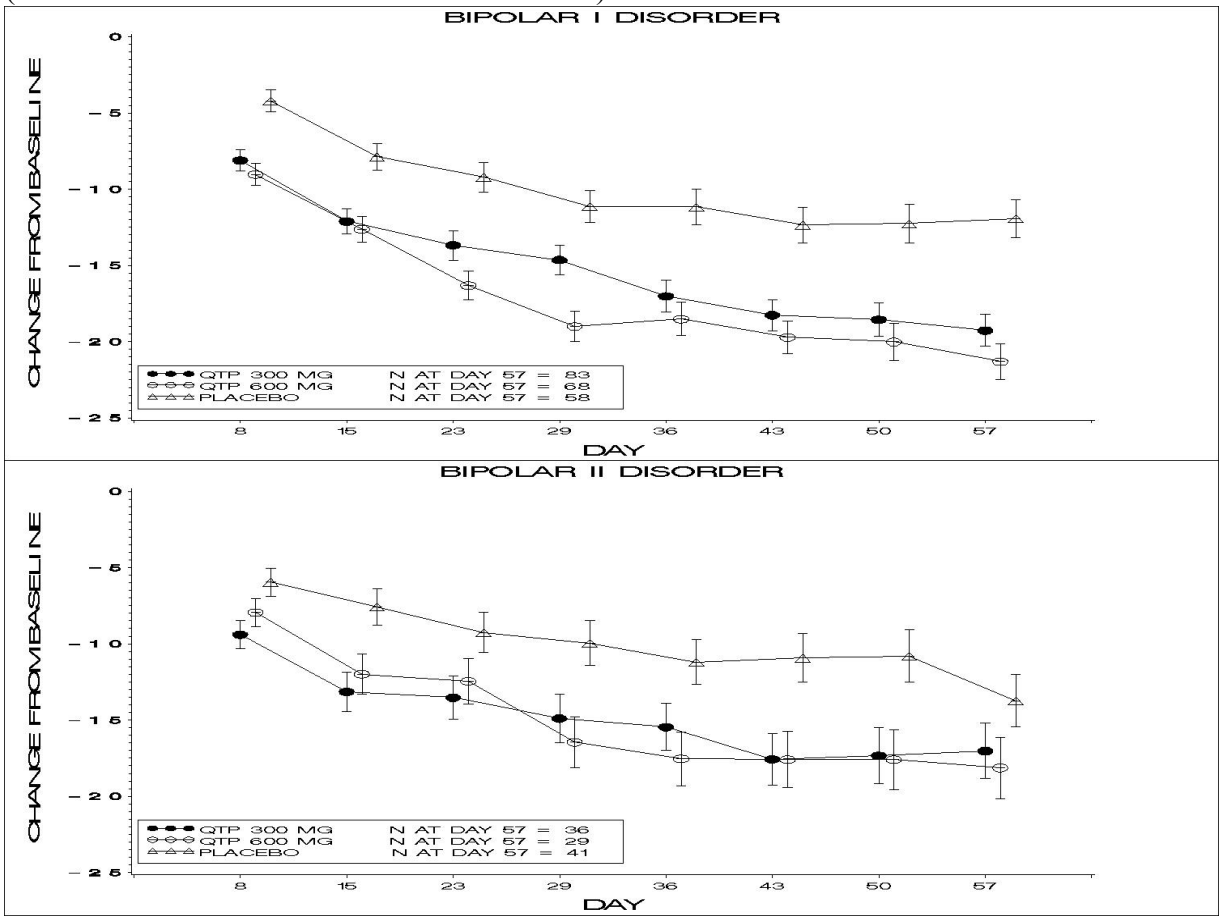

Table 11.2.1.7 MADRS Total Score and Change from Baseline by Race - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

RACE			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CAUCASIAN	MADRS TOTAL SCORE	VISIT																		
		DAY 1	141	30.5	5.10	30.0	13	45	144	30.3	5.43	30.0	16	48	129	30.5	5.48	31.0	20	47
		DAY 8	140	22.2	7.62	23.0	0	38	143	21.9	8.02	22.0	5	41	129	26.0	8.38	27.0	1	45
		DAY 15	141	18.6	8.62	19.0	0	38	144	18.8	8.75	19.0	0	42	129	23.8	9.24	25.0	2	45
		DAY 22	141	17.2	9.41	17.0	0	39	144	17.5	9.66	18.0	0	41	129	22.3	10.37	24.0	1	45
		DAY 29	141	16.6	9.29	16.0	0	38	144	15.1	10.11	13.5	0	37	129	21.6	10.75	22.0	1	45
		DAY 36	141	15.8	9.75	15.0	0	38	144	15.2	10.51	14.0	0	42	129	21.6	10.79	22.0	0	45
		DAY 43	141	15.0	9.79	15.0	0	38	144	15.1	10.56	14.0	0	38	129	21.2	10.98	22.0	0	45
		DAY 50	141	14.8	9.92	13.0	0	39	144	14.9	10.65	13.5	0	38	129	21.9	11.28	23.0	0	45
		DAY 57	141	14.4	10.80	12.0	0	39	144	14.4	10.84	13.0	0	38	129	20.8	11.48	23.0	0	45
	CHG FROM BASELINE	DAY 8	140	-8.3	7.16	-8.0	-32	11	143	-8.3	7.68	-8.0	-29	8	129	-4.5	7.21	-3.0	-31	7
		DAY 15	141	-11.8	8.35	-11.0	-36	4	144	-11.5	9.44	-11.0	-35	7	129	-6.8	8.05	-5.0	-27	9
		DAY 22	141	-13.3	8.68	-13.0	-41	3	144	-12.8	10.30	-12.0	-40	10	129	-8.2	9.55	-8.0	-31	9
		DAY 29	141	-13.9	9.29	-14.0	-41	5	144	-15.2	10.45	-15.5	-36	6	129	-8.9	9.87	-9.0	-32	9
		DAY 36	141	-14.7	9.34	-15.0	-38	5	144	-15.1	11.07	-15.5	-41	11	129	-8.9	9.89	-9.0	-33	10
		DAY 43	141	-15.5	9.40	-15.0	-41	5	144	-15.2	11.20	-16.5	-39	9	129	-9.4	9.91	-9.0	-33	9
		DAY 50	141	-15.7	9.50	-17.0	-41	5	144	-15.4	11.33	-15.5	-41	9	129	-8.6	10.44	-8.0	-33	15

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS213.SAS
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Table 11.2.1.7 MADRS Total Score and Change from Baseline by Race - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

RACE			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CAUCASIAN	CHG FROM BASELINE	VISIT DAY 57	141	-16.0	10.17	-17.0	-41	10	144	-15.9	11.11	-17.0	-39	9	129	-9.7	10.42	-8.0	-35	9
BLACK	MADRS TOTAL SCORE	DAY 1	23	28.9	4.24	29.0	23	39	18	31.0	4.77	31.0	23	42	26	30.7	3.94	32.0	21	37
		DAY 8	23	20.6	6.96	23.0	4	32	18	19.2	8.16	17.5	6	32	26	24.5	7.97	25.5	7	38
		DAY 15	23	16.3	9.13	19.0	0	32	18	16.9	7.23	17.0	4	34	26	20.5	8.38	22.0	4	34
		DAY 22	23	15.3	9.56	14.0	1	33	18	12.8	6.84	12.0	4	29	26	19.9	7.59	21.5	2	30
		DAY 29	23	14.6	9.47	14.0	0	34	18	10.6	7.60	8.0	0	24	26	18.6	9.20	19.0	1	34
		DAY 36	23	12.0	9.86	10.0	0	37	18	10.7	9.30	7.5	0	33	26	18.1	10.02	17.0	2	36
		DAY 43	23	10.8	9.68	7.0	0	37	18	8.6	8.63	6.0	0	33	26	17.2	9.35	18.0	1	36
		DAY 50	23	10.2	9.48	7.0	0	32	18	9.3	8.31	6.0	0	33	26	16.7	10.41	16.5	0	36
		DAY 57	23	10.5	8.46	7.0	0	33	18	7.6	8.86	4.5	0	33	26	16.8	10.98	14.5	0	37
	CHG FROM BASELINE	DAY 8	23	-8.3	7.02	-8.0	-25	4	18	-11.8	8.74	-11.0	-28	1	26	-6.2	7.70	-4.0	-24	4
		DAY 15	23	-12.6	8.78	-10.0	-28	4	18	-14.1	8.46	-12.5	-27	-2	26	-10.2	8.15	-8.0	-27	4
		DAY 22	23	-13.6	9.11	-15.0	-26	3	18	-18.2	8.82	-20.5	-29	2	26	-10.8	8.55	-8.0	-29	4
		DAY 29	23	-14.3	9.40	-16.0	-29	6	18	-20.4	8.75	-22.5	-33	-6	26	-12.1	9.75	-12.5	-32	4
		DAY 36	23	-17.0	10.23	-18.0	-33	3	18	-20.3	9.09	-23.0	-33	-4	26	-12.6	10.00	-12.0	-29	4
		DAY 43	23	-18.1	9.53	-20.0	-33	2	18	-22.4	7.87	-23.5	-33	-1	26	-13.5	9.83	-14.5	-32	4

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS213.SAS
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Table 11.2.1.7 MADRS Total Score and Change from Baseline by Race - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

RACE			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
BLACK	CHG FROM BASELINE	VISIT																		
		DAY 50	23	-18.7	9.73	-19.0	-35	3	18	-21.7	7.89	-23.0	-32	-8	26	-14.0	11.23	-15.5	-33	4
		DAY 57	23	-18.4	8.25	-18.0	-34	-5	18	-23.4	8.30	-24.5	-35	-4	26	-13.9	11.28	-14.5	-33	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS213.SAS
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Table 11.2.1.8 MADRS Total Score and Change from Baseline by Age Group - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

AGE GROUP			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
18-39	MADRS TOTAL SCORE	VISIT																		
		DAY 1	103	30.4	4.71	30.0	19	44	99	30.1	4.85	30.0	16	45	96	30.7	5.20	31.0	20	47
		DAY 8	102	21.6	7.32	22.5	0	37	99	21.0	8.18	21.0	5	38	96	25.0	8.38	26.0	1	41
		DAY 15	103	17.6	8.74	18.0	0	38	99	18.2	8.66	18.0	3	35	96	22.6	9.25	22.0	4	43
		DAY 22	103	16.3	9.46	15.0	0	39	99	15.9	9.50	16.0	0	41	96	21.2	10.11	22.0	1	43
		DAY 29	103	16.1	9.15	16.0	0	38	99	14.2	10.13	12.0	0	37	96	20.9	10.27	21.0	1	43
		DAY 36	103	14.3	9.59	15.0	0	37	99	14.5	10.76	13.0	0	42	96	20.7	11.07	20.5	2	43
		DAY 43	103	13.4	9.32	12.0	0	37	99	13.4	10.39	11.0	0	38	96	20.1	11.20	20.5	0	43
		DAY 50	103	13.6	9.77	11.0	0	39	99	13.9	10.67	12.0	0	38	96	21.0	11.45	21.5	0	43
		DAY 57	103	13.3	10.46	11.0	0	39	99	13.1	10.55	11.0	0	38	96	20.2	11.84	19.5	0	43
	CHG FROM BASELINE	DAY 8	102	-8.9	7.53	-8.0	-32	11	99	-9.1	7.76	-9.0	-29	8	96	-5.6	7.94	-5.0	-31	7
		DAY 15	103	-12.9	8.59	-13.0	-36	4	99	-11.9	9.02	-11.0	-31	5	96	-8.1	8.47	-7.0	-27	9
		DAY 22	103	-14.1	9.05	-15.0	-41	3	99	-14.2	9.65	-15.0	-34	10	96	-9.4	9.93	-8.0	-31	9
		DAY 29	103	-14.3	9.30	-15.0	-41	6	99	-15.9	10.29	-17.0	-34	4	96	-9.8	9.95	-9.5	-32	13
		DAY 36	103	-16.1	9.35	-17.0	-38	3	99	-15.6	11.02	-15.0	-34	11	96	-10.0	10.54	-10.0	-33	13
		DAY 43	103	-17.1	9.18	-18.0	-41	3	99	-16.7	10.55	-18.0	-39	7	96	-10.6	10.58	-10.0	-33	13
		DAY 50	103	-16.8	9.44	-18.0	-41	3	99	-16.2	10.83	-17.0	-37	7	96	-9.7	11.07	-8.0	-33	15

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS214.SAS
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Table 11.2.1.8 MADRS Total Score and Change from Baseline by Age Group - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

AGE GROUP			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
18-39	CHG FROM BASEL-INE	VISIT DAY 57	103	-17.2	10.03	-18.0	-41	10	99	-17.0	10.76	-17.0	-39	5	96	-10.5	11.31	-9.0	-35	13
40-65	MADRS TOTAL SCORE	DAY 1	69	30.2	5.50	30.0	13	45	71	30.7	5.86	30.0	18	48	73	30.5	5.39	31.0	20	44
		DAY 8	69	22.1	7.80	23.0	5	38	70	22.6	7.65	22.0	6	41	73	26.8	8.27	27.0	3	45
		DAY 15	69	19.7	8.48	19.0	3	40	71	19.0	8.57	19.0	0	42	73	24.3	9.00	25.0	2	46
		DAY 22	69	18.5	9.38	18.0	1	35	71	18.2	9.34	19.0	1	37	73	23.2	9.83	24.0	2	48
		DAY 29	69	17.0	9.45	16.0	0	38	71	15.2	9.60	14.0	0	37	73	22.4	11.00	23.0	1	48
		DAY 36	69	16.7	9.78	16.0	0	38	71	15.0	10.18	13.0	0	37	73	22.0	10.28	22.0	0	48
		DAY 43	69	15.9	10.25	15.0	0	38	71	15.6	10.78	13.0	0	37	73	21.7	10.38	22.0	0	48
		DAY 50	69	15.0	10.16	13.0	0	38	71	14.5	10.54	13.0	0	37	73	21.1	11.43	21.0	0	48
		DAY 57	69	14.8	10.48	14.0	0	38	71	14.2	10.86	12.0	0	37	73	20.2	11.23	21.0	0	48
	CHG FROM BASEL-INE	DAY 8	69	-8.0	6.65	-8.0	-30	4	70	-8.0	7.76	-8.0	-28	6	73	-3.7	6.24	-2.0	-24	6
		DAY 15	69	-10.4	7.61	-9.0	-25	4	71	-11.6	9.72	-11.0	-35	7	73	-6.2	7.38	-5.0	-26	7
		DAY 22	69	-11.7	7.98	-11.0	-26	5	71	-12.5	10.96	-11.0	-40	7	73	-7.4	8.63	-7.0	-27	7
		DAY 29	69	-13.2	9.21	-12.0	-34	5	71	-15.5	10.55	-17.0	-36	6	73	-8.1	10.08	-8.0	-32	8
		DAY 36	69	-13.5	9.27	-14.0	-33	5	71	-15.7	11.13	-17.0	-41	7	73	-8.5	9.26	-9.0	-29	10
		DAY 43	69	-14.2	9.45	-15.0	-33	5	71	-15.1	11.92	-17.0	-39	9	73	-8.8	9.47	-9.0	-32	9

(Continued)

Table 11.2.1.8 MADRS Total Score and Change from Baseline by Age Group - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

AGE GROUP			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
40-65	CHG FROM BASEL-INE	VISIT																		
		DAY 50	69	-15.1	9.69	-17.0	-35	5	71	-16.1	11.80	-17.0	-41	9	73	-9.4	10.70	-10.0	-33	9
		DAY 57	69	-15.4	9.63	-15.0	-34	5	71	-16.5	11.25	-18.0	-39	9	73	-10.3	10.08	-10.0	-33	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS214.SAS
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Table 11.2.1.9 MADRS Total Score and Change from Baseline by Sex - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

SEX			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MALE	MADRS TOTAL SCORE	VISIT																		
		DAY 1	79	30.3	5.01	30.0	13	41	71	29.5	4.76	30.0	18	43	64	31.0	6.09	30.5	21	47
		DAY 8	78	21.0	8.25	22.0	0	38	70	21.5	6.99	22.0	8	39	64	26.8	8.42	27.0	7	45
		DAY 15	79	17.3	9.32	17.0	0	40	71	18.3	7.96	19.0	3	35	64	25.0	8.88	25.0	4	46
		DAY 22	79	16.2	9.98	17.0	0	39	71	17.0	8.93	18.0	2	34	64	23.9	10.02	24.0	3	48
		DAY 29	79	14.7	9.28	15.0	0	37	71	14.4	9.50	13.0	0	33	64	22.4	10.54	22.0	1	48
		DAY 36	79	13.5	10.04	13.0	0	37	71	13.8	9.62	13.0	0	37	64	22.4	10.41	22.0	3	48
		DAY 43	79	13.0	9.57	12.0	0	37	71	13.8	10.21	11.0	0	37	64	22.7	10.28	22.5	0	48
		DAY 50	79	12.0	9.88	8.0	0	37	71	13.7	10.29	13.0	0	36	64	22.1	11.06	21.0	0	48
		DAY 57	79	11.8	10.34	8.0	0	37	71	13.0	10.21	12.0	0	34	64	21.7	10.97	20.5	0	48
	CHG FROM BASELINE	DAY 8	78	-9.4	8.01	-10.0	-32	11	70	-8.0	7.21	-8.0	-24	8	64	-4.3	7.36	-2.0	-31	6
		DAY 15	79	-13.0	8.50	-14.0	-36	3	71	-11.2	8.67	-10.0	-30	7	64	-6.1	7.47	-5.0	-26	9
		DAY 22	79	-14.0	8.99	-14.0	-41	3	71	-12.5	9.72	-11.0	-36	5	64	-7.1	8.90	-6.5	-30	9
		DAY 29	79	-15.5	9.42	-16.0	-41	4	71	-15.1	10.00	-14.0	-34	6	64	-8.6	9.76	-8.5	-32	7
		DAY 36	79	-16.7	9.79	-19.0	-38	3	71	-15.8	10.17	-15.0	-41	7	64	-8.6	9.63	-9.0	-28	7
		DAY 43	79	-17.2	9.60	-18.0	-41	3	71	-15.7	11.04	-17.0	-39	9	64	-8.3	9.14	-8.5	-31	8
		DAY 50	79	-18.3	9.95	-20.0	-41	3	71	-15.8	11.05	-15.0	-41	9	64	-9.0	10.17	-8.5	-31	7

(Continued)

Table 11.2.1.9 MADRS Total Score and Change from Baseline by Sex - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

SEX			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MALE	CHG FROM BASELINE	VISIT DAY 57	79	-18.5	10.17	-21.0	-41	10	71	-16.6	10.39	-17.0	-39	9	64	-9.4	9.93	-8.0	-31	7
FEMALE	MADRS TOTAL SCORE	DAY 1	93	30.4	5.08	30.0	19	45	99	30.9	5.58	31.0	16	48	105	30.3	4.71	31.0	20	41
		DAY 8	93	22.6	6.77	23.0	4	36	99	21.7	8.65	22.0	5	41	105	25.2	8.31	26.0	1	40
		DAY 15	93	19.4	8.01	20.0	2	38	99	18.7	9.08	18.0	0	42	105	22.3	9.22	22.0	2	43
		DAY 22	93	18.0	8.98	17.0	0	37	99	16.7	9.89	16.0	0	41	105	20.9	9.87	22.0	1	43
		DAY 29	93	18.0	9.00	17.0	0	38	99	14.7	10.23	12.0	0	37	105	21.0	10.63	21.0	1	43
		DAY 36	93	16.7	9.23	16.0	0	38	99	15.4	11.08	14.0	0	42	105	20.6	10.91	22.0	0	43
		DAY 43	93	15.5	9.82	15.0	0	38	99	14.7	10.88	12.0	0	38	105	19.6	11.08	21.0	0	43
		DAY 50	93	16.1	9.62	15.0	2	39	99	14.5	10.83	12.0	0	38	105	20.4	11.63	22.0	0	43
		DAY 57	93	15.6	10.30	15.0	1	39	99	14.0	11.01	12.0	0	38	105	19.3	11.85	19.0	0	43
	CHG FROM BASELINE	DAY 8	93	-7.8	6.35	-8.0	-25	4	99	-9.2	8.12	-8.0	-29	7	105	-5.1	7.28	-4.0	-30	7
		DAY 15	93	-11.0	8.01	-10.0	-32	4	99	-12.2	9.74	-12.0	-35	5	105	-8.0	8.33	-8.0	-27	7
		DAY 22	93	-12.4	8.41	-12.0	-34	5	99	-14.3	10.55	-15.0	-40	10	105	-9.4	9.67	-8.0	-31	9
		DAY 29	93	-12.4	8.91	-12.0	-34	6	99	-16.2	10.65	-18.0	-36	5	105	-9.3	10.20	-10.0	-32	13
		DAY 36	93	-13.7	8.83	-14.0	-34	5	99	-15.5	11.66	-17.0	-34	11	105	-9.8	10.25	-10.0	-33	13
		DAY 43	93	-14.8	9.06	-15.0	-34	5	99	-16.3	11.26	-18.0	-38	7	105	-10.7	10.62	-11.0	-33	13

(Continued)

Table 11.2.1.9 MADRS Total Score and Change from Baseline by Sex - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

SEX			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
FEMALE	CHG FROM BASELINE	VISIT																		
		DAY 50	93	-14.3	8.85	-15.0	-35	5	99	-16.4	11.38	-19.0	-40	7	105	-9.9	11.32	-9.0	-33	15
		DAY 57	93	-14.7	9.35	-15.0	-34	6	99	-16.9	11.36	-18.0	-39	5	105	-11.0	11.25	-11.0	-35	13

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS215.SAS
GENERATED: 12JUL2005 17:44:49 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	VISIT																		
	DAY 1	172	3.6	0.81	4.0	1	6	170	3.6	0.92	4.0	1	6	169	3.5	0.86	4.0	1	6
	DAY 8	171	2.7	1.18	3.0	0	6	169	2.6	1.20	3.0	0	5	169	3.0	1.19	3.0	0	6
	DAY 15	172	2.3	1.19	2.0	0	5	170	2.3	1.22	2.0	0	5	169	2.6	1.26	3.0	0	5
	DAY 22	172	2.1	1.27	2.0	0	5	170	2.0	1.38	2.0	0	5	169	2.4	1.41	3.0	0	5
	DAY 29	172	2.0	1.26	2.0	0	5	170	1.8	1.46	2.0	0	6	169	2.4	1.39	2.0	0	5
	DAY 36	172	1.9	1.34	2.0	0	5	170	1.7	1.54	2.0	0	6	169	2.3	1.42	2.0	0	5
	DAY 43	172	1.8	1.37	2.0	0	5	170	1.7	1.56	1.5	0	6	169	2.3	1.42	2.0	0	5
	DAY 50	172	1.8	1.43	2.0	0	5	170	1.7	1.54	2.0	0	6	169	2.3	1.52	2.0	0	5
	DAY 57	172	1.7	1.43	2.0	0	5	170	1.6	1.49	1.5	0	6	169	2.2	1.52	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	VISIT																		
	DAY 1	172	3.8	0.78	4.0	1	6	170	3.9	0.80	4.0	2	6	169	3.8	0.74	4.0	2	6
	DAY 8	171	2.8	1.23	3.0	0	6	169	2.8	1.23	3.0	0	5	169	3.2	1.21	3.0	0	6
	DAY 15	172	2.3	1.28	2.0	0	5	170	2.3	1.38	2.0	0	5	169	2.8	1.29	3.0	0	5
	DAY 22	172	2.2	1.38	2.0	0	5	170	2.0	1.43	2.0	0	5	169	2.6	1.44	3.0	0	5
	DAY 29	172	2.0	1.35	2.0	0	5	170	1.7	1.47	2.0	0	5	169	2.5	1.45	3.0	0	5
	DAY 36	172	1.9	1.41	2.0	0	5	170	1.8	1.55	2.0	0	6	169	2.5	1.54	3.0	0	5
	DAY 43	172	1.7	1.46	2.0	0	5	170	1.7	1.56	2.0	0	6	169	2.5	1.53	3.0	0	5
	DAY 50	172	1.7	1.48	1.5	0	5	170	1.6	1.54	1.5	0	6	169	2.4	1.59	3.0	0	5
	DAY 57	172	1.6	1.51	1.0	0	5	170	1.6	1.56	1.0	0	6	169	2.3	1.61	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	VISIT																		
	DAY 1	172	3.0	1.01	3.0	0	5	170	3.0	1.11	3.0	0	6	169	3.1	0.96	3.0	0	6
	DAY 8	171	2.5	1.13	3.0	0	5	169	2.5	1.16	2.0	0	6	169	2.8	1.07	3.0	0	5
	DAY 15	172	2.1	1.17	2.0	0	5	170	2.2	1.22	2.0	0	5	169	2.5	1.08	3.0	0	5
	DAY 22	172	2.1	1.17	2.0	0	5	170	2.1	1.32	2.0	0	5	169	2.4	1.15	2.0	0	5
	DAY 29	172	2.1	1.24	2.0	0	5	170	1.8	1.39	2.0	0	5	169	2.4	1.15	2.0	0	5
	DAY 36	172	1.9	1.28	2.0	0	5	170	1.8	1.44	2.0	0	5	169	2.4	1.19	2.0	0	5
	DAY 43	172	1.8	1.29	2.0	0	5	170	1.7	1.41	2.0	0	5	169	2.3	1.29	2.0	0	5
	DAY 50	172	1.8	1.31	2.0	0	5	170	1.7	1.37	2.0	0	5	169	2.4	1.28	2.0	0	5
	DAY 57	172	1.8	1.32	2.0	0	5	170	1.6	1.44	2.0	0	5	169	2.4	1.28	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	VISIT																		
	DAY 1	172	3.6	1.17	4.0	0	6	170	3.5	1.32	4.0	0	6	169	3.6	1.17	4.0	0	6
	DAY 8	171	1.2	1.42	1.0	0	5	169	1.3	1.54	1.0	0	6	169	2.9	1.58	3.0	0	6
	DAY 15	172	1.2	1.44	1.0	0	6	170	1.4	1.58	1.0	0	5	169	2.8	1.61	3.0	0	6
	DAY 22	172	1.3	1.59	1.0	0	6	170	1.4	1.63	0.0	0	6	169	2.6	1.63	3.0	0	6
	DAY 29	172	1.3	1.50	0.5	0	6	170	1.2	1.58	0.0	0	6	169	2.6	1.62	3.0	0	6
	DAY 36	172	1.2	1.44	0.5	0	5	170	1.1	1.51	0.0	0	6	169	2.5	1.71	3.0	0	6
	DAY 43	172	1.3	1.48	1.0	0	6	170	1.1	1.56	0.0	0	6	169	2.5	1.78	3.0	0	6
	DAY 50	172	1.2	1.43	1.0	0	5	170	1.2	1.48	0.0	0	6	169	2.5	1.72	3.0	0	6
	DAY 57	172	1.2	1.55	0.0	0	6	170	1.1	1.51	0.0	0	6	169	2.5	1.74	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	VISIT																		
	DAY 1	172	1.8	1.56	2.0	0	6	170	1.7	1.60	2.0	0	5	169	1.9	1.59	2.0	0	6
	DAY 8	171	1.1	1.30	0.0	0	5	169	1.1	1.34	0.0	0	5	169	1.4	1.51	2.0	0	6
	DAY 15	172	0.9	1.31	0.0	0	5	170	0.9	1.28	0.0	0	5	169	1.2	1.44	0.0	0	5
	DAY 22	172	0.9	1.24	0.0	0	5	170	0.9	1.29	0.0	0	6	169	1.4	1.47	1.0	0	5
	DAY 29	172	0.9	1.31	0.0	0	6	170	0.8	1.17	0.0	0	4	169	1.3	1.49	0.0	0	5
	DAY 36	172	0.7	1.20	0.0	0	5	170	0.8	1.27	0.0	0	6	169	1.2	1.48	0.0	0	5
	DAY 43	172	0.6	1.12	0.0	0	5	170	0.7	1.20	0.0	0	5	169	1.2	1.51	0.0	0	5
	DAY 50	172	0.7	1.15	0.0	0	5	170	0.7	1.21	0.0	0	6	169	1.2	1.54	0.0	0	6
	DAY 57	172	0.7	1.17	0.0	0	5	170	0.7	1.19	0.0	0	6	169	1.1	1.55	0.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	VISIT																		
	DAY 1	172	3.3	0.99	3.5	0	5	170	3.3	1.01	3.0	0	5	169	3.2	1.01	3.0	0	5
	DAY 8	171	2.7	1.21	3.0	0	5	169	2.6	1.29	3.0	0	5	169	2.8	1.15	3.0	0	5
	DAY 15	172	2.2	1.24	2.0	0	5	170	2.3	1.39	2.0	0	5	169	2.6	1.26	3.0	0	6
	DAY 22	172	2.0	1.43	2.0	0	5	170	2.0	1.45	2.0	0	6	169	2.6	1.28	3.0	0	6
	DAY 29	172	1.9	1.35	2.0	0	5	170	1.8	1.52	2.0	0	6	169	2.3	1.41	2.0	0	6
	DAY 36	172	1.8	1.33	2.0	0	5	170	1.9	1.54	2.0	0	6	169	2.3	1.42	2.0	0	6
	DAY 43	172	1.6	1.34	2.0	0	5	170	1.8	1.58	2.0	0	6	169	2.3	1.49	2.0	0	6
	DAY 50	172	1.6	1.39	2.0	0	5	170	1.8	1.55	2.0	0	6	169	2.3	1.47	2.0	0	6
	DAY 57	172	1.7	1.49	2.0	0	6	170	1.8	1.59	2.0	0	6	169	2.2	1.51	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	VISIT																		
	DAY 1	172	3.4	1.07	4.0	0	5	170	3.4	1.15	4.0	0	6	169	3.4	1.00	4.0	0	5
	DAY 8	171	2.7	1.20	3.0	0	5	169	2.8	1.30	3.0	0	5	169	2.9	1.21	3.0	0	5
	DAY 15	172	2.5	1.36	2.0	0	5	170	2.3	1.41	2.0	0	5	169	2.6	1.34	3.0	0	5
	DAY 22	172	2.1	1.47	2.0	0	5	170	2.2	1.43	2.0	0	6	169	2.5	1.38	3.0	0	5
	DAY 29	172	2.1	1.41	2.0	0	5	170	1.9	1.49	2.0	0	5	169	2.4	1.37	2.0	0	5
	DAY 36	172	1.9	1.45	2.0	0	5	170	1.9	1.48	2.0	0	5	169	2.4	1.41	2.0	0	5
	DAY 43	172	1.8	1.45	2.0	0	5	170	1.8	1.52	2.0	0	5	169	2.2	1.51	2.0	0	5
	DAY 50	172	1.8	1.48	2.0	0	5	170	1.8	1.57	2.0	0	5	169	2.3	1.51	2.0	0	5
	DAY 57	172	1.8	1.50	2.0	0	5	170	1.7	1.55	2.0	0	5	169	2.2	1.56	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	VISIT																		
	DAY 1	172	3.4	0.84	4.0	0	5	170	3.5	0.90	4.0	0	5	169	3.5	0.83	4.0	0	5
	DAY 8	171	2.7	1.15	3.0	0	5	169	2.6	1.32	3.0	0	6	169	2.9	1.16	3.0	0	5
	DAY 15	172	2.2	1.36	2.0	0	5	170	2.3	1.40	2.0	0	6	169	2.7	1.26	3.0	0	5
	DAY 22	172	1.9	1.43	2.0	0	5	170	2.1	1.51	2.0	0	6	169	2.4	1.43	2.0	0	5
	DAY 29	172	1.9	1.42	2.0	0	5	170	1.7	1.51	2.0	0	6	169	2.4	1.42	2.0	0	5
	DAY 36	172	1.8	1.47	2.0	0	5	170	1.7	1.53	2.0	0	6	169	2.4	1.46	2.0	0	5
	DAY 43	172	1.7	1.47	2.0	0	5	170	1.6	1.58	1.5	0	6	169	2.4	1.48	2.0	0	5
	DAY 50	172	1.7	1.42	2.0	0	5	170	1.6	1.57	1.0	0	6	169	2.4	1.51	3.0	0	5
	DAY 57	172	1.5	1.52	1.0	0	5	170	1.7	1.64	2.0	0	6	169	2.2	1.53	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	VISIT																		
	DAY 1	172	3.0	0.94	3.0	0	5	170	3.0	1.02	3.0	0	5	169	2.9	0.93	3.0	0	4
	DAY 8	171	2.3	1.23	2.0	0	5	169	2.2	1.31	2.0	0	5	169	2.5	1.13	3.0	0	4
	DAY 15	172	1.8	1.22	2.0	0	4	170	1.8	1.32	2.0	0	5	169	2.3	1.23	2.0	0	5
	DAY 22	172	1.8	1.27	2.0	0	5	170	1.5	1.36	2.0	0	5	169	2.0	1.28	2.0	0	5
	DAY 29	172	1.7	1.29	2.0	0	5	170	1.4	1.39	1.0	0	5	169	2.1	1.33	2.0	0	5
	DAY 36	172	1.5	1.30	2.0	0	4	170	1.4	1.39	1.0	0	5	169	2.1	1.33	2.0	0	5
	DAY 43	172	1.3	1.24	1.0	0	4	170	1.4	1.42	1.0	0	5	169	2.0	1.41	2.0	0	5
	DAY 50	172	1.4	1.28	1.0	0	4	170	1.4	1.44	1.0	0	5	169	2.1	1.41	2.0	0	5
	DAY 57	172	1.3	1.29	1.0	0	4	170	1.3	1.41	1.0	0	5	169	2.0	1.36	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	VISIT																		
	DAY 1	172	1.5	1.05	1.5	0	4	170	1.5	1.07	1.0	0	5	169	1.6	1.04	2.0	0	5
	DAY 8	171	1.1	1.11	1.0	0	4	169	1.0	0.98	1.0	0	4	169	1.4	1.24	1.0	0	5
	DAY 15	172	0.9	1.04	1.0	0	5	170	0.8	0.99	1.0	0	4	169	1.2	1.18	1.0	0	5
	DAY 22	172	0.8	1.02	0.0	0	4	170	0.7	0.93	0.0	0	4	169	1.1	1.21	1.0	0	5
	DAY 29	172	0.7	0.96	0.0	0	4	170	0.6	0.99	0.0	0	5	169	1.1	1.27	1.0	0	5
	DAY 36	172	0.7	0.96	0.0	0	4	170	0.6	0.98	0.0	0	5	169	1.2	1.35	1.0	0	5
	DAY 43	172	0.6	0.91	0.0	0	4	170	0.7	1.02	0.0	0	5	169	1.1	1.30	1.0	0	5
	DAY 50	172	0.6	0.92	0.0	0	4	170	0.7	1.03	0.0	0	5	169	1.1	1.30	1.0	0	5
	DAY 57	172	0.5	0.87	0.0	0	4	170	0.6	0.96	0.0	0	5	169	1.1	1.28	1.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS217.SAS
GENERATED: 12JUL2005 17:44:55 iceadmn3

Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	VISIT																		
	DAY 1	172	3.6	0.81	4.0	1	6	170	3.6	0.92	4.0	1	6	169	3.5	0.86	4.0	1	6
	DAY 8	171	2.7	1.18	3.0	0	6	169	2.6	1.20	3.0	0	5	169	3.0	1.19	3.0	0	6
	DAY 15	148	2.3	1.19	2.0	0	5	148	2.2	1.19	2.0	0	5	149	2.5	1.24	3.0	0	5
	DAY 22	139	2.0	1.28	2.0	0	5	133	1.9	1.38	2.0	0	4	143	2.3	1.43	2.0	0	5
	DAY 29	133	1.9	1.24	2.0	0	5	127	1.5	1.40	1.0	0	6	126	2.2	1.37	2.0	0	5
	DAY 36	130	1.7	1.32	2.0	0	5	113	1.4	1.52	1.0	0	6	119	2.1	1.40	2.0	0	5
	DAY 43	123	1.6	1.32	1.0	0	4	107	1.3	1.38	1.0	0	5	107	2.1	1.43	2.0	0	5
	DAY 50	121	1.5	1.39	1.0	0	5	101	1.3	1.40	1.0	0	6	102	2.0	1.52	2.0	0	5
	DAY 57	119	1.4	1.34	1.0	0	4	97	1.2	1.24	1.0	0	4	99	1.9	1.50	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
GENERATED: 12JUL2005 17:44:51 iceadmn3

Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	VISIT																		
	DAY 1	172	3.8	0.78	4.0	1	6	170	3.9	0.80	4.0	2	6	169	3.8	0.74	4.0	2	6
	DAY 8	171	2.8	1.23	3.0	0	6	169	2.8	1.23	3.0	0	5	169	3.2	1.21	3.0	0	6
	DAY 15	148	2.2	1.27	2.0	0	5	148	2.2	1.35	2.0	0	5	149	2.7	1.28	3.0	0	5
	DAY 22	139	2.1	1.37	2.0	0	5	133	1.8	1.38	2.0	0	5	143	2.4	1.45	3.0	0	5
	DAY 29	133	1.9	1.31	2.0	0	5	127	1.4	1.32	1.0	0	5	126	2.3	1.42	2.0	0	5
	DAY 36	130	1.7	1.35	1.5	0	5	113	1.5	1.48	1.0	0	6	119	2.2	1.53	2.0	0	5
	DAY 43	123	1.4	1.34	1.0	0	5	107	1.3	1.35	1.0	0	5	107	2.2	1.54	2.0	0	5
	DAY 50	121	1.4	1.38	1.0	0	5	101	1.2	1.33	1.0	0	4	102	2.1	1.59	2.0	0	5
	DAY 57	119	1.3	1.38	1.0	0	5	97	1.1	1.31	0.0	0	4	99	2.0	1.57	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
GENERATED: 12JUL2005 17:44:51 iceadmn3

Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	VISIT																		
	DAY 1	172	3.0	1.01	3.0	0	5	170	3.0	1.11	3.0	0	6	169	3.1	0.96	3.0	0	6
	DAY 8	171	2.5	1.13	3.0	0	5	169	2.5	1.16	2.0	0	6	169	2.8	1.07	3.0	0	5
	DAY 15	148	2.1	1.18	2.0	0	5	148	2.2	1.17	2.0	0	4	149	2.5	1.07	3.0	0	5
	DAY 22	139	2.1	1.17	2.0	0	5	133	1.9	1.29	2.0	0	5	143	2.3	1.13	2.0	0	4
	DAY 29	133	2.0	1.24	2.0	0	5	127	1.5	1.30	2.0	0	5	126	2.3	1.15	2.0	0	5
	DAY 36	130	1.8	1.28	2.0	0	5	113	1.4	1.33	2.0	0	5	119	2.3	1.14	2.0	0	5
	DAY 43	123	1.7	1.28	2.0	0	5	107	1.3	1.22	1.0	0	4	107	2.1	1.29	2.0	0	4
	DAY 50	121	1.6	1.30	2.0	0	5	101	1.4	1.21	2.0	0	4	102	2.2	1.27	2.0	0	4
	DAY 57	119	1.6	1.26	2.0	0	5	97	1.2	1.31	1.0	0	4	99	2.3	1.29	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
GENERATED: 12JUL2005 17:44:51 iceadmn3

Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	VISIT																		
	DAY 1	172	3.6	1.17	4.0	0	6	170	3.5	1.32	4.0	0	6	169	3.6	1.17	4.0	0	6
	DAY 8	171	1.2	1.42	1.0	0	5	169	1.3	1.54	1.0	0	6	169	2.9	1.58	3.0	0	6
	DAY 15	148	1.2	1.43	1.0	0	6	148	1.3	1.60	1.0	0	5	149	2.7	1.61	3.0	0	6
	DAY 22	139	1.3	1.63	1.0	0	6	133	1.2	1.59	0.0	0	6	143	2.6	1.63	3.0	0	6
	DAY 29	133	1.2	1.49	0.0	0	6	127	1.0	1.43	0.0	0	6	126	2.3	1.53	2.0	0	6
	DAY 36	130	1.2	1.42	0.0	0	5	113	0.8	1.29	0.0	0	5	119	2.2	1.64	2.0	0	6
	DAY 43	123	1.2	1.45	1.0	0	6	107	0.8	1.35	0.0	0	5	107	2.2	1.72	2.0	0	5
	DAY 50	121	1.1	1.37	1.0	0	5	101	0.9	1.28	0.0	0	4	102	2.1	1.62	2.0	0	5
	DAY 57	119	1.2	1.57	0.0	0	6	97	0.8	1.31	0.0	0	6	99	2.2	1.67	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	VISIT																		
	DAY 1	172	1.8	1.56	2.0	0	6	170	1.7	1.60	2.0	0	5	169	1.9	1.59	2.0	0	6
	DAY 8	171	1.1	1.30	0.0	0	5	169	1.1	1.34	0.0	0	5	169	1.4	1.51	2.0	0	6
	DAY 15	148	0.8	1.28	0.0	0	5	148	0.8	1.25	0.0	0	5	149	1.1	1.38	0.0	0	5
	DAY 22	139	0.8	1.17	0.0	0	4	133	0.8	1.27	0.0	0	6	143	1.3	1.45	1.0	0	5
	DAY 29	133	0.8	1.27	0.0	0	6	127	0.6	1.09	0.0	0	4	126	1.2	1.44	0.0	0	4
	DAY 36	130	0.6	1.06	0.0	0	4	113	0.7	1.26	0.0	0	6	119	1.0	1.35	0.0	0	4
	DAY 43	123	0.5	0.87	0.0	0	3	107	0.5	1.09	0.0	0	5	107	0.9	1.40	0.0	0	5
	DAY 50	121	0.5	0.93	0.0	0	4	101	0.5	1.10	0.0	0	6	102	1.0	1.45	0.0	0	6
	DAY 57	119	0.5	1.02	0.0	0	4	97	0.4	1.04	0.0	0	6	99	0.8	1.44	0.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	VISIT																		
	DAY 1	172	3.3	0.99	3.5	0	5	170	3.3	1.01	3.0	0	5	169	3.2	1.01	3.0	0	5
	DAY 8	171	2.7	1.21	3.0	0	5	169	2.6	1.29	3.0	0	5	169	2.8	1.15	3.0	0	5
	DAY 15	148	2.2	1.23	2.0	0	5	148	2.2	1.36	2.0	0	5	149	2.5	1.23	2.0	0	5
	DAY 22	139	2.0	1.44	2.0	0	5	133	1.9	1.37	2.0	0	6	143	2.5	1.27	3.0	0	5
	DAY 29	133	1.8	1.29	2.0	0	4	127	1.5	1.36	2.0	0	5	126	2.1	1.34	2.0	0	5
	DAY 36	130	1.6	1.24	2.0	0	4	113	1.5	1.37	2.0	0	5	119	2.1	1.37	2.0	0	5
	DAY 43	123	1.4	1.20	1.0	0	5	107	1.4	1.43	1.0	0	4	107	2.0	1.45	2.0	0	5
	DAY 50	121	1.4	1.31	1.0	0	4	101	1.3	1.37	1.0	0	4	102	2.0	1.42	2.0	0	6
	DAY 57	119	1.5	1.45	1.0	0	6	97	1.2	1.41	1.0	0	6	99	1.9	1.50	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	VISIT																		
	DAY 1	172	3.4	1.07	4.0	0	5	170	3.4	1.15	4.0	0	6	169	3.4	1.00	4.0	0	5
	DAY 8	171	2.7	1.20	3.0	0	5	169	2.8	1.30	3.0	0	5	169	2.9	1.21	3.0	0	5
	DAY 15	148	2.4	1.37	2.0	0	5	148	2.2	1.39	2.0	0	5	149	2.6	1.37	3.0	0	5
	DAY 22	139	2.0	1.50	2.0	0	5	133	2.0	1.41	2.0	0	6	143	2.5	1.41	3.0	0	5
	DAY 29	133	1.9	1.35	2.0	0	5	127	1.5	1.36	2.0	0	5	126	2.2	1.39	2.0	0	5
	DAY 36	130	1.6	1.35	2.0	0	5	113	1.5	1.33	2.0	0	4	119	2.2	1.41	2.0	0	5
	DAY 43	123	1.5	1.30	1.0	0	5	107	1.3	1.34	1.0	0	5	107	2.0	1.54	2.0	0	5
	DAY 50	121	1.4	1.32	1.0	0	4	101	1.3	1.42	1.0	0	5	102	2.1	1.54	2.0	0	5
	DAY 57	119	1.6	1.38	1.0	0	5	97	1.2	1.35	1.0	0	5	99	1.9	1.59	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	VISIT																		
	DAY 1	172	3.4	0.84	4.0	0	5	170	3.5	0.90	4.0	0	5	169	3.5	0.83	4.0	0	5
	DAY 8	171	2.7	1.15	3.0	0	5	169	2.6	1.32	3.0	0	6	169	2.9	1.16	3.0	0	5
	DAY 15	148	2.1	1.34	2.0	0	4	148	2.3	1.40	2.0	0	5	149	2.6	1.27	3.0	0	5
	DAY 22	139	1.8	1.43	2.0	0	5	133	1.9	1.51	2.0	0	6	143	2.3	1.44	2.0	0	5
	DAY 29	133	1.8	1.37	2.0	0	5	127	1.3	1.36	1.0	0	4	126	2.1	1.38	2.0	0	5
	DAY 36	130	1.5	1.38	1.0	0	4	113	1.4	1.41	1.0	0	5	119	2.1	1.45	2.0	0	5
	DAY 43	123	1.4	1.31	1.0	0	4	107	1.1	1.40	1.0	0	5	107	2.1	1.50	2.0	0	5
	DAY 50	121	1.4	1.26	1.0	0	4	101	1.1	1.39	1.0	0	6	102	2.1	1.54	2.0	0	5
	DAY 57	119	1.2	1.37	1.0	0	4	97	1.2	1.54	0.0	0	6	99	1.9	1.50	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	VISIT																		
	DAY 1	172	3.0	0.94	3.0	0	5	170	3.0	1.02	3.0	0	5	169	2.9	0.93	3.0	0	4
	DAY 8	171	2.3	1.23	2.0	0	5	169	2.2	1.31	2.0	0	5	169	2.5	1.13	3.0	0	4
	DAY 15	148	1.8	1.20	2.0	0	4	148	1.8	1.30	2.0	0	4	149	2.2	1.23	2.0	0	4
	DAY 22	139	1.7	1.26	2.0	0	5	133	1.4	1.32	1.0	0	4	143	1.9	1.30	2.0	0	5
	DAY 29	133	1.6	1.26	2.0	0	5	127	1.2	1.28	1.0	0	4	126	1.9	1.34	2.0	0	4
	DAY 36	130	1.4	1.24	1.0	0	4	113	1.1	1.25	1.0	0	4	119	1.8	1.32	2.0	0	4
	DAY 43	123	1.1	1.10	1.0	0	4	107	1.2	1.32	1.0	0	4	107	1.7	1.43	2.0	0	5
	DAY 50	121	1.2	1.20	1.0	0	4	101	1.1	1.33	1.0	0	4	102	1.8	1.46	2.0	0	4
	DAY 57	119	1.1	1.20	1.0	0	4	97	0.9	1.20	0.0	0	4	99	1.7	1.32	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.10.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	VISIT																		
	DAY 1	172	1.5	1.05	1.5	0	4	170	1.5	1.07	1.0	0	5	169	1.6	1.04	2.0	0	5
	DAY 8	171	1.1	1.11	1.0	0	4	169	1.0	0.98	1.0	0	4	169	1.4	1.24	1.0	0	5
	DAY 15	148	0.9	1.06	1.0	0	5	148	0.8	0.97	1.0	0	4	149	1.1	1.05	1.0	0	4
	DAY 22	139	0.8	1.06	0.0	0	4	133	0.6	0.91	0.0	0	4	143	1.0	1.11	1.0	0	4
	DAY 29	133	0.7	0.94	0.0	0	4	127	0.6	0.97	0.0	0	5	126	0.9	1.14	1.0	0	4
	DAY 36	130	0.7	0.93	0.0	0	4	113	0.5	0.95	0.0	0	5	119	1.0	1.27	1.0	0	4
	DAY 43	123	0.5	0.78	0.0	0	4	107	0.5	0.94	0.0	0	4	107	0.8	1.13	0.0	0	4
	DAY 50	121	0.5	0.80	0.0	0	4	101	0.6	0.98	0.0	0	4	102	0.8	1.11	0.0	0	4
	DAY 57	119	0.4	0.76	0.0	0	4	97	0.4	0.77	0.0	0	4	99	0.8	1.09	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	VISIT																		
	DAY 8	171	-0.9	1.27	-1.0	-5	2	169	-0.9	1.32	-1.0	-4	2	169	-0.6	1.10	0.0	-6	2
	DAY 15	172	-1.3	1.34	-1.0	-4	2	170	-1.3	1.45	-1.0	-5	3	169	-0.9	1.29	-1.0	-4	2
	DAY 22	172	-1.5	1.31	-1.0	-5	1	170	-1.6	1.62	-2.0	-6	2	169	-1.1	1.41	-1.0	-4	2
	DAY 29	172	-1.6	1.38	-2.0	-5	1	170	-1.8	1.67	-2.0	-6	3	169	-1.1	1.38	-1.0	-5	2
	DAY 36	172	-1.8	1.44	-2.0	-6	1	170	-1.9	1.72	-2.0	-5	3	169	-1.2	1.43	-1.0	-4	2
	DAY 43	172	-1.8	1.42	-2.0	-6	1	170	-1.9	1.74	-2.0	-6	3	169	-1.2	1.39	-1.0	-4	1
	DAY 50	172	-1.9	1.50	-2.0	-6	1	170	-1.9	1.72	-2.0	-6	3	169	-1.2	1.52	-1.0	-4	1
	DAY 57	172	-1.9	1.48	-2.0	-5	1	170	-2.0	1.62	-2.0	-5	3	169	-1.3	1.51	-1.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	VISIT																		
	DAY 8	171	-1.0	1.32	-1.0	-5	3	169	-1.1	1.30	-1.0	-5	2	169	-0.7	1.22	0.0	-6	2
	DAY 15	172	-1.5	1.40	-1.0	-5	1	170	-1.6	1.44	-1.0	-5	2	169	-1.0	1.33	-1.0	-4	2
	DAY 22	172	-1.7	1.48	-2.0	-5	2	170	-1.8	1.53	-2.0	-6	2	169	-1.3	1.46	-1.0	-5	2
	DAY 29	172	-1.8	1.53	-2.0	-6	3	170	-2.1	1.60	-2.0	-6	2	169	-1.3	1.49	-1.0	-4	2
	DAY 36	172	-1.9	1.53	-2.0	-5	2	170	-2.1	1.65	-2.0	-5	2	169	-1.3	1.57	-1.0	-5	2
	DAY 43	172	-2.1	1.59	-2.0	-5	2	170	-2.2	1.68	-2.0	-5	2	169	-1.3	1.51	-1.0	-4	2
	DAY 50	172	-2.1	1.62	-2.0	-5	2	170	-2.2	1.66	-2.0	-6	2	169	-1.4	1.57	-1.0	-4	2
	DAY 57	172	-2.2	1.62	-2.0	-5	1	170	-2.3	1.67	-2.0	-5	2	169	-1.5	1.56	-1.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	VISIT																		
	DAY 8	171	-0.5	1.23	0.0	-3	4	169	-0.5	1.33	0.0	-5	3	169	-0.3	1.18	0.0	-4	3
	DAY 15	172	-0.8	1.30	-1.0	-5	3	170	-0.8	1.44	-1.0	-5	2	169	-0.6	1.16	0.0	-4	3
	DAY 22	172	-0.9	1.36	-1.0	-4	4	170	-1.0	1.58	-1.0	-5	3	169	-0.7	1.27	-1.0	-5	2
	DAY 29	172	-0.9	1.47	-1.0	-4	4	170	-1.3	1.55	-1.0	-4	5	169	-0.7	1.33	-1.0	-4	3
	DAY 36	172	-1.0	1.46	-1.0	-4	3	170	-1.3	1.65	-1.0	-5	5	169	-0.7	1.32	-1.0	-4	3
	DAY 43	172	-1.1	1.50	-1.0	-4	4	170	-1.4	1.62	-1.0	-5	3	169	-0.8	1.49	-1.0	-5	3
	DAY 50	172	-1.2	1.46	-1.0	-5	3	170	-1.3	1.64	-1.0	-5	3	169	-0.7	1.47	-1.0	-4	3
	DAY 57	172	-1.2	1.44	-1.0	-4	3	170	-1.4	1.60	-2.0	-5	2	169	-0.7	1.45	-1.0	-5	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	VISIT																		
	DAY 8	171	-2.4	1.78	-3.0	-6	2	169	-2.2	2.04	-2.0	-6	6	169	-0.7	1.56	0.0	-5	3
	DAY 15	172	-2.4	1.80	-2.0	-6	2	170	-2.2	1.98	-2.5	-6	4	169	-0.9	1.67	-1.0	-6	3
	DAY 22	172	-2.2	1.81	-2.0	-6	3	170	-2.2	1.97	-2.0	-5	5	169	-1.0	1.76	-1.0	-6	2
	DAY 29	172	-2.3	1.79	-2.0	-6	2	170	-2.4	2.01	-3.0	-6	5	169	-1.0	1.67	-1.0	-6	4
	DAY 36	172	-2.4	1.65	-2.0	-6	2	170	-2.4	1.83	-3.0	-6	4	169	-1.1	1.82	-1.0	-6	4
	DAY 43	172	-2.3	1.68	-2.0	-6	2	170	-2.4	1.84	-3.0	-6	4	169	-1.1	1.91	-1.0	-6	4
	DAY 50	172	-2.4	1.70	-2.0	-6	2	170	-2.4	1.84	-3.0	-6	4	169	-1.1	1.79	-1.0	-6	4
	DAY 57	172	-2.4	1.83	-3.0	-6	4	170	-2.4	1.83	-3.0	-6	4	169	-1.1	1.79	-1.0	-6	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	VISIT																		
	DAY 8	171	-0.7	1.40	0.0	-5	3	169	-0.6	1.44	0.0	-4	2	169	-0.5	1.52	0.0	-4	4
	DAY 15	172	-0.9	1.53	0.0	-5	3	170	-0.8	1.65	0.0	-5	3	169	-0.7	1.56	0.0	-4	4
	DAY 22	172	-0.9	1.49	0.0	-5	2	170	-0.9	1.75	0.0	-5	4	169	-0.5	1.59	0.0	-4	4
	DAY 29	172	-0.9	1.66	-0.5	-5	6	170	-1.0	1.64	0.0	-5	3	169	-0.7	1.69	0.0	-4	4
	DAY 36	172	-1.1	1.58	-1.0	-5	3	170	-1.0	1.75	0.0	-5	4	169	-0.7	1.74	0.0	-4	4
	DAY 43	172	-1.1	1.52	-1.0	-5	3	170	-1.0	1.71	0.0	-5	3	169	-0.7	1.73	0.0	-6	4
	DAY 50	172	-1.1	1.62	-1.0	-5	3	170	-1.0	1.81	-0.5	-5	3	169	-0.7	1.82	0.0	-6	5
	DAY 57	172	-1.1	1.53	-1.0	-5	3	170	-1.1	1.74	0.0	-5	3	169	-0.8	1.83	0.0	-6	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	VISIT																		
	DAY 8	171	-0.6	1.21	0.0	-4	3	169	-0.7	1.35	0.0	-5	4	169	-0.4	1.19	0.0	-5	3
	DAY 15	172	-1.0	1.26	-1.0	-4	2	170	-1.0	1.54	-1.0	-5	4	169	-0.6	1.32	0.0	-5	3
	DAY 22	172	-1.3	1.40	-1.0	-4	2	170	-1.3	1.62	-1.0	-5	4	169	-0.7	1.30	-1.0	-4	2
	DAY 29	172	-1.3	1.46	-1.0	-4	3	170	-1.5	1.68	-2.0	-5	4	169	-0.9	1.51	-1.0	-5	4
	DAY 36	172	-1.5	1.51	-1.0	-5	3	170	-1.4	1.74	-1.0	-5	4	169	-0.9	1.43	-1.0	-5	4
	DAY 43	172	-1.7	1.45	-2.0	-5	2	170	-1.4	1.71	-2.0	-5	4	169	-1.0	1.56	-1.0	-5	4
	DAY 50	172	-1.6	1.53	-2.0	-5	2	170	-1.5	1.72	-1.0	-5	4	169	-0.9	1.55	-1.0	-5	4
	DAY 57	172	-1.6	1.61	-2.0	-5	4	170	-1.5	1.77	-2.0	-5	4	169	-1.0	1.57	-1.0	-5	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	VISIT																		
	DAY 8	171	-0.6	1.42	-1.0	-4	4	169	-0.5	1.55	0.0	-4	4	169	-0.6	1.23	0.0	-4	4
	DAY 15	172	-0.9	1.62	-1.0	-5	4	170	-1.1	1.52	-1.0	-5	4	169	-0.8	1.30	-1.0	-4	2
	DAY 22	172	-1.3	1.62	-1.0	-5	3	170	-1.2	1.69	-1.0	-5	4	169	-0.9	1.42	-1.0	-5	4
	DAY 29	172	-1.3	1.67	-1.0	-5	4	170	-1.5	1.79	-2.0	-5	4	169	-1.0	1.45	-1.0	-5	3
	DAY 36	172	-1.5	1.66	-2.0	-5	4	170	-1.5	1.77	-2.0	-5	4	169	-1.1	1.49	-1.0	-5	3
	DAY 43	172	-1.6	1.55	-2.0	-5	4	170	-1.6	1.75	-2.0	-5	4	169	-1.2	1.58	-1.0	-5	3
	DAY 50	172	-1.6	1.63	-2.0	-5	4	170	-1.6	1.91	-2.0	-5	4	169	-1.1	1.60	-1.0	-5	3
	DAY 57	172	-1.6	1.69	-2.0	-5	4	170	-1.7	1.77	-2.0	-5	4	169	-1.3	1.63	-1.0	-5	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	VISIT																		
	DAY 8	171	-0.7	1.24	-1.0	-4	2	169	-0.9	1.30	-1.0	-4	2	169	-0.6	1.14	0.0	-4	2
	DAY 15	172	-1.3	1.42	-1.0	-5	2	170	-1.2	1.56	-1.0	-5	4	169	-0.8	1.25	0.0	-4	2
	DAY 22	172	-1.5	1.49	-2.0	-5	2	170	-1.4	1.62	-1.0	-5	2	169	-1.1	1.47	-1.0	-4	2
	DAY 29	172	-1.5	1.55	-2.0	-5	2	170	-1.8	1.62	-2.0	-4	4	169	-1.1	1.50	-1.0	-4	2
	DAY 36	172	-1.7	1.63	-2.0	-5	3	170	-1.8	1.68	-2.0	-4	4	169	-1.1	1.52	-1.0	-4	2
	DAY 43	172	-1.7	1.61	-2.0	-5	2	170	-1.9	1.74	-2.0	-4	4	169	-1.1	1.50	-1.0	-4	2
	DAY 50	172	-1.7	1.55	-2.0	-5	2	170	-1.9	1.70	-2.0	-4	4	169	-1.1	1.56	-1.0	-4	2
	DAY 57	172	-1.9	1.60	-2.0	-5	2	170	-1.8	1.73	-2.0	-4	4	169	-1.3	1.56	-1.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	VISIT																		
	DAY 8	171	-0.7	1.14	0.0	-4	2	169	-0.7	1.31	-1.0	-4	4	169	-0.3	1.18	0.0	-4	2
	DAY 15	172	-1.2	1.32	-1.0	-4	2	170	-1.2	1.42	-1.0	-5	2	169	-0.6	1.26	0.0	-4	3
	DAY 22	172	-1.3	1.33	-1.0	-4	2	170	-1.4	1.49	-1.0	-5	3	169	-0.9	1.36	-1.0	-4	2
	DAY 29	172	-1.3	1.44	-2.0	-4	4	170	-1.5	1.49	-2.0	-4	3	169	-0.8	1.42	-1.0	-4	3
	DAY 36	172	-1.5	1.44	-2.0	-4	3	170	-1.6	1.57	-2.0	-4	4	169	-0.8	1.46	-1.0	-4	4
	DAY 43	172	-1.7	1.38	-2.0	-4	3	170	-1.5	1.56	-2.0	-5	4	169	-0.8	1.53	-1.0	-4	4
	DAY 50	172	-1.7	1.42	-2.0	-4	3	170	-1.5	1.59	-2.0	-5	4	169	-0.8	1.51	0.0	-4	3
	DAY 57	172	-1.7	1.44	-2.0	-4	2	170	-1.6	1.53	-2.0	-5	4	169	-0.9	1.44	-1.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	VISIT																		
	DAY 8	171	-0.4	1.04	0.0	-3	4	169	-0.5	1.02	0.0	-4	2	169	-0.2	1.03	0.0	-4	3
	DAY 15	172	-0.6	1.05	-1.0	-3	4	170	-0.7	1.10	-1.0	-4	2	169	-0.4	1.08	0.0	-4	3
	DAY 22	172	-0.7	1.08	-1.0	-4	3	170	-0.8	1.23	-1.0	-4	3	169	-0.5	1.12	0.0	-3	3
	DAY 29	172	-0.8	1.07	-1.0	-4	2	170	-0.8	1.29	-1.0	-4	4	169	-0.5	1.23	0.0	-4	4
	DAY 36	172	-0.8	1.09	-1.0	-4	2	170	-0.8	1.22	-1.0	-4	3	169	-0.4	1.25	0.0	-3	4
	DAY 43	172	-0.9	1.05	-1.0	-4	2	170	-0.8	1.23	-1.0	-4	2	169	-0.5	1.22	0.0	-4	3
	DAY 50	172	-0.9	1.05	-1.0	-4	3	170	-0.8	1.24	-1.0	-4	3	169	-0.5	1.22	0.0	-4	3
	DAY 57	172	-0.9	1.04	-1.0	-4	2	170	-0.9	1.24	-1.0	-4	2	169	-0.5	1.23	-1.0	-4	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	VISIT																		
	DAY 8	171	-0.9	1.27	-1.0	-5	2	169	-0.9	1.32	-1.0	-4	2	169	-0.6	1.10	0.0	-6	2
	DAY 15	148	-1.4	1.35	-1.0	-4	2	148	-1.3	1.46	-1.0	-5	3	149	-1.0	1.30	-1.0	-4	2
	DAY 22	139	-1.6	1.28	-2.0	-5	1	133	-1.7	1.65	-2.0	-6	2	143	-1.2	1.44	-1.0	-4	2
	DAY 29	133	-1.7	1.35	-2.0	-5	1	127	-2.1	1.59	-2.0	-6	3	126	-1.3	1.40	-1.0	-5	2
	DAY 36	130	-2.0	1.39	-2.0	-6	1	113	-2.2	1.63	-2.0	-5	3	119	-1.4	1.45	-1.0	-4	2
	DAY 43	123	-2.0	1.34	-2.0	-6	1	107	-2.3	1.60	-2.0	-6	3	107	-1.4	1.38	-1.0	-4	1
	DAY 50	121	-2.1	1.42	-2.0	-6	1	101	-2.3	1.62	-2.0	-6	2	102	-1.5	1.57	-1.5	-4	1
	DAY 57	119	-2.2	1.37	-2.0	-5	1	97	-2.4	1.40	-2.0	-5	0	99	-1.5	1.55	-2.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	VISIT																		
	DAY 8	171	-1.0	1.32	-1.0	-5	3	169	-1.1	1.30	-1.0	-5	2	169	-0.7	1.22	0.0	-6	2
	DAY 15	148	-1.6	1.40	-1.0	-5	1	148	-1.7	1.39	-2.0	-5	1	149	-1.1	1.36	-1.0	-4	2
	DAY 22	139	-1.7	1.50	-2.0	-5	2	133	-2.1	1.45	-2.0	-6	1	143	-1.3	1.50	-1.0	-5	2
	DAY 29	133	-1.9	1.53	-2.0	-6	3	127	-2.5	1.44	-2.0	-6	1	126	-1.4	1.50	-1.0	-4	2
	DAY 36	130	-2.1	1.50	-2.0	-5	2	113	-2.3	1.53	-2.0	-5	2	119	-1.6	1.59	-2.0	-5	2
	DAY 43	123	-2.4	1.53	-3.0	-5	2	107	-2.5	1.51	-3.0	-5	1	107	-1.5	1.52	-2.0	-4	2
	DAY 50	121	-2.5	1.54	-3.0	-5	2	101	-2.6	1.46	-3.0	-6	1	102	-1.6	1.59	-2.0	-4	2
	DAY 57	119	-2.5	1.52	-3.0	-5	1	97	-2.8	1.43	-3.0	-5	2	99	-1.7	1.51	-2.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	VISIT																		
	DAY 8	171	-0.5	1.23	0.0	-3	4	169	-0.5	1.33	0.0	-5	3	169	-0.3	1.18	0.0	-4	3
	DAY 15	148	-0.9	1.36	-1.0	-5	3	148	-0.9	1.43	-1.0	-5	2	149	-0.6	1.16	0.0	-4	3
	DAY 22	139	-0.9	1.43	-1.0	-4	4	133	-1.1	1.57	-1.0	-5	3	143	-0.7	1.27	-1.0	-5	2
	DAY 29	133	-1.0	1.54	-1.0	-4	4	127	-1.5	1.55	-2.0	-4	5	126	-0.7	1.37	-1.0	-4	3
	DAY 36	130	-1.1	1.51	-1.0	-4	3	113	-1.5	1.64	-2.0	-5	2	119	-0.8	1.28	-1.0	-4	3
	DAY 43	123	-1.3	1.58	-1.0	-4	4	107	-1.6	1.66	-2.0	-5	3	107	-1.0	1.53	-1.0	-5	3
	DAY 50	121	-1.4	1.48	-1.0	-5	3	101	-1.5	1.71	-1.0	-5	3	102	-0.8	1.50	-1.0	-4	2
	DAY 57	119	-1.3	1.46	-1.0	-4	3	97	-1.7	1.64	-2.0	-5	2	99	-0.8	1.49	-1.0	-5	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
GENERATED: 12JUL2005 17:44:59 iceadmn3

Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	VISIT																		
	DAY 8	171	-2.4	1.78	-3.0	-6	2	169	-2.2	2.04	-2.0	-6	6	169	-0.7	1.56	0.0	-5	3
	DAY 15	148	-2.4	1.81	-3.0	-6	2	148	-2.2	2.04	-3.0	-6	4	149	-0.9	1.66	-1.0	-6	3
	DAY 22	139	-2.2	1.80	-2.0	-5	3	133	-2.4	1.91	-3.0	-5	5	143	-1.0	1.80	-1.0	-6	2
	DAY 29	133	-2.3	1.75	-2.0	-5	2	127	-2.7	1.89	-3.0	-6	5	126	-1.2	1.65	-1.0	-6	4
	DAY 36	130	-2.4	1.56	-2.0	-5	2	113	-2.8	1.62	-3.0	-6	1	119	-1.3	1.89	-1.0	-6	4
	DAY 43	123	-2.3	1.60	-2.0	-5	2	107	-2.8	1.67	-3.0	-6	2	107	-1.4	1.95	-1.0	-6	3
	DAY 50	121	-2.3	1.62	-3.0	-5	2	101	-2.7	1.68	-3.0	-6	2	102	-1.4	1.76	-1.0	-6	3
	DAY 57	119	-2.3	1.83	-3.0	-5	4	97	-2.8	1.67	-3.0	-6	2	99	-1.4	1.79	-1.0	-6	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	VISIT																		
	DAY 8	171	-0.7	1.40	0.0	-5	3	169	-0.6	1.44	0.0	-4	2	169	-0.5	1.52	0.0	-4	4
	DAY 15	148	-0.9	1.58	0.0	-5	3	148	-0.9	1.67	0.0	-5	3	149	-0.7	1.54	0.0	-4	4
	DAY 22	139	-0.9	1.51	-1.0	-5	2	133	-1.0	1.78	-1.0	-5	4	143	-0.6	1.63	0.0	-4	4
	DAY 29	133	-1.0	1.72	-1.0	-5	6	127	-1.1	1.63	-1.0	-5	3	126	-0.7	1.72	0.0	-4	3
	DAY 36	130	-1.2	1.66	-1.0	-5	3	113	-1.0	1.70	-1.0	-5	4	119	-0.8	1.80	-1.0	-4	4
	DAY 43	123	-1.2	1.59	-1.0	-5	3	107	-1.1	1.62	-1.0	-5	3	107	-0.9	1.83	0.0	-6	4
	DAY 50	121	-1.3	1.70	-1.0	-5	3	101	-1.1	1.77	-1.0	-5	3	102	-0.8	1.96	0.0	-6	5
	DAY 57	119	-1.2	1.63	-1.0	-5	3	97	-1.2	1.64	-1.0	-5	3	99	-1.0	1.92	-1.0	-6	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
GENERATED: 12JUL2005 17:44:59 iceadmn3

Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	VISIT																		
	DAY 8	171	-0.6	1.21	0.0	-4	3	169	-0.7	1.35	0.0	-5	4	169	-0.4	1.19	0.0	-5	3
	DAY 15	148	-1.1	1.22	-1.0	-4	2	148	-1.1	1.46	-1.0	-4	3	149	-0.7	1.29	-1.0	-5	3
	DAY 22	139	-1.3	1.37	-1.0	-4	2	133	-1.4	1.50	-1.0	-5	2	143	-0.7	1.25	-1.0	-4	2
	DAY 29	133	-1.5	1.40	-2.0	-4	3	127	-1.7	1.52	-2.0	-5	3	126	-1.1	1.46	-1.0	-5	4
	DAY 36	130	-1.7	1.44	-2.0	-5	3	113	-1.7	1.60	-2.0	-5	3	119	-1.2	1.32	-1.0	-5	2
	DAY 43	123	-1.9	1.29	-2.0	-4	1	107	-1.8	1.53	-2.0	-5	2	107	-1.2	1.53	-1.0	-5	2
	DAY 50	121	-1.9	1.43	-2.0	-4	2	101	-1.9	1.55	-2.0	-5	2	102	-1.2	1.56	-1.0	-5	2
	DAY 57	119	-1.8	1.56	-2.0	-5	4	97	-2.0	1.64	-2.0	-5	2	99	-1.4	1.56	-1.0	-5	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	VISIT																		
	DAY 8	171	-0.6	1.42	-1.0	-4	4	169	-0.5	1.55	0.0	-4	4	169	-0.6	1.23	0.0	-4	4
	DAY 15	148	-0.9	1.63	-1.0	-5	4	148	-1.2	1.45	-1.0	-5	2	149	-0.9	1.32	-1.0	-4	2
	DAY 22	139	-1.3	1.62	-1.0	-5	3	133	-1.4	1.66	-1.0	-5	4	143	-1.0	1.46	-1.0	-5	4
	DAY 29	133	-1.5	1.64	-2.0	-5	4	127	-1.9	1.75	-2.0	-5	3	126	-1.2	1.52	-1.0	-5	3
	DAY 36	130	-1.7	1.54	-2.0	-5	4	113	-1.8	1.73	-2.0	-5	3	119	-1.2	1.50	-1.0	-5	2
	DAY 43	123	-1.9	1.34	-2.0	-5	1	107	-2.0	1.68	-2.0	-5	4	107	-1.4	1.61	-1.0	-5	1
	DAY 50	121	-1.9	1.44	-2.0	-5	2	101	-2.0	1.88	-2.0	-5	4	102	-1.4	1.66	-1.0	-5	2
	DAY 57	119	-1.9	1.55	-2.0	-5	2	97	-2.1	1.64	-2.0	-5	2	99	-1.5	1.67	-1.0	-5	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	VISIT																		
	DAY 8	171	-0.7	1.24	-1.0	-4	2	169	-0.9	1.30	-1.0	-4	2	169	-0.6	1.14	0.0	-4	2
	DAY 15	148	-1.3	1.43	-1.0	-5	2	148	-1.2	1.62	-1.0	-5	4	149	-0.8	1.28	-1.0	-4	2
	DAY 22	139	-1.6	1.51	-2.0	-5	2	133	-1.6	1.57	-2.0	-5	2	143	-1.1	1.52	-1.0	-4	2
	DAY 29	133	-1.7	1.55	-2.0	-5	2	127	-2.2	1.50	-2.0	-4	4	126	-1.4	1.53	-1.0	-4	2
	DAY 36	130	-1.9	1.62	-2.0	-5	3	113	-2.2	1.51	-2.0	-4	2	119	-1.3	1.58	-1.0	-4	2
	DAY 43	123	-2.1	1.44	-2.0	-5	2	107	-2.4	1.53	-3.0	-4	2	107	-1.3	1.52	-1.0	-4	2
	DAY 50	121	-2.1	1.42	-2.0	-5	1	101	-2.4	1.46	-3.0	-4	2	102	-1.4	1.64	-1.0	-4	2
	DAY 57	119	-2.2	1.46	-2.0	-5	1	97	-2.4	1.53	-3.0	-4	2	99	-1.6	1.58	-2.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	VISIT																		
	DAY 8	171	-0.7	1.14	0.0	-4	2	169	-0.7	1.31	-1.0	-4	4	169	-0.3	1.18	0.0	-4	2
	DAY 15	148	-1.2	1.31	-1.0	-4	2	148	-1.2	1.45	-1.0	-5	2	149	-0.6	1.27	0.0	-4	3
	DAY 22	139	-1.3	1.28	-1.0	-4	2	133	-1.5	1.53	-1.0	-5	3	143	-1.0	1.37	-1.0	-4	2
	DAY 29	133	-1.4	1.42	-2.0	-4	4	127	-1.7	1.49	-2.0	-4	3	126	-1.0	1.46	-1.0	-4	3
	DAY 36	130	-1.6	1.41	-2.0	-4	3	113	-1.8	1.60	-2.0	-4	4	119	-1.0	1.55	-1.0	-4	4
	DAY 43	123	-1.9	1.23	-2.0	-4	2	107	-1.7	1.60	-2.0	-5	4	107	-1.0	1.64	-1.0	-4	4
	DAY 50	121	-1.8	1.37	-2.0	-4	3	101	-1.7	1.56	-2.0	-5	2	102	-1.0	1.60	-1.0	-4	3
	DAY 57	119	-1.9	1.39	-2.0	-4	2	97	-1.9	1.42	-2.0	-5	2	99	-1.0	1.50	-1.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.10.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	VISIT																		
	DAY 8	171	-0.4	1.04	0.0	-3	4	169	-0.5	1.02	0.0	-4	2	169	-0.2	1.03	0.0	-4	3
	DAY 15	148	-0.6	1.10	-1.0	-3	4	148	-0.7	1.10	-1.0	-4	2	149	-0.5	1.04	0.0	-4	2
	DAY 22	139	-0.7	1.15	-1.0	-4	3	133	-0.9	1.21	-1.0	-4	3	143	-0.6	1.08	0.0	-3	2
	DAY 29	133	-0.8	1.06	-1.0	-3	2	127	-1.0	1.30	-1.0	-4	4	126	-0.7	1.20	-1.0	-4	4
	DAY 36	130	-0.8	1.09	-1.0	-4	2	113	-0.9	1.11	-1.0	-4	3	119	-0.6	1.23	-1.0	-3	4
	DAY 43	123	-1.0	1.02	-1.0	-3	1	107	-0.9	1.17	-1.0	-4	2	107	-0.7	1.12	-1.0	-4	2
	DAY 50	121	-1.0	1.02	-1.0	-3	3	101	-0.9	1.18	-1.0	-4	3	102	-0.7	1.12	-1.0	-4	2
	DAY 57	119	-1.1	1.00	-1.0	-4	1	97	-1.1	1.14	-1.0	-4	2	99	-0.8	1.15	-1.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.11.1 MADRS Item 1 Score (Apparent Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.6	0.81	-0.9	1.27	-0.94	0.106	-1.15	-0.73	.
	Q600MG	169	3.6	0.92	-0.9	1.32	-0.94	0.107	-1.15	-0.73	.
	P	169	3.5	0.86	-0.6	1.10	-0.55	0.106	-0.76	-0.34	.
	Q300MG VS P	.	.	.	.	.	-0.38	0.130	-0.64	-0.13	0.003
	Q600MG VS P	.	.	.	.	.	-0.39	0.131	-0.64	-0.13	0.003
DAY 15	Q300MG	172	3.6	0.81	-1.3	1.34	-1.32	0.120	-1.56	-1.08	.
	Q600MG	170	3.6	0.92	-1.3	1.45	-1.29	0.121	-1.53	-1.05	.
	P	169	3.5	0.86	-0.9	1.29	-0.92	0.121	-1.16	-0.68	.
	Q300MG VS P	.	.	.	.	.	-0.41	0.143	-0.69	-0.13	0.005
	Q600MG VS P	.	.	.	.	.	-0.38	0.144	-0.66	-0.10	0.009
DAY 22	Q300MG	172	3.6	0.81	-1.5	1.31	-1.52	0.134	-1.79	-1.25	.
	Q600MG	170	3.6	0.92	-1.6	1.62	-1.57	0.135	-1.84	-1.30	.
	P	169	3.5	0.86	-1.1	1.41	-1.08	0.135	-1.35	-0.81	.
	Q300MG VS P	.	.	.	.	.	-0.44	0.151	-0.74	-0.15	0.004
	Q600MG VS P	.	.	.	.	.	-0.49	0.152	-0.79	-0.19	0.001
DAY 29	Q300MG	172	3.6	0.81	-1.6	1.38	-1.62	0.141	-1.90	-1.34	.
	Q600MG	170	3.6	0.92	-1.8	1.67	-1.83	0.142	-2.11	-1.54	.

(Continued)

Table 11.2.1.11.1 MADRS Item 1 Score (Apparent Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	3.5	0.86	-1.1	1.38	-1.12	0.142	-1.41	-0.84	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.154	-0.80	-0.20	0.001
	Q600MG VS P	.	.	.	.	.	-0.70	0.155	-1.01	-0.40	<.001
DAY 36	Q300MG	172	3.6	0.81	-1.8	1.44	-1.71	0.138	-1.98	-1.43	.
	Q600MG	170	3.6	0.92	-1.9	1.72	-1.78	0.139	-2.06	-1.50	.
	P	169	3.5	0.86	-1.2	1.43	-1.15	0.139	-1.43	-0.87	.
	Q300MG VS P	.	.	.	.	.	-0.56	0.160	-0.87	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.63	0.161	-0.95	-0.32	<.001
DAY 43	Q300MG	172	3.6	0.81	-1.8	1.42	-1.71	0.134	-1.98	-1.45	.
	Q600MG	170	3.6	0.92	-1.9	1.74	-1.85	0.135	-2.12	-1.59	.
	P	169	3.5	0.86	-1.2	1.39	-1.15	0.135	-1.41	-0.88	.
	Q300MG VS P	.	.	.	.	.	-0.57	0.159	-0.88	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.71	0.160	-1.02	-0.39	<.001
DAY 50	Q300MG	172	3.6	0.81	-1.9	1.50	-1.83	0.142	-2.12	-1.55	.
	Q600MG	170	3.6	0.92	-1.9	1.72	-1.88	0.143	-2.16	-1.59	.
	P	169	3.5	0.86	-1.2	1.52	-1.19	0.142	-1.47	-0.90	.
	Q300MG VS P	.	.	.	.	.	-0.65	0.165	-0.97	-0.32	<.001

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS236.SAS
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Table 11.2.1.11.1 MADRS Item 1 Score (Apparent Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.69	0.166	-1.02	-0.36	<.001
DAY 57	Q300MG	172	3.6	0.81	-1.9	1.48	-1.89	0.140	-2.16	-1.61	.
	Q600MG	170	3.6	0.92	-2.0	1.62	-1.98	0.141	-2.26	-1.70	.
	P	169	3.5	0.86	-1.3	1.51	-1.32	0.141	-1.60	-1.04	.
	Q300MG VS P	.	.	.	.	.	-0.57	0.162	-0.88	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.66	0.163	-0.98	-0.34	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS236.SAS
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Table 11.2.1.11.2 MADRS Item 2 Score (Reported Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.8	0.78	-1.0	1.32	-1.01	0.111	-1.23	-0.79	.
	Q600MG	169	3.9	0.80	-1.1	1.30	-1.11	0.112	-1.33	-0.89	.
	P	169	3.8	0.74	-0.7	1.22	-0.66	0.112	-0.88	-0.44	.
	Q300MG VS P	.	.	.	.	.	-0.35	0.137	-0.62	-0.09	0.010
	Q600MG VS P	.	.	.	.	.	-0.45	0.137	-0.72	-0.18	0.001
DAY 15	Q300MG	172	3.8	0.78	-1.5	1.40	-1.47	0.127	-1.72	-1.22	.
	Q600MG	170	3.9	0.80	-1.6	1.44	-1.52	0.128	-1.77	-1.27	.
	P	169	3.8	0.74	-1.0	1.33	-0.97	0.127	-1.23	-0.72	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.147	-0.78	-0.21	<.001
	Q600MG VS P	.	.	.	.	.	-0.54	0.148	-0.83	-0.25	<.001
DAY 22	Q300MG	172	3.8	0.78	-1.7	1.48	-1.65	0.136	-1.92	-1.38	.
	Q600MG	170	3.9	0.80	-1.8	1.53	-1.82	0.137	-2.09	-1.55	.
	P	169	3.8	0.74	-1.3	1.46	-1.23	0.136	-1.50	-0.96	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.158	-0.73	-0.11	0.008
	Q600MG VS P	.	.	.	.	.	-0.59	0.159	-0.90	-0.28	<.001
DAY 29	Q300MG	172	3.8	0.78	-1.8	1.53	-1.75	0.143	-2.04	-1.47	.
	Q600MG	170	3.9	0.80	-2.1	1.60	-2.09	0.144	-2.38	-1.81	.

(Continued)

Table 11.2.1.11.2 MADRS Item 2 Score (Reported Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	3.8	0.74	-1.3	1.49	-1.24	0.144	-1.53	-0.95	.
	Q300MG VS P	.	.	.	.	.	-0.51	0.162	-0.83	-0.20	0.002
	Q600MG VS P	.	.	.	.	.	-0.85	0.163	-1.17	-0.53	<.001
DAY 36	Q300MG	172	3.8	0.78	-1.9	1.53	-1.85	0.141	-2.13	-1.57	.
	Q600MG	170	3.9	0.80	-2.1	1.65	-1.98	0.142	-2.26	-1.70	.
	P	169	3.8	0.74	-1.3	1.57	-1.29	0.142	-1.58	-1.01	.
	Q300MG VS P	.	.	.	.	.	-0.55	0.167	-0.88	-0.23	<.001
	Q600MG VS P	.	.	.	.	.	-0.68	0.168	-1.01	-0.35	<.001
DAY 43	Q300MG	172	3.8	0.78	-2.1	1.59	-2.01	0.137	-2.28	-1.74	.
	Q600MG	170	3.9	0.80	-2.2	1.68	-2.08	0.137	-2.35	-1.81	.
	P	169	3.8	0.74	-1.3	1.51	-1.25	0.137	-1.53	-0.98	.
	Q300MG VS P	.	.	.	.	.	-0.76	0.170	-1.09	-0.42	<.001
	Q600MG VS P	.	.	.	.	.	-0.83	0.171	-1.16	-0.49	<.001
DAY 50	Q300MG	172	3.8	0.78	-2.1	1.62	-2.08	0.140	-2.36	-1.81	.
	Q600MG	170	3.9	0.80	-2.2	1.66	-2.17	0.141	-2.45	-1.89	.
	P	169	3.8	0.74	-1.4	1.57	-1.33	0.140	-1.61	-1.05	.
	Q300MG VS P	.	.	.	.	.	-0.75	0.172	-1.09	-0.42	<.001

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS237.SAS
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Table 11.2.1.11.2 MADRS Item 2 Score (Reported Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.84	0.173	-1.18	-0.50	<.001
DAY 57	Q300MG	172	3.8	0.78	-2.2	1.62	-2.13	0.140	-2.41	-1.85	.
	Q600MG	170	3.9	0.80	-2.3	1.67	-2.26	0.141	-2.54	-1.98	.
	P	169	3.8	0.74	-1.5	1.56	-1.46	0.141	-1.74	-1.18	.
	Q300MG VS P	.	.	.	.	.	-0.67	0.173	-1.01	-0.33	<.001
	Q600MG VS P	.	.	.	.	.	-0.80	0.174	-1.14	-0.45	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS237.SAS
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Table 11.2.1.11.3 MADRS Item 3 Score (Inner Tension) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.0	1.01	-0.5	1.23	-0.52	0.109	-0.73	-0.30	.
	Q600MG	169	3.0	1.11	-0.5	1.33	-0.56	0.109	-0.78	-0.34	.
	P	169	3.1	0.96	-0.3	1.18	-0.35	0.109	-0.56	-0.13	.
	Q300MG VS P	.	.	.	.	.	-0.17	0.133	-0.43	0.09	0.205
	Q600MG VS P	.	.	.	.	.	-0.21	0.134	-0.48	0.05	0.112
DAY 15	Q300MG	172	3.0	1.01	-0.8	1.30	-0.85	0.112	-1.07	-0.62	.
	Q600MG	170	3.0	1.11	-0.8	1.44	-0.82	0.113	-1.04	-0.59	.
	P	169	3.1	0.96	-0.6	1.16	-0.57	0.113	-0.79	-0.35	.
	Q300MG VS P	.	.	.	.	.	-0.28	0.139	-0.55	-0.00	0.048
	Q600MG VS P	.	.	.	.	.	-0.25	0.140	-0.52	0.03	0.078
DAY 22	Q300MG	172	3.0	1.01	-0.9	1.36	-0.87	0.122	-1.11	-0.62	.
	Q600MG	170	3.0	1.11	-1.0	1.58	-1.01	0.123	-1.26	-0.77	.
	P	169	3.1	0.96	-0.7	1.27	-0.71	0.123	-0.96	-0.47	.
	Q300MG VS P	.	.	.	.	.	-0.15	0.151	-0.45	0.14	0.316
	Q600MG VS P	.	.	.	.	.	-0.30	0.152	-0.60	-0.00	0.050
DAY 29	Q300MG	172	3.0	1.01	-0.9	1.47	-0.94	0.130	-1.20	-0.68	.
	Q600MG	170	3.0	1.11	-1.3	1.55	-1.31	0.131	-1.57	-1.05	.

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS238.SAS
GENERATED: 12JUL2005 17:30:12 iceadmn3

Table 11.2.1.11.3 MADRS Item 3 Score (Inner Tension) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	3.1	0.96	-0.7	1.33	-0.67	0.131	-0.93	-0.41	.
	Q300MG VS P	.	.	.	.	.	-0.27	0.154	-0.58	0.03	0.077
	Q600MG VS P	.	.	.	.	.	-0.64	0.155	-0.95	-0.34	<.001
DAY 36	Q300MG	172	3.0	1.01	-1.0	1.46	-1.03	0.132	-1.29	-0.76	.
	Q600MG	170	3.0	1.11	-1.3	1.65	-1.26	0.133	-1.52	-1.00	.
	P	169	3.1	0.96	-0.7	1.32	-0.68	0.133	-0.95	-0.42	.
	Q300MG VS P	.	.	.	.	.	-0.34	0.158	-0.66	-0.03	0.029
	Q600MG VS P	.	.	.	.	.	-0.58	0.159	-0.89	-0.27	<.001
DAY 43	Q300MG	172	3.0	1.01	-1.1	1.50	-1.15	0.128	-1.40	-0.90	.
	Q600MG	170	3.0	1.11	-1.4	1.62	-1.35	0.129	-1.61	-1.10	.
	P	169	3.1	0.96	-0.8	1.49	-0.79	0.129	-1.05	-0.54	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.165	-0.68	-0.03	0.032
	Q600MG VS P	.	.	.	.	.	-0.56	0.166	-0.89	-0.23	<.001
DAY 50	Q300MG	172	3.0	1.01	-1.2	1.46	-1.21	0.120	-1.45	-0.98	.
	Q600MG	170	3.0	1.11	-1.3	1.64	-1.33	0.120	-1.57	-1.10	.
	P	169	3.1	0.96	-0.7	1.47	-0.71	0.120	-0.95	-0.48	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.164	-0.82	-0.18	0.002

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS238.SAS
GENERATED: 12JUL2005 17:30:12 iceadmn3

Table 11.2.1.11.3 MADRS Item 3 Score (Inner Tension) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.62	0.165	-0.94	-0.30	<.001
DAY 57	Q300MG	172	3.0	1.01	-1.2	1.44	-1.17	0.125	-1.42	-0.93	.
	Q600MG	170	3.0	1.11	-1.4	1.60	-1.43	0.126	-1.68	-1.18	.
	P	169	3.1	0.96	-0.7	1.45	-0.68	0.126	-0.93	-0.43	.
	Q300MG VS P	.	.	.	.	.	-0.49	0.161	-0.81	-0.18	0.002
	Q600MG VS P	.	.	.	.	.	-0.75	0.162	-1.06	-0.43	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS238.SAS
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Table 11.2.1.11.4 MADRS Item 4 Score (Reduced Sleep) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.6	1.17	-2.4	1.78	-2.50	0.155	-2.80	-2.19	.
	Q600MG	169	3.6	1.32	-2.2	2.04	-2.32	0.156	-2.63	-2.01	.
	P	169	3.6	1.17	-0.7	1.56	-0.76	0.156	-1.07	-0.45	.
	Q300MG VS P	.	.	.	.	.	-1.74	0.187	-2.10	-1.37	<.001
	Q600MG VS P	.	.	.	.	.	-1.56	0.188	-1.93	-1.19	<.001
DAY 15	Q300MG	172	3.6	1.17	-2.4	1.80	-2.42	0.155	-2.73	-2.12	.
	Q600MG	170	3.5	1.32	-2.2	1.98	-2.23	0.156	-2.54	-1.92	.
	P	169	3.6	1.17	-0.9	1.67	-0.88	0.155	-1.18	-0.57	.
	Q300MG VS P	.	.	.	.	.	-1.55	0.191	-1.92	-1.17	<.001
	Q600MG VS P	.	.	.	.	.	-1.36	0.191	-1.73	-0.98	<.001
DAY 22	Q300MG	172	3.6	1.17	-2.2	1.81	-2.31	0.152	-2.61	-2.01	.
	Q600MG	170	3.5	1.32	-2.2	1.97	-2.27	0.153	-2.57	-1.97	.
	P	169	3.6	1.17	-1.0	1.76	-1.01	0.152	-1.31	-0.71	.
	Q300MG VS P	.	.	.	.	.	-1.30	0.197	-1.69	-0.92	<.001
	Q600MG VS P	.	.	.	.	.	-1.26	0.197	-1.65	-0.87	<.001
DAY 29	Q300MG	172	3.6	1.17	-2.3	1.79	-2.41	0.146	-2.69	-2.12	.
	Q600MG	170	3.5	1.32	-2.4	2.01	-2.44	0.147	-2.73	-2.15	.

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS239.SAS
GENERATED: 12JUL2005 17:30:15 iceadmn3

Table 11.2.1.11.4 MADRS Item 4 Score (Reduced Sleep) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	3.6	1.17	-1.0	1.67	-1.08	0.146	-1.36	-0.79	.
	Q300MG VS P	.	.	.	.	.	-1.33	0.194	-1.71	-0.95	<.001
	Q600MG VS P	.	.	.	.	.	-1.37	0.195	-1.75	-0.98	<.001
DAY 36	Q300MG	172	3.6	1.17	-2.4	1.65	-2.44	0.143	-2.72	-2.15	.
	Q600MG	170	3.5	1.32	-2.4	1.83	-2.48	0.144	-2.77	-2.19	.
	P	169	3.6	1.17	-1.1	1.82	-1.16	0.144	-1.44	-0.88	.
	Q300MG VS P	.	.	.	.	.	-1.28	0.190	-1.65	-0.90	<.001
	Q600MG VS P	.	.	.	.	.	-1.32	0.191	-1.69	-0.95	<.001
DAY 43	Q300MG	172	3.6	1.17	-2.3	1.68	-2.33	0.149	-2.62	-2.04	.
	Q600MG	170	3.5	1.32	-2.4	1.84	-2.44	0.150	-2.74	-2.14	.
	P	169	3.6	1.17	-1.1	1.91	-1.16	0.150	-1.46	-0.87	.
	Q300MG VS P	.	.	.	.	.	-1.17	0.194	-1.55	-0.79	<.001
	Q600MG VS P	.	.	.	.	.	-1.28	0.195	-1.66	-0.89	<.001
DAY 50	Q300MG	172	3.6	1.17	-2.4	1.70	-2.39	0.156	-2.70	-2.08	.
	Q600MG	170	3.5	1.32	-2.4	1.84	-2.40	0.157	-2.71	-2.09	.
	P	169	3.6	1.17	-1.1	1.79	-1.10	0.157	-1.41	-0.79	.
	Q300MG VS P	.	.	.	.	.	-1.29	0.188	-1.66	-0.92	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS239.SAS
GENERATED: 12JUL2005 17:30:15 iceadmn3

Table 11.2.1.11.4 MADRS Item 4 Score (Reduced Sleep) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-1.30	0.189	-1.67	-0.93	<.001
DAY 57	Q300MG	172	3.6	1.17	-2.4	1.83	-2.41	0.155	-2.72	-2.10	.
	Q600MG	170	3.5	1.32	-2.4	1.83	-2.51	0.157	-2.82	-2.20	.
	P	169	3.6	1.17	-1.1	1.79	-1.13	0.156	-1.44	-0.82	.
	Q300MG VS P	.	.	.	.	.	-1.28	0.193	-1.66	-0.90	<.001
	Q600MG VS P	.	.	.	.	.	-1.38	0.194	-1.76	-1.00	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS239.SAS
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Table 11.2.1.11.5 MADRS Item 5 Score (Reduced Appetite) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	1.8	1.56	-0.7	1.40	-0.71	0.120	-0.95	-0.47	.
	Q600MG	169	1.7	1.60	-0.6	1.44	-0.68	0.121	-0.92	-0.44	.
	P	169	1.9	1.59	-0.5	1.52	-0.52	0.121	-0.76	-0.28	.
	Q300MG VS P	.	.	.	.	.	-0.19	0.156	-0.50	0.11	0.217
	Q600MG VS P	.	.	.	.	.	-0.16	0.156	-0.47	0.15	0.304
DAY 15	Q300MG	172	1.8	1.56	-0.9	1.53	-0.95	0.125	-1.19	-0.70	.
	Q600MG	170	1.7	1.60	-0.8	1.65	-0.92	0.126	-1.17	-0.67	.
	P	169	1.9	1.59	-0.7	1.56	-0.73	0.126	-0.98	-0.49	.
	Q300MG VS P	.	.	.	.	.	-0.21	0.165	-0.54	0.11	0.200
	Q600MG VS P	.	.	.	.	.	-0.18	0.166	-0.51	0.14	0.272
DAY 22	Q300MG	172	1.8	1.56	-0.9	1.49	-0.97	0.123	-1.21	-0.73	.
	Q600MG	170	1.7	1.60	-0.9	1.75	-0.92	0.124	-1.17	-0.68	.
	P	169	1.9	1.59	-0.5	1.59	-0.56	0.124	-0.81	-0.32	.
	Q300MG VS P	.	.	.	.	.	-0.41	0.167	-0.74	-0.08	0.015
	Q600MG VS P	.	.	.	.	.	-0.36	0.167	-0.69	-0.03	0.032
DAY 29	Q300MG	172	1.8	1.56	-0.9	1.66	-0.97	0.134	-1.24	-0.71	.
	Q600MG	170	1.7	1.60	-1.0	1.64	-1.03	0.135	-1.30	-0.77	.

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Table 11.2.1.11.5 MADRS Item 5 Score (Reduced Appetite) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	1.9	1.59	-0.7	1.69	-0.70	0.135	-0.97	-0.43	.
	Q300MG VS P	.	.	.	.	.	-0.28	0.172	-0.61	0.06	0.110
	Q600MG VS P	.	.	.	.	.	-0.33	0.173	-0.67	0.00	0.053
DAY 36	Q300MG	172	1.8	1.56	-1.1	1.58	-1.16	0.144	-1.45	-0.88	.
	Q600MG	170	1.7	1.60	-1.0	1.75	-1.06	0.145	-1.35	-0.78	.
	P	169	1.9	1.59	-0.7	1.74	-0.76	0.144	-1.04	-0.47	.
	Q300MG VS P	.	.	.	.	.	-0.41	0.175	-0.75	-0.06	0.021
	Q600MG VS P	.	.	.	.	.	-0.31	0.176	-0.65	0.04	0.082
DAY 43	Q300MG	172	1.8	1.56	-1.1	1.52	-1.19	0.138	-1.46	-0.92	.
	Q600MG	170	1.7	1.60	-1.0	1.71	-1.08	0.139	-1.36	-0.81	.
	P	169	1.9	1.59	-0.7	1.73	-0.79	0.138	-1.06	-0.51	.
	Q300MG VS P	.	.	.	.	.	-0.41	0.172	-0.74	-0.07	0.019
	Q600MG VS P	.	.	.	.	.	-0.30	0.173	-0.63	0.04	0.087
DAY 50	Q300MG	172	1.8	1.56	-1.1	1.62	-1.18	0.148	-1.47	-0.89	.
	Q600MG	170	1.7	1.60	-1.0	1.81	-1.13	0.149	-1.43	-0.84	.
	P	169	1.9	1.59	-0.7	1.82	-0.76	0.149	-1.06	-0.47	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.180	-0.77	-0.06	0.021

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS240.SAS
GENERATED: 12JUL2005 17:30:18 iceadmn3

Table 11.2.1.11.5 MADRS Item 5 Score (Reduced Appetite) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.37	0.181	-0.73	-0.01	0.041
DAY 57	Q300MG	172	1.8	1.56	-1.1	1.53	-1.20	0.146	-1.49	-0.91	.
	Q600MG	170	1.7	1.60	-1.1	1.74	-1.15	0.147	-1.44	-0.86	.
	P	169	1.9	1.59	-0.8	1.83	-0.86	0.147	-1.15	-0.57	.
	Q300MG VS P	.	.	.	.	.	-0.34	0.177	-0.69	0.01	0.056
	Q600MG VS P	.	.	.	.	.	-0.29	0.178	-0.64	0.06	0.107

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS240.SAS
GENERATED: 12JUL2005 17:30:18 iceadmn3

Table 11.2.1.11.6 MADRS Item 6 Score (Concentration Difficulties) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.3	0.99	-0.6	1.21	-0.59	0.106	-0.80	-0.38	.
	Q600MG	169	3.3	1.00	-0.7	1.35	-0.63	0.106	-0.84	-0.42	.
	P	169	3.2	1.01	-0.4	1.19	-0.38	0.106	-0.58	-0.17	.
	Q300MG VS P	.	.	.	.	.	-0.21	0.135	-0.48	0.05	0.117
	Q600MG VS P	.	.	.	.	.	-0.26	0.136	-0.53	0.01	0.057
DAY 15	Q300MG	172	3.3	0.99	-1.0	1.26	-1.04	0.107	-1.25	-0.83	.
	Q600MG	170	3.3	1.01	-1.0	1.54	-0.99	0.107	-1.20	-0.78	.
	P	169	3.2	1.01	-0.6	1.32	-0.64	0.107	-0.85	-0.43	.
	Q300MG VS P	.	.	.	.	.	-0.40	0.148	-0.69	-0.11	0.007
	Q600MG VS P	.	.	.	.	.	-0.36	0.149	-0.65	-0.06	0.017
DAY 22	Q300MG	172	3.3	0.99	-1.3	1.40	-1.27	0.121	-1.50	-1.03	.
	Q600MG	170	3.3	1.01	-1.3	1.62	-1.24	0.121	-1.48	-1.00	.
	P	169	3.2	1.01	-0.7	1.30	-0.64	0.121	-0.88	-0.40	.
	Q300MG VS P	.	.	.	.	.	-0.62	0.155	-0.93	-0.32	<.001
	Q600MG VS P	.	.	.	.	.	-0.59	0.156	-0.90	-0.29	<.001
DAY 29	Q300MG	172	3.3	0.99	-1.3	1.46	-1.35	0.135	-1.62	-1.08	.
	Q600MG	170	3.3	1.01	-1.5	1.68	-1.48	0.136	-1.75	-1.21	.

(Continued)

Table 11.2.1.11.6 MADRS Item 6 Score (Concentration Difficulties) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	3.2	1.01	-0.9	1.51	-0.88	0.136	-1.15	-0.61	.
	Q300MG VS P	.	.	.	.	.	-0.47	0.166	-0.79	-0.14	0.005
	Q600MG VS P	.	.	.	.	.	-0.60	0.167	-0.93	-0.27	<.001
DAY 36	Q300MG	172	3.3	0.99	-1.5	1.51	-1.50	0.122	-1.74	-1.26	.
	Q600MG	170	3.3	1.01	-1.4	1.74	-1.38	0.123	-1.62	-1.14	.
	P	169	3.2	1.01	-0.9	1.43	-0.88	0.123	-1.12	-0.64	.
	Q300MG VS P	.	.	.	.	.	-0.63	0.169	-0.96	-0.29	<.001
	Q600MG VS P	.	.	.	.	.	-0.50	0.170	-0.84	-0.17	0.003
DAY 43	Q300MG	172	3.3	0.99	-1.7	1.45	-1.63	0.125	-1.88	-1.39	.
	Q600MG	170	3.3	1.01	-1.4	1.71	-1.40	0.126	-1.65	-1.16	.
	P	169	3.2	1.01	-1.0	1.56	-0.93	0.125	-1.18	-0.69	.
	Q300MG VS P	.	.	.	.	.	-0.70	0.170	-1.03	-0.36	<.001
	Q600MG VS P	.	.	.	.	.	-0.47	0.171	-0.81	-0.13	0.006
DAY 50	Q300MG	172	3.3	0.99	-1.6	1.53	-1.61	0.132	-1.87	-1.35	.
	Q600MG	170	3.3	1.01	-1.5	1.72	-1.45	0.133	-1.71	-1.19	.
	P	169	3.2	1.01	-0.9	1.55	-0.89	0.132	-1.15	-0.63	.
	Q300MG VS P	.	.	.	.	.	-0.72	0.172	-1.06	-0.38	<.001

(Continued)

Table 11.2.1.11.6 MADRS Item 6 Score (Concentration Difficulties) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.56	0.173	-0.90	-0.22	0.001
DAY 57	Q300MG	172	3.3	0.99	-1.6	1.61	-1.60	0.139	-1.87	-1.33	.
	Q600MG	170	3.3	1.01	-1.5	1.77	-1.50	0.139	-1.77	-1.22	.
	P	169	3.2	1.01	-1.0	1.57	-0.99	0.139	-1.27	-0.72	.
	Q300MG VS P	.	.	.	.	.	-0.61	0.178	-0.96	-0.26	<.001
	Q600MG VS P	.	.	.	.	.	-0.51	0.179	-0.86	-0.16	0.005

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS241.SAS
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Table 11.2.1.11.7 MADRS Item 7 Score (Lassitude) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.4	1.08	-0.6	1.42	-0.63	0.115	-0.86	-0.41	.
	Q600MG	169	3.4	1.15	-0.5	1.55	-0.52	0.116	-0.75	-0.29	.
	P	169	3.4	1.00	-0.6	1.23	-0.54	0.115	-0.77	-0.32	.
	Q300MG VS P	.	.	.	.	.	-0.09	0.151	-0.39	0.20	0.542
	Q600MG VS P	.	.	.	.	.	0.02	0.152	-0.27	0.32	0.878
DAY 15	Q300MG	172	3.4	1.07	-0.9	1.62	-0.90	0.121	-1.14	-0.66	.
	Q600MG	170	3.4	1.15	-1.1	1.52	-1.04	0.122	-1.28	-0.80	.
	P	169	3.4	1.00	-0.8	1.30	-0.79	0.121	-1.03	-0.55	.
	Q300MG VS P	.	.	.	.	.	-0.12	0.160	-0.43	0.20	0.465
	Q600MG VS P	.	.	.	.	.	-0.25	0.160	-0.57	0.06	0.113
DAY 22	Q300MG	172	3.4	1.07	-1.3	1.62	-1.25	0.129	-1.50	-0.99	.
	Q600MG	170	3.4	1.15	-1.2	1.69	-1.11	0.130	-1.37	-0.85	.
	P	169	3.4	1.00	-0.9	1.42	-0.89	0.129	-1.14	-0.63	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.170	-0.70	-0.03	0.033
	Q600MG VS P	.	.	.	.	.	-0.22	0.170	-0.56	0.11	0.190
DAY 29	Q300MG	172	3.4	1.07	-1.3	1.67	-1.29	0.128	-1.54	-1.03	.
	Q600MG	170	3.4	1.15	-1.5	1.79	-1.46	0.129	-1.71	-1.20	.

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS242.SAS
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Table 11.2.1.11.7 MADRS Item 7 Score (Lassitude) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	3.4	1.00	-1.0	1.45	-0.96	0.129	-1.21	-0.70	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.175	-0.67	0.01	0.059
	Q600MG VS P	.	.	.	.	.	-0.50	0.176	-0.84	-0.15	0.005
DAY 36	Q300MG	172	3.4	1.07	-1.5	1.66	-1.45	0.130	-1.70	-1.19	.
	Q600MG	170	3.4	1.15	-1.5	1.77	-1.43	0.131	-1.69	-1.17	.
	P	169	3.4	1.00	-1.1	1.49	-1.01	0.130	-1.26	-0.75	.
	Q300MG VS P	.	.	.	.	.	-0.44	0.175	-0.78	-0.09	0.013
	Q600MG VS P	.	.	.	.	.	-0.42	0.176	-0.77	-0.08	0.017
DAY 43	Q300MG	172	3.4	1.07	-1.6	1.55	-1.51	0.126	-1.75	-1.26	.
	Q600MG	170	3.4	1.15	-1.6	1.75	-1.54	0.126	-1.79	-1.29	.
	P	169	3.4	1.00	-1.2	1.58	-1.15	0.126	-1.40	-0.90	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.175	-0.70	-0.01	0.041
	Q600MG VS P	.	.	.	.	.	-0.39	0.175	-0.73	-0.04	0.027
DAY 50	Q300MG	172	3.4	1.07	-1.6	1.63	-1.56	0.133	-1.82	-1.30	.
	Q600MG	170	3.4	1.15	-1.6	1.91	-1.53	0.133	-1.80	-1.27	.
	P	169	3.4	1.00	-1.1	1.60	-1.08	0.133	-1.34	-0.81	.
	Q300MG VS P	.	.	.	.	.	-0.49	0.184	-0.85	-0.13	0.008

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS242.SAS
GENERATED: 12JUL2005 17:30:24 iceadmn3

Table 11.2.1.11.7 MADRS Item 7 Score (Lassitude) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.46	0.185	-0.82	-0.10	0.013
DAY 57	Q300MG	172	3.4	1.07	-1.6	1.69	-1.52	0.131	-1.77	-1.26	.
	Q600MG	170	3.4	1.15	-1.7	1.77	-1.60	0.132	-1.86	-1.34	.
	P	169	3.4	1.00	-1.3	1.63	-1.20	0.132	-1.46	-0.94	.
	Q300MG VS P	.	.	.	.	.	-0.32	0.182	-0.68	0.04	0.080
	Q600MG VS P	.	.	.	.	.	-0.40	0.183	-0.76	-0.04	0.028

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS242.SAS
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Table 11.2.1.11.8 MADRS Item 8 Score (Inability to Feel) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.4	0.84	-0.7	1.24	-0.72	0.107	-0.93	-0.51	.
	Q600MG	169	3.5	0.90	-0.9	1.30	-0.85	0.108	-1.07	-0.64	.
	P	169	3.5	0.83	-0.6	1.14	-0.58	0.108	-0.79	-0.36	.
	Q300MG VS P	.	.	.	.	.	-0.14	0.132	-0.40	0.12	0.281
	Q600MG VS P	.	.	.	.	.	-0.28	0.133	-0.54	-0.02	0.038
DAY 15	Q300MG	172	3.4	0.84	-1.3	1.42	-1.24	0.122	-1.49	-1.00	.
	Q600MG	170	3.5	0.90	-1.2	1.56	-1.13	0.123	-1.37	-0.89	.
	P	169	3.5	0.83	-0.8	1.25	-0.78	0.122	-1.02	-0.54	.
	Q300MG VS P	.	.	.	.	.	-0.46	0.153	-0.76	-0.16	0.003
	Q600MG VS P	.	.	.	.	.	-0.35	0.153	-0.65	-0.05	0.023
DAY 22	Q300MG	172	3.4	0.84	-1.5	1.49	-1.47	0.127	-1.72	-1.21	.
	Q600MG	170	3.5	0.90	-1.4	1.62	-1.37	0.128	-1.62	-1.12	.
	P	169	3.5	0.83	-1.1	1.47	-1.03	0.127	-1.28	-0.77	.
	Q300MG VS P	.	.	.	.	.	-0.44	0.164	-0.76	-0.12	0.008
	Q600MG VS P	.	.	.	.	.	-0.35	0.165	-0.67	-0.02	0.037
DAY 29	Q300MG	172	3.4	0.84	-1.5	1.55	-1.48	0.129	-1.73	-1.22	.
	Q600MG	170	3.5	0.90	-1.8	1.62	-1.76	0.130	-2.02	-1.50	.

(Continued)

Table 11.2.1.11.8 MADRS Item 8 Score (Inability to Feel) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	3.5	0.83	-1.1	1.50	-1.05	0.130	-1.31	-0.79	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.167	-0.75	-0.10	0.011
	Q600MG VS P	.	.	.	.	.	-0.71	0.167	-1.04	-0.38	<.001
DAY 36	Q300MG	172	3.4	0.84	-1.7	1.63	-1.60	0.136	-1.87	-1.33	.
	Q600MG	170	3.5	0.90	-1.8	1.68	-1.69	0.137	-1.96	-1.42	.
	P	169	3.5	0.83	-1.1	1.52	-1.06	0.137	-1.33	-0.79	.
	Q300MG VS P	.	.	.	.	.	-0.54	0.172	-0.87	-0.20	0.002
	Q600MG VS P	.	.	.	.	.	-0.63	0.173	-0.97	-0.29	<.001
DAY 43	Q300MG	172	3.4	0.84	-1.7	1.61	-1.68	0.132	-1.95	-1.42	.
	Q600MG	170	3.5	0.90	-1.9	1.74	-1.79	0.133	-2.06	-1.53	.
	P	169	3.5	0.83	-1.1	1.50	-1.06	0.133	-1.32	-0.79	.
	Q300MG VS P	.	.	.	.	.	-0.63	0.174	-0.97	-0.29	<.001
	Q600MG VS P	.	.	.	.	.	-0.73	0.174	-1.08	-0.39	<.001
DAY 50	Q300MG	172	3.4	0.84	-1.7	1.55	-1.64	0.135	-1.91	-1.37	.
	Q600MG	170	3.5	0.90	-1.9	1.70	-1.80	0.136	-2.06	-1.53	.
	P	169	3.5	0.83	-1.1	1.56	-1.04	0.135	-1.31	-0.77	.
	Q300MG VS P	.	.	.	.	.	-0.60	0.172	-0.93	-0.26	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS243.SAS
GENERATED: 12JUL2005 17:30:27 iceadmn3

Table 11.2.1.11.8 MADRS Item 8 Score (Inability to Feel) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.75	0.172	-1.09	-0.42	<.001
DAY 57	Q300MG	172	3.4	0.84	-1.9	1.60	-1.84	0.142	-2.12	-1.56	.
	Q600MG	170	3.5	0.90	-1.8	1.73	-1.80	0.143	-2.08	-1.51	.
	P	169	3.5	0.83	-1.3	1.56	-1.25	0.143	-1.53	-0.97	.
	Q300MG VS P	.	.	.	.	.	-0.59	0.175	-0.93	-0.24	<.001
	Q600MG VS P	.	.	.	.	.	-0.55	0.176	-0.89	-0.20	0.002

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS243.SAS
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Table 11.2.1.11.9 MADRS Item 9 Score (Pessimistic Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	3.0	0.94	-0.7	1.14	-0.66	0.102	-0.86	-0.45	.
	Q600MG	169	2.9	1.02	-0.7	1.31	-0.71	0.103	-0.92	-0.51	.
	P	169	2.9	0.93	-0.3	1.18	-0.33	0.102	-0.53	-0.13	.
	Q300MG VS P	.	.	.	.	.	-0.32	0.131	-0.58	-0.07	0.014
	Q600MG VS P	.	.	.	.	.	-0.38	0.132	-0.64	-0.12	0.004
DAY 15	Q300MG	172	3.0	0.94	-1.2	1.32	-1.12	0.118	-1.35	-0.88	.
	Q600MG	170	3.0	1.02	-1.2	1.42	-1.09	0.119	-1.33	-0.86	.
	P	169	2.9	0.93	-0.6	1.26	-0.52	0.119	-0.75	-0.28	.
	Q300MG VS P	.	.	.	.	.	-0.60	0.143	-0.88	-0.32	<.001
	Q600MG VS P	.	.	.	.	.	-0.58	0.144	-0.86	-0.29	<.001
DAY 22	Q300MG	172	3.0	0.94	-1.3	1.33	-1.23	0.121	-1.47	-0.99	.
	Q600MG	170	3.0	1.02	-1.4	1.49	-1.39	0.122	-1.63	-1.15	.
	P	169	2.9	0.93	-0.9	1.36	-0.84	0.122	-1.08	-0.60	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.150	-0.69	-0.10	0.009
	Q600MG VS P	.	.	.	.	.	-0.55	0.151	-0.85	-0.26	<.001
DAY 29	Q300MG	172	3.0	0.94	-1.3	1.44	-1.29	0.135	-1.56	-1.02	.
	Q600MG	170	3.0	1.02	-1.5	1.49	-1.50	0.136	-1.77	-1.23	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS244.SAS
GENERATED: 12JUL2005 17:30:30 iceadmn3

Table 11.2.1.11.9 MADRS Item 9 Score (Pessimistic Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	2.9	0.93	-0.8	1.42	-0.81	0.136	-1.08	-0.54	.
	Q300MG VS P	.	.	.	.	.	-0.48	0.155	-0.79	-0.18	0.002
	Q600MG VS P	.	.	.	.	.	-0.69	0.155	-1.00	-0.38	<.001
DAY 36	Q300MG	172	3.0	0.94	-1.5	1.44	-1.47	0.134	-1.74	-1.20	.
	Q600MG	170	3.0	1.02	-1.6	1.57	-1.53	0.135	-1.80	-1.26	.
	P	169	2.9	0.93	-0.8	1.46	-0.81	0.135	-1.08	-0.55	.
	Q300MG VS P	.	.	.	.	.	-0.65	0.160	-0.97	-0.34	<.001
	Q600MG VS P	.	.	.	.	.	-0.71	0.161	-1.03	-0.40	<.001
DAY 43	Q300MG	172	3.0	0.94	-1.7	1.38	-1.64	0.139	-1.91	-1.36	.
	Q600MG	170	3.0	1.02	-1.5	1.56	-1.48	0.140	-1.75	-1.20	.
	P	169	2.9	0.93	-0.8	1.53	-0.83	0.140	-1.11	-0.55	.
	Q300MG VS P	.	.	.	.	.	-0.80	0.159	-1.11	-0.49	<.001
	Q600MG VS P	.	.	.	.	.	-0.64	0.160	-0.96	-0.33	<.001
DAY 50	Q300MG	172	3.0	0.94	-1.7	1.42	-1.66	0.140	-1.94	-1.38	.
	Q600MG	170	3.0	1.02	-1.5	1.59	-1.54	0.141	-1.82	-1.26	.
	P	169	2.9	0.93	-0.8	1.51	-0.80	0.141	-1.08	-0.52	.
	Q300MG VS P	.	.	.	.	.	-0.87	0.161	-1.18	-0.55	<.001

(Continued)

Table 11.2.1.11.9 MADRS Item 9 Score (Pessimistic Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.74	0.162	-1.06	-0.43	<.001
DAY 57	Q300MG	172	3.0	0.94	-1.7	1.44	-1.69	0.137	-1.96	-1.42	.
	Q600MG	170	3.0	1.02	-1.6	1.53	-1.59	0.138	-1.87	-1.32	.
	P	169	2.9	0.93	-0.9	1.44	-0.88	0.138	-1.16	-0.61	.
	Q300MG VS P	.	.	.	.	.	-0.81	0.156	-1.11	-0.50	<.001
	Q600MG VS P	.	.	.	.	.	-0.71	0.157	-1.02	-0.40	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS244.SAS
GENERATED: 12JUL2005 17:30:30 iceadmn3

Table 11.2.1.11.10 MADRS Item 10 Score (Suicidal Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	1.5	1.04	-0.4	1.04	-0.42	0.082	-0.58	-0.26	.
	Q600MG	169	1.5	1.07	-0.5	1.02	-0.49	0.082	-0.65	-0.33	.
	P	169	1.6	1.04	-0.2	1.03	-0.22	0.082	-0.38	-0.06	.
	Q300MG VS P	.	.	.	.	.	-0.20	0.109	-0.41	0.02	0.069
	Q600MG VS P	.	.	.	.	.	-0.27	0.109	-0.48	-0.05	0.015
DAY 15	Q300MG	172	1.5	1.05	-0.6	1.05	-0.59	0.087	-0.76	-0.42	.
	Q600MG	170	1.5	1.07	-0.7	1.10	-0.67	0.087	-0.84	-0.49	.
	P	169	1.6	1.04	-0.4	1.08	-0.38	0.087	-0.55	-0.21	.
	Q300MG VS P	.	.	.	.	.	-0.21	0.114	-0.43	0.02	0.074
	Q600MG VS P	.	.	.	.	.	-0.28	0.115	-0.51	-0.06	0.014
DAY 22	Q300MG	172	1.5	1.05	-0.7	1.08	-0.68	0.099	-0.88	-0.48	.
	Q600MG	170	1.5	1.07	-0.8	1.23	-0.79	0.100	-0.99	-0.59	.
	P	169	1.6	1.04	-0.5	1.12	-0.44	0.100	-0.63	-0.24	.
	Q300MG VS P	.	.	.	.	.	-0.24	0.120	-0.48	-0.01	0.041
	Q600MG VS P	.	.	.	.	.	-0.36	0.120	-0.59	-0.12	0.003
DAY 29	Q300MG	172	1.5	1.05	-0.8	1.07	-0.76	0.100	-0.96	-0.56	.
	Q600MG	170	1.5	1.07	-0.8	1.29	-0.82	0.101	-1.02	-0.62	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS245.SAS
GENERATED: 12JUL2005 17:30:33 iceadmn3

Table 11.2.1.11.10 MADRS Item 10 Score (Suicidal Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	1.6	1.04	-0.5	1.23	-0.45	0.101	-0.65	-0.25	.
	Q300MG VS P	.	.	.	.	.	-0.32	0.124	-0.56	-0.07	0.011
	Q600MG VS P	.	.	.	.	.	-0.37	0.125	-0.62	-0.13	0.003
DAY 36	Q300MG	172	1.5	1.05	-0.8	1.09	-0.73	0.095	-0.92	-0.54	.
	Q600MG	170	1.5	1.07	-0.8	1.22	-0.82	0.096	-1.01	-0.63	.
	P	169	1.6	1.04	-0.4	1.25	-0.38	0.096	-0.57	-0.19	.
	Q300MG VS P	.	.	.	.	.	-0.35	0.124	-0.60	-0.11	0.005
	Q600MG VS P	.	.	.	.	.	-0.44	0.125	-0.69	-0.20	<.001
DAY 43	Q300MG	172	1.5	1.05	-0.9	1.05	-0.83	0.100	-1.03	-0.63	.
	Q600MG	170	1.5	1.07	-0.8	1.23	-0.78	0.101	-0.99	-0.58	.
	P	169	1.6	1.04	-0.5	1.22	-0.44	0.101	-0.64	-0.24	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.121	-0.63	-0.15	0.001
	Q600MG VS P	.	.	.	.	.	-0.35	0.122	-0.59	-0.11	0.005
DAY 50	Q300MG	172	1.5	1.05	-0.9	1.05	-0.85	0.098	-1.05	-0.66	.
	Q600MG	170	1.5	1.07	-0.8	1.24	-0.80	0.099	-1.00	-0.61	.
	P	169	1.6	1.04	-0.5	1.22	-0.43	0.099	-0.62	-0.23	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.122	-0.66	-0.18	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS245.SAS
GENERATED: 12JUL2005 17:30:33 iceadmn3

Table 11.2.1.11.10 MADRS Item 10 Score (Suicidal Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.37	0.123	-0.62	-0.13	0.002
DAY 57	Q300MG	172	1.5	1.05	-0.9	1.04	-0.91	0.101	-1.11	-0.71	.
	Q600MG	170	1.5	1.07	-0.9	1.24	-0.88	0.101	-1.09	-0.68	.
	P	169	1.6	1.04	-0.5	1.23	-0.48	0.101	-0.68	-0.28	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.123	-0.67	-0.19	<.001
	Q600MG VS P	.	.	.	.	.	-0.41	0.124	-0.65	-0.16	0.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS245.SAS
GENERATED: 12JUL2005 17:30:33 iceadmn3

Table 11.2.1.12 MADRS Total Score Responder Summary (Criteria Reduction from Baseline)
Last Observation Carried Forward
Intent-to-Treat Population

RESPONSE RATE	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=172		N=170		N=169	
	N	%	N	%	N	%
>=70%	70	40.7	70	41.2	36	21.3
>=60%	86	50.0	89	52.4	46	27.2
>=50%	99	57.6	99	58.2	61	36.1
>=40%	114	66.3	116	68.2	73	43.2
>=30%	127	73.8	124	72.9	89	52.7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS212.SAS
GENERATED: 12JUL2005 17:44:42 iceadmn3

Table 11.2.1.13.1 MADRS Response (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	19	115	17	30	114	26	11	112	10	.	.	.	.
	BIPOLAR II	10	56	18	11	55	20	7	57	12	.	.	.	.
	ALL	29	171	17	41	169	24	18	169	11	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.092	1.59	0.92	2.76
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.001	2.28	1.36	3.80
DAY 15	BIPOLAR I	47	116	41	40	114	35	20	112	18	.	.	.	.
	BIPOLAR II	17	56	30	17	56	30	13	57	23	.	.	.	.
	ALL	64	172	37	57	170	34	33	169	20	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.91	1.32	2.74
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.004	1.72	1.18	2.49
DAY 22	BIPOLAR I	51	116	44	55	114	48	27	112	24	.	.	.	.
	BIPOLAR II	22	56	39	19	56	34	15	57	26	.	.	.	.
	ALL	73	172	42	74	170	44	42	169	25	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.71	1.25	2.34
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.75	1.28	2.40
DAY 29	BIPOLAR I	56	116	48	71	114	62	34	112	30	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226.SAS
GENERATED: 12JUL2005 17:29:40 iceadmn3

Table 11.2.1.13.1 MADRS Response (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 29	BIPOLAR II	27	56	48	27	56	48	18	57	32	.	.	.	.
	ALL	83	172	48	98	170	58	52	169	31	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.57	1.19	2.06
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.87	1.44	2.43
DAY 36	BIPOLAR I	66	116	57	64	114	56	33	112	29	.	.	.	.
	BIPOLAR II	22	56	39	24	56	43	19	57	33	.	.	.	.
	ALL	88	172	51	88	170	52	52	169	31	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.66	1.27	2.18
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.68	1.28	2.20
DAY 43	BIPOLAR I	66	116	57	73	114	64	31	112	28	.	.	.	.
	BIPOLAR II	26	56	46	26	56	46	21	57	37	.	.	.	.
	ALL	92	172	53	99	170	58	52	169	31	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.74	1.33	2.27
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.89	1.46	2.46
DAY 50	BIPOLAR I	68	116	59	69	114	61	33	112	29	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226.SAS
GENERATED: 12JUL2005 17:29:40 iceadmn3

Table 11.2.1.13.1 MADRS Response (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	27	56	48	26	56	46	19	57	33	.	.	.	.
	ALL	95	172	55	95	170	56	52	169	31	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.79	1.38	2.34
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.82	1.39	2.36
DAY 57	BIPOLAR I	72	116	62	73	114	64	37	112	33	.	.	.	.
	BIPOLAR II	27	56	48	26	56	46	24	57	42	.	.	.	.
	ALL	99	172	58	99	170	58	61	169	36	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.59	1.25	2.03
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.61	1.27	2.05

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226.SAS
GENERATED: 12JUL2005 17:29:40 iceadmn3

Table 11.2.1.13.2 MADRS Response (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P						
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	19	115	17	30	114	26	11	112	10	.	.	.	.
	BIPOLAR II	10	56	18	11	55	20	7	57	12	.	.	.	.
	ALL	29	171	17	41	169	24	18	169	11	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.092	1.59	0.92	2.76
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.001	2.28	1.36	3.80
DAY 15	BIPOLAR I	44	103	43	38	105	36	18	96	19	.	.	.	.
	BIPOLAR II	17	45	38	15	43	35	11	53	21	.	.	.	.
	ALL	61	148	41	53	148	36	29	149	19	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	2.12	1.45	3.10
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.002	1.84	1.24	2.73
DAY 22	BIPOLAR I	44	95	46	51	94	54	23	93	25	.	.	.	.
	BIPOLAR II	19	44	43	16	39	41	13	50	26	.	.	.	.
	ALL	63	139	45	67	133	50	36	143	25	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.80	1.28	2.52
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.99	1.43	2.77
DAY 29	BIPOLAR I	49	93	53	65	91	71	29	79	37	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS232.SAS
GENERATED: 12JUL2005 17:29:58 iceadmn3

Table 11.2.1.13.2 MADRS Response (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P						
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 29	BIPOLAR II	22	40	55	23	36	64	15	47	32	.	.	.	.
	ALL	71	133	53	88	127	69	44	126	35	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.003	1.52	1.14	2.03
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.96	1.50	2.56
DAY 36	BIPOLAR I	58	90	64	53	82	65	28	74	38	.	.	.	.
	BIPOLAR II	19	40	48	19	31	61	17	45	38	.	.	.	.
	ALL	77	130	59	72	113	64	45	119	38	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.001	1.55	1.18	2.04
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.68	1.28	2.21
DAY 43	BIPOLAR I	57	87	66	59	77	77	25	67	37	.	.	.	.
	BIPOLAR II	22	36	61	21	30	70	16	40	40	.	.	.	.
	ALL	79	123	64	80	107	75	41	107	38	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.68	1.27	2.21
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.95	1.49	2.55
DAY 50	BIPOLAR I	59	87	68	51	71	72	26	63	41	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS232.SAS
GENERATED: 12JUL2005 17:29:58 iceadmn3

Table 11.2.1.13.2 MADRS Response (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT												
		Q300MG			Q600MG			P				RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	20	34	59	20	30	67	15	39	38	.	.	.	.
	ALL	79	121	65	71	101	70	41	102	40	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.61	1.22	2.11
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.74	1.33	2.28
DAY 57	BIPOLAR I	59	83	71	52	68	76	25	58	43	.	.	.	.
	BIPOLAR II	22	36	61	20	29	69	21	41	51	.	.	.	.
	ALL	81	119	68	72	97	74	46	99	46	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.47	1.14	1.89
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.61	1.25	2.06

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS232.SAS
GENERATED: 12JUL2005 17:29:58 iceadmn3

Table 11.2.1.13.3 MADRS Response (CMH) at Final Assessment
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
EVENT	STRATA													
>=30% REDUCTION	BIPOLAR I	87	116	75	88	114	77	55	112	49	.	.	.	.
	BIPOLAR II	40	56	71	36	56	64	34	57	60	.	.	.	.
	ALL	127	172	74	124	170	73	89	169	53	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.40	1.19	1.66
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.39	1.17	1.64
>=40% REDUCTION	BIPOLAR I	79	116	68	84	114	74	41	112	37	.	.	.	.
	BIPOLAR II	35	56	63	32	56	57	32	57	56	.	.	.	.
	ALL	114	172	66	116	170	68	73	169	43	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.54	1.25	1.89
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.58	1.29	1.94
>=50% REDUCTION	BIPOLAR I	72	116	62	73	114	64	37	112	33	.	.	.	.
	BIPOLAR II	27	56	48	26	56	46	24	57	42	.	.	.	.
	ALL	99	172	58	99	170	58	61	169	36	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.59	1.25	2.03
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.61	1.27	2.05

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS227.SAS
GENERATED: 12JUL2005 17:29:44 iceadmn3

Table 11.2.1.13.4 MADRS Response (CMH) at Day 57
Observed Cases
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P						
EVENT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
>=30% REDUCTION	BIPOLAR I	71	83	86	59	68	87	32	58	55	.	.	.	.
	BIPOLAR II	28	36	78	23	29	79	27	41	66	.	.	.	.
	ALL	99	119	83	82	97	85	59	99	60	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.40	1.16	1.69
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.43	1.18	1.73
>=40% REDUCTION	BIPOLAR I	64	83	77	58	68	85	27	58	47	.	.	.	.
	BIPOLAR II	24	36	67	23	29	79	26	41	63	.	.	.	.
	ALL	88	119	74	81	97	84	53	99	54	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.39	1.12	1.74
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.59	1.28	1.96
>=50% REDUCTION	BIPOLAR I	59	83	71	52	68	76	25	58	43	.	.	.	.
	BIPOLAR II	22	36	61	20	29	69	21	41	51	.	.	.	.
	ALL	81	119	68	72	97	74	46	99	46	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.47	1.14	1.89
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.61	1.25	2.06

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS233.SAS
GENERATED: 12JUL2005 17:30:01 iceadmn3

Table 11.2.1.13.5 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Last Observation Carried Forward
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 8	Q300MG VS P		.	.	.	0.814
		BIPOLAR I	1.6822	0.8391	3.3723	.
		BIPOLAR II	1.4541	0.5955	3.5505	.
	Q600MG VS P		.	.	.	0.348
		BIPOLAR I	2.6794	1.4132	5.0802	.
		BIPOLAR II	1.6286	0.6808	3.8959	.
DAY 15	Q300MG VS P		.	.	.	0.154
		BIPOLAR I	2.2690	1.4405	3.5738	.
		BIPOLAR II	1.3310	0.7154	2.4765	.
	Q600MG VS P		.	.	.	0.326
		BIPOLAR I	1.9649	1.2291	3.1412	.
		BIPOLAR II	1.3310	0.7154	2.4765	.
DAY 22	Q300MG VS P		.	.	.	0.534
		BIPOLAR I	1.8238	1.2378	2.6870	.
		BIPOLAR II	1.4929	0.8675	2.5691	.
	Q600MG VS P		.	.	.	0.156
		BIPOLAR I	2.0013	1.3691	2.9254	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS228.SAS
GENERATED: 12JUL2005 17:29:46 iceadmn3

Table 11.2.1.13.5 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Last Observation Carried Forward
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 22	Q600MG VS P	BIPOLAR II	1.2893	0.7308	2.2746	.
DAY 29	Q300MG VS P		.	.	.	0.901
		BIPOLAR I	1.5903	1.1343	2.2295	.
		BIPOLAR II	1.5268	0.9555	2.4397	.
	Q600MG VS P		.	.	.	0.190
		BIPOLAR I	2.0516	1.4975	2.8106	.
		BIPOLAR II	1.5268	0.9555	2.4397	.
DAY 36	Q300MG VS P		.	.	.	0.063
		BIPOLAR I	1.9310	1.3919	2.6791	.
		BIPOLAR II	1.1786	0.7215	1.9252	.
	Q600MG VS P		.	.	.	0.136
		BIPOLAR I	1.9054	1.3708	2.6484	.
		BIPOLAR II	1.2857	0.7990	2.0688	.
DAY 43	Q300MG VS P		.	.	.	0.076
		BIPOLAR I	2.0556	1.4651	2.8842	.
		BIPOLAR II	1.2602	0.8106	1.9591	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS228.SAS
GENERATED: 12JUL2005 17:29:46 iceadmn3

Table 11.2.1.13.5 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Last Observation Carried Forward
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 43	Q600MG VS P		.	.	.	0.017
		BIPOLAR I	2.3135	1.6641	3.2163	.
		BIPOLAR II	1.2602	0.8106	1.9591	.
DAY 50	Q300MG VS P		.	.	.	0.210
		BIPOLAR I	1.9896	1.4378	2.7530	.
		BIPOLAR II	1.4464	0.9162	2.2834	.
	Q600MG VS P		.	.	.	0.117
		BIPOLAR I	2.0542	1.4878	2.8364	.
		BIPOLAR II	1.3929	0.8771	2.2120	.
DAY 57	Q300MG VS P		.	.	.	0.042
		BIPOLAR I	1.8788	1.3924	2.5352	.
		BIPOLAR II	1.1451	0.7616	1.7217	.
	Q600MG VS P		.	.	.	0.018
		BIPOLAR I	1.9384	1.4397	2.6097	.
		BIPOLAR II	1.1027	0.7285	1.6690	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS228.SAS
GENERATED: 12JUL2005 17:29:46 iceadmn3

Table 11.2.1.13.6 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Observed Cases
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 8	Q300MG VS P		.	.	.	0.814
		BIPOLAR I	1.6822	0.8391	3.3723	.
		BIPOLAR II	1.4541	0.5955	3.5505	.
	Q600MG VS P		.	.	.	0.348
		BIPOLAR I	2.6794	1.4132	5.0802	.
		BIPOLAR II	1.6286	0.6808	3.8959	.
DAY 15	Q300MG VS P		.	.	.	0.555
		BIPOLAR I	2.2783	1.4202	3.6550	.
		BIPOLAR II	1.8202	0.9540	3.4728	.
	Q600MG VS P		.	.	.	0.748
		BIPOLAR I	1.9302	1.1851	3.1436	.
		BIPOLAR II	1.6808	0.8635	3.2714	.
DAY 22	Q300MG VS P		.	.	.	0.722
		BIPOLAR I	1.8728	1.2361	2.8373	.
		BIPOLAR II	1.6608	0.9322	2.9590	.
	Q600MG VS P		.	.	.	0.280
		BIPOLAR I	2.1938	1.4702	3.2735	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS234.SAS
GENERATED: 12JUL2005 17:30:04 iceadmn3

Table 11.2.1.13.6 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Observed Cases
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 22	Q600MG VS P	BIPOLAR II	1.5779	0.8658	2.8758	.
DAY 29	Q300MG VS P		.	.	.	0.574
		BIPOLAR I	1.4353	1.0137	2.0322	.
		BIPOLAR II	1.7233	1.0422	2.8496	.
	Q600MG VS P		.	.	.	0.816
		BIPOLAR I	1.9458	1.4167	2.6726	.
		BIPOLAR II	2.0019	1.2332	3.2495	.
DAY 36	Q300MG VS P		.	.	.	0.206
		BIPOLAR I	1.7032	1.2246	2.3688	.
		BIPOLAR II	1.2574	0.7651	2.0663	.
	Q600MG VS P		.	.	.	0.809
		BIPOLAR I	1.7082	1.2243	2.3833	.
		BIPOLAR II	1.6224	1.0162	2.5902	.
DAY 43	Q300MG VS P		.	.	.	0.601
		BIPOLAR I	1.7559	1.2426	2.4812	.
		BIPOLAR II	1.5278	0.9641	2.4211	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS234.SAS
GENERATED: 12JUL2005 17:30:04 iceadmn3

Table 11.2.1.13.6 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Observed Cases
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 43	Q600MG VS P		.	.	.	0.473
		BIPOLAR I	2.0535	1.4704	2.8678	.
		BIPOLAR II	1.7500	1.1203	2.7336	.
DAY 50	Q300MG VS P		.	.	.	0.645
		BIPOLAR I	1.6432	1.1835	2.2816	.
		BIPOLAR II	1.5294	0.9402	2.4878	.
	Q600MG VS P		.	.	.	0.841
		BIPOLAR I	1.7405	1.2530	2.4177	.
		BIPOLAR II	1.7333	1.0825	2.7755	.
DAY 57	Q300MG VS P		.	.	.	0.186
		BIPOLAR I	1.6492	1.1904	2.2847	.
		BIPOLAR II	1.1931	0.8027	1.7735	.
	Q600MG VS P		.	.	.	0.269
		BIPOLAR I	1.7741	1.2835	2.4523	.
		BIPOLAR II	1.3465	0.9155	1.9804	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS234.SAS
GENERATED: 12JUL2005 17:30:04 iceadmn3

FIGURE 11.2.1.14 PERCENT OF PATIENTS RESPONDING (50% REDUCTION IN MADRS)

(LAST OBSERVATION CARRIED FORWARD- INTENT TO TREAT)

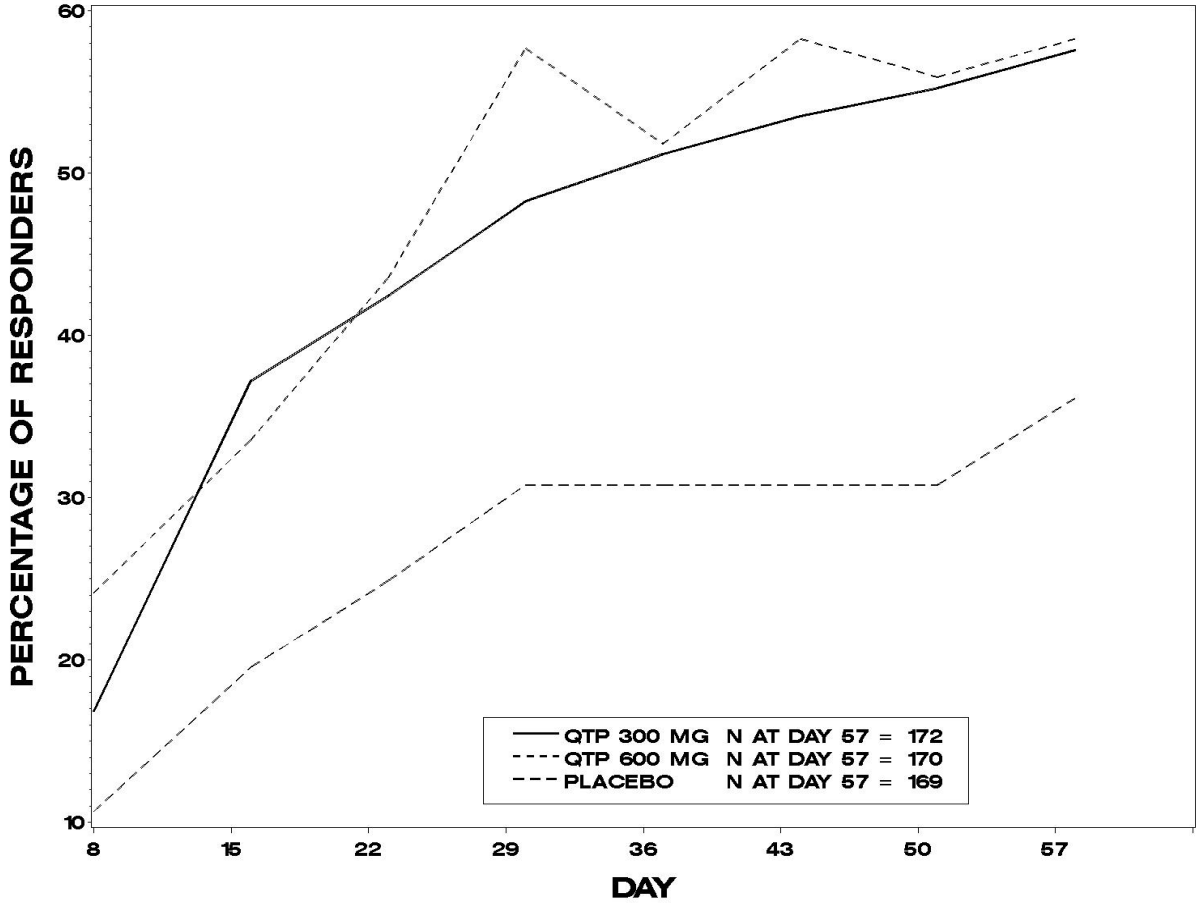

Table 11.2.1.15 MADRS Total Score Response of >=50% and Remission Rate
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		N	%	N	%	N	%
Response Rate >=50%	VISIT						
	DAY 8	29	16.9	41	24.1	18	10.7
	DAY 15	64	37.2	57	33.5	33	19.5
	DAY 22	73	42.4	74	43.5	42	24.9
	DAY 29	83	48.3	98	57.6	52	30.8
	DAY 36	88	51.2	88	51.8	52	30.8
	DAY 43	92	53.5	99	58.2	52	30.8
	DAY 50	95	55.2	95	55.9	52	30.8
	DAY 57	99	57.6	99	58.2	61	36.1
Remission Total Score <=12	DAY 8	18	10.5	23	13.5	13	7.7
	DAY 15	46	26.7	46	27.1	21	12.4
	DAY 22	60	34.9	63	37.1	30	17.8
	DAY 29	64	37.2	84	49.4	32	18.9
	DAY 36	71	41.3	82	48.2	42	24.9
	DAY 43	85	49.4	87	51.2	42	24.9

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS235.SAS
GENERATED: 12JUL2005 17:45:07 iceadmn3

Table 11.2.1.15 MADRS Total Score Response of >=50% and Remission Rate
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=172		N=170		N=169	
		N	%	N	%	N	%
Remission Total Score <=12	VISIT						
	DAY 50	89	51.7	85	50.0	44	26.0
	DAY 57	91	52.9	90	52.9	48	28.4

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS235.SAS
GENERATED: 12JUL2005 17:45:07 iceadmn3

Table 11.2.1.16.1 MADRS Remission Rate (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	15	115	13	18	114	16	8	112	7	.	.	.	.
	BIPOLAR II	3	56	5	5	55	9	5	57	9	.	.	.	.
	ALL	18	171	11	23	169	14	13	169	8	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.370	1.36	0.69	2.70
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.080	1.77	0.92	3.38
DAY 15	BIPOLAR I	33	116	28	34	114	30	13	112	12	.	.	.	.
	BIPOLAR II	13	56	23	12	56	21	8	57	14	.	.	.	.
	ALL	46	172	27	46	170	27	21	169	12	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	2.15	1.34	3.45
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.18	1.36	3.49
DAY 22	BIPOLAR I	43	116	37	48	114	42	19	112	17	.	.	.	.
	BIPOLAR II	17	56	30	15	56	27	11	57	19	.	.	.	.
	ALL	60	172	35	63	170	37	30	169	18	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.96	1.34	2.88
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.09	1.43	3.05
DAY 29	BIPOLAR I	46	116	40	60	114	53	20	112	18	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247.SAS
GENERATED: 12JUL2005 17:30:38 iceadmn3

Table 11.2.1.16.1 MADRS Remission Rate (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 29	BIPOLAR II	18	56	32	24	56	43	12	57	21	.	.	.	.
	ALL	64	172	37	84	170	49	32	169	19	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.96	1.36	2.84
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.61	1.84	3.69
DAY 36	BIPOLAR I	54	116	47	60	114	53	28	112	25	.	.	.	.
	BIPOLAR II	17	56	30	22	56	39	14	57	25	.	.	.	.
	ALL	71	172	41	82	170	48	42	169	25	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.001	1.66	1.21	2.28
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.94	1.43	2.63
DAY 43	BIPOLAR I	61	116	53	65	114	57	27	112	24	.	.	.	.
	BIPOLAR II	24	56	43	22	56	39	15	57	26	.	.	.	.
	ALL	85	172	49	87	170	51	42	169	25	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.99	1.47	2.69
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.06	1.52	2.78
DAY 50	BIPOLAR I	64	116	55	63	114	55	30	112	27	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247.SAS
GENERATED: 12JUL2005 17:30:38 iceadmn3

Table 11.2.1.16.1 MADRS Remission Rate (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 50	BIPOLAR II	25	56	45	22	56	39	14	57	25	.	.	.	.
	ALL	89	172	52	85	170	50	44	169	26	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.98	1.48	2.66
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.92	1.43	2.58
DAY 57	BIPOLAR I	67	116	58	67	114	59	30	112	27	.	.	.	.
	BIPOLAR II	24	56	43	23	56	41	18	57	32	.	.	.	.
	ALL	91	172	53	90	170	53	48	169	28	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.86	1.41	2.46
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.86	1.41	2.46

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247.SAS
GENERATED: 12JUL2005 17:30:38 iceadmn3

Table 11.2.1.16.2 MADRS Remission Rate (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA												
DAY 8	BIPOLAR I	15	115	13	18	114	16	8	112	7	.	.	.	.
	BIPOLAR II	3	56	5	5	55	9	5	57	9	.	.	.	.
	ALL	18	171	11	23	169	14	13	169	8	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.370	1.36	0.69	2.70
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.080	1.77	0.92	3.38
DAY 15	BIPOLAR I	30	103	29	32	105	30	12	96	13	.	.	.	.
	BIPOLAR II	13	45	29	10	43	23	8	53	15	.	.	.	.
	ALL	43	148	29	42	148	28	20	149	13	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	2.18	1.34	3.52
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.002	2.11	1.30	3.44
DAY 22	BIPOLAR I	37	95	39	44	94	47	16	93	17	.	.	.	.
	BIPOLAR II	15	44	34	13	39	33	11	50	22	.	.	.	.
	ALL	52	139	37	57	133	43	27	143	19	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.99	1.33	2.98
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.27	1.52	3.38
DAY 29	BIPOLAR I	39	93	42	54	91	59	17	79	22	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS246.SAS
GENERATED: 12JUL2005 17:30:35 iceadmn3

Table 11.2.1.16.2 MADRS Remission Rate (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 29	BIPOLAR II	14	40	35	21	36	58	12	47	26	.	.	.	.
	ALL	53	133	40	75	127	59	29	126	23	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.004	1.73	1.18	2.55
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.59	1.81	3.69
DAY 36	BIPOLAR I	46	90	51	49	82	60	24	74	32	.	.	.	.
	BIPOLAR II	14	40	35	18	31	58	14	45	31	.	.	.	.
	ALL	60	130	46	67	113	59	38	119	32	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.028	1.43	1.03	1.97
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.85	1.36	2.51
DAY 43	BIPOLAR I	52	87	60	51	77	66	22	67	33	.	.	.	.
	BIPOLAR II	20	36	56	18	30	60	13	40	33	.	.	.	.
	ALL	72	123	59	69	107	64	35	107	33	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.78	1.31	2.44
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.96	1.44	2.67
DAY 50	BIPOLAR I	55	87	63	46	71	65	24	63	38	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS246.SAS
GENERATED: 12JUL2005 17:30:35 iceadmn3

Table 11.2.1.16.2 MADRS Remission Rate (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT												
		Q300MG			Q600MG			P				RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	18	34	53	17	30	57	12	39	31	.	.	.	.
	ALL	73	121	60	63	101	62	36	102	35	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.68	1.24	2.26
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.74	1.29	2.36
DAY 57	BIPOLAR I	54	83	65	48	68	71	19	58	33	.	.	.	.
	BIPOLAR II	19	36	53	18	29	62	17	41	41	.	.	.	.
	ALL	73	119	61	66	97	68	36	99	36	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.69	1.24	2.30
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.89	1.39	2.56

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS246.SAS
GENERATED: 12JUL2005 17:30:35 iceadmn3

FIGURE 11.2.1.17 MADRS PERCENTAGE OF PATIENTS WITH REMISSION

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

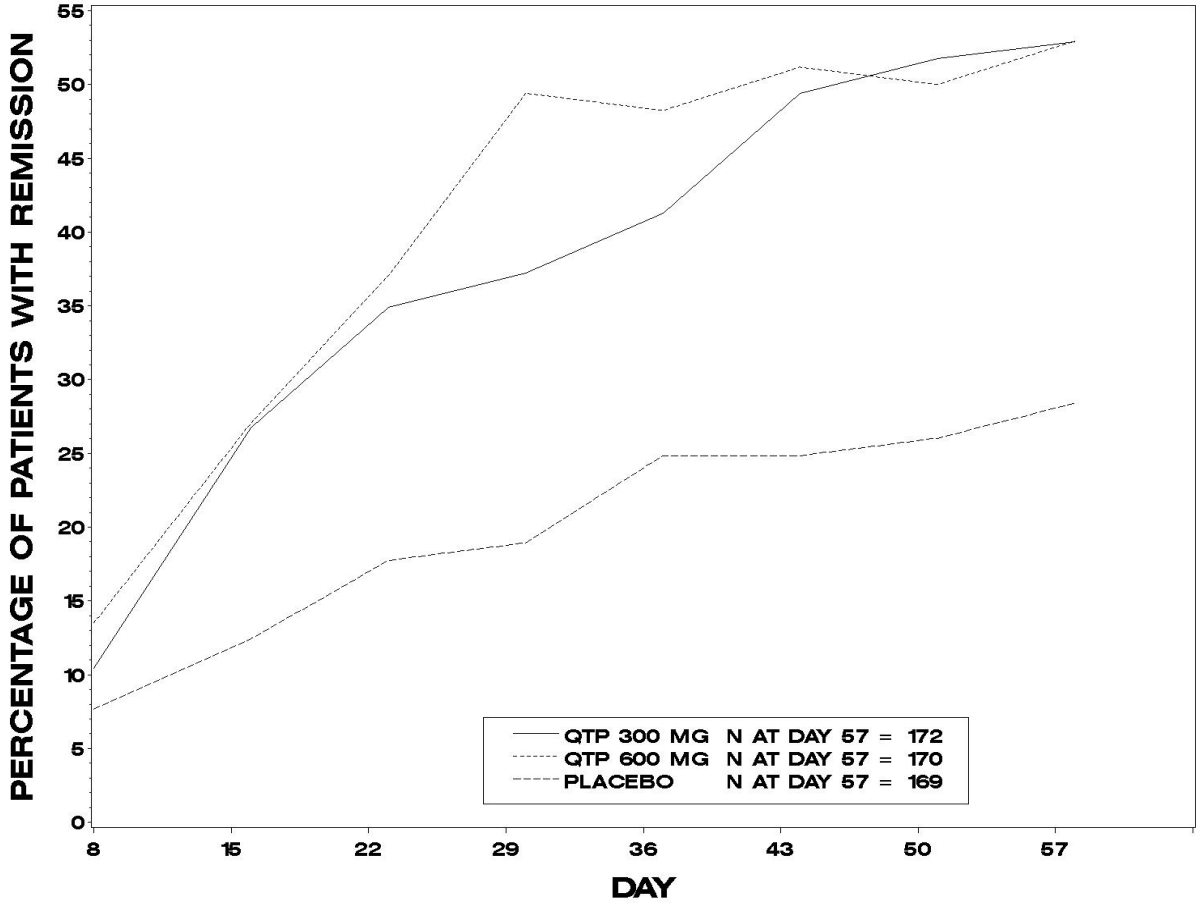

Table 11.2.2.1.1 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	VISIT																		
	SCREEN	172	24.3	3.05	23.5	20	35	170	24.8	3.61	24.0	20	34	169	24.7	3.37	24.0	20	35
	DAY 1	172	24.5	3.00	24.0	20	33	170	24.7	3.51	24.0	20	34	169	24.6	3.29	24.0	20	35
	DAY 8	171	16.8	5.39	17.0	1	30	169	16.9	5.63	16.0	6	33	169	20.2	5.99	21.0	2	35
	DAY 15	172	14.5	6.31	14.0	1	30	170	14.7	6.16	14.0	3	33	169	18.5	6.77	18.0	2	35
	DAY 22	172	13.5	6.85	13.0	0	30	170	13.3	6.72	13.0	0	33	169	17.6	7.32	18.0	1	35
	DAY 29	172	12.8	6.88	13.0	0	30	170	11.9	7.08	11.0	0	33	169	16.9	7.60	17.0	1	35
	DAY 36	172	12.0	7.28	11.0	0	30	170	11.7	7.52	11.0	0	33	169	16.6	7.95	17.0	0	35
	DAY 43	172	11.7	7.17	11.0	0	30	170	11.6	7.53	10.0	0	33	169	16.4	7.83	16.0	0	35
	DAY 50	172	11.3	7.09	10.0	0	30	170	11.2	7.64	10.0	0	33	169	16.5	8.24	17.0	0	35
	DAY 57	172	11.1	7.52	10.0	0	30	170	10.8	7.79	8.5	0	33	169	16.0	8.28	16.0	0	35
CHG FROM BASELINE	DAY 8	171	-7.8	5.24	-7.0	-22	7	169	-7.8	5.47	-8.0	-23	9	169	-4.4	5.24	-4.0	-20	5
	DAY 15	172	-10.0	5.95	-10.0	-22	7	170	-9.9	6.32	-10.0	-24	5	169	-6.1	6.13	-6.0	-22	6
	DAY 22	172	-11.0	6.36	-11.0	-26	7	170	-11.4	7.00	-12.0	-29	5	169	-7.0	6.76	-6.0	-23	8
	DAY 29	172	-11.8	6.62	-12.0	-26	7	170	-12.8	7.12	-13.0	-28	5	169	-7.7	7.06	-7.0	-26	8
	DAY 36	172	-12.6	6.80	-13.0	-26	7	170	-13.0	7.80	-13.0	-29	5	169	-8.0	7.48	-7.0	-29	8
	DAY 43	172	-12.8	6.65	-14.0	-26	7	170	-13.1	7.73	-13.0	-29	5	169	-8.2	7.21	-7.0	-26	8

(Continued)

Table 11.2.2.1.1 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	172	-13.3	6.72	-14.0	-26	7	170	-13.4	7.98	-14.0	-31	5	169	-8.1	7.72	-7.0	-27	8
	DAY 57	172	-13.4	6.91	-14.0	-27	7	170	-13.9	7.93	-14.0	-31	5	169	-8.6	7.70	-7.0	-27	8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD201.SAS
GENERATED: 12JUL2005 17:43:09 iceadmn3

Table 11.2.2.1.2 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	VISIT																		
	SCREEN	172	24.3	3.05	23.5	20	35	170	24.8	3.61	24.0	20	34	169	24.7	3.37	24.0	20	35
	DAY 1	172	24.5	3.00	24.0	20	33	170	24.7	3.51	24.0	20	34	169	24.6	3.29	24.0	20	35
	DAY 8	171	16.8	5.39	17.0	1	30	169	16.9	5.63	16.0	6	33	169	20.2	5.99	21.0	2	35
	DAY 15	148	13.9	6.12	14.0	1	29	148	14.4	5.96	14.0	3	29	149	18.0	6.43	18.0	2	32
	DAY 22	139	12.9	6.68	12.0	0	29	133	12.3	6.40	12.0	0	27	143	16.9	7.14	17.0	1	35
	DAY 29	133	11.6	6.31	12.0	0	28	127	10.2	6.28	9.0	0	27	126	15.2	7.01	15.0	1	33
	DAY 36	130	10.5	6.77	9.0	0	28	113	9.6	6.93	8.0	0	28	119	14.7	7.36	15.0	0	34
	DAY 43	123	9.8	6.37	10.0	0	27	107	9.1	6.53	7.0	0	26	107	14.6	7.36	15.0	0	33
	DAY 50	121	9.3	6.15	8.0	0	27	101	8.6	6.68	7.0	0	30	102	14.3	8.06	14.0	0	33
	DAY 57	119	9.4	6.80	8.0	0	27	97	7.7	6.54	6.0	0	25	99	13.9	7.95	13.0	0	31
CHG FROM BASELINE	DAY 8	171	-7.8	5.24	-7.0	-22	7	169	-7.8	5.47	-8.0	-23	9	169	-4.4	5.24	-4.0	-20	5
	DAY 15	148	-10.7	5.71	-11.0	-22	4	148	-10.3	6.26	-10.5	-24	4	149	-6.5	5.95	-6.0	-22	6
	DAY 22	139	-11.7	6.13	-12.0	-26	3	133	-12.6	6.73	-13.0	-29	3	143	-7.5	6.72	-7.0	-23	8
	DAY 29	133	-12.7	6.03	-12.0	-26	3	127	-14.5	6.47	-14.0	-28	-1	126	-9.2	6.73	-8.0	-26	5
	DAY 36	130	-13.8	6.24	-15.0	-26	2	113	-15.0	7.34	-16.0	-29	4	119	-9.6	7.35	-9.0	-29	7
	DAY 43	123	-14.4	5.85	-15.0	-26	0	107	-15.4	7.08	-17.0	-29	0	107	-9.8	7.02	-9.0	-24	3

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD200.SAS
GENERATED: 12JUL2005 17:43:07 iceadmn3

Table 11.2.2.1.2 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	121	-14.9	5.79	-16.0	-26	-2	101	-16.1	7.44	-17.0	-31	4	102	-10.1	7.85	-10.5	-27	6
	DAY 57	119	-15.0	6.06	-16.0	-27	3	97	-17.0	6.91	-18.0	-31	2	99	-10.6	7.73	-10.0	-27	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD200.SAS
GENERATED: 12JUL2005 17:43:07 iceadmn3

Table 11.2.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	24.5	3.00	-7.8	5.24	-8.01	0.473	-8.95	-7.07	.
	Q600MG	169	24.7	3.51	-7.8	5.47	-7.95	0.476	-8.89	-7.00	.
	P	169	24.6	3.29	-4.4	5.24	-4.64	0.475	-5.58	-3.70	.
	Q300MG VS P	.	.	.	.	.	-3.37	0.555	-4.46	-2.27	<.001
	Q600MG VS P	.	.	.	.	.	-3.30	0.558	-4.40	-2.21	<.001
DAY 15	Q300MG	172	24.5	3.00	-10.0	5.95	-10.16	0.570	-11.29	-9.02	.
	Q600MG	170	24.7	3.51	-9.9	6.32	-9.89	0.574	-11.04	-8.75	.
	P	169	24.6	3.29	-6.1	6.13	-6.23	0.574	-7.38	-5.09	.
	Q300MG VS P	.	.	.	.	.	-3.93	0.643	-5.19	-2.66	<.001
	Q600MG VS P	.	.	.	.	.	-3.66	0.647	-4.93	-2.39	<.001
DAY 22	Q300MG	172	24.5	3.00	-11.0	6.36	-11.08	0.578	-12.22	-9.93	.
	Q600MG	170	24.7	3.51	-11.4	7.00	-11.39	0.581	-12.54	-10.23	.
	P	169	24.6	3.29	-7.0	6.76	-7.03	0.580	-8.19	-5.88	.
	Q300MG VS P	.	.	.	.	.	-4.04	0.714	-5.44	-2.64	<.001
	Q600MG VS P	.	.	.	.	.	-4.35	0.717	-5.76	-2.94	<.001
DAY 29	Q300MG	172	24.5	3.00	-11.8	6.62	-11.77	0.645	-13.05	-10.49	.
	Q600MG	170	24.7	3.51	-12.8	7.12	-12.67	0.649	-13.96	-11.38	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204.SAS
GENERATED: 12JUL2005 17:29:07 iceadmn3

Table 11.2.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	24.6	3.29	-7.7	7.06	-7.67	0.649	-8.96	-6.38	.
	Q300MG VS P	.	.	.	.	.	-4.10	0.729	-5.53	-2.67	<.001
	Q600MG VS P	.	.	.	.	.	-5.00	0.733	-6.44	-3.56	<.001
DAY 36	Q300MG	172	24.5	3.00	-12.6	6.80	-12.45	0.649	-13.74	-11.16	.
	Q600MG	170	24.7	3.51	-13.0	7.80	-12.81	0.654	-14.11	-11.51	.
	P	169	24.6	3.29	-8.0	7.48	-7.93	0.653	-9.23	-6.64	.
	Q300MG VS P	.	.	.	.	.	-4.51	0.782	-6.05	-2.98	<.001
	Q600MG VS P	.	.	.	.	.	-4.87	0.786	-6.42	-3.33	<.001
DAY 43	Q300MG	172	24.5	3.00	-12.8	6.65	-12.59	0.638	-13.85	-11.32	.
	Q600MG	170	24.7	3.51	-13.1	7.73	-12.82	0.642	-14.10	-11.55	.
	P	169	24.6	3.29	-8.2	7.21	-8.02	0.641	-9.30	-6.75	.
	Q300MG VS P	.	.	.	.	.	-4.56	0.766	-6.07	-3.06	<.001
	Q600MG VS P	.	.	.	.	.	-4.80	0.770	-6.31	-3.29	<.001
DAY 50	Q300MG	172	24.5	3.00	-13.3	6.72	-13.21	0.649	-14.50	-11.92	.
	Q600MG	170	24.7	3.51	-13.4	7.98	-13.32	0.654	-14.62	-12.03	.
	P	169	24.6	3.29	-8.1	7.72	-8.06	0.652	-9.35	-6.77	.
	Q300MG VS P	.	.	.	.	.	-5.15	0.795	-6.71	-3.59	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204.SAS
GENERATED: 12JUL2005 17:29:07 iceadmn3

Table 11.2.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-5.27	0.799	-6.84	-3.70	<.001
DAY 57	Q300MG	172	24.5	3.00	-13.4	6.91	-13.38	0.664	-14.70	-12.07	.
	Q600MG	170	24.7	3.51	-13.9	7.93	-13.84	0.669	-15.16	-12.51	.
	P	169	24.6	3.29	-8.6	7.70	-8.54	0.667	-9.87	-7.22	.
	Q300MG VS P	.	.	.	.	.	-4.84	0.803	-6.42	-3.26	<.001
	Q600MG VS P	.	.	.	.	.	-5.29	0.807	-6.88	-3.71	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204.SAS
GENERATED: 12JUL2005 17:29:07 iceadmn3

Table 11.2.2.2.2 HAM-D Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	24.5	3.00	-7.8	5.24	-8.01	0.473	-8.95	-7.07	.
	Q600MG	169	24.7	3.51	-7.8	5.47	-7.95	0.476	-8.89	-7.00	.
	P	169	24.6	3.29	-4.4	5.24	-4.64	0.475	-5.58	-3.70	.
	Q300MG VS P	.	.	.	.	.	-3.37	0.555	-4.46	-2.27	<.001
	Q600MG VS P	.	.	.	.	.	-3.30	0.558	-4.40	-2.21	<.001
DAY 15	Q300MG	148	24.5	2.96	-10.7	5.71	-10.65	0.592	-11.83	-9.47	.
	Q600MG	148	24.7	3.63	-10.3	6.26	-10.23	0.594	-11.41	-9.04	.
	P	149	24.5	3.20	-6.5	5.95	-6.66	0.584	-7.82	-5.49	.
	Q300MG VS P	.	.	.	.	.	-3.99	0.667	-5.30	-2.68	<.001
	Q600MG VS P	.	.	.	.	.	-3.57	0.668	-4.88	-2.26	<.001
DAY 22	Q300MG	139	24.6	2.95	-11.7	6.13	-11.70	0.624	-12.94	-10.46	.
	Q600MG	133	24.8	3.68	-12.6	6.73	-12.53	0.639	-13.80	-11.26	.
	P	143	24.5	3.20	-7.5	6.72	-7.62	0.612	-8.84	-6.41	.
	Q300MG VS P	.	.	.	.	.	-4.07	0.760	-5.57	-2.58	<.001
	Q600MG VS P	.	.	.	.	.	-4.90	0.771	-6.42	-3.39	<.001
DAY 29	Q300MG	133	24.3	2.88	-12.7	6.03	-12.85	0.664	-14.17	-11.53	.
	Q600MG	127	24.7	3.73	-14.5	6.47	-14.33	0.678	-15.68	-12.98	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD210.SAS
GENERATED: 12JUL2005 17:29:19 iceadmn3

Table 11.2.2.2.2 HAM-D Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	126	24.4	3.12	-9.2	6.73	-9.22	0.672	-10.56	-7.88	.
	Q300MG VS P	.	.	.	.	.	-3.63	0.762	-5.13	-2.13	<.001
	Q600MG VS P	.	.	.	.	.	-5.11	0.775	-6.63	-3.59	<.001
DAY 36	Q300MG	130	24.3	2.87	-13.8	6.24	-13.74	0.684	-15.10	-12.38	.
	Q600MG	113	24.6	3.60	-15.0	7.34	-14.80	0.731	-16.25	-13.35	.
	P	119	24.4	3.11	-9.6	7.35	-9.63	0.699	-11.02	-8.24	.
	Q300MG VS P	.	.	.	.	.	-4.11	0.861	-5.80	-2.41	<.001
	Q600MG VS P	.	.	.	.	.	-5.17	0.896	-6.93	-3.41	<.001
DAY 43	Q300MG	123	24.3	2.74	-14.4	5.85	-14.07	0.691	-15.44	-12.70	.
	Q600MG	107	24.5	3.60	-15.4	7.08	-15.03	0.731	-16.48	-13.58	.
	P	107	24.3	3.01	-9.8	7.02	-9.59	0.720	-11.01	-8.16	.
	Q300MG VS P	.	.	.	.	.	-4.48	0.842	-6.14	-2.83	<.001
	Q600MG VS P	.	.	.	.	.	-5.44	0.873	-7.16	-3.72	<.001
DAY 50	Q300MG	121	24.3	2.78	-14.9	5.79	-14.91	0.706	-16.31	-13.50	.
	Q600MG	101	24.7	3.64	-16.1	7.44	-15.76	0.760	-17.27	-14.26	.
	P	102	24.5	3.14	-10.1	7.85	-10.06	0.744	-11.53	-8.58	.
	Q300MG VS P	.	.	.	.	.	-4.85	0.907	-6.64	-3.07	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD210.SAS
GENERATED: 12JUL2005 17:29:19 iceadmn3

Table 11.2.2.2.2 HAM-D Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-5.71	0.949	-7.57	-3.84	<.001
DAY 57	Q300MG	119	24.4	2.90	-15.0	6.06	-15.08	0.687	-16.44	-13.72	.
	Q600MG	97	24.7	3.66	-17.0	6.91	-16.93	0.754	-18.42	-15.44	.
	P	99	24.5	3.08	-10.6	7.73	-10.62	0.730	-12.06	-9.17	.
	Q300MG VS P	.	.	.	.	.	-4.46	0.927	-6.29	-2.64	<.001
	Q600MG VS P	.	.	.	.	.	-6.32	0.974	-8.23	-4.40	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD210.SAS
GENERATED: 12JUL2005 17:29:19 iceadmn3

Table 11.2.2.2.3 HAM-D Total Score Effect Size Change from Baseline
Last Observation Carried Forward
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.64	-0.86	-0.42
	Q600MG VS P	-0.62	-0.83	-0.40
DAY 15	Q300MG VS P	-0.65	-0.87	-0.43
	Q600MG VS P	-0.59	-0.81	-0.37
DAY 22	Q300MG VS P	-0.62	-0.83	-0.40
	Q600MG VS P	-0.63	-0.85	-0.41
DAY 29	Q300MG VS P	-0.60	-0.82	-0.38
	Q600MG VS P	-0.71	-0.92	-0.49
DAY 36	Q300MG VS P	-0.63	-0.85	-0.41
	Q600MG VS P	-0.64	-0.86	-0.42
DAY 43	Q300MG VS P	-0.66	-0.88	-0.44
	Q600MG VS P	-0.64	-0.86	-0.42
DAY 50	Q300MG VS P	-0.71	-0.93	-0.49
	Q600MG VS P	-0.67	-0.89	-0.45
DAY 57	Q300MG VS P	-0.66	-0.88	-0.44
	Q600MG VS P	-0.68	-0.90	-0.46

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD207.SAS
GENERATED: 12JUL2005 17:29:09 iceadmn3

Table 11.2.2.2.4 HAM-D Total Score Effect Size Change from Baseline
Observed Cases
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.64	-0.86	-0.42
	Q600MG VS P	-0.62	-0.83	-0.40
DAY 15	Q300MG VS P	-0.68	-0.92	-0.45
	Q600MG VS P	-0.58	-0.82	-0.35
DAY 22	Q300MG VS P	-0.63	-0.87	-0.39
	Q600MG VS P	-0.73	-0.97	-0.49
DAY 29	Q300MG VS P	-0.57	-0.82	-0.32
	Q600MG VS P	-0.77	-1.03	-0.52
DAY 36	Q300MG VS P	-0.60	-0.86	-0.35
	Q600MG VS P	-0.70	-0.97	-0.44
DAY 43	Q300MG VS P	-0.70	-0.97	-0.43
	Q600MG VS P	-0.77	-1.05	-0.49
DAY 50	Q300MG VS P	-0.71	-0.98	-0.44
	Q600MG VS P	-0.75	-1.03	-0.46
DAY 57	Q300MG VS P	-0.65	-0.92	-0.38
	Q600MG VS P	-0.86	-1.15	-0.57

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD211.SAS
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FIGURE 11.2.2.3.1 HAM-D TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

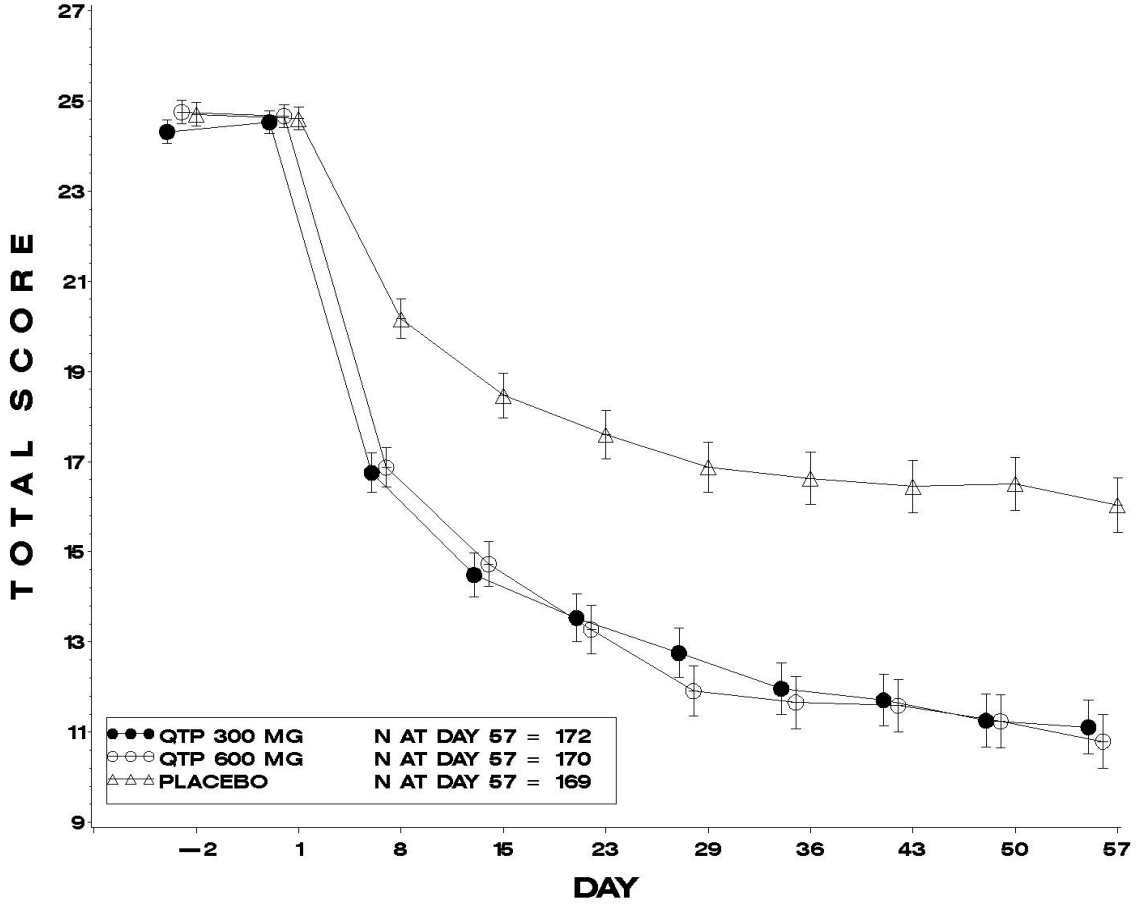

FIGURE 11.2.2.3.2 HAM-D TOTAL SCORE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

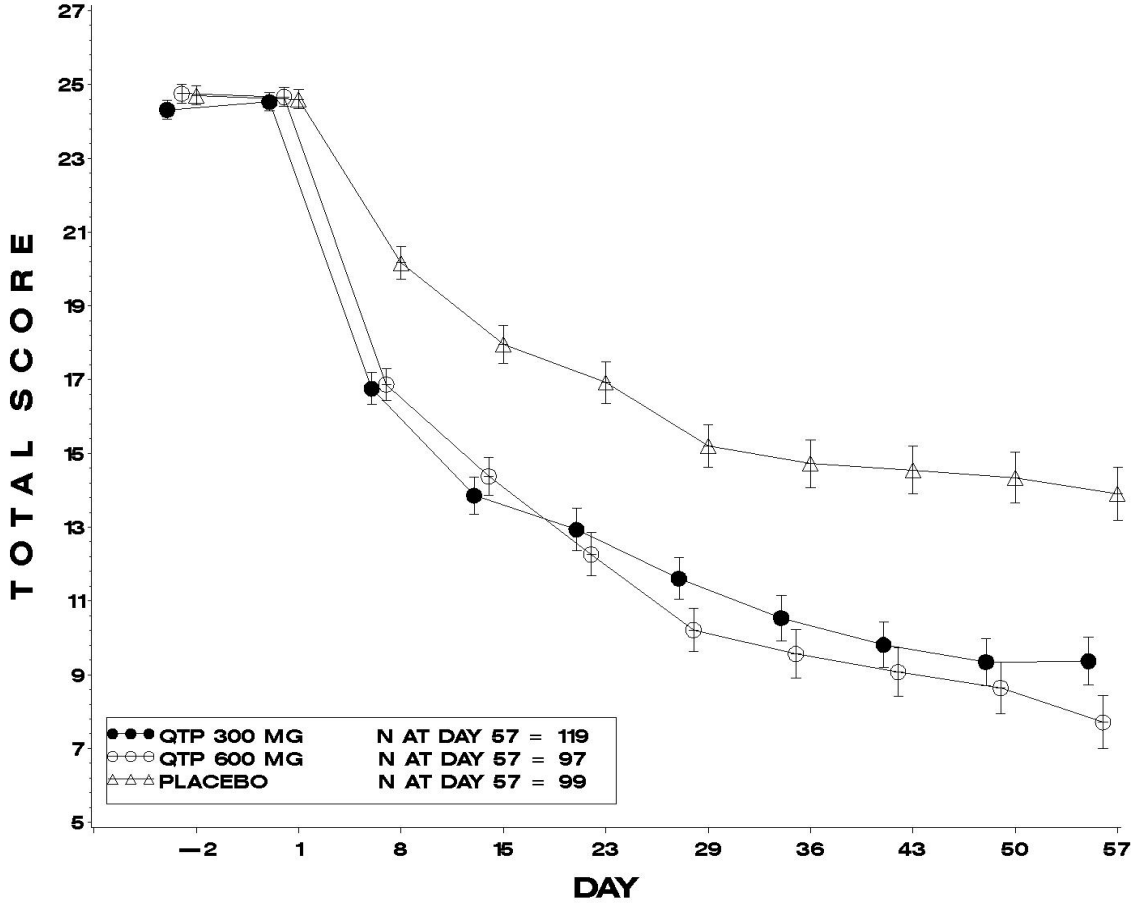

FIGURE 11.2.2.3.3 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN,SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

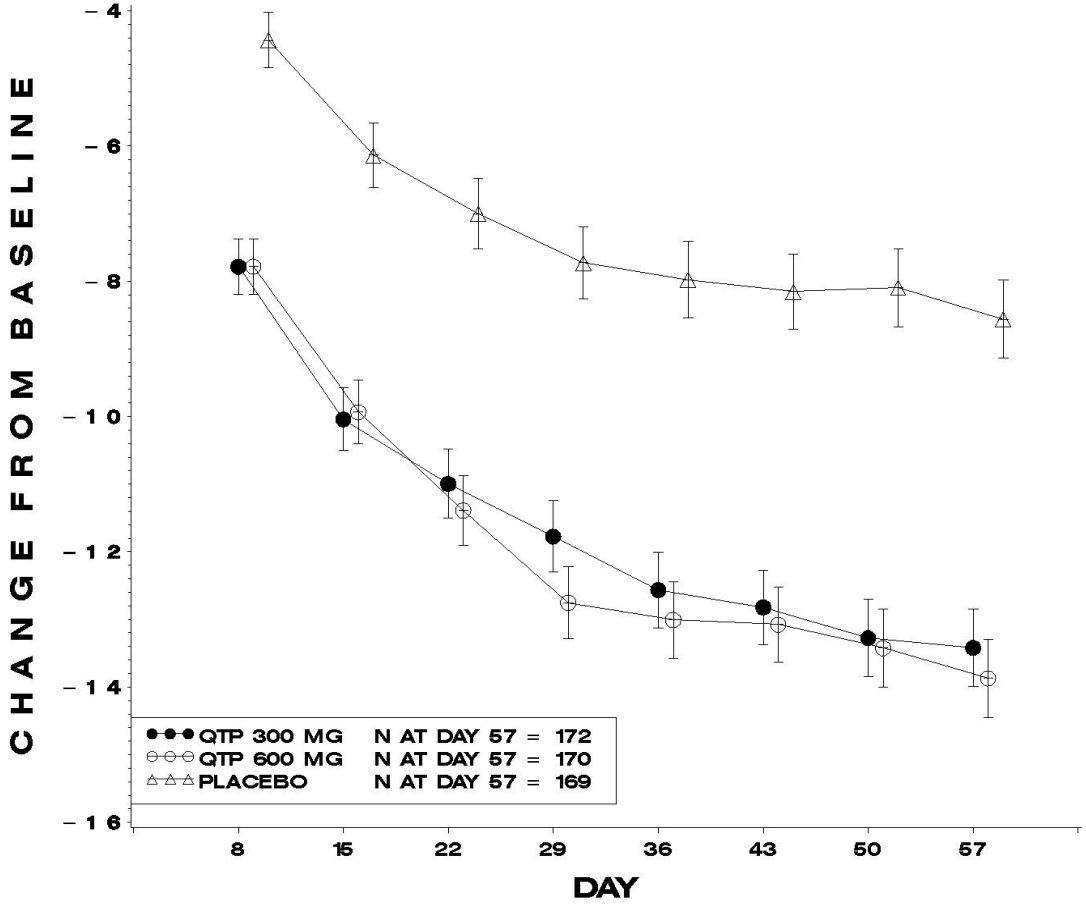

FIGURE 11.2.2.3.4 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

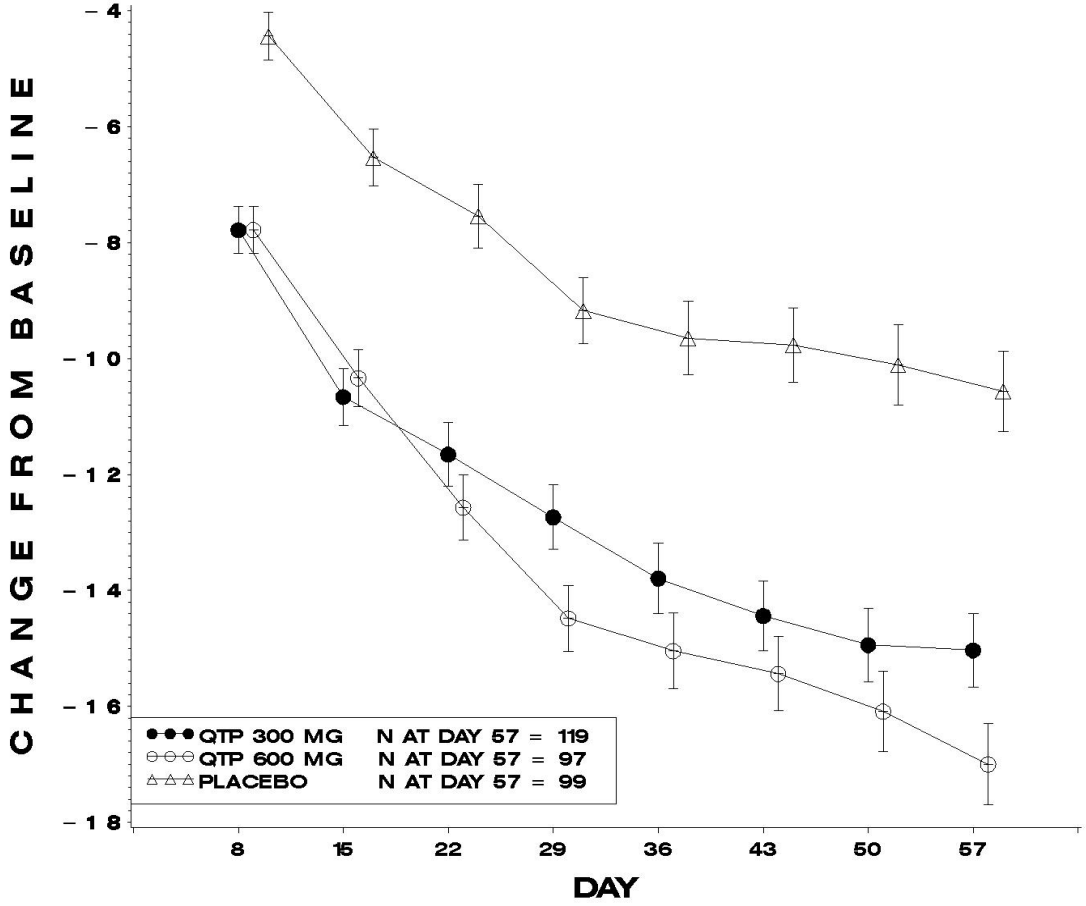

FIGURE 11.2.2.3.5 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

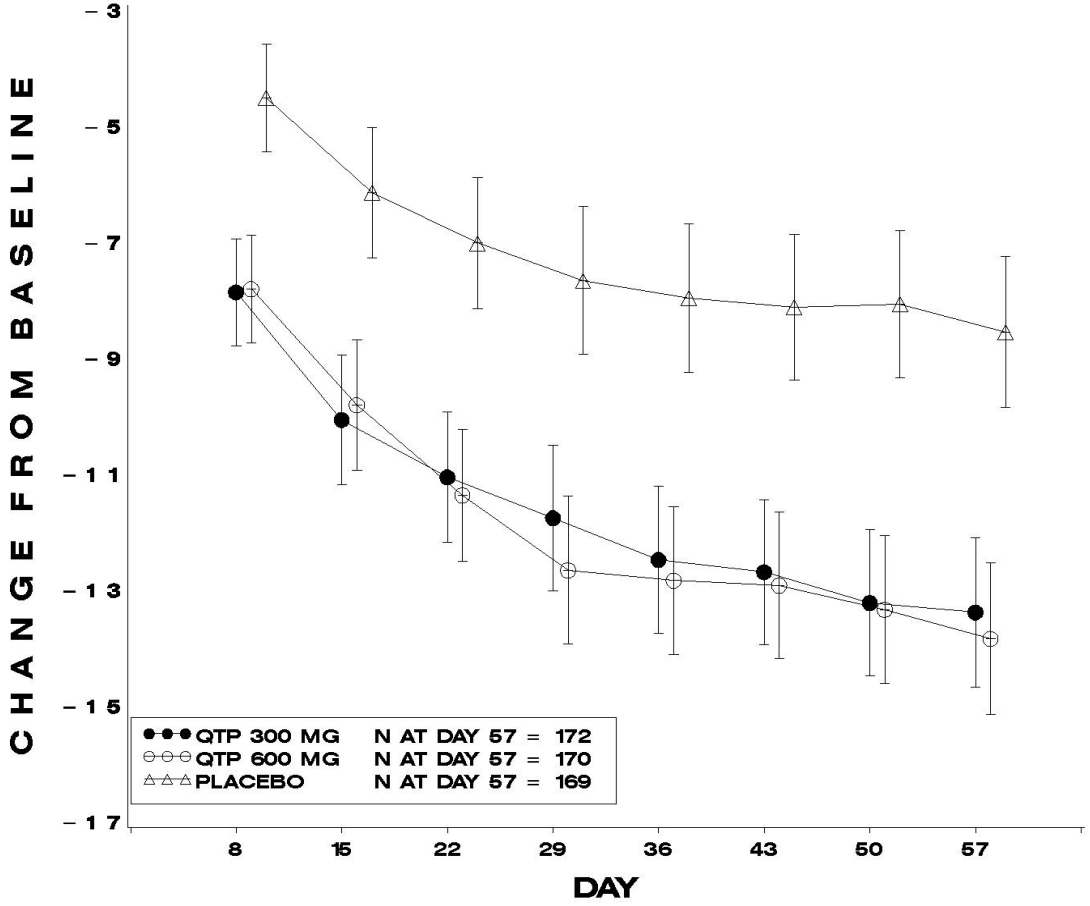

FIGURE 11.2.2.3.6 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(OBSERVED CASES - INTENT TO TREAT)

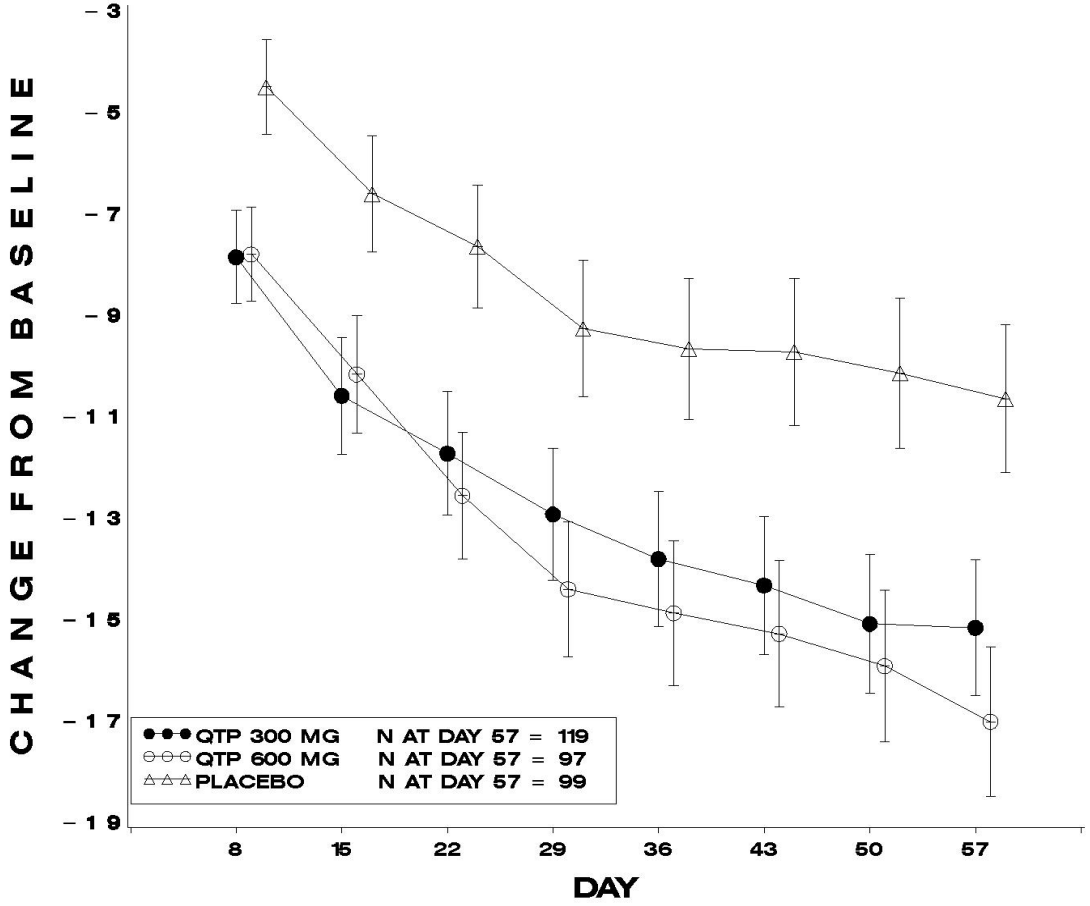

Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	VISIT																		
	SCREEN	116	24.4	3.09	24.0	20	35	114	24.8	3.58	24.5	20	34	112	25.0	3.61	25.0	20	35
	DAY 1	116	24.5	3.15	24.0	20	33	114	24.9	3.47	25.0	20	34	112	24.7	3.39	24.0	20	35
	DAY 8	115	17.0	5.77	17.0	1	30	114	17.1	5.94	16.5	6	33	112	20.7	6.00	21.5	2	35
	DAY 15	116	14.6	6.60	14.0	1	30	114	14.7	6.47	14.0	3	33	112	19.0	7.01	19.0	2	35
	DAY 22	116	13.3	7.19	12.0	0	30	114	13.1	7.14	13.0	0	33	112	18.2	7.56	18.0	2	35
	DAY 29	116	12.6	7.10	12.5	0	30	114	11.7	7.45	11.0	0	33	112	17.4	7.88	17.0	1	35
	DAY 36	116	11.4	7.63	10.5	0	30	114	11.4	7.86	10.5	0	33	112	17.3	8.25	17.0	0	35
	DAY 43	116	11.2	7.44	10.0	0	30	114	11.1	7.79	9.5	0	33	112	16.9	8.02	17.0	0	35
	DAY 50	116	10.9	7.53	9.0	0	30	114	11.0	7.93	9.0	0	33	112	17.0	8.53	18.0	0	35
	DAY 57	116	10.7	7.76	9.0	0	30	114	10.2	7.83	8.0	0	33	112	17.0	8.40	17.5	0	35
CHG FROM BASELINE	DAY 8	115	-7.5	5.46	-7.0	-22	7	114	-7.9	5.81	-8.0	-23	9	112	-4.0	5.25	-3.0	-20	5
	DAY 15	116	-9.9	6.05	-9.0	-22	7	114	-10.3	6.48	-11.0	-24	5	112	-5.7	6.50	-5.0	-22	6
	DAY 22	116	-11.2	6.62	-12.0	-26	7	114	-11.8	7.42	-12.5	-29	5	112	-6.5	6.85	-5.0	-23	8
	DAY 29	116	-11.9	6.77	-12.0	-26	7	114	-13.2	7.15	-14.0	-28	5	112	-7.3	7.36	-6.5	-26	8
	DAY 36	116	-13.0	7.06	-14.0	-26	7	114	-13.5	7.82	-15.0	-29	5	112	-7.4	7.83	-6.0	-29	8
	DAY 43	116	-13.3	6.88	-15.0	-26	7	114	-13.8	7.67	-15.0	-29	5	112	-7.7	7.49	-7.0	-24	8

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD203.SAS
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Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	116	-13.5	7.07	-14.5	-26	7	114	-14.0	7.99	-15.0	-31	5	112	-7.6	8.08	-6.0	-25	8
	DAY 57	116	-13.8	7.10	-15.0	-27	7	114	-14.7	7.73	-16.0	-31	5	112	-7.7	7.83	-6.0	-27	8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD203.SAS
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Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	VISIT																		
	SCREEN	56	24.1	2.98	23.0	20	33	56	24.6	3.69	24.0	20	34	57	24.1	2.79	24.0	20	34
	DAY 1	56	24.7	2.67	24.0	20	30	56	24.1	3.55	23.0	20	33	57	24.5	3.11	24.0	20	31
	DAY 8	56	16.2	4.52	16.0	7	24	55	16.4	4.96	16.0	6	28	57	19.1	5.87	20.0	4	32
	DAY 15	56	14.4	5.73	14.0	4	25	56	14.8	5.53	14.0	5	29	57	17.4	6.20	18.0	4	32
	DAY 22	56	14.1	6.13	14.0	3	29	56	13.6	5.81	13.0	2	25	57	16.4	6.71	17.0	1	30
	DAY 29	56	13.1	6.46	13.0	0	28	56	12.3	6.31	12.0	0	25	57	15.8	6.95	16.0	2	33
	DAY 36	56	13.0	6.40	13.0	2	28	56	12.1	6.81	12.0	0	25	57	15.4	7.21	15.0	2	34
	DAY 43	56	12.8	6.51	13.0	1	27	56	12.5	6.95	12.0	1	25	57	15.5	7.42	15.0	2	33
	DAY 50	56	11.9	6.11	12.5	1	24	56	11.8	7.05	11.0	0	26	57	15.5	7.58	15.0	1	33
	DAY 57	56	12.0	6.97	12.0	1	27	56	11.9	7.65	12.0	0	25	57	14.2	7.80	13.0	1	33
CHG FROM BASELINE	DAY 8	56	-8.4	4.74	-8.0	-19	1	55	-7.6	4.74	-8.0	-18	2	57	-5.4	5.14	-5.0	-17	3
	DAY 15	56	-10.3	5.80	-10.0	-22	4	56	-9.3	6.00	-9.5	-23	3	57	-7.1	5.26	-6.0	-19	3
	DAY 22	56	-10.5	5.82	-10.0	-20	2	56	-10.6	6.01	-11.5	-26	3	57	-8.1	6.51	-8.0	-23	5
	DAY 29	56	-11.5	6.37	-12.0	-25	3	56	-11.8	7.03	-13.0	-25	0	57	-8.6	6.39	-8.0	-23	5
	DAY 36	56	-11.6	6.20	-12.0	-25	2	56	-12.0	7.71	-11.5	-28	0	57	-9.1	6.68	-9.0	-26	7
	DAY 43	56	-11.9	6.10	-12.0	-24	0	56	-11.6	7.70	-11.5	-28	0	57	-9.0	6.61	-8.0	-26	4

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD203.SAS
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Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	56	-12.8	5.97	-12.0	-25	-1	56	-12.3	7.91	-12.0	-29	0	57	-9.0	6.94	-8.0	-27	4
	DAY 57	56	-12.6	6.49	-13.0	-26	3	56	-12.2	8.12	-12.5	-30	2	57	-10.2	7.20	-10.0	-26	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD203.SAS
GENERATED: 12JUL2005 17:43:14 iceadmn3

Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	VISIT																		
	SCREEN	116	24.4	3.09	24.0	20	35	114	24.8	3.58	24.5	20	34	112	25.0	3.61	25.0	20	35
	DAY 1	116	24.5	3.15	24.0	20	33	114	24.9	3.47	25.0	20	34	112	24.7	3.39	24.0	20	35
	DAY 8	115	17.0	5.77	17.0	1	30	114	17.1	5.94	16.5	6	33	112	20.7	6.00	21.5	2	35
	DAY 15	103	13.9	6.19	14.0	1	29	105	14.2	6.11	14.0	3	29	96	18.2	6.59	18.0	2	32
	DAY 22	95	12.4	6.77	11.0	0	29	94	11.9	6.52	12.0	0	27	93	17.4	7.26	18.0	2	35
	DAY 29	93	11.1	6.05	11.0	0	26	91	10.1	6.45	8.0	0	27	79	15.1	6.92	15.0	1	30
	DAY 36	90	9.7	6.63	8.0	0	24	82	9.6	7.12	8.0	0	28	74	14.9	7.46	16.0	0	32
	DAY 43	87	9.0	5.99	8.0	0	26	77	8.7	6.51	7.0	0	26	67	14.2	7.27	15.0	0	27
	DAY 50	87	8.7	5.99	7.0	0	27	71	8.4	6.64	6.0	0	30	63	14.2	8.35	14.0	0	29
	DAY 57	83	8.6	6.38	8.0	0	27	68	7.2	5.85	5.0	0	23	58	14.7	7.89	15.0	0	29
CHG FROM BASELINE	DAY 8	115	-7.5	5.46	-7.0	-22	7	114	-7.9	5.81	-8.0	-23	9	112	-4.0	5.25	-3.0	-20	5
	DAY 15	103	-10.5	5.58	-10.0	-22	3	105	-10.6	6.29	-11.0	-24	4	96	-6.3	6.30	-5.5	-22	6
	DAY 22	95	-12.1	6.14	-13.0	-26	3	94	-13.0	6.99	-14.0	-29	2	93	-7.2	6.69	-6.0	-23	8
	DAY 29	93	-13.0	5.75	-13.0	-26	1	91	-14.7	6.25	-14.0	-28	-1	79	-9.3	6.82	-8.0	-26	5
	DAY 36	90	-14.4	6.06	-16.0	-26	-1	82	-15.0	7.19	-16.0	-29	4	74	-9.5	7.68	-9.0	-29	4
	DAY 43	87	-15.0	5.64	-16.0	-26	-2	77	-15.8	6.75	-18.0	-29	0	67	-10.2	7.40	-9.0	-24	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD202.SAS
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Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG					QUETIAPINE 600 MG					PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	87	-15.3	5.84	-17.0	-26	-2	71	-16.3	7.15	-17.0	-31	4	63	-10.4	8.38	-10.0	-25	6
	DAY 57	83	-15.5	5.81	-16.0	-27	-1	68	-17.5	6.25	-19.0	-31	-2	58	-9.9	7.95	-9.0	-27	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD202.SAS
GENERATED: 12JUL2005 17:43:11 iceadmn3

Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	VISIT																		
	SCREEN	56	24.1	2.98	23.0	20	33	56	24.6	3.69	24.0	20	34	57	24.1	2.79	24.0	20	34
	DAY 1	56	24.7	2.67	24.0	20	30	56	24.1	3.55	23.0	20	33	57	24.5	3.11	24.0	20	31
	DAY 8	56	16.2	4.52	16.0	7	24	55	16.4	4.96	16.0	6	28	57	19.1	5.87	20.0	4	32
	DAY 15	45	13.7	6.02	13.0	4	25	43	14.8	5.61	14.0	5	29	53	17.5	6.17	18.0	4	32
	DAY 22	44	14.1	6.41	13.5	3	29	39	13.0	6.12	13.0	2	24	50	16.1	6.91	16.0	1	30
	DAY 29	40	12.8	6.79	12.5	0	28	36	10.5	5.92	9.5	0	23	47	15.3	7.23	16.0	2	33
	DAY 36	40	12.5	6.75	11.5	2	28	31	9.5	6.49	10.0	0	25	45	14.4	7.26	14.0	2	34
	DAY 43	36	11.8	6.91	10.5	1	27	30	10.0	6.60	9.0	1	23	40	15.1	7.56	15.0	2	33
	DAY 50	34	11.0	6.31	11.0	1	24	30	9.2	6.87	8.5	0	26	39	14.6	7.66	13.0	1	33
	DAY 57	36	11.1	7.52	10.5	1	27	29	9.0	7.89	7.0	0	25	41	12.8	7.99	12.0	1	31
CHG FROM BASELINE	DAY 8	56	-8.4	4.74	-8.0	-19	1	55	-7.6	4.74	-8.0	-18	2	57	-5.4	5.14	-5.0	-17	3
	DAY 15	45	-11.1	6.03	-11.0	-22	4	43	-9.6	6.18	-10.0	-23	3	53	-6.9	5.30	-6.0	-19	3
	DAY 22	44	-10.8	6.08	-11.5	-20	2	39	-11.5	5.99	-12.0	-26	3	50	-8.1	6.79	-8.0	-23	5
	DAY 29	40	-12.0	6.67	-12.0	-25	3	36	-13.8	7.04	-14.5	-25	-2	47	-9.0	6.63	-9.0	-23	5
	DAY 36	40	-12.5	6.50	-13.0	-25	2	31	-15.0	7.87	-15.0	-28	0	45	-10.0	6.85	-9.0	-26	7
	DAY 43	36	-13.1	6.19	-14.5	-24	0	30	-14.6	7.93	-14.5	-28	-2	40	-9.1	6.36	-8.0	-22	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD202.SAS
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Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	34	-13.9	5.62	-14.5	-25	-5	30	-15.6	8.19	-16.5	-29	0	39	-9.7	6.99	-11.0	-27	2
	DAY 57	36	-14.0	6.54	-14.5	-26	3	29	-15.9	8.28	-17.0	-30	2	41	-11.4	7.42	-12.0	-26	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD202.SAS
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Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. DEPRESSED MOOD	VISIT																		
	SCREEN	172	2.9	0.43	3.0	2	4	170	3.0	0.45	3.0	2	4	169	2.9	0.40	3.0	2	4
	DAY 1	172	2.9	0.46	3.0	2	4	170	2.9	0.48	3.0	2	4	169	2.9	0.44	3.0	2	4
	DAY 8	171	2.2	0.90	2.0	0	4	169	2.2	0.86	2.0	0	4	169	2.4	0.85	3.0	0	4
	DAY 15	172	1.8	0.95	2.0	0	4	170	1.8	1.02	2.0	0	4	169	2.2	0.96	2.0	0	4
	DAY 22	172	1.7	1.00	2.0	0	4	170	1.6	1.04	2.0	0	3	169	2.0	1.12	2.0	0	4
	DAY 29	172	1.6	0.96	2.0	0	3	170	1.4	1.10	1.0	0	4	169	1.9	1.06	2.0	0	4
	DAY 36	172	1.4	1.04	1.0	0	3	170	1.4	1.13	1.0	0	4	169	1.9	1.13	2.0	0	4
	DAY 43	172	1.3	1.08	1.0	0	3	170	1.3	1.15	1.0	0	4	169	1.9	1.11	2.0	0	4
	DAY 50	172	1.3	1.07	1.0	0	3	170	1.3	1.14	1.0	0	4	169	1.8	1.16	2.0	0	4
	DAY 57	172	1.2	1.11	1.0	0	3	170	1.2	1.15	1.0	0	4	169	1.8	1.18	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. FEELING OF GUILT	VISIT																		
	SCREEN	172	2.0	0.65	2.0	0	4	170	2.0	0.63	2.0	0	4	169	2.0	0.52	2.0	0	3
	DAY 1	172	1.9	0.69	2.0	0	4	170	2.0	0.64	2.0	0	4	169	1.9	0.61	2.0	0	3
	DAY 8	171	1.5	0.90	2.0	0	4	169	1.5	0.92	2.0	0	4	169	1.7	0.83	2.0	0	3
	DAY 15	172	1.3	0.97	1.0	0	4	170	1.2	0.98	1.0	0	3	169	1.4	0.91	2.0	0	4
	DAY 22	172	1.2	0.92	1.0	0	3	170	1.1	1.00	1.0	0	4	169	1.3	0.92	1.0	0	4
	DAY 29	172	1.1	0.92	1.0	0	3	170	0.9	0.98	1.0	0	3	169	1.3	0.95	1.0	0	4
	DAY 36	172	1.0	0.90	1.0	0	3	170	0.9	1.00	0.0	0	3	169	1.3	0.99	1.0	0	4
	DAY 43	172	0.9	0.90	1.0	0	3	170	0.9	0.99	1.0	0	3	169	1.3	0.99	1.0	0	4
	DAY 50	172	0.8	0.89	1.0	0	3	170	0.8	0.96	1.0	0	3	169	1.2	0.99	1.0	0	4
	DAY 57	172	0.8	0.89	1.0	0	3	170	0.8	0.97	0.0	0	3	169	1.2	0.96	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SUICIDE	VISIT																		
	SCREEN	172	1.0	0.83	1.0	0	3	170	1.2	0.84	1.0	0	3	169	1.1	0.79	1.0	0	3
	DAY 1	172	0.9	0.76	1.0	0	3	170	1.0	0.85	1.0	0	3	169	1.0	0.79	1.0	0	3
	DAY 8	171	0.6	0.76	0.0	0	3	169	0.6	0.73	0.0	0	3	169	0.8	0.85	1.0	0	3
	DAY 15	172	0.5	0.73	0.0	0	3	170	0.4	0.69	0.0	0	2	169	0.7	0.82	0.0	0	3
	DAY 22	172	0.4	0.71	0.0	0	3	170	0.4	0.63	0.0	0	2	169	0.6	0.84	0.0	0	3
	DAY 29	172	0.3	0.64	0.0	0	2	170	0.4	0.69	0.0	0	3	169	0.6	0.85	0.0	0	3
	DAY 36	172	0.3	0.62	0.0	0	2	170	0.3	0.63	0.0	0	3	169	0.6	0.88	0.0	0	3
	DAY 43	172	0.3	0.58	0.0	0	2	170	0.4	0.70	0.0	0	3	169	0.7	0.90	0.0	0	3
	DAY 50	172	0.3	0.63	0.0	0	3	170	0.3	0.65	0.0	0	3	169	0.6	0.88	0.0	0	3
	DAY 57	172	0.2	0.57	0.0	0	2	170	0.3	0.59	0.0	0	3	169	0.6	0.87	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA EARLY	VISIT																		
	SCREEN	172	1.5	0.78	2.0	0	2	170	1.5	0.78	2.0	0	2	169	1.5	0.80	2.0	0	2
	DAY 1	172	1.5	0.78	2.0	0	2	170	1.6	0.75	2.0	0	2	169	1.5	0.76	2.0	0	2
	DAY 8	171	0.5	0.75	0.0	0	2	169	0.5	0.75	0.0	0	2	169	1.2	0.84	1.0	0	2
	DAY 15	172	0.5	0.79	0.0	0	2	170	0.5	0.76	0.0	0	2	169	1.1	0.87	1.0	0	2
	DAY 22	172	0.5	0.78	0.0	0	2	170	0.5	0.79	0.0	0	2	169	1.0	0.92	1.0	0	2
	DAY 29	172	0.5	0.76	0.0	0	2	170	0.5	0.77	0.0	0	2	169	1.0	0.88	1.0	0	2
	DAY 36	172	0.5	0.75	0.0	0	2	170	0.4	0.75	0.0	0	2	169	1.0	0.89	1.0	0	2
	DAY 43	172	0.6	0.79	0.0	0	2	170	0.4	0.72	0.0	0	2	169	1.0	0.90	1.0	0	2
	DAY 50	172	0.5	0.75	0.0	0	2	170	0.4	0.71	0.0	0	2	169	1.0	0.90	1.0	0	2
	DAY 57	172	0.5	0.79	0.0	0	2	170	0.5	0.75	0.0	0	2	169	1.0	0.88	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INSOMNIA MIDDLE	VISIT																		
	SCREEN	172	1.5	0.72	2.0	0	2	170	1.5	0.66	2.0	0	2	169	1.5	0.72	2.0	0	2
	DAY 1	172	1.6	0.62	2.0	0	2	170	1.5	0.71	2.0	0	2	169	1.5	0.69	2.0	0	2
	DAY 8	171	0.5	0.73	0.0	0	2	169	0.6	0.76	0.0	0	2	169	1.1	0.83	1.0	0	2
	DAY 15	172	0.5	0.70	0.0	0	2	170	0.5	0.78	0.0	0	2	169	1.1	0.84	1.0	0	2
	DAY 22	172	0.6	0.75	0.0	0	2	170	0.5	0.75	0.0	0	2	169	1.0	0.83	1.0	0	2
	DAY 29	172	0.5	0.74	0.0	0	2	170	0.4	0.70	0.0	0	2	169	1.0	0.81	1.0	0	2
	DAY 36	172	0.6	0.77	0.0	0	2	170	0.5	0.73	0.0	0	2	169	0.9	0.84	1.0	0	2
	DAY 43	172	0.5	0.74	0.0	0	2	170	0.4	0.70	0.0	0	2	169	0.9	0.84	1.0	0	2
	DAY 50	172	0.5	0.73	0.0	0	2	170	0.5	0.71	0.0	0	2	169	1.0	0.83	1.0	0	2
	DAY 57	172	0.5	0.76	0.0	0	2	170	0.5	0.73	0.0	0	2	169	1.0	0.84	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
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Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. INSOMNIA LATE	VISIT																		
	SCREEN	172	1.2	0.84	1.0	0	2	170	1.1	0.83	1.0	0	2	169	1.2	0.76	1.0	0	2
	DAY 1	172	1.3	0.80	1.0	0	2	170	1.2	0.80	1.0	0	2	169	1.3	0.75	1.0	0	2
	DAY 8	171	0.4	0.64	0.0	0	2	169	0.4	0.65	0.0	0	2	169	1.1	0.85	1.0	0	2
	DAY 15	172	0.4	0.64	0.0	0	2	170	0.4	0.66	0.0	0	2	169	1.0	0.84	1.0	0	2
	DAY 22	172	0.4	0.65	0.0	0	2	170	0.4	0.70	0.0	0	2	169	0.9	0.83	1.0	0	2
	DAY 29	172	0.3	0.63	0.0	0	2	170	0.3	0.62	0.0	0	2	169	0.9	0.83	1.0	0	2
	DAY 36	172	0.3	0.59	0.0	0	2	170	0.3	0.62	0.0	0	2	169	0.9	0.87	1.0	0	2
	DAY 43	172	0.4	0.64	0.0	0	2	170	0.3	0.64	0.0	0	2	169	0.8	0.85	1.0	0	2
	DAY 50	172	0.4	0.64	0.0	0	2	170	0.3	0.63	0.0	0	2	169	0.8	0.82	1.0	0	2
	DAY 57	172	0.3	0.65	0.0	0	2	170	0.3	0.61	0.0	0	2	169	0.9	0.84	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. WORK AND ACTIVITIES	VISIT																		
	SCREEN	172	3.1	0.54	3.0	1	4	170	3.1	0.61	3.0	1	4	169	3.0	0.56	3.0	1	4
	DAY 1	172	2.9	0.60	3.0	1	4	170	3.0	0.63	3.0	1	4	169	2.9	0.62	3.0	0	4
	DAY 8	171	2.3	1.06	2.0	0	4	169	2.3	1.02	2.0	0	4	169	2.5	0.91	3.0	0	4
	DAY 15	172	2.0	1.17	2.0	0	4	170	2.0	1.16	2.0	0	4	169	2.2	1.03	2.0	0	4
	DAY 22	172	1.8	1.20	2.0	0	4	170	1.7	1.19	2.0	0	4	169	2.1	1.09	2.0	0	4
	DAY 29	172	1.6	1.23	1.0	0	4	170	1.6	1.20	1.0	0	4	169	2.0	1.10	2.0	0	4
	DAY 36	172	1.5	1.23	1.0	0	4	170	1.6	1.24	1.0	0	4	169	2.0	1.16	2.0	0	4
	DAY 43	172	1.5	1.16	1.0	0	4	170	1.5	1.29	1.0	0	4	169	2.0	1.19	2.0	0	4
	DAY 50	172	1.5	1.18	1.0	0	4	170	1.5	1.27	1.0	0	4	169	2.0	1.23	2.0	0	4
	DAY 57	172	1.4	1.25	1.0	0	4	170	1.4	1.28	1.0	0	4	169	1.9	1.26	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. RETARDATION	VISIT																		
	SCREEN	172	1.2	0.82	1.0	0	3	170	1.2	0.88	1.0	0	3	169	1.1	0.84	1.0	0	4
	DAY 1	172	1.1	0.81	1.0	0	3	170	1.1	0.81	1.0	0	3	169	1.1	0.84	1.0	0	3
	DAY 8	171	0.8	0.73	1.0	0	3	169	0.9	0.86	1.0	0	4	169	0.9	0.80	1.0	0	4
	DAY 15	172	0.7	0.66	1.0	0	2	170	0.7	0.80	1.0	0	4	169	0.6	0.74	0.0	0	4
	DAY 22	172	0.6	0.71	0.5	0	3	170	0.6	0.69	0.0	0	2	169	0.7	0.76	1.0	0	3
	DAY 29	172	0.6	0.70	0.0	0	2	170	0.5	0.72	0.0	0	3	169	0.7	0.72	1.0	0	2
	DAY 36	172	0.5	0.65	0.0	0	2	170	0.5	0.68	0.0	0	3	169	0.7	0.74	1.0	0	2
	DAY 43	172	0.5	0.61	0.0	0	2	170	0.5	0.70	0.0	0	3	169	0.6	0.73	0.0	0	3
	DAY 50	172	0.5	0.61	0.0	0	2	170	0.5	0.65	0.0	0	2	169	0.7	0.77	0.0	0	3
	DAY 57	172	0.5	0.64	0.0	0	2	170	0.5	0.66	0.0	0	2	169	0.6	0.72	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. AGITATION	VISIT																		
	SCREEN	172	1.2	0.90	1.0	0	4	170	1.3	0.91	1.0	0	4	169	1.2	0.86	1.0	0	4
	DAY 1	172	1.2	0.85	1.0	0	3	170	1.3	0.90	1.0	0	4	169	1.2	0.93	1.0	0	4
	DAY 8	171	0.9	0.81	1.0	0	3	169	1.1	0.96	1.0	0	4	169	0.9	0.78	1.0	0	3
	DAY 15	172	0.8	0.77	1.0	0	3	170	1.0	0.88	1.0	0	4	169	0.9	0.86	1.0	0	4
	DAY 22	172	0.7	0.78	0.0	0	3	170	0.8	0.86	1.0	0	3	169	0.8	0.84	1.0	0	4
	DAY 29	172	0.6	0.79	0.0	0	3	170	0.8	0.87	1.0	0	3	169	0.8	0.85	1.0	0	4
	DAY 36	172	0.7	0.86	1.0	0	3	170	0.7	0.84	1.0	0	3	169	0.8	0.84	1.0	0	4
	DAY 43	172	0.6	0.74	0.0	0	3	170	0.8	0.90	1.0	0	3	169	0.8	0.84	1.0	0	4
	DAY 50	172	0.6	0.77	0.0	0	3	170	0.8	0.87	1.0	0	3	169	0.8	0.85	1.0	0	4
	DAY 57	172	0.6	0.77	0.0	0	3	170	0.7	0.82	1.0	0	3	169	0.8	0.83	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. ANXIETY PSYCHIC	VISIT																		
	SCREEN	172	2.3	0.72	2.0	0	4	170	2.3	0.72	2.0	1	4	169	2.4	0.70	2.0	1	4
	DAY 1	172	2.4	0.75	2.0	0	4	170	2.4	0.75	2.0	0	4	169	2.3	0.72	2.0	1	4
	DAY 8	171	1.8	0.90	2.0	0	4	169	1.8	0.94	2.0	0	4	169	2.0	0.84	2.0	0	4
	DAY 15	172	1.7	0.93	2.0	0	4	170	1.6	0.92	2.0	0	4	169	1.9	0.91	2.0	0	4
	DAY 22	172	1.5	0.97	1.0	0	4	170	1.4	0.99	1.0	0	4	169	1.8	1.01	2.0	0	4
	DAY 29	172	1.5	1.02	1.0	0	4	170	1.3	1.03	1.0	0	4	169	1.8	0.94	2.0	0	4
	DAY 36	172	1.4	1.04	1.0	0	4	170	1.3	1.07	1.0	0	4	169	1.8	0.99	2.0	0	4
	DAY 43	172	1.4	1.03	1.0	0	4	170	1.3	1.04	1.0	0	4	169	1.8	0.99	2.0	0	4
	DAY 50	172	1.3	1.00	1.0	0	4	170	1.3	1.04	1.0	0	4	169	1.8	1.03	2.0	0	4
	DAY 57	172	1.3	0.99	1.0	0	4	170	1.2	1.06	1.0	0	4	169	1.8	0.94	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. ANXIETY SOMATIC	VISIT																		
	SCREEN	172	1.6	0.78	2.0	0	3	170	1.6	0.83	2.0	0	4	169	1.7	0.70	2.0	0	4
	DAY 1	172	1.6	0.72	2.0	0	3	170	1.6	0.81	2.0	0	3	169	1.7	0.72	2.0	0	3
	DAY 8	171	1.3	0.79	1.0	0	3	169	1.4	0.84	1.0	0	3	169	1.4	0.77	2.0	0	3
	DAY 15	172	1.1	0.81	1.0	0	3	170	1.3	0.81	1.0	0	3	169	1.3	0.86	1.0	0	3
	DAY 22	172	1.1	0.79	1.0	0	3	170	1.1	0.87	1.0	0	3	169	1.2	0.83	1.0	0	3
	DAY 29	172	1.1	0.83	1.0	0	3	170	1.1	0.93	1.0	0	3	169	1.2	0.83	1.0	0	4
	DAY 36	172	1.1	0.87	1.0	0	3	170	1.0	0.91	1.0	0	3	169	1.3	0.86	1.0	0	4
	DAY 43	172	1.0	0.84	1.0	0	3	170	1.0	0.92	1.0	0	4	169	1.2	0.85	1.0	0	3
	DAY 50	172	1.0	0.84	1.0	0	3	170	1.0	0.90	1.0	0	3	169	1.2	0.87	1.0	0	3
	DAY 57	172	1.0	0.87	1.0	0	3	170	1.0	0.93	1.0	0	3	169	1.2	0.87	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. SOMATIC SYMPTOMS GASTROINTESTINAL	VISIT																		
	SCREEN	172	0.8	0.75	1.0	0	2	170	0.8	0.73	1.0	0	2	169	0.8	0.76	1.0	0	2
	DAY 1	172	0.9	0.74	1.0	0	2	170	0.9	0.77	1.0	0	2	169	0.9	0.73	1.0	0	2
	DAY 8	171	0.5	0.62	0.0	0	2	169	0.5	0.66	0.0	0	2	169	0.7	0.69	1.0	0	2
	DAY 15	172	0.4	0.61	0.0	0	2	170	0.4	0.59	0.0	0	2	169	0.5	0.67	0.0	0	2
	DAY 22	172	0.4	0.60	0.0	0	2	170	0.4	0.63	0.0	0	2	169	0.6	0.69	0.0	0	2
	DAY 29	172	0.4	0.60	0.0	0	2	170	0.4	0.60	0.0	0	2	169	0.5	0.67	0.0	0	2
	DAY 36	172	0.4	0.61	0.0	0	2	170	0.4	0.58	0.0	0	2	169	0.5	0.67	0.0	0	2
	DAY 43	172	0.3	0.59	0.0	0	2	170	0.3	0.55	0.0	0	2	169	0.5	0.68	0.0	0	2
	DAY 50	172	0.3	0.57	0.0	0	2	170	0.3	0.54	0.0	0	2	169	0.6	0.70	0.0	0	2
	DAY 57	172	0.3	0.62	0.0	0	2	170	0.3	0.53	0.0	0	2	169	0.5	0.67	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
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Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. SOMATIC SYMPTOMS GENERAL	VISIT																		
	SCREEN	172	1.6	0.60	2.0	0	2	170	1.7	0.52	2.0	0	2	169	1.7	0.55	2.0	0	2
	DAY 1	172	1.6	0.54	2.0	0	2	170	1.7	0.53	2.0	0	2	169	1.7	0.53	2.0	0	2
	DAY 8	171	1.4	0.71	2.0	0	2	169	1.3	0.69	1.0	0	2	169	1.4	0.65	2.0	0	2
	DAY 15	172	1.1	0.74	1.0	0	2	170	1.2	0.73	1.0	0	2	169	1.3	0.73	1.0	0	2
	DAY 22	172	1.0	0.79	1.0	0	2	170	1.1	0.76	1.0	0	2	169	1.3	0.72	1.0	0	2
	DAY 29	172	1.0	0.74	1.0	0	2	170	0.9	0.74	1.0	0	2	169	1.2	0.76	1.0	0	2
	DAY 36	172	0.9	0.76	1.0	0	2	170	0.9	0.79	1.0	0	2	169	1.2	0.74	1.0	0	2
	DAY 43	172	1.0	0.77	1.0	0	2	170	0.9	0.80	1.0	0	2	169	1.2	0.80	1.0	0	2
	DAY 50	172	0.9	0.75	1.0	0	2	170	0.9	0.81	1.0	0	2	169	1.1	0.80	1.0	0	2
	DAY 57	172	0.9	0.79	1.0	0	2	170	0.8	0.77	1.0	0	2	169	1.1	0.80	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
14. GENITAL SYMPTOMS	VISIT																		
	SCREEN	172	1.1	0.88	1.0	0	2	170	1.2	0.82	1.0	0	2	169	1.3	0.81	2.0	0	2
	DAY 1	172	1.2	0.84	1.0	0	2	170	1.2	0.84	1.0	0	2	169	1.3	0.80	2.0	0	2
	DAY 8	171	1.0	0.85	1.0	0	2	169	1.0	0.87	1.0	0	2	169	1.2	0.83	1.0	0	2
	DAY 15	172	0.9	0.83	1.0	0	2	170	1.0	0.86	1.0	0	2	169	1.1	0.81	1.0	0	2
	DAY 22	172	0.8	0.82	1.0	0	2	170	0.8	0.84	1.0	0	2	169	1.2	0.79	1.0	0	2
	DAY 29	172	0.8	0.83	1.0	0	2	170	0.8	0.83	1.0	0	2	169	1.1	0.82	1.0	0	2
	DAY 36	172	0.8	0.83	1.0	0	2	170	0.8	0.84	0.5	0	2	169	1.1	0.82	1.0	0	2
	DAY 43	172	0.8	0.84	1.0	0	2	170	0.8	0.87	0.0	0	2	169	1.0	0.82	1.0	0	2
	DAY 50	172	0.8	0.84	1.0	0	2	170	0.8	0.85	0.5	0	2	169	1.1	0.83	1.0	0	2
	DAY 57	172	0.8	0.85	1.0	0	2	170	0.8	0.84	0.0	0	2	169	1.0	0.85	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
15. HYPOCHONDRIASIS	VISIT																		
	SCREEN	172	0.9	0.84	1.0	0	3	170	0.9	0.88	1.0	0	3	169	0.9	0.88	1.0	0	3
	DAY 1	172	1.0	0.81	1.0	0	3	170	0.9	0.88	1.0	0	3	169	0.9	0.80	1.0	0	3
	DAY 8	171	0.8	0.84	1.0	0	3	169	0.7	0.83	1.0	0	3	169	0.8	0.82	1.0	0	3
	DAY 15	172	0.7	0.85	0.5	0	3	170	0.6	0.84	0.0	0	3	169	0.8	0.80	1.0	0	3
	DAY 22	172	0.6	0.85	0.0	0	3	170	0.6	0.83	0.0	0	3	169	0.7	0.81	1.0	0	3
	DAY 29	172	0.6	0.89	0.0	0	3	170	0.5	0.76	0.0	0	3	169	0.7	0.78	0.0	0	3
	DAY 36	172	0.6	0.85	0.0	0	3	170	0.6	0.82	0.0	0	3	169	0.6	0.77	0.0	0	3
	DAY 43	172	0.5	0.82	0.0	0	3	170	0.6	0.79	0.0	0	3	169	0.6	0.76	0.0	0	3
	DAY 50	172	0.5	0.81	0.0	0	3	170	0.5	0.76	0.0	0	3	169	0.7	0.77	0.0	0	3
	DAY 57	172	0.5	0.79	0.0	0	3	170	0.6	0.78	0.0	0	3	169	0.6	0.73	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
16. LOSS OF WEIGHT[HISTORY]	VISIT																		
	SCREEN	172	0.4	0.70	0.0	0	2	170	0.4	0.72	0.0	0	2	169	0.5	0.77	0.0	0	2
	DAY 1	172	0.4	0.69	0.0	0	2	170	0.4	0.70	0.0	0	2	169	0.4	0.68	0.0	0	2
	DAY 8	171	0.1	0.39	0.0	0	2	169	0.1	0.48	0.0	0	3	169	0.2	0.47	0.0	0	2
	DAY 15	172	0.1	0.40	0.0	0	2	170	0.1	0.40	0.0	0	2	169	0.2	0.46	0.0	0	2
	DAY 22	172	0.2	0.48	0.0	0	2	170	0.1	0.33	0.0	0	2	169	0.1	0.46	0.0	0	2
	DAY 29	172	0.1	0.43	0.0	0	2	170	0.1	0.36	0.0	0	2	169	0.2	0.50	0.0	0	2
	DAY 36	172	0.1	0.45	0.0	0	2	170	0.1	0.41	0.0	0	2	169	0.2	0.45	0.0	0	2
	DAY 43	172	0.1	0.39	0.0	0	2	170	0.1	0.33	0.0	0	2	169	0.2	0.51	0.0	0	2
	DAY 50	172	0.1	0.36	0.0	0	2	170	0.1	0.36	0.0	0	2	169	0.2	0.47	0.0	0	2
	DAY 57	172	0.1	0.38	0.0	0	2	170	0.1	0.35	0.0	0	2	169	0.2	0.50	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
GENERATED: 12JUL2005 17:43:22 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
17. INSIGHT	VISIT																		
	SCREEN	172	0.1	0.25	0.0	0	2	170	0.1	0.30	0.0	0	2	169	0.1	0.28	0.0	0	1
	DAY 1	172	0.1	0.26	0.0	0	2	170	0.1	0.22	0.0	0	1	169	0.1	0.28	0.0	0	1
	DAY 8	171	0.0	0.24	0.0	0	2	169	0.0	0.11	0.0	0	1	169	0.0	0.15	0.0	0	1
	DAY 15	172	0.0	0.21	0.0	0	2	170	0.0	0.11	0.0	0	1	169	0.1	0.25	0.0	0	2
	DAY 22	172	0.0	0.24	0.0	0	2	170	0.0	0.23	0.0	0	2	169	0.0	0.19	0.0	0	1
	DAY 29	172	0.0	0.24	0.0	0	2	170	0.0	0.25	0.0	0	2	169	0.0	0.17	0.0	0	1
	DAY 36	172	0.0	0.20	0.0	0	2	170	0.0	0.08	0.0	0	1	169	0.0	0.21	0.0	0	1
	DAY 43	172	0.0	0.20	0.0	0	2	170	0.0	0.13	0.0	0	1	169	0.0	0.19	0.0	0	1
	DAY 50	172	0.0	0.20	0.0	0	2	170	0.0	0.08	0.0	0	1	169	0.0	0.19	0.0	0	1
	DAY 57	172	0.0	0.20	0.0	0	2	170	0.0	0.13	0.0	0	1	169	0.0	0.17	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD206.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. DEPRESSED MOOD	VISIT																		
	SCREEN	172	2.9	0.43	3.0	2	4	170	3.0	0.45	3.0	2	4	169	2.9	0.40	3.0	2	4
	DAY 1	172	2.9	0.46	3.0	2	4	170	2.9	0.48	3.0	2	4	169	2.9	0.44	3.0	2	4
	DAY 8	171	2.2	0.90	2.0	0	4	169	2.2	0.86	2.0	0	4	169	2.4	0.85	3.0	0	4
	DAY 15	148	1.8	0.95	2.0	0	4	148	1.7	1.02	2.0	0	4	149	2.1	0.93	2.0	0	3
	DAY 22	139	1.6	1.00	1.0	0	4	133	1.4	1.01	1.0	0	3	143	1.9	1.13	2.0	0	4
	DAY 29	133	1.5	0.92	1.0	0	3	127	1.2	1.03	1.0	0	4	126	1.6	1.01	2.0	0	4
	DAY 36	130	1.3	0.99	1.0	0	3	113	1.2	1.09	1.0	0	4	119	1.6	1.13	2.0	0	4
	DAY 43	123	1.1	1.00	1.0	0	3	107	1.1	1.08	1.0	0	4	107	1.6	1.09	2.0	0	3
	DAY 50	121	1.0	0.97	1.0	0	3	101	1.0	1.01	1.0	0	4	102	1.5	1.15	1.0	0	4
	DAY 57	119	1.0	1.00	1.0	0	3	97	0.9	1.00	1.0	0	3	99	1.5	1.15	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. FEELING OF GUILT	VISIT																		
	SCREEN	172	2.0	0.65	2.0	0	4	170	2.0	0.63	2.0	0	4	169	2.0	0.52	2.0	0	3
	DAY 1	172	1.9	0.69	2.0	0	4	170	2.0	0.64	2.0	0	4	169	1.9	0.61	2.0	0	3
	DAY 8	171	1.5	0.90	2.0	0	4	169	1.5	0.92	2.0	0	4	169	1.7	0.83	2.0	0	3
	DAY 15	148	1.2	0.96	1.0	0	4	148	1.2	0.97	1.0	0	3	149	1.4	0.90	2.0	0	3
	DAY 22	139	1.1	0.89	1.0	0	3	133	1.0	0.97	1.0	0	4	143	1.2	0.91	1.0	0	3
	DAY 29	133	1.0	0.88	1.0	0	3	127	0.7	0.88	0.0	0	3	126	1.1	0.90	1.0	0	3
	DAY 36	130	0.9	0.85	1.0	0	3	113	0.7	0.92	0.0	0	3	119	1.1	0.99	1.0	0	3
	DAY 43	123	0.8	0.81	1.0	0	3	107	0.7	0.88	0.0	0	3	107	1.1	0.98	1.0	0	3
	DAY 50	121	0.7	0.78	0.0	0	3	101	0.6	0.82	0.0	0	3	102	1.1	1.01	1.0	0	3
	DAY 57	119	0.7	0.78	0.0	0	3	97	0.5	0.82	0.0	0	3	99	1.0	0.90	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SUICIDE	VISIT																		
	SCREEN	172	1.0	0.83	1.0	0	3	170	1.2	0.84	1.0	0	3	169	1.1	0.79	1.0	0	3
	DAY 1	172	0.9	0.76	1.0	0	3	170	1.0	0.85	1.0	0	3	169	1.0	0.79	1.0	0	3
	DAY 8	171	0.6	0.76	0.0	0	3	169	0.6	0.73	0.0	0	3	169	0.8	0.85	1.0	0	3
	DAY 15	148	0.5	0.73	0.0	0	3	148	0.4	0.67	0.0	0	2	149	0.6	0.75	0.0	0	3
	DAY 22	139	0.4	0.71	0.0	0	3	133	0.3	0.63	0.0	0	2	143	0.5	0.78	0.0	0	2
	DAY 29	133	0.3	0.61	0.0	0	2	127	0.4	0.71	0.0	0	3	126	0.5	0.76	0.0	0	3
	DAY 36	130	0.3	0.61	0.0	0	2	113	0.3	0.62	0.0	0	3	119	0.5	0.80	0.0	0	3
	DAY 43	123	0.2	0.52	0.0	0	2	107	0.3	0.72	0.0	0	2	107	0.5	0.78	0.0	0	3
	DAY 50	121	0.2	0.61	0.0	0	3	101	0.3	0.64	0.0	0	3	102	0.5	0.74	0.0	0	2
	DAY 57	119	0.2	0.51	0.0	0	2	97	0.2	0.50	0.0	0	3	99	0.4	0.70	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA EARLY	VISIT																		
	SCREEN	172	1.5	0.78	2.0	0	2	170	1.5	0.78	2.0	0	2	169	1.5	0.80	2.0	0	2
	DAY 1	172	1.5	0.78	2.0	0	2	170	1.6	0.75	2.0	0	2	169	1.5	0.76	2.0	0	2
	DAY 8	171	0.5	0.75	0.0	0	2	169	0.5	0.75	0.0	0	2	169	1.2	0.84	1.0	0	2
	DAY 15	148	0.5	0.76	0.0	0	2	148	0.5	0.75	0.0	0	2	149	1.1	0.88	1.0	0	2
	DAY 22	139	0.5	0.75	0.0	0	2	133	0.4	0.75	0.0	0	2	143	1.0	0.93	1.0	0	2
	DAY 29	133	0.4	0.71	0.0	0	2	127	0.4	0.72	0.0	0	2	126	0.9	0.87	1.0	0	2
	DAY 36	130	0.4	0.72	0.0	0	2	113	0.3	0.66	0.0	0	2	119	0.8	0.87	1.0	0	2
	DAY 43	123	0.5	0.75	0.0	0	2	107	0.3	0.60	0.0	0	2	107	0.9	0.88	1.0	0	2
	DAY 50	121	0.5	0.70	0.0	0	2	101	0.3	0.58	0.0	0	2	102	0.8	0.89	1.0	0	2
	DAY 57	119	0.5	0.78	0.0	0	2	97	0.4	0.68	0.0	0	2	99	0.8	0.85	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INSOMNIA MIDDLE	VISIT																		
	SCREEN	172	1.5	0.72	2.0	0	2	170	1.5	0.66	2.0	0	2	169	1.5	0.72	2.0	0	2
	DAY 1	172	1.6	0.62	2.0	0	2	170	1.5	0.71	2.0	0	2	169	1.5	0.69	2.0	0	2
	DAY 8	171	0.5	0.73	0.0	0	2	169	0.6	0.76	0.0	0	2	169	1.1	0.83	1.0	0	2
	DAY 15	148	0.5	0.70	0.0	0	2	148	0.5	0.79	0.0	0	2	149	1.1	0.84	1.0	0	2
	DAY 22	139	0.6	0.76	0.0	0	2	133	0.5	0.74	0.0	0	2	143	0.9	0.82	1.0	0	2
	DAY 29	133	0.5	0.74	0.0	0	2	127	0.3	0.63	0.0	0	2	126	0.9	0.79	1.0	0	2
	DAY 36	130	0.5	0.76	0.0	0	2	113	0.4	0.67	0.0	0	2	119	0.8	0.80	1.0	0	2
	DAY 43	123	0.4	0.71	0.0	0	2	107	0.3	0.62	0.0	0	2	107	0.8	0.79	1.0	0	2
	DAY 50	121	0.4	0.70	0.0	0	2	101	0.4	0.65	0.0	0	2	102	0.8	0.80	1.0	0	2
	DAY 57	119	0.5	0.76	0.0	0	2	97	0.4	0.68	0.0	0	2	99	0.9	0.82	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. INSOMNIA LATE	VISIT																		
	SCREEN	172	1.2	0.84	1.0	0	2	170	1.1	0.83	1.0	0	2	169	1.2	0.76	1.0	0	2
	DAY 1	172	1.3	0.80	1.0	0	2	170	1.2	0.80	1.0	0	2	169	1.3	0.75	1.0	0	2
	DAY 8	171	0.4	0.64	0.0	0	2	169	0.4	0.65	0.0	0	2	169	1.1	0.85	1.0	0	2
	DAY 15	148	0.3	0.59	0.0	0	2	148	0.4	0.64	0.0	0	2	149	1.0	0.84	1.0	0	2
	DAY 22	139	0.3	0.59	0.0	0	2	133	0.3	0.66	0.0	0	2	143	0.8	0.81	1.0	0	2
	DAY 29	133	0.3	0.57	0.0	0	2	127	0.2	0.54	0.0	0	2	125	0.7	0.78	1.0	0	2
	DAY 36	130	0.2	0.48	0.0	0	2	113	0.2	0.54	0.0	0	2	119	0.7	0.83	0.0	0	2
	DAY 43	123	0.3	0.56	0.0	0	2	107	0.3	0.59	0.0	0	2	107	0.7	0.78	0.0	0	2
	DAY 50	121	0.3	0.57	0.0	0	2	101	0.3	0.60	0.0	0	2	102	0.6	0.73	0.0	0	2
	DAY 57	119	0.3	0.59	0.0	0	2	97	0.2	0.55	0.0	0	2	99	0.7	0.78	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. WORK AND ACTIVITIES	VISIT																		
	SCREEN	172	3.1	0.54	3.0	1	4	170	3.1	0.61	3.0	1	4	169	3.0	0.56	3.0	1	4
	DAY 1	172	2.9	0.60	3.0	1	4	170	3.0	0.63	3.0	1	4	169	2.9	0.62	3.0	0	4
	DAY 8	171	2.3	1.06	2.0	0	4	169	2.3	1.02	2.0	0	4	169	2.5	0.91	3.0	0	4
	DAY 15	148	1.9	1.19	2.0	0	4	148	1.9	1.18	2.0	0	4	149	2.2	1.04	2.0	0	4
	DAY 22	139	1.7	1.21	2.0	0	4	133	1.6	1.19	1.0	0	4	143	2.1	1.11	2.0	0	4
	DAY 29	133	1.4	1.21	1.0	0	4	127	1.3	1.13	1.0	0	4	126	1.8	1.10	2.0	0	4
	DAY 36	130	1.2	1.17	1.0	0	4	113	1.3	1.21	1.0	0	4	119	1.8	1.18	2.0	0	4
	DAY 43	123	1.3	1.07	1.0	0	4	107	1.1	1.22	1.0	0	4	107	1.8	1.24	2.0	0	4
	DAY 50	121	1.2	1.11	1.0	0	4	101	1.1	1.21	1.0	0	4	102	1.8	1.28	2.0	0	4
	DAY 57	119	1.2	1.18	1.0	0	4	97	1.0	1.19	1.0	0	4	99	1.7	1.29	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. RETARDATION	VISIT																		
	SCREEN	172	1.2	0.82	1.0	0	3	170	1.2	0.88	1.0	0	3	169	1.1	0.84	1.0	0	4
	DAY 1	172	1.1	0.81	1.0	0	3	170	1.1	0.81	1.0	0	3	169	1.1	0.84	1.0	0	3
	DAY 8	171	0.8	0.73	1.0	0	3	169	0.9	0.86	1.0	0	4	169	0.9	0.80	1.0	0	4
	DAY 15	148	0.7	0.66	1.0	0	2	148	0.7	0.82	1.0	0	4	149	0.6	0.73	0.0	0	4
	DAY 22	139	0.6	0.72	0.0	0	3	133	0.5	0.68	0.0	0	2	143	0.7	0.78	1.0	0	3
	DAY 29	133	0.5	0.69	0.0	0	2	127	0.5	0.70	0.0	0	3	126	0.6	0.69	0.0	0	2
	DAY 36	130	0.4	0.62	0.0	0	2	113	0.4	0.62	0.0	0	3	119	0.7	0.75	0.0	0	2
	DAY 43	123	0.4	0.56	0.0	0	2	107	0.4	0.62	0.0	0	3	107	0.6	0.74	0.0	0	3
	DAY 50	121	0.4	0.56	0.0	0	2	101	0.3	0.55	0.0	0	2	102	0.6	0.78	0.0	0	3
	DAY 57	119	0.5	0.61	0.0	0	2	97	0.3	0.55	0.0	0	2	99	0.6	0.69	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. AGITATION	VISIT																		
	SCREEN	172	1.2	0.90	1.0	0	4	170	1.3	0.91	1.0	0	4	169	1.2	0.86	1.0	0	4
	DAY 1	172	1.2	0.85	1.0	0	3	170	1.3	0.90	1.0	0	4	169	1.2	0.93	1.0	0	4
	DAY 8	171	0.9	0.81	1.0	0	3	169	1.1	0.96	1.0	0	4	169	0.9	0.78	1.0	0	3
	DAY 15	148	0.8	0.75	1.0	0	3	148	0.9	0.88	1.0	0	4	149	0.9	0.82	1.0	0	3
	DAY 22	139	0.6	0.77	0.0	0	3	133	0.8	0.84	1.0	0	3	143	0.8	0.77	1.0	0	3
	DAY 29	133	0.6	0.74	0.0	0	3	127	0.7	0.83	1.0	0	3	126	0.7	0.77	1.0	0	3
	DAY 36	130	0.7	0.86	0.0	0	3	113	0.5	0.73	0.0	0	3	119	0.7	0.75	1.0	0	3
	DAY 43	123	0.4	0.60	0.0	0	2	107	0.6	0.84	0.0	0	3	107	0.7	0.77	1.0	0	3
	DAY 50	121	0.5	0.66	0.0	0	3	101	0.6	0.77	0.0	0	3	102	0.7	0.79	0.0	0	3
	DAY 57	119	0.5	0.65	0.0	0	3	97	0.5	0.63	0.0	0	2	99	0.7	0.76	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. ANXIETY PSYCHIC	VISIT																		
	SCREEN	172	2.3	0.72	2.0	0	4	170	2.3	0.72	2.0	1	4	169	2.4	0.70	2.0	1	4
	DAY 1	172	2.4	0.75	2.0	0	4	170	2.4	0.75	2.0	0	4	169	2.3	0.72	2.0	1	4
	DAY 8	171	1.8	0.90	2.0	0	4	169	1.8	0.94	2.0	0	4	169	2.0	0.84	2.0	0	4
	DAY 15	148	1.6	0.92	2.0	0	4	148	1.6	0.89	1.0	0	4	149	1.9	0.89	2.0	0	4
	DAY 22	139	1.5	0.97	1.0	0	4	133	1.3	0.98	1.0	0	4	143	1.8	1.00	2.0	0	4
	DAY 29	133	1.4	1.03	1.0	0	4	127	1.2	0.97	1.0	0	4	126	1.6	0.89	2.0	0	3
	DAY 36	130	1.2	1.02	1.0	0	4	113	1.1	1.00	1.0	0	4	119	1.5	0.93	2.0	0	3
	DAY 43	123	1.3	1.01	1.0	0	4	107	1.1	0.93	1.0	0	4	107	1.6	0.95	2.0	0	3
	DAY 50	121	1.1	0.94	1.0	0	3	101	1.0	0.94	1.0	0	3	102	1.6	1.00	2.0	0	4
	DAY 57	119	1.1	0.90	1.0	0	3	97	0.9	0.95	1.0	0	4	99	1.6	0.86	2.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. ANXIETY SOMATIC	VISIT																		
	SCREEN	172	1.6	0.78	2.0	0	3	170	1.6	0.83	2.0	0	4	169	1.7	0.70	2.0	0	4
	DAY 1	172	1.6	0.72	2.0	0	3	170	1.6	0.81	2.0	0	3	169	1.7	0.72	2.0	0	3
	DAY 8	171	1.3	0.79	1.0	0	3	169	1.4	0.84	1.0	0	3	169	1.4	0.77	2.0	0	3
	DAY 15	148	1.1	0.79	1.0	0	3	148	1.2	0.78	1.0	0	3	149	1.3	0.86	1.0	0	3
	DAY 22	139	1.0	0.76	1.0	0	3	133	1.1	0.84	1.0	0	3	143	1.2	0.83	1.0	0	3
	DAY 29	133	1.0	0.81	1.0	0	3	127	0.9	0.86	1.0	0	3	126	1.2	0.83	1.0	0	4
	DAY 36	130	1.0	0.86	1.0	0	3	113	0.8	0.81	1.0	0	3	119	1.2	0.81	1.0	0	3
	DAY 43	123	0.8	0.78	1.0	0	3	107	0.8	0.83	1.0	0	4	107	1.1	0.82	1.0	0	3
	DAY 50	121	0.9	0.79	1.0	0	3	101	0.8	0.80	1.0	0	3	102	1.1	0.87	1.0	0	3
	DAY 57	119	0.8	0.83	1.0	0	3	97	0.7	0.80	0.0	0	3	99	0.9	0.84	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. SOMATIC SYMPTOMS GASTROINTESTINAL	VISIT																		
	SCREEN	172	0.8	0.75	1.0	0	2	170	0.8	0.73	1.0	0	2	169	0.8	0.76	1.0	0	2
	DAY 1	172	0.9	0.74	1.0	0	2	170	0.9	0.77	1.0	0	2	169	0.9	0.73	1.0	0	2
	DAY 8	171	0.5	0.62	0.0	0	2	169	0.5	0.66	0.0	0	2	169	0.7	0.69	1.0	0	2
	DAY 15	148	0.4	0.60	0.0	0	2	148	0.4	0.58	0.0	0	2	149	0.5	0.64	0.0	0	2
	DAY 22	139	0.4	0.57	0.0	0	2	133	0.4	0.63	0.0	0	2	143	0.6	0.68	0.0	0	2
	DAY 29	133	0.4	0.57	0.0	0	2	127	0.3	0.58	0.0	0	2	126	0.5	0.64	0.0	0	2
	DAY 36	130	0.3	0.56	0.0	0	2	113	0.3	0.57	0.0	0	2	119	0.5	0.62	0.0	0	2
	DAY 43	123	0.3	0.51	0.0	0	2	107	0.2	0.48	0.0	0	2	107	0.4	0.65	0.0	0	2
	DAY 50	121	0.2	0.47	0.0	0	2	101	0.2	0.47	0.0	0	2	102	0.5	0.67	0.0	0	2
	DAY 57	119	0.3	0.57	0.0	0	2	97	0.2	0.43	0.0	0	2	99	0.4	0.62	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. SOMATIC SYMPTOMS GENERAL	VISIT																		
	SCREEN	172	1.6	0.60	2.0	0	2	170	1.7	0.52	2.0	0	2	169	1.7	0.55	2.0	0	2
	DAY 1	172	1.6	0.54	2.0	0	2	170	1.7	0.53	2.0	0	2	169	1.7	0.53	2.0	0	2
	DAY 8	171	1.4	0.71	2.0	0	2	169	1.3	0.69	1.0	0	2	169	1.4	0.65	2.0	0	2
	DAY 15	148	1.0	0.73	1.0	0	2	148	1.2	0.71	1.0	0	2	149	1.3	0.73	1.0	0	2
	DAY 22	139	1.0	0.79	1.0	0	2	133	1.1	0.74	1.0	0	2	143	1.3	0.71	1.0	0	2
	DAY 29	133	0.9	0.73	1.0	0	2	127	0.8	0.70	1.0	0	2	126	1.2	0.73	1.0	0	2
	DAY 36	130	0.8	0.74	1.0	0	2	113	0.8	0.77	1.0	0	2	119	1.2	0.71	1.0	0	2
	DAY 43	123	0.9	0.75	1.0	0	2	107	0.8	0.79	1.0	0	2	107	1.1	0.79	1.0	0	2
	DAY 50	121	0.8	0.71	1.0	0	2	101	0.7	0.80	1.0	0	2	102	1.0	0.78	1.0	0	2
	DAY 57	119	0.8	0.77	1.0	0	2	97	0.7	0.72	1.0	0	2	99	1.1	0.78	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
14. GENITAL SYMPTOMS	VISIT																		
	SCREEN	172	1.1	0.88	1.0	0	2	170	1.2	0.82	1.0	0	2	169	1.3	0.81	2.0	0	2
	DAY 1	172	1.2	0.84	1.0	0	2	170	1.2	0.84	1.0	0	2	169	1.3	0.80	2.0	0	2
	DAY 8	171	1.0	0.85	1.0	0	2	169	1.0	0.87	1.0	0	2	169	1.2	0.83	1.0	0	2
	DAY 15	148	0.9	0.84	1.0	0	2	148	1.0	0.87	1.0	0	2	149	1.1	0.82	1.0	0	2
	DAY 22	139	0.8	0.82	1.0	0	2	133	0.8	0.83	1.0	0	2	143	1.1	0.79	1.0	0	2
	DAY 29	133	0.8	0.80	1.0	0	2	127	0.7	0.81	0.0	0	2	126	1.0	0.80	1.0	0	2
	DAY 36	130	0.7	0.81	0.5	0	2	113	0.6	0.81	0.0	0	2	119	1.0	0.80	1.0	0	2
	DAY 43	123	0.7	0.82	1.0	0	2	107	0.6	0.85	0.0	0	2	107	1.0	0.79	1.0	0	2
	DAY 50	121	0.7	0.82	0.0	0	2	101	0.6	0.82	0.0	0	2	102	1.0	0.82	1.0	0	2
	DAY 57	119	0.7	0.86	0.0	0	2	97	0.6	0.78	0.0	0	2	99	0.9	0.84	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
15. HYPOCHONDRIASIS	VISIT																		
	SCREEN	172	0.9	0.84	1.0	0	3	170	0.9	0.88	1.0	0	3	169	0.9	0.88	1.0	0	3
	DAY 1	172	1.0	0.81	1.0	0	3	170	0.9	0.88	1.0	0	3	169	0.9	0.80	1.0	0	3
	DAY 8	171	0.8	0.84	1.0	0	3	169	0.7	0.83	1.0	0	3	169	0.8	0.82	1.0	0	3
	DAY 15	148	0.6	0.78	0.0	0	3	148	0.5	0.76	0.0	0	3	149	0.8	0.79	1.0	0	3
	DAY 22	139	0.5	0.77	0.0	0	3	133	0.5	0.76	0.0	0	3	143	0.7	0.82	1.0	0	3
	DAY 29	133	0.5	0.81	0.0	0	3	127	0.4	0.63	0.0	0	2	126	0.6	0.76	0.0	0	3
	DAY 36	130	0.5	0.72	0.0	0	3	113	0.5	0.76	0.0	0	2	119	0.6	0.75	0.0	0	3
	DAY 43	123	0.4	0.64	0.0	0	3	107	0.4	0.67	0.0	0	3	107	0.6	0.76	0.0	0	2
	DAY 50	121	0.4	0.62	0.0	0	2	101	0.3	0.58	0.0	0	2	102	0.7	0.77	1.0	0	3
	DAY 57	119	0.3	0.60	0.0	0	3	97	0.3	0.61	0.0	0	3	99	0.6	0.72	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
16. LOSS OF WEIGHT[HISTORY]	VISIT																		
	SCREEN	172	0.4	0.70	0.0	0	2	170	0.4	0.72	0.0	0	2	169	0.5	0.77	0.0	0	2
	DAY 1	172	0.4	0.69	0.0	0	2	170	0.4	0.70	0.0	0	2	168	0.4	0.67	0.0	0	2
	DAY 8	171	0.1	0.39	0.0	0	2	169	0.1	0.48	0.0	0	3	169	0.2	0.47	0.0	0	2
	DAY 15	148	0.1	0.34	0.0	0	2	148	0.1	0.43	0.0	0	2	149	0.2	0.45	0.0	0	2
	DAY 22	139	0.2	0.43	0.0	0	2	133	0.1	0.33	0.0	0	2	143	0.1	0.40	0.0	0	2
	DAY 29	133	0.1	0.37	0.0	0	2	127	0.1	0.37	0.0	0	2	126	0.2	0.45	0.0	0	2
	DAY 36	130	0.1	0.40	0.0	0	2	113	0.1	0.45	0.0	0	2	119	0.1	0.33	0.0	0	2
	DAY 43	123	0.1	0.31	0.0	0	2	107	0.1	0.28	0.0	0	2	107	0.2	0.46	0.0	0	2
	DAY 50	121	0.0	0.25	0.0	0	2	101	0.1	0.35	0.0	0	2	102	0.1	0.39	0.0	0	2
	DAY 57	119	0.1	0.28	0.0	0	2	97	0.1	0.33	0.0	0	2	99	0.2	0.47	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
17. INSIGHT	VISIT																		
	SCREEN	172	0.1	0.25	0.0	0	2	170	0.1	0.30	0.0	0	2	169	0.1	0.28	0.0	0	1
	DAY 1	172	0.1	0.26	0.0	0	2	170	0.1	0.22	0.0	0	1	169	0.1	0.28	0.0	0	1
	DAY 8	171	0.0	0.24	0.0	0	2	169	0.0	0.11	0.0	0	1	169	0.0	0.15	0.0	0	1
	DAY 15	148	0.0	0.14	0.0	0	1	148	0.0	0.08	0.0	0	1	149	0.0	0.24	0.0	0	2
	DAY 22	139	0.0	0.19	0.0	0	1	133	0.0	0.24	0.0	0	2	143	0.0	0.17	0.0	0	1
	DAY 29	133	0.0	0.17	0.0	0	1	127	0.0	0.22	0.0	0	2	126	0.0	0.09	0.0	0	1
	DAY 36	130	0.0	0.09	0.0	0	1	113	0.0	0.00	0.0	0	0	119	0.0	0.18	0.0	0	1
	DAY 43	123	0.0	0.09	0.0	0	1	107	0.0	0.14	0.0	0	1	107	0.0	0.10	0.0	0	1
	DAY 50	121	0.0	0.09	0.0	0	1	101	0.0	0.00	0.0	0	0	102	0.0	0.14	0.0	0	1
	DAY 57	119	0.0	0.09	0.0	0	1	97	0.0	0.14	0.0	0	1	99	0.0	0.10	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD205.SAS
GENERATED: 12JUL2005 17:43:16 iceadmn3

Table 11.2.2.6.1 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	2.9	0.47	-0.7	0.87	-0.73	0.074	-0.88	-0.58	.
	Q600MG	169	2.9	0.48	-0.7	0.83	-0.73	0.075	-0.88	-0.58	.
	P	169	2.9	0.44	-0.4	0.83	-0.47	0.074	-0.62	-0.32	.
	Q300MG VS P	.	.	.	.	.	-0.26	0.088	-0.44	-0.09	0.003
	Q600MG VS P	.	.	.	.	.	-0.26	0.089	-0.44	-0.09	0.003
DAY 15	Q300MG	172	2.9	0.46	-1.0	0.95	-1.07	0.089	-1.24	-0.89	.
	Q600MG	170	2.9	0.48	-1.1	1.04	-1.09	0.089	-1.27	-0.92	.
	P	169	2.9	0.44	-0.7	0.96	-0.74	0.089	-0.92	-0.57	.
	Q300MG VS P	.	.	.	.	.	-0.32	0.101	-0.52	-0.12	0.002
	Q600MG VS P	.	.	.	.	.	-0.35	0.102	-0.55	-0.15	<.001
DAY 22	Q300MG	172	2.9	0.46	-1.2	1.01	-1.24	0.090	-1.42	-1.06	.
	Q600MG	170	2.9	0.48	-1.4	1.06	-1.33	0.090	-1.51	-1.15	.
	P	169	2.9	0.44	-0.9	1.12	-0.88	0.090	-1.05	-0.70	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.112	-0.58	-0.14	0.001
	Q600MG VS P	.	.	.	.	.	-0.46	0.112	-0.68	-0.24	<.001
DAY 29	Q300MG	172	2.9	0.46	-1.3	1.01	-1.32	0.090	-1.50	-1.14	.
	Q600MG	170	2.9	0.48	-1.5	1.14	-1.50	0.091	-1.68	-1.32	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD208.SAS
GENERATED: 12JUL2005 17:29:13 iceadmn3

Table 11.2.2.6.1 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	2.9	0.44	-1.0	1.09	-1.00	0.091	-1.18	-0.82	.
	Q300MG VS P	.	.	.	.	.	-0.32	0.111	-0.54	-0.10	0.004
	Q600MG VS P	.	.	.	.	.	-0.49	0.112	-0.71	-0.27	<.001
DAY 36	Q300MG	172	2.9	0.46	-1.5	1.07	-1.44	0.092	-1.62	-1.26	.
	Q600MG	170	2.9	0.48	-1.5	1.18	-1.42	0.092	-1.60	-1.24	.
	P	169	2.9	0.44	-1.0	1.16	-0.99	0.092	-1.17	-0.81	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.118	-0.68	-0.22	<.001
	Q600MG VS P	.	.	.	.	.	-0.43	0.118	-0.67	-0.20	<.001
DAY 43	Q300MG	172	2.9	0.46	-1.6	1.11	-1.52	0.094	-1.71	-1.33	.
	Q600MG	170	2.9	0.48	-1.6	1.18	-1.51	0.094	-1.70	-1.32	.
	P	169	2.9	0.44	-1.0	1.12	-0.98	0.094	-1.17	-0.79	.
	Q300MG VS P	.	.	.	.	.	-0.54	0.119	-0.77	-0.31	<.001
	Q600MG VS P	.	.	.	.	.	-0.53	0.119	-0.76	-0.29	<.001
DAY 50	Q300MG	172	2.9	0.46	-1.6	1.10	-1.61	0.093	-1.80	-1.43	.
	Q600MG	170	2.9	0.48	-1.7	1.17	-1.63	0.094	-1.81	-1.44	.
	P	169	2.9	0.44	-1.1	1.13	-1.05	0.093	-1.24	-0.87	.
	Q300MG VS P	.	.	.	.	.	-0.56	0.120	-0.80	-0.33	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD208.SAS
GENERATED: 12JUL2005 17:29:13 iceadmn3

Table 11.2.2.6.1 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.57	0.120	-0.81	-0.34	<.001
DAY 57	Q300MG	172	2.9	0.46	-1.7	1.14	-1.65	0.096	-1.84	-1.46	.
	Q600MG	170	2.9	0.48	-1.7	1.14	-1.68	0.097	-1.87	-1.49	.
	P	169	2.9	0.44	-1.1	1.20	-1.11	0.096	-1.30	-0.92	.
	Q300MG VS P	.	.	.	.	.	-0.54	0.122	-0.78	-0.30	<.001
	Q600MG VS P	.	.	.	.	.	-0.57	0.123	-0.81	-0.33	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD208.SAS
GENERATED: 12JUL2005 17:29:13 iceadmn3

Table 11.2.2.6.2 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	2.9	0.47	-0.7	0.87	-0.73	0.074	-0.88	-0.58	.
	Q600MG	169	2.9	0.48	-0.7	0.83	-0.73	0.075	-0.88	-0.58	.
	P	169	2.9	0.44	-0.4	0.83	-0.47	0.074	-0.62	-0.32	.
	Q300MG VS P	.	.	.	.	.	-0.26	0.088	-0.44	-0.09	0.003
	Q600MG VS P	.	.	.	.	.	-0.26	0.089	-0.44	-0.09	0.003
DAY 15	Q300MG	148	2.9	0.46	-1.1	0.96	-1.10	0.094	-1.28	-0.91	.
	Q600MG	148	2.9	0.47	-1.2	1.03	-1.16	0.094	-1.35	-0.98	.
	P	149	2.9	0.43	-0.8	0.95	-0.82	0.092	-1.01	-0.64	.
	Q300MG VS P	.	.	.	.	.	-0.27	0.108	-0.49	-0.06	0.012
	Q600MG VS P	.	.	.	.	.	-0.34	0.109	-0.55	-0.13	0.002
DAY 22	Q300MG	139	2.9	0.49	-1.3	1.02	-1.27	0.098	-1.46	-1.07	.
	Q600MG	133	2.9	0.47	-1.5	1.01	-1.46	0.101	-1.66	-1.26	.
	P	143	2.8	0.44	-1.0	1.14	-0.97	0.096	-1.16	-0.78	.
	Q300MG VS P	.	.	.	.	.	-0.30	0.122	-0.54	-0.06	0.014
	Q600MG VS P	.	.	.	.	.	-0.50	0.124	-0.74	-0.25	<.001
DAY 29	Q300MG	133	2.9	0.50	-1.4	0.99	-1.42	0.098	-1.61	-1.22	.
	Q600MG	127	2.9	0.47	-1.7	1.07	-1.68	0.101	-1.88	-1.48	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD212.SAS
GENERATED: 12JUL2005 17:29:25 iceadmn3

Table 11.2.2.6.2 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	126	2.8	0.45	-1.2	1.09	-1.23	0.099	-1.43	-1.03	.
	Q300MG VS P	.	.	.	.	.	-0.19	0.121	-0.43	0.05	0.119
	Q600MG VS P	.	.	.	.	.	-0.45	0.124	-0.70	-0.21	<.001
DAY 36	Q300MG	130	2.9	0.49	-1.6	1.05	-1.57	0.102	-1.77	-1.37	.
	Q600MG	113	2.9	0.49	-1.7	1.13	-1.57	0.110	-1.79	-1.36	.
	P	119	2.8	0.44	-1.2	1.18	-1.18	0.105	-1.39	-0.97	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.134	-0.66	-0.13	0.004
	Q600MG VS P	.	.	.	.	.	-0.39	0.140	-0.67	-0.12	0.005
DAY 43	Q300MG	123	2.9	0.48	-1.7	1.06	-1.70	0.106	-1.91	-1.49	.
	Q600MG	107	2.9	0.49	-1.8	1.15	-1.72	0.113	-1.94	-1.49	.
	P	107	2.8	0.44	-1.2	1.12	-1.18	0.111	-1.40	-0.96	.
	Q300MG VS P	.	.	.	.	.	-0.52	0.138	-0.79	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.54	0.143	-0.82	-0.25	<.001
DAY 50	Q300MG	121	2.9	0.49	-1.8	1.02	-1.82	0.105	-2.03	-1.61	.
	Q600MG	101	2.9	0.52	-1.9	1.08	-1.90	0.113	-2.13	-1.68	.
	P	102	2.8	0.45	-1.3	1.12	-1.33	0.111	-1.55	-1.11	.
	Q300MG VS P	.	.	.	.	.	-0.49	0.138	-0.76	-0.22	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD212.SAS
GENERATED: 12JUL2005 17:29:25 iceadmn3

Table 11.2.2.6.2 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.57	0.144	-0.86	-0.29	<.001
DAY 57	Q300MG	119	2.9	0.50	-1.9	1.06	-1.89	0.104	-2.10	-1.69	.
	Q600MG	97	2.9	0.52	-2.0	0.99	-2.02	0.114	-2.24	-1.79	.
	P	99	2.8	0.44	-1.3	1.21	-1.38	0.111	-1.60	-1.16	.
	Q300MG VS P	.	.	.	.	.	-0.51	0.143	-0.80	-0.23	<.001
	Q600MG VS P	.	.	.	.	.	-0.64	0.150	-0.93	-0.34	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD212.SAS
GENERATED: 12JUL2005 17:29:25 iceadmn3

Table 11.2.2.6.3 HAM-D Item 1 Score Effect Size Change from Baseline
Last Observation Carried Forward
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.31	-0.52	-0.09
	Q600MG VS P	-0.31	-0.53	-0.10
DAY 15	Q300MG VS P	-0.34	-0.55	-0.12
	Q600MG VS P	-0.35	-0.56	-0.13
DAY 22	Q300MG VS P	-0.34	-0.55	-0.13
	Q600MG VS P	-0.42	-0.63	-0.20
DAY 29	Q300MG VS P	-0.30	-0.52	-0.09
	Q600MG VS P	-0.44	-0.66	-0.23
DAY 36	Q300MG VS P	-0.41	-0.62	-0.19
	Q600MG VS P	-0.37	-0.59	-0.16
DAY 43	Q300MG VS P	-0.48	-0.70	-0.27
	Q600MG VS P	-0.46	-0.67	-0.24
DAY 50	Q300MG VS P	-0.50	-0.72	-0.29
	Q600MG VS P	-0.50	-0.71	-0.28
DAY 57	Q300MG VS P	-0.46	-0.68	-0.25
	Q600MG VS P	-0.49	-0.70	-0.27

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD209.SAS
GENERATED: 12JUL2005 17:29:16 iceadmn3

Table 11.2.2.6.4 HAM-D Item 1 Score Effect Size Change from Baseline
Observed Cases
Intent-to-Treat Population

VISIT	TREATMENT	EFFECT SIZE	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER
DAY 8	Q300MG VS P	-0.31	-0.52	-0.09
	Q600MG VS P	-0.31	-0.53	-0.10
DAY 15	Q300MG VS P	-0.29	-0.52	-0.06
	Q600MG VS P	-0.35	-0.57	-0.12
DAY 22	Q300MG VS P	-0.28	-0.51	-0.04
	Q600MG VS P	-0.46	-0.70	-0.22
DAY 29	Q300MG VS P	-0.18	-0.43	0.06
	Q600MG VS P	-0.42	-0.67	-0.17
DAY 36	Q300MG VS P	-0.35	-0.60	-0.10
	Q600MG VS P	-0.34	-0.60	-0.08
DAY 43	Q300MG VS P	-0.48	-0.74	-0.21
	Q600MG VS P	-0.47	-0.74	-0.20
DAY 50	Q300MG VS P	-0.46	-0.73	-0.19
	Q600MG VS P	-0.52	-0.80	-0.24
DAY 57	Q300MG VS P	-0.45	-0.72	-0.18
	Q600MG VS P	-0.57	-0.86	-0.29

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD213.SAS
GENERATED: 12JUL2005 17:29:28 iceadmn3

Table 11.2.3.1.1 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	VISIT																		
	SCREEN	172	4.4	0.52	4.0	3	6	170	4.5	0.64	4.0	3	6	169	4.3	0.60	4.0	3	6
	DAY 1	172	4.4	0.52	4.0	3	6	170	4.5	0.62	4.0	4	6	169	4.4	0.60	4.0	3	6
	DAY 8	171	3.9	0.83	4.0	1	5	169	3.9	0.86	4.0	2	6	169	4.2	0.77	4.0	2	6
	DAY 15	172	3.5	0.96	4.0	1	5	170	3.5	1.04	3.0	1	6	169	3.9	0.97	4.0	1	7
	DAY 22	172	3.3	1.05	3.0	1	5	170	3.2	1.18	3.0	1	5	169	3.8	1.11	4.0	1	7
	DAY 29	172	3.2	1.09	3.0	1	5	170	3.1	1.23	3.0	1	6	169	3.7	1.16	4.0	1	7
	DAY 36	172	3.0	1.21	3.0	1	5	170	3.0	1.26	3.0	1	6	169	3.7	1.18	4.0	1	7
	DAY 43	172	2.9	1.21	3.0	1	5	170	3.0	1.25	3.0	1	6	169	3.6	1.21	4.0	1	7
	DAY 50	172	2.9	1.20	3.0	1	5	170	3.0	1.30	3.0	1	6	169	3.6	1.30	4.0	1	7
	DAY 57	172	2.8	1.23	3.0	1	5	170	2.8	1.36	3.0	0	6	169	3.5	1.33	4.0	1	7
CHANGE FROM BASELINE	DAY 8	171	-0.6	0.83	0.0	-3	1	169	-0.6	0.73	0.0	-3	1	169	-0.2	0.57	0.0	-3	1
	DAY 15	172	-0.9	1.01	-1.0	-3	1	170	-1.0	0.95	-1.0	-3	1	169	-0.5	0.87	0.0	-3	2
	DAY 22	172	-1.1	1.06	-1.0	-4	1	170	-1.3	1.15	-1.0	-4	1	169	-0.6	1.03	0.0	-4	2
	DAY 29	172	-1.2	1.11	-1.0	-4	1	170	-1.5	1.23	-1.0	-4	1	169	-0.7	1.08	0.0	-4	2
	DAY 36	172	-1.4	1.20	-1.0	-4	1	170	-1.5	1.29	-1.0	-4	1	169	-0.8	1.12	0.0	-4	2
	DAY 43	172	-1.5	1.17	-1.0	-4	1	170	-1.5	1.27	-1.0	-4	1	169	-0.8	1.17	0.0	-4	2

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI201.SAS
GENERATED: 12JUL2005 17:39:50 iceadmn3

Table 11.2.3.1.1 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	VISIT																		
	DAY 50	172	-1.6	1.19	-1.0	-4	1	170	-1.6	1.34	-2.0	-4	1	169	-0.8	1.26	0.0	-4	2
	DAY 57	172	-1.6	1.22	-2.0	-4	1	170	-1.7	1.40	-2.0	-5	1	169	-0.9	1.28	-1.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI201.SAS
GENERATED: 12JUL2005 17:39:50 iceadmn3

Table 11.2.3.1.2 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	VISIT																		
	SCREEN	172	4.4	0.52	4.0	3	6	170	4.5	0.64	4.0	3	6	169	4.3	0.60	4.0	3	6
	DAY 1	172	4.4	0.52	4.0	3	6	170	4.5	0.62	4.0	4	6	169	4.4	0.60	4.0	3	6
	DAY 8	171	3.9	0.83	4.0	1	5	169	3.9	0.86	4.0	2	6	169	4.2	0.77	4.0	2	6
	DAY 15	148	3.5	0.95	4.0	1	5	147	3.5	1.07	3.0	1	6	148	3.9	0.94	4.0	1	6
	DAY 22	139	3.3	1.06	3.0	1	5	132	3.1	1.22	3.0	1	5	142	3.6	1.09	4.0	1	6
	DAY 29	133	3.1	1.08	3.0	1	5	127	2.8	1.20	3.0	1	6	127	3.5	1.10	4.0	1	6
	DAY 36	130	2.8	1.21	3.0	1	5	114	2.6	1.22	3.0	1	6	119	3.4	1.12	4.0	1	5
	DAY 43	122	2.6	1.16	3.0	1	5	107	2.6	1.16	3.0	1	5	106	3.3	1.19	4.0	1	5
	DAY 50	121	2.6	1.13	3.0	1	5	101	2.5	1.25	2.0	1	5	102	3.2	1.33	4.0	1	6
	DAY 57	119	2.5	1.16	3.0	1	5	96	2.2	1.24	2.0	0	5	101	3.1	1.30	3.0	1	5
CHANGE FROM BASELINE	DAY 8	171	-0.6	0.83	0.0	-3	1	169	-0.6	0.73	0.0	-3	1	169	-0.2	0.57	0.0	-3	1
	DAY 15	148	-1.0	1.02	-1.0	-3	1	147	-1.0	0.97	-1.0	-3	1	148	-0.5	0.88	0.0	-3	1
	DAY 22	139	-1.2	1.08	-1.0	-4	1	132	-1.4	1.17	-1.0	-4	1	142	-0.7	1.06	0.0	-4	1
	DAY 29	133	-1.3	1.12	-1.0	-4	1	127	-1.7	1.23	-2.0	-4	1	127	-0.9	1.13	-1.0	-4	1
	DAY 36	130	-1.6	1.22	-1.5	-4	1	114	-1.9	1.25	-2.0	-4	0	119	-1.0	1.19	-1.0	-4	1
	DAY 43	122	-1.8	1.16	-2.0	-4	1	107	-1.9	1.23	-2.0	-4	1	106	-1.0	1.24	-1.0	-4	1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI200.SAS
GENERATED: 12JUL2005 17:39:47 iceadmn3

Table 11.2.3.1.2 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	VISIT																		
	DAY 50	121	-1.8	1.17	-2.0	-4	1	101	-2.0	1.31	-2.0	-4	1	102	-1.1	1.35	-1.0	-4	1
	DAY 57	119	-1.9	1.20	-2.0	-4	1	96	-2.3	1.30	-3.0	-5	1	101	-1.2	1.33	-1.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI200.SAS
GENERATED: 12JUL2005 17:39:47 iceadmn3

Table 11.2.3.2.1 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	4.4	0.52	-0.6	0.83	-0.58	0.071	-0.72	-0.44	.
	Q600MG	169	4.5	0.62	-0.6	0.73	-0.56	0.071	-0.71	-0.42	.
	P	169	4.4	0.60	-0.2	0.57	-0.26	0.071	-0.40	-0.11	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.073	-0.47	-0.18	<.001
	Q600MG VS P	.	.	.	.	.	-0.31	0.073	-0.45	-0.16	<.001
DAY 15	Q300MG	172	4.4	0.52	-0.9	1.01	-0.93	0.094	-1.12	-0.75	.
	Q600MG	170	4.5	0.62	-1.0	0.95	-0.94	0.095	-1.13	-0.76	.
	P	169	4.4	0.60	-0.5	0.87	-0.52	0.095	-0.70	-0.33	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.095	-0.60	-0.23	<.001
	Q600MG VS P	.	.	.	.	.	-0.43	0.095	-0.62	-0.24	<.001
DAY 22	Q300MG	172	4.4	0.52	-1.1	1.06	-1.11	0.106	-1.32	-0.90	.
	Q600MG	170	4.5	0.62	-1.3	1.15	-1.22	0.106	-1.43	-1.01	.
	P	169	4.4	0.60	-0.6	1.03	-0.65	0.107	-0.87	-0.44	.
	Q300MG VS P	.	.	.	.	.	-0.46	0.109	-0.67	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.57	0.109	-0.78	-0.35	<.001
DAY 29	Q300MG	172	4.4	0.52	-1.2	1.11	-1.22	0.111	-1.44	-1.00	.
	Q600MG	170	4.5	0.62	-1.5	1.23	-1.38	0.111	-1.60	-1.16	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215.SAS
GENERATED: 12JUL2005 17:28:23 iceadmn3

Table 11.2.3.2.1 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	4.4	0.60	-0.7	1.08	-0.70	0.112	-0.92	-0.48	.
	Q300MG VS P	.	.	.	.	.	-0.52	0.115	-0.75	-0.29	<.001
	Q600MG VS P	.	.	.	.	.	-0.68	0.116	-0.91	-0.45	<.001
DAY 36	Q300MG	172	4.4	0.52	-1.4	1.20	-1.41	0.109	-1.63	-1.20	.
	Q600MG	170	4.5	0.62	-1.5	1.29	-1.43	0.110	-1.65	-1.21	.
	P	169	4.4	0.60	-0.8	1.12	-0.76	0.110	-0.97	-0.54	.
	Q300MG VS P	.	.	.	.	.	-0.66	0.124	-0.90	-0.41	<.001
	Q600MG VS P	.	.	.	.	.	-0.67	0.125	-0.92	-0.43	<.001
DAY 43	Q300MG	172	4.4	0.52	-1.5	1.17	-1.48	0.108	-1.69	-1.26	.
	Q600MG	170	4.5	0.62	-1.5	1.27	-1.40	0.108	-1.62	-1.19	.
	P	169	4.4	0.60	-0.8	1.17	-0.77	0.108	-0.99	-0.56	.
	Q300MG VS P	.	.	.	.	.	-0.70	0.125	-0.95	-0.46	<.001
	Q600MG VS P	.	.	.	.	.	-0.63	0.125	-0.88	-0.38	<.001
DAY 50	Q300MG	172	4.4	0.52	-1.6	1.19	-1.56	0.114	-1.78	-1.33	.
	Q600MG	170	4.5	0.62	-1.6	1.34	-1.47	0.115	-1.69	-1.24	.
	P	169	4.4	0.60	-0.8	1.26	-0.82	0.115	-1.05	-0.60	.
	Q300MG VS P	.	.	.	.	.	-0.74	0.130	-0.99	-0.48	<.001

(Continued)

Table 11.2.3.2.1 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.64	0.131	-0.90	-0.39	<.001
DAY 57	Q300MG	172	4.4	0.52	-1.6	1.22	-1.63	0.117	-1.86	-1.40	.
	Q600MG	170	4.5	0.62	-1.7	1.40	-1.66	0.118	-1.90	-1.43	.
	P	169	4.4	0.60	-0.9	1.28	-0.95	0.117	-1.18	-0.71	.
	Q300MG VS P	.	.	.	.	.	-0.68	0.135	-0.95	-0.42	<.001
	Q600MG VS P	.	.	.	.	.	-0.72	0.136	-0.98	-0.45	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215.SAS
GENERATED: 12JUL2005 17:28:23 iceadmn3

Table 11.2.3.2.2 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	4.4	0.52	-0.6	0.83	-0.58	0.071	-0.72	-0.44	.
	Q600MG	169	4.5	0.62	-0.6	0.73	-0.56	0.071	-0.71	-0.42	.
	P	169	4.4	0.60	-0.2	0.57	-0.26	0.071	-0.40	-0.11	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.073	-0.47	-0.18	<.001
	Q600MG VS P	.	.	.	.	.	-0.31	0.073	-0.45	-0.16	<.001
DAY 15	Q300MG	148	4.4	0.52	-1.0	1.02	-0.98	0.102	-1.19	-0.78	.
	Q600MG	147	4.5	0.63	-1.0	0.97	-1.00	0.103	-1.20	-0.79	.
	P	148	4.4	0.60	-0.5	0.88	-0.59	0.101	-0.79	-0.39	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.101	-0.59	-0.19	<.001
	Q600MG VS P	.	.	.	.	.	-0.41	0.102	-0.61	-0.20	<.001
DAY 22	Q300MG	139	4.4	0.52	-1.2	1.08	-1.17	0.116	-1.40	-0.94	.
	Q600MG	132	4.6	0.65	-1.4	1.17	-1.37	0.119	-1.60	-1.13	.
	P	142	4.4	0.59	-0.7	1.06	-0.77	0.116	-1.00	-0.54	.
	Q300MG VS P	.	.	.	.	.	-0.40	0.121	-0.64	-0.16	0.001
	Q600MG VS P	.	.	.	.	.	-0.59	0.123	-0.84	-0.35	<.001
DAY 29	Q300MG	133	4.4	0.52	-1.3	1.12	-1.35	0.123	-1.60	-1.11	.
	Q600MG	127	4.5	0.64	-1.7	1.23	-1.60	0.126	-1.85	-1.35	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI223.SAS
GENERATED: 12JUL2005 17:28:38 iceadmn3

Table 11.2.3.2.2 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	127	4.3	0.55	-0.9	1.13	-0.90	0.125	-1.15	-0.65	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.128	-0.70	-0.20	<.001
	Q600MG VS P	.	.	.	.	.	-0.70	0.131	-0.95	-0.44	<.001
DAY 36	Q300MG	130	4.4	0.52	-1.6	1.22	-1.60	0.122	-1.84	-1.35	.
	Q600MG	114	4.5	0.64	-1.9	1.25	-1.74	0.130	-2.00	-1.49	.
	P	119	4.4	0.58	-1.0	1.19	-1.01	0.125	-1.25	-0.76	.
	Q300MG VS P	.	.	.	.	.	-0.59	0.143	-0.87	-0.31	<.001
	Q600MG VS P	.	.	.	.	.	-0.74	0.149	-1.03	-0.44	<.001
DAY 43	Q300MG	122	4.4	0.53	-1.8	1.16	-1.70	0.124	-1.95	-1.46	.
	Q600MG	107	4.5	0.60	-1.9	1.23	-1.77	0.131	-2.03	-1.52	.
	P	106	4.3	0.57	-1.0	1.24	-1.00	0.129	-1.26	-0.74	.
	Q300MG VS P	.	.	.	.	.	-0.70	0.148	-0.99	-0.41	<.001
	Q600MG VS P	.	.	.	.	.	-0.77	0.153	-1.07	-0.47	<.001
DAY 50	Q300MG	121	4.4	0.52	-1.8	1.17	-1.81	0.133	-2.08	-1.55	.
	Q600MG	101	4.5	0.63	-2.0	1.31	-1.91	0.142	-2.19	-1.62	.
	P	102	4.3	0.54	-1.1	1.35	-1.15	0.140	-1.43	-0.88	.
	Q300MG VS P	.	.	.	.	.	-0.66	0.156	-0.97	-0.35	<.001

(Continued)

Table 11.2.3.2.2 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.75	0.165	-1.08	-0.43	<.001
DAY 57	Q300MG	119	4.4	0.53	-1.9	1.20	-1.90	0.132	-2.16	-1.64	.
	Q600MG	96	4.5	0.62	-2.3	1.30	-2.26	0.144	-2.55	-1.98	.
	P	101	4.3	0.57	-1.2	1.33	-1.28	0.139	-1.55	-1.00	.
	Q300MG VS P	.	.	.	.	.	-0.62	0.160	-0.94	-0.31	<.001
	Q600MG VS P	.	.	.	.	.	-0.98	0.169	-1.32	-0.65	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI223.SAS
GENERATED: 12JUL2005 17:28:38 iceadmn3

Table 11.2.3.2.3 CGI Severity of Illness Score Effect Size Change from Baseline
Last Observation Carried Forward
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.46	-0.67	-0.24
	Q600MG VS P	-0.47	-0.69	-0.25
DAY 15	Q300MG VS P	-0.44	-0.66	-0.23
	Q600MG VS P	-0.47	-0.68	-0.25
DAY 22	Q300MG VS P	-0.44	-0.65	-0.22
	Q600MG VS P	-0.52	-0.73	-0.30
DAY 29	Q300MG VS P	-0.47	-0.69	-0.26
	Q600MG VS P	-0.59	-0.81	-0.37
DAY 36	Q300MG VS P	-0.56	-0.78	-0.35
	Q600MG VS P	-0.56	-0.77	-0.34
DAY 43	Q300MG VS P	-0.60	-0.82	-0.38
	Q600MG VS P	-0.52	-0.73	-0.30
DAY 50	Q300MG VS P	-0.60	-0.81	-0.38
	Q600MG VS P	-0.49	-0.71	-0.28
DAY 57	Q300MG VS P	-0.55	-0.77	-0.33
	Q600MG VS P	-0.53	-0.75	-0.32

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI216.SAS
GENERATED: 12JUL2005 17:28:26 iceadmn3

Table 11.2.3.2.4 CGI Severity of Illness Score Effect Size Change from Baseline
Observed Cases
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.46	-0.67	-0.24
	Q600MG VS P	-0.47	-0.69	-0.25
DAY 15	Q300MG VS P	-0.41	-0.64	-0.18
	Q600MG VS P	-0.44	-0.67	-0.21
DAY 22	Q300MG VS P	-0.37	-0.61	-0.14
	Q600MG VS P	-0.53	-0.78	-0.29
DAY 29	Q300MG VS P	-0.40	-0.65	-0.16
	Q600MG VS P	-0.59	-0.84	-0.34
DAY 36	Q300MG VS P	-0.49	-0.74	-0.24
	Q600MG VS P	-0.60	-0.87	-0.34
DAY 43	Q300MG VS P	-0.59	-0.85	-0.32
	Q600MG VS P	-0.63	-0.90	-0.35
DAY 50	Q300MG VS P	-0.53	-0.79	-0.26
	Q600MG VS P	-0.57	-0.85	-0.29
DAY 57	Q300MG VS P	-0.50	-0.76	-0.23
	Q600MG VS P	-0.75	-1.04	-0.46

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI224.SAS
GENERATED: 12JUL2005 17:28:41 iceadmn3

FIGURE 11.2.3.3.1 CGI SEVERITY OF ILLNESS (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

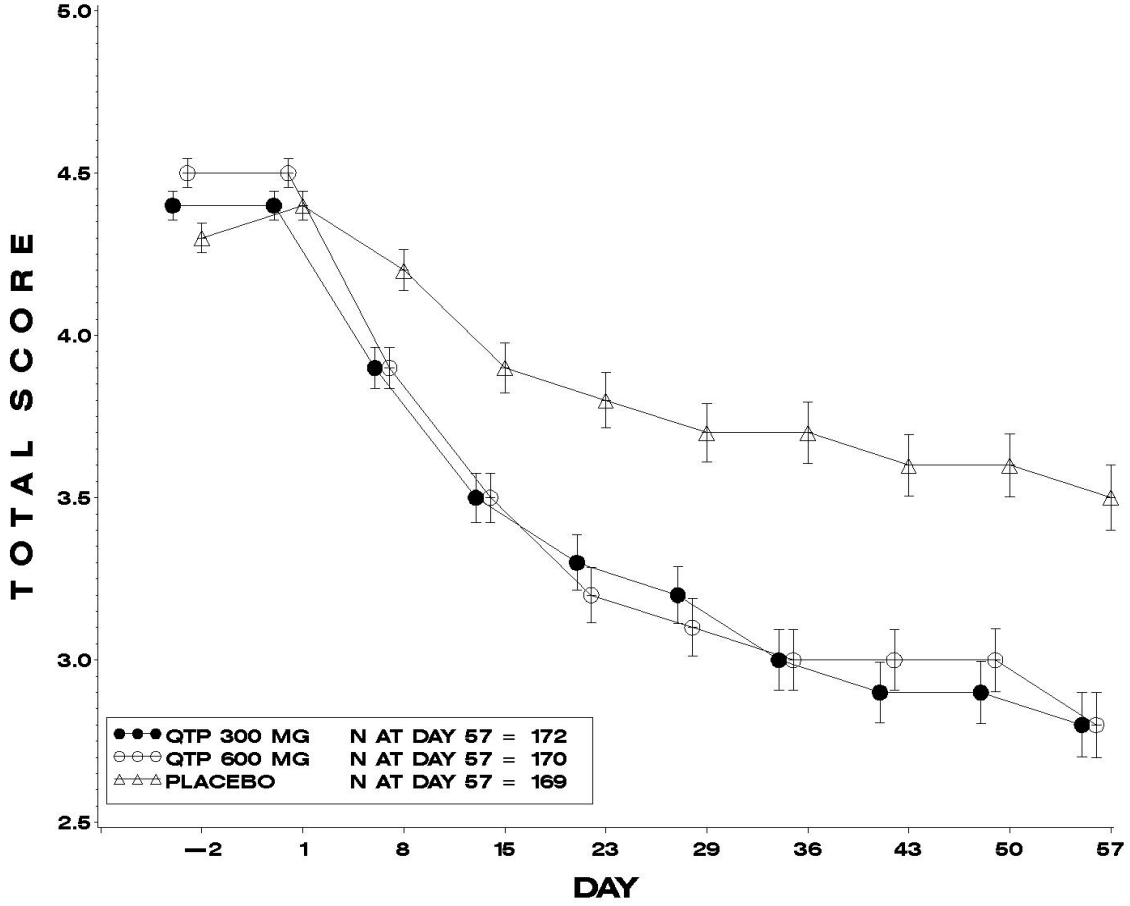

FIGURE 11.2.3.3.2 CGI SEVERITY OF ILLNESS CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

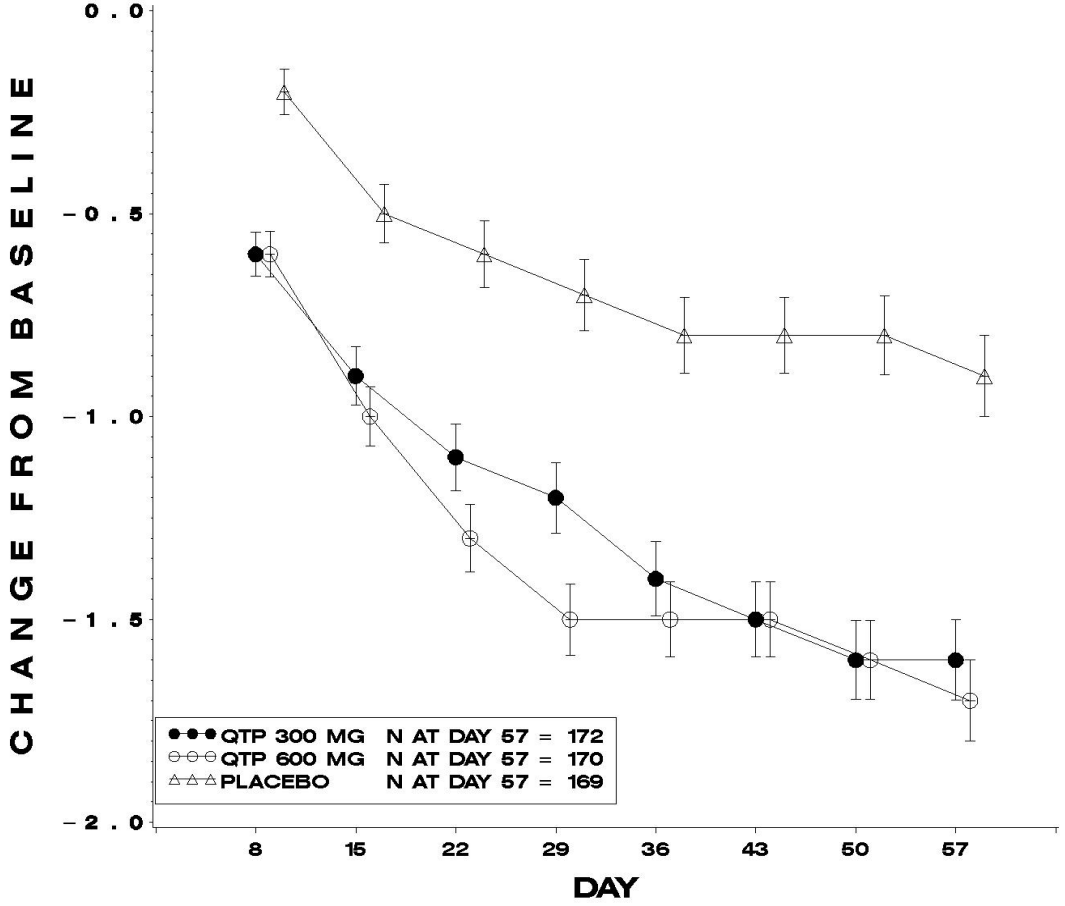

FIGURE 11.2.3.3.3 CGI SEVERITY OF ILLNESS CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)'

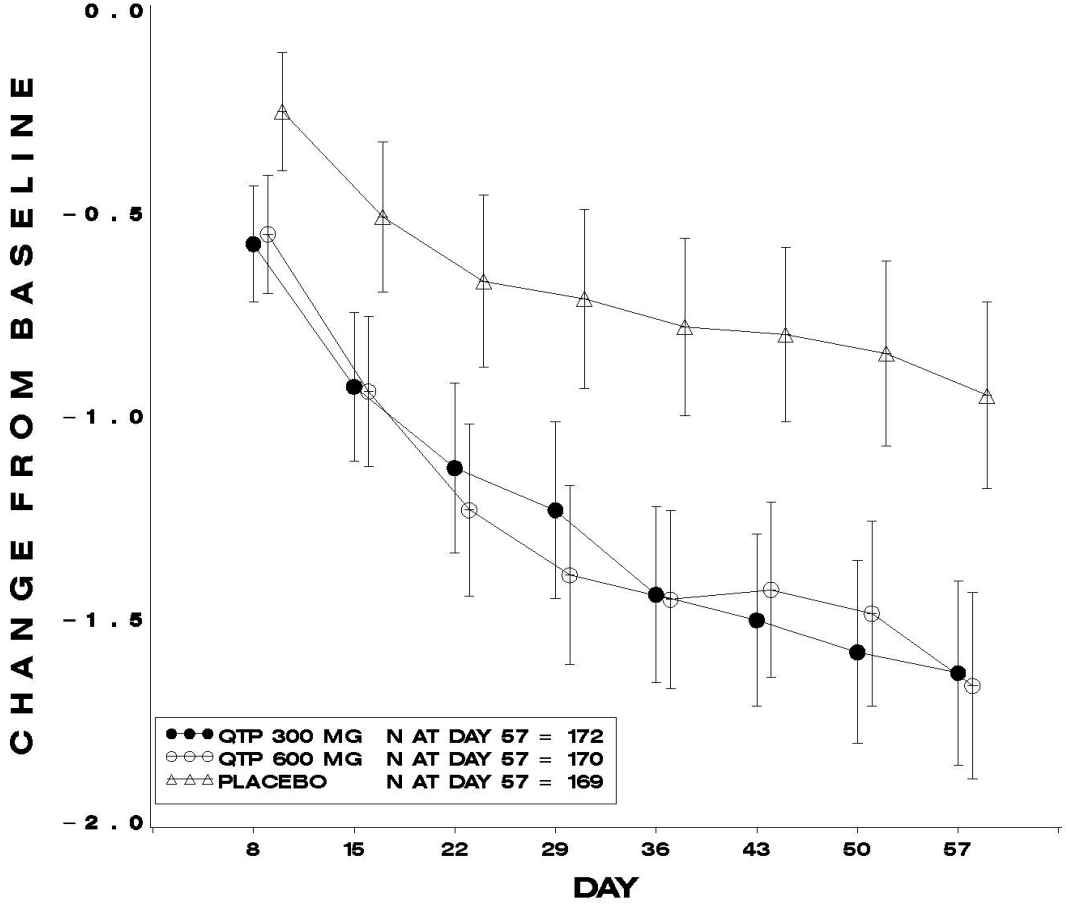

Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	VISIT																		
	SCREEN	116	4.4	0.53	4.0	3	6	114	4.5	0.64	4.0	3	6	112	4.4	0.64	4.0	3	6
	DAY 1	116	4.4	0.51	4.0	3	5	114	4.6	0.62	4.5	4	6	112	4.5	0.63	4.0	3	6
	DAY 8	115	3.8	0.88	4.0	1	5	114	3.9	0.89	4.0	2	6	112	4.3	0.75	4.0	3	6
	DAY 15	116	3.4	1.01	4.0	1	5	114	3.5	1.08	4.0	1	6	112	4.0	0.97	4.0	1	7
	DAY 22	116	3.2	1.11	3.0	1	5	114	3.1	1.23	3.0	1	5	112	3.8	1.15	4.0	1	7
	DAY 29	116	3.1	1.10	3.0	1	5	114	2.9	1.27	3.0	1	6	112	3.8	1.18	4.0	1	7
	DAY 36	116	2.8	1.25	3.0	1	5	114	2.9	1.27	3.0	1	6	112	3.7	1.25	4.0	1	7
	DAY 43	116	2.8	1.21	3.0	1	5	114	2.9	1.25	3.0	1	6	112	3.7	1.27	4.0	1	7
	DAY 50	116	2.7	1.20	3.0	1	5	114	2.8	1.33	3.0	1	6	112	3.6	1.33	4.0	1	7
	DAY 57	116	2.7	1.22	3.0	1	5	114	2.7	1.34	3.0	1	6	112	3.6	1.34	4.0	1	7
CHANGE FROM BASELINE	DAY 8	115	-0.6	0.87	0.0	-3	1	114	-0.6	0.78	-1.0	-3	1	112	-0.2	0.55	0.0	-2	1
	DAY 15	116	-1.0	1.05	-1.0	-3	1	114	-1.1	1.01	-1.0	-3	1	112	-0.5	0.85	0.0	-3	2
	DAY 22	116	-1.2	1.10	-1.0	-4	1	114	-1.5	1.19	-1.0	-4	0	112	-0.6	1.04	0.0	-4	2
	DAY 29	116	-1.3	1.13	-1.0	-4	1	114	-1.6	1.28	-2.0	-4	0	112	-0.7	1.10	0.0	-4	2
	DAY 36	116	-1.6	1.24	-2.0	-4	1	114	-1.7	1.30	-2.0	-4	0	112	-0.7	1.19	0.0	-4	2
	DAY 43	116	-1.6	1.19	-2.0	-4	0	114	-1.7	1.25	-2.0	-4	0	112	-0.8	1.23	0.0	-4	2

(Continued)

Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	VISIT																		
	DAY 50	116	-1.7	1.19	-2.0	-4	0	114	-1.7	1.34	-2.0	-4	1	112	-0.8	1.28	0.0	-4	2
	DAY 57	116	-1.7	1.20	-2.0	-4	0	114	-1.9	1.38	-2.0	-4	0	112	-0.8	1.29	0.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI203.SAS
GENERATED: 12JUL2005 17:39:55 iceadmn3

Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	VISIT																		
	SCREEN	56	4.4	0.50	4.0	4	5	56	4.4	0.62	4.0	3	6	57	4.2	0.51	4.0	3	5
	DAY 1	56	4.5	0.54	4.0	4	6	56	4.4	0.59	4.0	4	6	57	4.4	0.55	4.0	3	5
	DAY 8	56	3.9	0.70	4.0	2	5	55	3.9	0.80	4.0	2	6	57	4.1	0.81	4.0	2	5
	DAY 15	56	3.7	0.84	4.0	2	5	56	3.6	0.97	3.0	1	6	57	3.8	0.97	4.0	1	5
	DAY 22	56	3.6	0.87	4.0	2	5	56	3.5	1.03	3.5	1	5	57	3.7	1.02	4.0	1	5
	DAY 29	56	3.4	1.06	3.0	1	5	56	3.3	1.11	3.0	1	5	57	3.6	1.10	4.0	1	5
	DAY 36	56	3.4	1.05	3.0	1	5	56	3.2	1.22	3.0	1	5	57	3.5	1.02	4.0	1	5
	DAY 43	56	3.2	1.17	3.0	1	5	56	3.3	1.21	3.0	1	5	57	3.5	1.09	4.0	1	5
	DAY 50	56	3.2	1.14	3.0	1	5	56	3.2	1.22	3.0	1	5	57	3.5	1.24	4.0	1	6
	DAY 57	56	3.1	1.19	3.0	1	5	56	3.0	1.37	3.0	0	5	57	3.2	1.27	3.0	1	5
CHANGE FROM BASELINE	DAY 8	56	-0.5	0.76	0.0	-3	1	55	-0.5	0.60	0.0	-2	1	57	-0.3	0.63	0.0	-3	0
	DAY 15	56	-0.8	0.92	-1.0	-3	1	56	-0.8	0.81	-1.0	-3	1	57	-0.5	0.93	0.0	-3	0
	DAY 22	56	-0.9	0.94	-1.0	-3	0	56	-0.9	0.94	-1.0	-3	1	57	-0.7	1.02	0.0	-4	1
	DAY 29	56	-1.1	1.05	-1.0	-4	1	56	-1.1	1.04	-1.0	-3	1	57	-0.8	1.05	0.0	-3	1
	DAY 36	56	-1.1	1.06	-1.0	-4	1	56	-1.2	1.25	-1.0	-4	1	57	-0.8	0.99	-1.0	-3	1
	DAY 43	56	-1.3	1.10	-1.0	-4	1	56	-1.1	1.22	-1.0	-4	1	57	-0.8	1.07	-1.0	-3	1

(Continued)

Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	VISIT																		
	DAY 50	56	-1.3	1.16	-1.0	-4	1	56	-1.2	1.25	-1.0	-4	1	57	-0.8	1.25	0.0	-4	1
	DAY 57	56	-1.4	1.23	-1.0	-4	1	56	-1.4	1.39	-1.0	-5	1	57	-1.2	1.22	-1.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI203.SAS
GENERATED: 12JUL2005 17:39:55 iceadmn3

Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	VISIT																		
	SCREEN	116	4.4	0.53	4.0	3	6	114	4.5	0.64	4.0	3	6	112	4.4	0.64	4.0	3	6
	DAY 1	116	4.4	0.51	4.0	3	5	114	4.6	0.62	4.5	4	6	112	4.5	0.63	4.0	3	6
	DAY 8	115	3.8	0.88	4.0	1	5	114	3.9	0.89	4.0	2	6	112	4.3	0.75	4.0	3	6
	DAY 15	103	3.4	0.98	4.0	1	5	104	3.5	1.10	3.5	1	6	96	3.9	0.91	4.0	1	6
	DAY 22	95	3.1	1.12	3.0	1	5	93	2.9	1.23	3.0	1	5	92	3.7	1.09	4.0	1	6
	DAY 29	93	3.0	1.07	3.0	1	5	91	2.7	1.22	3.0	1	6	79	3.5	1.07	4.0	1	6
	DAY 36	90	2.6	1.21	3.0	1	5	83	2.6	1.22	3.0	1	6	74	3.3	1.14	4.0	1	5
	DAY 43	86	2.5	1.12	3.0	1	5	77	2.5	1.12	2.0	1	5	67	3.2	1.18	4.0	1	5
	DAY 50	87	2.4	1.08	2.0	1	5	71	2.3	1.22	2.0	1	5	63	3.1	1.28	4.0	1	5
	DAY 57	83	2.4	1.10	2.0	1	5	67	2.1	1.15	2.0	1	5	60	3.2	1.24	4.0	1	5
CHANGE FROM BASELINE	DAY 8	115	-0.6	0.87	0.0	-3	1	114	-0.6	0.78	-1.0	-3	1	112	-0.2	0.55	0.0	-2	1
	DAY 15	103	-1.0	1.05	-1.0	-3	1	104	-1.1	1.02	-1.0	-3	1	96	-0.5	0.83	0.0	-3	1
	DAY 22	95	-1.2	1.12	-1.0	-4	1	93	-1.6	1.18	-2.0	-4	0	92	-0.7	1.06	0.0	-4	1
	DAY 29	93	-1.4	1.15	-1.0	-4	1	91	-1.8	1.26	-2.0	-4	0	79	-0.9	1.14	-1.0	-4	1
	DAY 36	90	-1.7	1.26	-2.0	-4	1	83	-1.9	1.24	-2.0	-4	0	74	-1.1	1.26	-1.0	-4	1
	DAY 43	86	-1.8	1.16	-2.0	-4	0	77	-2.0	1.18	-2.0	-4	0	67	-1.1	1.32	-1.0	-4	1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI202.SAS
GENERATED: 12JUL2005 17:39:53 iceadmn3

Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	VISIT																		
	DAY 50	87	-1.9	1.15	-2.0	-4	0	71	-2.2	1.26	-2.0	-4	1	63	-1.2	1.33	-1.0	-4	1
	DAY 57	83	-2.0	1.16	-2.0	-4	0	67	-2.4	1.23	-3.0	-4	0	60	-1.1	1.38	-1.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI202.SAS
GENERATED: 12JUL2005 17:39:53 iceadmn3

Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	VISIT																		
	SCREEN	56	4.4	0.50	4.0	4	5	56	4.4	0.62	4.0	3	6	57	4.2	0.51	4.0	3	5
	DAY 1	56	4.5	0.54	4.0	4	6	56	4.4	0.59	4.0	4	6	57	4.4	0.55	4.0	3	5
	DAY 8	56	3.9	0.70	4.0	2	5	55	3.9	0.80	4.0	2	6	57	4.1	0.81	4.0	2	5
	DAY 15	45	3.6	0.87	4.0	2	5	43	3.5	1.01	3.0	1	6	52	3.8	1.01	4.0	1	5
	DAY 22	44	3.5	0.87	4.0	2	5	39	3.5	1.12	4.0	1	5	50	3.6	1.08	4.0	1	5
	DAY 29	40	3.3	1.09	3.0	1	5	36	3.1	1.15	3.0	1	5	48	3.5	1.17	4.0	1	5
	DAY 36	40	3.2	1.10	3.0	1	5	31	2.7	1.24	3.0	1	5	45	3.5	1.10	3.0	1	5
	DAY 43	36	3.0	1.21	3.0	1	5	30	2.8	1.24	3.0	1	5	39	3.5	1.19	4.0	1	5
	DAY 50	34	2.9	1.15	3.0	1	5	30	2.8	1.29	3.0	1	5	39	3.4	1.41	4.0	1	6
	DAY 57	36	2.9	1.21	3.0	1	5	29	2.4	1.43	2.0	0	5	41	3.0	1.39	3.0	1	5
CHANGE FROM BASELINE	DAY 8	56	-0.5	0.76	0.0	-3	1	55	-0.5	0.60	0.0	-2	1	57	-0.3	0.63	0.0	-3	0
	DAY 15	45	-0.9	0.94	-1.0	-3	1	43	-0.9	0.86	-1.0	-3	1	52	-0.6	0.96	0.0	-3	0
	DAY 22	44	-1.0	0.98	-1.0	-3	0	39	-0.9	1.00	-1.0	-3	1	50	-0.7	1.07	0.0	-4	1
	DAY 29	40	-1.2	1.07	-1.0	-4	1	36	-1.3	1.10	-1.0	-3	1	48	-0.8	1.12	0.0	-3	1
	DAY 36	40	-1.3	1.09	-1.0	-4	1	31	-1.7	1.29	-2.0	-4	0	45	-0.9	1.05	-1.0	-3	1
	DAY 43	36	-1.6	1.13	-1.0	-4	1	30	-1.6	1.33	-1.5	-4	1	39	-0.8	1.09	-1.0	-3	1

(Continued)

Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	VISIT																		
	DAY 50	34	-1.6	1.19	-1.0	-4	1	30	-1.6	1.35	-2.0	-4	1	39	-1.0	1.39	-1.0	-4	1
	DAY 57	36	-1.6	1.27	-1.5	-4	1	29	-2.1	1.44	-2.0	-5	1	41	-1.3	1.25	-1.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI202.SAS
GENERATED: 12JUL2005 17:39:53 iceadmn3

Table 11.2.3.5.1 CGI Severity of Illness Score Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 300 MG											
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
SCREEN	172	0	0	0	0	1	0.6	99	57.6	71	41.3	1	0.6
DAY 1	172	0	0	0	0	1	0.6	96	55.8	74	43.0	1	0.6
DAY 8	171	2	1.2	9	5.3	32	18.7	95	55.6	33	19.3	0	0
DAY 15	172	5	2.9	21	12.2	47	27.3	78	45.3	21	12.2	0	0
DAY 22	172	10	5.8	23	13.4	60	34.9	57	33.1	22	12.8	0	0
DAY 29	172	13	7.6	28	16.3	60	34.9	51	29.7	20	11.6	0	0
DAY 36	172	28	16.3	23	13.4	59	34.3	44	25.6	18	10.5	0	0
DAY 43	172	27	15.7	34	19.8	53	30.8	41	23.8	17	9.9	0	0
DAY 50	172	28	16.3	37	21.5	55	32.0	36	20.9	16	9.3	0	0
DAY 57	172	31	18.0	38	22.1	50	29.1	37	21.5	16	9.3	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI206.SAS
GENERATED: 12JUL2005 17:40:00 iceadmn3

Table 11.2.3.5.1 CGI Severity of Illness Score Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT													
		QUETIAPINE 600 MG													
		NOT ASSESSED		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL														
SCREEN	170	0	0	0	0	0	0	4	2.4	92	54.1	65	38.2	9	5.3
DAY 1	170	0	0	0	0	0	0	0	0	94	55.3	65	38.2	11	6.5
DAY 8	169	0	0	0	0	7	4.1	46	27.2	73	43.2	40	23.7	3	1.8
DAY 15	170	0	0	4	2.4	22	12.9	61	35.9	52	30.6	28	16.5	3	1.8
DAY 22	170	0	0	16	9.4	29	17.1	50	29.4	49	28.8	26	15.3	0	0
DAY 29	170	0	0	22	12.9	35	20.6	45	26.5	48	28.2	19	11.2	1	0.6
DAY 36	170	0	0	27	15.9	32	18.8	45	26.5	47	27.6	18	10.6	1	0.6
DAY 43	170	0	0	23	13.5	38	22.4	44	25.9	44	25.9	20	11.8	1	0.6
DAY 50	170	0	0	28	16.5	40	23.5	35	20.6	46	27.1	20	11.8	1	0.6
DAY 57	170	1	0.6	38	22.4	34	20.0	36	21.2	42	24.7	18	10.6	1	0.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI206.SAS
GENERATED: 12JUL2005 17:40:00 iceadmn3

Table 11.2.3.5.1 CGI Severity of Illness Score Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT													
		PLACEBO													
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL		AMONG THE MOST EXTREMELY ILL SUBJECTS	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL														
SCREEN	169	0	0	0	0	5	3.0	106	62.7	52	30.8	6	3.6	0	0
DAY 1	169	0	0	0	0	4	2.4	96	56.8	63	37.3	6	3.6	0	0
DAY 8	169	0	0	3	1.8	24	14.2	83	49.1	55	32.5	4	2.4	0	0
DAY 15	169	2	1.2	14	8.3	25	14.8	87	51.5	36	21.3	4	2.4	1	0.6
DAY 22	169	5	3.0	19	11.2	31	18.3	75	44.4	33	19.5	5	3.0	1	0.6
DAY 29	169	7	4.1	20	11.8	33	19.5	72	42.6	30	17.8	6	3.6	1	0.6
DAY 36	169	8	4.7	21	12.4	35	20.7	70	41.4	28	16.6	6	3.6	1	0.6
DAY 43	169	11	6.5	19	11.2	34	20.1	71	42.0	27	16.0	6	3.6	1	0.6
DAY 50	169	17	10.1	16	9.5	30	17.8	70	41.4	28	16.6	7	4.1	1	0.6
DAY 57	169	18	10.7	22	13.0	31	18.3	63	37.3	28	16.6	6	3.6	1	0.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI206.SAS
GENERATED: 12JUL2005 17:40:00 iceadmn3

Table 11.2.3.5.2 CGI Severity of Illness Score Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 300 MG											
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
SCREEN	172	0	0	0	0	1	0.6	99	57.6	71	41.3	1	0.6
DAY 1	172	0	0	0	0	1	0.6	96	55.8	74	43.0	1	0.6
DAY 8	171	2	1.2	9	5.3	32	18.7	95	55.6	33	19.3	0	0
DAY 15	148	4	2.7	21	14.2	41	27.7	67	45.3	15	10.1	0	0
DAY 22	139	9	6.5	21	15.1	49	35.3	44	31.7	16	11.5	0	0
DAY 29	133	12	9.0	25	18.8	48	36.1	37	27.8	11	8.3	0	0
DAY 36	130	27	20.8	20	15.4	45	34.6	29	22.3	9	6.9	0	0
DAY 43	122	25	20.5	29	23.8	39	32.0	22	18.0	7	5.7	0	0
DAY 50	121	26	21.5	31	25.6	41	33.9	17	14.0	6	5.0	0	0
DAY 57	119	27	22.7	32	26.9	33	27.7	22	18.5	5	4.2	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI205.SAS
GENERATED: 12JUL2005 17:39:57 iceadmn3

Table 11.2.3.5.2 CGI Severity of Illness Score Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT													
		QUETIAPINE 600 MG													
		NOT ASSESSED		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
STUDY DAY	TOTAL	N	%	N	%	N	%	N	%	N	%	N	%	N	%
SCREEN	170	0	0	0	0	0	0	4	2.4	92	54.1	65	38.2	9	5.3
DAY 1	170	0	0	0	0	0	0	0	0	94	55.3	65	38.2	11	6.5
DAY 8	169	0	0	0	0	7	4.1	46	27.2	73	43.2	40	23.7	3	1.8
DAY 15	147	0	0	4	2.7	21	14.3	52	35.4	44	29.9	23	15.6	3	2.0
DAY 22	132	0	0	15	11.4	27	20.5	37	28.0	34	25.8	19	14.4	0	0
DAY 29	127	0	0	21	16.5	31	24.4	35	27.6	31	24.4	8	6.3	1	0.8
DAY 36	114	0	0	26	22.8	25	21.9	33	28.9	24	21.1	5	4.4	1	0.9
DAY 43	107	0	0	22	20.6	30	28.0	29	27.1	21	19.6	5	4.7	0	0
DAY 50	101	0	0	28	27.7	28	27.7	19	18.8	20	19.8	6	5.9	0	0
DAY 57	96	1	1.0	37	38.5	20	20.8	21	21.9	13	13.5	4	4.2	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI205.SAS
GENERATED: 12JUL2005 17:39:57 iceadmn3

Table 11.2.3.5.2 CGI Severity of Illness Score Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT											
		PLACEBO											
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
SCREEN	169	0	0	0	0	5	3.0	106	62.7	52	30.8	6	3.6
DAY 1	169	0	0	0	0	4	2.4	96	56.8	63	37.3	6	3.6
DAY 8	169	0	0	3	1.8	24	14.2	83	49.1	55	32.5	4	2.4
DAY 15	148	2	1.4	14	9.5	22	14.9	78	52.7	30	20.3	2	1.4
DAY 22	142	5	3.5	19	13.4	27	19.0	64	45.1	24	16.9	3	2.1
DAY 29	127	7	5.5	19	15.0	28	22.0	54	42.5	18	14.2	1	0.8
DAY 36	119	8	6.7	21	17.6	27	22.7	47	39.5	16	13.4	0	0
DAY 43	106	11	10.4	14	13.2	24	22.6	42	39.6	15	14.2	0	0
DAY 50	102	17	16.7	12	11.8	19	18.6	39	38.2	14	13.7	1	1.0
DAY 57	101	15	14.9	18	17.8	21	20.8	32	31.7	15	14.9	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI205.SAS
GENERATED: 12JUL2005 17:39:57 iceadmn3

Table 11.2.3.6 CGI Severity of Illness Shift to Day 57
Last Observation Carried Forward
Intent-to-Treat Population

	QUETIAPINE 300 MG								
	TOTAL	NOT ASSESSED	NORMAL, NOT AT ALL ILL	BORDERLINE MENTALLY ILL	MILDLY ILL	MODERATELY ILL	MARKEDLY ILL	SEVERELY ILL	AMONG THE MOST EXTREMELY ILL SUBJECTS
BASELINE									
NOT ASSESSED	0	0	0	0	0	0	0	0	0
NORMAL, NOT AT ALL ILL	0	0	0	0	0	0	0	0	0
BORDERLINE MENTALLY ILL	0	0	0	0	0	0	0	0	0
MILDLY ILL	1	0	0	1	0	0	0	0	0
MODERATELY ILL	96	0	23	19	31	22	1	0	0
MARKEDLY ILL	74	0	8	18	18	15	15	0	0
SEVERELY ILL	1	0	0	0	1	0	0	0	0
AMONG THE MOST EXTREMELY ILL SUBJECTS	0	0	0	0	0	0	0	0	0
TOTAL	172	0	31	38	50	37	16	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI214.SAS
GENERATED: 12JUL2005 17:40:15 iceadmn3

Table 11.2.3.6 CGI Severity of Illness Shift to Day 57
Last Observation Carried Forward
Intent-to-Treat Population

	QUETIAPINE 600 MG								
	TOTAL	NOT ASSESSED	NORMAL, NOT AT ALL ILL	BORDERLINE MENTALLY ILL	MILDLY ILL	MODERATELY ILL	MARKEDLY ILL	SEVERELY ILL	AMONG THE MOST EXTREMELY ILL SUBJECTS
BASELINE									
NOT ASSESSED	0	0	0	0	0	0	0	0	0
NORMAL, NOT AT ALL ILL	0	0	0	0	0	0	0	0	0
BORDERLINE MENTALLY ILL	0	0	0	0	0	0	0	0	0
MILDLY ILL	0	0	0	0	0	0	0	0	0
MODERATELY ILL	94	0	24	17	20	31	2	0	0
MARKEDLY ILL	65	1	14	15	13	8	14	0	0
SEVERELY ILL	11	0	0	2	3	3	2	1	0
AMONG THE MOST EXTREMELY ILL SUBJECTS	0	0	0	0	0	0	0	0	0
TOTAL	170	1	38	34	36	42	18	1	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI214.SAS
GENERATED: 12JUL2005 17:40:15 iceadmn3

Table 11.2.3.6 CGI Severity of Illness Shift to Day 57
Last Observation Carried Forward
Intent-to-Treat Population

	PLACEBO								
	TOTAL	NOT ASSESSED	NORMAL, NOT AT ALL ILL	BORDERLINE MENTALLY ILL	MILDLY ILL	MODERATELY ILL	MARKEDLY ILL	SEVERELY ILL	AMONG THE MOST EXTREMELY ILL SUBJECTS
BASELINE									
NOT ASSESSED	0	0	0	0	0	0	0	0	0
NORMAL, NOT AT ALL ILL	0	0	0	0	0	0	0	0	0
BORDERLINE MENTALLY ILL	0	0	0	0	0	0	0	0	0
MILDLY ILL	4	0	1	0	1	2	0	0	0
MODERATELY ILL	96	0	12	13	23	43	5	0	0
MARKEDLY ILL	63	0	5	8	7	17	22	3	1
SEVERELY ILL	6	0	0	1	0	1	1	3	0
AMONG THE MOST EXTREMELY ILL SUBJECTS	0	0	0	0	0	0	0	0	0
TOTAL	169	0	18	22	31	63	28	6	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI214.SAS
GENERATED: 12JUL2005 17:40:15 iceadmn3

Table 11.2.4.1.1 CGI Improvement Score - Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 300 MG											
		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
DAY 8	171	5	2.9	27	15.8	74	43.3	58	33.9	7	4.1	0	0
DAY 15	172	14	8.1	46	26.7	71	41.3	35	20.3	6	3.5	0	0
DAY 22	172	23	13.4	57	33.1	54	31.4	34	19.8	3	1.7	1	0.6
DAY 29	172	24	14.0	64	37.2	50	29.1	27	15.7	7	4.1	0	0
DAY 36	172	40	23.3	58	33.7	45	26.2	22	12.8	7	4.1	0	0
DAY 43	172	45	26.2	58	33.7	42	24.4	20	11.6	7	4.1	0	0
DAY 50	172	51	29.7	56	32.6	37	21.5	21	12.2	7	4.1	0	0
DAY 57	172	55	32.0	55	32.0	32	18.6	22	12.8	8	4.7	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI211.SAS
GENERATED: 12JUL2005 17:40:06 iceadmn3

Table 11.2.4.1.1 CGI Improvement Score - Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 600 MG											
		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
STUDY DAY	TOTAL	N	%	N	%	N	%	N	%	N	%	N	%
DAY 8	169	1	0.6	36	21.3	73	43.2	55	32.5	3	1.8	1	0.6
DAY 15	170	15	8.8	53	31.2	60	35.3	38	22.4	4	2.4	0	0
DAY 22	170	33	19.4	46	27.1	52	30.6	33	19.4	6	3.5	0	0
DAY 29	170	49	28.8	43	25.3	40	23.5	34	20.0	3	1.8	1	0.6
DAY 36	170	49	28.8	39	22.9	37	21.8	33	19.4	11	6.5	1	0.6
DAY 43	170	50	29.4	41	24.1	36	21.2	32	18.8	9	5.3	2	1.2
DAY 50	170	55	32.4	34	20.0	42	24.7	30	17.6	7	4.1	2	1.2
DAY 57	170	61	35.9	34	20.0	33	19.4	35	20.6	6	3.5	1	0.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI211.SAS
GENERATED: 12JUL2005 17:40:06 iceadmn3

Table 11.2.4.1.1 CGI Improvement Score - Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT													
		PLACEBO													
		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL														
DAY 8	169	2	1.2	15	8.9	47	27.8	96	56.8	7	4.1	2	1.2	0	0
DAY 15	169	6	3.6	26	15.4	64	37.9	61	36.1	10	5.9	1	0.6	1	0.6
DAY 22	169	14	8.3	28	16.6	59	34.9	53	31.4	13	7.7	1	0.6	1	0.6
DAY 29	169	16	9.5	37	21.9	50	29.6	51	30.2	12	7.1	2	1.2	1	0.6
DAY 36	169	20	11.8	37	21.9	48	28.4	45	26.6	16	9.5	2	1.2	1	0.6
DAY 43	169	25	14.8	30	17.8	46	27.2	48	28.4	16	9.5	3	1.8	1	0.6
DAY 50	169	29	17.2	25	14.8	41	24.3	53	31.4	16	9.5	4	2.4	1	0.6
DAY 57	169	34	20.1	24	14.2	46	27.2	50	29.6	11	6.5	3	1.8	1	0.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI211.SAS
GENERATED: 12JUL2005 17:40:06 iceadmn3

Table 11.2.4.1.2 CGI Improvement Score - Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 300 MG											
		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
STUDY DAY	TOTAL	N	%	N	%	N	%	N	%	N	%	N	%
DAY 8	171	5	2.9	27	15.8	74	43.3	58	33.9	7	4.1	0	0
DAY 15	148	13	8.8	43	29.1	63	42.6	26	17.6	3	2.0	0	0
DAY 22	139	21	15.1	48	34.5	44	31.7	25	18.0	0	0	1	0.7
DAY 29	133	21	15.8	54	40.6	38	28.6	16	12.0	4	3.0	0	0
DAY 36	130	37	28.5	48	36.9	32	24.6	11	8.5	2	1.5	0	0
DAY 43	122	41	33.6	46	37.7	26	21.3	8	6.6	1	0.8	0	0
DAY 50	121	47	38.8	41	33.9	24	19.8	9	7.4	0	0	0	0
DAY 57	119	49	41.2	39	32.8	20	16.8	10	8.4	1	0.8	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI210.SAS
GENERATED: 12JUL2005 17:40:03 iceadmn3

Table 11.2.4.1.2 CGI Improvement Score - Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 600 MG											
		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
DAY 8	169	1	0.6	36	21.3	73	43.2	55	32.5	3	1.8	1	0.6
DAY 15	147	15	10.2	49	33.3	52	35.4	28	19.0	3	2.0	0	0
DAY 22	132	30	22.7	43	32.6	39	29.5	16	12.1	4	3.0	0	0
DAY 29	127	45	35.4	39	30.7	27	21.3	14	11.0	1	0.8	1	0.8
DAY 36	114	44	38.6	32	28.1	20	17.5	10	8.8	8	7.0	0	0
DAY 43	107	44	41.1	31	29.0	18	16.8	9	8.4	4	3.7	1	0.9
DAY 50	101	49	48.5	21	20.8	23	22.8	5	5.0	2	2.0	1	1.0
DAY 57	96	52	54.2	22	22.9	12	12.5	9	9.4	1	1.0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI210.SAS
GENERATED: 12JUL2005 17:40:03 iceadmn3

Table 11.2.4.1.2 CGI Improvement Score - Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT											
		PLACEBO											
		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
DAY 8	169	2	1.2	15	8.9	47	27.8	96	56.8	7	4.1	2	1.2
DAY 15	148	6	4.1	24	16.2	58	39.2	52	35.1	8	5.4	0	0
DAY 22	142	13	9.2	26	18.3	53	37.3	41	28.9	9	6.3	0	0
DAY 29	127	15	11.8	32	25.2	41	32.3	34	26.8	4	3.1	1	0.8
DAY 36	119	19	16.0	32	26.9	34	28.6	27	22.7	7	5.9	0	0
DAY 43	106	20	18.9	21	19.8	31	29.2	27	25.5	6	5.7	1	0.9
DAY 50	102	25	24.5	16	15.7	26	25.5	28	27.5	6	5.9	1	1.0
DAY 57	101	27	26.7	15	14.9	31	30.7	27	26.7	1	1.0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI210.SAS
GENERATED: 12JUL2005 17:40:03 iceadmn3

Table 11.2.4.2.1 CGI Improvement Score (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	4.4	0.52	3.2	0.86	3.20	0.078	3.05	3.36	.
	Q600MG	169	4.5	0.62	3.2	0.82	3.17	0.079	3.01	3.32	.
	P	169	4.4	0.60	3.6	0.81	3.57	0.078	3.41	3.72	.
	Q300MG VS P	.	.	.	.	.	-0.37	0.087	-0.54	-0.19	<.001
	Q600MG VS P	.	.	.	.	.	-0.40	0.088	-0.57	-0.23	<.001
DAY 15	Q300MG	172	4.4	0.52	2.8	0.96	2.85	0.092	2.67	3.03	.
	Q600MG	170	4.5	0.62	2.8	0.97	2.81	0.092	2.63	3.00	.
	P	169	4.4	0.60	3.3	0.98	3.31	0.092	3.12	3.49	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.103	-0.66	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.49	0.103	-0.70	-0.29	<.001
DAY 22	Q300MG	172	4.4	0.52	2.7	1.03	2.64	0.098	2.44	2.83	.
	Q600MG	170	4.5	0.62	2.6	1.11	2.60	0.099	2.40	2.80	.
	P	169	4.4	0.60	3.2	1.11	3.18	0.098	2.99	3.38	.
	Q300MG VS P	.	.	.	.	.	-0.54	0.116	-0.77	-0.32	<.001
	Q600MG VS P	.	.	.	.	.	-0.58	0.116	-0.81	-0.35	<.001
DAY 29	Q300MG	172	4.4	0.52	2.6	1.04	2.61	0.102	2.41	2.81	.
	Q600MG	170	4.5	0.62	2.4	1.19	2.46	0.103	2.25	2.66	.

(Continued)

Table 11.2.4.2.1 CGI Improvement Score (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	4.4	0.60	3.1	1.18	3.13	0.103	2.93	3.34	.
	Q300MG VS P	.	.	.	.	.	-0.52	0.121	-0.76	-0.28	<.001
	Q600MG VS P	.	.	.	.	.	-0.68	0.122	-0.91	-0.44	<.001
DAY 36	Q300MG	172	4.4	0.52	2.4	1.10	2.42	0.108	2.21	2.64	.
	Q600MG	170	4.5	0.62	2.5	1.30	2.56	0.109	2.34	2.77	.
	P	169	4.4	0.60	3.1	1.24	3.08	0.109	2.86	3.29	.
	Q300MG VS P	.	.	.	.	.	-0.65	0.129	-0.91	-0.40	<.001
	Q600MG VS P	.	.	.	.	.	-0.52	0.130	-0.77	-0.26	<.001
DAY 43	Q300MG	172	4.4	0.52	2.3	1.11	2.38	0.110	2.16	2.59	.
	Q600MG	170	4.5	0.62	2.5	1.30	2.53	0.110	2.32	2.75	.
	P	169	4.4	0.60	3.1	1.30	3.11	0.110	2.89	3.33	.
	Q300MG VS P	.	.	.	.	.	-0.73	0.132	-0.99	-0.48	<.001
	Q600MG VS P	.	.	.	.	.	-0.58	0.133	-0.84	-0.32	<.001
DAY 50	Q300MG	172	4.4	0.52	2.3	1.14	2.31	0.111	2.09	2.53	.
	Q600MG	170	4.5	0.62	2.4	1.28	2.48	0.111	2.26	2.70	.
	P	169	4.4	0.60	3.1	1.35	3.13	0.111	2.91	3.35	.
	Q300MG VS P	.	.	.	.	.	-0.82	0.135	-1.08	-0.56	<.001

(Continued)

Table 11.2.4.2.1 CGI Improvement Score (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.66	0.135	-0.92	-0.39	<.001
DAY 57	Q300MG	172	4.4	0.52	2.3	1.17	2.27	0.112	2.04	2.49	.
	Q600MG	170	4.5	0.62	2.4	1.29	2.37	0.113	2.15	2.59	.
	P	169	4.4	0.60	3.0	1.33	2.97	0.113	2.75	3.20	.
	Q300MG VS P	.	.	.	.	.	-0.71	0.135	-0.97	-0.44	<.001
	Q600MG VS P	.	.	.	.	.	-0.60	0.136	-0.87	-0.34	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220.SAS
GENERATED: 12JUL2005 17:28:29 iceadmn3

Table 11.2.4.2.2 CGI Improvement Score (ANCOVA)
Observed Cases
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	4.4	0.52	3.2	0.86	3.20	0.078	3.05	3.36	.
	Q600MG	169	4.5	0.62	3.2	0.82	3.17	0.079	3.01	3.32	.
	P	169	4.4	0.60	3.6	0.81	3.57	0.078	3.41	3.72	.
	Q300MG VS P	.	.	.	.	.	-0.37	0.087	-0.54	-0.19	<.001
	Q600MG VS P	.	.	.	.	.	-0.40	0.088	-0.57	-0.23	<.001
DAY 15	Q300MG	148	4.4	0.52	2.8	0.92	2.74	0.099	2.55	2.94	.
	Q600MG	147	4.5	0.63	2.7	0.96	2.70	0.100	2.50	2.90	.
	P	148	4.4	0.60	3.2	0.92	3.21	0.098	3.01	3.40	.
	Q300MG VS P	.	.	.	.	.	-0.46	0.105	-0.67	-0.26	<.001
	Q600MG VS P	.	.	.	.	.	-0.51	0.106	-0.72	-0.30	<.001
DAY 22	Q300MG	139	4.4	0.52	2.6	1.00	2.52	0.104	2.31	2.73	.
	Q600MG	132	4.6	0.65	2.4	1.06	2.36	0.107	2.14	2.57	.
	P	142	4.4	0.59	3.0	1.05	3.04	0.103	2.83	3.24	.
	Q300MG VS P	.	.	.	.	.	-0.52	0.121	-0.75	-0.28	<.001
	Q600MG VS P	.	.	.	.	.	-0.68	0.124	-0.92	-0.44	<.001
DAY 29	Q300MG	133	4.4	0.52	2.5	1.00	2.45	0.113	2.22	2.67	.
	Q600MG	127	4.5	0.64	2.1	1.09	2.16	0.116	1.93	2.39	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI225.SAS
GENERATED: 12JUL2005 17:28:43 iceadmn3

Table 11.2.4.2.2 CGI Improvement Score (ANCOVA)
Observed Cases
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	127	4.3	0.55	2.9	1.09	2.87	0.114	2.65	3.10	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.127	-0.68	-0.18	<.001
	Q600MG VS P	.	.	.	.	.	-0.72	0.130	-0.97	-0.46	<.001
DAY 36	Q300MG	130	4.4	0.52	2.2	0.99	2.13	0.121	1.89	2.37	.
	Q600MG	114	4.5	0.64	2.2	1.24	2.16	0.128	1.91	2.42	.
	P	119	4.4	0.58	2.8	1.15	2.73	0.123	2.49	2.98	.
	Q300MG VS P	.	.	.	.	.	-0.60	0.138	-0.87	-0.33	<.001
	Q600MG VS P	.	.	.	.	.	-0.57	0.144	-0.85	-0.29	<.001
DAY 43	Q300MG	122	4.4	0.53	2.0	0.94	2.07	0.123	1.82	2.31	.
	Q600MG	107	4.5	0.60	2.1	1.19	2.10	0.130	1.84	2.36	.
	P	106	4.3	0.57	2.8	1.23	2.85	0.129	2.60	3.11	.
	Q300MG VS P	.	.	.	.	.	-0.78	0.144	-1.07	-0.50	<.001
	Q600MG VS P	.	.	.	.	.	-0.75	0.149	-1.04	-0.46	<.001
DAY 50	Q300MG	121	4.4	0.52	2.0	0.94	1.97	0.120	1.73	2.21	.
	Q600MG	101	4.5	0.63	1.9	1.12	1.96	0.129	1.70	2.21	.
	P	102	4.3	0.54	2.8	1.30	2.77	0.127	2.52	3.03	.
	Q300MG VS P	.	.	.	.	.	-0.80	0.147	-1.09	-0.51	<.001

(Continued)

Table 11.2.4.2.2 CGI Improvement Score (ANCOVA)
Observed Cases
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.82	0.155	-1.12	-0.51	<.001
DAY 57	Q300MG	119	4.4	0.53	1.9	1.00	1.90	0.118	1.67	2.14	.
	Q600MG	96	4.5	0.62	1.8	1.05	1.75	0.128	1.50	2.01	.
	P	101	4.3	0.57	2.6	1.18	2.58	0.124	2.34	2.83	.
	Q300MG VS P	.	.	.	.	.	-0.68	0.142	-0.96	-0.40	<.001
	Q600MG VS P	.	.	.	.	.	-0.83	0.150	-1.13	-0.54	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI225.SAS
GENERATED: 12JUL2005 17:28:43 iceadmn3

Table 11.2.4.2.3 CGI Improvement Score Effect Size
Last Observation Carried Forward
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.44	-0.65	-0.22
	Q600MG VS P	-0.50	-0.71	-0.28
DAY 15	Q300MG VS P	-0.47	-0.68	-0.25
	Q600MG VS P	-0.51	-0.72	-0.29
DAY 22	Q300MG VS P	-0.51	-0.72	-0.29
	Q600MG VS P	-0.52	-0.74	-0.31
DAY 29	Q300MG VS P	-0.47	-0.68	-0.25
	Q600MG VS P	-0.57	-0.79	-0.35
DAY 36	Q300MG VS P	-0.56	-0.77	-0.34
	Q600MG VS P	-0.41	-0.62	-0.19
DAY 43	Q300MG VS P	-0.61	-0.83	-0.39
	Q600MG VS P	-0.44	-0.66	-0.23
DAY 50	Q300MG VS P	-0.66	-0.87	-0.44
	Q600MG VS P	-0.50	-0.71	-0.28
DAY 57	Q300MG VS P	-0.57	-0.78	-0.35
	Q600MG VS P	-0.46	-0.68	-0.25

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI221.SAS
GENERATED: 12JUL2005 17:28:32 iceadmn3

Table 11.2.4.2.4 CGI Improvement Score Effect Size
Observed Cases
Intent-to-Treat Population

VISIT	TREATMENT	EFFECT SIZE	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER
DAY 8	Q300MG VS P	-0.44	-0.65	-0.22
	Q600MG VS P	-0.50	-0.71	-0.28
DAY 15	Q300MG VS P	-0.50	-0.73	-0.27
	Q600MG VS P	-0.54	-0.77	-0.31
DAY 22	Q300MG VS P	-0.50	-0.74	-0.27
	Q600MG VS P	-0.64	-0.89	-0.40
DAY 29	Q300MG VS P	-0.41	-0.66	-0.16
	Q600MG VS P	-0.66	-0.91	-0.40
DAY 36	Q300MG VS P	-0.56	-0.81	-0.30
	Q600MG VS P	-0.48	-0.74	-0.22
DAY 43	Q300MG VS P	-0.72	-0.99	-0.46
	Q600MG VS P	-0.62	-0.90	-0.35
DAY 50	Q300MG VS P	-0.72	-0.99	-0.44
	Q600MG VS P	-0.67	-0.95	-0.39
DAY 57	Q300MG VS P	-0.63	-0.90	-0.36
	Q600MG VS P	-0.75	-1.03	-0.46

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI226.SAS
GENERATED: 12JUL2005 17:28:46 iceadmn3

Table 11.2.4.2.5 CGI Improvement (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P						
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	23	115	20	26	114	23	10	112	9	.	.	.	.
	BIPOLAR II	9	56	16	11	55	20	7	57	12	.	.	.	.
	ALL	32	171	19	37	169	22	17	169	10	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.024	1.86	1.07	3.23
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.003	2.18	1.28	3.72
DAY 15	BIPOLAR I	44	116	38	50	114	44	20	112	18	.	.	.	.
	BIPOLAR II	16	56	29	18	56	32	12	57	21	.	.	.	.
	ALL	60	172	35	68	170	40	32	169	19	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.84	1.27	2.68
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.11	1.47	3.04
DAY 22	BIPOLAR I	58	116	50	57	114	50	24	112	21	.	.	.	.
	BIPOLAR II	22	56	39	22	56	39	18	57	32	.	.	.	.
	ALL	80	172	47	79	170	46	42	169	25	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.87	1.37	2.55
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.87	1.37	2.55
DAY 29	BIPOLAR I	62	116	53	68	114	60	33	112	29	.	.	.	.

(Continued)

Table 11.2.4.2.5 CGI Improvement (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 29	BIPOLAR II	26	56	46	24	56	43	20	57	35	.	.	.	.
	ALL	88	172	51	92	170	54	53	169	31	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.63	1.25	2.13
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.72	1.32	2.25
DAY 36	BIPOLAR I	71	116	61	65	114	57	32	112	29	.	.	.	.
	BIPOLAR II	27	56	48	23	56	41	25	57	44	.	.	.	.
	ALL	98	172	57	88	170	52	57	169	34	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.69	1.32	2.17
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.54	1.18	1.99
DAY 43	BIPOLAR I	75	116	65	66	114	58	32	112	29	.	.	.	.
	BIPOLAR II	28	56	50	25	56	45	23	57	40	.	.	.	.
	ALL	103	172	60	91	170	54	55	169	33	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.84	1.43	2.37
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.65	1.27	2.14
DAY 50	BIPOLAR I	75	116	65	64	114	56	34	112	30	.	.	.	.

(Continued)

Table 11.2.4.2.5 CGI Improvement (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 50	BIPOLAR II	32	56	57	25	56	45	20	57	35	.	.	.	.
	ALL	107	172	62	89	170	52	54	169	32	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.95	1.52	2.50
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.64	1.26	2.13
DAY 57	BIPOLAR I	82	116	71	68	114	60	33	112	29	.	.	.	.
	BIPOLAR II	28	56	50	27	56	48	25	57	44	.	.	.	.
	ALL	110	172	64	95	170	56	58	169	34	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.86	1.47	2.37
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.63	1.27	2.09

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222.SAS
GENERATED: 12JUL2005 17:28:34 iceadmn3

Table 11.2.4.2.6 CGI Improvement (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P						
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	23	115	20	26	114	23	10	112	9	.	.	.	.
	BIPOLAR II	9	56	16	11	55	20	7	57	12	.	.	.	.
	ALL	32	171	19	37	169	22	17	169	10	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.024	1.86	1.07	3.23
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.003	2.18	1.28	3.72
DAY 15	BIPOLAR I	40	103	39	47	104	45	18	96	19	.	.	.	.
	BIPOLAR II	16	45	36	17	43	40	12	52	23	.	.	.	.
	ALL	56	148	38	64	147	44	30	148	20	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.87	1.28	2.75
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.15	1.48	3.13
DAY 22	BIPOLAR I	50	95	53	53	93	57	22	92	24	.	.	.	.
	BIPOLAR II	19	44	43	20	39	51	17	50	34	.	.	.	.
	ALL	69	139	50	73	132	55	39	142	27	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.81	1.32	2.50
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	2.03	1.49	2.78
DAY 29	BIPOLAR I	54	93	58	62	91	68	29	79	37	.	.	.	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI227.SAS
GENERATED: 12JUL2005 17:28:49 iceadmn3

Table 11.2.4.2.6 CGI Improvement (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 29	BIPOLAR II	21	40	53	22	36	61	18	48	38	.	.	.	.
	ALL	75	133	56	84	127	66	47	127	37	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.52	1.16	2.00
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.78	1.37	2.31
DAY 36	BIPOLAR I	62	90	69	56	83	67	27	74	36	.	.	.	.
	BIPOLAR II	23	40	58	20	31	65	24	45	53	.	.	.	.
	ALL	85	130	65	76	114	67	51	119	43	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.54	1.20	1.97
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.59	1.23	2.05
DAY 43	BIPOLAR I	65	86	76	54	77	70	24	67	36	.	.	.	.
	BIPOLAR II	22	36	61	21	30	70	17	39	44	.	.	.	.
	ALL	87	122	71	75	107	70	41	106	39	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.84	1.41	2.42
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.83	1.39	2.40
DAY 50	BIPOLAR I	65	87	75	50	71	70	25	63	40	.	.	.	.

(Continued)

Table 11.2.4.2.6 CGI Improvement (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT												
		Q300MG			Q600MG			P				RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	23	34	68	20	30	67	16	39	41	.	.	.	.
	ALL	88	121	73	70	101	69	41	102	40	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.80	1.39	2.35
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.72	1.31	2.26
DAY 57	BIPOLAR I	67	83	81	52	67	78	21	60	35	.	.	.	.
	BIPOLAR II	21	36	58	22	29	76	21	41	51	.	.	.	.
	ALL	88	119	74	74	96	77	42	101	42	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.79	1.36	2.34
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.89	1.45	2.47

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI227.SAS
GENERATED: 12JUL2005 17:28:49 iceadmn3

FIGURE 11.2.4.3 PERCENT OF PATIENTS RATED AS "MUCH" OR "VERY MUCH" IMPROVED ON CGI GLOBAL IMPROVEMENT SCALE

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

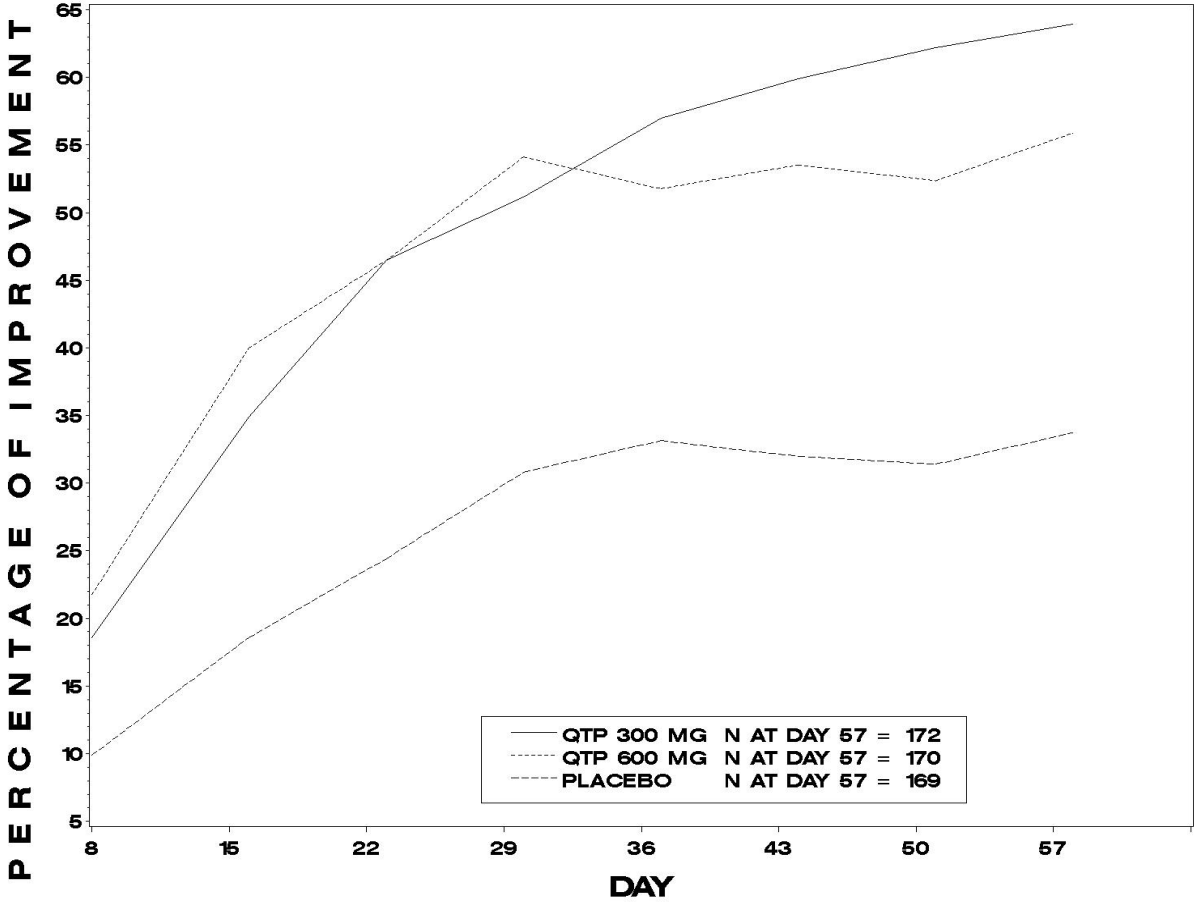

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 300 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	STUDY DAY	TOTAL												
	DAY 8	115	4	3.5	19	16.5	46	40.0	41	35.7	5	4.3	0	0
	DAY 15	116	8	6.9	36	31.0	47	40.5	23	19.8	2	1.7	0	0
	DAY 22	116	17	14.7	41	35.3	32	27.6	23	19.8	2	1.7	1	0.9
	DAY 29	116	17	14.7	45	38.8	33	28.4	18	15.5	3	2.6	0	0
	DAY 36	116	34	29.3	37	31.9	30	25.9	12	10.3	3	2.6	0	0
	DAY 43	116	36	31.0	39	33.6	27	23.3	10	8.6	4	3.4	0	0
	DAY 50	116	41	35.3	34	29.3	24	20.7	13	11.2	4	3.4	0	0
	DAY 57	116	44	37.9	38	32.8	17	14.7	13	11.2	4	3.4	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI213.SAS
GENERATED: 12JUL2005 17:40:12 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT									
			QUETIAPINE 300 MG									
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE	
			N	%	N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	STUDY DAY	TOTAL										
	DAY 8	56	1	1.8	8	14.3	28	50.0	17	30.4	2	3.6
	DAY 15	56	6	10.7	10	17.9	24	42.9	12	21.4	4	7.1
	DAY 22	56	6	10.7	16	28.6	22	39.3	11	19.6	1	1.8
	DAY 29	56	7	12.5	19	33.9	17	30.4	9	16.1	4	7.1
	DAY 36	56	6	10.7	21	37.5	15	26.8	10	17.9	4	7.1
	DAY 43	56	9	16.1	19	33.9	15	26.8	10	17.9	3	5.4
	DAY 50	56	10	17.9	22	39.3	13	23.2	8	14.3	3	5.4
	DAY 57	56	11	19.6	17	30.4	15	26.8	9	16.1	4	7.1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI213.SAS
GENERATED: 12JUL2005 17:40:12 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 600 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	STUDY DAY	TOTAL												
	DAY 8	114	1	0.9	25	21.9	50	43.9	36	31.6	1	0.9	1	0.9
	DAY 15	114	14	12.3	36	31.6	38	33.3	25	21.9	1	0.9	0	0
	DAY 22	114	30	26.3	27	23.7	32	28.1	22	19.3	3	2.6	0	0
	DAY 29	114	40	35.1	28	24.6	26	22.8	19	16.7	0	0	1	0.9
	DAY 36	114	39	34.2	26	22.8	24	21.1	18	15.8	6	5.3	1	0.9
	DAY 43	114	41	36.0	25	21.9	22	19.3	21	18.4	4	3.5	1	0.9
	DAY 50	114	45	39.5	19	16.7	27	23.7	19	16.7	2	1.8	2	1.8
	DAY 57	114	48	42.1	20	17.5	20	17.5	23	20.2	2	1.8	1	0.9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI213.SAS
GENERATED: 12JUL2005 17:40:12 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 600 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	STUDY DAY	TOTAL												
	DAY 8	55	0	0	11	20.0	23	41.8	19	34.5	2	3.6	0	0
	DAY 15	56	1	1.8	17	30.4	22	39.3	13	23.2	3	5.4	0	0
	DAY 22	56	3	5.4	19	33.9	20	35.7	11	19.6	3	5.4	0	0
	DAY 29	56	9	16.1	15	26.8	14	25.0	15	26.8	3	5.4	0	0
	DAY 36	56	10	17.9	13	23.2	13	23.2	15	26.8	5	8.9	0	0
	DAY 43	56	9	16.1	16	28.6	14	25.0	11	19.6	5	8.9	1	1.8
	DAY 50	56	10	17.9	15	26.8	15	26.8	11	19.6	5	8.9	0	0
	DAY 57	56	13	23.2	14	25.0	13	23.2	12	21.4	4	7.1	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI213.SAS
GENERATED: 12JUL2005 17:40:12 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT													
			PLACEBO													
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	STUDY DAY	TOTAL														
	DAY 8	112	1	0.9	9	8.0	27	24.1	67	59.8	6	5.4	2	1.8	0	0
	DAY 15	112	2	1.8	18	16.1	39	34.8	43	38.4	8	7.1	1	0.9	1	0.9
	DAY 22	112	6	5.4	18	16.1	40	35.7	35	31.3	11	9.8	1	0.9	1	0.9
	DAY 29	112	8	7.1	25	22.3	32	28.6	34	30.4	10	8.9	2	1.8	1	0.9
	DAY 36	112	11	9.8	21	18.8	30	26.8	34	30.4	13	11.6	2	1.8	1	0.9
	DAY 43	112	14	12.5	18	16.1	28	25.0	34	30.4	14	12.5	3	2.7	1	0.9
	DAY 50	112	18	16.1	16	14.3	27	24.1	34	30.4	12	10.7	4	3.6	1	0.9
	DAY 57	112	16	14.3	17	15.2	29	25.9	37	33.0	9	8.0	3	2.7	1	0.9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI213.SAS
GENERATED: 12JUL2005 17:40:12 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT									
			PLACEBO									
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE	
			N	%	N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	STUDY DAY	TOTAL										
	DAY 8	57	1	1.8	6	10.5	20	35.1	29	50.9	1	1.8
	DAY 15	57	4	7.0	8	14.0	25	43.9	18	31.6	2	3.5
	DAY 22	57	8	14.0	10	17.5	19	33.3	18	31.6	2	3.5
	DAY 29	57	8	14.0	12	21.1	18	31.6	17	29.8	2	3.5
	DAY 36	57	9	15.8	16	28.1	18	31.6	11	19.3	3	5.3
	DAY 43	57	11	19.3	12	21.1	18	31.6	14	24.6	2	3.5
	DAY 50	57	11	19.3	9	15.8	14	24.6	19	33.3	4	7.0
	DAY 57	57	18	31.6	7	12.3	17	29.8	13	22.8	2	3.5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI213.SAS
GENERATED: 12JUL2005 17:40:12 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 300 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	STUDY DAY	TOTAL												
	DAY 8	115	4	3.5	19	16.5	46	40.0	41	35.7	5	4.3	0	0
	DAY 15	103	7	6.8	33	32.0	43	41.7	20	19.4	0	0	0	0
	DAY 22	95	16	16.8	34	35.8	26	27.4	18	18.9	0	0	1	1.1
	DAY 29	93	16	17.2	38	40.9	26	28.0	12	12.9	1	1.1	0	0
	DAY 36	90	32	35.6	30	33.3	22	24.4	6	6.7	0	0	0	0
	DAY 43	86	33	38.4	32	37.2	17	19.8	3	3.5	1	1.2	0	0
	DAY 50	87	39	44.8	26	29.9	16	18.4	6	6.9	0	0	0	0
	DAY 57	83	39	47.0	28	33.7	10	12.0	6	7.2	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI212.SAS
GENERATED: 12JUL2005 17:40:09 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT									
			QUETIAPINE 300 MG									
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE	
			N	%	N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	STUDY DAY	TOTAL										
	DAY 8	56	1	1.8	8	14.3	28	50.0	17	30.4	2	3.6
	DAY 15	45	6	13.3	10	22.2	20	44.4	6	13.3	3	6.7
	DAY 22	44	5	11.4	14	31.8	18	40.9	7	15.9	0	0
	DAY 29	40	5	12.5	16	40.0	12	30.0	4	10.0	3	7.5
	DAY 36	40	5	12.5	18	45.0	10	25.0	5	12.5	2	5.0
	DAY 43	36	8	22.2	14	38.9	9	25.0	5	13.9	0	0
	DAY 50	34	8	23.5	15	44.1	8	23.5	3	8.8	0	0
	DAY 57	36	10	27.8	11	30.6	10	27.8	4	11.1	1	2.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI212.SAS
GENERATED: 12JUL2005 17:40:09 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 600 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	STUDY DAY	TOTAL												
	DAY 8	114	1	0.9	25	21.9	50	43.9	36	31.6	1	0.9	1	0.9
	DAY 15	104	14	13.5	33	31.7	35	33.7	21	20.2	1	1.0	0	0
	DAY 22	93	27	29.0	26	28.0	26	28.0	11	11.8	3	3.2	0	0
	DAY 29	91	36	39.6	26	28.6	20	22.0	8	8.8	0	0	1	1.1
	DAY 36	83	35	42.2	21	25.3	16	19.3	5	6.0	6	7.2	0	0
	DAY 43	77	36	46.8	18	23.4	12	15.6	8	10.4	3	3.9	0	0
	DAY 50	71	40	56.3	10	14.1	16	22.5	4	5.6	0	0	1	1.4
	DAY 57	67	40	59.7	12	17.9	7	10.4	8	11.9	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI212.SAS
GENERATED: 12JUL2005 17:40:09 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 600 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	STUDY DAY	TOTAL												
	DAY 8	55	0	0	11	20.0	23	41.8	19	34.5	2	3.6	0	0
	DAY 15	43	1	2.3	16	37.2	17	39.5	7	16.3	2	4.7	0	0
	DAY 22	39	3	7.7	17	43.6	13	33.3	5	12.8	1	2.6	0	0
	DAY 29	36	9	25.0	13	36.1	7	19.4	6	16.7	1	2.8	0	0
	DAY 36	31	9	29.0	11	35.5	4	12.9	5	16.1	2	6.5	0	0
	DAY 43	30	8	26.7	13	43.3	6	20.0	1	3.3	1	3.3	1	3.3
	DAY 50	30	9	30.0	11	36.7	7	23.3	1	3.3	2	6.7	0	0
	DAY 57	29	12	41.4	10	34.5	5	17.2	1	3.4	1	3.4	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI212.SAS
GENERATED: 12JUL2005 17:40:09 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT											
			PLACEBO											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
BIPOLAR I DISORDER	STUDY DAY	TOTAL												
	DAY 8	112	1	0.9	9	8.0	27	24.1	67	59.8	6	5.4	2	1.8
	DAY 15	96	2	2.1	16	16.7	38	39.6	34	35.4	6	6.3	0	0
	DAY 22	92	6	6.5	16	17.4	37	40.2	26	28.3	7	7.6	0	0
	DAY 29	79	8	10.1	21	26.6	25	31.6	22	27.8	2	2.5	1	1.3
	DAY 36	74	11	14.9	16	21.6	22	29.7	20	27.0	5	6.8	0	0
	DAY 43	67	13	19.4	11	16.4	19	28.4	18	26.9	5	7.5	1	1.5
	DAY 50	63	16	25.4	9	14.3	18	28.6	16	25.4	3	4.8	1	1.6
	DAY 57	60	12	20.0	9	15.0	19	31.7	20	33.3	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI212.SAS
GENERATED: 12JUL2005 17:40:09 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT									
			PLACEBO									
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE	
			N	%	N	%	N	%	N	%	N	%
BIPOLAR II DISORDER	STUDY DAY	TOTAL										
	DAY 8	57	1	1.8	6	10.5	20	35.1	29	50.9	1	1.8
	DAY 15	52	4	7.7	8	15.4	20	38.5	18	34.6	2	3.8
	DAY 22	50	7	14.0	10	20.0	16	32.0	15	30.0	2	4.0
	DAY 29	48	7	14.6	11	22.9	16	33.3	12	25.0	2	4.2
	DAY 36	45	8	17.8	16	35.6	12	26.7	7	15.6	2	4.4
	DAY 43	39	7	17.9	10	25.6	12	30.8	9	23.1	1	2.6
	DAY 50	39	9	23.1	7	17.9	8	20.5	12	30.8	3	7.7
	DAY 57	41	15	36.6	6	14.6	12	29.3	7	17.1	1	2.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI212.SAS
GENERATED: 12JUL2005 17:40:09 iceadmn3

Table 11.2.5.1.1 HAM-A Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	VISIT																		
	DAY 1	172	18.7	7.28	19.0	3	41	170	18.7	7.32	19.0	0	38	169	18.9	7.23	19.0	0	37
	DAY 8	171	14.2	6.57	14.0	0	38	169	14.9	7.12	15.0	0	37	168	16.2	7.27	16.0	0	36
	DAY 15	172	12.5	6.91	12.0	0	37	170	13.2	7.10	12.0	0	33	168	15.0	7.81	15.0	0	34
	DAY 22	172	11.8	7.06	11.0	0	37	170	12.1	8.08	11.0	0	38	168	14.1	7.53	14.0	0	38
	DAY 29	172	11.2	7.05	11.0	0	40	170	10.8	7.82	9.0	0	33	168	13.8	7.84	13.0	0	38
	DAY 36	172	10.8	7.45	10.0	0	40	170	10.7	7.96	10.0	0	33	168	13.6	8.12	13.0	0	38
	DAY 43	172	10.2	7.19	9.0	0	40	170	10.4	7.87	10.0	0	33	168	13.3	7.84	12.5	0	38
	DAY 50	172	10.0	7.17	9.0	0	40	170	10.3	7.83	9.0	0	33	168	13.5	8.72	12.0	0	38
	DAY 57	172	10.0	7.62	9.0	0	40	170	9.9	8.12	8.5	0	33	168	13.2	8.48	12.0	0	38
CHG FROM BASELINE	DAY 8	171	-4.4	5.30	-4.0	-22	9	169	-3.8	5.74	-4.0	-25	19	168	-2.7	5.06	-2.0	-21	14
	DAY 15	172	-6.2	6.37	-5.0	-27	10	170	-5.6	6.50	-5.0	-27	9	168	-4.0	5.90	-3.5	-22	15
	DAY 22	172	-6.9	6.90	-6.0	-30	10	170	-6.6	7.67	-6.0	-31	14	168	-4.8	6.42	-4.0	-23	17
	DAY 29	172	-7.5	7.27	-7.0	-29	14	170	-7.9	7.67	-7.0	-27	14	168	-5.1	6.54	-5.0	-24	15
	DAY 36	172	-7.9	7.47	-7.0	-31	10	170	-8.0	8.09	-8.0	-29	14	168	-5.3	7.07	-5.0	-27	22
	DAY 43	172	-8.5	7.53	-8.0	-35	7	170	-8.3	7.72	-8.0	-28	14	168	-5.6	7.26	-5.5	-29	15
	DAY 50	172	-8.6	7.27	-7.5	-31	11	170	-8.5	8.01	-7.0	-31	14	168	-5.4	7.73	-5.0	-32	18

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA201.SAS
GENERATED: 12JUL2005 17:42:46 iceadmn3

Table 11.2.5.1.1 HAM-A Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	172	-8.7	7.68	-8.5	-33	15	170	-8.8	7.88	-8.0	-28	14	168	-5.7	7.52	-5.0	-32	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA201.SAS
GENERATED: 12JUL2005 17:42:46 iceadmn3

Table 11.2.5.1.2 HAM-A Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	VISIT																		
	DAY 1	172	18.7	7.28	19.0	3	41	170	18.7	7.32	19.0	0	38	169	18.9	7.23	19.0	0	37
	DAY 8	171	14.2	6.57	14.0	0	38	169	14.9	7.12	15.0	0	37	168	16.2	7.27	16.0	0	36
	DAY 15	148	11.9	6.84	12.0	0	37	148	12.6	6.88	12.0	0	30	149	14.6	7.72	15.0	0	34
	DAY 22	139	11.2	6.97	10.0	0	37	133	11.1	7.83	10.0	0	38	143	13.5	7.53	13.0	0	38
	DAY 29	133	10.3	6.85	10.0	0	40	127	9.0	6.78	7.0	0	27	126	12.2	7.21	12.0	0	32
	DAY 36	130	9.5	6.85	9.0	0	29	113	8.5	6.84	7.0	0	32	119	11.7	7.30	11.0	0	33
	DAY 43	123	8.5	6.22	7.0	0	29	107	7.8	6.37	6.0	0	28	107	11.4	6.69	11.0	0	29
	DAY 50	121	8.4	6.17	8.0	0	27	101	7.6	6.29	6.0	0	27	102	11.7	8.36	9.5	0	29
	DAY 57	119	8.3	6.69	7.0	0	26	96	6.9	6.55	4.0	0	31	99	11.2	7.86	10.0	0	32
CHG FROM BASELINE	DAY 8	171	-4.4	5.30	-4.0	-22	9	169	-3.8	5.74	-4.0	-25	19	168	-2.7	5.06	-2.0	-21	14
	DAY 15	148	-6.8	6.53	-6.0	-27	10	148	-5.8	6.60	-5.0	-27	8	149	-4.0	5.88	-4.0	-22	15
	DAY 22	139	-7.6	7.08	-7.0	-30	10	133	-7.4	7.79	-6.0	-31	14	143	-5.0	6.49	-5.0	-23	17
	DAY 29	133	-8.4	7.51	-8.0	-29	14	127	-9.4	7.29	-9.0	-27	12	126	-5.8	6.57	-6.0	-24	15
	DAY 36	130	-9.1	7.72	-8.0	-31	10	113	-9.4	7.81	-9.0	-29	11	119	-6.2	7.33	-6.0	-27	22
	DAY 43	123	-9.8	7.63	-10.0	-35	7	107	-10.0	7.19	-10.0	-28	5	107	-6.1	7.71	-6.0	-29	15
	DAY 50	121	-10.0	7.29	-10.0	-31	11	101	-10.5	7.48	-10.0	-31	4	102	-6.1	8.50	-5.5	-32	18

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA200.SAS
GENERATED: 12JUL2005 17:42:43 iceadmn3

Table 11.2.5.1.2 HAM-A Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO				
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	119	-10.2	7.85	-10.0	-33	15	96	-11.2	7.21	-11.0	-28	1	99	-6.7	8.21	-6.0	-32	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA200.SAS
GENERATED: 12JUL2005 17:42:43 iceadmn3

Table 11.2.5.1.3 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I DISORDER		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	VISIT																		
	DAY 1	116	18.0	7.48	18.0	3	40	114	18.3	7.86	19.0	0	38	112	18.5	7.53	19.0	0	37
	DAY 8	115	13.9	7.07	13.0	0	38	114	14.4	7.33	15.0	0	37	111	16.1	7.60	16.0	0	33
	DAY 15	116	12.0	6.92	12.0	0	37	114	12.7	7.17	12.0	0	30	111	15.1	8.31	15.0	0	34
	DAY 22	116	11.2	7.36	10.0	0	37	114	11.1	7.94	10.0	0	30	111	14.4	7.89	14.0	0	38
	DAY 29	116	10.6	7.32	10.0	0	40	114	10.0	7.85	7.5	0	30	111	14.0	8.26	13.0	0	38
	DAY 36	116	10.0	7.80	8.5	0	40	114	10.1	8.14	8.0	0	32	111	14.0	8.80	14.0	0	38
	DAY 43	116	9.5	7.64	8.0	0	40	114	9.6	7.80	7.0	0	30	111	13.7	8.28	13.0	0	38
	DAY 50	116	9.2	7.41	8.0	0	40	114	9.4	7.70	7.0	0	30	111	13.5	9.14	11.0	0	38
	DAY 57	116	9.1	7.87	8.0	0	40	114	8.9	7.70	6.0	0	30	111	13.9	9.08	13.0	0	38
CHG FROM BASELINE	DAY 8	115	-4.1	5.34	-4.0	-22	9	114	-3.9	6.07	-3.5	-25	19	111	-2.4	5.19	-2.0	-21	14
	DAY 15	116	-6.0	6.19	-5.0	-27	7	114	-5.7	6.67	-5.0	-27	9	111	-3.4	5.96	-3.0	-20	15
	DAY 22	116	-6.8	7.11	-5.5	-30	10	114	-7.2	7.74	-6.0	-31	13	111	-4.0	6.12	-4.0	-20	17
	DAY 29	116	-7.4	7.16	-6.5	-29	5	114	-8.3	7.62	-8.0	-25	12	111	-4.5	6.45	-4.0	-23	15
	DAY 36	116	-8.0	7.62	-7.0	-31	10	114	-8.2	8.01	-7.5	-29	11	111	-4.5	7.13	-4.0	-22	22
	DAY 43	116	-8.5	7.57	-7.5	-35	5	114	-8.7	7.48	-8.0	-28	9	111	-4.8	7.01	-4.0	-21	15
	DAY 50	116	-8.8	7.25	-7.5	-31	4	114	-8.9	7.87	-8.0	-31	9	111	-4.9	7.43	-4.0	-23	18

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA211.SAS
GENERATED: 12JUL2005 17:43:01 iceadmn3

Table 11.2.5.1.3 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I DISORDER		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	116	-8.9	7.73	-9.0	-33	15	114	-9.5	7.76	-9.0	-28	9	111	-4.5	7.18	-4.0	-28	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA211.SAS
GENERATED: 12JUL2005 17:43:01 iceadmn3

Table 11.2.5.1.3 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II DISORDER		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	VISIT																		
	DAY 1	56	20.1	6.70	20.0	8	41	56	19.6	6.07	19.0	4	34	57	19.9	6.57	20.0	0	37
	DAY 8	56	15.0	5.41	15.0	5	30	55	16.0	6.60	15.0	4	33	57	16.5	6.61	17.0	0	36
	DAY 15	56	13.4	6.86	13.5	1	31	56	14.2	6.90	13.0	0	33	57	14.7	6.78	15.0	0	30
	DAY 22	56	12.9	6.31	13.5	0	25	56	14.3	8.01	12.5	2	38	57	13.6	6.80	14.0	0	28
	DAY 29	56	12.4	6.34	12.0	0	30	56	12.5	7.56	11.0	0	33	57	13.5	7.00	13.0	0	28
	DAY 36	56	12.5	6.40	13.0	0	24	56	12.0	7.50	11.0	0	33	57	12.8	6.62	13.0	0	28
	DAY 43	56	11.7	5.95	12.0	1	24	56	12.1	7.81	11.0	0	33	57	12.7	6.92	12.0	0	29
	DAY 50	56	11.7	6.40	12.0	1	24	56	12.0	7.88	11.0	0	33	57	13.5	7.91	13.0	0	29
	DAY 57	56	11.8	6.81	12.0	1	24	56	12.1	8.57	10.5	0	33	57	11.9	7.07	12.0	0	28
CHG FROM BASELINE	DAY 8	56	-5.0	5.22	-3.0	-18	5	55	-3.6	5.04	-4.0	-14	7	57	-3.4	4.77	-3.0	-14	10
	DAY 15	56	-6.7	6.75	-6.0	-25	10	56	-5.4	6.20	-5.5	-23	6	57	-5.2	5.64	-5.0	-22	7
	DAY 22	56	-7.1	6.51	-7.0	-23	8	56	-5.3	7.40	-5.5	-25	14	57	-6.3	6.76	-6.0	-23	7
	DAY 29	56	-7.7	7.57	-8.0	-27	14	56	-7.1	7.77	-6.0	-27	14	57	-6.4	6.61	-6.0	-24	8
	DAY 36	56	-7.6	7.20	-7.0	-27	8	56	-7.6	8.30	-8.0	-26	14	57	-7.1	6.69	-6.0	-27	7
	DAY 43	56	-8.4	7.50	-8.0	-29	7	56	-7.5	8.21	-6.0	-25	14	57	-7.2	7.54	-8.0	-29	9
	DAY 50	56	-8.4	7.36	-7.5	-27	11	56	-7.6	8.30	-7.0	-26	14	57	-6.4	8.27	-6.0	-32	9

(Continued)

Table 11.2.5.1.3 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II DISORDER		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	56	-8.3	7.64	-7.5	-27	14	56	-7.4	8.04	-6.0	-27	14	57	-8.0	7.69	-7.0	-32	7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA211.SAS
GENERATED: 12JUL2005 17:43:01 iceadmn3

Table 11.2.5.1.4 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I DISORDER		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	VISIT																		
	DAY 1	116	18.0	7.48	18.0	3	40	114	18.3	7.86	19.0	0	38	112	18.5	7.53	19.0	0	37
	DAY 8	115	13.9	7.07	13.0	0	38	114	14.4	7.33	15.0	0	37	111	16.1	7.60	16.0	0	33
	DAY 15	103	11.6	6.71	12.0	0	37	105	12.1	6.85	11.0	0	30	96	14.6	8.24	14.5	0	34
	DAY 22	95	10.6	7.19	10.0	0	37	94	9.9	7.20	9.5	0	28	93	13.7	7.88	13.0	0	38
	DAY 29	93	9.7	6.97	9.0	0	40	91	8.5	6.70	7.0	0	27	79	11.6	7.14	10.0	0	32
	DAY 36	90	8.5	6.79	7.0	0	29	82	8.5	7.15	7.0	0	32	74	11.6	7.80	11.0	0	33
	DAY 43	87	7.9	6.38	6.0	0	29	77	7.4	6.11	6.0	0	24	67	10.7	6.46	9.0	0	28
	DAY 50	87	7.6	5.89	6.0	0	27	71	7.0	5.77	6.0	0	25	63	10.8	8.27	8.0	0	29
	DAY 57	83	7.3	6.34	6.0	0	26	68	6.1	5.27	4.0	0	21	58	11.5	8.38	9.5	0	32
CHG FROM BASELINE	DAY 8	115	-4.1	5.34	-4.0	-22	9	114	-3.9	6.07	-3.5	-25	19	111	-2.4	5.19	-2.0	-21	14
	DAY 15	103	-6.4	6.32	-6.0	-27	7	105	-5.9	6.65	-5.0	-27	8	96	-3.4	5.92	-3.0	-20	15
	DAY 22	95	-7.4	7.27	-6.0	-30	10	94	-8.1	7.54	-6.5	-31	13	93	-4.2	6.11	-4.0	-20	17
	DAY 29	93	-8.2	7.42	-7.0	-29	5	91	-9.3	7.36	-9.0	-25	12	79	-5.3	6.34	-5.0	-23	15
	DAY 36	90	-9.1	7.82	-8.5	-31	10	82	-8.9	7.94	-9.0	-29	11	74	-5.2	7.43	-5.0	-22	22
	DAY 43	87	-9.9	7.74	-10.0	-35	5	77	-9.6	7.19	-10.0	-28	5	67	-5.6	7.60	-5.0	-21	15
	DAY 50	87	-10.1	7.38	-10.0	-31	4	71	-10.3	7.55	-10.0	-31	4	63	-5.9	8.21	-5.0	-23	18

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA210.SAS
GENERATED: 12JUL2005 17:42:59 iceadmn3

Table 11.2.5.1.4 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I DISORDER		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	83	-10.4	7.93	-11.0	-33	15	68	-11.4	7.29	-11.0	-28	1	58	-5.2	7.91	-5.0	-28	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA210.SAS
GENERATED: 12JUL2005 17:42:59 iceadmn3

Table 11.2.5.1.4 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II DISORDER		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	VISIT																		
	DAY 1	56	20.1	6.70	20.0	8	41	56	19.6	6.07	19.0	4	34	57	19.9	6.57	20.0	0	37
	DAY 8	56	15.0	5.41	15.0	5	30	55	16.0	6.60	15.0	4	33	57	16.5	6.61	17.0	0	36
	DAY 15	45	12.6	7.17	13.0	1	31	43	13.8	6.85	13.0	0	29	53	14.5	6.74	15.0	0	30
	DAY 22	44	12.6	6.30	13.0	0	25	39	13.9	8.61	11.0	2	38	50	13.3	6.90	13.5	0	28
	DAY 29	40	11.8	6.40	11.5	0	30	36	10.3	6.88	8.0	0	25	47	13.1	7.29	13.0	0	28
	DAY 36	40	11.7	6.53	11.5	0	23	31	8.7	6.05	7.0	0	22	45	11.9	6.49	11.0	0	27
	DAY 43	36	10.1	5.59	10.0	1	20	30	8.9	6.99	6.5	0	28	40	12.5	7.00	12.0	0	29
	DAY 50	34	10.5	6.43	10.0	1	21	30	9.1	7.28	8.0	0	27	39	13.1	8.41	12.0	0	29
	DAY 57	36	10.6	6.98	9.0	1	23	28	9.1	8.69	4.5	0	31	41	10.9	7.16	10.0	0	27
CHG FROM BASELINE	DAY 8	56	-5.0	5.22	-3.0	-18	5	55	-3.6	5.04	-4.0	-14	7	57	-3.4	4.77	-3.0	-14	10
	DAY 15	45	-7.5	7.01	-7.0	-25	10	43	-5.8	6.57	-6.0	-23	6	53	-5.0	5.72	-5.0	-22	7
	DAY 22	44	-8.1	6.69	-8.0	-23	8	39	-5.7	8.20	-6.0	-25	14	50	-6.4	6.97	-6.5	-23	7
	DAY 29	40	-8.8	7.80	-9.5	-27	14	36	-9.6	7.20	-9.0	-27	4	47	-6.5	6.95	-6.0	-24	8
	DAY 36	40	-9.1	7.58	-8.0	-27	8	31	-10.7	7.43	-9.0	-26	5	45	-7.8	6.95	-6.0	-27	7
	DAY 43	36	-9.8	7.46	-9.5	-29	7	30	-10.9	7.23	-11.0	-25	0	40	-7.0	7.90	-8.0	-29	9
	DAY 50	34	-9.5	7.16	-10.0	-23	11	30	-10.9	7.43	-9.5	-26	4	39	-6.4	9.05	-6.0	-32	9

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA210.SAS
GENERATED: 12JUL2005 17:42:59 iceadmn3

Table 11.2.5.1.4 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II DISORDER		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 57	36	-9.8	7.75	-9.0	-26	14	28	-10.8	7.14	-9.0	-27	1	41	-8.9	8.24	-8.0	-32	7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA210.SAS
GENERATED: 12JUL2005 17:42:59 iceadmn3

Table 11.2.5.2.1 HAM-A Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	18.6	7.30	-4.4	5.30	-4.57	0.451	-5.47	-3.68	.
	Q600MG	169	18.7	7.34	-3.8	5.74	-3.84	0.455	-4.75	-2.94	.
	P	168	18.9	7.25	-2.7	5.06	-2.72	0.455	-3.62	-1.82	.
	Q300MG VS P	.	.	.	.	.	-1.86	0.517	-2.87	-0.84	<.001
	Q600MG VS P	.	.	.	.	.	-1.13	0.520	-2.15	-0.10	0.031
DAY 15	Q300MG	172	18.7	7.28	-6.2	6.37	-6.39	0.539	-7.46	-5.31	.
	Q600MG	170	18.7	7.32	-5.6	6.50	-5.59	0.543	-6.67	-4.51	.
	P	168	18.9	7.25	-4.0	5.90	-3.89	0.544	-4.98	-2.81	.
	Q300MG VS P	.	.	.	.	.	-2.49	0.603	-3.68	-1.31	<.001
	Q600MG VS P	.	.	.	.	.	-1.70	0.606	-2.89	-0.51	0.005
DAY 22	Q300MG	172	18.7	7.28	-6.9	6.90	-6.95	0.551	-8.04	-5.85	.
	Q600MG	170	18.7	7.32	-6.6	7.67	-6.56	0.555	-7.66	-5.46	.
	P	168	18.9	7.25	-4.8	6.42	-4.66	0.555	-5.77	-3.56	.
	Q300MG VS P	.	.	.	.	.	-2.29	0.681	-3.62	-0.95	<.001
	Q600MG VS P	.	.	.	.	.	-1.89	0.684	-3.24	-0.55	0.006
DAY 29	Q300MG	172	18.7	7.28	-7.5	7.27	-7.48	0.596	-8.67	-6.29	.
	Q600MG	170	18.7	7.32	-7.9	7.67	-7.80	0.600	-9.00	-6.61	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202.SAS
GENERATED: 12JUL2005 17:28:54 iceadmn3

Table 11.2.5.2.1 HAM-A Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	168	18.9	7.25	-5.1	6.54	-4.94	0.601	-6.14	-3.74	.
	Q300MG VS P	.	.	.	.	.	-2.54	0.687	-3.89	-1.19	<.001
	Q600MG VS P	.	.	.	.	.	-2.86	0.691	-4.22	-1.50	<.001
DAY 36	Q300MG	172	18.7	7.28	-7.9	7.47	-7.81	0.596	-9.00	-6.63	.
	Q600MG	170	18.7	7.32	-8.0	8.09	-7.83	0.600	-9.02	-6.64	.
	P	168	18.9	7.25	-5.3	7.07	-5.19	0.600	-6.39	-4.00	.
	Q300MG VS P	.	.	.	.	.	-2.62	0.732	-4.06	-1.18	<.001
	Q600MG VS P	.	.	.	.	.	-2.64	0.735	-4.08	-1.19	<.001
DAY 43	Q300MG	172	18.7	7.28	-8.5	7.53	-8.36	0.565	-9.48	-7.24	.
	Q600MG	170	18.7	7.32	-8.3	7.72	-8.18	0.569	-9.30	-7.05	.
	P	168	18.9	7.25	-5.6	7.26	-5.44	0.569	-6.56	-4.31	.
	Q300MG VS P	.	.	.	.	.	-2.93	0.719	-4.34	-1.51	<.001
	Q600MG VS P	.	.	.	.	.	-2.74	0.722	-4.16	-1.32	<.001
DAY 50	Q300MG	172	18.7	7.28	-8.6	7.27	-8.53	0.577	-9.67	-7.38	.
	Q600MG	170	18.7	7.32	-8.5	8.01	-8.33	0.581	-9.48	-7.18	.
	P	168	18.9	7.25	-5.4	7.73	-5.20	0.580	-6.35	-4.05	.
	Q300MG VS P	.	.	.	.	.	-3.33	0.747	-4.80	-1.86	<.001

(Continued)

Table 11.2.5.2.1 HAM-A Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-3.13	0.750	-4.60	-1.66	<.001
DAY 57	Q300MG	172	18.7	7.28	-8.7	7.68	-8.64	0.581	-9.79	-7.49	.
	Q600MG	170	18.7	7.32	-8.8	7.88	-8.75	0.585	-9.91	-7.59	.
	P	168	18.9	7.25	-5.7	7.52	-5.54	0.584	-6.70	-4.38	.
	Q300MG VS P	.	.	.	.	.	-3.10	0.758	-4.59	-1.61	<.001
	Q600MG VS P	.	.	.	.	.	-3.20	0.761	-4.70	-1.71	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202.SAS
GENERATED: 12JUL2005 17:28:54 iceadmn3

Table 11.2.5.2.2 HAM-A Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	18.6	7.30	-4.4	5.30	-4.57	0.451	-5.47	-3.68	.
	Q600MG	169	18.7	7.34	-3.8	5.74	-3.84	0.455	-4.75	-2.94	.
	P	168	18.9	7.25	-2.7	5.06	-2.72	0.455	-3.62	-1.82	.
	Q300MG VS P	.	.	.	.	.	-1.86	0.517	-2.87	-0.84	<.001
	Q600MG VS P	.	.	.	.	.	-1.13	0.520	-2.15	-0.10	0.031
DAY 15	Q300MG	148	18.7	7.41	-6.8	6.53	-6.74	0.567	-7.87	-5.61	.
	Q600MG	148	18.4	7.39	-5.8	6.60	-5.89	0.568	-7.02	-4.76	.
	P	149	18.6	7.27	-4.0	5.88	-3.98	0.558	-5.09	-2.86	.
	Q300MG VS P	.	.	.	.	.	-2.76	0.645	-4.03	-1.50	<.001
	Q600MG VS P	.	.	.	.	.	-1.91	0.647	-3.18	-0.64	0.003
DAY 22	Q300MG	139	18.8	7.54	-7.6	7.08	-7.47	0.610	-8.68	-6.26	.
	Q600MG	133	18.5	7.25	-7.4	7.79	-7.40	0.624	-8.64	-6.17	.
	P	143	18.5	7.37	-5.0	6.49	-4.94	0.597	-6.13	-3.75	.
	Q300MG VS P	.	.	.	.	.	-2.53	0.743	-3.99	-1.07	<.001
	Q600MG VS P	.	.	.	.	.	-2.46	0.753	-3.94	-0.98	0.001
DAY 29	Q300MG	133	18.7	7.40	-8.4	7.51	-8.18	0.645	-9.46	-6.89	.
	Q600MG	127	18.4	7.31	-9.4	7.29	-9.22	0.658	-10.53	-7.91	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA206.SAS
GENERATED: 12JUL2005 17:29:01 iceadmn3

Table 11.2.5.2.2 HAM-A Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	126	17.9	7.03	-5.8	6.57	-5.90	0.652	-7.20	-4.60	.
	Q300MG VS P	.	.	.	.	.	-2.28	0.738	-3.73	-0.83	0.002
	Q600MG VS P	.	.	.	.	.	-3.32	0.751	-4.80	-1.85	<.001
DAY 36	Q300MG	130	18.6	7.34	-9.1	7.72	-8.76	0.646	-10.04	-7.48	.
	Q600MG	113	17.9	7.21	-9.4	7.81	-9.36	0.687	-10.73	-8.00	.
	P	119	17.9	7.28	-6.2	7.33	-6.18	0.659	-7.48	-4.87	.
	Q300MG VS P	.	.	.	.	.	-2.58	0.797	-4.15	-1.02	0.001
	Q600MG VS P	.	.	.	.	.	-3.19	0.830	-4.82	-1.55	<.001
DAY 43	Q300MG	123	18.4	7.04	-9.8	7.63	-9.30	0.615	-10.52	-8.08	.
	Q600MG	107	17.8	7.29	-10.0	7.19	-9.79	0.651	-11.07	-8.50	.
	P	107	17.5	7.19	-6.1	7.71	-6.20	0.639	-7.47	-4.94	.
	Q300MG VS P	.	.	.	.	.	-3.10	0.776	-4.62	-1.57	<.001
	Q600MG VS P	.	.	.	.	.	-3.58	0.803	-5.16	-2.00	<.001
DAY 50	Q300MG	121	18.3	7.09	-10.0	7.29	-9.51	0.639	-10.77	-8.24	.
	Q600MG	101	18.0	7.06	-10.5	7.48	-10.16	0.689	-11.52	-8.79	.
	P	102	17.8	7.11	-6.1	8.50	-6.07	0.673	-7.40	-4.74	.
	Q300MG VS P	.	.	.	.	.	-3.44	0.860	-5.13	-1.75	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA206.SAS
GENERATED: 12JUL2005 17:29:01 iceadmn3

Table 11.2.5.2.2 HAM-A Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-4.09	0.898	-5.85	-2.32	<.001
DAY 57	Q300MG	119	18.5	7.08	-10.2	7.85	-9.95	0.659	-11.26	-8.65	.
	Q600MG	96	18.2	7.10	-11.2	7.21	-11.11	0.725	-12.55	-9.68	.
	P	99	17.9	7.18	-6.7	8.21	-6.74	0.698	-8.13	-5.36	.
	Q300MG VS P	.	.	.	.	.	-3.21	0.883	-4.95	-1.47	<.001
	Q600MG VS P	.	.	.	.	.	-4.37	0.929	-6.20	-2.54	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA206.SAS
GENERATED: 12JUL2005 17:29:01 iceadmn3

Table 11.2.5.2.3 HAM-A Total Score Effect Size Change from Baseline
Last Observation Carried Forward
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.36	-0.57	-0.14
	Q600MG VS P	-0.21	-0.42	0.01
DAY 15	Q300MG VS P	-0.41	-0.62	-0.19
	Q600MG VS P	-0.27	-0.49	-0.06
DAY 22	Q300MG VS P	-0.34	-0.56	-0.13
	Q600MG VS P	-0.27	-0.48	-0.05
DAY 29	Q300MG VS P	-0.37	-0.58	-0.15
	Q600MG VS P	-0.40	-0.62	-0.19
DAY 36	Q300MG VS P	-0.36	-0.57	-0.15
	Q600MG VS P	-0.35	-0.56	-0.13
DAY 43	Q300MG VS P	-0.40	-0.61	-0.18
	Q600MG VS P	-0.37	-0.58	-0.15
DAY 50	Q300MG VS P	-0.44	-0.66	-0.23
	Q600MG VS P	-0.40	-0.61	-0.18
DAY 57	Q300MG VS P	-0.41	-0.62	-0.19
	Q600MG VS P	-0.42	-0.63	-0.20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA205.SAS
GENERATED: 12JUL2005 17:28:58 iceadmn3

Table 11.2.5.2.4 HAM-A Total Score Effect Size Change from Baseline
Observed Cases
Intent-to-Treat

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.36	-0.57	-0.14
	Q600MG VS P	-0.21	-0.42	0.01
DAY 15	Q300MG VS P	-0.44	-0.68	-0.21
	Q600MG VS P	-0.31	-0.53	-0.08
DAY 22	Q300MG VS P	-0.37	-0.61	-0.14
	Q600MG VS P	-0.34	-0.58	-0.11
DAY 29	Q300MG VS P	-0.32	-0.57	-0.08
	Q600MG VS P	-0.48	-0.73	-0.23
DAY 36	Q300MG VS P	-0.34	-0.59	-0.09
	Q600MG VS P	-0.42	-0.68	-0.16
DAY 43	Q300MG VS P	-0.40	-0.67	-0.14
	Q600MG VS P	-0.48	-0.75	-0.21
DAY 50	Q300MG VS P	-0.44	-0.70	-0.17
	Q600MG VS P	-0.51	-0.79	-0.23
DAY 57	Q300MG VS P	-0.40	-0.67	-0.13
	Q600MG VS P	-0.56	-0.85	-0.28

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA207.SAS
GENERATED: 12JUL2005 17:29:04 iceadmn3

FIGURE 11.2.5.3.1 HAM-A TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

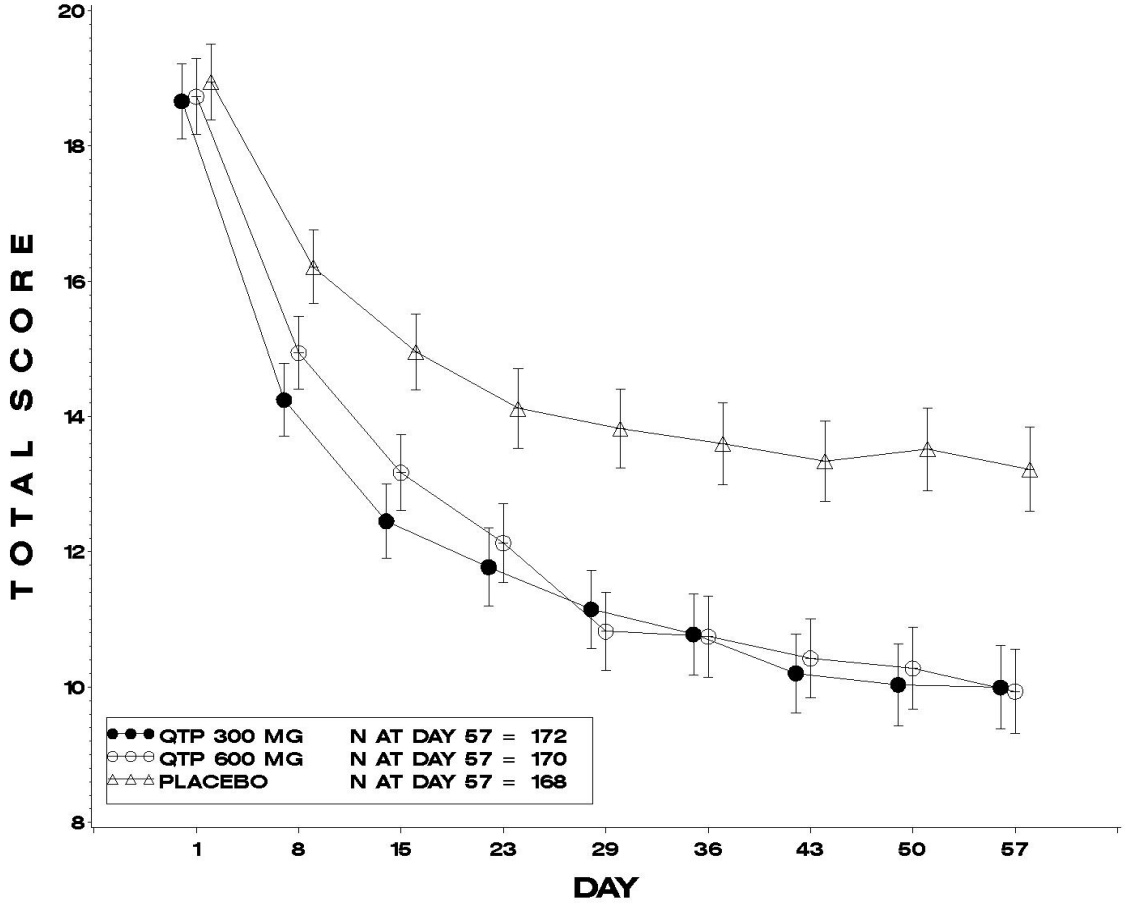

FIGURE 11.2.5.3.2 HAM-A TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

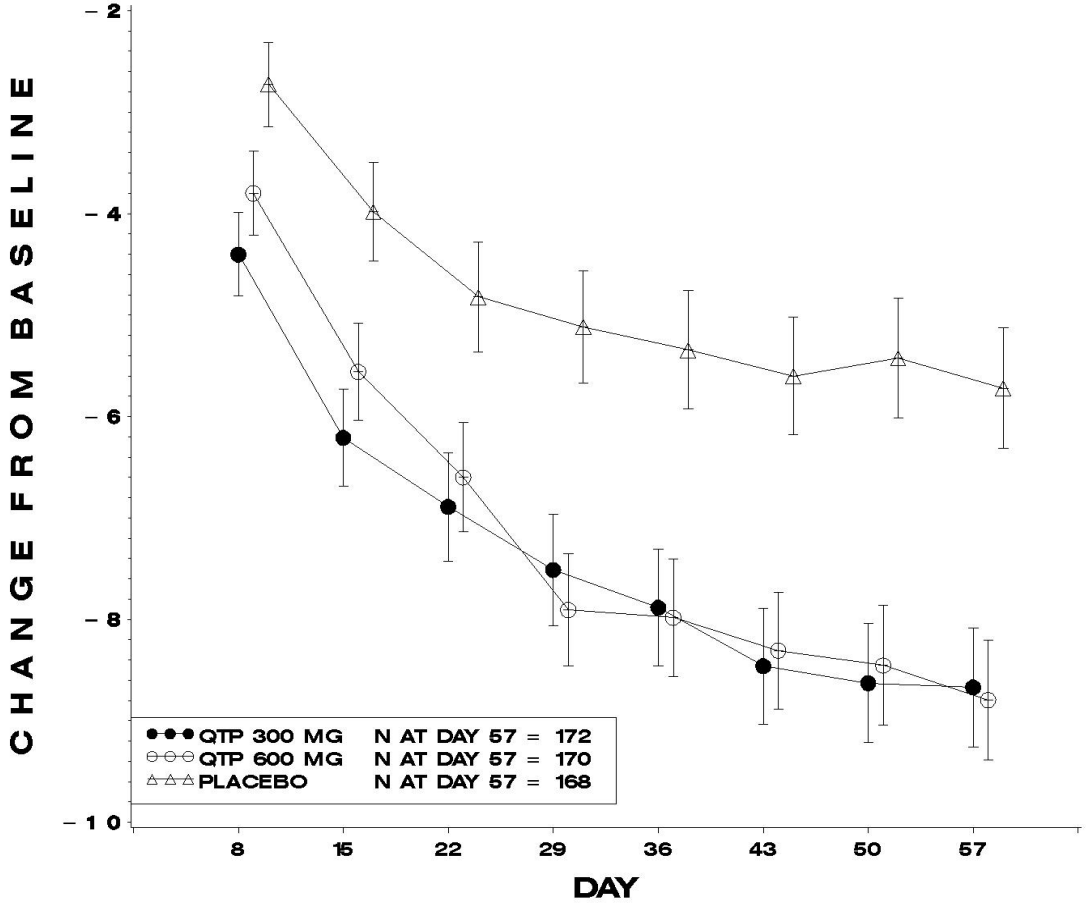

FIGURE 11.2.5.3.3 HAM-A TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

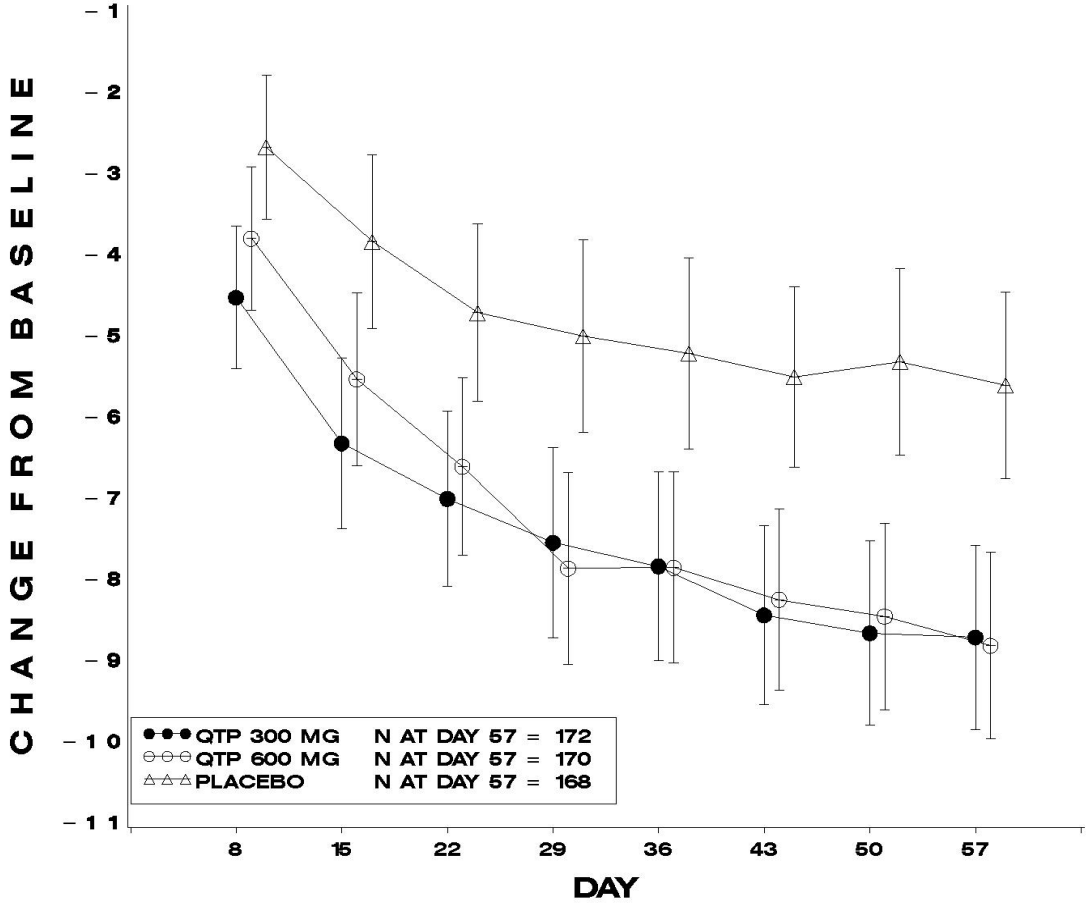

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ANXIOUS MOOD	VISIT																		
	DAY 1	172	2.2	0.85	2.0	0	4	170	2.2	0.90	2.0	0	4	169	2.2	0.86	2.0	0	4
	DAY 8	171	1.8	0.88	2.0	0	4	169	1.8	0.93	2.0	0	4	168	1.9	0.87	2.0	0	4
	DAY 15	172	1.6	0.92	2.0	0	4	170	1.6	0.97	2.0	0	4	168	1.8	0.98	2.0	0	4
	DAY 22	172	1.5	0.90	2.0	0	4	170	1.4	1.08	1.0	0	4	168	1.7	0.93	2.0	0	4
	DAY 29	172	1.5	0.94	1.5	0	4	170	1.3	1.05	1.0	0	4	168	1.7	0.96	2.0	0	4
	DAY 36	172	1.4	1.02	1.0	0	4	170	1.4	1.08	1.0	0	4	168	1.7	0.97	2.0	0	4
	DAY 43	172	1.4	0.97	1.0	0	4	170	1.3	1.07	1.0	0	4	168	1.7	1.00	2.0	0	4
	DAY 50	172	1.3	1.01	1.0	0	4	170	1.2	1.04	1.0	0	4	168	1.7	1.08	2.0	0	4
	DAY 57	172	1.3	1.02	1.0	0	4	170	1.2	1.09	1.0	0	4	168	1.7	1.01	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. TENSION	VISIT																		
	DAY 1	172	2.1	0.91	2.0	0	4	170	2.0	0.90	2.0	0	4	169	2.1	0.85	2.0	0	4
	DAY 8	171	1.6	0.94	2.0	0	4	169	1.6	0.95	2.0	0	4	168	1.8	0.95	2.0	0	4
	DAY 15	172	1.5	0.97	2.0	0	3	170	1.4	0.95	1.0	0	4	168	1.7	0.98	2.0	0	4
	DAY 22	172	1.4	0.93	1.0	0	4	170	1.4	1.02	1.0	0	4	168	1.6	1.01	2.0	0	4
	DAY 29	172	1.3	0.98	1.0	0	4	170	1.2	1.01	1.0	0	4	168	1.6	1.04	2.0	0	4
	DAY 36	172	1.3	0.99	1.0	0	4	170	1.2	1.00	1.0	0	4	168	1.6	1.01	2.0	0	4
	DAY 43	172	1.2	0.96	1.0	0	4	170	1.2	0.99	1.0	0	4	168	1.6	1.02	2.0	0	4
	DAY 50	172	1.2	1.00	1.0	0	4	170	1.1	0.95	1.0	0	4	168	1.5	1.13	2.0	0	4
	DAY 57	172	1.2	1.03	1.0	0	4	170	1.1	0.99	1.0	0	4	168	1.5	1.07	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. FEARS	VISIT																		
	DAY 1	172	0.6	0.91	0.0	0	4	170	0.6	0.82	0.0	0	3	169	0.7	0.89	0.0	0	4
	DAY 8	171	0.4	0.73	0.0	0	3	169	0.5	0.81	0.0	0	4	168	0.5	0.85	0.0	0	4
	DAY 15	172	0.3	0.67	0.0	0	3	170	0.4	0.70	0.0	0	3	168	0.5	0.83	0.0	0	4
	DAY 22	172	0.3	0.70	0.0	0	3	170	0.3	0.65	0.0	0	3	168	0.4	0.85	0.0	0	4
	DAY 29	172	0.3	0.63	0.0	0	3	170	0.3	0.61	0.0	0	3	168	0.4	0.77	0.0	0	4
	DAY 36	172	0.3	0.61	0.0	0	3	170	0.3	0.63	0.0	0	3	168	0.4	0.76	0.0	0	4
	DAY 43	172	0.3	0.58	0.0	0	3	170	0.2	0.59	0.0	0	3	168	0.4	0.75	0.0	0	4
	DAY 50	172	0.3	0.59	0.0	0	3	170	0.2	0.57	0.0	0	3	168	0.4	0.81	0.0	0	4
	DAY 57	172	0.3	0.57	0.0	0	3	170	0.2	0.56	0.0	0	3	168	0.4	0.82	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA	VISIT																		
	DAY 1	172	2.2	0.94	2.0	0	4	170	2.1	0.98	2.0	0	4	169	2.2	0.99	2.0	0	4
	DAY 8	171	0.8	0.98	0.0	0	4	169	0.8	0.98	0.0	0	4	168	1.8	1.11	2.0	0	4
	DAY 15	172	0.8	0.96	1.0	0	4	170	0.9	1.05	0.0	0	3	168	1.7	1.17	2.0	0	4
	DAY 22	172	0.9	1.01	1.0	0	4	170	0.9	1.12	0.0	0	4	168	1.5	1.13	1.5	0	4
	DAY 29	172	0.8	0.90	1.0	0	4	170	0.8	1.12	0.0	0	4	168	1.5	1.09	1.5	0	4
	DAY 36	172	0.8	0.91	1.0	0	4	170	0.7	1.06	0.0	0	4	168	1.5	1.16	1.0	0	4
	DAY 43	172	0.8	0.97	1.0	0	4	170	0.7	1.03	0.0	0	4	168	1.5	1.16	1.0	0	4
	DAY 50	172	0.8	0.94	1.0	0	4	170	0.7	1.03	0.0	0	4	168	1.5	1.16	1.5	0	4
	DAY 57	172	0.8	1.03	0.0	0	4	170	0.7	1.03	0.0	0	4	168	1.5	1.14	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INTELLECTUAL	VISIT																		
	DAY 1	172	1.9	0.90	2.0	0	4	170	1.9	0.89	2.0	0	3	169	2.0	0.94	2.0	0	4
	DAY 8	171	1.5	0.93	2.0	0	4	169	1.6	0.98	2.0	0	4	168	1.8	0.93	2.0	0	3
	DAY 15	172	1.3	0.94	1.0	0	4	170	1.4	1.05	1.0	0	4	168	1.5	0.97	2.0	0	4
	DAY 22	172	1.2	0.92	1.0	0	3	170	1.2	1.03	1.0	0	4	168	1.5	0.94	2.0	0	4
	DAY 29	172	1.2	0.93	1.0	0	4	170	1.1	1.06	1.0	0	4	168	1.4	0.95	1.0	0	4
	DAY 36	172	1.1	0.94	1.0	0	4	170	1.2	1.07	1.0	0	4	168	1.4	0.98	1.0	0	4
	DAY 43	172	1.0	0.88	1.0	0	3	170	1.1	1.08	1.0	0	4	168	1.4	1.00	1.0	0	4
	DAY 50	172	1.0	0.93	1.0	0	3	170	1.1	1.04	1.0	0	4	168	1.4	1.08	1.0	0	4
	DAY 57	172	1.0	0.94	1.0	0	3	170	1.1	1.08	1.0	0	4	168	1.3	1.07	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. DEPRESSED MOOD	VISIT																		
	DAY 1	172	2.7	0.57	3.0	1	4	170	2.6	0.66	3.0	0	4	169	2.6	0.66	3.0	0	4
	DAY 8	171	2.1	0.81	2.0	0	4	169	2.0	0.87	2.0	0	4	168	2.2	0.88	2.0	0	4
	DAY 15	172	1.8	0.95	2.0	0	4	170	1.7	0.98	2.0	0	4	168	2.0	0.99	2.0	0	4
	DAY 22	172	1.6	0.98	2.0	0	4	170	1.5	1.02	2.0	0	3	168	1.9	1.04	2.0	0	4
	DAY 29	172	1.5	0.99	2.0	0	4	170	1.3	1.05	1.0	0	3	168	1.8	1.05	2.0	0	4
	DAY 36	172	1.4	1.05	1.0	0	4	170	1.4	1.10	1.0	0	4	168	1.8	1.11	2.0	0	4
	DAY 43	172	1.4	1.08	1.0	0	4	170	1.3	1.11	1.0	0	4	168	1.8	1.10	2.0	0	4
	DAY 50	172	1.3	1.08	1.0	0	4	170	1.3	1.13	1.0	0	4	168	1.8	1.16	2.0	0	4
	DAY 57	172	1.2	1.12	1.0	0	4	170	1.2	1.14	1.0	0	4	168	1.7	1.15	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. SOMATIC (MUSCULAR)	VISIT																		
	DAY 1	172	1.0	0.96	1.0	0	3	170	1.1	0.91	1.0	0	3	169	1.1	0.99	1.0	0	4
	DAY 8	171	0.9	0.95	1.0	0	4	169	0.9	0.87	1.0	0	3	168	0.9	0.89	1.0	0	3
	DAY 15	172	0.8	0.88	1.0	0	4	170	0.8	0.86	1.0	0	3	168	0.8	0.86	1.0	0	3
	DAY 22	172	0.7	0.89	0.0	0	4	170	0.7	0.86	0.0	0	3	168	0.8	0.87	1.0	0	3
	DAY 29	172	0.7	0.91	0.0	0	4	170	0.6	0.83	0.0	0	3	168	0.8	0.87	1.0	0	3
	DAY 36	172	0.7	0.91	0.0	0	4	170	0.6	0.83	0.0	0	3	168	0.8	0.87	1.0	0	3
	DAY 43	172	0.6	0.83	0.0	0	4	170	0.6	0.83	0.0	0	3	168	0.8	0.86	1.0	0	3
	DAY 50	172	0.6	0.84	0.0	0	4	170	0.6	0.83	0.0	0	3	168	0.8	0.92	1.0	0	3
	DAY 57	172	0.6	0.87	0.0	0	4	170	0.6	0.82	0.0	0	3	168	0.8	0.88	0.5	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. SOMATIC (SENSORY)	VISIT																		
	DAY 1	172	0.6	0.79	0.0	0	3	170	0.7	0.81	1.0	0	3	169	0.6	0.85	0.0	0	4
	DAY 8	171	0.5	0.68	0.0	0	3	169	0.7	0.80	0.0	0	3	168	0.6	0.73	0.0	0	2
	DAY 15	172	0.5	0.69	0.0	0	3	170	0.5	0.73	0.0	0	3	168	0.5	0.71	0.0	0	3
	DAY 22	172	0.5	0.70	0.0	0	3	170	0.5	0.75	0.0	0	3	168	0.5	0.66	0.0	0	2
	DAY 29	172	0.4	0.64	0.0	0	3	170	0.4	0.68	0.0	0	3	168	0.5	0.66	0.0	0	2
	DAY 36	172	0.4	0.64	0.0	0	3	170	0.4	0.65	0.0	0	3	168	0.5	0.74	0.0	0	3
	DAY 43	172	0.4	0.62	0.0	0	3	170	0.4	0.67	0.0	0	3	168	0.5	0.69	0.0	0	2
	DAY 50	172	0.4	0.63	0.0	0	3	170	0.4	0.66	0.0	0	3	168	0.5	0.70	0.0	0	3
	DAY 57	172	0.4	0.61	0.0	0	3	170	0.4	0.72	0.0	0	4	168	0.5	0.72	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. CARDIOVASCULAR SYMPTOMS	VISIT																		
	DAY 1	172	0.7	0.82	0.0	0	3	170	0.6	0.79	0.0	0	3	169	0.6	0.75	0.0	0	3
	DAY 8	171	0.6	0.73	0.0	0	3	169	0.7	0.85	0.0	0	3	168	0.5	0.73	0.0	0	3
	DAY 15	172	0.4	0.72	0.0	0	3	170	0.5	0.74	0.0	0	3	168	0.4	0.71	0.0	0	3
	DAY 22	172	0.5	0.73	0.0	0	3	170	0.4	0.73	0.0	0	3	168	0.4	0.65	0.0	0	2
	DAY 29	172	0.4	0.65	0.0	0	3	170	0.4	0.70	0.0	0	3	168	0.4	0.64	0.0	0	2
	DAY 36	172	0.4	0.69	0.0	0	3	170	0.4	0.68	0.0	0	3	168	0.4	0.66	0.0	0	3
	DAY 43	172	0.3	0.66	0.0	0	3	170	0.3	0.66	0.0	0	3	168	0.3	0.59	0.0	0	2
	DAY 50	172	0.4	0.67	0.0	0	3	170	0.4	0.64	0.0	0	3	168	0.4	0.64	0.0	0	2
	DAY 57	172	0.4	0.71	0.0	0	3	170	0.4	0.69	0.0	0	3	168	0.4	0.67	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. RESPIRATORY SYMPTOMS	VISIT																		
	DAY 1	172	0.5	0.72	0.0	0	3	170	0.5	0.73	0.0	0	3	169	0.5	0.74	0.0	0	2
	DAY 8	171	0.4	0.61	0.0	0	3	169	0.4	0.66	0.0	0	3	168	0.4	0.75	0.0	0	3
	DAY 15	172	0.3	0.58	0.0	0	3	170	0.4	0.62	0.0	0	3	168	0.4	0.74	0.0	0	3
	DAY 22	172	0.3	0.56	0.0	0	3	170	0.4	0.68	0.0	0	3	168	0.4	0.66	0.0	0	3
	DAY 29	172	0.2	0.52	0.0	0	3	170	0.3	0.66	0.0	0	3	168	0.4	0.66	0.0	0	2
	DAY 36	172	0.2	0.50	0.0	0	3	170	0.3	0.59	0.0	0	3	168	0.4	0.61	0.0	0	2
	DAY 43	172	0.2	0.49	0.0	0	3	170	0.3	0.59	0.0	0	3	168	0.3	0.62	0.0	0	2
	DAY 50	172	0.2	0.49	0.0	0	3	170	0.3	0.57	0.0	0	3	168	0.4	0.66	0.0	0	2
	DAY 57	172	0.3	0.57	0.0	0	3	170	0.3	0.57	0.0	0	3	168	0.4	0.69	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. GASTROINTESTINAL SYMPTOMS	VISIT																		
	DAY 1	172	0.9	0.95	1.0	0	4	170	0.9	1.00	1.0	0	4	169	0.9	0.89	1.0	0	3
	DAY 8	171	0.7	0.89	0.0	0	3	169	0.9	0.91	1.0	0	4	168	0.9	0.87	1.0	0	3
	DAY 15	172	0.7	0.88	0.0	0	3	170	0.8	0.87	1.0	0	3	168	0.8	0.93	0.0	0	3
	DAY 22	172	0.6	0.85	0.0	0	3	170	0.8	0.92	1.0	0	4	168	0.6	0.78	0.0	0	3
	DAY 29	172	0.6	0.83	0.0	0	3	170	0.7	0.88	0.0	0	3	168	0.7	0.79	1.0	0	3
	DAY 36	172	0.6	0.83	0.0	0	3	170	0.7	0.90	0.0	0	3	168	0.7	0.83	0.0	0	4
	DAY 43	172	0.6	0.81	0.0	0	3	170	0.6	0.85	0.0	0	4	168	0.7	0.79	0.0	0	3
	DAY 50	172	0.6	0.80	0.0	0	3	170	0.6	0.88	0.0	0	3	168	0.6	0.78	0.0	0	3
	DAY 57	172	0.6	0.85	0.0	0	3	170	0.6	0.85	0.0	0	4	168	0.6	0.78	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. GENITOURINARY SYMPTOMS	VISIT																		
	DAY 1	172	1.1	1.13	1.0	0	4	170	1.3	1.15	1.0	0	4	169	1.2	1.14	1.0	0	4
	DAY 8	171	1.0	1.05	1.0	0	4	169	1.1	1.02	1.0	0	3	168	1.1	1.14	1.0	0	4
	DAY 15	172	0.9	1.02	1.0	0	4	170	1.0	1.05	1.0	0	4	168	1.1	1.10	1.0	0	4
	DAY 22	172	0.8	1.00	0.0	0	4	170	0.8	1.00	0.5	0	3	168	1.1	1.09	1.0	0	4
	DAY 29	172	0.8	0.98	0.0	0	3	170	0.8	1.00	0.0	0	3	168	1.0	1.07	1.0	0	4
	DAY 36	172	0.7	0.96	0.0	0	3	170	0.8	1.03	0.0	0	3	168	1.0	1.09	1.0	0	4
	DAY 43	172	0.7	0.97	0.0	0	3	170	0.8	1.04	0.0	0	3	168	0.9	1.08	1.0	0	4
	DAY 50	172	0.7	0.94	0.0	0	3	170	0.8	1.04	0.0	0	3	168	1.0	1.12	1.0	0	4
	DAY 57	172	0.7	0.96	0.0	0	3	170	0.7	0.96	0.0	0	3	168	1.0	1.11	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. AUTONOMIC SYMPTOMS	VISIT																		
	DAY 1	172	0.9	0.94	1.0	0	3	170	0.9	0.88	1.0	0	3	169	1.1	0.93	1.0	0	4
	DAY 8	171	1.0	0.87	1.0	0	4	169	1.0	0.91	1.0	0	4	168	0.9	0.90	1.0	0	4
	DAY 15	172	0.9	0.86	1.0	0	4	170	0.9	0.89	1.0	0	4	168	0.8	0.89	1.0	0	3
	DAY 22	172	0.8	0.86	1.0	0	4	170	0.9	0.90	1.0	0	4	168	0.8	0.83	1.0	0	3
	DAY 29	172	0.8	0.80	1.0	0	3	170	0.8	0.88	1.0	0	4	168	0.8	0.84	1.0	0	3
	DAY 36	172	0.7	0.77	1.0	0	3	170	0.7	0.85	0.0	0	4	168	0.8	0.86	1.0	0	3
	DAY 43	172	0.7	0.81	0.0	0	3	170	0.7	0.87	0.0	0	4	168	0.7	0.83	0.0	0	3
	DAY 50	172	0.7	0.77	1.0	0	3	170	0.7	0.88	0.0	0	4	168	0.7	0.85	0.0	0	3
	DAY 57	172	0.7	0.78	1.0	0	3	170	0.6	0.85	0.0	0	4	168	0.7	0.81	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
14. BEHAVIOR AT INTERVIEW	VISIT																		
	DAY 1	172	1.2	0.93	1.0	0	4	170	1.2	0.92	1.0	0	4	169	1.2	0.82	1.0	0	3
	DAY 8	171	0.9	0.84	1.0	0	3	169	0.9	0.87	1.0	0	3	168	1.0	0.83	1.0	0	3
	DAY 15	172	0.8	0.86	1.0	0	3	170	0.9	0.86	1.0	0	3	168	0.9	0.81	1.0	0	3
	DAY 22	172	0.7	0.84	0.0	0	3	170	0.8	0.87	1.0	0	4	168	0.9	0.81	1.0	0	3
	DAY 29	172	0.6	0.80	0.0	0	3	170	0.7	0.87	1.0	0	4	168	0.9	0.88	1.0	0	3
	DAY 36	172	0.7	0.83	0.0	0	4	170	0.7	0.87	1.0	0	4	168	0.9	0.85	1.0	0	3
	DAY 43	172	0.7	0.83	0.5	0	3	170	0.8	0.92	1.0	0	4	168	0.9	0.84	1.0	0	3
	DAY 50	172	0.7	0.78	0.0	0	3	170	0.8	0.89	1.0	0	4	168	0.9	0.92	1.0	0	4
	DAY 57	172	0.6	0.80	0.0	0	3	170	0.8	0.87	1.0	0	4	168	0.8	0.88	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA204.SAS
GENERATED: 12JUL2005 17:42:53 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ANXIOUS MOOD	VISIT																		
	DAY 1	172	2.2	0.85	2.0	0	4	170	2.2	0.90	2.0	0	4	169	2.2	0.86	2.0	0	4
	DAY 8	171	1.8	0.88	2.0	0	4	169	1.8	0.93	2.0	0	4	168	1.9	0.87	2.0	0	4
	DAY 15	148	1.6	0.94	2.0	0	4	148	1.6	0.95	2.0	0	4	149	1.8	0.97	2.0	0	4
	DAY 22	139	1.5	0.91	1.0	0	4	133	1.3	1.07	1.0	0	4	143	1.7	0.90	2.0	0	4
	DAY 29	133	1.4	0.96	1.0	0	4	127	1.2	0.99	1.0	0	4	126	1.5	0.91	2.0	0	4
	DAY 36	130	1.3	1.04	1.0	0	4	113	1.2	1.00	1.0	0	4	119	1.6	0.92	2.0	0	3
	DAY 43	123	1.2	0.96	1.0	0	4	107	1.1	0.96	1.0	0	4	107	1.5	0.97	2.0	0	3
	DAY 50	121	1.1	0.98	1.0	0	4	101	0.9	0.84	1.0	0	3	102	1.6	1.09	1.0	0	4
	DAY 57	119	1.1	0.95	1.0	0	3	96	0.9	0.91	1.0	0	4	99	1.6	0.99	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. TENSION	VISIT																		
	DAY 1	172	2.1	0.91	2.0	0	4	170	2.0	0.90	2.0	0	4	169	2.1	0.85	2.0	0	4
	DAY 8	171	1.6	0.94	2.0	0	4	169	1.6	0.95	2.0	0	4	168	1.8	0.95	2.0	0	4
	DAY 15	148	1.4	0.98	1.5	0	3	148	1.4	0.97	1.0	0	4	149	1.7	0.96	2.0	0	4
	DAY 22	139	1.4	0.90	1.0	0	4	133	1.3	1.04	1.0	0	4	143	1.5	0.98	2.0	0	3
	DAY 29	133	1.2	0.96	1.0	0	4	127	1.0	0.95	1.0	0	4	126	1.4	0.98	1.0	0	4
	DAY 36	130	1.2	0.96	1.0	0	4	113	1.0	0.94	1.0	0	3	119	1.4	0.93	1.0	0	3
	DAY 43	123	1.0	0.87	1.0	0	4	107	1.0	0.93	1.0	0	3	107	1.4	0.96	1.0	0	3
	DAY 50	121	1.0	0.94	1.0	0	4	101	0.8	0.79	1.0	0	3	102	1.2	1.10	1.0	0	4
	DAY 57	119	1.0	0.92	1.0	0	3	96	0.7	0.84	0.0	0	3	99	1.3	1.04	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. FEARS	VISIT																		
	DAY 1	172	0.6	0.91	0.0	0	4	170	0.6	0.82	0.0	0	3	169	0.7	0.89	0.0	0	4
	DAY 8	171	0.4	0.73	0.0	0	3	169	0.5	0.81	0.0	0	4	168	0.5	0.85	0.0	0	4
	DAY 15	148	0.3	0.67	0.0	0	3	148	0.4	0.69	0.0	0	3	149	0.5	0.79	0.0	0	3
	DAY 22	139	0.3	0.67	0.0	0	3	133	0.3	0.63	0.0	0	3	143	0.4	0.79	0.0	0	3
	DAY 29	133	0.3	0.57	0.0	0	3	127	0.2	0.52	0.0	0	2	126	0.3	0.63	0.0	0	3
	DAY 36	130	0.2	0.54	0.0	0	3	113	0.2	0.50	0.0	0	3	119	0.3	0.66	0.0	0	3
	DAY 43	123	0.2	0.50	0.0	0	2	107	0.1	0.45	0.0	0	2	107	0.3	0.64	0.0	0	3
	DAY 50	121	0.2	0.52	0.0	0	2	101	0.1	0.41	0.0	0	2	102	0.3	0.76	0.0	0	3
	DAY 57	119	0.2	0.48	0.0	0	2	96	0.1	0.37	0.0	0	2	99	0.4	0.78	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
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Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA	VISIT																		
	DAY 1	172	2.2	0.94	2.0	0	4	170	2.1	0.98	2.0	0	4	169	2.2	0.99	2.0	0	4
	DAY 8	171	0.8	0.98	0.0	0	4	169	0.8	0.98	0.0	0	4	168	1.8	1.11	2.0	0	4
	DAY 15	148	0.8	0.93	0.0	0	4	148	0.8	1.05	0.0	0	3	149	1.6	1.16	2.0	0	4
	DAY 22	139	0.8	0.97	1.0	0	4	133	0.8	1.08	0.0	0	4	143	1.4	1.11	1.0	0	4
	DAY 29	133	0.8	0.86	1.0	0	3	127	0.6	1.01	0.0	0	4	126	1.3	1.04	1.0	0	4
	DAY 36	130	0.7	0.84	0.0	0	4	113	0.5	0.87	0.0	0	3	119	1.3	1.13	1.0	0	4
	DAY 43	123	0.8	0.94	1.0	0	4	107	0.4	0.74	0.0	0	3	107	1.3	1.13	1.0	0	4
	DAY 50	121	0.7	0.86	0.0	0	3	101	0.5	0.78	0.0	0	3	102	1.2	1.12	1.0	0	3
	DAY 57	119	0.8	0.99	0.0	0	4	96	0.5	0.81	0.0	0	3	99	1.2	1.08	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
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Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INTELLECTUAL	VISIT																		
	DAY 1	172	1.9	0.90	2.0	0	4	170	1.9	0.89	2.0	0	3	169	2.0	0.94	2.0	0	4
	DAY 8	171	1.5	0.93	2.0	0	4	169	1.6	0.98	2.0	0	4	168	1.8	0.93	2.0	0	3
	DAY 15	148	1.3	0.95	1.0	0	4	148	1.3	1.03	1.0	0	4	149	1.4	0.96	1.0	0	4
	DAY 22	139	1.1	0.91	1.0	0	3	133	1.1	0.98	1.0	0	4	143	1.5	0.95	2.0	0	4
	DAY 29	133	1.2	0.91	1.0	0	4	127	0.9	0.96	1.0	0	3	126	1.2	0.89	1.0	0	3
	DAY 36	130	1.0	0.92	1.0	0	4	113	0.9	0.94	1.0	0	3	119	1.2	0.96	1.0	0	3
	DAY 43	123	0.9	0.79	1.0	0	3	107	0.8	0.96	1.0	0	3	107	1.2	0.96	1.0	0	3
	DAY 50	121	0.9	0.89	1.0	0	3	101	0.8	0.90	1.0	0	3	102	1.2	1.08	1.0	0	3
	DAY 57	119	0.9	0.91	1.0	0	3	96	0.8	0.98	1.0	0	4	99	1.1	1.06	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. DEPRESSED MOOD	VISIT																		
	DAY 1	172	2.7	0.57	3.0	1	4	170	2.6	0.66	3.0	0	4	169	2.6	0.66	3.0	0	4
	DAY 8	171	2.1	0.81	2.0	0	4	169	2.0	0.87	2.0	0	4	168	2.2	0.88	2.0	0	4
	DAY 15	148	1.7	0.97	2.0	0	4	148	1.7	0.99	2.0	0	4	149	1.9	0.98	2.0	0	4
	DAY 22	139	1.5	0.97	2.0	0	4	133	1.4	1.00	1.0	0	3	143	1.8	1.04	2.0	0	4
	DAY 29	133	1.4	0.98	1.0	0	4	127	1.2	0.98	1.0	0	3	126	1.6	1.01	2.0	0	4
	DAY 36	130	1.2	0.97	1.0	0	4	113	1.1	1.05	1.0	0	4	119	1.6	1.09	2.0	0	4
	DAY 43	123	1.1	0.99	1.0	0	4	107	1.0	0.97	1.0	0	4	107	1.6	1.07	2.0	0	3
	DAY 50	121	1.0	0.99	1.0	0	4	101	1.0	1.04	1.0	0	4	102	1.5	1.16	1.0	0	4
	DAY 57	119	0.9	0.98	1.0	0	3	96	0.9	1.02	1.0	0	4	99	1.5	1.11	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
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Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. SOMATIC (MUSCULAR)	VISIT																		
	DAY 1	172	1.0	0.96	1.0	0	3	170	1.1	0.91	1.0	0	3	169	1.1	0.99	1.0	0	4
	DAY 8	171	0.9	0.95	1.0	0	4	169	0.9	0.87	1.0	0	3	168	0.9	0.89	1.0	0	3
	DAY 15	148	0.7	0.86	0.0	0	4	148	0.7	0.87	0.0	0	3	149	0.8	0.86	1.0	0	3
	DAY 22	139	0.7	0.87	0.0	0	4	133	0.6	0.84	0.0	0	3	143	0.8	0.90	1.0	0	3
	DAY 29	133	0.6	0.91	0.0	0	4	127	0.5	0.79	0.0	0	3	126	0.7	0.86	0.5	0	3
	DAY 36	130	0.6	0.87	0.0	0	4	113	0.5	0.78	0.0	0	3	119	0.7	0.85	0.0	0	3
	DAY 43	123	0.4	0.70	0.0	0	3	107	0.5	0.74	0.0	0	3	107	0.7	0.86	0.0	0	3
	DAY 50	121	0.5	0.74	0.0	0	4	101	0.5	0.77	0.0	0	3	102	0.8	0.96	0.0	0	3
	DAY 57	119	0.5	0.79	0.0	0	4	96	0.4	0.69	0.0	0	3	99	0.6	0.87	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
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Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. SOMATIC (SENSORY)	VISIT																		
	DAY 1	172	0.6	0.79	0.0	0	3	170	0.7	0.81	1.0	0	3	169	0.6	0.85	0.0	0	4
	DAY 8	171	0.5	0.68	0.0	0	3	169	0.7	0.80	0.0	0	3	168	0.6	0.73	0.0	0	2
	DAY 15	148	0.4	0.67	0.0	0	3	148	0.5	0.70	0.0	0	3	149	0.5	0.69	0.0	0	3
	DAY 22	139	0.4	0.68	0.0	0	3	133	0.5	0.72	0.0	0	3	143	0.4	0.66	0.0	0	2
	DAY 29	133	0.3	0.59	0.0	0	3	127	0.3	0.62	0.0	0	2	126	0.4	0.61	0.0	0	2
	DAY 36	130	0.3	0.54	0.0	0	2	113	0.3	0.57	0.0	0	3	119	0.4	0.72	0.0	0	3
	DAY 43	123	0.2	0.50	0.0	0	2	107	0.3	0.62	0.0	0	3	107	0.3	0.60	0.0	0	2
	DAY 50	121	0.2	0.52	0.0	0	2	101	0.3	0.59	0.0	0	3	102	0.4	0.65	0.0	0	3
	DAY 57	119	0.2	0.47	0.0	0	2	96	0.3	0.70	0.0	0	4	99	0.4	0.67	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
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Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. CARDIOVASCULAR SYMPTOMS	VISIT																		
	DAY 1	172	0.7	0.82	0.0	0	3	170	0.6	0.79	0.0	0	3	169	0.6	0.75	0.0	0	3
	DAY 8	171	0.6	0.73	0.0	0	3	169	0.7	0.85	0.0	0	3	168	0.5	0.73	0.0	0	3
	DAY 15	148	0.3	0.64	0.0	0	3	148	0.4	0.64	0.0	0	2	149	0.4	0.71	0.0	0	3
	DAY 22	139	0.4	0.68	0.0	0	3	133	0.3	0.64	0.0	0	3	143	0.4	0.64	0.0	0	2
	DAY 29	133	0.3	0.54	0.0	0	3	127	0.3	0.59	0.0	0	3	126	0.4	0.61	0.0	0	2
	DAY 36	130	0.3	0.57	0.0	0	2	113	0.2	0.56	0.0	0	3	119	0.3	0.59	0.0	0	3
	DAY 43	123	0.2	0.47	0.0	0	3	107	0.2	0.50	0.0	0	2	107	0.2	0.48	0.0	0	2
	DAY 50	121	0.2	0.49	0.0	0	2	101	0.2	0.44	0.0	0	2	102	0.3	0.59	0.0	0	2
	DAY 57	119	0.3	0.60	0.0	0	3	96	0.3	0.58	0.0	0	3	99	0.3	0.65	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. RESPIRATORY SYMPTOMS	VISIT																		
	DAY 1	172	0.5	0.72	0.0	0	3	170	0.5	0.73	0.0	0	3	169	0.5	0.74	0.0	0	2
	DAY 8	171	0.4	0.61	0.0	0	3	169	0.4	0.66	0.0	0	3	168	0.4	0.75	0.0	0	3
	DAY 15	148	0.3	0.60	0.0	0	3	148	0.3	0.56	0.0	0	2	149	0.4	0.74	0.0	0	3
	DAY 22	139	0.3	0.59	0.0	0	3	133	0.4	0.67	0.0	0	3	143	0.4	0.66	0.0	0	3
	DAY 29	133	0.2	0.53	0.0	0	3	127	0.3	0.62	0.0	0	2	126	0.4	0.62	0.0	0	2
	DAY 36	130	0.2	0.44	0.0	0	2	113	0.3	0.51	0.0	0	2	119	0.3	0.51	0.0	0	2
	DAY 43	123	0.2	0.41	0.0	0	2	107	0.2	0.51	0.0	0	2	107	0.3	0.52	0.0	0	2
	DAY 50	121	0.2	0.43	0.0	0	2	101	0.2	0.43	0.0	0	2	102	0.3	0.62	0.0	0	2
	DAY 57	119	0.2	0.53	0.0	0	2	96	0.2	0.44	0.0	0	2	99	0.4	0.68	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. GASTROINTESTINAL SYMPTOMS	VISIT																		
	DAY 1	172	0.9	0.95	1.0	0	4	170	0.9	1.00	1.0	0	4	169	0.9	0.89	1.0	0	3
	DAY 8	171	0.7	0.89	0.0	0	3	169	0.9	0.91	1.0	0	4	168	0.9	0.87	1.0	0	3
	DAY 15	148	0.6	0.86	0.0	0	3	148	0.7	0.84	1.0	0	3	149	0.8	0.93	0.0	0	3
	DAY 22	139	0.6	0.84	0.0	0	3	133	0.7	0.90	0.0	0	4	143	0.6	0.76	0.0	0	3
	DAY 29	133	0.6	0.81	0.0	0	3	127	0.6	0.81	0.0	0	2	126	0.7	0.78	0.5	0	3
	DAY 36	130	0.5	0.77	0.0	0	3	113	0.6	0.86	0.0	0	3	119	0.6	0.82	0.0	0	4
	DAY 43	123	0.5	0.71	0.0	0	3	107	0.4	0.74	0.0	0	4	107	0.6	0.75	0.0	0	3
	DAY 50	121	0.5	0.70	0.0	0	2	101	0.5	0.81	0.0	0	3	102	0.5	0.75	0.0	0	3
	DAY 57	119	0.5	0.78	0.0	0	3	96	0.4	0.73	0.0	0	4	99	0.5	0.73	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
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Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. GENITOURINARY SYMPTOMS	VISIT																		
	DAY 1	172	1.1	1.13	1.0	0	4	170	1.3	1.15	1.0	0	4	169	1.2	1.14	1.0	0	4
	DAY 8	171	1.0	1.05	1.0	0	4	169	1.1	1.02	1.0	0	3	168	1.1	1.14	1.0	0	4
	DAY 15	148	0.8	0.99	0.0	0	4	148	0.9	1.06	1.0	0	4	149	1.1	1.08	1.0	0	4
	DAY 22	139	0.7	0.94	0.0	0	4	133	0.7	0.96	0.0	0	3	143	1.0	1.07	1.0	0	4
	DAY 29	133	0.7	0.89	0.0	0	3	127	0.7	0.93	0.0	0	3	126	0.9	0.98	1.0	0	3
	DAY 36	130	0.7	0.88	0.0	0	3	113	0.6	0.97	0.0	0	3	119	0.8	0.96	0.0	0	3
	DAY 43	123	0.6	0.85	0.0	0	3	107	0.6	1.00	0.0	0	3	107	0.8	0.96	0.0	0	3
	DAY 50	121	0.6	0.81	0.0	0	3	101	0.6	1.00	0.0	0	3	102	0.9	1.03	1.0	0	3
	DAY 57	119	0.6	0.87	0.0	0	3	96	0.5	0.83	0.0	0	3	99	0.9	1.02	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. AUTONOMIC SYMPTOMS	VISIT																		
	DAY 1	172	0.9	0.94	1.0	0	3	170	0.9	0.88	1.0	0	3	169	1.1	0.93	1.0	0	4
	DAY 8	171	1.0	0.87	1.0	0	4	169	1.0	0.91	1.0	0	4	168	0.9	0.90	1.0	0	4
	DAY 15	148	0.8	0.87	1.0	0	4	148	0.9	0.87	1.0	0	3	149	0.8	0.88	1.0	0	3
	DAY 22	139	0.8	0.88	1.0	0	4	133	0.8	0.84	1.0	0	3	143	0.8	0.82	1.0	0	3
	DAY 29	133	0.8	0.80	1.0	0	3	127	0.6	0.80	0.0	0	3	126	0.7	0.84	1.0	0	3
	DAY 36	130	0.6	0.74	0.0	0	2	113	0.6	0.73	0.0	0	3	119	0.7	0.83	0.0	0	3
	DAY 43	123	0.6	0.79	0.0	0	3	107	0.6	0.77	0.0	0	3	107	0.5	0.77	0.0	0	3
	DAY 50	121	0.6	0.73	1.0	0	3	101	0.6	0.79	0.0	0	4	102	0.6	0.83	0.0	0	3
	DAY 57	119	0.6	0.74	0.0	0	3	96	0.5	0.73	0.0	0	3	99	0.5	0.70	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
14. BEHAVIOR AT INTERVIEW	VISIT																		
	DAY 1	172	1.2	0.93	1.0	0	4	170	1.2	0.92	1.0	0	4	169	1.2	0.82	1.0	0	3
	DAY 8	171	0.9	0.84	1.0	0	3	169	0.9	0.87	1.0	0	3	168	1.0	0.83	1.0	0	3
	DAY 15	148	0.8	0.86	1.0	0	3	148	0.9	0.87	1.0	0	3	149	0.9	0.79	1.0	0	3
	DAY 22	139	0.7	0.80	0.0	0	3	133	0.8	0.86	1.0	0	4	143	0.8	0.78	1.0	0	3
	DAY 29	133	0.6	0.73	0.0	0	3	127	0.6	0.77	0.0	0	3	126	0.8	0.84	1.0	0	3
	DAY 36	130	0.6	0.76	0.0	0	4	113	0.5	0.72	0.0	0	3	119	0.7	0.74	1.0	0	3
	DAY 43	123	0.6	0.72	0.0	0	3	107	0.6	0.83	0.0	0	3	107	0.7	0.75	1.0	0	2
	DAY 50	121	0.6	0.68	0.0	0	3	101	0.6	0.71	0.0	0	2	102	0.7	0.92	0.0	0	4
	DAY 57	119	0.5	0.67	0.0	0	3	96	0.5	0.66	0.0	0	3	99	0.6	0.80	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA203.SAS
GENERATED: 12JUL2005 17:42:48 iceadmn3

Table 11.2.6.1 QLESQ Total Score and Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

QLESQ TOTAL SCORE		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
QLESQ TOTAL SCORE	VISIT																		
	DAY 1	172	35.9	8.30	36.0	17	64	169	34.3	7.98	34.0	15	55	169	34.6	7.77	35.0	14	63
	DAY 29	156	44.6	9.30	44.0	18	69	154	44.9	10.42	45.0	14	66	154	40.1	10.06	41.0	16	66
	DAY 57	122	47.7	9.66	48.0	17	70	98	50.2	10.62	53.0	18	67	107	43.4	10.72	43.0	20	67
	FINAL	156	46.2	10.20	46.0	17	70	158	46.2	11.71	47.5	14	67	158	40.9	10.86	41.0	16	67
CHG FROM BASELINE	DAY 29	156	8.5	9.67	8.0	-15	36	153	10.8	10.68	11.0	-17	44	154	6.0	9.15	5.0	-18	35
	DAY 57	122	11.7	10.42	10.5	-9	43	97	16.3	10.34	16.0	-13	45	107	8.9	10.12	10.0	-10	37
	FINAL	156	10.1	10.75	9.0	-14	43	157	12.0	11.64	12.0	-17	45	158	6.7	9.93	6.0	-18	37

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ200.SAS
GENERATED: 12JUL2005 17:46:12 iceadmn3

Table 11.2.6.2.1 QLESQ Total Score Change from Baseline (ANCOVA)
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	156	36.1	7.86	8.5	9.67	9.04	0.763	7.53	10.56	.
	Q600MG	153	34.0	8.07	10.8	10.68	10.41	0.765	8.89	11.93	.
	P	154	34.2	7.45	6.0	9.15	5.63	0.762	4.12	7.13	.
	Q300MG VS P	.	.	.	.	.	3.42	1.040	1.37	5.46	0.001
	Q600MG VS P	.	.	.	.	.	4.79	1.040	2.74	6.83	<.001
DAY 57	Q300MG	122	36.0	8.11	11.7	10.42	12.48	0.892	10.72	14.23	.
	Q600MG	97	33.8	8.60	16.3	10.34	15.94	0.994	13.98	17.89	.
	P	107	34.5	7.78	8.9	10.12	8.82	0.925	7.00	10.64	.
	Q300MG VS P	.	.	.	.	.	3.66	1.264	1.17	6.14	0.004
	Q600MG VS P	.	.	.	.	.	7.12	1.335	4.49	9.74	<.001
FINAL	Q300MG	156	36.1	7.87	10.1	10.75	10.77	0.836	9.13	12.41	.
	Q600MG	157	34.1	8.21	12.0	11.64	11.71	0.829	10.09	13.34	.
	P	158	34.2	7.43	6.7	9.93	6.44	0.826	4.82	8.06	.
	Q300MG VS P	.	.	.	.	.	4.33	1.151	2.06	6.59	<.001
	Q600MG VS P	.	.	.	.	.	5.27	1.144	3.03	7.52	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202.SAS
GENERATED: 12JUL2005 17:33:00 iceadmn3

Table 11.2.6.2.2 QLESQ Total Score Effect Size Change from Baseline
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 29	Q300MG VS P	0.36	0.14	0.59
	Q600MG VS P	0.48	0.25	0.71
DAY 57	Q300MG VS P	0.36	0.09	0.62
	Q600MG VS P	0.70	0.41	0.98
FINAL	Q300MG VS P	0.42	0.19	0.64
	Q600MG VS P	0.49	0.26	0.71

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ203.SAS
GENERATED: 12JUL2005 17:33:03 iceadmn3

Table 11.2.6.2.3 QLESQ %Maximum Total Score Change from Baseline (ANCOVA)
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	156	39.5	14.03	15.1	17.22	16.16	1.361	13.46	18.85	.
	Q600MG	153	35.7	14.40	19.4	19.05	18.59	1.365	15.88	21.30	.
	P	154	36.0	13.27	10.7	16.35	10.07	1.359	7.38	12.76	.
	Q300MG VS P	.	.	.	.	.	6.09	1.856	2.44	9.73	0.001
	Q600MG VS P	.	.	.	.	.	8.52	1.856	4.87	12.17	<.001
DAY 57	Q300MG	122	39.3	14.49	21.0	18.62	22.32	1.596	19.18	25.46	.
	Q600MG	97	35.4	15.35	29.1	18.49	28.47	1.777	24.97	31.96	.
	P	107	36.6	13.85	16.0	18.13	15.80	1.654	12.55	19.06	.
	Q300MG VS P	.	.	.	.	.	6.51	2.261	2.06	10.96	0.004
	Q600MG VS P	.	.	.	.	.	12.67	2.387	7.97	17.36	<.001
FINAL	Q300MG	156	39.5	14.05	18.1	19.20	19.27	1.493	16.33	22.20	.
	Q600MG	157	35.9	14.65	21.5	20.80	20.93	1.482	18.02	23.85	.
	P	158	36.0	13.24	12.1	17.78	11.54	1.476	8.64	14.44	.
	Q300MG VS P	.	.	.	.	.	7.72	2.058	3.68	11.77	<.001
	Q600MG VS P	.	.	.	.	.	9.39	2.044	5.37	13.41	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ204.SAS
GENERATED: 12JUL2005 17:33:05 iceadmn3

Table 11.2.6.2.4 QLESQ %Maximum Total Score Effect Size Change from Baseline by Visit Day
Intent-to-treat population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 29	Q300MG VS P	0.36	0.14	0.59
	Q600MG VS P	0.48	0.25	0.71
DAY 57	Q300MG VS P	0.35	0.09	0.62
	Q600MG VS P	0.69	0.41	0.97
FINAL	Q300MG VS P	0.42	0.19	0.64
	Q600MG VS P	0.49	0.26	0.71

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ205.SAS
GENERATED: 12JUL2005 17:33:08 iceadmn3

Table 11.2.6.3 QLESQ Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
BIPOLAR I	QLESQ TOTAL SCORE	VISIT																		
		DAY 1	116	35.5	8.84	35.5	17	64	113	33.9	8.09	34.0	15	55	112	34.2	7.84	34.0	14	63
		DAY 29	105	44.7	9.88	44.0	18	69	103	45.5	9.78	46.0	26	66	103	39.3	9.98	40.0	16	60
		DAY 57	86	47.6	9.86	47.0	17	70	70	50.6	10.80	54.0	18	67	65	42.2	10.76	41.0	20	63
		FINAL	105	46.4	10.74	46.0	17	70	107	47.1	11.54	48.0	18	67	106	39.3	10.81	39.0	16	63
	CHG FROM BASE-LINE	DAY 29	105	8.8	9.94	8.0	-15	36	102	11.7	10.64	11.5	-17	44	103	5.7	8.64	5.0	-18	31
		DAY 57	86	11.8	10.63	11.0	-9	43	69	16.8	10.62	17.0	-13	45	65	7.7	9.71	6.0	-6	32
		FINAL	105	10.6	10.98	9.0	-14	43	106	13.1	11.83	13.0	-17	45	106	5.6	9.45	4.0	-18	32
BIPOLAR II	QLESQ TOTAL SCORE	DAY 1	56	36.7	7.04	37.0	23	53	56	35.0	7.77	35.0	16	52	57	35.3	7.64	36.0	18	54
		DAY 29	51	44.3	8.06	44.0	24	61	51	43.9	11.63	44.0	14	66	51	41.8	10.12	42.0	20	66
		DAY 57	36	48.1	9.27	50.0	24	63	28	49.4	10.32	50.0	33	66	42	45.3	10.53	46.0	23	67
		FINAL	51	45.8	9.07	45.0	24	63	51	44.4	11.98	43.0	14	66	52	44.1	10.34	43.0	23	67
	CHG FROM BASE-LINE	DAY 29	51	7.7	9.11	7.0	-10	26	51	9.2	10.66	9.0	-15	35	51	6.5	10.18	6.0	-12	35
		DAY 57	36	11.7	10.06	10.0	-5	32	28	15.0	9.69	13.0	-2	36	42	10.8	10.57	11.0	-10	37
		FINAL	51	9.2	10.31	9.0	-6	32	51	9.8	10.99	10.0	-15	36	52	9.0	10.58	10.5	-11	37

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ201.SAS
GENERATED: 12JUL2005 17:46:14 iceadmn3

Table 11.2.7.1.1 PSQI Total Score and Components - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
PSQI TOTAL SCORE	VISIT																		
	DAY 1	165	11.6	3.82	12.0	2	20	166	11.7	4.16	12.0	2	21	165	11.6	3.84	12.0	3	19
	DAY 29	154	6.6	3.51	6.0	0	16	152	6.5	4.19	5.0	0	20	151	9.2	4.10	9.0	1	19
	DAY 57	120	5.9	3.72	5.0	0	18	95	4.9	3.24	4.0	0	16	106	7.9	3.90	7.5	0	19
	FINAL	154	6.4	3.74	6.0	0	18	155	6.2	4.11	6.0	0	20	154	8.8	4.24	8.5	0	19
PATIENT SLEEP QUALITY	DAY 1	171	1.9	0.76	2.0	0	3	170	2.0	0.77	2.0	0	3	169	2.0	0.82	2.0	0	3
	DAY 29	156	0.9	0.80	1.0	0	3	156	0.9	0.84	1.0	0	3	153	1.5	0.86	1.0	0	3
	DAY 57	123	0.9	0.71	1.0	0	3	98	0.6	0.63	0.0	0	3	106	1.3	0.85	1.0	0	3
	FINAL	157	1.0	0.79	1.0	0	3	160	0.8	0.82	1.0	0	3	156	1.5	0.88	1.0	0	3
SLEEP LATENCY	DAY 1	169	2.2	0.97	3.0	0	3	170	2.3	0.95	3.0	0	3	166	2.3	1.02	3.0	0	3
	DAY 29	156	1.2	1.06	1.0	0	3	156	1.3	1.04	1.0	0	3	152	1.8	1.09	2.0	0	3
	DAY 57	123	1.3	1.05	1.0	0	3	98	1.1	0.98	1.0	0	3	106	1.7	1.03	2.0	0	3
	FINAL	157	1.3	1.05	1.0	0	3	160	1.3	1.06	1.0	0	3	155	1.8	1.06	2.0	0	3
SLEEP DURATION	DAY 1	171	1.5	0.95	1.0	0	3	170	1.4	1.04	1.0	0	3	167	1.6	1.07	1.0	0	3
	DAY 29	156	0.7	0.84	0.0	0	3	155	0.5	0.78	0.0	0	3	153	1.3	0.99	1.0	0	3
	DAY 57	123	0.6	0.76	0.0	0	3	98	0.4	0.65	0.0	0	3	106	1.1	0.87	1.0	0	3
	FINAL	157	0.7	0.80	1.0	0	3	159	0.5	0.78	0.0	0	3	156	1.2	0.97	1.0	0	3

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI200.SAS
GENERATED: 12JUL2005 17:46:01 iceadmn3

Table 11.2.7.1.1 PSQI Total Score and Components - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HABITUAL SLEEP EFFICIENCY	VISIT																		
	DAY 1	170	1.4	1.23	1.0	0	3	169	1.4	1.21	1.0	0	3	167	1.5	1.28	1.0	0	3
	DAY 29	155	0.7	1.07	0.0	0	3	154	0.7	1.09	0.0	0	3	152	1.2	1.21	1.0	0	3
	DAY 57	122	0.6	0.98	0.0	0	3	97	0.5	0.90	0.0	0	3	106	0.9	1.08	1.0	0	3
	FINAL	156	0.6	1.03	0.0	0	3	157	0.7	1.06	0.0	0	3	155	1.1	1.14	1.0	0	3
SLEEP DISTURBANCES	DAY 1	167	1.6	0.66	2.0	0	3	167	1.7	0.74	2.0	0	3	167	1.7	0.72	2.0	0	3
	DAY 29	155	1.2	0.61	1.0	0	3	154	1.3	0.67	1.0	0	3	152	1.5	0.67	1.0	0	3
	DAY 57	121	1.1	0.64	1.0	0	3	96	1.0	0.66	1.0	0	3	106	1.4	0.62	1.0	0	3
	FINAL	155	1.1	0.64	1.0	0	3	158	1.2	0.71	1.0	0	3	155	1.4	0.66	1.0	0	3
SLEEP MEDICATION	DAY 1	171	0.8	1.23	0.0	0	3	170	0.8	1.20	0.0	0	3	169	0.7	1.11	0.0	0	3
	DAY 29	156	0.4	0.91	0.0	0	3	156	0.4	0.86	0.0	0	3	153	0.4	0.88	0.0	0	3
	DAY 57	123	0.3	0.84	0.0	0	3	98	0.3	0.82	0.0	0	3	106	0.2	0.63	0.0	0	3
	FINAL	157	0.4	0.88	0.0	0	3	160	0.4	0.92	0.0	0	3	156	0.3	0.82	0.0	0	3
DAYTIME DYSFUNCTION	DAY 1	171	1.9	0.79	2.0	0	3	170	2.0	0.67	2.0	1	3	169	2.0	0.70	2.0	0	3
	DAY 29	156	1.5	0.83	1.0	0	3	156	1.4	0.83	1.0	0	3	153	1.6	0.73	2.0	0	3
	DAY 57	123	1.1	0.85	1.0	0	3	98	1.1	0.85	1.0	0	3	106	1.4	0.77	1.0	0	3
	FINAL	157	1.3	0.91	1.0	0	3	160	1.4	0.90	1.0	0	3	156	1.5	0.77	2.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI200.SAS
GENERATED: 12JUL2005 17:46:01 iceadmn3

Table 11.2.7.1.2 PSQI Total Score Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

PSQI TOTAL SCORE CHANGE FROM BASELINE	TREATMENT																	
	QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
VISIT																		
DAY 29	148	-4.7	4.21	-4.0	-17	4	151	-5.3	4.89	-5.0	-17	8	147	-2.5	4.18	-3.0	-15	12
DAY 57	117	-5.3	4.30	-5.0	-18	7	93	-6.4	4.33	-6.0	-16	4	102	-3.8	4.14	-3.0	-16	5
FINAL	150	-5.0	4.34	-5.0	-18	7	152	-5.4	4.82	-5.0	-17	8	150	-3.0	4.25	-3.0	-16	12

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI202.SAS
GENERATED: 12JUL2005 17:46:06 iceadmn3

Table 11.2.7.2.1 PSQI Total Score and Components by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
PSQI TOTAL SCORE	VISIT																		
	DAY 1	110	11.2	3.84	11.0	2	20	111	11.9	4.17	11.0	2	21	110	11.5	4.08	12.0	3	19
	DAY 29	104	6.6	3.60	6.0	1	16	103	6.6	4.47	5.0	0	20	101	9.5	4.21	9.0	1	19
	DAY 57	84	5.7	3.43	5.0	1	18	68	5.0	3.34	4.0	0	16	64	8.1	3.60	8.0	0	17
	FINAL	103	6.1	3.54	5.0	1	18	106	6.2	4.27	5.5	0	20	103	9.3	4.19	9.0	0	18
PATIENT SLEEP QUALITY	DAY 1	115	1.9	0.78	2.0	0	3	114	2.1	0.78	2.0	0	3	112	2.0	0.81	2.0	0	3
	DAY 29	105	1.0	0.80	1.0	0	3	105	1.0	0.89	1.0	0	3	102	1.5	0.86	1.0	0	3
	DAY 57	87	0.8	0.66	1.0	0	3	70	0.6	0.63	0.5	0	3	64	1.4	0.85	1.0	0	3
	FINAL	106	0.9	0.77	1.0	0	3	109	0.9	0.85	1.0	0	3	104	1.6	0.86	2.0	0	3
SLEEP LATENCY	DAY 1	114	2.2	0.89	2.0	0	3	114	2.3	0.96	3.0	0	3	110	2.2	1.03	3.0	0	3
	DAY 29	105	1.4	1.07	1.0	0	3	105	1.3	1.05	1.0	0	3	102	1.9	1.04	2.0	0	3
	DAY 57	87	1.3	1.06	1.0	0	3	70	1.1	0.95	1.0	0	3	64	1.7	1.00	2.0	0	3
	FINAL	106	1.3	1.04	1.0	0	3	109	1.3	1.05	1.0	0	3	104	1.9	1.03	2.0	0	3
SLEEP DURATION	DAY 1	115	1.5	0.94	1.0	0	3	114	1.5	1.02	1.0	0	3	111	1.5	1.12	1.0	0	3
	DAY 29	105	0.7	0.89	0.0	0	3	105	0.5	0.80	0.0	0	3	102	1.3	1.06	1.0	0	3
	DAY 57	87	0.6	0.74	0.0	0	3	70	0.4	0.64	0.0	0	3	64	1.1	0.86	1.0	0	3
	FINAL	106	0.7	0.81	0.5	0	3	109	0.5	0.79	0.0	0	3	104	1.3	1.00	1.0	0	3

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI201.SAS
GENERATED: 12JUL2005 17:46:03 iceadmn3

Table 11.2.7.2.1 PSQI Total Score and Components by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HABITUAL SLEEP EFFICIENCY	VISIT																		
	DAY 1	114	1.3	1.18	1.0	0	3	114	1.4	1.19	1.0	0	3	111	1.4	1.29	1.0	0	3
	DAY 29	105	0.8	1.05	0.0	0	3	105	0.7	1.10	0.0	0	3	102	1.2	1.20	1.0	0	3
	DAY 57	86	0.5	0.92	0.0	0	3	70	0.5	0.97	0.0	0	3	64	0.9	1.07	0.5	0	3
	FINAL	105	0.6	0.98	0.0	0	3	108	0.6	1.08	0.0	0	3	104	1.1	1.18	1.0	0	3
SLEEP DISTURBANCES	DAY 1	112	1.7	0.65	2.0	0	3	111	1.7	0.72	2.0	0	3	111	1.7	0.72	2.0	0	3
	DAY 29	104	1.2	0.58	1.0	0	3	103	1.3	0.68	1.0	0	3	101	1.5	0.67	1.0	0	3
	DAY 57	85	1.1	0.60	1.0	0	3	68	1.0	0.62	1.0	0	2	64	1.4	0.63	1.0	0	3
	FINAL	104	1.1	0.58	1.0	0	3	107	1.2	0.68	1.0	0	3	103	1.4	0.68	1.0	0	3
SLEEP MEDICATION	DAY 1	115	0.8	1.22	0.0	0	3	114	0.8	1.23	0.0	0	3	112	0.7	1.15	0.0	0	3
	DAY 29	105	0.3	0.84	0.0	0	3	105	0.4	0.91	0.0	0	3	102	0.5	0.97	0.0	0	3
	DAY 57	87	0.2	0.71	0.0	0	3	70	0.4	0.89	0.0	0	3	64	0.2	0.68	0.0	0	3
	FINAL	106	0.2	0.66	0.0	0	3	109	0.5	0.99	0.0	0	3	104	0.4	0.93	0.0	0	3
DAYTIME DYSFUNCTION	DAY 1	115	1.9	0.79	2.0	0	3	114	2.0	0.69	2.0	1	3	112	2.1	0.73	2.0	0	3
	DAY 29	105	1.4	0.77	1.0	0	3	105	1.4	0.82	1.0	0	3	102	1.7	0.73	2.0	0	3
	DAY 57	87	1.1	0.83	1.0	0	3	70	1.1	0.86	1.0	0	3	64	1.4	0.81	1.0	0	3
	FINAL	106	1.2	0.85	1.0	0	3	109	1.3	0.90	1.0	0	3	104	1.6	0.79	2.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI201.SAS
GENERATED: 12JUL2005 17:46:03 iceadmn3

Table 11.2.7.2.1 PSQI Total Score and Components by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
PSQI TOTAL SCORE	VISIT																		
	DAY 1	55	12.3	3.71	12.0	6	19	55	11.3	4.14	12.0	3	18	55	11.7	3.34	12.0	3	19
	DAY 29	50	6.5	3.33	6.0	0	15	49	6.1	3.53	5.0	1	17	50	8.8	3.86	9.0	1	17
	DAY 57	36	6.5	4.33	5.5	0	16	27	4.8	3.03	5.0	0	11	42	7.6	4.35	7.0	0	19
	FINAL	51	7.0	4.09	6.0	0	16	49	6.1	3.77	6.0	0	17	51	7.8	4.18	7.0	0	19
PATIENT SLEEP QUALITY	DAY 1	56	2.1	0.71	2.0	1	3	56	1.9	0.73	2.0	1	3	57	1.9	0.85	2.0	0	3
	DAY 29	51	0.9	0.82	1.0	0	3	51	0.8	0.73	1.0	0	2	51	1.5	0.86	1.0	0	3
	DAY 57	36	1.1	0.78	1.0	0	3	28	0.5	0.64	0.0	0	2	42	1.2	0.85	1.0	0	3
	FINAL	51	1.1	0.83	1.0	0	3	51	0.8	0.76	1.0	0	2	52	1.3	0.87	1.0	0	3
SLEEP LATENCY	DAY 1	55	2.2	1.12	3.0	0	3	56	2.3	0.94	3.0	0	3	56	2.4	0.99	3.0	0	3
	DAY 29	51	1.0	1.01	1.0	0	3	51	1.2	1.03	1.0	0	3	50	1.7	1.18	2.0	0	3
	DAY 57	36	1.3	1.05	1.0	0	3	28	1.1	1.07	1.0	0	3	42	1.5	1.09	1.0	0	3
	FINAL	51	1.2	1.06	1.0	0	3	51	1.3	1.07	1.0	0	3	51	1.6	1.12	1.0	0	3
SLEEP DURATION	DAY 1	56	1.7	0.97	1.5	0	3	56	1.2	1.05	1.0	0	3	56	1.6	0.99	2.0	0	3
	DAY 29	51	0.6	0.75	0.0	0	3	50	0.5	0.76	0.0	0	3	51	1.2	0.85	1.0	0	3
	DAY 57	36	0.7	0.82	0.5	0	3	28	0.5	0.69	0.0	0	3	42	1.0	0.90	1.0	0	3
	FINAL	51	0.7	0.81	1.0	0	3	50	0.5	0.76	0.0	0	3	52	1.0	0.88	1.0	0	3

(Continued)

Table 11.2.7.2.1 PSQI Total Score and Components by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HABITUAL SLEEP EFFICIENCY	VISIT																		
	DAY 1	56	1.7	1.31	2.0	0	3	55	1.5	1.26	1.0	0	3	56	1.6	1.28	2.0	0	3
	DAY 29	50	0.7	1.12	0.0	0	3	49	0.7	1.09	0.0	0	3	50	1.3	1.26	1.0	0	3
	DAY 57	36	0.7	1.11	0.0	0	3	27	0.4	0.70	0.0	0	2	42	1.0	1.12	1.0	0	3
	FINAL	51	0.7	1.15	0.0	0	3	49	0.7	1.02	0.0	0	3	51	1.0	1.07	1.0	0	3
SLEEP DISTURBANCES	DAY 1	55	1.6	0.68	2.0	0	3	56	1.8	0.79	2.0	0	3	56	1.7	0.74	2.0	0	3
	DAY 29	51	1.2	0.65	1.0	0	2	51	1.3	0.66	1.0	0	3	51	1.5	0.67	1.0	0	3
	DAY 57	36	1.1	0.75	1.0	0	3	28	1.0	0.74	1.0	0	3	42	1.4	0.62	1.0	0	3
	FINAL	51	1.1	0.75	1.0	0	3	51	1.2	0.76	1.0	0	3	52	1.3	0.62	1.0	0	3
SLEEP MEDICATION	DAY 1	56	0.9	1.25	0.0	0	3	56	0.8	1.15	0.0	0	3	57	0.6	1.05	0.0	0	3
	DAY 29	51	0.5	1.05	0.0	0	3	51	0.3	0.75	0.0	0	3	51	0.2	0.61	0.0	0	3
	DAY 57	36	0.5	1.08	0.0	0	3	28	0.1	0.57	0.0	0	3	42	0.2	0.55	0.0	0	3
	FINAL	51	0.6	1.18	0.0	0	3	51	0.2	0.74	0.0	0	3	52	0.2	0.51	0.0	0	3
DAYTIME DYSFUNCTION	DAY 1	56	2.1	0.78	2.0	0	3	56	1.9	0.62	2.0	1	3	57	1.8	0.62	2.0	1	3
	DAY 29	51	1.6	0.91	2.0	0	3	51	1.5	0.83	1.0	0	3	51	1.5	0.70	2.0	0	3
	DAY 57	36	1.2	0.91	1.0	0	3	28	1.1	0.83	1.0	0	3	42	1.3	0.72	1.0	0	3
	FINAL	51	1.4	1.02	1.0	0	3	51	1.4	0.90	1.0	0	3	52	1.4	0.72	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI201.SAS
GENERATED: 12JUL2005 17:46:03 iceadmn3

Table 11.2.7.2.2 PSQI Total Score Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
BIPOLAR I	VISIT																		
	DAY 29	99	-4.4	4.43	-4.0	-17	4	102	-5.3	5.03	-6.0	-17	8	99	-2.3	4.44	-3.0	-15	12
	DAY 57	81	-5.2	4.54	-5.0	-18	7	67	-6.5	4.55	-6.0	-16	4	62	-3.6	4.22	-3.0	-14	5
	FINAL	100	-5.0	4.50	-5.0	-18	7	104	-5.6	5.02	-5.0	-17	8	101	-2.6	4.43	-3.0	-14	12
BIPOLAR II	DAY 29	49	-5.5	3.64	-5.0	-12	3	49	-5.2	4.64	-4.0	-15	6	48	-2.9	3.59	-3.0	-11	6
	DAY 57	36	-5.5	3.78	-5.5	-14	3	26	-6.3	3.75	-6.0	-15	3	40	-4.1	4.03	-4.0	-16	5
	FINAL	50	-5.1	4.05	-5.0	-14	3	48	-5.2	4.39	-4.5	-15	6	49	-3.9	3.76	-4.0	-16	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI203.SAS
GENERATED: 12JUL2005 17:46:08 iceadmn3

Table 11.2.7.3.1 PSQI Total Score Change from Baseline (ANCOVA)
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	148	11.3	3.78	-4.7	4.21	-4.96	0.310	-5.57	-4.35	.
	Q600MG	151	11.7	4.18	-5.3	4.89	-5.28	0.307	-5.89	-4.68	.
	P	147	11.7	3.83	-2.5	4.18	-2.47	0.311	-3.09	-1.86	.
	Q300MG VS P	.	.	.	.	.	-2.48	0.430	-3.33	-1.64	<.001
	Q600MG VS P	.	.	.	.	.	-2.81	0.428	-3.65	-1.97	<.001
DAY 57	Q300MG	117	11.2	3.70	-5.3	4.30	-5.40	0.328	-6.05	-4.75	.
	Q600MG	93	11.4	4.45	-6.4	4.33	-6.44	0.368	-7.17	-5.71	.
	P	102	11.6	3.71	-3.8	4.14	-3.68	0.343	-4.36	-3.00	.
	Q300MG VS P	.	.	.	.	.	-1.72	0.463	-2.63	-0.81	<.001
	Q600MG VS P	.	.	.	.	.	-2.76	0.490	-3.72	-1.79	<.001
FINAL	Q300MG	150	11.4	3.82	-5.0	4.34	-5.16	0.319	-5.79	-4.53	.
	Q600MG	152	11.6	4.16	-5.4	4.82	-5.46	0.319	-6.09	-4.83	.
	P	150	11.7	3.82	-3.0	4.25	-2.94	0.320	-3.57	-2.31	.
	Q300MG VS P	.	.	.	.	.	-2.22	0.436	-3.07	-1.36	<.001
	Q600MG VS P	.	.	.	.	.	-2.52	0.434	-3.37	-1.66	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204.SAS
GENERATED: 12JUL2005 17:32:55 iceadmn3

Table 11.2.7.3.2 PSQI Total Score Effect Size Change from Baseline
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 29	Q300MG VS P	-0.59	-0.83	-0.36
	Q600MG VS P	-0.62	-0.85	-0.38
DAY 57	Q300MG VS P	-0.41	-0.67	-0.14
	Q600MG VS P	-0.65	-0.94	-0.36
FINAL	Q300MG VS P	-0.52	-0.75	-0.29
	Q600MG VS P	-0.55	-0.78	-0.32

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI205.SAS
GENERATED: 12JUL2005 17:32:58 iceadmn3

Table 11.3.1.1 Exposure to Randomized Treatment - Descriptive Statistics
Safety Population

		TREATMENT		
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO
DAYS ON RANDOMIZED TREATMENT	N	179	180	180
	MEAN	44.4	40.3	43.0
	SD	19.43	20.65	18.28
	MEDIAN	56.0	55.0	55.0
	MIN	3	1	1
	MAX	64	62	64
DAYS WITH TREATMENT	N	179	180	180
	MEAN	43.7	39.7	42.2
	SD	19.25	20.53	18.07
	MEDIAN	55.0	54.0	54.0
	MIN	3	1	1
	MAX	62	60	63
MEDIAN DOSE OVER STUDY	N	179	180	180
	MEAN	275.3	502.4	0.0
	SD	56.90	156.53	0.00
	MEDIAN	300.0	600.0	0.0
	MIN	0	0	0
	MAX	300	600	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN200.SAS
GENERATED: 12JUL2005 17:45:46 iceadmn3

Table 11.3.1.1 Exposure to Randomized Treatment - Descriptive Statistics
Safety Population

		TREATMENT		
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO
MEAN DOSE OVER STUDY	N	179	180	180
	MEAN	260.3	462.1	0.0
	SD	45.30	138.58	0.00
	MEDIAN	281.0	531.5	0.0
	MIN	50	31	0
	MAX	344	624	0
CUMULATIVE DOSE OVER STUDY	N	179	180	180
	MEAN	12145.0	21034.4	0.0
	SD	5687.50	12076.36	0.00
	MEDIAN	15350.0	27650.0	0.0
	MIN	350	50	0
	MAX	19250	33050	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN200.SAS
GENERATED: 12JUL2005 17:45:46 iceadmn3

Table 11.3.1.2 Total Subject Days on Randomized Treatment - Descriptive Statistics
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N	DAYS	N	DAYS	N	DAYS
TOTAL EXPOSURE	179	7946	180	7257	180	7735

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN204.SAS
GENERATED: 12JUL2005 17:45:54 iceadmn3

Table 11.3.1.3 Subjects with Dose Reduction by Bipolar Diagnosis and Withdrawal Status
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		N	%	N	%	N	%
OVERALL	OVERALL	30	16.8	40	22.2	9	5.0
	- COMPLETERS	24	13.4	20	11.1	4	2.2
	- ALL WITHDRAWALS	6	3.4	20	11.1	5	2.8
	- LOST TO FOLLOW-UP	1	0.6	4	2.2	3	1.7
	- ADVERSE EVENT	3	1.7	14	7.8	1	0.6
	- PROTOCOL/NONCOMPLIANCE	1	0.6	0	0	0	0
	- LACK OF EFFICACY	1	0.6	0	0	1	0.6
	- INFORMED CONSENT WITHDRAWN	0	0	2	1.1	0	0
BIPOLAR I	OVERALL	20	11.2	31	17.2	6	3.3
	- COMPLETERS	18	10.1	15	8.3	2	1.1
	- ALL WITHDRAWALS	2	1.1	16	8.9	4	2.2
	- LOST TO FOLLOW-UP	0	0	3	1.7	2	1.1
	- ADVERSE EVENT	2	1.1	11	6.1	1	0.6
	- LACK OF EFFICACY	0	0	0	0	1	0.6
	- INFORMED CONSENT WITHDRAWN	0	0	2	1.1	0	0
BIPOLAR II	OVERALL	10	5.6	9	5.0	3	1.7

(Continued)

Table 11.3.1.3 Subjects with Dose Reduction by Bipolar Diagnosis and Withdrawal Status
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		N	%	N	%	N	%
BIPOLAR II	- COMPLETERS	6	3.4	5	2.8	2	1.1
	- ALL WITHDRAWALS	4	2.2	4	2.2	1	0.6
	- LOST TO FOLLOW-UP	1	0.6	1	0.6	1	0.6
	- ADVERSE EVENT	1	0.6	3	1.7	0	0
	- PROTOCOL/NONCOMPLIANCE	1	0.6	0	0	0	0
	- LACK OF EFFICACY	1	0.6	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN201.SAS
GENERATED: 12JUL2005 17:45:48 iceadmn3

Table 11.3.1.4 Compliance
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		N	%	N	%	N	%
OVERALL	OVERALL	179	100.0	180	100.0	180	100.0
	- COMPLETERS	121	67.6	98	54.4	107	59.4
	- ALL WITHDRAWALS	58	32.4	82	45.6	73	40.6
	- LOST TO FOLLOW-UP	12	6.7	21	11.7	11	6.1
	- ADVERSE EVENT	29	16.2	47	26.1	16	8.9
	- PROTOCOL/NONCOMPLIANCE	8	4.5	4	2.2	10	5.6
	- INFORMED CONSENT WITHDRAWN	5	2.8	6	3.3	12	6.7
	- LACK OF EFFICACY	4	2.2	1	0.6	24	13.3
	- OTHER	0	0	3	1.7	0	0
FULL COMPLIANCE (>=80%)	OVERALL	176	98.3	177	98.3	178	98.9
	- COMPLETERS	121	67.6	98	54.4	107	59.4
	- ALL WITHDRAWALS	55	30.7	79	43.9	71	39.4
	- LOST TO FOLLOW-UP	11	6.1	21	11.7	11	6.1
	- ADVERSE EVENT	27	15.1	44	24.4	15	8.3
	- PROTOCOL/NONCOMPLIANCE	8	4.5	4	2.2	9	5.0
	- INFORMED CONSENT WITHDRAWN	5	2.8	6	3.3	12	6.7

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN202.SAS
GENERATED: 12JUL2005 17:45:50 iceadmn3

Table 11.3.1.4 Compliance
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		N	%	N	%	N	%
FULL COMPLIANCE (>=80%)	- LACK OF EFFICACY	4	2.2	1	0.6	24	13.3
	- OTHER	0	0	3	1.7	0	0
NON-COMPLIANCE (<70%)	OVERALL	3	1.7	2	1.1	1	0.6
	- ALL WITHDRAWALS	3	1.7	2	1.1	1	0.6
	- LOST TO FOLLOW-UP	1	0.6	0	0	0	0
	- ADVERSE EVENT	2	1.1	2	1.1	0	0
	- PROTOCOL/NONCOMPLIANCE	0	0	0	0	1	0.6
PARTIAL COMPLIANCE (>=70% & <80%)	OVERALL	0	0	1	0.6	1	0.6
	- ALL WITHDRAWALS	0	0	1	0.6	1	0.6
	- ADVERSE EVENT	0	0	1	0.6	1	0.6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN202.SAS
GENERATED: 12JUL2005 17:45:50 iceadmn3

Table 11.3.1.5 Compliance by Withdrawal Status
Safety Population

	TREATMENT														
	QUETIAPINE 300 MG (N=179)						QUETIAPINE 600 MG (N=180)								
	>=80			<70			>=80			>=70-<80			<70		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
OVERALL	179	176	98.3	179	3	1.7	180	177	98.3	180	1	0.6	180	2	1.1
- COMPLETERS	121	121	100.0	0	0	0	98	98	100.0	0	0	0	0	0	0
- ALL WITHDRAWALS	58	55	94.8	58	3	5.2	82	79	96.3	82	1	1.2	82	2	2.4
- LOST TO FOLLOW-UP	12	11	91.7	12	1	8.3	21	21	100.0	0	0	0	0	0	0
- ADVERSE EVENT	29	27	93.1	29	2	6.9	47	44	93.6	47	1	2.1	47	2	4.3
- PROTOCOL/NONCOMPLIANCE	8	8	100.0	0	0	0	4	4	100.0	0	0	0	0	0	0
- INFORMED CONSENT WITHDRAWN	5	5	100.0	0	0	0	6	6	100.0	0	0	0	0	0	0
- LACK OF EFFICACY	4	4	100.0	0	0	0	1	1	100.0	0	0	0	0	0	0
- OTHER	0	0	0	0	0	0	3	3	100.0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN203.SAS
GENERATED: 12JUL2005 17:45:52 iceadmn3

Table 11.3.1.5 Compliance by Withdrawal Status
Safety Population

	TREATMENT								
	PLACEBO (N=180)								
	>=80			>=70-<80			<70		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
OVERALL	180	178	98.9	180	1	0.6	180	1	0.6
- COMPLETERS	107	107	100.0	0	0	0	0	0	0
- ALL WITHDRAWALS	73	71	97.3	73	1	1.4	73	1	1.4
- LOST TO FOLLOW-UP	11	11	100.0	0	0	0	0	0	0
- ADVERSE EVENT	16	15	93.8	16	1	6.3	0	0	0
- PROTOCOL/NONCOMPLIANCE	10	9	90.0	0	0	0	10	1	10.0
- INFORMED CONSENT WITHDRAWN	12	12	100.0	0	0	0	0	0	0
- LACK OF EFFICACY	24	24	100.0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN203.SAS
GENERATED: 12JUL2005 17:45:52 iceadmn3

Table 11.3.1.6 Compliance by Withdrawal Status
Intent-to-treat population

	TREATMENT														
	QUETIAPINE 300 MG (N=172)						QUETIAPINE 600 MG (N=170)								
	>=80			<70			>=80			>=70-<80			<70		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
OVERALL	172	170	98.8	172	2	1.2	170	167	98.2	170	1	0.6	170	2	1.2
- COMPLETERS	121	121	100.0	0	0	0	98	98	100.0	0	0	0	0	0	0
- ALL WITHDRAWALS	51	49	96.1	51	2	3.9	72	69	95.8	72	1	1.4	72	2	2.8
- LOST TO FOLLOW-UP	9	9	100.0	0	0	0	16	16	100.0	0	0	0	0	0	0
- ADVERSE EVENT	27	25	92.6	27	2	7.4	43	40	93.0	43	1	2.3	43	2	4.7
- PROTOCOL/NONCOMPLIANCE	7	7	100.0	0	0	0	4	4	100.0	0	0	0	0	0	0
- INFORMED CONSENT WITHDRAWN	4	4	100.0	0	0	0	6	6	100.0	0	0	0	0	0	0
- LACK OF EFFICACY	4	4	100.0	0	0	0	1	1	100.0	0	0	0	0	0	0
- OTHER	0	0	0	0	0	0	2	2	100.0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN205.SAS
GENERATED: 12JUL2005 17:45:56 iceadmn3

Table 11.3.1.6 Compliance by Withdrawal Status
Intent-to-treat population

	TREATMENT								
	PLACEBO (N=169)								
	>=80			>=70-<80			<70		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
OVERALL	169	167	98.8	169	1	0.6	169	1	0.6
- COMPLETERS	105	105	100.0	0	0	0	0	0	0
- ALL WITHDRAWALS	64	62	96.9	64	1	1.6	64	1	1.6
- LOST TO FOLLOW-UP	9	9	100.0	0	0	0	0	0	0
- ADVERSE EVENT	10	9	90.0	10	1	10.0	0	0	0
- PROTOCOL/NONCOMPLIANCE	9	8	88.9	0	0	0	9	1	11.1
- INFORMED CONSENT WITHDRAWN	12	12	100.0	0	0	0	0	0	0
- LACK OF EFFICACY	24	24	100.0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN205.SAS
GENERATED: 12JUL2005 17:45:56 iceadmn3

Table 11.3.2.1 Overview of Adverse Events
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SAFETY POPULATION	179	100.0	180	100.0	180	100.0
AT LEAST ONE ADVERSE EVENT	166	92.7	165	91.7	148	82.2
SERIOUS ADVERSE EVENT	6	3.4	9	5.0	16	8.9
ADVERSE EVENT LEADING TO DEATH	0	0	0	0	0	0
STUDY DRUG-RELATED ADVERSE EVENT	152	84.9	156	86.7	85	47.2
WITHDRAWALS DUE TO ADVERSE EVENT	29	16.2	47	26.1	15	8.3

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG200.SAS
GENERATED: 12JUL2005 17:38:59 iceadmn3

Table 11.3.2.2 Overview of Adverse Events by Bipolar Diagnosis
Safety Population

	TREATMENT											
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SAFETY POPULATION	120	100.0	120	100.0	118	100.0	59	100.0	60	100.0	62	100.0
AT LEAST ONE ADVERSE EVENT	108	90.0	107	89.2	100	84.7	58	98.3	58	96.7	48	77.4
SERIOUS ADVERSE EVENT	5	4.2	6	5.0	14	11.9	1	1.7	3	5.0	2	3.2
ADVERSE EVENT LEADING TO DEATH	0	0	0	0	0	0	0	0	0	0	0	0
STUDY DRUG-RELATED ADVERSE EVENT	95	79.2	101	84.2	57	48.3	57	96.6	55	91.7	28	45.2
WITHDRAWALS DUE TO ADVERSE EVENT	16	13.3	28	23.3	13	11.0	13	22.0	19	31.7	2	3.2

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG201.SAS
GENERATED: 12JUL2005 17:39:02 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY ADVERSE EVENT		166	92.7	165	91.7	148	82.2
BLOOD AND LYMPHATIC SYSTEM DISORDERS	TOTAL	1	0.6	0	0	0	0
	LYMPHADENOPATHY	1	0.6	0	0	0	0
CARDIAC DISORDERS	TOTAL	12	6.7	7	3.9	5	2.8
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	1	0.6	0	0	0	0
	PALPITATIONS	8	4.5	5	2.8	3	1.7
	TACHYCARDIA NOS	3	1.7	2	1.1	1	0.6
	VENTRICULAR EXTRASYSTOLES	0	0	0	0	1	0.6
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	TOTAL	0	0	1	0.6	0	0
	FACTOR II DEFICIENCY	0	0	1	0.6	0	0
EAR AND LABYRINTH DISORDERS	TOTAL	6	3.4	5	2.8	2	1.1
	CERUMEN IMPACTION	1	0.6	0	0	0	0
	EAR CONGESTION	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EAR AND LABYRINTH DISORDERS	EAR DISCOMFORT	1	0.6	0	0	0	0
	EAR PAIN	0	0	1	0.6	0	0
	EAR PRURITUS	1	0.6	0	0	0	0
	TINNITUS	2	1.1	3	1.7	2	1.1
	VERTIGO	1	0.6	1	0.6	0	0
EYE DISORDERS	TOTAL	9	5.0	16	8.9	8	4.4
	ALTERED VISUAL DEPTH PERCEPTION	0	0	1	0.6	0	0
	ASTIGMATISM	0	0	1	0.6	0	0
	BLEPHARITIS	1	0.6	0	0	0	0
	BLEPHAROSPASM	0	0	0	0	1	0.6
	DRY EYE NOS	1	0.6	0	0	0	0
	EYE PAIN	0	0	0	0	1	0.6
	EYELIDS PRURITUS	0	0	1	0.6	0	0
	PHOTOPHOBIA	0	0	0	0	2	1.1

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	PHOTOPSIA	1	0.6	0	0	1	0.6
	VISION BLURRED	5	2.8	13	7.2	3	1.7
	VISUAL ACUITY REDUCED	1	0.6	1	0.6	0	0
GASTROINTESTINAL DISORDERS	TOTAL	108	60.3	109	60.6	63	35.0
	ABDOMINAL DISCOMFORT	0	0	0	0	1	0.6
	ABDOMINAL DISTENSION	1	0.6	2	1.1	1	0.6
	ABDOMINAL PAIN LOWER	1	0.6	1	0.6	0	0
	ABDOMINAL PAIN NOS	0	0	2	1.1	6	3.3
	ABDOMINAL PAIN UPPER	1	0.6	3	1.7	4	2.2
	APHTHOUS STOMATITIS	0	0	0	0	1	0.6
	APTYALISM	0	0	1	0.6	0	0
	CHAPPED LIPS	0	0	1	0.6	0	0
	CHEILITIS	1	0.6	0	0	0	0
	CONSTIPATION	21	11.7	20	11.1	8	4.4

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	DIARRHOEA NOS	8	4.5	11	6.1	15	8.3
	DRY MOUTH	79	44.1	73	40.6	14	7.8
	DUODENAL ULCER HAEMORRHAGE	0	0	0	0	1	0.6
	DYSPEPSIA	12	6.7	17	9.4	10	5.6
	DYSPHAGIA	0	0	6	3.3	0	0
	FAECES HARD	0	0	1	0.6	0	0
	FLATULENCE	2	1.1	4	2.2	2	1.1
	FOOD POISONING NOS	1	0.6	0	0	1	0.6
	FREQUENT BOWEL MOVEMENTS	0	0	0	0	1	0.6
	GASTROINTESTINAL PAIN NOS	0	0	0	0	1	0.6
	GASTROOESOPHAGEAL REFLUX DISEASE	1	0.6	5	2.8	2	1.1
	GINGIVAL PAIN	1	0.6	0	0	0	0
	GLOSSODYNIA	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	HAEMORRHOIDS	1	0.6	0	0	0	0
	INTESTINAL OBSTRUCTION NOS	0	0	1	0.6	0	0
	IRRITABLE BOWEL SYNDROME	0	0	0	0	1	0.6
	NAUSEA	14	7.8	16	8.9	23	12.8
	ORAL PAIN	0	0	0	0	1	0.6
	PANCREATITIS NOS	0	0	0	0	1	0.6
	SWOLLEN TONGUE	0	0	1	0.6	0	0
	TONGUE DISORDER NOS	3	1.7	0	0	0	0
	TOOTH DISORDER NOS	0	0	1	0.6	0	0
	TOOTH LOSS	1	0.6	0	0	0	0
	TOOTHACHE	4	2.2	4	2.2	4	2.2
	VOMITING NOS	11	6.1	4	2.2	2	1.1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	41	22.9	59	32.8	31	17.2
	ASTHENIA	0	0	3	1.7	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	1	0.6	0	0	0	0
	CHEST PAIN	2	1.1	4	2.2	2	1.1
	CHEST TIGHTNESS	1	0.6	2	1.1	1	0.6
	DRUG WITHDRAWAL SYNDROME	0	0	1	0.6	0	0
	FATIGUE	16	8.9	21	11.7	13	7.2
	FEELING ABNORMAL	1	0.6	0	0	0	0
	FEELING COLD	1	0.6	4	2.2	2	1.1
	FEELING HOT	0	0	0	0	1	0.6
	FEELING JITTERY	0	0	3	1.7	0	0
	GAIT ABNORMAL	1	0.6	0	0	0	0
	HERNIA NOS	0	0	1	0.6	0	0
	INFLUENZA LIKE ILLNESS	4	2.2	4	2.2	4	2.2
	LETHARGY	11	6.1	16	8.9	3	1.7
	MUCOUS MEMBRANE DISORDER NOS	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	0	0	3	1.7	2	1.1
	PAIN NOS	0	0	5	2.8	2	1.1
	PYREXIA	3	1.7	1	0.6	3	1.7
	RIGORS	0	0	1	0.6	1	0.6
	SENSATION OF BLOOD FLOW	0	0	1	0.6	1	0.6
	SLUGGISHNESS	2	1.1	2	1.1	1	0.6
	THIRST	2	1.1	0	0	2	1.1
HEPATOBILIARY DISORDERS	TOTAL	0	0	0	0	1	0.6
	CHOLECYSTITIS NOS	0	0	0	0	1	0.6
IMMUNE SYSTEM DISORDERS	TOTAL	2	1.1	0	0	1	0.6
	DRUG HYPERSENSITIVITY	0	0	0	0	1	0.6
	HYPERSENSITIVITY NOS	1	0.6	0	0	0	0
	SEASONAL ALLERGY	1	0.6	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	27	15.1	23	12.8	37	20.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INFECTIONS AND INFESTATIONS	EAR INFECTION NOS	1	0.6	1	0.6	0	0
	EAR INFECTION VIRAL NOS	0	0	0	0	1	0.6
	FUNGAL INFECTION NOS	1	0.6	0	0	0	0
	GASTROENTERITIS VIRAL NOS	2	1.1	2	1.1	3	1.7
	GINGIVAL INFECTION	1	0.6	0	0	0	0
	HERPES SIMPLEX	2	1.1	0	0	2	1.1
	INFLUENZA	3	1.7	1	0.6	5	2.8
	KIDNEY INFECTION NOS	0	0	1	0.6	0	0
	NASOPHARYNGITIS	2	1.1	2	1.1	4	2.2
	OTITIS MEDIA NOS	0	0	0	0	1	0.6
	PHARYNGITIS STREPTOCOCCAL	0	0	1	0.6	0	0
	PROSTATE INFECTION	0	0	0	0	1	0.6
	SCABIES INFESTATION	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INFECTIONS AND INFESTATIONS	SIALOADENITIS NOS	0	0	0	0	1	0.6
	SINUSITIS NOS	2	1.1	1	0.6	3	1.7
	STAPHYLOCOCCAL INFECTION	0	0	0	0	1	0.6
	TINEA VERSICOLOUR	1	0.6	0	0	0	0
	TOOTH INFECTION	2	1.1	0	0	0	0
	UPPER RESPIRATORY TRACT INFECTION NOS	9	5.0	13	7.2	18	10.0
	URINARY TRACT INFECTION NOS	1	0.6	1	0.6	0	0
	VAGINOSIS FUNGAL NOS	0	0	0	0	1	0.6
	VIRAL INFECTION NOS	2	1.1	1	0.6	2	1.1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	12	6.7	13	7.2	22	12.2
	ACCIDENTAL OVERDOSE	3	1.7	4	2.2	7	3.9
	ARTHROPOD BITE	1	0.6	0	0	1	0.6
	BACK INJURY NOS	0	0	1	0.6	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EXCORIATION	0	0	1	0.6	0	0
	HIP FRACTURE	0	0	0	0	1	0.6
	INJURY	4	2.2	3	1.7	1	0.6
	JOINT SPRAIN	0	0	0	0	4	2.2
	LIMB INJURY NOS	1	0.6	0	0	0	0
	MUSCLE STRAIN	0	0	1	0.6	1	0.6
	NON-ACCIDENTAL OVERDOSE	0	0	2	1.1	2	1.1
	PERIORBITAL HAEMATOMA	0	0	1	0.6	0	0
	POST PROCEDURAL COMPLICATION	0	0	0	0	1	0.6
	POST PROCEDURAL PAIN	0	0	0	0	2	1.1
	SCRATCH	2	1.1	0	0	0	0
	SKIN LACERATION	1	0.6	0	0	2	1.1
	SPINAL FRACTURE NOS	0	0	0	0	1	0.6
	SUNBURN	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	THERMAL BURN	1	0.6	0	0	1	0.6
INVESTIGATIONS	TOTAL	3	1.7	13	7.2	2	1.1
	BLOOD IN STOOL	0	0	0	0	1	0.6
	BLOOD URINE	0	0	1	0.6	0	0
	WEIGHT DECREASED	0	0	1	0.6	0	0
	WEIGHT INCREASED	3	1.7	11	6.1	1	0.6
METABOLISM AND NUTRITION DISORDERS	TOTAL	9	5.0	13	7.2	6	3.3
	ALCOHOL INTOLERANCE	1	0.6	1	0.6	0	0
	APPETITE DECREASED NOS	1	0.6	2	1.1	3	1.7
	APPETITE INCREASED NOS	7	3.9	10	5.6	3	1.7
	FLUID RETENTION	0	0	1	0.6	0	0
	FOOD CRAVING	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	30	16.8	33	18.3	23	12.8
	ARTHRALGIA	5	2.8	8	4.4	6	3.3
	ARTHRITIS NOS	0	0	1	0.6	0	0
	BACK PAIN	7	3.9	5	2.8	5	2.8
	BUTTOCK PAIN	0	0	1	0.6	0	0
	CHEST WALL PAIN	1	0.6	0	0	0	0
	DUPUYTREN'S CONTRACTURE	0	0	1	0.6	0	0
	FACIAL PAIN	0	0	1	0.6	1	0.6
	FLANK PAIN	0	0	1	0.6	0	0
	GROIN PAIN	0	0	1	0.6	0	0
	INTERVERTEBRAL DISC HERNIATION	0	0	0	0	1	0.6
	JOINT STIFFNESS	1	0.6	1	0.6	0	0
	JOINT SWELLING	1	0.6	0	0	0	0
	LIMB DISCOMFORT NOS	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE CRAMP	5	2.8	2	1.1	1	0.6
	MUSCLE RIGIDITY	0	0	0	0	1	0.6
	MUSCLE SPASMS	2	1.1	0	0	2	1.1
	MUSCLE STIFFNESS	0	0	1	0.6	0	0
	MUSCLE TIGHTNESS	2	1.1	0	0	1	0.6
	MUSCLE TWITCHING	2	1.1	4	2.2	3	1.7
	MUSCLE WEAKNESS NOS	0	0	1	0.6	0	0
	MUSCULOSKELETAL PAIN	0	0	1	0.6	0	0
	MUSCULOSKELETAL STIFFNESS	0	0	2	1.1	0	0
	MYALGIA	1	0.6	4	2.2	2	1.1
	NECK PAIN	4	2.2	1	0.6	2	1.1
	PAIN IN EXTREMITY	2	1.1	9	5.0	4	2.2
	PERIARTHRITIS	0	0	1	0.6	0	0
	SENSATION OF HEAVINESS	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	TOTAL	2	1.1	0	0	0	0
	CHRONIC LYMPHOCYTIC LEUKAEMIA NOS	1	0.6	0	0	0	0
	UTERINE FIBROIDS	1	0.6	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	134	74.9	132	73.3	74	41.1
	AKATHISIA	9	5.0	9	5.0	2	1.1
	AMNESIA	0	0	1	0.6	0	0
	ATAXIA	0	0	2	1.1	0	0
	BALANCE IMPAIRED NOS	7	3.9	2	1.1	1	0.6
	CARPAL TUNNEL SYNDROME	0	0	0	0	1	0.6
	COGNITIVE DISORDER	0	0	0	0	1	0.6
	CONVULSIONS NOS	0	0	1	0.6	1	0.6
	COORDINATION ABNORMAL NOS	2	1.1	1	0.6	0	0
	DISTURBANCE IN ATTENTION	1	0.6	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	DIZZINESS	30	16.8	41	22.8	15	8.3
	DIZZINESS POSTURAL	1	0.6	3	1.7	1	0.6
	DYSARTHRIA	5	2.8	2	1.1	0	0
	DYSGEUSIA	2	1.1	2	1.1	0	0
	DYSKINESIA	4	2.2	2	1.1	0	0
	DYSTONIA	2	1.1	5	2.8	1	0.6
	EXTRAPYRAMIDAL DISORDER	0	0	2	1.1	1	0.6
	HEADACHE	22	12.3	18	10.0	36	20.0
	HEMIPARESIS	0	0	0	0	1	0.6
	HYPERREFLEXIA	0	0	1	0.6	0	0
	HYPERSOMNIA	5	2.8	6	3.3	1	0.6
	HYPOAESTHESIA	2	1.1	3	1.7	1	0.6
	HYPOREFLEXIA	0	0	0	0	1	0.6
	MEMORY IMPAIRMENT	4	2.2	0	0	0	0

(Continued)

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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	MENTAL IMPAIRMENT NOS	0	0	0	0	1	0.6
	MIGRAINE NOS	1	0.6	2	1.1	0	0
	MUSCLE CONTRACTIONS INVOLUNTARY	0	0	1	0.6	0	0
	MYOCLONUS	1	0.6	0	0	0	0
	PARAESTHESIA	4	2.2	7	3.9	3	1.7
	PSYCHOMOTOR HYPERACTIVITY	0	0	1	0.6	0	0
	RESTLESS LEGS SYNDROME	4	2.2	3	1.7	0	0
	SCIATICA	0	0	0	0	1	0.6
	SEDATION	53	29.6	58	32.2	11	6.1
	SENSORY DISTURBANCE NOS	1	0.6	0	0	0	0
	SINUS HEADACHE	1	0.6	0	0	0	0
	SOMNOLENCE	49	27.4	44	24.4	15	8.3
	SPEECH DISORDER	1	0.6	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	SYNCOPE	0	0	1	0.6	1	0.6
	TENSION HEADACHE	1	0.6	2	1.1	1	0.6
	TREMOR	5	2.8	5	2.8	1	0.6
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	TOTAL	0	0	0	0	1	0.6
	ECTOPIC PREGNANCY	0	0	0	0	1	0.6
PSYCHIATRIC DISORDERS	TOTAL	37	20.7	38	21.1	34	18.9
	ABNORMAL DREAMS	6	3.4	4	2.2	3	1.7
	ACUTE PSYCHOSIS	0	0	0	0	1	0.6
	AGITATION	1	0.6	2	1.1	4	2.2
	ANGER	0	0	1	0.6	0	0
	ANXIETY	4	2.2	4	2.2	5	2.8
	BIPOLAR I DISORDER	0	0	1	0.6	0	0
	BLUNTED AFFECT	1	0.6	0	0	0	0
	BRADYPHRENIA	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	BRUXISM	0	0	2	1.1	1	0.6
	CONFUSIONAL STATE	1	0.6	1	0.6	0	0
	CONVERSION DISORDER	1	0.6	0	0	0	0
	DELUSION NOS	0	0	1	0.6	0	0
	DEPRESSION	1	0.6	1	0.6	0	0
	DEREALISATION	1	0.6	0	0	0	0
	DISORIENTATION	1	0.6	0	0	0	0
	DISSOCIATIVE DISORDER NOS	0	0	0	0	1	0.6
	FLAT AFFECT	1	0.6	1	0.6	0	0
	HALLUCINATION, AUDITORY	1	0.6	2	1.1	2	1.1
	HALLUCINATION, VISUAL	0	0	2	1.1	0	0
	HYPNAGOGIC HALLUCINATION	0	0	1	0.6	0	0
	HYPOMANIA	1	0.6	1	0.6	0	0
	ILLUSION	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	INSOMNIA	8	4.5	7	3.9	9	5.0
	IRRITABILITY	2	1.1	5	2.8	1	0.6
	LIBIDO DECREASED	2	1.1	2	1.1	2	1.1
	LIBIDO INCREASED	0	0	1	0.6	1	0.6
	LOGORRHOEA	0	0	1	0.6	0	0
	LOSS OF LIBIDO	1	0.6	1	0.6	0	0
	MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	1	0.6
	MANIA	2	1.1	1	0.6	2	1.1
	MENTAL STATUS CHANGES	0	0	1	0.6	0	0
	MIDDLE INSOMNIA	0	0	1	0.6	0	0
	MOOD SWINGS	1	0.6	0	0	0	0
	NERVOUSNESS	0	0	2	1.1	0	0
	NIGHTMARE	4	2.2	2	1.1	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	OBSESSIVE-COMPULSIVE DISORDER	0	0	0	0	1	0.6
	ONYCHOPHAGIA	1	0.6	0	0	0	0
	PANIC ATTACK	0	0	1	0.6	1	0.6
	PANIC DISORDER NOS	1	0.6	0	0	0	0
	PARANOIA	1	0.6	1	0.6	0	0
	RESTLESSNESS	2	1.1	1	0.6	2	1.1
	SLEEP WALKING	1	0.6	0	0	0	0
	SUICIDAL IDEATION	3	1.7	3	1.7	3	1.7
	SUICIDE ATTEMPT	1	0.6	1	0.6	0	0
	SUSPICIOUSNESS	2	1.1	0	0	0	0
	TENSION	0	0	1	0.6	0	0
	THOUGHT BLOCKING	1	0.6	1	0.6	0	0
RENAL AND URINARY DISORDERS	TOTAL	8	4.5	8	4.4	5	2.8
	BLADDER DISORDER NOS	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RENAL AND URINARY DISORDERS	DYSURIA	0	0	1	0.6	0	0
	ENURESIS	2	1.1	0	0	0	0
	MICTURITION URGENCY	3	1.7	0	0	1	0.6
	NEPHROLITHIASIS	0	0	1	0.6	0	0
	POLLAKIURIA	1	0.6	4	2.2	3	1.7
	URINARY HESITATION	1	0.6	0	0	1	0.6
	URINARY INCONTINENCE	1	0.6	1	0.6	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	7	3.9	6	3.3	8	4.4
	ADNEXA UTERI PAIN	1	0.6	0	0	0	0
	BREAST CYST	1	0.6	0	0	0	0
	DYSMENORRHOEA	2	1.1	3	1.7	2	1.1
	ERECTILE DYSFUNCTION NOS	1	0.6	2	1.1	4	2.2
	MENSES DELAYED	1	0.6	0	0	0	0
	MENSTRUATION IRREGULAR	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	NIPPLE EXUDATE BLOODY	1	0.6	0	0	0	0
	POLYMENORRHOEA	2	1.1	0	0	0	0
	PROSTATITIS	0	0	1	0.6	0	0
	SEXUAL DYSFUNCTION NOS	1	0.6	0	0	2	1.1
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	34	19.0	31	17.2	24	13.3
	ASTHMA NOS	0	0	1	0.6	2	1.1
	BRONCHITIS NOS	2	1.1	1	0.6	3	1.7
	BRONCHOSPASM NOS	0	0	0	0	1	0.6
	CHOKING SENSATION	2	1.1	0	0	0	0
	COUGH	7	3.9	6	3.3	1	0.6
	DYSPNOEA	5	2.8	7	3.9	4	2.2
	EPISTAXIS	1	0.6	0	0	0	0
	HICCUPS	0	0	0	0	1	0.6
	HOARSENESS	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LARYNGITIS NOS	0	0	0	0	1	0.6
	NASAL CONGESTION	10	5.6	12	6.7	3	1.7
	NASAL DRYNESS	1	0.6	0	0	0	0
	NASAL OEDEMA	1	0.6	0	0	0	0
	NASOPHARYNGITIS	4	2.2	2	1.1	2	1.1
	PHARYNGEAL ERYTHEMA	1	0.6	0	0	0	0
	PHARYNGOLARYNGEAL PAIN	3	1.7	3	1.7	5	2.8
	PRODUCTIVE COUGH	1	0.6	0	0	2	1.1
	PULMONARY CONGESTION	1	0.6	0	0	1	0.6
	RHINORRHOEA	0	0	0	0	1	0.6
	SINUS CONGESTION	5	2.8	4	2.2	2	1.1
	SINUS PAIN	0	0	1	0.6	0	0
	THROAT TIGHTNESS	0	0	2	1.1	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	8	4.5	17	9.4	16	8.9

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ACNE NOS	0	0	1	0.6	1	0.6
	ALOPECIA	0	0	1	0.6	0	0
	CONTUSION	0	0	1	0.6	1	0.6
	DERMATITIS ALLERGIC	0	0	0	0	1	0.6
	DERMATITIS CONTACT	1	0.6	2	1.1	0	0
	DERMATITIS EXFOLIATIVE NOS	0	0	0	0	1	0.6
	ECCHYMOSIS	1	0.6	0	0	1	0.6
	ERYTHEMA	1	0.6	0	0	1	0.6
	INCREASED TENDENCY TO BRUISE	0	0	0	0	1	0.6
	NIGHT SWEATS	2	1.1	4	2.2	1	0.6
	PRURITUS	1	0.6	1	0.6	2	1.1
	PRURITUS GENERALISED	0	0	0	0	1	0.6
	RASH NOS	1	0.6	1	0.6	3	1.7

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SKIN IRRITATION	0	0	0	0	1	0.6
	SKIN LESION NOS	0	0	2	1.1	0	0
	SKIN ULCER	0	0	0	0	1	0.6
	SUBCUTANEOUS NODULE	0	0	1	0.6	0	0
	SWEATING INCREASED	1	0.6	3	1.7	2	1.1
SOCIAL CIRCUMSTANCES	TOTAL	2	1.1	4	2.2	0	0
	DRUG ABUSER NOS	2	1.1	4	2.2	0	0
SURGICAL AND MEDICAL PROCEDURES	TOTAL	1	0.6	0	0	0	0
	TOOTH EXTRACTION NOS	1	0.6	0	0	0	0
VASCULAR DISORDERS	TOTAL	14	7.8	15	8.3	9	5.0
	DEEP VEIN THROMBOSIS	0	0	1	0.6	1	0.6
	FLUSHING	5	2.8	5	2.8	2	1.1
	HAEMATOMA NOS	0	0	0	0	1	0.6
	HYPERTENSION NOS	3	1.7	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VASCULAR DISORDERS	HYPOTENSION NOS	0	0	2	1.1	0	0
	ORTHOSTATIC HYPOTENSION	6	3.4	7	3.9	6	3.3

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG202.SAS
GENERATED: 12JUL2005 17:39:04 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
ANY ADVERSE EVENT		108	90.0	107	89.2	100	84.7	58	98.3	58	96.7	48	77.4
BLOOD AND LYMPHATIC SYSTEM DISORDERS	TOTAL	1	0.8	0	0	0	0	0	0	0	0	0	0
	LYMPHADENOPATHY	1	0.8	0	0	0	0	0	0	0	0	0	0
CARDIAC DISORDERS	TOTAL	6	5.0	5	4.2	4	3.4	6	10.2	2	3.3	1	1.6
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	0	0	0	0	0	0	1	1.7	0	0	0	0
	PALPITATIONS	4	3.3	5	4.2	3	2.5	4	6.8	0	0	0	0
	TACHYCARDIA NOS	2	1.7	0	0	1	0.8	1	1.7	2	3.3	0	0
	VENTRICULAR EXTRASYSTOLES	0	0	0	0	0	0	0	0	0	0	1	1.6
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	TOTAL	0	0	1	0.8	0	0	0	0	0	0	0	0
	FACTOR II DEFICIENCY	0	0	1	0.8	0	0	0	0	0	0	0	0
EAR AND LABYRINTH DISORDERS	TOTAL	5	4.2	5	4.2	2	1.7	1	1.7	0	0	0	0
	CERUMEN IMPACTION	1	0.8	0	0	0	0	0	0	0	0	0	0
	EAR CONGESTION	1	0.8	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
EAR AND LABYRINTH DISORDERS	EAR DISCOMFORT	1	0.8	0	0	0	0	0	0	0	0	0	0
	EAR PAIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	EAR PRURITUS	1	0.8	0	0	0	0	0	0	0	0	0	0
	TINNITUS	1	0.8	3	2.5	2	1.7	1	1.7	0	0	0	0
	VERTIGO	1	0.8	1	0.8	0	0	0	0	0	0	0	0
EYE DISORDERS	TOTAL	7	5.8	9	7.5	4	3.4	2	3.4	7	11.7	4	6.5
	ALTERED VISUAL DEPTH PERCEPTION	0	0	0	0	0	0	0	0	1	1.7	0	0
	ASTIGMATISM	0	0	1	0.8	0	0	0	0	0	0	0	0
	BLEPHARITIS	1	0.8	0	0	0	0	0	0	0	0	0	0
	BLEPHAROSPASM	0	0	0	0	0	0	0	0	0	0	1	1.6
	DRY EYE NOS	1	0.8	0	0	0	0	0	0	0	0	0	0
	EYE PAIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	EYELIDS PRURITUS	0	0	1	0.8	0	0	0	0	0	0	0	0
	PHOTOPHOBIA	0	0	0	0	1	0.8	0	0	0	0	1	1.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	PHOTOPSIA	0	0	0	0	0	0	1	1.7	0	0	1	1.6
	VISION BLURRED	4	3.3	7	5.8	2	1.7	1	1.7	6	10.0	1	1.6
	VISUAL ACUITY REDUCED	1	0.8	1	0.8	0	0	0	0	0	0	0	0
GASTROINTESTINAL DISORDERS	TOTAL	70	58.3	75	62.5	41	34.7	38	64.4	34	56.7	22	35.5
	ABDOMINAL DISCOMFORT	0	0	0	0	1	0.8	0	0	0	0	0	0
	ABDOMINAL DISTENSION	1	0.8	2	1.7	1	0.8	0	0	0	0	0	0
	ABDOMINAL PAIN LOWER	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	ABDOMINAL PAIN NOS	0	0	1	0.8	4	3.4	0	0	1	1.7	2	3.2
	ABDOMINAL PAIN UPPER	1	0.8	2	1.7	3	2.5	0	0	1	1.7	1	1.6
	APHTHOUS STOMATITIS	0	0	0	0	1	0.8	0	0	0	0	0	0
	APTYALISM	0	0	1	0.8	0	0	0	0	0	0	0	0
	CHAPPED LIPS	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
GASTROINTESTINAL DISORDERS	CHEILITIS	1	0.8	0	0	0	0	0	0	0	0	0	0
	CONSTIPATION	12	10.0	14	11.7	4	3.4	9	15.3	6	10.0	4	6.5
	DIARRHOEA NOS	4	3.3	9	7.5	8	6.8	4	6.8	2	3.3	7	11.3
	DRY MOUTH	51	42.5	50	41.7	9	7.6	28	47.5	23	38.3	5	8.1
	DUODENAL ULCER HAEMORRHAGE	0	0	0	0	1	0.8	0	0	0	0	0	0
	DYSPEPSIA	9	7.5	12	10.0	6	5.1	3	5.1	5	8.3	4	6.5
	DYSPHAGIA	0	0	2	1.7	0	0	0	0	4	6.7	0	0
	FAECES HARD	0	0	1	0.8	0	0	0	0	0	0	0	0
	FLATULENCE	1	0.8	3	2.5	1	0.8	1	1.7	1	1.7	1	1.6
	FOOD POISONING NOS	0	0	0	0	0	0	1	1.7	0	0	1	1.6
	FREQUENT BOWEL MOVEMENTS	0	0	0	0	0	0	0	0	0	0	1	1.6
	GASTROINTESTINAL PAIN NOS	0	0	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	1	0.8	5	4.2	1	0.8	0	0	0	0	1	1.6
	GINGIVAL PAIN	0	0	0	0	0	0	1	1.7	0	0	0	0
	GLOSSODYNIA	1	0.8	0	0	0	0	0	0	0	0	0	0
	HAEMORRHOIDS	1	0.8	0	0	0	0	0	0	0	0	0	0
	INTESTINAL OBSTRUCTION NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	IRRITABLE BOWEL SYNDROME	0	0	0	0	1	0.8	0	0	0	0	0	0
	NAUSEA	10	8.3	11	9.2	15	12.7	4	6.8	5	8.3	8	12.9
	ORAL PAIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	PANCREATITIS NOS	0	0	0	0	0	0	0	0	0	0	1	1.6
	SWOLLEN TONGUE	0	0	0	0	0	0	0	0	1	1.7	0	0
	TONGUE DISORDER NOS	1	0.8	0	0	0	0	2	3.4	0	0	0	0
	TOOTH DISORDER NOS	0	0	0	0	0	0	0	0	1	1.7	0	0
	TOOTH LOSS	1	0.8	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
GASTROINTESTINAL DISORDERS	TOOTHACHE	3	2.5	3	2.5	2	1.7	1	1.7	1	1.7	2	3.2
	VOMITING NOS	9	7.5	3	2.5	2	1.7	2	3.4	1	1.7	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	24	20.0	38	31.7	20	16.9	17	28.8	21	35.0	11	17.7
	ASTHENIA	0	0	3	2.5	0	0	0	0	0	0	0	0
	CHEST DISCOMFORT	1	0.8	0	0	0	0	0	0	0	0	0	0
	CHEST PAIN	1	0.8	4	3.3	2	1.7	1	1.7	0	0	0	0
	CHEST TIGHTNESS	1	0.8	2	1.7	0	0	0	0	0	0	1	1.6
	DRUG WITHDRAWAL SYNDROME	0	0	0	0	0	0	0	0	1	1.7	0	0
	FATIGUE	9	7.5	9	7.5	9	7.6	7	11.9	12	20.0	4	6.5
	FEELING ABNORMAL	0	0	0	0	0	0	1	1.7	0	0	0	0
	FEELING COLD	1	0.8	3	2.5	1	0.8	0	0	1	1.7	1	1.6
	FEELING HOT	0	0	0	0	1	0.8	0	0	0	0	0	0
	FEELING JITTERY	0	0	3	2.5	0	0	0	0	0	0	0	0
	GAIT ABNORMAL	1	0.8	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	HERNIA NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	INFLUENZA LIKE ILLNESS	2	1.7	3	2.5	2	1.7	2	3.4	1	1.7	2	3.2
	LETHARGY	4	3.3	9	7.5	1	0.8	7	11.9	7	11.7	2	3.2
	MUCOUS MEMBRANE DISORDER NOS	1	0.8	0	0	0	0	0	0	0	0	0	0
	OEDEMA PERIPHERAL	0	0	3	2.5	2	1.7	0	0	0	0	0	0
	PAIN NOS	0	0	5	4.2	1	0.8	0	0	0	0	1	1.6
	PYREXIA	2	1.7	1	0.8	3	2.5	1	1.7	0	0	0	0
	RIGORS	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	SENSATION OF BLOOD FLOW	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	SLUGGISHNESS	2	1.7	1	0.8	0	0	0	0	1	1.7	1	1.6
	THIRST	2	1.7	0	0	2	1.7	0	0	0	0	0	0
HEPATOBILIARY DISORDERS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	CHOLECYSTITIS NOS	0	0	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
IMMUNE SYSTEM DISORDERS	TOTAL	2	1.7	0	0	1	0.8	0	0	0	0	0	0
	DRUG HYPERSENSITIVITY	0	0	0	0	1	0.8	0	0	0	0	0	0
	HYPERSENSITIVITY NOS	1	0.8	0	0	0	0	0	0	0	0	0	0
	SEASONAL ALLERGY	1	0.8	0	0	0	0	0	0	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	21	17.5	15	12.5	24	20.3	6	10.2	8	13.3	13	21.0
	EAR INFECTION NOS	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	EAR INFECTION VIRAL NOS	0	0	0	0	0	0	0	0	0	0	1	1.6
	FUNGAL INFECTION NOS	1	0.8	0	0	0	0	0	0	0	0	0	0
	GASTROENTERITIS VIRAL NOS	0	0	0	0	2	1.7	2	3.4	2	3.3	1	1.6
	GINGIVAL INFECTION	1	0.8	0	0	0	0	0	0	0	0	0	0
	HERPES SIMPLEX	2	1.7	0	0	1	0.8	0	0	0	0	1	1.6
	INFLUENZA	2	1.7	0	0	3	2.5	1	1.7	1	1.7	2	3.2

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INFECTIONS AND INFESTATIONS	KIDNEY INFECTION NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	NASOPHARYNGITIS	2	1.7	0	0	3	2.5	0	0	2	3.3	1	1.6
	OTITIS MEDIA NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	PHARYNGITIS STREPTOCOCCAL	0	0	1	0.8	0	0	0	0	0	0	0	0
	PROSTATE INFECTION	0	0	0	0	1	0.8	0	0	0	0	0	0
	SCABIES INFESTATION	1	0.8	0	0	0	0	0	0	0	0	0	0
	SIALOADENITIS NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	SINUSITIS NOS	2	1.7	0	0	1	0.8	0	0	1	1.7	2	3.2
	STAPHYLOCOCCAL INFECTION	0	0	0	0	0	0	0	0	0	0	1	1.6
	TINEA VERSICOLOUR	1	0.8	0	0	0	0	0	0	0	0	0	0
	TOOTH INFECTION	2	1.7	0	0	0	0	0	0	0	0	0	0
	UPPER RESPIRATORY TRACT INFECTION NOS	6	5.0	10	8.3	13	11.0	3	5.1	3	5.0	5	8.1

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION NOS	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	VAGINOSIS FUNGAL NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	VIRAL INFECTION NOS	1	0.8	1	0.8	2	1.7	1	1.7	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	7	5.8	10	8.3	15	12.7	5	8.5	3	5.0	7	11.3
	ACCIDENTAL OVERDOSE	1	0.8	4	3.3	4	3.4	2	3.4	0	0	3	4.8
	ARTHROPOD BITE	0	0	0	0	0	0	1	1.7	0	0	1	1.6
	BACK INJURY NOS	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	EXCORIATION	0	0	0	0	0	0	0	0	1	1.7	0	0
	HIP FRACTURE	0	0	0	0	1	0.8	0	0	0	0	0	0
	INJURY	2	1.7	3	2.5	1	0.8	2	3.4	0	0	0	0
	JOINT SPRAIN	0	0	0	0	2	1.7	0	0	0	0	2	3.2
	LIMB INJURY NOS	1	0.8	0	0	0	0	0	0	0	0	0	0
	MUSCLE STRAIN	0	0	1	0.8	1	0.8	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	NON-ACCIDENTAL OVERDOSE	0	0	2	1.7	2	1.7	0	0	0	0	0	0
	PERIORBITAL HAEMATOMA	0	0	0	0	0	0	0	0	1	1.7	0	0
	POST PROCEDURAL COMPLICATION	0	0	0	0	1	0.8	0	0	0	0	0	0
	POST PROCEDURAL PAIN	0	0	0	0	2	1.7	0	0	0	0	0	0
	SCRATCH	2	1.7	0	0	0	0	0	0	0	0	0	0
	SKIN LACERATION	1	0.8	0	0	2	1.7	0	0	0	0	0	0
	SPINAL FRACTURE NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	SUNBURN	0	0	0	0	1	0.8	0	0	0	0	0	0
	THERMAL BURN	1	0.8	0	0	0	0	0	0	0	0	1	1.6
INVESTIGATIONS	TOTAL	2	1.7	12	10.0	2	1.7	1	1.7	1	1.7	0	0
	BLOOD IN STOOL	0	0	0	0	1	0.8	0	0	0	0	0	0
	BLOOD URINE	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INVESTIGATIONS	WEIGHT DECREASED	0	0	1	0.8	0	0	0	0	0	0	0	0
	WEIGHT INCREASED	2	1.7	10	8.3	1	0.8	1	1.7	1	1.7	0	0
METABOLISM AND NUTRITION DISORDERS	TOTAL	6	5.0	8	6.7	4	3.4	3	5.1	5	8.3	2	3.2
	ALCOHOL INTOLERANCE	1	0.8	0	0	0	0	0	0	1	1.7	0	0
	APPETITE DECREASED NOS	1	0.8	2	1.7	1	0.8	0	0	0	0	2	3.2
	APPETITE INCREASED NOS	4	3.3	6	5.0	3	2.5	3	5.1	4	6.7	0	0
	FLUID RETENTION	0	0	0	0	0	0	0	0	1	1.7	0	0
	FOOD CRAVING	0	0	0	0	0	0	0	0	1	1.7	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	20	16.7	21	17.5	17	14.4	10	16.9	12	20.0	6	9.7
	ARTHRALGIA	3	2.5	4	3.3	5	4.2	2	3.4	4	6.7	1	1.6
	ARTHRITIS NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	BACK PAIN	4	3.3	2	1.7	3	2.5	3	5.1	3	5.0	2	3.2
	BUTTOCK PAIN	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	CHEST WALL PAIN	1	0.8	0	0	0	0	0	0	0	0	0	0
	DUPUYTREN'S CONTRACTURE	0	0	1	0.8	0	0	0	0	0	0	0	0
	FACIAL PAIN	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	FLANK PAIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	GROIN PAIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	INTERVERTEBRAL DISC HERNIATION	0	0	0	0	1	0.8	0	0	0	0	0	0
	JOINT STIFFNESS	1	0.8	0	0	0	0	0	0	1	1.7	0	0
	JOINT SWELLING	1	0.8	0	0	0	0	0	0	0	0	0	0
	LIMB DISCOMFORT NOS	0	0	0	0	0	0	0	0	1	1.7	0	0
	MUSCLE CRAMP	3	2.5	1	0.8	1	0.8	2	3.4	1	1.7	0	0
	MUSCLE RIGIDITY	0	0	0	0	1	0.8	0	0	0	0	0	0
	MUSCLE SPASMS	2	1.7	0	0	2	1.7	0	0	0	0	0	0
	MUSCLE STIFFNESS	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE TIGHTNESS	1	0.8	0	0	1	0.8	1	1.7	0	0	0	0
	MUSCLE TWITCHING	0	0	3	2.5	2	1.7	2	3.4	1	1.7	1	1.6
	MUSCLE WEAKNESS NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	MUSCULOSKELETAL PAIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	MUSCULOSKELETAL STIFFNESS	0	0	2	1.7	0	0	0	0	0	0	0	0
	MYALGIA	1	0.8	3	2.5	0	0	0	0	1	1.7	2	3.2
	NECK PAIN	3	2.5	1	0.8	1	0.8	1	1.7	0	0	1	1.6
	PAIN IN EXTREMITY	1	0.8	8	6.7	4	3.4	1	1.7	1	1.7	0	0
	PERIARTHRITIS	0	0	0	0	0	0	0	0	1	1.7	0	0
	SENSATION OF HEAVINESS	0	0	0	0	1	0.8	0	0	0	0	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	TOTAL	1	0.8	0	0	0	0	1	1.7	0	0	0	0
	CHRONIC LYMPHOCYTIC LEUKAEMIA NOS	0	0	0	0	0	0	1	1.7	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	UTERINE FIBROIDS	1	0.8	0	0	0	0	0	0	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	88	73.3	87	72.5	52	44.1	46	78.0	45	75.0	22	35.5
	AKATHISIA	5	4.2	6	5.0	0	0	4	6.8	3	5.0	2	3.2
	AMNESIA	0	0	1	0.8	0	0	0	0	0	0	0	0
	ATAXIA	0	0	2	1.7	0	0	0	0	0	0	0	0
	BALANCE IMPAIRED NOS	4	3.3	2	1.7	0	0	3	5.1	0	0	1	1.6
	CARPAL TUNNEL SYNDROME	0	0	0	0	0	0	0	0	0	0	1	1.6
	COGNITIVE DISORDER	0	0	0	0	1	0.8	0	0	0	0	0	0
	CONVULSIONS NOS	0	0	1	0.8	0	0	0	0	0	0	1	1.6
	COORDINATION ABNORMAL NOS	1	0.8	1	0.8	0	0	1	1.7	0	0	0	0
	DISTURBANCE IN ATTENTION	0	0	0	0	0	0	1	1.7	1	1.7	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NERVOUS SYSTEM DISORDERS	DIZZINESS	19	15.8	27	22.5	10	8.5	11	18.6	14	23.3	5	8.1
	DIZZINESS POSTURAL	1	0.8	2	1.7	1	0.8	0	0	1	1.7	0	0
	DYSARTHRIA	2	1.7	2	1.7	0	0	3	5.1	0	0	0	0
	DYSGEUSIA	2	1.7	0	0	0	0	0	0	2	3.3	0	0
	DYSKINESIA	3	2.5	1	0.8	0	0	1	1.7	1	1.7	0	0
	DYSTONIA	1	0.8	5	4.2	1	0.8	1	1.7	0	0	0	0
	EXTRAPYRAMIDAL DISORDER	0	0	1	0.8	1	0.8	0	0	1	1.7	0	0
	HEADACHE	17	14.2	9	7.5	25	21.2	5	8.5	9	15.0	11	17.7
	HEMIPARESIS	0	0	0	0	1	0.8	0	0	0	0	0	0
	HYPERREFLEXIA	0	0	1	0.8	0	0	0	0	0	0	0	0
	HYPERSOMNIA	4	3.3	5	4.2	1	0.8	1	1.7	1	1.7	0	0
	HYPOAESTHESIA	2	1.7	1	0.8	1	0.8	0	0	2	3.3	0	0
	HYPOREFLEXIA	0	0	0	0	0	0	0	0	0	0	1	1.6
	MEMORY IMPAIRMENT	4	3.3	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NERVOUS SYSTEM DISORDERS	MENTAL IMPAIRMENT NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	MIGRAINE NOS	1	0.8	2	1.7	0	0	0	0	0	0	0	0
	MUSCLE CONTRACTIONS INVOLUNTARY	0	0	0	0	0	0	0	0	1	1.7	0	0
	MYOCLONUS	1	0.8	0	0	0	0	0	0	0	0	0	0
	PARAESTHESIA	4	3.3	6	5.0	1	0.8	0	0	1	1.7	2	3.2
	PSYCHOMOTOR HYPERACTIVITY	0	0	1	0.8	0	0	0	0	0	0	0	0
	RESTLESS LEGS SYNDROME	3	2.5	2	1.7	0	0	1	1.7	1	1.7	0	0
	SCIATICA	0	0	0	0	1	0.8	0	0	0	0	0	0
	SEDATION	25	20.8	31	25.8	6	5.1	28	47.5	27	45.0	5	8.1
	SENSORY DISTURBANCE NOS	0	0	0	0	0	0	1	1.7	0	0	0	0
	SINUS HEADACHE	1	0.8	0	0	0	0	0	0	0	0	0	0
	SOMNOLENCE	39	32.5	37	30.8	12	10.2	10	16.9	7	11.7	3	4.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NERVOUS SYSTEM DISORDERS	SPEECH DISORDER	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	SYNCOPE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	TENSION HEADACHE	1	0.8	1	0.8	1	0.8	0	0	1	1.7	0	0
	TREMOR	3	2.5	3	2.5	0	0	2	3.4	2	3.3	1	1.6
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	ECTOPIC PREGNANCY	0	0	0	0	1	0.8	0	0	0	0	0	0
PSYCHIATRIC DISORDERS	TOTAL	24	20.0	25	20.8	25	21.2	13	22.0	13	21.7	9	14.5
	ABNORMAL DREAMS	4	3.3	3	2.5	2	1.7	2	3.4	1	1.7	1	1.6
	ACUTE PSYCHOSIS	0	0	0	0	1	0.8	0	0	0	0	0	0
	AGITATION	1	0.8	1	0.8	3	2.5	0	0	1	1.7	1	1.6
	ANGER	0	0	0	0	0	0	0	0	1	1.7	0	0
	ANXIETY	1	0.8	3	2.5	3	2.5	3	5.1	1	1.7	2	3.2
	BIPOLAR I DISORDER	0	0	0	0	0	0	0	0	1	1.7	0	0
	BLUNTED AFFECT	1	0.8	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	BRADYPHRENIA	0	0	1	0.8	0	0	0	0	0	0	0	0
	BRUXISM	0	0	0	0	1	0.8	0	0	2	3.3	0	0
	CONFUSIONAL STATE	1	0.8	0	0	0	0	0	0	1	1.7	0	0
	CONVERSION DISORDER	1	0.8	0	0	0	0	0	0	0	0	0	0
	DELUSION NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	DEPRESSION	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	DEREALISATION	0	0	0	0	0	0	1	1.7	0	0	0	0
	DISORIENTATION	0	0	0	0	0	0	1	1.7	0	0	0	0
	DISSOCIATIVE DISORDER NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	FLAT AFFECT	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	HALLUCINATION, AUDITORY	1	0.8	2	1.7	2	1.7	0	0	0	0	0	0
	HALLUCINATION, VISUAL	0	0	1	0.8	0	0	0	0	1	1.7	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	HYPNAGOGIC HALLUCINATION	0	0	1	0.8	0	0	0	0	0	0	0	0
	HYPOMANIA	0	0	0	0	0	0	1	1.7	1	1.7	0	0
	ILLUSION	0	0	0	0	1	0.8	0	0	0	0	0	0
	INSOMNIA	6	5.0	7	5.8	6	5.1	2	3.4	0	0	3	4.8
	IRRITABILITY	2	1.7	2	1.7	1	0.8	0	0	3	5.0	0	0
	LIBIDO DECREASED	1	0.8	2	1.7	1	0.8	1	1.7	0	0	1	1.6
	LIBIDO INCREASED	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	LOGORRHOEA	0	0	1	0.8	0	0	0	0	0	0	0	0
	LOSS OF LIBIDO	0	0	0	0	0	0	1	1.7	1	1.7	0	0
	MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	MANIA	2	1.7	1	0.8	2	1.7	0	0	0	0	0	0
	MENTAL STATUS CHANGES	0	0	0	0	0	0	0	0	1	1.7	0	0
	MIDDLE INSOMNIA	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	MOOD SWINGS	1	0.8	0	0	0	0	0	0	0	0	0	0
	NERVOUSNESS	0	0	0	0	0	0	0	0	2	3.3	0	0
	NIGHTMARE	3	2.5	2	1.7	0	0	1	1.7	0	0	0	0
	OBSESSIVE-COMPULSIVE DISORDER	0	0	0	0	1	0.8	0	0	0	0	0	0
	ONYCHOPHAGIA	1	0.8	0	0	0	0	0	0	0	0	0	0
	PANIC ATTACK	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	PANIC DISORDER NOS	0	0	0	0	0	0	1	1.7	0	0	0	0
	PARANOIA	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	RESTLESSNESS	1	0.8	0	0	0	0	1	1.7	1	1.7	2	3.2
	SLEEP WALKING	0	0	0	0	0	0	1	1.7	0	0	0	0
	SUICIDAL IDEATION	3	2.5	2	1.7	3	2.5	0	0	1	1.7	0	0
	SUICIDE ATTEMPT	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	SUSPICIOUSNESS	0	0	0	0	0	0	2	3.4	0	0	0	0
	TENSION	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	THOUGHT BLOCKING	1	0.8	0	0	0	0	0	0	1	1.7	0	0
RENAL AND URINARY DISORDERS	TOTAL	4	3.3	7	5.8	5	4.2	4	6.8	1	1.7	0	0
	BLADDER DISORDER NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	DYSURIA	0	0	0	0	0	0	0	0	1	1.7	0	0
	ENURESIS	2	1.7	0	0	0	0	0	0	0	0	0	0
	MICTURITION URGENCY	1	0.8	0	0	1	0.8	2	3.4	0	0	0	0
	NEPHROLITHIASIS	0	0	1	0.8	0	0	0	0	0	0	0	0
	POLLAKIURIA	1	0.8	4	3.3	3	2.5	0	0	0	0	0	0
	URINARY HESITATION	0	0	0	0	1	0.8	1	1.7	0	0	0	0
	URINARY INCONTINENCE	0	0	1	0.8	0	0	1	1.7	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	5	4.2	2	1.7	5	4.2	2	3.4	4	6.7	3	4.8
	ADNEXA UTERI PAIN	1	0.8	0	0	0	0	0	0	0	0	0	0
	BREAST CYST	1	0.8	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	DYSMENORRHOEA	2	1.7	2	1.7	1	0.8	0	0	1	1.7	1	1.6
	ERECTILE DYSFUNCTION NOS	1	0.8	0	0	3	2.5	0	0	2	3.3	1	1.6
	MENSES DELAYED	0	0	0	0	0	0	1	1.7	0	0	0	0
	MENSTRUATION IRREGULAR	1	0.8	0	0	0	0	0	0	0	0	0	0
	NIPPLE EXUDATE BLOODY	1	0.8	0	0	0	0	0	0	0	0	0	0
	POLYMENORRHOEA	1	0.8	0	0	0	0	1	1.7	0	0	0	0
	PROSTATITIS	0	0	0	0	0	0	0	0	1	1.7	0	0
	SEXUAL DYSFUNCTION NOS	0	0	0	0	1	0.8	1	1.7	0	0	1	1.6
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	25	20.8	19	15.8	14	11.9	9	15.3	12	20.0	10	16.1
	ASTHMA NOS	0	0	0	0	1	0.8	0	0	1	1.7	1	1.6
	BRONCHITIS NOS	1	0.8	0	0	1	0.8	1	1.7	1	1.7	2	3.2
	BRONCHOSPASM NOS	0	0	0	0	0	0	0	0	0	0	1	1.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	CHOKING SENSATION	1	0.8	0	0	0	0	1	1.7	0	0	0	0
	COUGH	6	5.0	2	1.7	1	0.8	1	1.7	4	6.7	0	0
	DYSPNOEA	1	0.8	4	3.3	1	0.8	4	6.8	3	5.0	3	4.8
	EPISTAXIS	1	0.8	0	0	0	0	0	0	0	0	0	0
	HICCUPS	0	0	0	0	0	0	0	0	0	0	1	1.6
	HOARSENESS	0	0	1	0.8	0	0	0	0	0	0	0	0
	LARYNGITIS NOS	0	0	0	0	0	0	0	0	0	0	1	1.6
	NASAL CONGESTION	9	7.5	8	6.7	3	2.5	1	1.7	4	6.7	0	0
	NASAL DRYNESS	0	0	0	0	0	0	1	1.7	0	0	0	0
	NASAL OEDEMA	1	0.8	0	0	0	0	0	0	0	0	0	0
	NASOPHARYNGITIS	4	3.3	2	1.7	2	1.7	0	0	0	0	0	0
	PHARYNGEAL ERYTHEMA	1	0.8	0	0	0	0	0	0	0	0	0	0
	PHARYNGOLARYNGEAL PAIN	3	2.5	2	1.7	3	2.5	0	0	1	1.7	2	3.2
	PRODUCTIVE COUGH	1	0.8	0	0	2	1.7	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY CONGESTION	1	0.8	0	0	0	0	0	0	0	0	1	1.6
	RHINORRHOEA	0	0	0	0	1	0.8	0	0	0	0	0	0
	SINUS CONGESTION	4	3.3	2	1.7	1	0.8	1	1.7	2	3.3	1	1.6
	SINUS PAIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	THROAT TIGHTNESS	0	0	2	1.7	0	0	0	0	0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	5	4.2	9	7.5	13	11.0	3	5.1	8	13.3	3	4.8
	ACNE NOS	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	ALOPECIA	0	0	1	0.8	0	0	0	0	0	0	0	0
	CONTUSION	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	DERMATITIS ALLERGIC	0	0	0	0	1	0.8	0	0	0	0	0	0
	DERMATITIS CONTACT	0	0	1	0.8	0	0	1	1.7	1	1.7	0	0
	DERMATITIS EXFOLIATIVE NOS	0	0	0	0	0	0	0	0	0	0	1	1.6
	ECCHYMOSIS	1	0.8	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	1	0.8	0	0	1	0.8	0	0	0	0	0	0
	INCREASED TENDENCY TO BRUISE	0	0	0	0	0	0	0	0	0	0	1	1.6
	NIGHT SWEATS	0	0	2	1.7	1	0.8	2	3.4	2	3.3	0	0
	PRURITUS	1	0.8	1	0.8	2	1.7	0	0	0	0	0	0
	PRURITUS GENERALISED	0	0	0	0	1	0.8	0	0	0	0	0	0
	RASH NOS	1	0.8	1	0.8	2	1.7	0	0	0	0	1	1.6
	SKIN IRRITATION	0	0	0	0	1	0.8	0	0	0	0	0	0
	SKIN LESION NOS	0	0	0	0	0	0	0	0	2	3.3	0	0
	SKIN ULCER	0	0	0	0	1	0.8	0	0	0	0	0	0
	SUBCUTANEOUS NODULE	0	0	1	0.8	0	0	0	0	0	0	0	0
	SWEATING INCREASED	1	0.8	2	1.7	1	0.8	0	0	1	1.7	1	1.6
SOCIAL CIRCUMSTANCES	TOTAL	2	1.7	2	1.7	0	0	0	0	2	3.3	0	0
	DRUG ABUSER NOS	2	1.7	2	1.7	0	0	0	0	2	3.3	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
SURGICAL AND MEDICAL PROCEDURES	TOTAL	0	0	0	0	0	0	1	1.7	0	0	0	0
	TOOTH EXTRACTION NOS	0	0	0	0	0	0	1	1.7	0	0	0	0
VASCULAR DISORDERS	TOTAL	6	5.0	10	8.3	5	4.2	8	13.6	5	8.3	4	6.5
	DEEP VEIN THROMBOSIS	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	FLUSHING	2	1.7	3	2.5	1	0.8	3	5.1	2	3.3	1	1.6
	HAEMATOMA NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	HYPERTENSION NOS	1	0.8	1	0.8	0	0	2	3.4	0	0	0	0
	HYPOTENSION NOS	0	0	1	0.8	0	0	0	0	1	1.7	0	0
	ORTHOSTATIC HYPOTENSION	3	2.5	5	4.2	2	1.7	3	5.1	2	3.3	4	6.5

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG203.SAS
GENERATED: 12JUL2005 17:39:08 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DRY MOUTH	79	44.1	73	40.6	14	7.8
SEDATION	53	29.6	58	32.2	11	6.1
SOMNOLENCE	49	27.4	44	24.4	15	8.3
DIZZINESS	30	16.8	41	22.8	15	8.3
HEADACHE	22	12.3	18	10.0	36	20.0
CONSTIPATION	21	11.7	20	11.1	8	4.4
FATIGUE	16	8.9	21	11.7	13	7.2
NAUSEA	14	7.8	16	8.9	23	12.8
DYSPEPSIA	12	6.7	17	9.4	10	5.6
LETHARGY	11	6.1	16	8.9	3	1.7
VOMITING NOS	11	6.1	4	2.2	2	1.1
NASAL CONGESTION	10	5.6	12	6.7	3	1.7
AKATHISIA	9	5.0	9	5.0	2	1.1
UPPER RESPIRATORY TRACT INFECTION NOS	9	5.0	13	7.2	18	10.0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DIARRHOEA NOS	8	4.5	11	6.1	15	8.3
INSOMNIA	8	4.5	7	3.9	9	5.0
PALPITATIONS	8	4.5	5	2.8	3	1.7
APPETITE INCREASED NOS	7	3.9	10	5.6	3	1.7
BACK PAIN	7	3.9	5	2.8	5	2.8
BALANCE IMPAIRED NOS	7	3.9	2	1.1	1	0.6
COUGH	7	3.9	6	3.3	1	0.6
ABNORMAL DREAMS	6	3.4	4	2.2	3	1.7
NASOPHARYNGITIS	6	3.4	4	2.2	6	3.3
ORTHOSTATIC HYPOTENSION	6	3.4	7	3.9	6	3.3
ARTHRALGIA	5	2.8	8	4.4	6	3.3
DYSARTHRIA	5	2.8	2	1.1	0	0
DYSPNOEA	5	2.8	7	3.9	4	2.2
FLUSHING	5	2.8	5	2.8	2	1.1

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
HYPERSOMNIA	5	2.8	6	3.3	1	0.6
MUSCLE CRAMP	5	2.8	2	1.1	1	0.6
SINUS CONGESTION	5	2.8	4	2.2	2	1.1
TREMOR	5	2.8	5	2.8	1	0.6
VISION BLURRED	5	2.8	13	7.2	3	1.7
ANXIETY	4	2.2	4	2.2	5	2.8
DYSKINESIA	4	2.2	2	1.1	0	0
INFLUENZA LIKE ILLNESS	4	2.2	4	2.2	4	2.2
INJURY	4	2.2	3	1.7	1	0.6
MEMORY IMPAIRMENT	4	2.2	0	0	0	0
NECK PAIN	4	2.2	1	0.6	2	1.1
NIGHTMARE	4	2.2	2	1.1	0	0
PARAESTHESIA	4	2.2	7	3.9	3	1.7
RESTLESS LEGS SYNDROME	4	2.2	3	1.7	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
TOOTHACHE	4	2.2	4	2.2	4	2.2
ACCIDENTAL OVERDOSE	3	1.7	4	2.2	7	3.9
HYPERTENSION NOS	3	1.7	1	0.6	0	0
INFLUENZA	3	1.7	1	0.6	5	2.8
MICTURITION URGENCY	3	1.7	0	0	1	0.6
PHARYNGOLARYNGEAL PAIN	3	1.7	3	1.7	5	2.8
PYREXIA	3	1.7	1	0.6	3	1.7
SUICIDAL IDEATION	3	1.7	3	1.7	3	1.7
TACHYCARDIA NOS	3	1.7	2	1.1	1	0.6
TONGUE DISORDER NOS	3	1.7	0	0	0	0
WEIGHT INCREASED	3	1.7	11	6.1	1	0.6
BRONCHITIS NOS	2	1.1	1	0.6	3	1.7
CHEST PAIN	2	1.1	4	2.2	2	1.1
CHOKING SENSATION	2	1.1	0	0	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
COORDINATION ABNORMAL NOS	2	1.1	1	0.6	0	0
DRUG ABUSER NOS	2	1.1	4	2.2	0	0
DYSGEUSIA	2	1.1	2	1.1	0	0
DYSMENORRHOEA	2	1.1	3	1.7	2	1.1
DYSTONIA	2	1.1	5	2.8	1	0.6
ENURESIS	2	1.1	0	0	0	0
FLATULENCE	2	1.1	4	2.2	2	1.1
GASTROENTERITIS VIRAL NOS	2	1.1	2	1.1	3	1.7
HERPES SIMPLEX	2	1.1	0	0	2	1.1
HYPOAESTHESIA	2	1.1	3	1.7	1	0.6
IRRITABILITY	2	1.1	5	2.8	1	0.6
LIBIDO DECREASED	2	1.1	2	1.1	2	1.1
MANIA	2	1.1	1	0.6	2	1.1
MUSCLE SPASMS	2	1.1	0	0	2	1.1

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCLE TIGHTNESS	2	1.1	0	0	1	0.6
MUSCLE TWITCHING	2	1.1	4	2.2	3	1.7
NIGHT SWEATS	2	1.1	4	2.2	1	0.6
PAIN IN EXTREMITY	2	1.1	9	5.0	4	2.2
POLYMENORRHOEA	2	1.1	0	0	0	0
RESTLESSNESS	2	1.1	1	0.6	2	1.1
SCRATCH	2	1.1	0	0	0	0
SINUSITIS NOS	2	1.1	1	0.6	3	1.7
SLUGGISHNESS	2	1.1	2	1.1	1	0.6
SUSPICIOUSNESS	2	1.1	0	0	0	0
THIRST	2	1.1	0	0	2	1.1
TINNITUS	2	1.1	3	1.7	2	1.1
TOOTH INFECTION	2	1.1	0	0	0	0
VIRAL INFECTION NOS	2	1.1	1	0.6	2	1.1

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ABDOMINAL DISTENSION	1	0.6	2	1.1	1	0.6
ABDOMINAL PAIN LOWER	1	0.6	1	0.6	0	0
ABDOMINAL PAIN UPPER	1	0.6	3	1.7	4	2.2
ADNEXA UTERI PAIN	1	0.6	0	0	0	0
AGITATION	1	0.6	2	1.1	4	2.2
ALCOHOL INTOLERANCE	1	0.6	1	0.6	0	0
APPETITE DECREASED NOS	1	0.6	2	1.1	3	1.7
ARTHROPOD BITE	1	0.6	0	0	1	0.6
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1	0.6	0	0	0	0
BLEPHARITIS	1	0.6	0	0	0	0
BLUNTED AFFECT	1	0.6	0	0	0	0
BREAST CYST	1	0.6	0	0	0	0
CERUMEN IMPACTION	1	0.6	0	0	0	0
CHEILITIS	1	0.6	0	0	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CHEST DISCOMFORT	1	0.6	0	0	0	0
CHEST TIGHTNESS	1	0.6	2	1.1	1	0.6
CHEST WALL PAIN	1	0.6	0	0	0	0
CHRONIC LYMPHOCYTIC LEUKAEMIA NOS	1	0.6	0	0	0	0
CONFUSIONAL STATE	1	0.6	1	0.6	0	0
CONVERSION DISORDER	1	0.6	0	0	0	0
DEPRESSION	1	0.6	1	0.6	0	0
DEREALISATION	1	0.6	0	0	0	0
DERMATITIS CONTACT	1	0.6	2	1.1	0	0
DISORIENTATION	1	0.6	0	0	0	0
DISTURBANCE IN ATTENTION	1	0.6	1	0.6	0	0
DIZZINESS POSTURAL	1	0.6	3	1.7	1	0.6
DRY EYE NOS	1	0.6	0	0	0	0
EAR CONGESTION	1	0.6	0	0	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EAR DISCOMFORT	1	0.6	0	0	0	0
EAR INFECTION NOS	1	0.6	1	0.6	0	0
EAR PRURITUS	1	0.6	0	0	0	0
ECCHYMOSIS	1	0.6	0	0	1	0.6
EPISTAXIS	1	0.6	0	0	0	0
ERECTILE DYSFUNCTION NOS	1	0.6	2	1.1	4	2.2
ERYTHEMA	1	0.6	0	0	1	0.6
FEELING ABNORMAL	1	0.6	0	0	0	0
FEELING COLD	1	0.6	4	2.2	2	1.1
FLAT AFFECT	1	0.6	1	0.6	0	0
FOOD POISONING NOS	1	0.6	0	0	1	0.6
FUNGAL INFECTION NOS	1	0.6	0	0	0	0
GAIT ABNORMAL	1	0.6	0	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE	1	0.6	5	2.8	2	1.1

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GINGIVAL INFECTION	1	0.6	0	0	0	0
GINGIVAL PAIN	1	0.6	0	0	0	0
GLOSSODYNIA	1	0.6	0	0	0	0
HAEMORRHOIDS	1	0.6	0	0	0	0
HALLUCINATION, AUDITORY	1	0.6	2	1.1	2	1.1
HYPERSENSITIVITY NOS	1	0.6	0	0	0	0
HYPOMANIA	1	0.6	1	0.6	0	0
JOINT STIFFNESS	1	0.6	1	0.6	0	0
JOINT SWELLING	1	0.6	0	0	0	0
LIMB INJURY NOS	1	0.6	0	0	0	0
LOSS OF LIBIDO	1	0.6	1	0.6	0	0
LYMPHADENOPATHY	1	0.6	0	0	0	0
MENSES DELAYED	1	0.6	0	0	0	0
MENSTRUATION IRREGULAR	1	0.6	0	0	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MIGRAINE NOS	1	0.6	2	1.1	0	0
MOOD SWINGS	1	0.6	0	0	0	0
MUCOUS MEMBRANE DISORDER NOS	1	0.6	0	0	0	0
MYALGIA	1	0.6	4	2.2	2	1.1
MYOCLONUS	1	0.6	0	0	0	0
NASAL DRYNESS	1	0.6	0	0	0	0
NASAL OEDEMA	1	0.6	0	0	0	0
NIPPLE EXUDATE BLOODY	1	0.6	0	0	0	0
ONYCHOPHAGIA	1	0.6	0	0	0	0
PANIC DISORDER NOS	1	0.6	0	0	0	0
PARANOIA	1	0.6	1	0.6	0	0
PHARYNGEAL ERYTHEMA	1	0.6	0	0	0	0
PHOTOPSIA	1	0.6	0	0	1	0.6
POLLAKIURIA	1	0.6	4	2.2	3	1.7

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PRODUCTIVE COUGH	1	0.6	0	0	2	1.1
PRURITUS	1	0.6	1	0.6	2	1.1
PULMONARY CONGESTION	1	0.6	0	0	1	0.6
RASH NOS	1	0.6	1	0.6	3	1.7
SCABIES INFESTATION	1	0.6	0	0	0	0
SEASONAL ALLERGY	1	0.6	0	0	0	0
SENSORY DISTURBANCE NOS	1	0.6	0	0	0	0
SEXUAL DYSFUNCTION NOS	1	0.6	0	0	2	1.1
SINUS HEADACHE	1	0.6	0	0	0	0
SKIN LACERATION	1	0.6	0	0	2	1.1
SLEEP WALKING	1	0.6	0	0	0	0
SPEECH DISORDER	1	0.6	1	0.6	0	0
SUICIDE ATTEMPT	1	0.6	1	0.6	0	0
SWEATING INCREASED	1	0.6	3	1.7	2	1.1

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
TENSION HEADACHE	1	0.6	2	1.1	1	0.6
THERMAL BURN	1	0.6	0	0	1	0.6
THOUGHT BLOCKING	1	0.6	1	0.6	0	0
TINEA VERSICOLOUR	1	0.6	0	0	0	0
TOOTH EXTRACTION NOS	1	0.6	0	0	0	0
TOOTH LOSS	1	0.6	0	0	0	0
URINARY HESITATION	1	0.6	0	0	1	0.6
URINARY INCONTINENCE	1	0.6	1	0.6	0	0
URINARY TRACT INFECTION NOS	1	0.6	1	0.6	0	0
UTERINE FIBROIDS	1	0.6	0	0	0	0
VERTIGO	1	0.6	1	0.6	0	0
VISUAL ACUITY REDUCED	1	0.6	1	0.6	0	0
ABDOMINAL PAIN NOS	0	0	2	1.1	6	3.3
ACNE NOS	0	0	1	0.6	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALOPECIA	0	0	1	0.6	0	0
ALTERED VISUAL DEPTH PERCEPTION	0	0	1	0.6	0	0
AMNESIA	0	0	1	0.6	0	0
ANGER	0	0	1	0.6	0	0
APTYALISM	0	0	1	0.6	0	0
ARTHRITIS NOS	0	0	1	0.6	0	0
ASTHENIA	0	0	3	1.7	0	0
ASTHMA NOS	0	0	1	0.6	2	1.1
ASTIGMATISM	0	0	1	0.6	0	0
ATAXIA	0	0	2	1.1	0	0
BACK INJURY NOS	0	0	1	0.6	1	0.6
BIPOLAR I DISORDER	0	0	1	0.6	0	0
BLADDER DISORDER NOS	0	0	1	0.6	0	0
BLOOD URINE	0	0	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BRADYPHRENIA	0	0	1	0.6	0	0
BRUXISM	0	0	2	1.1	1	0.6
BUTTOCK PAIN	0	0	1	0.6	0	0
CHAPPED LIPS	0	0	1	0.6	0	0
CONTUSION	0	0	1	0.6	1	0.6
CONVULSIONS NOS	0	0	1	0.6	1	0.6
DEEP VEIN THROMBOSIS	0	0	1	0.6	1	0.6
DELUSION NOS	0	0	1	0.6	0	0
DRUG WITHDRAWAL SYNDROME	0	0	1	0.6	0	0
DUPUYTREN'S CONTRACTURE	0	0	1	0.6	0	0
DYSPHAGIA	0	0	6	3.3	0	0
DYSURIA	0	0	1	0.6	0	0
EAR PAIN	0	0	1	0.6	0	0
EXCORIATION	0	0	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EXTRAPYRAMIDAL DISORDER	0	0	2	1.1	1	0.6
EYELIDS PRURITUS	0	0	1	0.6	0	0
FACIAL PAIN	0	0	1	0.6	1	0.6
FACTOR II DEFICIENCY	0	0	1	0.6	0	0
FAECES HARD	0	0	1	0.6	0	0
FEELING JITTERY	0	0	3	1.7	0	0
FLANK PAIN	0	0	1	0.6	0	0
FLUID RETENTION	0	0	1	0.6	0	0
FOOD CRAVING	0	0	1	0.6	0	0
GROIN PAIN	0	0	1	0.6	0	0
HALLUCINATION, VISUAL	0	0	2	1.1	0	0
HERNIA NOS	0	0	1	0.6	0	0
HOARSENESS	0	0	1	0.6	0	0
HYPERREFLEXIA	0	0	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
HYPNAGOGIC HALLUCINATION	0	0	1	0.6	0	0
HYPOTENSION NOS	0	0	2	1.1	0	0
INTESTINAL OBSTRUCTION NOS	0	0	1	0.6	0	0
KIDNEY INFECTION NOS	0	0	1	0.6	0	0
LIBIDO INCREASED	0	0	1	0.6	1	0.6
LIMB DISCOMFORT NOS	0	0	1	0.6	0	0
LOGORRHOEA	0	0	1	0.6	0	0
MENTAL STATUS CHANGES	0	0	1	0.6	0	0
MIDDLE INSOMNIA	0	0	1	0.6	0	0
MUSCLE CONTRACTIONS INVOLUNTARY	0	0	1	0.6	0	0
MUSCLE STIFFNESS	0	0	1	0.6	0	0
MUSCLE STRAIN	0	0	1	0.6	1	0.6
MUSCLE WEAKNESS NOS	0	0	1	0.6	0	0
MUSCULOSKELETAL PAIN	0	0	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL STIFFNESS	0	0	2	1.1	0	0
NEPHROLITHIASIS	0	0	1	0.6	0	0
NERVOUSNESS	0	0	2	1.1	0	0
NON-ACCIDENTAL OVERDOSE	0	0	2	1.1	2	1.1
OEDEMA PERIPHERAL	0	0	3	1.7	2	1.1
PAIN NOS	0	0	5	2.8	2	1.1
PANIC ATTACK	0	0	1	0.6	1	0.6
PERIARTHRITIS	0	0	1	0.6	0	0
PERIORBITAL HAEMATOMA	0	0	1	0.6	0	0
PHARYNGITIS STREPTOCOCCAL	0	0	1	0.6	0	0
PROSTATITIS	0	0	1	0.6	0	0
PSYCHOMOTOR HYPERACTIVITY	0	0	1	0.6	0	0
RIGORS	0	0	1	0.6	1	0.6
SENSATION OF BLOOD FLOW	0	0	1	0.6	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SINUS PAIN	0	0	1	0.6	0	0
SKIN LESION NOS	0	0	2	1.1	0	0
SUBCUTANEOUS NODULE	0	0	1	0.6	0	0
SWOLLEN TONGUE	0	0	1	0.6	0	0
SYNCOPE	0	0	1	0.6	1	0.6
TENSION	0	0	1	0.6	0	0
THROAT TIGHTNESS	0	0	2	1.1	0	0
TOOTH DISORDER NOS	0	0	1	0.6	0	0
WEIGHT DECREASED	0	0	1	0.6	0	0
ABDOMINAL DISCOMFORT	0	0	0	0	1	0.6
ACUTE PSYCHOSIS	0	0	0	0	1	0.6
APHTHOUS STOMATITIS	0	0	0	0	1	0.6
BLEPHAROSPASM	0	0	0	0	1	0.6
BLOOD IN STOOL	0	0	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BRONCHOSPASM NOS	0	0	0	0	1	0.6
CARPAL TUNNEL SYNDROME	0	0	0	0	1	0.6
CHOLECYSTITIS NOS	0	0	0	0	1	0.6
COGNITIVE DISORDER	0	0	0	0	1	0.6
DERMATITIS ALLERGIC	0	0	0	0	1	0.6
DERMATITIS EXFOLIATIVE NOS	0	0	0	0	1	0.6
DISSOCIATIVE DISORDER NOS	0	0	0	0	1	0.6
DRUG HYPERSENSITIVITY	0	0	0	0	1	0.6
DUODENAL ULCER HAEMORRHAGE	0	0	0	0	1	0.6
EAR INFECTION VIRAL NOS	0	0	0	0	1	0.6
ECTOPIC PREGNANCY	0	0	0	0	1	0.6
EYE PAIN	0	0	0	0	1	0.6
FEELING HOT	0	0	0	0	1	0.6
FREQUENT BOWEL MOVEMENTS	0	0	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL PAIN NOS	0	0	0	0	1	0.6
HAEMATOMA NOS	0	0	0	0	1	0.6
HEMIPARESIS	0	0	0	0	1	0.6
HICCUPS	0	0	0	0	1	0.6
HIP FRACTURE	0	0	0	0	1	0.6
HYPOREFLEXIA	0	0	0	0	1	0.6
ILLUSION	0	0	0	0	1	0.6
INCREASED TENDENCY TO BRUISE	0	0	0	0	1	0.6
INTERVERTEBRAL DISC HERNIATION	0	0	0	0	1	0.6
IRRITABLE BOWEL SYNDROME	0	0	0	0	1	0.6
JOINT SPRAIN	0	0	0	0	4	2.2
LARYNGITIS NOS	0	0	0	0	1	0.6
MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	1	0.6
MENTAL IMPAIRMENT NOS	0	0	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCLE RIGIDITY	0	0	0	0	1	0.6
OBSESSIVE-COMPULSIVE DISORDER	0	0	0	0	1	0.6
ORAL PAIN	0	0	0	0	1	0.6
OTITIS MEDIA NOS	0	0	0	0	1	0.6
PANCREATITIS NOS	0	0	0	0	1	0.6
PHOTOPHOBIA	0	0	0	0	2	1.1
POST PROCEDURAL COMPLICATION	0	0	0	0	1	0.6
POST PROCEDURAL PAIN	0	0	0	0	2	1.1
PROSTATE INFECTION	0	0	0	0	1	0.6
PRURITUS GENERALISED	0	0	0	0	1	0.6
RHINORRHOEA	0	0	0	0	1	0.6
SCIATICA	0	0	0	0	1	0.6
SENSATION OF HEAVINESS	0	0	0	0	1	0.6
SIALOADENITIS NOS	0	0	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SKIN IRRITATION	0	0	0	0	1	0.6
SKIN ULCER	0	0	0	0	1	0.6
SPINAL FRACTURE NOS	0	0	0	0	1	0.6
STAPHYLOCOCCAL INFECTION	0	0	0	0	1	0.6
SUNBURN	0	0	0	0	1	0.6
VAGINOSIS FUNGAL NOS	0	0	0	0	1	0.6
VENTRICULAR EXTRASYSTOLES	0	0	0	0	1	0.6

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG204.SAS
GENERATED: 12JUL2005 17:39:11 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS																								
TOTAL	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHADENOPATHY	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CARDIAC DISORDERS																								
TOTAL	5	2.8	7	3.9	0	0	12	6.7	6	3.3	0	0	1	0.6	7	3.9	3	1.7	2	1.1	0	0	5	2.8
ATRIOVENTRICULAR BLOCK FIRST DEGREE	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PALPITATIONS	5	2.8	3	1.7	0	0	8	4.5	4	2.2	0	0	1	0.6	5	2.8	2	1.1	1	0.6	0	0	3	1.7
TACHYCARDIA NOS	0	0	3	1.7	0	0	3	1.7	2	1.1	0	0	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6
VENTRICULAR EXTRASYSTOLES	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
CONGENITAL, FAMILIAL AND GENETIC DISORDERS																								
TOTAL	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
CONGENITAL, FAMILIAL AND GENETIC DISORDERS																								
FACTOR II DEFICIENCY	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
EAR AND LABYRINTH DISORDERS																								
TOTAL	5	2.8	1	0.6	0	0	6	3.4	3	1.7	2	1.1	0	0	5	2.8	2	1.1	0	0	0	0	2	1.1
CERUMEN IMPACTION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EAR CONGESTION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EAR DISCOMFORT	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EAR PAIN	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
EAR PRURITUS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TINNITUS	1	0.6	1	0.6	0	0	2	1.1	2	1.1	1	0.6	0	0	3	1.7	2	1.1	0	0	0	0	2	1.1
VERTIGO	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
EYE DISORDERS																								
TOTAL	7	3.9	2	1.1	0	0	9	5.0	8	4.4	7	3.9	1	0.6	16	8.9	6	3.3	1	0.6	1	0.6	8	4.4
ALTERED VISUAL DEPTH PERCEPTION	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
ASTIGMATISM	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
BLEPHARITIS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BLEPHAROSPASM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
DRY EYE NOS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE PAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
EYELIDS PRURITUS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
PHOTOPHOBIA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.1	0	0	0	0	2	1.1
PHOTOPSIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
VISION BLURRED	3	1.7	2	1.1	0	0	5	2.8	6	3.3	6	3.3	1	0.6	13	7.2	2	1.1	0	0	1	0.6	3	1.7

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
EYE DISORDERS																								
VISUAL ACUITY REDUCED	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
GASTROINTESTINAL DISORDERS																								
TOTAL	63	35.2	57	31.8	8	4.5	108	60.3	63	35.0	47	26.1	14	7.8	109	60.6	41	22.8	31	17.2	6	3.3	63	35.0
ABDOMINAL DISCOMFORT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
ABDOMINAL DISTENSION	0	0	1	0.6	0	0	1	0.6	0	0	2	1.1	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6
ABDOMINAL PAIN LOWER	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
ABDOMINAL PAIN NOS	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1	4	2.2	2	1.1	0	0	6	3.3
ABDOMINAL PAIN UPPER	1	0.6	0	0	0	0	1	0.6	1	0.6	2	1.1	0	0	3	1.7	3	1.7	1	0.6	0	0	4	2.2
APHTHOUS STOMATITIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS																								
APTYALISM	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
CHAPPED LIPS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
CHEILITIS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CONSTIPATION	14	7.8	7	3.9	0	0	21	11.7	12	6.7	8	4.4	0	0	20	11.1	5	2.8	3	1.7	0	0	8	4.4
DIARRHOEA NOS	4	2.2	4	2.2	0	0	8	4.5	3	1.7	7	3.9	1	0.6	11	6.1	8	4.4	5	2.8	2	1.1	15	8.3
DRY MOUTH	42	23.5	30	16.8	7	3.9	79	44.1	38	21.1	27	15.0	8	4.4	73	40.6	10	5.6	4	2.2	0	0	14	7.8
DUODENAL ULCER HAEMORRHAGE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
DYSPEPSIA	6	3.4	5	2.8	1	0.6	12	6.7	8	4.4	8	4.4	1	0.6	17	9.4	6	3.3	2	1.1	2	1.1	10	5.6
DYSPHAGIA	0	0	0	0	0	0	0	0	2	1.1	4	2.2	0	0	6	3.3	0	0	0	0	0	0	0	0
FAECES HARD	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
FLATULENCE	1	0.6	1	0.6	0	0	2	1.1	4	2.2	0	0	0	0	4	2.2	1	0.6	1	0.6	0	0	2	1.1

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS																								
FOOD POISONING NOS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
FREQUENT BOWEL MOVEMENTS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
GASTROINTESTINAL PAIN NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
GASTROOESOPHAGEAL REFLUX DISEASE	1	0.6	0	0	0	0	1	0.6	3	1.7	2	1.1	0	0	5	2.8	1	0.6	1	0.6	0	0	2	1.1
GINGIVAL PAIN	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GLOSSODYNIA	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HAEMORRHOIDS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTESTINAL OBSTRUCTION NOS	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
IRRITABLE BOWEL SYNDROME	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS																								
NAUSEA	4	2.2	9	5.0	1	0.6	14	7.8	10	5.6	4	2.2	2	1.1	16	8.9	8	4.4	14	7.8	1	0.6	23	12.8
ORAL PAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
PANCREATITIS NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
SWOLLEN TONGUE	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
TONGUE DISORDER NOS	2	1.1	1	0.6	0	0	3	1.7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOOTH DISORDER NOS	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
TOOTH LOSS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOOTHACHE	2	1.1	2	1.1	0	0	4	2.2	2	1.1	1	0.6	1	0.6	4	2.2	3	1.7	1	0.6	0	0	4	2.2
VOMITING NOS	3	1.7	8	4.5	0	0	11	6.1	0	0	3	1.7	1	0.6	4	2.2	0	0	2	1.1	0	0	2	1.1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS																								
TOTAL	15	8.4	26	14.5	4	2.2	41	22.9	29	16.1	27	15.0	11	6.1	59	32.8	19	10.6	13	7.2	3	1.7	31	17.2

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS																								
ASTHENIA	0	0	0	0	0	0	0	0	2	1.1	1	0.6	0	0	3	1.7	0	0	0	0	0	0	0	0
CHEST DISCOMFORT	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CHEST PAIN	1	0.6	0	0	1	0.6	2	1.1	2	1.1	2	1.1	0	0	4	2.2	2	1.1	0	0	0	0	2	1.1
CHEST TIGHTNESS	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	1	0.6	2	1.1	1	0.6	0	0	0	0	1	0.6
DRUG WITHDRAWAL SYNDROME	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
FATIGUE	5	2.8	10	5.6	1	0.6	16	8.9	9	5.0	7	3.9	5	2.8	21	11.7	5	2.8	5	2.8	3	1.7	13	7.2
FEELING ABNORMAL	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FEELING COLD	1	0.6	0	0	0	0	1	0.6	3	1.7	1	0.6	0	0	4	2.2	2	1.1	0	0	0	0	2	1.1
FEELING HOT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
FEELING JITTERY	0	0	0	0	0	0	0	0	2	1.1	0	0	1	0.6	3	1.7	0	0	0	0	0	0	0	0
GAIT ABNORMAL	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS																								
HERNIA NOS	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
INFLUENZA LIKE ILLNESS	1	0.6	2	1.1	1	0.6	4	2.2	1	0.6	1	0.6	2	1.1	4	2.2	1	0.6	3	1.7	0	0	4	2.2
LETHARGY	0	0	10	5.6	1	0.6	11	6.1	5	2.8	10	5.6	1	0.6	16	8.9	1	0.6	2	1.1	0	0	3	1.7
MUCOUS MEMBRANE DISORDER NOS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OEDEMA PERIPHERAL	0	0	0	0	0	0	0	0	1	0.6	2	1.1	0	0	3	1.7	2	1.1	0	0	0	0	2	1.1
PAIN NOS	0	0	0	0	0	0	0	0	2	1.1	3	1.7	0	0	5	2.8	1	0.6	1	0.6	0	0	2	1.1
PYREXIA	2	1.1	1	0.6	0	0	3	1.7	1	0.6	0	0	0	0	1	0.6	2	1.1	1	0.6	0	0	3	1.7
RIGORS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
SENSATION OF BLOOD FLOW	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	0	0	1	0.6
SLUGGISHNESS	0	0	2	1.1	0	0	2	1.1	1	0.6	1	0.6	0	0	2	1.1	1	0.6	0	0	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS																								
THIRST	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1
HEPATOBILIARY DISORDERS																								
TOTAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
CHOLECYSTITIS NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
IMMUNE SYSTEM DISORDERS																								
TOTAL	0	0	2	1.1	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
DRUG HYPERSENSITIVITY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
HYPERSENSITIVITY NOS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SEASONAL ALLERGY	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS																								
TOTAL	16	8.9	11	6.1	0	0	27	15.1	10	5.6	12	6.7	1	0.6	23	12.8	16	8.9	19	10.6	2	1.1	37	20.6
EAR INFECTION NOS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
EAR INFECTION VIRAL NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
FUNGAL INFECTION NOS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GASTROENTERITIS VIRAL NOS	1	0.6	1	0.6	0	0	2	1.1	1	0.6	1	0.6	0	0	2	1.1	1	0.6	2	1.1	0	0	3	1.7
GINGIVAL INFECTION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HERPES SIMPLEX	2	1.1	0	0	0	0	2	1.1	0	0	0	0	0	0	0	0	2	1.1	0	0	0	0	2	1.1
INFLUENZA	2	1.1	1	0.6	0	0	3	1.7	0	0	1	0.6	0	0	1	0.6	0	0	5	2.8	0	0	5	2.8
KIDNEY INFECTION NOS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
NASOPHARYNGITIS	1	0.6	1	0.6	0	0	2	1.1	2	1.1	0	0	0	0	2	1.1	0	0	3	1.7	1	0.6	4	2.2

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS																								
OTITIS MEDIA NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
PHARYNGITIS STREPTOCOCCAL	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
PROSTATE INFECTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
SCABIES INFESTATION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SIALOADENITIS NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
SINUSITIS NOS	1	0.6	1	0.6	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6	1	0.6	2	1.1	0	0	3	1.7
STAPHYLOCOCCAL INFECTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
TINEA VERSICOLOUR	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOOTH INFECTION	2	1.1	0	0	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UPPER RESPIRATORY TRACT INFECTION NOS	3	1.7	6	3.4	0	0	9	5.0	5	2.8	8	4.4	0	0	13	7.2	11	6.1	6	3.3	1	0.6	18	10.0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS																								
URINARY TRACT INFECTION NOS	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
VAGINOSIS FUNGAL NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
VIRAL INFECTION NOS	2	1.1	0	0	0	0	2	1.1	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS																								
TOTAL	4	2.2	6	3.4	2	1.1	12	6.7	7	3.9	6	3.3	0	0	13	7.2	14	7.8	7	3.9	2	1.1	22	12.2
ACCIDENTAL OVERDOSE	2	1.1	1	0.6	0	0	3	1.7	3	1.7	1	0.6	0	0	4	2.2	6	3.3	1	0.6	0	0	7	3.9
ARTHROPOD BITE	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
BACK INJURY NOS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6
EXCORIATION	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
HIP FRACTURE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS																								
INJURY	1	0.6	2	1.1	1	0.6	4	2.2	2	1.1	1	0.6	0	0	3	1.7	0	0	1	0.6	0	0	1	0.6
JOINT SPRAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	1.7	1	0.6	0	0	4	2.2
LIMB INJURY NOS	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MUSCLE STRAIN	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
NON-ACCIDENTAL OVERDOSE	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1	0	0	1	0.6	1	0.6	2	1.1
PERIORBITAL HAEMATOMA	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
POST PROCEDURAL COMPLICATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
POST PROCEDURAL PAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.1	0	0	2	1.1
SCRATCH	2	1.1	0	0	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS																								
SKIN LACERATION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1
SPINAL FRACTURE NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
SUNBURN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
THERMAL BURN	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
INVESTIGATIONS																								
TOTAL	2	1.1	1	0.6	0	0	3	1.7	7	3.9	6	3.3	0	0	13	7.2	1	0.6	1	0.6	0	0	2	1.1
BLOOD IN STOOL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
BLOOD URINE	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
WEIGHT DECREASED	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
WEIGHT INCREASED	2	1.1	1	0.6	0	0	3	1.7	6	3.3	5	2.8	0	0	11	6.1	0	0	1	0.6	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
METABOLISM AND NUTRITION DISORDERS																								
TOTAL	4	2.2	4	2.2	1	0.6	9	5.0	6	3.3	7	3.9	1	0.6	13	7.2	2	1.1	4	2.2	0	0	6	3.3
ALCOHOL INTOLERANCE	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
APPETITE DECREASED NOS	0	0	1	0.6	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.1	1	0.6	2	1.1	0	0	3	1.7
APPETITE INCREASED NOS	3	1.7	3	1.7	1	0.6	7	3.9	4	2.2	5	2.8	1	0.6	10	5.6	1	0.6	2	1.1	0	0	3	1.7
FLUID RETENTION	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
FOOD CRAVING	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS																								
TOTAL	13	7.3	13	7.3	5	2.8	30	16.8	13	7.2	23	12.8	3	1.7	33	18.3	10	5.6	13	7.2	1	0.6	23	12.8
ARTHRALGIA	0	0	4	2.2	1	0.6	5	2.8	5	2.8	3	1.7	0	0	8	4.4	1	0.6	5	2.8	0	0	6	3.3
ARTHRITIS NOS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS																								
BACK PAIN	3	1.7	2	1.1	2	1.1	7	3.9	3	1.7	2	1.1	0	0	5	2.8	1	0.6	3	1.7	1	0.6	5	2.8
BUTTOCK PAIN	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
CHEST WALL PAIN	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DUPUYTREN'S CONTRACTURE	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
FACIAL PAIN	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6
FLANK PAIN	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
GROIN PAIN	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
INTERVERTEBRAL DISC HERNIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
JOINT STIFFNESS	0	0	0	0	1	0.6	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
JOINT SWELLING	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS																								
LIMB DISCOMFORT NOS	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
MUSCLE CRAMP	4	2.2	1	0.6	0	0	5	2.8	0	0	1	0.6	1	0.6	2	1.1	1	0.6	0	0	0	0	1	0.6
MUSCLE RIGIDITY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
MUSCLE SPASMS	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	2	1.1	0	0	2	1.1
MUSCLE STIFFNESS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
MUSCLE TIGHTNESS	0	0	2	1.1	0	0	2	1.1	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
MUSCLE TWITCHING	1	0.6	1	0.6	0	0	2	1.1	1	0.6	1	0.6	2	1.1	4	2.2	2	1.1	1	0.6	0	0	3	1.7
MUSCLE WEAKNESS NOS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
MUSCULOSKELETAL PAIN	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
MUSCULOSKELETAL STIFFNESS	0	0	0	0	0	0	0	0	0	0	2	1.1	0	0	2	1.1	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS																								
MYALGIA	1	0.6	0	0	0	0	1	0.6	1	0.6	3	1.7	0	0	4	2.2	2	1.1	0	0	0	0	2	1.1
NECK PAIN	2	1.1	2	1.1	0	0	4	2.2	1	0.6	0	0	0	0	1	0.6	0	0	2	1.1	0	0	2	1.1
PAIN IN EXTREMITY	1	0.6	1	0.6	0	0	2	1.1	3	1.7	6	3.3	0	0	9	5.0	1	0.6	3	1.7	0	0	4	2.2
PERIARTHRITIS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
SENSATION OF HEAVINESS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)																								
TOTAL	0	0	2	1.1	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CHRONIC LYMPHOCYTIC LEUKAEMIA NOS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UTERINE FIBROIDS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS																								
TOTAL	67	37.4	82	45.8	22	12.3	134	74.9	63	35.0	83	46.1	23	12.8	132	73.3	39	21.7	42	23.3	7	3.9	74	41.1
AKATHISIA	4	2.2	5	2.8	0	0	9	5.0	4	2.2	5	2.8	0	0	9	5.0	2	1.1	0	0	0	0	2	1.1
AMNESIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
ATAXIA	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0
BALANCE IMPAIRED NOS	2	1.1	4	2.2	1	0.6	7	3.9	2	1.1	0	0	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6
CARPAL TUNNEL SYNDROME	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
COGNITIVE DISORDER	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
CONVULSIONS NOS	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	1	0.6
COORDINATION ABNORMAL NOS	1	0.6	0	0	1	0.6	2	1.1	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
DISTURBANCE IN ATTENTION	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS																								
DIZZINESS	19	10.6	9	5.0	2	1.1	30	16.8	20	11.1	12	6.7	9	5.0	41	22.8	9	5.0	4	2.2	2	1.1	15	8.3
DIZZINESS POSTURAL	0	0	1	0.6	0	0	1	0.6	1	0.6	2	1.1	0	0	3	1.7	1	0.6	0	0	0	0	1	0.6
DYSARTHRIA	1	0.6	3	1.7	1	0.6	5	2.8	0	0	1	0.6	1	0.6	2	1.1	0	0	0	0	0	0	0	0
DYSGEUSIA	1	0.6	1	0.6	0	0	2	1.1	2	1.1	0	0	0	0	2	1.1	0	0	0	0	0	0	0	0
DYSKINESIA	2	1.1	2	1.1	0	0	4	2.2	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0
DYSTONIA	1	0.6	1	0.6	0	0	2	1.1	2	1.1	3	1.7	0	0	5	2.8	0	0	1	0.6	0	0	1	0.6
EXTRAPYRAMIDAL DISORDER	0	0	0	0	0	0	0	0	2	1.1	0	0	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6
HEADACHE	8	4.5	12	6.7	2	1.1	22	12.3	2	1.1	13	7.2	3	1.7	18	10.0	13	7.2	22	12.2	1	0.6	36	20.0
HEMIPARESIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
HYPERREFLEXIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
HYPERSOMNIA	0	0	5	2.8	0	0	5	2.8	1	0.6	4	2.2	1	0.6	6	3.3	0	0	1	0.6	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS																								
HYPOAESTHESIA	1	0.6	1	0.6	0	0	2	1.1	1	0.6	2	1.1	0	0	3	1.7	1	0.6	0	0	0	0	1	0.6
HYPOREFLEXIA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
MEMORY IMPAIRMENT	2	1.1	2	1.1	0	0	4	2.2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MENTAL IMPAIRMENT NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
MIGRAINE NOS	0	0	0	0	1	0.6	1	0.6	0	0	0	0	2	1.1	2	1.1	0	0	0	0	0	0	0	0
MUSCLE CONTRACTIONS INVOLUNTARY	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
MYOCLONUS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARAESTHESIA	2	1.1	2	1.1	0	0	4	2.2	5	2.8	2	1.1	0	0	7	3.9	2	1.1	1	0.6	0	0	3	1.7
PSYCHOMOTOR HYPERACTIVITY	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
RESTLESS LEGS SYNDROME	1	0.6	1	0.6	2	1.1	4	2.2	1	0.6	2	1.1	0	0	3	1.7	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS																								
SCIATICA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
SEDATION	13	7.3	35	19.6	5	2.8	53	29.6	12	6.7	37	20.6	9	5.0	58	32.2	4	2.2	5	2.8	2	1.1	11	6.1
SENSORY DISTURBANCE NOS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SINUS HEADACHE	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOMNOLENCE	19	10.6	20	11.2	10	5.6	49	27.4	18	10.0	19	10.6	7	3.9	44	24.4	9	5.0	6	3.3	0	0	15	8.3
SPEECH DISORDER	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
SYNCOPE	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
TENSION HEADACHE	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6
TREMOR	4	2.2	1	0.6	0	0	5	2.8	3	1.7	2	1.1	0	0	5	2.8	0	0	1	0.6	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS																								
TOTAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
ECTOPIC PREGNANCY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
PSYCHIATRIC DISORDERS																								
TOTAL	16	8.9	21	11.7	7	3.9	37	20.7	10	5.6	18	10.0	16	8.9	38	21.1	6	3.3	22	12.2	8	4.4	34	18.9
ABNORMAL DREAMS	2	1.1	4	2.2	0	0	6	3.4	2	1.1	1	0.6	1	0.6	4	2.2	0	0	3	1.7	0	0	3	1.7
ACUTE PSYCHOSIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
AGITATION	1	0.6	0	0	0	0	1	0.6	2	1.1	0	0	0	0	2	1.1	1	0.6	2	1.1	1	0.6	4	2.2
ANGER	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
ANXIETY	1	0.6	2	1.1	1	0.6	4	2.2	0	0	3	1.7	1	0.6	4	2.2	1	0.6	4	2.2	0	0	5	2.8
BIPOLAR I DISORDER	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
BLUNTED AFFECT	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
BRADYPHRENIA	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
BRUXISM	0	0	0	0	0	0	0	0	0	0	2	1.1	0	0	2	1.1	1	0.6	0	0	0	0	1	0.6
CONFUSIONAL STATE	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
CONVERSION DISORDER	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DELUSION NOS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
DEPRESSION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
DEREALISATION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DISORIENTATION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DISSOCIATIVE DISORDER NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
FLAT AFFECT	0	0	1	0.6	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
HALLUCINATION, AUDITORY	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	1	0.6	2	1.1	1	0.6	0	0	1	0.6	2	1.1

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
HALLUCINATION, VISUAL	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0
HYPNAGOGIC HALLUCINATION	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
HYPOMANIA	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
ILLUSION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
INSOMNIA	1	0.6	6	3.4	1	0.6	8	4.5	1	0.6	3	1.7	3	1.7	7	3.9	0	0	8	4.4	1	0.6	9	5.0
IRRITABILITY	0	0	0	0	2	1.1	2	1.1	1	0.6	3	1.7	1	0.6	5	2.8	0	0	1	0.6	0	0	1	0.6
LIBIDO DECREASED	1	0.6	1	0.6	0	0	2	1.1	0	0	1	0.6	1	0.6	2	1.1	0	0	0	0	2	1.1	2	1.1
LIBIDO INCREASED	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6
LOGORRHOEA	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
LOSS OF LIBIDO	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
MANIA	0	0	0	0	2	1.1	2	1.1	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	1	0.6	2	1.1
MENTAL STATUS CHANGES	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
MIDDLE INSOMNIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
MOOD SWINGS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NERVOUSNESS	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0
NIGHTMARE	2	1.1	1	0.6	1	0.6	4	2.2	0	0	1	0.6	1	0.6	2	1.1	0	0	0	0	0	0	0	0
OBSESSIVE-COMPULSIVE DISORDER	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
ONYCHOPHAGIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PANIC ATTACK	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	1	0.6	0	0	1	0.6
PANIC DISORDER NOS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARANOIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
RESTLESSNESS	1	0.6	1	0.6	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6	0	0	2	1.1	0	0	2	1.1
SLEEP WALKING	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUICIDAL IDEATION	1	0.6	1	0.6	1	0.6	3	1.7	0	0	0	0	3	1.7	3	1.7	0	0	2	1.1	1	0.6	3	1.7
SUICIDE ATTEMPT	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
SUSPICIOUSNESS	2	1.1	0	0	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TENSION	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
THOUGHT BLOCKING	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
RENAL AND URINARY DISORDERS																								
TOTAL	4	2.2	4	2.2	0	0	8	4.5	5	2.8	3	1.7	0	0	8	4.4	2	1.1	3	1.7	0	0	5	2.8
BLADDER DISORDER NOS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
DYSURIA	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RENAL AND URINARY DISORDERS																								
ENURESIS	0	0	2	1.1	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MICTURITION URGENCY	1	0.6	2	1.1	0	0	3	1.7	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
NEPHROLITHIASIS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
POLLAKIURIA	1	0.6	0	0	0	0	1	0.6	3	1.7	1	0.6	0	0	4	2.2	2	1.1	1	0.6	0	0	3	1.7
URINARY HESITATION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
URINARY INCONTINENCE	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS																								
TOTAL	3	1.7	4	2.2	1	0.6	7	3.9	3	1.7	2	1.1	1	0.6	6	3.3	2	1.1	6	3.3	0	0	8	4.4
ADNEXA UTERI PAIN	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BREAST CYST	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DYSMENORRHOEA	0	0	2	1.1	0	0	2	1.1	2	1.1	1	0.6	0	0	3	1.7	0	0	2	1.1	0	0	2	1.1

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
REPRODUCTIVE SYSTEM AND BREAST DISORDERS																								
ERECTILE DYSFUNCTION NOS	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.1	2	1.1	2	1.1	0	0	4	2.2
MENSES DELAYED	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MENSTRUATION IRREGULAR	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NIPPLE EXUDATE BLOODY	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
POLYMENORRHOEA	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROSTATITIS	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
SEXUAL DYSFUNCTION NOS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	2	1.1	0	0	2	1.1
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS																								
TOTAL	22	12.3	14	7.8	1	0.6	34	19.0	14	7.8	17	9.4	2	1.1	31	17.2	10	5.6	14	7.8	1	0.6	24	13.3

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS																								
ASTHMA NOS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	1	0.6	2	1.1
BRONCHITIS NOS	1	0.6	1	0.6	0	0	2	1.1	0	0	1	0.6	0	0	1	0.6	0	0	3	1.7	0	0	3	1.7
BRONCHOSPASM NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
CHOKING SENSATION	2	1.1	0	0	0	0	2	1.1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COUGH	5	2.8	2	1.1	0	0	7	3.9	1	0.6	4	2.2	1	0.6	6	3.3	1	0.6	0	0	0	0	1	0.6
DYSPNOEA	4	2.2	1	0.6	0	0	5	2.8	2	1.1	4	2.2	1	0.6	7	3.9	2	1.1	2	1.1	0	0	4	2.2
EPISTAXIS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HICCUPS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
HOARSENESS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
LARYNGITIS NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
NASAL CONGESTION	7	3.9	3	1.7	0	0	10	5.6	4	2.2	8	4.4	0	0	12	6.7	2	1.1	1	0.6	0	0	3	1.7

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS																								
NASAL DRYNESS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NASAL OEDEMA	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NASOPHARYNGITIS	1	0.6	2	1.1	1	0.6	4	2.2	2	1.1	0	0	0	0	2	1.1	1	0.6	1	0.6	0	0	2	1.1
PHARYNGEAL ERYTHEMA	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PHARYNGOLARYNGEAL PAIN	2	1.1	1	0.6	0	0	3	1.7	3	1.7	0	0	0	0	3	1.7	2	1.1	3	1.7	0	0	5	2.8
PRODUCTIVE COUGH	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	2	1.1	0	0	2	1.1
PULMONARY CONGESTION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
RHINORRHOEA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
SINUS CONGESTION	1	0.6	4	2.2	0	0	5	2.8	2	1.1	2	1.1	0	0	4	2.2	0	0	2	1.1	0	0	2	1.1
SINUS PAIN	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS																								
THROAT TIGHTNESS	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	2	1.1	0	0	0	0	0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS																								
TOTAL	5	2.8	3	1.7	0	0	8	4.5	7	3.9	9	5.0	1	0.6	17	9.4	13	7.2	3	1.7	1	0.6	16	8.9
ACNE NOS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
ALOPECIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
CONTUSION	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6
DERMATITIS ALLERGIC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
DERMATITIS CONTACT	0	0	1	0.6	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0
DERMATITIS EXFOLIATIVE NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
ECCHYMOSIS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS																								
ERYTHEMA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
INCREASED TENDENCY TO BRUISE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
NIGHT SWEATS	1	0.6	1	0.6	0	0	2	1.1	2	1.1	2	1.1	0	0	4	2.2	1	0.6	0	0	0	0	1	0.6
PRURITUS	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.1
PRURITUS GENERALISED	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
RASH NOS	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	3	1.7	0	0	0	0	3	1.7
SKIN IRRITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
SKIN LESION NOS	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.1	0	0	0	0	0	0	0	0
SKIN ULCER	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
SUBCUTANEOUS NODULE	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
SWEATING INCREASED	1	0.6	0	0	0	0	1	0.6	0	0	2	1.1	1	0.6	3	1.7	1	0.6	0	0	1	0.6	2	1.1

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
SOCIAL CIRCUMSTANCES																								
TOTAL	1	0.6	1	0.6	0	0	2	1.1	1	0.6	1	0.6	2	1.1	4	2.2	0	0	0	0	0	0	0	0
DRUG ABUSER NOS	1	0.6	1	0.6	0	0	2	1.1	1	0.6	1	0.6	2	1.1	4	2.2	0	0	0	0	0	0	0	0
SURGICAL AND MEDICAL PROCEDURES																								
TOTAL	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOOTH EXTRACTION NOS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VASCULAR DISORDERS																								
TOTAL	6	3.4	8	4.5	0	0	14	7.8	5	2.8	9	5.0	2	1.1	15	8.3	5	2.8	3	1.7	1	0.6	9	5.0
DEEP VEIN THROMBOSIS	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	0	0	1	0.6
FLUSHING	2	1.1	3	1.7	0	0	5	2.8	2	1.1	3	1.7	0	0	5	2.8	1	0.6	1	0.6	0	0	2	1.1
HAEMATOMA NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
HYPERTENSION NOS	1	0.6	2	1.1	0	0	3	1.7	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=179								N=180								N=180							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
VASCULAR DISORDERS																								
HYPOTENSION NOS	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	2	1.1	0	0	0	0	0	0	0	0
ORTHOSTATIC HYPOTENSION	3	1.7	3	1.7	0	0	6	3.4	2	1.1	5	2.8	0	0	7	3.9	3	1.7	2	1.1	1	0.6	6	3.3

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG205.SAS
GENERATED: 12JUL2005 17:39:14 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

SYSTEM ORGAN CLASS	PREFERRED TERM	TREATMENT: QUETIAPINE 300 MG N=179 NO.OF PTS	%	QUETIAPINE 600 MG N=180 NO.OF PTS	%	PLACEBO N=180 NO.OF PTS	%
ANY ADVERSE EVENT		146	81.6	155	86.1	96	53.3
CARDIAC DISORDERS	TOTAL	7	3.9	4	2.2	4	2.2
	PALPITATIONS	6	3.4	3	1.7	3	1.7
	TACHYCARDIA NOS	1	0.6	1	0.6	0	0
	VENTRICULAR EXTRASYSTOLES	0	0	0	0	1	0.6
EAR AND LABYRINTH DISORDERS	TOTAL	0	0	2	1.1	1	0.6
	TINNITUS	0	0	1	0.6	1	0.6
	VERTIGO	0	0	1	0.6	0	0
EYE DISORDERS	TOTAL	5	2.8	9	5.0	2	1.1
	ALTERED VISUAL DEPTH PERCEPTION	0	0	1	0.6	0	0
	ASTIGMATISM	0	0	1	0.6	0	0
	BLEPHARITIS	1	0.6	0	0	0	0
	DRY EYE NOS	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	PHOTOPHOBIA	0	0	0	0	1	0.6
	PHOTOPSIA	1	0.6	0	0	0	0
	VISION BLURRED	2	1.1	7	3.9	1	0.6
GASTROINTESTINAL DISORDERS	TOTAL	83	46.4	87	48.3	28	15.6
	ABDOMINAL DISTENSION	0	0	2	1.1	1	0.6
	ABDOMINAL PAIN NOS	0	0	0	0	3	1.7
	ABDOMINAL PAIN UPPER	0	0	0	0	2	1.1
	APTYALISM	0	0	1	0.6	0	0
	CONSTIPATION	9	5.0	10	5.6	4	2.2
	DIARRHOEA NOS	4	2.2	4	2.2	5	2.8
	DRY MOUTH	70	39.1	66	36.7	7	3.9
	DYSPEPSIA	5	2.8	11	6.1	4	2.2
	DYSPHAGIA	0	0	4	2.2	0	0
	FLATULENCE	1	0.6	3	1.7	2	1.1

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL PAIN NOS	0	0	0	0	1	0.6
	GASTROOESOPHAGEAL REFLUX DISEASE	0	0	2	1.1	2	1.1
	NAUSEA	8	4.5	9	5.0	8	4.4
	TONGUE DISORDER NOS	3	1.7	0	0	0	0
	TOOTH DISORDER NOS	0	0	1	0.6	0	0
	TOOTHACHE	1	0.6	1	0.6	2	1.1
	VOMITING NOS	1	0.6	2	1.1	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	28	15.6	41	22.8	12	6.7
	ASTHENIA	0	0	1	0.6	0	0
	CHEST PAIN	1	0.6	3	1.7	1	0.6
	CHEST TIGHTNESS	1	0.6	2	1.1	0	0
	DRUG WITHDRAWAL SYNDROME	0	0	1	0.6	0	0
	FATIGUE	11	6.1	19	10.6	7	3.9

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING ABNORMAL	1	0.6	0	0	0	0
	FEELING COLD	1	0.6	1	0.6	0	0
	FEELING JITTERY	0	0	1	0.6	0	0
	INFLUENZA LIKE ILLNESS	0	0	0	0	1	0.6
	LETHARGY	9	5.0	13	7.2	2	1.1
	MUCOUS MEMBRANE DISORDER NOS	1	0.6	0	0	0	0
	PYREXIA	1	0.6	0	0	0	0
	SENSATION OF BLOOD FLOW	0	0	1	0.6	1	0.6
	SLUGGISHNESS	2	1.1	2	1.1	0	0
	THIRST	1	0.6	0	0	0	0
HEPATOBILIARY DISORDERS	TOTAL	0	0	0	0	1	0.6
	CHOLECYSTITIS NOS	0	0	0	0	1	0.6
INFECTIONS AND INFESTATIONS	TOTAL	6	3.4	2	1.1	9	5.0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INFECTIONS AND INFESTATIONS	GASTROENTERITIS VIRAL NOS	1	0.6	0	0	0	0
	HERPES SIMPLEX	1	0.6	0	0	1	0.6
	INFLUENZA	0	0	0	0	1	0.6
	NASOPHARYNGITIS	1	0.6	1	0.6	1	0.6
	SINUSITIS NOS	1	0.6	1	0.6	0	0
	UPPER RESPIRATORY TRACT INFECTION NOS	2	1.1	0	0	5	2.8
	VIRAL INFECTION NOS	0	0	0	0	1	0.6
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	3	1.7	6	3.3	5	2.8
	ACCIDENTAL OVERDOSE	1	0.6	3	1.7	0	0
	ARTHROPOD BITE	1	0.6	0	0	0	0
	HIP FRACTURE	0	0	0	0	1	0.6
	INJURY	0	0	2	1.1	1	0.6
	JOINT SPRAIN	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	NON-ACCIDENTAL OVERDOSE	0	0	1	0.6	2	1.1
	SKIN LACERATION	1	0.6	0	0	2	1.1
	SPINAL FRACTURE NOS	0	0	0	0	1	0.6
INVESTIGATIONS	TOTAL	1	0.6	2	1.1	1	0.6
	WEIGHT INCREASED	1	0.6	2	1.1	1	0.6
METABOLISM AND NUTRITION DISORDERS	TOTAL	3	1.7	7	3.9	1	0.6
	ALCOHOL INTOLERANCE	0	0	1	0.6	0	0
	APPETITE DECREASED NOS	0	0	0	0	1	0.6
	APPETITE INCREASED NOS	3	1.7	6	3.3	0	0
	FOOD CRAVING	0	0	1	0.6	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	10	5.6	18	10.0	7	3.9
	ARTHRALGIA	1	0.6	4	2.2	2	1.1
	BACK PAIN	2	1.1	1	0.6	4	2.2
	DUPUYTREN'S CONTRACTURE	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	JOINT STIFFNESS	1	0.6	1	0.6	0	0
	LIMB DISCOMFORT NOS	0	0	1	0.6	0	0
	MUSCLE CRAMP	2	1.1	2	1.1	0	0
	MUSCLE RIGIDITY	0	0	0	0	1	0.6
	MUSCLE SPASMS	1	0.6	0	0	0	0
	MUSCLE TIGHTNESS	1	0.6	0	0	0	0
	MUSCLE TWITCHING	0	0	4	2.2	0	0
	MUSCLE WEAKNESS NOS	0	0	1	0.6	0	0
	MYALGIA	0	0	3	1.7	0	0
	NECK PAIN	1	0.6	1	0.6	1	0.6
	PAIN IN EXTREMITY	1	0.6	4	2.2	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	116	64.8	115	63.9	46	25.6
	AKATHISIA	7	3.9	7	3.9	0	0
	BALANCE IMPAIRED NOS	7	3.9	2	1.1	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	CARPAL TUNNEL SYNDROME	0	0	0	0	1	0.6
	COGNITIVE DISORDER	0	0	0	0	1	0.6
	CONVULSIONS NOS	0	0	0	0	1	0.6
	COORDINATION ABNORMAL NOS	2	1.1	1	0.6	0	0
	DISTURBANCE IN ATTENTION	1	0.6	1	0.6	0	0
	DIZZINESS	20	11.2	36	20.0	9	5.0
	DIZZINESS POSTURAL	1	0.6	1	0.6	0	0
	DYSARTHRIA	4	2.2	2	1.1	0	0
	DYSGEUSIA	2	1.1	1	0.6	0	0
	DYSKINESIA	2	1.1	2	1.1	0	0
	DYSTONIA	1	0.6	4	2.2	1	0.6
	EXTRAPYRAMIDAL DISORDER	0	0	0	0	1	0.6
	HEADACHE	11	6.1	11	6.1	21	11.7
	HYPERSOMNIA	3	1.7	6	3.3	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	0	0	2	1.1	0	0
	MEMORY IMPAIRMENT	1	0.6	0	0	0	0
	MIGRAINE NOS	0	0	1	0.6	0	0
	MYOCLONUS	1	0.6	0	0	0	0
	PARAESTHESIA	3	1.7	5	2.8	2	1.1
	RESTLESS LEGS SYNDROME	3	1.7	2	1.1	0	0
	SEDATION	48	26.8	53	29.4	7	3.9
	SENSORY DISTURBANCE NOS	1	0.6	0	0	0	0
	SOMNOLENCE	45	25.1	37	20.6	8	4.4
	SPEECH DISORDER	1	0.6	0	0	0	0
	SYNCOPE	0	0	1	0.6	0	0
	TENSION HEADACHE	0	0	1	0.6	0	0
	TREMOR	4	2.2	2	1.1	1	0.6
PSYCHIATRIC DISORDERS	TOTAL	19	10.6	15	8.3	14	7.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	ABNORMAL DREAMS	5	2.8	4	2.2	2	1.1
	AGITATION	0	0	0	0	1	0.6
	ANGER	0	0	1	0.6	0	0
	ANXIETY	3	1.7	2	1.1	3	1.7
	BRUXISM	0	0	1	0.6	0	0
	CONFUSIONAL STATE	1	0.6	1	0.6	0	0
	DEREALISATION	1	0.6	0	0	0	0
	DISORIENTATION	1	0.6	0	0	0	0
	FLAT AFFECT	1	0.6	1	0.6	0	0
	HALLUCINATION, AUDITORY	1	0.6	1	0.6	0	0
	HALLUCINATION, VISUAL	0	0	1	0.6	0	0
	HYPNAGOGIC HALLUCINATION	0	0	1	0.6	0	0
	INSOMNIA	3	1.7	1	0.6	4	2.2
	IRRITABILITY	1	0.6	3	1.7	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	LIBIDO DECREASED	0	0	1	0.6	1	0.6
	LIBIDO INCREASED	0	0	1	0.6	1	0.6
	LOSS OF LIBIDO	1	0.6	0	0	0	0
	MIDDLE INSOMNIA	0	0	1	0.6	0	0
	NERVOUSNESS	0	0	1	0.6	0	0
	NIGHTMARE	4	2.2	2	1.1	0	0
	PANIC DISORDER NOS	1	0.6	0	0	0	0
	PARANOIA	1	0.6	1	0.6	0	0
	RESTLESSNESS	2	1.1	0	0	0	0
	SUICIDAL IDEATION	0	0	0	0	1	0.6
	SUSPICIOUSNESS	1	0.6	0	0	0	0
RENAL AND URINARY DISORDERS	TOTAL	3	1.7	5	2.8	2	1.1
	DYSURIA	0	0	1	0.6	0	0
	ENURESIS	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
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Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	2	1.1	0	0	0	0
	POLLAKIURIA	0	0	4	2.2	1	0.6
	URINARY HESITATION	0	0	0	0	1	0.6
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	3	1.7	2	1.1	1	0.6
	BREAST CYST	1	0.6	0	0	0	0
	DYSMENORRHOEA	1	0.6	1	0.6	0	0
	ERECTILE DYSFUNCTION NOS	0	0	1	0.6	1	0.6
	NIPPLE EXUDATE BLOODY	1	0.6	0	0	0	0
	POLYMENORRHOEA	1	0.6	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	11	6.1	13	7.2	6	3.3
	COUGH	0	0	3	1.7	0	0
	DYSPNOEA	3	1.7	3	1.7	1	0.6
	HICCUPS	0	0	0	0	1	0.6
	NASAL CONGESTION	4	2.2	4	2.2	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
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Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	NASAL DRYNESS	1	0.6	0	0	0	0
	NASAL OEDEMA	1	0.6	0	0	0	0
	NASOPHARYNGITIS	0	0	1	0.6	1	0.6
	PHARYNGOLARYNGEAL PAIN	0	0	1	0.6	2	1.1
	RHINORRHOEA	0	0	0	0	1	0.6
	SINUS CONGESTION	2	1.1	3	1.7	0	0
	THROAT TIGHTNESS	0	0	1	0.6	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	4	2.2	8	4.4	3	1.7
	ACNE NOS	0	0	0	0	1	0.6
	CONTUSION	0	0	0	0	1	0.6
	DERMATITIS CONTACT	0	0	1	0.6	0	0
	NIGHT SWEATS	1	0.6	1	0.6	0	0
	PRURITUS	1	0.6	1	0.6	0	0
	RASH NOS	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
GENERATED: 12JUL2005 17:39:35 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SKIN LESION NOS	0	0	1	0.6	0	0
	SUBCUTANEOUS NODULE	0	0	1	0.6	0	0
	SWEATING INCREASED	1	0.6	3	1.7	1	0.6
VASCULAR DISORDERS	TOTAL	7	3.9	9	5.0	4	2.2
	DEEP VEIN THROMBOSIS	0	0	1	0.6	1	0.6
	FLUSHING	2	1.1	1	0.6	1	0.6
	HAEMATOMA NOS	0	0	0	0	1	0.6
	HYPERTENSION NOS	1	0.6	0	0	0	0
	HYPOTENSION NOS	0	0	1	0.6	0	0
	ORTHOSTATIC HYPOTENSION	4	2.2	6	3.3	1	0.6

Note: This table includes adverse events which occurred from start of study treatment to last dose.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG214.SAS
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Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY DRUG RELATED		152	84.9	156	86.7	85	47.2
CARDIAC DISORDERS	TOTAL	10	5.6	4	2.2	3	1.7
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	1	0.6	0	0	0	0
	PALPITATIONS	7	3.9	2	1.1	3	1.7
	TACHYCARDIA NOS	2	1.1	2	1.1	0	0
EAR AND LABYRINTH DISORDERS	TOTAL	3	1.7	2	1.1	1	0.6
	TINNITUS	2	1.1	2	1.1	1	0.6
	VERTIGO	1	0.6	0	0	0	0
EYE DISORDERS	TOTAL	5	2.8	10	5.6	4	2.2
	ALTERED VISUAL DEPTH PERCEPTION	0	0	1	0.6	0	0
	BLEPHAROSPASM	0	0	0	0	1	0.6
	EYE PAIN	0	0	0	0	1	0.6
	EYELIDS PRURITUS	0	0	1	0.6	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	VISION BLURRED	4	2.2	9	5.0	2	1.1
	VISUAL ACUITY REDUCED	1	0.6	0	0	0	0
GASTROINTESTINAL DISORDERS	TOTAL	96	53.6	96	53.3	33	18.3
	ABDOMINAL DISTENSION	0	0	2	1.1	1	0.6
	ABDOMINAL PAIN NOS	0	0	0	0	2	1.1
	ABDOMINAL PAIN UPPER	0	0	1	0.6	2	1.1
	APTYALISM	0	0	1	0.6	0	0
	CHAPPED LIPS	0	0	1	0.6	0	0
	CONSTIPATION	20	11.2	16	8.9	5	2.8
	DIARRHOEA NOS	4	2.2	3	1.7	4	2.2
	DRY MOUTH	78	43.6	72	40.0	12	6.7
	DYSPEPSIA	6	3.4	9	5.0	6	3.3
	DYSPHAGIA	0	0	6	3.3	0	0
	FLATULENCE	2	1.1	1	0.6	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	FREQUENT BOWEL MOVEMENTS	0	0	0	0	1	0.6
	GASTROINTESTINAL PAIN NOS	0	0	0	0	1	0.6
	GASTROOESOPHAGEAL REFLUX DISEASE	1	0.6	2	1.1	1	0.6
	NAUSEA	9	5.0	11	6.1	13	7.2
	SWOLLEN TONGUE	0	0	1	0.6	0	0
	TONGUE DISORDER NOS	3	1.7	0	0	0	0
	TOOTH DISORDER NOS	0	0	1	0.6	0	0
	VOMITING NOS	4	2.2	2	1.1	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	30	16.8	42	23.3	15	8.3
	ASTHENIA	0	0	3	1.7	0	0
	CHEST PAIN	1	0.6	1	0.6	0	0
	CHEST TIGHTNESS	0	0	0	0	1	0.6
	FATIGUE	14	7.8	18	10.0	9	5.0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
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Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING ABNORMAL	1	0.6	0	0	0	0
	FEELING COLD	0	0	3	1.7	0	0
	FEELING JITTERY	0	0	3	1.7	0	0
	GAIT ABNORMAL	1	0.6	0	0	0	0
	LETHARGY	10	5.6	15	8.3	3	1.7
	MUCOUS MEMBRANE DISORDER NOS	1	0.6	0	0	0	0
	OEDEMA PERIPHERAL	0	0	2	1.1	2	1.1
	SENSATION OF BLOOD FLOW	0	0	1	0.6	0	0
	SLUGGISHNESS	2	1.1	2	1.1	0	0
	THIRST	1	0.6	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	3	1.7	0	0
	ACCIDENTAL OVERDOSE	0	0	1	0.6	0	0
	EXCORIATION	0	0	1	0.6	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
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Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	0	0	1	0.6	0	0
INVESTIGATIONS	TOTAL	3	1.7	8	4.4	0	0
	WEIGHT INCREASED	3	1.7	8	4.4	0	0
METABOLISM AND NUTRITION DISORDERS	TOTAL	8	4.5	11	6.1	5	2.8
	ALCOHOL INTOLERANCE	1	0.6	1	0.6	0	0
	APPETITE DECREASED NOS	0	0	1	0.6	3	1.7
	APPETITE INCREASED NOS	7	3.9	9	5.0	2	1.1
	FLUID RETENTION	0	0	1	0.6	0	0
	FOOD CRAVING	0	0	1	0.6	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	12	6.7	11	6.1	9	5.0
	ARTHRALGIA	1	0.6	4	2.2	2	1.1
	BACK PAIN	1	0.6	0	0	1	0.6
	FACIAL PAIN	0	0	0	0	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
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Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	JOINT STIFFNESS	1	0.6	1	0.6	0	0
	LIMB DISCOMFORT NOS	0	0	1	0.6	0	0
	MUSCLE CRAMP	3	1.7	2	1.1	1	0.6
	MUSCLE SPASMS	1	0.6	0	0	0	0
	MUSCLE TIGHTNESS	2	1.1	0	0	1	0.6
	MUSCLE TWITCHING	2	1.1	3	1.7	1	0.6
	MUSCLE WEAKNESS NOS	0	0	1	0.6	0	0
	MYALGIA	0	0	1	0.6	2	1.1
	PAIN IN EXTREMITY	1	0.6	0	0	0	0
	SENSATION OF HEAVINESS	0	0	0	0	1	0.6
NERVOUS SYSTEM DISORDERS	TOTAL	127	70.9	126	70.0	58	32.2
	AKATHISIA	9	5.0	9	5.0	2	1.1
	ATAXIA	0	0	1	0.6	0	0
	BALANCE IMPAIRED NOS	7	3.9	2	1.1	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	COORDINATION ABNORMAL NOS	2	1.1	1	0.6	0	0
	DISTURBANCE IN ATTENTION	1	0.6	1	0.6	0	0
	DIZZINESS	28	15.6	37	20.6	8	4.4
	DIZZINESS POSTURAL	1	0.6	3	1.7	1	0.6
	DYSARTHRIA	5	2.8	2	1.1	0	0
	DYSGEUSIA	1	0.6	2	1.1	0	0
	DYSKINESIA	3	1.7	2	1.1	0	0
	DYSTONIA	2	1.1	4	2.2	1	0.6
	EXTRAPYRAMIDAL DISORDER	0	0	2	1.1	1	0.6
	HEADACHE	9	5.0	11	6.1	28	15.6
	HYPERSOMNIA	4	2.2	6	3.3	1	0.6
	HYPOAESTHESIA	0	0	1	0.6	0	0
	HYPOREFLEXIA	0	0	0	0	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	MEMORY IMPAIRMENT	4	2.2	0	0	0	0
	MENTAL IMPAIRMENT NOS	0	0	0	0	1	0.6
	MUSCLE CONTRACTIONS INVOLUNTARY	0	0	1	0.6	0	0
	MYOCLONUS	1	0.6	0	0	0	0
	PARAESTHESIA	3	1.7	3	1.7	2	1.1
	PSYCHOMOTOR HYPERACTIVITY	0	0	1	0.6	0	0
	RESTLESS LEGS SYNDROME	4	2.2	2	1.1	0	0
	SEDATION	52	29.1	58	32.2	11	6.1
	SOMNOLENCE	49	27.4	44	24.4	12	6.7
	SPEECH DISORDER	1	0.6	1	0.6	0	0
	SYNCOPE	0	0	1	0.6	0	0
	TENSION HEADACHE	0	0	1	0.6	1	0.6
	TREMOR	4	2.2	5	2.8	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	TOTAL	22	12.3	26	14.4	18	10.0
	ABNORMAL DREAMS	6	3.4	1	0.6	2	1.1
	AGITATION	1	0.6	0	0	2	1.1
	ANGER	0	0	1	0.6	0	0
	ANXIETY	4	2.2	2	1.1	4	2.2
	BLUNTED AFFECT	1	0.6	0	0	0	0
	BRADYPHRENIA	0	0	1	0.6	0	0
	BRUXISM	0	0	2	1.1	1	0.6
	CONFUSIONAL STATE	1	0.6	1	0.6	0	0
	DEREALISATION	1	0.6	0	0	0	0
	FLAT AFFECT	1	0.6	0	0	0	0
	HALLUCINATION, AUDITORY	1	0.6	0	0	1	0.6
	HALLUCINATION, VISUAL	0	0	2	1.1	0	0
	HYPOMANIA	0	0	1	0.6	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	ILLUSION	0	0	0	0	1	0.6
	INSOMNIA	1	0.6	5	2.8	5	2.8
	IRRITABILITY	2	1.1	5	2.8	1	0.6
	LIBIDO DECREASED	2	1.1	2	1.1	1	0.6
	LOGORRHOEA	0	0	1	0.6	0	0
	LOSS OF LIBIDO	1	0.6	1	0.6	0	0
	MANIA	0	0	1	0.6	1	0.6
	MIDDLE INSOMNIA	0	0	1	0.6	0	0
	NERVOUSNESS	0	0	1	0.6	0	0
	NIGHTMARE	3	1.7	1	0.6	0	0
	OBSESSIVE-COMPULSIVE DISORDER	0	0	0	0	1	0.6
	PANIC ATTACK	0	0	0	0	1	0.6
	PANIC DISORDER NOS	1	0.6	0	0	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	PARANOIA	1	0.6	1	0.6	0	0
	RESTLESSNESS	2	1.1	1	0.6	0	0
	SLEEP WALKING	1	0.6	0	0	0	0
	SUSPICIOUSNESS	1	0.6	0	0	0	0
	TENSION	0	0	1	0.6	0	0
	THOUGHT BLOCKING	1	0.6	1	0.6	0	0
RENAL AND URINARY DISORDERS	TOTAL	7	3.9	6	3.3	3	1.7
	BLADDER DISORDER NOS	0	0	1	0.6	0	0
	DYSURIA	0	0	1	0.6	0	0
	ENURESIS	2	1.1	0	0	0	0
	MICTURITION URGENCY	2	1.1	0	0	1	0.6
	POLLAKIURIA	1	0.6	3	1.7	1	0.6
	URINARY HESITATION	1	0.6	0	0	1	0.6
	URINARY INCONTINENCE	1	0.6	1	0.6	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	4	2.2	2	1.1	4	2.2
	ERECTILE DYSFUNCTION NOS	1	0.6	2	1.1	3	1.7
	MENSES DELAYED	1	0.6	0	0	0	0
	POLYMENORRHOEA	2	1.1	0	0	0	0
	SEXUAL DYSFUNCTION NOS	1	0.6	0	0	1	0.6
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	11	6.1	13	7.2	2	1.1
	CHOKING SENSATION	1	0.6	0	0	0	0
	COUGH	0	0	1	0.6	0	0
	DYSPNOEA	4	2.2	4	2.2	1	0.6
	EPISTAXIS	1	0.6	0	0	0	0
	HICCUPS	0	0	0	0	1	0.6
	HOARSENESS	0	0	1	0.6	0	0
	NASAL CONGESTION	2	1.1	5	2.8	0	0
	NASAL DRYNESS	1	0.6	0	0	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	SINUS CONGESTION	2	1.1	1	0.6	0	0
	THROAT TIGHTNESS	0	0	2	1.1	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	5	2.8	7	3.9	5	2.8
	ERYTHEMA	0	0	0	0	1	0.6
	INCREASED TENDENCY TO BRUISE	0	0	0	0	1	0.6
	NIGHT SWEATS	2	1.1	4	2.2	1	0.6
	PRURITUS	1	0.6	1	0.6	0	0
	RASH NOS	1	0.6	0	0	2	1.1
	SWEATING INCREASED	1	0.6	2	1.1	0	0
VASCULAR DISORDERS	TOTAL	10	5.6	9	5.0	6	3.3
	FLUSHING	3	1.7	2	1.1	1	0.6
	HYPERTENSION NOS	1	0.6	0	0	0	0
	HYPOTENSION NOS	0	0	1	0.6	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	6	3.4	7	3.9	5	2.8

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG206.SAS
GENERATED: 12JUL2005 17:39:17 iceadmn3

Table 11.3.3.1 Deaths

NOTE:

NO DATA MEETS THE CRITERIA FOR ENTRY INTO THIS TABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG213.SAS
GENERATED: 12JUL2005 17:39:33 iceadmn3

Table 11.3.3.2 Adverse Events that Lead to Death

NOTE: THERE WERE NO ADVERSE EVENTS THAT LEAD TO DEATH.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG101.SAS
GENERATED: 12JUL2005 17:38:46 iceadmn3

11.3.3.3 Narratives of deaths

There were no deaths reported in this study.

Table 11.3.4.1.1 Serious Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY SERIOUS EVENT		6	3.4	9	5.0	16	8.9
GASTROINTESTINAL DISORDERS	TOTAL	0	0	1	0.6	2	1.1
	DUODENAL ULCER HAEMORRHAGE	0	0	0	0	1	0.6
	INTESTINAL OBSTRUCTION NOS	0	0	1	0.6	0	0
	PANCREATITIS NOS	0	0	0	0	1	0.6
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	0	0	3	1.7	0	0
	CHEST PAIN	0	0	1	0.6	0	0
	HERNIA NOS	0	0	1	0.6	0	0
	INFLUENZA LIKE ILLNESS	0	0	1	0.6	0	0
HEPATOBILIARY DISORDERS	TOTAL	0	0	0	0	1	0.6
	CHOLECYSTITIS NOS	0	0	0	0	1	0.6
IMMUNE SYSTEM DISORDERS	TOTAL	0	0	0	0	1	0.6
	DRUG HYPERSENSITIVITY	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG207.SAS
GENERATED: 12JUL2005 17:39:20 iceadmn3

Table 11.3.4.1.1 Serious Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	1	0.6	1	0.6	2	1.1
	HIP FRACTURE	0	0	0	0	1	0.6
	INJURY	1	0.6	0	0	0	0
	NON-ACCIDENTAL OVERDOSE	0	0	1	0.6	1	0.6
	SPINAL FRACTURE NOS	0	0	0	0	1	0.6
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	0	0	0	0	1	0.6
	INTERVERTEBRAL DISC HERNIATION	0	0	0	0	1	0.6
NERVOUS SYSTEM DISORDERS	TOTAL	0	0	1	0.6	2	1.1
	CONVULSIONS NOS	0	0	0	0	1	0.6
	HEMIPARESIS	0	0	0	0	1	0.6
	MIGRAINE NOS	0	0	1	0.6	0	0
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	TOTAL	0	0	0	0	1	0.6
	ECTOPIC PREGNANCY	0	0	0	0	1	0.6
PSYCHIATRIC DISORDERS	TOTAL	4	2.2	4	2.2	5	2.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG207.SAS
GENERATED: 12JUL2005 17:39:20 iceadmn3

Table 11.3.4.1.1 Serious Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	ACUTE PSYCHOSIS	0	0	0	0	1	0.6
	BIPOLAR I DISORDER	0	0	1	0.6	0	0
	CONVERSION DISORDER	1	0.6	0	0	0	0
	DEPRESSION	0	0	1	0.6	0	0
	HALLUCINATION, AUDITORY	0	0	0	0	1	0.6
	MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	1	0.6
	MANIA	0	0	0	0	1	0.6
	MENTAL STATUS CHANGES	0	0	1	0.6	0	0
	SUICIDAL IDEATION	2	1.1	2	1.1	2	1.1
	SUICIDE ATTEMPT	1	0.6	1	0.6	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	1	0.6	1	0.6	0	0
	ADNEXA UTERI PAIN	1	0.6	0	0	0	0
	PROSTATITIS	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG207.SAS
GENERATED: 12JUL2005 17:39:20 iceadmn3

Table 11.3.4.1.1 Serious Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	0	0	0	0	1	0.6
	ASTHMA NOS	0	0	0	0	1	0.6
VASCULAR DISORDERS	TOTAL	0	0	1	0.6	1	0.6
	DEEP VEIN THROMBOSIS	0	0	1	0.6	1	0.6

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG207.SAS
GENERATED: 12JUL2005 17:39:20 iceadmn3

Table 11.3.4.1.2 Serious Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY SERIOUS EVENT		5	4.2	6	5.0	14	11.9	1	1.7	3	5.0	2	3.2
GASTROINTESTINAL DISORDERS	TOTAL	0	0	1	0.8	1	0.8	0	0	0	0	1	1.6
	DUODENAL ULCER HAEMORRHAGE	0	0	0	0	1	0.8	0	0	0	0	0	0
	INTESTINAL OBSTRUCTION NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	PANCREATITIS NOS	0	0	0	0	0	0	0	0	0	0	1	1.6
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	0	0	3	2.5	0	0	0	0	0	0	0	0
	CHEST PAIN	0	0	1	0.8	0	0	0	0	0	0	0	0
	HERNIA NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	INFLUENZA LIKE ILLNESS	0	0	1	0.8	0	0	0	0	0	0	0	0
HEPATOBILIARY DISORDERS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	CHOLECYSTITIS NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
IMMUNE SYSTEM DISORDERS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG208.SAS
GENERATED: 12JUL2005 17:39:22 iceadmn3

Table 11.3.4.1.2 Serious Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
IMMUNE SYSTEM DISORDERS	DRUG HYPERSENSITIVITY	0	0	0	0	1	0.8	0	0	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	1	0.8	2	1.7	1	1.7	0	0	0	0
	HIP FRACTURE	0	0	0	0	1	0.8	0	0	0	0	0	0
	INJURY	0	0	0	0	0	0	1	1.7	0	0	0	0
	NON-ACCIDENTAL OVERDOSE	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	SPINAL FRACTURE NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	INTERVERTEBRAL DISC HERNIATION	0	0	0	0	1	0.8	0	0	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	0	0	1	0.8	1	0.8	0	0	0	0	1	1.6
	CONVULSIONS NOS	0	0	0	0	0	0	0	0	0	0	1	1.6
	HEMIPARESIS	0	0	0	0	1	0.8	0	0	0	0	0	0
	MIGRAINE NOS	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG208.SAS
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Table 11.3.4.1.2 Serious Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	ECTOPIC PREGNANCY	0	0	0	0	1	0.8	0	0	0	0	0	0
PSYCHIATRIC DISORDERS	TOTAL	4	3.3	2	1.7	5	4.2	0	0	2	3.3	0	0
	ACUTE PSYCHOSIS	0	0	0	0	1	0.8	0	0	0	0	0	0
	BIPOLAR I DISORDER	0	0	0	0	0	0	0	0	1	1.7	0	0
	CONVERSION DISORDER	1	0.8	0	0	0	0	0	0	0	0	0	0
	DEPRESSION	0	0	1	0.8	0	0	0	0	0	0	0	0
	HALLUCINATION, AUDITORY	0	0	0	0	1	0.8	0	0	0	0	0	0
	MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	MANIA	0	0	0	0	1	0.8	0	0	0	0	0	0
	MENTAL STATUS CHANGES	0	0	0	0	0	0	0	0	1	1.7	0	0
	SUICIDAL IDEATION	2	1.7	1	0.8	2	1.7	0	0	1	1.7	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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GENERATED: 12JUL2005 17:39:22 iceadmn3

Table 11.3.4.1.2 Serious Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	SUICIDE ATTEMPT	1	0.8	1	0.8	0	0	0	0	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	1	0.8	0	0	0	0	0	0	1	1.7	0	0
	ADNEXA UTERI PAIN	1	0.8	0	0	0	0	0	0	0	0	0	0
	PROSTATITIS	0	0	0	0	0	0	0	0	1	1.7	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	ASTHMA NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
VASCULAR DISORDERS	TOTAL	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	DEEP VEIN THROMBOSIS	0	0	1	0.8	1	0.8	0	0	0	0	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0020013	23 YRS CAUCASIAN MALE	17MAR2003-17MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	13	SEV	N	Y	N	N	N	N	YES NO	Permanently Stopped
	E0022022	23 YRS CAUCASIAN FEMALE	09FEB2003-18MAR2003	ON	CONVERSION DISORDER (Psychiatric disorders) [CONVERSION DISORDER]	38	42	MOD	N	N	Y	N	N	N	YES NO	None
	E0022036	22 YRS CAUCASIAN MALE	12MAY2003-14MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	3	77	MOD	N	N	Y	N	N	N	NO NO	None
	E0023034	18 YRS CAUCASIAN FEMALE	31JUL2003-01AUG2003	ON	ADNEXA UTERI PAIN (Reproductive system and breast disorders) [OVARIAN CYST PAIN]	2	53	SEV	N	N	Y	N	N	N	NO NO	None
	E0028045	46 YRS CAUCASIAN MALE	26JUL2003-29JUL2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH ACUTE PSYCHOSIS]	4	39	SEV	N	N	Y	N	N	N	YES NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0028045	46 YRS CAUCASIAN MALE	11AUG2003-27AUG2003	POST	BIPOLAR I DISORDER (Psychiatric disorders) [BIPOLAR AFFECTIVE DISORDER MIXED STATE WITH MOOD CONGRUENT PSYCHOSIS]	17	UNK	SEV	N	N	Y	N	N	N	YES NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	27 YRS BLACK MALE	30MAY2003-19JUN2003	ON	INJURY (Injury, poisoning and procedural complications) [STAB WOUNDS]	21	36	SEV	N	N	Y	N	N	N	NO NO	None

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^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	36 YRS BLACK FEMALE	30DEC2002-CONTINUE	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU - LIKE SYMPTOMS]	UNK	49	SEV	N	N	Y	N	N	N	NO NO	None
	E0010014	38 YRS CAUCASIAN FEMALE	26FEB2003-31MAR2003	ON	HERNIA NOS (General disorders and administration site conditions) [RECURRENT BOWEL HERNIA]	34	30	SEV	N	N	Y	N	N	N	NO NO	None
			31MAR2003-31MAR2003	ON	INTESTINAL OBSTRUCTION NOS (Gastrointestinal disorders) [STRANGULATED BOWEL]	1	63	SEV	N	N	Y	N	N	N	NO NO	None
	E0018007	42 YRS CAUCASIAN FEMALE	31DEC2002-20MAR2003	ON	DEEP VEIN THROMBOSIS (Vascular disorders) [RECURRENT DEEP VEIN THROMBOSIS WITHOUT PULMONARY EMBOLISM]	80	5	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped
			01JAN2003-01JAN2003	ON	MIGRAINE NOS (Nervous system disorders) [MIGRAINE HEADACHE]	1	6	SEV	N	N	Y	N	N	N	NO NO	None

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^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	22 YRS CAUCASIAN FEMALE	11NOV2002-11NOV2002	ON	NON-ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [OVERDOSE OF STUDY MEDICATION (INTENTIONAL)]	1	39	MOD	N	N	N	N	N	Y	NO NO	None
	E0028023	54 YRS BLACK MALE	09MAR2003-09MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	48	SEV	N	N	Y	N	N	N	YES NO	None
	E0039028	39 YRS BLACK MALE	08MAY2003-08MAY2003	ON	CHEST PAIN (General disorders and administration site conditions) [CHEST PAIN (NOT CARDIAC RELATED)]	1	46	MOD	N	N	Y	N	N	N	NO NO	None
			09MAY2003-16MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	8	47	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped
			20MAY2003-03JUN2003	ON	DEPRESSION (Psychiatric disorders) [WORSENING OF DEPRESSION]	15	58	SEV	N	N	Y	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
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^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	46 YRS CAUCASIAN MALE	29JAN2003-03FEB2003	ON	PROSTATITIS (Reproductive system and breast disorders) [ACUTE PROSTATITIS]	6	57	SEV	N	N	Y	N	N	N	NO NO	None
	E0026023	20 YRS CAUCASIAN MALE	27JUN2003-28JUN2003	ON	MENTAL STATUS CHANGES (Psychiatric disorders) [ALTERED MENTAL STATUS]	2	59	SEV	N	N	Y	N	N	N	NO NO	None
	E0028032	36 YRS CAUCASIAN MALE	18MAY2003-28MAY2003	ON	BIPOLAR I DISORDER (Psychiatric disorders) [MIXED EPISODE WITH PSYCHOSIS]	11	55	SEV	N	N	Y	N	N	N	NO NO	None
					SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	11	55	SEV	N	N	Y	N	N	N	NO NO	None

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# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0002016	56 YRS CAUCASIAN FEMALE	14AUG2003-20AUG2003	ON	HEMIPARESIS (Nervous system disorders) [RIGHT SIDED WEAKNESS]	7	22	MOD	N	N	Y	N	N	N	NO NO	None
	E0004006	37 YRS CAUCASIAN FEMALE	16JAN2003-23JAN2003	ON	DRUG HYPERSENSITIVITY (Immune system disorders) [HYPERSENSITIVITY REACTION TO LAMICTAL]	8	74	SEV	N	N	Y	N	N	N	NO NO	None
	E0005019	22 YRS CAUCASIAN FEMALE	16JAN2003-16JAN2003	ON	NON-ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [INTENTIONAL OVERDOSE (OVER THE COUNTER SLEEPING PILL)]	1	2	MOD	N	N	N	N	N	Y	YES NO	Permanently Stopped
	E0007003	53 YRS CAUCASIAN MALE	21FEB2003-27FEB2003	ON	DUODENAL ULCER HAEMORRHAGE (Gastrointestinal disorders) [BLEEDING ULCER (DUODENAL)]	7	23	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped

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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0022011	28 YRS CAUCASIAN MALE	30NOV2002-06MAR2003	ON	HIP FRACTURE (Injury, poisoning and procedural complications) [HIP FRACTURE]	97	2	MIL	N	N	Y	N	N	N	YES NO	Permanently Stopped
					SPINAL FRACTURE NOS (Injury, poisoning and procedural complications) [MULTIPLE VERTEBRAL FRACTURES T11 - L4]	97	2	MIL	N	N	Y	N	N	N	YES NO	Permanently Stopped
			04DEC2002-20MAY2003	ON	DEEP VEIN THROMBOSIS (Vascular disorders) [DEEP VEIN THROMBOSIS LEFT LEG]	168	6	MIL	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0026028	35 YRS CAUCASIAN MALE	11JUL2003-CONTINUE	ON	MAJOR DEPRESSIVE DISORDER NOS (Psychiatric disorders) [PSYCHOTIC: DEPRESSION]	UNK	22	SEV	N	N	Y	N	N	N	YES NO	None
			15JUL2003-18JUL2003	ON	ACUTE PSYCHOSIS (Psychiatric disorders) [ACUTE PSYCHOSIS]	4	26	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped

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# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0028003	53 YRS CAUCASIAN FEMALE	03OCT2002-04NOV2002	ON	CHOLECYSTITIS NOS (Hepatobiliary disorders) [CHOLECYSTITIS EXACERBATION]	33	4	SEV	N	N	Y	N	N	N	NO NO	None
	E0028031	35 YRS CAUCASIAN MALE	27MAR2003-31MAR2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [SELF MUTILATING AUDITORY HALLUCINATIONS]	5	17	SEV	N	N	Y	N	N	N	YES NO	None
	E0033010	26 YRS BLACK FEMALE	19MAR2003-19MAR2003	ON	ECTOPIC PREGNANCY (Pregnancy, puerperium and perinatal conditions) [ECTOPIC PREGNANCY]	1	44	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0033014	53 YRS CAUCASIAN MALE	18APR2003-CONTINUE	ON	INTERVERTEBRAL DISC HERNIATION (Musculoskeletal and connective tissue disorders) [HERNIATED SPINAL DISC PAIN]	UNK	31	MOD	N	N	Y	N	N	N	NO NO	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0035002	46 YRS CAUCASIAN MALE	14DEC2002-CONTINUE	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	UNK	24	MOD	N	N	Y	N	N	N	NO NO	None
	E0039030	52 YRS CAUCASIAN FEMALE	06JUN2003-08JUN2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	3	75	SEV	N	N	Y	N	N	N	NO NO	None
	E0039038	40 YRS BLACK FEMALE	05MAY2003-09MAY2003	ON	ASTHMA NOS (Respiratory, thoracic and mediastinal disorders) [ASTHMA ATTACK]	5	13	SEV	N	N	Y	N	N	N	NO NO	Temporarily Stopped
	E0041010	32 YRS CAUCASIAN MALE	07JUN2003-13JUN2003	ON	MANIA (Psychiatric disorders) [MANIC EPISODE]	7	39	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG102.SAS
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Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0014001	25 YRS CAUCASIAN FEMALE	22MAR2003-29MAR2003	ON	PANCREATITIS NOS (Gastrointestinal disorders) [PANCREATITIS]	8	25	SEV	N	N	Y	N	N	N	NO NO	Temporarily Stopped
	E0026027	40 YRS CAUCASIAN FEMALE	19JUN2003-19JUN2003	ON	CONVULSIONS NOS (Nervous system disorders) [SEIZURE]	1	1	SEV	N	N	N	N	N	Y	YES NO	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

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11.3.4.3 Narratives of serious adverse events other than death

Study 5077US/0049 Patient 0002/016 placebo

Serious: Hemiparesis

This narrative concerns a 56-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of right-sided weakness (MedDRA: hemiparesis) on Day 22 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. On Day 23, the patient was hospitalized for a sudden onset of weakness on the right side of her body. The table below outlines the assessments performed. No evidence of stroke was found. The patient was treated with clopidogrel bisulfate (PLAVIX®, Bristol-Myers Squibb and Sanofi-Synthelabo) 75 mg/day for prophylaxis. The serious adverse event of right-sided weakness resolved with sequelae right sided weakness (reduced intensity) on Day 28 at discharge. Study treatment was not withdrawn due to this event.

Table 1 Clinical Assessments

Study day	Assessments	Results
Day 23	CT brain without contrast	Intermediate age small lacunar infarct of subcortical white matter of left frontal lobe
Day 24	Anticardiolipin antibody level	Less than 14
	Antiphospholipid level	Less than 11
	Protein S	105%
	Protein C	124%
	Factor V Leiden	0.96
	Antithrombin III	84%
	Magnetic Resonance Imaging (MRI) brain	Findings do not suggest acute ischemia
	Bilateral carotid doppler	1-39% stenosis of the right common and proximal internal carotid artery (ICA). Left proximal carotid artery velocities suggested stenosis in the severe range (60-79%).
	Magnetic Resonance Angiography (MRA) head	No evidence of aneurysm or malformation
	Two dimensional echocardiogram	No stenosis or insufficiency for aortic valve, pulmonic valve, and tricuspid valve. Mitral valve has no stenosis and trace regurgitation. Left ventricle (LV) shows normal E:A ratio
Day 26	MRA of the neck	No hemodynamically significant stenosis

The patient had a relevant medical history of high cholesterol and hypertension. The patient's screening and final visit physical examinations were unremarkable. Before entering the study, the patient was treated with simvastatin (ZOCOR®, Merck) 40 mg/day for high cholesterol, valsartan / hydrochlorothiazide (DIOVAN HCT®, Novartis) 80 mg/day for hypertension, and aspirin 500 mg/day for prophylaxis. The patient continued treatment with these medications throughout the study.

The investigator considered the hemiparesis to be not related to study treatment.

Study 5077US/0049 Patient 0004/006 placebo

Serious: Drug Hypersensitivity

This narrative concerns a 37-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of hypersensitivity reaction to Lamictal®, (MedDRA: drug hypersensitivity) that was considered by the investigator to be severe in intensity. The patient completed the study and started lamotrigine (LAMICTAL®, GlaxoSmithKline) 50 mg/day on the day of the final study visit, one day after the final dose of study medication. Twelve days after the final dose of study medication (placebo), the patient experienced headache, fever of 103 degrees Fahrenheit, and body aches. The patient was not experiencing any symptoms of rash. Fourteen days after the final dose of study medication, the subject was hospitalized with fever and a rash on her face and arms. The patient was given vancomycin and levofloxacin (LEVAQUIN®, Ortho-McNeil) for treatment of this event. The table below outlines the assessments performed during this patient's hospitalization.

Table 2 Clinical Assessments

Study day	Assessments	Results
14 days after last dose of study medication	Elevated AST	78
	Elevated ALT	53
	Direct Bilirubin	0.3
	WBC	2.75
	Ultrasound	Fatty Liver

Eighteen days after the final dose of study medication, the event resolved and the patient was discharged from the hospital. The patient had a relevant medical history of allergic reactions to penicillin, sulfa, and betadine. The screening and final visit physical examinations were unremarkable.

The investigator considered the drug hypersensitivity to be not related to study treatment.

Study 5077US/0049 Patient 0005/019 placebo

Serious: Non-accidental Overdose

This narrative concerns a 22-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of intentional overdose (over the counter sleeping pills) (MedDRA: non-accidental overdose) on Day 2 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. Per the patient's report, she was feeling depressed and hopeless on Day 2, and took an overdose of over the counter sleeping pills. The patient could not remember the amount or type of medication taken, but reported that it was possibly one bottle of diphenhydramine hydrochloride (NYTOL®, GlaxoSmithKline) tablets. The patient reported that she was found by a friend and taken to the emergency room, where her stomach was pumped; however, she was not admitted to the hospital. The event of non-accidental overdose resolved on Day 2. Hospital records for this event were not available; therefore, the information regarding the event and emergency room treatment was reported based on the patient's verbal report and could not be confirmed. The patient reported this event to the study site staff on Day 9, and at that time denied any suicidal ideations and refused hospitalization. The investigator considered the non-accidental overdose to be an important medical event, and withdrew study treatment. The patient's last dose of study treatment was on Day 7.

The patient did not have any relevant medical history. Before entering the study, the patient was treated with acetaminophen / diphenhydramine hydrochloride (TYLENOL® PM, McNeil Consumer) for insomnia secondary to bipolar disorder. No relevant concomitant medications were taken during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the non-accidental overdose to be not related to study treatment.

Study 5077US/0049 Patient 0007/003 placebo

Serious: Duodenal Ulcer Hemorrhage

This narrative concerns a 53-year-old white man with bipolar I disorder.

The patient had a serious adverse event of bleeding ulcer (duodenal) (MedDRA: duodenal ulcer hemorrhage) beginning on Day 23 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. According to hospital records, on Day 23 the patient had shortness of breath, black stool, and fatigue. On Day 27 the patient was brought to the Emergency Room in an ambulance with severe stomach pain and was diagnosed with a duodenal ulcer hemorrhage. The investigator withdrew study treatment for this event. The patient's last dose of study treatment was on Day 26. During the hospitalization, the patient was treated with lansoprazole / amoxicillin / clarithromycin (PREVPAC®, TAP Pharmaceuticals) 1 tab/day, and pantoprazole sodium (PROTONIX®, Wyeth) 80 mg/day for bleeding ulcer. Two days after the last dose of study treatment, the

patient was given midazolam (VERSED®, Roche) 3 mg IV, and meperidine hydrochloride (DEMEROL®, Sanofi-Synthelabo) 50 mg IV for an Esophago-Gastro-Duodenoscopy (EGD) procedure. The table below outlines the assessments performed during the patient's hospitalization. Three days after the last dose of study treatment, the serious adverse event of duodenal ulcer hemorrhage resolved and the patient was discharged from the hospital.

Table 3 Clinical Assessments

Study day	Assessments	Results
One day after last dose	X-ray Thoracic Spine	Thoracic Spondylosis/Kyphosis
	X-Ray Chest PA/LAT	Placement of nasogastric tube – no disease.
Two days after last dose	EGD with coagulation of bleeding site and biopsy	Active duodenal ulcer
Three days after last dose	RBCCT	3.23 (reference range = 4.60-6.20)
	HGB	10.1 (reference range = 13.5-18.0)
	HCT	29.6 (reference range = 42.0-52.0)

The patient had a relevant medical history of anemia, chronic obstructive pulmonary disease, coronary artery disease, hyperlipidemia, hypertension, peptic ulcer disease, and status post cardiac stent. Before entering the study, the patient was treated with lisinopril 20 mg/day and felodipine 5 mg/day for hypertension; these medications were continued concomitantly during study treatment. The patient took acetaminophen (TYLENOL®, McNeil Consumer) 2925 mg/day on Days 25 and 26 for right hip pain. Medical records indicated that the patient also took acetaminophen / hydrocodone bitartrate (LORTAB®, UCB Pharma) 5 mg/day and metaxalone (SKELAXIN®, Monarch) 400 mg/day starting on Day 8 and continuing throughout study treatment for back pain. The patient did not disclose this information to the site personnel during the study. The screening and final visit physical examinations were unremarkable.

The investigator considered the duodenal ulcer hemorrhage to be not related to study treatment.

Study 5077US/0049 Patient 0009/001 600 mg

Serious: Influenza Like Illness

This narrative concerns a 36-year-old black woman with bipolar I disorder.

The patient had a serious adverse event of flu-like symptoms (MedDRA: influenza like illness) on Day 49 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The patient reported taking her last dose of study treatment on Day

56. One day after the last reported dose of study treatment, the patient was hospitalized due to the influenza like illness. The patient was treated and discharged from the hospital two days after she reported taking her last dose of study treatment. The investigator did not consider the event significant enough to warrant withdrawal from study treatment. However, the patient did not return for another study visit and was lost to follow up. The patient did not return the last study treatment blister card dispensed; therefore, for data collection purposes, the final day of dosing prescribed on this blister card (Day 57) was used as the last study treatment dose. The day of resolution of influenza like illness is unknown.

On Day 48, the patient had a non-serious adverse event of somnolence that was considered by the investigator to be mild in intensity and related to study drug. On Day 49 of randomized treatment, the patient had a non-serious adverse event of nasal congestion that was considered by the investigator to be mild in intensity and not related to study medication. The patient had a relevant medical history of insomnia, headaches, and migraine headaches. Before entering the study, the patient had been treated with aspirin / salicylamide / caffeine (BC®POWDER, GlaxoSmithKline) and aspirin / acetaminophen / caffeine (GOODY'S® POWDER, GlaxoSmithKline) for headaches and acetaminophen / aspirin / caffeine (EXCEDRIN® MIGRAINE, Bristol-Myers) for migraine headaches. During the study, the patient was given aspirin for headaches and acetaminophen / pseudoephedrine hydrochloride (ALKA SELTZER PLUS® COLD AND SINUS, Bayer) for nasal congestion. The screening physical examination revealed moderate obesity. The final visit physical examination was not performed.

The investigator considered the influenza like illness to be not related to study treatment.

Study 5077US/0049 Patient 0010/014 600 mg

This narrative concerns a 38-year-old white woman with bipolar I disorder.

Serious: Hernia NOS

The patient had a serious adverse event of recurrent bowel hernia (MedDRA: hernia NOS) on Day 30 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity.

Also on Day 30 of randomized treatment, the patient had a non-serious adverse event of constipation that was considered by the investigator to be mild in intensity and related to study treatment. This adverse event of constipation had not resolved prior to the final study visit and was therefore continuing at study completion.

The investigator considered the hernia NOS to be not related to study treatment.

Serious: Intestinal Obstruction NOS

The patient had a serious adverse event of strangulated bowel (MedDRA: intestinal obstruction NOS) seven days after the final dose of study medication was taken. The event

was considered by the investigator to be severe in intensity. The patient had a serious adverse event of hernia NOS on Day 30 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. After completing the study, the patient underwent a scheduled hernia repair and abdominoplasty seven days after taking the final dose of study medication. During the surgery the intestinal obstruction was found and a bowel resection was performed. After the surgery the patient was given cephalexin (KEFLEX®, Dista) as prophylaxis and hydrocodone for pain management. The event resolved and the patient was discharged from the hospital ten days after the final dose of study medication.

The investigator considered the intestinal obstruction NOS to be not related to study treatment.

The patient had a medical history of an appendectomy, cholecystectomy, elevated blood sugar, incarcerated hernia repair, obesity, hypertension, and unilateral oophorectomy. Before entering the study, the patient had been treated with lisinopril / hydrochlorothiazide (PRINZIDE®, Merck) one tablet daily for hypertension and acetaminophen / pseudoephedrine / diphenhydramine hydrochloride (BENADRYL® ALLERGY, Pfizer Consumer) as needed for mild insomnia. During the study, the patient continued to take lisinopril / hydrochlorothiazide (PRINZIDE®, Merck) for hypertension. The screening and final study visit physical examinations were unremarkable.

Study 5077US/0049 Patient 0014/001 placebo

Serious: Pancreatitis NOS

This narrative concerns a 25-year-old white woman with bipolar II disorder.

The patient had a serious adverse event of pancreatitis (MedDRA: pancreatitis NOS) on Day 25 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. The patient was evaluated at the study site on Day 28 and was doing well. On Day 29 the patient was hospitalized due to severe abdominal pain. The patient reported at hospitalization that she had experienced upset stomach, diarrhea, back pain, upper abdominal pain, and dehydration, starting on Day 25. A physical exam revealed abdominal tenderness. An abdominal CT scan was performed and revealed mild pancreatitis. A diagnosis of pancreatitis was made; however, the attending physician indicated that bulimia nervosa appeared to be associated with the pancreatitis and suspected that it was the underlying etiology. On Day 29 the patient was treated with 12.5 mg of dolasetron mesylate (ANZEMET®, Aventis) and 50 mg of promethazine hydrochloride (PHENERGAN®, Wyeth-Ayerst) for nausea and heparin for hypercoagulativity. On Days 29 and 30, famotidine was given for heartburn and hydromorphone hydrochloride (DILAUDID®, Abbott) for pain. On Days 30 and 32, enoxaparin was given for hypercoagulativity. On Days 31 and 32, acetaminophen / hydrocodone bitartrate (LORTAB®, UCB Pharma) was given for pain and ranitidine for heartburn. On Day 32, the event of pancreatitis resolved, and patient was discharged from the hospital. Treatment with study medication was temporarily withdrawn from Day 29 to Day 31.

Table 4 Clinical Assessments

Study day	Assessments	Results
Day 29	Amylase, serum	152 U/L
	Alkaline Phosphatase	793 U/L
	Lipase, serum or plasma	2450 U/L

From Day 3 to Day 28, the patient had a non-serious adverse event of fatigue that was considered by the investigator to be severe in intensity and related to study drug. From Day 10 to Day 35 the patient had a non-serious adverse event of frequent bowel movements that was considered by the investigator to be mild in intensity and related to study medication. The patient had a relevant medical history of back pain, cholecystectomy, hysterectomy, joint pain, kidney/renal failure, and pelvic pain. During the hospitalization, the patient reported a medical history of bulimia, chronic hypokolemia, history of neurologic disorder of unknown etiology, and history of deep vein thrombosis; however, the subject did not report this medical history to the site study staff at the screening visit. Before entering the study, the patient had not been treated with any relevant medications. The screening and final visit physical examinations were unremarkable.

The investigator considered the pancreatitis to be not related to study treatment.

Study 5077US/0049 Patient 0018/007 600 mg

This narrative concerns a 42-year-old white woman with bipolar I disorder.

Serious: Deep Vein Thrombosis

This narrative concerns a 42-year-old white woman with bipolar I disorder.

The patient had a serious adverse event (SAE) of recurrent deep vein thrombosis without pulmonary embolism (MedDRA: deep vein thrombosis) on Day 5, one day after the last dose of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. On Day 4 of randomized treatment, the patient had a non-serious adverse event of worsening of left leg pain that was considered by the investigator to be moderate in intensity and not related to study treatment. One day after the last dose of study treatment, the patient was seen in the Emergency Room for left lower extremity swelling and cramping. An ultrasound showed clotting in her left femoral vein system and a diagnosis of deep vein thrombosis (DVT) was made. The patient was admitted to the hospital and treated with enoxaparin sodium (LOVENOX®, Aventis) and warfarin sodium (COUMADIN®, Bristol-Myers Squibb). The table below provides Prothrombin levels that were measured during this event. The investigator withdrew study treatment and the patient's last dose was on Day 4. The patient was discharged from the hospital two days after admission. The final physical examination, performed eleven days after the last dose of study treatment, revealed increased

left leg circumference secondary to deep vein thrombosis. The serious adverse event of deep vein thrombosis resolved eighty days after the last dose of study treatment.

Table 5 Assessments performed in relation to event

Study day	Prothrombin Levels
One day after last dose	Protime – 10.0
Four days after last dose	Protime – 14.4
Five days after last dose	Protime – 20.7
Six days after last dose	Protime – 19.9
Seven days after last dose	Protime – 26.0
Eight days after last dose	Protime – 29.2
Nine days after last dose	Protime – 30.4

The investigator considered the deep vein thrombosis to be not related to study treatment.

Serious: Migraine NOS

The patient had a serious adverse event (SAE) of migraine headache (MedDRA: migraine NOS) two days after her last dose of randomized study treatment to 600 mg which was considered by the investigator to be severe in intensity. The day after the patient was admitted to the hospital for treatment of deep vein thrombosis, she had a migraine NOS that extended her hospitalization. Per hospital records, there were no medications given to treat this event and the migraine NOS resolved the same day. The patient was discharged from the hospital two days after admission.

The investigator considered the migraine NOS to be not related to study treatment.

Three days after the last dose of study treatment, the patient had non-serious adverse events of chest pain and nausea that were considered by the investigator to be moderate in intensity and not related to study treatment. According to hospital records, seventeen days after the last dose of study treatment, the patient had an adverse event of Factor II deficiency, based on the results of tests ordered during the hospitalization for work-up of hypercoaguable state in this woman with a third episode of DVT. This event was considered by the investigator to be mild in intensity and not related to study treatment. The patient had a relevant past medical history of deep vein thrombosis, ankle fracture with open reduction and internal fixation, and a relevant current medical history of intermittent leg pain and migraines. The screening physical examination was unremarkable. Before entering the study, the patient was treated with conjugated estrogen (PREMARIN®, Wyeth) 1.25 mg/day for hormone replacement therapy, which was discontinued during her hospitalization one day after the last dose of study treatment. During the study, the patient was given a calcium supplement, hydromorphone hydrochloride (DILAUDID®, Abbott), and morphine for left leg pain.

Study 5077US/0049 Patient 0020/013 300 mg

Serious: Suicide Attempt

This narrative concerns a 23-year-old white man with bipolar I disorder.

The patient had a serious adverse event of suicide attempt one day after the last dose of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The patient took his regularly scheduled study treatment dose on Day 12 of randomized treatment. The next day, the patient had an argument with a friend and his girlfriend, and the patient took an unknown amount of acetaminophen / diphenhydramine hydrochloride (TYLENOL® PM, McNeil Consumer), acetaminophen / codeine (TYLENOL® #3, Ortho-McNeil), and oxycodone / acetaminophen (PERCOCET®, Endo). A total of approximately 60 pills were taken. The patient became unconscious, and the patient's girlfriend called an ambulance. The patient was treated in the emergency room with 50 grams of charcoal with sorbitol, and 5 cc of sodium chloride. Naloxone hydrochloride (NARCAN®, Endo) 0.4 mg was given as a narcotic antagonist and 1000 cc of sodium chloride was given for hydration. The patient was released from the emergency room that same day, and the event of suicide attempt was considered resolved. The patient did not take any study treatment doses after Day 12. The patient reported the suicide attempt to the site personnel eight days after the last dose of study treatment. Nine days after the last dose of study treatment, the patient returned to the study site for his final study visit and was evaluated by the investigator. During this visit, no acute distress was noted, no physical complaints were reported, and the patient reported no thoughts, plans, or intentions of harming himself. The event of suicide attempt was determined to be life threatening by the investigator, and the investigator withdrew treatment due to this event.

Table 6 Clinical Assessments

Study day	Assessments	Results
One day after last dose	ETOH Blood Level	143 (units not available)
	Blood Tylenol Level	33 (units not available)

The patient did not have any relevant medical history. The patient was not taking any medications before entering the study. The screening and final visit physical examinations were unremarkable.

The investigator considered the suicide attempt to be not related to study treatment.

Study 5077US/0049 Patient 0022/011 placebo

This narrative concerns a 28-year-old white man with bipolar I disorder.

Serious: Hip Fracture

Serious: Spinal Fracture NOS

The patient had a serious adverse events of hip fracture and multiple spinal fractures T11-L4 (MedRA: spinal fracture NOS) one day after his first and only dose of randomized treatment to placebo, both of which were considered by the investigator to be mild in intensity. The patient took his first and only confirmed dose of study treatment on Day 1. The next day, the patient was involved in a skiing accident resulting in a hip fracture and spinal fracture. Study treatment was withdrawn due to these events and a subsequent deep vein thrombosis (see below). The patient was initially hospitalized out of state and then transferred to a local hospital one day later. The patient was treated with traction and did not require surgery. Hydromorphone hydrochloride (DILAUDID®, Abbott), promethazine hydrochloride (PHENERGAN®, Wyeth-Ayerst), meperidine hydrochloride (DEMEROL®, Sanofi-Synthelabo), morphine sulfate, diazepam (VALIUM®, Roche), and midazolam (VERSED®, Roche) were given for pain management. The patient was also treated with metoclopramide (REGLAN®, Schwarz) and Lactated Ringer's Solution. The patient was discharged from the hospital seven days after he took his first and only dose of study medication. The hip fracture was considered resolved once the patient was considered independently ambulatory and pain free, ninety-seven days after the patient took his first and only dose of study medication.

The investigator considered the hip fracture and the spinal fracture NOS to be not related to study treatment.

Serious: Deep Vein Thrombosis

The patient had a serious adverse event of deep vein thrombosis left leg (MedDRA: deep vein thrombosis) while hospitalized for hip spinal fractures sustained in a skiing accident. The thrombosis started five days after his first and only dose of randomized treatment to placebo that was considered by the investigator to be mild in intensity. Treatment with warfarin sodium (COUMADIN®, Bristol-Myers Squibb) and enoxaparin sodium (LOVENOX®, Aventis) continued until the event resolved. The patient was discharged from the hospital seven days after he took his first and only dose of study medication. The deep vein thrombosis resolved 172 days after he took his first and only dose of study medication.

The investigator considered the deep vein thrombosis to be not related to study treatment.

The patient did not have any relevant medical history. The screening physical examination was unremarkable. The final physical examination was not done.

Study 5077US/0049 Patient 0022/022 300 mg

Serious: Conversion Disorder

This narrative concerns a 23-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of conversion disorder beginning on Day 42 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. On Day 46 the patient was admitted to the hospital for evaluation of numbness and weakness in her lower extremities. At admission, a MRI of the spine and CBC were performed. The results of both tests were normal. Based on her previous episodes of rapid onset of symptoms in the midst of psychosocial stressors, and the lack of physical cause for the patient's symptoms, the investigator determined conversion disorder to be the most likely cause of the event. The investigator did not consider the event significant enough to warrant withdrawal of study treatment. However, the patient decided to withdraw from study treatment as a result of this event. The last dose of study treatment was taken on Day 45. The patient was discharged from the hospital five days after the last dose of study treatment. Thirty-four days after the last dose of study treatment, the serious adverse event of conversion disorder resolved.

The patient had a relevant medical history of orthostatic dizziness. The patient's screening physical examination was unremarkable. The end of study physical examination revealed loss of soft touch sensation, motor activity, and vibration sense attributed to the conversion disorder. During the study, the patient had non-serious adverse events of akathisia and myoclonus that were considered to be moderate in intensity and related to study treatment. The akathisia was treated with lorazepam 3 mg/day. Both of these non-serious adverse events began on Day 2 and continued through Day 20 of randomized treatment. The patient also had a non-serious adverse event of sedation that was considered by the investigator to be moderate in intensity and related to study treatment. This event began on Day 2 and was ongoing as of the patient's last study visit, fifteen days after the last dose of study treatment.

The investigator considered the conversion disorder to be not related to study treatment.

Study 5077US/0049 Patient 0022/036 300 mg

Serious: Suicidal Ideation

This narrative concerns a 22-year-old white man with bipolar I disorder.

The patient had a serious adverse event of suicidal ideation twenty-one days after completing randomized treatment to 300 mg. This event was considered by the investigator to be moderate in intensity. The patient sent a letter to a friend detailing his suicide plan of jumping from a bridge. The friend contacted police and the patient was involuntarily hospitalized twenty-one days after the final dose of study medication. No actual suicide attempt was made. The patient was depressed and suicidal at hospital admission. The patient's lithium dose was increased from 900 mg (the dose prescribed four days after study

completion) to 1200 mg and he was started on fluoxetine. The patient was no longer suicidal twenty-three days after the final dose of study medication and the event was considered resolved. Temazepam (RESTORIL®, Mallinckrodt) was given for bipolar disorder thirty-three, thirty-five, thirty-eight, and forty-one days after the final dose of study medication. The patient was discharged from the hospital forty-four days after the final dose of study medication. At discharge, the patient was free of suicidal ideation, his depression had improved, and a treatment plan was in place.

The patient had no relevant medical history. No relevant medications were taken prior to study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the suicidal ideation to be not related to study treatment.

Study 5077US/0049 Patient 0023/034 300 mg

Serious: Adnexa Uteri Pain

This narrative concerns an 18-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of ovarian cyst pain (MedDRA: adnexa uteri pain) four days after the last dose of randomized study treatment to 300 mg that was considered by the investigator to be severe in intensity. The investigator did not consider the event significant enough to warrant withdrawal from the study. However, the investigator withdrew the patient because of poor protocol compliance. The last dose of study treatment was taken on Day 49. The onset of ovarian cyst pain occurred four days after the last dose of study treatment. Study treatment was not withdrawn for this event. Per patient report, hospital discharge occurred five days after the last dose of study treatment. The patient refused to release medical records from the hospitalization; therefore, no further information is available with regard to the event.

The patient's medical history and screening physical examination were unremarkable. The final visit physical examination performed nine days after the last dose was significant for ovarian cyst. Before entering the study, the patient was not taking any medications. During the study, the patient took ibuprofen 400 mg/day for a non-serious adverse event of dysmenorrhea from Day 17 to Day 19. This event was considered to be moderate in intensity and not related to study treatment. On Days 24 through 28 and Day 32 through four days after the last dose of study treatment the subject had two non-serious adverse events of nausea that were both considered by the investigator to be moderate in intensity and not related to study treatment.

The investigator considered the adnexa uteri pain to be not related to study treatment.

Study 5077US/0049 Patient 0026/003 600 mg

Serious: Prostatitis

This narrative concerns a 46-year-old white man with bipolar II disorder.

The patient had a serious adverse event of acute prostatitis (MedDRA: prostatitis) on Day 57 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. On Day 50 of randomized treatment the patient had fever, chills, night sweats, diarrhea, vomiting, dysuria, headache, nuchal rigidity, and increased urinary frequency. On Day 57 the patient was hospitalized for these symptoms. The table below outlines the assessments performed during this hospitalization. According to hospital records, prior to cerebrospinal fluid (CSF) results, the patient was given ceftriaxone sodium 2 mg IV every 12 hours for suspected meningitis. With growth of Klebsiella in the urine, and only two white blood cells (WBC) detected in spinal fluid, a prostatic exam was performed which showed a mildly enlarged, firm prostate. The patient was switched to levofloxacin 500 mg/day for acute prostatitis. The patient also received morphine hydrochloride and hydrocodone with acetaminophen for the acute prostatitis. Study treatment was not discontinued for this event and the patient took his final dose of study treatment on Day 57 while in the hospital. The patient was discharged in stable condition three days after the completion of study treatment. Five days after the completion of study treatment the prostatitis resolved.

Table 7 Clinical Assessments

Study day	Assessments	Results with details from hospital records
Day 57	Chest x-ray	Normal
Day 57	Head CT	Normal
Day 57	Acute abdominal series	Reported as normal with the exception of some air filled non-dilated small bowel loops in the right mid-abdomen
Day 57	Lumbar Puncture	CSF with 2 WBCs, protein = 87 gm/dL, and negative Gram stain
Day 57	Blood cultures	No growth
Day 57	Liver function tests	Essentially normal
Day 57	EKG	Normal
Day 57	Urine culture	Grew greater than 100,000 colony-forming units of Klebsiella that was sensitive to fluoroquinolones as well as third generation cephalosporins

Hospital records showed that the patient also had a relevant medical history of hepatitis B, human immunodeficiency virus (HIV), non-Hodgkin's lymphoma, and seizure disorder. This information was not disclosed to the site personnel at the screening visit. The patient's screening physical examination was unremarkable. The end of study physical examination revealed a diffusely tender abdomen, which was attributed to the diagnosis of prostatitis.

Before entering the study, the patient was taking topiramate (TOPAMAX®, Ortho-McNeil), gabapentin (NEURONTIN®, Parke-Davis), lopinavir / ritonavir (KALETRA®, Abbott) for HIV, and lamivudine / zidovudine (COMBIVIR®, GlaxoSmithKline) for HIV. These medications were not disclosed at screen and according to hospital records, were continued by the patient during the study.

The investigator considered the prostatitis to be not related to study treatment.

Study 5077US/0049 Patient 0026/023 600 mg

Serious: Mental Status Changes

This narrative concerns a 20-year-old white man with bipolar II disorder.

The patient had a serious adverse event of altered mental status (MedDRA: mental status changes) three days after the completion of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The patient arrived at the study clinic for his final scheduled visit somnolent, unsteady, incoherent, and complaining of nausea and dizziness. Several sets of vital signs were recorded during the patient's visit; on one occasion, the patient was hypotensive (60/48) and tachycardic (150 bpm). The hypotension was reported as a non-serious adverse event. The patient reported that he had not eaten in three days and the attending physician suspected dehydration. The patient was given juice and food. Following oral food and fluid, the patient's vital signs were normal, but the patient's level of somnolence increased to the point of being difficult to arouse. The patient was taken via ambulance to the emergency room and admitted for evaluation. Per medical records, the subject did not receive any treatment for this event. Assessments performed during the patient's hospitalization are listed in the table below. Based on the results of these assessments, it was concluded that the patient's mental status changes were likely of psychiatric etiology. Four days after the completion of randomized treatment the serious adverse event of mental status changes was considered to be resolved and the patient was discharged from the hospital.

Table 8 Clinical Assessments

Study day	Assessments	Results
Three days after completion	CT Scan	Normal
	Chest x-ray	Normal
	Liver Function Tests	ALT = 13 units/L (5-35 units/L) AST = 16 units/L (10-40 units/L)
	Electrolytes	Normal
	Creatinine	1.0 mg/dL (0.3-1.0 mg/dL)
	Glucose	78 mg/dL (less than 140 mg/dL)

Study day	Assessments	Results
	CPK	111 IU/L (15-190 IU/L)
	Ammonia	33 uMol/L (11-35 umol/L)
	ETOH level	Less than 4 mg/dL
	Tylenol level	Less than 10 mcg/mL (toxic levels greater than 150 mcg/mL)
	CBC	Within normal limits, except for mild anemia
	Salicylate level	Less than 10 mg/dL (toxic levels greater than 30 mg/dL)
	Urine drug screen	Negative
	Hemoglobin	13.2 g/dL (14-18 g/dL)

The patient had a relevant medical history of past alcohol abuse. The screening physical examination was unremarkable. An end of study physical examination was not performed.

The investigator considered the mental status changes to be not related to study treatment.

Study 5077US/0049 Patient 0026/027 placebo

Serious: Convulsions NOS

This narrative concerns a 40-year-old white woman with bipolar II disorder.

The patient had a serious adverse event of seizure (MedDRA: convulsions NOS) on Day 1 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. On Day 7 of randomized treatment, the patient contacted the study site to report that she had experienced a possible seizure on the day of her baseline visit, prior to taking her first dose of study medication. The patient stated that after leaving the study site, she went to the grocery store and woke up in an ambulance. While in the emergency room, she was told that she had a possible seizure. The patient was started on phenytoin (DILANTIN®, Parke-Davis) 300 mg/day for seizures. The patient stated that she left the hospital against medical advice and that she was not admitted to the hospital. After being informed of the event, the investigator discontinued study treatment. The patient's last dose of study treatment was on Day 5. The patient refused to sign a medical release for hospital records, but did admit to having a history of seizures. This information was not provided at screen.

The patient's screening physical examination was unremarkable. The subject refused to return to the clinic for a follow-up examination. The patient's medical history was unremarkable except for a past history of seizures. No relevant medications were given prior to study treatment.

The investigator considered the convulsions NOS to be not related to study treatment.

Study 5077US/0049 Patient 0026/028 placebo

Serious: Major Depressive Disorder NOS

This narrative concerns a 35-year-old white man with bipolar I disorder.

The patient had a serious adverse event (SAE) of psychotic depression (MedDRA: major depressive disorder NOS) on Day 22 of randomized treatment to placebo that was considered by the investigator to be severe in intensity.

Nine days after the patient's last dose of study treatment, the patient returned to the study site for an early termination visit. During the early termination visit, the patient informed the study staff that he had been previously admitted to the hospital for major depressive disorder NOS on Day 22 of randomized treatment. Hospital records for this hospitalization (Days 22-24) were reviewed. According to the patient, he continued to take study medication during the hospitalization for major depressive disorder, although this is not reflected in the hospital records. The patient took his last dose of study treatment on Day 25. During the hospitalization for this event, the patient was treated with gabapentin (NEURONTIN®, Parke-Davis), oxcarbazepine (TRILEPTAL®, Novartis), risperidone (RISPERDAL®, Janssen), quetiapine fumarate (SEROQUEL®, AstraZeneca), and escitalopram oxalate (LEXAPRO®, Forest) for bipolar condition, acetaminophen (TYLENOL®, McNeil Consumer) for headache, zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) for insomnia, clonazepam (KLONOPIN®, Roche) for agitation, ramipril (ALTACE®, Monarch) and atenolol for hypertension, and pantoprazole sodium (PROTONIX®, Wyeth) for gastro-reflux. The patient was discharged against medical advice on Day 24 of randomized treatment. At the time of the early termination visit, the event of major depressive disorder was ongoing. The patient was lost to follow-up after the early termination visit and it is unknown when the event resolved.

The investigator considered the major depressive disorder NOS to be not related to study treatment.

Serious: Acute Psychosis

The patient had a serious adverse event of acute psychosis on Day 26 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. According to Emergency Room admission records, the patient was brought to the hospital by police, and admitted for paranoid schizophrenia, auditory hallucinations, suicidal ideation, left anterior chest pain, and palpitations. The patient stated that he used amphetamines the evening prior to his admission, however urine drug screen results were negative for amphetamines. A urine test for alcohol was also negative. The patient took his last dose of study treatment on Day 25, one day before admission to the hospital for acute psychosis. At his early termination visit nine days after the last dose of study treatment, the patient reported that he was hospitalized for four days. The patient did not provide a release form for hospital records and was lost to

follow-up after the early termination visit; therefore, confirmation and details of this hospitalization are not available. During the early termination visit, the patient informed the coordinator that he had been hospitalized for a major depressive disorder from Day 22 to Day 24, prior to the hospitalization for acute psychosis (see separate narrative). The investigator withdrew the patient from the study because of these two serious adverse events.

The investigator considered the serious adverse event of acute psychosis to be not related to study treatment.

The patient's medical history and screening and final visit physical examinations were unremarkable. No relevant medications were taken prior to study treatment.

Note: This patient was enrolled at two separate study sites. His other enrollment number was (E0028031). Both sites reported this patient as having a serious adverse event. The separate narratives reflect the information provided by the separate sites.

Study 5077US/0049 Patient 0028/003 placebo

Serious: Cholecystitis NOS

This narrative concerns a 53-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of cholecystitis exacerbation (MedDRA: cholecystitis NOS) on Day 4 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. The patient had a history of cholecystitis that was asymptomatic at screen. Exacerbation of the cholecystitis began on Day 4. The patient took oxycodone / acetaminophen (PERCOCET®, Endo) for the event on Day 15 and Day 16. Due to worsening symptoms, a cholecystectomy was scheduled. On Day 36, the cholecystectomy was performed and the cholecystitis resolved. The patient remained in the hospital overnight for post-operative care and she was discharged on Day 37. Treatment was not withdrawn due to this event and the patient's final dose of study medication was taken on Day 57.

The patient had a non-serious adverse event of post procedural pain starting on Day 36 and ending on Day 42 that was considered by the investigator to be moderate in intensity and not related to study treatment. The patient had a relevant medical history of past cholecystitis, current obesity, and was post menopausal. The patient had not been treated with any relevant medications before entering the study. The patient took an herbal preparation as prophylaxis from Day 18 to Day 22. General anaesthesia was used on Day 36 for gall bladder surgery. Surgery pain was treated with meperidine hydrochloride (DEMEROL®, Sanofi-Synthelabo) on Day 36 and hydrocodone bitartrate / acetaminophen (VICODIN®, Abbott) from Day 37 to Day 38. The screening physical examination was unremarkable. The final visit physical examination revealed a cholecystectomy scar on the abdomen.

The investigator considered the cholecystitis NOS to be not related to study treatment.

Study 5077US/0049 Patient 0028/007 600 mg

Serious: Non-accidental Overdose

This narrative concerns a 22-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of overdose of study medication (intentional) (MedDRA: non-accidental overdose) on Day 39 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The patient used crystal methamphetamine on Day 38. The morning of Day 39 the patient began experiencing a panic attack and took 8 tabs of study medication in an attempt to alleviate the panic attack symptoms. The patient had nausea and vomiting after taking the 8 tabs of study medication. The patient's husband took her to the emergency room where she was given 50 grams of activated charcoal, a NG tube, and 20 MEQ of potassium chloride (KCL). The patient recovered and was discharged on that same day. This event was considered by the investigator to be an important medical event. The study medication overdose was intentional, but was not considered a suicide attempt. The patient returned to the clinic on Day 42 and was withdrawn from the study due to the illicit drug use with methamphetamine. The final dose of study medication was taken on Day 41.

Table 9 Clinical Assessments

Study day	Assessments	Results
Day 39	Potassium	3.1 mmol/L
	Glucose	155 mg/dL
	Creatinine	0.6 mg/dL
	Toxicology	Positive for Amphetamines
	RDW	10.9 %
	Neutrophils	71.1 %
	Lymphs	15.7 %

The patient had a non-serious adverse event of drug abuse (methamphetamine) on Day 38 which was considered by the investigator to be severe in intensity and not related to study drug. The patient had a non-serious adverse event of panic attack on Day 39, which was considered by the investigator to be severe in intensity and not related to study drug. Also on Day 39, the patient had non-serious adverse events of nausea and vomiting, which were considered by the investigator to be severe in intensity and related to study drug. The patient had a relevant past medical history of polysubstance abuse. No relevant concomitant medications were taken prior to study treatment. During the study, the patient was treated with activated charcoal and KCL on Day 39 for treatment of non-accidental overdose. No other relevant concomitant medications were given during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the non-accidental overdose to be not related to study treatment.

Study 5077US/0049 Patient 0028/023 600 mg

Serious: Suicide Attempt

This narrative concerns a 55-year-old black man with bipolar I disorder.

The patient had a serious adverse event of suicide attempt on Day 48 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The patient reported his last dose of study medication was taken on Day 48. At some point prior to the suicide attempt, the patient began experiencing suicidal ideation (exact start date unknown). On the day of the suicide attempt, the patient was found unconscious and transported by ambulance to the acute care hospital where he was admitted to the intensive care unit for management of a drug or alcohol overdose. An initial blood alcohol level was 0.186%. The patient was treated with naloxone hydrochloride (NARCAN®, Endo) because, at the time the ambulance technicians first found him, he was wearing several medication skin patches thought to be fentanyl transdermal system (DURAGESIC®, Janssen) patches. He was also managed with charcoal by gastric lavage. His initial urine drug screen was negative, however, and the final diagnoses from the acute care hospital were suicide attempt and alcohol overdose. The patient was treated with sertraline hydrochloride (ZOLOFT®, Pfizer) for depression, beginning on the day of hospital admission (Day 48). The event of suicide attempt resolved on Day 48; however, the patient continued to experience suicidal ideation. Three days after the patient's last dose of study medication, he was stabilized and transferred to a mental hospital for further treatment because he continued to pose a risk to himself. Suicidal ideation resolved and the patient was discharged twenty-four days after the last dose of study medication. Study treatment was withdrawn due to the suicide attempt.

Table 10 Clinical Assessments Performed During Hospitalization

Study day	Assessments	Results
Day 48	CT Scan	Head; showed no acute disease and showed evidence of old, small left cerebellar stroke
	Urine Drug Screen	Negative
	ETOH Blood Level	0.186
Two days after last dose	EEG	No evidence of seizure focus

The patient had a non-serious adverse event of seizure two days after the last dose of study medication, and was treated with 1 mg of lorazepam (ATIVAN®, Wyeth Ayerst) and phenytoin (DILANTIN®, Parke-Davis) 900 mg/day. These events were considered by the investigator to be severe in intensity and not related to study medication. The patient reported

a medical history of chronic back pain at the screening visit. Hospital records indicated that the patient also had a medical history of hypothyroidism, past alcohol abuse, past polysubstance abuse, hepatitis C, seizure disorder (secondary to head trauma), myocardial infarction, and stroke. The patient did not disclose this medical history to the site personnel at the screening visit. The patient did not report taking any relevant medications prior to entering the study. However, according to the medical records, the managing physicians at the two hospitals learned that the patient had been prescribed phenytoin (DILANTIN®, Parke-Davis) intermittently for many years for management of his seizure disorder. The patient had not taken the prescribed phenytoin (DILANTIN®, Parke-Davis) for several weeks or months prior to hospital admission because he had run out of his prescription. In addition, the patient told his hospital physicians that he commonly acquired medication in Mexico, including hydrocodone bitartrate and acetaminophen (VICODIN®, Abbott) and oxycodone hydrochloride controlled-release (OXYCONTIN®, Purdue Pharma), which he takes for his chronic back pain. The screening and final visit physical examinations were unremarkable.

The investigator considered the suicide attempt to be not related to study treatment.

Study 5077US/0049 Patient 0028/031 placebo

Serious: Hallucination, Auditory

This narrative concerns a 35-year-old white man with bipolar I disorder.

The patient had a serious adverse event of self mutilating auditory hallucinations (MedDRA: hallucination, auditory) one day after the last dose of randomized treatment to placebo that was considered by the investigator to be severe in intensity. The patient took his last dose of study treatment on Day 16. Three days after the last dose of study treatment, the patient went to the hospital emergency room with auditory hallucinations that were telling him to self mutilate. The patient was considered a danger to himself and was admitted to the behavioral health unit of the hospital for treatment. Four days after the last dose of study treatment the patient began treatment with gabapentin (NEURONTIN®, Parke-Davis) 1800 mg/day, lithium 1200 mg/day, risperidone (RISPERDAL®, Janssen) 2 mg/day, benztropine mesylate (COGENTIN®, Merck) 0.5 mg/day, and clonazepam (KLONOPIN®, Roche) 1 mg/day for bipolar disorder. The self mutilating auditory hallucinations resolved five days after the last dose of study treatment and the patient was discharged from the hospital. The investigator did not consider the event significant enough to warrant withdrawal of study treatment. However, the patient withdrew from the study due to this event. The patient's final study visit was twenty-two days after the he took his final dose of study medication.

The patient had non-serious adverse events of headache and somnolence starting on Day 3 and ending two days after the last dose of study treatment. These events were considered by the investigator to be mild and moderate in intensity, respectively, and related to study treatment. The patient did not have any relevant medical history. No relevant medications were taken prior to the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the hallucination, auditory to be not related to study treatment.

Note: This patient was enrolled at two separate study sites. His other enrollment number was (E0026028). Both sites reported this patient as having a serious adverse event. The separate narratives reflect the information provided by the separate sites.

Study 5077US/0049 Patient 0028/032 600 mg

Serious: Bipolar I Disorder

Serious: Suicidal Ideation

This narrative concerns a 36-year-old white man with bipolar II disorder.

The patient had a serious adverse event of mixed episode with psychosis (MedDRA: bipolar I disorder) on Day 55 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. Eighteen days after the last dose of study treatment the patient returned to the clinic for his last study visit and reported that he was not able to return sooner because he had been hospitalized. On Day 56 of randomized treatment the patient took his last dose of study treatment. One day later, he went to his normally scheduled psychiatric visit and was hospitalized for bipolar I disorder and suicidal ideation. The patient had auditory hallucinations telling him to self-mutilate and kill himself, and was treated for superficial self-inflicted cuts from a razor on both his right and left forearms. He also had urinary incontinence, which was attributed to his instability. Significant assessments performed during this hospitalization are listed in the table below. During his hospitalization, the patient was treated with bupropion (WELLBUTRIN®, GlaxoSmithKline), olanzapine (ZYPREXA®, Lilly), topiramate (TOPAMAX®, Ortho-McNeil), risperidone (RISPERDAL®, Janssen), and doxepin hydrochloride (SINEQUAN®, Pfizer). Nine days after the patient's last dose of study treatment, the serious adverse event of bipolar I disorder resolved and the patient was discharged without psychosis.

Table 11 Clinical Assessments

Study day	Assessments	Results
Day 57	Urine drug screen	Positive for Propoxyphene
Day 57	Urinalysis	Ketones 1+
Day 57	Urinalysis	Specific gravity – 1.030 (reference range > 1.005)

Hospital records indicated that the patient had a medical history of suicidal ideation, auditory hallucinations, self-mutilation, and urinary incontinence, although the patient did not admit to this history at screen. The screening and final visit physical examinations were unremarkable.

The investigator considered the bipolar I disorder and suicidal ideation to be not related to study treatment.

Study 5077US/0049 Patient 0028/045 300 mg

Serious: Suicidal Ideation

This narrative concerns a 46-year-old white man with bipolar I disorder.

The patient had a serious adverse event of suicidal ideation with acute psychosis (MedDRA: suicidal ideation) on Day 39 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The patient visited the study site on Day 13 and did not contact the site personnel again until Day 72. On Day 72 the patient reported that since his last visit to the study site, he had been hospitalized for suicidal ideation. On Day 39 the patient presented at the emergency room complaining of being delusional, having a persecution complex, and feeling suicidal. The patient did not have a suicide plan. The patient was hypomanic with pressured speech, had disorganized thoughts, and lability. The patient was also having auditory hallucinations and appeared paranoid with psychotic features. The patient voluntarily admitted himself to the hospital on Day 39. During the hospitalization, the patient was treated with aripiprazole (ABILIFY®, Bristol-Myers Squibb and Otsuka America Pharmaceuticals), lithium, topiramate (TOPAMAX®, Ortho-McNeil), haloperidol (HALDOL®, Ortho-McNeil), lorazepam (ATIVAN®, Wyeth Ayerst), methocarbamol (ROBAXIN®, Schwarz Pharma), and quetiapine fumarate (SEROQUEL®, AstraZeneca). The suicidal ideation resolved on Day 42, and the patient was discharged from the hospital on Day 44. The patient withdrew from the study due to this event. The patient's last study treatment blister card was dispensed on Day 13, containing nine days of study treatment doses. The patient's final study treatment day and dose is unknown. However, for the purpose of case report form completion, Day 21 has been used as the estimated last dose of study treatment. The patient's final study visit was on Day 86.

Table 12 Clinical Assessments Performed During Hospitalization (Days 39 – 44)

Study day	Assessments	Results
UNK	WBC	7.6 x 10^3/mm^3
	Hematocrit	39.7 %
	MCV	92 FL
	Platelets	153 x 10^3/μL
	BUN	7 mg/dL
	Creatinine	0.9 mg/dL
	Potassium	3.5 mmol/L
	Librium	< 0.2
	Sodium	144 mmol/L
	Bicarbonate	28 mmol/L
	Chloride	113 mmol/L

Study day	Assessments	Results
	Glucose	81 mg/dL
	Calcium	8.9 mg/dL
	Ethanol	No Measurable Amount
	Toxicology Screen	Positive for Amphetamine

The patient had non-serious adverse events of dyskinesia, headache, and insomnia starting on Day 28 and ongoing at the patient's final study visit (Day 86). These events were considered by the investigator to be moderate in intensity and not related to study treatment. The patient had a non-serious adverse event of mania starting on Day 28 and ending on Day 42 that was considered by the investigator to be severe in intensity and not related to study treatment. The patient had a non-serious adverse event of methamphetamine abuse starting on Day 45 and ending on Day 56. The patient also had a non-serious adverse event of injury resulting from a falling episode secondary to methamphetamine abuse starting and ending on Day 55. Both of these events were considered by the investigator to be moderate in intensity and not related to study treatment.

The investigator considered the suicidal ideation to be not related to study treatment.

Serious: Bipolar I Disorder

The patient had a serious adverse event of bipolar affective disorder mixed state with mood congruent psychosis (MedDRA: bipolar I disorder) on Day 55 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The patient visited the study site on Day 13 and did not contact the site personnel again until Day 72. On Day 72 the patient reported that since his last visit to the study site, he had been hospitalized for bipolar I disorder. The patient was initially taken to the hospital on Day 55 for acute insomnia. The patient had fallen asleep while at a local market and paramedics were called. The patient was arousable at the scene by the paramedics. The patient reported that he had not slept in four days due to methamphetamine use. Once at the emergency room, the patient had a physical exam, laboratory exam, and a CT scan of the head performed, all of which were unremarkable. During the emergency room stay, the patient demonstrated manic features, delusions, paranoia, irritability, and grave disability. At that time the subject was admitted to the psychiatric unit. The patient was complaining of being depressed, anxious, having trouble sleeping, and a poor appetite. The patient was treated for bipolar I disorder. On Day 71 the patient was considered medically stable and was discharged from the hospital. The patient withdrew from the study due to this event.

Table 13 Clinical Assessments Performed During Hospitalization (Days 55 – 71)

Study day	Assessments	Results
UNK	Urine Drug Screen	Positive for Amphetamine
	Chemistry	Unremarkable

Study day	Assessments	Results
	CBC	Unremarkable
	Urine Profile	Unremarkable
	Blood Alcohol Level	Negative

The investigator considered the bipolar I disorder to be not related to study treatment.

The patient had a relevant past medical history of post traumatic stress disorder, concussion, and substance dependence and a relevant current medical history of hypothyroidism. Before entering the study, the patient had been treated with lithium for bipolar disorder for approximately 16 years, bupropion (WELLBUTRIN®, GlaxoSmithKline) for depression for approximately 3 years, and topiramate (TOPAMAX®, Ortho-McNeil) for bipolar disorder for approximately 3 years. Medical records indicated that the patient was also prescribed aripiprazole (ABILIFY®, Bristol-Myers Squibb and Otsuka America Pharmaceuticals) for bipolar disorder approximately one month prior to study entry. However, the patient did not disclose this information at screen, and it is unknown if this medication was taken concomitantly during study treatment. The patient was also being treated with levothyroxine (SYNTHROID®, Abbott) for hypothyroidism, which continued through study treatment. Seven days prior to randomization, the patient was given lorazepam (ATIVAN®, Wyeth Ayerst) for anxiety, which continued through study treatment. The following relevant medications were given on Day 28 of the study and were ongoing at the patient's final study visit: lithium, bupropion (WELLBUTRIN®, GlaxoSmithKline), topiramate (TOPAMAX®, Ortho-McNeil), paroxetine hydrochloride (PAXIL®, GlaxoSmithKline), aripiprazole (ABILIFY®, Bristol-Myers Squibb and Otsuka America Pharmaceuticals), quetiapine fumarate (SEROQUEL®, AstraZeneca), and divalproex sodium (DEPAKOTE®, Abbott). Bupropion (WELLBUTRIN® SR, GlaxoSmithKline) was given for bipolar disorder on Day 59 and was ongoing at the patient's final study visit. Also given during the study were haloperidol (HALDOL®, Ortho-McNeil) for extreme restlessness and methocarbamol (ROBAXIN®, Schwarz Pharma) for muscle spasms, both starting on Day 28 of the study and ongoing at the patient's final study visit. The screening and final visit physical examinations were unremarkable.

Study 5077US/0049 Patient 0031/021 300 mg

Serious: Injury

This narrative concerns a 27-year-old black man with bipolar II disorder.

The patient had a serious adverse event of stab wounds (MedDRA: injury) on Day 36 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The patient was attacked by someone he knew and stabbed with scissors in the neck, shoulder, and knee. The patient was hospitalized as a result of this event. During the hospitalization, the patient had suture repair of lacerations in the neck, knee, and shoulder

(with local anaesthetic) and was managed with intravenous fluids and oral analgesics. The patient was discharged from the hospital on Day 37. The event ended on Day 56, as the wounds were considered by the investigator to be healed. The investigator did not withdraw treatment due to this event. The final dose of study medication was taken on Day 54 of randomized treatment.

The patient had a non-serious adverse event of worsening of depression due to stab wounds starting on Day 36 of randomized treatment and ending on Day 47 that was considered by the investigator to be mild in intensity and not related to the study treatment. The patient did not have any relevant medical history. The screening physical examination was unremarkable. The final visit physical exam revealed the sutures for treatment of the injury. No medications were taken prior to study treatment.

The investigator considered the injury to be not related to study treatment.

Study 5077US/0049 Patient 0033/010 placebo

Serious: Ectopic Pregnancy

This narrative concerns a 26-year-old black woman with bipolar I disorder.

The patient had a serious adverse event of ectopic pregnancy diagnosed on Day 44 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. On Day 43 (day of last dose of study treatment), the patient was seen by her doctor. A pregnancy test was performed with positive results. The patient was discontinued from study treatment due to this event. According to hospital records, the patient reported having abdominal pain and vaginal bleeding at least one week prior to her doctor visit. An ultrasound was performed one day after the last dose of study treatment, which showed fluid in the abdomen and a right ovarian cyst. The patient was sent to the emergency room and exploratory surgery was performed that evening in order to rule out an ectopic pregnancy. During the surgery, the patient was diagnosed with an ectopic pregnancy, the left fallopian tube with pregnancy was removed as well as the cyst on the right ovary, and the fluid was removed from the abdomen. The event was considered resolved immediately following the surgery. The patient remained in the hospital for four days after the surgery for observation. According to hospital records, the patient was given general anaesthesia on the day of the surgery, was treated with antibiotics, and was given acetaminophen (TYLENOL®, McNeil Consumer) for pain.

Table 14 Clinical Assessments

Study day	Assessments	Results
One day after last dose	CBC	Not clinically significant
	Urinalysis	Not clinically significant
	UHCG	Positive
	Beta HCG	7133 mIU/L

The patient did not have any relevant medical history. No medications were taken by the patient before entering the study. No additional relevant concomitant medications were taken during study treatment. The screening physical examination was unremarkable. The final visit physical examination revealed a post-surgical suprapubic incision, well-healed.

The investigator considered the ectopic pregnancy to be not related to study treatment.

Study 5077US/0049 Patient 0033/014 placebo

Serious: Intervertebral Disc Herniation

This narrative concerns a 53-year-old white man with bipolar I disorder.

The patient had a serious adverse event of herniated spinal disc pain (MedDRA: intervertebral disc herniation) on Day 31 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. The patient visited the study site on Day 34 for his regularly scheduled study visit and was prescribed ibuprofen (ADVIL®, Wyeth Consumer) 200 mg/day for this pain and for an unrelated non-serious adverse event (headache). One day after the last dose of study treatment, the patient contacted the site personnel and indicated that he had been hospitalized since his Day 34 visit due to "a problem with a herniated spinal disc." The patient reported that during his hospitalization, he received parenteral analgesics. The patient also reported that he did not take study medication on some or all days of the hospitalization. The patient withdrew himself from the study and did not return to the study site for another study visit. The hospitalization and discharge days for this event were not confirmed. The event was ongoing as of the last contact with the patient, one day after the last dose of study treatment. The last confirmed dose of study medication was taken on Day 40. The investigator did not withdraw treatment due to this event.

The patient had a relevant medical history of current herniated spinal disc. Before entering the study, the patient was not treated with any medication relevant to the intervertebral disc herniation. The screening physical examination was unremarkable. A final visit physical examination was not done.

The investigator considered the intervertebral disc herniation to be not related to study treatment.

Study 5077US/0049 Patient 0035/002 placebo

Serious: Suicidal Ideation

This narrative concerns a 46-year-old white man with bipolar I disorder.

The patient had a serious adverse event of suicidal ideation on Day 24 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. The patient was hospitalized on Day 24 due to suicidal ideation. The patient had no suicide plan and no attempt was made. The patient was contacted by the site personnel during the hospitalization on Day 27. He reported during this contact that he became suicidal after arguing with his girlfriend. The last confirmed dose of study medication was taken on Day 27. The event was ongoing as of the study site personnel's last contact with the patient on Day 27. The investigator did not consider the event significant enough to warrant withdrawal of study treatment. However, the patient withdrew from the study and did not return for any additional study visits.

The patient had a relevant past medical history of alcohol (ETOH) and cocaine abuse three months prior to study treatment. Before entering the study, the patient had been treated with divalproex sodium (DEPAKOTE®, Abbott) 1000 mg/day as a mood stabilizer for 3 years. Treatment with this medication was discontinued nine days before the patient began study treatment. The patient also took 1 mg of lorazepam (ATIVAN®, Wyeth Ayerst) for insomnia eight days before study treatment began. The patient was not treated with any concomitant medications during the study. The screening physical examination was unremarkable. A final visit physical examination was not performed.

The investigator considered the suicidal ideation to be not related to study treatment.

Study 5077US/0049 Patient 0039/028 600 mg

Serious: Chest Pain

This narrative concerns a 39-year-old black man with bipolar I disorder.

The patient had a serious adverse event of chest pain (not cardiac related) (MedDRA: chest pain) on Day 46 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. Treatment was not withdrawn due to this event. On Day 46 this patient was hospitalized due to chest pain. An electrocardiogram (ECG) was done revealing non-specific s-t changes, but was otherwise normal. A chest x-ray was also done and indicated early Chronic Obstructive Pulmonary Disease (COPD) with no active lung disease and normal heart. Myocardial infarction was ruled out during this hospitalization. The patient

was given a urine drug test and results were positive for cocaine. On Day 46 the event of chest pain resolved and the patient was discharged from the hospital on Day 47. The table below outlines selected assessments performed during this patient's hospitalization.

Table 15 Clinical Assessments

Study day	Assessments	Results
Day 46	Urine Drug Test	Positive Cocaine
	Lithium	Less than 0.10 mmol/L
	ECG	WNL
	CXR	Early COPD with no active lung disease and normal heart
	CK	297 u/L , CKMB 0.9
	CK	281 u/L , CKMB 0.4
	CK	243 u/L , CKMB 0.3
	CK	239 u/L , CKMB 0.3
	CK	193 u/L , CKMB < 0.3
		normal ranges: CK (24-195 u/L) , CKMB (<2.4mg/mL)
		CKMB levels obtained from medical records

The investigator considered the chest pain to be not related to study treatment.

The patient had two adverse events of worsening hypertension that were considered by the investigator to be mild in intensity and not related to study medication. The first event started on Day 22 of randomized treatment and ended on Day 29 of randomized treatment. The second worsening of hypertension adverse event started on Day 43 of randomized treatment and ended fifteen days after the final dose of study medication was taken. During the study, the patient was given metoprolol 100 mg/day starting on Day 23 and hydrochlorothiazide 25 mg/day starting on Day 44 of randomized treatment for hypertension. Both medications were ongoing on the day of discontinuation.

Serious: Suicidal Ideation

During discharge from a hospitalization for chest pain on Day 47, the patient had a serious adverse event of suicidal ideation. The patient was transferred to a psychiatric hospital on that same day (Day 47) due to the suicidal ideation and remained hospitalized until Day 54. During the hospitalization for suicidal ideation the patient had increased auditory hallucinations and admitted to recent cocaine use. The investigator withdrew study treatment due to suicidal ideation. The patient had been taking risperidone (RISPERDAL®, Janssen) 3 mg/day and lithium 900 mg/day for bipolar disorder starting nineteen days prior to the baseline visit through two days after the final dose of study medication was taken on Day 51. The patient did not disclose to the site personnel that he was taking these medications concomitantly with study treatment. The patient had a non-serious adverse event of increased auditory hallucinations starting two days after the patient's final dose of study medication that

was considered by the investigator to be severe in intensity and not related to the study treatment. This adverse event had not resolved as of the last contact with the patient. Three days after the final dose of study medication was taken, the patient started risperidone (RISPERDAL®, Janssen) 1mg/day and lithium 600 mg/day. The suicidal ideation resolved three days after the patient's last dose of study medication, and the patient was discharged from the hospital. The patient's final study visit was also completed three days after the last dose of study medication.

The investigator considered the suicidal ideation to be not related to study treatment.

Serious: Depression

The patient had a serious adverse event of worsening of depression (MedDRA: depression) on Day 58, seven days after taking his last dose of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The patient reported that he was hospitalized for worsening of depression from fifteen days to twenty-four days after his last dose of study medication. According to the patient, the event of worsening of depression resolved twenty-one days after the patient's last dose of study medication. When the site personnel requested hospital records, the hospital indicated that there was no record of the patient being hospitalized during the dates reported by the patient.

The investigator considered the depression to be not related to study treatment.

The patient had a medical history of hypertension, acid reflux, angina, obesity, and pain in neck and shoulders. The screening and final physical examinations revealed obesity.

Study 5077US/0049 Patient 0039/030 placebo

Serious: Suicidal Ideation

This narrative concerns a 52-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of suicidal ideation nineteen days after the final dose of study medication. The event was considered by the investigator to be severe in intensity. At the final study visit, one day after the final dose of study medication, the patient was prescribed open-label quetiapine fumarate (SEROQUEL®, AstraZeneca) 200 mg/day. The actual start date of this medication is unknown. Twelve days after the final dose of study medication, the patient returned to the site and requested a decreased dose of quetiapine fumarate (SEROQUEL®, AstraZeneca). She was prescribed 25 mg, but did not have the prescription filled. The last confirmed dose of open-label quetiapine fumarate (SEROQUEL®, AstraZeneca) 200 mg/day was eleven days after the final dose of study medication. The patient was hospitalized nineteen days after the final dose of study medication due to suicidal ideation. Per hospital records the patient was described as hopeless, helpless, tearful, and suicidal at admission. Upon admission, the patient admitted to a history of multiple personality disorder, alcohol and drug dependence, and pathological gambling. During the hospitalization the patient was given fluoxetine hydrochloride (PROZAC®, Dista), initially 20 mg/day, then increased to 40 mg/day for depression. Other medications given during the

patient's hospitalization include trazodone 50 mg/day for insomnia, ibuprofen 400 mg for pain, and Mylanta (MYLANTA®, Johnson & Johnson - Merck Consumer Pharmaceutical Company) 30 cc for nausea. The patient was also given one dose of haloperidol (HALDOL®, Ortho-McNeil) for agitation. The serious adverse event of suicidal ideation resolved and the patient was discharged in stable condition twenty-five days after the final dose of study medication. The table below outlines the assessments performed during the patient's hospitalization. The exact date of the assessments is unknown.

Table 16 Clinical Assessments

Study day	Assessments	Results
UNK	AST	86 IU/L
	ALT	80 IU/L
	Potassium	3.4 mEq/L
	Calcium	8.7 mg/dL

The patient had a medical history of insomnia, arthritis, hepatitis C, obesity, and is post menopausal. According to the medical records, the patient also had a current medical history of hepatitis A and hepatitis B; however, these conditions were not disclosed to the site personnel during the screening visit. The screening and final visit physical examinations were unremarkable. Before entering the study, the patient had been treated with fluoxetine hydrochloride (PROZAC®, Dista) 20 mg/day for bipolar depression for approximately seven years. At the time of the baseline visit, the patient had not taken a dose in thirty days. Also before entering the study, the patient had been treated with temazepam 15 mg/day for insomnia for approximately eight months. At the time of the baseline visit the patient had not taken a dose in twenty-six days. No relevant concomitant medications were given during the study.

The investigator considered the suicidal ideation to be not related to study treatment.

Study 5077US/0049 Patient 0039/038 placebo

Serious: Asthma NOS

This narrative concerns a 40-year-old black woman with bipolar I disorder.

The patient had a serious adverse event of asthma attack (MedDRA: asthma NOS) on Day 13 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. The patient was hospitalized due to this event on Day 13. At the time of admission, the patient had been smoking crack cocaine and drinking alcohol for approximately three days; the admitting diagnoses included alcoholic ketoacidosis and alcohol withdrawal. Per hospital medical records, a psychiatric consultation was also performed on Day 14. The attending psychiatrist noted suicidal ideations and referred to the patient's use of crack

cocaine and alcohol as a suicide attempt. During the hospital stay the study treatment was temporarily stopped and the patient did not take study treatment doses on Days 14 – 16. Management of the patient's asthma included albuterol (Day 13 and ongoing), prednisone (Days 13-29), cortisone (Day 17), dexamethasone (DECADRON®, Merck) (Days 13 to 17), guaifenesin (ROBITUSSIN®, Wyeth Consumer Health Care) (Days 13 to 17), fluticasone propionate (FLOVENT®, GlaxoSmithKline), and azithromycin (Day 18 and ongoing). From Day 13 to Day 15, the patient received diazepam 5 mg/day for anxiety and on Day 13 the patient also received 2 mg of lorazepam (ATIVAN®, Wyeth Ayerst) for anxiety. The asthma resolved on Day 17 and the patient was discharged from the hospital on Day 18. The study treatment was restarted on Day 17.

Table 17 Clinical Assessments

Study day	Assessments	Results
Day 12	Urine protein	100 mg/dL
	Urine glucose	100 mg/dL
	Urine ketone	40 mg/dL
	Arterial oxygen saturation	95 %
Day 14	WBC	17.1 $x10^3/\mu L$
Day 15	Serum glucose	447 mg/dL
	WBC	14.0 $x10^3/\mu L$
Day 16	Serum glucose	216 mg/dL
	Glycohemoglobin ACZ	11.5%
	Hepatitis C	Positive
	WBC	16.2 $x10^3/\mu L$
Day 17	Serum glucose	361 mg/dl
	WBC	11.8 $x10^3/\mu L$
Day 18	Serum glucose	292 mg/dL
	WBC	15.8 $x10^3/\mu L$

The patient had a non-serious adverse event of accidental overdose of study medication on Day 13 (two doses were taken). This event was considered by the investigator to be moderate in intensity and not related to study treatment. The patient had a relevant medical history of asthma and obesity. The patient also tested positive for hepatitis C during hospitalization. However, a history of hepatitis C was not disclosed to the site personnel at the screening visit. The patient had not taken any relevant medications prior to study treatment. No additional relevant medications were taken during the study. The screening and final visit physical examinations were unremarkable.

The investigator considered the asthma NOS to be not related to study treatment.

Study 5077US/0049 Patient 0041/010 placebo

Serious: Mania

This narrative concerns a 32-year-old white man with bipolar I disorder.

The patient had a serious adverse event of manic episode (MedDRA: mania) on Day 39 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. The patient had decreased need for sleep, increase in irritability, reports of inappropriate social responses, feelings of restlessness, racing thoughts, difficulty concentrating, increased libido, and euphoric mood. The symptoms began on Day 39 and the patient was hospitalized due to mania on Day 43. The investigator withdrew study treatment for this event. The final dose of study treatment was taken on Day 42. During the 3-day hospitalization, the patient was treated with open-label quetiapine fumarate (SEROQUEL®, AstraZeneca) for mania (100 mg one day after last dose and 200 mg two days after last dose and at discharge), lorazepam (ATIVAN®, Wyeth Ayerst) for insomnia (1 mg/day one and two days after last dose), and divalproex sodium (DEPAKOTE®, Abbott) for mania (750 mg/day one, two, and three days after last dose). The manic episode resolved three days after the last dose of study treatment and the patient was discharged.

The patient had a relevant medical history of intermittent anxiety, intermittent agitation, and intermittent insomnia. Before entering the study, the patient had been treated for approximately seven weeks with divalproex sodium (DEPAKOTE® ER, Abbott) 1500 mg/day for bipolar disorder. Treatment with divalproex sodium (DEPAKOTE® ER, Abbott) was discontinued eight days before the patient took the first dose of study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the mania to be not related to study treatment.

Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY EVENT LEADING TO DISCONTINUATION		29	16.2	47	26.1	15	8.3
EYE DISORDERS	TOTAL	0	0	1	0.6	0	0
	VISION BLURRED	0	0	1	0.6	0	0
GASTROINTESTINAL DISORDERS	TOTAL	3	1.7	4	2.2	1	0.6
	CONSTIPATION	0	0	1	0.6	0	0
	DRY MOUTH	0	0	2	1.1	0	0
	DUODENAL ULCER HAEMORRHAGE	0	0	0	0	1	0.6
	DYSPHAGIA	0	0	1	0.6	0	0
	NAUSEA	3	1.7	0	0	0	0
	TOOTH DISORDER NOS	0	0	1	0.6	0	0
	VOMITING NOS	1	0.6	0	0	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	4	2.2	2	1.1	0	0
	FATIGUE	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG209.SAS
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Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	0	0	1	0.6	0	0
	LETHARGY	4	2.2	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	0	0	2	1.1
	HIP FRACTURE	0	0	0	0	1	0.6
	NON-ACCIDENTAL OVERDOSE	0	0	0	0	1	0.6
	SPINAL FRACTURE NOS	0	0	0	0	1	0.6
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	0	0	3	1.7	1	0.6
	BACK PAIN	0	0	0	0	1	0.6
	JOINT STIFFNESS	0	0	1	0.6	0	0
	LIMB DISCOMFORT NOS	0	0	1	0.6	0	0
	MUSCLE CRAMP	0	0	1	0.6	0	0
	MUSCLE TWITCHING	0	0	1	0.6	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	TOTAL	1	0.6	0	0	0	0
	CHRONIC LYMPHOCYTIC LEUKAEMIA NOS	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG209.SAS
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Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	TOTAL	20	11.2	31	17.2	2	1.1
	AKATHISIA	1	0.6	3	1.7	0	0
	BALANCE IMPAIRED NOS	3	1.7	0	0	0	0
	CONVULSIONS NOS	0	0	0	0	1	0.6
	COORDINATION ABNORMAL NOS	1	0.6	0	0	0	0
	DISTURBANCE IN ATTENTION	1	0.6	0	0	0	0
	DIZZINESS	1	0.6	6	3.3	0	0
	DYSARTHRIA	1	0.6	1	0.6	0	0
	DYSKINESIA	1	0.6	0	0	0	0
	DYSTONIA	0	0	1	0.6	0	0
	EXTRAPYRAMIDAL DISORDER	0	0	0	0	1	0.6
	HEADACHE	0	0	1	0.6	0	0
	PARAESTHESIA	0	0	1	0.6	0	0
	RESTLESS LEGS SYNDROME	1	0.6	2	1.1	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG209.SAS
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Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	SEDATION	10	5.6	17	9.4	0	0
	SOMNOLENCE	7	3.9	5	2.8	0	0
	SYNCOPE	0	0	1	0.6	0	0
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	TOTAL	0	0	0	0	1	0.6
	ECTOPIC PREGNANCY	0	0	0	0	1	0.6
PSYCHIATRIC DISORDERS	TOTAL	7	3.9	11	6.1	7	3.9
	ACUTE PSYCHOSIS	0	0	0	0	1	0.6
	ANXIETY	2	1.1	1	0.6	1	0.6
	BRUXISM	0	0	1	0.6	0	0
	CONFUSIONAL STATE	0	0	1	0.6	0	0
	CONVERSION DISORDER	1	0.6	0	0	0	0
	DELUSION NOS	0	0	1	0.6	0	0
	DISORIENTATION	1	0.6	0	0	0	0
	DISSOCIATIVE DISORDER NOS	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG209.SAS
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Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	FLAT AFFECT	0	0	1	0.6	0	0
	HALLUCINATION, AUDITORY	0	0	0	0	1	0.6
	HYPOMANIA	0	0	1	0.6	0	0
	INSOMNIA	0	0	0	0	1	0.6
	IRRITABILITY	1	0.6	2	1.1	0	0
	LIBIDO DECREASED	0	0	1	0.6	0	0
	LOSS OF LIBIDO	1	0.6	0	0	0	0
	MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	1	0.6
	MANIA	0	0	1	0.6	2	1.1
	PANIC DISORDER NOS	1	0.6	0	0	0	0
	PARANOIA	1	0.6	1	0.6	0	0
	RESTLESSNESS	1	0.6	0	0	0	0
	SUICIDAL IDEATION	1	0.6	1	0.6	0	0
	SUICIDE ATTEMPT	1	0.6	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG209.SAS
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Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	SUSPICIOUSNESS	1	0.6	0	0	0	0
RENAL AND URINARY DISORDERS	TOTAL	0	0	1	0.6	0	0
	URINARY INCONTINENCE	0	0	1	0.6	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	1	0.6	2	1.1	0	0
	DYSPNOEA	1	0.6	1	0.6	0	0
	NASAL CONGESTION	0	0	1	0.6	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	0	0	1	0.6	1	0.6
	RASH NOS	0	0	0	0	1	0.6
	SWEATING INCREASED	0	0	1	0.6	0	0
SOCIAL CIRCUMSTANCES	TOTAL	0	0	2	1.1	0	0
	DRUG ABUSER NOS	0	0	2	1.1	0	0
VASCULAR DISORDERS	TOTAL	1	0.6	3	1.7	1	0.6
	DEEP VEIN THROMBOSIS	0	0	1	0.6	1	0.6
	ORTHOSTATIC HYPOTENSION	1	0.6	2	1.1	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG209.SAS
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Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
ANY EVENT LEADING TO DISCONTINUATION		16	13.3	28	23.3	13	11.0	13	22.0	19	31.7	2	3.2
EYE DISORDERS	TOTAL	0	0	0	0	0	0	0	0	1	1.7	0	0
	VISION BLURRED	0	0	0	0	0	0	0	0	1	1.7	0	0
GASTROINTESTINAL DISORDERS	TOTAL	2	1.7	1	0.8	1	0.8	1	1.7	3	5.0	0	0
	CONSTIPATION	0	0	0	0	0	0	0	0	1	1.7	0	0
	DRY MOUTH	0	0	1	0.8	0	0	0	0	1	1.7	0	0
	DUODENAL ULCER HAEMORRHAGE	0	0	0	0	1	0.8	0	0	0	0	0	0
	DYSPHAGIA	0	0	0	0	0	0	0	0	1	1.7	0	0
	NAUSEA	2	1.7	0	0	0	0	1	1.7	0	0	0	0
	TOOTH DISORDER NOS	0	0	0	0	0	0	0	0	1	1.7	0	0
	VOMITING NOS	1	0.8	0	0	0	0	0	0	0	0	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	1	0.8	1	0.8	0	0	3	5.1	1	1.7	0	0
	FATIGUE	0	0	0	0	0	0	0	0	1	1.7	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG210.SAS
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Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	0	0	1	0.8	0	0	0	0	0	0	0	0
	LETHARGY	1	0.8	0	0	0	0	3	5.1	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	0	0	2	1.7	0	0	0	0	0	0
	HIP FRACTURE	0	0	0	0	1	0.8	0	0	0	0	0	0
	NON-ACCIDENTAL OVERDOSE	0	0	0	0	1	0.8	0	0	0	0	0	0
	SPINAL FRACTURE NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	0	0	0	0	1	0.8	0	0	3	5.0	0	0
	BACK PAIN	0	0	0	0	1	0.8	0	0	0	0	0	0
	JOINT STIFFNESS	0	0	0	0	0	0	0	0	1	1.7	0	0
	LIMB DISCOMFORT NOS	0	0	0	0	0	0	0	0	1	1.7	0	0
	MUSCLE CRAMP	0	0	0	0	0	0	0	0	1	1.7	0	0
	MUSCLE TWITCHING	0	0	0	0	0	0	0	0	1	1.7	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG210.SAS
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Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	TOTAL	0	0	0	0	0	0	1	1.7	0	0	0	0
	CHRONIC LYMPHOCYTIC LEUKAEMIA NOS	0	0	0	0	0	0	1	1.7	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	11	9.2	17	14.2	1	0.8	9	15.3	14	23.3	1	1.6
	AKATHISIA	0	0	2	1.7	0	0	1	1.7	1	1.7	0	0
	BALANCE IMPAIRED NOS	0	0	0	0	0	0	3	5.1	0	0	0	0
	CONVULSIONS NOS	0	0	0	0	0	0	0	0	0	0	1	1.6
	COORDINATION ABNORMAL NOS	1	0.8	0	0	0	0	0	0	0	0	0	0
	DISTURBANCE IN ATTENTION	0	0	0	0	0	0	1	1.7	0	0	0	0
	DIZZINESS	1	0.8	1	0.8	0	0	0	0	5	8.3	0	0
	DYSARTHRIA	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	DYSKINESIA	1	0.8	0	0	0	0	0	0	0	0	0	0
	DYSTONIA	0	0	1	0.8	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG210.SAS
GENERATED: 12JUL2005 17:39:28 iceadmn3

Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NERVOUS SYSTEM DISORDERS	EXTRAPYRAMIDAL DISORDER	0	0	0	0	1	0.8	0	0	0	0	0	0
	HEADACHE	0	0	0	0	0	0	0	0	1	1.7	0	0
	PARAESTHESIA	0	0	0	0	0	0	0	0	1	1.7	0	0
	RESTLESS LEGS SYNDROME	1	0.8	1	0.8	0	0	0	0	1	1.7	0	0
	SEDATION	5	4.2	7	5.8	0	0	5	8.5	10	16.7	0	0
	SOMNOLENCE	5	4.2	4	3.3	0	0	2	3.4	1	1.7	0	0
	SYNCOPE	0	0	1	0.8	0	0	0	0	0	0	0	0
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	TOTAL	0	0	0	0	1	0.8	0	0	0	0	0	0
	ECTOPIC PREGNANCY	0	0	0	0	1	0.8	0	0	0	0	0	0
PSYCHIATRIC DISORDERS	TOTAL	4	3.3	8	6.7	6	5.1	3	5.1	3	5.0	1	1.6
	ACUTE PSYCHOSIS	0	0	0	0	1	0.8	0	0	0	0	0	0
	ANXIETY	0	0	1	0.8	0	0	2	3.4	0	0	1	1.6
	BRUXISM	0	0	0	0	0	0	0	0	1	1.7	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	0	0	0	0	0	0	0	0	1	1.7	0	0
	CONVERSION DISORDER	1	0.8	0	0	0	0	0	0	0	0	0	0
	DELUSION NOS	0	0	1	0.8	0	0	0	0	0	0	0	0
	DISORIENTATION	0	0	0	0	0	0	1	1.7	0	0	0	0
	DISSOCIATIVE DISORDER NOS	0	0	0	0	1	0.8	0	0	0	0	0	0
	FLAT AFFECT	0	0	1	0.8	0	0	0	0	0	0	0	0
	HALLUCINATION, AUDITORY	0	0	0	0	1	0.8	0	0	0	0	0	0
	HYPOMANIA	0	0	0	0	0	0	0	0	1	1.7	0	0
	INSOMNIA	0	0	0	0	1	0.8	0	0	0	0	0	0
	IRRITABILITY	1	0.8	1	0.8	0	0	0	0	1	1.7	0	0
	LIBIDO DECREASED	0	0	1	0.8	0	0	0	0	0	0	0	0
	LOSS OF LIBIDO	0	0	0	0	0	0	1	1.7	0	0	0	0
	MAJOR DEPRESSIVE DISORDER NOS	0	0	0	0	1	0.8	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG210.SAS
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Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	MANIA	0	0	1	0.8	2	1.7	0	0	0	0	0	0
	PANIC DISORDER NOS	0	0	0	0	0	0	1	1.7	0	0	0	0
	PARANOIA	0	0	1	0.8	0	0	1	1.7	0	0	0	0
	RESTLESSNESS	0	0	0	0	0	0	1	1.7	0	0	0	0
	SUICIDAL IDEATION	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	SUICIDE ATTEMPT	1	0.8	1	0.8	0	0	0	0	0	0	0	0
	SUSPICIOUSNESS	0	0	0	0	0	0	1	1.7	0	0	0	0
RENAL AND URINARY DISORDERS	TOTAL	0	0	1	0.8	0	0	0	0	0	0	0	0
	URINARY INCONTINENCE	0	0	1	0.8	0	0	0	0	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	0	0	0	0	0	0	1	1.7	2	3.3	0	0
	DYSPNOEA	0	0	0	0	0	0	1	1.7	1	1.7	0	0
	NASAL CONGESTION	0	0	0	0	0	0	0	0	1	1.7	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	0	0	0	0	1	0.8	0	0	1	1.7	0	0
	RASH NOS	0	0	0	0	1	0.8	0	0	0	0	0	0

(Continued)

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG210.SAS
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Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=120		N=120		N=118		N=59		N=60		N=62	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SWEATING INCREASED	0	0	0	0	0	0	0	0	1	1.7	0	0
SOCIAL CIRCUMSTANCES	TOTAL	0	0	1	0.8	0	0	0	0	1	1.7	0	0
	DRUG ABUSER NOS	0	0	1	0.8	0	0	0	0	1	1.7	0	0
VASCULAR DISORDERS	TOTAL	1	0.8	2	1.7	1	0.8	0	0	1	1.7	0	0
	DEEP VEIN THROMBOSIS	0	0	1	0.8	1	0.8	0	0	0	0	0	0
	ORTHOSTATIC HYPOTENSION	1	0.8	1	0.8	0	0	0	0	1	1.7	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

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GENERATED: 12JUL2005 17:39:28 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	48 YRS CAUCASIAN MALE	24JUL2003-27JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	4	1	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0004013	24 YRS CAUCASIAN FEMALE	15JAN2003-07FEB2003	ON	SEDATION (Nervous system disorders) [AM SEDATION]	24	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0005004	36 YRS CAUCASIAN FEMALE	02OCT2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
	E0005013	43 YRS CAUCASIAN FEMALE	07NOV2002-11NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT RELATED TO ORTHOSTATIC HYPOTENSION)]	5	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG103.SAS
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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0005013	43 YRS CAUCASIAN FEMALE	07NOV2002-13NOV2002	ON	DYSKINESIA (Nervous system disorders) [MOTOR INCOORDINATION (DYSKINESIA)]	7	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	7	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0005027	41 YRS CAUCASIAN MALE	12MAR2003-31MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	20	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0006018	57 YRS CAUCASIAN MALE	13MAR2003-17MAR2003	ON	SOMNOLENCE (Nervous system disorders) [EXTREME SLEEPINESS]	5	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			15MAR2003-17MAR2003	ON	COORDINATION ABNORMAL NOS (Nervous system disorders) [LOSS OF COORDINATION (NOT DUE TO EPS)]	3	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0010032	38 YRS CAUCASIAN FEMALE	11JUL2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATIVISM]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14JUL2003-CONTINUE	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	UNK	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					ORTHOSTATIC HYPOTENSION (Vascular disorders) [FAINTING FEELING (DUE TO POSTURAL HYPOTENSION)]	UNK	5	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0013007	49 YRS CAUCASIAN MALE	20MAR2003-30MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019004	32 YRS CAUCASIAN FEMALE	05DEC2002-CONTINUE	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	UNK	29	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
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Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG103.SAS
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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0020013	23 YRS CAUCASIAN MALE	17MAR2003-17MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	13	SEV	YES	N	Y	N	N	N	N	YES NO	Permanently Stopped
	E0022022	23 YRS CAUCASIAN FEMALE	09FEB2003-18MAR2003	ON	CONVERSION DISORDER (Psychiatric disorders) [CONVERSION DISORDER]	38	42	MOD	YES	N	N	Y	N	N	N	YES NO	None
	E0022035	20 YRS CAUCASIAN FEMALE	20FEB2003-24FEB2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	5	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0023044	44 YRS CAUCASIAN FEMALE	20JUL2003-CONTINUE	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS (NOT DUE TO EPS)]	UNK	5	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0026010	31 YRS CAUCASIAN MALE	23JAN2003-28JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0026010	31 YRS CAUCASIAN MALE	23JAN2003-28JAN2003	ON	VOMITING NOS (Gastrointestinal disorders) [EMESIS]	6	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0028045	46 YRS CAUCASIAN MALE	26JUL2003-29JUL2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH ACUTE PSYCHOSIS]	4	39	SEV	YES	N	N	Y	N	N	N	YES NO	None
			11AUG2003-27AUG2003	POST	BIPOLAR I DISORDER (Psychiatric disorders) [BIPOLAR AFFECTIVE DISORDER MIXED STATE WITH MOOD CONGRUENT PSYCHOSIS]	17	UNK	SEV	YES	N	N	Y	N	N	N	YES NO	None
	E0034002	55 YRS CAUCASIAN MALE	26MAR2003-18APR2003	ON	SOMNOLENCE (Nervous system disorders) [DAYTIME DROWSINESS]	24	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0005036	40 YRS CAUCASIAN FEMALE	06MAY2003-13MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0007008	42 YRS CAUCASIAN FEMALE	18APR2003-25APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0009009	23 YRS CAUCASIAN FEMALE	12MAR2003-22MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0015003	54 YRS CAUCASIAN FEMALE	25NOV2002-04DEC2002	ON	SEDATION (Nervous system disorders) [EXCESSIVE SEDATION]	10	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019014	24 YRS CAUCASIAN MALE	10JAN2003-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARY]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	24 YRS CAUCASIAN MALE	12JAN2003-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [EQUILIBRIUM PROBLEMS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019027	26 YRS HISPANIC FEMALE	28FEB2003-03MAR2003	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [PROBLEMS WITH EQUILITRIUM]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [EXCESSIVE SEDATION]	4	2	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			28FEB2003-06MAR2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0019039	35 YRS CAUCASIAN MALE	01MAY2003-04MAY2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	4	1	MOD	NO	N	N	N	N	N	N	YES YES	None
			03MAY2003-04MAY2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	2	3	MOD	NO	N	N	N	N	N	N	YES YES	None
					BALANCE IMPAIRED NOS (Nervous system disorders) [DECREASED EQUILITRIUM (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					DISORIENTATION (Psychiatric disorders) [DISORIENTATION]	2	3	MIL	NO	N	N	N	N	N	N	YES NO	None
					DISTURBANCE IN ATTENTION (Nervous system disorders) [DECREASED CONCENTRATION]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019039	35 YRS CAUCASIAN MALE	03MAY2003-04MAY2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					PANIC DISORDER NOS (Psychiatric disorders) [PANIC DISORDER SYMPTOMS]	2	3	MOD	NO	N	N	N	N	N	N	YES YES	None
					PARANOIA (Psychiatric disorders) [PARANOIA]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					SUSPICIOUSNESS (Psychiatric disorders) [SUSPICIOUSNESS]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
			03MAY2003-05JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA (NOT DUE TO EPS)]	34	3	MOD	NO	N	N	N	N	N	N	YES YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	44 YRS CAUCASIAN MALE	07MAY2003-CONTINUE	ON	CHRONIC LYMPHOCYTIC LEUKAEMIA NOS (Neoplasms benign, malignant and unspecified (incl cysts and polyps)) [CHRONIC LYMPHOCYTIC LEUKEMIA]	UNK	17	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0031029	24 YRS CAUCASIAN MALE	21JUN2003-07JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	17	4	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
	E0033006	38 YRS CAUCASIAN MALE	25JAN2003-CONTINUE	ON	LOSS OF LIBIDO (Psychiatric disorders) [LOSS OF LIBIDO,]	UNK	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0035013	28 YRS CAUCASIAN FEMALE	08FEB2003-12FEB2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	5	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR II)	E0035013	28 YRS CAUCASIAN FEMALE	08FEB2003-12FEB2003	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS NOT DUE TO EPS]	5	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0035015	33 YRS HISPANIC FEMALE	11FEB2003-16FEB2003	ON	SEDATION (Nervous system disorders) [EXTREME SEDATION]	6	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0039052	37 YRS BLACK FEMALE	23JUN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	4	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0003016	33 YRS CAUCASIAN FEMALE	09JUN2003-12JUN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	4	19	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0004001	33 YRS HISPANIC FEMALE	30SEP2002-12OCT2002	ON	SEDATION (Nervous system disorders) [SEDATION]	13	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			21OCT2002-01NOV2002	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH IN P.M.]	12	22	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	12	22	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0005009	24 YRS CAUCASIAN MALE	29OCT2002-03NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	6	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0005022	25 YRS CAUCASIAN MALE	04FEB2003-04MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	29	7	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0005025	40 YRS CAUCASIAN FEMALE	28FEB2003-14MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	15	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
			15MAR2003-05APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	22	17	MIL	NO	N	N	N	N	N	N	YES YES	None
	E0010002	46 YRS CAUCASIAN MALE	25NOV2002-25NOV2002	ON	DIZZINESS (Nervous system disorders) [FAINTING FEELING (NOT DUE TO POSTURAL HYPOTENSION)]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					FEELING COLD (General disorders and administration site conditions) [COLD FLASH]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0010002	46 YRS CAUCASIAN MALE	25NOV2002-25NOV2002	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [LIGHTHEADED DUE TO ORTHOSTATIC HYPOTENSION]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010023	28 YRS CAUCASIAN FEMALE	20APR2003-28APR2003	ON	PARANOIA (Psychiatric disorders) [PARANOID THINKING]	9	4	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010027	32 YRS CAUCASIAN MALE	28JUN2003-03JUL2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	6	13	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0013006	28 YRS CAUCASIAN FEMALE	20MAR2003-20MAR2003	ON	DYSTONIA (Nervous system disorders) [DYSTONIA]	1	8	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0013014	48 YRS CAUCASIAN MALE	24JUN2003-24JUN2003	ON	AKATHISIA (Nervous system disorders) [(RESTLESSNESS) AKATHISIA]	1	22	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0014007	22 YRS CAUCASIAN FEMALE	03APR2003-19APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	17	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0014012	55 YRS CAUCASIAN FEMALE	29MAY2003-25JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	28	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0018007	42 YRS CAUCASIAN FEMALE	31DEC2002-20MAR2003	ON	DEEP VEIN THROMBOSIS (Vascular disorders) [RECURRENT DEEP VEIN THROMBOSIS WITHOUT PULMONARY EMBOLISM]	80	5	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0022025	46 YRS CAUCASIAN FEMALE	29JAN2003-05FEB2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEG SYNDROME (WORSENING) "NOT DUE TO EPS"]	8	2	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0022038	39 YRS CAUCASIAN MALE	05APR2003-10APR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	6	37	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0022058	43 YRS CAUCASIAN MALE	22APR2003-24MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	33	2	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0022062	63 YRS CAUCASIAN MALE	05MAY2003-21MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	17	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0028007	22 YRS CAUCASIAN FEMALE	10NOV2002-10NOV2002	ON	DRUG ABUSER NOS (Social circumstances) [DRUG ABUSE (METHAMPHETAMINE)]	1	38	SEV	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0028023	54 YRS BLACK MALE	09MAR2003-09MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	48	SEV	YES	N	N	Y	N	N	N	YES NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028025	27 YRS CAUCASIAN MALE	13JAN2003-25JAN2003	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED LIBIDO]	13	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			15JAN2003-25JAN2003	ON	FLAT AFFECT (Psychiatric disorders) [FLAT AFFECT]	11	3	SEV	NO	N	N	N	N	N	N	YES NO	None
	E0029008	22 YRS CAUCASIAN FEMALE	19DEC2002-19DEC2002	ON	SYNCOPE (Nervous system disorders) [FAINTING (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	1	4	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
	E0029012	39 YRS CAUCASIAN FEMALE	14FEB2003-20MAR2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGY IN AM.]	35	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0029015	45 YRS CAUCASIAN FEMALE	25FEB2003-10MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	14	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0030024	30 YRS CAUCASIAN FEMALE	13JUL2003-16JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	4	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0030025	63 YRS BLACK FEMALE	15AUG2003-CONTINUE	ON	DELUSION NOS (Psychiatric disorders) [DELUSIONAL THINKING]	UNK	36	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0036002	32 YRS CAUCASIAN FEMALE	12JUL2003-17JUL2003	ON	MANIA (Psychiatric disorders) [MANIA]	6	26	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0036007	35 YRS CAUCASIAN FEMALE	11JUL2003-14JUL2003	ON	URINARY INCONTINENCE (Renal and urinary disorders) [INTERMITTENT URINARY INCONTINENCE SECONDARY TO SEDATION]	4	9	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	35 YRS CAUCASIAN FEMALE	14JUL2003-15JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	2	12	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0039028	39 YRS BLACK MALE	09MAY2003-16MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	8	47	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0001006	29 YRS CAUCASIAN MALE	11JUL2003-17JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	7	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JUL2003-CONTINUE	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [LIPS TWITCHING NOT DUE TO EPS]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JUL2003-17JUL2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [MUSCLE CRAMPS NOT DUE TO EPS]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [MUSCLE TWITCHING NOT DUE TO EPS]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0005033	33 YRS CAUCASIAN FEMALE	20APR2003-14MAY2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	25	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0005038	31 YRS CAUCASIAN FEMALE	14MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0007009	29 YRS CAUCASIAN FEMALE	19APR2003-24APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	6	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0011020	33 YRS CAUCASIAN MALE	09MAY2003-10MAY2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS, SECONDARY TO POSTURAL HYPOTENSION]	2	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0018003	27 YRS CAUCASIAN FEMALE	29NOV2002-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATED]	UNK	4	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0018013	44 YRS CAUCASIAN MALE	25JAN2003-29JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	5	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019024	26 YRS CAUCASIAN MALE	31JAN2003-06FEB2003	ON	CONFUSIONAL STATE (Psychiatric disorders) [CONFUSION]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DIZZINESS (Nervous system disorders) [LIGHTHEADED (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [DIFFICULTY BREATHING]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	31JAN2003-06FEB2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SOMNOLENCE (Nervous system disorders) [DROWSY]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					TOOTH DISORDER NOS (Gastrointestinal disorders) [WEIRD FEELING IN TEETH]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			01FEB2003-06FEB2003	ON	LIMB DISCOMFORT NOS (Musculoskeletal and connective tissue disorders) [UNCOMFORTABLE FEELING IN LEGS AND ARMS]	6	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			04FEB2003-06FEB2003	ON	BRUXISM (Psychiatric disorders) [BRUXISM]	3	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	04FEB2003-06FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	3	6	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	3	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019031	47 YRS CAUCASIAN MALE	13MAR2003-17MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	5	1	SEV	NO	N	N	N	N	N	N	YES YES	None
			14MAR2003-16MAR2003	ON	JOINT STIFFNESS (Musculoskeletal and connective tissue disorders) [TIGHTNESS IN JOINTS (NOT DUE TO EPS)]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None
					PARAESTHESIA (Nervous system disorders) [TINGLING IN ARMS]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019031	47 YRS CAUCASIAN MALE	14MAR2003-16MAR2003	ON	PARAESTHESIA (Nervous system disorders) [TINGLING IN LEGS]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None
	E0019035	34 YRS CAUCASIAN FEMALE	20MAR2003-24APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	36	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			03APR2003-24APR2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS AT NIGHT NOT DUE TO EPS]	22	17	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			11APR2003-24APR2003	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	14	25	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019042	27 YRS CAUCASIAN FEMALE	15JUN2003-18JUN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	4	12	MIL	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023023	35 YRS CAUCASIAN FEMALE	26APR2003-29APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY NOT DUE TO POSTURAL HYPOTENSION]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	None
					SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0023029	46 YRS HISPANIC FEMALE	24MAY2003-28MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0023029	46 YRS HISPANIC FEMALE	24MAY2003-28MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0026005	57 YRS CAUCASIAN FEMALE	30DEC2002-11JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	13	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0026009	43 YRS CAUCASIAN FEMALE	17JAN2003-19JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	3	3	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0031010	37 YRS OTHER FEMALE	19FEB2003-CONTINUE	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0031015	27 YRS CAUCASIAN FEMALE	27MAR2003-04APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	9	2	MIL	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031015	27 YRS CAUCASIAN FEMALE	29MAR2003-04APR2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	None
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					VISION BLURRED (Eye disorders) [BLURRED VISION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	None
	E0033009	46 YRS CAUCASIAN FEMALE	13FEB2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [MORE SEVERE HEADACHES]	UNK	2	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0039043	20 YRS CAUCASIAN MALE	01JUN2003-CONTINUE	ON	DRUG ABUSER NOS (Social circumstances) [DRUG ABUSE WITH COCAINE]	UNK	25	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped

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PLACEBO (BIPOLAR I)	E0002004	33 YRS CAUCASIAN FEMALE	17JAN2003-CONTINUE	PRE	DEPRESSION (Psychiatric disorders) [ANXIETY RELATED TO DEPRESSION]	UNK	-8	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0005019	22 YRS CAUCASIAN FEMALE	16JAN2003-16JAN2003	ON	NON-ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [INTENTIONAL OVERDOSE (OVER THE COUNTER SLEEPING PILL)]	1	2	MOD	YES	N	N	N	N	N	Y	YES NO	Permanently Stopped
	E0007003	53 YRS CAUCASIAN MALE	21FEB2003-27FEB2003	ON	DUODENAL ULCER HAEMORRHAGE (Gastrointestinal disorders) [BLEEDING ULCER (DUODENAL)]	7	23	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0007006	39 YRS BLACK MALE	22MAR2003-31MAR2003	ON	RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	10	18	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG103.SAS
GENERATED: 12JUL2005 17:38:50 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0009012	28 YRS CAUCASIAN MALE	25JUN2003-26JUN2003	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [EPS (INVOLUNTARY MOVEMENT OF MOUTH) - DYSTONIA]	2	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010028	32 YRS HISPANIC FEMALE	02JUL2003-24JUL2003	ON	INSOMNIA (Psychiatric disorders) [WORSENING OF INSOMNIA]	23	17	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0011008	23 YRS CAUCASIAN MALE	13FEB2003-CONTINUE	ON	MANIA (Psychiatric disorders) [ONSET OF MANIC SYMPTOMS]	UNK	15	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0014004	29 YRS CAUCASIAN FEMALE	13MAR2003-03APR2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN - LEFT SIDE]	22	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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Note: The adverse events are coded using MedDRA version 6.0.

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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0022011	28 YRS CAUCASIAN MALE	30NOV2002-06MAR2003	ON	HIP FRACTURE (Injury, poisoning and procedural complications) [HIP FRACTURE]	97	2	MIL	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
					SPINAL FRACTURE NOS (Injury, poisoning and procedural complications) [MULTIPLE VERTEBRAL FRACTURES T11 - L4]	97	2	MIL	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
			04DEC2002-20MAY2003	ON	DEEP VEIN THROMBOSIS (Vascular disorders) [DEEP VEIN THROMBOSIS LEFT LEG]	168	6	MIL	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0026028	35 YRS CAUCASIAN MALE	11JUL2003-CONTINUE	ON	MAJOR DEPRESSIVE DISORDER NOS (Psychiatric disorders) [PSYCHOTIC: DEPRESSION]	UNK	22	SEV	YES	N	N	Y	N	N	N	YES NO	None
			15JUL2003-18JUL2003	ON	ACUTE PSYCHOSIS (Psychiatric disorders) [ACUTE PSYCHOSIS]	4	26	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

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** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

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GENERATED: 12JUL2005 17:38:50 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0028031	35 YRS CAUCASIAN MALE	27MAR2003-31MAR2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [SELF MUTILATING AUDITORY HALLUCINATIONS]	5	17	SEV	YES	N	N	Y	N	N	N	YES NO	None
	E0029039	30 YRS HISPANIC FEMALE	26JUL2003-26JUL2003	ON	DISSOCIATIVE DISORDER NOS (Psychiatric disorders) [DISSOCIATIVE EPISODE]	1	12	MOD	NO	N	N	N	N	N	N	YES NO	None
	E0033010	26 YRS BLACK FEMALE	19MAR2003-19MAR2003	ON	ECTOPIC PREGNANCY (Pregnancy, puerperium and perinatal conditions) [ECTOPIC PREGNANCY]	1	44	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0041010	32 YRS CAUCASIAN MALE	07JUN2003-13JUN2003	ON	MANIA (Psychiatric disorders) [MANIC EPISODE]	7	39	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

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GENERATED: 12JUL2005 17:38:50 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PRE/ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0026027	40 YRS CAUCASIAN FEMALE	19JUN2003-19JUN2003	ON	CONVULSIONS NOS (Nervous system disorders) [SEIZURE]	1	1	SEV	YES	N	N	N	N	N	Y	YES NO	Permanently Stopped
	E0029038	61 YRS CAUCASIAN MALE	08JUL2003-14JUL2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	7	2	MOD	NO	N	N	N	N	N	N	YES YES	None

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* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

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GENERATED: 12JUL2005 17:38:50 iceadmn3

11.3.5.3 Narratives of discontinuations due to adverse events

Study 5077US/0049 Patient 0001/006 600 mg

Withdrawal: Fatigue, Muscle Cramps, Muscle Twitching, Muscle Twitching

This narrative concerns a 29-year-old white man with bipolar II disorder.

The patient had non-serious adverse events of fatigue, muscle cramps not due to Extrapyramidal Syndrome (EPS) (MedDRA: muscle cramps), muscle twitching not due to EPS (MedDRA: muscle twitching), and lips twitching not due to EPS (MedDRA: muscle twitching). The patient had fatigue on Day 1 through Day 7 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. Muscle cramps and muscle twitching not due to EPS occurred on Day 2 through Day 7 with intensities of severe. Lips twitching not due to EPS occurred on Day 2 and had an intensity of moderate according to the investigator. The investigator withdrew treatment due to these events. The patient took his final dose of study medication on Day 5. The fatigue, muscle cramps, and muscle twitching not due to EPS resolved two days after the final dose of study medication. The lips twitching not due to EPS had not resolved as of the last contact with the patient, ten days after the last dose of study medication.

The patient's medical history revealed asthma, seasonal allergies, and sleep apnea. Before entering the study, the patient had been treated with cetirizine hydrochloride (ZYRTEC®, Pfizer) and fluticasone propionate (FLONASE®, GlaxoSmithKline) for allergies and Metabolife (METABOLIFE®, Metabolife International, Inc.) for weight loss. No additional concomitant medications were given during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the fatigue, muscle cramps, muscle twitching not due to EPS, and lips twitching not due to EPS to be related to study treatment.

Study 5077US/0049 Patient 0002/004 placebo

Withdrawal: Depression

This narrative concerns a 33-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of anxiety related to depression (MedDRA: depression) eight days prior to randomized treatment to placebo that was considered by the investigator to be moderate in intensity. The patient was treated with lorazepam (ATIVAN®, Wyeth Ayerst) 3 mg/day for anxiety, and zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 10 mg/day for insomnia. At baseline, the patient's anxiety was ongoing for eight days. The patient was assigned to a treatment cohort and issued blinded medication for the first week of the study. The anxiety did not resolve. The investigator withdrew the patient from study treatment due to this ongoing adverse event. The patient did not return for any follow-up visit

and the resolution of the depression is unknown. It is also not known how much, if any, of the study medication was taken.

The patient's medical history was unremarkable. The screening physical examination revealed pluritic chest pain. Before entering the study, the patient was treated with olanzapine (ZYPREXA®, Lilly) 5 mg/day for bipolar disorder and clonazepam (KLONOPIN®, Roche) 1 mg/day for anxiety; these drugs were discontinued eight and five days prior to baseline.

The investigator considered the depression to be not related to study treatment.

Study 5077US/0049 Patient 0002/018 300 mg

Withdrawal: Somnolence

This narrative concerns a 48-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of drowsiness (MedDRA: somnolence) on Day 1 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. Although the investigator did not determine the somnolence to be severe enough to warrant withdrawing the patient, the patient withdrew from the study due to somnolence. The last dose of study medication was taken on Day 3 and the somnolence resolved one day after the last dose of study treatment.

The patient had a medical history of arthritis. No medications were taken prior to or during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0003/016 600 mg

Withdrawal: Irritability

This narrative concerns a 33-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of irritability on Day 19 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment and the patient's final dose of study medication was on Day 21. The irritability ended one day after the last dose of study treatment.

The patient had a non-serious adverse event of feeling jittery starting on Day 3 and ending twenty-two days after the final dose of study treatment. This adverse event was considered by the investigator to be severe in intensity and related to study medication. The patient had a non-serious adverse event of insomnia starting on Day 13 and ending one day after the last dose of study treatment that was considered by the investigator to be severe in intensity and

related to the study treatment. The patient had a relevant medical history of past anxiety. The screening and final visit physical examinations were unremarkable. The patient was not taking any relevant medications prior to or during the study.

The investigator considered the irritability to be related to study treatment.

Study 5077US/0049 Patient 0004/001 600 mg

Withdrawal: Sedation and Dysarthria

This narrative concerns a 33-year-old hispanic woman with bipolar I disorder.

The patient had non-serious adverse events of sedation and slurred speech in P.M. (MedDRA: dysarthria). Sedation occurred during randomized treatment to 600 mg on Days 1 through 13, Days 13 through 22, and Day 22 through two days after the last dose of study treatment with intensities of moderate, mild, and severe, respectively. Dysarthria occurred on Days 7 through 13 and Day 22 through two days after the last dose of study treatment with intensities of mild and moderate, respectively. The dose of study medication was reduced due to these events. The dose was reduced by two tablets on Days 6, 11, 12, 14-16, and 18-21. The patient missed her doses on Days 13 and 17, and the dose was reduced by one tablet on Days 22 through 31. The patient did not take any doses of study medication after Day 31. Both dysarthria and sedation continued after dose reduction. The patient requested that study treatment be stopped due to the dysarthria and sedation. The investigator determined that only the sedation was severe enough to warrant withdrawal. Both adverse events resolved two days after the patient's last dose of study treatment.

The patient had a non-serious adverse event of dizziness on Days 1 through 13, Days 13 through 22, and Day 22 through two days after the last dose of study treatment with intensities of moderate, mild, and severe, respectively. Dizziness also contributed to the decision to reduce the dose of study medication. The dizziness was considered by the investigator to be related to the study treatment. The patient's relevant medical history revealed dysmenorrhea, irritable bowel syndrome, headaches, and nausea. The patient was not taking any relevant medications prior to or during study treatment. The screening and final visit physical examinations revealed right tympanic membrane blocked by serum. The final visit physical examination also revealed pain on percussion of bilateral flanks.

The investigator considered the sedation and dysarthria to be related to study treatment.

Study 5077US/0049 Patient 0004/013 300 mg

Withdrawal: Sedation

This narrative concerns a 24-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of AM sedation (MedDRA: Sedation) on Day 2 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment and the patient's final dose of study medication was on Day 22. The sedation ended three days after the last dose of study medication.

The patient had a medical history of asthma and obesity. The screening and final visit physical examinations revealed that the patient was slightly obese. Before entering the study, the patient had been treated with albuterol for asthma starting approximately 12 years prior to treatment and continuing during study treatment. During the study, the patient took propoxyphene napsylate / acetaminophen (DARVOCET-N®, AAI Pharma), hydrocodone bitartrate / ibuprofen (VICOPROFEN®, Abbott), and morphine sulfate (KADIAN-SR®, Alpharma Branded) 20 mg/day to treat a non-serious adverse event of left breast cyst. The propoxyphene napsylate / acetaminophen (DARVOCET-N®, AAI Pharma) was started on Day 2 and stopped on Day 3. It was then started again on Day 20 and was continuing at the final visit. Hydrocodone bitartrate / ibuprofen (VICOPROFEN®, Abbott) was taken from Day 17 to Day 19 and the morphine sulfate (KADIAN- SR®, Alpharma Branded) was taken on Day 19 only.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0005/004 300 mg

Withdrawal: Lethargy and Sedation

This narrative concerns a 36-year-old white woman with bipolar I disorder.

The patient had non-serious adverse events of lethargy and sedation on Day 2 of randomized treatment to 300 mg that were considered by the investigator to be moderate in intensity. The investigator reduced the dose of medication due to these adverse events on Day 15. These events continued after the dose reduction. The investigator determined that these events were not significant enough to warrant withdrawal from study treatment; however, the patient decided to withdraw from study treatment due to these events. The patient took her final reduced dose of study medication on Day 21. The patient did not return to the clinic for a final visit and the day of resolution for the lethargy and sedation is unknown.

The patient had a relevant past medical history of anemia (iron deficiency) and a relevant current medical history of heart murmur and shortness of breath. No additional medications were given prior to or during the study treatment. The screening physical examination revealed a heart murmur. The final visit physical exam was not done.

The investigator considered the lethargy and sedation to be related to study treatment.

Study 5077US/0049 Patient 0005/009 600 mg

Withdrawal: Sedation

This narrative concerns a 24-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The patient took his final dose of study medication on Day 4 and the event resolved two days later.

The patient had a relevant medical history of current sinusitis and migraine headaches. No relevant medications were given prior to or during the study treatment. The screening physical examination was unremarkable. The final visit physical exam was not done.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0005/013 300 mg

Withdrawal: Sedation, Dizziness, and Dyskinesia

This narrative concerns a 43-year-old white woman with bipolar I disorder.

The patient had non-serious adverse events of sedation, dizziness not related to orthostatic hypotension (MedDRA: dizziness), and motor incoordination (dyskinesia) (MedDRA: dyskinesia) on Day 1 of randomized treatment to 300 mg that were considered by the investigator to be moderate in intensities. The investigator withdrew study treatment due to these events. The patient took her last dose of study medication on Day 4 and the event of dizziness resolved one day later. The events of sedation and dyskinesia resolved three days after the patient took her last dose of study medication.

The patient had a medical history of current rhinitus/sinusitis, sinus headaches, recurrent neck pain, nausea, insomnia, indigestion, constipation, gallstones in the past, and is allergic to sulfa drugs. Before entering the study, the patient was treated with alprazolam (XANAX®, Pharmacia and Upjohn) 0.5 mg/day and acetaminophen / pseudoephedrine / diphenhydramine hydrochloride (BENADRYL® ALLERGY, Pfizer Consumer) 50 mg/day for insomnia. These medications were discontinued prior to study treatment. The patient was given zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 20 mg/day for insomnia and phosphorated carbohydrate solution (EMETROL®, Pfizer) 2 tbsp/day for nausea starting prior to study treatment and continuing after the patient's final study visit. The screening physical examination was unremarkable. The final visit physical examination was not done.

The investigator considered the sedation, dizziness, and dyskinesia to be related to study treatment.

Study 5077US/0049 Patient 0005/019 placebo

Withdrawal: Non-accidental Overdose

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0005/022 600 mg

Withdrawal: Sedation

This narrative concerns a 25-year-old white man with bipolar I disorder.

The patient had two non-serious adverse events of sedation during randomized treatment to 600 mg that were both considered by the investigator to be moderate in intensity. The first episode of sedation began on Day 3 and resolved on Day 4. The second episode began on Day 7. The investigator reduced the dose of study medication due to the sedation. The patient took a reduced dose of study medication from Day 24 through Day 31 and on Day 33. The patient did not take any study medication on Day 32. The sedation continued during the dose reduction. The investigator withdrew the study treatment due to the sedation. The patient took his final dose of study medication on Day 33. The sedation resolved two days after the patient took the final dose of study medication.

The patient's medical history was unremarkable. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered both events of sedation to be related to study treatment.

Study 5077US/0049 Patient 0005/025 600 mg

Withdrawal: Sedation

This narrative concerns a 40-year-old white woman with bipolar I disorder.

The patient had two non-serious adverse events of sedation during randomized treatment to 600 mg. The first episode of sedation began on Day 2, resolved on Day 16, and was considered by the investigator to be moderate in intensity. The second episode began on Day 17 and was considered by the investigator to be mild in intensity. On Day 15, the patient began taking a reduced dose of study medication due to sedation. The sedation continued during the dose reduction. The investigator did not consider the event significant enough to warrant withdrawal of study treatment. However, the patient decided to withdraw study treatment as a result of this event. The patient took her final dose of study treatment on Day 35, and the second episode of sedation resolved three days later.

The patient had a relevant medical history of hypothyroidism. Before entering the study, the patient was treated with levothyroxine (SYNTHROID®, Abbott) 75 µg/day for

hypothyroidism, and continued treatment with this medication during study treatment. No additional medications were taken during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0005/027 300 mg

Withdrawal: Sedation

This narrative concerns a 41-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of sedation on Day 2 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator reduced the dose of study medication on Days 16 through 19 due to this event; however, the sedation continued through the dose reduction. The investigator withdrew study treatment due to the sedation. The patient took his final dose of study medication on Day 19 and the event resolved two days later.

The patient had a relevant medical history of current exercise induced asthma, hyperlipidemia, seasonal allergies, sinus headaches, and vertigo. Before entering the study, the patient was treated with escitalopram oxalate (LEXAPRO®, Forest) 10 mg/day for depression, which was stopped ten days prior to study treatment, and loratadine (CLARITIN®, Schering) 10 mg/day for seasonal allergies, which continued through study treatment. No additional relevant concomitant medications were given prior to or during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0005/033 600 mg

Withdrawal: Nasal Congestion

This narrative concerns a 33-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of nasal congestion on Day 6 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. During the study, the patient was treated with 4-Way Nasal Spray and cetirizine hydrochloride (ZYRTEC®, Pfizer) on Day 12, fluticasone propionate (FLONASE®, GlaxoSmithKline) and fexofenadine hydrochloride (ALLEGRA®, Aventis) on Day 13, loratadine (CLARITIN®, Schering) 10 mg/day and Dristan Nasal Spray (DRISTAN® NASAL SPRAY, Whitehall-Robins, Inc.) on Day 14, and pseudoephedrine hydrochloride (SUDAFED®, Pfizer) 120 mg/day and fexofenadine hydrochloride (ALLEGRA®, Aventis) from Day 16 though Day 21. The patient's dose of study medication was reduced from 4 to 3 tablets per day on Day 11 and from Day 15 to Day 19, to 2 tablets per day on Day 12 and Day 13, and took no tablets on

Day 14. The investigator withdrew study treatment due to this event. The patient took her final dose of study medication on Day 19 and the event resolved ten days later.

The patient had no relevant medical history. Before entering the study, the patient was not taking any relevant medications except for Nyquil (NYQUIL®, Vicks) 2 tbsps/day, taken to manage insomnia. During the study, the patient was given Nyquil (NYQUIL®, Vicks) 2 tbsps/day and zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 10 mg/day for insomnia. The screening and final visit physical examinations were unremarkable.

The investigator considered the nasal congestion to be related to study treatment.

Study 5077US/0049 Patient 0005/036 300 mg

Withdrawal: Sedation

This narrative concerns a 40-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment to 300 mg considered by the investigator to be moderate in intensity. The patient's Day 5 dose of study medication was not taken due to sedation. The investigator withdrew study treatment due to this event. The patient took her final dose of study medication on Day 7 and the event resolved one day later.

The patient had no relevant medical history. No relevant medications were given prior to the study treatment. The patient had non-serious adverse events of dyskinesia, dry mouth, akathisia, and sinus congestion all starting on Day 1 and ending one day after the patient took her last dose of study medication. All events were considered by the investigator to be related to study drug and to be moderate in intensity except for dyskinesia, which was mild in intensity. During the study, the patient was given celecoxib (CELEBREX®, Pharmacia and Upjohn) 200 mg/day for headaches and benztropine mesylate (COGENTIN®, Merck) 1 mg/day for restless legs. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0005/038 600 mg

Withdrawal: Sedation

This narrative concerns a 31-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment to 600 mg considered by the investigator to be moderate in intensity. The dose of study medication was reduced from 4 to 3 tablets per day from Day 16 through Day 22, but the

sedation continued. The investigator withdrew study treatment due to this event. The patient took her final dose of study medication on Day 22. This event had not resolved at the time of the site personnel's last contact with the patient, which occurred one day after the final dose of study medication.

Other non-serious adverse events during the study included akathisia (Day 1 and ongoing at last patient contact, judged related to study medication by the investigator), dysphagia (Day 1 to Day 19, judged related to study medication by the investigator), and dyspnoea (Day 10 and ongoing at last patient contact, judged related to study medication by the investigator). The patient had a relevant medical history of asthma, constipation, and headaches. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations revealed obesity.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0006/018 300 mg

Withdrawal: Somnolence and Coordination Abnormal NOS

This narrative concerns a 57-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of extreme sleepiness (MedDRA: somnolence) on Day 1 of randomized treatment to 300 mg considered by the investigator to be severe in intensity. The patient also had a non-serious adverse event of loss of coordination (not due to Extrapyramidal Syndrome) (MedDRA: coordination abnormal NOS) on Day 3 of randomized treatment that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to these events. The patient took his last dose of study treatment on Day 4. The somnolence and coordination abnormal NOS resolved one day after the patient's last dose of study treatment.

The patient's medical history was unremarkable. The screening and final visit physical examinations revealed bilateral ear occlusion. The patient did not take any relevant medications prior to or during study treatment. On Day 2 of randomized treatment, the patient had a non-serious adverse event of dysarthria that was considered by the investigator to be moderate in intensity and related to study treatment. One day after the patient's last dose of study treatment, this event resolved.

The investigator considered the somnolence and coordination abnormal NOS to be related to study treatment.

Study 5077US/0049 Patient 0007/003 placebo

Withdrawal: Duodenal Ulcer Hemorrhage

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0007/006 placebo

Withdrawal: Rash NOS

This narrative concerns a 39-year-old black man with bipolar I disorder.

The patient had a non-serious adverse event of rash (MedDRA: rash NOS) on Day 18 of randomized treatment to placebo considered by the investigator to be mild in intensity. The investigator withdrew study treatment on Day 22. The final dispensed blister card was not returned to the site personnel by the patient. The date of final dose was based on the maximum number of available doses dispensed on the blister card. The patient's final dose of study medication was estimated to have been taken on Day 23. The rash resolved four days after the patient took his estimated final dose of study medication.

The patient had no relevant medical history. No concomitant medications were taken prior to or during the study treatment. The screening visit physical examination was unremarkable. The final visit physical examination performed on Day 22, revealed rash on the extremities, thorax, and scalp.

The investigator considered the rash NOS to be related to study treatment.

Study 5077US/0049 Patient 0007/008 300 mg

Withdrawal: Sedation

This narrative concerns a 42-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment to 300 mg considered by the investigator to be moderate in intensity. On Day 4 the patient took 1 of the 2 prescribed tablets, on Days 5 and 6 the patient did not take any study medication, and on Day 7 the patient only took 1 of the 3 prescribed tablets. The investigator withdrew study treatment and the patient took her final dose of study medication on Day 7. The sedation resolved one day after her final dose of study medication.

The patient had no relevant medical history. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations revealed obesity.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0007/009 600 mg

Withdrawal: Sedation

This narrative concerns a 29-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 3 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator determined that this event was severe enough to warrant withdrawal. The patient took her final dose of study medication on Day 5. The sedation resolved three days after the final dose of study medication.

The patient had no relevant medical history. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0009/009 300 mg

Withdrawal: Somnolence

This narrative concerns a 23-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of drowsiness (MedDRA: somnolence) on Day 1 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the study treatment due to the somnolence. The patient took her final dose of study medication on Day 10. The somnolence resolved one day after the patient took her final dose of study medication.

The patient had a relevant medical history of current insomnia and current toothache. Before entering the study, the patient had been treated with hydrocodone bitartrate / acetaminophen (VICODIN®, Abbott) and acetaminophen (TYLENOL®, McNeil Consumer) for the toothache. The hydrocodone bitartrate / acetaminophen (VICODIN®, Abbott) was last used 15 days prior to the patient's first dose of study medication. The patient continued to take acetaminophen (TYLENOL®, McNeil Consumer) during the study treatment. No additional medications were given during the study treatment. The screening visit physical examination revealed mild inspiratory wheezing. The final visit physical examination was unremarkable.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0009/012 placebo

Withdrawal: Extrapyramidal Disorder

This narrative concerns a 28-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of Extrapyramidal Syndrome (EPS) (involuntary movement of mouth) – dystonia (MedDRA: extrapyramidal disorder) on Day 1 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. The patient only took the first dose of study medication. The extrapyramidal disorder resolved one day after the patient took his final dose of study medication. The investigator withdrew study treatment as a result of the extrapyramidal disorder.

The patient had a relevant current medical history of headaches. Before entering the study, the patient had been treated with ibuprofen / pseudoephedrine (ADVIL® COLD AND SINUS, Wyeth Consumer) for headaches. The last dose of this medication was taken sixteen days prior to the patient's first dose of study medication. The patient began treatment with escitalopram oxalate (LEXAPRO®, Forest) 10 mg/day for bipolar depression nine days after the last dose of study medication was taken. The screening and final visit physical examinations were unremarkable.

The investigator considered the extrapyramidal disorder to be related to study treatment.

Study 5077US/0049 Patient 0010/002 600 mg

Withdrawal: Orthostatic Hypotension, Dizziness, Feeling Cold

This narrative concerns a 46-year-old white man with bipolar I disorder.

The patient had non-serious adverse events of light-headed (due to orthostatic hypotension) (MedDRA: orthostatic hypotension), fainting feeling (not due to postural hypotension) (MedDRA: dizziness), and cold flash (MedDRA: feeling cold) on Day 1 of randomized treatment to 600 mg that were all considered by the investigator to be mild in intensity. The patient took his first and only dose of study treatment on Day 1. The investigator withdrew study treatment due to these events. On Day 1 the non-serious adverse events of orthostatic hypotension, dizziness, and feeling cold resolved.

The patient's medical history and final visit physical examination were unremarkable. The patient's screening physical examination revealed mild hyperemia of the left ear canal and tympanic membrane. The patient was given lorazepam 1 mg/day for anxiety starting eleven days prior to study treatment and continuing through study treatment. The patient did not take any additional relevant concomitant medications prior to or during the study.

The investigator considered the orthostatic hypotension, dizziness, and feeling cold to be related to study treatment.

Study 5077US/0049 Patient 0010/023 600 mg

Withdrawal: Paranoia

This narrative concerns a 28-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of paranoid thinking (MedDRA: paranoia) on Day 4 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient took her last dose of study treatment on Day 11. The adverse event of paranoia resolved one day after the patient's last dose of study treatment.

The patient's medical history and screening and final visit physical examinations were unremarkable. For two months prior to entering the study, the patient had been treated with amphetamine / dextroamphetamine (ADDERALL®, Shire) 15 mg/day (as needed) and venlafaxine hydrochloride (EFFEXOR®, Wyeth) 150 mg/day for depression. The patient discontinued treatment with these medications twenty days prior to entering the study. The patient was not treated with any concomitant medications during the study.

The investigator considered the paranoia to be related to study treatment.

Study 5077US/0049 Patient 0010/027 600 mg

Withdrawal: Anxiety

This narrative concerns a 32-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of increased anxiety (MedDRA: anxiety) on Day 13 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. Four days prior to the first dose of study treatment, the patient began treatment with lorazepam 3 mg/day for severe anxiety [secondary to bipolar depression]. The patient continued to take lorazepam concomitantly throughout the study. Beginning on Day 13, the patient had increased anxiety. The investigator withdrew study treatment due to the increased anxiety, and the patient took his last dose of study treatment on Day 13. The adverse event of increased anxiety resolved five days after the patient took his last dose of study treatment.

The patient's medical history and screening and final visit physical examinations were unremarkable. Before entering the study, the patient was not taking any medications. Eleven days prior to the first dose of study treatment, the patient began treatment with zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 5 mg/day for sleep. The patient continued to take this medication concomitantly during the study.

The investigator considered the anxiety to be related to study treatment.

Study 5077US/0049 Patient 0010/028 placebo

Withdrawal: Insomnia

This narrative concerns a 32-year-old hispanic woman with bipolar I disorder.

The patient had a non-serious adverse event of worsening of insomnia (MedDRA: insomnia) on Day 17 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. The patient was given zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 10 mg/day for insomnia seven days prior to baseline through Day 23 of randomized treatment. The patient took her last dose of study treatment on Day 28, and the investigator withdrew the patient from the study on Day 30. Eleven days after the last dose of study treatment, the insomnia resolved.

The patient had a relevant current medical history of insomnia. The patient's screening and final visit physical examinations were unremarkable. On Day 13 of randomized treatment, the patient had anxiety that was considered by the investigator to be moderate in intensity and related to study treatment. This event resolved four days after the discontinuation of study treatment. On Day 4 the patient had a headache, which was considered by the investigator to be mild in intensity and related to study treatment. This event resolved four days after the discontinuation of study treatment. During the study the patient was given lorazepam (ATIVAN®, Wyeth Ayerst) 3 mg/day for agitation.

The investigator considered the insomnia to be related to study treatment.

Study 5077US/0049 Patient 0010/032 300 mg

Withdrawal: Sedation, Nausea, and Orthostatic Hypotension

This narrative concerns a 38-year-old white woman with bipolar I disorder.

The patient had non-serious adverse events of sedativism (MedDRA: sedation), nausea, and fainting feeling (due to postural hypotension) (MedDRA: orthostatic hypotension). Sedation occurred on Day 2 of randomized treatment to 300 mg and was considered by the investigator to be moderate in intensity. Nausea and orthostatic hypotension occurred on Day 5 of randomized treatment and were considered by the investigator to be moderate and mild in intensity, respectively. The investigator withdrew study treatment for these events. The patient took her last dose of study treatment on Day 6. At the time of final study assessments, two days after the last dose of study treatment, the non-serious adverse events of sedation, nausea, and orthostatic hypotension were ongoing.

The patient had a relevant medical history of mild pharyngeal hyperemia. The screening physical examination revealed mild pharyngeal hyperemia. The final visit physical examination was unremarkable. The patient was not treated with any non-study medications prior to or during the study.

The investigator considered the sedation, nausea, and orthostatic hypotension to be related to study treatment.

Study 5077US/0049 Patient 0011/008 placebo

Withdrawal: Mania

This narrative concerns a 23-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of onset of manic symptoms (MedDRA: mania) four days after the last dose of randomized treatment to placebo that was considered by the investigator to be mild in intensity. The patient took his last dose of study treatment on Day 11. Four days later, the patient returned to the clinic for a premature discontinuation visit. During this visit, the investigator determined that the patient was experiencing mania and that the withdrawal of study treatment was warranted. Mania was ongoing at the time of the site personnel's last contact with the patient (at the premature discontinuation visit).

The patient's medical history and screening and final visit physical examinations were unremarkable. The patient was not treated with any medications prior to or during the study.

The investigator considered the mania to be related to study treatment.

Study 5077US/0049 Patient 0011/020 600 mg

Withdrawal: Orthostatic Hypotension

This narrative concerns a 33-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of dizziness secondary to postural hypotension (MedDRA: orthostatic hypotension) on Day 2 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew the patient from study treatment. The patient took his last dose on Day 2 and the orthostatic hypotension resolved one day later.

The patient had a non-serious adverse event of sedation that started on Day 2 and resolved two days after the last dose of study treatment. This event was considered by the investigator to be moderate in intensity and related to study treatment. No relevant concomitant medications were given prior to or during study treatment. The patient's medical history and screening and final visit physical examinations were unremarkable.

The investigator considered the orthostatic hypotension to be related to study treatment.

Study 5077US/0049 Patient 0013/006 600 mg

Withdrawal: Dystonia

This narrative concerns a 28-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of dystonia on Day 8 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The patient took study medication on Day 1, as instructed. However, she did not take study medication on Day 2 through Day 5. The patient then took study medication on Day 6 through Day 8, using the doses labeled for Day 2 through Day 4, respectively. The investigator withdrew study treatment due to the dystonia. The patient's last dose of study medication was on Day 8. The dystonia also resolved on Day 8.

The patient had non-serious adverse events of irritability and somnolence from Day 3 to Day 10 that were considered by the investigator to be moderate in intensity and related to study treatment. The patient had a non-serious adverse event of dizziness from Day 5 to Day 9 that was considered by the investigator to be moderate in intensity and related to study treatment. The patient had a non-serious adverse event of sensation of throbbing vessels (sensation of blood rushing in the veins) on Day 8 that was considered by the investigator to be severe in intensity and related to study treatment. The patient had a relevant medical history of headaches. Before entering the study, the patient had been treated with acetaminophen (TYLENOL®, McNeil Consumer) 1000 mg/day for headaches and this medication continued through study treatment. No additional medications were given during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the dystonia to be related to study treatment.

Study 5077US/0049 Patient 0013/007 300 mg

Withdrawal: Somnolence

This narrative concerns a 49-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of drowsiness (MedDRA: somnolence) on Day 1 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The patient took his last dose of study medication on Day 9. The somnolence resolved two days later.

The patient's medical history revealed type II diabetes and high cholesterol. Before entering the study, the patient had been treated with metformin hydrochloride (GLUCOPHAGE® XR, Bristol-Myers Squibb) 1000 mg/day for diabetes and atorvastatin (LIPITOR®, Pfizer) 10 mg/day for high cholesterol. These medications continued through study treatment. No additional medications were given during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0013/014 600 mg

Withdrawal: Akathisia and Pruritus

This narrative concerns a 48-year-old white man with bipolar I disorder.

The patient had non-serious adverse events of (restlessness) akathisia (MedDRA: akathisia) and itchiness (MedDRA: pruritus) on Day 4 of randomized treatment to 600 mg that were determined to be moderate in intensity. The investigator withdrew study treatment due to these events. Akathisia and pruritis occurred during randomized treatment on Day 4 through Day 20 and again for one day, two days after the patient's last dose, with intensities of moderate for both events. The patient's last dose of study treatment was taken on Day 20.

The patient had a non-serious adverse event of nightmare starting on Day 2 that was ongoing as of the site personnel's last contact with the patient, eight days after the last dose of study treatment. This event was considered by the investigator to be moderate in intensity and related to study treatment. The patient's medical history was unremarkable. Before entering the study, the patient had been treated with clonazepam 0.5 mg/day for approximately two years and gabapentin (NEURONTIN®, Parke-Davis) 300 mg/day for approximately two years, both for anxiety. Zaleplon (SONATA®, King) 25 mg/day was given for insomnia for approximately two years and paroxetine hydrochloride (PAXIL®, GlaxoSmithKline) 50 mg/day was given for depression for approximately five months. All of these medications were discontinued prior to study treatment. No medications were started during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the akathisia and pruritus to be related to study treatment.

Study 5077US/0049 Patient 0014/004 placebo

Withdrawal: Back Pain

This narrative concerns a 29-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of back pain-left side (MedDRA: back pain) on Day 2 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient took the final dose of study medication on Day 19 and the event of back pain resolved four days later.

The patient had a relevant medical history of current back pain, headaches, joint pain, and neck pain. No relevant medications were given prior to or during the study treatment. The screening visit physical examination revealed decreased strength upper extremity bilateral,

decreased breath sounds, and tender hypogastrium. The final visit physical exam was unremarkable.

The investigator considered the back pain to be related to study treatment.

Study 5077US/0049 Patient 0014/007 600 mg

Withdrawal: Sedation

This narrative concerns a 22-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of sedation on Day 3 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient took her final dose of study medication on Day 17 and the sedation resolved two days later.

The patient had non-serious adverse events of fatigue and hypersomnia both starting on Day 3 and ending two days after the patient took her last dose of study medication. Both of these events were considered by the investigator to be severe in intensity and related to study treatment. Other non-serious adverse events included throat tightness (Day 7 to two days after the last dose of study medication; moderate in intensity), tremor (Day 4 to two days after last dose of study medication; moderate in intensity), orthostatic hypotension (Day 3 to two days after last dose; severe in intensity), and tension (Day 15 to two days after last dose; severe in intensity), all judged by the investigator to be related to study treatment. Because of these adverse events, the dose of study medication was reduced from four tablets daily to three tablets daily on Day 14, to two tablets daily from Day 9 through Day 12, and Day 15, and to one tablet daily on Day 8 and Day 17. No study medication was taken on Day 13 or Day 16. The patient had no relevant medical history. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0014/012 600 mg

Withdrawal: Akathisia

This narrative concerns a 55-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of akathisia on Day 3 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The study medication was held on Day 5. From Day 9 to Day 28 the dose was reduced due to akathisia. The patient took her final dose of study medication on Day 28 and the akathisia resolved two days later.

The patient had a relevant medical history of loss of consciousness (past) and tremors in the hands and head (current). Before entering the study, the patient was treated with clonazepam (KLONOPIN®, Roche) 1 mg/day for sleep and ibuprofen for muscle pain, which were discontinued prior to study treatment. Acetaminophen / aspirin / caffeine (EXCEDRIN®, Bristol-Myers) was taken as needed for migraines and aspirin was taken as needed for muscle pain. These medications started prior to study entry and continued during the study. Also during the study, the patient was given propranolol 40 mg/day and acetaminophen / pseudoephedrine / diphenhydramine hydrochloride (BENADRYL®, Pfizer Consumer) 10 mg/day for akathisia. Propranolol was started on Day 15 and was continuing at the time of the site personnel's last contact with the subject. Acetaminophen / pseudoephedrine / diphenhydramine hydrochloride (BENADRYL®, Pfizer Consumer) was given on Day 19 and Day 20. The screening and final physical examination revealed fine tremors in the hands and neck.

The investigator considered the akathisia to be related to study treatment.

Study 5077US/0049 Patient 0015/003 300 mg

Withdrawal: Sedation

This narrative concerns a 54-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of excessive sedation (MedDRA: sedation) on Day 1 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The patient took her final dose of study medication on Day 7 and the sedation resolved three days later.

The patient had no relevant medical history. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0018/003 600 mg

Withdrawal: Sedation

This narrative concerns a 27-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedated (MedDRA: sedation) on Day 4 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment, and the patient took her last dose of

study medication on Day 12. The sedation had not resolved at the time of the site personnel's last contact with the patient, three days after the last dose of study treatment.

The patient had a non-serious adverse event of dizziness on Day 2 that was considered by the investigator to be moderate in intensity and related to study treatment; dizziness resolved on Day 2. The patient had a non-serious adverse event of lethargy on Day 4, which was considered by the investigator to be moderate in intensity and related to study treatment. The lethargy had not resolved as of the site personnel's last contact with the patient. The patient's medical history revealed kidney stones, migraines, obesity, and seasonal allergies. The patient did not take any relevant concomitant medications before entering the study. Sumatriptan succinate (IMITREX®, GlaxoSmithKline) 50 mg/day and naproxen sodium (ALEVE®, Bayer Consumer) 275 mg/day were given for migraine headaches prior to the patient starting study medication. These medications were not given during study treatment. No additional medications were taken during the study. The screening and final visit physical examinations revealed obesity.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0018/007 600 mg

Withdrawal: Deep Vein Thrombosis

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0018/013 600 mg

Withdrawal: Akathisia

This narrative concerns a 44-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of akathisia on Day 2 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment and the patient took his last dose of study medication on Day 4. The akathisia resolved two days after the patient took his last dose of study medication.

The patient had a non-serious adverse event of sedation on Day 2 that was considered by the investigator to be moderate in intensity and related to study treatment. This event resolved two days after the patient took his last dose of study medication. The patient also had a non-serious adverse event of headache starting two days after the patient took his last dose of study medication and ending one day later. This event was considered by the investigator to be moderate in intensity and related to study treatment. The patient's medical history revealed allergies to codeine, diphenhydramine, ibuprofen, and hydrocodone bitartrate / acetaminophen (VICODIN®, Abbott). The medical history also included past alcohol abuse, current contact dermatitis, current headaches, and current insomnia. Before entering the study, the patient

was treated with acetaminophen / diphenhydramine (EXCEDRIN® PM, Bristol-Myers Squibb) for insomnia, which was ongoing as of the site personnel's last contact with the patient. During the study, aspirin was given to treat increased intensity of headaches. No additional medications were taken during the study. The screening physical examination revealed contact dermatitis. The final visit physical examination was unremarkable.

The investigator considered the akathisia to be related to study treatment.

Study 5077US/0049 Patient 0019/004 300 mg

Withdrawal: Irritability

This narrative concerns a 32-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of irritability on Day 29 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient took her last dose of study medication on Day 42. This event was not resolved at the time of last patient contact, one day after the final dose of study medication.

The patient had a relevant medical history of anxiety. The patient's screening and final visit physical examinations were unremarkable. The patient did not take any relevant concomitant medications prior to, or during the study. On Day 2 of randomized treatment, the patient had a non-serious adverse event of abnormal dreams that was considered by the investigator to be moderate in intensity and related to study treatment. On Day 18 the patient had a non-serious adverse event of mania that was considered by the investigator to be severe in intensity and not related to study treatment. These adverse events were not resolved at the time of last patient contact, one day after the final dose of study medication.

The investigator considered the irritability to be related to study treatment.

Study 5077US/0049 Patient 0019/014 300 mg

Withdrawal: Lethargy and Balance Impaired NOS

This narrative concerns a 24-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of lethargy on Day 2 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The patient also had a non-serious adverse event of equilibrium problems (not due to orthostatic hypotension) (MedDRA: balance impaired NOS) on Day 4 of randomized treatment that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to these events. The patient took his last dose of study medication on Day 4. Lethargy and

balance impaired NOS were ongoing at the time of last patient contact, ten days after the final dose of study medication.

The patient had a current medical history of diarrhea, influenza, and stomach cramps. The patient's screening and final visit physical examinations were unremarkable. The patient did not take any relevant concomitant medications prior to or during the study. On Day 2 of randomized treatment, the patient had non-serious adverse events of dysarthria and flat affect, which were both considered by the investigator to be moderate in intensity and related to study treatment. These events were ongoing at the time of last patient contact, ten days after the final dose of study medication.

The investigator considered the lethargy and balance impaired NOS to be related to study treatment.

Study 5077US/0049 Patient 0019/024 600 mg

Withdrawal: Dizziness (lightheaded), Confusional state, Somnolence, Tooth disorder NOS, Dyspnoea (difficulty breathing,) Dyspnoea (shortness of breath), Limb discomfort NOS, Dizziness (dizziness), Dysphagia, and Bruxism

This narrative concerns a 26-year-old white man with bipolar II disorder.

The patient had non-serious adverse events of lightheaded (not due to orthostatic hypotension) (MedDRA: dizziness), confusion (MedDRA: confusional state), drowsy (MedDRA: somnolence), weird feeling in teeth (MedDRA: tooth disorder NOS), difficulty breathing (MedDRA: dyspnoea), and shortness of breath (MedDRA: dyspnoea) all on Day 2 of randomized treatment to 600 mg that were each considered by the investigator to be severe in intensity. On Day 3 the patient had uncomfortable feeling in legs and arms (MedDRA: limb discomfort NOS) that was considered by the investigator to be severe in intensity. On Day 6 of randomized treatment, the patient had dizziness (not due to orthostatic hypotension) (MedDRA: dizziness), difficulty swallowing (MedDRA: dysphagia), and bruxism which were considered by the investigator to be severe, moderate, and moderate in intensity, respectively. The investigator withdrew study treatment due to these events. The patient did not return his blister card. The patient's last dose of study medication was estimated to be Day 9 based on the number of doses dispensed. On Day 8 the adverse events listed above resolved.

The patient's medical history and screening and final visit physical examinations were unremarkable. The patient did not take any relevant concomitant medications prior to or during the study.

The investigator considered the non-serious adverse events listed above to be related to study treatment.

Study 5077US/0049 Patient 0019/027 300 mg

Withdrawal: Lethargy, Dysarthria, Balance Impaired NOS, and Sedation

This narrative concerns a 26-year-old hispanic woman with bipolar II disorder.

The patient had non-serious adverse events of lethargy, slurred speech (MedDRA: dysarthria), and problems with equilibrium (MedDRA: balance impaired NOS) on Day 2 of randomized treatment to 300 mg that were considered by the investigator to be severe in intensity. The patient had a non-serious adverse event of excessive sedation (MedDRA: sedation) on Day 2 of randomized treatment that was considered by the investigator to be mild in intensity. The investigator withdrew study treatment due to these events. On Day 3 the patient took her last dose of study treatment. Two days after the patient's last dose, the dysarthria, balance impaired NOS, and sedation resolved. Five days after the patient's last dose, the lethargy resolved.

The patient had a non-serious adverse event of sinus headache starting one day prior to study treatment and ending on Day 1. The patient did not take any relevant concomitant medications prior to the study. During the study, the patient was given pseudoephedrine hydrochloride (SUDAFED®, Pfizer) for sinus headache. The patient had a relevant medical history of chronic ear infections. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered the lethargy, dysarthria, balance impaired NOS, and sedation to be related to study treatment.

Study 5077US/0049 Patient 0019/031 600 mg

Withdrawal: Sedation, Paraesthesia, Paraesthesia, and Joint stiffness

This narrative concerns a 47-year-old white man with bipolar II disorder.

The patient had non-serious adverse events of sedation, tingling in arms (MedDRA: paraesthesia), tingling in legs (MedDRA: paraesthesia), and tightness in joints (not due to Extrapyramidal Syndrome) (MedDRA: joint stiffness). The sedation began on Day 1 of randomized treatment to 600 mg and was considered by the investigator to be severe in intensity. The paraesthesia (of the arms), paraesthesia (of the legs), and the joint stiffness began on Day 2 of randomized treatment and were considered by the investigator to be moderate in intensity. The investigator did not judge the events to be significant enough to warrant the withdrawal of study treatment. However, the patient elected to discontinue study treatment due to these events. On Day 4 the patient took his last dose of randomized treatment. That same day, the paraesthesia (of the arms), paraesthesia (of the legs), and the joint stiffness resolved. One day after the patient's last dose of study treatment, the sedation resolved.

The patient's medical history and screening and final visit physical examinations were unremarkable. The patient did not take any relevant concomitant medications prior to or during the study.

The investigator considered the sedation, paraesthesia (of the arms), paraesthesia (of the legs), and joint stiffness to be related to study treatment.

Study 5077US/0049 Patient 0019/035 600 mg

Withdrawal: Sedation, Restless Legs Syndrome, and Hypomania

This narrative concerns a 34-year-old white woman with bipolar II disorder.

The patient had non-serious adverse events of sedation, restless legs at night not due to Extrapyramidal Syndrome (EPS) (MedDRA: restless legs syndrome), and hypomania on Days 3, 17, and 25 respectively, of randomized treatment to 600 mg. These events were considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to these events. On Day 30 the patient took her last dose of study treatment. Eight days after the patient's last dose, the sedation, restless legs syndrome, and hypomania resolved.

The patient had a medical history of tension headaches. The screening and final visit physical examinations were unremarkable. Before entering the study, the patient was not taking any medications. During the study the patient took acetaminophen (TYLENOL®, McNeil Consumer) for tension headache. On Day 8 of randomized treatment the subject had a non-serious adverse event of anger that was considered by the investigator to be severe in intensity and related to study treatment. This event was ongoing at the time of last patient contact, eight days after the final dose of study medication.

The investigator considered the sedation, restless legs syndrome, and hypomania to be related to study treatment.

Study 5077US/0049 Patient 0019/039 300 mg

Withdrawal: Lethargy, Disturbance In Attention, Paranoia, Suspiciousness, Dyspnoea, Balance Impaired NOS, Akathisia, Disorientation, Anxiety, and Panic Disorder NOS

This narrative concerns a 35-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of lethargy on Day 1 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The patient also had non-serious adverse events of decreased concentration (MedDRA: disturbance in attention), paranoia, suspiciousness, shortness of breath (MedDRA: dyspnoea), decreased equilibrium (not due to orthostatic hypotension) (MedDRA: balance impaired NOS), akathisia (not due to Extrapyramidal Syndrome) (MedDRA: akathisia), disorientation, anxiety, and panic disorder symptoms (MedDRA: panic disorder NOS) that all began on Day 3 of

randomized treatment. The investigator judged the disturbance in attention, paranoia, suspiciousness, dyspnoea, balance impaired NOS, and disorientation to be mild in intensity. The investigator judged the akathisia, anxiety, and panic disorder NOS to be moderate in intensity. The investigator did not judge these events to be significant enough to warrant the patient's withdrawal, however the patient elected to discontinue study treatment due to these adverse events. The patient took his last dose of study treatment on Day 3 of randomized treatment. One day after the patient's last dose, the lethargy, disturbance in attention, paranoia, suspiciousness, dyspnoea, balance impaired NOS, disorientation, anxiety, and panic disorder NOS resolved. Thirty-three days after the discontinuation of study treatment, the akathisia resolved.

The patient's medical history and screening and final visit physical examinations were unremarkable. The patient did not take any medications prior to, or during the study.

With the exception of the non-serious adverse event of disorientation, the investigator considered the adverse events described above to be related to study treatment.

Study 5077US/0049 Patient 0019/042 600 mg

Withdrawal: Irritability

This narrative concerns a 27-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of irritability on Day 12 of randomized treatment to 600 mg that was considered by the investigator to be mild in intensity. The investigator did not consider the irritability to be significant enough to warrant discontinuation; however the patient elected to withdraw from study treatment due to the irritability. The patient took her last dose of study medication on Day 14, and the irritability resolved one day later.

The patient had a current medical history of migraine and tension headaches. The patient's screening and final visit physical examinations were unremarkable. The patient did not take any relevant concomitant medications prior to, or during the study. Other non-serious adverse events reported by the patient included sedation (moderate intensity, attributed to study medication, beginning on Day 2 and ongoing at the final visit), tremor (moderate intensity, attributed to study medication, beginning on Day 11 and resolving on Day 15), and lethargy (moderate intensity, attributed to study medication, beginning on Day 12 and resolving on Day 15).

The investigator considered the irritability to be related to study treatment.

Study 5077US/0049 Patient 0020/013 300 mg

Withdrawal: Suicide Attempt

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0022/011 placebo

Withdrawal: Hip Fracture, Spinal Fracture NOS, Deep Vein Thrombosis

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0022/022 300 mg

Withdrawal: Conversion Disorder

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0022/025 600 mg

Withdrawal: Restless Legs Syndrome

This narrative concerns a 46-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of restless leg syndrome (worsening) "not due to [Extrapyramidal Syndrome] EPS" (MedDRA: restless legs syndrome) on Day 2 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The patient took her last dose of study medication on Day 7. Two days after the patient's last dose of study medication the restless legs syndrome resolved.

The patient had a relevant medical history of restless leg syndrome. The patient's screening and final visit physical examinations were unremarkable. Before entering the study, the patient took lorazepam (ATIVAN®, Wyeth Ayerst) for bipolar 3 mg/day from twenty days to nineteen days before the first dose, 2 mg/day from eighteen days to fifteen days before the first dose, and 1 mg/day from fourteen days to eleven days before the first dose. During the study, the patient took lorazepam (ATIVAN®, Wyeth Ayerst) 3 mg/day from Day 1 to Day 8.

The investigator considered the restless legs syndrome to be not related to study treatment.

Study 5077US/0049 Patient 0022/035 300 mg

Withdrawal: Somnolence

This narrative concerns a 20-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of somnolence on Day 2 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to somnolence. The patient took her last dose of

study treatment on Day 5 of randomized treatment, and the somnolence resolved one day later.

The patient's medical history and screening and final visit physical examinations were unremarkable. The patient did not take any relevant medications prior to or during the study.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0022/038 600 mg

Withdrawal: Somnolence

This narrative concerns a 39-year-old white man with bipolar I disorder.

The patient had two non-serious adverse events of somnolence during randomized treatment to 600 mg that were considered by the investigator to be mild in intensity. The patient's first episode of somnolence began on Day 5 of randomized treatment. Beginning on Day 12, the investigator decreased the patient's daily dose of study treatment by one tablet due to the somnolence. The first episode of somnolence resolved on Day 22. The second episode of somnolence began on Day 37. The investigator withdrew study treatment due to the somnolence. The patient took his last dose of study treatment on Day 41. The somnolence resolved one day after the patient's last dose of study treatment.

The patient's medical history was unremarkable. The screening and final visit physical examinations revealed a mild bilateral hand tremor. The patient did not take any relevant medications prior to or during the study.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0022/058 600 mg

Withdrawal: Somnolence

This narrative concerns a 43-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of somnolence on Day 2 of randomized treatment to 600 mg that was considered by the investigator to be mild in intensity. Beginning on Day 15, the patient's daily dose of study treatment was reduced to three tablets. The patient continued to have somnolence throughout the dose reduction. The investigator withdrew study treatment due to this event. The patient took his last dose of study medication on Day 31, and the somnolence resolved three days later.

The patient's medical history and screening and final visit physical examinations were unremarkable. The patient did not take any relevant medications prior to or during the study.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0022/062 600 mg

Withdrawal: Somnolence

This narrative concerns a 63-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of somnolence on Day 1 of randomized treatment to 600 mg that was considered by the investigator to be mild in intensity. The investigator withdrew study treatment due to this event. The patient took his last dose of study treatment on Day 16 of randomized treatment. One day after the patient took his last dose of study treatment the somnolence resolved.

The patient's relevant medical history included sleep apnea for which he required treatment during the study with loratadine (CLARITIN®, Schering) 10 mg/day on Days 9 and 10, diphenhydramine hydrochloride 25 mg/day starting on Day 11 and ongoing as of the last contact with the patient, three days after the last dose of study treatment, and oxymetazoline hydrochloride on Days 11 through 15. Prior to the study, the patient had been treated for bipolar disorder with modafinil (PROVIGIL®, Cephalon), nefazodone hydrochloride (SERZONE®, Bristol-Myers Squibb), clonazepam, lithium, and oxcarbazepine (TRILEPTAL®, Novartis). During the study, supplemental treatment with lorazepam was prescribed for bipolar disorder from seven days before the first dose of study treatment through Day 10. The screening and final visit physical examinations were unremarkable.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0023/023 600 mg

Withdrawal: Dizziness, Sweating Increased, and Sedation

This narrative concerns a 35-year-old white woman with bipolar II disorder.

The patient had non-serious adverse events of dizzy (not due to postural hypotension) (MedDRA: dizziness), sweating (MedDRA: sweating increased), and sedation on Day 2 of randomized treatment to 600 mg that were considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to dizziness. However, the patient decided to withdraw from study treatment due to sweating increased and sedation as well as the dizziness. The patient took her last dose of study treatment on Day 3. The events of dizziness, sweating increased, and sedation resolved two days later.

The patient's medical history and screening and final visit physical examinations were unremarkable. The patient did not take any relevant concomitant medications prior to or during the study.

The investigator considered the dizziness, sweating increased, and sedation to be related to study treatment.

Study 5077US/0049 Patient 0023/029 600 mg

Withdrawal: Sedation, Dry Mouth, and Dizziness

This narrative concerns a 46-year-old hispanic woman with bipolar II disorder.

The patient had non-serious adverse events of sedation, dry mouth, and dizziness (not due to postural hypotension) (MedDRA: dizziness) on Day 2 of randomized treatment to 600 mg that were each considered by the investigator to be severe in intensity. On Day 3 the patient discontinued study treatment as a result of these events. The investigator determined the sedation, dry mouth, and dizziness to be significant enough to warrant the patient's withdrawal from the study. Three days after the patient's last dose of study treatment, these non-serious adverse events resolved.

The patient's medical history and screening visit physical examination were unremarkable. The final visit physical examination was not done. The patient did not take any medications prior to or during the study.

The investigator considered the sedation, dry mouth, and dizziness to be related to study treatment.

Study 5077US/0049 Patient 0023/044 300 mg

Withdrawal: Restless Legs Syndrome

This narrative concerns a 44-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of restless legs (not due to Extrapyramidal Syndrome) (MedDRA: restless legs syndrome) on Day 5 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient took her last dose of study medication on Day 25. The event of restless legs syndrome had not resolved at the time of the last patient contact, three days after the last dose of study medication.

The patient had a relevant past medical history of spondylolisthesis (surgical repair). The patient's screening and final visit physical examinations were unremarkable. Before entering the study the patient was taking venlafaxine hydrochloride (EFFEXOR® XR, Wyeth) 150 mg/day and lamotrigine (LAMICTAL®, GlaxoSmithKline) 200 mg/day. Both of these medications were discontinued six days prior to baseline. The patient did not take any relevant concomitant medications during the study.

The investigator considered the restless legs syndrome to be related to study treatment.

Study 5077US/0049 Patient 0026/005 600 mg

Withdrawal: Sedation

This narrative concerns a 57-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. On Day 7 treatment was withdrawn for this event. Six days after the discontinuation of study treatment the sedation resolved.

The patient had a relevant current medical history of head tremor and insomnia, and a relevant past medical history of loss of consciousness. The screening physical examination revealed a mild head tremor. The final visit physical examination showed the mild head tremor to be resolved. The patient did not take any relevant concomitant medications during the study. Before entering the study, the patient had been treated with paroxetine hydrochloride (PAXIL®, GlaxoSmithKline) for depression. The patient took 20 mg/day from approximately seven years before study treatment to eight days before study treatment and 10 mg/day from seven days before study treatment to five days before study treatment. During the study, the patient had non-serious adverse events of dry mouth, dizziness, dyspnoea, and irritability. These events started on Day 1 of randomized treatment and resolved six days after the discontinuation of study treatment. The investigator judged these events to be related to study treatment.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0026/009 600 mg

Withdrawal: Dizziness

This narrative concerns a 43-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of dizzy (not due to postural hypotension) (MedDRA: dizziness) on Day 3 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. On Day 4, the patient discontinued study treatment as a result of the dizziness; however, the investigator did not judge the event significant enough to warrant withdrawal. The non-serious adverse event of dizziness resolved one day after the last dose of study treatment.

The patient's medical history and screening and final visit physical examinations were unremarkable. During the study the patient had non-serious adverse events of headache and vision blurred that began on Day 3 of study treatment and resolved one day after the last dose of study treatment. These events were considered by the investigator to be severe in intensity and related to study treatment. Before entering the study, the patient had been taking

topiramate (TOPAMAX®, Ortho-McNeil) 600 mg/day for bipolar. This medication was discontinued nine days prior to the first dose of study treatment. Topiramate (TOPAMAX®, Ortho-McNeil) 200 mg/day was restarted one day after the last dose of study treatment.

The investigator considered the dizziness to be related to study treatment.

Study 5077US/0049 Patient 0026/010 300 mg

Withdrawal: Nausea and Vomiting NOS

This narrative concerns a 31-year-old white man with bipolar I disorder.

The patient had non-serious adverse events of nausea and emesis (MedDRA: vomiting NOS) on Day 2 of randomized treatment to 300 mg. The investigator considered the nausea to be severe in intensity, and the vomiting to be moderate in intensity. The investigator discontinued study treatment for these events. The patient took his last dose of study treatment on Day 5. Two days after the discontinuation of study treatment, the non-serious adverse events of nausea and vomiting NOS resolved.

The patient's medical history and screening and final visit physical examinations were unremarkable. The subject did not take any concomitant medications prior to or during the study.

The investigator considered the nausea and vomiting NOS to be related to study treatment.

Study 5077US/0049 Patient 0026/027 placebo

Withdrawal: Convulsions NOS

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0026/028 placebo

Withdrawal: Major Depressive Disorder NOS, Acute Psychosis

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0028/007 600 mg

Withdrawal: Drug Abuser NOS

This narrative concerns a 22-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of drug abuse (methamphetamine) (MedDRA: drug abuser NOS) on Day 38 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The patient used methamphetamine on Day 38. The event was resolved on that same day. The patient returned to the clinic one day after the final dose of study medication and was withdrawn from the study due to the illicit drug use. The final dose of study medication was taken on Day 41.

On Day 39, the patient had a non-serious adverse event of panic attack, which was considered by the investigator to be severe in intensity and not related to study drug. In an attempt to control the panic attack, the patient took an overdose of 8 tablets of study medication on Day 39 of randomized treatment. This overdose was reported as a serious adverse event (non-accidental overdose) and was considered by the investigator to be moderate in intensity and not related to study treatment (see separate narrative). The patient had non-serious adverse events of nausea and vomiting NOS on Day 39, which were considered by the investigator to be severe in intensity and related to study drug. The patient had a relevant past medical history of polysubstance abuse. No relevant medications were taken prior to study treatment. During the study, the patient was treated with 50 g of activated charcoal and 20 MEQ of potassium chloride (KCL) on Day 39 for treatment of non-accidental overdose of study medication. The screening and final visit physical examinations were unremarkable.

The investigator considered the illicit drug use (drug abuser NOS) to be not related to study treatment.

Study 5077US/0049 Patient 0028/023 600 mg

Withdrawal: Suicide Attempt

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0028/025 600 mg

Withdrawal: Libido Decreased and Flat Affect

This narrative concerns a 27-year-old white man with bipolar I disorder.

The patient had non-serious adverse events of decreased libido (MedDRA: libido decreased) and flat affect. Libido decreased began on Day 1 and flat affect began on Day 3 of randomized treatment to 600 mg. Both events were considered by the investigator to be severe in intensity. The investigator determined that the libido decreased was severe enough to warrant withdrawal of study treatment. The patient determined that the flat affect also contributed to his decision to withdraw from study treatment. The patient's last dose of study treatment was taken on Day 12. Both adverse events resolved one day after the patient's final dose of study treatment.

The patient had a non-serious adverse event of fatigue starting on Day 3 and ending one day after the patient's final dose of study medication. This event was considered by the investigator to be severe in intensity and not related to study treatment. The patient had a relevant past medical history of Wolf Parkinson White syndrome, and a relevant current medical history of hay fever, headaches, and insomnia. Before entering the study, the patient had been treated with melatonin 2 mg/day for insomnia and divalproex sodium (DEPAKOTE®, Abbott) 1000 mg/day for bipolar disorder, which were discontinued one day and fifteen days prior to study treatment, respectively. No relevant concomitant medications were given during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the libido decreased to be related to study treatment and the flat affect to be not related to study treatment.

Study 5077US/0049 Patient 0028/031 placebo

Withdrawal: Hallucination, Auditory

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0028/045 300 mg

Withdrawal: Suicidal Ideation, Bipolar I Disorder

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0029/008 600 mg

Withdrawal: Syncope

This narrative concerns a 22-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of fainting (not due to orthostatic hypotension) (MedDRA: syncope) on Day 4 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator decided to reduce the dose of study medication due to the syncope. However, the patient decided to withdraw from study treatment as a result of this event. The syncope resolved on Day 4. The patient took her final dose of study medication on Day 5.

The patient had a non-serious adverse event of dizziness starting on Day 3 and ending one day after the patient took her final dose of study medication. The patient also had a non-serious adverse event of dyspnoea starting on Day 4 and ending one day after the patient took her final dose of study medication. Dizziness was considered by the investigator to be severe in intensity and related to study treatment. Dyspnoea was considered by the investigator to be

moderate in intensity and related to study treatment. The patient had a relevant current medical history of headaches, endometriosis, lower right quadrant tenderness, and iron deficient anemia. No relevant medications were given prior to or during the study treatment. The screening visit physical examination revealed lower right quadrant tenderness. The final physical exam was unchanged.

The investigator considered the syncope to be related to study treatment.

Study 5077US/0049 Patient 0029/012 600 mg

Withdrawal: Somnolence

This narrative concerns a 39-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of groggy in A.M. (MedDRA: somnolence) on Day 4 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. Beginning on Day 15, the patient's dose of study medication was reduced from 4 to 3 tablets per day. On Day 23, no study medication was taken. The patient took her final dose of study medication on Day 35. The event resolved three days after the patient's final dose of study medication.

The patient had no relevant medical history. No relevant medications were given prior to the study treatment. During the study, the patient was given lorazepam 1 mg/day for anxiety from Day 4 through Day 14. The screening and final visit physical examinations were unremarkable.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0029/015 600 mg

Withdrawal: Sedation

This narrative concerns a 45-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of sedation on Day 2 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment as a result of this event. The patient was not compliant with dosing from Day 8 to Day 10. The patient took 3 of 4 prescribed tablets on Day 8 and 2 of 4 prescribed tablets on Days 9 and 10. The patient took her final dose of study medication on Day 10. The event resolved five days after the patient's final dose of study medication.

The patient had no relevant medical history. Before entering the study, the patient had been treated with zaleplon (SONATA®, King) for insomnia. During the study, the patient was given zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 5 mg/day for insomnia (bipolar

disorder) and lorazepam (ATIVAN®, Wyeth Ayerst) 2 mg/day for anxiety (bipolar disorder). These medications were started six days prior to treatment and were continuing at the final study visit. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0029/038 placebo

Withdrawal: Anxiety

This narrative concerns a 61-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of anxiety on Day 2 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. The investigator did not determine that this event was significant enough to warrant withdrawal; however, the patient considered this event significant enough to warrant withdrawal from study treatment. The patient took his final dose of study medication on Day 7. The event resolved one day after the patient's final dose of study medication.

The patient had no relevant medical history. Before entering the study, the patient had been treated with St. John's Wort for depression. No concomitant medications were given during study treatment. The screening visit physical examination was unremarkable. A final visit physical exam was not performed.

The investigator considered the anxiety to be related to study treatment.

Study 5077US/0049 Patient 0029/039 placebo

Withdrawal: Dissociative Disorder NOS

This narrative concerns a 30-year-old hispanic woman with bipolar I disorder.

The patient had a non-serious adverse event of dissociative episode (MedDRA: dissociative disorder NOS) on Day 12 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. The event of dissociative disorder NOS resolved on that same day. The investigator did not consider the event significant enough to warrant withdrawal of study treatment. However, the patient decided to withdraw study treatment as a result of this event. The patient took her final dose of study medication on Day 13.

The patient had no relevant medical history. No relevant medications were given prior to the study treatment. During the study, the patient was given zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 10 mg/day, as needed, for worsening of insomnia. The screening and final visit physical examinations were unremarkable, except for a facial scar.

The investigator considered the dissociative disorder NOS to be not related to study treatment.

Study 5077US/0049 Patient 0030/024 600 mg

Withdrawal: Dry Mouth

This narrative concerns a 30-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of dry mouth on Day 3 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The investigator determined that this event was severe enough to warrant withdrawal from study treatment. The patient took her final dose of study medication on Day 5. The event resolved one day after the patient's final dose of study medication.

The patient had a non-serious adverse event of gingival infection that started four days prior to study treatment and was continuing as of the site personnel's last contact with the subject, three days after the patient's final dose of study medication. The patient had no relevant medical history. No relevant medications were given prior to study treatment. During the study, the patient was given penicillin 250 mg/day for a gingival infection starting four days prior to study treatment and continuing at the time of the site personnel's last contact with the subject. The screening and final visit physical examinations were unremarkable.

The investigator considered the dry mouth to be related to study treatment.

Study 5077US/0049 Patient 0030/025 600 mg

Withdrawal: Delusion NOS

This narrative concerns a 63-year-old black woman with bipolar I disorder.

The patient had a non-serious adverse event of delusional thinking (MedDRA: delusion NOS) on Day 36 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment as a result of this event. The patient took her final dose of study medication on Day 39. The event had not resolved at the time of the site personnel's last contact with the patient, one day after the last dose of study treatment.

The patient had no relevant medical history. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the delusion NOS to be not related to study treatment.

Study 5077US/0049 Patient 0031/010 600 mg

Withdrawal: Sedation

This narrative concerns a 37-year-old Italian/Native American woman with bipolar II disorder.

The patient had a non-serious adverse event of daytime sedation (MedDRA: sedation) on Day 1 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The patient took her final dose of study medication on Day 14. The event had not resolved at the time of the site personnel's last contact with the subject, two days after the last dose of study treatment.

The patient also had a non-serious adverse event of hypersomnia starting on Day 1. This event was also continuing as of the site personnel's last contact with the subject. The investigator reduced the study dose due to this event. The dose was reduced from 4 tablets to 3 tablets per day from Day 9 to Day 14. Hypersomnia was considered by the investigator to be moderate in intensity and related to study treatment. The patient had a medical history of current pneumonia and current stomach aches. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0031/015 600 mg

Withdrawal: Sedation, Vision Blurred, Dizziness, and Constipation

This narrative concerns a 27-year-old white woman with bipolar II disorder.

The patient had non-serious adverse events of daytime sedation (MedDRA: sedation), blurred vision (MedDRA: vision blurred), lightheadedness not due to postural hypotension (MedDRA: dizziness), and constipation. Constipation started on Day 2 of randomized treatment to 600 mg and was considered by the investigator to be mild in intensity. Sedation, vision blurred, and dizziness started on Day 4 and were considered by the investigator to be moderate in intensity. The investigator withdrew study treatment as a result of the sedation. The patient felt that the events of vision blurred, dizziness, and constipation also contributed to the decision to withdraw treatment. The patient took her final dose of study medication on Day 6 and the events of sedation, vision blurred, dizziness, and constipation ended four days later.

The patient did not have any relevant medical history. No relevant medications were taken prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation, vision blurred, dizziness, and constipation to be related to study treatment.

Study 5077US/0049 Patient 0031/020 300 mg

Withdrawal: Chronic Lymphocytic Leukaemia NOS

This narrative concerns a 44-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of chronic lymphocytic leukemia (MedDRA: chronic lymphocytic leukaemia NOS) on Day 17 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The patient took his final dose of study medication on Day 22. The event was continuing as of the patient's last study visit, one day after the last dose of study treatment.

The patient had no relevant medical history. No relevant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the chronic lymphocytic leukaemia NOS to be not related to study treatment.

Study 5077US/0049 Patient 0031/029 300 mg

Withdrawal: Nausea

This narrative concerns a 24-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of nausea on Day 4 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator reduced the dose of study medication for this event. The patient took 2 tablets of study medication on Day 11 and Day 12 and 3 tablets on Day 13 and Day 14. The patient decided to withdraw from study treatment as a result of this event and took his final dose of study medication on Day 14. The event of nausea ended six days later.

The patient had a non-serious adverse event of coordination abnormal NOS starting on Day 4 and ending six days after the patient took his last dose of study medication. The investigator considered this event mild in intensity and related to study treatment. Non-serious adverse events of akathisia and vision blurred started on Day 2 and were considered by the investigator to be mild in intensity and related to study treatment. The event of vision blurred ended two days after the patient took his last dose of study medication and akathisia ended one day later. The patient had a relevant medical history of a past concussion, current toothache, and current migraines. No relevant medications were given prior to or during the

study treatment. The screening visit physical examination was unremarkable. The final visit physical exam was not performed.

The investigator considered the nausea to be related to study treatment.

Study 5077US/0049 Patient 0033/006 300 mg

Withdrawal: Loss of Libido

This narrative concerns a 38-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of loss of libido on Day 3 of randomized treatment to 300 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment for this event. The patient reported that he stopped study medication after the dose on Day 9; however, study medication use for the second study week could not be confirmed because the patient did not return the week 2 blister card. For data collection purposes, the last dose of study medication was estimated to be Day 16, based on the total number of prescribed doses available on the week 2 blister card. The loss of libido was ongoing at the time of the patient's final visit, five days after the estimated last dose of study medication.

The patient had non-serious adverse events of dyspnoea, speech disorder, and palpitations starting on Day 2 and ongoing at the patient's final visit. The patient did not take his Day 7 dose of study treatment due to these events. The dyspnoea and speech disorder were considered by the investigator to be mild in intensity and related to the study treatment. The palpitations were considered by the investigator to be moderate in intensity and related to the study treatment. The patient did not have any relevant medical history. The screening and final visit physical examinations were unremarkable. The patient was not taking any medications prior to or during randomized treatment.

The investigator considered the loss of libido to be related to study treatment.

Study 5077US/0049 Patient 0033/009 600 mg

Withdrawal: Headache

This narrative concerns a 46-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of more severe headaches (MedDRA: headache) on Day 2 of randomized treatment to 600 mg that was considered by the investigator to be severe in intensity. The patient discontinued study treatment and withdrew from the study on Day 7. The patient did not return for study visits after the baseline visit and did not return the blister card with unused medication. In the Case Report Form for this study, treatment

duration was entered as nine days, the maximum possible exposure from the single blister card that was dispensed. The headache was ongoing as of Day 7.

The patient had a non-serious adverse event of insomnia that started seven days before the baseline visit and was ongoing when she withdrew from the study. This event was considered by the investigator to be moderate in intensity and not related to the study treatment. The patient had a medical history of asthma, chronic bronchitis, and headaches. The screening physical examination was unremarkable. The final visit physical examination was not performed. Before entering the study, the patient was not taking any medications. During the study, the patient was given zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 5 mg/day for insomnia.

The investigator considered the headache to be related to study treatment.

Study 5077US/0049 Patient 0033/010 placebo

Withdrawal: Ectopic Pregnancy

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0034/002 300 mg

Withdrawal: Somnolence

This narrative concerns a 55-year-old white man with bipolar I disorder.

The patient had a non-serious adverse event of daytime drowsiness (MedDRA: somnolence) on Day 2 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient took his final dose of study medication on Day 21 and the event resolved four days later.

The patient had a non-serious adverse event of insomnia starting six days prior to baseline and ending on Day 1. This event was considered moderate in intensity and was considered not related to study treatment. The patient had a non-serious adverse event of influenza like illness starting on Day 12 and ending on Day 16. This event was considered mild in intensity and was not considered related to study treatment. The patient had a non-serious adverse event of bronchitis NOS starting on Day 17 and ending six days after the final dose of study medication. This event was considered mild in intensity and was considered not related to study treatment. The patient had no relevant medical history. Before entering the study, the patient was treated with divalproex sodium (DEPAKOTE®, Abbott) 1000 mg/day and venlafaxine hydrochloride (EFFEXOR®, Wyeth) 150 mg/day for bipolar disorder. During the study, the patient was treated with acetaminophen (TYLENOL®, McNeil Consumer) 325 mg/day and tussin 2 tsps/day for flu symptoms, and amoxicillin/ clavulanate potassium

(AUGMENTIN® XR, GlaxoSmithKline) 325 mg/day and guaifenesin 200 mg/day for bronchitis. The screening and final visit physical examinations were unremarkable.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0035/013 300 mg

Withdrawal: Restlessness and Anxiety

This narrative concerns a 28-year-old white woman with bipolar II disorder.

The patient had non-serious adverse events of restlessness not due to EPS (MedDRA: restlessness) and anxiety beginning on Day 5 of randomized treatment to 300 mg that were considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to these events. Per study medication records, the patient reported that she stopped taking study medication due to these adverse events; however, her final dose of study medication was taken on Day 3, two days prior to the onset of restlessness and anxiety. Restlessness and anxiety resolved four days after onset, six days after the final dose of study medication.

The patient had no relevant medical history. Before entering the study, the patient was treated with carbamazepine (TEGRETOL®, Novartis) 500 mg/day for mood stabilization, risperidone (RISPERDAL®, Janssen) 4 mg/day for psychosis, and acetaminophen / pseudoephedrine / diphenhydramine hydrochloride (BENADRYL®, Pfizer Consumer) 50 mg/day for insomnia, all of which were discontinued prior to study treatment. The patient re-started these medications one day after taking her final dose of study medication. These medications were continuing as of the final study visit, four days after the final dose of study medication. The screening physical examination was unremarkable. A final visit physical examination was not performed.

The investigator considered the restlessness and anxiety to be related to study treatment.

Study 5077US/0049 Patient 0035/015 300 mg

Withdrawal: Sedation

This narrative concerns a 33-year-old hispanic woman with bipolar II disorder.

The patient had a non-serious adverse event of extreme sedation (MedDRA: sedation) on Day 1 of randomized treatment to 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient took her final dose of study medication on Day 5 and sedation resolved one day later.

The patient had a relevant medical history of asthma and weather allergies. No concomitant medications were given prior to or during the study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation to be related to study treatment.

Study 5077US/0049 Patient 0036/002 600 mg

Withdrawal: Mania

This narrative concerns a 32-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of mania on Day 22 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The patient continued to have mania with moderate intensity through Day 25. On Day 26, the intensity of mania increased to severe. The patient returned for a study visit on Day 28 and the investigator withdrew study treatment. The final dose of study medication was taken on Day 27 and the event of mania resolved four days later.

The patient had a non-serious adverse event of somnolence from Day 1 through Day 28. This event was considered by the investigator to be severe in intensity and related to study treatment. The patient had a relevant medical history of intermittent migraine headaches and intermittent non-specific headaches. No relevant medications were taken prior to or during study treatment. The screening and final visit physical examinations were unremarkable.

The investigator considered the mania to be related to study treatment.

Study 5077US/0049 Patient 0036/007 600 mg

Withdrawal: Sedation and Urinary Incontinence

This narrative concerns a 35-year-old white woman with bipolar I disorder.

The patient had non-serious adverse events of sedation and intermittent urinary incontinence secondary to sedation (MedDRA: urinary incontinence) during randomized treatment to 600 mg. The patient had sedation on Day 8 through Day 10 and Day 12 through Day 13 with intensities of severe and moderate, respectively. The patient had urinary incontinence on Day 9 through Day 12 with an intensity of moderate. The subject began taking a reduced dose of study medication on Day 9 and stopped the study medication on Day 13 due to sedation. Urinary incontinence resolved on Day 12 and sedation resolved on Day 13. The investigator determined that sedation and urinary incontinence warranted withdrawal of the patient from the study treatment.

The patient had a non-serious adverse event of hypoaesthesia (intermittent numbness in both legs) starting on Day 1 and ending on Day 4 that was considered by the investigator to be

moderate in intensity and not related to the study treatment. The patient had a non-serious adverse event of somnolence starting on Day 5 and ending on Day 8 with an intensity of moderate. The somnolence was considered by the investigator to be related to the study treatment. The patient had a relevant medical history of intermittent migraine headaches and seasonal allergies. Before entering the study, the patient had been treated with venlafaxine hydrochloride (EFFEXOR®, Wyeth) 150 mg/day for bipolar depression for approximately 3 months and acetaminophen / pseudoephedrine (TYLENOL SINUS®, McNeil Consumer) as needed for seasonal allergies. During the study the patient was given acetaminophen / chlorpheniramine / pseudoephedrine (SINUTAB® MAXIMUM STRENGTH SINUS ALLERGY, Pfizer Consumer) for seasonal allergies on Day 4. The screening and final visit physical examinations were unremarkable.

The investigator considered the sedation and urinary incontinence to be related to study treatment.

Study 5077US/0049 Patient 0039/028 600 mg

Withdrawal: Suicidal Ideation

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study 5077US/0049 Patient 0039/043 600 mg

Withdrawal: Drug Abuser NOS

This narrative concerns a 20-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of drug abuse with cocaine (MedDRA: drug abuser NOS) on Day 25 of randomized treatment to 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event. The patient did not return his last study medication blister card. The patient's last dose of study medication was estimated to be Day 37 based on the number of doses dispensed. The adverse event of drug abuser NOS was not resolved at the time of the patient's last study visit on Day 37, twelve days after the onset of the event.

The patient had a relevant past medical history of alcohol and cocaine abuse. The screening physical examination was unremarkable. The final visit physical examination was not performed. The patient did not take any relevant concomitant medications prior to or during the study.

The investigator considered the drug abuser NOS to be not related to study treatment.

Study 5077US/0049 Patient 0039/052 300 mg

Withdrawal: Somnolence

This narrative concerns a 37-year-old black woman with bipolar II disorder.

The patient had a non-serious adverse event of drowsiness (MedDRA: somnolence) on Day 4 of randomized treatment to 300 mg that was considered by the investigator to be mild in intensity. The investigator withdrew study treatment due to this event. The patient failed to take some or all of her study medication on half of the study days (Days 3, 5, 6, 7, 10, and 12). The patient took her last dose of study medication on Day 13. The event of somnolence was ongoing as of the patient's last study visit, one day after the final dose of study medication.

The patient had a relevant medical history of insomnia, non-insulin dependent diabetes mellitus, and obesity. The patient's screening and final visit physical examinations were unremarkable. No relevant medications were taken prior to or during the study.

The investigator considered the somnolence to be related to study treatment.

Study 5077US/0049 Patient 0041/010 placebo

Withdrawal: Mania

See Serious Adverse Event narrative section regarding withdrawal for this event.

Table 11.3.6.1 Other Adverse Events of Interest

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO. of PTS	%	NO. of PTS	%	NO. of PTS	%
ANY ADVERSE EVENT	PREFERRED TERM						
		28	15.6	28	15.6	15	8.3
EPS	TOTAL	21	11.7	23	12.8	8	4.4
	AKATHISIA	9	5.0	9	5.0	2	1.1
	DYSKINESIA	4	2.2	2	1.1	0	0
	DYSTONIA	2	1.1	5	2.8	1	0.6
	EXTRAPYRAMIDAL DISORDER	0	0	2	1.1	1	0.6
	MUSCLE CONTRACTIONS INVOLUNTARY	0	0	1	0.6	0	0
	MUSCLE RIGIDITY	0	0	0	0	1	0.6
	PSYCHOMOTOR HYPERACTIVITY	0	0	1	0.6	0	0
	RESTLESSNESS	2	1.1	1	0.6	2	1.1
	TREMOR	5	2.8	5	2.8	1	0.6
DIABETES	TOTAL	2	1.1	0	0	2	1.1
	THIRST	2	1.1	0	0	2	1.1
SUICIDALITY	TOTAL	4	2.2	3	1.7	3	1.7
	SUICIDAL IDEATION	3	1.7	3	1.7	3	1.7

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG212.SAS
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Table 11.3.6.1 Other Adverse Events of Interest

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=179		N=180		N=180	
		NO. of PTS	%	NO. of PTS	%	NO. of PTS	%
SUICIDALITY	PREFERRED TERM						
	SUICIDE ATTEMPT	1	0.6	1	0.6	0	0
TREATMENT EMERGENT MANIA	TOTAL	3	1.7	2	1.1	2	1.1
	HYPOMANIA	1	0.6	1	0.6	0	0
	MANIA	2	1.1	1	0.6	2	1.1

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG212.SAS
GENERATED: 12JUL2005 17:39:31 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0005013	43 YRS CAUCASIAN FEMALE	07NOV2002-13NOV2002	ON	DYSKINESIA (Nervous system disorders) [MOTOR INCOORDINATION (DYSKINESIA)]	7	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0013007	49 YRS CAUCASIAN MALE	20MAR2003-30MAR2003	ON	AKATHISIA (Nervous system disorders) [RESTLESSNESS (DUE TO EPS) AKATHISIA]	11	1	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0014010	40 YRS CAUCASIAN FEMALE	30APR2003-02MAY2003	ON	DYSTONIA (Nervous system disorders) [JAW HYPERTONUS (DUE TO EPS) DYSTONIA]	3	9	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0016004	36 YRS CAUCASIAN MALE	10FEB2003-CONTINUE	ON	TREMOR (Nervous system disorders) [PHYSICAL TREMORS (NOT DUE TO EPS.)]	UNK	8	MIL	NO	N	N	N	N	N	N	NO NO	None
		E0018001	24 YRS CAUCASIAN FEMALE	07DEC2002-23DEC2002	ON	DYSKINESIA (Nervous system disorders) [NOCTURNAL MYOCLONUS (NOT DUE TO EPS)]	17	40	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0019011	50 YRS HISPANIC FEMALE	27NOV2002-CONTINUE	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS DUE TO EPS (AKATHISIA)]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0022017	41 YRS CAUCASIAN MALE	20DEC2002-22JAN2003	ON	TREMOR (Nervous system disorders) [TREMOR NOT DUE TO EPS]	34	2	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0022022	23 YRS CAUCASIAN FEMALE	31DEC2002-18JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0022031	36 YRS CAUCASIAN MALE	28FEB2003-CONTINUE	ON	AKATHISIA (Nervous system disorders) [MOTOR RESTLESSNESS (DUE TO EPS AKATHISIA)]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
		E0028029	39 YRS HISPANIC MALE	12FEB2003-18FEB2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	7	9	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
		E0028045	46 YRS CAUCASIAN MALE	15JUL2003-CONTINUE	ON	DYSKINESIA (Nervous system disorders) [DYSKINESIA]	UNK	28	MOD	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0033015	34 YRS CAUCASIAN FEMALE	16APR2003-16APR2003	ON	TREMOR (Nervous system disorders) [HAND TREMORS (NOT DUE TO EPS)]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0039024	35 YRS CAUCASIAN FEMALE	28FEB2003-07MAY2003	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS POST DOSE (NOT DUE TO EPS)]	69	2	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR II)	E0005030	19 YRS CAUCASIAN FEMALE	27MAR2003-CONTINUE	ON	DYSTONIA (Nervous system disorders) [DYSTONIA]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0005036	40 YRS CAUCASIAN FEMALE	06MAY2003-13MAY2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS DUE TO EPS (AKATHISIA)]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
						DYSKINESIA (Nervous system disorders) [DECREASED COORDINATION SECONDARY TO EPS (DYSKINESIA)]	8	1	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0009002	47 YRS CAUCASIAN MALE	20NOV2002-27NOV2002	ON	TREMOR (Nervous system disorders) [TREMORS - (NOT DUE TO EPS)]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR II)	E0019039	35 YRS CAUCASIAN MALE	03MAY2003-05JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA (NOT DUE TO EPS)]	34	3	MOD	NO	N	N	N	N	N	N	YES YES	None
		E0031029	24 YRS CAUCASIAN MALE	19JUN2003-04JUL2003	ON	AKATHISIA (Nervous system disorders) [AKATHESIA]	16	2	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0033021	27 YRS CAUCASIAN FEMALE	14JUL2003-CONTINUE	ON	TREMOR (Nervous system disorders) [TREMORS - (NOT DUE TO EPS)]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0035013	28 YRS CAUCASIAN FEMALE	08FEB2003-12FEB2003	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS NOT DUE TO EPS]	5	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR II)	E0040003	50 YRS CAUCASIAN FEMALE	23JUL2003-04AUG2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	13	5	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0002011	35 YRS CAUCASIAN FEMALE	30APR2003-10MAY2003	ON	DYSTONIA (Nervous system disorders) [JOINT STIFFNESS DUE TO EPS DYSTONIA]	11	2	MIL	NO	N	N	N	N	N	N	NO NO	None
				30APR2003-16MAY2003	ON	DYSKINESIA (Nervous system disorders) [MUSCLE TWITCHINGS IN LOWER EXTREMITIES DUE TO EPS - DYSKINESIA]	17	2	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0005007	44 YRS CAUCASIAN FEMALE	30OCT2002-CONTINUE	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None

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EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0005007	44 YRS CAUCASIAN FEMALE	30OCT2002-CONTINUE	ON	DYSTONIA (Nervous system disorders) [MUSCLE TENSION SECONDARY TO EPS (DYSTONIA)]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0005009	24 YRS CAUCASIAN MALE	30OCT2002-01NOV2002	ON	AKATHISIA (Nervous system disorders) [PARESTHESIA RELATED TO EPS (AKATHISIA)]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0005025	40 YRS CAUCASIAN FEMALE	04MAR2003-11MAR2003	ON	DYSTONIA (Nervous system disorders) [MUSCLE TENSION (DUE TO EPS - DYSTONIA)]	8	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0005025	40 YRS CAUCASIAN FEMALE	15MAR2003-CONTINUE	ON	DYSTONIA (Nervous system disorders) [MUSCLE TIGHTNESS (DUE TO EPS - DYSTONIA)]	UNK	17	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0007005	34 YRS CAUCASIAN FEMALE	01FEB2003-24FEB2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS (AKATHISIA)]	24	2	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0013006	28 YRS CAUCASIAN FEMALE	20MAR2003-20MAR2003	ON	DYSTONIA (Nervous system disorders) [DYSTONIA]	1	8	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0013014	48 YRS CAUCASIAN MALE	06JUN2003-22JUN2003	ON	AKATHISIA (Nervous system disorders) [(RESTLESSNESS) AKATHISIA]	17	4	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0013014	48 YRS CAUCASIAN MALE	24JUN2003-24JUN2003	ON	AKATHISIA (Nervous system disorders) [(RESTLESSNESS) AKATHISIA]	1	22	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0014007	22 YRS CAUCASIAN FEMALE	04APR2003-19APR2003	ON	TREMOR (Nervous system disorders) [TREMOR (NOT DUE TO EPS)]	16	4	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
		E0014012	55 YRS CAUCASIAN FEMALE	29MAY2003-25JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	28	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0019015	24 YRS CAUCASIAN FEMALE	01FEB2003-11FEB2003	ON	PSYCHOMOTOR HYPERACTIVITY (Nervous system disorders) [HYPERACTIVITY]	11	31	MOD	NO	N	N	N	N	N	N	NO YES	None

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EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0020010	31 YRS CAUCASIAN FEMALE	05MAR2003-19MAR2003	ON	AKATHISIA (Nervous system disorders) [BILATERAL HAND TREMORS (DUE TO EPS - AKATHISIA)]	15	29	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0020023	46 YRS CAUCASIAN MALE	01JUL2003-15JUL2003	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [BRADYKINESIA (DUE TO EPS)]	15	15	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0030014	32 YRS CAUCASIAN FEMALE	22FEB2003-25FEB2003	ON	DYSTONIA (Nervous system disorders) [OPTIC MUSCLE STIFFNESS DUE TO EPS (DYSTONIA)]	4	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0039026	45 YRS BLACK FEMALE	10MAR2003-10MAR2003	ON	TREMOR (Nervous system disorders) [TREMORS RIGHT HAND (NOT DUE TO EPS)]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0041004	35 YRS CAUCASIAN MALE	10FEB2003-23FEB2003	ON	TREMOR (Nervous system disorders) [TREMOR (NOT DUE TO EPS)]	14	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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EPS	QUETIAPINE 600 MG (BIPOLAR II)	E0005031	29 YRS CAUCASIAN FEMALE	02MAY2003-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE STIFFNESS OF BACK (SECONDARY TO EPS)]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0005038	31 YRS CAUCASIAN FEMALE	14MAY2003-CONTINUE	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0018002	53 YRS CAUCASIAN MALE	06DEC2002-12DEC2002	ON	DYSKINESIA (Nervous system disorders) [NOCTURNAL MYOCLONES (NOT DUE TO EPS)]	7	8	MOD	NO	N	N	N	N	N	N	NO YES	None

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EPS	QUETIAPINE 600 MG (BIPOLAR II)	E0018002	53 YRS CAUCASIAN MALE	25DEC2002-CONTINUE	ON	MUSCLE CONTRACTIONS INVOLUNTARY (Nervous system disorders) [MUSCLE FASCICULATION (NOT DUE TO EPS)]	UNK	27	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0018013	44 YRS CAUCASIAN MALE	25JAN2003-29JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	5	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0019016	26 YRS CAUCASIAN FEMALE	24JAN2003-CONTINUE	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS (NOT DUE TO EPS)]	UNK	19	MOD	NO	N	N	N	N	N	N	NO YES	None

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EPS	QUETIAPINE 600 MG (BIPOLAR II)	E0019021	41 YRS CAUCASIAN MALE	01FEB2003-17FEB2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEG DUE TO EPS (AKATHISIA)]	17	3	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0019042	27 YRS CAUCASIAN FEMALE	14JUN2003-18JUN2003	ON	TREMOR (Nervous system disorders) [HAND TREMORS (NOT DUE TO EPS)]	5	11	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0037012	21 YRS CAUCASIAN MALE	22AUG2003-08SEP2003	ON	TREMOR (Nervous system disorders) [BILATERAL HAND TREMOR (NOT DUE TO EPS)]	18	38	MIL	NO	N	N	N	N	N	N	NO YES	None

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EPS	PLACEBO (BIPOLAR I)	E0009012	28 YRS CAUCASIAN MALE	25JUN2003-26JUN2003	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [EPS (INVOLUNTARY MOVEMENT OF MOUTH) - DYSTONIA]	2	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0020017	41 YRS CAUCASIAN FEMALE	04APR2003-14APR2003	ON	DYSTONIA (Nervous system disorders) [BILATERAL CALF PAIN (DUE TO EPS - DYSTONIA)]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None
						DYSTONIA (Nervous system disorders) [LEFT ELBOW RIGIDITY (DUE TO EPS - DYSTONIA)]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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EPS	PLACEBO (BIPOLAR I)	E0020017	41 YRS CAUCASIAN FEMALE	04APR2003-30MAY2003	ON	DYSTONIA (Nervous system disorders) [RIGHT CERVICAL AREA ACHE "EXACERBATED" (DUE TO EPS - DYSTONIA) (NECK)]	57	2	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0020020	36 YRS CAUCASIAN FEMALE	12MAY2003-17MAY2003	ON	MUSCLE RIGIDITY (Musculoskeletal and connective tissue disorders) [LEFT SHOULDER RIGIDITY (NOT DUE TO EPS)]	6	1	MIL	NO	N	N	N	N	N	N	NO NO	None

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EPS	PLACEBO (BIPOLAR II)	E0005041	52 YRS CAUCASIAN FEMALE	10JUL2003-12JUL2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS SECONDARY TO EPS (AKATHISIA)]	3	17	MIL	NO	N	N	N	N	N	N	NO YES	None
				21JUL2003-22JUL2003	ON	AKATHISIA (Nervous system disorders) [JITTERINESS SECONDARY TO EPS (AKATHISIA)]	2	28	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0018005	24 YRS CAUCASIAN MALE	14JAN2003-26JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHESIA]	13	26	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0019046	35 YRS CAUCASIAN FEMALE	01AUG2003-02AUG2003	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS (NOT DUE TO EPS)]	2	37	MOD	NO	N	N	N	N	N	N	NO NO	None

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** WD=WITHDRAWN.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG106.SAS
GENERATED: 12JUL2005 17:38:57 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	PLACEBO (BIPOLAR II)	E0019048	34 YRS CAUCASIAN FEMALE	11JUL2003-16JUL2003	ON	TREMOR (Nervous system disorders) [TREMOR (HANDS) "NOT DUE TO EPS"]	6	2	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0029004	34 YRS BLACK FEMALE	21DEC2002-25DEC2002	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS (NOT DUE TO EPS)]	5	33	MOD	NO	N	N	N	N	N	N	NO NO	None

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
DIABETES	QUETIAPINE 300 MG (BIPOLAR I)	E0006005	37 YRS CAUCASIAN FEMALE	10DEC2002-12JAN2003	ON	THIRST (General disorders and administration site conditions) [INCREASED THIRST]	34	6	MOD	NO	N	N	N	N	N	N	NO YES	None
				13JAN2003-CONTINUE	ON	THIRST (General disorders and administration site conditions) [INTERMITTENT THIRST]	UNK	40	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0027003	50 YRS CAUCASIAN FEMALE	27FEB2003-06MAR2003	ON	THIRST (General disorders and administration site conditions) [INCREASED THIRST]	8	31	MIL	NO	N	N	N	N	N	N	NO NO	None

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
DIABETES	PLACEBO (BIPOLAR I)	E0014017	23 YRS CAUCASIAN FEMALE	09JUL2003-23JUL2003	ON	THIRST (General disorders and administration site conditions) [THIRSTY]	15	13	MIL	NO	N	N	N	N	N	N	NO NO	None
		E0028010	28 YRS CAUCASIAN FEMALE	13NOV2002-03DEC2002	ON	THIRST (General disorders and administration site conditions) [INCREASED THIRST]	21	9	MOD	NO	N	N	N	N	N	N	NO NO	Dose Changed

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	QUETIAPINE 300 MG (BIPOLAR I)	E0028045	46 YRS CAUCASIAN MALE	26JUL2003-29JUL2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH ACUTE PSYCHOSIS]	4	39	SEV	YES	N	N	Y	N	N	N	YES NO	None
		E0020013	23 YRS CAUCASIAN MALE	17MAR2003-17MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	13	SEV	YES	N	Y	N	N	N	N	YES NO	Permanently Stopped
		E0022036	22 YRS CAUCASIAN MALE	12MAY2003-14MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	3	77	MOD	YES	N	N	Y	N	N	N	NO NO	None

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	QUETIAPINE 300 MG (BIPOLAR I)	E0036005	19 YRS CAUCASIAN FEMALE	19AUG2003-19AUG2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION, WITH NO PLAN OR INTENT]	1	50	MIL	NO	N	N	N	N	N	N	NO NO	None

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	QUETIAPINE 600 MG (BIPOLAR I)	E0028023	54 YRS BLACK MALE	09MAR2003-09MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	48	SEV	YES	N	N	Y	N	N	N	YES NO	None
				15MAR2003-02APR2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDE IDEATION]	19	54	SEV	NO	N	N	N	N	N	N	NO NO	None
		E0039028	39 YRS BLACK MALE	09MAY2003-16MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	8	47	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	QUETIAPINE 600 MG (BIPOLAR II)	E0028032	36 YRS CAUCASIAN MALE	18MAY2003-28MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	11	55	SEV	YES	N	N	Y	N	N	N	NO NO	None

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	PLACEBO (BIPOLAR I)	E0022070	59 YRS CAUCASIAN MALE	16JUN2003-18JUN2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [ACTIVE SUICIDAL IDEATION]	3	5	MOD	NO	N	N	N	N	N	N	NO NO	None
		E0035002	46 YRS CAUCASIAN MALE	14DEC2002-CONTINUE	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	UNK	24	MOD	YES	N	N	Y	N	N	N	NO NO	None
		E0039030	52 YRS CAUCASIAN FEMALE	06JUN2003-08JUN2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	3	75	SEV	YES	N	N	Y	N	N	N	NO NO	None

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
TREATMENT EMERGENT MANIA	QUETIAPINE 300 MG (BIPOLAR I)	E0028045	46 YRS CAUCASIAN MALE	15JUL2003-29JUL2003	ON	MANIA (Psychiatric disorders) [MANIC EPISODE]	15	28	SEV	NO	N	N	N	N	N	N	NO NO	None
		E0019004	32 YRS CAUCASIAN FEMALE	24NOV2002-CONTINUE	ON	MANIA (Psychiatric disorders) [DECREASED NEED TO SLEEP (INCREASED ENERGY) (MANIA)]	UNK	18	SEV	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT EMERGENT MANIA	QUETIAPINE 300 MG (BIPOLAR II)	E0019007	39 YRS CAUCASIAN FEMALE	01JAN2003-CONTINUE	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	UNK	50	MOD	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT EMERGENT MANIA	QUETIAPINE 600 MG (BIPOLAR I)	E0036002	32 YRS CAUCASIAN FEMALE	08JUL2003-11JUL2003	ON	MANIA (Psychiatric disorders) [MANIA]	4	22	MOD	NO	N	N	N	N	N	N	NO YES	None
				12JUL2003-17JUL2003	ON	MANIA (Psychiatric disorders) [MANIA]	6	26	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT EMERGENT MANIA	QUETIAPINE 600 MG (BIPOLAR II)	E0019035	34 YRS CAUCASIAN FEMALE	11APR2003-24APR2003	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	14	25	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT EMERGENT MANIA	PLACEBO (BIPOLAR I)	E0011008	23 YRS CAUCASIAN MALE	13FEB2003-CONTINUE	ON	MANIA (Psychiatric disorders) [ONSET OF MANIC SYMPTOMS]	UNK	15	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0041010	32 YRS CAUCASIAN MALE	07JUN2003-13JUN2003	ON	MANIA (Psychiatric disorders) [MANIC EPISODE]	7	39	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	MALE	39-39	X10E9/L	0.19	0.56	1	X10E9/L	0.19	0.56
	MALE	24-24	X10E9/L	0.42	1.26	1	X10E9/L	0.42	1.26
	FEMALE	45-45	X10E9/L	0.48	1.44	1	X10E9/L	0.48	1.44
	BOTH	39-60	X10E9/L	0.5	1.49	1	X10E9/L	0.50	1.49
	FEMALE	25-34	X10E9/L	0.51	1.54	1	X10E9/L	0.51	1.54
	BOTH	30-30	X10E9/L	0.53	1.58	1	X10E9/L	0.53	1.58
	BOTH	35-52	X10E9/L	0.54	1.63	1	X10E9/L	0.54	1.63
	BOTH	52-52	X10E9/L	0.56	1.68	1	X10E9/L	0.56	1.68
	BOTH	22-49	X10E9/L	0.57	1.72	1	X10E9/L	0.57	1.72
	BOTH	26-52	X10E9/L	0.59	1.77	1	X10E9/L	0.59	1.77
	BOTH	28-36	X10E9/L	0.6	1.82	1	X10E9/L	0.60	1.82
	FEMALE	25-25	X10E9/L	0.62	1.81	1	X10E9/L	0.62	1.81
	FEMALE	20-57	X10E9/L	0.62	1.86	1	X10E9/L	0.62	1.86
	BOTH	24-47	X10E9/L	0.64	1.91	1	X10E9/L	0.64	1.91
	BOTH	20-49	X10E9/L	0.65	1.96	1	X10E9/L	0.65	1.96
	BOTH	22-56	X10E9/L	0.67	2	1	X10E9/L	0.67	2.00
	BOTH	19-54	X10E9/L	0.68	2.05	1	X10E9/L	0.68	2.05
	BOTH	28-58	X10E9/L	0.7	2.1	1	X10E9/L	0.70	2.10
	BOTH	22-62	X10E9/L	0.71	2.14	1	X10E9/L	0.71	2.14
	BOTH	30-52	X10E9/L	0.73	2.19	1	X10E9/L	0.73	2.19
	BOTH	33-62	X10E9/L	0.74	2.24	1	X10E9/L	0.74	2.24
	BOTH	25-58	X10E9/L	0.76	2.28	1	X10E9/L	0.76	2.28
	BOTH	26-55	X10E9/L	0.78	2.33	1	X10E9/L	0.78	2.33
	BOTH	21-58	X10E9/L	0.79	2.38	1	X10E9/L	0.79	2.38
	BOTH	23-50	X10E9/L	0.81	2.42	1	X10E9/L	0.81	2.42
	BOTH	30-63	X10E9/L	0.82	2.47	1	X10E9/L	0.82	2.47
	BOTH	24-50	X10E9/L	0.84	2.52	1	X10E9/L	0.84	2.52
	BOTH	27-57	X10E9/L	0.85	2.56	1	X10E9/L	0.85	2.56
	BOTH	22-59	X10E9/L	0.87	2.61	1	X10E9/L	0.87	2.61
	BOTH	19-59	X10E9/L	0.88	2.66	1	X10E9/L	0.88	2.66
	BOTH	20-55	X10E9/L	0.9	2.7	1	X10E9/L	0.90	2.70
	BOTH	29-45	X10E9/L	0.91	2.75	1	X10E9/L	0.91	2.75
	BOTH	25-59	X10E9/L	0.93	2.8	1	X10E9/L	0.93	2.80
	BOTH	19-51	X10E9/L	0.95	2.84	1	X10E9/L	0.95	2.84
	BOTH	23-54	X10E9/L	0.96	2.89	1	X10E9/L	0.96	2.89
	BOTH	18-41	X10E9/L	0.98	2.94	1	X10E9/L	0.98	2.94
	BOTH	27-55	X10E9/L	0.99	2.98	1	X10E9/L	0.99	2.98
	BOTH	18-40	X10E9/L	1.01	3.03	1	X10E9/L	1.01	3.03
	BOTH	18-60	X10E9/L	1.02	3.08	1	X10E9/L	1.02	3.08

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	BOTH	25-59	X10E9/L	1.04	3.12	1	X10E9/L	1.04	3.12
	BOTH	23-46	X10E9/L	1.05	3.17	1	X10E9/L	1.05	3.17
	BOTH	18-59	X10E9/L	1.07	3.22	1	X10E9/L	1.07	3.22
	BOTH	18-55	X10E9/L	1.09	3.26	1	X10E9/L	1.09	3.26
	BOTH	23-58	X10E9/L	1.1	3.31	1	X10E9/L	1.10	3.31
	BOTH	19-52	X10E9/L	1.12	3.36	1	X10E9/L	1.12	3.36
	BOTH	19-58	X10E9/L	1.13	3.4	1	X10E9/L	1.13	3.40
	BOTH	18-63	X10E9/L	1.15	3.45	1	X10E9/L	1.15	3.45
	BOTH	20-59	X10E9/L	1.16	3.5	1	X10E9/L	1.16	3.50
	BOTH	19-42	X10E9/L	1.18	3.54	1	X10E9/L	1.18	3.54
	BOTH	19-63	X10E9/L	1.19	3.59	1	X10E9/L	1.19	3.59
	BOTH	22-47	X10E9/L	1.21	3.63	1	X10E9/L	1.21	3.63
	BOTH	20-54	X10E9/L	1.22	3.68	1	X10E9/L	1.22	3.68
	BOTH	24-40	X10E9/L	1.24	3.73	1	X10E9/L	1.24	3.73
	BOTH	18-58	X10E9/L	1.26	3.77	1	X10E9/L	1.26	3.77
	BOTH	22-58	X10E9/L	1.27	3.82	1	X10E9/L	1.27	3.82
	BOTH	18-50	X10E9/L	1.29	3.87	1	X10E9/L	1.29	3.87
	BOTH	19-41	X10E9/L	1.3	3.91	1	X10E9/L	1.30	3.91
	BOTH	22-57	X10E9/L	1.32	3.96	1	X10E9/L	1.32	3.96
	BOTH	20-58	X10E9/L	1.33	4.01	1	X10E9/L	1.33	4.01
	BOTH	33-54	X10E9/L	1.35	4.05	1	X10E9/L	1.35	4.05
	BOTH	18-60	X10E9/L	1.36	4.1	1	X10E9/L	1.36	4.10
	BOTH	20-44	X10E9/L	1.38	4.15	1	X10E9/L	1.38	4.15
	MALE	45-45	X10E9/L	1.39	4.03	1	X10E9/L	1.39	4.03
	BOTH	24-42	X10E9/L	1.4	4.19	1	X10E9/L	1.40	4.19
	BOTH	18-48	X10E9/L	1.41	4.24	1	X10E9/L	1.41	4.24
	BOTH	29-62	X10E9/L	1.43	4.29	1	X10E9/L	1.43	4.29
	BOTH	19-50	X10E9/L	1.44	4.33	1	X10E9/L	1.44	4.33
	BOTH	27-59	X10E9/L	1.46	4.38	1	X10E9/L	1.46	4.38
	BOTH	21-60	X10E9/L	1.47	4.43	1	X10E9/L	1.47	4.43
	BOTH	23-35	X10E9/L	1.49	4.47	1	X10E9/L	1.49	4.47
	BOTH	34-40	X10E9/L	1.5	4.52	1	X10E9/L	1.50	4.52
	BOTH	26-53	X10E9/L	1.52	4.57	1	X10E9/L	1.52	4.57
	BOTH	28-52	X10E9/L	1.53	4.61	1	X10E9/L	1.53	4.61
	FEMALE	20-54	X10E9/L	1.55	4.66	1	X10E9/L	1.55	4.66
	BOTH	22-35	X10E9/L	1.57	4.71	1	X10E9/L	1.57	4.71
	BOTH	31-54	X10E9/L	1.58	4.75	1	X10E9/L	1.58	4.75
	BOTH	21-23	X10E9/L	1.6	4.8	1	X10E9/L	1.60	4.80
	BOTH	22-40	X10E9/L	1.61	4.85	1	X10E9/L	1.61	4.85

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	FEMALE	25-62	X10E9/L	1.63	4.89	1	X10E9/L	1.63	4.89
	FEMALE	20-24	X10E9/L	1.64	4.94	1	X10E9/L	1.64	4.94
	BOTH	46-46	X10E9/L	1.66	4.99	1	X10E9/L	1.66	4.99
	BOTH	40-40	X10E9/L	1.67	5.03	1	X10E9/L	1.67	5.03
	BOTH	20-46	X10E9/L	1.69	5.08	1	X10E9/L	1.69	5.08
	BOTH	18-45	X10E9/L	1.71	5.13	1	X10E9/L	1.71	5.13
	BOTH	36-56	X10E9/L	1.72	5.17	1	X10E9/L	1.72	5.17
	BOTH	34-53	X10E9/L	1.74	5.22	1	X10E9/L	1.74	5.22
	FEMALE	43-43	X10E9/L	1.75	5.27	1	X10E9/L	1.75	5.27
	FEMALE	19-21	X10E9/L	1.77	5.31	1	X10E9/L	1.77	5.31
	BOTH	21-35	X10E9/L	1.78	5.36	1	X10E9/L	1.78	5.36
	BOTH	36-44	X10E9/L	1.8	5.41	1	X10E9/L	1.80	5.41
	BOTH	21-46	X10E9/L	1.81	5.45	1	X10E9/L	1.81	5.45
	BOTH	25-25	X10E9/L	1.83	5.5	1	X10E9/L	1.83	5.50
	BOTH	24-24	X10E9/L	1.84	5.55	1	X10E9/L	1.84	5.55
	BOTH	50-50	X10E9/L	1.86	5.59	1	X10E9/L	1.86	5.59
	BOTH	25-50	X10E9/L	1.88	5.64	1	X10E9/L	1.88	5.64
	FEMALE	23-31	X10E9/L	1.89	5.69	1	X10E9/L	1.89	5.69
	FEMALE	30-31	X10E9/L	1.91	5.73	1	X10E9/L	1.91	5.73
	MALE	32-32	X10E9/L	1.92	5.78	1	X10E9/L	1.92	5.78
	MALE	43-43	X10E9/L	1.94	5.83	1	X10E9/L	1.94	5.83
	MALE	43-43	X10E9/L	1.97	5.92	1	X10E9/L	1.97	5.92
	FEMALE	42-42	X10E9/L	2	6.01	1	X10E9/L	2.00	6.01
	FEMALE	52-52	X10E9/L	2.02	6.06	1	X10E9/L	2.02	6.06
	FEMALE	20-23	X10E9/L	2.05	6.15	1	X10E9/L	2.05	6.15
	FEMALE	40-40	X10E9/L	2.08	6.24	1	X10E9/L	2.08	6.24
	FEMALE	32-32	X10E9/L	2.09	6.29	1	X10E9/L	2.09	6.29
	MALE	49-49	X10E9/L	2.11	6.34	1	X10E9/L	2.11	6.34
	FEMALE	35-35	X10E9/L	2.12	6.38	1	X10E9/L	2.12	6.38
	BOTH	26-26	X10E9/L	2.14	6.43	1	X10E9/L	2.14	6.43
	MALE	35-41	X10E9/L	2.15	6.48	1	X10E9/L	2.15	6.48
	MALE	46-46	X10E9/L	2.17	6.52	1	X10E9/L	2.17	6.52
	MALE	44-44	X10E9/L	2.2	6.62	1	X10E9/L	2.20	6.62
	MALE	41-41	X10E9/L	2.28	6.85	1	X10E9/L	2.28	6.85
	FEMALE	26-26	X10E9/L	2.31	6.94	1	X10E9/L	2.31	6.94
	FEMALE	32-32	X10E9/L	2.33	6.99	1	X10E9/L	2.33	6.99
	BOTH	35-35	X10E9/L	2.39	7.18	1	X10E9/L	2.39	7.18
	MALE	53-53	X10E9/L	2.42	7.27	1	X10E9/L	2.42	7.27
	MALE	31-31	X10E9/L	2.43	7.32	1	X10E9/L	2.43	7.32

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	MALE	46-46	X10E9/L	2.68	8.06	1	X10E9/L	2.68	8.06
	MALE	44-44	X10E9/L	2.82	8.48	1	X10E9/L	2.82	8.48
	MALE	44-44	X10E9/L	3.01	9.04	1	X10E9/L	3.01	9.04
	MALE	35-35	X10E9/L	3.26	9.79	1	X10E9/L	3.26	9.79
	MALE	44-44	X10E9/L	3.63	10.9	1	X10E9/L	3.63	10.90
MONOCYTES(CALC)	MALE	39-39	X10E9/L	0.05	0.11	1	X10E9/L	0.05	0.11
	FEMALE	25-25	X10E9/L	0.07	0.28	1	X10E9/L	0.07	0.28
	MALE	24-24	X10E9/L	0.11	0.25	1	X10E9/L	0.11	0.25
	FEMALE	45-45	X10E9/L	0.12	0.29	1	X10E9/L	0.12	0.29
	BOTH	39-60	X10E9/L	0.13	0.3	1	X10E9/L	0.13	0.30
	BOTH	25-34	X10E9/L	0.13	0.31	1	X10E9/L	0.13	0.31
	BOTH	30-30	X10E9/L	0.14	0.32	1	X10E9/L	0.14	0.32
	BOTH	35-52	X10E9/L	0.14	0.33	1	X10E9/L	0.14	0.33
	BOTH	52-52	X10E9/L	0.14	0.34	1	X10E9/L	0.14	0.34
	BOTH	22-49	X10E9/L	0.15	0.35	1	X10E9/L	0.15	0.35
	BOTH	26-52	X10E9/L	0.15	0.36	1	X10E9/L	0.15	0.36
	BOTH	28-36	X10E9/L	0.16	0.37	1	X10E9/L	0.16	0.37
	BOTH	20-57	X10E9/L	0.16	0.38	1	X10E9/L	0.16	0.38
	BOTH	24-47	X10E9/L	0.16	0.39	1	X10E9/L	0.16	0.39
	MALE	45-45	X10E9/L	0.16	0.62	1	X10E9/L	0.16	0.62
	BOTH	20-49	X10E9/L	0.17	0.39	1	X10E9/L	0.17	0.39
	BOTH	22-56	X10E9/L	0.17	0.4	1	X10E9/L	0.17	0.40
	BOTH	19-54	X10E9/L	0.18	0.41	1	X10E9/L	0.18	0.41
	BOTH	28-58	X10E9/L	0.18	0.42	1	X10E9/L	0.18	0.42
	BOTH	22-62	X10E9/L	0.18	0.43	1	X10E9/L	0.18	0.43
	BOTH	30-52	X10E9/L	0.19	0.44	1	X10E9/L	0.19	0.44
	BOTH	33-62	X10E9/L	0.19	0.45	1	X10E9/L	0.19	0.45
	BOTH	25-58	X10E9/L	0.2	0.46	1	X10E9/L	0.20	0.46
	BOTH	26-55	X10E9/L	0.2	0.47	1	X10E9/L	0.20	0.47
	BOTH	21-58	X10E9/L	0.2	0.48	1	X10E9/L	0.20	0.48
	BOTH	23-50	X10E9/L	0.21	0.49	1	X10E9/L	0.21	0.49
	BOTH	30-63	X10E9/L	0.21	0.5	1	X10E9/L	0.21	0.50
	BOTH	24-50	X10E9/L	0.22	0.51	1	X10E9/L	0.22	0.51
	BOTH	27-57	X10E9/L	0.22	0.52	1	X10E9/L	0.22	0.52
	BOTH	22-59	X10E9/L	0.22	0.53	1	X10E9/L	0.22	0.53
	BOTH	19-59	X10E9/L	0.23	0.54	1	X10E9/L	0.23	0.54
	BOTH	20-55	X10E9/L	0.23	0.55	1	X10E9/L	0.23	0.55
	BOTH	29-45	X10E9/L	0.24	0.55	1	X10E9/L	0.24	0.55

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
MONOCYTES(CALC)	BOTH	25-59	X10E9/L	0.24	0.56	1	X10E9/L	0.24	0.56
	BOTH	19-51	X10E9/L	0.24	0.57	1	X10E9/L	0.24	0.57
	BOTH	23-54	X10E9/L	0.25	0.58	1	X10E9/L	0.25	0.58
	BOTH	18-41	X10E9/L	0.25	0.59	1	X10E9/L	0.25	0.59
	BOTH	27-55	X10E9/L	0.26	0.6	1	X10E9/L	0.26	0.60
	BOTH	18-40	X10E9/L	0.26	0.61	1	X10E9/L	0.26	0.61
	BOTH	18-60	X10E9/L	0.26	0.62	1	X10E9/L	0.26	0.62
	BOTH	25-59	X10E9/L	0.27	0.63	1	X10E9/L	0.27	0.63
	BOTH	23-46	X10E9/L	0.27	0.64	1	X10E9/L	0.27	0.64
	BOTH	18-59	X10E9/L	0.28	0.65	1	X10E9/L	0.28	0.65
	BOTH	18-55	X10E9/L	0.28	0.66	1	X10E9/L	0.28	0.66
	BOTH	23-58	X10E9/L	0.28	0.67	1	X10E9/L	0.28	0.67
	BOTH	19-52	X10E9/L	0.29	0.68	1	X10E9/L	0.29	0.68
	BOTH	19-58	X10E9/L	0.29	0.69	1	X10E9/L	0.29	0.69
	BOTH	18-63	X10E9/L	0.3	0.7	1	X10E9/L	0.30	0.70
	BOTH	19-59	X10E9/L	0.3	0.71	1	X10E9/L	0.30	0.71
	BOTH	19-63	X10E9/L	0.31	0.72	1	X10E9/L	0.31	0.72
	BOTH	22-47	X10E9/L	0.31	0.73	1	X10E9/L	0.31	0.73
	BOTH	20-54	X10E9/L	0.32	0.74	1	X10E9/L	0.32	0.74
	BOTH	24-40	X10E9/L	0.32	0.75	1	X10E9/L	0.32	0.75
	BOTH	18-58	X10E9/L	0.32	0.76	1	X10E9/L	0.32	0.76
	BOTH	22-58	X10E9/L	0.33	0.77	1	X10E9/L	0.33	0.77
	BOTH	18-50	X10E9/L	0.33	0.78	1	X10E9/L	0.33	0.78
	BOTH	19-41	X10E9/L	0.34	0.79	1	X10E9/L	0.34	0.79
	BOTH	22-57	X10E9/L	0.34	0.8	1	X10E9/L	0.34	0.80
	BOTH	20-58	X10E9/L	0.34	0.81	1	X10E9/L	0.34	0.81
	BOTH	33-54	X10E9/L	0.35	0.82	1	X10E9/L	0.35	0.82
	BOTH	18-60	X10E9/L	0.35	0.83	1	X10E9/L	0.35	0.83
	BOTH	20-44	X10E9/L	0.36	0.84	1	X10E9/L	0.36	0.84
	BOTH	24-42	X10E9/L	0.36	0.85	1	X10E9/L	0.36	0.85
	BOTH	18-48	X10E9/L	0.36	0.86	1	X10E9/L	0.36	0.86
	BOTH	29-62	X10E9/L	0.37	0.86	1	X10E9/L	0.37	0.86
	BOTH	19-50	X10E9/L	0.37	0.87	1	X10E9/L	0.37	0.87
	BOTH	27-59	X10E9/L	0.38	0.88	1	X10E9/L	0.38	0.88
	BOTH	21-60	X10E9/L	0.38	0.89	1	X10E9/L	0.38	0.89
	BOTH	23-35	X10E9/L	0.38	0.9	1	X10E9/L	0.38	0.90
	BOTH	34-40	X10E9/L	0.39	0.91	1	X10E9/L	0.39	0.91
	BOTH	26-53	X10E9/L	0.39	0.92	1	X10E9/L	0.39	0.92
	BOTH	28-52	X10E9/L	0.4	0.93	1	X10E9/L	0.40	0.93

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
MONOCYTES(CALC)	BOTH	20-54	X10E9/L	0.4	0.94	1	X10E9/L	0.40	0.94
	BOTH	22-35	X10E9/L	0.4	0.95	1	X10E9/L	0.40	0.95
	BOTH	31-54	X10E9/L	0.41	0.96	1	X10E9/L	0.41	0.96
	BOTH	21-23	X10E9/L	0.41	0.97	1	X10E9/L	0.41	0.97
	BOTH	22-40	X10E9/L	0.42	0.98	1	X10E9/L	0.42	0.98
	BOTH	25-62	X10E9/L	0.42	0.99	1	X10E9/L	0.42	0.99
	BOTH	20-24	X10E9/L	0.42	1	1	X10E9/L	0.42	1.00
	BOTH	46-46	X10E9/L	0.43	1.01	1	X10E9/L	0.43	1.01
	BOTH	40-40	X10E9/L	0.43	1.02	1	X10E9/L	0.43	1.02
	BOTH	20-46	X10E9/L	0.44	1.02	1	X10E9/L	0.44	1.02
	BOTH	18-45	X10E9/L	0.44	1.03	1	X10E9/L	0.44	1.03
	BOTH	36-56	X10E9/L	0.44	1.04	1	X10E9/L	0.44	1.04
	BOTH	34-53	X10E9/L	0.45	1.05	1	X10E9/L	0.45	1.05
	BOTH	43-43	X10E9/L	0.45	1.06	1	X10E9/L	0.45	1.06
	FEMALE	19-21	X10E9/L	0.46	1.07	1	X10E9/L	0.46	1.07
	FEMALE	21-35	X10E9/L	0.46	1.08	1	X10E9/L	0.46	1.08
	FEMALE	36-44	X10E9/L	0.46	1.09	1	X10E9/L	0.46	1.09
	BOTH	21-46	X10E9/L	0.47	1.1	1	X10E9/L	0.47	1.10
	BOTH	25-25	X10E9/L	0.47	1.11	1	X10E9/L	0.47	1.11
	BOTH	24-24	X10E9/L	0.48	1.12	1	X10E9/L	0.48	1.12
	BOTH	50-50	X10E9/L	0.48	1.13	1	X10E9/L	0.48	1.13
	BOTH	25-50	X10E9/L	0.48	1.14	1	X10E9/L	0.48	1.14
	FEMALE	23-31	X10E9/L	0.49	1.15	1	X10E9/L	0.49	1.15
	FEMALE	30-31	X10E9/L	0.49	1.16	1	X10E9/L	0.49	1.16
	MALE	32-32	X10E9/L	0.5	1.17	1	X10E9/L	0.50	1.17
	MALE	43-43	X10E9/L	0.5	1.18	1	X10E9/L	0.50	1.18
	MALE	43-43	X10E9/L	0.51	1.19	1	X10E9/L	0.51	1.19
	FEMALE	42-42	X10E9/L	0.52	1.21	1	X10E9/L	0.52	1.21
	FEMALE	52-52	X10E9/L	0.52	1.22	1	X10E9/L	0.52	1.22
	FEMALE	20-23	X10E9/L	0.53	1.24	1	X10E9/L	0.53	1.24
	FEMALE	40-40	X10E9/L	0.54	1.26	1	X10E9/L	0.54	1.26
	FEMALE	32-32	X10E9/L	0.54	1.27	1	X10E9/L	0.54	1.27
	BOTH	49-49	X10E9/L	0.54	1.28	1	X10E9/L	0.54	1.28
	FEMALE	35-35	X10E9/L	0.55	1.29	1	X10E9/L	0.55	1.29
	FEMALE	26-26	X10E9/L	0.55	1.3	1	X10E9/L	0.55	1.30
	MALE	35-41	X10E9/L	0.56	1.31	1	X10E9/L	0.56	1.31
	MALE	46-46	X10E9/L	0.56	1.32	1	X10E9/L	0.56	1.32
	MALE	44-44	X10E9/L	0.57	1.33	1	X10E9/L	0.57	1.33
	MALE	41-41	X10E9/L	0.59	1.38	1	X10E9/L	0.59	1.38

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
MONOCYTES(CALC)	FEMALE	26-26	X10E9/L	0.6	1.4	1	X10E9/L	0.60	1.40
	FEMALE	32-32	X10E9/L	0.6	1.41	1	X10E9/L	0.60	1.41
	BOTH	35-35	X10E9/L	0.62	1.45	1	X10E9/L	0.62	1.45
	MALE	53-53	X10E9/L	0.62	1.47	1	X10E9/L	0.62	1.47
	MALE	31-31	X10E9/L	0.63	1.48	1	X10E9/L	0.63	1.48
	MALE	46-46	X10E9/L	0.69	1.63	1	X10E9/L	0.69	1.63
	MALE	44-44	X10E9/L	0.73	1.71	1	X10E9/L	0.73	1.71
	MALE	44-44	X10E9/L	0.78	1.82	1	X10E9/L	0.78	1.82
	MALE	35-35	X10E9/L	0.84	1.97	1	X10E9/L	0.84	1.97
	MALE	44-44	X10E9/L	0.94	2.2	1	X10E9/L	0.94	2.20
NEUTROPHILS(CALC)	MALE	39-39	X10E9/L	0.49	0.92	1	X10E9/L	0.49	0.92
	MALE	24-24	X10E9/L	1.1	2.08	1	X10E9/L	1.10	2.08
	FEMALE	45-45	X10E9/L	1.27	2.39	1	X10E9/L	1.27	2.39
	BOTH	39-60	X10E9/L	1.31	2.46	1	X10E9/L	1.31	2.46
	FEMALE	25-34	X10E9/L	1.35	2.54	1	X10E9/L	1.35	2.54
	BOTH	30-30	X10E9/L	1.39	2.62	1	X10E9/L	1.39	2.62
	BOTH	35-52	X10E9/L	1.43	2.7	1	X10E9/L	1.43	2.70
	BOTH	52-52	X10E9/L	1.47	2.77	1	X10E9/L	1.47	2.77
	BOTH	22-49	X10E9/L	1.51	2.85	1	X10E9/L	1.51	2.85
	BOTH	26-52	X10E9/L	1.55	2.93	1	X10E9/L	1.55	2.93
	BOTH	28-36	X10E9/L	1.6	3	1	X10E9/L	1.60	3.00
	FEMALE	25-25	X10E9/L	1.63	2.81	1	X10E9/L	1.63	2.81
	BOTH	20-57	X10E9/L	1.64	3.08	1	X10E9/L	1.64	3.08
	BOTH	24-47	X10E9/L	1.68	3.16	1	X10E9/L	1.68	3.16
	BOTH	20-49	X10E9/L	1.72	3.23	1	X10E9/L	1.72	3.23
	BOTH	22-56	X10E9/L	1.76	3.31	1	X10E9/L	1.76	3.31
	BOTH	19-54	X10E9/L	1.8	3.39	1	X10E9/L	1.80	3.39
	BOTH	28-58	X10E9/L	1.84	3.47	1	X10E9/L	1.84	3.47
	BOTH	22-62	X10E9/L	1.88	3.54	1	X10E9/L	1.88	3.54
	BOTH	30-52	X10E9/L	1.92	3.62	1	X10E9/L	1.92	3.62
	BOTH	33-62	X10E9/L	1.96	3.7	1	X10E9/L	1.96	3.70
	BOTH	25-58	X10E9/L	2	3.77	1	X10E9/L	2.00	3.77
	BOTH	26-55	X10E9/L	2.05	3.85	1	X10E9/L	2.05	3.85
	BOTH	21-58	X10E9/L	2.09	3.93	1	X10E9/L	2.09	3.93
	BOTH	23-50	X10E9/L	2.13	4	1	X10E9/L	2.13	4.00
	BOTH	30-63	X10E9/L	2.17	4.08	1	X10E9/L	2.17	4.08
	BOTH	24-50	X10E9/L	2.21	4.16	1	X10E9/L	2.21	4.16
	BOTH	27-57	X10E9/L	2.25	4.24	1	X10E9/L	2.25	4.24

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC)	BOTH	22-59	X10E9/L	2.29	4.31	1	X10E9/L	2.29	4.31
	BOTH	19-59	X10E9/L	2.33	4.39	1	X10E9/L	2.33	4.39
	BOTH	20-55	X10E9/L	2.37	4.47	1	X10E9/L	2.37	4.47
	BOTH	29-45	X10E9/L	2.41	4.54	1	X10E9/L	2.41	4.54
	BOTH	25-59	X10E9/L	2.45	4.62	1	X10E9/L	2.45	4.62
	BOTH	19-51	X10E9/L	2.49	4.7	1	X10E9/L	2.49	4.70
	BOTH	23-54	X10E9/L	2.54	4.77	1	X10E9/L	2.54	4.77
	BOTH	18-41	X10E9/L	2.58	4.85	1	X10E9/L	2.58	4.85
	BOTH	27-55	X10E9/L	2.62	4.93	1	X10E9/L	2.62	4.93
	BOTH	18-40	X10E9/L	2.66	5.01	1	X10E9/L	2.66	5.01
	BOTH	18-60	X10E9/L	2.7	5.08	1	X10E9/L	2.70	5.08
	BOTH	25-59	X10E9/L	2.74	5.16	1	X10E9/L	2.74	5.16
	BOTH	23-46	X10E9/L	2.78	5.24	1	X10E9/L	2.78	5.24
	BOTH	18-59	X10E9/L	2.82	5.31	1	X10E9/L	2.82	5.31
	BOTH	18-55	X10E9/L	2.86	5.39	1	X10E9/L	2.86	5.39
	BOTH	23-58	X10E9/L	2.9	5.47	1	X10E9/L	2.90	5.47
	BOTH	19-52	X10E9/L	2.94	5.54	1	X10E9/L	2.94	5.54
	BOTH	19-58	X10E9/L	2.99	5.62	1	X10E9/L	2.99	5.62
	BOTH	18-63	X10E9/L	3.03	5.7	1	X10E9/L	3.03	5.70
	BOTH	20-59	X10E9/L	3.07	5.78	1	X10E9/L	3.07	5.78
	BOTH	19-42	X10E9/L	3.11	5.85	1	X10E9/L	3.11	5.85
	BOTH	19-63	X10E9/L	3.15	5.93	1	X10E9/L	3.15	5.93
	BOTH	22-47	X10E9/L	3.19	6.01	1	X10E9/L	3.19	6.01
	BOTH	20-54	X10E9/L	3.23	6.08	1	X10E9/L	3.23	6.08
	BOTH	24-40	X10E9/L	3.27	6.16	1	X10E9/L	3.27	6.16
	BOTH	18-58	X10E9/L	3.31	6.24	1	X10E9/L	3.31	6.24
	BOTH	22-58	X10E9/L	3.35	6.31	1	X10E9/L	3.35	6.31
	BOTH	18-50	X10E9/L	3.39	6.39	1	X10E9/L	3.39	6.39
	BOTH	19-41	X10E9/L	3.44	6.47	1	X10E9/L	3.44	6.47
	BOTH	22-57	X10E9/L	3.48	6.55	1	X10E9/L	3.48	6.55
	BOTH	20-58	X10E9/L	3.52	6.62	1	X10E9/L	3.52	6.62
	BOTH	33-54	X10E9/L	3.56	6.7	1	X10E9/L	3.56	6.70
	BOTH	18-60	X10E9/L	3.6	6.78	1	X10E9/L	3.60	6.78
	MALE	45-45	X10E9/L	3.61	6.23	1	X10E9/L	3.61	6.23
	BOTH	20-44	X10E9/L	3.64	6.85	1	X10E9/L	3.64	6.85
	BOTH	24-42	X10E9/L	3.68	6.93	1	X10E9/L	3.68	6.93
	BOTH	18-48	X10E9/L	3.72	7.01	1	X10E9/L	3.72	7.01
	BOTH	29-62	X10E9/L	3.76	7.08	1	X10E9/L	3.76	7.08
	BOTH	19-50	X10E9/L	3.8	7.16	1	X10E9/L	3.80	7.16

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC)	BOTH	27-59	X10E9/L	3.84	7.24	1	X10E9/L	3.84	7.24
	BOTH	21-60	X10E9/L	3.89	7.32	1	X10E9/L	3.89	7.32
	BOTH	23-35	X10E9/L	3.93	7.39	1	X10E9/L	3.93	7.39
	BOTH	34-40	X10E9/L	3.97	7.47	1	X10E9/L	3.97	7.47
	BOTH	26-53	X10E9/L	4.01	7.55	1	X10E9/L	4.01	7.55
	BOTH	28-52	X10E9/L	4.05	7.62	1	X10E9/L	4.05	7.62
	FEMALE	20-54	X10E9/L	4.09	7.7	1	X10E9/L	4.09	7.70
	BOTH	22-35	X10E9/L	4.13	7.78	1	X10E9/L	4.13	7.78
	BOTH	31-54	X10E9/L	4.17	7.85	1	X10E9/L	4.17	7.85
	BOTH	21-23	X10E9/L	4.21	7.93	1	X10E9/L	4.21	7.93
	BOTH	22-40	X10E9/L	4.25	8.01	1	X10E9/L	4.25	8.01
	FEMALE	25-62	X10E9/L	4.29	8.09	1	X10E9/L	4.29	8.09
	FEMALE	20-24	X10E9/L	4.34	8.16	1	X10E9/L	4.34	8.16
	BOTH	46-46	X10E9/L	4.38	8.24	1	X10E9/L	4.38	8.24
	BOTH	40-40	X10E9/L	4.42	8.32	1	X10E9/L	4.42	8.32
	BOTH	20-46	X10E9/L	4.46	8.39	1	X10E9/L	4.46	8.39
	BOTH	18-45	X10E9/L	4.5	8.47	1	X10E9/L	4.50	8.47
	BOTH	36-56	X10E9/L	4.54	8.55	1	X10E9/L	4.54	8.55
	BOTH	34-53	X10E9/L	4.58	8.62	1	X10E9/L	4.58	8.62
	FEMALE	43-43	X10E9/L	4.62	8.7	1	X10E9/L	4.62	8.70
	FEMALE	19-21	X10E9/L	4.66	8.78	1	X10E9/L	4.66	8.78
	BOTH	21-35	X10E9/L	4.7	8.86	1	X10E9/L	4.70	8.86
	BOTH	36-44	X10E9/L	4.74	8.93	1	X10E9/L	4.74	8.93
	BOTH	21-46	X10E9/L	4.79	9.01	1	X10E9/L	4.79	9.01
	BOTH	25-25	X10E9/L	4.83	9.09	1	X10E9/L	4.83	9.09
	BOTH	24-24	X10E9/L	4.87	9.16	1	X10E9/L	4.87	9.16
	BOTH	50-50	X10E9/L	4.91	9.24	1	X10E9/L	4.91	9.24
	BOTH	25-50	X10E9/L	4.95	9.32	1	X10E9/L	4.95	9.32
	FEMALE	23-31	X10E9/L	4.99	9.39	1	X10E9/L	4.99	9.39
	FEMALE	30-31	X10E9/L	5.03	9.47	1	X10E9/L	5.03	9.47
	MALE	32-32	X10E9/L	5.07	9.55	1	X10E9/L	5.07	9.55
	MALE	43-43	X10E9/L	5.11	9.63	1	X10E9/L	5.11	9.63
	MALE	43-43	X10E9/L	5.19	9.78	1	X10E9/L	5.19	9.78
	FEMALE	42-42	X10E9/L	5.28	9.93	1	X10E9/L	5.28	9.93
	FEMALE	52-52	X10E9/L	5.32	10.01	1	X10E9/L	5.32	10.01
	FEMALE	20-23	X10E9/L	5.4	10.16	1	X10E9/L	5.40	10.16
	FEMALE	40-40	X10E9/L	5.48	10.32	1	X10E9/L	5.48	10.32
	FEMALE	32-32	X10E9/L	5.52	10.4	1	X10E9/L	5.52	10.40
	MALE	49-49	X10E9/L	5.56	10.47	1	X10E9/L	5.56	10.47

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC)	FEMALE	35-35	X10E9/L	5.6	10.55	1	X10E9/L	5.60	10.55
	BOTH	26-26	X10E9/L	5.64	10.63	1	X10E9/L	5.64	10.63
	MALE	35-41	X10E9/L	5.69	10.7	1	X10E9/L	5.69	10.70
	MALE	46-46	X10E9/L	5.73	10.78	1	X10E9/L	5.73	10.78
	MALE	44-44	X10E9/L	5.81	10.93	1	X10E9/L	5.81	10.93
	MALE	41-41	X10E9/L	6.01	11.32	1	X10E9/L	6.01	11.32
	FEMALE	26-26	X10E9/L	6.09	11.47	1	X10E9/L	6.09	11.47
	FEMALE	32-32	X10E9/L	6.14	11.55	1	X10E9/L	6.14	11.55
	BOTH	35-35	X10E9/L	6.3	11.86	1	X10E9/L	6.30	11.86
	MALE	53-53	X10E9/L	6.38	12.01	1	X10E9/L	6.38	12.01
	MALE	31-31	X10E9/L	6.42	12.09	1	X10E9/L	6.42	12.09
	MALE	46-46	X10E9/L	7.08	13.32	1	X10E9/L	7.08	13.32
	MALE	44-44	X10E9/L	7.44	14.01	1	X10E9/L	7.44	14.01
	MALE	44-44	X10E9/L	7.93	14.94	1	X10E9/L	7.93	14.94
	MALE	35-35	X10E9/L	8.59	16.17	1	X10E9/L	8.59	16.17
	MALE	44-44	X10E9/L	9.57	18.02	1	X10E9/L	9.57	18.02
HEMATOCRIT	FEMALE	25-25	%	34.3	46.6	0.01	Vol Fraction	0.34	0.47
	FEMALE	18-63	%	35.0	47.0	0.01	Vol Fraction	0.35	0.47
	MALE	18-65	%	40.0	52.0	0.01	Vol Fraction	0.40	0.52
	MALE	45-45	%	40.8	51.9	0.01	Vol Fraction	0.41	0.52
HEMOGLOBIN	FEMALE	18-63	G/DL	11.6	16.2	1	G/DL	11.60	16.20
	FEMALE	25-25	G/DL	12.1	15.9	1	G/DL	12.10	15.90
	MALE	18-65	G/DL	13.0	17.5	1	G/DL	13.00	17.50
	MALE	45-45	G/DL	14.6	17.8	1	G/DL	14.60	17.80
RBC	FEMALE	18-63	X10E6/UL	3.8	5.5	1	X10E12/L	3.80	5.50
	FEMALE	25-25	M/UL	3.88	5.46	1	X10E12/L	3.88	5.46
	MALE	18-65	X10E6/UL	4.1	5.9	1	X10E12/L	4.10	5.90
	MALE	45-45	M/UL	4.69	6.07	1	X10E12/L	4.69	6.07
PLATELET COUNT	BOTH	18-63	X10E3/UL	140	450	1	X10E9/L	140.00	450.00
	BOTH	25-25	K/UL	177	406	1	X10E9/L	177.00	406.00
WBC	BOTH	25-25	K/UL	3.20	10.60	1	X10E9/L	3.20	10.60
	BOTH	18-63	X10E3/UL	4.1	12.3	1	X10E9/L	4.10	12.30
NEUTROPHILS	BOTH	18-63	%	40.9	77.0	1	%	40.90	77.00

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

			ORIGINAL			*REPORTED UNIT CONVERSION FACTOR	REPORTED		
LAB TEST	SEX	AGE RANGE	UNITS	LOWER RANGE	UPPER RANGE		UNITS	LOWER RANGE	UPPER RANGE
NEUTROPHILS	BOTH	25-25	%	44.0	76.0	1	%	44.00	76.00
NEUTROPHILS(CALC) AGRAN	MALE	39-39	X10E9/L	0.49	0.92	1	X10E9/L	0.49	0.92
	MALE	24-24	X10E9/L	1.1	2.08	1	X10E9/L	1.10	2.08
	FEMALE	45-45	X10E9/L	1.27	2.39	1	X10E9/L	1.27	2.39
	BOTH	39-60	X10E9/L	1.31	2.46	1	X10E9/L	1.31	2.46
	FEMALE	25-34	X10E9/L	1.35	2.54	1	X10E9/L	1.35	2.54
	BOTH	30-30	X10E9/L	1.39	2.62	1	X10E9/L	1.39	2.62
	BOTH	35-52	X10E9/L	1.43	2.7	1	X10E9/L	1.43	2.70
	BOTH	52-52	X10E9/L	1.47	2.77	1	X10E9/L	1.47	2.77
	BOTH	22-49	X10E9/L	1.51	2.85	1	X10E9/L	1.51	2.85
	BOTH	26-52	X10E9/L	1.55	2.93	1	X10E9/L	1.55	2.93
	BOTH	28-36	X10E9/L	1.6	3	1	X10E9/L	1.60	3.00
	FEMALE	25-25	X10E9/L	1.63	2.81	1	X10E9/L	1.63	2.81
	BOTH	20-57	X10E9/L	1.64	3.08	1	X10E9/L	1.64	3.08
	BOTH	24-47	X10E9/L	1.68	3.16	1	X10E9/L	1.68	3.16
	BOTH	20-49	X10E9/L	1.72	3.23	1	X10E9/L	1.72	3.23
	BOTH	22-56	X10E9/L	1.76	3.31	1	X10E9/L	1.76	3.31
	BOTH	19-54	X10E9/L	1.8	3.39	1	X10E9/L	1.80	3.39
	BOTH	28-58	X10E9/L	1.84	3.47	1	X10E9/L	1.84	3.47
	BOTH	22-62	X10E9/L	1.88	3.54	1	X10E9/L	1.88	3.54
	BOTH	30-52	X10E9/L	1.92	3.62	1	X10E9/L	1.92	3.62
	BOTH	33-62	X10E9/L	1.96	3.7	1	X10E9/L	1.96	3.70
	BOTH	25-58	X10E9/L	2	3.77	1	X10E9/L	2.00	3.77
	BOTH	26-55	X10E9/L	2.05	3.85	1	X10E9/L	2.05	3.85
	BOTH	21-58	X10E9/L	2.09	3.93	1	X10E9/L	2.09	3.93
	BOTH	23-50	X10E9/L	2.13	4	1	X10E9/L	2.13	4.00
	BOTH	30-63	X10E9/L	2.17	4.08	1	X10E9/L	2.17	4.08
	BOTH	24-50	X10E9/L	2.21	4.16	1	X10E9/L	2.21	4.16
	BOTH	27-57	X10E9/L	2.25	4.24	1	X10E9/L	2.25	4.24
	BOTH	22-59	X10E9/L	2.29	4.31	1	X10E9/L	2.29	4.31
	BOTH	19-59	X10E9/L	2.33	4.39	1	X10E9/L	2.33	4.39
	BOTH	20-55	X10E9/L	2.37	4.47	1	X10E9/L	2.37	4.47
	BOTH	29-45	X10E9/L	2.41	4.54	1	X10E9/L	2.41	4.54
	BOTH	25-59	X10E9/L	2.45	4.62	1	X10E9/L	2.45	4.62
	BOTH	19-51	X10E9/L	2.49	4.7	1	X10E9/L	2.49	4.70
	BOTH	23-54	X10E9/L	2.54	4.77	1	X10E9/L	2.54	4.77
	BOTH	18-41	X10E9/L	2.58	4.85	1	X10E9/L	2.58	4.85

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC) AGRAN	BOTH	27-55	X10E9/L	2.62	4.93	1	X10E9/L	2.62	4.93
	BOTH	18-40	X10E9/L	2.66	5.01	1	X10E9/L	2.66	5.01
	BOTH	18-60	X10E9/L	2.7	5.08	1	X10E9/L	2.70	5.08
	BOTH	25-59	X10E9/L	2.74	5.16	1	X10E9/L	2.74	5.16
	BOTH	23-46	X10E9/L	2.78	5.24	1	X10E9/L	2.78	5.24
	BOTH	18-59	X10E9/L	2.82	5.31	1	X10E9/L	2.82	5.31
	BOTH	18-55	X10E9/L	2.86	5.39	1	X10E9/L	2.86	5.39
	BOTH	23-58	X10E9/L	2.9	5.47	1	X10E9/L	2.90	5.47
	BOTH	19-52	X10E9/L	2.94	5.54	1	X10E9/L	2.94	5.54
	BOTH	19-58	X10E9/L	2.99	5.62	1	X10E9/L	2.99	5.62
	BOTH	18-63	X10E9/L	3.03	5.7	1	X10E9/L	3.03	5.70
	BOTH	20-59	X10E9/L	3.07	5.78	1	X10E9/L	3.07	5.78
	BOTH	19-42	X10E9/L	3.11	5.85	1	X10E9/L	3.11	5.85
	BOTH	19-63	X10E9/L	3.15	5.93	1	X10E9/L	3.15	5.93
	BOTH	22-47	X10E9/L	3.19	6.01	1	X10E9/L	3.19	6.01
	BOTH	20-54	X10E9/L	3.23	6.08	1	X10E9/L	3.23	6.08
	BOTH	24-40	X10E9/L	3.27	6.16	1	X10E9/L	3.27	6.16
	BOTH	18-58	X10E9/L	3.31	6.24	1	X10E9/L	3.31	6.24
	BOTH	22-58	X10E9/L	3.35	6.31	1	X10E9/L	3.35	6.31
	BOTH	18-50	X10E9/L	3.39	6.39	1	X10E9/L	3.39	6.39
	BOTH	19-41	X10E9/L	3.44	6.47	1	X10E9/L	3.44	6.47
	BOTH	22-57	X10E9/L	3.48	6.55	1	X10E9/L	3.48	6.55
	BOTH	20-58	X10E9/L	3.52	6.62	1	X10E9/L	3.52	6.62
	BOTH	33-54	X10E9/L	3.56	6.7	1	X10E9/L	3.56	6.70
	BOTH	18-60	X10E9/L	3.6	6.78	1	X10E9/L	3.60	6.78
	MALE	45-45	X10E9/L	3.61	6.23	1	X10E9/L	3.61	6.23
	BOTH	20-44	X10E9/L	3.64	6.85	1	X10E9/L	3.64	6.85
	BOTH	24-42	X10E9/L	3.68	6.93	1	X10E9/L	3.68	6.93
	BOTH	18-48	X10E9/L	3.72	7.01	1	X10E9/L	3.72	7.01
	BOTH	29-62	X10E9/L	3.76	7.08	1	X10E9/L	3.76	7.08
	BOTH	19-50	X10E9/L	3.8	7.16	1	X10E9/L	3.80	7.16
	BOTH	27-59	X10E9/L	3.84	7.24	1	X10E9/L	3.84	7.24
	BOTH	21-60	X10E9/L	3.89	7.32	1	X10E9/L	3.89	7.32
	BOTH	23-35	X10E9/L	3.93	7.39	1	X10E9/L	3.93	7.39
	BOTH	34-40	X10E9/L	3.97	7.47	1	X10E9/L	3.97	7.47
	BOTH	26-53	X10E9/L	4.01	7.55	1	X10E9/L	4.01	7.55
	BOTH	28-52	X10E9/L	4.05	7.62	1	X10E9/L	4.05	7.62
	FEMALE	20-54	X10E9/L	4.09	7.7	1	X10E9/L	4.09	7.70

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC) AGRAN	BOTH	22-35	X10E9/L	4.13	7.78	1	X10E9/L	4.13	7.78
	BOTH	31-54	X10E9/L	4.17	7.85	1	X10E9/L	4.17	7.85
	BOTH	21-23	X10E9/L	4.21	7.93	1	X10E9/L	4.21	7.93
	BOTH	22-40	X10E9/L	4.25	8.01	1	X10E9/L	4.25	8.01
	FEMALE	25-62	X10E9/L	4.29	8.09	1	X10E9/L	4.29	8.09
	FEMALE	20-24	X10E9/L	4.34	8.16	1	X10E9/L	4.34	8.16
	BOTH	46-46	X10E9/L	4.38	8.24	1	X10E9/L	4.38	8.24
	BOTH	40-40	X10E9/L	4.42	8.32	1	X10E9/L	4.42	8.32
	BOTH	20-46	X10E9/L	4.46	8.39	1	X10E9/L	4.46	8.39
	BOTH	18-45	X10E9/L	4.5	8.47	1	X10E9/L	4.50	8.47
	BOTH	36-56	X10E9/L	4.54	8.55	1	X10E9/L	4.54	8.55
	BOTH	34-53	X10E9/L	4.58	8.62	1	X10E9/L	4.58	8.62
	FEMALE	43-43	X10E9/L	4.62	8.7	1	X10E9/L	4.62	8.70
	FEMALE	19-21	X10E9/L	4.66	8.78	1	X10E9/L	4.66	8.78
	BOTH	21-35	X10E9/L	4.7	8.86	1	X10E9/L	4.70	8.86
	BOTH	36-44	X10E9/L	4.74	8.93	1	X10E9/L	4.74	8.93
	BOTH	21-46	X10E9/L	4.79	9.01	1	X10E9/L	4.79	9.01
	BOTH	25-25	X10E9/L	4.83	9.09	1	X10E9/L	4.83	9.09
	BOTH	24-24	X10E9/L	4.87	9.16	1	X10E9/L	4.87	9.16
	BOTH	50-50	X10E9/L	4.91	9.24	1	X10E9/L	4.91	9.24
	BOTH	25-50	X10E9/L	4.95	9.32	1	X10E9/L	4.95	9.32
	FEMALE	23-31	X10E9/L	4.99	9.39	1	X10E9/L	4.99	9.39
	FEMALE	30-31	X10E9/L	5.03	9.47	1	X10E9/L	5.03	9.47
	MALE	32-32	X10E9/L	5.07	9.55	1	X10E9/L	5.07	9.55
	MALE	43-43	X10E9/L	5.11	9.63	1	X10E9/L	5.11	9.63
	MALE	43-43	X10E9/L	5.19	9.78	1	X10E9/L	5.19	9.78
	FEMALE	42-42	X10E9/L	5.28	9.93	1	X10E9/L	5.28	9.93
	FEMALE	52-52	X10E9/L	5.32	10.01	1	X10E9/L	5.32	10.01
	FEMALE	20-23	X10E9/L	5.4	10.16	1	X10E9/L	5.40	10.16
	FEMALE	40-40	X10E9/L	5.48	10.32	1	X10E9/L	5.48	10.32
	FEMALE	32-32	X10E9/L	5.52	10.4	1	X10E9/L	5.52	10.40
	MALE	49-49	X10E9/L	5.56	10.47	1	X10E9/L	5.56	10.47
	FEMALE	35-35	X10E9/L	5.6	10.55	1	X10E9/L	5.60	10.55
	BOTH	26-26	X10E9/L	5.64	10.63	1	X10E9/L	5.64	10.63
	MALE	35-41	X10E9/L	5.69	10.7	1	X10E9/L	5.69	10.70
	MALE	46-46	X10E9/L	5.73	10.78	1	X10E9/L	5.73	10.78
	MALE	44-44	X10E9/L	5.81	10.93	1	X10E9/L	5.81	10.93
	MALE	41-41	X10E9/L	6.01	11.32	1	X10E9/L	6.01	11.32

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC) AGRAN	FEMALE	26-26	X10E9/L	6.09	11.47	1	X10E9/L	6.09	11.47
	FEMALE	32-32	X10E9/L	6.14	11.55	1	X10E9/L	6.14	11.55
	BOTH	35-35	X10E9/L	6.3	11.86	1	X10E9/L	6.30	11.86
	MALE	53-53	X10E9/L	6.38	12.01	1	X10E9/L	6.38	12.01
	MALE	31-31	X10E9/L	6.42	12.09	1	X10E9/L	6.42	12.09
	MALE	46-46	X10E9/L	7.08	13.32	1	X10E9/L	7.08	13.32
	MALE	44-44	X10E9/L	7.44	14.01	1	X10E9/L	7.44	14.01
	MALE	44-44	X10E9/L	7.93	14.94	1	X10E9/L	7.93	14.94
	MALE	35-35	X10E9/L	8.59	16.17	1	X10E9/L	8.59	16.17
	MALE	44-44	X10E9/L	9.57	18.02	1	X10E9/L	9.57	18.02
EOSINOPHILS	BOTH	18-18	%	0.0	4.8	1	%	0.00	4.80
	BOTH	19-63	%	0.0	6.0	1	%	0.00	6.00
EOSINOPHILS(CALC)	MALE	39-39	X10E9/L	0	0.07	1	X10E9/L	0.00	0.07
	MALE	24-24	X10E9/L	0	0.16	1	X10E9/L	0.00	0.16
	BOTH	39-60	X10E9/L	0	0.19	1	X10E9/L	0.00	0.19
	BOTH	25-34	X10E9/L	0	0.2	1	X10E9/L	0.00	0.20
	BOTH	35-52	X10E9/L	0	0.21	1	X10E9/L	0.00	0.21
	BOTH	22-52	X10E9/L	0	0.22	1	X10E9/L	0.00	0.22
	BOTH	26-52	X10E9/L	0	0.23	1	X10E9/L	0.00	0.23
	BOTH	20-57	X10E9/L	0	0.24	1	X10E9/L	0.00	0.24
	BOTH	20-49	X10E9/L	0	0.25	1	X10E9/L	0.00	0.25
	BOTH	19-56	X10E9/L	0	0.26	1	X10E9/L	0.00	0.26
	BOTH	28-58	X10E9/L	0	0.27	1	X10E9/L	0.00	0.27
	BOTH	22-62	X10E9/L	0	0.28	1	X10E9/L	0.00	0.28
	BOTH	25-62	X10E9/L	0	0.29	1	X10E9/L	0.00	0.29
	BOTH	18-55	X10E9/L	0	0.3	1	X10E9/L	0.00	0.30
	BOTH	18-58	X10E9/L	0	0.31	1	X10E9/L	0.00	0.31
	BOTH	18-63	X10E9/L	0	0.32	1	X10E9/L	0.00	0.32
	BOTH	18-57	X10E9/L	0	0.33	1	X10E9/L	0.00	0.33
	BOTH	18-59	X10E9/L	0	0.34	1	X10E9/L	0.00	0.34
	BOTH	20-55	X10E9/L	0	0.35	1	X10E9/L	0.00	0.35
	BOTH	18-59	X10E9/L	0	0.36	1	X10E9/L	0.00	0.36
	BOTH	19-54	X10E9/L	0	0.37	1	X10E9/L	0.00	0.37
	BOTH	25-55	X10E9/L	0	0.38	1	X10E9/L	0.00	0.38
	BOTH	18-40	X10E9/L	0	0.39	1	X10E9/L	0.00	0.39
	BOTH	18-60	X10E9/L	0	0.4	1	X10E9/L	0.00	0.40

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
EOSINOPHILS(CALC)	BOTH	20-59	X10E9/L	0	0.41	1	X10E9/L	0.00	0.41
	BOTH	18-55	X10E9/L	0	0.42	1	X10E9/L	0.00	0.42
	BOTH	19-58	X10E9/L	0	0.43	1	X10E9/L	0.00	0.43
	BOTH	18-63	X10E9/L	0	0.44	1	X10E9/L	0.00	0.44
	BOTH	20-59	X10E9/L	0	0.45	1	X10E9/L	0.00	0.45
	BOTH	19-63	X10E9/L	0	0.46	1	X10E9/L	0.00	0.46
	BOTH	20-54	X10E9/L	0	0.47	1	X10E9/L	0.00	0.47
	BOTH	24-40	X10E9/L	0	0.48	1	X10E9/L	0.00	0.48
	BOTH	20-58	X10E9/L	0	0.49	1	X10E9/L	0.00	0.49
	BOTH	19-50	X10E9/L	0	0.5	1	X10E9/L	0.00	0.50
	BOTH	22-57	X10E9/L	0	0.51	1	X10E9/L	0.00	0.51
	BOTH	20-58	X10E9/L	0	0.52	1	X10E9/L	0.00	0.52
	BOTH	18-60	X10E9/L	0	0.53	1	X10E9/L	0.00	0.53
	BOTH	24-42	X10E9/L	0	0.54	1	X10E9/L	0.00	0.54
	BOTH	21-62	X10E9/L	0	0.55	1	X10E9/L	0.00	0.55
	BOTH	19-59	X10E9/L	0	0.56	1	X10E9/L	0.00	0.56
	BOTH	21-60	X10E9/L	0	0.57	1	X10E9/L	0.00	0.57
	BOTH	23-40	X10E9/L	0	0.58	1	X10E9/L	0.00	0.58
	BOTH	26-53	X10E9/L	0	0.59	1	X10E9/L	0.00	0.59
	BOTH	20-54	X10E9/L	0	0.6	1	X10E9/L	0.00	0.60
	BOTH	22-54	X10E9/L	0	0.61	1	X10E9/L	0.00	0.61
	BOTH	21-40	X10E9/L	0	0.62	1	X10E9/L	0.00	0.62
	BOTH	25-62	X10E9/L	0	0.63	1	X10E9/L	0.00	0.63
	BOTH	20-46	X10E9/L	0	0.64	1	X10E9/L	0.00	0.64
	BOTH	20-46	X10E9/L	0	0.65	1	X10E9/L	0.00	0.65
	BOTH	21-45	X10E9/L	0	0.66	1	X10E9/L	0.00	0.66
	BOTH	34-56	X10E9/L	0	0.67	1	X10E9/L	0.00	0.67
	BOTH	19-43	X10E9/L	0	0.68	1	X10E9/L	0.00	0.68
	BOTH	21-35	X10E9/L	0	0.69	1	X10E9/L	0.00	0.69
	BOTH	21-46	X10E9/L	0	0.7	1	X10E9/L	0.00	0.70
	BOTH	24-25	X10E9/L	0	0.71	1	X10E9/L	0.00	0.71
	BOTH	50-50	X10E9/L	0	0.72	1	X10E9/L	0.00	0.72
	BOTH	23-50	X10E9/L	0	0.73	1	X10E9/L	0.00	0.73
	BOTH	30-31	X10E9/L	0	0.74	1	X10E9/L	0.00	0.74
	MALE	43-43	X10E9/L	0	0.75	1	X10E9/L	0.00	0.75
	MALE	43-43	X10E9/L	0	0.76	1	X10E9/L	0.00	0.76
	BOTH	42-42	X10E9/L	0	0.77	1	X10E9/L	0.00	0.77
	BOTH	52-52	X10E9/L	0	0.78	1	X10E9/L	0.00	0.78
	BOTH	20-23	X10E9/L	0	0.79	1	X10E9/L	0.00	0.79

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
EOSINOPHILS(CALC)	BOTH	40-40	X10E9/L	0	0.8	1	X10E9/L	0.00	0.80
	BOTH	32-32	X10E9/L	0	0.81	1	X10E9/L	0.00	0.81
	BOTH	35-35	X10E9/L	0	0.82	1	X10E9/L	0.00	0.82
	BOTH	26-26	X10E9/L	0	0.83	1	X10E9/L	0.00	0.83
	MALE	46-46	X10E9/L	0	0.84	1	X10E9/L	0.00	0.84
	MALE	44-44	X10E9/L	0	0.85	1	X10E9/L	0.00	0.85
	MALE	41-41	X10E9/L	0	0.88	1	X10E9/L	0.00	0.88
	BOTH	26-26	X10E9/L	0	0.89	1	X10E9/L	0.00	0.89
	BOTH	32-32	X10E9/L	0	0.9	1	X10E9/L	0.00	0.90
	BOTH	35-35	X10E9/L	0	0.92	1	X10E9/L	0.00	0.92
	MALE	31-53	X10E9/L	0	0.94	1	X10E9/L	0.00	0.94
	MALE	46-46	X10E9/L	0	1.04	1	X10E9/L	0.00	1.04
	MALE	44-44	X10E9/L	0	1.09	1	X10E9/L	0.00	1.09
	MALE	44-44	X10E9/L	0	1.16	1	X10E9/L	0.00	1.16
	MALE	35-35	X10E9/L	0	1.26	1	X10E9/L	0.00	1.26
	MALE	44-44	X10E9/L	0	1.4	1	X10E9/L	0.00	1.40
BASOPHILS	BOTH	25-25	%	0.0	1.7	1	%	0.00	1.70
	BOTH	18-63	%	0.0	2.4	1	%	0.00	2.40
LYMPHS	BOTH	25-25	%	14.7	42.6	1	%	14.70	42.60
	BOTH	18-63	%	15.5	46.6	1	%	15.50	46.60
MONOCYTES	BOTH	25-25	%	2.0	7.5	1	%	2.00	7.50
	BOTH	18-63	%	4.0	9.4	1	%	4.00	9.40

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
HEMATOCRIT (VOL. FRACTION)	BSLN	155	0.43	0.04	0.4	0.3	0.5	139	0.43	0.04	0.4	0.3	0.5	149	0.42	0.04	0.4	0.3	0.6
	FINAL	155	0.42	0.03	0.4	0.3	0.5	139	0.42	0.04	0.4	0.3	0.5	149	0.41	0.05	0.4	0.2	0.5
	CHG FROM BSLN	155	-0.01	0.02	-0.0	-0.1	0.1	139	-0.01	0.02	-0.0	-0.1	0.1	149	-0.01	0.03	-0.0	-0.3	0.0
HEMOGLOBIN (G/DL)	BSLN	155	14.39	1.40	14.4	10.3	17.6	142	14.48	1.33	14.4	11.9	18.3	149	14.21	1.41	14.1	10.9	18.9
	FINAL	155	14.15	1.24	14.2	10.7	17.1	142	14.16	1.32	14.2	11.2	17.9	149	14.01	1.63	14.1	6.4	17.6
	CHG FROM BSLN	155	-0.24	0.78	-0.3	-2.6	4.1	142	-0.32	0.82	-0.3	-2.4	3.3	149	-0.20	1.08	-0.1	-9.8	1.8
TOTAL RBC COUNT (10**12/L)	BSLN	155	4.71	0.43	4.7	3.7	5.8	142	4.70	0.41	4.7	3.8	5.9	149	4.64	0.46	4.6	3.5	5.6
	FINAL	155	4.64	0.39	4.7	3.6	5.5	142	4.60	0.42	4.6	3.6	5.9	149	4.57	0.54	4.6	2.0	5.7
	CHG FROM BSLN	155	-0.08	0.25	-0.1	-0.9	0.9	142	-0.10	0.30	-0.1	-0.9	1.6	149	-0.07	0.37	0.0	-3.1	0.8
PLATELETS (10**9/L)	BSLN	154	260.13	66.55	254.0	103.0	571.0	138	261.19	62.53	256.0	117.0	497.0	146	258.25	63.11	253.0	93.0	498.0
	FINAL	154	255.46	64.97	249.0	87.0	465.0	138	254.42	55.93	252.5	146.0	429.0	146	254.05	67.65	244.0	24.0	442.0
	CHG FROM BSLN	154	-4.67	44.35	-5.0	-112.0	295.0	138	-6.77	41.62	-7.0	-194.0	105.0	146	-4.21	48.08	-3.0	-197.0	173.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
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Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

LAB TEST	WINDOWED VISIT	QUETIAPINE 300 MG N	MEAN	SD	MED	MIN	MAX	QUETIAPINE 600 MG N	MEAN	SD	MED	MIN	MAX	PLACEBO N	MEAN	SD	MED	MIN	MAX
TOTAL WBC COUNT (10**9-/L)	BSLN	155	7.30	2.44	7.0	3.6	23.4	142	7.18	2.21	6.8	3.1	14.7	149	7.06	2.33	6.6	2.7	15.6
	FINAL	155	7.02	2.39	6.5	3.3	18.2	142	6.65	2.10	6.3	3.4	15.4	149	6.73	2.23	6.3	1.2	13.9
	CHG FROM BSLN	155	-0.28	1.59	-0.2	-5.2	6.6	142	-0.53	1.90	-0.5	-7.2	5.1	149	-0.33	1.82	-0.3	-7.1	5.9
NEUTROPHILS (%)	BSLN	155	60.93	8.74	60.9	19.0	80.0	142	61.01	9.26	61.0	27.3	90.2	149	60.01	9.49	60.9	32.9	80.0
	FINAL	155	60.67	9.49	60.8	19.0	85.7	142	59.82	8.89	60.3	25.0	80.5	149	60.20	9.16	60.8	33.0	86.4
	CHG FROM BSLN	155	-0.26	9.06	-0.4	-40.1	36.2	142	-1.19	9.30	-1.3	-25.9	29.8	149	0.20	8.66	0.0	-20.7	26.8
NEUTROPHILS (10**9-/L) AGRAN	BSLN	155	4.48	1.70	4.1	1.8	10.6	142	4.49	1.87	4.1	1.4	10.1	149	4.32	1.78	4.0	1.1	11.0
	FINAL	155	4.34	1.87	4.0	0.8	11.4	142	4.06	1.73	3.7	1.2	12.4	149	4.14	1.75	4.0	1.0	9.9
	CHG FROM BSLN	155	-0.15	1.46	-0.1	-4.0	8.0	142	-0.43	1.79	-0.4	-6.3	4.9	149	-0.18	1.49	-0.2	-5.1	4.3
EOSINOPHILS (%)	BSLN	155	2.46	1.71	2.0	0.0	8.1	142	2.41	1.53	2.2	0.2	10.6	149	2.57	1.91	2.1	0.1	10.8
	FINAL	155	2.70	2.10	2.2	0.1	16.0	142	2.66	2.03	2.3	0.0	12.9	149	2.41	1.66	2.0	0.2	9.5
	CHG FROM BSLN	155	0.24	1.92	0.2	-6.3	11.7	142	0.25	1.52	0.2	-4.1	5.6	149	-0.16	1.53	-0.1	-6.0	5.3

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
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Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

LAB TEST	WINDOWED VISIT	QUETIAPINE 300 MG N	MEAN	SD	MED	MIN	MAX	QUETIAPINE 600 MG N	MEAN	SD	MED	MIN	MAX	PLACEBO N	MEAN	SD	MED	MIN	MAX
EOSINOPHILS (10**9/L)	BSLN	155	0.18	0.13	0.1	0.0	0.9	142	0.16	0.11	0.2	0.0	0.7	149	0.18	0.16	0.1	0.0	1.1
	FINAL	155	0.18	0.13	0.2	0.0	0.9	142	0.17	0.14	0.2	0.0	1.1	149	0.16	0.11	0.1	0.0	0.6
	CHG FROM BSLN	155	0.00	0.12	0.0	-0.5	0.7	142	0.00	0.10	0.0	-0.3	0.4	149	-0.02	0.13	-0.0	-0.6	0.3
BASOPHILS (%)	BSLN	155	0.35	0.27	0.3	0.0	2.0	142	0.38	0.27	0.3	0.0	1.9	149	0.35	0.24	0.3	0.0	2.0
	FINAL	155	0.36	0.22	0.3	0.0	1.6	142	0.35	0.23	0.3	0.0	2.0	149	0.35	0.22	0.3	0.0	1.3
	CHG FROM BSLN	155	0.01	0.33	0.0	-1.5	1.5	142	-0.03	0.36	0.0	-1.7	1.9	149	0.00	0.31	0.0	-1.8	1.1
BASOPHILS (10**9/L)	BSLN	155	0.02	0.02	0.0	0.0	0.2	142	0.03	0.03	0.0	0.0	0.2	149	0.02	0.02	0.0	0.0	0.2
	FINAL	155	0.02	0.01	0.0	0.0	0.1	142	0.02	0.02	0.0	0.0	0.1	149	0.02	0.01	0.0	0.0	0.1
	CHG FROM BSLN	155	-0.00	0.02	0.0	-0.2	0.1	142	-0.00	0.03	0.0	-0.2	0.1	149	-0.00	0.02	0.0	-0.2	0.1
LYMPHOCYTES (%)	BSLN	155	30.41	8.42	29.3	13.7	79.0	142	30.09	8.07	29.5	9.0	59.1	149	30.84	9.01	30.1	12.0	58.3
	FINAL	155	30.27	8.42	29.7	10.8	77.9	142	30.78	7.90	30.2	14.1	64.0	149	30.63	8.63	29.5	10.0	54.4
	CHG FROM BSLN	155	-0.13	7.87	-0.3	-25.5	25.2	142	0.68	7.74	0.4	-24.8	25.9	149	-0.21	7.34	0.0	-23.2	19.8

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
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Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

LAB TEST	WINDOWED VISIT	QUETIAPINE 300 MG N	MEAN	SD	MED	MIN	MAX	QUETIAPINE 600 MG N	MEAN	SD	MED	MIN	MAX	PLACEBO N	MEAN	SD	MED	MIN	MAX
LYMPHOCYTES (10**9/L)	BSLN	155	2.20	1.44	2.1	0.8	18.5	142	2.07	0.60	2.1	0.9	4.3	149	2.11	0.80	2.0	0.7	5.6
	FINAL	155	2.07	1.14	1.9	1.0	14.2	142	1.99	0.60	1.9	0.8	3.9	149	2.00	0.71	1.9	0.1	5.4
	CHG FROM BSLN	155	-0.13	0.59	-0.1	-4.3	1.6	142	-0.09	0.45	-0.1	-1.0	1.5	149	-0.11	0.58	-0.1	-2.2	2.2
MONOCYTES (%)	BSLN	155	5.79	2.14	5.8	0.1	11.3	142	6.11	2.15	5.9	0.2	12.2	149	6.17	2.13	6.0	0.6	12.5
	FINAL	155	5.99	2.00	5.8	0.1	13.0	142	6.36	2.39	6.1	0.4	15.7	149	6.35	2.31	6.1	0.0	13.0
	CHG FROM BSLN	155	0.20	1.96	0.2	-5.5	5.1	142	0.25	2.22	0.1	-5.4	10.3	149	0.18	2.04	0.1	-6.9	7.9
MONOCYTES (10**9/L)	BSLN	155	0.41	0.16	0.4	0.0	0.9	142	0.42	0.16	0.4	0.0	1.1	149	0.42	0.17	0.4	0.1	1.0
	FINAL	155	0.40	0.15	0.4	0.0	0.8	142	0.41	0.16	0.4	0.0	0.9	149	0.41	0.18	0.4	0.0	1.2
	CHG FROM BSLN	155	-0.00	0.14	-0.0	-0.3	0.6	142	-0.01	0.15	-0.0	-0.8	0.4	149	-0.01	0.15	-0.0	-0.5	0.5

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
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Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
HEMATOCRIT	BASELINE												
	LOW	10	6	4	0	4	2	2	0	10	6	4	0
	NORMAL	145	3	141	1	134	5	127	2	136	7	129	0
	HIGH	0	0	0	0	1	0	1	0	3	0	3	0
HEMOGLOBIN	LOW	5	4	1	0	1	1	0	0	8	6	2	0
	NORMAL	149	2	147	0	139	4	135	0	139	6	132	1
	HIGH	1	0	1	0	2	0	1	1	2	0	2	0
TOTAL RBC COUNT	LOW	3	0	3	0	0	0	0	0	6	4	2	0
	NORMAL	152	1	151	0	142	2	140	0	143	7	136	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
PLATELETS	LOW	3	1	2	0	2	0	2	0	3	3	0	0
	NORMAL	149	1	146	2	135	0	135	0	142	1	141	0
	HIGH	2	0	0	2	1	0	1	0	1	0	1	0
TOTAL WBC COUNT	LOW	1	1	0	0	5	0	5	0	9	7	2	0
	NORMAL	150	7	140	3	133	3	128	2	138	9	128	1
	HIGH	4	0	1	3	4	0	1	3	2	0	2	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA202.SAS
GENERATED: 12JUL2005 17:43:53 iceadmn3

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
NEUTROPHILS (%)	BASELINE												
	LOW	3	2	1	0	3	1	2	0	5	0	5	0
	NORMAL	148	1	142	5	133	1	130	2	141	5	135	1
	HIGH	4	0	1	3	6	0	6	0	3	0	3	0
NEUTROPHILS (10**9/L) AGRAN	LOW	3	1	2	0	3	1	2	0	5	0	5	0
	NORMAL	148	1	142	5	133	1	130	2	141	5	135	1
	HIGH	4	0	1	3	6	0	6	0	3	0	3	0
EOSINOPHILS (%)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	147	0	144	3	139	0	135	4	140	0	137	3
	HIGH	8	0	6	2	3	0	1	2	9	0	6	3
EOSINOPHILS (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	147	0	144	3	139	0	135	4	141	0	138	3
	HIGH	8	0	6	2	3	0	1	2	8	0	6	2
BASOPHILS (%)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
BASOPHILS (10**9/L)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHOCYTES (%)	LOW	3	2	1	0	5	0	5	0	2	0	2	0
	NORMAL	148	6	141	1	132	3	128	1	136	3	129	4
	HIGH	4	0	2	2	5	0	3	2	11	0	8	3
LYMPHOCYTES (10**9/L)	LOW	3	2	1	0	5	0	5	0	2	0	2	0
	NORMAL	148	6	141	1	132	3	128	1	136	3	129	4
	HIGH	4	0	2	2	5	0	3	2	11	0	8	3
MONOCYTES (%)	LOW	32	13	19	0	19	7	12	0	17	5	11	1
	NORMAL	115	9	98	8	113	10	95	8	124	10	103	11
	HIGH	8	0	6	2	10	0	5	5	8	0	4	4
MONOCYTES (10**9/L)	LOW	32	13	19	0	18	7	11	0	17	5	11	1
	NORMAL	115	9	98	8	114	10	96	8	124	10	103	11
	HIGH	8	0	6	2	10	0	5	5	8	0	4	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA202.SAS
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Table 11.3.7.1.1.3.2 Hematology Findings Exceeding Laboratory Norms
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
HEMATOCRIT	3/145 (2.1%)	5/135 (3.7%)	7/139 (5.0%)	1/155 (0.6%)	2/138 (1.4%)	0/146 (0.0%)
HEMOGLOBIN	2/150 (1.3%)	4/141 (2.8%)	6/141 (4.3%)	0/154 (0.0%)	0/140 (0.0%)	1/147 (0.7%)
RBC	1/152 (0.7%)	2/142 (1.4%)	7/143 (4.9%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
PLATELET COUNT	1/151 (0.7%)	0/136 (0.0%)	1/143 (0.7%)	2/152 (1.3%)	0/137 (0.0%)	0/145 (0.0%)
WBC	7/154 (4.5%)	3/137 (2.2%)	9/140 (6.4%)	3/151 (2.0%)	2/138 (1.4%)	1/147 (0.7%)
NEUTROPHILS	1/152 (0.7%)	1/139 (0.7%)	5/144 (3.5%)	5/151 (3.3%)	2/136 (1.5%)	1/146 (0.7%)
NEUTROPHILS(CALC) AGRAN	1/152 (0.7%)	1/139 (0.7%)	5/144 (3.5%)	5/151 (3.3%)	2/136 (1.5%)	1/146 (0.7%)
EOSINOPHILS	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	3/147 (2.0%)	4/139 (2.9%)	3/140 (2.1%)
EOSINOPHILS(CALC)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	3/147 (2.0%)	4/139 (2.9%)	3/141 (2.1%)
BASOPHILS	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
BASOPHILS(CALC)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
LYMPHS	6/152 (3.9%)	3/137 (2.2%)	3/147 (2.0%)	1/151 (0.7%)	1/137 (0.7%)	4/138 (2.9%)
LYMPHS(CALC)	6/152 (3.9%)	3/137 (2.2%)	3/147 (2.0%)	1/151 (0.7%)	1/137 (0.7%)	4/138 (2.9%)
MONOCYTES	9/123 (7.3%)	10/123 (8.1%)	10/132 (7.6%)	8/147 (5.4%)	8/132 (6.1%)	12/141 (8.5%)
MONOCYTES(CALC)	9/123 (7.3%)	10/124 (8.1%)	10/132 (7.6%)	8/147 (5.4%)	8/132 (6.1%)	12/141 (8.5%)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA205.SAS
GENERATED: 12JUL2005 17:44:04 iceadmn3

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
HEMATOCRIT	BASELINE												
	LOW	2	1	1	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	153	1	152	0	139	0	139	0	147	4	143	0
	HIGH	0	0	0	0	0	0	0	0	1	0	1	0
HEMOGLOBIN	LOW	2	1	1	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	153	1	152	0	142	0	142	0	148	3	145	0
	HIGH	0	0	0	0	0	0	0	0	1	0	1	0
TOTAL RBC COUNT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	142	0	149	1	148	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
PLATELETS	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	154	1	153	0	138	0	138	0	145	2	143	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA203.SAS
GENERATED: 12JUL2005 17:43:57 iceadmn3

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL WBC COUNT	BASELINE												
	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	154	0	154	0	142	0	142	0	148	1	147	0
	HIGH	1	0	0	1	0	0	0	0	0	0	0	0
NEUTROPHILS (10**9/L) AGRAN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	153	0	151	2	141	0	140	1	147	0	147	0
	HIGH	2	0	0	2	1	0	0	1	2	0	2	0
NEUTROPHILS (10**9/L)	LOW	0	0	0	0	2	0	2	0	2	1	1	0
	NOT CLINICALLY IMPORTANT	153	1	150	2	139	1	137	1	145	2	143	0
	HIGH	2	0	0	2	1	0	0	1	2	0	2	0
EOSINOPHILS (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	141	1	147	0	147	0
	HIGH	0	0	0	0	0	0	0	0	2	0	2	0

(Continued)

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
BASOPHILS (10**9/L)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHOCYTES (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	154	0	154	0	142	0	142	0	149	1	148	0
	HIGH	1	0	0	1	0	0	0	0	0	0	0	0
MONOCYTES (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA203.SAS
GENERATED: 12JUL2005 17:43:57 iceadmn3

Table 11.3.7.1.1.3.4 Potentially Clinically Important Hematology Findings
Categorical Shifts from Baseline to Final

LAB PARAMETER	SHIFT TO LOW			SHIFT TO HIGH		
	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
HEMATOCRIT	1/153 (0.7%)	0/139 (0.0%)	4/148 (2.7%)	0/155 (0.0%)	0/139 (0.0%)	0/148 (0.0%)
HEMOGLOBIN	1/153 (0.7%)	0/142 (0.0%)	3/149 (2.0%)	0/155 (0.0%)	0/142 (0.0%)	0/148 (0.0%)
RBC	0/155 (0.0%)	0/142 (0.0%)	1/149 (0.7%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
PLATELET COUNT	1/154 (0.6%)	0/138 (0.0%)	2/145 (1.4%)	0/154 (0.0%)	0/138 (0.0%)	0/146 (0.0%)
WBC	0/155 (0.0%)	0/142 (0.0%)	1/148 (0.7%)	0/154 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
NEUTROPHILS(CALC) AGRAN	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	2/153 (1.3%)	1/141 (0.7%)	0/147 (0.0%)
NEUTROPHILS(CALC)	1/155 (0.6%)	1/140 (0.7%)	2/147 (1.4%)	2/153 (1.3%)	1/141 (0.7%)	0/147 (0.0%)
EOSINOPHILS(CALC)	NA	NA	NA	0/155 (0.0%)	1/142 (0.7%)	0/147 (0.0%)
BASOPHILS(CALC)	NA	NA	NA	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
LYMPHS(CALC)	0/155 (0.0%)	0/142 (0.0%)	1/149 (0.7%)	0/154 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
MONOCYTES(CALC)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA204.SAS
GENERATED: 12JUL2005 17:44:00 iceadmn3

11.3.6.3 Narratives of other significant adverse events

No narratives of other significant adverse events are included in this clinical study report.

Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
BASOPHILS(CALC)	MALE	39-39	X10E9/L	0	0.03	1	X10E9/L	0.00	0.03
	BOTH	25-25	X10E9/L	0	0.06	1	X10E9/L	0.00	0.06
	BOTH	45-45	X10E9/L	0	0.07	1	X10E9/L	0.00	0.07
	BOTH	25-60	X10E9/L	0	0.08	1	X10E9/L	0.00	0.08
	BOTH	22-52	X10E9/L	0	0.09	1	X10E9/L	0.00	0.09
	BOTH	20-57	X10E9/L	0	0.1	1	X10E9/L	0.00	0.10
	BOTH	19-62	X10E9/L	0	0.11	1	X10E9/L	0.00	0.11
	BOTH	21-62	X10E9/L	0	0.12	1	X10E9/L	0.00	0.12
	BOTH	22-63	X10E9/L	0	0.13	1	X10E9/L	0.00	0.13
	BOTH	19-59	X10E9/L	0	0.14	1	X10E9/L	0.00	0.14
	BOTH	18-55	X10E9/L	0	0.15	1	X10E9/L	0.00	0.15
	BOTH	18-60	X10E9/L	0	0.16	1	X10E9/L	0.00	0.16
	BOTH	18-59	X10E9/L	0	0.17	1	X10E9/L	0.00	0.17
	BOTH	18-63	X10E9/L	0	0.18	1	X10E9/L	0.00	0.18
	BOTH	18-58	X10E9/L	0	0.19	1	X10E9/L	0.00	0.19
	BOTH	18-58	X10E9/L	0	0.2	1	X10E9/L	0.00	0.20
	BOTH	18-60	X10E9/L	0	0.21	1	X10E9/L	0.00	0.21
	BOTH	18-62	X10E9/L	0	0.22	1	X10E9/L	0.00	0.22
	BOTH	21-60	X10E9/L	0	0.23	1	X10E9/L	0.00	0.23
	BOTH	20-54	X10E9/L	0	0.24	1	X10E9/L	0.00	0.24
	BOTH	20-62	X10E9/L	0	0.25	1	X10E9/L	0.00	0.25
	BOTH	18-46	X10E9/L	0	0.26	1	X10E9/L	0.00	0.26
	BOTH	19-56	X10E9/L	0	0.27	1	X10E9/L	0.00	0.27
	BOTH	21-46	X10E9/L	0	0.28	1	X10E9/L	0.00	0.28
	BOTH	23-50	X10E9/L	0	0.29	1	X10E9/L	0.00	0.29
	BOTH	30-31	X10E9/L	0	0.3	1	X10E9/L	0.00	0.30
	BOTH	42-52	X10E9/L	0	0.31	1	X10E9/L	0.00	0.31
	BOTH	20-40	X10E9/L	0	0.32	1	X10E9/L	0.00	0.32
	BOTH	26-35	X10E9/L	0	0.33	1	X10E9/L	0.00	0.33
	MALE	44-46	X10E9/L	0	0.34	1	X10E9/L	0.00	0.34
	MALE	41-41	X10E9/L	0	0.35	1	X10E9/L	0.00	0.35
	BOTH	26-32	X10E9/L	0	0.36	1	X10E9/L	0.00	0.36
	BOTH	35-35	X10E9/L	0	0.37	1	X10E9/L	0.00	0.37
	MALE	31-31	X10E9/L	0	0.38	1	X10E9/L	0.00	0.38
	MALE	46-46	X10E9/L	0	0.42	1	X10E9/L	0.00	0.42
	MALE	44-44	X10E9/L	0	0.44	1	X10E9/L	0.00	0.44
	MALE	44-44	X10E9/L	0	0.47	1	X10E9/L	0.00	0.47
	MALE	35-35	X10E9/L	0	0.5	1	X10E9/L	0.00	0.50
	MALE	44-44	X10E9/L	0	0.56	1	X10E9/L	0.00	0.56

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
GENERATED: 12JUL2005 17:43:43 iceadmn3

Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	MALE	39-39	X10E9/L	0.19	0.56	1	X10E9/L	0.19	0.56
	MALE	24-24	X10E9/L	0.42	1.26	1	X10E9/L	0.42	1.26
	FEMALE	45-45	X10E9/L	0.48	1.44	1	X10E9/L	0.48	1.44
	BOTH	39-60	X10E9/L	0.5	1.49	1	X10E9/L	0.50	1.49
	FEMALE	25-34	X10E9/L	0.51	1.54	1	X10E9/L	0.51	1.54
	BOTH	30-30	X10E9/L	0.53	1.58	1	X10E9/L	0.53	1.58
	BOTH	35-52	X10E9/L	0.54	1.63	1	X10E9/L	0.54	1.63
	BOTH	52-52	X10E9/L	0.56	1.68	1	X10E9/L	0.56	1.68
	BOTH	22-49	X10E9/L	0.57	1.72	1	X10E9/L	0.57	1.72
	BOTH	26-52	X10E9/L	0.59	1.77	1	X10E9/L	0.59	1.77
	BOTH	28-36	X10E9/L	0.6	1.82	1	X10E9/L	0.60	1.82
	FEMALE	25-25	X10E9/L	0.62	1.81	1	X10E9/L	0.62	1.81
	FEMALE	20-57	X10E9/L	0.62	1.86	1	X10E9/L	0.62	1.86
	BOTH	24-47	X10E9/L	0.64	1.91	1	X10E9/L	0.64	1.91
	BOTH	20-49	X10E9/L	0.65	1.96	1	X10E9/L	0.65	1.96
	BOTH	22-56	X10E9/L	0.67	2	1	X10E9/L	0.67	2.00
	BOTH	19-54	X10E9/L	0.68	2.05	1	X10E9/L	0.68	2.05
	BOTH	28-58	X10E9/L	0.7	2.1	1	X10E9/L	0.70	2.10
	BOTH	22-62	X10E9/L	0.71	2.14	1	X10E9/L	0.71	2.14
	BOTH	30-52	X10E9/L	0.73	2.19	1	X10E9/L	0.73	2.19
	BOTH	33-62	X10E9/L	0.74	2.24	1	X10E9/L	0.74	2.24
	BOTH	25-58	X10E9/L	0.76	2.28	1	X10E9/L	0.76	2.28
	BOTH	26-55	X10E9/L	0.78	2.33	1	X10E9/L	0.78	2.33
	BOTH	21-58	X10E9/L	0.79	2.38	1	X10E9/L	0.79	2.38
	BOTH	23-50	X10E9/L	0.81	2.42	1	X10E9/L	0.81	2.42
	BOTH	30-63	X10E9/L	0.82	2.47	1	X10E9/L	0.82	2.47
	BOTH	24-50	X10E9/L	0.84	2.52	1	X10E9/L	0.84	2.52
	BOTH	27-57	X10E9/L	0.85	2.56	1	X10E9/L	0.85	2.56
	BOTH	22-59	X10E9/L	0.87	2.61	1	X10E9/L	0.87	2.61
	BOTH	19-59	X10E9/L	0.88	2.66	1	X10E9/L	0.88	2.66
	BOTH	20-55	X10E9/L	0.9	2.7	1	X10E9/L	0.90	2.70
	BOTH	29-45	X10E9/L	0.91	2.75	1	X10E9/L	0.91	2.75
	BOTH	25-59	X10E9/L	0.93	2.8	1	X10E9/L	0.93	2.80
	BOTH	19-51	X10E9/L	0.95	2.84	1	X10E9/L	0.95	2.84
	BOTH	23-54	X10E9/L	0.96	2.89	1	X10E9/L	0.96	2.89
	BOTH	18-41	X10E9/L	0.98	2.94	1	X10E9/L	0.98	2.94
	BOTH	27-55	X10E9/L	0.99	2.98	1	X10E9/L	0.99	2.98
	BOTH	18-40	X10E9/L	1.01	3.03	1	X10E9/L	1.01	3.03
	BOTH	18-60	X10E9/L	1.02	3.08	1	X10E9/L	1.02	3.08

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
GENERATED: 12JUL2005 17:43:43 iceadmn3

Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	BOTH	25-59	X10E9/L	1.04	3.12	1	X10E9/L	1.04	3.12
	BOTH	23-46	X10E9/L	1.05	3.17	1	X10E9/L	1.05	3.17
	BOTH	18-59	X10E9/L	1.07	3.22	1	X10E9/L	1.07	3.22
	BOTH	18-55	X10E9/L	1.09	3.26	1	X10E9/L	1.09	3.26
	BOTH	23-58	X10E9/L	1.1	3.31	1	X10E9/L	1.10	3.31
	BOTH	19-52	X10E9/L	1.12	3.36	1	X10E9/L	1.12	3.36
	BOTH	19-58	X10E9/L	1.13	3.4	1	X10E9/L	1.13	3.40
	BOTH	18-63	X10E9/L	1.15	3.45	1	X10E9/L	1.15	3.45
	BOTH	20-59	X10E9/L	1.16	3.5	1	X10E9/L	1.16	3.50
	BOTH	19-42	X10E9/L	1.18	3.54	1	X10E9/L	1.18	3.54
	BOTH	19-63	X10E9/L	1.19	3.59	1	X10E9/L	1.19	3.59
	BOTH	22-47	X10E9/L	1.21	3.63	1	X10E9/L	1.21	3.63
	BOTH	20-54	X10E9/L	1.22	3.68	1	X10E9/L	1.22	3.68
	BOTH	24-40	X10E9/L	1.24	3.73	1	X10E9/L	1.24	3.73
	BOTH	18-58	X10E9/L	1.26	3.77	1	X10E9/L	1.26	3.77
	BOTH	22-58	X10E9/L	1.27	3.82	1	X10E9/L	1.27	3.82
	BOTH	18-50	X10E9/L	1.29	3.87	1	X10E9/L	1.29	3.87
	BOTH	19-41	X10E9/L	1.3	3.91	1	X10E9/L	1.30	3.91
	BOTH	22-57	X10E9/L	1.32	3.96	1	X10E9/L	1.32	3.96
	BOTH	20-58	X10E9/L	1.33	4.01	1	X10E9/L	1.33	4.01
	BOTH	33-54	X10E9/L	1.35	4.05	1	X10E9/L	1.35	4.05
	BOTH	18-60	X10E9/L	1.36	4.1	1	X10E9/L	1.36	4.10
	BOTH	20-44	X10E9/L	1.38	4.15	1	X10E9/L	1.38	4.15
	MALE	45-45	X10E9/L	1.39	4.03	1	X10E9/L	1.39	4.03
	BOTH	24-42	X10E9/L	1.4	4.19	1	X10E9/L	1.40	4.19
	BOTH	18-48	X10E9/L	1.41	4.24	1	X10E9/L	1.41	4.24
	BOTH	29-62	X10E9/L	1.43	4.29	1	X10E9/L	1.43	4.29
	BOTH	19-50	X10E9/L	1.44	4.33	1	X10E9/L	1.44	4.33
	BOTH	27-59	X10E9/L	1.46	4.38	1	X10E9/L	1.46	4.38
	BOTH	21-60	X10E9/L	1.47	4.43	1	X10E9/L	1.47	4.43
	BOTH	23-35	X10E9/L	1.49	4.47	1	X10E9/L	1.49	4.47
	BOTH	34-40	X10E9/L	1.5	4.52	1	X10E9/L	1.50	4.52
	BOTH	26-53	X10E9/L	1.52	4.57	1	X10E9/L	1.52	4.57
	BOTH	28-52	X10E9/L	1.53	4.61	1	X10E9/L	1.53	4.61
	FEMALE	20-54	X10E9/L	1.55	4.66	1	X10E9/L	1.55	4.66
	BOTH	22-35	X10E9/L	1.57	4.71	1	X10E9/L	1.57	4.71
	BOTH	31-54	X10E9/L	1.58	4.75	1	X10E9/L	1.58	4.75
	BOTH	21-23	X10E9/L	1.6	4.8	1	X10E9/L	1.60	4.80
	BOTH	22-40	X10E9/L	1.61	4.85	1	X10E9/L	1.61	4.85

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	FEMALE	25-62	X10E9/L	1.63	4.89	1	X10E9/L	1.63	4.89
	FEMALE	20-24	X10E9/L	1.64	4.94	1	X10E9/L	1.64	4.94
	BOTH	46-46	X10E9/L	1.66	4.99	1	X10E9/L	1.66	4.99
	BOTH	40-40	X10E9/L	1.67	5.03	1	X10E9/L	1.67	5.03
	BOTH	20-46	X10E9/L	1.69	5.08	1	X10E9/L	1.69	5.08
	BOTH	18-45	X10E9/L	1.71	5.13	1	X10E9/L	1.71	5.13
	BOTH	36-56	X10E9/L	1.72	5.17	1	X10E9/L	1.72	5.17
	BOTH	34-53	X10E9/L	1.74	5.22	1	X10E9/L	1.74	5.22
	FEMALE	43-43	X10E9/L	1.75	5.27	1	X10E9/L	1.75	5.27
	FEMALE	19-21	X10E9/L	1.77	5.31	1	X10E9/L	1.77	5.31
	BOTH	21-35	X10E9/L	1.78	5.36	1	X10E9/L	1.78	5.36
	BOTH	36-44	X10E9/L	1.8	5.41	1	X10E9/L	1.80	5.41
	BOTH	21-46	X10E9/L	1.81	5.45	1	X10E9/L	1.81	5.45
	BOTH	25-25	X10E9/L	1.83	5.5	1	X10E9/L	1.83	5.50
	BOTH	24-24	X10E9/L	1.84	5.55	1	X10E9/L	1.84	5.55
	BOTH	50-50	X10E9/L	1.86	5.59	1	X10E9/L	1.86	5.59
	BOTH	25-50	X10E9/L	1.88	5.64	1	X10E9/L	1.88	5.64
	FEMALE	23-31	X10E9/L	1.89	5.69	1	X10E9/L	1.89	5.69
	FEMALE	30-31	X10E9/L	1.91	5.73	1	X10E9/L	1.91	5.73
	MALE	32-32	X10E9/L	1.92	5.78	1	X10E9/L	1.92	5.78
	MALE	43-43	X10E9/L	1.94	5.83	1	X10E9/L	1.94	5.83
	MALE	43-43	X10E9/L	1.97	5.92	1	X10E9/L	1.97	5.92
	FEMALE	42-42	X10E9/L	2	6.01	1	X10E9/L	2.00	6.01
	FEMALE	52-52	X10E9/L	2.02	6.06	1	X10E9/L	2.02	6.06
	FEMALE	20-23	X10E9/L	2.05	6.15	1	X10E9/L	2.05	6.15
	FEMALE	40-40	X10E9/L	2.08	6.24	1	X10E9/L	2.08	6.24
	FEMALE	32-32	X10E9/L	2.09	6.29	1	X10E9/L	2.09	6.29
	MALE	49-49	X10E9/L	2.11	6.34	1	X10E9/L	2.11	6.34
	FEMALE	35-35	X10E9/L	2.12	6.38	1	X10E9/L	2.12	6.38
	BOTH	26-26	X10E9/L	2.14	6.43	1	X10E9/L	2.14	6.43
	MALE	35-41	X10E9/L	2.15	6.48	1	X10E9/L	2.15	6.48
	MALE	46-46	X10E9/L	2.17	6.52	1	X10E9/L	2.17	6.52
	MALE	44-44	X10E9/L	2.2	6.62	1	X10E9/L	2.20	6.62
	MALE	41-41	X10E9/L	2.28	6.85	1	X10E9/L	2.28	6.85
	FEMALE	26-26	X10E9/L	2.31	6.94	1	X10E9/L	2.31	6.94
	FEMALE	32-32	X10E9/L	2.33	6.99	1	X10E9/L	2.33	6.99
	BOTH	35-35	X10E9/L	2.39	7.18	1	X10E9/L	2.39	7.18
	MALE	53-53	X10E9/L	2.42	7.27	1	X10E9/L	2.42	7.27
	MALE	31-31	X10E9/L	2.43	7.32	1	X10E9/L	2.43	7.32

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
LYMPHS(CALC)	MALE	46-46	X10E9/L	2.68	8.06	1	X10E9/L	2.68	8.06
	MALE	44-44	X10E9/L	2.82	8.48	1	X10E9/L	2.82	8.48
	MALE	44-44	X10E9/L	3.01	9.04	1	X10E9/L	3.01	9.04
	MALE	35-35	X10E9/L	3.26	9.79	1	X10E9/L	3.26	9.79
	MALE	44-44	X10E9/L	3.63	10.9	1	X10E9/L	3.63	10.90
MONOCYTES(CALC)	MALE	39-39	X10E9/L	0.05	0.11	1	X10E9/L	0.05	0.11
	FEMALE	25-25	X10E9/L	0.07	0.28	1	X10E9/L	0.07	0.28
	MALE	24-24	X10E9/L	0.11	0.25	1	X10E9/L	0.11	0.25
	FEMALE	45-45	X10E9/L	0.12	0.29	1	X10E9/L	0.12	0.29
	BOTH	39-60	X10E9/L	0.13	0.3	1	X10E9/L	0.13	0.30
	BOTH	25-34	X10E9/L	0.13	0.31	1	X10E9/L	0.13	0.31
	BOTH	30-30	X10E9/L	0.14	0.32	1	X10E9/L	0.14	0.32
	BOTH	35-52	X10E9/L	0.14	0.33	1	X10E9/L	0.14	0.33
	BOTH	52-52	X10E9/L	0.14	0.34	1	X10E9/L	0.14	0.34
	BOTH	22-49	X10E9/L	0.15	0.35	1	X10E9/L	0.15	0.35
	BOTH	26-52	X10E9/L	0.15	0.36	1	X10E9/L	0.15	0.36
	BOTH	28-36	X10E9/L	0.16	0.37	1	X10E9/L	0.16	0.37
	BOTH	20-57	X10E9/L	0.16	0.38	1	X10E9/L	0.16	0.38
	BOTH	24-47	X10E9/L	0.16	0.39	1	X10E9/L	0.16	0.39
	MALE	45-45	X10E9/L	0.16	0.62	1	X10E9/L	0.16	0.62
	BOTH	20-49	X10E9/L	0.17	0.39	1	X10E9/L	0.17	0.39
	BOTH	22-56	X10E9/L	0.17	0.4	1	X10E9/L	0.17	0.40
	BOTH	19-54	X10E9/L	0.18	0.41	1	X10E9/L	0.18	0.41
	BOTH	28-58	X10E9/L	0.18	0.42	1	X10E9/L	0.18	0.42
	BOTH	22-62	X10E9/L	0.18	0.43	1	X10E9/L	0.18	0.43
	BOTH	30-52	X10E9/L	0.19	0.44	1	X10E9/L	0.19	0.44
	BOTH	33-62	X10E9/L	0.19	0.45	1	X10E9/L	0.19	0.45
	BOTH	25-58	X10E9/L	0.2	0.46	1	X10E9/L	0.20	0.46
	BOTH	26-55	X10E9/L	0.2	0.47	1	X10E9/L	0.20	0.47
	BOTH	21-58	X10E9/L	0.2	0.48	1	X10E9/L	0.20	0.48
	BOTH	23-50	X10E9/L	0.21	0.49	1	X10E9/L	0.21	0.49
	BOTH	30-63	X10E9/L	0.21	0.5	1	X10E9/L	0.21	0.50
	BOTH	24-50	X10E9/L	0.22	0.51	1	X10E9/L	0.22	0.51
	BOTH	27-57	X10E9/L	0.22	0.52	1	X10E9/L	0.22	0.52
	BOTH	22-59	X10E9/L	0.22	0.53	1	X10E9/L	0.22	0.53
	BOTH	19-59	X10E9/L	0.23	0.54	1	X10E9/L	0.23	0.54
	BOTH	20-55	X10E9/L	0.23	0.55	1	X10E9/L	0.23	0.55
	BOTH	29-45	X10E9/L	0.24	0.55	1	X10E9/L	0.24	0.55

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
MONOCYTES(CALC)	BOTH	25-59	X10E9/L	0.24	0.56	1	X10E9/L	0.24	0.56
	BOTH	19-51	X10E9/L	0.24	0.57	1	X10E9/L	0.24	0.57
	BOTH	23-54	X10E9/L	0.25	0.58	1	X10E9/L	0.25	0.58
	BOTH	18-41	X10E9/L	0.25	0.59	1	X10E9/L	0.25	0.59
	BOTH	27-55	X10E9/L	0.26	0.6	1	X10E9/L	0.26	0.60
	BOTH	18-40	X10E9/L	0.26	0.61	1	X10E9/L	0.26	0.61
	BOTH	18-60	X10E9/L	0.26	0.62	1	X10E9/L	0.26	0.62
	BOTH	25-59	X10E9/L	0.27	0.63	1	X10E9/L	0.27	0.63
	BOTH	23-46	X10E9/L	0.27	0.64	1	X10E9/L	0.27	0.64
	BOTH	18-59	X10E9/L	0.28	0.65	1	X10E9/L	0.28	0.65
	BOTH	18-55	X10E9/L	0.28	0.66	1	X10E9/L	0.28	0.66
	BOTH	23-58	X10E9/L	0.28	0.67	1	X10E9/L	0.28	0.67
	BOTH	19-52	X10E9/L	0.29	0.68	1	X10E9/L	0.29	0.68
	BOTH	19-58	X10E9/L	0.29	0.69	1	X10E9/L	0.29	0.69
	BOTH	18-63	X10E9/L	0.3	0.7	1	X10E9/L	0.30	0.70
	BOTH	19-59	X10E9/L	0.3	0.71	1	X10E9/L	0.30	0.71
	BOTH	19-63	X10E9/L	0.31	0.72	1	X10E9/L	0.31	0.72
	BOTH	22-47	X10E9/L	0.31	0.73	1	X10E9/L	0.31	0.73
	BOTH	20-54	X10E9/L	0.32	0.74	1	X10E9/L	0.32	0.74
	BOTH	24-40	X10E9/L	0.32	0.75	1	X10E9/L	0.32	0.75
	BOTH	18-58	X10E9/L	0.32	0.76	1	X10E9/L	0.32	0.76
	BOTH	22-58	X10E9/L	0.33	0.77	1	X10E9/L	0.33	0.77
	BOTH	18-50	X10E9/L	0.33	0.78	1	X10E9/L	0.33	0.78
	BOTH	19-41	X10E9/L	0.34	0.79	1	X10E9/L	0.34	0.79
	BOTH	22-57	X10E9/L	0.34	0.8	1	X10E9/L	0.34	0.80
	BOTH	20-58	X10E9/L	0.34	0.81	1	X10E9/L	0.34	0.81
	BOTH	33-54	X10E9/L	0.35	0.82	1	X10E9/L	0.35	0.82
	BOTH	18-60	X10E9/L	0.35	0.83	1	X10E9/L	0.35	0.83
	BOTH	20-44	X10E9/L	0.36	0.84	1	X10E9/L	0.36	0.84
	BOTH	24-42	X10E9/L	0.36	0.85	1	X10E9/L	0.36	0.85
	BOTH	18-48	X10E9/L	0.36	0.86	1	X10E9/L	0.36	0.86
	BOTH	29-62	X10E9/L	0.37	0.86	1	X10E9/L	0.37	0.86
	BOTH	19-50	X10E9/L	0.37	0.87	1	X10E9/L	0.37	0.87
	BOTH	27-59	X10E9/L	0.38	0.88	1	X10E9/L	0.38	0.88
	BOTH	21-60	X10E9/L	0.38	0.89	1	X10E9/L	0.38	0.89
	BOTH	23-35	X10E9/L	0.38	0.9	1	X10E9/L	0.38	0.90
	BOTH	34-40	X10E9/L	0.39	0.91	1	X10E9/L	0.39	0.91
	BOTH	26-53	X10E9/L	0.39	0.92	1	X10E9/L	0.39	0.92
	BOTH	28-52	X10E9/L	0.4	0.93	1	X10E9/L	0.40	0.93

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
MONOCYTES(CALC)	BOTH	20-54	X10E9/L	0.4	0.94	1	X10E9/L	0.40	0.94
	BOTH	22-35	X10E9/L	0.4	0.95	1	X10E9/L	0.40	0.95
	BOTH	31-54	X10E9/L	0.41	0.96	1	X10E9/L	0.41	0.96
	BOTH	21-23	X10E9/L	0.41	0.97	1	X10E9/L	0.41	0.97
	BOTH	22-40	X10E9/L	0.42	0.98	1	X10E9/L	0.42	0.98
	BOTH	25-62	X10E9/L	0.42	0.99	1	X10E9/L	0.42	0.99
	BOTH	20-24	X10E9/L	0.42	1	1	X10E9/L	0.42	1.00
	BOTH	46-46	X10E9/L	0.43	1.01	1	X10E9/L	0.43	1.01
	BOTH	40-40	X10E9/L	0.43	1.02	1	X10E9/L	0.43	1.02
	BOTH	20-46	X10E9/L	0.44	1.02	1	X10E9/L	0.44	1.02
	BOTH	18-45	X10E9/L	0.44	1.03	1	X10E9/L	0.44	1.03
	BOTH	36-56	X10E9/L	0.44	1.04	1	X10E9/L	0.44	1.04
	BOTH	34-53	X10E9/L	0.45	1.05	1	X10E9/L	0.45	1.05
	BOTH	43-43	X10E9/L	0.45	1.06	1	X10E9/L	0.45	1.06
	FEMALE	19-21	X10E9/L	0.46	1.07	1	X10E9/L	0.46	1.07
	FEMALE	21-35	X10E9/L	0.46	1.08	1	X10E9/L	0.46	1.08
	FEMALE	36-44	X10E9/L	0.46	1.09	1	X10E9/L	0.46	1.09
	BOTH	21-46	X10E9/L	0.47	1.1	1	X10E9/L	0.47	1.10
	BOTH	25-25	X10E9/L	0.47	1.11	1	X10E9/L	0.47	1.11
	BOTH	24-24	X10E9/L	0.48	1.12	1	X10E9/L	0.48	1.12
	BOTH	50-50	X10E9/L	0.48	1.13	1	X10E9/L	0.48	1.13
	BOTH	25-50	X10E9/L	0.48	1.14	1	X10E9/L	0.48	1.14
	FEMALE	23-31	X10E9/L	0.49	1.15	1	X10E9/L	0.49	1.15
	FEMALE	30-31	X10E9/L	0.49	1.16	1	X10E9/L	0.49	1.16
	MALE	32-32	X10E9/L	0.5	1.17	1	X10E9/L	0.50	1.17
	MALE	43-43	X10E9/L	0.5	1.18	1	X10E9/L	0.50	1.18
	MALE	43-43	X10E9/L	0.51	1.19	1	X10E9/L	0.51	1.19
	FEMALE	42-42	X10E9/L	0.52	1.21	1	X10E9/L	0.52	1.21
	FEMALE	52-52	X10E9/L	0.52	1.22	1	X10E9/L	0.52	1.22
	FEMALE	20-23	X10E9/L	0.53	1.24	1	X10E9/L	0.53	1.24
	FEMALE	40-40	X10E9/L	0.54	1.26	1	X10E9/L	0.54	1.26
	FEMALE	32-32	X10E9/L	0.54	1.27	1	X10E9/L	0.54	1.27
	BOTH	49-49	X10E9/L	0.54	1.28	1	X10E9/L	0.54	1.28
	FEMALE	35-35	X10E9/L	0.55	1.29	1	X10E9/L	0.55	1.29
	FEMALE	26-26	X10E9/L	0.55	1.3	1	X10E9/L	0.55	1.30
	MALE	35-41	X10E9/L	0.56	1.31	1	X10E9/L	0.56	1.31
	MALE	46-46	X10E9/L	0.56	1.32	1	X10E9/L	0.56	1.32
	MALE	44-44	X10E9/L	0.57	1.33	1	X10E9/L	0.57	1.33
	MALE	41-41	X10E9/L	0.59	1.38	1	X10E9/L	0.59	1.38

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
MONOCYTES(CALC)	FEMALE	26-26	X10E9/L	0.6	1.4	1	X10E9/L	0.60	1.40
	FEMALE	32-32	X10E9/L	0.6	1.41	1	X10E9/L	0.60	1.41
	BOTH	35-35	X10E9/L	0.62	1.45	1	X10E9/L	0.62	1.45
	MALE	53-53	X10E9/L	0.62	1.47	1	X10E9/L	0.62	1.47
	MALE	31-31	X10E9/L	0.63	1.48	1	X10E9/L	0.63	1.48
	MALE	46-46	X10E9/L	0.69	1.63	1	X10E9/L	0.69	1.63
	MALE	44-44	X10E9/L	0.73	1.71	1	X10E9/L	0.73	1.71
	MALE	44-44	X10E9/L	0.78	1.82	1	X10E9/L	0.78	1.82
	MALE	35-35	X10E9/L	0.84	1.97	1	X10E9/L	0.84	1.97
	MALE	44-44	X10E9/L	0.94	2.2	1	X10E9/L	0.94	2.20
NEUTROPHILS(CALC)	MALE	39-39	X10E9/L	0.49	0.92	1	X10E9/L	0.49	0.92
	MALE	24-24	X10E9/L	1.1	2.08	1	X10E9/L	1.10	2.08
	FEMALE	45-45	X10E9/L	1.27	2.39	1	X10E9/L	1.27	2.39
	BOTH	39-60	X10E9/L	1.31	2.46	1	X10E9/L	1.31	2.46
	FEMALE	25-34	X10E9/L	1.35	2.54	1	X10E9/L	1.35	2.54
	BOTH	30-30	X10E9/L	1.39	2.62	1	X10E9/L	1.39	2.62
	BOTH	35-52	X10E9/L	1.43	2.7	1	X10E9/L	1.43	2.70
	BOTH	52-52	X10E9/L	1.47	2.77	1	X10E9/L	1.47	2.77
	BOTH	22-49	X10E9/L	1.51	2.85	1	X10E9/L	1.51	2.85
	BOTH	26-52	X10E9/L	1.55	2.93	1	X10E9/L	1.55	2.93
	BOTH	28-36	X10E9/L	1.6	3	1	X10E9/L	1.60	3.00
	FEMALE	25-25	X10E9/L	1.63	2.81	1	X10E9/L	1.63	2.81
	BOTH	20-57	X10E9/L	1.64	3.08	1	X10E9/L	1.64	3.08
	BOTH	24-47	X10E9/L	1.68	3.16	1	X10E9/L	1.68	3.16
	BOTH	20-49	X10E9/L	1.72	3.23	1	X10E9/L	1.72	3.23
	BOTH	22-56	X10E9/L	1.76	3.31	1	X10E9/L	1.76	3.31
	BOTH	19-54	X10E9/L	1.8	3.39	1	X10E9/L	1.80	3.39
	BOTH	28-58	X10E9/L	1.84	3.47	1	X10E9/L	1.84	3.47
	BOTH	22-62	X10E9/L	1.88	3.54	1	X10E9/L	1.88	3.54
	BOTH	30-52	X10E9/L	1.92	3.62	1	X10E9/L	1.92	3.62
	BOTH	33-62	X10E9/L	1.96	3.7	1	X10E9/L	1.96	3.70
	BOTH	25-58	X10E9/L	2	3.77	1	X10E9/L	2.00	3.77
	BOTH	26-55	X10E9/L	2.05	3.85	1	X10E9/L	2.05	3.85
	BOTH	21-58	X10E9/L	2.09	3.93	1	X10E9/L	2.09	3.93
	BOTH	23-50	X10E9/L	2.13	4	1	X10E9/L	2.13	4.00
	BOTH	30-63	X10E9/L	2.17	4.08	1	X10E9/L	2.17	4.08
	BOTH	24-50	X10E9/L	2.21	4.16	1	X10E9/L	2.21	4.16
	BOTH	27-57	X10E9/L	2.25	4.24	1	X10E9/L	2.25	4.24

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC)	BOTH	22-59	X10E9/L	2.29	4.31	1	X10E9/L	2.29	4.31
	BOTH	19-59	X10E9/L	2.33	4.39	1	X10E9/L	2.33	4.39
	BOTH	20-55	X10E9/L	2.37	4.47	1	X10E9/L	2.37	4.47
	BOTH	29-45	X10E9/L	2.41	4.54	1	X10E9/L	2.41	4.54
	BOTH	25-59	X10E9/L	2.45	4.62	1	X10E9/L	2.45	4.62
	BOTH	19-51	X10E9/L	2.49	4.7	1	X10E9/L	2.49	4.70
	BOTH	23-54	X10E9/L	2.54	4.77	1	X10E9/L	2.54	4.77
	BOTH	18-41	X10E9/L	2.58	4.85	1	X10E9/L	2.58	4.85
	BOTH	27-55	X10E9/L	2.62	4.93	1	X10E9/L	2.62	4.93
	BOTH	18-40	X10E9/L	2.66	5.01	1	X10E9/L	2.66	5.01
	BOTH	18-60	X10E9/L	2.7	5.08	1	X10E9/L	2.70	5.08
	BOTH	25-59	X10E9/L	2.74	5.16	1	X10E9/L	2.74	5.16
	BOTH	23-46	X10E9/L	2.78	5.24	1	X10E9/L	2.78	5.24
	BOTH	18-59	X10E9/L	2.82	5.31	1	X10E9/L	2.82	5.31
	BOTH	18-55	X10E9/L	2.86	5.39	1	X10E9/L	2.86	5.39
	BOTH	23-58	X10E9/L	2.9	5.47	1	X10E9/L	2.90	5.47
	BOTH	19-52	X10E9/L	2.94	5.54	1	X10E9/L	2.94	5.54
	BOTH	19-58	X10E9/L	2.99	5.62	1	X10E9/L	2.99	5.62
	BOTH	18-63	X10E9/L	3.03	5.7	1	X10E9/L	3.03	5.70
	BOTH	20-59	X10E9/L	3.07	5.78	1	X10E9/L	3.07	5.78
	BOTH	19-42	X10E9/L	3.11	5.85	1	X10E9/L	3.11	5.85
	BOTH	19-63	X10E9/L	3.15	5.93	1	X10E9/L	3.15	5.93
	BOTH	22-47	X10E9/L	3.19	6.01	1	X10E9/L	3.19	6.01
	BOTH	20-54	X10E9/L	3.23	6.08	1	X10E9/L	3.23	6.08
	BOTH	24-40	X10E9/L	3.27	6.16	1	X10E9/L	3.27	6.16
	BOTH	18-58	X10E9/L	3.31	6.24	1	X10E9/L	3.31	6.24
	BOTH	22-58	X10E9/L	3.35	6.31	1	X10E9/L	3.35	6.31
	BOTH	18-50	X10E9/L	3.39	6.39	1	X10E9/L	3.39	6.39
	BOTH	19-41	X10E9/L	3.44	6.47	1	X10E9/L	3.44	6.47
	BOTH	22-57	X10E9/L	3.48	6.55	1	X10E9/L	3.48	6.55
	BOTH	20-58	X10E9/L	3.52	6.62	1	X10E9/L	3.52	6.62
	BOTH	33-54	X10E9/L	3.56	6.7	1	X10E9/L	3.56	6.70
	BOTH	18-60	X10E9/L	3.6	6.78	1	X10E9/L	3.60	6.78
	MALE	45-45	X10E9/L	3.61	6.23	1	X10E9/L	3.61	6.23
	BOTH	20-44	X10E9/L	3.64	6.85	1	X10E9/L	3.64	6.85
	BOTH	24-42	X10E9/L	3.68	6.93	1	X10E9/L	3.68	6.93
	BOTH	18-48	X10E9/L	3.72	7.01	1	X10E9/L	3.72	7.01
	BOTH	29-62	X10E9/L	3.76	7.08	1	X10E9/L	3.76	7.08
	BOTH	19-50	X10E9/L	3.8	7.16	1	X10E9/L	3.80	7.16

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC)	BOTH	27-59	X10E9/L	3.84	7.24	1	X10E9/L	3.84	7.24
	BOTH	21-60	X10E9/L	3.89	7.32	1	X10E9/L	3.89	7.32
	BOTH	23-35	X10E9/L	3.93	7.39	1	X10E9/L	3.93	7.39
	BOTH	34-40	X10E9/L	3.97	7.47	1	X10E9/L	3.97	7.47
	BOTH	26-53	X10E9/L	4.01	7.55	1	X10E9/L	4.01	7.55
	BOTH	28-52	X10E9/L	4.05	7.62	1	X10E9/L	4.05	7.62
	FEMALE	20-54	X10E9/L	4.09	7.7	1	X10E9/L	4.09	7.70
	BOTH	22-35	X10E9/L	4.13	7.78	1	X10E9/L	4.13	7.78
	BOTH	31-54	X10E9/L	4.17	7.85	1	X10E9/L	4.17	7.85
	BOTH	21-23	X10E9/L	4.21	7.93	1	X10E9/L	4.21	7.93
	BOTH	22-40	X10E9/L	4.25	8.01	1	X10E9/L	4.25	8.01
	FEMALE	25-62	X10E9/L	4.29	8.09	1	X10E9/L	4.29	8.09
	FEMALE	20-24	X10E9/L	4.34	8.16	1	X10E9/L	4.34	8.16
	BOTH	46-46	X10E9/L	4.38	8.24	1	X10E9/L	4.38	8.24
	BOTH	40-40	X10E9/L	4.42	8.32	1	X10E9/L	4.42	8.32
	BOTH	20-46	X10E9/L	4.46	8.39	1	X10E9/L	4.46	8.39
	BOTH	18-45	X10E9/L	4.5	8.47	1	X10E9/L	4.50	8.47
	BOTH	36-56	X10E9/L	4.54	8.55	1	X10E9/L	4.54	8.55
	BOTH	34-53	X10E9/L	4.58	8.62	1	X10E9/L	4.58	8.62
	FEMALE	43-43	X10E9/L	4.62	8.7	1	X10E9/L	4.62	8.70
	FEMALE	19-21	X10E9/L	4.66	8.78	1	X10E9/L	4.66	8.78
	BOTH	21-35	X10E9/L	4.7	8.86	1	X10E9/L	4.70	8.86
	BOTH	36-44	X10E9/L	4.74	8.93	1	X10E9/L	4.74	8.93
	BOTH	21-46	X10E9/L	4.79	9.01	1	X10E9/L	4.79	9.01
	BOTH	25-25	X10E9/L	4.83	9.09	1	X10E9/L	4.83	9.09
	BOTH	24-24	X10E9/L	4.87	9.16	1	X10E9/L	4.87	9.16
	BOTH	50-50	X10E9/L	4.91	9.24	1	X10E9/L	4.91	9.24
	BOTH	25-50	X10E9/L	4.95	9.32	1	X10E9/L	4.95	9.32
	FEMALE	23-31	X10E9/L	4.99	9.39	1	X10E9/L	4.99	9.39
	FEMALE	30-31	X10E9/L	5.03	9.47	1	X10E9/L	5.03	9.47
	MALE	32-32	X10E9/L	5.07	9.55	1	X10E9/L	5.07	9.55
	MALE	43-43	X10E9/L	5.11	9.63	1	X10E9/L	5.11	9.63
	MALE	43-43	X10E9/L	5.19	9.78	1	X10E9/L	5.19	9.78
	FEMALE	42-42	X10E9/L	5.28	9.93	1	X10E9/L	5.28	9.93
	FEMALE	52-52	X10E9/L	5.32	10.01	1	X10E9/L	5.32	10.01
	FEMALE	20-23	X10E9/L	5.4	10.16	1	X10E9/L	5.40	10.16
	FEMALE	40-40	X10E9/L	5.48	10.32	1	X10E9/L	5.48	10.32
	FEMALE	32-32	X10E9/L	5.52	10.4	1	X10E9/L	5.52	10.40
	MALE	49-49	X10E9/L	5.56	10.47	1	X10E9/L	5.56	10.47

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

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Table 11.3.7.1.1.1 Hematology Conversion Factors

			ORIGINAL			*REPORTED UNIT CONVERSION FACTOR	REPORTED		
LAB TEST	SEX	AGE RANGE	UNITS	LOWER RANGE	UPPER RANGE		UNITS	LOWER RANGE	UPPER RANGE
NEUTROPHILS(CALC)	FEMALE	35-35	X10E9/L	5.6	10.55	1	X10E9/L	5.60	10.55
	BOTH	26-26	X10E9/L	5.64	10.63	1	X10E9/L	5.64	10.63
	MALE	35-41	X10E9/L	5.69	10.7	1	X10E9/L	5.69	10.70
	MALE	46-46	X10E9/L	5.73	10.78	1	X10E9/L	5.73	10.78
	MALE	44-44	X10E9/L	5.81	10.93	1	X10E9/L	5.81	10.93
	MALE	41-41	X10E9/L	6.01	11.32	1	X10E9/L	6.01	11.32
	FEMALE	26-26	X10E9/L	6.09	11.47	1	X10E9/L	6.09	11.47
	FEMALE	32-32	X10E9/L	6.14	11.55	1	X10E9/L	6.14	11.55
	BOTH	35-35	X10E9/L	6.3	11.86	1	X10E9/L	6.30	11.86
	MALE	53-53	X10E9/L	6.38	12.01	1	X10E9/L	6.38	12.01
	MALE	31-31	X10E9/L	6.42	12.09	1	X10E9/L	6.42	12.09
	MALE	46-46	X10E9/L	7.08	13.32	1	X10E9/L	7.08	13.32
	MALE	44-44	X10E9/L	7.44	14.01	1	X10E9/L	7.44	14.01
	MALE	44-44	X10E9/L	7.93	14.94	1	X10E9/L	7.93	14.94
	MALE	35-35	X10E9/L	8.59	16.17	1	X10E9/L	8.59	16.17
	MALE	44-44	X10E9/L	9.57	18.02	1	X10E9/L	9.57	18.02
HEMATOCRIT	FEMALE	25-25	%	34.3	46.6	0.01	Vol Fraction	0.34	0.47
	FEMALE	18-63	%	35.0	47.0	0.01	Vol Fraction	0.35	0.47
	MALE	18-65	%	40.0	52.0	0.01	Vol Fraction	0.40	0.52
	MALE	45-45	%	40.8	51.9	0.01	Vol Fraction	0.41	0.52
HEMOGLOBIN	FEMALE	18-63	G/DL	11.6	16.2	1	G/DL	11.60	16.20
	FEMALE	25-25	G/DL	12.1	15.9	1	G/DL	12.10	15.90
	MALE	18-65	G/DL	13.0	17.5	1	G/DL	13.00	17.50
	MALE	45-45	G/DL	14.6	17.8	1	G/DL	14.60	17.80
RBC	FEMALE	18-63	X10E6/UL	3.8	5.5	1	X10E12/L	3.80	5.50
	FEMALE	25-25	M/UL	3.88	5.46	1	X10E12/L	3.88	5.46
	MALE	18-65	X10E6/UL	4.1	5.9	1	X10E12/L	4.10	5.90
	MALE	45-45	M/UL	4.69	6.07	1	X10E12/L	4.69	6.07
PLATELET COUNT	BOTH	18-63	X10E3/UL	140	450	1	X10E9/L	140.00	450.00
	BOTH	25-25	K/UL	177	406	1	X10E9/L	177.00	406.00
WBC	BOTH	25-25	K/UL	3.20	10.60	1	X10E9/L	3.20	10.60
	BOTH	18-63	X10E3/UL	4.1	12.3	1	X10E9/L	4.10	12.30
NEUTROPHILS	BOTH	18-63	%	40.9	77.0	1	%	40.90	77.00

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

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Table 11.3.7.1.1.1 Hematology Conversion Factors

			ORIGINAL			*REPORTED UNIT CONVERSION FACTOR	REPORTED		
LAB TEST	SEX	AGE RANGE	UNITS	LOWER RANGE	UPPER RANGE		UNITS	LOWER RANGE	UPPER RANGE
NEUTROPHILS	BOTH	25-25	%	44.0	76.0	1	%	44.00	76.00
NEUTROPHILS(CALC) AGRAN	MALE	39-39	X10E9/L	0.49	0.92	1	X10E9/L	0.49	0.92
	MALE	24-24	X10E9/L	1.1	2.08	1	X10E9/L	1.10	2.08
	FEMALE	45-45	X10E9/L	1.27	2.39	1	X10E9/L	1.27	2.39
	BOTH	39-60	X10E9/L	1.31	2.46	1	X10E9/L	1.31	2.46
	FEMALE	25-34	X10E9/L	1.35	2.54	1	X10E9/L	1.35	2.54
	BOTH	30-30	X10E9/L	1.39	2.62	1	X10E9/L	1.39	2.62
	BOTH	35-52	X10E9/L	1.43	2.7	1	X10E9/L	1.43	2.70
	BOTH	52-52	X10E9/L	1.47	2.77	1	X10E9/L	1.47	2.77
	BOTH	22-49	X10E9/L	1.51	2.85	1	X10E9/L	1.51	2.85
	BOTH	26-52	X10E9/L	1.55	2.93	1	X10E9/L	1.55	2.93
	BOTH	28-36	X10E9/L	1.6	3	1	X10E9/L	1.60	3.00
	FEMALE	25-25	X10E9/L	1.63	2.81	1	X10E9/L	1.63	2.81
	BOTH	20-57	X10E9/L	1.64	3.08	1	X10E9/L	1.64	3.08
	BOTH	24-47	X10E9/L	1.68	3.16	1	X10E9/L	1.68	3.16
	BOTH	20-49	X10E9/L	1.72	3.23	1	X10E9/L	1.72	3.23
	BOTH	22-56	X10E9/L	1.76	3.31	1	X10E9/L	1.76	3.31
	BOTH	19-54	X10E9/L	1.8	3.39	1	X10E9/L	1.80	3.39
	BOTH	28-58	X10E9/L	1.84	3.47	1	X10E9/L	1.84	3.47
	BOTH	22-62	X10E9/L	1.88	3.54	1	X10E9/L	1.88	3.54
	BOTH	30-52	X10E9/L	1.92	3.62	1	X10E9/L	1.92	3.62
	BOTH	33-62	X10E9/L	1.96	3.7	1	X10E9/L	1.96	3.70
	BOTH	25-58	X10E9/L	2	3.77	1	X10E9/L	2.00	3.77
	BOTH	26-55	X10E9/L	2.05	3.85	1	X10E9/L	2.05	3.85
	BOTH	21-58	X10E9/L	2.09	3.93	1	X10E9/L	2.09	3.93
	BOTH	23-50	X10E9/L	2.13	4	1	X10E9/L	2.13	4.00
	BOTH	30-63	X10E9/L	2.17	4.08	1	X10E9/L	2.17	4.08
	BOTH	24-50	X10E9/L	2.21	4.16	1	X10E9/L	2.21	4.16
	BOTH	27-57	X10E9/L	2.25	4.24	1	X10E9/L	2.25	4.24
	BOTH	22-59	X10E9/L	2.29	4.31	1	X10E9/L	2.29	4.31
	BOTH	19-59	X10E9/L	2.33	4.39	1	X10E9/L	2.33	4.39
	BOTH	20-55	X10E9/L	2.37	4.47	1	X10E9/L	2.37	4.47
	BOTH	29-45	X10E9/L	2.41	4.54	1	X10E9/L	2.41	4.54
	BOTH	25-59	X10E9/L	2.45	4.62	1	X10E9/L	2.45	4.62
	BOTH	19-51	X10E9/L	2.49	4.7	1	X10E9/L	2.49	4.70
	BOTH	23-54	X10E9/L	2.54	4.77	1	X10E9/L	2.54	4.77
	BOTH	18-41	X10E9/L	2.58	4.85	1	X10E9/L	2.58	4.85

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC) AGRAN	BOTH	27-55	X10E9/L	2.62	4.93	1	X10E9/L	2.62	4.93
	BOTH	18-40	X10E9/L	2.66	5.01	1	X10E9/L	2.66	5.01
	BOTH	18-60	X10E9/L	2.7	5.08	1	X10E9/L	2.70	5.08
	BOTH	25-59	X10E9/L	2.74	5.16	1	X10E9/L	2.74	5.16
	BOTH	23-46	X10E9/L	2.78	5.24	1	X10E9/L	2.78	5.24
	BOTH	18-59	X10E9/L	2.82	5.31	1	X10E9/L	2.82	5.31
	BOTH	18-55	X10E9/L	2.86	5.39	1	X10E9/L	2.86	5.39
	BOTH	23-58	X10E9/L	2.9	5.47	1	X10E9/L	2.90	5.47
	BOTH	19-52	X10E9/L	2.94	5.54	1	X10E9/L	2.94	5.54
	BOTH	19-58	X10E9/L	2.99	5.62	1	X10E9/L	2.99	5.62
	BOTH	18-63	X10E9/L	3.03	5.7	1	X10E9/L	3.03	5.70
	BOTH	20-59	X10E9/L	3.07	5.78	1	X10E9/L	3.07	5.78
	BOTH	19-42	X10E9/L	3.11	5.85	1	X10E9/L	3.11	5.85
	BOTH	19-63	X10E9/L	3.15	5.93	1	X10E9/L	3.15	5.93
	BOTH	22-47	X10E9/L	3.19	6.01	1	X10E9/L	3.19	6.01
	BOTH	20-54	X10E9/L	3.23	6.08	1	X10E9/L	3.23	6.08
	BOTH	24-40	X10E9/L	3.27	6.16	1	X10E9/L	3.27	6.16
	BOTH	18-58	X10E9/L	3.31	6.24	1	X10E9/L	3.31	6.24
	BOTH	22-58	X10E9/L	3.35	6.31	1	X10E9/L	3.35	6.31
	BOTH	18-50	X10E9/L	3.39	6.39	1	X10E9/L	3.39	6.39
	BOTH	19-41	X10E9/L	3.44	6.47	1	X10E9/L	3.44	6.47
	BOTH	22-57	X10E9/L	3.48	6.55	1	X10E9/L	3.48	6.55
	BOTH	20-58	X10E9/L	3.52	6.62	1	X10E9/L	3.52	6.62
	BOTH	33-54	X10E9/L	3.56	6.7	1	X10E9/L	3.56	6.70
	BOTH	18-60	X10E9/L	3.6	6.78	1	X10E9/L	3.60	6.78
	MALE	45-45	X10E9/L	3.61	6.23	1	X10E9/L	3.61	6.23
	BOTH	20-44	X10E9/L	3.64	6.85	1	X10E9/L	3.64	6.85
	BOTH	24-42	X10E9/L	3.68	6.93	1	X10E9/L	3.68	6.93
	BOTH	18-48	X10E9/L	3.72	7.01	1	X10E9/L	3.72	7.01
	BOTH	29-62	X10E9/L	3.76	7.08	1	X10E9/L	3.76	7.08
	BOTH	19-50	X10E9/L	3.8	7.16	1	X10E9/L	3.80	7.16
	BOTH	27-59	X10E9/L	3.84	7.24	1	X10E9/L	3.84	7.24
	BOTH	21-60	X10E9/L	3.89	7.32	1	X10E9/L	3.89	7.32
	BOTH	23-35	X10E9/L	3.93	7.39	1	X10E9/L	3.93	7.39
	BOTH	34-40	X10E9/L	3.97	7.47	1	X10E9/L	3.97	7.47
	BOTH	26-53	X10E9/L	4.01	7.55	1	X10E9/L	4.01	7.55
	BOTH	28-52	X10E9/L	4.05	7.62	1	X10E9/L	4.05	7.62
	FEMALE	20-54	X10E9/L	4.09	7.7	1	X10E9/L	4.09	7.70

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
NEUTROPHILS(CALC) AGRAN	BOTH	22-35	X10E9/L	4.13	7.78	1	X10E9/L	4.13	7.78
	BOTH	31-54	X10E9/L	4.17	7.85	1	X10E9/L	4.17	7.85
	BOTH	21-23	X10E9/L	4.21	7.93	1	X10E9/L	4.21	7.93
	BOTH	22-40	X10E9/L	4.25	8.01	1	X10E9/L	4.25	8.01
	FEMALE	25-62	X10E9/L	4.29	8.09	1	X10E9/L	4.29	8.09
	FEMALE	20-24	X10E9/L	4.34	8.16	1	X10E9/L	4.34	8.16
	BOTH	46-46	X10E9/L	4.38	8.24	1	X10E9/L	4.38	8.24
	BOTH	40-40	X10E9/L	4.42	8.32	1	X10E9/L	4.42	8.32
	BOTH	20-46	X10E9/L	4.46	8.39	1	X10E9/L	4.46	8.39
	BOTH	18-45	X10E9/L	4.5	8.47	1	X10E9/L	4.50	8.47
	BOTH	36-56	X10E9/L	4.54	8.55	1	X10E9/L	4.54	8.55
	BOTH	34-53	X10E9/L	4.58	8.62	1	X10E9/L	4.58	8.62
	FEMALE	43-43	X10E9/L	4.62	8.7	1	X10E9/L	4.62	8.70
	FEMALE	19-21	X10E9/L	4.66	8.78	1	X10E9/L	4.66	8.78
	BOTH	21-35	X10E9/L	4.7	8.86	1	X10E9/L	4.70	8.86
	BOTH	36-44	X10E9/L	4.74	8.93	1	X10E9/L	4.74	8.93
	BOTH	21-46	X10E9/L	4.79	9.01	1	X10E9/L	4.79	9.01
	BOTH	25-25	X10E9/L	4.83	9.09	1	X10E9/L	4.83	9.09
	BOTH	24-24	X10E9/L	4.87	9.16	1	X10E9/L	4.87	9.16
	BOTH	50-50	X10E9/L	4.91	9.24	1	X10E9/L	4.91	9.24
	BOTH	25-50	X10E9/L	4.95	9.32	1	X10E9/L	4.95	9.32
	FEMALE	23-31	X10E9/L	4.99	9.39	1	X10E9/L	4.99	9.39
	FEMALE	30-31	X10E9/L	5.03	9.47	1	X10E9/L	5.03	9.47
	MALE	32-32	X10E9/L	5.07	9.55	1	X10E9/L	5.07	9.55
	MALE	43-43	X10E9/L	5.11	9.63	1	X10E9/L	5.11	9.63
	MALE	43-43	X10E9/L	5.19	9.78	1	X10E9/L	5.19	9.78
	FEMALE	42-42	X10E9/L	5.28	9.93	1	X10E9/L	5.28	9.93
	FEMALE	52-52	X10E9/L	5.32	10.01	1	X10E9/L	5.32	10.01
	FEMALE	20-23	X10E9/L	5.4	10.16	1	X10E9/L	5.40	10.16
	FEMALE	40-40	X10E9/L	5.48	10.32	1	X10E9/L	5.48	10.32
	FEMALE	32-32	X10E9/L	5.52	10.4	1	X10E9/L	5.52	10.40
	MALE	49-49	X10E9/L	5.56	10.47	1	X10E9/L	5.56	10.47
	FEMALE	35-35	X10E9/L	5.6	10.55	1	X10E9/L	5.60	10.55
	BOTH	26-26	X10E9/L	5.64	10.63	1	X10E9/L	5.64	10.63
	MALE	35-41	X10E9/L	5.69	10.7	1	X10E9/L	5.69	10.70
	MALE	46-46	X10E9/L	5.73	10.78	1	X10E9/L	5.73	10.78
	MALE	44-44	X10E9/L	5.81	10.93	1	X10E9/L	5.81	10.93
	MALE	41-41	X10E9/L	6.01	11.32	1	X10E9/L	6.01	11.32

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

			ORIGINAL			*REPORTED UNIT	REPORTED		
LAB TEST	SEX	AGE RANGE	UNITS	LOWER RANGE	UPPER RANGE	CONVERSION FACTOR	UNITS	LOWER RANGE	UPPER RANGE
NEUTROPHILS(CALC) AGRAN	FEMALE	26-26	X10E9/L	6.09	11.47	1	X10E9/L	6.09	11.47
	FEMALE	32-32	X10E9/L	6.14	11.55	1	X10E9/L	6.14	11.55
	BOTH	35-35	X10E9/L	6.3	11.86	1	X10E9/L	6.30	11.86
	MALE	53-53	X10E9/L	6.38	12.01	1	X10E9/L	6.38	12.01
	MALE	31-31	X10E9/L	6.42	12.09	1	X10E9/L	6.42	12.09
	MALE	46-46	X10E9/L	7.08	13.32	1	X10E9/L	7.08	13.32
	MALE	44-44	X10E9/L	7.44	14.01	1	X10E9/L	7.44	14.01
	MALE	44-44	X10E9/L	7.93	14.94	1	X10E9/L	7.93	14.94
	MALE	35-35	X10E9/L	8.59	16.17	1	X10E9/L	8.59	16.17
	MALE	44-44	X10E9/L	9.57	18.02	1	X10E9/L	9.57	18.02
EOSINOPHILS	BOTH	18-18	%	0.0	4.8	1	%	0.00	4.80
	BOTH	19-63	%	0.0	6.0	1	%	0.00	6.00
EOSINOPHILS(CALC)	MALE	39-39	X10E9/L	0	0.07	1	X10E9/L	0.00	0.07
	MALE	24-24	X10E9/L	0	0.16	1	X10E9/L	0.00	0.16
	BOTH	39-60	X10E9/L	0	0.19	1	X10E9/L	0.00	0.19
	BOTH	25-34	X10E9/L	0	0.2	1	X10E9/L	0.00	0.20
	BOTH	35-52	X10E9/L	0	0.21	1	X10E9/L	0.00	0.21
	BOTH	22-52	X10E9/L	0	0.22	1	X10E9/L	0.00	0.22
	BOTH	26-52	X10E9/L	0	0.23	1	X10E9/L	0.00	0.23
	BOTH	20-57	X10E9/L	0	0.24	1	X10E9/L	0.00	0.24
	BOTH	20-49	X10E9/L	0	0.25	1	X10E9/L	0.00	0.25
	BOTH	19-56	X10E9/L	0	0.26	1	X10E9/L	0.00	0.26
	BOTH	28-58	X10E9/L	0	0.27	1	X10E9/L	0.00	0.27
	BOTH	22-62	X10E9/L	0	0.28	1	X10E9/L	0.00	0.28
	BOTH	25-62	X10E9/L	0	0.29	1	X10E9/L	0.00	0.29
	BOTH	18-55	X10E9/L	0	0.3	1	X10E9/L	0.00	0.30
	BOTH	18-58	X10E9/L	0	0.31	1	X10E9/L	0.00	0.31
	BOTH	18-63	X10E9/L	0	0.32	1	X10E9/L	0.00	0.32
	BOTH	18-57	X10E9/L	0	0.33	1	X10E9/L	0.00	0.33
	BOTH	18-59	X10E9/L	0	0.34	1	X10E9/L	0.00	0.34
	BOTH	20-55	X10E9/L	0	0.35	1	X10E9/L	0.00	0.35
	BOTH	18-59	X10E9/L	0	0.36	1	X10E9/L	0.00	0.36
	BOTH	19-54	X10E9/L	0	0.37	1	X10E9/L	0.00	0.37
	BOTH	25-55	X10E9/L	0	0.38	1	X10E9/L	0.00	0.38
	BOTH	18-40	X10E9/L	0	0.39	1	X10E9/L	0.00	0.39
	BOTH	18-60	X10E9/L	0	0.4	1	X10E9/L	0.00	0.40

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
EOSINOPHILS(CALC)	BOTH	20-59	X10E9/L	0	0.41	1	X10E9/L	0.00	0.41
	BOTH	18-55	X10E9/L	0	0.42	1	X10E9/L	0.00	0.42
	BOTH	19-58	X10E9/L	0	0.43	1	X10E9/L	0.00	0.43
	BOTH	18-63	X10E9/L	0	0.44	1	X10E9/L	0.00	0.44
	BOTH	20-59	X10E9/L	0	0.45	1	X10E9/L	0.00	0.45
	BOTH	19-63	X10E9/L	0	0.46	1	X10E9/L	0.00	0.46
	BOTH	20-54	X10E9/L	0	0.47	1	X10E9/L	0.00	0.47
	BOTH	24-40	X10E9/L	0	0.48	1	X10E9/L	0.00	0.48
	BOTH	20-58	X10E9/L	0	0.49	1	X10E9/L	0.00	0.49
	BOTH	19-50	X10E9/L	0	0.5	1	X10E9/L	0.00	0.50
	BOTH	22-57	X10E9/L	0	0.51	1	X10E9/L	0.00	0.51
	BOTH	20-58	X10E9/L	0	0.52	1	X10E9/L	0.00	0.52
	BOTH	18-60	X10E9/L	0	0.53	1	X10E9/L	0.00	0.53
	BOTH	24-42	X10E9/L	0	0.54	1	X10E9/L	0.00	0.54
	BOTH	21-62	X10E9/L	0	0.55	1	X10E9/L	0.00	0.55
	BOTH	19-59	X10E9/L	0	0.56	1	X10E9/L	0.00	0.56
	BOTH	21-60	X10E9/L	0	0.57	1	X10E9/L	0.00	0.57
	BOTH	23-40	X10E9/L	0	0.58	1	X10E9/L	0.00	0.58
	BOTH	26-53	X10E9/L	0	0.59	1	X10E9/L	0.00	0.59
	BOTH	20-54	X10E9/L	0	0.6	1	X10E9/L	0.00	0.60
	BOTH	22-54	X10E9/L	0	0.61	1	X10E9/L	0.00	0.61
	BOTH	21-40	X10E9/L	0	0.62	1	X10E9/L	0.00	0.62
	BOTH	25-62	X10E9/L	0	0.63	1	X10E9/L	0.00	0.63
	BOTH	20-46	X10E9/L	0	0.64	1	X10E9/L	0.00	0.64
	BOTH	20-46	X10E9/L	0	0.65	1	X10E9/L	0.00	0.65
	BOTH	21-45	X10E9/L	0	0.66	1	X10E9/L	0.00	0.66
	BOTH	34-56	X10E9/L	0	0.67	1	X10E9/L	0.00	0.67
	BOTH	19-43	X10E9/L	0	0.68	1	X10E9/L	0.00	0.68
	BOTH	21-35	X10E9/L	0	0.69	1	X10E9/L	0.00	0.69
	BOTH	21-46	X10E9/L	0	0.7	1	X10E9/L	0.00	0.70
	BOTH	24-25	X10E9/L	0	0.71	1	X10E9/L	0.00	0.71
	BOTH	50-50	X10E9/L	0	0.72	1	X10E9/L	0.00	0.72
	BOTH	23-50	X10E9/L	0	0.73	1	X10E9/L	0.00	0.73
	BOTH	30-31	X10E9/L	0	0.74	1	X10E9/L	0.00	0.74
	MALE	43-43	X10E9/L	0	0.75	1	X10E9/L	0.00	0.75
	MALE	43-43	X10E9/L	0	0.76	1	X10E9/L	0.00	0.76
	BOTH	42-42	X10E9/L	0	0.77	1	X10E9/L	0.00	0.77
	BOTH	52-52	X10E9/L	0	0.78	1	X10E9/L	0.00	0.78
	BOTH	20-23	X10E9/L	0	0.79	1	X10E9/L	0.00	0.79

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
EOSINOPHILS(CALC)	BOTH	40-40	X10E9/L	0	0.8	1	X10E9/L	0.00	0.80
	BOTH	32-32	X10E9/L	0	0.81	1	X10E9/L	0.00	0.81
	BOTH	35-35	X10E9/L	0	0.82	1	X10E9/L	0.00	0.82
	BOTH	26-26	X10E9/L	0	0.83	1	X10E9/L	0.00	0.83
	MALE	46-46	X10E9/L	0	0.84	1	X10E9/L	0.00	0.84
	MALE	44-44	X10E9/L	0	0.85	1	X10E9/L	0.00	0.85
	MALE	41-41	X10E9/L	0	0.88	1	X10E9/L	0.00	0.88
	BOTH	26-26	X10E9/L	0	0.89	1	X10E9/L	0.00	0.89
	BOTH	32-32	X10E9/L	0	0.9	1	X10E9/L	0.00	0.90
	BOTH	35-35	X10E9/L	0	0.92	1	X10E9/L	0.00	0.92
	MALE	31-53	X10E9/L	0	0.94	1	X10E9/L	0.00	0.94
	MALE	46-46	X10E9/L	0	1.04	1	X10E9/L	0.00	1.04
	MALE	44-44	X10E9/L	0	1.09	1	X10E9/L	0.00	1.09
	MALE	44-44	X10E9/L	0	1.16	1	X10E9/L	0.00	1.16
	MALE	35-35	X10E9/L	0	1.26	1	X10E9/L	0.00	1.26
	MALE	44-44	X10E9/L	0	1.4	1	X10E9/L	0.00	1.40
BASOPHILS	BOTH	25-25	%	0.0	1.7	1	%	0.00	1.70
	BOTH	18-63	%	0.0	2.4	1	%	0.00	2.40
LYMPHS	BOTH	25-25	%	14.7	42.6	1	%	14.70	42.60
	BOTH	18-63	%	15.5	46.6	1	%	15.50	46.60
MONOCYTES	BOTH	25-25	%	2.0	7.5	1	%	2.00	7.50
	BOTH	18-63	%	4.0	9.4	1	%	4.00	9.40

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

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Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

LAB TEST	WINDOWED VISIT	QUETIAPINE 300 MG N	MEAN	SD	MED	MIN	MAX	QUETIAPINE 600 MG N	MEAN	SD	MED	MIN	MAX	PLACEBO N	MEAN	SD	MED	MIN	MAX
HEMATOCRIT (VOL. FRACTION)	BSLN	155	0.43	0.04	0.4	0.3	0.5	139	0.43	0.04	0.4	0.3	0.5	149	0.42	0.04	0.4	0.3	0.6
	FINAL	155	0.42	0.03	0.4	0.3	0.5	139	0.42	0.04	0.4	0.3	0.5	149	0.41	0.05	0.4	0.2	0.5
	CHG FROM BSLN	155	-0.01	0.02	-0.0	-0.1	0.1	139	-0.01	0.02	-0.0	-0.1	0.1	149	-0.01	0.03	-0.0	-0.3	0.0
HEMOGLOBIN (G/DL)	BSLN	155	14.39	1.40	14.4	10.3	17.6	142	14.48	1.33	14.4	11.9	18.3	149	14.21	1.41	14.1	10.9	18.9
	FINAL	155	14.15	1.24	14.2	10.7	17.1	142	14.16	1.32	14.2	11.2	17.9	149	14.01	1.63	14.1	6.4	17.6
	CHG FROM BSLN	155	-0.24	0.78	-0.3	-2.6	4.1	142	-0.32	0.82	-0.3	-2.4	3.3	149	-0.20	1.08	-0.1	-9.8	1.8
TOTAL RBC COUNT (10**12/L)	BSLN	155	4.71	0.43	4.7	3.7	5.8	142	4.70	0.41	4.7	3.8	5.9	149	4.64	0.46	4.6	3.5	5.6
	FINAL	155	4.64	0.39	4.7	3.6	5.5	142	4.60	0.42	4.6	3.6	5.9	149	4.57	0.54	4.6	2.0	5.7
	CHG FROM BSLN	155	-0.08	0.25	-0.1	-0.9	0.9	142	-0.10	0.30	-0.1	-0.9	1.6	149	-0.07	0.37	0.0	-3.1	0.8
PLATELETS (10**9/L)	BSLN	154	260.13	66.55	254.0	103.0	571.0	138	261.19	62.53	256.0	117.0	497.0	146	258.25	63.11	253.0	93.0	498.0
	FINAL	154	255.46	64.97	249.0	87.0	465.0	138	254.42	55.93	252.5	146.0	429.0	146	254.05	67.65	244.0	24.0	442.0
	CHG FROM BSLN	154	-4.67	44.35	-5.0	-112.0	295.0	138	-6.77	41.62	-7.0	-194.0	105.0	146	-4.21	48.08	-3.0	-197.0	173.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
GENERATED: 12JUL2005 17:43:46 iceadmn3

Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
TOTAL WBC COUNT (10**9-/L)	BSLN	155	7.30	2.44	7.0	3.6	23.4	142	7.18	2.21	6.8	3.1	14.7	149	7.06	2.33	6.6	2.7	15.6
	FINAL	155	7.02	2.39	6.5	3.3	18.2	142	6.65	2.10	6.3	3.4	15.4	149	6.73	2.23	6.3	1.2	13.9
	CHG FROM BSLN	155	-0.28	1.59	-0.2	-5.2	6.6	142	-0.53	1.90	-0.5	-7.2	5.1	149	-0.33	1.82	-0.3	-7.1	5.9
NEUTROPHILS (%)	BSLN	155	60.93	8.74	60.9	19.0	80.0	142	61.01	9.26	61.0	27.3	90.2	149	60.01	9.49	60.9	32.9	80.0
	FINAL	155	60.67	9.49	60.8	19.0	85.7	142	59.82	8.89	60.3	25.0	80.5	149	60.20	9.16	60.8	33.0	86.4
	CHG FROM BSLN	155	-0.26	9.06	-0.4	-40.1	36.2	142	-1.19	9.30	-1.3	-25.9	29.8	149	0.20	8.66	0.0	-20.7	26.8
NEUTROPHILS (10**9-/L) AGRAN	BSLN	155	4.48	1.70	4.1	1.8	10.6	142	4.49	1.87	4.1	1.4	10.1	149	4.32	1.78	4.0	1.1	11.0
	FINAL	155	4.34	1.87	4.0	0.8	11.4	142	4.06	1.73	3.7	1.2	12.4	149	4.14	1.75	4.0	1.0	9.9
	CHG FROM BSLN	155	-0.15	1.46	-0.1	-4.0	8.0	142	-0.43	1.79	-0.4	-6.3	4.9	149	-0.18	1.49	-0.2	-5.1	4.3
EOSINOPHILS (%)	BSLN	155	2.46	1.71	2.0	0.0	8.1	142	2.41	1.53	2.2	0.2	10.6	149	2.57	1.91	2.1	0.1	10.8
	FINAL	155	2.70	2.10	2.2	0.1	16.0	142	2.66	2.03	2.3	0.0	12.9	149	2.41	1.66	2.0	0.2	9.5
	CHG FROM BSLN	155	0.24	1.92	0.2	-6.3	11.7	142	0.25	1.52	0.2	-4.1	5.6	149	-0.16	1.53	-0.1	-6.0	5.3

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
GENERATED: 12JUL2005 17:43:46 iceadmn3

Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

LAB TEST	WINDOWED VISIT	QUETIAPINE 300 MG N	MEAN	SD	MED	MIN	MAX	QUETIAPINE 600 MG N	MEAN	SD	MED	MIN	MAX	PLACEBO N	MEAN	SD	MED	MIN	MAX
EOSINOPHILS (10**9/L)	BSLN	155	0.18	0.13	0.1	0.0	0.9	142	0.16	0.11	0.2	0.0	0.7	149	0.18	0.16	0.1	0.0	1.1
	FINAL	155	0.18	0.13	0.2	0.0	0.9	142	0.17	0.14	0.2	0.0	1.1	149	0.16	0.11	0.1	0.0	0.6
	CHG FROM BSLN	155	0.00	0.12	0.0	-0.5	0.7	142	0.00	0.10	0.0	-0.3	0.4	149	-0.02	0.13	-0.0	-0.6	0.3
BASOPHILS (%)	BSLN	155	0.35	0.27	0.3	0.0	2.0	142	0.38	0.27	0.3	0.0	1.9	149	0.35	0.24	0.3	0.0	2.0
	FINAL	155	0.36	0.22	0.3	0.0	1.6	142	0.35	0.23	0.3	0.0	2.0	149	0.35	0.22	0.3	0.0	1.3
	CHG FROM BSLN	155	0.01	0.33	0.0	-1.5	1.5	142	-0.03	0.36	0.0	-1.7	1.9	149	0.00	0.31	0.0	-1.8	1.1
BASOPHILS (10**9/L)	BSLN	155	0.02	0.02	0.0	0.0	0.2	142	0.03	0.03	0.0	0.0	0.2	149	0.02	0.02	0.0	0.0	0.2
	FINAL	155	0.02	0.01	0.0	0.0	0.1	142	0.02	0.02	0.0	0.0	0.1	149	0.02	0.01	0.0	0.0	0.1
	CHG FROM BSLN	155	-0.00	0.02	0.0	-0.2	0.1	142	-0.00	0.03	0.0	-0.2	0.1	149	-0.00	0.02	0.0	-0.2	0.1
LYMPHOCYTES (%)	BSLN	155	30.41	8.42	29.3	13.7	79.0	142	30.09	8.07	29.5	9.0	59.1	149	30.84	9.01	30.1	12.0	58.3
	FINAL	155	30.27	8.42	29.7	10.8	77.9	142	30.78	7.90	30.2	14.1	64.0	149	30.63	8.63	29.5	10.0	54.4
	CHG FROM BSLN	155	-0.13	7.87	-0.3	-25.5	25.2	142	0.68	7.74	0.4	-24.8	25.9	149	-0.21	7.34	0.0	-23.2	19.8

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
GENERATED: 12JUL2005 17:43:46 iceadmn3

Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
LYMPHOCYTES (10**9/L)	BSLN	155	2.20	1.44	2.1	0.8	18.5	142	2.07	0.60	2.1	0.9	4.3	149	2.11	0.80	2.0	0.7	5.6
	FINAL	155	2.07	1.14	1.9	1.0	14.2	142	1.99	0.60	1.9	0.8	3.9	149	2.00	0.71	1.9	0.1	5.4
	CHG FROM BSLN	155	-0.13	0.59	-0.1	-4.3	1.6	142	-0.09	0.45	-0.1	-1.0	1.5	149	-0.11	0.58	-0.1	-2.2	2.2
MONOCYTES (%)	BSLN	155	5.79	2.14	5.8	0.1	11.3	142	6.11	2.15	5.9	0.2	12.2	149	6.17	2.13	6.0	0.6	12.5
	FINAL	155	5.99	2.00	5.8	0.1	13.0	142	6.36	2.39	6.1	0.4	15.7	149	6.35	2.31	6.1	0.0	13.0
	CHG FROM BSLN	155	0.20	1.96	0.2	-5.5	5.1	142	0.25	2.22	0.1	-5.4	10.3	149	0.18	2.04	0.1	-6.9	7.9
MONOCYTES (10**9/L)	BSLN	155	0.41	0.16	0.4	0.0	0.9	142	0.42	0.16	0.4	0.0	1.1	149	0.42	0.17	0.4	0.1	1.0
	FINAL	155	0.40	0.15	0.4	0.0	0.8	142	0.41	0.16	0.4	0.0	0.9	149	0.41	0.18	0.4	0.0	1.2
	CHG FROM BSLN	155	-0.00	0.14	-0.0	-0.3	0.6	142	-0.01	0.15	-0.0	-0.8	0.4	149	-0.01	0.15	-0.0	-0.5	0.5

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA201.SAS
GENERATED: 12JUL2005 17:43:46 iceadmn3

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
HEMATOCRIT	BASELINE												
	LOW	10	6	4	0	4	2	2	0	10	6	4	0
	NORMAL	145	3	141	1	134	5	127	2	136	7	129	0
	HIGH	0	0	0	0	1	0	1	0	3	0	3	0
HEMOGLOBIN	LOW	5	4	1	0	1	1	0	0	8	6	2	0
	NORMAL	149	2	147	0	139	4	135	0	139	6	132	1
	HIGH	1	0	1	0	2	0	1	1	2	0	2	0
TOTAL RBC COUNT	LOW	3	0	3	0	0	0	0	0	6	4	2	0
	NORMAL	152	1	151	0	142	2	140	0	143	7	136	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
PLATELETS	LOW	3	1	2	0	2	0	2	0	3	3	0	0
	NORMAL	149	1	146	2	135	0	135	0	142	1	141	0
	HIGH	2	0	0	2	1	0	1	0	1	0	1	0
TOTAL WBC COUNT	LOW	1	1	0	0	5	0	5	0	9	7	2	0
	NORMAL	150	7	140	3	133	3	128	2	138	9	128	1
	HIGH	4	0	1	3	4	0	1	3	2	0	2	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA202.SAS
GENERATED: 12JUL2005 17:43:53 iceadmn3

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
NEUTROPHILS (%)	BASELINE												
	LOW	3	2	1	0	3	1	2	0	5	0	5	0
	NORMAL	148	1	142	5	133	1	130	2	141	5	135	1
	HIGH	4	0	1	3	6	0	6	0	3	0	3	0
NEUTROPHILS (10**9/L) AGRAN	LOW	3	1	2	0	3	1	2	0	5	0	5	0
	NORMAL	148	1	142	5	133	1	130	2	141	5	135	1
	HIGH	4	0	1	3	6	0	6	0	3	0	3	0
EOSINOPHILS (%)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	147	0	144	3	139	0	135	4	140	0	137	3
	HIGH	8	0	6	2	3	0	1	2	9	0	6	3
EOSINOPHILS (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	147	0	144	3	139	0	135	4	141	0	138	3
	HIGH	8	0	6	2	3	0	1	2	8	0	6	2
BASOPHILS (%)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA202.SAS
GENERATED: 12JUL2005 17:43:53 iceadmn3

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
BASOPHILS (10**9/L)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHOCYTES (%)	LOW	3	2	1	0	5	0	5	0	2	0	2	0
	NORMAL	148	6	141	1	132	3	128	1	136	3	129	4
	HIGH	4	0	2	2	5	0	3	2	11	0	8	3
LYMPHOCYTES (10**9/L)	LOW	3	2	1	0	5	0	5	0	2	0	2	0
	NORMAL	148	6	141	1	132	3	128	1	136	3	129	4
	HIGH	4	0	2	2	5	0	3	2	11	0	8	3
MONOCYTES (%)	LOW	32	13	19	0	19	7	12	0	17	5	11	1
	NORMAL	115	9	98	8	113	10	95	8	124	10	103	11
	HIGH	8	0	6	2	10	0	5	5	8	0	4	4
MONOCYTES (10**9/L)	LOW	32	13	19	0	18	7	11	0	17	5	11	1
	NORMAL	115	9	98	8	114	10	96	8	124	10	103	11
	HIGH	8	0	6	2	10	0	5	5	8	0	4	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA202.SAS
GENERATED: 12JUL2005 17:43:53 iceadmn3

Table 11.3.7.1.1.3.2 Hematology Findings Exceeding Laboratory Norms
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
HEMATOCRIT	3/145 (2.1%)	5/135 (3.7%)	7/139 (5.0%)	1/155 (0.6%)	2/138 (1.4%)	0/146 (0.0%)
HEMOGLOBIN	2/150 (1.3%)	4/141 (2.8%)	6/141 (4.3%)	0/154 (0.0%)	0/140 (0.0%)	1/147 (0.7%)
RBC	1/152 (0.7%)	2/142 (1.4%)	7/143 (4.9%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
PLATELET COUNT	1/151 (0.7%)	0/136 (0.0%)	1/143 (0.7%)	2/152 (1.3%)	0/137 (0.0%)	0/145 (0.0%)
WBC	7/154 (4.5%)	3/137 (2.2%)	9/140 (6.4%)	3/151 (2.0%)	2/138 (1.4%)	1/147 (0.7%)
NEUTROPHILS	1/152 (0.7%)	1/139 (0.7%)	5/144 (3.5%)	5/151 (3.3%)	2/136 (1.5%)	1/146 (0.7%)
NEUTROPHILS(CALC) AGRAN	1/152 (0.7%)	1/139 (0.7%)	5/144 (3.5%)	5/151 (3.3%)	2/136 (1.5%)	1/146 (0.7%)
EOSINOPHILS	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	3/147 (2.0%)	4/139 (2.9%)	3/140 (2.1%)
EOSINOPHILS(CALC)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	3/147 (2.0%)	4/139 (2.9%)	3/141 (2.1%)
BASOPHILS	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
BASOPHILS(CALC)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
LYMPHS	6/152 (3.9%)	3/137 (2.2%)	3/147 (2.0%)	1/151 (0.7%)	1/137 (0.7%)	4/138 (2.9%)
LYMPHS(CALC)	6/152 (3.9%)	3/137 (2.2%)	3/147 (2.0%)	1/151 (0.7%)	1/137 (0.7%)	4/138 (2.9%)
MONOCYTES	9/123 (7.3%)	10/123 (8.1%)	10/132 (7.6%)	8/147 (5.4%)	8/132 (6.1%)	12/141 (8.5%)
MONOCYTES(CALC)	9/123 (7.3%)	10/124 (8.1%)	10/132 (7.6%)	8/147 (5.4%)	8/132 (6.1%)	12/141 (8.5%)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA205.SAS
GENERATED: 12JUL2005 17:44:04 iceadmn3

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
HEMATOCRIT	BASELINE												
	LOW	2	1	1	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	153	1	152	0	139	0	139	0	147	4	143	0
	HIGH	0	0	0	0	0	0	0	0	1	0	1	0
HEMOGLOBIN	LOW	2	1	1	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	153	1	152	0	142	0	142	0	148	3	145	0
	HIGH	0	0	0	0	0	0	0	0	1	0	1	0
TOTAL RBC COUNT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	142	0	149	1	148	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
PLATELETS	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	154	1	153	0	138	0	138	0	145	2	143	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA203.SAS
GENERATED: 12JUL2005 17:43:57 iceadmn3

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL WBC COUNT	BASELINE												
	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	154	0	154	0	142	0	142	0	148	1	147	0
	HIGH	1	0	0	1	0	0	0	0	0	0	0	0
NEUTROPHILS (10**9/L) AGRAN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	153	0	151	2	141	0	140	1	147	0	147	0
	HIGH	2	0	0	2	1	0	0	1	2	0	2	0
NEUTROPHILS (10**9/L)	LOW	0	0	0	0	2	0	2	0	2	1	1	0
	NOT CLINICALLY IMPORTANT	153	1	150	2	139	1	137	1	145	2	143	0
	HIGH	2	0	0	2	1	0	0	1	2	0	2	0
EOSINOPHILS (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	141	1	147	0	147	0
	HIGH	0	0	0	0	0	0	0	0	2	0	2	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA203.SAS
GENERATED: 12JUL2005 17:43:57 iceadmn3

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
BASOPHILS (10**9/L)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHOCYTES (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	154	0	154	0	142	0	142	0	149	1	148	0
	HIGH	1	0	0	1	0	0	0	0	0	0	0	0
MONOCYTES (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	142	0	142	0	149	0	149	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA203.SAS
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Table 11.3.7.1.1.3.4 Potentially Clinically Important Hematology Findings
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
HEMATOCRIT	1/153 (0.7%)	0/139 (0.0%)	4/148 (2.7%)	0/155 (0.0%)	0/139 (0.0%)	0/148 (0.0%)
HEMOGLOBIN	1/153 (0.7%)	0/142 (0.0%)	3/149 (2.0%)	0/155 (0.0%)	0/142 (0.0%)	0/148 (0.0%)
RBC	0/155 (0.0%)	0/142 (0.0%)	1/149 (0.7%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
PLATELET COUNT	1/154 (0.6%)	0/138 (0.0%)	2/145 (1.4%)	0/154 (0.0%)	0/138 (0.0%)	0/146 (0.0%)
WBC	0/155 (0.0%)	0/142 (0.0%)	1/148 (0.7%)	0/154 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
NEUTROPHILS(CALC) AGRAN	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	2/153 (1.3%)	1/141 (0.7%)	0/147 (0.0%)
NEUTROPHILS(CALC)	1/155 (0.6%)	1/140 (0.7%)	2/147 (1.4%)	2/153 (1.3%)	1/141 (0.7%)	0/147 (0.0%)
EOSINOPHILS(CALC)	NA	NA	NA	0/155 (0.0%)	1/142 (0.7%)	0/147 (0.0%)
BASOPHILS(CALC)	NA	NA	NA	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
LYMPHS(CALC)	0/155 (0.0%)	0/142 (0.0%)	1/149 (0.7%)	0/154 (0.0%)	0/142 (0.0%)	0/149 (0.0%)
MONOCYTES(CALC)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)	0/155 (0.0%)	0/142 (0.0%)	0/149 (0.0%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA204.SAS
GENERATED: 12JUL2005 17:44:00 iceadmn3

FIGURE 11.3.7.1.1.4 1 SHIFT PLOT: ERYTHROCYTES - RBC (X10**12/L)

(SAFETY)

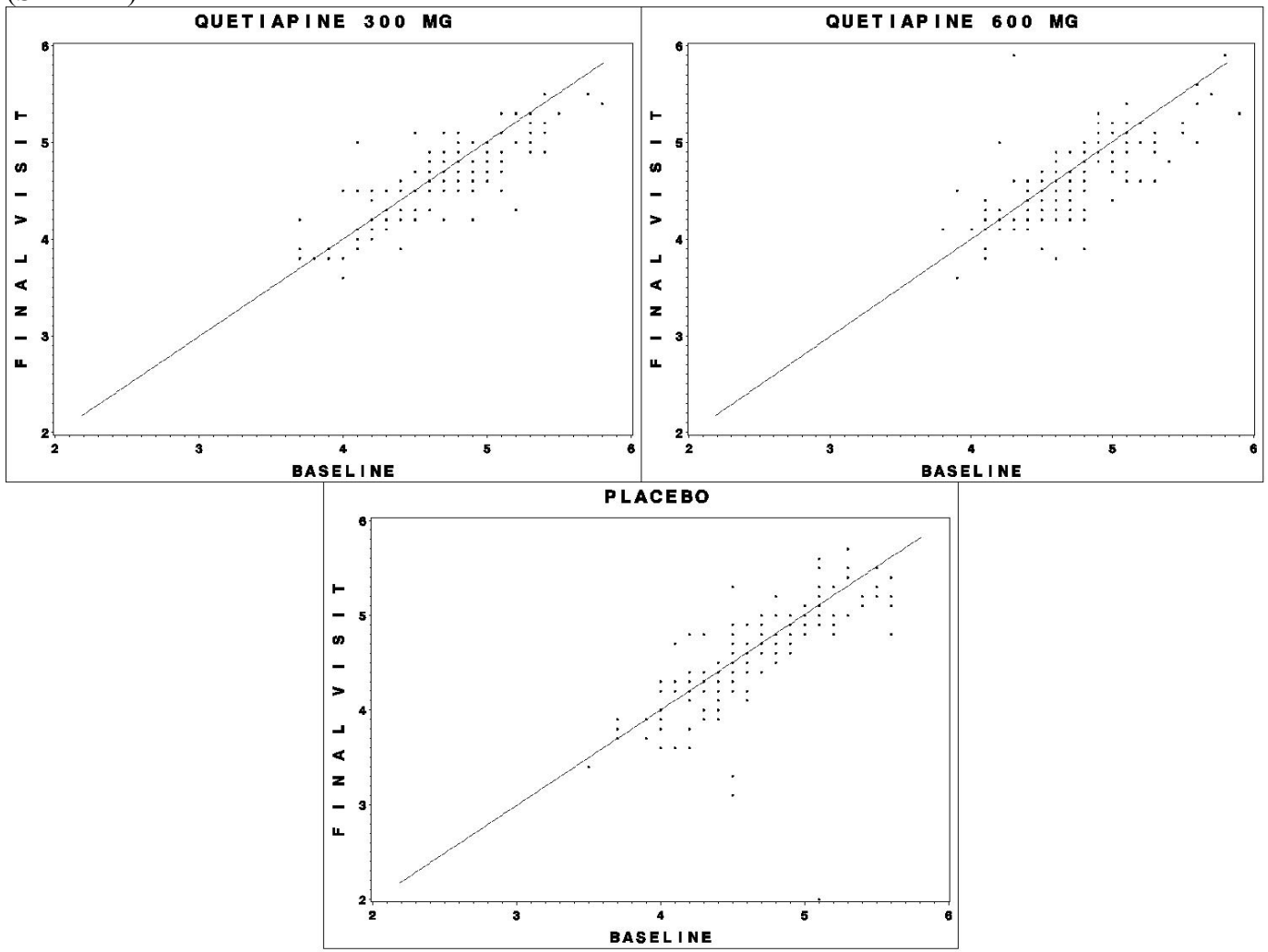

FIGURE 11.3.7.1.1.4.2 SHIFT PLOT: HEMATOCRIT - PCV (VOL FRACTION)

(SAFETY)

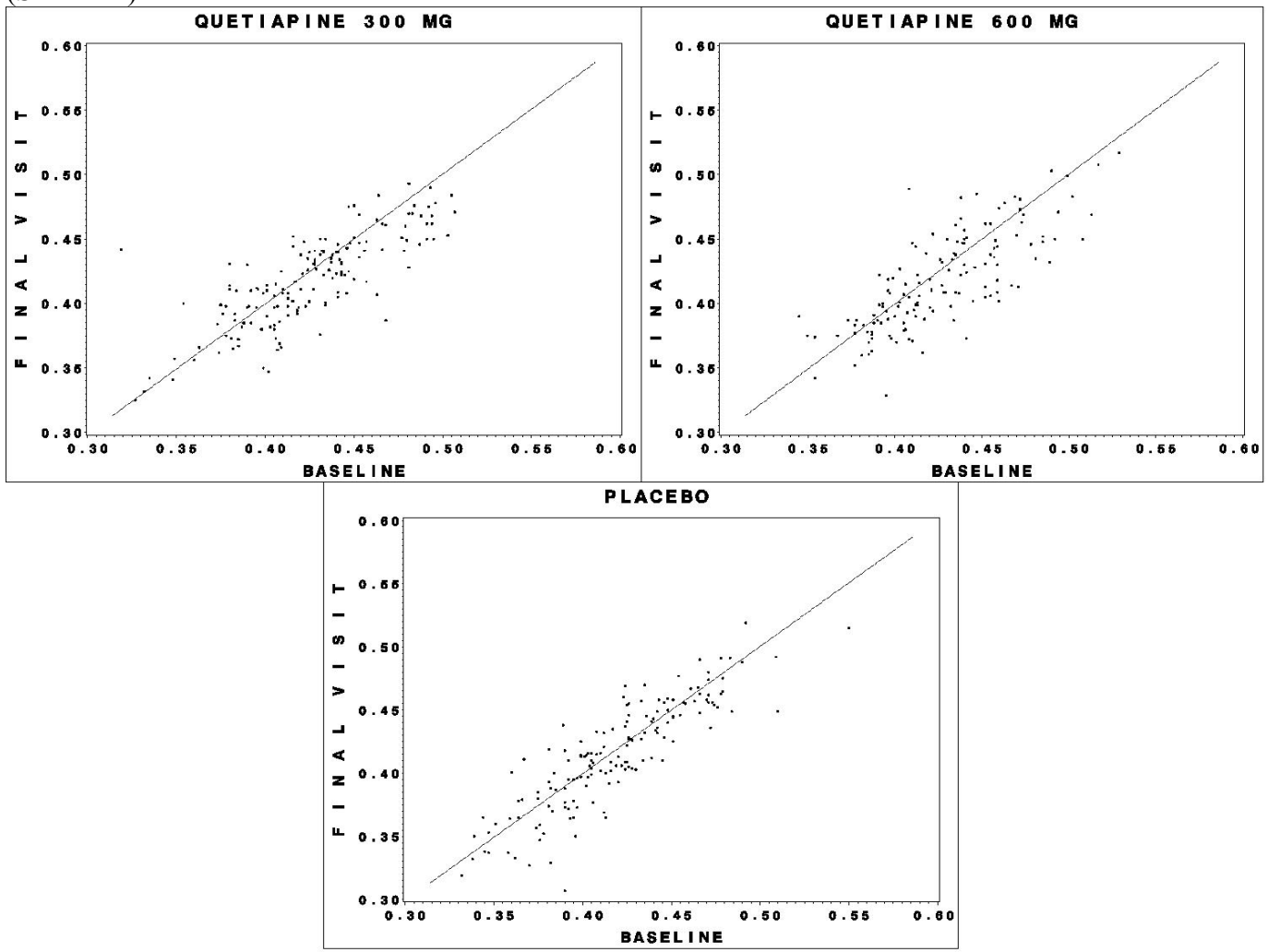

FIGURE 11.3.7.1.1.4.3 SHIFT PLOT: HEMOGLOBIN (G/DL)

(SAFETY)

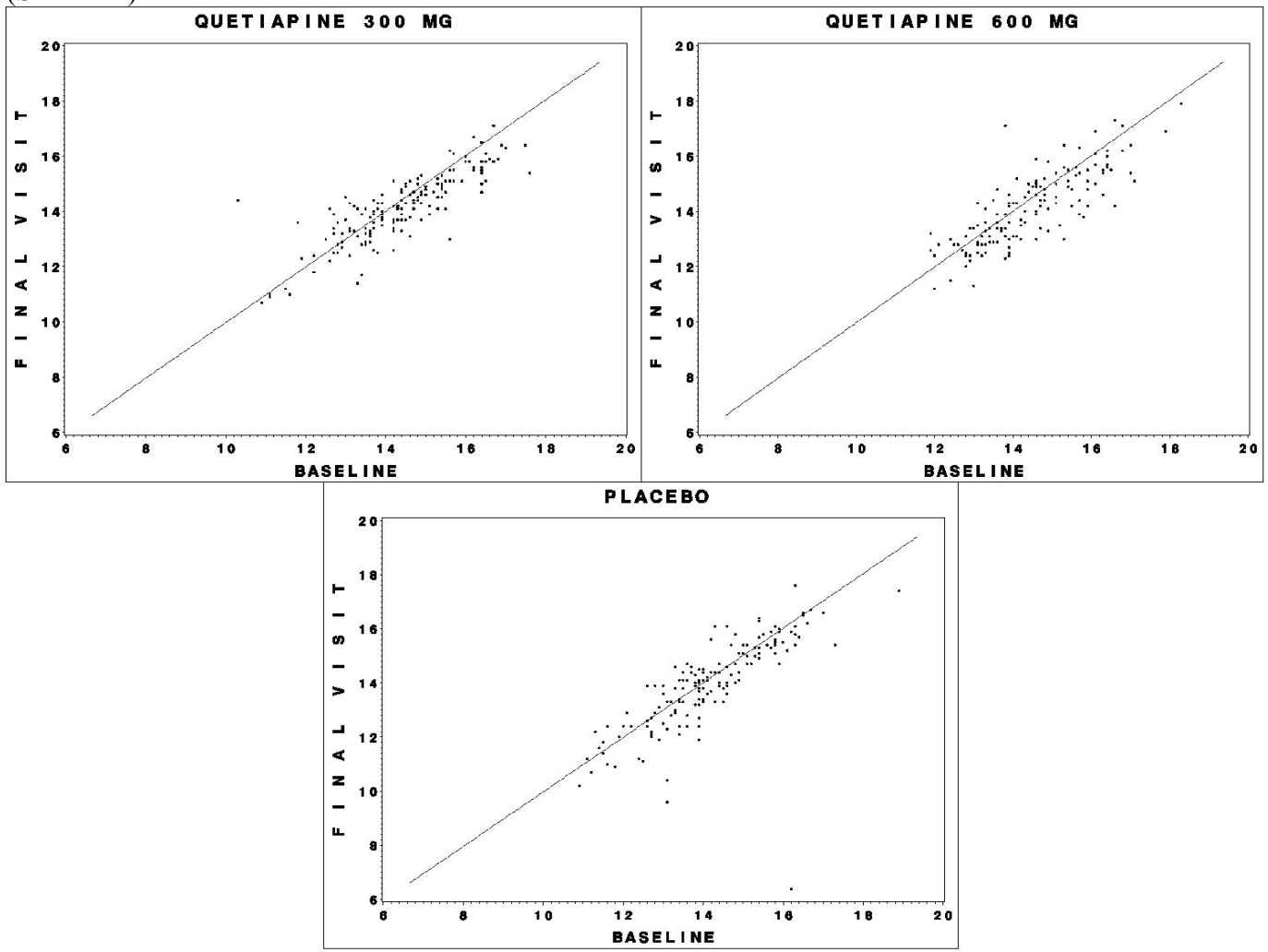

FIGURE 11.3.7.1.1.4.4 SHIFT PLOT: PLATELETS (X10**9/L)

(SAFETY)

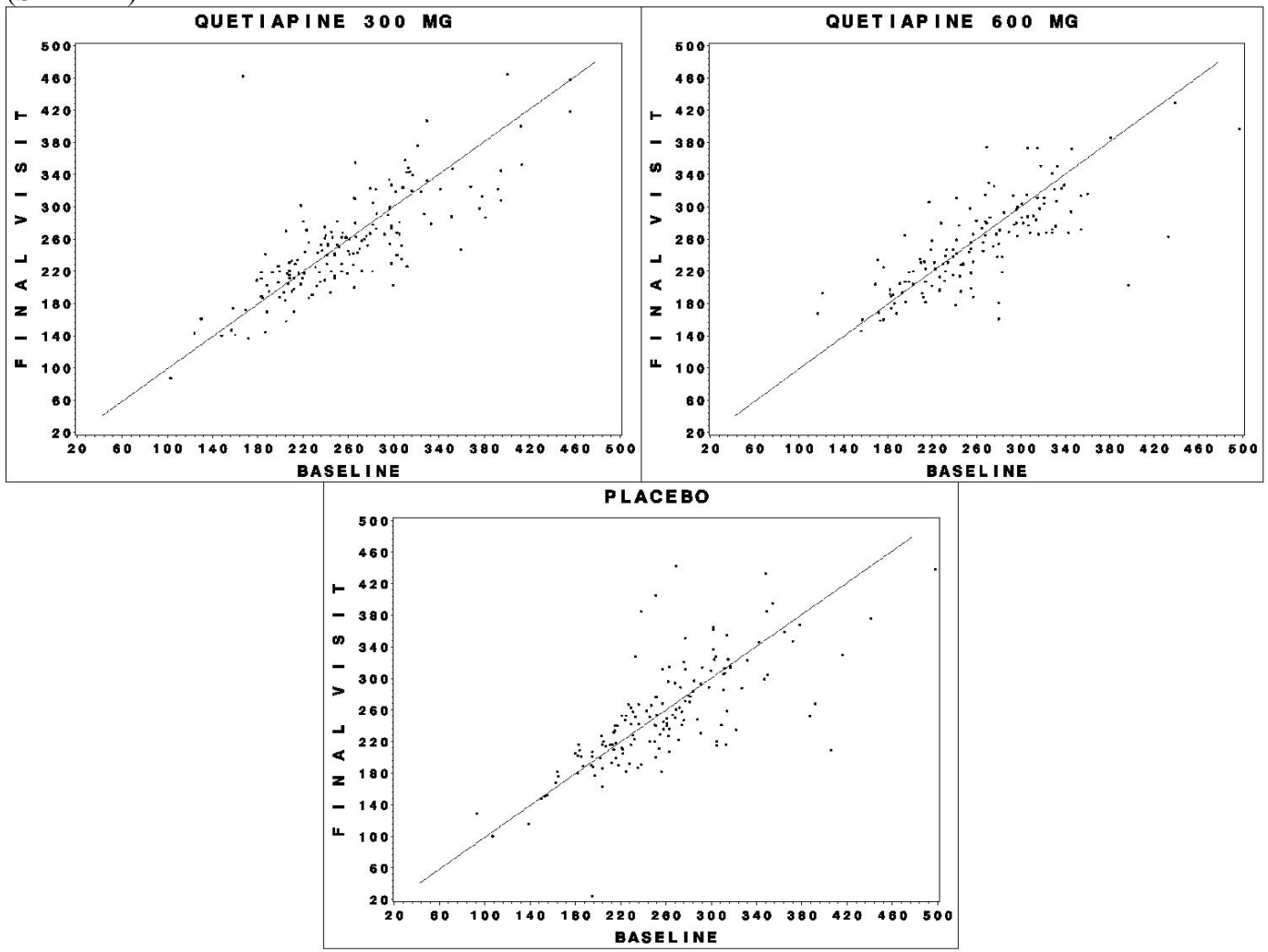

FIGURE 11.3.7.1.1.4.5 SHIFT PLOT: TOTAL WBC (X10**9/L)

(SAFETY)

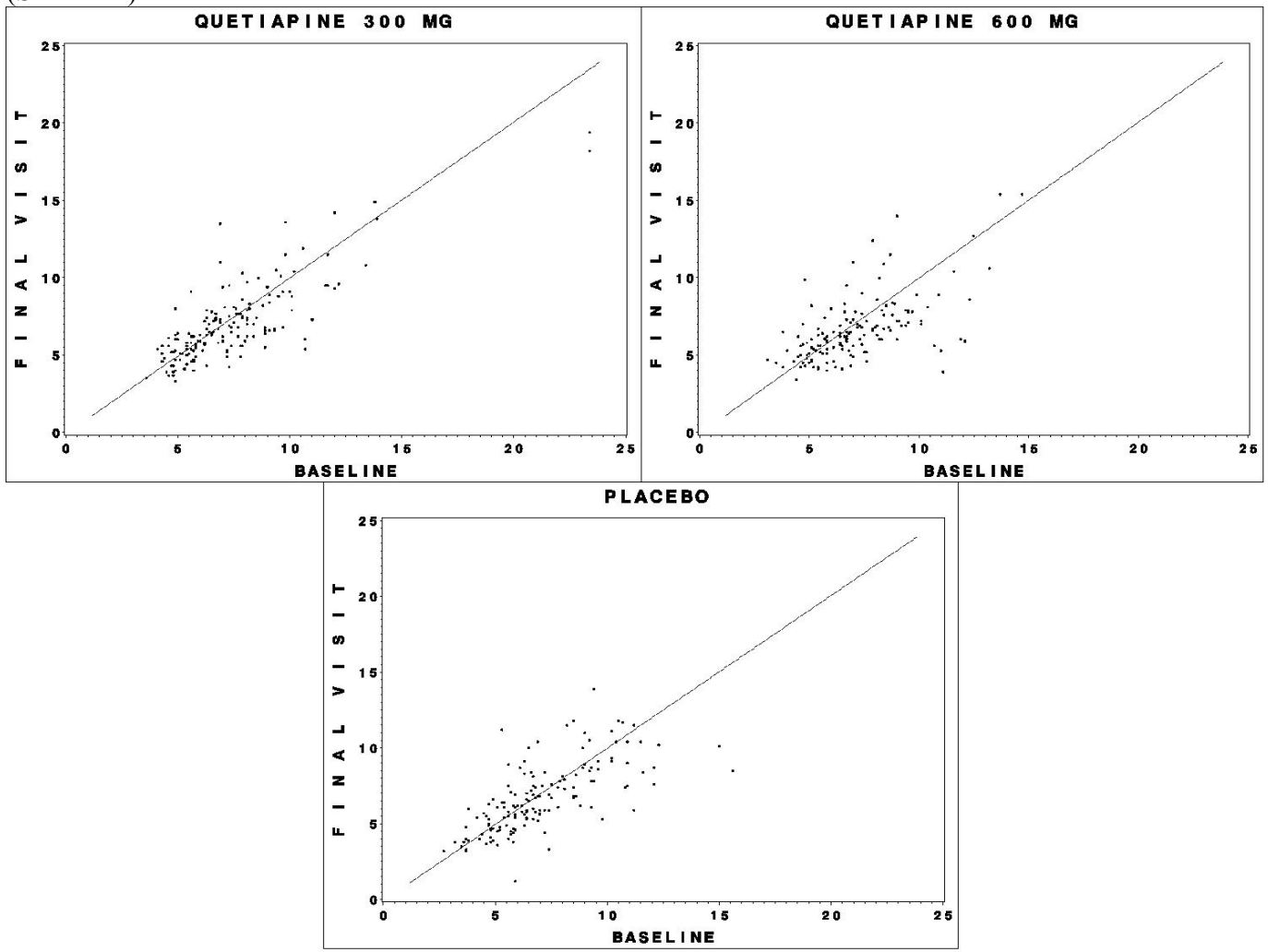

FIGURE 11.3.7.1.1.4.6 SHIFT PLOT: LYMPHOCYTES (%)

(SAFETY)

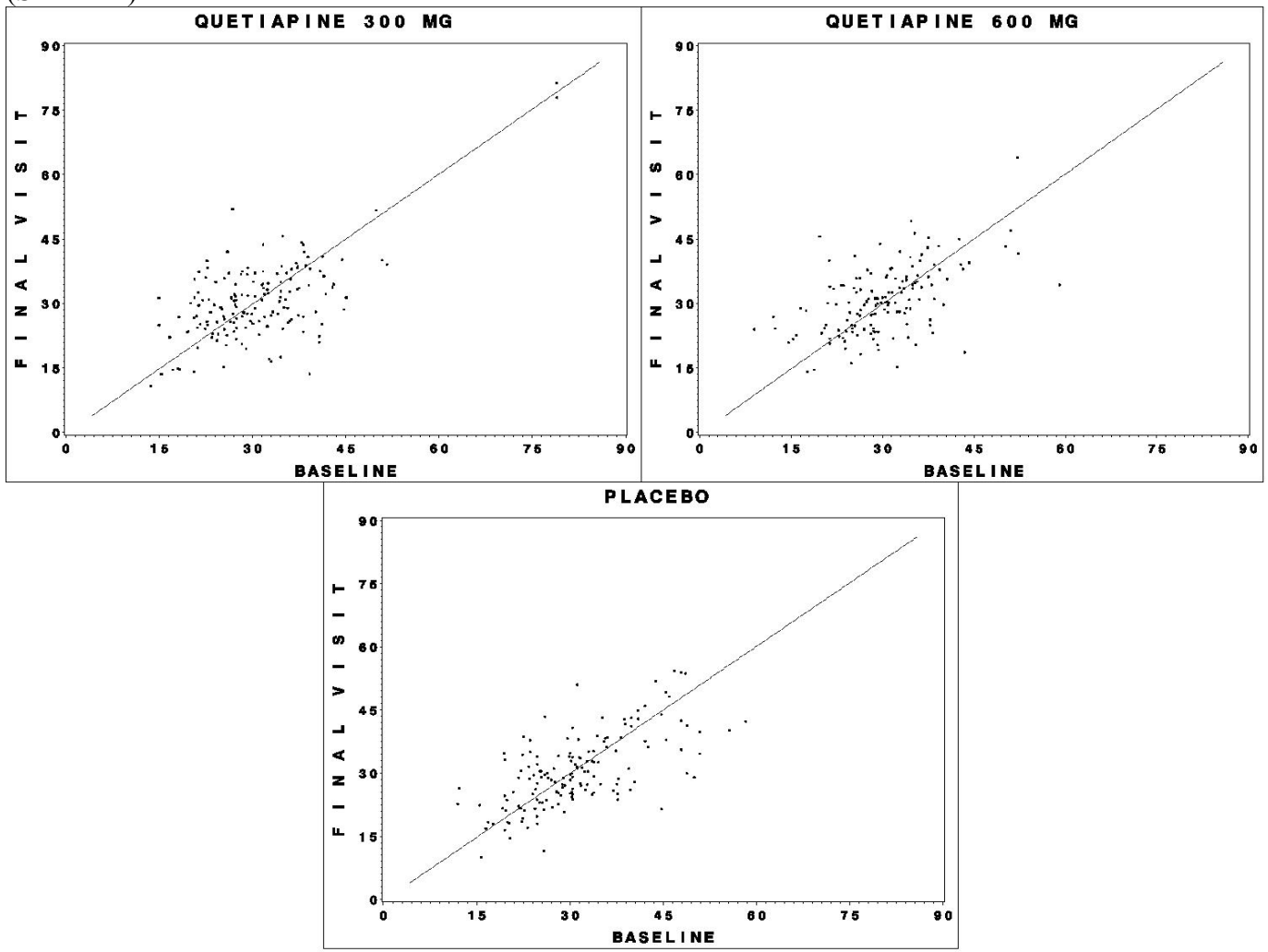

FIGURE 11.3.7.1.1.4.7 SHIFT PLOT: EOSINOPHILS (%)

(SAFETY)

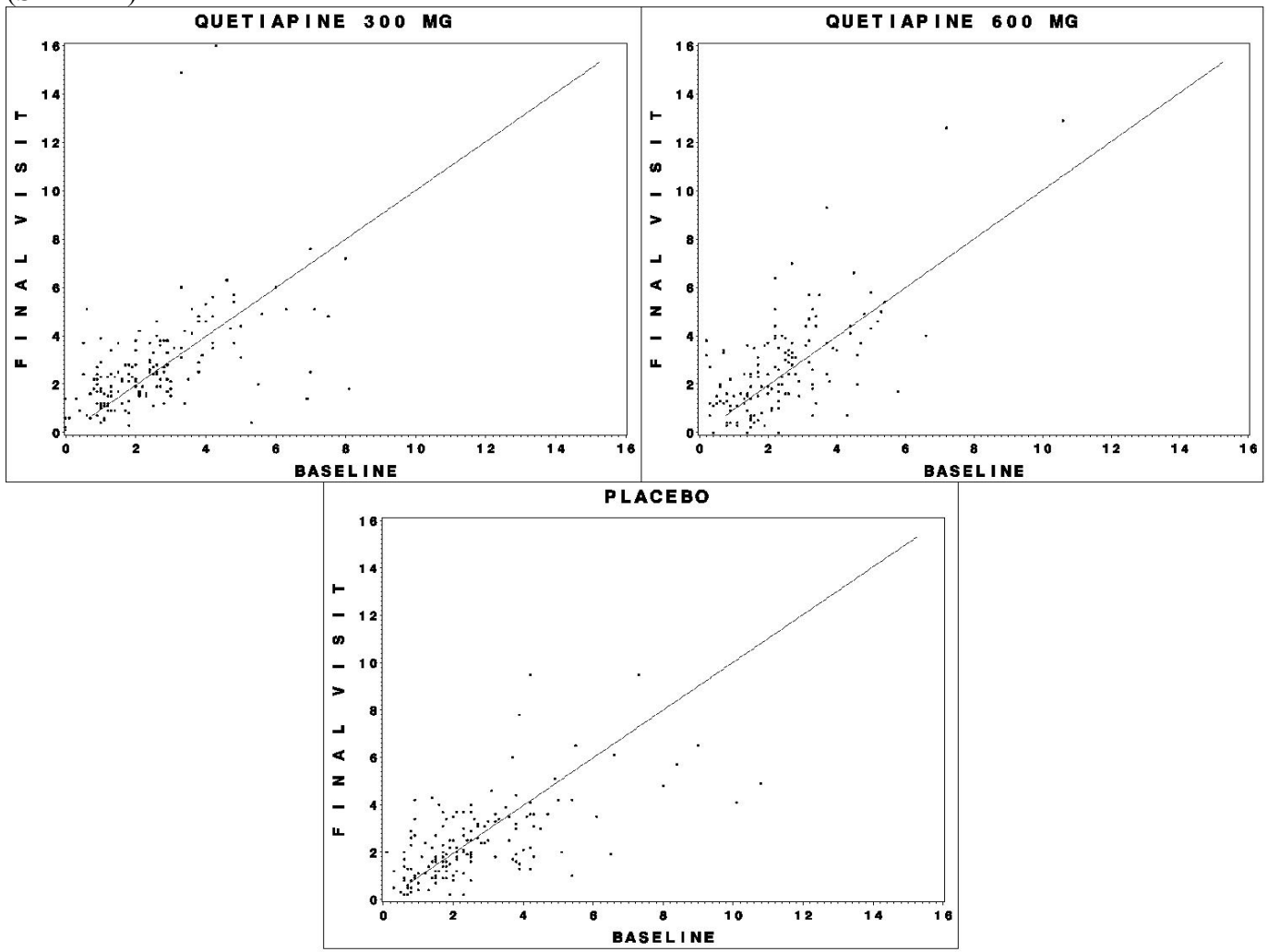

FIGURE 11.3.7.1.1.4.8 SHIFT PLOT: BASOPHILS (%)

(SAFETY)

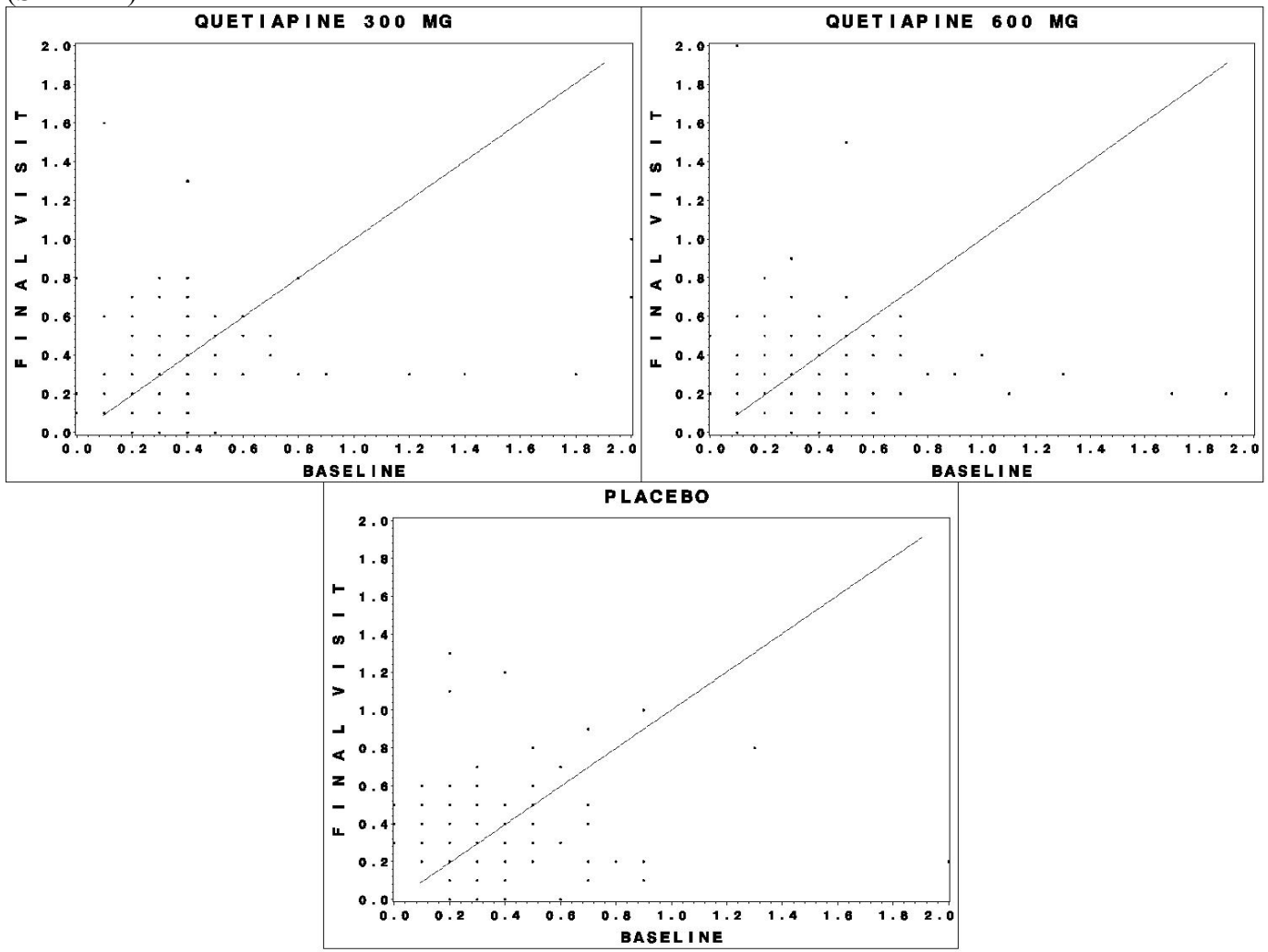

FIGURE 11.3.7.1.1.4.9 SHIFT PLOT: MONOCYTES (%)

(SAFETY)

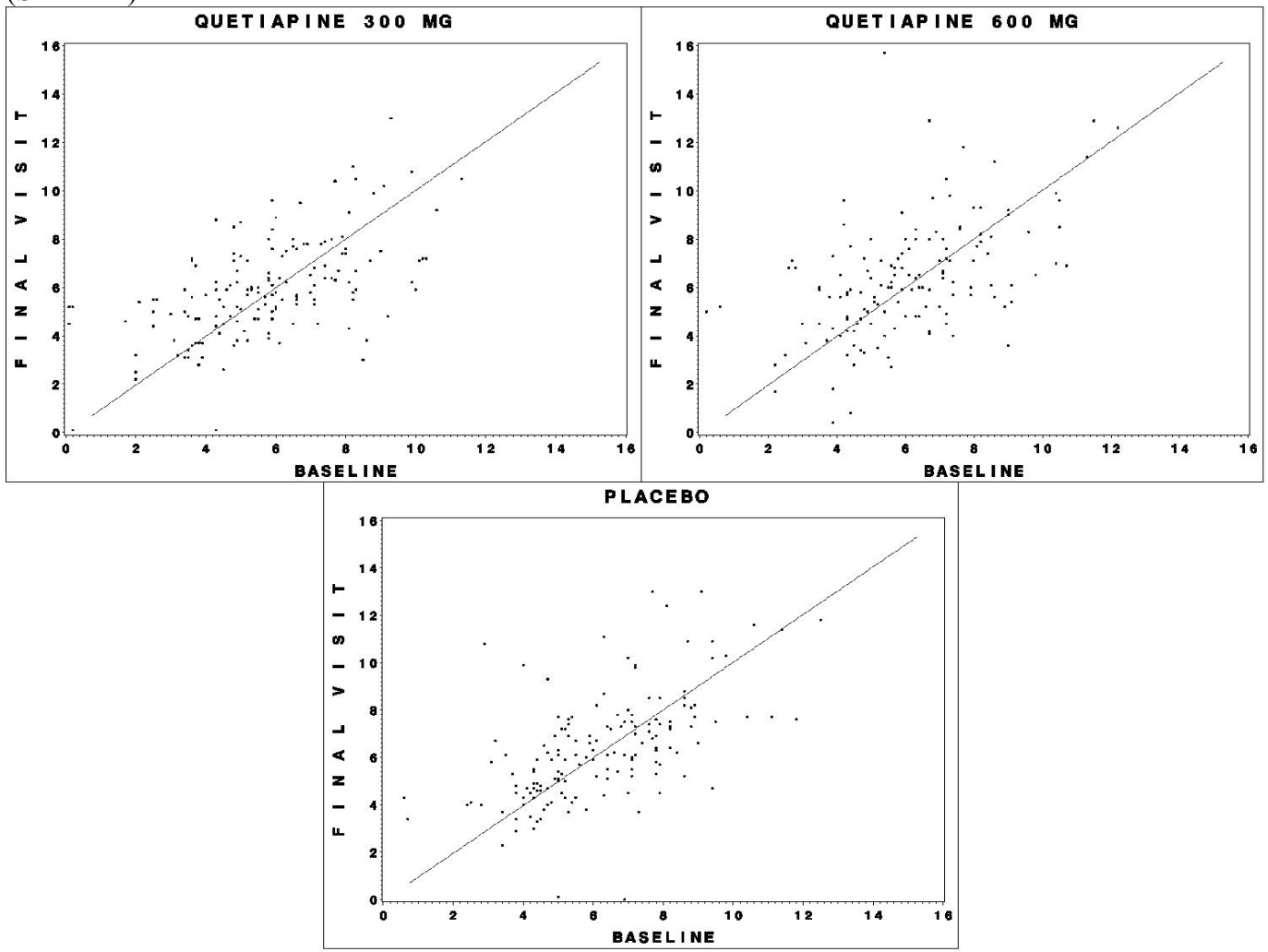

FIGURE 11.3.7.1.1.4.10 SHIFT PLOT: NEUTROPHILS (%)

(SAFETY)

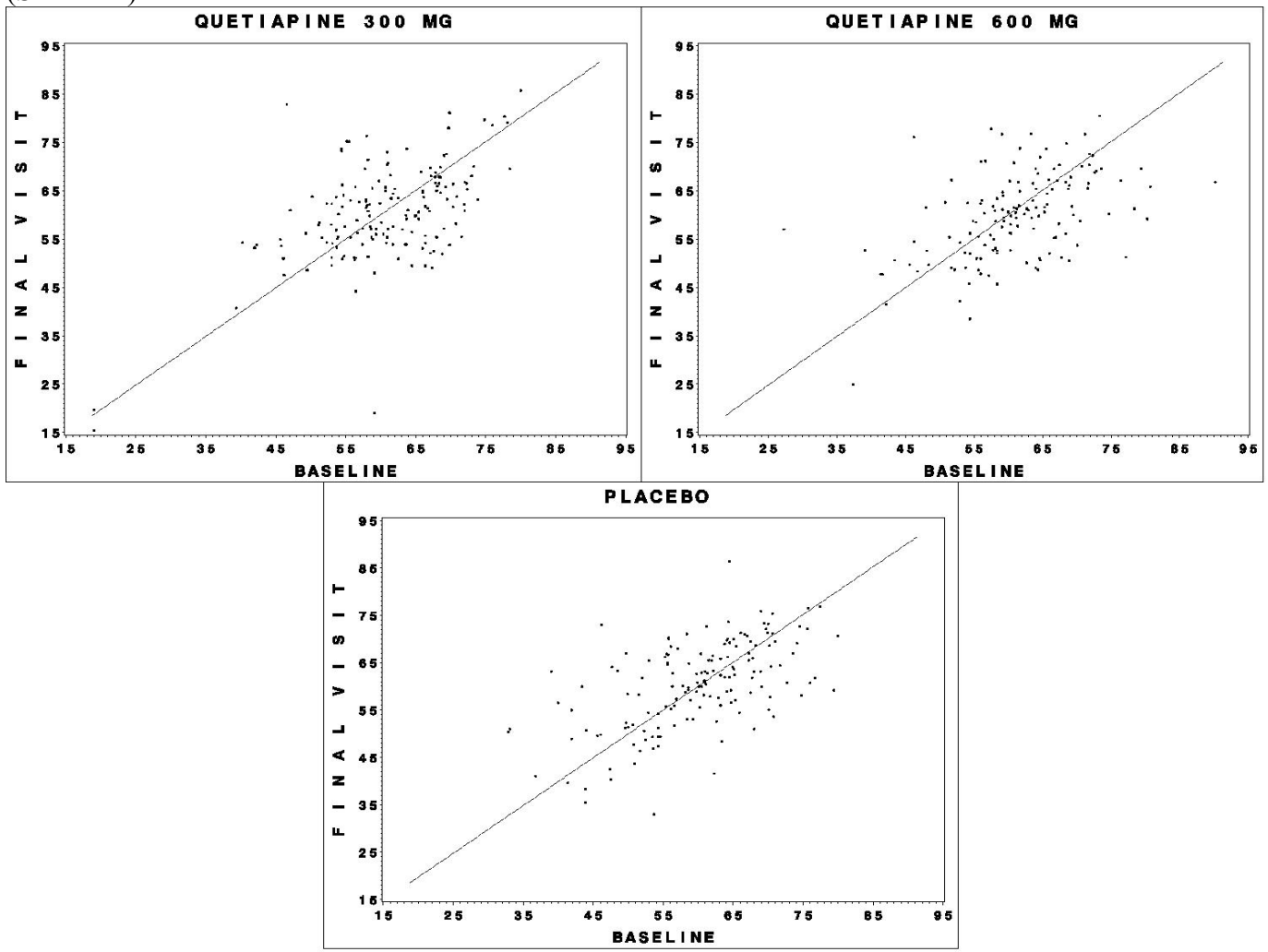

Table 11.3.7.1.2.1 Chemistry Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
RANDOM GLUCOSE	BOTH	18-65	MG/DL	68	118	1	MG/DL	68	118
AST (SGOT)	FEMALE	18-63	IU/L	10	36	1	U/L	10	36
	MALE	18-65	IU/L	10	45	1	U/L	10	45
ALT (SGPT)	FEMALE	18-63	IU/L	6	37	1	U/L	6	37
	MALE	18-65	IU/L	6	48	1	U/L	6	48
ALKALINE PHOSPHATASE	BOTH	18-65	IU/L	31	121	1	U/L	31	121
TOTAL BILIRUBIN	BOTH	18-65	MG/DL	0.2	1.2	1	MG/DL	0.2	1.2
CREATININE	FEMALE	18-63	MG/DL	0.4	1.2	1	MG/DL	0.4	1.2
	MALE	18-65	MG/DL	0.5	1.3	1	MG/DL	0.5	1.3
FASTING GLUCOSE	BOTH	18-65	MG/DL	68	118	1	MG/DL	68	118
INSULIN	BOTH	18-65	uIU/mL	3	16	6.945	PMOL/L	20.835	111.12
SODIUM	BOTH	18-65	MEQ/L	132	147	1	MMOL/L	132	147
POTASSIUM	BOTH	18-65	MEQ/L	3.3	5.5	1	MMOL/L	3.3	5.5
CHLORIDE	BOTH	18-65	MEQ/L	94	111	1	MMOL/L	94	111
BICARBONATE	BOTH	18-65	MEQ/L	21	33	1	MMOL/L	21	33
TRIGLYCERIDE	BOTH	18-65	MG/DL	45	250	1	MG/DL	45	250
CHOLESTEROL, TOTAL	BOTH	18-65	MG/DL	130	200	1	MG/DL	130	200
DIRECT HDL - CHOLESTEROL	BOTH	18-65	mg/dL	40	80	1	MG/DL	40	80
LDL-CALC	BOTH	18-65	mg/dL	0	130	1	MG/DL	0	130
TSH	BOTH	21-65	uIU/mL	0.35	5.50	1	UIU/ML	0.35	5.5
	MALE	18-20	uIU/mL	0.70	6.40	1	UIU/ML	0.7	6.4
THYROXINE (T4)	BOTH	22-64	UG/DL	4.5	12.0	12.87	NMOL/L	57.915	154.44

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM200.SAS
GENERATED: 12JUL2005 17:40:54 iceadmn3

Table 11.3.7.1.2.1 Chemistry Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
THYROXINE (T4)	MALE	65-65	UG/DL	5.0	10.7	12.87	NMOL/L	64.35	137.71
	MALE	18-21	UG/DL	5.3	10.5	12.87	NMOL/L	68.211	135.14
	FEMALE	18-21	UG/DL	5.7	11.4	12.87	NMOL/L	73.359	146.72
T3-UPTAKE	BOTH	18-65	%	22	40	1	%	22	40

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM200.SAS
GENERATED: 12JUL2005 17:40:54 iceadmn3

Table 11.3.7.1.2.2 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
AST (U/L)	BSLN	156	24.07	11.78	21.0	10.0	96.0	148	23.93	10.83	21.0	12.0	74.0	152	23.40	9.75	20.5	9.0	78.0
	FINAL	156	23.42	8.83	21.0	11.0	81.0	148	25.26	11.06	23.0	8.0	84.0	152	23.72	16.89	21.0	9.0	145.0
	CHG FROM BSLN	156	-0.65	10.04	0.0	-68.0	24.0	148	1.33	9.16	1.0	-34.0	32.0	152	0.32	15.38	-1.0	-33.0	123.0
ALT (U/L)	BSLN	156	26.68	17.63	21.0	6.0	128.0	148	26.72	19.96	20.0	8.0	110.0	152	23.01	13.05	19.0	7.0	96.0
	FINAL	156	27.12	17.27	21.0	7.0	101.0	148	28.64	19.29	23.0	5.0	136.0	152	23.52	16.10	19.0	6.0	128.0
	CHG FROM BSLN	156	0.44	13.97	0.0	-93.0	42.0	148	1.93	16.56	1.0	-89.0	59.0	152	0.51	13.60	0.0	-48.0	89.0
ALKALINE PHOSPHATASE (U/L)	BSLN	156	82.46	27.18	79.0	27.0	220.0	148	80.05	21.87	78.0	39.0	158.0	152	81.14	25.74	77.0	34.0	178.0
	FINAL	156	86.54	27.71	82.0	33.0	218.0	148	84.97	22.24	84.0	45.0	157.0	152	82.55	32.21	79.0	35.0	310.0
	CHG FROM BSLN	156	4.08	12.01	3.0	-20.0	45.0	148	4.93	13.41	3.0	-30.0	48.0	152	1.41	16.94	0.0	-28.0	159.0
TOTAL BILIRUBIN (MG/DL)	BSLN	156	0.48	0.29	0.4	0.1	2.0	148	0.52	0.26	0.5	0.1	1.9	152	0.46	0.21	0.4	0.1	1.3
	FINAL	156	0.42	0.24	0.4	0.1	2.3	148	0.46	0.27	0.4	0.1	2.1	152	0.46	0.26	0.4	0.1	2.2
	CHG FROM BSLN	156	-0.06	0.20	0.0	-0.9	0.4	148	-0.06	0.26	-0.1	-0.8	1.0	152	-0.00	0.23	0.0	-1.2	1.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM201.SAS
GENERATED: 13JUL2005 12:52:08 iceadmn3

Table 11.3.7.1.2.2 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
CREATININE (MG/DL)	BSLN	156	0.83	0.18	0.8	0.5	1.5	148	0.82	0.16	0.8	0.5	1.2	152	0.79	0.17	0.8	0.5	1.3
	FINAL	156	0.85	0.17	0.8	0.5	1.3	148	0.85	0.18	0.8	0.4	1.3	152	0.80	0.17	0.8	0.4	1.4
	CHG FROM BSLN	156	0.01	0.12	0.0	-0.4	0.3	148	0.03	0.12	0.0	-0.2	0.6	152	0.01	0.12	0.0	-0.5	0.4
FASTING GLUCOSE (MG/DL)	BSLN	156	86.56	12.77	85.0	58.0	174.0	148	85.93	11.67	85.0	52.0	130.0	152	86.68	14.94	84.0	60.0	192.0
	FINAL	156	89.74	14.41	87.5	62.0	156.0	148	91.82	18.72	88.5	63.0	177.0	152	90.47	30.34	86.0	58.0	410.0
	CHG FROM BSLN	156	3.19	13.47	2.5	-32.0	65.0	148	5.89	17.11	3.0	-40.0	72.0	152	3.80	25.60	1.0	-99.0	247.0
INSULIN (PMOL/L)	BSLN	156	99.86	120.32	69.5	6.9	1020.9	143	80.62	104.95	55.6	13.9	1145.9	151	98.56	173.99	55.6	6.9	1951.5
	FINAL	156	143.40	205.48	86.8	6.9	1562.6	143	174.69	324.14	90.3	6.9	2722.4	151	109.83	103.44	83.3	13.9	791.7
	CHG FROM BSLN	156	43.54	191.69	6.9	-764.0	1298.7	143	94.07	257.71	27.8	-173.6	2298.8	151	11.27	183.96	13.9	-1798.8	486.2
INSULIN (UIU/ML)	BSLN	156	14.38	17.33	10.0	1.0	147.0	143	11.61	15.11	8.0	2.0	165.0	151	14.19	25.05	8.0	1.0	281.0
	FINAL	156	20.65	29.59	12.5	1.0	225.0	143	25.15	46.67	13.0	1.0	392.0	151	15.81	14.89	12.0	2.0	114.0
	CHG FROM BSLN	156	6.27	27.60	1.0	-110.0	187.0	143	13.55	37.11	4.0	-25.0	331.0	151	1.62	26.49	2.0	-259.0	70.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM201.SAS
GENERATED: 13JUL2005 12:52:08 iceadmn3

Table 11.3.7.1.2.2 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
SODIUM (MEQ/L)	BSLN	156	141.94	2.34	142.0	135.0	148.0	147	142.15	2.29	142.0	137.0	149.0	152	141.86	2.62	142.0	135.0	148.0
	FINAL	156	142.19	2.64	142.0	132.0	151.0	147	141.65	2.24	142.0	132.0	146.0	152	141.93	2.79	142.0	132.0	152.0
	CHG FROM BSLN	156	0.25	2.89	0.0	-9.0	10.0	147	-0.50	2.57	-1.0	-11.0	6.0	152	0.07	3.21	0.0	-11.0	11.0
POTASSIUM (MEQ/L)	BSLN	156	4.43	0.43	4.4	3.5	5.8	147	4.44	0.39	4.4	3.5	5.6	152	4.39	0.40	4.4	3.2	5.4
	FINAL	156	4.41	0.42	4.4	3.5	5.7	147	4.34	0.40	4.3	3.4	5.9	152	4.37	0.38	4.4	3.5	5.5
	CHG FROM BSLN	156	-0.01	0.46	0.0	-1.6	1.5	147	-0.10	0.45	-0.1	-1.6	0.9	152	-0.02	0.46	0.0	-1.0	1.2
CHLORIDE (MEQ/L)	BSLN	156	105.26	2.63	105.0	98.0	116.0	147	105.42	2.64	105.0	99.0	113.0	152	105.10	2.70	105.0	97.0	111.0
	FINAL	156	106.28	2.56	106.0	97.0	112.0	147	105.82	2.48	106.0	99.0	112.0	152	105.80	2.92	106.0	95.0	113.0
	CHG FROM BSLN	156	1.02	3.13	1.0	-8.0	10.0	147	0.40	2.93	1.0	-8.0	9.0	152	0.70	3.16	1.0	-9.0	12.0
BICARBONATE (MEQ/L)	BSLN	156	25.54	2.85	25.5	17.0	33.0	148	25.52	2.45	26.0	20.0	32.0	152	25.70	2.46	26.0	19.0	32.0
	FINAL	156	25.04	2.81	25.0	17.0	33.0	148	25.19	2.55	25.0	17.0	32.0	152	25.42	2.40	26.0	18.0	30.0
	CHG FROM BSLN	156	-0.50	3.42	0.0	-8.0	10.0	148	-0.33	3.14	-0.5	-7.0	7.0	152	-0.28	3.12	0.0	-8.0	7.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM201.SAS
GENERATED: 13JUL2005 12:52:08 iceadmn3

Table 11.3.7.1.2.2 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
TRIGLYCERIDE (MG/DL)	BSLN	156	150.78	91.43	124.0	34.0	540.0	148	149.13	109.51	113.0	34.0	650.0	152	158.09	151.58	108.5	38.0	1240.0
	FINAL	156	185.94	141.97	146.0	53.0	877.0	148	170.83	132.79	133.0	35.0	1000.0	152	164.56	182.31	120.5	31.0	1930.0
	CHG FROM BSLN	156	35.17	98.89	13.5	-203.0	378.0	148	21.70	78.19	12.0	-268.0	350.0	152	6.47	140.59	2.0	-1050.0	900.0
TOTAL CHOLESTEROL (MG/DL)	BSLN	156	196.65	40.97	198.0	100.0	298.0	148	196.32	47.13	190.0	108.0	353.0	152	194.76	41.51	192.5	101.0	320.0
	FINAL	156	197.90	42.78	195.5	104.0	368.0	148	198.01	46.59	193.5	108.0	336.0	152	193.65	49.17	192.0	91.0	466.0
	CHG FROM BSLN	156	1.25	27.27	3.0	-102.0	109.0	148	1.70	27.87	-2.5	-85.0	99.0	152	-1.11	32.28	-2.0	-106.0	194.0
DIRECT HDL (MG/DL)	BSLN	156	50.09	16.96	47.0	23.0	124.0	148	48.95	14.46	45.0	21.0	106.0	152	48.45	13.26	46.0	23.0	94.0
	FINAL	156	50.30	18.51	47.0	25.0	131.0	148	47.45	14.19	44.0	21.0	97.0	152	48.19	13.23	47.0	24.0	92.0
	CHG FROM BSLN	156	0.21	8.83	0.0	-24.0	29.0	148	-1.49	9.99	-1.0	-56.0	31.0	152	-0.26	8.19	0.0	-39.0	23.0
LDL CALCULATED (MG/DL)	BSLN	156	116.97	34.43	117.0	33.0	213.0	148	118.92	40.45	113.0	33.0	270.0	152	115.60	32.54	114.0	31.0	189.0
	FINAL	156	113.32	35.95	105.0	49.0	270.0	148	117.79	37.56	118.0	34.0	258.0	152	112.69	34.48	113.5	31.0	235.0
	CHG FROM BSLN	156	-3.65	24.76	-3.0	-89.0	83.0	148	-1.13	26.30	-2.5	-75.0	96.0	152	-2.91	24.59	-1.0	-78.0	77.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM201.SAS
GENERATED: 13JUL2005 12:52:08 iceadmn3

Table 11.3.7.1.2.2 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
TSH (MIU-/L)	BSLN	156	1.85	1.03	1.6	0.3	5.6	141	1.57	0.77	1.5	0.3	4.1	152	1.81	1.05	1.6	0.3	5.3
	FINAL	156	1.96	1.27	1.7	0.1	7.3	141	1.50	0.85	1.4	0.1	5.8	152	1.88	1.49	1.6	0.1	12.9
	CHG FROM BSLN	156	0.11	1.09	0.1	-3.9	4.7	141	-0.07	0.91	-0.1	-2.9	3.7	152	0.08	1.22	0.0	-2.9	8.5
THYROXINE (T4) (NMOL/L)	BSLN	156	106.28	20.99	104.2	64.4	186.6	148	107.57	24.10	104.9	55.3	177.6	152	106.30	23.30	104.2	33.5	176.3
	FINAL	156	96.65	19.74	95.9	52.8	145.4	148	89.64	24.32	84.9	51.5	212.4	152	105.46	21.18	104.2	51.5	176.3
	CHG FROM BSLN	156	-9.63	18.41	-10.3	-57.9	57.9	148	-17.93	24.43	-14.2	-86.2	57.9	152	-0.84	17.86	1.3	-78.5	46.3
T3-UPTAKE (%)	BSLN	156	32.54	3.55	32.0	20.0	41.0	148	32.97	4.31	33.0	22.0	47.0	152	32.31	4.39	32.0	22.0	49.0
	FINAL	156	33.23	4.08	33.0	24.0	45.0	148	33.89	3.78	34.0	24.0	44.0	152	33.33	4.00	33.5	21.0	46.0
	CHG FROM BSLN	156	0.69	3.47	0.0	-10.0	12.0	148	0.91	3.81	1.0	-8.0	12.0	152	1.02	3.33	1.0	-7.0	8.0

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM201.SAS
GENERATED: 13JUL2005 12:52:08 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
AST	BASELINE												
	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NORMAL	146	0	141	5	137	1	129	7	141	1	137	3
	HIGH	10	0	7	3	11	0	4	7	10	0	6	4
ALT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	138	0	128	10	134	2	118	14	138	0	136	2
	HIGH	18	0	7	11	14	0	6	8	14	0	8	6
ALKALINE PHOSPHATASE	LOW	1	0	1	0	0	0	0	0	0	0	0	0
	NORMAL	148	0	139	9	141	0	137	4	143	0	140	3
	HIGH	7	0	1	6	7	0	2	5	9	0	1	8
TOTAL BILIRUBIN	LOW	5	1	4	0	1	0	1	0	2	0	2	0
	NORMAL	147	2	145	0	145	4	138	3	149	4	143	2
	HIGH	4	0	2	2	2	0	2	0	1	1	0	0
CREATININE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	155	0	148	0	148	0	152	0	151	1
	HIGH	1	0	1	0	0	0	0	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM202.SAS
GENERATED: 12JUL2005 17:41:02 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
FASTING GLUCOSE	BASELINE												
	LOW	4	2	2	0	4	0	4	0	4	2	2	0
	NORMAL	149	1	144	4	141	4	128	9	145	1	137	7
	HIGH	3	0	0	3	3	0	2	1	3	0	1	2
INSULIN	LOW	3	1	2	0	3	0	3	0	8	0	6	2
	NORMAL	120	3	85	32	117	2	78	37	110	1	83	26
	HIGH	33	0	8	25	23	0	2	21	33	0	13	20
SODIUM	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	154	0	151	3	144	0	144	0	151	0	149	2
	HIGH	2	0	2	0	3	0	3	0	1	0	1	0
POTASSIUM	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NORMAL	154	0	151	3	146	0	145	1	151	0	151	0
	HIGH	2	0	2	0	1	0	1	0	0	0	0	0
CHLORIDE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	154	1	145	0	144	1	152	0	150	2
	HIGH	1	0	1	0	2	0	2	0	0	0	0	0
BICARBONATE	LOW	6	0	6	0	3	0	3	0	2	0	2	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM202.SAS
GENERATED: 12JUL2005 17:41:02 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
BICARBONATE	BASELINE												
	NORMAL	150	9	141	0	145	7	138	0	150	2	148	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
TRIGLYCERIDE	LOW	3	0	3	0	4	1	3	0	3	1	2	0
	NORMAL	137	0	115	22	125	3	114	8	126	4	114	8
	HIGH	16	0	2	14	19	0	5	14	23	0	9	14
TOTAL CHOLESTEROL	LOW	4	2	2	0	5	2	3	0	7	5	2	0
	NORMAL	76	2	64	10	87	5	65	17	79	2	68	9
	HIGH	76	0	17	59	56	0	12	44	66	0	16	50
DIRECT HDL	LOW	41	29	12	0	43	31	12	0	39	31	8	0
	NORMAL	104	20	82	2	100	15	85	0	109	13	94	2
	HIGH	11	0	1	10	5	0	2	3	4	0	1	3
LDL CALCULATED	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	99	0	89	10	99	0	82	17	98	0	87	11
	HIGH	57	0	21	36	49	0	16	33	54	0	19	35
TSH	LOW	3	0	3	0	3	0	3	0	5	3	2	0
	NORMAL	152	1	148	3	138	5	132	1	147	2	141	4

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM202.SAS
GENERATED: 12JUL2005 17:41:02 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
TSH	BASELINE												
	HIGH	1	0	1	0	0	0	0	0	0	0	0	0
THYROXINE (T4)	LOW	0	0	0	0	1	0	1	0	1	1	0	0
	NORMAL	151	2	149	0	138	7	129	2	146	1	144	1
	HIGH	5	0	5	0	9	0	8	1	5	0	3	2
T3-UPTAKE	LOW	1	0	1	0	0	0	0	0	0	0	0	0
	NORMAL	154	0	146	8	140	0	136	4	147	1	146	0
	HIGH	1	0	1	0	8	0	6	2	5	0	2	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM202.SAS
GENERATED: 12JUL2005 17:41:02 iceadmn3

Table 11.3.7.1.2.3.2 Chemistry Findings Exceeding Laboratory Norms
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
AST (SGOT)	0/156 (0.0%)	1/148 (0.7%)	1/151 (0.7%)	5/146 (3.4%)	7/137 (5.1%)	3/142 (2.1%)
ALT (SGPT)	0/156 (0.0%)	2/148 (1.4%)	0/152 (0.0%)	10/138 (7.2%)	14/134 (10.4%)	2/138 (1.4%)
ALKALINE PHOSPHATASE	0/155 (0.0%)	0/148 (0.0%)	0/152 (0.0%)	9/149 (6.0%)	4/141 (2.8%)	3/143 (2.1%)
TOTAL BILIRUBIN	2/151 (1.3%)	4/147 (2.7%)	5/150 (3.3%)	0/152 (0.0%)	3/146 (2.1%)	2/151 (1.3%)
CREATININE	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)	0/155 (0.0%)	0/148 (0.0%)	1/152 (0.7%)
FASTING GLUCOSE	1/152 (0.7%)	4/144 (2.8%)	1/148 (0.7%)	4/153 (2.6%)	9/145 (6.2%)	7/149 (4.7%)
INSULIN	3/153 (2.0%)	2/140 (1.4%)	1/143 (0.7%)	32/123 (26.0%)	37/120 (30.8%)	28/118 (23.7%)
SODIUM	0/156 (0.0%)	0/147 (0.0%)	0/152 (0.0%)	3/154 (1.9%)	0/144 (0.0%)	2/151 (1.3%)
POTASSIUM	0/156 (0.0%)	0/147 (0.0%)	0/151 (0.0%)	3/154 (1.9%)	1/146 (0.7%)	0/152 (0.0%)
CHLORIDE	0/156 (0.0%)	0/147 (0.0%)	0/152 (0.0%)	1/155 (0.6%)	1/145 (0.7%)	2/152 (1.3%)
BICARBONATE	9/150 (6.0%)	7/145 (4.8%)	2/150 (1.3%)	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)
TRIGLYCERIDE	0/153 (0.0%)	3/144 (2.1%)	4/149 (2.7%)	22/140 (15.7%)	8/129 (6.2%)	8/129 (6.2%)
CHOLESTEROL, TOTAL	2/152 (1.3%)	5/143 (3.5%)	2/145 (1.4%)	10/ 80 (12.5%)	17/ 92 (18.5%)	9/ 86 (10.5%)
DIRECT HDL - CHOLESTEROL	20/115 (17.4%)	15/105 (14.3%)	13/113 (11.5%)	2/145 (1.4%)	0/143 (0.0%)	2/148 (1.4%)
LDL-CALC	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)	10/ 99 (10.1%)	17/ 99 (17.2%)	11/ 98 (11.2%)
TSH	1/153 (0.7%)	5/138 (3.6%)	2/147 (1.4%)	3/155 (1.9%)	1/141 (0.7%)	4/152 (2.6%)
THYROXINE (T4)	2/156 (1.3%)	7/147 (4.8%)	1/151 (0.7%)	0/151 (0.0%)	2/139 (1.4%)	1/147 (0.7%)
T3-UPTAKE	0/155 (0.0%)	0/148 (0.0%)	1/152 (0.7%)	8/155 (5.2%)	4/140 (2.9%)	0/147 (0.0%)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM205.SAS
GENERATED: 12JUL2005 17:41:14 iceadmn3

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH
AST	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	0	156	0	148	0	148	0	152	0	149	3
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
ALT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	0	156	0	148	0	147	1	152	0	151	1
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	0	156	0	148	0	148	0	152	0	152	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL BILIRUBIN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	154	0	154	0	147	0	146	1	152	0	151	1
	HIGH	2	0	1	1	1	0	1	0	0	0	0	0

(Continued)

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
CREATININE	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	0	156	0	148	0	148	0	152	0	152	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
FASTING GLUCOSE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	154	0	150	4	146	0	140	6	149	0	144	5
	HIGH	2	0	0	2	2	0	1	1	3	0	1	2
RANDOM GLUCOSE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	0	156	0	148	0	148	0	152	0	151	1
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
INSULIN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	0	156	0	143	0	143	0	151	0	151	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
SODIUM	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	1	155	0	147	1	146	0	152	1	150	1
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
POTASSIUM	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	152	0	148	4	145	0	144	1	152	0	151	1
	HIGH	4	0	4	0	2	0	2	0	0	0	0	0
CHLORIDE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	156	0	156	0	147	0	147	0	152	0	152	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
BICARBONATE	LOW	1	0	1	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	140	2	137	1	143	1	137	5	143	1	136	6
	HIGH	15	0	14	1	5	0	4	1	9	0	9	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM203.SAS
GENERATED: 12JUL2005 17:41:06 iceadmn3

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TRIGLYCERIDE	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	119	0	100	19	119	0	103	16	121	0	112	9
	HIGH	37	0	11	26	29	0	6	23	31	0	10	21
TOTAL CHOLESTEROL	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	135	0	122	13	123	0	115	8	131	0	123	8
	HIGH	21	0	7	14	25	0	8	17	21	0	12	9
DIRECT HDL	LOW	45	32	13	0	47	37	10	0	47	33	14	0
	NOT CLINICALLY IMPORTANT	111	18	93	0	101	15	86	0	105	14	91	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LDL CALCULATED	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	142	0	132	10	125	0	119	6	136	0	130	6
	HIGH	14	0	7	7	23	0	10	13	16	0	10	6

(Continued)

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH
TSH	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	153	0	148	5	141	0	140	1	151	0	147	4
	HIGH	3	0	3	0	0	0	0	0	1	0	1	0
THYROXINE (T4)	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	155	0	155	0	148	0	147	1	151	0	151	0
	HIGH	1	0	1	0	0	0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM203.SAS
GENERATED: 12JUL2005 17:41:06 iceadmn3

Table 11.3.7.1.2.3.4 Potentially Clinically Important Chemistry Findings
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
AST (SGOT)	NA	NA	NA	0/156 (0.0%)	0/148 (0.0%)	3/152 (2.0%)
ALT (SGPT)	NA	NA	NA	0/156 (0.0%)	1/148 (0.7%)	1/152 (0.7%)
ALKALINE PHOSPHATASE	NA	NA	NA	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)
TOTAL BILIRUBIN	NA	NA	NA	0/154 (0.0%)	1/147 (0.7%)	1/152 (0.7%)
CREATININE	NA	NA	NA	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)
FASTING GLUCOSE	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)	4/154 (2.6%)	6/146 (4.1%)	5/149 (3.4%)
RANDOM GLUCOSE	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)	0/156 (0.0%)	0/148 (0.0%)	1/152 (0.7%)
SODIUM	1/156 (0.6%)	1/147 (0.7%)	1/152 (0.7%)	0/156 (0.0%)	0/147 (0.0%)	1/152 (0.7%)
POTASSIUM	0/156 (0.0%)	0/147 (0.0%)	0/152 (0.0%)	4/152 (2.6%)	1/145 (0.7%)	1/152 (0.7%)
CHLORIDE	0/156 (0.0%)	0/147 (0.0%)	0/152 (0.0%)	0/156 (0.0%)	0/147 (0.0%)	0/152 (0.0%)
BICARBONATE	2/155 (1.3%)	1/148 (0.7%)	1/152 (0.7%)	1/141 (0.7%)	5/143 (3.5%)	6/143 (4.2%)
TRIGLYCERIDE	NA	NA	NA	19/119 (16.0%)	16/119 (13.4%)	9/121 (7.4%)
CHOLESTEROL, TOTAL	NA	NA	NA	13/135 (9.6%)	8/123 (6.5%)	8/131 (6.1%)
DIRECT HDL - CHOLESTEROL	18/111 (16.2%)	15/101 (14.9%)	14/105 (13.3%)	0/156 (0.0%)	0/148 (0.0%)	0/152 (0.0%)
LDL-CALC	NA	NA	NA	10/142 (7.0%)	6/125 (4.8%)	6/136 (4.4%)
TSH	NA	NA	NA	5/153 (3.3%)	1/141 (0.7%)	4/151 (2.6%)
THYROXINE (T4)	0/156 (0.0%)	0/148 (0.0%)	0/151 (0.0%)	0/155 (0.0%)	1/148 (0.7%)	0/152 (0.0%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM204.SAS
GENERATED: 12JUL2005 17:41:10 iceadmn3

Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=157						QUETIAPINE 600 MG N=148					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	156	86.56	12.77	85.0	58.0	174.0	148	85.93	11.67	85.0	52.0	130.0
		FINAL	156	89.74	14.41	87.5	62.0	156.0	148	91.82	18.72	88.5	63.0	177.0
		CHG FROM BSLN	156	3.19	13.47	2.5	-32.0	65.0	148	5.89	17.11	3.0	-40.0	72.0
	INSULIN (UIU/ML)	BSLN	156	14.38	17.33	10.0	1.0	147.0	143	11.61	15.11	8.0	2.0	165.0
		FINAL	156	20.65	29.59	12.5	1.0	225.0	143	25.15	46.67	13.0	1.0	392.0
		CHG FROM BSLN	156	6.27	27.60	1.0	-110.0	187.0	143	13.55	37.11	4.0	-25.0	331.0
	HOMA-R	BSLN	144	3.15	4.26	2.1	0.2	37.0	138	2.56	3.77	1.7	0.3	40.7
		FINAL	144	4.87	9.07	2.4	0.2	76.0	138	6.82	16.37	2.7	0.2	166.3
		CHG FROM BSLN	144	1.72	8.52	0.4	-29.9	68.5	138	4.26	13.33	1.1	-6.4	125.6
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	6	104.83	41.02	85.0	71.0	174.0	7	106.86	21.72	113.0	81.0	130.0
		FINAL	6	107.50	33.53	94.0	71.0	156.0	7	111.57	39.24	100.0	76.0	177.0
		CHG FROM BSLN	6	2.67	19.41	9.0	-32.0	20.0	7	4.71	36.55	-5.0	-27.0	64.0
	INSULIN (UIU/ML)	BSLN	7	26.00	21.69	16.0	7.0	64.0	7	13.14	6.15	12.0	5.0	22.0
		FINAL	7	22.71	17.88	16.0	7.0	57.0	7	14.00	12.17	12.0	1.0	37.0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM206.SAS
GENERATED: 13JUL2005 12:52:25 iceadmn3

Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=157						N=148					
			N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT												
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	7	-3.29	5.44	-1.0	-12.0	3.0	7	0.86	11.36	-4.0	-8.0	20.0
	HOMA-R	BSLN	6	5.32	4.27	4.8	1.5	13.1	7	3.54	1.76	3.8	1.0	5.4
		FINAL	6	5.28	4.21	4.4	1.2	13.1	7	4.77	5.63	2.8	0.2	16.2
		CHG FROM BSLN	6	-0.05	0.76	-0.2	-1.1	0.8	7	1.23	5.22	-1.2	-2.5	10.7
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	34	92.47	13.10	92.0	58.0	121.0	30	92.47	12.26	89.0	64.0	112.0
		FINAL	34	95.03	15.35	93.0	68.0	132.0	30	98.33	25.28	92.0	66.0	175.0
		CHG FROM BSLN	34	2.56	13.72	2.5	-24.0	28.0	30	5.87	23.67	0.5	-40.0	72.0
	INSULIN (UIU/ML)	BSLN	34	25.32	29.02	15.5	6.0	147.0	27	24.59	30.48	18.0	7.0	165.0
		FINAL	34	33.21	34.65	20.0	4.0	172.0	27	51.44	75.95	25.0	6.0	392.0
		CHG FROM BSLN	34	7.88	40.58	3.5	-110.0	118.0	27	26.85	49.35	6.0	-25.0	227.0
	HOMA-R	BSLN	30	6.44	7.72	3.3	1.3	37.0	26	5.74	7.71	3.5	1.3	40.7
		FINAL	30	8.36	10.84	5.0	0.8	52.6	26	16.44	32.56	5.9	1.2	166.3
		CHG FROM BSLN	30	1.91	11.80	1.2	-29.9	38.9	26	10.70	25.43	1.5	-6.4	125.6

(Continued)

Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=157						N=148					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	116	83.88	7.90	83.0	62.0	99.0	111	82.84	8.21	84.0	52.0	99.0
		FINAL	116	87.28	11.50	86.0	62.0	137.0	111	88.81	13.06	87.0	63.0	138.0
		CHG FROM BSLN	116	3.40	13.20	2.0	-28.0	65.0	111	5.97	13.05	3.0	-18.0	57.0
	INSULIN (UIU/ML)	BSLN	115	10.43	8.93	8.0	1.0	58.0	109	8.29	4.60	7.0	2.0	23.0
		FINAL	115	16.81	27.63	10.0	1.0	225.0	109	19.36	35.39	12.0	1.0	350.0
		CHG FROM BSLN	115	6.37	23.47	1.0	-21.0	187.0	109	11.06	34.00	4.0	-8.0	331.0
	HOMA-R	BSLN	108	2.11	1.69	1.7	0.2	12.4	105	1.71	0.98	1.5	0.3	5.1
		FINAL	108	3.88	8.54	2.0	0.2	76.0	105	4.57	8.24	2.3	0.2	76.0
		CHG FROM BSLN	108	1.77	7.68	0.2	-5.1	68.5	105	2.87	8.01	1.1	-2.0	72.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM206.SAS
GENERATED: 13JUL2005 12:52:25 iceadmn3

Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=152					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	152	86.68	14.94	84.0	60.0	192.0
		FINAL	152	90.47	30.34	86.0	58.0	410.0
		CHG FROM BSLN	152	3.80	25.60	1.0	-99.0	247.0
	INSULIN (UIU/ML)	BSLN	151	14.19	25.05	8.0	1.0	281.0
		FINAL	151	15.81	14.89	12.0	2.0	114.0
		CHG FROM BSLN	151	1.62	26.49	2.0	-259.0	70.0
	HOMA-R	BSLN	144	3.56	11.24	1.8	0.2	133.1
		FINAL	144	3.62	4.45	2.4	0.4	41.3
		CHG FROM BSLN	144	0.06	11.59	0.3	-128.1	29.1
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	7	127.71	38.27	116.0	91.0	192.0
		FINAL	7	152.29	117.90	93.0	83.0	410.0
		CHG FROM BSLN	7	24.57	108.01	-8.0	-99.0	247.0
	INSULIN (UIU/ML)	BSLN	6	61.33	107.85	20.0	9.0	281.0
		FINAL	6	19.00	9.12	19.5	4.0	31.0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=152					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	6	-42.33	106.27	-0.5	-259.0	7.0
	HOMA-R	BSLN	5	29.98	57.69	6.0	2.1	133.1
		FINAL	5	4.84	2.77	5.0	0.8	7.5
		CHG FROM BSLN	5	-25.14	57.54	1.1	-128.1	1.5
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	36	89.22	12.24	91.5	63.0	113.0
		FINAL	36	90.47	14.09	88.0	66.0	147.0
		CHG FROM BSLN	36	1.25	13.17	0.0	-24.0	34.0
	INSULIN (UIU/ML)	BSLN	36	19.72	12.41	17.0	3.0	48.0
		FINAL	36	23.06	20.56	16.0	3.0	114.0
		CHG FROM BSLN	36	3.33	17.52	2.0	-34.0	70.0
	HOMA-R	BSLN	32	4.39	3.09	3.4	0.6	12.3
		FINAL	32	5.79	7.31	3.8	0.7	41.3
		CHG FROM BSLN	32	1.40	6.11	0.2	-6.6	29.1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=152					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	109	83.20	7.65	83.0	60.0	98.0
		FINAL	109	86.50	13.69	85.0	58.0	156.0
		CHG FROM BSLN	109	3.30	13.47	2.0	-22.0	66.0
	INSULIN (UIU/ML)	BSLN	109	9.77	11.40	7.0	1.0	97.0
		FINAL	109	13.25	11.94	9.0	2.0	64.0
		CHG FROM BSLN	109	3.48	15.51	2.0	-86.0	62.0
	HOMA-R	BSLN	107	2.08	2.61	1.5	0.2	23.0
		FINAL	107	2.91	2.97	2.0	0.4	17.9
		CHG FROM BSLN	107	0.84	3.77	0.3	-20.8	14.5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=157						N=148					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	144	0.3463	0.0433	0.3405	0.2395	0.5402	138	0.3525	0.0381	0.3529	0.2371	0.4660
		FINAL	144	0.3358	0.0466	0.3338	0.2228	0.5317	138	0.3299	0.0515	0.3294	0.2071	0.5317
		CHG FROM BSLN	144	-0.0106	0.0426	-0.0075	-0.1541	0.1230	138	-0.0227	0.0460	-0.0237	-0.1243	0.1482
DIABETIC	QUICKI	BSLN	6	0.3147	0.0364	0.3041	0.2684	0.3591	7	0.3260	0.0322	0.3132	0.2993	0.3835
		FINAL	6	0.3142	0.0355	0.3078	0.2685	0.3709	7	0.3537	0.0918	0.3280	0.2620	0.5317
		CHG FROM BSLN	6	-0.0005	0.0128	0.0023	-0.0233	0.0131	7	0.0277	0.0740	0.0208	-0.0719	0.1482
DIABETIC RISK	QUICKI	BSLN	30	0.3114	0.0314	0.3194	0.2395	0.3673	26	0.3159	0.0315	0.3178	0.2371	0.3676
		FINAL	30	0.3059	0.0364	0.3022	0.2310	0.3950	26	0.2966	0.0433	0.2959	0.2071	0.3722
		CHG FROM BSLN	30	-0.0056	0.0404	-0.0148	-0.0646	0.1230	26	-0.0192	0.0272	-0.0213	-0.0749	0.0317
NON DIABETIC	QUICKI	BSLN	108	0.3578	0.0405	0.3534	0.2701	0.5402	105	0.3634	0.0333	0.3591	0.3016	0.4660
		FINAL	108	0.3453	0.0461	0.3427	0.2228	0.5317	105	0.3365	0.0468	0.3366	0.2228	0.5317
		CHG FROM BSLN	108	-0.0125	0.0443	-0.0058	-0.1541	0.0922	105	-0.0269	0.0459	-0.0294	-0.1243	0.1307

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM206.SAS
GENERATED: 13JUL2005 12:52:25 iceadmn3

Table 11.3.7.1.2.3.5 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO N=152					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	144	0.3542	0.0501	0.3496	0.2113	0.5420
		FINAL	144	0.3384	0.0405	0.3354	0.2367	0.4595
		CHG FROM BSLN	144	-0.0158	0.0496	-0.0131	-0.2027	0.0907
DIABETIC	QUICKI	BSLN	5	0.2957	0.0524	0.2953	0.2113	0.3411
		FINAL	5	0.3181	0.0455	0.3020	0.2870	0.3966
		CHG FROM BSLN	5	0.0224	0.0497	-0.0058	-0.0249	0.0907
DIABETIC RISK	QUICKI	BSLN	32	0.3215	0.0340	0.3186	0.2705	0.4192
		FINAL	32	0.3160	0.0357	0.3142	0.2367	0.4129
		CHG FROM BSLN	32	-0.0055	0.0340	-0.0085	-0.0625	0.0701
NON DIABETIC	QUICKI	BSLN	107	0.3668	0.0479	0.3604	0.2519	0.5420
		FINAL	107	0.3461	0.0392	0.3445	0.2590	0.4595
		CHG FROM BSLN	107	-0.0207	0.0525	-0.0156	-0.2027	0.0896

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM206.SAS
GENERATED: 13JUL2005 12:52:25 iceadmn3

Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=121						QUETIAPINE 600 MG N=98					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	121	85.69	10.53	85.0	58.0	136.0	98	85.10	11.63	85.0	52.0	130.0
		FINAL	121	88.93	13.63	86.0	62.0	156.0	98	90.23	15.61	88.0	63.0	172.0
		CHG FROM BSLN	121	3.25	14.18	3.0	-28.0	65.0	98	5.13	15.07	3.5	-27.0	72.0
	INSULIN (UIU/ML)	BSLN	120	14.40	18.88	9.0	1.0	147.0	96	12.13	17.28	8.0	2.0	165.0
		FINAL	120	20.07	29.42	11.0	1.0	225.0	96	27.04	54.43	12.0	1.0	392.0
		CHG FROM BSLN	120	5.67	28.85	1.0	-110.0	187.0	96	14.92	42.78	4.0	-8.0	331.0
	HOMA-R	BSLN	111	3.16	4.65	2.1	0.2	37.0	92	2.66	4.31	1.7	0.4	40.7
		FINAL	111	4.59	8.82	2.2	0.2	76.0	92	7.31	19.17	2.6	0.2	166.3
		CHG FROM BSLN	111	1.43	8.74	0.2	-29.9	68.5	92	4.65	15.48	1.1	-2.5	125.6
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	4	94.25	28.65	85.0	71.0	136.0	5	105.60	22.81	113.0	81.0	130.0
		FINAL	4	108.00	32.14	94.0	88.0	156.0	5	89.80	13.24	86.0	76.0	107.0
		CHG FROM BSLN	4	13.75	5.68	13.5	8.0	20.0	5	-15.80	11.43	-22.0	-27.0	-2.0
	INSULIN (UIU/ML)	BSLN	4	30.50	25.20	25.5	7.0	64.0	5	13.60	6.58	12.0	5.0	22.0
		FINAL	4	26.50	21.02	19.5	10.0	57.0	5	8.00	5.70	10.0	1.0	14.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
GENERATED: 13JUL2005 12:52:35 iceadmn3

Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=121						QUETIAPINE 600 MG N=98					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	4	-4.00	6.78	-3.5	-12.0	3.0	5	-5.60	2.61	-6.0	-8.0	-2.0
	HOMA-R	BSLN	4	6.53	4.83	5.7	1.5	13.1	5	3.56	1.67	3.8	1.0	5.4
		FINAL	4	6.64	4.58	5.6	2.3	13.1	5	1.84	1.32	2.6	0.2	3.0
		CHG FROM BSLN	4	0.12	0.93	0.4	-1.1	0.8	5	-1.72	0.73	-1.7	-2.5	-0.8
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	25	91.12	12.44	91.0	58.0	107.0	20	90.85	11.29	87.5	64.0	105.0
		FINAL	25	91.92	13.64	88.0	68.0	127.0	20	99.15	23.67	94.0	69.0	172.0
		CHG FROM BSLN	25	0.80	14.07	1.0	-24.0	28.0	20	8.30	20.96	3.0	-16.0	72.0
	INSULIN (UIU/ML)	BSLN	25	26.36	33.09	15.0	6.0	147.0	19	25.42	35.14	14.0	7.0	165.0
		FINAL	25	27.92	23.56	20.0	4.0	101.0	19	55.74	86.73	31.0	7.0	392.0
		CHG FROM BSLN	25	1.56	38.98	3.0	-110.0	72.0	19	30.32	53.03	7.0	-3.0	227.0
	HOMA-R	BSLN	22	6.76	8.76	3.1	1.3	37.0	18	5.91	8.94	3.4	1.3	40.7
		FINAL	22	6.07	5.66	5.0	0.8	26.4	18	18.32	37.90	6.6	1.7	166.3
		CHG FROM BSLN	22	-0.69	9.84	1.0	-29.9	16.1	18	12.40	29.12	2.9	-0.8	125.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=121						QUETIAPINE 600 MG N=98					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	92	83.84	7.98	83.0	62.0	99.0	73	82.12	8.50	83.0	52.0	99.0
		FINAL	92	87.29	11.86	86.0	62.0	137.0	73	87.82	11.95	87.0	63.0	138.0
		CHG FROM BSLN	92	3.46	14.33	2.0	-28.0	65.0	73	5.70	12.21	4.0	-18.0	57.0
	INSULIN (UIU/ML)	BSLN	91	10.41	9.54	7.0	1.0	58.0	72	8.51	4.83	7.0	2.0	23.0
		FINAL	91	17.63	30.93	9.0	1.0	225.0	72	20.79	42.08	12.0	1.0	350.0
		CHG FROM BSLN	91	7.22	26.13	0.0	-21.0	187.0	72	12.28	40.44	4.0	-8.0	331.0
	HOMA-R	BSLN	85	2.07	1.78	1.5	0.2	12.4	69	1.75	1.01	1.5	0.4	5.1
		FINAL	85	4.11	9.60	1.8	0.2	76.0	69	4.83	9.61	2.3	0.2	76.0
		CHG FROM BSLN	85	2.04	8.62	0.1	-5.1	68.5	69	3.09	9.35	1.1	-2.0	72.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO					
			N=105					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	105	85.42	11.07	84.0	60.0	137.0
		FINAL	105	88.80	16.67	87.0	58.0	172.0
		CHG FROM BSLN	105	3.38	14.55	1.0	-22.0	66.0
	INSULIN (UIU/ML)	BSLN	105	12.21	10.82	8.0	1.0	50.0
		FINAL	105	16.03	15.92	12.0	2.0	114.0
		CHG FROM BSLN	105	3.82	13.90	2.0	-28.0	70.0
	HOMA-R	BSLN	101	2.60	2.52	1.6	0.2	12.3
		FINAL	101	3.69	4.86	2.5	0.4	41.3
		CHG FROM BSLN	101	1.09	4.12	0.4	-6.6	29.1
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	5	107.80	18.89	100.0	91.0	137.0
		FINAL	5	112.60	37.38	91.0	83.0	172.0
		CHG FROM BSLN	5	4.80	28.73	-8.0	-10.0	56.0
	INSULIN (UIU/ML)	BSLN	5	17.40	7.96	19.0	9.0	28.0
		FINAL	5	18.40	10.06	17.0	4.0	31.0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers
Safety Population

			PLACEBO					
			N=105					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	5	1.00	5.70	3.0	-6.0	7.0
	HOMA-R	BSLN	4	4.20	2.34	4.1	2.1	6.4
		FINAL	4	4.79	3.19	5.4	0.8	7.5
		CHG FROM BSLN	4	0.59	1.35	1.2	-1.4	1.5
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	27	87.63	12.33	86.0	63.0	113.0
		FINAL	27	90.96	15.62	88.0	66.0	147.0
		CHG FROM BSLN	27	3.33	13.54	1.0	-15.0	34.0
	INSULIN (UIU/ML)	BSLN	27	19.96	12.77	18.0	3.0	48.0
		FINAL	27	25.04	22.77	17.0	3.0	114.0
		CHG FROM BSLN	27	5.07	17.58	2.0	-24.0	70.0
	HOMA-R	BSLN	25	4.36	3.27	3.2	0.6	12.3
		FINAL	25	6.21	8.18	3.2	0.7	41.3
		CHG FROM BSLN	25	1.85	6.59	0.4	-6.6	29.1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO					
			N=105					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	73	83.07	7.76	83.0	60.0	98.0
		FINAL	73	86.37	13.73	86.0	58.0	156.0
		CHG FROM BSLN	73	3.30	13.92	1.0	-22.0	66.0
	INSULIN (UIU/ML)	BSLN	73	8.99	8.48	6.0	1.0	50.0
		FINAL	73	12.53	11.39	9.0	2.0	64.0
		CHG FROM BSLN	73	3.55	12.82	2.0	-28.0	62.0
	HOMA-R	BSLN	72	1.91	1.85	1.3	0.2	9.9
		FINAL	72	2.75	2.64	1.9	0.4	14.8
		CHG FROM BSLN	72	0.85	2.97	0.4	-6.2	14.5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=121						N=98					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	111	0.3489	0.0450	0.3422	0.2395	0.5402	92	0.3511	0.0370	0.3526	0.2371	0.4620
		FINAL	111	0.3401	0.0493	0.3396	0.2228	0.5317	92	0.3308	0.0538	0.3317	0.2071	0.5317
		CHG FROM BSLN	111	-0.0088	0.0449	-0.0045	-0.1541	0.1230	92	-0.0203	0.0469	-0.0217	-0.0980	0.1482
DIABETIC	QUICKI	BSLN	4	0.3054	0.0383	0.2971	0.2684	0.3591	5	0.3252	0.0337	0.3132	0.2993	0.3835
		FINAL	4	0.3003	0.0278	0.2984	0.2685	0.3358	5	0.3858	0.0898	0.3301	0.3248	0.5317
		CHG FROM BSLN	4	-0.0051	0.0133	-0.0026	-0.0233	0.0079	5	0.0606	0.0578	0.0255	0.0169	0.1482
DIABETIC RISK	QUICKI	BSLN	22	0.3130	0.0339	0.3231	0.2395	0.3673	18	0.3171	0.0325	0.3193	0.2371	0.3676
		FINAL	22	0.3105	0.0336	0.3022	0.2482	0.3950	18	0.2942	0.0433	0.2920	0.2071	0.3531
		CHG FROM BSLN	22	-0.0025	0.0449	-0.0138	-0.0646	0.1230	18	-0.0230	0.0223	-0.0254	-0.0634	0.0138
NON DIABETIC	QUICKI	BSLN	85	0.3602	0.0419	0.3591	0.2701	0.5402	69	0.3619	0.0321	0.3611	0.3020	0.4620
		FINAL	85	0.3496	0.0498	0.3480	0.2228	0.5317	69	0.3364	0.0482	0.3366	0.2228	0.5317
		CHG FROM BSLN	85	-0.0106	0.0461	-0.0037	-0.1541	0.0922	69	-0.0255	0.0459	-0.0252	-0.0980	0.1307

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.6 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO					
			N=105					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	QUICKI	BSLN	101	0.3577	0.0524	0.3550	0.2705	0.5420
		FINAL	101	0.3386	0.0413	0.3322	0.2367	0.4595
		CHG FROM BSLN	101	-0.0190	0.0519	-0.0164	-0.2027	0.0896
DIABETIC	QUICKI	BSLN	4	0.3168	0.0263	0.3166	0.2928	0.3411
		FINAL	4	0.3221	0.0515	0.3023	0.2870	0.3966
		CHG FROM BSLN	4	0.0053	0.0367	-0.0063	-0.0249	0.0587
DIABETIC RISK	QUICKI	BSLN	25	0.3233	0.0361	0.3216	0.2705	0.4192
		FINAL	25	0.3158	0.0381	0.3206	0.2367	0.4129
		CHG FROM BSLN	25	-0.0075	0.0321	-0.0166	-0.0580	0.0625
NON DIABETIC	QUICKI	BSLN	72	0.3719	0.0519	0.3666	0.2776	0.5420
		FINAL	72	0.3475	0.0390	0.3466	0.2646	0.4595
		CHG FROM BSLN	72	-0.0244	0.0573	-0.0165	-0.2027	0.0896

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			QUETIAPINE 300 MG N=157						QUETIAPINE 600 MG N=148					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	RANDOM GLUCOSE (MG/DL)	BSLN	156	86.56	12.77	85.0	58.0	174.0	148	85.93	11.67	85.0	52.0	130.0
		FINAL	156	89.74	14.41	87.5	62.0	156.0	148	91.82	18.72	88.5	63.0	177.0
		CHG FROM BSLN	156	3.19	13.47	2.5	-32.0	65.0	148	5.89	17.11	3.0	-40.0	72.0
	INSULIN (UIU/ML)	BSLN	156	14.38	17.33	10.0	1.0	147.0	143	11.61	15.11	8.0	2.0	165.0
		FINAL	156	20.65	29.59	12.5	1.0	225.0	143	25.15	46.67	13.0	1.0	392.0
		CHG FROM BSLN	156	6.27	27.60	1.0	-110.0	187.0	143	13.55	37.11	4.0	-25.0	331.0
	HOMA-R	BSLN	144	3.15	4.26	2.1	0.2	37.0	138	2.56	3.77	1.7	0.3	40.7
		FINAL	144	4.87	9.07	2.4	0.2	76.0	138	6.82	16.37	2.7	0.2	166.3
		CHG FROM BSLN	144	1.72	8.52	0.4	-29.9	68.5	138	4.26	13.33	1.1	-6.4	125.6
DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	6	104.83	41.02	85.0	71.0	174.0	5	97.80	18.67	91.0	81.0	122.0
		FINAL	6	107.50	33.53	94.0	71.0	156.0	5	99.40	32.39	86.0	76.0	155.0
		CHG FROM BSLN	6	2.67	19.41	9.0	-32.0	20.0	5	1.60	36.49	-5.0	-27.0	64.0
	INSULIN (UIU/ML)	BSLN	7	26.00	21.69	16.0	7.0	64.0	5	12.60	7.23	11.0	5.0	22.0
		FINAL	7	22.71	17.88	16.0	7.0	57.0	5	10.20	8.23	12.0	1.0	21.0

(Continued)

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM208.SAS
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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			QUETIAPINE 300 MG N=157						QUETIAPINE 600 MG N=148					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	7	-3.29	5.44	-1.0	-12.0	3.0	5	-2.40	9.32	-6.0	-8.0	14.0
	HOMA-R	BSLN	6	5.32	4.27	4.8	1.5	13.1	5	3.10	1.87	3.1	1.0	5.4
		FINAL	6	5.28	4.21	4.4	1.2	13.1	5	2.92	3.12	2.8	0.2	8.0
		CHG FROM BSLN	6	-0.05	0.76	-0.2	-1.1	0.8	5	-0.19	3.77	-1.7	-2.5	6.5
DIABETIC RISK	RANDOM GLUCOSE (MG/DL)	BSLN	27	88.93	11.99	88.0	58.0	110.0	21	87.67	12.77	86.0	64.0	129.0
		FINAL	27	93.96	15.10	93.0	68.0	127.0	21	99.52	28.03	89.0	69.0	177.0
		CHG FROM BSLN	27	5.04	13.12	6.0	-24.0	28.0	21	11.86	20.59	8.0	-16.0	72.0
	INSULIN (UIU/ML)	BSLN	27	25.70	32.06	15.0	6.0	147.0	20	27.30	34.64	19.5	7.0	165.0
		FINAL	27	36.37	35.45	23.0	8.0	172.0	20	59.20	84.74	31.5	8.0	392.0
		CHG FROM BSLN	27	10.67	42.52	5.0	-110.0	118.0	20	31.90	54.29	12.0	-25.0	227.0
	HOMA-R	BSLN	23	6.50	8.67	3.0	1.3	37.0	20	6.22	8.61	4.4	1.3	40.7
		FINAL	23	9.05	11.14	5.4	1.9	52.6	20	18.25	35.95	6.6	1.8	166.3
		CHG FROM BSLN	23	2.56	12.40	1.5	-29.9	38.9	20	12.04	27.94	2.9	-6.4	125.6

(Continued)

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM208.SAS
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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			QUETIAPINE 300 MG N=157						QUETIAPINE 600 MG N=148					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	123	85.15	9.38	84.0	62.0	121.0	122	85.14	10.95	84.0	52.0	130.0
		FINAL	123	87.95	12.10	86.0	62.0	137.0	122	90.18	15.68	88.0	63.0	175.0
		CHG FROM BSLN	123	2.80	13.33	2.0	-28.0	65.0	122	5.04	15.29	3.0	-40.0	63.0
	INSULIN (UIU/ML)	BSLN	122	11.20	9.68	8.0	1.0	58.0	118	8.91	5.57	7.0	2.0	40.0
		FINAL	122	17.05	27.69	10.0	1.0	225.0	118	20.02	35.23	12.0	1.0	350.0
		CHG FROM BSLN	122	5.84	24.00	1.0	-42.0	187.0	118	11.11	33.39	4.0	-8.0	331.0
	HOMA-R	BSLN	115	2.37	2.08	1.9	0.2	12.4	113	1.89	1.37	1.6	0.3	11.1
		FINAL	115	4.01	8.61	2.2	0.2	76.0	113	4.97	8.99	2.4	0.2	76.0
		CHG FROM BSLN	115	1.65	7.81	0.2	-10.9	68.5	113	3.08	8.45	0.9	-2.2	72.8

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM208.SAS
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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			PLACEBO					
			N=152					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	RANDOM GLUCOSE (MG/DL)	BSLN	152	86.68	14.94	84.0	60.0	192.0
		FINAL	152	90.47	30.34	86.0	58.0	410.0
		CHG FROM BSLN	152	3.80	25.60	1.0	-99.0	247.0
	INSULIN (UIU/ML)	BSLN	151	14.19	25.05	8.0	1.0	281.0
		FINAL	151	15.81	14.89	12.0	2.0	114.0
		CHG FROM BSLN	151	1.62	26.49	2.0	-259.0	70.0
	HOMA-R	BSLN	144	3.56	11.24	1.8	0.2	133.1
		FINAL	144	3.62	4.45	2.4	0.4	41.3
		CHG FROM BSLN	144	0.06	11.59	0.3	-128.1	29.1
DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	6	126.17	41.68	108.0	91.0	192.0
		FINAL	6	156.50	128.57	92.0	83.0	410.0
		CHG FROM BSLN	6	30.33	117.14	-6.0	-99.0	247.0
	INSULIN (UIU/ML)	BSLN	5	69.80	118.33	21.0	9.0	281.0
		FINAL	5	18.00	9.82	17.0	4.0	31.0

(Continued)

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM208.SAS
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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			PLACEBO					
			N=152					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	5	-51.80	115.95	-4.0	-259.0	7.0
	HOMA-R	BSLN	4	35.87	64.85	4.1	2.1	133.1
		FINAL	4	4.17	2.68	4.3	0.8	7.2
		CHG FROM BSLN	4	-31.70	64.25	-0.1	-128.1	1.5
DIABETIC RISK	RANDOM GLUCOSE (MG/DL)	BSLN	30	87.37	14.13	85.5	63.0	137.0
		FINAL	30	89.77	12.68	87.5	66.0	127.0
		CHG FROM BSLN	30	2.40	11.31	1.0	-15.0	30.0
	INSULIN (UIU/ML)	BSLN	30	20.80	11.92	18.5	3.0	48.0
		FINAL	30	23.03	13.17	24.0	5.0	71.0
		CHG FROM BSLN	30	2.23	14.07	3.0	-34.0	25.0
	HOMA-R	BSLN	28	4.50	2.83	4.0	0.6	11.5
		FINAL	28	5.15	3.41	4.4	1.0	16.8
		CHG FROM BSLN	28	0.64	3.64	0.8	-6.6	7.3

(Continued)

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM208.SAS
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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			PLACEBO					
			N=152					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	116	84.46	8.98	83.5	60.0	113.0
		FINAL	116	87.24	14.55	86.0	58.0	156.0
		CHG FROM BSLN	116	2.78	13.90	1.0	-24.0	66.0
	INSULIN (UIU/ML)	BSLN	116	10.09	11.53	7.0	1.0	97.0
		FINAL	116	13.85	14.99	9.0	2.0	114.0
		CHG FROM BSLN	116	3.77	16.39	2.0	-86.0	70.0
	HOMA-R	BSLN	112	2.17	2.73	1.5	0.2	23.0
		FINAL	112	3.22	4.66	2.0	0.4	41.3
		CHG FROM BSLN	112	1.05	4.56	0.3	-20.8	29.1

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM208.SAS
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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=157						N=148					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	144	0.3463	0.0433	0.3405	0.2395	0.5402	138	0.3525	0.0381	0.3529	0.2371	0.4660
		FINAL	144	0.3358	0.0466	0.3338	0.2228	0.5317	138	0.3299	0.0515	0.3294	0.2071	0.5317
		CHG FROM BSLN	144	-0.0106	0.0426	-0.0075	-0.1541	0.1230	138	-0.0227	0.0460	-0.0237	-0.1243	0.1482
DIABETIC	QUICKI	BSLN	6	0.3147	0.0364	0.3041	0.2684	0.3591	5	0.3339	0.0354	0.3232	0.2993	0.3835
		FINAL	6	0.3142	0.0355	0.3078	0.2685	0.3709	5	0.3768	0.0987	0.3280	0.2847	0.5317
		CHG FROM BSLN	6	-0.0005	0.0128	0.0023	-0.0233	0.0131	5	0.0428	0.0828	0.0255	-0.0719	0.1482
DIABETIC RISK	QUICKI	BSLN	23	0.3144	0.0328	0.3239	0.2395	0.3673	20	0.3145	0.0337	0.3076	0.2371	0.3676
		FINAL	23	0.2983	0.0308	0.2995	0.2310	0.3466	20	0.2886	0.0388	0.2919	0.2071	0.3487
		CHG FROM BSLN	23	-0.0161	0.0295	-0.0181	-0.0646	0.0514	20	-0.0260	0.0212	-0.0254	-0.0749	0.0239
NON DIABETIC	QUICKI	BSLN	115	0.3544	0.0420	0.3474	0.2701	0.5402	113	0.3601	0.0347	0.3571	0.2739	0.4660
		FINAL	115	0.3444	0.0459	0.3396	0.2228	0.5317	113	0.3351	0.0470	0.3344	0.2228	0.5317
		CHG FROM BSLN	115	-0.0100	0.0457	-0.0044	-0.1541	0.1230	113	-0.0250	0.0455	-0.0252	-0.1243	0.1307

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

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Table 11.3.7.1.2.3.7 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose)
Safety Population

			PLACEBO					
			N=152					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	QUICKI	BSLN	144	0.3542	0.0501	0.3496	0.2113	0.5420
		FINAL	144	0.3384	0.0405	0.3354	0.2367	0.4595
		CHG FROM BSLN	144	-0.0158	0.0496	-0.0131	-0.2027	0.0907
DIABETIC	QUICKI	BSLN	4	0.2964	0.0604	0.3166	0.2113	0.3411
		FINAL	4	0.3258	0.0485	0.3091	0.2885	0.3966
		CHG FROM BSLN	4	0.0294	0.0544	0.0260	-0.0249	0.0907
DIABETIC RISK	QUICKI	BSLN	28	0.3195	0.0346	0.3121	0.2726	0.4192
		FINAL	28	0.3110	0.0267	0.3078	0.2609	0.3820
		CHG FROM BSLN	28	-0.0085	0.0323	-0.0112	-0.0625	0.0701
NON DIABETIC	QUICKI	BSLN	112	0.3650	0.0480	0.3592	0.2519	0.5420
		FINAL	112	0.3457	0.0404	0.3447	0.2367	0.4595
		CHG FROM BSLN	112	-0.0192	0.0523	-0.0145	-0.2027	0.0896

Rapid Cyclers include those with a diagnosis of >=4 manic or depressive episodes in the past year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM208.SAS
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Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=121						QUETIAPINE 600 MG N=98					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	RANDOM GLUCOSE (MG/DL)	BSLN	121	85.69	10.53	85.0	58.0	136.0	98	85.10	11.63	85.0	52.0	130.0
		FINAL	121	88.93	13.63	86.0	62.0	156.0	98	90.23	15.61	88.0	63.0	172.0
		CHG FROM BSLN	121	3.25	14.18	3.0	-28.0	65.0	98	5.13	15.07	3.5	-27.0	72.0
	INSULIN (UIU/ML)	BSLN	120	14.40	18.88	9.0	1.0	147.0	96	12.13	17.28	8.0	2.0	165.0
		FINAL	120	20.07	29.42	11.0	1.0	225.0	96	27.04	54.43	12.0	1.0	392.0
		CHG FROM BSLN	120	5.67	28.85	1.0	-110.0	187.0	96	14.92	42.78	4.0	-8.0	331.0
	HOMA-R	BSLN	111	3.16	4.65	2.1	0.2	37.0	92	2.66	4.31	1.7	0.4	40.7
		FINAL	111	4.59	8.82	2.2	0.2	76.0	92	7.31	19.17	2.6	0.2	166.3
		CHG FROM BSLN	111	1.43	8.74	0.2	-29.9	68.5	92	4.65	15.48	1.1	-2.5	125.6
DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	4	94.25	28.65	85.0	71.0	136.0	4	99.50	21.11	97.5	81.0	122.0
		FINAL	4	108.00	32.14	94.0	88.0	156.0	4	85.50	10.50	83.0	76.0	100.0
		CHG FROM BSLN	4	13.75	5.68	13.5	8.0	20.0	4	-14.00	12.36	-13.5	-27.0	-2.0
	INSULIN (UIU/ML)	BSLN	4	30.50	25.20	25.5	7.0	64.0	4	14.00	7.53	14.5	5.0	22.0
		FINAL	4	26.50	21.02	19.5	10.0	57.0	4	7.50	6.45	7.5	1.0	14.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM209.SAS
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Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=121						N=98					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	4	-4.00	6.78	-3.5	-12.0	3.0	4	-6.50	1.91	-7.0	-8.0	-4.0
	HOMA-R	BSLN	4	6.53	4.83	5.7	1.5	13.1	4	3.48	1.92	3.8	1.0	5.4
		FINAL	4	6.64	4.58	5.6	2.3	13.1	4	1.64	1.43	1.7	0.2	3.0
		CHG FROM BSLN	4	0.12	0.93	0.4	-1.1	0.8	4	-1.85	0.78	-2.1	-2.5	-0.8
DIABETIC RISK	RANDOM GLUCOSE (MG/DL)	BSLN	20	88.05	12.04	87.0	58.0	107.0	15	86.33	9.24	86.0	64.0	102.0
		FINAL	20	91.55	14.54	87.0	68.0	127.0	15	97.47	25.20	89.0	69.0	172.0
		CHG FROM BSLN	20	3.50	13.50	5.0	-24.0	28.0	15	11.13	21.10	8.0	-16.0	72.0
	INSULIN (UIU/ML)	BSLN	20	26.95	36.43	14.5	6.0	147.0	14	29.79	40.31	22.5	7.0	165.0
		FINAL	20	32.55	24.18	23.5	8.0	101.0	14	67.71	98.21	35.5	8.0	392.0
		CHG FROM BSLN	20	5.60	41.94	5.0	-110.0	72.0	14	37.93	59.04	17.5	0.0	227.0
	HOMA-R	BSLN	17	6.95	9.82	3.0	1.3	37.0	14	6.77	10.04	4.9	1.3	40.7
		FINAL	17	7.22	5.97	5.4	1.9	26.4	14	21.50	42.50	7.5	1.8	166.3
		CHG FROM BSLN	17	0.27	10.82	1.5	-29.9	16.1	14	14.73	32.58	4.0	0.2	125.6

(Continued)

Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=121						N=98					
			N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT												
NON DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	97	84.85	8.91	84.0	62.0	106.0	79	84.14	11.13	84.0	52.0	130.0
		FINAL	97	87.61	11.82	86.0	62.0	137.0	79	89.10	13.13	88.0	63.0	139.0
		CHG FROM BSLN	97	2.76	14.47	2.0	-28.0	65.0	79	4.96	13.07	4.0	-23.0	57.0
	INSULIN (UIU/ML)	BSLN	96	11.11	10.30	8.0	1.0	58.0	78	8.86	4.92	7.5	2.0	23.0
		FINAL	96	17.20	30.17	9.0	1.0	225.0	78	20.74	40.80	11.5	1.0	350.0
		CHG FROM BSLN	96	6.08	26.17	0.0	-42.0	187.0	78	11.88	39.24	4.0	-8.0	331.0
	HOMA-R	BSLN	90	2.30	2.15	1.6	0.2	12.4	74	1.84	1.05	1.6	0.4	5.1
		FINAL	90	4.00	9.34	1.9	0.2	76.0	74	4.93	9.52	2.4	0.2	76.0
		CHG FROM BSLN	90	1.70	8.54	0.1	-10.9	68.5	74	3.09	9.25	1.0	-2.0	72.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM209.SAS
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Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers Safety Population

			PLACEBO					
			N=105					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	RANDOM GLUCOSE (MG/DL)	BSLN	105	85.42	11.07	84.0	60.0	137.0
		FINAL	105	88.80	16.67	87.0	58.0	172.0
		CHG FROM BSLN	105	3.38	14.55	1.0	-22.0	66.0
	INSULIN (UIU/ML)	BSLN	105	12.21	10.82	8.0	1.0	50.0
		FINAL	105	16.03	15.92	12.0	2.0	114.0
		CHG FROM BSLN	105	3.82	13.90	2.0	-28.0	70.0
	HOMA-R	BSLN	101	2.60	2.52	1.6	0.2	12.3
		FINAL	101	3.69	4.86	2.5	0.4	41.3
		CHG FROM BSLN	101	1.09	4.12	0.4	-6.6	29.1
DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	4	100.50	10.97	97.5	91.0	116.0
		FINAL	4	109.00	42.15	90.5	83.0	172.0
		CHG FROM BSLN	4	8.50	31.76	-6.0	-10.0	56.0
	INSULIN (UIU/ML)	BSLN	4	17.00	9.13	15.5	9.0	28.0
		FINAL	4	17.00	11.05	16.5	4.0	31.0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM209.SAS
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Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers Safety Population

			PLACEBO					
			N=105					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (UIU/ML)	CHG FROM BSLN	4	0.00	6.06	-0.5	-6.0	7.0
	HOMA-R	BSLN	3	3.45	2.21	2.2	2.1	6.0
		FINAL	3	3.88	3.21	3.6	0.8	7.2
		CHG FROM BSLN	3	0.42	1.60	1.2	-1.4	1.5
DIABETIC RISK	RANDOM GLUCOSE (MG/DL)	BSLN	25	87.36	14.82	86.0	63.0	137.0
		FINAL	25	90.04	13.60	88.0	66.0	127.0
		CHG FROM BSLN	25	2.68	12.22	1.0	-15.0	30.0
	INSULIN (UIU/ML)	BSLN	25	19.96	11.82	18.0	3.0	48.0
		FINAL	25	23.12	13.83	24.0	5.0	71.0
		CHG FROM BSLN	25	3.16	12.22	4.0	-24.0	23.0
	HOMA-R	BSLN	23	4.31	2.90	3.8	0.6	11.5
		FINAL	23	5.19	3.65	3.7	1.0	16.8
		CHG FROM BSLN	23	0.88	3.46	1.1	-6.6	7.3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM209.SAS
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Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers
Safety Population

			PLACEBO					
			N=105					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	RANDOM GLUCOSE (MG/DL)	BSLN	76	83.99	8.92	83.0	60.0	113.0
		FINAL	76	87.33	15.19	86.0	58.0	156.0
		CHG FROM BSLN	76	3.34	14.28	1.0	-22.0	66.0
	INSULIN (UIU/ML)	BSLN	76	9.41	9.23	6.0	1.0	50.0
		FINAL	76	13.64	16.20	9.0	2.0	114.0
		CHG FROM BSLN	76	4.24	14.75	2.0	-28.0	70.0
	HOMA-R	BSLN	75	2.04	2.17	1.3	0.2	12.3
		FINAL	75	3.22	5.17	1.8	0.4	41.3
		CHG FROM BSLN	75	1.18	4.38	0.3	-6.2	29.1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM209.SAS
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Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=121						N=98					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	111	0.3489	0.0450	0.3422	0.2395	0.5402	92	0.3511	0.0370	0.3526	0.2371	0.4620
		FINAL	111	0.3401	0.0493	0.3396	0.2228	0.5317	92	0.3308	0.0538	0.3317	0.2071	0.5317
		CHG FROM BSLN	111	-0.0088	0.0449	-0.0045	-0.1541	0.1230	92	-0.0203	0.0469	-0.0217	-0.0980	0.1482
DIABETIC	QUICKI	BSLN	4	0.3054	0.0383	0.2971	0.2684	0.3591	4	0.3283	0.0382	0.3151	0.2993	0.3835
		FINAL	4	0.3003	0.0278	0.2984	0.2685	0.3358	4	0.3998	0.0973	0.3713	0.3248	0.5317
		CHG FROM BSLN	4	-0.0051	0.0133	-0.0026	-0.0233	0.0079	4	0.0715	0.0604	0.0585	0.0208	0.1482
DIABETIC RISK	QUICKI	BSLN	17	0.3153	0.0354	0.3248	0.2395	0.3673	14	0.3143	0.0362	0.3032	0.2371	0.3676
		FINAL	17	0.2998	0.0272	0.2992	0.2482	0.3466	14	0.2871	0.0417	0.2873	0.2071	0.3487
		CHG FROM BSLN	17	-0.0155	0.0334	-0.0207	-0.0646	0.0514	14	-0.0273	0.0156	-0.0294	-0.0501	-0.0047
NON DIABETIC	QUICKI	BSLN	90	0.3571	0.0431	0.3550	0.2701	0.5402	74	0.3593	0.0325	0.3572	0.3020	0.4620
		FINAL	90	0.3494	0.0487	0.3477	0.2228	0.5317	74	0.3353	0.0476	0.3354	0.2228	0.5317
		CHG FROM BSLN	90	-0.0077	0.0478	-0.0029	-0.1541	0.1230	74	-0.0240	0.0454	-0.0230	-0.0980	0.1307

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM209.SAS
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Table 11.3.7.1.2.3.8 Glucose and Insulin Descriptive Statistics by Diabetic Status (Random Glucose) for Completers Safety Population

			PLACEBO N=105					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	101	0.3577	0.0524	0.3550	0.2705	0.5420
		FINAL	101	0.3386	0.0413	0.3322	0.2367	0.4595
		CHG FROM BSLN	101	-0.0190	0.0519	-0.0164	-0.2027	0.0896
DIABETIC	QUICKI	BSLN	3	0.3248	0.0256	0.3379	0.2953	0.3411
		FINAL	3	0.3338	0.0562	0.3161	0.2885	0.3966
		CHG FROM BSLN	3	0.0090	0.0440	-0.0068	-0.0249	0.0587
DIABETIC RISK	QUICKI	BSLN	23	0.3223	0.0359	0.3135	0.2726	0.4192
		FINAL	23	0.3113	0.0273	0.3147	0.2609	0.3820
		CHG FROM BSLN	23	-0.0110	0.0282	-0.0166	-0.0580	0.0483
NON DIABETIC	QUICKI	BSLN	75	0.3698	0.0523	0.3660	0.2705	0.5420
		FINAL	75	0.3472	0.0411	0.3480	0.2367	0.4595
		CHG FROM BSLN	75	-0.0226	0.0574	-0.0164	-0.2027	0.0896

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM209.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Analysis (ANCOVA)
Safety Population

			BASELINE		ASSESSMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
RANDOM GLUCOSE (MG/DL)	TREATMENT										
	Q300MG	156	259.7	38.32	9.6	40.42	24.50	6.646	11.42	37.58	.
	Q600MG	148	257.8	35.01	17.7	51.32	32.67	6.805	19.28	46.07	.
	P	152	260.0	44.81	11.4	76.79	26.15	6.642	13.08	39.22	.
	Q300MG VS Q600MG	.	.	.	.	.	-2.72	2.194	-7.04	1.59	0.215
	Q300MG VS P	.	.	.	.	.	-0.55	2.179	-4.83	3.73	0.801
	Q600MG VS P	.	.	.	.	.	2.18	2.212	-2.17	6.52	0.326
INSULIN (UIU/ML) (LOG 10 TRANSFORMED)	Q300MG	156	6.9	2.35	7.7	2.71	7.46	0.255	6.96	7.96	.
	Q600MG	143	6.5	2.03	7.9	2.94	7.97	0.263	7.46	8.49	.
	P	151	6.6	2.57	7.3	2.34	7.27	0.256	6.76	7.77	.
	Q300MG VS Q600MG	.	.	.	.	.	-0.17	0.086	-0.34	-0.00	0.046
	Q300MG VS P	.	.	.	.	.	0.06	0.085	-0.10	0.23	0.450
	Q600MG VS P	.	.	.	.	.	0.24	0.086	0.07	0.41	0.007
HOMA-R	Q300MG	144	9.4	12.78	14.6	27.21	13.01	3.728	5.68	20.34	.
	Q600MG	138	7.7	11.32	20.5	49.11	19.75	3.790	12.30	27.20	.
	P	144	10.7	33.73	10.9	13.35	8.03	3.794	0.57	15.49	.
	Q300MG VS Q600MG	.	.	.	.	.	-2.25	1.236	-4.68	0.18	0.070

(Continued)

Assessment: Glucose - change from baseline, all others - final assessment.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CHEM210.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Analysis (ANCOVA)
Safety Population

			BASELINE		ASSESSMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
HOMA-R	TREATMENT										
	Q300MG VS P	.	.	.	.	.	1.66	1.224	-0.75	4.06	0.176
	Q600MG VS P	.	.	.	.	.	3.91	1.239	1.47	6.34	0.002

Assessment: Glucose - change from baseline, all others - final assessment.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CHEM210.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Analysis (ANCOVA)
Safety Population

			BASELINE		ASSESSMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
QUICKI	TREATMENT										
	Q300MG	144	1.0390	0.1299	1.0073	0.1399	1.0159	0.0144	0.9876	1.0443	.
	Q600MG	138	1.0576	0.1142	0.9897	0.1544	0.9893	0.0146	0.9606	1.0179	.
	P	144	1.0627	0.1503	1.0153	0.1216	1.0163	0.0143	0.9881	1.0445	.
	Q300MG VS Q600MG	.	.	.	.	.	0.0089	0.0048	-0.0005	0.0182	0.062
	Q300MG VS P	.	.	.	.	.	-0.0001	0.0047	-0.0094	0.0091	0.978
	Q600MG VS P	.	.	.	.	.	-0.0090	0.0048	-0.0184	0.0003	0.059

Assessment: Glucose - change from baseline, all others - final assessment.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CHEM210.SAS
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FIGURE 11.3.7.1.2.4.1 SHIFT PLOT: AST (U/L)

(SAFETY)

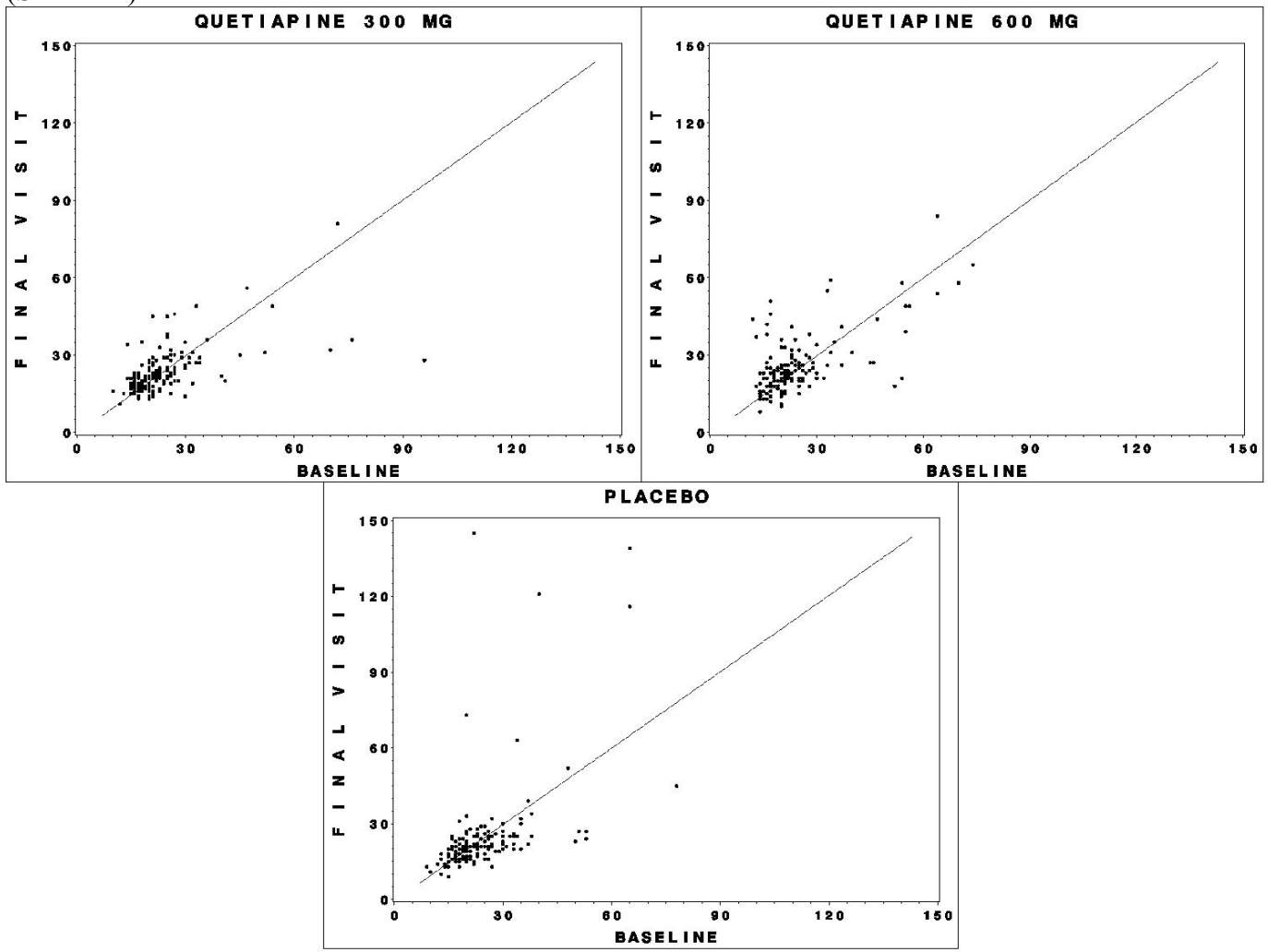

FIGURE 11.3.7.1.2.4.2 SHIFT PLOT: ALT (U/L)

(SAFETY)

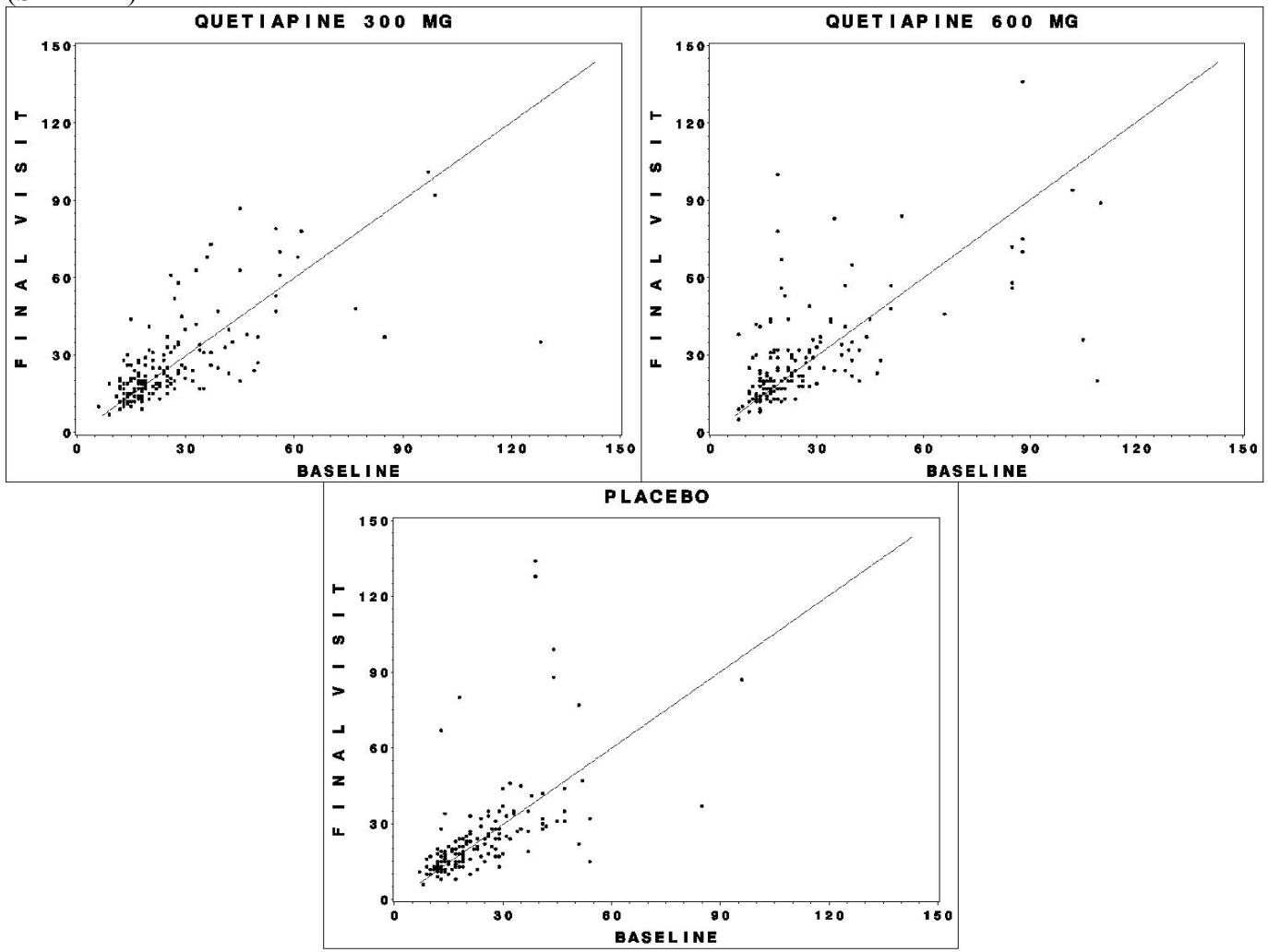

FIGURE 11.3.7.1.2.4.3 SHIFT PLOT: CREATININE (MG/DL)

(SAFETY)

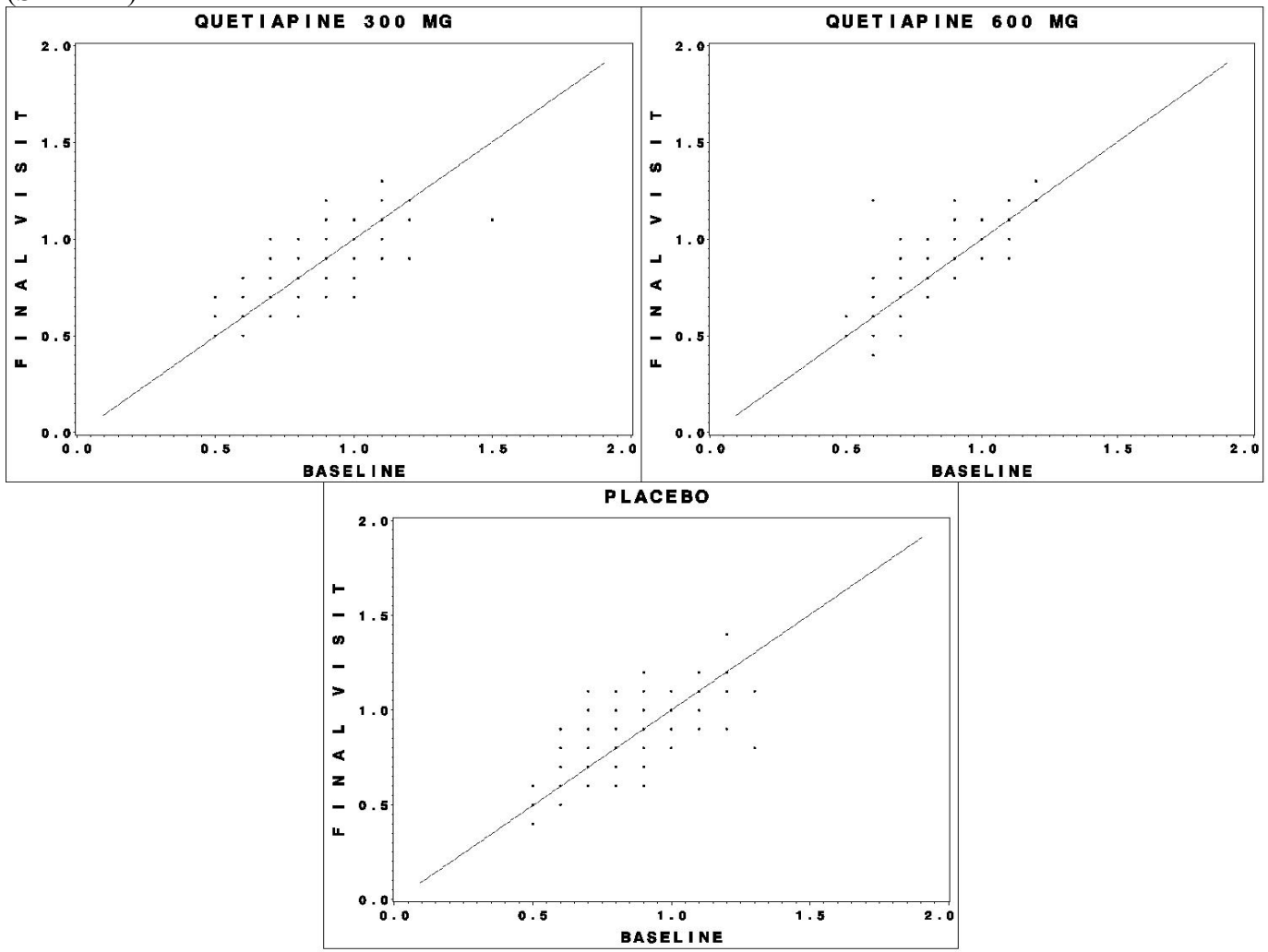

FIGURE 11.3.7.1.2.4.4 SHIFT PLOT: GLUCOSE (MG/DL)

(SAFETY)

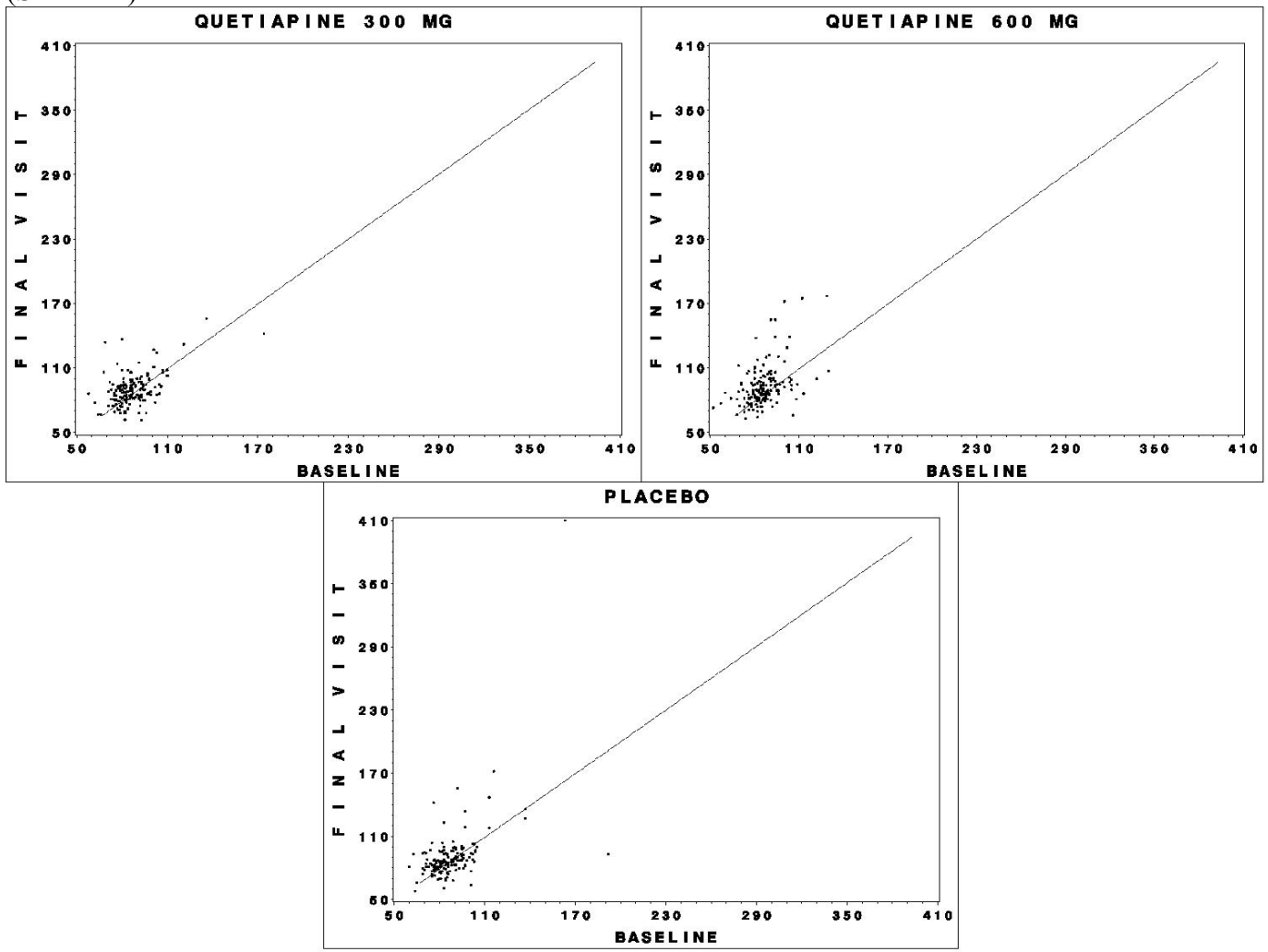

FIGURE 11.3.7.1.2.4.5 SHIFT PLOT: TSH (MIU/L)

(SAFETY)

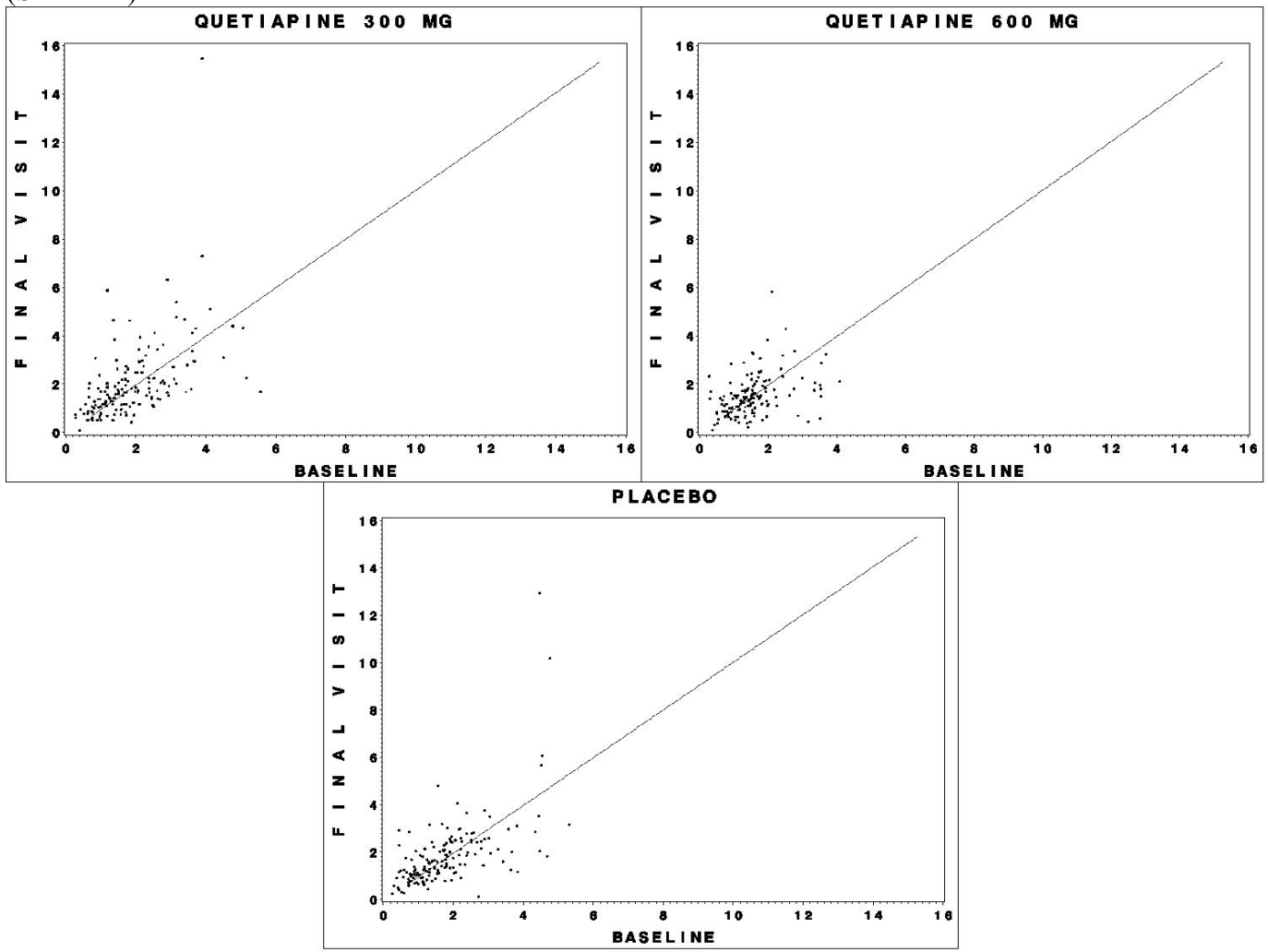

FIGURE 11.3.7.1.2.4.6 SHIFT PLOT: THYROXINE - T4 (NMOL/L)

(SAFETY)

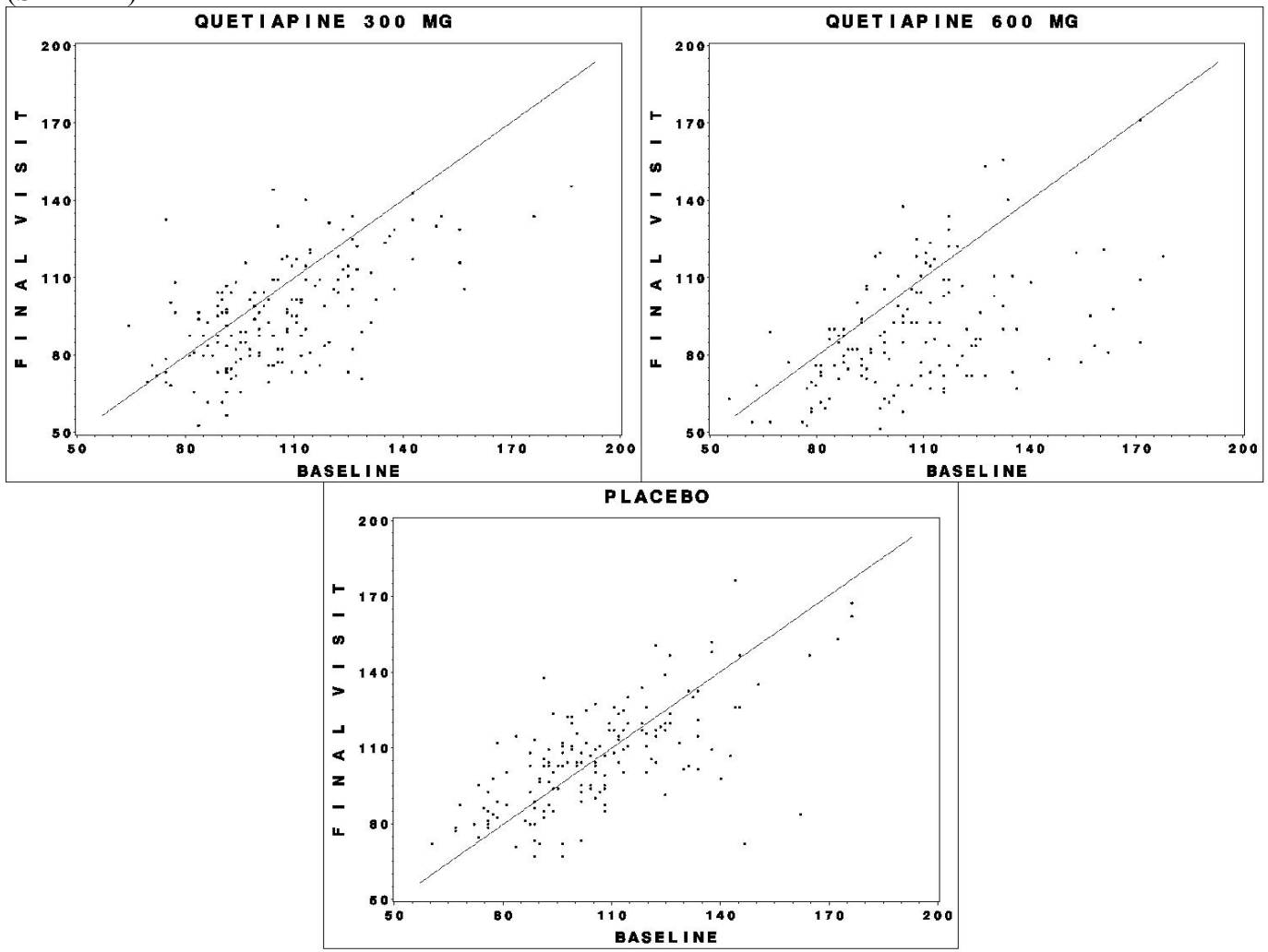

FIGURE 11.3.7.1.2.4.7 SHIFT PLOT: SODIUM (MEQ/L)

(SAFETY)

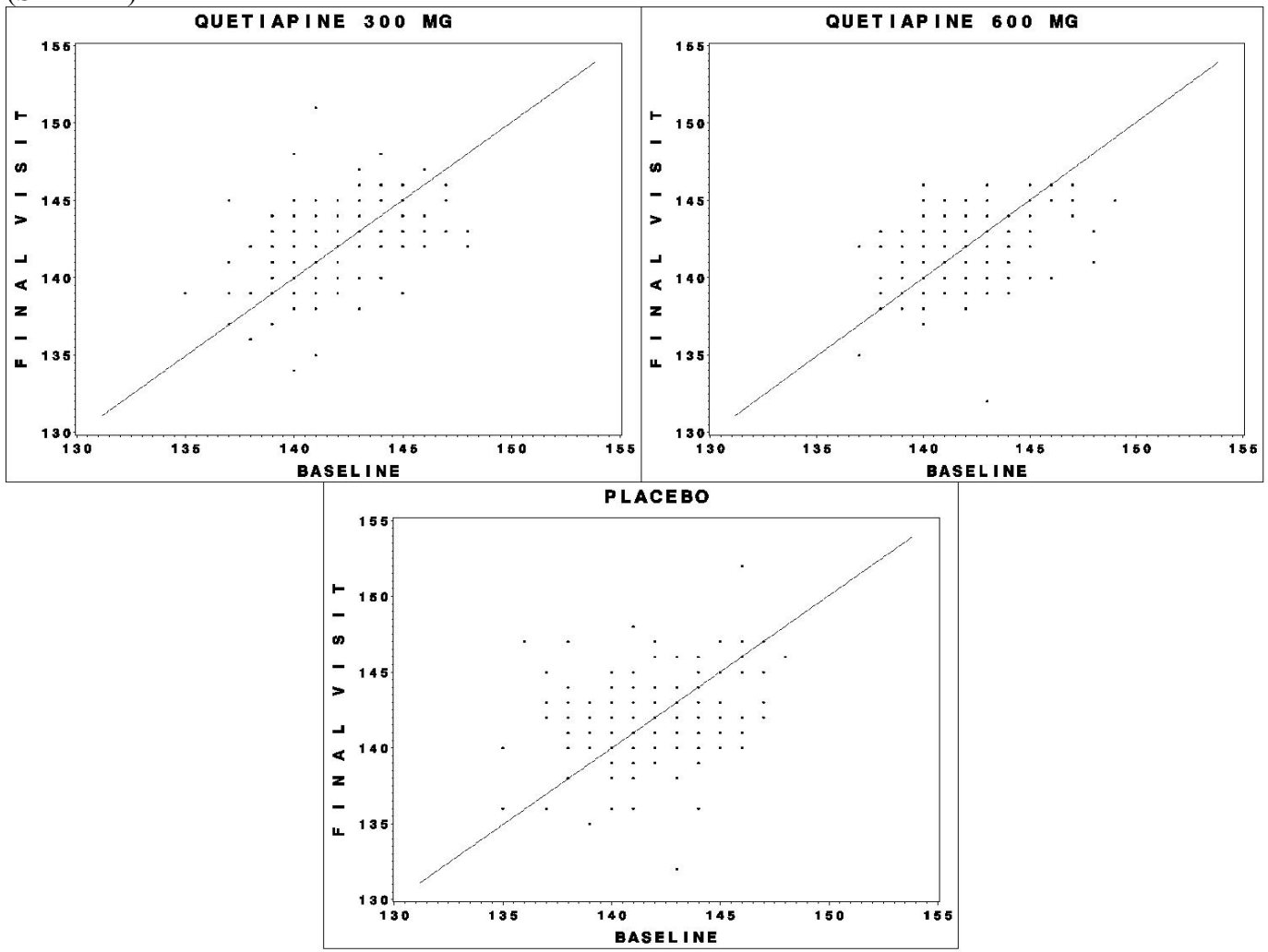

FIGURE 11.3.7.1.2.4.8 SHIFT PLOT: POTASSIUM (MEQ/L)

(SAFETY)

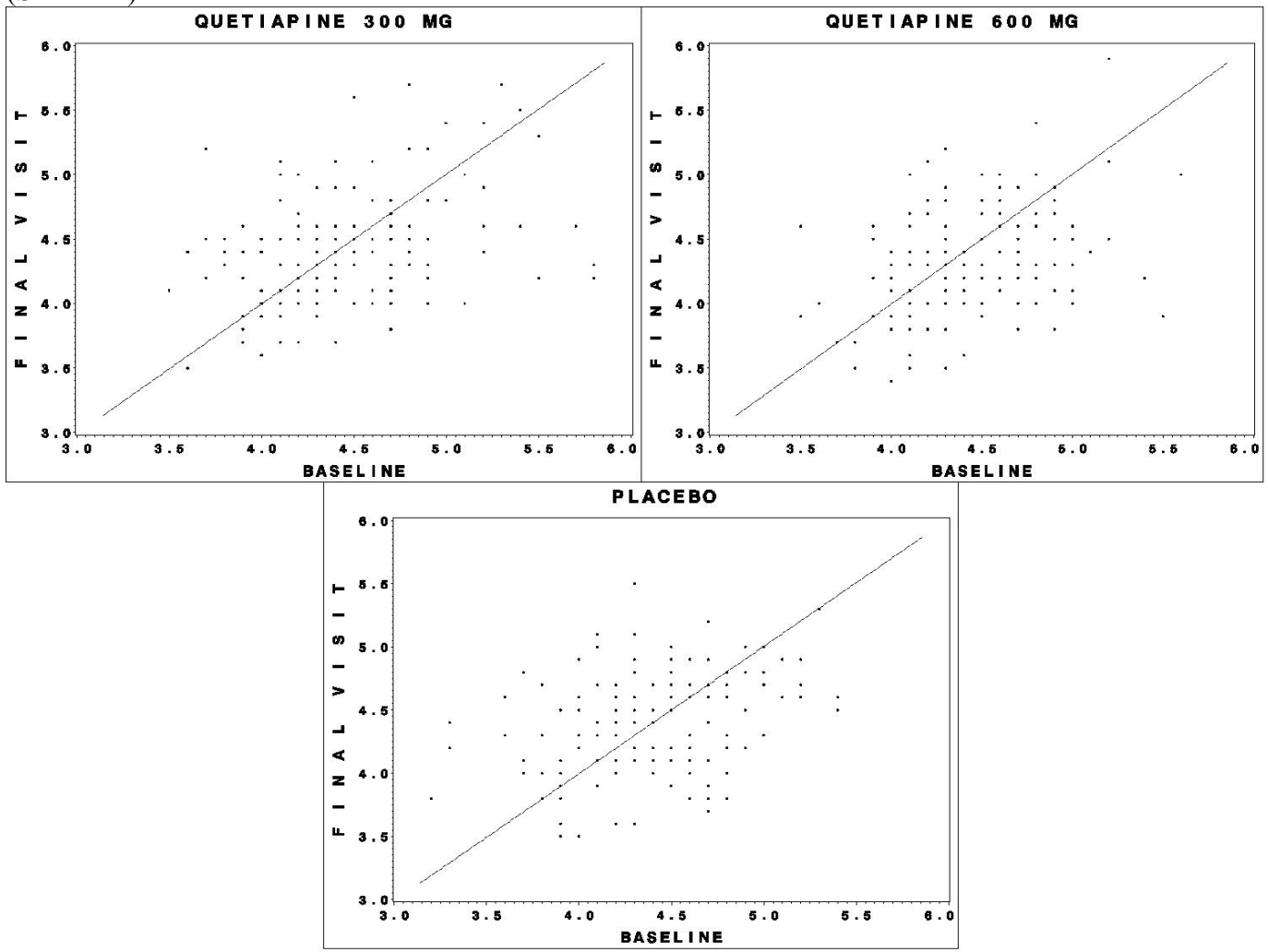

FIGURE 11.3.7.1.2.4.9 SHIFT PLOT: CHLORIDE (MEQ/L)

(SAFETY)

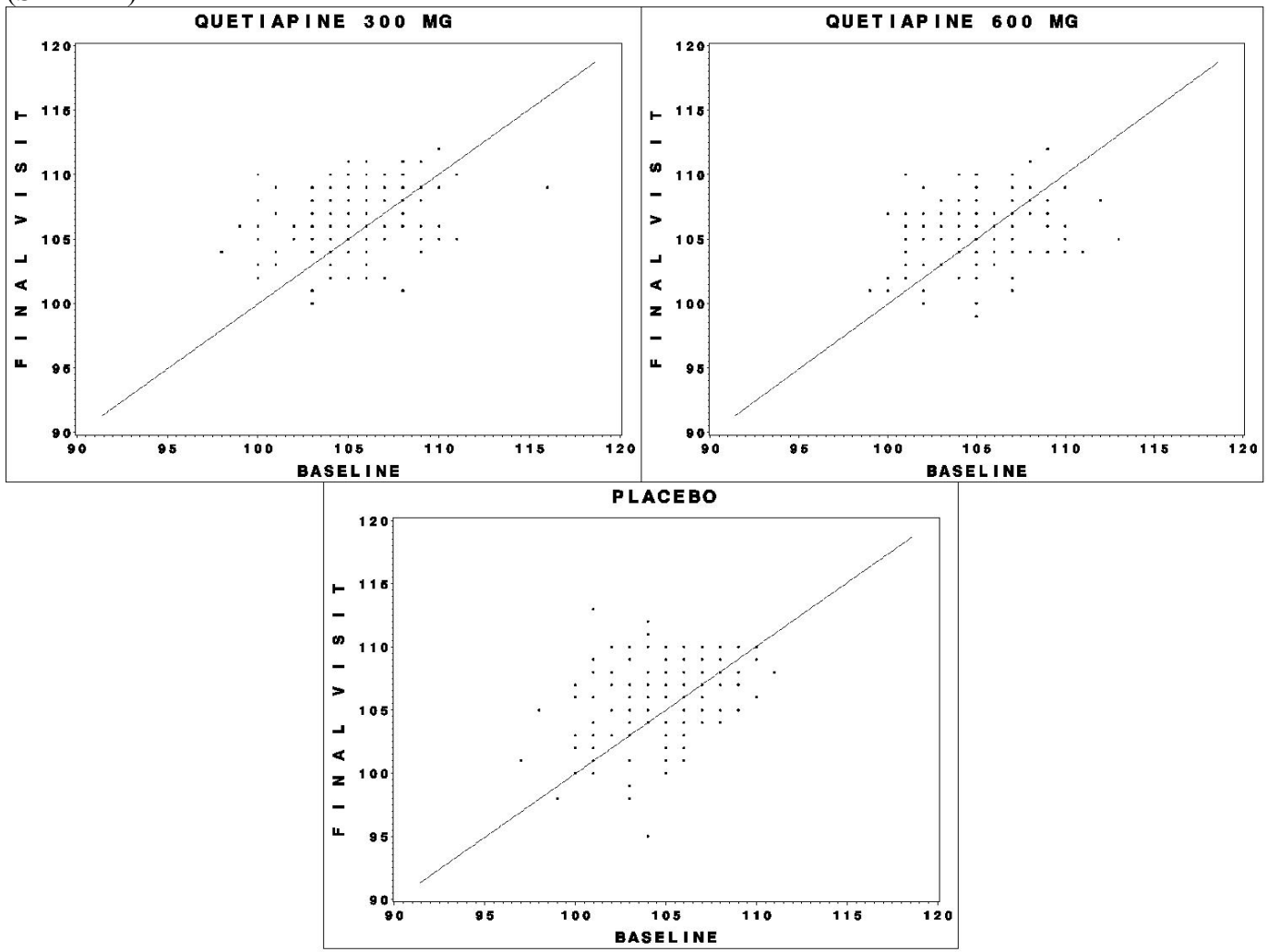

FIGURE 11.3.7.1.2.4.10 SHIFT PLOT: BICARBONATE (MEQ/L)

(SAFETY)

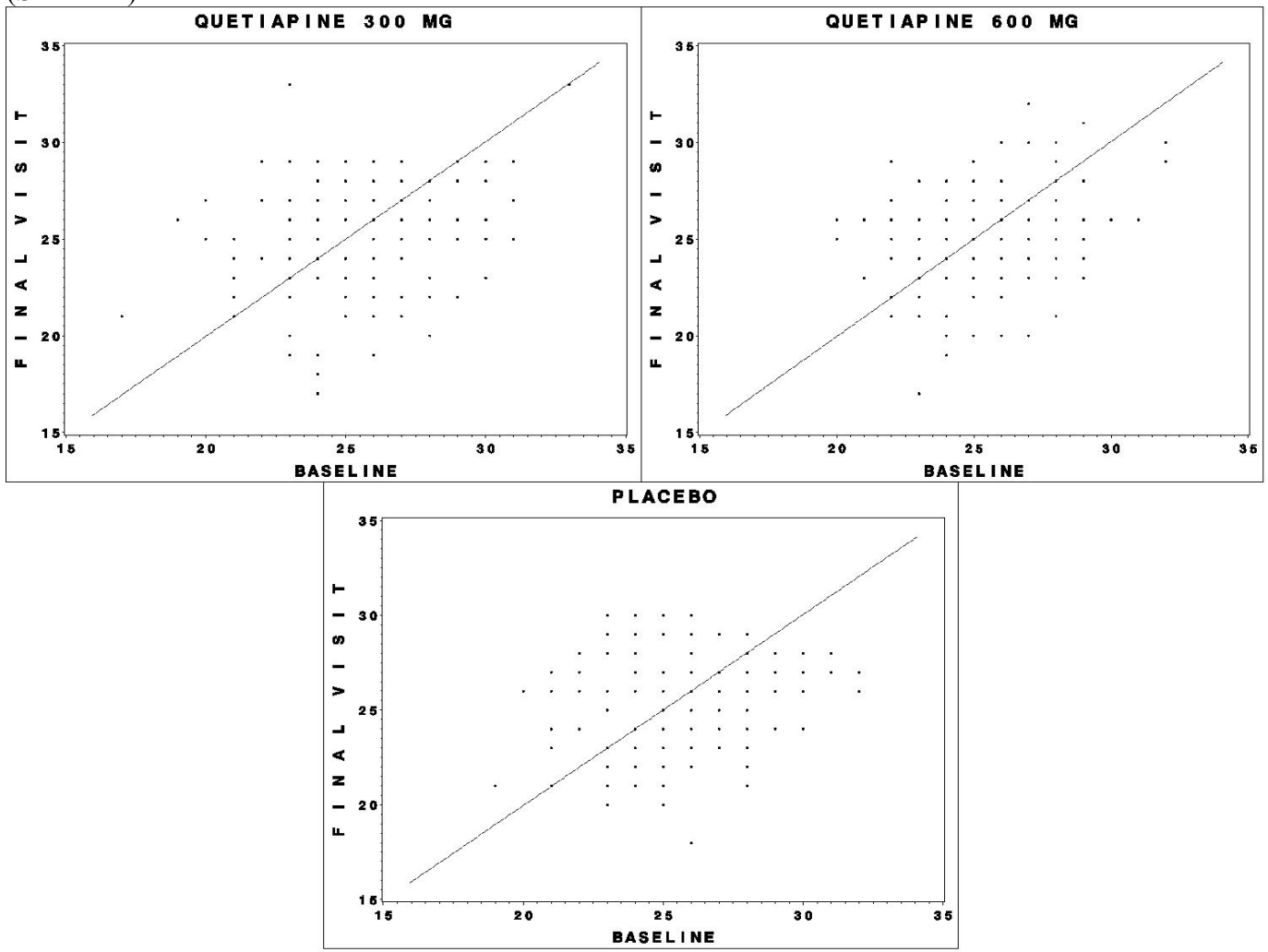

FIGURE 11.3.7.1.2.4.11 CUMULATIVE PERCENTAGE OF PATIENTS BY TIME OF BLOOD SAMPLING FOR CLINICAL LABS (BASELINE)

(SAFETY)

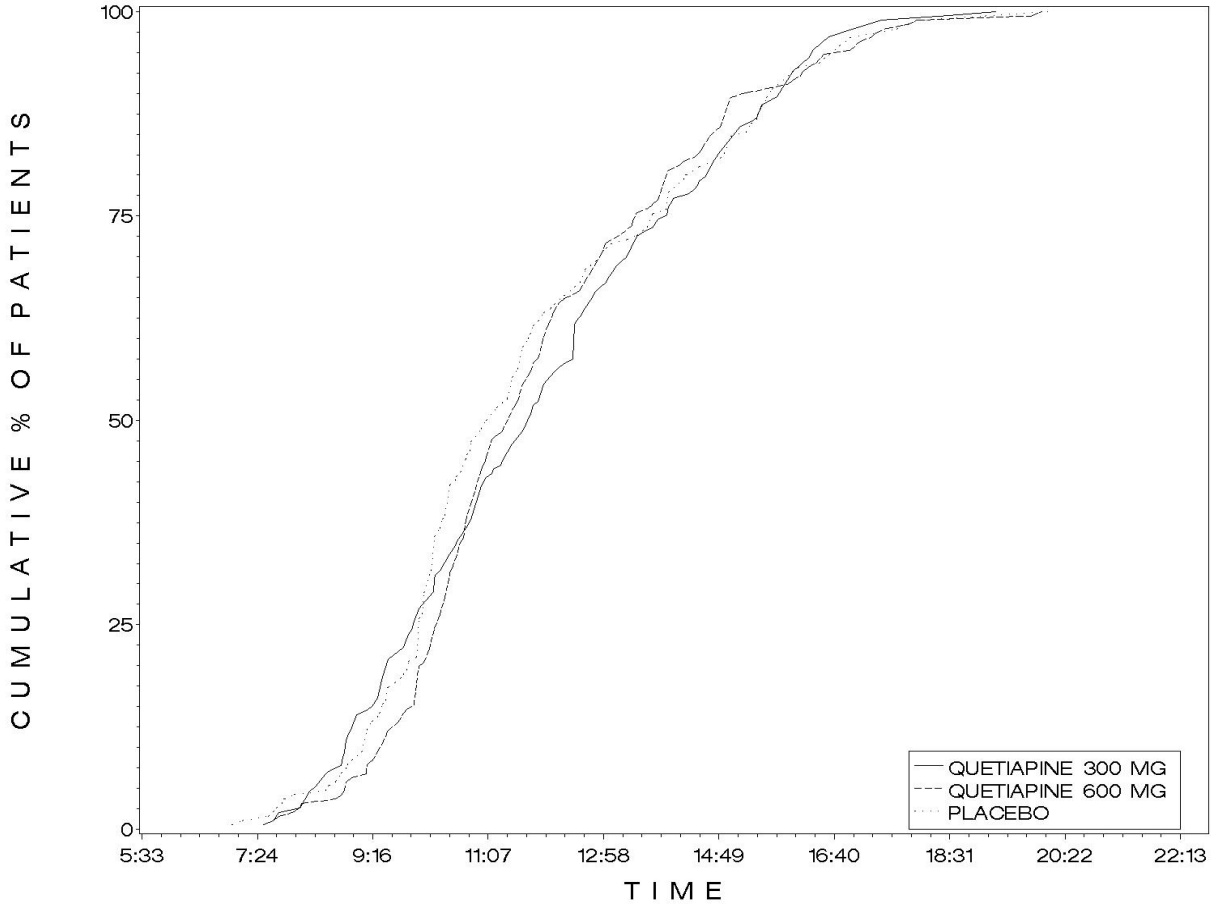

FIGURE 11.3.7.1.2.4.12 CUMULATIVE PERCENTAGE OF PATIENTS BY TIME OF BLOOD SAMPLING FOR CLINICAL LABS (FINAL)

(SAFETY)

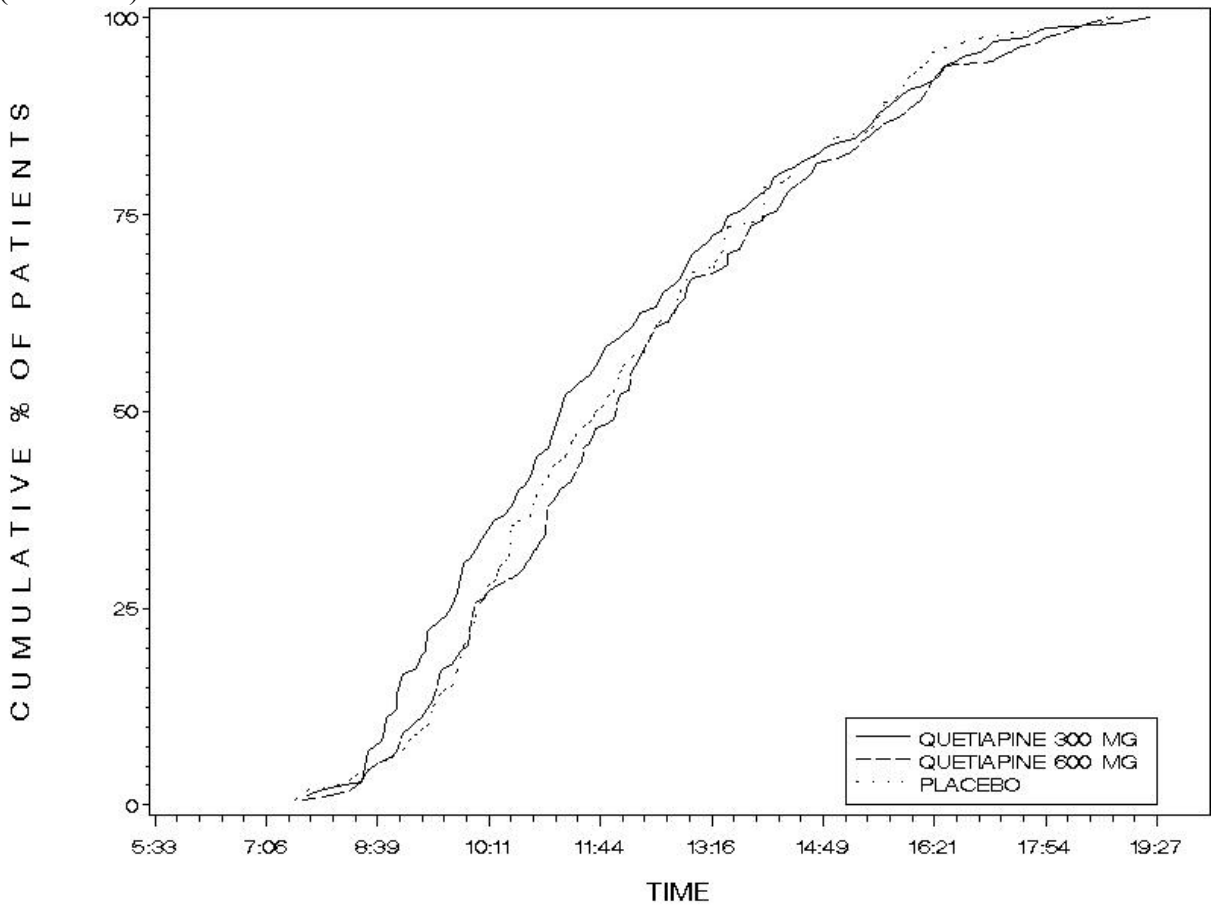

Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0005004	BSLN	*	24SEP2002	12:00	-7	0.323	L	10.5	L#	4.5		265	
		BSLN		01OCT2002	15:46	1	0.274	L#	8.6	L#	3.7	L	292	
	E0023038	BSLN		20JUN2003	12:45	-10	0.319	L#	10.3	L#	4.1		359	
		FINAL		16SEP2003	18:30	79	0.442		14.4		5.0		247	
	E0037006	BSLN		07MAR2003	12:00	-7	0.387		12.9		4.3		103	L
		FINAL		09MAY2003	12:18	57	0.382		13.2		4.3		87	L#
	E0039053	BSLN	*	16JUN2003	13:25	-25	0.332	L#	10.9	L#	4.3		251	
		BSLN		07JUL2003	12:40	-4	0.360	L#	11.5	L#	4.6		277	
		FINAL		08SEP2003	12:45	60	0.356	L#	11.2	L#	4.6		252	
	E0039057	BSLN	*	02JUL2003	19:50	-12			13.5		5.0		317	
		BSLN		11JUL2003	16:25	-3	0.402		13.3		4.9		266	
		FINAL		09SEP2003	9:25	58	0.347	L#	11.4	L#	4.2		310	

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

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Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	BSLN	15JAN2003	10:00	-6	0.319 L#	10.8 L#	3.4 L	151

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA102.SAS
GENERATED: 12JUL2005 17:43:36 iceadmn3

Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0009010	BSLN	27FEB2003	16:55	-14	0.542 H	18.3 H	6.2 H#	357

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA102.SAS
GENERATED: 12JUL2005 17:43:36 iceadmn3

Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
PLACEBO (BIPOLAR I)	E0006020	BSLN		02MAY2003	13:30	-11	0.466		16.2		5.1		195	
		FINAL		08JUL2003	14:45	57	0.183	L#	6.4	L#	2.0	L#	24	L#
		FINAL	*	10JUL2003	16:30	59	0.463		15.9		5.1		207	
	E0007003	BSLN		13JAN2003	10:30	-17	0.378	L	12.9	L	3.7	L	387	
		FINAL		01APR2003	13:30	62	0.352	L#	11.9	L	3.7	L	252	
	E0011009	BSLN		23DEC2002	14:30	-4	0.550	H#	18.9	H#	5.6		207	
		FINAL		20FEB2003	9:00	56	0.515		17.4		5.2		214	
	E0013005	BSLN		13FEB2003	11:42	-5	0.399	L	14.1		4.5		93	L#
		FINAL		15APR2003	12:16	57	0.425		14.2		4.8		129	L
	E0028011	BSLN	*	16OCT2002	15:10	-50	0.370	L#	12.0	L	4.1		219	
		BSLN		03DEC2002	9:30	-2	0.364	L#	12.2	L	4.0	L	204	
		FINAL		30JAN2003	12:35	57	0.378	L	12.4	L	4.0	L	163	
	E0030003	BSLN		10DEC2002	9:00	-6	0.338	L	10.9	L	3.9		233	
		FINAL		21MAR2003	9:50	96	0.332	L	10.2	L#	3.9		251	
	E0039030	BSLN		12MAR2003	8:55	-12	0.408		13.6		4.5		107	L
		FINAL		19MAY2003	9:15	57	0.433		14.7		4.7		100	L#

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#: potentially clinically important.

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Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR II)	E0011011	BSLN		12FEB2003	12:00	-8	0.332	L	11.2	L	3.5	L	221
		FINAL		16APR2003	8:30	56	0.319	L#	10.7	L	3.4	L	253
	E0014001	BSLN	*	18FEB2003	15:45	-8			13.2		4.6		293
		BSLN	*	25FEB2003	9:58	-1	0.406		13.6		4.8		302
		BSLN		25FEB2003	10:15	-1	0.390		13.1		4.5		269
		FINAL		08APR2003	11:10	42	0.290	L#	9.6	L#	3.1	L	442
		FINAL	*	16APR2003	10:40	50	0.307	L#	10.4	L#	3.3	L	261

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (CALC) AGRAN (X10 **9/L)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSINO-PHILS (CALC) (X10 **9/L)	BASO-PHILS (CALC) (X10 **9/L)	LYMPHO-CYTES (CALC) (X10 **9/L)	MONO-CYTES (CALC) (X10 **9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	BSLN	30OCT2002	8:40	-8	6.9	3.22	3.22	0.37	0.0	2.7	0.6
		FINAL	23DEC2002	15:35	47	13.5H	11.18H#	11.18H#	0.05	0.0	1.9L	0.4L
	E0020007	BSLN	10JAN2003	12:00	-5	13.8H	10.12 #	10.12 #	0.25	0.0	2.7	0.7
		FINAL	25MAR2003	18:50	70	14.9H	10.43 #	10.43 #	0.36	0.0	3.5	0.6L
	E0022017	BSLN	05DEC2002	12:35	-14	13.9H	10.56 #	10.56 #	0.13	0.0	2.5	0.7
		FINAL	07MAR2003	9:47	79	13.8H	10.85H#	10.85H#	0.23	0.0	2.1L	0.6
	E0023045	BSLN	10JUL2003	11:40	-7	5.3	3.13	3.13	0.23	0.0	1.4	0.5
		FINAL	15SEP2003	11:00	61	4.1	0.78L	0.78L#	0.66H	0.0	2.1H	0.5H

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA103.SAS
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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (CALC) AGRAN (X10 **9/L)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSINO-PHILS (CALC) (X10 **9/L)	BASO-PHILS (CALC) (X10 **9/L)	LYMPHO-CYTES (CALC) (X10 **9/L)	MONO-CYTES (CALC) (X10 **9/L)
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	BSLN		07FEB2003	12:55	-10	12.0	9.32H	9.32H	0.20	0.0	2.1	0.4L
		FINAL		18APR2003	12:15	61	14.2H	11.42H#	11.42H#	0.13	0.0	2.1L	0.5L
	E0031020	BSLN		14APR2003	10:35	-7	23.4H#	4.45L	4.45L	0.00	0.0	18.5H#	0.5L
		FINAL	*	29APR2003	9:30	9	19.4H#	2.99L	2.99L	0.12	0.0	15.8H#	0.5L
		FINAL		13MAY2003	10:50	23	18.2H#	3.57L	3.57L	0.04	0.0	14.2H#	0.4L

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA103.SAS
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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (CALC) AGRAN (X10 **9/L)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSINO-PHILS (CALC) (X10 **9/L)	BASO-PHILS (CALC) (X10 **9/L)	LYMPHO-CYTES (CALC) (X10 **9/L)	MONO-CYTES (CALC) (X10 **9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0005022	BSLN	27JAN2003	10:30	-2	5.4	1.47L	1.47L#	0.18	0.0	3.2H	0.5H
		FINAL	11MAR2003	10:10	42	6.7	3.82	3.82	0.12	0.0	2.3	0.4
	E0007015	BSLN	10JUL2003	7:35	-6	5.1	1.91L	1.91L	0.14	0.0	2.7H	0.4
		FINAL	10SEP2003	7:40	57	4.6	1.15L	1.15L#	0.32H	0.0	2.9H	0.2
	E0015008	BSLN	16DEC2002	7:45	-3	8.4	3.72	3.72	1.23H#	0.0	2.9	0.5
	E0036007	BSLN	27JUN2003	10:00	-6	13.7H	10.06 #	10.06 #	0.29	0.1	2.6	0.7
		FINAL	18JUL2003	9:15	16	15.4H	12.40H#	12.40H#	0.15	0.1	2.3L	0.5L
	E0037009	BSLN	12MAY2003	9:15	-4	9.9	6.38	6.38	0.71H	0.0	2.3	0.5
		FINAL	10JUL2003	16:05	56	8.9	4.33	4.33	1.12H#	0.0	3.0	0.4
	E0039026	BSLN	03MAR2003	9:05	-4	3.1L	1.35	1.35 #	0.15	0.0	1.3	0.2
		FINAL	02MAY2003	9:20	57	4.7	2.38	2.38	0.23	0.0	1.8	0.3

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA103.SAS
GENERATED: 12JUL2005 17:43:39 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (CALC) AGRAN (X10 **9/L)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSINO-PHILS (CALC) (X10 **9/L)	BASO-PHILS (CALC) (X10 **9/L)	LYMPHO-CYTES (CALC) (X10 **9/L)	MONO-CYTES (CALC) (X10 **9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0019008	BSLN	*	06NOV2002	12:35	-15	9.1	4.53	4.53	1.12H#	0.0	3.1	0.3L
		BSLN		13NOV2002	10:30	-8	5.6	3.40	3.40	0.40H	0.0	1.4	0.4
	E0026003	BSLN	*	25NOV2002	12:20	-9	17.3H#	15.03H#	15.03H#	0.07	0.0	1.3L	0.9
		BSLN		02DEC2002	9:25	-2	10.4	9.38H	9.38H	0.02	0.0	0.9L	0.1L
		FINAL		03FEB2003	10:50	62	8.1	5.41	5.41	0.31	0.0	1.9	0.4
	E0031006	BSLN		31JAN2003	11:25	-18	14.7H	9.04	9.04	0.37	0.1	4.2	1.0
		FINAL		15APR2003	9:25	57	15.4H	10.29 #	10.29 #	0.60	0.1	3.6	0.8
	E0033009	BSLN		22JAN2003	13:40	-21	10.9	7.13	7.13	1.18H#	0.1	2.1	0.5

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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (CALC) AGRAN (X10 **9/L)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSINO-PHILS (CALC) (X10 **9/L)	BASO-PHILS (CALC) (X10 **9/L)	LYMPHO-CYTES (CALC) (X10 **9/L)	MONO-CYTES (CALC) (X10 **9/L)
PLACEBO (BIPOLAR I)	E0006020	BSLN		02MAY2003	13:30	-11	5.9	3.81	3.81	0.15	0.0	1.5	0.4
		FINAL		08JUL2003	14:45	57	1.2L#	1.04H	1.04H#	0.02	0.0	0.1L#	0.0L
		FINAL	*	10JUL2003	16:30	59	6.1	4.22	4.22	0.10	0.0	1.3	0.5
	E0011009	BSLN		23DEC2002	14:30	-4	10.4	5.51	5.51	1.05H#	0.1	3.0	0.8
		FINAL		20FEB2003	9:00	56	10.4	6.80	6.80	0.43	0.0	2.8	0.4L
	E0013005	BSLN		13FEB2003	11:42	-5	5.1	3.18	3.18	0.11	0.0	1.3	0.5
		FINAL		15APR2003	12:16	57	3.6L	1.50	1.50 #	0.13	0.0	1.6	0.4H
	E0022065	BSLN		01MAY2003	9:30	-6	15.0H	10.65 #	10.65 #	0.30	0.0	1.8L	0.9
		FINAL		02JUL2003	8:50	57	10.1	7.02	7.02	0.10	0.1	2.3	0.6
	E0022070	BSLN		05JUN2003	11:40	-7	9.6	5.75	5.75	1.04H#	0.0	2.3	0.5
		FINAL		18JUN2003	15:15	7	9.1	5.53	5.53	0.45	0.1	2.7	0.4
	E0028001	BSLN		07OCT2002	14:00	-3	15.6H	10.95 #	10.95 #	0.48	0.1	3.5	0.7
		FINAL		03DEC2002	9:50	55	8.5	5.83	5.83	0.39	0.0	1.8	0.4
	E0029001	BSLN		25SEP2002	8:45	-6	21.0H#	15.12 #	15.12 #	0.21	0.0	3.4	1.3
	E0030003	BSLN		10DEC2002	9:00	-6	3.2L	1.05L	1.05L#	0.13	0.0	1.8H	0.2
		FINAL		21MAR2003	9:50	96	3.8L	1.92	1.92	0.08	0.1	1.5	0.2
	E0039023	BSLN	*	05FEB2003	10:37	-19	3.7L	0.70L	0.70L#	0.47H	0.0	2.0H	0.5H
		BSLN		14FEB2003	9:30	-10	6.7	2.92	2.92	0.40	0.0	2.9	0.5

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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (CALC) AGRAN (X10 **9/L)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSINO-PHILS (CALC) (X10 **9/L)	BASO-PHILS (CALC) (X10 **9/L)	LYMPHO-CYTES (CALC) (X10 **9/L)	MONO-CYTES (CALC) (X10 **9/L)
PLACEBO (BIPOLAR II)	E0035009	BSLN	23DEC2002	14:50	-4	2.7L#	1.12	1.12 #	0.02	0.0	1.2	0.3H
		FINAL	19FEB2003	8:55	55	3.2L	1.27L	1.27L#	0.09	0.0	1.6H	0.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA103.SAS
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Table 11.3.7.2.2.1 Chemistry Data for Liver Function Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	BSLN		29MAY2003	11:55	-7	26	43	66.0		2.0	H#
		FINAL	*	12JUN2003	8:50	8					2.0	H#
		FINAL		29JUL2003	8:25	55	22	35	68.0		2.3	H#
QUETIAPINE 300 MG (BIPOLAR II)	E0005011	BSLN	*	17OCT2002	15:00	-7	23	28	90.0		2.2	H#
		BSLN		22OCT2002	16:30	-2	21	29	86.0		1.0	
	E0009002	BSLN		30OCT2002	11:45	-20	19	43	99.0		1.8	H#
		FINAL		15JAN2003	13:47	58	20	35	91.0		1.3	H
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	BSLN		23SEP2002	11:00	-7	14	8	54.0		1.2	
		FINAL		05NOV2002	13:30	37	14	9	56.0		2.1	H#
	E0005007	BSLN		02OCT2002	12:40	-7	64H	88H	81.0		0.6	
		FINAL		04DEC2002	14:20	57	84H	136H#	76.0		0.2	
		FINAL	*	14JAN2003	10:50	98	54H	75H				
	E0022068	BSLN		14MAY2003	10:23	-9	16	18	43.0		1.9	H#
	E0022071	BSLN		16JUN2003	11:40	-14	33	45	110.0		1.9	H#
		FINAL		26AUG2003	9:33	58	26	44	100.0		1.1	
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	BSLN	*	22MAY2003	12:00	-33	105H	148H#	95.0		0.4	
		BSLN		19JUN2003	10:00	-5	70H	110H	81.0		0.4	
		FINAL		19AUG2003	11:00	57	58H	89H	82.0		0.6	
PLACEBO (BIPOLAR I)	E0014018	BSLN		24JUN2003	16:35	-7	22	13	84.0		0.8	
		FINAL		27AUG2003	16:00	58	145H#	67H	84.0		0.5	
		FINAL	*	24SEP2003	16:45	86	15	13	74.0		0.6	
	E0039030	BSLN		12MAR2003	8:55	-12	65H	44H	134.0	H	0.8	

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Table 11.3.7.2.2.1 Chemistry Data for Liver Function Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0039030	FINAL		19MAY2003	9:15	57	116H#	88H	152.0	H	1.2	
		FINAL	*	30MAY2003	9:50	68	139H#	99H	152.0	H	1.4	H
PLACEBO (BIPOLAR II)	E0029038	BSLN		30JUN2003	9:25	-7	13	18	64.0		2.3	H#
	E0034007	BSLN		07MAY2003	14:05	-9	40H	39H	50.0		1.2	
		FINAL		14JUL2003	11:15	60	121H#	128H#	73.0		2.2	H#
		FINAL	*	28JUL2003	11:48	74	121H#	134H#	68.0		1.2	
	E0035004	BSLN		22NOV2002	11:45	-5	136H#	126H	100.0		0.8	

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Table 11.3.7.2.2.2 Chemistry Data for Renal Tests - Potentially Clinically Important

NOTE: THERE WERE NO POTENTIALLY CLINICALLY IMPORTANT 'RENAL' DATA.

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Table 11.3.7.2.2.3 Chemistry Data for Diabetic Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	BASELINE BMI	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	BSLN		23APR2003	8:45	-12	33.9	136.0 H#	111.1
		FINAL		02JUL2003	10:30	59	33.9	156.0 H#	111.1
	E0013007	BSLN		14MAR2003	8:48	-6	27.8	174.0 H#	69.5
		FINAL		07APR2003	17:15	19	27.8	142.0 H#	76.4
	E0018001	BSLN		22OCT2002	16:15	-7	33.0	80.0	263.9 H
		FINAL		24DEC2002	9:55	57	33.0	137.0 H#	1562.6 H
	E0034002	BSLN		18MAR2003	9:25	-7	33.9	121.0 H	194.5 H
		FINAL		16APR2003	14:40	23	33.9	132.0 H#	625.1 H
	E0039057	BSLN		02JUL2003	19:50	-12	30.6	69.0	27.8
		FINAL		09SEP2003	9:25	58	30.6	134.0 H#	423.6 H
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	BSLN		12DEC2002	10:43	-7	36.6	101.0	97.2
		FINAL		13FEB2003	8:00	57	36.6	127.0 H#	111.1
	E0019027	BSLN		20FEB2003	10:50	-7	36.1	206.0 H#	291.7 H
		FINAL		06MAR2003	9:14	8	36.1		243.1 H
	E0039052	BSLN	*	29MAY2003	10:25	-22	38.5	145.0 H#	
		BSLN		29MAY2003	10:25	-22	38.5		159.7 H
		BSLN		13JUN2003	12:10	-7	38.5	92.0	
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	BSLN		23SEP2002	15:00	-9	29.5	94.0	111.1
		FINAL		26NOV2002	13:25	56	29.5	106.0	236.1 H
		FINAL	*	20DEC2002	9:50	80	29.5	155.0 H#	1041.8 H
		FINAL	*	02JAN2003	10:10	93	29.5	139.0 H#	354.2 H
	E0005008	BSLN		08OCT2002	18:00	-7	42.9	100.0	1145.9 H
		FINAL		11DEC2002	16:00	58	42.9	172.0 H#	2722.4 H
		FINAL	*	06JAN2003	9:30	84	42.9		618.1 H

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Table 11.3.7.2.2.3 Chemistry Data for Diabetic Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	BASELINE BMI	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	FINAL	*	24FEB2003	10:30	133	42.9	116.0	423.6 H
		FINAL	*	12MAR2003	16:30	149	42.9	92.0	194.5 H
	E0010029	BSLN		10JUN2003	9:25	-9	44.6	145.0 H#	222.2 H
	E0015001	BSLN		11NOV2002	9:10	-18	30.3	112.0	277.8 H
		FINAL		20JAN2003	7:30	53	30.3	175.0 H#	729.2 H
	E0020004	BSLN		21NOV2002	15:20	-18	31.5	91.0	48.6
		FINAL		22JAN2003	16:15	45	31.5	155.0 H#	145.8 H
		FINAL	*	24FEB2003	11:50	78	31.5	107.0	48.6
	E0022046	BSLN		14MAR2003	8:00	-6	30.0	130.0 H#	83.3
		FINAL		16MAY2003	8:05	58	30.0	107.0	69.5
	E0026007	BSLN		06JAN2003	10:30	-10	36.5	102.0	159.7 H
		FINAL		12MAR2003	14:25	56	36.5	129.0 H#	611.2 H
		FINAL	*	13MAR2003	13:05	57	36.5		1034.8 H
	E0028037	BSLN	*	18APR2003	8:30	-56	29.3	301.0 H#	62.5
		BSLN	*	24APR2003	7:50	-50	29.3	370.0 H#	
		BSLN		04JUN2003	8:33	-9	29.3	113.0	76.4
		FINAL		08AUG2003	15:30	57	29.3	86.0	20.8
QUETIAPINE 600 MG (BIPOLAR II)	E0019035	BSLN		11MAR2003	9:28	-7	43.3	129.0 H#	118.1 H
		FINAL		17APR2003	14:30	31	43.3	177.0 H#	257.0 H
	E0026003	BSLN	*	25NOV2002	12:20	-9	26.4	128.0 H#	312.5 H
		BSLN		02DEC2002	9:25	-2	26.4	104.0	97.2
		FINAL		03FEB2003	10:50	62	26.4	139.0 H#	451.4 H
	E0026015	BSLN		20FEB2003	11:30	-7	21.5	81.0	69.5
		FINAL		25APR2003	9:50	58	21.5	138.0 H#	291.7 H

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Table 11.3.7.2.2.3 Chemistry Data for Diabetic Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	BASELINE BMI	FASTING GLUCOSE (MG/DL)		INSULIN (PMOL/L)	
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	27.0	76.0		41.7	
		FINAL		26FEB2003	8:45	59	27.0	142.0	H#	132.0	H
	E0004006	BSLN		28OCT2002	9:55	-7	33.4	113.0		305.6	H
		FINAL		06JAN2003	10:55	64	33.4	147.0	H#	791.7	H
		FINAL	*	15JAN2003	8:30	73	33.4	118.0		104.2	
	E0025001	BSLN		25MAR2003	16:00	-7	54.7	192.0	H#	1951.5	H
		FINAL		23APR2003	10:30	23	54.7	93.0		152.8	H
	E0028001	BSLN		07OCT2002	14:00	-3	36.8	116.0		145.8	H
		FINAL		03DEC2002	9:50	55	36.8	172.0	H#	118.1	H
	E0029032	BSLN		22MAY2003	12:45	-19	31.5	97.0		55.6	
		FINAL		01JUL2003	12:00	22	31.5	134.0	H#	201.4	H
	E0039038	BSLN	*	27MAR2003	10:10	-27	37.7	291.0	H#	493.1	H
		BSLN		21APR2003	10:16	-2	37.7	163.0	H#	590.3	H
		FINAL		20JUN2003	11:15	59	37.7	410.0	H#		
PLACEBO (BIPOLAR II)	E0007010	BSLN		14APR2003	8:10	-4	35.7	137.0	H#	132.0	H
		FINAL	*	21APR2003	8:30	4	35.7	136.0	H#		
		FINAL		13JUN2003	7:40	57	35.7	127.0	H#	166.7	H
		FINAL	*	16JUN2003	7:50	60	35.7	136.0	H#		
	E0029024	BSLN		11MAR2003	12:10	-6	19.9	92.0		20.8	
		FINAL		20MAY2003	14:45	65	19.9	156.0	H#	125.0	H

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Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	BSLN		16JUL2003	13:25	-7	140	4.2	105.0	24.0	
		FINAL		04AUG2003	9:40	12	134	4.1	102.0	18.0	L#
	E0005037	BSLN		30APR2003	12:00	-6	144	4.4	103.0	31.0	#
		FINAL		02JUL2003	12:15	57	142	4.4	106.0	25.0	
	E0010012	BSLN		30DEC2002	9:48	-7	145	4.9	109.0	31.0	#
		FINAL		05MAR2003	13:59	58	143	4.0	105.0	25.0	
	E0010024	BSLN		23APR2003	8:45	-11	144	4.6	109.0	31.0	#
		FINAL		02JUL2003	10:30	59	142	4.8	108.0	27.0	
	E0013009	BSLN		26MAR2003	9:09	-6	143	5.5 #	107.0	28.0	
		FINAL		29MAY2003	17:50	58	143	5.3	106.0	25.0	
	E0019025	BSLN		30JAN2003	14:40	-6	142	5.7 H#	104.0	25.0	
		FINAL		03APR2003	13:30	57	144	4.6	107.0	26.0	
	E0019043	BSLN		21MAY2003	11:04	-12	141	5.8 H#	103.0	27.0	
		FINAL	*	17JUN2003	12:10	15	140	4.3	106.0	24.0	
		FINAL		29JUL2003	11:38	57	135	4.2	101.0	22.0	
	E0020007	BSLN		10JAN2003	12:00	-4	143	3.7	108.0	17.0	L#
		FINAL		25MAR2003	18:50	70	144	4.2	111.0	21.0	
	E0022018	BSLN		04DEC2002	10:15	-7	144	4.9	105.0	30.0	#
		FINAL		11FEB2003	8:40	62	146	4.8	106.0	28.0	
	E0025002	BSLN		27MAR2003	11:05	-6	142	4.2	104.0	30.0	#
		FINAL		29MAY2003	11:40	57	139	4.0	106.0	25.0	
	E0028008	BSLN		08OCT2002	12:45	-6	143	3.6	105.0	30.0	#
		FINAL		10DEC2002	12:30	57	144	3.5	105.0	25.0	
	E0028009	BSLN		10OCT2002	10:45	-4	144	4.1	107.0	23.0	

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#: potentially clinically important.

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GENERATED: 12JUL2005 17:40:45 iceadmn3

Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	FINAL		12DEC2002	13:50	59	140	4.3	102.0	33.0	#
	E0030001	BSLN		12NOV2002	15:15	-6	140	4.5	100.0	21.0	
		FINAL		16JAN2003	12:07	59	145	5.6 H#	105.0	25.0	
	E0030015	BSLN		13FEB2003	12:05	-7	146	5.2	105.0	33.0	#
		FINAL		22APR2003	12:10	61	144	4.4	106.0	33.0	#
	E0031003	BSLN		03DEC2002	16:07	-6	145	4.8	107.0	20.0	L
		FINAL		04FEB2003	16:20	57	144	5.7 H#	105.0	27.0	
	E0039006	BSLN	*	11NOV2002	10:05	-48	125L#	3.6	90.0 L#	17.0	L#
		BSLN	*	22NOV2002	9:20	-37	144	4.4	107.0	22.0	
		BSLN		10DEC2002	11:35	-19	145	4.2	107.0	25.0	
		FINAL		24FEB2003	10:58	57	144	4.1	108.0	21.0	
	E0039041	BSLN		08APR2003	9:40	-6	142	4.3	106.0	30.0	#
		FINAL		11JUN2003	11:25	58	140	4.6	102.0	28.0	
	E0041008	BSLN		26MAR2003	15:35	-11	143	4.9	101.0	31.0	#
		FINAL		02JUN2003	15:30	57	142	4.2	103.0	29.0	
	E0042001	BSLN		17JUN2003	9:45	-14	139	3.8	99.0	31.0	#
		FINAL		26AUG2003	10:50	56	143	4.3	106.0	25.0	
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	BSLN		15MAY2003	12:30	-6	141	4.7	102.0	31.0	#
		FINAL		17JUL2003	17:30	57	142	4.3	106.0	25.0	
	E0015003	BSLN		13NOV2002	12:20	-11	139	5.1	103.0	24.0	
		FINAL		02DEC2002	10:55	8	137	4.0	101.0	17.0	L#
	E0019007	BSLN		06NOV2002	10:32	-6	144	5.3	103.0	27.0	
		FINAL		07JAN2003	8:30	56	148H	5.7 H#	105.0	29.0	

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM109.SAS
GENERATED: 12JUL2005 17:40:45 iceadmn3

Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	BSLN		06MAR2003	14:50	-25	141		4.0		105.0		29.0	
		FINAL		28MAY2003	11:00	58	132	#	4.6		97.0		23.0	
	E0022064	BSLN		01MAY2003	10:40	-4	145		5.5	#	107.0		30.0	#
		FINAL		01JUL2003	12:30	57	145		4.2		110.0		26.0	
	E0023017	BSLN		20MAR2003	11:00	-4	144		4.0		104.0		30.0	#
		FINAL		22MAY2003	12:30	59	143		4.0		106.0		29.0	
	E0029030	BSLN	*	13MAY2003	11:20	-13	141		4.4		108.0		28.0	
		BSLN		20MAY2003	12:55	-6	140		4.2		108.0		30.0	#
		FINAL		23JUL2003	17:25	58	142		4.2		109.0		23.0	
	E0031008	BSLN		05FEB2003	11:40	-22	144		5.4		104.0		26.0	
		FINAL		24APR2003	13:17	56	142		5.5	#	108.0		24.0	
	E0040003	BSLN		09JUL2003	14:00	-9	143		4.3		105.0		31.0	#
		FINAL		12SEP2003	11:00	56	138		4.2		104.0		27.0	
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	BSLN		28JAN2003	9:10	-5	143		5.5	#	105.0		22.0	
		FINAL		31MAR2003	16:20	57	140		3.9		105.0		26.0	
	E0005008	BSLN		08OCT2002	18:00	-6	144		4.6		102.0		30.0	#
		FINAL		11DEC2002	16:00	58	141		4.4		100.0		26.0	
	E0005022	BSLN		27JAN2003	10:30	-1	143		4.2		105.0		28.0	
		FINAL		11MAR2003	10:10	42	145		4.3		108.0		30.0	#
	E0010014	BSLN		14JAN2003	9:05	-13	140		4.7		102.0		31.0	#
		FINAL		25MAR2003	11:05	57	144		4.2		106.0		26.0	
	E0013014	BSLN		08MAY2003	11:15	-25	144		4.8		107.0		29.0	
		FINAL		30JUN2003	12:21	28	142		5.0		105.0		31.0	#

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM109.SAS
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Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	BSLN		13MAY2003	9:45	-5	144	4.4	107.0	27.0	
		FINAL		14JUL2003	13:25	57	143	4.1	101.0	32.0	#
	E0022058	BSLN		14APR2003	10:25	-6	140	4.5	105.0	30.0	#
		FINAL		22MAY2003	14:00	32	140	5.0	105.0	26.0	
	E0023003	BSLN	*	08NOV2002	16:00	-38	140	4.9	100.0	30.0	#
		BSLN		12DEC2002	10:00	-4	139	4.6	102.0	21.0	
		FINAL		11FEB2003	14:00	57	140	4.4	100.0	26.0	
	E0026002	BSLN		05NOV2002	10:15	-6	147	5.6 H#	108.0	23.0	
		FINAL		09JAN2003	9:25	59	146	5.0	109.0	23.0	
	E0026013	BSLN		05FEB2003	12:20	-7	141	4.0	101.0	32.0	#
		FINAL		14APR2003	10:00	61	140	3.8	103.0	30.0	#
	E0028007	BSLN		01OCT2002	10:30	-2	143	4.1	105.0	21.0	
		FINAL		14NOV2002	12:45	42	132 #	3.6	99.0	26.0	
	E0030025	BSLN	*	24JUN2003	16:35	-16	160H#	5.1	119.0 H	25.0	
		BSLN		07JUL2003	10:20	-3	143	4.2	108.0	24.0	
		FINAL		19AUG2003	16:45	40				21.0	
	E0031027	BSLN		28MAY2003	9:10	-5	142	5.2	107.0	26.0	
		FINAL		29JUL2003	14:40	57	143	5.9 H#	108.0	25.0	
	E0037009	BSLN		12MAY2003	9:15	-3	139	4.3	104.0	23.0	
		FINAL		10JUL2003	16:05	56	139	3.5	105.0	17.0	L#
	E0039028	BSLN		03MAR2003	14:15	-20	142	3.9	106.0	27.0	
		FINAL		16MAY2003	12:25	54	145	4.6	106.0	30.0	#
QUETIAPINE 600 MG (BIPOLAR II)	E0019002	BSLN		29OCT2002	10:45	-13	141	4.6	107.0	17.0	L#

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Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	BSLN		06MAR2003	11:35	-6	141		4.3		102.0		32.0	#
		FINAL		25MAR2003	10:08	13	143		4.0		106.0		29.0	
	E0023019	BSLN		21MAR2003	14:00	-16	142		4.3		106.0		26.0	
		FINAL		03JUN2003	13:30	58	143		4.4		105.0		30.0	#
PLACEBO (BIPOLAR I)	E0002008	BSLN		14FEB2003	16:00	-10	137		4.3		103.0		25.0	
		FINAL		23APR2003	14:25	58	136		4.5		104.0		30.0	#
	E0002016	BSLN		14JUL2003	11:00	-9	142		4.1		104.0		30.0	#
		FINAL		17SEP2003	11:15	56	146		5.0		112.0	H	26.0	
	E0003008	BSLN		21JAN2003	12:45	-6	142		5.5	#	107.0		29.0	
	E0004003	BSLN		02OCT2002	11:00	-7	141		4.8		100.0		30.0	#
	E0005017	BSLN	*	11DEC2002	10:30	-18	145		4.8		107.0		25.0	
		BSLN		23DEC2002	12:30	-6	140		5.0		107.0		26.0	
		FINAL		04MAR2003	13:00	65	142		4.3		104.0		30.0	#
	E0006020	BSLN		02MAY2003	13:30	-10	142		4.2		105.0		26.0	
		FINAL		08JUL2003	14:45	57	139		4.6		104.0		27.0	
		FINAL	*	10JUL2003	16:30	59	142		4.0		104.0		30.0	#
	E0007003	BSLN		13JAN2003	10:30	-16	143		5.4		104.0		26.0	
		FINAL		01APR2003	13:30	62	132	#	4.5		95.0		27.0	
	E0011009	BSLN		19DEC2002	10:15	-7	140		4.3		100.0		26.0	
		FINAL		20FEB2003	9:00	56	143		4.5		102.0		18.0	L#
	E0014015	BSLN		11JUN2003	10:15	-6	140		4.9		105.0		31.0	#
	E0018015	BSLN		21JAN2003	11:20	-6	142		5.0		104.0		31.0	#
		FINAL		27MAR2003	10:50	59	144		5.0		107.0		27.0	

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Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0022004	BSLN	*	17OCT2002	8:48	-10	143	4.8	102.0	30.0	#
		BSLN		28OCT2002	9:47	1	146	5.3	105.0	28.0	
		FINAL		23DEC2002	10:15	57	146	5.3	110.0	29.0	
	E0022042	BSLN		05MAR2003	9:50	-6	147	4.5	107.0	30.0	#
		FINAL		12MAY2003	9:35	62	142	4.8	105.0	27.0	
	E0023001	BSLN		24OCT2002	13:30	-21	140	4.5	101.0	31.0	#
		FINAL		14JAN2003	13:30	61	138	4.8	103.0	28.0	
	E0026024	BSLN		25APR2003	12:30	-6	141	4.1	110.0	13.0	L#
	E0028003	BSLN		23SEP2002	9:10	-6	146	4.3	107.0	26.0	
		FINAL		26NOV2002	9:20	58	152H#	4.9	110.0	22.0	
	E0028010	BSLN		15OCT2002	11:00	-20	139	4.5	101.0	30.0	#
		FINAL	*	19NOV2002	12:40	15	141	4.9	102.0	26.0	
		FINAL		31DEC2002	9:20	57	141	3.9	104.0	24.0	
	E0028011	BSLN	*	22OCT2002	8:30	-43	142	4.1	103.0	29.0	
		BSLN		25NOV2002	9:00	-9	146	4.7	107.0	23.0	
		FINAL		30JAN2003	12:35	57	142	4.1	104.0	30.0	#
	E0029001	BSLN		25SEP2002	8:45	-5	139	4.0	102.0	30.0	#
	E0035007	BSLN		13DEC2002	12:40	-5	141	4.1	103.0	30.0	#
		FINAL		11FEB2003	10:10	55	141	4.3	98.0	28.0	
	E0035020	BSLN		15APR2003	8:15	-2	145	4.0	108.0	30.0	#
	E0039007	BSLN		25NOV2002	13:20	-8	148H	4.4	108.0	32.0	#
		FINAL		29JAN2003	14:15	57	146	4.4	105.0	27.0	
PLACEBO (BIPOLAR II)	E0014014	BSLN		03JUN2003	16:35	-6	146	4.5	110.0	25.0	

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Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR II)	E0014014	FINAL	06AUG2003	10:50	58	145		4.5		106.0		30.0	#
	E0019033	BSLN	10MAR2003	16:05	-7	146		4.3		104.0		26.0	
		FINAL	16MAY2003	8:30	60	145		5.5	#	107.0		30.0	#
	E0022075	BSLN	27JUN2003	7:45	-10	144		4.5		103.0		31.0	#
		FINAL	03SEP2003	9:15	58	141		4.1		104.0		28.0	
	E0029019	BSLN	24FEB2003	9:30	-6	145		4.3		108.0		24.0	
		FINAL	17MAR2003	9:50	15	145		4.1		108.0		30.0	#
	E0033007	BSLN	15JAN2003	15:20	-12	142		5.0		104.0		32.0	#
		FINAL	27MAR2003	15:35	59	143		4.7		107.0		26.0	

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GENERATED: 12JUL2005 17:40:45 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	BSLN		28MAR2003	10:00	-7	427	H#	222	H	28	L#	128	
	E0002015	BSLN		22MAY2003	10:15	-13	278	H#	248	H#	50		142	H
	E0002018	BSLN		16JUL2003	13:25	-8	464	H#	241	H#	27	L#	130	
		FINAL		04AUG2003	9:40	12	273	H#	215	H	31	L#	129	
	E0003004	BSLN	*	03DEC2002	11:48	-14	160		178		42		104	
		BSLN		17DEC2002	9:20	1	128		187		44		117	
		FINAL		07JAN2003	15:40	22	153		154		34	L#	89	
	E0003005	BSLN		16DEC2002	15:00	-7	260	H#	238	H	31	L#	155	H
		FINAL		18FEB2003	8:55	58	460	H#	241	H#	32	L#	117	
	E0003015	BSLN		29APR2003	11:30	-6	162		204	H	67		105	
		FINAL		02JUL2003	14:45	59	148		249	H#	68		151	H
	E0004013	BSLN		08JAN2003	10:00	-6	161		191		33	L#	126	
		FINAL		19FEB2003	8:20	37	215	#	202	H	33	L#	126	
	E0004018	BSLN		12MAR2003	10:50	-7	152		167		46		91	
		FINAL		13MAY2003	13:45	56	80		149		37	L#	96	
	E0004021	BSLN		07MAY2003	15:55	-7	264	H#	215	H	41		121	
		FINAL		09JUL2003	14:10	57	524	H#	205	H	29	L#	96	
	E0005002	BSLN		23SEP2002	10:00	-10	540	H#	223	H	38	L#	102	
		FINAL		25NOV2002	8:30	54	877	H#	252	H#	29	L#	97	
	E0005027	BSLN		04MAR2003	7:45	-7	504	H#	191		34	L#	68	
		FINAL		03APR2003	8:15	24	709	H#	185		28	L#	56	
	E0005037	BSLN		30APR2003	12:00	-7	272	H#	264	H#	37	L#	173	H#
		FINAL		02JUL2003	12:15	57	359	H#	210	H	29	L#	109	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM110.SAS
GENERATED: 12JUL2005 17:40:48 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	FINAL	*	16JUL2003	11:00	71	280	H#	259	H#	36	L#	167	H#
	E0005042	BSLN		19JUN2003	11:30	-5	191		215	H	45		132	H
		FINAL		18AUG2003	16:25	56	162		199		32	L#	135	H
	E0006005	BSLN		25NOV2002	12:15	-10	158		162		31	L#	99	
		FINAL		30JAN2003	16:10	57	166		169		44		92	
	E0006018	BSLN		07MAR2003	12:40	-6	94		148		31	L#	98	
		FINAL		24MAR2003	10:45	12	77		138		34	L#	89	
	E0007013	BSLN		10JUN2003	9:25	-3	248	#	233	H	70		113	
		FINAL		07AUG2003	9:20	56	200	#	256	H#	81	H	135	H
	E0010004	BSLN		05DEC2002	11:10	-6	282	H#	287	H#	56		175	H#
		FINAL		06FEB2003	12:40	58	283	H#	269	H#	47		165	H#
	E0010012	BSLN		30DEC2002	9:48	-8	211	#	220	H	50		128	
		FINAL		05MAR2003	13:59	58	477	H#	235	H	41		153	H
	E0010024	BSLN		23APR2003	8:45	-12	311	H#	203	H	34	L#	107	
		FINAL		02JUL2003	10:30	59	376	H#	221	H	39	L#	107	
	E0010032	BSLN		03JUL2003	11:30	-7	109		149		42		85	
		FINAL		17JUL2003	11:38	8	166		164		35	L#	96	
	E0011025	BSLN		20JUN2003	14:30	-6	136		291	H#	65		199	H#
		FINAL		22AUG2003	10:00	58	145		259	H#	57		173	H#
	E0013007	BSLN		14MAR2003	8:48	-6	189		225	H	56		131	H
		FINAL		07APR2003	17:15	19	465	H#	227	H	53		123	
	E0013009	BSLN		26MAR2003	9:09	-7	132		231	H	52		153	H
		FINAL		29MAY2003	17:50	58	171		245	H#	60		151	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	BSLN		15APR2003	17:20	-7	211	#	142		29	L#	71	
		FINAL		17JUN2003	18:10	57	289	H#	161		26	L#	77	
	E0016001	BSLN		02JAN2003	8:50	-20	142		231	H	66		137	H
		FINAL		19MAR2003	12:00	57	159		246	H#	52		162	H#
	E0016004	BSLN		27JAN2003	9:30	-7	304	H#	177		33	L#	83	
	E0018001	BSLN		22OCT2002	16:15	-7	306	H#	135		23	L#	51	
		FINAL		24DEC2002	9:55	57	292	H#	161		37	L#	66	
	E0018006	BSLN		10DEC2002	17:15	-7	172		176		40	#	102	
		FINAL		27FEB2003	12:10	73	177		174		38	L#	101	
	E0019004	BSLN		30OCT2002	8:40	-8	263	H#	181		46		82	
		FINAL		19DEC2002	12:55	43	116		179		57		99	
	E0019043	BSLN		21MAY2003	11:04	-13	203	#	174		63		70	
		FINAL	*	17JUN2003	12:10	15	227	#	192		64		83	
		FINAL		29JUL2003	11:38	57	363	H#	212	H	54		85	
	E0020006	BSLN		26NOV2002	18:00	-20	239	#	217	H	42		127	
		FINAL		08JAN2003	10:00	24	165		202	H	51		118	
	E0020007	BSLN		10JAN2003	12:00	-5	74		145		34	L#	96	
		FINAL		25MAR2003	18:50	70	106		159		47		91	
	E0020011	BSLN		19FEB2003	13:45	-7	450	H#	287	H#	31	L#	180	H#
		FINAL		23APR2003	14:30	57	803	H#	264	H#	25	L#	143	H
		FINAL	*	07MAY2003	12:00	71	620	H#	258	H#	26	L#	134	H
	E0020013	BSLN		26FEB2003	14:15	-7	103		159		44		94	
		FINAL		25MAR2003	12:00	21	242	#	172		38	L#	86	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	BSLN	05DEC2002	12:35	-14	240	#	235	H	28	L#	159	H
		FINAL	07MAR2003	9:47	79	197		226	H	29	L#	158	H
	E0022027	BSLN	24JAN2003	7:40	-13	137		208	H	35	L#	146	H
		FINAL	03APR2003	9:00	57	126		159		34	L#	100	
	E0022030	BSLN	10FEB2003	7:40	-4	159		137		34	L#	71	
	E0022031	BSLN	11FEB2003	10:25	-7	202	#	264	H#	47		177	H#
		FINAL	15APR2003	9:30	57	258	H#	216	H	35	L#	129	
	E0022032	BSLN	12FEB2003	8:05	-6	213	#	206	H	35	L#	128	
		FINAL	18APR2003	10:30	60	171		230	H	46		150	H
	E0022036	BSLN	14FEB2003	8:55	-11	105		153		41		91	
		FINAL	22APR2003	7:36	57	87		135		39	L#	79	
	E0023013	BSLN	13FEB2003	11:00	-14	161		232	H	47		153	H
		FINAL	06MAR2003	11:00	8	135		130		39	L#	64	
	E0023034	BSLN	03JUN2003	14:00	-6	93		148		40	#	89	
		FINAL	05AUG2003	16:00	58	204	#	138		28	L#	69	
	E0023038	BSLN	20JUN2003	12:45	-10	318	H#	192		35	L#	93	
		FINAL	16SEP2003	18:30	79	298	H#	208	H	36	L#	112	
	E0025002	BSLN	27MAR2003	11:05	-7	139		297	H#	84	H	185	H#
		FINAL	29MAY2003	11:40	57	175		292	H#	90	H	167	H#
	E0026017	BSLN	26FEB2003	11:50	-8	217	#	289	H#	33	L#	213	H#
		FINAL	21MAR2003	11:10	16	309	H#	258	H#	29	L#	167	H#
	E0026018	BSLN	06MAR2003	16:30	-14	127		125	L	26	L#	74	
		FINAL	15MAY2003	14:15	57	128		130		26	L#	78	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	BSLN		01MAY2003	11:40	-8	242	#	221	H	30	L#	143	H
		FINAL		03JUL2003	9:30	56	263H	#	256	H#	47		156	H
	E0027003	BSLN		08JAN2003	14:40	-20	293H	#	251	H#	35	L#	157	H
		FINAL		25MAR2003	11:55	57	270H	#	254	H#	46		154	H
	E0028004	BSLN		27SEP2002	9:45	-3	85		164		30	L#	117	
		FINAL		09OCT2002	14:30	10	67		194		42		139	H
	E0028008	BSLN		08OCT2002	12:45	-7	335H	#	174		32	L#	75	
		FINAL		10DEC2002	12:30	57	132		159		31	L#	102	
	E0028009	BSLN		10OCT2002	10:45	-5	121		205	H	46		135	H
		FINAL		12DEC2002	13:50	59	153		248	H#	49		168	H#
	E0028016	BSLN		07NOV2002	10:15	-7	87		175		50		108	
		FINAL		09JAN2003	11:50	57	223	#	182		38	L#	99	
	E0028017		*	12NOV2002	9:45		123		144		37	L#	82	
	E0028027	BSLN		14JAN2003	10:15	-7	96		244	H#	44		181	H#
	E0028029	BSLN		28JAN2003	10:00	-7	162		275	H#	50		193	H#
		FINAL		04APR2003	10:55	60	200	#	241	H#	45		156	H
	E0028034	BSLN		20MAR2003	9:40	-12	214	#	195		35	L#	117	
		FINAL		02JUN2003	12:54	63	418H	#	211	H	32	L#	111	
	E0028038	BSLN		18APR2003	10:20	-7	223	#	239	H	57		137	H
		FINAL		18JUN2003	13:45	55	181		186		56		94	
	E0028043	BSLN		29MAY2003	11:55	-7	219	#	203	H	39	L#	120	
		FINAL		29JUL2003	8:25	55	273H	#	186		35	L#	96	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	BSLN	*	14NOV2002	13:00	-13	111		181		52		107	
		BSLN		21NOV2002	10:30	-6	89		162		38	L#	106	
		FINAL		21JAN2003	12:50	56	103		173		56		96	
	E0030001	BSLN		12NOV2002	15:15	-7	183		270	H#	124	H	109	
		FINAL		16JAN2003	12:07	59	83		255	H#	115	H	123	
	E0030008	BSLN		07JAN2003	14:33	-7	153		233	H	55		147	H
		FINAL		18MAR2003	10:42	64	130		240	H#	56		158	H
	E0030011	BSLN		16JAN2003	16:10	-11	78		136		43		77	
		FINAL		24MAR2003	14:35	57	169		168		39	L#	95	
	E0030022	BSLN		10JUN2003	11:15	-6	126		248	H#	52		171	H#
		FINAL		14AUG2003	15:30	60	161		229	H	47		150	H
	E0034002	BSLN		18MAR2003	9:25	-7	374H#		186		36	L#	75	
		FINAL		16APR2003	14:40	23	312H#		156		32	L#	62	
	E0034003	BSLN		11APR2003	10:10	-13	101		219	H	53		146	H
		FINAL		19JUN2003	15:50	57	288H#		218	H	44		116	
	E0034006	BSLN		25APR2003	11:33	-21	223 #		219	H	31	L#	143	H
		FINAL		10JUL2003	9:54	56	382H#		235	H	28	L#	131	H
	E0035005	BSLN		26NOV2002	10:00	-7	156		257	H#	56		170	H#
	E0035014	BSLN		28JAN2003	11:10	-6	73		240	H#	79		146	H
		FINAL		31MAR2003	9:20	57	60		205	H	76		117	
	E0037002	BSLN		18DEC2002	12:10	-8	60		138		36	L#	90	
		FINAL		20FEB2003	13:25	57	53		157		44		102	
	E0037005	BSLN		27FEB2003	15:00	-7	120		205	H	57		124	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	FINAL		01MAY2003	14:15	57	112		240	H#	61		157	H
	E0039006	BSLN	*	11NOV2002	10:05	-49	105		272	H#	34	L#	217	H#
		BSLN	*	22NOV2002	9:20	-38	86		217	H	30	L#	170	H#
		BSLN		10DEC2002	11:35	-20	104		204	H	36	L#	147	H
		FINAL		24FEB2003	10:58	57	72		225	H	37	L#	174	H#
	E0039024	BSLN		14FEB2003	8:50	-13	143		202	H	43		130	
		FINAL		25APR2003	16:05	58	209	#	191		44		105	
	E0039044	BSLN		06MAY2003	10:30	-16	167		231	H	43		155	H
		FINAL		23JUL2003	18:20	63	527	H#	201	H	30	L#	94	
	E0039046		*	06MAY2003	11:46		164		168		30	L#	105	
			*	03JUN2003	10:25		207	#	163		33	L#	89	
	E0039051	BSLN		23MAY2003	9:30	-24	67		212	H	55		144	H
		FINAL		12AUG2003	14:45	58	272	H#	192		36	L#	102	
	E0039053	BSLN		16JUN2003	13:25	-25	100		150		38	L#	92	
		FINAL		08SEP2003	12:45	60	206	#	175		43		91	
	E0041003	BSLN		16JAN2003	17:30	-12	218	#	187		46		97	
		FINAL		25MAR2003	9:55	57	109		197		50		125	
	E0041008	BSLN		26MAR2003	15:35	-12	183		251	H#	54		160	H#
		FINAL		02JUN2003	15:30	57	143		161		59		73	
	E0042001	BSLN		17JUN2003	9:45	-15	113		209	H	52		134	H
		FINAL		26AUG2003	10:50	56	87		266	H#	60		189	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	BSLN		08APR2003	9:55	-10	248	#	216	H	36	L#	130	
		FINAL		02JUL2003	14:00	76	489	H#	214	H	35	L#	112	
		FINAL	*	12AUG2003	11:30	117	192		215	H	34	L#	143	H
	E0009002	BSLN		30OCT2002	11:45	-20	105		164		44		99	
		FINAL		15JAN2003	13:47	58	184		151		32	L#	82	
	E0009006	BSLN		23JAN2003	17:50	-5	117		176		38	L#	115	
		FINAL		25MAR2003	16:20	57	110		239	H	50		167	H#
	E0009009	BSLN		27FEB2003	15:00	-13	204	#	183		40	#	102	
		FINAL		24MAR2003	13:40	13	148		176		47		99	
	E0010015	BSLN		30JAN2003	10:35	-21	117		208	H	37	L#	148	H
		FINAL		15APR2003	13:29	55	334	H#	199		30	L#	102	
	E0011004	BSLN		17DEC2002	11:00	-7	169		131		24	L#	73	
		FINAL		18FEB2003	9:00	57	272	H#	158		26	L#	78	
	E0011007	BSLN		12DEC2002	10:43	-7	175		247	H#	55		157	H
		FINAL		13FEB2003	8:00	57	254	H#	265	H#	51		163	H#
	E0011018	BSLN		15MAY2003	12:30	-7	161		153		41		80	
		FINAL		17JUL2003	17:30	57	184		150		40	#	73	
	E0011024	BSLN		17JUN2003	12:10	-7	77		210	H	57		138	H
		FINAL		21AUG2003	13:00	59	88		258	H#	57		183	H#
	E0015003	BSLN		13NOV2002	12:20	-12	234	#	298	H#	50		201	H#
		FINAL		02DEC2002	10:55	8	612	H#	348	H#	51		212	H#
	E0019003	BSLN		30OCT2002	9:10	-22	208	#	197		48		107	
		FINAL		16JAN2003	11:25	57	180		189		41		112	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	BSLN	*	17DEC2002	11:02	-23	84		116	L	39	L#	60	
		BSLN		26DEC2002	10:25	-14	122		114	L	35	L#	55	
		FINAL		22JAN2003	9:00	14	115		104	L	32	L#	49	
	E0019018	BSLN		14JAN2003	10:45	-16	85		190		40	#	133	H
		FINAL		27MAR2003	9:30	57	102		206	H	39	L#	147	H
	E0019022	BSLN		23JAN2003	12:00	-7	106		164		31	L#	112	
		FINAL		27MAR2003	15:10	57	168		170		31	L#	105	
	E0019032	BSLN		06MAR2003	14:50	-26	65		259	H#	59		187	H#
		FINAL		28MAY2003	11:00	58	104		368	H#	77		270	H#
	E0023002	BSLN		25OCT2002	16:00	-11	173		179		28	L#	116	
	E0023017	BSLN		20MAR2003	11:00	-5	167		130		36	L#	61	
		FINAL		22MAY2003	12:30	59	203	#	133		43		49	
	E0023021	BSLN	*	10APR2003	10:20	-13	216	#	237	H	44		150	H
		BSLN		16APR2003	15:00	-7	134		240	H#	43		170	H#
		FINAL		17JUN2003	16:00	56	267H	#	244	H#	39	L#	152	H
	E0023027	BSLN		07MAY2003	13:30	-9	428H	#	233	H	30	L#	151	H
		FINAL		09JUL2003	13:00	55	270H	#	208	H	30	L#	124	
	E0023030	BSLN		21MAY2003	10:00	-13	161		262	H#	73		157	H
		FINAL		30JUL2003	15:30	58	410H	#	279	H#	57		168	H#
	E0027005	BSLN		19DEC2002	14:50	-7	197		233	H	62		132	H
		FINAL		20FEB2003	11:28	57	530H	#	288	H#	46		173	H#
	E0029026	BSLN		07APR2003	9:10	-7	173		197		42		120	
		FINAL		10JUN2003	15:00	58	99		175		34	L#	121	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	BSLN	*	13MAY2003	11:20	-14	73		149		44		90	
		BSLN		20MAY2003	12:55	-7	86		141		39	L#	85	
		FINAL		23JUL2003	17:25	58	94		157		55		83	
	E0031008	BSLN		05FEB2003	11:40	-23	144		235	H	49		157	H
		FINAL		24APR2003	13:17	56	114		235	H	51		161	H#
	E0031020	BSLN		14APR2003	10:35	-7	230	#	243	H#	44		153	H
		FINAL		13MAY2003	10:50	23	187		225	H	39	L#	149	H
	E0031029	BSLN		05JUN2003	10:45	-13	243	#	210	H	52		109	
	E0033002	BSLN		23DEC2002	12:15	-18	242	#	218	H	35	L#	135	H
		FINAL		07MAR2003	11:25	57	170		232	H	39	L#	159	H
	E0035015	BSLN		03FEB2003	10:30	-8	198		243	H#	43		160	H#
		FINAL		18FEB2003	11:20	8	258	H#	266	H#	43		171	H#
	E0035023	BSLN		06MAY2003	10:30	-7	97		198		33	L#	146	H
	E0039056	BSLN		01JUL2003	12:50	-14	118		232	H	33	L#	175	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	104	196	35 L#	140 H
		FINAL	02MAY2003	10:30	61	140	197	35 L#	134 H
	E0002011	BSLN	16APR2003	11:30	-13	124	184	46	113
		FINAL	25JUN2003	11:20	58	221 #	192	45	103
	E0003010	BSLN	28JAN2003	9:10	-6	113	264 H#	84 H	157 H
		FINAL	31MAR2003	16:20	57	127	254 H#	83 H	146 H
	E0003011	BSLN	28JAN2003	11:47	-7	131	145	37 L#	82
	E0004009	BSLN	17DEC2002	10:10	-9	133	196	46	123
		FINAL	19FEB2003	16:00	56	193	249 H#	64	146 H
	E0004015	BSLN	06FEB2003	10:05	-14	121	234 H	40 #	170 H#
		FINAL	15APR2003	9:10	55	156	252 H#	38 L#	183 H#
	E0005003	BSLN	23SEP2002	15:00	-9	444H#	211 H	33 L#	113
		FINAL	26NOV2002	13:25	56	474H#	199	30 L#	87
		FINAL *	20DEC2002	9:50	80	314H#	197		
	E0005005	BSLN	24SEP2002	15:20	-6	89	157	39 L#	100
	E0005007	BSLN	02OCT2002	12:40	-7	105	214 H	34 L#	159 H
		FINAL	04DEC2002	14:20	57	120	196	35 L#	137 H
		FINAL *	23DEC2002	10:00	76		209 H		
	E0005008	BSLN	08OCT2002	18:00	-7	308H#	241 H#	64	115
		FINAL	11DEC2002	16:00	58	475H#	237 H	52	145 H
		FINAL *	24FEB2003	10:30	133	274H#	256 H#	53	148 H
		FINAL *	12MAR2003	16:30	149	163	196	54	109
	E0005010	BSLN	14OCT2002	13:00	-7	135	132	27 L#	78
		FINAL	17DEC2002	14:25	58	212 #	155	28 L#	85

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	FINAL	*	23DEC2002	16:00	64	235 #		136		24	L#	65	
	E0005012	BSLN		24OCT2002	7:00	-21	158		237	H	38	L#	167	H#
		FINAL		07JAN2003	11:00	55	106		232	H	41		170	H#
	E0005022	BSLN		27JAN2003	10:30	-2	64		143		43		87	
		FINAL		11MAR2003	10:10	42	56		122	L	32	L#	79	
	E0005025	BSLN		20FEB2003	13:20	-7	200 #		353	H#	43		270	H#
		FINAL		03APR2003	11:30	36	180		334	H#	40	#	258	H#
	E0007005	BSLN		27JAN2003	14:30	-4	381H#		232	H	37	L#	119	
		FINAL		28MAR2003	13:30	57	528H#		220	H	33	L#	112	
		FINAL	*	11APR2003	11:00	71	221 #		197		36	L#	117	
	E0010002	BSLN		14NOV2002	10:36	-11	123		140		33	L#	82	
		FINAL		02DEC2002	9:05	8	232 #		163		38	L#	79	
	E0010029	BSLN		10JUN2003	9:25	-9	252H#		218	H	47		121	
	E0011022	BSLN		02JUN2003	11:00	-7	215 #		210	H	41		126	
		FINAL		05AUG2003	10:30	58	399H#		235	H	43		112	
	E0013006	BSLN		06MAR2003	10:15	-7	147		141		30	L#	82	
		FINAL		24MAR2003	12:42	12	179		154		30	L#	88	
	E0014005	BSLN		04MAR2003	17:20	-7	434H#		284	H#	36	L#	172	H#
		FINAL		06MAY2003	12:20	57	208 #		199		39	L#	118	
	E0014007	BSLN		25MAR2003	17:50	-7	131		156		38	L#	92	
		FINAL		22APR2003	13:50	22	82		133		42		75	
	E0014011	BSLN		06MAY2003	16:45	-7	275H#		193		38	L#	100	
		FINAL		08JUL2003	15:50	57	249 #		221	H	37	L#	134	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	BSLN		11NOV2002	9:10	-18	175		184		40	#	109	
		FINAL		20JAN2003	7:30	53	249	#	188		43		95	
	E0016003	BSLN		10JAN2003	9:30	-14	97		189		36	L#	134	H
	E0016005	BSLN		21FEB2003	8:45	-4	99		247	H#	47		180	H#
		FINAL		22APR2003	8:30	57	142		230	H	44		158	H
	E0018007	BSLN		16DEC2002	10:15	-11	387	H#	226	H	40	#	109	
		FINAL		10JAN2003	14:15	15	270	H#	223	H	30	L#	139	H
	E0019015	BSLN		19DEC2002	10:49	-14	90		193		44		131	H
		FINAL		27FEB2003	11:23	57	191		197		38	L#	121	
	E0020004	BSLN		21NOV2002	15:20	-18	120		145		41		80	
		FINAL		22JAN2003	16:15	45	212	#	209	H	42		125	
		FINAL	*	24FEB2003	11:50	78	214	#	260	H#	50		167	H#
	E0020021	BSLN		13MAY2003	9:45	-6	112		256	H#	57		177	H#
		FINAL		14JUL2003	13:25	57	131		241	H#	62		153	H
	E0020023	BSLN		09JUN2003	19:05	-8	113		210	H	50		137	H
		FINAL		11AUG2003	11:40	56	87		255	H#	54		184	H#
	E0022007	BSLN		01NOV2002	10:23	-6	50		146		40	#	96	
	E0022019	BSLN		06DEC2002	10:10	-5	137		195		34	L#	134	H
		FINAL		06FEB2003	11:20	58	102		224	H	40	#	164	H#
	E0022025	BSLN		08JAN2003	10:10	-20	173		161		35	L#	91	
		FINAL		04FEB2003	11:30	8	186		191		36	L#	118	
	E0022034	BSLN		12FEB2003	12:40	-6	203	#	270	H#	39	L#	190	H#
		FINAL		15APR2003	14:00	57	215	#	271	H#	35	L#	193	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	BSLN	27FEB2003	11:15	-7	99	211 H	34 L#	157 H
		FINAL	01MAY2003	12:50	57	136	230 H	35 L#	168 H#
	E0022046	BSLN	14MAR2003	8:00	-6	575H#	317 H#	36 L#	185 H#
		FINAL	16MAY2003	8:05	58	526H#	313 H#	42	177 H#
	E0022048	BSLN	26MAR2003	9:58	-6	91	112 L	32 L#	62
	E0022053	BSLN	04APR2003	12:50	-7	99	235 H	48	167 H#
	E0022062	BSLN	28APR2003	7:43	-7	132	172	39 L#	107
		FINAL	23MAY2003	7:40	19	125	156	42	89
	E0022071	BSLN	16JUN2003	11:40	-14	211 #	346 H#	73	231 H#
		FINAL	26AUG2003	9:33	58	181	271 H#	61	174 H#
	E0023006	BSLN	10DEC2002	10:30	-7	264H#	178	35 L#	90
		FINAL	11FEB2003	11:50	57	115	186	38 L#	125
	E0023010	BSLN	28JAN2003	9:30	-7	345H#	302 H#	55	178 H#
		FINAL	31MAR2003	10:00	56	524H#	336 H#	45	115
	E0026007	BSLN	06JAN2003	10:30	-10	215 #	261 H#	32 L#	186 H#
		FINAL	12MAR2003	14:25	56	145	183	37 L#	117
	E0028007	BSLN	01OCT2002	10:30	-3	37L	167	61	99
		FINAL	14NOV2002	12:45	42	54	108 L	36 L#	61
	E0028023	BSLN	15JAN2003	10:00	-6	203 #	160	50	69
		FINAL	27JUN2003	15:00	158	249 #	229 H	39 L#	140 H
	E0028025	BSLN	08JAN2003	12:07	-5	95	114 L	40 #	55
		FINAL	27JAN2003	9:25	15	118	134	40 #	70

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	BSLN		18MAR2003	10:50	-9	265	H#	273	H#	43		177	H#
		FINAL		22MAY2003	10:50	57	303	H#	273	H#	34	L#	178	H#
	E0028035	BSLN		27MAR2003	12:00	-7	128		267	H#	35	L#	206	H#
		FINAL		29MAY2003	15:40	57	211	#	253	H#	40	#	171	H#
	E0028037	BSLN	*	18APR2003	8:30	-56	610	H#	292	H#	42		171	H#
		BSLN	*	24APR2003	7:50	-50	1190	H#	336	H#	38	L#	143	H
		BSLN		04JUN2003	8:33	-9	215	#	189		48		98	
		FINAL		08AUG2003	15:30	57	68		164		69		81	
	E0028039	BSLN		05MAY2003	7:10	-4	149		178		32	L#	116	
		FINAL		05JUN2003	12:30	28	142		175		25	L#	122	
	E0029011	BSLN		14JAN2003	11:20	-8	163		199		38	L#	128	
	E0029018	BSLN	*	26FEB2003	16:25	-8	389	H#	180		29	L#	73	
		BSLN		06MAR2003	16:05	1	500	H#	205	H	27	L#	66	
	E0030024	BSLN		17JUN2003	15:35	-24	299	H#	275	H#	59		156	H
		FINAL		18JUL2003	15:35	8	222	#	296	H#	41		211	H#
	E0033012	BSLN		05FEB2003	15:26	-5	93		178		39	L#	120	
	E0034001	BSLN		17MAR2003	10:03	-3	86		242	H#	56		169	H#
		FINAL		15MAY2003	9:55	57	122		231	H	56		151	H
	E0034004	BSLN		11APR2003	11:15	-10	240	#	199		35	L#	116	
		FINAL		16JUN2003	12:03	57	282	H#	186		32	L#	98	
	E0035021	BSLN		18APR2003	10:45	-7	77		145		41		89	
		FINAL		20JUN2003	8:15	57	82		146		39	L#	91	
	E0036002	BSLN		10JUN2003	13:45	-7	130		196		39	L#	131	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	FINAL		15JUL2003	10:05	29	106		183		44		118	
	E0036006	BSLN	*	24JUN2003	16:45	-9	267	H#	268	H#	40	#	175	H#
		BSLN		01JUL2003	10:58	-2	304	H#	269	H#	36	L#	172	H#
		FINAL		28AUG2003	9:50	57	316	H#	272	H#	35	L#	174	H#
	E0036007	BSLN		27JUN2003	10:00	-6	116		195		42		130	
		FINAL		18JUL2003	9:15	16	188		250	H#	47		165	H#
	E0037009	BSLN		12MAY2003	9:15	-4	207	#	222	H	59		122	
		FINAL		10JUL2003	16:05	56	461	H#	243	H#	41		147	H
	E0039011	BSLN		16DEC2002	17:40	-17	318	H#	285	H#	44		177	H#
	E0039028	BSLN		03MAR2003	14:15	-21	125		126	L	39	L#	62	
		FINAL		16MAY2003	12:25	54	125		138		48		65	
	E0039032	BSLN		07MAR2003	13:45	-7	92		173		39	L#	116	
		FINAL		04APR2003	11:45	22	59		178		44		122	
	E0039042	BSLN		25APR2003	10:15	-12	66		208	H	96	H	99	
		FINAL		02JUL2003	12:50	57	211	#	204	H	40	#	122	
	E0041004	BSLN		27JAN2003	10:15	-3	116		206	H	43		140	H
		FINAL		31MAR2003	12:00	61	129		183		36	L#	121	
	E0042002	BSLN		02JUL2003	12:10	-7	174		149		31	L#	83	
		FINAL		02SEP2003	10:25	56	343	H#	155		30	L#	56	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN		23JUN2003	10:00	-18	103	108	L	43		44	
		FINAL		25JUL2003	9:00	15	118	121	L	34	L#	63	
	E0005033	BSLN		08APR2003	14:00	-8	51	225	H	50		165	H#
		FINAL		06MAY2003	11:20	21	41L	208	H	45		155	H
	E0005038	BSLN		05MAY2003	11:40	-9	80	148		36	L#	96	
		FINAL		05JUN2003	13:00	23	144	163		32	L#	102	
	E0009010	BSLN		27FEB2003	16:55	-14	260H#	188		28	L#	108	
	E0009011	BSLN		28APR2003	14:17	-8	315H#	137		41		33	
		FINAL		03JUL2003	15:40	59	305H#	124	L	29	L#	34	
	E0010005	BSLN		11DEC2002	10:15	-7	203 #	202	H	38	L#	123	
	E0011016	BSLN		14APR2003	10:00	-7	275H#	240	H#	36	L#	149	H
		FINAL		16JUN2003	9:45	57	412H#	237	H	32	L#	154	H
	E0018002	BSLN		15NOV2002	15:35	-14	139	218	H	45		145	H
		FINAL		22JAN2003	16:20	55	166	199		38	L#	128	
	E0018003	BSLN		19NOV2002	13:05	-7	515H#	125	L	21	L#	44	
		FINAL		10DEC2002	11:00	15	247 #	121	L	21	L#	51	
	E0018013	BSLN		17JAN2003	14:15	-7	182	198		30	L#	132	H
		FINAL		06FEB2003	16:10	14	190	186		27	L#	121	
	E0019008	BSLN	*	06NOV2002	12:35	-15	119	190		35	L#	131	H
		BSLN		13NOV2002	10:30	-8	74	157		32	L#	110	
	E0019016	BSLN		30DEC2002	16:55	-7	198	159		37	L#	82	
		FINAL		03MAR2003	16:00	57	235 #	186		36	L#	103	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	BSLN		16JAN2003	11:45	-14	385	H#	268	H#	39	L#	152	H
		FINAL		03MAR2003	13:18	33	388	H#	246	H#	34	L#	134	H
	E0019031	BSLN		06MAR2003	11:35	-7	650	H#	323	H#	35	L#	160	H#
		FINAL		25MAR2003	10:08	13	1000	H#	333	H#	32	L#	125	
	E0019035	BSLN		11MAR2003	9:28	-7	426	H#	247	H#	29	L#	154	H
		FINAL		17APR2003	14:30	31	418	H#	215	H	30	L#	126	
	E0019040	BSLN		08MAY2003	15:25	-12	220	#	198		34	L#	120	
		FINAL		17JUL2003	9:50	59	150		202	H	34	L#	138	H
	E0020024	BSLN		12JUN2003	15:40	-11	100		167		46		101	
		FINAL		20AUG2003	18:45	59	241	#	163		41		74	
	E0022044	BSLN		12MAR2003	9:50	-6	106		191		49		121	
		FINAL		12MAY2003	9:55	56	107		241	H#	80		140	H
	E0023011	BSLN		28JAN2003	11:45	-7	557	H#	211	H	36	L#	124	
		FINAL		01APR2003	12:00	57	573	H#	283	H#	40	#	153	H
	E0023014	BSLN		14FEB2003	15:00	-7	96		135		55		61	
		FINAL		25APR2003	14:00	64	213	#	234	H	63		128	
	E0023019	BSLN		21MAR2003	14:00	-17	122		163		71		68	
		FINAL		03JUN2003	13:30	58	119		233	H	45		164	H#
	E0023022	BSLN		10APR2003	16:00	-8	95		243	H#	63		161	H#
		FINAL		12JUN2003	15:40	56	96		202	H	72		111	
	E0023031	BSLN	*	22MAY2003	12:00	-33	390	H#	353	H#	48		227	H#
		BSLN		19JUN2003	10:00	-5	150		293	H#	39	L#	224	H#
		FINAL		19AUG2003	11:00	57	267	H#	319	H#	44		222	H#

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM110.SAS
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	BSLN		03JUL2003	11:00	-6	97	268	H#	71		178	H#
		FINAL		05SEP2003	13:00	59	130	294	H#	59		209	H#
	E0026003	BSLN	*	25NOV2002	12:20	-9	323H#	161		30	L#	66	
		BSLN	*	02DEC2002	9:25	-2						137	H
		BSLN		02DEC2002	9:25	-2	164	216	H	46		159	H
		FINAL		03FEB2003	10:50	62	284H#	183		24	L#	102	
	E0026005	BSLN		23DEC2002	12:40	-7	87	221	H	106	H	98	
		FINAL		06JAN2003	15:25	8	94	263	H#	95	H	149	H
	E0026009	BSLN		10JAN2003	10:20	-5	103	220	H	38	L#	161	H#
		FINAL		21JAN2003	9:50	7	115	193		44		126	
	E0026023	BSLN		23APR2003	10:50	-7	72	142		37	L#	91	
		FINAL		27JUN2003	12:25	59	57	122	L	36	L#	75	
	E0027016	BSLN	*	19MAR2003	11:55	-21	113	156		33	L#	100	
		BSLN		04APR2003	9:50	-5	113	180		34	L#	123	
		FINAL		03JUN2003	10:18	56	113	171		31	L#	117	
	E0028032	BSLN		13MAR2003	13:58	-12	191	318	H#	44		236	H#
		FINAL		06JUN2003	11:38	74	499H#	267	H#	32	L#	161	H#
	E0029003	BSLN		28OCT2002	12:30	-7	97	211	H	45		147	H
		FINAL		30DEC2002	9:45	57	156	186		36	L#	119	
	E0031011	BSLN		18FEB2003	11:50	-9	150	254	H#	47		177	H#
		FINAL		24APR2003	9:25	57	165	256	H#	47		176	H#
	E0031031	BSLN		01JUL2003	10:30	-7	161	185		39	L#	114	
		FINAL		28AUG2003	10:35	52	88	166		38	L#	110	
	E0034009	BSLN		10JUN2003	13:00	-9	129	192		43		123	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0034009	FINAL	18AUG2003	17:25	61	253H#	200	42	107
	E0037007	BSLN	04APR2003	11:30	-7	148	229 H	39 L#	160 H#
	E0037012	BSLN	11JUL2003	13:00	-5	57	170	38 L#	121
		FINAL	08SEP2003	13:20	55	240 #	174	34 L#	92

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0002003	BSLN		03JAN2003	11:50	-19	305	H#	246	H#	51		134	H
		FINAL		18MAR2003	12:10	56	380	H#	216	H	43		97	
	E0002004	BSLN		14JAN2003	8:15	-11	223	#	154		40	#	69	
	E0002008	BSLN		14FEB2003	16:00	-11	1240	H#	320	H#	30	L#	83	
		FINAL		23APR2003	14:25	58	190		214	H	38	L#	138	H
	E0002016	BSLN		14JUL2003	11:00	-10	233	#	207	H	59		101	
		FINAL		17SEP2003	11:15	56	468	H#	318	H#	50		175	H#
	E0004003	BSLN		02OCT2002	11:00	-8	369	H#	228	H	44		110	
	E0004006	BSLN		28OCT2002	9:55	-7	110		176		40	#	114	
		FINAL		06JAN2003	10:55	64	96		176		41		116	
	E0005006	BSLN	*	24SEP2002	15:30	-9	392	H#	158		37	L#	43	
		BSLN		03OCT2002	8:30	1	254	H#	170		31	L#	88	
	E0005019	BSLN		19DEC2002	14:00	-27	105		147		44		82	
		FINAL		23JAN2003	15:45	9	122		142		34	L#	84	
	E0005039	BSLN		15MAY2003	9:00	-7	187		232	H	36	L#	159	H
		FINAL		16JUL2003	8:40	56	180		217	H	34	L#	147	H
	E0006020	BSLN		02MAY2003	13:30	-11	118		237	H	47		166	H#
		FINAL		08JUL2003	14:45	57	114		229	H	39	L#	167	H#
		FINAL	*	10JUL2003	16:30	59	204	#	239	H	37	L#	161	H#
	E0007001	BSLN	*	16DEC2002	9:25	-15	224	#	287	H#	45		197	H#
		BSLN		26DEC2002	9:25	-5	206	#	264	H#	43		180	H#
		FINAL		24FEB2003	8:43	56	276	H#	285	H#	42		188	H#
		FINAL	*	10MAR2003	8:54	70	193		270	H#	44		187	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0007006	BSLN		24FEB2003	11:00	-9	75		131		37	L#	79	
		FINAL		27MAR2003	10:50	23	143		159		39	L#	91	
	E0009004	BSLN	*	19NOV2002	12:30	-7	784	H#	332	H#	51		126	
		BSLN		25NOV2002	12:55	-1	243	#	263	H#	52		162	H#
		FINAL		18DEC2002	14:50	23	719	H#	315	H#	64		138	H
	E0009012	BSLN		16JUN2003	14:45	-9	226	#	215	H	37	L#	133	H
		FINAL		03JUL2003	17:45	9	113		209	H	47		139	H
	E0011008	BSLN	*	17DEC2002	12:30	-44	85		130		24	L#	89	
		BSLN		23JAN2003	9:20	-7	67		130		42		75	
		FINAL		13FEB2003	12:30	15	93		135		30	L#	86	
	E0011009	BSLN		19DEC2002	10:15	-8	264	H#	233	H	45		135	H
		FINAL		20FEB2003	9:00	56	338	H#	243	H#	45		130	
	E0011010	BSLN		03FEB2003	10:00	-7	85		260	H#	65		178	H#
		FINAL		19MAR2003	8:45	38	122		198		55		119	
	E0013001	BSLN		01NOV2002	8:50	-13	266	H#	234	H	37	L#	144	H
		FINAL		10JAN2003	10:45	58	222	#	222	H	28	L#	150	H
	E0013005	BSLN		13FEB2003	11:42	-5	95		175		45		111	
		FINAL		15APR2003	12:16	57	240	#	191		31	L#	112	
	E0014004	BSLN		04MAR2003	11:40	-8	167		217	H	44		140	H
		FINAL		15APR2003	11:40	35	265	H#	208	H	36	L#	119	
	E0014009	BSLN	*	15APR2003	14:45	-8	389	H#	211	H	41		92	
		BSLN		17APR2003	12:30	-6	185		204	H	47		120	
		FINAL		16MAY2003	8:55	24	112		210	H	40	#	148	H
	E0014018	BSLN		24JUN2003	16:35	-7	47		149		44		96	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0014018	FINAL		27AUG2003	16:00	58	61		137		38	L#	87	
		FINAL	*	24SEP2003	16:45	86	57		132		40	#	81	
	E0015005	BSLN		25NOV2002	13:15	-7	83		249	H#	58		174	H#
		FINAL		18DEC2002	9:30	17	85		236	H	62		157	H
	E0017002	BSLN		08MAY2003	17:00	-26	327	H#	213	H	49		99	
		FINAL		13JUN2003	16:00	11	86		242	H#	49		176	H#
	E0018009	BSLN		17DEC2002	10:45	-20	187		209	H	34	L#	138	H
		FINAL		14JAN2003	13:15	9	101		201	H	41		140	H
	E0018015	BSLN		21JAN2003	11:20	-7	188		216	H	40	#	138	H
		FINAL		27MAR2003	10:50	59	92		231	H	43		170	H#
	E0020015	BSLN		18MAR2003	13:30	-9	174		222	H	36	L#	151	H
		FINAL		23MAY2003	13:40	58	172		192		28	L#	130	
	E0020022	BSLN		09JUN2003	13:05	-7	190		245	H#	55		152	H
		FINAL		11AUG2003	9:30	57	152		227	H	51		146	H
	E0022004	BSLN	*	17OCT2002	8:48	-11	172		228	H	35	L#	159	H
		BSLN		28OCT2002	9:47	1	183		218	H	41		140	H
		FINAL		23DEC2002	10:15	57	125		238	H	46		167	H#
	E0022005	BSLN		18OCT2002	7:40	-21	190		216	H	35	L#	143	H
		FINAL		03JAN2003	9:20	57	172		243	H#	42		167	H#
	E0022015	BSLN	*	29NOV2002	13:50	-11	85		125	L	50		58	
		BSLN	*	03DEC2002	10:10	-7	70		115	L	52		49	
		BSLN		10DEC2002	16:10	1	204	#	124	L	52		31	
		FINAL		06FEB2003	9:50	59	74		120	L	51		54	
	E0022020	BSLN		05DEC2002	12:21	-7	75		162		34	L#	113	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0022020	FINAL	23JAN2003	16:20	43	65	126 L	33 L#	80
		FINAL *	28JAN2003	10:35	48	72	121 L	37 L#	70
	E0022023	BSLN	20DEC2002	14:28	-5	285H#	213 H	36 L#	120
		FINAL	20FEB2003	10:05	58	527H#	244 H#	34 L#	106
	E0022029	BSLN	10FEB2003	12:30	-9	387H#	283 H#	32 L#	174 H#
		FINAL	14APR2003	9:45	55	199	221 H	30 L#	151 H
	E0022041	BSLN	11MAR2003	9:53	-7	180	192	47	109
		FINAL	13MAY2003	9:18	57	242 #	219 H	63	108
	E0022042	BSLN	05MAR2003	9:50	-7	263H#	205 H	44	108
		FINAL	12MAY2003	9:35	62	362H#	222 H	47	103
	E0022054	BSLN	07APR2003	11:25	-4	115	163	27 L#	113
	E0022070	BSLN	05JUN2003	11:40	-7	255H#	231 H	36 L#	144 H
		FINAL	18JUN2003	15:15	7	474H#	259 H#	34 L#	152 H
	E0023001	BSLN	24OCT2002	13:30	-22	98	238 H	53	165 H#
		FINAL	14JAN2003	13:30	61	160	226 H	51	143 H
	E0023009	BSLN	24JAN2003	11:30	-18	103	250 H#	40 #	189 H#
		FINAL	08APR2003	11:15	57	133	289 H#	47	215 H#
	E0023028	BSLN	16MAY2003	12:15	-13	93	249 H#	78	152 H
		FINAL	21JUL2003	11:00	54	66	185	92 H	80
	E0023033	BSLN	30MAY2003	12:10	-6	348H#	193	33 L#	90
		FINAL	12JUN2003	13:15	8	292H#	182	30 L#	94
	E0023047	BSLN	11JUL2003	15:00	-7	80	169	78	75
		FINAL	16SEP2003	13:00	61	113	133	39 L#	71

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0025001	BSLN		25MAR2003	16:00	-7	320H#	191	23 L#	104
		FINAL		23APR2003	10:30	23	136	160	27 L#	106
	E0028001	BSLN		07OCT2002	14:00	-3	510H#	253 H#	30 L#	162 H#
		FINAL		03DEC2002	9:50	55	461H#	354 H#	24 L#	235 H#
	E0028011	BSLN	*	22OCT2002	8:30	-44	204 #	197	31 L#	125
		BSLN		25NOV2002	9:00	-10	176	190	32 L#	123
		FINAL		30JAN2003	12:35	57	299H#	183	29 L#	94
	E0028030	BSLN		26FEB2003	11:30	-6	124	176	40 #	111
		FINAL		30APR2003	12:35	58	99	213 H	44	149 H
	E0028031	BSLN		06MAR2003	9:00	-5	188	237 H	36 L#	163 H#
		FINAL		17APR2003	13:30	38	155	209 H	46	132 H
	E0028047	BSLN		09JUL2003	10:40	-5	153	197	42	124
		FINAL		09SEP2003	10:24	58	162	178	38 L#	108
	E0029001	BSLN		25SEP2002	8:45	-6	126	164	36 L#	103
	E0029014	BSLN		28JAN2003	9:35	-7	118	245 H#	85 H	136 H
		FINAL		01APR2003	11:20	57	184	235 H	83 H	115
	E0029023	BSLN		01APR2003	8:47	-7	291H#	234 H	52	124
		FINAL		10JUN2003	11:10	64	167	230 H	51	146 H
	E0029032	BSLN		22MAY2003	12:45	-19	109	180	36 L#	122
		FINAL		01JUL2003	12:00	22	113	162	32 L#	107
	E0029039	BSLN		10JUL2003	13:02	-5	68	194	40 #	140 H
		FINAL		28JUL2003	15:30	14	60	162	47	103
	E0030009	BSLN		14JAN2003	9:55	-9	345H#	288 H#	53	166 H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0030009	FINAL		19MAR2003	10:35	56	283	H#	274	H#	50		167	H#
	E0030016	BSLN		21FEB2003	11:50	-10	90		192		38	L#	136	H
		FINAL		22APR2003	18:55	51	333	H#	168		36	L#	65	
	E0030021	BSLN		13MAY2003	17:25	-7	84		172		39	L#	116	
	E0031001	BSLN		14NOV2002	11:48	-7	231	#	204	H	36	L#	122	
	E0031023	BSLN		22APR2003	14:03	-7	416	H#	153		24	L#	88	
		FINAL		24JUN2003	11:48	57	280	H#	194		27	L#	111	
	E0033014	BSLN		12MAR2003	17:25	-7	255	H#	226	H	36	L#	139	H
	E0035002	BSLN		14NOV2002	10:50	-7	154		193		40	#	122	
	E0035007	BSLN		13DEC2002	12:40	-6	151		191		43		118	
		FINAL		11FEB2003	10:10	55	206	#	214	H	53		120	
	E0035011	BSLN		13JAN2003	8:35	-22	283	H#	240	H#	35	L#	148	H
		FINAL		01APR2003	9:00	57	288	H#	196		34	L#	104	
	E0039023	BSLN		05FEB2003	10:37	-19	109		150		40	#	88	
	E0039038	BSLN	*	27MAR2003	10:10	-27	104		241	H#	80		140	H
		BSLN		21APR2003	10:16	-2	89		231	H	81	H	132	H
		FINAL		20JUN2003	11:15	59	159		242	H#	88	H	122	
	E0039059	BSLN		07JUL2003	11:10	-4	242	#	243	H#	35	L#	160	H#
		FINAL		05SEP2003	11:10	57	205	#	239	H	37	L#	161	H#
	E0041010	BSLN		23APR2003	14:45	-7	502	H#	272	H#	34	L#	168	H#
		FINAL		11JUN2003	15:30	43	350	H#	244	H#	39	L#	135	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0041011	BSLN	15MAY2003	16:00	-7	215 #	143	39 L#	61
		FINAL	17JUL2003	14:30	57	210 #	146	39 L#	65
	E0041012	BSLN	05JUN2003	12:28	-14	262H#	208 H	42	114
		FINAL	14AUG2003	11:45	57	405H#	218 H	41	125

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:48 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR II)	E0001004	BSLN		23APR2003	11:00	-8	89		171		34	L#	119	
		FINAL		27JUN2003	12:45	58	111		195		35	L#	138	H
	E0005034	BSLN		09APR2003	9:30	-6	179		225	H	40	#	149	H
		FINAL		09JUN2003	13:00	56	110		153		35	L#	96	
	E0005041	BSLN		17JUN2003	11:55	-7	198		212	H	39	L#	133	H
		FINAL		18AUG2003	10:10	56	153		221	H	37	L#	153	H
	E0007004	BSLN		28JAN2003	8:05	-2	1030H#		272	H#	41		98	
		FINAL		13FEB2003	8:30	15	1930H#		466	H#	39	L#	80	
	E0007010	BSLN		14APR2003	8:10	-4	180		191		37	L#	118	
		FINAL	*	21APR2003	8:30	4	234	#	183		31	L#	105	
		FINAL		13JUN2003	7:40	57	192		165		32	L#	95	
		FINAL	*	16JUN2003	7:50	60	142		173		33	L#	112	
	E0007012	BSLN		12MAY2003	8:50	-4	272H#		199		29	L#	116	
		FINAL		02JUL2003	11:35	48	155		205	H	34	L#	140	H
	E0009007	BSLN		27JAN2003	15:25	-7	163		212	H	31	L#	148	H
		FINAL		03MAR2003	15:40	29	158		232	H	35	L#	165	H#
	E0009008	BSLN		04FEB2003	13:37	-8	94		173		40	#	114	
		FINAL		08APR2003	12:35	56	123		213	H	47		141	H
	E0011001	BSLN		25OCT2002	16:00	-7	70		242	H#	73		155	H
		FINAL		26DEC2002	8:30	56	72		224	H	67		143	H
	E0011013	BSLN		25MAR2003	9:45	-23	181		207	H	34	L#	137	H
		FINAL		12JUN2003	8:45	57	260H#		200		34	L#	114	
	E0014001	BSLN		18FEB2003	15:45	-8	139		112	L	47		37	
		FINAL		08APR2003	11:10	42	121		91	L	33	L#	34	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM110.SAS
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR II)	E0014001	FINAL	*	16APR2003	10:40	50	188	125	L	42		45	
	E0015004	BSLN		25NOV2002	8:50	-7	90	111	L	36	L#	57	
		FINAL		29JAN2003	8:45	59	52	113	L	43		60	
	E0019038	BSLN	*	10APR2003	12:30	-14	52	134		39	L#	85	
		BSLN		17APR2003	11:05	-7	47	101	L	38	L#	54	
		FINAL		19JUN2003	9:40	57	69	106	L	36	L#	56	
	E0022006	BSLN		22OCT2002	10:10	-21	308H#	185		36	L#	87	
		FINAL		07JAN2003	7:40	57	234 #	159		35	L#	77	
	E0022047	BSLN		21MAR2003	8:10	-7	660H#	317	H#	30	L#	70	
		FINAL		23MAY2003	9:45	57	537H#	341	H#	36	L#	77	
	E0023012	BSLN		31JAN2003	15:30	-6	214 #	167		40	#	84	
		FINAL		04APR2003	12:15	58	193	144		31	L#	74	
	E0023018	BSLN		18MAR2003	13:30	-9	85	175		79		79	
		FINAL		22MAY2003	10:15	57	123	176		40	#	111	
	E0023036	BSLN		10JUN2003	12:00	-10	93	164		35	L#	110	
		FINAL		13AUG2003	17:00	55	89	146		43		85	
	E0023046	BSLN		11JUL2003	10:00	-12	160	167		38	L#	97	
		FINAL		16SEP2003	14:00	56	120	187		41		122	
	E0026006	BSLN		31DEC2002	10:35	-8	201 #	204	H	37	L#	127	
	E0029002		*	07NOV2002	8:10		319H#	276	H#	64		148	H
	E0029004	BSLN		13NOV2002	14:50	-6	81	158		43		99	
		FINAL		17JAN2003	8:25	60	84	143		40	#	86	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM110.SAS
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR II)	E0029019	BSLN		24FEB2003	9:30	-7	360	H#	261	H#	36	L#	153	H
		FINAL		17MAR2003	9:50	15	168		198		36	L#	128	
	E0029038	BSLN		30JUN2003	9:25	-7	143		185		40	#	116	
	E0031004	BSLN		12DEC2002	13:59	-7	168		232	H	53		145	H
		FINAL		14FEB2003	10:50	58	434	H#	243	H#	43		137	H
	E0031019	BSLN		03APR2003	11:25	-8	165		238	H	36	L#	169	H#
		FINAL		12MAY2003	16:40	32	184		202	H	30	L#	135	H
	E0031022	BSLN		21APR2003	12:40	-7	356	H#	235	H	46		118	
	E0034007	BSLN		07MAY2003	14:05	-9	94		255	H#	65		171	H#
		FINAL		14JUL2003	11:15	60	73		249	H#	88	H	146	H
		FINAL	*	28JUL2003	11:48	74	187		305	H#	90	H	178	H#
	E0035004	BSLN		22NOV2002	11:45	-5	337	H#	282	H#	53		162	H#
	E0039003	BSLN		12NOV2002	11:19	-13	149		181		55		96	
		FINAL		02JAN2003	14:06	39	226	#	143		44		54	
	E0041002	BSLN		13JAN2003	14:35	-8	80		214	H	42		156	H
		FINAL		11MAR2003	10:35	50	70		192		37	L#	141	H
	E0041005	BSLN		28FEB2003	12:31	-5	84		209	H	31	L#	161	H#
		FINAL		30APR2003	14:08	57	177		185		43		107	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM110.SAS
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Table 11.3.7.2.2.6 Chemistry Data for Thyroid Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	BSLN		16JUL2003	13:25	-8	4		77		31	
		FINAL		07AUG2003	8:10	15	5	#	108		30	
	E0003015	BSLN		29APR2003	11:30	-6	2		187	H#	27	
		FINAL		02JUL2003	14:45	59	1		145		28	
	E0022008	BSLN		05NOV2002	10:00	-7	5	#	69		39	
		FINAL		07JAN2003	9:45	57	2		69		42	H
	E0022018	BSLN		04DEC2002	10:15	-8	5	#	99		30	
		FINAL		11FEB2003	8:40	62	4		104		34	
	E0022056	BSLN		11APR2003	8:07	-6	6H	#	88		37	
	E0030001	BSLN		12NOV2002	15:15	-7	3		108		27	
		FINAL		16JAN2003	12:07	59	5	#	89		28	
QUETIAPINE 300 MG (BIPOLAR II)	E0009002	BSLN		30OCT2002	11:45	-20	4		131		35	
		FINAL		15JAN2003	13:47	58	7H	#	93		35	
		FINAL	*	21JAN2003	12:20	64	15H	#				
	E0010015	BSLN	*	30JAN2003	10:35	-21	7H	#				
		BSLN		30JAN2003	10:35	-21			84		32	
		BSLN		17FEB2003	13:50	-3	5					
		FINAL		15APR2003	13:29	55	4		53	L	31	
	E0019003	BSLN		30OCT2002	9:10	-22	6H	#	99		28	
		FINAL		16JAN2003	11:25	57	2		94		34	
	E0022073	BSLN		20JUN2003	14:10	-6	1		133		33	
		FINAL		21AUG2003	9:45	57	6H	#	102		37	
	E0040003	BSLN		09JUL2003	14:00	-10	3		91		33	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM111.SAS
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Table 11.3.7.2.2.6 Chemistry Data for Thyroid Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	FINAL		12SEP2003	11:00	56	6H#	75		41	H
		FINAL	*	25SEP2003	11:30	69	2	66		38	
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	BSLN		05NOV2002	16:30	-8	2	103		33	
		FINAL		06JAN2003	10:00	55	6H#	68		37	
	E0029015	BSLN		11FEB2003	10:05	-13		154		42	H
		FINAL		14MAR2003	10:30	19	0L	212	H#	36	
QUETIAPINE 600 MG (BIPOLAR II)	E0019008	BSLN	*	06NOV2002	12:35	-15	7H#	122		28	
		BSLN		13NOV2002	10:30	-8	6H#	153		30	
	E0023031	BSLN	*	22MAY2003	12:00	-33	7H#	88		30	
		BSLN		19JUN2003	10:00	-5	3	154		33	
		FINAL		19AUG2003	11:00	57	3	77		32	
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	4	120		35	
		FINAL		26FEB2003	8:45	59	13H#	116		32	
	E0018015	BSLN		21JAN2003	11:20	-7	5	89		30	
		FINAL		27MAR2003	10:50	59	6H#	113		30	
	E0022005	BSLN	*	18OCT2002	7:40	-21	19H#				
		BSLN		18OCT2002	7:40	-21		76		29	
		BSLN		01NOV2002	11:15	-7	5				
		FINAL		03JAN2003	9:20	57	10H#	80		30	
	E0022011	BSLN		21NOV2002	9:25	-8	5 #	100		37	
	E0023001	BSLN	*	24OCT2002	13:30	-22	10H#	99		34	
		BSLN		13NOV2002	13:30	-2	2	134		34	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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Table 11.3.7.2.2.6 Chemistry Data for Thyroid Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
PLACEBO (BIPOLAR I)	E0023001	FINAL		14JAN2003	13:30	61	2		121		35	
	E0035011	BSLN		13JAN2003	8:35	-22	5		104		27	
		FINAL		01APR2003	9:00	57	6H#		94		28	
	E0039038	BSLN		27MAR2003	10:10	-27	5 #		176	H	22	
		FINAL		20JUN2003	11:15	59	3		167	H	26	
PLACEBO (BIPOLAR II)	E0011013	BSLN	*	25MAR2003	9:45	-23	15H#					
		BSLN		25MAR2003	9:45	-23			93		30	
		BSLN		15APR2003	9:00	-2	2					
		FINAL		12JUN2003	8:45	57	4		109		35	
	E0014001	BSLN		18FEB2003	15:45	-8	1		33	L#	49	H
		FINAL		08APR2003	11:10	42	1		51	L	46	H
	E0029002		*	07NOV2002	8:10		20H#		108		30	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM111.SAS
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11.3.7.3 Narratives for subjects with abnormal laboratory results

No narratives for subjects with abnormal laboratory results are presented in this clinical study report.

Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE PULSE (BPM)	VISIT																		
	SCREEN	176	70.6	9.39	72.0	48	96	178	69.9	10.72	68.0	51	109	180	71.5	9.03	72.0	48	99
	DAY 1	177	71.6	10.13	72.0	48	98	180	72.5	11.90	72.0	48	119	179	71.5	8.83	72.0	52	100
	DAY 8	173	74.9	10.22	76.0	53	100	169	76.4	11.42	76.0	52	119	175	72.4	8.97	72.0	56	104
	DAY 15	148	77.2	11.11	76.0	54	123	149	78.7	11.42	80.0	52	120	155	73.5	10.39	72.0	52	120
	DAY 22	146	76.5	9.92	76.0	52	100	134	79.8	11.48	80.0	52	112	146	72.3	8.86	72.0	48	104
	DAY 29	133	76.0	10.15	78.0	56	100	127	80.5	10.97	80.0	56	113	130	72.6	8.68	72.0	48	96
	DAY 36	130	75.3	10.96	75.5	48	126	115	79.4	11.08	80.0	54	117	125	72.4	8.90	72.0	52	96
	DAY 43	123	76.3	10.61	76.0	52	107	107	79.6	12.17	80.0	52	112	110	73.8	9.07	72.0	60	123
	DAY 50	123	76.4	10.42	76.0	52	105	102	81.1	12.54	80.0	52	113	106	73.0	8.23	72.0	56	96
	DAY 57	121	75.3	10.20	76.0	52	111	99	78.8	11.49	80.0	50	104	105	71.6	8.52	71.0	56	102
	FINAL	176	75.1	9.94	76.0	52	111	171	77.3	11.00	78.0	50	104	175	72.7	9.34	72.0	56	104
SUPINE SYSTOLIC BP (MMHG)	SCREEN	176	118.9	13.21	120.0	85	168	178	119.8	13.72	120.0	88	168	180	118.8	13.61	118.0	90	172
	DAY 1	177	118.5	12.68	118.0	85	154	180	118.9	13.53	120.0	90	174	179	118.7	12.92	118.0	90	154
	DAY 8	173	119.6	13.49	120.0	90	161	169	120.7	13.95	122.0	90	188	175	118.6	14.12	118.0	90	170
	DAY 15	148	121.0	12.69	120.0	98	170	149	120.3	12.63	120.0	90	162	155	118.1	13.10	118.0	84	150
	DAY 22	146	121.2	13.05	120.0	90	157	134	119.6	13.14	120.0	90	158	146	118.0	12.74	118.0	90	160
	DAY 29	133	119.7	12.48	118.0	90	155	127	120.1	13.73	120.0	86	170	130	117.6	14.25	118.0	92	168

(Continued)

Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE SYSTOLIC BP (MMHG)	VISIT																		
	DAY 36	130	120.1	12.39	120.0	88	152	115	121.3	13.40	122.0	92	152	125	117.3	14.00	118.0	85	162
	DAY 43	124	121.6	11.42	120.5	95	160	107	120.8	13.54	120.0	92	154	110	117.9	13.66	118.0	80	160
	DAY 50	123	120.9	11.87	120.0	90	155	102	120.9	12.81	120.0	90	166	106	118.7	13.70	119.0	80	152
	DAY 57	121	119.6	11.25	120.0	90	152	99	119.4	13.98	120.0	80	174	105	117.8	15.30	116.0	80	162
	FINAL	176	119.8	11.51	120.0	88	152	171	119.0	13.78	120.0	80	174	175	117.8	15.31	116.0	80	162
SUPINE DIASTOLIC BP (MMHG)	SCREEN	176	77.1	9.04	78.0	58	100	178	75.2	8.86	76.0	56	96	180	76.1	9.88	76.0	58	120
	DAY 1	177	76.0	9.29	78.0	44	100	180	75.0	9.66	75.5	50	100	179	74.8	8.99	74.0	58	100
	DAY 8	173	77.2	9.21	78.0	60	105	169	76.1	10.20	76.0	53	128	175	75.1	8.68	74.0	56	100
	DAY 15	148	78.1	9.95	78.0	52	109	149	76.6	9.11	78.0	50	102	155	74.0	8.84	72.0	60	100
	DAY 22	146	77.1	8.36	78.0	58	99	134	76.7	9.71	78.0	58	100	146	74.2	9.37	74.0	54	95
	DAY 29	133	76.8	9.14	76.0	60	100	127	75.6	9.18	76.0	50	98	130	74.0	9.18	74.0	58	102
	DAY 36	130	77.1	8.77	78.0	56	101	115	75.5	9.25	76.0	58	100	125	74.9	9.64	74.0	48	110
	DAY 43	124	78.9	8.88	80.0	55	104	107	76.9	9.59	78.0	58	100	110	74.1	10.54	74.0	48	100
	DAY 50	123	77.6	8.78	78.0	60	100	102	76.8	9.66	78.0	57	104	106	74.7	10.15	74.0	56	110
	DAY 57	121	77.8	8.46	80.0	54	98	99	77.1	10.21	78.0	40	106	105	74.9	10.27	74.0	56	110
	FINAL	176	76.8	8.67	78.0	54	98	171	76.4	10.46	76.0	40	110	175	74.4	10.05	74.0	48	110

(Continued)

Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING PULSE (BPM)	VISIT																		
	SCREEN	177	75.3	10.01	76.0	52	106	179	76.0	10.34	76.0	56	104	178	76.1	9.81	76.0	52	126
	DAY 1	176	77.3	10.55	78.0	56	109	180	78.6	12.83	77.0	54	123	179	75.9	9.18	76.0	52	105
	DAY 8	173	80.6	10.90	80.0	56	109	169	82.5	12.82	80.0	56	123	175	77.7	9.01	78.0	56	104
	DAY 15	148	82.1	11.03	82.0	60	126	149	85.4	13.32	84.0	58	155	155	78.3	9.95	78.0	53	101
	DAY 22	146	82.5	12.32	82.0	57	121	134	86.3	13.56	86.0	62	155	146	77.2	9.24	76.0	50	102
	DAY 29	133	82.7	11.78	82.0	60	126	127	86.0	12.01	84.0	60	128	130	77.3	9.48	78.0	52	102
	DAY 36	130	81.6	12.21	80.0	58	142	115	84.8	12.73	84.0	58	131	125	77.3	9.67	76.0	56	100
	DAY 43	123	82.0	10.87	82.0	58	111	107	85.4	12.78	84.0	60	120	110	77.7	9.57	76.0	60	104
	DAY 50	123	82.4	11.55	80.0	56	123	102	87.2	14.69	86.5	58	139	106	77.8	8.58	76.0	60	96
	DAY 57	121	80.6	10.89	80.0	60	120	99	83.9	12.87	84.0	58	117	105	75.8	11.00	74.0	58	120
	FINAL	176	79.9	10.56	80.0	60	120	171	82.7	12.08	82.0	58	117	175	76.9	10.37	76.0	56	120
STANDING SYSTOLIC BP (MMHG)	SCREEN	178	119.3	13.10	118.0	80	158	179	119.7	14.00	118.0	88	166	180	118.5	13.32	118.0	90	160
	DAY 1	177	119.5	13.74	118.0	90	157	180	118.3	13.95	118.0	90	172	179	118.3	13.31	118.0	90	160
	DAY 8	173	119.6	12.85	120.0	90	158	169	119.4	13.56	120.0	90	188	175	118.4	15.19	118.0	90	179
	DAY 15	148	120.1	12.56	120.0	90	173	149	119.4	14.22	118.0	90	174	155	118.3	13.97	118.0	84	160
	DAY 22	146	120.2	12.45	120.0	93	163	134	118.7	14.05	120.0	83	160	146	117.3	13.11	118.0	88	162
	DAY 29	133	119.8	12.84	120.0	90	163	127	119.9	13.93	120.0	84	168	130	118.0	14.87	118.0	88	168

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT203.SAS
GENERATED: 12JUL2005 17:46:59 iceadmn3

Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING SYSTOLIC BP (MMHG)	VISIT																		
	DAY 36	130	120.0	13.81	120.0	90	191	115	119.4	13.82	120.0	90	150	125	118.0	14.19	116.0	90	164
	DAY 43	124	119.9	11.57	120.0	86	157	107	120.3	13.56	120.0	72	156	109	117.8	14.04	116.0	82	150
	DAY 50	123	119.7	11.26	120.0	96	155	102	120.6	13.75	120.0	92	170	106	118.1	13.33	117.5	80	152
	DAY 57	121	119.4	11.97	120.0	90	148	99	119.4	13.17	120.0	84	160	105	117.4	13.85	118.0	90	158
	FINAL	176	119.9	12.07	120.0	90	148	171	118.4	13.87	120.0	72	162	175	117.4	13.97	118.0	88	162
STANDING DIASTOLIC BP (MMHG)	SCREEN	178	78.9	9.17	80.0	60	100	179	77.4	8.99	78.0	56	103	179	77.6	9.02	78.0	58	120
	DAY 1	177	78.7	9.45	80.0	58	106	180	77.5	9.93	78.0	57	102	179	77.3	8.78	78.0	50	110
	DAY 8	173	78.9	9.06	80.0	58	110	169	77.3	10.36	78.0	48	112	175	77.0	8.95	76.0	55	115
	DAY 15	148	80.5	9.24	80.0	48	116	149	78.0	9.78	80.0	54	106	155	76.7	9.15	76.0	58	108
	DAY 22	146	79.0	9.17	80.0	56	105	134	78.2	9.69	79.0	56	104	146	76.4	9.54	77.0	56	110
	DAY 29	133	79.2	9.62	79.0	58	110	127	78.0	9.17	79.0	54	100	130	76.8	9.52	76.0	56	112
	DAY 36	130	79.3	9.04	80.0	56	102	115	78.3	9.04	78.0	60	102	125	77.3	8.72	77.0	60	110
	DAY 43	124	81.1	8.99	80.0	58	102	107	79.3	9.62	80.0	56	102	109	76.6	9.72	75.0	54	108
	DAY 50	123	80.1	8.88	80.0	46	100	102	79.1	10.04	78.0	59	118	106	77.2	10.15	77.5	56	110
	DAY 57	121	79.4	8.34	80.0	56	100	99	79.1	8.91	80.0	58	108	105	77.5	10.19	76.0	60	112
	FINAL	176	78.9	8.53	80.0	56	102	171	78.2	10.31	78.0	50	118	175	77.1	9.72	76.0	58	112

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT203.SAS
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Table 11.3.8.1.1.2 Vital Sign Orthostatic Changes - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
PULSE (BPM)	VISIT																		
	SCREEN	175	4.6	5.94	4.0	-12	27	178	6.0	7.74	4.0	-16	30	178	4.7	7.65	4.0	-20	53
	DAY 1	175	5.6	6.55	4.0	-8	36	180	6.2	7.98	4.0	-12	55	179	4.3	5.80	4.0	-12	28
	DAY 8	173	5.7	7.49	4.0	-23	26	169	6.1	7.48	4.0	-16	32	175	5.4	5.77	4.0	-12	20
	DAY 15	148	4.9	7.22	4.0	-20	28	149	6.7	9.04	6.0	-16	51	155	4.8	6.34	4.0	-20	21
	DAY 22	146	6.0	7.18	4.0	-12	28	134	6.5	8.30	4.0	-12	55	146	4.8	6.48	4.0	-12	26
	DAY 29	133	6.7	9.07	4.0	-16	32	127	5.6	7.20	4.0	-12	29	130	4.7	6.00	4.0	-14	24
	DAY 36	130	6.2	7.27	4.0	-12	28	115	5.4	8.82	4.0	-12	42	125	4.9	6.31	4.0	-8	27
	DAY 43	123	5.7	6.55	4.0	-8	28	107	5.9	7.03	4.0	-10	32	110	3.9	6.44	4.0	-19	25
	DAY 50	123	6.1	7.55	4.0	-8	32	102	6.1	7.54	4.0	-12	35	106	4.8	6.51	4.0	-8	24
	DAY 57	121	5.3	7.17	4.0	-16	32	99	5.2	9.23	4.0	-14	46	105	4.2	6.29	4.0	-8	40
	FINAL	176	4.9	7.06	4.0	-16	32	171	5.4	8.47	4.0	-14	46	175	4.2	5.97	4.0	-8	40
SYSTOLIC BP (mmHg)	SCREEN	176	0.2	8.13	0.0	-31	22	178	-0.2	7.38	0.0	-22	26	180	-0.4	7.11	0.0	-40	20
	DAY 1	176	1.0	7.37	2.0	-22	20	180	-0.6	6.87	0.0	-18	27	179	-0.4	6.63	0.0	-16	28
	DAY 8	173	-0.0	7.65	0.0	-24	41	169	-1.3	7.87	0.0	-28	20	175	-0.2	8.30	0.0	-41	30
	DAY 15	148	-0.9	7.64	0.0	-24	30	149	-0.9	8.21	0.0	-23	21	155	0.2	6.46	0.0	-16	17
	DAY 22	146	-1.0	7.67	0.0	-29	18	134	-1.0	8.87	-0.5	-39	27	146	-0.6	8.28	0.0	-50	22
	DAY 29	133	0.1	8.29	0.0	-22	32	127	-0.2	8.18	0.0	-24	22	130	0.3	7.48	0.0	-25	24

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT204.SAS
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Table 11.3.8.1.1.2 Vital Sign Orthostatic Changes - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SYSTOLIC BP (mmHg)	VISIT																		
	DAY 36	130	-0.1	8.43	0.0	-38	41	115	-1.9	7.89	-2.0	-26	18	125	0.7	6.91	0.0	-18	32
	DAY 43	124	-1.8	8.88	-1.0	-39	22	107	-0.5	8.30	0.0	-43	21	109	0.0	8.54	0.0	-36	28
	DAY 50	123	-1.2	8.94	0.0	-44	19	102	-0.3	8.73	0.0	-35	30	106	-0.6	6.49	0.0	-18	18
	DAY 57	121	-0.2	7.50	0.0	-27	19	99	0.0	6.81	0.0	-20	28	105	-0.4	7.60	0.0	-24	20
	FINAL	176	0.1	7.57	0.0	-27	32	171	-0.6	7.03	0.0	-28	28	175	-0.4	8.07	0.0	-50	20
DIASTOLIC BP (mmHg)	SCREEN	176	1.8	5.82	2.0	-12	20	178	2.2	6.44	1.0	-10	30	179	1.6	6.21	2.0	-17	24
	DAY 1	176	2.8	6.61	2.0	-13	28	180	2.5	5.59	2.0	-10	20	179	2.5	5.73	2.0	-13	23
	DAY 8	173	1.8	5.57	2.0	-15	18	169	1.2	6.06	2.0	-16	16	175	1.9	6.06	2.0	-24	16
	DAY 15	148	2.4	5.74	2.0	-14	24	149	1.4	5.95	2.0	-15	28	155	2.7	5.57	2.0	-12	22
	DAY 22	146	1.9	6.57	2.0	-26	22	134	1.4	7.28	2.0	-16	34	146	2.2	5.85	2.0	-10	26
	DAY 29	133	2.4	5.95	2.0	-14	22	127	2.4	6.32	2.0	-27	21	130	2.8	5.62	2.0	-14	28
	DAY 36	130	2.2	6.89	2.0	-32	22	115	2.8	6.57	2.0	-14	20	125	2.4	6.58	2.0	-10	29
	DAY 43	124	2.3	6.50	2.0	-16	33	107	2.3	5.17	2.0	-12	20	109	2.6	5.36	2.0	-10	18
	DAY 50	123	2.5	7.33	2.0	-34	24	102	2.4	6.89	2.0	-20	24	106	2.5	4.85	2.0	-11	18
	DAY 57	121	1.7	7.57	2.0	-31	32	99	1.9	5.59	2.0	-14	24	105	2.6	5.65	2.0	-8	22
	FINAL	176	2.1	6.86	2.0	-31	32	171	1.8	5.37	2.0	-15	24	175	2.7	5.51	2.0	-12	22

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT204.SAS
GENERATED: 12JUL2005 17:47:02 iceadmn3

Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE PULSE (BPM)	VISIT																		
	DAY 8	171	3.2	10.51	2.0	-24	28	169	3.8	12.11	4.0	-49	38	175	0.8	8.63	0.0	-36	29
	DAY 15	146	5.6	11.78	6.0	-28	44	149	6.3	11.15	6.0	-40	36	155	2.4	10.66	0.0	-28	60
	DAY 22	144	5.1	10.38	4.0	-18	40	134	7.5	11.51	8.0	-28	46	146	1.2	9.21	0.0	-20	32
	DAY 29	131	4.8	11.19	4.0	-21	34	127	8.6	11.68	8.0	-28	40	130	1.7	8.63	2.0	-18	28
	DAY 36	128	4.2	11.69	4.0	-20	48	115	7.6	12.17	6.0	-20	50	125	1.4	8.75	2.0	-20	22
	DAY 43	121	4.9	10.28	4.0	-23	36	107	7.5	12.40	6.0	-21	56	110	2.9	10.14	4.0	-20	62
	DAY 50	121	5.1	12.99	5.0	-24	44	102	9.0	11.88	10.0	-16	44	106	2.7	7.73	4.0	-20	24
	DAY 57	119	3.9	11.05	4.0	-25	35	99	6.6	11.62	7.0	-22	36	105	1.3	8.63	0.0	-20	26
	FINAL	174	3.4	10.90	2.0	-25	35	171	4.7	12.48	4.0	-49	36	175	1.1	9.51	0.0	-36	32
SUPINE SYSTOLIC BP (MMHG)	DAY 8	171	1.0	12.29	0.0	-44	38	169	1.9	11.76	2.0	-34	38	175	0.3	9.36	0.0	-30	34
	DAY 15	146	1.9	11.27	0.0	-22	35	149	1.4	10.99	1.0	-32	28	155	-0.4	10.18	0.0	-30	32
	DAY 22	144	2.9	13.03	2.0	-42	40	134	1.1	12.03	0.0	-32	38	146	-0.3	11.03	0.0	-25	44
	DAY 29	131	0.6	12.26	0.0	-46	40	127	1.3	13.66	0.0	-60	41	130	-0.7	11.38	-2.0	-30	38
	DAY 36	128	1.2	11.97	0.0	-30	38	115	2.6	12.18	2.0	-38	28	125	-1.7	12.35	-2.0	-32	36
	DAY 43	122	2.5	11.65	2.0	-28	32	107	2.0	13.44	2.0	-50	49	110	-1.5	12.28	-2.0	-30	48
	DAY 50	121	1.5	12.21	2.0	-30	42	102	1.9	11.88	0.0	-30	36	106	-0.7	10.71	0.0	-30	30
	DAY 57	119	-0.3	10.98	0.0	-32	32	99	0.7	13.55	1.0	-36	44	105	-1.0	12.39	-2.0	-30	38

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT205.SAS
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Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE SYSTOLIC BP (MMHG)	VISIT --- FINAL	174	1.0	11.44	0.0	-32	32	171	0.2	12.76	0.0	-50	44	175	-0.5	11.82	-1.0	-30	44
SUPINE DIASTOLIC BP (MMHG)	DAY 8	171	1.1	8.62	2.0	-18	24	169	1.2	8.82	0.0	-30	36	175	0.3	7.20	0.0	-24	20
	DAY 15	146	2.0	8.58	2.0	-22	26	149	1.4	9.07	2.0	-30	26	155	-0.9	8.40	0.0	-26	24
	DAY 22	144	1.4	8.93	0.0	-18	24	134	1.9	9.12	2.0	-22	24	146	-0.8	8.33	0.0	-25	34
	DAY 29	131	0.9	8.40	0.0	-16	26	127	0.6	9.67	0.0	-42	32	130	-1.0	7.84	0.0	-28	21
	DAY 36	128	1.3	9.39	2.0	-20	26	115	1.0	10.08	0.0	-22	38	125	-0.6	8.59	0.0	-25	24
	DAY 43	122	2.8	9.14	2.0	-18	30	107	1.9	9.49	2.0	-32	40	110	-1.4	8.69	-1.0	-24	18
	DAY 50	121	1.7	9.65	0.0	-24	25	102	1.4	10.74	2.5	-26	30	106	-1.1	9.02	0.0	-22	21
	DAY 57	119	1.9	10.27	2.0	-30	28	99	2.2	9.46	3.0	-25	30	105	-0.6	9.06	0.0	-24	23
	FINAL	174	0.8	9.83	0.0	-30	28	171	1.3	10.13	2.0	-32	30	175	-0.4	8.69	0.0	-24	23
STANDING PULSE (BPM)	DAY 8	173	3.4	10.73	4.0	-31	32	169	3.9	12.20	4.0	-40	44	175	1.8	9.41	0.0	-28	30
	DAY 15	148	4.6	11.30	4.0	-22	29	149	6.7	12.44	6.0	-26	62	155	2.7	10.42	0.0	-20	36
	DAY 22	146	5.2	10.82	4.0	-18	40	134	8.0	12.54	8.0	-24	50	146	1.5	9.58	0.0	-20	30
	DAY 29	133	5.3	11.19	4.0	-19	35	127	7.8	11.98	8.0	-26	46	130	1.6	9.06	0.5	-28	25
	DAY 36	130	4.4	12.03	4.0	-24	48	115	6.8	13.55	6.0	-34	50	125	1.8	10.11	1.0	-23	42
	DAY 43	123	4.7	10.45	4.0	-24	44	107	7.1	13.35	4.0	-26	62	110	1.9	8.63	2.0	-20	20

(Continued)

Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING PULSE (BPM)	VISIT																		
	DAY 50	123	5.1	13.14	4.0	-28	44	102	8.9	12.94	9.0	-18	58	106	2.9	9.25	2.0	-20	22
	DAY 57	121	3.1	11.53	2.0	-22	40	99	5.3	14.66	4.0	-43	46	105	0.9	10.05	0.0	-27	31
	FINAL	176	2.8	11.17	2.0	-28	40	171	4.1	13.62	3.0	-43	46	175	1.0	9.84	0.0	-28	31
STANDING SYSTOLIC BP (MMHG)	DAY 8	173	-0.1	11.47	0.0	-42	44	169	1.1	11.75	2.0	-37	44	175	0.3	9.75	0.0	-30	33
	DAY 15	148	0.3	10.96	0.0	-26	26	149	1.0	12.20	0.0	-30	40	155	-0.0	10.55	0.0	-42	30
	DAY 22	146	1.3	12.58	0.0	-31	44	134	0.3	12.86	0.0	-42	32	146	-0.9	11.12	0.0	-35	32
	DAY 29	133	0.0	11.71	0.0	-26	26	127	1.4	13.05	2.0	-60	30	130	-0.5	11.86	0.0	-30	38
	DAY 36	130	0.5	13.73	0.0	-52	58	115	0.9	12.22	3.0	-40	33	125	-0.8	11.80	0.0	-34	34
	DAY 43	124	-0.1	12.30	0.0	-45	22	107	1.4	13.01	2.0	-72	25	109	-1.6	11.07	0.0	-28	28
	DAY 50	123	-0.2	12.58	0.0	-46	36	102	1.8	12.17	2.0	-28	35	106	-1.5	10.33	-1.0	-30	20
	DAY 57	121	-0.9	12.15	-2.0	-48	26	99	1.0	13.14	0.0	-25	33	105	-1.8	11.36	-2.0	-36	22
	FINAL	176	0.3	12.53	0.0	-48	44	171	0.2	13.04	0.0	-72	33	175	-0.6	10.89	0.0	-36	26
STANDING DIASTOLIC BP (MMHG)	DAY 8	173	0.1	8.74	0.0	-34	20	169	-0.1	8.39	0.0	-31	28	175	-0.3	7.98	0.0	-24	26
	DAY 15	148	1.5	8.38	0.0	-22	22	149	0.4	9.41	0.0	-23	38	155	-0.8	8.13	0.0	-25	20
	DAY 22	146	0.5	9.19	0.0	-28	26	134	0.8	9.82	0.0	-26	31	146	-1.0	8.52	0.0	-32	16
	DAY 29	133	0.2	9.84	2.0	-30	26	127	0.5	9.59	0.0	-36	22	130	-0.9	8.49	-2.0	-30	28
	DAY 36	130	0.5	9.18	0.0	-31	30	115	1.0	9.44	1.0	-40	32	125	-0.7	8.61	0.0	-24	34

(Continued)

Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING DIASTOLIC BP (MMHG)	VISIT																		
	DAY 43	124	2.3	9.47	1.0	-20	30	107	1.3	9.76	0.0	-40	26	109	-1.5	8.94	-1.0	-27	24
	DAY 50	123	1.2	10.15	1.0	-46	24	102	1.3	10.26	1.5	-26	28	106	-0.9	9.40	0.0	-30	20
	DAY 57	121	0.5	10.00	0.0	-30	20	99	1.6	8.89	2.0	-25	26	105	-0.6	8.31	0.0	-22	22
	FINAL	176	0.2	9.57	0.0	-30	22	171	0.6	9.62	2.0	-40	26	175	-0.2	8.09	0.0	-22	22

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT205.SAS
GENERATED: 12JUL2005 17:47:04 iceadmn3

Table 11.3.8.1.1.4 Vital Signs Potentially Clinically Important Shift to Final Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
SUPINE PULSE (BPM)	BASELINE												
	LOW	1	0	1	0	2	0	2	0	0	0	0	0
	NORMAL	173	0	173	0	169	0	169	0	175	0	175	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
SUPINE SYSTOLIC BP (MMHG)	LOW	2	0	2	0	1	0	1	0	2	0	2	0
	NORMAL	172	2	170	0	170	2	168	0	173	5	168	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
SUPINE DIASTOLIC BP (MMHG)	LOW	1	0	1	0	1	0	1	0	0	0	0	0
	NORMAL	173	0	173	0	170	1	167	2	175	1	171	3
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
STANDING PULSE (BPM)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	176	0	176	0	168	0	168	0	175	0	175	0
	HIGH	0	0	0	0	3	0	3	0	0	0	0	0
STANDING SYSTOLIC BP (MMHG)	LOW	2	0	2	0	1	1	0	0	1	0	1	0
	NORMAL	174	2	172	0	170	3	167	0	174	7	167	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT206.SAS
GENERATED: 12JUL2005 17:47:07 iceadmn3

Table 11.3.8.1.1.4 Vital Signs Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
STANDING DIASTOLIC BP (MMHG)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NORMAL	174	0	174	0	171	1	167	3	173	0	171	2
	HIGH	2	0	2	0	0	0	0	0	1	0	0	1

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT206.SAS
GENERATED: 12JUL2005 17:47:07 iceadmn3

Table 11.3.8.1.1.4 Vital Signs Potentially Clinically Important Shift to Final Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
			FINAL			FINAL			FINAL	
		TOTAL	SIGNIFICANT CHANGE	NORMAL	TOTAL	SIGNIFICANT CHANGE	NORMAL	TOTAL	SIGNIFICANT CHANGE	NORMAL
ORTHOSTATIC CHANGE PULSE (BPM)	BASELINE									
	SIGNIFICANT CHANGE	8	1	7	11	4	7	2	1	1
	NORMAL	166	6	160	160	11	149	173	2	171
ORTHOSTATIC CHANGE SYSTOLIC BP (MMHG)	SIGNIFICANT CHANGE	2	0	2	0	0	0	0	0	0
	NORMAL	172	1	171	171	2	169	175	5	170
ORTHOSTATIC CHANGE DIASTOLIC BP (MMHG)	SIGNIFICANT CHANGE	0	0	0	0	0	0	0	0	0
	NORMAL	174	2	172	171	0	171	175	0	175
ORTHOSTATIC HYPOTENSION	SIGNIFICANT CHANGE	0	0	0	0	0	0	0	0	0
	NORMAL	174	0	174	171	1	170	175	1	174

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT206.SAS
GENERATED: 12JUL2005 17:47:07 iceadmn3

Table 11.3.8.1.1.5 Potentially Clinically Important Vital Signs
Safety Population

PARAMETER	SHIFT TO LOW			SHIFT TO HIGH		
	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
SUPINE PULSE (BPM)	0/173 (0.0%)	0/169 (0.0%)	0/175 (0.0%)	0/174 (0.0%)	0/171 (0.0%)	0/175 (0.0%)
SUPINE SYSTOLIC BP (MMHG)	2/172 (1.2%)	2/170 (1.2%)	5/173 (2.9%)	0/174 (0.0%)	0/171 (0.0%)	0/175 (0.0%)
SUPINE DIASTOLIC BP (MMHG)	0/173 (0.0%)	1/170 (0.6%)	1/175 (0.6%)	0/174 (0.0%)	2/171 (1.2%)	3/175 (1.7%)
STANDING PULSE (BPM)	0/176 (0.0%)	0/171 (0.0%)	0/175 (0.0%)	0/176 (0.0%)	0/168 (0.0%)	0/175 (0.0%)
STANDING SYSTOLIC BP (MMHG)	2/174 (1.1%)	3/170 (1.8%)	7/174 (4.0%)	0/176 (0.0%)	0/171 (0.0%)	0/175 (0.0%)
STANDING DIASTOLIC BP (MMHG)	0/176 (0.0%)	1/171 (0.6%)	0/174 (0.0%)	0/174 (0.0%)	3/171 (1.8%)	2/174 (1.1%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT207.SAS
GENERATED: 12JUL2005 17:47:10 iceadmn3

Table 11.3.8.1.1.6 Potentially Clinically Important Orthostatic Change Findings
Safety Population

	SHIFT TO CLINICALLY IMPORTANT		
PARAMETER	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
ORTHOSTATIC CHANGE PULSE (BPM)	6/166 (3.6%)	11/160 (6.9%)	2/173 (1.2%)
ORTHOSTATIC CHANGE SYSTOLIC BP (MMHG)	1/172 (0.6%)	2/171 (1.2%)	5/175 (2.9%)
ORTHOSTATIC CHANGE DIASTOLIC BP (MMHG)	2/174 (1.1%)	0/171 (0.0%)	0/175 (0.0%)
ORTHOSTATIC HYPOTENSION	0/174 (0.0%)	1/171 (0.6%)	1/175 (0.6%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT208.SAS
GENERATED: 12JUL2005 17:47:13 iceadmn3

Table 11.3.8.1.2.1 ECG Rates and Intervals - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	MEDIAN	SD	MIN	MAX
HEART RATE (BEATS/MIN)	BSLN	179	65.74	65.0	10.58	42	99	179	65.12	63.0	11.41	42	104	180	65.92	66.0	10.03	41	93
	FINAL	155	71.59	71.0	12.02	40	102	147	74.87	75.0	11.94	47	104	150	67.55	66.0	11.88	47	109
	CHG FROM BSLN	155	6.39	6.0	10.85	-28	40	146	9.78	8.0	10.88	-27	43	150	1.69	2.0	10.21	-29	40
PR INTERVAL (MSEC)	BSLN	179	153.42	152.0	20.79	114	231	178	154.18	152.5	19.67	109	233	180	153.27	152.0	20.54	106	229
	FINAL	155	153.88	151.0	21.70	111	266	147	154.90	155.0	19.23	110	217	150	154.06	153.0	19.76	115	207
	CHG FROM BSLN	155	-0.09	-2.0	16.66	-49	58	146	-0.51	-1.0	15.81	-48	51	150	0.63	0.0	15.58	-45	46
QRS INTERVAL (MSEC)	BSLN	179	90.58	90.0	6.75	76	115	179	90.86	91.0	6.11	74	107	180	90.59	91.0	6.37	75	112
	FINAL	155	90.32	90.0	6.07	76	114	147	90.63	90.0	6.16	79	113	150	89.52	90.0	6.07	76	114
	CHG FROM BSLN	155	-0.48	0.0	6.54	-21	21	146	-0.38	0.0	6.19	-17	15	150	-0.86	-1.0	6.26	-17	17
QT INTERVAL (MSEC)	BSLN	179	375.51	375.0	26.07	311	448	179	376.87	376.0	27.16	318	452	180	378.86	379.0	27.26	322	465
	FINAL	155	362.91	362.0	24.53	307	429	147	358.29	358.0	24.80	299	431	150	375.54	375.0	26.23	304	435
	CHG FROM BSLN	155	-14.75	-15.0	26.67	-96	52	146	-19.21	-22.0	26.37	-75	47	150	-4.91	-5.5	25.20	-106	68
FRIDERICIA QTC INTERVAL (MSEC)	BSLN	179	385.07	384.0	21.61	319	460	179	384.89	384.0	20.24	335	431	180	388.93	389.5	22.01	335	450
	FINAL	155	382.64	383.0	17.97	342	444	147	383.73	385.0	18.41	335	428	150	388.34	390.0	20.83	329	440
	CHG FROM BSLN	155	-3.70	-3.0	21.13	-82	54	146	-1.67	-2.0	19.38	-56	68	150	-2.09	-0.5	19.32	-49	47

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG200.SAS
GENERATED: 12JUL2005 17:42:31 iceadmn3

FIGURE 11.3.8.1.2.2 BUBBLE PLOT OF CHANGE IN QTC (FRIDERICIA) INTERVALS

(SAFETY)

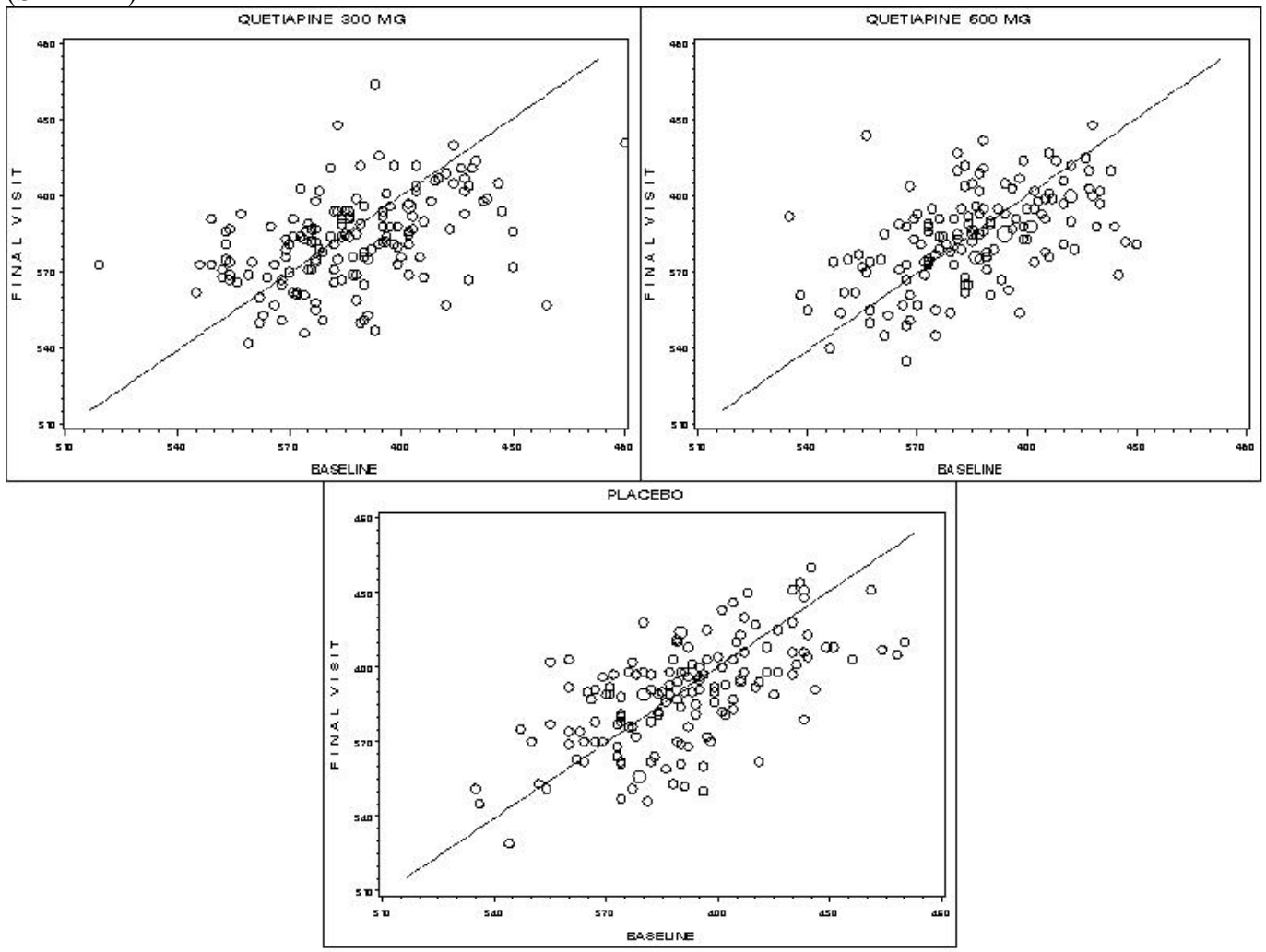

Table 11.3.8.1.2.3 ECG Overall Evaluation Shift to Final
Safety Population

	TREATMENT						
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		
	FINAL		FINAL		FINAL		
	ABNORMAL	NORMAL	ABNORMAL	NORMAL	ABNORMAL	NORMAL	TOTAL
BASELINE							
ABNORMAL	14	4	17	8	15	5	63
NORMAL	10	127	5	116	9	121	388
TOTAL	24	131	22	124	24	126	451

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG201.SAS
GENERATED: 12JUL2005 17:42:33 iceadmn3

Table 11.3.8.1.2.4 ECG Rates and Intervals Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH	TOTAL	LOW	NORMAL	HIGH
HEART RATE (BEATS/MIN)	BASELINE												
	LOW	5	2	3	0	8	0	8	0	7	0	7	0
	NORMAL	150	1	149	0	138	2	136	0	143	3	140	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
PR INTERVAL (MSEC)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	153	0	152	1	145	0	145	0	149	0	149	0
	HIGH	2	0	0	2	1	0	0	1	1	0	1	0
QRS INTERVAL (MSEC)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	155	0	146	0	146	0	150	0	150	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
QT INTERVAL (MSEC)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	155	0	155	0	146	0	146	0	150	0	150	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
FRIDERICIA QTC INTERVAL (MSEC)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NORMAL	154	0	154	0	146	0	146	0	149	0	149	0
	HIGH	1	0	1	0	0	0	0	0	1	0	1	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG202.SAS
GENERATED: 12JUL2005 17:42:35 iceadmn3

Table 11.3.8.1.2.5 Potentially Clinically Important ECG Findings
Safety Population

PARAMETER	SHIFT TO LOW			SHIFT TO HIGH		
	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
HEART RATE (BEATS/MIN)	1/150 (0.7%)	2/138 (1.4%)	3/143 (2.1%)	0/155 (0.0%)	0/146 (0.0%)	0/150 (0.0%)
PR INTERVAL (MSEC)	NA	NA	NA	1/153 (0.7%)	0/145 (0.0%)	0/149 (0.0%)
QRS INTERVAL (MSEC)	0/155 (0.0%)	0/146 (0.0%)	0/150 (0.0%)	0/155 (0.0%)	0/146 (0.0%)	0/150 (0.0%)
QT INTERVAL (MSEC)	0/155 (0.0%)	0/146 (0.0%)	0/150 (0.0%)	0/155 (0.0%)	0/146 (0.0%)	0/150 (0.0%)
FRIDERICIA QTC INTERVAL (MSEC)	NA	NA	NA	0/154 (0.0%)	0/146 (0.0%)	0/149 (0.0%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG203.SAS
GENERATED: 12JUL2005 17:42:37 iceadmn3

Table 11.3.8.1.3.1.1 Weight and BMI - Descriptive Statistics
Last Observation Carried Forward
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
WEIGHT(KG)	VISIT																		
	BASELINE	177	86.7	20.80	86.0	47	159	176	84.8	21.98	81.0	41	159	180	83.5	21.85	80.5	44	149
	FINAL	155	87.1	20.16	86.0	47	153	144	86.3	21.88	81.0	43	158	153	83.6	22.60	81.0	46	149
	CHG FRM BSLN	155	1.0	3.14	1.0	-12	11	143	1.6	3.89	1.0	-20	12	153	0.2	2.30	0.0	-8	8
BMI(KG/M^2)	BASELINE	177	29.7	6.86	28.1	19	51	176	29.1	6.78	27.5	17	50	180	29.2	7.70	27.7	18	55
	FINAL	155	29.9	6.77	28.4	19	53	144	29.4	6.74	27.8	17	51	153	29.3	7.98	27.8	18	55
	CHG FRM BSLN	155	0.4	1.07	0.3	-4	4	143	0.5	1.35	0.4	-8	4	153	0.1	0.83	0.0	-3	3

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT200.SAS
GENERATED: 12JUL2005 17:46:52 iceadmn3

Table 11.3.8.1.3.1.2 Weight and BMI - Descriptive Statistics
Observed Cases
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
WEIGHT(KG)	VISIT																		
	BASELINE	177	86.7	20.80	86.0	47	159	176	84.8	21.98	81.0	41	159	180	83.5	21.85	80.5	44	149
	FINAL	121	86.3	19.93	86.0	47	153	96	88.4	20.80	82.5	53	153	105	84.5	24.00	81.0	49	149
	CHG FRM BSLN	121	1.1	3.23	1.0	-12	11	96	2.0	4.55	2.0	-20	12	105	0.2	2.32	0.0	-8	8
BMI(KG/M^2)	BASELINE	177	29.7	6.86	28.1	19	51	176	29.1	6.78	27.5	17	50	180	29.2	7.70	27.7	18	55
	FINAL	121	29.6	6.59	28.6	19	53	96	29.9	6.57	28.1	20	51	105	30.0	8.48	28.0	18	55
	CHG FRM BSLN	121	0.4	1.09	0.3	-3	4	96	0.6	1.58	0.7	-8	4	105	0.1	0.85	0.0	-2	3

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT210.SAS
GENERATED: 12JUL2005 17:47:19 iceadmn3

Table 11.3.8.1.3.2 Weight and BMI by Baseline BMI Category - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
0 - <18.5	WEIGHT(-KG)	VISIT																		
		BASELINE	.	.	.	.	.	.	2	42.5	2.12	42.5	41	44	3	50.7	6.11	52.0	44	56
		FINAL	.	.	.	.	.	.	2	43.0	0.00	43.0	43	43	2	48.0	2.83	48.0	46	50
		CHG FRM BSLN	.	.	.	.	.	.	2	0.5	2.12	0.5	-1	2	2	0.0	2.83	0.0	-2	2
	BMI(KG/-M^2)	BASELINE	.	.	.	.	.	.	2	17.2	0.07	17.2	17	17	3	17.9	0.44	17.7	18	18
		FINAL	.	.	.	.	.	.	2	17.4	0.78	17.4	17	18	2	18.1	0.49	18.1	18	18
		CHG FRM BSLN	.	.	.	.	.	.	2	0.2	0.85	0.2	-0	1	2	0.0	1.06	0.0	-1	1
18.5 - <25	WEIGHT(-KG)	BASELINE	49	66.2	8.80	64.0	47	86	51	66.9	9.13	66.0	50	88	57	63.8	8.36	65.0	47	79
		FINAL	44	67.9	9.11	67.0	47	91	40	69.2	9.73	68.0	53	94	48	63.4	8.29	66.0	47	79
		CHG FRM BSLN	44	1.6	3.55	1.0	-12	8	40	1.9	2.92	1.0	-2	11	48	-0.3	1.99	0.0	-6	6
	BMI(KG/-M^2)	BASELINE	49	22.4	1.63	22.8	19	25	51	22.8	1.50	23.0	19	25	57	22.1	1.87	22.0	19	25
		FINAL	44	23.0	2.07	23.1	19	27	40	23.4	1.60	23.6	20	27	48	22.0	1.97	21.9	18	26
		CHG FRM BSLN	44	0.6	1.15	0.4	-3	2	40	0.6	0.95	0.3	-1	4	48	-0.1	0.68	0.0	-2	2
25 - <30	WEIGHT(-KG)	BASELINE	59	81.9	9.32	83.0	64	100	65	80.9	11.82	80.0	57	119	53	80.7	11.31	80.0	53	109
		FINAL	50	81.8	9.74	83.0	61	100	56	83.0	12.77	81.0	58	130	45	80.0	11.50	81.0	58	111

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT201.SAS
GENERATED: 12JUL2005 17:46:55 iceadmn3

Table 11.3.8.1.3.2 Weight and BMI by Baseline BMI Category - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
25 - <30	WEIGHT(-KG)	VISIT																		
		CHG FRM BSLN	50	0.5	2.63	0.0	-5	8	56	1.6	3.95	1.0	-10	12	45	0.2	2.05	0.0	-4	6
	BMI(KG/-M^2)	BASELINE	59	27.6	1.27	27.5	25	30	65	27.5	1.46	27.1	25	30	53	27.2	1.31	27.0	25	29
		FINAL	50	27.7	1.75	27.8	24	32	56	28.1	1.99	27.8	24	33	45	27.2	1.56	27.4	24	31
		CHG FRM BSLN	50	0.2	0.93	0.0	-2	3	56	0.6	1.31	0.5	-3	4	45	0.1	0.79	0.0	-2	3
30 - <40	WEIGHT(-KG)	BASELINE	50	99.4	12.52	97.0	78	136	42	98.6	13.88	98.0	75	134	51	97.7	12.42	96.0	73	135
		FINAL	47	100.7	12.33	99.0	81	133	34	100.7	15.76	103.5	67	135	45	97.5	13.07	95.0	74	138
		CHG FRM BSLN	47	1.3	3.02	2.0	-7	11	34	1.6	4.82	2.0	-20	9	45	0.0	2.37	0.0	-8	7
	BMI(KG/-M^2)	BASELINE	50	33.8	2.67	34.0	30	39	42	33.6	2.48	33.4	30	39	51	34.3	2.95	35.0	30	40
		FINAL	47	34.4	2.73	34.6	30	39	34	34.1	3.39	34.6	26	41	45	34.5	3.15	35.1	28	40
		CHG FRM BSLN	47	0.5	1.02	0.6	-2	4	34	0.5	1.78	0.6	-8	3	45	0.0	0.84	0.0	-3	3
>=40	WEIGHT(-KG)	BASELINE	19	120.7	20.82	117.0	90	159	16	127.3	19.80	127.0	100	159	16	123.8	18.43	120.0	81	149
		FINAL	14	120.2	20.76	119.5	90	153	11	129.2	20.60	130.0	96	158	13	127.5	19.84	127.0	82	149
		CHG FRM BSLN	14	0.4	3.76	1.0	-10	6	11	1.2	4.21	0.0	-4	9	13	2.1	3.17	1.0	-5	8

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT201.SAS
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Table 11.3.8.1.3.2 Weight and BMI by Baseline BMI Category - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
>=40	BMI(KG/-M^2)	VISIT																		
		BASELINE	19	43.8	3.67	41.9	40	51	16	45.1	2.74	45.4	40	50	16	46.5	4.59	46.4	41	55
		FINAL	14	44.2	4.43	42.4	38	53	11	46.2	3.28	46.2	39	51	13	47.8	4.64	48.5	41	55
		CHG FRM BSLN	14	0.1	1.40	0.3	-4	2	11	0.4	1.56	0.0	-2	3	13	0.8	1.17	0.5	-2	3

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT201.SAS
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Table 11.3.8.1.3.3 Weight and BMI by Diabetic Status (Fasting Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT									
			QUETIAPINE 300 MG						QUETIAPINE 600 MG			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT												
ALL	WEIGHT(KG)	BASELINE	177	86.7	20.80	86.0	47	159	176	84.8	21.98	81.0	41	159
		FINAL	155	87.1	20.16	86.0	47	153	144	86.3	21.88	81.0	43	158
		CHG FRM BSLN	155	1.0	3.14	1.0	-12	11	143	1.6	3.89	1.0	-20	12
	BMI(KG/M^2)	BASELINE	177	29.7	6.86	28.1	19	51	176	29.1	6.78	27.5	17	50
		FINAL	155	29.9	6.77	28.4	19	53	144	29.4	6.74	27.8	17	51
		CHG FRM BSLN	155	0.4	1.07	0.3	-4	4	143	0.5	1.35	0.4	-8	4
DIABETIC	WEIGHT(KG)	BASELINE	8	99.5	18.21	97.0	72	136	9	99.7	16.30	97.0	75	129
		FINAL	8	100.5	17.28	99.5	73	133	6	93.7	18.92	88.0	78	130
		CHG FRM BSLN	8	1.0	1.93	1.0	-3	3	6	-0.8	7.31	-2.0	-10	11
	BMI(KG/M^2)	BASELINE	8	34.0	6.32	35.9	22	41	9	34.6	7.15	30.0	29	45
		FINAL	8	34.3	6.39	36.7	22	41	6	31.9	5.83	31.4	26	43
		CHG FRM BSLN	8	0.4	0.65	0.4	-1	1	6	-0.4	2.14	-0.8	-3	3
DIABETIC RISK	WEIGHT(KG)	BASELINE	39	107.6	23.35	101.0	64	159	38	103.3	28.45	101.5	41	159
		FINAL	32	107.2	22.47	104.5	64	153	30	106.2	28.64	106.5	43	158
		CHG FRM BSLN	32	0.4	3.44	0.0	-10	6	30	2.0	3.58	1.5	-8	9
	BMI(KG/M^2)	BASELINE	39	38.0	7.41	38.6	21	51	38	36.0	8.55	36.6	17	50

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

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Table 11.3.8.1.3.3 Weight and BMI by Diabetic Status (Fasting Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT									
			QUETIAPINE 300 MG						QUETIAPINE 600 MG			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT												
DIABETIC RISK	BMI(KG/M^2)	FINAL	32	37.9	7.64	37.6	19	53	30	37.0	8.83	38.1	18	51
		CHG FRM BSLN	32	0.1	1.21	0.0	-4	2	30	0.7	1.25	0.5	-3	3
NON DIABETIC	WEIGHT(KG)	BASELINE	130	79.6	14.81	79.5	47	123	129	78.4	15.85	76.0	44	122
		FINAL	115	80.5	14.95	81.0	47	126	108	80.4	15.85	78.0	43	122
		CHG FRM BSLN	115	1.2	3.12	1.0	-12	11	107	1.7	3.72	1.0	-20	12
	BMI(KG/M^2)	BASELINE	130	26.9	3.98	27.2	19	35	129	26.6	4.01	26.4	17	35
		FINAL	115	27.3	4.21	27.2	19	38	108	27.2	4.03	27.1	17	36
		CHG FRM BSLN	115	0.4	1.06	0.3	-3	4	107	0.5	1.32	0.4	-8	4

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT209.SAS
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Table 11.3.8.1.3.3 Weight and BMI by Diabetic Status (Fasting Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT					
			PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT						
ALL	WEIGHT(KG)	BASELINE	180	83.5	21.85	80.5	44	149
		FINAL	153	83.6	22.60	81.0	46	149
		CHG FRM BSLN	153	0.2	2.30	0.0	-8	8
	BMI(KG/M^2)	BASELINE	180	29.2	7.70	27.7	18	55
		FINAL	153	29.3	7.98	27.8	18	55
		CHG FRM BSLN	153	0.1	0.83	0.0	-3	3
DIABETIC	WEIGHT(KG)	BASELINE	7	121.4	20.98	114.0	93	149
		FINAL	7	120.1	20.45	114.0	92	146
		CHG FRM BSLN	7	-1.3	1.80	-1.0	-5	0
	BMI(KG/M^2)	BASELINE	7	41.6	8.03	37.7	36	55
		FINAL	7	41.1	7.70	37.3	35	53
		CHG FRM BSLN	7	-0.5	0.64	-0.4	-2	0
DIABETIC RISK	WEIGHT(KG)	BASELINE	47	101.5	20.36	98.0	50	146
		FINAL	38	102.4	22.67	98.5	49	149
		CHG FRM BSLN	38	1.1	2.15	1.0	-3	8
	BMI(KG/M^2)	BASELINE	47	37.3	7.16	36.8	21	53

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT209.SAS
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Table 11.3.8.1.3.3 Weight and BMI by Diabetic Status (Fasting Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT					
			PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT						
DIABETIC RISK	BMI(KG/M^2)	FINAL	38	38.0	7.57	36.6	20	55
		CHG FRM BSLN	38	0.4	0.78	0.4	-1	3
NON DIABETIC	WEIGHT(KG)	BASELINE	126	74.7	15.13	73.0	44	113
		FINAL	108	74.6	15.17	72.5	46	113
		CHG FRM BSLN	108	-0.1	2.29	0.0	-8	7
	BMI(KG/M^2)	BASELINE	126	25.4	3.96	25.5	18	34
		FINAL	108	25.5	4.08	25.8	18	35
		CHG FRM BSLN	108	-0.0	0.83	0.0	-3	3

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT209.SAS
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Table 11.3.8.1.3.4 Weight and BMI by Diabetic Status (Random Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT									
			QUETIAPINE 300 MG						QUETIAPINE 600 MG			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT												
ALL	WEIGHT(KG)	BASELINE	177	86.7	20.80	86.0	47	159	176	84.8	21.98	81.0	41	159
		FINAL	155	87.1	20.16	86.0	47	153	144	86.3	21.88	81.0	43	158
		CHG FRM BSLN	155	1.0	3.14	1.0	-12	11	143	1.6	3.89	1.0	-20	12
	BMI(KG/M^2)	BASELINE	177	29.7	6.86	28.1	19	51	176	29.1	6.78	27.5	17	50
		FINAL	155	29.9	6.77	28.4	19	53	144	29.4	6.74	27.8	17	51
		CHG FRM BSLN	155	0.4	1.07	0.3	-4	4	143	0.5	1.35	0.4	-8	4
DIABETIC	WEIGHT(KG)	BASELINE	8	99.5	18.21	97.0	72	136	7	102.6	15.49	97.0	87	129
		FINAL	8	100.5	17.28	99.5	73	133	5	96.8	19.33	91.0	82	130
		CHG FRM BSLN	8	1.0	1.93	1.0	-3	3	5	-1.6	7.89	-4.0	-10	11
	BMI(KG/M^2)	BASELINE	8	34.0	6.32	35.9	22	41	7	34.0	7.19	29.9	29	45
		FINAL	8	34.3	6.39	36.7	22	41	5	32.0	6.51	31.5	26	43
		CHG FRM BSLN	8	0.4	0.65	0.4	-1	1	5	-0.8	2.22	-1.7	-3	3
DIABETIC RISK	WEIGHT(KG)	BASELINE	31	115.1	19.26	113.0	90	159	26	116.9	22.58	116.0	81	159
		FINAL	25	114.7	18.28	115.0	90	153	20	120.4	21.86	127.0	81	158
		CHG FRM BSLN	25	0.5	3.49	0.0	-10	6	20	2.3	3.48	1.0	-3	9
	BMI(KG/M^2)	BASELINE	31	40.9	4.68	40.5	35	51	26	41.3	4.84	40.2	35	50

(Continued)

Table 11.3.8.1.3.4 Weight and BMI by Diabetic Status (Random Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT									
			QUETIAPINE 300 MG						QUETIAPINE 600 MG			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT												
DIABETIC RISK	BMI(KG/M^2)	FINAL	25	40.8	5.05	39.4	34	53	20	42.2	5.16	40.7	35	51
		CHG FRM BSLN	25	0.2	1.25	0.0	-4	2	20	0.8	1.21	0.4	-1	3
NON DIABETIC	WEIGHT(KG)	BASELINE	138	79.5	14.65	79.5	47	123	143	78.1	15.70	76.0	41	122
		FINAL	122	80.5	14.87	81.0	47	126	119	80.2	15.85	78.0	43	122
		CHG FRM BSLN	122	1.2	3.14	1.0	-12	11	118	1.7	3.71	1.0	-20	12
	BMI(KG/M^2)	BASELINE	138	26.9	4.02	27.2	19	35	143	26.6	3.96	26.4	17	35
		FINAL	122	27.3	4.30	27.4	19	38	119	27.2	4.03	27.1	17	36
		CHG FRM BSLN	122	0.4	1.06	0.3	-3	4	118	0.6	1.32	0.4	-8	4

(Continued)

Table 11.3.8.1.3.4 Weight and BMI by Diabetic Status (Random Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT					
			PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT						
ALL	WEIGHT(KG)	BASELINE	180	83.5	21.85	80.5	44	149
		FINAL	153	83.6	22.60	81.0	46	149
		CHG FRM BSLN	153	0.2	2.30	0.0	-8	8
	BMI(KG/M^2)	BASELINE	180	29.2	7.70	27.7	18	55
		FINAL	153	29.3	7.98	27.8	18	55
		CHG FRM BSLN	153	0.1	0.83	0.0	-3	3
DIABETIC	WEIGHT(KG)	BASELINE	6	122.8	22.62	122.0	93	149
		FINAL	6	121.7	21.96	122.0	92	146
		CHG FRM BSLN	6	-1.2	1.94	-0.5	-5	0
	BMI(KG/M^2)	BASELINE	6	42.6	8.32	38.2	36	55
		FINAL	6	42.2	7.90	37.8	36	53
		CHG FRM BSLN	6	-0.4	0.70	-0.2	-2	0
DIABETIC RISK	WEIGHT(KG)	BASELINE	37	107.2	17.60	104.0	81	146
		FINAL	32	108.1	19.68	104.0	81	149
		CHG FRM BSLN	32	1.2	2.24	1.0	-3	8
	BMI(KG/M^2)	BASELINE	37	40.0	5.14	38.5	35	53

(Continued)

Table 11.3.8.1.3.4 Weight and BMI by Diabetic Status (Random Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT					
			PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		VISIT						
DIABETIC RISK	BMI(KG/M^2)	FINAL	32	40.3	5.73	38.4	35	55
		CHG FRM BSLN	32	0.4	0.82	0.4	-1	3
NON DIABETIC	WEIGHT(KG)	BASELINE	137	75.4	15.48	74.0	44	113
		FINAL	115	74.8	15.18	73.0	46	113
		CHG FRM BSLN	115	-0.1	2.26	0.0	-8	7
	BMI(KG/M^2)	BASELINE	137	25.6	4.03	25.7	18	35
		FINAL	115	25.6	4.11	25.9	18	35
		CHG FRM BSLN	115	-0.0	0.81	0.0	-3	3

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Table 11.3.8.1.3.5 Patients with Substantial Weight Gain (>=7%) by BMI Group
Safety Population

BMI GROUP	TREATMENT								
	QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
0 - <18.5	0	0	0	2	0	0.0	2	0	0.0
18.5 - <25	44	12	27.3	40	7	17.5	48	1	2.1
25 - <30	50	2	4.0	56	7	12.5	45	1	2.2
30 - <40	47	1	2.1	34	2	5.9	45	1	2.2
>=40	14	0	0.0	11	0	0.0	13	0	0.0
TOTAL	155	15	9.7	143	16	11.2	153	3	2.0

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from weight/bmi analysis
Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT202.SAS
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FIGURE 11.3.8.1.3.6 BUBBLE PLOT OF CHANGE IN WEIGHT (KG)

(SAFETY - EXCLUDING SUBJECTS E0041009, E0019020,
E0026029 & E0035013 DUE TO DATA ERRORS)

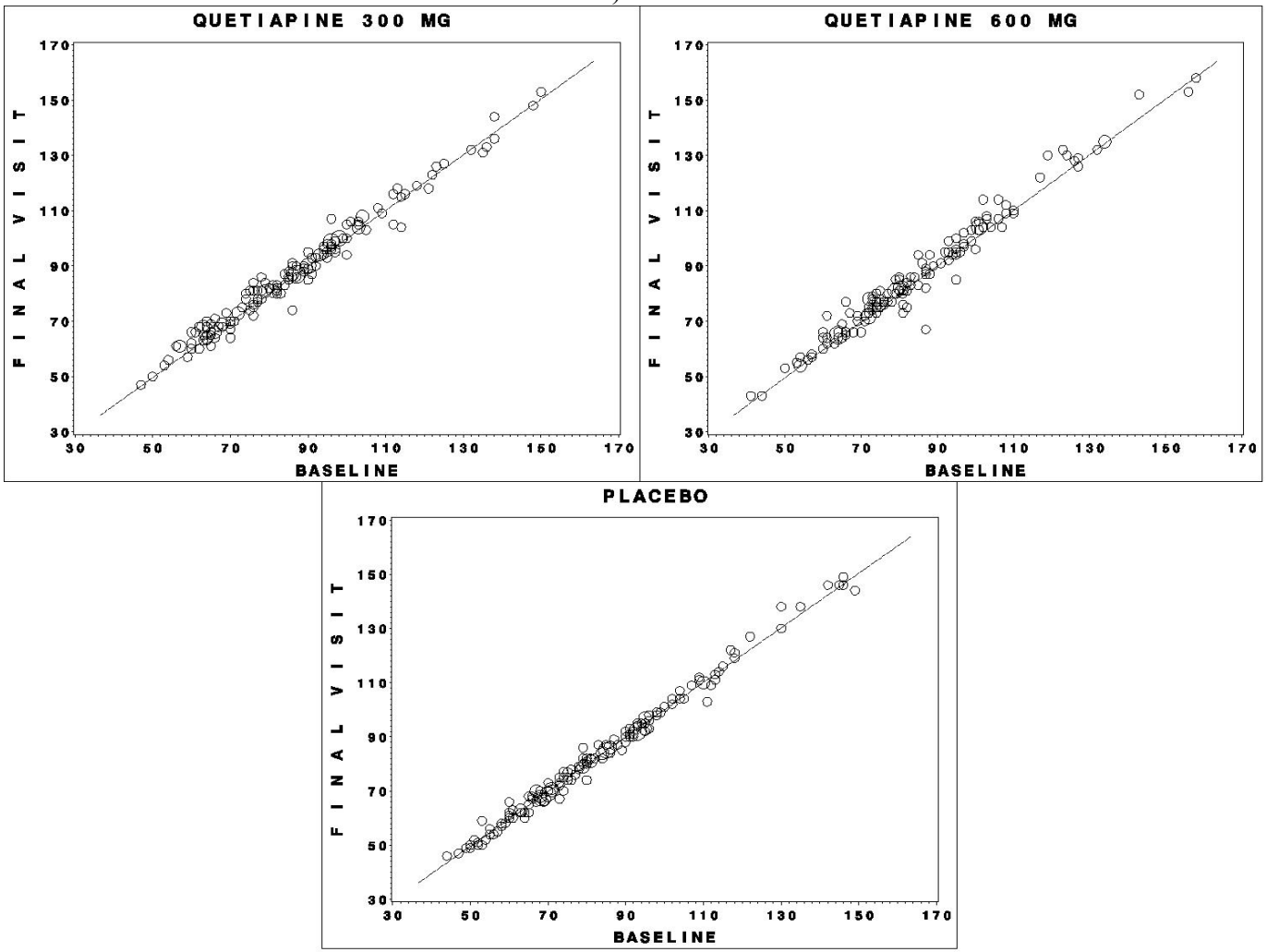

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Table 11.3.8.1.4.1 Metabolic Risk Factors, Shift from Baseline To End of Treatment (Fasting Glucose)
Safety Population

Number of metabolic risk factors at baseline	END OF TREATMENT											
	QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
	N=154				N=146				N=152			
	<3factors		>=3factors		<3factors		>=3factors		<3factors		>=3factors	
	N	%	N	%	N	%	N	%	N	%	N	%
0	39	25.3	0	0	39	26.7	0	0	46	30.3	0	0
1	38	24.7	5	3.2	33	22.6	5	3.4	36	23.7	1	0.7
2	25	16.2	13	8.4	20	13.7	15	10.3	26	17.1	3	2.0
>=3	6	3.9	28	18.2	6	4.1	28	19.2	9	5.9	31	20.4
Total	108	70.1	46	29.9	98	67.1	48	32.9	117	77.0	35	23.0

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from this table

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Table 11.3.8.1.4.2 Metabolic Risk Factors, Shift from Baseline To End of Treatment (Random Glucose)
Safety Population

Number of metabolic risk factors at baseline	END OF TREATMENT											
	QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
	N=154				N=146				N=152			
	<3factors		>=3factors		<3factors		>=3factors		<3factors		>=3factors	
	N	%	N	%	N	%	N	%	N	%	N	%
0	39	25.3	0	0	39	26.7	0	0	46	30.3	0	0
1	39	25.3	4	2.6	34	23.3	4	2.7	36	23.7	1	0.7
2	26	16.9	12	7.8	21	14.4	15	10.3	27	17.8	3	2.0
>=3	6	3.9	28	18.2	6	4.1	27	18.5	9	5.9	30	19.7
Total	110	71.4	44	28.6	100	68.5	46	31.5	118	77.6	34	22.4

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from this table

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND201.SAS
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Table 11.3.8.1.4.3 Metabolic Risk Factors, Treatment Emergent Development of >=3 Risk Factors at Any Time by Sub-Criteria
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=179			N=180			N=180		
		N*	n	%	N*	n	%	N*	n	%
METABOLIC RISK FASTING GLUCOSE	SHIFT TO >= 3 CRITERIA	145	18	12.4	146	20	13.7	140	4	2.9
METABOLIC RISK RANDOM GLUCOSE	SHIFT TO >= 3 CRITERIA	145	16	11.0	147	19	12.9	141	4	2.8
BMI (Kg/m2)	SHIFT TO >= 30	119	5	4.2	130	10	7.7	124	2	1.6
BLOOD PRESSURE SYSTOLIC (mm Hg)	SHIFT TO >= 130	143	11	7.7	141	16	11.3	146	7	4.8
BLOOD PRESSURE DIASTOLIC (mm Hg)	SHIFT TO >= 85	148	14	9.5	148	11	7.4	151	4	2.6
BLOOD PRESSURE OVERALL (mm Hg)	SHIFT TO >= 130 systolic or >= 85 diastolic	138	17	12.3	134	20	14.9	143	7	4.9
TRIGLYCERIDES (mg/dL)	SHIFT TO >= 150	114	28	24.6	132	23	17.4	122	13	10.7
HDL CHOLESTEROL (mg/dL)	SHIFT TO < 40 (MEN) < 50 (WOMEN)	115	21	18.3	109	17	15.6	105	12	11.4
GLUCOSE (FASTING) (mg/dL)	SHIFT TO >= 110	171	7	4.1	172	12	7.0	172	5	2.9

(Continued)

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from this table
* Number of Patients at risk, i.e., not fulfilling the criteria at baseline.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND203.SAS
GENERATED: 12JUL2005 17:46:29 iceadmn3

Table 11.3.8.1.4.3 Metabolic Risk Factors, Treatment Emergent Development of >=3 Risk Factors at Any Time by Sub-Criteria
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=179			N=180			N=180		
		N*	n	%	N*	n	%	N*	n	%
GLUCOSE (RANDOM) (mg/dL)	SHIFT TO >= 140	173	0	0	175	3	1.7	174	3	1.7

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from this table
* Number of Patients at risk, i.e., not fulfilling the criteria at baseline.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND203.SAS
GENERATED: 12JUL2005 17:46:29 iceadmn3

Table 11.3.8.1.4.4 Metabolic Risk Factors Without Increased Triglycerides
Treatment Emergent Development of >=3 Risk Factors at Any Time
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=179			N=180			N=180		
		N	n	%	N	n	%	N	n	%
METABOLIC RISK FASTING GLUCOSE	SHIFT TO >= 3 CRITERIA	161	11	6.8	163	11	6.7	157	4	2.5
METABOLIC RISK RANDOM GLUCOSE	SHIFT TO >= 3 CRITERIA	162	7	4.3	163	10	6.1	159	3	1.9

due to data errors Subjects E0041009, E0019020, E0026029, and E0035013 have been excluded from this table
* Number of Patients at risk, i.e., not fulfilling the criteria at baseline.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND204.SAS
GENERATED: 12JUL2005 17:46:32 iceadmn3

Table 11.3.8.1.5.1 SAS Total Score and Change from Baseline - Descriptive Statistics
Safety Population

	TREATMENT																	
	QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STUDY DAY																		
DAY 1 (BASELINE)	179	0.5	1.11	0.0	0	6	179	0.6	1.20	0.0	0	7	179	0.6	1.19	0.0	0	9
FINAL	151	0.3	0.74	0.0	0	4	145	0.6	1.29	0.0	0	10	150	0.3	0.64	0.0	0	3
CHG FRM BSLN	151	-0.2	1.08	0.0	-6	4	144	-0.1	1.36	0.0	-4	10	149	-0.3	1.15	0.0	-9	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS200.SAS
GENERATED: 12JUL2005 17:46:19 iceadmn3

Table 11.3.8.1.5.2 SAS Total Score Increase from Baseline (Logistic Regression)
Safety Population

	BASELINE SCORE			OBSERVED FREQUENCY			LOGISTIC REGRESSION ESTIMATED EFFECT			LOGISTIC REGRESSION EST. ODDS RATIO		
	TTL PTS	MEAN	SD	TTL OBS	N EVT	%	EST.	SE	P-VALUE	ODDS	LOWER	UPPER
TREATMENT												
Q300MG	151	0.5	1.11	151	14	9	.	.	.	.	.	.
Q600MG	144	0.7	1.30	144	22	15	.	.	.	.	.	.
P	149	0.6	1.19	149	13	9	.	.	.	.	.	.
Q300MG VS P	.	.	.	.	.	.	0.06	0.405	0.888	1.06	0.48	2.34
Q600MG VS P	.	.	.	.	.	.	0.66	0.373	0.075	1.94	0.93	4.03

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/SAS201.SAS
GENERATED: 12JUL2005 17:33:10 iceadmn3

Table 11.3.8.1.5.3 SAS Total Score, Categorical Change from Baseline Summary
Safety Population

	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
	N	%	N	%	N	%
IMPROVED	33	21.9	29	20.1	34	22.8
NO CHANGE	104	68.9	93	64.6	102	68.5
WORSENED	14	9.3	22	15.3	13	8.7
TOTAL	151	100.0	144	100.0	149	100.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS202.SAS
GENERATED: 12JUL2005 17:46:21 iceadmn3

FIGURE 11.3.8.1.5.4 BUBBLE PLOT OF SAS SCORE

(SAFETY)

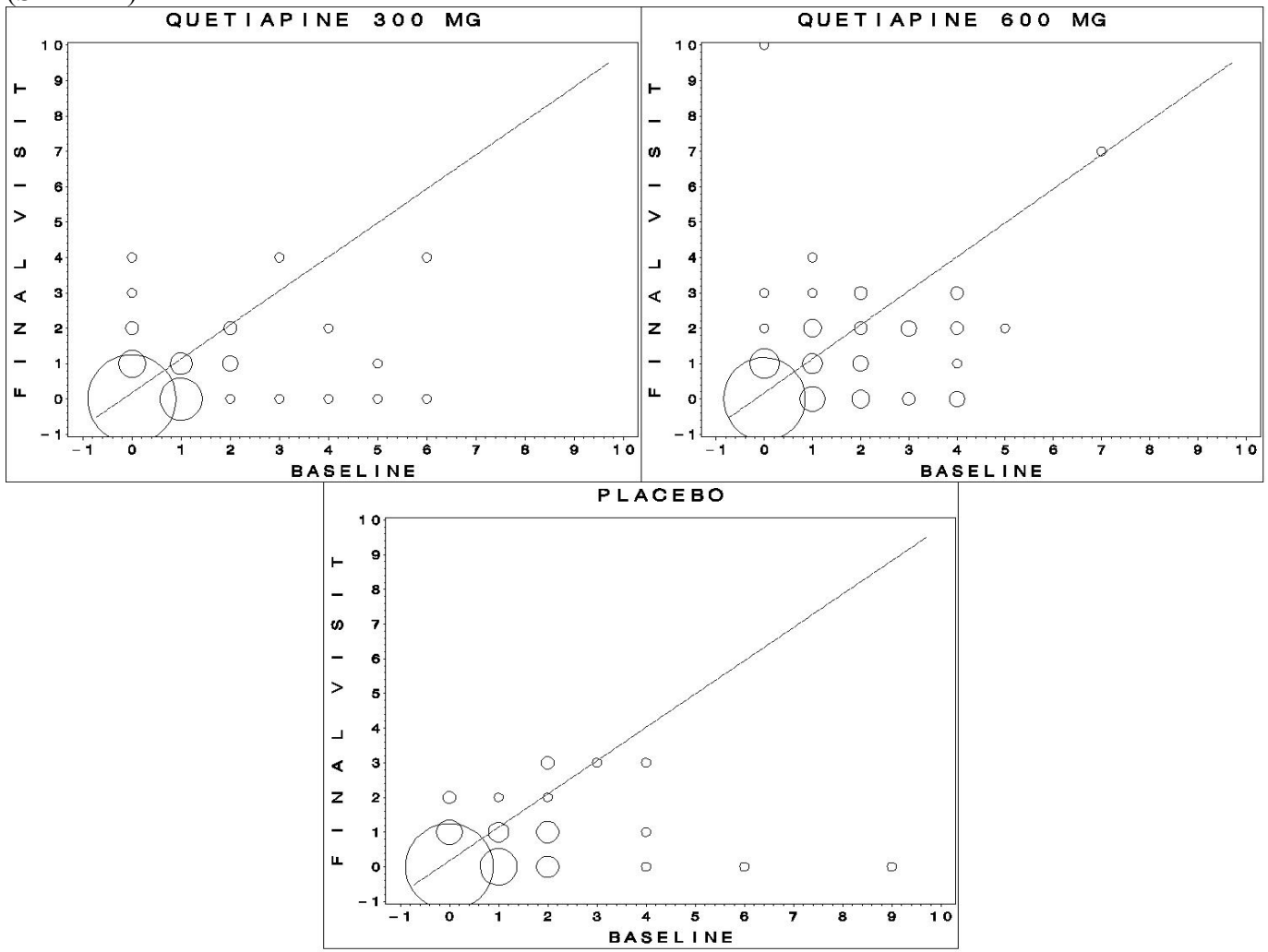

Table 11.3.8.1.6.1 BARS Global Assessment and Change from Baseline - Descriptive Statistics
Safety Population

	TREATMENT																	
	QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STUDY DAY																		
DAY 1 (BASELINE)	179	0.3	0.54	0.0	0	2	180	0.3	0.63	0.0	0	3	179	0.3	0.61	0.0	0	3
FINAL	153	0.2	0.55	0.0	0	3	145	0.3	0.80	0.0	0	4	150	0.1	0.38	0.0	0	2
CHG FRM BSLN	153	-0.1	0.65	0.0	-2	3	145	-0.0	0.84	0.0	-3	3	149	-0.1	0.55	0.0	-2	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/BARS200.SAS
GENERATED: 12JUL2005 17:39:40 iceadmn3

Table 11.3.8.1.6.2 BARS Global Assessment Increase from Baseline (Logistic Regression)
Safety Population

	BASELINE SCORE			OBSERVED FREQUENCY			LOGISTIC REGRESSION ESTIMATED EFFECT			LOGISTIC REGRESSION EST. ODDS RATIO		
	TTL PTS	MEAN	SD	TTL OBS	N EVT	%	EST.	SE	P-VALUE	ODDS	LOWER	UPPER
TREATMENT												
Q300MG	153	0.3	0.55	153	14	9	.	.	.	.	.	.
Q600MG	145	0.3	0.64	145	18	12	.	.	.	.	.	.
P	149	0.2	0.51	149	13	9	.	.	.	.	.	.
Q300MG VS P	.	.	.	.	.	.	0.06	0.404	0.888	1.06	0.48	2.34
Q600MG VS P	.	.	.	.	.	.	0.39	0.386	0.306	1.48	0.70	3.16

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/BARS201.SAS
GENERATED: 12JUL2005 17:28:17 iceadmn3

Table 11.3.8.1.6.3 BARS Global Assessment Change from Baseline Summary
Safety Population

	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
	N	%	N	%	N	%
IMPROVED	24	15.7	27	18.6	24	16.1
NO CHANGE	115	75.2	100	69.0	112	75.2
WORSENED	14	9.2	18	12.4	13	8.7
TOTAL	153	100.0	145	100.0	149	100.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/BARS202.SAS
GENERATED: 12JUL2005 17:39:42 iceadmn3

FIGURE 11.3.8.1.6.4 BUBBLE PLOT OF BARS SCORE

(SAFETY)

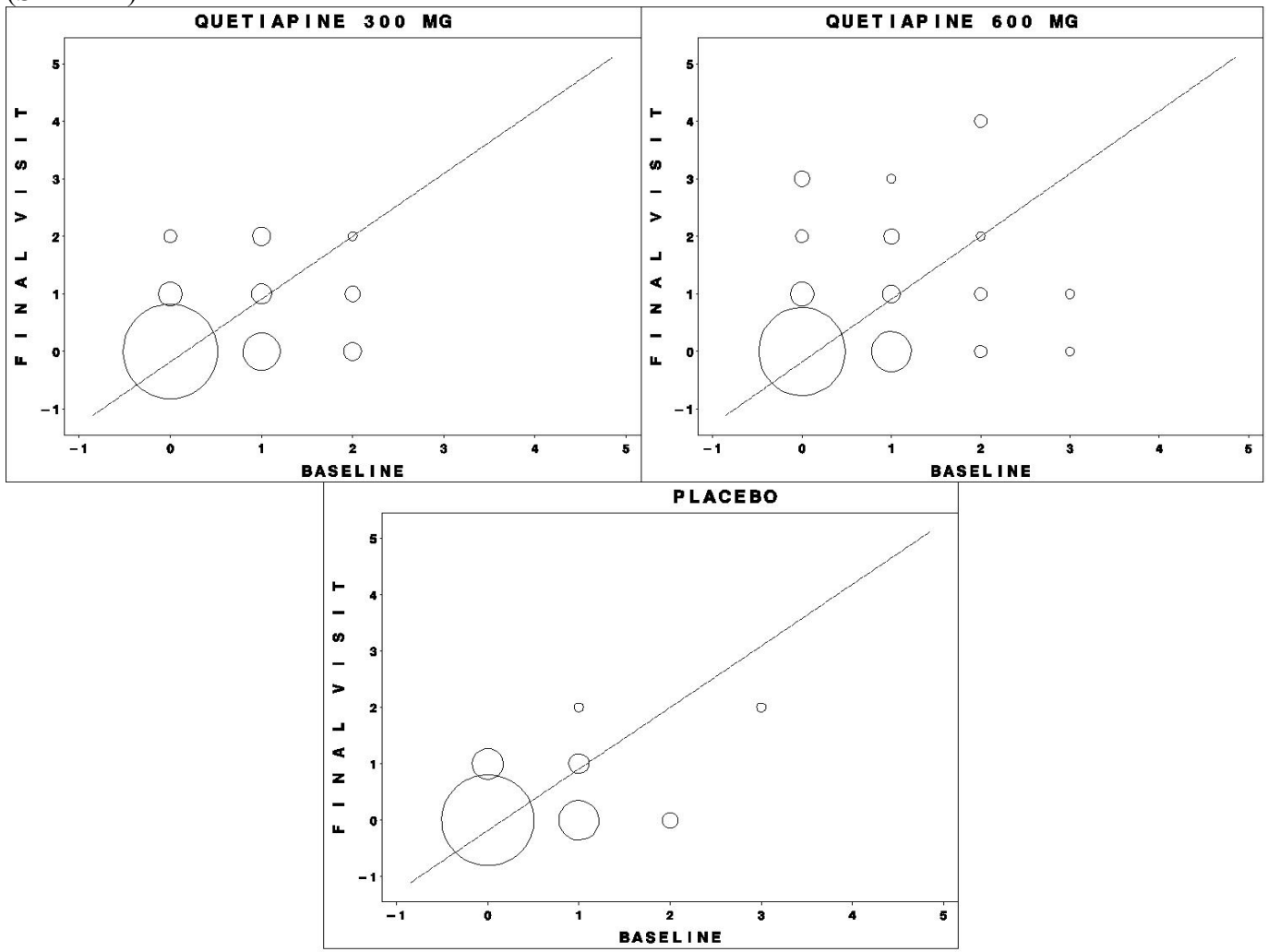

Table 11.3.8.1.7.1 YMRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	VISIT																		
	SCREEN	167	4.9	2.84	5.0	0	12	168	4.8	3.24	4.0	0	12	163	4.9	3.21	4.0	0	12
	DAY 1	172	5.2	2.81	5.0	0	12	170	5.2	3.02	5.0	0	13	169	5.1	3.14	5.0	0	12
	DAY 8	171	4.4	3.63	4.0	0	21	169	4.9	4.08	4.0	0	23	169	5.4	4.46	5.0	0	28
	DAY 15	172	4.6	3.67	4.0	0	21	170	4.8	4.12	4.0	0	23	169	5.4	4.38	4.0	0	23
	DAY 22	172	4.2	3.49	3.0	0	21	170	4.6	4.21	4.0	0	23	169	4.8	4.37	4.0	0	19
	DAY 29	172	4.2	3.49	3.0	0	21	170	4.2	4.69	3.0	0	31	169	5.1	4.51	4.0	0	23
	DAY 36	172	4.4	4.19	3.5	0	23	170	4.3	5.01	3.0	0	31	169	4.9	4.54	4.0	0	23
	DAY 43	172	4.0	3.93	3.0	0	21	170	4.5	5.00	3.0	0	31	169	5.5	5.55	4.0	0	30
	DAY 50	172	4.0	3.96	3.0	0	21	170	4.3	4.88	3.0	0	31	169	5.1	5.26	4.0	0	30
	DAY 57	172	3.8	4.06	3.0	0	27	170	4.1	4.82	3.0	0	31	169	5.1	4.89	4.0	0	30
CHG FROM BASELINE	DAY 8	171	-0.9	3.32	-1.0	-9	14	169	-0.4	3.89	0.0	-8	18	169	0.3	3.73	0.0	-11	21
	DAY 15	172	-0.7	3.63	-1.0	-9	14	170	-0.4	4.06	-1.0	-7	18	169	0.3	4.07	0.0	-11	17
	DAY 22	172	-1.0	3.48	-1.0	-10	14	170	-0.6	4.30	-1.0	-10	18	169	-0.3	3.99	-1.0	-11	15
	DAY 29	172	-1.1	3.54	-1.0	-9	14	170	-1.0	4.76	-2.0	-11	26	169	-0.0	3.90	0.0	-11	19
	DAY 36	172	-0.8	4.21	-1.0	-10	17	170	-0.9	5.25	-2.0	-12	26	169	-0.2	4.04	0.0	-11	19
	DAY 43	172	-1.2	4.20	-1.0	-10	17	170	-0.8	5.15	-1.5	-12	26	169	0.4	4.90	0.0	-11	24

(Continued)

Table 11.3.8.1.7.1 YMRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	172	-1.2	4.03	-1.0	-10	17	170	-1.0	5.00	-2.0	-11	26	169	-0.0	4.71	0.0	-11	19
	DAY 57	172	-1.5	4.18	-2.0	-10	20	170	-1.2	4.96	-2.0	-11	26	169	-0.0	4.33	0.0	-11	19

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS201.SAS
GENERATED: 12JUL2005 17:47:30 iceadmn3

Table 11.3.8.1.7.2 YMRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	VISIT																		
	SCREEN	167	4.9	2.84	5.0	0	12	168	4.8	3.24	4.0	0	12	163	4.9	3.21	4.0	0	12
	DAY 1	172	5.2	2.81	5.0	0	12	170	5.2	3.02	5.0	0	13	169	5.1	3.14	5.0	0	12
	DAY 8	171	4.4	3.63	4.0	0	21	169	4.9	4.08	4.0	0	23	169	5.4	4.46	5.0	0	28
	DAY 15	148	4.4	3.48	4.0	0	19	148	4.5	3.77	4.0	0	22	149	5.5	4.49	4.0	0	23
	DAY 22	139	4.0	3.33	3.0	0	15	133	4.3	3.85	4.0	0	22	143	4.7	4.45	4.0	0	19
	DAY 29	133	3.8	3.18	3.0	0	16	127	3.4	4.34	2.0	0	31	126	4.7	4.33	4.0	0	23
	DAY 36	129	4.2	4.21	3.0	0	23	113	3.3	3.77	2.0	0	22	119	4.1	3.78	3.0	0	19
	DAY 43	123	3.4	3.28	3.0	0	19	107	3.6	3.86	3.0	0	16	107	5.0	5.67	4.0	0	30
	DAY 50	121	3.2	3.24	2.0	0	15	101	3.2	3.39	2.0	0	15	102	4.0	4.54	3.0	0	24
	DAY 57	119	3.2	3.67	2.0	0	27	96	2.7	2.89	2.0	0	15	99	4.2	3.86	3.0	0	20
CHG FROM BASELINE	DAY 8	171	-0.9	3.32	-1.0	-9	14	169	-0.4	3.89	0.0	-8	18	169	0.3	3.73	0.0	-11	21
	DAY 15	148	-0.8	3.55	-1.0	-9	10	148	-0.7	3.70	-1.0	-7	17	149	0.5	4.13	0.0	-11	17
	DAY 22	139	-1.2	3.37	-1.0	-10	7	133	-0.9	4.03	-1.0	-10	17	143	-0.4	4.04	-1.0	-11	15
	DAY 29	133	-1.4	3.42	-1.0	-9	10	127	-1.5	4.62	-2.0	-11	26	126	-0.2	3.36	0.0	-8	11
	DAY 36	129	-1.0	4.36	-1.0	-10	17	113	-1.6	4.22	-2.0	-12	18	119	-0.8	3.41	-1.0	-11	12
	DAY 43	123	-1.7	3.81	-2.0	-10	14	107	-1.3	4.10	-2.0	-12	12	107	0.2	4.92	0.0	-7	24

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS200.SAS
GENERATED: 12JUL2005 17:47:27 iceadmn3

Table 11.3.8.1.7.2 YMRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	121	-1.9	3.48	-2.0	-10	10	101	-1.7	3.54	-2.0	-11	7	102	-0.6	4.26	-1.0	-10	17
	DAY 57	119	-2.0	4.10	-3.0	-9	20	96	-2.1	3.28	-2.0	-10	7	99	-0.7	3.42	0.0	-9	11

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS200.SAS
GENERATED: 12JUL2005 17:47:27 iceadmn3

Table 11.3.8.1.7.3 YMRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	171	5.2	2.81	-0.9	3.32	-0.98	0.331	-1.63	-0.32	.
	Q600MG	169	5.3	3.03	-0.4	3.89	-0.51	0.334	-1.17	0.15	.
	P	169	5.1	3.14	0.3	3.73	0.29	0.333	-0.37	0.95	.
	Q300MG VS P	.	.	.	.	.	-1.27	0.372	-2.00	-0.54	<.001
	Q600MG VS P	.	.	.	.	.	-0.80	0.374	-1.54	-0.07	0.032
DAY 15	Q300MG	172	5.2	2.81	-0.7	3.63	-0.75	0.340	-1.43	-0.08	.
	Q600MG	170	5.2	3.02	-0.4	4.06	-0.50	0.342	-1.18	0.18	.
	P	169	5.1	3.14	0.3	4.07	0.20	0.341	-0.48	0.88	.
	Q300MG VS P	.	.	.	.	.	-0.95	0.395	-1.73	-0.17	0.017
	Q600MG VS P	.	.	.	.	.	-0.70	0.398	-1.48	0.08	0.078
DAY 22	Q300MG	172	5.2	2.81	-1.0	3.48	-0.97	0.353	-1.68	-0.27	.
	Q600MG	170	5.2	3.02	-0.6	4.30	-0.58	0.356	-1.29	0.13	.
	P	169	5.1	3.14	-0.3	3.99	-0.24	0.356	-0.95	0.47	.
	Q300MG VS P	.	.	.	.	.	-0.73	0.391	-1.50	0.03	0.061
	Q600MG VS P	.	.	.	.	.	-0.34	0.393	-1.11	0.43	0.387
DAY 29	Q300MG	172	5.2	2.81	-1.1	3.54	-1.03	0.376	-1.78	-0.28	.
	Q600MG	170	5.2	3.02	-1.0	4.76	-1.01	0.379	-1.76	-0.25	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS204.SAS
GENERATED: 12JUL2005 17:33:14 iceadmn3

Table 11.3.8.1.7.3 YMRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	169	5.1	3.14	-0.0	3.90	0.06	0.379	-0.69	0.82	.
	Q300MG VS P	.	.	.	.	.	-1.09	0.413	-1.90	-0.28	0.009
	Q600MG VS P	.	.	.	.	.	-1.07	0.415	-1.89	-0.25	0.010
DAY 36	Q300MG	172	5.2	2.81	-0.8	4.21	-0.78	0.397	-1.57	0.01	.
	Q600MG	170	5.2	3.02	-0.9	5.25	-0.94	0.400	-1.74	-0.15	.
	P	169	5.1	3.14	-0.2	4.04	-0.15	0.399	-0.95	0.64	.
	Q300MG VS P	.	.	.	.	.	-0.63	0.461	-1.53	0.28	0.176
	Q600MG VS P	.	.	.	.	.	-0.79	0.464	-1.70	0.12	0.088
DAY 43	Q300MG	172	5.2	2.81	-1.2	4.20	-1.12	0.421	-1.96	-0.28	.
	Q600MG	170	5.2	3.02	-0.8	5.15	-0.70	0.424	-1.54	0.14	.
	P	169	5.1	3.14	0.4	4.90	0.35	0.423	-0.49	1.20	.
	Q300MG VS P	.	.	.	.	.	-1.48	0.490	-2.44	-0.51	0.003
	Q600MG VS P	.	.	.	.	.	-1.05	0.493	-2.02	-0.08	0.033
DAY 50	Q300MG	172	5.2	2.81	-1.2	4.03	-1.22	0.419	-2.06	-0.39	.
	Q600MG	170	5.2	3.02	-1.0	5.00	-0.95	0.422	-1.79	-0.11	.
	P	169	5.1	3.14	-0.0	4.71	-0.03	0.421	-0.87	0.80	.
	Q300MG VS P	.	.	.	.	.	-1.19	0.469	-2.11	-0.27	0.011

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS204.SAS
GENERATED: 12JUL2005 17:33:14 iceadmn3

Table 11.3.8.1.7.3 YMRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.92	0.472	-1.85	0.01	0.052
DAY 57	Q300MG	172	5.2	2.81	-1.5	4.18	-1.36	0.420	-2.19	-0.52	.
	Q600MG	170	5.2	3.02	-1.2	4.96	-1.09	0.423	-1.94	-0.25	.
	P	169	5.1	3.14	-0.0	4.33	0.06	0.423	-0.78	0.91	.
	Q300MG VS P	.	.	.	.	.	-1.42	0.455	-2.31	-0.52	0.002
	Q600MG VS P	.	.	.	.	.	-1.15	0.458	-2.05	-0.25	0.012

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS204.SAS
GENERATED: 12JUL2005 17:33:14 iceadmn3

Table 11.3.8.1.7.4 YMRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
VISIT	TREATMENT	N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
DAY 8	Q300MG	171	5.2	2.81	-0.9	3.32	-0.98	0.331	-1.63	-0.32	.
	Q600MG	169	5.3	3.03	-0.4	3.89	-0.51	0.334	-1.17	0.15	.
	P	169	5.1	3.14	0.3	3.73	0.29	0.333	-0.37	0.95	.
	Q300MG VS P	.	.	.	.	.	-1.27	0.372	-2.00	-0.54	<.001
	Q600MG VS P	.	.	.	.	.	-0.80	0.374	-1.54	-0.07	0.032
DAY 15	Q300MG	148	5.2	2.88	-0.8	3.55	-0.84	0.336	-1.51	-0.17	.
	Q600MG	148	5.2	3.05	-0.7	3.70	-0.77	0.337	-1.44	-0.11	.
	P	149	5.0	3.11	0.5	4.13	0.33	0.329	-0.32	0.99	.
	Q300MG VS P	.	.	.	.	.	-1.17	0.412	-1.98	-0.36	0.005
	Q600MG VS P	.	.	.	.	.	-1.11	0.413	-1.92	-0.30	0.008
DAY 22	Q300MG	139	5.2	2.90	-1.2	3.37	-1.10	0.369	-1.83	-0.36	.
	Q600MG	133	5.2	3.02	-0.9	4.03	-0.81	0.377	-1.56	-0.06	.
	P	143	5.1	3.17	-0.4	4.04	-0.34	0.363	-1.07	0.38	.
	Q300MG VS P	.	.	.	.	.	-0.75	0.417	-1.57	0.07	0.071
	Q600MG VS P	.	.	.	.	.	-0.46	0.423	-1.29	0.37	0.275
DAY 29	Q300MG	133	5.2	2.79	-1.4	3.42	-1.20	0.415	-2.04	-0.37	.
	Q600MG	127	4.9	2.93	-1.5	4.62	-1.46	0.421	-2.30	-0.62	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS211.SAS
GENERATED: 12JUL2005 17:33:22 iceadmn3

Table 11.3.8.1.7.4 YMRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	126	5.0	3.25	-0.2	3.36	-0.08	0.420	-0.92	0.76	.
	Q300MG VS P	.	.	.	.	.	-1.12	0.432	-1.97	-0.27	0.010
	Q600MG VS P	.	.	.	.	.	-1.37	0.440	-2.24	-0.51	0.002
DAY 36	Q300MG	129	5.1	2.81	-1.0	4.36	-0.89	0.400	-1.69	-0.10	.
	Q600MG	113	5.0	2.92	-1.6	4.22	-1.59	0.422	-2.43	-0.75	.
	P	119	4.9	3.15	-0.8	3.41	-0.81	0.407	-1.62	-0.00	.
	Q300MG VS P	.	.	.	.	.	-0.08	0.463	-0.99	0.83	0.862
	Q600MG VS P	.	.	.	.	.	-0.78	0.481	-1.72	0.17	0.108
DAY 43	Q300MG	123	5.1	2.81	-1.7	3.81	-1.55	0.467	-2.48	-0.61	.
	Q600MG	107	4.9	2.90	-1.3	4.10	-1.19	0.489	-2.17	-0.22	.
	P	107	4.8	3.11	0.2	4.92	0.14	0.484	-0.83	1.10	.
	Q300MG VS P	.	.	.	.	.	-1.68	0.523	-2.71	-0.65	0.001
	Q600MG VS P	.	.	.	.	.	-1.33	0.542	-2.40	-0.26	0.015
DAY 50	Q300MG	121	5.1	2.83	-1.9	3.48	-1.78	0.416	-2.61	-0.94	.
	Q600MG	101	4.9	2.94	-1.7	3.54	-1.69	0.438	-2.56	-0.82	.
	P	102	4.6	3.11	-0.6	4.26	-0.85	0.433	-1.71	0.01	.
	Q300MG VS P	.	.	.	.	.	-0.92	0.443	-1.79	-0.05	0.038

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS211.SAS
GENERATED: 12JUL2005 17:33:22 iceadmn3

Table 11.3.8.1.7.4 YMRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.84	0.464	-1.75	0.08	0.072
DAY 57	Q300MG	119	5.1	2.87	-2.0	4.10	-1.77	0.407	-2.58	-0.95	.
	Q600MG	96	4.9	2.92	-2.1	3.28	-2.08	0.433	-2.94	-1.22	.
	P	99	4.9	3.10	-0.7	3.42	-0.66	0.424	-1.51	0.18	.
	Q300MG VS P	.	.	.	.	.	-1.10	0.425	-1.94	-0.27	0.010
	Q600MG VS P	.	.	.	.	.	-1.41	0.447	-2.29	-0.53	0.002

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS211.SAS
GENERATED: 12JUL2005 17:33:22 iceadmn3

Table 11.3.8.1.7.5 YMRS Total Score Effect Size Change from Baseline
Last Observation Carried Forward
Intent-to-Treat Population

			95% CONFIDENCE INTERVAL	
		EFFECT SIZE	LOWER	UPPER
VISIT	TREATMENT			
DAY 8	Q300MG VS P	-0.36	-0.57	-0.15
	Q600MG VS P	-0.21	-0.42	0.00
DAY 15	Q300MG VS P	-0.25	-0.46	-0.03
	Q600MG VS P	-0.17	-0.39	0.04
DAY 22	Q300MG VS P	-0.20	-0.41	0.02
	Q600MG VS P	-0.08	-0.30	0.13
DAY 29	Q300MG VS P	-0.29	-0.51	-0.08
	Q600MG VS P	-0.25	-0.46	-0.03
DAY 36	Q300MG VS P	-0.15	-0.36	0.06
	Q600MG VS P	-0.17	-0.38	0.04
DAY 43	Q300MG VS P	-0.32	-0.54	-0.11
	Q600MG VS P	-0.21	-0.42	0.00
DAY 50	Q300MG VS P	-0.27	-0.48	-0.06
	Q600MG VS P	-0.19	-0.40	0.02
DAY 57	Q300MG VS P	-0.33	-0.55	-0.12
	Q600MG VS P	-0.25	-0.46	-0.03

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS209.SAS
GENERATED: 12JUL2005 17:33:16 iceadmn3

Table 11.3.8.1.7.6 YMRS Total Score Effect Size Change from Baseline
Observed Cases
Intent-to-Treat Population

VISIT	TREATMENT	EFFECT SIZE	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER
DAY 8	Q300MG VS P	-0.36	-0.57	-0.15
	Q600MG VS P	-0.21	-0.42	0.00
DAY 15	Q300MG VS P	-0.30	-0.53	-0.08
	Q600MG VS P	-0.28	-0.51	-0.05
DAY 22	Q300MG VS P	-0.20	-0.44	0.03
	Q600MG VS P	-0.11	-0.35	0.12
DAY 29	Q300MG VS P	-0.33	-0.58	-0.09
	Q600MG VS P	-0.34	-0.59	-0.09
DAY 36	Q300MG VS P	-0.02	-0.27	0.23
	Q600MG VS P	-0.20	-0.46	0.06
DAY 43	Q300MG VS P	-0.39	-0.65	-0.12
	Q600MG VS P	-0.29	-0.56	-0.02
DAY 50	Q300MG VS P	-0.24	-0.50	0.02
	Q600MG VS P	-0.21	-0.49	0.06
DAY 57	Q300MG VS P	-0.29	-0.56	-0.02
	Q600MG VS P	-0.42	-0.71	-0.14

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS212.SAS
GENERATED: 12JUL2005 17:33:25 iceadmn3

FIGURE 11.3.8.1.7.7 YMRS TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

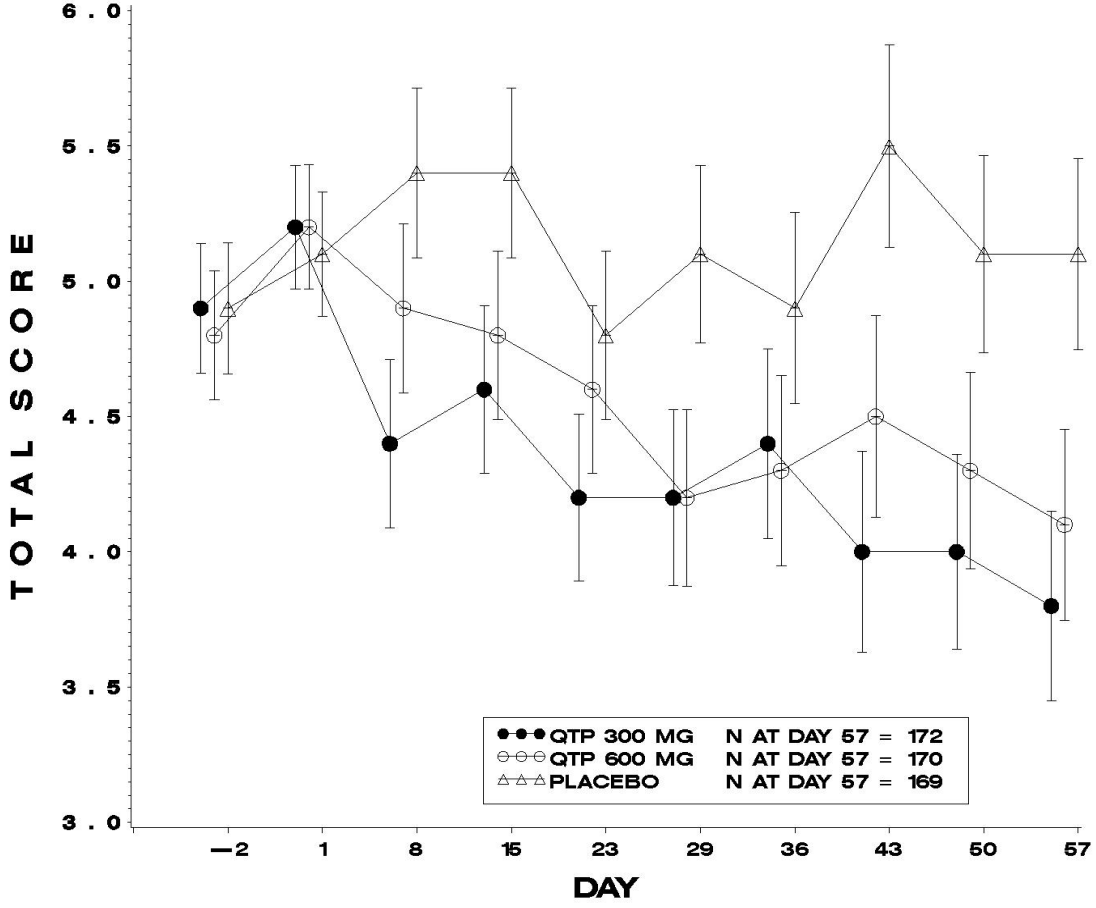

FIGURE 11.3.8.1.7.8 YMRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

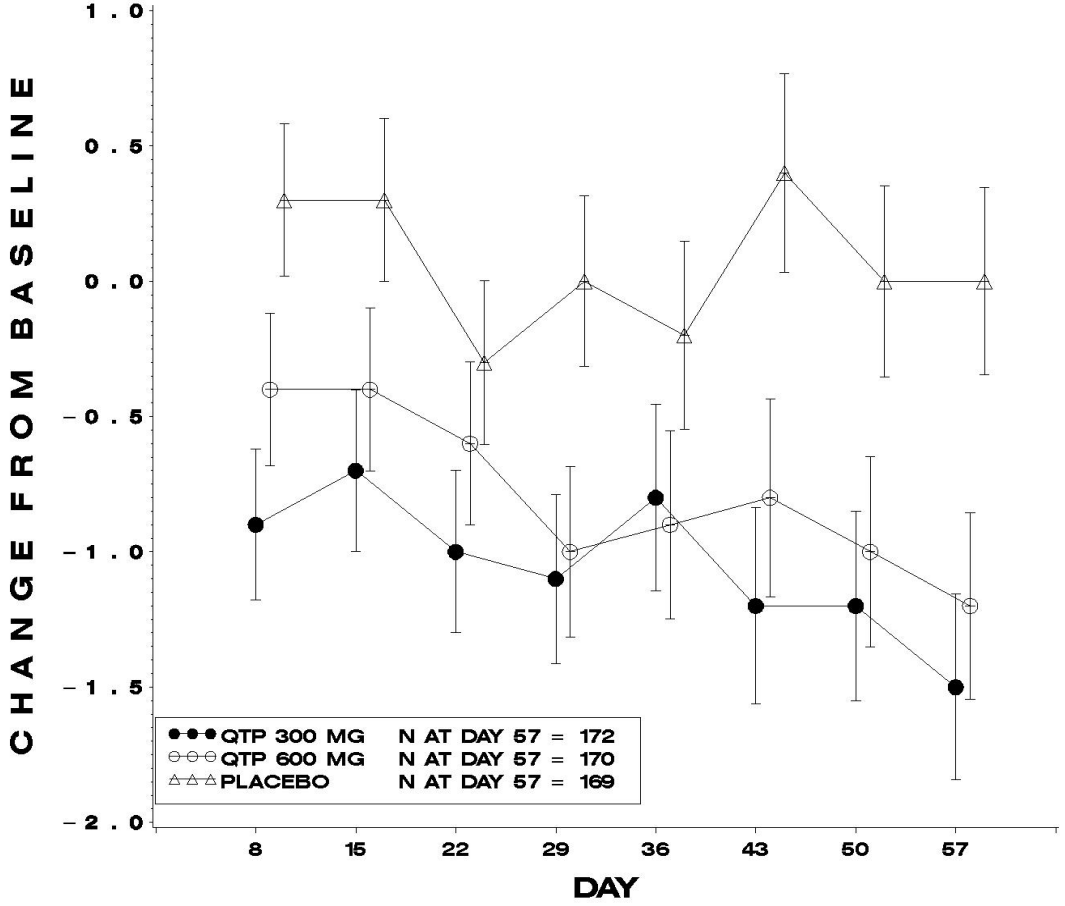

FIGURE 11.3.8.1.7.9 YMRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

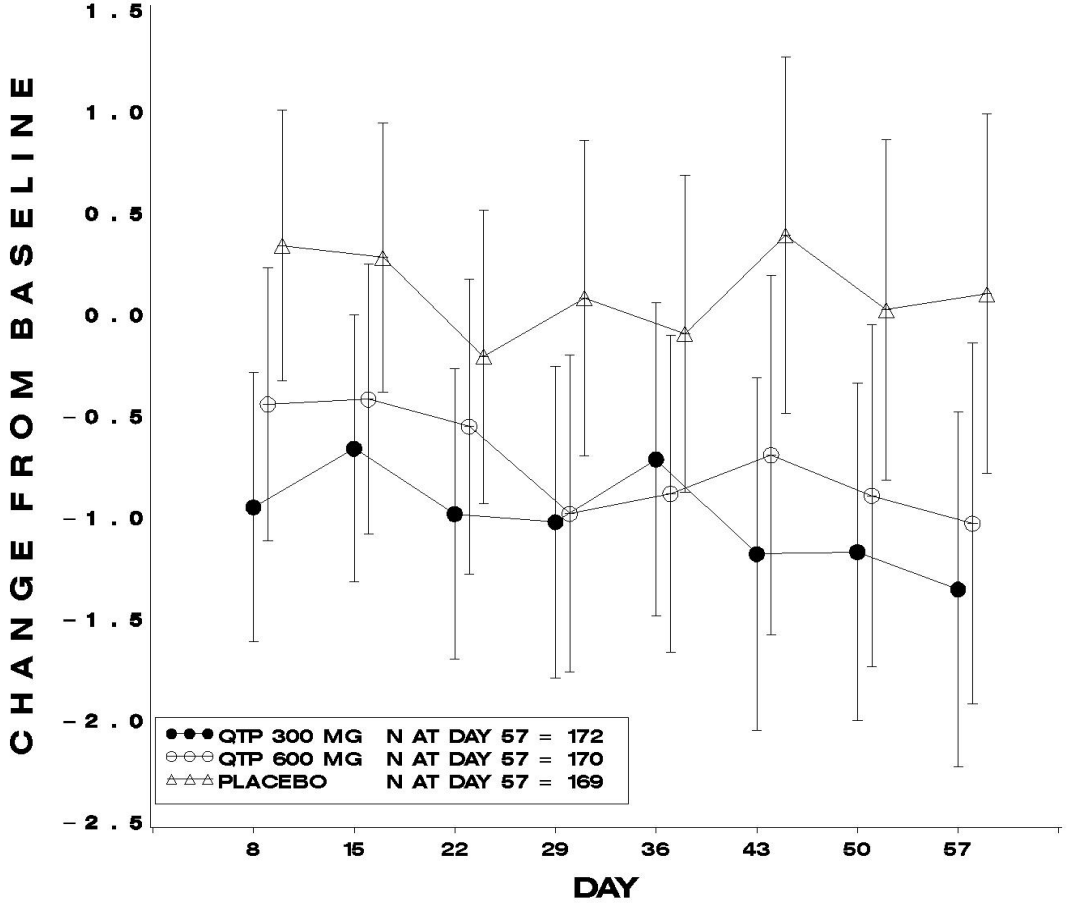

Table 11.3.8.1.7.10 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	VISIT																		
	SCREEN	111	4.5	2.84	5.0	0	12	112	4.7	3.36	4.0	0	12	106	4.8	3.50	5.0	0	12
	DAY 1	116	5.0	2.80	5.0	0	12	114	5.1	3.11	5.0	0	13	112	5.1	3.31	5.0	0	12
	DAY 8	115	4.4	3.75	3.0	0	21	114	4.6	3.67	4.0	0	18	112	5.5	4.29	5.0	0	28
	DAY 15	116	4.8	3.87	4.0	0	21	114	4.7	4.24	4.0	0	22	112	5.5	4.71	4.0	0	23
	DAY 22	116	4.1	3.62	3.0	0	21	114	4.4	4.14	4.0	0	22	112	4.9	4.55	4.0	0	19
	DAY 29	116	4.1	3.63	3.0	0	21	114	3.8	4.46	2.0	0	31	112	5.3	4.77	4.0	0	23
	DAY 36	116	4.4	4.16	3.0	0	21	114	4.0	4.85	3.0	0	31	112	5.3	4.88	4.0	0	23
	DAY 43	116	4.1	4.19	3.0	0	21	114	4.1	4.84	3.0	0	31	112	5.6	5.88	4.0	0	30
	DAY 50	116	3.8	4.17	2.5	0	21	114	4.0	4.84	3.0	0	31	112	5.4	5.69	4.0	0	30
	DAY 57	116	3.8	4.47	2.5	0	27	114	3.7	4.68	2.0	0	31	112	5.4	5.42	4.0	0	30
CHG FROM BASELINE	DAY 8	115	-0.7	3.54	-1.0	-9	14	114	-0.5	3.58	0.0	-7	12	112	0.3	3.74	0.0	-11	21
	DAY 15	116	-0.3	3.93	-1.0	-9	14	114	-0.4	4.00	-1.0	-7	17	112	0.4	4.48	0.0	-11	17
	DAY 22	116	-0.9	3.79	-1.0	-10	14	114	-0.8	4.38	-1.0	-10	17	112	-0.2	4.24	0.0	-11	14
	DAY 29	116	-1.0	3.85	-1.0	-9	14	114	-1.3	4.56	-2.0	-11	26	112	0.2	4.22	0.0	-11	19
	DAY 36	116	-0.7	4.31	-1.0	-9	17	114	-1.1	5.23	-2.0	-11	26	112	0.1	4.48	0.0	-11	19
	DAY 43	116	-0.9	4.52	-1.0	-10	17	114	-1.0	5.13	-2.0	-11	26	112	0.5	5.31	0.0	-11	24

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS203.SAS
GENERATED: 12JUL2005 17:47:35 iceadmn3

Table 11.3.8.1.7.10 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	116	-1.3	4.39	-1.0	-10	17	114	-1.1	4.91	-2.0	-11	26	112	0.3	5.25	0.0	-11	19
	DAY 57	116	-1.3	4.51	-2.0	-8	20	114	-1.4	4.82	-2.0	-11	26	112	0.2	4.94	0.0	-11	19

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS203.SAS
GENERATED: 12JUL2005 17:47:35 iceadmn3

Table 11.3.8.1.7.10 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	VISIT																		
	SCREEN	56	5.6	2.71	5.0	2	12	56	5.0	3.00	5.0	0	12	57	5.0	2.62	4.0	0	12
	DAY 1	56	5.6	2.83	5.0	0	12	56	5.5	2.83	5.0	1	12	57	5.0	2.81	4.0	0	11
	DAY 8	56	4.4	3.41	4.0	0	17	55	5.4	4.79	4.0	0	23	57	5.4	4.80	4.0	0	21
	DAY 15	56	4.1	3.21	3.5	0	15	56	5.1	3.87	4.5	0	23	57	5.2	3.67	4.0	0	17
	DAY 22	56	4.5	3.22	4.0	0	15	56	5.2	4.34	4.0	0	23	57	4.5	4.00	4.0	0	15
	DAY 29	56	4.4	3.21	4.0	0	15	56	5.1	5.06	4.0	0	26	57	4.6	3.95	4.0	0	15
	DAY 36	56	4.6	4.30	4.0	0	23	56	4.9	5.31	4.0	0	26	57	4.3	3.73	4.0	0	14
	DAY 43	56	3.9	3.36	3.0	0	13	56	5.2	5.29	4.0	0	26	57	5.1	4.85	4.0	0	28
	DAY 50	56	4.4	3.47	4.0	0	15	56	4.8	4.96	3.0	0	26	57	4.4	4.23	4.0	0	17
	DAY 57	56	3.7	3.08	3.0	0	13	56	4.8	5.06	4.0	0	26	57	4.5	3.60	4.0	0	14
CHG FROM BASELINE	DAY 8	56	-1.2	2.80	-1.0	-7	6	55	-0.1	4.48	-1.0	-8	18	57	0.4	3.73	0.0	-6	14
	DAY 15	56	-1.4	2.79	-1.0	-9	4	56	-0.4	4.21	-2.0	-6	18	57	0.2	3.15	0.0	-6	8
	DAY 22	56	-1.1	2.73	-1.0	-9	4	56	-0.3	4.15	-1.0	-8	18	57	-0.5	3.45	-1.0	-7	15
	DAY 29	56	-1.2	2.82	-1.0	-8	10	56	-0.5	5.15	-1.0	-9	23	57	-0.4	3.17	-1.0	-7	8
	DAY 36	56	-1.0	4.01	-1.0	-10	15	56	-0.6	5.30	-1.5	-12	23	57	-0.7	2.97	-1.0	-7	7
	DAY 43	56	-1.7	3.43	-2.0	-10	11	56	-0.4	5.21	-1.0	-12	23	57	0.1	4.02	0.0	-7	18

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS203.SAS
GENERATED: 12JUL2005 17:47:35 iceadmn3

Table 11.3.8.1.7.10 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	56	-1.2	3.19	-1.0	-10	5	56	-0.7	5.21	-2.0	-9	23	57	-0.6	3.37	-1.0	-9	7
	DAY 57	56	-1.9	3.39	-1.5	-10	6	56	-0.7	5.26	-2.0	-8	23	57	-0.5	2.75	0.0	-6	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS203.SAS
GENERATED: 12JUL2005 17:47:35 iceadmn3

Table 11.3.8.1.7.11 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	VISIT																		
	SCREEN	111	4.5	2.84	5.0	0	12	112	4.7	3.36	4.0	0	12	106	4.8	3.50	5.0	0	12
	DAY 1	116	5.0	2.80	5.0	0	12	114	5.1	3.11	5.0	0	13	112	5.1	3.31	5.0	0	12
	DAY 8	115	4.4	3.75	3.0	0	21	114	4.6	3.67	4.0	0	18	112	5.5	4.29	5.0	0	28
	DAY 15	103	4.6	3.63	4.0	0	19	105	4.4	4.13	4.0	0	22	96	5.5	4.88	4.0	0	23
	DAY 22	95	3.8	3.35	3.0	0	12	94	3.9	3.90	3.0	0	22	93	4.6	4.62	3.0	0	19
	DAY 29	93	3.8	3.28	3.0	0	16	91	3.1	4.11	2.0	0	31	79	4.7	4.43	4.0	0	23
	DAY 36	89	4.1	4.09	3.0	0	20	82	3.3	3.76	2.0	0	22	74	4.0	3.77	3.0	0	19
	DAY 43	87	3.4	3.37	2.0	0	19	77	3.4	3.83	2.0	0	16	67	4.7	5.94	3.0	0	30
	DAY 50	87	2.9	3.16	2.0	0	14	71	3.2	3.64	2.0	0	15	63	3.8	4.64	3.0	0	24
	DAY 57	83	3.2	4.09	2.0	0	27	68	2.5	2.82	2.0	0	12	58	3.9	4.07	3.0	0	20
CHG FROM BASELINE	DAY 8	115	-0.7	3.54	-1.0	-9	14	114	-0.5	3.58	0.0	-7	12	112	0.3	3.74	0.0	-11	21
	DAY 15	103	-0.4	3.76	-1.0	-9	10	105	-0.7	3.82	-1.0	-7	17	96	0.5	4.61	0.0	-11	17
	DAY 22	95	-1.4	3.64	-1.0	-10	7	94	-1.0	4.28	-1.5	-10	17	93	-0.4	4.31	-1.0	-11	14
	DAY 29	93	-1.4	3.66	-1.0	-9	9	91	-1.7	4.37	-2.0	-11	26	79	-0.3	3.43	0.0	-8	11
	DAY 36	89	-1.0	4.35	-1.0	-9	17	82	-1.6	4.42	-2.0	-11	18	74	-0.9	3.62	-0.5	-11	12
	DAY 43	87	-1.7	3.96	-2.0	-10	14	77	-1.3	4.29	-2.0	-11	12	67	0.0	5.21	-1.0	-7	24

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS202.SAS
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Table 11.3.8.1.7.11 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	87	-2.2	3.60	-2.0	-10	10	71	-1.6	3.63	-2.0	-11	6	63	-0.6	4.65	-1.0	-10	17
	DAY 57	83	-2.0	4.37	-3.0	-8	20	68	-2.2	3.16	-2.0	-10	7	58	-0.9	3.85	-0.5	-9	11

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS202.SAS
GENERATED: 12JUL2005 17:47:32 iceadmn3

Table 11.3.8.1.7.11 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	VISIT																		
	SCREEN	56	5.6	2.71	5.0	2	12	56	5.0	3.00	5.0	0	12	57	5.0	2.62	4.0	0	12
	DAY 1	56	5.6	2.83	5.0	0	12	56	5.5	2.83	5.0	1	12	57	5.0	2.81	4.0	0	11
	DAY 8	56	4.4	3.41	4.0	0	17	55	5.4	4.79	4.0	0	23	57	5.4	4.80	4.0	0	21
	DAY 15	45	4.0	3.10	3.0	0	15	43	4.7	2.75	5.0	0	11	53	5.4	3.71	5.0	0	17
	DAY 22	44	4.5	3.27	4.0	0	15	39	5.0	3.68	5.0	0	16	50	4.7	4.15	4.0	0	15
	DAY 29	40	4.0	2.96	3.0	0	15	36	4.4	4.81	3.0	0	26	47	4.8	4.21	4.0	0	15
	DAY 36	40	4.2	4.52	4.0	0	23	31	3.6	3.86	2.0	0	12	45	4.3	3.85	3.0	0	14
	DAY 43	36	3.3	3.10	3.0	0	13	30	3.9	3.99	3.0	0	14	40	5.6	5.19	4.5	0	28
	DAY 50	34	4.0	3.35	4.0	0	15	30	3.2	2.75	2.5	0	9	39	4.2	4.43	2.0	0	17
	DAY 57	36	3.1	2.50	2.5	0	9	28	3.2	3.06	2.5	0	15	41	4.6	3.55	4.0	0	14
CHG FROM BASELINE	DAY 8	56	-1.2	2.80	-1.0	-7	6	55	-0.1	4.48	-1.0	-8	18	57	0.4	3.73	0.0	-6	14
	DAY 15	45	-1.5	2.90	-1.0	-9	4	43	-0.8	3.44	-2.0	-6	7	53	0.4	3.11	0.0	-4	8
	DAY 22	44	-1.0	2.72	-1.0	-9	4	39	-0.6	3.42	-1.0	-8	8	50	-0.4	3.53	-1.0	-7	15
	DAY 29	40	-1.4	2.85	-2.0	-6	10	36	-0.8	5.20	-1.0	-9	23	47	-0.2	3.27	0.0	-7	8
	DAY 36	40	-1.0	4.45	-1.0	-10	15	31	-1.8	3.68	-2.0	-12	7	45	-0.6	3.08	-1.0	-7	7
	DAY 43	36	-1.6	3.50	-2.0	-9	11	30	-1.5	3.65	-1.0	-12	6	40	0.4	4.44	0.0	-7	18

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS202.SAS
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Table 11.3.8.1.7.11 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	VISIT																		
	DAY 50	34	-1.0	3.02	-1.0	-7	4	30	-2.0	3.37	-2.0	-9	7	39	-0.7	3.61	-1.0	-9	7
	DAY 57	36	-1.9	3.45	-2.0	-9	6	28	-1.9	3.61	-2.0	-8	7	41	-0.4	2.73	0.0	-6	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS202.SAS
GENERATED: 12JUL2005 17:47:32 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ELEVATED MOOD	VISIT																		
	SCREEN	167	0.2	0.42	0.0	0	2	168	0.1	0.28	0.0	0	1	163	0.2	0.48	0.0	0	3
	DAY 1	172	0.2	0.39	0.0	0	2	170	0.2	0.46	0.0	0	2	169	0.2	0.39	0.0	0	2
	DAY 8	171	0.3	0.61	0.0	0	3	169	0.3	0.59	0.0	0	2	169	0.3	0.64	0.0	0	3
	DAY 15	172	0.3	0.59	0.0	0	3	170	0.3	0.64	0.0	0	3	169	0.3	0.56	0.0	0	3
	DAY 22	172	0.3	0.56	0.0	0	2	170	0.3	0.59	0.0	0	2	169	0.2	0.54	0.0	0	3
	DAY 29	172	0.3	0.62	0.0	0	2	170	0.3	0.59	0.0	0	2	169	0.3	0.55	0.0	0	3
	DAY 36	172	0.3	0.60	0.0	0	3	170	0.3	0.60	0.0	0	2	169	0.2	0.55	0.0	0	3
	DAY 43	172	0.3	0.61	0.0	0	3	170	0.3	0.61	0.0	0	2	169	0.4	0.71	0.0	0	3
	DAY 50	172	0.3	0.64	0.0	0	3	170	0.4	0.66	0.0	0	2	169	0.2	0.56	0.0	0	3
	DAY 57	172	0.3	0.61	0.0	0	4	170	0.3	0.62	0.0	0	2	169	0.3	0.59	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. INCREASED MOTOR ACTIVITY	VISIT																		
	SCREEN	167	0.2	0.44	0.0	0	2	168	0.1	0.42	0.0	0	3	163	0.2	0.56	0.0	0	3
	DAY 1	172	0.2	0.46	0.0	0	3	170	0.2	0.62	0.0	0	3	169	0.3	0.57	0.0	0	3
	DAY 8	171	0.3	0.65	0.0	0	4	169	0.3	0.66	0.0	0	3	169	0.3	0.69	0.0	0	3
	DAY 15	172	0.3	0.60	0.0	0	3	170	0.3	0.62	0.0	0	3	169	0.3	0.64	0.0	0	3
	DAY 22	172	0.3	0.62	0.0	0	3	170	0.4	0.63	0.0	0	3	169	0.3	0.69	0.0	0	3
	DAY 29	172	0.3	0.61	0.0	0	3	170	0.3	0.67	0.0	0	4	169	0.3	0.66	0.0	0	3
	DAY 36	172	0.3	0.65	0.0	0	3	170	0.3	0.68	0.0	0	4	169	0.3	0.63	0.0	0	3
	DAY 43	172	0.2	0.60	0.0	0	3	170	0.4	0.74	0.0	0	4	169	0.4	0.75	0.0	0	3
	DAY 50	172	0.3	0.60	0.0	0	3	170	0.4	0.71	0.0	0	4	169	0.3	0.64	0.0	0	3
	DAY 57	172	0.2	0.52	0.0	0	3	170	0.3	0.69	0.0	0	4	169	0.3	0.65	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SEXUAL INTEREST	VISIT																		
	SCREEN	167	0.1	0.26	0.0	0	2	168	0.1	0.49	0.0	0	3	163	0.1	0.25	0.0	0	2
	DAY 1	172	0.0	0.23	0.0	0	2	170	0.1	0.40	0.0	0	3	169	0.1	0.29	0.0	0	2
	DAY 8	171	0.1	0.40	0.0	0	3	169	0.1	0.43	0.0	0	3	169	0.1	0.41	0.0	0	3
	DAY 15	172	0.1	0.38	0.0	0	3	170	0.2	0.53	0.0	0	3	169	0.1	0.38	0.0	0	2
	DAY 22	172	0.1	0.35	0.0	0	3	170	0.2	0.55	0.0	0	3	169	0.1	0.47	0.0	0	2
	DAY 29	172	0.1	0.43	0.0	0	3	170	0.2	0.49	0.0	0	2	169	0.1	0.43	0.0	0	2
	DAY 36	172	0.1	0.46	0.0	0	3	170	0.2	0.50	0.0	0	2	169	0.1	0.46	0.0	0	2
	DAY 43	172	0.1	0.42	0.0	0	3	170	0.2	0.45	0.0	0	2	169	0.2	0.50	0.0	0	3
	DAY 50	172	0.1	0.41	0.0	0	3	170	0.1	0.51	0.0	0	3	169	0.1	0.44	0.0	0	3
	DAY 57	172	0.1	0.34	0.0	0	3	170	0.1	0.44	0.0	0	2	169	0.1	0.44	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. SLEEP	VISIT																		
	SCREEN	167	1.2	0.95	2.0	0	3	168	1.0	0.95	1.0	0	3	163	1.1	0.97	1.0	0	3
	DAY 1	172	1.2	0.96	2.0	0	3	170	1.1	0.96	1.0	0	3	169	1.2	0.96	2.0	0	3
	DAY 8	171	0.4	0.76	0.0	0	3	169	0.4	0.75	0.0	0	3	169	1.1	1.00	1.0	0	3
	DAY 15	172	0.4	0.83	0.0	0	4	170	0.4	0.77	0.0	0	2	169	1.0	0.98	1.0	0	3
	DAY 22	172	0.5	0.79	0.0	0	3	170	0.5	0.79	0.0	0	3	169	0.9	0.94	1.0	0	3
	DAY 29	172	0.4	0.77	0.0	0	3	170	0.4	0.71	0.0	0	2	169	1.0	0.99	1.0	0	4
	DAY 36	172	0.4	0.76	0.0	0	3	170	0.4	0.72	0.0	0	3	169	0.9	1.02	0.0	0	4
	DAY 43	172	0.4	0.76	0.0	0	3	170	0.4	0.76	0.0	0	3	169	0.9	1.04	1.0	0	4
	DAY 50	172	0.4	0.71	0.0	0	3	170	0.4	0.71	0.0	0	2	169	0.9	1.04	1.0	0	4
	DAY 57	172	0.4	0.75	0.0	0	3	170	0.4	0.70	0.0	0	2	169	0.9	1.03	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. IRRITABILTY	VISIT																		
	SCREEN	167	1.7	1.26	2.0	0	4	168	1.9	1.34	2.0	0	6	163	1.6	1.23	2.0	0	6
	DAY 1	172	2.0	1.24	2.0	0	6	170	2.1	1.27	2.0	0	6	169	1.8	1.28	2.0	0	6
	DAY 8	171	1.8	1.31	2.0	0	6	169	1.8	1.37	2.0	0	6	169	1.7	1.24	2.0	0	5
	DAY 15	172	1.7	1.28	2.0	0	6	170	1.7	1.33	2.0	0	6	169	1.7	1.31	2.0	0	5
	DAY 22	172	1.6	1.29	2.0	0	6	170	1.5	1.39	2.0	0	6	169	1.5	1.22	2.0	0	4
	DAY 29	172	1.5	1.25	2.0	0	6	170	1.4	1.48	1.0	0	6	169	1.5	1.39	2.0	0	7
	DAY 36	172	1.5	1.33	2.0	0	6	170	1.4	1.44	2.0	0	6	169	1.6	1.48	2.0	0	7
	DAY 43	172	1.4	1.33	2.0	0	6	170	1.5	1.52	2.0	0	6	169	1.6	1.50	2.0	0	7
	DAY 50	172	1.3	1.31	1.0	0	6	170	1.3	1.41	1.0	0	6	169	1.6	1.60	2.0	0	7
	DAY 57	172	1.3	1.31	2.0	0	6	170	1.3	1.43	1.0	0	6	169	1.6	1.48	2.0	0	7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
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Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. SPEECH (RATE AND AMOUNT)	VISIT																		
	SCREEN	167	0.4	0.85	0.0	0	4	168	0.3	0.72	0.0	0	4	163	0.5	0.95	0.0	0	4
	DAY 1	172	0.3	0.79	0.0	0	4	170	0.3	0.69	0.0	0	4	169	0.3	0.77	0.0	0	4
	DAY 8	171	0.3	0.85	0.0	0	4	169	0.6	1.13	0.0	0	6	169	0.4	0.97	0.0	0	4
	DAY 15	172	0.5	1.06	0.0	0	5	170	0.5	1.08	0.0	0	6	169	0.6	1.08	0.0	0	5
	DAY 22	172	0.4	0.98	0.0	0	4	170	0.5	1.10	0.0	0	6	169	0.4	0.97	0.0	0	4
	DAY 29	172	0.4	0.95	0.0	0	4	170	0.5	1.11	0.0	0	6	169	0.4	0.96	0.0	0	4
	DAY 36	172	0.5	1.06	0.0	0	5	170	0.5	1.19	0.0	0	6	169	0.4	0.97	0.0	0	4
	DAY 43	172	0.4	1.00	0.0	0	4	170	0.5	1.16	0.0	0	6	169	0.5	1.04	0.0	0	4
	DAY 50	172	0.5	0.99	0.0	0	4	170	0.5	1.16	0.0	0	6	169	0.4	0.96	0.0	0	4
	DAY 57	172	0.4	1.01	0.0	0	5	170	0.5	1.12	0.0	0	6	169	0.5	1.00	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
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Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LANGUAGE - THOUGHT DISORDER	VISIT																		
	SCREEN	167	0.4	0.63	0.0	0	3	168	0.4	0.72	0.0	0	3	163	0.4	0.70	0.0	0	2
	DAY 1	172	0.5	0.67	0.0	0	3	170	0.4	0.66	0.0	0	2	169	0.5	0.72	0.0	0	2
	DAY 8	171	0.4	0.66	0.0	0	3	169	0.4	0.67	0.0	0	2	169	0.6	0.74	0.0	0	2
	DAY 15	172	0.4	0.67	0.0	0	2	170	0.4	0.65	0.0	0	2	169	0.5	0.66	0.0	0	2
	DAY 22	172	0.3	0.59	0.0	0	2	170	0.4	0.69	0.0	0	3	169	0.5	0.72	0.0	0	2
	DAY 29	172	0.3	0.58	0.0	0	2	170	0.3	0.64	0.0	0	2	169	0.5	0.76	0.0	0	3
	DAY 36	172	0.4	0.64	0.0	0	3	170	0.3	0.66	0.0	0	3	169	0.5	0.73	0.0	0	3
	DAY 43	172	0.4	0.62	0.0	0	3	170	0.4	0.69	0.0	0	3	169	0.5	0.77	0.0	0	3
	DAY 50	172	0.3	0.62	0.0	0	3	170	0.4	0.66	0.0	0	2	169	0.5	0.75	0.0	0	3
	DAY 57	172	0.3	0.60	0.0	0	3	170	0.3	0.63	0.0	0	2	169	0.5	0.72	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. CONTENT	VISIT																		
	SCREEN	167	0.1	0.47	0.0	0	2	168	0.1	0.46	0.0	0	2	163	0.1	0.47	0.0	0	2
	DAY 1	172	0.2	0.48	0.0	0	2	170	0.2	0.53	0.0	0	2	169	0.1	0.39	0.0	0	2
	DAY 8	171	0.2	0.57	0.0	0	4	169	0.3	0.77	0.0	0	4	169	0.2	0.65	0.0	0	4
	DAY 15	172	0.2	0.61	0.0	0	4	170	0.2	0.79	0.0	0	6	169	0.2	0.75	0.0	0	6
	DAY 22	172	0.2	0.59	0.0	0	4	170	0.2	0.73	0.0	0	6	169	0.2	0.73	0.0	0	6
	DAY 29	172	0.1	0.48	0.0	0	4	170	0.3	0.83	0.0	0	6	169	0.2	0.79	0.0	0	6
	DAY 36	172	0.2	0.68	0.0	0	4	170	0.3	0.84	0.0	0	6	169	0.3	0.78	0.0	0	6
	DAY 43	172	0.2	0.60	0.0	0	4	170	0.3	0.82	0.0	0	6	169	0.3	0.90	0.0	0	6
	DAY 50	172	0.2	0.66	0.0	0	4	170	0.3	0.87	0.0	0	6	169	0.3	0.81	0.0	0	6
	DAY 57	172	0.2	0.85	0.0	0	8	170	0.2	0.77	0.0	0	6	169	0.2	0.76	0.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. DISRUPTIVE - AGGRESSIVE BEHAVIOUR	VISIT																		
	SCREEN	167	0.4	0.80	0.0	0	4	168	0.5	0.90	0.0	0	4	163	0.5	0.91	0.0	0	4
	DAY 1	172	0.5	0.96	0.0	0	5	170	0.5	0.93	0.0	0	4	169	0.6	0.94	0.0	0	4
	DAY 8	171	0.4	0.86	0.0	0	4	169	0.5	0.99	0.0	0	5	169	0.6	0.95	0.0	0	5
	DAY 15	172	0.5	1.05	0.0	0	8	170	0.6	1.08	0.0	0	8	169	0.5	0.92	0.0	0	4
	DAY 22	172	0.4	0.81	0.0	0	3	170	0.4	0.95	0.0	0	5	169	0.5	0.95	0.0	0	4
	DAY 29	172	0.4	0.86	0.0	0	4	170	0.4	1.02	0.0	0	5	169	0.5	1.01	0.0	0	5
	DAY 36	172	0.5	1.06	0.0	0	7	170	0.4	1.02	0.0	0	5	169	0.4	1.01	0.0	0	5
	DAY 43	172	0.4	0.87	0.0	0	4	170	0.5	1.09	0.0	0	6	169	0.5	1.12	0.0	0	6
	DAY 50	172	0.4	0.88	0.0	0	4	170	0.4	0.98	0.0	0	5	169	0.6	1.18	0.0	0	6
	DAY 57	172	0.4	0.84	0.0	0	4	170	0.4	1.03	0.0	0	5	169	0.5	1.08	0.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. APPEARANCE	VISIT																		
	SCREEN	167	0.2	0.44	0.0	0	2	168	0.2	0.42	0.0	0	2	163	0.1	0.42	0.0	0	3
	DAY 1	172	0.2	0.45	0.0	0	2	170	0.1	0.43	0.0	0	3	169	0.1	0.36	0.0	0	2
	DAY 8	171	0.1	0.42	0.0	0	2	169	0.1	0.39	0.0	0	2	169	0.1	0.37	0.0	0	2
	DAY 15	172	0.2	0.45	0.0	0	3	170	0.1	0.44	0.0	0	3	169	0.1	0.29	0.0	0	1
	DAY 22	172	0.1	0.40	0.0	0	3	170	0.2	0.44	0.0	0	2	169	0.1	0.31	0.0	0	2
	DAY 29	172	0.2	0.45	0.0	0	3	170	0.1	0.46	0.0	0	4	169	0.1	0.34	0.0	0	2
	DAY 36	172	0.2	0.52	0.0	0	3	170	0.1	0.40	0.0	0	3	169	0.1	0.32	0.0	0	1
	DAY 43	172	0.2	0.53	0.0	0	3	170	0.1	0.42	0.0	0	2	169	0.1	0.32	0.0	0	1
	DAY 50	172	0.2	0.50	0.0	0	3	170	0.1	0.40	0.0	0	2	169	0.1	0.35	0.0	0	2
	DAY 57	172	0.1	0.47	0.0	0	3	170	0.1	0.42	0.0	0	2	169	0.1	0.31	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.12 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. INSIGHT	VISIT																		
	SCREEN	167	0.0	0.23	0.0	0	2	168	0.0	0.15	0.0	0	1	163	0.0	0.19	0.0	0	1
	DAY 1	172	0.0	0.24	0.0	0	3	170	0.0	0.17	0.0	0	1	169	0.0	0.13	0.0	0	1
	DAY 8	171	0.0	0.25	0.0	0	3	169	0.0	0.13	0.0	0	1	169	0.0	0.13	0.0	0	1
	DAY 15	172	0.0	0.27	0.0	0	3	170	0.0	0.15	0.0	0	1	169	0.0	0.17	0.0	0	1
	DAY 22	172	0.0	0.25	0.0	0	3	170	0.0	0.24	0.0	0	2	169	0.0	0.15	0.0	0	1
	DAY 29	172	0.0	0.25	0.0	0	3	170	0.0	0.25	0.0	0	3	169	0.0	0.15	0.0	0	1
	DAY 36	172	0.0	0.25	0.0	0	3	170	0.0	0.33	0.0	0	4	169	0.0	0.17	0.0	0	1
	DAY 43	172	0.0	0.25	0.0	0	3	170	0.0	0.11	0.0	0	1	169	0.0	0.15	0.0	0	1
	DAY 50	172	0.0	0.25	0.0	0	3	170	0.0	0.11	0.0	0	1	169	0.0	0.17	0.0	0	1
	DAY 57	172	0.0	0.25	0.0	0	3	170	0.0	0.11	0.0	0	1	169	0.0	0.15	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS208.SAS
GENERATED: 12JUL2005 17:47:44 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ELEVATED MOOD	VISIT																		
	SCREEN	167	0.2	0.42	0.0	0	2	168	0.1	0.28	0.0	0	1	163	0.2	0.48	0.0	0	3
	DAY 1	172	0.2	0.39	0.0	0	2	170	0.2	0.46	0.0	0	2	169	0.2	0.39	0.0	0	2
	DAY 8	171	0.3	0.61	0.0	0	3	169	0.3	0.59	0.0	0	2	169	0.3	0.64	0.0	0	3
	DAY 15	148	0.3	0.58	0.0	0	3	148	0.3	0.62	0.0	0	3	149	0.3	0.58	0.0	0	3
	DAY 22	139	0.3	0.54	0.0	0	2	133	0.3	0.55	0.0	0	2	143	0.2	0.57	0.0	0	3
	DAY 29	133	0.4	0.64	0.0	0	2	127	0.2	0.54	0.0	0	2	126	0.3	0.53	0.0	0	2
	DAY 36	129	0.3	0.62	0.0	0	3	113	0.3	0.53	0.0	0	2	119	0.3	0.54	0.0	0	2
	DAY 43	123	0.2	0.57	0.0	0	3	107	0.2	0.56	0.0	0	2	107	0.5	0.79	0.0	0	3
	DAY 50	121	0.3	0.59	0.0	0	2	101	0.4	0.65	0.0	0	2	102	0.2	0.54	0.0	0	2
	DAY 57	119	0.3	0.58	0.0	0	4	96	0.3	0.59	0.0	0	2	99	0.3	0.58	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. INCREASED MOTOR ACTIVITY	VISIT																		
	SCREEN	167	0.2	0.44	0.0	0	2	168	0.1	0.42	0.0	0	3	163	0.2	0.56	0.0	0	3
	DAY 1	172	0.2	0.46	0.0	0	3	170	0.2	0.62	0.0	0	3	169	0.3	0.57	0.0	0	3
	DAY 8	171	0.3	0.65	0.0	0	4	169	0.3	0.66	0.0	0	3	169	0.3	0.69	0.0	0	3
	DAY 15	148	0.2	0.57	0.0	0	3	148	0.3	0.59	0.0	0	3	149	0.4	0.66	0.0	0	3
	DAY 22	139	0.3	0.60	0.0	0	3	133	0.3	0.61	0.0	0	3	143	0.3	0.72	0.0	0	3
	DAY 29	133	0.3	0.61	0.0	0	3	127	0.3	0.63	0.0	0	4	126	0.3	0.57	0.0	0	3
	DAY 36	129	0.3	0.67	0.0	0	3	113	0.2	0.51	0.0	0	2	119	0.2	0.45	0.0	0	2
	DAY 43	123	0.2	0.59	0.0	0	3	107	0.3	0.64	0.0	0	3	107	0.4	0.74	0.0	0	3
	DAY 50	121	0.3	0.59	0.0	0	3	101	0.3	0.55	0.0	0	3	102	0.2	0.49	0.0	0	2
	DAY 57	119	0.2	0.51	0.0	0	3	96	0.2	0.52	0.0	0	3	99	0.2	0.49	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SEXUAL INTEREST	VISIT																		
	SCREEN	167	0.1	0.26	0.0	0	2	168	0.1	0.49	0.0	0	3	163	0.1	0.25	0.0	0	2
	DAY 1	172	0.0	0.23	0.0	0	2	170	0.1	0.40	0.0	0	3	169	0.1	0.29	0.0	0	2
	DAY 8	171	0.1	0.40	0.0	0	3	169	0.1	0.43	0.0	0	3	169	0.1	0.41	0.0	0	3
	DAY 15	148	0.1	0.33	0.0	0	2	148	0.2	0.51	0.0	0	3	149	0.1	0.39	0.0	0	2
	DAY 22	139	0.0	0.24	0.0	0	2	133	0.2	0.52	0.0	0	3	143	0.2	0.48	0.0	0	2
	DAY 29	133	0.1	0.37	0.0	0	2	127	0.1	0.45	0.0	0	2	126	0.1	0.40	0.0	0	2
	DAY 36	129	0.1	0.42	0.0	0	3	113	0.1	0.41	0.0	0	2	119	0.1	0.44	0.0	0	2
	DAY 43	123	0.0	0.25	0.0	0	2	107	0.1	0.32	0.0	0	1	107	0.1	0.51	0.0	0	3
	DAY 50	121	0.0	0.24	0.0	0	2	101	0.1	0.44	0.0	0	3	102	0.1	0.31	0.0	0	2
	DAY 57	119	0.0	0.24	0.0	0	2	96	0.1	0.28	0.0	0	2	99	0.1	0.31	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. SLEEP	VISIT																		
	SCREEN	167	1.2	0.95	2.0	0	3	168	1.0	0.95	1.0	0	3	163	1.1	0.97	1.0	0	3
	DAY 1	172	1.2	0.96	2.0	0	3	170	1.1	0.96	1.0	0	3	169	1.2	0.96	2.0	0	3
	DAY 8	171	0.4	0.76	0.0	0	3	169	0.4	0.75	0.0	0	3	169	1.1	1.00	1.0	0	3
	DAY 15	148	0.4	0.80	0.0	0	4	148	0.4	0.74	0.0	0	2	149	1.0	0.96	1.0	0	3
	DAY 22	139	0.5	0.76	0.0	0	3	133	0.4	0.75	0.0	0	3	143	0.8	0.89	1.0	0	3
	DAY 29	133	0.4	0.75	0.0	0	2	127	0.3	0.61	0.0	0	2	126	0.8	0.89	1.0	0	3
	DAY 36	129	0.4	0.71	0.0	0	3	113	0.3	0.63	0.0	0	3	119	0.6	0.87	0.0	0	3
	DAY 43	123	0.4	0.72	0.0	0	2	107	0.3	0.70	0.0	0	3	107	0.8	0.94	0.0	0	3
	DAY 50	121	0.4	0.66	0.0	0	2	101	0.3	0.64	0.0	0	2	102	0.7	0.90	0.0	0	3
	DAY 57	119	0.3	0.71	0.0	0	3	96	0.3	0.62	0.0	0	2	99	0.7	0.88	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. IRRITABILTY	VISIT																		
	SCREEN	167	1.7	1.26	2.0	0	4	168	1.9	1.34	2.0	0	6	163	1.6	1.23	2.0	0	6
	DAY 1	172	2.0	1.24	2.0	0	6	170	2.1	1.27	2.0	0	6	169	1.8	1.28	2.0	0	6
	DAY 8	171	1.8	1.31	2.0	0	6	169	1.8	1.37	2.0	0	6	169	1.7	1.24	2.0	0	5
	DAY 15	148	1.7	1.34	2.0	0	6	148	1.6	1.25	2.0	0	6	149	1.7	1.30	2.0	0	5
	DAY 22	139	1.6	1.38	2.0	0	6	133	1.4	1.31	2.0	0	5	143	1.4	1.20	2.0	0	4
	DAY 29	133	1.5	1.28	2.0	0	6	127	1.1	1.36	1.0	0	6	126	1.5	1.40	2.0	0	7
	DAY 36	129	1.4	1.37	2.0	0	6	113	1.2	1.21	1.0	0	5	119	1.4	1.38	2.0	0	5
	DAY 43	123	1.3	1.37	1.0	0	6	107	1.2	1.36	1.0	0	6	107	1.5	1.42	2.0	0	6
	DAY 50	121	1.0	1.24	0.0	0	6	101	0.9	1.03	0.0	0	5	102	1.3	1.54	1.0	0	6
	DAY 57	119	1.2	1.27	1.0	0	6	96	0.8	1.08	0.0	0	5	99	1.4	1.32	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. SPEECH (RATE AND AMOUNT)	VISIT																		
	SCREEN	167	0.4	0.85	0.0	0	4	168	0.3	0.72	0.0	0	4	163	0.5	0.95	0.0	0	4
	DAY 1	172	0.3	0.79	0.0	0	4	170	0.3	0.69	0.0	0	4	169	0.3	0.77	0.0	0	4
	DAY 8	171	0.3	0.85	0.0	0	4	169	0.6	1.13	0.0	0	6	169	0.4	0.97	0.0	0	4
	DAY 15	148	0.4	1.02	0.0	0	5	148	0.4	0.90	0.0	0	5	149	0.7	1.11	0.0	0	5
	DAY 22	139	0.4	0.88	0.0	0	4	133	0.5	0.97	0.0	0	4	143	0.4	0.97	0.0	0	4
	DAY 29	133	0.4	0.78	0.0	0	3	127	0.4	0.97	0.0	0	6	126	0.4	0.93	0.0	0	4
	DAY 36	129	0.4	0.96	0.0	0	5	113	0.5	0.97	0.0	0	4	119	0.3	0.84	0.0	0	4
	DAY 43	123	0.3	0.81	0.0	0	4	107	0.4	0.94	0.0	0	4	107	0.6	1.01	0.0	0	4
	DAY 50	121	0.3	0.78	0.0	0	4	101	0.4	0.88	0.0	0	4	102	0.3	0.83	0.0	0	4
	DAY 57	119	0.3	0.81	0.0	0	5	96	0.3	0.74	0.0	0	4	99	0.5	0.93	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LANGUAGE - THOUGHT DISORDER	VISIT																		
	SCREEN	167	0.4	0.63	0.0	0	3	168	0.4	0.72	0.0	0	3	163	0.4	0.70	0.0	0	2
	DAY 1	172	0.5	0.67	0.0	0	3	170	0.4	0.66	0.0	0	2	169	0.5	0.72	0.0	0	2
	DAY 8	171	0.4	0.66	0.0	0	3	169	0.4	0.67	0.0	0	2	169	0.6	0.74	0.0	0	2
	DAY 15	148	0.4	0.67	0.0	0	2	148	0.4	0.63	0.0	0	2	149	0.5	0.65	0.0	0	2
	DAY 22	139	0.3	0.59	0.0	0	2	133	0.4	0.67	0.0	0	3	143	0.5	0.72	0.0	0	2
	DAY 29	133	0.3	0.57	0.0	0	2	127	0.2	0.54	0.0	0	2	126	0.5	0.73	0.0	0	3
	DAY 36	129	0.3	0.63	0.0	0	3	113	0.2	0.54	0.0	0	3	119	0.4	0.63	0.0	0	2
	DAY 43	123	0.3	0.54	0.0	0	2	107	0.3	0.60	0.0	0	3	107	0.4	0.71	0.0	0	3
	DAY 50	121	0.3	0.55	0.0	0	2	101	0.3	0.56	0.0	0	2	102	0.4	0.64	0.0	0	2
	DAY 57	119	0.2	0.52	0.0	0	2	96	0.2	0.47	0.0	0	2	99	0.4	0.61	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. CONTENT	VISIT																		
	SCREEN	167	0.1	0.47	0.0	0	2	168	0.1	0.46	0.0	0	2	163	0.1	0.47	0.0	0	2
	DAY 1	172	0.2	0.48	0.0	0	2	170	0.2	0.53	0.0	0	2	169	0.1	0.39	0.0	0	2
	DAY 8	171	0.2	0.57	0.0	0	4	169	0.3	0.77	0.0	0	4	169	0.2	0.65	0.0	0	4
	DAY 15	148	0.2	0.56	0.0	0	2	148	0.2	0.81	0.0	0	6	149	0.3	0.79	0.0	0	6
	DAY 22	139	0.2	0.53	0.0	0	2	133	0.2	0.58	0.0	0	4	143	0.2	0.76	0.0	0	6
	DAY 29	133	0.1	0.30	0.0	0	2	127	0.2	0.73	0.0	0	4	126	0.2	0.62	0.0	0	4
	DAY 36	129	0.2	0.63	0.0	0	4	113	0.2	0.68	0.0	0	3	119	0.2	0.57	0.0	0	2
	DAY 43	123	0.1	0.32	0.0	0	2	107	0.2	0.66	0.0	0	4	107	0.3	0.80	0.0	0	4
	DAY 50	121	0.1	0.46	0.0	0	2	101	0.2	0.77	0.0	0	4	102	0.2	0.60	0.0	0	3
	DAY 57	119	0.2	0.82	0.0	0	8	96	0.1	0.48	0.0	0	3	99	0.2	0.50	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. DISRUPTIVE - AGGRESSIVE BEHAVIOUR	VISIT																		
	SCREEN	167	0.4	0.80	0.0	0	4	168	0.5	0.90	0.0	0	4	163	0.5	0.91	0.0	0	4
	DAY 1	172	0.5	0.96	0.0	0	5	170	0.5	0.93	0.0	0	4	169	0.6	0.94	0.0	0	4
	DAY 8	171	0.4	0.86	0.0	0	4	169	0.5	0.99	0.0	0	5	169	0.6	0.95	0.0	0	5
	DAY 15	148	0.5	1.07	0.0	0	8	148	0.6	1.08	0.0	0	8	149	0.5	0.94	0.0	0	4
	DAY 22	139	0.4	0.78	0.0	0	3	133	0.4	0.93	0.0	0	5	143	0.5	0.97	0.0	0	4
	DAY 29	133	0.3	0.83	0.0	0	4	127	0.3	0.92	0.0	0	5	126	0.6	1.08	0.0	0	5
	DAY 36	129	0.5	1.09	0.0	0	7	113	0.3	0.79	0.0	0	5	119	0.4	0.93	0.0	0	4
	DAY 43	123	0.3	0.71	0.0	0	3	107	0.3	0.93	0.0	0	6	107	0.5	1.08	0.0	0	6
	DAY 50	121	0.3	0.73	0.0	0	4	101	0.3	0.69	0.0	0	3	102	0.5	1.07	0.0	0	4
	DAY 57	119	0.3	0.75	0.0	0	4	96	0.3	0.79	0.0	0	4	99	0.4	0.89	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. APPEARANCE	VISIT																		
	SCREEN	167	0.2	0.44	0.0	0	2	168	0.2	0.42	0.0	0	2	163	0.1	0.42	0.0	0	3
	DAY 1	172	0.2	0.45	0.0	0	2	170	0.1	0.43	0.0	0	3	169	0.1	0.36	0.0	0	2
	DAY 8	171	0.1	0.42	0.0	0	2	169	0.1	0.39	0.0	0	2	169	0.1	0.37	0.0	0	2
	DAY 15	148	0.1	0.40	0.0	0	2	148	0.1	0.45	0.0	0	3	149	0.1	0.27	0.0	0	1
	DAY 22	139	0.1	0.34	0.0	0	2	133	0.2	0.44	0.0	0	2	143	0.1	0.30	0.0	0	2
	DAY 29	133	0.1	0.39	0.0	0	2	127	0.1	0.46	0.0	0	4	126	0.1	0.34	0.0	0	2
	DAY 36	129	0.2	0.50	0.0	0	2	113	0.1	0.35	0.0	0	3	119	0.1	0.30	0.0	0	1
	DAY 43	123	0.2	0.47	0.0	0	3	107	0.1	0.38	0.0	0	2	107	0.1	0.32	0.0	0	1
	DAY 50	121	0.2	0.45	0.0	0	3	101	0.1	0.29	0.0	0	2	102	0.1	0.35	0.0	0	2
	DAY 57	119	0.1	0.43	0.0	0	3	96	0.1	0.28	0.0	0	1	99	0.1	0.22	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.13 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. INSIGHT	VISIT																		
	SCREEN	167	0.0	0.23	0.0	0	2	168	0.0	0.15	0.0	0	1	163	0.0	0.19	0.0	0	1
	DAY 1	172	0.0	0.24	0.0	0	3	170	0.0	0.17	0.0	0	1	169	0.0	0.13	0.0	0	1
	DAY 8	171	0.0	0.25	0.0	0	3	169	0.0	0.13	0.0	0	1	169	0.0	0.13	0.0	0	1
	DAY 15	148	0.0	0.14	0.0	0	1	148	0.0	0.08	0.0	0	1	149	0.0	0.14	0.0	0	1
	DAY 22	139	0.0	0.08	0.0	0	1	133	0.0	0.24	0.0	0	2	143	0.0	0.08	0.0	0	1
	DAY 29	133	0.0	0.09	0.0	0	1	127	0.0	0.27	0.0	0	3	126	0.0	0.09	0.0	0	1
	DAY 36	129	0.0	0.09	0.0	0	1	113	0.0	0.39	0.0	0	4	119	0.0	0.13	0.0	0	1
	DAY 43	123	0.0	0.09	0.0	0	1	107	0.0	0.00	0.0	0	0	107	0.0	0.10	0.0	0	1
	DAY 50	121	0.0	0.09	0.0	0	1	101	0.0	0.00	0.0	0	0	102	0.0	0.14	0.0	0	1
	DAY 57	119	0.0	0.09	0.0	0	1	96	0.0	0.00	0.0	0	0	99	0.0	0.10	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS207.SAS
GENERATED: 12JUL2005 17:47:39 iceadmn3

Table 11.3.8.1.7.14 Treatment Emergent Mania (Events Criteria Met)
Safety Population

	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=179		N=180		N=180	
	n	%	n	%	n	%
MedDRA or YMRS	7	3.9	4	2.2	7	3.9
YMRS Alone	4	2.2	4	2.2	6	3.3
MedDRA Alone	3	1.7	2	1.1	2	1.1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS205.SAS
GENERATED: 12JUL2005 17:47:37 iceadmn3

Table 11.3.8.1.7.15 Treatment Emergent Mania (CMH)
Safety Population

	TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
	Q300MG			Q600MG			P						
	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
STRATA													
BIPOLAR I	6	120	5.00	1	120	0.83	7	118	5.93	.	.	.	.
BIPOLAR II	1	59	1.69	3	60	5.00	0	62	0.00	.	.	.	.
ALL	7	179	3.91	4	180	2.22	7	180	3.89	.	.	.	.
Q300 VS P	.	.	.	.	.	.	.	.	.	0.982	0.99	0.36	2.74
Q600 VS P	.	.	.	.	.	.	.	.	.	0.356	0.57	0.17	1.92

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/YMRS210.SAS
GENERATED: 12JUL2005 17:33:19 iceadmn3

Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	SCREEN	25MAR2003	-10	80	124	80	78	122	80	-2	-2	0
		DAY 1	04APR2003	1	82	142	100	80	152	106 H	-2	10	6
		BASELINE			82	142	100	80	152	106 H	-2	10	6
		DAY 8	10APR2003	7	84	120	94	80	120	88	-4	0	-6
		FINAL		7	84	120	94	80	120	88	-4	0	-6
	E0003004	SCREEN	03DEC2002	-14	64	128	90	76	120	80	12	-8	-10
		DAY 1	17DEC2002	1	72	112	82	80	90 L	70	8	-22 Y	-12
		BASELINE			72	112	82	80	90 L	70	8	-22 Y	-12
		DAY 22	07JAN2003	22	74	132	70	88	134	82	14	2	12
		FINAL		22	74	132	70	88	134	82	14	2	12
	E0004018	SCREEN	12MAR2003	-7	60	118	74	64	120	78	4	2	4
		DAY 1	19MAR2003	1	64	112	70	72	118	78	8	6	8
		BASELINE			64	112	70	72	118	78	8	6	8
		DAY 8	26MAR2003	8	88	126	72	92	130	80	4	4	8
		DAY 15	02APR2003	15	88	122	70	96	124	84	8	2	14
		DAY 22	09APR2003	22	76	128	82	88	130	88	12	2	6
		DAY 29	16APR2003	29	80	128	80	90	124	88	10	-4	8
		DAY 36	23APR2003	36	88	122	80	94	120	86	6	-2	6
		DAY 43	30APR2003	43	80	124	80	88	120	82	8	-4	2
		DAY 50	06MAY2003	49	80	108	70	100	100	68	20 Y	-8	-2
		DAY 57	13MAY2003	56	76	110	78	84	112	82	8	2	4
		FINAL		56	76	110	78	84	112	82	8	2	4
	E0006005	SCREEN	25NOV2002	-10	64	100	72	75	104	78	11	4	6
		DAY 1	05DEC2002	1	74	146	82	88	142	92	14	-4	10
		BASELINE			74	146	82	88	142	92	14	-4	10
		DAY 8	12DEC2002	8	76	102	70	96	100	68	20 Y	-2	-2
		DAY 15	20DEC2002	16	89	127	76	106	132	87	17	5	11
		DAY 22	30DEC2002	26	81	123	69	107	127	76	26 Y	4	7
		DAY 29	03JAN2003	30	86	119	67	100	126	72	14	7	5

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT102.SAS
GENERATED: 12JUL2005 17:46:45 iceadmn3

Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 36	09JAN2003	36	83	134	86	84	117	87	1	-17	1
		DAY 43	16JAN2003	43	78	118	78	90	135	85	12	17	7
		DAY 50	23JAN2003	50	76	140	80	78	96	46 L	2	-44 Y	-34 Y
		DAY 57	30JAN2003	57	76	115	65	98	123	70	22 Y	8	5
		FINAL		57	76	115	65	98	123	70	22 Y	8	5
	E0010004	SCREEN	05DEC2002	-6	64	90 L	60	70	96	68	6	6	8
		DAY 1	11DEC2002	1	60	110	84	64	100	78	4	-10	-6
		BASELINE			60	110	84	64	100	78	4	-10	-6
		DAY 8	18DEC2002	8	68	104	68	84	98	62	16	-6	-6
		DAY 15	26DEC2002	16	61	130	80	71	110	82	10	-20 Y	2
		DAY 22	02JAN2003	23	66	126	80	68	120	72	2	-6	-8
		DAY 36	13JAN2003	34	67	116	76	81	110	70	14	-6	-6
		DAY 43	21JAN2003	42	61	126	88	74	118	82	13	-8	-6
		DAY 50	31JAN2003	52	66	112	74	86	98	68	20 Y	-14	-6
		DAY 57	06FEB2003	58	60	120	80	72	110	70	12	-10	-10
		FINAL		58	60	120	80	72	110	70	12	-10	-10
	E0010024	SCREEN	23APR2003	-12	62	114	78	78	132	96	16	18	18
		DAY 1	05MAY2003	1	50	124	80	56	132	88	6	8	8
		BASELINE			50	124	80	56	132	88	6	8	8
		DAY 8	12MAY2003	8	62	110	70	88	124	88	26 Y	14	18
		DAY 15	19MAY2003	15	78	130	78	84	124	80	6	-6	2
		DAY 22	27MAY2003	23	88	140	90	86	140	90	-2	0	0
		DAY 29	04JUN2003	31	74	140	94	76	140	100	2	0	6
		DAY 36	11JUN2003	38	98	130	86	104	144	96	6	14	10
		DAY 43	18JUN2003	45	76	140	88	72	140	72	-4	0	-16
		DAY 50	25JUN2003	52	86	130	88	98	134	90	12	4	2
		DAY 57	02JUL2003	59	84	130	78	84	130	80	0	0	2
		FINAL		59	84	130	78	84	130	80	0	0	2
	E0011025	SCREEN	20JUN2003	-6	68	118	74	70	120	74	2	2	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT102.SAS
GENERATED: 12JUL2005 17:46:45 iceadmn3

Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	DAY 1	26JUN2003	1	84	100	80	88	100	75	4	0	-5
		BASELINE			84	100	80	88	100	75	4	0	-5
		DAY 8	02JUL2003	7	90	100	70	88	100	72	-2	0	2
		DAY 15	10JUL2003	15	84	102	80	88	100	82	4	-2	2
		DAY 22	17JUL2003	22	92	120	80	90	118	80	-2	-2	0
		DAY 29	22JUL2003	27	84	90 L	68	82	90 L	60	-2	0	-8
		DAY 36	30JUL2003	35	88	100	60	84	100	62	-4	0	2
		DAY 43	07AUG2003	43	84	100	70	86	102	70	2	2	0
		DAY 50	14AUG2003	50	82	102	70	84	100	72	2	-2	2
		DAY 57	22AUG2003	58	80	100	70	82	100	72	2	0	2
		FINAL		58	80	100	70	82	100	72	2	0	2
	E0014006	SCREEN	11MAR2003	-14	84	118	88	92	110	84	8	-8	-4
		DAY 1	25MAR2003	1	80	124	84	92	110	80	12	-14	-4
		BASELINE			80	124	84	92	110	80	12	-14	-4
		DAY 8	02APR2003	9	84	120	82	96	124	78	12	4	-4
		DAY 15	09APR2003	16	80	122	90	92	120	88	12	-2	-2
		DAY 22	16APR2003	23	88	120	90	96	112	88	8	-8	-2
		DAY 29	23APR2003	30	100	130	78	108	120	84	8	-10	6
		DAY 36	30APR2003	37	84	130	80	96	130	84	12	0	4
		DAY 43	07MAY2003	44	88	126	84	96	110	80	8	-16	-4
		DAY 50	14MAY2003	51	88	120	80	92	124	88	4	4	8
		DAY 57	21MAY2003	58	100	124	74	120	110	80	20 Y	-14	6
		FINAL		58	100	124	74	120	110	80	20 Y	-14	6
	E0014010	SCREEN	15APR2003	-7	76	140	84	103	140	80	27 Y	0	-4
		DAY 1	22APR2003	1	80	134	86	88	124	88	8	-10	2
		BASELINE			80	134	86	88	124	88	8	-10	2
		DAY 8	30APR2003	9	86	132	90	92	118	80	6	-14	-10
		DAY 15	07MAY2003	16	88	138	88	96	122	74	8	-16	-14
		DAY 22	14MAY2003	23	78	138	88	84	126	88	6	-12	0
		DAY 29	21MAY2003	30	84	118	78	88	112	76	4	-6	-2

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT102.SAS
GENERATED: 12JUL2005 17:46:45 iceadmn3

Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	DAY 36	28MAY2003	37	82	130	88	86	126	90	4	-4	2
		DAY 43	03JUN2003	43	76	116	84	80	112	84	4	-4	0
		DAY 50	11JUN2003	51	76	118	82	78	114	80	2	-4	-2
		DAY 57	17JUN2003	57	80	124	84	82	120	82	2	-4	-2
		FINAL		57	80	124	84	82	120	82	2	-4	-2
	E0016001	SCREEN	02JAN2003	-20				86	141	88			
		DAY 1	22JAN2003	1				89	122	68			
		BASELINE						89	122	68			
		DAY 8	29JAN2003	8	80	126	72	86	134	82	6	8	10
		DAY 15	05FEB2003	15	69	118	74	72	124	84	3	6	10
		DAY 22	12FEB2003	22	76	128	84	98	142	94	22 Y	14	10
		DAY 29	19FEB2003	29	78	129	83	87	141	94	9	12	11
		DAY 36	26FEB2003	36	84	128	84	96	142	92	12	14	8
		DAY 43	05MAR2003	43	76	124	86	88	136	92	12	12	6
		DAY 50	12MAR2003	50	80	121	79	87	128	84	7	7	5
		DAY 57	19MAR2003	57	89	124	80	96	131	85	7	7	5
		FINAL		57	89	124	80	96	131	85	7	7	5
	E0019011	SCREEN	12NOV2002	-9	76	120	80	80	140	84	4	20	4
		DAY 1	21NOV2002	1	80	120	70	84	125	65	4	5	-5
		BASELINE			80	120	70	84	125	65	4	5	-5
		DAY 8	27NOV2002	7	84	130	70	88	130	75	4	0	5
		DAY 15	05DEC2002	15	80	130	80	84	132	75	4	2	-5
		DAY 22	12DEC2002	22	66	132	88	90	116	62	24 Y	-16	-26 Y
		DAY 29	19DEC2002	29	84	108	68	88	120	74	4	12	6
		DAY 43	02JAN2003	43	88	120	80	92	118	85	4	-2	5
		DAY 50	09JAN2003	50	60	110	70	64	120	80	4	10	10
		DAY 57	16JAN2003	57	84	112	78	96	112	80	12	0	2
		FINAL		57	84	112	78	96	112	80	12	0	2
	E0019025	SCREEN	30JAN2003	-7	68	120	75	68	120	80	0	0	5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	DAY 1	06FEB2003	1	60	110	70	64	110	75	4	0	5
		BASELINE			60	110	70	64	110	75	4	0	5
		DAY 8	13FEB2003	8	80	112	70	88	110	75	8	-2	5
		DAY 15	20FEB2003	15	80	108	72	88	100	68	8	-8	-4
		DAY 22	27FEB2003	22	80	110	76	88	104	80	8	-6	4
		DAY 29	06MAR2003	29	80	110	70	88	100	74	8	-10	4
		DAY 36	13MAR2003	36	80	110	72	84	108	80	4	-2	8
		DAY 43	20MAR2003	43	78	102	68	82	100	74	4	-2	6
		DAY 50	27MAR2003	50	80	118	80	88	115	75	8	-3	-5
		DAY 57	03APR2003	57	80	102	60	88	90 L	60	8	-12	0
		FINAL		57	80	102	60	88	90 L	60	8	-12	0
	E0020007	SCREEN	19DEC2002	-27	78	102	62	82	98	60	4	-4	-2
		DAY 1	15JAN2003	1	70	108	70	72	104	68	2	-4	-2
		BASELINE			70	108	70	72	104	68	2	-4	-2
		DAY 8	22JAN2003	8	60	92	60	64	94	60	4	2	0
		DAY 57	25MAR2003	70	70	90 L	58	74	100	60	4	10	2
		FINAL		70	70	90 L	58	74	100	60	4	10	2
	E0022008	SCREEN	05NOV2002	-7	64	120	72	68	110	68	4	-10	-4
		DAY 1	12NOV2002	1	62	112	44 L	82	131	66	20 Y	19	22
		BASELINE			62	112	44 L	82	131	66	20 Y	19	22
		DAY 8	19NOV2002	8	80	120	62	84	115	72	4	-5	10
		DAY 15	26NOV2002	15	70	120	70	64	110	68	-6	-10	-2
		DAY 22	03DEC2002	22	78	120	68	66	100	62	-12	-20 Y	-6
		DAY 29	12DEC2002	31	66	122	70	75	116	74	9	-6	4
		DAY 36	17DEC2002	36	64	120	70	70	115	72	6	-5	2
		DAY 43	24DEC2002	43	62	125	74	66	110	70	4	-15	-4
		DAY 50	31DEC2002	50	68	120	68	70	126	70	2	6	2
		DAY 57	07JAN2003	57	68	120	66	78	132	74	10	12	8
		FINAL		57	68	120	66	78	132	74	10	12	8

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	SCREEN	03DEC2002	-16	64	110	80	76	100	78	12	-10	-2
		DAY 1	19DEC2002	1	60	120	82	96	116	82	36 Y	-4	0
		BASELINE			60	120	82	96	116	82	36 Y	-4	0
		DAY 8	26DEC2002	8	72	134	94	92	110	96	20 Y	-24 Y	2
		DAY 15	03JAN2003	16	76	126	86	104	116	92	28 Y	-10	6
		DAY 22	09JAN2003	22	80	122	76	108	128	98	28 Y	6	22
		DAY 29	17JAN2003	30	64	116	76	96	128	98	32 Y	12	22
		DAY 36	22JAN2003	35	80	116	72	92	122	94	12	6	22
		DAY 43	31JAN2003	44	76	114	76	104	122	98	28 Y	8	22
		DAY 50	06FEB2003	50	72	122	78	104	126	90	32 Y	4	12
		DAY 57	13FEB2003	57	88	138	86	96	132	100	8	-6	14
		FINAL		57	88	138	86	96	132	100	8	-6	14
	E0022018	SCREEN	04DEC2002	-8	72	128	78	76	118	80	4	-10	2
		DAY 1	12DEC2002	1	88	130	90	88	126	80	0	-4	-10
		BASELINE			88	130	90	88	126	80	0	-4	-10
		DAY 8	19DEC2002	8	80	128	78	100	120	76	20 Y	-8	-2
		DAY 15	26DEC2002	15	76	126	72	84	112	76	8	-14	4
		DAY 22	02JAN2003	22	84	118	76	80	114	76	-4	-4	0
		DAY 29	09JAN2003	29	84	126	76	100	116	68	16	-10	-8
		DAY 36	16JAN2003	36	76	124	80	88	118	76	12	-6	-4
		DAY 43	23JAN2003	43	84	118	76	96	114	74	12	-4	-2
		DAY 50	30JAN2003	50	88	116	72	100	108	82	12	-8	10
		DAY 57	06FEB2003	57	80	110	74	88	108	76	8	-2	2
		FINAL		57	80	110	74	88	108	76	8	-2	2
	E0022022	SCREEN	16DEC2002	-14	76	102	62	88	102	74	12	0	12
		DAY 1	30DEC2002	1	80	110	70	78	114	72	-2	4	2
		BASELINE			80	110	70	78	114	72	-2	4	2
		DAY 8	06JAN2003	8	76	108	64	88	108	68	12	0	4
		DAY 15	14JAN2003	16	88	98	54	84	96	60	-4	-2	6
		DAY 22	21JAN2003	23	88	100	78	88	112	68	0	12	-10

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	DAY 29	28JAN2003	30	68	104	60	92	96	66	24 Y	-8	6
		DAY 36	04FEB2003	37	64	112	68	88	98	70	24 Y	-14	2
		DAY 57	27FEB2003	60									
		FINAL		60	64	112	68	88	98	70	24 Y	-14	2
	E0022032	SCREEN	11FEB2003	-7	86	116	78	92	108	78	6	-8	0
		DAY 1	18FEB2003	1	82	124	76	96	108	74	14	-16	-2
		BASELINE			82	124	76	96	108	74	14	-16	-2
		DAY 8	28FEB2003	11	78	104	72	74	108	76	-4	4	4
		DAY 15	04MAR2003	15	84	114	78	84	108	76	0	-6	-2
		DAY 22	11MAR2003	22	76	120	76	84	114	76	8	-6	0
		DAY 29	21MAR2003	32	78	108	62	82	116	70	4	8	8
		DAY 36	27MAR2003	38	88	100	56	92	98	70	4	-2	14
		DAY 43	03APR2003	45	80	108	64	88	106	70	8	-2	6
		DAY 50	10APR2003	52	74	136	94	96	122	96	22 Y	-14	2
		DAY 57	18APR2003	60	76	108	62	74	106	66	-2	-2	4
		FINAL		60	76	108	62	74	106	66	-2	-2	4
	E0022036	SCREEN	13FEB2003	-12	72	122	74	80	114	84	8	-8	10
		DAY 1	25FEB2003	1	72	120	68	96	108	96	24 Y	-12	28
		BASELINE			72	120	68	96	108	96	24 Y	-12	28
		DAY 8	03MAR2003	7	78	110	64	98	102	80	20 Y	-8	16
		DAY 15	10MAR2003	14	88	122	82	96	124	86	8	2	4
		DAY 22	18MAR2003	22	80	110	68	88	102	80	8	-8	12
		DAY 29	25MAR2003	29	80	110	74	88	102	82	8	-8	8
		DAY 36	01APR2003	36	84	112	68	88	110	82	4	-2	14
		DAY 43	08APR2003	43	78	122	74	96	118	88	18	-4	14
		DAY 50	15APR2003	50	78	100	72	88	102	72	10	2	0
		DAY 57	22APR2003	57	64	102	58	80	104	72	16	2	14
		FINAL		57	64	102	58	80	104	72	16	2	14
	E0022060	SCREEN	23APR2003	-7	48 L	124	74	63	132	90	15	8	16

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	DAY 1	30APR2003	1	48 L	116	78	60	124	88	12	8	10
		BASELINE			48 L	116	78	60	124	88	12	8	10
		DAY 8	05MAY2003	6	53	126	72	75	126	80	22 Y	0	8
		DAY 15	12MAY2003	13	60	104	68	66	122	72	6	18	4
		DAY 22	19MAY2003	20	57	124	74	57	124	80	0	0	6
		DAY 29	28MAY2003	29	60	116	62	66	118	74	6	2	12
		DAY 36	02JUN2003	34	63	114	70	69	122	72	6	8	2
		DAY 43	10JUN2003	42	60	112	60	63	120	76	3	8	16
		DAY 50	17JUN2003	49	63	124	70	72	118	68	9	-6	-2
		DAY 57	24JUN2003	56	52	110	70	60	116	74	8	6	4
		FINAL		56	52	110	70	60	116	74	8	6	4
	E0023015	SCREEN	04MAR2003	-7	82	120	84	86	128	86	4	8	2
		DAY 1	11MAR2003	1	70	120	68	76	120	70	6	0	2
		BASELINE			70	120	68	76	120	70	6	0	2
		DAY 8	18MAR2003	8	63	127	86	68	120	80	5	-7	-6
		DAY 15	25MAR2003	15	81	105	67	105	135	91	24 Y	30	24
		DAY 22	01APR2003	22	75	90 L	60	81	93	56	6	3	-4
		DAY 29	08APR2003	29	79	116	75	105	100	73	26 Y	-16	-2
		DAY 36	15APR2003	36	86	108	73	109	118	71	23 Y	10	-2
		DAY 43	22APR2003	43	82	95	55	86	110	88	4	15	33
		DAY 50	29APR2003	50	72	128	70	98	128	72	26 Y	0	2
		DAY 57	06MAY2003	57	87	99	71	97	103	69	10	4	-2
		FINAL		57	87	99	71	97	103	69	10	4	-2
	E0023034	SCREEN	03JUN2003	-6	86	99	62		109	70		10	8
		DAY 1	09JUN2003	1	88	104	64	109	105	64	21 Y	1	0
		BASELINE			88	104	64	109	105	64	21 Y	1	0
		DAY 8	16JUN2003	8	96	130	83	99	113	68	3	-17	-15
		DAY 15	23JUN2003	15	88	121	80	88	120	80	0	-1	0
		DAY 22	30JUN2003	22	100	113	66	121 H	131	78	21 Y	18	12
		DAY 29	07JUL2003	29	97	114	72	126 H	116	74	29 Y	2	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	DAY 36		14JUL2003	36	126 H	121	69	142 H	109	56	16	-12	-13
		DAY 43		22JUL2003	44	107	136	80	111	122	80	4	-14	0
		DAY 57		05AUG2003	58	100	130	80	101	126	84	1	-4	4
		FINAL			58	100	130	80	101	126	84	1	-4	4
	E0023037	SCREEN		11JUN2003	-7	68	128	88	70	128	88	2	0	0
		DAY 1		18JUN2003	1	59	154	98	67	157	100	8	3	2
		BASELINE				59	154	98	67	157	100	8	3	2
		DAY 8		24JUN2003	7	86	148	92	90	150	90	4	2	-2
		DAY 15		01JUL2003	14	76	159	109 H	89	162	116 H	13	3	7
		DAY 29	*	14JUL2003	27	65	158	103	78	148	106 H	13	-10	3
		DAY 29		18JUL2003	31	71	155	100	76	163	110 H	5	8	10
		DAY 36		25JUL2003	38	77	143	101	96	105	69	19	-38 Y	-32 Y
		DAY 43		01AUG2003	45	74	140	98	79	128	86	5	-12	-12
		DAY 50		08AUG2003	52	97	137	84	98	130	80	1	-7	-4
		DAY 57		15AUG2003	59	94	139	86	86	132	84	-8	-7	-2
		FINAL			59	94	139	86	86	132	84	-8	-7	-2
	E0023038	SCREEN		20JUN2003	-10	78	150	98	88	150	96	10	0	-2
		DAY 1		30JUN2003	1	79	149	89	92	157	94	13	8	5
		BASELINE				79	149	89	92	157	94	13	8	5
		DAY 8		09JUL2003	10	91	149	82	100	154	86	9	5	4
		DAY 15		15JUL2003	16	82	144	88	88	134	86	6	-10	-2
		DAY 22		21JUL2003	22	87	153	89	96	144	84	9	-9	-5
		DAY 29		28JUL2003	29	86	155	82	90	135	80	4	-20 Y	-2
		DAY 36		07AUG2003	39	74	124	79	78	120	77	4	-4	-2
		DAY 43		13AUG2003	45	93	138	83	87	125	87	-6	-13	4
		DAY 50		21AUG2003	53	84	139	95	78	155	98	-6	16	3
		DAY 57		27AUG2003	59	84	136	91	99	109	72	15	-27 Y	-19
		FINAL			59	84	136	91	99	109	72	15	-27 Y	-19
	E0026018	SCREEN		06MAR2003	-14	73	138	67	86	139	72	13	1	5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	DAY 1		20MAR2003	1	88	113	72	94	132	75	6	19	3
		BASELINE				88	113	72	94	132	75	6	19	3
		DAY 8		27MAR2003	8	82	136	76	90	134	73	8	-2	-3
		DAY 15		03APR2003	15	87	142	65	91	123	79	4	-19	14
		DAY 22		10APR2003	22	84	145	81	89	116	77	5	-29 Y	-4
		DAY 29		17APR2003	29	70	121	70	88	139	79	18	18	9
		DAY 36		24APR2003	36	94	133	80	98	145	79	4	12	-1
		DAY 43		01MAY2003	43	80	115	73	96	117	68	16	2	-5
		DAY 50		08MAY2003	50	79	121	72	88	105	69	9	-16	-3
		DAY 57		15MAY2003	57	71	126	63	80	127	84	9	1	21
		FINAL			57	71	126	63	80	127	84	9	1	21
	E0026025	SCREEN		01MAY2003	-8	75	136	82	78	123	88	3	-13	6
		DAY 1		09MAY2003	1	98	127	82	102	133	86	4	6	4
		BASELINE				98	127	82	102	133	86	4	6	4
		DAY 8		15MAY2003	7	78	134	88	97	131	96	19	-3	8
		DAY 15		22MAY2003	14	76	115	88	80	130	76	4	15	-12
		DAY 22		29MAY2003	21	80	132	90	84	141	96	4	9	6
		DAY 29		05JUN2003	28	92	153	87	90	148	95	-2	-5	8
		DAY 36		13JUN2003	36	80	150	90	96	191 H	102	16	41	12
		DAY 43		20JUN2003	43	90	150	90	89	148	102	-1	-2	12
		DAY 50		27JUN2003	50	75	138	88	77	132	87	2	-6	-1
		DAY 57		03JUL2003	56	90	130	87	85	145	56	-5	15	-31 Y
		FINAL			56	90	130	87	85	145	56	-5	15	-31 Y
	E0028004	SCREEN		27SEP2002	-3	48 L	100	70	52	110	70	4	10	0
		DAY 1		30SEP2002	1	74	92	68	74	100	82	0	8	14
		BASELINE				74	92	68	74	100	82	0	8	14
		DAY 8		07OCT2002	8	63	100	80	62	100	70	-1	0	-10
		DAY 8	*	09OCT2002	10	64	108	80	76	110	80	12	2	0
		FINAL			10	64	108	80	76	110	80	12	2	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	SCREEN	08OCT2002	-7	68	130	78	68	118	76	0	-12	-2
		DAY 1	15OCT2002	1	70	100	60	68	120	60	-2	20	0
		BASELINE			70	100	60	68	120	60	-2	20	0
		DAY 8	22OCT2002	8	68	121	68	68	116	72	0	-5	4
		DAY 15	29OCT2002	15	76	112	70	76	105	78	0	-7	8
		DAY 22	07NOV2002	24	68	138	70	68	130	72	0	-8	2
		DAY 29	14NOV2002	31	68	128	76	68	126	78	0	-2	2
		DAY 36	21NOV2002	38	64	110	70	64	122	70	0	12	0
		DAY 43	26NOV2002	43	62	110	68	66	110	78	4	0	10
		DAY 50	03DEC2002	50	56	118	78	56	114	56	0	-4	-22 Y
		DAY 57	10DEC2002	57	68	110	70	68	110	74	0	0	4
		FINAL		57	68	110	70	68	110	74	0	0	4
	E0028009	SCREEN	10OCT2002	-5	54	115	70	56	115	70	2	0	0
		DAY 1	15OCT2002	1	56	118	60	60	115	60	4	-3	0
		BASELINE			56	118	60	60	115	60	4	-3	0
		DAY 8	23OCT2002	9	54	100	70	56	110	70	2	10	0
		DAY 15	31OCT2002	17	64	116	80	82	116	82	18	0	2
		DAY 22	07NOV2002	24	60	102	80	82	100	80	22 Y	-2	0
		DAY 29	14NOV2002	31	56	114	76	72	98	82	16	-16	6
		DAY 36	19NOV2002	36	66	114	78	88	110	90	22 Y	-4	12
		DAY 43	26NOV2002	43	60	118	82	64	118	90	4	0	8
		DAY 50	03DEC2002	50	60	102	78	60	108	78	0	6	0
		DAY 57	12DEC2002	59	68	118	70	72	112	64	4	-6	-6
		FINAL		59	68	118	70	72	112	64	4	-6	-6
	E0028016	SCREEN	07NOV2002	-7	68	130	72	68	118	80	0	-12	8
		DAY 1	14NOV2002	1	64	118	88	64	110	80	0	-8	-8
		BASELINE			64	118	88	64	110	80	0	-8	-8
		DAY 8	21NOV2002	8	68	120	82	68	116	80	0	-4	-2
		DAY 15	26NOV2002	13	76	126	82	88	124	90	12	-2	8
		DAY 22	05DEC2002	22	76	130	88	76	119	90	0	-11	2

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L: Potentially Clinically Important low.
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	DAY 29	12DEC2002	29	76	140	86	76	118	90	0	-22 Y	4
		DAY 36	19DEC2002	36	64	120	78	64	120	82	0	0	4
		DAY 43	26DEC2002	43	80	112	80	80	120	78	0	8	-2
		DAY 50	02JAN2003	50	76	128	72	80	124	70	4	-4	-2
		DAY 57	09JAN2003	57	80	126	80	88	122	88	8	-4	8
		FINAL		57	80	126	80	88	122	88	8	-4	8
	E0028027	SCREEN	14JAN2003	-7	60	110	92	62	110	88	2	0	-4
		DAY 1	21JAN2003	1	66	110	88	66	110	90	0	0	2
		BASELINE			66	110	88	66	110	90	0	0	2
		DAY 8	28JAN2003	8	64	140	98	68	134	92	4	-6	-6
		DAY 15	04FEB2003	15	80	110	90	76	108	90	-4	-2	0
		DAY 22	11FEB2003	22	70	114	92	70	120	92	0	6	0
		DAY 29	20FEB2003	31	62	120	80	79	112	74	17	-8	-6
		DAY 36	28FEB2003	39	72	88 L	70	76	90 L	68	4	2	-2
		FINAL		39	72	88 L	70	76	90 L	68	4	2	-2
	E0028034	SCREEN	20MAR2003	-12	64	122	82	68	114	76	4	-8	-6
		DAY 1	01APR2003	1	76	122	70	92	110	66	16	-12	-4
		BASELINE			76	122	70	92	110	66	16	-12	-4
		DAY 8	08APR2003	8	68	114	84	80	116	84	12	2	0
		DAY 15	15APR2003	15	84	122	84	92	100	76	8	-22 Y	-8
		DAY 22	22APR2003	22	80	122	70	88	116	66	8	-6	-4
		DAY 29	01MAY2003	31	92	126	80	100	122	78	8	-4	-2
		DAY 36	06MAY2003	36	88	120	80	100	120	76	12	0	-4
		DAY 43	13MAY2003	43	88	128	64	100	118	66	12	-10	2
		DAY 50	21MAY2003	51	88	124	76	96	122	74	8	-2	-2
		DAY 57	02JUN2003	63	80	116	88	88	104	84	8	-12	-4
		FINAL		63	80	116	88	88	104	84	8	-12	-4
	E0028038	SCREEN	18APR2003	-7	72	140	88	84	124	82	12	-16	-6
		DAY 1	25APR2003	1	74	142	84	80	126	82	6	-16	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	BASELINE			74	142	84	80	126	82	6	-16	-2
		DAY 8	02MAY2003	8	76	136	88	88	134	84	12	-2	-4
		DAY 15	08MAY2003	14	77	130	88	70	130	88	-7	0	0
		DAY 29	22MAY2003	28	80	136	80	92	130	84	12	-6	4
		DAY 36	30MAY2003	36	88	152	98	92	138	88	4	-14	-10
		DAY 43	05JUN2003	42		138	90		110	80		-28 Y	-10
		DAY 50	12JUN2003	49	88	145	92	80	140	90	-8	-5	-2
		DAY 57	18JUN2003	55	72	140	80	78	130	82	6	-10	2
		FINAL		55	72	140	80	78	130	82	6	-10	2
	E0028043	SCREEN	29MAY2003	-7	60	146	92	64	144	88	4	-2	-4
		DAY 1	05JUN2003	1	70	154	98	74	150	94	4	-4	-4
		BASELINE			70	154	98	74	150	94	4	-4	-4
		DAY 8	12JUN2003	8	80	155	105 H	100	150	110 H	20 Y	-5	5
		DAY 15	19JUN2003	15	74	140	100	64	138	104	-10	-2	4
		DAY 22	26JUN2003	22	78	130	80	80	130	86	2	0	6
		DAY 29	01JUL2003	27	100	140	100	98	130	98	-2	-10	-2
		DAY 36	08JUL2003	34	60	130	86	64	130	90	4	0	4
		DAY 43	15JUL2003	41	80	140	100	80	140	102	0	0	2
		DAY 50	22JUL2003	48	76	142	92	76	128	94	0	-14	2
		DAY 57	29JUL2003	55	60	130	80	80	140	88	20 Y	10	8
		FINAL		55	60	130	80	80	140	88	20 Y	10	8
	E0028045	SCREEN	09JUN2003	-9	74	140	82	80	120	70	6	-20 Y	-12
		DAY 1	18JUN2003	1	72	126	84	84	132	88	12	6	4
		BASELINE			72	126	84	84	132	88	12	6	4
		DAY 8	25JUN2003	8	80	112	74	78	115	86	-2	3	12
		DAY 15	30JUN2003	13	106	120	78	110	115	86	4	-5	8
		DAY 57	11SEP2003	86	76	115	78	76	100	80	0	-15	2
		FINAL		86	76	115	78	76	100	80	0	-15	2
	E0029005	SCREEN	14NOV2002	-13	78	102	74	80	108	68	2	6	-6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	DAY 1		27NOV2002	1	56	118	82	80	110	82	24 Y	-8	0
		BASELINE				56	118	82	80	110	82	24 Y	-8	0
		DAY 8		03DEC2002	7	72	120	84	96	110	82	24 Y	-10	-2
		DAY 15		09DEC2002	13	84	134	92	92	134	90	8	0	-2
		DAY 22		16DEC2002	20	96	108	70	112	104	80	16	-4	10
		DAY 29		23DEC2002	27	80	118	76	112	126	80	32 Y	8	4
		DAY 36		30DEC2002	34	92	110	76	92	110	82	0	0	6
		DAY 43		07JAN2003	42	76	110	80	104	110	82	28 Y	0	2
		DAY 50		14JAN2003	49	80	90 L	64	100	106	80	20 Y	16	16
		DAY 57		21JAN2003	56	80	110	80	92	110	82	12	0	2
		FINAL			56	80	110	80	92	110	82	12	0	2
	E0030015	SCREEN		13FEB2003	-8	52	122	86	56	132	92	4	10	6
		DAY 1		21FEB2003	1	68	118	74	74	116	82	6	-2	8
		BASELINE				68	118	74	74	116	82	6	-2	8
		DAY 8		03MAR2003	11	60	126	74	68	120	70	8	-6	-4
		DAY 15		11MAR2003	19	60	130	74	88	136	80	28 Y	6	6
		DAY 29		19MAR2003	27	56	114	64	80	120	80	24 Y	6	16
		DAY 36		26MAR2003	34	56	130	80	72	124	84	16	-6	4
		DAY 43		02APR2003	41	52	112	82	80	110	84	28 Y	-2	2
		DAY 50		09APR2003	48	52	110	80	72	112	78	20 Y	2	-2
		DAY 57	*	17APR2003	56	52	130	80	68	110	84	16	-20 Y	4
		DAY 57		22APR2003	61	60	120	84	72	124	90	12	4	6
		FINAL			61	60	120	84	72	124	90	12	4	6
	E0030022	SCREEN		06JUN2003	-10	64	124	92	62	122	91	-2	-2	-1
		DAY 1		16JUN2003	1	72	122	80	88	124	84	16	2	4
		BASELINE				72	122	80	88	124	84	16	2	4
		DAY 8		20JUN2003	5	68	118	90	78	120	90	10	2	0
		DAY 15		30JUN2003	15	68	112	84	80	118	88	12	6	4
		DAY 22		07JUL2003	22	68	134	90	80	134	90	12	0	0
		DAY 29		14JUL2003	29	60	124	90	90	126	90	30 Y	2	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	DAY 36		21JUL2003	36	60	128	88	64	124	88	4	-4	0
		DAY 43		29JUL2003	44	60	124	88	64	120	90	4	-4	2
		DAY 50		05AUG2003	51	68	128	92	68	122	96	0	-6	4
		DAY 57		14AUG2003	60	72	124	88	76	128	90	4	4	2
		FINAL			60	72	124	88	76	128	90	4	4	2
	E0031002	SCREEN		20NOV2002	-7	74	120	88	76	118	82	2	-2	-6
		DAY 1		27NOV2002	1	60	122	62	74	118	72	14	-4	10
		BASELINE				60	122	62	74	118	72	14	-4	10
		DAY 8		06DEC2002	10	80	90 L	70	84	105	75	4	15	5
		DAY 15		12DEC2002	16	68	112	80	72	110	80	4	-2	0
		DAY 22		19DEC2002	23	70	118	64	64	120	68	-6	2	4
		DAY 29		27DEC2002	31	60	110	68	64	118	72	4	8	4
		DAY 36		02JAN2003	37	58	108	58	67	110	64	9	2	6
		DAY 50	*	13JAN2003	48	66	118	62	60	124	68	-6	6	6
		DAY 50		17JAN2003	52	68	110	64	72	114	70	4	4	6
		DAY 57		22JAN2003	57	66	104	60	70	116	70	4	12	10
		FINAL			57	66	104	60	70	116	70	4	12	10
	E0033015	SCREEN		03APR2003	-7	52	100	70	60	100	72	8	0	2
		DAY 1		10APR2003	1	60	98	68	64	100	70	4	2	2
		BASELINE				60	98	68	64	100	70	4	2	2
		DAY 8		17APR2003	8	56	90 L	70	64	100	70	8	10	0
		DAY 15		22APR2003	13	56	98	62	64	100	66	8	2	4
		DAY 15	*	28APR2003	19	52	110	70	68	110	70	16	0	0
		DAY 29		06MAY2003	27	60	100	60	84	100	64	24 Y	0	4
		DAY 36		13MAY2003	34	48 L	90 L	70	60	96	70	12	6	0
		DAY 43		20MAY2003	41	56	100	70	64	100	70	8	0	0
		DAY 50		27MAY2003	48	56	100	70	72	110	70	16	10	0
		DAY 57		04JUN2003	56	64	100	70	68	100	70	4	0	0
		FINAL			56	64	100	70	68	100	70	4	0	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0034002	SCREEN	14MAR2003	-11	72	145	100	88	130	95	16	-15	-5
		DAY 1	25MAR2003	1	68	150	100	80	145	105 H	12	-5	5
		BASELINE			68	150	100	80	145	105 H	12	-5	5
		DAY 8	01APR2003	8	84	140	88	96	132	86	12	-8	-2
		DAY 15	08APR2003	15	72	128	88	92	130	94	20 Y	2	6
		DAY 22	15APR2003	22	76	132	85	80	138	90	4	6	5
		FINAL		22	76	132	85	80	138	90	4	6	5
	E0034003	SCREEN	11APR2003	-13	68	120	80	84	115	70	16	-5	-10
		DAY 1	24APR2003	1	68	116	74	84	118	78	16	2	4
		BASELINE			68	116	74	84	118	78	16	2	4
		DAY 8	01MAY2003	8	72	114	80	92	118	82	20 Y	4	2
		DAY 15	08MAY2003	15	84	126	82	102	128	88	18	2	6
		DAY 22	15MAY2003	22	88	110	80	96	118	85	8	8	5
		DAY 29	22MAY2003	29	68	120	85	84	125	80	16	5	-5
		DAY 36	29MAY2003	36	68	115	70	96	120	85	28 Y	5	15
		DAY 43	05JUN2003	43	84	120	80	100	118	76	16	-2	-4
		DAY 50	12JUN2003	50	76	125	75	92	130	90	16	5	15
		DAY 57	19JUN2003	57	68	115	85	80	125	90	12	10	5
		FINAL		57	68	115	85	80	125	90	12	10	5
	E0034006	SCREEN	25APR2003	-21	56	120	65	72	130	80	16	10	15
		DAY 1	16MAY2003	1	76	125	70	80	130	90	4	5	20
		BASELINE			76	125	70	80	130	90	4	5	20
		DAY 8	23MAY2003	8	68	130	80	92	120	85	24 Y	-10	5
		DAY 15	02JUN2003	18	80	124	86	88	122	82	8	-2	-4
		DAY 22	09JUN2003	25	76	125	80	86	110	70	10	-15	-10
		DAY 29	13JUN2003	29	80	108	74	84	110	72	4	2	-2
		DAY 36	20JUN2003	36	74	125	90	88	110	85	14	-15	-5
		DAY 43	27JUN2003	43	86	135	85	84	139	90	-2	4	5
		DAY 50	03JUL2003	49	68	130	95	80	140	100	12	10	5
		DAY 57	10JUL2003	56	68	125	85	80	130	90	12	5	5

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	FINAL		56	68	125	85	80	130	90	12	5	5
	E0034008	SCREEN	15MAY2003	-9	72	116	78	84	118	82	12	2	4
		DAY 1	23MAY2003	-1	64	130	70	76	110	85	12	-20 Y	15
		BASELINE			64	130	70	76	110	85	12	-20 Y	15
		DAY 8	02JUN2003	10	92	125	90	104	120	85	12	-5	-5
		DAY 15	06JUN2003	14	64	122	85	76	110	80	12	-12	-5
		DAY 22	13JUN2003	21	74	102	70	78	106	70	4	4	0
		DAY 29	20JUN2003	28	68	114	80	72	108	76	4	-6	-4
		DAY 36	27JUN2003	35	64	120	80	72	130	85	8	10	5
		DAY 43	07JUL2003	45	68	120	85	88	125	95	20 Y	5	10
		DAY 50	14JUL2003	52	64	110	70	88	110	80	24 Y	0	10
		DAY 57	21JUL2003	59	68	125	80	88	120	85	20 Y	-5	5
		FINAL		59	68	125	80	88	120	85	20 Y	-5	5
	E0036005	SCREEN	24JUN2003	-7	93	109	68	94	107	71	1	-2	3
		DAY 1	01JUL2003	1	61	103	66	71	100	66	10	-3	0
		BASELINE			61	103	66	71	100	66	10	-3	0
		DAY 8	08JUL2003	8	75	106	65	89	103	66	14	-3	1
		DAY 15	15JUL2003	15	86	122	65	95	119	76	9	-3	11
		DAY 22	23JUL2003	23	78	109	72	96	119	73	18	10	1
		DAY 29	29JUL2003	29	91	113	78	96	119	79	5	6	1
		DAY 36	05AUG2003	36	90	118	78	84	123	73	-6	5	-5
		DAY 43	12AUG2003	43	66	120	69	72	120	73	6	0	4
		DAY 50	19AUG2003	50	105	120	73	115	110	74	10	-10	1
		DAY 57	27AUG2003	58	77	111	67	109	116	81	32 Y	5	14
		FINAL		58	77	111	67	109	116	81	32 Y	5	14
	E0037005	SCREEN	26FEB2003	-8	72	118	70	68	114	70	-4	-4	0
		DAY 1	06MAR2003	1	72	114	70	72	110	70	0	-4	0
		BASELINE			72	114	70	72	110	70	0	-4	0
		DAY 8	13MAR2003	8	80	121	80	80	115	80	0	-6	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	DAY 15	20MAR2003	15	60	115	80	80	115	70	20 Y	0	-10
		DAY 22	27MAR2003	22	60	114	78	60	116	80	0	2	2
		DAY 29	03APR2003	29	72	118	70	72	118	72	0	0	2
		DAY 36	10APR2003	36	84	130	80	84	130	80	0	0	0
		DAY 43	17APR2003	43	80	132	80	84	128	80	4	-4	0
		DAY 50	24APR2003	50	80	130	90	80	130	90	0	0	0
		DAY 57	01MAY2003	57	68	130	98	72	120	70	4	-10	-28 Y
		FINAL		57	68	130	98	72	120	70	4	-10	-28 Y
	E0039006	SCREEN	10DEC2002	-20	88	134	86	94	138	94	6	4	8
		DAY 1	30DEC2002	1	68	124	90	80	116	86	12	-8	-4
		BASELINE			68	124	90	80	116	86	12	-8	-4
		DAY 8	06JAN2003	8	88	108	78	65	102	80	-23	-6	2
		DAY 15	13JAN2003	15	64	156	108 H	68	132	100	4	-24 Y	-8
		DAY 22	20JAN2003	22	77	140	98	97	128	102	20 Y	-12	4
		DAY 29	28JAN2003	30	84	140	96	72	128	90	-12	-12	-6
		DAY 36	04FEB2003	37	76	112	74	88	116	78	12	4	4
		DAY 43	10FEB2003	43	60	126	94	72	118	96	12	-8	2
		DAY 50	18FEB2003	51	88	130	96	89	112	90	1	-18	-6
		DAY 57	24FEB2003	57	76	116	82	84	114	86	8	-2	4
		FINAL		57	76	116	82	84	114	86	8	-2	4
	E0039041	SCREEN	07APR2003	-8	60	122	80	64	116	78	4	-6	-2
		DAY 1	15APR2003	1	64	120	82	68	124	84	4	4	2
		BASELINE			64	120	82	68	124	84	4	4	2
		DAY 8	22APR2003	8	68	132	86	88	120	88	20 Y	-12	2
		DAY 15	29APR2003	15	88	140	92	86	132	86	-2	-8	-6
		DAY 22	06MAY2003	22	62	124	86	66	128	84	4	4	-2
		DAY 29	13MAY2003	29	64	118	86	76	124	88	12	6	2
		DAY 36	20MAY2003	36	66	134	80	78	130	86	12	-4	6
		DAY 43	27MAY2003	43	64	132	88	70	122	100	6	-10	12
		DAY 50	03JUN2003	50	60	128	78	78	132	86	18	4	8

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 57	11JUN2003	58	58	126	86	68	122	84	10	-4	-2
		FINAL		58	58	126	86	68	122	84	10	-4	-2
	E0039057	SCREEN	02JUL2003	-12	60	118	82	68	128	100	8	10	18
		DAY 1	14JUL2003	1	60	124	78	76	118	90	16	-6	12
		BASELINE			60	124	78	76	118	90	16	-6	12
		DAY 8	22JUL2003	9	60	118	74	76	114	86	16	-4	12
		DAY 15	28JUL2003	15	60	122	80	68	124	90	8	2	10
		DAY 22	04AUG2003	22	60	110	68	77	110	80	17	0	12
		DAY 29	12AUG2003	30	62	126	80	80	112	90	18	-14	10
		DAY 36	18AUG2003	36	66	118	70	77	128	88	11	10	18
		DAY 43	26AUG2003	44	60	118	80	64	114	80	4	-4	0
		DAY 50	02SEP2003	51	72	138	68	92	110	78	20 Y	-28 Y	10
		DAY 57	09SEP2003	58	64	124	70	72	110	80	8	-14	10
		FINAL		58	64	124	70	72	110	80	8	-14	10
QUETIAPINE 300 MG (BIPOLAR II)	E0005030	SCREEN	18MAR2003	-8	76	96	60	80	90 L	60	4	-6	0
		DAY 1	26MAR2003	1	80	98	64	84	96	60	4	-2	-4
		BASELINE			80	98	64	84	96	60	4	-2	-4
		DAY 8	02APR2003	8	76	98	60	72	104	60	-4	6	0
		DAY 15	09APR2003	15	84	108	66	100	110	70	16	2	4
		DAY 22	16APR2003	22	84	100	60	88	110	68	4	10	8
		FINAL		22	84	100	60	88	110	68	4	10	8
	E0006015	SCREEN	06FEB2003	-5	64	120	62	76	114	60	12	-6	-2
		DAY 1	11FEB2003	1	72	116	64	70	135	85	-2	19	21
		BASELINE			72	116	64	70	135	85	-2	19	21
		DAY 8	18FEB2003	8	92	129	76	88	131	90	-4	2	14
		DAY 15	25FEB2003	15	88	128	76	90	127	83	2	-1	7
		DAY 22	04MAR2003	22	87	126	83	86	131	79	-1	5	-4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	DAY 29	11MAR2003	29	74	126	83	72	128	93	-2	2	10
		DAY 36	18MAR2003	36	75	128	77	101	122	80	26 Y	-6	3
		DAY 43	25MAR2003	43	78	129	78	88	123	88	10	-6	10
		DAY 50	01APR2003	50	84	110	78	84	108	78	0	-2	0
		DAY 57	08APR2003	57	84	127	77	80	128	83	-4	1	6
		FINAL		57	84	127	77	80	128	83	-4	1	6
	E0009002	SCREEN	29OCT2002	-21	78	104	78	80	102	80	2	-2	2
		DAY 1	19NOV2002	1	64	132	84	84	136	90	20 Y	4	6
		BASELINE			64	132	84	84	136	90	20 Y	4	6
		DAY 8	26NOV2002	8	84	118	80	80	116	82	-4	-2	2
		DAY 15	03DEC2002	15	80	120	78	78	118	82	-2	-2	4
		DAY 22	10DEC2002	22	84	126	84	86	124	82	2	-2	-2
		DAY 29	18DEC2002	30	60	110	84	88	120	90	28 Y	10	6
		DAY 36	23DEC2002	35	68	132	80	68	134	86	0	2	6
		DAY 43	30DEC2002	42	80	122	82	84	118	80	4	-4	-2
		DAY 50	07JAN2003	50	60	134	90	68	134	94	8	0	4
		DAY 57	15JAN2003	58	68	130	80	70	132	84	2	2	4
		FINAL		58	68	130	80	70	132	84	2	2	4
	E0009006	SCREEN	22JAN2003	-6	78	110	60	74	110	70	-4	0	10
		DAY 1	28JAN2003	1	76	100	64	82	100	70	6	0	6
		BASELINE			76	100	64	82	100	70	6	0	6
		DAY 8	04FEB2003	8	60	128	70	80	134	84	20 Y	6	14
		DAY 15	11FEB2003	15	82	120	70	84	120	80	2	0	10
		DAY 22	18FEB2003	22	80	140	80	78	138	78	-2	-2	-2
		DAY 29	25FEB2003	29	82	110	60	82	110	68	0	0	8
		DAY 36	04MAR2003	36	80	118	70	80	116	68	0	-2	-2
		DAY 43	11MAR2003	43	86	124	62	78	120	60	-8	-4	-2
		DAY 50	18MAR2003	50	82	110	70	80	110	70	-2	0	0
		DAY 57	25MAR2003	57	84	110	84	80	120	86	-4	10	2
		FINAL		57	84	110	84	80	120	86	-4	10	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0009009	SCREEN	27FEB2003	-13	60	100	70	80	120	80	20 Y	20	10
		DAY 1	12MAR2003	1	78	110	62	80	120	76	2	10	14
		BASELINE			78	110	62	80	120	76	2	10	14
		DAY 8	19MAR2003	8	88	124	60	86	110	70	-2	-14	10
		DAY 15	24MAR2003	13	60	130	60	68	120	70	8	-10	10
		FINAL		13	60	130	60	68	120	70	8	-10	10
	E0011004	SCREEN	17DEC2002	-7	68	124	68	78	122	66	10	-2	-2
		DAY 1	24DEC2002	1	62	118	76	69	120	80	7	2	4
		BASELINE			62	118	76	69	120	80	7	2	4
		DAY 8	31DEC2002	8	60	112	80	64	114	82	4	2	2
		DAY 15	07JAN2003	15	54	124	74	77	119	86	23 Y	-5	12
		DAY 22	14JAN2003	22	72	124	86	80	118	84	8	-6	-2
		DAY 29	21JAN2003	29	68	124	76	78	128	78	10	4	2
		DAY 36	28JAN2003	36	64	118	78	72	114	78	8	-4	0
		DAY 43	04FEB2003	43	68	120	78	76	118	82	8	-2	4
		DAY 50	11FEB2003	50	60	124	82	72	126	82	12	2	0
		DAY 57	18FEB2003	57	64	120	82	76	114	82	12	-6	0
		FINAL		57	64	120	82	76	114	82	12	-6	0
	E0019007	SCREEN	06NOV2002	-7	84	105	60	84	105	65	0	0	5
		DAY 1	13NOV2002	1	68	105	70	80	105	70	12	0	0
		BASELINE			68	105	70	80	105	70	12	0	0
		DAY 8	21NOV2002	9	64	90 L	70	72	100	72	8	10	2
		DAY 15	27NOV2002	15	76	98	66	80	104	78	4	6	12
		DAY 22	05DEC2002	23	68	100	65	72	100	65	4	0	0
		DAY 29	12DEC2002	30	64	90 L	68	70	90 L	72	6	0	4
		DAY 36	17DEC2002	35	64	92	65	68	90 L	68	4	-2	3
		DAY 43	24DEC2002	42	68	95	65	72	98	68	4	3	3
		DAY 50	30DEC2002	48	68	112	72	76	116	80	8	4	8
		DAY 57	07JAN2003	56	68	110	78	68	118	80	0	8	2
		FINAL		56	68	110	78	68	118	80	0	8	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	SCREEN	17DEC2002	-23	56	85 L	60	56	90 L	60	0	5	0
		DAY 1	09JAN2003	1	60	85 L	58	60	95	65	0	10	7
		BASELINE			60	85 L	58	60	95	65	0	10	7
		DAY 8	20JAN2003	12	60	95	65	64	100	65	4	5	0
		FINAL		12	60	95	65	64	100	65	4	5	0
	E0019022	SCREEN	23JAN2003	-7	76	118	78	100	118	80	24 Y	0	2
		DAY 1	30JAN2003	1	88	125	74	92	120	75	4	-5	1
		BASELINE			88	125	74	92	120	75	4	-5	1
		DAY 8	06FEB2003	8	84	130	85	88	130	85	4	0	0
		DAY 15	13FEB2003	15	90	110	80	90	115	85	0	5	5
		DAY 22	20FEB2003	22	84	120	75	90	122	80	6	2	5
		DAY 29	27FEB2003	29	76	125	75	90	125	80	14	0	5
		DAY 36	06MAR2003	36	68	118	80	80	122	84	12	4	4
		DAY 43	13MAR2003	43	104	120	84	104	120	88	0	0	4
		DAY 50	20MAR2003	50	92	130	80	100	130	85	8	0	5
		DAY 57	27MAR2003	57	84	128	80	88	130	85	4	2	5
		FINAL		57	84	128	80	88	130	85	4	2	5
	E0019032	SCREEN	06MAR2003	-26	72	92	62	76	94	60	4	2	-2
		DAY 1	01APR2003	1	64	110	70	80	110	75	16	0	5
		BASELINE			64	110	70	80	110	75	16	0	5
		DAY 8	08APR2003	8	80	110	60	92	110	70	12	0	10
		DAY 15	15APR2003	15	84	105	60	88	100	70	4	-5	10
		DAY 22	21APR2003	21	100	120	86	120	110	82	20 Y	-10	-4
		DAY 29	29APR2003	29	96	118	70	108	115	80	12	-3	10
		DAY 36	07MAY2003	37	76	102	78	96	102	82	20 Y	0	4
		DAY 43	14MAY2003	44	80	110	78	88	110	75	8	0	-3
		DAY 50	21MAY2003	51	68	105	70	72	110	70	4	5	0
		DAY 57	27MAY2003	57	64	100	78	64	98	80	0	-2	2
		FINAL		57	64	100	78	64	98	80	0	-2	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019036	SCREEN	18MAR2003	-7	74	118	72	80	140	68	6	22	-4
		DAY 1	25MAR2003	1	60	125	65	80	130	70	20 Y	5	5
		BASELINE			60	125	65	80	130	70	20 Y	5	5
		DAY 8	31MAR2003	7	80	130	70	88	125	70	8	-5	0
		DAY 15	10APR2003	17	76	130	70	88	110	70	12	-20 Y	0
		DAY 22	15APR2003	22	68	120	70	84	120	80	16	0	10
		DAY 29	22APR2003	29	60	120	70	68	130	75	8	10	5
		DAY 36	29APR2003	36	60	130	70	80	128	78	20 Y	-2	8
		FINAL		36	60	130	70	80	128	78	20 Y	-2	8
	E0019041	SCREEN	14MAY2003	-7	76	102	80	68	108	70	-8	6	-10
		DAY 1	21MAY2003	1	72	100	60	68	95	60	-4	-5	0
		BASELINE			72	100	60	68	95	60	-4	-5	0
		DAY 8	28MAY2003	8	68	100	65	74	95	60	6	-5	-5
		DAY 15	04JUN2003	15	64	100	52	68	90 L	48 L	4	-10	-4
		DAY 22	12JUN2003	23	66	100	70	70	100	65	4	0	-5
		DAY 29	18JUN2003	29	80	108	60	84	100	60	4	-8	0
		DAY 36	25JUN2003	36	56	102	64	84	104	58	28 Y	2	-6
		DAY 43	02JUL2003	43	64	108	72	76	90 L	58	12	-18	-14
		DAY 50	09JUL2003	50	64	104	66	72	102	64	8	-2	-2
		DAY 57	16JUL2003	57	64	110	70	76	115	75	12	5	5
		FINAL		57	64	110	70	76	115	75	12	5	5
	E0019049	SCREEN	03JUL2003	-7	72	118	68	84	112	78	12	-6	10
		DAY 1	10JUL2003	1	62	118	64	70	116	68	8	-2	4
		BASELINE			62	118	64	70	116	68	8	-2	4
		DAY 8	17JUL2003	8	88	120	75	92	105	80	4	-15	5
		DAY 15	24JUL2003	15	84	108	70	96	106	78	12	-2	8
		DAY 22	31JUL2003	22	76	122	76	96	118	78	20 Y	-4	2
		DAY 29	07AUG2003	29	76	120	80	92	122	76	16	2	-4
		DAY 36	14AUG2003	36	84	125	78	84	120	75	0	-5	-3
		DAY 50	26AUG2003	48	84	120	80	88	115	75	4	-5	-5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	DAY 57	08SEP2003	61	76	126	80	76	116	84	0	-10	4
		FINAL		61	76	126	80	76	116	84	0	-10	4
	E0022052	SCREEN	01APR2003	-9	76	120	82	80	118	80	4	-2	-2
		DAY 1	10APR2003	1	81	126	78	81	124	86	0	-2	8
		BASELINE			81	126	78	81	124	86	0	-2	8
		DAY 8	17APR2003	8	69	130	78	90	122	76	21 Y	-8	-2
		DAY 15	24APR2003	15	87	128	74	96	118	86	9	-10	12
		DAY 22	01MAY2003	22	96	128	70	102	132	84	6	4	14
		DAY 29	08MAY2003	29	63	120	74	90	124	78	27 Y	4	4
		DAY 36	15MAY2003	36	64	124	76	64	112	70	0	-12	-6
		DAY 43	22MAY2003	43	87	124	72	90	114	74	3	-10	2
		DAY 50	29MAY2003	50	69	124	78	87	122	82	18	-2	4
		DAY 57	05JUN2003	57	88	124	82	88	126	84	0	2	2
		FINAL		57	88	124	82	88	126	84	0	2	2
	E0022073	SCREEN	19JUN2003	-7	66	106	64	75	102	62	9	-4	-2
		DAY 1	26JUN2003	1	72	102	70	81	100	74	9	-2	4
		BASELINE			72	102	70	81	100	74	9	-2	4
		DAY 8	03JUL2003	8	80	100	62	84	96	74	4	-4	12
		DAY 15	10JUL2003	15	66	102	68	80	92	70	14	-10	2
		DAY 22	17JUL2003	22	80	106	58	100	102	60	20 Y	-4	2
		DAY 29	24JUL2003	29	81	112	64	105	104	64	24 Y	-8	0
		DAY 36	31JUL2003	36	75	98	62	79	100	68	4	2	6
		DAY 43	07AUG2003	43	64	106	68	76	110	74	12	4	6
		DAY 50	14AUG2003	50	68	106	62	72	108	66	4	2	4
		DAY 57	21AUG2003	57	82	116	70	90	104	74	8	-12	4
		FINAL		57	82	116	70	90	104	74	8	-12	4
	E0023002	SCREEN	25OCT2002	-11	70	116	64	72	114	72	2	-2	8
		DAY 1	05NOV2002	1	60	98	70	72	108	80	12	10	10
		BASELINE			60	98	70	72	108	80	12	10	10

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H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	DAY 8	12NOV2002	8	68	110	76	76	118	82	8	8	6
		DAY 15	19NOV2002	15	80	108	75	84	115	80	4	7	5
		DAY 22	25NOV2002	21	72	120	76	88	120	70	16	0	-6
		DAY 29	03DEC2002	29	79	115	73	107	131	66	28 Y	16	-7
		DAY 36	10DEC2002	36	72	120	80	60	126	74	-12	6	-6
		FINAL		36	72	120	80	60	126	74	-12	6	-6
	E0023017	SCREEN	14MAR2003	-11	78	127	86	78	149	97	0	22	11
		DAY 1	25MAR2003	1	76	128	80	78	140	80	2	12	0
		BASELINE			76	128	80	78	140	80	2	12	0
		DAY 8	03APR2003	10	77	104	63	85	110	70	8	6	7
		DAY 15	10APR2003	17	69	115	71	71	114	70	2	-1	-1
		DAY 22	18APR2003	25	68	100	70	80	110	74	12	10	4
		DAY 29	24APR2003	31	78	128	80	80	130	80	2	2	0
		DAY 36	01MAY2003	38	90	128	84	94	124	80	4	-4	-4
		DAY 43	08MAY2003	45	75	110	71	78	108	70	3	-2	-1
		DAY 50	15MAY2003	52	78	155	90	100	121	75	22 Y	-34 Y	-15
		DAY 57	22MAY2003	59	78	132	71	84	130	70	6	-2	-1
		FINAL		59	78	132	71	84	130	70	6	-2	-1
	E0023021	SCREEN	10APR2003	-13	90	141	98	94	139	96	4	-2	-2
		DAY 1	23APR2003	1	88	118	86	88	122	92	0	4	6
		BASELINE			88	118	86	88	122	92	0	4	6
		DAY 8	29APR2003	7	86	110	80	94	115	86	8	5	6
		DAY 15	06MAY2003	14	74	113	64	88	118	70	14	5	6
		DAY 22	13MAY2003	21	78	116	81	100	132	95	22 Y	16	14
		DAY 29	20MAY2003	28	79	114	71	97	104	76	18	-10	5
		DAY 36	29MAY2003	37	85	118	76	109	121	83	24 Y	3	7
		DAY 43	03JUN2003	42	92	120	77	96	124	80	4	4	3
		DAY 50	10JUN2003	49	77	109	71	84	112	82	7	3	11
		DAY 57	17JUN2003	56	111	122	66	100	141	98	-11	19	32
		FINAL		56	111	122	66	100	141	98	-11	19	32

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	SCREEN	07MAY2003	-9	64	93	65	68	93	63	4	0	-2
		DAY 1	16MAY2003	1	79	124	80	99	129	86	20 Y	5	6
		BASELINE			79	124	80	99	129	86	20 Y	5	6
		DAY 8	21MAY2003	6	63	136	96	68	140	98	5	4	2
		DAY 15	30MAY2003	15	123 H	159	102	126 H	152	105 H	3	-7	3
		DAY 22	05JUN2003	21	88	148	99	107	163	105 H	19	15	6
		DAY 29	11JUN2003	27	76	134	96	80	136	96	4	2	0
		DAY 36	18JUN2003	34	88	136	100	88	130	90	0	-6	-10
		DAY 43	27JUN2003	43	76	138	104	80	130	98	4	-8	-6
		DAY 50	02JUL2003	48	105	134	88	123 H	137	82	18	3	-6
		DAY 57	09JUL2003	55	85	143	85	90	140	86	5	-3	1
		FINAL		55	85	143	85	90	140	86	5	-3	1
	E0023030	SCREEN	16MAY2003	-18	84	125	86	80	120	84	-4	-5	-2
		DAY 1	03JUN2003	1	89	115	81	102	131	94	13	16	13
		BASELINE			89	115	81	102	131	94	13	16	13
		DAY 8	10JUN2003	8	100	107	78	104	148	87	4	41	9
		DAY 15	17JUN2003	15	99	131	91	109	132	91	10	1	0
		DAY 22	24JUN2003	22	87	110	73	96	121	80	9	11	7
		DAY 29	01JUL2003	29	79	127	85	89	130	90	10	3	5
		DAY 36	08JUL2003	36	91	127	88	99	152	99	8	25	11
		DAY 43	15JUL2003	43	92	125	86	97	86 L	82	5	-39 Y	-4
		DAY 50	21JUL2003	49	100	142	100	104	141	98	4	-1	-2
		DAY 57	30JUL2003	58	86	135	93	97	148	98	11	13	5
		FINAL		58	86	135	93	97	148	98	11	13	5
	E0023040	SCREEN	25JUN2003	-8	80	120	76	76	117	80	-4	-3	4
		DAY 1	03JUL2003	1	81	117	82	80	117	80	-1	0	-2
		BASELINE			81	117	82	80	117	80	-1	0	-2
		DAY 8	12JUL2003	10	82	121	82	86	123	84	4	2	2
		DAY 15	17JUL2003	15	77	114	81	81	126	88	4	12	7
		DAY 22	25JUL2003	23	86	132	89	84	108	71	-2	-24 Y	-18

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023040	DAY 36	*	05AUG2003	34	76	127	86	75	133	73	-1	6	-13
		DAY 36		08AUG2003	37	88	93	67	93	101	69	5	8	2
		DAY 43		18AUG2003	47	77	127	84	80	117	90	3	-10	6
		DAY 57	*	28AUG2003	57	68	125	85	84	132	88	16	7	3
		DAY 57		05SEP2003	65	63	117	86	63	126	84	0	9	-2
		FINAL			65	63	117	86	63	126	84	0	9	-2
	E0026014	SCREEN		12FEB2003	-7	68	168	97	71	137	97	3	-31 Y	0
		DAY 1		19FEB2003	1	68	148	99	74	142	102	6	-6	3
		BASELINE				68	148	99	74	142	102	6	-6	3
		DAY 8		26FEB2003	8	86	140	99	87	138	95	1	-2	-4
		DAY 15		05MAR2003	15	75	126	91	76	123	88	1	-3	-3
		DAY 22		12MAR2003	22	85	142	90	86	138	95	1	-4	5
		DAY 29		19MAR2003	29	90	140	90	74	129	94	-16	-11	4
		FINAL			29	90	140	90	74	129	94	-16	-11	4
	E0027005	SCREEN		19DEC2002	-7									
		DAY 1		26DEC2002	1	80	130	84	84	128	80	4	-2	-4
		BASELINE				80	130	84	84	128	80	4	-2	-4
		DAY 8		02JAN2003	8	96	130	85	92	120	80	-4	-10	-5
		DAY 15		09JAN2003	15	100	120	90	84	120	88	-16	0	-2
		DAY 22		16JAN2003	22	72	140	94	76	130	90	4	-10	-4
		DAY 29		23JAN2003	29	88	122	84	92	110	70	4	-12	-14
		DAY 36		30JAN2003	36	84	130	86	90	120	76	6	-10	-10
		DAY 43		06FEB2003	43	88	160	100	96	130	90	8	-30 Y	-10
		DAY 50		12FEB2003	49	75	136	84	90	138	88	15	2	4
		DAY 57		20FEB2003	57	84	130	90	84	120	90	0	-10	0
		FINAL			57	84	130	90	84	120	90	0	-10	0
	E0029021	SCREEN		03MAR2003	-15	64	110	80	80	110	80	16	0	0
		DAY 1		18MAR2003	1	64	100	62	60	102	62	-4	2	0
		BASELINE				64	100	62	60	102	62	-4	2	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	DAY 8		25MAR2003	8	68	112	72	60	112	70	-8	0	-2
		DAY 15		01APR2003	15	72	102	70	68	100	68	-4	-2	-2
		DAY 22		07APR2003	21	60	102	62	60	100	64	0	-2	2
		DAY 29		15APR2003	29	72	100	60	68	108	64	-4	8	4
		DAY 36		22APR2003	36	64	102	68	60	100	68	-4	-2	0
		DAY 43		29APR2003	43	92	102	68	104	90 L	68	12	-12	0
		DAY 50		06MAY2003	50	80	98	60	80	102	64	0	4	4
		DAY 57		15MAY2003	59	88	104	76	100	98	64	12	-6	-12
		FINAL			59	88	104	76	100	98	64	12	-6	-12
	E0029026	SCREEN		07APR2003	-7	76	122	80	92	114	78	16	-8	-2
		DAY 1		14APR2003	1	72	118	82	80	100	70	8	-18	-12
		BASELINE				72	118	82	80	100	70	8	-18	-12
		DAY 8		21APR2003	8	84	98	74	96	100	76	12	2	2
		DAY 15		28APR2003	15	84	108	84	96	120	80	12	12	-4
		DAY 22		05MAY2003	22	88	124	82	100	110	84	12	-14	2
		DAY 29		12MAY2003	29	80	120	80	100	114	78	20 Y	-6	-2
		DAY 36		19MAY2003	36	80	108	76	100	110	70	20 Y	2	-6
		DAY 43		28MAY2003	45	88	114	74	100	90 L	70	12	-24 Y	-4
		DAY 50		02JUN2003	50	84	118	80	88	112	84	4	-6	4
		DAY 57		10JUN2003	58	76	110	70	92	110	76	16	0	6
		FINAL			58	76	110	70	92	110	76	16	0	6
	E0033021	SCREEN		25JUN2003	-7	60	90 L	62	76	80 L	64	16	-10	2
		DAY 1		02JUL2003	1	56	90 L	70	72	90 L	74	16	0	4
		BASELINE				56	90 L	70	72	90 L	74	16	0	4
		DAY 8		11JUL2003	10	58	90 L	67	74	90 L	70	16	0	3
		DAY 22	*	21JUL2003	20	60	100	60	76	98	66	16	-2	6
		DAY 22		25JUL2003	24	72	90 L	68	80	100	70	8	10	2
		DAY 29		01AUG2003	31	76	90 L	64	80	96	66	4	6	2
		DAY 36		06AUG2003	36	72	112	74	68	110	70	-4	-2	-4
		DAY 50		18AUG2003	48	76	96	70	76	96	72	0	0	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	FINAL		48	76	96	70	76	96	72	0	0	2
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	SCREEN	28JAN2003	-7	92	118	70	100	124	72	8	6	2
		DAY 1	04FEB2003	1	92	110	72	98	120	70	6	10	-2
		BASELINE			92	110	72	98	120	70	6	10	-2
		DAY 8	11FEB2003	8	84	118	72	110	130	80	26 Y	12	8
		DAY 15	18FEB2003	15	88	110	72	94	114	78	6	4	6
		FINAL		15	88	110	72	94	114	78	6	4	6
	E0003020	SCREEN	24JUN2003	-29	62	126	82	80	112	76	18	-14	-6
		DAY 1	23JUL2003	1	64	110	50 L	70	118	70	6	8	20
		BASELINE			64	110	50 L	70	118	70	6	8	20
		DAY 8	29JUL2003	7	66	130	84	86	124	76	20 Y	-6	-8
		DAY 15	06AUG2003	15	62	118	76	84	132	80	22 Y	14	4
		DAY 22	13AUG2003	22	84	108	70	88	118	78	4	10	8
		DAY 29	20AUG2003	29	76	130	76	80	132	80	4	2	4
		DAY 36	27AUG2003	36	76	126	88	82	124	88	6	-2	0
		DAY 43	03SEP2003	43	72	134	90	78	130	88	6	-4	-2
		DAY 50	10SEP2003	50	80	120	80	76	110	70	-4	-10	-10
		DAY 57	17SEP2003	57	72	110	80	72	114	80	0	4	0
		FINAL		57	72	110	80	72	114	80	0	4	0
	E0004001	SCREEN	23SEP2002	-7	54	100	60	56	98	58	2	-2	-2
		DAY 1	30SEP2002	1	64	98	62	60	96	58	-4	-2	-4
		BASELINE			64	98	62	60	96	58	-4	-2	-4
		DAY 8	07OCT2002	8	64	98	60	68	92	62	4	-6	2
		DAY 22	21OCT2002	22	64	98	62	72	100	68	8	2	6
		DAY 29	28OCT2002	29	80	94	60	84	86 L	60	4	-8	0
		DAY 36	05NOV2002	37	76	100	62	84	92	60	8	-8	-2
		FINAL		37	76	100	62	84	92	60	8	-8	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	SCREEN	07JAN2003	-7	56	114	62	62	100	60	6	-14	-2
		DAY 1	14JAN2003	1	56	104	72	68	100	70	12	-4	-2
		BASELINE			56	104	72	68	100	70	12	-4	-2
		DAY 8	21JAN2003	8	76	90 L	62	88	106	64	12	16	2
		DAY 15	28JAN2003	15	64	104	60	72	108	68	8	4	8
		DAY 22	04FEB2003	22	80	94	58	88	90 L	56	8	-4	-2
		DAY 29	11FEB2003	29	84	100	70	88	102	72	4	2	2
		DAY 36	18FEB2003	36	92	94	68	100	100	74	8	6	6
		DAY 43	25FEB2003	43	68	92	62	72	100	70	4	8	8
		DAY 50	04MAR2003	50	72	100	60	90	98	64	18	-2	4
		DAY 57	11MAR2003	57	84	98	70	92	100	72	8	2	2
		FINAL		57	84	98	70	92	100	72	8	2	2
	E0005025	SCREEN	20FEB2003	-7	80	116	68	84	110	64	4	-6	-4
		DAY 1	27FEB2003	1	80	110	60	80	106	60	0	-4	0
		BASELINE			80	110	60	80	106	60	0	-4	0
		DAY 8	06MAR2003	8	88	110	60	100	100	56	12	-10	-4
		DAY 15	14MAR2003	16	88	90 L	60	88	94	60	0	4	0
		DAY 22	20MAR2003	22	88	106	64	88	100	60	0	-6	-4
		DAY 29	27MAR2003	29	68	100	58	80	90 L	54	12	-10	-4
		DAY 36	03APR2003	36	80	100	64	88	104	66	8	4	2
		FINAL		36	80	100	64	88	104	66	8	4	2
	E0006019	SCREEN	26MAR2003	-12	78	127	72	82	131	78	4	4	6
		DAY 1	07APR2003	1	58	118	72	75	116	84	17	-2	12
		BASELINE			58	118	72	75	116	84	17	-2	12
		DAY 8	14APR2003	8	70	129	90	86	129	79	16	0	-11
		DAY 15	21APR2003	15	83	119	85	88	112	88	5	-7	3
		DAY 22	28APR2003	22	66	122	87	82	131	90	16	9	3
		DAY 29	05MAY2003	29	70	119	71	93	113	84	23 Y	-6	13
		DAY 36	12MAY2003	36	68	117	72	90	129	84	22 Y	12	12
		DAY 43	19MAY2003	43	66	112	64	70	116	78	4	4	14

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 50	27MAY2003	51	71	104	72	93	115	76	22 Y	11	4
		DAY 57	03JUN2003	58	70	120	80	77	122	82	7	2	2
		FINAL		58	70	120	80	77	122	82	7	2	2
	E0007005	SCREEN	27JAN2003	-4	80	114	70	82	110	72	2	-4	2
		DAY 1	31JAN2003	1	70	110	68	72	104	70	2	-6	2
		BASELINE			70	110	68	72	104	70	2	-6	2
		DAY 8	07FEB2003	8	70	108	76	74	112	78	4	4	2
		DAY 15	14FEB2003	15	70	100	70	78	108	70	8	8	0
		DAY 22	22FEB2003	23	72	98	72	78	104	70	6	6	-2
		DAY 29	03MAR2003	32	78	100	70	82	102	70	4	2	0
		DAY 36	10MAR2003	39	76	104	70	84	100	72	8	-4	2
		DAY 43	14MAR2003	43	70	96	70	76	100	72	6	4	2
		DAY 50	21MAR2003	50	82	90 L	60	88	96	64	6	6	4
		DAY 57	28MAR2003	57	72	94	62	78	98	60	6	4	-2
		FINAL		57	72	94	62	78	98	60	6	4	-2
	E0010002	SCREEN	14NOV2002	-11	68	102	78	70	115	80	2	13	2
		DAY 1	25NOV2002	1	106	110	60	122 H	102	72	16	-8	12
		BASELINE			106	110	60	122 H	102	72	16	-8	12
		DAY 8	02DEC2002	8	72	110	74	82	114	80	10	4	6
		FINAL		8	72	110	74	82	114	80	10	4	6
	E0010009	SCREEN	18DEC2002	-8	56	130	70	65	130	64	9	0	-6
		DAY 1	26DEC2002	1	56	138	88	60	136	88	4	-2	0
		BASELINE			56	138	88	60	136	88	4	-2	0
		DAY 8	02JAN2003	8	66	120	76	76	110	76	10	-10	0
		DAY 15	09JAN2003	15	74	140	82	89	120	80	15	-20 Y	-2
		DAY 22	17JAN2003	23	72	110	78	84	108	78	12	-2	0
		DAY 29	22JAN2003	28	68	128	76	76	104	80	8	-24 Y	4
		DAY 36	30JAN2003	36	82	138	66	90	146	86	8	8	20
		DAY 43	05FEB2003	42	84	124	82	90	108	76	6	-16	-6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	DAY 50	13FEB2003	50	68	126	62	86	118	72	18	-8	10
		DAY 57	19FEB2003	56	74	126	80	89	126	82	15	0	2
		FINAL		56	74	126	80	89	126	82	15	0	2
	E0010014	SCREEN	14JAN2003	-14	52	120	70	68	124	70	16	4	0
		DAY 1	28JAN2003	1	49 L	126	66	65	114	66	16	-12	0
		BASELINE			49 L	126	66	65	114	66	16	-12	0
		DAY 8	04FEB2003	8	58	112	68	70	102	66	12	-10	-2
		DAY 15	11FEB2003	15	58	104	62	77	106	64	19	2	2
		DAY 22	18FEB2003	22	52	118	70	66	120	76	14	2	6
		DAY 29	25FEB2003	29	58	108	68	76	110	70	18	2	2
		DAY 36	04MAR2003	36	54	120	70	74	110	78	20 Y	-10	8
		DAY 43	11MAR2003	43	52	112	70	70	112	70	18	0	0
		DAY 50	18MAR2003	50	52	110	74	66	110	70	14	0	-4
		DAY 57	25MAR2003	57	51	118	78	58	110	80	7	-8	2
		FINAL		57	51	118	78	58	110	80	7	-8	2
	E0010017	SCREEN	05FEB2003	-20	61	114	62	79	110	80	18	-4	18
		DAY 1	25FEB2003	1	68	124	66	72	128	80	4	4	14
		BASELINE			68	124	66	72	128	80	4	4	14
		DAY 8	03MAR2003	7	60	110	70	76	100	60	16	-10	-10
		DAY 15	10MAR2003	14	84	112	68	100	120	70	16	8	2
		DAY 22	18MAR2003	22	64	120	72	86	126	86	22 Y	6	14
		DAY 29	25MAR2003	29	80	110	68	86	112	76	6	2	8
		DAY 36	01APR2003	36	84	110	76	92	116	80	8	6	4
		DAY 43	08APR2003	43	84	120	78	94	112	80	10	-8	2
		DAY 50	15APR2003	50	72	126	76	88	128	80	16	2	4
		DAY 57	22APR2003	57	69	110	66	78	112	76	9	2	10
		FINAL		57	69	110	66	78	112	76	9	2	10
	E0010023	SCREEN	10APR2003	-7	72	108	70	78	94	74	6	-14	4
		DAY 1	17APR2003	1	72	110	60	92	108	68	20 Y	-2	8

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010023	BASELINE			72	110	60	92	108	68	20 Y	-2	8
		DAY 8	24APR2003	8	72	98	68	88	104	70	16	6	2
		DAY 15	01MAY2003	15	72	100	64	98	96	70	26 Y	-4	6
		FINAL		15	72	100	64	98	96	70	26 Y	-4	6
	E0010027	SCREEN	05JUN2003	-11	66	118	70	82	112	70	16	-6	0
		DAY 1	16JUN2003	1	80	110	90	80	110	82	0	0	-8
		BASELINE			80	110	90	80	110	82	0	0	-8
		DAY 8	23JUN2003	8	78	120	74	110	118	78	32 Y	-2	4
		DAY 15	01JUL2003	16	76	110	80	80	120	82	4	10	2
		FINAL		16	76	110	80	80	120	82	4	10	2
	E0010029	SCREEN	10JUN2003	-9	75	120	84	96	134	90	21 Y	14	6
		DAY 1	19JUN2003	1	88	120	80	88	120	89	0	0	9
		BASELINE			88	120	80	88	120	89	0	0	9
		DAY 8	25JUN2003	7	92	138	94	104	134	94	12	-4	0
		FINAL		7	92	138	94	104	134	94	12	-4	0
	E0016005	SCREEN	20FEB2003	-5	64	118	78	86	108	84	22 Y	-10	6
		DAY 1	25FEB2003	1	81	118	72	96	126	84	15	8	12
		BASELINE			81	118	72	96	126	84	15	8	12
		DAY 8	04MAR2003	8	88	122	79	95	128	85	7	6	6
		DAY 15	11MAR2003	15	81	111	69	91	132	86	10	21	17
		DAY 22	18MAR2003	22	78	115	76	83	126	81	5	11	5
		DAY 29	25MAR2003	29	76	116	82	84	126	76	8	10	-6
		DAY 36	01APR2003	36	74	118	69	86	132	81	12	14	12
		DAY 43	08APR2003	43	82	140	81	87	150	88	5	10	7
		DAY 57	22APR2003	57	91	105	73	98	117	76	7	12	3
		FINAL		57	91	105	73	98	117	76	7	12	3
	E0019005	SCREEN	30OCT2002	-6	60	140	86	62	140	88	2	0	2
		DAY 1	05NOV2002	1	64	130	70	72	125	70	8	-5	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	BASELINE				64	130	70	72	125	70	8	-5	0
		DAY 8		12NOV2002	8	54	110	60	62	110	65	8	0	5
		DAY 15		19NOV2002	15	72	120	80	64	128	78	-8	8	-2
		DAY 22		26NOV2002	22	68	135	80	76	125	70	8	-10	-10
		DAY 29		05DEC2002	31	60	120	82	80	124	78	20 Y	4	-4
		DAY 36		12DEC2002	38	70	118	70	68	115	70	-2	-3	0
		DAY 43		19DEC2002	45	68	112	80	72	115	80	4	3	0
		DAY 57	*	30DEC2002	56	80	130	74	88	136	78	8	6	4
		DAY 57		02JAN2003	59	88	120	72	94	120	78	6	0	6
		FINAL			59	88	120	72	94	120	78	6	0	6
	E0019015	SCREEN		19DEC2002	-14	56	110	84	76	100	82	20 Y	-10	-2
		DAY 1		02JAN2003	1	60	110	90	80	120	90	20 Y	10	0
		BASELINE				60	110	90	80	120	90	20 Y	10	0
		DAY 8		09JAN2003	8	72	112	92	76	110	90	4	-2	-2
		DAY 15		16JAN2003	15	72	128	80	80	126	82	8	-2	2
		DAY 22		23JAN2003	22	60	117	75	62	118	80	2	1	5
		DAY 29		30JAN2003	29	80	130	85	84	135	85	4	5	0
		DAY 36		06FEB2003	36	84	135	80	76	140	90	-8	5	10
		DAY 43		13FEB2003	43	80	130	80	88	135	80	8	5	0
		DAY 50		20FEB2003	50	90	125	85	90	130	90	0	5	5
		DAY 57		27FEB2003	57	50	120	104	96	124	100	46 Y	4	-4
		FINAL			57	50	120	104	96	124	100	46 Y	4	-4
	E0020004	SCREEN		21NOV2002	-18	78	160	80	82	162	84	4	2	4
		DAY 1		09DEC2002	1	84	140	80	80	144	82	-4	4	2
		BASELINE				84	140	80	80	144	82	-4	4	2
		DAY 8		16DEC2002	8	82	138	80	80	140	82	-2	2	2
		DAY 8	*	20DEC2002	12	80	178	100	86	180 H	104	6	2	4
		DAY 22		31DEC2002	23	74	122	78	76	120	78	2	-2	0
		DAY 29		07JAN2003	30	76	170	92	80	168	90	4	-2	-2
		DAY 36		14JAN2003	37	76	152	82	70	148	80	-6	-4	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	DAY 43	22JAN2003	45	80	138	80	84	138	82	4	0	2
		FINAL		45	80	138	80	84	138	82	4	0	2
	E0020021	SCREEN	13MAY2003	-6	70	134	82	76	140	84	6	6	2
		DAY 1	19MAY2003	1	72	130	80	70	128	82	-2	-2	2
		BASELINE			72	130	80	70	128	82	-2	-2	2
		DAY 8	23MAY2003	5	62	128	86	64	130	86	2	2	0
		DAY 15	02JUN2003	15	76	142	82	80	148	84	4	6	2
		DAY 22	10JUN2003	23	78	140	82	80	144	80	2	4	-2
		DAY 29	16JUN2003	29	92	140	80	88	140	90	-4	0	10
		DAY 36	23JUN2003	36	80	140	76	88	138	76	8	-2	0
		DAY 43	30JUN2003	43	88	130	78	88	130	80	0	0	2
		DAY 50	07JUL2003	50	94	166	98	90	160	98	-4	-6	0
		DAY 57	14JUL2003	57	88	174	106 H	80	160	108 H	-8	-14	2
		FINAL		57	88	174	106 H	80	160	108 H	-8	-14	2
	E0022007	SCREEN	01NOV2002	-6	52	112	69	64	120	73	12	8	4
		DAY 1	07NOV2002	1	64	108	68	68	112	72	4	4	4
		BASELINE			64	108	68	68	112	72	4	4	4
		DAY 8	14NOV2002	8	72	124	62	100	114	76	28 Y	-10	14
		DAY 15	22NOV2002	16	84	104	62	88	102	64	4	-2	2
		DAY 22	02DEC2002	26	72	112	58	88	100	68	16	-12	10
		DAY 29	09DEC2002	33	74	112	70	78	104	72	4	-8	2
		FINAL		33	74	112	70	78	104	72	4	-8	2
	E0022010	SCREEN	14NOV2002	-7	59	135	69	75	133	70	16	-2	1
		DAY 1	21NOV2002	1	68	124	68	72	118	68	4	-6	0
		BASELINE			68	124	68	72	118	68	4	-6	0
		DAY 8	29NOV2002	9	84	122	64	80	120	70	-4	-2	6
		DAY 15	06DEC2002	16	84	142	78	88	142	106 H	4	0	28
		DAY 22	12DEC2002	22	72	130	68	80	136	72	8	6	4
		DAY 36	26DEC2002	36	78	142	64	78	144	68	0	2	4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	DAY 43	02JAN2003	43	84	146	70	88	142	86	4	-4	16
		DAY 50	09JAN2003	50	80	134	72	100	132	96	20 Y	-2	24
		DAY 57	16JAN2003	57	76	134	70	72	132	76	-4	-2	6
		FINAL		57	76	134	70	72	132	76	-4	-2	6
	E0022019	SCREEN	04DEC2002	-7	68	122	64	84	130	88	16	8	24
		DAY 1	11DEC2002	1	60	120	76	80	126	90	20 Y	6	14
		BASELINE			60	120	76	80	126	90	20 Y	6	14
		DAY 8	19DEC2002	9	80	146	78	88	118	90	8	-28 Y	12
		DAY 15	26DEC2002	16	88	144	84	96	132	88	8	-12	4
		DAY 22	03JAN2003	24	96	134	96	112	142	100	16	8	4
		DAY 29	09JAN2003	30	96	126	82	108	136	98	12	10	16
		DAY 36	17JAN2003	38	92	132	96	100	138	92	8	6	-4
		DAY 43	24JAN2003	45	80	140	94	92	124	94	12	-16	0
		DAY 50	30JAN2003	51	100	134	92	112	132	104	12	-2	12
		DAY 57	06FEB2003	58	76	124	80	92	118	92	16	-6	12
		FINAL		58	76	124	80	92	118	92	16	-6	12
	E0022033	SCREEN	11FEB2003	-7	64	112	78	60	120	72	-4	8	-6
		DAY 1	18FEB2003	1	76	104	64	72	100	66	-4	-4	2
		BASELINE			76	104	64	72	100	66	-4	-4	2
		DAY 8	25FEB2003	8	60	130	76	76	132	84	16	2	8
		DAY 15	04MAR2003	15	74	128	80	88	128	88	14	0	8
		DAY 22	11MAR2003	22	80	128	80	88	128	82	8	0	2
		DAY 29	18MAR2003	29	64	130	76	78	106	82	14	-24 Y	6
		DAY 36	27MAR2003	38	68	128	80	68	110	82	0	-18	2
		DAY 43	01APR2003	43	68	118	72	78	118	80	10	0	8
		DAY 50	08APR2003	50	72	120	70	80	118	78	8	-2	8
		DAY 57	15APR2003	57	60	120	70	72	128	82	12	8	12
		FINAL		57	60	120	70	72	128	82	12	8	12
	E0022039	SCREEN	27FEB2003	-7	64	90 L	58	68	116	70	4	26	12

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	DAY 1	06MAR2003	1	74	110	84	78	120	82	4	10	-2
		BASELINE			74	110	84	78	120	82	4	10	-2
		DAY 8	13MAR2003	8	88	118	70	96	122	78	8	4	8
		DAY 15	20MAR2003	15	84	122	82	88	118	90	4	-4	8
		DAY 22	27MAR2003	22	72	120	82	78	108	84	6	-12	2
		DAY 29	04APR2003	30	88	118	78	98	108	72	10	-10	-6
		DAY 36	10APR2003	36	84	124	78	80	118	84	-4	-6	6
		DAY 43	18APR2003	44	78	118	82	80	112	80	2	-6	-2
		DAY 50	24APR2003	50	78	112	78	84	122	78	6	10	0
		DAY 57	01MAY2003	57	84	108	76	116	106	74	32 Y	-2	-2
		FINAL		57	84	108	76	116	106	74	32 Y	-2	-2
	E0022046	SCREEN	13MAR2003	-7	88	132	74	97	138	72	9	6	-2
		DAY 1	20MAR2003	1	68	128	64	70	124	70	2	-4	6
		BASELINE			68	128	64	70	124	70	2	-4	6
		DAY 8	27MAR2003	8	68	146	84	70	140	74	2	-6	-10
		DAY 15	04APR2003	16	100	150	68	108	146	70	8	-4	2
		DAY 22	11APR2003	23	96	146	80	116	132	66	20 Y	-14	-14
		DAY 29	18APR2003	30	88	144	74	108	130	70	20 Y	-14	-4
		DAY 36	24APR2003	36	96	136	90	96	128	78	0	-8	-12
		DAY 43	02MAY2003	44	112	142	70	120	138	74	8	-4	4
		DAY 50	12MAY2003	54	92	128	72	110	124	68	18	-4	-4
		DAY 57	16MAY2003	58	104	130	72	116	128	78	12	-2	6
		FINAL		58	104	130	72	116	128	78	12	-2	6
	E0022051	SCREEN	31MAR2003	-7	68	110	66	96	114	68	28 Y	4	2
		DAY 1	07APR2003	1	72	124	66	76	110	72	4	-14	6
		BASELINE			72	124	66	76	110	72	4	-14	6
		DAY 8	14APR2003	8	60	112	74	64	102	72	4	-10	-2
		DAY 15	21APR2003	15	68	108	74	88	114	68	20 Y	6	-6
		DAY 22	28APR2003	22	84	118	64	96	110	72	12	-8	8
		DAY 29	05MAY2003	29	100	130	80	88	116	82	-12	-14	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	DAY 36	12MAY2003	36	80	138	74	80	112	68	0	-26 Y	-6
		DAY 43	19MAY2003	43	76	120	80	72	112	68	-4	-8	-12
		DAY 50	28MAY2003	52	84	120	74	88	110	78	4	-10	4
		DAY 57	02JUN2003	57	88	120	72	88	116	76	0	-4	4
		FINAL		57	88	120	72	88	116	76	0	-4	4
	E0022053	SCREEN	04APR2003	-7	56	106	60	76	126	84	20 Y	20	24
		DAY 1	11APR2003	1	60	110	60	66	118	70	6	8	10
		BASELINE			60	110	60	66	118	70	6	8	10
	E0022058	SCREEN	11APR2003	-10	64	110	80	84	126	88	20 Y	16	8
		DAY 1	21APR2003	1	80	122	76	88	118	72	8	-4	-4
		BASELINE			80	122	76	88	118	72	8	-4	-4
		DAY 8	28APR2003	8	75	130	74	87	114	80	12	-16	6
		DAY 15	05MAY2003	15	80	132	86	100	110	80	20 Y	-22 Y	-6
		DAY 22	12MAY2003	22	88	126	74	88	112	80	0	-14	6
		DAY 29	19MAY2003	29	88	110	68	84	126	78	-4	16	10
		DAY 29 *	22MAY2003	32	78	120	78	80	118	80	2	-2	2
		FINAL		32	78	120	78	80	118	80	2	-2	2
	E0022061	SCREEN	24APR2003	-6	72	118	74	68	118	80	-4	0	6
		DAY 1	30APR2003	1	76	120	68	84	114	62	8	-6	-6
		BASELINE			76	120	68	84	114	62	8	-6	-6
		DAY 8	07MAY2003	8	84	122	56	68	118	70	-16	-4	14
		DAY 15	14MAY2003	15	80	114	54	104	110	54	24 Y	-4	0
		DAY 22	22MAY2003	23	88	112	62	76	102	70	-12	-10	8
		DAY 29	28MAY2003	29	80	114	54	96	114	60	16	0	6
		DAY 36	04JUN2003	36	80	122	60	76	110	70	-4	-12	10
		DAY 50	18JUN2003	50	88	118	60	96	110	66	8	-8	6
		DAY 57	26JUN2003	58	84	114	64	108	104	68	24 Y	-10	4
		FINAL		58	84	114	64	108	104	68	24 Y	-10	4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	SCREEN		25APR2003	-10	78	156	86	96	144	88	18	-12	2
		DAY 1		05MAY2003	1	80	152	88	78	156	94	-2	4	6
		BASELINE				80	152	88	78	156	94	-2	4	6
		DAY 8		12MAY2003	8	100	164	78	100	138	90	0	-26 Y	12
		DAY 15		19MAY2003	15	84	162	102	92	148	98	8	-14	-4
		DAY 15	*	23MAY2003	19	88	162	110 H	84	162	108 H	-4	0	-2
		FINAL			19	88	162	110 H	84	162	108 H	-4	0	-2
	E0022071	SCREEN		16JUN2003	-14	72	138	88	86	146	94	14	8	6
		DAY 1		30JUN2003	1	60	132	78	78	136	92	18	4	14
		BASELINE				60	132	78	78	136	92	18	4	14
		DAY 8		07JUL2003	8	90	124	78	88	136	82	-2	12	4
		DAY 15		14JUL2003	15	78	128	76	80	130	72	2	2	-4
		DAY 22		21JUL2003	22	72	124	78	90	124	88	18	0	10
		DAY 29		28JUL2003	29	82	138	88	102	126	94	20 Y	-12	6
		DAY 36		04AUG2003	36	84	140	86	104	132	96	20 Y	-8	10
		DAY 43		11AUG2003	43	84	136	86	102	142	90	18	6	4
		DAY 50		18AUG2003	50	74	132	84	84	124	92	10	-8	8
		DAY 57		25AUG2003	57	82	138	92	88	128	90	6	-10	-2
		FINAL			57	82	138	92	88	128	90	6	-10	-2
	E0023003	SCREEN		12DEC2002	-5	79	148	86	74	129	80	-5	-19	-6
		DAY 1		17DEC2002	1	72	104	80	76	110	84	4	6	4
		BASELINE				72	104	80	76	110	84	4	6	4
		DAY 8		23DEC2002	7	68	134	89	72	125	84	4	-9	-5
		DAY 15		30DEC2002	14	88	118	64	80	124	70	-8	6	6
		DAY 22		07JAN2003	22	86	104	78	80	100	78	-6	-4	0
		DAY 29		16JAN2003	31	86	117	70	88	114	68	2	-3	-2
		DAY 36		21JAN2003	36	88	124	84	88	120	80	0	-4	-4
		DAY 43		28JAN2003	43	90	98	65	92	100	67	2	2	2
		DAY 50		06FEB2003	52	68	108	68	72	110	70	4	2	2
		DAY 57		11FEB2003	57	82	127	88	110	107	74	28 Y	-20 Y	-14

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	FINAL		57	82	127	88	110	107	74	28 Y	-20 Y	-14
	E0023025	SCREEN	01MAY2003	-14	100	126	65	96	120	57	-4	-6	-8
		DAY 1	15MAY2003	1	72	115	60	76	114	64	4	-1	4
		BASELINE			72	115	60	76	114	64	4	-1	4
		DAY 8	22MAY2003	8	80	126	73	88	120	70	8	-6	-3
		DAY 15	29MAY2003	15	85	132	79	105	146	93	20 Y	14	14
		DAY 22	05JUN2003	22	92	117	58	119	140	92	27 Y	23	34
		DAY 29	12JUN2003	29	92	120	60	90	124	70	-2	4	10
		DAY 36	19JUN2003	36	97	119	79	90	118	76	-7	-1	-3
		DAY 43	27JUN2003	44	96	116	72	96	110	72	0	-6	0
		DAY 50	03JUL2003	50	80	110	82	84	120	80	4	10	-2
		DAY 57	10JUL2003	57	72	103	68	76	100	65	4	-3	-3
		FINAL		57	72	103	68	76	100	65	4	-3	-3
	E0023039	SCREEN	24JUN2003	-7	88	121	80	94	136	87	6	15	7
		DAY 1	01JUL2003	1	60	120	79	81	108	73	21 Y	-12	-6
		BASELINE			60	120	79	81	108	73	21 Y	-12	-6
		DAY 8	08JUL2003	8	85	126	74	102	102	71	17	-24 Y	-3
		DAY 15	15JUL2003	15	72	110	73	80	108	73	8	-2	0
		DAY 22	22JUL2003	22	86	100	72	96	103	67	10	3	-5
		DAY 29	29JUL2003	29	86	115	79	100	112	79	14	-3	0
		DAY 36	05AUG2003	36	93	109	76	131 H	111	74	38 Y	2	-2
		DAY 43	12AUG2003	43	77	101	70	109	109	71	32 Y	8	1
		DAY 50	19AUG2003	50	104	90 L	65	139 H	120	82	35 Y	30	17
		DAY 57	26AUG2003	57	89	115	82	117	114	75	28 Y	-1	-7
		FINAL		57	89	115	82	117	114	75	28 Y	-1	-7
	E0026002	SCREEN	05NOV2002	-7	77	116	73	70	129	84	-7	13	11
		DAY 1	12NOV2002	1	70	105	70	82	111	84	12	6	14
		BASELINE			70	105	70	82	111	84	12	6	14
		DAY 8	19NOV2002	8	86	131	81	93	132	80	7	1	-1

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 15	26NOV2002	15	75	99	83	79	101	76	4	2	-7
		DAY 22	03DEC2002	22	85	143	87	89	123	77	4	-20 Y	-10
		DAY 29	11DEC2002	30	75	146	93	78	129	85	3	-17	-8
		DAY 36	18DEC2002	37	75	132	85	75	121	76	0	-11	-9
		DAY 43	26DEC2002	45	74	154	89	75	111	81	1	-43 Y	-8
		DAY 50	02JAN2003	52	75	135	86	74	100	67	-1	-35 Y	-19
		DAY 57	09JAN2003	59	70	126	75	70	113	77	0	-13	2
		FINAL		59	70	126	75	70	113	77	0	-13	2
	E0026007	SCREEN	06JAN2003	-10	70	131	69	72	129	66	2	-2	-3
		DAY 1	16JAN2003	1	72	140	76	80	130	72	8	-10	-4
		BASELINE			72	140	76	80	130	72	8	-10	-4
		DAY 8	23JAN2003	8	82	114	66	90	112	60	8	-2	-6
		DAY 15	30JAN2003	15	77	127	79	92	104	64	15	-23 Y	-15
		DAY 22	06FEB2003	22	90	154	83	96	115	68	6	-39 Y	-15
		DAY 29	13FEB2003	29	80	132	73	86	126	94	6	-6	21
		DAY 36	19FEB2003	35	77	113	67	83	108	67	6	-5	0
		DAY 43	26FEB2003	42	90	117	74	96	115	68	6	-2	-6
		DAY 50	05MAR2003	49	81	135	63	97	143	76	16	8	13
		DAY 57	12MAR2003	56	92	116	70	91	123	67	-1	7	-3
		FINAL		56	92	116	70	91	123	67	-1	7	-3
	E0028007	SCREEN	01OCT2002	-3	60	100	70	68	100	70	8	0	0
		DAY 1	04OCT2002	1	60	110	70	62	108	70	2	-2	0
		BASELINE			60	110	70	62	108	70	2	-2	0
		DAY 8	11OCT2002	8	64	110	60	68	110	60	4	0	0
		DAY 15	16OCT2002	13	52	90 L	50 L	58	98	58	6	8	8
		DAY 22	23OCT2002	20	70	98	60	70	102	60	0	4	0
		DAY 29	31OCT2002	28	80	90 L	54	88	94	58	8	4	4
		DAY 36	07NOV2002	35	56	128	78	58	114	68	2	-14	-10
		DAY 43	14NOV2002	42	56	104	58	60	104	56	4	0	-2
		FINAL		42	56	104	58	60	104	56	4	0	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	SCREEN	14JAN2003	-7	72	114	78	74	106	90	2	-8	12
		DAY 1	21JAN2003	1	64	150	92	68	144	102	4	-6	10
		BASELINE			64	150	92	68	144	102	4	-6	10
		DAY 8	30JAN2003	10	52	188 H	128 H	56	188 H	112 H	4	0	-16
		DAY 15	04FEB2003	15	70	122	92	78	140	94	8	18	2
		DAY 22	11FEB2003	22	76	118	84	80	102	80	4	-16	-4
		DAY 29	17FEB2003	28	74	90 L	70	78	84 L	70	4	-6	0
		DAY 36	27FEB2003	38	68	112	70	70	104	62	2	-8	-8
		DAY 43	04MAR2003	43	72	100	60	76	72 L	62	4	-28 Y	2
		DAY 57	27JUN2003	158									
		FINAL		158	72	100	60	76	72 L	62	4	-28 Y	2
	E0028025	SCREEN	08JAN2003	-5	62	114	76	74	108	70	12	-6	-6
		DAY 1	13JAN2003	1	60	106	78	72	94	72	12	-12	-6
		BASELINE			60	106	78	72	94	72	12	-12	-6
		DAY 8	17JAN2003	5	76	114	70	80	110	70	4	-4	0
		DAY 15	27JAN2003	15	56	120	86	76	124	90	20 Y	4	4
		FINAL		15	56	120	86	76	124	90	20 Y	4	4
	E0028033	SCREEN	18MAR2003	-9	66	108	72	76	102	68	10	-6	-4
		DAY 1	27MAR2003	1	76	106	62	84	102	60	8	-4	-2
		BASELINE			76	106	62	84	102	60	8	-4	-2
		DAY 8	03APR2003	8	78	112	72	104	108	78	26 Y	-4	6
		DAY 15	10APR2003	15	98	118	68	146 H	98	68	48 Y	-20 Y	0
		DAY 22	17APR2003	22	80	114	78	100	110	72	20 Y	-4	-6
		DAY 29	24APR2003	29	88	96	62	108	100	66	20 Y	4	4
		DAY 36	01MAY2003	36	60	94	68	88	90 L	74	28 Y	-4	6
		DAY 43	08MAY2003	43	84	120	70	100	116	68	16	-4	-2
		DAY 50	15MAY2003	50	84	108	68	108	104	62	24 Y	-4	-6
		DAY 57	22MAY2003	57	76	112	72	100	108	74	24 Y	-4	2
		FINAL		57	76	112	72	100	108	74	24 Y	-4	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	SCREEN		04JUN2003	-9	68	130	70	72	130	82	4	0	12
		DAY 1		12JUN2003	-1	68	140	80	66	140	82	-2	0	2
		BASELINE				68	140	80	66	140	82	-2	0	2
		DAY 8		20JUN2003	8	76	122	84	80	122	86	4	0	2
		DAY 15		25JUN2003	13	74	132	86	86	110	80	12	-22 Y	-6
		DAY 15	*	01JUL2003	19	80	130	82	78	115	70	-2	-15	-12
		DAY 22		08JUL2003	26	74	136	86	80	132	86	6	-4	0
		DAY 36		16JUL2003	34	80	130	78	80	116	72	0	-14	-6
		DAY 43		23JUL2003	41	78	118	80	80	116	82	2	-2	2
		DAY 50		30JUL2003	48	84	118	86	84	122	86	0	4	0
		DAY 57		08AUG2003	57	80	120	80	78	120	70	-2	0	-10
		FINAL			57	80	120	80	78	120	70	-2	0	-10
	E0028039	SCREEN		02MAY2003	-7	72	120	82	92	118	76	20 Y	-2	-6
		DAY 1		08MAY2003	-1	72	110	70	92	104	66	20 Y	-6	-4
		BASELINE				72	110	70	92	104	66	20 Y	-6	-4
		DAY 8		16MAY2003	8	88	118	72	100	120	74	12	2	2
		DAY 15		22MAY2003	14	84	108	72	100	104	70	16	-4	-2
		DAY 22		29MAY2003	21	92	110	76	106	104	76	14	-6	0
		DAY 29		05JUN2003	28	88	110	70	96	112	70	8	2	0
		FINAL			28	88	110	70	96	112	70	8	2	0
	E0028046	SCREEN		17JUN2003	-8	78	120	78	82	115	74	4	-5	-4
		DAY 1		25JUN2003	1	62	100	78	86	100	78	24 Y	0	0
		BASELINE				62	100	78	86	100	78	24 Y	0	0
	E0028048	SCREEN		11JUL2003	-6	64	98	60	66	98	70	2	0	10
		DAY 1		17JUL2003	1	64	96	58	76	92	62	12	-4	4
		BASELINE				64	96	58	76	92	62	12	-4	4
		DAY 8		24JUL2003	8	68	98	64	78	98	76	10	0	12
		DAY 15		31JUL2003	15	70	100	70	76	98	70	6	-2	0
		DAY 22		06AUG2003	21	68	90 L	58	80	90 L	64	12	0	6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	DAY 29	14AUG2003	29	58	86 L	58	72	94	58	14	8	0
		DAY 36	21AUG2003	36	64	92	64	84	98	78	20 Y	6	14
		DAY 43	29AUG2003	44	68	115	60	88	110	62	20 Y	-5	2
		DAY 57	09SEP2003	55	72	80 L	40 L	88	84 L	64	16	4	24
		FINAL		55	72	80 L	40 L	88	84 L	64	16	4	24
	E0029008	SCREEN	09DEC2002	-7	64	96	56	80	98	56	16	2	0
		DAY 1	16DEC2002	1	68	96	58	72	92	60	4	-4	2
		BASELINE			68	96	58	72	92	60	4	-4	2
		DAY 8	23DEC2002	8	72	94	56	76	90 L	50 L	4	-4	-6
		FINAL		8	72	94	56	76	90 L	50 L	4	-4	-6
	E0029011	SCREEN	14JAN2003	-8	68	104	68	76	110	70	8	6	2
		DAY 1	21JAN2003	-1	80	120	70	76	126	76	-4	6	6
		BASELINE			80	120	70	76	126	76	-4	6	6
		DAY 8	28JAN2003	7	72	132	74	92	130	70	20 Y	-2	-4
		DAY 15	04FEB2003	14	84	140	70	112	140	82	28 Y	0	12
		DAY 22	13FEB2003	23	72	138	90	100	120	90	28 Y	-18	0
		FINAL		23	72	138	90	100	120	90	28 Y	-18	0
	E0030014	SCREEN	12FEB2003	-9	60	88 L	60	80	88 L	60	20 Y	0	0
		DAY 1	21FEB2003	1	60	102	68	64	98	64	4	-4	-4
		BASELINE			60	102	68	64	98	64	4	-4	-4
		DAY 8	28FEB2003	8	60	106	68	68	100	66	8	-6	-2
		DAY 15	07MAR2003	15	60	104	72	72	100	68	12	-4	-4
		DAY 22	14MAR2003	22	68	108	70	80	108	70	12	0	0
		DAY 29	21MAR2003	29	72	108	70	80	104	78	8	-4	8
		DAY 36	27MAR2003	35	60	100	64	88	104	74	28 Y	4	10
		DAY 43	04APR2003	43	60	100	62	72	100	64	12	0	2
		DAY 50	11APR2003	50	60	102	70	72	106	70	12	4	0
		DAY 57	22APR2003	61	60	100	74	84	104	70	24 Y	4	-4
		FINAL		61	60	100	74	84	104	70	24 Y	4	-4

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	SCREEN		13MAY2003	-16	68	134	62	80	128	78	12	-6	16
		DAY 1		29MAY2003	1	60	120	66	80	126	74	20 Y	6	8
		BASELINE				60	120	66	80	126	74	20 Y	6	8
		DAY 8		05JUN2003	8	72	130	70	88	130	76	16	0	6
		DAY 15		12JUN2003	15	80	120	76	88	120	80	8	0	4
		DAY 22		17JUN2003	20	60	128	90	80	124	90	20 Y	-4	0
		DAY 29		24JUN2003	27	68	130	60	88	126	66	20 Y	-4	6
		FINAL			27	68	130	60	88	126	66	20 Y	-4	6
	E0030025	SCREEN		24JUN2003	-17	60	130	70	60	130	70	0	0	0
		DAY 1		11JUL2003	1	48 L	118	74	64	120	80	16	2	6
		BASELINE				48 L	118	74	64	120	80	16	2	6
		DAY 8		18JUL2003	8	60	118	80	64	120	84	4	2	4
		DAY 15		25JUL2003	15	56	112	84	64	118	84	8	6	0
		DAY 22		31JUL2003	21	60	114	78	64	110	80	4	-4	2
		DAY 29		11AUG2003	32	68	118	86	72	112	88	4	-6	2
		DAY 36		19AUG2003	40	68	112	80	72	114	84	4	2	4
		FINAL			40	68	112	80	72	114	84	4	2	4
	E0034004	SCREEN		11APR2003	-10	64	118	86	62	110	78	-2	-8	-8
		DAY 1		21APR2003	1	76	145	95	80	130	100	4	-15	5
		BASELINE				76	145	95	80	130	100	4	-15	5
		DAY 8		30APR2003	10	76	135	90	88	110	80	12	-25 Y	-10
		DAY 15		05MAY2003	15	76	122	82	88	126	80	12	4	-2
		DAY 22		13MAY2003	23	92	128	88	96	124	82	4	-4	-6
		DAY 29		19MAY2003	29	96	128	86	100	122	78	4	-6	-8
		DAY 29	*	23MAY2003	33	92	135	75	108	130	80	16	-5	5
		DAY 43		02JUN2003	43	92	122	84	92	126	86	0	4	2
		DAY 50		09JUN2003	50	88	135	90	100	120	80	12	-15	-10
		DAY 57		16JUN2003	57	80	110	70	66	105	75	-14	-5	5
		FINAL			57	80	110	70	66	105	75	-14	-5	5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	SCREEN	10JUN2003	-7	64	102	64	69	111	69	5	9	5
		DAY 1	17JUN2003	1	71	100	66	92	127	74	21 Y	27	8
		BASELINE			71	100	66	92	127	74	21 Y	27	8
		DAY 8	24JUN2003	8	68	114	75	93	104	77	25 Y	-10	2
		DAY 15	30JUN2003	14	92	115	76	108	115	74	16	0	-2
		DAY 22	08JUL2003	22	90	108	69	105	113	75	15	5	6
		DAY 29	14JUL2003	28	96	121	74	105	110	70	9	-11	-4
		FINAL		28	96	121	74	105	110	70	9	-11	-4
	E0036006	SCREEN	24JUN2003	-9	89	127	79	103	128	91	14	1	12
		DAY 1	03JUL2003	1	104	124	80	121 H	133	88	17	9	8
		BASELINE			104	124	80	121 H	133	88	17	9	8
		DAY 8	10JUL2003	8	91	128	80	98	139	93	7	11	13
		DAY 15	18JUL2003	16	120	135	84	104	136	88	-16	1	4
		DAY 22	25JUL2003	23	112	135	92	125 H	137	97	13	2	5
		DAY 29	31JUL2003	29	113	131	86	128 H	131	87	15	0	1
		DAY 36	07AUG2003	36	98	131	84	120	129	90	22 Y	-2	6
		DAY 43	13AUG2003	42	96	139	89	107	132	94	11	-7	5
		DAY 50	20AUG2003	49	111	138	83	128 H	139	85	17	1	2
		DAY 57	27AUG2003	56	96	129	86	116	131	87	20 Y	2	1
		FINAL		56	96	129	86	116	131	87	20 Y	2	1
	E0039028	SCREEN	03MAR2003	-21	70	140	90	78	142	92	8	2	2
		DAY 1	24MAR2003	1	76	134	98	80	150	100	4	16	2
		BASELINE			76	134	98	80	150	100	4	16	2
		DAY 8	31MAR2003	8	86	144	96	100	148	100	14	4	4
		DAY 15	07APR2003	15	80	134	96	96	148	98	16	14	2
		DAY 22	14APR2003	22	84	138	100	92	150	104	8	12	4
		DAY 29	21APR2003	29	80	130	90	92	140	98	12	10	8
		DAY 36	28APR2003	36	80	130	88	72	148	102	-8	18	14
		DAY 43	05MAY2003	43	80	142	100	80	138	102	0	-4	2
		DAY 50	16MAY2003	54	96	136	104	92	144	118 H	-4	8	14

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039028	FINAL		54	96	136	104	92	144	118 H	-4	8	14
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	SCREEN	22OCT2002	-7	60	130	90	68	142	80	8	12	-10
		DAY 1	29OCT2002	1	88	120	90	88	120	90	0	0	0
		BASELINE			88	120	90	88	120	90	0	0	0
		DAY 15	14NOV2002	17	84	130	80	88	140	90	4	10	10
		DAY 22	19NOV2002	22	96	130	90	94	130	88	-2	0	-2
		DAY 29	26NOV2002	29	80	140	84	84	130	82	4	-10	-2
		DAY 36	03DEC2002	36	84	120	80	88	124	84	4	4	4
		DAY 43	10DEC2002	43	84	130	80	96	122	90	12	-8	10
		DAY 50	17DEC2002	50	76	114	84	88	94	64	12	-20 Y	-20 Y
		DAY 57	23DEC2002	56	74	118	70	70	120	78	-4	2	8
		FINAL		56	74	118	70	70	120	78	-4	2	8
	E0009010	SCREEN	27FEB2003	-14	60	120	70	90	130	100	30 Y	10	30
		DAY 1	13MAR2003	1	74	120	78	78	120	82	4	0	4
		BASELINE			74	120	78	78	120	82	4	0	4
		DAY 8	20MAR2003	8	80	130	92	82	130	90	2	0	-2
		DAY 15	26MAR2003	14	100	122	70	88	118	72	-12	-4	2
		DAY 22	02APR2003	21	88	120	74	86	122	76	-2	2	2
		FINAL		21	88	120	74	86	122	76	-2	2	2
	E0009011	SCREEN	28APR2003	-8	80	130	76	80	120	82	0	-10	6
		DAY 1	06MAY2003	1	74	110	60	76	116	64	2	6	4
		BASELINE			74	110	60	76	116	64	2	6	4
		DAY 8	12MAY2003	7	88	130	70	90	126	70	2	-4	0
		DAY 15	19MAY2003	14	86	110	70	90	110	74	4	0	4
		DAY 22	27MAY2003	22	100	120	68	98	118	70	-2	-2	2
		DAY 29	03JUN2003	29	76	100	60	76	100	60	0	0	0
		DAY 36	10JUN2003	36	86	100	60	90	90 L	60	4	-10	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0009011	DAY 43	17JUN2003	43	80	104	62	78	102	64	-2	-2	2
		DAY 50	24JUN2003	50	60	104	66	60	102	64	0	-2	-2
		DAY 57	03JUL2003	59	60	90 L	60	62	98	64	2	8	4
		FINAL		59	60	90 L	60	62	98	64	2	8	4
	E0019008	SCREEN	06NOV2002	-15	56	100	70	84	110	72	28 Y	10	2
		DAY 1	21NOV2002	1	72	110	82	76	98	72	4	-12	-10
		BASELINE			72	110	82	76	98	72	4	-12	-10
		DAY 8	27NOV2002	7	92	110	85	100	125	80	8	15	-5
		DAY 15	05DEC2002	15	76	110	75	84	112	80	8	2	5
		DAY 22	12DEC2002	22	84	112	80	100	102	68	16	-10	-12
		DAY 29	19DEC2002	29	72	102	68	96	100	78	24 Y	-2	10
		FINAL		29	72	102	68	96	100	78	24 Y	-2	10
	E0019035	SCREEN	11MAR2003	-7	80	126	86	88	122	80	8	-4	-6
		DAY 1	18MAR2003	1	82	134	80	86	126	78	4	-8	-2
		BASELINE			82	134	80	86	126	78	4	-8	-2
		DAY 8	27MAR2003	10	78	140	74	80	130	74	2	-10	0
		DAY 15	03APR2003	17	84	130	70	104	130	75	20 Y	0	5
		DAY 22	10APR2003	24	88	130	90	92	130	80	4	0	-10
		DAY 29	17APR2003	31	88	135	85	96	135	90	8	0	5
		FINAL		31	88	135	85	96	135	90	8	0	5
	E0019042	SCREEN	28MAY2003	-7	72	118	70	80	130	80	8	12	10
		DAY 1	04JUN2003	1	66	124	76	92	118	82	26 Y	-6	6
		BASELINE			66	124	76	92	118	82	26 Y	-6	6
		DAY 8	12JUN2003	9	76	122	62	96	120	62	20 Y	-2	0
		DAY 15	19JUN2003	16	66	118	62	80	122	74	14	4	12
		FINAL		16	66	118	62	80	122	74	14	4	12
	E0022044	SCREEN	11MAR2003	-7	74	116	82	76	110	72	2	-6	-10
		DAY 1	18MAR2003	1	80	102	70	84	104	76	4	2	6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0022044	BASELINE			80	102	70	84	104	76	4	2	6
		DAY 8	25MAR2003	8	84	100	68	96	98	70	12	-2	2
		DAY 15	01APR2003	15	92	110	80	100	112	90	8	2	10
		DAY 22	08APR2003	22	88	108	64	100	118	70	12	10	6
		DAY 29	15APR2003	29	88	112	74	96	116	84	8	4	10
		DAY 36	22APR2003	36	100	122	88	120	112	88	20 Y	-10	0
		DAY 43	29APR2003	43	104	122	78	116	102	82	12	-20 Y	4
		DAY 50	06MAY2003	50	96	126	80	104	120	84	8	-6	4
		DAY 57	12MAY2003	56	88	130	92	84	132	94	-4	2	2
		FINAL		56	88	130	92	84	132	94	-4	2	2
	E0023007	SCREEN	07JAN2003	-7	68	110	76	80	112	78	12	2	2
		DAY 1	14JAN2003	1	74	116	80	80	110	90	6	-6	10
		BASELINE			74	116	80	80	110	90	6	-6	10
		DAY 8	21JAN2003	8	80	110	82	80	112	80	0	2	-2
		DAY 15	28JAN2003	15	97	136	88	88	128	86	-9	-8	-2
		DAY 22	07FEB2003	25	97	140	95	88	130	86	-9	-10	-9
		DAY 29	11FEB2003	29	97	119	77	126 H	136	93	29 Y	17	16
		DAY 36	18FEB2003	36	80	132	92	82	124	78	2	-8	-14
		DAY 43	25FEB2003	43	80	130	85	80	129	85	0	-1	0
		DAY 50	04MAR2003	50	76	133	94	76	145	83	0	12	-11
		DAY 57	11MAR2003	57	52	100	70	60	104	76	8	4	6
		FINAL		57	52	100	70	60	104	76	8	4	6
	E0023011	SCREEN	28JAN2003	-7	68	110	67	72	108	70	4	-2	3
		DAY 1	04FEB2003	1	58	118	72	58	120	70	0	2	-2
		BASELINE			58	118	72	58	120	70	0	2	-2
		DAY 8	11FEB2003	8	88	112	78	88	108	80	0	-4	2
		DAY 15	21FEB2003	18	80	104	78	80	108	82	0	4	4
		DAY 22	25FEB2003	22	77	127	80	87	148	101	10	21	21
		DAY 29	04MAR2003	29	70	126	78	80	140	80	10	14	2
		DAY 36	11MAR2003	36	64	124	74	84	128	70	20 Y	4	-4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	DAY 43	18MAR2003	43	76	120	70	80	120	76	4	0	6
		DAY 50	27MAR2003	52	78	141	94	78	136	90	0	-5	-4
		DAY 57	01APR2003	57	89	114	76	90	121	79	1	7	3
		FINAL		57	89	114	76	90	121	79	1	7	3
	E0023019	SCREEN	21MAR2003	-17	78	145	77	80	138	76	2	-7	-1
		DAY 1	07APR2003	1	100	127	87	123 H	141	98	23 Y	14	11
		BASELINE			100	127	87	123 H	141	98	23 Y	14	11
		DAY 8	15APR2003	9	95	134	78	123 H	154	89	28 Y	20	11
		DAY 15	22APR2003	16	104	140	88	155 H	151	79	51 Y	11	-9
		DAY 22	02MAY2003	26	72	117	79	99	144	90	27 Y	27	11
		DAY 29	06MAY2003	30	95	126	88	117	130	80	22 Y	4	-8
		DAY 36	13MAY2003	37	86	129	88	95	137	86	9	8	-2
		DAY 43	20MAY2003	44	84	132	86	107	137	88	23 Y	5	2
		DAY 50	29MAY2003	53	97	121	79	113	147	79	16	26	0
		DAY 57	03JUN2003	58	93	129	90	95	131	92	2	2	2
		FINAL		58	93	129	90	95	131	92	2	2	2
	E0023022	SCREEN	10APR2003	-8	80	115	71	84	110	70	4	-5	-1
		DAY 1	18APR2003	1	64	114	67	119	120	80	55 Y	6	13
		BASELINE			64	114	67	119	120	80	55 Y	6	13
		DAY 8	25APR2003	8	88	108	80	92	106	76	4	-2	-4
		DAY 15	01MAY2003	14	100	126	65	93	105	57	-7	-21 Y	-8
		DAY 22	08MAY2003	21	100	131	70	155 H	141	88	55 Y	10	18
		DAY 29	15MAY2003	28	103	108	73	96	112	72	-7	4	-1
		DAY 36	22MAY2003	35	73	126	76	115	108	71	42 Y	-18	-5
		DAY 43	30MAY2003	43	77	108	65	109	108	69	32 Y	0	4
		DAY 50	06JUN2003	50	104	112	63	123 H	124	65	19	12	2
		DAY 57	12JUN2003	56	72	122	84	76	118	80	4	-4	-4
		FINAL		56	72	122	84	76	118	80	4	-4	-4
	E0023023	SCREEN	17APR2003	-8	84	89 L	65	88	91	67	4	2	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	DAY 1	25APR2003	1	80	108	80	86	110	82	6	2	2
		BASELINE			80	108	80	86	110	82	6	2	2
		DAY 8	01MAY2003	7	89	110	68	86	104	53	-3	-6	-15
		FINAL		7	89	110	68	86	104	53	-3	-6	-15
	E0023043	SCREEN	07JUL2003	-7	100	138	91	96	143	97	-4	5	6
		DAY 1	14JUL2003	1	102	104	57	98	97	57	-4	-7	0
		BASELINE			102	104	57	98	97	57	-4	-7	0
		DAY 8	23JUL2003	10	100	105	53	111	98	48 L	11	-7	-5
		DAY 15	28JUL2003	15	100	97	62	98	96	60	-2	-1	-2
		DAY 22	05AUG2003	23	111	98	67	113	83 L	56	2	-15	-11
		DAY 29	12AUG2003	30	105	125	89	105	101	62	0	-24 Y	-27 Y
		DAY 36	19AUG2003	37	102	130	81	115	130	81	13	0	0
		DAY 43	26AUG2003	44	96	112	70	90	110	74	-6	-2	4
		DAY 50	02SEP2003	51	113	113	66	119	93	59	6	-20 Y	-7
		DAY 57	09SEP2003	58	102	100	68	100	98	70	-2	-2	2
		FINAL		58	102	100	68	100	98	70	-2	-2	2
	E0026003	SCREEN	25NOV2002	-9	51	131	72	77	122	80	26 Y	-9	8
		DAY 1	04DEC2002	1	91	129	92	108	122	85	17	-7	-7
		BASELINE			91	129	92	108	122	85	17	-7	-7
		DAY 8	12DEC2002	9	119	122	94	120	123	98	1	1	4
		DAY 15	19DEC2002	16	100	129	98	107	135	84	7	6	-14
		DAY 22	26DEC2002	23	100	119	79	100	116	86	0	-3	7
		DAY 29	02JAN2003	30	98	106	79	100	128	83	2	22	4
		DAY 36	09JAN2003	37	78	138	91	80	134	96	2	-4	5
		DAY 43	16JAN2003	44	110	123	87	110	114	79	0	-9	-8
		DAY 50	23JAN2003	51	110	107	78	111	94	64	1	-13	-14
		DAY 57	03FEB2003	62	98	129	95	101	132	99	3	3	4
		FINAL		62	98	129	95	101	132	99	3	3	4
	E0026005	SCREEN	23DEC2002	-7	82	168	80	70	146	76	-12	-22 Y	-4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0026005	DAY 1	30DEC2002	1	60	150	100	60	152	100	0	2	0
		BASELINE			60	150	100	60	152	100	0	2	0
		DAY 8	06JAN2003	8	68	144	98	68	137	100	0	-7	2
		FINAL		8	68	144	98	68	137	100	0	-7	2
	E0026009	SCREEN	10JAN2003	-5	63	113	66	68	114	73	5	1	7
		DAY 1	15JAN2003	1	119	131	87	118	114	88	-1	-17	1
		BASELINE			119	131	87	118	114	88	-1	-17	1
		DAY 8	21JAN2003	7	70	97	57	90	107	63	20 Y	10	6
		FINAL		7	70	97	57	90	107	63	20 Y	10	6
	E0028032	SCREEN	13MAR2003	-12	66	122	82	72	118	78	6	-4	-4
		DAY 1	25MAR2003	1	56	100	76	80	94	82	24 Y	-6	6
		BASELINE			56	100	76	80	94	82	24 Y	-6	6
		DAY 8	01APR2003	8	68	122	70	76	118	74	8	-4	4
		DAY 15	08APR2003	15	68	112	78	84	120	86	16	8	8
		DAY 22	15APR2003	22	64	100	78	78	104	90	14	4	12
		DAY 29	22APR2003	29	64	120	82	76	118	84	12	-2	2
		DAY 36	30APR2003	37	70	108	72	70	100	80	0	-8	8
		DAY 43	06MAY2003	43	64	110	70	76	112	70	12	2	0
		DAY 50	13MAY2003	50	76	134	86	88	128	84	12	-6	-2
		DAY 57	06JUN2003	74	80	120	78	76	122	80	-4	2	2
		FINAL		74	80	120	78	76	122	80	-4	2	2
	E0029003	SCREEN	28OCT2002	-7	72	92	60	76	90 L	64	4	-2	4
		DAY 1	04NOV2002	1	80	100	60	92	110	64	12	10	4
		BASELINE			80	100	60	92	110	64	12	10	4
		DAY 8	11NOV2002	8	68	90 L	54	80	104	70	12	14	16
		DAY 15	18NOV2002	15	80	110	60	84	90 L	60	4	-20 Y	0
		DAY 22	25NOV2002	22	84	110	60	92	110	70	8	0	10
		DAY 29	02DEC2002	29	84	114	74	92	120	78	8	6	4
		DAY 36	09DEC2002	36	80	120	76	92	124	76	12	4	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 43	16DEC2002	43	84	114	70	92	110	90	8	-4	20
		DAY 50	23DEC2002	50	80	112	80	80	118	76	0	6	-4
		DAY 57	30DEC2002	57	68	100	60	88	98	80	20 Y	-2	20
		FINAL		57	68	100	60	88	98	80	20 Y	-2	20
	E0034009	SCREEN	10JUN2003	-9	52	130	80	72	120	75	20 Y	-10	-5
		DAY 1	19JUN2003	1	64	130	90	72	120	85	8	-10	-5
		BASELINE			64	130	90	72	120	85	8	-10	-5
		DAY 8	27JUN2003	9	80	115	90	88	120	80	8	5	-10
		DAY 15	03JUL2003	15	80	135	85	96	130	90	16	-5	5
		DAY 22	10JUL2003	22	80	130	90	96	135	95	16	5	5
		DAY 29	18JUL2003	30	68	140	85	76	150	100	8	10	15
		DAY 36	25JUL2003	37	72	150	100	88	145	95	16	-5	-5
		DAY 43	31JUL2003	43	64	150	100	81	145	95	17	-5	-5
		DAY 50	07AUG2003	50	68	130	70	88	125	85	20 Y	-5	15
		DAY 57	18AUG2003	61	76	135	80	88	142	90	12	7	10
		FINAL		61	76	135	80	88	142	90	12	7	10
	E0037007	SCREEN	04APR2003	-7	68	100	70	84	105	70	16	5	0
		DAY 1	11APR2003	1	56	90 L	70	56	90 L	70	0	0	0
		BASELINE			56	90 L	70	56	90 L	70	0	0	0
		DAY 8	17APR2003	7	80	92	70	80	90 L	70	0	-2	0
		FINAL		7	80	92	70	80	90 L	70	0	-2	0
	E0039019	SCREEN	20JAN2003	-17	72	132	96	80	124	88	8	-8	-8
		DAY 1	06FEB2003	1	88	126	92	96	124	96	8	-2	4
		BASELINE			88	126	92	96	124	96	8	-2	4
		DAY 8	13FEB2003	8	66	134	92	62	124	94	-4	-10	2
		DAY 15	20FEB2003	15	83	118	90	96	114	86	13	-4	-4
		DAY 22	27FEB2003	22	88	102	78	96	106	78	8	4	0
		DAY 29	07MAR2003	30	84	98	50 L	88	100	60	4	2	10
		DAY 36	13MAR2003	36	96	116	90	100	110	88	4	-6	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	DAY 43	20MAR2003	43	80	110	84	88	108	86	8	-2	2
		DAY 50	27MAR2003	50	90	110	80	78	108	84	-12	-2	4
		DAY 57	03APR2003	57	90	118	88	94	112	90	4	-6	2
		FINAL		57	90	118	88	94	112	90	4	-6	2
	E0039043	SCREEN	25APR2003	-13	62	120	74	70	118	70	8	-2	-4
		DAY 1	08MAY2003	1	78	134	76	95	118	86	17	-16	10
		BASELINE			78	134	76	95	118	86	17	-16	10
		DAY 8	15MAY2003	8	66	120	80	90	108	82	24 Y	-12	2
		DAY 15	23MAY2003	16	85	128	88	96	118	88	11	-10	0
		DAY 22	29MAY2003	22	74	122	76	92	106	60	18	-16	-16
		DAY 29	05JUN2003	29	80	124	78	88	120	86	8	-4	8
		DAY 36	13JUN2003	37	80	144	84	88	126	90	8	-18	6
		FINAL		37	80	144	84	88	126	90	8	-18	6
PLACEBO (BIPOLAR I)	E0005017	SCREEN	11DEC2002	-19	80	130	96	80	124	94	0	-6	-2
		DAY 1	30DEC2002	1	80	130	94	80	124	94	0	-6	0
		BASELINE			80	130	94	80	124	94	0	-6	0
		DAY 8	06JAN2003	8	68	124	94	68	120	70	0	-4	-24 Y
		DAY 15	14JAN2003	16	64	120	90	68	120	90	4	0	0
		DAY 22	22JAN2003	24	72	130	94	72	126	90	0	-4	-4
		DAY 29	30JAN2003	32	76	130	94	76	130	90	0	0	-4
		DAY 36	04FEB2003	37	60	124	84	60	122	82	0	-2	-2
		DAY 43	13FEB2003	46	60	130	86	60	120	86	0	-10	0
		DAY 50	20FEB2003	53	60	120	76	60	116	70	0	-4	-6
		DAY 57	04MAR2003	65	60	120	80	60	120	78	0	0	-2
		FINAL		65	60	120	80	60	120	78	0	0	-2
	E0005026	SCREEN	26FEB2003	-8	72	96	60	68	96	60	-4	0	0
		DAY 1	06MAR2003	1	64	94	60	60	96	66	-4	2	6
		BASELINE			64	94	60	60	96	66	-4	2	6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0005026	DAY 8	13MAR2003	8	76	96	64	80	90 L	60	4	-6	-4
		DAY 15	20MAR2003	15	76	84 L	60	80	84 L	60	4	0	0
		DAY 22	25MAR2003	20	80	90 L	58	80	88 L	58	0	-2	0
		FINAL		20	80	90 L	58	80	88 L	58	0	-2	0
	E0010008	SCREEN	11DEC2002	-7	84	110	68	86	100	64	2	-10	-4
		DAY 1	18DEC2002	1	95	110	66	105	100	70	10	-10	4
		BASELINE			95	110	66	105	100	70	10	-10	4
		DAY 8	26DEC2002	9	72	102	56	80	100	60	8	-2	4
		DAY 15	02JAN2003	16	94	118	70	97	120	70	3	2	0
		DAY 22	08JAN2003	22	80	108	60	89	106	56	9	-2	-4
		DAY 29	15JAN2003	29	88	122	60	102	102	66	14	-20 Y	6
		FINAL		29	88	122	60	102	102	66	14	-20 Y	6
	E0010018	SCREEN	26FEB2003	-21	68	108	74	80	110	80	12	2	6
		DAY 1	19MAR2003	1	68	118	80	85	110	80	17	-8	0
		BASELINE			68	118	80	85	110	80	17	-8	0
		DAY 8	26MAR2003	8	56	100	68	60	100	70	4	0	2
		DAY 15	02APR2003	15	74	110	70	84	124	80	10	14	10
		DAY 22	09APR2003	22	76	104	70	88	108	76	12	4	6
		DAY 29	16APR2003	29	72	104	64	80	104	68	8	0	4
		DAY 36	23APR2003	36	66	106	70	90	110	72	24 Y	4	2
		DAY 43	01MAY2003	44	80	112	80	86	108	74	6	-4	-6
		DAY 57	14MAY2003	57	78	100	70	84	108	70	6	8	0
		FINAL		57	78	100	70	84	108	70	6	8	0
	E0014002	SCREEN	19FEB2003	-7	60	120	74	68	110	72	8	-10	-2
		DAY 1	26FEB2003	1	64	135	78	80	120	80	16	-15	2
		BASELINE			64	135	78	80	120	80	16	-15	2
		DAY 8	04MAR2003	7	64	124	70	80	110	70	16	-14	0
		DAY 15	12MAR2003	15	74	110	78	88	110	80	14	0	2
		DAY 22	20MAR2003	23	76	110	80	86	110	74	10	0	-6
		DAY 29	27MAR2003	30	48 L	112	88	52	108	85	4	-4	-3

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0014002	DAY 43		10APR2003	44	60	110	70	63	120	78	3	10	8
		FINAL			44	60	110	70	63	120	78	3	10	8
	E0014017	SCREEN		17JUN2003	-10	72	110	70	80	112	70	8	2	0
		DAY 1		27JUN2003	1	80	124	70	88	118	76	8	-6	6
		BASELINE				80	124	70	88	118	76	8	-6	6
		DAY 8		02JUL2003	6	84	116	80	84	116	86	0	0	6
		DAY 15		09JUL2003	13	80	126	80	84	120	84	4	-6	4
		DAY 22		16JUL2003	20	76	130	82	88	102	80	12	-28 Y	-2
		DAY 29		23JUL2003	27	76	132	86	98	124	88	22 Y	-8	2
		DAY 29	*	29JUL2003	33	72	120	70	80	120	80	8	0	10
		DAY 36		05AUG2003	40	88	114	70	88	112	80	0	-2	10
		DAY 43		12AUG2003	47	80	122	80	84	110	80	4	-12	0
		DAY 50		19AUG2003	54	84	122	76	84	112	82	0	-10	6
		FINAL			54	84	122	76	84	112	82	0	-10	6
	E0022004	SCREEN		17OCT2002	-11	72	120	82	84	100	70	12	-20 Y	-12
		DAY 1		28OCT2002	1	68	110	78	74	115	72	6	5	-6
		BASELINE				68	110	78	74	115	72	6	5	-6
		DAY 8		04NOV2002	8	70	110	68	78	100	74	8	-10	6
		DAY 15		11NOV2002	15	72	120	80	74	116	72	2	-4	-8
		DAY 22		19NOV2002	23	70	110	78	76	115	78	6	5	0
		DAY 29		26NOV2002	30	74	100	68	72	98	65	-2	-2	-3
		DAY 36		02DEC2002	36	68	110	70	74	115	78	6	5	8
		DAY 43		10DEC2002	44	74	110	66	80	116	68	6	6	2
		DAY 50		16DEC2002	50	76	110	60	78	110	58	2	0	-2
		DAY 57		23DEC2002	57	80	100	60	86	110	72	6	10	12
		FINAL			57	80	100	60	86	110	72	6	10	12
	E0022005	SCREEN		17OCT2002	-22	76	122	82	80	128	106 H	4	6	24
		DAY 1		08NOV2002	1	68	130	80	80	126	94	12	-4	14
		BASELINE				68	130	80	80	126	94	12	-4	14
		DAY 8		15NOV2002	8	66	120	68	78	115	70	12	-5	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0022005	DAY 15	22NOV2002	15	58	125	70	69	110	69	11	-15	-1
		DAY 22	29NOV2002	22	62	120	70	72	115	78	10	-5	8
		DAY 29	06DEC2002	29	74	115	76	80	110	70	6	-5	-6
		DAY 36	13DEC2002	36	78	120	78	82	110	72	4	-10	-6
		DAY 43	20DEC2002	43	68	120	80	74	110	70	6	-10	-10
		DAY 50	27DEC2002	50	70	115	70	74	110	64	4	-5	-6
		DAY 57	03JAN2003	57	72	100	66	76	90 L	72	4	-10	6
		FINAL		57	72	100	66	76	90 L	72	4	-10	6
	E0022015	SCREEN	29NOV2002	-11	86	112	62		116	76		4	14
		DAY 1	10DEC2002	1	76	120	58	88	126	68	12	6	10
		BASELINE			76	120	58	88	126	68	12	6	10
		DAY 8	17DEC2002	8	64	112	66	68	122	76	4	10	10
		DAY 15	26DEC2002	17	64	108	68	68	106	72	4	-2	4
		DAY 22	02JAN2003	24	68	114	60	84	108	78	16	-6	18
		DAY 29	09JAN2003	31	76	112	66	76	110	60	0	-2	-6
		DAY 36	16JAN2003	38	72	106	60	72	118	70	0	12	10
		DAY 43	23JAN2003	45	80	104	56	92	110	66	12	6	10
		DAY 50	30JAN2003	52	76	114	58	88	116	56	12	2	-2
		DAY 57	06FEB2003	59	72	110	66	92	120	78	20 Y	10	12
		FINAL		59	72	110	66	92	120	78	20 Y	10	12
	E0022020	SCREEN	05DEC2002	-7	60	110	58	86	106	80	26 Y	-4	22
		DAY 1	12DEC2002	1	56	102	58	58	98	68	2	-4	10
		BASELINE			56	102	58	58	98	68	2	-4	10
		DAY 8	19DEC2002	8	64	110	70	82	110	64	18	0	-6
		DAY 15	26DEC2002	15	64	110	60	78	112	70	14	2	10
		DAY 22	02JAN2003	22	72	112	64	88	108	68	16	-4	4
		DAY 29	10JAN2003	30	60	94	58	64	102	60	4	8	2
		DAY 36	16JAN2003	36	76	106	48 L	100	104	66	24 Y	-2	18
		DAY 43	23JAN2003	43	76	94	48 L	76	102	64	0	8	16
		FINAL		43	76	94	48 L	76	102	64	0	8	16

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022023	SCREEN	19DEC2002	-6	80	118	72	84	118	76	4	0	4
		DAY 1	24DEC2002	-1	78	122	70	88	120	72	10	-2	2
		BASELINE			78	122	70	88	120	72	10	-2	2
		DAY 8	02JAN2003	9	72	116	70	84	118	84	12	2	14
		DAY 15	09JAN2003	16	72	128	72	80	120	82	8	-8	10
		DAY 22	16JAN2003	23	60	102	68	80	108	70	20 Y	6	2
		DAY 29	23JAN2003	30	68	104	68	88	128	74	20 Y	24	6
		DAY 36	30JAN2003	37	64	102	64	72	104	62	8	2	-2
		DAY 43	06FEB2003	44	72	112	60	76	118	58	4	6	-2
		DAY 50	13FEB2003	51	76	102	62	92	118	80	16	16	18
		DAY 57	20FEB2003	58	72	112	78	88	128	72	16	16	-6
		FINAL		58	72	112	78	88	128	72	16	16	-6
	E0022029	SCREEN	05FEB2003	-14	72	128	66	104	116	70	32 Y	-12	4
		DAY 1	19FEB2003	1	75	134	72	84	118	74	9	-16	2
		BASELINE			75	134	72	84	118	74	9	-16	2
		DAY 8	26FEB2003	8	72	116	64	84	122	74	12	6	10
		DAY 15	03MAR2003	13	69	120	66	90	126	74	21 Y	6	8
		DAY 22	12MAR2003	22	72	110	72	84	126	74	12	16	2
		DAY 29	18MAR2003	28	78	116	64	78	126	70	0	10	6
		DAY 36	26MAR2003	36	63	108	70	90	118	78	27 Y	10	8
		DAY 43	02APR2003	43	66	104	72	84	98	74	18	-6	2
		DAY 50	07APR2003	48	68	126	72	80	124	80	12	-2	8
		DAY 57	14APR2003	55	78	132	78	84	118	82	6	-14	4
		FINAL		55	78	132	78	84	118	82	6	-14	4
	E0022065	SCREEN	30APR2003	-7	64	100	68	68	112	78	4	12	10
		DAY 1	07MAY2003	1	72	94	62	87	96	70	15	2	8
		BASELINE			72	94	62	87	96	70	15	2	8
		DAY 8	14MAY2003	8	76	106	62	92	94	70	16	-12	8
		DAY 15	21MAY2003	15	64	96	62	80	92	64	16	-4	2
		DAY 22	28MAY2003	22	72	92	60	84	94	62	12	2	2
		DAY 29	04JUN2003	29	75	92	60	90	88 L	56	15	-4	-4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0022065	DAY 36		11JUN2003	36	64	104	72	64	92	62	0	-12	-10
		DAY 43		18JUN2003	43	81	104	60	90	98	62	9	-6	2
		DAY 50		25JUN2003	50	69	98	58	78	106	64	9	8	6
		DAY 57		02JUL2003	57	64	110	62	68	108	60	4	-2	-2
		FINAL			57	64	110	62	68	108	60	4	-2	-2
	E0023001	SCREEN		24OCT2002	-22	60	120	76	60	118	78	0	-2	2
		DAY 1		15NOV2002	1	60	128	76	64	130	80	4	2	4
		BASELINE				60	128	76	64	130	80	4	2	4
		DAY 8		22NOV2002	8	60	124	70	68	104	76	8	-20 Y	6
		DAY 15		29NOV2002	15	120	102	66	100	109	67	-20	7	1
		DAY 22		06DEC2002	22	64	128	84	88	112	84	24 Y	-16	0
		DAY 29		16DEC2002	32	72	110	74	66	104	76	-6	-6	2
		DAY 36		23DEC2002	39	65	124	64	71	138	93	6	14	29
		DAY 43		30DEC2002	46	75	131	81	74			-1		
		DAY 50		07JAN2003	54	64	130	84	72	122	76	8	-8	-8
		DAY 57		14JAN2003	61	70	120	84	72	116	80	2	-4	-4
		FINAL			61	70	120	84	72	116	80	2	-4	-4
	E0023028	SCREEN		16MAY2003	-13	99	129	86	79	124	80	-20	-5	-6
		DAY 1		29MAY2003	1	68	122	85	77	116	79	9	-6	-6
		BASELINE				68	122	85	77	116	79	9	-6	-6
		DAY 8		05JUN2003	8	75	136	85	86	95	70	11	-41 Y	-15
		DAY 15		12JUN2003	15	65	118	77	69	104	70	4	-14	-7
		DAY 22		19JUN2003	22	71	115	76	70	108	71	-1	-7	-5
		DAY 29		25JUN2003	28	96	121	80	82	115	79	-14	-6	-1
		DAY 43		09JUL2003	42	84	114	76	82	110	74	-2	-4	-2
		DAY 50		16JUL2003	49	85	115	71	83	112	76	-2	-3	5
		DAY 50	*	21JUL2003	54	80	141	93	74	130	89	-6	-11	-4
		FINAL			54	80	141	93	74	130	89	-6	-11	-4
	E0023033	SCREEN		30MAY2003	-6	75	133	93	78	135	96	3	2	3
		DAY 1		05JUN2003	1	82	146	95	92	136	94	10	-10	-1

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0023033	BASELINE			82	146	95	92	136	94	10	-10	-1
		DAY 8	12JUN2003	8	90	160	98	85	162	108 H	-5	2	10
		FINAL		8	90	160	98	85	162	108 H	-5	2	10
	E0023047	SCREEN	11JUL2003	-7	73	117	75	126 H	115	77	53 Y	-2	2
		DAY 1	18JUL2003	1	61	130	61	89	120	84	28 Y	-10	23
		BASELINE			61	130	61	89	120	84	28 Y	-10	23
		DAY 8	25JUL2003	8	67	119	68	76	143	69	9	24	1
		DAY 15	31JUL2003	14	61	117	71	76	125	81	15	8	10
		DAY 22	08AUG2003	22	85	139	95	87	151	95	2	12	0
		DAY 29	15AUG2003	29	69	143	82	72	148	86	3	5	4
		DAY 36	21AUG2003	35	78	131	85	97	142	80	19	11	-5
		DAY 43	29AUG2003	43	123 H	123	78	104	121	72	-19	-2	-6
		DAY 50	05SEP2003	50	85	129	82	92	121	77	7	-8	-5
		DAY 57	12SEP2003	57	80	138	83	120	118	81	40 Y	-20 Y	-2
		FINAL		57	80	138	83	120	118	81	40 Y	-20 Y	-2
	E0026020	SCREEN	28MAR2003	-4	82	161	84	85	155	67	3	-6	-17
		DAY 1	01APR2003	1	74	116	76	72	131	63	-2	15	-13
		BASELINE			74	116	76	72	131	63	-2	15	-13
		DAY 8	08APR2003	8	87	115	67	90	131	61	3	16	-6
		DAY 15	15APR2003	15	73	137	74	72	146	63	-1	9	-11
		DAY 22	22APR2003	22	70	160	71	78	110	74	8	-50 Y	3
		FINAL		22	70	160	71	78	110	74	8	-50 Y	3
	E0028001	SCREEN	07OCT2002	-3	72	110	80	72	118	80	0	8	0
		DAY 1	10OCT2002	1	74	128	88	73	122	82	-1	-6	-6
		BASELINE			74	128	88	73	122	82	-1	-6	-6
		DAY 8	16OCT2002	7	70	130	90	72	130	90	2	0	0
		DAY 15	23OCT2002	14	72	136	90	82	140	90	10	4	0
		DAY 22	29OCT2002	20	70	128	80	72	122	90	2	-6	10
		DAY 29	05NOV2002	27	74	130	102	88	140	110 H	14	10	8
		DAY 36	12NOV2002	34	70	122	88	78	126	88	8	4	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0028001	DAY 43	19NOV2002	41	78	134	94	84	150	104	6	16	10
		DAY 50	26NOV2002	48	82	120	92	92	118	98	10	-2	6
		DAY 57	03DEC2002	55	90	138	98	94	116	96	4	-22 Y	-2
		FINAL		55	90	138	98	94	116	96	4	-22 Y	-2
	E0028005	SCREEN	30SEP2002	-3	60	90 L	70	60	90 L	70	0	0	0
		DAY 1	03OCT2002	1	68	90 L	60	68	98	70	0	8	10
		BASELINE			68	90 L	60	68	98	70	0	8	10
		DAY 8	11OCT2002	9	61	98	70	68	100	70	7	2	0
		DAY 29	31OCT2002	29	58	98	62	62	96	68	4	-2	6
		FINAL		29	58	98	62	62	96	68	4	-2	6
	E0028011	SCREEN	25NOV2002	-10	76	130	82	80	130	70	4	0	-12
		DAY 1	05DEC2002	1	72	136	78	88	128	80	16	-8	2
		BASELINE			72	136	78	88	128	80	16	-8	2
		DAY 8	12DEC2002	8	74	136	86	86	122	90	12	-14	4
		DAY 15	19DEC2002	15	68	110	70	76	118	80	8	8	10
		DAY 22	26DEC2002	22	70	122	88	78	118	90	8	-4	2
		DAY 29	02JAN2003	29	72	128	82	80	118	78	8	-10	-4
		DAY 36	09JAN2003	36	78	116	88	84	112	90	6	-4	2
		DAY 43	16JAN2003	43	66	130	80	86	120	90	20 Y	-10	10
		DAY 50	23JAN2003	50	76	118	86	94	124	98	18	6	12
		DAY 57	30JAN2003	57	82	132	76	98	128	84	16	-4	8
		FINAL		57	82	132	76	98	128	84	16	-4	8
	E0028030	SCREEN	26FEB2003	-6	60	122	82	84	120	80	24 Y	-2	-2
		DAY 1	04MAR2003	1	56	118	86	76	114	92	20 Y	-4	6
		BASELINE			56	118	86	76	114	92	20 Y	-4	6
		DAY 8	11MAR2003	8	74	100	78	70	106	94	-4	6	16
		DAY 15	18MAR2003	15	80	118	76	88	112	78	8	-6	2
		DAY 22	25MAR2003	22	84	116	80	80	112	78	-4	-4	-2
		DAY 29	01APR2003	29	68	112	72	92	106	74	24 Y	-6	2
		DAY 36	08APR2003	36	64	120	76	80	106	72	16	-14	-4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0028030	DAY 43	17APR2003	45	72	122	72	88	100	72	16	-22 Y	0
		DAY 50	22APR2003	50	60	120	64	84	110	68	24 Y	-10	4
		DAY 57	30APR2003	58	70	110	78	70	110	86	0	0	8
		FINAL		58	70	110	78	70	110	86	0	0	8
	E0028047	SCREEN	08JUL2003	-6	78	170	120 H	74	160	120 H	-4	-10	0
		DAY 1	14JUL2003	1	64	130	100	60	130	100	-4	0	0
		BASELINE			64	130	100	60	130	100	-4	0	0
		DAY 8	21JUL2003	8	68	140	100	72	140	115 H	4	0	15
		DAY 15	29JUL2003	16	66	148	100	78	160	108 H	12	12	8
		DAY 22	05AUG2003	23	62	140	94	62	162	110 H	0	22	16
		DAY 29	12AUG2003	30	61	168	101	60	168	112 H	-1	0	11
		DAY 36	19AUG2003	37	62	160	110 H	78	160	110 H	16	0	0
		DAY 43	26AUG2003	44	60	140	100	60	140	100	0	0	0
		DAY 50	02SEP2003	51	62	150	110 H	62	148	110 H	0	-2	0
		DAY 57	09SEP2003	58	70	162	108 H	66	144	100	-4	-18	-8
		FINAL		58	70	162	108 H	66	144	100	-4	-18	-8
	E0029014	SCREEN	28JAN2003	-7	60	102	60	84	106	62	24 Y	4	2
		DAY 1	04FEB2003	1	60	90 L	60	72	100	50 L	12	10	-10
		BASELINE			60	90 L	60	72	100	50 L	12	10	-10
		DAY 8	11FEB2003	8	60	114	80	72	100	76	12	-14	-4
		DAY 15	18FEB2003	15	64	104	64	68	94	62	4	-10	-2
		DAY 22	25FEB2003	22	68	118	64	64	118	64	-4	0	0
		DAY 29	06MAR2003	31	76	96	58	76	104	64	0	8	6
		DAY 36	11MAR2003	36	68	126	76	76	134	84	8	8	8
		DAY 43	20MAR2003	45	72	138	76	84	122	74	12	-16	-2
		DAY 50	27MAR2003	52	72	120	68	80	110	70	8	-10	2
		DAY 57	01APR2003	57	56	114	70	60	108	64	4	-6	-6
		FINAL		57	56	114	70	60	108	64	4	-6	-6
	E0029039	SCREEN	10JUL2003	-5	60	100	70	60	90 L	70	0	-10	0
		DAY 1	15JUL2003	1	56	100	64	64	90 L	60	8	-10	-4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0029039	BASELINE			56	100	64	64	90 L	60	8	-10	-4
		DAY 8	23JUL2003	9	64	100	70	64	90 L	70	0	-10	0
		DAY 15	28JUL2003	14	88	98	60	84	92	58	-4	-6	-2
		FINAL		14	88	98	60	84	92	58	-4	-6	-2
	E0030009	SCREEN	10JAN2003	-13	72	136	86	80	134	90	8	-2	4
		DAY 1	23JAN2003	1	64	144	90	64	128	94	0	-16	4
		BASELINE			64	144	90	64	128	94	0	-16	4
		DAY 8	29JAN2003	7	60	126	78	72	130	80	12	4	2
		DAY 15	07FEB2003	16	56	126	72	60	122	76	4	-4	4
		DAY 36	27FEB2003	36	64	122	74	64	120	80	0	-2	6
		DAY 43	06MAR2003	43	68	126	80	76	128	80	8	2	0
		DAY 50	12MAR2003	49	68	134	80	76	126	80	8	-8	0
		DAY 57	19MAR2003	56	64	140	80	72	116	80	8	-24 Y	0
		FINAL		56	64	140	80	72	116	80	8	-24 Y	0
	E0030021	SCREEN	13MAY2003	-7	60	100	60	80	100	70	20 Y	0	10
		DAY 1	20MAY2003	1	68	100	64	80	102	70	12	2	6
		BASELINE			68	100	64	80	102	70	12	2	6
		DAY 8	27MAY2003	8	68	98	68	80	100	72	12	2	4
		DAY 15	03JUN2003	15	60	132	74	80	124	70	20 Y	-8	-4
		DAY 22	10JUN2003	22	68	131	70	70	128	71	2	-3	1
		DAY 29	17JUN2003	29	60	111	70	80	108	70	20 Y	-3	0
		FINAL		29	60	111	70	80	108	70	20 Y	-3	0
	E0033010	SCREEN	22JAN2003	-13	72	110	70	84	110	72	12	0	2
		DAY 1	04FEB2003	1	76	110	68	80	96	62	4	-14	-6
		BASELINE			76	110	68	80	96	62	4	-14	-6
		DAY 8	11FEB2003	8	76	112	80	84	110	76	8	-2	-4
		DAY 15	20FEB2003	17	76	104	70	88	100	70	12	-4	0
		DAY 22	27FEB2003	24	68	100	68	72	90 L	68	4	-10	0
		DAY 29	04MAR2003	29	64	110	74	76	100	76	12	-10	2
		DAY 36	14MAR2003	39	76	102	68	76	108	70	0	6	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0033010	DAY 50	26MAR2003	51	60	100	60	76	90 L	68	16	-10	8
		FINAL		51	60	100	60	76	90 L	68	16	-10	8
	E0033014	SCREEN	12MAR2003	-7	76	102	78	80	110	80	4	8	2
		DAY 1	19MAR2003	1	84	110	86	84	100	82	0	-10	-4
		BASELINE			84	110	86	84	100	82	0	-10	-4
		DAY 8	26MAR2003	8	80	100	76	92	90 L	76	12	-10	0
		DAY 15	03APR2003	16	84	90 L	72	92	100	80	8	10	8
		DAY 22	11APR2003	24	88	110	82	92	98	78	4	-12	-4
		DAY 29	16APR2003	29	72	104	82	84	100	86	12	-4	4
		DAY 36	21APR2003	34	72	90 L	74	76	100	80	4	10	6
		FINAL		34	72	90 L	74	76	100	80	4	10	6
	E0037004	SCREEN	06FEB2003	-7	72	130	100	72	130	96	0	0	-4
		DAY 1	13FEB2003	1	72	128	74	68	128	76	-4	0	2
		BASELINE			72	128	74	68	128	76	-4	0	2
		DAY 8	21FEB2003	9	64	127	83	76	119	90	12	-8	7
		DAY 15	27FEB2003	15	80	103	80	76	120	85	-4	17	5
		DAY 22	06MAR2003	22	76	112	68	76	112	70	0	0	2
		DAY 29	13MAR2003	29	70	118	80	78	120	90	8	2	10
		DAY 36	20MAR2003	36	76	120	80	96	120	70	20 Y	0	-10
		DAY 43	28MAR2003	44	64	120	78	80	120	80	16	0	2
		DAY 50	04APR2003	51	68	120	80	80	117	80	12	-3	0
		DAY 57	10APR2003	57	72	120	90	72	120	90	0	0	0
		FINAL		57	72	120	90	72	120	90	0	0	0
	E0041012	SCREEN	05JUN2003	-14	82	126	92	80	130	96	-2	4	4
		DAY 1	19JUN2003	1	82	150	90	86	156	110 H	4	6	20
		BASELINE			82	150	90	86	156	110 H	4	6	20
		DAY 8	26JUN2003	8	88	148	88	90	148	90	2	0	2
		DAY 15	03JUL2003	15	86	148	86	86	148	88	0	0	2
		DAY 22	10JUL2003	22	80	140	80	84	142	78	4	2	-2
		DAY 29	17JUL2003	29	82	138	80	84	136	80	2	-2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0041012	DAY 36	24JUL2003	36	84	132	92	84	130	86	0	-2	-6
		DAY 43	31JUL2003	43	88	134	88	86	132	84	-2	-2	-4
		DAY 50	07AUG2003	50	78	152	94	76	150	90	-2	-2	-4
		DAY 57	14AUG2003	57	76	160	110 H	78	150	112 H	2	-10	2
		FINAL		57	76	160	110 H	78	150	112 H	2	-10	2
PLACEBO (BIPOLAR II)	E0001004	SCREEN	23APR2003	-8	60	90 L	60	60	90 L	60	0	0	0
		DAY 1	01MAY2003	1	60	95	70	65	100	70	5	5	0
		BASELINE			60	95	70	65	100	70	5	5	0
		DAY 8	09MAY2003	9	60	120	70	62	120	75	2	0	5
		DAY 15	16MAY2003	16	62	120	70	65	125	75	3	5	5
		DAY 22	23MAY2003	23	60	110	65	62	110	70	2	0	5
		DAY 29	29MAY2003	29	62	120	75	63	120	80	1	0	5
		DAY 36	06JUN2003	37	62	110	70	63	115	75	1	5	5
		DAY 43	12JUN2003	43	80	110	70	80	100	70	0	-10	0
		DAY 50	20JUN2003	51	62	110	80	64	115	80	2	5	0
		DAY 57	02JUL2003	63	82	98	70	82	98	70	0	0	0
		FINAL		63	82	98	70	82	98	70	0	0	0
	E0005023	SCREEN	28JAN2003	-8	76	106	68	80	108	70	4	2	2
		DAY 1	05FEB2003	1	72	100	70	72	104	74	0	4	4
		BASELINE			72	100	70	72	104	74	0	4	4
		DAY 8	13FEB2003	9	80	100	64	80	100	60	0	0	-4
		DAY 15	20FEB2003	16	96	104	64	100	100	62	4	-4	-2
		DAY 22	27FEB2003	23	72	100	70	72	100	64	0	0	-6
		DAY 29	06MAR2003	30	72	100	70	72	100	70	0	0	0
		DAY 36	13MAR2003	37	80	100	70	80	96	68	0	-4	-2
		DAY 43	18MAR2003	42	80	100	60	80	100	60	0	0	0
		DAY 50	26MAR2003	50	80	100	60	80	90 L	60	0	-10	0
		DAY 57	01APR2003	56	80	90 L	60	80	90 L	60	0	0	0
		FINAL		56	80	90 L	60	80	90 L	60	0	0	0

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0005034	SCREEN		08APR2003	-7	60	95	60	60	107	63	0	12	3
		DAY 1		15APR2003	1	68	100	60	68	100	60	0	0	0
		BASELINE				68	100	60	68	100	60	0	0	0
		DAY 8		23APR2003	9	68	100	70	68	90 L	60	0	-10	-10
		DAY 15		01MAY2003	17	76	118	70	68	122	80	-8	4	10
		DAY 22		06MAY2003	22	68	110	70	68	100	60	0	-10	-10
		DAY 29		13MAY2003	29	64	108	64	64	100	60	0	-8	-4
		DAY 36		22MAY2003	38	60	120	80	60	110	70	0	-10	-10
		DAY 43		28MAY2003	44	60	120	70	60	110	70	0	-10	0
		DAY 50		05JUN2003	52	80	110	70	80	110	70	0	0	0
		DAY 57		09JUN2003	56	80	110	70	74	110	70	-6	0	0
		FINAL			56	80	110	70	74	110	70	-6	0	0
	E0007012	SCREEN		02MAY2003	-14	70	110	70	74	104	68	4	-6	-2
		DAY 1		16MAY2003	1	72	104	60	76	108	66	4	4	6
		BASELINE				72	104	60	76	108	66	4	4	6
		DAY 8		23MAY2003	8	70	94	64	74	100	68	4	6	4
		DAY 15		29MAY2003	14	72	90 L	60	76	96	64	4	6	4
		DAY 22		06JUN2003	22	72	92	60	78	94	64	6	2	4
		DAY 29		13JUN2003	29	68	92	64	72	96	66	4	4	2
		DAY 36		20JUN2003	36	72	106	70	76	110	74	4	4	4
		DAY 43		25JUN2003	41	74	94	68	74	98	64	0	4	-4
		DAY 43	*	01JUL2003	47	70	100	70	74	106	74	4	6	4
		FINAL			47	70	100	70	74	106	74	4	6	4
	E0009008	SCREEN		04FEB2003	-8	66	118	80	70	120	80	4	2	0
		DAY 1		12FEB2003	1	72	130	84	76	128	86	4	-2	2
		BASELINE				72	130	84	76	128	86	4	-2	2
		DAY 8		19FEB2003	8	68	100	60	72	106	72	4	6	12
		DAY 15		25FEB2003	14	78	100	70	80	110	70	2	10	0
		DAY 22		04MAR2003	21	60	120	70	70	120	80	10	0	10
		DAY 29		11MAR2003	28	80	120	84	78	120	80	-2	0	-4
		DAY 36		18MAR2003	35	60	100	64	80	110	80	20 Y	10	16

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0009008	DAY 43	26MAR2003	43	66	100	60	68	110	76	2	10	16
		DAY 50	03APR2003	51	72	100	70	76	106	74	4	6	4
		DAY 57	08APR2003	56	68	100	60	74	100	70	6	0	10
		FINAL		56	68	100	60	74	100	70	6	0	10
	E0014001	SCREEN	18FEB2003	-8	72	95	63	75	92	65	3	-3	2
		DAY 1	26FEB2003	1	68	100	68	69	97	72	1	-3	4
		BASELINE			68	100	68	69	97	72	1	-3	4
		DAY 8	05MAR2003	8	72	90 L	65	75	100	67	3	10	2
		DAY 15	12MAR2003	15	96	96	60	100	94	62	4	-2	2
		DAY 22	19MAR2003	22	84	100	66	92	90 L	66	8	-10	0
		DAY 29	25MAR2003	28	84	105	70	88	95	63	4	-10	-7
		DAY 36	01APR2003	35	80	100	70	82	105	68	2	5	-2
		FINAL		35	80	100	70	82	105	68	2	5	-2
	E0014014	SCREEN	03JUN2003	-7	60	115	76	62	110	70	2	-5	-6
		DAY 1	10JUN2003	1	54	110	74	56	114	74	2	4	0
		BASELINE			54	110	74	56	114	74	2	4	0
		DAY 8	18JUN2003	9	56	115	78	60	120	76	4	5	-2
		DAY 15	24JUN2003	15	52	112	68	56	108	68	4	-4	0
		DAY 22	03JUL2003	24	48 L	128	90	50	126	87	2	-2	-3
		DAY 29	10JUL2003	31	60	120	77	63	123	78	3	3	1
		DAY 36	18JUL2003	39	52	112	68	56	110	70	4	-2	2
		DAY 50	30JUL2003	51	64	122	72	66	120	72	2	-2	0
		DAY 57	06AUG2003	58	60	126	74	64	124	72	4	-2	-2
		FINAL		58	60	126	74	64	124	72	4	-2	-2
	E0019038	SCREEN	10APR2003	-14	60	105	60	64	110	65	4	5	5
		DAY 1	24APR2003	1	60	105	65	66	108	65	6	3	0
		BASELINE			60	105	65	66	108	65	6	3	0
		DAY 8	01MAY2003	8	56	120	70	76	118	78	20 Y	-2	8
		DAY 15	07MAY2003	14	60	110	60	66	105	60	6	-5	0
		DAY 22	14MAY2003	21	62	112	58	72	108	70	10	-4	12

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0019038	DAY 29	21MAY2003	28	60	110	65	64	115	70	4	5	5
		DAY 36	28MAY2003	35	64	105	65	64	110	70	0	5	5
		DAY 43	04JUN2003	42	62	118	50 L	68	82 L	60	6	-36 Y	10
		DAY 50	11JUN2003	49	60	110	65	64	120	70	4	10	5
		DAY 57	18JUN2003	56	60	104	60	72	110	68	12	6	8
		FINAL		56	60	104	60	72	110	68	12	6	8
	E0019046	SCREEN	19JUN2003	-7	60	110	70	68	110	70	8	0	0
		DAY 1	26JUN2003	1	64	102	70	60	104	78	-4	2	8
		BASELINE			64	102	70	60	104	78	-4	2	8
		DAY 8	03JUL2003	8	68	98	68	60	100	80	-8	2	12
		DAY 15	10JUL2003	15	60	102	94	80	100	82	20 Y	-2	-12
		DAY 22	17JUL2003	22	60	100	75	68	95	70	8	-5	-5
		DAY 29	24JUL2003	29	64	94	76	80	94	76	16	0	0
		DAY 36	30JUL2003	35	64	100	70	70	95	70	6	-5	0
		DAY 50	14AUG2003	50	64	105	75	70	95	75	6	-10	0
		DAY 57	21AUG2003	57	68	112	76	64	100	74	-4	-12	-2
		FINAL		57	68	112	76	64	100	74	-4	-12	-2
	E0019047	SCREEN	26JUN2003	-12	72	112	72	76	116	76	4	4	4
		DAY 1	08JUL2003	1	68	118	64	84	116	82	16	-2	18
		BASELINE			68	118	64	84	116	82	16	-2	18
		DAY 8	17JUL2003	10	68	120	70	82	118	75	14	-2	5
		DAY 15	24JUL2003	17	80	122	68	100	118	82	20 Y	-4	14
		DAY 22	31JUL2003	24	76	118	64	100	116	76	24 Y	-2	12
		DAY 29	07AUG2003	31	88	118	74	100	124	76	12	6	2
		DAY 36	14AUG2003	38	76	116	60	84	122	78	8	6	18
		DAY 43	21AUG2003	45	80	112	60	88	110	60	8	-2	0
		DAY 50	28AUG2003	52	80	115	70	84	105	70	4	-10	0
		DAY 57	04SEP2003	59	80	122	74	84	118	74	4	-4	0
		FINAL		59	80	122	74	84	118	74	4	-4	0
	E0022047	SCREEN	21MAR2003	-7	72	118	80	76	120	82	4	2	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0022047	DAY 1	28MAR2003	1	64	110	82	68	108	80	4	-2	-2
		BASELINE			64	110	82	68	108	80	4	-2	-2
		DAY 8	04APR2003	8	68	118	74	80	102	80	12	-16	6
		DAY 15	11APR2003	15	78	118	82	72	104	80	-6	-14	-2
		DAY 22	17APR2003	21	64	132	82	80	110	80	16	-22 Y	-2
		DAY 29	25APR2003	29	64	118	76	78	110	80	14	-8	4
		DAY 36	02MAY2003	36	68	120	76	72	118	82	4	-2	6
		DAY 43	09MAY2003	43	72	122	82	76	126	80	4	4	-2
		DAY 50	16MAY2003	50	64	132	76	88	124	82	24 Y	-8	6
		DAY 57	23MAY2003	57	72	122	80	84	130	102	12	8	22
		FINAL		57	72	122	80	84	130	102	12	8	22
	E0022075	SCREEN	25JUN2003	-13	66	112	76	78	108	80	12	-4	4
		DAY 1	08JUL2003	1	57	110	68	66	122	74	9	12	6
		BASELINE			57	110	68	66	122	74	9	12	6
		DAY 8	15JUL2003	8	60	114	74	72	106	72	12	-8	-2
		DAY 15	22JUL2003	15	66	104	68	75	106	78	9	2	10
		DAY 22	29JUL2003	22	60	106	74	63	102	80	3	-4	6
		DAY 29	05AUG2003	29	68	102	64	80	100	66	12	-2	2
		DAY 36	12AUG2003	36	62	106	60	76	116	68	14	10	8
		DAY 43	19AUG2003	43	64	106	64	76	110	68	12	4	4
		DAY 50	26AUG2003	50	64	104	60	84	108	64	20 Y	4	4
		DAY 57	03SEP2003	58	72	104	58	76	120	72	4	16	14
		FINAL		58	72	104	58	76	120	72	4	16	14
	E0023016	SCREEN	15MAY2003	-7	82	120	75	84	120	75	2	0	0
		DAY 1	22MAY2003	1	79	117	83	78	106	74	-1	-11	-9
		BASELINE			79	117	83	78	106	74	-1	-11	-9
		DAY 8	29MAY2003	8	78	94	64	97	105	74	19	11	10
		DAY 15	05JUN2003	15	76	103	69	84	108	70	8	5	1
		DAY 22	12JUN2003	22	69	103	70	95	101	61	26 Y	-2	-9
		DAY 29	19JUN2003	29	63	101	67	70	108	71	7	7	4
		DAY 36	26JUN2003	36	74	85 L	58	78	98	64	4	13	6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0023016	DAY 43	01JUL2003	41	70	91	63	85	104	73	15	13	10
		DAY 50	14JUL2003	54	72	94	64	84	100	68	12	6	4
		DAY 57	17JUL2003	57	80	96	74	84	102	70	4	6	-4
		FINAL		57	80	96	74	84	102	70	4	6	-4
	E0023046	SCREEN	11JUL2003	-12	84	126	88	97	122	84	13	-4	-4
		DAY 1	23JUL2003	1	69	136	85	86	146	92	17	10	7
		BASELINE			69	136	85	86	146	92	17	10	7
		DAY 8	01AUG2003	10	72	170	90	86	179	94	14	9	4
		DAY 15	08AUG2003	17	74	111	70	91	104	68	17	-7	-2
		DAY 22	14AUG2003	23	69	115	60	72	111	61	3	-4	1
		DAY 29	22AUG2003	31	75	133	69	85	127	75	10	-6	6
		DAY 36	28AUG2003	37	73	109	69	76	112	72	3	3	3
		DAY 43	04SEP2003	44	79	115	65	104	119	65	25 Y	4	0
		DAY 50	11SEP2003	51	72	121	64	84	127	80	12	6	16
		DAY 57	16SEP2003	56	81	127	73	91	124	79	10	-3	6
		FINAL		56	81	127	73	91	124	79	10	-3	6
	E0026006	SCREEN	31DEC2002	-8	73	128	66	78	129	77	5	1	11
		DAY 1	08JAN2003	1	65	133	75	71	139	81	6	6	6
		BASELINE			65	133	75	71	139	81	6	6	6
		DAY 8	15JAN2003	8	94	167	83	94	136	81	0	-31 Y	-2
		DAY 15	22JAN2003	15	90	144	80	101	146	91	11	2	11
		DAY 22	29JAN2003	22	87	128	77	94	131	83	7	3	6
		DAY 29	05FEB2003	29	82	152	77	96	127	73	14	-25 Y	-4
		DAY 36	12FEB2003	36	87	132	74	93	122	71	6	-10	-3
		DAY 43	19FEB2003	43	72	140	76	80	142	80	8	2	4
		FINAL		43	72	140	76	80	142	80	8	2	4
	E0026027	SCREEN	05JUN2003	-14	64	143	79	72	103	74	8	-40 Y	-5
		DAY 1	19JUN2003	1	83	146	81	85	132	79	2	-14	-2
		BASELINE			83	146	81	85	132	79	2	-14	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0029004	SCREEN	13NOV2002	-6	80	98	62	84	100	72	4	2	10
		DAY 1	19NOV2002	1	80	100	70	92	96	70	12	-4	0
		BASELINE			80	100	70	92	96	70	12	-4	0
		DAY 8	26NOV2002	8	64	116	76	84	116	80	20 Y	0	4
		DAY 15	04DEC2002	16	80	112	78	82	110	76	2	-2	-2
		DAY 22	12DEC2002	24	72	106	74	84	122	78	12	16	4
		DAY 36	26DEC2002	38	84	100	60	96	108	82	12	8	22
		DAY 43	02JAN2003	45	84	98	60	72	98	70	-12	0	10
		DAY 50	09JAN2003	52	80	104	72	76	110	78	-4	6	6
		DAY 57	16JAN2003	59	76	100	72	84	90 L	68	8	-10	-4
		FINAL		59	76	100	72	84	90 L	68	8	-10	-4
	E0029019	SCREEN	24FEB2003	-7	60	110	76	64	92	70	4	-18	-6
		DAY 1	03MAR2003	1	60	110	80	68	110	78	8	0	-2
		BASELINE			60	110	80	68	110	78	8	0	-2
		DAY 8	10MAR2003	8	56	130	88	68	110	90	12	-20 Y	2
		DAY 15	17MAR2003	15	60	112	78	60	108	76	0	-4	-2
		FINAL		15	60	112	78	60	108	76	0	-4	-2
	E0029024	SCREEN	11MAR2003	-6	48 L	114	84	52	130	80	4	16	-4
		DAY 1	17MAR2003	1	52	102	78	52	102	68	0	0	-10
		BASELINE			52	102	78	52	102	68	0	0	-10
		DAY 8	25MAR2003	9	56	100	78	56	102	70	0	2	-8
		DAY 15	02APR2003	17	56	92	64	56	96	64	0	4	0
		DAY 22	09APR2003	24	52	118	68	66	108	64	14	-10	-4
		DAY 29	17APR2003	32	60	102	62	60	98	62	0	-4	0
		DAY 36	24APR2003	39	60	96	60	60	96	60	0	0	0
		DAY 50	05MAY2003	50	72	100	60	64	98	60	-8	-2	0
		DAY 57 *	12MAY2003	57	54	90 L	62	54	92	60	0	2	-2
		DAY 57	20MAY2003	65	58	110	60	58	108	60	0	-2	0
		FINAL		65	58	110	60	58	108	60	0	-2	0
	E0031013	SCREEN	06MAR2003	-7	68	130	86	100	128	88	32 Y	-2	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0031013	DAY 1	13MAR2003	1	86	138	80	82	142	84	-4	4	4
		BASELINE			86	138	80	82	142	84	-4	4	4
		DAY 8	20MAR2003	8	78	140	82	74	148	90	-4	8	8
		DAY 15	27MAR2003	15	66	138	78	69	142	86	3	4	8
		DAY 22	04APR2003	23	74	134	82	86	138	86	12	4	4
		DAY 29	11APR2003	30	88	130	78	86	132	86	-2	2	8
		DAY 36	17APR2003	36	96	140	86	99	142	90	3	2	4
		DAY 43	24APR2003	43	78	140	88	82	146	94	4	6	6
		DAY 50	01MAY2003	50	80	140	88	88	142	90	8	2	2
		DAY 57	08MAY2003	57	68	138	90	66	142	90	-2	4	0
		FINAL		57	68	138	90	66	142	90	-2	4	0
	E0033013	SCREEN	06FEB2003	-13	64	100	70	76	90 L	70	12	-10	0
		DAY 1	19FEB2003	1	68	108	72	72	110	76	4	2	4
		BASELINE			68	108	72	72	110	76	4	2	4
		DAY 8	26FEB2003	8	60	100	70	72	100	80	12	0	10
		DAY 15	05MAR2003	15	64	100	70	80	110	74	16	10	4
		DAY 22	13MAR2003	23	60	110	90	72	100	86	12	-10	-4
		DAY 29	19MAR2003	29	68	98	70	72	100	74	4	2	4
		DAY 36	27MAR2003	37	68	88 L	60	76	90 L	64	8	2	4
		DAY 43	01APR2003	42	60	80 L	60	76	90 L	70	16	10	10
		DAY 50	10APR2003	51	56	80 L	60	68	80 L	68	12	0	8
		DAY 57	16APR2003	57	64	80 L	60	76	90 L	78	12	10	18
		FINAL		57	64	80 L	60	76	90 L	78	12	10	18
	E0033016	SCREEN	17APR2003	-21	60	100	70	76	100	72	16	0	2
		DAY 1	08MAY2003	1	68	106	60	76	100	66	8	-6	6
		BASELINE			68	106	60	76	100	66	8	-6	6
		DAY 8	13MAY2003	6	80	110	64	88	106	72	8	-4	8
		DAY 15	20MAY2003	13	60	90 L	70	72	100	80	12	10	10
		DAY 22	28MAY2003	21	68	110	70	76	108	70	8	-2	0
		DAY 29	09JUN2003	33	60	100	70	76	100	70	16	0	0
		DAY 43	17JUN2003	41	68	118	74	76	110	70	8	-8	-4

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0033016	DAY 43	*	23JUN2003	47	68	110	80	80	94	76	12	-16	-4
		DAY 50		27JUN2003	51	68	100	62	72	100	60	4	0	-2
		DAY 57		02JUL2003	56	60	90 L	64	64	90 L	68	4	0	4
		FINAL			56	60	90 L	64	64	90 L	68	4	0	4
	E0033022	SCREEN		09JUL2003	-5	76	100	76	80	98	70	4	-2	-6
		DAY 1		14JUL2003	1	80	100	78	84	100	70	4	0	-8
		BASELINE				80	100	78	84	100	70	4	0	-8
		DAY 8		23JUL2003	10	64	90 L	62	80	90 L	60	16	0	-2
		DAY 15		30JUL2003	17	68	100	70	80	90 L	70	12	-10	0
		DAY 22		06AUG2003	24	64	100	68	68	110	70	4	10	2
		DAY 29		11AUG2003	29	70	120	74	80	124	80	10	4	6
		DAY 36		18AUG2003	36	60	110	72	68	100	70	8	-10	-2
		DAY 43		26AUG2003	44	64	110	70	68	110	72	4	0	2
		DAY 50		04SEP2003	53	64	100	70	68	100	72	4	0	2
		DAY 57		11SEP2003	60	64	110	70	68	110	72	4	0	2
		FINAL			60	64	110	70	68	110	72	4	0	2
	E0034007	SCREEN		07MAY2003	-9	76	110	90	80	120	85	4	10	-5
		DAY 1		16MAY2003	1	62	122	82	68	138	88	6	16	6
		BASELINE				62	122	82	68	138	88	6	16	6
		DAY 8		24MAY2003	9	68	130	90	72	125	85	4	-5	-5
		DAY 15		02JUN2003	18	62	128	84	72	128	88	10	0	4
		DAY 22		09JUN2003	25	72	128	88	68	126	94	-4	-2	6
		DAY 29		16JUN2003	32	72	140	90	80	130	85	8	-10	-5
		DAY 36		20JUN2003	36	64	125	85	68	130	80	4	5	-5
		DAY 43		30JUN2003	46	74	160	100	68	140	95	-6	-20 Y	-5
		DAY 50		07JUL2003	53	80	140	95	88	135	100	8	-5	5
		DAY 57		14JUL2003	60	68	160	105 H	64	158	108 H	-4	-2	3
		FINAL			60	68	160	105 H	64	158	108 H	-4	-2	3
	E0041005	SCREEN		24FEB2003	-9	72	150	100	76	148	92	4	-2	-8
		DAY 1		05MAR2003	1	76	140	92	78	148	92	2	8	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0041005	BASELINE			76	140	92	78	148	92	2	8	0
		DAY 8	11MAR2003	7	74	140	98	74	148	90	0	8	-8
		DAY 15	19MAR2003	15	82	138	90	92	150	96	10	12	6
		DAY 22	26MAR2003	22	80	140	90	80	142	100	0	2	10
		DAY 29	02APR2003	29	80	110	90	88	130	96	8	20	6
		DAY 36	09APR2003	36	60	110	80	66	120	76	6	10	-4
		DAY 43	16APR2003	43	80	132	100	84	150	108 H	4	18	8
		DAY 50	23APR2003	50	60	150	98	80	150	100	20 Y	0	2
		DAY 57	30APR2003	57	88	138	86	88	140	84	0	2	-2
		FINAL		57	88	138	86	88	140	84	0	2	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	SCREEN	14JAN2003	-21	64	130	90				70	132	80			
		DAY 1	04FEB2003	1	64	132	90				76	132	80			
		BASELINE			64	132	90				76	132	80			
		DAY 8	12FEB2003	9	76	140	78	12	8	-12	84	138	74	8	6	-6
		DAY 15	19FEB2003	16	72	118	72	8	-14	-18	80	120	76	4	-12	-4
		DAY 22	26FEB2003	23	76	116	76	12	-16	-14	80	118	72	4	-14	-8
		DAY 29	05MAR2003	30	76	122	82	12	-10	-8	80	128	84	4	-4	4
		DAY 36	11MAR2003	36	84	120	80	20I	-12	-10	88	132	84	12	0	4
		DAY 43	18MAR2003	43	80	130	80	16I	-2	-10	84	142	82	8	10	2
		DAY 50	25MAR2003	50	80	108	66	16I	-24D	-24D	80	112	76	4	-20D	-4
		DAY 57	02APR2003	58	78	124	76	14	-8	-14	80	112	68	4	-20D	-12
		FINAL		58	78	124	76	14	-8	-14	80	112	68	4	-20D	-12
	E0002010	SCREEN	25MAR2003	-10	80	124	80				78	122	80			
		DAY 1	04APR2003	1	82	142	100				80	152	106H			
		BASELINE			82	142	100				80	152	106H			
		DAY 8	10APR2003	7	84	120	94	2	-22D	-6	80	120	88	0	-32D	-18
		FINAL		7	84	120	94	2	-22D	-6	80	120	88	0	-32D	-18
	E0002012	SCREEN	16APR2003	-5	60	102	58				72	104	60			
		DAY 1	21APR2003	1	64	102	66				72	108	68			
		BASELINE			64	102	66				72	108	68			
		DAY 8	29APR2003	9	64	102	68	0	0	2	68	108	70	-4	0	2
		DAY 15	06MAY2003	16	64	104	68	0	2	2	72	110	82	0	2	14
		DAY 22	15MAY2003	25	56	100	64	-8	-2	-2	60	108	68	-12	0	0
		DAY 29	21MAY2003	31	60	110	70	-4	8	4	60	108	72	-12	0	4
		DAY 36	28MAY2003	38	64	102	58	0	0	-8	64	114	66	-8	6	-2
		DAY 43	04JUN2003	45	60	100	70	-4	-2	4	62	104	70	-10	-4	2
		DAY 50	11JUN2003	52	56	102	70	-8	0	4	56	112	74	-16D	4	6
		DAY 57	16JUN2003	57	56	100	62	-8	-2	-4	60	102	68	-12	-6	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0002012	FINAL		57	56	100	62	-8	-2	-4	60	102	68	-12	-6	0
	E0003004	SCREEN	03DEC2002	-14	64	128	90				76	120	80			
		DAY 1	17DEC2002	1	72	112	82				80	90L	70			
		BASELINE			72	112	82				80	90L	70			
		DAY 22	07JAN2003	22	74	132	70	2	20I	-12	88	134	82	8	44I	12
		FINAL		22	74	132	70	2	20I	-12	88	134	82	8	44I	12
	E0003007	SCREEN	19DEC2002	-14	84	110	78				80	120	70			
		DAY 1	02JAN2003	1	72	130	78				88	125	82			
		BASELINE			72	130	78				88	125	82			
		DAY 8	09JAN2003	8	72	110	68	0	-20D	-10	80	110	70	-8	-15	-12
		DAY 15	16JAN2003	15	84	120	75	12	-10	-3	92	124	72	4	-1	-10
		DAY 22	23JAN2003	22	82	120	64	10	-10	-14	100	126	80	12	1	-2
		DAY 29	30JAN2003	29	70	118	84	-2	-12	6	76	118	86	-12	-7	4
		DAY 36	07FEB2003	37	70	118	78	-2	-12	0	76	122	80	-12	-3	-2
		DAY 43	13FEB2003	43	70	126	74	-2	-4	-4	72	122	80	-16D	-3	-2
		DAY 50	20FEB2003	50	88	118	68	16I	-12	-10	106	110	76	18I	-15	-6
		DAY 57	27FEB2003	57	92	106	70	20I	-24D	-8	76	106	72	-12	-19	-10
		FINAL		57	92	106	70	20I	-24D	-8	76	106	72	-12	-19	-10
	E0003015	SCREEN	29APR2003	-6	60	118	74				64	110	84			
		DAY 1	05MAY2003	1	60	112	70				68	100	72			
		BASELINE			60	112	70				68	100	72			
		DAY 8	13MAY2003	9	62	108	70	2	-4	0	74	110	74	6	10	2
		DAY 15	19MAY2003	15	56	100	70	-4	-12	0	60	110	74	-8	10	2
		DAY 22	27MAY2003	23	52	120	70	-8	8	0	60	110	80	-8	10	8
		DAY 29	04JUN2003	31	68	100	70	8	-12	0	68	110	70	0	10	-2
		DAY 36	10JUN2003	37	60	104	70	0	-8	0	68	106	78	0	6	6
		DAY 43	17JUN2003	44	66	100	72	6	-12	2	78	118	80	10	18	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	DAY 50	24JUN2003	51	74	110	78	14	-2	8	86	106	80	18I	6	8
		DAY 57	02JUL2003	59	74	100	68	14	-12	-2	68	96	64	0	-4	-8
		FINAL		59	74	100	68	14	-12	-2	68	96	64	0	-4	-8
	E0004002	SCREEN	24SEP2002	-7	68	114	70				70	112	68			
		DAY 1	01OCT2002	1	70	110	64				72	112	60			
		BASELINE			70	110	64				72	112	60			
		DAY 8	10OCT2002	10	76	108	62	6	-2	-2	88	120	66	16I	8	6
		DAY 15	17OCT2002	17	84	108	62	14	-2	-2	90	110	70	18I	-2	10
		DAY 22	22OCT2002	22	88	110	72	18I	0	8	86	104	70	14	-8	10
		DAY 29	29OCT2002	29	84	110	62	14	0	-2	80	104	64	8	-8	4
		DAY 36	05NOV2002	36	96	122	60	26I	12	-4	100	108	76	28I	-4	16
		DAY 43	12NOV2002	43	96	108	74	26I	-2	10	88	102	70	16I	-10	10
		DAY 50	19NOV2002	50	90	110	60	20I	0	-4	96	108	74	24I	-4	14
		DAY 57	26NOV2002	57	88	120	68	18I	10	4	96	114	76	24I	2	16
		FINAL		57	88	120	68	18I	10	4	96	114	76	24I	2	16
	E0004018	SCREEN	12MAR2003	-7	60	118	74				64	120	78			
		DAY 1	19MAR2003	1	64	112	70				72	118	78			
		BASELINE			64	112	70				72	118	78			
		DAY 8	26MAR2003	8	88	126	72	24I	14	2	92	130	80	20I	12	2
		DAY 15	02APR2003	15	88	122	70	24I	10	0	96	124	84	24I	6	6
		DAY 22	09APR2003	22	76	128	82	12	16	12	88	130	88	16I	12	10
		DAY 29	16APR2003	29	80	128	80	16I	16	10	90	124	88	18I	6	10
		DAY 36	23APR2003	36	88	122	80	24I	10	10	94	120	86	22I	2	8
		DAY 43	30APR2003	43	80	124	80	16I	12	10	88	120	82	16I	2	4
		DAY 50	06MAY2003	49	80	108	70	16I	-4	0	100	100	68	28I	-18	-10
		DAY 57	13MAY2003	56	76	110	78	12	-2	8	84	112	82	12	-6	4
		FINAL		56	76	110	78	12	-2	8	84	112	82	12	-6	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0005004	SCREEN	24SEP2002	-7	68	112	70				66	108	64			
		DAY 1	01OCT2002	1	60	100	60				60	96	58			
		BASELINE			60	100	60				60	96	58			
		DAY 8	10OCT2002	10	80	116	70	20I	16	10	80	110	70	20I	14	12
		DAY 15	15OCT2002	15	84	126	68	24I	26I	8	84	118	66	24I	22I	8
		FINAL		15	84	126	68	24I	26I	8	84	118	66	24I	22I	8
	E0005013	SCREEN	30OCT2002	-8	72	110	70				72	100	70			
		DAY 1	07NOV2002	1	64	110	80				64	110	74			
		BASELINE			64	110	80				64	110	74			
		DAY 43	19DEC2002	43	80	120	80	16I	10	0	80	120	80	16I	10	6
		FINAL		43	80	120	80	16I	10	0	80	120	80	16I	10	6
	E0005024	SCREEN	05FEB2003	-5	68	120	84				68	120	78			
		DAY 1	10FEB2003	1	60	124	80				60	120	80			
		BASELINE			60	124	80				60	120	80			
		DAY 8	18FEB2003	9	64	120	74	4	-4	-6	64	110	70	4	-10	-10
		DAY 15	26FEB2003	17	80	110	70	20I	-14	-10	80	100	70	20I	-20D	-10
		DAY 22	06MAR2003	25	80	110	80	20I	-14	0	80	100	70	20I	-20D	-10
		DAY 29	13MAR2003	32	68	110	80	8	-14	0	68	100	74	8	-20D	-6
		DAY 36	20MAR2003	39	72	110	74	12	-14	-6	72	110	70	12	-10	-10
		DAY 43	25MAR2003	44	68	110	70	8	-14	-10	68	100	60	8	-20D	-20D
		DAY 50	02APR2003	52	88	120	80	28I	-4	0	84	110	70	24I	-10	-10
		DAY 57	09APR2003	59	64	110	70	4	-14	-10	64	100	68	4	-20D	-12
		FINAL		59	64	110	70	4	-14	-10	64	100	68	4	-20D	-12
	E0005027	SCREEN	03MAR2003	-8	60	130	80				60	124	80			
		DAY 1	11MAR2003	1	60	112	80				60	110	75			
		BASELINE			60	112	80				60	110	75			
		DAY 8	19MAR2003	9	84	120	80	24I	8	0	80	120	80	20I	10	5

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	DAY 15	26MAR2003	16	68	120	78	8	8	-2	68	120	80	8	10	5
		DAY 22	03APR2003	24	60	120	80	0	8	0	60	110	80	0	0	5
		FINAL		24	60	120	80	0	8	0	60	110	80	0	0	5
	E0005037	SCREEN	30APR2003	-7	60	130	80				60	130	70			
		DAY 1	07MAY2003	1	96	140	86				96	130	86			
		BASELINE			96	140	86				96	130	86			
		DAY 8	15MAY2003	9	86	140	88	-10	0	2	86	140	86	-10	10	0
		DAY 15	22MAY2003	16	86	140	86	-10	0	0	86	140	84	-10	10	-2
		DAY 22	27MAY2003	21	80	140	90	-16D	0	4	80	130	88	-16D	0	2
		DAY 29	05JUN2003	30	80	138	90	-16D	-2	4	80	134	88	-16D	4	2
		DAY 36	12JUN2003	37	80	130	84	-16D	-10	-2	80	126	80	-16D	-4	-6
		DAY 50	25JUN2003	50	80	126	82	-16D	-14	-4	80	130	86	-16D	0	0
		DAY 57	02JUL2003	57	80	134	78	-16D	-6	-8	80	134	82	-16D	4	-4
		FINAL		57	80	134	78	-16D	-6	-8	80	134	82	-16D	4	-4
	E0005042	SCREEN	19JUN2003	-5	64	126	84				64	124	84			
		DAY 1	24JUN2003	1	84	124	80				84	122	80			
		BASELINE			84	124	80				84	122	80			
		DAY 8	02JUL2003	9	60	118	84	-24D	-6	4	64	118	82	-20D	-4	2
		DAY 15	09JUL2003	16	80	120	80	-4	-4	0	80	116	80	-4	-6	0
		DAY 22	16JUL2003	23	88	138	82	4	14	2	92	140	80	8	18	0
		DAY 29	23JUL2003	30	84	130	80	0	6	0	84	124	80	0	2	0
		DAY 36	30JUL2003	37	76	136	84	-8	12	4	76	120	84	-8	-2	4
		DAY 43	06AUG2003	44	82	126	82	-2	2	2	82	120	80	-2	-2	0
		DAY 50	12AUG2003	50	68	126	82	-16D	2	2	72	120	80	-12	-2	0
		DAY 57	18AUG2003	56	80	128	84	-4	4	4	88	128	80	4	6	0
		FINAL		56	80	128	84	-4	4	4	88	128	80	4	6	0
	E0006005	SCREEN	25NOV2002	-10	64	100	72				75	104	78			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 1	05DEC2002	1	74	146	82				88	142	92			
		BASELINE			74	146	82				88	142	92			
		DAY 8	12DEC2002	8	76	102	70	2	-44D	-12	96	100	68	8	-42D	-24D
		DAY 15	20DEC2002	16	89	127	76	15I	-19	-6	106	132	87	18I	-10	-5
		DAY 22	30DEC2002	26	81	123	69	7	-23D	-13	107	127	76	19I	-15	-16
		DAY 29	03JAN2003	30	86	119	67	12	-27D	-15	100	126	72	12	-16	-20D
		DAY 36	09JAN2003	36	83	134	86	9	-12	4	84	117	87	-4	-25D	-5
		DAY 43	16JAN2003	43	78	118	78	4	-28D	-4	90	135	85	2	-7	-7
		DAY 50	23JAN2003	50	76	140	80	2	-6	-2	78	96	46L	-10	-46D	-46D
		DAY 57	30JAN2003	57	76	115	65	2	-31D	-17	98	123	70	10	-19	-22D
		FINAL		57	76	115	65	2	-31D	-17	98	123	70	10	-19	-22D
	E0007013	SCREEN	06JUN2003	-7	64	108	64				68	104	60			
		DAY 1	13JUN2003	1	70	94	62				72	100	66			
		BASELINE			70	94	62				72	100	66			
		DAY 8	20JUN2003	8	72	114	68	2	20I	6	76	116	72	4	16	6
		DAY 15	26JUN2003	14	70	110	70	0	16	8	72	108	72	0	8	6
		DAY 22	03JUL2003	21	70	116	70	0	22I	8	72	120	70	0	20I	4
		DAY 29	10JUL2003	28	72	120	70	2	26I	8	76	126	72	4	26I	6
		DAY 36	17JUL2003	35	70	114	70	0	20I	8	72	116	74	0	16	8
		DAY 43	24JUL2003	42	70	122	74	0	28I	12	76	116	70	4	16	4
		DAY 50	01AUG2003	50	76	136	76	6	42I	14	80	134	80	8	34I	14
		DAY 57	07AUG2003	56	72	126	80	2	32I	18	76	122	80	4	22I	14
		FINAL		56	72	126	80	2	32I	18	76	122	80	4	22I	14
	E0010004	SCREEN	05DEC2002	-6	64	90L	60				70	96	68			
		DAY 1	11DEC2002	1	60	110	84				64	100	78			
		BASELINE			60	110	84				64	100	78			
		DAY 8	18DEC2002	8	68	104	68	8	-6	-16	84	98	62	20I	-2	-16
		DAY 15	26DEC2002	16	61	130	80	1	20I	-4	71	110	82	7	10	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	DAY 22	02JAN2003	23	66	126	80	6	16	-4	68	120	72	4	20I	-6
		DAY 36	13JAN2003	34	67	116	76	7	6	-8	81	110	70	17I	10	-8
		DAY 43	21JAN2003	42	61	126	88	1	16	4	74	118	82	10	18	4
		DAY 50	31JAN2003	52	66	112	74	6	2	-10	86	98	68	22I	-2	-10
		DAY 57	06FEB2003	58	60	120	80	0	10	-4	72	110	70	8	10	-8
		FINAL		58	60	120	80	0	10	-4	72	110	70	8	10	-8
	E0010012	SCREEN	30DEC2002	-8	65	132	90				66	130	90			
		DAY 1	07JAN2003	1	94	128	78				90	144	88			
		BASELINE			94	128	78				90	144	88			
		DAY 8	14JAN2003	8	84	118	76	-10	-10	-2	79	130	80	-11	-14	-8
		DAY 15	21JAN2003	15	84	130	80	-10	2	2	82	142	92	-8	-2	4
		DAY 22	28JAN2003	22	84	130	84	-10	2	6	74	136	94	-16D	-8	6
		DAY 29	04FEB2003	29	88	142	86	-6	14	8	91	126	90	1	-18	2
		DAY 36	11FEB2003	36	80	118	90	-14	-10	12	80	110	84	-10	-34D	-4
		DAY 43	18FEB2003	43	86	144	90	-8	16	12	88	140	90	-2	-4	2
		DAY 50	25FEB2003	50	88	138	88	-6	10	10	82	130	86	-8	-14	-2
		DAY 57	05MAR2003	58	80	126	84	-14	-2	6	78	132	88	-12	-12	0
		FINAL		58	80	126	84	-14	-2	6	78	132	88	-12	-12	0
	E0010024	SCREEN	23APR2003	-12	62	114	78				78	132	96			
		DAY 1	05MAY2003	1	50	124	80				56	132	88			
		BASELINE			50	124	80				56	132	88			
		DAY 8	12MAY2003	8	62	110	70	12	-14	-10	88	124	88	32I	-8	0
		DAY 15	19MAY2003	15	78	130	78	28I	6	-2	84	124	80	28I	-8	-8
		DAY 22	27MAY2003	23	88	140	90	38I	16	10	86	140	90	30I	8	2
		DAY 29	04JUN2003	31	74	140	94	24I	16	14	76	140	100	20I	8	12
		DAY 36	11JUN2003	38	98	130	86	48I	6	6	104	144	96	48I	12	8
		DAY 43	18JUN2003	45	76	140	88	26I	16	8	72	140	72	16I	8	-16
		DAY 50	25JUN2003	52	86	130	88	36I	6	8	98	134	90	42I	2	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	DAY 57	02JUL2003	59	84	130	78	34I	6	-2	84	130	80	28I	-2	-8
		FINAL		59	84	130	78	34I	6	-2	84	130	80	28I	-2	-8
	E0011025	SCREEN	20JUN2003	-6	68	118	74				70	120	74			
		DAY 1	26JUN2003	1	84	100	80				88	100	75			
		BASELINE			84	100	80				88	100	75			
		DAY 8	02JUL2003	7	90	100	70	6	0	-10	88	100	72	0	0	-3
		DAY 15	10JUL2003	15	84	102	80	0	2	0	88	100	82	0	0	7
		DAY 22	17JUL2003	22	92	120	80	8	20I	0	90	118	80	2	18	5
		DAY 29	22JUL2003	27	84	90L	68	0	-10	-12	82	90L	60	-6	-10	-15
		DAY 36	30JUL2003	35	88	100	60	4	0	-20D	84	100	62	-4	0	-13
		DAY 43	07AUG2003	43	84	100	70	0	0	-10	86	102	70	-2	2	-5
		DAY 50	14AUG2003	50	82	102	70	-2	2	-10	84	100	72	-4	0	-3
		DAY 57	22AUG2003	58	80	100	70	-4	0	-10	82	100	72	-6	0	-3
		FINAL		58	80	100	70	-4	0	-10	82	100	72	-6	0	-3
	E0013009	SCREEN	26MAR2003	-7	72	128	80				66	126	80			
		DAY 1	02APR2003	1	66	112	80				66	112	80			
		BASELINE			66	112	80				66	112	80			
		DAY 8	09APR2003	8	66	128	86	0	16	6	66	120	86	0	8	6
		DAY 15	16APR2003	15	72	124	82	6	12	2	72	120	80	6	8	0
		DAY 22	24APR2003	23	72	120	70	6	8	-10	64	120	70	-2	8	-10
		DAY 29	01MAY2003	30	84	120	70	18I	8	-10	70	120	70	4	8	-10
		DAY 36	07MAY2003	36	60	124	80	-6	12	0	64	120	80	-2	8	0
		DAY 43	16MAY2003	45	72	120	62	6	8	-18	64	120	70	-2	8	-10
		DAY 50	21MAY2003	50	88	120	78	22I	8	-2	80	120	80	14	8	0
		DAY 57	29MAY2003	58	60	120	80	-6	8	0	68	120	80	2	8	0
		FINAL		58	60	120	80	-6	8	0	68	120	80	2	8	0
	E0014006	SCREEN	11MAR2003	-14	84	118	88				92	110	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	DAY 1	25MAR2003	1	80	124	84				92	110	80			
		BASELINE			80	124	84				92	110	80			
		DAY 8	02APR2003	9	84	120	82	4	-4	-2	96	124	78	4	14	-2
		DAY 15	09APR2003	16	80	122	90	0	-2	6	92	120	88	0	10	8
		DAY 22	16APR2003	23	88	120	90	8	-4	6	96	112	88	4	2	8
		DAY 29	23APR2003	30	100	130	78	20I	6	-6	108	120	84	16I	10	4
		DAY 36	30APR2003	37	84	130	80	4	6	-4	96	130	84	4	20I	4
		DAY 43	07MAY2003	44	88	126	84	8	2	0	96	110	80	4	0	0
		DAY 50	14MAY2003	51	88	120	80	8	-4	-4	92	124	88	0	14	8
		DAY 57	21MAY2003	58	100	124	74	20I	0	-10	120	110	80	28I	0	0
		FINAL		58	100	124	74	20I	0	-10	120	110	80	28I	0	0
	E0016001	SCREEN	02JAN2003	-20							86	141	88			
		DAY 1	22JAN2003	1							89	122	68			
		BASELINE									89	122	68			
		DAY 8	29JAN2003	8	80	126	72				86	134	82	-3	12	14
		DAY 15	05FEB2003	15	69	118	74				72	124	84	-17D	2	16
		DAY 22	12FEB2003	22	76	128	84				98	142	94	9	20I	26
		DAY 29	19FEB2003	29	78	129	83				87	141	94	-2	19	26
		DAY 36	26FEB2003	36	84	128	84				96	142	92	7	20I	24
		DAY 43	05MAR2003	43	76	124	86				88	136	92	-1	14	24
		DAY 50	12MAR2003	50	80	121	79				87	128	84	-2	6	16
		DAY 57	19MAR2003	57	89	124	80				96	131	85	7	9	17
		FINAL		57	89	124	80				96	131	85	7	9	17
	E0018001	SCREEN	22OCT2002	-7	64	122	70				60	120	72			
		DAY 1	29OCT2002	1	64	122	78									
		BASELINE			64	122	70				60	120	72			
		DAY 8	05NOV2002	8	84	126	80	20I	4	10	76	122	80	16I	2	8
		DAY 15	13NOV2002	16	76	116	66	12	-6	-4	76	116	68	16I	-4	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	DAY 22	20NOV2002	23	78	112	72	14	-10	2	82	112	74	22I	-8	2
		DAY 29	27NOV2002	30	80	110	68	16I	-12	-2	80	112	68	20I	-8	-4
		DAY 36	04DEC2002	37	72	114	72	8	-8	2	73	116	73	13	-4	1
		DAY 43	11DEC2002	44	84	128	78	20I	6	8	84	130	78	24I	10	6
		DAY 50	18DEC2002	51	84	130	82	20I	8	12	84	130	82	24I	10	10
		DAY 57	24DEC2002	57	86	126	82	22I	4	12	88	126	84	28I	6	12
		FINAL		57	86	126	82	22I	4	12	88	126	84	28I	6	12
	E0018006	SCREEN	10DEC2002	-7	64	112	72				68	112	76			
		DAY 1	17DEC2002	1	68	122	74				72	124	74			
		BASELINE			68	122	74				72	124	74			
		DAY 8	23DEC2002	7	80	128	90	12	6	16	84	126	88	12	2	14
		DAY 15	31DEC2002	15	68	132	86	0	10	12	72	124	86	0	0	12
		DAY 22	07JAN2003	22	72	124	82	4	2	8	76	118	84	4	-6	10
		DAY 29	14JAN2003	29	80	116	82	12	-6	8	84	120	84	12	-4	10
		DAY 36	21JAN2003	36	84	118	84	16I	-4	10	80	124	84	8	0	10
		DAY 43	28JAN2003	43	64	128	88	-4	6	14	72	132	92	0	8	18
		DAY 50	06FEB2003	52	84	118	80	16I	-4	6	80	124	78	8	0	4
		DAY 57	13FEB2003	59	68	128	78	0	6	4	72	126	82	0	2	8
		FINAL		59	68	128	78	0	6	4	72	126	82	0	2	8
	E0019004	SCREEN	30OCT2002	-8	64	120	90				70	120	80			
		DAY 1	07NOV2002	1	68	120	75				68	123	80			
		BASELINE			68	120	75				68	123	80			
		DAY 8	14NOV2002	8	72	110	80	4	-10	5	72	110	80	4	-13	0
		DAY 15	21NOV2002	15	68	115	75	0	-5	0	68	120	80	0	-3	0
		DAY 22	26NOV2002	20	72	125	80	4	5	5	76	120	75	8	-3	-5
		DAY 29	05DEC2002	29	60	110	80	-8	-10	5	60	115	80	-8	-8	0
		DAY 36	12DEC2002	36	70	140	84	2	20I	9	80	146	98	12	23I	18
		DAY 43	19DEC2002	43	72	135	82	4	15	7	76	135	80	8	12	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	FINAL		43	72	135	82	4	15	7	76	135	80	8	12	0
	E0019011	SCREEN	12NOV2002	-9	76	120	80				80	140	84			
		DAY 1	21NOV2002	1	80	120	70				84	125	65			
		BASELINE			80	120	70				84	125	65			
		DAY 8	27NOV2002	7	84	130	70	4	10	0	88	130	75	4	5	10
		DAY 15	05DEC2002	15	80	130	80	0	10	10	84	132	75	0	7	10
		DAY 22	12DEC2002	22	66	132	88	-14	12	18	90	116	62	6	-9	-3
		DAY 29	19DEC2002	29	84	108	68	4	-12	-2	88	120	74	4	-5	9
		DAY 43	02JAN2003	43	88	120	80	8	0	10	92	118	85	8	-7	20
		DAY 50	09JAN2003	50	60	110	70	-20D	-10	0	64	120	80	-20D	-5	15
		DAY 57	16JAN2003	57	84	112	78	4	-8	8	96	112	80	12	-13	15
		FINAL		57	84	112	78	4	-8	8	96	112	80	12	-13	15
	E0019025	SCREEN	30JAN2003	-7	68	120	75				68	120	80			
		DAY 1	06FEB2003	1	60	110	70				64	110	75			
		BASELINE			60	110	70				64	110	75			
		DAY 8	13FEB2003	8	80	112	70	20I	2	0	88	110	75	24I	0	0
		DAY 15	20FEB2003	15	80	108	72	20I	-2	2	88	100	68	24I	-10	-7
		DAY 22	27FEB2003	22	80	110	76	20I	0	6	88	104	80	24I	-6	5
		DAY 29	06MAR2003	29	80	110	70	20I	0	0	88	100	74	24I	-10	-1
		DAY 36	13MAR2003	36	80	110	72	20I	0	2	84	108	80	20I	-2	5
		DAY 43	20MAR2003	43	78	102	68	18I	-8	-2	82	100	74	18I	-10	-1
		DAY 50	27MAR2003	50	80	118	80	20I	8	10	88	115	75	24I	5	0
		DAY 57	03APR2003	57	80	102	60	20I	-8	-10	88	90L	60	24I	-20D	-15
		FINAL		57	80	102	60	20I	-8	-10	88	90L	60	24I	-20D	-15
	E0019043	SCREEN	21MAY2003	-13	64	110	84				68	132	82			
		DAY 1	03JUN2003	1	72	120	78				80	122	84			
		BASELINE			72	120	78				80	122	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	DAY 8		10JUN2003	8	92	122	74	20I	2	-4	80	128	88	0	6	4
		DAY 15		17JUN2003	15	88	115	75	16I	-5	-3	84	118	80	4	-4	-4
		DAY 22		24JUN2003	22	84	130	82	12	10	4	92	130	80	12	8	-4
		DAY 29		01JUL2003	29	88	116	78	16I	-4	0	84	112	78	4	-10	-6
		DAY 36		08JUL2003	36	76	134	86	4	14	8	80	130	88	0	8	4
		DAY 43		15JUL2003	43	76	138	84	4	18	6	82	134	86	2	12	2
		DAY 50		22JUL2003	50	80	120	70	8	0	-8	80	120	78	0	-2	-6
		DAY 57		29JUL2003	57	76	112	78	4	-8	0	92	116	80	12	-6	-4
		FINAL			57	76	112	78	4	-8	0	92	116	80	12	-6	-4
	E0020001	SCREEN		15OCT2002	-14	60	122	90				62	120	88			
		DAY 1		29OCT2002	1	62	110	78				60	114	74			
		BASELINE				62	110	78				60	114	74			
		DAY 8		05NOV2002	8	78	148	78	16I	38I	0	82	158	82	22I	44I	8
		DAY 15		12NOV2002	15	72	120	82	10	10	4	78	118	82	18I	4	8
		DAY 22		19NOV2002	22	80	128	78	18I	18	0	80	124	76	20I	10	2
		DAY 29		26NOV2002	29	78	140	80	16I	30I	2	82	138	80	22I	24I	6
		DAY 36		03DEC2002	36	78	126	78	16I	16	0	80	128	78	20I	14	4
		DAY 43		10DEC2002	43	80	124	76	18I	14	-2	82	126	78	22I	12	4
		DAY 50		16DEC2002	49	70	130	88	8	20I	10	68	120	86	8	6	12
		DAY 50	*	20DEC2002	53	76	120	78	14	10	0	80	118	78	20I	4	4
		FINAL			53	76	120	78	14	10	0	80	118	78	20I	4	4
	E0020006	SCREEN		26NOV2002	-20	78	124	72				74	120	70			
		DAY 1		16DEC2002	1	72	128	80				76	134	82			
		BASELINE				72	128	80				76	134	82			
		DAY 8		20DEC2002	5	88	122	70	16I	-6	-10	84	122	64	8	-12	-18
		DAY 22		08JAN2003	24	76	150	80	4	22I	0	70	148	80	-6	14	-2
		FINAL			24	76	150	80	4	22I	0	70	148	80	-6	14	-2

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I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	SCREEN	19FEB2003	-7	78	118	72				80	120	72			
		DAY 1	26FEB2003	1	68	120	76				70	118	74			
		BASELINE			68	120	76				70	118	74			
		DAY 8	05MAR2003	8	78	124	78	10	4	2	80	118	78	10	0	4
		DAY 15	12MAR2003	15	72	108	72	4	-12	-4	80	106	74	10	-12	0
		DAY 22	20MAR2003	23	70	118	70	2	-2	-6	76	112	70	6	-6	-4
		DAY 29	26MAR2003	29	72	100	60	4	-20D	-16	74	98	58	4	-20D	-16
		DAY 36	02APR2003	36	60	100	60	-8	-20D	-16	58	98	60	-12	-20D	-14
		DAY 43	09APR2003	43	64	118	76	-4	-2	0	62	116	76	-8	-2	2
		DAY 50	16APR2003	50	60	110	68	-8	-10	-8	62	110	70	-8	-8	-4
		DAY 57	23APR2003	57	74	120	88	6	0	12	72	118	88	2	0	14
		FINAL		57	74	120	88	6	0	12	72	118	88	2	0	14
	E0022008	SCREEN	05NOV2002	-7	64	120	72				68	110	68			
		DAY 1	12NOV2002	1	62	112	44L				82	131	66			
		BASELINE			62	112	44L				82	131	66			
		DAY 8	19NOV2002	8	80	120	62	18I	8	18	84	115	72	2	-16	6
		DAY 15	26NOV2002	15	70	120	70	8	8	26	64	110	68	-18D	-21D	2
		DAY 22	03DEC2002	22	78	120	68	16I	8	24	66	100	62	-16D	-31D	-4
		DAY 29	12DEC2002	31	66	122	70	4	10	26	75	116	74	-7	-15	8
		DAY 36	17DEC2002	36	64	120	70	2	8	26	70	115	72	-12	-16	6
		DAY 43	24DEC2002	43	62	125	74	0	13	30I	66	110	70	-16D	-21D	4
		DAY 50	31DEC2002	50	68	120	68	6	8	24	70	126	70	-12	-5	4
		DAY 57	07JAN2003	57	68	120	66	6	8	22	78	132	74	-4	1	8
		FINAL		57	68	120	66	6	8	22	78	132	74	-4	1	8
	E0022017	SCREEN	03DEC2002	-16	64	110	80				76	100	78			
		DAY 1	19DEC2002	1	60	120	82				96	116	82			
		BASELINE			60	120	82				96	116	82			
		DAY 8	26DEC2002	8	72	134	94	12	14	12	92	110	96	-4	-6	14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	DAY 15	03JAN2003	16	76	126	86	16I	6	4	104	116	92	8	0	10
		DAY 22	09JAN2003	22	80	122	76	20I	2	-6	108	128	98	12	12	16
		DAY 29	17JAN2003	30	64	116	76	4	-4	-6	96	128	98	0	12	16
		DAY 36	22JAN2003	35	80	116	72	20I	-4	-10	92	122	94	-4	6	12
		DAY 43	31JAN2003	44	76	114	76	16I	-6	-6	104	122	98	8	6	16
		DAY 50	06FEB2003	50	72	122	78	12	2	-4	104	126	90	8	10	8
		DAY 57	13FEB2003	57	88	138	86	28I	18	4	96	132	100	0	16	18
		FINAL		57	88	138	86	28I	18	4	96	132	100	0	16	18
	E0022018	SCREEN	04DEC2002	-8	72	128	78				76	118	80			
		DAY 1	12DEC2002	1	88	130	90				88	126	80			
		BASELINE			88	130	90				88	126	80			
		DAY 8	19DEC2002	8	80	128	78	-8	-2	-12	100	120	76	12	-6	-4
		DAY 15	26DEC2002	15	76	126	72	-12	-4	-18	84	112	76	-4	-14	-4
		DAY 22	02JAN2003	22	84	118	76	-4	-12	-14	80	114	76	-8	-12	-4
		DAY 29	09JAN2003	29	84	126	76	-4	-4	-14	100	116	68	12	-10	-12
		DAY 36	16JAN2003	36	76	124	80	-12	-6	-10	88	118	76	0	-8	-4
		DAY 43	23JAN2003	43	84	118	76	-4	-12	-14	96	114	74	8	-12	-6
		DAY 50	30JAN2003	50	88	116	72	0	-14	-18	100	108	82	12	-18	2
		DAY 57	06FEB2003	57	80	110	74	-8	-20D	-16	88	108	76	0	-18	-4
		FINAL		57	80	110	74	-8	-20D	-16	88	108	76	0	-18	-4
	E0022022	SCREEN	16DEC2002	-14	76	102	62				88	102	74			
		DAY 1	30DEC2002	1	80	110	70				78	114	72			
		BASELINE			80	110	70				78	114	72			
		DAY 8	06JAN2003	8	76	108	64	-4	-2	-6	88	108	68	10	-6	-4
		DAY 15	14JAN2003	16	88	98	54	8	-12	-16	84	96	60	6	-18	-12
		DAY 22	21JAN2003	23	88	100	78	8	-10	8	88	112	68	10	-2	-4
		DAY 29	28JAN2003	30	68	104	60	-12	-6	-10	92	96	66	14	-18	-6
		DAY 36	04FEB2003	37	64	112	68	-16D	2	-2	88	98	70	10	-16	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	DAY 57	27FEB2003	60												
		FINAL		60	64	112	68	-16D	2	-2	88	98	70	10	-16	-2
	E0022027	SCREEN	23JAN2003	-14	60	108	74				64	128	88			
		DAY 1	06FEB2003	1	58	116	80				64	122	78			
		BASELINE			58	116	80				64	122	78			
		DAY 8	13FEB2003	8	70	116	72	12	0	-8	72	108	70	8	-14	-8
		DAY 15	20FEB2003	15	64	104	70	6	-12	-10	72	112	70	8	-10	-8
		DAY 22	27FEB2003	22	64	108	64	6	-8	-16	68	106	74	4	-16	-4
		DAY 29	06MAR2003	29	56	114	70	-2	-2	-10	64	114	84	0	-8	6
		DAY 36	13MAR2003	36	60	110	70	2	-6	-10	76	106	68	12	-16	-10
		DAY 43	20MAR2003	43	64	114	74	6	-2	-6	72	110	72	8	-12	-6
		DAY 50	27MAR2003	50	74	120	76	16I	4	-4	76	118	78	12	-4	0
		DAY 57	03APR2003	57	60	108	70	2	-8	-10	66	110	74	2	-12	-4
		FINAL		57	60	108	70	2	-8	-10	66	110	74	2	-12	-4
	E0022030	SCREEN	07FEB2003	-7	88	128	82				84	138	88			
		DAY 1	14FEB2003	1	88	108	82				96	110	80			
		BASELINE			88	108	82				96	110	80			
		DAY 8	20FEB2003	7	80	122	72	-8	14	-10	96	128	88	0	18	8
		DAY 15	28FEB2003	15	88	108	72	0	0	-10	80	118	84	-16D	8	4
		DAY 22	07MAR2003	22	88	126	68	0	18	-14	96	128	72	0	18	-8
		FINAL		22	88	126	68	0	18	-14	96	128	72	0	18	-8
	E0022031	SCREEN	10FEB2003	-8	64	102	70				60	102	80			
		DAY 1	18FEB2003	1	60	110	78				64	118	74			
		BASELINE			60	110	78				64	118	74			
		DAY 8	25FEB2003	8	76	126	80	16I	16	2	84	110	74	20I	-8	0
		DAY 15	04MAR2003	15	80	118	84	20I	8	6	88	122	88	24I	4	14
		DAY 22	11MAR2003	22	84	122	72	24I	12	-6	88	124	74	24I	6	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022031	DAY 29	18MAR2003	29	80	124	72	20I	14	-6	88	112	86	24I	-6	12
		DAY 36	25MAR2003	36	80	124	80	20I	14	2	88	120	80	24I	2	6
		DAY 43	01APR2003	43	80	118	80	20I	8	2	84	122	90	20I	4	16
		DAY 50	08APR2003	50	84	110	68	24I	0	-10	78	112	78	14	-6	4
		DAY 57	15APR2003	57	78	110	76	18I	0	-2	84	122	84	20I	4	10
		FINAL		57	78	110	76	18I	0	-2	84	122	84	20I	4	10
	E0022032	SCREEN	11FEB2003	-7	86	116	78				92	108	78			
		DAY 1	18FEB2003	1	82	124	76				96	108	74			
		BASELINE			82	124	76				96	108	74			
		DAY 8	28FEB2003	11	78	104	72	-4	-20D	-4	74	108	76	-22D	0	2
		DAY 15	04MAR2003	15	84	114	78	2	-10	2	84	108	76	-12	0	2
		DAY 22	11MAR2003	22	76	120	76	-6	-4	0	84	114	76	-12	6	2
		DAY 29	21MAR2003	32	78	108	62	-4	-16	-14	82	116	70	-14	8	-4
		DAY 36	27MAR2003	38	88	100	56	6	-24D	-20D	92	98	70	-4	-10	-4
		DAY 43	03APR2003	45	80	108	64	-2	-16	-12	88	106	70	-8	-2	-4
		DAY 50	10APR2003	52	74	136	94	-8	12	18	96	122	96	0	14	22
		DAY 57	18APR2003	60	76	108	62	-6	-16	-14	74	106	66	-22D	-2	-8
		FINAL		60	76	108	62	-6	-16	-14	74	106	66	-22D	-2	-8
	E0022036	SCREEN	13FEB2003	-12	72	122	74				80	114	84			
		DAY 1	25FEB2003	1	72	120	68				96	108	96			
		BASELINE			72	120	68				96	108	96			
		DAY 8	03MAR2003	7	78	110	64	6	-10	-4	98	102	80	2	-6	-16
		DAY 15	10MAR2003	14	88	122	82	16I	2	14	96	124	86	0	16	-10
		DAY 22	18MAR2003	22	80	110	68	8	-10	0	88	102	80	-8	-6	-16
		DAY 29	25MAR2003	29	80	110	74	8	-10	6	88	102	82	-8	-6	-14
		DAY 36	01APR2003	36	84	112	68	12	-8	0	88	110	82	-8	2	-14
		DAY 43	08APR2003	43	78	122	74	6	2	6	96	118	88	0	10	-8
		DAY 50	15APR2003	50	78	100	72	6	-20D	4	88	102	72	-8	-6	-24D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	DAY 57	22APR2003	57	64	102	58	-8	-18	-10	80	104	72	-16D	-4	-24D
		FINAL		57	64	102	58	-8	-18	-10	80	104	72	-16D	-4	-24D
	E0022056	SCREEN	09APR2003	-8	84	128	82				88	142	88			
		DAY 1	17APR2003	1	78	112	68				84	114	78			
		BASELINE			78	112	68				84	114	78			
		DAY 8	24APR2003	8	88	110	70	10	-2	2	96	102	72	12	-12	-6
		DAY 15	01MAY2003	15	88	108	70	10	-4	2	96	112	76	12	-2	-2
		DAY 22	08MAY2003	22	100	106	68	22I	-6	0	104	110	80	20I	-4	2
		FINAL		22	100	106	68	22I	-6	0	104	110	80	20I	-4	2
	E0022060	SCREEN	23APR2003	-7	48L	124	74				63	132	90			
		DAY 1	30APR2003	1	48L	116	78				60	124	88			
		BASELINE			48L	116	78				60	124	88			
		DAY 8	05MAY2003	6	53	126	72	5	10	-6	75	126	80	15I	2	-8
		DAY 15	12MAY2003	13	60	104	68	12	-12	-10	66	122	72	6	-2	-16
		DAY 22	19MAY2003	20	57	124	74	9	8	-4	57	124	80	-3	0	-8
		DAY 29	28MAY2003	29	60	116	62	12	0	-16	66	118	74	6	-6	-14
		DAY 36	02JUN2003	34	63	114	70	15I	-2	-8	69	122	72	9	-2	-16
		DAY 43	10JUN2003	42	60	112	60	12	-4	-18	63	120	76	3	-4	-12
		DAY 50	17JUN2003	49	63	124	70	15I	8	-8	72	118	68	12	-6	-20D
		DAY 57	24JUN2003	56	52	110	70	4	-6	-8	60	116	74	0	-8	-14
		FINAL		56	52	110	70	4	-6	-8	60	116	74	0	-8	-14
	E0022063	SCREEN	30APR2003	-7	69	108	78				81	110	86			
		DAY 1	07MAY2003	1	78	112	84				81	98	86			
		BASELINE			78	112	84				81	98	86			
		DAY 8	12MAY2003	6	69	110	74	-9	-2	-10	72	110	80	-9	12	-6
		DAY 15	21MAY2003	15	81	108	76	3	-4	-8	84	110	82	3	12	-4
		DAY 22	28MAY2003	22	69	108	80	-9	-4	-4	75	112	82	-6	14	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	DAY 29		04JUN2003	29	72	108	70	-6	-4	-14	75	104	66	-6	6	-20D
		DAY 36		11JUN2003	36	78	102	64	0	-10	-20D	78	112	70	-3	14	-16
		FINAL			36	78	102	64	0	-10	-20D	78	112	70	-3	14	-16
	E0023008	SCREEN		23JAN2003	-7	68	110	67				70	108	66			
		DAY 1		30JAN2003	1	76	108	68				72	108	66			
		BASELINE				76	108	68				72	108	66			
		DAY 8		06FEB2003	8	79	99	71	3	-9	3	81	102	72	9	-6	6
		DAY 15		13FEB2003	15	97	125	85	21I	17	17	91	131	85	19I	23I	19
		DAY 22		20FEB2003	22	80	102	74	4	-6	6	80	100	70	8	-8	4
		DAY 29		25FEB2003	27	90	108	76	14	0	8	88	110	76	16I	2	10
		DAY 36		06MAR2003	36	76	112	74	0	4	6	80	100	70	8	-8	4
		DAY 43		11MAR2003	41	76	103	63	0	-5	-5	92	125	72	20I	17	6
		DAY 50		18MAR2003	48	76	124	76	0	16	8	81	110	77	9	2	11
		DAY 50	*	24MAR2003	54	78	114	74	2	6	6	78	114	76	6	6	10
		FINAL			54	78	114	74	2	6	6	78	114	76	6	6	10
	E0023015	SCREEN		04MAR2003	-7	82	120	84				86	128	86			
		DAY 1		11MAR2003	1	70	120	68				76	120	70			
		BASELINE				70	120	68				76	120	70			
		DAY 8		18MAR2003	8	63	127	86	-7	7	18	68	120	80	-8	0	10
		DAY 15		25MAR2003	15	81	105	67	11	-15	-1	105	135	91	29I	15	21
		DAY 22		01APR2003	22	75	90L	60	5	-30D	-8	81	93	56	5	-27D	-14
		DAY 29		08APR2003	29	79	116	75	9	-4	7	105	100	73	29I	-20D	3
		DAY 36		15APR2003	36	86	108	73	16I	-12	5	109	118	71	33I	-2	1
		DAY 43		22APR2003	43	82	95	55	12	-25D	-13	86	110	88	10	-10	18
		DAY 50		29APR2003	50	72	128	70	2	8	2	98	128	72	22I	8	2
		DAY 57		06MAY2003	57	87	99	71	17I	-21D	3	97	103	69	21I	-17	-1
		FINAL			57	87	99	71	17I	-21D	3	97	103	69	21I	-17	-1

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	SCREEN		03JUN2003	-6	86	99	62					109	70			
		DAY 1		09JUN2003	1	88	104	64				109	105	64			
		BASELINE				88	104	64				109	105	64			
		DAY 8		16JUN2003	8	96	130	83	8	26I	19	99	113	68	-10	8	4
		DAY 15		23JUN2003	15	88	121	80	0	17	16	88	120	80	-21D	15	16
		DAY 22		30JUN2003	22	100	113	66	12	9	2	121H	131	78	12	26I	14
		DAY 29		07JUL2003	29	97	114	72	9	10	8	126H	116	74	17I	11	10
		DAY 36		14JUL2003	36	126H	121	69	38I	17	5	142H	109	56	33I	4	-8
		DAY 43		22JUL2003	44	107	136	80	19I	32I	16	111	122	80	2	17	16
		DAY 57		05AUG2003	58	100	130	80	12	26I	16	101	126	84	-8	21I	20
		FINAL			58	100	130	80	12	26I	16	101	126	84	-8	21I	20
	E0023037	SCREEN		11JUN2003	-7	68	128	88				70	128	88			
		DAY 1		18JUN2003	1	59	154	98				67	157	100			
		BASELINE				59	154	98				67	157	100			
		DAY 8		24JUN2003	7	86	148	92	27I	-6	-6	90	150	90	23I	-7	-10
		DAY 15		01JUL2003	14	76	159	109H	17I	5	11	89	162	116H	22I	5	16
		DAY 29	*	14JUL2003	27	65	158	103	6	4	5	78	148	106H	11	-9	6
		DAY 29		18JUL2003	31	71	155	100	12	1	2	76	163	110H	9	6	10
		DAY 36		25JUL2003	38	77	143	101	18I	-11	3	96	105	69	29I	-52D	-31D
		DAY 43		01AUG2003	45	74	140	98	15I	-14	0	79	128	86	12	-29D	-14
		DAY 50		08AUG2003	52	97	137	84	38I	-17	-14	98	130	80	31I	-27D	-20D
		DAY 57		15AUG2003	59	94	139	86	35I	-15	-12	86	132	84	19I	-25D	-16
		FINAL			59	94	139	86	35I	-15	-12	86	132	84	19I	-25D	-16
	E0023038	SCREEN		20JUN2003	-10	78	150	98				88	150	96			
		DAY 1		30JUN2003	1	79	149	89				92	157	94			
		BASELINE				79	149	89				92	157	94			
		DAY 8		09JUL2003	10	91	149	82	12	0	-7	100	154	86	8	-3	-8
		DAY 15		15JUL2003	16	82	144	88	3	-5	-1	88	134	86	-4	-23D	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023038	DAY 22	21JUL2003	22	87	153	89	8	4	0	96	144	84	4	-13	-10
		DAY 29	28JUL2003	29	86	155	82	7	6	-7	90	135	80	-2	-22D	-14
		DAY 36	07AUG2003	39	74	124	79	-5	-25D	-10	78	120	77	-14	-37D	-17
		DAY 43	13AUG2003	45	93	138	83	14	-11	-6	87	125	87	-5	-32D	-7
		DAY 50	21AUG2003	53	84	139	95	5	-10	6	78	155	98	-14	-2	4
		DAY 57	27AUG2003	59	84	136	91	5	-13	2	99	109	72	7	-48D	-22D
		FINAL		59	84	136	91	5	-13	2	99	109	72	7	-48D	-22D
	E0023044	SCREEN	08JUL2003	-8	78	130	90				84	134	90			
		DAY 1	16JUL2003	1	81	118	81				85	120	80			
		BASELINE			81	118	81				85	120	80			
		DAY 8	22JUL2003	7	93	108	74	12	-10	-7	109	127	87	24I	7	7
		DAY 15	29JUL2003	14	79	115	77	-2	-3	-4	84	110	76	-1	-10	-4
		DAY 22	05AUG2003	21	84	121	80	3	3	-1	88	120	78	3	0	-2
		DAY 29	12AUG2003	28	72	114	81	-9	-4	0	82	146	102	-3	26I	22
		FINAL		28	72	114	81	-9	-4	0	82	146	102	-3	26I	22
	E0023045	SCREEN	10JUL2003	-7	80	115	78				84	99	69			
		DAY 1	17JUL2003	1	66	110	66				68	110	60			
		BASELINE			66	110	66				68	110	60			
		DAY 8	24JUL2003	8	74	94	61	8	-16	-5	80	98	64	12	-12	4
		DAY 15	31JUL2003	15	74	100	70	8	-10	4	76	98	68	8	-12	8
		DAY 22	07AUG2003	22	70	100	70	4	-10	4	72	100	72	4	-10	12
		DAY 29	14AUG2003	29	88	110	76	22I	0	10	80	113	74	12	3	14
		DAY 36	21AUG2003	36	82	124	71	16I	14	5	86	120	70	18I	10	10
		DAY 43	28AUG2003	43	84	120	76	18I	10	10	88	118	70	20I	8	10
		DAY 50	04SEP2003	50	94	118	80	28I	8	14	90	120	84	22I	10	24
		DAY 57	11SEP2003	57	86	118	80	20I	8	14	80	134	71	12	24I	11
		FINAL		57	86	118	80	20I	8	14	80	134	71	12	24I	11

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	SCREEN	27MAR2003	-7	84	130	90				76	120	82			
		DAY 1	03APR2003	1	64	120	72				72	116	70			
		BASELINE			64	120	72				72	116	70			
		DAY 8	10APR2003	8	60	120	88	-4	0	16	72	130	90	0	14	20
		DAY 15	17APR2003	15	64	120	80	0	0	8	72	116	70	0	0	0
		DAY 22	24APR2003	22	64	120	70	0	0	-2	64	116	80	-8	0	10
		DAY 29	01MAY2003	29	72	130	82	8	10	10	72	120	78	0	4	8
		DAY 36	08MAY2003	36	72	120	82	8	0	10	72	120	80	0	4	10
		DAY 43	15MAY2003	43	84	130	80	20I	10	8	88	120	88	16I	4	18
		DAY 50	22MAY2003	50	80	120	70	16I	0	-2	88	130	80	16I	14	10
		DAY 57	29MAY2003	57	68	120	88	4	0	16	80	120	80	8	4	10
		FINAL		57	68	120	88	4	0	16	80	120	80	8	4	10
	E0026010	SCREEN	15JAN2003	-7	68	138	62				80	145	74			
		DAY 1	22JAN2003	1	61	129	70				66	142	71			
		BASELINE			61	129	70				66	142	71			
		DAY 8	30JAN2003	9	78	121	60	17I	-8	-10	86	138	68	20I	-4	-3
		FINAL		9	78	121	60	17I	-8	-10	86	138	68	20I	-4	-3
	E0026018	SCREEN	06MAR2003	-14	73	138	67				86	139	72			
		DAY 1	20MAR2003	1	88	113	72				94	132	75			
		BASELINE			88	113	72				94	132	75			
		DAY 8	27MAR2003	8	82	136	76	-6	23I	4	90	134	73	-4	2	-2
		DAY 15	03APR2003	15	87	142	65	-1	29I	-7	91	123	79	-3	-9	4
		DAY 22	10APR2003	22	84	145	81	-4	32I	9	89	116	77	-5	-16	2
		DAY 29	17APR2003	29	70	121	70	-18D	8	-2	88	139	79	-6	7	4
		DAY 36	24APR2003	36	94	133	80	6	20I	8	98	145	79	4	13	4
		DAY 43	01MAY2003	43	80	115	73	-8	2	1	96	117	68	2	-15	-7
		DAY 50	08MAY2003	50	79	121	72	-9	8	0	88	105	69	-6	-27D	-6
		DAY 57	15MAY2003	57	71	126	63	-17D	13	-9	80	127	84	-14	-5	9

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	FINAL		57	71	126	63	-17D	13	-9	80	127	84	-14	-5	9
	E0026025	SCREEN	01MAY2003	-8	75	136	82				78	123	88			
		DAY 1	09MAY2003	1	98	127	82				102	133	86			
		BASELINE			98	127	82				102	133	86			
		DAY 8	15MAY2003	7	78	134	88	-20D	7	6	97	131	96	-5	-2	10
		DAY 15	22MAY2003	14	76	115	88	-22D	-12	6	80	130	76	-22D	-3	-10
		DAY 22	29MAY2003	21	80	132	90	-18D	5	8	84	141	96	-18D	8	10
		DAY 29	05JUN2003	28	92	153	87	-6	26I	5	90	148	95	-12	15	9
		DAY 36	13JUN2003	36	80	150	90	-18D	23I	8	96	191H	102	-6	58I	16
		DAY 43	20JUN2003	43	90	150	90	-8	23I	8	89	148	102	-13	15	16
		DAY 50	27JUN2003	50	75	138	88	-23D	11	6	77	132	87	-25D	-1	1
		DAY 57	03JUL2003	56	90	130	87	-8	3	5	85	145	56	-17D	12	-30D
		FINAL		56	90	130	87	-8	3	5	85	145	56	-17D	12	-30D
	E0026029	SCREEN	02JUL2003	-7	63	100	60				72	103	65			
		DAY 1	09JUL2003	1	86	103	64				80	105	70			
		BASELINE			86	103	64				80	105	70			
		DAY 8	16JUL2003	8	92	126	69	6	23I	5	94	135	73	14	30I	3
		DAY 22	28JUL2003	20	100	130	72	14	27I	8	100	120	68	20I	15	-2
		FINAL		20	100	130	72	14	27I	8	100	120	68	20I	15	-2
	E0026030	SCREEN	02JUL2003	-7	66	123	69				66	121	70			
		DAY 1	09JUL2003	1	90	126	66				84	133	69			
		BASELINE			90	126	66				84	133	69			
		DAY 8	16JUL2003	8	72	147	72	-18D	21I	6	80	142	68	-4	9	-1
		DAY 15	23JUL2003	15	72	123	66	-18D	-3	0	82	130	74	-2	-3	5
		DAY 22	30JUL2003	22	86	139	78	-4	13	12	90	131	83	6	-2	14
		DAY 29	04AUG2003	27	77	114	62	-13	-12	-4	89	126	77	5	-7	8
		DAY 36	12AUG2003	35	73	110	85	-17D	-16	19	73	120	85	-11	-13	16

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	DAY 43	19AUG2003	42	67	115	68	-23D	-11	2	74	116	72	-10	-17	3
		DAY 50	26AUG2003	49	75	105	63	-15D	-21D	-3	80	110	70	-4	-23D	1
		DAY 57	03SEP2003	57	65	126	73	-25D	0	7	72	130	80	-12	-3	11
		FINAL		57	65	126	73	-25D	0	7	72	130	80	-12	-3	11
	E0026031	SCREEN	10JUL2003	-11	80	140	83				92	139	84			
		DAY 1	21JUL2003	1	90	120	70				89	130	72			
		BASELINE			90	120	70				89	130	72			
		DAY 8	28JUL2003	8	72	137	72	-18D	17	2	70	140	68	-19D	10	-4
		DAY 15	04AUG2003	15	86	132	72	-4	12	2	82	140	66	-7	10	-6
		DAY 22	11AUG2003	22	73	147	83	-17D	27I	13	85	144	87	-4	14	15
		DAY 29	18AUG2003	29	83	136	82	-7	16	12	90	150	80	1	20I	8
		DAY 36	25AUG2003	36	82	140	80	-8	20I	10	84	142	76	-5	12	4
		DAY 43	02SEP2003	44	86	121	80	-4	1	10	90	123	90	1	-7	18
		DAY 50	08SEP2003	50	72	126	80	-18D	6	10	80	130	76	-9	0	4
		DAY 57	15SEP2003	57	72	110	80	-18D	-10	10	78	122	76	-11	-8	4
		FINAL		57	72	110	80	-18D	-10	10	78	122	76	-11	-8	4
	E0027003	SCREEN *	08JAN2003	-20							86	142	84			
		SCREEN	23JAN2003	-5							78	126	82			
		BASELINE									78	126	82			
		DAY 8	06FEB2003	10	80	130	90				96	120	92	18I	-6	10
		DAY 15	13FEB2003	17	104	142	90				104	132	88	26I	6	6
		DAY 22	19FEB2003	23	92	130	90				104	126	88	26I	0	6
		DAY 29	27FEB2003	31	96	130	94				100	134	96	22I	8	14
		DAY 36	06MAR2003	38	96	120	92				100	114	92	22I	-12	10
		DAY 43	13MAR2003	45	88	124	86				88	134	90	10	8	8
		DAY 50	20MAR2003	52	98	138	98				104	130	92	26I	4	10
		DAY 57	25MAR2003	57	92	152	86				94	148	84	16I	22I	2
		FINAL		57	92	152	86				94	148	84	16I	22I	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	SCREEN	01OCT2002	-3	60	100	70				56	100	70			
		DAY 1	04OCT2002	1	68	102	60				68	98	70			
		BASELINE			68	102	60				68	98	70			
		DAY 8	11OCT2002	8	68	130	80	0	28I	20	70	128	70	2	30I	0
		DAY 15	16OCT2002	13	60	122	70	-8	20I	10	62	120	70	-6	22I	0
		DAY 22	23OCT2002	20	76	118	82	8	16	22	78	124	90	10	26I	20
		DAY 29	31OCT2002	28	68	115	70	0	13	10	62	122	70	-6	24I	0
		DAY 36	07NOV2002	35	70	112	80	2	10	20	84	114	76	16I	16	6
		DAY 43	14NOV2002	42	68	118	82	0	16	22	78	118	84	10	20I	14
		DAY 50	21NOV2002	49	68	130	84	0	28I	24	74	118	92	6	20I	22
		DAY 57	04DEC2002	62	64	110	76	-4	8	16	64	108	80	-4	10	10
		FINAL		62	64	110	76	-4	8	16	64	108	80	-4	10	10
	E0028008	SCREEN	08OCT2002	-7	68	130	78				68	118	76			
		DAY 1	15OCT2002	1	70	100	60				68	120	60			
		BASELINE			70	100	60				68	120	60			
		DAY 8	22OCT2002	8	68	121	68	-2	21I	8	68	116	72	0	-4	12
		DAY 15	29OCT2002	15	76	112	70	6	12	10	76	105	78	8	-15	18
		DAY 22	07NOV2002	24	68	138	70	-2	38I	10	68	130	72	0	10	12
		DAY 29	14NOV2002	31	68	128	76	-2	28I	16	68	126	78	0	6	18
		DAY 36	21NOV2002	38	64	110	70	-6	10	10	64	122	70	-4	2	10
		DAY 43	26NOV2002	43	62	110	68	-8	10	8	66	110	78	-2	-10	18
		DAY 50	03DEC2002	50	56	118	78	-14	18	18	56	114	56	-12	-6	-4
		DAY 57	10DEC2002	57	68	110	70	-2	10	10	68	110	74	0	-10	14
		FINAL		57	68	110	70	-2	10	10	68	110	74	0	-10	14
	E0028009	SCREEN	10OCT2002	-5	54	115	70				56	115	70			
		DAY 1	15OCT2002	1	56	118	60				60	115	60			
		BASELINE			56	118	60				60	115	60			
		DAY 8	23OCT2002	9	54	100	70	-2	-18	10	56	110	70	-4	-5	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	DAY 15	31OCT2002	17	64	116	80	8	-2	20	82	116	82	22I	1	22
		DAY 22	07NOV2002	24	60	102	80	4	-16	20	82	100	80	22I	-15	20
		DAY 29	14NOV2002	31	56	114	76	0	-4	16	72	98	82	12	-17	22
		DAY 36	19NOV2002	36	66	114	78	10	-4	18	88	110	90	28I	-5	30I
		DAY 43	26NOV2002	43	60	118	82	4	0	22	64	118	90	4	3	30I
		DAY 50	03DEC2002	50	60	102	78	4	-16	18	60	108	78	0	-7	18
		DAY 57	12DEC2002	59	68	118	70	12	0	10	72	112	64	12	-3	4
		FINAL		59	68	118	70	12	0	10	72	112	64	12	-3	4
	E0028016	SCREEN	07NOV2002	-7	68	130	72				68	118	80			
		DAY 1	14NOV2002	1	64	118	88				64	110	80			
		BASELINE			64	118	88				64	110	80			
		DAY 8	21NOV2002	8	68	120	82	4	2	-6	68	116	80	4	6	0
		DAY 15	26NOV2002	13	76	126	82	12	8	-6	88	124	90	24I	14	10
		DAY 22	05DEC2002	22	76	130	88	12	12	0	76	119	90	12	9	10
		DAY 29	12DEC2002	29	76	140	86	12	22I	-2	76	118	90	12	8	10
		DAY 36	19DEC2002	36	64	120	78	0	2	-10	64	120	82	0	10	2
		DAY 43	26DEC2002	43	80	112	80	16I	-6	-8	80	120	78	16I	10	-2
		DAY 50	02JAN2003	50	76	128	72	12	10	-16	80	124	70	16I	14	-10
		DAY 57	09JAN2003	57	80	126	80	16I	8	-8	88	122	88	24I	12	8
		FINAL		57	80	126	80	16I	8	-8	88	122	88	24I	12	8
	E0028027	SCREEN	14JAN2003	-7	60	110	92				62	110	88			
		DAY 1	21JAN2003	1	66	110	88				66	110	90			
		BASELINE			66	110	88				66	110	90			
		DAY 8	28JAN2003	8	64	140	98	-2	30I	10	68	134	92	2	24I	2
		DAY 15	04FEB2003	15	80	110	90	14	0	2	76	108	90	10	-2	0
		DAY 22	11FEB2003	22	70	114	92	4	4	4	70	120	92	4	10	2
		DAY 29	20FEB2003	31	62	120	80	-4	10	-8	79	112	74	13	2	-16
		DAY 36	28FEB2003	39	72	88L	70	6	-22D	-18	76	90L	68	10	-20D	-22D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	FINAL		39	72	88L	70	6	-22D	-18	76	90L	68	10	-20D	-22D
	E0028029	SCREEN	28JAN2003	-7	56	110	80				62	112	88			
		DAY 1	04FEB2003	1	72	118	74				76	118	92			
		BASELINE			72	118	74				76	118	92			
		DAY 8	11FEB2003	8	72	124	64	0	6	-10	76	120	58	0	2	-34D
		DAY 15	17FEB2003	14	88	114	84	16I	-4	10	88	108	92	12	-10	0
		DAY 22	27FEB2003	24	80	130	78	8	12	4	84	132	76	8	14	-16
		DAY 29	06MAR2003	31	72	122	70	0	4	-4	90	110	62	14	-8	-30D
		DAY 36	13MAR2003	38	78	120	74	6	2	0	84	114	80	8	-4	-12
		DAY 43	20MAR2003	45	72	120	80	0	2	6	76	118	84	0	0	-8
		DAY 50	27MAR2003	52	78	122	90	6	4	16	76	110	84	0	-8	-8
		DAY 57	04APR2003	60	68	122	90	-4	4	16	68	118	84	-8	0	-8
		FINAL		60	68	122	90	-4	4	16	68	118	84	-8	0	-8
	E0028034	SCREEN	20MAR2003	-12	64	122	82				68	114	76			
		DAY 1	01APR2003	1	76	122	70				92	110	66			
		BASELINE			76	122	70				92	110	66			
		DAY 8	08APR2003	8	68	114	84	-8	-8	14	80	116	84	-12	6	18
		DAY 15	15APR2003	15	84	122	84	8	0	14	92	100	76	0	-10	10
		DAY 22	22APR2003	22	80	122	70	4	0	0	88	116	66	-4	6	0
		DAY 29	01MAY2003	31	92	126	80	16I	4	10	100	122	78	8	12	12
		DAY 36	06MAY2003	36	88	120	80	12	-2	10	100	120	76	8	10	10
		DAY 43	13MAY2003	43	88	128	64	12	6	-6	100	118	66	8	8	0
		DAY 50	21MAY2003	51	88	124	76	12	2	6	96	122	74	4	12	8
		DAY 57	02JUN2003	63	80	116	88	4	-6	18	88	104	84	-4	-6	18
		FINAL		63	80	116	88	4	-6	18	88	104	84	-4	-6	18
	E0028043	SCREEN	29MAY2003	-7	60	146	92				64	144	88			
		DAY 1	05JUN2003	1	70	154	98				74	150	94			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	BASELINE			70	154	98				74	150	94			
		DAY 8	12JUN2003	8	80	155	105H	10	1	7	100	150	110H	26I	0	16
		DAY 15	19JUN2003	15	74	140	100	4	-14	2	64	138	104	-10	-12	10
		DAY 22	26JUN2003	22	78	130	80	8	-24D	-18	80	130	86	6	-20D	-8
		DAY 29	01JUL2003	27	100	140	100	30I	-14	2	98	130	98	24I	-20D	4
		DAY 36	08JUL2003	34	60	130	86	-10	-24D	-12	64	130	90	-10	-20D	-4
		DAY 43	15JUL2003	41	80	140	100	10	-14	2	80	140	102	6	-10	8
		DAY 50	22JUL2003	48	76	142	92	6	-12	-6	76	128	94	2	-22D	0
		DAY 57	29JUL2003	55	60	130	80	-10	-24D	-18	80	140	88	6	-10	-6
		FINAL		55	60	130	80	-10	-24D	-18	80	140	88	6	-10	-6
	E0028045	SCREEN	09JUN2003	-9	74	140	82				80	120	70			
		DAY 1	18JUN2003	1	72	126	84				84	132	88			
		BASELINE			72	126	84				84	132	88			
		DAY 8	25JUN2003	8	80	112	74	8	-14	-10	78	115	86	-6	-17	-2
		DAY 15	30JUN2003	13	106	120	78	34I	-6	-6	110	115	86	26I	-17	-2
		DAY 57	11SEP2003	86	76	115	78	4	-11	-6	76	100	80	-8	-32D	-8
		FINAL		86	76	115	78	4	-11	-6	76	100	80	-8	-32D	-8
	E0029005	SCREEN	14NOV2002	-13	78	102	74				80	108	68			
		DAY 1	27NOV2002	1	56	118	82				80	110	82			
		BASELINE			56	118	82				80	110	82			
		DAY 8	03DEC2002	7	72	120	84	16I	2	2	96	110	82	16I	0	0
		DAY 15	09DEC2002	13	84	134	92	28I	16	10	92	134	90	12	24I	8
		DAY 22	16DEC2002	20	96	108	70	40I	-10	-12	112	104	80	32I	-6	-2
		DAY 29	23DEC2002	27	80	118	76	24I	0	-6	112	126	80	32I	16	-2
		DAY 36	30DEC2002	34	92	110	76	36I	-8	-6	92	110	82	12	0	0
		DAY 43	07JAN2003	42	76	110	80	20I	-8	-2	104	110	82	24I	0	0
		DAY 50	14JAN2003	49	80	90L	64	24I	-28D	-18	100	106	80	20I	-4	-2
		DAY 57	21JAN2003	56	80	110	80	24I	-8	-2	92	110	82	12	0	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	FINAL			56	80	110	80	24I	-8	-2	92	110	82	12	0	0
	E0030001	SCREEN		12NOV2002	-7	80	120	78				88	126	84			
		DAY 1		19NOV2002	1	68	120	84				80	124	84			
		BASELINE				68	120	84				80	124	84			
		DAY 8		26NOV2002	8	80	110	66	12	-10	-18	84	110	68	4	-14	-16
		DAY 15		03DEC2002	15	80	138	88	12	18	4	84	134	86	4	10	2
		DAY 22		10DEC2002	22	84	110	74	16I	-10	-10	88	112	74	8	-12	-10
		DAY 29		17DEC2002	29	92	120	76	24I	0	-8	92	120	80	12	-4	-4
		DAY 43		02JAN2003	45	72	110	72	4	-10	-12	84	108	78	4	-16	-6
		DAY 50		09JAN2003	52	88	114	76	20I	-6	-8	88	126	80	8	2	-4
		DAY 57		16JAN2003	59	80	120	80	12	0	-4	80	120	82	0	-4	-2
		FINAL			59	80	120	80	12	0	-4	80	120	82	0	-4	-2
	E0030008	SCREEN		07JAN2003	-7	62	110	70				63	106	72			
		DAY 1		14JAN2003	1	60	112	70				60	108	76			
		BASELINE				60	112	70				60	108	76			
		DAY 8		23JAN2003	10	72	110	80	12	-2	10	80	118	86	20I	10	10
		DAY 15		30JAN2003	17	80	118	84	20I	6	14	80	112	84	20I	4	8
		DAY 22		07FEB2003	25	64	108	70	4	-4	0	80	104	76	20I	-4	0
		DAY 29		14FEB2003	32	80	110	70	20I	-2	0	88	104	70	28I	-4	-6
		DAY 36		21FEB2003	39	68	112	76	8	0	6	76	108	78	16I	0	2
		DAY 50		03MAR2003	49	64	118	74	4	6	4	72	110	80	12	2	4
		DAY 57	*	11MAR2003	57	60	110	70	0	-2	0	64	104	80	4	-4	4
		DAY 57		18MAR2003	64	80	108	86	20I	-4	16	72	110	76	12	2	0
		FINAL			64	80	108	86	20I	-4	16	72	110	76	12	2	0
	E0030015	SCREEN		13FEB2003	-8	52	122	86				56	132	92			
		DAY 1		21FEB2003	1	68	118	74				74	116	82			
		BASELINE				68	118	74				74	116	82			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	DAY 8		03MAR2003	11	60	126	74	-8	8	0	68	120	70	-6	4	-12
		DAY 15		11MAR2003	19	60	130	74	-8	12	0	88	136	80	14	20I	-2
		DAY 29		19MAR2003	27	56	114	64	-12	-4	-10	80	120	80	6	4	-2
		DAY 36		26MAR2003	34	56	130	80	-12	12	6	72	124	84	-2	8	2
		DAY 43		02APR2003	41	52	112	82	-16D	-6	8	80	110	84	6	-6	2
		DAY 50		09APR2003	48	52	110	80	-16D	-8	6	72	112	78	-2	-4	-4
		DAY 57	*	17APR2003	56	52	130	80	-16D	12	6	68	110	84	-6	-6	2
		DAY 57		22APR2003	61	60	120	84	-8	2	10	72	124	90	-2	8	8
		FINAL			61	60	120	84	-8	2	10	72	124	90	-2	8	8
	E0030022	SCREEN		06JUN2003	-10	64	124	92				62	122	91			
		DAY 1		16JUN2003	1	72	122	80				88	124	84			
		BASELINE				72	122	80				88	124	84			
		DAY 8		20JUN2003	5	68	118	90	-4	-4	10	78	120	90	-10	-4	6
		DAY 15		30JUN2003	15	68	112	84	-4	-10	4	80	118	88	-8	-6	4
		DAY 22		07JUL2003	22	68	134	90	-4	12	10	80	134	90	-8	10	6
		DAY 29		14JUL2003	29	60	124	90	-12	2	10	90	126	90	2	2	6
		DAY 36		21JUL2003	36	60	128	88	-12	6	8	64	124	88	-24D	0	4
		DAY 43		29JUL2003	44	60	124	88	-12	2	8	64	120	90	-24D	-4	6
		DAY 50		05AUG2003	51	68	128	92	-4	6	12	68	122	96	-20D	-2	12
		DAY 57		14AUG2003	60	72	124	88	0	2	8	76	128	90	-12	4	6
		FINAL			60	72	124	88	0	2	8	76	128	90	-12	4	6
	E0031002	SCREEN		20NOV2002	-7	74	120	88				76	118	82			
		DAY 1		27NOV2002	1	60	122	62				74	118	72			
		BASELINE				60	122	62				74	118	72			
		DAY 8		06DEC2002	10	80	90L	70	20I	-32D	8	84	105	75	10	-13	3
		DAY 15		12DEC2002	16	68	112	80	8	-10	18	72	110	80	-2	-8	8
		DAY 22		19DEC2002	23	70	118	64	10	-4	2	64	120	68	-10	2	-4
		DAY 29		27DEC2002	31	60	110	68	0	-12	6	64	118	72	-10	0	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	DAY 36		02JAN2003	37	58	108	58	-2	-14	-4	67	110	64	-7	-8	-8
		DAY 50	*	13JAN2003	48	66	118	62	6	-4	0	60	124	68	-14	6	-4
		DAY 50		17JAN2003	52	68	110	64	8	-12	2	72	114	70	-2	-4	-2
		DAY 57		22JAN2003	57	66	104	60	6	-18	-2	70	116	70	-4	-2	-2
		FINAL			57	66	104	60	6	-18	-2	70	116	70	-4	-2	-2
	E0031003	SCREEN		03DEC2002	-7	72	110	78				78	118	82			
		DAY 1		10DEC2002	1	78	116	80				90	112	80			
		BASELINE				78	116	80				90	112	80			
		DAY 8		17DEC2002	8	92	128	84	14	12	4	96	124	81	6	12	1
		DAY 15		23DEC2002	14	90	110	72	12	-6	-8	94	114	74	4	2	-6
		DAY 22		31DEC2002	22	74	119	76	-4	3	-4	80	120	80	-10	8	0
		DAY 29		07JAN2003	29	80	122	68	2	6	-12	88	124	68	-2	12	-12
		DAY 36		15JAN2003	37	64	112	74	-14	-4	-6	75	114	76	-15D	2	-4
		DAY 43		21JAN2003	43	90	120	78	12	4	-2	90	124	84	0	12	4
		DAY 50		30JAN2003	52	78	124	76	0	8	-4	86	130	80	-4	18	0
		DAY 57		04FEB2003	57	74	124	76	-4	8	-4	90	130	82	0	18	2
		FINAL			57	74	124	76	-4	8	-4	90	130	82	0	18	2
	E0033015	SCREEN		03APR2003	-7	52	100	70				60	100	72			
		DAY 1		10APR2003	1	60	98	68				64	100	70			
		BASELINE				60	98	68				64	100	70			
		DAY 8		17APR2003	8	56	90L	70	-4	-8	2	64	100	70	0	0	0
		DAY 15		22APR2003	13	56	98	62	-4	0	-6	64	100	66	0	0	-4
		DAY 15	*	28APR2003	19	52	110	70	-8	12	2	68	110	70	4	10	0
		DAY 29		06MAY2003	27	60	100	60	0	2	-8	84	100	64	20I	0	-6
		DAY 36		13MAY2003	34	48L	90L	70	-12	-8	2	60	96	70	-4	-4	0
		DAY 43		20MAY2003	41	56	100	70	-4	2	2	64	100	70	0	0	0
		DAY 50		27MAY2003	48	56	100	70	-4	2	2	72	110	70	8	10	0
		DAY 57		04JUN2003	56	64	100	70	4	2	2	68	100	70	4	0	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	FINAL		56	64	100	70	4	2	2	68	100	70	4	0	0
	E0034002	SCREEN	14MAR2003	-11	72	145	100				88	130	95			
		DAY 1	25MAR2003	1	68	150	100				80	145	105H			
		BASELINE			68	150	100				80	145	105H			
		DAY 8	01APR2003	8	84	140	88	16I	-10	-12	96	132	86	16I	-13	-19
		DAY 15	08APR2003	15	72	128	88	4	-22D	-12	92	130	94	12	-15	-11
		DAY 22	15APR2003	22	76	132	85	8	-18	-15	80	138	90	0	-7	-15
		FINAL		22	76	132	85	8	-18	-15	80	138	90	0	-7	-15
	E0034003	SCREEN	11APR2003	-13	68	120	80				84	115	70			
		DAY 1	24APR2003	1	68	116	74				84	118	78			
		BASELINE			68	116	74				84	118	78			
		DAY 8	01MAY2003	8	72	114	80	4	-2	6	92	118	82	8	0	4
		DAY 15	08MAY2003	15	84	126	82	16I	10	8	102	128	88	18I	10	10
		DAY 22	15MAY2003	22	88	110	80	20I	-6	6	96	118	85	12	0	7
		DAY 29	22MAY2003	29	68	120	85	0	4	11	84	125	80	0	7	2
		DAY 36	29MAY2003	36	68	115	70	0	-1	-4	96	120	85	12	2	7
		DAY 43	05JUN2003	43	84	120	80	16I	4	6	100	118	76	16I	0	-2
		DAY 50	12JUN2003	50	76	125	75	8	9	1	92	130	90	8	12	12
		DAY 57	19JUN2003	57	68	115	85	0	-1	11	80	125	90	-4	7	12
		FINAL		57	68	115	85	0	-1	11	80	125	90	-4	7	12
	E0034006	SCREEN	25APR2003	-21	56	120	65				72	130	80			
		DAY 1	16MAY2003	1	76	125	70				80	130	90			
		BASELINE			76	125	70				80	130	90			
		DAY 8	23MAY2003	8	68	130	80	-8	5	10	92	120	85	12	-10	-5
		DAY 15	02JUN2003	18	80	124	86	4	-1	16	88	122	82	8	-8	-8
		DAY 22	09JUN2003	25	76	125	80	0	0	10	86	110	70	6	-20D	-20D
		DAY 29	13JUN2003	29	80	108	74	4	-17	4	84	110	72	4	-20D	-18

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L: Potentially Clinically Important low. H: Potentially Clinically Important high.

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	DAY 36	20JUN2003	36	74	125	90	-2	0	20	88	110	85	8	-20D	-5
		DAY 43	27JUN2003	43	86	135	85	10	10	15	84	139	90	4	9	0
		DAY 50	03JUL2003	49	68	130	95	-8	5	25	80	140	100	0	10	10
		DAY 57	10JUL2003	56	68	125	85	-8	0	15	80	130	90	0	0	0
		FINAL		56	68	125	85	-8	0	15	80	130	90	0	0	0
	E0034008	SCREEN	15MAY2003	-9	72	116	78				84	118	82			
		DAY 1	23MAY2003	-1	64	130	70				76	110	85			
		BASELINE			64	130	70				76	110	85			
		DAY 8	02JUN2003	10	92	125	90	28I	-5	20	104	120	85	28I	10	0
		DAY 15	06JUN2003	14	64	122	85	0	-8	15	76	110	80	0	0	-5
		DAY 22	13JUN2003	21	74	102	70	10	-28D	0	78	106	70	2	-4	-15
		DAY 29	20JUN2003	28	68	114	80	4	-16	10	72	108	76	-4	-2	-9
		DAY 36	27JUN2003	35	64	120	80	0	-10	10	72	130	85	-4	20I	0
		DAY 43	07JUL2003	45	68	120	85	4	-10	15	88	125	95	12	15	10
		DAY 50	14JUL2003	52	64	110	70	0	-20D	0	88	110	80	12	0	-5
		DAY 57	21JUL2003	59	68	125	80	4	-5	10	88	120	85	12	10	0
		FINAL		59	68	125	80	4	-5	10	88	120	85	12	10	0
	E0035005	SCREEN	26NOV2002	-7	96	114	80				104	118	84			
		DAY 1	03DEC2002	1	90	114	80				96	118	82			
		BASELINE			90	114	80				96	118	82			
		DAY 8	12DEC2002	10	90	116	68	0	2	-12	94	118	72	-2	0	-10
		DAY 15	17DEC2002	15	88	118	68	-2	4	-12	90	118	76	-6	0	-6
		DAY 22	24DEC2002	22	82	114	72	-8	0	-8	88	116	78	-8	-2	-4
		DAY 29	31DEC2002	29	82	112	70	-8	-2	-10	84	114	74	-12	-4	-8
		DAY 36	07JAN2003	36	82	114	70	-8	0	-10	88	114	76	-8	-4	-6
		DAY 43	14JAN2003	43	84	114	72	-6	0	-8	86	114	78	-10	-4	-4
		DAY 50	21JAN2003	50	66	124	64	-24D	10	-16	68	126	68	-28D	8	-14
		FINAL		50	66	124	64	-24D	10	-16	68	126	68	-28D	8	-14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	SCREEN	24JUN2003	-7	93	109	68				94	107	71			
		DAY 1	01JUL2003	1	61	103	66				71	100	66			
		BASELINE			61	103	66				71	100	66			
		DAY 8	08JUL2003	8	75	106	65	14	3	-1	89	103	66	18I	3	0
		DAY 15	15JUL2003	15	86	122	65	25I	19	-1	95	119	76	24I	19	10
		DAY 22	23JUL2003	23	78	109	72	17I	6	6	96	119	73	25I	19	7
		DAY 29	29JUL2003	29	91	113	78	30I	10	12	96	119	79	25I	19	13
		DAY 36	05AUG2003	36	90	118	78	29I	15	12	84	123	73	13	23I	7
		DAY 43	12AUG2003	43	66	120	69	5	17	3	72	120	73	1	20I	7
		DAY 50	19AUG2003	50	105	120	73	44I	17	7	115	110	74	44I	10	8
		DAY 57	27AUG2003	58	77	111	67	16I	8	1	109	116	81	38I	16	15
		FINAL		58	77	111	67	16I	8	1	109	116	81	38I	16	15
	E0037005	SCREEN	26FEB2003	-8	72	118	70				68	114	70			
		DAY 1	06MAR2003	1	72	114	70				72	110	70			
		BASELINE			72	114	70				72	110	70			
		DAY 8	13MAR2003	8	80	121	80	8	7	10	80	115	80	8	5	10
		DAY 15	20MAR2003	15	60	115	80	-12	1	10	80	115	70	8	5	0
		DAY 22	27MAR2003	22	60	114	78	-12	0	8	60	116	80	-12	6	10
		DAY 29	03APR2003	29	72	118	70	0	4	0	72	118	72	0	8	2
		DAY 36	10APR2003	36	84	130	80	12	16	10	84	130	80	12	20I	10
		DAY 43	17APR2003	43	80	132	80	8	18	10	84	128	80	12	18	10
		DAY 50	24APR2003	50	80	130	90	8	16	20	80	130	90	8	20I	20
		DAY 57	01MAY2003	57	68	130	98	-4	16	28	72	120	70	0	10	0
		FINAL		57	68	130	98	-4	16	28	72	120	70	0	10	0
	E0039006	SCREEN	10DEC2002	-20	88	134	86				94	138	94			
		DAY 1	30DEC2002	1	68	124	90				80	116	86			
		BASELINE			68	124	90				80	116	86			
		DAY 8	06JAN2003	8	88	108	78	20I	-16	-12	65	102	80	-15D	-14	-6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	DAY 15	13JAN2003	15	64	156	108H	-4	32I	18	68	132	100	-12	16	14
		DAY 22	20JAN2003	22	77	140	98	9	16	8	97	128	102	17I	12	16
		DAY 29	28JAN2003	30	84	140	96	16I	16	6	72	128	90	-8	12	4
		DAY 36	04FEB2003	37	76	112	74	8	-12	-16	88	116	78	8	0	-8
		DAY 43	10FEB2003	43	60	126	94	-8	2	4	72	118	96	-8	2	10
		DAY 50	18FEB2003	51	88	130	96	20I	6	6	89	112	90	9	-4	4
		DAY 57	24FEB2003	57	76	116	82	8	-8	-8	84	114	86	4	-2	0
		FINAL		57	76	116	82	8	-8	-8	84	114	86	4	-2	0
	E0039015	SCREEN	02JAN2003	-21	50	126	80				56	118	82			
		DAY 1	23JAN2003	1	54	136	86				63	140	92			
		BASELINE			54	136	86				63	140	92			
		DAY 8	30JAN2003	8	56	142	92	2	6	6	64	136	98	1	-4	6
		DAY 15	06FEB2003	15	60	136	96	6	0	10	72	142	98	9	2	6
		DAY 22	14FEB2003	23	62	130	78	8	-6	-8	70	126	96	7	-14	4
		DAY 29	20FEB2003	29	58	116	76	4	-20D	-10	60	120	86	-3	-20D	-6
		DAY 36	27FEB2003	36	58	140	86	4	4	0	64	138	94	1	-2	2
		DAY 43	06MAR2003	43	56	132	92	2	-4	6	58	126	94	-5	-14	2
		DAY 50	14MAR2003	51	56	118	80	2	-18	-6	64	128	88	1	-12	-4
		DAY 57	20MAR2003	57	56	128	96	2	-8	10	60	132	94	-3	-8	2
		FINAL		57	56	128	96	2	-8	10	60	132	94	-3	-8	2
	E0039024	SCREEN	05FEB2003	-22	74	110	76				84	112	80			
		DAY 1	27FEB2003	1	88	112	82				80	118	88			
		BASELINE			88	112	82				80	118	88			
		DAY 8	05MAR2003	7	70	98	68	-18D	-14	-14	70	100	68	-10	-18	-20D
		DAY 15	11MAR2003	13	60	106	78	-28D	-6	-4	64	110	82	-16D	-8	-6
		DAY 22	20MAR2003	22	84	100	70	-4	-12	-12	86	108	60	6	-10	-28D
		DAY 29	27MAR2003	29	88	110	76	0	-2	-6	92	120	90	12	2	2
		DAY 36	03APR2003	36	72	102	64	-16D	-10	-18	88	108	86	8	-10	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	DAY 43	10APR2003	43	68	116	82	-20D	4	0	76	120	90	-4	2	2
		DAY 50	17APR2003	50	74	104	76	-14	-8	-6	78	114	90	-2	-4	2
		DAY 57	24APR2003	57	64	100	66	-24D	-12	-16	68	110	80	-12	-8	-8
		FINAL		57	64	100	66	-24D	-12	-16	68	110	80	-12	-8	-8
	E0039025	SCREEN	26FEB2003	-20	60	134	96				64	130	100			
		DAY 1	18MAR2003	1	68	134	86				69	126	96			
		BASELINE			68	134	86				69	126	96			
		DAY 8	25MAR2003	8	80	114	80	12	-20D	-6	84	116	86	15I	-10	-10
		DAY 15	01APR2003	15	88	126	98	20I	-8	12	84	126	100	15I	0	4
		DAY 22	10APR2003	24	68	136	94	0	2	8	76	134	104	7	8	8
		DAY 29	15APR2003	29	70	122	96	2	-12	10	72	130	98	3	4	2
		DAY 36	22APR2003	36	60	130	94	-8	-4	8	68	128	98	-1	2	2
		DAY 43	29APR2003	43	70	120	92	2	-14	6	78	122	96	9	-4	0
		DAY 50	06MAY2003	50	84	126	88	16I	-8	2	88	120	84	19I	-6	-12
		DAY 57	27MAY2003	71	80	138	96	12	4	10	88	134	98	19I	8	2
		FINAL		71	80	138	96	12	4	10	88	134	98	19I	8	2
	E0039041	SCREEN	07APR2003	-8	60	122	80				64	116	78			
		DAY 1	15APR2003	1	64	120	82				68	124	84			
		BASELINE			64	120	82				68	124	84			
		DAY 8	22APR2003	8	68	132	86	4	12	4	88	120	88	20I	-4	4
		DAY 15	29APR2003	15	88	140	92	24I	20I	10	86	132	86	18I	8	2
		DAY 22	06MAY2003	22	62	124	86	-2	4	4	66	128	84	-2	4	0
		DAY 29	13MAY2003	29	64	118	86	0	-2	4	76	124	88	8	0	4
		DAY 36	20MAY2003	36	66	134	80	2	14	-2	78	130	86	10	6	2
		DAY 43	27MAY2003	43	64	132	88	0	12	6	70	122	100	2	-2	16
		DAY 50	03JUN2003	50	60	128	78	-4	8	-4	78	132	86	10	8	2
		DAY 57	11JUN2003	58	58	126	86	-6	6	4	68	122	84	0	-2	0
		FINAL		58	58	126	86	-6	6	4	68	122	84	0	-2	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	SCREEN	05MAY2003	-17	72	102	80				78	108	82			
		DAY 1	22MAY2003	1	64	108	76				80	104	78			
		BASELINE			64	108	76				80	104	78			
		DAY 8	29MAY2003	8	77	118	80	13	10	4	80	116	86	0	12	8
		DAY 15	04JUN2003	14	100	120	86	36I	12	10	80	106	80	0	2	2
		DAY 22	11JUN2003	21	92	114	76	28I	6	0	100	120	88	20I	16	10
		DAY 29	18JUN2003	28	98	112	84	34I	4	8	100	118	90	20I	14	12
		DAY 36	26JUN2003	36	84	106	84	20I	-2	8	92	110	90	12	6	12
		DAY 43	02JUL2003	42	100	130	88	36I	22I	12	102	120	84	22I	16	6
		DAY 50	09JUL2003	49	77	126	80	13	18	4	88	128	88	8	24I	10
		FINAL		49	77	126	80	13	18	4	88	128	88	8	24I	10
	E0039051	SCREEN	22MAY2003	-25	92	128	76				106	136	80			
		DAY 1	16JUN2003	1	78	126	88				80	136	84			
		BASELINE			78	126	88				80	136	84			
		DAY 8	23JUN2003	8	66	124	90	-12	-2	2	72	130	92	-8	-6	8
		DAY 15	30JUN2003	15	66	134	84	-12	8	-4	72	124	80	-8	-12	-4
		DAY 22	07JUL2003	22	80	136	86	2	10	-2	78	138	92	-2	2	8
		DAY 29	14JUL2003	29	86	136	96	8	10	8	88	120	90	8	-16	6
		DAY 36	22JUL2003	37	88	140	88	10	14	0	97	130	96	17I	-6	12
		DAY 43	28JUL2003	43	90	146	98	12	20I	10	88	128	92	8	-8	8
		DAY 50	04AUG2003	50	80	132	96	2	6	8	76	126	90	-4	-10	6
		DAY 57	12AUG2003	58	90	124	80	12	-2	-8	93	112	80	13	-24D	-4
		FINAL		58	90	124	80	12	-2	-8	93	112	80	13	-24D	-4
	E0039053	SCREEN	16JUN2003	-25	64	156	96				74	140	92			
		DAY 1	11JUL2003	1	84	140	86				88	150	96			
		BASELINE			84	140	86				88	150	96			
		DAY 8	18JUL2003	8	84	152	80	0	12	-6	88	142	90	0	-8	-6
		DAY 15	25JUL2003	15	76	148	80	-8	8	-6	84	142	82	-4	-8	-14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	DAY 22	01AUG2003	22	80	130	80	-4	-10	-6	88	126	86	0	-24D	-10
		DAY 29	07AUG2003	28	68	144	88	-16D	4	2	76	142	84	-12	-8	-12
		DAY 36	14AUG2003	35	74	140	74	-10	0	-12	82	126	80	-6	-24D	-16
		DAY 43	21AUG2003	42	85	134	80	1	-6	-6	100	126	88	12	-24D	-8
		DAY 50	29AUG2003	50	84	126	72	0	-14	-14	100	118	86	12	-32D	-10
		DAY 57	08SEP2003	60	80	136	90	-4	-4	4	84	124	88	-4	-26D	-8
		FINAL		60	80	136	90	-4	-4	4	84	124	88	-4	-26D	-8
	E0039057	SCREEN	02JUL2003	-12	60	118	82				68	128	100			
		DAY 1	14JUL2003	1	60	124	78				76	118	90			
		BASELINE			60	124	78				76	118	90			
		DAY 8	22JUL2003	9	60	118	74	0	-6	-4	76	114	86	0	-4	-4
		DAY 15	28JUL2003	15	60	122	80	0	-2	2	68	124	90	-8	6	0
		DAY 22	04AUG2003	22	60	110	68	0	-14	-10	77	110	80	1	-8	-10
		DAY 29	12AUG2003	30	62	126	80	2	2	2	80	112	90	4	-6	0
		DAY 36	18AUG2003	36	66	118	70	6	-6	-8	77	128	88	1	10	-2
		DAY 43	26AUG2003	44	60	118	80	0	-6	2	64	114	80	-12	-4	-10
		DAY 50	02SEP2003	51	72	138	68	12	14	-10	92	110	78	16I	-8	-12
		DAY 57	09SEP2003	58	64	124	70	4	0	-8	72	110	80	-4	-8	-10
		FINAL		58	64	124	70	4	0	-8	72	110	80	-4	-8	-10
	E0041003	SCREEN	16JAN2003	-12	80	110	72				84	112	76			
		DAY 1	28JAN2003	1	72	108	66				72	114	70			
		BASELINE			72	108	66				72	114	70			
		DAY 8	04FEB2003	8	68	108	80	-4	0	14	76	120	88	4	6	18
		DAY 15	11FEB2003	15	76	132	82	4	24I	16	80	140	84	8	26I	14
		DAY 22	18FEB2003	22	76	136	78	4	28I	12	76	134	82	4	20I	12
		DAY 29	25FEB2003	29	72	148	86	0	40I	20	76	136	80	4	22I	10
		DAY 36	04MAR2003	36	84	146	80	12	38I	14	86	142	84	14	28I	14
		DAY 43	11MAR2003	43	80	126	80	8	18	14	80	130	84	8	16	14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 50	18MAR2003	50	64	126	80	-8	18	14	72	126	82	0	12	12
		DAY 57	25MAR2003	57	80	118	82	8	10	16	88	120	88	16I	6	18
		FINAL		57	80	118	82	8	10	16	88	120	88	16I	6	18
	E0041008	SCREEN	26MAR2003	-12	84	122	80				88	126	82			
		DAY 1	07APR2003	1	77	120	80				84	122	80			
		BASELINE			77	120	80				84	122	80			
		DAY 8	14APR2003	8	60	110	80	-17D	-10	0	66	110	76	-18D	-12	-4
		DAY 15	22APR2003	16	66	118	80	-11	-2	0	72	110	72	-12	-12	-8
		DAY 22	28APR2003	22	66	120	70	-11	0	-10	66	118	70	-18D	-4	-10
		DAY 29	05MAY2003	29	82	110	80	5	-10	0	80	110	76	-4	-12	-4
		DAY 36	12MAY2003	36	80	112	80	3	-8	0	84	108	78	0	-14	-2
		DAY 43	21MAY2003	45	76	116	82	-1	-4	2	78	112	78	-6	-10	-2
		DAY 50	27MAY2003	51	72	118	80	-5	-2	0	70	116	78	-14	-6	-2
		DAY 57	02JUN2003	57	76	118	78	-1	-2	-2	84	114	80	0	-8	0
		FINAL		57	76	118	78	-1	-2	-2	84	114	80	0	-8	0
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	SCREEN	26FEB2003	-14	72	120	80				72	120	80			
		DAY 1	12MAR2003	1	70	120	75				70	130	80			
		BASELINE			70	120	75				70	130	80			
		DAY 8	19MAR2003	8	64	120	70	-6	0	-5	68	120	70	-2	-10	-10
		DAY 15	26MAR2003	15	68	130	70	-2	10	-5	70	130	70	0	0	-10
		DAY 22	02APR2003	22	80	150	90	10	30I	15	82	152	82	12	22I	2
		DAY 29	09APR2003	29	64	120	80	-6	0	5	64	120	80	-6	-10	0
		DAY 36	16APR2003	36	72	140	80	2	20I	5	72	140	80	2	10	0
		DAY 43	23APR2003	43	65	130	75	-5	10	0	68	135	80	-2	5	0
		DAY 50	30APR2003	50	63	125	80	-7	5	5	65	130	85	-5	0	5
		DAY 57	07MAY2003	57	74	120	75	4	0	0	74	120	75	4	-10	-5

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	FINAL		57	74	120	75	4	0	0	74	120	75	4	-10	-5
	E0003018	SCREEN	06MAY2003	-7	54	124	90				62	128	84			
		DAY 1	13MAY2003	1	62	118	78				68	116	84			
		BASELINE			62	118	78				68	116	84			
		DAY 8	20MAY2003	8	70	138	88	8	20I	10	76	128	88	8	12	4
		DAY 15	27MAY2003	15	70	130	88	8	12	10	88	124	88	20I	8	4
		DAY 22	03JUN2003	22	66	118	90	4	0	12	70	112	88	2	-4	4
		DAY 29	10JUN2003	29	68	112	82	6	-6	4	72	108	80	4	-8	-4
		DAY 36	17JUN2003	36	70	120	86	8	2	8	72	118	84	4	2	0
		DAY 43	24JUN2003	43	66	126	90	4	8	12	70	120	88	2	4	4
		DAY 50	02JUL2003	51	72	126	94	10	8	16	82	132	98	14	16	14
		DAY 57	08JUL2003	57	72	110	80	10	-8	2	64	106	72	-4	-10	-12
		FINAL		57	72	110	80	10	-8	2	64	106	72	-4	-10	-12
	E0005030	SCREEN	18MAR2003	-8	76	96	60				80	90L	60			
		DAY 1	26MAR2003	1	80	98	64				84	96	60			
		BASELINE			80	98	64				84	96	60			
		DAY 8	02APR2003	8	76	98	60	-4	0	-4	72	104	60	-12	8	0
		DAY 15	09APR2003	15	84	108	66	4	10	2	100	110	70	16I	14	10
		DAY 22	16APR2003	22	84	100	60	4	2	-4	88	110	68	4	14	8
		FINAL		22	84	100	60	4	2	-4	88	110	68	4	14	8
	E0006015	SCREEN	06FEB2003	-5	64	120	62				76	114	60			
		DAY 1	11FEB2003	1	72	116	64				70	135	85			
		BASELINE			72	116	64				70	135	85			
		DAY 8	18FEB2003	8	92	129	76	20I	13	12	88	131	90	18I	-4	5
		DAY 15	25FEB2003	15	88	128	76	16I	12	12	90	127	83	20I	-8	-2
		DAY 22	04MAR2003	22	87	126	83	15I	10	19	86	131	79	16I	-4	-6
		DAY 29	11MAR2003	29	74	126	83	2	10	19	72	128	93	2	-7	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	DAY 36	18MAR2003	36	75	128	77	3	12	13	101	122	80	31I	-13	-5
		DAY 43	25MAR2003	43	78	129	78	6	13	14	88	123	88	18I	-12	3
		DAY 50	01APR2003	50	84	110	78	12	-6	14	84	108	78	14	-27D	-7
		DAY 57	08APR2003	57	84	127	77	12	11	13	80	128	83	10	-7	-2
		FINAL		57	84	127	77	12	11	13	80	128	83	10	-7	-2
	E0007008	SCREEN	07APR2003	-11	70	118	70				78	124	74			
		DAY 1	18APR2003	1	70	98	60				70	106	68			
		BASELINE			70	98	60				70	106	68			
		DAY 8	25APR2003	8	70	118	80	0	20I	20	74	124	80	4	18	12
		FINAL		8	70	118	80	0	20I	20	74	124	80	4	18	12
	E0009002	SCREEN	29OCT2002	-21	78	104	78				80	102	80			
		DAY 1	19NOV2002	1	64	132	84				84	136	90			
		BASELINE			64	132	84				84	136	90			
		DAY 8	26NOV2002	8	84	118	80	20I	-14	-4	80	116	82	-4	-20D	-8
		DAY 15	03DEC2002	15	80	120	78	16I	-12	-6	78	118	82	-6	-18	-8
		DAY 22	10DEC2002	22	84	126	84	20I	-6	0	86	124	82	2	-12	-8
		DAY 29	18DEC2002	30	60	110	84	-4	-22D	0	88	120	90	4	-16	0
		DAY 36	23DEC2002	35	68	132	80	4	0	-4	68	134	86	-16D	-2	-4
		DAY 43	30DEC2002	42	80	122	82	16I	-10	-2	84	118	80	0	-18	-10
		DAY 50	07JAN2003	50	60	134	90	-4	2	6	68	134	94	-16D	-2	4
		DAY 57	15JAN2003	58	68	130	80	4	-2	-4	70	132	84	-14	-4	-6
		FINAL		58	68	130	80	4	-2	-4	70	132	84	-14	-4	-6
	E0009006	SCREEN	22JAN2003	-6	78	110	60				74	110	70			
		DAY 1	28JAN2003	1	76	100	64				82	100	70			
		BASELINE			76	100	64				82	100	70			
		DAY 8	04FEB2003	8	60	128	70	-16D	28I	6	80	134	84	-2	34I	14
		DAY 15	11FEB2003	15	82	120	70	6	20I	6	84	120	80	2	20I	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	DAY 22	18FEB2003	22	80	140	80	4	40I	16	78	138	78	-4	38I	8
		DAY 29	25FEB2003	29	82	110	60	6	10	-4	82	110	68	0	10	-2
		DAY 36	04MAR2003	36	80	118	70	4	18	6	80	116	68	-2	16	-2
		DAY 43	11MAR2003	43	86	124	62	10	24I	-2	78	120	60	-4	20I	-10
		DAY 50	18MAR2003	50	82	110	70	6	10	6	80	110	70	-2	10	0
		DAY 57	25MAR2003	57	84	110	84	8	10	20	80	120	86	-2	20I	16
		FINAL		57	84	110	84	8	10	20	80	120	86	-2	20I	16
	E0009009	SCREEN	27FEB2003	-13	60	100	70				80	120	80			
		DAY 1	12MAR2003	1	78	110	62				80	120	76			
		BASELINE			78	110	62				80	120	76			
		DAY 8	19MAR2003	8	88	124	60	10	14	-2	86	110	70	6	-10	-6
		DAY 15	24MAR2003	13	60	130	60	-18D	20I	-2	68	120	70	-12	0	-6
		FINAL		13	60	130	60	-18D	20I	-2	68	120	70	-12	0	-6
	E0010015	SCREEN	29JAN2003	-22	72	140	96				76	150	100			
		DAY 1	20FEB2003	1	86	138	88				88	146	90			
		BASELINE			86	138	88				88	146	90			
		DAY 8	27FEB2003	8	92	142	94	6	4	6	94	136	92	6	-10	2
		DAY 15	06MAR2003	15	76	130	90	-10	-8	2	84	120	88	-4	-26D	-2
		DAY 22	13MAR2003	22	78	156	90	-8	18	2	78	140	90	-10	-6	0
		DAY 29	20MAR2003	29	68	138	88	-18D	0	0	80	136	90	-8	-10	0
		DAY 36	26MAR2003	35	84	142	90	-2	4	2	80	140	90	-8	-6	0
		DAY 43	02APR2003	42	73	138	90	-13	0	2	85	134	94	-3	-12	4
		DAY 50	09APR2003	49	80	138	88	-6	0	0	88	130	80	0	-16	-10
		DAY 57	15APR2003	55	76	130	90	-10	-8	2	82	136	94	-6	-10	4
		FINAL		55	76	130	90	-10	-8	2	82	136	94	-6	-10	4
	E0011007	SCREEN	12DEC2002	-7	88	118	72				92	126	82			
		DAY 1	19DEC2002	1	97	113	84				93	121	92			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	BASELINE			97	113	84				93	121	92			
		DAY 8	26DEC2002	8	98	117	91	1	4	7	78	117	89	-15D	-4	-3
		DAY 15	02JAN2003	15	86	127	90	-11	14	6	90	130	90	-3	9	-2
		DAY 22	09JAN2003	22	88	130	86	-9	17	2	92	128	84	-1	7	-8
		DAY 29	17JAN2003	30	76	128	88	-21D	15	4	88	130	82	-5	9	-10
		DAY 36	23JAN2003	36	84	132	90	-13	19	6	86	138	88	-7	17	-4
		DAY 43	30JAN2003	43	78	130	86	-19D	17	2	82	132	90	-11	11	-2
		DAY 50	06FEB2003	50	76	132	80	-21D	19	-4	80	128	82	-13	7	-10
		DAY 57	13FEB2003	57	84	124	86	-13	11	2	96	118	84	3	-3	-8
		FINAL		57	84	124	86	-13	11	2	96	118	84	3	-3	-8
	E0011024	SCREEN	17JUN2003	-7	74	108	78				72	112	80			
		DAY 1	24JUN2003	1	64	108	78				65	110	78			
		BASELINE			64	108	78				65	110	78			
		DAY 8	01JUL2003	8	85	118	76	21I	10	-2	80	122	80	15I	12	2
		DAY 15	08JUL2003	15	84	115	80	20I	7	2	82	110	80	17I	0	2
		DAY 22	15JUL2003	22	60	120	80	-4	12	2	62	118	80	-3	8	2
		DAY 29	22JUL2003	29	64	128	80	0	20I	2	62	128	80	-3	18	2
		DAY 36	30JUL2003	37	72	110	70	8	2	-8	70	112	70	5	2	-8
		DAY 43	05AUG2003	43	72	110	72	8	2	-6	70	112	70	5	2	-8
		DAY 50	12AUG2003	50	82	120	78	18I	12	0	84	118	76	19I	8	-2
		DAY 57	21AUG2003	59	86	120	76	22I	12	-2	88	122	78	23I	12	0
		FINAL		59	86	120	76	22I	12	-2	88	122	78	23I	12	0
	E0019003	SCREEN	29OCT2002	-23	68	122	78				68	110	78			
		DAY 1	21NOV2002	1	68	125	80				68	122	80			
		BASELINE			68	125	80				68	122	80			
		DAY 8	27NOV2002	7	68	110	80	0	-15	0	72	115	80	4	-7	0
		DAY 15	09DEC2002	19	72	120	60	4	-5	-20D	84	118	70	16I	-4	-10
		DAY 22	16DEC2002	26	72	120	70	4	-5	-10	88	118	70	20I	-4	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	SUPINE CHANGE FROM BASELINE PULSE	SUPINE CHANGE FROM BASELINE SYS	SUPINE CHANGE FROM BASELINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	STANDING CHANGE FROM BASELINE PULSE	STANDING CHANGE FROM BASELINE SYS	STANDING CHANGE FROM BASELINE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	DAY 36		24DEC2002	34	72	118	70	4	-7	-10	76	122	80	8	0	0
		DAY 36	*	30DEC2002	40	64	118	78	-4	-7	-2	80	122	82	12	0	2
		DAY 43		06JAN2003	47	68	110	64	0	-15	-16	72	114	70	4	-8	-10
		DAY 57	*	14JAN2003	55	64	130	90	-4	5	10	76	124	88	8	2	8
		DAY 57		16JAN2003	57	68	122	82	0	-3	2	84	118	74	16I	-4	-6
		FINAL			57	68	122	82	0	-3	2	84	118	74	16I	-4	-6
	E0019022	SCREEN		23JAN2003	-7	76	118	78				100	118	80			
		DAY 1		30JAN2003	1	88	125	74				92	120	75			
		BASELINE				88	125	74				92	120	75			
		DAY 8		06FEB2003	8	84	130	85	-4	5	11	88	130	85	-4	10	10
		DAY 15		13FEB2003	15	90	110	80	2	-15	6	90	115	85	-2	-5	10
		DAY 22		20FEB2003	22	84	120	75	-4	-5	1	90	122	80	-2	2	5
		DAY 29		27FEB2003	29	76	125	75	-12	0	1	90	125	80	-2	5	5
		DAY 36		06MAR2003	36	68	118	80	-20D	-7	6	80	122	84	-12	2	9
		DAY 43		13MAR2003	43	104	120	84	16I	-5	10	104	120	88	12	0	13
		DAY 50		20MAR2003	50	92	130	80	4	5	6	100	130	85	8	10	10
		DAY 57		27MAR2003	57	84	128	80	-4	3	6	88	130	85	-4	10	10
		FINAL			57	84	128	80	-4	3	6	88	130	85	-4	10	10
	E0019027	SCREEN		20FEB2003	-7	72	126	80				68	118	80			
		DAY 1		27FEB2003	1	76	120	80				80	114	80			
		BASELINE				76	120	80				80	114	80			
		DAY 8		06MAR2003	8	64	130	78	-12	10	-2	64	125	80	-16D	11	0
		FINAL			8	64	130	78	-12	10	-2	64	125	80	-16D	11	0
	E0019032	SCREEN		06MAR2003	-26	72	92	62				76	94	60			
		DAY 1		01APR2003	1	64	110	70				80	110	75			
		BASELINE				64	110	70				80	110	75			
		DAY 8		08APR2003	8	80	110	60	16I	0	-10	92	110	70	12	0	-5

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT103.SAS
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	DAY 15	15APR2003	15	84	105	60	20I	-5	-10	88	100	70	8	-10	-5
		DAY 22	21APR2003	21	100	120	86	36I	10	16	120	110	82	40I	0	7
		DAY 29	29APR2003	29	96	118	70	32I	8	0	108	115	80	28I	5	5
		DAY 36	07MAY2003	37	76	102	78	12	-8	8	96	102	82	16I	-8	7
		DAY 43	14MAY2003	44	80	110	78	16I	0	8	88	110	75	8	0	0
		DAY 50	21MAY2003	51	68	105	70	4	-5	0	72	110	70	-8	0	-5
		DAY 57	27MAY2003	57	64	100	78	0	-10	8	64	98	80	-16D	-12	5
		FINAL		57	64	100	78	0	-10	8	64	98	80	-16D	-12	5
	E0019036	SCREEN	18MAR2003	-7	74	118	72				80	140	68			
		DAY 1	25MAR2003	1	60	125	65				80	130	70			
		BASELINE			60	125	65				80	130	70			
		DAY 8	31MAR2003	7	80	130	70	20I	5	5	88	125	70	8	-5	0
		DAY 15	10APR2003	17	76	130	70	16I	5	5	88	110	70	8	-20D	0
		DAY 22	15APR2003	22	68	120	70	8	-5	5	84	120	80	4	-10	10
		DAY 29	22APR2003	29	60	120	70	0	-5	5	68	130	75	-12	0	5
		DAY 36	29APR2003	36	60	130	70	0	5	5	80	128	78	0	-2	8
		FINAL		36	60	130	70	0	5	5	80	128	78	0	-2	8
	E0019039	SCREEN	22APR2003	-9	80	142	90				84	132	92			
		DAY 1	01MAY2003	1	72	140	90				80	138	88			
		BASELINE			72	140	90				80	138	88			
		DAY 8	08MAY2003	8	88	140	80	16I	0	-10	96	140	82	16I	2	-6
		FINAL		8	88	140	80	16I	0	-10	96	140	82	16I	2	-6
	E0019041	SCREEN	14MAY2003	-7	76	102	80				68	108	70			
		DAY 1	21MAY2003	1	72	100	60				68	95	60			
		BASELINE			72	100	60				68	95	60			
		DAY 8	28MAY2003	8	68	100	65	-4	0	5	74	95	60	6	0	0
		DAY 15	04JUN2003	15	64	100	52	-8	0	-8	68	90L	48L	0	-5	-12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	DAY 22	12JUN2003	23	66	100	70	-6	0	10	70	100	65	2	5	5
		DAY 29	18JUN2003	29	80	108	60	8	8	0	84	100	60	16I	5	0
		DAY 36	25JUN2003	36	56	102	64	-16D	2	4	84	104	58	16I	9	-2
		DAY 43	02JUL2003	43	64	108	72	-8	8	12	76	90L	58	8	-5	-2
		DAY 50	09JUL2003	50	64	104	66	-8	4	6	72	102	64	4	7	4
		DAY 57	16JUL2003	57	64	110	70	-8	10	10	76	115	75	8	20I	15
		FINAL		57	64	110	70	-8	10	10	76	115	75	8	20I	15
	E0019049	SCREEN	03JUL2003	-7	72	118	68				84	112	78			
		DAY 1	10JUL2003	1	62	118	64				70	116	68			
		BASELINE			62	118	64				70	116	68			
		DAY 8	17JUL2003	8	88	120	75	26I	2	11	92	105	80	22I	-11	12
		DAY 15	24JUL2003	15	84	108	70	22I	-10	6	96	106	78	26I	-10	10
		DAY 22	31JUL2003	22	76	122	76	14	4	12	96	118	78	26I	2	10
		DAY 29	07AUG2003	29	76	120	80	14	2	16	92	122	76	22I	6	8
		DAY 36	14AUG2003	36	84	125	78	22I	7	14	84	120	75	14	4	7
		DAY 50	26AUG2003	48	84	120	80	22I	2	16	88	115	75	18I	-1	7
		DAY 57	08SEP2003	61	76	126	80	14	8	16	76	116	84	6	0	16
		FINAL		61	76	126	80	14	8	16	76	116	84	6	0	16
	E0022052	SCREEN	01APR2003	-9	76	120	82				80	118	80			
		DAY 1	10APR2003	1	81	126	78				81	124	86			
		BASELINE			81	126	78				81	124	86			
		DAY 8	17APR2003	8	69	130	78	-12	4	0	90	122	76	9	-2	-10
		DAY 15	24APR2003	15	87	128	74	6	2	-4	96	118	86	15I	-6	0
		DAY 22	01MAY2003	22	96	128	70	15I	2	-8	102	132	84	21I	8	-2
		DAY 29	08MAY2003	29	63	120	74	-18D	-6	-4	90	124	78	9	0	-8
		DAY 36	15MAY2003	36	64	124	76	-17D	-2	-2	64	112	70	-17D	-12	-16
		DAY 43	22MAY2003	43	87	124	72	6	-2	-6	90	114	74	9	-10	-12
		DAY 50	29MAY2003	50	69	124	78	-12	-2	0	87	122	82	6	-2	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	DAY 57	05JUN2003	57	88	124	82	7	-2	4	88	126	84	7	2	-2
		FINAL		57	88	124	82	7	-2	4	88	126	84	7	2	-2
	E0022064	SCREEN	29APR2003	-7	72	118	82				75	124	88			
		DAY 1	06MAY2003	1	60	118	70				75	132	92			
		BASELINE			60	118	70				75	132	92			
		DAY 8	12MAY2003	7	69	122	74	9	4	4	75	120	80	0	-12	-12
		DAY 15	20MAY2003	15	75	114	66	15I	-4	-4	90	122	78	15I	-10	-14
		DAY 22	27MAY2003	22	72	122	78	12	4	8	90	130	84	15I	-2	-8
		DAY 29	03JUN2003	29	86	120	70	26I	2	0	90	126	78	15I	-6	-14
		DAY 36	10JUN2003	36	72	126	72	12	8	2	80	132	78	5	0	-14
		DAY 43	17JUN2003	43	84	124	72	24I	6	2	90	126	76	15I	-6	-16
		DAY 50	24JUN2003	50	78	122	70	18I	4	0	81	124	78	6	-8	-14
		DAY 57	01JUL2003	57	72	124	76	12	6	6	75	128	80	0	-4	-12
		FINAL		57	72	124	76	12	6	6	75	128	80	0	-4	-12
	E0022073	SCREEN	19JUN2003	-7	66	106	64				75	102	62			
		DAY 1	26JUN2003	1	72	102	70				81	100	74			
		BASELINE			72	102	70				81	100	74			
		DAY 8	03JUL2003	8	80	100	62	8	-2	-8	84	96	74	3	-4	0
		DAY 15	10JUL2003	15	66	102	68	-6	0	-2	80	92	70	-1	-8	-4
		DAY 22	17JUL2003	22	80	106	58	8	4	-12	100	102	60	19I	2	-14
		DAY 29	24JUL2003	29	81	112	64	9	10	-6	105	104	64	24I	4	-10
		DAY 36	31JUL2003	36	75	98	62	3	-4	-8	79	100	68	-2	0	-6
		DAY 43	07AUG2003	43	64	106	68	-8	4	-2	76	110	74	-5	10	0
		DAY 50	14AUG2003	50	68	106	62	-4	4	-8	72	108	66	-9	8	-8
		DAY 57	21AUG2003	57	82	116	70	10	14	0	90	104	74	9	4	0
		FINAL		57	82	116	70	10	14	0	90	104	74	9	4	0
	E0023002	SCREEN	25OCT2002	-11	70	116	64				72	114	72			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	DAY 1	05NOV2002	1	60	98	70				72	108	80			
		BASELINE			60	98	70				72	108	80			
		DAY 8	12NOV2002	8	68	110	76	8	12	6	76	118	82	4	10	2
		DAY 15	19NOV2002	15	80	108	75	20I	10	5	84	115	80	12	7	0
		DAY 22	25NOV2002	21	72	120	76	12	22I	6	88	120	70	16I	12	-10
		DAY 29	03DEC2002	29	79	115	73	19I	17	3	107	131	66	35I	23I	-14
		DAY 36	10DEC2002	36	72	120	80	12	22I	10	60	126	74	-12	18	-6
		FINAL		36	72	120	80	12	22I	10	60	126	74	-12	18	-6
	E0023017	SCREEN	14MAR2003	-11	78	127	86				78	149	97			
		DAY 1	25MAR2003	1	76	128	80				78	140	80			
		BASELINE			76	128	80				78	140	80			
		DAY 8	03APR2003	10	77	104	63	1	-24D	-17	85	110	70	7	-30D	-10
		DAY 15	10APR2003	17	69	115	71	-7	-13	-9	71	114	70	-7	-26D	-10
		DAY 22	18APR2003	25	68	100	70	-8	-28D	-10	80	110	74	2	-30D	-6
		DAY 29	24APR2003	31	78	128	80	2	0	0	80	130	80	2	-10	0
		DAY 36	01MAY2003	38	90	128	84	14	0	4	94	124	80	16I	-16	0
		DAY 43	08MAY2003	45	75	110	71	-1	-18	-9	78	108	70	0	-32D	-10
		DAY 50	15MAY2003	52	78	155	90	2	27I	10	100	121	75	22I	-19	-5
		DAY 57	22MAY2003	59	78	132	71	2	4	-9	84	130	70	6	-10	-10
		FINAL		59	78	132	71	2	4	-9	84	130	70	6	-10	-10
	E0023021	SCREEN	10APR2003	-13	90	141	98				94	139	96			
		DAY 1	23APR2003	1	88	118	86				88	122	92			
		BASELINE			88	118	86				88	122	92			
		DAY 8	29APR2003	7	86	110	80	-2	-8	-6	94	115	86	6	-7	-6
		DAY 15	06MAY2003	14	74	113	64	-14	-5	-22D	88	118	70	0	-4	-22D
		DAY 22	13MAY2003	21	78	116	81	-10	-2	-5	100	132	95	12	10	3
		DAY 29	20MAY2003	28	79	114	71	-9	-4	-15	97	104	76	9	-18	-16
		DAY 36	29MAY2003	37	85	118	76	-3	0	-10	109	121	83	21I	-1	-9

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	DAY 43	03JUN2003	42	92	120	77	4	2	-9	96	124	80	8	2	-12
		DAY 50	10JUN2003	49	77	109	71	-11	-9	-15	84	112	82	-4	-10	-10
		DAY 57	17JUN2003	56	111	122	66	23I	4	-20D	100	141	98	12	19	6
		FINAL		56	111	122	66	23I	4	-20D	100	141	98	12	19	6
	E0023027	SCREEN	07MAY2003	-9	64	93	65				68	93	63			
		DAY 1	16MAY2003	1	79	124	80				99	129	86			
		BASELINE			79	124	80				99	129	86			
		DAY 8	21MAY2003	6	63	136	96	-16D	12	16	68	140	98	-31D	11	12
		DAY 15	30MAY2003	15	123H	159	102	44I	35I	22	126H	152	105H	27I	23I	19
		DAY 22	05JUN2003	21	88	148	99	9	24I	19	107	163	105H	8	34I	19
		DAY 29	11JUN2003	27	76	134	96	-3	10	16	80	136	96	-19D	7	10
		DAY 36	18JUN2003	34	88	136	100	9	12	20	88	130	90	-11	1	4
		DAY 43	27JUN2003	43	76	138	104	-3	14	24	80	130	98	-19D	1	12
		DAY 50	02JUL2003	48	105	134	88	26I	10	8	123H	137	82	24I	8	-4
		DAY 57	09JUL2003	55	85	143	85	6	19	5	90	140	86	-9	11	0
		FINAL		55	85	143	85	6	19	5	90	140	86	-9	11	0
	E0023030	SCREEN	16MAY2003	-18	84	125	86				80	120	84			
		DAY 1	03JUN2003	1	89	115	81				102	131	94			
		BASELINE			89	115	81				102	131	94			
		DAY 8	10JUN2003	8	100	107	78	11	-8	-3	104	148	87	2	17	-7
		DAY 15	17JUN2003	15	99	131	91	10	16	10	109	132	91	7	1	-3
		DAY 22	24JUN2003	22	87	110	73	-2	-5	-8	96	121	80	-6	-10	-14
		DAY 29	01JUL2003	29	79	127	85	-10	12	4	89	130	90	-13	-1	-4
		DAY 36	08JUL2003	36	91	127	88	2	12	7	99	152	99	-3	21I	5
		DAY 43	15JUL2003	43	92	125	86	3	10	5	97	86L	82	-5	-45D	-12
		DAY 50	21JUL2003	49	100	142	100	11	27I	19	104	141	98	2	10	4
		DAY 57	30JUL2003	58	86	135	93	-3	20I	12	97	148	98	-5	17	4
		FINAL		58	86	135	93	-3	20I	12	97	148	98	-5	17	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023040	SCREEN		25JUN2003	-8	80	120	76				76	117	80			
		DAY 1		03JUL2003	1	81	117	82				80	117	80			
		BASELINE				81	117	82				80	117	80			
		DAY 8		12JUL2003	10	82	121	82	1	4	0	86	123	84	6	6	4
		DAY 15		17JUL2003	15	77	114	81	-4	-3	-1	81	126	88	1	9	8
		DAY 22		25JUL2003	23	86	132	89	5	15	7	84	108	71	4	-9	-9
		DAY 36	*	05AUG2003	34	76	127	86	-5	10	4	75	133	73	-5	16	-7
		DAY 36		08AUG2003	37	88	93	67	7	-24D	-15	93	101	69	13	-16	-11
		DAY 43		18AUG2003	47	77	127	84	-4	10	2	80	117	90	0	0	10
		DAY 57	*	28AUG2003	57	68	125	85	-13	8	3	84	132	88	4	15	8
		DAY 57		05SEP2003	65	63	117	86	-18D	0	4	63	126	84	-17D	9	4
		FINAL			65	63	117	86	-18D	0	4	63	126	84	-17D	9	4
	E0026014	SCREEN		12FEB2003	-7	68	168	97				71	137	97			
		DAY 1		19FEB2003	1	68	148	99				74	142	102			
		BASELINE				68	148	99				74	142	102			
		DAY 8		26FEB2003	8	86	140	99	18I	-8	0	87	138	95	13	-4	-7
		DAY 15		05MAR2003	15	75	126	91	7	-22D	-8	76	123	88	2	-19	-14
		DAY 22		12MAR2003	22	85	142	90	17I	-6	-9	86	138	95	12	-4	-7
		DAY 29		19MAR2003	29	90	140	90	22I	-8	-9	74	129	94	0	-13	-8
		FINAL			29	90	140	90	22I	-8	-9	74	129	94	0	-13	-8
	E0026019	SCREEN		10MAR2003	-7	72	136	81				75	147	91			
		DAY 1		17MAR2003	1	73	138	84				83	148	85			
		BASELINE				73	138	84				83	148	85			
		DAY 8		24MAR2003	8	85	161	89	12	23I	5	88	157	88	5	9	3
		DAY 15		31MAR2003	15	98	170	95	25I	32I	11	96	173	96	13	25I	11
		DAY 22		07APR2003	22	82	157	83	9	19	-1	88	138	89	5	-10	4
		DAY 29		14APR2003	29	83	148	87	10	10	3	88	154	85	5	6	0
		DAY 36		21APR2003	36	74	140	76	1	2	-8	76	146	82	-7	-2	-3

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0026019	DAY 43	28APR2003	43	70	136	77	-3	-2	-7	71	157	80	-12	9	-5
		DAY 50	05MAY2003	50	88	108	75	15I	-30D	-9	92	127	79	9	-21D	-6
		DAY 57	12MAY2003	57	78	151	54	5	13	-30D	89	148	60	6	0	-25D
		FINAL		57	78	151	54	5	13	-30D	89	148	60	6	0	-25D
	E0027005	SCREEN	19DEC2002	-7												
		DAY 1	26DEC2002	1	80	130	84				84	128	80			
		BASELINE			80	130	84				84	128	80			
		DAY 8	02JAN2003	8	96	130	85	16I	0	1	92	120	80	8	-8	0
		DAY 15	09JAN2003	15	100	120	90	20I	-10	6	84	120	88	0	-8	8
		DAY 22	16JAN2003	22	72	140	94	-8	10	10	76	130	90	-8	2	10
		DAY 29	23JAN2003	29	88	122	84	8	-8	0	92	110	70	8	-18	-10
		DAY 36	30JAN2003	36	84	130	86	4	0	2	90	120	76	6	-8	-4
		DAY 43	06FEB2003	43	88	160	100	8	30I	16	96	130	90	12	2	10
		DAY 50	12FEB2003	49	75	136	84	-5	6	0	90	138	88	6	10	8
		DAY 57	20FEB2003	57	84	130	90	4	0	6	84	120	90	0	-8	10
		FINAL		57	84	130	90	4	0	6	84	120	90	0	-8	10
	E0029009	SCREEN	13JAN2003	-7	60	100	70				68	110	80			
		DAY 1	20JAN2003	1	56	108	68				60	110	78			
		BASELINE			56	108	68				60	110	78			
		DAY 8	27JAN2003	8	60	110	70	4	2	2	64	110	80	4	0	2
		DAY 15	03FEB2003	15	64	120	84	8	12	16	72	114	90	12	4	12
		DAY 22	11FEB2003	23	60	120	84	4	12	16	64	120	90	4	10	12
		DAY 29	17FEB2003	29	72	100	72	16I	-8	4	80	98	80	20I	-12	2
		DAY 36	24FEB2003	36	64	118	80	8	10	12	68	118	90	8	8	12
		DAY 43	03MAR2003	43	60	130	80	4	22I	12	76	130	84	16I	20I	6
		DAY 50	11MAR2003	51	68	104	72	12	-4	4	76	110	80	16I	0	2
		DAY 57	18MAR2003	58	64	118	80	8	10	12	68	104	68	8	-6	-10
		FINAL		58	64	118	80	8	10	12	68	104	68	8	-6	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	SCREEN	03MAR2003	-15	64	110	80				80	110	80			
		DAY 1	18MAR2003	1	64	100	62				60	102	62			
		BASELINE			64	100	62				60	102	62			
		DAY 8	25MAR2003	8	68	112	72	4	12	10	60	112	70	0	10	8
		DAY 15	01APR2003	15	72	102	70	8	2	8	68	100	68	8	-2	6
		DAY 22	07APR2003	21	60	102	62	-4	2	0	60	100	64	0	-2	2
		DAY 29	15APR2003	29	72	100	60	8	0	-2	68	108	64	8	6	2
		DAY 36	22APR2003	36	64	102	68	0	2	6	60	100	68	0	-2	6
		DAY 43	29APR2003	43	92	102	68	28I	2	6	104	90L	68	44I	-12	6
		DAY 50	06MAY2003	50	80	98	60	16I	-2	-2	80	102	64	20I	0	2
		DAY 57	15MAY2003	59	88	104	76	24I	4	14	100	98	64	40I	-4	2
		FINAL		59	88	104	76	24I	4	14	100	98	64	40I	-4	2
	E0029026	SCREEN	07APR2003	-7	76	122	80				92	114	78			
		DAY 1	14APR2003	1	72	118	82				80	100	70			
		BASELINE			72	118	82				80	100	70			
		DAY 8	21APR2003	8	84	98	74	12	-20D	-8	96	100	76	16I	0	6
		DAY 15	28APR2003	15	84	108	84	12	-10	2	96	120	80	16I	20I	10
		DAY 22	05MAY2003	22	88	124	82	16I	6	0	100	110	84	20I	10	14
		DAY 29	12MAY2003	29	80	120	80	8	2	-2	100	114	78	20I	14	8
		DAY 36	19MAY2003	36	80	108	76	8	-10	-6	100	110	70	20I	10	0
		DAY 43	28MAY2003	45	88	114	74	16I	-4	-8	100	90L	70	20I	-10	0
		DAY 50	02JUN2003	50	84	118	80	12	0	-2	88	112	84	8	12	14
		DAY 57	10JUN2003	58	76	110	70	4	-8	-12	92	110	76	12	10	6
		FINAL		58	76	110	70	4	-8	-12	92	110	76	12	10	6
	E0029030	SCREEN	13MAY2003	-14	56	110	80				60	110	80			
		DAY 1	27MAY2003	1	56	100	64				60	98	66			
		BASELINE			56	100	64				60	98	66			
		DAY 8	03JUN2003	8	68	130	88	12	30I	24	68	114	80	8	16	14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	DAY 15	10JUN2003	15	68	112	80	12	12	16	72	118	80	12	20I	14
		DAY 22	17JUN2003	22	72	110	84	16I	10	20	72	124	82	12	26I	16
		DAY 29	26JUN2003	31	80	130	80	24I	30I	16	88	120	70	28I	22I	4
		DAY 36	02JUL2003	37	80	120	76	24I	20I	12	80	118	70	20I	20I	4
		DAY 43	09JUL2003	44	76	110	70	20I	10	6	92	120	80	32I	22I	14
		DAY 50	16JUL2003	51	80	132	70	24I	32I	6	96	134	80	36I	36I	14
		DAY 57	23JUL2003	58	64	120	78	8	20I	14	72	124	84	12	26I	18
		FINAL		58	64	120	78	8	20I	14	72	124	84	12	26I	18
	E0031008	SCREEN	05FEB2003	-23	64	128	80				68	134	88			
		DAY 1	28FEB2003	1	60	136	80				68	138	84			
		BASELINE			60	136	80				68	138	84			
		DAY 8	07MAR2003	8	72	114	76	12	-22D	-4	78	122	80	10	-16	-4
		DAY 15	13MAR2003	14	70	142	84	10	6	4	68	138	84	0	0	0
		DAY 22	21MAR2003	22	80	136	74	20I	0	-6	84	140	76	16I	2	-8
		DAY 29	28MAR2003	29	66	114	76	6	-22D	-4	72	118	68	4	-20D	-16
		DAY 36	04APR2003	36	68	120	68	8	-16	-12	74	120	72	6	-18	-12
		DAY 43	10APR2003	42	78	118	74	18I	-18	-6	86	120	80	18I	-18	-4
		DAY 50	17APR2003	49	80	138	82	20I	2	2	82	136	84	14	-2	0
		DAY 57	24APR2003	56	68	126	80	8	-10	0	72	130	84	4	-8	0
		FINAL		56	68	126	80	8	-10	0	72	130	84	4	-8	0
	E0031021	SCREEN	18APR2003	-7	60	118	66				64	122	70			
		DAY 1	25APR2003	1	60	112	68				66	116	72			
		BASELINE			60	112	68				66	116	72			
		DAY 8	02MAY2003	8	62	124	70	2	12	2	66	130	74	0	14	2
		DAY 15	09MAY2003	15	64	122	68	4	10	0	68	128	72	2	12	0
		DAY 22	16MAY2003	22	76	125	80	16I	13	12	84	120	78	18I	4	6
		DAY 29	23MAY2003	29	62	116	68	2	4	0	70	124	78	4	8	6
		DAY 36	29MAY2003	35	70	116	78	10	4	10	76	120	80	10	4	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			SUPINE CHANGE FROM BASELINE			STANDING			STANDING CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 43		06JUN2003	43	64	124	88	4	12	20	68	130	90	2	14	18
		DAY 43	*	10JUN2003	47	72	124	86	12	12	18	76	132	88	10	16	16
		DAY 57		19JUN2003	56	70	118	68	10	6	0	76	120	70	10	4	-2
		FINAL			56	70	118	68	10	6	0	76	120	70	10	4	-2
	E0033002	SCREEN		23DEC2002	-18	68	120	78				76	110	78			
		DAY 1		10JAN2003	1	76	150	84				80	138	88			
		BASELINE				76	150	84				80	138	88			
		DAY 8		16JAN2003	7	92	130	80	16I	-20D	-4	100	128	80	20I	-10	-8
		DAY 15		24JAN2003	15	92	132	88	16I	-18	4	84	132	84	4	-6	-4
		DAY 22		30JAN2003	21	68	108	70	-8	-42D	-14	76	114	76	-4	-24D	-12
		DAY 29		06FEB2003	28	80	104	70	4	-46D	-14	80	112	76	0	-26D	-12
		DAY 36		13FEB2003	35	72	120	78	-4	-30D	-6	80	130	84	0	-8	-4
		DAY 43		24FEB2003	46	72	122	80	-4	-28D	-4	76	126	86	-4	-12	-2
		DAY 50		28FEB2003	50	76	120	80	0	-30D	-4	84	130	80	4	-8	-8
		DAY 57		07MAR2003	57	76	118	78	0	-32D	-6	80	120	82	0	-18	-6
		FINAL			57	76	118	78	0	-32D	-6	80	120	82	0	-18	-6
	E0033006	SCREEN		15JAN2003	-8	64	110	80				76	118	86			
		DAY 1		23JAN2003	1	64	100	70				72	106	80			
		BASELINE				64	100	70				72	106	80			
		DAY 8		30JAN2003	8	60	120	84	-4	20I	14	76	126	88	4	20I	8
		DAY 22		12FEB2003	21	68	120	80	4	20I	10	72	120	86	0	14	6
		FINAL			21	68	120	80	4	20I	10	72	120	86	0	14	6
	E0033021	SCREEN		25JUN2003	-7	60	90L	62				76	80L	64			
		DAY 1		02JUL2003	1	56	90L	70				72	90L	74			
		BASELINE				56	90L	70				72	90L	74			
		DAY 8		11JUL2003	10	58	90L	67	2	0	-3	74	90L	70	2	0	-4
		DAY 22	*	21JUL2003	20	60	100	60	4	10	-10	76	98	66	4	8	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	DAY 22	25JUL2003	24	72	90L	68	16I	0	-2	80	100	70	8	10	-4
		DAY 29	01AUG2003	31	76	90L	64	20I	0	-6	80	96	66	8	6	-8
		DAY 36	06AUG2003	36	72	112	74	16I	22I	4	68	110	70	-4	20I	-4
		DAY 50	18AUG2003	48	76	96	70	20I	6	0	76	96	72	4	6	-2
		FINAL		48	76	96	70	20I	6	0	76	96	72	4	6	-2
	E0035023	SCREEN	06MAY2003	-7	82	108	78				88	110	82			
		DAY 1	13MAY2003	1	60	114	72				62	116	80			
		BASELINE			60	114	72				62	116	80			
		DAY 8	20MAY2003	8	68	112	78	8	-2	6	72	114	82	10	-2	2
		DAY 15	29MAY2003	17	70	112	76	10	-2	4	74	114	80	12	-2	0
		DAY 22	03JUN2003	22	74	112	76	14	-2	4	76	114	76	14	-2	-4
		DAY 29	10JUN2003	29	76	112	74	16I	-2	2	80	114	78	18I	-2	-2
		FINAL		29	76	112	74	16I	-2	2	80	114	78	18I	-2	-2
	E0039052	SCREEN	29MAY2003	-22	84	126	88				88	118	92			
		DAY 1	20JUN2003	1	88	118	88				92	120	90			
		BASELINE			88	118	88				92	120	90			
		DAY 8	27JUN2003	8	64	126	96	-24D	8	8	68	120	92	-24D	0	2
		DAY 15	03JUL2003	14	74	134	92	-14	16	4	78	122	94	-14	2	4
		FINAL		14	74	134	92	-14	16	4	78	122	94	-14	2	4
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	SCREEN	19FEB2003	-12	64	112	70				68	110	68			
		DAY 1	03MAR2003	1	64	102	74				64	110	80			
		BASELINE			64	102	74				64	110	80			
		DAY 8	11MAR2003	9	72	108	68	8	6	-6	80	122	84	16I	12	4
		DAY 15	18MAR2003	16	78	106	64	14	4	-10	78	114	68	14	4	-12
		DAY 22	25MAR2003	23	70	110	68	6	8	-6	72	110	70	8	0	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 29	01APR2003	30	72	106	66	8	4	-8	72	110	72	8	0	-8
		DAY 36	08APR2003	37	78	98	60	14	-4	-14	82	110	76	18I	0	-4
		DAY 43	15APR2003	44	76	106	72	12	4	-2	80	110	72	16I	0	-8
		DAY 50	24APR2003	53	76	108	68	12	6	-6	78	118	76	14	8	-4
		DAY 57	02MAY2003	61	72	104	72	8	2	-2	68	110	80	4	0	0
		FINAL		61	72	104	72	8	2	-2	68	110	80	4	0	0
	E0003010	SCREEN	27JAN2003	-7	70	118	70				72	120	72			
		DAY 1	03FEB2003	1	70	118	72				76	124	80			
		BASELINE			70	118	72				76	124	80			
		DAY 8	10FEB2003	8	70	130	90	0	12	18	88	126	90	12	2	10
		DAY 15	19FEB2003	17	82	124	82	12	6	10	84	120	80	8	-4	0
		DAY 22	27FEB2003	25	88	108	74	18I	-10	2	96	98	60	20I	-26D	-20D
		DAY 29	03MAR2003	29	84	138	88	14	20I	16	90	120	88	14	-4	8
		DAY 36	14MAR2003	40	90	140	88	20I	22I	16	92	140	90	16I	16	10
		DAY 43	20MAR2003	46	100	128	86	30I	10	14	90	138	92	14	14	12
		DAY 50	25MAR2003	51	84	140	84	14	22I	12	90	126	92	14	2	12
		DAY 57	31MAR2003	57	79	128	86	9	10	14	90	136	98	14	12	18
		FINAL		57	79	128	86	9	10	14	90	136	98	14	12	18
	E0003016	SCREEN	01MAY2003	-21	68	110	78				84	114	80			
		DAY 1	22MAY2003	1	70	110	84				68	108	84			
		BASELINE			70	110	84				68	108	84			
		DAY 8	29MAY2003	8	92	130	80	22I	20I	-4	104	124	84	36I	16	0
		DAY 15	05JUN2003	15	84	122	88	14	12	4	96	118	86	28I	10	2
		DAY 22	12JUN2003	22	86	108	80	16I	-2	-4	90	116	72	22I	8	-12
		FINAL		22	86	108	80	16I	-2	-4	90	116	72	22I	8	-12
	E0003019	SCREEN	19JUN2003	-8	58	112	76				60	112	82			
		DAY 1	27JUN2003	1	56	116	94				58	118	90			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	BASELINE				56	116	94				58	118	90			
		DAY 8		03JUL2003	7	64	120	84	8	4	-10	62	114	86	4	-4	-4
		DAY 15		10JUL2003	14	60	120	82	4	4	-12	66	112	82	8	-6	-8
		DAY 15	*	15JUL2003	19	62	110	68	6	-6	-26D	64	114	76	6	-4	-14
		DAY 29		29JUL2003	33	72	134	86	16I	18	-8	78	138	90	20I	20I	0
		DAY 43		07AUG2003	42	70	126	88	14	10	-6	66	124	88	8	6	-2
		DAY 50		14AUG2003	49	66	124	82	10	8	-12	72	122	82	14	4	-8
		DAY 57		21AUG2003	56	68	140	92	12	24I	-2	70	132	90	12	14	0
		FINAL			56	68	140	92	12	24I	-2	70	132	90	12	14	0
	E0003020	SCREEN		24JUN2003	-29	62	126	82				80	112	76			
		DAY 1		23JUL2003	1	64	110	50L				70	118	70			
		BASELINE				64	110	50L				70	118	70			
		DAY 8		29JUL2003	7	66	130	84	2	20I	34I	86	124	76	16I	6	6
		DAY 15		06AUG2003	15	62	118	76	-2	8	26	84	132	80	14	14	10
		DAY 22		13AUG2003	22	84	108	70	20I	-2	20	88	118	78	18I	0	8
		DAY 29		20AUG2003	29	76	130	76	12	20I	26	80	132	80	10	14	10
		DAY 36		27AUG2003	36	76	126	88	12	16	38I	82	124	88	12	6	18
		DAY 43		03SEP2003	43	72	134	90	8	24I	40I	78	130	88	8	12	18
		DAY 50		10SEP2003	50	80	120	80	16I	10	30I	76	110	70	6	-8	0
		DAY 57		17SEP2003	57	72	110	80	8	0	30I	72	114	80	2	-4	10
		FINAL			57	72	110	80	8	0	30I	72	114	80	2	-4	10
	E0004001	SCREEN		23SEP2002	-7	54	100	60				56	98	58			
		DAY 1		30SEP2002	1	64	98	62				60	96	58			
		BASELINE				64	98	62				60	96	58			
		DAY 8		07OCT2002	8	64	98	60	0	0	-2	68	92	62	8	-4	4
		DAY 22		21OCT2002	22	64	98	62	0	0	0	72	100	68	12	4	10
		DAY 29		28OCT2002	29	80	94	60	16I	-4	-2	84	86L	60	24I	-10	2
		DAY 36		05NOV2002	37	76	100	62	12	2	0	84	92	60	24I	-4	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	FINAL		37	76	100	62	12	2	0	84	92	60	24I	-4	2
	E0004009	SCREEN	17DEC2002	-9	64	108	70				72	104	64			
		DAY 1	26DEC2002	1	76	100	58				88	102	64			
		BASELINE			76	100	58				88	102	64			
		DAY 8	02JAN2003	8	88	100	62	12	0	4	88	102	60	0	0	-4
		DAY 15	08JAN2003	14	96	102	66	20I	2	8	100	108	64	12	6	0
		DAY 22	15JAN2003	21	88	100	60	12	0	2	100	104	70	12	2	6
		DAY 29	22JAN2003	28	96	116	64	20I	16	6	104	100	70	16I	-2	6
		DAY 36	29JAN2003	35	80	110	62	4	10	4	88	98	62	0	-4	-2
		DAY 43	05FEB2003	42	96	100	60	20I	0	2	100	104	64	12	2	0
		DAY 50	12FEB2003	49	84	100	70	8	0	12	100	92	68	12	-10	4
		DAY 57	19FEB2003	56	90	100	68	14	0	10	104	102	72	16I	0	8
		FINAL		56	90	100	68	14	0	10	104	102	72	16I	0	8
	E0004012	SCREEN	07JAN2003	-7	56	114	62				62	100	60			
		DAY 1	14JAN2003	1	56	104	72				68	100	70			
		BASELINE			56	104	72				68	100	70			
		DAY 8	21JAN2003	8	76	90L	62	20I	-14	-10	88	106	64	20I	6	-6
		DAY 15	28JAN2003	15	64	104	60	8	0	-12	72	108	68	4	8	-2
		DAY 22	04FEB2003	22	80	94	58	24I	-10	-14	88	90L	56	20I	-10	-14
		DAY 29	11FEB2003	29	84	100	70	28I	-4	-2	88	102	72	20I	2	2
		DAY 36	18FEB2003	36	92	94	68	36I	-10	-4	100	100	74	32I	0	4
		DAY 43	25FEB2003	43	68	92	62	12	-12	-10	72	100	70	4	0	0
		DAY 50	04MAR2003	50	72	100	60	16I	-4	-12	90	98	64	22I	-2	-6
		DAY 57	11MAR2003	57	84	98	70	28I	-6	-2	92	100	72	24I	0	2
		FINAL		57	84	98	70	28I	-6	-2	92	100	72	24I	0	2
	E0004015	SCREEN	06FEB2003	-14	60	120	88				76	118	86			
		DAY 1	20FEB2003	1	64	120	82				72	118	90			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	BASELINE			64	120	82				72	118	90			
		DAY 8	25FEB2003	6	88	130	84	24I	10	2	96	122	90	24I	4	0
		DAY 15	04MAR2003	13	80	124	80	16I	4	-2	92	112	82	20I	-6	-8
		DAY 22	11MAR2003	20	88	120	90	24I	0	8	96	128	92	24I	10	2
		DAY 29	18MAR2003	27	80	138	82	16I	18	0	88	132	88	16I	14	-2
		DAY 36	25MAR2003	34	80	128	90	16I	8	8	90	124	92	18I	6	2
		DAY 43	01APR2003	41	88	142	84	24I	22I	2	92	136	88	20I	18	-2
		DAY 50	08APR2003	48	84	130	90	20I	10	8	86	122	90	14	4	0
		DAY 57	15APR2003	55	84	122	90	20I	2	8	88	118	88	16I	0	-2
		FINAL		55	84	122	90	20I	2	8	88	118	88	16I	0	-2
	E0005003	SCREEN	23SEP2002	-9							80	134	86			
		DAY 1	02OCT2002	1	68	128	80				72	134	86			
		BASELINE			68	128	80				72	134	86			
		DAY 8	09OCT2002	8	72	134	86	4	6	6	84	134	84	12	0	-2
		DAY 15	16OCT2002	15	76	132	80	8	4	0	82	130	76	10	-4	-10
		DAY 22	23OCT2002	22	92	116	70	24I	-12	-10	92	116	76	20I	-18	-10
		DAY 29	30OCT2002	29	80	140	78	12	12	-2	88	136	78	16I	2	-8
		DAY 36	06NOV2002	36	88	134	82	20I	6	2	92	136	90	20I	2	4
		DAY 43	14NOV2002	44	88	140	90	20I	12	10	96	136	90	24I	2	4
		DAY 50	21NOV2002	51	84	128	86	16I	0	6	88	130	90	16I	-4	4
		DAY 57	26NOV2002	56	92	128	78	24I	0	-2	88	130	86	16I	-4	0
		FINAL		56	92	128	78	24I	0	-2	88	130	86	16I	-4	0
	E0005007	SCREEN	02OCT2002	-7												
		DAY 1	09OCT2002	1	60	98	64				68	96	64			
		BASELINE			60	98	64				68	96	64			
		DAY 8	16OCT2002	8	72	124	78	12	26I	14	68	112	70	0	16	6
		DAY 15	23OCT2002	15	80	118	78	20I	20I	14	76	110	64	8	14	0
		DAY 22	30OCT2002	22	84	104	76	24I	6	12	80	100	70	12	4	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 29	06NOV2002	29	80	112	72	20I	14	8	88	110	74	20I	14	10
		DAY 36	14NOV2002	37	84	116	72	24I	18	8	88	110	70	20I	14	6
		DAY 43	20NOV2002	43	72	106	64	12	8	0	80	100	64	12	4	0
		DAY 50	26NOV2002	49	84	118	68	24I	20I	4	88	120	74	20I	24I	10
		DAY 57	04DEC2002	57	84	116	78	24I	18	14	88	118	76	20I	22I	12
		FINAL		57	84	116	78	24I	18	14	88	118	76	20I	22I	12
	E0005008	SCREEN	08OCT2002	-7	80	150	82				80	148	80			
		DAY 1	15OCT2002	1	92	126	68				92	126	64			
		BASELINE			92	126	68				92	126	64			
		DAY 8	22OCT2002	8	96	130	84	4	4	16	96	134	80	4	8	16
		DAY 15	29OCT2002	15	92	138	84	0	12	16	92	138	82	0	12	18
		DAY 22	06NOV2002	23	100	148	88	8	22I	20	92	140	86	0	14	22
		DAY 29	13NOV2002	30	92	146	88	0	20I	20	92	140	86	0	14	22
		DAY 36	18NOV2002	35	84	145	80	-8	19	12	84	138	80	-8	12	16
		DAY 43	25NOV2002	42	88	140	86	-4	14	18	88	140	88	-4	14	24
		DAY 50	02DEC2002	49	88	134	82	-4	8	14	88	136	82	-4	10	18
		DAY 57	11DEC2002	58	88	130	84	-4	4	16	88	134	80	-4	8	16
		FINAL		58	88	130	84	-4	4	16	88	134	80	-4	8	16
	E0005010	SCREEN	14OCT2002	-7	68	120	80				68	110	70			
		DAY 1	21OCT2002	1	64	120	70				64	110	64			
		BASELINE			64	120	70				64	110	64			
		DAY 8	28OCT2002	8	64	110	70	0	-10	0	64	110	68	0	0	4
		DAY 15	04NOV2002	15	80	110	68	16I	-10	-2	80	100	64	16I	-10	0
		DAY 22	13NOV2002	24	80	110	70	16I	-10	0	80	100	60	16I	-10	-4
		DAY 29	19NOV2002	30	88	120	80	24I	0	10	88	120	76	24I	10	12
		DAY 36	26NOV2002	37	76	124	70	12	4	0	76	110	60	12	0	-4
		DAY 43	03DEC2002	44	80	114	74	16I	-6	4	80	104	68	16I	-6	4
		DAY 50	09DEC2002	50	80	116	74	16I	-4	4	80	110	70	16I	0	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	DAY 57		17DEC2002	58	80	128	74	16I	8	4	80	124	74	16I	14	10
		FINAL			58	80	128	74	16I	8	4	80	124	74	16I	14	10
	E0005012	SCREEN		24OCT2002	-21	68	104	70				68	100	72			
		DAY 1		14NOV2002	1	64	140	88				64	138	88			
		BASELINE				64	140	88				64	138	88			
		DAY 8		20NOV2002	7	80	130	80	16I	-10	-8	80	130	80	16I	-8	-8
		DAY 15		26NOV2002	13	68	124	80	4	-16	-8	68	124	80	4	-14	-8
		DAY 22		06DEC2002	23	80	124	82	16I	-16	-6	80	120	78	16I	-18	-10
		DAY 29		10DEC2002	27	80	120	80	16I	-20D	-8	80	120	76	16I	-18	-12
		DAY 36		18DEC2002	35	80	120	80	16I	-20D	-8	80	120	80	16I	-18	-8
		DAY 36	*	23DEC2002	40	64	120	80	0	-20D	-8	64	124	80	0	-14	-8
		DAY 50		02JAN2003	50	80	120	74	16I	-20D	-14	80	122	80	16I	-16	-8
		DAY 57		07JAN2003	55	80	126	80	16I	-14	-8	80	124	82	16I	-14	-6
		FINAL			55	80	126	80	16I	-14	-8	80	124	82	16I	-14	-6
	E0005014	SCREEN		05NOV2002	-8	60	100	70				60	100	70			
		DAY 1		13NOV2002	1	60	106	66				60	100	70			
		BASELINE				60	106	66				60	100	70			
		DAY 8		20NOV2002	8	60	110	64	0	4	-2	60	110	66	0	10	-4
		DAY 15		27NOV2002	15	60	110	70	0	4	4	60	100	64	0	0	-6
		DAY 22		03DEC2002	21	80	110	74	20I	4	8	80	100	70	20I	0	0
		DAY 29		11DEC2002	29	80	110	70	20I	4	4	80	110	70	20I	10	0
		DAY 36		17DEC2002	35	80	110	70	20I	4	4	80	110	68	20I	10	-2
		DAY 43		23DEC2002	41	80	112	80	20I	6	14	80	110	80	20I	10	10
		DAY 50		30DEC2002	48	80	120	76	20I	14	10	80	110	74	20I	10	4
		DAY 57		06JAN2003	55	80	114	80	20I	8	14	80	110	74	20I	10	4
		FINAL			55	80	114	80	20I	8	14	80	110	74	20I	10	4
	E0005022	SCREEN		23JAN2003	-6	64	120	80				64	120	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005022	DAY 1	29JAN2003	1	72	110	70				72	120	80			
		BASELINE			72	110	70				72	120	80			
		DAY 8	04FEB2003	7	72	110	80	0	0	10	72	110	80	0	-10	0
		DAY 15	11FEB2003	14	64	114	74	-8	4	4	64	104	74	-8	-16	-6
		DAY 22	21FEB2003	24	64	110	70	-8	0	0	64	100	70	-8	-20D	-10
		DAY 29	26FEB2003	29	64	120	70	-8	10	0	64	118	70	-8	-2	-10
		DAY 36	06MAR2003	37	60	110	80	-12	0	10	60	100	80	-12	-20D	0
		FINAL		37	60	110	80	-12	0	10	60	100	80	-12	-20D	0
	E0005025	SCREEN	20FEB2003	-7	80	116	68				84	110	64			
		DAY 1	27FEB2003	1	80	110	60				80	106	60			
		BASELINE			80	110	60				80	106	60			
		DAY 8	06MAR2003	8	88	110	60	8	0	0	100	100	56	20I	-6	-4
		DAY 15	14MAR2003	16	88	90L	60	8	-20D	0	88	94	60	8	-12	0
		DAY 22	20MAR2003	22	88	106	64	8	-4	4	88	100	60	8	-6	0
		DAY 29	27MAR2003	29	68	100	58	-12	-10	-2	80	90L	54	0	-16	-6
		DAY 36	03APR2003	36	80	100	64	0	-10	4	88	104	66	8	-2	6
		FINAL		36	80	100	64	0	-10	4	88	104	66	8	-2	6
	E0006019	SCREEN	26MAR2003	-12	78	127	72				82	131	78			
		DAY 1	07APR2003	1	58	118	72				75	116	84			
		BASELINE			58	118	72				75	116	84			
		DAY 8	14APR2003	8	70	129	90	12	11	18	86	129	79	11	13	-5
		DAY 15	21APR2003	15	83	119	85	25I	1	13	88	112	88	13	-4	4
		DAY 22	28APR2003	22	66	122	87	8	4	15	82	131	90	7	15	6
		DAY 29	05MAY2003	29	70	119	71	12	1	-1	93	113	84	18I	-3	0
		DAY 36	12MAY2003	36	68	117	72	10	-1	0	90	129	84	15I	13	0
		DAY 43	19MAY2003	43	66	112	64	8	-6	-8	70	116	78	-5	0	-6
		DAY 50	27MAY2003	51	71	104	72	13	-14	0	93	115	76	18I	-1	-8
		DAY 57	03JUN2003	58	70	120	80	12	2	8	77	122	82	2	6	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	FINAL		58	70	120	80	12	2	8	77	122	82	2	6	-2
	E0007005	SCREEN	27JAN2003	-4	80	114	70				82	110	72			
		DAY 1	31JAN2003	1	70	110	68				72	104	70			
		BASELINE			70	110	68				72	104	70			
		DAY 8	07FEB2003	8	70	108	76	0	-2	8	74	112	78	2	8	8
		DAY 15	14FEB2003	15	70	100	70	0	-10	2	78	108	70	6	4	0
		DAY 22	22FEB2003	23	72	98	72	2	-12	4	78	104	70	6	0	0
		DAY 29	03MAR2003	32	78	100	70	8	-10	2	82	102	70	10	-2	0
		DAY 36	10MAR2003	39	76	104	70	6	-6	2	84	100	72	12	-4	2
		DAY 43	14MAR2003	43	70	96	70	0	-14	2	76	100	72	4	-4	2
		DAY 50	21MAR2003	50	82	90L	60	12	-20D	-8	88	96	64	16I	-8	-6
		DAY 57	28MAR2003	57	72	94	62	2	-16	-6	78	98	60	6	-6	-10
		FINAL		57	72	94	62	2	-16	-6	78	98	60	6	-6	-10
	E0009001	SCREEN	29OCT2002	-14	70	134	96				74	128	94			
		DAY 1	12NOV2002	1	88	130	94				86	128	92			
		BASELINE			88	130	94				86	128	92			
		DAY 8	21NOV2002	10	88	140	86	0	10	-8	92	136	94	6	8	2
		DAY 15	26NOV2002	15	80	126	70	-8	-4	-24D	82	110	74	-4	-18	-18
		DAY 22	04DEC2002	23	74	130	88	-14	0	-6	80	128	90	-6	0	-2
		DAY 29	10DEC2002	29	60	136	84	-28D	6	-10	76	140	90	-10	12	-2
		DAY 36	17DEC2002	36	80	128	78	-8	-2	-16	82	130	80	-4	2	-12
		DAY 43	23DEC2002	42	78	120	78	-10	-10	-16	82	120	76	-4	-8	-16
		DAY 50	30DEC2002	49	76	120	68	-12	-10	-26D	80	110	72	-6	-18	-20D
		FINAL		49	76	120	68	-12	-10	-26D	80	110	72	-6	-18	-20D
	E0010002	SCREEN	14NOV2002	-11	68	102	78				70	115	80			
		DAY 1	25NOV2002	1	106	110	60				122H	102	72			
		BASELINE			106	110	60				122H	102	72			

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I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT103.SAS
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010002	DAY 8	02DEC2002	8	72	110	74	-34D	0	14	82	114	80	-40D	12	8
		FINAL		8	72	110	74	-34D	0	14	82	114	80	-40D	12	8
	E0010009	SCREEN	18DEC2002	-8	56	130	70				65	130	64			
		DAY 1	26DEC2002	1	56	138	88				60	136	88			
		BASELINE			56	138	88				60	136	88			
		DAY 8	02JAN2003	8	66	120	76	10	-18	-12	76	110	76	16I	-26D	-12
		DAY 15	09JAN2003	15	74	140	82	18I	2	-6	89	120	80	29I	-16	-8
		DAY 22	17JAN2003	23	72	110	78	16I	-28D	-10	84	108	78	24I	-28D	-10
		DAY 29	22JAN2003	28	68	128	76	12	-10	-12	76	104	80	16I	-32D	-8
		DAY 36	30JAN2003	36	82	138	66	26I	0	-22D	90	146	86	30I	10	-2
		DAY 43	05FEB2003	42	84	124	82	28I	-14	-6	90	108	76	30I	-28D	-12
		DAY 50	13FEB2003	50	68	126	62	12	-12	-26D	86	118	72	26I	-18	-16
		DAY 57	19FEB2003	56	74	126	80	18I	-12	-8	89	126	82	29I	-10	-6
		FINAL		56	74	126	80	18I	-12	-8	89	126	82	29I	-10	-6
	E0010014	SCREEN	14JAN2003	-14	52	120	70				68	124	70			
		DAY 1	28JAN2003	1	49L	126	66				65	114	66			
		BASELINE			49L	126	66				65	114	66			
		DAY 8	04FEB2003	8	58	112	68	9	-14	2	70	102	66	5	-12	0
		DAY 15	11FEB2003	15	58	104	62	9	-22D	-4	77	106	64	12	-8	-2
		DAY 22	18FEB2003	22	52	118	70	3	-8	4	66	120	76	1	6	10
		DAY 29	25FEB2003	29	58	108	68	9	-18	2	76	110	70	11	-4	4
		DAY 36	04MAR2003	36	54	120	70	5	-6	4	74	110	78	9	-4	12
		DAY 43	11MAR2003	43	52	112	70	3	-14	4	70	112	70	5	-2	4
		DAY 50	18MAR2003	50	52	110	74	3	-16	8	66	110	70	1	-4	4
		DAY 57	25MAR2003	57	51	118	78	2	-8	12	58	110	80	-7	-4	14
		FINAL		57	51	118	78	2	-8	12	58	110	80	-7	-4	14
	E0010017	SCREEN	05FEB2003	-20	61	114	62				79	110	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	DAY 1	25FEB2003	1	68	124	66				72	128	80			
		BASELINE			68	124	66				72	128	80			
		DAY 8	03MAR2003	7	60	110	70	-8	-14	4	76	100	60	4	-28D	-20D
		DAY 15	10MAR2003	14	84	112	68	16I	-12	2	100	120	70	28I	-8	-10
		DAY 22	18MAR2003	22	64	120	72	-4	-4	6	86	126	86	14	-2	6
		DAY 29	25MAR2003	29	80	110	68	12	-14	2	86	112	76	14	-16	-4
		DAY 36	01APR2003	36	84	110	76	16I	-14	10	92	116	80	20I	-12	0
		DAY 43	08APR2003	43	84	120	78	16I	-4	12	94	112	80	22I	-16	0
		DAY 50	15APR2003	50	72	126	76	4	2	10	88	128	80	16I	0	0
		DAY 57	22APR2003	57	69	110	66	1	-14	0	78	112	76	6	-16	-4
		FINAL		57	69	110	66	1	-14	0	78	112	76	6	-16	-4
	E0010027	SCREEN	05JUN2003	-11	66	118	70				82	112	70			
		DAY 1	16JUN2003	1	80	110	90				80	110	82			
		BASELINE			80	110	90				80	110	82			
		DAY 8	23JUN2003	8	78	120	74	-2	10	-16	110	118	78	30I	8	-4
		DAY 15	01JUL2003	16	76	110	80	-4	0	-10	80	120	82	0	10	0
		FINAL		16	76	110	80	-4	0	-10	80	120	82	0	10	0
	E0010029	SCREEN	10JUN2003	-9	75	120	84				96	134	90			
		DAY 1	19JUN2003	1	88	120	80				88	120	89			
		BASELINE			88	120	80				88	120	89			
		DAY 8	25JUN2003	7	92	138	94	4	18	14	104	134	94	16I	14	5
		FINAL		7	92	138	94	4	18	14	104	134	94	16I	14	5
	E0011022	SCREEN	02JUN2003	-7	70	130	80				72	136	78			
		DAY 1	09JUN2003	1	68	130	86				72	132	86			
		BASELINE			68	130	86				72	132	86			
		DAY 8	16JUN2003	8	88	126	80	20I	-4	-6	96	128	76	24I	-4	-10
		DAY 15	24JUN2003	16	90	122	82	22I	-8	-4	88	118	78	16I	-14	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	DAY 22	01JUL2003	23	82	110	68	14	-20D	-18	86	114	70	14	-18	-16
		DAY 29	08JUL2003	30	88	110	74	20I	-20D	-12	84	102	68	12	-30D	-18
		DAY 36	15JUL2003	37	90	124	82	22I	-6	-4	90	120	80	18I	-12	-6
		DAY 43	24JUL2003	46	82	124	82	14	-6	-4	82	120	80	10	-12	-6
		DAY 50	31JUL2003	53	78	124	82	10	-6	-4	82	120	78	10	-12	-8
		DAY 57	05AUG2003	58	82	120	84	14	-10	-2	86	116	80	14	-16	-6
		FINAL		58	82	120	84	14	-10	-2	86	116	80	14	-16	-6
	E0013012	SCREEN	29APR2003	-8	72	114	80				72	118	80			
		DAY 1	07MAY2003	1	72	128	82				72	128	80			
		BASELINE			72	128	82				72	128	80			
		DAY 8	16MAY2003	10	72	140	80	0	12	-2	64	140	80	-8	12	0
		DAY 15	22MAY2003	16	76	120	78	4	-8	-4	72	122	78	0	-6	-2
		DAY 22	30MAY2003	24	60	120	62	-12	-8	-20D	64	120	70	-8	-8	-10
		DAY 29	05JUN2003	30	68	122	76	-4	-6	-6	68	122	80	-4	-6	0
		DAY 36	12JUN2003	37	64	120	74	-8	-8	-8	68	120	80	-4	-8	0
		DAY 43	19JUN2003	44	68	120	68	-4	-8	-14	68	120	70	-4	-8	-10
		DAY 50	25JUN2003	50	68	120	78	-4	-8	-4	72	126	80	0	-2	0
		DAY 57	02JUL2003	57	72	140	88	0	12	6	72	138	90	0	10	10
		FINAL		57	72	140	88	0	12	6	72	138	90	0	10	10
	E0013014	SCREEN	08MAY2003	-26	62	120	80				64	120	80			
		DAY 1	03JUN2003	1	60	126	84				64	120	84			
		BASELINE			60	126	84				64	120	84			
		DAY 8	10JUN2003	8	64	120	82	4	-6	-2	64	120	80	0	0	-4
		DAY 15	19JUN2003	17	84	118	80	24I	-8	-4	80	120	82	16I	0	-2
		DAY 29	30JUN2003	28	68	122	80	8	-4	-4	68	120	80	4	0	-4
		FINAL		28	68	122	80	8	-4	-4	68	120	80	4	0	-4
	E0014005	SCREEN	04MAR2003	-7	82	140	95				80	138	95			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	DAY 1	11MAR2003	1	88	124	86				98	118	86			
		BASELINE			88	124	86				98	118	86			
		DAY 8	18MAR2003	8	98	140	98	10	16	12	100	135	98	2	17	12
		DAY 15	25MAR2003	15	95	125	93	7	1	7	100	125	98	2	7	12
		DAY 22	01APR2003	22	94	135	95	6	11	9	100	125	95	2	7	9
		DAY 29	08APR2003	29	100	120	90	12	-4	4	102	125	90	4	7	4
		DAY 36	16APR2003	37	100	116	78	12	-8	-8	116	116	86	18I	-2	0
		DAY 43	23APR2003	44	105	128	82	17I	4	-4	116	124	88	18I	6	2
		DAY 50	29APR2003	50	102	130	95	14	6	9	102	140	95	4	22I	9
		DAY 57	06MAY2003	57	100	125	92	12	1	6	92	130	93	-6	12	7
		FINAL		57	100	125	92	12	1	6	92	130	93	-6	12	7
	E0014007	SCREEN	25MAR2003	-7	62	128	88				68	128	87			
		DAY 1	01APR2003	1	92	120	87				93	120	87			
		BASELINE			92	120	87				93	120	87			
		DAY 8	08APR2003	8	79	98	75	-13	-22D	-12	80	110	80	-13	-10	-7
		DAY 15	15APR2003	15	90	110	82	-2	-10	-5	93	120	90	0	0	3
		DAY 22	22APR2003	22	80	128	82	-12	8	-5	84	134	82	-9	14	-5
		FINAL		22	80	128	82	-12	8	-5	84	134	82	-9	14	-5
	E0016003	SCREEN	10JAN2003	-14	74	128	88				80	132	90			
		DAY 1	24JAN2003	1	72	126	79				82	138	88			
		BASELINE			72	126	79				82	138	88			
		DAY 8	31JAN2003	8	90	128	80	18I	2	1	86	132	84	4	-6	-4
		DAY 15	07FEB2003	15	82	126	84	10	0	5	89	138	92	7	0	4
		DAY 22	14FEB2003	22	86	128	92	14	2	13	94	132	84	12	-6	-4
		DAY 29	21FEB2003	29	89	121	78	17I	-5	-1	98	132	89	16I	-6	1
		DAY 36	27FEB2003	35	86	121	81	14	-5	2	92	132	86	10	-6	-2
		DAY 43	07MAR2003	43	89	136	94	17I	10	15	96	142	98	14	4	10
		FINAL		43	89	136	94	17I	10	15	96	142	98	14	4	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	SCREEN		20FEB2003	-5	64	118	78				86	108	84			
		DAY 1		25FEB2003	1	81	118	72				96	126	84			
		BASELINE				81	118	72				96	126	84			
		DAY 8		04MAR2003	8	88	122	79	7	4	7	95	128	85	-1	2	1
		DAY 15		11MAR2003	15	81	111	69	0	-7	-3	91	132	86	-5	6	2
		DAY 22		18MAR2003	22	78	115	76	-3	-3	4	83	126	81	-13	0	-3
		DAY 29		25MAR2003	29	76	116	82	-5	-2	10	84	126	76	-12	0	-8
		DAY 36		01APR2003	36	74	118	69	-7	0	-3	86	132	81	-10	6	-3
		DAY 43		08APR2003	43	82	140	81	1	22I	9	87	150	88	-9	24I	4
		DAY 57		22APR2003	57	91	105	73	10	-13	1	98	117	76	2	-9	-8
		FINAL			57	91	105	73	10	-13	1	98	117	76	2	-9	-8
	E0019005	SCREEN		30OCT2002	-6	60	140	86				62	140	88			
		DAY 1		05NOV2002	1	64	130	70				72	125	70			
		BASELINE				64	130	70				72	125	70			
		DAY 8		12NOV2002	8	54	110	60	-10	-20D	-10	62	110	65	-10	-15	-5
		DAY 15		19NOV2002	15	72	120	80	8	-10	10	64	128	78	-8	3	8
		DAY 22		26NOV2002	22	68	135	80	4	5	10	76	125	70	4	0	0
		DAY 29		05DEC2002	31	60	120	82	-4	-10	12	80	124	78	8	-1	8
		DAY 36		12DEC2002	38	70	118	70	6	-12	0	68	115	70	-4	-10	0
		DAY 43		19DEC2002	45	68	112	80	4	-18	10	72	115	80	0	-10	10
		DAY 57	*	30DEC2002	56	80	130	74	16I	0	4	88	136	78	16I	11	8
		DAY 57		02JAN2003	59	88	120	72	24I	-10	2	94	120	78	22I	-5	8
		FINAL			59	88	120	72	24I	-10	2	94	120	78	22I	-5	8
	E0019015	SCREEN		19DEC2002	-14	56	110	84				76	100	82			
		DAY 1		02JAN2003	1	60	110	90				80	120	90			
		BASELINE				60	110	90				80	120	90			
		DAY 8		09JAN2003	8	72	112	92	12	2	2	76	110	90	-4	-10	0
		DAY 15		16JAN2003	15	72	128	80	12	18	-10	80	126	82	0	6	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	DAY 22		23JAN2003	22	60	117	75	0	7	-15	62	118	80	-18D	-2	-10
		DAY 29		30JAN2003	29	80	130	85	20I	20I	-5	84	135	85	4	15	-5
		DAY 36		06FEB2003	36	84	135	80	24I	25I	-10	76	140	90	-4	20I	0
		DAY 43		13FEB2003	43	80	130	80	20I	20I	-10	88	135	80	8	15	-10
		DAY 50		20FEB2003	50	90	125	85	30I	15	-5	90	130	90	10	10	0
		DAY 57		27FEB2003	57	50	120	104	-10	10	14	96	124	100	16I	4	10
		FINAL			57	50	120	104	-10	10	14	96	124	100	16I	4	10
	E0020004	SCREEN		21NOV2002	-18	78	160	80				82	162	84			
		DAY 1		09DEC2002	1	84	140	80				80	144	82			
		BASELINE				84	140	80				80	144	82			
		DAY 8		16DEC2002	8	82	138	80	-2	-2	0	80	140	82	0	-4	0
		DAY 8	*	20DEC2002	12	80	178	100	-4	38I	20	86	180H	104	6	36I	22
		DAY 22		31DEC2002	23	74	122	78	-10	-18	-2	76	120	78	-4	-24D	-4
		DAY 29		07JAN2003	30	76	170	92	-8	30I	12	80	168	90	0	24I	8
		DAY 36		14JAN2003	37	76	152	82	-8	12	2	70	148	80	-10	4	-2
		DAY 43		22JAN2003	45	80	138	80	-4	-2	0	84	138	82	4	-6	0
		FINAL			45	80	138	80	-4	-2	0	84	138	82	4	-6	0
	E0020010	SCREEN		28JAN2003	-8	70	104	70				76	110	68			
		DAY 1		05FEB2003	1	66	102	80				64	106	80			
		BASELINE				66	102	80				64	106	80			
		DAY 8		12FEB2003	8	80	110	70	14	8	-10	76	112	72	12	6	-8
		DAY 15		19FEB2003	15	80	120	88	14	18	8	78	118	90	14	12	10
		DAY 22		26FEB2003	22	78	120	86	12	18	6	76	118	88	12	12	8
		DAY 29		05MAR2003	29	84	120	72	18I	18	-8	80	124	74	16I	18	-6
		DAY 36		10MAR2003	34	80	120	78	14	18	-2	82	120	80	18I	14	0
		DAY 43		17MAR2003	41	64	122	70	-2	20I	-10	64	118	70	0	12	-10
		DAY 50		25MAR2003	49	74	120	74	8	18	-6	76	122	72	12	16	-8
		DAY 57		02APR2003	57	80	144	82	14	42I	2	84	130	84	20I	24I	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020010	FINAL		57	80	144	82	14	42I	2	84	130	84	20I	24I	4
	E0020014	SCREEN	11MAR2003	-7	64	118	76				68	112	74			
		DAY 1	18MAR2003	1	76	112	72				72	120	74			
		BASELINE			76	112	72				72	120	74			
		DAY 8	25MAR2003	8	78	122	76	2	10	4	84	124	74	12	4	0
		DAY 15	01APR2003	15	82	140	88	6	28I	16	80	160	90	8	40I	16
		DAY 22	08APR2003	22	76	148	90	0	36I	18	74	152	90	2	32I	16
		DAY 29	15APR2003	29	78	124	80	2	12	8	80	128	84	8	8	10
		DAY 36	22APR2003	36	80	140	70	4	28I	-2	82	138	72	10	18	-2
		DAY 43	29APR2003	43	64	124	82	-12	12	10	70	126	84	-2	6	10
		DAY 50	06MAY2003	50	80	126	76	4	14	4	78	120	76	6	0	2
		DAY 57	12MAY2003	56	62	132	72	-14	20I	0	68	130	74	-4	10	0
		FINAL		56	62	132	72	-14	20I	0	68	130	74	-4	10	0
	E0020021	SCREEN	13MAY2003	-6	70	134	82				76	140	84			
		DAY 1	19MAY2003	1	72	130	80				70	128	82			
		BASELINE			72	130	80				70	128	82			
		DAY 8	23MAY2003	5	62	128	86	-10	-2	6	64	130	86	-6	2	4
		DAY 15	02JUN2003	15	76	142	82	4	12	2	80	148	84	10	20I	2
		DAY 22	10JUN2003	23	78	140	82	6	10	2	80	144	80	10	16	-2
		DAY 29	16JUN2003	29	92	140	80	20I	10	0	88	140	90	18I	12	8
		DAY 36	23JUN2003	36	80	140	76	8	10	-4	88	138	76	18I	10	-6
		DAY 43	30JUN2003	43	88	130	78	16I	0	-2	88	130	80	18I	2	-2
		DAY 50	07JUL2003	50	94	166	98	22I	36I	18	90	160	98	20I	32I	16
		DAY 57	14JUL2003	57	88	174	106H	16I	44I	26	80	160	108H	10	32I	26
		FINAL		57	88	174	106H	16I	44I	26	80	160	108H	10	32I	26
	E0020023	SCREEN	09JUN2003	-8	62	118	80				60	120	80			
		DAY 1	16JUN2003	-1	54	110	80				60	120	88			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	BASELINE			54	110	80				60	120	88			
		DAY 8	24JUN2003	8	64	110	80	10	0	0	64	118	80	4	-2	-8
		DAY 15	30JUN2003	14	76	112	88	22I	2	8	80	116	90	20I	-4	2
		DAY 22	07JUL2003	21	60	102	72	6	-8	-8	62	106	72	2	-14	-16
		DAY 29	14JUL2003	28	78	110	80	24I	0	0	82	108	80	22I	-12	-8
		DAY 36	21JUL2003	35	72	94	58	18I	-16	-22D	78	92	70	18I	-28D	-18
		DAY 43	28JUL2003	42	80	128	78	26I	18	-2	78	120	78	18I	0	-10
		DAY 50	04AUG2003	49	74	106	86	20I	-4	6	80	108	86	20I	-12	-2
		DAY 57	11AUG2003	56	60	110	88	6	0	8	58	100	88	-2	-20D	0
		FINAL		56	60	110	88	6	0	8	58	100	88	-2	-20D	0
	E0022007	SCREEN	01NOV2002	-6	52	112	69				64	120	73			
		DAY 1	07NOV2002	1	64	108	68				68	112	72			
		BASELINE			64	108	68				68	112	72			
		DAY 8	14NOV2002	8	72	124	62	8	16	-6	100	114	76	32I	2	4
		DAY 15	22NOV2002	16	84	104	62	20I	-4	-6	88	102	64	20I	-10	-8
		DAY 22	02DEC2002	26	72	112	58	8	4	-10	88	100	68	20I	-12	-4
		DAY 29	09DEC2002	33	74	112	70	10	4	2	78	104	72	10	-8	0
		FINAL		33	74	112	70	10	4	2	78	104	72	10	-8	0
	E0022010	SCREEN	14NOV2002	-7	59	135	69				75	133	70			
		DAY 1	21NOV2002	1	68	124	68				72	118	68			
		BASELINE			68	124	68				72	118	68			
		DAY 8	29NOV2002	9	84	122	64	16I	-2	-4	80	120	70	8	2	2
		DAY 15	06DEC2002	16	84	142	78	16I	18	10	88	142	106H	16I	24I	38I
		DAY 22	12DEC2002	22	72	130	68	4	6	0	80	136	72	8	18	4
		DAY 36	26DEC2002	36	78	142	64	10	18	-4	78	144	68	6	26I	0
		DAY 43	02JAN2003	43	84	146	70	16I	22I	2	88	142	86	16I	24I	18
		DAY 50	09JAN2003	50	80	134	72	12	10	4	100	132	96	28I	14	28
		DAY 57	16JAN2003	57	76	134	70	8	10	2	72	132	76	0	14	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	FINAL			57	76	134	70	8	10	2	72	132	76	0	14	8
	E0022012	SCREEN		21NOV2002	-14	64	126	60				68	118	72			
		DAY 1		05DEC2002	1	60	122	62				64	122	68			
		BASELINE				60	122	62				64	122	68			
		DAY 8		12DEC2002	8	64	122	72	4	0	10	68	110	68	4	-12	0
		DAY 15		19DEC2002	15	76	116	68	16I	-6	6	90	116	74	26I	-6	6
		DAY 15	*	23DEC2002	19	76	110	68	16I	-12	6	84	108	74	20I	-14	6
		DAY 29		02JAN2003	29	78	108	68	18I	-14	6	78	120	80	14	-2	12
		DAY 36		09JAN2003	36	90	126	64	30I	4	2	90	110	78	26I	-12	10
		DAY 43		16JAN2003	43	88	124	64	28I	2	2	100	128	72	36I	6	4
		DAY 50		23JAN2003	50	81	122	68	21I	0	6	84	122	80	20I	0	12
		DAY 57		30JAN2003	57	84	112	68	24I	-10	6	84	128	70	20I	6	2
		FINAL			57	84	112	68	24I	-10	6	84	128	70	20I	6	2
	E0022019	SCREEN		04DEC2002	-7	68	122	64				84	130	88			
		DAY 1		11DEC2002	1	60	120	76				80	126	90			
		BASELINE				60	120	76				80	126	90			
		DAY 8		19DEC2002	9	80	146	78	20I	26I	2	88	118	90	8	-8	0
		DAY 15		26DEC2002	16	88	144	84	28I	24I	8	96	132	88	16I	6	-2
		DAY 22		03JAN2003	24	96	134	96	36I	14	20	112	142	100	32I	16	10
		DAY 29		09JAN2003	30	96	126	82	36I	6	6	108	136	98	28I	10	8
		DAY 36		17JAN2003	38	92	132	96	32I	12	20	100	138	92	20I	12	2
		DAY 43		24JAN2003	45	80	140	94	20I	20I	18	92	124	94	12	-2	4
		DAY 50		30JAN2003	51	100	134	92	40I	14	16	112	132	104	32I	6	14
		DAY 57		06FEB2003	58	76	124	80	16I	4	4	92	118	92	12	-8	2
		FINAL			58	76	124	80	16I	4	4	92	118	92	12	-8	2
	E0022033	SCREEN		11FEB2003	-7	64	112	78				60	120	72			
		DAY 1		18FEB2003	1	76	104	64				72	100	66			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	BASELINE			76	104	64				72	100	66			
		DAY 8	25FEB2003	8	60	130	76	-16D	26I	12	76	132	84	4	32I	18
		DAY 15	04MAR2003	15	74	128	80	-2	24I	16	88	128	88	16I	28I	22
		DAY 22	11MAR2003	22	80	128	80	4	24I	16	88	128	82	16I	28I	16
		DAY 29	18MAR2003	29	64	130	76	-12	26I	12	78	106	82	6	6	16
		DAY 36	27MAR2003	38	68	128	80	-8	24I	16	68	110	82	-4	10	16
		DAY 43	01APR2003	43	68	118	72	-8	14	8	78	118	80	6	18	14
		DAY 50	08APR2003	50	72	120	70	-4	16	6	80	118	78	8	18	12
		DAY 57	15APR2003	57	60	120	70	-16D	16	6	72	128	82	0	28I	16
		FINAL		57	60	120	70	-16D	16	6	72	128	82	0	28I	16
	E0022034	SCREEN	11FEB2003	-7	64	136	84				70	138	86			
		DAY 1	18FEB2003	1	66	128	78				76	142	78			
		BASELINE			66	128	78				76	142	78			
		DAY 8	25FEB2003	8	60	128	74	-6	0	-4	75	138	82	-1	-4	4
		DAY 15	04MAR2003	15	60	126	74	-6	-2	-4	69	114	80	-7	-28D	2
		DAY 22	11MAR2003	22	75	124	80	9	-4	2	78	120	82	2	-22D	4
		DAY 29	18MAR2003	29	68	116	78	2	-12	0	75	128	84	-1	-14	6
		DAY 36	25MAR2003	36	87	140	78	21I	12	0	75	138	86	-1	-4	8
		DAY 43	01APR2003	43	78	118	74	12	-10	-4	90	130	84	14	-12	6
		DAY 50	07APR2003	49	96	132	80	30I	4	2	92	126	86	16I	-16	8
		DAY 57	15APR2003	57	81	120	76	15I	-8	-2	84	118	80	8	-24D	2
		FINAL		57	81	120	76	15I	-8	-2	84	118	80	8	-24D	2
	E0022038	SCREEN	20FEB2003	-8	56	128	84				64	142	88			
		DAY 1	28FEB2003	1	60	118	74				78	118	80			
		BASELINE			60	118	74				78	118	80			
		DAY 8	07MAR2003	8	60	128	72	0	10	-2	72	122	88	-6	4	8
		DAY 15	14MAR2003	15	80	130	78	20I	12	4	88	120	70	10	2	-10
		DAY 22	21MAR2003	22	78	140	82	18I	22I	8	88	130	80	10	12	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	DAY 29	28MAR2003	29	76	128	68	16I	10	-6	88	130	80	10	12	0
		DAY 36	04APR2003	36	84	134	60	24I	16	-14	96	124	72	18I	6	-8
		DAY 43	11APR2003	43	56	130	72	-4	12	-2	64	130	78	-14	12	-2
		FINAL		43	56	130	72	-4	12	-2	64	130	78	-14	12	-2
	E0022039	SCREEN	27FEB2003	-7	64	90L	58				68	116	70			
		DAY 1	06MAR2003	1	74	110	84				78	120	82			
		BASELINE			74	110	84				78	120	82			
		DAY 8	13MAR2003	8	88	118	70	14	8	-14	96	122	78	18I	2	-4
		DAY 15	20MAR2003	15	84	122	82	10	12	-2	88	118	90	10	-2	8
		DAY 22	27MAR2003	22	72	120	82	-2	10	-2	78	108	84	0	-12	2
		DAY 29	04APR2003	30	88	118	78	14	8	-6	98	108	72	20I	-12	-10
		DAY 36	10APR2003	36	84	124	78	10	14	-6	80	118	84	2	-2	2
		DAY 43	18APR2003	44	78	118	82	4	8	-2	80	112	80	2	-8	-2
		DAY 50	24APR2003	50	78	112	78	4	2	-6	84	122	78	6	2	-4
		DAY 57	01MAY2003	57	84	108	76	10	-2	-8	116	106	74	38I	-14	-8
		FINAL		57	84	108	76	10	-2	-8	116	106	74	38I	-14	-8
	E0022046	SCREEN	13MAR2003	-7	88	132	74				97	138	72			
		DAY 1	20MAR2003	1	68	128	64				70	124	70			
		BASELINE			68	128	64				70	124	70			
		DAY 8	27MAR2003	8	68	146	84	0	18	20	70	140	74	0	16	4
		DAY 15	04APR2003	16	100	150	68	32I	22I	4	108	146	70	38I	22I	0
		DAY 22	11APR2003	23	96	146	80	28I	18	16	116	132	66	46I	8	-4
		DAY 29	18APR2003	30	88	144	74	20I	16	10	108	130	70	38I	6	0
		DAY 36	24APR2003	36	96	136	90	28I	8	26	96	128	78	26I	4	8
		DAY 43	02MAY2003	44	112	142	70	44I	14	6	120	138	74	50I	14	4
		DAY 50	12MAY2003	54	92	128	72	24I	0	8	110	124	68	40I	0	-2
		DAY 57	16MAY2003	58	104	130	72	36I	2	8	116	128	78	46I	4	8
		FINAL		58	104	130	72	36I	2	8	116	128	78	46I	4	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022048	SCREEN	25MAR2003	-7	54	104	64				72	98	62			
		DAY 1	01APR2003	1	64	98	58				72	98	64			
		BASELINE			64	98	58				72	98	64			
		DAY 8	08APR2003	8	80	104	60	16I	6	2	80	100	64	8	2	0
		DAY 15	15APR2003	15	74	118	62	10	20I	4	74	110	62	2	12	-2
		DAY 22	24APR2003	24	68	102	64	4	4	6	80	100	70	8	2	6
		DAY 29	02MAY2003	32	78	110	66	14	12	8	84	102	72	12	4	8
		DAY 36	06MAY2003	36	72	110	64	8	12	6	60	108	70	-12	10	6
		DAY 43	13MAY2003	43	64	104	64	0	6	6	72	110	68	0	12	4
		DAY 50	23MAY2003	53	78	104	70	14	6	12	80	102	72	8	4	8
		FINAL		53	78	104	70	14	6	12	80	102	72	8	4	8
	E0022051	SCREEN	31MAR2003	-7	68	110	66				96	114	68			
		DAY 1	07APR2003	1	72	124	66				76	110	72			
		BASELINE			72	124	66				76	110	72			
		DAY 8	14APR2003	8	60	112	74	-12	-12	8	64	102	72	-12	-8	0
		DAY 15	21APR2003	15	68	108	74	-4	-16	8	88	114	68	12	4	-4
		DAY 22	28APR2003	22	84	118	64	12	-6	-2	96	110	72	20I	0	0
		DAY 29	05MAY2003	29	100	130	80	28I	6	14	88	116	82	12	6	10
		DAY 36	12MAY2003	36	80	138	74	8	14	8	80	112	68	4	2	-4
		DAY 43	19MAY2003	43	76	120	80	4	-4	14	72	112	68	-4	2	-4
		DAY 50	28MAY2003	52	84	120	74	12	-4	8	88	110	78	12	0	6
		DAY 57	02JUN2003	57	88	120	72	16I	-4	6	88	116	76	12	6	4
		FINAL		57	88	120	72	16I	-4	6	88	116	76	12	6	4
	E0022061	SCREEN	24APR2003	-6	72	118	74				68	118	80			
		DAY 1	30APR2003	1	76	120	68				84	114	62			
		BASELINE			76	120	68				84	114	62			
		DAY 8	07MAY2003	8	84	122	56	8	2	-12	68	118	70	-16D	4	8
		DAY 15	14MAY2003	15	80	114	54	4	-6	-14	104	110	54	20I	-4	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 22		22MAY2003	23	88	112	62	12	-8	-6	76	102	70	-8	-12	8
		DAY 29		28MAY2003	29	80	114	54	4	-6	-14	96	114	60	12	0	-2
		DAY 36		04JUN2003	36	80	122	60	4	2	-8	76	110	70	-8	-4	8
		DAY 50		18JUN2003	50	88	118	60	12	-2	-8	96	110	66	12	-4	4
		DAY 57		26JUN2003	58	84	114	64	8	-6	-4	108	104	68	24I	-10	6
		FINAL			58	84	114	64	8	-6	-4	108	104	68	24I	-10	6
	E0022062	SCREEN		25APR2003	-10	78	156	86				96	144	88			
		DAY 1		05MAY2003	1	80	152	88				78	156	94			
		BASELINE				80	152	88				78	156	94			
		DAY 8		12MAY2003	8	100	164	78	20I	12	-10	100	138	90	22I	-18	-4
		DAY 15		19MAY2003	15	84	162	102	4	10	14	92	148	98	14	-8	4
		DAY 15	*	23MAY2003	19	88	162	110H	8	10	22	84	162	108H	6	6	14
		FINAL			19	88	162	110H	8	10	22	84	162	108H	6	6	14
	E0022068	SCREEN		14MAY2003	-9	72	112	70				68	114	78			
		DAY 1		22MAY2003	-1	60	96	56				68	92	60			
		BASELINE				60	96	56				68	92	60			
		DAY 8		29MAY2003	7	80	98	62	20I	2	6	76	98	64	8	6	4
		DAY 15		05JUN2003	14	84	110	70	24I	14	14	80	102	68	12	10	8
		FINAL			14	84	110	70	24I	14	14	80	102	68	12	10	8
	E0022069	SCREEN		03JUN2003	-7	57	96	68				72	106	74			
		DAY 1		10JUN2003	1	66	108	70				72	118	74			
		BASELINE				66	108	70				72	118	74			
		DAY 8		17JUN2003	8	76	124	66	10	16	-4	88	126	82	16I	8	8
		DAY 15		24JUN2003	15	72	112	74	6	4	4	84	122	82	12	4	8
		DAY 22		01JUL2003	22	68	122	62	2	14	-8	68	116	82	-4	-2	8
		DAY 29		08JUL2003	29	60	118	80	-6	10	10	64	112	78	-8	-6	4
		DAY 36		15JUL2003	36	69	112	64	3	4	-6	75	122	80	3	4	6

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
L: Potentially Clinically Important low. H: Potentially Clinically Important high.

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	DAY 43	22JUL2003	43	56	104	68	-10	-4	-2	72	106	80	0	-12	6
		DAY 50	29JUL2003	50	66	110	66	0	2	-4	66	116	64	-6	-2	-10
		DAY 57	05AUG2003	57	72	114	72	6	6	2	80	106	68	8	-12	-6
		FINAL		57	72	114	72	6	6	2	80	106	68	8	-12	-6
	E0022071	SCREEN	16JUN2003	-14	72	138	88				86	146	94			
		DAY 1	30JUN2003	1	60	132	78				78	136	92			
		BASELINE			60	132	78				78	136	92			
		DAY 8	07JUL2003	8	90	124	78	30I	-8	0	88	136	82	10	0	-10
		DAY 15	14JUL2003	15	78	128	76	18I	-4	-2	80	130	72	2	-6	-20D
		DAY 22	21JUL2003	22	72	124	78	12	-8	0	90	124	88	12	-12	-4
		DAY 29	28JUL2003	29	82	138	88	22I	6	10	102	126	94	24I	-10	2
		DAY 36	04AUG2003	36	84	140	86	24I	8	8	104	132	96	26I	-4	4
		DAY 43	11AUG2003	43	84	136	86	24I	4	8	102	142	90	24I	6	-2
		DAY 50	18AUG2003	50	74	132	84	14	0	6	84	124	92	6	-12	0
		DAY 57	25AUG2003	57	82	138	92	22I	6	14	88	128	90	10	-8	-2
		FINAL		57	82	138	92	22I	6	14	88	128	90	10	-8	-2
	E0023003	SCREEN	12DEC2002	-5	79	148	86				74	129	80			
		DAY 1	17DEC2002	1	72	104	80				76	110	84			
		BASELINE			72	104	80				76	110	84			
		DAY 8	23DEC2002	7	68	134	89	-4	30I	9	72	125	84	-4	15	0
		DAY 15	30DEC2002	14	88	118	64	16I	14	-16	80	124	70	4	14	-14
		DAY 22	07JAN2003	22	86	104	78	14	0	-2	80	100	78	4	-10	-6
		DAY 29	16JAN2003	31	86	117	70	14	13	-10	88	114	68	12	4	-16
		DAY 36	21JAN2003	36	88	124	84	16I	20I	4	88	120	80	12	10	-4
		DAY 43	28JAN2003	43	90	98	65	18I	-6	-15	92	100	67	16I	-10	-17
		DAY 50	06FEB2003	52	68	108	68	-4	4	-12	72	110	70	-4	0	-14
		DAY 57	11FEB2003	57	82	127	88	10	23I	8	110	107	74	34I	-3	-10
		FINAL		57	82	127	88	10	23I	8	110	107	74	34I	-3	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	SCREEN	10DEC2002	-7	65	116	74				66	120	70			
		DAY 1	17DEC2002	1	60	114	70				70	120	70			
		BASELINE			60	114	70				70	120	70			
		DAY 8	23DEC2002	7	86	143	78	26I	29I	8	89	130	75	19I	10	5
		DAY 15	02JAN2003	17	75	120	80	15I	6	10	75	114	76	5	-6	6
		DAY 22	07JAN2003	22	80	98	60	20I	-16	-10	88	110	70	18I	-10	0
		DAY 29	16JAN2003	31	72	143	82	12	29I	12	76	130	76	6	10	6
		DAY 36	21JAN2003	36	72	104	70	12	-10	0	80	104	70	10	-16	0
		DAY 43	28JAN2003	43	72	102	70	12	-12	0	74	110	80	4	-10	10
		DAY 50	04FEB2003	50	66	120	57	6	6	-13	78	121	71	8	1	1
		DAY 57	11FEB2003	57	63	119	58	3	5	-12	78	133	67	8	13	-3
		FINAL		57	63	119	58	3	5	-12	78	133	67	8	13	-3
	E0023010	SCREEN	28JAN2003	-7	72	118	72				70	118	72			
		DAY 1	04FEB2003	1	78	127	79				76	130	89			
		BASELINE			78	127	79				76	130	89			
		DAY 8	11FEB2003	8	78	121	71	0	-6	-8	76	110	58	0	-20D	-31D
		DAY 15	18FEB2003	15	76	112	84	-2	-15	5	80	108	80	4	-22D	-9
		DAY 22	25FEB2003	22	89	111	73	11	-16	-6	96	130	85	20I	0	-4
		DAY 29	04MAR2003	29	85	142	98	7	15	19	95	148	99	19I	18	10
		DAY 36	11MAR2003	36	70	120	70	-8	-7	-9	76	130	78	0	0	-11
		DAY 43	18MAR2003	43	75	137	96	-3	10	17	87	133	93	11	3	4
		DAY 50	25MAR2003	50	88	126	80	10	-1	1	91	135	88	15I	5	-1
		DAY 57	31MAR2003	56	84	134	80	6	7	1	85	130	76	9	0	-13
		FINAL		56	84	134	80	6	7	1	85	130	76	9	0	-13
	E0023025	SCREEN	01MAY2003	-14	100	126	65				96	120	57			
		DAY 1	15MAY2003	1	72	115	60				76	114	64			
		BASELINE			72	115	60				76	114	64			
		DAY 8	22MAY2003	8	80	126	73	8	11	13	88	120	70	12	6	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0023025	DAY 15	29MAY2003	15	85	132	79	13	17	19	105	146	93	29I	32I	29
		DAY 22	05JUN2003	22	92	117	58	20I	2	-2	119	140	92	43I	26I	28
		DAY 29	12JUN2003	29	92	120	60	20I	5	0	90	124	70	14	10	6
		DAY 36	19JUN2003	36	97	119	79	25I	4	19	90	118	76	14	4	12
		DAY 43	27JUN2003	44	96	116	72	24I	1	12	96	110	72	20I	-4	8
		DAY 50	03JUL2003	50	80	110	82	8	-5	22	84	120	80	8	6	16
		DAY 57	10JUL2003	57	72	103	68	0	-12	8	76	100	65	0	-14	1
		FINAL		57	72	103	68	0	-12	8	76	100	65	0	-14	1
	E0023039	SCREEN	24JUN2003	-7	88	121	80				94	136	87			
		DAY 1	01JUL2003	1	60	120	79				81	108	73			
		BASELINE			60	120	79				81	108	73			
		DAY 8	08JUL2003	8	85	126	74	25I	6	-5	102	102	71	21I	-6	-2
		DAY 15	15JUL2003	15	72	110	73	12	-10	-6	80	108	73	-1	0	0
		DAY 22	22JUL2003	22	86	100	72	26I	-20D	-7	96	103	67	15I	-5	-6
		DAY 29	29JUL2003	29	86	115	79	26I	-5	0	100	112	79	19I	4	6
		DAY 36	05AUG2003	36	93	109	76	33I	-11	-3	131H	111	74	50I	3	1
		DAY 43	12AUG2003	43	77	101	70	17I	-19	-9	109	109	71	28I	1	-2
		DAY 50	19AUG2003	50	104	90L	65	44I	-30D	-14	139H	120	82	58I	12	9
		DAY 57	26AUG2003	57	89	115	82	29I	-5	3	117	114	75	36I	6	2
		FINAL		57	89	115	82	29I	-5	3	117	114	75	36I	6	2
	E0026002	SCREEN	05NOV2002	-7	77	116	73				70	129	84			
		DAY 1	12NOV2002	1	70	105	70				82	111	84			
		BASELINE			70	105	70				82	111	84			
		DAY 8	19NOV2002	8	86	131	81	16I	26I	11	93	132	80	11	21I	-4
		DAY 15	26NOV2002	15	75	99	83	5	-6	13	79	101	76	-3	-10	-8
		DAY 22	03DEC2002	22	85	143	87	15I	38I	17	89	123	77	7	12	-7
		DAY 29	11DEC2002	30	75	146	93	5	41I	23	78	129	85	-4	18	1
		DAY 36	18DEC2002	37	75	132	85	5	27I	15	75	121	76	-7	10	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 43	26DEC2002	45	74	154	89	4	49I	19	75	111	81	-7	0	-3
		DAY 50	02JAN2003	52	75	135	86	5	30I	16	74	100	67	-8	-11	-17
		DAY 57	09JAN2003	59	70	126	75	0	21I	5	70	113	77	-12	2	-7
		FINAL		59	70	126	75	0	21I	5	70	113	77	-12	2	-7
	E0026007	SCREEN	06JAN2003	-10	70	131	69				72	129	66			
		DAY 1	16JAN2003	1	72	140	76				80	130	72			
		BASELINE			72	140	76				80	130	72			
		DAY 8	23JAN2003	8	82	114	66	10	-26D	-10	90	112	60	10	-18	-12
		DAY 15	30JAN2003	15	77	127	79	5	-13	3	92	104	64	12	-26D	-8
		DAY 22	06FEB2003	22	90	154	83	18I	14	7	96	115	68	16I	-15	-4
		DAY 29	13FEB2003	29	80	132	73	8	-8	-3	86	126	94	6	-4	22
		DAY 36	19FEB2003	35	77	113	67	5	-27D	-9	83	108	67	3	-22D	-5
		DAY 43	26FEB2003	42	90	117	74	18I	-23D	-2	96	115	68	16I	-15	-4
		DAY 50	05MAR2003	49	81	135	63	9	-5	-13	97	143	76	17I	13	4
		DAY 57	12MAR2003	56	92	116	70	20I	-24D	-6	91	123	67	11	-7	-5
		FINAL		56	92	116	70	20I	-24D	-6	91	123	67	11	-7	-5
	E0026013	SCREEN	05FEB2003	-8	80	139	73				80	134	74			
		DAY 1	13FEB2003	1	70	140	70				68	142	72			
		BASELINE			70	140	70				68	142	72			
		DAY 8	20FEB2003	8	88	129	71	18I	-11	1	91	132	80	23I	-10	8
		DAY 15	27FEB2003	15	94	136	75	24I	-4	5	104	132	79	36I	-10	7
		DAY 22	06MAR2003	22	87	149	79	17I	9	9	89	134	78	21I	-8	6
		DAY 29	13MAR2003	29	89	116	74	19I	-24D	4	85	135	73	17I	-7	1
		DAY 36	20MAR2003	36	88	116	72	18I	-24D	2	86	122	78	18I	-20D	6
		DAY 43	27MAR2003	43	98	126	80	28I	-14	10	98	132	71	30I	-10	-1
		DAY 50	03APR2003	50	80	130	70	10	-10	0	82	136	72	14	-6	0
		DAY 57	14APR2003	61	83	104	67	13	-36D	-3	86	132	74	18I	-10	2
		FINAL		61	83	104	67	13	-36D	-3	86	132	74	18I	-10	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	SCREEN	01OCT2002	-3	60	100	70				68	100	70			
		DAY 1	04OCT2002	1	60	110	70				62	108	70			
		BASELINE			60	110	70				62	108	70			
		DAY 8	11OCT2002	8	64	110	60	4	0	-10	68	110	60	6	2	-10
		DAY 15	16OCT2002	13	52	90L	50L	-8	-20D	-20D	58	98	58	-4	-10	-12
		DAY 22	23OCT2002	20	70	98	60	10	-12	-10	70	102	60	8	-6	-10
		DAY 29	31OCT2002	28	80	90L	54	20I	-20D	-16	88	94	58	26I	-14	-12
		DAY 36	07NOV2002	35	56	128	78	-4	18	8	58	114	68	-4	6	-2
		DAY 43	14NOV2002	42	56	104	58	-4	-6	-12	60	104	56	-2	-4	-14
		FINAL		42	56	104	58	-4	-6	-12	60	104	56	-2	-4	-14
	E0028023	SCREEN	14JAN2003	-7	72	114	78				74	106	90			
		DAY 1	21JAN2003	1	64	150	92				68	144	102			
		BASELINE			64	150	92				68	144	102			
		DAY 8	30JAN2003	10	52	188H	128H	-12	38I	36I	56	188H	112H	-12	44I	10
		DAY 15	04FEB2003	15	70	122	92	6	-28D	0	78	140	94	10	-4	-8
		DAY 22	11FEB2003	22	76	118	84	12	-32D	-8	80	102	80	12	-42D	-22D
		DAY 29	17FEB2003	28	74	90L	70	10	-60D	-22D	78	84L	70	10	-60D	-32D
		DAY 36	27FEB2003	38	68	112	70	4	-38D	-22D	70	104	62	2	-40D	-40D
		DAY 43	04MAR2003	43	72	100	60	8	-50D	-32D	76	72L	62	8	-72D	-40D
		DAY 57	27JUN2003	158												
		FINAL		158	72	100	60	8	-50D	-32D	76	72L	62	8	-72D	-40D
	E0028025	SCREEN	08JAN2003	-5	62	114	76				74	108	70			
		DAY 1	13JAN2003	1	60	106	78				72	94	72			
		BASELINE			60	106	78				72	94	72			
		DAY 8	17JAN2003	5	76	114	70	16I	8	-8	80	110	70	8	16	-2
		DAY 15	27JAN2003	15	56	120	86	-4	14	8	76	124	90	4	30I	18
		FINAL		15	56	120	86	-4	14	8	76	124	90	4	30I	18

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	SCREEN	18MAR2003	-9	66	108	72				76	102	68			
		DAY 1	27MAR2003	1	76	106	62				84	102	60			
		BASELINE			76	106	62				84	102	60			
		DAY 8	03APR2003	8	78	112	72	2	6	10	104	108	78	20I	6	18
		DAY 15	10APR2003	15	98	118	68	22I	12	6	146H	98	68	62I	-4	8
		DAY 22	17APR2003	22	80	114	78	4	8	16	100	110	72	16I	8	12
		DAY 29	24APR2003	29	88	96	62	12	-10	0	108	100	66	24I	-2	6
		DAY 36	01MAY2003	36	60	94	68	-16D	-12	6	88	90L	74	4	-12	14
		DAY 43	08MAY2003	43	84	120	70	8	14	8	100	116	68	16I	14	8
		DAY 50	15MAY2003	50	84	108	68	8	2	6	108	104	62	24I	2	2
		DAY 57	22MAY2003	57	76	112	72	0	6	10	100	108	74	16I	6	14
		FINAL		57	76	112	72	0	6	10	100	108	74	16I	6	14
	E0028035	SCREEN	27MAR2003	-7	60	118	82				68	110	80			
		DAY 1	03APR2003	1	60	136	82				64	126	76			
		BASELINE			60	136	82				64	126	76			
		DAY 8	10APR2003	8	60	124	76	0	-12	-6	64	110	70	0	-16	-6
		DAY 15	17APR2003	15	68	134	88	8	-2	6	84	120	82	20I	-6	6
		DAY 22	24APR2003	22	72	130	82	12	-6	0	76	122	72	12	-4	-4
		DAY 29	01MAY2003	29	80	134	86	20I	-2	4	72	136	84	8	10	8
		DAY 36	08MAY2003	36	68	138	94	8	2	12	76	120	90	12	-6	14
		DAY 50	22MAY2003	50	72	134	78	12	-2	-4	80	124	84	16I	-2	8
		DAY 57	29MAY2003	57	76	144	86	16I	8	4	80	136	82	16I	10	6
		FINAL		57	76	144	86	16I	8	4	80	136	82	16I	10	6
	E0028037	SCREEN	04JUN2003	-9	68	130	70				72	130	82			
		DAY 1	12JUN2003	-1	68	140	80				66	140	82			
		BASELINE			68	140	80				66	140	82			
		DAY 8	20JUN2003	8	76	122	84	8	-18	4	80	122	86	14	-18	4
		DAY 15	25JUN2003	13	74	132	86	6	-8	6	86	110	80	20I	-30D	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	DAY 15	*	01JUL2003	19	80	130	82	12	-10	2	78	115	70	12	-25D	-12
		DAY 22		08JUL2003	26	74	136	86	6	-4	6	80	132	86	14	-8	4
		DAY 36		16JUL2003	34	80	130	78	12	-10	-2	80	116	72	14	-24D	-10
		DAY 43		23JUL2003	41	78	118	80	10	-22D	0	80	116	82	14	-24D	0
		DAY 50		30JUL2003	48	84	118	86	16I	-22D	6	84	122	86	18I	-18	4
		DAY 57		08AUG2003	57	80	120	80	12	-20D	0	78	120	70	12	-20D	-12
		FINAL			57	80	120	80	12	-20D	0	78	120	70	12	-20D	-12
	E0028039	SCREEN		02MAY2003	-7	72	120	82				92	118	76			
		DAY 1		08MAY2003	-1	72	110	70				92	104	66			
		BASELINE				72	110	70				92	104	66			
		DAY 8		16MAY2003	8	88	118	72	16I	8	2	100	120	74	8	16	8
		DAY 15		22MAY2003	14	84	108	72	12	-2	2	100	104	70	8	0	4
		DAY 22		29MAY2003	21	92	110	76	20I	0	6	106	104	76	14	0	10
		DAY 29		05JUN2003	28	88	110	70	16I	0	0	96	112	70	4	8	4
		FINAL			28	88	110	70	16I	0	0	96	112	70	4	8	4
	E0029011	SCREEN		14JAN2003	-8	68	104	68				76	110	70			
		DAY 1		21JAN2003	-1	80	120	70				76	126	76			
		BASELINE				80	120	70				76	126	76			
		DAY 8		28JAN2003	7	72	132	74	-8	12	4	92	130	70	16I	4	-6
		DAY 15		04FEB2003	14	84	140	70	4	20I	0	112	140	82	36I	14	6
		DAY 22		13FEB2003	23	72	138	90	-8	18	20	100	120	90	24I	-6	14
		FINAL			23	72	138	90	-8	18	20	100	120	90	24I	-6	14
	E0029012	SCREEN		04FEB2003	-7	56	110	70				56	104	68			
		DAY 1		11FEB2003	1	78	132	82				78	130	80			
		BASELINE				78	132	82				78	130	80			
		DAY 8		19FEB2003	9	64	128	80	-14	-4	-2	72	122	70	-6	-8	-10
		DAY 15		26FEB2003	16	72	126	72	-6	-6	-10	78	122	70	0	-8	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	DAY 22	03MAR2003	21	84	126	90	6	-6	8	88	124	80	10	-6	0
		DAY 29	11MAR2003	29	80	112	68	2	-20D	-14	80	118	74	2	-12	-6
		DAY 36	18MAR2003	36	80	126	64	2	-6	-18	88	122	72	10	-8	-8
		FINAL		36	80	126	64	2	-6	-18	88	122	72	10	-8	-8
	E0029015	SCREEN	11FEB2003	-13	80	116	68				88	112	64			
		DAY 1	24FEB2003	1	100	140	80				96	132	80			
		BASELINE			100	140	80				96	132	80			
		DAY 8	03MAR2003	8	84	114	78	-16D	-26D	-2	88	122	84	-8	-10	4
		DAY 15	11MAR2003	16	60	108	60	-40D	-32D	-20D	76	104	58	-20D	-28D	-22D
		FINAL		16	60	108	60	-40D	-32D	-20D	76	104	58	-20D	-28D	-22D
	E0030014	SCREEN	12FEB2003	-9	60	88L	60				80	88L	60			
		DAY 1	21FEB2003	1	60	102	68				64	98	64			
		BASELINE			60	102	68				64	98	64			
		DAY 8	28FEB2003	8	60	106	68	0	4	0	68	100	66	4	2	2
		DAY 15	07MAR2003	15	60	104	72	0	2	4	72	100	68	8	2	4
		DAY 22	14MAR2003	22	68	108	70	8	6	2	80	108	70	16I	10	6
		DAY 29	21MAR2003	29	72	108	70	12	6	2	80	104	78	16I	6	14
		DAY 36	27MAR2003	35	60	100	64	0	-2	-4	88	104	74	24I	6	10
		DAY 43	04APR2003	43	60	100	62	0	-2	-6	72	100	64	8	2	0
		DAY 50	11APR2003	50	60	102	70	0	0	2	72	106	70	8	8	6
		DAY 57	22APR2003	61	60	100	74	0	-2	6	84	104	70	20I	6	6
		FINAL		61	60	100	74	0	-2	6	84	104	70	20I	6	6
	E0030020	SCREEN	13MAY2003	-16	68	134	62				80	128	78			
		DAY 1	29MAY2003	1	60	120	66				80	126	74			
		BASELINE			60	120	66				80	126	74			
		DAY 8	05JUN2003	8	72	130	70	12	10	4	88	130	76	8	4	2
		DAY 15	12JUN2003	15	80	120	76	20I	0	10	88	120	80	8	-6	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	DAY 22	17JUN2003	20	60	128	90	0	8	24	80	124	90	0	-2	16
		DAY 29	24JUN2003	27	68	130	60	8	10	-6	88	126	66	8	0	-8
		FINAL		27	68	130	60	8	10	-6	88	126	66	8	0	-8
	E0030025	SCREEN	24JUN2003	-17	60	130	70				60	130	70			
		DAY 1	11JUL2003	1	48L	118	74				64	120	80			
		BASELINE			48L	118	74				64	120	80			
		DAY 8	18JUL2003	8	60	118	80	12	0	6	64	120	84	0	0	4
		DAY 15	25JUL2003	15	56	112	84	8	-6	10	64	118	84	0	-2	4
		DAY 22	31JUL2003	21	60	114	78	12	-4	4	64	110	80	0	-10	0
		DAY 29	11AUG2003	32	68	118	86	20I	0	12	72	112	88	8	-8	8
		DAY 36	19AUG2003	40	68	112	80	20I	-6	6	72	114	84	8	-6	4
		FINAL		40	68	112	80	20I	-6	6	72	114	84	8	-6	4
	E0031027	SCREEN	27MAY2003	-7	60	118	60				68	124	66			
		DAY 1	03JUN2003	1	60	105	70				68	108	80			
		BASELINE			60	105	70				68	108	80			
		DAY 8	11JUN2003	9	74	118	70	14	13	0	76	118	72	8	10	-8
		DAY 15	17JUN2003	15	64	108	70	4	3	0	70	114	72	2	6	-8
		DAY 22	24JUN2003	22	76	128	62	16I	23I	-8	80	130	64	12	22I	-16
		DAY 29	01JUL2003	29	70	120	62	10	15	-8	66	128	70	-2	20I	-10
		DAY 36	09JUL2003	37	64	118	64	4	13	-6	74	124	70	6	16	-10
		DAY 43	15JUL2003	43	58	114	60	-2	9	-10	64	116	68	-4	8	-12
		DAY 50	22JUL2003	50	70	108	62	10	3	-8	76	120	70	8	12	-10
		DAY 57	29JUL2003	57	62	106	74	2	1	4	70	110	70	2	2	-10
		FINAL		57	62	106	74	2	1	4	70	110	70	2	2	-10
	E0031030	SCREEN	17JUN2003	-7	62	108	76				74	110	82			
		DAY 1	24JUN2003	1	68	112	80				76	116	84			
		BASELINE			68	112	80				76	116	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	DAY 8	01JUL2003	8	68	126	78	0	14	-2	76	120	84	0	4	0
		DAY 15	08JUL2003	15	88	126	74	20I	14	-6	86	130	76	10	14	-8
		DAY 22	16JUL2003	23	60	112	82	-8	0	2	70	120	84	-6	4	0
		DAY 29	23JUL2003	30	68	119	76	0	7	-4	76	120	80	0	4	-4
		DAY 36	31JUL2003	38	66	112	80	-2	0	0	74	124	86	-2	8	2
		DAY 43	08AUG2003	46	64	114	76	-4	2	-4	74	118	82	-2	2	-2
		DAY 50	14AUG2003	52	60	111	72	-8	-1	-8	64	114	76	-12	-2	-8
		DAY 57	21AUG2003	59	64	114	72	-4	2	-8	70	120	74	-6	4	-10
		FINAL		59	64	114	72	-4	2	-8	70	120	74	-6	4	-10
	E0034001	SCREEN	17MAR2003	-3	62	110	72				64	104	70			
		DAY 1	20MAR2003	1	56	100	55				72	95	68			
		BASELINE			56	100	55				72	95	68			
		DAY 8	27MAR2003	8	64	110	65	8	10	10	76	126	80	4	31I	12
		DAY 15	03APR2003	15	64	118	78	8	18	23	72	112	80	0	17	12
		DAY 22	10APR2003	22	60	110	70	4	10	15	72	105	80	0	10	12
		DAY 29	17APR2003	29	56	105	70	0	5	15	68	100	80	-4	5	12
		DAY 36	24APR2003	36	60	110	70	4	10	15	72	105	80	0	10	12
		DAY 43	01MAY2003	43	60	110	70	4	10	15	76	100	80	4	5	12
		DAY 50	08MAY2003	50	56	114	74	0	14	19	64	112	78	-8	17	10
		DAY 57	15MAY2003	57	64	120	75	8	20I	20	72	110	80	0	15	12
		FINAL		57	64	120	75	8	20I	20	72	110	80	0	15	12
	E0034004	SCREEN	11APR2003	-10	64	118	86				62	110	78			
		DAY 1	21APR2003	1	76	145	95				80	130	100			
		BASELINE			76	145	95				80	130	100			
		DAY 8	30APR2003	10	76	135	90	0	-10	-5	88	110	80	8	-20D	-20D
		DAY 15	05MAY2003	15	76	122	82	0	-23D	-13	88	126	80	8	-4	-20D
		DAY 22	13MAY2003	23	92	128	88	16I	-17	-7	96	124	82	16I	-6	-18
		DAY 29	19MAY2003	29	96	128	86	20I	-17	-9	100	122	78	20I	-8	-22D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	DAY 29	*	23MAY2003	33	92	135	75	16I	-10	-20D	108	130	80	28I	0	-20D
		DAY 43		02JUN2003	43	92	122	84	16I	-23D	-11	92	126	86	12	-4	-14
		DAY 50		09JUN2003	50	88	135	90	12	-10	-5	100	120	80	20I	-10	-20D
		DAY 57		16JUN2003	57	80	110	70	4	-35D	-25D	66	105	75	-14	-25D	-25D
		FINAL			57	80	110	70	4	-35D	-25D	66	105	75	-14	-25D	-25D
	E0036002	SCREEN		10JUN2003	-7	64	102	64				69	111	69			
		DAY 1		17JUN2003	1	71	100	66				92	127	74			
		BASELINE				71	100	66				92	127	74			
		DAY 8		24JUN2003	8	68	114	75	-3	14	9	93	104	77	1	-23D	3
		DAY 15		30JUN2003	14	92	115	76	21I	15	10	108	115	74	16I	-12	0
		DAY 22		08JUL2003	22	90	108	69	19I	8	3	105	113	75	13	-14	1
		DAY 29		14JUL2003	28	96	121	74	25I	21I	8	105	110	70	13	-17	-4
		FINAL			28	96	121	74	25I	21I	8	105	110	70	13	-17	-4
	E0036006	SCREEN		24JUN2003	-9	89	127	79				103	128	91			
		DAY 1		03JUL2003	1	104	124	80				121H	133	88			
		BASELINE				104	124	80				121H	133	88			
		DAY 8		10JUL2003	8	91	128	80	-13	4	0	98	139	93	-23D	6	5
		DAY 15		18JUL2003	16	120	135	84	16I	11	4	104	136	88	-17D	3	0
		DAY 22		25JUL2003	23	112	135	92	8	11	12	125H	137	97	4	4	9
		DAY 29		31JUL2003	29	113	131	86	9	7	6	128H	131	87	7	-2	-1
		DAY 36		07AUG2003	36	98	131	84	-6	7	4	120	129	90	-1	-4	2
		DAY 43		13AUG2003	42	96	139	89	-8	15	9	107	132	94	-14	-1	6
		DAY 50		20AUG2003	49	111	138	83	7	14	3	128H	139	85	7	6	-3
		DAY 57		27AUG2003	56	96	129	86	-8	5	6	116	131	87	-5	-2	-1
		FINAL			56	96	129	86	-8	5	6	116	131	87	-5	-2	-1
	E0036007	SCREEN		26JUN2003	-7	88	122	86				89	126	89			
		DAY 1		03JUL2003	1	78	127	86				93	116	82			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	BASELINE			78	127	86				93	116	82			
		DAY 8	08JUL2003	6	109	130	86	31I	3	0	113	132	82	20I	16	0
		DAY 15	18JUL2003	16	79	123	82	1	-4	-4	90	123	88	-3	7	6
		FINAL		16	79	123	82	1	-4	-4	90	123	88	-3	7	6
	E0039011	SCREEN	16DEC2002	-17	80	142	94				84	144	96			
		DAY 1	02JAN2003	1	72	144	88				72	138	100			
		BASELINE			72	144	88				72	138	100			
		DAY 8	09JAN2003	8	64	146	96	-8	2	8	72	142	100	0	4	0
		DAY 15	16JAN2003	15	64	136	86	-8	-8	-2	67	140	100	-5	2	0
		DAY 22	23JAN2003	22	78	124	90	6	-20D	2	79	122	86	7	-16	-14
		DAY 29	03FEB2003	33	80	134	86	8	-10	-2	80	132	88	8	-6	-12
		DAY 36	06FEB2003	36	76	136	86	4	-8	-2	80	122	92	8	-16	-8
		DAY 43	13FEB2003	43	84	120	88	12	-24D	0	82	132	92	10	-6	-8
		DAY 50	19FEB2003	49	84	128	80	12	-16	-8	86	128	88	14	-10	-12
		FINAL		49	84	128	80	12	-16	-8	86	128	88	14	-10	-12
	E0039018	SCREEN	14JAN2003	-9	76	128	76				80	124	82			
		DAY 1	23JAN2003	1	64	124	76				72	126	84			
		BASELINE			64	124	76				72	126	84			
		DAY 8	30JAN2003	8	72	136	82	8	12	6	76	122	76	4	-4	-8
		DAY 15	06FEB2003	15	70	120	80	6	-4	4	72	130	90	0	4	6
		DAY 22	13FEB2003	22	78	114	76	14	-10	0	74	126	88	2	0	4
		DAY 29	20FEB2003	29	79	122	76	15I	-2	0	75	126	80	3	0	-4
		FINAL		29	79	122	76	15I	-2	0	75	126	80	3	0	-4
	E0039028	SCREEN	03MAR2003	-21	70	140	90				78	142	92			
		DAY 1	24MAR2003	1	76	134	98				80	150	100			
		BASELINE			76	134	98				80	150	100			
		DAY 8	31MAR2003	8	86	144	96	10	10	-2	100	148	100	20I	-2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039028	DAY 15	07APR2003	15	80	134	96	4	0	-2	96	148	98	16I	-2	-2
		DAY 22	14APR2003	22	84	138	100	8	4	2	92	150	104	12	0	4
		DAY 29	21APR2003	29	80	130	90	4	-4	-8	92	140	98	12	-10	-2
		DAY 36	28APR2003	36	80	130	88	4	-4	-10	72	148	102	-8	-2	2
		DAY 43	05MAY2003	43	80	142	100	4	8	2	80	138	102	0	-12	2
		DAY 50	16MAY2003	54	96	136	104	20I	2	6	92	144	118H	12	-6	18
		FINAL		54	96	136	104	20I	2	6	92	144	118H	12	-6	18
	E0039032	SCREEN	07MAR2003	-7	60	116	70				76	118	80			
		DAY 1	14MAR2003	1	85	136	70				88	130	80			
		BASELINE			85	136	70				88	130	80			
		DAY 8	19MAR2003	6	73	118	80	-12	-18	10	75	110	90	-13	-20D	10
		DAY 15	28MAR2003	15	74	128	90	-11	-8	20	80	134	90	-8	4	10
		FINAL		15	74	128	90	-11	-8	20	80	134	90	-8	4	10
	E0039034	SCREEN	12MAR2003	-7	76	120	82				76	122	82			
		DAY 1	19MAR2003	1	76	118	76				88	104	70			
		BASELINE			76	118	76				88	104	70			
		DAY 8	26MAR2003	8	68	122	82	-8	4	6	70	118	78	-18D	14	8
		DAY 15	02APR2003	15	70	128	74	-6	10	-2	70	126	72	-18D	22I	2
		DAY 22	09APR2003	22	68	122	78	-8	4	2	72	118	80	-16D	14	10
		DAY 29	16APR2003	29	82	116	68	6	-2	-8	92	118	80	4	14	10
		DAY 36	24APR2003	37	70	106	70	-6	-12	-6	76	110	72	-12	6	2
		DAY 43	30APR2003	43	80	126	76	4	8	0	76	124	84	-12	20I	14
		DAY 50	09MAY2003	52	80	120	78	4	2	2	88	120	82	0	16	12
		DAY 57	14MAY2003	57	88	128	84	12	10	8	80	116	72	-8	12	2
		FINAL		57	88	128	84	12	10	8	80	116	72	-8	12	2
	E0039042	SCREEN	24APR2003	-13	60	132	80				64	138	86			
		DAY 1	07MAY2003	1	66	124	84				64	126	90			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	BASELINE			66	124	84				64	126	90			
		DAY 8	14MAY2003	8	76	136	88	10	12	4	84	130	90	20I	4	0
		DAY 15	21MAY2003	15	80	108	70	14	-16	-14	84	116	76	20I	-10	-14
		DAY 22	28MAY2003	22	68	120	84	2	-4	0	73	132	90	9	6	0
		DAY 29	05JUN2003	30	84	126	86	18I	2	2	84	132	80	20I	6	-10
		DAY 36	11JUN2003	36	82	130	90	16I	6	6	80	128	96	16I	2	6
		DAY 43	18JUN2003	43	88	120	80	22I	-4	-4	92	130	90	28I	4	0
		DAY 50	25JUN2003	50	84	124	78	18I	0	-6	88	120	90	24I	-6	0
		DAY 57	02JUL2003	57	75	112	60	9	-12	-24D	76	108	70	12	-18	-20D
		FINAL		57	75	112	60	9	-12	-24D	76	108	70	12	-18	-20D
	E0041004	SCREEN	22JAN2003	-8	64	118	88				80	114	86			
		DAY 1	30JAN2003	1	78	110	80				80	108	84			
		BASELINE			78	110	80				80	108	84			
		DAY 8	10FEB2003	12	76	138	92	-2	28I	12	88	120	90	8	12	6
		DAY 15	14FEB2003	16	80	110	78	2	0	-2	88	108	78	8	0	-6
		DAY 22	20FEB2003	22	100	136	90	22I	26I	10	100	130	90	20I	22I	6
		DAY 29	27FEB2003	29	92	100	78	14	-10	-2	92	110	70	12	2	-14
		DAY 36	07MAR2003	37	80	108	68	2	-2	-12	80	100	60	0	-8	-24D
		DAY 43	14MAR2003	44	72	120	82	-6	10	2	78	130	88	-2	22I	4
		DAY 50	21MAR2003	51	78	100	68	0	-10	-12	76	110	80	-4	2	-4
		DAY 57	31MAR2003	61	76	110	68	-2	0	-12	84	110	70	4	2	-14
		FINAL		61	76	110	68	-2	0	-12	84	110	70	4	2	-14
	E0041009	SCREEN	22APR2003	-9	62	110	58				74	112	80			
		DAY 1	01MAY2003	1	66	112	70				70	112	76			
		BASELINE			66	112	70				70	112	76			
		DAY 8	08MAY2003	8	78	120	80	12	8	10	80	122	78	10	10	2
		DAY 15	15MAY2003	15	84	122	84	18I	10	14	80	124	80	10	12	4
		DAY 22	22MAY2003	22	74	122	82	8	10	12	76	120	80	6	8	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	DAY 36	03JUN2003	34	72	124	82	6	12	12	74	122	80	4	10	4
		DAY 43	16JUN2003	47	80	110	80	14	-2	10	90	122	74	20I	10	-2
		FINAL		47	80	110	80	14	-2	10	90	122	74	20I	10	-2
	E0042002	SCREEN	02JUL2003	-7	64	130	90				64	120	90			
		DAY 1	09JUL2003	1	76	110	80				72	120	80			
		BASELINE			76	110	80				72	120	80			
		DAY 8	15JUL2003	7	68	100	70	-8	-10	-10	64	102	70	-8	-18	-10
		DAY 15	22JUL2003	14	76	110	80	0	0	0	80	100	80	8	-20D	0
		DAY 22	29JUL2003	21	80	110	80	4	0	0	84	100	78	12	-20D	-2
		DAY 29	05AUG2003	28	76	110	70	0	0	-10	76	110	80	4	-10	0
		DAY 36	12AUG2003	35	76	120	70	0	10	-10	84	110	80	12	-10	0
		DAY 43	19AUG2003	42	76	120	80	0	10	0	88	110	90	16I	-10	10
		DAY 50	26AUG2003	49	76	110	70	0	0	-10	76	102	70	4	-18	-10
		DAY 57	02SEP2003	56	72	100	70	-4	-10	-10	80	102	80	8	-18	0
		FINAL		56	72	100	70	-4	-10	-10	80	102	80	8	-18	0
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	SCREEN	23JUN2003	-18	60	130	80				60	130	80			
		DAY 1	11JUL2003	1	60	120	70				62	125	75			
		BASELINE			60	120	70				62	125	75			
		DAY 8	18JUL2003	8	62	104	78	2	-16	8	62	104	80	0	-21D	5
		FINAL		8	62	104	78	2	-16	8	62	104	80	0	-21D	5
	E0003002	SCREEN	22OCT2002	-7	60	130	90				68	142	80			
		DAY 1	29OCT2002	1	88	120	90				88	120	90			
		BASELINE			88	120	90				88	120	90			
		DAY 15	14NOV2002	17	84	130	80	-4	10	-10	88	140	90	0	20I	0
		DAY 22	19NOV2002	22	96	130	90	8	10	0	94	130	88	6	10	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 29	26NOV2002	29	80	140	84	-8	20I	-6	84	130	82	-4	10	-8
		DAY 36	03DEC2002	36	84	120	80	-4	0	-10	88	124	84	0	4	-6
		DAY 43	10DEC2002	43	84	130	80	-4	10	-10	96	122	90	8	2	0
		DAY 50	17DEC2002	50	76	114	84	-12	-6	-6	88	94	64	0	-26D	-26D
		DAY 57	23DEC2002	56	74	118	70	-14	-2	-20D	70	120	78	-18D	0	-12
		FINAL		56	74	118	70	-14	-2	-20D	70	120	78	-18D	0	-12
	E0005031	SCREEN	26MAR2003	-7	64	100	60				64	98	60			
		DAY 1	02APR2003	1	84	98	62				84	100	64			
		BASELINE			84	98	62				84	100	64			
		DAY 8	09APR2003	8	84	100	60	0	2	-2	84	98	60	0	-2	-4
		DAY 15	16APR2003	15	76	96	68	-8	-2	6	80	94	68	-4	-6	4
		DAY 22	24APR2003	23	76	110	70	-8	12	8	76	100	70	-8	0	6
		DAY 29	01MAY2003	30	66	110	66	-18D	12	4	68	115	68	-16D	15	4
		DAY 36	07MAY2003	36	68	100	60	-16D	2	-2	72	104	66	-12	4	2
		DAY 43	14MAY2003	43	80	98	60	-4	0	-2	80	110	68	-4	10	4
		FINAL		43	80	98	60	-4	0	-2	80	110	68	-4	10	4
	E0005038	SCREEN	05MAY2003	-9	84	116	76				80	114	76			
		DAY 1	14MAY2003	1	76	126	80				72	120	80			
		BASELINE			76	126	80				72	120	80			
		DAY 8	22MAY2003	9	80	110	70	4	-16	-10	88	118	80	16I	-2	0
		DAY 15	28MAY2003	15	88	106	70	12	-20D	-10	92	96	64	20I	-24D	-16
		DAY 22	05JUN2003	23	72	120	80	-4	-6	0	88	120	78	16I	0	-2
		FINAL		23	72	120	80	-4	-6	0	88	120	78	16I	0	-2
	E0009010	SCREEN	27FEB2003	-14	60	120	70				90	130	100			
		DAY 1	13MAR2003	1	74	120	78				78	120	82			
		BASELINE			74	120	78				78	120	82			
		DAY 8	20MAR2003	8	80	130	92	6	10	14	82	130	90	4	10	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0009010	DAY 15	26MAR2003	14	100	122	70	26I	2	-8	88	118	72	10	-2	-10
		DAY 22	02APR2003	21	88	120	74	14	0	-4	86	122	76	8	2	-6
		FINAL		21	88	120	74	14	0	-4	86	122	76	8	2	-6
	E0009011	SCREEN	28APR2003	-8	80	130	76				80	120	82			
		DAY 1	06MAY2003	1	74	110	60				76	116	64			
		BASELINE			74	110	60				76	116	64			
		DAY 8	12MAY2003	7	88	130	70	14	20I	10	90	126	70	14	10	6
		DAY 15	19MAY2003	14	86	110	70	12	0	10	90	110	74	14	-6	10
		DAY 22	27MAY2003	22	100	120	68	26I	10	8	98	118	70	22I	2	6
		DAY 29	03JUN2003	29	76	100	60	2	-10	0	76	100	60	0	-16	-4
		DAY 36	10JUN2003	36	86	100	60	12	-10	0	90	90L	60	14	-26D	-4
		DAY 43	17JUN2003	43	80	104	62	6	-6	2	78	102	64	2	-14	0
		DAY 50	24JUN2003	50	60	104	66	-14	-6	6	60	102	64	-16D	-14	0
		DAY 57	03JUL2003	59	60	90L	60	-14	-20D	0	62	98	64	-14	-18	0
		FINAL		59	60	90L	60	-14	-20D	0	62	98	64	-14	-18	0
	E0011016	SCREEN	14APR2003	-7	72	132	88				84	128	86			
		DAY 1	21APR2003	1	72	138	88				88	136	80			
		BASELINE			72	138	88				88	136	80			
		DAY 8	28APR2003	8	84	132	86	12	-6	-2	98	128	88	10	-8	8
		DAY 15	05MAY2003	15	92	138	88	20I	0	0	92	136	88	4	0	8
		DAY 22	12MAY2003	22	92	124	88	20I	-14	0	92	120	86	4	-16	6
		DAY 29	19MAY2003	29	92	130	88	20I	-8	0	98	128	86	10	-8	6
		DAY 36	27MAY2003	37	90	128	84	18I	-10	-4	94	130	88	6	-6	8
		DAY 43	02JUN2003	43	88	140	88	16I	2	0	92	134	88	4	-2	8
		DAY 50	09JUN2003	50	92	136	88	20I	-2	0	96	138	88	8	2	8
		DAY 57	16JUN2003	57	92	132	88	20I	-6	0	96	130	86	8	-6	6
		FINAL		57	92	132	88	20I	-6	0	96	130	86	8	-6	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	SCREEN	19NOV2002	-7	72	112	80				80	116	80			
		DAY 1	26NOV2002	1	80	118	70				84	122	74			
		BASELINE			80	118	70				84	122	74			
		DAY 8	03DEC2002	8	64	124	78	-16D	6	8	76	126	80	-8	4	6
		DAY 15	10DEC2002	15	72	128	76	-8	10	6	74	130	80	-10	8	6
		FINAL		15	72	128	76	-8	10	6	74	130	80	-10	8	6
	E0018013	SCREEN	17JAN2003	-7	64	122	72				68	122	74			
		DAY 1	24JAN2003	1	76	124	74				88	126	76			
		BASELINE			76	124	74				88	126	76			
		DAY 8	31JAN2003	8	64	130	70	-12	6	-4	72	134	72	-16D	8	-4
		FINAL		8	64	130	70	-12	6	-4	72	134	72	-16D	8	-4
	E0019008	SCREEN	06NOV2002	-15	56	100	70				84	110	72			
		DAY 1	21NOV2002	1	72	110	82				76	98	72			
		BASELINE			72	110	82				76	98	72			
		DAY 8	27NOV2002	7	92	110	85	20I	0	3	100	125	80	24I	27I	8
		DAY 15	05DEC2002	15	76	110	75	4	0	-7	84	112	80	8	14	8
		DAY 22	12DEC2002	22	84	112	80	12	2	-2	100	102	68	24I	4	-4
		DAY 29	19DEC2002	29	72	102	68	0	-8	-14	96	100	78	20I	2	6
		FINAL		29	72	102	68	0	-8	-14	96	100	78	20I	2	6
	E0019009	SCREEN	06NOV2002	-8	72	105	65				72	110	70			
		DAY 1	14NOV2002	1	80	110	68				72	110	62			
		BASELINE			80	110	68				72	110	62			
		DAY 8	21NOV2002	8	80	98	68	0	-12	0	78	98	60	6	-12	-2
		DAY 15	27NOV2002	14	80	110	76	0	0	8	82	112	82	10	2	20
		DAY 22	05DEC2002	22	72	108	70	-8	-2	2	78	108	70	6	-2	8
		DAY 29	10DEC2002	27	90	102	62	10	-8	-6	96	100	64	24I	-10	2
		FINAL		27	90	102	62	10	-8	-6	96	100	64	24I	-10	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	SCREEN	30DEC2002	-7	84	120	84				86	110	90			
		DAY 1	06JAN2003	1	92	124	80				88	120	80			
		BASELINE			92	124	80				88	120	80			
		DAY 8	13JAN2003	8	88	120	78	-4	-4	-2	96	118	80	8	-2	0
		DAY 15	20JAN2003	15	84	110	75	-8	-14	-5	80	110	78	-8	-10	-2
		DAY 22	27JAN2003	22	84	115	80	-8	-9	0	80	120	80	-8	0	0
		DAY 29	03FEB2003	29	88	120	78	-4	-4	-2	92	124	80	4	4	0
		DAY 36	10FEB2003	36	96	115	70	4	-9	-10	100	118	70	12	-2	-10
		DAY 43	17FEB2003	43	84	120	85	-8	-4	5	86	120	80	-2	0	0
		DAY 50	27FEB2003	53	96	120	82	4	-4	2	104	120	86	16I	0	6
		DAY 57	03MAR2003	57	96	118	80	4	-6	0	96	120	80	8	0	0
		FINAL		57	96	118	80	4	-6	0	96	120	80	8	0	0
	E0019020	SCREEN	16JAN2003	-7	80	108	72				88	106	68			
		DAY 1	23JAN2003	1	80	110	70				80	105	65			
		BASELINE			80	110	70				80	105	65			
		DAY 8	30JAN2003	8	88	120	78	8	10	8	92	122	82	12	17	17
		DAY 15	06FEB2003	15	68	122	80	-12	12	10	76	122	85	-4	17	20
		DAY 22	13FEB2003	22	76	120	75	-4	10	5	88	125	80	8	20I	15
		DAY 29	20FEB2003	29	76	108	70	-4	-2	0	88	115	80	8	10	15
		DAY 36	27FEB2003	36	84	110	70	4	0	0	92	115	70	12	10	5
		DAY 43	06MAR2003	43	80	100	76	0	-10	6	96	110	78	16I	5	13
		DAY 50	13MAR2003	50	92	108	60	12	-2	-10	96	100	72	16I	-5	7
		DAY 57	27MAR2003	64	86	112	68	6	2	-2	84	120	70	4	15	5
		FINAL		64	86	112	68	6	2	-2	84	120	70	4	15	5
	E0019035	SCREEN	11MAR2003	-7	80	126	86				88	122	80			
		DAY 1	18MAR2003	1	82	134	80				86	126	78			
		BASELINE			82	134	80				86	126	78			
		DAY 8	27MAR2003	10	78	140	74	-4	6	-6	80	130	74	-6	4	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0019035	DAY 15	03APR2003	17	84	130	70	2	-4	-10	104	130	75	18I	4	-3
		DAY 22	10APR2003	24	88	130	90	6	-4	10	92	130	80	6	4	2
		DAY 29	17APR2003	31	88	135	85	6	1	5	96	135	90	10	9	12
		FINAL		31	88	135	85	6	1	5	96	135	90	10	9	12
	E0019040	SCREEN	08MAY2003	-12	92	130	82				94	150	90			
		DAY 1	20MAY2003	1	96	130	90				100	140	90			
		BASELINE			96	130	90				100	140	90			
		DAY 8	29MAY2003	10	96	122	88	0	-8	-2	100	130	88	0	-10	-2
		DAY 15	05JUN2003	17	116	124	80	20I	-6	-10	116	130	88	16I	-10	-2
		DAY 22	12JUN2003	24	96	128	90	0	-2	0	112	118	82	12	-22D	-8
		DAY 29	18JUN2003	30	98	142	82	2	12	-8	104	124	88	4	-16	-2
		DAY 36	26JUN2003	38	100	122	82	4	-8	-8	104	124	90	4	-16	0
		DAY 43	03JUL2003	45	96	138	92	0	8	2	104	136	94	4	-4	4
		DAY 50	10JUL2003	52	100	132	88	4	2	-2	108	130	90	8	-10	0
		DAY 57	17JUL2003	59	92	122	80	-4	-8	-10	98	128	85	-2	-12	-5
		FINAL		59	92	122	80	-4	-8	-10	98	128	85	-2	-12	-5
	E0019042	SCREEN	28MAY2003	-7	72	118	70				80	130	80			
		DAY 1	04JUN2003	1	66	124	76				92	118	82			
		BASELINE			66	124	76				92	118	82			
		DAY 8	12JUN2003	9	76	122	62	10	-2	-14	96	120	62	4	2	-20D
		DAY 15	19JUN2003	16	66	118	62	0	-6	-14	80	122	74	-12	4	-8
		FINAL		16	66	118	62	0	-6	-14	80	122	74	-12	4	-8
	E0020024	SCREEN	12JUN2003	-11	76	118	64				80	110	68			
		DAY 1	23JUN2003	1	52	110	70				54	110	70			
		BASELINE			52	110	70				54	110	70			
		DAY 8	30JUN2003	8	90	110	72	38I	0	2	98	108	72	44I	-2	2
		DAY 15	07JUL2003	15	74	112	70	22I	2	0	88	104	78	34I	-6	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 22	15JUL2003	23	98	112	62	46I	2	-8	104	106	64	50I	-4	-6
		DAY 29	21JUL2003	29	92	110	80	40I	0	10	90	112	80	36I	2	10
		DAY 36	28JUL2003	36	102	118	66	50I	8	-4	98	100	70	44I	-10	0
		DAY 43	04AUG2003	43	108	112	68	56I	2	-2	116	116	68	62I	6	-2
		DAY 50	12AUG2003	51	86	106	70	34I	-4	0	86	120	78	32I	10	8
		DAY 57	20AUG2003	59	80	118	76	28I	8	6	88	120	74	34I	10	4
		FINAL		59	80	118	76	28I	8	6	88	120	74	34I	10	4
	E0022044	SCREEN	11MAR2003	-7	74	116	82				76	110	72			
		DAY 1	18MAR2003	1	80	102	70				84	104	76			
		BASELINE			80	102	70				84	104	76			
		DAY 8	25MAR2003	8	84	100	68	4	-2	-2	96	98	70	12	-6	-6
		DAY 15	01APR2003	15	92	110	80	12	8	10	100	112	90	16I	8	14
		DAY 22	08APR2003	22	88	108	64	8	6	-6	100	118	70	16I	14	-6
		DAY 29	15APR2003	29	88	112	74	8	10	4	96	116	84	12	12	8
		DAY 36	22APR2003	36	100	122	88	20I	20I	18	120	112	88	36I	8	12
		DAY 43	29APR2003	43	104	122	78	24I	20I	8	116	102	82	32I	-2	6
		DAY 50	06MAY2003	50	96	126	80	16I	24I	10	104	120	84	20I	16	8
		DAY 57	12MAY2003	56	88	130	92	8	28I	22	84	132	94	0	28I	18
		FINAL		56	88	130	92	8	28I	22	84	132	94	0	28I	18
	E0023007	SCREEN	07JAN2003	-7	68	110	76				80	112	78			
		DAY 1	14JAN2003	1	74	116	80				80	110	90			
		BASELINE			74	116	80				80	110	90			
		DAY 8	21JAN2003	8	80	110	82	6	-6	2	80	112	80	0	2	-10
		DAY 15	28JAN2003	15	97	136	88	23I	20I	8	88	128	86	8	18	-4
		DAY 22	07FEB2003	25	97	140	95	23I	24I	15	88	130	86	8	20I	-4
		DAY 29	11FEB2003	29	97	119	77	23I	3	-3	126H	136	93	46I	26I	3
		DAY 36	18FEB2003	36	80	132	92	6	16	12	82	124	78	2	14	-12
		DAY 43	25FEB2003	43	80	130	85	6	14	5	80	129	85	0	19	-5

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	DAY 50		04MAR2003	50	76	133	94	2	17	14	76	145	83	-4	35I	-7
		DAY 57		11MAR2003	57	52	100	70	-22D	-16	-10	60	104	76	-20D	-6	-14
		FINAL			57	52	100	70	-22D	-16	-10	60	104	76	-20D	-6	-14
	E0023011	SCREEN		28JAN2003	-7	68	110	67				72	108	70			
		DAY 1		04FEB2003	1	58	118	72				58	120	70			
		BASELINE				58	118	72				58	120	70			
		DAY 8		11FEB2003	8	88	112	78	30I	-6	6	88	108	80	30I	-12	10
		DAY 15		21FEB2003	18	80	104	78	22I	-14	6	80	108	82	22I	-12	12
		DAY 22		25FEB2003	22	77	127	80	19I	9	8	87	148	101	29I	28I	31I
		DAY 29		04MAR2003	29	70	126	78	12	8	6	80	140	80	22I	20I	10
		DAY 36		11MAR2003	36	64	124	74	6	6	2	84	128	70	26I	8	0
		DAY 43		18MAR2003	43	76	120	70	18I	2	-2	80	120	76	22I	0	6
		DAY 50		27MAR2003	52	78	141	94	20I	23I	22	78	136	90	20I	16	20
		DAY 57		01APR2003	57	89	114	76	31I	-4	4	90	121	79	32I	1	9
		FINAL			57	89	114	76	31I	-4	4	90	121	79	32I	1	9
	E0023014	SCREEN		14FEB2003	-7	109	138	93				96	136	92			
		DAY 1		21FEB2003	1	80	118	76				84	100	70			
		BASELINE				80	118	76				84	100	70			
		DAY 8		02MAR2003	10	84	116	74	4	-2	-2	88	100	74	4	0	4
		DAY 15		06MAR2003	14	84	120	80	4	2	4	86	112	76	2	12	6
		DAY 22		18MAR2003	26	88	128	88	8	10	12	94	132	90	10	32I	20
		DAY 29		25MAR2003	33	102	133	78	22I	15	2	102	128	78	18I	28I	8
		DAY 36		01APR2003	40	87	121	79	7	3	3	80	120	80	-4	20I	10
		DAY 50		09APR2003	48	92	109	72	12	-9	-4	92	112	70	8	12	0
		DAY 50	*	15APR2003	54	92	118	71	12	0	-5	92	118	71	8	18	1
		DAY 57		25APR2003	64	92	122	84	12	4	8	90	124	84	6	24I	14
		FINAL			64	92	122	84	12	4	8	90	124	84	6	24I	14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023019	SCREEN	21MAR2003	-17	78	145	77				80	138	76			
		DAY 1	07APR2003	1	100	127	87				123H	141	98			
		BASELINE			100	127	87				123H	141	98			
		DAY 8	15APR2003	9	95	134	78	-5	7	-9	123H	154	89	0	13	-9
		DAY 15	22APR2003	16	104	140	88	4	13	1	155H	151	79	32I	10	-19
		DAY 22	02MAY2003	26	72	117	79	-28D	-10	-8	99	144	90	-24D	3	-8
		DAY 29	06MAY2003	30	95	126	88	-5	-1	1	117	130	80	-6	-11	-18
		DAY 36	13MAY2003	37	86	129	88	-14	2	1	95	137	86	-28D	-4	-12
		DAY 43	20MAY2003	44	84	132	86	-16D	5	-1	107	137	88	-16D	-4	-10
		DAY 50	29MAY2003	53	97	121	79	-3	-6	-8	113	147	79	-10	6	-19
		DAY 57	03JUN2003	58	93	129	90	-7	2	3	95	131	92	-28D	-10	-6
		FINAL		58	93	129	90	-7	2	3	95	131	92	-28D	-10	-6
	E0023022	SCREEN	10APR2003	-8	80	115	71				84	110	70			
		DAY 1	18APR2003	1	64	114	67				119	120	80			
		BASELINE			64	114	67				119	120	80			
		DAY 8	25APR2003	8	88	108	80	24I	-6	13	92	106	76	-27D	-14	-4
		DAY 15	01MAY2003	14	100	126	65	36I	12	-2	93	105	57	-26D	-15	-23D
		DAY 22	08MAY2003	21	100	131	70	36I	17	3	155H	141	88	36I	21I	8
		DAY 29	15MAY2003	28	103	108	73	39I	-6	6	96	112	72	-23D	-8	-8
		DAY 36	22MAY2003	35	73	126	76	9	12	9	115	108	71	-4	-12	-9
		DAY 43	30MAY2003	43	77	108	65	13	-6	-2	109	108	69	-10	-12	-11
		DAY 50	06JUN2003	50	104	112	63	40I	-2	-4	123H	124	65	4	4	-15
		DAY 57	12JUN2003	56	72	122	84	8	8	17	76	118	80	-43D	-2	0
		FINAL		56	72	122	84	8	8	17	76	118	80	-43D	-2	0
	E0023023	SCREEN	17APR2003	-8	84	89L	65				88	91	67			
		DAY 1	25APR2003	1	80	108	80				86	110	82			
		BASELINE			80	108	80				86	110	82			
		DAY 8	01MAY2003	7	89	110	68	9	2	-12	86	104	53	0	-6	-29D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	FINAL		7	89	110	68	9	2	-12	86	104	53	0	-6	-29D
	E0023031	SCREEN	22MAY2003	-33	85	148	95				104	159	103			
		DAY 1	24JUN2003	1	90	136	87				94	140	93			
		BASELINE			90	136	87				94	140	93			
		DAY 8	01JUL2003	8	85	104	73	-5	-32D	-14	88	103	76	-6	-37D	-17
		DAY 15	08JUL2003	15	90	148	94	0	12	7	98	140	90	4	0	-3
		DAY 22	15JUL2003	22	74	111	75	-16D	-25D	-12	86	132	87	-8	-8	-6
		DAY 29	22JUL2003	29	85	131	88	-5	-5	1	88	130	86	-6	-10	-7
		DAY 36	29JUL2003	36	89	140	90	-1	4	3	94	148	92	0	8	-1
		DAY 43	05AUG2003	43	99	150	90	9	14	3	96	156	99	2	16	6
		DAY 50	12AUG2003	50	109	132	90	19I	-4	3	108	131	90	14	-9	-3
		DAY 57	19AUG2003	57	93	136	95	3	0	8	96	138	95	2	-2	2
		FINAL		57	93	136	95	3	0	8	96	138	95	2	-2	2
	E0023041	SCREEN	02JUL2003	-7	72	106	70				82	119	82			
		DAY 1	09JUL2003	1	80	121	82				79	115	78			
		BASELINE			80	121	82				79	115	78			
		DAY 8	16JUL2003	8	79	124	79	-1	3	-3	84	127	86	5	12	8
		DAY 15	24JUL2003	16	80	120	80	0	-1	-2	84	116	76	5	1	-2
		DAY 22	30JUL2003	22	96	125	87	16I	4	5	109	124	87	30I	9	9
		DAY 29	06AUG2003	29	92	119	77	12	-2	-5	98	118	74	19I	3	-4
		DAY 36	13AUG2003	36	117	105	80	37I	-16	-2	107	114	69	28I	-1	-9
		DAY 43	20AUG2003	43	97	107	74	17I	-14	-8	100	118	80	21I	3	2
		DAY 50	27AUG2003	50	105	110	71	25I	-11	-11	119	104	72	40I	-11	-6
		DAY 57	05SEP2003	59	99	124	79	19I	3	-3	96	111	78	17I	-4	0
		FINAL		59	99	124	79	19I	3	-3	96	111	78	17I	-4	0
	E0023043	SCREEN	07JUL2003	-7	100	138	91				96	143	97			
		DAY 1	14JUL2003	1	102	104	57				98	97	57			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	BASELINE			102	104	57				98	97	57			
		DAY 8	23JUL2003	10	100	105	53	-2	1	-4	111	98	48L	13	1	-9
		DAY 15	28JUL2003	15	100	97	62	-2	-7	5	98	96	60	0	-1	3
		DAY 22	05AUG2003	23	111	98	67	9	-6	10	113	83L	56	15I	-14	-1
		DAY 29	12AUG2003	30	105	125	89	3	21I	32I	105	101	62	7	4	5
		DAY 36	19AUG2003	37	102	130	81	0	26I	24	115	130	81	17I	33I	24
		DAY 43	26AUG2003	44	96	112	70	-6	8	13	90	110	74	-8	13	17
		DAY 50	02SEP2003	51	113	113	66	11	9	9	119	93	59	21I	-4	2
		DAY 57	09SEP2003	58	102	100	68	0	-4	11	100	98	70	2	1	13
		FINAL		58	102	100	68	0	-4	11	100	98	70	2	1	13
	E0026003	SCREEN	25NOV2002	-9	51	131	72				77	122	80			
		DAY 1	04DEC2002	1	91	129	92				108	122	85			
		BASELINE			91	129	92				108	122	85			
		DAY 8	12DEC2002	9	119	122	94	28I	-7	2	120	123	98	12	1	13
		DAY 15	19DEC2002	16	100	129	98	9	0	6	107	135	84	-1	13	-1
		DAY 22	26DEC2002	23	100	119	79	9	-10	-13	100	116	86	-8	-6	1
		DAY 29	02JAN2003	30	98	106	79	7	-23D	-13	100	128	83	-8	6	-2
		DAY 36	09JAN2003	37	78	138	91	-13	9	-1	80	134	96	-28D	12	11
		DAY 43	16JAN2003	44	110	123	87	19I	-6	-5	110	114	79	2	-8	-6
		DAY 50	23JAN2003	51	110	107	78	19I	-22D	-14	111	94	64	3	-28D	-21D
		DAY 57	03FEB2003	62	98	129	95	7	0	3	101	132	99	-7	10	14
		FINAL		62	98	129	95	7	0	3	101	132	99	-7	10	14
	E0026009	SCREEN	10JAN2003	-5	63	113	66				68	114	73			
		DAY 1	15JAN2003	1	119	131	87				118	114	88			
		BASELINE			119	131	87				118	114	88			
		DAY 8	21JAN2003	7	70	97	57	-49D	-34D	-30D	90	107	63	-28D	-7	-25D
		FINAL		7	70	97	57	-49D	-34D	-30D	90	107	63	-28D	-7	-25D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	SCREEN	20FEB2003	-7	78	120	85				85	131	87			
		DAY 1	27FEB2003	1	88	113	73				98	107	65			
		BASELINE			88	113	73				98	107	65			
		DAY 8	07MAR2003	9	98	109	69	10	-4	-4	100	91	61	2	-16	-4
		DAY 15	13MAR2003	15	86	127	86	-2	14	13	88	130	72	-10	23I	7
		DAY 22	20MAR2003	22	89	128	78	1	15	5	92	120	88	-6	13	23
		DAY 29	27MAR2003	29	76	130	72	-12	17	-1	72	128	68	-26D	21I	3
		DAY 36	03APR2003	36	90	140	80	2	27I	7	100	138	97	2	31I	32I
		DAY 43	10APR2003	43	89	120	80	1	7	7	100	110	80	2	3	15
		DAY 50	17APR2003	50	93	126	83	5	13	10	94	117	81	-4	10	16
		DAY 57	25APR2003	58	88	133	77	0	20I	4	92	140	78	-6	33I	13
		FINAL		58	88	133	77	0	20I	4	92	140	78	-6	33I	13
	E0026023	SCREEN	23APR2003	-7	52	117	57				61	109	70			
		DAY 1	30APR2003	1	86	106	59				96	112	61			
		BASELINE			86	106	59				96	112	61			
		DAY 8	07MAY2003	8	66	101	63	-20D	-5	4	76	107	62	-20D	-5	1
		DAY 15	14MAY2003	15	76	110	60	-10	4	1	78	112	61	-18D	0	0
		DAY 22	21MAY2003	22	88	116	68	2	10	9	90	109	65	-6	-3	4
		DAY 29	28MAY2003	29	78	100	58	-8	-6	-1	96	104	65	0	-8	4
		DAY 36	04JUN2003	36	66	108	59	-20D	2	0	62	115	68	-34D	3	7
		DAY 43	11JUN2003	43	65	104	63	-21D	-2	4	70	125	65	-26D	13	4
		DAY 50	18JUN2003	50	70	110	58	-16D	4	-1	87	116	68	-9	4	7
		DAY 57	27JUN2003	59	77	104	55	-9	-2	-4	65	103	58	-31D	-9	-3
		FINAL		59	77	104	55	-9	-2	-4	65	103	58	-31D	-9	-3
	E0027016	SCREEN	19MAR2003	-21	72	110	70				80	110	75			
		DAY 1	09APR2003	1	68	130	90				80	124	90			
		BASELINE			68	130	90				80	124	90			
		DAY 8	14APR2003	6	84	122	80	16I	-8	-10	74	124	78	-6	0	-12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	DAY 15	22APR2003	14	84	140	60	16I	10	-30D	100	140	70	20I	16	-20D
		DAY 22	29APR2003	21	84	120	68	16I	-10	-22D	88	122	70	8	-2	-20D
		DAY 29	05MAY2003	27	94	120	70	26I	-10	-20D	96	122	68	16I	-2	-22D
		DAY 36	14MAY2003	36	64	126	72	-4	-4	-18	80	122	72	0	-2	-18
		DAY 43	19MAY2003	41	68	128	76	0	-2	-14	80	124	70	0	0	-20D
		DAY 50	27MAY2003	49	76	120	70	8	-10	-20D	92	116	72	12	-8	-18
		DAY 57	03JUN2003	56	72	105	75	4	-25D	-15	76	105	75	-4	-19	-15
		FINAL		56	72	105	75	4	-25D	-15	76	105	75	-4	-19	-15
	E0027018	SCREEN	21MAR2003	-4	80	120	82				84	116	80			
		DAY 1	25MAR2003	1	80	122	80				96	114	78			
		BASELINE			80	122	80				96	114	78			
		DAY 8	02APR2003	9	88	130	84	8	8	4	92	130	78	-4	16	0
		DAY 15	08APR2003	15	98	124	82	18I	2	2	88	120	80	-8	6	2
		DAY 22	15APR2003	22	98	130	90	18I	8	10	88	130	92	-8	16	14
		DAY 29	22APR2003	29	92	120	92	12	-2	12	84	130	92	-12	16	14
		DAY 36	29APR2003	36	84	124	80	4	2	0	92	120	80	-4	6	2
		DAY 43	05MAY2003	42	80	128	90	0	6	10	84	124	92	-12	10	14
		DAY 50	13MAY2003	50	72	134	92	-8	12	12	88	130	94	-8	16	16
		DAY 57	22MAY2003	59	86	124	82	6	2	2	88	122	80	-8	8	2
		FINAL		59	86	124	82	6	2	2	88	122	80	-8	8	2
	E0028032	SCREEN	13MAR2003	-12	66	122	82				72	118	78			
		DAY 1	25MAR2003	1	56	100	76				80	94	82			
		BASELINE			56	100	76				80	94	82			
		DAY 8	01APR2003	8	68	122	70	12	22I	-6	76	118	74	-4	24I	-8
		DAY 15	08APR2003	15	68	112	78	12	12	2	84	120	86	4	26I	4
		DAY 22	15APR2003	22	64	100	78	8	0	2	78	104	90	-2	10	8
		DAY 29	22APR2003	29	64	120	82	8	20I	6	76	118	84	-4	24I	2
		DAY 36	30APR2003	37	70	108	72	14	8	-4	70	100	80	-10	6	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	DAY 43	06MAY2003	43	64	110	70	8	10	-6	76	112	70	-4	18	-12
		DAY 50	13MAY2003	50	76	134	86	20I	34I	10	88	128	84	8	34I	2
		DAY 57	06JUN2003	74	80	120	78	24I	20I	2	76	122	80	-4	28I	-2
		FINAL		74	80	120	78	24I	20I	2	76	122	80	-4	28I	-2
	E0029003	SCREEN	28OCT2002	-7	72	92	60				76	90L	64			
		DAY 1	04NOV2002	1	80	100	60				92	110	64			
		BASELINE			80	100	60				92	110	64			
		DAY 8	11NOV2002	8	68	90L	54	-12	-10	-6	80	104	70	-12	-6	6
		DAY 15	18NOV2002	15	80	110	60	0	10	0	84	90L	60	-8	-20D	-4
		DAY 22	25NOV2002	22	84	110	60	4	10	0	92	110	70	0	0	6
		DAY 29	02DEC2002	29	84	114	74	4	14	14	92	120	78	0	10	14
		DAY 36	09DEC2002	36	80	120	76	0	20I	16	92	124	76	0	14	12
		DAY 43	16DEC2002	43	84	114	70	4	14	10	92	110	90	0	0	26
		DAY 50	23DEC2002	50	80	112	80	0	12	20	80	118	76	-12	8	12
		DAY 57	30DEC2002	57	68	100	60	-12	0	0	88	98	80	-4	-12	16
		FINAL		57	68	100	60	-12	0	0	88	98	80	-4	-12	16
	E0031005	SCREEN	13DEC2002	-7	80	110	70				88	118	80			
		DAY 1	20DEC2002	1	68	120	80				80	120	84			
		BASELINE			68	120	80				80	120	84			
		DAY 8	27DEC2002	8	72	128	84	4	8	4	86	124	86	6	4	2
		DAY 15	03JAN2003	15	66	124	80	-2	4	0	72	128	84	-8	8	0
		DAY 22	10JAN2003	22	75	130	78	7	10	-2	82	128	80	2	8	-4
		DAY 29	17JAN2003	29	78	130	74	10	10	-6	88	132	80	8	12	-4
		DAY 36	24JAN2003	36	66	128	84	-2	8	4	70	128	86	-10	8	2
		DAY 43	30JAN2003	42	80	130	82	12	10	2	88	134	84	8	14	0
		DAY 50	07FEB2003	50	76	132	86	8	12	6	70	140	88	-10	20I	4
		DAY 57	14FEB2003	57	80	138	86	12	18	6	82	140	88	2	20I	4
		FINAL		57	80	138	86	12	18	6	82	140	88	2	20I	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0031006	SCREEN	31JAN2003	-18	77	156	80				90	166	82			
		DAY 1	18FEB2003	1	75	164	76				90	172	80			
		BASELINE			75	164	76				90	172	80			
		DAY 8	26FEB2003	9	88	142	72	13	-22D	-4	100	138	70	10	-34D	-10
		DAY 15	05MAR2003	16	92	160	86	17I	-4	10	98	174	86	8	2	6
		DAY 22	11MAR2003	22	74	158	80	-1	-6	4	78	160	76	-12	-12	-4
		DAY 29	18MAR2003	29	70	142	72	-5	-22D	-4	80	148	76	-10	-24D	-4
		DAY 36	25MAR2003	36	88	148	82	13	-16	6	94	150	84	4	-22D	4
		DAY 43	02APR2003	44	88	146	82	13	-18	6	92	150	80	2	-22D	0
		DAY 50	07APR2003	49	96	162	88	21I	-2	12	104	170	94	14	-2	14
		DAY 57	15APR2003	57	76	148	82	1	-16	6	88	150	88	-2	-22D	8
		FINAL		57	76	148	82	1	-16	6	88	150	88	-2	-22D	8
	E0031011	SCREEN	18FEB2003	-9	68	129	74				74	138	80			
		DAY 1	27FEB2003	1	82	144	76				86	148	82			
		BASELINE			82	144	76				86	148	82			
		DAY 8	06MAR2003	8	78	138	80	-4	-6	4	78	140	78	-8	-8	-4
		DAY 15	13MAR2003	15	68	136	82	-14	-8	6	86	138	84	0	-10	2
		DAY 22	20MAR2003	22	98	144	88	16I	0	12	104	152	94	18I	4	12
		DAY 29	27MAR2003	29	84	130	76	2	-14	0	86	132	74	0	-16	-8
		DAY 36	03APR2003	36	88	136	80	6	-8	4	86	138	78	0	-10	-4
		DAY 43	11APR2003	44	76	126	74	-6	-18	-2	84	128	76	-2	-20D	-6
		DAY 50	17APR2003	50	66	130	78	-16D	-14	2	68	128	76	-18D	-20D	-6
		DAY 57	24APR2003	57	70	120	80	-12	-24D	4	74	126	82	-12	-22D	0
		FINAL		57	70	120	80	-12	-24D	4	74	126	82	-12	-22D	0
	E0031015	SCREEN	14MAR2003	-12	76	110	72				80	112	74			
		DAY 1	26MAR2003	1	64	124	72				72	128	74			
		BASELINE			64	124	72				72	128	74			
		DAY 8	01APR2003	7	92	130	76	28I	6	4	88	134	82	16I	6	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	FINAL		7	92	130	76	28I	6	4	88	134	82	16I	6	8
	E0034009	SCREEN	10JUN2003	-9	52	130	80				72	120	75			
		DAY 1	19JUN2003	1	64	130	90				72	120	85			
		BASELINE			64	130	90				72	120	85			
		DAY 8	27JUN2003	9	80	115	90	16I	-15	0	88	120	80	16I	0	-5
		DAY 15	03JUL2003	15	80	135	85	16I	5	-5	96	130	90	24I	10	5
		DAY 22	10JUL2003	22	80	130	90	16I	0	0	96	135	95	24I	15	10
		DAY 29	18JUL2003	30	68	140	85	4	10	-5	76	150	100	4	30I	15
		DAY 36	25JUL2003	37	72	150	100	8	20I	10	88	145	95	16I	25I	10
		DAY 43	31JUL2003	43	64	150	100	0	20I	10	81	145	95	9	25I	10
		DAY 50	07AUG2003	50	68	130	70	4	0	-20D	88	125	85	16I	5	0
		DAY 57	18AUG2003	61	76	135	80	12	5	-10	88	142	90	16I	22I	5
		FINAL		61	76	135	80	12	5	-10	88	142	90	16I	22I	5
	E0037007	SCREEN	04APR2003	-7	68	100	70				84	105	70			
		DAY 1	11APR2003	1	56	90L	70				56	90L	70			
		BASELINE			56	90L	70				56	90L	70			
		DAY 8	17APR2003	7	80	92	70	24I	2	0	80	90L	70	24I	0	0
		FINAL		7	80	92	70	24I	2	0	80	90L	70	24I	0	0
	E0037012	SCREEN	11JUL2003	-5	60	100	80				60	100	80			
		DAY 1	16JUL2003	1	60	106	68				60	106	70			
		BASELINE			60	106	68				60	106	70			
		DAY 8	24JUL2003	9	64	110	70	4	4	2	64	112	68	4	6	-2
		DAY 15	01AUG2003	17	76	116	68	16I	10	0	76	114	64	16I	8	-6
		DAY 22	08AUG2003	24	84	118	65	24I	12	-3	86	124	70	26I	18	0
		DAY 29	15AUG2003	31	86	124	68	26I	18	0	90	124	70	30I	18	0
		DAY 36	22AUG2003	38	70	114	72	10	8	4	75	118	82	15I	12	12
		DAY 43	29AUG2003	45	68	110	68	8	4	0	68	114	70	8	8	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 50	05SEP2003	52	70	122	82	10	16	14	70	120	90	10	14	20
		DAY 57	08SEP2003	55	60	108	60	0	2	-8	60	108	62	0	2	-8
		FINAL		55	60	108	60	0	2	-8	60	108	62	0	2	-8
	E0039019	SCREEN	20JAN2003	-17	72	132	96				80	124	88			
		DAY 1	06FEB2003	1	88	126	92				96	124	96			
		BASELINE			88	126	92				96	124	96			
		DAY 8	13FEB2003	8	66	134	92	-22D	8	0	62	124	94	-34D	0	-2
		DAY 15	20FEB2003	15	83	118	90	-5	-8	-2	96	114	86	0	-10	-10
		DAY 22	27FEB2003	22	88	102	78	0	-24D	-14	96	106	78	0	-18	-18
		DAY 29	07MAR2003	30	84	98	50L	-4	-28D	-42D	88	100	60	-8	-24D	-36D
		DAY 36	13MAR2003	36	96	116	90	8	-10	-2	100	110	88	4	-14	-8
		DAY 43	20MAR2003	43	80	110	84	-8	-16	-8	88	108	86	-8	-16	-10
		DAY 50	27MAR2003	50	90	110	80	2	-16	-12	78	108	84	-18D	-16	-12
		DAY 57	03APR2003	57	90	118	88	2	-8	-4	94	112	90	-2	-12	-6
		FINAL		57	90	118	88	2	-8	-4	94	112	90	-2	-12	-6
	E0039043	SCREEN	25APR2003	-13	62	120	74				70	118	70			
		DAY 1	08MAY2003	1	78	134	76				95	118	86			
		BASELINE			78	134	76				95	118	86			
		DAY 8	15MAY2003	8	66	120	80	-12	-14	4	90	108	82	-5	-10	-4
		DAY 15	23MAY2003	16	85	128	88	7	-6	12	96	118	88	1	0	2
		DAY 22	29MAY2003	22	74	122	76	-4	-12	0	92	106	60	-3	-12	-26D
		DAY 29	05JUN2003	29	80	124	78	2	-10	2	88	120	86	-7	2	0
		DAY 36	13JUN2003	37	80	144	84	2	10	8	88	126	90	-7	8	4
		FINAL		37	80	144	84	2	10	8	88	126	90	-7	8	4
PLACEBO (BIPOLAR I)	E0002003	SCREEN	03JAN2003	-19	80	120	78				76	116	72			
		DAY 1	22JAN2003	1	68	100	80				72	100	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0002003	BASELINE			68	100	80				72	100	80			
		DAY 8	29JAN2003	8	64	102	72	-4	2	-8	72	98	60	0	-2	-20D
		DAY 15	05FEB2003	15	76	110	60	8	10	-20D	80	102	62	8	2	-18
		DAY 22	12FEB2003	22	64	102	62	-4	2	-18	76	104	66	4	4	-14
		DAY 29	19FEB2003	29	80	112	60	12	12	-20D	78	100	64	6	0	-16
		DAY 36	26FEB2003	36	64	112	66	-4	12	-14	66	112	72	-6	12	-8
		DAY 43	05MAR2003	43	78	112	66	10	12	-14	76	110	68	4	10	-12
		DAY 50	11MAR2003	49	76	108	68	8	8	-12	74	106	66	2	6	-14
		DAY 57	18MAR2003	56	64	120	68	-4	20I	-12	76	110	68	4	10	-12
		FINAL		56	64	120	68	-4	20I	-12	76	110	68	4	10	-12
	E0002008	SCREEN	05FEB2003	-20	64	122	70				64	120	70			
		DAY 1	25FEB2003	1	72	128	74				68	126	82			
		BASELINE			72	128	74				68	126	82			
		DAY 8	05MAR2003	9	74	120	82	2	-8	8	78	128	88	10	2	6
		DAY 15	13MAR2003	17	80	122	80	8	-6	6	78	128	82	10	2	0
		DAY 22	20MAR2003	24	70	118	76	-2	-10	2	78	120	82	10	-6	0
		DAY 29	27MAR2003	31	76	110	72	4	-18	-2	72	116	84	4	-10	2
		DAY 36	03APR2003	38	70	110	60	-2	-18	-14	80	120	82	12	-6	0
		DAY 43	11APR2003	46	76	126	82	4	-2	8	72	118	72	4	-8	-10
		DAY 50	16APR2003	51	78	116	86	6	-12	12	84	126	88	16I	0	6
		DAY 57	23APR2003	58	74	108	68	2	-20D	-6	80	118	70	12	-8	-12
		FINAL		58	74	108	68	2	-20D	-6	80	118	70	12	-8	-12
	E0002016	SCREEN	14JUL2003	-10	62	130	82				64	118	72			
		DAY 1	24JUL2003	1	64	136	72				66	138	70			
		BASELINE			64	136	72				66	138	70			
		DAY 8	30JUL2003	7	68	128	78	4	-8	6	68	130	82	2	-8	12
		DAY 15	06AUG2003	14	68	128	70	4	-8	-2	68	132	68	2	-6	-2
		DAY 22	13AUG2003	21	68	126	68	4	-10	-4	68	118	68	2	-20D	-2
		DAY 29	21AUG2003	29	68	130	74	4	-6	2	68	128	76	2	-10	6

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0002016	DAY 36	27AUG2003	35	64	130	70	0	-6	-2	68	120	74	2	-18	4
		DAY 43	03SEP2003	42	64	126	70	0	-10	-2	68	112	68	2	-26D	-2
		DAY 50	11SEP2003	50	64	122	72	0	-14	0	66	116	70	0	-22D	0
		DAY 57	17SEP2003	56	66	138	82	2	2	10	66	138	86	0	0	16
		FINAL		56	66	138	82	2	2	10	66	138	86	0	0	16
	E0003008	SCREEN	21JAN2003	-7	80	118	80				92	128	88			
		DAY 1	28JAN2003	1	78	122	78				82	124	80			
		BASELINE			78	122	78				82	124	80			
		DAY 8	04FEB2003	8	70	120	78	-8	-2	0	88	120	70	6	-4	-10
		DAY 15	11FEB2003	15	78	126	70	0	4	-8	82	110	64	0	-14	-16
		DAY 22	18FEB2003	22	82	108	64	4	-14	-14	78	102	60	-4	-22D	-20D
		FINAL		22	82	108	64	4	-14	-14	78	102	60	-4	-22D	-20D
	E0004016	SCREEN	12FEB2003	-7	64	110	62				68	102	68			
		DAY 1	19FEB2003	1	68	100	60				68	96	62			
		BASELINE			68	100	60				68	96	62			
		DAY 8	26FEB2003	8	64	108	64	-4	8	4	68	118	70	0	22I	8
		DAY 15	05MAR2003	15	60	104	70	-8	4	10	64	110	74	-4	14	12
		DAY 22	13MAR2003	23	64	110	80	-4	10	20	60	102	76	-8	6	14
		DAY 36	26MAR2003	36	60	104	68	-8	4	8	60	100	64	-8	4	2
		DAY 43	03APR2003	44	82	104	64	14	4	4	86	110	70	18I	14	8
		DAY 50	10APR2003	51	64	100	70	-4	0	10	60	108	74	-8	12	12
		DAY 57	17APR2003	58	60	94	62	-8	-6	2	64	100	60	-4	4	-2
		FINAL		58	60	94	62	-8	-6	2	64	100	60	-4	4	-2
	E0005006	SCREEN	24SEP2002	-9	64	110	68				64	100	60			
		DAY 1	03OCT2002	1	62	110	68				62	100	62			
		BASELINE			62	110	68				62	100	62			
		DAY 8	14OCT2002	12	76	110	70	14	0	2	82	112	72	20I	12	10
		FINAL		12	76	110	70	14	0	2	82	112	72	20I	12	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0005017	SCREEN	11DEC2002	-19	80	130	96				80	124	94			
		DAY 1	30DEC2002	1	80	130	94				80	124	94			
		BASELINE			80	130	94				80	124	94			
		DAY 8	06JAN2003	8	68	124	94	-12	-6	0	68	120	70	-12	-4	-24D
		DAY 15	14JAN2003	16	64	120	90	-16D	-10	-4	68	120	90	-12	-4	-4
		DAY 22	22JAN2003	24	72	130	94	-8	0	0	72	126	90	-8	2	-4
		DAY 29	30JAN2003	32	76	130	94	-4	0	0	76	130	90	-4	6	-4
		DAY 36	04FEB2003	37	60	124	84	-20D	-6	-10	60	122	82	-20D	-2	-12
		DAY 43	13FEB2003	46	60	130	86	-20D	0	-8	60	120	86	-20D	-4	-8
		DAY 50	20FEB2003	53	60	120	76	-20D	-10	-18	60	116	70	-20D	-8	-24D
		DAY 57	04MAR2003	65	60	120	80	-20D	-10	-14	60	120	78	-20D	-4	-16
		FINAL		65	60	120	80	-20D	-10	-14	60	120	78	-20D	-4	-16
	E0005019	SCREEN	19DEC2002	-27	88	112	74				88	110	74			
		DAY 1	15JAN2003	1	96	108	70				92	110	76			
		BASELINE			96	108	70				92	110	76			
		DAY 8	23JAN2003	9	60	118	78	-36D	10	8	64	114	80	-28D	4	4
		FINAL		9	60	118	78	-36D	10	8	64	114	80	-28D	4	4
	E0005026	SCREEN	26FEB2003	-8	72	96	60				68	96	60			
		DAY 1	06MAR2003	1	64	94	60				60	96	66			
		BASELINE			64	94	60				60	96	66			
		DAY 8	13MAR2003	8	76	96	64	12	2	4	80	90L	60	20I	-6	-6
		DAY 15	20MAR2003	15	76	84L	60	12	-10	0	80	84L	60	20I	-12	-6
		DAY 22	25MAR2003	20	80	90L	58	16I	-4	-2	80	88L	58	20I	-8	-8
		FINAL		20	80	90L	58	16I	-4	-2	80	88L	58	20I	-8	-8
	E0005039	SCREEN	15MAY2003	-7	68	130	80				72	124	78			
		DAY 1	22MAY2003	1	64	130	80				64	126	80			
		BASELINE			64	130	80				64	126	80			
		DAY 8	28MAY2003	7	76	138	86	12	8	6	76	136	86	12	10	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0005039	DAY 15	05JUN2003	15	64	130	82	0	0	2	64	130	84	0	4	4
		DAY 22	12JUN2003	22	80	134	84	16I	4	4	80	130	84	16I	4	4
		DAY 29	18JUN2003	28	64	130	84	0	0	4	64	124	84	0	-2	4
		DAY 36	24JUN2003	34	60	130	80	-4	0	0	60	126	80	-4	0	0
		DAY 43	03JUL2003	43	60	130	84	-4	0	4	60	130	84	-4	4	4
		DAY 50	10JUL2003	50	64	130	84	0	0	4	64	134	84	0	8	4
		DAY 57	16JUL2003	56	68	134	78	4	4	-2	64	136	86	0	10	6
		FINAL		56	68	134	78	4	4	-2	64	136	86	0	10	6
	E0005043	SCREEN	01JUL2003	-8	60	110	72				60	110	72			
		DAY 1	09JUL2003	1	60	120	70				60	110	70			
		BASELINE			60	120	70				60	110	70			
		DAY 8	17JUL2003	9	64	120	62	4	0	-8	66	118	64	6	8	-6
		DAY 15	24JUL2003	16	60	110	76	0	-10	6	60	110	70	0	0	0
		DAY 22	31JUL2003	23	60	110	70	0	-10	0	60	110	70	0	0	0
		DAY 29	07AUG2003	30	60	110	70	0	-10	0	60	110	70	0	0	0
		DAY 36	13AUG2003	36	60	100	70	0	-20D	0	60	100	70	0	-10	0
		DAY 43	20AUG2003	43	64	118	70	4	-2	0	60	110	70	0	0	0
		DAY 50	27AUG2003	50	64	116	68	4	-4	-2	72	110	64	12	0	-6
		DAY 57	03SEP2003	57	60	126	76	0	6	6	68	124	70	8	14	0
		FINAL		57	60	126	76	0	6	6	68	124	70	8	14	0
	E0006020	SCREEN	02MAY2003	-11	58	100	72				60	120	80			
		DAY 1	13MAY2003	1	72	133	90				70	132	89			
		BASELINE			72	133	90				70	132	89			
		DAY 8	20MAY2003	8	72	133	81	0	0	-9	74	134	85	4	2	-4
		DAY 15	27MAY2003	15	88	132	77	16I	-1	-13	90	132	99	20I	0	10
		DAY 22	03JUN2003	22	86	130	76	14	-3	-14	88	132	85	18I	0	-4
		DAY 29	10JUN2003	29	76	129	77	4	-4	-13	78	136	82	8	4	-7
		DAY 36	17JUN2003	36	66	134	83	-6	1	-7	68	138	87	-2	6	-2
		DAY 43	24JUN2003	43	68	138	84	-4	5	-6	70	138	84	0	6	-5

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0006020	DAY 50		01JUL2003	50	78	132	86	6	-1	-4	82	150	90	12	18	1
		DAY 57		08JUL2003	57	68	131	87	-4	-2	-3	72	132	95	2	0	6
		FINAL			57	68	131	87	-4	-2	-3	72	132	95	2	0	6
	E0007001	SCREEN		10DEC2002	-21	74	130	78				71	124	80			
		DAY 1		31DEC2002	1	70	110	70				74	118	76			
		BASELINE				70	110	70				74	118	76			
		DAY 8		07JAN2003	8	68	112	70	-2	2	0	76	116	74	2	-2	-2
		DAY 15		14JAN2003	15	70	108	70	0	-2	0	72	110	74	-2	-8	-2
		DAY 22		21JAN2003	22	72	110	70	2	0	0	76	108	70	2	-10	-6
		DAY 29		28JAN2003	29	70	102	72	0	-8	2	78	110	78	4	-8	2
		DAY 36		04FEB2003	36	72	104	70	2	-6	0	76	110	76	2	-8	0
		DAY 43		11FEB2003	43	70	100	70	0	-10	0	74	94	70	0	-24D	-6
		DAY 50		18FEB2003	50	66	104	70	-4	-6	0	70	108	76	-4	-10	0
		DAY 50	*	22FEB2003	54	70	110	72	0	0	2	78	116	78	4	-2	2
		FINAL			54	70	110	72	0	0	2	78	116	78	4	-2	2
	E0009004	SCREEN		19NOV2002	-7	84	142	94				86	138	88			
		DAY 1		26NOV2002	1	72	140	84				80	136	84			
		BASELINE				72	140	84				80	136	84			
		DAY 8		04DEC2002	9	70	140	90	-2	0	6	74	138	88	-6	2	4
		DAY 15		11DEC2002	16	80	150	98	8	10	14	78	148	90	-2	12	6
		DAY 22		18DEC2002	23	104	130	94	32I	-10	10	102	132	96	22I	-4	12
		FINAL			23	104	130	94	32I	-10	10	102	132	96	22I	-4	12
	E0009012	SCREEN		16JUN2003	-9	76	110	74				80	110	80			
		DAY 1		25JUN2003	1	80	122	80				80	124	82			
		BASELINE				80	122	80				80	124	82			
		DAY 8		03JUL2003	9	72	100	70	-8	-22D	-10	72	108	74	-8	-16	-8
		FINAL			9	72	100	70	-8	-22D	-10	72	108	74	-8	-16	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0010008	SCREEN		11DEC2002	-7	84	110	68				86	100	64			
		DAY 1		18DEC2002	1	95	110	66				105	100	70			
		BASELINE				95	110	66				105	100	70			
		DAY 8		26DEC2002	9	72	102	56	-23D	-8	-10	80	100	60	-25D	0	-10
		DAY 15		02JAN2003	16	94	118	70	-1	8	4	97	120	70	-8	20I	0
		DAY 22		08JAN2003	22	80	108	60	-15D	-2	-6	89	106	56	-16D	6	-14
		DAY 29		15JAN2003	29	88	122	60	-7	12	-6	102	102	66	-3	2	-4
		FINAL			29	88	122	60	-7	12	-6	102	102	66	-3	2	-4
	E0010018	SCREEN		26FEB2003	-21	68	108	74				80	110	80			
		DAY 1		19MAR2003	1	68	118	80				85	110	80			
		BASELINE				68	118	80				85	110	80			
		DAY 8		26MAR2003	8	56	100	68	-12	-18	-12	60	100	70	-25D	-10	-10
		DAY 15		02APR2003	15	74	110	70	6	-8	-10	84	124	80	-1	14	0
		DAY 22		09APR2003	22	76	104	70	8	-14	-10	88	108	76	3	-2	-4
		DAY 29		16APR2003	29	72	104	64	4	-14	-16	80	104	68	-5	-6	-12
		DAY 36		23APR2003	36	66	106	70	-2	-12	-10	90	110	72	5	0	-8
		DAY 43		01MAY2003	44	80	112	80	12	-6	0	86	108	74	1	-2	-6
		DAY 57		14MAY2003	57	78	100	70	10	-18	-10	84	108	70	-1	-2	-10
		FINAL			57	78	100	70	10	-18	-10	84	108	70	-1	-2	-10
	E0011010	SCREEN		03FEB2003	-7	64	112	74				72	110	76			
		DAY 1		10FEB2003	1	64	110	72				72	108	74			
		BASELINE				64	110	72				72	108	74			
		DAY 8		17FEB2003	8	64	110	72	0	0	0	72	107	78	0	-1	4
		DAY 15		24FEB2003	15	72	110	70	8	0	-2	84	104	72	12	-4	-2
		DAY 22		03MAR2003	22	68	112	78	4	2	6	76	110	80	4	2	6
		DAY 29		10MAR2003	29	58	103	68	-6	-7	-4	52	100	70	-20D	-8	-4
		DAY 36		17MAR2003	36	72	108	72	8	-2	0	88	104	72	16I	-4	-2
		DAY 36	*	19MAR2003	38	72	104	74	8	-6	2	80	104	76	8	-4	2
		FINAL			38	72	104	74	8	-6	2	80	104	76	8	-4	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0013003	SCREEN	06NOV2002	-6	66	140	90				72	140	92			
		DAY 1	12NOV2002	1	72	144	90				72	138	90			
		BASELINE			72	144	90				72	138	90			
		DAY 8	19NOV2002	8	72	160	90	0	16	0	72	160	96	0	22I	6
		DAY 15	26NOV2002	15	66	140	90	-6	-4	0	66	150	90	-6	12	0
		DAY 22	03DEC2002	22	72	140	90	0	-4	0	72	146	94	0	8	4
		DAY 29	11DEC2002	30	66	162	94	-6	18	4	66	164	98	-6	26I	8
		DAY 36	18DEC2002	37	82	162	98	10	18	8	78	164	98	6	26I	8
		DAY 43	23DEC2002	42	86	156	92	14	12	2	84	150	90	12	12	0
		DAY 50	30DEC2002	49	72	140	90	0	-4	0	66	144	90	-6	6	0
		DAY 57	06JAN2003	56	60	136	90	-12	-8	0	60	142	90	-12	4	0
		FINAL		56	60	136	90	-12	-8	0	60	142	90	-12	4	0
	E0013005	SCREEN	13FEB2003	-5	72	120	80				72	120	80			
		DAY 1	18FEB2003	1	66	120	74				72	120	78			
		BASELINE			66	120	74				72	120	78			
		DAY 8	25FEB2003	8	60	115	68	-6	-5	-6	60	115	76	-12	-5	-2
		DAY 15	04MAR2003	15	60	120	80	-6	0	6	66	120	80	-6	0	2
		DAY 22	11MAR2003	22	72	115	70	6	-5	-4	66	118	76	-6	-2	-2
		DAY 29	19MAR2003	30	72	124	80	6	4	6	72	120	80	0	0	2
		DAY 36	25MAR2003	36	66	100	80	0	-20D	6	66	110	80	-6	-10	2
		DAY 43	02APR2003	44	72	118	70	6	-2	-4	66	116	70	-6	-4	-8
		DAY 50	08APR2003	50	64	120	80	-2	0	6	64	120	78	-8	0	0
		DAY 57	15APR2003	57	66	132	80	0	12	6	66	132	80	-6	12	2
		FINAL		57	66	132	80	0	12	6	66	132	80	-6	12	2
	E0013013	SCREEN	01MAY2003	-5	60	114	78				64	114	80			
		DAY 1	06MAY2003	1	80	112	60				68	112	64			
		BASELINE			80	112	60				68	112	64			
		DAY 8	12MAY2003	7	68	118	70	-12	6	10	68	118	68	0	6	4
		DAY 15	19MAY2003	14	60	120	80	-20D	8	20	68	114	76	0	2	12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0013013	DAY 22		27MAY2003	22	60	120	80	-20D	8	20	60	124	80	-8	12	16
		DAY 22	*	30MAY2003	25	64	112	78	-16D	0	18	68	110	80	0	-2	16
		FINAL			25	64	112	78	-16D	0	18	68	110	80	0	-2	16
	E0014002	SCREEN		19FEB2003	-7	60	120	74				68	110	72			
		DAY 1		26FEB2003	1	64	135	78				80	120	80			
		BASELINE				64	135	78				80	120	80			
		DAY 8		04MAR2003	7	64	124	70	0	-11	-8	80	110	70	0	-10	-10
		DAY 15		12MAR2003	15	74	110	78	10	-25D	0	88	110	80	8	-10	0
		DAY 22		20MAR2003	23	76	110	80	12	-25D	2	86	110	74	6	-10	-6
		DAY 29		27MAR2003	30	48L	112	88	-16D	-23D	10	52	108	85	-28D	-12	5
		DAY 43		10APR2003	44	60	110	70	-4	-25D	-8	63	120	78	-17D	0	-2
		FINAL			44	60	110	70	-4	-25D	-8	63	120	78	-17D	0	-2
	E0014015	SCREEN		11JUN2003	-7	80	120	90				84	120	80			
		DAY 1		18JUN2003	1	80	120	80				82	123	80			
		BASELINE				80	120	80				82	123	80			
		DAY 8		26JUN2003	9	80	100	75	0	-20D	-5	85	110	85	3	-13	5
		FINAL			9	80	100	75	0	-20D	-5	85	110	85	3	-13	5
	E0014018	SCREEN		24JUN2003	-7	70	118	76				68	120	72			
		DAY 1		01JUL2003	1	68	117	75				66	112	80			
		BASELINE				68	117	75				66	112	80			
		DAY 8		09JUL2003	9	92	120	78	24I	3	3	96	110	76	30I	-2	-4
		DAY 15		16JUL2003	16	92	115	75	24I	-2	0	94	110	78	28I	-2	-2
		DAY 22		22JUL2003	22	64	110	70	-4	-7	-5	68	110	80	2	-2	0
		DAY 29		29JUL2003	29	80	100	60	12	-17	-15	78	110	80	12	-2	0
		DAY 36		05AUG2003	36	80	110	78	12	-7	3	83	116	77	17I	4	-3
		DAY 43		12AUG2003	43	82	115	78	14	-2	3	80	114	75	14	2	-5
		DAY 50		19AUG2003	50	76	115	82	8	-2	7	76	117	80	10	5	0
		DAY 57		27AUG2003	58	64	125	76	-4	8	1	66	120	82	0	8	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0014018	FINAL		58	64	125	76	-4	8	1	66	120	82	0	8	2
	E0018015	SCREEN	21JAN2003	-7	68	110	68				80	110	70			
		DAY 1	28JAN2003	1	68	102	68				72	104	68			
		BASELINE			68	102	68				72	104	68			
		DAY 8	04FEB2003	8	64	108	72	-4	6	4	72	106	72	0	2	4
		DAY 15	13FEB2003	17	88	118	78	20I	16	10	96	122	78	24I	18	10
		DAY 22	20FEB2003	24	76	118	68	8	16	0	88	116	68	16I	12	0
		DAY 29	26FEB2003	30	64	112	64	-4	10	-4	64	118	70	-8	14	2
		DAY 36	06MAR2003	38	72	120	70	4	18	2	76	122	72	4	18	4
		DAY 43	13MAR2003	45	64	104	62	-4	2	-6	72	104	68	0	0	0
		DAY 50	20MAR2003	52	72	104	66	4	2	-2	76	106	68	4	2	0
		DAY 57	27MAR2003	59	60	110	68	-8	8	0	64	112	70	-8	8	2
		FINAL		59	60	110	68	-8	8	0	64	112	70	-8	8	2
	E0020015	SCREEN	18MAR2003	-9	76	128	72				80	112	74			
		DAY 1	27MAR2003	1	78	114	72				80	116	70			
		BASELINE			78	114	72				80	116	70			
		DAY 8	03APR2003	8	80	116	70	2	2	-2	76	122	72	-4	6	2
		DAY 15	10APR2003	15	98	114	90	20I	0	18	99	116	90	19I	0	20
		DAY 22	16APR2003	21	80	124	78	2	10	6	82	118	74	2	2	4
		DAY 29	23APR2003	28	88	130	80	10	16	8	90	130	82	10	14	12
		DAY 36	30APR2003	35	78	136	72	0	22I	0	80	140	80	0	24I	10
		DAY 43	08MAY2003	43	82	112	62	4	-2	-10	80	114	70	0	-2	0
		DAY 50	15MAY2003	50	78	112	74	0	-2	2	80	110	74	0	-6	4
		DAY 57	23MAY2003	58	72	100	80	-6	-14	8	74	98	78	-6	-18	8
		FINAL		58	72	100	80	-6	-14	8	74	98	78	-6	-18	8
	E0020017	SCREEN	27MAR2003	-7	76	104	68				72	106	70			
		DAY 1	03APR2003	1	64	100	60				62	102	62			
		BASELINE			64	100	60				62	102	62			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0020017	DAY 8		10APR2003	8	74	116	70	10	16	10	72	114	72	10	12	10
		DAY 15		17APR2003	15	88	106	78	24I	6	18	86	102	80	24I	0	18
		DAY 22		22APR2003	20	74	116	74	10	16	14	80	120	76	18I	18	14
		DAY 29		29APR2003	27	74	122	74	10	22I	14	72	116	74	10	14	12
		DAY 29	*	05MAY2003	33	76	118	72	12	18	12	70	112	72	8	10	10
		DAY 36		12MAY2003	40	80	100	60	16I	0	0	86	104	66	24I	2	4
		DAY 50		20MAY2003	48	78	118	74	14	18	14	80	108	70	18I	6	8
		DAY 57		03JUN2003	62	78	120	74	14	20I	14	80	118	74	18I	16	12
		FINAL			62	78	120	74	14	20I	14	80	118	74	18I	16	12
	E0020022	SCREEN		09JUN2003	-7	80	126	76				78	128	78			
		DAY 1		16JUN2003	1	64	112	84				66	120	88			
		BASELINE				64	112	84				66	120	88			
		DAY 8		23JUN2003	8	58	132	76	-6	20I	-8	60	124	70	-6	4	-18
		DAY 15		30JUN2003	15	58	112	84	-6	0	0	60	114	86	-6	-6	-2
		DAY 22		07JUL2003	22	58	114	80	-6	2	-4	68	120	94	2	0	6
		DAY 29		14JUL2003	29	68	100	80	4	-12	-4	70	112	82	4	-8	-6
		DAY 36		21JUL2003	36	78	108	74	14	-4	-10	76	116	78	10	-4	-10
		DAY 43		28JUL2003	43	68	104	72	4	-8	-12	70	110	74	4	-10	-14
		DAY 50		04AUG2003	50	68	110	80	4	-2	-4	70	108	80	4	-12	-8
		DAY 57		11AUG2003	57	64	112	70	0	0	-14	60	104	80	-6	-16	-8
		FINAL			57	64	112	70	0	0	-14	60	104	80	-6	-16	-8
	E0022001	SCREEN		07OCT2002	-21	62	136	96					142	97			
		DAY 1		28OCT2002	1	64	132	98				64	132	92			
		BASELINE				64	132	98				64	132	92			
		DAY 8		04NOV2002	8	68	128	90	4	-4	-8	80	126	88	16I	-6	-4
		DAY 15		11NOV2002	15	72	136	92	8	4	-6	72	124	94	8	-8	2
		DAY 22		18NOV2002	22	80	138	88	16I	6	-10	88	132	86	24I	0	-6
		DAY 29		26NOV2002	30	68	158	90	4	26I	-8	76	160	94	12	28I	2
		DAY 36		02DEC2002	36	68	142	90	4	10	-8	72	144	84	8	12	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022001	DAY 43	09DEC2002	43	68	132	86	4	0	-12	72	124	90	8	-8	-2
		DAY 50	16DEC2002	50	72	136	80	8	4	-18	76	130	88	12	-2	-4
		DAY 57	26DEC2002	60	64	146	82	0	14	-16	68	138	90	4	6	-2
		FINAL		60	64	146	82	0	14	-16	68	138	90	4	6	-2
	E0022005	SCREEN	17OCT2002	-22	76	122	82				80	128	106H			
		DAY 1	08NOV2002	1	68	130	80				80	126	94			
		BASELINE			68	130	80				80	126	94			
		DAY 8	15NOV2002	8	66	120	68	-2	-10	-12	78	115	70	-2	-11	-24D
		DAY 15	22NOV2002	15	58	125	70	-10	-5	-10	69	110	69	-11	-16	-25D
		DAY 22	29NOV2002	22	62	120	70	-6	-10	-10	72	115	78	-8	-11	-16
		DAY 29	06DEC2002	29	74	115	76	6	-15	-4	80	110	70	0	-16	-24D
		DAY 36	13DEC2002	36	78	120	78	10	-10	-2	82	110	72	2	-16	-22D
		DAY 43	20DEC2002	43	68	120	80	0	-10	0	74	110	70	-6	-16	-24D
		DAY 50	27DEC2002	50	70	115	70	2	-15	-10	74	110	64	-6	-16	-30D
		DAY 57	03JAN2003	57	72	100	66	4	-30D	-14	76	90L	72	-4	-36D	-22D
		FINAL		57	72	100	66	4	-30D	-14	76	90L	72	-4	-36D	-22D
	E0022015	SCREEN	29NOV2002	-11	86	112	62					116	76			
		DAY 1	10DEC2002	1	76	120	58				88	126	68			
		BASELINE			76	120	58				88	126	68			
		DAY 8	17DEC2002	8	64	112	66	-12	-8	8	68	122	76	-20D	-4	8
		DAY 15	26DEC2002	17	64	108	68	-12	-12	10	68	106	72	-20D	-20D	4
		DAY 22	02JAN2003	24	68	114	60	-8	-6	2	84	108	78	-4	-18	10
		DAY 29	09JAN2003	31	76	112	66	0	-8	8	76	110	60	-12	-16	-8
		DAY 36	16JAN2003	38	72	106	60	-4	-14	2	72	118	70	-16D	-8	2
		DAY 43	23JAN2003	45	80	104	56	4	-16	-2	92	110	66	4	-16	-2
		DAY 50	30JAN2003	52	76	114	58	0	-6	0	88	116	56	0	-10	-12
		DAY 57	06FEB2003	59	72	110	66	-4	-10	8	92	120	78	4	-6	10
		FINAL		59	72	110	66	-4	-10	8	92	120	78	4	-6	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022016	SCREEN	03DEC2002	-14	76	118	62				72	120	70			
		DAY 1	17DEC2002	1	68	130	70				72	114	78			
		BASELINE			68	130	70				72	114	78			
		DAY 8	26DEC2002	10	72	128	68	4	-2	-2	80	118	80	8	4	2
		DAY 15	30DEC2002	14	78	120	66	10	-10	-4	78	122	72	6	8	-6
		DAY 22	06JAN2003	21	66	114	56	-2	-16	-14	78	116	64	6	2	-14
		DAY 29	13JAN2003	28	84	128	66	16I	-2	-4	88	118	68	16I	4	-10
		DAY 36	21JAN2003	36	64	98	58	-4	-32D	-12	62	94	60	-10	-20D	-18
		DAY 43	30JAN2003	45	78	120	62	10	-10	-8	84	116	72	12	2	-6
		DAY 50	06FEB2003	52	84	126	70	16I	-4	0	94	116	76	22I	2	-2
		DAY 57	11FEB2003	57	68	120	70	0	-10	0	64	118	74	-8	4	-4
		FINAL		57	68	120	70	0	-10	0	64	118	74	-8	4	-4
	E0022020	SCREEN	05DEC2002	-7	60	110	58				86	106	80			
		DAY 1	12DEC2002	1	56	102	58				58	98	68			
		BASELINE			56	102	58				58	98	68			
		DAY 8	19DEC2002	8	64	110	70	8	8	12	82	110	64	24I	12	-4
		DAY 15	26DEC2002	15	64	110	60	8	8	2	78	112	70	20I	14	2
		DAY 22	02JAN2003	22	72	112	64	16I	10	6	88	108	68	30I	10	0
		DAY 29	10JAN2003	30	60	94	58	4	-8	0	64	102	60	6	4	-8
		DAY 36	16JAN2003	36	76	106	48L	20I	4	-10	100	104	66	42I	6	-2
		DAY 43	23JAN2003	43	76	94	48L	20I	-8	-10	76	102	64	18I	4	-4
		FINAL		43	76	94	48L	20I	-8	-10	76	102	64	18I	4	-4
	E0022023	SCREEN	19DEC2002	-6	80	118	72				84	118	76			
		DAY 1	24DEC2002	-1	78	122	70				88	120	72			
		BASELINE			78	122	70				88	120	72			
		DAY 8	02JAN2003	9	72	116	70	-6	-6	0	84	118	84	-4	-2	12
		DAY 15	09JAN2003	16	72	128	72	-6	6	2	80	120	82	-8	0	10
		DAY 22	16JAN2003	23	60	102	68	-18D	-20D	-2	80	108	70	-8	-12	-2
		DAY 29	23JAN2003	30	68	104	68	-10	-18	-2	88	128	74	0	8	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022023	DAY 36		30JAN2003	37	64	102	64	-14	-20D	-6	72	104	62	-16D	-16	-10
		DAY 43		06FEB2003	44	72	112	60	-6	-10	-10	76	118	58	-12	-2	-14
		DAY 50		13FEB2003	51	76	102	62	-2	-20D	-8	92	118	80	4	-2	8
		DAY 57		20FEB2003	58	72	112	78	-6	-10	8	88	128	72	0	8	0
		FINAL			58	72	112	78	-6	-10	8	88	128	72	0	8	0
	E0022029	SCREEN		05FEB2003	-14	72	128	66				104	116	70			
		DAY 1		19FEB2003	1	75	134	72				84	118	74			
		BASELINE				75	134	72				84	118	74			
		DAY 8		26FEB2003	8	72	116	64	-3	-18	-8	84	122	74	0	4	0
		DAY 15		03MAR2003	13	69	120	66	-6	-14	-6	90	126	74	6	8	0
		DAY 22		12MAR2003	22	72	110	72	-3	-24D	0	84	126	74	0	8	0
		DAY 29		18MAR2003	28	78	116	64	3	-18	-8	78	126	70	-6	8	-4
		DAY 36		26MAR2003	36	63	108	70	-12	-26D	-2	90	118	78	6	0	4
		DAY 43		02APR2003	43	66	104	72	-9	-30D	0	84	98	74	0	-20D	0
		DAY 50		07APR2003	48	68	126	72	-7	-8	0	80	124	80	-4	6	6
		DAY 57		14APR2003	55	78	132	78	3	-2	6	84	118	82	0	0	8
		FINAL			55	78	132	78	3	-2	6	84	118	82	0	0	8
	E0022043	SCREEN		10MAR2003	-10	66	106	80				72	102	80			
		DAY 1		20MAR2003	1	63	116	80				66	108	78			
		BASELINE				63	116	80				66	108	78			
		DAY 8		26MAR2003	7	63	106	70	0	-10	-10	81	110	82	15I	2	4
		DAY 15		03APR2003	15	69	114	76	6	-2	-4	81	112	80	15I	4	2
		DAY 22		10APR2003	22	60	118	72	-3	2	-8	66	116	78	0	8	0
		DAY 29		17APR2003	29	66	124	76	3	8	-4	75	120	88	9	12	10
		DAY 36		24APR2003	36	69	118	74	6	2	-6	75	112	80	9	4	2
		DAY 43		01MAY2003	43	66	116	70	3	0	-10	72	120	88	6	12	10
		DAY 50		08MAY2003	50	66	118	72	3	2	-8	84	114	84	18I	6	6
		DAY 50	*	12MAY2003	54	63	112	70	0	-4	-10	66	120	86	0	12	8
		FINAL			54	63	112	70	0	-4	-10	66	120	86	0	12	8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022054	SCREEN		04APR2003	-7	88	144	68				80	132	86			
		DAY 1		11APR2003	1	78	116	70				86	110	66			
		BASELINE				78	116	70				86	110	66			
		DAY 8		18APR2003	8	80	124	70	2	8	0	88	122	74	2	12	8
		DAY 15		28APR2003	18	82	124	68	4	8	-2	88	120	78	2	10	12
		DAY 22		02MAY2003	22	96	126	62	18I	10	-8	100	118	66	14	8	0
		DAY 29		12MAY2003	32	84	134	76	6	18	6	88	126	82	2	16	16
		DAY 36		16MAY2003	36	86	116	74	8	0	4	80	122	78	-6	12	12
		FINAL			36	86	116	74	8	0	4	80	122	78	-6	12	12
	E0022059	SCREEN		22APR2003	-14	64	130	70				68	126	80			
		DAY 1		06MAY2003	1	72	108	66				80	104	72			
		BASELINE				72	108	66				80	104	72			
		DAY 8		13MAY2003	8	72	100	68	0	-8	2	80	112	78	0	8	6
		DAY 15		20MAY2003	15	80	102	60	8	-6	-6	78	102	68	-2	-2	-4
		DAY 22		27MAY2003	22	64	102	70	-8	-6	4	60	102	72	-20D	-2	0
		DAY 29		03JUN2003	29	78	106	64	6	-2	-2	83	120	76	3	16	4
		DAY 36		10JUN2003	36	64	98	68	-8	-10	2	80	104	70	0	0	-2
		DAY 43		17JUN2003	43	76	98	56	4	-10	-10	72	100	66	-8	-4	-6
		DAY 43	*	20JUN2003	46	76	104	52	4	-4	-14	76	106	64	-4	2	-8
		DAY 57		08JUL2003	64	64	102	70	-8	-6	4	64	102	68	-16D	-2	-4
		FINAL			64	64	102	70	-8	-6	4	64	102	68	-16D	-2	-4
	E0022065	SCREEN		30APR2003	-7	64	100	68				68	112	78			
		DAY 1		07MAY2003	1	72	94	62				87	96	70			
		BASELINE				72	94	62				87	96	70			
		DAY 8		14MAY2003	8	76	106	62	4	12	0	92	94	70	5	-2	0
		DAY 15		21MAY2003	15	64	96	62	-8	2	0	80	92	64	-7	-4	-6
		DAY 22		28MAY2003	22	72	92	60	0	-2	-2	84	94	62	-3	-2	-8
		DAY 29		04JUN2003	29	75	92	60	3	-2	-2	90	88L	56	3	-8	-14
		DAY 36		11JUN2003	36	64	104	72	-8	10	10	64	92	62	-23D	-4	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022065	DAY 43	18JUN2003	43	81	104	60	9	10	-2	90	98	62	3	2	-8
		DAY 50	25JUN2003	50	69	98	58	-3	4	-4	78	106	64	-9	10	-6
		DAY 57	02JUL2003	57	64	110	62	-8	16	0	68	108	60	-19D	12	-10
		FINAL		57	64	110	62	-8	16	0	68	108	60	-19D	12	-10
	E0022070	SCREEN	05JUN2003	-7	68	120	64				76	120	70			
		DAY 1	12JUN2003	1	84	116	68				88	114	70			
		BASELINE			84	116	68				88	114	70			
		DAY 8	18JUN2003	7	76	130	84	-8	14	16	72	124	78	-16D	10	8
		FINAL		7	76	130	84	-8	14	16	72	124	78	-16D	10	8
	E0023001	SCREEN	24OCT2002	-22	60	120	76				60	118	78			
		DAY 1	15NOV2002	1	60	128	76				64	130	80			
		BASELINE			60	128	76				64	130	80			
		DAY 8	22NOV2002	8	60	124	70	0	-4	-6	68	104	76	4	-26D	-4
		DAY 15	29NOV2002	15	120	102	66	60I	-26D	-10	100	109	67	36I	-21D	-13
		DAY 22	06DEC2002	22	64	128	84	4	0	8	88	112	84	24I	-18	4
		DAY 29	16DEC2002	32	72	110	74	12	-18	-2	66	104	76	2	-26D	-4
		DAY 36	23DEC2002	39	65	124	64	5	-4	-12	71	138	93	7	8	13
		DAY 43	30DEC2002	46	75	131	81	15I	3	5	74			10		
		DAY 50	07JAN2003	54	64	130	84	4	2	8	72	122	76	8	-8	-4
		DAY 57	14JAN2003	61	70	120	84	10	-8	8	72	116	80	8	-14	0
		FINAL		61	70	120	84	10	-8	8	72	116	80	8	-14	0
	E0023009	SCREEN	24JAN2003	-18	82	118	76				80	120	78			
		DAY 1	11FEB2003	1	86	134	76				96	127	80			
		BASELINE			86	134	76				96	127	80			
		DAY 8	18FEB2003	8	80	128	78	-6	-6	2	80	132	76	-16D	5	-4
		DAY 15	27FEB2003	17	76	134	76	-10	0	0	80	134	74	-16D	7	-6
		DAY 22	04MAR2003	22	85	109	72	-1	-25D	-4	92	129	81	-4	2	1
		DAY 29	11MAR2003	29	80	128	74	-6	-6	-2	76	120	70	-20D	-7	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0023009	DAY 36	18MAR2003	36	80	119	70	-6	-15	-6	93	129	81	-3	2	1
		DAY 43	25MAR2003	43	87	105	73	1	-29D	-3	102	133	78	6	6	-2
		DAY 50	03APR2003	52	86	118	68	0	-16	-8	93	119	81	-3	-8	1
		DAY 57	08APR2003	57	92	109	72	6	-25D	-4	90	107	70	-6	-20D	-10
		FINAL		57	92	109	72	6	-25D	-4	90	107	70	-6	-20D	-10
	E0023028	SCREEN	16MAY2003	-13	99	129	86				79	124	80			
		DAY 1	29MAY2003	1	68	122	85				77	116	79			
		BASELINE			68	122	85				77	116	79			
		DAY 8	05JUN2003	8	75	136	85	7	14	0	86	95	70	9	-21D	-9
		DAY 15	12JUN2003	15	65	118	77	-3	-4	-8	69	104	70	-8	-12	-9
		DAY 22	19JUN2003	22	71	115	76	3	-7	-9	70	108	71	-7	-8	-8
		DAY 29	25JUN2003	28	96	121	80	28I	-1	-5	82	115	79	5	-1	0
		DAY 43	09JUL2003	42	84	114	76	16I	-8	-9	82	110	74	5	-6	-5
		DAY 50	16JUL2003	49	85	115	71	17I	-7	-14	83	112	76	6	-4	-3
		DAY 50 *	21JUL2003	54	80	141	93	12	19	8	74	130	89	-3	14	10
		FINAL		54	80	141	93	12	19	8	74	130	89	-3	14	10
	E0023033	SCREEN	30MAY2003	-6	75	133	93				78	135	96			
		DAY 1	05JUN2003	1	82	146	95				92	136	94			
		BASELINE			82	146	95				92	136	94			
		DAY 8	12JUN2003	8	90	160	98	8	14	3	85	162	108H	-7	26I	14
		FINAL		8	90	160	98	8	14	3	85	162	108H	-7	26I	14
	E0023047	SCREEN	11JUL2003	-7	73	117	75				126H	115	77			
		DAY 1	18JUL2003	1	61	130	61				89	120	84			
		BASELINE			61	130	61				89	120	84			
		DAY 8	25JUL2003	8	67	119	68	6	-11	7	76	143	69	-13	23I	-15
		DAY 15	31JUL2003	14	61	117	71	0	-13	10	76	125	81	-13	5	-3
		DAY 22	08AUG2003	22	85	139	95	24I	9	34I	87	151	95	-2	31I	11
		DAY 29	15AUG2003	29	69	143	82	8	13	21	72	148	86	-17D	28I	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0023047	DAY 36	21AUG2003	35	78	131	85	17I	1	24	97	142	80	8	22I	-4
		DAY 43	29AUG2003	43	123H	123	78	62I	-7	17	104	121	72	15I	1	-12
		DAY 50	05SEP2003	50	85	129	82	24I	-1	21	92	121	77	3	1	-7
		DAY 57	12SEP2003	57	80	138	83	19I	8	22	120	118	81	31I	-2	-3
		FINAL		57	80	138	83	19I	8	22	120	118	81	31I	-2	-3
	E0025001	SCREEN	25MAR2003	-7	68	130	72				84	126	78			
		DAY 1	01APR2003	1	80	136	88				76	130	90			
		BASELINE			80	136	88				76	130	90			
		DAY 8	10APR2003	10	64	135	80	-16D	-1	-8	80	130	80	4	0	-10
		DAY 15	16APR2003	16	72	110	62	-8	-26D	-26D	76	112	70	0	-18	-20D
		DAY 22	23APR2003	23	76	130	78	-4	-6	-10	80	120	70	4	-10	-20D
		FINAL		23	76	130	78	-4	-6	-10	80	120	70	4	-10	-20D
	E0026012	SCREEN	05FEB2003	-15	57	134	86				53	145	90			
		DAY 1	20FEB2003	1	63	133	86				65	146	82			
		BASELINE			63	133	86				65	146	82			
		DAY 8	27FEB2003	8	71	123	74	8	-10	-12	73	134	87	8	-12	5
		DAY 15	06MAR2003	15	59	123	71	-4	-10	-15	53	136	92	-12	-10	10
		DAY 22	13MAR2003	22	68	146	80	5	13	-6	74	154	86	9	8	4
		DAY 29	20MAR2003	29	68	123	79	5	-10	-7	75	134	93	10	-12	11
		DAY 36	27MAR2003	36	72	126	83	9	-7	-3	72	133	89	7	-13	7
		DAY 43	03APR2003	43	72	140	72	9	7	-14	74	138	72	9	-8	-10
		DAY 50	10APR2003	50	69	128	80	6	-5	-6	77	122	84	12	-24D	2
		DAY 57	17APR2003	57	68	116	71	5	-17	-15	67	121	84	2	-25D	2
		FINAL		57	68	116	71	5	-17	-15	67	121	84	2	-25D	2
	E0026020	SCREEN	28MAR2003	-4	82	161	84				85	155	67			
		DAY 1	01APR2003	1	74	116	76				72	131	63			
		BASELINE			74	116	76				72	131	63			
		DAY 8	08APR2003	8	87	115	67	13	-1	-9	90	131	61	18I	0	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0026020	DAY 15	15APR2003	15	73	137	74	-1	21I	-2	72	146	63	0	15	0
		DAY 22	22APR2003	22	70	160	71	-4	44I	-5	78	110	74	6	-21D	11
		FINAL		22	70	160	71	-4	44I	-5	78	110	74	6	-21D	11
	E0028001	SCREEN	07OCT2002	-3	72	110	80				72	118	80			
		DAY 1	10OCT2002	1	74	128	88				73	122	82			
		BASELINE			74	128	88				73	122	82			
		DAY 8	16OCT2002	7	70	130	90	-4	2	2	72	130	90	-1	8	8
		DAY 15	23OCT2002	14	72	136	90	-2	8	2	82	140	90	9	18	8
		DAY 22	29OCT2002	20	70	128	80	-4	0	-8	72	122	90	-1	0	8
		DAY 29	05NOV2002	27	74	130	102	0	2	14	88	140	110H	15I	18	28
		DAY 36	12NOV2002	34	70	122	88	-4	-6	0	78	126	88	5	4	6
		DAY 43	19NOV2002	41	78	134	94	4	6	6	84	150	104	11	28I	22
		DAY 50	26NOV2002	48	82	120	92	8	-8	4	92	118	98	19I	-4	16
		DAY 57	03DEC2002	55	90	138	98	16I	10	10	94	116	96	21I	-6	14
		FINAL		55	90	138	98	16I	10	10	94	116	96	21I	-6	14
	E0028003	SCREEN	23SEP2002	-7	58	112	88				70	116	90			
		DAY 1	30SEP2002	1	60	122	80				64	120	80			
		BASELINE			60	122	80				64	120	80			
		DAY 8	07OCT2002	8	73	122	80	13	0	0	76	118	80	12	-2	0
		DAY 15	16OCT2002	17	72	130	90	12	8	10	71	132	90	7	12	10
		DAY 22	22OCT2002	23	66	130	90	6	8	10	78	120	80	14	0	0
		DAY 29	29OCT2002	30	60	134	78	0	12	-2	72	138	78	8	18	-2
		DAY 36	07NOV2002	39	64	142	86	4	20I	6	74	142	88	10	22I	8
		DAY 43	12NOV2002	44	66	130	80	6	8	0	68	128	80	4	8	0
		DAY 50	19NOV2002	51	66	130	92	6	8	12	76	112	84	12	-8	4
		DAY 57	26NOV2002	58	72	132	82	12	10	2	72	134	76	8	14	-4
		FINAL		58	72	132	82	12	10	2	72	134	76	8	14	-4
	E0028010	SCREEN	15OCT2002	-21	60	118	78				62	118	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028010	DAY 1	05NOV2002	1	70	104	60				70	118	68			
		BASELINE			70	104	60				70	118	68			
		DAY 8	12NOV2002	8	60	102	70	-10	-2	10	62	110	70	-8	-8	2
		DAY 15	19NOV2002	15	74	112	68	4	8	8	78	98	70	8	-20D	2
		DAY 22	25NOV2002	21	70	104	58	0	0	-2	80	112	84	10	-6	16
		DAY 29	03DEC2002	29	68	114	68	-2	10	8	80	128	68	10	10	0
		DAY 36	10DEC2002	36	64	110	64	-6	6	4	76	104	68	6	-14	0
		DAY 43	17DEC2002	43	74	114	60	4	10	0	72	128	72	2	10	4
		DAY 50	23DEC2002	49	76	98	60	6	-6	0	84	102	70	14	-16	2
		DAY 57	31DEC2002	57	60	118	68	-10	14	8	64	112	66	-6	-6	-2
		FINAL		57	60	118	68	-10	14	8	64	112	66	-6	-6	-2
	E0028011	SCREEN	25NOV2002	-10	76	130	82				80	130	70			
		DAY 1	05DEC2002	1	72	136	78				88	128	80			
		BASELINE			72	136	78				88	128	80			
		DAY 8	12DEC2002	8	74	136	86	2	0	8	86	122	90	-2	-6	10
		DAY 15	19DEC2002	15	68	110	70	-4	-26D	-8	76	118	80	-12	-10	0
		DAY 22	26DEC2002	22	70	122	88	-2	-14	10	78	118	90	-10	-10	10
		DAY 29	02JAN2003	29	72	128	82	0	-8	4	80	118	78	-8	-10	-2
		DAY 36	09JAN2003	36	78	116	88	6	-20D	10	84	112	90	-4	-16	10
		DAY 43	16JAN2003	43	66	130	80	-6	-6	2	86	120	90	-2	-8	10
		DAY 50	23JAN2003	50	76	118	86	4	-18	8	94	124	98	6	-4	18
		DAY 57	30JAN2003	57	82	132	76	10	-4	-2	98	128	84	10	0	4
		FINAL		57	82	132	76	10	-4	-2	98	128	84	10	0	4
	E0028030	SCREEN	26FEB2003	-6	60	122	82				84	120	80			
		DAY 1	04MAR2003	1	56	118	86				76	114	92			
		BASELINE			56	118	86				76	114	92			
		DAY 8	11MAR2003	8	74	100	78	18I	-18	-8	70	106	94	-6	-8	2
		DAY 15	18MAR2003	15	80	118	76	24I	0	-10	88	112	78	12	-2	-14
		DAY 22	25MAR2003	22	84	116	80	28I	-2	-6	80	112	78	4	-2	-14

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028030	DAY 29	01APR2003	29	68	112	72	12	-6	-14	92	106	74	16I	-8	-18
		DAY 36	08APR2003	36	64	120	76	8	2	-10	80	106	72	4	-8	-20D
		DAY 43	17APR2003	45	72	122	72	16I	4	-14	88	100	72	12	-14	-20D
		DAY 50	22APR2003	50	60	120	64	4	2	-22D	84	110	68	8	-4	-24D
		DAY 57	30APR2003	58	70	110	78	14	-8	-8	70	110	86	-6	-4	-6
		FINAL		58	70	110	78	14	-8	-8	70	110	86	-6	-4	-6
	E0028031	SCREEN	06MAR2003	-5	92	126	84				84	124	86			
		DAY 1	11MAR2003	1	84	122	74				88	108	74			
		BASELINE			84	122	74				88	108	74			
		DAY 8	18MAR2003	8	88	118	84	4	-4	10	96	108	76	8	0	2
		DAY 15	25MAR2003	15	92	130	82	8	8	8	96	132	86	8	24I	12
		DAY 36	17APR2003	38	96	130	76	12	8	2	100	124	74	12	16	0
		FINAL		38	96	130	76	12	8	2	100	124	74	12	16	0
	E0028047	SCREEN	08JUL2003	-6	78	170	120H				74	160	120H			
		DAY 1	14JUL2003	1	64	130	100				60	130	100			
		BASELINE			64	130	100				60	130	100			
		DAY 8	21JUL2003	8	68	140	100	4	10	0	72	140	115H	12	10	15
		DAY 15	29JUL2003	16	66	148	100	2	18	0	78	160	108H	18I	30I	8
		DAY 22	05AUG2003	23	62	140	94	-2	10	-6	62	162	110H	2	32I	10
		DAY 29	12AUG2003	30	61	168	101	-3	38I	1	60	168	112H	0	38I	12
		DAY 36	19AUG2003	37	62	160	110H	-2	30I	10	78	160	110H	18I	30I	10
		DAY 43	26AUG2003	44	60	140	100	-4	10	0	60	140	100	0	10	0
		DAY 50	02SEP2003	51	62	150	110H	-2	20I	10	62	148	110H	2	18	10
		DAY 57	09SEP2003	58	70	162	108H	6	32I	8	66	144	100	6	14	0
		FINAL		58	70	162	108H	6	32I	8	66	144	100	6	14	0
	E0029014	SCREEN	28JAN2003	-7	60	102	60				84	106	62			
		DAY 1	04FEB2003	1	60	90L	60				72	100	50L			
		BASELINE			60	90L	60				72	100	50L			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0029014	DAY 8		11FEB2003	8	60	114	80	0	24I	20	72	100	76	0	0	26
		DAY 15		18FEB2003	15	64	104	64	4	14	4	68	94	62	-4	-6	12
		DAY 22		25FEB2003	22	68	118	64	8	28I	4	64	118	64	-8	18	14
		DAY 29		06MAR2003	31	76	96	58	16I	6	-2	76	104	64	4	4	14
		DAY 36		11MAR2003	36	68	126	76	8	36I	16	76	134	84	4	34I	34I
		DAY 43		20MAR2003	45	72	138	76	12	48I	16	84	122	74	12	22I	24
		DAY 50		27MAR2003	52	72	120	68	12	30I	8	80	110	70	8	10	20
		DAY 57		01APR2003	57	56	114	70	-4	24I	10	60	108	64	-12	8	14
		FINAL			57	56	114	70	-4	24I	10	60	108	64	-12	8	14
	E0029033	SCREEN		27MAY2003	-6	60	110	70				64	100	80			
		DAY 1		02JUN2003	1	60	104	70				72	118	80			
		BASELINE				60	104	70				72	118	80			
		DAY 8		09JUN2003	8	64	114	68	4	10	-2	76	144	78	4	26I	-2
		DAY 15		16JUN2003	15	60	118	70	0	14	0	76	114	76	4	-4	-4
		DAY 22		23JUN2003	22	64	104	68	4	0	-2	76	110	80	4	-8	0
		DAY 29		30JUN2003	29	64	118	70	4	14	0	68	136	80	-4	18	0
		FINAL			29	64	118	70	4	14	0	68	136	80	-4	18	0
	E0029039	SCREEN		10JUL2003	-5	60	100	70				60	90L	70			
		DAY 1		15JUL2003	1	56	100	64				64	90L	60			
		BASELINE				56	100	64				64	90L	60			
		DAY 8		23JUL2003	9	64	100	70	8	0	6	64	90L	70	0	0	10
		DAY 15		28JUL2003	14	88	98	60	32I	-2	-4	84	92	58	20I	2	-2
		FINAL			14	88	98	60	32I	-2	-4	84	92	58	20I	2	-2
	E0030003	SCREEN		03DEC2002	-13	72	122	84				80	110	80			
		DAY 1		16DEC2002	1	68	130	78				80	118	70			
		BASELINE				68	130	78				80	118	70			
		DAY 8		23DEC2002	8	60	130	70	-8	0	-8	60	126	70	-20D	8	0
		DAY 8	*	24DEC2002	9	60	120	70	-8	-10	-8	72	122	74	-8	4	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0030003	FINAL		9	60	120	70	-8	-10	-8	72	122	74	-8	4	4
	E0030009	SCREEN	10JAN2003	-13	72	136	86				80	134	90			
		DAY 1	23JAN2003	1	64	144	90				64	128	94			
		BASELINE			64	144	90				64	128	94			
		DAY 8	29JAN2003	7	60	126	78	-4	-18	-12	72	130	80	8	2	-14
		DAY 15	07FEB2003	16	56	126	72	-8	-18	-18	60	122	76	-4	-6	-18
		DAY 36	27FEB2003	36	64	122	74	0	-22D	-16	64	120	80	0	-8	-14
		DAY 43	06MAR2003	43	68	126	80	4	-18	-10	76	128	80	12	0	-14
		DAY 50	12MAR2003	49	68	134	80	4	-10	-10	76	126	80	12	-2	-14
		DAY 57	19MAR2003	56	64	140	80	0	-4	-10	72	116	80	8	-12	-14
		FINAL		56	64	140	80	0	-4	-10	72	116	80	8	-12	-14
	E0030016	SCREEN	21FEB2003	-10	68	120	62				80	114	70			
		DAY 1	03MAR2003	1	76	126	78				76	112	76			
		BASELINE			76	126	78				76	112	76			
		DAY 8	10MAR2003	8	84	124	80	8	-2	2	88	118	84	12	6	8
		DAY 15	17MAR2003	15	84	130	80	8	4	2	88	116	80	12	4	4
		DAY 22	25MAR2003	23	80	124	78	4	-2	0	96	120	76	20I	8	0
		DAY 29	02APR2003	31	88	138	80	12	12	2	88	120	80	12	8	4
		DAY 36	09APR2003	38	92	120	80	16I	-6	2	96	112	82	20I	0	6
		DAY 50	22APR2003	51	84	128	76	8	2	-2	88	120	80	12	8	4
		FINAL		51	84	128	76	8	2	-2	88	120	80	12	8	4
	E0030021	SCREEN	13MAY2003	-7	60	100	60				80	100	70			
		DAY 1	20MAY2003	1	68	100	64				80	102	70			
		BASELINE			68	100	64				80	102	70			
		DAY 8	27MAY2003	8	68	98	68	0	-2	4	80	100	72	0	-2	2
		DAY 15	03JUN2003	15	60	132	74	-8	32I	10	80	124	70	0	22I	0
		DAY 22	10JUN2003	22	68	131	70	0	31I	6	70	128	71	-10	26I	1
		DAY 29	17JUN2003	29	60	111	70	-8	11	6	80	108	70	0	6	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0030021	FINAL		29	60	111	70	-8	11	6	80	108	70	0	6	0
	E0031001	SCREEN	14NOV2002	-7	78	126	88				82	122	86			
		DAY 1	21NOV2002	1	68	124	80				76	126	84			
		BASELINE			68	124	80				76	126	84			
		DAY 8	27NOV2002	7	58	124	68	-10	0	-12	64	124	74	-12	-2	-10
		DAY 15	05DEC2002	15	64	126	74	-4	2	-6	76	128	74	0	2	-10
		DAY 22	11DEC2002	21	66	126	80	-2	2	0	60	128	82	-16D	2	-2
		DAY 29	20DEC2002	30	62	118	64	-6	-6	-16	66	114	66	-10	-12	-18
		FINAL		30	62	118	64	-6	-6	-16	66	114	66	-10	-12	-18
	E0031017	SCREEN	25MAR2003	-7	60	112	68				66	118	74			
		DAY 1	01APR2003	1	69	124	72				76	128	74			
		BASELINE			69	124	72				76	128	74			
		DAY 8	07APR2003	7	70	126	72	1	2	0	66	130	74	-10	2	0
		DAY 15	15APR2003	15	88	129	68	19I	5	-4	84	132	74	8	4	0
		DAY 22	22APR2003	22	70	120	70	1	-4	-2	66	126	74	-10	-2	0
		DAY 29	29APR2003	29	70	126	72	1	2	0	72	128	76	-4	0	2
		FINAL		29	70	126	72	1	2	0	72	128	76	-4	0	2
	E0031023	SCREEN	21APR2003	-8	72	136	84				76	140	86			
		DAY 1	29APR2003	1	74	140	82				78	142	84			
		BASELINE			74	140	82				78	142	84			
		DAY 8	07MAY2003	9	80	140	80	6	0	-2	78	144	82	0	2	-2
		DAY 15	13MAY2003	15	84	142	82	10	2	0	88	146	86	10	4	2
		DAY 22	20MAY2003	22	86	144	80	12	4	-2	88	146	84	10	4	0
		DAY 29	27MAY2003	29	80	142	84	6	2	2	86	148	88	8	6	4
		DAY 36	04JUN2003	37	96	130	90	22I	-10	8	100	140	90	22I	-2	6
		DAY 43	10JUN2003	43	72	134	84	-2	-6	2	86	140	90	8	-2	6
		DAY 50	17JUN2003	50	74	136	84	0	-4	2	76	140	90	-2	-2	6
		DAY 57	24JUN2003	57	78	140	78	4	0	-4	86	144	88	8	2	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0031023	FINAL		57	78	140	78	4	0	-4	86	144	88	8	2	4
	E0033001	SCREEN	23DEC2002	-17	68	120	80				80	120	88			
		DAY 1	09JAN2003	1	80	120	72				86	120	76			
		BASELINE			80	120	72				86	120	76			
		DAY 8	16JAN2003	8	64	104	70	-16D	-16	-2	76	108	84	-10	-12	8
		DAY 15	23JAN2003	15	68	120	78	-12	0	6	76	116	86	-10	-4	10
		DAY 22	30JAN2003	22	64	110	80	-16D	-10	8	76	120	82	-10	0	6
		FINAL		22	64	110	80	-16D	-10	8	76	120	82	-10	0	6
	E0033010	SCREEN	22JAN2003	-13	72	110	70				84	110	72			
		DAY 1	04FEB2003	1	76	110	68				80	96	62			
		BASELINE			76	110	68				80	96	62			
		DAY 8	11FEB2003	8	76	112	80	0	2	12	84	110	76	4	14	14
		DAY 15	20FEB2003	17	76	104	70	0	-6	2	88	100	70	8	4	8
		DAY 22	27FEB2003	24	68	100	68	-8	-10	0	72	90L	68	-8	-6	6
		DAY 29	04MAR2003	29	64	110	74	-12	0	6	76	100	76	-4	4	14
		DAY 36	14MAR2003	39	76	102	68	0	-8	0	76	108	70	-4	12	8
		DAY 50	26MAR2003	51	60	100	60	-16D	-10	-8	76	90L	68	-4	-6	6
		FINAL		51	60	100	60	-16D	-10	-8	76	90L	68	-4	-6	6
	E0033014	SCREEN	12MAR2003	-7	76	102	78				80	110	80			
		DAY 1	19MAR2003	1	84	110	86				84	100	82			
		BASELINE			84	110	86				84	100	82			
		DAY 8	26MAR2003	8	80	100	76	-4	-10	-10	92	90L	76	8	-10	-6
		DAY 15	03APR2003	16	84	90L	72	0	-20D	-14	92	100	80	8	0	-2
		DAY 22	11APR2003	24	88	110	82	4	0	-4	92	98	78	8	-2	-4
		DAY 29	16APR2003	29	72	104	82	-12	-6	-4	84	100	86	0	0	4
		DAY 36	21APR2003	34	72	90L	74	-12	-20D	-12	76	100	80	-8	0	-2
		FINAL		34	72	90L	74	-12	-20D	-12	76	100	80	-8	0	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0035002	SCREEN	14NOV2002	-7	80	106	76				84	108	78			
		DAY 1	21NOV2002	1	62	110	86				74	112	80			
		BASELINE			62	110	86				74	112	80			
		DAY 8	27NOV2002	7	80	106	72	18I	-4	-14	86	106	78	12	-6	-2
		DAY 15	05DEC2002	15	60	102	70	-2	-8	-16	70	110	70	-4	-2	-10
		DAY 22	12DEC2002	22	68	108	64	6	-2	-22D	72	110	72	-2	-2	-8
		FINAL		22	68	108	64	6	-2	-22D	72	110	72	-2	-2	-8
	E0035011	SCREEN	09JAN2003	-26	80	122	74				88	124	80			
		DAY 1	04FEB2003	1	82	124	88				88	126	86			
		BASELINE			82	124	88				88	126	86			
		DAY 8	11FEB2003	8	82	124	84	0	0	-4	88	126	84	0	0	-2
		DAY 15	18FEB2003	15	80	124	78	-2	0	-10	88	128	82	0	2	-4
		DAY 22	25FEB2003	22	82	120	82	0	-4	-6	88	122	80	0	-4	-6
		DAY 29	04MAR2003	29	80	118	76	-2	-6	-12	88	122	80	0	-4	-6
		DAY 36	11MAR2003	36	68	132	80	-14	8	-8	72	136	84	-16D	10	-2
		DAY 43	18MAR2003	43	76	132	78	-6	8	-10	78	134	80	-10	8	-6
		DAY 50	25MAR2003	50	76	124	74	-6	0	-14	80	128	78	-8	2	-8
		DAY 57	01APR2003	57	80	128	78	-2	4	-10	82	130	82	-6	4	-4
		FINAL		57	80	128	78	-2	4	-10	82	130	82	-6	4	-4
	E0035020	SCREEN	11APR2003	-7	68	100	72				72	102	78			
		DAY 1	18APR2003	1	64	102	72				68	104	76			
		BASELINE			64	102	72				68	104	76			
		DAY 8	25APR2003	8	72	98	62	8	-4	-10	78	102	68	10	-2	-8
		DAY 15	01MAY2003	14	76	100	64	12	-2	-8	84	106	68	16I	2	-8
		DAY 22	09MAY2003	22	78	102	70	14	0	-2	80	104	78	12	0	2
		DAY 29	15MAY2003	28	78	102	64	14	0	-8	82	102	78	14	-2	2
		DAY 36	23MAY2003	36	76	100	68	12	-2	-4	84	104	72	16I	0	-4
		DAY 43	30MAY2003	43	80	100	74	16I	-2	2	88	102	76	20I	-2	0
		DAY 50	06JUN2003	50	76	104	70	12	2	-2	80	108	74	12	4	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0035020	DAY 57	13JUN2003	57	70	102	76	6	0	4	74	104	80	6	0	4
		FINAL		57	70	102	76	6	0	4	74	104	80	6	0	4
	E0037004	SCREEN	06FEB2003	-7	72	130	100				72	130	96			
		DAY 1	13FEB2003	1	72	128	74				68	128	76			
		BASELINE			72	128	74				68	128	76			
		DAY 8	21FEB2003	9	64	127	83	-8	-1	9	76	119	90	8	-9	14
		DAY 15	27FEB2003	15	80	103	80	8	-25D	6	76	120	85	8	-8	9
		DAY 22	06MAR2003	22	76	112	68	4	-16	-6	76	112	70	8	-16	-6
		DAY 29	13MAR2003	29	70	118	80	-2	-10	6	78	120	90	10	-8	14
		DAY 36	20MAR2003	36	76	120	80	4	-8	6	96	120	70	28I	-8	-6
		DAY 43	28MAR2003	44	64	120	78	-8	-8	4	80	120	80	12	-8	4
		DAY 50	04APR2003	51	68	120	80	-4	-8	6	80	117	80	12	-11	4
		DAY 57	10APR2003	57	72	120	90	0	-8	16	72	120	90	4	-8	14
		FINAL		57	72	120	90	0	-8	16	72	120	90	4	-8	14
	E0039007	SCREEN	25NOV2002	-9	68	118	76				70	120	72			
		DAY 1	04DEC2002	1	76	126	88				88	128	86			
		BASELINE			76	126	88				88	128	86			
		DAY 8	11DEC2002	8	80	132	88	4	6	0	96	124	94	8	-4	8
		DAY 15	18DEC2002	15	92	118	80	16I	-8	-8	88	112	88	0	-16	2
		DAY 22	23DEC2002	20	80	122	88	4	-4	0	96	118	90	8	-10	4
		DAY 29	30DEC2002	27	72	114	86	-4	-12	-2	76	118	90	-12	-10	4
		DAY 36	08JAN2003	36	80	116	84	4	-10	-4	80	126	96	-8	-2	10
		DAY 43	15JAN2003	43	80	110	80	4	-16	-8	88	120	88	0	-8	2
		DAY 50	22JAN2003	50	80	108	80	4	-18	-8	86	110	86	-2	-18	0
		DAY 57	29JAN2003	57	72	116	82	-4	-10	-6	84	124	90	-4	-4	4
		FINAL		57	72	116	82	-4	-10	-6	84	124	90	-4	-4	4
	E0039022	SCREEN	04FEB2003	-21	88	130	68				85	132	80			
		DAY 1	25FEB2003	1	64	128	80				68	132	86			

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT103.SAS
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039022	BASELINE			64	128	80				68	132	86			
		DAY 8	06MAR2003	10	72	112	70	8	-16	-10	74	102	78	6	-30D	-8
		DAY 15	11MAR2003	15	76	118	78	12	-10	-2	80	116	86	12	-16	0
		DAY 22	18MAR2003	22	80	126	78	16I	-2	-2	82	124	88	14	-8	2
		DAY 29	25MAR2003	29	84	110	60	20I	-18	-20D	80	116	80	12	-16	-6
		DAY 36	01APR2003	36	76	120	68	12	-8	-12	74	122	88	6	-10	2
		DAY 43	07APR2003	42	68	114	76	4	-14	-4	63	116	86	-5	-16	0
		DAY 50	15APR2003	50	68	102	68	4	-26D	-12	68	108	70	0	-24D	-16
		DAY 57	24APR2003	59	60	106	66	-4	-22D	-14	64	102	70	-4	-30D	-16
		FINAL		59	60	106	66	-4	-22D	-14	64	102	70	-4	-30D	-16
	E0039031	SCREEN	05MAR2003	-19	82	100	70				80	98	74			
		DAY 1	24MAR2003	1	74	98	70				76	94	64			
		BASELINE			74	98	70				76	94	64			
		DAY 8	31MAR2003	8	88	104	70	14	6	0	100	94	72	24I	0	8
		DAY 15	07APR2003	15	92	100	60	18I	2	-10	90	98	60	14	4	-4
		DAY 22	15APR2003	23	82	102	60	8	4	-10	84	112	80	8	18	16
		DAY 29	21APR2003	29	82	104	70	8	6	0	84	106	80	8	12	16
		DAY 36	28APR2003	36	92	104	74	18I	6	4	84	108	80	8	14	16
		DAY 43	05MAY2003	43	90	104	70	16I	6	0	96	108	80	20I	14	16
		DAY 50	13MAY2003	51	88	110	70	14	12	0	92	114	78	16I	20I	14
		DAY 57	20MAY2003	58	72	106	66	-2	8	-4	80	108	74	4	14	10
		FINAL		58	72	106	66	-2	8	-4	80	108	74	4	14	10
	E0039037	SCREEN	26MAR2003	-21	76	124	74				92	122	88			
		DAY 1	16APR2003	1	84	126	78				80	122	78			
		BASELINE			84	126	78				80	122	78			
		DAY 8	23APR2003	8	88	132	72	4	6	-6	96	136	80	16I	14	2
		DAY 15	01MAY2003	16	84	128	76	0	2	-2	96	124	88	16I	2	10
		DAY 22	07MAY2003	22	72	104	78	-12	-22D	0	72	102	76	-8	-20D	-2
		DAY 29	15MAY2003	30	88	122	88	4	-4	10	96	116	90	16I	-6	12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039037	DAY 36	21MAY2003	36	80	128	80	-4	2	2	88	130	88	8	8	10
		DAY 43	28MAY2003	43	72	120	76	-12	-6	-2	74	120	74	-6	-2	-4
		DAY 50	05JUN2003	51	96	126	70	12	0	-8	96	124	78	16I	2	0
		DAY 57	12JUN2003	58	76	128	88	-8	2	10	82	132	92	2	10	14
		FINAL		58	76	128	88	-8	2	10	82	132	92	2	10	14
	E0039038	SCREEN	26MAR2003	-28	80	126	90				82	132	86			
		DAY 1	23APR2003	1	60	116	82				64	120	84			
		BASELINE			60	116	82				64	120	84			
		DAY 8	30APR2003	8	72	116	88	12	0	6	78	120	92	14	0	8
		DAY 22	15MAY2003	23	72	106	74	12	-10	-8	76	110	70	12	-10	-14
		DAY 29	21MAY2003	29	76	110	70	16I	-6	-12	80	116	80	16I	-4	-4
		DAY 36	29MAY2003	37	76	136	98	16I	20I	16	88	118	90	24I	-2	6
		DAY 57	20JUN2003	59	68	110	78	8	-6	-4	76	116	82	12	-4	-2
		FINAL		59	68	110	78	8	-6	-4	76	116	82	12	-4	-2
	E0039047	SCREEN	12MAY2003	-7	84	134	86				92	120	82			
		DAY 1	19MAY2003	1	70	134	88				84	128	90			
		BASELINE			70	134	88				84	128	90			
		DAY 8	27MAY2003	9	76	148	86	6	14	-2	88	130	80	4	2	-10
		DAY 15	03JUN2003	16	63	142	96	-7	8	8	76	128	98	-8	0	8
		DAY 22	09JUN2003	22	64	144	90	-6	10	2	80	130	92	-4	2	2
		DAY 29	16JUN2003	29	80	126	60	10	-8	-28D	78	130	88	-6	2	-2
		DAY 36	23JUN2003	36	62	124	86	-8	-10	-2	72	130	90	-12	2	0
		DAY 43	30JUN2003	43	64	130	86	-6	-4	-2	74	116	84	-10	-12	-6
		DAY 50	07JUL2003	50	65	134	88	-5	0	0	80	128	96	-4	0	6
		DAY 57	14JUL2003	57	76	142	86	6	8	-2	68	126	90	-16D	-2	0
		FINAL		57	76	142	86	6	8	-2	68	126	90	-16D	-2	0
	E0039059	SCREEN	03JUL2003	-8	68	122	70				68	134	72			
		DAY 1	11JUL2003	1	60	114	68				68	124	78			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039059	BASELINE			60	114	68				68	124	78			
		DAY 8	18JUL2003	8	76	120	68	16I	6	0	80	126	70	12	2	-8
		DAY 15	25JUL2003	15	73	116	70	13	2	2	74	116	80	6	-8	2
		DAY 22	01AUG2003	22	60	118	90	0	4	22	70	106	80	2	-18	2
		DAY 29	07AUG2003	28	60	106	60	0	-8	-8	68	110	70	0	-14	-8
		DAY 36	15AUG2003	36	60	120	78	0	6	10	69	108	80	1	-16	2
		DAY 43	21AUG2003	42	64	122	80	4	8	12	64	122	78	-4	-2	0
		DAY 50	29AUG2003	50	60	114	60	0	0	-8	72	120	60	4	-4	-18
		DAY 57	05SEP2003	57	56	110	70	-4	-4	2	60	118	74	-8	-6	-4
		FINAL		57	56	110	70	-4	-4	2	60	118	74	-8	-6	-4
	E0041007	SCREEN	05MAR2003	-8	60	110	68				78	124	88			
		DAY 1	13MAR2003	1	80	130	60				88	140	78			
		BASELINE			80	130	60				88	140	78			
		DAY 8	20MAR2003	8	79	120	60	-1	-10	0	80	140	70	-8	0	-8
		DAY 15	27MAR2003	15	82	130	70	2	0	10	88	140	80	0	0	2
		DAY 22	03APR2003	22	70	110	60	-10	-20D	0	72	120	70	-16D	-20D	-8
		DAY 29	10APR2003	29	62	112	70	-18D	-18	10	66	110	70	-22D	-30D	-8
		DAY 36	17APR2003	36	68	120	82	-12	-10	22	80	116	84	-8	-24D	6
		DAY 43	25APR2003	44	76	110	78	-4	-20D	18	80	112	78	-8	-28D	0
		DAY 50	01MAY2003	50	66	117	76	-14	-13	16	70	118	80	-18D	-22D	2
		DAY 57	08MAY2003	57	72	114	76	-8	-16	16	80	120	78	-8	-20D	0
		FINAL		57	72	114	76	-8	-16	16	80	120	78	-8	-20D	0
	E0041012	SCREEN	05JUN2003	-14	82	126	92				80	130	96			
		DAY 1	19JUN2003	1	82	150	90				86	156	110H			
		BASELINE			82	150	90				86	156	110H			
		DAY 8	26JUN2003	8	88	148	88	6	-2	-2	90	148	90	4	-8	-20D
		DAY 15	03JUL2003	15	86	148	86	4	-2	-4	86	148	88	0	-8	-22D
		DAY 22	10JUL2003	22	80	140	80	-2	-10	-10	84	142	78	-2	-14	-32D
		DAY 29	17JUL2003	29	82	138	80	0	-12	-10	84	136	80	-2	-20D	-30D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0041012	DAY 36	24JUL2003	36	84	132	92	2	-18	2	84	130	86	-2	-26D	-24D
		DAY 43	31JUL2003	43	88	134	88	6	-16	-2	86	132	84	0	-24D	-26D
		DAY 50	07AUG2003	50	78	152	94	-4	2	4	76	150	90	-10	-6	-20D
		DAY 57	14AUG2003	57	76	160	110H	-6	10	20	78	150	112H	-8	-6	2
		FINAL		57	76	160	110H	-6	10	20	78	150	112H	-8	-6	2
PLACEBO (BIPOLAR II)	E0001004	SCREEN	23APR2003	-8	60	90L	60				60	90L	60			
		DAY 1	01MAY2003	1	60	95	70				65	100	70			
		BASELINE			60	95	70				65	100	70			
		DAY 8	09MAY2003	9	60	120	70	0	25I	0	62	120	75	-3	20I	5
		DAY 15	16MAY2003	16	62	120	70	2	25I	0	65	125	75	0	25I	5
		DAY 22	23MAY2003	23	60	110	65	0	15	-5	62	110	70	-3	10	0
		DAY 29	29MAY2003	29	62	120	75	2	25I	5	63	120	80	-2	20I	10
		DAY 36	06JUN2003	37	62	110	70	2	15	0	63	115	75	-2	15	5
		DAY 43	12JUN2003	43	80	110	70	20I	15	0	80	100	70	15I	0	0
		DAY 50	20JUN2003	51	62	110	80	2	15	10	64	115	80	-1	15	10
		DAY 57	02JUL2003	63	82	98	70	22I	3	0	82	98	70	17I	-2	0
		FINAL		63	82	98	70	22I	3	0	82	98	70	17I	-2	0
	E0005023	SCREEN	28JAN2003	-8	76	106	68				80	108	70			
		DAY 1	05FEB2003	1	72	100	70				72	104	74			
		BASELINE			72	100	70				72	104	74			
		DAY 8	13FEB2003	9	80	100	64	8	0	-6	80	100	60	8	-4	-14
		DAY 15	20FEB2003	16	96	104	64	24I	4	-6	100	100	62	28I	-4	-12
		DAY 22	27FEB2003	23	72	100	70	0	0	0	72	100	64	0	-4	-10
		DAY 29	06MAR2003	30	72	100	70	0	0	0	72	100	70	0	-4	-4
		DAY 36	13MAR2003	37	80	100	70	8	0	0	80	96	68	8	-8	-6
		DAY 43	18MAR2003	42	80	100	60	8	0	-10	80	100	60	8	-4	-14
		DAY 50	26MAR2003	50	80	100	60	8	0	-10	80	90L	60	8	-14	-14
		DAY 57	01APR2003	56	80	90L	60	8	-10	-10	80	90L	60	8	-14	-14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0005023	FINAL		56	80	90L	60	8	-10	-10	80	90L	60	8	-14	-14
	E0005034	SCREEN	08APR2003	-7	60	95	60				60	107	63			
		DAY 1	15APR2003	1	68	100	60				68	100	60			
		BASELINE			68	100	60				68	100	60			
		DAY 8	23APR2003	9	68	100	70	0	0	10	68	90L	60	0	-10	0
		DAY 15	01MAY2003	17	76	118	70	8	18	10	68	122	80	0	22I	20
		DAY 22	06MAY2003	22	68	110	70	0	10	10	68	100	60	0	0	0
		DAY 29	13MAY2003	29	64	108	64	-4	8	4	64	100	60	-4	0	0
		DAY 36	22MAY2003	38	60	120	80	-8	20I	20	60	110	70	-8	10	10
		DAY 43	28MAY2003	44	60	120	70	-8	20I	10	60	110	70	-8	10	10
		DAY 50	05JUN2003	52	80	110	70	12	10	10	80	110	70	12	10	10
		DAY 57	09JUN2003	56	80	110	70	12	10	10	74	110	70	6	10	10
		FINAL		56	80	110	70	12	10	10	74	110	70	6	10	10
	E0005041	SCREEN	17JUN2003	-7	76	130	80				72	132	80			
		DAY 1	24JUN2003	1	76	102	72				68	110	68			
		BASELINE			76	102	72				68	110	68			
		DAY 8	01JUL2003	8	76	114	76	0	12	4	76	114	78	8	4	10
		DAY 15	08JUL2003	15	64	110	62	-12	8	-10	64	110	64	-4	0	-4
		DAY 22	16JUL2003	23	68	130	82	-8	28I	10	64	128	84	-4	18	16
		DAY 29	22JUL2003	29	64	118	76	-12	16	4	68	122	80	0	12	12
		DAY 36	28JUL2003	35	68	124	74	-8	22I	2	72	120	76	4	10	8
		DAY 43	04AUG2003	42	76	116	68	0	14	-4	72	120	74	4	10	6
		DAY 50	11AUG2003	49	76	120	78	0	18	6	80	116	76	12	6	8
		DAY 57	18AUG2003	56	68	112	70	-8	10	-2	64	108	70	-4	-2	2
		FINAL		56	68	112	70	-8	10	-2	64	108	70	-4	-2	2
	E0009007	SCREEN	27JAN2003	-7	80	138	88				80	130	88			
		DAY 1	03FEB2003	1	92	130	80				80	120	88			
		BASELINE			92	130	80				80	120	88			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0009007	DAY 8	10FEB2003	8	70	130	84	-22D	0	4	80	134	88	0	14	0
		DAY 15	17FEB2003	15	64	130	80	-28D	0	0	80	134	84	0	14	-4
		DAY 22	25FEB2003	23	78	130	72	-14	0	-8	80	130	80	0	10	-8
		DAY 29	03MAR2003	29	80	120	84	-12	-10	4	86	120	90	6	0	2
		FINAL		29	80	120	84	-12	-10	4	86	120	90	6	0	2
	E0009008	SCREEN	04FEB2003	-8	66	118	80				70	120	80			
		DAY 1	12FEB2003	1	72	130	84				76	128	86			
		BASELINE			72	130	84				76	128	86			
		DAY 8	19FEB2003	8	68	100	60	-4	-30D	-24D	72	106	72	-4	-22D	-14
		DAY 15	25FEB2003	14	78	100	70	6	-30D	-14	80	110	70	4	-18	-16
		DAY 22	04MAR2003	21	60	120	70	-12	-10	-14	70	120	80	-6	-8	-6
		DAY 29	11MAR2003	28	80	120	84	8	-10	0	78	120	80	2	-8	-6
		DAY 36	18MAR2003	35	60	100	64	-12	-30D	-20D	80	110	80	4	-18	-6
		DAY 43	26MAR2003	43	66	100	60	-6	-30D	-24D	68	110	76	-8	-18	-10
		DAY 50	03APR2003	51	72	100	70	0	-30D	-14	76	106	74	0	-22D	-12
		DAY 57	08APR2003	56	68	100	60	-4	-30D	-24D	74	100	70	-2	-28D	-16
		FINAL		56	68	100	60	-4	-30D	-24D	74	100	70	-2	-28D	-16
	E0011001	SCREEN	25OCT2002	-7	68	118	78				72	118	80			
		DAY 1	01NOV2002	1	72	118	78				76	116	78			
		BASELINE			72	118	78				76	116	78			
		DAY 8	07NOV2002	7	84	120	68	12	2	-10	72	112	78	-4	-4	0
		DAY 15	14NOV2002	14	72	118	72	0	0	-6	80	122	74	4	6	-4
		DAY 22	21NOV2002	21	78	122	70	6	4	-8	72	118	70	-4	2	-8
		DAY 29	27NOV2002	27	88	116	68	16I	-2	-10	84	118	70	8	2	-8
		DAY 36	05DEC2002	35	76	118	72	4	0	-6	80	112	72	4	-4	-6
		DAY 43	12DEC2002	42	84	108	72	12	-10	-6	92	110	74	16I	-6	-4
		DAY 50	19DEC2002	49	77	118	74	5	0	-4	88	129	74	12	13	-4
		DAY 57	26DEC2002	56	68	104	71	-4	-14	-7	66	103	75	-10	-13	-3
		FINAL		56	68	104	71	-4	-14	-7	66	103	75	-10	-13	-3

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0011013	SCREEN	25MAR2003	-23	80	138	98				68	140	88			
		DAY 1	17APR2003	1	64	132	84				76	132	86			
		BASELINE			64	132	84				76	132	86			
		DAY 8	24APR2003	8	68	126	84	4	-6	0	76	126	88	0	-6	2
		DAY 15	01MAY2003	15	64	120	84	0	-12	0	68	120	86	-8	-12	0
		DAY 22	08MAY2003	22	68	112	80	4	-20D	-4	72	114	82	-4	-18	-4
		DAY 29	15MAY2003	29	72	122	80	8	-10	-4	76	124	82	0	-8	-4
		DAY 36	22MAY2003	36	80	130	88	16I	-2	4	84	128	90	8	-4	4
		DAY 43	29MAY2003	43	76	128	84	12	-4	0	80	126	88	4	-6	2
		DAY 50	05JUN2003	50	72	126	82	8	-6	-2	76	124	82	0	-8	-4
		DAY 57	12JUN2003	57	68	130	86	4	-2	2	72	130	88	-4	-2	2
		FINAL		57	68	130	86	4	-2	2	72	130	88	-4	-2	2
	E0013008	SCREEN	19MAR2003	-7	72	120	80				72	120	80			
		DAY 1	26MAR2003	1	66	120	80				72	120	80			
		BASELINE			66	120	80				72	120	80			
		DAY 8	02APR2003	8	60	115	80	-6	-5	0	66	118	80	-6	-2	0
		DAY 15	09APR2003	15	66	120	60	0	0	-20D	60	118	62	-12	-2	-18
		DAY 22	17APR2003	23	76	122	68	10	2	-12	74	120	70	2	0	-10
		DAY 29	23APR2003	29	72	120	80	6	0	0	66	120	80	-6	0	0
		DAY 36	30APR2003	36	80	124	80	14	4	0	80	124	78	8	4	-2
		DAY 43	07MAY2003	43	68	120	76	2	0	-4	64	120	76	-8	0	-4
		DAY 50	12MAY2003	48	68	120	64	2	0	-16	60	120	68	-12	0	-12
		DAY 57	19MAY2003	55	68	112	80	2	-8	0	64	116	78	-8	-4	-2
		FINAL		55	68	112	80	2	-8	0	64	116	78	-8	-4	-2
	E0014001	SCREEN	18FEB2003	-8	72	95	63				75	92	65			
		DAY 1	26FEB2003	1	68	100	68				69	97	72			
		BASELINE			68	100	68				69	97	72			
		DAY 8	05MAR2003	8	72	90L	65	4	-10	-3	75	100	67	6	3	-5
		DAY 15	12MAR2003	15	96	96	60	28I	-4	-8	100	94	62	31I	-3	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0014001	DAY 22	19MAR2003	22	84	100	66	16I	0	-2	92	90L	66	23I	-7	-6
		DAY 29	25MAR2003	28	84	105	70	16I	5	2	88	95	63	19I	-2	-9
		DAY 36	01APR2003	35	80	100	70	12	0	2	82	105	68	13	8	-4
		FINAL		35	80	100	70	12	0	2	82	105	68	13	8	-4
	E0014013	SCREEN	20MAY2003	-7	90	98	67				92	107	67			
		DAY 1	27MAY2003	1	74	110	70				78	116	68			
		BASELINE			74	110	70				78	116	68			
		DAY 8	04JUN2003	9	78	110	76	4	0	6	82	100	68	4	-16	0
		DAY 15	13JUN2003	18	74	104	68	0	-6	-2	78	98	66	0	-18	-2
		DAY 22	18JUN2003	23	74	114	66	0	4	-4	82	102	64	4	-14	-4
		DAY 29	25JUN2003	30	80	102	78	6	-8	8	82	102	76	4	-14	8
		DAY 36	02JUL2003	37	82	112	70	8	2	0	88	110	72	10	-6	4
		DAY 43	10JUL2003	45	88	102	70	14	-8	0	90	100	70	12	-16	2
		DAY 50	16JUL2003	51	90	114	68	16I	4	-2	96	104	70	18I	-12	2
		DAY 57	23JUL2003	58	84	102	64	10	-8	-6	96	100	64	18I	-16	-4
		FINAL		58	84	102	64	10	-8	-6	96	100	64	18I	-16	-4
	E0018005	SCREEN	10DEC2002	-10	60	118	76				64	122	78			
		DAY 1	20DEC2002	1	76	122	70				76	124	72			
		BASELINE			76	122	70				76	124	72			
		DAY 8	27DEC2002	8	76	128	78	0	6	8	80	128	76	4	4	4
		DAY 8 *	31DEC2002	12	76	120	72	0	-2	2	80	120	74	4	-4	2
		DAY 22	10JAN2003	22	64	118	78	-12	-4	8	72	124	78	-4	0	6
		DAY 29	17JAN2003	29	64	124	76	-12	2	6	68	122	76	-8	-2	4
		DAY 36	24JAN2003	36	76	128	72	0	6	2	80	130	76	4	6	4
		DAY 43	31JAN2003	43	64	112	68	-12	-10	-2	68	114	68	-8	-10	-4
		DAY 50	07FEB2003	50	72	120	70	-4	-2	0	76	126	72	0	2	0
		DAY 57	14FEB2003	57	60	120	70	-16D	-2	0	64	122	70	-12	-2	-2
		FINAL		57	60	120	70	-16D	-2	0	64	122	70	-12	-2	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0019019	SCREEN	14JAN2003	-9	72	115	75				80	120	70			
		DAY 1	23JAN2003	1	60	105	68				64	105	75			
		BASELINE			60	105	68				64	105	75			
		DAY 8	30JAN2003	8	72	118	80	12	13	12	76	122	85	12	17	10
		DAY 15	06FEB2003	15	76	115	70	16I	10	2	84	125	80	20I	20I	5
		FINAL		15	76	115	70	16I	10	2	84	125	80	20I	20I	5
	E0019033	SCREEN	10MAR2003	-8	64	120	80				72	120	70			
		DAY 1	18MAR2003	1	70	110	70				74	120	80			
		BASELINE			70	110	70				74	120	80			
		DAY 8	27MAR2003	10	68	110	60	-2	0	-10	76	110	75	2	-10	-5
		DAY 15	03APR2003	17	68	110	60	-2	0	-10	80	100	60	6	-20D	-20D
		DAY 22	10APR2003	24	64	110	60	-6	0	-10	72	110	62	-2	-10	-18
		DAY 29	14APR2003	28	64	110	70	-6	0	0	68	100	70	-6	-20D	-10
		DAY 36	22APR2003	36	68	120	74	-2	10	4	76	110	70	2	-10	-10
		DAY 43	01MAY2003	45	72	110	59	2	0	-11	76	110	70	2	-10	-10
		DAY 50	08MAY2003	52	74	122	72	4	12	2	72	116	68	-2	-4	-12
		DAY 57	15MAY2003	59	72	104	62	2	-6	-8	80	102	60	6	-18	-20D
		FINAL		59	72	104	62	2	-6	-8	80	102	60	6	-18	-20D
	E0019038	SCREEN	10APR2003	-14	60	105	60				64	110	65			
		DAY 1	24APR2003	1	60	105	65				66	108	65			
		BASELINE			60	105	65				66	108	65			
		DAY 8	01MAY2003	8	56	120	70	-4	15	5	76	118	78	10	10	13
		DAY 15	07MAY2003	14	60	110	60	0	5	-5	66	105	60	0	-3	-5
		DAY 22	14MAY2003	21	62	112	58	2	7	-7	72	108	70	6	0	5
		DAY 29	21MAY2003	28	60	110	65	0	5	0	64	115	70	-2	7	5
		DAY 36	28MAY2003	35	64	105	65	4	0	0	64	110	70	-2	2	5
		DAY 43	04JUN2003	42	62	118	50L	2	13	-15	68	82L	60	2	-26D	-5
		DAY 50	11JUN2003	49	60	110	65	0	5	0	64	120	70	-2	12	5
		DAY 57	18JUN2003	56	60	104	60	0	-1	-5	72	110	68	6	2	3

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0019038	FINAL		56	60	104	60	0	-1	-5	72	110	68	6	2	3
	E0019046	SCREEN	19JUN2003	-7	60	110	70				68	110	70			
		DAY 1	26JUN2003	1	64	102	70				60	104	78			
		BASELINE			64	102	70				60	104	78			
		DAY 8	03JUL2003	8	68	98	68	4	-4	-2	60	100	80	0	-4	2
		DAY 15	10JUL2003	15	60	102	94	-4	0	24	80	100	82	20I	-4	4
		DAY 22	17JUL2003	22	60	100	75	-4	-2	5	68	95	70	8	-9	-8
		DAY 29	24JUL2003	29	64	94	76	0	-8	6	80	94	76	20I	-10	-2
		DAY 36	30JUL2003	35	64	100	70	0	-2	0	70	95	70	10	-9	-8
		DAY 50	14AUG2003	50	64	105	75	0	3	5	70	95	75	10	-9	-3
		DAY 57	21AUG2003	57	68	112	76	4	10	6	64	100	74	4	-4	-4
		FINAL		57	68	112	76	4	10	6	64	100	74	4	-4	-4
	E0019047	SCREEN	26JUN2003	-12	72	112	72				76	116	76			
		DAY 1	08JUL2003	1	68	118	64				84	116	82			
		BASELINE			68	118	64				84	116	82			
		DAY 8	17JUL2003	10	68	120	70	0	2	6	82	118	75	-2	2	-7
		DAY 15	24JUL2003	17	80	122	68	12	4	4	100	118	82	16I	2	0
		DAY 22	31JUL2003	24	76	118	64	8	0	0	100	116	76	16I	0	-6
		DAY 29	07AUG2003	31	88	118	74	20I	0	10	100	124	76	16I	8	-6
		DAY 36	14AUG2003	38	76	116	60	8	-2	-4	84	122	78	0	6	-4
		DAY 43	21AUG2003	45	80	112	60	12	-6	-4	88	110	60	4	-6	-22D
		DAY 50	28AUG2003	52	80	115	70	12	-3	6	84	105	70	0	-11	-12
		DAY 57	04SEP2003	59	80	122	74	12	4	10	84	118	74	0	2	-8
		FINAL		59	80	122	74	12	4	10	84	118	74	0	2	-8
	E0019048	SCREEN	03JUL2003	-7	68	126	76				80	126	86			
		DAY 1	10JUL2003	1	72	122	80				84	130	82			
		BASELINE			72	122	80				84	130	82			
		DAY 8	17JUL2003	8	72	120	75	0	-2	-5	76	120	80	-8	-10	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0019048	DAY 15	22JUL2003	13	76	122	80	4	0	0	76	126	85	-8	-4	3
		DAY 22	31JUL2003	22	80	120	80	8	-2	0	76	118	78	-8	-12	-4
		DAY 29	07AUG2003	29	80	122	78	8	0	-2	84	120	76	0	-10	-6
		DAY 36	14AUG2003	36	80	110	70	8	-12	-10	72	104	78	-12	-26D	-4
		DAY 43	21AUG2003	43	76	112	75	4	-10	-5	82	110	75	-2	-20D	-7
		DAY 50	28AUG2003	50	76	124	82	4	2	2	72	110	80	-12	-20D	-2
		DAY 57	03SEP2003	56	68	116	84	-4	-6	4	72	114	80	-12	-16	-2
		FINAL		56	68	116	84	-4	-6	4	72	114	80	-12	-16	-2
	E0022006	SCREEN	21OCT2002	-22	93	121	83				101	115	80			
		DAY 1	12NOV2002	1	64	120	68				68	108	70			
		BASELINE			64	120	68				68	108	70			
		DAY 8	19NOV2002	8	84	112	64	20I	-8	-4	84	98	68	16I	-10	-2
		DAY 15	26NOV2002	15	76	102	68	12	-18	0	92	100	72	24I	-8	2
		DAY 22	03DEC2002	22	72	104	54	8	-16	-14	72	102	60	4	-6	-10
		DAY 29	10DEC2002	29	68	108	68	4	-12	0	72	98	72	4	-10	2
		DAY 36	17DEC2002	36	68	100	58	4	-20D	-10	78	100	62	10	-8	-8
		DAY 43	24DEC2002	43	84	100	52	20I	-20D	-16	78	98	54	10	-10	-16
		DAY 50	31DEC2002	50	66	94	56	2	-26D	-12	75	100	62	7	-8	-8
		DAY 57	07JAN2003	57	90	110	56	26I	-10	-12	84	98	66	16I	-10	-4
		FINAL		57	90	110	56	26I	-10	-12	84	98	66	16I	-10	-4
	E0022047	SCREEN	21MAR2003	-7	72	118	80				76	120	82			
		DAY 1	28MAR2003	1	64	110	82				68	108	80			
		BASELINE			64	110	82				68	108	80			
		DAY 8	04APR2003	8	68	118	74	4	8	-8	80	102	80	12	-6	0
		DAY 15	11APR2003	15	78	118	82	14	8	0	72	104	80	4	-4	0
		DAY 22	17APR2003	21	64	132	82	0	22I	0	80	110	80	12	2	0
		DAY 29	25APR2003	29	64	118	76	0	8	-6	78	110	80	10	2	0
		DAY 36	02MAY2003	36	68	120	76	4	10	-6	72	118	82	4	10	2
		DAY 43	09MAY2003	43	72	122	82	8	12	0	76	126	80	8	18	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0022047	DAY 50	16MAY2003	50	64	132	76	0	22I	-6	88	124	82	20I	16	2
		DAY 57	23MAY2003	57	72	122	80	8	12	-2	84	130	102	16I	22I	22
		FINAL		57	72	122	80	8	12	-2	84	130	102	16I	22I	22
	E0022075	SCREEN	25JUN2003	-13	66	112	76				78	108	80			
		DAY 1	08JUL2003	1	57	110	68				66	122	74			
		BASELINE			57	110	68				66	122	74			
		DAY 8	15JUL2003	8	60	114	74	3	4	6	72	106	72	6	-16	-2
		DAY 15	22JUL2003	15	66	104	68	9	-6	0	75	106	78	9	-16	4
		DAY 22	29JUL2003	22	60	106	74	3	-4	6	63	102	80	-3	-20D	6
		DAY 29	05AUG2003	29	68	102	64	11	-8	-4	80	100	66	14	-22D	-8
		DAY 36	12AUG2003	36	62	106	60	5	-4	-8	76	116	68	10	-6	-6
		DAY 43	19AUG2003	43	64	106	64	7	-4	-4	76	110	68	10	-12	-6
		DAY 50	26AUG2003	50	64	104	60	7	-6	-8	84	108	64	18I	-14	-10
		DAY 57	03SEP2003	58	72	104	58	15I	-6	-10	76	120	72	10	-2	-2
		FINAL		58	72	104	58	15I	-6	-10	76	120	72	10	-2	-2
	E0023012	SCREEN	31JAN2003	-6	88	136	88				86	140	80			
		DAY 1	06FEB2003	1	88	116	62				97	144	83			
		BASELINE			88	116	62				97	144	83			
		DAY 8	17FEB2003	12	76	118	76	-12	2	14	80	116	74	-17D	-28D	-9
		DAY 15	20FEB2003	15	76	110	76	-12	-6	14	80	120	74	-17D	-24D	-9
		DAY 22	28FEB2003	23	80	126	70	-8	10	8	80	120	70	-17D	-24D	-13
		DAY 29	07MAR2003	30	82	126	72	-6	10	10	85	147	81	-12	3	-2
		DAY 36	14MAR2003	37	75	110	80	-13	-6	18	91	142	75	-6	-2	-8
		DAY 43	21MAR2003	44	74	118	68	-14	2	6	78	145	77	-19D	1	-6
		DAY 50	28MAR2003	51	85	129	60	-3	13	-2	80	126	64	-17D	-18	-19
		DAY 57	04APR2003	58	68	120	70	-20D	4	8	70	124	68	-27D	-20D	-15
		FINAL		58	68	120	70	-20D	4	8	70	124	68	-27D	-20D	-15
	E0023016	SCREEN	15MAY2003	-7	82	120	75				84	120	75			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0023016	DAY 1	22MAY2003	1	79	117	83				78	106	74			
		BASELINE			79	117	83				78	106	74			
		DAY 8	29MAY2003	8	78	94	64	-1	-23D	-19	97	105	74	19I	-1	0
		DAY 15	05JUN2003	15	76	103	69	-3	-14	-14	84	108	70	6	2	-4
		DAY 22	12JUN2003	22	69	103	70	-10	-14	-13	95	101	61	17I	-5	-13
		DAY 29	19JUN2003	29	63	101	67	-16D	-16	-16	70	108	71	-8	2	-3
		DAY 36	26JUN2003	36	74	85L	58	-5	-32D	-25D	78	98	64	0	-8	-10
		DAY 43	01JUL2003	41	70	91	63	-9	-26D	-20D	85	104	73	7	-2	-1
		DAY 50	14JUL2003	54	72	94	64	-7	-23D	-19	84	100	68	6	-6	-6
		DAY 57	17JUL2003	57	80	96	74	1	-21D	-9	84	102	70	6	-4	-4
		FINAL		57	80	96	74	1	-21D	-9	84	102	70	6	-4	-4
	E0023018	SCREEN	18MAR2003	-9	66	140	94				71	129	84			
		DAY 1	27MAR2003	1	60	113	75				66	110	74			
		BASELINE			60	113	75				66	110	74			
		DAY 8	03APR2003	8	70	120	76	10	7	1	74	120	70	8	10	-4
		DAY 15	10APR2003	15	69	115	71	9	2	-4	70	110	70	4	0	-4
		DAY 22	16APR2003	21	86	120	80	26I	7	5	91	116	76	25I	6	2
		DAY 29	24APR2003	29	84	120	80	24I	7	5	88	114	72	22I	4	-2
		DAY 36	02MAY2003	37	66	110	79	6	-3	4	68	108	76	2	-2	2
		DAY 43	12MAY2003	47	67	133	91	7	20I	16	68	130	90	2	20I	16
		DAY 50	15MAY2003	50	64	136	95	4	23I	20	70	125	84	4	15	10
		DAY 57	22MAY2003	57	71	128	82	11	15	7	80	126	80	14	16	6
		FINAL		57	71	128	82	11	15	7	80	126	80	14	16	6
	E0023036	SCREEN	10JUN2003	-10	86	121	73				85	120	70			
		DAY 1	20JUN2003	1	88	119	71				90	120	74			
		BASELINE			88	119	71				90	120	74			
		DAY 8	26JUN2003	7	99	110	63	11	-9	-8	104	104	55	14	-16	-19
		DAY 15	02JUL2003	13	88	124	81	0	5	10	90	120	80	0	0	6
		DAY 22	09JUL2003	20	99	100	61	11	-19	-10	99	104	64	9	-16	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0023036	DAY 29		16JUL2003	27	95	105	75	7	-14	4	95	100	61	5	-20D	-13
		DAY 29	*	22JUL2003	33	90	104	64	2	-15	-7	90	100	60	0	-20D	-14
		DAY 36		29JUL2003	40	80	116	67	-8	-3	-4	90	104	60	0	-16	-14
		DAY 43		05AUG2003	47	99	110	82	11	-9	11	101	110	80	11	-10	6
		DAY 57		13AUG2003	55	102	110	63	14	-9	-8	111	121	75	21I	1	1
		FINAL			55	102	110	63	14	-9	-8	111	121	75	21I	1	1
	E0023046	SCREEN		11JUL2003	-12	84	126	88				97	122	84			
		DAY 1		23JUL2003	1	69	136	85				86	146	92			
		BASELINE				69	136	85				86	146	92			
		DAY 8		01AUG2003	10	72	170	90	3	34I	5	86	179	94	0	33I	2
		DAY 15		08AUG2003	17	74	111	70	5	-25D	-15	91	104	68	5	-42D	-24D
		DAY 22		14AUG2003	23	69	115	60	0	-21D	-25D	72	111	61	-14	-35D	-31D
		DAY 29		22AUG2003	31	75	133	69	6	-3	-16	85	127	75	-1	-19	-17
		DAY 36		28AUG2003	37	73	109	69	4	-27D	-16	76	112	72	-10	-34D	-20D
		DAY 43		04SEP2003	44	79	115	65	10	-21D	-20D	104	119	65	18I	-27D	-27D
		DAY 50		11SEP2003	51	72	121	64	3	-15	-21D	84	127	80	-2	-19	-12
		DAY 57		16SEP2003	56	81	127	73	12	-9	-12	91	124	79	5	-22D	-13
		FINAL			56	81	127	73	12	-9	-12	91	124	79	5	-22D	-13
	E0026006	SCREEN		31DEC2002	-8	73	128	66				78	129	77			
		DAY 1		08JAN2003	1	65	133	75				71	139	81			
		BASELINE				65	133	75				71	139	81			
		DAY 8		15JAN2003	8	94	167	83	29I	34I	8	94	136	81	23I	-3	0
		DAY 15		22JAN2003	15	90	144	80	25I	11	5	101	146	91	30I	7	10
		DAY 22		29JAN2003	22	87	128	77	22I	-5	2	94	131	83	23I	-8	2
		DAY 29		05FEB2003	29	82	152	77	17I	19	2	96	127	73	25I	-12	-8
		DAY 36		12FEB2003	36	87	132	74	22I	-1	-1	93	122	71	22I	-17	-10
		DAY 43		19FEB2003	43	72	140	76	7	7	1	80	142	80	9	3	-1
		FINAL			43	72	140	76	7	7	1	80	142	80	9	3	-1

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0029004	SCREEN		13NOV2002	-6	80	98	62				84	100	72			
		DAY 1		19NOV2002	1	80	100	70				92	96	70			
		BASELINE				80	100	70				92	96	70			
		DAY 8		26NOV2002	8	64	116	76	-16D	16	6	84	116	80	-8	20I	10
		DAY 15		04DEC2002	16	80	112	78	0	12	8	82	110	76	-10	14	6
		DAY 22		12DEC2002	24	72	106	74	-8	6	4	84	122	78	-8	26I	8
		DAY 36		26DEC2002	38	84	100	60	4	0	-10	96	108	82	4	12	12
		DAY 43		02JAN2003	45	84	98	60	4	-2	-10	72	98	70	-20D	2	0
		DAY 50		09JAN2003	52	80	104	72	0	4	2	76	110	78	-16D	14	8
		DAY 57		16JAN2003	59	76	100	72	-4	0	2	84	90L	68	-8	-6	-2
		FINAL			59	76	100	72	-4	0	2	84	90L	68	-8	-6	-2
	E0029019	SCREEN		24FEB2003	-7	60	110	76				64	92	70			
		DAY 1		03MAR2003	1	60	110	80				68	110	78			
		BASELINE				60	110	80				68	110	78			
		DAY 8		10MAR2003	8	56	130	88	-4	20I	8	68	110	90	0	0	12
		DAY 15		17MAR2003	15	60	112	78	0	2	-2	60	108	76	-8	-2	-2
		FINAL			15	60	112	78	0	2	-2	60	108	76	-8	-2	-2
	E0029024	SCREEN		11MAR2003	-6	48L	114	84				52	130	80			
		DAY 1		17MAR2003	1	52	102	78				52	102	68			
		BASELINE				52	102	78				52	102	68			
		DAY 8		25MAR2003	9	56	100	78	4	-2	0	56	102	70	4	0	2
		DAY 15		02APR2003	17	56	92	64	4	-10	-14	56	96	64	4	-6	-4
		DAY 22		09APR2003	24	52	118	68	0	16	-10	66	108	64	14	6	-4
		DAY 29		17APR2003	32	60	102	62	8	0	-16	60	98	62	8	-4	-6
		DAY 36		24APR2003	39	60	96	60	8	-6	-18	60	96	60	8	-6	-8
		DAY 50		05MAY2003	50	72	100	60	20I	-2	-18	64	98	60	12	-4	-8
		DAY 57	*	12MAY2003	57	54	90L	62	2	-12	-16	54	92	60	2	-10	-8
		DAY 57		20MAY2003	65	58	110	60	6	8	-18	58	108	60	6	6	-8
		FINAL			65	58	110	60	6	8	-18	58	108	60	6	6	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0031004	SCREEN	12DEC2002	-7	80	120	64				80	110	70			
		DAY 1	19DEC2002	1	75	124	66				68	126	80			
		BASELINE			75	124	66				68	126	80			
		DAY 8	27DEC2002	9	82	122	68	7	-2	2	90	132	80	22I	6	0
		DAY 15	03JAN2003	16	86	122	64	11	-2	-2	88	129	72	20I	3	-8
		DAY 22	09JAN2003	22	86	129	78	11	5	12	74	122	74	6	-4	-6
		DAY 29	16JAN2003	29	72	129	68	-3	5	2	70	130	70	2	4	-10
		DAY 36	23JAN2003	36	78	124	72	3	0	6	76	124	74	8	-2	-6
		DAY 43	30JAN2003	43	68	124	78	-7	0	12	74	136	86	6	10	6
		DAY 50	06FEB2003	50	78	124	74	3	0	8	76	126	76	8	0	-4
		DAY 57	13FEB2003	57	74	116	72	-1	-8	6	88	122	80	20I	-4	0
		FINAL		57	74	116	72	-1	-8	6	88	122	80	20I	-4	0
	E0031013	SCREEN	06MAR2003	-7	68	130	86				100	128	88			
		DAY 1	13MAR2003	1	86	138	80				82	142	84			
		BASELINE			86	138	80				82	142	84			
		DAY 8	20MAR2003	8	78	140	82	-8	2	2	74	148	90	-8	6	6
		DAY 15	27MAR2003	15	66	138	78	-20D	0	-2	69	142	86	-13	0	2
		DAY 22	04APR2003	23	74	134	82	-12	-4	2	86	138	86	4	-4	2
		DAY 29	11APR2003	30	88	130	78	2	-8	-2	86	132	86	4	-10	2
		DAY 36	17APR2003	36	96	140	86	10	2	6	99	142	90	17I	0	6
		DAY 43	24APR2003	43	78	140	88	-8	2	8	82	146	94	0	4	10
		DAY 50	01MAY2003	50	80	140	88	-6	2	8	88	142	90	6	0	6
		DAY 57	08MAY2003	57	68	138	90	-18D	0	10	66	142	90	-16D	0	6
		FINAL		57	68	138	90	-18D	0	10	66	142	90	-16D	0	6
	E0031016	SCREEN	17MAR2003	-7	62	130	62				66	128	62			
		DAY 1	24MAR2003	1	56	110	58				72	112	64			
		BASELINE			56	110	58				72	112	64			
		DAY 8	31MAR2003	8	78	114	58	22I	4	0	88	120	62	16I	8	-2
		DAY 15	07APR2003	15	62	116	60	6	6	2	70	120	62	-2	8	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0031016	DAY 22	14APR2003	22	64	118	60	8	8	2	72	122	64	0	10	0
		FINAL		22	64	118	60	8	8	2	72	122	64	0	10	0
	E0031022	SCREEN	21APR2003	-7	62	108	66				66	114	74			
		DAY 1	28APR2003	1	60	110	66				70	110	70			
		BASELINE			60	110	66				70	110	70			
		DAY 8	06MAY2003	9	64	120	74	4	10	8	66	124	80	-4	14	10
		DAY 15	13MAY2003	16	62	118	72	2	8	6	66	124	78	-4	14	8
		DAY 22	20MAY2003	23	70	130	70	10	20I	4	68	140	76	-2	30I	6
		DAY 29	27MAY2003	30	66	124	70	6	14	4	74	128	72	4	18	2
		FINAL		30	66	124	70	6	14	4	74	128	72	4	18	2
	E0033007	SCREEN	15JAN2003	-13	80	122	86				80	128	84			
		DAY 1	28JAN2003	1	76	126	80				84	128	88			
		BASELINE			76	126	80				84	128	88			
		DAY 8	04FEB2003	8	72	128	80	-4	2	0	76	122	84	-8	-6	-4
		DAY 15	12FEB2003	16	76	140	80	0	14	0	80	130	86	-4	2	-2
		DAY 22	20FEB2003	24	80	122	80	4	-4	0	84	124	88	0	-4	0
		DAY 29	25FEB2003	29	80	128	84	4	2	4	86	138	92	2	10	4
		DAY 36	04MAR2003	36	84	138	88	8	12	8	88	130	86	4	2	-2
		DAY 43	13MAR2003	45	80	120	80	4	-6	0	84	130	90	0	2	2
		DAY 50	18MAR2003	50	80	120	86	4	-6	6	88	126	88	4	-2	0
		DAY 57	27MAR2003	59	80	100	80	4	-26D	0	80	120	80	-4	-8	-8
		FINAL		59	80	100	80	4	-26D	0	80	120	80	-4	-8	-8
	E0033013	SCREEN	06FEB2003	-13	64	100	70				76	90L	70			
		DAY 1	19FEB2003	1	68	108	72				72	110	76			
		BASELINE			68	108	72				72	110	76			
		DAY 8	26FEB2003	8	60	100	70	-8	-8	-2	72	100	80	0	-10	4
		DAY 15	05MAR2003	15	64	100	70	-4	-8	-2	80	110	74	8	0	-2
		DAY 22	13MAR2003	23	60	110	90	-8	2	18	72	100	86	0	-10	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0033013	DAY 29	19MAR2003	29	68	98	70	0	-10	-2	72	100	74	0	-10	-2
		DAY 36	27MAR2003	37	68	88L	60	0	-20D	-12	76	90L	64	4	-20D	-12
		DAY 43	01APR2003	42	60	80L	60	-8	-28D	-12	76	90L	70	4	-20D	-6
		DAY 50	10APR2003	51	56	80L	60	-12	-28D	-12	68	80L	68	-4	-30D	-8
		DAY 57	16APR2003	57	64	80L	60	-4	-28D	-12	76	90L	78	4	-20D	2
		FINAL		57	64	80L	60	-4	-28D	-12	76	90L	78	4	-20D	2
	E0033022	SCREEN	09JUL2003	-5	76	100	76				80	98	70			
		DAY 1	14JUL2003	1	80	100	78				84	100	70			
		BASELINE			80	100	78				84	100	70			
		DAY 8	23JUL2003	10	64	90L	62	-16D	-10	-16	80	90L	60	-4	-10	-10
		DAY 15	30JUL2003	17	68	100	70	-12	0	-8	80	90L	70	-4	-10	0
		DAY 22	06AUG2003	24	64	100	68	-16D	0	-10	68	110	70	-16D	10	0
		DAY 29	11AUG2003	29	70	120	74	-10	20I	-4	80	124	80	-4	24I	10
		DAY 36	18AUG2003	36	60	110	72	-20D	10	-6	68	100	70	-16D	0	0
		DAY 43	26AUG2003	44	64	110	70	-16D	10	-8	68	110	72	-16D	10	2
		DAY 50	04SEP2003	53	64	100	70	-16D	0	-8	68	100	72	-16D	0	2
		DAY 57	11SEP2003	60	64	110	70	-16D	10	-8	68	110	72	-16D	10	2
		FINAL		60	64	110	70	-16D	10	-8	68	110	72	-16D	10	2
	E0034007	SCREEN	07MAY2003	-9	76	110	90				80	120	85			
		DAY 1	16MAY2003	1	62	122	82				68	138	88			
		BASELINE			62	122	82				68	138	88			
		DAY 8	24MAY2003	9	68	130	90	6	8	8	72	125	85	4	-13	-3
		DAY 15	02JUN2003	18	62	128	84	0	6	2	72	128	88	4	-10	0
		DAY 22	09JUN2003	25	72	128	88	10	6	6	68	126	94	0	-12	6
		DAY 29	16JUN2003	32	72	140	90	10	18	8	80	130	85	12	-8	-3
		DAY 36	20JUN2003	36	64	125	85	2	3	3	68	130	80	0	-8	-8
		DAY 43	30JUN2003	46	74	160	100	12	38I	18	68	140	95	0	2	7
		DAY 50	07JUL2003	53	80	140	95	18I	18	13	88	135	100	20I	-3	12
		DAY 57	14JUL2003	60	68	160	105H	6	38I	23	64	158	108H	-4	20I	20

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	SUPINE CHANGE FROM BASELINE PULSE	SUPINE CHANGE FROM BASELINE SYS	SUPINE CHANGE FROM BASELINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	STANDING CHANGE FROM BASELINE PULSE	STANDING CHANGE FROM BASELINE SYS	STANDING CHANGE FROM BASELINE DIA
PLACEBO (BIPOLAR II)	E0034007	FINAL			60	68	160	105H	6	38I	23	64	158	108H	-4	20I	20
	E0035009	SCREEN		20DEC2002	-7	88	102	76				90	104	80			
		DAY 1		27DEC2002	1	88	102	70				92	104	76			
		BASELINE				88	102	70				92	104	76			
		DAY 8		31DEC2002	5	80	114	64	-8	12	-6	84	120	60	-8	16	-16
		DAY 15		08JAN2003	13	82	122	60	-6	20I	-10	88	124	64	-4	20I	-12
		DAY 22		15JAN2003	20	80	120	64	-8	18	-6	86	122	60	-6	18	-16
		DAY 29		22JAN2003	27	78	120	64	-10	18	-6	84	120	66	-8	16	-10
		DAY 36		29JAN2003	34	70	118	70	-18D	16	0	74	120	72	-18D	16	-4
		DAY 43		05FEB2003	41	74	122	62	-14	20I	-8	82	120	68	-10	16	-8
		DAY 43	*	11FEB2003	47	60	116	70	-28D	14	0	66	120	72	-26D	16	-4
		DAY 57		19FEB2003	55	80	116	64	-8	14	-6	84	118	72	-8	14	-4
		FINAL			55	80	116	64	-8	14	-6	84	118	72	-8	14	-4
	E0035010	SCREEN		06JAN2003	-4	82	140	92				88	142	96			
		DAY 1		10JAN2003	1	82	126	90				88	130	92			
		BASELINE				82	126	90				88	130	92			
		DAY 8		17JAN2003	8	82	122	80	0	-4	-10	86	124	76	-2	-6	-16
		DAY 15		24JAN2003	15	78	128	80	-4	2	-10	80	130	82	-8	0	-10
		DAY 22		31JAN2003	22	68	132	80	-14	6	-10	74	132	88	-14	2	-4
		DAY 29		07FEB2003	29	68	138	82	-14	12	-8	70	144	88	-18D	14	-4
		DAY 36		14FEB2003	36	82	132	88	0	6	-2	86	134	86	-2	4	-6
		DAY 43		24FEB2003	46	82	130	86	0	4	-4	88	132	84	0	2	-8
		DAY 50		28FEB2003	50	82	132	78	0	6	-12	86	134	82	-2	4	-10
		DAY 57		06MAR2003	56	84	132	78	2	6	-12	88	132	86	0	2	-6
		FINAL			56	84	132	78	2	6	-12	88	132	86	0	2	-6
	E0041005	SCREEN		24FEB2003	-9	72	150	100				76	148	92			
		DAY 1		05MAR2003	1	76	140	92				78	148	92			
		BASELINE				76	140	92				78	148	92			

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
L: Potentially Clinically Important low. H: Potentially Clinically Important high.

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0041005	DAY 8	11MAR2003	7	74	140	98	-2	0	6	74	148	90	-4	0	-2
		DAY 15	19MAR2003	15	82	138	90	6	-2	-2	92	150	96	14	2	4
		DAY 22	26MAR2003	22	80	140	90	4	0	-2	80	142	100	2	-6	8
		DAY 29	02APR2003	29	80	110	90	4	-30D	-2	88	130	96	10	-18	4
		DAY 36	09APR2003	36	60	110	80	-16D	-30D	-12	66	120	76	-12	-28D	-16
		DAY 43	16APR2003	43	80	132	100	4	-8	8	84	150	108H	6	2	16
		DAY 50	23APR2003	50	60	150	98	-16D	10	6	80	150	100	2	2	8
		DAY 57	30APR2003	57	88	138	86	12	-2	-6	88	140	84	10	-8	-8
		FINAL		57	88	138	86	12	-2	-6	88	140	84	10	-8	-8

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
L: Potentially Clinically Important low. H: Potentially Clinically Important high.

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS				CHANGE FROM BASELINE	
							PR	QRS	QT	FRIDER-ICIA QTC	VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	BASELINE	19DEC2002/11:05	-14	81	81	144	92	349	386		
		FINAL	27FEB2003/9:20	57	56	56	156	89	401	392	-25 D	-25 D
	E0004002	BASELINE	24SEP2002/11:00	-7	68	68	136	83	367	383		
		FINAL	26NOV2002/11:15	57	83	84	140	92	383	428	15 I	16 I
	E0004013	BASELINE	08JAN2003/10:40	-6	76	76	152	89	368	399		
		FINAL	05FEB2003/13:25	23	92	92	141	92	330	380	16 I	16 I
	E0005002	BASELINE	23SEP2002/10:00	-10	81	81	131	83	353	390		
		FINAL	25NOV2002/8:45	54	100	101	122	83	307	365	19 I	20 I
	E0005042	BASELINE	19JUN2003/12:50	-5	58	58	149	83	410	406		
		FINAL	18AUG2003/16:40	56	74	75	191	93	363	390	16 I	17 I
	E0006005	BASELINE	25NOV2002/12:45	-10	65	66	179	115	386	397		
		FINAL	30JAN2003/11:20	57	84	84	176	101	347	388	19 I	18 I
	E0006018	BASELINE	06MAR2003/12:04	-7	66	66	201	88	364	376		
		FINAL	24MAR2003/10:50	12	70	71	215 H	81	367	387	4	5
	E0007013	BASELINE	06JUN2003/15:50	-7	54	54	165	95	416	402		
		FINAL	07AUG2003/10:10	56	75	76	169	100	367	396	21 I	22 I
	E0010012	BASELINE	30DEC2002/9:32	-8	63	63	159	84	392	398		
		FINAL	05MAR2003/13:40	58	80	80	157	92	375	412	17 I	17 I
	E0010024	BASELINE	23APR2003/10:26	-12	52	52	138	85	383	365		
		FINAL	02JUL2003/10:25	59	73	73	166	87	363	388	21 I	21 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE	
					VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRICULAR RATE	ATRIAL RATE
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	BASELINE	11MAR2003/16:10	-14	51	51	139	108	439	416		
		FINAL	28MAY2003/15:15	65	68	69	157	100	394	411	17 I	18 I
	E0014010	BASELINE	15APR2003/17:09	-7	68	67	156	98	409	427		
		FINAL	17JUN2003/16:55	57	96	97	125	90	336	394	28 I	30 I
	E0019043	BASELINE	21MAY2003/12:07	-13	58	58	158	89	364	359		
		FINAL	29JUL2003/11:24	57	76	76	159	85	342	369	18 I	18 I
	E0022060	BASELINE	23APR2003/15:25	-7	42 L	42 L	121	88	394	349		
		FINAL	24JUN2003/9:30	56	40 L	40 L	151	83	429	373	-2	-2
	E0023013	BASELINE	13FEB2003/11:00	-14	62	61	123	88	426	430		
		FINAL	06MAR2003/11:15	8	83	82	137	86	335	372	21 I	21 I
	E0023015	BASELINE	04MAR2003/11:00	-7	57	57	180	91	389	382		
		FINAL	06MAY2003/10:20	57	77	76	131	90	337	366	20 I	19 I
	E0026017	BASELINE	26FEB2003/12:05	-8	51	51	124	93	425	402		
		FINAL	21MAR2003/11:20	16	46 L	46 L	150	92	404	369	-5	-5
	E0026025	BASELINE	01MAY2003/11:40	-8	68	68	178	95	387	404		
		FINAL	03JUL2003/10:05	56	84	83	157	97	360	402	16 I	15 I
	E0026029	BASELINE	02JUL2003/11:25	-7	52	52	149	86	412	392		
		FINAL	28JUL2003/13:40	20	92	92	146	88	328	379	40 I	40 I
	E0028016	BASELINE	07NOV2002/10:10	-7	70	70	222 H	87	376	396		
		FINAL	09JAN2003/11:59	57	71	71	266 H	92	363	384	1	1

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE	
					VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRICULAR RATE	ATRIAL RATE
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	BASELINE *	14NOV2002/12:30	-13	76	76	122	95	344	372		
		BASELINE	27NOV2002/12:20	1	62	61	142	92	383	386		
		FINAL	21JAN2003/12:35	56	80	81	143	89	355	391	18 I	20 I
	E0030008	BASELINE	07JAN2003/14:15	-7	59	60	164	110	382	381		
		FINAL	18MAR2003/11:35	64	75	75	176	114	381	411	16 I	15 I
	E0030015	BASELINE	13FEB2003/12:15	-8	48 L	48 L	134	94	396	368		
		FINAL	22APR2003/12:00	61	49 L	49 L	136	89	377	351	1	1
	E0030022	BASELINE	10JUN2003/11:30	-6	65	65	137	89	359	370		
		FINAL	14AUG2003/16:00	60	82	82	128	97	334	370	17 I	17 I
	E0035024	BASELINE	15MAY2003/11:12	-8	66	66	158	86	361	373		
		FINAL	18JUL2003/9:00	57	81	81	150	82	347	384	15 I	15 I
	E0039025	BASELINE	26FEB2003/11:07	-20	58	57	147	105	400	395		
		FINAL	27MAY2003/10:05	71	84	84	137	97	350	392	26 I	27 I
	E0039051	BASELINE	22MAY2003/15:40	-25	97	98	155	87	314	369		
		FINAL	12AUG2003/14:55	58	80	80	177	84	344	379	-17 D	-18 D
	E0041008	BASELINE	26MAR2003/16:00	-12	91	91	155	87	355	409		
		FINAL	02JUN2003/15:45	57	63	64	152	90	399	406	-28 D	-27 D

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS				CHANGE FROM BASELINE	
							PR	QRS	QT	FRIDER-ICIA QTC	VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	BASELINE	06FEB2003/12:25	-5	60	59	143	99	353	352		
		FINAL	08APR2003/11:48	57	75	75	160	94	342	368	15 I	16 I
	E0006016	BASELINE	07FEB2003/13:14	-10	51	51	231 H	96	396	374		
		FINAL	18APR2003/12:30	61	57	57	219 H	91	391	383	6	6
	E0011018	BASELINE	15MAY2003/12:50	-7	57	57	192	97	378	371		
		FINAL	17JUL2003/17:45	57	74	74	168	89	364	391	17 I	17 I
	E0011024	BASELINE	17JUN2003/12:40	-7	52	52	178	94	415	395		
		FINAL	21AUG2003/13:45	59	70	71	165	95	367	388	18 I	19 I
	E0019022	BASELINE	23JAN2003/11:40	-7	54	54	137	95	362	349		
		FINAL	27MAR2003/15:45	57	92	92	132	84	339	391	38 I	38 I
	E0019027	BASELINE	20FEB2003/10:20	-7	63	62	133	96	386	391		
		FINAL	06MAR2003/8:35	8	97	96	138	88	319	375	34 I	34 I
	E0019039	BASELINE	22APR2003/10:30	-9	67	67	170	93	364	378		
		FINAL	08MAY2003/16:00	8	86	86	151	91	356	402	19 I	19 I
	E0022052	BASELINE	01APR2003/10:55	-9	71	71	134	85	385	408		
		FINAL	05JUN2003/9:45	57	88	88	133	85	350	398	17 I	17 I
	E0022073	BASELINE	19JUN2003/12:45	-7	63	63	153	81	362	368		
		FINAL	21AUG2003/10:35	57	87	88	150	93	322	365	24 I	25 I
	E0023021	BASELINE	10APR2003/10:40	-13	53	53	176	88	421	403		
		FINAL	17JUN2003/16:00	56	89	89	170	83	339	387	36 I	36 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE	
					VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	BASELINE	07MAY2003/13:00	-9	63	63	142	95	398	404		
		FINAL	09JUL2003/13:45	55	77	78	140	80	371	404	14	15 I
	E0023030	BASELINE	21MAY2003/10:30	-13	62	62	152	93	386	390		
		FINAL	30JUL2003/16:30	58	86	86	150	100	352	396	24 I	24 I
	E0026014	BASELINE	12FEB2003/12:00	-7	66	66	151	94	376	389		
		FINAL	19MAR2003/10:15	29	91	92	143	91	359	412	25 I	26 I
	E0029021	BASELINE *	03MAR2003/10:23	-15	69	69	144	93	371	389		
		BASELINE	18MAR2003/9:30	1	67	68	165	84	358	372		
		FINAL	15MAY2003/13:20	59	92	92	152	85	314	362	25 I	24 I
	E0035023	BASELINE	06MAY2003/10:41	-7	47 L	47 L	167	87	384	353		

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	VENTRI-CULAR RATE		ATRIAL RATE		INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	BASELINE		19JUN2003/11:20	-8	53		53		159	101	400	384		
		FINAL		21AUG2003/9:00	56	78		77		150	89	357	389	25 I	24 I
	E0004001	BASELINE		23SEP2002/11:40	-7	47	L	47	L	180	96	379	349		
		FINAL		05NOV2002/13:25	37	81		81		173	81	319	354	34 I	34 I
	E0004009	BASELINE		17DEC2002/9:45	-9	60		61		131	99	396	397		
		FINAL		19FEB2003/16:10	56	103		104		147	84	327	391	43 I	43 I
	E0004012	BASELINE		07JAN2003/12:30	-7	48	L	48	L	125	74	452	420		
		FINAL		11MAR2003/11:25	57	70		70		121	87	377	397	22 I	22 I
	E0004015	BASELINE		06FEB2003/9:40	-14	57		57		139	90	383	376		
		FINAL		15APR2003/9:20	55	75		75		170	90	363	391	18 I	18 I
	E0005003	BASELINE		23SEP2002/15:10	-9	60		60		145	100	368	368		
		FINAL		26NOV2002/13:30	56	90		90		148	96	307	351	30 I	30 I
	E0005007	BASELINE		02OCT2002/13:15	-7	66		66		156	84	405	417		
		FINAL		04DEC2002/14:10	57	86		87		135	90	357	403	20 I	21 I
	E0005009	BASELINE		09OCT2002/10:30	-20	49	L	49	L	154	90	384	359		
	E0005014	BASELINE		05NOV2002/16:30	-8	58		57		150	100	393	387		
		FINAL	*	06JAN2003/9:45	55	73		73		154	97	368	393	15 I	16 I
		FINAL		06JAN2003/11:45	55	83		83		152	97	361	402	25 I	26 I
	E0007005	BASELINE		27JAN2003/13:30	-4	63		62		149	89	371	377		
		FINAL		28MAR2003/12:30	57	79		80		156	86	350	384	16 I	18 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	BASELINE	09JUL2003/19:35	-7	58	58	131	100	387	382		
		FINAL	10SEP2003/17:20	57	80	80	150	95	358	395	22 I	22 I
	E0010002	BASELINE	14NOV2002/14:45	-11	63	62	164	92	400	405		
		FINAL	02DEC2002/9:00	8	88	89	140	91	344	391	25 I	27 I
	E0010009	BASELINE	18DEC2002/11:33	-8	55	55	153	94	431	419		
		FINAL	19FEB2003/13:40	56	71	71	142	90	366	388	16 I	16 I
	E0010010	BASELINE	20DEC2002/8:52	-10	42 L	42 L	144	84	430	381		
		FINAL	13JAN2003/10:15	15	58	58	139	87	388	383	16 I	16 I
	E0010014	BASELINE	14JAN2003/8:51	-14	57	58	135	103	404	398		
		FINAL	25MAR2003/10:50	57	47 L	47 L	148	106	384	354	-10	-11
	E0010017	BASELINE	05FEB2003/10:46	-20	58	58	161	91	378	373		
		FINAL	22APR2003/10:03	57	78	78	146	91	343	374	20 I	20 I
	E0011022	BASELINE	02JUN2003/11:15	-7	89	90	128	92	360	412		
		FINAL	05AUG2003/10:35	58	104	104	125	86	333	400	15 I	14
	E0013006	BASELINE	06MAR2003/10:22	-7	70	70	162	104	380	400		
		FINAL	24MAR2003/12:45	12	85	85	159	87	341	383	15 I	15 I
	E0013012	BASELINE	29APR2003/10:40	-8	72	72	161	88	400	425		
		FINAL	02JUL2003/10:10	57	87	87	200	93	326	369	15 I	15 I
	E0013014	BASELINE	08MAY2003/11:23	-26	53	53	233 H	86	398	383		
		FINAL	30JUN2003/12:27	28	54	54	217 H	87	380	368	1	1

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE	
					VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRICULAR RATE	ATRIAL RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	BASELINE	08NOV2002/10:35	-21	51	51	163	92	404	383		
		FINAL	20JAN2003/7:45	53	68	69	160	102	387	404	17 I	18 I
	E0016005	BASELINE	20FEB2003/13:40	-5	59	59	147	90	410	408		
		FINAL	22APR2003/8:05	57	80	80	144	86	375	414	21 I	21 I
	E0019015	BASELINE	19DEC2002/10:05	-14	56	57	190	93	415	407		
		FINAL	27FEB2003/11:10	57	76	76	157	91	368	399	20 I	19 I
	E0020021	BASELINE	13MAY2003/10:00	-6	63	63	159	93	362	367		
		FINAL	14JUL2003/9:55	57	84	85	142	97	299	335	21 I	22 I
	E0022007	BASELINE	01NOV2002/11:35	-6	47 L	47 L	152	93	402	370		
	E0022012	BASELINE	21NOV2002/12:15	-14	57	57	113	95	394	386		
		FINAL	30JAN2003/12:35	57	73	73	135	97	352	376	16 I	16 I
	E0022039	BASELINE	27FEB2003/11:30	-7	52	52	198	97	401	383		
		FINAL	01MAY2003/13:05	57	92	91	182	91	357	412	40 I	39 I
	E0022051	BASELINE	31MAR2003/11:35	-7	63	63	167	78	381	387		
		FINAL	02JUN2003/11:00	57	80	80	151	81	350	385	17 I	17 I
	E0022053	BASELINE	04APR2003/13:52	-7	49 L	49 L	154	88	408	381		
	E0022061	BASELINE	24APR2003/10:05	-6	67	68	141	94	375	389		
		FINAL	26JUN2003/12:43	58	84	84	162	96	332	371	17 I	16 I
	E0023039	BASELINE	24JUN2003/13:45	-7	68	68	167	82	386	402		
		FINAL	26AUG2003/13:00	57	86	86	148	86	351	395	18 I	18 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0026007	BASELINE	06JAN2003/10:35	-10	65	65	158	85	406	418		
		FINAL	12MAR2003/14:30	56	89	90	167	83	351	400	24 I	25 I
	E0028037	BASELINE *	18APR2003/8:05	-56	86	85	136	83	374	421		
		BASELINE	04JUN2003/9:00	-9	57	57	146	95	394	388		
		FINAL	08AUG2003/14:30	57	79	78	143	94	360	395	22 I	21 I
	E0034004	BASELINE	11APR2003/11:22	-10	62	63	142	95	354	357		
		FINAL	16JUN2003/12:22	57	85	86	146	83	333	374	23 I	23 I
	E0035021	BASELINE	18APR2003/10:26	-7	57	57	151	87	367	361		
		FINAL	20JUN2003/8:23	57	74	74	139	87	359	385	17 I	17 I
	E0036002	BASELINE	10JUN2003/12:12	-7	59	59	140	89	412	410		
		FINAL	14JUL2003/14:05	28	83	83	139	84	342	381	24 I	24 I
	E0039042	BASELINE	24APR2003/15:15	-13	57	57	165	96	389	381		
		FINAL	02JUL2003/13:00	57	86	86	162	89	371	417	29 I	29 I
	E0041004	BASELINE	22JAN2003/16:00	-8	56	56	167	90	376	367		
		FINAL	31MAR2003/12:40	61	76	76	168	90	339	367	20 I	20 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BASELINE	23JUN2003/12:20	-18	56	57	159	86	388	378		
		FINAL	25JUL2003/9:59	15	48 L	48 L	166	87	411	381	-8	-9
	E0003002	BASELINE	22OCT2002/10:40	-7	59	58	200	81	406	402		
		FINAL	23DEC2002/15:45	56	74	75	169	87	373	402	15 I	17 I
	E0007009	BASELINE	09APR2003/18:55	-8	61	61	145	101	385	386		
		FINAL	28APR2003/17:45	12	87	87	155	95	350	396	26 I	26 I
	E0009011	BASELINE	28APR2003/14:10	-8	82	82	204	91	342	379		
		FINAL	03JUL2003/15:45	59	55	55	201	93	388	378	-27 D	-27 D
	E0011016	BASELINE	14APR2003/10:15	-7	65	65	162	92	363	373		
		FINAL	16JUN2003/10:30	57	86	87	165	84	332	375	21 I	22 I
	E0019016	BASELINE	30DEC2002/17:15	-7	78	78	155	91	322	351		
		FINAL	03MAR2003/16:16	57	96	96	151	90	321	375	18 I	18 I
	E0019024	BASELINE	23JAN2003/16:43	-7	68	68	147	96	366	381		
		FINAL	06FEB2003/14:00	8	84	84	158	103	344	385	16 I	16 I
	E0019031	BASELINE	06MAR2003/11:54	-7	48 L	48 L	185	96	384	355		
		FINAL	25MAR2003/10:50	13	68	69	184	93	356	372	20 I	21 I
	E0023022	BASELINE	10APR2003/15:40	-8	51	51	158	86	376	357		
		FINAL	12JUN2003/15:45	56	70	70	152	88	332	350	19 I	19 I
	E0026003	BASELINE	25NOV2002/12:25	-9	54	55	143	85	401	388		
		FINAL	03FEB2003/11:05	62	95	95	158	82	331	386	41 I	40 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS				CHANGE FROM BASELINE	
							PR	QRS	QT	FRIDER-ICIA QTC	VENTRI-CULAR RATE	ATRIAL RATE
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	BASELINE	20FEB2003/11:35	-7	62	63	158	90	370	375		
		FINAL	25APR2003/10:10	58	85	85	143	90	307	345	23 I	22 I
	E0026023	BASELINE	23APR2003/10:55	-7	51	51	149	107	367	347		
		FINAL	27JUN2003/12:30	59	76	77	164	101	345	374	25 I	26 I
	E0034009	BASELINE	10JUN2003/12:40	-9	53	54	170	92	427	410		
		FINAL	18AUG2003/17:10	61	78	78	165	85	364	397	25 I	24 I
	E0037012	BASELINE	11JUL2003/13:25	-5	54	54	132	93	350	338		
		FINAL	08SEP2003/13:45	55	81	81	138	92	326	361	27 I	27 I

1606

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	VENTRI-CULAR RATE		ATRIAL RATE		INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE
PLACEBO (BIPOLAR I)	E0007003	BASELINE		03JAN2003/4:30	-27	82		82		159	96	382	424		
		FINAL		10MAR2003/12:45	40	109		108		127	91	339	413	27 I	26 I
	E0009004	BASELINE		19NOV2002/12:20	-7	81		81		158	78	364	402		
		FINAL		18DEC2002/14:35	23	97		97		154	85	325	381	16 I	16 I
	E0011008	BASELINE	*	17DEC2002/12:10	-44	43	L	43	L	139	89	436	390		
		BASELINE		23JAN2003/9:40	-7	57		57		153	95	395	388		
		FINAL		13FEB2003/13:30	15	47	L	47	L	145	90	384	353	-10	-10
	E0013001	BASELINE		01NOV2002/9:05	-13	88		90		147	95	322	366		
		FINAL		10JAN2003/10:52	58	64		64		191	92	379	387	-24 D	-26 D
	E0014004	BASELINE		04MAR2003/11:15	-8	53		53		164	97	424	407		
		FINAL		15APR2003/11:25	35	67		68		190	99	391	406	14	15 I
	E0014017	BASELINE		17JUN2003/16:37	-10	60		60		177	83	354	355		
		FINAL		19AUG2003/15:55	54	76		76		137	86	372	402	16 I	16 I
	E0015005	BASELINE		25NOV2002/13:30	-7	55		55		174	96	402	391		
		FINAL		18DEC2002/9:10	17	48	L	48	L	197	86	429	398	-7	-7
	E0018009	BASELINE		17DEC2002/11:00	-20	63		64		123	91	353	360		
		FINAL		14JAN2003/13:10	9	81		81		137	93	339	374	18 I	17 I
	E0020020	BASELINE		07MAY2003/15:00	-5	74		73		170	89	356	381		
		FINAL		23MAY2003/16:20	12	58		57		191	84	351	346	-16 D	-16 D
	E0022016	BASELINE		03DEC2002/12:25	-14	57		57		140	95	380	374		
		FINAL		11FEB2003/11:10	57	72		73		170	80	358	381	15 I	16 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS					CHANGE FROM BASELINE	
					VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRI-CULAR RATE	ATRIAL RATE
PLACEBO (BIPOLAR I)	E0022070	BASELINE	05JUN2003/11:55	-7	66	66	169	97	376	389		
		FINAL	18JUN2003/15:30	7	81	81	169	111	372	411	15 I	15 I
	E0023009	BASELINE	24JAN2003/11:50	-18	69	69	128	78	393	411		
		FINAL	08APR2003/11:30	57	85	84	125	95	351	394	16 I	15 I
	E0023028	BASELINE	16MAY2003/12:30	-13	55	56	132	94	409	399		
		FINAL	21JUL2003/10:15	54	72	72	128	85	369	392	17 I	16 I
	E0028001	BASELINE	20SEP2002/12:55	-20	84	85	142	87	355	396		
		FINAL	03DEC2002/10:00	55	69	69	167	84	343	360	-15 D	-16 D
	E0028031	BASELINE	06MAR2003/9:15	-5	85	85	180	90	330	370		
		FINAL	17APR2003/13:20	38	104	104	191	92	324	389	19 I	19 I
	E0030016	BASELINE	21FEB2003/11:55	-10	69	69	154	90	371	389		
		FINAL	22APR2003/18:50	51	88	87	154	86	341	387	19 I	18 I
	E0035020	BASELINE	11APR2003/11:15	-7	79	80	166	89	382	420		
		FINAL	13JUN2003/8:20	57	50	50	157	92	422	397	-29 D	-30 D
	E0037003	BASELINE	22JAN2003/13:55	-8	80	80	133	88	334	367		
		FINAL	20FEB2003/16:45	22	101	100	140	94	318	378	21 I	20 I
	E0039022	BASELINE	04FEB2003/14:21	-21	81	81	137	93	354	390		
		FINAL	24APR2003/12:15	59	57	57	127	87	422	414	-24 D	-24 D
	E0039037	BASELINE	26MAR2003/18:40	-21	66	65	144	99	381	392		
		FINAL	12JUN2003/11:45	58	82	82	141	91	331	368	16 I	17 I
	E0039059	BASELINE	03JUL2003/16:10	-8	68	68	152	92	389	406		

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS					CHANGE FROM BASELINE	
					VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC	VENTRI-CULAR RATE	ATRIAL RATE
PLACEBO (BIPOLAR I)	E0039059	FINAL	05SEP2003/11:20	57	50	51	150	83	418	394	-18 D	-17 D
	E0041007	BASELINE	05MAR2003/14:00	-8	56	56	229 H	91	363	355		
		FINAL	08MAY2003/13:40	57	73	73	203	81	353	377	17 I	17 I

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE	
					VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRICULAR RATE	ATRIAL RATE
PLACEBO (BIPOLAR II)	E0007004	BASELINE	24JAN2003/7:50	-6	61	61	163	85	410	411		
		FINAL	12FEB2003/18:35	14	101	102	178	85	304	362	40 I	41 I
	E0011013	BASELINE	25MAR2003/10:10	-23	82	82	122	91	380	422		
		FINAL	12JUN2003/9:15	57	62	63	152	88	433	434	-20 D	-19 D
	E0018005	BASELINE	10DEC2002/15:30	-10	50	50	142	87	358	336		
		FINAL	14FEB2003/16:45	57	47 L	47 L	136	93	374	345	-3	-3
	E0023036	BASELINE	10JUN2003/12:00	-10	74	73	226 H	93	342	366		
	E0041005	BASELINE	24FEB2003/11:20	-9	62	62	154	101	379	383		
		FINAL	30APR2003/14:15	57	82	83	167	99	327	364	20 I	21 I

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12. APPENDICES

AstraZeneca

Clinical Study Report: Appendix 12.1

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1
Study information

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AstraZeneca

Clinical Study Report: Appendix 12.1.1

Drug Substance	Quetiapine fumarate
Study Code	5077US/0049

Appendix 12.1.1
Protocol and protocol amendments

Version of protocol or protocol amendment	Date of issue
Final protocol	July 14, 2003
Protocol amendment 1	September 30, 2002
Protocol amendment 2	December 4, 2002
Protocol amendment 3	April 21, 2003
Protocol amendment 4	May 12, 2003

AstraZeneca

Clinical Study Protocol	
Drug Substance	Quetiapine Fumarate
Study Code	5077US/0049
Version No.	6
Date	July 14, 2003

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

The following amendment(s) have been made to this protocol since the date of preparation:

Amendment No.	**1**	**Date of amendment**	**September 30,2002**
Amendment No	**2**		**December 4, 2002**
Amendment No.	**3**		**April 21, 2003**
Amendment No.	**4**		**May 12, 2003**
Amendment No.	**5**		**July 14, 2003**

Administrative	**1**	**Date of administrative change**	**September 30, 2002**
Change No.	**2**		**July 14, 2003**

PROTOCOL SYNOPSIS

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

Investigator

Multicenter trial: << To be determined >>

Study center(s) and number of subjects planned

A total of approximately 740 subjects will be screened to enroll approximately 530 into the trial in order to obtain approximately 504 evaluable patients, defined as those who have a baseline visit and at least one post baseline assessment. It is expected that approximately 75 centers will participate in the trial, with each center enrolling 8 patients (maximum 70).

Study period		**Phase of development**
Estimated date of first subject enrolled	September, 2002	IIIb
Estimated date of last subject completed	March, 2004	

Objectives

Primary:

To evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

1. the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score
2. the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at final assessment
3. the change from baseline to each assessment in the MADRS total score

4. the change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S)

5. the Clinical Global Impression - Change (CGI-C).

Secondary:

1. to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

2. to evaluate the effect of quetiapine on anxiety compared to placebo by comparing

   - the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

   - the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

3. to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by comparing

   - the incidence and nature of all adverse events

   - the incidence and nature of drug-related adverse events

   - subject withdrawal due to adverse events during double-blind treatment

   - the number of patients having clinically significant changes in vital signs from baseline to end of treatment

   - the change in Simpson-Angus Scale (SAS) total score

   - the change in the Barnes Akathisa Rating Scale (BARS) total score from baseline to end of treatment

   - the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Exploratory

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment.

Hypotheses:

Primary:

1. Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

2. Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

Secondary hypotheses are defined in Section 3.1.

Study design

Study 5077US/0049 is a randomized, multicenter, double-blind, placebo-controlled, double-dummy, parallel group, fixed-dose comparison of quetiapine vs placebo in the treatment of bipolar depression. This study will be stratified 1:1 for bipolar I and bipolar II.

Target subject population

Outpatients, aged 18 to 65 years, with a diagnosis of bipolar I or bipolar II disorder with a current major depressive episode of duration less than one year but greater than 4 weeks will be enrolled in the trial. The HAM-D (17-item scale) score must be ≥20, the HAM-D item 1 (depressed mood) score must be ≥2, and the YMRS score must be ≤12 at both Visit 1and Visit 2 (randomization) to be eligible for entry into the trial.

Investigational product, dosage and mode of administration

Study drug will be titrated in a blinded manner to a total daily dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and to a total daily dose of 600 mg/day by Day 8 in the 600-mg/day treatment group. Thereafter, oral doses of quetiapine fumarate will be administered in a blinded fashion once daily at bedtime (qhs) in a total daily dose of 300 or 600 mg/day. One-time dose reductions for intolerability of 100 mg/day in both the 300 mg/day and in the 600 mg/day treatment groups will be allowed at the discretion of the Investigator after Day 8.

Comparator, dosage and mode of administration

Placebo will be administered once daily with tablets matching in number and appearance to blinded quetiapine dosing.

Duration of treatment

Patients will receive double-blind, double-dummy treatment for up to 8 weeks (56 days), following an initial washout period of between 7 to 28 days (depending on the medications involved) and will come in to the clinic on Day 57 for final assessments.

Endpoints

- **Efficacy**

  Primary efficacy endpoint is the change from baseline to final assessment in the MADRS total score.

  Secondary efficacy endpoints are the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at study endpoint, the change from baseline to each assessment (observed cases) in the MADRS total score, and the change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, and CGI-S and the CGI-C.; the change from baseline to each assessment (observed cases) and final assessment in the YMRS, and the HAM-A total scores.

- **Safety**

  Safety endpoints are the incidence and nature of all adverse events, the incidence of drug-related adverse events, the incidence of subject withdrawal due to adverse events, and the incidence of clinically significant changes in vital signs, weight, and body mass index during double-blind treatment. Tolerability endpoints are the change in the SAS total score from baseline to final assessment, the change in BARS total score from baseline to final assessment, and the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

- **Quality of life**

  Exploratory quality of life endpoints are the change from baseline in the PSQI score and Q-Les-Q total score.

Statistical methods

All statistical comparisons will be 2-sided tests for the difference between active study medication and placebo. The primary analysis will be analysis of covariance (ANCOVA) for the change from baseline to final assessment for total MADRS score. The ANCOVA model will include terms for treatment, and stratum, with the baseline MADRS score as a covariate. Pair-wise comparisons of each dose with placebo will be assessed within this model as planned comparisons. In order to adjust for multiple comparisons with placebo a step-up

procedure will be employed with a rule for tests of significance based on ordered p-values, maintaining an overall experiment wise type I error rate of 0.05. The proportion of patients having a $\geq$ 50% reduction from baseline to final assessment in MADRS will be compared across treatments using a logistic model. Change from baseline in MADRS scores at each assessment (observed cases), and change from baseline in HAM-D, HAM-D item 1, CGI-S, YMRS, HAM-A, Q-Les-Q and PSQI score at each assessment (observed cases) and LOCF, will be analyzed using the same ANCOVA model as for the primary endpoint. The CGI-C will be analyzed using the ANCOVA model with the baseline CGI-S as a covariate.

The change from baseline in SAS and BARS score data will be assessed using the same ANCOVA model as the primary endpoint. The incidence of EPS AEs and overall AEs will be reported using descriptive statistics. Vital signs, weight, and body mass index will be tabulated using descriptive statistics at baseline, final assessment, and for change from baseline. Descriptive statistics will also be used to describe the proportion of patients whose final Q-Les-Q is within community norm levels.

Repeated measures analysis of variance (ANOVA)will be performed to evaluate whether there are significant differences among treatments across time for MADRS, HAM-D, and HAM-A total scores.

Efficacy analyses will be conducted on a modified intention-to-treat (MITT) population. A per-protocol (PP) analysis will be conducted for the primary analysis measure (change from baseline MADRS) to evaluate sensitivity of the response. The safety population will include all subjects who took study medication.

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APPENDICES

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

The following abbreviations and specialist terms are used in this study protocol.

Table 1 Abbreviations and specialist terms

Abbreviation or specialist term	Explanation
AE	Adverse event (see definition in Section 4.4.2.1)
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BP	Bipolar Disorder
BPD	Bipolar Depression
CGI	Clinical Global Impression
CGI-C	Clinical Global Impression - Change
CGI-S	Clinical Global Impression - Severity
CMH	Cochran-Mantel Haenszel
CRF	Case Report Form
CRS	Concordant Rater systems
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition
EPS	Extrapyramidal symptoms
ECG	Electrocardiogram
GCP	Good Clinical Practice

Abbreviation or specialist term	Explanation
HAM-A	Hamilton Rating Scale for Depression
HAM-D	Hamilton Rating Scale for Anxiety
ICH	International Conference on Harmonisation
ICI-D	Interactive Computor Interview-Depression
ICTI	Interactive Clinical Technologies, Incorporated
IEC	Independent Ethics Committee
IRB	Institutional Review Board
IVRS	Interactive Voice Response System
LOCF	Last Observation Carried Forward
MADRS	Montgomery-Asberg Depression Rating Scale
MITT	Modified Intent to Treat
OAE	Other significant adverse event (ie, an adverse event of special interest in this clinical development; see definition in Section 4.4.2.1). The classification of OAEs will be performed by AstraZeneca drug safety physicians after the study is complete.
PSQI	Pittsburgh Sleep Quality Index
Principal investigator	The investigator who leads the study conduct at an individual study center. Every study center has a principal investigator.
Qhs	at bedtime
Q-Les-Q	Quality of Life Enjoyment Satisfaction Questionnaire
SAE	Serious adverse event (see definition in Section 4.4.2.1).
SAS	Simpson Angus Scale
SSRI	Selective serotonin reuptake inhibitors

Abbreviation or specialist term	Explanation
UNI	Universal Systems Incorporated
YMRS	Young Mania Rating Scale

1. INTRODUCTION

1.1 Background

Quetiapine fumarate (SEROQUEL®, quetiapine) is a dibenzothiazepine derivative approved by the United States Food and Drug Administration (FDA) on 26 September 1997 following clinical development by AstraZeneca Pharmaceuticals LP (also referred to as the sponsor) for the treatment of subjects with schizophrenia. Quetiapine fumarate is designated chemically as bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl) piperazin-1-yl]ethoxy)ethanol] fumarate

Quetiapine has been studied in a toxicological and clinical program directed at supporting clinical evaluation in man. The results of these studies are presented in the Investigator's Brochure dated January 2002. The Professional Information Brochure (PIB) contains the current prescribing information for quetiapine.

1.2 Rationale for this study

The bipolar disorders are psychiatric disorders in which a disturbance in mood is the predominant feature. Bipolar I disorder is characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes. Bipolar II disorder is characterized by one or more major depressive episodes accompanied by at least one hypomanic episode. Bipolar depression refers to the major depressive episodes that occur with bipolar I and II disorder.

The prevalence of bipolar disorder is estimated to be 1 to 3.5%, evenly divided between men and women. The length of time between onset and symptoms and proper diagnosis and treatment is approximately 10 years and it is estimated that only 60% of those suffering from a bipolar disorder are receiving appropriate pharmacotherapy.

Although there is extensive and emerging literature guiding the treatment of the manic phase of bipolar I disorder as well as many approved compounds for the treatment of unipolar depression, the treatment of bipolar depression has not been widely studied and treatment guidelines are in their infancy. The use of currently available antidepressants for monotherapy for bipolar depression is often problematic as they may increase the "switch" into hypomania or mania from depression, or increase cycle acceleration. The adjunctive use of mood stabilizing medications such as lithium carbonate (LiCO3) is common and may decrease the likelihood of these complications.

Evidence indicates that medications with mood stabilizing properties which produced low levels of mania, hypomania, or cycle acceleration may be useful as monotherapy in the treatment of bipolar depression. The antiepileptic lamotrigine produced improvement in HAM-D and MADRS scores in a 7-week, double-blind, placebo controlled trial for the

patients who completed this study (Calabrese 1999). More recently, the anti-manic agent divalproex demonstrated numerical improvement over placebo in the percentage of patients with bipolar depression having a 50% reduction in the HAM-D scores without mania in an 8 week trial (Sachs, 2001) but this difference was not statistically significant. Lithium carbonate, also approved for the treatment of mania, has been demonstrated to be effective as a monotherapeutic agent in approximately 50% of patients with bipolar depression (Bauer). However, there are efficacy and tolerability limitations which may prohibit widespread use of the above therapies.

A large multicentered, double-blind, placebo controlled trial was recently completed, which demonstrated efficacy of the atypical antipsychotic olanzapine as monotherapy for the treatment of bipolar depression (Tohen, 2002). The endpoint mean MADRS change was significantly greater for patients on olanzapine (-15.0 points) than for those on placebo (-11.9 points). Treatment-emergent mania did not differ significantly between groups. There also is evidence from small uncontrolled studies that other atypical antipsychotics such as risperidone, and clozapine have mild to moderate antidepressant activity when used in patients with mood disorders. These small studies also indicate that these compounds are unlikely to cause patients to “switch” into mania.

The potential efficacy of quetiapine in depressive symptoms is provided in data from the Quetiapine Experience with Safety and Tolerability Trial (QUEST) and from investigator-initiated trials in mood disorder patients. In an open-label trial evaluating the safety and tolerability of quetiapine over 700 subjects with schizophrenia and other psychotic disorders were randomized to treatment with quetiapine or risperidone. Quetiapine-treated patients experienced a greater improvement in depressive symptoms compared with risperidone-treated patients, with a mean difference of 1.3 points on the HAM-D after adjustment for baseline differences (P=0.028) (Mullen et al, 2001).

A trial of quetiapine in 20 neuroleptic-dependent patients with bipolar or schizoaffective disorder also suggested positive effects on the depressive and psychotic symptoms in these disorders (Sajatovic et al, 2001). Overall, in 10 patients with bipolar disorder and 10 with schizoaffective disorder who received open-label quetiapine to optimum clinical dosage (25 to 800-mg), significant improvement in Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), and HAM-D scores was noted.

In summary, the paucity of satisfactory treatments available signify an unmet medical need for the treatment of bipolar depression. There are signals of efficacy from clinical trials for the antidepressant properties of atypical antipsychotics such as quetiapine.

2. STUDY OBJECTIVES

2.1 Primary objective

The primary objectives of the study are to evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks by comparing

1. the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

2. the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at final assessment

3. the change from baseline to each assessment in the MADRS total score

4. the change from baseline to each assessment in the total Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S), and the Clinical Global Impression - Change (CGI-C).

2.2 Secondary objective

The secondary objectives of the study are:

1. to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

2. to evaluate the effect of quetiapine on anxiety compared to placebo by

   - the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

   - the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

3. to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by

   - the incidence and nature of overall adverse events

   - the incidence and nature of drug-related adverse events

   - subject withdrawal due to adverse events during double-blind treatment

- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Experimental:

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in sleep quality using the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment

3. HYPOTHESES, STUDY PLAN AND PROCEDURES

3.1 Hypotheses

Primary:

1. Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to edpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

2. Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

1. Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

2. Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

3. Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

4. Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

5. Quetiapine at a dose of 300 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

6. Quetiapine at a dose of 600 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

7. Quetiapine at a dose of 300-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

8. Quetiapine at a dose of 600-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

9. Quetiapine at a dose of 300 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

10. Quetiapine at a dose of 600 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

11. Quetiapine at a dose of 300 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

12. Quetiapine at a dose of 600 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

13. Quetiapine at a dose of 300 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

14. Quetiapine at a dose of 600 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

3.2 Overall study design and flow chart

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial will consist of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects will be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment of 8 patients per center (maximum 70). Subjects are required to have a HAM-D (17-item scale) score of $\geq$ 20 and a YMRS of =12 at screening baseline (Visit 1).

The trial comprises the following 2 periods:

- Washout period
  Subjects will undergo HAM-D, SCID, YMRS, and safety evaluations at screen (Visit 1) and if they qualify to participate they will commence a washout of antidepressant, antipsychotic, and mood stabilizer medications. The number of days for washout will depend on the medication they are taking. These medications must be discontinued for a period of at least 7 days prior to randomization (Day 1, Visit 2), with the exception of fluoxetine which must be discontinued for a period of 14 days prior to randomization (Day 1, Visit 2) and depot injections of haloperidol decanoate or fluphenazine decanoate which need 28 days washout before randomization.

- 8-week double-blind randomized treatment period (Weeks 1 to 8)
  Eligible subjects will be randomized on Day 1 (Visit 2) to 1 of 3 treatment groups: quetiapine 300 mg/day, quetiapine 600 mg/day, or placebo. The randomization will be done using a stratification based on diagnosis. Treatment will be administered once daily at bedtime for 8 weeks (Days 1 - 56). Subjects will not receive medication on Day 57 which is only for final assessments. Doses will be titrated to achieve target doses of 300 mg/day within 4 days or 600 mg/day within 8 days. A dose reduction of 100 mg is allowed to improve patient tolerance in each treatment group. MADRS assessments (used to evaluate the primary efficacy variable) will be performed at Days 1, 8, 15, 22, 29, 36, 43, 50, and 57.

Figure 1 Study flow chart

			Treatment										
Day	**Screen**	**Washout [b]**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9-14**	**15-56**	**57**
	Visit 1		**Visit 2**							**Visit 3**		**Visits 4-9**	**Visit 10**
Dose: 300-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	
Dose: 600-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	400-mg	400-mg	400-mg	600-mg	600-mg	600-mg	

[a] One time dose reductions of 100 mg/day in 300-mg and 600-mg may occur after Day 8

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers for 7 to 28 days depending on the medication involved (eg. haloperidol decanoate or fluphenazine decanoate for 28 days), prior to randomization. Patients on fluoxitine must discontinue for 14 days.

Table 2 Study plan

Study plan	Screen	Washout[a]	Double-blind treatment phase Weeks 1 through 8								
Days			**1**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**
Visits	**1**		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Informed consent	√										
Medical history	√										
Inclusion/Exclusion criteria	√		√								
Structured Clinical Interview for DSM-IV (SCID)	√										
Physical examination[d]	√										√
Urine toxicology screen	√										
Pregnancy tests (females)	√										
Vital signs, height, weight[c,e]	√		√	√	√	√	√	√	√	√	√
12-lead electrocardiogram	√		√[b]								√
Clinical chemistry and hematology	√		√[b]								√
Hamilton Rating Scale for Depression (17-item)	√		√	√	√	√	√	√	√	√	√
Montgomery-Asberg Depression Rating Scale			√	√	√	√	√	√	√	√	√
Young Mania Rating Scale	√		√	√	√	√	√	√	√	√	√
Hamilton Rating Scale for Anxiety			√	√	√	√	√	√	√	√	√
Clinical Global Impression - Severity	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression -Change				√	√	√	√	√	√	√	√
Barnes-Akathisia Rating Scale			√								√
Simpson-Angus Scale			√								√
Pittsburgh Sleep Quality Index			√				√				√
Quality of Life Enjoyment Satisfaction Questionnaire			√				√				√
Dispense study medication			√	√	√	√	√	√	√	√	
Adverse events	√	√	√	√	√	√	√	√	√	√	√

[a] Washout of antidepressants, antipsychotics, mood stabilizer for 7 to 28 days depending on the medications involved and a 14-day washout for fluoxetine.

[b] Repeat laboratory tests and ECG only if results outside of normal range and clinically significant at Screening

c Height and weight on screen and weight on Day 57

d Physical exam includes ophthalmoscopic exam on screen

e Blood pressure will be obtained in supine and standing positions

3.3 Rationale for study design, doses and control groups

This trial is designed as a double-blind placebo-controlled evaluation of Seroquel as monotherapy in bipolar depression. There is no currently approved compound for use in bipolar depression, nor is there a clinically accepted "gold standard". Conventional antidepressants have fallen out of favor because of their ability to induce manic symptoms. Antidepressants approved forthe treatment of unipolar depression have not been demonstrated to improve mood symptoms relative to placebo (Nemeroff et al Am J Psychiatry 158:6 June 2001). Moreover, there is a high placebo response rates of approximately 30% found in bipolar depression trials. Thus, the use of a placebo treatment arm for comparison is clinically justified.

Trial treatment will be administered as quetiapine monotherapy in order to more clearly identify a treatment effect of quetiapine on bipolar depression. Quetiapine fumarate will be administered once daily at bedtime. The current label specifies twice daily (BID) but a double-blind crossover study in bipolar patients indicated that once daily (qd) is well tolerated and as effective as BID dosing (Chengappa, 2002).

A period of 7 to 28 days is adequate for washout of most psychoactive medications including antidepressants, antipsychotics (including depot agents), and mood stabilizers to ensure that subjects are stable and continue to have adequate depressive symptoms requiring treatment, prior to randomization into the trial. The double-blind treatment period of 8 weeks is consistent with the time period that is required to see a clinically meaningful response in depressive symptoms.

The trial is designed as a fixed-dose evaluation due to the failure of flexible dose regimens in other psychiatric disorders. The dosages are based on clinical trial data with quetiapine in patients with a mood disorder. In the QUEST trial, the average dose of quetiapine in patients with a primary mood disorder (N=316) was approximately 250 mg/day at 16 weeks. In 20 patients with bipolar or schizoaffective disorder treated with open-label quetiapine, the mean dose was approximately200 mg/day (Sajatovic). Based on this data, 300 mg/day administered as monotherapy is an appropriate low-dose treatment arm, and 600 mg/day is an appropriate high-dose treatment arm that should exhibit efficacy without a high rate of AEs or noncompliance.

The MADRS is a standardized, well-validated measure of depressive symptoms that is sensitive to treatment effects in depressed outpatients.

3.4 Selection of study population

3.4.1 Study selection record

Investigators must keep a record of subjects who underwent screening but were not randomized into the trial.

3.4.2 Inclusion criteria

At screen (Visit 1) subjects must fulfill all of the following criteria:

1. Documented ability to provide informed consent before beginning any study-specific procedures.

2. Male and female patients between 18 and 65 years of age, inclusive

3. Females of childbearing potential must be using a reliable method of contraception. Reliable methods include hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

4. Women must have a negative pregnancy test

5. Meets DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x), confirmed by the amended version (by Dr. Michael First) of the Structured Clinical Interview for DSM-IV (SCID) as administered by an AstraZeneca approved clinician with a signed confirmation by the Principal Investigator

6. Outpatient status

7. HAM-D (17-item) total score of 20 or greater

8. HAM-D item 1 (depressed mood) score ≥2

9. YMRS total ≤12

At randomization (Visit 2) subjects must fulfill the following criteria:

1. HAM-D (17-item) total score of 20 or greater

2. HAM-D item 1 (depressed mood) score ≥2

3. YMRS total ≤12

3.4.3 Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

1. Patients with a current Axis I disorder other than bipolar disorder within 6 months of screening

2. Patients whose current episode of depression exceeds 12 months or is less than 4 weeks

3. History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode

4. Patients who meet DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening

5. Patients with a positive urine toxicology screen for illicit substances of abuse

6. Patients who are unable to discontinue all psychoactive medications (excluding prn benzodiazepines), including antidepressants, antipsychotics, and mood stabilizer, at least 7 days prior to randomization and consistent with the pharmacokinetics of the drug

   – Patients treated with fluoxetine who have not discontinued this medication for at least 14 days prior to randomization.

   – Patients treated with haloperiodol decanoate or fluphenazine decanoate who have not discontinued these medications 28 days prior to randomization.

7. Patient who have not discontinued the use of potent P450 inhibitors and inducers (See Section 4.3, Table 13)

8. Patients who in the investigators opinion will require initiation of psychotherapy during the study period. Note: ongoing psychotherapy for a minimum of 3 months may continue.

9. Patients who, in the investigator's judgment, pose a current serious suicidal or homicidal risk at Visit 1 (HAM-D item 3 score of 3 or greater), or have made a suicide attempt within the past 6 months

10. Patients with a history of clinically significant cardiac, renal, neurologic, cerebrovascular, metabolic, or pulmonary disease, or other disease or clinical finding that is unstable or that, in the opinion of the investigator, would be negatively affected by trial medication or that would affect trial medication

11. Patients who have had a myocardial infarction within 1 year before Visit 1

12. Patients with clinically significant abnormal laboratory findings at Visit 1

13. Patients with renal impairment (serum creatinine $\geq$1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal)

14. Patients whose TSH is ≥10% over the upper normal limit. Patients maintained on thyroid medication must be euthyroid for a period of at least 3 months before Visit 1

15. Patients with clinically significant abnormalities on ECG

16. Women who have a positive human chorionic gonadotropin (HCG) pregnancy test at Visit 1 or who are lactating or planning to become pregnant during the course of the study

17. Patients who have participated in a clinical trial of an investigational drug within the past 3 months

18. Patients who, in the opinion of the investigator, would be non-compliant with the visit schedule or study procedures

19. History of orthostatic hypotension or conditions that would predispose them to hypotension (eg dehydration, hypovolemia)

20. Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of Seroquel tablets, as judged by the investigator

3.4.4 Restrictions

Subjects will be required to adhere to the following special restrictions:

1. Use of any psychoactive drugs including antidepressants, hypnotics (with the exceptions noted in Section 4.3), mood stabilizing drugs, and antipsychotics is not permitted from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

2. Use of cytochrome P450 3A4 inducers and potent inhibitors are not permitted from 14 days prior to randomization to end of study (see Table 13)

3.4.4.1 Criteria for discontinuation

Subjects may be discontinued from study treatment and assessments at any time, at the discretion of the investigator(s). Specific reasons for discontinuing a subject from this study are:

1. Withdrawal of informed consent

2. Worsening psychiatric symptoms such that the symptoms constitute a danger to themselves or to others

3. Use of psychotropic medications at any time during the double-blind treatment period.

4. Pregnancy at any time during the double-blind treatment period.

5. Clinically significant or serious adverse event that would not be consistent with continuation in the study, as determined by the investigator, AstraZeneca, or the subject.

3.4.4.2 Voluntary discontinuation by a subject

Subjects are free to discontinue their participation in the study at any time, without prejudice to further treatment. Subjects who discontinue from the study should always be asked about the reason(s) for their discontinuation and about the presence of any adverse events. They should be seen and assessed by an investigator(s) (see Section 3.4.4.4). Adverse events should be followed up and any diary cards, questionnaires (eg, for Quality of Life assessments) and investigational products should be returned by the subject.

3.4.4.3 Incorrectly enrolled or randomized subjects

Incorrectly enrolled subjects will be discontinued from further study treatment and assessments. If a subject is given the incorrect randomized treatment, the subject should be continued on the treatment dispensed and Interactive Clinical Technologies, Inc. (ICTI), the vendor providing the randomization patient assignment) should be notified of the error. The next patient randomized at the site will be assigned an appropriate kit number by ICTI, accounting for the error.

3.4.4.4 Procedures for discontinuation

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination
- Vital signs and weight
- 12-lead ECG
- HAM-D
- MADRS
- ICI-D
- YMRS
- HAM-A

- CGI-C
- CGI-S
- SAS
- BARS
- PSQI
- Q les Q
- Adverse events assessment

Psychiatric assessments (HAM-D, MADRS, YMRS, HAM-A, CGI-C, CGI-S, Q les Q, and PSQI) should not be performed on subjects who have missed 72 hours of study drug before any study visit. Due to the pharmacokinetic profile of quetiapine, these assessments are of questionable clinical accuracy.

3.5 Treatments

3.5.1 Investigational products

3.5.1.1 Identity of investigational product and comparators

Investigational product will consist of 25-mg, 100-mg, and 200-mg tablets of quetiapine fumarate and matching placebo tablets as shown in Table 3.

Table 3 Trial medication

Tablet strength	Formulation number	Tablet color
25-mg quetiapine	F12804	peach
25- mg placebo	F12636	peach
100-mg quetiapine	F12689	yellow
100-mg placebo	F12637	yellow
200-mg quetiapine	F12690	white
200-mg placebo	F12638	white

3.5.1.2 Doses and treatment regimens

Quetiapine and placebo for each trial center will be packaged in blister cards. The 8-week supply will consist of 8 double-blind blister cards. The 8 double-blind blister cards will be packaged in subject-specific cartons.

Trial medication will be provided for each subject in an 8-card carton that contains the following:

- 1-week titration double-blind treatment cards for Days 1-7
- seven 1-week double-blind treatment cards for Days 8-56, with individual cards provided for treatment Days 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, and 50-56. Each one-week blister card will include a 2-day treatment overage to accommodate visit schedules.

The Week 1 titration card will consist of 25 mg tablets, 100-mg tablets, and 200-mg tablets or matching placebo, as described below, for each of the 300 mg/day and 600 mg/day treatment groups and placebo treatment group.

Blister cards for Weeks 2 through 8, for each treatment group, will consist of 9 days of dosing with the same number of pills for each group (300-mg, 600-mg, and placebo) respectively. The cards for each treatment group will consist of 2 yellow tablets and 2 white tablets per day at bedtime.

Quetiapine or placebo will be administered once a day at bedtime with dose titration to reach a target dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and 600 mg/day by Day 8 in the 600 mg/day group. The schedule for quetiapine or placebo administration is shown in Tables 4, 5, and 6.

Table 4 Dose administration schedule for 300-mg double-blind quetiapine

Trial Day	Quetiapine 300 mg/day and placebo				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablet/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 6	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 7	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 8	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg
Days 9-56	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg

Table 5 Dose administration schedule for 600-mg double-blind quetiapine

Trial Day	Quetiapine 600 mg/day and placebo tablets				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablets/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 6	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 7	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 8	0	2 tablets/100-mg	0	2 tablets/400-mg	0
Days 9-56	0	2 tablets/100-mg	0	2 tablets/400-mg	0

Table 6 Dose administration schedule for double-blind placebo

Trial Day	Placebo 25mg	Placebo 100 mg	Placebo 200 mg
Day 1	2 tablets/50-mg	0	0
Day 2	0	1 tablet/100-mg	0
Day 3	0	0	1 tablet/200-mg
Day 4	0	1 tablet/100-mg	1 tablet/200-mg
Day 5	0	2 tablets/100-mg	1 tablet/200-mg
Day 6	0	2 tablets/100-mg	1 tablet/200-mg
Day 7	0	2 tablets/100-mg	1 tablet/200-mg
Day 8	0	2 tablets/100-mg	2 tablets/400-mg
Days 9-56	0	2 tablets/100-mg	2 tablets/400-mg

Dosing Reduction

Dose reductions for intolerability will be allowed after Day 8. In the 300-mg/day group, dose reductions of 100 mg/day will be achieved by reducing the dose by one 100-mg tablets. In the 600-mg/day group, a dose reduction of 100 mg/day will be achieved by reducing the bedtime dose by one 100-mg tablets active drug. This dose reduction can occur anytime after Day 8. Each column in the blister packs will be numbered 1-4. By Day 6 columns 1 and 2 of the blister packs will each contain a 100-mg tablet. In both the 300-mg /day group and the 600-mg/day group, column 1 will contain active medication thus ensuring that by eliminating the first column (column #1) of medication they are reducing their dose by 100-mg. Each tablet in the placebo treatment group will also indicate the same corresponding numbers (columns #1-4) as the active treatment groups even though no active product is packaged. This will ensure the blind is maintained.

Table 7 Week 1 Blister pack for 300-mg/Day Quetiapine Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 8 Week 2-8 300-mg/Day Quetiapine Blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
2	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
3	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
4	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 9 Week 1 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 10 Week 2-8 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
2	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
3	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
4	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 11 Week 1 Blister Pack for Placebo Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg placebo	25-mg placebo		
2	100-mg placebo			
3	200-mg placebo			
4	100-mg placebo	200-mg placebo		
5	100-mg placebo	100-mg placebo	200-mg placebo	
6	100-mg placebo	100-mg placebo	200-mg placebo	
7	100-mg placebo	100-mg placebo	200-mg placebo	
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Table 12 Week 2-8 Blister pack for Placebo/Day Group

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
2	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
3	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
4	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
5	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
6	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
7	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

3.5.1.3 Labeling

All trial supplies will be provided by AstraZeneca.

The blister cards Days 1- 56 will be supplied in subject-specific cartons. Each blister card will be labeled with a two-panel, double-blind label. The left portion of the label will remain on the blister card. The right portion of the label will be affixed to the appropriate Case Report Form (CRF) as part of the individual's permanent record. The label will contain at least the following information: trial number, code assignment and storage condition. The carton for the 8 blister cards for Days 1-56 will be labeled with a single-panel double-blind label. The label will contain at least the following information: trial number, storage conditions, and instructions to dispense according to protocol.

3.5.1.4 Storage

All investigational products must be kept in a secure and locked location, at room temperature and protected from light and moisture.

3.5.1.5 Accountability

The investigational materials are to be prescribed only by the investigator or the sub-investigators named in Form FDA-1572. Under no circumstances will the investigator allow the investigational drug to be used other than as directed by the protocol without prior AstraZeneca approval.

The investigator must maintain accurate records accounting for the receipt of the investigational materials (ICTI provides a acknowledge the receipt of drug shipment module for this purpose) and for the disposition of the material. This record keeping consists of a dispensing record that includes the identification of the person to who the drug is dispensed, the quantity and the date of dispensing, and documentation of any unused drug returned to the investigator. This record is in addition to any drug accountability information recorded on the subject's hospital or clinic chart.

Starting with Week 1, each patient will return the blister card for the preceding week to the clinic. The clinic will tabulate the returned pills to aid in drug accountability.

At the termination of the study or at the request of the sponsor, the Clinical Research Associate must return any unused study supplies to Universal Systems Incorporated (USI), at the address listed below, for destruction. This return will be documented on an Investigational Product Return Invoice supplied by AstraZeneca.

USI
2084-900 Lake Industrial Court
Conyers, GA 30013

3.5.2 Method of assigning subjects to treatment groups

This trial will be established with a non-specific labeling (NCSL) randomization that will be stratified by bipolar type. Randomization to trial treatment will be done via an Interactive Voice Response System (IVRS) at ICTI on Day 1 (Visit 2) in balanced blocks within each stratum in order to ensure relative balance among treatment groups and strata (Bipolar I and Bipolar II)in terms of total number of subjects. The randomization schedule will be created under the auspices of AstraZeneca Quantitative Decision Sciences Group and will provide allocation of subject numbers to the treatment regiments. Number and size of tablets will be identical for the 3 treatment arms. Clinical supplies will contain a 4-digit subject number which is allocated to the treatment arm through the randomization scheme. A separate randomization will be used to provide kits of packaged drugs to the sites. The IVRS system at ICTI will allocate a kit number at the site for the treatment assigned through the stratified randomization.

Subject eligibility will be established before treatment randomization. Subjects will be randomized centrally sequentially within the stratum, as subjects are eligible for enrollment/randomization. If a subject discontinues from the study, the subject number will not be reused, and the subject will not be allowed to re-enter the study.

The randomization is centralized and the assigned randomized patient number and associated kit numbers will not be sequential within a site.

3.5.3 Blinding and procedures for unblinding the study

3.5.3.1 Methods for ensuring blinding

All packaging will be identical with placebo and active tablets identical in size and color. The number of tablets dispensed on each card will be identical across all treatment arms.

The randomization for the kit assignments will be generated by the study statistician and provided directly to packaging with a copy going to ICTI Clinical Supplies Management Group. The stratified patient randomization will be generated by an AstraZeneca randomization staff member not associated with the trial and will be provided directly to ICTI for incorporation into the IVRS system. No member of the study team in AstraZeneca, at investigational sites or the CRO organization handing data will have access to the randomization scheme during the conduct of the study.

3.5.3.2 Methods for unblinding the study

Individual treatment codes, indicating the treatment randomization for each randomized subject, will be available to the investigator(s) or pharmacists at the study center through the use of a concealed panel on the label.

The treatment code must not be broken except in medical emergencies when the appropriate management of the subject necessitates knowledge of the treatment randomization. The investigator(s) must document and report to AstraZeneca any breaking of the treatment code. AstraZeneca retains the right to break the code in order to report serious adverse events to regulatory authorities.

Treatment codes will not be broken for the planned analyses of data until all decisions on the evaluability of the data from each individual subject have been made and documented.

3.5.4 Treatment compliance

Compliance will be assessed based on returned tablet counts. The percent compliance will be calculated as the number of tablets taken (dispensed - returned) divided by the prescribed number of tablets (number of days times number of tablets per day) expressed as a percent. Based on this calculation a subject with at least 75% compliance with study medication during study participation will be classified as compliant.

Furthermore, if there are any significant irregularities in compliance, in the opinion of the investigator, the patient should be withdrawn from the study.

4. CONCURRENT TREATMENT

4.1 General medications

Nonpsychotropic medication, including over-the counter medications, taken by the subject before entry into the trial may be continued during the trial. Medications required to treat illnesses or complaints that occur during the trial may be used at the discretion of the investigator. Use of cytochrome P450 inducers and potent inhibitors is restricted (see Table 13 below).

Women who enter the trial with an intrauterine device in place, using oral contraceptives, or using injectable or implantable hormonal agents designed to prevent pregnancy may continue these treatments throughout the trial.

The specific type of medication (trade or generic name), the indication for use, and the dates of usage should be reported on the CRF entitled Concurrent Treatment.

Medication which is considered necessary for the subject's safety and well being may be given at the discretion of the investigator(s). The administration of all medication (including investigational products) must be recorded in the appropriate sections of the case report form (CRF).

4.2 Use of psychoactive medications

The use of psychoactive drugs other than those specifically allowed during the trial (ie, lorazepam and zolpidem tartrate) is restricted (see Section 4.3, Table 13).

4.3 Summary of permitted concurrent medications

Medications specifically prohibited or restricted, and those permitted during the trial are listed in Table 13

Table 13 Permitted, restricted, and prohibited medications

Use category	Type of medication
Permitted	Previous medications for medical, nonpsychiatric illnesses Oral contraceptives and contraceptive devices
Restricted	Zolpidem tartrate 5-10 mg at bedtime for insomnia Lorazepam 1-3 mg per day for severe anxiety These drugs may be prescribed during the first 3 weeks of the study as long as they do not interfere with any assessments
Prohibited	Potent cytochrome P450 3A4 inducers (including but not limited to barbiturates, carbamazepine, rifampin, and St John's Wort) Potent cytochrome P450 3A4 inhibitors (including but not limited to ketoconazole, itraconazoole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir, and saquinavir) Antipsychotic medications (including but not limited to phenothiazines, risperidone, olanzapine, ziprasidone, clozapine, loxapine, thiothixene, molindone) Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a period of 7 to 28 days depending on the medications involved (eg. 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

5. STUDY MEASUREMENTS AND ENDPOINTS

5.1 Primary endpoint

The primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score. This endpoint is used as the basis for the sample size calculation, as provided in Section 6.1.

5.2 Screening and demographic measurements

The following data are to be collected at screening:

- date of birth, sex, and race
- vital signs, height, weight
- supine and standing blood pressure and pulse
- significant medical history
- physical examination including ophthalmoscopic exam
- 12-lead electrocardiogram
- clinical chemistry and hematology
- pregnancy test (if female of childbearing potential)
- HAM-D assessment
- YMRS
- DSM-IV diagnosis, based on SCID assessment

5.3 Efficacy measurements and endpoints

The following assessments will be used to evaluate efficacy:

- change from baseline to final assessment in MADRS total score
- percentage of subjects with $\geq$50% reduction from baseline in MADRS total score at final assessment
- the change from baseline in each assessment (observed cases) in the MADRS total score

- the change from baseline to each assessment (observed cases) and final assessment in the CGI-S
- the CGI-C at final assessment
- the change from baseline to each assessment (observed cases) and final assessment in the YMRS
- the change from baseline to each assessment (observed cases) and final assessment in the total HAM-A

Evaluation using each of these scales should be performed by the same trained/certified staff member who has been approved by AstraZeneca for all assessments of the scale for an individual subject.

5.3.1 Summary of efficacy objectives and endpoints

Table 14 shows how the efficacy endpoints of this study relate to the study objectives.

Table 14 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Primary	Primary measure		
evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks	change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score; ls means, 95% CI at final assessment ; descriptive statistics by statum	ANCOVA for the change from baseline to final assessment for total MADRS score. Pair-wise comparisons of each dose with placebo using step up procedure	Reductions in MADRS compared with placebo will indicate doses which are effective in treating depressive episode
	Secondary measure		
	percentage of subjects meeting the MADRS responder criteria ; n, percentage responders at each assessment, final assessment ; descriptive statistics by statum	Logistic model	Higher response rates will indicate doses which are effective in treating depressive episode in treating depressive episode
	change from baseline to each assessment for the MADRS total score, and each assessment and final assessment Clinical Global Impression - Severity (CGI-S); ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment (LOCF) for CGI-S. Pair-wise comparisons of each dose with placebo	Reductions in scales compared with placebo will indicate doses which are effective in treating depressive episode
	Clinical Global Impression - Change (CGI-C); ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the CGI-C for each assessment and final assessment (LOCF). Pair-wise comparisons	Greater improvements in CGI-C will indicate doses which are effective compared with placebo

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Primary	Primary measure		
		of each dose with placebo	
Secondary			
evaluate the efficacy of quetiapine compared to placebo in the incidence of treatment -emergent mania	change from baseline to each assessment and final assessment in the YMRS total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for YMRS total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	No significant increase in the YMRS compared to placebo will indicate doses which do not result in treatment-emergent mania
evaluate the effect of quetiapine compared to placebo on symptoms of anxiety	change from baseline to each assessment and final assessment in the HAM-A total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for HAM-A total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Improvement in the HAM-A compared to placebo will indicate efficacy in treating anxiety component of the depressive episode

The methods for collecting efficacy data are presented below.

5.3.2 Montgomery-Asberg Depression Rating Scale (MADRS)

5.3.2.1 Methods of assessment

The MADRS will be performed at each visit during the trials using the validated MADRS instrument by certified staff at each site.

5.3.2.2 Calculation or derivation of endpoint

The change from baseline to final LOCF will be calculated for total MADRS score. A subject will be classified as a responder if the % change from baseline, calculated as the (change from baseline divided by the baseline) multiplied by 100 indicates a ≥ 50% reduction in baseline total MADRS score.

5.3.3 Hamilton Rating Scale for Depression (HAM-D)

5.3.3.1 Methods of assessment

The HAM-D will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-D and HAM-D item #1.

5.3.4 Clinical Global Impression - Severity (CGI-S)

5.3.4.1 Methods of assessment

The CGI-S will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.4.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in CGI-S.

5.3.5 Clinical Global Impression - Change (CGI-C)

5.3.5.1 Methods of assessment

The CGI-C will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.5.2 Calculation or derivation of endpoint

The CGI-C is a measure of change from baseline and therefore requires no further derivation.

5.3.6 Hamilton Rating Scale for Anxiety (HAM-A)

5.3.6.1 Methods of assessment

The HAM-A will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.6.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-A.

5.3.7 Young Mania Rating Scale (YMRS)

5.3.7.1 Methods of assessment

The YMRS will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.7.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in YMRS.

5.4 Safety measurements and endpoints

The following measurements will be used to assess safety:

- adverse event reporting (both general adverse events and serious adverse events), coded using MedDRA system of nomenclature
- fasting clinical laboratory tests (including chemistry and hematology)
- vital signs(taken in both the standing and supine positions)
- ECG tests
- Simpson-Angus Scale
- Barnes-Akathesia Rating Scale

5.4.1 Summary of safety objectives and endpoints

Table 15 shows how the safety endpoints of this study relate to the study objectives.

Table 15 Safety objectives and endpoints relating to each objective

Objective	Endpoints and statistic	Planned analysis	Significance of results
evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	incidence and nature of adverse events during double-blind treatment ; n, % incidence per event, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	no new safety issues identified
	incidence of drug-related adverse events during double-blind treatment ; n, % incidence; titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of subject withdrawal due to adverse events; n, % withdrawn, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of clinically significant changes in vital signs; n, % at each assessment and final visit	descriptive statistics only	
	change in the SAS total score ; mean change, standard deviation, baseline to final assessment (LOCF)	descriptive statistics only	
	the change in BARS total score	descriptive statistics only	
	incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment	descriptive statistics only	

The methods for collecting safety data are described below.

5.4.2 Adverse Events

5.4.2.1 Definitions

The definitions of adverse events (AEs), serious adverse events (SAEs) and other significant adverse events (OAEs) are given below. It is of the utmost importance that all staff involved in the study is familiar with the content of this section. The principal investigator is responsible for ensuring this.

(a) Adverse Event

An adverse event is the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver) or the abnormal results of an investigation (eg, laboratory findings, electrocardiogram). In clinical studies, an AE can include an undesirable medical condition occurring at any time, including run-in or washout periods, even if no study treatment has been administered.

(b) Serious Adverse Event

A serious adverse event is an AE occurring during any study phase (ie, run-in, treatment, washout, follow-up), and at any dose of the investigational product, comparator or placebo, that fulfills one or more of the following criteria:

- results in death
- is immediately life-threatening
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- is a congenital abnormality or birth defect
- is an important medical event that may jeopardize the subject or may require medical intervention to prevent one of the outcomes listed above?

The causality of SAEs (ie, their relationship to study treatment) will be assessed by the investigator(s), who in completing the relevant case report form must answer “yes” or “no” to the question “Do you consider that there is a reasonable possibility that the event may have been caused by the drug?” For further guidance on the definition of a SAE and a guide to the interpretation of the causality question, see Appendix F.

(c) Other significant adverse event

An AstraZeneca expert will identify OAEs during the evaluation of safety data for the Clinical Study Report. Significant adverse events of particular clinical importance, other than SAEs and those AEs leading to discontinuation of the subject from study treatment, will be classified as OAEs. Examples of these are marked hematological and other laboratory abnormalities, and certain events that lead to intervention (other than those already classified as serious), dose reduction or significant additional treatment. For each OAE, a narrative will be written and included in the Clinical Study Report.

5.4.2.2 Recording of adverse events

All AEs and SAEs that occur before, during treatment, or within 30 days following the cessation of treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. If any SAEs are recorded during the 30-day follow-up period, all concomitant medications taken during the 30-day follow-up should also be recorded on the CRF. A description of the event, its intensity, duration, action taken (eg, treatment and follow-up tests), and outcome should be given, along with the investigator's causality assessment of the relationship of the event to the study drug. If a diagnosis of the subject's condition has been made, then the diagnosis should be recorded as the SAE. In instances of well recognized syndromes (eg, fever, runny nose, cough) they can be recorded as "flu". However, if a diagnosis of the subject's condition has not been made, or if the individual symptoms are not well recognized, then the individual symptoms should be recorded separately.

In general, abnormal laboratory tests or vital signs should not be reported as AEs unless they fulfill the criteria for an SAE or lead to discontinuation. If an abnormal laboratory test result or vital sign is associated with clinical signs and symptoms, the sign or symptom should be reported as an AE, and the associated test result or vital sign should be recorded on the appropriate CRF.

A causality assessment must be recorded for all AEs. The CRF asks the question, "In your medical judgement, is there a reasonable possibility that the event may have been caused by the study therapy?" If there is any valid reason, even if undetermined or untested, for suspecting a possible cause-and-effect relationship between the study drug and the occurrence of the AE, then this should be answered "yes." Otherwise, if no valid reason exists for suggesting a possible relationship, then this should be answered "no." If more than 1 AE is identified, a causality assessment must be made for each AE.

It is important to distinguish between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined by the criteria in Section 5.4.2.1 (b). An AE of severe intensity need not necessarily be considered serious. For example, nausea which persists for several hours may be considered severe nausea, but not a SAE. On the other hand, a stroke that results in only a limited degree of disability may be considered a mild stroke but would be a SAE.

Any detrimental change in the subject's condition after the subject enters the study will be discussed with the investigator. Where the detrimental change is considered by the investigator to constitute a progression or relapse of bipolar depression or a lack of efficacy, then this will not be considered an AE even where this necessitates or prolongs hospitalization. When there is deterioration in the condition for which the medicine is being used, there may be uncertainty as to whether this is lack of efficacy or an AE. In such cases, unless AstraZeneca or the reporting physician considers that the medicine contributed to the deterioration, the deterioration should be considered lack of efficacy. However, if it is believed that the medicine may have contributed to the deterioration, then this should be treated as an AE.

Study drug abuse is an SAE, even when there are no symptoms or additional AEs and should be reported according to the guidelines in Section 5.4.2.3. Misuse of study drug is an AE but is not considered an SAE unless accompanied by serious sequelae.

Should an overdose occur, it must be reported in accordance with the procedures described in Section 10.3 Procedures in case of overdose. All overdoses, with or without associated symptoms, should be reported as AEs.

Suicide and attempted suicide, irrespective of the method, but occurring in connection with the use of study drug, should be reported as AEs (serious or non-serious). This event should be identified as suicide or attempted suicide, and the method of the suicide or attempt should be provided. If an attempted suicide meets the criteria for an SAE, the event must be reported according to the guidelines in Section 10.4.

Should a pregnancy occur, it must be reported in accordance with the procedures described in Section 10.5. Procedures in case of pregnancy. Pregnancy in itself is not regarded as an AE unless there is a suspicion that an investigational product may have interfered with the effectiveness of a contraceptive medication.

5.4.2.3 Reporting of serious adverse events

Investigators and other site personnel must inform appropriate AstraZeneca representatives of any SAE that occurs in the course of the study within 1 day (i.e. immediately but no later than the end of the next business day) of when he or she becomes aware of it.

The AstraZeneca representative will work with the investigator to compile all the necessary information and ensure that the appropriate AstraZeneca Drug Safety Department receives a report by day 1 for all fatal and life-threatening cases and by day 5 for all other SAEs.

Follow-up information on SAEs must also be reported by the investigator within the same time frames.

If a non-serious AE becomes serious, this and other relevant follow-up information must also be provided to AstraZeneca within 1 day as described above.

After initial notification, the AstraZeneca representatives have 4 days to work with the investigator to compile all the necessary information to ensure that the appropriate AstraZeneca Drug Safety Department receives a complete report by day 5. Follow-up information on SAEs should also be reported by the investigator within the same time frames. If a non-serious case becomes serious, this and other relevant follow-up information should also be provided to AstraZeneca within 1 day as described in the paragraph above

All SAEs have to be reported, whether or not considered causally related to the investigational product. All SAEs will be recorded in the case report form. The investigator is responsible for informing the Ethics Committee and/or the Regulatory Authority of the SAE as per local requirements.

5.4.3 Laboratory safety measurements and variables

Blood (under fasting conditions) and urine specimens will be collected for laboratory test analysis and these samples will be processed by a central laboratory (Quintiles Central Laboratory).

5.4.3.1 Methods of assessment

- Fasting hematology: hemoglobin, hematocrit, red blood cell count, total and differential white blood cell counts and platelet count
- Fasting clinical chemistry: total bilirubin, alkaline phosphatase, alanine transaminase(ALT), aspartate transaminase(AST), sodium, potassium, chloride, creatinine, glucose, insulin, bicarbonate, high-density lipoprotein cholesterol, triglycerides, low-density lipoprotein cholesterol and total cholesterol
- Thyroid function tests: thyroid stimulating hormone (TSH), Triiodothyronine resin uptake (T3RU), and total thyroxine (T4)
- Serum pregnancy tests
- Urine toxicology screen

5.4.3.2 Calculation or derivation of endpoints

Change from baseline will be derived for all subjects who have a screening laboratory test and a final laboratory test. The change from baseline is the final test value minus the screening test value. Laboratory test values will also be compared to the laboratory standard normal ranges and flagged with H or L if they are outside of the normal range. In addition, treatment emergent laboratory changes identified using computerized methods to compare results or changes from baseline to standard extended ranges will be flagged at the subject and test level.

5.4.4 Vital signs measurement

5.4.4.1 Methods of assessment

A standard blood pressure cuff will be used to obtain systolic and diastolic blood pressure. The assessment will be done first with the subject in the supine position for 3 minutes and again within 3 minutes of the subject attaining a standing position. Pulse will be measured for 1 minute.

5.4.4.2 Calculation or derivation of endpoints

Change from baseline will derived be as the value at the visit minus the screen value for the same assessment and position. In addition the change within a visit between the standing and supine blood pressure assessments will be calculated for both systolic and diastolic blood pressures. This difference will be calculated as supine minus standing. A subject will be classified as having calculated postural hypotension if either the systolic blood pressure difference indicates a decrease >20 mmHg or the diastolic blood pressure difference indicates a decrease >15 mmHg.

5.4.5 ECG safety measurements and variables

5.4.5.1 Methods of assessment

A 12 lead ECG assessment will be done using an ECG machine compatible with the requirements for eResearch the central evaluation laboratory. The central laboratory will supply the interval data, rates and standard interpretation of the ECG test results.

eResearch
30 south 17th Street
Philadelphia, PA 19103-4001

5.4.5.2 Calculations and derivations of endpoint

Change from baseline for interval data and rate data will be derived by subtracting the screen value from the final assessment value. Values outside the extended range in Appendix XX will be flagged.

5.4.6 Simpson-Angus Scale (SAS)

5.4.6.1 Methods of assessment

The SAS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.6.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.4.7 Barnes-Akathisia Rating Scale (BARS)

5.4.7.1 Methods of assessment

The BARS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.7.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.5 Quality of Life endpoint

The following assessment will be used to assess the effect of quetiapine compared with placebo on quality of life as assessed by:

- the PSQI
- the short form Q-Les-Q

5.5.1 Summary of quality of life objectives and endpoints

Table 16 shows how the efficacy endpoints of this study relate to the study objectives.

Table 16 Quality of life objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Secondary evaluate the effect of quetiapine compared to placebo on quality of sleep	Secondary measure change from baseline to final assessment in PSQI; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for PSQI total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Reduction in PSQI compared with placebo indicates improvement of sleep quality
evaluate the effect of quetiapine compared to placebo on the overall quality of life	change from baseline to final assessment in Q-Les-Q; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for Q-Les-Q total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Increase in Q-Les-Q compared with placebo indicates improvement of overall quality of life

The methods of collecting quality of life data are described below.

5.5.2 PSQI

5.5.2.1 Methods of assessment

The PSQI will be performed at scheduled visits during the trial by a patient at each site. The 9 self-rated questions will be incorporated into 7 component scores which are added together to yield one total "global" score. Higher scores indicate more severe difficulties in sleep quality.

5.5.2.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the PSQI.

5.5.3 Q-Les-Q

5.5.3.1 Methods of assessment

The Q-Les-Q is a patient self assessment questionnaire which will be completed at scheduled visits during the trial by a patient at each site. The short form has 14 self-rated questions, the first 12 will be incorporated into a total score. Higher scores indicate better quality of life.

5.5.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the Q-Les-Q.

5.6 Interactive Computer Interview for Depression (ICI-D)

Participating in the Interactive Computer Interview for Depression (ICI-D) is voluntary for all the sites. Participation by the subjects at these sites is also voluntary. At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the MADRS. Raters or other site staff will first enter the subject's MADRS scores into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

For quality assurance purposes, if an above-threshold variance is detected between the ICI-D and the MADRS on individual items or the overall score, a CRS clinician (Ph.D. or MD) will contact the applicable rater for a monitoring consultation. The CRS clinician will discuss possible reasons for the discrepancy, review conventions for scoring and offer additional training if necessary.

The ICI-D will also provide an additional check of the patient's suicide status. The ICI-D will alert the rater if the patient reports suicidal plans. If the patient did not verbalize these thoughts during the interview /assessment process, the rater could then take the appropriate clinical steps.

A standard operating procedure for ICI-D will be provided to the sites.

5.7 Genetic sampling and storage

There will be no genetic sampling in this trial.

5.8 Volume of blood sampling and handling of biological samples

The total volume of blood that will be drawn from each subject in this study is as follows:

Table 17 Volume of blood to be drawn from each subject

Assessment		Sample volume (ml)	N of samples	Total volume (ml)	
				Women	Men
Safety	Clinical chemistry				
	Hematology	18	2	36	36
	Serum Pregnancy [a]	2	1	2	
Total				38	36

[a] Women only.

Sample handling and storage will be defined by the central laboratory which will be handling the analysis and reporting or results from samples.

6. DATA MANAGEMENT

Case Report Forms (CRFs) will be provided for recording of data. The forms will be in triplicate with carbonless paper. Data will be recorded legibly onto the CRFs with black ink, preferably with a ballpoint pen. If any data are not available, omissions will be indicated on the CRFs. Corrections should be made legibly and be initialed and dated. Correction fluid or covering labels must not be used. The top original and the first copy of the completed form will collected and returned to AstraZeneca/AstraZeneca's agent and the second copy will be retained by the investigator.

Data received electronically by AstraZeneca from a validated source will be loaded directly into the trial database for analysis.

7. STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

7.1 Determination of sample size

Since there is no data using the MADRS instrument in the assessment of quetiapine in treating bipolar subjects with depression, the sample size estimation was based on published data from the lamotrigine monotherapy (Calabrese et al, 1999) and olanzapine trials (Tohen et al, 2002). The percentage change in the HAM-D across these lamotrigine studies in bipolar depression is similar to that observed with quetiapine. MADRS scores correlate significantly with those of the HAM-D (Montgomery Asberg 1979).

Sample size was estimated using an Bonferroni correction for the 2 comparisons with placebo. A clinically meaningful 3.6-unit difference between quetiapine treatment and placebo was used to estimate the effect size (with 3.1 units considered a minimally effective and detectable difference). The variability used for calculation was 10 units, the variability seen in the olanzapine study. A sample size of 168 subjects/arm (504 subjects total) would provide 85% power for 2-sided pair-wise comparisons with placebo at α=0.025 which provides an overall experiment wise type I error rate of 0.05. Therefore, 740 patients will be screened and approximately 530 subjects randomized (allowing for a 5% early drop out rate), to insure 504 subjects with post baseline data available for analysis (MITT analysis population). This sample size will provide 72% power to detect a 3.1 unit difference from placebo.

7.2 Statistical evaluation

7.2.1 Methods of statistical analysis

A comprehensive Statistical Analysis Plan (SAP) will be prepared before unblinding of the data.

Missing data for final visit resulting from patient drop outs will be imputed using an LOCF approach. Patients with post baseline data (MITT population) will have their last trial assessment carried forward as the final assessment for analyses.

7.2.2 Study endpoints

Primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score.

Secondary efficacy endpoints:

1. Percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at study endpoint

2. Change from baseline to each assessment (observed cases) in the MADRS total score

3. Change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, CGI-S, CGI-C, and Young Mania Rating Scale.

4. Change in the PSQI score from baseline to final assessment

Safety endpoints:

1. Incidence and nature of adverse events during double-blind treatment

2. Incidence of drug-related adverse events during double-blind treatment

3. Incidence of subject withdrawal due to adverse events

4. Incidence of clinically significant changes in hematology and chemistry laboratory results, vital signs, electrocardiograms, weight, and body mass index.
Tolerability endpoints:

5. Change in the SAS total score from baseline to final assessment

6. Change in BARS total score from baseline to final assessment

7. Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment

Quality of Life endpoints:

1. Change in Q-Les-Q total score from baseline to final assessment

2. Proportion of patients achieving community norm levels in Q-Les-Q at final assessment

7.2.3 Statistical analyses

The randomization will be stratified by Bipolar type (I or II) in order to assure balance across treatments for the type of patient enrolled. The stratification will be incorporated into the statistical analysis models and descriptive statistics will be provided for each stratum.

For each statistical model run, the assumptions for the model will be evaluated. If the assumptions are not reasonably met, the data may be transformed to meet assumptions or a non-parametric test performed.

All statistical comparisons will be based on 2-sided testing approaches for testing the difference between active study medication dose and placebo.

7.2.3.1 Study populations for analysis

The modified intention to treat population (MITT) will be the population for efficacy and quality of life evaluation. The MITT population will include all randomized subjects who were received study treatment and had at least one post baseline efficacy assessment with a last observation carried forward approach for final assessment.

The safety population will include all subjects who provide consent and received study medication.

7.2.3.2 Primary Analysis

The primary analysis will use analysis of covariance (ANCOVA) model for the change from baseline at final assessment for the MADRS. The model will include terms for treatment, stratum, with the baseline MADRS as a covariate. The Simes-Hommel step-up procedure will be used to adjust for the 2 comparisons with placebo (Simes-Hommel, 1988). The p-values obtained from the pair-wise comparisons will be ordered as follows: $P(1) \leq P(2)$. The following rule will be used to assess statistical significance:

1. If $P(2) \leq 0.05$, then reject both null hypotheses associated with P(2) and P(1); else proceed to the next step;

2. If $P(1) \leq 0.025$, then reject the null hypothesis associated with P(1).

7.2.3.3 Secondary Analyses of efficacy and quality of life

The secondary endpoint for responder, defined as a subject who has a 50% reduction in MADRS score from baseline to final assessment, will be analyzed by comparing the proportion of subjects responding across treatments using a logistic model which includes treatment, stratum, and center in the model. The secondary endpoints based on change from baseline for scales at an assessment time will be analyzed using the same model as the primary endpoint. Nominal p-values will be used for all secondary endpoint comparisons.

Exploratory repeated measures analysis of variance model will also be conducted to evaluate whether there are significant differences among treatments across time for the MADRS and HAM-D scores.

Descriptive statistics will be used to report stratum, item scores, and subscale scores.

7.2.3.4 Safety analyses

Adverse events will be coded using the MedDRA dictionary. Numbers of events and incidence rates for AEs in each treatment group will be summarized by preferred term and system organ class. An event that occurred one or more times on the date of, or subsequent to, randomization will contribute one observation to the numerator of the incidence rate. The denominator will comprise all patients exposed to study treatment.

Adverse events that lead to premature withdrawal of subjects will be tabulated for each treatment group.

All laboratory assessments, vital signs, ECG (rates and intervals) results, and weight and body mass index will be tabulated using descriptive statistics at baseline, final assessment and including change from baseline. Descriptive statistics will include n, mean, standard deviation, minimum and maximum value.

7.2.3.5 Tolerability analyses

The change from baseline in SAS and BARS score data will be summarized using descriptive statistics (mean, standard deviation, median, minimum and maximum).

Incidence rates of EPS adverse events will be compared and tabulated using descriptive statistics.

7.2.3.6 Interim analysis

No interim analysis is planned

7.2.3.7 Data or safety monitoring committee

There will be no data or safety monitoring committee.

8. STUDY MANAGEMENT

8.1 Monitoring

Before the study begins, a representative of AstraZeneca or company representing AstraZeneca will visit the investigational site to

- determine the adequacy of the facilities
- discuss with the investigator(s) (and other personnel involved with the study) their responsibilities with regard to protocol adherence, and the responsibilities of AstraZeneca or its representatives.

During the study, a monitor from AstraZeneca or company representing AstraZeneca will have regular contacts with the investigational site, including visits to

- provide information and support to the investigator(s)
- confirm that facilities remain acceptable
- confirm that the investigational team is adhering to the protocol, that data are being accurately recorded in the case report forms (CRFs), and that investigational product accountability checks are being performed.
- perform source data verification (a comparison of the data in the CRFs with the subject's records at the hospital or practice, and other records relevant to the study). This will require direct access to all original records for each subject (eg, clinic charts).

The monitor or another AstraZeneca representative will be available between visits if the investigator(s) or other staff at the center needs information and advice.

8.2 Audits and inspections

Authorized representatives of AstraZeneca, a regulatory authority, an Independent Ethics Committee (IEC) or an Institutional Review Board (IRB) may visit the center to perform audits or inspections, including source data verification. The purpose of an AstraZeneca audit or inspection is to systematically and independently examine all study related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed, and accurately reported according to the protocol, Good Clinical Practice (GCP), guidelines of the International Conference on Harmonization (ICH), and any applicable regulatory requirements. The investigator should contact AstraZeneca immediately if contacted by a regulatory agency about an inspection at his or her center.

8.3 Training of staff

The principal investigator will maintain a record of all individuals involved in the study (medical, nursing and other staff). He or she will ensure that appropriate training relevant to the study is given to all of these staff, and that any new information of relevance to the performance of this study is forwarded to the staff involved.

8.4 Changes to the protocol

Study procedures will not be changed without the mutual agreement of the international principal investigator(s) and AstraZeneca.

If it is necessary for the study protocol to be amended, the amendment or a new version of the study protocol must be notified to or approved by each IEC or IRB, and in many countries also the local regulatory authority, before implementation. Local requirements must be followed.

If a protocol amendment requires a change to a particular center's Written Informed Consent Form, then AstraZeneca and the center's IEC or IRB must be notified. Approval of the revised Written Informed Consent Form by AstraZeneca and by the IEC or IRB is required before the revised form is used.

AstraZeneca will distribute amendments and new versions of the protocol to each principal investigator(s), who in turn is responsible for the distribution of these documents to his or her IEC or IRB, and to the staff at his or her center. The distribution of these documents to the regulatory authority will be handled according to local practice.

8.5 Study agreements

The principal investigator at each center must comply with all the terms, conditions, and obligations of the study agreement for this study. In the event of any inconsistency between this protocol and the study agreement, this study agreement shall prevail.

8.6 Study timetable and termination

It is anticipated that the first subject will be enrolled in September 2002 and that the last subject will complete the study in March 2004.

9. ETHICS

9.1 Ethics review

The final study protocol, including the final version of the Written Informed Consent Form, must be approved or given a favorable opinion in writing by an IEC or IRB as appropriate. The investigator must submit written approval to AstraZeneca before he or she can enroll any subject into the study.

The principal investigator(s) is responsible for informing the IEC or IRB of any amendment to the protocol in accordance with local requirements. In addition, the IEC or IRB must approve all advertising used to recruit subjects for the study. The protocol must be reapproved by the IEC or IRB annually, as local regulations require.

Either the investigator(s) or AstraZeneca must submit progress reports to the IEC or IRB according to local regulations and guidelines. The principal investigator(s) must also provide the IEC or IRB with any reports of serious adverse events from the study site.

The principal investigator(s) is also responsible for providing the IRB with reports of any serious adverse events from any other study conducted with the investigational product. This information will be provided to the principal investigator(s) by AstraZeneca.

9.2 Ethical conduct of the study

The study will be performed in accordance with the ethical principles in the Declaration of Helsinki (see Appendix C), Good Clinical Practice, and applicable regulatory requirements.

9.3 Subject information and consent

The principal investigator(s) at each center will ensure that the subject is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Subjects must also be notified that they are free to discontinue from the study at any time. The subject should be given the opportunity to ask questions and allowed time to consider the information provided.

The subject's signed and dated informed consent must be obtained before conducting any procedure specifically for the study, including the following:

The principal investigator(s) must store the original, signed Written Informed Consent Form. A copy of the Written Informed Consent Form must be given to the subject.

A sample Written Informed Consent Form is enclosed (Appendix B). If modifications are made according to local requirements, the new version has to be approved by AstraZeneca.

9.4 Subject data protection

AstraZeneca recognises the importance of protecting the privacy of patient (subject) data. Therefore, for study sites within the US or in studies where foreign subjects' protected health information **(subject data)** will come into the US through a covered entity (eg, Central Lab/Reader), the Informed Consent Form will incorporate, or be accompanied by, a separate document incorporating HIPAA-compliant wording by which subjects authorize the use and disclosure of their Protected Health Information by the Investigator and by those persons who need that information for the purposes of the study.

The Written Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. The subjects' names will not be recorded in this database. The Written Informed Consent Form will also explain that for data verification purposes, authorized representatives of AstraZeneca, a regulatory authority, an IEC or IRB may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

10. EMERGENCY PROCEDURES

10.1 AstraZeneca emergency contact procedure

In the case of a medical emergency, contact AstraZeneca personnel shown below.

Wayne Macfadden MD
Project Physician
302-886-1147 (telephone)
302-886-5567 (fax)
REDACTED

Robin McCoy RN
Senior Clinical Research Scientist
302-886-4650 (telephone)
302-886-5567 (fax)
REDACTED

Contact AstraZeneca switchboard on 1-800-236-9933 and ask to be put in contact with the person on call for the Seroquel clinical team.

10.2 Procedures in case of medical emergency

The principal investigator(s) is responsible for ensuring that procedures and expertise are available to cope with medical emergencies during the study.

10.3 Procedures in case of overdose

For the purpose of this trial all overdoses should be reported as adverse events. However, all cases of overdose must be reported immediately, within 1 day, if sequelae meeting the criteria for serious adverse event have occurred in association with the overdose. In all instances, the overdose substance should be stated and whether the overdose was accidental or intentional. If the overdose was a suicide attempt, this fact should be clearly stated. Adverse events

(serious and non-serious) arising as the result of an overdose should be recorded on an adverse event form as "sequelae to overdose." For example "nausea as sequelae to overdose."

10.4 Suicide

Suicide and suicide attempt, irrespective of the method, but in connection with the use of trial drug, should be reported as a serious adverse event (in accordance with the definition provided in Section 5.4.2.1). This event should be identified as suicide or suicide attempt, and the method of the suicide or the suicide attempt should be provided. Suicidal thoughts should also be regarded as adverse events.

10.5 Procedures in case of pregnancy

Pregnancy itself is not regarded as an adverse event unless there is a suspicion that the investigational product under study may have interfered with the effectiveness of a contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) must be followed up and documented even if the subject was discontinued from the study.

All reports of congenital abnormalities/birth defects are SAEs. Spontaneous miscarriages should also be reported and handled as SAEs. Elective abortions without complications should not be handled as AEs. All outcomes of pregnancy must be reported to AstraZeneca on the pregnancy outcomes report form.

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Appendix A
Signatures

IND No. 32,123

SIGNATURE OF PRINCIPAL INVESTIGATOR

Title of report

A Multicenter, Double-blind, Randomized, Placebo-controlled, double-dummy Trial of the User of Quetiapine fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

I agree to the terms of this study protocol. I will conduct the study according to the procedures specified herein, and according to the principles of Good Clinical Practice (GCP) and local regulations.

Centre No.: 0001

Signature: Joseph Calabrese 10/14/03

Joseph Calabrese, MD
University Hospitals of Cleveland
Mood Disorders Program
11400 Euclid Avenue, Suite 200
Cleveland, OH 44106

Date

AstraZeneca

Clinical Study Protocol: Appendix B	
Study Code	5077US/0049
Version No.	1
Appendix Date	August 6, 2002

Appendix B

Sample written informed consent form

A sample informed consent is provided under separate cover.

Appendix C

Declaration of Helsinki

Recommendations guiding physicians in biomedical research involving human subjects.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975 and the 35th World Medical Assembly, Venice, Italy, October 1983 and the 41st World Medical Assembly Hong Kong, September 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of The World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient´s interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject´s physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject´s freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor´s consent must be obtained in addition to the consent of the minor´s legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with professional care (Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo studies where no proven diagnostic or therapeutic method exists.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical re-search involving human subjects

(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to thepatient´s illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

Appendix D

Investigators and study administrative structure

STAFF AT INVESTIGATIONAL SITE(S)

Centre No.	**Centre address**	**Name** (First name, Last name)	**Qualifications**	**Position**	**Role in the study**
<<>>					Principal investigator

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A list of participating investigators will be provided upon request.

ASTRAZENECA STUDY PERSONNEL

Name (First name, Last name)	**Position**	**Role in the study**
Robin McCoy	Senior Clinical Research Scientist	Clinical Management Lead
Margaret Minkwitz	Director Biostatistics Project Team	Biostatistician
Wayne Macfadden	Medical Director Clinical Research	Medical advisor
Jeris Minor	Data Analyst	Data Analyst
Elaine Yu	Assistant Director Health Economics	Health Economics
Ellen Quimby	IPS Demand Manager	IPS Representative
Jennifer Mahoney	Safety Representative	Safety
Patti Neal	Regulatory Representative	Regulatory
Richard White	Director Health Economics	Health Economics

OTHER PARTICIPANTS

Organisation and address	**Name** (First name, Last name)	**Qualifications/Position**	**Role in study**
Lineberry Research Associates 79 Alexander Drive Bldg 4401, Suite 400Research Triangle Park, NC 27709 See CRO Personnel List	Kelly Abernathy	RN	Project Manager

AstraZeneca

Clinical Study Protocol: Appendix E	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix E

Insurance and indemnity

For the US, this Appendix E is not applicable. Please refer to the clinical study agreement for information regardingAstraZeneca's obligation to insure and indemnify institution and investigator.

INSURANCE AND INDEMNITY

AstraZeneca's liability is covered by a liability insurance policy with AstraZeneca Insurance Company Limited, policy No.: L/702938.

With respect to any liability directly or indirectly caused by the investigational products in connection with this Clinical Study, AstraZeneca assumes liability by law on behalf of the investigator(s) and his assistants for possible injury to the subject provided the investigator(s) and his assistants have followed the instructions of AstraZeneca in accordance with this protocol and any amendments thereto, that the investigational products administered to the subject in this Clinical Study have been supplied by AstraZeneca and that the investigator and his assistants have in general performed this clinical study in accordance with scientific practice and currently acceptable techniques and know-how.

AstraZeneca can forward a letter of indemnity if needed by the investigator(s)/institution.

Appendix F
Additional safety information

1. FURTHER GUIDANCE ON THE DEFINITION OF A SERIOUS ADVERSE EVENT (SAE)

Life threatening

'Life-threatening' means that the subject was at immediate risk of death from the adverse event as it occurred or it is suspected that use or continued use of the product would result in the subject's death. 'Life-threatening' does not mean that had an adverse event occurred in a more severe form it might have caused death (ie hepatitis that resolved without hepatic failure).

Hospitalisation

Out-subject treatment in an emergency room is not in itself a serious adverse event, although the reasons for it may be (eg, bronchospasm, laryngeal oedema). Hospital admissions and/or surgical operations planned before or during a study are not considered adverse events if the illness or disease existed before the subject was enrolled in the study, provided that it did not deteriorate in an unexpected way during the study.

Important medical event or medical intervention

Medical and scientific judgement should be exercised in deciding whether a case is serious in a situation where important medical events may not be immediately life-threatening or result in death, hospitalisation, disability or incapacity but may jeopardise the subject or may require medical intervention to prevent one or more outcomes listed in the definition of serious. These should usually be considered as serious. Examples of such events are:

- Angioedema not severe enough to require intubation but requiring iv. hydrocortisone treatment
- Hepatotoxicity caused by paracetamol (acetaminophen) overdose requiring treatment with N-acetylcysteine
- Intensive treatment in an emergency room or at home for allergic bronchospasm
- Blood dyscrasias (eg, neutropenia or anaemia requiring blood transfusion, etc.) or convulsions that do not result in hospitalisation
- Development of drug dependency or drug abuse

2. FURTHER GUIDANCE ON THE ASSESSMENT OF CAUSALITY

The following factors should be considered when deciding if there is a "reasonable possibility" that an adverse event (AE) may have been caused by the investigational product.

- **Time course of events and exposure to suspect drug**. Has the subject actually received the suspect drug? Did the AE occur in a reasonable temporal relationship to the administration of suspect drug?

- **Consistency with known drug profile**. Was the AE consistent with the previous knowledge of the suspect drug (pharmacology and toxicology) or drugs of the same pharmacological class? OR could the AE be anticipated from its pharmacological properties?

- **Dechallenge experience**. Did the AE resolve or improve on stopping or reducing the dose of the suspect drug?

- **No alternative cause**. The AE cannot be reasonably explained by another aetiology such as the underlying disease, other drugs, other host or environmental factors.

- **Rechallenge experience**. Did the AE reoccur if the suspected drug was reintroduced after having been stopped? AstraZeneca would not normally recommend or support a rechallenge.

- **Laboratory tests**. Has a specific laboratory investigation confirmed the relationship?

A "reasonable possibility" could be considered to exist for an AE where one or more of these factors exist.

In contrast, there would not be a "reasonable possibility" of causality if none of the above criteria apply or where there is evidence of exposure and a reasonable time course but any dechallenge (if performed) is negative or ambiguous or there is another more likely cause of the AE.

In difficult cases, other factors could be considered such as:

- Is this a recognised feature of overdose of the drug?

- Is there a known mechanism

Ambiguous cases should be considered as being a “reasonable possibility” of a causal relationship unless further evidence becomes available to refute this.

Appendix G
Additional information necessary for studies conducted in Japan

Not Applicable

1. LABELLING AND PACKAGING OF THE INVESTIGATIONAL PRODUCT

<< Insert copy of the label.>>

2. PROCEDURES FOR RANDOMISATION (REGISTRATION)

<<>>

3. ORGANISATIONAL STRUCTURE OF THE STUDY

3.1 Study sponsor

AstraZeneca K.K.
<< Name >>Executive President
Umeda Sky Building, Tower East,
1-88, 1-chome, Ohyodo-naka, Kita-ku, Osaka 531-0076, Japan

3.2 Medical expert from the sponsor

AstraZeneca K.K., Clinical Strategy Department:
<< Name >>(Physician responsible for the protocol)

3.3 Responsible person for the product, monitor, and auditor

Clinical Project Manager (CPM)

Clinical Strategy Department, Osaka office	<< Telephone number>>
Clinical Project Manager	<< Name >>

Monitors

Clinical Operations Department, Osaka office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Clinical Operations Department, Tokyo office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Auditor

Regulatory Affairs Department	<< Telephone number>>
Clinical Audit Department Manager	<< Name >>

See AstraZeneca medical emergency contact numbers (Section 9).

3.4 Co-ordinating investigator(s) (Co-ordinating committee)

<< Name >>
<< Job title>>
<< Associated hospital name>>

3.5 Person in charge of PMS management (if applicable)

AstraZeneca K.K.,
<< Name >>
Drug Safety &PMS Department Manager

3.6 Independent Data Monitoring Committee (IDMC) (if applicable)

<< Name >>
<< Job title>>
<<Associated hospital name>>

3.7 Subject inclusion registration centre

<<>>

3.8 Laboratory

<<>>

3.9 Contract Research Organisation (CRO)

<<>>

3.10 Safety Committee (In house)

May have responsibility for reviewing the following major issues around JNDA and clinical trials proposed by R&D departments such as CSD, COD or RA

A) Major changes for protocol and IB due to safety reasons

B) Across the board key code break due to safety reasons

C) Actions required due to significant safety issues ensuring for products under/for NDA

D) Discontinuation of clinical trials or test drug recall due to safety reasons

E) Other issues to ensure safety in clinical trials

4. LIST OF INVESTIGATORS AND MEDICAL INSTITUTIONS

Centre No.	Study Institutions	Department	Address	Telephone	Investigators	Job Title
<<>>						

5. ADDITIONAL REPORTING RELATED WITH SECTION 4.4.2 ADVERSE EVENTS (FOR JAPANESE PHASE III OR IV STUDY)

<<>>

AstraZeneca

Clinical Study Protocol Amendment

Amendment No.	5
Study Code	5077US/0049
Date	July 14, 2003

Sponsor:

AstraZeneca Pharmaceuticals LP, Wilmington, Delaware, USA

Centers affected by the amendment:

All centers

The protocol for the study is to be amended as follows:

1. Page 48 Section 5.4.2.2 Recording of adverse events

Original text

All AEs and SAEs that occur before, during treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. **Following cessation of treatment, SAEs, whether or not related to the study drug, must be collected for 7 days and recorded on the CRF provided by the sponsor. If any SAEs are recorded during the 7-day follow-up period, all concomitant medications taken during the 7-day follow-up period should also be recorded on the CRF.**

Amended text

All AEs and SAEs that occur before, during treatment or within 30 days following the cessation of treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. If any SAEs are recorded during the 30-day follow-up period, all concomitant medications taken during the 30-day follow-up period should also be recorded on the CRF.

2. **Page 63 Section 9.4 Subject data protection**

Original text

The Written Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. The subjects' names will not be recorded in this database. The Written Informed Consent Form will also explain that for data verification purposes, authorized representatives of AstraZeneca, a regulatory authority, an IEC or IRB may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

Amended text

AstraZeneca recognizes the importance of protection the privacy of patient (subject) data. Therefore, for study sites within the US or in studies where foreign subjects' protected health information (subject data) will come into the US through a covered entity (e.g., Central Lab/Reader), the Informed consent Form will incorporate, or be accompanied by , a separate document incorporating HIPAA-compliant wording by which subjects authorize the use and disclosure of their Protected Health Information by the Investigator and by those persons who need that information for the purposes the study.

The Written Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. The subjects' names will not be recorded in this database. The Written Informed Consent Form will also explain that for data verification purposes, authorized representatives of AstraZeneca, a regulatory authority, an IEC or IRB may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

Reasons for making the amendment:

1. The procedure for reporting adverse events and serious adverse events for a period of 30 days after cessation of study treatment was established for all patients enrolled into the trial at the request of the FDA.

2. The requirement of the informed consent to include HIPAA-compliant wording for subject authorization of the use and disclosure of the Protected Health Information was included in the protocol.

Amended Clinical Study Protocol	
Drug Substance	Quetiapine Fumarate
Study Code	5077US/0049
Edition No.	Version 6
Date	14 July 2003

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

AstraZeneca confirms that all revisions contained in the Clinical Study Protocol Amendment Revision Summaries (1, 2, 3, 4, and 5) have been accurately reflected in the amended clinical trial protocol, Protocol 5077US/0049.

AstraZeneca Research and Development site representative

Wayne Macfadden MD
Clinical Study Team Physician
AstraZeneca Pharmaceuticals LP
Wilmington, DE
302-886-1147

7/18/03
Date
(Day Month Year)

AstraZeneca Research and Development site representative

Robin McCoy RN SCRS
Clinical Study Team Leader
AstraZeneca Pharmaceuticals LP
Wilmington, DE
302-886-4650

7/21/03
Date

The following Amendment(s) and Administrative Changes have been made to this protocol since the date of preparation:

Amendment No.		Date of Amendment	
Amendment No.	1	Date of amendment	September 30,2002
Amendment No	2		December 4, 2002
Amendment No.	3		April 21, 2003
Amendment No.	4		May 12, 2003
Amendment No.	5		July 14, 2003
Administrative Change No.	1	Date of administrative change	September 30, 2002
Administrative Change No.	2	Date of administrative change	July 14, 2003

AstraZeneca

Clinical Study Protocol	
Drug Substance	quetiapine fumarate
Study Code	5077US/0049
Version No.	2
Date	September 30, 2002

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

The following amendment(s) have been made to this protocol since the date of preparation:

Amendment No.	**1**	**Date of amendment**	**September 30,2002**
Administrative Change No.	**1**	**Date of administrative change**	**September 30, 2002**

PROTOCOL SYNOPSIS

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

Investigator

Multicenter trial: << To be determined >>

Study center(s) and number of subjects planned

A total of approximately 740 subjects will be screened to enroll approximately 530 into the trial in order to obtain approximately 504 evaluable patients, defined as those who have a baseline visit and at least one post baseline assessment. It is expected that approximately 75 centers will participate in the trial, with each center enrolling 8 patients (minimum 4, maximum 50).

Study period		**Phase of development**
Estimated date of first subject enrolled	September, 2002	IIIb
Estimated date of last subject completed	March, 2004	

Objectives

Primary:

To evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S)

(5) the Clinical Global Impression - Change (CGI-C).

Secondary:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by comparing

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by comparing

- the incidence and nature of all adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment
- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score from baseline to end of treatment
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Exploratory

(1) to evaluate the efficacy of quetiapine on sleep quality by comparing the change in the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

(2) to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment.

Hypotheses:

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

Secondary hypotheses are defined in Section 3.1.

Study design

Study 5077US/0049 is a randomized, multicenter, double-blind, placebo-controlled, double-dummy, parallel group, fixed-dose comparison of quetiapine vs placebo in the treatment of bipolar depression. This study will be stratified 1:1 for bipolar I and bipolar II.

Target subject population

Outpatients, aged 18 to 65 years, with a diagnosis of bipolar I or bipolar II disorder with a current major depressive episode of duration less than one year but greater than 4 weeks will be enrolled in the trial. The HAM-D (17-item scale) score must be ≥2, the HAM-D item 1 (depressed mood) score must be $\geq$ 2, and the YMRS score must be ≤12 at both Visit 1and Visit 2 (randomization) to be eligible for entry into the trial.

Investigational product, dosage and mode of administration

Study drug will be titrated in a blinded manner to a total daily dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and to a total daily dose of 600 mg/day by Day 8 in the 600-mg/day treatment group. Thereafter, oral doses of quetiapine fumarate will be administered in a blinded fashion once daily at bedtime (qhs) in a total daily dose of 300 or 600 mg/day. One-time dose reductions for intolerability of 100 mg/day in both the 300 mg/day and in the 600 mg/day treatment groups will be allowed at the discretion of the Investigator after Day 8.

Comparator, dosage and mode of administration

Placebo will be administered once daily with tablets matching in number and appearance to blinded quetiapine dosing.

Duration of treatment

Patients will receive double-blind, double-dummy treatment for up to 8 weeks (56 days), following an initial washout period of between 7 to 28 days (depending on the medications involved) and will come in to the clinic on Day 57 for final assessments.

Endpoints

- **Efficacy**

  Primary efficacy endpoint is the change from baseline to final assessment in the MADRS total score.

  Secondary efficacy endpoints are the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at study endpoint, the change from baseline to each assessment (observed cases) in the MADRS total score, and the change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, and CGI-S and the CGI-C.; the change from baseline to each assessment (observed cases) and final assessment in the YMRS, and the HAM-A total scores.

- **Safety**

  Safety endpoints are the incidence and nature of all adverse events, the incidence of drug-related adverse events, the incidence of subject withdrawal due to adverse events, and the incidence of clinically significant changes in vital signs, weight, and body mass index during double-blind treatment. Tolerability endpoints are the change in the SAS total score from baseline to final assessment, the change in BARS total score from baseline to final

assessment, and the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

- **Quality of life**

  Exploratory quality of life endpoints are the change from baseline in the PSQI score and Q-Les-Q total score.

Statistical methods

All statistical comparisons will be 2-sided tests for the difference between active study medication and placebo. The primary analysis will be analysis of covariance (ANCOVA) for the change from baseline to final assessment for total MADRS score. The ANCOVA model will include terms for treatment, and stratum, with the baseline MADRS score as a covariate. Pair-wise comparisons of each dose with placebo will be assessed within this model as planned comparisons. In order to adjust for multiple comparisons with placebo a step-up procedure will be employed with a rule for tests of significance based on ordered p-values, maintaining an overall experiment wise type I error rate of 0.05. The proportion of patients having a $\geq$ 50% reduction from baseline to final assessment in MADRS will be compared across treatments using a logistic model. Change from baseline in MADRS scores at each assessment (observed cases), and change from baseline in HAM-D, HAM-D item 1, CGI-S, YMRS, HAM-A, Q-Les-Q and PSQI score at each assessment (observed cases) and LOCF, will be analyzed using the same ANCOVA model as for the primary endpoint. The CGI-C will be analyzed using the ANCOVA model with the baseline CGI-S as a covariate.

The change from baseline in SAS and BARS score data will be assessed using the same ANCOVA model as the primary endpoint. The incidence of EPS AEs and overall AEs will be reported using descriptive statistics. Vital signs, weight, and body mass index will be tabulated using descriptive statistics at baseline, final assessment, and for change from baseline. Descriptive statistics will also be used to describe the proportion of patients whose final Q-Les-Q is within community norm levels.

Repeated measures analysis of variance (ANOVA)will be performed to evaluate whether there are significant differences among treatments across time for MADRS, HAM-D, and HAM-A total scores.

Efficacy analyses will be conducted on a modified intention-to-treat (MITT) population. A per-protocol (PP) analysis will be conducted for the primary analysis measure (change from baseline MADRS) to evaluate sensitivity of the response. The safety population will include all subjects who took study medication.

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APPENDICES

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

The following abbreviations and specialist terms are used in this study protocol.

Table 1 Abbreviations and specialist terms

Abbreviation or specialist term	Explanation
AE	Adverse event (see definition in Section 4.4.2.1)
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BP	Bipolar Disorder
BPD	Bipolar Depression
CGI	Clinical Global Impression
CGI-C	Clinical Global Impression - Change
CGI-S	Clinical Global Impression - Severity
CMH	Cochran-Mantel Haenszel
CRF	Case Report Form
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition
EPS	Extrapyramidal symptoms
ECG	Electrocardiogram
GCP	Good Clinical Practice
HAM-A	Hamilton Rating Scale for Depression
HAM-D	Hamilton Rating Scale for Anxiety
ICH	International Conference on Harmonisation
ICTI	Interactive Clinical Technologies, Incorporated
IEC	Independent Ethics Committee
IRB	Institutional Review Board
IVRS	Interactive Voice Response System
LOCF	Last Observation Carried Forward

Abbreviation or specialist term	Explanation
MADRS	Montgomery-Asberg Depression Rating Scale
MITT	Modified Intent to Treat
OAE	Other significant adverse event (ie, an adverse event of special interest in this clinical development; see definition in Section 4.4.2.1). The classification of OAEs will be performed by AstraZeneca drug safety physicians after the study is complete.
PSQI	Pittsburgh Sleep Quality Index
Principal investigator	The investigator who leads the study conduct at an individual study center. Every study center has a principal investigator.
Qhs	at bedtime
Q-Les-Q	Quality of Life Enjoyment Satisfaction Questionnaire
SAE	Serious adverse event (see definition in Section 4.4.2.1).
SAS	Simpson Angus Scale
SSRI	Selective serotonin reuptake inhibitors
UNI	Universal Systems Incorporated
YMRS	Young Mania Rating Scale

1 INTRODUCTION

1.1 Background

Quetiapine fumarate (SEROQUEL™, quetiapine) is a dibenzothiazepine derivative approved by the United States Food and Drug Administration (FDA) on 26 September 1997 following clinical development by AstraZeneca Pharmaceuticals LP (also referred to as the sponsor) for the treatment of subjects with schizophrenia. Quetiapine fumarate is designated chemically as bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl) piperazin-1-yl]ethoxy)ethanol] fumarate

Quetiapine has been studied in a toxicological and clinical program directed at supporting clinical evaluation in man. The results of these studies are presented in the Investigator's Brochure dated January 2002. The Professional Information Brochure (PIB) contains the current prescribing information for quetiapine.

1.2 Rationale for this study

The bipolar disorders are psychiatric disorders in which a disturbance in mood is the predominant feature. Bipolar I disorder is characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes. Bipolar II disorder is characterized by one or more major depressive episodes accompanied by at least one hypomanic episode. Bipolar depression refers to the major depressive episodes that occur with bipolar I and II disorder.

The prevalence of bipolar disorder is estimated to be 1 to 3.5%, evenly divided between men and women. The length of time between onset and symptoms and proper diagnosis and treatment is approximately 10 years and it is estimated that only 60% of those suffering from a bipolar disorder are receiving appropriate pharmacotherapy.

Although there is extensive and emerging literature guiding the treatment of the manic phase of bipolar I disorder as well as many approved compounds for the treatment of unipolar depression, the treatment of bipolar depression has not been widely studied and treatment guidelines are in their infancy. The use of currently available antidepressants for monotherapy for bipolar depression is often problematic as they may increase the "switch" into hypomania or mania from depression, or increase cycle acceleration. The adjunctive use of mood stabilizing medications such as lithium carbonate (LiCO3) is common and may decrease the likelihood of these complications.

Evidence indicates that medications with mood stabilizing properties which produced low levels of mania, hypomania, or cycle acceleration may be useful as monotherapy in the treatment of bipolar depression. The antiepileptic lamotrigine produced improvement in

HAM-D and MADRS scores in a 7-week, double-blind, placebo controlled trial for the patients who completed this study (Calabrese 1999). More recently, the anti-manic agent divalproex demonstrated numerical improvement over placebo in the percentage of patients with bipolar depression having a 50% reduction in the HAM-D scores without mania in an 8 week trial (Sachs, 2001) but this difference was not statistically significant. Lithium carbonate, also approved for the treatment of mania, has been demonstrated to be effective as a monotherapeutic agent in approximately 50% of patients with bipolar depression (Bauer). However, there are efficacy and tolerability limitations which mkay prohibit widespread use of the above therapies.

A large multicentered, double-blind, placebo controlled trial was recently completed, which demonstrated efficacy of the atypical antipsychotic olanzapine as monotherapy for the treatment of bipolar depression (Tohen, 2002). The endpoint mean MADRS change was significantly greater for patients on olanzapine (-15.0 points) than for those on placebo (-11.9 points). Treatment-emergent mania did not differ significantly between groups. There also is evidence from small uncontrolled studies that other atypical antipsychotics such as risperidone, and clozapine have mild to moderate antidepressant activity when used in patients with mood disorders. These small studies also indicate that these compounds are unlikely to cause patients to “switch” into mania.

The potential efficacy of quetiapine in depressive symptoms is provided in data from the Quetiapine Experience with Safety and Tolerability Trial (QUEST) and from investigator-initiated trials in mood disorder patients. In an open-label trial evaluating the safety and tolerability of quetiapine over 700 subjects with schizophrenia and other psychotic disorders were randomized to treatment with quetiapine or risperidone. Quetiapine-treated patients experienced a greater improvement in depressive symptoms compared with risperidone-treated patients, with a mean difference of 1.3 points on the HAM-D after adjustment for baseline differences (P=0.028) (Mullen et al, 2001).

A trial of quetiapine in 20 neuroleptic-dependent patients with bipolar or schizoaffective disorder also suggested positive effects on the depressive and psychotic symptoms in these disorders (Sajatovic et al, 2001). Overall, in 10 patients with bipolar disorder and 10 with schizoaffective disorder who received open-label quetiapine to optimum clinical dosage (25 to 800-mg), significant improvement in Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), and HAM-D scores was noted.

In summary, the paucity of satisfactory treatments available signify an unmet medical need for the treatment of bipolar depression. There are signals of efficacy from clinical trials for the antidepressant properties of atypical antipsychotics such as quetiapine.

2 STUDY OBJECTIVES

2.1 Primary objective

The primary objectives of the study are to evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the total Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S), and the Clinical Global Impression - Change (CGI-C).

2.2 Secondary objective

The secondary objectives of the study are:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by

- the incidence and nature of overall adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment

- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Experimental:

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in sleep quality using the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment
2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment

3 HYPOTHESES, STUDY PLAN AND PROCEDURES

3.1 Hypotheses

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

(1) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(2) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(3) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(4) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(5) Quetiapine at a dose of 300 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(6) Quetiapine at a dose of 600 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(7) Quetiapine at a dose of 300-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(8) Quetiapine at a dose of 600-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(9) Quetiapine at a dose of 300 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(10) Quetiapine at a dose of 600 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(11) Quetiapine at a dose of 300 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(12) Quetiapine at a dose of 600 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(13) Quetiapine at a dose of 300 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

(14) Quetiapine at a dose of 600 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

3.2 Overall study design and flow chart

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial will consist of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects will be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment

of 8 patients per center (minimum 4 maximum 30). Subjects are required to have a HAM-D (17-item scale) score of $\geq$ 20 and a YMRS of $\leq$12 at screening baseline (Visit 1).

The trial comprises the following 2 periods:

- Washout period
  Subjects will undergo HAM-D, SCID, YMRS, and safety evaluations at screen (Visit 1) and if they qualify to participate they will commence a washout of antidepressant, antipsychotic, and mood stabilizer medications. The number of days for washout will depend on the medication they are taking. These medications must be discontinued for a period of at least 7 days prior to randomization (Day 1, Visit 2), with the exception of fluoxetine which must be discontinued for a period of 14 days prior to randomization (Day 1, Visit 2) and depot injections of haloperidol decanoate or fluphenazine decanoate which need 28 days washout before randomization.

- 8-week double-blind randomized treatment period (Weeks 1 to 8)
  Eligible subjects will be randomized on Day 1 (Visit 2) to 1 of 3 treatment groups: quetiapine 300 mg/day, quetiapine 600 mg/day, or placebo. The randomization will be done using a stratification based on diagnosis. Treatment will be administered once daily at bedtime for 8 weeks (Days 1 - 56). Subjects will not receive medication on Day 57 which is only for final assessments. Doses will be titrated to achieve target doses of 300 mg/day within 4 days or 600 mg/day within 8 days. A dose reduction of 100 mg is allowed to improve patient tolerance in each treatment group. MADRS assessments (used to evaluate the primary efficacy variable) will be performed at Days 1, 8, 15, 22, 29, 36, 43, 50, and 57.

Figure 1 Study flow chart

			Treatment										
Day	**Screen**	**Washout [b]**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9-14**	**15-56**	**57**
	Visit 1		**Visit 2**							**Visit 3**		**Visits 4-9**	**Visit 10**
Dose: 300-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	
Dose: 600-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	400-mg	400-mg	400-mg	600-mg	600-mg	600-mg	

[a] One time dose reductions of 100 mg/day in 300-mg and 600-mg may occur after Day 8

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers for 5 elimination half-lives, prior to randomization. Patients on fluoxitine must discontinue for 14 days and those on haloperidol decanoate or fluphenazine decanoate for 28 days.

Table 2 Study plan

Study plan	Screen	Washout [a]	Double-blind treatment phase Weeks 1 through 8								
Days			**1**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**
Visits	**1**		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Informed consent	√										
Medical history	√										
Inclusion/Exclusion criteria	√		√								
Structured Clinical Interview for DSM-IV (SCID)	√										
Physical examination [d]	√										√
Urine toxicology screen	√										
Pregnancy tests (females)	√										
Vital signs, height, weight [c,e]	√		√	√	√	√	√	√	√	√	√
12-lead electrocardiogram	√		√[b]								√
Clinical chemistry and hematology	√		√[b]								√
Hamilton Rating Scale for Depression (17-item)	√		√	√	√	√	√	√	√	√	√
Montgomery-Asberg Depression Rating Scale			√	√	√	√	√	√	√	√	√
Young Mania Rating Scale	√		√	√	√	√	√	√	√	√	√
Hamilton Rating Scale for Anxiety			√	√	√	√	√	√	√	√	√
Clinical Global Impression - Severity	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression -Change				√	√	√	√	√	√	√	√
Barnes-Akathisia Rating Scale			√								√
Simpson-Angus Scale			√								√
Pittsburgh Sleep Quality Index			√				√				√
Quality of Life Enjoyment Satisfaction Questionnaire			√				√				√
Dispense study medication			√	√	√	√	√	√	√	√	
Adverse events	√	√	√	√	√	√	√	√	√	√	√

[a] Washout of antidepressants, antipsychotics, mood stabilizer for at least 7 days; 14-day washout for fluoxetine and 28 days for haloperidol or fluphenazine decanoate

[b] Repeat laboratory tests and ECG only if results outside of normal range and clinically significant at Screening

c Height and weight on screen and weight on Day 57
d Physical exam includes ophthalmoscopic exam on screen
e Blood pressure will be obtained in supine and standing positions

3.3 Rationale for study design, doses and control groups

This trial is designed as a double-blind placebo-controlled evaluation of Seroquel as monotherapy in bipolar depression. There is no currently approved compound for use in bipolar depression, nor is there a clinically accepted "gold standard". Conventional antidepressants have fallen out of favor because of their ability to induce manic symptoms. Antidepressants approved forthe treatment of unipolar depression have not been demonstrated to improve mood symptoms relative to placebo (Nemeroff et al Am J Psychiatry 158:6 June 2001). Moreover, there is a high placebo response rates of approximately 30% found in bipolar depression trials. Thus, the use of a placebo treatment arm for comparison is clinically justified.

Trial treatment will be administered as quetiapine monotherapy in order to more clearly identify a treatment effect of quetiapine on bipolar depression. Quetiapine fumarate will be administered once daily at bedtime. The current label specifies twice daily (BID) but a double-blind crossover study in bipolar patients indicated that once daily (qd) is well tolerated and as effective as BID dosing (Chengappa, 2002).

A period of 7 to 28 days is adequate for washout of most psychoactive medications including antidepressants, antipsychotics (including depot agents), and mood stabilizers to ensure that subjects are stable and continue to have adequate depressive symptoms requiring treatment, prior to randomization into the trial. The double-blind treatment period of 8 weeks is consistent with the time period that is required to see a clinically meaningful response in depressive symptoms.

The trial is designed as a fixed-dose evaluation due to the failure of flexible dose regimens in other psychiatric disorders. The dosages are based on clinical trial data with quetiapine in patients with a mood disorder. In the QUEST trial, the average dose of quetiapine in patients with a primary mood disorder (N=316) was approximately 250 mg/day at 16 weeks. In 20 patients with bipolar or schizoaffective disorder treated with open-label quetiapine, the mean dose was approximately200 mg/day (Sajatovic). Based on this data, 300 mg/day administered as monotherapy is an appropriate low-dose treatment arm, and 600 mg/day is an appropriate high-dose treatment arm that should exhibit efficacy without a high rate of AEs or noncompliance.

The MADRS is a standardized, well-validated measure of depressive symptoms that is sensitive to treatment effects in depressed outpatients.

3.4 Selection of study population

3.4.1 Study selection record

Investigators must keep a record of subjects who underwent screening but were not randomized into the trial.

3.4.2 Inclusion criteria

At screen (Visit 1) subjects must fulfill all of the following criteria:

(1) Documented ability to provide informed consent before beginning any study-specific procedures.

(2) Male and female patients between 18 and 65 years of age, inclusive

(3) Females of childbearing potential, be using a reliable method of contraception. Reliable methods include hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

(4) Women must have a negative pregnancy test

(5) Meets DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x), confirmed by the amended version(by Dr. Michael First) of the Structured Clinical Interview for DSM-IV (SCID) as administered by an AstraZeneca approved clinician with a signed confirmation by the Principal Investigator

(6) Outpatient status

(7) HAM-D (17-item) total score of 20 or greater

(8) HAM-D item 1 (depressed mood) score $\geq$2

(9) YMRS total $\leq$12

At randomization (Visit 2) subjects must fulfill the following criteria:

(1) HAM-D (17-item) total score of 20 or greater

(2) HAM-D item 1 (depressed mood) score $\geq$2

(3) YMRS total $\leq$12

3.4.3 Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

(1) Patients with a current Axis I disorder other than bipolar disorder within 6 months of screening

(2) Patients whose current episode of depression exceeds 12 months or is less than 4 weeks

(3) History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode

(4) Patients who meet DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening

(5) Patients with a positive urine toxicology screen for illicit substances of abuse

(6) Patients who are unable to discontinue all psychoactive medications (excluding prn benzodiazapines), including antidepressants, antipsychotics, and mood stabilizer, at least 7 days prior to randomization and consistent with the pharmacokinetics of the drug

- Patients treated with fluoxetine who have not discontinued this medication for at least 14 days prior to randomization.
- Patients treated with haloperiodol decanoate or fluphenazine decanoate who have not discontinued these medications 28 days prior to randomization.

(7) Patient who have not discontinued the use of potent P450 inhibitors and inducers (See Section 4.3, Table 13)

(8) Patients who in the investigators opinion will require initiation of psychotherapy during the study period. Note: ongoing psychotherapy for a minimum of 3 months may continue.

(9) Patients who, in the investigator's judgment, pose a current serious suicidal or homicidal risk at Visit 1 (HAM-D item 3 score of 3 or greater), or have made a suicide attempt within the past 6 months

(10) Patients with a history of clinically significant cardiac, renal, neurologic, cerebrovascular, metabolic, or pulmonary disease, or other disease or clinical finding that is unstable or that, in the opinion of the investigator, would be negatively affected by trial medication or that would affect trial medication

(11) Patients who have had a myocardial infarction within 1 year before Visit 1

(12) Patients with clinically significant abnormal laboratory findings at Visit 1

(13) Patients with renal impairment (serum creatinine ≥1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal)

(14) Patients whose TSH is ≥10% over the upper normal limit. Patients maintained on thyroid medication must be euthyroid for a period of at least 3 months before Visit 1

(15) Patients with clinically significant abnormalities on ECG

(16) Women who have a positive human chorionic gonadotropin (HCG) pregnancy test at Visit 1 or who are lactating or planning to become pregnant during the course of the study

(17) Patients who have participated in a clinical trial of an investigational drug within the past 3 months

(18) Patients who, in the opinion of the investigator, would be non-compliant with the visit schedule or study procedures

(19) History of orthostatic hypotension or conditions that would predispose them to hypotension (eg dehydration, hypovolemia)

(20) Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of Seroquel tablets, as judged by the investigator

3.4.4 Restrictions

Subjects will be required to adhere to the following special restrictions:

1) Use of any psychoactive drugs including antidepressants, hypnotics (with the exceptions noted in Section 4.3), mood stabilizing drugs, and antipsychotics is not permitted from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

2) Use of cytochrome P450 3A4 inducers and potent inhibitors are not permitted from 14 days prior to randomization to end of study (see Table 13)

3.4.4.1 Criteria for discontinuation

Subjects may be discontinued from study treatment and assessments at any time, at the discretion of the investigator(s). Specific reasons for discontinuing a subject from this study are:

1. Withdrawal of informed consent

2. Worsening psychiatric symptoms such that the symptoms constitute a danger to themselves or to others

3. Use of psychotropic medications at any time during the double-blind treatment period.

4. Pregnancy at any time during the double-blind treatment period.

5. Clinically significant or serious adverse event that would not be consistent with continuation in the study, as determined by the investigator, AstraZeneca, or the subject.

3.4.4.2 Voluntary discontinuation by a subject

Subjects are free to discontinue their participation in the study at any time, without prejudice to further treatment. Subjects who discontinue from the study should always be asked about the reason(s) for their discontinuation and about the presence of any adverse events. They should be seen and assessed by an investigator(s) (see Section 3.4.4.4). Adverse events should be followed up and any diary cards, questionnaires (eg, for Quality of Life assessments) and investigational products should be returned by the subject.

3.4.4.3 Incorrectly enrolled or randomized subjects

Incorrectly enrolled subjects will be discontinued from further study treatment and assessments. If a subject is given the incorrect randomized treatment, the subject should be continued on the treatment dispensed and Interactive Clinical Technologies, Inc. (ICTI), the vendor providing the randomization patient assignment) should be notified of the error. The next patient randomized at the site will be assigned an appropriate kit number by ICTI, accounting for the error.

3.4.4.4 Procedures for discontinuation

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination including an ophthalmoscopic exam
- Vital signs and weight
- HAM-D
- MADRS
- YMRS
- HAM-A

- SAS
- BARS
- PSQI
- Adverse events assessment

3.5 Treatments

3.5.1 Investigational products

3.5.1.1 Identity of investigational product and comparators

Investigational product will consist of 25-mg , 100-mg, and 200-mg tablets of quetiapine fumarate and matching placebo tablets as shown in Table 3.

Table 3 Trial medication

Tablet strength	Formulation number	Tablet color
25-mg quetiapine	F12804	peach
25- mg placebo	F12636	peach
100-mg quetiapine	F12689	yellow
100-mg placebo	F12637	yellow
200-mg quetiapine	F12690	white
200-mg placebo	F12638	white

3.5.1.2 Doses and treatment regimens

Quetiapine and placebo for each trial center will be packaged in blister cards. The 8-week supply will consist of 8 double-blind blister cards. The 8 double-blind blister cards will be packaged in subject-specific cartons.

Trial medication will be provided for each subject in an 8-card carton that contains the following:

- 1-week titration double-blind treatment cards for Days 1-7
- seven 1-week double-blind treatment cards for Days 8-56, with individual cards provided for treatment Days 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, and 50-56.
  Each one-week blister card will include a 2-day treatment overage to accommodate visit schedules.

The Week 1 titration card will consist of 25 mg tablets, 100-mg tablets, and 200-mg tablets or matching placebo, as described below, for each of the 300 mg/day and 600 mg/day treatment groups and placebo treatment group.

Blister cards for Weeks 2 through 8, for each treatment group, will consist of 9 days of dosing with the same number of pills for each group (300-mg,600-mg, and placebo) respectively. The cards for each treatment group will consist of 2 yellow tablets and 2 white tablets per day at bedtime.

Quetiapine or placebo will be administered once a day at bedtime with dose titration to reach a target dose of 300 mg/day by Day 4 in the 300 mg/day treatment group and 600 mg/day by Day 8 in the 600 mg/day group. The schedule for quetiapine or placebo administration is shown in Tables 4, 5, and 6.

Table 4 Dose administration schedule for 300-mg double-blind quetiapine

Trial Day	**Quetiapine 300 mg/day and placebo**				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablet/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 6	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 7	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 8	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg
Days 9-56	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg

Table 5 Dose administration schedule for 600-mg double-blind quetiapine

Trial Day	Quetiapine 600 mg/day and placebo tablets				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablets/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 6	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 7	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 8	0	2 tablets/100-mg	0	2 tablets/400-mg	0
Days 9-56	0	2 tablets/100-mg	0	2 tablets/400-mg	0

Table 6 Dose administration schedule for double-blind placebo

Trial Day			
	Placebo 25mg	**Placebo 100 mg**	**Placebo 200 mg**
Day 1	2 tablets/50-mg	0	0
Day 2	0	1 tablet/100-mg	0
Day 3	0	0	1 tablet/200-mg
Day 4	0	1 tablet/100-mg	1 tablet/200-mg
Day 5	0	2 tablets/100-mg	1 tablet/200-mg
Day 6	0	2 tablets/100-mg	1 tablet/200-mg
Day 7	0	2 tablets/100-mg	1 tablet/200-mg
Day 8	0	2 tablets/100-mg	2 tablets/400-mg
Days 9-56	0	2 tablets/100-mg	2 tablets/400-mg

Dosing Reduction

Dose reductions for intolerability will be allowed after Day 8. In the 300-mg/day group, dose reductions of 100 mg/day will be achieved by reducing the dose by one 100-mg tablets. In the 600-mg/day group, a dose reduction of 100 mg/day will be achieved by reducing the bedtime dose by one 100-mg tablets active drug. This dose reduction can occur anytime after Day 8. Each column in the blister packs will be numbered 1-4. By Day 6 columns 1 and 2 of the blister packs will each contain a 100-mg tablet. In both the 300-mg /day group and the 600-mg/day group, column 1 will contain active medication thus ensuring that by eliminating the first column (column #1) of medication they are reducing their dose by 100-mg. Each tablet in the placebo treatment group will also indicate the same corresponding numbers (columns #1-4) as the active treatment groups even though no active product is packaged. This will ensure the blind is maintained.

Table 7 Week 1 Blister pack for 300-mg/Day Quetiapine Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 8 Week 2-8 300-mg/Day Quetiapine Blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
2	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
3	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
4	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 9 Week 1 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 10 Week 2-8 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
2	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
3	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
4	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 11 Week 1 Blister Pack for Placebo Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg placebo	25-mg placebo		
2	100-mg placebo			
3	200-mg placebo			
4	100-mg placebo	200-mg placebo		
5	100-mg placebo	100-mg placebo	200-mg placebo	
6	100-mg placebo	100-mg placebo	200-mg placebo	
7	100-mg placebo	100-mg placebo	200-mg placebo	
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Table 12 Week 2-8 Blister pack for Placebo/Day Group

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
2	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
3	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
4	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
5	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
6	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
7	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

3.5.1.3 Labeling

All trial supplies will be provided by AstraZeneca.

The blister cards Days 1- 56 will be supplied in subject-specific cartons. Each blister card will be labeled with a two-panel, double-blind label. The left portion of the label will remain on the blister card. The right portion of the label will be affixed to the appropriate Case Report Form (CRF) as part of the individual's permanent record. The label will contain at least the following information: trial number, code assignment and storage condition. The carton for the 8 blister cards for Days 1-56 will be labeled with a single-panel double-blind label. The label will contain at least the following information: trial number, storage conditions, and instructions to dispense according to protocol.

3.5.1.4 Storage

All investigational products must be kept in a secure and locked location, at room temperature and protected from light and moisture.

3.5.1.5 Accountability

The investigational materials are to be prescribed only by the investigator or the sub-investigators named in Form FDA-1572. Under no circumstances will the investigator allow the

investigational drug to be used other than as directed by the protocol without prior AstraZeneca approval.

The investigator must maintain accurate records accounting for the receipt of the investigational materials (ICTI provides a acknowledge the receipt of drug shipment module for this purpose) and for the disposition of the material. This record keeping consists of a dispensing record that includes the identification of the person to who the drug is dispensed, the quantity and the date of dispensing, and documentation of any unused drug returned to the investigator. This record is in addition to any drug accountability information recorded on the subject's hospital or clinic chart.

Starting with Week 1, each patient will return the blister card for the preceding week to the clinic. The clinic will tabulate the returned pills to aid in drug accountability.

At the termination of the study or at the request of the sponsor, the Clinical Research Associate must return any unused study supplies to Universal Systems Incorporated (USI), at the address listed below, for destruction. This return will be documented on an Investigational Product Return Invoice supplied by AstraZeneca.

USI
2084-900 Lake Industrial Court
Conyers, GA 30013

3.5.2 Method of assigning subjects to treatment groups

This trial will be established with a non-specific labeling (NCSL) randomization which will be stratified by bipolar type. Randomization to trial treatment will be done via an Interactive Voice Response System (IVRS) at ICTI on Day 1 (Visit 2) in balanced blocks within each stratum in order to ensure relative balance among treatment groups and strata (Bipolar I and Bipolar II)in terms of total number of subjects. The randomization schedule will be created under the auspices of AstraZeneca Quantitative Decision Sciences Group and will provide allocation of subject numbers to the treatment regiments. Number and size of tablets will be identical for the 3 treatment arms. Clinical supplies will contain a 4-digit subject number which is allocated to the treatment arm through the randomization scheme. A separate randomization will be used to provide kits of packaged drugs to the sites. The IVRS system at ICTI will allocate a kit number at the site for the treatment assigned through the stratified randomization.

Subject eligibility will be established before treatment randomization. Subjects will be randomized centrally sequentially within the stratum, as subjects are eligible for enrollment/randomization. If a subject discontinues from the study, the subject number will not be reused, and the subject will not be allowed to re-enter the study.

The randomization is centralized and the assigned randomized patient number and associated kit numbers will not be sequential within a site.

3.5.3 Blinding and procedures for unblinding the study

3.5.3.1 Methods for ensuring blinding

All packaging will be identical with placebo and active tablets identical in size and color. The number of tablets dispensed on each card will be identical across all treatment arms.

The randomization for the kit assignments will be generated by the study statistician and provided directly to packaging with a copy going to ICTI Clinical Supplies Management Group. The stratified patient randomization will be generated by an AstraZeneca randomization staff member not associated with the trial and will be provided directly to ICTI for incorporation into the IVRS system. No member of the study team in AstraZeneca, at investigational sites or the CRO organization handing data will have access to the randomization scheme during the conduct of the study.

3.5.3.2 Methods for unblinding the study

Individual treatment codes, indicating the treatment randomization for each randomized subject, will be available to the investigator(s) or pharmacists at the study center through the use of a concealed panel on the label.

The treatment code must not be broken except in medical emergencies when the appropriate management of the subject necessitates knowledge of the treatment randomization. The investigator(s) must document and report to AstraZeneca any breaking of the treatment code. AstraZeneca retains the right to break the code in order to report serious adverse events to regulatory authorities.

Treatment codes will not be broken for the planned analyses of data until all decisions on the evaluability of the data from each individual subject have been made and documented.

3.5.4 Treatment compliance

Compliance will be assessed based on returned tablet counts. The percent compliance will be calculated as the number of tablets taken (dispensed - returned) divided by the prescribed number of tablets (number of days times number of tablets per day) expressed as a percent. Based on this calculation a subject with at least 75% compliance with study medication during study participation will be classified as compliant.

Furthermore, if there are any significant irregularities in compliance, in the opinion of the investigator, the patient should be withdrawn from the study.

4 CONCURRENT TREATMENT

4.1 General medications

Nonpsychotropic medication, including over-the counter medications, taken by the subject before entry into the trial may be continued during the trial. Medications required to treat illnesses or complaints that occur during the trial may be used at the discretion of the investigator. Use of cytochrome P450 inducers and potent inhibitors is restricted (see Table 13 below).

Women who enter the trial with an intrauterine device in place, using oral contraceptives, or using injectable or implantable hormonal agents designed to prevent pregnancy may continue these treatments throughout the trial.

The specific type of medication (trade or generic name), the indication for use, and the dates of usage should be reported on the CRF entitled Concurrent Treatment.

Medication which is considered necessary for the subject's safety and well being may be given at the discretion of the investigator(s). The administration of all medication (including investigational products) must be recorded in the appropriate sections of the case report form (CRF).

4.2 Use of psychoactive medications

The use of psychoactive drugs other than those specifically allowed during the trial (ie, lorazepam and zolpidem tartrate) is restricted (see Section 4.3, Table 13).

4.3 Summary of permitted concurrent medications

Medications specifically prohibited or restricted, and those permitted during the trial are listed in Table 13

Table 13 Permitted, restricted, and prohibited medications

Use category	Type of medication
Permitted	Previous medications for medical, nonpsychiatric illnesses Oral contraceptives and contraceptive devices
Restricted	Zolpidem tartrate 5-10 mg at bedtime for insomnia Lorazepam 1-3 mg per day for severe anxiety These drugs may be prescribed during the first 3 weeks of the study as long as they do not interfere with any assessments
Prohibited	Potent cytochrome P450 3A4 inducers (including but not limited to barbiturates, carbamazepine, rifampin, and St John's Wort) Potent cytochrome P450 3A4 inhibitors (including but not limited to ketoconazole, itraconazoole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir, and saquinavir) Antipsychotic medications (including but not limited to phenothiazines, risperidone, olanzapine, ziprasidone, clozapine, loxapine, thiothixene, molindone) Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

5 STUDY MEASUREMENTS AND ENDPOINTS

5.1 Primary endpoint

The primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score. This endpoint is used as the basis for the sample size calculation, as provided in Section 6.1.

5.2 Screening and demographic measurements

The following data are to be collected at screening:

- date of birth, sex, and race
- vital signs, height, weight
- supine and standing blood pressure and pulse
- significant medical history
- physical examination including ophthalmoscopic exam
- 12-lead electrocardiogram
- clinical chemistry and hematology
- pregnancy test (if female of childbearing potential)
- HAM-D assessment
- YMRS
- DSM-IV diagnosis, based on SCID assessment

5.3 Efficacy measurements and endpoints

The following assessments will be used to evaluate efficacy:

- change from baseline to final assessment in MADRS total score
- percentage of subjects with $\geq$50% reduction from baseline in MADRS total score at final assessment
- the change from baseline in each assessment (observed cases) in the MADRS total score

- the change from baseline to each assessment (observed cases) and final assessment in the CGI-S
- the CGI-C at final assessment
- the change from baseline to each assessment (observed cases) and final assessment in the YMRS
- the change from baseline to each assessment (observed cases) and final assessment in the total HAM-A

Evaluation using each of these scales should be performed by the same trained/certified staff member who has been approved by AstraZeneca for all assessments of the scale for an individual subject.

5.3.1 Summary of efficacy objectives and endpoints

Table 17 shows how the efficacy endpoints of this study relate to the study objectives.

Table 14 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Primary	Primary measure		
evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks	change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score; ls means, 95% CI at final assessment ; descriptive statistics by statum	ANCOVA for the change from baseline to final assessment for total MADRS score. Pair-wise comparisons of each dose with placebo using step up procedure	Reductions in MADRS compared with placebo will indicate doses which are effective in treating depressive episode
	Secondary measure		
	percentage of subjects meeting the MADRS responder criteria ; n, percentage responders at each assessment, final assessment ; descriptive statistics by statum	Logistic model	Higher response rates will indicate doses which are effective in treating depressive episode in treating depressive episode
	change from baseline to each assessment for the MADRS total score, and each assessment and final	ANCOVA for the change from baseline to each assessment and final assessment	Reductions in scales compared with placebo will indicate doses which are effective in

	assessment Clinical Global Impression - Severity (CGI-S); ls means, 95% CI; descriptive statistics by stratum	(LOCF) for CGI-S. Pair-wise comparisons of each dose with placebo	treating depressive episode
	Clinical Global Impression - Change (CGI-C); ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the CGI-C for each assessment and final assessment (LOCF). Pair-wise comparisons of each dose with placebo	Greater improvements in CGI-C will indicate doses which are effective compared with placebo
Secondary			
evaluate the efficacy of quetiapine compared to placebo in the incidence of treatment -emergent mania	change from baseline to each assessment and final assessment in the YMRS total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for YMRS total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	No significant increase in the YMRS compared to placebo will indicate doses which do not result in treatment-emergent mania
evaluate the effect of quetiapine compared to placebo on symptoms of anxiety	change from baseline to each assessment and final assessment in the HAM-A total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for HAM-A total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Improvement in the HAM-A compared to placebo will indicate efficacy in treating anxiety component of the depressive episode

The methods for collecting efficacy data are presented below.

5.3.2 Montgomery-Asberg Depression Rating Scale (MADRS)

5.3.2.1 Methods of assessment

The MADRS will be performed at each visit during the trials using the validated MADRS instrument by certified staff at each site.

5.3.2.2 Calculation or derivation of endpoint

The change from baseline to final LOCF will be calculated for total MADRS score. A subject will be classified as a responder if the % change from baseline, calculated as the (change from

baseline divided by the baseline) multiplied by 100 indicates a ≥ 50% reduction in baseline total MADRS score.

5.3.3 Hamilton Rating Scale for Depression (HAM-D)

5.3.3.1 Methods of assessment

The HAM-D will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-D and HAM-D item #1.

5.3.4 Clinical Global Impression - Severity (CGI-S)

5.3.4.1 Methods of assessment

The CGI-S will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.4.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in CGI-S.

5.3.5 Clinical Global Impression - Change (CGI-C)

5.3.5.1 Methods of assessment

The CGI-C will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.5.2 Calculation or derivation of endpoint

The CGI-C is a measure of change from baseline and therefore requires no further derivation.

5.3.6 Hamilton Rating Scale for Anxiety (HAM-A)

5.3.6.1 Methods of assessment

The HAM-A will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.6.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-A.

5.3.7 Young Mania Rating Scale (YMRS)

5.3.7.1 Methods of assessment

The YMRS will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.7.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in YMRS.

5.4 Safety measurements and endpoints

The following measurements will be used to assess safety:

- adverse event reporting (both general adverse events and serious adverse events), coded using MedDRA system of nomenclature
- fasting clinical laboratory tests (including chemistry and hematology)
- vital signs(taken in both the standing and supine positions)
- ECG tests
- Simpson-Angus Scale
- Barnes-Akathesia Rating Scale

5.4.1 Summary of safety objectives and endpoints

Table 13 shows how the safety endpoints of this study relate to the study objectives.

Table 15 Safety objectives and endpoints relating to each objective

Objective	Endpoints and statistic	Planned analysis	Significance of results
evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	incidence and nature of adverse events during double-blind treatment ; n, % incidence per event, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	no new safety issues identified
	incidence of drug-related adverse events during double-blind treatment ; n, % incidence; titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of subject withdrawal due to adverse events; n, % withdrawn, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of clinically significant changes in vital signs; n, % at each assessment and final visit	descriptive statistics only	
	change in the SAS total score ; mean change, standard deviation, baseline to final assessment (LOCF)	descriptive statistics only	
	the change in BARS total score	descriptive statistics only	
	incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment	descriptive statistics only	

The methods for collecting safety data are described below.

5.4.2 Adverse Events

5.4.2.1 Definitions

The definitions of adverse events (AEs), serious adverse events (SAEs) and other significant adverse events (OAEs) are given below. It is of the utmost importance that all staff involved in the study is familiar with the content of this section. The principal investigator is responsible for ensuring this.

(a) Adverse Event

An adverse event is the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver) or the abnormal results of an investigation (eg, laboratory findings, electrocardiogram). In clinical studies, an AE can include an undesirable medical condition occurring at any time, including run-in or washout periods, even if no study treatment has been administered.

(b) Serious Adverse Event

A serious adverse event is an AE occurring during any study phase (ie, run-in, treatment, washout, follow-up), and at any dose of the investigational product, comparator or placebo, that fulfills one or more of the following criteria:

- results in death
- is immediately life-threatening
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- is a congenital abnormality or birth defect
- is an important medical event that may jeopardize the subject or may require medical intervention to prevent one of the outcomes listed above?

The causality of SAEs (ie, their relationship to study treatment) will be assessed by the investigator(s), who in completing the relevant case report form must answer “yes” or “no” to the question “Do you consider that there is a reasonable possibility that the event may have been caused by the drug?” For further guidance on the definition of a SAE and a guide to the interpretation of the causality question, see Appendix F.

(c) Other significant adverse event

An AstraZeneca expert will identify OAEs during the evaluation of safety data for the Clinical Study Report. Significant adverse events of particular clinical importance, other than SAEs and those AEs leading to discontinuation of the subject from study treatment, will be classified as OAEs. Examples of these are marked hematological and other laboratory abnormalities, and certain events that lead to intervention (other than those already classified as serious), dose reduction or significant additional treatment. For each OAE, a narrative will be written and included in the Clinical Study Report.

5.4.2.2 Recording of adverse events

All AEs that occur before treatment, during treatment, or within 30 days following the cessation of treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. A description of the event, its intensity, duration, action taken (eg, treatment and follow-up tests), and outcome should be given, along with the investigator's causality assessment of the relationship of the event to the study drug. If a diagnosis of the subject's condition has been made, then the diagnosis should be recorded as the SAE. In instances of well recognized syndromes (eg, fever, runny nose, cough) they can be recorded as "flu". However, if a diagnosis of the subject's condition has not been made, or if the individual symptoms are not well recognized, then the individual symptoms should be recorded separately.

In general, abnormal laboratory tests or vital signs should not be reported as AEs unless they fulfill the criteria for an SAE or lead to discontinuation. If an abnormal laboratory test result or vital sign is associated with clinical signs and symptoms, the sign or symptom should be reported as an AE, and the associated test result or vital sign should be recorded on the appropriate CRF.

A causality assessment must be recorded for all AEs. The CRF asks the question, "In your medical judgement, is there a reasonable possibility that the event may have been caused by the study therapy?" If there is any valid reason, even if undetermined or untested, for suspecting a possible cause-and-effect relationship between the study drug and the occurrence of the AE, then this should be answered "yes." Otherwise, if no valid reason exists for suggesting a possible relationship, then this should be answered "no." If more than 1 AE is identified, a causality assessment must be made for each AE.

It is important to distinguish between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined by the criteria in Section 5.4.2.1 b. An AE of severe intensity need not necessarily be considered serious. For example, nausea which persists for several hours may be considered severe nausea, but not a SAE. On the other hand, a stroke which results in only a limited degree of disability may be considered a mild stroke but would be a SAE.

Any detrimental change in the subject's condition after the subject enters the study will be discussed with the investigator. Where the detrimental change is considered by the investigator to constitute a progression or relapse of bipolar depression or a lack of efficacy, then this will not be considered an AE even where this necessitates or prolongs hospitalization. When there is deterioration in the condition for which the medicine is being used, there may be uncertainty as to whether this is lack of efficacy or an AE. In such cases, unless AstraZeneca or the reporting physician considers that the medicine contributed to the deterioration, the deterioration should be considered lack of efficacy. However, if it is believed that the medicine may have contributed to the deterioration, then this should be treated as an AE.

Study drug abuse is an SAE, even when there are no symptoms or additional AEs and should be reported according to the guidelines in Section 5.4.2.3. Misuse of study drug is an AE but is not considered an SAE unless accompanied by serious sequelae.

Should an overdose occur, it must be reported in accordance with the procedures described in Section 10.3 Procedures in case of overdose. All overdoses, with or without associated symptoms, should be reported as AEs.

Suicide and attempted suicide, irrespective of the method, but occurring in connection with the use of study drug, should be reported as AEs (serious or non-serious). This event should be identified as suicide or attempted suicide, and the method of the suicide or attempt should be provided. If an attempted suicide meets the criteria for an SAE, the event must be reported according to the guidelines in Section 10.4.

Should a pregnancy occur, it must be reported in accordance with the procedures described in Section 10.5. Procedures in case of pregnancy. Pregnancy in itself is not regarded as an AE unless there is a suspicion that an investigational product may have interfered with the effectiveness of a contraceptive medication.

5.4.2.3 Reporting of serious adverse events

Investigators and other site personnel must inform appropriate AstraZeneca representatives of any SAE that occurs in the course of the study within 1 day (i.e. immediately but no later than the end of the next business day) of when he or she becomes aware of it.

The AstraZeneca representative will work with the investigator to compile all the necessary information and ensure that the appropriate AstraZeneca Drug Safety Department receives a report by day 1 for all fatal and life-threatening cases and by day 5 for all other SAEs.

Follow-up information on SAEs must also be reported by the investigator within the same time frames.

If a non-serious AE becomes serious, this and other relevant follow-up information must also be provided to AstraZeneca within 1 day as described above.

After initial notification, the AstraZeneca representatives have 4 days to work with the investigator to compile all the necessary information to ensure that the appropriate AstraZeneca Drug Safety Department receives a complete report by day 5. Follow-up information on SAEs should also be reported by the investigator within the same time frames. If a non-serious case becomes serious, this and other relevant follow-up information should also be provided to AstraZeneca within 1 day as described in the paragraph above

All SAEs have to be reported, whether or not considered causally related to the investigational product. All SAEs will be recorded in the case report form. The investigator is responsible for informing the Ethics Committee and/or the Regulatory Authority of the SAE as per local requirements.

5.4.3 Laboratory safety measurements and variables

Blood (under fasting conditions) and urine specimens will be collected for laboratory test analysis and these samples will be processed by a central laboratory (Quintiles Central Laboratory).

5.4.3.1 Methods of assessment

- Fasting hematology: hemoglobin, hematocrit, red blood cell count, total and differential white blood cell counts and platelet count
- Fasting clinical chemistry: total bilirubin, alkaline phosphatase, alanine transaminase(ALT), aspartate transaminase(AST), sodium, potassium, chloride, creatinine, glucose, insulin, bicarbonate, high-density lipoprotein cholesterol, triglycerides, low-density lipoprotein cholesterol and total cholesterol
- Thyroid function tests: thyroid stimulating hormone (TSH), Triiodothyronine resin uptake (T3RU), and total thyroxine (T4)
- Serum pregnancy tests
- Urine toxicology screen

5.4.3.2 Calculation or derivation of endpoints

Change from baseline will be derived for all subjects who have a screening laboratory test and a final laboratory test. The change from baseline is the final test value minus the screening test value. Laboratory test values will also be compared to the laboratory standard normal ranges and

flagged with H or L if they are outside of the normal range. In addition, treatment emergent laboratory changes, identified using computerized methods to compare results or changes from baseline to standard extended ranges will be flagged at the subject and test level.

5.4.4 Vital signs measurement

5.4.4.1 Methods of assessment

A standard blood pressure cuff will be used to obtain systolic and diastolic blood pressure. The assessment will be done first with the subject in the supine position for 3 minutes and again within 3 minutes of the subject attaining a standing position. Pulse will be measured for 1 minute.

5.4.4.2 Calculation or derivation of endpoints

Change from baseline will derived be as the value at the visit minus the screen value for the same assessment and position. In addition the change within a visit between the standing and supine blood pressure assessments will be calculated for both systolic and diastolic blood pressures. This difference will be calculated as supine minus standing . A subject will be classified as having calculated postural hypotension if either the systolic blood pressure difference indicates a decrease >20 mmHg or the diastolic blood pressure difference indicates a decrease >15 mmHg.

5.4.5 ECG safety measurements and variables

5.4.5.1 Methods of assessment

A 12 lead ECG assessment will be done using an ECG machine compatible with the requirements for eResearch the central evaluation laboratory. The central laboratory will supply the interval data, rates and standard interpretation of the ECG test results.

eResearch
30 south 17th Street
Philadelphia, PA 19103-4001

5.4.5.2 Calculations and derivations of endpoint

Change from baseline for interval data and rate data will be derived by subtracting the screen value from the final assessment value. Values outside the extended range in Appendix XX will be flagged.

5.4.6 Simpson-Angus Scale (SAS)

5.4.6.1 Methods of assessment

The SAS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.6.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.4.7 Barnes-Akathisia Rating Scale (BARS)

5.4.7.1 Methods of assessment

The BARS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.7.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.5 Quality of Life endpoint

The following assessment will be used to assess the effect of quetiapine compared with placebo on quality of life as assessed by:

- the PSQI
- the short form Q-Les-Q

5.5.1 Summary of quality of life objectives and endpoints

Table 19 shows how the efficacy endpoints of this study relate to the study objectives.

Table 19 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Secondary	Secondary measure		
evaluate the effect of quetiapine compared to placebo on quality of sleep	change from baseline to final assessment in PSQI; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for PSQI total score, with MADRS score as covariate. Pair-wise comparisons of	Reduction in PSQI compared with placebo indicates improvement of sleep quality

		each dose with placebo	
evaluate the effect of quetiapine compared to placebo on the overall quality of life	change from baseline to final assessment in Q-Les-Q; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for Q-Les-Q total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Increase in Q-Les-Q compared with placebo indicates improvement of overall quality of life

The methods of collecting quality of life data are described below.

5.5.2 PSQI

5.5.2.1 Methods of assessment

The PSQI will be performed at scheduled visits during the trial by a patient at each site. The 9 self-rated questions will be incorporated into 7 component scores which are added together to yield one total "global" score. Higher scores indicate more severe difficulties in sleep quality.

5.5.2.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the PSQI.

5.5.3 Q-Les-Q

5.5.3.1 Methods of assessment

The Q-Les-Q is a patient self assessment questionnaire which will be completed at scheduled visits during the trial by a patient at each site. The short form has 14 self-rated questions, the first 12 will be incorporated into a total score. Higher scores indicate better quality of life.

5.5.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the Q-Les-Q.

5.6 Genetic sampling and storage

There will be no genetic sampling in this trial.

5.7 Volume of blood sampling and handling of biological samples

The total volume of blood that will be drawn from each subject in this study is as follows:

Table 16 Volume of blood to be drawn from each subject

Assessment		Sample volume (ml)	N of samples	Total volume (ml)	
				Women	Men
Safety	Clinical chemistry				
	Hematology	18	2	36	36
	Serum Pregnancy [a]	2	1	2	
Total				38	36

[a] Women only.

Sample handling and storage will be defined by the central laboratory which will be handling the analysis and reporting or results from samples.

6 DATA MANAGEMENT

Case Report Forms (CRFs) will be provided for recording of data. The forms will be in triplicate with carbonless paper. Data will be recorded legibly onto the CRFs with black ink, preferably with a ballpoint pen. If any data are not available, omissions will be indicated on the CRFs. Corrections should be made legibly and be initialed and dated. Correction fluid or covering labels must not be used. The top original and the first copy of the completed form will collected and returned to AstraZeneca/AstraZeneca's agent and the second copy will be retained by the investigator.

Data received electronically by AstraZeneca from a validated source will be loaded directly into the trial database for analysis.

7 STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

7.1 Determination of sample size

Since there is no data using the MADRS instrument in the assessment of quetiapine in treating bipolar subjects with depression, the sample size estimation was based on published data from the lamotrigine monotherapy (Calabrese et al, 1999) and olanzapine trials (Tohen et al, 2002). The percentage change in the HAM-D across these lamotrigine studies in bipolar depression is similar to that observed with quetiapine. MADRS scores correlate significantly with those of the HAM-D (Montgomery Asberg 1979).

Sample size was estimated using an Bonferroni correction for the 2 comparisons with placebo. A clinically meaningful 3.6-unit difference between quetiapine treatment and placebo was used to estimate the effect size (with 3.1 units considered a minimally effective and detectable difference). The variability used for calculation was 10 units, the variability seen in the olanzapine study. A sample size of 168 subjects/arm (504 subjects total) would provide 85% power for 2-sided pair-wise comparisons with placebo at α=0.025 which provides an overall experiment wise type I error rate of 0.05. Therefore, 740 patients will be screened and approximately 530 subjects randomized (allowing for a 5% early drop out rate), to insure 504 subjects with post baseline data available for analysis (MITT analysis population). This sample size will provide 72% power to detect a 3.1 unit difference from placebo.

7.2 Statistical evaluation

7.2.1 Methods of statistical analysis

A comprehensive Statistical Analysis Plan (SAP) will be prepared before unblinding of the data.

Missing data for final visit resulting from patient drop outs will be imputed using an LOCF approach. Patients with post baseline data (MITT population) will have their last trial assessment carried forward as the final assessment for analyses.

7.2.2 Study endpoints

Primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score.

Secondary efficacy endpoints:

(1) Percentage of patients with a ≥50% reduction from baseline in the MADRS total score at study endpoint

(2) Change from baseline to each assessment (observed cases) in the MADRS total score

(3) Change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, CGI-S, CGI-C, and Young Mania Rating Scale.

(4) Change in the PSQI score from baseline to final assessment

Safety endpoints:

(1) Incidence and nature of adverse events during double-blind treatment

(2) Incidence of drug-related adverse events during double-blind treatment

(3) Incidence of subject withdrawal due to adverse events

(4) Incidence of clinically significant changes in hematology and chemistry laboratory results, vital signs, electrocardiograms, weight, and body mass index.
Tolerability endpoints:

(5) Change in the SAS total score from baseline to final assessment

(6) Change in BARS total score from baseline to final assessment

(7) Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment

Quality of Life endpoints:

(1) Change in Q-Les-Q total score from baseline to final assessment

(2) Proportion of patients achieving community norm levels in Q-Les-Q at final assessment

7.2.3 Statistical analyses

The randomization will be stratified by Bipolar type (I or II) in order to assure balance across treatments for the type of patient enrolled. The stratification will be incorporated into the statistical analysis models and descriptive statistics will be provided for each stratum.

For each statistical model run, the assumptions for the model will be evaluated. If the assumptions are not reasonably met, the data may be transformed to meet assumptions or a non-parametric test performed.

All statistical comparisons will be based on 2-sided testing approaches for testing the difference between active study medication dose and placebo.

7.2.3.1 Study populations for analysis

The modified intention to treat population (MITT) will be the population for efficacy and quality of life evaluation. The MITT population will include all randomized subjects who were received study treatment and had at least one post baseline efficacy assessment with a last observation carried forward approach for final assessment.

The safety population will include all subjects who provide consent and received study medication.

7.2.3.2 Primary Analysis

The primary analysis will use analysis of covariance (ANCOVA) model for the change from baseline at final assessment for the MADRS. The model will include terms for treatment, stratum, with the baseline MADRS as a covariate. The Simes-Hommel step-up procedure will be used to adjust for the 2 comparisons with placebo (Simes-Hommel, 1988). The p-values obtained from the pair-wise comparisons will be ordered as follows: $P(1) \leq P(2)$. The following rule will be used to assess statistical significance:

1) If $P(2) \leq 0.05$, then reject both null hypotheses associated with P(2) and P(1); else proceed to the next step;

2) If $P(1) \leq 0.025$, then reject the null hypothesis associated with P(1).

7.2.3.3 Secondary Analyses of efficacy and quality of life

The secondary endpoint for responder, defined as a subject who has a 50% reduction in MADRS score from baseline to final assessment, will be analyzed by comparing the proportion of subjects responding across treatments using a logistic model which includes treatment, stratum, and center in the model. The secondary endpoints based on change from baseline for scales at an assessment time will be analyzed using the same model as the primary endpoint. Nominal p-values will be used for all secondary endpoint comparisons.

Exploratory repeated measures analysis of variance model will also be conducted to evaluate whether there are significant differences among treatments across time for the MADRS and HAM-D scores.

Descriptive statistics will be used to report stratum, item scores, and subscale scores.

7.2.3.4 Safety analyses

Adverse events will be coded using the MedDRA dictionary. Numbers of events and incidence rates for AEs in each treatment group will be summarized by preferred term and system organ class. An event that occurred one or more times on the date of, or subsequent to, randomization will contribute one observation to the numerator of the incidence rate. The denominator will comprise all patients exposed to study treatment.

Adverse events that lead to premature withdrawal of subjects will be tabulated for each treatment group.

All laboratory assessments, vital signs, ECG (rates and intervals) results, and weight and body mass index will be tabulated using descriptive statistics at baseline, final assessment and including change from baseline. Descriptive statistics will include n, mean, standard deviation, minimum and maximum value.

7.2.3.5 Tolerability analyses

The change from baseline in SAS and BARS score data will be summarized using descriptive statistics (mean, standard deviation, median, minimum and maximum).

Incidence rates of EPS adverse events will be compared and tabulated using descriptive statistics.

7.2.3.6 Interim analysis

No interim analysis is planned

7.2.3.7 Data or safety monitoring committee

There will be no data or safety monitoring committee.

8 STUDY MANAGEMENT

8.1 Monitoring

Before the study begins, a representative of AstraZeneca or company representing AstraZeneca will visit the investigational site to

- determine the adequacy of the facilities
- discuss with the investigator(s) (and other personnel involved with the study) their responsibilities with regard to protocol adherence, and the responsibilities of AstraZeneca or its representatives.

During the study, a monitor from AstraZeneca or company representing AstraZeneca will have regular contacts with the investigational site, including visits to

- provide information and support to the investigator(s)
- confirm that facilities remain acceptable
- confirm that the investigational team is adhering to the protocol, that data are being accurately recorded in the case report forms (CRFs), and that investigational product accountability checks are being performed.
- perform source data verification (a comparison of the data in the CRFs with the subject's records at the hospital or practice, and other records relevant to the study). This will require direct access to all original records for each subject (eg, clinic charts).

The monitor or another AstraZeneca representative will be available between visits if the investigator(s) or other staff at the center need information and advice.

8.2 Audits and inspections

Authorized representatives of AstraZeneca, a regulatory authority, an Independent Ethics Committee (IEC) or an Institutional Review Board (IRB) may visit the center to perform audits or inspections, including source data verification. The purpose of an AstraZeneca audit or inspection is to systematically and independently examine all study related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed, and accurately reported according to the protocol, Good Clinical Practice (GCP), guidelines of the International Conference on Harmonization (ICH), and any applicable regulatory requirements. The investigator should contact AstraZeneca immediately if contacted by a regulatory agency about an inspection at his or her center.

8.3 Training of staff

The principal investigator will maintain a record of all individuals involved in the study (medical, nursing and other staff). He or she will ensure that appropriate training relevant to the study is given to all of these staff, and that any new information of relevance to the performance of this study is forwarded to the staff involved.

8.4 Changes to the protocol

Study procedures will not be changed without the mutual agreement of the international principal investigator(s) and AstraZeneca.

If it is necessary for the study protocol to be amended, the amendment or a new version of the study protocol must be notified to or approved by each IEC or IRB, and in many countries also the local regulatory authority, before implementation. Local requirements must be followed.

If a protocol amendment requires a change to a particular center's Written Informed Consent Form, then AstraZeneca and the center's IEC or IRB must be notified. Approval of the revised Written Informed Consent Form by AstraZeneca and by the IEC or IRB is required before the revised form is used.

AstraZeneca will distribute amendments and new versions of the protocol to each principal investigator(s), who in turn is responsible for the distribution of these documents to his or her IEC or IRB, and to the staff at his or her center. The distribution of these documents to the regulatory authority will be handled according to local practice.

8.5 Study agreements

The principal investigator at each center must comply with all the terms, conditions, and obligations of the study agreement for this study. In the event of any inconsistency between this protocol and the study agreement, this study agreement shall prevail.

8.6 Study timetable and termination

It is anticipated that the first subject will be enrolled in September 2002 and that the last subject will complete the study in March 2004.

9 ETHICS

9.1 Ethics review

The final study protocol, including the final version of the Written Informed Consent Form, must be approved or given a favorable opinion in writing by an IEC or IRB as appropriate. The investigator must submit written approval to AstraZeneca before he or she can enroll any subject into the study.

The principal investigator(s) is responsible for informing the IEC or IRB of any amendment to the protocol in accordance with local requirements. In addition, the IEC or IRB must approve all advertising used to recruit subjects for the study. The protocol must be reapproved by the IEC or IRB annually, as local regulations require.

Either the investigator(s) or AstraZeneca must submit progress reports to the IEC or IRB according to local regulations and guidelines. The principal investigator(s) must also provide the IEC or IRB with any reports of serious adverse events from the study site.

The principal investigator(s) is also responsible for providing the IRB with reports of any serious adverse events from any other study conducted with the investigational product. This information will be provided to the principal investigator(s) by AstraZeneca.

9.2 Ethical conduct of the study

The study will be performed in accordance with the ethical principles in the Declaration of Helsinki (see Appendix C), Good Clinical Practice, and applicable regulatory requirements.

9.3 Subject information and consent

The principal investigator(s) at each center will ensure that the subject is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Subjects must also be notified that they are free to discontinue from the study at any time. The subject should be given the opportunity to ask questions and allowed time to consider the information provided.

The subject’s signed and dated informed consent must be obtained before conducting any procedure specifically for the study, including the following:

The principal investigator(s) must store the original, signed Written Informed Consent Form. A copy of the Written Informed Consent Form must be given to the subject.

A sample Written Informed Consent Form is enclosed (Appendix B). If modifications are made according to local requirements, the new version has to be approved by AstraZeneca.

9.4 Subject data protection

The Written Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. The subjects' names will not be recorded in this database. The Written Informed Consent Form will also explain that for data verification purposes, authorized representatives of AstraZeneca, a regulatory authority, an IEC or IRB may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

10 EMERGENCY PROCEDURES

10.1 AstraZeneca emergency contact procedure

In the case of a medical emergency, contact AstraZeneca personnel shown below.

Wayne Macfadden MD
Project Physician
302-886-1147 (telephone)
302-886-5567 (fax)
REDACTED

Robin McCoy RN
Senior Clinical Research Scientist
302-886-4650 (telephone)
302-886-5567 (fax)
REDACTED

Contact AstraZeneca switchboard on 1-800-236-9933 and ask to be put in contact with the person on call for the Seroquel clinical team.

10.2 Procedures in case of medical emergency

The principal investigator(s) is responsible for ensuring that procedures and expertise are available to cope with medical emergencies during the study.

10.3 Procedures in case of overdose

For the purpose of this trial all overdoses should be reported as adverse events. However, all cases of overdose must be reported immediately, within 1 day, if sequelae meeting the criteria for serious adverse event have occurred in association with the overdose. In all instances, the overdose substance should be stated and whether the overdose was accidental or intentional. If the overdose was a suicide attempt, this fact should be clearly stated. Adverse events (serious and non-serious) arising as the result of an overdose should be recorded on an adverse event form as “sequelae to overdose.” For example ”nausea as sequelae to overdose.”

10.4 Suicide

Suicide and suicide attempt, irrespective of the method, but in connection with the use of trial drug, should be reported as a serious adverse event (in accordance with the definition provided in Section 5.4.2.1). This event should be identified as suicide or suicide attempt, and the method of the suicide or the suicide attempt should be provided. Suicidal thoughts should also be regarded as adverse events.

10.5 Procedures in case of pregnancy

Pregnancy itself is not regarded as an adverse event unless there is a suspicion that the investigational product under study may have interfered with the effectiveness of a contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) must be followed up and documented even if the subject was discontinued from the study.

All reports of congenital abnormalities/birth defects are SAEs. Spontaneous miscarriages should also be reported and handled as SAEs. Elective abortions without complications should not be handled as AEs. All outcomes of pregnancy must be reported to AstraZeneca on the pregnancy outcomes report form.

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AstraZeneca

Clinical Study Protocol: Appendix A	
Study Code	5077US/0049
Version No.	2
Appendix Date	September 30, 2002

Appendix A
Signatures

IND No. 32,123

SIGNATURE OF PRINCIPAL INVESTIGATOR

Title of report

A Multicenter, Double-blind, Randomized, Placebo-controlled, double-dummy Trial of the User of Quetiapine fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

I agree to the terms of this study protocol. I will conduct the study according to the procedures specified herein, and according to the principles of Good Clinical Practice (GCP) and local regulations.

Centre No.: 0001

Signature: Joseph Calabrese 10/14/03

Joseph Calabrese, MD
University Hospitals of Cleveland
Mood Disorders Program
11400 Euclid Avenue, Suite 200
Cleveland, OH 44106

Date

AstraZeneca

Clinical Study Protocol: Appendix B	
Study Code	5077US/0049
Version No.	1
Appendix Date	August 6, 2002

Appendix B
Sample written informed consent form

A sample informed consent is provided under separate cover.

Appendix C

Declaration of Helsinki

Recommendations guiding physicians in biomedical research involving human subjects.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975 and the 35th World Medical Assembly, Venice, Italy, October 1983 and the 41st World Medical Assembly Hong Kong, September 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of The World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient´s interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject´s physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject´s freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor´s consent must be obtained in addition to the consent of the minor´s legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with professional care (Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo studies where no proven diagnostic or therapeutic method exists.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical re-search involving human subjects

(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to thepatient´s illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

Appendix D

Investigators and study administrative structure

STAFF AT INVESTIGATIONAL SITE(S)

Centre No.	**Centre address**	**Name** (First name, Last name)	**Qualifications**	**Position**	**Role in the study**
<<>>					Principal investigator

A list of participating investigators will be provided upon request.

ASTRAZENECA STUDY PERSONNEL

Name (First name, Last name)	**Position**	**Role in the study**
Robin McCoy	Senior Clinical Research Scientist	Clinical Management Lead
Margaret Minkwitz	Director Biostatistics Project Team	Biostatistician
Wayne Macfadden	Medical Director Clinical Research	Medical advisor
Jeris Minor	Data Analyst	Data Analyst
Elaine Yu	Assistant Director Health Economics	Health Economics
Ellen Quimby	IPS Demand Manager	IPS Representative
Jennifer Mahoney	Safety Representative	Safety
Patti Neal	Regulatory Representative	Regulatory
Richard White	Director Health Economics	Health Economics

OTHER PARTICIPANTS

Organisation and address	**Name** (First name, Last name)	**Qualifications/Position**	**Role in study**
Lineberry Research Associates 79 Alexander Drive Bldg 4401, Suite 400Research Triangle Park, NC 27709 See CRO Personnel List	Kelly Abernathy	RN	Project Manager

AstraZeneca

Clinical Study Protocol: Appendix E	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix E

Insurance and indemnity

For the US, this Appendix E is not applicable. Please refer to the clinical study agreement for information regardingAstraZeneca's obligation to insure and indemnify institution and investigator.

INSURANCE AND INDEMNITY

AstraZeneca's liability is covered by a liability insurance policy with AstraZeneca Insurance Company Limited, policy No.: L/702938.

With respect to any liability directly or indirectly caused by the investigational products in connection with this Clinical Study, AstraZeneca assumes liability by law on behalf of the investigator(s) and his assistants for possible injury to the subject provided the investigator(s) and his assistants have followed the instructions of AstraZeneca in accordance with this protocol and any amendments thereto, that the investigational products administered to the subject in this Clinical Study have been supplied by AstraZeneca and that the investigator and his assistants have in general performed this clinical study in accordance with scientific practice and currently acceptable techniques and know-how.

AstraZeneca can forward a letter of indemnity if needed by the investigator(s)/institution.

Appendix F
Additional safety information

1. FURTHER GUIDANCE ON THE DEFINITION OF A SERIOUS ADVERSE EVENT (SAE)

Life threatening

'Life-threatening' means that the subject was at immediate risk of death from the adverse event as it occurred or it is suspected that use or continued use of the product would result in the subject's death. 'Life-threatening' does not mean that had an adverse event occurred in a more severe form it might have caused death (ie hepatitis that resolved without hepatic failure).

Hospitalisation

Out-subject treatment in an emergency room is not in itself a serious adverse event, although the reasons for it may be (eg, bronchospasm, laryngeal oedema). Hospital admissions and/or surgical operations planned before or during a study are not considered adverse events if the illness or disease existed before the subject was enrolled in the study, provided that it did not deteriorate in an unexpected way during the study.

Important medical event or medical intervention

Medical and scientific judgement should be exercised in deciding whether a case is serious in a situation where important medical events may not be immediately life-threatening or result in death, hospitalisation, disability or incapacity but may jeopardise the subject or may require medical intervention to prevent one or more outcomes listed in the definition of serious. These should usually be considered as serious. Examples of such events are:

- Angioedema not severe enough to require intubation but requiring iv. hydrocortisone treatment
- Hepatotoxicity caused by paracetamol (acetaminophen) overdose requiring treatment with N-acetylcysteine
- Intensive treatment in an emergency room or at home for allergic bronchospasm
- Blood dyscrasias (eg, neutropenia or anaemia requiring blood transfusion, etc.) or convulsions that do not result in hospitalisation
- Development of drug dependency or drug abuse

2. FURTHER GUIDANCE ON THE ASSESSMENT OF CAUSALITY

The following factors should be considered when deciding if there is a "reasonable possibility" that an adverse event (AE) may have been caused by the investigational product.

- **Time course of events and exposure to suspect drug**. Has the subject actually received the suspect drug? Did the AE occur in a reasonable temporal relationship to the administration of suspect drug?

- **Consistency with known drug profile**. Was the AE consistent with the previous knowledge of the suspect drug (pharmacology and toxicology) or drugs of the same pharmacological class? OR could the AE be anticipated from its pharmacological properties?

- **Dechallenge experience**. Did the AE resolve or improve on stopping or reducing the dose of the suspect drug?

- **No alternative cause**. The AE cannot be reasonably explained by another aetiology such as the underlying disease, other drugs, other host or environmental factors.

- **Rechallenge experience**. Did the AE reoccur if the suspected drug was reintroduced after having been stopped? AstraZeneca would not normally recommend or support a rechallenge.

- **Laboratory tests**. Has a specific laboratory investigation confirmed the relationship?

A "reasonable possibility" could be considered to exist for an AE where one or more of these factors exist.

In contrast, there would not be a "reasonable possibility" of causality if none of the above criteria apply or where there is evidence of exposure and a reasonable time course but any dechallenge (if performed) is negative or ambiguous or there is another more likely cause of the AE.

In difficult cases, other factors could be considered such as:

- Is this a recognised feature of overdose of the drug?

- Is there a known mechanism

Ambiguous cases should be considered as being a “reasonable possibility” of a causal relationship unless further evidence becomes available to refute this.

Appendix G
Additional information necessary for studies conducted in Japan

Not Applicable

1. LABELLING AND PACKAGING OF THE INVESTIGATIONAL PRODUCT

<< Insert copy of the label.>>

2. PROCEDURES FOR RANDOMISATION (REGISTRATION)

<<>>

3. ORGANISATIONAL STRUCTURE OF THE STUDY

3.1 Study sponsor

AstraZeneca K.K.
<< Name >>Executive President
Umeda Sky Building, Tower East,
1-88, 1-chome, Ohyodo-naka, Kita-ku, Osaka 531-0076, Japan

3.2 Medical expert from the sponsor

AstraZeneca K.K., Clinical Strategy Department:
<< Name >>(Physician responsible for the protocol)

3.3 Responsible person for the product, monitor, and auditor

Clinical Project Manager (CPM)

Clinical Strategy Department, Osaka office	<< Telephone number>>
Clinical Project Manager	<< Name >>

Monitors

Clinical Operations Department, Osaka office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Clinical Operations Department, Tokyo office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Auditor

Regulatory Affairs Department	<< Telephone number>>
Clinical Audit Department Manager	<< Name >>

See AstraZeneca medical emergency contact numbers (Section 9).

3.4 Co-ordinating investigator(s) (Co-ordinating committee)

<< Name >>
<< Job title>>
<< Associated hospital name>>

3.5 Person in charge of PMS management (if applicable)

AstraZeneca K.K.,
<< Name >>
Drug Safety &PMS Department Manager

3.6 Independent Data Monitoring Committee (IDMC) (if applicable)

<< Name >>
<< Job title>>
<<Associated hospital name>>

3.7 Subject inclusion registration centre

<<>>

3.8 Laboratory

<<>>

3.9 Contract Research Organisation (CRO)

<<>>

3.10 Safety Committee (In house)

May have responsibility for reviewing the following major issues around JNDA and clinical trials proposed by R&D departments such as CSD, COD or RA

A) Major changes for protocol and IB due to safety reasons

B) Across the board key code break due to safety reasons

C) Actions required due to significant safety issues ensuring for products under/for NDA

D) Discontinuation of clinical trials or test drug recall due to safety reasons

E) Other issues to ensure safety in clinical trials

4. LIST OF INVESTIGATORS AND MEDICAL INSTITUTIONS

Centre No.	Study Institutions	Department	Address	Telephone	Investigators	Job Title
<<>>						

5. ADDITIONAL REPORTING RELATED WITH SECTION 4.4.2 ADVERSE EVENTS (FOR JAPANESE PHASE III OR IV STUDY)

<<>>

AstraZeneca

Clinical Study Protocol Amendment

Amendment No.	1
Study Code	5077US/0049
Date	September 30, 2002

Sponsor:

AstraZeneca LP 1800 Concord Pike, Wilmington, DE 19850 USA >>

Centres affected by the amendment:

All centers

The protocol for the study is to be amended as follows:

1. Page 22, Study Plan

Removed BARS, SAS, Q les Q, and PSQI from Screen, and Days 8, 15, 22, 36, and 43

2. Page 22, study Plan Postscript b

Laboratory tests and ECG will only be repeated if “abnormal” and “clinically significant”

3. Page 24, Section 3.4.2 Inclusion Criteria # 3

Was:

Sexually active females of childbearing potential, be using a reliable method of contraception. Reliable methods include hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

Now reads:

Females of childbearing potential, be using a reliable method of contraception. Reliable methods include hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

4. Page 24, Section 3.4.2 Inclusion Criteria

Added YMRS ≤12 to inclusion criteria

5. Page 25, Section 3.4.3 Exclusion Criteria # 3

Was:

Patients who have been treated with antidepressant therapy for their current episode for more than three weeks prior to Visit 1

Now reads:

History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode

6. Page 25, Section 3.4.3 Exclusion Criteria

Removed Exclusion Criteria # 5

Patients who meet DSM IV criteria for substance abuse within 3 months

7. Page 25, Section 3.4.3 Exclusion Criteria # 6

Was:

Patients who are unable to discontinue all psychoactive medications (excluding prn benzodiazapines), including antidepressants, antipsychotics, and mood stabilizer, **5 elimination half lives** prior to randomization.

Now reads:

Patients who are unable to discontinue all psychoactive medications (excluding prn benzodiazapines), including antidepressants, antipsychotics, and mood stabilizer, at least **7 days** prior to randomization and consistent with the pharmacokinetics of the drug

8. Page 49, Section 5.4.3.1, Bullet 2

Creatinine added to blood draw on Screen and Day 57

9. Page 50, Section5.4.4.1

We will not be collecting respirations

Reasons for making the amendment:

1. Shorten the length of time the subject was at the clinic to improve subject retention
2. Washout may be anywhere from 7 to 28 days depending on the drugs that the subject has been taking prior to randomization
3. The term “sexually active” implies that abstinence is an acceptable form of birth control in this study and it is not.
4. Eliminating patients in mixed episodes
5. Eliminating non-responders
6. It was not necessary
7. Clarified that washout must be at least 7 days instead of 5 half lives which could be less than 7 days.
8. Because Exclusion Criteria # 13 states that patients with Creatinine of ≥1.5 mg/dl are excluded
9. We do not need respirations collected

Signed agreement to the amendment:

<< The general rule is that those who signed the protocol should sign the amendment, except for local amendments. >>

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

.....	.....
Date	AstraZeneca signatory
(day month, year)	Wayne Macfadden MD

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

Centre No.: <<>>

. . . . .	. . . . .
Date (day month, year)	Principal investigator << Name and Address >>

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

.....	.....
Date (day month, year)	AstraZeneca Signatory Gil Block Treatment Area Medical Lead

CLINICAL TRIAL PROTOCOL AMENDMENT

Protocol Title: A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Seroquel in the Treatment of Patients with Bipolar Depression

I. Amendment details

Trial number: 5077US/0049	Amendment number: 1	Amendment date: September 24, 2002
Drug: Seroquel	IND number:	NDA number: 32,132

Reason for Amendment:

1. Added YMRS to Inclusion Criteria
2. Clarified Exclusion # 3
3. Removed exclusion #5 as unnecessary..
4. Added Creatinine to blood draw.
5. Removed request for repeat labs and ECG if Day 1 is more than 1 week from screen, because washout may be for 7 to 28 days depending on the drugs that the patient has been taking.
6. Removed BARS, SAS, Q les Q, and PSQI from Screen, and Days 8, 15, 22, 36, 43, and 57
7. Removed "sexually active" from inclusion criteria #3
8. Exclusion Criteria # 6 changed from "5 elimination half lives" to "7 days"
9. We will not be collecting respirations

Is amendment likely to affect subject consent? YES	Y X	N
IRB approval required before implementation ? YES (written approval or notification that they do not wish to review it - only safety amendments may be implemented immediately)	Y X	N
IRB notification required ? YES	Y - mandatory for all	

Description of amendment: See attachment	Listed below:	See attachment: X

For amendments requiring formal IRB approval the effective date will be the date of IRB approval

II. Signatures

Printed Name :	Signature:	Date:

Wayne Macfadden MD Study Team Physician	W MacFadden	9/25/02
Printed Name : Margaret Minkwitz Study Team Statistician	Signature: Margaret Minkwitz	Date: 9/25/02
Printed Name : Rick Sax PRC Chair	Signature: Without CL Book for RS	Date: 9/30/2002
This revision is consistent with the Clinical Supplies Action Plan (CSAP)		
PPP version number: 1	LP version number:	AP version number:
Printed Name : Robin McCoy Study Team Chair	Signature: Robin McCoy	Date: 9/25/02

AstraZeneca

Clinical Study Protocol	
Drug Substance	quetiapine fumarate
Study Code	5077US/0049
Version No.	3
Date	December 4, 2002

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

The following amendment(s) have been made to this protocol since the date of preparation:

Amendment No. 1		**Date of amendment**	**September 30,2002**
Amendment No 2			**December 4, 2002**
Administrative Change No.	**1**	**Date of administrative change**	**September 30, 2002**

PROTOCOL SYNOPSIS

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

Investigator

Multicenter trial: << To be determined >>

Study center(s) and number of subjects planned

A total of approximately 740 subjects will be screened to enroll approximately 530 into the trial in order to obtain approximately 504 evaluable patients, defined as those who have a baseline visit and at least one post baseline assessment. It is expected that approximately 75 centers will participate in the trial, with each center enrolling 8 patients (minimum 4, maximum 50).

Study period		**Phase of development**
Estimated date of first subject enrolled	September, 2002	IIIb
Estimated date of last subject completed	March, 2004	

Objectives

Primary:

To evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S)

(5) the Clinical Global Impression - Change (CGI-C).

Secondary:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by comparing

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by comparing

- the incidence and nature of all adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment
- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score from baseline to end of treatment
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Exploratory

(1) to evaluate the efficacy of quetiapine on sleep quality by comparing the change in the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

(2) to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment.

Hypotheses:

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

Secondary hypotheses are defined in Section 3.1.

Study design

Study 5077US/0049 is a randomized, multicenter, double-blind, placebo-controlled, double-dummy, parallel group, fixed-dose comparison of quetiapine vs placebo in the treatment of bipolar depression. This study will be stratified 1:1 for bipolar I and bipolar II.

Target subject population

Outpatients, aged 18 to 65 years, with a diagnosis of bipolar I or bipolar II disorder with a current major depressive episode of duration less than one year but greater than 4 weeks will be enrolled in the trial. The HAM-D (17-item scale) score must be ≥20, the HAM-D item 1 (depressed mood) score must be $\geq$ 2, and the YMRS score must be ≤12 at both Visit 1and Visit 2 (randomization) to be eligible for entry into the trial.

Investigational product, dosage and mode of administration

Study drug will be titrated in a blinded manner to a total daily dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and to a total daily dose of 600 mg/day by Day 8 in the 600-mg/day treatment group. Thereafter, oral doses of quetiapine fumarate will be administered in a blinded fashion once daily at bedtime (qhs) in a total daily dose of 300 or 600 mg/day. One-time dose reductions for intolerability of 100 mg/day in both the 300 mg/day and in the 600 mg/day treatment groups will be allowed at the discretion of the Investigator after Day 8.

Comparator, dosage and mode of administration

Placebo will be administered once daily with tablets matching in number and appearance to blinded quetiapine dosing.

Duration of treatment

Patients will receive double-blind, double-dummy treatment for up to 8 weeks (56 days), following an initial washout period of between 7 to 28 days (depending on the medications involved) and will come in to the clinic on Day 57 for final assessments.

Endpoints

- **Efficacy**

  Primary efficacy endpoint is the change from baseline to final assessment in the MADRS total score.

  Secondary efficacy endpoints are the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at study endpoint, the change from baseline to each assessment (observed cases) in the MADRS total score, and the change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, and CGI-S and the CGI-C.; the change from baseline to each assessment (observed cases) and final assessment in the YMRS, and the HAM-A total scores.

- **Safety**

  Safety endpoints are the incidence and nature of all adverse events, the incidence of drug-related adverse events, the incidence of subject withdrawal due to adverse events, and the incidence of clinically significant changes in vital signs, weight, and body mass index during double-blind treatment. Tolerability endpoints are the change in the SAS total score from baseline to final assessment, the change in BARS total score from baseline to final

assessment, and the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

- **Quality of life**

  Exploratory quality of life endpoints are the change from baseline in the PSQI score and Q-Les-Q total score.

Statistical methods

All statistical comparisons will be 2-sided tests for the difference between active study medication and placebo. The primary analysis will be analysis of covariance (ANCOVA) for the change from baseline to final assessment for total MADRS score. The ANCOVA model will include terms for treatment, and stratum, with the baseline MADRS score as a covariate. Pair-wise comparisons of each dose with placebo will be assessed within this model as planned comparisons. In order to adjust for multiple comparisons with placebo a step-up procedure will be employed with a rule for tests of significance based on ordered p-values, maintaining an overall experiment wise type I error rate of 0.05. The proportion of patients having a $\geq$ 50% reduction from baseline to final assessment in MADRS will be compared across treatments using a logistic model. Change from baseline in MADRS scores at each assessment (observed cases), and change from baseline in HAM-D, HAM-D item 1, CGI-S, YMRS, HAM-A, Q-Les-Q and PSQI score at each assessment (observed cases) and LOCF, will be analyzed using the same ANCOVA model as for the primary endpoint. The CGI-C will be analyzed using the ANCOVA model with the baseline CGI-S as a covariate.

The change from baseline in SAS and BARS score data will be assessed using the same ANCOVA model as the primary endpoint. The incidence of EPS AEs and overall AEs will be reported using descriptive statistics. Vital signs, weight, and body mass index will be tabulated using descriptive statistics at baseline, final assessment, and for change from baseline. Descriptive statistics will also be used to describe the proportion of patients whose final Q-Les-Q is within community norm levels.

Repeated measures analysis of variance (ANOVA)will be performed to evaluate whether there are significant differences among treatments across time for MADRS, HAM-D, and HAM-A total scores.

Efficacy analyses will be conducted on a modified intention-to-treat (MITT) population. A per-protocol (PP) analysis will be conducted for the primary analysis measure (change from baseline MADRS) to evaluate sensitivity of the response. The safety population will include all subjects who took study medication.

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APPENDICES

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

The following abbreviations and specialist terms are used in this study protocol.

Table 1 Abbreviations and specialist terms

Abbreviation or specialist term	Explanation
AE	Adverse event (see definition in Section 4.4.2.1)
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BP	Bipolar Disorder
BPD	Bipolar Depression
CGI	Clinical Global Impression
CGI-C	Clinical Global Impression - Change
CGI-S	Clinical Global Impression - Severity
CMH	Cochran-Mantel Haenszel
CRF	Case Report Form
CRS	Concordant Rater systems
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition
EPS	Extrapyramidal symptoms
ECG	Electrocardiogram
GCP	Good Clinical Practice
HAM-A	Hamilton Rating Scale for Depression
HAM-D	Hamilton Rating Scale for Anxiety
ICH	International Conference on Harmonisation
ICI-D	Interactive Computor Interview-Depression
ICTI	Interactive Clinical Technologies, Incorporated
IEC	Independent Ethics Committee
IRB	Institutional Review Board

Abbreviation or specialist term	Explanation
IVRS	Interactive Voice Response System
LOCF	Last Observation Carried Forward
MADRS	Montgomery-Asberg Depression Rating Scale
MITT	Modified Intent to Treat
OAE	Other significant adverse event (ie, an adverse event of special interest in this clinical development; see definition in Section 4.4.2.1). The classification of OAEs will be performed by AstraZeneca drug safety physicians after the study is complete.
PSQI	Pittsburgh Sleep Quality Index
Principal investigator	The investigator who leads the study conduct at an individual study center. Every study center has a principal investigator.
Qhs	at bedtime
Q-Les-Q	Quality of Life Enjoyment Satisfaction Questionnaire
SAE	Serious adverse event (see definition in Section 4.4.2.1).
SAS	Simpson Angus Scale
SSRI	Selective serotonin reuptake inhibitors
UNI	Universal Systems Incorporated
YMRS	Young Mania Rating Scale

1 INTRODUCTION

1.1 Background

Quetiapine fumarate (SEROQUEL®, quetiapine) is a dibenzothiazepine derivative approved by the United States Food and Drug Administration (FDA) on 26 September 1997 following clinical development by AstraZeneca Pharmaceuticals LP (also referred to as the sponsor) for the treatment of subjects with schizophrenia. Quetiapine fumarate is designated chemically as bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl) piperazin-1-yl]ethoxy)ethanol] fumarate

Quetiapine has been studied in a toxicological and clinical program directed at supporting clinical evaluation in man. The results of these studies are presented in the Investigator's Brochure dated January 2002. The Professional Information Brochure (PIB) contains the current prescribing information for quetiapine.

1.2 Rationale for this study

The bipolar disorders are psychiatric disorders in which a disturbance in mood is the predominant feature. Bipolar I disorder is characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes. Bipolar II disorder is characterized by one or more major depressive episodes accompanied by at least one hypomanic episode. Bipolar depression refers to the major depressive episodes that occur with bipolar I and II disorder.

The prevalence of bipolar disorder is estimated to be 1 to 3.5%, evenly divided between men and women. The length of time between onset and symptoms and proper diagnosis and treatment is approximately 10 years and it is estimated that only 60% of those suffering from a bipolar disorder are receiving appropriate pharmacotherapy.

Although there is extensive and emerging literature guiding the treatment of the manic phase of bipolar I disorder as well as many approved compounds for the treatment of unipolar depression, the treatment of bipolar depression has not been widely studied and treatment guidelines are in their infancy. The use of currently available antidepressants for monotherapy for bipolar depression is often problematic as they may increase the "switch" into hypomania or mania from depression, or increase cycle acceleration. The adjunctive use of mood stabilizing medications such as lithium carbonate (LiCO3) is common and may decrease the likelihood of these complications.

Evidence indicates that medications with mood stabilizing properties which produced low levels of mania, hypomania, or cycle acceleration may be useful as monotherapy in the treatment of bipolar depression. The antiepileptic lamotrigine produced improvement in

HAM-D and MADRS scores in a 7-week, double-blind, placebo controlled trial for the patients who completed this study (Calabrese 1999). More recently, the anti-manic agent divalproex demonstrated numerical improvement over placebo in the percentage of patients with bipolar depression having a 50% reduction in the HAM-D scores without mania in an 8 week trial (Sachs, 2001) but this difference was not statistically significant. Lithium carbonate, also approved for the treatment of mania, has been demonstrated to be effective as a monotherapeutic agent in approximately 50% of patients with bipolar depression (Bauer). However, there are efficacy and tolerability limitations which mkay prohibit widespread use of the above therapies.

A large multicentered, double-blind, placebo controlled trial was recently completed, which demonstrated efficacy of the atypical antipsychotic olanzapine as monotherapy for the treatment of bipolar depression (Tohen, 2002). The endpoint mean MADRS change was significantly greater for patients on olanzapine (-15.0 points) than for those on placebo (-11.9 points). Treatment-emergent mania did not differ significantly between groups. There also is evidence from small uncontrolled studies that other atypical antipsychotics such as risperidone, and clozapine have mild to moderate antidepressant activity when used in patients with mood disorders. These small studies also indicate that these compounds are unlikely to cause patients to “switch” into mania.

The potential efficacy of quetiapine in depressive symptoms is provided in data from the Quetiapine Experience with Safety and Tolerability Trial (QUEST) and from investigator-initiated trials in mood disorder patients. In an open-label trial evaluating the safety and tolerability of quetiapine over 700 subjects with schizophrenia and other psychotic disorders were randomized to treatment with quetiapine or risperidone. Quetiapine-treated patients experienced a greater improvement in depressive symptoms compared with risperidone-treated patients, with a mean difference of 1.3 points on the HAM-D after adjustment for baseline differences (P=0.028) (Mullen et al, 2001).

A trial of quetiapine in 20 neuroleptic-dependent patients with bipolar or schizoaffective disorder also suggested positive effects on the depressive and psychotic symptoms in these disorders (Sajatovic et al, 2001). Overall, in 10 patients with bipolar disorder and 10 with schizoaffective disorder who received open-label quetiapine to optimum clinical dosage (25 to 800-mg), significant improvement in Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), and HAM-D scores was noted.

In summary, the paucity of satisfactory treatments available signify an unmet medical need for the treatment of bipolar depression. There are signals of efficacy from clinical trials for the antidepressant properties of atypical antipsychotics such as quetiapine.

2 STUDY OBJECTIVES

2.1 Primary objective

The primary objectives of the study are to evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the total Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S), and the Clinical Global Impression - Change (CGI-C).

2.2 Secondary objective

The secondary objectives of the study are:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by

- the incidence and nature of overall adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment

- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Experimental:

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in sleep quality using the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment
2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment

3 HYPOTHESES, STUDY PLAN AND PROCEDURES

3.1 Hypotheses

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

(1) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(2) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(3) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(4) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(5) Quetiapine at a dose of 300 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(6) Quetiapine at a dose of 600 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(7) Quetiapine at a dose of 300-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(8) Quetiapine at a dose of 600-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(9) Quetiapine at a dose of 300 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(10) Quetiapine at a dose of 600 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(11) Quetiapine at a dose of 300 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(12) Quetiapine at a dose of 600 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(13) Quetiapine at a dose of 300 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

(14) Quetiapine at a dose of 600 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

3.2 Overall study design and flow chart

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial will consist of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects will be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment

of 8 patients per center (minimum 4 maximum 30). Subjects are required to have a HAM-D (17-item scale) score of $\geq$ 20 and a YMRS of $\leq$12 at screening baseline (Visit 1).

The trial comprises the following 2 periods:

- Washout period
  Subjects will undergo HAM-D, SCID, YMRS, and safety evaluations at screen (Visit 1) and if they qualify to participate they will commence a washout of antidepressant, antipsychotic, and mood stabilizer medications. The number of days for washout will depend on the medication they are taking. These medications must be discontinued for a period of at least 7 days prior to randomization (Day 1, Visit 2), with the exception of fluoxetine which must be discontinued for a period of 14 days prior to randomization (Day 1, Visit 2) and depot injections of haloperidol decanoate or fluphenazine decanoate which need 28 days washout before randomization.

- 8-week double-blind randomized treatment period (Weeks 1 to 8)
  Eligible subjects will be randomized on Day 1 (Visit 2) to 1 of 3 treatment groups: quetiapine 300 mg/day, quetiapine 600 mg/day, or placebo. The randomization will be done using a stratification based on diagnosis. Treatment will be administered once daily at bedtime for 8 weeks (Days 1 - 56). Subjects will not receive medication on Day 57 which is only for final assessments. Doses will be titrated to achieve target doses of 300 mg/day within 4 days or 600 mg/day within 8 days. A dose reduction of 100 mg is allowed to improve patient tolerance in each treatment group. MADRS assessments (used to evaluate the primary efficacy variable) will be performed at Days 1, 8, 15, 22, 29, 36, 43, 50, and 57.

Figure 1 Study flow chart

			Treatment										
Day	**Screen**	**Washout [b]**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9-14**	**15-56**	**57**
	Visit 1		**Visit 2**							**Visit 3**		**Visits 4-9**	**Visit 10**
Dose: 300-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	
Dose: 600-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	400-mg	400-mg	400-mg	600-mg	600-mg	600-mg	

[a] One time dose reductions of 100 mg/day in 300-mg and 600-mg may occur after Day 8

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers for 5 elimination half-lives, prior to randomization. Patients on fluoxitine must discontinue for 14 days and those on haloperidol decanoate or fluphenazine decanoate for 28 days.

Table 2 Study plan

Study plan	Screen	Washout [a]	Double-blind treatment phase Weeks 1 through 8								
Days			**1**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**
Visits	**1**		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Informed consent	√										
Medical history	√										
Inclusion/Exclusion criteria	√		√								
Structured Clinical Interview for DSM-IV (SCID)	√										
Physical examination [d]	√										√
Urine toxicology screen	√										
Pregnancy tests (females)	√										
Vital signs, height, weight [c,e]	√		√	√	√	√	√	√	√	√	√
12-lead electrocardiogram	√		√[b]								√
Clinical chemistry and hematology	√		√[b]								√
Hamilton Rating Scale for Depression (17-item)	√		√	√	√	√	√	√	√	√	√
Montgomery-Asberg Depression Rating Scale			√	√	√	√	√	√	√	√	√
Interactive Computer Interview-Depression			√	√	√	√	√	√	√	√	√
Young Mania Rating Scale	√		√	√	√	√	√	√	√	√	√
Hamilton Rating Scale for Anxiety			√	√	√	√	√	√	√	√	√
Clinical Global Impression - Severity	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression -Change				√	√	√	√	√	√	√	√
Barnes-Akathisia Rating Scale			√								√
Simpson-Angus Scale			√								√
Pittsburgh Sleep Quality Index			√				√				√
Quality of Life Enjoyment Satisfaction Questionnaire			√				√				√
Dispense study medication			√	√	√	√	√	√	√	√	
Adverse events	√	√	√	√	√	√	√	√	√	√	√

[a] Washout of antidepressants, antipsychotics, mood stabilizer for at least 7 days; 14-day washout for fluoxetine and 28 days for haloperidol or fluphenazine decanoate

[b] Repeat laboratory tests and ECG only if results outside of normal range and clinically significant at Screening

c Height and weight on screen and weight on Day 57
d Physical exam includes ophthalmoscopic exam on screen
e Blood pressure will be obtained in supine and standing positions

3.3 Rationale for study design, doses and control groups

This trial is designed as a double-blind placebo-controlled evaluation of Seroquel as monotherapy in bipolar depression. There is no currently approved compound for use in bipolar depression, nor is there a clinically accepted "gold standard". Conventional antidepressants have fallen out of favor because of their ability to induce manic symptoms. Antidepressants approved forthe treatment of unipolar depression have not been demonstrated to improve mood symptoms relative to placebo (Nemeroff et al Am J Psychiatry 158:6 June 2001). Moreover, there is a high placebo response rates of approximately 30% found in bipolar depression trials. Thus, the use of a placebo treatment arm for comparison is clinically justified.

Trial treatment will be administered as quetiapine monotherapy in order to more clearly identify a treatment effect of quetiapine on bipolar depression. Quetiapine fumarate will be administered once daily at bedtime. The current label specifies twice daily (BID) but a double-blind crossover study in bipolar patients indicated that once daily (qd) is well tolerated and as effective as BID dosing (Chengappa, 2002).

A period of 7 to 28 days is adequate for washout of most psychoactive medications including antidepressants, antipsychotics (including depot agents), and mood stabilizers to ensure that subjects are stable and continue to have adequate depressive symptoms requiring treatment, prior to randomization into the trial. The double-blind treatment period of 8 weeks is consistent with the time period that is required to see a clinically meaningful response in depressive symptoms.

The trial is designed as a fixed-dose evaluation due to the failure of flexible dose regimens in other psychiatric disorders. The dosages are based on clinical trial data with quetiapine in patients with a mood disorder. In the QUEST trial, the average dose of quetiapine in patients with a primary mood disorder (N=316) was approximately 250 mg/day at 16 weeks. In 20 patients with bipolar or schizoaffective disorder treated with open-label quetiapine, the mean dose was approximately200 mg/day (Sajatovic). Based on this data, 300 mg/day administered as monotherapy is an appropriate low-dose treatment arm, and 600 mg/day is an appropriate high-dose treatment arm that should exhibit efficacy without a high rate of AEs or noncompliance.

The MADRS is a standardized, well-validated measure of depressive symptoms that is sensitive to treatment effects in depressed outpatients.

3.4 Selection of study population

3.4.1 Study selection record

Investigators must keep a record of subjects who underwent screening but were not randomized into the trial.

3.4.2 Inclusion criteria

At screen (Visit 1) subjects must fulfill all of the following criteria:

(1) Documented ability to provide informed consent before beginning any study-specific procedures.

(2) Male and female patients between 18 and 65 years of age, inclusive

(3) Females of childbearing potential, be using a reliable method of contraception. Reliable methods include hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

(4) Women must have a negative pregnancy test

(5) Meets DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x), confirmed by the amended version(by Dr. Michael First) of the Structured Clinical Interview for DSM-IV (SCID) as administered by an AstraZeneca approved clinician with a signed confirmation by the Principal Investigator

(6) Outpatient status

(7) HAM-D (17-item) total score of 20 or greater

(8) HAM-D item 1 (depressed mood) score $\geq$2

(9) YMRS total $\leq$12

At randomization (Visit 2) subjects must fulfill the following criteria:

(1) HAM-D (17-item) total score of 20 or greater

(2) HAM-D item 1 (depressed mood) score $\geq$2

(3) YMRS total $\leq$12

3.4.3 Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

(1) Patients with a current Axis I disorder other than bipolar disorder within 6 months of screening

(2) Patients whose current episode of depression exceeds 12 months or is less than 4 weeks

(3) History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode

(4) Patients who meet DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening

(5) Patients with a positive urine toxicology screen for illicit substances of abuse

(6) Patients who are unable to discontinue all psychoactive medications (excluding prn benzodiazapines), including antidepressants, antipsychotics, and mood stabilizer, at least 7 days prior to randomization and consistent with the pharmacokinetics of the drug

- Patients treated with fluoxetine who have not discontinued this medication for at least 14 days prior to randomization.
- Patients treated with haloperiodol decanoate or fluphenazine decanoate who have not discontinued these medications 28 days prior to randomization.

(7) Patient who have not discontinued the use of potent P450 inhibitors and inducers (See Section 4.3, Table 13)

(8) Patients who in the investigators opinion will require initiation of psychotherapy during the study period. Note: ongoing psychotherapy for a minimum of 3 months may continue.

(9) Patients who, in the investigator's judgment, pose a current serious suicidal or homicidal risk at Visit 1 (HAM-D item 3 score of 3 or greater), or have made a suicide attempt within the past 6 months

(10) Patients with a history of clinically significant cardiac, renal, neurologic, cerebrovascular, metabolic, or pulmonary disease, or other disease or clinical finding that is unstable or that, in the opinion of the investigator, would be negatively affected by trial medication or that would affect trial medication

(11) Patients who have had a myocardial infarction within 1 year before Visit 1

(12) Patients with clinically significant abnormal laboratory findings at Visit 1

(13) Patients with renal impairment (serum creatinine ≥1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal)

(14) Patients whose TSH is ≥10% over the upper normal limit. Patients maintained on thyroid medication must be euthyroid for a period of at least 3 months before Visit 1

(15) Patients with clinically significant abnormalities on ECG

(16) Women who have a positive human chorionic gonadotropin (HCG) pregnancy test at Visit 1 or who are lactating or planning to become pregnant during the course of the study

(17) Patients who have participated in a clinical trial of an investigational drug within the past 3 months

(18) Patients who, in the opinion of the investigator, would be non-compliant with the visit schedule or study procedures

(19) History of orthostatic hypotension or conditions that would predispose them to hypotension (eg dehydration, hypovolemia)

(20) Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of Seroquel tablets, as judged by the investigator

3.4.4 Restrictions

Subjects will be required to adhere to the following special restrictions:

1) Use of any psychoactive drugs including antidepressants, hypnotics (with the exceptions noted in Section 4.3), mood stabilizing drugs, and antipsychotics is not permitted from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

2) Use of cytochrome P450 3A4 inducers and potent inhibitors are not permitted from 14 days prior to randomization to end of study (see Table 13)

3.4.4.1 Criteria for discontinuation

Subjects may be discontinued from study treatment and assessments at any time, at the discretion of the investigator(s). Specific reasons for discontinuing a subject from this study are:

1. Withdrawal of informed consent

2. Worsening psychiatric symptoms such that the symptoms constitute a danger to themselves or to others

3. Use of psychotropic medications at any time during the double-blind treatment period.

4. Pregnancy at any time during the double-blind treatment period.

5. Clinically significant or serious adverse event that would not be consistent with continuation in the study, as determined by the investigator, AstraZeneca, or the subject.

3.4.4.2 Voluntary discontinuation by a subject

Subjects are free to discontinue their participation in the study at any time, without prejudice to further treatment. Subjects who discontinue from the study should always be asked about the reason(s) for their discontinuation and about the presence of any adverse events. They should be seen and assessed by an investigator(s) (see Section 3.4.4.4). Adverse events should be followed up and any diary cards, questionnaires (eg, for Quality of Life assessments) and investigational products should be returned by the subject.

3.4.4.3 Incorrectly enrolled or randomized subjects

Incorrectly enrolled subjects will be discontinued from further study treatment and assessments. If a subject is given the incorrect randomized treatment, the subject should be continued on the treatment dispensed and Interactive Clinical Technologies, Inc. (ICTI), the vendor providing the randomization patient assignment) should be notified of the error. The next patient randomized at the site will be assigned an appropriate kit number by ICTI, accounting for the error.

3.4.4.4 Procedures for discontinuation

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination including an ophthalmoscopic exam
- Vital signs and weight
- HAM-D
- MADRS
- ICI-D
- YMRS

- HAM-A
- SAS
- BARS
- PSQI
- Adverse events assessment

3.5 Treatments

3.5.1 Investigational products

3.5.1.1 Identity of investigational product and comparators

Investigational product will consist of 25-mg , 100-mg, and 200-mg tablets of quetiapine fumarate and matching placebo tablets as shown in Table 3.

Table 3 Trial medication

Tablet strength	Formulation number	Tablet color
25-mg quetiapine	F12804	peach
25- mg placebo	F12636	peach
100-mg quetiapine	F12689	yellow
100-mg placebo	F12637	yellow
200-mg quetiapine	F12690	white
200-mg placebo	F12638	white

3.5.1.2 Doses and treatment regimens

Quetiapine and placebo for each trial center will be packaged in blister cards. The 8-week supply will consist of 8 double-blind blister cards. The 8 double-blind blister cards will be packaged in subject-specific cartons.

Trial medication will be provided for each subject in an 8-card carton that contains the following:

- 1-week titration double-blind treatment cards for Days 1-7
- seven 1-week double-blind treatment cards for Days 8-56, with individual cards provided for treatment Days 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, and 50-56.

Each one-week blister card will include a 2-day treatment overage to accommodate visit schedules.

The Week 1 titration card will consist of 25 mg tablets, 100-mg tablets, and 200-mg tablets or matching placebo, as described below, for each of the 300 mg/day and 600 mg/day treatment groups and placebo treatment group.

Blister cards for Weeks 2 through 8, for each treatment group, will consist of 9 days of dosing with the same number of pills for each group (300-mg,600-mg, and placebo) respectively. The cards for each treatment group will consist of 2 yellow tablets and 2 white tablets per day at bedtime.

Quetiapine or placebo will be administered once a day at bedtime with dose titration to reach a target dose of 300 mg/day by Day 4 in the 300 mg/day treatment group and 600 mg/day by Day 8 in the 600 mg/day group. The schedule for quetiapine or placebo administration is shown in Tables 4, 5, and 6.

Table 4 Dose administration schedule for 300-mg double-blind quetiapine

Trial Day	Quetiapine 300 mg/day and placebo				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablet/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 6	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 7	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 8	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg
Days 9-56	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg

Table 5 Dose administration schedule for 600-mg double-blind quetiapine

Trial Day	Quetiapine 600 mg/day and placebo tablets				
	Quetiapine 25 mg	Quetiapine 100 mg	Placebo 100 mg	Quetiapine 200 mg	Placebo 200 mg
Day 1	2 tablets/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 6	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 7	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 8	0	2 tablets/100-mg	0	2 tablets/400-mg	0
Days 9-56	0	2 tablets/100-mg	0	2 tablets/400-mg	0

Table 6 Dose administration schedule for double-blind placebo

Trial Day			
	Placebo 25mg	Placebo 100 mg	Placebo 200 mg
Day 1	2 tablets/50-mg	0	0
Day 2	0	1 tablet/100-mg	0
Day 3	0	0	1 tablet/200-mg
Day 4	0	1 tablet/100-mg	1 tablet/200-mg
Day 5	0	2 tablets/100-mg	1 tablet/200-mg
Day 6	0	2 tablets/100-mg	1 tablet/200-mg
Day 7	0	2 tablets/100-mg	1 tablet/200-mg
Day 8	0	2 tablets/100-mg	2 tablets/400-mg
Days 9-56	0	2 tablets/100-mg	2 tablets/400-mg

Dosing Reduction

Dose reductions for intolerability will be allowed after Day 8. In the 300-mg/day group, dose reductions of 100 mg/day will be achieved by reducing the dose by one 100-mg tablets. In the 600-mg/day group, a dose reduction of 100 mg/day will be achieved by reducing the bedtime dose by one 100-mg tablets active drug. This dose reduction can occur anytime after Day 8. Each column in the blister packs will be numbered 1-4. By Day 6 columns 1 and 2 of the blister packs will each contain a 100-mg tablet. In both the 300-mg /day group and the 600-mg/day group, column 1 will contain active medication thus ensuring that by eliminating the first column (column #1) of medication they are reducing their dose by 100-mg. Each tablet in the placebo treatment group will also indicate the same corresponding numbers (columns #1-4) as the active treatment groups even though no active product is packaged. This will ensure the blind is maintained.

Table 7 Week 1 Blister pack for 300-mg/Day Quetiapine Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 8 Week 2-8 300-mg/Day Quetiapine Blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
2	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
3	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
4	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 9 Week 1 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 10 Week 2-8 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
2	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
3	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
4	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 11 Week 1 Blister Pack for Placebo Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg placebo	25-mg placebo		
2	100-mg placebo			
3	200-mg placebo			
4	100-mg placebo	200-mg placebo		
5	100-mg placebo	100-mg placebo	200-mg placebo	
6	100-mg placebo	100-mg placebo	200-mg placebo	
7	100-mg placebo	100-mg placebo	200-mg placebo	
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Table 12 Week 2-8 Blister pack for Placebo/Day Group

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
2	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
3	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
4	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
5	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
6	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
7	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

3.5.1.3 Labeling

All trial supplies will be provided by AstraZeneca.

The blister cards Days 1- 56 will be supplied in subject-specific cartons. Each blister card will be labeled with a two-panel, double-blind label. The left portion of the label will remain on the blister card. The right portion of the label will be affixed to the appropriate Case Report Form (CRF) as part of the individual's permanent record. The label will contain at least the following information: trial number, code assignment and storage condition. The carton for the 8 blister cards for Days 1-56 will be labeled with a single-panel double-blind label. The label will contain at least the following information: trial number, storage conditions, and instructions to dispense according to protocol.

3.5.1.4 Storage

All investigational products must be kept in a secure and locked location, at room temperature and protected from light and moisture.

3.5.1.5 Accountability

The investigational materials are to be prescribed only by the investigator or the sub-investigators named in Form FDA-1572. Under no circumstances will the investigator allow the

investigational drug to be used other than as directed by the protocol without prior AstraZeneca approval.

The investigator must maintain accurate records accounting for the receipt of the investigational materials (ICTI provides a acknowledge the receipt of drug shipment module for this purpose) and for the disposition of the material. This record keeping consists of a dispensing record that includes the identification of the person to who the drug is dispensed, the quantity and the date of dispensing, and documentation of any unused drug returned to the investigator. This record is in addition to any drug accountability information recorded on the subject's hospital or clinic chart.

Starting with Week 1, each patient will return the blister card for the preceding week to the clinic. The clinic will tabulate the returned pills to aid in drug accountability.

At the termination of the study or at the request of the sponsor, the Clinical Research Associate must return any unused study supplies to Universal Systems Incorporated (USI), at the address listed below, for destruction. This return will be documented on an Investigational Product Return Invoice supplied by AstraZeneca.

USI
2084-900 Lake Industrial Court
Conyers, GA 30013

3.5.2 Method of assigning subjects to treatment groups

This trial will be established with a non-specific labeling (NCSL) randomization which will be stratified by bipolar type. Randomization to trial treatment will be done via an Interactive Voice Response System (IVRS) at ICTI on Day 1 (Visit 2) in balanced blocks within each stratum in order to ensure relative balance among treatment groups and strata (Bipolar I and Bipolar II)in terms of total number of subjects. The randomization schedule will be created under the auspices of AstraZeneca Quantitative Decision Sciences Group and will provide allocation of subject numbers to the treatment regiments. Number and size of tablets will be identical for the 3 treatment arms. Clinical supplies will contain a 4-digit subject number which is allocated to the treatment arm through the randomization scheme. A separate randomization will be used to provide kits of packaged drugs to the sites. The IVRS system at ICTI will allocate a kit number at the site for the treatment assigned through the stratified randomization.

Subject eligibility will be established before treatment randomization. Subjects will be randomized centrally sequentially within the stratum, as subjects are eligible for enrollment/randomization. If a subject discontinues from the study, the subject number will not be reused, and the subject will not be allowed to re-enter the study.

The randomization is centralized and the assigned randomized patient number and associated kit numbers will not be sequential within a site.

3.5.3 Blinding and procedures for unblinding the study

3.5.3.1 Methods for ensuring blinding

All packaging will be identical with placebo and active tablets identical in size and color. The number of tablets dispensed on each card will be identical across all treatment arms.

The randomization for the kit assignments will be generated by the study statistician and provided directly to packaging with a copy going to ICTI Clinical Supplies Management Group. The stratified patient randomization will be generated by an AstraZeneca randomization staff member not associated with the trial and will be provided directly to ICTI for incorporation into the IVRS system. No member of the study team in AstraZeneca, at investigational sites or the CRO organization handing data will have access to the randomization scheme during the conduct of the study.

3.5.3.2 Methods for unblinding the study

Individual treatment codes, indicating the treatment randomization for each randomized subject, will be available to the investigator(s) or pharmacists at the study center through the use of a concealed panel on the label.

The treatment code must not be broken except in medical emergencies when the appropriate management of the subject necessitates knowledge of the treatment randomization. The investigator(s) must document and report to AstraZeneca any breaking of the treatment code. AstraZeneca retains the right to break the code in order to report serious adverse events to regulatory authorities.

Treatment codes will not be broken for the planned analyses of data until all decisions on the evaluability of the data from each individual subject have been made and documented.

3.5.4 Treatment compliance

Compliance will be assessed based on returned tablet counts. The percent compliance will be calculated as the number of tablets taken (dispensed - returned) divided by the prescribed number of tablets (number of days times number of tablets per day) expressed as a percent. Based on this calculation a subject with at least 75% compliance with study medication during study participation will be classified as compliant.

Furthermore, if there are any significant irregularities in compliance, in the opinion of the investigator, the patient should be withdrawn from the study.

4 CONCURRENT TREATMENT

4.1 General medications

Nonpsychotropic medication, including over-the counter medications, taken by the subject before entry into the trial may be continued during the trial. Medications required to treat illnesses or complaints that occur during the trial may be used at the discretion of the investigator. Use of cytochrome P450 inducers and potent inhibitors is restricted (see Table 13 below).

Women who enter the trial with an intrauterine device in place, using oral contraceptives, or using injectable or implantable hormonal agents designed to prevent pregnancy may continue these treatments throughout the trial.

The specific type of medication (trade or generic name), the indication for use, and the dates of usage should be reported on the CRF entitled Concurrent Treatment.

Medication which is considered necessary for the subject's safety and well being may be given at the discretion of the investigator(s). The administration of all medication (including investigational products) must be recorded in the appropriate sections of the case report form (CRF).

4.2 Use of psychoactive medications

The use of psychoactive drugs other than those specifically allowed during the trial (ie, lorazepam and zolpidem tartrate) is restricted (see Section 4.3, Table 13).

4.3 Summary of permitted concurrent medications

Medications specifically prohibited or restricted, and those permitted during the trial are listed in Table 13

Table 13 Permitted, restricted, and prohibited medications

Use category	Type of medication
Permitted	Previous medications for medical, nonpsychiatric illnesses Oral contraceptives and contraceptive devices
Restricted	Zolpidem tartrate 5-10 mg at bedtime for insomnia Lorazepam 1-3 mg per day for severe anxiety These drugs may be prescribed during the first 3 weeks of the study as long as they do not interfere with any assessments
Prohibited	Potent cytochrome P450 3A4 inducers (including but not limited to barbiturates, carbamazepine, rifampin, and St John's Wort) Potent cytochrome P450 3A4 inhibitors (including but not limited to ketoconazole, itraconazoole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir, and saquinavir) Antipsychotic medications (including but not limited to phenothiazines, risperidone, olanzapine, ziprasidone, clozapine, loxapine, thiothixene, molindone) Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

5 STUDY MEASUREMENTS AND ENDPOINTS

5.1 Primary endpoint

The primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score. This endpoint is used as the basis for the sample size calculation, as provided in Section 6.1.

5.2 Screening and demographic measurements

The following data are to be collected at screening:

- date of birth, sex, and race
- vital signs, height, weight
- supine and standing blood pressure and pulse
- significant medical history
- physical examination including ophthalmoscopic exam
- 12-lead electrocardiogram
- clinical chemistry and hematology
- pregnancy test (if female of childbearing potential)
- HAM-D assessment
- YMRS
- DSM-IV diagnosis, based on SCID assessment

5.3 Efficacy measurements and endpoints

The following assessments will be used to evaluate efficacy:

- change from baseline to final assessment in MADRS total score
- percentage of subjects with $\geq$50% reduction from baseline in MADRS total score at final assessment
- the change from baseline in each assessment (observed cases) in the MADRS total score

- the change from baseline to each assessment (observed cases) and final assessment in the CGI-S
- the CGI-C at final assessment
- the change from baseline to each assessment (observed cases) and final assessment in the YMRS
- the change from baseline to each assessment (observed cases) and final assessment in the total HAM-A

Evaluation using each of these scales should be performed by the same trained/certified staff member who has been approved by AstraZeneca for all assessments of the scale for an individual subject.

5.3.1 Summary of efficacy objectives and endpoints

Table 17 shows how the efficacy endpoints of this study relate to the study objectives.

Table 14 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Primary	Primary measure		
evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks	change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score; ls means, 95% CI at final assessment ; descriptive statistics by statum	ANCOVA for the change from baseline to final assessment for total MADRS score. Pair-wise comparisons of each dose with placebo using step up procedure	Reductions in MADRS compared with placebo will indicate doses which are effective in treating depressive episode
	Secondary measure		
	percentage of subjects meeting the MADRS responder criteria ; n, percentage responders at each assessment, final assessment ; descriptive statistics by statum	Logistic model	Higher response rates will indicate doses which are effective in treating depressive episode in treating depressive episode
	change from baseline to each assessment for the MADRS total score, and each assessment and final	ANCOVA for the change from baseline to each assessment and final assessment	Reductions in scales compared with placebo will indicate doses which are effective in

	assessment Clinical Global Impression - Severity (CGI-S); ls means, 95% CI; descriptive statistics by stratum	(LOCF) for CGI-S. Pair-wise comparisons of each dose with placebo	treating depressive episode
	Clinical Global Impression - Change (CGI-C); ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the CGI-C for each assessment and final assessment (LOCF). Pair-wise comparisons of each dose with placebo	Greater improvements in CGI-C will indicate doses which are effective compared with placebo
Secondary			
evaluate the efficacy of quetiapine compared to placebo in the incidence of treatment -emergent mania	change from baseline to each assessment and final assessment in the YMRS total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for YMRS total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	No significant increase in the YMRS compared to placebo will indicate doses which do not result in treatment-emergent mania
evaluate the effect of quetiapine compared to placebo on symptoms of anxiety	change from baseline to each assessment and final assessment in the HAM-A total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for HAM-A total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Improvement in the HAM-A compared to placebo will indicate efficacy in treating anxiety component of the depressive episode

The methods for collecting efficacy data are presented below.

5.3.2 Montgomery-Asberg Depression Rating Scale (MADRS)

5.3.2.1 Methods of assessment

The MADRS will be performed at each visit during the trials using the validated MADRS instrument by certified staff at each site.

5.3.2.2 Calculation or derivation of endpoint

The change from baseline to final LOCF will be calculated for total MADRS score. A subject will be classified as a responder if the % change from baseline, calculated as the (change from

baseline divided by the baseline) multiplied by 100 indicates a ≥ 50% reduction in baseline total MADRS score.

5.3.3 Hamilton Rating Scale for Depression (HAM-D)

5.3.3.1 Methods of assessment

The HAM-D will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-D and HAM-D item #1.

5.3.4 Clinical Global Impression - Severity (CGI-S)

5.3.4.1 Methods of assessment

The CGI-S will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.4.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in CGI-S.

5.3.5 Clinical Global Impression - Change (CGI-C)

5.3.5.1 Methods of assessment

The CGI-C will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.5.2 Calculation or derivation of endpoint

The CGI-C is a measure of change from baseline and therefore requires no further derivation.

5.3.6 Hamilton Rating Scale for Anxiety (HAM-A)

5.3.6.1 Methods of assessment

The HAM-A will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.6.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-A.

5.3.7 Young Mania Rating Scale (YMRS)

5.3.7.1 Methods of assessment

The YMRS will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.7.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in YMRS.

5.4 Safety measurements and endpoints

The following measurements will be used to assess safety:

- adverse event reporting (both general adverse events and serious adverse events), coded using MedDRA system of nomenclature
- fasting clinical laboratory tests (including chemistry and hematology)
- vital signs(taken in both the standing and supine positions)
- ECG tests
- Simpson-Angus Scale
- Barnes-Akathesia Rating Scale

5.4.1 Summary of safety objectives and endpoints

Table 13 shows how the safety endpoints of this study relate to the study objectives.

Table 15 Safety objectives and endpoints relating to each objective

Objective	Endpoints and statistic	Planned analysis	Significance of results
evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	incidence and nature of adverse events during double-blind treatment ; n, % incidence per event, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	no new safety issues identified
	incidence of drug-related adverse events during double-blind treatment ; n, % incidence; titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of subject withdrawal due to adverse events; n, % withdrawn, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of clinically significant changes in vital signs; n, % at each assessment and final visit	descriptive statistics only	
	change in the SAS total score ; mean change, standard deviation, baseline to final assessment (LOCF)	descriptive statistics only	
	the change in BARS total score	descriptive statistics only	
	incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment	descriptive statistics only	

The methods for collecting safety data are described below.

5.4.2 Adverse Events

5.4.2.1 Definitions

The definitions of adverse events (AEs), serious adverse events (SAEs) and other significant adverse events (OAEs) are given below. It is of the utmost importance that all staff involved in the study is familiar with the content of this section. The principal investigator is responsible for ensuring this.

(a) Adverse Event

An adverse event is the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver) or the abnormal results of an investigation (eg, laboratory findings, electrocardiogram). In clinical studies, an AE can include an undesirable medical condition occurring at any time, including run-in or washout periods, even if no study treatment has been administered.

(b) Serious Adverse Event

A serious adverse event is an AE occurring during any study phase (ie, run-in, treatment, washout, follow-up), and at any dose of the investigational product, comparator or placebo, that fulfills one or more of the following criteria:

- results in death
- is immediately life-threatening
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- is a congenital abnormality or birth defect
- is an important medical event that may jeopardize the subject or may require medical intervention to prevent one of the outcomes listed above?

The causality of SAEs (ie, their relationship to study treatment) will be assessed by the investigator(s), who in completing the relevant case report form must answer “yes” or “no” to the question “Do you consider that there is a reasonable possibility that the event may have been caused by the drug?” For further guidance on the definition of a SAE and a guide to the interpretation of the causality question, see Appendix F.

(c) Other significant adverse event

An AstraZeneca expert will identify OAEs during the evaluation of safety data for the Clinical Study Report. Significant adverse events of particular clinical importance, other than SAEs and those AEs leading to discontinuation of the subject from study treatment, will be classified as OAEs. Examples of these are marked hematological and other laboratory abnormalities, and certain events that lead to intervention (other than those already classified as serious), dose reduction or significant additional treatment. For each OAE, a narrative will be written and included in the Clinical Study Report.

5.4.2.2 Recording of adverse events

All AEs that occur before treatment, during treatment, or within 30 days following the cessation of treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. A description of the event, its intensity, duration, action taken (eg, treatment and follow-up tests), and outcome should be given, along with the investigator's causality assessment of the relationship of the event to the study drug. If a diagnosis of the subject's condition has been made, then the diagnosis should be recorded as the SAE. In instances of well recognized syndromes (eg, fever, runny nose, cough) they can be recorded as "flu". However, if a diagnosis of the subject's condition has not been made, or if the individual symptoms are not well recognized, then the individual symptoms should be recorded separately.

In general, abnormal laboratory tests or vital signs should not be reported as AEs unless they fulfill the criteria for an SAE or lead to discontinuation. If an abnormal laboratory test result or vital sign is associated with clinical signs and symptoms, the sign or symptom should be reported as an AE, and the associated test result or vital sign should be recorded on the appropriate CRF.

A causality assessment must be recorded for all AEs. The CRF asks the question, "In your medical judgement, is there a reasonable possibility that the event may have been caused by the study therapy?" If there is any valid reason, even if undetermined or untested, for suspecting a possible cause-and-effect relationship between the study drug and the occurrence of the AE, then this should be answered "yes." Otherwise, if no valid reason exists for suggesting a possible relationship, then this should be answered "no." If more than 1 AE is identified, a causality assessment must be made for each AE.

It is important to distinguish between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined by the criteria in Section 5.4.2.1 b. An AE of severe intensity need not necessarily be considered serious. For example, nausea which persists for several hours may be considered severe nausea, but not a SAE. On the other hand, a stroke which results in only a limited degree of disability may be considered a mild stroke but would be a SAE.

Any detrimental change in the subject's condition after the subject enters the study will be discussed with the investigator. Where the detrimental change is considered by the investigator to constitute a progression or relapse of bipolar depression or a lack of efficacy, then this will not be considered an AE even where this necessitates or prolongs hospitalization. When there is deterioration in the condition for which the medicine is being used, there may be uncertainty as to whether this is lack of efficacy or an AE. In such cases, unless AstraZeneca or the reporting physician considers that the medicine contributed to the deterioration, the deterioration should be considered lack of efficacy. However, if it is believed that the medicine may have contributed to the deterioration, then this should be treated as an AE.

Study drug abuse is an SAE, even when there are no symptoms or additional AEs and should be reported according to the guidelines in Section 5.4.2.3. Misuse of study drug is an AE but is not considered an SAE unless accompanied by serious sequelae.

Should an overdose occur, it must be reported in accordance with the procedures described in Section 10.3 Procedures in case of overdose. All overdoses, with or without associated symptoms, should be reported as AEs.

Suicide and attempted suicide, irrespective of the method, but occurring in connection with the use of study drug, should be reported as AEs (serious or non-serious). This event should be identified as suicide or attempted suicide, and the method of the suicide or attempt should be provided. If an attempted suicide meets the criteria for an SAE, the event must be reported according to the guidelines in Section 10.4.

Should a pregnancy occur, it must be reported in accordance with the procedures described in Section 10.5. Procedures in case of pregnancy. Pregnancy in itself is not regarded as an AE unless there is a suspicion that an investigational product may have interfered with the effectiveness of a contraceptive medication.

5.4.2.3 Reporting of serious adverse events

Investigators and other site personnel must inform appropriate AstraZeneca representatives of any SAE that occurs in the course of the study within 1 day (i.e. immediately but no later than the end of the next business day) of when he or she becomes aware of it.

The AstraZeneca representative will work with the investigator to compile all the necessary information and ensure that the appropriate AstraZeneca Drug Safety Department receives a report by day 1 for all fatal and life-threatening cases and by day 5 for all other SAEs.

Follow-up information on SAEs must also be reported by the investigator within the same time frames.

If a non-serious AE becomes serious, this and other relevant follow-up information must also be provided to AstraZeneca within 1 day as described above.

After initial notification, the AstraZeneca representatives have 4 days to work with the investigator to compile all the necessary information to ensure that the appropriate AstraZeneca Drug Safety Department receives a complete report by day 5. Follow-up information on SAEs should also be reported by the investigator within the same time frames. If a non-serious case becomes serious, this and other relevant follow-up information should also be provided to AstraZeneca within 1 day as described in the paragraph above

All SAEs have to be reported, whether or not considered causally related to the investigational product. All SAEs will be recorded in the case report form. The investigator is responsible for informing the Ethics Committee and/or the Regulatory Authority of the SAE as per local requirements.

5.4.3 Laboratory safety measurements and variables

Blood (under fasting conditions) and urine specimens will be collected for laboratory test analysis and these samples will be processed by a central laboratory (Quintiles Central Laboratory).

5.4.3.1 Methods of assessment

- Fasting hematology: hemoglobin, hematocrit, red blood cell count, total and differential white blood cell counts and platelet count
- Fasting clinical chemistry: total bilirubin, alkaline phosphatase, alanine transaminase(ALT), aspartate transaminase(AST), sodium, potassium, chloride, creatinine, glucose, insulin, bicarbonate, high-density lipoprotein cholesterol, triglycerides, low-density lipoprotein cholesterol and total cholesterol
- Thyroid function tests: thyroid stimulating hormone (TSH), Triiodothyronine resin uptake (T3RU), and total thyroxine (T4)
- Serum pregnancy tests
- Urine toxicology screen

5.4.3.2 Calculation or derivation of endpoints

Change from baseline will be derived for all subjects who have a screening laboratory test and a final laboratory test. The change from baseline is the final test value minus the screening test value. Laboratory test values will also be compared to the laboratory standard normal ranges and

flagged with H or L if they are outside of the normal range. In addition, treatment emergent laboratory changes, identified using computerized methods to compare results or changes from baseline to standard extended ranges will be flagged at the subject and test level.

5.4.4 Vital signs measurement

5.4.4.1 Methods of assessment

A standard blood pressure cuff will be used to obtain systolic and diastolic blood pressure. The assessment will be done first with the subject in the supine position for 3 minutes and again within 3 minutes of the subject attaining a standing position. Pulse will be measured for 1 minute.

5.4.4.2 Calculation or derivation of endpoints

Change from baseline will derived be as the value at the visit minus the screen value for the same assessment and position. In addition the change within a visit between the standing and supine blood pressure assessments will be calculated for both systolic and diastolic blood pressures. This difference will be calculated as supine minus standing . A subject will be classified as having calculated postural hypotension if either the systolic blood pressure difference indicates a decrease >20 mmHg or the diastolic blood pressure difference indicates a decrease >15 mmHg.

5.4.5 ECG safety measurements and variables

5.4.5.1 Methods of assessment

A 12 lead ECG assessment will be done using an ECG machine compatible with the requirements for eResearch the central evaluation laboratory. The central laboratory will supply the interval data, rates and standard interpretation of the ECG test results.

eResearch
30 south 17th Street
Philadelphia, PA 19103-4001

5.4.5.2 Calculations and derivations of endpoint

Change from baseline for interval data and rate data will be derived by subtracting the screen value from the final assessment value. Values outside the extended range in Appendix XX will be flagged.

5.4.6 Simpson-Angus Scale (SAS)

5.4.6.1 Methods of assessment

The SAS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.6.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.4.7 Barnes-Akathisia Rating Scale (BARS)

5.4.7.1 Methods of assessment

The BARS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.7.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.5 Quality of Life endpoint

The following assessment will be used to assess the effect of quetiapine compared with placebo on quality of life as assessed by:

- the PSQI
- the short form Q-Les-Q

5.5.1 Summary of quality of life objectives and endpoints

Table 19 shows how the efficacy endpoints of this study relate to the study objectives.

Table 19 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Secondary	Secondary measure		
evaluate the effect of quetiapine compared to placebo on quality of sleep	change from baseline to final assessment in PSQI; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for PSQI total score, with MADRS score as covariate. Pair-wise comparisons of	Reduction in PSQI compared with placebo indicates improvement of sleep quality

		each dose with placebo	
evaluate the effect of quetiapine compared to placebo on the overall quality of life	change from baseline to final assessment in Q-Les-Q; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for Q-Les-Q total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Increase in Q-Les-Q compared with placebo indicates improvement of overall quality of life

The methods of collecting quality of life data are described below.

5.5.2 PSQI

5.5.2.1 Methods of assessment

The PSQI will be performed at scheduled visits during the trial by a patient at each site. The 9 self-rated questions will be incorporated into 7 component scores which are added together to yield one total "global" score. Higher scores indicate more severe difficulties in sleep quality.

5.5.2.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the PSQI.

5.5.3 Q-Les-Q

5.5.3.1 Methods of assessment

The Q-Les-Q is a patient self assessment questionnaire which will be completed at scheduled visits during the trial by a patient at each site. The short form has 14 self-rated questions, the first 12 will be incorporated into a total score. Higher scores indicate better quality of life.

5.5.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the Q-Les-Q.

5.6 Interactive Computer Interview for Depression (ICI-D)

At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the

MADRS. Raters or other site staff will first enter the subject's MADRS scores into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

For quality assurance purposes, if an above-threshold variance is detected between the ICI-D and the MADRS on individual items or the overall score, a CRS clinician (Ph.D. or MD) will contact the applicable rater for a monitoring consultation. The CRS clinician will discuss possible reasons for the discrepancy, review conventions for scoring and offer additional training if necessary.

The ICI-D will also provide an additional check of the patient's suicide status. The ICI-D will alert the rater if the patient reports suicidal plans. If the patient did not verbalize these thoughts during the interview /assessment process, the rater could then take the appropriate clinical steps.

A standard operating procedure for ICI-D will be provided to the sites.

5.7 Genetic sampling and storage

There will be no genetic sampling in this trial.

5.8 Volume of blood sampling and handling of biological samples

The total volume of blood that will be drawn from each subject in this study is as follows:

Table 16 Volume of blood to be drawn from each subject

Assessment		Sample volume (ml)	N of samples	Total volume (ml)	
				Women	Men
Safety	Clinical chemistry				
	Hematology	18	2	36	36
	Serum Pregnancy [a]	2	1	2	
Total				38	36

[a] Women only.

Sample handling and storage will be defined by the central laboratory which will be handling the analysis and reporting or results from samples.

6 DATA MANAGEMENT

Case Report Forms (CRFs) will be provided for recording of data. The forms will be in triplicate with carbonless paper. Data will be recorded legibly onto the CRFs with black ink, preferably with a ballpoint pen. If any data are not available, omissions will be indicated on the CRFs. Corrections should be made legibly and be initialed and dated. Correction fluid or covering labels must not be used. The top original and the first copy of the completed form will collected and returned to AstraZeneca/AstraZeneca's agent and the second copy will be retained by the investigator.

Data received electronically by AstraZeneca from a validated source will be loaded directly into the trial database for analysis.

7 STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

7.1 Determination of sample size

Since there is no data using the MADRS instrument in the assessment of quetiapine in treating bipolar subjects with depression, the sample size estimation was based on published data from the lamotrigine monotherapy (Calabrese et al, 1999) and olanzapine trials (Tohen et al, 2002). The percentage change in the HAM-D across these lamotrigine studies in bipolar depression is similar to that observed with quetiapine. MADRS scores correlate significantly with those of the HAM-D (Montgomery Asberg 1979).

Sample size was estimated using an Bonferroni correction for the 2 comparisons with placebo. A clinically meaningful 3.6-unit difference between quetiapine treatment and placebo was used to estimate the effect size (with 3.1 units considered a minimally effective and detectable difference). The variability used for calculation was 10 units, the variability seen in the olanzapine study. A sample size of 168 subjects/arm (504 subjects total) would provide 85% power for 2-sided pair-wise comparisons with placebo at α=0.025 which provides an overall experiment wise type I error rate of 0.05. Therefore, 740 patients will be screened and approximately 530 subjects randomized (allowing for a 5% early drop out rate), to insure 504 subjects with post baseline data available for analysis (MITT analysis population). This sample size will provide 72% power to detect a 3.1 unit difference from placebo.

7.2 Statistical evaluation

7.2.1 Methods of statistical analysis

A comprehensive Statistical Analysis Plan (SAP) will be prepared before unblinding of the data.

Missing data for final visit resulting from patient drop outs will be imputed using an LOCF approach. Patients with post baseline data (MITT population) will have their last trial assessment carried forward as the final assessment for analyses.

7.2.2 Study endpoints

Primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score.

Secondary efficacy endpoints:

(1) Percentage of patients with a ≥50% reduction from baseline in the MADRS total score at study endpoint

(2) Change from baseline to each assessment (observed cases) in the MADRS total score

(3) Change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, CGI-S, CGI-C, and Young Mania Rating Scale.

(4) Change in the PSQI score from baseline to final assessment

Safety endpoints:

(1) Incidence and nature of adverse events during double-blind treatment

(2) Incidence of drug-related adverse events during double-blind treatment

(3) Incidence of subject withdrawal due to adverse events

(4) Incidence of clinically significant changes in hematology and chemistry laboratory results, vital signs, electrocardiograms, weight, and body mass index.
Tolerability endpoints:

(5) Change in the SAS total score from baseline to final assessment

(6) Change in BARS total score from baseline to final assessment

(7) Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment

Quality of Life endpoints:

(1) Change in Q-Les-Q total score from baseline to final assessment

(2) Proportion of patients achieving community norm levels in Q-Les-Q at final assessment

7.2.3 Statistical analyses

The randomization will be stratified by Bipolar type (I or II) in order to assure balance across treatments for the type of patient enrolled. The stratification will be incorporated into the statistical analysis models and descriptive statistics will be provided for each stratum.

For each statistical model run, the assumptions for the model will be evaluated. If the assumptions are not reasonably met, the data may be transformed to meet assumptions or a non-parametric test performed.

All statistical comparisons will be based on 2-sided testing approaches for testing the difference between active study medication dose and placebo.

7.2.3.1 Study populations for analysis

The modified intention to treat population (MITT) will be the population for efficacy and quality of life evaluation. The MITT population will include all randomized subjects who were received study treatment and had at least one post baseline efficacy assessment with a last observation carried forward approach for final assessment.

The safety population will include all subjects who provide consent and received study medication.

7.2.3.2 Primary Analysis

The primary analysis will use analysis of covariance (ANCOVA) model for the change from baseline at final assessment for the MADRS. The model will include terms for treatment, stratum, with the baseline MADRS as a covariate. The Simes-Hommel step-up procedure will be used to adjust for the 2 comparisons with placebo (Simes-Hommel, 1988). The p-values obtained from the pair-wise comparisons will be ordered as follows: $P(1) \leq P(2)$. The following rule will be used to assess statistical significance:

1) If $P(2) \leq 0.05$, then reject both null hypotheses associated with P(2) and P(1); else proceed to the next step;

2) If $P(1) \leq 0.025$, then reject the null hypothesis associated with P(1).

7.2.3.3 Secondary Analyses of efficacy and quality of life

The secondary endpoint for responder, defined as a subject who has a 50% reduction in MADRS score from baseline to final assessment, will be analyzed by comparing the proportion of subjects responding across treatments using a logistic model which includes treatment, stratum, and center in the model. The secondary endpoints based on change from baseline for scales at an assessment time will be analyzed using the same model as the primary endpoint. Nominal p-values will be used for all secondary endpoint comparisons.

Exploratory repeated measures analysis of variance model will also be conducted to evaluate whether there are significant differences among treatments across time for the MADRS and HAM-D scores.

Descriptive statistics will be used to report stratum, item scores, and subscale scores.

7.2.3.4 Safety analyses

Adverse events will be coded using the MedDRA dictionary. Numbers of events and incidence rates for AEs in each treatment group will be summarized by preferred term and system organ class. An event that occurred one or more times on the date of, or subsequent to, randomization will contribute one observation to the numerator of the incidence rate. The denominator will comprise all patients exposed to study treatment.

Adverse events that lead to premature withdrawal of subjects will be tabulated for each treatment group.

All laboratory assessments, vital signs, ECG (rates and intervals) results, and weight and body mass index will be tabulated using descriptive statistics at baseline, final assessment and including change from baseline. Descriptive statistics will include n, mean, standard deviation, minimum and maximum value.

7.2.3.5 Tolerability analyses

The change from baseline in SAS and BARS score data will be summarized using descriptive statistics (mean, standard deviation, median, minimum and maximum).

Incidence rates of EPS adverse events will be compared and tabulated using descriptive statistics.

7.2.3.6 Interim analysis

No interim analysis is planned

7.2.3.7 Data or safety monitoring committee

There will be no data or safety monitoring committee.

8 STUDY MANAGEMENT

8.1 Monitoring

Before the study begins, a representative of AstraZeneca or company representing AstraZeneca will visit the investigational site to

- determine the adequacy of the facilities
- discuss with the investigator(s) (and other personnel involved with the study) their responsibilities with regard to protocol adherence, and the responsibilities of AstraZeneca or its representatives.

During the study, a monitor from AstraZeneca or company representing AstraZeneca will have regular contacts with the investigational site, including visits to

- provide information and support to the investigator(s)
- confirm that facilities remain acceptable
- confirm that the investigational team is adhering to the protocol, that data are being accurately recorded in the case report forms (CRFs), and that investigational product accountability checks are being performed.
- perform source data verification (a comparison of the data in the CRFs with the subject's records at the hospital or practice, and other records relevant to the study). This will require direct access to all original records for each subject (eg, clinic charts).

The monitor or another AstraZeneca representative will be available between visits if the investigator(s) or other staff at the center need information and advice.

8.2 Audits and inspections

Authorized representatives of AstraZeneca, a regulatory authority, an Independent Ethics Committee (IEC) or an Institutional Review Board (IRB) may visit the center to perform audits or inspections, including source data verification. The purpose of an AstraZeneca audit or inspection is to systematically and independently examine all study related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed, and accurately reported according to the protocol, Good Clinical Practice (GCP), guidelines of the International Conference on Harmonization (ICH), and any applicable regulatory requirements. The investigator should contact AstraZeneca immediately if contacted by a regulatory agency about an inspection at his or her center.

8.3 Training of staff

The principal investigator will maintain a record of all individuals involved in the study (medical, nursing and other staff). He or she will ensure that appropriate training relevant to the study is given to all of these staff, and that any new information of relevance to the performance of this study is forwarded to the staff involved.

8.4 Changes to the protocol

Study procedures will not be changed without the mutual agreement of the international principal investigator(s) and AstraZeneca.

If it is necessary for the study protocol to be amended, the amendment or a new version of the study protocol must be notified to or approved by each IEC or IRB, and in many countries also the local regulatory authority, before implementation. Local requirements must be followed.

If a protocol amendment requires a change to a particular center's Written Informed Consent Form, then AstraZeneca and the center's IEC or IRB must be notified. Approval of the revised Written Informed Consent Form by AstraZeneca and by the IEC or IRB is required before the revised form is used.

AstraZeneca will distribute amendments and new versions of the protocol to each principal investigator(s), who in turn is responsible for the distribution of these documents to his or her IEC or IRB, and to the staff at his or her center. The distribution of these documents to the regulatory authority will be handled according to local practice.

8.5 Study agreements

The principal investigator at each center must comply with all the terms, conditions, and obligations of the study agreement for this study. In the event of any inconsistency between this protocol and the study agreement, this study agreement shall prevail.

8.6 Study timetable and termination

It is anticipated that the first subject will be enrolled in September 2002 and that the last subject will complete the study in March 2004.

9 ETHICS

9.1 Ethics review

The final study protocol, including the final version of the Written Informed Consent Form, must be approved or given a favorable opinion in writing by an IEC or IRB as appropriate. The investigator must submit written approval to AstraZeneca before he or she can enroll any subject into the study.

The principal investigator(s) is responsible for informing the IEC or IRB of any amendment to the protocol in accordance with local requirements. In addition, the IEC or IRB must approve all advertising used to recruit subjects for the study. The protocol must be reapproved by the IEC or IRB annually, as local regulations require.

Either the investigator(s) or AstraZeneca must submit progress reports to the IEC or IRB according to local regulations and guidelines. The principal investigator(s) must also provide the IEC or IRB with any reports of serious adverse events from the study site.

The principal investigator(s) is also responsible for providing the IRB with reports of any serious adverse events from any other study conducted with the investigational product. This information will be provided to the principal investigator(s) by AstraZeneca.

9.2 Ethical conduct of the study

The study will be performed in accordance with the ethical principles in the Declaration of Helsinki (see Appendix C), Good Clinical Practice, and applicable regulatory requirements.

9.3 Subject information and consent

The principal investigator(s) at each center will ensure that the subject is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Subjects must also be notified that they are free to discontinue from the study at any time. The subject should be given the opportunity to ask questions and allowed time to consider the information provided.

The subject’s signed and dated informed consent must be obtained before conducting any procedure specifically for the study, including the following:

The principal investigator(s) must store the original, signed Written Informed Consent Form. A copy of the Written Informed Consent Form must be given to the subject.

A sample Written Informed Consent Form is enclosed (Appendix B). If modifications are made according to local requirements, the new version has to be approved by AstraZeneca.

9.4 Subject data protection

The Written Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. The subjects' names will not be recorded in this database. The Written Informed Consent Form will also explain that for data verification purposes, authorized representatives of AstraZeneca, a regulatory authority, an IEC or IRB may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

10 EMERGENCY PROCEDURES

10.1 AstraZeneca emergency contact procedure

In the case of a medical emergency, contact AstraZeneca personnel shown below.

Wayne Macfadden MD
Project Physician
302-886-1147 (telephone)
302-886-5567 (fax)
REDACTED

Robin McCoy RN
Senior Clinical Research Scientist
302-886-4650 (telephone)
302-886-5567 (fax)
REDACTED

Contact AstraZeneca switchboard on 1-800-236-9933 and ask to be put in contact with the person on call for the Seroquel clinical team.

10.2 Procedures in case of medical emergency

The principal investigator(s) is responsible for ensuring that procedures and expertise are available to cope with medical emergencies during the study.

10.3 Procedures in case of overdose

For the purpose of this trial all overdoses should be reported as adverse events. However, all cases of overdose must be reported immediately, within 1 day, if sequelae meeting the criteria for serious adverse event have occurred in association with the overdose. In all instances, the overdose substance should be stated and whether the overdose was accidental or intentional. If the overdose was a suicide attempt, this fact should be clearly stated. Adverse events (serious and non-serious) arising as the result of an overdose should be recorded on an adverse event form as “sequelae to overdose.” For example ”nausea as sequelae to overdose.”

10.4 Suicide

Suicide and suicide attempt, irrespective of the method, but in connection with the use of trial drug, should be reported as a serious adverse event (in accordance with the definition provided in Section 5.4.2.1). This event should be identified as suicide or suicide attempt, and the method of the suicide or the suicide attempt should be provided. Suicidal thoughts should also be regarded as adverse events.

10.5 Procedures in case of pregnancy

Pregnancy itself is not regarded as an adverse event unless there is a suspicion that the investigational product under study may have interfered with the effectiveness of a contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) must be followed up and documented even if the subject was discontinued from the study.

All reports of congenital abnormalities/birth defects are SAEs. Spontaneous miscarriages should also be reported and handled as SAEs. Elective abortions without complications should not be handled as AEs. All outcomes of pregnancy must be reported to AstraZeneca on the pregnancy outcomes report form.

11 REFERENCES

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Clinical Study Protocol: Appendix A

Study Code	5077US/0049
Version No.	2
Appendix Date	September 30, 2002

Appendix A
Signatures

IND No. 32,123

SIGNATURE OF PRINCIPAL INVESTIGATOR

Title of report

A Multicenter, Double-blind, Randomized, Placebo-controlled, double-dummy Trial of the User of Quetiapine fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

I agree to the terms of this study protocol. I will conduct the study according to the procedures specified herein, and according to the principles of Good Clinical Practice (GCP) and local regulations.

Centre No.: 0001

Signature: Joseph Calabrese 10/14/03

Joseph Calabrese, MD
University Hospitals of Cleveland
Mood Disorders Program
11400 Euclid Avenue, Suite 200
Cleveland, OH 44106

Date

AstraZeneca

Clinical Study Protocol: Appendix B	
Study Code	5077US/0049
Version No.	1
Appendix Date	August 6, 2002

Appendix B
Sample written informed consent form

A sample informed consent is provided under separate cover.

Appendix C

Declaration of Helsinki

Recommendations guiding physicians in biomedical research involving human subjects.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975 and the 35th World Medical Assembly, Venice, Italy, October 1983 and the 41st World Medical Assembly Hong Kong, September 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of The World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient´s interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject´s physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject´s freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor´s consent must be obtained in addition to the consent of the minor´s legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with professional care (Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo studies where no proven diagnostic or therapeutic method exists.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical re-search involving human subjects

(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to thepatient´s illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

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Clinical Study Protocol: Appendix D	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix D

Investigators and study administrative structure

STAFF AT INVESTIGATIONAL SITE(S)

Centre No.	**Centre address**	**Name** (First name, Last name)	**Qualifications**	**Position**	**Role in the study**
<<>>					Principal investigator

A list of participating investigators will be provided upon request.

ASTRAZENECA STUDY PERSONNEL

Name (First name, Last name)	**Position**	**Role in the study**
Robin McCoy	Senior Clinical Research Scientist	Clinical Management Lead
Margaret Minkwitz	Director Biostatistics Project Team	Biostatistician
Wayne Macfadden	Medical Director Clinical Research	Medical advisor
Jeris Minor	Data Analyst	Data Analyst
Elaine Yu	Assistant Director Health Economics	Health Economics
Ellen Quimby	IPS Demand Manager	IPS Representative
Jennifer Mahoney	Safety Representative	Safety
Patti Neal	Regulatory Representative	Regulatory
Richard White	Director Health Economics	Health Economics

OTHER PARTICIPANTS

Organisation and address	**Name** (First name, Last name)	**Qualifications/Position**	**Role in study**
Lineberry Research Associates 79 Alexander Drive Bldg 4401, Suite 400Research Triangle Park, NC 27709 See CRO Personnel List	Kelly Abernathy	RN	Project Manager

AstraZeneca

Clinical Study Protocol: Appendix E	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix E

Insurance and indemnity

For the US, this Appendix E is not applicable. Please refer to the clinical study agreement for information regardingAstraZeneca's obligation to insure and indemnify institution and investigator.

INSURANCE AND INDEMNITY

AstraZeneca's liability is covered by a liability insurance policy with AstraZeneca Insurance Company Limited, policy No.: L/702938.

With respect to any liability directly or indirectly caused by the investigational products in connection with this Clinical Study, AstraZeneca assumes liability by law on behalf of the investigator(s) and his assistants for possible injury to the subject provided the investigator(s) and his assistants have followed the instructions of AstraZeneca in accordance with this protocol and any amendments thereto, that the investigational products administered to the subject in this Clinical Study have been supplied by AstraZeneca and that the investigator and his assistants have in general performed this clinical study in accordance with scientific practice and currently acceptable techniques and know-how.

AstraZeneca can forward a letter of indemnity if needed by the investigator(s)/institution.

AstraZeneca

Clinical Study protocol: Appendix F	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8 2002

Appendix F
Additional safety information

1. FURTHER GUIDANCE ON THE DEFINITION OF A SERIOUS ADVERSE EVENT (SAE)

Life threatening

'Life-threatening' means that the subject was at immediate risk of death from the adverse event as it occurred or it is suspected that use or continued use of the product would result in the subject's death. 'Life-threatening' does not mean that had an adverse event occurred in a more severe form it might have caused death (ie hepatitis that resolved without hepatic failure).

Hospitalisation

Out-subject treatment in an emergency room is not in itself a serious adverse event, although the reasons for it may be (eg, bronchospasm, laryngeal oedema). Hospital admissions and/or surgical operations planned before or during a study are not considered adverse events if the illness or disease existed before the subject was enrolled in the study, provided that it did not deteriorate in an unexpected way during the study.

Important medical event or medical intervention

Medical and scientific judgement should be exercised in deciding whether a case is serious in a situation where important medical events may not be immediately life-threatening or result in death, hospitalisation, disability or incapacity but may jeopardise the subject or may require medical intervention to prevent one or more outcomes listed in the definition of serious. These should usually be considered as serious. Examples of such events are:

- Angioedema not severe enough to require intubation but requiring iv. hydrocortisone treatment
- Hepatotoxicity caused by paracetamol (acetaminophen) overdose requiring treatment with N-acetylcysteine
- Intensive treatment in an emergency room or at home for allergic bronchospasm
- Blood dyscrasias (eg, neutropenia or anaemia requiring blood transfusion, etc.) or convulsions that do not result in hospitalisation
- Development of drug dependency or drug abuse

2. FURTHER GUIDANCE ON THE ASSESSMENT OF CAUSALITY

The following factors should be considered when deciding if there is a "reasonable possibility" that an adverse event (AE) may have been caused by the investigational product.

- **Time course of events and exposure to suspect drug**. Has the subject actually received the suspect drug? Did the AE occur in a reasonable temporal relationship to the administration of suspect drug?

- **Consistency with known drug profile**. Was the AE consistent with the previous knowledge of the suspect drug (pharmacology and toxicology) or drugs of the same pharmacological class? OR could the AE be anticipated from its pharmacological properties?

- **Dechallenge experience**. Did the AE resolve or improve on stopping or reducing the dose of the suspect drug?

- **No alternative cause**. The AE cannot be reasonably explained by another aetiology such as the underlying disease, other drugs, other host or environmental factors.

- **Rechallenge experience**. Did the AE reoccur if the suspected drug was reintroduced after having been stopped? AstraZeneca would not normally recommend or support a rechallenge.

- **Laboratory tests**. Has a specific laboratory investigation confirmed the relationship?

A "reasonable possibility" could be considered to exist for an AE where one or more of these factors exist.

In contrast, there would not be a "reasonable possibility" of causality if none of the above criteria apply or where there is evidence of exposure and a reasonable time course but any dechallenge (if performed) is negative or ambiguous or there is another more likely cause of the AE.

In difficult cases, other factors could be considered such as:

- Is this a recognised feature of overdose of the drug?

- Is there a known mechanism

Ambiguous cases should be considered as being a “reasonable possibility” of a causal relationship unless further evidence becomes available to refute this.

Appendix G
Additional information necessary for studies conducted in Japan

Not Applicable

1. LABELLING AND PACKAGING OF THE INVESTIGATIONAL PRODUCT

<< Insert copy of the label.>>

2. PROCEDURES FOR RANDOMISATION (REGISTRATION)

<<>>

3. ORGANISATIONAL STRUCTURE OF THE STUDY

3.1 Study sponsor

AstraZeneca K.K.
<< Name >>Executive President
Umeda Sky Building, Tower East,
1-88, 1-chome, Ohyodo-naka, Kita-ku, Osaka 531-0076, Japan

3.2 Medical expert from the sponsor

AstraZeneca K.K., Clinical Strategy Department:
<< Name >>(Physician responsible for the protocol)

3.3 Responsible person for the product, monitor, and auditor

Clinical Project Manager (CPM)

Clinical Strategy Department, Osaka office	<< Telephone number>>
Clinical Project Manager	<< Name >>

Monitors

Clinical Operations Department, Osaka office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Clinical Operations Department, Tokyo office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Auditor

Regulatory Affairs Department	<< Telephone number>>
Clinical Audit Department Manager	<< Name >>

See AstraZeneca medical emergency contact numbers (Section 9).

3.4 Co-ordinating investigator(s) (Co-ordinating committee)

<< Name >>
<< Job title>>
<< Associated hospital name>>

3.5 Person in charge of PMS management (if applicable)

AstraZeneca K.K.,
<< Name >>
Drug Safety &PMS Department Manager

3.6 Independent Data Monitoring Committee (IDMC) (if applicable)

<< Name >>
<< Job title>>
<<Associated hospital name>>

3.7 Subject inclusion registration centre

<<>>

3.8 Laboratory

<<>>

3.9 Contract Research Organisation (CRO)

<<>>

3.10 Safety Committee (In house)

May have responsibility for reviewing the following major issues around JNDA and clinical trials proposed by R&D departments such as CSD, COD or RA

A) Major changes for protocol and IB due to safety reasons

B) Across the board key code break due to safety reasons

C) Actions required due to significant safety issues ensuring for products under/for NDA

D) Discontinuation of clinical trials or test drug recall due to safety reasons

E) Other issues to ensure safety in clinical trials

4. LIST OF INVESTIGATORS AND MEDICAL INSTITUTIONS

Centre No.	Study Institutions	Department	Address	Telephone	Investigators	Job Title
<<>>						

5. ADDITIONAL REPORTING RELATED WITH SECTION 4.4.2 ADVERSE EVENTS (FOR JAPANESE PHASE III OR IV STUDY)

<<>>

AstraZeneca

Clinical Study Protocol Amendment

Amendment No.	2
Study Code	5077US/0049
Date	December 4, 2002

Sponsor:

AstraZeneca LP 1800 Concord Pike, Wilmington, DE 19850 USA

Centres affected by the amendment:

All centers who agree to participate in the Interactive Computer Interview-Depression

The protocol for the study is to be amended as follows:

Page 12 List of Abbreviations

Added ICI-D Interactive Computer Interview-Depression

CRS Concordant Rater Systems

Page 22 Table 2 Study Plan

Added Interactive Computer interview for depression on Days 1, 8, 15, 22, 29,36, 43, 50, and 57

Page 27 Section 3.4.4.4 Procedures for discontinuation

Added ICI-D

Page 53 Section 5.6 Interactive Computer Interview for Depression (ICI-D)

At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the MADRS. Raters or other site staff will first enter the subject's MADRS scores

into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

For quality assurance purposes, if an above-threshold variance is detected between the ICI-D and the MADRS on individual items or the overall score, a CRS clinician (Ph.D. or MD) will contact the applicable rater for a monitoring consultation. The CRS clinician will discuss possible reasons for the discrepancy, review conventions for scoring and offer additional training if necessary. Given that the correlation between the ICI-D and the MADRS is being evaluated, no changes to the MADRS scores will be done.

The ICI-D will also provide an additional check of the patient's suicide status. The ICI-D will alert the rater if the patient reports suicidal plans. If the patient did not verbalize these thoughts during the interview /assessment process, the rater could then take the appropriate clinical steps.

A standard operating procedure for ICI-D will be provided to the sites.

Reasons for making the amendment:

The intent of the computerized patient's self-report of depression symptoms is to test a quality monitoring and training tool for the investigators and raters at each participating site. This process may help to achieve more accurate recordings of the MADRS in future studies, the primary outcome variable in this study, by ensuring rapid feedback to the raters of any significant variance between the rater administered scale and the patient's self-. This feedback will alert the raters of possible patient misstatements, or misunderstandings report scale of the MADRS questions, which may facilitate future interview assessments.

Signed agreement to the amendment:

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

. . . . .	. . . . .
Date (day month, year)	AstraZeneca signatory Wayne Macfadden Project Physician

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

.....	.....
Date (day month, year)	AstraZeneca Signatory Gil Block Treatment Area Medical lead

AstraZeneca

Clinical Study Protocol Amendment

Amendment No.	2
Study Code	5077US/0049
Date	December 4, 2002

Sponsor:

AstraZeneca LP 1800 Concord Pike, Wilmington, DE 19850 USA

Centres affected by the amendment:

All centers who agree to participate in the Interactive Computer Interview-Depression

The protocol for the study is to be amended as follows:

Page 12 List of Abbreviations

Added ICI-D Interactive Computer Interview-Depression

CRS Concordant Rater Systems

Page 22 Table 2 Study Plan

Added Interactive Computer interview for depression on Days 1, 8, 15, 22, 29,36, 43, 50, and 57

Page 27 Section 3.4.4.4 Procedures for discontinuation

Added ICI-D

Page 53 Section 5.6 Interactive Computer Interview for Depression (ICI-D)

At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the MADRS. Raters or other site staff will first enter the subject's MADRS scores

into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

For quality assurance purposes, if an above-threshold variance is detected between the ICI-D and the MADRS on individual items or the overall score, a CRS clinician (Ph.D. or MD) will contact the applicable rater for a monitoring consultation. The CRS clinician will discuss possible reasons for the discrepancy, review conventions for scoring and offer additional training if necessary. Given that the correlation between the ICI-D and the MADRS is being evaluated, no changes to the MADRS scores will be done.

The ICI-D will also provide an additional check of the patient's suicide status. The ICI-D will alert the rater if the patient reports suicidal plans. If the patient did not verbalize these thoughts during the interview /assessment process, the rater could then take the appropriate clinical steps.

A standard operating procedure for ICI-D will be provided to the sites.

Reasons for making the amendment:

The intent of the computerized patient's self-report of depression symptoms is to test a quality monitoring and training tool for the investigators and raters at each participating site. This process may help to achieve more accurate recordings of the MADRS in future studies, the primary outcome variable in this study, by ensuring rapid feedback to the raters of any significant variance between the rater administered scale and the patient's self-. This feedback will alert the raters of possible patient misstatements, or misunderstandings report scale of the MADRS questions, which may facilitate future interview assessments.

Signed agreement to the amendment:

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

2/4/02 — Date (day month, year)

AstraZeneca signatory
Wayne Macfadden
Project Physician

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

9 Dec 2002
Date
(day month, year)

AstraZeneca Signatory
Gil Block
Treatment Area Medical lead

AstraZeneca

Clinical Study Protocol	
Drug Substance	quetiapine fumarate
Study Code	5077US/0049
Version No.	4
Date	April 21, 2003

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

The following amendment(s) have been made to this protocol since the date of preparation:

Amendment No.	**1**	**Date of amendment**	**September 30,2002**
Amendment No	**2**		**December 4, 2002**
Amendment No.	**3**		**April 21, 2003**
Administrative Change No.	**1**	**Date of administrative change**	**September 30, 2002**

PROTOCOL SYNOPSIS

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

Investigator

Multicenter trial: << To be determined >>

Study center(s) and number of subjects planned

A total of approximately 740 subjects will be screened to enroll approximately 530 into the trial in order to obtain approximately 504 evaluable patients, defined as those who have a baseline visit and at least one post baseline assessment. It is expected that approximately 75 centers will participate in the trial, with each center enrolling 8 patients (minimum 4, maximum 50).

Study period		**Phase of development**
Estimated date of first subject enrolled	September, 2002	IIIb
Estimated date of last subject completed	March, 2004	

Objectives

Primary:

To evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S)

(5) the Clinical Global Impression - Change (CGI-C).

Secondary:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by comparing

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by comparing

- the incidence and nature of all adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment
- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score from baseline to end of treatment
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Exploratory

(1) to evaluate the efficacy of quetiapine on sleep quality by comparing the change in the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

(2) to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment.

Hypotheses:

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

Secondary hypotheses are defined in Section 3.1.

Study design

Study 5077US/0049 is a randomized, multicenter, double-blind, placebo-controlled, double-dummy, parallel group, fixed-dose comparison of quetiapine vs placebo in the treatment of bipolar depression. This study will be stratified 1:1 for bipolar I and bipolar II.

Target subject population

Outpatients, aged 18 to 65 years, with a diagnosis of bipolar I or bipolar II disorder with a current major depressive episode of duration less than one year but greater than 4 weeks will be enrolled in the trial. The HAM-D (17-item scale) score must be ≥20, the HAM-D item 1 (depressed mood) score must be ≥ 2, and the YMRS score must be ≤12 at both Visit 1and Visit 2 (randomization) to be eligible for entry into the trial.

Investigational product, dosage and mode of administration

Study drug will be titrated in a blinded manner to a total daily dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and to a total daily dose of 600 mg/day by Day 8 in the 600-mg/day treatment group. Thereafter, oral doses of quetiapine fumarate will be administered in a blinded fashion once daily at bedtime (qhs) in a total daily dose of 300 or 600 mg/day. One-time dose reductions for intolerability of 100 mg/day in both the 300 mg/day and in the 600 mg/day treatment groups will be allowed at the discretion of the Investigator after Day 8.

Comparator, dosage and mode of administration

Placebo will be administered once daily with tablets matching in number and appearance to blinded quetiapine dosing.

Duration of treatment

Patients will receive double-blind, double-dummy treatment for up to 8 weeks (56 days), following an initial washout period of between 7 to 28 days (depending on the medications involved) and will come in to the clinic on Day 57 for final assessments.

Endpoints

- **Efficacy**

  Primary efficacy endpoint is the change from baseline to final assessment in the MADRS total score.

  Secondary efficacy endpoints are the percentage of patients with a $\geq$50% reduction from baseline in the MADRS total score at study endpoint, the change from baseline to each assessment (observed cases) in the MADRS total score, and the change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, and CGI-S and the CGI-C.; the change from baseline to each assessment (observed cases) and final assessment in the YMRS, and the HAM-A total scores.

- **Safety**

  Safety endpoints are the incidence and nature of all adverse events, the incidence of drug-related adverse events, the incidence of subject withdrawal due to adverse events, and the incidence of clinically significant changes in vital signs, weight, and body mass index during double-blind treatment. Tolerability endpoints are the change in the SAS total score from baseline to final assessment, the change in BARS total score from baseline to final

assessment, and the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

- **Quality of life**

  Exploratory quality of life endpoints are the change from baseline in the PSQI score and Q-Les-Q total score.

Statistical methods

All statistical comparisons will be 2-sided tests for the difference between active study medication and placebo. The primary analysis will be analysis of covariance (ANCOVA) for the change from baseline to final assessment for total MADRS score. The ANCOVA model will include terms for treatment, and stratum, with the baseline MADRS score as a covariate. Pair-wise comparisons of each dose with placebo will be assessed within this model as planned comparisons. In order to adjust for multiple comparisons with placebo a step-up procedure will be employed with a rule for tests of significance based on ordered p-values, maintaining an overall experiment wise type I error rate of 0.05. The proportion of patients having a $\geq$ 50% reduction from baseline to final assessment in MADRS will be compared across treatments using a logistic model. Change from baseline in MADRS scores at each assessment (observed cases), and change from baseline in HAM-D, HAM-D item 1, CGI-S, YMRS, HAM-A, Q-Les-Q and PSQI score at each assessment (observed cases) and LOCF, will be analyzed using the same ANCOVA model as for the primary endpoint. The CGI-C will be analyzed using the ANCOVA model with the baseline CGI-S as a covariate.

The change from baseline in SAS and BARS score data will be assessed using the same ANCOVA model as the primary endpoint. The incidence of EPS AEs and overall AEs will be reported using descriptive statistics. Vital signs, weight, and body mass index will be tabulated using descriptive statistics at baseline, final assessment, and for change from baseline. Descriptive statistics will also be used to describe the proportion of patients whose final Q-Les-Q is within community norm levels.

Repeated measures analysis of variance (ANOVA)will be performed to evaluate whether there are significant differences among treatments across time for MADRS, HAM-D, and HAM-A total scores.

Efficacy analyses will be conducted on a modified intention-to-treat (MITT) population. A per-protocol (PP) analysis will be conducted for the primary analysis measure (change from baseline MADRS) to evaluate sensitivity of the response. The safety population will include all subjects who took study medication.

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APPENDICES

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

The following abbreviations and specialist terms are used in this study protocol.

Table 1 Abbreviations and specialist terms

Abbreviation or specialist term	Explanation
AE	Adverse event (see definition in Section 4.4.2.1)
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BP	Bipolar Disorder
BPD	Bipolar Depression
CGI	Clinical Global Impression
CGI-C	Clinical Global Impression - Change
CGI-S	Clinical Global Impression - Severity
CMH	Cochran-Mantel Haenszel
CRF	Case Report Form
CRS	Concordant Rater systems
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition
EPS	Extrapyramidal symptoms
ECG	Electrocardiogram
GCP	Good Clinical Practice
HAM-A	Hamilton Rating Scale for Depression
HAM-D	Hamilton Rating Scale for Anxiety
ICH	International Conference on Harmonisation
ICI-D	Interactive Computor Interview-Depression
ICTI	Interactive Clinical Technologies, Incorporated
IEC	Independent Ethics Committee

Abbreviation or specialist term	Explanation
IRB	Institutional Review Board
IVRS	Interactive Voice Response System
LOCF	Last Observation Carried Forward
MADRS	Montgomery-Asberg Depression Rating Scale
MITT	Modified Intent to Treat
OAE	Other significant adverse event (ie, an adverse event of special interest in this clinical development; see definition in Section 4.4.2.1). The classification of OAEs will be performed by AstraZeneca drug safety physicians after the study is complete.
PSQI	Pittsburgh Sleep Quality Index
Principal investigator	The investigator who leads the study conduct at an individual study center. Every study center has a principal investigator.
Qhs	at bedtime
Q-Les-Q	Quality of Life Enjoyment Satisfaction Questionnaire
SAE	Serious adverse event (see definition in Section 4.4.2.1).
SAS	Simpson Angus Scale
SSRI	Selective serotonin reuptake inhibitors
UNI	Universal Systems Incorporated
YMRS	Young Mania Rating Scale

1 INTRODUCTION

1.1 Background

Quetiapine fumarate (SEROQUEL®, quetiapine) is a dibenzothiazepine derivative approved by the United States Food and Drug Administration (FDA) on 26 September 1997 following clinical development by AstraZeneca Pharmaceuticals LP (also referred to as the sponsor) for the treatment of subjects with schizophrenia. Quetiapine fumarate is designated chemically as bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl) piperazin-1-yl]ethoxy)ethanol] fumarate

Quetiapine has been studied in a toxicological and clinical program directed at supporting clinical evaluation in man. The results of these studies are presented in the Investigator's Brochure dated January 2002. The Professional Information Brochure (PIB) contains the current prescribing information for quetiapine.

1.2 Rationale for this study

The bipolar disorders are psychiatric disorders in which a disturbance in mood is the predominant feature. Bipolar I disorder is characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes. Bipolar II disorder is characterized by one or more major depressive episodes accompanied by at least one hypomanic episode. Bipolar depression refers to the major depressive episodes that occur with bipolar I and II disorder.

The prevalence of bipolar disorder is estimated to be 1 to 3.5%, evenly divided between men and women. The length of time between onset and symptoms and proper diagnosis and treatment is approximately 10 years and it is estimated that only 60% of those suffering from a bipolar disorder are receiving appropriate pharmacotherapy.

Although there is extensive and emerging literature guiding the treatment of the manic phase of bipolar I disorder as well as many approved compounds for the treatment of unipolar depression, the treatment of bipolar depression has not been widely studied and treatment guidelines are in their infancy. The use of currently available antidepressants for monotherapy for bipolar depression is often problematic as they may increase the "switch" into hypomania or mania from depression, or increase cycle acceleration. The adjunctive use of mood stabilizing medications such as lithium carbonate (LiCO3) is common and may decrease the likelihood of these complications.

Evidence indicates that medications with mood stabilizing properties which produced low levels of mania, hypomania, or cycle acceleration may be useful as monotherapy in the treatment of bipolar depression. The antiepileptic lamotrigine produced improvement in HAM-

D and MADRS scores in a 7-week, double-blind, placebo controlled trial for the patients who completed this study (Calabrese 1999). More recently, the anti-manic agent divalproex demonstrated numerical improvement over placebo in the percentage of patients with bipolar depression having a 50% reduction in the HAM-D scores without mania in an 8 week trial (Sachs, 2001) but this difference was not statistically significant. Lithium carbonate, also approved for the treatment of mania, has been demonstrated to be effective as a monotherapeutic agent in approximately 50% of patients with bipolar depression (Bauer). However, there are efficacy and tolerability limitations which mkay prohibit widespread use of the above therapies.

A large multicentered, double-blind, placebo controlled trial was recently completed, which demonstrated efficacy of the atypical antipsychotic olanzapine as monotherapy for the treatment of bipolar depression (Tohen, 2002). The endpoint mean MADRS change was significantly greater for patients on olanzapine (-15.0 points) than for those on placebo (-11.9 points). Treatment-emergent mania did not differ significantly between groups. There also is evidence from small uncontrolled studies that other atypical antipsychotics such as risperidone, and clozapine have mild to moderate antidepressant activity when used in patients with mood disorders. These small studies also indicate that these compounds are unlikely to cause patients to “switch” into mania.

The potential efficacy of quetiapine in depressive symptoms is provided in data from the Quetiapine Experience with Safety and Tolerability Trial (QUEST) and from investigator-initiated trials in mood disorder patients. In an open-label trial evaluating the safety and tolerability of quetiapine over 700 subjects with schizophrenia and other psychotic disorders were randomized to treatment with quetiapine or risperidone. Quetiapine-treated patients experienced a greater improvement in depressive symptoms compared with risperidone-treated patients, with a mean difference of 1.3 points on the HAM-D after adjustment for baseline differences (P=0.028) (Mullen et al, 2001).

A trial of quetiapine in 20 neuroleptic-dependent patients with bipolar or schizoaffective disorder also suggested positive effects on the depressive and psychotic symptoms in these disorders (Sajatovic et al, 2001). Overall, in 10 patients with bipolar disorder and 10 with schizoaffective disorder who received open-label quetiapine to optimum clinical dosage (25 to 800-mg), significant improvement in Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), and HAM-D scores was noted.

In summary, the paucity of satisfactory treatments available signify an unmet medical need for the treatment of bipolar depression. There are signals of efficacy from clinical trials for the antidepressant properties of atypical antipsychotics such as quetiapine.

2 STUDY OBJECTIVES

2.1 Primary objective

The primary objectives of the study are to evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the total Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S), and the Clinical Global Impression - Change (CGI-C).

2.2 Secondary objective

The secondary objectives of the study are:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by

- the incidence and nature of overall adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment

- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Experimental:

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in sleep quality using the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment
2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment

3 HYPOTHESES, STUDY PLAN AND PROCEDURES

3.1 Hypotheses

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

(1) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(2) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(3) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(4) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(5) Quetiapine at a dose of 300 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(6) Quetiapine at a dose of 600 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(7) Quetiapine at a dose of 300-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(8) Quetiapine at a dose of 600-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(9) Quetiapine at a dose of 300 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(10) Quetiapine at a dose of 600 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(11) Quetiapine at a dose of 300 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(12) Quetiapine at a dose of 600 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(13) Quetiapine at a dose of 300 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

(14) Quetiapine at a dose of 600 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

3.2 Overall study design and flow chart

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial will consist of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects will be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment of

8 patients per center (minimum 4 maximum 30). Subjects are required to have a HAM-D (17-item scale) score of $\geq$ 20 and a YMRS of $\leq$12 at screening baseline (Visit 1).

The trial comprises the following 2 periods:

- Washout period
  Subjects will undergo HAM-D, SCID, YMRS, and safety evaluations at screen (Visit 1) and if they qualify to participate they will commence a washout of antidepressant, antipsychotic, and mood stabilizer medications. The number of days for washout will depend on the medication they are taking. These medications must be discontinued for a period of at least 7 days prior to randomization (Day 1, Visit 2), with the exception of fluoxetine which must be discontinued for a period of 14 days prior to randomization (Day 1, Visit 2) and depot injections of haloperidol decanoate or fluphenazine decanoate which need 28 days washout before randomization.

- 8-week double-blind randomized treatment period (Weeks 1 to 8)
  Eligible subjects will be randomized on Day 1 (Visit 2) to 1 of 3 treatment groups: quetiapine 300 mg/day, quetiapine 600 mg/day, or placebo. The randomization will be done using a stratification based on diagnosis. Treatment will be administered once daily at bedtime for 8 weeks (Days 1 - 56). Subjects will not receive medication on Day 57 which is only for final assessments. Doses will be titrated to achieve target doses of 300 mg/day within 4 days or 600 mg/day within 8 days. A dose reduction of 100 mg is allowed to improve patient tolerance in each treatment group. MADRS assessments (used to evaluate the primary efficacy variable) will be performed at Days 1, 8, 15, 22, 29, 36, 43, 50, and 57.

Figure 1 Study flow chart

			Treatment										
Day	**Screen**	**Washout [b]**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9-14**	**15-56**	**57**
	Visit 1		**Visit 2**							**Visit 3**		**Visits 4-9**	**Visit 10**
Dose: 300-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	
Dose: 600-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	400-mg	400-mg	400-mg	600-mg	600-mg	600-mg	

[a] One time dose reductions of 100 mg/day in 300-mg and 600-mg may occur after Day 8

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers for 7 to 28 days depending on the medication involved (eg. haloperidol decanoate or fluphenazine decanoate for 28 days), prior to randomization. Patients on fluoxitine must discontinue for 14 days.

Table 2 Study plan

Study plan	Screen	Washout [a]	Double-blind treatment phase Weeks 1 through 8								
Days			**1**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**
Visits	**1**		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Informed consent	√										
Medical history	√										
Inclusion/Exclusion criteria	√		√								
Structured Clinical Interview for DSM-IV (SCID)	√										
Physical examination [d]	√										√
Urine toxicology screen	√										
Pregnancy tests (females)	√										
Vital signs, height, weight [c,e]	√		√	√	√	√	√	√	√	√	√
12-lead electrocardiogram	√		√[b]								√
Clinical chemistry and hematology	√		√[b]								√
Hamilton Rating Scale for Depression (17-item)	√		√	√	√	√	√	√	√	√	√
Montgomery-Asberg Depression Rating Scale			√	√	√	√	√	√	√	√	√
Interactive Computer Interview-Depression			√	√	√	√	√	√	√	√	√
Young Mania Rating Scale	√		√	√	√	√	√	√	√	√	√
Hamilton Rating Scale for Anxiety			√	√	√	√	√	√	√	√	√
Clinical Global Impression - Severity	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression -Change				√	√	√	√	√	√	√	√
Barnes-Akathisia Rating Scale			√								√
Simpson-Angus Scale			√								√
Pittsburgh Sleep Quality Index			√				√				√
Quality of Life Enjoyment Satisfaction Questionnaire			√				√				√
Dispense study medication			√	√	√	√	√	√	√	√	
Adverse events	√	√	√	√	√	√	√	√	√	√	√

[a] Washout of antidepressants, antipsychotics, mood stabilizer for 7 to 28daysdepending on the medications involved and a 14-day washout for fluoxetine.

[b] Repeat laboratory tests and ECG only if results outside of normal range and clinically significant at Screening

[c] Height and weight on screen and weight on Day 57

[d] Physical exam includes ophthalmoscopic exam on screen

[e] Blood pressure will be obtained in supine and standing positions

3.3 Rationale for study design, doses and control groups

This trial is designed as a double-blind placebo-controlled evaluation of Seroquel as monotherapy in bipolar depression. There is no currently approved compound for use in bipolar depression, nor is there a clinically accepted "gold standard". Conventional antidepressants have fallen out of favor because of their ability to induce manic symptoms. Antidepressants approved forthe treatment of unipolar depression have not been demonstrated to improve mood symptoms relative to placebo (Nemeroff et al Am J Psychiatry 158:6 June 2001). Moreover, there is a high placebo response rates of approximately 30% found in bipolar depression trials. Thus, the use of a placebo treatment arm for comparison is clinically justified.

Trial treatment will be administered as quetiapine monotherapy in order to more clearly identify a treatment effect of quetiapine on bipolar depression. Quetiapine fumarate will be administered once daily at bedtime. The current label specifies twice daily (BID) but a double-blind crossover study in bipolar patients indicated that once daily (qd) is well tolerated and as effective as BID dosing (Chengappa, 2002).

A period of 7 to 28 days is adequate for washout of most psychoactive medications including antidepressants, antipsychotics (including depot agents), and mood stabilizers to ensure that subjects are stable and continue to have adequate depressive symptoms requiring treatment, prior to randomization into the trial. The double-blind treatment period of 8 weeks is consistent with the time period that is required to see a clinically meaningful response in depressive symptoms.

The trial is designed as a fixed-dose evaluation due to the failure of flexible dose regimens in other psychiatric disorders. The dosages are based on clinical trial data with quetiapine in patients with a mood disorder. In the QUEST trial, the average dose of quetiapine in patients with a primary mood disorder (N=316) was approximately 250 mg/day at 16 weeks. In 20 patients with bipolar or schizoaffective disorder treated with open-label quetiapine, the mean dose was approximately200 mg/day (Sajatovic). Based on this data, 300 mg/day administered as monotherapy is an appropriate low-dose treatment arm, and 600 mg/day is an appropriate high-dose treatment arm that should exhibit efficacy without a high rate of AEs or noncompliance.

The MADRS is a standardized, well-validated measure of depressive symptoms that is sensitive to treatment effects in depressed outpatients.

3.4 Selection of study population

3.4.1 Study selection record

Investigators must keep a record of subjects who underwent screening but were not randomized into the trial.

3.4.2 Inclusion criteria

At screen (Visit 1) subjects must fulfill all of the following criteria:

(1) Documented ability to provide informed consent before beginning any study-specific procedures.

(2) Male and female patients between 18 and 65 years of age, inclusive

(3) Females of childbearing potential, be using a reliable method of contraception. Reliable methods include hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

(4) Women must have a negative pregnancy test

(5) Meets DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x), confirmed by the amended version(by Dr. Michael First) of the Structured Clinical Interview for DSM-IV (SCID) as administered by an AstraZeneca approved clinician with a signed confirmation by the Principal Investigator

(6) Outpatient status

(7) HAM-D (17-item) total score of 20 or greater

(8) HAM-D item 1 (depressed mood) score $\geq$2

(9) YMRS total $\leq$12

At randomization (Visit 2) subjects must fulfill the following criteria:

(1) HAM-D (17-item) total score of 20 or greater

(2) HAM-D item 1 (depressed mood) score $\geq$2

(3) YMRS total $\leq$12

3.4.3 Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

(1) Patients with a current Axis I disorder other than bipolar disorder within 6 months of screening

(2) Patients whose current episode of depression exceeds 12 months or is less than 4 weeks

(3) History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode

(4) Patients who meet DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening

(5) Patients with a positive urine toxicology screen for illicit substances of abuse

(6) Patients who are unable to discontinue all psychoactive medications (excluding prn benzodiazepines), including antidepressants, antipsychotics, and mood stabilizer, at least 7 days prior to randomization and consistent with the pharmacokinetics of the drug

- Patients treated with fluoxetine who have not discontinued this medication for at least 14 days prior to randomization.
- Patients treated with haloperiodol decanoate or fluphenazine decanoate who have not discontinued these medications 28 days prior to randomization.

(7) Patient who have not discontinued the use of potent P450 inhibitors and inducers (See Section 4.3, Table 13)

(8) Patients who in the investigators opinion will require initiation of psychotherapy during the study period. Note: ongoing psychotherapy for a minimum of 3 months may continue.

(9) Patients who, in the investigator's judgment, pose a current serious suicidal or homicidal risk at Visit 1 (HAM-D item 3 score of 3 or greater), or have made a suicide attempt within the past 6 months

(10) Patients with a history of clinically significant cardiac, renal, neurologic, cerebrovascular, metabolic, or pulmonary disease, or other disease or clinical finding that is unstable or that, in the opinion of the investigator, would be negatively affected by trial medication or that would affect trial medication

(11) Patients who have had a myocardial infarction within 1 year before Visit 1

(12) Patients with clinically significant abnormal laboratory findings at Visit 1

(13) Patients with renal impairment (serum creatinine ≥1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal)

(14) Patients whose TSH is ≥10% over the upper normal limit. Patients maintained on thyroid medication must be euthyroid for a period of at least 3 months before Visit 1

(15) Patients with clinically significant abnormalities on ECG

(16) Women who have a positive human chorionic gonadotropin (HCG) pregnancy test at Visit 1 or who are lactating or planning to become pregnant during the course of the study

(17) Patients who have participated in a clinical trial of an investigational drug within the past 3 months

(18) Patients who, in the opinion of the investigator, would be non-compliant with the visit schedule or study procedures

(19) History of orthostatic hypotension or conditions that would predispose them to hypotension (eg dehydration, hypovolemia)

(20) Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of Seroquel tablets, as judged by the investigator

3.4.4 Restrictions

Subjects will be required to adhere to the following special restrictions:

1) Use of any psychoactive drugs including antidepressants, hypnotics (with the exceptions noted in Section 4.3), mood stabilizing drugs, and antipsychotics is not permitted from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

2) Use of cytochrome P450 3A4 inducers and potent inhibitors are not permitted from 14 days prior to randomization to end of study (see Table 13)

3.4.4.1 Criteria for discontinuation

Subjects may be discontinued from study treatment and assessments at any time, at the discretion of the investigator(s). Specific reasons for discontinuing a subject from this study are:

1. Withdrawal of informed consent

2. Worsening psychiatric symptoms such that the symptoms constitute a danger to themselves or to others

3. Use of psychotropic medications at any time during the double-blind treatment period.

4. Pregnancy at any time during the double-blind treatment period.

5. Clinically significant or serious adverse event that would not be consistent with continuation in the study, as determined by the investigator, AstraZeneca, or the subject.

3.4.4.2 Voluntary discontinuation by a subject

Subjects are free to discontinue their participation in the study at any time, without prejudice to further treatment. Subjects who discontinue from the study should always be asked about the reason(s) for their discontinuation and about the presence of any adverse events. They should be seen and assessed by an investigator(s) (see Section 3.4.4.4). Adverse events should be followed up and any diary cards, questionnaires (eg, for Quality of Life assessments) and investigational products should be returned by the subject.

3.4.4.3 Incorrectly enrolled or randomized subjects

Incorrectly enrolled subjects will be discontinued from further study treatment and assessments. If a subject is given the incorrect randomized treatment, the subject should be continued on the treatment dispensed and Interactive Clinical Technologies, Inc. (ICTI), the vendor providing the randomization patient assignment) should be notified of the error. The next patient randomized at the site will be assigned an appropriate kit number by ICTI, accounting for the error.

3.4.4.4 Procedures for discontinuation

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination
- Vital signs and weight
- 12-lead ECG
- HAM-D
- MADRS

- ICI-D
- YMRS
- HAM-A
- SAS
- BARS
- PSQI
- Adverse events assessment

3.5 Treatments

3.5.1 Investigational products

3.5.1.1 Identity of investigational product and comparators

Investigational product will consist of 25-mg , 100-mg, and 200-mg tablets of quetiapine fumarate and matching placebo tablets as shown in Table 3.

Table 3 Trial medication

Tablet strength	Formulation number	Tablet color
25-mg quetiapine	F12804	peach
25- mg placebo	F12636	peach
100-mg quetiapine	F12689	yellow
100-mg placebo	F12637	yellow
200-mg quetiapine	F12690	white
200-mg placebo	F12638	white

3.5.1.2 Doses and treatment regimens

Quetiapine and placebo for each trial center will be packaged in blister cards. The 8-week supply will consist of 8 double-blind blister cards. The 8 double-blind blister cards will be packaged in subject-specific cartons.

Trial medication will be provided for each subject in an 8-card carton that contains the following:

- 1-week titration double-blind treatment cards for Days 1-7

- seven 1-week double-blind treatment cards for Days 8-56, with individual cards provided for treatment Days 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, and 50-56.
  Each one-week blister card will include a 2-day treatment overage to accommodate visit schedules.

The Week 1 titration card will consist of 25 mg tablets, 100-mg tablets, and 200-mg tablets or matching placebo, as described below, for each of the 300 mg/day and 600 mg/day treatment groups and placebo treatment group.

Blister cards for Weeks 2 through 8, for each treatment group, will consist of 9 days of dosing with the same number of pills for each group (300-mg,600-mg, and placebo) respectively. The cards for each treatment group will consist of 2 yellow tablets and 2 white tablets per day at bedtime.

Quetiapine or placebo will be administered once a day at bedtime with dose titration to reach a target dose of 300 mg/day by Day 4 in the 300 mg/day treatment group and 600 mg/day by Day 8 in the 600 mg/day group. The schedule for quetiapine or placebo administration is shown in Tables 4, 5, and 6.

Table 4 Dose administration schedule for 300-mg double-blind quetiapine

Trial Day	Quetiapine 300 mg/day and placebo				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablet/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 6	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 7	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 8	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg
Days 9-56	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg

Table 5 Dose administration schedule for 600-mg double-blind quetiapine

Trial Day	Quetiapine 600 mg/day and placebo tablets				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablets/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 6	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 7	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 8	0	2 tablets/100-mg	0	2 tablets/400-mg	0
Days 9-56	0	2 tablets/100-mg	0	2 tablets/400-mg	0

Table 6 Dose administration schedule for double-blind placebo

Trial Day			
	Placebo 25mg	**Placebo 100 mg**	**Placebo 200 mg**
Day 1	2 tablets/50-mg	0	0
Day 2	0	1 tablet/100-mg	0
Day 3	0	0	1 tablet/200-mg
Day 4	0	1 tablet/100-mg	1 tablet/200-mg
Day 5	0	2 tablets/100-mg	1 tablet/200-mg
Day 6	0	2 tablets/100-mg	1 tablet/200-mg
Day 7	0	2 tablets/100-mg	1 tablet/200-mg
Day 8	0	2 tablets/100-mg	2 tablets/400-mg
Days 9-56	0	2 tablets/100-mg	2 tablets/400-mg

Dosing Reduction

Dose reductions for intolerability will be allowed after Day 8. In the 300-mg/day group, dose reductions of 100 mg/day will be achieved by reducing the dose by one 100-mg tablets. In the 600-mg/day group, a dose reduction of 100 mg/day will be achieved by reducing the bedtime dose by one 100-mg tablets active drug. This dose reduction can occur anytime after Day 8. Each column in the blister packs will be numbered 1-4. By Day 6 columns 1 and 2 of the blister packs will each contain a 100-mg tablet. In both the 300-mg /day group and the 600-mg/day group, column 1 will contain active medication thus ensuring that by eliminating the first column (column #1) of medication they are reducing their dose by 100-mg. Each tablet in the placebo treatment group will also indicate the same corresponding numbers (columns #1-4) as the active treatment groups even though no active product is packaged. This will ensure the blind is maintained.

Table 7 Week 1 Blister pack for 300-mg/Day Quetiapine Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 8 Week 2-8 300-mg/Day Quetiapine Blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
2	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
3	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
4	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 9 Week 1 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 10 Week 2-8 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
2	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
3	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
4	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 11 Week 1 Blister Pack for Placebo Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg placebo	25-mg placebo		
2	100-mg placebo			
3	200-mg placebo			
4	100-mg placebo	200-mg placebo		
5	100-mg placebo	100-mg placebo	200-mg placebo	
6	100-mg placebo	100-mg placebo	200-mg placebo	
7	100-mg placebo	100-mg placebo	200-mg placebo	
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Table 12 Week 2-8 Blister pack for Placebo/Day Group

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
2	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
3	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
4	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
5	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
6	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
7	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

3.5.1.3 Labeling

All trial supplies will be provided by AstraZeneca.

The blister cards Days 1- 56 will be supplied in subject-specific cartons. Each blister card will be labeled with a two-panel, double-blind label. The left portion of the label will remain on the blister card. The right portion of the label will be affixed to the appropriate Case Report Form (CRF) as part of the individual's permanent record. The label will contain at least the following information: trial number, code assignment and storage condition. The carton for the 8 blister cards for Days 1-56 will be labeled with a single-panel double-blind label. The label will contain at least the following information: trial number, storage conditions, and instructions to dispense according to protocol.

3.5.1.4 Storage

All investigational products must be kept in a secure and locked location, at room temperature and protected from light and moisture.

3.5.1.5 Accountability

The investigational materials are to be prescribed only by the investigator or the sub-investigators named in Form FDA-1572. Under no circumstances will the investigator allow the investigational drug to be used other than as directed by the protocol without prior AstraZeneca approval.

The investigator must maintain accurate records accounting for the receipt of the investigational materials (ICTI provides a acknowledge the receipt of drug shipment module for this purpose) and for the disposition of the material. This record keeping consists of a dispensing record that includes the identification of the person to who the drug is dispensed, the quantity and the date of dispensing, and documentation of any unused drug returned to the investigator. This record is in addition to any drug accountability information recorded on the subject's hospital or clinic chart.

Starting with Week 1, each patient will return the blister card for the preceding week to the clinic. The clinic will tabulate the returned pills to aid in drug accountability.

At the termination of the study or at the request of the sponsor, the Clinical Research Associate must return any unused study supplies to Universal Systems Incorporated (USI), at the address listed below, for destruction. This return will be documented on an Investigational Product Return Invoice supplied by AstraZeneca.

USI
2084-900 Lake Industrial Court
Conyers, GA 30013

3.5.2 Method of assigning subjects to treatment groups

This trial will be established with a non-specific labeling (NCSL) randomization which will be stratified by bipolar type. Randomization to trial treatment will be done via an Interactive Voice Response System (IVRS) at ICTI on Day 1 (Visit 2) in balanced blocks within each stratum in order to ensure relative balance among treatment groups and strata (Bipolar I and Bipolar II)in terms of total number of subjects. The randomization schedule will be created under the auspices of AstraZeneca Quantitative Decision Sciences Group and will provide allocation of subject numbers to the treatment regiments. Number and size of tablets will be identical for the 3 treatment arms. Clinical supplies will contain a 4-digit subject number which is allocated to the treatment arm through the randomization scheme. A separate randomization will be used to provide kits of packaged drugs to the sites. The IVRS system at ICTI will allocate a kit number at the site for the treatment assigned through the stratified randomization.

Subject eligibility will be established before treatment randomization. Subjects will be randomized centrally sequentially within the stratum, as subjects are eligible for enrollment/randomization. If

a subject discontinues from the study, the subject number will not be reused, and the subject will not be allowed to re-enter the study.

The randomization is centralized and the assigned randomized patient number and associated kit numbers will not be sequential within a site.

3.5.3 Blinding and procedures for unblinding the study

3.5.3.1 Methods for ensuring blinding

All packaging will be identical with placebo and active tablets identical in size and color. The number of tablets dispensed on each card will be identical across all treatment arms.

The randomization for the kit assignments will be generated by the study statistician and provided directly to packaging with a copy going to ICTI Clinical Supplies Management Group. The stratified patient randomization will be generated by an AstraZeneca randomization staff member not associated with the trial and will be provided directly to ICTI for incorporation into the IVRS system. No member of the study team in AstraZeneca, at investigational sites or the CRO organization handing data will have access to the randomization scheme during the conduct of the study.

3.5.3.2 Methods for unblinding the study

Individual treatment codes, indicating the treatment randomization for each randomized subject, will be available to the investigator(s) or pharmacists at the study center through the use of a concealed panel on the label.

The treatment code must not be broken except in medical emergencies when the appropriate management of the subject necessitates knowledge of the treatment randomization. The investigator(s) must document and report to AstraZeneca any breaking of the treatment code. AstraZeneca retains the right to break the code in order to report serious adverse events to regulatory authorities.

Treatment codes will not be broken for the planned analyses of data until all decisions on the evaluability of the data from each individual subject have been made and documented.

3.5.4 Treatment compliance

Compliance will be assessed based on returned tablet counts. The percent compliance will be calculated as the number of tablets taken (dispensed - returned) divided by the prescribed number of tablets (number of days times number of tablets per day) expressed as a percent. Based on this

calculation a subject with at least 75% compliance with study medication during study participation will be classified as compliant.

Furthermore, if there are any significant irregularities in compliance, in the opinion of the investigator, the patient should be withdrawn from the study.

4 CONCURRENT TREATMENT

4.1 General medications

Nonpsychotropic medication, including over-the counter medications, taken by the subject before entry into the trial may be continued during the trial. Medications required to treat illnesses or complaints that occur during the trial may be used at the discretion of the investigator. Use of cytochrome P450 inducers and potent inhibitors is restricted (see Table 13 below).

Women who enter the trial with an intrauterine device in place, using oral contraceptives, or using injectable or implantable hormonal agents designed to prevent pregnancy may continue these treatments throughout the trial.

The specific type of medication (trade or generic name), the indication for use, and the dates of usage should be reported on the CRF entitled Concurrent Treatment.

Medication which is considered necessary for the subject's safety and well being may be given at the discretion of the investigator(s). The administration of all medication (including investigational products) must be recorded in the appropriate sections of the case report form (CRF).

4.2 Use of psychoactive medications

The use of psychoactive drugs other than those specifically allowed during the trial (ie, lorazepam and zolpidem tartrate) is restricted (see Section 4.3, Table 13).

4.3 Summary of permitted concurrent medications

Medications specifically prohibited or restricted, and those permitted during the trial are listed in Table 13

Table 13 Permitted, restricted, and prohibited medications

Use category	Type of medication
Permitted	Previous medications for medical, nonpsychiatric illnesses Oral contraceptives and contraceptive devices
Restricted	Zolpidem tartrate 5-10 mg at bedtime for insomnia Lorazepam 1-3 mg per day for severe anxiety These drugs may be prescribed during the first 3 weeks of the study as long as they do not interfere with any assessments
Prohibited	Potent cytochrome P450 3A4 inducers (including but not limited to barbiturates, carbamazepine, rifampin, and St John's Wort) Potent cytochrome P450 3A4 inhibitors (including but not limited to ketoconazole, itraconazoole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir, and saquinavir) Antipsychotic medications (including but not limited to phenothiazines, risperidone, olanzapine, ziprasidone, clozapine, loxapine, thiothixene, molindone) Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a period of 7 to 28 days depending on the medications involved (eg. 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

5 STUDY MEASUREMENTS AND ENDPOINTS

5.1 Primary endpoint

The primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score. This endpoint is used as the basis for the sample size calculation, as provided in Section 6.1.

5.2 Screening and demographic measurements

The following data are to be collected at screening:

- date of birth, sex, and race
- vital signs, height, weight
- supine and standing blood pressure and pulse
- significant medical history
- physical examination including ophthalmoscopic exam
- 12-lead electrocardiogram
- clinical chemistry and hematology
- pregnancy test (if female of childbearing potential)
- HAM-D assessment
- YMRS
- DSM-IV diagnosis, based on SCID assessment

5.3 Efficacy measurements and endpoints

The following assessments will be used to evaluate efficacy:

- change from baseline to final assessment in MADRS total score
- percentage of subjects with $\geq$50% reduction from baseline in MADRS total score at final assessment
- the change from baseline in each assessment (observed cases) in the MADRS total score

- the change from baseline to each assessment (observed cases) and final assessment in the CGI-S
- the CGI-C at final assessment
- the change from baseline to each assessment (observed cases) and final assessment in the YMRS
- the change from baseline to each assessment (observed cases) and final assessment in the total HAM-A

Evaluation using each of these scales should be performed by the same trained/certified staff member who has been approved by AstraZeneca for all assessments of the scale for an individual subject.

5.3.1 Summary of efficacy objectives and endpoints

Table 17 shows how the efficacy endpoints of this study relate to the study objectives.

Table 14 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Primary	Primary measure		
evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks	change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score; ls means, 95% CI at final assessment ; descriptive statistics by statum	ANCOVA for the change from baseline to final assessment for total MADRS score. Pair-wise comparisons of each dose with placebo using step up procedure	Reductions in MADRS compared with placebo will indicate doses which are effective in treating depressive episode
	Secondary measure		
	percentage of subjects meeting the MADRS responder criteria ; n, percentage responders at each assessment, final assessment ; descriptive statistics by statum	Logistic model	Higher response rates will indicate doses which are effective in treating depressive episode in treating depressive episode
	change from baseline to each assessment for the MADRS total score, and	ANCOVA for the change from baseline to each assessment	Reductions in scales compared with placebo will indicate doses

	each assessment and final assessment Clinical Global Impression - Severity (CGI-S); ls means, 95% CI; descriptive statistics by stratum	and final assessment (LOCF) for CGI-S. Pair-wise comparisons of each dose with placebo	which are effective in treating depressive episode
	Clinical Global Impression - Change (CGI-C); ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the CGI-C for each assessment and final assessment (LOCF). Pair-wise comparisons of each dose with placebo	Greater improvements in CGI-C will indicate doses which are effective compared with placebo
Secondary			
evaluate the efficacy of quetiapine compared to placebo in the incidence of treatment -emergent mania	change from baseline to each assessment and final assessment in the YMRS total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for YMRS total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	No significant increase in the YMRS compared to placebo will indicate doses which do not result in treatment-emergent mania
evaluate the effect of quetiapine compared to placebo on symptoms of anxiety	change from baseline to each assessment and final assessment in the HAM-A total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for HAM-A total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Improvement in the HAM-A compared to placebo will indicate efficacy in treating anxiety component of the depressive episode

The methods for collecting efficacy data are presented below.

5.3.2 Montgomery-Asberg Depression Rating Scale (MADRS)

5.3.2.1 Methods of assessment

The MADRS will be performed at each visit during the trials using the validated MADRS instrument by certified staff at each site.

5.3.2.2 Calculation or derivation of endpoint

The change from baseline to final LOCF will be calculated for total MADRS score. A subject will be classified as a responder if the % change from baseline, calculated as the (change from baseline divided by the baseline) multiplied by 100 indicates a ≥ 50% reduction in baseline total MADRS score.

5.3.3 Hamilton Rating Scale for Depression (HAM-D)

5.3.3.1 Methods of assessment

The HAM-D will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-D and HAM-D item #1.

5.3.4 Clinical Global Impression - Severity (CGI-S)

5.3.4.1 Methods of assessment

The CGI-S will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.4.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in CGI-S.

5.3.5 Clinical Global Impression - Change (CGI-C)

5.3.5.1 Methods of assessment

The CGI-C will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.5.2 Calculation or derivation of endpoint

The CGI-C is a measure of change from baseline and therefore requires no further derivation.

5.3.6 Hamilton Rating Scale for Anxiety (HAM-A)

5.3.6.1 Methods of assessment

The HAM-A will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.6.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-A.

5.3.7 Young Mania Rating Scale (YMRS)

5.3.7.1 Methods of assessment

The YMRS will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.7.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in YMRS.

5.4 Safety measurements and endpoints

The following measurements will be used to assess safety:

- adverse event reporting (both general adverse events and serious adverse events), coded using MedDRA system of nomenclature
- fasting clinical laboratory tests (including chemistry and hematology)
- vital signs(taken in both the standing and supine positions)
- ECG tests
- Simpson-Angus Scale
- Barnes-Akathesia Rating Scale

5.4.1 Summary of safety objectives and endpoints

Table 13 shows how the safety endpoints of this study relate to the study objectives.

Table 15 Safety objectives and endpoints relating to each objective

Objective	Endpoints and statistic	Planned analysis	Significance of results
evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	incidence and nature of adverse events during double-blind treatment ; n, % incidence per event, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	no new safety issues identified
	incidence of drug-related adverse events during double-blind treatment ; n, % incidence; titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of subject withdrawal due to adverse events; n, % withdrawn, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of clinically significant changes in vital signs; n, % at each assessment and final visit	descriptive statistics only	
	change in the SAS total score ; mean change, standard deviation, baseline to final assessment (LOCF)	descriptive statistics only	
	the change in BARS total score	descriptive statistics only	
	incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment	descriptive statistics only	

The methods for collecting safety data are described below.

5.4.2 Adverse Events

5.4.2.1 Definitions

The definitions of adverse events (AEs), serious adverse events (SAEs) and other significant adverse events (OAEs) are given below. It is of the utmost importance that all staff involved in the study is familiar with the content of this section. The principal investigator is responsible for ensuring this.

(a) Adverse Event

An adverse event is the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver) or the abnormal results of an investigation (eg, laboratory findings, electrocardiogram). In clinical studies, an AE can include an undesirable medical condition occurring at any time, including run-in or washout periods, even if no study treatment has been administered.

(b) Serious Adverse Event

A serious adverse event is an AE occurring during any study phase (ie, run-in, treatment, washout, follow-up), and at any dose of the investigational product, comparator or placebo, that fulfills one or more of the following criteria:

- results in death
- is immediately life-threatening
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- is a congenital abnormality or birth defect
- is an important medical event that may jeopardize the subject or may require medical intervention to prevent one of the outcomes listed above?

The causality of SAEs (ie, their relationship to study treatment) will be assessed by the investigator(s), who in completing the relevant case report form must answer “yes” or “no” to the question “Do you consider that there is a reasonable possibility that the event may have been caused by the drug?” For further guidance on the definition of a SAE and a guide to the interpretation of the causality question, see Appendix F.

(c) Other significant adverse event

An AstraZeneca expert will identify OAEs during the evaluation of safety data for the Clinical Study Report. Significant adverse events of particular clinical importance, other than SAEs and those AEs leading to discontinuation of the subject from study treatment, will be classified as OAEs. Examples of these are marked hematological and other laboratory abnormalities, and certain events that lead to intervention (other than those already classified as serious), dose reduction or significant additional treatment. For each OAE, a narrative will be written and included in the Clinical Study Report.

5.4.2.2 Recording of adverse events

All AEs and SAEs that occur before and during treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. Following cessation of treatment, SAEs, whether or not related to the study drug, must be collected for 7 days and recorded on the CRF provided by the sponsor. If any SAEs are recorded during the 7 day follow-up period, all concomitant medications taken during the 7 day follow-up period should also be recorded on the CRF. A description of the event, its intensity, duration, action taken (eg, treatment and follow-up tests), and outcome should be given, along with the investigator's causality assessment of the relationship of the event to the study drug. If a diagnosis of the subject's condition has been made, then the diagnosis should be recorded as the SAE. In instances of well recognized syndromes (eg, fever, runny nose, cough) they can be recorded as "flu". However, if a diagnosis of the subject's condition has not been made, or if the individual symptoms are not well recognized, then the individual symptoms should be recorded separately.

In general, abnormal laboratory tests or vital signs should not be reported as AEs unless they fulfill the criteria for an SAE or lead to discontinuation. If an abnormal laboratory test result or vital sign is associated with clinical signs and symptoms, the sign or symptom should be reported as an AE, and the associated test result or vital sign should be recorded on the appropriate CRF.

A causality assessment must be recorded for all AEs. The CRF asks the question, "In your medical judgement, is there a reasonable possibility that the event may have been caused by the study therapy?" If there is any valid reason, even if undetermined or untested, for suspecting a possible cause-and-effect relationship between the study drug and the occurrence of the AE, then this should be answered "yes." Otherwise, if no valid reason exists for suggesting a possible relationship, then this should be answered "no." If more than 1 AE is identified, a causality assessment must be made for each AE.

It is important to distinguish between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined by the criteria in Section 5.4.2.1 b. An AE of severe intensity need

not necessarily be considered serious. For example, nausea which persists for several hours may be considered severe nausea, but not a SAE. On the other hand, a stroke which results in only a limited degree of disability may be considered a mild stroke but would be a SAE.

Any detrimental change in the subject's condition after the subject enters the study will be discussed with the investigator. Where the detrimental change is considered by the investigator to constitute a progression or relapse of bipolar depression or a lack of efficacy, then this will not be considered an AE even where this necessitates or prolongs hospitalization. When there is deterioration in the condition for which the medicine is being used, there may be uncertainty as to whether this is lack of efficacy or an AE. In such cases, unless AstraZeneca or the reporting physician considers that the medicine contributed to the deterioration, the deterioration should be considered lack of efficacy. However, if it is believed that the medicine may have contributed to the deterioration, then this should be treated as an AE.

Study drug abuse is an SAE, even when there are no symptoms or additional AEs and should be reported according to the guidelines in Section 5.4.2.3. Misuse of study drug is an AE but is not considered an SAE unless accompanied by serious sequelae.

Should an overdose occur, it must be reported in accordance with the procedures described in Section 10.3 Procedures in case of overdose. All overdoses, with or without associated symptoms, should be reported as AEs.

Suicide and attempted suicide, irrespective of the method, but occurring in connection with the use of study drug, should be reported as AEs (serious or non-serious). This event should be identified as suicide or attempted suicide, and the method of the suicide or attempt should be provided. If an attempted suicide meets the criteria for an SAE, the event must be reported according to the guidelines in Section 10.4.

Should a pregnancy occur, it must be reported in accordance with the procedures described in Section 10.5. Procedures in case of pregnancy. Pregnancy in itself is not regarded as an AE unless there is a suspicion that an investigational product may have interfered with the effectiveness of a contraceptive medication.

5.4.2.3 Reporting of serious adverse events

Investigators and other site personnel must inform appropriate AstraZeneca representatives of any SAE that occurs in the course of the study within 1 day (i.e. immediately but no later than the end of the next business day) of when he or she becomes aware of it.

The AstraZeneca representative will work with the investigator to compile all the necessary information and ensure that the appropriate AstraZeneca Drug Safety Department receives a report by day 1 for all fatal and life-threatening cases and by day 5 for all other SAEs.

Follow-up information on SAEs must also be reported by the investigator within the same time frames.

If a non-serious AE becomes serious, this and other relevant follow-up information must also be provided to AstraZeneca within 1 day as described above.

After initial notification, the AstraZeneca representatives have 4 days to work with the investigator to compile all the necessary information to ensure that the appropriate AstraZeneca Drug Safety Department receives a complete report by day 5. Follow-up information on SAEs should also be reported by the investigator within the same time frames. If a non-serious case becomes serious, this and other relevant follow-up information should also be provided to AstraZeneca within 1 day as described in the paragraph above

All SAEs have to be reported, whether or not considered causally related to the investigational product. All SAEs will be recorded in the case report form. The investigator is responsible for informing the Ethics Committee and/or the Regulatory Authority of the SAE as per local requirements.

5.4.3 Laboratory safety measurements and variables

Blood (under fasting conditions) and urine specimens will be collected for laboratory test analysis and these samples will be processed by a central laboratory (Quintiles Central Laboratory).

5.4.3.1 Methods of assessment

- Fasting hematology: hemoglobin, hematocrit, red blood cell count, total and differential white blood cell counts and platelet count
- Fasting clinical chemistry: total bilirubin, alkaline phosphatase, alanine transaminase(ALT), aspartate transaminase(AST), sodium, potassium, chloride, creatinine, glucose, insulin, bicarbonate, high-density lipoprotein cholesterol, triglycerides, low-density lipoprotein cholesterol and total cholesterol
- Thyroid function tests: thyroid stimulating hormone (TSH), Triiodothyronine resin uptake (T3RU), and total thyroxine (T4)
- Serum pregnancy tests
- Urine toxicology screen

5.4.3.2 Calculation or derivation of endpoints

Change from baseline will be derived for all subjects who have a screening laboratory test and a final laboratory test. The change from baseline is the final test value minus the screening test value. Laboratory test values will also be compared to the laboratory standard normal ranges and flagged with H or L if they are outside of the normal range. In addition, treatment emergent laboratory changes, identified using computerized methods to compare results or changes from baseline to standard extended ranges will be flagged at the subject and test level.

5.4.4 Vital signs measurement

5.4.4.1 Methods of assessment

A standard blood pressure cuff will be used to obtain systolic and diastolic blood pressure. The assessment will be done first with the subject in the supine position for 3 minutes and again within 3 minutes of the subject attaining a standing position. Pulse will be measured for 1 minute.

5.4.4.2 Calculation or derivation of endpoints

Change from baseline will derived be as the value at the visit minus the screen value for the same assessment and position. In addition the change within a visit between the standing and supine blood pressure assessments will be calculated for both systolic and diastolic blood pressures. This difference will be calculated as supine minus standing . A subject will be classified as having calculated postural hypotension if either the systolic blood pressure difference indicates a decrease >20 mmHg or the diastolic blood pressure difference indicates a decrease >15 mmHg.

5.4.5 ECG safety measurements and variables

5.4.5.1 Methods of assessment

A 12 lead ECG assessment will be done using an ECG machine compatible with the requirements for eResearch the central evaluation laboratory. The central laboratory will supply the interval data, rates and standard interpretation of the ECG test results.

eResearch
30 south 17th Street
Philadelphia, PA 19103-4001

5.4.5.2 Calculations and derivations of endpoint

Change from baseline for interval data and rate data will be derived by subtracting the screen value from the final assessment value. Values outside the extended range in Appendix XX will be flagged.

5.4.6 Simpson-Angus Scale (SAS)

5.4.6.1 Methods of assessment

The SAS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.6.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.4.7 Barnes-Akathisia Rating Scale (BARS)

5.4.7.1 Methods of assessment

The BARS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.7.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.5 Quality of Life endpoint

The following assessment will be used to assess the effect of quetiapine compared with placebo on quality of life as assessed by:

- the PSQI
- the short form Q-Les-Q

5.5.1 Summary of quality of life objectives and endpoints

Table 19 shows how the efficacy endpoints of this study relate to the study objectives.

Table 19 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Secondary	Secondary measure		

evaluate the effect of quetiapine compared to placebo on quality of sleep	change from baseline to final assessment in PSQI; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for PSQI total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Reduction in PSQI compared with placebo indicates improvement of sleep quality
evaluate the effect of quetiapine compared to placebo on the overall quality of life	change from baseline to final assessment in Q-Les-Q; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for Q-Les-Q total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Increase in Q-Les-Q compared with placebo indicates improvement of overall quality of life

The methods of collecting quality of life data are described below.

5.5.2 PSQI

5.5.2.1 Methods of assessment

The PSQI will be performed at scheduled visits during the trial by a patient at each site. The 9 self-rated questions will be incorporated into 7 component scores which are added together to yield one total "global" score. Higher scores indicate more severe difficulties in sleep quality.

5.5.2.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the PSQI.

5.5.3 Q-Les-Q

5.5.3.1 Methods of assessment

The Q-Les-Q is a patient self assessment questionnaire which will be completed at scheduled visits during the trial by a patient at each site. The short form has 14 self-rated questions, the first 12 will be incorporated into a total score. Higher scores indicate better quality of life.

5.5.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the Q-Les-Q.

5.6 Interactive Computer Interview for Depression (ICI-D)

At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the MADRS. Raters or other site staff will first enter the subject's MADRS scores into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

For quality assurance purposes, if an above-threshold variance is detected between the ICI-D and the MADRS on individual items or the overall score, a CRS clinician (Ph.D. or MD) will contact the applicable rater for a monitoring consultation. The CRS clinician will discuss possible reasons for the discrepancy, review conventions for scoring and offer additional training if necessary.

The ICI-D will also provide an additional check of the patient's suicide status. The ICI-D will alert the rater if the patient reports suicidal plans. If the patient did not verbalize these thoughts during the interview /assessment process, the rater could then take the appropriate clinical steps.

A standard operating procedure for ICI-D will be provided to the sites.

5.7 Genetic sampling and storage

There will be no genetic sampling in this trial.

5.8 Volume of blood sampling and handling of biological samples

The total volume of blood that will be drawn from each subject in this study is as follows:

Table 16 Volume of blood to be drawn from each subject

Assessment		Sample volume (ml)	N of samples	Total volume (ml)	
				Women	Men
Safety	Clinical chemistry				
	Hematology	18	2	36	36
	Serum Pregnancy[a]	2	1	2	
Total				38	36

[a] Women only.

Sample handling and storage will be defined by the central laboratory which will be handling the analysis and reporting or results from samples.

6 DATA MANAGEMENT

Case Report Forms (CRFs) will be provided for recording of data. The forms will be in triplicate with carbonless paper. Data will be recorded legibly onto the CRFs with black ink, preferably with a ballpoint pen. If any data are not available, omissions will be indicated on the CRFs. Corrections should be made legibly and be initialed and dated. Correction fluid or covering labels must not be used. The top original and the first copy of the completed form will collected and returned to AstraZeneca/AstraZeneca's agent and the second copy will be retained by the investigator.

Data received electronically by AstraZeneca from a validated source will be loaded directly into the trial database for analysis.

7 STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

7.1 Determination of sample size

Since there is no data using the MADRS instrument in the assessment of quetiapine in treating bipolar subjects with depression, the sample size estimation was based on published data from the lamotrigine monotherapy (Calabrese et al, 1999) and olanzapine trials (Tohen et al, 2002). The percentage change in the HAM-D across these lamotrigine studies in bipolar depression is similar to that observed with quetiapine. MADRS scores correlate significantly with those of the HAM-D (Montgomery Asberg 1979).

Sample size was estimated using an Bonferroni correction for the 2 comparisons with placebo. A clinically meaningful 3.6-unit difference between quetiapine treatment and placebo was used to estimate the effect size (with 3.1 units considered a minimally effective and detectable difference). The variability used for calculation was 10 units, the variability seen in the olanzapine study. A sample size of 168 subjects/arm (504 subjects total) would provide 85% power for 2-sided pair-wise comparisons with placebo at α=0.025 which provides an overall experiment wise type I error rate of 0.05. Therefore, 740 patients will be screened and approximately 530 subjects randomized (allowing for a 5% early drop out rate), to insure 504 subjects with post baseline data available for analysis (MITT analysis population). This sample size will provide 72% power to detect a 3.1 unit difference from placebo.

7.2 Statistical evaluation

7.2.1 Methods of statistical analysis

A comprehensive Statistical Analysis Plan (SAP) will be prepared before unblinding of the data.

Missing data for final visit resulting from patient drop outs will be imputed using an LOCF approach. Patients with post baseline data (MITT population) will have their last trial assessment carried forward as the final assessment for analyses.

7.2.2 Study endpoints

Primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score.

Secondary efficacy endpoints:

(1) Percentage of patients with a ≥50% reduction from baseline in the MADRS total score at study endpoint

(2) Change from baseline to each assessment (observed cases) in the MADRS total score

(3) Change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, CGI-S, CGI-C, and Young Mania Rating Scale.

(4) Change in the PSQI score from baseline to final assessment

Safety endpoints:

(1) Incidence and nature of adverse events during double-blind treatment

(2) Incidence of drug-related adverse events during double-blind treatment

(3) Incidence of subject withdrawal due to adverse events

(4) Incidence of clinically significant changes in hematology and chemistry laboratory results, vital signs, electrocardiograms, weight, and body mass index.
Tolerability endpoints:

(5) Change in the SAS total score from baseline to final assessment

(6) Change in BARS total score from baseline to final assessment

(7) Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment

Quality of Life endpoints:

(1) Change in Q-Les-Q total score from baseline to final assessment

(2) Proportion of patients achieving community norm levels in Q-Les-Q at final assessment

7.2.3 Statistical analyses

The randomization will be stratified by Bipolar type (I or II) in order to assure balance across treatments for the type of patient enrolled. The stratification will be incorporated into the statistical analysis models and descriptive statistics will be provided for each stratum.

For each statistical model run, the assumptions for the model will be evaluated. If the assumptions are not reasonably met, the data may be transformed to meet assumptions or a non-parametric test performed.

All statistical comparisons will be based on 2-sided testing approaches for testing the difference between active study medication dose and placebo.

7.2.3.1 Study populations for analysis

The modified intention to treat population (MITT) will be the population for efficacy and quality of life evaluation. The MITT population will include all randomized subjects who were received study treatment and had at least one post baseline efficacy assessment with a last observation carried forward approach for final assessment.

The safety population will include all subjects who provide consent and received study medication.

7.2.3.2 Primary Analysis

The primary analysis will use analysis of covariance (ANCOVA) model for the change from baseline at final assessment for the MADRS. The model will include terms for treatment, stratum, with the baseline MADRS as a covariate. The Simes-Hommel step-up procedure will be used to adjust for the 2 comparisons with placebo (Simes-Hommel, 1988). The p-values obtained from the pair-wise comparisons will be ordered as follows: $P(1) \leq P(2)$. The following rule will be used to assess statistical significance:

1) If $P(2) \leq 0.05$, then reject both null hypotheses associated with P(2) and P(1); else proceed to the next step;

2) If $P(1) \leq 0.025$, then reject the null hypothesis associated with P(1).

7.2.3.3 Secondary Analyses of efficacy and quality of life

The secondary endpoint for responder, defined as a subject who has a 50% reduction in MADRS score from baseline to final assessment, will be analyzed by comparing the proportion of subjects responding across treatments using a logistic model which includes treatment, stratum, and center in the model. The secondary endpoints based on change from baseline for scales at an assessment time will be analyzed using the same model as the primary endpoint. Nominal p-values will be used for all secondary endpoint comparisons.

Exploratory repeated measures analysis of variance model will also be conducted to evaluate whether there are significant differences among treatments across time for the MADRS and HAM-D scores.

Descriptive statistics will be used to report stratum, item scores, and subscale scores.

7.2.3.4 Safety analyses

Adverse events will be coded using the MedDRA dictionary. Numbers of events and incidence rates for AEs in each treatment group will be summarized by preferred term and system organ class. An event that occurred one or more times on the date of, or subsequent to, randomization will contribute one observation to the numerator of the incidence rate. The denominator will comprise all patients exposed to study treatment.

Adverse events that lead to premature withdrawal of subjects will be tabulated for each treatment group.

All laboratory assessments, vital signs, ECG (rates and intervals) results, and weight and body mass index will be tabulated using descriptive statistics at baseline, final assessment and including change from baseline. Descriptive statistics will include n, mean, standard deviation, minimum and maximum value.

7.2.3.5 Tolerability analyses

The change from baseline in SAS and BARS score data will be summarized using descriptive statistics (mean, standard deviation, median, minimum and maximum).

Incidence rates of EPS adverse events will be compared and tabulated using descriptive statistics.

7.2.3.6 Interim analysis

No interim analysis is planned

7.2.3.7 Data or safety monitoring committee

There will be no data or safety monitoring committee.

8 STUDY MANAGEMENT

8.1 Monitoring

Before the study begins, a representative of AstraZeneca or company representing AstraZeneca will visit the investigational site to

- determine the adequacy of the facilities
- discuss with the investigator(s) (and other personnel involved with the study) their responsibilities with regard to protocol adherence, and the responsibilities of AstraZeneca or its representatives.

During the study, a monitor from AstraZeneca or company representing AstraZeneca will have regular contacts with the investigational site, including visits to

- provide information and support to the investigator(s)
- confirm that facilities remain acceptable
- confirm that the investigational team is adhering to the protocol, that data are being accurately recorded in the case report forms (CRFs), and that investigational product accountability checks are being performed.
- perform source data verification (a comparison of the data in the CRFs with the subject's records at the hospital or practice, and other records relevant to the study). This will require direct access to all original records for each subject (eg, clinic charts).

The monitor or another AstraZeneca representative will be available between visits if the investigator(s) or other staff at the center need information and advice.

8.2 Audits and inspections

Authorized representatives of AstraZeneca, a regulatory authority, an Independent Ethics Committee (IEC) or an Institutional Review Board (IRB) may visit the center to perform audits or inspections, including source data verification. The purpose of an AstraZeneca audit or inspection is to systematically and independently examine all study related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed, and accurately reported according to the protocol, Good Clinical Practice (GCP), guidelines of the International Conference on Harmonization (ICH), and any applicable regulatory requirements. The investigator should contact AstraZeneca immediately if contacted by a regulatory agency about an inspection at his or her center.

8.3 Training of staff

The principal investigator will maintain a record of all individuals involved in the study (medical, nursing and other staff). He or she will ensure that appropriate training relevant to the study is given to all of these staff, and that any new information of relevance to the performance of this study is forwarded to the staff involved.

8.4 Changes to the protocol

Study procedures will not be changed without the mutual agreement of the international principal investigator(s) and AstraZeneca.

If it is necessary for the study protocol to be amended, the amendment or a new version of the study protocol must be notified to or approved by each IEC or IRB, and in many countries also the local regulatory authority, before implementation. Local requirements must be followed.

If a protocol amendment requires a change to a particular center's Written Informed Consent Form, then AstraZeneca and the center's IEC or IRB must be notified. Approval of the revised Written Informed Consent Form by AstraZeneca and by the IEC or IRB is required before the revised form is used.

AstraZeneca will distribute amendments and new versions of the protocol to each principal investigator(s), who in turn is responsible for the distribution of these documents to his or her IEC or IRB, and to the staff at his or her center. The distribution of these documents to the regulatory authority will be handled according to local practice.

8.5 Study agreements

The principal investigator at each center must comply with all the terms, conditions, and obligations of the study agreement for this study. In the event of any inconsistency between this protocol and the study agreement, this study agreement shall prevail.

8.6 Study timetable and termination

It is anticipated that the first subject will be enrolled in September 2002 and that the last subject will complete the study in March 2004.

9 ETHICS

9.1 Ethics review

The final study protocol, including the final version of the Written Informed Consent Form, must be approved or given a favorable opinion in writing by an IEC or IRB as appropriate. The investigator must submit written approval to AstraZeneca before he or she can enroll any subject into the study.

The principal investigator(s) is responsible for informing the IEC or IRB of any amendment to the protocol in accordance with local requirements. In addition, the IEC or IRB must approve all advertising used to recruit subjects for the study. The protocol must be reapproved by the IEC or IRB annually, as local regulations require.

Either the investigator(s) or AstraZeneca must submit progress reports to the IEC or IRB according to local regulations and guidelines. The principal investigator(s) must also provide the IEC or IRB with any reports of serious adverse events from the study site.

The principal investigator(s) is also responsible for providing the IRB with reports of any serious adverse events from any other study conducted with the investigational product. This information will be provided to the principal investigator(s) by AstraZeneca.

9.2 Ethical conduct of the study

The study will be performed in accordance with the ethical principles in the Declaration of Helsinki (see Appendix C), Good Clinical Practice, and applicable regulatory requirements.

9.3 Subject information and consent

The principal investigator(s) at each center will ensure that the subject is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Subjects must also be notified that they are free to discontinue from the study at any time. The subject should be given the opportunity to ask questions and allowed time to consider the information provided.

The subject's signed and dated informed consent must be obtained before conducting any procedure specifically for the study, including the following:

The principal investigator(s) must store the original, signed Written Informed Consent Form. A copy of the Written Informed Consent Form must be given to the subject.

A sample Written Informed Consent Form is enclosed (Appendix B). If modifications are made according to local requirements, the new version has to be approved by AstraZeneca.

9.4 Subject data protection

The Written Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. The subjects' names will not be recorded in this database. The Written Informed Consent Form will also explain that for data verification purposes, authorized representatives of AstraZeneca, a regulatory authority, an IEC or IRB may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

10 EMERGENCY PROCEDURES

10.1 AstraZeneca emergency contact procedure

In the case of a medical emergency, contact AstraZeneca personnel shown below.

Wayne Macfadden MD
Project Physician
302-886-1147 (telephone)
302-886-5567 (fax)
REDACTED

Robin McCoy RN
Senior Clinical Research Scientist
302-886-4650 (telephone)
302-886-5567 (fax)
REDACTED

Contact AstraZeneca switchboard on 1-800-236-9933 and ask to be put in contact with the person on call for the Seroquel clinical team.

10.2 Procedures in case of medical emergency

The principal investigator(s) is responsible for ensuring that procedures and expertise are available to cope with medical emergencies during the study.

10.3 Procedures in case of overdose

For the purpose of this trial all overdoses should be reported as adverse events. However, all cases of overdose must be reported immediately, within 1 day, if sequelae meeting the criteria for serious adverse event have occurred in association with the overdose. In all instances, the overdose substance should be stated and whether the overdose was accidental or intentional. If the overdose was a suicide attempt, this fact should be clearly stated. Adverse events (serious and non-serious) arising as the result of an overdose should be recorded on an adverse event form as "sequelae to overdose." For example "nausea as sequelae to overdose."

10.4 Suicide

Suicide and suicide attempt, irrespective of the method, but in connection with the use of trial drug, should be reported as a serious adverse event (in accordance with the definition provided in Section 5.4.2.1). This event should be identified as suicide or suicide attempt, and the method of the suicide or the suicide attempt should be provided. Suicidal thoughts should also be regarded as adverse events.

10.5 Procedures in case of pregnancy

Pregnancy itself is not regarded as an adverse event unless there is a suspicion that the investigational product under study may have interfered with the effectiveness of a contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) must be followed up and documented even if the subject was discontinued from the study.

All reports of congenital abnormalities/birth defects are SAEs. Spontaneous miscarriages should also be reported and handled as SAEs. Elective abortions without complications should not be handled as AEs. All outcomes of pregnancy must be reported to AstraZeneca on the pregnancy outcomes report form.

11 REFERENCES

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Appendix A
Signatures

IND No. 32,123

SIGNATURE OF PRINCIPAL INVESTIGATOR

Title of report

A Multicenter, Double-blind, Randomized, Placebo-controlled, double-dummy Trial of the User of Quetiapine fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

I agree to the terms of this study protocol. I will conduct the study according to the procedures specified herein, and according to the principles of Good Clinical Practice (GCP) and local regulations.

Centre No.: 0001

Signature: Joseph Calabrese 10/14/03

Joseph Calabrese, MD
University Hospitals of Cleveland
Mood Disorders Program
11400 Euclid Avenue, Suite 200
Cleveland, OH 44106

Date

AstraZeneca

Clinical Study Protocol: Appendix B	
Study Code	5077US/0049
Version No.	1
Appendix Date	August 6, 2002

Appendix B
Sample written informed consent form

A sample informed consent is provided under separate cover.

Appendix C

Declaration of Helsinki

Recommendations guiding physicians in biomedical research involving human subjects.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975 and the 35th World Medical Assembly, Venice, Italy, October 1983 and the 41st World Medical Assembly Hong Kong, September 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of The World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient´s interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject´s physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject´s freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor´s consent must be obtained in addition to the consent of the minor´s legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with professional care (Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo studies where no proven diagnostic or therapeutic method exists.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical re-search involving human subjects

(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to thepatient´s illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

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Clinical Study Protocol: Appendix D	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix D

Investigators and study administrative structure

STAFF AT INVESTIGATIONAL SITE(S)

Centre No.	**Centre address**	**Name** (First name, Last name)	**Qualifications**	**Position**	**Role in the study**
<<>>					Principal investigator

A list of participating investigators will be provided upon request.

ASTRAZENECA STUDY PERSONNEL

Name (First name, Last name)	**Position**	**Role in the study**
Robin McCoy	Senior Clinical Research Scientist	Clinical Management Lead
Margaret Minkwitz	Director Biostatistics Project Team	Biostatistician
Wayne Macfadden	Medical Director Clinical Research	Medical advisor
Jeris Minor	Data Analyst	Data Analyst
Elaine Yu	Assistant Director Health Economics	Health Economics
Ellen Quimby	IPS Demand Manager	IPS Representative
Jennifer Mahoney	Safety Representative	Safety
Patti Neal	Regulatory Representative	Regulatory
Richard White	Director Health Economics	Health Economics

OTHER PARTICIPANTS

Organisation and address	**Name** (First name, Last name)	**Qualifications/Position**	**Role in study**
Lineberry Research Associates 79 Alexander Drive Bldg 4401, Suite 400Research Triangle Park, NC 27709 See CRO Personnel List	Kelly Abernathy	RN	Project Manager

AstraZeneca

Clinical Study Protocol: Appendix E	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix E

Insurance and indemnity

For the US, this Appendix E is not applicable. Please refer to the clinical study agreement for information regardingAstraZeneca's obligation to insure and indemnify institution and investigator.

INSURANCE AND INDEMNITY

AstraZeneca's liability is covered by a liability insurance policy with AstraZeneca Insurance Company Limited, policy No.: L/702938.

With respect to any liability directly or indirectly caused by the investigational products in connection with this Clinical Study, AstraZeneca assumes liability by law on behalf of the investigator(s) and his assistants for possible injury to the subject provided the investigator(s) and his assistants have followed the instructions of AstraZeneca in accordance with this protocol and any amendments thereto, that the investigational products administered to the subject in this Clinical Study have been supplied by AstraZeneca and that the investigator and his assistants have in general performed this clinical study in accordance with scientific practice and currently acceptable techniques and know-how.

AstraZeneca can forward a letter of indemnity if needed by the investigator(s)/institution.

AstraZeneca

Clinical Study protocol: Appendix F	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8 2002

Appendix F
Additional safety information

1. FURTHER GUIDANCE ON THE DEFINITION OF A SERIOUS ADVERSE EVENT (SAE)

Life threatening

'Life-threatening' means that the subject was at immediate risk of death from the adverse event as it occurred or it is suspected that use or continued use of the product would result in the subject's death. 'Life-threatening' does not mean that had an adverse event occurred in a more severe form it might have caused death (ie hepatitis that resolved without hepatic failure).

Hospitalisation

Out-subject treatment in an emergency room is not in itself a serious adverse event, although the reasons for it may be (eg, bronchospasm, laryngeal oedema). Hospital admissions and/or surgical operations planned before or during a study are not considered adverse events if the illness or disease existed before the subject was enrolled in the study, provided that it did not deteriorate in an unexpected way during the study.

Important medical event or medical intervention

Medical and scientific judgement should be exercised in deciding whether a case is serious in a situation where important medical events may not be immediately life-threatening or result in death, hospitalisation, disability or incapacity but may jeopardise the subject or may require medical intervention to prevent one or more outcomes listed in the definition of serious. These should usually be considered as serious. Examples of such events are:

- Angioedema not severe enough to require intubation but requiring iv. hydrocortisone treatment
- Hepatotoxicity caused by paracetamol (acetaminophen) overdose requiring treatment with N-acetylcysteine
- Intensive treatment in an emergency room or at home for allergic bronchospasm
- Blood dyscrasias (eg, neutropenia or anaemia requiring blood transfusion, etc.) or convulsions that do not result in hospitalisation
- Development of drug dependency or drug abuse

2. FURTHER GUIDANCE ON THE ASSESSMENT OF CAUSALITY

The following factors should be considered when deciding if there is a "reasonable possibility" that an adverse event (AE) may have been caused by the investigational product.

- **Time course of events and exposure to suspect drug**. Has the subject actually received the suspect drug? Did the AE occur in a reasonable temporal relationship to the administration of suspect drug?

- **Consistency with known drug profile**. Was the AE consistent with the previous knowledge of the suspect drug (pharmacology and toxicology) or drugs of the same pharmacological class? OR could the AE be anticipated from its pharmacological properties?

- **Dechallenge experience**. Did the AE resolve or improve on stopping or reducing the dose of the suspect drug?

- **No alternative cause**. The AE cannot be reasonably explained by another aetiology such as the underlying disease, other drugs, other host or environmental factors.

- **Rechallenge experience**. Did the AE reoccur if the suspected drug was reintroduced after having been stopped? AstraZeneca would not normally recommend or support a rechallenge.

- **Laboratory tests**. Has a specific laboratory investigation confirmed the relationship?

A "reasonable possibility" could be considered to exist for an AE where one or more of these factors exist.

In contrast, there would not be a "reasonable possibility" of causality if none of the above criteria apply or where there is evidence of exposure and a reasonable time course but any dechallenge (if performed) is negative or ambiguous or there is another more likely cause of the AE.

In difficult cases, other factors could be considered such as:

- Is this a recognised feature of overdose of the drug?

- Is there a known mechanism

Ambiguous cases should be considered as being a “reasonable possibility” of a causal relationship unless further evidence becomes available to refute this.

AstraZeneca

Clinical Study protocol: Appendix G	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix G
Additional information necessary for studies conducted in Japan

Not Applicable

1. LABELLING AND PACKAGING OF THE INVESTIGATIONAL PRODUCT

<< Insert copy of the label.>>

2. PROCEDURES FOR RANDOMISATION (REGISTRATION)

<<>>

3. ORGANISATIONAL STRUCTURE OF THE STUDY

3.1 Study sponsor

AstraZeneca K.K.
<< Name >>Executive President
Umeda Sky Building, Tower East,
1-88, 1-chome, Ohyodo-naka, Kita-ku, Osaka 531-0076, Japan

3.2 Medical expert from the sponsor

AstraZeneca K.K., Clinical Strategy Department:
<< Name >>(Physician responsible for the protocol)

3.3 Responsible person for the product, monitor, and auditor

Clinical Project Manager (CPM)

Clinical Strategy Department, Osaka office	<< Telephone number>>
Clinical Project Manager	<< Name >>

Monitors

Clinical Operations Department, Osaka office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Clinical Operations Department, Tokyo office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Auditor

Regulatory Affairs Department	<< Telephone number>>
Clinical Audit Department Manager	<< Name >>

See AstraZeneca medical emergency contact numbers (Section 9).

3.4 Co-ordinating investigator(s) (Co-ordinating committee)

<< Name >>
<< Job title>>
<< Associated hospital name>>

3.5 Person in charge of PMS management (if applicable)

AstraZeneca K.K.,
<< Name >>
Drug Safety &PMS Department Manager

3.6 Independent Data Monitoring Committee (IDMC) (if applicable)

<< Name >>
<< Job title>>
<<Associated hospital name>>

3.7 Subject inclusion registration centre

<<>>

3.8 Laboratory

<<>>

3.9 Contract Research Organisation (CRO)

<<>>

3.10 Safety Committee (In house)

May have responsibility for reviewing the following major issues around JNDA and clinical trials proposed by R&D departments such as CSD, COD or RA

A) Major changes for protocol and IB due to safety reasons

B) Across the board key code break due to safety reasons

C) Actions required due to significant safety issues ensuring for products under/for NDA

D) Discontinuation of clinical trials or test drug recall due to safety reasons

E) Other issues to ensure safety in clinical trials

4. LIST OF INVESTIGATORS AND MEDICAL INSTITUTIONS

Centre No.	Study Institutions	Department	Address	Telephone	Investigators	Job Title
<<>>						

5. ADDITIONAL REPORTING RELATED WITH SECTION 4.4.2 ADVERSE EVENTS (FOR JAPANESE PHASE III OR IV STUDY)

<<>>

AstraZeneca

Clinical Study Protocol Amendment	
Amendment No.	3
Study Code	5077US/0049
Date	April 14, 2003

Sponsor:

AstraZeneca Pharmaceuticals LP, Wilmington, Delaware, USA

Centres affected by the amendment:

All centers

The protocol for the study is to be amended as follows:

1. Page 47 Section 5.4.2.2 Recording of adverse events

Original text

All AEs that occur before treatment, during treatment, or within 30 days following the cessation of treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor.

Amended text

All AEs and SAEs that occur before and during treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. **Following cessation of treatment, SAEs, whether or not related to the study drug, must be collected for 7 days and recorded on the CRF provided by the sponsor. If any SAEs are recorded during the 7 day follow-up period, all concomitant medications taken during the 7 day follow-up period should also be recorded on the CRF.**

2. Page 39 Summary of permitted medications Table 13 last paragraph

Original text

Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a **period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.**

Amended text

Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a **period of 7 to 28 days depending on the medications involved (eg. 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.**

3. Page 21 Figure 1 Study Flow chart

Original text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers from a **period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study.**
Fluoxetine must be discontinued at least 14 days prior to randomization.

Amended text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers **for 7 to 28 days depending on the medication involved (eg. haloperidol decanoate or fluphenazine decanoate for 28 days), prior to randomization. Patients on fluoxitine must discontinue for 14 days.**

4. Page 22 Table 1 Study plan

Original text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers from a **period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study.**
Fluoxetine must be discontinued at least 14 days prior to randomization.

Amended text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers **for 7 to 28 days depending on the medication involved (eg. haloperidol decanoate or fluphenazine decanoate for 28 days), prior to randomization. Patients on fluoxitine must discontinue for 14 days.**

5. Page 27 Section 3.4.4.4 Procedures for discontinuation

Original text

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination including **ophthalmoscopic exam**
- Vital signs and weight
- HAM-D
- MADRS
- ICI-D
- YMRS
- HAM-A
- SAS
- BARS
- PSQI
- Adverse events assessment

Amended text

12-lead ECG added and opthalmoscopic exam removed.

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- **Physical examination**
- Vital signs and weight
- **12-lead ECG**

- HAM-D
- MADRS
- ICI-D
- YMRS
- HAM-A
- SAS
- BARS
- PSQI
- Adverse events assessment

Reasons for making the amendment:

1. The procedure for reporting adverse events for 30 days after cessation of study treatment was changed; adverse events and serious adverse events will be reported for the period of 7 days after cessation of study treatment. These events, whether or not related to study drug, must be recorded on the CRF provided by the Sponsor. If any SAEs are recorded for this follow-up period, all concomitant medications taken during this period should also be recorded on the CRF.

The follow up period for reporting SAEs is being modified from 30 to 7 days after the last dose of study drug to be consistent with the known half-life of Seroquel and to ensure reporting of SAEs for a period corresponding with five half-lives of the drug.

2. Changed to make consistent with the rest of the protocol.

3. Changed to make consistent with the rest of the protocol.

4. Changed to make consistent with the rest of the protocol.

5. Changed to make consistent with the rest of protocol

Signed agreement to the amendment:

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

. . . . .	. . . . .
Date (day month, year)	AstraZeneca signatory Wayne Macfadden MD Project Physician

Signed agreement to the amendment:

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

. . . . .	. . . . .
Date	AstraZeneca signatory
(day month, year)	Gil Block
	Treatment Area Medical Lead

AstraZeneca

Clinical Study Protocol Amendment

Amendment No.	3
Study Code	5077US/0049
Date	April 21, 2003

Sponsor:

AstraZeneca Pharmaceuticals LP, Wilmington, Delaware, USA

Centres affected by the amendment:

All centers

The protocol for the study is to be amended as follows:

1. Page 47 Section 5.4.2.2 Recording of adverse events

Original text

All AEs that occur before treatment, during treatment, or within 30 days following the cessation of treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor.

Amended text

All AEs and SAEs that occur before and during treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. **Following cessation of treatment, SAEs, whether or not related to the study drug, must be collected for 7 days and recorded on the CRF provided by the sponsor. If any SAEs are recorded during the 7 day follow-up period, all concomitant medications taken during the 7 day follow-up period should also be recorded on the CRF.**

2. Page 39 Summary of permitted medications Table 13 last paragraph

Original text

Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a **period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.**

Amended text

Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a **period of 7 to 28 days depending on the medications involved (eg. 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.**

3. Page 21 Figure 1 Study Flow chart

Original text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers from a **period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study.**
Fluoxetine must be discontinued at least 14 days prior to randomization.

Amended text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers **for 7 to 28 days depending on the medication involved (eg. haloperidol decanoate or fluphenazine decanoate for 28 days), prior to randomization. Patients on fluoxitine must discontinue for 14 days.**

4. Page 22 Table 1 Study plan

Original text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers from a **period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study.**
Fluoxetine must be discontinued at least 14 days prior to randomization.

Amended text

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers **for 7 to 28 days depending on the medication involved (eg. haloperidol decanoate or fluphenazine decanoate for 28 days), prior to randomization. Patients on fluoxitine must discontinue for 14 days.**

5. Page 27 Section 3.4.4.4 Procedures for discontinuation

Original text

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination including **ophthalmoscopic exam**
- Vital signs and weight
- HAM-D
- MADRS
- ICI-D
- YMRS
- HAM-A
- SAS
- BARS
- PSQI
- Adverse events assessment

Amended text

12-lead ECG added and opthalmoscopic exam removed.

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- **Physical examination**
- Vital signs and weight

- **12-lead ECG**
- HAM-D
- MADRS
- ICI-D
- YMRS
- HAM-A
- SAS
- BARS
- PSQI
- Adverse events assessment

Reasons for making the amendment:

1. The procedure for reporting adverse events for 30 days after cessation of study treatment was changed; adverse events and serious adverse events will be reported for the period of 7 days after cessation of study treatment. These events, whether or not related to study drug, must be recorded on the CRF provided by the Sponsor. If any SAEs are recorded for this follow-up period, all concomitant medications taken during this period should also be recorded on the CRF.

The follow up period for reporting SAEs is being modified from 30 to 7 days after the last dose of study drug to be consistent with the known half-life of Seroquel and to ensure reporting of SAEs for a period corresponding with five half-lives of the drug.

2. Changed to make consistent with the rest of the protocol.

3. Changed to make consistent with the rest of the protocol.

4. Changed to make consistent with the rest of the protocol.

5. Changed to make consistent with the rest of protocol

Signed agreement to the amendment:

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

4/21/03
Date
(day month, year)

AstraZeneca signatory
Wayne Macfadden MD
Project Physician

Signed agreement to the amendment:

I agree to the terms of this protocol amendment.

Study Code: 5077US/0049

April 21, 2003
Date
(day month, year)

AstraZeneca signatory
Gil Block
Treatment Area Medical Lead

AstraZeneca

Clinical Study Protocol	
Drug Substance	quetiapine fumarate
Study Code	5077US/0049
Version No.	5
Date	May 12, 2003

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

The following amendment(s) have been made to this protocol since the date of preparation:

Amendment No.	**1**	**Date of amendment**	**September 30,2002**
Amendment No	**2**		**December 4, 2002**
Amendment No.	**3**		**April 21, 2003**
Amendment No.	**4**		**May 12, 2003**
Administrative Change No.	**1**	**Date of administrative change**	**September 30, 2002**

PROTOCOL SYNOPSIS

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

Investigator

Multicenter trial: << To be determined >>

Study center(s) and number of subjects planned

A total of approximately 740 subjects will be screened to enroll approximately 530 into the trial in order to obtain approximately 504 evaluable patients, defined as those who have a baseline visit and at least one post baseline assessment. It is expected that approximately 75 centers will participate in the trial, with each center enrolling 8 patients (maximum 70).

Study period		**Phase of development**
Estimated date of first subject enrolled	September, 2002	IIIb
Estimated date of last subject completed	March, 2004	

Objectives

Primary:

To evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S)

(5) the Clinical Global Impression - Change (CGI-C).

Secondary:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by comparing

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by comparing

- the incidence and nature of all adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment
- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score from baseline to end of treatment
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Exploratory

(1) to evaluate the efficacy of quetiapine on sleep quality by comparing the change in the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment

(2) to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment.

Hypotheses:

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

Secondary hypotheses are defined in Section 3.1.

Study design

Study 5077US/0049 is a randomized, multicenter, double-blind, placebo-controlled, double-dummy, parallel group, fixed-dose comparison of quetiapine vs placebo in the treatment of bipolar depression. This study will be stratified 1:1 for bipolar I and bipolar II.

Target subject population

Outpatients, aged 18 to 65 years, with a diagnosis of bipolar I or bipolar II disorder with a current major depressive episode of duration less than one year but greater than 4 weeks will be enrolled in the trial. The HAM-D (17-item scale) score must be ≥20, the HAM-D item 1 (depressed mood) score must be ≥2, and the YMRS score must be ≤12 at both Visit 1and Visit 2 (randomization) to be eligible for entry into the trial.

Investigational product, dosage and mode of administration

Study drug will be titrated in a blinded manner to a total daily dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and to a total daily dose of 600 mg/day by Day 8 in the 600-mg/day treatment group. Thereafter, oral doses of quetiapine fumarate will be administered in a blinded fashion once daily at bedtime (qhs) in a total daily dose of 300 or 600 mg/day. One-time dose reductions for intolerability of 100 mg/day in both the 300 mg/day and in the 600 mg/day treatment groups will be allowed at the discretion of the Investigator after Day 8.

Comparator, dosage and mode of administration

Placebo will be administered once daily with tablets matching in number and appearance to blinded quetiapine dosing.

Duration of treatment

Patients will receive double-blind, double-dummy treatment for up to 8 weeks (56 days), following an initial washout period of between 7 to 28 days (depending on the medications involved) and will come in to the clinic on Day 57 for final assessments.

Endpoints

- **Efficacy**

  Primary efficacy endpoint is the change from baseline to final assessment in the MADRS total score.

  Secondary efficacy endpoints are the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at study endpoint, the change from baseline to each assessment (observed cases) in the MADRS total score, and the change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, and CGI-S and the CGI-C.; the change from baseline to each assessment (observed cases) and final assessment in the YMRS, and the HAM-A total scores.

- **Safety**

  Safety endpoints are the incidence and nature of all adverse events, the incidence of drug-related adverse events, the incidence of subject withdrawal due to adverse events, and the incidence of clinically significant changes in vital signs, weight, and body mass index during double-blind treatment. Tolerability endpoints are the change in the SAS total score from baseline to final assessment, the change in BARS total score from baseline to final

assessment, and the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

- **Quality of life**

  Exploratory quality of life endpoints are the change from baseline in the PSQI score and Q-Les-Q total score.

Statistical methods

All statistical comparisons will be 2-sided tests for the difference between active study medication and placebo. The primary analysis will be analysis of covariance (ANCOVA) for the change from baseline to final assessment for total MADRS score. The ANCOVA model will include terms for treatment, and stratum, with the baseline MADRS score as a covariate. Pair-wise comparisons of each dose with placebo will be assessed within this model as planned comparisons. In order to adjust for multiple comparisons with placebo a step-up procedure will be employed with a rule for tests of significance based on ordered p-values, maintaining an overall experiment wise type I error rate of 0.05. The proportion of patients having a $\geq$ 50% reduction from baseline to final assessment in MADRS will be compared across treatments using a logistic model. Change from baseline in MADRS scores at each assessment (observed cases), and change from baseline in HAM-D, HAM-D item 1, CGI-S, YMRS, HAM-A, Q-Les-Q and PSQI score at each assessment (observed cases) and LOCF, will be analyzed using the same ANCOVA model as for the primary endpoint. The CGI-C will be analyzed using the ANCOVA model with the baseline CGI-S as a covariate.

The change from baseline in SAS and BARS score data will be assessed using the same ANCOVA model as the primary endpoint. The incidence of EPS AEs and overall AEs will be reported using descriptive statistics. Vital signs, weight, and body mass index will be tabulated using descriptive statistics at baseline, final assessment, and for change from baseline. Descriptive statistics will also be used to describe the proportion of patients whose final Q-Les-Q is within community norm levels.

Repeated measures analysis of variance (ANOVA)will be performed to evaluate whether there are significant differences among treatments across time for MADRS, HAM-D, and HAM-A total scores.

Efficacy analyses will be conducted on a modified intention-to-treat (MITT) population. A per-protocol (PP) analysis will be conducted for the primary analysis measure (change from baseline MADRS) to evaluate sensitivity of the response. The safety population will include all subjects who took study medication.

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APPENDICES

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

The following abbreviations and specialist terms are used in this study protocol.

Table 1 Abbreviations and specialist terms

Abbreviation or specialist term	Explanation
AE	Adverse event (see definition in Section 4.4.2.1)
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BP	Bipolar Disorder
BPD	Bipolar Depression
CGI	Clinical Global Impression
CGI-C	Clinical Global Impression - Change
CGI-S	Clinical Global Impression - Severity
CMH	Cochran-Mantel Haenszel
CRF	Case Report Form
CRS	Concordant Rater systems
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition
EPS	Extrapyramidal symptoms
ECG	Electrocardiogram
GCP	Good Clinical Practice
HAM-A	Hamilton Rating Scale for Depression
HAM-D	Hamilton Rating Scale for Anxiety
ICH	International Conference on Harmonisation
ICI-D	Interactive Computor Interview-Depression
ICTI	Interactive Clinical Technologies, Incorporated
IEC	Independent Ethics Committee

Abbreviation or specialist term	Explanation
IRB	Institutional Review Board
IVRS	Interactive Voice Response System
LOCF	Last Observation Carried Forward
MADRS	Montgomery-Asberg Depression Rating Scale
MITT	Modified Intent to Treat
OAE	Other significant adverse event (ie, an adverse event of special interest in this clinical development; see definition in Section 4.4.2.1). The classification of OAEs will be performed by AstraZeneca drug safety physicians after the study is complete.
PSQI	Pittsburgh Sleep Quality Index
Principal investigator	The investigator who leads the study conduct at an individual study center. Every study center has a principal investigator.
Qhs	at bedtime
Q-Les-Q	Quality of Life Enjoyment Satisfaction Questionnaire
SAE	Serious adverse event (see definition in Section 4.4.2.1).
SAS	Simpson Angus Scale
SSRI	Selective serotonin reuptake inhibitors
UNI	Universal Systems Incorporated
YMRS	Young Mania Rating Scale

1 INTRODUCTION

1.1 Background

Quetiapine fumarate (SEROQUEL®, quetiapine) is a dibenzothiazepine derivative approved by the United States Food and Drug Administration (FDA) on 26 September 1997 following clinical development by AstraZeneca Pharmaceuticals LP (also referred to as the sponsor) for the treatment of subjects with schizophrenia. Quetiapine fumarate is designated chemically as bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl) piperazin-1-yl]ethoxy)ethanol] fumarate

Quetiapine has been studied in a toxicological and clinical program directed at supporting clinical evaluation in man. The results of these studies are presented in the Investigator's Brochure dated January 2002. The Professional Information Brochure (PIB) contains the current prescribing information for quetiapine.

1.2 Rationale for this study

The bipolar disorders are psychiatric disorders in which a disturbance in mood is the predominant feature. Bipolar I disorder is characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes. Bipolar II disorder is characterized by one or more major depressive episodes accompanied by at least one hypomanic episode. Bipolar depression refers to the major depressive episodes that occur with bipolar I and II disorder.

The prevalence of bipolar disorder is estimated to be 1 to 3.5%, evenly divided between men and women. The length of time between onset and symptoms and proper diagnosis and treatment is approximately 10 years and it is estimated that only 60% of those suffering from a bipolar disorder are receiving appropriate pharmacotherapy.

Although there is extensive and emerging literature guiding the treatment of the manic phase of bipolar I disorder as well as many approved compounds for the treatment of unipolar depression, the treatment of bipolar depression has not been widely studied and treatment guidelines are in their infancy. The use of currently available antidepressants for monotherapy for bipolar depression is often problematic as they may increase the "switch" into hypomania or mania from depression, or increase cycle acceleration. The adjunctive use of mood stabilizing medications such as lithium carbonate (LiCO3) is common and may decrease the likelihood of these complications.

Evidence indicates that medications with mood stabilizing properties which produced low levels of mania, hypomania, or cycle acceleration may be useful as monotherapy in the treatment of bipolar depression. The antiepileptic lamotrigine produced improvement in HAM-

D and MADRS scores in a 7-week, double-blind, placebo controlled trial for the patients who completed this study (Calabrese 1999). More recently, the anti-manic agent divalproex demonstrated numerical improvement over placebo in the percentage of patients with bipolar depression having a 50% reduction in the HAM-D scores without mania in an 8 week trial (Sachs, 2001) but this difference was not statistically significant. Lithium carbonate, also approved for the treatment of mania, has been demonstrated to be effective as a monotherapeutic agent in approximately 50% of patients with bipolar depression (Bauer). However, there are efficacy and tolerability limitations which may prohibit widespread use of the above therapies.

A large multicentered, double-blind, placebo controlled trial was recently completed, which demonstrated efficacy of the atypical antipsychotic olanzapine as monotherapy for the treatment of bipolar depression (Tohen, 2002). The endpoint mean MADRS change was significantly greater for patients on olanzapine (-15.0 points) than for those on placebo (-11.9 points). Treatment-emergent mania did not differ significantly between groups. There also is evidence from small uncontrolled studies that other atypical antipsychotics such as risperidone, and clozapine have mild to moderate antidepressant activity when used in patients with mood disorders. These small studies also indicate that these compounds are unlikely to cause patients to “switch” into mania.

The potential efficacy of quetiapine in depressive symptoms is provided in data from the Quetiapine Experience with Safety and Tolerability Trial (QUEST) and from investigator-initiated trials in mood disorder patients. In an open-label trial evaluating the safety and tolerability of quetiapine over 700 subjects with schizophrenia and other psychotic disorders were randomized to treatment with quetiapine or risperidone. Quetiapine-treated patients experienced a greater improvement in depressive symptoms compared with risperidone-treated patients, with a mean difference of 1.3 points on the HAM-D after adjustment for baseline differences (P=0.028) (Mullen et al, 2001).

A trial of quetiapine in 20 neuroleptic-dependent patients with bipolar or schizoaffective disorder also suggested positive effects on the depressive and psychotic symptoms in these disorders (Sajatovic et al, 2001). Overall, in 10 patients with bipolar disorder and 10 with schizoaffective disorder who received open-label quetiapine to optimum clinical dosage (25 to 800-mg), significant improvement in Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), and HAM-D scores was noted.

In summary, the paucity of satisfactory treatments available signify an unmet medical need for the treatment of bipolar depression. There are signals of efficacy from clinical trials for the antidepressant properties of atypical antipsychotics such as quetiapine.

2 STUDY OBJECTIVES

2.1 Primary objective

The primary objectives of the study are to evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks by comparing

(1) the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

(2) the percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

(3) the change from baseline to each assessment in the MADRS total score

(4) the change from baseline to each assessment in the total Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression - Severity (CGI-S), and the Clinical Global Impression - Change (CGI-C).

2.2 Secondary objective

The secondary objectives of the study are:

(1) to evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who have an increase of >4 points at any time on the Young Mania Rating Scale (YMRS)

(2) to evaluate the effect of quetiapine on anxiety compared to placebo by

- the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score
- the change from baseline to each assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

(3) to evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by

- the incidence and nature of overall adverse events
- the incidence and nature of drug-related adverse events
- subject withdrawal due to adverse events during double-blind treatment

- the number of patients having clinically significant changes in vital signs from baseline to end of treatment
- the change in Simpson-Angus Scale (SAS) total score
- the change in the Barnes Akathisa Rating Scale (BARS) total score
- the incidence of adverse events related to extrapyramidal symptoms during double-blind treatment

Experimental:

1. to evaluate the efficacy of quetiapine on sleep quality by comparing the change in sleep quality using the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment
2. to evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment

3 HYPOTHESES, STUDY PLAN AND PROCEDURES

3.1 Hypotheses

Primary:

(1) Quetiapine fumarate at a dose of 300 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

(2) Quetiapine fumarate at a dose of 600 mg/day will be superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline to endpoint on the Montgomery-Asberg Depression Rating Scale (MADRS) total score in patients with bipolar depression.

Secondary:

(1) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(2) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score in patients with bipolar depression.

(3) Quetiapine at a dose of 300 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(4) Quetiapine at a dose of 600 mg/day will be more effective than placebo in reducing the level of depressive symptoms as measured by change from baseline in the HAM-D item 1 in patients with bipolar depression.

(5) Quetiapine at a dose of 300 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(6) Quetiapine at a dose of 600 mg/day will be more effective than placebo in improving the patient's clinical status as measured by the CGI-C rating and the change from baseline in the CGI-S in patients with bipolar depression.

(7) Quetiapine at a dose of 300-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(8) Quetiapine at a dose of 600-mg/day will be no worse than placebo in producing treatment-emergent manic symptoms as measured by the change from baseline in the YMRS in patients with bipolar depression.

(9) Quetiapine at a dose of 300 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(10) Quetiapine at a dose of 600 mg/day will be similar or better than placebo in producing anxiety symptoms as measured by change from baseline in HAM-A in patients with bipolar depression.

(11) Quetiapine at a dose of 300 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(12) Quetiapine at a dose of 600 mg/day will be safe and well tolerated compared to placebo in patients with bipolar depression as measured by incidence of adverse events and change from baseline in SAS and BARS.

(13) Quetiapine at a dose of 300 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

(14) Quetiapine at a dose of 600 mg/day will provide improved quality of sleep and quality of life compared to placebo in patients with bipolar depression as measured by the PSQI and Q-Les-Q.

3.2 Overall study design and flow chart

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial will consist of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects will be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment of

8 patients per center (maximum 70). Subjects are required to have a HAM-D (17-item scale) score of $\geq$ 20 and a YMRS of =12 at screening baseline (Visit 1).

The trial comprises the following 2 periods:

- Washout period
  Subjects will undergo HAM-D, SCID, YMRS, and safety evaluations at screen (Visit 1) and if they qualify to participate they will commence a washout of antidepressant, antipsychotic, and mood stabilizer medications. The number of days for washout will depend on the medication they are taking. These medications must be discontinued for a period of at least 7 days prior to randomization (Day 1, Visit 2), with the exception of fluoxetine which must be discontinued for a period of 14 days prior to randomization (Day 1, Visit 2) and depot injections of haloperidol decanoate or fluphenazine decanoate which need 28 days washout before randomization.

- 8-week double-blind randomized treatment period (Weeks 1 to 8)
  Eligible subjects will be randomized on Day 1 (Visit 2) to 1 of 3 treatment groups: quetiapine 300 mg/day, quetiapine 600 mg/day, or placebo. The randomization will be done using a stratification based on diagnosis. Treatment will be administered once daily at bedtime for 8 weeks (Days 1 - 56). Subjects will not receive medication on Day 57 which is only for final assessments. Doses will be titrated to achieve target doses of 300 mg/day within 4 days or 600 mg/day within 8 days. A dose reduction of 100 mg is allowed to improve patient tolerance in each treatment group. MADRS assessments (used to evaluate the primary efficacy variable) will be performed at Days 1, 8, 15, 22, 29, 36, 43, 50, and 57.

Figure 1 Study flow chart

			Treatment										
Day	**Screen**	**Washout [b]**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9-14**	**15-56**	**57**
	Visit 1		**Visit 2**							**Visit 3**		**Visits 4-9**	**Visit 10**
Dose: 300-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	300-mg	
Dose: 600-mg [a] or placebo group			50-mg	100-mg	200-mg	300-mg	400-mg	400-mg	400-mg	600-mg	600-mg	600-mg	

[a] One time dose reductions of 100 mg/day in 300-mg and 600-mg may occur after Day 8

[b] Washout all psychoactive medications, including antidepressants, antipsychotics, and mood stabilizers for 7 to 28 days depending on the medication involved (eg. haloperidol decanoate or fluphenazine decanoate for 28 days), prior to randomization. Patients on fluoxitine must discontinue for 14 days.

Table 2 Study plan

Study plan	Screen	Washout [a]	Double-blind treatment phase Weeks 1 through 8								
Days			**1**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**
Visits	**1**		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Informed consent	√										
Medical history	√										
Inclusion/Exclusion criteria	√		√								
Structured Clinical Interview for DSM-IV (SCID)	√										
Physical examination [d]	√										√
Urine toxicology screen	√										
Pregnancy tests (females)	√										
Vital signs, height, weight [c,e]	√		√	√	√	√	√	√	√	√	√
12-lead electrocardiogram	√		√[b]								√
Clinical chemistry and hematology	√		√[b]								√
Hamilton Rating Scale for Depression (17-item)	√		√	√	√	√	√	√	√	√	√
Montgomery-Asberg Depression Rating Scale			√	√	√	√	√	√	√	√	√
Interactive Computer Interview-Depression			√	√	√	√	√	√	√	√	√
Young Mania Rating Scale	√		√	√	√	√	√	√	√	√	√
Hamilton Rating Scale for Anxiety			√	√	√	√	√	√	√	√	√
Clinical Global Impression - Severity	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression -Change				√	√	√	√	√	√	√	√
Barnes-Akathisia Rating Scale			√								√
Simpson-Angus Scale			√								√
Pittsburgh Sleep Quality Index			√				√				√
Quality of Life Enjoyment Satisfaction Questionnaire			√				√				√
Dispense study medication			√	√	√	√	√	√	√	√	
Adverse events	√	√	√	√	√	√	√	√	√	√	√

[a] Washout of antidepressants, antipsychotics, mood stabilizer for 7 to 28daysdepending on the medications involved and a 14-day washout for fluoxetine.

[b] Repeat laboratory tests and ECG only if results outside of normal range and clinically significant at Screening

[c] Height and weight on screen and weight on Day 57

[d] Physical exam includes ophthalmoscopic exam on screen

[e] Blood pressure will be obtained in supine and standing positions

3.3 Rationale for study design, doses and control groups

This trial is designed as a double-blind placebo-controlled evaluation of Seroquel as monotherapy in bipolar depression. There is no currently approved compound for use in bipolar depression, nor is there a clinically accepted "gold standard". Conventional antidepressants have fallen out of favor because of their ability to induce manic symptoms. Antidepressants approved forthe treatment of unipolar depression have not been demonstrated to improve mood symptoms relative to placebo (Nemeroff et al Am J Psychiatry 158:6 June 2001). Moreover, there is a high placebo response rates of approximately 30% found in bipolar depression trials. Thus, the use of a placebo treatment arm for comparison is clinically justified.

Trial treatment will be administered as quetiapine monotherapy in order to more clearly identify a treatment effect of quetiapine on bipolar depression. Quetiapine fumarate will be administered once daily at bedtime. The current label specifies twice daily (BID) but a double-blind crossover study in bipolar patients indicated that once daily (qd) is well tolerated and as effective as BID dosing (Chengappa, 2002).

A period of 7 to 28 days is adequate for washout of most psychoactive medications including antidepressants, antipsychotics (including depot agents), and mood stabilizers to ensure that subjects are stable and continue to have adequate depressive symptoms requiring treatment, prior to randomization into the trial. The double-blind treatment period of 8 weeks is consistent with the time period that is required to see a clinically meaningful response in depressive symptoms.

The trial is designed as a fixed-dose evaluation due to the failure of flexible dose regimens in other psychiatric disorders. The dosages are based on clinical trial data with quetiapine in patients with a mood disorder. In the QUEST trial, the average dose of quetiapine in patients with a primary mood disorder (N=316) was approximately 250 mg/day at 16 weeks. In 20 patients with bipolar or schizoaffective disorder treated with open-label quetiapine, the mean dose was approximately200 mg/day (Sajatovic). Based on this data, 300 mg/day administered as monotherapy is an appropriate low-dose treatment arm, and 600 mg/day is an appropriate high-dose treatment arm that should exhibit efficacy without a high rate of AEs or noncompliance.

The MADRS is a standardized, well-validated measure of depressive symptoms that is sensitive to treatment effects in depressed outpatients.

3.4 Selection of study population

3.4.1 Study selection record

Investigators must keep a record of subjects who underwent screening but were not randomized into the trial.

3.4.2 Inclusion criteria

At screen (Visit 1) subjects must fulfill all of the following criteria:

(1) Documented ability to provide informed consent before beginning any study-specific procedures.

(2) Male and female patients between 18 and 65 years of age, inclusive

(3) Females of childbearing potential, be using a reliable method of contraception. Reliable methods include hormonal contraceptives (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

(4) Women must have a negative pregnancy test

(5) Meets DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x), confirmed by the amended version(by Dr. Michael First) of the Structured Clinical Interview for DSM-IV (SCID) as administered by an AstraZeneca approved clinician with a signed confirmation by the Principal Investigator

(6) Outpatient status

(7) HAM-D (17-item) total score of 20 or greater

(8) HAM-D item 1 (depressed mood) score ≥2

(9) YMRS total ≤12

At randomization (Visit 2) subjects must fulfill the following criteria:

(1) HAM-D (17-item) total score of 20 or greater

(2) HAM-D item 1 (depressed mood) score ≥2

(3) YMRS total ≤12

3.4.3 Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

(1) Patients with a current Axis I disorder other than bipolar disorder within 6 months of screening

(2) Patients whose current episode of depression exceeds 12 months or is less than 4 weeks

(3) History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode

(4) Patients who meet DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening

(5) Patients with a positive urine toxicology screen for illicit substances of abuse

(6) Patients who are unable to discontinue all psychoactive medications (excluding prn benzodiazepines), including antidepressants, antipsychotics, and mood stabilizer, at least 7 days prior to randomization and consistent with the pharmacokinetics of the drug

- Patients treated with fluoxetine who have not discontinued this medication for at least 14 days prior to randomization.
- Patients treated with haloperiodol decanoate or fluphenazine decanoate who have not discontinued these medications 28 days prior to randomization.

(7) Patient who have not discontinued the use of potent P450 inhibitors and inducers (See Section 4.3, Table 13)

(8) Patients who in the investigators opinion will require initiation of psychotherapy during the study period. Note: ongoing psychotherapy for a minimum of 3 months may continue.

(9) Patients who, in the investigator's judgment, pose a current serious suicidal or homicidal risk at Visit 1 (HAM-D item 3 score of 3 or greater), or have made a suicide attempt within the past 6 months

(10) Patients with a history of clinically significant cardiac, renal, neurologic, cerebrovascular, metabolic, or pulmonary disease, or other disease or clinical finding that is unstable or that, in the opinion of the investigator, would be negatively affected by trial medication or that would affect trial medication

(11) Patients who have had a myocardial infarction within 1 year before Visit 1

(12) Patients with clinically significant abnormal laboratory findings at Visit 1

(13) Patients with renal impairment (serum creatinine ≥1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal)

(14) Patients whose TSH is ≥10% over the upper normal limit. Patients maintained on thyroid medication must be euthyroid for a period of at least 3 months before Visit 1

(15) Patients with clinically significant abnormalities on ECG

(16) Women who have a positive human chorionic gonadotropin (HCG) pregnancy test at Visit 1 or who are lactating or planning to become pregnant during the course of the study

(17) Patients who have participated in a clinical trial of an investigational drug within the past 3 months

(18) Patients who, in the opinion of the investigator, would be non-compliant with the visit schedule or study procedures

(19) History of orthostatic hypotension or conditions that would predispose them to hypotension (eg dehydration, hypovolemia)

(20) Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of Seroquel tablets, as judged by the investigator Restrictions

Subjects will be required to adhere to the following special restrictions:

1) Use of any psychoactive drugs including antidepressants, hypnotics (with the exceptions noted in Section 4.3), mood stabilizing drugs, and antipsychotics is not permitted from a period of 5 elimination half-lives (28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

2) Use of cytochrome P450 3A4 inducers and potent inhibitors are not permitted from 14 days prior to randomization to end of study (see Table 13)

3.4.3.1 Criteria for discontinuation

Subjects may be discontinued from study treatment and assessments at any time, at the discretion of the investigator(s). Specific reasons for discontinuing a subject from this study are:

1. Withdrawal of informed consent

2. Worsening psychiatric symptoms such that the symptoms constitute a danger to themselves or to others

3. Use of psychotropic medications at any time during the double-blind treatment period.

4. Pregnancy at any time during the double-blind treatment period.

5. Clinically significant or serious adverse event that would not be consistent with continuation in the study, as determined by the investigator, AstraZeneca, or the subject.

3.4.3.2 Voluntary discontinuation by a subject

Subjects are free to discontinue their participation in the study at any time, without prejudice to further treatment. Subjects who discontinue from the study should always be asked about the reason(s) for their discontinuation and about the presence of any adverse events. They should be seen and assessed by an investigator(s) (see Section 3.4.4.4). Adverse events should be followed up and any diary cards, questionnaires (eg, for Quality of Life assessments) and investigational products should be returned by the subject.

3.4.3.3 Incorrectly enrolled or randomized subjects

Incorrectly enrolled subjects will be discontinued from further study treatment and assessments. If a subject is given the incorrect randomized treatment, the subject should be continued on the treatment dispensed and Interactive Clinical Technologies, Inc. (ICTI), the vendor providing the randomization patient assignment) should be notified of the error. The next patient randomized at the site will be assigned an appropriate kit number by ICTI, accounting for the error.

3.4.3.4 Procedures for discontinuation

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination
- Vital signs and weight
- 12-lead ECG
- HAM-D
- MADRS
- ICI-D

- YMRS
- HAM-A
- CGI-C
- CGI-S
- SAS
- BARS
- PSQI
- Q les Q
- Adverse events assessment

Psychiatric assessments (HAM-D, MADRS, YMRS, HAM-A, CGI-C, CGI-S, Q les Q, and PSQI) should not be performed on subjects who have missed 72 hours of study drug before any study visit. Due to the pharmacokinetic profile of quetiapine, these assessments are of questionable clinical accuracy.

3.5 Treatments

3.5.1 Investigational products

3.5.1.1 Identity of investigational product and comparators

Investigational product will consist of 25-mg , 100-mg, and 200-mg tablets of quetiapine fumarate and matching placebo tablets as shown in Table 3.

Table 3 Trial medication

Tablet strength	Formulation number	Tablet color
25-mg quetiapine	F12804	peach
25- mg placebo	F12636	peach
100-mg quetiapine	F12689	yellow
100-mg placebo	F12637	yellow
200-mg quetiapine	F12690	white
200-mg placebo	F12638	white

3.5.1.2 Doses and treatment regimens

Quetiapine and placebo for each trial center will be packaged in blister cards. The 8-week supply will consist of 8 double-blind blister cards. The 8 double-blind blister cards will be packaged in subject-specific cartons.

Trial medication will be provided for each subject in an 8-card carton that contains the following:

- 1-week titration double-blind treatment cards for Days 1-7
- seven 1-week double-blind treatment cards for Days 8-56, with individual cards provided for treatment Days 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, and 50-56.
  Each one-week blister card will include a 2-day treatment overage to accommodate visit schedules.

The Week 1 titration card will consist of 25 mg tablets, 100-mg tablets, and 200-mg tablets or matching placebo, as described below, for each of the 300 mg/day and 600 mg/day treatment groups and placebo treatment group.

Blister cards for Weeks 2 through 8, for each treatment group, will consist of 9 days of dosing with the same number of pills for each group (300-mg,600-mg, and placebo) respectively. The cards for each treatment group will consist of 2 yellow tablets and 2 white tablets per day at bedtime.

Quetiapine or placebo will be administered once a day at bedtime with dose titration to reach a target dose of 300 mg/day by Day 4 in the 300 mg/day treatment group and 600 mg/day by Day 8 in the 600 mg/day group. The schedule for quetiapine or placebo administration is shown in Tables 4, 5, and 6.

Table 4 Dose administration schedule for 300-mg double-blind quetiapine

Trial Day	Quetiapine 300 mg/day and placebo				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablet/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 6	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 7	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	0
Day 8	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg
Days 9-56	0	1 tablet/100-mg	1 tablet/100-mg	1 tablet/200-mg	1 tablet/200-mg

Table 5 Dose administration schedule for 600-mg double-blind quetiapine

Trial Day	Quetiapine 600 mg/day and placebo tablets				
	Quetiapine 25 mg	**Quetiapine 100 mg**	**Placebo 100 mg**	**Quetiapine 200 mg**	**Placebo 200 mg**
Day 1	2 tablets/50-mg	0	0	0	0
Day 2	0	1 tablet/100-mg	0	0	0
Day 3	0	0	0	1 tablet/200-mg	0
Day 4	0	1 tablet/100-mg	0	1 tablet/200-mg	0
Day 5	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 6	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 7	0	2 tablets/100-mg	0	1 tablet/200-mg	0
Day 8	0	2 tablets/100-mg	0	2 tablets/400-mg	0
Days 9-56	0	2 tablets/100-mg	0	2 tablets/400-mg	0

Table 6 Dose administration schedule for double-blind placebo

Trial Day	Placebo 25mg	Placebo 100 mg	Placebo 200 mg
Day 1	2 tablets/50-mg	0	0
Day 2	0	1 tablet/100-mg	0
Day 3	0	0	1 tablet/200-mg
Day 4	0	1 tablet/100-mg	1 tablet/200-mg
Day 5	0	2 tablets/100-mg	1 tablet/200-mg
Day 6	0	2 tablets/100-mg	1 tablet/200-mg
Day 7	0	2 tablets/100-mg	1 tablet/200-mg
Day 8	0	2 tablets/100-mg	2 tablets/400-mg
Days 9-56	0	2 tablets/100-mg	2 tablets/400-mg

Dosing Reduction

Dose reductions for intolerability will be allowed after Day 8. In the 300-mg/day group, dose reductions of 100 mg/day will be achieved by reducing the dose by one 100-mg tablets. In the 600-mg/day group, a dose reduction of 100 mg/day will be achieved by reducing the bedtime dose by one 100-mg tablets active drug. This dose reduction can occur anytime after Day 8. Each column in the blister packs will be numbered 1-4. By Day 6 columns 1 and 2 of the blister packs will each contain a 100-mg tablet. In both the 300-mg /day group and the 600-mg/day group, column 1 will contain active medication thus ensuring that by eliminating the first column (column #1) of medication they are reducing their dose by 100-mg. Each tablet in the placebo treatment group will also indicate the same corresponding numbers (columns #1-4) as the active treatment groups even though no active product is packaged. This will ensure the blind is maintained.

Table 7 Week 1 Blister pack for 300-mg/Day Quetiapine Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 8 Week 2-8 300-mg/Day Quetiapine Blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
2	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
3	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
4	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 9 Week 1 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 10 Week 2-8 600-mg/Day Quetiapine Blister Pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
2	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
3	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
4	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 11 Week 1 Blister Pack for Placebo Group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg placebo	25-mg placebo		
2	100-mg placebo			
3	200-mg placebo			
4	100-mg placebo	200-mg placebo		
5	100-mg placebo	100-mg placebo	200-mg placebo	
6	100-mg placebo	100-mg placebo	200-mg placebo	
7	100-mg placebo	100-mg placebo	200-mg placebo	
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Table 12 Week 2-8 Blister pack for Placebo/Day Group

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
2	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
3	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
4	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
5	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
6	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
7	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

3.5.1.3 Labeling

All trial supplies will be provided by AstraZeneca.

The blister cards Days 1- 56 will be supplied in subject-specific cartons. Each blister card will be labeled with a two-panel, double-blind label. The left portion of the label will remain on the blister card. The right portion of the label will be affixed to the appropriate Case Report Form (CRF) as part of the individual's permanent record. The label will contain at least the following information: trial number, code assignment and storage condition. The carton for the 8 blister cards for Days 1-56 will be labeled with a single-panel double-blind label. The label will contain at least the following information: trial number, storage conditions, and instructions to dispense according to protocol.

3.5.1.4 Storage

All investigational products must be kept in a secure and locked location, at room temperature and protected from light and moisture.

3.5.1.5 Accountability

The investigational materials are to be prescribed only by the investigator or the sub-investigators named in Form FDA-1572. Under no circumstances will the investigator allow the investigational drug to be used other than as directed by the protocol without prior AstraZeneca approval.

The investigator must maintain accurate records accounting for the receipt of the investigational materials (ICTI provides a acknowledge the receipt of drug shipment module for this purpose) and for the disposition of the material. This record keeping consists of a dispensing record that includes the identification of the person to who the drug is dispensed, the quantity and the date of dispensing, and documentation of any unused drug returned to the investigator. This record is in addition to any drug accountability information recorded on the subject's hospital or clinic chart.

Starting with Week 1, each patient will return the blister card for the preceding week to the clinic. The clinic will tabulate the returned pills to aid in drug accountability.

At the termination of the study or at the request of the sponsor, the Clinical Research Associate must return any unused study supplies to Universal Systems Incorporated (USI), at the address listed below, for destruction. This return will be documented on an Investigational Product Return Invoice supplied by AstraZeneca.

USI
2084-900 Lake Industrial Court
Conyers, GA 30013

3.5.2 Method of assigning subjects to treatment groups

This trial will be established with a non-specific labeling (NCSL) randomization which will be stratified by bipolar type. Randomization to trial treatment will be done via an Interactive Voice Response System (IVRS) at ICTI on Day 1 (Visit 2) in balanced blocks within each stratum in order to ensure relative balance among treatment groups and strata (Bipolar I and Bipolar II)in terms of total number of subjects. The randomization schedule will be created under the auspices of AstraZeneca Quantitative Decision Sciences Group and will provide allocation of subject numbers to the treatment regiments. Number and size of tablets will be identical for the 3 treatment arms. Clinical supplies will contain a 4-digit subject number which is allocated to the treatment arm through the randomization scheme. A separate randomization will be used to provide kits of packaged drugs to the sites. The IVRS system at ICTI will allocate a kit number at the site for the treatment assigned through the stratified randomization.

Subject eligibility will be established before treatment randomization. Subjects will be randomized centrally sequentially within the stratum, as subjects are eligible for enrollment/randomization. If

a subject discontinues from the study, the subject number will not be reused, and the subject will not be allowed to re-enter the study.

The randomization is centralized and the assigned randomized patient number and associated kit numbers will not be sequential within a site.

3.5.3 Blinding and procedures for unblinding the study

3.5.3.1 Methods for ensuring blinding

All packaging will be identical with placebo and active tablets identical in size and color. The number of tablets dispensed on each card will be identical across all treatment arms.

The randomization for the kit assignments will be generated by the study statistician and provided directly to packaging with a copy going to ICTI Clinical Supplies Management Group. The stratified patient randomization will be generated by an AstraZeneca randomization staff member not associated with the trial and will be provided directly to ICTI for incorporation into the IVRS system. No member of the study team in AstraZeneca, at investigational sites or the CRO organization handing data will have access to the randomization scheme during the conduct of the study.

3.5.3.2 Methods for unblinding the study

Individual treatment codes, indicating the treatment randomization for each randomized subject, will be available to the investigator(s) or pharmacists at the study center through the use of a concealed panel on the label.

The treatment code must not be broken except in medical emergencies when the appropriate management of the subject necessitates knowledge of the treatment randomization. The investigator(s) must document and report to AstraZeneca any breaking of the treatment code. AstraZeneca retains the right to break the code in order to report serious adverse events to regulatory authorities.

Treatment codes will not be broken for the planned analyses of data until all decisions on the evaluability of the data from each individual subject have been made and documented.

3.5.4 Treatment compliance

Compliance will be assessed based on returned tablet counts. The percent compliance will be calculated as the number of tablets taken (dispensed - returned) divided by the prescribed number of tablets (number of days times number of tablets per day) expressed as a percent. Based on this

calculation a subject with at least 75% compliance with study medication during study participation will be classified as compliant.

Furthermore, if there are any significant irregularities in compliance, in the opinion of the investigator, the patient should be withdrawn from the study.

4 CONCURRENT TREATMENT

4.1 General medications

Nonpsychotropic medication, including over-the counter medications, taken by the subject before entry into the trial may be continued during the trial. Medications required to treat illnesses or complaints that occur during the trial may be used at the discretion of the investigator. Use of cytochrome P450 inducers and potent inhibitors is restricted (see Table 13 below).

Women who enter the trial with an intrauterine device in place, using oral contraceptives, or using injectable or implantable hormonal agents designed to prevent pregnancy may continue these treatments throughout the trial.

The specific type of medication (trade or generic name), the indication for use, and the dates of usage should be reported on the CRF entitled Concurrent Treatment.

Medication which is considered necessary for the subject's safety and well being may be given at the discretion of the investigator(s). The administration of all medication (including investigational products) must be recorded in the appropriate sections of the case report form (CRF).

4.2 Use of psychoactive medications

The use of psychoactive drugs other than those specifically allowed during the trial (ie, lorazepam and zolpidem tartrate) is restricted (see Section 4.3, Table 13).

4.3 Summary of permitted concurrent medications

Medications specifically prohibited or restricted, and those permitted during the trial are listed in Table 13

Table 13 Permitted, restricted, and prohibited medications

Use category	Type of medication
Permitted	Previous medications for medical, nonpsychiatric illnesses Oral contraceptives and contraceptive devices
Restricted	Zolpidem tartrate 5-10 mg at bedtime for insomnia Lorazepam 1-3 mg per day for severe anxiety These drugs may be prescribed during the first 3 weeks of the study as long as they do not interfere with any assessments
Prohibited	Potent cytochrome P450 3A4 inducers (including but not limited to barbiturates, carbamazepine, rifampin, and St John's Wort) Potent cytochrome P450 3A4 inhibitors (including but not limited to ketoconazole, itraconazoole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir, and saquinavir) Antipsychotic medications (including but not limited to phenothiazines, risperidone, olanzapine, ziprasidone, clozapine, loxapine, thiothixene, molindone) Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a period of 7 to 28 days depending on the medications involved (eg. 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine must be discontinued at least 14 days prior to randomization.

5 STUDY MEASUREMENTS AND ENDPOINTS

5.1 Primary endpoint

The primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score. This endpoint is used as the basis for the sample size calculation, as provided in Section 6.1.

5.2 Screening and demographic measurements

The following data are to be collected at screening:

- date of birth, sex, and race
- vital signs, height, weight
- supine and standing blood pressure and pulse
- significant medical history
- physical examination including ophthalmoscopic exam
- 12-lead electrocardiogram
- clinical chemistry and hematology
- pregnancy test (if female of childbearing potential)
- HAM-D assessment
- YMRS
- DSM-IV diagnosis, based on SCID assessment

5.3 Efficacy measurements and endpoints

The following assessments will be used to evaluate efficacy:

- change from baseline to final assessment in MADRS total score
- percentage of subjects with $\geq$50% reduction from baseline in MADRS total score at final assessment
- the change from baseline in each assessment (observed cases) in the MADRS total score

- the change from baseline to each assessment (observed cases) and final assessment in the CGI-S
- the CGI-C at final assessment
- the change from baseline to each assessment (observed cases) and final assessment in the YMRS
- the change from baseline to each assessment (observed cases) and final assessment in the total HAM-A

Evaluation using each of these scales should be performed by the same trained/certified staff member who has been approved by AstraZeneca for all assessments of the scale for an individual subject.

5.3.1 Summary of efficacy objectives and endpoints

Table 14 shows how the efficacy endpoints of this study relate to the study objectives.

Table 14 Efficacy objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Primary	Primary measure		
evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks	change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score; ls means, 95% CI at final assessment ; descriptive statistics by statum	ANCOVA for the change from baseline to final assessment for total MADRS score. Pair-wise comparisons of each dose with placebo using step up procedure	Reductions in MADRS compared with placebo will indicate doses which are effective in treating depressive episode
	Secondary measure		
	percentage of subjects meeting the MADRS responder criteria ; n, percentage responders at each assessment, final assessment ; descriptive statistics by statum	Logistic model	Higher response rates will indicate doses which are effective in treating depressive episode in treating depressive episode
	change from baseline to each assessment for the MADRS total score, and	ANCOVA for the change from baseline to each assessment	Reductions in scales compared with placebo will indicate doses

	each assessment and final assessment Clinical Global Impression - Severity (CGI-S); ls means, 95% CI; descriptive statistics by stratum	and final assessment (LOCF) for CGI-S. Pair-wise comparisons of each dose with placebo	which are effective in treating depressive episode
	Clinical Global Impression - Change (CGI-C); ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the CGI-C for each assessment and final assessment (LOCF). Pair-wise comparisons of each dose with placebo	Greater improvements in CGI-C will indicate doses which are effective compared with placebo
Secondary			
evaluate the efficacy of quetiapine compared to placebo in the incidence of treatment -emergent mania	change from baseline to each assessment and final assessment in the YMRS total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for YMRS total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	No significant increase in the YMRS compared to placebo will indicate doses which do not result in treatment-emergent mania
evaluate the effect of quetiapine compared to placebo on symptoms of anxiety	change from baseline to each assessment and final assessment in the HAM-A total score; ls means, 95% CI; descriptive statistics by stratum	ANCOVA for the change from baseline to each assessment and final assessment for HAM-A total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Improvement in the HAM-A compared to placebo will indicate efficacy in treating anxiety component of the depressive episode

The methods for collecting efficacy data are presented below.

5.3.2 Montgomery-Asberg Depression Rating Scale (MADRS)

5.3.2.1 Methods of assessment

The MADRS will be performed at each visit during the trials using the validated MADRS instrument by certified staff at each site.

5.3.2.2 Calculation or derivation of endpoint

The change from baseline to final LOCF will be calculated for total MADRS score. A subject will be classified as a responder if the % change from baseline, calculated as the (change from baseline divided by the baseline) multiplied by 100 indicates a ≥ 50% reduction in baseline total MADRS score.

5.3.3 Hamilton Rating Scale for Depression (HAM-D)

5.3.3.1 Methods of assessment

The HAM-D will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-D and HAM-D item #1.

5.3.4 Clinical Global Impression - Severity (CGI-S)

5.3.4.1 Methods of assessment

The CGI-S will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.4.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in CGI-S.

5.3.5 Clinical Global Impression - Change (CGI-C)

5.3.5.1 Methods of assessment

The CGI-C will be performed at scheduled visits during the trial by a trained professional at each site.

5.3.5.2 Calculation or derivation of endpoint

The CGI-C is a measure of change from baseline and therefore requires no further derivation.

5.3.6 Hamilton Rating Scale for Anxiety (HAM-A)

5.3.6.1 Methods of assessment

The HAM-A will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.6.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in HAM-A.

5.3.7 Young Mania Rating Scale (YMRS)

5.3.7.1 Methods of assessment

The YMRS will be performed at scheduled visits during the trial by a certified staff member at each site.

5.3.7.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in YMRS.

5.4 Safety measurements and endpoints

The following measurements will be used to assess safety:

- adverse event reporting (both general adverse events and serious adverse events), coded using MedDRA system of nomenclature
- fasting clinical laboratory tests (including chemistry and hematology)
- vital signs(taken in both the standing and supine positions)
- ECG tests
- Simpson-Angus Scale
- Barnes-Akathesia Rating Scale

5.4.1 Summary of safety objectives and endpoints

Table 15 shows how the safety endpoints of this study relate to the study objectives.

Table 15 Safety objectives and endpoints relating to each objective

Objective	Endpoints and statistic	Planned analysis	Significance of results
evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	incidence and nature of adverse events during double-blind treatment ; n, % incidence per event, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	no new safety issues identified
	incidence of drug-related adverse events during double-blind treatment ; n, % incidence; titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of subject withdrawal due to adverse events; n, % withdrawn, placebo run-in, titration week and 7 weeks of therapy	descriptive statistics only	
	incidence of clinically significant changes in vital signs; n, % at each assessment and final visit	descriptive statistics only	
	change in the SAS total score ; mean change, standard deviation, baseline to final assessment (LOCF)	descriptive statistics only	
	the change in BARS total score	descriptive statistics only	
	incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment	descriptive statistics only	

The methods for collecting safety data are described below.

5.4.2 Adverse Events

5.4.2.1 Definitions

The definitions of adverse events (AEs), serious adverse events (SAEs) and other significant adverse events (OAEs) are given below. It is of the utmost importance that all staff involved in the study is familiar with the content of this section. The principal investigator is responsible for ensuring this.

(a) Adverse Event

An adverse event is the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver) or the abnormal results of an investigation (eg, laboratory findings, electrocardiogram). In clinical studies, an AE can include an undesirable medical condition occurring at any time, including run-in or washout periods, even if no study treatment has been administered.

(b) Serious Adverse Event

A serious adverse event is an AE occurring during any study phase (ie, run-in, treatment, washout, follow-up), and at any dose of the investigational product, comparator or placebo, that fulfills one or more of the following criteria:

- results in death
- is immediately life-threatening
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- is a congenital abnormality or birth defect
- is an important medical event that may jeopardize the subject or may require medical intervention to prevent one of the outcomes listed above?

The causality of SAEs (ie, their relationship to study treatment) will be assessed by the investigator(s), who in completing the relevant case report form must answer “yes” or “no” to the question “Do you consider that there is a reasonable possibility that the event may have been caused by the drug?” For further guidance on the definition of a SAE and a guide to the interpretation of the causality question, see Appendix F.

(c) Other significant adverse event

An AstraZeneca expert will identify OAEs during the evaluation of safety data for the Clinical Study Report. Significant adverse events of particular clinical importance, other than SAEs and those AEs leading to discontinuation of the subject from study treatment, will be classified as OAEs. Examples of these are marked hematological and other laboratory abnormalities, and certain events that lead to intervention (other than those already classified as serious), dose reduction or significant additional treatment. For each OAE, a narrative will be written and included in the Clinical Study Report.

5.4.2.2 Recording of adverse events

All AEs and SAEs that occur before and during treatment, whether or not related to the study drug, must be recorded on the CRF provided by the sponsor. Following cessation of treatment, SAEs, whether or not related to the study drug, must be collected for 7 days and recorded on the CRF provided by the sponsor. If any SAEs are recorded during the 7 day follow-up period, all concomitant medications taken during the 7 day follow-up period should also be recorded on the CRF. A description of the event, its intensity, duration, action taken (eg, treatment and follow-up tests), and outcome should be given, along with the investigator's causality assessment of the relationship of the event to the study drug. If a diagnosis of the subject's condition has been made, then the diagnosis should be recorded as the SAE. In instances of well recognized syndromes (eg, fever, runny nose, cough) they can be recorded as "flu". However, if a diagnosis of the subject's condition has not been made, or if the individual symptoms are not well recognized, then the individual symptoms should be recorded separately.

In general, abnormal laboratory tests or vital signs should not be reported as AEs unless they fulfill the criteria for an SAE or lead to discontinuation. If an abnormal laboratory test result or vital sign is associated with clinical signs and symptoms, the sign or symptom should be reported as an AE, and the associated test result or vital sign should be recorded on the appropriate CRF.

A causality assessment must be recorded for all AEs. The CRF asks the question, "In your medical judgement, is there a reasonable possibility that the event may have been caused by the study therapy?" If there is any valid reason, even if undetermined or untested, for suspecting a possible cause-and-effect relationship between the study drug and the occurrence of the AE, then this should be answered "yes." Otherwise, if no valid reason exists for suggesting a possible relationship, then this should be answered "no." If more than 1 AE is identified, a causality assessment must be made for each AE.

It is important to distinguish between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined by the criteria in Section 5.4.2.1 b. An AE of severe intensity need

not necessarily be considered serious. For example, nausea which persists for several hours may be considered severe nausea, but not a SAE. On the other hand, a stroke which results in only a limited degree of disability may be considered a mild stroke but would be a SAE.

Any detrimental change in the subject's condition after the subject enters the study will be discussed with the investigator. Where the detrimental change is considered by the investigator to constitute a progression or relapse of bipolar depression or a lack of efficacy, then this will not be considered an AE even where this necessitates or prolongs hospitalization. When there is deterioration in the condition for which the medicine is being used, there may be uncertainty as to whether this is lack of efficacy or an AE. In such cases, unless AstraZeneca or the reporting physician considers that the medicine contributed to the deterioration, the deterioration should be considered lack of efficacy. However, if it is believed that the medicine may have contributed to the deterioration, then this should be treated as an AE.

Study drug abuse is an SAE, even when there are no symptoms or additional AEs and should be reported according to the guidelines in Section 5.4.2.3. Misuse of study drug is an AE but is not considered an SAE unless accompanied by serious sequelae.

Should an overdose occur, it must be reported in accordance with the procedures described in Section 10.3 Procedures in case of overdose. All overdoses, with or without associated symptoms, should be reported as AEs.

Suicide and attempted suicide, irrespective of the method, but occurring in connection with the use of study drug, should be reported as AEs (serious or non-serious). This event should be identified as suicide or attempted suicide, and the method of the suicide or attempt should be provided. If an attempted suicide meets the criteria for an SAE, the event must be reported according to the guidelines in Section 10.4.

Should a pregnancy occur, it must be reported in accordance with the procedures described in Section 10.5. Procedures in case of pregnancy. Pregnancy in itself is not regarded as an AE unless there is a suspicion that an investigational product may have interfered with the effectiveness of a contraceptive medication.

5.4.2.3 Reporting of serious adverse events

Investigators and other site personnel must inform appropriate AstraZeneca representatives of any SAE that occurs in the course of the study within 1 day (i.e. immediately but no later than the end of the next business day) of when he or she becomes aware of it.

The AstraZeneca representative will work with the investigator to compile all the necessary information and ensure that the appropriate AstraZeneca Drug Safety Department receives a report by day 1 for all fatal and life-threatening cases and by day 5 for all other SAEs.

Follow-up information on SAEs must also be reported by the investigator within the same time frames.

If a non-serious AE becomes serious, this and other relevant follow-up information must also be provided to AstraZeneca within 1 day as described above.

After initial notification, the AstraZeneca representatives have 4 days to work with the investigator to compile all the necessary information to ensure that the appropriate AstraZeneca Drug Safety Department receives a complete report by day 5. Follow-up information on SAEs should also be reported by the investigator within the same time frames. If a non-serious case becomes serious, this and other relevant follow-up information should also be provided to AstraZeneca within 1 day as described in the paragraph above

All SAEs have to be reported, whether or not considered causally related to the investigational product. All SAEs will be recorded in the case report form. The investigator is responsible for informing the Ethics Committee and/or the Regulatory Authority of the SAE as per local requirements.

5.4.3 Laboratory safety measurements and variables

Blood (under fasting conditions) and urine specimens will be collected for laboratory test analysis and these samples will be processed by a central laboratory (Quintiles Central Laboratory).

5.4.3.1 Methods of assessment

- Fasting hematology: hemoglobin, hematocrit, red blood cell count, total and differential white blood cell counts and platelet count
- Fasting clinical chemistry: total bilirubin, alkaline phosphatase, alanine transaminase(ALT), aspartate transaminase(AST), sodium, potassium, chloride, creatinine, glucose, insulin, bicarbonate, high-density lipoprotein cholesterol, triglycerides, low-density lipoprotein cholesterol and total cholesterol
- Thyroid function tests: thyroid stimulating hormone (TSH), Triiodothyronine resin uptake (T3RU), and total thyroxine (T4)
- Serum pregnancy tests
- Urine toxicology screen

5.4.3.2 Calculation or derivation of endpoints

Change from baseline will be derived for all subjects who have a screening laboratory test and a final laboratory test. The change from baseline is the final test value minus the screening test value. Laboratory test values will also be compared to the laboratory standard normal ranges and flagged with H or L if they are outside of the normal range. In addition, treatment emergent laboratory changes, identified using computerized methods to compare results or changes from baseline to standard extended ranges will be flagged at the subject and test level.

5.4.4 Vital signs measurement

5.4.4.1 Methods of assessment

A standard blood pressure cuff will be used to obtain systolic and diastolic blood pressure. The assessment will be done first with the subject in the supine position for 3 minutes and again within 3 minutes of the subject attaining a standing position. Pulse will be measured for 1 minute.

5.4.4.2 Calculation or derivation of endpoints

Change from baseline will derived be as the value at the visit minus the screen value for the same assessment and position. In addition the change within a visit between the standing and supine blood pressure assessments will be calculated for both systolic and diastolic blood pressures. This difference will be calculated as supine minus standing . A subject will be classified as having calculated postural hypotension if either the systolic blood pressure difference indicates a decrease >20 mmHg or the diastolic blood pressure difference indicates a decrease >15 mmHg.

5.4.5 ECG safety measurements and variables

5.4.5.1 Methods of assessment

A 12 lead ECG assessment will be done using an ECG machine compatible with the requirements for eResearch the central evaluation laboratory. The central laboratory will supply the interval data, rates and standard interpretation of the ECG test results.

eResearch
30 south 17th Street
Philadelphia, PA 19103-4001

5.4.5.2 Calculations and derivations of endpoint

Change from baseline for interval data and rate data will be derived by subtracting the screen value from the final assessment value. Values outside the extended range in Appendix XX will be flagged.

5.4.6 Simpson-Angus Scale (SAS)

5.4.6.1 Methods of assessment

The SAS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.6.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.4.7 Barnes-Akathisia Rating Scale (BARS)

5.4.7.1 Methods of assessment

The BARS instrument will be administered by study staff to assess EPS symptoms in the subject.

5.4.7.2 Calculations and derivations of endpoint

Changes from baseline score will be assessed.

5.5 Quality of Life endpoint

The following assessment will be used to assess the effect of quetiapine compared with placebo on quality of life as assessed by:

- the PSQI
- the short form Q-Les-Q

5.5.1 Summary of quality of life objectives and endpoints

Table 16 shows how the efficacy endpoints of this study relate to the study objectives.

Table 16 Quality of life objectives and endpoints relating to each objective

Objective	Endpoint(s) and statistics	Planned analysis	Significance of results
Secondary	Secondary measure		
evaluate the effect of quetiapine compared to placebo on quality of sleep	change from baseline to final assessment in PSQI; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for PSQI total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Reduction in PSQI compared with placebo indicates improvement of sleep quality
evaluate the effect of quetiapine compared to placebo on the overall quality of life	change from baseline to final assessment in Q-Les-Q; ls means, 95% CI	ANCOVA for the change from baseline to each assessment and final assessment for Q-Les-Q total score, with MADRS score as covariate. Pair-wise comparisons of each dose with placebo	Increase in Q-Les-Q compared with placebo indicates improvement of overall quality of life

The methods of collecting quality of life data are described below.

5.5.2 PSQI

5.5.2.1 Methods of assessment

The PSQI will be performed at scheduled visits during the trial by a patient at each site. The 9 self-rated questions will be incorporated into 7 component scores which are added together to yield one total "global" score. Higher scores indicate more severe difficulties in sleep quality.

5.5.2.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the PSQI.

5.5.3 Q-Les-Q

5.5.3.1 Methods of assessment

The Q-Les-Q is a patient self assessment questionnaire which will be completed at scheduled visits during the trial by a patient at each site. The short form has 14 self-rated questions, the first 12 will be incorporated into a total score. Higher scores indicate better quality of life.

5.5.3.2 Calculation or derivation of endpoint

The change from baseline will be calculated at each assessment (observed cases) and final assessment in the Q-Les-Q.

5.6 Interactive Computer Interview for Depression (ICI-D)

Participating in the Interactive Computer Interview for Depression (ICI-D) is voluntary for all the sites. Participation by the subjects at these sites is also voluntary. At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the MADRS. Raters or other site staff will first enter the subject's MADRS scores into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

For quality assurance purposes, if an above-threshold variance is detected between the ICI-D and the MADRS on individual items or the overall score, a CRS clinician (Ph.D. or MD) will contact the applicable rater for a monitoring consultation. The CRS clinician will discuss possible reasons for the discrepancy, review conventions for scoring and offer additional training if necessary.

The ICI-D will also provide an additional check of the patient's suicide status. The ICI-D will alert the rater if the patient reports suicidal plans. If the patient did not verbalize these thoughts during the interview /assessment process, the rater could then take the appropriate clinical steps.

A standard operating procedure for ICI-D will be provided to the sites.

5.7 Genetic sampling and storage

There will be no genetic sampling in this trial.

5.8 Volume of blood sampling and handling of biological samples

The total volume of blood that will be drawn from each subject in this study is as follows:

Table 17 Volume of blood to be drawn from each subject

Assessment		Sample volume (ml)	N of samples	Total volume (ml)	
				Women	Men
Safety	Clinical chemistry				
	Hematology	18	2	36	36
	Serum Pregnancy[a]	2	1	2	
Total				38	36

[a] Women only.

Sample handling and storage will be defined by the central laboratory which will be handling the analysis and reporting or results from samples.

6 DATA MANAGEMENT

Case Report Forms (CRFs) will be provided for recording of data. The forms will be in triplicate with carbonless paper. Data will be recorded legibly onto the CRFs with black ink, preferably with a ballpoint pen. If any data are not available, omissions will be indicated on the CRFs. Corrections should be made legibly and be initialed and dated. Correction fluid or covering labels must not be used. The top original and the first copy of the completed form will collected and returned to AstraZeneca/AstraZeneca's agent and the second copy will be retained by the investigator.

Data received electronically by AstraZeneca from a validated source will be loaded directly into the trial database for analysis.

7 STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

7.1 Determination of sample size

Since there is no data using the MADRS instrument in the assessment of quetiapine in treating bipolar subjects with depression, the sample size estimation was based on published data from the lamotrigine monotherapy (Calabrese et al, 1999) and olanzapine trials (Tohen et al, 2002). The percentage change in the HAM-D across these lamotrigine studies in bipolar depression is similar to that observed with quetiapine. MADRS scores correlate significantly with those of the HAM-D (Montgomery Asberg 1979).

Sample size was estimated using an Bonferroni correction for the 2 comparisons with placebo. A clinically meaningful 3.6-unit difference between quetiapine treatment and placebo was used to estimate the effect size (with 3.1 units considered a minimally effective and detectable difference). The variability used for calculation was 10 units, the variability seen in the olanzapine study. A sample size of 168 subjects/arm (504 subjects total) would provide 85% power for 2-sided pair-wise comparisons with placebo at α=0.025 which provides an overall experiment wise type I error rate of 0.05. Therefore, 740 patients will be screened and approximately 530 subjects randomized (allowing for a 5% early drop out rate), to insure 504 subjects with post baseline data available for analysis (MITT analysis population). This sample size will provide 72% power to detect a 3.1 unit difference from placebo.

7.2 Statistical evaluation

7.2.1 Methods of statistical analysis

A comprehensive Statistical Analysis Plan (SAP) will be prepared before unblinding of the data.

Missing data for final visit resulting from patient drop outs will be imputed using an LOCF approach. Patients with post baseline data (MITT population) will have their last trial assessment carried forward as the final assessment for analyses.

7.2.2 Study endpoints

Primary efficacy endpoint is the change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score.

Secondary efficacy endpoints:

(1) Percentage of patients with a ≥50% reduction from baseline in the MADRS total score at study endpoint

(2) Change from baseline to each assessment (observed cases) in the MADRS total score

(3) Change from baseline to each assessment (observed cases) and final assessment in the total HAM-D, HAM-D Item 1, CGI-S, CGI-C, and Young Mania Rating Scale.

(4) Change in the PSQI score from baseline to final assessment

Safety endpoints:

(1) Incidence and nature of adverse events during double-blind treatment

(2) Incidence of drug-related adverse events during double-blind treatment

(3) Incidence of subject withdrawal due to adverse events

(4) Incidence of clinically significant changes in hematology and chemistry laboratory results, vital signs, electrocardiograms, weight, and body mass index.
Tolerability endpoints:

(5) Change in the SAS total score from baseline to final assessment

(6) Change in BARS total score from baseline to final assessment

(7) Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment

Quality of Life endpoints:

(1) Change in Q-Les-Q total score from baseline to final assessment

(2) Proportion of patients achieving community norm levels in Q-Les-Q at final assessment

7.2.3 Statistical analyses

The randomization will be stratified by Bipolar type (I or II) in order to assure balance across treatments for the type of patient enrolled. The stratification will be incorporated into the statistical analysis models and descriptive statistics will be provided for each stratum.

For each statistical model run, the assumptions for the model will be evaluated. If the assumptions are not reasonably met, the data may be transformed to meet assumptions or a non-parametric test performed.

All statistical comparisons will be based on 2-sided testing approaches for testing the difference between active study medication dose and placebo.

7.2.3.1 Study populations for analysis

The modified intention to treat population (MITT) will be the population for efficacy and quality of life evaluation. The MITT population will include all randomized subjects who were received study treatment and had at least one post baseline efficacy assessment with a last observation carried forward approach for final assessment.

The safety population will include all subjects who provide consent and received study medication.

7.2.3.2 Primary Analysis

The primary analysis will use analysis of covariance (ANCOVA) model for the change from baseline at final assessment for the MADRS. The model will include terms for treatment, stratum, with the baseline MADRS as a covariate. The Simes-Hommel step-up procedure will be used to adjust for the 2 comparisons with placebo (Simes-Hommel, 1988). The p-values obtained from the pair-wise comparisons will be ordered as follows: $P(1) \leq P(2)$. The following rule will be used to assess statistical significance:

1) If $P(2) \leq 0.05$, then reject both null hypotheses associated with P(2) and P(1); else proceed to the next step;

2) If $P(1) \leq 0.025$, then reject the null hypothesis associated with P(1).

7.2.3.3 Secondary Analyses of efficacy and quality of life

The secondary endpoint for responder, defined as a subject who has a 50% reduction in MADRS score from baseline to final assessment, will be analyzed by comparing the proportion of subjects responding across treatments using a logistic model which includes treatment, stratum, and center in the model. The secondary endpoints based on change from baseline for scales at an assessment time will be analyzed using the same model as the primary endpoint. Nominal p-values will be used for all secondary endpoint comparisons.

Exploratory repeated measures analysis of variance model will also be conducted to evaluate whether there are significant differences among treatments across time for the MADRS and HAM-D scores.

Descriptive statistics will be used to report stratum, item scores, and subscale scores.

7.2.3.4 Safety analyses

Adverse events will be coded using the MedDRA dictionary. Numbers of events and incidence rates for AEs in each treatment group will be summarized by preferred term and system organ class. An event that occurred one or more times on the date of, or subsequent to, randomization will contribute one observation to the numerator of the incidence rate. The denominator will comprise all patients exposed to study treatment.

Adverse events that lead to premature withdrawal of subjects will be tabulated for each treatment group.

All laboratory assessments, vital signs, ECG (rates and intervals) results, and weight and body mass index will be tabulated using descriptive statistics at baseline, final assessment and including change from baseline. Descriptive statistics will include n, mean, standard deviation, minimum and maximum value.

7.2.3.5 Tolerability analyses

The change from baseline in SAS and BARS score data will be summarized using descriptive statistics (mean, standard deviation, median, minimum and maximum).

Incidence rates of EPS adverse events will be compared and tabulated using descriptive statistics.

7.2.3.6 Interim analysis

No interim analysis is planned

7.2.3.7 Data or safety monitoring committee

There will be no data or safety monitoring committee.

8 STUDY MANAGEMENT

8.1 Monitoring

Before the study begins, a representative of AstraZeneca or company representing AstraZeneca will visit the investigational site to

- determine the adequacy of the facilities
- discuss with the investigator(s) (and other personnel involved with the study) their responsibilities with regard to protocol adherence, and the responsibilities of AstraZeneca or its representatives.

During the study, a monitor from AstraZeneca or company representing AstraZeneca will have regular contacts with the investigational site, including visits to

- provide information and support to the investigator(s)
- confirm that facilities remain acceptable
- confirm that the investigational team is adhering to the protocol, that data are being accurately recorded in the case report forms (CRFs), and that investigational product accountability checks are being performed.
- perform source data verification (a comparison of the data in the CRFs with the subject's records at the hospital or practice, and other records relevant to the study). This will require direct access to all original records for each subject (eg, clinic charts).

The monitor or another AstraZeneca representative will be available between visits if the investigator(s) or other staff at the center need information and advice.

8.2 Audits and inspections

Authorized representatives of AstraZeneca, a regulatory authority, an Independent Ethics Committee (IEC) or an Institutional Review Board (IRB) may visit the center to perform audits or inspections, including source data verification. The purpose of an AstraZeneca audit or inspection is to systematically and independently examine all study related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed, and accurately reported according to the protocol, Good Clinical Practice (GCP), guidelines of the International Conference on Harmonization (ICH), and any applicable regulatory requirements. The investigator should contact AstraZeneca immediately if contacted by a regulatory agency about an inspection at his or her center.

8.3 Training of staff

The principal investigator will maintain a record of all individuals involved in the study (medical, nursing and other staff). He or she will ensure that appropriate training relevant to the study is given to all of these staff, and that any new information of relevance to the performance of this study is forwarded to the staff involved.

8.4 Changes to the protocol

Study procedures will not be changed without the mutual agreement of the international principal investigator(s) and AstraZeneca.

If it is necessary for the study protocol to be amended, the amendment or a new version of the study protocol must be notified to or approved by each IEC or IRB, and in many countries also the local regulatory authority, before implementation. Local requirements must be followed.

If a protocol amendment requires a change to a particular center's Written Informed Consent Form, then AstraZeneca and the center's IEC or IRB must be notified. Approval of the revised Written Informed Consent Form by AstraZeneca and by the IEC or IRB is required before the revised form is used.

AstraZeneca will distribute amendments and new versions of the protocol to each principal investigator(s), who in turn is responsible for the distribution of these documents to his or her IEC or IRB, and to the staff at his or her center. The distribution of these documents to the regulatory authority will be handled according to local practice.

8.5 Study agreements

The principal investigator at each center must comply with all the terms, conditions, and obligations of the study agreement for this study. In the event of any inconsistency between this protocol and the study agreement, this study agreement shall prevail.

8.6 Study timetable and termination

It is anticipated that the first subject will be enrolled in September 2002 and that the last subject will complete the study in March 2004.

9 ETHICS

9.1 Ethics review

The final study protocol, including the final version of the Written Informed Consent Form, must be approved or given a favorable opinion in writing by an IEC or IRB as appropriate. The investigator must submit written approval to AstraZeneca before he or she can enroll any subject into the study.

The principal investigator(s) is responsible for informing the IEC or IRB of any amendment to the protocol in accordance with local requirements. In addition, the IEC or IRB must approve all advertising used to recruit subjects for the study. The protocol must be reapproved by the IEC or IRB annually, as local regulations require.

Either the investigator(s) or AstraZeneca must submit progress reports to the IEC or IRB according to local regulations and guidelines. The principal investigator(s) must also provide the IEC or IRB with any reports of serious adverse events from the study site.

The principal investigator(s) is also responsible for providing the IRB with reports of any serious adverse events from any other study conducted with the investigational product. This information will be provided to the principal investigator(s) by AstraZeneca.

9.2 Ethical conduct of the study

The study will be performed in accordance with the ethical principles in the Declaration of Helsinki (see Appendix C), Good Clinical Practice, and applicable regulatory requirements.

9.3 Subject information and consent

The principal investigator(s) at each center will ensure that the subject is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Subjects must also be notified that they are free to discontinue from the study at any time. The subject should be given the opportunity to ask questions and allowed time to consider the information provided.

The subject's signed and dated informed consent must be obtained before conducting any procedure specifically for the study, including the following:

The principal investigator(s) must store the original, signed Written Informed Consent Form. A copy of the Written Informed Consent Form must be given to the subject.

A sample Written Informed Consent Form is enclosed (Appendix B). If modifications are made according to local requirements, the new version has to be approved by AstraZeneca.

9.4 Subject data protection

AstraZeneca recognises the importance of protecting the privacy of patient (subject) data. Therefore, for study sites within the US or in studies where foreign subjects' protected health information **(subject data)** will come into the US through a covered entity (eg, Central Lab/Reader), the Informed Consent Form will incorporate, or be accompanied by, a separate document incorporating HIPAA-compliant wording by which subjects authorize the use and disclosure of their Protected Health Information by the Investigator and by those persons who need that information for the purposes of the study.

The Written Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. The subjects' names will not be recorded in this database. The Written Informed Consent Form will also explain that for data verification purposes, authorized representatives of AstraZeneca, a regulatory authority, an IEC or IRB may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

10 EMERGENCY PROCEDURES

10.1 AstraZeneca emergency contact procedure

In the case of a medical emergency, contact AstraZeneca personnel shown below.

Wayne Macfadden MD
Project Physician
302-886-1147 (telephone)
302-886-5567 (fax)
REDACTED

Robin McCoy RN
Senior Clinical Research Scientist
302-886-4650 (telephone)
302-886-5567 (fax)
REDACTED

Contact AstraZeneca switchboard on 1-800-236-9933 and ask to be put in contact with the person on call for the Seroquel clinical team.

10.2 Procedures in case of medical emergency

The principal investigator(s) is responsible for ensuring that procedures and expertise are available to cope with medical emergencies during the study.

10.3 Procedures in case of overdose

For the purpose of this trial all overdoses should be reported as adverse events. However, all cases of overdose must be reported immediately, within 1 day, if sequelae meeting the criteria for serious adverse event have occurred in association with the overdose. In all instances, the overdose substance should be stated and whether the overdose was accidental or intentional. If the overdose was a suicide attempt, this fact should be clearly stated. Adverse events (serious and non-serious) arising as the result of an overdose should be recorded on an adverse event form as "sequelae to overdose." For example "nausea as sequelae to overdose."

10.4 Suicide

Suicide and suicide attempt, irrespective of the method, but in connection with the use of trial drug, should be reported as a serious adverse event (in accordance with the definition provided in Section 5.4.2.1). This event should be identified as suicide or suicide attempt, and the method of the suicide or the suicide attempt should be provided. Suicidal thoughts should also be regarded as adverse events.

10.5 Procedures in case of pregnancy

Pregnancy itself is not regarded as an adverse event unless there is a suspicion that the investigational product under study may have interfered with the effectiveness of a contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) must be followed up and documented even if the subject was discontinued from the study.

All reports of congenital abnormalities/birth defects are SAEs. Spontaneous miscarriages should also be reported and handled as SAEs. Elective abortions without complications should not be handled as AEs. All outcomes of pregnancy must be reported to AstraZeneca on the pregnancy outcomes report form.

11 REFERENCES

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Clinical Study Protocol: Appendix A	
Study Code	5077US/0049
Version No.	2
Appendix Date	September 30, 2002

Appendix A
Signatures

IND No. 32,123

SIGNATURE OF PRINCIPAL INVESTIGATOR

Title of report

A Multicenter, Double-blind, Randomized, Placebo-controlled, double-dummy Trial of the User of Quetiapine fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

I agree to the terms of this study protocol. I will conduct the study according to the procedures specified herein, and according to the principles of Good Clinical Practice (GCP) and local regulations.

Centre No.: 0001

Signature: Joseph Calabrese 10/14/03

Joseph Calabrese, MD
University Hospitals of Cleveland
Mood Disorders Program
11400 Euclid Avenue, Suite 200
Cleveland, OH 44106

Date

AstraZeneca

Clinical Study Protocol: Appendix B	
Study Code	5077US/0049
Version No.	1
Appendix Date	August 6, 2002

Appendix B

Sample written informed consent form

A sample informed consent is provided under separate cover.

AstraZeneca

Clinical Study Protocol: Appendix C

Study Code	5077US/0049
Version No.	1
Appendix Date	August 6, 2002

Appendix C

Declaration of Helsinki

Recommendations guiding physicians in biomedical research involving human subjects.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975 and the 35th World Medical Assembly, Venice, Italy, October 1983 and the 41st World Medical Assembly Hong Kong, September 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of The World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient´s interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject´s physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject´s freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor´s consent must be obtained in addition to the consent of the minor´s legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with professional care (Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo studies where no proven diagnostic or therapeutic method exists.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical re-search involving human subjects

(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to thepatient´s illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

AstraZeneca

Clinical Study Protocol: Appendix D	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix D

Investigators and study administrative structure

STAFF AT INVESTIGATIONAL SITE(S)

Centre No.	**Centre address**	**Name** (First name, Last name)	**Qualifications**	**Position**	**Role in the study**
<<>>					Principal investigator

A list of participating investigators will be provided upon request.

ASTRAZENECA STUDY PERSONNEL

Name (First name, Last name)	**Position**	**Role in the study**
Robin McCoy	Senior Clinical Research Scientist	Clinical Management Lead
Margaret Minkwitz	Director Biostatistics Project Team	Biostatistician
Wayne Macfadden	Medical Director Clinical Research	Medical advisor
Jeris Minor	Data Analyst	Data Analyst
Elaine Yu	Assistant Director Health Economics	Health Economics
Ellen Quimby	IPS Demand Manager	IPS Representative
Jennifer Mahoney	Safety Representative	Safety
Patti Neal	Regulatory Representative	Regulatory
Richard White	Director Health Economics	Health Economics

OTHER PARTICIPANTS

Organisation and address	**Name** (First name, Last name)	**Qualifications/Position**	**Role in study**
Lineberry Research Associates 79 Alexander Drive Bldg 4401, Suite 400Research Triangle Park, NC 27709 See CRO Personnel List	Kelly Abernathy	RN	Project Manager

AstraZeneca

Clinical Study Protocol: Appendix E	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix E

Insurance and indemnity

For the US, this Appendix E is not applicable. Please refer to the clinical study agreement for information regardingAstraZeneca's obligation to insure and indemnify institution and investigator.

INSURANCE AND INDEMNITY

AstraZeneca's liability is covered by a liability insurance policy with AstraZeneca Insurance Company Limited, policy No.: L/702938.

With respect to any liability directly or indirectly caused by the investigational products in connection with this Clinical Study, AstraZeneca assumes liability by law on behalf of the investigator(s) and his assistants for possible injury to the subject provided the investigator(s) and his assistants have followed the instructions of AstraZeneca in accordance with this protocol and any amendments thereto, that the investigational products administered to the subject in this Clinical Study have been supplied by AstraZeneca and that the investigator and his assistants have in general performed this clinical study in accordance with scientific practice and currently acceptable techniques and know-how.

AstraZeneca can forward a letter of indemnity if needed by the investigator(s)/institution.

AstraZeneca

Clinical Study protocol: Appendix F	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8 2002

Appendix F
Additional safety information

1. FURTHER GUIDANCE ON THE DEFINITION OF A SERIOUS ADVERSE EVENT (SAE)

Life threatening

'Life-threatening' means that the subject was at immediate risk of death from the adverse event as it occurred or it is suspected that use or continued use of the product would result in the subject's death. 'Life-threatening' does not mean that had an adverse event occurred in a more severe form it might have caused death (ie hepatitis that resolved without hepatic failure).

Hospitalisation

Out-subject treatment in an emergency room is not in itself a serious adverse event, although the reasons for it may be (eg, bronchospasm, laryngeal oedema). Hospital admissions and/or surgical operations planned before or during a study are not considered adverse events if the illness or disease existed before the subject was enrolled in the study, provided that it did not deteriorate in an unexpected way during the study.

Important medical event or medical intervention

Medical and scientific judgement should be exercised in deciding whether a case is serious in a situation where important medical events may not be immediately life-threatening or result in death, hospitalisation, disability or incapacity but may jeopardise the subject or may require medical intervention to prevent one or more outcomes listed in the definition of serious. These should usually be considered as serious. Examples of such events are:

- Angioedema not severe enough to require intubation but requiring iv. hydrocortisone treatment
- Hepatotoxicity caused by paracetamol (acetaminophen) overdose requiring treatment with N-acetylcysteine
- Intensive treatment in an emergency room or at home for allergic bronchospasm
- Blood dyscrasias (eg, neutropenia or anaemia requiring blood transfusion, etc.) or convulsions that do not result in hospitalisation
- Development of drug dependency or drug abuse

2. FURTHER GUIDANCE ON THE ASSESSMENT OF CAUSALITY

The following factors should be considered when deciding if there is a "reasonable possibility" that an adverse event (AE) may have been caused by the investigational product.

- **Time course of events and exposure to suspect drug**. Has the subject actually received the suspect drug? Did the AE occur in a reasonable temporal relationship to the administration of suspect drug?

- **Consistency with known drug profile**. Was the AE consistent with the previous knowledge of the suspect drug (pharmacology and toxicology) or drugs of the same pharmacological class? OR could the AE be anticipated from its pharmacological properties?

- **Dechallenge experience**. Did the AE resolve or improve on stopping or reducing the dose of the suspect drug?

- **No alternative cause**. The AE cannot be reasonably explained by another aetiology such as the underlying disease, other drugs, other host or environmental factors.

- **Rechallenge experience**. Did the AE reoccur if the suspected drug was reintroduced after having been stopped? AstraZeneca would not normally recommend or support a rechallenge.

- **Laboratory tests**. Has a specific laboratory investigation confirmed the relationship?

A "reasonable possibility" could be considered to exist for an AE where one or more of these factors exist.

In contrast, there would not be a "reasonable possibility" of causality if none of the above criteria apply or where there is evidence of exposure and a reasonable time course but any dechallenge (if performed) is negative or ambiguous or there is another more likely cause of the AE.

In difficult cases, other factors could be considered such as:

- Is this a recognised feature of overdose of the drug?

- Is there a known mechanism

Ambiguous cases should be considered as being a “reasonable possibility” of a causal relationship unless further evidence becomes available to refute this.

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Clinical Study protocol: Appendix G	
Study Code	5077US/0049
Version No.	1
Appendix date	August 8, 2002

Appendix G
Additional information necessary for studies conducted in Japan

Not Applicable

1. LABELLING AND PACKAGING OF THE INVESTIGATIONAL PRODUCT

<< Insert copy of the label.>>

2. PROCEDURES FOR RANDOMISATION (REGISTRATION)

<<>>

3. ORGANISATIONAL STRUCTURE OF THE STUDY

3.1 Study sponsor

AstraZeneca K.K.
<< Name >>Executive President
Umeda Sky Building, Tower East,
1-88, 1-chome, Ohyodo-naka, Kita-ku, Osaka 531-0076, Japan

3.2 Medical expert from the sponsor

AstraZeneca K.K., Clinical Strategy Department:
<< Name >>(Physician responsible for the protocol)

3.3 Responsible person for the product, monitor, and auditor

Clinical Project Manager (CPM)

Clinical Strategy Department, Osaka office	<< Telephone number>>
Clinical Project Manager	<< Name >>

Monitors

Clinical Operations Department, Osaka office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Clinical Operations Department, Tokyo office	<< Telephone number>>
Clinical Monitoring Group Manager	<< Name >> << Associated hospital name>>

Auditor

Regulatory Affairs Department	<< Telephone number>>
Clinical Audit Department Manager	<< Name >>

See AstraZeneca medical emergency contact numbers (Section 9).

3.4 Co-ordinating investigator(s) (Co-ordinating committee)

<< Name >>
<< Job title>>
<< Associated hospital name>>

3.5 Person in charge of PMS management (if applicable)

AstraZeneca K.K.,
<< Name >>
Drug Safety &PMS Department Manager

3.6 Independent Data Monitoring Committee (IDMC) (if applicable)

<< Name >>
<< Job title>>
<<Associated hospital name>>

3.7 Subject inclusion registration centre

<<>>

3.8 Laboratory

<<>>

3.9 Contract Research Organisation (CRO)

<<>>

3.10 Safety Committee (In house)

May have responsibility for reviewing the following major issues around JNDA and clinical trials proposed by R&D departments such as CSD, COD or RA

A) Major changes for protocol and IB due to safety reasons

B) Across the board key code break due to safety reasons

C) Actions required due to significant safety issues ensuring for products under/for NDA

D) Discontinuation of clinical trials or test drug recall due to safety reasons

E) Other issues to ensure safety in clinical trials

4. LIST OF INVESTIGATORS AND MEDICAL INSTITUTIONS

Centre No.	Study Institutions	Department	Address	Telephone	Investigators	Job Title
<<>>						

5. ADDITIONAL REPORTING RELATED WITH SECTION 4.4.2 ADVERSE EVENTS (FOR JAPANESE PHASE III OR IV STUDY)

<<>>

AstraZeneca

Clinical Study Protocol Amendment	
Amendment No.	4
Study Code	5077US/0049
Date	May 12, 2003

Sponsor:

AstraZeneca Pharmaceuticals LP, Wilmington, Delaware, USA

Centers affected by the amendment:

All centers

The protocol for the study is to be amended as follows:

1. Page 2 Study center (s) and number of subjects planned

Original text

A total of approximately 740 subjects will be screened to enroll approximately 530 into the trial in order to obtain approximately 504 evaluable patients, defined as those who have a baseline visit and at least one post baseline assessment. It is expected that approximately 75 centers will participate in the trial, with each center enrolling 8 patients **(minimum 4, maximum 50).**

Amended text

A total of approximately 740 subjects will be screened to enroll approximately 530 into the trial in order to obtain approximately 504 evaluable patients, defined as those who have a baseline visit and at least one post baseline assessment. It is expected that approximately 75 centers will participate in the trial, with each center enrolling 8 patients **(maximum 70)**.

2. Page 19-20 3.2 Overall study design and flow chart

Original text

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial will consist of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects will be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment of 8 patients per center **(minimum 4, maximum 30).** Subjects are required to have a HAM-D (17-item scale) score of $\geq$ 20 and a YMRS of =12 at screening baseline (Visit 1).

Amended text

This multicenter, double-blind, randomized, placebo-controlled, double-dummy, parallel group trial will consist of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult subjects with bipolar disorder. A total of approximately 740 subjects will be screened to obtain 530 enrolled subjects to yield 504 evaluable subjects at approximately 75 centers, with a target enrollment of 8 patients per center **(maximum 70).** Subjects are required to have a HAM-D (17-item scale) score of $\geq$ 20 and a YMRS of =12 at screening baseline (Visit 1).

3. Page 27-28 3.4.4.4 Procedures for discontinuation

Original text

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination
- Vital signs and weight
- 12-lead ECG
- HAM-D
- MADRS
- ICI-D
- YMRS
- HAM-A

- SAS
- BARS
- PSQI
- Adverse events assessment

Amended text

All study procedures required at Day 57 should be conducted when a patient discontinues from the trial. Procedures required at discontinuation are:

- Physical examination
- Vital signs and weight
- 12-lead ECG
- HAM-D
- MADRS
- ICI-D
- YMRS
- HAM-A
- **CGI-C**
- **CGI-S**
- SAS
- BARS
- PSQI
- **Q les Q**
- Adverse events assessment

Psychiatric assessments (HAM-D, MADRS, YMRS, HAM-A, CGI-C, CGI-S, Q les Q, and PSQI) should not be performed on subjects who have missed 72 hours of study drug before any study visit. Due to the pharmacokinetic profile of quetiapine, these

assessments are of questionable clinical value.

4. Page 54 5.6 Interactive Computer interview for depression

Original text

At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the MADRS. Raters or other site staff will first enter the subject's MADRS scores into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

Amended text

Participating in the Interactive Computer Interview for Depression (ICI-D) is voluntary for all the sites. Participation by the subjects at these sites is also voluntary. At each study visit, subjects at all participating sites will complete a computer-based self-report measure of depression severity (the interactive computer interview or ICI-D) after completing the MADRS. Raters or other site staff will first enter the subject's MADRS scores into a computer supplied by the sponsor. Subjects will then complete a computer-based self-report measure of depression severity . This measure will not be considered primary or source data, and will be recorded on a coded, anonymized form. This data will be securely transmitted to Concordant Rater Systems (CRS) for ongoing quality control.

5. Page 64 9.4 Subject data Protection

Additional Text

AstraZeneca recognises the importance of protecting the privacy of patient (subject) data. Therefore, for study sites within the US or in studies where foreign subjects' protected health information **(subject data)** will come into the US through a covered entity (eg, Central Lab/Reader), the Informed Consent Form will incorporate, or be accompanied by, a separate document incorporating HIPAA-compliant wording by which subjects authorize the use and disclosure of their Protected Health Information by the Investigator and by those persons who need that information for the purposes of the study.

Rationale

1.

A few investigative sites have been unable to recruit four patients, due to the patient populations they treat. However, these sites have been compliant with GCP and the protocol. We believe the quality of data is adequate, and we are thus removing the requirement for a minimum enrollment of 4 subjects per site.

The distribution of subject enrollment across sites has been balanced; therefore, it is unnecessary to limit individual sites to a maximum of 50 subjects. The increase to a maximum of 70 subjects will not adversely affect the outcome of the study, as no one site will treat more than 14% of randomized subjects.

2.

See the rationale above.

3.

The serum half-life of Seroquel is approximately 4 hours. While the duration of psychotropic effects are unknown, it is reasonable to assume that some of Seroquel's putative antidepressant and anxiolytic properties may wane after 72 hours. Thus, psychiatric assessments after this duration are of questionable clinical accuracy.

4.

Clarified that the ICI-D is voluntary for the sites and voluntary for the subjects.

5.

Inserted addition text per HIPAA regulations.

AstraZeneca

Amended Clinical Study Protocol	
Drug Substance	Quetiapine Fumarate
Study Code	5077US/0049
Version No.	5
Date	12 May 2003

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

AstraZeneca confirms that all revisions contained in the Clinical Study Protocol Amendment Revision Summary have been accurately reflected in the amended clinical trial protocol, Protocol 5077US/0049.

AstraZeneca Research and Development site representative

6/25/03
Date

Wayne Macfadden MD
Clinical Study Team Physician
AstraZeneca LP
Wilmington, Delaware
302-886-1147

AstraZeneca Research and Development site representative

6/23/03
Date

Robin McCoy RN SCRS
Clinical Study Team Leader
AstraZeneca LP
Wilmington, Delaware
302-886-4650

The following Amendment(s) and Administrative Changes have been made to this protocol since the date of preparation:

Amendment No. 4	**Date of Amendment 5/12/03**	**Local Amendment No.**	**Date of local Amendment**
Amendment No. 3	**Date of Amendment 4/21/03**		
Amendment No. 2	**Date of Amendment 12/4/02**		
Amendment No. 1	**Date of Amendment 9/30/02**		
Administrative change No. 1	**Date of Administrative Change 9/30/02**	**Local Administrative change No.**	**Date of local Administrative Change**

1(1)

AstraZeneca

Clinical Study Report: Appendix 12.1.2

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.2
Sample Case Report Form

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Centre No. |0|0| | | Visit No. 1

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | | | |
year mm dd

AW02:09

Demography

DEM

Date of birth

year mm dd

Sex

Male ☐ 1

Female ☐ 2

Race

Caucasian ☐ 1

Black ☐ 2

Oriental ☐ 3

Hispanic ☐ 4

..... ☐ 99

Other

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 1

AW02:09

Medical History, Past and Current

HISM

Has Subject any relevant medical conditions other than bipolar disorder No ☐0 Yes ☐1 If Yes, please specify below

Condition

	Past	Current
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2
.....	☐1	☐2

☞ **If medication is currently being taken for any of the above conditions, fill in MED, Section 12**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 1

AW02:09

DSM-IV Diagnosis Criteria

DSMIV

Date of assessment |2|0|0| | | | | | (year mm dd)

Bipolar disorder subtype (tick one only)

☐ 1 Bipolar I disorder, most recent episode depressed - 296.5

☐ 2 Bipolar II disorder - 296.89

AW02:09

Psychiatric History

HISPSYC

Year of first known **depressed** episode | | | | |

Total number of prior **depressed** episodes over **lifetime** | | |

Total number of prior **depressed** episodes over the **past year** | | |

Year of first known **manic** or **hypomanic** episode | | | | |

Total number of prior **manic** or **hypomanic** episodes over **lifetime** | | |

Total number of prior **manic** or **hypomanic** episodes over the **past year** | | |

Study code 5077US/0049 Subj initials ..... E code |E|0|0|_|_|_|_|

Visit No. 1

AW02:09

Eligibility Criteria

CRITIE

Date Subject signed consent |2|0|0|_|_|_|_| year mm dd

Date of randomization |2|0|0|_|_|_|_| year mm dd

Randomization code |_|_|_|_|

Kit number |_|_|_|_|

Inclusion criteria

		No	Yes
1	Documented ability to provide informed consent before beginning any study-specific procedures.	☐ 0	☐ 1
2	Male and female Subjects between 18 and 65 years of age, inclusive.	☐ 0	☐ 1
3	Females of childbearing potential, should be using a reliable method of contraception. Reliable methods include hormonal contraceptives, (eg, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation.	☐ 0	☐ 1
4	Women must have a negative pregnancy test.	☐ 0	☐ 1
5	Meets DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x), confirmed by the amended version (by Dr. Michael First) of the Structured Clinical Interview for DSM-IV (SCID) as administered by the Principal Investigator or an AstraZeneca approved clinician with a signed confirmation by the Principal Investigator.	☐ 0	☐ 1
6	Outpatient status.	☐ 0	☐ 1
7	HAM-D (17-item) total score of 20 or greater	☐ 0	☐ 1
8	HAM-D item 1 (depressed mood) score ≥ 2	☐ 0	☐ 1
9	YMRS ≤ 12	☐ 0	☐ 1

At randomization (Visit 2) Subjects must fulfill the following criteria:

1	HAM-D (17-item) total score of 20 or greater	☐ 0	☐ 1
2	HAM-D item 1 (depressed mood) score ≥ 2	☐ 0	☐ 1
3	YMRS ≤ 12	☐ 0	☐ 1

All Inclusion Criteria must be answered Yes for the Subject to qualify for this study

continued

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Eligibility Criteria, continued

CRITIE

Exclusion criteria

		No	Yes
1	Subjects with a current Axis I disorder other than bipolar disorder within 6 months of screening.	☐ 0	☐ 1
2	Subjects whose current episode of depression exceeds 12 months or is less than 4 weeks.	☐ 0	☐ 1
3	Subjects who have a history of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode.	☐ 0	☐ 1
4	Subjects who meet DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening.	☐ 0	☐ 1
5	Subjects with a positive urine toxicology screen for illicit substances of abuse.	☐ 0	☐ 1
6	Subjects who are unable to discontinue all psychoactive medications (excluding prn benzodiazipines), including antidepressants, antipsychotics, and mood stabilizer, at least **7 days** prior to randomization, and consistent with the pharmacokinetics of the drug. - Subjects treated with fluoxetine who have not discontinued this medication for at least 14 days prior to randomization. - Subjects who have not discontinued haloperidol decanoate or fluphenazine decanoate for 28 days prior to randomization	☐ 0	☐ 1
7	Subjects who have not discontinued the use of potent P450 inhibitors and inducers.	☐ 0	☐ 1
8	Subjects who in the investigators opinion will require initiation of psychotherapy during the study period. Note: Ongoing psychotherapy for a minimum of 3 months may continue.	☐ 0	☐ 1
9	Subjects who, in the investigator's judgment, pose a current serious suicidal or homicidal risk at Visit 1 (HAM-D item 3 score of 3 or greater), or have made a suicide attempt within the past 6 months.	☐ 0	☐ 1
10	Subjects with a history of clinically significant cardiac, renal, neurologic, cerebrovascular, metabolic, or pulmonary disease, or other disease or clinical finding that is unstable or that, in the opinion of the investigator, would be negatively affected by trial medication or that would affect trial medication.	☐ 0	☐ 1
11	Subjects who have had a myocardial infarction within 1 year before Visit 1.	☐ 0	☐ 1
12	Subjects with clinically significant abnormal lab findings at Visit 1.	☐ 0	☐ 1
13	Subjects with renal impairment (serum creatinine ≥ 1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal).	☐ 0	☐ 1
14	Subjects whose TSH is ≥ 10% over the upper normal limit. Subjects maintained on thyroid medication must be euthyroid for a period of at least 3 months before Visit 1.	☐ 0	☐ 1
15	Subjects with clinically significant abnormalities on ECG.	☐ 0	☐ 1

continued

Study code 5077US/0049 Subj initials .... E code |E|0|0| | | | | |

Visit No. 1

AW02:09

Eligibility Criteria, continued

CRITIE

Exclusion criteria, continued

		No	Yes
16	Women who have a positive human chorionic gonadotropin (HCG) pregnancy test at Visit 1 or who are or lactating or planning on becoming pregnant during the course of the study.	☐ 0	☐ 1
17	Subjects who have participated in a clinical trial of an investigational drug within the past 3 months.	☐ 0	☐ 1
18	Subjects, who in the opinion of the investigator, would be non-compliant with the visit schedule or study procedures.	☐ 0	☐ 1
19	History of orthostatic hypotension or condition's that would predispose them to hypotension (eg, dehydration, hypovolemia).	☐ 0	☐ 1
20	Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of Seroquel tablets, as judged by the investigator.	☐ 0	☐ 1

All Exclusion Criteria must be answered No for the Subject to qualify for this study

Subject fulfills all inclusion and exclusion criteria — No ☐ 0 Yes ☐ 1

If No, was the Subject randomized — No ☐ 0 Yes ☐ 1

Date of approval |2|0|0| | | | | | (year mm dd) Initials ....

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Physical Examination

PHYS

Assessment date |2|0|0| | | | | (year mm dd)

	Normal	Abnormal	Not done	*Specification of abnormalities*
General appearance	☐0	☐1	☐95	.....
Skin	☐0	☐1	☐95	.....
Head and neck	☐0	☐1	☐95	.....
Lymph nodes	☐0	☐1	☐95	.....
Thyroid	☐0	☐1	☐95	.....
Musculoskeletal/Extremities	☐0	☐1	☐95	.....
Cardiovascular	☐0	☐1	☐95	.....
Lungs	☐0	☐1	☐95	.....
Abdomen	☐0	☐1	☐95	.....
Neurological	☐0	☐1	☐95	.....

AW02:09

Eye Examination

EYEX

Was a physical examination performed including an ophthalmoscopic examination of the lens by a method adequate to detect cataract formation ☐No 0 ☐Yes 1

	Normal	Abnormal	*Specification of abnormalities*
Eyes	☐0	☐1	.....

AW02:09

Urine Toxicology Screen

UTS

Screen date |2|0|0| | | | | | | | |
year mm dd

Urine toxicology results Neg ☐0 Pos ☐1

AW02:09

Pregnancy Test

PREG

Assessment applicable for Subject No ☐0 Yes ☐1 If Yes, fill in below

Sampling date |2|0|0| | | | | | | | |
year mm dd

Pregnancy test, serum Neg ☐0 Pos ☐1 If Positive, withdraw Subject and fill in TERMAW, Section 14

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 1

AW02:09

Vital Signs, Weight, Height VIT

Assessment date |2|0|0| | | | | | (year mm dd)

Pulse, supine |_|_|_| beats/min

Blood pressure, supine |_|_|_| / |_|_|_| mmHg (systolic / diastolic)

Pulse, standing |_|_|_| beats/min

Blood pressure, standing |_|_|_| / |_|_|_| mmHg (systolic / diastolic)

Weight |_|_|_| kg

Height |_|_|_| cm

AW02:09

Electrocardiogram ECGQ

Was an ECG performed No ☐ 0 Yes ☐ 1

Date of ECG |2|0|0| | | | | | (year mm dd)

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Laboratory Assessments

LAB1

Blood samples have been collected No ☐0 Yes ☐1

Sample date |2|0|0| | | | | year mm dd

Sample time | | : | | 24-hour clock

Sample ID
Attach Sample ID label here

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Elevated Mood

|_| 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

|_| 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

|_| 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

|_| 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 1

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

- 0 - Absent
- 2 - Subjectively increased
- 4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment
- 6 - Frequently irritable during the interview; short, curt throughout
- 8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

- 0 - No increase
- 2 - Feels talkative
- 4 - Increased rate or amount at times, verbose at times
- 6 - Push; consistently increased rate and amount; difficult to interrupt
- 8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

- 0 - Absent
- 1 - Circumstantial; mild distractibility; quick thoughts
- 2 - Distractible; loses goal of thought; change topics frequently; racing thoughts
- 3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia
- 4 - Incoherent; communication impossible

8. Content

- 0 - Normal
- 2 - Questionable plans, new interests
- 4 - Special project(s); hyperreligious
- 6 - Grandiose or paranoid ideas; ideas of reference
- 8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 1

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

|_| 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

|_| 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

|_| 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 1

AW02:09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | |
year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

Not assessed ☐ 0

Normal, not at all ill ☐ 1

Borderline mentally ill ☐ 2

Mildly ill ☐ 3

Moderately ill ☐ 4

Markedly ill ☐ 5

Severely ill ☐ 6

Among the most extremely ill Subjects ☐ 7

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | (year mm dd)

AW02:09

Vital Signs

VIT

Assessment date |2|0|0| | | | | (year mm dd)

Pulse, supine | | | | beats/min

Blood pressure, supine | | | | / | | | | mmHg (systolic / diastolic)

Pulse, standing | | | | beats/min

Blood pressure, standing | | | | / | | | | mmHg (systolic / diastolic)

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02.09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 |_|_|

Rater´s initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0|_|_|_|_|

Visit No. 2

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0|_|_|_|_| year mm dd

1. Elevated Mood

|_| 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

|_| 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

|_| 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

|_| 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 2

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

☐ 0 - Absent

2 - Subjectively increased

4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment

6 - Frequently irritable during the interview; short, curt throughout

8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

☐ 0 - No increase

2 - Feels talkative

4 - Increased rate or amount at times, verbose at times

6 - Push; consistently increased rate and amount; difficult to interrupt

8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

☐ 0 - Absent

1 - Circumstantial; mild distractibility; quick thoughts

2 - Distractible; loses goal of thought; change topics frequently; racing thoughts

3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia

4 - Incoherent; communication impossible

8. Content

☐ 0 - Normal

2 - Questionable plans, new interests

4 - Special project(s); hyperreligious

6 - Grandiose or paranoid ideas; ideas of reference

8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 2

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

☐ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

☐ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

☐ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Hamilton Rating Scale for Anxiety HAMA

Date of assessment |2|0|0| | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability |__|

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax |__|

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds |__|

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors |__|

Intellectual

Difficulty in concentration, poor memory |__|

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing |__|

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone |__|

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation |__|

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea |__|

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 2

AW02:09

Hamilton Rating Scale for Anxiety, continued HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea ☐

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation ☐

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence ☐

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair ☐

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. ☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Clinical Global Impressions

CGI

Date of assessment |2|0|0| | | | | | |
year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

Not assessed ☐ 0

Normal, not at all ill ☐ 1

Borderline mentally ill ☐ 2

Mildly ill ☐ 3

Moderately ill ☐ 4

Markedly ill ☐ 5

Severely ill ☐ 6

Among the most extremely ill Subjects ☐ 7

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Barnes Akathisia Rating Scale

BARS

Ref. Barnes TRE. A rating scale for drug-induced akathisia. Br J Psychiatry. 1989; 154: 672-676.

Date of assessment |2|0|0| | | | | | (year mm dd)

A. Objective

Normal occasional fidgety movements of the limbs ☐0

Presence of characteristic restless movements: shuffling or tramping movements of the legs and feet, or swinging of one leg while sitting, and/or rocking from foot to foot or 'walking on the spot' when standing, but movements present for less than half the time observed ☐1

Observed phenomena, as described above, which are present for at least half the observation period ☐2

Subject is constantly engaged in characteristic restless movements, and/or has the inability to remain seated or standing without walking or pacing, during the time observed ☐3

B. Subjective

Awareness of restlessness

Absence of inner restlessness ☐0

Non-specific sense of inner restlessness ☐1

Subject is aware of an inability to keep the legs still, a desire to move the legs, and/or complains of inner restlessness aggravated specifically by being required to stand still ☐2

Awareness of an intense compulsion to move most of the time and/or reports a strong desire to walk or pace most of the time ☐3

Distress related to restlessness

No distress ☐0

Mild ☐1

Moderate ☐2

Severe ☐3

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 2

AW02:09

Barnes Akathisia Rating Scale, continued

BARS

C. Global clinical assessment of akathisia

Absent

No evidence of awareness of restlessness. Observation of characteristic movements of akathisia in the absence of a subjective report of inner restlessness or compulsive desire to move the legs should be classified as pseudoakathisia ☐ 0

Questionable

Non-specific inner tension and fidgety movements ☐ 1

Mild akathisia

Awareness of restlessness in the legs and/or inner restlessness worse when required to stand still. Fidgety movements present, but characteristic restless movements of akathisia not necessarily observed. Condition causes little or no distress ☐ 2

Moderate akathisia

Awareness of restlessness as described for mild akathisia above, combined with characteristic restless movements such as rocking from foot to foot when standing. Subject finds the condition distressing ☐ 3

Marked akathisia

Subjective experience of restlessness includes a compulsive desire to walk or pace. However, the Subject is able to remain seated for at least five minutes. The condition is obviously distressing ☐ 4

Severe akathisia

The Subject reports a strong compulsion to pace up and down most of the time. Unable to sit or lie down for more than a few minutes. Constant restlessness which is associated with intense distress and insomnia ☐ 5

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Simpson-Angus Scale

SAS

Ref. Modified from Simpson GN, Angus JWS. A rating scale for extrapyramidal side effects. Acta Psychiatr Scand. 1970;212 (suppl):11-19

Date of assessment |2|0|0| | | | | | (year mm dd)

1. Gait

- Normal ☐ 0
- Mild diminution in swing while the Subject is walking ☐ 1
- Obvious diminution in swing suggesting shoulder rigidity ☐ 2
- Stiff gait with little or no arm swing noticeable ☐ 3
- Rigid gait with arms slightly pronated; or stooped-shuffling gait with propulsion and repropulsion ☐ 4
- Not ratable ☐ 9

2. Arm dropping

- Normal, free fall with loud slap and rebound ☐ 0
- Fall slowed slightly with less audible contact and little rebound ☐ 1
- Fall slowed, no rebound ☐ 2
- Marked slowing, no slap at all ☐ 3
- Arms fall as though against resistance; as though through glue ☐ 4
- Not ratable ☐ 9

3. Shoulder shaking

- Normal ☐ 0
- Slight stiffness and resistance ☐ 1
- Moderate stiffness and resistance ☐ 2
- Marked rigidity with difficulty in passive movement ☐ 3
- Extreme stiffness and rigidity with almost a frozen joint ☐ 4
- Not ratable ☐ 9

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 2

AW02:09

Simpson-Angus Scale, continued

SAS

4. Elbow rigidity

- Normal ☐ 0
- Slight stiffness and resistance ☐ 1
- Moderate stiffness and resistance ☐ 2
- Marked rigidity with difficulty in passive movement ☐ 3
- Extreme stiffness and rigidity with almost a frozen joint ☐ 4
- Not ratable ☐ 9

5. Wrist rigidity

- Normal ☐ 0
- Slight stiffness and resistance ☐ 1
- Moderate stiffness and resistance ☐ 2
- Marked rigidity with difficulty in passive movement ☐ 3
- Extreme stiffness and rigidity with almost a frozen joint ☐ 4
- Not ratable ☐ 9

6. Head rotation

- Loose, no resistance ☐ 0
- Slight resistance to movement although the time to rotate may be normal ☐ 1
- Resistance is apparent and the time of rotation is shortened ☐ 2
- Resistance is obvious and rotation is slowed ☐ 3
- Head appears stiff and rotation is difficult to carry out ☐ 4
- Not ratable ☐ 9

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Simpson-Angus Scale, continued

SAS

7. Glabella tap

0 - 5 blinks	☐ 0
6 - 10 blinks	☐ 1
11 - 15 blinks	☐ 2
16 - 20 blinks	☐ 3
21 or more blinks	☐ 4
Not ratable	☐ 9

8. Tremor

Normal	☐ 0
Mild finger tremor, obvious to sight and touch	☐ 1
Tremor of hand or arm occurring spasmodically	☐ 2
Persistent tremor of one or more limbs	☐ 3
Whole body tremor	☐ 4
Not ratable	☐ 9

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 2

AW02:09

Simpson-Angus Scale, continued

SAS

9. Salivation

Normal	☐ 0
Excess salivation so that pooling takes place if mouth is open and tongue is raised	☐ 1
Excess salivation is present and might occasionally result in difficulty in speaking	☐ 2
Speaking with difficulty because of excess salivation	☐ 3
Frank drooling	☐ 4
Not ratable	☐ 9

10. Akathisia

No restlessness reported or observed	☐ 0
Mild restlessness observed, e.g. occasional jiggling of the foot occurs when Subject is seated	☐ 1
Moderate restlessness observed, e.g. on several occasions, jiggles foot, crosses and uncrosses legs, or twists a part of the body	☐ 2
Restlessness is frequently observed, e.g. the foot or leg moving most of the time	☐ 3
Restlessness persistently observed, e.g. Subject cannot sit still, may get up and walk	☐ 4
Not ratable	☐ 9

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Pittsburgh Sleep Quality Index PSQI

Reprinted from Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. (1989). The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Research: 28(2), 193-213, with permission of Elsevier Sceince.

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

Date of assessment |2|0|0| | | | | (year mm dd)

1. During the past month, when have you usually gone to bed at night?

USUAL BED TIME |_|_| : |_|_| (24-hour clock)

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES |_|_|_|

3.During the past month, when have you usually gotten up in the morning?

USUAL GETTING UP TIME |_|_| : |_|_| (24-hour clock)

4. During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT |_|_|

For each of the remaining questions, check the one best response. Please answer all questions.

5. **During the past month, how often have you had trouble sleeping because you....**

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes	☐ 0	☐ 1	☐ 2	☐ 3
b. Wake up in the middle of the night or early morning	☐ 0	☐ 1	☐ 2	☐ 3
c. Have to get up to use the bathroom	☐ 0	☐ 1	☐ 2	☐ 3
d. Cannot breathe comfortably	☐ 0	☐ 1	☐ 2	☐ 3
e. Cough or snore loudly	☐ 0	☐ 1	☐ 2	☐ 3
f. Feel too cold	☐ 0	☐ 1	☐ 2	☐ 3
g. Feel too hot	☐ 0	☐ 1	☐ 2	☐ 3
h. Had bad dreams	☐ 0	☐ 1	☐ 2	☐ 3
i. Have pain	☐ 0	☐ 1	☐ 2	☐ 3
j. Other reason(s), please describe:	☐ 0	☐ 1	☐ 2	☐ 3

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Pittsburgh Sleep Quality Index, continued PSQI

6. During the past month, how would you rate your sleep quality overall?

Very good	Fairly good	Fairly bad	Very bad
☐ 0	☐ 1	☐ 2	☐ 3

7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
☐ 0	☐ 1	☐ 2	☐ 3

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
☐ 0	☐ 1	☐ 2	☐ 3

9. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?

No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
☐ 0	☐ 1	☐ 2	☐ 3

10. Do you have a bed partner or roommate?

No bed partner or roommate	Partner/roommate in other room	Partner in same room, but not same bed	Partner in same bed
☐ 0	☐ 1	☐ 2	☐ 3

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Pittsburgh Sleep Quality Index, continued PSQI

If you have a roommate or bed partner, ask him/her how often in the past month you have had...

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Loud snoring	☐ 0	☐ 1	☐ 2	☐ 3
b. Long pauses between breaths while sleeping	☐ 0	☐ 1	☐ 2	☐ 3
c. Legs twitching or jerking while you sleep	☐ 0	☐ 1	☐ 2	☐ 3
d. Episodes of disorientation or confusion during sleep	☐ 0	☐ 1	☐ 2	☐ 3
e. Other restlessness while you sleep; please describe.....	☐ 0	☐ 1	☐ 2	☐ 3

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 2

AW02:09

Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form QLESSF

Available from Jean Endicott, Ph.D., Dept. of Research Assessment and Training, Unit 123, 1051 Riverside Drive, New York, NY 10032, USA

Date of assessment |2|0|0| | | | | (year mm dd)

General Activities
Taking everything into consideration, during the past week how satisfied have you been with your... (indicate one box only)

Overall level of satisfaction

	Very poor	*Poor*	*Fair*	*Good*	*Very good*
Physical health	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
mood	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
work	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
household activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
social relationship	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
family relationship	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
leisure time activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ability to function in daily life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
sexual drive, interest and/or performance*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
economic situation	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
living/housing situation*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ability to get around physically without feeling dizzy or unsteady or falling*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
your vision in terms of ability to do work or hobbies*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
overall sense of well being	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
medications, if not taking any , indicate here ☐ 0 and leave item blank	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How would you rate your overall life satisfaction and contentment during the past week	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

*If satisfaction is very poor, poor, or fair on these items, please UNDERLINE the factor(s) associated with a lack of satisfaction

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | |
year mm dd

AW02:09

Vital Signs

VIT

Assessment date |2|0|0| | | | | |
year mm dd

Pulse, supine |_|_|_| beats/min

Blood pressure, supine |_|_|_| / |_|_|_| mmHg
systolic diastolic

Pulse, standing |_|_|_| beats/min

Blood pressure, standing |_|_|_| / |_|_|_| mmHg
systolic diastolic

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

Study code 5077US/0049 Subj initials ..... E code [E|0|0| | | | |]

Visit No. 3

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 3

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 3

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 3

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 |_|_|

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Elevated Mood

|_| 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

|_| 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

|_| 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

|_| 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

|_| 0 - Absent

2 - Subjectively increased

4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment

6 - Frequently irritable during the interview; short, curt throughout

8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

|_| 0 - No increase

2 - Feels talkative

4 - Increased rate or amount at times, verbose at times

6 - Push; consistently increased rate and amount; difficult to interrupt

8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

|_| 0 - Absent

1 - Circumstantial; mild distractibility; quick thoughts

2 - Distractible; loses goal of thought; change topics frequently; racing thoughts

3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia

4 - Incoherent; communication impossible

8. Content

|_| 0 - Normal

2 - Questionable plans, new interests

4 - Special project(s); hyperreligious

6 - Grandiose or paranoid ideas; ideas of reference

8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

└┘ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

└┘ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

└┘ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater´s initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Hamilton Rating Scale for Anxiety HAMA

Date of assessment |2|0|0| | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability |__|

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax |__|

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds |__|

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors |__|

Intellectual

Difficulty in concentration, poor memory |__|

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing |__|

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone |__|

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation |__|

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea |__|

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0|_|_|_|_|

Visit No. 3

AW02:09

Hamilton Rating Scale for Anxiety, continued HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea ☐

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation ☐

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence ☐

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair ☐

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. ☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 3

AW02:09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | | |
year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

- Not assessed ☐ 0
- Normal, not at all ill ☐ 1
- Borderline mentally ill ☐ 2
- Mildly ill ☐ 3
- Moderately ill ☐ 4
- Markedly ill ☐ 5
- Severely ill ☐ 6
- Among the most extremely ill Subjects ☐ 7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

- Not assessed ☐ 0
- Very much improved ☐ 1
- Much improved ☐ 2
- Minimally improved ☐ 3
- No change ☐ 4
- Minimally worse ☐ 5
- Much worse ☐ 6
- Very much worse ☐ 7

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | |
year mm dd

AW02:09

Vital Signs

VIT

Assessment date |2|0|0| | | | | |
year mm dd

Pulse, supine |_|_|_| beats/min

Blood pressure, supine |_|_|_| / |_|_|_| mmHg
systolic diastolic

Pulse, standing |_|_|_| beats/min

Blood pressure, standing |_|_|_| / |_|_|_| mmHg
systolic diastolic

Study code 5077US/0049 Subj initials .... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Hamilton Rating Scale for Depression

HAMD

Date of assessment |2|0|0| | | | | |
year mm dd

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

Study code 5077US/0049 Subj initials ..... E code [E|0|0| | | | | |]

Visit No. 4

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code [E|0|0| | | | | |]

Visit No. 4

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 4

AW02.09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 4

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 4

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 4

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 ☐☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 4

AW02:09

Young Mania Rating Scale YMRS

Date of assessment 2 0 0 (year) (mm) (dd)

1. Elevated Mood

☐ 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

☐ 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

☐ 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

☐ 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

☐ 0 - Absent

2 - Subjectively increased

4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment

6 - Frequently irritable during the interview; short, curt throughout

8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

☐ 0 - No increase

2 - Feels talkative

4 - Increased rate or amount at times, verbose at times

6 - Push; consistently increased rate and amount; difficult to interrupt

8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

☐ 0 - Absent

1 - Circumstantial; mild distractibility; quick thoughts

2 - Distractible; loses goal of thought; change topics frequently; racing thoughts

3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia

4 - Incoherent; communication impossible

8. Content

☐ 0 - Normal

2 - Questionable plans, new interests

4 - Special project(s); hyperreligious

6 - Grandiose or paranoid ideas; ideas of reference

8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

☐ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

☐ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

☐ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 4

AW02:09

Hamilton Rating Scale for Anxiety HAMA

Date of assessment |2|0|0| | | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability |__|

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax |__|

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds |__|

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors |__|

Intellectual

Difficulty in concentration, poor memory |__|

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing |__|

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone |__|

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation |__|

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea |__|

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Hamilton Rating Scale for Anxiety, continued HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea ☐

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation ☐

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence ☐

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair ☐

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. ☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 4

AW02:09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | | year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

Not assessed ☐ 0

Normal, not at all ill ☐ 1

Borderline mentally ill ☐ 2

Mildly ill ☐ 3

Moderately ill ☐ 4

Markedly ill ☐ 5

Severely ill ☐ 6

Among the most extremely ill Subjects ☐ 7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

Not assessed ☐ 0

Very much improved ☐ 1

Much improved ☐ 2

Minimally improved ☐ 3

No change ☐ 4

Minimally worse ☐ 5

Much worse ☐ 6

Very much worse ☐ 7

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | (year mm dd)

AW02:09

Vital Signs

VIT

Assessment date |2|0|0| | | | | (year mm dd)

Pulse, supine | | | | beats/min

Blood pressure, supine | | | | (systolic) / | | | | (diastolic) mmHg

Pulse, standing | | | | beats/min

Blood pressure, standing | | | | (systolic) / | | | | (diastolic) mmHg

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 5

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 5

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 5

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | | | | |
year mm dd

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 5

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 5

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 5

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 |_|_|

Rater´s initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Elevated Mood

|_| 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

|_| 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

|_| 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

|_| 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

☐ 0 - Absent

2 - Subjectively increased

4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment

6 - Frequently irritable during the interview; short, curt throughout

8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

☐ 0 - No increase

2 - Feels talkative

4 - Increased rate or amount at times, verbose at times

6 - Push; consistently increased rate and amount; difficult to interrupt

8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

☐ 0 - Absent

1 - Circumstantial; mild distractibility; quick thoughts

2 - Distractible; loses goal of thought; change topics frequently; racing thoughts

3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia

4 - Incoherent; communication impossible

8. Content

☐ 0 - Normal

2 - Questionable plans, new interests

4 - Special project(s); hyperreligious

6 - Grandiose or paranoid ideas; ideas of reference

8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 5

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

|_| 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

|_| 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

|_| 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater´s initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 5

AW02:09

Hamilton Rating Scale for Anxiety HAMA

Date of assessment |2|0|0| | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability |__|

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax |__|

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds |__|

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors |__|

Intellectual

Difficulty in concentration, poor memory |__|

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing |__|

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone |__|

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation |__|

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea |__|

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Hamilton Rating Scale for Anxiety, continued HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea |_|

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation |_|

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence |_|

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair |_|

Behavior at interview
Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. |_|

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 5

AW02:09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | | | |
year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

Not assessed ☐ 0

Normal, not at all ill ☐ 1

Borderline mentally ill ☐ 2

Mildly ill ☐ 3

Moderately ill ☐ 4

Markedly ill ☐ 5

Severely ill ☐ 6

Among the most extremely ill Subjects ☐ 7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

Not assessed ☐ 0

Very much improved ☐ 1

Much improved ☐ 2

Minimally improved ☐ 3

No change ☐ 4

Minimally worse ☐ 5

Much worse ☐ 6

Very much worse ☐ 7

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | | |
year mm dd

AW02:09

Vital Signs

VIT

Assessment date |2|0|0| | | | | | |
year mm dd

Pulse, supine |_|_|_| beats/min

Blood pressure, supine |_|_|_| / |_|_|_| mmHg
systolic diastolic

Pulse, standing |_|_|_| beats/min

Blood pressure, standing |_|_|_| / |_|_|_| mmHg
systolic diastolic

Study code 5077US/0049 Subj initials ..... E code [E|0|0| | | | | |]

Visit No. 6

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment [2|0|0| | | | |] year mm dd

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 6

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 6

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code E 0

Visit No. 6

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 ☐☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 6

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Elevated Mood

└┘ 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

└┘ 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

└┘ 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

└┘ 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

☐ 0 - Absent

2 - Subjectively increased

4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment

6 - Frequently irritable during the interview; short, curt throughout

8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

☐ 0 - No increase

2 - Feels talkative

4 - Increased rate or amount at times, verbose at times

6 - Push; consistently increased rate and amount; difficult to interrupt

8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

☐ 0 - Absent

1 - Circumstantial; mild distractibility; quick thoughts

2 - Distractible; loses goal of thought; change topics frequently; racing thoughts

3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia

4 - Incoherent; communication impossible

8. Content

☐ 0 - Normal

2 - Questionable plans, new interests

4 - Special project(s); hyperreligious

6 - Grandiose or paranoid ideas; ideas of reference

8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 6

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

☐ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

☐ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

☐ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater´s initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 6

AW02:09

Hamilton Rating Scale for Anxiety

HAMA

Date of assessment |2|0|0| | | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability ☐

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax ☐

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds ☐

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors ☐

Intellectual

Difficulty in concentration, poor memory ☐

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing ☐

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone ☐

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation ☐

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea ☐

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 6

AW02:09

Hamilton Rating Scale for Anxiety, continued HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea ☐

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation ☐

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence ☐

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair ☐

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. ☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | | | |
year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

Not assessed ☐0

Normal, not at all ill ☐1

Borderline mentally ill ☐2

Mildly ill ☐3

Moderately ill ☐4

Markedly ill ☐5

Severely ill ☐6

Among the most extremely ill Subjects ☐7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

Not assessed ☐0

Very much improved ☐1

Much improved ☐2

Minimally improved ☐3

No change ☐4

Minimally worse ☐5

Much worse ☐6

Very much worse ☐7

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 6

AW02:09

Pittsburgh Sleep Quality Index PSQI

Reprinted from Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. (1989). The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Research: 28(2), 193-213, with permission of Elsevier Sceince.

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

Date of assessment |2|0|0| | | | | | (year mm dd)

1. During the past month, when have you usually gone to bed at night?

USUAL BED TIME | | | : | | (24-hour clock)

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES | | |

3.During the past month, when have you usually gotten up in the morning?

USUAL GETTING UP TIME | | | : | | (24-hour clock)

4. During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT | | |

For each of the remaining questions, check the one best response. Please answer all questions.

5. **During the past month, how often have you had trouble sleeping because you....**

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes	☐ 0	☐ 1	☐ 2	☐ 3
b. Wake up in the middle of the night or early morning	☐ 0	☐ 1	☐ 2	☐ 3
c. Have to get up to use the bathroom	☐ 0	☐ 1	☐ 2	☐ 3
d. Cannot breathe comfortably	☐ 0	☐ 1	☐ 2	☐ 3
e. Cough or snore loudly	☐ 0	☐ 1	☐ 2	☐ 3
f. Feel too cold	☐ 0	☐ 1	☐ 2	☐ 3
g. Feel too hot	☐ 0	☐ 1	☐ 2	☐ 3
h. Had bad dreams	☐ 0	☐ 1	☐ 2	☐ 3
i. Have pain	☐ 0	☐ 1	☐ 2	☐ 3
j. Other reason(s), please describe:	☐ 0	☐ 1	☐ 2	☐ 3

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Pittsburgh Sleep Quality Index, continued PSQI

6. During the past month, how would you rate your sleep quality overall?

Very good	Fairly good	Fairly bad	Very bad
☐ 0	☐ 1	☐ 2	☐ 3

7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
☐ 0	☐ 1	☐ 2	☐ 3

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
☐ 0	☐ 1	☐ 2	☐ 3

9. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?

No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
☐ 0	☐ 1	☐ 2	☐ 3

10. Do you have a bed partner or roommate?

No bed partner or roommate	Partner/roommate in other room	Partner in same room, but not same bed	Partner in same bed
☐ 0	☐ 1	☐ 2	☐ 3

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 6

AW02:09

Pittsburgh Sleep Quality Index, continued PSQI

If you have a roommate or bed partner, ask him/her how often in the past month you have had...

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Loud snoring	☐ 0	☐ 1	☐ 2	☐ 3
b. Long pauses between breaths while sleeping	☐ 0	☐ 1	☐ 2	☐ 3
c. Legs twitching or jerking while you sleep	☐ 0	☐ 1	☐ 2	☐ 3
d. Episodes of disorientation or confusion during sleep	☐ 0	☐ 1	☐ 2	☐ 3
e. Other restlessness while you sleep; please describe.....	☐ 0	☐ 1	☐ 2	☐ 3

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Visit No. 6

AW02:09

Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form QLESSF

Available from Jean Endicott, Ph.D., Dept. of Research Assessment and Training, Unit 123, 1051 Riverside Drive, New York, NY 10032, USA

Date of assessment |2|0|0| | | | | (year mm dd)

General Activities
Taking everything into consideration, during the past week how satisfied have you been with your... (indicate one box only)

Overall level of satisfaction

	Very poor	*Poor*	*Fair*	*Good*	*Very good*
Physical health	☐1	☐2	☐3	☐4	☐5
mood	☐1	☐2	☐3	☐4	☐5
work	☐1	☐2	☐3	☐4	☐5
household activities	☐1	☐2	☐3	☐4	☐5
social relationship	☐1	☐2	☐3	☐4	☐5
family relationship	☐1	☐2	☐3	☐4	☐5
leisure time activities	☐1	☐2	☐3	☐4	☐5
ability to function in daily life	☐1	☐2	☐3	☐4	☐5
sexual drive, interest and/or performance*	☐1	☐2	☐3	☐4	☐5
economic situation	☐1	☐2	☐3	☐4	☐5
living/housing situation*	☐1	☐2	☐3	☐4	☐5
ability to get around physically without feeling dizzy or unsteady or falling*	☐1	☐2	☐3	☐4	☐5
your vision in terms of ability to do work or hobbies*	☐1	☐2	☐3	☐4	☐5
overall sense of well being	☐1	☐2	☐3	☐4	☐5
medications, if not taking any , indicate here ☐0 and leave item blank	☐1	☐2	☐3	☐4	☐5
How would you rate your overall life satisfaction and contentment during the past week	☐1	☐2	☐3	☐4	☐5

*If satisfaction is very poor, poor, or fair on these items, please UNDERLINE the factor(s) associated with a lack of satisfaction

Study code 5077US/0049 Subj initials ..... E code [E|0|0| | | | | |]

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AW02:09

Visit

VISIT

Visit date [2|0|0| | | | |]
year mm dd

AW02:09

Vital Signs

VIT

Assessment date [2|0|0| | | | |]
year mm dd

Pulse, supine [| | |] beats/min

Blood pressure, supine [| | |] / [| | |] mmHg
systolic diastolic

Pulse, standing [| | |] beats/min

Blood pressure, standing [| | |] / [| | |] mmHg
systolic diastolic

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 7

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code [E|0|0| | | | | |]

Visit No. 7

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

2002-10-31

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Visit No. 7

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐ 0 Normal or increased appetite

☐ 1

☐ 2 Slightly reduced appetite

☐ 3

☐ 4 No appetite; food is tasteless

☐ 5

☐ 6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐ 0 No difficulties in concentrating

☐ 1

☐ 2 Occasional difficulties in collecting one's thoughts

☐ 3

☐ 4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐ 5

☐ 6 Unable to read or converse without great difficulty

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 |_|_|

Rater's initials

2002-10-31

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Visit No. 7

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | |
year mm dd

1. Elevated Mood

└┘ 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

└┘ 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

└┘ 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

└┘ 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

- ☐ 0 - Absent
- 2 - Subjectively increased
- 4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment
- 6 - Frequently irritable during the interview; short, curt throughout
- 8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

- ☐ 0 - No increase
- 2 - Feels talkative
- 4 - Increased rate or amount at times, verbose at times
- 6 - Push; consistently increased rate and amount; difficult to interrupt
- 8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

- ☐ 0 - Absent
- 1 - Circumstantial; mild distractibility; quick thoughts
- 2 - Distractible; loses goal of thought; change topics frequently; racing thoughts
- 3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia
- 4 - Incoherent; communication impossible

8. Content

- ☐ 0 - Normal
- 2 - Questionable plans, new interests
- 4 - Special project(s); hyperreligious
- 6 - Grandiose or paranoid ideas; ideas of reference
- 8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 7

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

└┘ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

└┘ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

└┘ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater´s initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Hamilton Rating Scale for Anxiety HAMA

Date of assessment |2|0|0| | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability ☐

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax ☐

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds ☐

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors ☐

Intellectual

Difficulty in concentration, poor memory ☐

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing ☐

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone ☐

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation ☐

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea ☐

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0|_|_|_|_|_|

Visit No. 7

AW02:09

Hamilton Rating Scale for Anxiety, continued HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea ☐

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation ☐

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence ☐

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair ☐

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. ☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 7

AW02:09

Clinical Global Impressions

CGI

Date of assessment |2|0|0| | | | | (year mm dd)

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

- Not assessed ☐ 0
- Normal, not at all ill ☐ 1
- Borderline mentally ill ☐ 2
- Mildly ill ☐ 3
- Moderately ill ☐ 4
- Markedly ill ☐ 5
- Severely ill ☐ 6
- Among the most extremely ill Subjects ☐ 7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

- Not assessed ☐ 0
- Very much improved ☐ 1
- Much improved ☐ 2
- Minimally improved ☐ 3
- No change ☐ 4
- Minimally worse ☐ 5
- Much worse ☐ 6
- Very much worse ☐ 7

Rater's initials

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Visit No. 8

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | | (year mm dd)

AW02:09

Vital Signs

VIT

Assessment date |2|0|0| | | | | | (year mm dd)

Pulse, supine | | | | beats/min

Blood pressure, supine | | | | (systolic) / | | | | (diastolic) mmHg

Pulse, standing | | | | beats/min

Blood pressure, standing | | | | (systolic) / | | | | (diastolic) mmHg

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 8

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 8

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 8

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Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 8

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

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AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | | | | |
year mm dd

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

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AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code [E|0|0| | | | |]

Visit No. 8

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 [| |]

Rater's initials

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Visit No. 8

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | | (year mm dd)

1. Elevated Mood

- 0 - Absent
- 1 - Mildly or possibly increased on questioning
- 2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content
- 3 - Elevated; inappropriate to content; humorous
- 4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

- 0 - Absent
- 1 - Subjectively increased
- 2 - Animated; gestures increased
- 3 - Excessive energy; hyperactive at times; restless (can be calmed)
- 4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

- 0 - Normal; not increased
- 1 - Mildly or possibly increased
- 2 - Definite subjective increase on questioning
- 3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report
- 4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

- 0 - Reports no decrease in sleep
- 1 - Sleeping less than normal amount by up to one hour
- 2 - Sleeping less than normal by more than one hour
- 3 - Reports decreased need for sleep
- 4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 8

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

- [ ] 0 - Absent
- 2 - Subjectively increased
- 4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment
- 6 - Frequently irritable during the interview; short, curt throughout
- 8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

- [ ] 0 - No increase
- 2 - Feels talkative
- 4 - Increased rate or amount at times, verbose at times
- 6 - Push; consistently increased rate and amount; difficult to interrupt
- 8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

- [ ] 0 - Absent
- 1 - Circumstantial; mild distractibility; quick thoughts
- 2 - Distractible; loses goal of thought; change topics frequently; racing thoughts
- 3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia
- 4 - Incoherent; communication impossible

8. Content

- [ ] 0 - Normal
- 2 - Questionable plans, new interests
- 4 - Special project(s); hyperreligious
- 6 - Grandiose or paranoid ideas; ideas of reference
- 8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 8

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

☐ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

☐ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

☐ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 8

AW02:09

Hamilton Rating Scale for Anxiety HAMA

Date of assessment |2|0|0| | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability |_|

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax |_|

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds |_|

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors |_|

Intellectual

Difficulty in concentration, poor memory |_|

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing |_|

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone |_|

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation |_|

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea |_|

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 8

AW02:09

Hamilton Rating Scale for Anxiety, continued HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea |__|

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation |__|

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence |__|

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair |__|

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. |__|

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 8

AW02:09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | | | | |
year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

- Not assessed ☐ 0
- Normal, not at all ill ☐ 1
- Borderline mentally ill ☐ 2
- Mildly ill ☐ 3
- Moderately ill ☐ 4
- Markedly ill ☐ 5
- Severely ill ☐ 6
- Among the most extremely ill Subjects ☐ 7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

- Not assessed ☐ 0
- Very much improved ☐ 1
- Much improved ☐ 2
- Minimally improved ☐ 3
- No change ☐ 4
- Minimally worse ☐ 5
- Much worse ☐ 6
- Very much worse ☐ 7

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Visit

VISIT

Visit date |2|0|0| | | | | | |
year mm dd

AW02:09

Vital Signs

VIT

Assessment date |2|0|0| | | | | | |
year mm dd

Pulse, supine | | | | beats/min

Blood pressure, supine | | | | / | | | | mmHg
systolic diastolic

Pulse, standing | | | | beats/min

Blood pressure, standing | | | | / | | | | mmHg
systolic diastolic

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02.09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 9

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | | (year mm dd)

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 9

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 9

AW02.09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 |_|_|

Rater´s initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Elevated Mood

|_| 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

|_| 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

|_| 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

|_| 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

☐ 0 - Absent

2 - Subjectively increased

4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment

6 - Frequently irritable during the interview; short, curt throughout

8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

☐ 0 - No increase

2 - Feels talkative

4 - Increased rate or amount at times, verbose at times

6 - Push; consistently increased rate and amount; difficult to interrupt

8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

☐ 0 - Absent

1 - Circumstantial; mild distractibility; quick thoughts

2 - Distractible; loses goal of thought; change topics frequently; racing thoughts

3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia

4 - Incoherent; communication impossible

8. Content

☐ 0 - Normal

2 - Questionable plans, new interests

4 - Special project(s); hyperreligious

6 - Grandiose or paranoid ideas; ideas of reference

8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 9

AW02.09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

☐ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

☐ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

☐ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Hamilton Rating Scale for Anxiety HAMA

Date of assessment |2|0|0| | | | | | (year mm dd)

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability ☐

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax ☐

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds ☐

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors ☐

Intellectual

Difficulty in concentration, poor memory ☐

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing ☐

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone ☐

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation ☐

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea ☐

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02:09

Hamilton Rating Scale for Anxiety, continued

HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea ☐

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation ☐

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence ☐

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair ☐

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. ☐

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 9

AW02.09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

Not assessed ☐ 0

Normal, not at all ill ☐ 1

Borderline mentally ill ☐ 2

Mildly ill ☐ 3

Moderately ill ☐ 4

Markedly ill ☐ 5

Severely ill ☐ 6

Among the most extremely ill Subjects ☐ 7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

Not assessed ☐ 0

Very much improved ☐ 1

Much improved ☐ 2

Minimally improved ☐ 3

No change ☐ 4

Minimally worse ☐ 5

Much worse ☐ 6

Very much worse ☐ 7

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Visit VISIT

Visit date |2|0|0| | | | | (year mm dd)

AW02:09

Vital Signs, Weight VIT

Assessment date |2|0|0| | | | | (year mm dd)

Pulse, supine | | | | beats/min

Blood pressure, supine | | | | / | | | | mmHg (systolic / diastolic)

Pulse, standing | | | | beats/min

Blood pressure, standing | | | | / | | | | mmHg (systolic / diastolic)

Weight | | | | kg

AW02:09

Electrocardiogram ECGQ

Was an ECG performed No ☐0 Yes ☐1

Date of ECG |2|0|0| | | | | (year mm dd)

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Laboratory Assessments

LAB1

Blood samples have been collected No ☐0 Yes ☐1

Sample date |2|0|0| | | | | | | |
year mm dd

Sample time | | | : | | |
24-hour clock

Sample ID
Attach Sample ID label here

Study code 5077US/0049 Subj initials ..... E code |E|0|0|_|_|_|_|

Visit No. 10

AW02:09

Physical Examination, Follow-up

PHYSF

Assessment date |2|0|0|_|_|_|_| year mm dd

	Normal	*Abnormal*		*Not done*	*Specification of new or aggravated abnormalities (compared with baseline)*
		Same as baseline	New or aggravated		
General appearance	☐ 0	☐ 1	☐ 2	☐ 95	.....
Skin	☐ 0	☐ 1	☐ 2	☐ 95	.....
Head and neck	☐ 0	☐ 1	☐ 2	☐ 95	.....
Lymph nodes	☐ 0	☐ 1	☐ 2	☐ 95	.....
Thyroid	☐ 0	☐ 1	☐ 2	☐ 95	.....
Musculoskeletal/ Extremities	☐ 0	☐ 1	☐ 2	☐ 95	.....
Cardiovascular	☐ 0	☐ 1	☐ 2	☐ 95	.....
Lungs	☐ 0	☐ 1	☐ 2	☐ 95	.....
Abdomen	☐ 0	☐ 1	☐ 2	☐ 95	.....
Neurological	☐ 0	☐ 1	☐ 2	☐ 95	.....

☞ **If any new or aggravated abnormalities imply a deterioration compared with baseline (=Visit 1), fill in AELOGAW, Section 13**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Hamilton Rating Scale for Depression HAMD

Date of assessment |2|0|0| | | | | (year mm dd)

1. Depressed mood (sadness, hopeless, helpless, worthless)

☐0 Absent

☐1 These feeling states indicated only on questioning

☐2 These feeling states spontaneously reported verbally

☐3 Communicates feeling states non-verbally (ie, through facial expression, posture, voice, and tendency to weep)

☐4 Subject reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

2. Feeling of guilt

☐0 Absent

☐1 Self-reproach, feels he has let people down

☐2 Ideas of guilt or rumination over past errors or sinful deeds

☐3 Present illness is a punishment. Delusions of guilt

☐4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

☐0 Absent

☐1 Feels life is not worth living

☐2 Wishes he were dead or any thoughts of possible death to self

☐3 Suicide ideas or gesture

☐4 Attempts at suicide (any serious attempt rates 4)

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

4. Insomnia early

☐0 No difficulty falling asleep

☐1 Complains of occasional difficulty falling asleep (eg, more than 30 minutes)

☐2 Complains of nightly difficulty falling asleep

5. Insomnia middle

☐0 No difficulty

☐1 Subject complains of being restless and disturbed during the night

☐2 Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia late

☐0 No difficulty

☐1 Waking in early hours of the morning but goes back to sleep

☐2 Unable to fall asleep again if he gets out of bed

7. Work and activities

☐0 No difficulty

☐1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

☐2 Loss of interest in activity; hobbies or work - either directly reported by Subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

☐3 Decrease in actual time spent in activities or decrease in productivity

☐4 Stopped working because of present illness.

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

8. Retardation: psychomotor
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

☐0 Normal speech and thought

☐1 Slight retardation at interview

☐2 Obvious retardation at interview

☐3 Interview difficult

☐4 Complete stupor

9. Agitation

☐0 None

☐1 Fidgetiness

☐2 Playing with hands, hair, etc

☐3 Moving about, can't sit still

☐4 Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety (psychological)

☐0 No difficulty

☐1 Subjective tension and irritability

☐2 Worrying about minor matters

☐3 Apprehensive attitude apparent in face or speech

☐4 Fears expressed without questioning

continues

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

11. Anxiety somatic

Physiological concomitants of anxiety (ie, effects of autonomic overactivity, "butterflies", indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (ie, dry mouth, constipation)

☐0 Absent

☐1 Mild

☐2 Moderate

☐3 Severe

☐4 Incapacitating

12. Somatic symptoms (gastrointestinal)

☐0 None

☐1 Loss of appetite but eating without encouragement from others. Food intake about normal

☐2 Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. Somatic symptoms general

☐0 None

☐1 Heaviness in limbs, back, or head; backaches, headache, muscle aches; loss of energy and fatigability

☐2 Any clear-cut symptom rates 2

14. Genital symptoms

(symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

☐0 Absent

☐1 Mild

☐2 Severe

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Hamilton Rating Scale for Depression, continued HAMD

15. Hypochondriasis

☐0 Not present

☐1 Self-absorption (bodily)

☐2 Preoccupation with health

☐3 Frequent complaints, requests for help, etc

☐4 Hypochondriacal delusions

16. Loss of weight)

A. When rating by history

☐0 No weight loss

☐1 Probable weight loss associated with present illness

☐2 Definite (according to Subject) weight loss

☐3 Not assessed

17. Insight

☐0 Acknowledges being depressed and ill

☐1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc

☐2 Denies being ill at all

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Montgomery-Asberg Depression Rating Scale MADRS

Date of assessment |2|0|0| | | | | (year mm dd)

1. Apparent sadness

Representing despondency, gloom, and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture.
Rate by depth and inability to brighten up.

☐0 No sadness

☐1

☐2 Looks dispirited but does brighten up without difficulty

☐3

☐4 Appears sad and unhappy most of the time

☐5

☐6 Looks miserable all the time; extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency, or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐0 Occasional sadness in keeping with the circumstances

☐1

☐2 Sad or low but brightens up without difficulty

☐3

☐4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

☐5

☐6 Continuous or unvarying sadness, misery, or despondence

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish.
Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐0 Placid; only fleeting inner tension

☐1

☐2 Occasional feelings of edginess and ill-defined discomfort

☐3

☐4 Continuous feelings of inner tension or intermittent panic which Subject can only master with some difficulty

☐5

☐6 Unrelenting dread or anguish; overwhelming panic

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to Subject's own normal pattern when well.

☐0 Sleeps as usual

☐1

☐2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

☐3

☐4 Sleep reduced or broken by at least two hours

☐5

☐6 Less than two or three hours sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.
Rate by loss of desire for food or the need to force oneself to eat.

☐0 Normal or increased appetite

☐1

☐2 Slightly reduced appetite

☐3

☐4 No appetite; food is tasteless

☐5

☐6 Needs persuasion to eat at all

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.
Rate according to intensity, frequency, and degree of incapacity produced.

☐0 No difficulties in concentrating

☐1

☐2 Occasional difficulties in collecting one's thoughts

☐3

☐4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

☐5

☐6 Unable to read or converse without great difficulty

continues

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

☐0 Hardly any difficulty in getting started; no sluggishness

☐1

☐2 Difficulties in starting activities

☐3

☐4 Difficulties in starting simple routine activities which are carried out with effort

☐5

☐6 Complete lassitude; unable to do anything without help

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐0 Normal interest in the surroundings and in other people

☐1

☐2 Reduced ability to enjoy usual interests

☐3

☐4 Loss of interest in the surroundings; loss of feelings for friends and acquaintances

☐5

☐6 The experience of being emotionally paralyzed; inability to feel anger, grief, or pleasure; and a complete or even painful failure to feel for close relatives

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Montgomery-Asberg Depression Rating Scale, continued MADRS

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

☐0 No pessimistic thoughts

☐1

☐2 Fluctuating ideas of failure, self-reproach, or self depreciation

☐3

☐4 Persistent self-accusations, or definite but still rational ideas of guilt or sin; increasingly pessimistic about the future

☐5

☐6 Delusions of ruin, remorse, or unredeemable sin; self-accusations which are absurd and unshakable

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
Suicidal attempts should not in themselves influence the rating.

☐0 Enjoys life or takes it as it comes

☐1

☐2 Weary of life; only fleeting suicidal thoughts

☐3

☐4 Probably better off dead; suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions

☐5

☐6 Explicit plans for suicide when there is an opportunity; active preparations for suicide

Total score item 1-10 |_|_|

Rater´s initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Young Mania Rating Scale YMRS

Date of assessment |2|0|0| | | | | | | |
year mm dd

1. Elevated Mood

└┘ 0 - Absent

1 - Mildly or possibly increased on questioning

2 - Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content

3 - Elevated; inappropriate to content; humorous

4 - Euphoric; inappropriate laughter; singing

2. Increased Motor Activity - Energy

└┘ 0 - Absent

1 - Subjectively increased

2 - Animated; gestures increased

3 - Excessive energy; hyperactive at times; restless (can be calmed)

4 - Motor excitement; continuous hyperactivity (cannot be calmed)

3. Sexual Interest

└┘ 0 - Normal; not increased

1 - Mildly or possibly increased

2 - Definite subjective increase on questioning

3 - Spontaneous sexual content; elaborates on sexual matters; hypersexual by self report

4 - Overt sexual acts (towards patients, staff, or interviewer)

4. Sleep

└┘ 0 - Reports no decrease in sleep

1 - Sleeping less than normal amount by up to one hour

2 - Sleeping less than normal by more than one hour

3 - Reports decreased need for sleep

4 - Denies need for sleep

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Young Mania Rating Scale, continued YMRS

5. Irritability

☐ 0 - Absent

2 - Subjectively increased

4 - Irritable at times during the interview; recent episodes of anger or annoyance on ward or in usual environment

6 - Frequently irritable during the interview; short, curt throughout

8 - Hostile, uncooperative; interview impossible

6. Speech (Rate and Amount)

☐ 0 - No increase

2 - Feels talkative

4 - Increased rate or amount at times, verbose at times

6 - Push; consistently increased rate and amount; difficult to interrupt

8 - Pressured; uninterruptible, continuous speech

7. Language - Thought Disorder

☐ 0 - Absent

1 - Circumstantial; mild distractibility; quick thoughts

2 - Distractible; loses goal of thought; change topics frequently; racing thoughts

3 - Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia

4 - Incoherent; communication impossible

8. Content

☐ 0 - Normal

2 - Questionable plans, new interests

4 - Special project(s); hyperreligious

6 - Grandiose or paranoid ideas; ideas of reference

8 - Delusions; hallucinations

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Young Mania Rating Scale, continued YMRS

9. Disruptive - Aggressive Behaviour

└┘ 0 - Absent, cooperative

2 - Sarcastic; loud at times, guarded

4 - Demanding; threats on ward

6 - Threatens interviewer; shouting during interview; interview difficult

8 - Assaultive; destructive; interview impossible

10. Appearance

└┘ 0 - Appropriate dress and grooming

1 - Minimally unkempt

2 - Poorly groomed; moderately dishevelled; overdressed

3 - Dishevelled; partly clothed; garish make-up

4 - Completely unkempt; decorated; bizarre garb

11. Insight

└┘ 0 - Present; admits illness; agrees with need for treatment

1 - Possibly ill

2 - Admits behaviour change, but denies illness

3 - Admits possible change in behaviour, but denies illness

4 - Denies any behaviour change

Rater's initials

Study code 5077US/0049 Subj initials .... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Hamilton Rating Scale for Anxiety

HAMA

Date of assessment |2|0|0| | | | | |
year mm dd

Anxious mood

Worries, anticipation of the worst, fearful anticipation, irritability ☐

Tension

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax ☐

Fears

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds ☐

Insomnia

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors ☐

Intellectual

Difficulty in concentration, poor memory ☐

Depressed mood

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing ☐

Somatic (Muscular)

Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone ☐

Somatic (Sensory)

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation ☐

Cardiovascular symptoms

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea ☐

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Hamilton Rating Scale for Anxiety, continued

HAMA

Respiratory symptoms

Pressure or constriction in chest, choking feelings, sighing, dyspnea |__|

Gastrointestinal symptoms

Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation |__|

Genitourinary symptoms

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence |__|

Autonomic symptoms

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair |__|

Behavior at interview

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc. |__|

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Clinical Global Impressions CGI

Date of assessment |2|0|0| | | | | | |
year mm dd

1. Severity of illness

Considering your total clinical experience with this particular population, how mentally ill is Subject at this time?

- Not assessed ☐ 0
- Normal, not at all ill ☐ 1
- Borderline mentally ill ☐ 2
- Mildly ill ☐ 3
- Moderately ill ☐ 4
- Markedly ill ☐ 5
- Severely ill ☐ 6
- Among the most extremely ill Subjects ☐ 7

2. Global improvement

Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment
Compared to Subject's condition at admission to the project, how much has Subject changed?

- Not assessed ☐ 0
- Very much improved ☐ 1
- Much improved ☐ 2
- Minimally improved ☐ 3
- No change ☐ 4
- Minimally worse ☐ 5
- Much worse ☐ 6
- Very much worse ☐ 7

Rater's initials

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Barnes Akathisia Rating Scale

BARS

Ref. Barnes TRE. A rating scale for drug-induced akathisia. Br J Psychiatry. 1989; 154: 672-676.

Date of assessment |2|0|0| | | | | | (year mm dd)

A. Objective

Normal occasional fidgety movements of the limbs ☐ 0

Presence of characteristic restless movements: shuffling or tramping movements of the legs and feet, or swinging of one leg while sitting, and/or rocking from foot to foot or 'walking on the spot' when standing, but movements present for less than half the time observed ☐ 1

Observed phenomena, as described above, which are present for at least half the observation period ☐ 2

Subject is constantly engaged in characteristic restless movements, and/or has the inability to remain seated or standing without walking or pacing, during the time observed ☐ 3

B. Subjective

Awareness of restlessness

Absence of inner restlessness ☐ 0

Non-specific sense of inner restlessness ☐ 1

Subject is aware of an inability to keep the legs still, a desire to move the legs, and/or complains of inner restlessness aggravated specifically by being required to stand still ☐ 2

Awareness of an intense compulsion to move most of the time and/or reports a strong desire to walk or pace most of the time ☐ 3

Distress related to restlessness

No distress ☐ 0

Mild ☐ 1

Moderate ☐ 2

Severe ☐ 3

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Barnes Akathisia Rating Scale, continued BARS

C. Global clinical assessment of akathisia

Absent

No evidence of awareness of restlessness. Observation of characteristic movements of akathisia in the absence of a subjective report of inner restlessness or compulsive desire to move the legs should be classified as pseudoakathisia ☐0

Questionable

Non-specific inner tension and fidgety movements ☐1

Mild akathisia

Awareness of restlessness in the legs and/or inner restlessness worse when required to stand still. Fidgety movements present, but characteristic restless movements of akathisia not necessarily observed. Condition causes little or no distress ☐2

Moderate akathisia

Awareness of restlessness as described for mild akathisia above, combined with characteristic restless movements such as rocking from foot to foot when standing. Subject finds the condition distressing ☐3

Marked akathisia

Subjective experience of restlessness includes a compulsive desire to walk or pace. However, the Subject is able to remain seated for at least five minutes. The condition is obviously distressing ☐4

Severe akathisia

The Subject reports a strong compulsion to pace up and down most of the time. Unable to sit or lie down for more than a few minutes. Constant restlessness which is associated with intense distress and insomnia ☐5

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Simpson-Angus Scale

SAS

Ref. Modified from Simpson GN, Angus JWS. A rating scale for extrapyramidal side effects. Acta Psychiatr Scand. 1970;212 (suppl):11-19

Date of assessment |2|0|0| | | | | (year mm dd)

1. Gait

- Normal ☐ 0
- Mild diminution in swing while the Subject is walking ☐ 1
- Obvious diminution in swing suggesting shoulder rigidity ☐ 2
- Stiff gait with little or no arm swing noticeable ☐ 3
- Rigid gait with arms slightly pronated; or stooped-shuffling gait with propulsion and repropulsion ☐ 4
- Not ratable ☐ 9

2. Arm dropping

- Normal, free fall with loud slap and rebound ☐ 0
- Fall slowed slightly with less audible contact and little rebound ☐ 1
- Fall slowed, no rebound ☐ 2
- Marked slowing, no slap at all ☐ 3
- Arms fall as though against resistance; as though through glue ☐ 4
- Not ratable ☐ 9

3. Shoulder shaking

- Normal ☐ 0
- Slight stiffness and resistance ☐ 1
- Moderate stiffness and resistance ☐ 2
- Marked rigidity with difficulty in passive movement ☐ 3
- Extreme stiffness and rigidity with almost a frozen joint ☐ 4
- Not ratable ☐ 9

continues

AW02:09

Simpson-Angus Scale, continued

SAS

4. Elbow rigidity

- Normal ☐ 0
- Slight stiffness and resistance ☐ 1
- Moderate stiffness and resistance ☐ 2
- Marked rigidity with difficulty in passive movement ☐ 3
- Extreme stiffness and rigidity with almost a frozen joint ☐ 4
- Not ratable ☐ 9

5. Wrist rigidity

- Normal ☐ 0
- Slight stiffness and resistance ☐ 1
- Moderate stiffness and resistance ☐ 2
- Marked rigidity with difficulty in passive movement ☐ 3
- Extreme stiffness and rigidity with almost a frozen joint ☐ 4
- Not ratable ☐ 9

6. Head rotation

- Loose, no resistance ☐ 0
- Slight resistance to movement although the time to rotate may be normal ☐ 1
- Resistance is apparent and the time of rotation is shortened ☐ 2
- Resistance is obvious and rotation is slowed ☐ 3
- Head appears stiff and rotation is difficult to carry out ☐ 4
- Not ratable ☐ 9

continues

AW02:09

Simpson-Angus Scale, continued

SAS

7. Glabella tap

0 - 5 blinks	☐ 0
6 - 10 blinks	☐ 1
11 - 15 blinks	☐ 2
16 - 20 blinks	☐ 3
21 or more blinks	☐ 4
Not ratable	☐ 9

8. Tremor

Normal	☐ 0
Mild finger tremor, obvious to sight and touch	☐ 1
Tremor of hand or arm occurring spasmodically	☐ 2
Persistent tremor of one or more limbs	☐ 3
Whole body tremor	☐ 4
Not ratable	☐ 9

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 10

AW02:09

Simpson-Angus Scale, continued

SAS

9. Salivation

Normal	☐ 0
Excess salivation so that pooling takes place if mouth is open and tongue is raised	☐ 1
Excess salivation is present and might occasionally result in difficulty in speaking	☐ 2
Speaking with difficulty because of excess salivation	☐ 3
Frank drooling	☐ 4
Not ratable	☐ 9

10. Akathisia

No restlessness reported or observed	☐ 0
Mild restlessness observed, e.g. occasional jiggling of the foot occurs when Subject is seated	☐ 1
Moderate restlessness observed, e.g. on several occasions, jiggles foot, crosses and uncrosses legs, or twists a part of the body	☐ 2
Restlessness is frequently observed, e.g. the foot or leg moving most of the time	☐ 3
Restlessness persistently observed, e.g. Subject cannot sit still, may get up and walk	☐ 4
Not ratable	☐ 9

Rater's initials

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Pittsburgh Sleep Quality Index PSQI

Reprinted from Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. (1989). The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Research: 28(2), 193-213, with permission of Elsevier Sceince.

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

Date of assessment |2|0|0| | | | | | (year mm dd)

1. During the past month, when have you usually gone to bed at night?

USUAL BED TIME |_|_| : |_|_| (24-hour clock)

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES |_|_|_|

3.During the past month, when have you usually gotten up in the morning?

USUAL GETTING UP TIME |_|_| : |_|_| (24-hour clock)

4. During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT |_|_|

For each of the remaining questions, check the one best response. Please answer all questions.

5. **During the past month, how often have you had trouble sleeping because you....**

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes	☐ 0	☐ 1	☐ 2	☐ 3
b. Wake up in the middle of the night or early morning	☐ 0	☐ 1	☐ 2	☐ 3
c. Have to get up to use the bathroom	☐ 0	☐ 1	☐ 2	☐ 3
d. Cannot breathe comfortably	☐ 0	☐ 1	☐ 2	☐ 3
e. Cough or snore loudly	☐ 0	☐ 1	☐ 2	☐ 3
f. Feel too cold	☐ 0	☐ 1	☐ 2	☐ 3
g. Feel too hot	☐ 0	☐ 1	☐ 2	☐ 3
h. Had bad dreams	☐ 0	☐ 1	☐ 2	☐ 3
i. Have pain	☐ 0	☐ 1	☐ 2	☐ 3
j. Other reason(s), please describe:	☐ 0	☐ 1	☐ 2	☐ 3

continues

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

Visit No. 10

AW02:09

Pittsburgh Sleep Quality Index, continued PSQI

6. During the past month, how would you rate your sleep quality overall?

Very good	Fairly good	Fairly bad	Very bad
☐ 0	☐ 1	☐ 2	☐ 3

7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
☐ 0	☐ 1	☐ 2	☐ 3

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
☐ 0	☐ 1	☐ 2	☐ 3

9. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?

No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
☐ 0	☐ 1	☐ 2	☐ 3

10. Do you have a bed partner or roommate?

No bed partner or roommate	Partner/roommate in other room	Partner in same room, but not same bed	Partner in same bed
☐ 0	☐ 1	☐ 2	☐ 3

continues

Study code 5077US/0049 Subj initials ..... E code E 0 0

Visit No. 10

AW02:09

Pittsburgh Sleep Quality Index, continued PSQI

If you have a roommate or bed partner, ask him/her how often in the past month you have had...

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Loud snoring	☐ 0	☐ 1	☐ 2	☐ 3
b. Long pauses between breaths while sleeping	☐ 0	☐ 1	☐ 2	☐ 3
c. Legs twitching or jerking while you sleep	☐ 0	☐ 1	☐ 2	☐ 3
d. Episodes of disorientation or confusion during sleep	☐ 0	☐ 1	☐ 2	☐ 3
e. Other restlessness while you sleep; please describe.....	☐ 0	☐ 1	☐ 2	☐ 3

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

Visit No. 10

AW02:09

Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form QLESSF

Available from Jean Endicott, Ph.D., Dept. of Research Assessment and Training, Unit 123, 1051 Riverside Drive, New York, NY 10032, USA

Date of assessment |2|0|0| | | | | (year mm dd)

General Activities
Taking everything into consideration, during the past week how satisfied have you been with your... (indicate one box only)

Overall level of satisfaction

	Very poor	*Poor*	*Fair*	*Good*	*Very good*
Physical health	☐1	☐2	☐3	☐4	☐5
mood	☐1	☐2	☐3	☐4	☐5
work	☐1	☐2	☐3	☐4	☐5
household activities	☐1	☐2	☐3	☐4	☐5
social relationship	☐1	☐2	☐3	☐4	☐5
family relationship	☐1	☐2	☐3	☐4	☐5
leisure time activities	☐1	☐2	☐3	☐4	☐5
ability to function in daily life	☐1	☐2	☐3	☐4	☐5
sexual drive, interest and/or performance*	☐1	☐2	☐3	☐4	☐5
economic situation	☐1	☐2	☐3	☐4	☐5
living/housing situation*	☐1	☐2	☐3	☐4	☐5
ability to get around physically without feeling dizzy or unsteady or falling*	☐1	☐2	☐3	☐4	☐5
your vision in terms of ability to do work or hobbies*	☐1	☐2	☐3	☐4	☐5
overall sense of well being	☐1	☐2	☐3	☐4	☐5
medications, if not taking any , indicate here ☐0 and leave item blank	☐1	☐2	☐3	☐4	☐5
How would you rate your overall life satisfaction and contentment during the past week	☐1	☐2	☐3	☐4	☐5

*If satisfaction is very poor, poor, or fair on these items, please UNDERLINE the factor(s) associated with a lack of satisfaction

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Prescription Record

PRESN

(Visit 2, Week 1)

	Date (year mm dd)	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	2 0 0	2		.....
Day 2	2 0 0	1		.....
Day 3	2 0 0	1		.....
Day 4	2 0 0	2		.....
Day 5	2 0 0	3		.....
Day 6	2 0 0	3		.....
Day 7	2 0 0	3		.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	2 0 0	4		.....
Extra day	2 0 0	4		.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Prescription Record

PRESN

(Visit 3, Week 2)

	Date (year mm dd)	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	|2|0|0| | | | |	|4|	_|	.....
Day 2	|2|0|0| | | | |	|4|	_|	.....
Day 3	|2|0|0| | | | |	|4|	_|	.....
Day 4	|2|0|0| | | | |	|4|	_|	.....
Day 5	|2|0|0| | | | |	|4|	_|	.....
Day 6	|2|0|0| | | | |	|4|	_|	.....
Day 7	|2|0|0| | | | |	|4|	_|	.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	|2|0|0| | | | |	|4|	_|	.....
Extra day	|2|0|0| | | | |	|4|	_|	.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

AW02:09

Prescription Record

PRESN

(Visit 4, Week 3)

	Date year mm dd	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	|2|0|0| | | | |	|4|	| |	.....
Day 2	|2|0|0| | | | |	|4|	| |	.....
Day 3	|2|0|0| | | | |	|4|	| |	.....
Day 4	|2|0|0| | | | |	|4|	| |	.....
Day 5	|2|0|0| | | | |	|4|	| |	.....
Day 6	|2|0|0| | | | |	|4|	| |	.....
Day 7	|2|0|0| | | | |	|4|	| |	.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	|2|0|0| | | | |	|4|	| |	.....
Extra day	|2|0|0| | | | |	|4|	| |	.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Prescription Record

PRESN

(Visit 5, Week 4)

	Date year mm dd	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	|2|0|0| | | | |	|4|	| |	.....
Day 2	|2|0|0| | | | |	|4|	| |	.....
Day 3	|2|0|0| | | | |	|4|	| |	.....
Day 4	|2|0|0| | | | |	|4|	| |	.....
Day 5	|2|0|0| | | | |	|4|	| |	.....
Day 6	|2|0|0| | | | |	|4|	| |	.....
Day 7	|2|0|0| | | | |	|4|	| |	.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	|2|0|0| | | | |	|4|	| |	.....
Extra day	|2|0|0| | | | |	|4|	| |	.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Prescription Record

PRESN

(Visit 6, Week 5)

	Date (year mm dd)	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	|2|0|0| | | | |	|4|	|	.....
Day 2	|2|0|0| | | | |	|4|	|	.....
Day 3	|2|0|0| | | | |	|4|	|	.....
Day 4	|2|0|0| | | | |	|4|	|	.....
Day 5	|2|0|0| | | | |	|4|	|	.....
Day 6	|2|0|0| | | | |	|4|	|	.....
Day 7	|2|0|0| | | | |	|4|	|	.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	|2|0|0| | | | |	|4|	|	.....
Extra day	|2|0|0| | | | |	|4|	|	.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Prescription Record

PRESN

(Visit 7, Week 6)

	Date year mm dd	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	|2|0|0| | | | |	|4|	| |	.....
Day 2	|2|0|0| | | | |	|4|	| |	.....
Day 3	|2|0|0| | | | |	|4|	| |	.....
Day 4	|2|0|0| | | | |	|4|	| |	.....
Day 5	|2|0|0| | | | |	|4|	| |	.....
Day 6	|2|0|0| | | | |	|4|	| |	.....
Day 7	|2|0|0| | | | |	|4|	| |	.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	|2|0|0| | | | |	|4|	| |	.....
Extra day	|2|0|0| | | | |	|4|	| |	.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Prescription Record

PRESN

(Visit 8, Week 7)

	Date year mm dd	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	|2|0|0| | | | |	|4|	| |	.....
Day 2	|2|0|0| | | | |	|4|	| |	.....
Day 3	|2|0|0| | | | |	|4|	| |	.....
Day 4	|2|0|0| | | | |	|4|	| |	.....
Day 5	|2|0|0| | | | |	|4|	| |	.....
Day 6	|2|0|0| | | | |	|4|	| |	.....
Day 7	|2|0|0| | | | |	|4|	| |	.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	|2|0|0| | | | |	|4|	| |	.....
Extra day	|2|0|0| | | | |	|4|	| |	.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

Study code 5077US/0049 Subj initials ..... E code |E|0|0|_|_|_|_|

AW02:09

Prescription Record

PRESN

(Visit 9, Week 8)

	Date (year mm dd)	Number of tablets dispensed	Number of tablets returned	Comment
Day 1	|2|0|0|_|_|_|_|	|4|	|_|	.....
Day 2	|2|0|0|_|_|_|_|	|4|	|_|	.....
Day 3	|2|0|0|_|_|_|_|	|4|	|_|	.....
Day 4	|2|0|0|_|_|_|_|	|4|	|_|	.....
Day 5	|2|0|0|_|_|_|_|	|4|	|_|	.....
Day 6	|2|0|0|_|_|_|_|	|4|	|_|	.....
Day 7	|2|0|0|_|_|_|_|	|4|	|_|	.....

Did the Subject take the extra day doses No ☐ 0 Yes ☐ 1

Always complete the extra day number returned even if the Subject did not take the extra day doses

Extra day	|2|0|0|_|_|_|_|	|4|	|_|	.....
Extra day	|2|0|0|_|_|_|_|	|4|	|_|	.....

☞ **If investigational therapy was prematurely stopped because of an adverse event, make sure that AELOGAW, Section 13, has been filled in**

Study code 5077US/0049 Subj initials ..... E code E 0 0

AW02:09

Subject Drug Accountability SAC

Package ID
Visit 2 Please attach label here

Package ID
Visit 3 Please attach label here

Package ID
Visit 4 Please attach label here

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | | |

AW02:09

Subject Drug Accountability

SAC

Package ID
Visit 5 Please attach label here

Package ID
Visit 6 Please attach label here

Package ID
Visit 7 Please attach label here

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Subject Drug Accountability

SAC

Package ID
Visit 8 Please attach label here

Package ID
Visit 9 Please attach label here

AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E 0 0

AW02:09

Medication on Entry and Including Wash-out Medications

MED1

None ☐0

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
1	.....	.....	.....		2 0 0	or ☐1	.....
2	.....	.....	.....		2 0 0	or ☐1	.....
3	.....	.....	.....		2 0 0	or ☐1	.....
4	.....	.....	.....		2 0 0	or ☐1	.....
5	.....	.....	.....		2 0 0	or ☐1	.....
6	.....	.....	.....		2 0 0	or ☐1	.....
7	.....	.....	.....		2 0 0	or ☐1	.....
8	.....	.....	.....		2 0 0	or ☐1	.....

☞ **If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.**

2002-10-31

AW02:09

Medication on Entry and Including Wash-out Medications

MED1

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
9					2 0 0	or ☐ 1	
10					2 0 0	or ☐ 1	
11					2 0 0	or ☐ 1	
12					2 0 0	or ☐ 1	
13					2 0 0	or ☐ 1	
14					2 0 0	or ☐ 1	
15					2 0 0	or ☐ 1	
16					2 0 0	or ☐ 1	

☞ **If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.**

2002-10-31

Page 210.01

AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E 0 0

AW02:09

Medication on Entry and Including Wash-out Medications

MED1

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
17					2 0 0	or ☐ 1	
18					2 0 0	or ☐ 1	
19					2 0 0	or ☐ 1	
20					2 0 0	or ☐ 1	
21					2 0 0	or ☐ 1	
22					2 0 0	or ☐ 1	
23					2 0 0	or ☐ 1	
24					2 0 0	or ☐ 1	

☞ **If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.**

2002-10-31

Page 210.02

AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E 0 0

AW02:09

Medication on Entry and Including Wash-out Medications

MED1

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
25					2 0 0	or ☐ 1	
26					2 0 0	or ☐ 1	
27					2 0 0	or ☐ 1	
28					2 0 0	or ☐ 1	
29					2 0 0	or ☐ 1	
30					2 0 0	or ☐ 1	
31					2 0 0	or ☐ 1	
32					2 0 0	or ☐ 1	

☞ **If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.**

2002-10-31

Page 210.03

AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E 0 0

AW02:09

Medications Initiated During the Study

MED

None ☐0

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
1	.....	.....	.....		2 0 0	or ☐1	.....
2	.....	.....	.....		2 0 0	or ☐1	.....
3	.....	.....	.....		2 0 0	or ☐1	.....
4	.....	.....	.....		2 0 0	or ☐1	.....
5	.....	.....	.....		2 0 0	or ☐1	.....
6	.....	.....	.....		2 0 0	or ☐1	.....
7	.....	.....	.....		2 0 0	or ☐1	.....
8	.....	.....	.....		2 0 0	or ☐1	.....

☞ **If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.**

2002-10-31

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AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E|0|0|_|_|_|_|

AW02MV 60:

Medications Initiated During the Study

MED

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
9	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....
10	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....
11	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....
12	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....
13	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....
14	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....
15	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....
16	.....	.....	.....	_|_|_|_|_|_|_|_	2|0|0|_|_|_|_	or ☐ 1	.....

If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.

2002-10-31

Page 211.01

AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E 0 0

AW02:09

Medications Initiated During the Study

MED

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
17					2 0 0	or ☐ 1	
18					2 0 0	or ☐ 1	
19					2 0 0	or ☐ 1	
20					2 0 0	or ☐ 1	
21					2 0 0	or ☐ 1	
22					2 0 0	or ☐ 1	
23					2 0 0	or ☐ 1	
24					2 0 0	or ☐ 1	

☞ **If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.**

2002-10-31

Page 211.02

AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E 0 0

AW02:09

Medications Initiated During the Study

MED

	Trade name	Total daily dose	Unit	Treatment started year mm dd	Treatment stopped year mm dd	Medication continues	Reason for therapy
25					2 0 0	or ☐ 1	
26					2 0 0	or ☐ 1	
27					2 0 0	or ☐ 1	
28					2 0 0	or ☐ 1	
29					2 0 0	or ☐ 1	
30					2 0 0	or ☐ 1	
31					2 0 0	or ☐ 1	
32					2 0 0	or ☐ 1	

☞ **If any changes in therapy were made because of an adverse event, make sure that the AELOGAW has been filled in.**

2002-10-31

Page 211.03

AstraZeneca

Study code 5077US/0049 Subj initials ..... E code E|0|0|_|_|_|_|

AW02:09

Adverse Events

AELOGAW

None ☐0

AE No	Adverse Event	Date AE started / stopped (year mm dd)	Ongoing Yes	Serious* No	Serious* Yes	Serious AE due to*: Death	Life threatening	Hospitalization	Disability/incapacity	Congenital abnormality/birth defect	Important medical event	Action taken, invest product 0-3	AE caused Subject to discontinue the study No	AE caused Subject to discontinue the study Yes	Intensity 1-3	Causality No	Causality Yes
1		Date started 2|0|0|_|_|_|_| Date stopped 2|0|0|_|_|_|_|	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1
2		Date started 2|0|0|_|_|_|_| Date stopped 2|0|0|_|_|_|_|	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1
3		Date started 2|0|0|_|_|_|_| Date stopped 2|0|0|_|_|_|_|	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1
4		Date started 2|0|0|_|_|_|_| Date stopped 2|0|0|_|_|_|_|	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1

*☞ **If one or more "Serious AE due to" outcomes is ticked, IMMEDIATELY notify AstraZeneca, LP or their designate identified on the Instruction page, within one day of when the Investigator became aware of the Serious AE.**

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AW02:69

Adverse Events

AELOGAW

AE No	Adverse Event	Date AE started / stopped (year mm dd)	Ongoing (Yes)	Serious* (No / Yes)	Serious AE due to* (Death / Life threatening / Hospitalization / Disability/incapacity / Congenital abnormality/birth defect / Important medical event)	Action taken, invest product (0-3)	AE caused Subject to discontinue the study (No / Yes)	Intensity (1-3)	Causality (No / Yes)
5		Date started 2 0 0 / Date stopped 2 0 0	☐1	☐0 ☐1	☐1 ☐1 ☐1 ☐1 ☐1 ☐1	☐	☐0 ☐1	☐	☐0 ☐1
6		Date started 2 0 0 / Date stopped 2 0 0	☐1	☐0 ☐1	☐1 ☐1 ☐1 ☐1 ☐1 ☐1	☐	☐0 ☐1	☐	☐0 ☐1
7		Date started 2 0 0 / Date stopped 2 0 0	☐1	☐0 ☐1	☐1 ☐1 ☐1 ☐1 ☐1 ☐1	☐	☐0 ☐1	☐	☐0 ☐1
8		Date started 2 0 0 / Date stopped 2 0 0	☐1	☐0 ☐1	☐1 ☐1 ☐1 ☐1 ☐1 ☐1	☐	☐0 ☐1	☐	☐0 ☐1

*☞ **If one or more "Serious AE due to" outcomes is ticked, IMMEDIATELY notify AstraZeneca, LP or their designate identified on the Instruction page, within one day of when the Investigator became aware of the Serious AE.**

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AW02:09

Adverse Events

AELOGAW

AE No	Adverse Event	Date AE started / stopped (year mm dd)	Ongoing	Serious*		Serious AE due to*						Action taken, invest product	AE caused Subject to discontinue the study		Intensity	Causality	
						Death	Life threatening	Hospitalization	Disability/incapacity	Congenital abnormality/birth defect	Important medical event						
			Yes	No	Yes							0-3	No	Yes	1-3	No	Yes
9		Date started 2 0 0 / Date stopped 2 0 0	1	0	1	1	1	1	1	1	1		0	1		0	1
10		Date started 2 0 0 / Date stopped 2 0 0	1	0	1	1	1	1	1	1	1		0	1		0	1
11		Date started 2 0 0 / Date stopped 2 0 0	1	0	1	1	1	1	1	1	1		0	1		0	1
12		Date started 2 0 0 / Date stopped 2 0 0	1	0	1	1	1	1	1	1	1		0	1		0	1

*☞ **If one or more "Serious AE due to" outcomes is ticked, IMMEDIATELY notify AstraZeneca, LP or their designate identified on the Instruction page, within one day of when the Investigator became aware of the Serious AE.**

2002-10-31

Adverse Events

AELOGAW

AE No	Adverse Event	Date AE started / stopped (year mm dd)	Ongoing	Serious*	Serious AE due to*						Action taken, invest product	AE caused Subject to discontinue the study		Intensity	Causality	
			Yes	No	Yes	Death	Life threatening	Hospitalization	Disability/incapacity	Congenital abnormality/birth defect	Important medical event	0-3	No	Yes	1-3	No	Yes
13		Date started 2 0 0 _ _ _ _ Date stopped 2 0 0 _ _ _ _	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1
14		Date started 2 0 0 _ _ _ _ Date stopped 2 0 0 _ _ _ _	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1
15		Date started 2 0 0 _ _ _ _ Date stopped 2 0 0 _ _ _ _	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1
16		Date started 2 0 0 _ _ _ _ Date stopped 2 0 0 _ _ _ _	☐1	☐0	☐1	☐1	☐1	☐1	☐1	☐1	☐1	_	☐0	☐1	_	☐0	☐1

*☞ **If one or more "Serious AE due to" outcomes is ticked, IMMEDIATELY notify AstraZeneca, LP or their designate identified on the Instruction page, within one day of when the Investigator became aware of the Serious AE.**

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Study Termination

TERMAW

Date Study completed |2|0|0| | | | | (year mm dd)

Was Subject's participation in the study prematurely discontinued No ☐0 Yes ☐1

Main reason for study termination (one only)

Completed treatment period ☐0

Lack of efficacy ☐8

Adverse event ☐3 Please make sure that AELOGAW, Section 13 has been filled in

Subject lost to follow-up ☐2

Protocol noncompliance (protocol violations or deviations) ☐4 Please specify .....

Informed consent withdrawn ☐5

Other (e.g. Investigator's discretion, sponsor initiated termination of study, patient moved, etc) ☐9 Please specify .....

AW02:09

Statement Of Death

DEATH

Date of death |2|0|0| | | | | (year mm dd)

Primary cause of death .....

Autopsy

Autopsy performed No ☐0 Yes ☐1

2002-10-31

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Signature

SIGN

By signing and dating this page for the study and Subject identified above, I declare that the information on this and all other pages of this Case Report Form has been reviewed by me or my delegate, and is accurate and complete.

|2|0|0| | | | |
year mm dd

.....
Principal Investigator's signature

.....
Principal Investigator's name (in block letters)

Section 16
Local Laboratory Tests
(Unscheduled)

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Laboratory Assessments, Chemistry

LABC

Unscheduled

Sampling date |2|0|0| | | | | year mm dd

Sampling time | | : | | 24-hour clock

Subject fasting No ☐ 0 Yes ☐ 1

AstraZeneca use only

Laboratory ID | | | | | |

Laboratory name .....

Clinical chemistry - Blood	Value
Total bilirubin	
Alkaline phosphatase	
Alanine transaminase (ALT)	
Aspartate transaminase (AST)	
Sodium	
Potassium	
Chloride	
Glucose	
Insulin	
Bicarbonate	
Cholesterol HDL	
Triglycerides	
Cholesterol LDL	
Total Cholesterol	
Thyroid-stimulating hormone (TSH)	
Triiodothyronine resin uptake (T3RU)	
Total thyroxine (T4)	
Creatinine	

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02:09

Laboratory Assessments, Haematology

LABH

Unscheduled

Sampling date |2|0|0| | | | | | | year mm dd

Sampling time | | : | | | 24-hour clock

Subject fasting No ☐ 0 Yes ☐ 1

AstraZeneca use only

Laboratory ID | | | | | |

Laboratory name .....

Hæmatology - blood	Value
Hæmoglobin	
Hematocrit	
Red blood cell count	
WBC count - total	
Neutrophils %	
Lymphocytes %	
Monocytes %	
Eosinophils %	
Basophils %	
Platelets	

Study code 5077US/0049 Subj initials ..... E code |E|0|0| | | | |

AW02-09

Urine Toxicology Screen

UTS

Screen date |2|0|0| | | | | |
year mm dd

Urine toxicology results Neg ☐ 0 Pos ☐ 1

AstraZeneca

Clinical Study Report: Appendix 12.1.3

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.3

Independent Ethics Committees/Institutional Review Boards consulted, and samples of written Subject Information and Consent Form

12.1.3.1 Independent Ethics Committees/Institutional Review Boards consulted

Site Number	Name & Address of IRB	Chairman of IRB	Date of Approval
1	University Hospitals of Cleveland IRB for Human Investigation Lakeside, Suite 1400 Cleveland, OH 44106	William T. Dahms, MD	15 October 02
2	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
3	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
4	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	17 September 02
5	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	17 September 02
6	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	17 September 02
7	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	15 October 02
8	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
9	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
10	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
11	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	10 September 02
12	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02

Site Number	Name & Address of IRB	Chairman of IRB	Date of Approval
13	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
14	University of Utah IRB 20 North 1900 East, 101 MREB Salt Lake City, UT 84132-3101	Mark A. Munger, Pharm.D.	04 December 02
15	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	17 September 02
16	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	22 October 02
17	Office of Regulatory Affairs University of Pennsylvania 133 S. 36th Street, Mezzanine Level Philadelphia, PA 19104-3246	Federalwide Assurance #: 00004028 (This IRB does not provide a chairperson name)	9 January 03
18	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
19	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
20	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
21	Administrative Panel on Human Subjects Administrative Panels Office Stanford, CA 94305-5401	Donald R. Stanski, MD	12 November 02
22	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
23	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
24	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
25	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	26 February 03

Site Number	Name & Address of IRB	Chairman of IRB	Date of Approval
26	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
27	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	8 October 02
28	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	17 September 02
29	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	17 September 02
30	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
31	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
32	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
33	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	25 November 02
34	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	11 February 03
35	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	1 October 02
36	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	29 Apr 03
37	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
38	Internal Review Board 140 Health Professions Way University of Cincinnati Medical Center Eden and Bethesda Avenues Cincinnati, OH 45267-0567	Peter T. Frame, MD	23 Apr 03

Site Number	Name & Address of IRB	Chairman of IRB	Date of Approval
39	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	24 September 02
40	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	27 May 03
41	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	8 October 02
42	IntegReview Ethical Review Board 1825 Fortview Road, Suite 110 Austin, TX 78704	Fred Kopec, JD	3 June 03

12.1.3.2 Samples of written Subject Information and Consent Form

1 Master Informed Consent, September 17, 2002

2 Informed Consent with HIPAA language added, March 21, 2003

3 Informed Consent with Addendum for participation in ICI-D (See Section 5.6.1), February 21, 2003

APPROVED BY
INTEGREVIEW
SEPTEMBER 17, 2002

INFORMED CONSENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF DRUG/DEVICE COMPANY:	AstraZeneca Pharmaceuticals LP
CITY AND STATE:	Wilmington, DE
NUMBER AND NAME OF STUDY:	5077US/0049; "A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression"
STUDY DOCTOR:	Richard H. Weisler, M.D.
ADDRESS OF STUDY SITE:	2841 Plaza Place, Suite 100 Raleigh, NC 27612
TELEPHONE NUMBERS, DAYTIME & AFTER HOURS:	919-872-5900

Introduction

You have been asked to participate in a clinical research study. For you to be able to decide to be part of this study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. Once you understand the study, you will be asked to sign this form if you wish to participate. If you are in any other research study, you cannot take part in this study.

Your healthcare provider may be a doctor for this research project, and as a doctor, if you choose to be a subject in the study, is interested both in your clinical welfare (safety and health) and in the conduct of this study. The doctor is being paid by AstraZeneca to conduct this study. Before entering this study or at any time during the study, you may ask for a second opinion about your care from another doctor who is in no way associated with this study. You are not under any obligation to participate in a research project offered by your doctor nor will your treatment be affected by not participating. At any time during the study you may decide you no longer want to participate in this study; in other words, you may say "no".

If you are not completely truthful with the study doctor and study staff regarding your health history, you may harm yourself by participating in this study.

Read this information carefully and please ask any questions to the study doctor or the study staff.

Purpose of the Research Study

You have been asked to participate in this research study because you have been diagnosed with bipolar disorder and are currently having a depressive episode (feeling depressed). This research study is designed to determine how effective quetiapine (Seroquel™) is compared to placebo (a non-drug tablet, like a sugar pill that will look like quetiapine) for the treatment of your depressive episode. This study will also look at how safe quetiapine is in treating bipolar depression, as well as examine the effects of quetiapine on your overall ability to function and sleep.

Subject Initials: _____

**APPROVED BY
INTEGREVIEW
SEPTEMBER 17, 2002**

There will be approximately 600 patients enrolled from approximately 75 sites.

Quetiapine (Seroquel) is an antipsychotic drug developed by AstraZeneca Pharmaceuticals (AstraZeneca). Seroquel is under investigation for use in treating bipolar disorders, but was approved by the United States Food and Drug Administration (FDA) for the treatment of schizophrenia. "Investigational" means the formulation being tested has not been approved by the United States Food and Drug Administration (FDA) for sale as a prescription or over-the-counter medication. Information from previous studies suggests it has antidepressant actions (the way it works in your body).

What Will Happen During The Study

If you choose to participate in this research study as a subject, you will first undergo several screening procedures that will be done over a period of at least 1 day and possibly a few days. These tests will determine if you are eligible to participate in the study. You will have to stop any medications that you were receiving for your bipolar disease from the time you are screened for the study through the end of the study. As a result of the washout (stopping your medications) your condition may worsen.

Once you have been enrolled in this study you will randomly (like the flip of a coin) be assigned to one of three treatments. The treatment will be either 600 mg of quetiapine per day, 300 mg quetiapine per day, or placebo. Your chance of receiving quetiapine is twice that of placebo, that is, you have a 66% chance of receiving quetiapine and a 33% chance of receiving pills that contain no active drug. Neither you nor your study doctor or research nurse will know if you are taking quetiapine or placebo. Your condition may worsen as a result of receiving either placebo or study drug.

This is an outpatient (not in a hospital) study of 9 weeks duration plus 1 day for final assessments. You will come into the clinic on the first day of each week for assessments and to receive your study drug for the following week.

At your first visit (screening visit), the study doctor will need to see whether you should participate. The study doctor will ask you questions about your medical condition and perform the following tests:

- Your medical history and a physical examination. For your own safety, it is your responsibility to tell the doctor all of your past and present diseases, allergies and medical conditions that you are aware of and all drugs and medications that you currently take.
- Measure your height, weight, blood pressure, and heart rate.
- Take a blood sample (through a needle in a vein) for routine testing of hematology, (red and white blood cells), fasting (no food or drink except water for 12 hours before the blood draw) and clinical chemistry (tests of lipid levels, glucose, insulin and liver and thyroid function).
- If you are a woman, you may also have a blood test for pregnancy; if this test is positive, you will not be able to participate in this study.
- An electrocardiogram (ECG - an electrical tracing of your heart function).
- Three question and answer tests: one to rate your depression, one to see how you sleep, and one to rate the severity of your condition.

You will be asked to stop all of your medications previously used to treat your depressive episode.

If you are determined to be eligible to participate in the study, you will return to the study doctor's office at Visit 2 (anywhere from

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30 days after your first visit), you will be given study drug which will be either quetiapine (Seroquel) or placebo, and the following tests will be done:

- seven evaluations (question and answer) of your mental condition, involuntary limb movements, and how well you sleep during the night
- a repeat ECG and/or blood tests [hematology (red and white blood cells) and fasting clinical chemistry (tests lipid levels, glucose, insulin, liver and thyroid function)] if they were abnormal at screening

At your visit during Weeks 2 through 8 you will also be given these tests:

- six evaluations for your mental condition, overall functioning, and how well you sleep during the night

Additional tests will also be given at Weeks 3, 5, 6, and 8 for limb movements.

On Day 57, the last day of the study, you will be given the following tests:

- physical examination
- routine testing of hematology (red and white blood cells) and fasting clinical chemistry (tests of lipid levels, glucose, insulin, and liver and thyroid function)
- electrocardiogram
- nine evaluations for your mental condition, overall functioning, and limb movements, and how well you sleep during the night

Possible Side Effects and Risks of the Treatment

As a result of stopping the medications you are currently taking, your condition may worsen. Your condition may worsen as a result of taking placebo.

All therapies may cause some side effects or other reactions. You should know about possible risks and discomforts associated with quetiapine (Seroquel) before you decide to participate in this study.

The most common side affects reported in people taking quetiapine (Seroquel) are:

- headache
- sleepiness
- dizziness
- constipation
- dry mouth
- decreased blood pressure on standing (symptoms may be dizziness, fast heart rate, and fainting)
- increased heart rate

A very rare side effect of antipsychotic drugs, including quetiapine (Seroquel), is Neuroleptic Malignant Syndrome. The symptoms are high fever, stiff muscles, fast heart rate, high or low blood pressure, sweating, and possibly kidney failure. Sometimes this illness results in death. Another rare side effect of antipsychotic drugs is a disorder called tardive dyskinesia, which causes uncontrollable body movements such a lip and tongue smacking. Sometimes the movements are permanent.

Some people treated with Seroquel have had mild and temporary increases in liver chemicals (seen in their blood stream).

Animal studies have shown a slight risk of developing cloudiness in the lens but this increased risk has not been seen in patients taking the medication in clinical research studies. Other side effects may occur, some of which are not known and cannot be predicted. With your full cooperation regarding the instructions given by your physician, frequent examination, and the performance of laboratory tests, the chance of these unwanted side effects

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happening can be minimized, or if they happen they can be treated quickly.

In addition to the side effects for the study drug quetiapine (Seroquel), there may be other risks to you that are not known at the present time, including life threatening reactions.

During the screening period, on Day 1 of the study, and upon completion of the study, approximately 2 ½ tablespoons (36 ml) of blood (38 ml for women) will be drawn from a vein in your arm using standard medical procedures. The risks of venipuncture (inserting a needle in your vein to take blood) include the occurrence of discomfort and/or bruising at the site of the puncture and, less commonly, fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, or bleeding from the puncture site. There also could be infection at the site.

If you are not completely truthful with the study doctor and study staff regarding any side effects, you may harm yourself by participating in this study.

New Findings

You will be informed of any new information about the study drug that becomes known during the course of this study, which might affect your willingness to continue participation.

Women of Childbearing Potential

There might be unknown risks to an unborn child or breast-fed child if you are or if you become pregnant during the study.

Due to these risks, you must not participate in this study if you are pregnant or plan to become pregnant during the research study period, or are breast-feeding a child.

If you are a woman of child-bearing potential:

- By signing this consent form, you confirm to the best of your knowledge that you are not pregnant now and you do not intend to become pregnant during this study.
- A pregnancy test will be done to confirm that you are not pregnant before your participation in this study.

If you are a sexually active female of childbearing potential, you need to be using a reliable method of contraception. Reliable methods include:

- oral contraceptive
- long-term injectable or implantable hormonal contraceptive
- condom and diaphragm
- condom and foam
- condom and sponge
- intrauterine device (IUD)
- tubal ligation

If at any time during this study you think you might be pregnant, or later learn that you were pregnant during the study, you must contact the study doctor immediately for further instructions regarding your participation in this study and follow up.

Possible Benefits of the Study

You will not experience any direct health benefits during or following completion of this study. However, your participation will provide information about the study treatment(s) and bipolar depression that may benefit others.

Alternatives to Participating in this Study

Although there are approved treatments for mania alone (eg: lithium, valproic acid) and depression alone (SSRIs), there are no approved medications for depression associated with bipolar disorder.

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Payment for Injury Related to the Study

If you experience any side effect or injury, notify your study doctor immediately so that you can receive appropriate medical treatment.

If you suffer any side effect or other physical injury resulting directly from the research study drug, AstraZeneca will provide reimbursement for the reasonable costs of medical treatment if:

- You took the study drug as instructed by your study doctor
- Your injury was not deliberately caused
- The study doctor was immediately notified about your injury
- You followed the medical advice of the study doctor

You will not be reimbursed for lost wages or other damages or losses or for medical expenses that have been covered by your medical or hospital insurance or by third party or governmental programs providing such coverage. No other form of compensation is offered from AstraZeneca except remedies available under the law. Compensation for medical expenses is not an admission of fault or liability by AstraZeneca or anyone else.

Legal Rights

You will not lose any of your legal rights as a research subject by signing this consent form.

Additional Costs

The study drug, study doctor's visits, and laboratory tests related to this study will be provided at no cost to you. Neither your insurance company nor you will be charged for the services provided in the normal course of the conduct of this study.

Your Participation in the Study

Your participation in this study is entirely voluntary. You cannot be forced to be in this study. You may not want to be in this study or you may leave the study at any time without punishment or loss of benefits to which you are entitled and without affecting your future medical care. The study doctor, the Drug Company, IntegReview, or the FDA may take you out of the study without your permission at any time for the following reasons:

- if you do not follow the instructions of the study doctor
- if it is discovered that you do not meet the study requirements
- if the study is cancelled
- if it appears to be medically harmful to you

If you leave the study or if you are taken out of the study for any reason, you may be asked to return to the study doctor's office for a final visit. This is to make sure that you are in good health.

You must return all unused study drug and the containers to your study doctor.

Payment for Participation

You will not be paid for your participation in this study.

Release Of Your Medical Records And Privacy (Confidentiality)

All study data will be kept confidential; however, authorized personnel from AstraZeneca, its representatives, the FDA, other Department of Health and Human Services agencies, government agencies in other countries, and IntegReview, the Institutional Review Board (IRB) may have access to the data. The data and results from this study may

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also be presented at meetings or in publications, but in those presentations study participants will not be identified by name.

Whom To Contact

For answers to questions about this research or to report a research related injury, contact:

Richard H. Weisler, M.D.
919-872-5900 daytime and after hours

To protect the rights and safety of subjects involved in research projects the FDA requires approval of this Informed Consent document by an Institutional Review Board (IRB). This means the IRB has approved the information provided in the Informed Consent for use when enrolling subjects into this study. IntegReview Ethical Review Board has approved this research study and informed consent document. IntegReview is a group of scientific and non-scientific people that review research studies. Ethical review boards must follow the Food and Drug Administration (FDA) rules regarding the protection of the rights and welfare of human subjects involved in medical research studies. Questions about your rights as a study subject may be addressed to:

Chairperson
IntegReview
1825 Fortview Road, Suite 110
Austin, Texas 78704
512-326-3001 between 8 a.m. and 5 p.m.
Central Time (call collect)
integreview@integreview.com

New Findings

You will be told about any significant new findings about the study drug. This information can help you decide if you wish to continue your participation in the study.

Experimental Subject's Bill of Rights

As a subject involved in an investigational drug study, you have the following rights.

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risk reasonably to be expressed from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time. The subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any

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element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

The Reason for Institutional Review Boards and Informed Consent

What is a consent form?
The Informed Consent document contains the required information as found in and required by the United States regulations regarding the protection of human subjects (Code of Federal Regulations, Title 21, Part 50-Protection of Human Subjects). As required by this regulation, the informed consent must be reviewed and approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is any board, committee or other group which reviews, approves, and does continuing review of biomedical research involving human subjects. The primary purpose of such review is to guarantee the protection of the rights and welfare of the human subjects.

IRBs were established as the result of unfair treatment of human subjects. Prior to this, other committees existed as a requirement of the United States Public Health Service (USPHS) policy established in 1965. IRBs are regulated by the Food and Drug Administration and the National Institutes of Health (NIH).

What does an IRB mean to me?
The purpose of the IRB is to inform and protect human subjects through the information provided in the informed consent document. Therefore, the IRB is acting as a supporter for the research subject. This means that the IRB, during its review of the informed consent document, has the right and responsibility to ensure that the research subject is fully informed of the procedures involved in the study as well as the risks and other treatments that are available if participation in the study is refused.

How can I tell that an IRB has reviewed and approved this study?
The date that IntegReview approved the study design as well as the information in this Informed Consent document is printed on the top of each page of this Informed Consent form. **THIS DOES NOT MEAN THE IRB HAS APPROVED YOUR PARTICIPATION IN THE STUDY.** It is a FDA requirement that the study design (Protocol), Informed Consent form, any advertising materials, and other instructions to the subject (Subject Instructions, Patient Diaries, etc.) be reviewed and approved by an IRB. Although IRB approval is granted for the study doctor to conduct the study, you must evaluate the information in this Informed Consent form for yourself and decide whether or not you wish to participate.

IntegReview, the IRB for this study
IntegReview is an independent IRB whose board members are individuals who work in the Austin community. IntegReview provides services nation-wide to research professionals.

FDA regulations require that the committee have at least five members with varying backgrounds to provide complete and adequate review of research activities.

To fulfill these requirements the IntegReview Board currently includes physicians, pharmacists, Ph.Ds., a toxicologist (someone who studies the harmful effects of chemicals), a psychologist, an oral surgeon, and lay members (non-scientific).

The telephone number of the Chair is available in every informed consent document in the contacts section. You may contact the Chair with concerns regarding your rights as a subject.

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Agreement to Be in the Study

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

A. Do you understand the information in this consent form? _____

B. Have you been able to ask questions and talk about the study? _____

C. Have all of your questions been answered to your satisfaction? _____

D. Do you think you received enough information about the study? _____

E. Do you understand that you can leave the study at any time without giving a reason and without affecting your medical care? _____

F. Do you understand that your medical records from this study may be reviewed by the Drug Company and by government authorities? _____

If you answered NO to any of these six questions, you should not sign this consent form.

When you sign this consent form you agree that:

- you have had a chance to ask questions
- you understand English
- you want to be in the study

You will not lose any of your legal rights by signing this consent form.

_____

Signature of Study Subject or Legally Authorized Representative Date (Month/Day/Year)
DO NOT SIGN AFTER SEPTEMBER 10, 2003

_____

Printed Name of Study Subject

_____

Signature of Person Explaining Informed Consent Date (Month/Day/Year)

You will be given a copy of this informed consent to keep.

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THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

mdc/master: 9-10-02 dao/site: 9-17-02
\\ntserver\group\current ic's\astrazeneca\5077us-0049\Weisler.doc

STUDY PARTICIPANT SURVEY
(OPTIONAL)
INFORMED CONSENT DOCUMENT AND PROCESS

As mentioned in the informed consent document, IntegReview is an ethical review board responsible for ensuring the safety and welfare of subjects involved in medical and biomedical research. We spend a great deal of time reviewing the informed consent document to make sure you are given enough information to make an informed decision whether or not you wish to participate in the study. In addition, we want to be sure the document is easy to read and understand.

You can assist us in this process by providing feedback regarding your experience as a research study subject. The following questions are designed to let our board members know how to improve the informed consent documents.

Please provide as much information as you feel is necessary. *This information will be kept confidential by IntegReview.* ***You may use additional pages if needed.***

1. Your age: _____

2. Highest level of education completed: _____

3. Two column format of informed consent document: ☐ Easier to read than one column

   ☐ More difficult to read than one column ☐ No difference between one or two column format

4. Words/phrases were understood: ☐ Yes ☐ No

What words/phrases did you **not** understand? _____

5. Did the study doctor or one of the staff explain what you did not understand? ☐ Yes ☐ No

6. Overall ease of reading informed consent document: ☐ Excellent ☐ Good ☐ Satisfactory ☐ Poor

7. Were you offered/allowed to take the informed consent document home to read and/or discuss with family members/friends? ☐ Yes ☐ No

8. If no, would you have preferred the option? ☐ Yes ☐ No

9. Did the study doctor or one of the study staff read the informed consent to you? ☐ Yes ☐ No

10. Did you feel you had enough time to read the informed consent before you were asked to make a decision? ☐ Yes ☐ No

11. Did you feel comfortable asking questions after you read the informed consent document? ☐ Yes ☐ No

12. Was there information not in the document that you feel should have been included? ☐ Yes ☐ No
If so, please explain: _____

What suggestions do you have for IntegReview that would improve the informed consent document and the process of obtaining informed consent? _____

PLEASE RETURN TO INTEGREVIEW
1825 FORTVIEW ROAD, SUITE 110
AUSTIN, TX 78704
512-326-3446 FAX
OR COMPLETE THE FORM ONLINE BY VISITING WWW.INTEGREVIEW.COM AND CLICKING ON THE "SUBJECT FEEDBACK" BUTTON

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INFORMED CONSENT
AGREEMENT TO BE IN A RESEARCH STUDY AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

NAME OF DRUG/DEVICE COMPANY:	AstraZeneca Pharmaceuticals LP
CITY AND STATE:	Wilmington, DE
NUMBER AND NAME OF STUDY:	5077US/0049; "A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression"
STUDY DOCTOR:	Richard H. Weisler, M.D.
ADDRESS OF STUDY SITE:	700 Spring Forest Road, Suite 125 Raleigh, NC 27609
TELEPHONE NUMBERS, DAYTIME & AFTER HOURS:	919-872-5900

Introduction

You have been asked to participate in a clinical research study. For you to be able to decide to be part of this study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form will also explain how your medical information will be used and who may see it. Once you understand the study, you will be asked to sign this form if you wish to participate and to allow your medical information to be collected, used and shared with certain persons involved in the study. If you are in any other research study, you cannot take part in this study.

Your healthcare provider may be an investigator (or your study doctor) for this research project, and as an investigator he/she is interested both in your clinical welfare (safety and health) and in the conduct of this study. Your study doctor is being paid by AstraZeneca to conduct this study. Before entering this study or at any time during the study, you may ask for a second opinion about your care from another doctor who is in no way associated with this study. You are not under any obligation to participate in a research project offered by your doctor nor will your treatment be affected by not participating. At any time during the study you may decide you no longer want to participate in this study; in other words, you may say "no".

If you are not completely truthful with the study doctor and study staff regarding your health history, you may harm yourself by participating in this study.

Read this information carefully and please ask any questions to the study doctor or the study staff.

Purpose of the Research Study

You have been asked to participate in this research study because you have been diagnosed with bipolar disorder and are currently having a depressive episode (feeling depressed). This research study is designed to determine how effective quetiapine (Seroquel™) is compared to placebo (a non-drug tablet, like a sugar pill that

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will look like quetiapine) for the treatment of your depressive episode. This study will also look at how safe quetiapine is in treating bipolar depression, as well as examine the effects of quetiapine on your overall ability to function and sleep.

There will be approximately 740 patients screened to obtain 530 enrolled patients from approximately 75 sites.

Seroquel™ was approved by the United States Food and Drug Administration (FDA) in 1997 for the treatment of schizophrenia. For the purposes of this study, it is being tested for the treatment of depressive episodes related to bipolar disorder. Therefore, it is an 'investigational product'. 'Investigational' means the formulation and/or indication being tested has not been approved by the United States Food and Drug Administration (FDA) for sale as prescription and/or over-the-counter medication. However, information from previous studies suggests it has antidepressant actions (the way it works in your body).

For the purpose of this study, the medication you may receive is an investigational product. Investigational products are similar to controlled substances, in that, if prescribed, they should not be distributed to others. In addition, if you decide you would like to stop taking the medication, you will be asked to return all unused investigational product.

What Will Happen During The Study

This is an outpatient (not in the hospital) study. It consists of a screening phase that lasts from 7 up to 28 days, depending on your current medication, followed by an eight week treatment phase.

If you decide to participate in this research study as a subject, you will first undergo a series of screening procedures that will be done over a period of at least 1 day. These procedures will determine if you are eligible to participate in the study.

The screening phase of this study starts once you have signed this consent form. The screening phase consists of a series of routine tests and psychiatric assessments. As a result of conducting these tests and assessments, your study doctor may determine you should not participate. In this case, you will be provided with other options for the treatment of your condition. For your own safety, it is your responsibility to tell the doctor all of your past and present diseases, allergies, medical conditions (that you are aware of), and all drugs (including non-prescribed drugs) that you are currently taking.

The screening phase entails the following psychiatric and other medical assessments:

- A thorough interview, inquiring about your current and past mental/medical conditions. This will help your doctor determine your correct diagnosis.
- Two additional, question and answer, assessments that will rate the severity of your depression and to check for possible symptoms of mania.
- A complete medical history review, including diseases or conditions that may be unrelated to your bipolar disorder.
- A physical exam, including an eye exam. If you have a history of cataracts, you should inform your study doctor.
- Measurement of your height, weight, blood pressure and heart rate.
- Collection of a blood sample (through a needle in a vein) for routine testing of hematology (red and white blood cells), fasting (no food or drink except water for 12 hours before the blood draw) clinical chemistry (tests of lipid levels, glucose, insulin, creatinine, and liver and thyroid function).

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- If you are a woman, you will also have a blood test for pregnancy; if this test is positive, you will not be able to participate in this study.
- An electrocardiogram (ECG – an electrical tracing of your heart function).
- Collection of a urine sample in order to test for illicit substances of abuse. The results of this test will be kept confidential. It is a required test in order to ensure your safety and cannot be used against you in a court of law. If you have used an illicit substance of abuse, you should inform your study doctor. If you have any issues with this test being performed, discuss them with your study doctor prior to deciding to participate in this study. Illicit substance use is not permitted in this study.
- You will be asked to stop all of your medications currently used to treat your depressive episode and/or your bipolar disorder. You will be required to not use these medications from the time you are screened for the study throughout your participation. Your study doctor will instruct you in discontinuing the use of your current medications in order to ensure your safety. If you notice a worsening in your symptoms during this period, contact your study doctor immediately.
- If abnormal results are reported from the ECG, labs or urine sample, you may be asked to return to the office for a retest. Any abnormal results reported to your study doctor will be discussed with you in order for you to obtain the proper follow-up.

Once the initial screening phase is complete and your study doctor has determined you are eligible to proceed in the study, you will return to your study doctor's office for Visit 2. This will occur anywhere from 7-28 days after your first visit. At Visit 2, the final screening will occur and your study doctor will assess whether you will be able to participate in the study.

The final screening assessment consists of the following:

- Your study doctor will repeat the same two, question and answer, assessments which rate the severity of your depression and to check for possible symptoms of mania, that were conducted at your initial screening visit.

Once these assessments are complete and your study doctor has determined you are eligible to participate, you will be randomly (like the flip of a coin) assigned to one of the three treatments. The treatments will be either 600 mg of quetiapine per day, 300 mg of quetiapine per day, or placebo. Your chance of receiving quetiapine is twice that of placebo, that is, you have a 66% chance of receiving quetiapine and a 33% chance of receiving pills that contain no active drug. Neither you nor your study doctor or research nurse will know if you are taking quetiapine or placebo. Your condition may worsen as a result of receiving either placebo or study drug.

In addition to being randomized to treatment, the following psychiatric and medical assessments will be conducted at Visit 2:

- Six evaluations (question and answer) of your mental condition, involuntary limb movements, how well you sleep at night and your quality of life will be conducted. The sleep assessment is a self-assessment questionnaire, which means you will complete it on your own.
- Your blood pressure and heart rate will be recorded.

You will then be asked to come back to your study doctor's office on a weekly basis for the course of 8 weeks. Study medication is dispensed at each study visit during the treatment phase.

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Visits 3 through 10 will consist of the following:

- The same two, question and answer, assessments which rate the severity of your depression and possible symptoms of mania will be conducted at each study visit. In addition, another depression assessment will be conducted along with an anxiety assessment.
- Your blood pressure and heart rate will be recorded.

In addition to the above assessments, the assessments of your sleep and quality of life will be conducted again at Visit 6.

At your final visit, Visit 10, the following psychiatric and medical assessments will be conducted:

- Physical Exam
- Testing of hematology (red and white blood cells) and fasting clinical chemistry (tests of lipid levels, glucose, insulin, creatinine, liver and thyroid function).
- Electrocardiogram (ECG)
- Weight, blood pressure and heart rate
- A final evaluation of all the psychiatric assessments, including sleep assessment, will be conducted at this visit.

If you decide, at any point during the treatment phase of the study, that you no longer want to participate, or if you are taken out of the study, you will be asked to return to your study doctor's office for a final visit. This is to make sure you are in good health and you have not experienced any negative health effects as a result of your study participation.

Possible Side Effects and Risks of the Treatment

As a result of stopping the medications you are currently taking, your condition may worsen. Your condition may worsen as a result of taking placebo.

All therapies may cause some side effects or other reactions. You should know about possible risks and discomforts associated with quetiapine (Seroquel™) before you decide to participate in this study.

The most common side affects reported in people taking quetiapine (Seroquel™) are:

- headache
- sleepiness
- dizziness
- constipation
- dry mouth
- decreased blood pressure on standing (symptoms may be dizziness, fast heart rate, and fainting)
- increased heart rate

A very rare side effect of antipsychotic drugs, including quetiapine (Seroquel™), is Neuroleptic Malignant Syndrome. The symptoms are high fever, stiff muscles, fast heart rate, high or low blood pressure, sweating, and possibly kidney failure. Sometimes this illness results in death. Another rare side effect of antipsychotic drugs is a disorder called tardive dyskinesia, which causes uncontrollable body movements such a lip and tongue smacking. Sometimes the movements are permanent.

Some people treated with Seroquel™ have had mild and temporary increases in liver chemicals (seen in their blood stream).

Animal studies have shown a slight risk of developing cloudiness in the lens of the eye, but this increased risk has not been seen in patients taking the medication in clinical research studies. Other side effects may occur, some of which are not known and cannot be predicted. With your full cooperation regarding the

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instructions given by your physician, frequent examination and the performance of laboratory tests, if these unwanted side effects happen, they can be treated quickly and the potential for your discomfort can be minimized.

In addition to the side effects for the study drug quetiapine (Seroquel™), there may be other risks to you that are not known at the present time.

During the screening period, and upon completion of the study, approximately 2 ½ tablespoons (36 ml) of blood (38 ml for women) will be drawn from a vein in your arm using standard medical procedures. The risks of venipuncture (inserting a needle in your vein to take blood) include the occurrence of discomfort and/or bruising at the site of the puncture and, less commonly, fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, or bleeding from the puncture site. There also could be infection at the site.

If you are not completely truthful with the study doctor and study staff regarding any side effects, you may harm yourself by participating in this study.

New Findings

You will be informed of any new information about the study drug that becomes known during the course of this study, which might affect your willingness to continue participation.

Women of Childbearing Potential

There might be unknown risks to an unborn child or breast-fed child if you are or if you become pregnant during the study.

Due to these risks, you must not participate in this study if you are pregnant or plan to become pregnant during the research study period, or are breast-feeding a child.

If you are a woman of child-bearing potential:

- By signing this consent form, you confirm to the best of your knowledge that you are not pregnant now and you do not intend to become pregnant during this study.
- A pregnancy test will be done to confirm that you are not pregnant before your participation in this study.

If you are a female of childbearing potential, you need to be using a reliable method of contraception. Reliable methods include:

- oral contraceptive
- long-term injectable or implantable hormonal contraceptive
- condom and diaphragm
- condom and foam
- condom and sponge
- intrauterine device (IUD)
- tubal ligation

If at any time during this study you think you might be pregnant, or later learn that you were pregnant during the study, you must contact the study doctor immediately for further instructions regarding your participation in this study and follow up.

Possible Benefits of the Study

You will not experience any direct health benefits during or following completion of this study. However, your participation will provide information about the study treatment(s) and bipolar depression that may benefit others.

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Alternatives to Participating in this Study

Although there are approved treatments for mania alone (eg: lithium, valproic acid) and depression alone (SSRIs), there are no approved medications for depression associated with bipolar disorder.

Payment for Injury Related to the Study

If you experience any side effect or injury, notify your study doctor immediately so that you can receive appropriate medical treatment.

If you suffer any side effect or other physical injury resulting directly from the research study drug, AstraZeneca will provide reimbursement for the reasonable costs of medical treatment if:

- You took the study drug as instructed by your study doctor
- Your injury was not deliberately caused
- The study doctor was immediately notified about your injury
- You followed the medical advice of the study doctor

You will not be reimbursed for lost wages or other damages or losses or for medical expenses that have been covered by your medical or hospital insurance or by third party or governmental programs providing such coverage. No other form of compensation is offered from AstraZeneca except remedies available under the law. Compensation for medical expenses is not an admission of fault or liability by AstraZeneca or anyone else.

Legal Rights

You will not lose any of your legal rights as a research subject by signing this consent form.

Additional Costs

The study drug, study doctor's visits, and laboratory tests related to this study will be provided at no cost to you. Neither your insurance company nor you will be charged for the services provided in the normal course of the conduct of this study.

Your Participation in the Study

Your participation in this study is entirely voluntary. You cannot be forced to be in this study. You may not want to be in this study or you may leave the study at any time without punishment or loss of benefits to which you are entitled and without affecting your future medical care. The study doctor, the Drug Company, IntegReview, or the FDA may take you out of the study without your permission at any time for the following reasons:

- if you do not follow the instructions of the study doctor
- if it is discovered that you do not meet the study requirements
- if the study is cancelled
- if it appears to be medically harmful to you

If you leave the study or if you are taken out of the study for any reason, you will be asked to return to the study doctor's office for a final visit. This is to make sure that you are in good health.

You must return all unused study drug and the containers to your study doctor.

Payment for Participation

You will not be paid for your participation in this study.

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Confidentiality And Authorization To Collect, Use And Disclose Your Medical Information

The following sections explain how your medical information will be collected, used and shared with certain other persons involved in the study and describes your rights, including the right to see your medical information.

Purpose Of This Authorization

You are being asked to permit the collection, use and sharing of your medical information so that the safety and effectiveness of the study drug can be evaluated as described on page 2 ("Purpose of the Research Study").

What Does Medical Information Mean?

Your medical information is information about your physical or mental health or condition. It includes your previous medical records and information about you created or collected during the study (for example, the dates or results of various tests or examinations). This information may identify you because it may contain, for example, your name, address, telephone number, photograph, date of birth, social security number, race or ethnic origin or other unique identifiers.

Use And Disclosure Of Your Medical Information

If you sign this form, you allow the study doctor to collect and use your medical information to carry out this study. You also allow the study doctor to share your medical information with:

- the study sponsor, including its affiliates, its representatives and its contractors who work on behalf of the study sponsor to conduct the study
- other doctors and health care professionals who are involved in the study
- the Institutional Review Board (IRB) that watches over the study; and
- government agencies overseeing this study or the study drug, including the Food and Drug Administration (FDA), other Department of Health and Human Services agencies, and government agencies in the United States and other countries.

Will Persons Looking At Your Medical Information Be Able To Identify You?

That part of your medical information sent by the study doctor to the study sponsor ("study data") usually does not identify you personally (for example, by name, address, or social security number). Instead, the study doctor will use your initials, date of birth and an assigned code number on the study data sent to the study sponsor. However, the study sponsor, its representatives and contractors, regulatory authorities and other supervising bodies may look at all your medical information at the study doctor's site. The reason these persons may look at your medical information is to make sure the study has been done properly and that study data has been collected correctly, or for other reasons allowed by law.

Notice On Re-disclosure Of Your Medical Information And Confidentiality

Federal law provides that the study doctor can only share your medical information with those persons whom you have permitted to see it. However, if you sign this form, those persons may share your medical information with other persons. Federal law does not protect you against this. (The laws of your state may provide additional privacy protection.)

Publication Of Study Results

Except as explained above, your medical information will be kept confidential. The data and results from this study may also be

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presented at meetings or in publications, but in those presentations people taking part in the study will not be identified by name.

Your Right To See And/Or Copy Your Medical Information

You have the right to see and copy your medical information related to the study for as long as the study doctor holds this information. However, you may not be able to see some of your records related to the study until after the study has been completed, otherwise it could spoil the study.

Withdrawing Your Authorization

You may withdraw your Authorization (permission) regarding your medical information at any time by writing to the study doctor at the following address: 700 Spring Forest Road, Suite 125, Raleigh, NC 27609. If you withdraw this Authorization, the study doctor will no longer use your medical information or share it with others under the Authorization for this study, unless the study doctor needs to do so to protect the study data. However, the study sponsor may still use information about you that was shared with the study sponsor before you withdrew your Authorization. If you withdraw your Authorization, you cannot continue to take part in the study.

Expiration Of Your Authorization

Your Authorization does not have an expiration date.

Whom To Contact

For answers to questions about this research or to report a research related injury, contact:

Richard H. Weisler, M.D.
919-872-5900 daytime and after hours

To protect the rights and safety of subjects involved in research projects the FDA requires approval of this Informed Consent document by an Institutional Review Board (IRB). This means the IRB has approved the information provided in the Informed Consent for use when enrolling subjects into this study. IntegReview Ethical Review Board has approved this research study and informed consent document. IntegReview is a group of scientific and non-scientific people that review research studies. Ethical review boards must follow the Food and Drug Administration (FDA) rules regarding the protection of the rights and welfare of human subjects involved in medical research studies. Questions about your rights as a study subject may be addressed to:

Chairperson
IntegReview
1825 Fortview Road, Suite 110
Austin, Texas 78704
512-326-3001 between 8 a.m. and 5 p.m.
Central Time (call collect)
integreview@integreview.com

Experimental Subject's Bill of Rights

As a subject involved in an investigational drug study, you have the following rights.

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risk reasonably to be expressed from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

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5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time. The subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

The Reason for Institutional Review Boards and Informed Consent

What is a consent form?
The Informed Consent document contains the required information as found in and required by the United States regulations regarding the protection of human subjects (Code of Federal Regulations, Title 21, Part 50-Protection of Human Subjects). As required by this regulation, the informed consent must be reviewed and approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is any board, committee or other group which reviews, approves, and does continuing review of biomedical research involving human subjects. The primary purpose of such review is to guarantee the protection of the rights and welfare of the human subjects.

IRBs were established as the result of unfair treatment of human subjects. Prior to this, other committees existed as a requirement of the United States Public Health Service (USPHS) policy established in 1965. IRBs are regulated by the Food and Drug Administration and the National Institutes of Health (NIH).

What does an IRB mean to me?
The purpose of the IRB is to inform and protect human subjects through the information provided in the informed consent document. Therefore, the IRB is acting as a supporter for the research subject. This means that the IRB, during its review of the informed consent document, has the right and responsibility to ensure that the research subject is fully informed of the procedures involved in the study as well as the risks and other treatments that are available if participation in the study is refused.

How can I tell that an IRB has reviewed and approved this study?
The date that IntegReview approved the study design as well as the information in this Informed Consent document is printed on the top of each page of this Informed Consent form. **THIS DOES NOT MEAN THE IRB HAS APPROVED YOUR PARTICIPATION IN THE STUDY.** It is a FDA requirement that the study design (Protocol), Informed Consent form, any advertising materials, and other instructions to the subject (Subject Instructions, Patient Diaries, etc.) be reviewed and approved by an IRB. Although IRB approval is granted for the study doctor to conduct the study, you must evaluate the information in this Informed

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Consent form for yourself and decide whether or not you wish to participate.

IntegReview, the IRB for this study
IntegReview is an independent IRB whose board members are individuals who work in the Austin community. IntegReview provides services nation-wide to research professionals.

FDA regulations require that the committee have at least five members with varying backgrounds to provide complete and adequate review of research activities.

To fulfill these requirements the IntegReview Board currently includes physicians, pharmacists, Ph.Ds., a toxicologist (someone who studies the harmful effects of chemicals), a psychologist, an oral surgeon, and lay members (non-scientific).

The telephone number of the Chair is available in every informed consent document in the contacts section. You may contact the Chair with concerns regarding your rights as a subject.

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Agreement to Be in the Study

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

A. Do you understand the information in this consent form? _____

B. Have you been able to ask questions and talk about the study? _____

C. Have all of your questions been answered to your satisfaction? _____

D. Do you think you received enough information about the study? _____

E. Do you understand that you can leave the study at any time without giving a reason and without affecting your medical care? _____

F. Do you understand that your medical records from this study may be reviewed by the Drug Company and by government authorities? _____

If you answered NO to any of these six questions, you should not sign this consent form.

When you sign this consent form you agree that:

- you have had a chance to ask questions
- you understand English
- you want to be in the study

You will not lose any of your legal rights by signing this consent form.

_____

Signature of Study Subject or Legally Authorized Representative — Date (Month/Day/Year)

DO NOT SIGN AFTER SEPTEMBER 10, 2003

_____

Printed Name of Study Subject

_____

Signature of Person Explaining Informed Consent — Date (Month/Day/Year)

You will be given a copy of this informed consent to keep.

Subject Initials: _____

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

mdc/master: 9-10-02 dao/site: 9-17-02 ac/site: 10-2-02 rtg/master: 10-8-02 lma/master: 1-14-03 dao/master: 3-21-03
\\ntserver\group\current ic's\AstraZeneca\5077US-0049\Weisler.doc

STUDY PARTICIPANT SURVEY
(OPTIONAL)
INFORMED CONSENT DOCUMENT AND PROCESS

As mentioned in the informed consent document, IntegReview is an ethical review board responsible for ensuring the safety and welfare of subjects involved in medical and biomedical research. We spend a great deal of time reviewing the informed consent document to make sure you are given enough information to make an informed decision whether or not you wish to participate in the study. In addition, we want to be sure the document is easy to read and understand.

You can assist us in this process by providing feedback regarding your experience as a research study subject. The following questions are designed to let our board members know how to improve the informed consent documents.

Please provide as much information as you feel is necessary. *This information will be kept confidential by IntegReview.* ***You may use additional pages if needed.***

1. Your age: _____

2. Highest level of education completed: _____

3. Two column format of informed consent document: ☐ Easier to read than one column

   ☐ More difficult to read than one column ☐ No difference between one or two column format

4. Words/phrases were understood: ☐ Yes ☐ No

What words/phrases did you **not** understand? _____
_____
_____
_____

5. Did the study doctor or one of the staff explain what you did not understand? ☐ Yes ☐ No

6. Overall ease of reading informed consent document: ☐ Excellent ☐ Good ☐ Satisfactory ☐ Poor

7. Were you offered/allowed to take the informed consent document home to read and/or discuss with family members/friends? ☐ Yes ☐ No

8. If no, would you have preferred the option? ☐ Yes ☐ No

9. Did the study doctor or one of the study staff read the informed consent to you? ☐ Yes ☐ No

10. Did you feel you had enough time to read the informed consent before you were asked to make a decision? ☐ Yes ☐ No

11. Did you feel comfortable asking questions after you read the informed consent document? ☐ Yes ☐ No

12. Was there information not in the document that you feel should have been included? ☐ Yes ☐ No
If so, please explain: _____
_____
_____
_____

What suggestions do you have for IntegReview that would improve the informed consent document and the process of obtaining informed consent? _____
_____
_____

PLEASE RETURN TO INTEGREVIEW
1825 FORTVIEW ROAD, SUITE 110
AUSTIN, TX 78704
512-326-3446 FAX
OR COMPLETE THE FORM ONLINE BY VISITING WWW.INTEGREVIEW.COM AND CLICKING ON THE "SUBJECT FEEDBACK" BUTTON

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INFORMED CONSENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF DRUG/DEVICE COMPANY:	AstraZeneca Pharmaceuticals LP
CITY AND STATE:	Wilmington, DE
NUMBER AND NAME OF STUDY:	5077US/0049; "A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression"
STUDY DOCTOR:	Janice Miller, M.D.
ADDRESS OF STUDY SITE:	Clinical Neuroscience Solutions, Inc. 5601 Corporate Way, Bldg. 2, Suite # 210 West Palm Beach, FL 33407
TELEPHONE NUMBERS, DAYTIME & AFTER HOURS:	561-616-9595

Introduction

You have been asked to participate in a clinical research study. For you to be able to decide to be part of this study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. Once you understand the study, you will be asked to sign this form if you wish to participate. If you are in any other research study, you cannot take part in this study.

Your healthcare provider may be an investigator (or your study doctor) for this research project, and as an investigator he/she is interested both in your clinical welfare (safety and health) and in the conduct of this study. Your study doctor is being paid by AstraZeneca to conduct this study. Before entering this study or at any time during the study, you may ask for a second opinion about your care from another doctor who is in no way associated with this study. You are not under any obligation to participate in a research project offered by your doctor nor will your treatment be affected by not participating. At any time during the study you may decide you no longer want to participate in this study; in other words, you may say "no".

If you are not completely truthful with the study doctor and study staff regarding your health history, you may harm yourself by participating in this study.

Read this information carefully and please ask any questions to the study doctor or the study staff.

Purpose of the Research Study

You have been asked to participate in this research study because you have been diagnosed with bipolar disorder and are currently having a depressive episode (feeling depressed). This research study is designed to determine how effective quetiapine (Seroquel™) is compared to placebo (a non-drug tablet, like a sugar pill that will look like quetiapine) for the treatment of your depressive episode. This study will also look at how safe quetiapine is in treating bipolar depression, as well as examine the effects of

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quetiapine on your overall ability to function and sleep.

There will be approximately 740 patients screened to obtain 530 enrolled patients from approximately 75 sites.

Seroquel™ was approved by the United States Food and Drug Administration (FDA) in 1997 for the treatment of schizophrenia. For the purposes of this study, it is being tested for the treatment of depressive episodes related to bipolar disorder. Therefore, it is an 'investigational product'. 'Investigational' means the formulation and/or indication being tested has not been approved by the United States Food and Drug Administration (FDA) for sale as prescription and/or over-the-counter medication. However, information from previous studies suggests it has antidepressant actions (the way it works in your body).

For the purpose of this study, the medication you may receive is an investigational product. Investigational products are similar to controlled substances, in that, if prescribed, they should not be distributed to others. In addition, if you decide you would like to stop taking the medication, you will be asked to return all unused investigational product.

What Will Happen During The Study

This is an outpatient (not in the hospital) study. It consists of a screening phase that lasts from 7 up to 28 days, depending on your current medication, followed by an eight week treatment phase.

If you decide to participate in this research study as a subject, you will first undergo a series of screening procedures that will be done over a period of at least 1 day. These procedures will determine if you are eligible to participate in the study.

The screening phase of this study starts once you have signed this consent form. The screening phase consists of a series of routine tests and psychiatric assessments. As a result of conducting these tests and assessments, your study doctor may determine you should not participate. In this case, you will be provided with other options for the treatment of your condition. For your own safety, it is your responsibility to tell the doctor all of your past and present diseases, allergies, medical conditions (that you are aware of), and all drugs (including non-prescribed drugs) that you are currently taking.

The screening phase entails the following psychiatric and other medical assessments:

- A thorough interview, inquiring about your current and past mental/medical conditions. This will help your doctor determine your correct diagnosis.
- Two additional, question and answer, assessments that will rate the severity of your depression and to check for possible symptoms of mania.
- A complete medical history review, including diseases or conditions that may be unrelated to your bipolar disorder.
- A physical exam, including an eye exam. If you have a history of cataracts, you should inform your study doctor.
- Measurement of your height, weight, blood pressure and heart rate.
- Collection of a blood sample (through a needle in a vein) for routine testing of hematology (red and white blood cells), fasting (no food or drink except water for 12 hours before the blood draw) clinical chemistry (tests of lipid levels, glucose, insulin, creatinine, and liver and thyroid function).
- If you are a woman, you will also have a blood test for pregnancy; if this test is positive, you will not be able to participate in this study.

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- An electrocardiogram (ECG – an electrical tracing of your heart function).
- Collection of a urine sample in order to test for illicit substances of abuse. The results of this test will be kept confidential. It is a required test in order to ensure your safety and cannot be used against you in a court of law. If you have used an illicit substance of abuse, you should inform your study doctor. If you have any issues with this test being performed, discuss them with your study doctor prior to deciding to participate in this study. Illicit substance use is not permitted in this study.
- You will be asked to stop all of your medications currently used to treat your depressive episode and/or your bipolar disorder. You will be required to not use these medications from the time you are screened for the study throughout your participation. Your study doctor will instruct you in discontinuing the use of your current medications in order to ensure your safety. If you notice a worsening in your symptoms during this period, contact your study doctor immediately.
- If abnormal results are reported from the ECG, labs or urine sample, you may be asked to return to the office for a retest. Any abnormal results reported to your study doctor will be discussed with you in order for you to obtain the proper follow-up.

Once the initial screening phase is complete and your study doctor has determined you are eligible to proceed in the study, you will return to your study doctor's office for Visit 2. This will occur anywhere from 7-28 days after your first visit. At Visit 2, the final screening will occur and your study doctor will assess whether you will be able to participate in the study.

The final screening assessment consists of the following:

- Your study doctor will repeat the same two, question and answer, assessments which rate the severity of your depression and to check for possible symptoms of mania, that were conducted at your initial screening visit.

Once these assessments are complete and your study doctor has determined you are eligible to participate, you will be randomly (like the flip of a coin) assigned to one of the three treatments. The treatments will be either 600 mg of quetiapine per day, 300 mg of quetiapine per day, or placebo. Your chance of receiving quetiapine is twice that of placebo, that is, you have a 66% chance of receiving quetiapine and a 33% chance of receiving pills that contain no active drug. Neither you nor your study doctor or research nurse will know if you are taking quetiapine or placebo. Your condition may worsen as a result of receiving either placebo or study drug.

In addition to being randomized to treatment, the following psychiatric and medical assessments will be conducted at Visit 2:

- Six evaluations (question and answer) of your mental condition, involuntary limb movements, how well you sleep at night and your quality of life will be conducted. The sleep assessment is a self-assessment questionnaire, which means you will complete it on your own.
- Your blood pressure and heart rate will be recorded.

You will then be asked to come back to your study doctor's office on a weekly basis for the course of 8 weeks. Study medication is dispensed at each study visit during the treatment phase.

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Visits 3 through 10 will consist of the following:

- The same two, question and answer, assessments which rate the severity of your depression and possible symptoms of mania will be conducted at each study visit. In addition, another depression assessment will be conducted along with an anxiety assessment.
- Your blood pressure and heart rate will be recorded.

In addition to the above assessments, the assessments of your sleep and quality of life will be conducted again at Visit 6.

At your final visit, Visit 10, the following psychiatric and medical assessments will be conducted:

- Physical Exam
- Testing of hematology (red and white blood cells) and fasting clinical chemistry (tests of lipid levels, glucose, insulin, creatinine, liver and thyroid function).
- Electrocardiogram (ECG)
- Weight, blood pressure and heart rate
- A final evaluation of all the psychiatric assessments, including sleep assessment, will be conducted at this visit.

If you decide, at any point during the treatment phase of the study, that you no longer want to participate, or if you are taken out of the study, you will be asked to return to your study doctor's office for a final visit. This is to make sure you are in good health and you have not experienced any negative health effects as a result of your study participation.

Possible Side Effects and Risks of the Treatment

As a result of stopping the medications you are currently taking, your condition may worsen. Your condition may worsen as a result of taking placebo.

All therapies may cause some side effects or other reactions. You should know about possible risks and discomforts associated with quetiapine (Seroquel™) before you decide to participate in this study.

The most common side affects reported in people taking quetiapine (Seroquel™) are:

- headache
- sleepiness
- dizziness
- constipation
- dry mouth
- decreased blood pressure on standing (symptoms may be dizziness, fast heart rate, and fainting)
- increased heart rate

A very rare side effect of antipsychotic drugs, including quetiapine (Seroquel™), is Neuroleptic Malignant Syndrome. The symptoms are high fever, stiff muscles, fast heart rate, high or low blood pressure, sweating, and possibly kidney failure. Sometimes this illness results in death. Another rare side effect of antipsychotic drugs is a disorder called tardive dyskinesia, which causes uncontrollable body movements such a lip and tongue smacking. Sometimes the movements are permanent.

Some people treated with Seroquel™ have had mild and temporary increases in liver chemicals (seen in their blood stream).

Animal studies have shown a slight risk of developing cloudiness in the lens of the eye, but this increased risk has not been seen in patients taking the medication in clinical research studies. Other side effects may occur, some of which are not known and cannot be predicted. With your full cooperation regarding the

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instructions given by your physician, frequent examination and the performance of laboratory tests, if these unwanted side effects happen, they can be treated quickly and the potential for your discomfort can be minimized.

In addition to the side effects for the study drug quetiapine (Seroquel™), there may be other risks to you that are not known at the present time.

During the screening period, and upon completion of the study, approximately 2 ½ tablespoons (36 ml) of blood (38 ml for women) will be drawn from a vein in your arm using standard medical procedures. The risks of venipuncture (inserting a needle in your vein to take blood) include the occurrence of discomfort and/or bruising at the site of the puncture and, less commonly, fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, or bleeding from the puncture site. There also could be infection at the site.

If you are not completely truthful with the study doctor and study staff regarding any side effects, you may harm yourself by participating in this study.

New Findings

You will be informed of any new information about the study drug that becomes known during the course of this study, which might affect your willingness to continue participation.

Women of Childbearing Potential

There might be unknown risks to an unborn child or breast-fed child if you are or if you become pregnant during the study.

Due to these risks, you must not participate in this study if you are pregnant or plan to become pregnant during the research study period, or are breast-feeding a child.

If you are a woman of child-bearing potential:

- By signing this consent form, you confirm to the best of your knowledge that you are not pregnant now and you do not intend to become pregnant during this study.
- A pregnancy test will be done to confirm that you are not pregnant before your participation in this study.

If you are a female of childbearing potential, you need to be using a reliable method of contraception. Reliable methods include:

- oral contraceptive
- long-term injectable or implantable hormonal contraceptive
- condom and diaphragm
- condom and foam
- condom and sponge
- intrauterine device (IUD)
- tubal ligation

If at any time during this study you think you might be pregnant, or later learn that you were pregnant during the study, you must contact the study doctor immediately for further instructions regarding your participation in this study and follow up.

Possible Benefits of the Study

You will not experience any direct health benefits during or following completion of this study. However, your participation will provide information about the study treatment(s) and bipolar depression that may benefit others.

Alternatives to Participating in this Study

Although there are approved treatments for mania alone (eg: lithium, valproic acid) and depression alone (SSRIs), there are no approved

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medications for depression associated with bipolar disorder.

Payment for Injury Related to the Study

If you experience any side effect or injury, notify your study doctor immediately so that you can receive appropriate medical treatment.

If you suffer any side effect or other physical injury resulting directly from the research study drug, AstraZeneca will provide reimbursement for the reasonable costs of medical treatment if:

- You took the study drug as instructed by your study doctor
- Your injury was not deliberately caused
- The study doctor was immediately notified about your injury
- You followed the medical advice of the study doctor

You will not be reimbursed for lost wages or other damages or losses or for medical expenses that have been covered by your medical or hospital insurance or by third party or governmental programs providing such coverage. No other form of compensation is offered from AstraZeneca except remedies available under the law. Compensation for medical expenses is not an admission of fault or liability by AstraZeneca or anyone else.

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You will not lose any of your legal rights as a research subject by signing this consent form.

Additional Costs

The study drug, study doctor's visits, and laboratory tests related to this study will be provided at no cost to you. Neither your insurance company nor you will be charged for the services provided in the normal course of the conduct of this study.

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Your participation in this study is entirely voluntary. You cannot be forced to be in this study. You may not want to be in this study or you may leave the study at any time without punishment or loss of benefits to which you are entitled and without affecting your future medical care. The study doctor, the Drug Company, IntegReview, or the FDA may take you out of the study without your permission at any time for the following reasons:

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- if it is discovered that you do not meet the study requirements
- if the study is cancelled
- if it appears to be medically harmful to you

If you leave the study or if you are taken out of the study for any reason, you will be asked to return to the study doctor's office for a final visit. This is to make sure that you are in good health.

You must return all unused study drug and the containers to your study doctor.

Payment for Participation

You will not be paid for your participation in this study.

Release Of Your Medical Records And Privacy (Confidentiality)

All study data will be kept confidential; however, authorized personnel from AstraZeneca, its representatives, the FDA, other Department of Health and Human Services agencies, government agencies in other countries, and IntegReview, the Institutional Review Board (IRB) may have access to the data. The data and results from this study may also be presented at meetings or in publications,

Subject Initials: _____

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but in those presentations study participants will not be identified by name.

Whom To Contact

For answers to questions about this research or to report a research related injury, contact:

Janice Miller, M.D.
561-616-9595 daytime and after hours

To protect the rights and safety of subjects involved in research projects the FDA requires approval of this Informed Consent document by an Institutional Review Board (IRB). This means the IRB has approved the information provided in the Informed Consent for use when enrolling subjects into this study. IntegReview Ethical Review Board has approved this research study and informed consent document. IntegReview is a group of scientific and non-scientific people that review research studies. Ethical review boards must follow the Food and Drug Administration (FDA) rules regarding the protection of the rights and welfare of human subjects involved in medical research studies. Questions about your rights as a study subject may be addressed to:

Chairperson
IntegReview
1825 Fortview Road, Suite 110
Austin, Texas 78704
512-326-3001 between 8 a.m. and 5 p.m.
Central Time (call collect)
integreview@integreview.com

Experimental Subject's Bill of Rights

As a subject involved in an investigational drug study, you have the following rights.

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risk reasonably to be expressed from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time. The subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Subject Initials: _____

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The Reason for Institutional Review Boards and Informed Consent

What is a consent form?
The Informed Consent document contains the required information as found in and required by the United States regulations regarding the protection of human subjects (Code of Federal Regulations, Title 21, Part 50-Protection of Human Subjects). As required by this regulation, the informed consent must be reviewed and approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is any board, committee or other group which reviews, approves, and does continuing review of biomedical research involving human subjects. The primary purpose of such review is to guarantee the protection of the rights and welfare of the human subjects.

IRBs were established as the result of unfair treatment of human subjects. Prior to this, other committees existed as a requirement of the United States Public Health Service (USPHS) policy established in 1965. IRBs are regulated by the Food and Drug Administration and the National Institutes of Health (NIH).

What does an IRB mean to me?
The purpose of the IRB is to inform and protect human subjects through the information provided in the informed consent document. Therefore, the IRB is acting as a supporter for the research subject. This means that the IRB, during its review of the informed consent document, has the right and responsibility to ensure that the research subject is fully informed of the procedures involved in the study as well as the risks and other treatments that are available if participation in the study is refused.

How can I tell that an IRB has reviewed and approved this study?
The date that IntegReview approved the study design as well as the information in this Informed Consent document is printed on the top of each page of this Informed Consent form. **THIS DOES NOT MEAN THE IRB HAS APPROVED YOUR PARTICIPATION IN THE STUDY.** It is a FDA requirement that the study design (Protocol), Informed Consent form, any advertising materials, and other instructions to the subject (Subject Instructions, Patient Diaries, etc.) be reviewed and approved by an IRB. Although IRB approval is granted for the study doctor to conduct the study, you must evaluate the information in this Informed Consent form for yourself and decide whether or not you wish to participate.

IntegReview, the IRB for this study
IntegReview is an independent IRB whose board members are individuals who work in the Austin community. IntegReview provides services nation-wide to research professionals.

FDA regulations require that the committee have at least five members with varying backgrounds to provide complete and adequate review of research activities.

To fulfill these requirements the IntegReview Board currently includes physicians, pharmacists, Ph.Ds., a toxicologist (someone who studies the harmful effects of chemicals), a psychologist, an oral surgeon, and lay members (non-scientific).

The telephone number of the Chair is available in every informed consent document in the contacts section. You may contact the Chair with concerns regarding your rights as a subject.

Subject Initials: _____

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Agreement to Be in the Study

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

A. Do you understand the information in this consent form? _____

B. Have you been able to ask questions and talk about the study? _____

C. Have all of your questions been answered to your satisfaction? _____

D. Do you think you received enough information about the study? _____

E. Do you understand that you can leave the study at any time without giving a reason and without affecting your medical care? _____

F. Do you understand that your medical records from this study may be reviewed by the Drug Company and by government authorities? _____

If you answered NO to any of these six questions, you should not sign this consent form.

When you sign this consent form you agree that:

- you have had a chance to ask questions
- you understand English
- you want to be in the study

You will not lose any of your legal rights by signing this consent form.

_____

Signature of Study Subject or Legally Authorized Representative Date (Month/Day/Year)
DO NOT SIGN AFTER SEPTEMBER 10, 2003

_____

Printed Name of Study Subject

_____

Signature of Person Explaining Informed Consent Date (Month/Day/Year)

You will be given a copy of this informed consent to keep.

Subject Initials: _____

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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Addendum to Informed Consent
Consent to Perform

AstraZeneca Trial 5077US/0049 "A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression"

Part of this study involves the use of a computer to answer some questions about your depression. This is a computer-based self-report measure of depression severity that you will perform after you have answered the questions asked by a study clinician. It may help ensure that your study doctor accurately assessed your depression.

There is no direct benefit to you in having these tests performed. None of the results will be reported in the Clinical Trial Report that is written at the end of the study. None of the results will be provided to you, your family, the investigator, or to any other physician who is treating you or may treat you in the future. Neither your insurance company nor your employer will have any access to these test results.

Participation in this part of the study is optional. You will receive the same treatment and care under the study protocol whether or not you decide to perform the computer-based self-report. If you decide to participate, you will be asked to do this at each visit after one of the severity of depression interviews is done. It will take about 15 minutes of your time.

I have read and I understand this section.

I consent to the computer- based self-report described in this section.

You will not lose any of your legal rights by signing this consent form

_____

Signature of Study Subject or Legally Authorized Representative Date (Month/Day/Year)

DO NOT SIGN AFTER SEPTEMBER 10, 2003

_____

Printed Name of Study Subject

_____

Signature of Person Explaining Informed Consent Date (Month/Day/Year)

You will be given a copy of this informed consent to keep.

Subject Initials: _____

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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STUDY PARTICIPANT SURVEY
(OPTIONAL)
INFORMED CONSENT DOCUMENT AND PROCESS

As mentioned in the informed consent document, IntegReview is an ethical review board responsible for ensuring the safety and welfare of subjects involved in medical and biomedical research. We spend a great deal of time reviewing the informed consent document to make sure you are given enough information to make an informed decision whether or not you wish to participate in the study. In addition, we want to be sure the document is easy to read and understand.

You can assist us in this process by providing feedback regarding your experience as a research study subject. The following questions are designed to let our board members know how to improve the informed consent documents.

Please provide as much information as you feel is necessary. *This information will be kept confidential by IntegReview.* ***You may use additional pages if needed.***

1. Your age: _____

2. Highest level of education completed: _____

3. Two column format of informed consent document: ☐ Easier to read than one column

   ☐ More difficult to read than one column ☐ No difference between one or two column format

4. Words/phrases were understood: ☐ Yes ☐ No

What words/phrases did you **not** understand? _____

_____

_____

_____

5. Did the study doctor or one of the staff explain what you did not understand? ☐ Yes ☐ No

6. Overall ease of reading informed consent document: ☐ Excellent ☐ Good ☐ Satisfactory ☐ Poor

7. Were you offered/allowed to take the informed consent document home to read and/or discuss with family members/friends? ☐ Yes ☐ No

8. If no, would you have preferred the option? ☐ Yes ☐ No

9. Did the study doctor or one of the study staff read the informed consent to you? ☐ Yes ☐ No

10. Did you feel you had enough time to read the informed consent before you were asked to make a decision? ☐ Yes ☐ No

11. Did you feel comfortable asking questions after you read the informed consent document? ☐ Yes ☐ No

12. Was there information not in the document that you feel should have been included? ☐ Yes ☐ No
If so, please explain: _____

_____

_____

_____

What suggestions do you have for IntegReview that would improve the informed consent document and the process of obtaining informed consent? _____

_____

_____

PLEASE RETURN TO INTEGREVIEW
1825 FORTVIEW ROAD, SUITE 110
AUSTIN, TX 78704
512-326-3446 FAX
OR COMPLETE THE FORM ONLINE BY VISITING WWW.INTEGREVIEW.COM AND CLICKING ON THE "SUBJECT FEEDBACK" BUTTON

AstraZeneca

Clinical Study Report: Appendix 12.1.4

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.4
Participants in the study

12.1.4.1 List of staff at investigational site(s)

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0001	Joseph Calabrese	University Hospitals of Cleveland, Mood Disorders Program, 11400 Euclid Avenue, Suite 200 Cleveland, OH 44106	MD	Principal Investigator
USA	0001	Aditi Mehta	University Hospitals of Cleveland, Mood Disorders Program, 11400 Euclid Avenue, Suite 200 Cleveland, OH 44106	MD	Sub-Investigator
USA	0001	Melvin D. Shelton	University Hospitals of Cleveland, Mood Disorders Program, 11400 Euclid Avenue, Suite 200 Cleveland, OH 44106	MD, PhD	Sub-Investigator
USA	0001	Omar Elhaj	University Hospitals of Cleveland, Mood Disorders Program, 11400 Euclid Avenue, Suite 200 Cleveland, OH 44106	MD	Sub-Investigator
USA	0001	Poonam Singh	University Hospitals of Cleveland, Mood Disorders Program, 11400 Euclid Avenue, Suite 200 Cleveland, OH 44106	MD	Sub-Investigator
USA	0002	Mohammed Y. Alam	American Medical Research, Inc 1200 Harger Road, Suite 415 Oak Brook, IL 60523	MD	Principal Investigator
USA	0002	Syed H. Anwar	American Medical Research, Inc 1200 Harger Road, Suite 415 Oak Brook, IL 60523	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0002	Gulzar S. Fidai	American Medical Research, Inc 1200 Harger Road, Suite 415 Oak Brook, IL 60523	MD	Sub-Investigator
USA	0002	Sandeep Gaonkar	American Medical Research, Inc 1200 Harger Road, Suite 415 Oak Brook, IL 60523	MD	Sub-Investigator
USA	0002	Nageswara R. Nagarakanti	American Medical Research, Inc 1200 Harger Road, Suite 415 Oak Brook, IL 60523	MD	Sub-Investigator
USA	0002	Ziauddin Ahmed	American Medical Research, Inc 1200 Harger Road, Suite 415 Oak Brook, IL 60523	MD	Sub-Investigator
USA	0002	Khaja Aliuddin	American Medical Research, Inc 1200 Harger Road, Suite 415 Oak Brook, IL 60523	MD	Sub-Investigator
USA	0003	Valerie Arnold	Clinical NeuroScience Solutions 6401 Poplar Avenue Memphis, TN 38119	MD	Principal Investigator
USA	0003	Lora J. McGill	Clinical NeuroScience Solutions 6401 Poplar Avenue Memphis, TN 38119	MD	Sub-Investigator
USA	0003	Steven N. Rice	Clinical NeuroScience Solutions 6401 Poplar Avenue Memphis, TN 38119	MD	Sub-Investigator
USA	0004	Charles Bailey	Clinical NeuroScience Solutions 77 West Underwood Street, Suite 420 Orlando, FL 32806	MD	Principal Investigator
USA	0004	Linda Harper	Clinical NeuroScience Solutions 77 West Underwood Street, Suite 420 Orlando, FL 32806	MD	Sub-Investigator
USA	0004	Richard Saini	Clinical NeuroScience Solutions 77 West Underwood Street, Suite 420 Orlando, FL 32806	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0004	Scott West	Clinical NeuroScience Solutions 77 West Underwood Street, Suite 420 Orlando, FL 32806	MD	Sub-Investigator
USA	0005	Richard Weisler	Richard H. Weisler, M.D. & Associates 700 Spring Forest Road, Suite 125 Raleigh, NC 27609	MD	Principal Investigator
USA	0005	Diana Dell	Richard H. Weisler, M.D. & Associates 700 Spring Forest Road, Suite 125 Raleigh, NC 27609	MD	Sub-Investigator
USA	0005	Susan Van Meter	Richard H. Weisler, M.D. & Associates 700 Spring Forest Road, Suite 125 Raleigh, NC 27609	MD	Sub-Investigator
USA	0005	Beth A. Ridgeway	Richard H. Weisler, M.D. & Associates 700 Spring Forest Road, Suite 125 Raleigh, NC 27609	MD	Sub-Investigator
USA	0006	Lawrence D. Ginsberg	Red Oak Psychiatry Services 17115 Red Oak Dr., Suite 109 Houston, TX 77090	MD	Principal Investigator
USA	0006	Robert Bogan	Red Oak Psychiatry Services 17115 Red Oak Dr., Suite 109 Houston, TX 77090	MD	Sub-Investigator
USA	0006	Terry W. Hugg	Red Oak Psychiatry Services 17115 Red Oak Dr., Suite 109 Houston, TX 77090	MD	Sub-Investigator
USA	0007	Irving S. Kolin	Kolin Research Group 1065 West Morse Boulevard, Suite 202 Winter Park, FL 32789	MD, PA	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0007	Thomas Guest	Kolin Research Group 1065 West Morse Boulevard, Suite 202 Winter Park, FL 32789	PhD	Sub-Investigator
USA	0007	Lillian T. Saavedra	Kolin Research Group 1065 West Morse Boulevard, Suite 202 Winter Park, FL 32789	MD	Sub-Investigator
USA	0008	David W. Brown	Community Clinical Research 4411 Medical Parkway Austin, TX 78756-3313	MD	Principal Investigator
USA	0008	Susan D. Thompson	Community Clinical Research 4411 Medical Parkway Austin, TX 78756-3313	MD	Sub-Investigator
USA	0008	Mark Kutcher	Community Clinical Research 4411 Medical Parkway Austin, TX 78756-3313	MD	Sub-Investigator
USA	0009	John S. Carman	Carman Research 4015 South Cobb Dr., Suite 245 Smyrna, GA 30080	MD	Principal Investigator
USA	0009	Vicky E. Spratlin	Carman Research 4015 South Cobb Dr., Suite 245 Smyrna, GA 30080	MD	Sub-Investigator
USA	0010	Andrew Cutler	CORE Research 807 West Morse Boulevard, Suite 101 Winter Park, FL 32789	MD	Principal Investigator
USA	0010	Aparna Kopuri	CORE Research 807 West Morse Boulevard, Suite 101 Winter Park, FL 32789	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0010	Richard D. Knapp	CORE Research 807 West Morse Boulevard, Suite 101 Winter Park, FL 32789	DO	Sub-Investigator
USA	0010	Jairo R. Nunez	CORE Research 807 West Morse Boulevard, Suite 101 Winter Park, FL 32789	MD	Sub-Investigator
USA	0011	Bernadette D'Souza	Midwest Clinical Research Center Suite 234 9000 North Main St. Dayton, OH 45415	MD	Principal Investigator
USA	0013	Naresh Emmanuel	Carolina Clinical Research Services, LLC Suite H 712 Richland Street Columbia, SC 29201	MD	Principal Investigator
USA	0014	Fred Reimherr, MD	University of Utah Medical Center Room 5R218 30 North 1900 East Salt Lake City, UT 84132-2502	MD	Principal Investigator
USA	0014	Poonam Soni	University of Utah Medical Center Room 5R218 30 North 1900 East Salt Lake City, UT 84132-2502	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0014	Robert E. Strong	University of Utah Medical Center Room 5R218 30 North 1900 East Salt Lake City, UT 84132-2502	DO	Sub-Investigator
USA	0015	Abbey Strauss	Clinical Neuroscience, Inc. Suite 101 8200 Jog Road Boynton Beach, FL 33437	MD	Principal Investigator
USA	0015	Abe Marcadis	Clinical Neuroscience, Inc. Suite 101 8200 Jog Road Boynton Beach, FL 33437	MD	Sub-Investigator
USA	0016	William T. Granger, III	American Medical Research Associates Suite 103 1301 N. McCarron Blvd. Sparks, NV 89431	MD	Principal Investigator
USA	0017	Laslo Gyulai	University of Pennsylvania Medical Center Suite 670, Dept. of Psychiatry 3535 Market Street Philadelphia, PA 19104	MD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0017	Alice Chang	University of Pennsylvania Medical Center Suite 670, Dept. of Psychiatry 3535 Market Street Philadelphia, PA 19104	MD	Sub-Investigator
USA	0017	Chang-Gyu Hahn	University of Pennsylvania Medical Center Suite 670, Dept. of Psychiatry 3535 Market Street Philadelphia, PA 19104	MD	Sub-Investigator
USA	0017	Julie Pickholtz	University of Pennsylvania Medical Center Suite 670, Dept. of Psychiatry 3535 Market Street Philadelphia, PA 19104	PhD	Sub-Investigator
USA	0018	Saul Helfing	Oregon Center for Clinical Investigators, Inc Suite 120 2230 NW Pettygrove Street Portland, OR 97210	MD	Principal Investigator
USA	0019	George Joseph	Clinical Neuroscience Solutions Suite 108 4063 Salisbury Road Jacksonville, FL 32216	MD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0019	John M. Joyce	Clinical Neuroscience Solutions Suite 108 4063 Salisbury Road Jacksonville, FL 32216	MD	Sub-Investigator
USA	0019	Kamalesh Pai	Clinical Neuroscience Solutions Suite 108 4063 Salisbury Road Jacksonville, FL 32216	MD	Sub-Investigator
USA	0020	Leon I Rosenberg	Center for Emotional Fitness Suite 303 110 Martar Avenue Moorestown, NJ 08057	MD	Principal Investigator
USA	0021	Terrence Ketter	Stanford University School of Medicine Bipolar Disorders Clinic 401 Quarry Road Stanford, CA 94305-5723	MD	Principal Investigator
USA	0021	Olga Becker	Stanford University School of Medicine Bipolar Disorders Clinic 401 Quarry Road Stanford, CA 94305-5723	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0021	Cecylia Nowakowska	Stanford University School of Medicine Bipolar Disorders Clinic 401 Quarry Road Stanford, CA 94305-5723	MD	Sub-Investigator
USA	0021	Po W. Wang, MD	Stanford University School of Medicine Bipolar Disorders Clinic 401 Quarry Road Stanford, CA 94305-5723	MD	Sub-Investigator
USA	0022	Arif Khan	Northwest Clinical Research Center 1900 116th Avenue NE Bellevue, WA 98004	MD	Principal Investigator
USA	0022	Richard Charlat	Northwest Clinical Research Center 1900 116th Avenue NE Bellevue, WA 98004	MD	Sub-Investigator
USA	0022	Mark J. Kasper	Northwest Clinical Research Center 1900 116th Avenue NE Bellevue, WA 98004	MD	Sub-Investigator
USA	0022	Jerry Steiert	Northwest Clinical Research Center 1900 116th Avenue NE Bellevue, WA 98004	MD	Sub-Investigator
USA	0022	Claire Waltman	Northwest Clinical Research Center 1900 116th Avenue NE Bellevue, WA 98004	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0023	James Knutson	Suite 101 512 6th Street South Kirkland, WA 98033	MD	Principal Investigator
USA	0023	Howard Quint, MD	Suite 101 512 6th Street South Kirkland, WA 98033	MD	Sub-Investigator
USA	0023	Donald Rice	Suite 101 512 6th Street South Kirkland, WA 98033	MD	Sub-Investigator
USA	0024	Elly R. Lee	Protocare Trials 16259 Laguna Canyon Road Irvine, CA 96218	MD	Principal Investigator
USA	0024	Penny K Randall	Protocare Trials 16259 Laguna Canyon Road Irvine, CA 96218	MD	Sub-Investigator
USA	0024	Sid Rosenblatt	Protocare Trials 16259 Laguna Canyon Road Irvine, CA 96218	MD	Sub-Investigator
USA	0025	Leon Rubenfaer	Pioneer Pharmaceutical Research Suite 110 33497 23 Mile road New Baltimore, MI 48047	MD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0025	Sarva Sarvananda	Pioneer Pharmaceutical Research Suite 110 33497 23 Mile road New Baltimore, MI 48047	MD	Sub-Investigator
USA	0026	David Marks	Optimum Health Services Suite 116 7200 Parkway Dr. Le Mesa, CA 91942	MD	Principal Investigator
USA	0026	Prakash Bhatia	Optimum Health Services Suite 116 7200 Parkway Dr. Le Mesa, CA 91942	MD	Sub-Investigator
USA	0026	Yuval Estrov	Optimum Health Services Suite 116 7200 Parkway Dr. Le Mesa, CA 91942	MD	Sub-Investigator
USA	0026	Loren Green	Optimum Health Services Suite 116 7200 Parkway Dr. Le Mesa, CA 91942	PhD	Sub-Investigator
USA	0027	Gregory Mattingly	St. Charles Psychiatric Associates Suite 390 330 First Capital Dr. St. Charles, MO 63301	MD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0027	Richard Anderson	St. Charles Psychiatric Associates Suite 390 330 First Capital Dr. St. Charles, MO 63301	MD	Sub-Investigator
USA	0027	John Canale	St. Charles Psychiatric Associates Suite 390 330 First Capital Dr. St. Charles, MO 63301	MD	Sub-Investigator
USA	0027	Howard Ilivicky	St. Charles Psychiatric Associates Suite 390 330 First Capital Dr. St. Charles, MO 63301	MD	Sub-Investigator
USA	0028	Charles Merideth	Affiliated Research Institute Suite 350 8989 Rio San Diego Dr. San Diego, CA 92108	MD	Principal Investigator
USA	0028	Marc Capobianco	Affiliated Research Institute Suite 350 8989 Rio San Diego Dr. San Diego, CA 92108	MD	Sub-Investigator
USA	0029	Janice Miller	Clinical Neuroscience Solutions Building 2, Suite 210 5601 Corporate Way West Palm Beach, FL 33407	MD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0029	Arnold Hartman	Clinical Neuroscience Solutions Building 2, Suite 210 5601 Corporate Way West Palm Beach, FL 33407	MD	Sub-Investigator
USA	0029	Ann Marie Laughlin	Clinical Neuroscience Solutions Building 2, Suite 210 5601 Corporate Way West Palm Beach, FL 33407	MD	Sub-Investigator
USA	0030	Dennis J. Munjack	Southwestern Research, Inc. Suite 216 435 N. Bedford Dr. Beverly Hills, CA 90210	MD	Principal Investigator
USA	0030	John J. Murphy	Southwestern Research, Inc. Suite 216 435 N. Bedford Dr. Beverly Hills, CA 90210	MD	Sub-Investigator
USA	0030	Brock H. Summers	Southwestern Research, Inc. Suite 216 435 N. Bedford Dr. Beverly Hills, CA 90210	MD	Sub-Investigator
USA	0031	William J. Privitera	Future Search Trials Suite 200 4200 Marathon Blvd. Austin, TX 78756	MD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0031	Judy Forgason	Future Search Trials Suite 200 4200 Marathon Blvd. Austin, TX 78756	MD	Sub-Investigator
USA	0031	Donald J. Garcia, Jr.	Future Search Trials Suite 200 4200 Marathon Blvd. Austin, TX 78756	MD	Sub-Investigator
USA	0031	J. Byron Stone	Future Search Trials Suite 200 4200 Marathon Blvd. Austin, TX 78756	MD	Sub-Investigator
USA	0032	Javad Razani	Golden State Behavioral Medical Group Suite 200-H 222 West Eulalia Street Glendale, CA 91204	MD	Principal Investigator
USA	0032	Nadina C. Jose	Golden State Behavioral Medical Group Suite 200-H 222 West Eulalia Street Glendale, CA 91204	MD	Sub-Investigator
USA	0033	Ari Kiev	Social Psychiarty Research Institute Suite 2H 150 East 69th Street New York, NY 10021	MD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0033	Nicholas Vatakis	Social Psychiarty Research Institute Suite 2H 150 East 69th Street New York, NY 10021	MD	Sub-Investigator
USA	0034	Ramanath Gopalan	Comprehensive NeuroScience of Northern VA 6066 Leesburg Pike Falls Church, VA 22041	MD	Principal Investigator
USA	0034	Audrey Moss	Comprehensive NeuroScience of Northern VA 6066 Leesburg Pike Falls Church, VA 22041	MD	Sub-Investigator
USA	0035	David Sack	Comprehesive Neuroscience, Inc. Suite G 11050 E. Artesia Blvd. Cerritos, CA 90703	MD	Principal Investigator
USA	0035	Lisa Anthony	Comprehesive Neuroscience, Inc. Suite G 11050 E. Artesia Blvd. Cerritos, CA 90703	PhD	Sub-Investigator
USA	0035	George Karamigios	Comprehesive Neuroscience, Inc. Suite G 11050 E. Artesia Blvd. Cerritos, CA 90703	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0035	Morteza Marandi	Comprehesive Neuroscience, Inc. Suite G 11050 E. Artesia Blvd. Cerritos, CA 90703	MD	Sub-Investigator
USA	0035	Craig Wronski	Comprehensive NeuroScience of Northern VA Suite G 11050 E. Artesia Blvd. Cerritos, CA 90703	DO	Sub-Investigator
USA	0036	Guy E. Brannon	Brentwood Research Institute Suite 400 1002 Highland Avenue Shreveport, LA 71101	MD	Principal Investigator
USA	0036	Robert A. Woodward	Brentwood Research Institute Suite 400 1002 Highland Avenue Shreveport, LA 71101	MD	Sub-Investigator
USA	0037	David P. Walling	Collaborative NeuroScience Network, LLC Suite 3 12772 Valley View Street Garden Grove, CA 92845	PhD	Principal Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0037	Armen Goenjian	Collaborative NeuroScience Network, LLC Suite 3 12772 Valley View Street Garden Grove, CA 92845	MD	Sub-Investigator
USA	0038	Paul E. Keck, Jr.	Psychiatric Professional Services, Inc. 231 Albert-Sabin Way Cincinnati, OH 45267-0559	MD	Principal Investigator
USA	0038	Renu Kotwal	Psychiatric Professional Services, Inc. 231 Albert-Sabin Way Cincinnati, OH 45267-0559	MD	Sub-Investigator
USA	0038	Susan McElroy	Psychiatric Professional Services, Inc. 231 Albert-Sabin Way Cincinnati, OH 45267-0559	MD	Sub-Investigator
USA	0038	Erik Nelson	Psychiatric Professional Services, Inc. 231 Albert-Sabin Way Cincinnati, OH 45267-0559	MD	Sub-Investigator
USA	0039	Howard A. Hassman	CNS Research Institute, PC 130 White Horse Pike Clementon, NJ 08021	MD	Principal Investigator
USA	0039	Steven J. Glass	CNS Research Institute, PC 130 White Horse Pike Clementon, NJ 08021	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0039	Barbara Kelly	CNS Research Institute, PC 130 White Horse Pike Clementon, NJ 08021	PhD	Sub-Investigator
USA	0039	Frank C. McManus	CNS Research Institute, PC 130 White Horse Pike Clementon, NJ 08021	PhD	Sub-Investigator
USA	0039	Alexander M. Uy	CNS Research Institute, PC 130 White Horse Pike Clementon, NJ 08021	MD	Sub-Investigator
USA	0040	Michael Levy	Behavioral Medical Research of Staten Island 1361 Hylan Blvd. Staten Island, NY 10305	MD	Principal Investigator
USA	0040	Mohammed Hashmi	Behavioral Medical Research of Staten Island 1361 Hylan Blvd. Staten Island, NY 10305	MD	Sub-Investigator
USA	0040	Adam Smith	Behavioral Medical Research of Staten Island 1361 Hylan Blvd. Staten Island, NY 10305	MD	Sub-Investigator
USA	0041	Robert A. Riesenberg	Atlanta Center for Medical Research 811 Juniper Street NE Atlanta, GA 30308	MD	Principal Investigator
USA	0041	James McNight	Atlanta Center for Medical Research 811 Juniper Street NE Atlanta, GA 30308	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0041	D.S. Siddappa	Atlanta Center for Medical Research 811 Juniper Street NE Atlanta, GA 30308	MD	Sub-Investigator
USA	0042	Harry E. Logue	Birmingham Psychiatry Pharmaceutical Studies, Inc. Suite 900 One Independence Plaza Birmingham, AL 35209	MD	Principal Investigator
USA	0042	R.Wyatt Feagin	Birmingham Psychiatry Pharmaceutical Studies, Inc. Suite 900 One Independence Plaza Birmingham, AL 35209	MD	Sub-Investigator
USA	0042	Joseph G. Gregory	Birmingham Psychiatry Pharmaceutical Studies, Inc. Suite 900 One Independence Plaza Birmingham, AL 35209	MD	Sub-Investigator
USA	0042	James A. Hagemeyer	Birmingham Psychiatry Pharmaceutical Studies, Inc. Suite 900 One Independence Plaza Birmingham, AL 35209	MD	Sub-Investigator

Country	**Centre No.**	**Name** (First name, Last name)	**Centre address**	**Qualifications**	**Role in the study**
USA	0042	James M. Lee	Birmingham Psychiatry Pharmaceutical Studies, Inc. Suite 900 One Independence Plaza Birmingham, AL 35209	MD	Sub-Investigator
USA	0042	Lyle E. Shehi	Birmingham Psychiatry Pharmaceutical Studies, Inc. Suite 900 One Independence Plaza Birmingham, AL 35209	MD	Sub-Investigator

12.1.4.2 AstraZeneca study personnel

Name (First name, Last name)	**Address**	**Qualifications**	**Present Position**	**Role in the study**
Robin McCoy	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	ADN	Senior Clinical Research Scientist	Clinical Study Team Leader
Wayne Macfadden	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	MD	Director, Clinical Research	Clinical Study Team Physician
Margaret Minkwitz	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	PhD	Director, Biostatistics Project Team	Clinical Study Team Statistician
Jeris Minor	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	BA	Clinical Data Analyst	Database Manager
Nadine Everett	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	BS	Principal Statistical Programmer	Team SAS Programmer
Joy Russo	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	AA	Senior Statistical Programmer	Statistical Programmer
Deborah Rolfe	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	BA, ADN, MA	Drug Safety Scientist	Drug Safety Monitor
James Gaddy	AstraZeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19850 USA	PhD	Medical Communication Scientist	Clinical Study Report Author

12.1.4.3 Study committee(s)

Committee name and address	**Member name** (First name, Last name)	**Qualifications**	**Role in committee**
None			

12.1.4.4 Other participants

Name (First name, Last name)	**Organisation and address**	**Qualifications**	**Role in study**
Kelly Abernathy	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	Project Manager
Charlie Lineberry	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	PhD	Scientific Project Advisor
Connie Douglas	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS, MS	Clinical Operations Project Advisor and Regulatory Task Mgr.
Derry Ridgway	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	MD	Medical Monitor
Steve Grossman	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	MD	Medical Monitor back-up

Name (First name, Last name)	**Organisation and address**	**Qualifications**	**Role in study**
David Lineberry	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	Lead Monitor: Trip Rpt. and Financial Task Mgr.
Florence Bobo	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709		Telephone Rpt. and Monitoring Oversight Task Mgr., Floating Monitor
Shelby Gainer	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	Rater and File Task Mgr., and Database Support
Sherrie LaRue	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS, MS	In-house Monitor and SAE Task Mgr.
Hazar Granko	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	PhD	Study Monitor
Karen Lakey	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	Study Monitor

Name (First name, Last name)	**Organisation and address**	**Qualifications**	**Role in study**
Donna Walton	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BA, AAS	Study Monitor
Dianne O'Dell	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	PhD	Study Monitor
Abby Wear	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BA	Study Monitor
Yuki Dalphin	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BA	Study Monitor
Susie Gardner	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709		Contract Study Monitor (West Coast Sites)
Brett Gordon	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	Back-up monitor

Name (First name, Last name)	**Organisation and address**	**Qualifications**	**Role in study**
Bryan Proctor	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BA	Clinical Trials Assistant: In-house monitor support (labs and logs)
Marie Smith	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709		COSS: Travel and Administrative Support
Patty Hubbard	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709		COSS: Files and Administrative support
Jessica Mason	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	CDM Project Leader
Jim Welch	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS, MS	Programmer
Christine Fleeman	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	Data Coordinator and Coding

Name (First name, Last name)	**Organisation and address**	**Qualifications**	**Role in study**
Kendra Glass	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709		Data Coordinator
Ann Wiley	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709		CDM File Management
Ginny Bray	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709		Data Entry
Tameka Bryan	Lineberry Research Associates 79 TW Alexander Drive Bldg. 4401, Suite 400 Research Triangle Park, NC 27709	BS	Data Entry
Lisa McCormick	eResearch Technology 30 South 17th Street Philadelphia, PA 119103	BA	Project Manager
Denise Evans	Quintiles Laboratories Quintiles Transnational Corporation PO Box 13979 Research Triangle Park, NC 27709	BS	Project Manager

Name (First name, Last name)	**Organisation and address**	**Qualifications**	**Role in study**
Dan DeBonis	Concordant Rater Systems 2004 Beacon Street #205 Boston, MA 02108	BA	Technical Advisor
Dan Lewis	Concordant Rater Systems 2004 Beacon Street #205 Boston, MA 02108	JD	Project Manager
Kelley O'Neill	Interactive Clinical Technologies	BS	Project Manager
Jennifer Lafty	Interactive Clinical Technologies		Project Specialist

12.1.4.5 CVs of investigators and other medically qualified participants

Centre Number	Name of investigator or other medically qualified participants
0001	Joseph Calabrese, MD
0002	Mohammed Alam, MD
0003	Valerie Arnold, MD
0004	Charles Bailey, MD
0005	Richard Weisler, MD
0006	Lawrence Ginsberg, MD
0007	Irving Kolin, MD
0008	David Brown, MD
0009	John Carman, MD
0010	Andrew Cutler, MD
0011	Bernadette D'Souza, MD
0013	Naresh Emmanuel, MD
0014	Frederick Reimherr, MD
0015	Abbey Strauss, MD
0016	William Granger, MD
0017	Laszlo Gyulai, MD
0018	Saul Helfing, MD
0019	George Joseph, MD
0020	Leon Rosenberg, MD
0021	Terrence Ketter, MD
0022	Arfulla Khan, MD
0023	James Knutson, MD
0024	Elly Lee, MD
0025	Leon Rubenfaer, MD
0026	David Marks, MD
0027	Greg Mattingly, MD
0028	Charles Merideth, MD
0029	Janice Miller, MD
0030	Dennis Munjack, MD
0031	William Privitera, MD
0032	Javad Razani, MD

Centre Number	Name of investigator or other medically qualified participants
0033	Ari Kiev, MD
0034	Ram Gopolan, MD
0035	David Sack, MD
0036	Guy E. Brannon, MD
0037	David Walling, Ph.D.
0038	Paul Keck, MD
0039	Howard Hassman, DO
0040	Michael Levy, MD
0041	Robert Riesenberg, MD
042	H. E. Logue, MD

JOSEPH R. CALABRESE, M.D.

J Calabrese 7/9/02

- Curriculum Vitae -

(7/6/02 Revision)

HOME ADDRESS: REDACTED

OFFICE ADDRESS:
Mood Disorders Program
11400 Euclid Avenue, Suite 200
Cleveland, Ohio 44106

Telephone: 216/844-2865
Home: REDACTED
FAX 216/844-2875
E-mail: jrc8@po.cwru.edu

DATE & PLACE OF BIRTH: February 7, 1953
Cleveland, Ohio

EDUCATION:

9/72 – 5/76	B.S. Xavier University (major in biology, summa cum laude)
7/76 – 6/80	M.D. Ohio State University College of Medicine (degree awarded with honors in psychiatry)
7/80 – 6/84	Resident in Psychiatry Cleveland Clinic Foundation Cleveland, Ohio
7/82 - 6/83	Chief Resident Department of Psychiatry Cleveland Clinic Foundation Cleveland, Ohio
7/83 – 6/84	Chief Resident Department of Psychiatry Cleveland Clinic Foundation Cleveland, Ohio
7/84 – 6/86	Research Fellowship, Intramural Program Section on Clinical Neuroendocrinology, Phil Gold, M.D. Biological Psychiatry Branch, Director, Robert Post, M.D. National Institute of Mental Health Bethesda, Maryland

PROFESSIONAL EXPERIENCE:

11/89 - Present	Director, Mood Disorders Program Department of Psychiatry University Hospitals of Cleveland Cleveland, Ohio
5/96 - Present	Professor of Psychiatry with tenure Case Western Reserve University School of Medicine Cleveland, Ohio
9/96 - Present	Co-Director, Stanley Foundation Bipolar Disorders Clinical Research Center Case Western Reserve University School of Medicine Cleveland, Ohio
9/94 – 9/00	Vice Chairman, Clinical Affairs Department of Psychiatry University Hospitals of Cleveland Cleveland, Ohio
5/97 – 5/98	Associate Medical Director for Behavioral Health QualChoice Health Plan, Inc. Cleveland, Ohio
12/94 – 5/97	President & Chief Executive Office University Behavioral Health Care, Inc. Cleveland, Ohio
5/89 – 5/96	Associate Professor of Psychiatry Case Western Reserve University School of Medicine Cleveland, Ohio
12/89 – 1/95	Medical Director, Adult Inpatient Unit University Hospitals of Cleveland Cleveland, Ohio
7/86 – 11/89	Head, Manic Depressive Clinic Department of Psychiatry Cleveland Clinic Foundation Cleveland, Ohio

COMMUNITY SERVICE:

6/02 – Present	External Advisor to Canadian Consortium on Bipolar Disorder
9/00 – Present	Member, Chapter Professional Advisors Committee, DMDA
1/97 - Present	Medical Advisor, Alliance Mentally Ill of Metro Cleveland

	National Alliance for the Mentally Ill Cleveland, Ohio
9/92 - Present	Member, Scientific Advisory Board National Depressive and Manic Depressive Association Chicago, Illinois
9/92 - Present	Medical Advisor, Alliance for the Mentally Ill of Cuyahoga County National Alliance for The Mentally Ill Cleveland, Ohio
1/87 - Present	Professional Advisor, Cleveland Chapter National Depressive and Manic Depressive Association Cleveland, Ohio

PHARMACEUTICAL CONSULTATION/ADVISORY BOARDS:

5/91 - Present	Abbott Pharmaceuticals Chicago, Illinois
7/94 - Present	Glaxo Wellcome London, England
8/97 - Present	Eli Lilly Indianapolis, IN
11/97 - Present	Janssen-Cilag Brussels, Belgium
4/97 – 4/00	Parke Davis/Warner Lambert Ann Arbor, Michigan
4/98 - Present	Robert Wood Johnson Pharmaceutical Research Institute New Jersey
4/99	SmithKline Beecham Pharmaceuticals London, United Kingdom
3/99 - Present	TAP Holdings, Inc. Chicago, Illinois
6/99 - Present	UCB, Pharma Atlanta, Georgia
9/00 – Present	Astra Zeneca New Jersey
5/00 – Present	Novartis New Jersey

7/00	Teva Pharmaceuticals Israel
7/00 – Present	Shire Laboratories, Inc. Rockville, MD
1/01 – Present	Elan Pharmaceuticals

COMMITTEE INVOLVEMENT:

5/00 – 3/01	Behavioral Health Peer Review Committee QualChoice Health Plan, Inc University Hospitals Health System
7/00 – 7/01	Impaired Physicians/Provider Committee University Hospitals of Cleveland
6/92 - Present	Executive Committee Department of Psychiatry University Hospitals of Cleveland
6/92 - Present	Pharmacy and Therapeutics Committee University Hospitals of Cleveland
5/95 – 3/01	Clinical Quality Improvement Committee QualChoice Health Plan, Inc. University Hospitals Health System
5/98 – 3/01	Credentialing Committee QualChoice Health Plan, Inc. University Hospitals Health System
6/97 - Present	Board of Trustees Clinical Neuroscience Research Foundation Department of Psychiatry
6/94 - Present	Board of Trustees University Psychiatrists of Cleveland, Inc. Department of Psychiatry Practice Plan
3/96 – 9/98	Managed Care Contracting Committee University Faculty Practice Association Case Western Reserve University University Hospitals of Cleveland
4/95 – 4/96	Ad Hoc Grant Reviewer Medical Research Council of Canada
5/94 – 7/98	Medical Advisory Council

	QualChoice Health Plan, Inc. University Hospitals Health System
1/90 – 7/92	Chairman, Electroconvulsive Therapy Committee Department of Psychiatry University Hospitals of Cleveland
4/90 – 4/91	Depression Panel, Council on Scientific Affairs American Medical Association Chicago, Illinois
1/90 – 3/93	Education Committee Department of Psychiatry University Hospitals of Cleveland
7/89 – 9/97	Examiner, American of Psychiatry and Neurology Deerfield, Illinois
7/86 – 11/89	Human Research Committee, CNS, Cleveland Clinic Foundation
7/86 – 11/89	Education Committee Department of Psychiatry Cleveland Clinic Foundation

HONORS & AWARDS:

6/93	Annual Staff Teacher of the Year, Department of Psychiatry, CWRU School of Medicine, University Hospitals of Cleveland
9/91	National Young Investigator Research Award, National Depressive and Manic Depressive Association
6/89	Annual Staff Teacher of the Year Award, Department of Psychiatry, Cleveland Clinic Foundation
6/88	Annual Staff Teacher of the Year Award, Department of Psychiatry, Cleveland Clinic Foundation
6/84	Richard M. Steinhilber, M.D. Resident Research Award, Department of Psychiatry, Cleveland Clinic Foundation
6/80	Award for outstanding performance in psychiatry, Ohio State University College of Medicine
6/76	Graduated Summa Cum Laude and with honors in biology and philosophy, Xavier University
7/74	Northeast Ohio Heart Association Medical Student Research Award, Cleveland Clinic Foundation

6/73	Northeast Ohio Heart Association Medical Student Research Award, Cleveland Clinic Foundation
BOARD CERTIFICATION:	Diplomate, American Board of Psychiatry and Neurology, 1989
AFFILIATIONS:	American Psychiatric Association European College of Neuropsychopharmacology (by invitation) Society of Biological Psychiatry International Society for Bipolar Disorders American Medical Association
EDITORIAL BOARDS:	Bipolar Disorder Bipolar Disorders: Reviews and Commentaries
REFEREE FOR JOURNALS:	Acta Psychiatrica Scandinavica American Journal of Psychiatry Annals of Neurology Archives of General Psychiatry Biological Psychiatry Bipolar Disorder –Internat'l Journal Psychiatry & Neuroscience European Neuropsychopharmacology European Psychiatry Family Practice JAMA Journal of Bipolar Disorder Journal of Clinical Psychiatry Journal of Clinical Psychopharmacology Journal of Psychiatric Research International Clinical Psychopharmacology Neurology Neuropsychobiology Neuropsychopharmacology Psychiatry Research Psychosomatic Medicine Psychosomatics Therapeutic Drug Monitoring

RESEARCH

NIMH/FEDERAL FUNDED:

1. Center for Excellence in the Treatment of Bipolar Disorder and Other Serious Mental Illnesses Accompanied by Alcohol/Drug Abuse Across the Life Cycle. PI – Joseph R. Calabrese, M.D., Co-PI – Robert Findling, M.D.

Source:	Health Resources and Services Administration (HRSA), U.S. Dept. HHS
Project Dates:	1/1/02
Total Amount:	$984,488

The primary objective of this project is to fund the start-up costs, as well as ongoing development costs, associated with the development of a research-oriented treatment center for dual diagnosis bipolar disorder across the life cycle.

2. Combination Therapy in Rapid Cycling Bipolar Disorder (R21). PI – Joseph R. Calabrese, M.D.

Source:	R21 (Exploratory/Development Grant) MH-62650
Project Dates:	2/1/2002 – 1/311/2005
Total Award:	$573,750

The primary objective of this study is to compare the efficacy of the triple regimen lithium/divalproex/blinded lamotrigine to lithium/divalproex/placebo in the acute and continuation treatment of patients with rapid cycling bipolar disorder over a six month randomized phase.

3. Double, Longitudinal Evaluation of the Efficacy and Safety of the Combination of Lithium and Depakote Versus Lithium Monotherapy in Rapid-Cycling Bipolar Patients Who Are Abusing Alcohol, Cannabis, and/or Cocaine (RO1-S). PI – Joseph R. Calabrese, M.D.

Source:	R01 MH-50165S (Supplement)
Project Dates:	10/1/97 – 12/01
Contracted Amount:	$674,938

The primary objective of this study is to compare the efficacy of the combination of lithium and divalproex as compared to lithium monotherapy in the prevention of episodes in patients with rapid cycling bipolar disorder who are currently abusing alcohol, cannabis, and/or cocaine.

4. Double-Blind, Longitudinal Evaluation of the Efficacy and Safety of Depakote and Lithium in Rapid-Cycling Bipolar Patients (RO1). PI – Joseph R. Calabrese, M.D.

Source:	R01 MH-50165
Project Dates:	4/95 to 12/01
Contracted Amount:	$1,232,471

The primary objective of this study was to compare the efficacy of lithium monotherapy to divalproex monotherapy in the prevention of episodes in patients with rapid cycling bipolar disorder.

5. Systematic Treatment Enhancement Program (STEP) for Bipolar Disorder - A NIMH multicenter study designed to carry out a series of health effectiveness trials. Site PI – Joseph R. Calabrese, M.D.

Source:	MH-98-DS-001 (subcontract from Mass. Gen'l Hospital)
Project Dates:	8/99 to 3/2004
Contracted Amount:	$628,329

The primary objective of this study is to improve the treatment of bipolar disorder by 1) implementing model practice procedures across a network of clinicians, 2) determine the most effective somatic and psychosocial intervention strategies for the depressed phase of the illness, 3) determine which interventions most effectively prevent relapse, 4) provide a systematic means for the translation of novel treatments into clinician practice, and 5) estimate the costs and quality of life outcomes in both the acute and long-term setting.

6. Pediatric Bipolar Collaborative Mood Stabilizer Trial. Coordinating PI, Robert Kowatch, Site PI, Robert Findling, Senior Advisor/Medical Monitor – Joseph R. Calabrese, M.D. 10%

Source:	R01 MH-60814

Project Dates:	9/00 to 9/04
Contracted Amount:	$1,000,000

The primary objective of this project is to compare the efficacy of lithium, divalproex, and placebo in the acute management of mania and mixed states in children and adolescents with bipolar I disorder to test the hypothesis that divalproex and lithium are equal in efficacy and both are superior to placebo.

7. Clinical Research Center for the Study of Major Psychoses. Co-PI. - Psychopharmacology Core Joseph R. Calabrese, M.D. Herbert Meltzer, M.D. – Center Director

Source:	NIMH
Project Dates:	9/92 to 8/94

FOUNDATION SUPPORT:

1. Multicenter Study of Lithium, Divalproex, and Blinded Lamotrigine versus Lithium, Divalproex, and Placebo in the Acute and Continuation Care of Patients with Rapid Cycling Bipolar Disorder Comorbid with Alcohol, Cannabis, and/or Cocaine Abuse or Dependence– A Two Site Study. Co-PI – Joseph R. Calabrese, M.D.

Source:	Stanley Foundation
Project Dates:	8/00 – 8/02
Contracted Amount:	$800,000

2. Multicenter Study of Lithium, Divalproex, and Blinded Lamotrigine versus Lithium, Divalproex, and Placebo in the Acute and Continuation Care of Patients with Rapid Cycling Bipolar Disorder – A Two Site Study. PI – Joseph R. Calabrese, M.D.

Source:	Stanley Foundation
Project Dates:	8/00 – 8/02
Contracted Amount:	$300,000

3. Pilot Study on the Longitudinal Evaluation of the Efficacy and Safety of Depakote and Lithium in Rapid-Cycling Bipolar Patients. PI – Joseph R. Calabrese, M.D.

Source:	Stanley Foundation
Project Dates:	7/94 - 7/97
Contracted Amount:	$150,000

4. The Stanley Foundation Clinical Research Center (Co-Director with Robert Findling, MD)

   Efficacy of Lithium vs. Divalproex in the Prevention of Recurrence in Bipolar Disorder in Children and Adolescents. Co-PI - Joseph R. Calabrese, M.D.

   Efficacy of Divalproex vs. Placebo in the Prevention of the Syndrome of Bipolar Disorder in Sub-syndromal Children at High-Risk. Co-PI - Joseph R. Calabrese, M.D.

   The Identification of Subsyndromal Mood Disorders in Children at High Risk for Developing Bipolar Disorder. Co-PI - Joseph R. Calabrese, M.D.

Source:	Stanley Foundation

Projected Dates:	7/96 - 7/01
Contracted Amount:	$1,825,000

5. Affective Instability: Quantification, Conceptualization, and Clinical Significance. Co-PI - Joseph R. Calabrese, M.D.

Source:	NARSAD
Projected Dates:	7/94 - 7/96
Contracted Amount:	$60,000/year

PHARMACEUTICAL SUPPORT:

1. An International, Multicenter, Large Simple Trial (LST) to Compare the Cardiovascular Safety of Ziprasidone and Olanzapine. PI – Joseph R. Calabrese, M.D.

Source:	Pfizer
Project Dates:	5/02-5/04
Contracted Amount:	$17,100

2. A Double-Blind, Randomized, Multicenter, Parallel-Dose Study to Evaluate the Efficacy and Safety of Zonisamide 300mg and 600mg/day and Placebo in Subjects with Bipolar 1 Disorder Currently Experiencing a Recurrent Manic or Mixed Episode. PI – Joseph R. Calabrese, M.D.

Source:	Elan
Project Dates:	5/02-5/04
Contracted Amount:	$89,348

3. A double-blind, multicenter, placebo- and active controlled acute and extension study of MK-0869 in the treatment of patients with major depressive disorder with melancholic features. PI – Joseph R. Calabrese, M.D.

Source:	Merck
Project Dates:	10/01 – 2/03
Contracted Amount:	$122,287

4. Olanzapine in Treatment Refractory Mania. PI – Joseph R. Calabrese, M.D.

Source:	Lilly
Project Dates:	5/1/01 – 4/02
Contracted Amount:	$241,000

5. A Double-Blind Placebo Controlled Maintenance Study Comparing the Effectiveness of the SSRIs to Escitalopram in the Prevention of Major Depressive Episodes. PI – Joseph R. Calabrese, M.D.

Source:	Forest Labs
Project Dates:	10/00 – 10/01
Contracted Amount:	$125,000

6. A Double-Blind Controlled Study Comparing Two Doses of Lamotrigine to Placebo in the Treatment of Bipolar I Depression (40910). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome
Project Dates:	11/00 – 11/01
Contracted Amount:	$150,000

7. A Multicenter Study of the Efficacy and Safety of Levetiracetam in Acute Mania in Adults with Bipolar Disorder. PI – Joseph R. Calabrese, M.D.

Source:	UCB Pharma
Project Dates:	11/00 – 11/0
Contracted Amount:	$100,000

8. Phase II Multicenter Randomized Comparison of Three Doses of TAK-637 (a substance P antagonist) Versus Placebo in the Treatment of Subjects with Major Depressive Disorder. Principal Investigator.

Source:	Tap Holdings Inc.
Project Dates:	3/00 – 2/01
Contracted Amount:	$183,880

9. Flexible Dose Comparison of the Safety and Efficacy of Lu 26-054, Citalopram, and Placebo in the Treatment of Major Depression. PI – Joseph R. Calabrese, M.D.

Source:	Forest Laboratories, Inc.
Project Dates:	9/99 – 4/00
Contracted Amount:	$87,800

10. Placebo-Controlled Evaluation of the Safety and Efficacy of Lu 26-054 in the Prevention of Depression Relapse. PI – Joseph R. Calabrese, M.D.

Source:	Forest Laboratories, Inc.
Project Dates:	9/99 – 9/01
Contracted Amount:	$135,558

11. A Multicentre, Double-Blind, Placebo-Controlled, Flexible-Dose Evaluation of the Safety and Efficacy of Lamotrigine in the Long Term Treatment of Patients Who Have Bipolar Disorder With Rapid Cycling (611). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome, Inc.
Projected Dates:	1/99 - 5/99
Contracted Amount:	$80,000

12. A Multicenter, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Lamotrigine Compared to Placebo in the Treatment of an Acute Hospitalized Manic or Mixed Episodes in Patients Who Have Bipolar Disorder (609). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome, Inc.
Projected Dates:	1/99 - 1/2000
Contracted Amount:	$125,000

13. An Open-Label Evaluation of the Efficacy, Safety and Dosing of Citalopram in Outpatients With Depression. PI – Joseph R. Calabrese, M.D.

Source:	Forest Laboratories, Inc.
Projected Dates:	7/98 - 3/99
Contracted Amount:	$30,000

14. Citalopram Treatment of Depressed Patients Discontinued For Paroxetine Adverse Events. PI – Joseph R. Calabrese, M.D.

Source:	Forest Laboratories, Inc.
Projected Dates:	7/98 - 3/99
Contracted Amount:	$30,000

15. Citalopram Treatment of Depressed Patients Discontinued From Fluoxetine For Adverse Events. PI – Joseph R. Calabrese, M.D.

Source:	Forest Laboratories, Inc.
Projected Dates:	7/98 - 3/99
Contracted Amount:	$30,000

16. A Multicentre, Double-Blind, Placebo-Controlled, Fixed-Dose Evaluation of the Safety and Efficacy of Lamotrigine in the Long Term Treatment of Patients Who Have Bipolar I and II Disorder With Rapid Cycling (614). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome, Inc.
Projected Dates:	4/96 - 7/99
Contracted Amount:	$98,028

17. An Open, Multicentre, Flexible-Dose Continuation Study of Lamotrigine in Patients with Bipolar Disorder (604). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome, Inc.
Projected Dates:	6/96 - 7/98
Contracted Amount:	$48,600

18. A Multicentre, Double-Blind, Placebo-Controlled, Randomized, Fixed-Dose Evaluation of the Safety and Efficacy of Lamotrigine in the Long Term Prevention of Relapse and Recurrence of Depression and/or Mania in Patients with Bipolar I Disorder Presenting Depressed (605). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome, Inc.
Projected Dates:	5/97 - 10/99
Contracted Amount:	$192,215

19. A Multicentre, Double-Blind, Double Dummy, Placebo and Lithium-Controlled, Randomized, Fixed-Dose Evaluation of the Safety and Efficacy of Lamotrigine in the Long-Term Prevention of Relapse and Recurrence of Mania and/or Depression in Patients with Bipolar I Disorder Presenting Manic (606). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome, Inc.
Projected Dates:	5/97 - 10/99
Contracted Amount:	$136,771

20. A Double-Blind Controlled Study Comparing Lamotrigine to Placebo in the Treatment of Bipolar I

Depression (602). PI – Joseph R. Calabrese, M.D.

Source:	Glaxo Wellcome, Inc.
Projected Dates:	7/97 - 7/99
Contracted Amount:	$132,070

21. An Open, Multicentre, Prospective Evaluation of the Spectrum of Efficacy of Lamotrigine in Bipolar I and II Disorder (601). PI – Joseph R. Calabrese, M.D.

Source:	Burroughs Wellcome
Project Dates:	12/94 - 12/96
Contracted Amount:	$61,812

22. Olanzapine Added to Mood Stabilizers in the Treatment of Bipolar Disorder. PI – Joseph R. Calabrese, M.D.

Source:	Lilly Research
Project Dates:	9/1/97 - 9/1/99
Contracted Amount:	$226,250

23. Gabapentin Adjunctive Treatment in Patients with Bipolar Disorder. PI – Joseph R. Calabrese, M.D.

Source:	Parke-Davis / Werner Lambert
Projected Dates:	5/96 - 7/97
Contracted Amount:	$62,060

24. Topiramate Pilot, Open-Label Safety and Tolerability Trial in Adults with Acute Mania Protocol. PI – Joseph R. Calabrese, M.D.

Source:	R.W. Johnson Pharmaceutical Research Institute
Projected Dates:	12/96 – 5 /97
Contracted Amount:	$24,706

25. Double-Blind, Placebo-Controlled, Parallel Group, Comparative Study of Venlafaxine and Fluoxetine in Depressed Outpatients to Measure Onset of Clinical Activity. PI – Joseph R. Calabrese, M.D.

Source:	Wyeth Ayerst
Projected Dates:	9/95 - 9/96
Contracted Amount:	$249,102

26. Double-Blind, Longitudinal Evaluation of the Efficacy and Safety of Depakote Versus Lithium and Placebo in Bipolar Disorder. PI – Joseph R. Calabrese, M.D.

Source:	Abbott Laboratories
Project Dates:	5/93 to 4/96
Contracted Amount:	$307,544

27. A Double-Blind, Placebo-Controlled, Comparison of Imipramine and Paroxetine in the Treatment of Bipolar Depression. PI – Joseph R. Calabrese, M.D.

Source:	SmithKline Beecham
Project Dates:	1/94 to 1/95

Contracted Amount: $119,280

28. Amesergide/Fluoxetine/Placebo in Major Depressive Disorder. PI – Joseph R. Calabrese, M.D.

Source:	Lilly Research Laboratories
Project Dates:	4/92 to 12/92
Contracted Amount:	$352,150

29. A Phase II, Multicenter, Randomized, Double-Blind, Dose Finding Study of Three Different Doses of Roxindole vs. Placebo in Outpatient Suffering from Depression. PI – Joseph R. Calabrese, M.D.

Source:	E. Merck
Project Dates:	5/93 to 6/94
Contracted Amount:	$137,525

30. A Pilot Study Evaluating the Safety and Efficacy of Clozapine in the Acute Management of Refractory Bipolar and Schizoaffective Mania. Co-PI - Joseph R. Calabrese, M.D.

Source:	Sandoz Pharmaceuticals
Project Dates:	12/92 to 12/93
Contracted Amount:	$75,250

31. Comparison of the Efficacy and Safety of Depakote and Lithium in the Treatment of the Manic Phase of Bipolar Disorders: A Placebo-Controlled Study. PI – Joseph R. Calabrese, M.D.

Source:	Abbott Laboratories
Project Dates:	8/90 to 5/92
Contracted Amount:	$97,440

32. Safety of Valproate in Manic Patients: A Retrospective Case Study. PI – Joseph R. Calabrese, M.D.

Source:	Abbott Laboratories
Project Dates:	1/92 to 6/92
Contracted Amount:	$45,625

33. Valproate Therapy in Patients Previously Randomized to Depakote in Abbott Study M87-016 or M88-267: A Retrospective Cohort Study. PI – Joseph R. Calabrese, M.D.

Source:	Abbott Laboratories
Project Dates:	3/92 to 7/92
Contracted Amount:	$2,441

34. DSM-IV Rapid-Cycling Study. Co-PI - Joseph R. Calabrese, M.D.

Source:	MacArthur Foundation
Project Dates:	5/91 to 8/91
Contracted Amount:	$1,000

35. A Multicentre, Randomized, Double-Blind, Placebo-Controlled Comparison of Paroxetine and Fluoxetine in the Treatment of Major Depressive Disorder. PI – Joseph R. Calabrese, M.D.

Source: SmithKline Beecham Pharmaceuticals

Project Dates:	**4/91 to 2/92**
Contracted Amount:	**$116,120**

36. Biology of Mania: Mechanism of Action of Mood Stabilizers. PI – Joseph R. Calabrese, M.D.

Source:	Abbott Laboratories
Project Dates:	8/90 to 5/92
Contracted Amount:	$5,000

37. Double-Blind, Placebo-Controlled Trial of Fluoxetine in the Treatment of Borderline Personality Disorder. Co-PI - Joseph R. Calabrese, M.D.

Source:	Lilly Research Laboratories
Project Dates:	9/90 - 12/91
Contracted Amount:	$47,833

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13. **Calabrese JR**, Gulledge AD: Carbamazepine, clonazepam use during pregnancy. Psychosomatics 1986 Jun;27(6):464. Letter.

14. **Calabrese JR**, Skwerer RG, Gulledge AD, Gill CG, Mullen JD, Rodgers DA, Taylor PC, Golding LA, Lytle BW, Cosgrove DM, Bazarel MG, Loop FD: Incidence of postoperative delirium following myocardial revascularization: A prospective study. Cleve Clinic J Med 1987 Jan-Feb;54(1):29-32.

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JOSEPH RICHARD CALABRESE JR.,MD

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Experience of clinical research (number of clinical studies sponsored by the pharmaceutical industry to which the individual has contributed)	26

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Ratings Experience

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Medical Director, Adolescent Sexual Offender Program, Parkwood Behavioral Health System; 2000 - Present

Consulting Psychiatrist, Youth Villages of Memphis; 1999-Present

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American Academy of Child and Adolescent Psychiatry representative to the American Medical Association; 1998-Present

Clinical Assistant Professor, University of Tennessee; 1995-Present

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- Work Group on Quality Issues, 1996-Present
- Committee on Residential Treatment, 1997-Present
- "Catchers in the Rye" Advocacy Award, 1998

American Psychiatric Association

American Medical Association

Memphis and Shelby County Medical Society:

- Board of Directors, 1997-1999
- Nominating Committee, 1998
- Ethics Committee, 2001-Present

American Physicians Art Association

Tennessee Psychiatric Association

Tennessee Medical Society

- Shelby County Medical Society Alternate Delegate, 2001-Present

Publications

"Beauty is Only Name Deep: The Effect of First Name on Rating Physical Attraction" Journal of Applied Social Psychology, Vol. 10:5

Arnold VK, et al, "Fear of Anticipated Disaster in Psychiatric Patients" Journal of the Tennessee Medical Association, Vol. 85:4, April 1992

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"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Depressive Disorders" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 37:1234-1238, 1998 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Language and Learning Disorders" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 37:10, 1998 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Obsessive-Compulsive Disorder" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 37:1110-1116, 1998 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children, Adolescents, and Adults with Autism and Other Pervasive Developmental Disorders" American Academy of Child and Adolescent Psychiatry, Quality Issues

Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 38:1611-1615, 1999 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children, Adolescents, and Adults with Mental Retardation and Comorbid Mental Disorders" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 38:1606-1610, 1999 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents who are Sexually Abusive of Others" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 39:127-130, 2000 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Schizophrenia" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 39:1580-1582, 2000 Supplement

"Practice Parameters for the Assessment and Treatment of Children and Adolescents with Schizophrenia" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 40:7, 2001 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Suicidal Behavior" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 40:495-499, 2001 Supplement

"Practice Parameters for the Assessment and Treatment of ECT" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, In press

"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Stimulant Medications" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 40:1352-1355, 2001 Supplement

"Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Seclusion and Restraint" American Academy of Child and Adolescent Psychiatry, Quality Issues Work Group for Practice Parameters for Assessment and Treatment, Journal of the American Academy of Child and Adolescent Psychiatry, Vol. 40:1356-1358, 2001 Supplement

Presentations

"Fear of Anticipate Disaster in Psychiatric Patient", Annual Meeting of the Southern Association for Research in Psychiatry. Tampa, FL, 1991

"Difference in Self-Reported Fear in PTSD v Panic Patients", Annual Meeting of Southern Association of Research in Psychiatry. Tampa, FL, April 1991

"Reasons Given for Attrition in Inpatient Alcohol and Drug Treatment Program", Poster Session, Annual Scientific Assembly of the Southern Medical Association. Atlanta, GA, November 1991

"Separation Anxiety (Diagnosis and Practice Management)", Teaching Conference, LeBonheur Children's Medical Center, Memphis, TN, April 1992

"Child Asthma and its Relationship to Negative Self-Esteem, Depression and Suicidal Ideation", Annual Meeting of the Southern Association for Research in Psychiatry. Memphis, TN, March 1993

"Protocols for the Use of Psychotropic Medication in Children and Adolescents", Poster Session, Annual Meeting of the Southern Association for Research in Psychiatry. Memphis, TN, March 1993

"The Magic Pill – Why it Doesn't Exist!" National Conference of the American Re-Education Association. Nashville, TN, August 1994

"Child and Adolescent Depression", Public Forum, National Depression Screening Day. Memphis, TN, October 1995

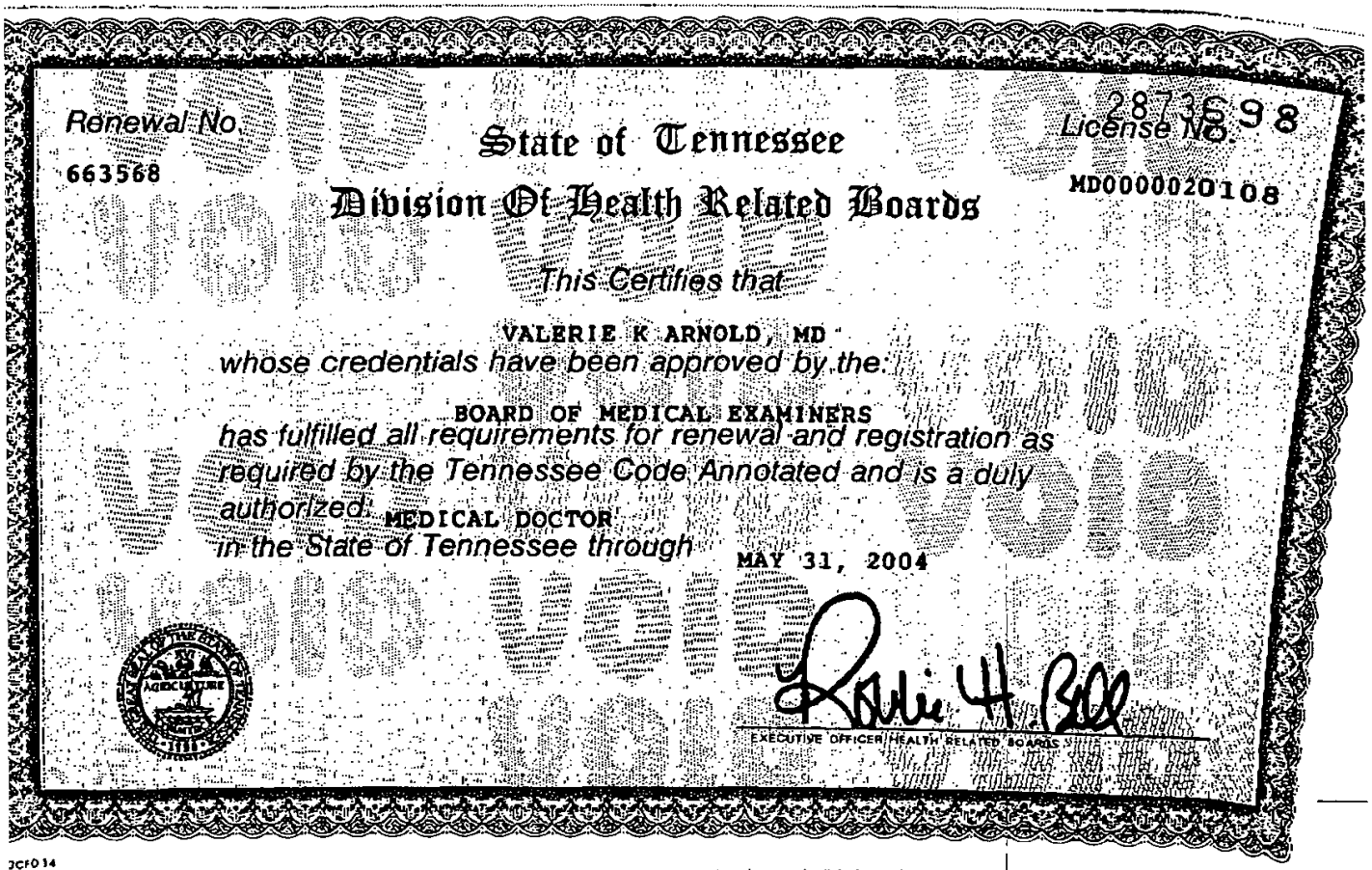
"Survey of Rural Communities Expressed Needs for Emotionally Disturbed Youth", Poster Session, Annual Meeting of the American Academy of Child and Adolescent Psychiatry. New Orleans, LA, October 1995

"Child and Adolescent Depression", Public Forum, National Depression Screening Day. Memphis, TN, October 1996

"Transforming Service Delivery and Public Policy Through Research and Innovation", Workshop, Annual Meeting of the American Academy of Child and Adolescent Psychiatry. Toronto, Canada, October 1997

Presentation of the New Clinical Application of Practice Parameters: Psychiatric Care of Persons with Mental Retardation." Annual Meeting of the American Academy of Child and Adolescent Psychiatry and Annual Meeting of the Canadian Academy of Child Psychiatry, Chicago, 1999

Version Date August 13, 2002



Renewal No.
663568

State of Tennessee

License No.
2736898

Division Of Health Related Boards

MD0000020108

This Certifies that

VALERIE K ARNOLD, MD

whose credentials have been approved by the:

BOARD OF MEDICAL EXAMINERS

has fulfilled all requirements for renewal and registration as required by the Tennessee Code Annotated and is a duly authorized MEDICAL DOCTOR in the State of Tennessee through MAY 31, 2004

EXECUTIVE OFFICER, HEALTH RELATED BOARDS

JCF014

C 9/9/02

Birth	February 4, 1946
Affiliation	**Investigator and Medical Director** Clinical Neuroscience Solutions, Inc. 77 West Underwood Street, Third Floor, Orlando, Florida 32806 10/1998-Present
Education	Lee College, Baytown, TX; Associate of the Arts, 1977 University of Houston, Clear Lake City, TX; Bachelor of Science, 1979 University of Houston, Clear Lake City, TX; Master of Science, 1981 University of Texas at Houston Medical School, Houston, TX; Doctor of Medicine, 1985
Professional Training	University of Florida, Gainesville, Florida; Department of Psychiatry PGY 1 July, 1985-June, 1986 Three months Neurology, One month Psychiatry Consultation Liaison, Two months Alcohol and Drug Rehabilitation, Six months General Medicine PGY 2 July, 1986-June, 1987 Six months Adult Outpatient Psychiatry, Four months Inpatient Psychiatry, GVAMC, Two months Supervision Of Adult Admission Unit North East Florida State Hospital, MacClenny PGY 3 July, 1987-June, 1988 Three months Psychiatry Consultation Liaison, Three months Child and Adolescent Outpatient Psychiatry, Four months Adult Inpatient Psychiatry at Shands Teaching Hospital, Two months Child and Adolescent Inpatient at Shands Teaching Hospital PGY 4 July, 1988-June, 1989 Six months Chief Clinical Resident of Shands Adult Inpatient Unit, Two months Adult Inpatient Psychiatric Unit, Jacksonville Hospital, Two months Geriatric Inpatient/Consultation Liaison Psychiatry GVAMC, Two months Private Practice-Elective
License/ Accreditation	Florida: ME-0048759 American Board of Psychiatry and Neurology, Inc, 1992 Addiction Medicine, 1993

Population Experience	*Children and Adolescents:* 16 years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Mental Retardation, ADHD and Disruptive Behaviors disorders, Tic disorders, Psychotic disorders, Depressive disorders, Bipolar disorders, Anxiety disorders, Somatoform disorders, Eating disorders, Sleep disorders, Impulse-Control disorders, Adjustment disorders, and Personality disorders *Adults:* 16 years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Mental Retardation, ADHD and Disruptive Behaviors disorders, Substance Abuse/ Dependence disorders, Psychotic disorders, Depressive disorders, Bipolar disorders, Anxiety disorders, Somatoform disorders, Eating disorders, Sleep disorders, Impulse-Control disorders, Adjustment disorders, and Personality disorders *Geriatrics:* 16 years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Mental Retardation, ADHD and Disruptive Behaviors disorders, Delirium, Dementia, Substance Abuse/Dependence disorders, Psychotic disorders, Depressive disorders, Bipolar disorders, Anxiety disorders, Somatoform disorders, Eating disorders, Sleep disorders, Impulse-Control disorders, Adjustment disorders, and Personality disorders
Clinical Skills	CPR, ECG interpretation, phlebotomy, physical examinations, and lab interpretations
Ratings Experience	*Diagnostic Evaluations:* SCID, K-SADS, DICA, and MINI *Scales:* ADAS, ADHD rating scale, AIMS, Barnes, BPRS, CIBIC, CGI, CGI-SD, SDI, Conners, Global Assessment Scale, Hachinski Scale, Hamilton Anxiety Rating Scale, Hamilton Depression Scale, MADRS, PANSS (including SCI-PANSS), PDSS, PAAS, Quality of Life Assessment, Resource Utilization, SADS-C, Simpson-Angus, Tourette Rage Attack Questionnaire, Tourette Symptom Importance Test, Y-BOCS, and the Y-MRS
Hospital Appointments	Medical Director, Rational Therapy Center; 1989-2001 Medical Director, Lakewood Residential Treatment Center; 1989-1993 Clinical Director, Getting Well Program; 1991-1994 Clinical Director, Chemical Dependency Treatment, South Seminole Hospital; 1990-1991 Medical Director, MCC (Managed Care); 1993-1995 Medical Director, Orlando Regional Behavioral Health Center, Outpatient Chemical Dependency Treatment Program; 1997-1998 Staff Psychiatrist, Lakeside Alternatives, Day Treatment Program; 1997-1998 Staff Psychiatrist, Seminole Community Mental Health, Outpatient Child and Adolescent Psychiatry; 1997-1999 Staff Psychiatrist, Osceola Community Mental Health, Outpatient Child and Adolescent Psychiatry; 1998-2000

Committee Appointments	Chairman, Utilization Review Committee, South Seminole Hospital; 1990-1992
	Chairman, Quality Assurance Review Committee, South Seminole Hospital; 1990-1992
Educational Conferences	Harvard Medical School: Child and Adolescent Psychopharmacology, 1999 and 2000
	Harvard Medical School: Attention Deficit/ Hyperactivity Disorder, 2001 NCDEU: 2001 NCDEU: 2002 AAPP: Good Clinical Practices, 2001
Version Date	November 1, 2001

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

5077US/0049:0004

DATE	LICENSE NO.	CONTROL NO.
01/29/2002	ME 48759	91328

E MEDICAL DOCTOR
MED BELOW HAS MET ALL REQUIREMENTS OF
E LAWS AND RULES OF THE STATE OF FLORIDA.
PIRATION DATE: **JANUARY 31, 2005**
ARLES EDWARD BAILEY, JR
TN: M. B.
WEST UNDERWOOD STREET
D FLOOR
LANDO, FL 32806

AC# 081653

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/29/2002	ME 48759	91328

THE **MEDICAL DOCTOR**
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.
EXPIRATION DATE: **JANUARY 31, 2005**
CHARLES EDWARD BAILEY, JR

AT LEAST 90 DAYS PRIOR TO TH EXPIRATION DATE SHOWN ON THIS LICENSE, A NOTICE OF RENEWAL WILL BE SENT TO YOUR LAST KNOWN ADDRESS. IF YOU HAVE NOT RECEIVED YOUR NOTICE 60 DAYS PRIOR TO THE EXPIRATION DATE, PLEASE CALL (850) 410-3359.

JEB BUSH
GOVERNOR

JOHN O. AGWUNOBI, M.D., M.B.A.
SECRETARY

DISPLAY IF REQUIRED BY LAW

EXPIRATION DATE: **JANUARY 31, 2005**

OUR LICENSE NUMBER IS **ME 48759** ,PLEASE USE IT IN ALL CORRESPONDENCE WITH YOUR BOARD/COUNCIL. EACH IC[illegible]SEE IS SOLELY RESPONSIBLE FOR NOTIFYING THE DEPARTMENT IN WRITING OF THE LICENSEE'S CURRENT MAILING [illegible]ESS. USE THIS SECTION TO REPORT NAME AND/OR MAILING ADDRESS CHANGES.

[illegible]E CHANGES REQUIRE LEGAL DOCUMENTATION SHOWING THE NAME CHANGE. PLEASE MAKE SURE THAT A PHOTOCOPY OF NE OF THE FOLLOWING ACCOMPANIES THIS FORM: A MARRIAGE LICENSE (MARRIAGE LICENSE MUST INDICATE THE ORIGINAL IGNATURE AND SEAL FROM THE CLERK OF THE COURT), A DIVORCE DECREE INDICATING RESTORATION OF YOUR MAIDEN NAME R A COURT ORDER (E.G., ADOPTION, NAME CHANGE, OR FEDERAL IDENTITY CHANGE). ANY ONE OF THESE WILL BE ACCEPTED NLESS THE DEPARTMENT HAS A QUESTION ABOUT THE AUTHENTICITY OF THE DOCUMENT. **A DRIVER'S LICENSE OR SOCIAI ECURITY CARD IS NOT CONSIDERED LEGAL DOCUMENTATION.**

O REQUEST A DUPLICATE LICENSE SUBMIT THIS FORM AND A CHECK, PAYABLE TO THE DEPARTMENT OF HEALTH, IN THE MOUNT OF $25.00.

☐ REQUEST DUPLICATE LICENSE

SIGNATURE REQUIRED

DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE
LICENSURE SERVICES
4052 BALD CYPRESS WAY, BIN #C-10
TALLAHASSEE, FLORIDA 32399-3260

☐ NAME CHANGE (ATTACH LEGAL DOCUMENTATION)

ROM: _____
LAST FIRST MIDDLE

O: _____
LAST FIRST MIDDLE

☐ MAILING ADDRESS CHANGE

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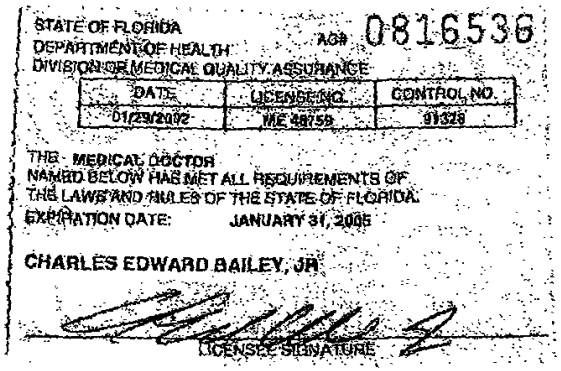

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

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EXPIRATION DATE: JANUARY 31, 2005

CHARLES EDWARD BAILEY, JR

LICENSEE SIGNATURE

507US/0049:0004

RICHARD H. WEISLER, M.D.
2841 Plaza Place
Suite 100
Raleigh, North Carolina 27612

CURRICULUM VITAE
Revised 4-30-02

PERSONAL DATA

NAME:	RICHARD H. WEISLER, M.D.
BORN:	JANUARY 30, 1951, GREENSBORO, NORTH CAROLINA
OFFICE ADDRESS:	2841 PLAZA PLACE SUITE 100 RALEIGH, NORTH CAROLINA 27612 (919) 872-5900
MARITAL STATUS:	MARRIED; THREE CHILDREN
LICENSURE:	Licensed North Carolina Board of Medical Examiners: RI2506 Certification, American Board of Psychiatry: 1982 DEA Registration: AW 807 0346

EDUCATION

Tulane University, New Orleans, Louisiana 1969-1970, 1971-1972
BS Cum Laude with departmental honors with distinction in psychology, minors in economics and chemistry.

University of Glasgow, Glasgow, Scotland 1970-1971
Junior year abroad program. Honors in social psychology and political economy.

University of Nairobi, Nairobi, Kenya, Spring, 1971
Cross-cultural research on future aspirations of children and family structure.

University of North Carolina, Chapel Hill, North Carolina 1973-1976
M.D., Honors senior year

FELLOWSHIPS

U.S. Junior Public Health Fellowship, Summer of 1974.
Worked as assistant to Dr. Sarah Morrow in the Guilford County Health Department.

North Carolina Medical Foundation Scholarship, Spring of 1975.
Worked in Washington, D.C. with Congressman Richardson Preyer and Paul Rogers on Health Subcommittee to draft the Clean Air Act and Health Insurance for the unemployed.

PROFESSIONAL TRAINING & CONTINUING EDUCATION

GCP Training with AAPP, & UNC October 1999.

Regular CME at APA, NCDEU, ACNP, grand rounds and symposiums.

International Pharmaco EEG advanced training course, 1988, Kobe, Japan.

Psychiatry resident, University of North Carolina, Chapel Hill, North Carolina and Dorothea Dix Hospital, January 1977-June 1980

Senior resident, outpatient psychiatry clinic, North Carolina Memorial Hospital, March 1979-February 1980.

Medical internship consisting of four months of in- and out-patient medicine and neurology at Dorothea Dix Hospital and one month of family practice and emergency medicine at New Hanover Hospital in Wilmington, North Carolina.

Coordinated the services of more than thirty residents and thirty psychologists, social workers, and medical students. Co-chaired the multi-disciplinary treatment conference where all referrals and new patients were reviewed and matched for optimal treatment modality and therapist. Co-taught with Roger Spencer, M.D. the yearlong course for second year residents on diagnostic and treatment interviewing. Supervised all medical students and many of the residents on cases.

Senior resident, inpatient psychiatry, North Carolina Memorial Hospital, January 1980-June 1980.

Assist Seymour Halleck, M.D. in running an eighteen-bed acute inpatient ward. Conduct team meetings and supervise all residents, psychology interns, and students.

Consult-liaison psychiatrist for eighteen family practice and eight internal medicine residents at Moses Cone Hospital in Greensboro, North Carolina, 1979-1980.

Supervised by Dr. Morris Lipton on psychopharmacology and treatment, 1978-1980.

Personal psychoanalysis by Dr. Charles Keith, training and supervisory analyst, University of North Carolina-Duke University.

Psychiatric consultant at IBM Medical Unit in the Research Triangle Park, North Carolina, with William Hollister, M.D., 1980.

PROFESSIONAL EXPERIENCE

Regular CME at APA, NCDEU, ACNP, grand rounds and symposiums

Private practice of psychiatry, Raleigh, North Carolina – 1980 to present
As a group, we follow several thousand patients with a mixture of psychiatric problems. We have patients with unipolar and bipolar disorders, generalized anxiety disorders, posttraumatic stress disorder, dementia, obsessive-compulsive disorder, sleep disorders, schizophrenia, and migraines. Ages of patients range from 6 to 92. We also treat patients with drug and/or alcohol abuse.

Attending psychiatrist, Holly Hill Hospital, 3019 Falstaff Road Raleigh, North Carolina 27610 1980-present.

Director of electrophysiology and neuroimaging, Holly Hill Hospital, 3019 Falstaff Road Raleigh, North Carolina, 27610, 1987 to 1998.

Adjunct Associate of Psychiatry, Duke University Medical Center, Durham, North Carolina, 1989 to present.

Adjunct Professor of Psychiatry, UNC School of Medicine, Chapel Hill, North Carolina.

Clinical assistant professor of psychiatry, North Carolina Memorial Hospital, Chapel Hill, North Carolina, 1980 to 1995.
Taught weekly course for psychiatry residents on interviewing diagnostic and treatment skills. 1980-1985: Multiple lectures of anxiety, affective and personality disorders, treatment approaches, community psychiatry, and electroencephalography.

Psychiatric consultant, Wake Medical Center, Raleigh Community Hospital, and Rex Hospital, Raleigh, North Carolina, 1980 to present.

Alcohol and drug rehabilitation consultant, Charter North Ridge Hospital, Raleigh, North Carolina, 1982 to 1990.

Psychiatric consultant, Trentham Mental Health Center, Raleigh, North Carolina, 1980-1981.

Psychiatric consultant, Rockingham County Mental Health Center, Reidsville, North Carolina, 1979- 1980.
Provided diagnostic evaluations, treatment, supervision, and education of the staff.

Emergency room physician, Central Prison Hospital, Raleigh, North Carolina, 1978-1980.

Instructor of psychology, Livingstone College, Salisbury, North Carolina, Fall of 1972.

RESEARCH

PRINCIPAL INVESTIGATOR – A double-blind study of Nefazodone comparing once daily and twice daily dosage: Bristol Myers Squibb, Princeton, New Jersey, 1991 and completed.

PRINCIPAL INVESTIGATOR – A placebo-controlled comparison of Nefazodone and Fluoxetine in elderly patients with major depressive disorder: Bristol Myers Squibb, Princeton, New Jersey 1991 and completed. Protocol # CN 104-056-009.

PRINCIPAL INVESTIGATOR – Study of the safety and efficacy of Bupropion and Trazodone in depressed patients: Burroughs Wellcome Company, Research Triangle Park, and North Carolina 1990-1991.

PRINCIPAL INVESTIGATOR – A multi-center double-blind evaluation of the safety and efficacy of Fluparoxan in the treatment of patients with major depressive disorder: Glaxo Pharmaceuticals, Inc, 1990 and completed.

PRINCIPAL INVESTIGATOR – 36 patient Fluparoxan double-blind study for major depression, Glaxo Pharmaceuticals, Inc. 1989-1990.

PRINCIPAL INVESTIGATOR – 42 patients double-blind study for generalized anxiety disorder, Glaxo Pharmaceuticals, Inc. 1989-1990

PRINCIPAL INVESTIGATOR –Wellbutrin plasma level response study, Burroughs Wellcome Company 1989-1990 Anafranil for obsessive-compulsive disorder, Ciba-Geigy Pharmaceuticals. Study conducted under humanitarian protocol, 1989 and completed.

INVESTIGATOR – Wellbutrin surveillance study, Burroughs Wellcome Company, 1988 and completed.

CO-INVESTIGATOR with Dr. Arthur Prange in two studies assessing thyroid function in generalized anxiety disorder and major depression and its effect on treatment outcome, University of North Carolina at Chapel Hill 1989. Completed

CO-INVESTIGATOR with Dr. Charles Nemeroff and Dr. K. Ranga Krishnan in two studies assessing CRF and neurotransmitter receptor sites in generalized anxiety disorder and major depression, Duke University Medical Center, Durham, North Carolina, 1989. Completed.

HCA GRANT to evaluate the applicability of evoked potentials and computer enhancement of EEG in psychiatric hospitals. 1989, completed.

PRINCIPAL INVESTIGATOR – 48 patient double-blind study for Wellbutrin-Burroughs Wellcome Company, 1987. Study established 300 mg. daily dosage as effective. Study completed.

PRINCIPAL INVESTIGATOR – Prozac humanitarian protocol, Eli Lilly Company 1987. Study completed.

PRINCIPAL INVESTIGATOR – 150 plus patients Wellbutrin humanitarian protocol, Burroughs Wellcome Company, Research Triangle Park, North Carolina 1984-1988. Protocol # 39-A.

PRINCIPAL INVESTIGATOR – A double-blind, placebo-controlled, dose ranging evaluation of Ondansetron vs. Diazepam in the treatment of generalized anxiety disorder – Glaxo Pharmaceuticals, Inc., 1991 and completed. Protocol S3A-210.

PRINCIPAL INVESTIGATOR – A double-blind, placebo-controlled evaluation of an investigational compound vs. placebo in the treatment of generalized anxiety disorder – Ciba-Geigy, 1991 and completed.

PRINCIPAL INVESTIGATOR – A double-blind, placebo-controlled evaluation of an investigational compound vs. Ativan in the treatment of generalized anxiety disorder – Eli Lilly and Company, 1991 and completed.

PRINCIPAL INVESTIGATOR – A double-blind, placebo-controlled evaluation of the safety and efficacy of Ondansetron in the treatment of primary degenerative dementia of the Alzheimer's type – Glaxo Pharmaceuticals, Inc., 1991 and completed. Protocol # S3A-222.

PRINCIPAL INVESTIGATOR – An open-label multi-center non-randomized safety study of Nefazodone in patients with mood disorders – Bristol Myers Squibb Pharmaceuticals, 1992 and completed. Protocol # CN-104-138-009.

PRINCIPAL INVESTIGATOR – A multi–center dose response evaluation of the safety and efficacy of Bupropion HCI sustained-release vs. placebo in depressed outpatients - Burroughs Wellcome Company, 1992 and completed. Protocol #93

PRINCIPAL INVESTIGATOR – A double-blind, placebo-controlled multi-center trial of the safety and efficacy of Buspar in anxious patients with co-existing depressive symptoms – Bristol Myers Squibb Pharmaceuticals, Inc., 1992-1993. Protocol # CN-101-045.

PRINCIPAL INVESTIGATOR – A Multi-Center Trial to Evaluate the Efficacy and Safety of Sertraline in the Treatment of Major Depression – Roerig Pharmaceuticals, 1991-1993. Protocol # R-0198.

PRINCIPAL INVESTIGATOR – Short and long-term discontinuation of Alprazolam in the treatment of panic disorders with agoraphobia –Upjohn Pharmaceuticals, 1992 and completed. Protocol # M2000/0474.

PRINCIPAL INVESTIGATOR – The safety and efficacy of Nefazodone in preventing relapse of patients with major depression – Bristol Myers Squibb Pharmaceuticals, 1992 and completed.

PRINCIPAL INVESTIGATOR – A randomized double-blind, placebo-controlled study of the safety and efficacy of two doses of Ondansetron vs. placebo in the treatment of social phobia – Glaxo pharmaceuticals, inc., 1992 and completed. Protocol # S3A-342.

PRINCIPAL INVESTIGATOR – A placebo-controlled study on Nefazodone vs. placebo in severely depressed inpatients – Bristol Myers Squibb Pharmaceutical Research, 1992 and completed. Protocol # CN-105-101.

PRINCIPAL INVESTIGATOR - A placebo-controlled study of Valnacrone vs. placebo in the treatment of Alzheimer's patients – Hoechst-Roussel Pharmaceutical Company, 1992 and completed. Protocol # HP029-303.

PRINCIPAL INVESTIGATOR – The safety and efficacy of Depakote in the prevention of mania in patients with bipolar disorder – Abbott laboratories, 1993 and completed. Protocol # M92-822.

PRINCIPAL INVESTIGATOR – A multi-center evaluation of the safety and efficacy of two flexible doses of Wellbutrin sustained release vs. placebo in depressed outpatients – Burroughs Wellcome Company, 1993 and completed.

PRINCIPAL INVESTIGATOR – A multi-center evaluation of the safety and efficacy of two flexible doses of Wellbutrin sustained release vs. placebo in depressed outpatients – Burroughs Wellcome Company, 1993 and completed.

PRINCIPAL INVESTIGATOR – The safety and efficacy of 12.5 and 25 mg. of Sumatriptan suppositories in acute treatment of multiple migraine attacks – Glaxo Pharmaceuticals, 1993 and completed. Protocol # S2B-353.

PRINCIPAL INVESTIGATOR – Double-blind study of Sertraline vs. placebo in the treatment of patients with panic disorder – Pfizer Pharmaceuticals, 1994 and completed. Protocol # 93-CE21-0629-030.

PRINCIPAL INVESTIGATOR – One year open label extension study of Sertraline followed by a double-blind comparison of Sertraline and placebo in outpatients with panic disorder – Pfizer Pharmaceuticals, 1994 and completed. Protocol #1803-95-12R2.

PRINCIPAL INVESTIGATOR – Clinical evaluation of extended-release oral Physostigmine in the treatment of patients with dementia of the Alzheimer's type – Forest Laboratories, Inc., 1994 and completed. Protocol # 1028B

PRINCIPAL INVESTIGATOR – One-year open label extension study of extended release oral Physostigmine in the treatment of patients with dementia of the Alzheimer's type – Forest laboratories, inc., 1995 and completed. 1995: Collaboration with Duke University Medical Center, Dr. K. Ranga Krishnan and Dr. Jonathan R. T. Davidson for the purpose of sharing research projects.

PRINCIPAL INVESTIGATOR – A prospective, multi-center, open-label study of Serzone (Nefazodone) in the management of patients with symptoms of depression in general psychiatric practices – Bristol Myers Squibb Pharmaceuticals, Inc., 1994 and completed.

PRINCIPAL INVESTIGATOR – Fluoxetine in depressed patients who failed Sertraline – Eli Lilly laboratories, 1994 and completed. Protocol # B1Y-MC-HCHF.

PRINCIPAL INVESTIGATOR – A double-blind comparison of Sertraline and placebo in outpatients with post-traumatic stress disorder – Pfizer Pharmaceuticals, 1994 and completed. Protocol # 93-CE21-0640-0641.

PRINCIPAL INVESTIGATOR –Double-blind, placebo-controlled fixed dose evaluation of the safety and efficacy of oral Ondansetron in the treatment of patients with panic disorder – Glaxo Pharmaceuticals, 1994 and completed. Protocol # S3AA-3009.

PRINCIPAL INVESTIGATOR – Open-label study of oral Ondansetron in the treatment of patients with panic disorder – an additional 18-month study for patients who completed the initial double-blind study – 1995 and completed.

PRINCIPAL INVESTIGATOR – Venlafaxine-ER in the treatment of adult patients with major depressive illness – Wyeth Ayerst Research, 1994 and completed. Protocol # 0600-B-209-US.

PRINCIPAL INVESTIGATOR – Venlafaxine-ER in the treatment of adult patients with generalized anxiety disorder – Wyeth Ayerst Research, 1995 and completed. Protocol # 0600-B-210-US.

PRINCIPAL INVESTIGATOR – A phase III, 14 day, multi-center, randomized, double-blind, comparative, placebo-controlled, parallel group, safety, tolerance, and efficacy study of 5 mg and 10 mg of CL 284,846 (Zaleplon), compared with 5 mg of Zolpidem in

elderly patients with insomnia, with a 12 month open-label extension phase. Wyeth Ayerst. Protocol # W-AR 897A1-306-US (formerly ACY D79-22). 1995.

PRINCIPAL INVESTIGATOR – A double-blind study of Valproate vs. Lithium in the treatment of patients with bipolar disorder – Abbot laboratories, 1994 and completed. Protocol # M93-111.

PRINCIPAL INVESTIGATOR – A double-blind study of Nefazodone vs. placebo, qd and bid dosing – Bristol Myers Squibb, 1994 and completed.

CO-INVESTIGATOR – An open-label pilot study of Fluvoxamine in the treatment of patients with posttraumatic stress disorder – Upjohn/Solvay Pharmaceuticals, 1995 and completed. Protocol # 114-8-25.

CO-INVESTIGATOR – A comparison study of Flesinoxan vs. Buspirone vs. placebo in the treatment of generalized anxiety disorder – Solvay pharmaceuticals, 1995, completed. Protocol # 128-2-07.

CO-INVESTIGATOR – A double-blind study of Gabapentin vs. placebo in the treatment of patients with social phobia – Parke Davis Pharmaceuticals, 1996, completed. Protocol # 945-203.

CO-INVESTIGATOR – A double-blind study of E2020 vs. placebo in the treatment of primary dementia of the Alzheimer's type – Pfizer Pharmaceuticals, 1996, completed.

PRINCIPAL CO-INVESTIGATOR – An open-label study of ENA713, dose titration study in the treatment of primary dementia of the Alzheimer's type - Sandoz Pharmaceuticals, 1996, completed.

PRINCIPAL INVESTIGATOR – An open-label pilot study of Nefazodone in posttraumatic stress disorder – Bristol Myers Squibb Pharmaceutical Company 1996, completed. Protocol # CN104-138-009.

PRINCIPAL INVESTIGATOR – A comparison study of Pindalol vs. Prozac in the treatment of major depression in adults – Eli Lilly Pharmaceuticals, 1996, completed.

PRINCIPAL INVESTIGATOR – A double-blind study of Lamictal in the treatment of bipolar patients in depressed phase – Glaxo Wellcome, Inc., 1996, completed. Protocol # 105-602.

PRINCIPAL INVESTIGATOR – One-year open label extension study of Lamictal in the treatment of bipolar patients in depressed phase – Glaxo Wellcome inc., 1996, completed. Protocol # 105-604.

PRINCIPAL INVESTIGATOR – Clinical trial of Paroxetine in the treatment of patients with panic disorder – Smithkline Beecham, Inc. October 1996 and completed. Protocol # 29060-495.

PRINCIPAL INVESTIGATOR – A twenty-four week, double-blind, placebo-controlled multi-center study to evaluate the efficacy and safety of Sertraline in outpatients with major depression following recent myocardial infarction. Pfizer Pharmaceuticals, 1996, completed. Protocol # 96-R-0052

CO-INVESTIGATOR – with Dr. Eileen P. Ahearn, M.D., Ph.D. in genetic research of bipolar patients and their families – 1997, completed.

CO-INVESTIGATOR – with Ranga Krishnan, M.D. and Bernard Carroll, M.D. in the NIH study of late life depression 1997 and in progress.

PRINCIPAL INVESTIGATOR – Double-blind study of Serzone in the treatment of panic disorder - Bristol Myers Squibb Pharmaceutical, 1997, completed.

PRINCIPAL INVESTIGATOR – Double-blind study of Olanzapine in addition to Lithium or Valproate in the treatment of bipolar disorder – Eli Lilly and Company, 1997, completed.

PRINCIPAL INVESTIGATOR – A ten week, double-blind, placebo-controlled multi-center study to evaluate the efficacy and safety of oral CP-93,393-1 in outpatients with generalized anxiety disorder 129-110-568 – Pfizer, 1997.

PRINCIPAL INVESTIGATOR – Double-blind study of Zoloft in the treatment of depression in elderly adults – Pfizer Pharmaceuticals 1997, completed.

PRINCIPAL INVESTIGATOR – Double-blind study of an investigational compound for the treatment of depression in the adult population – Sanofi Pharmaceuticals 1997, completed. Protocol # DRI 2412.

PRINCIPAL INVESTIGATOR – with Dr. Jonathan R. T. Davidson – open label study of Remeron in the treatment of adults with posttraumatic stress disorder – Organon Pharmaceuticals 1997, completed. Protocol # WIRB 9070440.

PRINCIPAL INVESTIGATOR – Double-blind study of the use of Ziprasidone in the use of patients with mania – Pfizer Pharmaceuticals, 1998 and in progress.

PRINCIPAL INVESTIGATOR – Clinical trial of an investigational compound for treatment of patients with susceptibility for Alzheimer's disease – Merck Pharmaceuticals 1998 and in progress.

PRINCIPAL INVESTIGATOR – Clinical trial of Olanzapine or placebo in the treatment of patients with bipolar disorder – inpatient trial – Eli Lilly and Company 1997 and in progress.

CO-INVESTIGATOR – Six-month open label treatment with Fluoxetine followed by randomization to Fluoxetine or Placebo for patients with posttraumatic stress disorder, 1997 and in progress. NIMH grant with Dr. Jonathan R. T. Davidson.

PRINCIPAL INVESTIGATOR – Clinical trial of Depakote CR in the treatment of inpatients with bipolar disorder – Abbott Laboratories 1998, completed.

PRINCIPAL INVESTIGATOR – Randomized double-blind, placebo-controlled clinical trial of an investigative compound for the treatment of major depression in adults – Merck Germany, 1998, completed. Protocol # 68-843-009.

PRINCIPAL INVESTIGATOR – Placebo-controlled clinical trial of Gabapentin in the treatment of inpatients with mania – Parke Davis Research, 1999, completed.

CO-PRINCIPAL INVESTIGATOR – with Duke University for trial of Hypericum in adults with major depression sponsored by NIH. 1999 completed. Protocol # R-0552.

PRINCIPAL INVESTIGATOR – Placebo-controlled trial of Paroxetine for the treatment of generalized anxiety disorder in adults, Smithkline Beecham research. 1999 completed.

PRINCIPAL INVESTIGATOR – Long-term open-label treatment of Major Depression with R-Fluoxetine Hydrochloride for evaluation of safety, Eli Lilly and Company, 1999 and completed.

PRINCIPAL INVESTIGATOR - R-Fluoxetine versus Placebo in the treatment of generalized anxiety disorder, Eli Lilly and Company, 1999 and completed. Protocol # H5Z-MC-LUAH WIRB 99080.

PRINCIPAL INVESTIGATOR – Randomized, double-blind study with Olanzapine added to mood stabilizers in the treatment of bipolar disorder, Lilly, 1999 and completed. Protocol # F1D-MC-HGFU.

PRINCIPAL INVESTIGATOR – Randomized, double-blind, placebo-controlled multi-center trial to demonstrate the clinical efficacy and safety of two different doses of Ginkgo biloba special extract Egb 761 in patients suffering from dementia of the alzheimer's type according to DSM-IV and NINCDS / ADRDA criteria, Schwabe, 1999 and completed. Protocol # 523001.01.030.

PRINCIPAL INVESTIGATOR – A three-week, multi-center, randomized, double-blind, placebo-controlled, parallel-group safety and efficacy study of Extended-Release Carbamazepine in patients with bipolar disorder, Shire Laboratories, 1999 in progress. Protocol # 150-301.

PRINCIPAL INVESTIGATOR – A three-week, multi-center, randomized, double-blind, placebo-controlled, parallel-group safety and efficacy study of Extended-Release Carbamazepine in Lithium-Failure patients with bipolar disorder, Shire Laboratories, 1999 and completed. Protocol #105-302.

PRINCIPAL INVESTIGATOR – A six-month, open-label, multi-center study of Extended-Release Carbamazepine in patients with bipolar disorder – An extension of Protocols 105.301 and 105.302, Shire Laboratories, 1999, in progress. Protocol # 105-303.

PRINCIPAL INVESTIGATOR – A multi-center, randomized, double-blind, placebo controlled study of Aripiprazole in the maintenance treatment of patients with bipolar disorder – Bristol Myers Squibb, 2000, in progress. Protocol # CN 138-010.

PRINCIPAL INVESTIGATOR – Safety and efficacy of Depakote as combination therapy in the treatment of psychosis associated with schizophrenia – Abbott Laboratories, 2000 and completed. Protocol # M99-010 WIRB 991080.

PRINCIPAL INVESTIGATOR – A multi-center, randomized, double-blind, placebo controlled study of flexible doses of Aripiprazole in the treatment of hospitalized patients with acute mania – Bristol Myers Squibb, 2000, in progress. Protocol # CN-138-009.

PRINCIPAL INVESTIGATOR – A multi-center, randomized, double-blind safety and tolerability study of flexible doses of Aripiprazole and Olanzapine in the treatment of patients with acute schizophrenia, Bristol Myers Squibb, 2000 in progress. Protocol #138-002. Amendment 4.

PRINCIPAL INVESTIGATOR – With Eileen P. Ahearn, M.D., Ph.D. of genetic research of psychiatric illness sponsored by Richard H. Weisler, M.D., 2000 and completed. National Association for Research in Schizophrenia and Depression grant.

PRINCIPAL INVESTIGATOR – A study of Mirtazapine in the treatment of posttraumatic stress disorder, Duke University Medical Center/NIH, 2000 in progress.

PRINCIPAL INVESTIGATOR – A multi-center, double-blind, placebo-controlled, fixed-dose evaluation of the safety, efficacy, and tolerability of Lamictal (Lamotrigine) in the treatment of a major depressive episode in patients with type I bipolar disorder, Glaxo Wellcome, Inc., 2000 in progress. Protocol # SCA40910.

PRINCIPAL INVESTIGATOR – A double-blind, placebo-controlled, comparative efficacy study of Venlafaxine ER and Sertraline in producing remission in outpatients with major depressive disorder, Wyeth Ayerst Research, 2000 in progress. Protocol # 0600B1-414-US.

PRINCIPAL INVESTIGATOR – The efficacy and safety of flexible dosage ranges of Risperidone vs. Placebo in the treatment of manic episodes associated with bipolar I disorder, Janssen Pharmaceutica Products, L.P., 2000 in progress. Protocol # RIS-USA-239.

PRINCIPAL INVESTIGATOR – A nine-week, open label, multi-center, safety study of single dosage ranges of Risperidone in the treatment of manic episodes associated with bipolar I disorder, Janssen Pharmaceutica Products, L.P., 2000 in progress. Protocol #RIS-INT-81.

PRINCIPAL INVESTIGATOR – A multi-center, double-blind, randomized, placebo-controlled trial of the safety and efficacy of Seroquel (Quetiapine Fumarate) as add-on therapy with Lithium or Divalproex in the treatment of acute mania, AstraZeneca Pharmaceuticals LP, 2000 in progress. Protocol # 5077IL/0099 WIRB 20001003.

PRINCIPAL INVESTIGATOR – An open-label randomized assessment of the efficacy and tolerability of Venlafaxine Extended Release in Serotonin-Selective Reuptake Inhibitor (SSRI)-Failure patients with major depression, Wyeth Ayerst Laboratories, 2000 in progress. Protocol # 0600B1-915.

PRINCIPAL INVESTIGATOR – Granisetron for the treatment of Paroxetine-associated sexual dysfunction in men: A preliminary open trial, SmithKline Beecham, 2000 and completed. Protocol # 29060/731

PRINCIPAL INVESTIGATOR – Phase II multi-center, randomized comparison of TAK-637 versus Placebo in the treatment of subjects with major depressive disorder, TAP Pharmaceutical Products Inc., 2000 and completed. Protocol # TAK-637-99-301.

PRINCIPAL INVESTIGATOR – Open label long-term safety study of Venlafaxine ER in children and adolescents with major depressive disorder, Wyeth Ayerst Research, 2000 in progress. Protocol # 0600B1-395-US.

PRINCIPAL INVESTIGATOR – Double-blind, placebo-controlled study of Venlafaxine ER in children and adolescents with generalized anxiety disorder, 2000 in progress. Protocol # 0600B2-397-US.

PRINCIPAL INVESTIGATOR – A double-blind, placebo-controlled, parallel-group, flexible-dose study of Venlafaxine ER in adolescent outpatients with social anxiety disorder, Wyeth Ayerst Research, 2000 in progress. Protocol # 0600B4-389-US.

PRINCIPAL INVESTIGATOR – A double-blind study, placebo-controlled study of a flexible dose of Venlafaxine ER in adult outpatients with generalized anxiety disorder, Wyeth Ayerst Research, 2000 and completed.

PRINCIPAL INVESTIGATOR – A double-blind, multi-center, acute study of two doses of L-830982 versus Lorazepam and Placebo in the treatment of outpatients with

generalized anxiety disorder, Merck & Company, 2000 and completed. Protocol # 066-01 WIRB 20001446.

PRINCIPAL INVESTIGATOR – An open-label study of the safety, tolerability, and efficacy of up to 90 mg Buspirone Hydrochloride Extended Release in patients with generalized anxiety disorder, Biovail Laboratories, 2000 & 2001 and completed. Protocol #B99.CT0L.008.BUS.P02.

PRINCIPAL INVESTIGATOR – Duloxetine once-daily dosing versus placebo in the acute treatment of major depression, Eli Lilly and Company, 2000 and completed. Protocol No F-15-MC-HMBH.

PRINCIPAL INVESTIGATOR – Genetic Research Study of Psychiatric Illness, sponsored -Richard H. Weisler, M.D.. Protocol No: WIRB 9990472, 2000.

OFFICES HELD AND HONORS AWARDED

UNC Psychiatry Department/ Board of Visitors 2000 and continuing.

National Depressive and Manic-Depressive Board of Scientific Advisors

President, Medical staff – Holly Hill Hospital, Raleigh, North Carolina, 1986-1987.

Chairman, Department of Psychiatry – Wake Medical Center, Raleigh, North Carolina, 1986-1987.

Vice-President, Medical staff – Holly Hill Hospital, Raleigh, North Carolina, 1984.

Secretary, Medical staff – Holly Hill Hospital, Raleigh, North Carolina, 1984.

Secretary, Raleigh Academy of Psychiatry, 1982-1983.

Member, Wake Medical Education Foundation Board of Directors, 1986 – present.

Member, Medical Executive Committee, Holly Hill Hospital, 1981-1989.

Member, Scientific Board of Advisors, North Carolina Depressive and Manic-Depressive Association, 1994 –present.

Member, Medical Executive Committee, Wake Medical Center, 1986-1987.

Outstanding Teacher Award, University of North Carolina, Department of Psychiatry, Chapel Hill, North Carolina, 1982.

Member, International Who's Who in Medicine.

Member, Triangle Area Who's Who in Medicine

PRESENTATIONS AND WORKSHOPS

1977- Present – Presented over 700 invited lectures, grand rounds, and case conferences, nationally and internationally. Lectures include discussion on bipolar disorders, major depressive episodes, anxiety disorders, genetics of psychiatric disorders, sleep disorders, attention deficit disorders, smoking cessation, psychosis, and managed care, with emphasis on pharmacotherapy, diagnosis and treatment. Other topics include psychotherapy for borderline personality disorders, cognitive therapy, and research updates.

National Speakers Bureau – Glaxo Smith Kline, Bristol Myers Squibb Pharmaceuticals, Pfizer Pharmaceuticals, Abbott Laboratories, Organon Pharmaceuticals, Solvay Pharmaceuticals, Eli Lilly and Company, Wyeth Ayerst, Forrest Laboratories, Marketing Consultant and/or Scientific Consultant – Training of Pharmaceutical Representatives and Marketing Departments – Glaxo Smith Kline, Burroughs Wellcome Company, Upjohn Pharmaceuticals, Wyeth Ayerst Research, Bristol Myers Squibb, Smith Kline Beecham Pharmaceuticals, and Eli Lilly and Company, Organon, and Glaxo Wellcome Pharmaceuticals.

1972 Honors Thesis – Tulane University, "Role Relevant Skills Variable as a Predictor of Hypnotic Susceptibility"

1980 Stress Management Workshop, IBM Management, with William Hollister, M.D.

1988 Present – Local and National Public Radio and Television Appearances for discussion of depressive and anxiety disorder, pharmacotherapy, and environmental medicine.

POSTERS

1996 Managed Care Article in Psychiatric Times.
MRI Article co-authored with Dr. Eileen P. Ahearn.
Wyeth Ayerst Research Article on Use of Effexor in Generalized Anxiety.
POSTER: Venlafaxine XR for Use in Major Depressive Episodes.
POSTER: Open Label Fluoxamine in PTSD – NCDEU.

1997 POSTER: "Double-Blind Comparison of Sertraline and Placebo in Patients with Post Traumatic Stress Disorder (PTSD)" – Co-authored with Jonathan Davidson, M.D., Peter Londborg, Teri Pearlstein, Carolyn Sikes, Gail Farfel. Presented in December 1997 at the American College of Neuropharmacology Meeting, Kanuela, Hawaii.

1997 North Carolina Depressive and Manic-Depressive Association – Brochure for Teens about Depressive Illness entitled "Sometimes It Isn't Easy" Abstract, ACNP.

1998 POSTER ABSTRACT: "Cost Effectiveness of Divalproex Sodium vs. Lithium in Long-Term Therapy for Bipolar Disorder". Presented at ACNP 1998 Annual Meeting.

1998 POSTER ABSTRACT: " Lamotrigine: Evidence for Antidepressant Activity in Bipolar Disorder". Co-authored with J Apter, J Downs, D Goldstein, I Kolin, B. Lydiard, S McElroy, D Rudd, T. Shiovitz, T Suppes, H Udelman, C Zarate.

1999 Poster presentation at ACNP Meeting in Puerto Rico -"A Pilot Study of Mirtazapine in Post traumatic Stress Disorder". Paper submitted.

ABSTRACTS

1992 "Treatment Strategies for Lithium-Resistant Bipolar Depression" Presented at the symposium management of patients who are non-responders to or non-tolerators of initial antidepressant therapy –McLean, Virginia Journal of Clinical Psychiatry.

1994 ABSTRACT: "Use of Lamotrigine in the Treatment of Bipolar Disorder": Presented at the Annual Meeting for the American Psychiatric Association held in Philadelphia, Pennsylvania in May, 1994. Initial report of Lamotrigine use in Bipolar Disorder.

1997 "A Placebo-Controlled Study of Gabapentin in Social Phobia" – Paper co-authored with Atul Pande, Jonathan Davidson, J. Greist, J. Jefferson, S. Sutherland Paper. Submitted.

1999 "A Double-Blind Placebo-Controlled Study of Lamotrigine Monotherapy in Outpatients with Bipolar I Depression" – Results of this trial published in the Journal of Clinical Psychiatry February 1999.

1999 ABSTRACT: "Pregabalin, A Novel Agent in the Treatment of Generalized Anxiety Disorder: A Placebo-Controlled Trial" ACNP Meeting Poster 2000. Co-authored wit AC Pande, J Crockatt, DE Feltner, CA Janney, WT Smith, PD Londborg, RJ Bielski, DL Zimbroff, JT Davidson, ML Dumaw.

1999 ABSTRACT: "Time to Onset of Antidepressant Action with Venlafaxine: Analysis of Data". Submitted to Journal of Clinical Psychopharmacology. Co-authored with R. Entsuah, K Rickels, WT Smith, L. Aguiar.

2000 ABSTRACT: "Investigation of Notch3 as a Candidate Gene for Bipolar Disorder Using Brain Hyperintensities as an Endophenotype". Co-authored with EP Ahearn, MC Speer, YT Chen, DC Steffens, F Cassidy, S VanMeter, JM Provenzale, KR Krishnan.

2000 ABSTRACT: "A Comparison of the Safety and Efficacy of Divalproex Sodium and Olanzapine in the Treatment of Bipolar Disorder". Coauthored J Zajecka, J Davidson, KW Sommerville, G Sachs, A Swann, P Wozniak. ACNP Meeting.

PUBLICATIONS

1990 "A Fixed Dose (300 mg) Efficacy Study of Bupropion and Placebo in Depressed Outpatients. Co-authored with CG Lineberry, JA Johnston, RN Raymond, JS Carman, WF Boyer, Burroughs Wellcome Company. The Journal of Clinical Psychopharmacology, May 1990, 51 (5) p194-9.

1991 "A 102-Center Prospective Study of Seizure in Association with Bupropion". Collaboration with JA Johnston, CG Lineberry, JA Ascher, J Davidson, MA Khayrallah, JP Feighner, P. Stark, Burroughs. Burroughs Wellcome Company. The Journal of Clinical Psychiatry, Nov 1991, 52 (11): 450-6.

"Roundtable Discussion Comparing Currently Available Antidepressants and an Ideal Antidepressant, "The Journal of Clinical Psychiatry Evolving Standards of Antidepressant Therapy-Monograph Series: May, 1991, Vol. 9, No. 1.

"A Profile of Bupropion: A Nonserotonergic Alternative, "The Journal of Clinical Psychiatry Monograph Series: May, 1991, Vol. . 9, No. 1."

1992 "Treatment Strategies for Lithium-Resistant Bipolar Depression", Journal of Clinical Psychiatry Monograph, May 1992 10 (1) p27-32.

1994 "Comparison of Bupropion and Trazodone for the Treatment of Major Depression": Journal of Clinical Psychopharmacology, June 1994, 14 (3) p170-9. Coauthored with JA Johnston, CG Lineberry, B Samara, RJ Branconnier, AA Billow.

1994 "Efficacy of Buspirone in Generalized Anxiety Disorder with Co-existing Depressive Symptoms": Journal of Clinical Psychiatry, (United States) July 1996 57 (7) p287-91. Co-authored with JJ Sramek, M Tansman, A Suri, M Hornig-Rohan, JD Amsterdam, Stahl.

1995 "Economic Evaluation of Drug Treatment for Psychiatric Disorders: The New Clinical Trial Protocol" Co-authored with GA Zarkin, HG Grabowski, J Mauskopf and HA Bannerman. Psychopharmacology: The Fourth Generation of Progress 1995, p1897-1905.

1996 "Understanding and Treating Mania and Depression in Bipolar Disorder" Case Study, Primary Psychiatry, June 1996.

1996 "Treatment of Post Traumatic Stress Disorder with Nefazodone", In Press International Clinical Psychopharmacology (England), May 1998, 13 (3) p111-3 – Co-Authored with Jonathan Davidson M.D., Mary Malik, Ph.D., Kathryn M. Connor, M.D

1997 "Adjunctive Use of Olanzapine in Mood disorders: 5 Case Reports" Written in collaboration with Eileen P. Ahearn, M.D., Ph.D., Jonathan R. T. Davidson, M.D., and Charles D. Wallace, M.D. Annals of Clinical Psychiatry (United States). Dec1997, 9 (4) p259-62.

1997 Presented at the American Psychiatric Association: "Efficacy of Once-Daily Venlafaxine Extended Release (XR) for Symptoms of Anxiety in Depressed Outpatients " Written by John Feighner, M.D. with research conducted by Richard H. Weisler, M.D. and other. Submitted.

1997 "Efficacy and Tolerability of Once-Daily Venlafaxine Extended Release (XR) in Outpatients with Major Depression – Journal of Clinical Psychiatry, 58:9, September 1997. Michael Thase for the Venlafaxine XR 209 Study Group.

1997 "Fluoxetine Treatment of Patients With Major Depressive Disorder Who Failed Initial Treatment With Sertraline". Co-authored by Michael E. Thase, M.D., Sharon Blomgren, M.D., Martin A. Birkett, Jerry T. Apter, M.D., Rosalinda G. Tepner. Journal of Clinical Psychiatry 1997; 58:16-21.

1998 "Fluvoxamine in Civilians with Post Traumatic Stress Disorder. Written in collaboration with Jonathan R. T. Davidson, M.D., Mary Malik, Ph.D., Larry A. Tupler, Ph.D. Journal of Clinical Psychopharmacology (United States), Vol. 18 (1) p93-5, February 1998.

1998 "Familial Leukoencephalopathy in Bipolar Disorder" – Submitted to American Journal of Psychiatry (United States) 155 (11) p1605-7, November 1998. Written by Eileen P. Ahearn, M.D., Ph.D. in collaboration with David C. Steffens, M.D., Frederick Cassidy, M.D., Susan A. Van Meter, M.D., James M. Provenzale, M.D., Michael F. Seldin, M.D., Ph.D., and K. Ranga Rama Krishnan, M.D. Study conducted in conjunction with Eileen P. Ahearn, M.D., Ph.D., K. Ranga Rama Krishnan, M.D. and others from Duke UniversityMedical Center, Dept of Psychiatry and Behavioral Sciences, and the Dept. of Medicine, Division of Molecular Medicine and Human Genetics of the University Of California.

1998 "Successful Outcome Following Long Term Lamotrigine Treatment of Severe Bipolar Disorder": 3 case reports – Submitted to the Annals of Psychiatry.

Written in collaboration with Jonathan R.T. Davidson M.D., Eileen P. Ahearn, M.D., Ph.D. and Charles D. Wallace, M.D

1998 "Psychometric Properties of the Social Phobia Inventory (SPIN)": A New Self-Rating Scale. The British Journal of Psychiatry, London, United Kingdom. Co-authored with Kathryn Connor, M.D, Jonathan Davidson, M.D. Andrew Sherwood, Ph.D., Erik Churchhill, Andrew Sherwood, Edna Foa, Atul Pande, Brinda Wita, and Larry Tupler, April 2000, 176 p379-86.

1998 "A Double-Blind Placebo-Controlled Study of Lamotrigine Monotherapy in Outpatients with Bipolar I Depression " in collaboration with J.R. Calabrese, M.D. C. L. Bowden, M.D. G. S. Sachs M.D., J. A. Ascher; M.D. E. Monaghan; G. D. Rudd; MS PharmD for the Lamictal 602 Study Group – Presented in part at the 1999 Annual Meeting of the American Psychiatric Association.

1998 Draft manuscript of the Physostigmine Study 1028 – "A 24-Week Randomized Trial of Controlled-Release Physostigmine in Alzheimer's Disease" with Dr. Leon J. Thal and the Physostigmine Study Group.

1998 "Outcome Update: A Comparative Cost-Effectiveness Study of Depakote and Usual Care Versus Lithium and Usual Care in the Treatment of Bipolar Disorder (Abbott Study M93-111)". Co-authored with DA Revicki, RM Hirschfeld, PE Keck, EP Ahearn.

1999 "Safety Profile of Sustained-Release Bupropion in Depression: Results of Three Clinical Trials. In collaboration with EC Settle, SM Stahl, SR Batey, JA Johnston, JA Ascher. Clinical Therapy. March 1999, 21 (3): p454-63.

1999 "Treatment of Social Phobia with Gabapentin: Placebo-Controlled Study" (United States), Aug 1999, 19 (4) p341-8. Journal of Clinical Psychopharmacology.

1999 "Social Phobia: Issues in Assessment and Management" Epilepsia Vol. 40, Suppl. 6 1999. in collaboration with Kathryn M. Conner, M.D., Jonathan R. T. Davidson, M.D., Suzanne Sutherland, M.D.

1999 "Nefazodone in Post-Traumatic Stress Disorder: Results from Six Open-Label Trials". Co-authored with R. Hidalgo, M. A. Hertzberg, T. Mellman, F. Petty, P. Tucker, S. Zisook, S. Chen, E. Churchill and J. Davidson. Lippincott, Williams, & Wilkins Publishers. – International Clinical Psychopharmacology, Vol. 14., No. 2 March 1999.

1999 "Alternative Therapy Use by Psychiatric Outpatients" – Research report for publication in the Journal of Nervous and Mental Disease, Vol. 187, No. 11. p692-95. 1999. Written by Patricia R. Knaudt, M.D., Kathryn M. Connor, M.D., L. Eric Churchill, M.S., Jonathan R. T. Davidson, M.D.

1999 "Potential Neurostabilizing Effects of Donepezil's in Patients with Alzheimer's Disease: Measurement of N-acetylaspartate Levels Using Proton Magnetic Resonance Spectroscopy in a Randomized, Placebo-Controlled Trial . Written in collaboration with K. R. Krishnan, P. M. Doraiswamy, J. Mintzer, Xin Yu, C. Perdomo, J. R. Leni, S. Rogers. Paper submitted to American Journal of Psychiatry.

2000 Behavior Therapy for Obsessive-Compulsive Disorder Guided by a Computer or by a Clinician Compared with Relaxation as a Control. Collaboration with JH Greist, IM Marks, L. Baer, KA Kobak, KW Wenzel, MJ Hirsch, JM Mantle.

2000 "A Pilot Study of Mirtazapine in Post traumatic Stress Disorder". (United States) Jan 1999, issue of International Clinical Psychopharmacology 14 (1) p29-31. Co-authored with KM Connor, JT Davidson, EP Ahearn.

2000 "A Comparison of the Safety and Efficacy of Divalproex Sodium and Olanzapine in the Treatment of Bipolar Disorder". Coauthored J Zajecka, J Davidson, KW Sommerville, G Sachs, A Swann, P Wozniak. Paper Submitted to American Journal of Psychiatry.

2001 "MRI Correlates of Suicide Attempt History in Unipolar Depression". Co-authored EP Ahearn, KR Jamison, DC Steffens, F Cassidy, JM Provenzale, A Lehman, BJ Carroll, KR Krishnan. Biological Psychiatry. 16:28:56 p1-5.

2001 Zaleplon, A Novel Nonbenzodiazepine Hypnotic, Effectively Treats Insomnia in Elderly Patients Without Causing Rebound Effects". Written in collaboration with Sonia Ancoli-Israel, Ph.D., James K. Walsh, Ph.D., Richard M. Mangano, Ph.D., and Masamoto Fujimori, M.D., for the Zaleplon Clinical Study Group. The Primary Care Companion to The Journal of Clinical Psychiatry, Vol. 1, No. 4, pp. 114-120, August 1999.

Richard H. Weisler, MD, PA & Associates; Psychiatry and Clinical Trials
2841 Plaza Place, Suite 100 Raleigh, NC 27612
(919) 872-5900 Fax (919) 872-5428

I confirm that the attached is my curriculum vitae and that all information contained within is accurate and current as of this date:

Richard H. Weisler, MD
Printed Name

Signature

9/9/10
Date

5077US/0049:0005

NORTH CAROLINA MEDICAL BOARD

PHYSICIAN CERTIFICATE OF REGISTRATION

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LICENSE NO: 21381

RICHARD HARRY WEISLER MD

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EXECUTIVE DIRECTOR

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NORTH CAROLINA MEDICAL BOARD

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REGISTRATION REQUIRED 01/30/2003

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THIS IS TO CERTIFY THAT THE PHYSICIAN NAMED BELOW HAS REGISTERED WITH THE BOARD AND HAS PAID THE REGISTRATION FEE FOR THE YEAR ABOVE AS REQUIRED BY THE GENERAL STATUTES OF NORTH CAROLINA, SECTION 90-15.1 AND RULES PROMULGATED PURSUANT THERETO.

RICHARD HARRY WEISLER MD
LICENSE NO: 21381

EXECUTIVE DIRECTOR
P.O. BOX 20007
RALEIGH, N.C. 27619

PLEASE DETACH AND DISCARD THIS PORTION.

RED OAK PSYCHIATRY ASSOCIATES, PA
17115 Red Oak Drive, Suite 109
Houston, Texas 77090
Fax (281) 893-8082
(281) 893-4111

LAWRENCE D. GINSBERG, M.D.
CURRICULUM VITAE
M.D. Texas License Number G7406

PROFESSIONAL ACTIVITIES:

1. President of Red Oak Psychiatry Associates, P.A. January 1991 - present.
2. Psychiatrist in private practice 1985 - present.
3. Medical Director, Gulf Pines Behavioral Health Services, March 1, 1994 - March 1998.
4. Assistant Medical Director, Gulf Pines Hospital, January 1991 - February 1994.
5. Clinical Director of Adolescent Services, Gulf Pines Hospital, November 1986-February 1994.
6. Chief of Staff, Gulf Pines Hospital, 1989 and 1991.
7. Peer Reviewer for Spectrum Review Services, January 1994 - present.
8. Peer Reviewer for One Health Plan of Texas, August 1996 - present.
9. Consultant, Texas Board of Medical Examiners, March 1997 - present.
10. Medical Director of Compliance and Quality Management, Cypress Creek Hospital, March 2, 1998 - present.

PROFESSIONAL MEMBERSHIPS:

American Medical Association; American Psychiatric Association; Texas Psychiatric Society; Houston Psychiatric Society; Harris County Medical Society, American Academy of Psychiatry and the Law; Texas Medical Association; American Society of Addiction Medicine; American College of Physician Executives; American Society for Adolescent Psychiatry; American College of Legal Medicine; American College of Forensic Examiners; American Society of Clinical Psychopharmacology

PUBLICATIONS:

The Effect of Steroidal and Nonsteroidal Anti-Inflammatory Agents on Ultraviolet-Induced Inflammation, Eaglestein, W.H., Ginsberg, L.D., and Mertz, P.M., Archives of Dermatology, Vol. 115, December, 1979.

Decisions Without Data, Ginsberg, L.D., Chapter in Psychiatry: A Problem-Oriented Approach, Moffic, S., Silverman, S., and Adams, G., Medical Exam Publishing Company, January, 1986.

The Insanity Defense and Alternatives, Ginsberg, L.D., The Houston Lawyer, May-June, 1986, Vol. 23, No. 5.

Mullen J., Reinstein M., Bari M., Ginsberg L.D., Sandler N.: Quetiapine and Risperidone in Outpatients with Psychotic Disorders: Results of the QUEST Trial, Schizophrenia Research 36(1-3): 290, April 1999.

DeVeaugh-Geiss J., Conners C.K., Sarkis E.H., Winner P.K., Ginsberg L.D., Hemphill J.M., Laurenza A., Asgharnejad M., Barrows C.F., Webster C.J.,: Open Label Efficacy of 1555U88 for the Treatment of ADHD in Children. Submitted to NCDEU.

DeVeaugh-Geiss J., Conners C.K., Sarkis E.H., Winner P.K., Ginsberg L.D., Hemphill J.M., Laurenza A., Asgharnejad M., Barrows C.F., Webster C.J.: Efficacy of GW320659 in Children with Attention-Deficit/Hyperactivity Disorder. Submitted to AACAP and ECNP.

9/6/02

Ginsberg, L., Adler, L., Casat, C., Huey, L., Lee, D.M., Earl, N., Montgomery, P.: Lamotrigine: Evidence for Mood Stabilization in Bipolar I Depression. Poster presented at NCDEU 2001.

Ginsberg, L.: Topiramate Use in Refractory Bipolar Disorder. Poster to be presented at American Psychiatric Association Institute on Psychiatric Services in October 2002.

EDUCATION:

University of Miami, Coral Gables, Florida, B.S. in Chemistry, magna cum laude, 1974-1977
University of Miami School of Medicine, M.D., 1977-1981

POST GRADUATE TRAINING:

Internship - University of Miami Affiliated Hospitals, Miami, Florida, Pediatric Internship, 1981-1982
Residency - Baylor College of Medicine, Department of Psychiatry, Houston, Texas, 1982-1985

CERTIFICATION:

Certified by examination in Addiction Medicine by The American Society of Addiction Medicine, April 1991 and, Recertified 2001, Diplomate Board Certified Forensic Examiner, The American Board of Forensic Examiners, July 1996, Diplomate of American Board of Forensic Medicine, The American Board of Forensic Medicine, Dec. 1996 Certified Medical Review Officer, the Medical Review Officer Certification Council, August 1997.

AREAS OF SPECIAL INTEREST:

Psychopharmacology, Addiction Medicine, Forensic Psychiatry, Administrative Psychiatry

RESEARCH EXPERIENCE:

Co-investigator with James Claghorn, MD (1988 - 1989) for the following Phase III inpatient trials:
Anafranil (clomipramine)
Clozaril (clozapine)
Luvox (favoxamine/fluvoxamine)

Co-investigator with Kenneth Blum, Ph.D. (1992) for the following inpatient Phase IV trial:
Neurecover

Principal investigator (1992) for the following pre and post clinical trials for Quintiles:
Zoloft (sertraline)

Principal investigator (1996-1997) for a post-clinical study for Strategic Advantage Inc.:
ReVia

Principal investigator (1997-1998) for a phase IV outpatient open-label randomized study for Zeneca:
Seroquel (quetiapine)

Principal investigator (1998) for a Phase II outpatient double-blind, placebo controlled study for Glaxo-Wellcome:
1555U88/GW320659

Principal investigator (1998-2000) for three Phase II-III long-term outpatient studies for Glaxo-Wellcome:
Lamictal (lamotrigine)

Principal investigator (1998-1999) for a Phase II-III inpatient double-blind, placebo controlled study for Glaxo-Wellcome:
Lamictal (lamotrigine)

Principal investigator (1998-1999) for a Phase II outpatient open label, uncontrolled dose titration pediatric study for GlaxoWellcome:
1555U88/GW320659

Principal investigator (1999) for a Phase IIIb outpatient double-blind, placebo controlled, fixed dose comparison study for SmithKline Beecham:
Paxil (paroxetine)

Principal investigator (1999-2000) for a Phase II inpatient/outpatient randomized, double-blind, placebo and active controlled efficacy and safety study for Novartis:
Zomaril (iloperidone)

Principal investigator (1999) for a Phase II outpatient, open-label safety and efficacy study for Hoechst Marion Roussel:
M100907

Principal investigator (2000) for an outpatient, double-blind, randomized, parallel, placebo-controlled study for Eli Lilly and Company:
Prozac (fluoxetine)

Principal investigator (2000) for a child/adolescent outpatient, randomized, double-blind efficacy and safety study for Organon:
Remeron (mirtazapine)

Principal investigator (1999-2001) for an outpatient, randomized, double-blind study for Eli Lilly and Company:
Prozac and Zyprexa (fluoxetine and olanzapine)

Principal investigator (1999-2001) for a Phase III outpatient, placebo controlled study for Pfizer:
Pregabalin

Principal investigator (2000-2001) for a Phase III outpatient, placebo controlled study for Pfizer:
Pregabalin

Principal investigator (1999-2001) for a Phase II/III outpatient sustained efficacy, placebo controlled study for Pfizer:
Pregabalin

Principal investigator for an ongoing outpatient open label study for Pfizer:
Pregabalin

Principal investigator (2000) for an outpatient open-label study for Alza:
Concerta (methylphenidate HCL)

Principal investigator (2000) for a randomized, double-blind, placebo and active treatment controlled study for Pharmacia & Upjohn:
Reboxetine

Principal investigator (2001) for an inpatient randomized, double-blind, placebo controlled study for Bristol-Myers-Squibb:
Aripiprazole

Principal investigator (2001) for an ongoing randomized, double-blind, fixed dose study for Bristol-Myers-Squibb:
Aripiprazole

Principal investigator (2000 – 2001) for a double-blind, placebo controlled efficacy study for Eli Lilly and Co.:
Duloxetine

Principal investigator (2000- 2002) for an outpatient, double-blind, placebo controlled fixed dose study for GlaxoSmithKline:
Lamictal (lamotrigine)

Principal investigator for an ongoing outpatient, double-blind, placebo controlled pediatric study for Wyeth-Ayerst:
Effexor XR (venlafaxine)

Principal investigator (2001) for an outpatient, double-blind, placebo controlled and open label study for Sepracor:
Zopiclone

Principal investigator (2001) for an outpatient, double-blind, placebo controlled comparison study for GlaxoSmithKline:
Paxil CR (paroxetine)

Principal investigator (2000) for an outpatient, double-blind, placebo controlled study for Pfizer/Parke-Davis:
Pagoclone

Principal investigator for an outpatient, open-label study with a double-blind extension phase for Wyeth-Ayerst:
Effexor XR (venlafaxine)

Principal investigator for an ongoing outpatient, double-blind, placebo comparison study for Wyeth-Ayerst:
Effexor XR (venlafaxine)

Principal investigator (2001) for an outpatient, open-label pediatric study for Shire:
Adderall XR

Principal investigator (2001) for an outpatient, open-label pediatric study for:
Metadate CD

Principal investigator for an outpatient, double-blind, placebo controlled adolescent study for Wyeth-Ayerst:
Effexor XR (venlafaxine)

Principal investigator (2001- 2002) for an outpatient, double-blind, placebo controlled flexible dose study for GlaxoSmithKline:
Paxil CR (paroxetine)

Principal investigator (2001-2002) for an outpatient, double-blind, placebo controlled study for Pfizer:
Pagoclone

Principal investigator for an ongoing outpatient, double-blind, placebo controlled study for GlaxoSmithKline:
Vilazodone

Principal investigator for an ongoing outpatient, randomized, open-label study for Neurocrine Biosciences:
NBI34060-IR-0105

Principal investigator for an ongoing inpatient, randomized, double-blind, dose-ranging study for Bristol-Myers-Squibb:
Intramuscular Aripiprazole

Principal investigator for an ongoing inpatient, randomized, double-blind study for Bristol-Myers-Squibb:
Aripiprazole

Principal investigator for an ongoing outpatient, randomized, double-blind, placebo controlled study for Alkermes:
Medisorb Naltrexone

Principal investigator (2002) for an outpatient, double-blind, placebo controlled fixed dose study for Pharmacia/ORION Pharma:
Deramciclane

Principal investigator (in start-up phase) for an ongoing outpatient, double-blind, randomized placebo controlled study for UCB Pharma, Inc.:
Levetiracetam

Principal investigator for an ongoing outpatient, double-blind, randomized efficacy and safety study for Eli Lilly and Co.:
OFC (Olanzapine-Fluoxetine Combination)

Principal investigator (in start-up phase) for an ongoing inpatient, randomized, double-blind, placebo controlled, parallel-dose study for Elan Pharmaceuticals:
Zonisamide

Principal investigator (2002) for a retrospective efficacy study in refractory bipolar disorder for Ortho-McNeil:
Topamax (topiramate)

Principal investigator for an ongoing post-marketing study comparing cardiovascular safety for Pfizer:
Zyprexa & Geodon

Principal investigator (in start-up phase) for an inpatient, double-blind, randomized placebo controlled study for Shire Pharmaceutical:
Over Encapsulated Carbatrol (carbamazepine extended-release)

LECTURES AND/OR CONSULTANT PANELS FOR PHARMACEUTICAL COMPANIES:

Alza
Astra Zeneca
Bristol-Myers-Squibb
Cephalon
Celltech
Eli Lilly
Forest Pharmaceuticals
GlaxoSmithKline
Janssen
Novartis
Organon
Pharmacia & Upjohn
Pfizer
Shire
Solvay
Wyeth
UCB Pharma

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AG3157763	09-30-2004	$210.00

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3,3N,4,5	PRACTITICNER	09-07-2001

GINSBERG, LAWRENCE D MD
17115 RED OAK DRIVE SUITE 109
HOUSTON, TX 77090

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

FORM DEA-223 (10/96)

TEXAS STATE BOARD OF MEDICAL EXAMINERS

P.O. BOX 2018 • AUSTIN, TEXAS 78768-2018

PHYSICIAN PERMIT

LICENSE/PERMIT NUMBER

G7406

EXPIRATION DATE

02-28-2003

LAWRENCE DAVID GINSBERG, MD
SUITE 109
17115 RED OAK
HOUSTON TX 77090-2641

THIS CERTIFIES THAT THE LICENSEE/PERMIT HOLDER NAMED AND NUMBERED HEREON HAS PROVIDED THIS BOARD THE INFORMATION REQUIRED AND HAS PAID THE FEE FOR ANNUAL REGISTRATION FOR THE YEAR INDICATED ABOVE

PLEASE KEEP THIS BOARD NOTIFIED OF CHANGE OF ADDRESS

5077US/0049:0006

CURRICULUM VITAE 5077US/0049:0007

IRVING S. KOLIN, M.D.

1065 WEST MORSE BOULEVARD, Suite 202
WINTER PARK, FLORIDA 32789

EDUCATION

UNIVERSITY OF BUFFALO SCHOOL OF ARTS AND SCIENCES
Buffalo, New York
1957-1961
Major: Psychology
Degree: B.A. cum laude, Phi Beta Kappa

STATE UNIVERSITY Of NEW YORK SCHOOL OF MEDICINE
Buffalo, New York
1961-1965
Degree: M.D.

INTERNSHIP

STRAIGHT PEDIATRICS, CORNELL UNIVERSITY MEDICAL COLLEGE,
NEW YORK HOSPITAL
525 E. 68th Street, New York, New York 10021
July 1965 –July 1966

RESIDENCY

PSYCHIATRY, CORNELL IJNIVERSITY MEDICAL COLLEGE,
NEW YORK HOSPITAL, PAYNE WHITNEY CLINIC
525 E. 68th Street, New York, New York 10021
July 1966 – July 1969

CHILD PSYCHIATRY, CORNELL UNIVERSITY MEDICAL COLLEGE
NEW YORK HOSPITAL, PAYNE WHITNEY CLINIC
525 E. 68th Street, New York, New York 10021
July 1968 – July 1969

TEACHING POSITIONS

TEACHING FELLOW, PSYCHIATRY
CORNELL UNIVERSITY MEDICAL COLLEGE
New York, New York 1967 - 1969

CLINICAL PROFESSOR, DEPARTMENT OF PSYCHOLOGY
VISITING FACULTY, UNIVERSITY OF CENTRAL, FLORIDA
Orlando, Florida 1973 - 1975

S/Kolin 10/03/02

TEACHING POSITIONS (Continued)

TEACHING FACULTY, MEDICAL RESIDENT PROGRAM
ORLANDO REGIONAL MEDICAL CENTER
Orlando, Florida 1977 to present

TEACHING FACULTY, FAMILY PRACTICE RESIDENCY PROGRAM
FLORIDA HOSPITAL
Orlando, Florida 1984 to 1990

CLINICAL INSTRUCTOR, PSYCHIATRY
UNIVERSITY OF FLORIDA COLLEGE OF MEDICINE
Gainesville, Florida 1971 - 1972

CLINICAL ASSISTANT PROFESSOR, DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF FLORIDA COLLEGE OF MEDICINE
Gainesville, Florida 1972 - 1986

COURTESY CLINICAL ASSOCIATE PROFESSOR, DEPT. OF
PSYCHIATRY UNIVERSITY OF FLORIDA COLLECE OF MEDICINE
Gainesville, Florida 1986 to present

TEACHING FACULTY, THE OSLER INSTITUTE
PSYCHIATRIC BOARD REVIEW COURSES,
1994 to present

BOARD CERTIFIED

Diplomate, American Board of Psychiatry and Neurology
Adult Psychiatry, 1972

Diplomate, American Board of Psychiatry and Neurology
with Added Qualifications in Geriatric Psychiatry, 1992

Diplomate, American Board of Psychiatry and Neurology
with Added Qualifications in Addiction Psychiatry, 1993

Diplomate, American Board of Psychiatry and Neurology
with Added Qualifications in Forensic Psychiatry, 1994

BOARD EXAMINATIONS COMMITTEE

Part II Examiner, Oral Examination, American Board of Psychiatry and Neurology, 1979, 1980, 1983, 1984 and 1987

CERTIFICATION

Certification by Examination American Society of Addiction Medicine, 1987

Certification by Examination American Board of Quality Assurance and Utilization Review, 1991

Diplomate, American Academy of Pain Management, 1991

Certification by Examination American Society of Adolescent Psychiatry, 1993

Senior Disability Analyst and Diplomate, American Board of Disability Analysts, 1997

Certification by Examination American Society of Clinical Psychopharmacology, 1998

RESEARCH POSITIONS

Resident Research Fellow, Cornell University Medical College, Department of Psychiatry, 1966-69

Principal Investigator, Wallace Laboratories, 1975-78

Principal Investigator, Upjohn Incorporated, 1980 to 1996

University of Central Florida Institutional Review Board (for the use of Human Subjects in Research), 1980 - 1981

Principal Investigator, Burroughs Wellcome Company, 1987 to 1990

Principal Investigator, G.H. Besselaar Associates, 1987 to 1990

Principal Investigator, Sandoz Pharmaceuticals Corp., 1991 - 1993

Principal Investigator, International Clinical Research Associates, 1991 to 1994

RESEARCH POSITIONS (Continued)

Principal Investigator, Imperial Chemical Industries Pharmaceuticals Group, 1992 - 1993

Principal Investigator, ClinTrials, Inc., 1992 - 1994

Principal Investigator, TAP Pharmaceuticals, Inc., 1993 - 1994

Principal Investigator, Dupont Merck Pharmaceutical Co., 1993, 1995-1996

Principal Investigator, Boehring Ingelheim, 1995

Principal Investigator, Janssen Research Foundation, 1995 - 1997

Principal Investigator, Hoechst Marion Roussel, Inc. Pharmaceuticals, 1996 - 1998

Principal Investigator, Worldwide Clinical Trials, Inc., 1996 - 1998

Principal Investigator, Pharmacia & Upjohn, 1996 - 1999

Principal Investigator, Eisai America, Inc., 1996 - 1997

Principal Investigator, Zeneca Pharmaceuticals, 1997

Principal Investigator, Bristol-Myers Squibb Company, 1997 - 1999

Principal Investigator, Titan Pharmaceuticals, Inc., 1997

Principal Investigator, IBAH, Inc., 1997

Principal Investigator, Bayer Corporation, 1998

Principal Investigator, Novartis Pharmaceuticals Corporation, 1998 - 1999

Principal Investigator, Forest Laboratories, 1998

Principal Investigator, Somerset Pharmaceuticals, 1998

Principal Investigator, Solvay Pharmaceuticals, 1998

Principal Investigator Parke-Davis, 1999 - 2000

RESEARCH POSITIONS (Continued)

Principal Investigator, Wyeth-Ayerst Research, 2000

Principal Investigator, Eli Lilly/NIMH, 1995 to present

Principal Investigator, Quintiles Pacific, Inc. 1996 to present

Principal Investigator, Pfizer, 1996 to present

Principal Investigator, Glaxo Wellcome, Inc., 1997 to present

Principal Investigator, Otsuka Maryland Research Institute, 1997 - present

Principal Investigator, Organon, 2000

RESEARCH TRIALS

Fixed-Dose, Double-Blind Study Comparing Efficacy of Deanol Tablets vs. Placebo in the Treatment of Depressive Disorder - 1977

Double-Blind Comparison of Alprazolam and Diazepam for Subchronic Withdrawal From Alcohol - 1981

Fixed~Dose, Double-Blind Study Comparing Efficacy and Safety of Alprazolam Tablets vs. Imipramine - 1983

A Phase II, Parallel Group, Placebo Controlled Study to Evaluate the Efficacy and Safety of Antianxiety Medication in Outpatients with Generalized Anxiety Disorder - 1987

Prospective Open Evaluation of the Seizure Incidence with Bupropion Hydrochloride - 1987

Fixed-Dose, Double-Blind Study Comparing Efficacy of Antidepressant vs. Placebo in the Treatment of Geriatric Depression - 1987

Fixed-Dose, Double-Blind Study Comparing Efficacy and Safety of Antianxiety Tablets vs. Placebo in the Treatment of Panic Disorder, Using Once Daily Dosing - 1991

Randomized Double-Blind, Placebo-Controlled Study Comparing Efficacy and Safety of Antianxiety Medication in the Treatment of Generalized Anxiety Disorder – 1992

RESEARCH TRIALS (Continued)

Double-Blind, Placebo-Controlled Comparison of Low and High Dosage Regimens of Seroquel in the Treatment of Hospitalized Patients With Subchronic or Chronic Schizophrenia - 1992

Open Label Study of the Safety of Antianxiety Medication in the Treatment of Generalized Anxiety Disorder - 1993

A Randomized Comparative Study of Paroxetine in the Treatment of Depression as used in a Clinical Practice Setting - 1993

Short and Long Term Study of Alprazolam in the Treatment of Panic Disorder with Agoraphobia - 1992 - 1994

Double-Blind, Fixed Dose, Comparing Antianxiety Medication (2, 4, and 8 mg/day), with Placebo in Generalized Anxiety Disorder - 1993

Safety Surveillance Study for Wellbutrin Sustained Release #28, 676 Study #208 - 1993 - 1994

An Open-Label, Long-Term Safety Study of Antianxiety Medication In the treatment of Generalized Anxiety Disorder- 1994

Dupont Merck Pharmaceutical Company DUP 393-101 "An Open Label Usage Study of Trexan*R* (ReVia) as Adjunctive Treatment with Psychosocial Therapy for Individuals with Alcoholism - 1993 to 1995

Fixed-Dose, Placebo-Controlled Study of Antidepressant Capsules in the Treatment of Mixed Anxiety and Depressive Disorder - 1994 to 1995

Eli Lilly/NIMH Open Label Olanzapine Trial - 1995 - 1996

Double-Blind, Placebo-Controlled Clinical Dose-Finding Trial Comparing Fixed Dosages of Antipsychotic Medication - 1995-1996

Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Opiate Antagonist 50 mg, Administered Once Daily with a Nicotine Patch as Adjunctive Treatment of Psychosocial Therapy for Prevention of Smoking Relapse - 1996

Placebo-Controlled Trial of Antidepressant and Fluoxetine in the Treatment of Patients with Major Depression - 1996

RESEARCH TRIALS (Continued)

Phase II of Multicenter, Randomized, Double-Blind, Placebo and Active Controlled Study of Antipsychotic in Schizophrenic and Schizoaffective Patients - 1996

An Open-Label, Multicenter Clinical Trial Evaluating the Safety and Efficacy of Donepezil Hydrochloride (E2020) in Patients With Alzheimer's Disease - 1996 - 1997

A Multicenter, Double-Blind, Placebo-Controlled, Fixed-Dose Evaluation of the Safety and Efficacy of an Anticonvulsant in the Treatment of A Major Depressive Episode in Patients Suffering From Bipolar Disorder - 1997

An Open, Multicenter, Flexible Dose Continuation Study of An Anticonvulsant in Patients with Bipolar Disorder - 1997

A Multicenter, Double-Blind, Placebo-Controlled, Randomized, Fixed-Dose Evaluation of the Safety and Efficacy of an Anticonvulsant in the Long-Term Prevention of Relapse and Recurrence of Depression and/or Mania in Patients With Bipolar I Disorder - 1997

A Multicenter, Double-Blind, Double-Dummy, Placebo and Lithium-Controlled, Randomized, Flexible-Dose Evaluation Of the Safety and Efficacy of an Anticonvulsant in the Long-Term Prevention of Relapse and Recurrence of Mania and/or Depression in Patients with Bipolar I Disorder - 1997

A Double-Blind, Randomized Trial of Three Fixed Doses of Transdermal 5HT1 Agonist Compared to Placebo in the Treatment of Anxious Outpatients - 1997

A Multicenter, Randomized, Double-Blind, Placebo and Active Controlled Study of Antipsychotic Medication in Schizophrenic and Schizoaffective Patients - 1997

A Multicenter, Open-Label, Long-Term Followup, Safety Study Of Antipsychotic Medication in Schizophrenic and Schizoaffective Patients Who Participated in the Study 100907PR0015 (9/24/96) – 1997

A Comparison of Risperidone and Haloperidol for Prevention of Relapse in Subjects with Schizophrenia and Schizoaffective Disorders - 1997

A Double-Blind Flexible Dose Study of Transdermal 5HTI Agonist in the Treatment of Children With Attention-Deficit Hyperactivity Disorder – 1997

RESEARCH TRIALS (Continued)

An Open-Label, Long Term, Flexible Dose Safety Study of Transdermal 5HT1 Agonist in the Treatment of Childhood Attention-Deficit Hyperactivity Disorder - 1997

A Multicenter, Double-Blind, Randomized Comparison of Zolmitriptan and Sumatriptan in the Acute Treatment of Multiple Migraine Headaches - 1997

A Double-Blind Placebo Controlled, Parallel Group Study to Evaluate the Efficacy of a Second Sumatriptan Succinate Tablet (25 or 50 mg) in the Acute Treatment of Migraine - 1997

A Phase II Double-Blind Placebo-Controlled Study of Antipsychotic Medication in the Treatment of Psychosis - 1997

An Open-Label Follow-On Study of the Long Term Safety of Antipsychotic Medication in Patients with Psychosis- 1997 to present

A Double-Blind Placebo-Controlled, Haloperidol-Referenced Study of the Safety and Efficacy of Three Doses of Antipsychotic Medication Administered to Schizophrenic Patients for 42 Days - 1997

An Open-Label Assessment of the Long-Term Safety of Antipsychotic Medication - 1997

Antidepressant versus placebo in the treatment of Major Depressive Disorder - 1997

ChE Inhibitor in Alzheimer's Disease - 1998

A Double-Blind, Placebo-Controlled, Parallel Group Assessment of the Safety and Efficacy of Antidepressant Transdermal System in Patients with Major Depression - 1998

A Multicenter, Placebo and Active Control, Double-Blind Randomized Study of the Efficacy and Safety of Antipsychotic Medication in Schizophrenic and Schizoaffective Patients - 1998

A Multicenter, Open-Label, Long-Term Follow-Up Safety Study Of Antipsychotic Tablets in Schizophrenic and Schizoaffective Subjects Who Participated in Double Blind Antipsychotic - 1998

RESEARCH TRIALS (Continued)

CELEXA Clinical Experience Trial, Protocol CIT-MD4-98-I5-000 Parke-Davis - 1998

A Prospective, Randomized, Double-Blind, Placebo-and-Active Controlled, Multicenter Study to Evaluate the Efficacy and Safety Of Three Fixed Doses of Antipsychotic Medication (4, 8, and 12 mg/d) Given b.i.d. for 42 days to Schizophrenic Patients With Acute or Subacute Exacerbation, Followed by a Double-Blind, Active-Controlled, Flexible-Dose, Long-Term, 6-Month Phase with Antipsychotic Medication (4, 8, 12, or 16 mg/d) given q.d. - 1998

A Phase III, Open-Label, Treatment-Switching Study from Orally Administered Antipsychotic Monotherapy to Orally Administered Antipsychotic Medication Monotherapy in the Treatment of Chronic Schizophrenic and Schizoaffective Patients. Otsuka America Pharmaceutical, Inc. - 1999

An Open-Label Follow-on Study of the Long-Term Safety of Antipsychotic Medication Administered Orally in Patients with Psychotic Disorders or Psychotic Behaviors of Dementia. Otsuka America Pharmaceutical, Inc. - 1999

A Double-Blind, Placebo-Controlled, Parallel Assessment of the Safety And Efficacy of an Antidepressant Transdermal System in Patients with Major Depression - 1999

An Open-Label Study to Assess the Safety of an Antidepressant Transdermal System in Patients with Major Depression - 1999

The Multiple-Dose Pharmacokinetics of an Antidepressant in Children and Adolescents - 1999

A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Fixed-Dose 7-Week Evaluation of the Efficacy and Safety of an Anticonvulsive Agent in Treatment of a Major Depressive Episode in Unipolar Depressed Patients - 1999

A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study Evaluating the Efficacy and Safety Of Two Fixed Dose Ranges of an Anticonvulsive Agent (15-30 MG and 45-60 MG) in Children and Adolescents (AGED 6 to 17) With Generalized Anxiety Disorder – 1999

RESEARCH TRIALS (Continued)

A Sustained Efficacy Study of an Antianxiety Agent in Patients With Generalized Anxiety Disorder- 1999 - 2001

A Placebo-Controlled Study of an Antianxiety Agent and Paroxetine In Patients with Panic Disorder - 1999 - 2001

Open-Label Safety Study of an Antianxiety Agent in Patients With Anxiety Disorders - 1999 - 2001

A Double-Blind, Placebo-Controlled Study of a Flexible Dose Of an Antidepressant in Adult Outpatients with Generalized Social Anxiety Disorder - 2000 - 2001

A Double-Blind, Placebo-Controlled Study of a Flexible Dose of An Antidepressant in Adolescent Outpatients with Generalized Social Anxiety Disorder - 2000 - 2001

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of an Antidepressant in Outpatient Children and Adolescents with Major Depressive Disorder - 2000 - 2001

A Multicenter, Double-Blind, Placebo-Controlled Fixed Dose Evaluation of the Safety and Efficacy and Tolerability of an Anticonvulsive Agent in the treatment of a Major Depressive Episode in Patients with Type I Bipolar Disorder - 2001

A Multicenter, Randomized, Double-Blind Placebo-Controlled study of the Efficacy and Safety of antidepressant orally disintegrating tablets in subjects with Major Depressive Disorder - 2001

A Double-Blind, Placebo-Controlled, Parallel-groups, flexible dose study of an Antidepressant in Adolescents with Panic Disorder - 2001

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, fixed dose, efficacy and safety study of an Antidepressant in outpatient children and adolescents with Major Depressive Disorder - 2001

(NOTE: Some trade names of medication withheld pursuant to sponsor agreements)

PUBLICATIONS

Kolin, I., NEMALINE MYOPATHY, American Journal Diseases of Children, Vol. 114, No. 1, July 1967

Kolin, I., et al STUDIES OF SCHOOL AGE CHILDREN WITH MENINGOMYELOCELE, The Journal of Pediatrics, St. Louis, Vol. 78, No.6, June 1971

Kolin, I., Baker, J.L., Jr., Bartlett, E.S., PSYCHOSEXUAL ASPECTS OF MAMMARY AUGMENTATION, Medical Aspects of Human Sexuality, Vol. 8, No. 12, December 1974

PUBLICATIONS (Continued)

Baker, J.L., Jr., Kolin, I., Bartlett, ES., Contribution, MEDICAL ASPECTS OF HUMAN SEXUALITY, Vol. 10, No. 3, March 1976 and Vol. 10, No. 6, June 1976

Kolin, I., Linet, 0., DOUBLE-BLIND COMPARISON OF ALPRAZOLAM AND DIAZEPAM FOR SUBCHRONIC WITHDRAWAL FROM ALCOHOL, The Journal of Clinical Psychiatry, Vol. 42, No. 4, 1981

McGuire, I., Borowy, T., Kolin 1., ATTITUDES TOWARD MENTAL HEALTH PROFESSIONALS IN A HOSPITAL BASED COMMUNITY MENTAL HEALTH CENTER, Community Mental Health Journal, Vol. 22, No. 1, Spring 1986

Kolin, I., PRACTITIONER'S CORNER, "Practice Life From Private Care to Managed Care", Journal of Practical Psychiatry and Behavioral Health, Vol 1, No. 1, Spring, 1995

Kolin, I. ASK THE EXPERT, 'What is the Role of Naltrexone in the Treatment of Alcohol Dependency", Journal Of Practical Psychiatry and Behavioral Health, Vol. II, No. 3, Spring 1996

Croop, R., Kolin, I., et al, For the Naltrexone Usage Study Group "THE SAFETY PROFILE OF NALTREXONE IN THE TREATMENT OF ALCOHOLISM, Results From a Multicenter Usage Study", Archives of General Psychiatry, Volume 54, December 1997

Apter, J., Kolin, I., et al, Poster, American College of Neuropsychopharmacology, 37th Annual Meeting, Lamotrigine: Evidence of Antidepressant Activity in Bipolar Disorder.", December 17, 1998.

BOOK CONSULTANT

Peter Golenbock, WILD, HIGH AND TIGHT, The Life of Billy Martin, St. Martin's Press, New York, New York, 1994

Eddie Fisher, BEEN THERE DONE THAT, St. Martin's Press, New York, New York, 1999.

SPEAKERS BUREAU

Dupont-Merck, Roerig-Pfizer, Eli Lilly Co., Glaxo Wellcome, Organon, Medical World Conferences, Forest Laboratories, Parke-Davis, Wyeth-Ayerst, SmithKline Beacham

TELEVISION RADIO NEWS APPEARANCES

WFTV 9 (ABC), WMFE 24 (PBS), WOFL 35 (FOX), WESH 2 (NBC), WKIS 740 (AM), WDBO 580 (AM, WKMG 6 (CBS), CNBC (Cable), PUBLIC BROADCASTING - MEXICO, AMERICA'S HEALTH NETWORK, SALLY JESSE RAPHAEL, CENTRAL FLORIDA NEWS

INTERNET CHAT ROOM HOST

America's Health Network Attn.Com

CONFERENCE

University of Florida, CHAIRMAN National C.M.E. Program in Psychiatry, PSYCHIATRIC PERSPECTIVES, 1982 to 1994

PEER REVIEW EXAMINER

American Psychiatric Association, 1981 to 1990

LICENSES

National Board of Medical Examiners,

Diplomate	July 1, 1966	No. 82921
New York State	November 30, 1966	No. 97938
California	October 7, 1968	No. G15528
Florida	September 12, 1969	No. 14534

MEDICAL SOCIETIES

The American College of Psychiatrists, Fellow
American Psychiatric Association, Fellow
American Orthopsychiatric Association, Fellow
American Medical Association
American Academy of Child Psychiatry
American Society of Addiction Medicine
American Academy of Psychiatrists
in Alcoholism and Addiction, Founding Member
American Pain Society, Diplomate
Florida Medical Association
Orange County Medical Society
Florida Psychiatric Society, President,
Central Florida Chapter, 1980, 1981
Central Florida Adolescent Society, Secretary,
1983 - 1984, President 1985

MILITARY

U.S. Navy Medical Corps, Lieutenant Commander,
Department of Neuropsychiatry, Naval Hospital
Orlando, Florida July 1969 – July 1971

EMPLOYMENT

Private Practice, 1065 West Morse Boulevard,
Winter Park, Florida 1971 to present

Psychiatric Consultant, Lucerne Spinal Injury
Center, Humana Hospital Lucerne
Orlando, Florida 1976 to 1995

Psychiatric Consultant, Burn Unit,
Orlando Regional Medical Center
Orlando, Florida 1978 to 1995

Psychiatric Consultant, Orange Memorial Hospital
Comprehensive Community Mental Health Center
Orlando, Florida 1971 - 1972

Chief of Psychiatry, Orange Memorial Hospital
Orlando, Florida 1977 - 1982

Medical Director, Orlando Regional Medical Center
Comprehensive Community Mental Health Center
Orlando. Florida 1977 - 1989

Founding Medical Director, Florida Hospital Center for
Psychiatry, Medical Psychiatric Unit B, 1984 - 1988

Founding Medical Director, Florida Hospital Center for
Psychiatry, Addictions Treatment Unit, 1984 - 1989

Medical Director, Glenbeigh Hospital - Orlando,
Glenbeigh Health Sources, 1989 - 1994

Administrative Director of Psychiatry, Princeton Hospital –
1996 to 1998

Medical Staff, Orlando Regional Heathcare Systems –
1971 to present

Psychiatric Staff - Florida Hospital 1984 to Present

REFERENCES

Robert Michels, M.D.
Walsh McDermott University Professor of Medicine
University Professor of Psychiatry
Cornell University Medical College
New York, New York 10021

Dwight Evans, M.D.
Chairman of Psychiatry
University of Pennsylvania
Department of Psychiatry
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Charles B. Nemeroff, M.D.
Chairman, Department of Psychiatry and Behavioral Sciences
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Alan Schatzberg, M.D.
Kenneth T. Norris, Jr. Professor
Chairman of Psychiatry
Stanford University
School of Medicine
Stanford, California

HONORS & AWARDS

American Medical Association Physician's Recognition Award in Continuing Education, 1974 to present

Who's Who in the South and Southwest, Fifteenth Edition, (Marquis Who's Who, Chicago, Illinois)

Dictionary of International Biography, Volume 14, (International Biographical Center, Cambridge, England)

The Best Doctors in America, Southeast Edition, 1996-97

The Best Doctors in Orlando, 1999

CIVIC

Rotary International, 1971 to 1981
Mental Health Association, Orange County, 1973 to present, (President 1977-78)
NARPA, National Association of Responsible Professional Athletes, Co-Founder & Medical Advisor, 1992 to 1998

PERSONAL

Born: Brooklyn, New York, February 15, 1940)

Married: REDACTED

Children:

AC# 0793218

507700 : 0007

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/04/2002	ME 14534	77702

THE MEDICAL DOCTOR
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.
EXPIRATION DATE: JANUARY 31, 2004

IRVING S KOLIN
1065 WEST MORSE BLVD
SUITE 202
WINTER PARK, FL 32789-3747

JEB BUSH
GOVERNOR

JOHN O. AGWUNOBI, M.D., M.B.A.
SECRETARY

DISPLAY IF REQUIRED BY LAW

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3,3N,4,5	PRACTITIONER	12-20-2001

KELIN, IRVING S MD
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SUITE 202
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Form DEA-223 (10/96)

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

5077US/0049:0007

David W. Brown, M.D.

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Fax: (512) 336-6415

Texas License Number: H2267
Texas DPS Registration: M0067777
DEA Registration: BB3262805

Education

St. Mary's University, San Antonio, Texas; BA in Biology, graduated Magna cum laude, 1982.

University of Texas Medical School at Houston, Houston, Texas; M.D.,1986.

Residency

Department of Psychiatry, University of Texas Medical School at Houston, Houston, Texas; 1986-1990.

Psychiatry Resident in Training Examination (PRITE), overall national percentile scores:
1989: psychiatry -- 97, neurology -- 96;
1988: psychiatry -- 97, neurology -- 98.

PGY4 activities included one year of clinical EEG interpretation, supervised by Edward L. Reilly, M.D. and Nashaat Boutros, M.D.

Fellowship

Biological Psychiatry Branch, National Institute of Mental Health, Bethesda, Maryland; 6/90 - 7/91.

Fellowship provided training in conducting clinical drug trials and in the correlation of quantitative EEG with neuro-imaging and in the neuroscience of anxiety and affective disorders. Fellowship supervised by Robert M. Post, M.D.

Board Eligibility Certification

American Board of Psychiatry and Neurology, Board Certified, February, 1993. Board Certificate Number: 36730.
American Medical Electroencephalographic Association, Board Eligible, 7/90.

Publications

Fry J, Scharf M, Berkowitz D, Brown D, Claghorn J, Ferguson, J, Karacan I, Lahmeyer H, Mendels, J, Pascualy R, Vogel G, Walsh, J, and Wooten V: A Phase III, 28 Day, Multicenter, Randomized, Double-Blind Comparator-and Placebo-Controlled, Parallel-Group Safety, Tolerability, and Efficacy Study of 5, 10, and 20 MG of Zaleplon, Compared With 10 MG of Zolpidem or Placebo, In Adult Outpatients with Insomnia; Sleep. 1998; 21 (suppl):262.

Brown D, Gutierrez-Esteinou R, Hong-Lin Su, and O'Brien B: The safety and efficacy of risperidone 8mg QD and 4 mg QD compared to placebo in the treatment of schizophrenia; Presented at ACNP in San Juan, Puerto Rico, December 1996.

Brown, DW, Ketter TA, Crumlish J, Post RM: Carbamazepine induced increases in total serum cholesterol - clinical and theoretical implications; Journal of Clinical Psychopharmacology, December, 1992.

Wolfe HG, Bartke A, Amador A, Van Sickle M, Dalterio S, Brown DW: Effects of inhibitory and stimulatory photoperiods and sexual maturation on the ability of hamster testes to respond to hCG in vitro; International Journal of Andrology, 8(1985) 232-242.

Bartke A, Matt KS, Amador AG, Klemcke HG, Brown DW, Gonzales D, Hogan MD: Testicular function of strains of mice selected for differences in gonadotropin induced ovulation rate; Journal of Endocrinology, 90 (1981) 367-373.

Presentations

"Safety of Risperidone as Add-on Therapy to Mood Stabilizers in the Maintenance Treatment of Bipolar Disorder" and "Risperidone vs. Placebo as Combination Therapy to Mood Stabilizers In The Treatment of Manic Phase of Bipolar Disorder: Focus on Efficacy" for the American Psychiatric Association's Annual Scientific Poster Session in Chicago, 5/00.

"Update on the Treatment of Schizophrenia" for Austin Association of Psychiatric Nurses, CEU program, Austin, Texas 6/98.

"Update on the Treatment of Depression" for Internal Medicine Grand Rounds, Brackenridge Hospital, Sponsored by Central Texas Medical Foundation and Eli Lilly and Company, Austin, Texas, 3/98.

"Advances in the Treatment of Bipolar Disorder" for Austin Manic Depressive Association, Austin, Texas, 2/98.

"Atypical Neuroleptics" for Austin Chapter of The National Alliance for Mental Illness, Austin, Texas, 2/98.

"New Treatments for Schizophrenia" for Primary Care Physicians, Fairfield, Texas, 8/97.

"New Treatment for Schizophrenia" for Primary Care Physicians, Waco, Texas, 7/97.

"New Treatments for Alzheimer's Disease" for National Alzheimer's Association -Austin Chapter, Austin, Texas, 3/97.

"Bipolar Disorder and Kindling" for Austin Manic Depressive Association, Austin, Texas, 2/97.

"Pharmacotherapy for Depression" for Austin Association of Physician Assistants, Austin, Texas, 9/95.

"New Treatments for Schizophrenia" for Medco Behavioral Health, Houston, Texas, 8/95; Dallas, Texas, 9/95.

"Successful Strategies for Patient Enrollment and Retainment" for Janssen Research Foundation, West Palm Beach, Florida, 12/95.

"Psychiatric Presentations of Epilepsy" for Seton Hospital Grand Rounds, Austin, Texas, 11/95.

"Advances in the Treatment of Bipolar Disorder" for the Depressive-Manic Depressive Association of Austin, Austin, Texas, 10/95.

"Pharmacology of Geriatric Depression" for the Waco Veterans Administration Medical Center/ telecast to the Temple Veterans Administration Medical Center, Waco, Texas, 7/95.

"Pharmacotherapy Update for Therapists" for Personal Performance Consultants, Austin, Texas, 4/95.

"Interview on Bipolar Disorder" for Good Morning, Austin, K-BVO Television Station, Austin, Texas, 3/95.
"Kindling and Bipolar Disorder" for St. David's Hospital Family Practice Department, Austin, Texas, 10/94.

"Biological Explanations for Mood Disorders" for the Texas Alliance for the Mentally Ill 1993 Convention, Austin, Texas, 9/93.

Biology and Bipolar Disorder" for C.P.C. Capital Hospital Spring Lecture Series, Austin, Texas, 3/93.

Mark Ryan 01/14/02

"Kindling Hypothesis" for the University of Arkansas School for Medical Sciences (UAMS) Symposium, "Current Perspectives on Bipolar Disorder," Little Rock, Arkansas, 3/92.

"Pharmacological Treatment of Post-Traumatic Stress Disorder" for the UAMS Symposium, "Panic Disorder in Minorities and the Underserved," Little Rock, Arkansas, 6/92.

Participation in Clinical Research

F1D-MC-HGJX, A Comparison of Fasting Triglyceride Levels in Cohorts with Schizophrenia and Related Disorders Treated Chronically with Olanzapine, Risperidone, and Typical Antipsychotics, Principal Investigator, Sponsored by Lilly Resarch Laboratories, 2001-present.

SB-659746-A/014, A randomized, double-blind, parallel-group, placebo-controlled flexible-dose study evaluating efficacy and safety of SB-659746-A in patients with major depressive disorder, Principal Investigator; Sponsored by GlaxoSmithKline, 2001-present.

061-00, A double-blind, multicenter, placebo- and active-controlled acute and extension study of 2 doses of MK-0869 in the treatment of patients with major depressive disorder, Principal Investigator; Sponsored by Merck & Co., Inc., 2001-present.

CN138-050, Randomized, double-blind, dose-ranging study of intramuscular aripiprazole in the treatment of acute agitation in patients with a diagnosis of schizophrenia, schizoaffective, or schizophreniform disorder, Principal Investigator, Sponsored by Bristol-Myers Squibb, 2001-present.

DRI3650, A double-blind, placebo- and paroxetine-controlle, multicenter, dose-ranging study evaluating the efficacy and safety of SR142801 in outpatients with major depressive disorder, Principal Investigator; Sponsored by Sanofi Synthelabo Research, 2001-present.

5077US/0043, A multicenter, double-blind, randomized comparison of the efficacy and safety of Quetiapine Fumarate (Seroquel) and Risperidone (Risperdal) and the treatment of patients with schizophrenia, Principal Investigator; Sponsored by AstraZeneca Pharmaceuticals LP, 2001-present.

SCT-MD-17, An open label extension study of the safety and efficacy of LU 26-054 in patients with generalized anxiety disorder, Principal Investigator; Sponsored by Janssen Research Foundation, 2001-present.

RIS-USA-265, An open label, long term safety trial of Risperidone long acting microspheres in the treatment of subjects diagnosed with schizophrenia, Principal Investigator; Sponsored by Janssen Research Foundation, 2001-present.

RIS-USA-259, Open label trial exploring a switching regimen from oral neuroleptics, other than Risperidone to Risperidone depot microspheres, Principal Investigator; Sponsored by Janssen Research Foundation, 2001-present.

F1D-EW-LOBE(b), A study to assess the safety, tolerability and pharmacokinetics of single and multiple doses of an intramuscular formulation of depot Olanzapine (Pamoate Salt) in stable schizophrenic subjects, Principal Investigator; Sponsored by Lilly Research Laboratories, 2001-present.

BR29060-785, A double-blind, placebo controlled, fixed-dosage study comparing the efficacy and tolerability of Paroxetine CR and Citalopram to placebo in the treatment of major depressive disorder with anxiety, Principal Investigator; Sponsored by GlaxoSmithKline, 2001.

SCT-MD-06, Flexible dose comparison of the safety and efficacy of Escitalopram and placebo in the treatment of generalized anxiety disorder, Principal Investigator; Sponsored by Forest Laboratories, Inc. 2001-present.

5077IL/0099, A multicenter, double-blind, randomized, placebo-controlled trial of the safety and efficacy of Seroquel (Quetiapine Fumarate) as add-on therapy with lithium or Divalproex in the treatment of acute mania, Principal Investigator; Sponsored by AstraZeneca, 2001.

01/14/02

5077IL/0041, A multicenter, double-blind, randomized comparison of the efficacy and safety of sustained-release formulation Quetiapine Fumarate (Seroquel) and placebo in the treatment of patients with schizophrenia, Principal Investigator; Sponsored by AstraZeneca, 2001-present.

RIS-USA-235, A randomized trial of oral Risperidone versus intramuscular Haloperidol in the emergency treatment of acute psychosis, Principal Investigator; Sponsored by Janssen Research Foundation, 2001.

F1D-US-HGJB, A controlled trial of Olanzapine versus Quetiapine in the treatment of schizophrenic and schizoaffective subjects with prominent negative symptoms, Principal Investigator; Sponsored by Lilly Research Laboratories, 2000-present

CN138-047, A multicenter, randomized, double-blind, placebo controlled, 26 week study of a fixed dose of Aripiprazole in the treatment of stabilized patients with chronic schizophrenia, Principal Investigator; Sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000-present.

RIS-USA-239, The efficacy and safety of flexible dosage ranges of Risperidone vs placebo in the treatment of manic episodes associated with bipolar I disorder, Principal Investigator; Sponsored by Janssen Research Foundation, 2000-present.

RIS-INT-81, A nine-week, open-label, multi-center, safety study of flexible dosage ranges of Risperidone in the treatment of manic episodes associated with Bipolar I Disorder, Principal Investigator; Sponsored by Janssen Research Foundation, 2000-present.

A1601048, A multicenter, double-blind, randomized, placebo-controlled parallel group comparative study of the efficacy and safety of oral Eletriptan (40 MG) and Sumatriptan (100 MG) given for the acute treatment of migraine, Principal Investigator; Sponsored by Pfizer Pharmaceuticals Group, 2000-2001.

387GCNS0069-012, Pharmacogenomics blood sampling protocol, Principal Investigator; Sponsored by Pharmacia & Upjohn Company, 2000-2001.

387GCNS0069-011, PNU-101387G: Double-blind, randomized, placebo- and Olanzapine-controlled, dose-finding study in the treatment of psychotic disorders, Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

950E-CNS-0005-087, Open-label Reboxetine continuation therapy, Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

M2020/0046, Reboxetine, placebo, and Paroxetine comparison in patients with Major Depressive Disorder, Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

M2020/0047, Reboxetine, placebo, and Paroxetine comparison in patients with Major Depressive Disorder, Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000.

950ECNS0323-001, Pharmacogenomics blood sampling protocol, Principal Investigator; sponsored by Pharmacia & Upjohn Company, 2000-2001.

041505, Long-term maintenance of subjects with schizophrenia with Org5222, Principal Investigator; sponsored by Organon Inc., 2000-present.

041013, A double blind, three-armed, fixed-dose, placebo controlled dose-finding study with sublingual Org 5222 in subjects with acute phase schizophrenia, Principal Investigator; sponsored by Organon Inc., 2000-present.

M99-082, A double-blind, placebo-controlled study of Depakote in the treatment of behavioral agitation in elderly patients with dementia, Principal Investigator; sponsored by Abbott Laboratories, 2000-2001.

04/4/02

CN138-010, A multicenter, randomized, double-blind, placebo controlled study of Aripiprazole in the maintenance of patients with bipolar disorder; Principal Investigator, sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000-present.

M99-010, Safety and efficacy of Depakote as combination therapy in the treatment of psychosis associated with schizophrenia; Principal Investigator, sponsored by Abbott Laboratories, 2000-2001.

CN138-007, A multicenter, randomized, double-blind, placebo controlled study of two fixed doses of Aripiprazole in the treatment of patients with acute mania; Principal Investigator; sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000-present.

CN138-001-031, A multicenter, randomized, double-blind, placebo controlled study of three fixed doses of Aripiprazole in the treatment of patients with acute schizophrenia; Principal Investigator; sponsored by Bristol-Myers Squibb Pharmaceutical Research Institute, 2000.

RIS-USA-196, Risperidone depot (microspheres) in the treatment of subjects with schizophrenia or schizoaffective disorder, Principal Investigator; sponsored by Janssen Research Foundation, 1999-present.

RIS-USA-121, Risperidone depot (microspheres) vs. placebo in the treatment of subjects with schizophrenia, Principal Investigator; sponsored by Janssen Research Foundation, 1999-2001.

H5Z-MC-LUAB, R-Fluoxetine versus placebo in the treatment of major depression, Principal Investigator; sponsored by Eli Lilly and Company, 1999-2001.

1008-84, Open-label safety study of Pregabalin (CI-1008) in patients with anxiety disorders, Principal Investigator; sponsored by Parke-Davis Pharmaceutical Research, 1999-2001.

1008-92, A placebo-controlled study of Pregabalin and Paroxetine in patients with panic disorder, Principal Investigator; sponsored by Parke-Davis Pharmaceutical Research, 1999 –2001.

173-98-203, A phase II, randomized, double-blind, placebo-controlled, fixed dose study of oral OPC 14523 and Prozac in the treatment of outpatients with moderate depression, Principal Investigator; sponsored by Otsuka America Pharmaceuticals, Inc, 1999 –2001.

128-116B, A 260- week (5-year), open extension study evaluating the safety and outcome of 40-200 mg daily of oral Ziprasidone or 1-8 mg BID of oral Risperidone daily in the treatment of subjects who have participated in previous Ziprasidone clinical trials, Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1999 – present.

2918, A comparison of the efficacy and safety of befloxatone 2.5mg OD versus placebo in outpatients with moderate to severe major depressive disorders; a randomized, double-blind, 8-week multi-center phase II trial, Principal Investigator; sponsored by Synthelabo Research, 1999.

EMD 128 130-008, A double-blind, randomized, multicenter, parallel group design study to evaluate the efficacy and safety of two dose ranges of EMD 128 130 in comparison with placebo and Haloperidol in the treatment of schizophrenia, Principal Investigator; sponsored by Merck KGaA, 1999-2000.

RIS-INT-50, Risperidone versus Olanzapine in the treatment of schizophrenia in elderly subjects, Principal Investigator; sponsored by Janssen Research Foundation, 1999.

F1D-MC-HGGU, Olanzapine versus Risperidone and placebo in the treatment of psychosis and associated behavioral disturbances in patients with dementia, Principal Investigator; sponsored by Eli Lilly and Company, 1999-present.

041002, A double-blind, five-armed, fixed-dose, active- and placebo-controlled dose-finding study with sublingual Org 5222 in subjects with acute phase schizophrenia, Principal Investigator; sponsored by Organon Inc., 1999-2000.

Harold Brown 01/19/06

041500, Extension to 041002, Principal Investigator; sponsored by Organon Inc., 1999-2000.

F1D-MC-HGGL(a), Allelic Variation in schizophrenia, Principal Investigator; sponsored by Eli Lilly and Company, 1999.

S1420015, A randomized, double-blind, placebo-controlled, parallel group study to measure the efficacy and safety of nicotine gum (2mg and 4mg for smoking cessation by gradual reduction, Principal Investigator; sponsored by Smith-Kline Beecham, 1999.

NKP608A-141, A randomized, double-blind, dose-range finding, multicenter, parallel-group, active and Placebo-controlled trial of the safety and efficacy of NKP608A in patients with moderate to severe major depressive disorder, Principal Investigator; sponsored by Novartis Pharmaceuticals, 1999.

NKP608A-107, A multicenter, randomized, double-blind, parallel-group, placebo-controlled, dose-range finding trial to evaluate the safety and efficacy of 4 doses of NKP608A in patients with social phobia, Principal Investigator; sponsored by Novartis Pharmaceuticals, 1999.

31-98-218, An open-label, follow-on study of the long-term safety of Aripiprazole in patients with chronic schizophrenia, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-present.

31-98-217, a multi-center, randomized, double-blind, active-controlled study to compare the long-term maintenance effects and safety of Aripiprazole and Haloperidol following acute relapse in schizophrenic patients, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-1999.

31-98-204, An open-label pilot study to determine tolerability of oral Aripiprazole in patients with first-episode schizophrenia or schizoaffective disorder, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-present.

31-98-222, An open-label follow-on study of the long-term safety of Aripiprazole administered orally in patients with psychotic disorders or psychotic behaviors of dementia, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-present.

F1D-US-HGHQ, A phase IIIb, multicenter, randomized, double-blind, parallel study of the efficacy of Olanzapine verses Divalproex in the treatment of acute mania, Principal Investigator; sponsored by Eli Lilly and Company, 1998-2000.

M97-696, Evaluation of the efficacy and safety of Depakote ER in the treatment of the manic phase of bipolar disorder: a placebo-controlled study, Principal Investigator; sponsored by Abbott Laboratories,1999.

97-M-05, A six-month open-label safety trial of *d-threo*-methylphenidate hydrochloride (*d*-MPH) in children with symptoms of attention deficit hyperactivity disorder (ADHD), Principal Investigator; sponsored by Celgene Corporation, 1999.

DFI 3024, A double-blind and Haloperidol-controlled, multicenter study evaluating the safety and efficacy of SR 46349B in schizophrenic patients, Principal Investigator; sponsored by Sanofi Pharmaceuticals, 1998-2000.

DFI 3138, A double-blind, placebo and Haloperidol-controlled, multicenter study evaluating the safety and efficacy of SR 142801 in schizophrenic patients, Principal Investigator; sponsored by Sanofi Pharmaceuticals, 1998-2000.

31-98-220, An open-label follow-on study of the long-term safety of Aripiprazole administered orally in patients with Psychosis, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-present.

31-98-213, An open-label study of the neurocognitive effects of Aripiprazole compared to Olanzapine administered orally in patients with psychosis, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998-2000.

04/14/02

31-97-203, An open-label follow-on study of the long-term safety of Aripiprazole in patients with psychosis, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc, 1998-present.

31-97-202, A phase III double-blind placebo-controlled study of Aripiprazole in the treatment of psychosis, with Risperidone as active control, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1998.

F1D-MC-HGHW, A double-blind randomized comparison of the efficacy and safety of short-acting intramuscular Olanzapine, short-acting intramuscular Lorazepam and intramuscular placebo in acutely agitated patients diagnosed with mania associated with bipolar disorder, Principal Investigator; sponsored by Eli Lilly and Company, 1998-2000.

F1D-MC-HGGN, The comparative efficacy of Olanzapine, Risperidone, and Haloperidol for cognition in schizophrenia, Principal Investigator; sponsored by Eli Lilly and Company, 1998-2000.

ILP-3000, A prospective, randomized, double-blind, placebo- and active-controlled, multicenter study to evaluate the efficacy and safety of three fixed doses of Iloperidone (4,8, and 12 mg/d) given BID for 42 days to schizophrenic patients with acute or subacute exacerbation, followed by a double-blind, active-controlled, flexible-dose, long-term, 20 week phase with Iloperidone (4, 8, 12, or 16 mg/d) given q.d, Principal Investigator; sponsored by Novartis Pharmaceuticals, 1998 –1999.

ILP-3007, part 2, A prospective, randomized, double-blind, active-controlled, flexible-dose, parallel-group, multicenter study to evaluate the safety, tolerability and efficacy of Iloperidone compared with Risperidone (both 0.5 to 4.0 mg/d given b.i.d.) in treating psychotic and behavioral symptoms in institutionalized elderly patients with dementia, Principal Investigator; sponsored by Novartis Pharmaceuticals, 1998-2000.

128-108E-719, A 156 (3 year), double-blind extension study evaluating the safety and efficacy of two dose regimens of oral Ziprasidone (CP,88,059-1) (80-120 mg, QD, and 40-80 mg, BID) and Haloperidol (5-20 mg daily in the maintenance treatment of outpatients with schizophrenia or schizoaffective disorder who have successfully completed protocol 128-108, Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1996-1999.

160-108, UK-116, 044, A multi-center, randomized, open-label, comparative study of the safety, toleration, and efficacy of oral Eletriptan for long term treatment of subjects with acute migraine, Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997-1999.

128-108, Forty-week, double-blind study evaluating the safety and efficacy of two dose regiments of oral Ziprasidone (CP88, 059-1) (80-120 mg, QD, and 40-80 mg, BID) and Haloperidol (5-20 mg daily) in the maintenance treatment of outpatients with schizophrenia or schizoaffective disorder, Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1996.

31-94-202, A dose ranging study of the efficacy and tolerability of OPC – 14597 in acutely relapsing hospitalized schizophrenic patients, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1995-1997.

E2020-A001-313, An open-label, multi-center clinical trial evaluating the safety and efficacy of Donepezil Hydrochloride in patients with Alzheimer's disease; Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997.

31-95-201, An open-label study of the tolerability and safety of OPC-14597in schizophrenic patients, Principal Investigator; sponsored by Otsuka America Pharmaceutical, Inc., 1995-1996.

BRL-029060/648, A 12 week, double-blind, placebo controlled, parallel group study to assess the efficacy and tolerability of Paroxetine in patients suffering from posttraumatic stress disorder (PTSD); Principal Investigator, sponsored by Smith-Kline Beecham, 1999.

BRL 029060/641, A randomized, double-blind, placebo-controlled, fixed dosage trial to evaluate the efficacy and tolerability of 20 and 40 mg/day Paroxetine in patients with generalized anxiety disorder, Principal Investigator; sponsored by Smith-Kline Beecham, 1999.

EMD 68 843-009, A double-blind, randomized, multicenter, parallel designed study to evaluate the efficacy and safety of individual maximum tolerated doses of EMD 68 843 in comparison with placebo and fluoxetine in outpatients with major depressive disorder, Principal Investigator; sponsored by Merck KGaA, 1998-1999.

EMD 68 843-010, A double-blind, randomized, multicenter, parallel designed study to evaluate the efficacy and safety of individual maximum tolerated doses of EMD 68 843 in comparison with placebo and fluoxetine in outpatients with major depressive disorder, Principal Investigator; sponsored by Merck KGaA, 1998-1999.

M97-817, An open-label extension study of Depakote in the treatment of signs and symptoms of mania in elderly patients with dementia, Principal Investigator; sponsored by Abbott Laboratories, 1998-1999.

M97-738, A double-blind, placebo-controlled study of Depakote in the treatment of signs and symptoms of mania in elderly patients with dementia, Principal Investigator; sponsored by Abbott Laboratories, 1998-1999.

B1Y-US-HCIR, Fluoxetine versus placebo in geriatric nursing home and assisted living patients with major depression, Principal Investigator; sponsored by Eli Lilly and Company, 1998 - 1999.

128-602, A phase III, randomized, placebo-controlled study evaluating the safety and outcome of treatment with oral Ziprasidone in subjects with mania who are receiving Lithium, Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1998 - 1999.

128-602E-0243, An open extension study evaluating the safety and outcome of 40-160 mg daily of oral Ziprasidone in the Treatment of subjects who have participated in protocol 602, Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1998 - 1999.

RIS-USA-102, The safety and efficacy of Risperdal (Risperidone) vs. placebo vs. Haloperidol as add-on therapy to mood stabilizers in the treatment of the manic phase of bipolar disorder, Principal Investigator; sponsored by Janssen Research Foundation, 1998-1999.

M100907/3005, A multicenter, open-label, long-term follow-up safety study of M100907 tablets in schizophrenic and schizoaffective subjects who participated in protocol M100907/3001 or protocol M100907/3002, Principal Investigator; sponsored by Hoechst Marion Roussel, 1998 – 1999.

M100907/3001, A multicenter, placebo and active control, double-blind, randomized study of the efficacy, safety and pharmacokenetics of M100907 (10 and 20 mg per day) in schizophrenic and schizoaffective patients (3001), Principal Investigator; sponsored by Hoechst Marion Roussel, 1998 – 1999.

B1Y-MC-HCIZ, Weekly enteric-coated Fluoxetine Hydrochloride versus daily Fluoxetine or placebo in the continuation treatment of major depressive disorder, Principal Investigator; sponsored by Eli Lilly and Company, 1998 – 1999.

160-103, A multicenter, double-blind, randomized, placebo-controlled, paralleled group study of the efficacy and safety of escalating the dose of oral Eletriptan in subjects with acute migraines, Principal Investigator; sponsored by Pfizer Pharmaceuticals, 1997-1999.

RIS-USA-113, Risperidone versus Olanzapine in the treatment of schizophrenia, Principal Investigator; sponsored by Janssen Research Foundation, 1997-1999.

RIS-USA-112, Risperidone versus Olanzapine in the treatment of schizophrenia, Principal Investigator; sponsored by Janssen Research Foundation 1997-1998

Mind Pharm 04/14/02

5077US/0049:0009

CURRICULUM VITAE

9/17/02

NAME: JOHN S. CARMAN, M.D.

SOCIAL SECURITY NUMBER: REDACTED

DATE AND PLACE OF BIRTH: March 3, 1945; Teaneck, New Jersey

HOME ADDRESS: REDACTED

WORK ADDRESS: Carman Research, 4015 South Cobb Drive, Suite 245, Smyrna, Georgia 30080

MARITAL STATUS: Married

EDUCATION AND TRAINING:

1963 - 1967 - B.S., Magna cum Laude in Chemistry, University of Notre Dame; South Bend, Indiana
1967 - 1971 - M.D., State University of New York, Upstate Medical Center (UMC); Syracuse, New York
1971 - 1974 - Resident in Psychiatry, University of North Carolina Memorial Hospital; Chapel Hill, North Carolina

FULL TIME PROFESSIONAL POSITIONS:

1973 - 1974 - Clinical Associate and Admissions Coordinator, Biological Psychiatry Branch, National Institute of Mental Health (NIMH); Bethesda, Maryland
1974 - 1978 - Clinical Associate and Ward Administrator, Laboratory of Clinical Psychopharmacology, Division of Special Mental Health Research, Intramural Research Program, NIMH; Washington, D.C.
1978 - 1981 - Associate Professor in Psychiatry, University of Alabama in Birmingham (UAB); Birmingham, Alabama
1979 - 1981 - Clinical Service Coordinator, Adult Inpatient Psychiatric Unit, University Hospital, UAB
1979 - 1981 - Preceptor in Clinical Psychopharmacology, UAB
1981 - Director, Psychopharmacology Clinic, UAB
1981 - 1983 - Director, Adult Treatment Service, Brawner Psychiatric Institute (BPI); Smyrna, Georgia
1981 - 1999 - Active Staff, Brawner Psychiatric Institute (BPI); Smyrna, Georgia
1982 - 1983 - Director of Geropsychiatry, Brawner Psychiatric Institute (BPI); Smyrna, Georgia
1982 - 1988 - Clinical Assistant Professor of Psychiatry, Emory University, School of Medicine
1984 - 1988 - Director of Research, Center for Psychiatry Studies; Smyrna, Georgia
1988-Present- Director, Carman Research; Smyrna, Georgia
1996-Present- Active Staff, Ridgeview Institute; Smyrna, Georgia
2000 - 2000 - Active Staff, Charter Midtown; Atlanta, Georgia

OTHER PROFESSIONAL EXPERIENCE AND ACTIVITIES:

1967 - Research Fellow in Pediatric Endocrinolgy, Suny Upstate Medical Center
1968 - Research Fellow in Psychologic Testing, Suny Upstate Medical Center
1969 - Research Fellow in Anesthesiology, Suny Upstate Medical Center
1969 - 1971 - Medical Extern, Onandaga County Penitentiary; Jamesville, New York
1975 - 1976 - Staff Psychiatrist, Alexandria Mental Health Center, Virginia
1977 - 1978 - Staff Psychiatrist, Mount Vernon Mental Health Center, Virginia
1980 - 1981 - Leader, Psychiatric Resident's Sensitivity Training Group, UAB
1980 - 1981 - PSRO Committee, Neuroscience Program, UAB
1981- General Clinical Research Center - Scientific Advisory Committee, UAB
1981 - 1982 - Clinical Management Committee, BPI
1981 - 1996 - Institutional Review Board for Research Involving Human Subjects, BPI

HONORS AND AWARDS:

1966 - 1967 - Student President, College of Science, University of Notre Dame
1963 - 1967 - Academic Tuition Scholarship at Notre Dame
1967 - 1971 - New York State Regents Scholarship in Medicine at Suny Upstate Medical Center
1978 - Clinical Science A.E. Bennett Award from the Society of Biological Psychiatry
1979 - Curt P. Richter Award from the International Society of Psychoneuroendocrinology
1998 - Exemplary Psychiatrist Award: NAMI and NAMI-Austell-Douglasville South Cobb

BOARD CERTIFICATIONS:

1972 - National Board of Medical Examiners 120376
1977 - American Board of Psychiatry and Neurology 16066

MEDICAL LICENSURES:

1971 - 1974 - North Carolina
1975 - 1980 - Virginia #25724
1978-Present- Alabama 8550
1981-Present- Georgia 023143

MEMBERSHIPS:

American Medical Association
American Psychiatric Association
Society of Biological Psychiatry
International Society of Psychoneuroendocrinology

MILITARY SERVICE:

1973 - 1978 - Assistant Surgeon (04), U.S. Public Health Service, Honorable Discharge

RESEARCH GRANTS OR CONTRACTS AWARDED:

I. INDICATION: MAJOR DEPRESSIVE DISORDER

Drug	# Of Studies	Pivotal *	Company
Bupropion	3	*	Burroughs Wellcome
BW647	2		Burroughs Wellcome
Oxaprotaline	1		Ciba Geigy
Trazodone	1		Mead Johnson
Adinazolam	1		Upjohn
Fluoxetine	1		Eli Lilly
Indalpine	1		Rorer
Citalopram	1		Pfizer
Citalopram	1	*	Lundbeck
Citalopram	1	*	Forest
Mianserin	1		Organon
Etoperidone	3		McNeil
Dothiepin	1		Boots

RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

I. INDICATION: MAJOR DEPRESSIVE DISORDER - Cont'd

Drug	# Of Studies	Pivotal *	Company
Mirtazepine	2	*	Organon
Gepirone	2		Bristol Meyers
Venlafaxine	4	*	Wyeth Ayerst
Venlafaxine ER	2	*	Wyeth Ayerst
Fluvoxamine	2		Reid Rowell/Solvay
MDL72394	1		Merrell Dow
Zalospirone	1		Wyeth Ayerst
Ipsapirone	1		Miles/Bayer
Ipsapirone ER	2		Miles/Bayer
Sertraline	3		Pfizer
Paroxetine	2		SmithKline Beecham
Org4428	2		Organon
A75200	1		Abbott
Flesinoxan	1		Solvay
Filbaurin	1	*	Boehringer Ingelheim
CP93,393	1		Pfizer
(MK 0869)	5	*	Merck
YM992	1		Yamanouchi USA

RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

I. INDICATION: MAJOR DEPRESSIVE DISORDER - Cont'd

Drug	# Of Studies	Pivotal *	Company
NS 2389	1		NeuroSearch
SR46349B	1		Sanofi
SR 142801	1		Sanofi
CP 122721	1		Pfizer
CP 448187	1		Pfizer
Selegiline STS	2		Somerset
NPS 1506	1	*	NPS
OPC 14523	1		Otsuka
Prozac SR	1		Eli Lilly
Olanzapine/Prozac	1		Eli Lilly
KW-6002	2		Kyowa
Escitalopram	1		Forest
Org 33062 ER	2		Organon
INN 00835	1		Innapharma
Org 34517	1		Organon
C-1073 (Mifepristone)	1		Corcept
Risperidone	1		Janssen

RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

II. INDICATION: MANIA

Drug	# Of Studies	Pivotal *	Company
BW234	1		Burroughs Wellcome
Ziprasidone	1		Pfizer
Olanzapine	2		Eli Lilly
Depakote	1		Abbott
Topiramate	1		R.W. Johnson
Seroquel	1		Astra Zeneca

III. INDICATION: SCHIZOPHRENIA/SCHIZOAFFECTIVE DISORDER

Drug	# Of Studies	Pivotal *	Company
Pimozide	1		Sandoz
Mellaril Concentrate	1		Sandoz
Remoxipride	1		Merck
Risperidone	4	*	Janssen
Seroquel	6	*	Astra Zeneca
Olanzapine	1	*	Eli Lilly
Sertindole	2		Abbott
Ziprasidone	3	*	Pfizer
Aripiprazole	3		Otsuka
ORG 5222	5		Organon
M100907	1		Hoechst

RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

III. INDICATION: SCHIZOPHRENIA/SCHIZOAFFECTIVE DISORDER - Cont'd

Drug	# Of Studies	Pivotal *	Company
SR 46349 B	1		Sanofi
SR 142801	1		Sanofi
MK 0869	1		Merck
Depakote potentiation	1		Abbott
Iloperidone	1		Novartis

IV. INDICATION: GENERALIZED ANXIETY DISORDER

Drug	# Of Studies	Pivotal *	Company
Alpidem	1		Lorex
Gepirone	1		Bristol-Meyers
Ipsapirone	1		Miles/Bayer
Adinazolam SR	1		Upjohn
Zalospirone	1		Wyeth-Ayerst
Abecarnil	2		Sandoz
LY237733	1		Eli Lilly
Buspar BID	1		Bristol Meyers
DN2327	1		TAP
Adatanserin	1		Wyeth-Ayerst
Venlafaxine ER	1	*	Wyeth-Ayerst
CP93,393	1		Pfizer

RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

IV. INDICATION: GENERALIZED ANXIETY DISORDER - Cont'd

Drug	# Of Studies	Pivotal *	Company
Flesinoxan	1		Solvay
L-830982	1		Merck
Pregabalin	1		Parke-Davis
Lu 26-054	2		Forest
Deramciclane	1		Pharmacia
Gabitril™	1		Cephalon

V. INDICATION: PANIC DISORDER

Drug	# Of Studies	Pivotal *	Company
Xanax SR	1		Upjohn
Paroxetine	1	*	SmithKline Beecham
Paroxetine CR	1		SmithKline Beecham
Sertraline	1	*	Pfizer
Pregabalin	1		Parke-Davis
Venlafaxine ER	1		Wyeth-Ayerst

VI. INDICATION: ALZHEIMER'S DISEASE

Drug	# Of Studies	Pivotal *	Company
Metrifonate	1		Miles/Bayer
Tacrine GTTS	1		Parke Davis
Lazabemide	1		Protodigm

RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

VI. INDICATION: ALZHEIMER'S DISEASE - Cont'd

Drug	# Of Studies	Pivotal *	Company
Exelon	1		Novartis
Idebenone	1		Takeda
Memantine	1		Merz

VII. INDICATION: SOCIAL PHOBIA

Drug	# Of Studies	Pivotal *	Company
Venlafaxine ER	1		Wyeth-Ayerst

VIII. INDICATION: PREMENSTRUAL DYSPHORIC DISORDER

Drug	# Of Studies	Pivotal *	Company
Drospirenone	1		Berlex

PRESENTATIONS:

1. Carman, J.S., Post, R.M., Goodwin, F.K., Bunney, W.E., Teplitz, T.A.: Calcium, ECT, Lithium and Mood. The Annual Meeting of the American Psychiatric Association, New Research Program, Detroit, Michigan, May, 1974.

2. Stoddard, F.J., Post, R.M., Gillin, J.C., Bunney, W.E., Carman, J.S.: Phasic Changes in Manic-Depressive Illness. The Annual Meeting of the American Psychiatric Association, New Research Program, Detroit, Michigan, May, 1974.

3. Bunney, W.E., Post, R.M., Stoddard, F.J., Gillin, J.C., Buchsbaum, M.S., Carman, J.S.: Cyclic Biologic Changes in Manic-Depressive Illness. The 9th Congress, Collegium Internationale Neuropsychopharmacologicum, Paris, July, 1974.

4. Post, R.M., Gerner, R.H., Carman, J.S., Bunney, W.E.: A Dopamine-Receptor Stimulator in Depression. The Annual Meeting of the American Psychiatric Association, Anaheim, California, May, 1975.

5. Carman, J.S., Wyatt, R.J.: Alternations in CSF and Serum Total Calcium with Changes in Psychiatric State. The Conference on Neuroregulators and Hypotheses of Psychiatric Disorders, Asilomar, California, January, 1976.

PRESENTATIONS - Cont'd:

6. Jimerson, D.C., Post, R.M., Carman, J.S., Van Kammen, D.P., Wood, J.H., Goodwin, F.K., Bunney, W.E. : CSF Electrolytes: Calcium and Depression. The Annual Meeting of the American Psychiatric Association, Miami, Florida, May, 1976.

7. Carman, J.S., Wyatt, R.J.: Calcium: Pacesetting the Periodic Psychoses. The Annual Meeting of the American Psychiatric Association, Atlanta, Georgia, May, 1978.

8. Carman, J.S.: Calcium: Bivalent Cation in the Bivalent Psychoses. A.E. Bennett Award Paper, The Annual Meeting of the Society for Biologic Psychiatry, Atlanta,Georgia, May, 1978.

9. Freed, W.J., Perlow, M.J., Carman, J.S., Wyatt, R.J.: Calcitonin Reduces Feeding in Man, Monkey and Rat. The Annual Meeting of the Society for Neurosciences, St. Louis, Missouri, November, 1978.

10. Gillin, J.C., Kleinman, J.E., Nasrallah, H.S., Bigelow, L.B., Rogol, A., Luchins, D., Carman, J.S., Weinberger, D.R., Wyatt, R.J.: Inhibition of Dopamine Synthesis in Chronic Schizophrenia: A Follow-up Study. The 4th International Catecholamine Symposium, Asimolar, California, 1978.

11. Post, R.M., Gerner, R.J., Jimerson, D.C., Carman, J.S., Rey, A.C., Bunney, W.E.: The Effects of Piribedil on Mood, Sleep, Endocrine Function, and Amine Metabolism in Depressed Patients. The International Symposium on Piribedil, a Dopaminergic Agonist, Munich, Germany, November, 1978.

12. Carman, J.S.: Calcitonin and Other Calcitropic Hormones in the Periodic Psychoses. Curt P. Richter Award Essay, The 10th Congress of the International Society of Psychoneuro-endocrinology, Park City, Utah, 1980.

13. Carman, J.S., Post, R.M., Ballenger, J.C., Becker, K.L., Silva, O.: Radioimmunoassayable Calcitonin in Human CSF: Relationship to Psychiatric Diagnosis. The 35th Annual Meeting of the Society of Biologic Psychiatry, Boston, Massachusetts, September, 1980.

14. Carman, J.S., Wyatt, E.S., Hall, K.R., Crews, E.L.: Dexamethasone Non-Suppression: Predictor of Thymoleptic Response in Catatonic and Schizoaffective Patients. The 35th Annual Meeting of the Society of Biologic Psychiatry, Boston, Massachusetts, September, 1980.

15. Carman, J.S., Wyatt, E.S., Dohn, H.H., Hall, K.R., Crews, E.L., Ledbetter, J.: RBC/plasma Lithium Ratio (LR) as a Predictor of Acute Antimanic Response to Lithium in Affective, Shizoaffective or Paranoid Schizophrenic Patients. The 35th Annual Meeting of the Society of Biologic Psychiatry, Boston, Massachusetts, September, 1980.

PRESENTATIONS - Cont'd:

16. Wyatt, E.S., Carman, J.S., Crews, E.L., Spencer, S., Bush, J.: Computerized Cerebral Tomography in Schizophrenia. The 35th Annual Meeting of the Society of Biologic Psychiatry, Boston, Massachusetts, September, 1980.

17. Smith, W.B., Carman, J.S., Wyatt, E.S.: Calcitonin in Chronic Pain. The 36th Annual Meeting of the Society of Biologic Psychiatry, New Orleans, Louisiana, May, 1981.

18. Carman, J.S., Wyatt, E.S., Hall, K.R., Crews, E.L.: DST Predicts Thymoleptic Response in RDC Schizophrenics. The Annual Meeting of the American Psychiatric Association, New Research Program; New Orleans, Louisiana, May, 1981.

19. Wyatt, E.S., Carman, J.S., Crews, E.L., Spencer, S., Bush, J.: Computerized Cerebral Tomography in Schizophrenia. The 134th Annual Meeting of the American Psychological Association New Research Program, New Orleans, Louisiana, May, 1981.

20. Carman, J.S., Post, R.M., Ballenger, J.C., Goodwin, F.K., : Calcitonin in Affective Disorder. The XII Congress of the International Society of Psychoneuroendocrinology, Montreal, Canada, May, 1981.

21. Carman, J.S., Smith, W.B., Wyatt, E.S., Lukensmeyer, W.: Calcitonin in Chronic Pain. The XII Congress of the International Society of Psychoneuroendocrinology, Montreal, Canada, May, 1981.

22. Carman, J.S., Wyatt, E.S., Hall, K.R., Crews, E.L., Scalise, M., Watts, D., Hoppers, L.: Dexamethasone Non-Suppression: Predictor of Thymoleptic Response in Catatonic and Paranoid Schizophrenics and Schizoaffective Patients. The XII Congress of the International Society of Psychoneuroendocrinology, Montreal, Canada, May, 1981.

23. Carman, J.S., Wyatt, E.S., Dohn, H.H., Hall, K.R., Crews, E.L.: RBC/Plasma Lithium Ratio as a Predictor of Acute Response to Lithium in Manic, Schizoaffective Patients. The III World Congress of Biologic Psychiatry in the Symposium on Predictors of Response to Psychotropic Drugs at, Stockholm, Sweden, June, 1981.

24. Carman, J.S., Wyatt, E.S., Hall, K.R., Crews, E.L.: Dexamethasone Non-Suppression: Predictor of Thymoleptic Response in Schizophrenic and Schizoaffective Patients. The III World Congress of Biologic Psychiatry in the Symposium on Predictors of Response to Psychotropic Drugs, Stockholm, Sweden, June, 1981.

25. Carman, J.S., Post, R.M., Ballenger, J.C., Goodwin, F.K.: Reduced CSF Calcitonin in Mania. The III World Congress of Biologic Psychiatry in the Symposium on Neuropeptides in CSF, Stockholm, Sweden, June, 1981.

26. Carman, J.S.: Calcium in Manic Depressive Illness. The Wayne State University, Lafayette Clinic, Detroit, Michigan, January, 1982.

PRESENTATIONS - Cont'd:

27. Carman, J.S.: Biological Predictors of Psychotropic Drug Response. The Fair Oaks Hospital, Summit, New Jersey, March, 1982.

28. Carman, J.S.: Psychopharmacology - 1982. The Annual Meeting of the Georgia Psychological Association, Savannah, Georgia, May, 1982.

29. Carman, J.S.: Predictors of Response to Psychotropic Drugs. The South Carolina Psychiatric Association, Charleston, South Carolina, 1983.

30. Carman, J.S., Tarry, M.H., Wyatt-Knowles, E.S.: BW647 in Depression. The Annual Meeting of the Society of Biological Psychiatry, New York, April, 1983.

31. Carman, J.S., Wyatt-Knowles, E.S., Tarry, M.H., Dren, A., Manberg, P.: BW234 in Mania. The Annual Meeting of the Society of Biological Psychiatry, New York, April, 1983.

32. Carman, J.S., Wyatt-Knowles, E.S., Fleck, R., Martin, D., Gold, M.S.: Neuroleptic Compliance in Schizophrenic Outpatients. The Annual Meeting of the National Association of Private Psychiatric Hospital, Palm Springs, California, January, 1984.

33. Carman, J.S., Wyatt-Knowles, E.S., Fleck, R., Martin, D., Gold, M.S.: Monitoring Neuroleptic Compliance in Schizophrenic Outpatients. The XVth Congress of the International Society of Psychoneuroendocrinology, Vienna, Austria, July, 1984.

34. Carman, J.S., Wyatt-Knowles, E.S.: Drug Research in the Private Psychiatric Setting. The 52nd Annual Meeting of the National Association of Private Psychiatric Hospitals, Marco Island, Florida, January, 1985.

35. Carman, J.S., Wyatt-Knowles, E.S.: BW234 in Mania. The IVth World Congress of Biological Psychiatry, Philadelphia, Pennsylvania, 1985.

36. Carman, J.S., Wyatt-Knowles, E.S.: Calcium and Affective Illness. The IVth World Congress of Biological Psychiatry, Philadelphia, Pennsylvania, 1985.

37. Carman, J.S.: Lithium in Teenagers. The Annual Meeting of Georgia Adolescent Psychiatry, Atlanta, Georgia, December 11, 1985.

38. Carman, J.S.: Update on Clinical Psychopharmacology. The Annual Symposium of Alabama State Department of Continued Education, Tuscaloosa, Alabama and Mobile, Alabama, April 30 and May 1, 1986.

39. Carman, J.S., Ahdieh, H., Wyatt-Knowles, E.S., Warga, E., Panagides, J.: Mianserin vs. Amitriptyline vs. Placebo in Major Depression. The 30th Annual Meeting of the NCDEU, Key Biscayne, Florida, June, 1990.

PRESENTATIONS - Cont'd:

40. Derivan, A., Borison, R., Carman, J., Crowder, J., Cunningham, L., Diamond, B.: Six-week Comparison of Venlafaxine, Trazodone, and Placebo in Major Depression. The ACNP meeting, San Juan, 1991.

41. Feighner, J., Overo, K., Fieve, R., Carman, J.S., Cunningham, L., Schwartz, G.: Fixed Dose Comparison of Citalopram vs. Placebo in the Treatment of Outpatients with Moderate to Severe Depression. The 37th Annual Meeting of the NCDEU, Boca Raton, Florida, May 1997.

ABSTRACTS AND LETTERS:

42. Carman, J.S.,: Methylphenidate in Akathisia. LANCET II: 1093, 1972.

43. Carman, J.S.: Hyperdopaminergic States: A Continuum. LANCET II: 1249, 1972.

44. Carman, J.S.: Physostigmine in Tardive Dyskinesia. LANCET II: 1424-1425, 1972.

45. Carman, J.S.: Pigment and Kinesia. LANCET I: 374, 1973.

46. Carman, J.S.: Lithium in Chorea. LANCET I: 611, 1973.

47. Carman, J.S.: Imipramine in Hyperacusic Depression. American Journal of Psychiatry 130: 937, 1973.

48. Carman, J.S.: M.I.F.: Inhibitor of O-methylation?. LANCET I: 1247, 1973.

49. Carman, J.S., Tucker, L.S.: Benztropine in Childhood Hyperkinesis. LANCET II: 1337, 1973.

50. Carman, J.S., Post, R.M., Goodwin, F.K., Bunney, W.E., Teplitz, T.A.: Calcium, ECT, Lithium and Mood. New Research Program of the 127th Annual Meeting of the American Psychiatric Association; Detroit, Michigan, May, 1974.

51. Stoddard, F.J., Post, R.M., Gillin, J.C., Bunney, W.E., Carman, J.S.: Phasic Changes in Manic-Depressive Illness. New Research Program of the 127th Annual Meeting of the American Psychiatric Association; Detroit, Michigan, May, 1974.

52. Post, R.M., Gerner, R.H., Carman, J.S., Bunney, W.E.: A Dopamine-Receptor Stimulator in Depression. Proceedings of the 128th Annual Meeting of the American Psychiatric Association; Anaheim, California, May, 1975.

ABSTRACTS AND LETTERS (cont.):

53. Jimerson, D.C., Post, R.M., Carman, J.S., Van Kammen, D.P., Wood, J.H., Goodwin, F.D., Bunney, W.E. : CSF Electrolytes: Calcium and Depression. Proceedings of the 129th Annual Meeting of the American Psychiatric Association; Asimolar, California, January, 1976.

54. Carman, J.S., Post, R.M., Goodwin, F.J., Buswell, R.: Melatonin, MSH and Psychosis: A Reply. American Journal of Psychiatry 134: 583-584, 1977.

55. Carman, J.S., Wyatt, R.J.: Calcium: Pacesetting the Periodic Psychoses. Proceedings of the 131st Annual Meeting of the American Psychiatric Association; Atlanta, Georgia, May, 1978.

56. Carman, J.S., Post, R.M., Ballenger, J.C., Becker, K.L., Silva, O.: Radioimmunoassayable Calcitonin in Human CSF: Relationship to Psychiatric Diagnosis. Abstracts of the 35th Annual Meeting of the Society of Biologic Psychiatry; Boston, Massachusetts, September, 1980.

57. Carman, J.S., Wyatt, E.S., Hall, K.R., Crews, E.L., Hoppers, L., Scalise, M.: Dexamethasone Non-Suppression: Predictor of Thymoleptic Response in Catatonic and Schizoaffective Patients. Abstracts of the 35th Annual Meeting of the Society of Biologic Psychiatry; Boston, Massachusetts, September, 1980.

58. Carman, J. S., Wyatt, E.S., Dohn, H.H., Hall, K.R., Crews, E.L., Ledbetter, J.: RBC/Plasma Lithium Ration (LR) as a Predictor of Acute Antimanic Response to Lithium in Affective, Schizoaffective or Paranoid Schizophrenic Patients. Abstracts of the 35th Annual Meeting of the Society of Biologic Psychiatry; Boston, Massachusetts, September, 1980.

59. Smith, W.B., Carman, J.S., Wyatt, E.S.: Calcitonin in Chronic Pain. Abstracts of the 36th Annual Meeting of the Society of Biologic Psychiatry; New Orleans, Lousiana, May 1981.

60. Wyatt, E.S., Carman, J.S., Crews, E.L., Spencer, S., Bush, J.: Computerized Cerebral Tomography in Schizophrenia. Abstracts of the 36th Annual Meeting of the Society of Biologic Psychiatry; New Orleans, Louisiana, May, 1981.

61. Carman, J.S., Wyatt, E.S., Hall, K.R., Crews, E.L., Hoppers, L., Scalise, M.: DST and Thymoleptic Response in RDC Schizophrenics. New Research Program of the 134th Annual Meeting of the American Psychiatric Association; New Orleans, Louisiana, May, 1981. (NR48)

ABSTRACTS AND LETTERS - Cont'd:

62. Wyatt, E.S., Carman, J.S., Crews, E.L., Spencer, S., Bush, J.: Computerized Cerebral Tomography in Schizophrenia. New Research Program of the 134th Annual Meeting of the American Psychiatric Association; New Orleans, Louisiana, May, 1981. (NR49)

63. Carman, J.S., Post, R.M., Ballenger, J.C., Goodwin, F.K.: Calcitonin in Affective Disorders. Neuroendocrinology Letters 3: 115, 1981.

64. Carman, J. S., Smith, W.B., Wyatt, E.S., Lukenmeyer, W.: Calcitonin in Chronic Pain. Neuroendocrinology Letters 3: 122, 1981.

65. Carman, J.S., Wyatt, E.S., Hall, K.R., Crews, E.L., Hoppers, L., Scalise, M.: Dexamethasone Non-Suppression: Predictor of Thymoleptic Response in Catatonic, Paranoid, and Schizoaffective Patients. Neuroendocrinology Letters 3: 122, 1981.

66. Carman, J.S., Tarry, M.H., Wyatt-Knowles, E.S.: BW647 in Depression. Abstracts of the 38th Annual Meeting of the Society of Biologic Psychiatry; New York City, New York, April, 1983.

67. Carman, J.S., Wyatt, E.S., Tarry, M.H., Dren, A., Manberg, P. : BW234 in Mania, Abstracts of the 38th Annual Meeting of the Society of Biologic Psychiatry; New York City, New York, April, 1983.

68. Carman, J.S., Wyatt, E.S.: BW234 in Mania. Abstracts of the 14th World Congress Biological Psychiatry; Philadelphia, Pennsylvania, September 8-13, 1986.

69. Carman, J.S., Wyatt, E.S.: Calcium in Affective Disorder. Abstracts of the 14th. World Congress Biological Psychiatry; Philadelphia, Pennsylvania, September 8-13, 1986.

70. Harrigan, E.P., Reeves, K.R.: The Efficacy and Safety of Two Fixed Doses of Ziprasidone in Schizophrenia and Schizoaffective Disorder. Abstract #471 of the 10th World Congress of Psychiatry, Madrid, Spain, 1996, (Carman, J.S., member of the Ziprasidone study group).

71. Fawcett, J.A., Gelenberg, A., Harrison, W., Hirschfeld, R.M.A., Keller, M.B., Klein, D.N., Kocsis, J., Koran, L.M., Markowitz, J., McCullough, J.P., Micelli, R., Rush, A.J., Schatzberg, A., Thase, M.E.: The Treatment of Chronic Depression: Study Design and Rationale for Evaluating the Comparative Efficacy of Sertraline and Imipramine, Draft for Archives of General Psychiatry, 1997, (Carman, J.S., acknowledged).

PUBLICATIONS:

72. Prange, A.J., Sisk, J.L., Wilson, I.C., Morris, C.E., Hall, C.D., Carman, J.S.: Balance, Permission, and Discrimination Among Amines: A Theoretical Consideration of the Actions of l-Tryptophan in Disorders of Movement and Affect. Serotonin and Behavior, (Usdin, E. and Barchas, J.S., eds.), New York, Academic Press, 539-548, 1973.

73. Carman, J.S., Schoulson, I., Chase, T.M.: Lithium Carbonate Alone in Huntington's Chorea. Lancet I: 811-812, 1974.

74. Carman, J.S., Post, R.M., Teplitz, T.A., Goodwin, F.K.: Divalent Cations in Predicting Antidepressant Response to Lithium. Lancet II: 1454, 1974.

75. Post, R.M., Gerner, R.H., Carman, J.S., Bunney, W.E.: Effect of Low Doses of a Dopamine Receptor Stimulator in Mania. Lancet I: 203-204, 1976.

76. Green, R.A., Barchas, J.D., Elliott, G.R., Carman, J.S., Wyatt, R.J.: The Tryptolines: Effect of Intraventricular Administration on Spontaneous Motor Activity of Rats. Pharmacologic Biochemical Behaviour 5: 383-385, 1976.

77. Carman, J.S., Buswell, R.T., Post, R.M., Goodwin, F.K.: Negative Effects of Melatonin on Depression. American Journal of Psychiatry 133: 1181-1186, 1976.

78. Carman, J.S., Post, R.M., Goodwin, F.K., Bunney, W.E.: Calcium and Electro-convulsive Therapy of Severe Depressive Illness. Biological Psychiatry 12: 5-17, 1977.

79. Bigelow, L.B., Nasrallah, H.S., Carman, J.S., Gillin, J.C., Wyatt, R.J.: Baclofen Treatment in Chronic Schizophrenia. American Journal of Psychiatry 134: 318-319, 1977.

80. Carman, J.S., Wyatt, R.J.: Alterations in CSF and Serum Total Calcium with Changes in Psychiatric State: Neuroregulators and Psychiatric Disorders (Usdin, E., Hamburg, D.A., and Barchas, J.S., eds.), New York, Oxford University Press, 488-494, 1977.

81. Carman, J.S., Wyatt, R.J.: Calcitonin and Malignant Catatonia. Lancet II: 1124-1125, 1977.

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89. Carman, J.S., Wyatt, R.J.: Calcium: Pacesetting the Periodic Psychoses. American Journal of Psychiatry 136: 1035-1039, 1979.

90. Carman, J.S., Post, R.M., Runkle, D.C., Bunney, W.E., Wyatt, R.J.: Increased Serum Calcium and Phosphorus with the "Switch" into Manic or Excited Psychotic States. Britian Journal of Psychiatry 135: 55-61, 1979.

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94. Carman, J.S., Crew, E.L., Bancroft, A., Wyatt, E., Cooper, B., Ledbetter, J., Daniels, J., Monson, S., Bond, W.: Calcium and Calcium-Regulating Hormones in the Biphasic Periodic Psychoses. Journal of Operational Psychiatry 11: 5, 1980.

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111. Carman, J.S., Wyatt, E.S., Fleck, R., Martin, D., Gold, M.: Neuroleptic Compliance in Schizophrenic Outpatients. Psychiatric Hospital 15: 173-178, 1984.

112. Carman, J.S., Wyatt-Knowles, E.S.: Calcium and Affective Disorder: Biological Psychiatry 1985. (eds.: Bridges, W.H., Josiasson, R.C., Shagas, C., Simpson, G.M., Stoff, D., Weiss, K.J.) Elsevier Press, New York, 323-325, 1986.

113. Crews, E.L., Wyatt, E.S., Carman, J.S.: Salmon Calcitonin: Effects on Tardive Dyskinesia.

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114. Hall, K.R., Carman, J.S., Wyatt, E.S.: Bupropion: Antimanic Prophylaxis and Spectrum of Antidepressant Efficacy and Its Relationship to Dexamethasone Suppression of a Dopaminergic Thymoleptic.

115. Carman, J.S.: Marked but Asymptomatic Thyroid Hormone Elevations in a Paranoid Schizophrenic on Low Phenylalamine Diet.

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121. Walczak, D.D., Halikas, J.A., Carman, J.S., et al: The Oral Dose-Effect Relationship for Fluvoxamine: A Fixed-Dose Comparison Against Placebo in Depressed Outpatients. Annals of Clinical Psychiatry.

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129. **Acknowledgments:** Adler, L., Burnie, G., Apter, J., Baumel, B., Bralliar, R., Carman, J., Cunningham, L., Hartford, J., Kirby, L., Mihtar, H., Nunez, M., Sambunaris, A., Shrivastava, R., Tilker, H., Weiss, K.,: "A Double-blind, Placebo-controlled Trial of the Safety and Efficacy of Selegiline Transdermal System (STS) Without Dietary Restrictions in Patients with Major Depression". Journal of Clinical Psychiatry.

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1983-1989 M.D. University of Virginia, School of Medicine
Charlottesville, VA; Alpha Omega Alpha Medical Honor Society

1979-1983 B.S. (Biology), Haverford College, Philadelphia, PA

PROFESSIONAL TRAINING:

1993-1994 Chief Resident, Dept. of Psychiatric Medicine, University of Virginia
Charlottesville, VA

1990-1994 Psychiatry Residency, University of Virginia, Health Sciences Center
Charlottesville, VA

1989-1993 Internal Medicine Residency, University of Virginia, Health Sciences Center
Charlottesville, VA

1989-1990 Internship, University of Virginia, Health Sciences Center
Charlottesville, VA

ACADEMIC AND PROFESSIONAL:

1999 **Clinical Assistant Professor, Dept. of Psychiatry and Behavioral Medicine**
University of South Florida, Tampa, FL

1999- **Instructor, Dept. of Psychology**
University of Central Florida, Orlando, FL

1998-2002 **Medical Director and Director of Psychopharmacology Research,** Lakeside Alternatives Behavioral Healthcare Systems, Orlando FL

1998	**Medical Director and President** CORE Research, Inc., Orlando, FL
1996-1998	**Co-Medical Director, Co-Director of Psychopharmacology Research Program and Vice President,** Psychiatric Institute of Florida, Orlando, FL
1995-1996	**Director of Psychiatric Medicine and Psychiatry Grand Rounds Coordinator** Florida Hospital, Center for Psychiatry Orlando, FL
1994-1995	**Director of Consultation-Liaison Psychiatry, Dept. of Psychiatry** Biologic Sciences Division, University of Chicago, Chicago, IL
1994-1995	**Director of Adult Inpatient Services, Dept. of Psychiatry** Biologic Sciences Division University of Chicago, Chicago, IL
1994-1995	**Director of Psychiatric Medicine, Dept. of Psychiatry** Biologic Sciences Division University of Chicago, Chicago, IL
1994-1995	**Assistant Professor, Dept. of Psychiatry** Biologic Sciences Division University of Chicago, Chicago, IL
1993-1994	**Chief Resident, Dept. of Psychiatric Medicine** University of Virginia Charlottesville, VA
1993-1994	**Consulting Psychiatrist, HIV Clinic, Division of Infectious Disease, Dept. of Internal Medicine** University of Virginia Health Sciences Center Charlottesville, VA
1992-1993	**Psychiatry Clerkship Coordinator** University of Virginia, School of Medicine, Charlottesville, VA
1992	**National Depression Screening Day Coordinator** University of Virginia Dept. of Psychiatric Medicine, Charlottesville, VA

HOSPITAL APPOINTMENTS:

1998-present	Director, Medical Grand Rounds, Lakeside Alternatives, Orlando, FL
1998-present	Medical Director, Lakeside Alternatives, Orlando, FL
1997-present	Medical Director, Clozaril Clinic, Lakeside Alternatives, Orlando, FL
1995-present	Medical Staff, Florida Hospital, Orlando, FL
1997-1998	Medical Director, Partial Hospitalization Program Lakeside Alternatives Behavioral Healthcare System Orlando, FL
1996-1998	Medical Staff, Charter Behavioral Center Systems, Orlando, FL
1996-1997	Medical Staff, University Behavioral Center, Orlando, FL

1996-1997	Medical Staff, Lakewood Adult Care Center, Orlando, FL
1995-1996	Assistant Professor, University of Chicago Hospitals Chicago, IL
1993-1994	Central Virginia Training Center, Lynchburg, VA
1990-1994	Medical Staff, Western State Hospital, Staunton, VA
1989-1994	Resident Physician, University of Virginia Hospitals Charlottesville, VA

HONORS:

1999	Distinguished Clinical Professional Award, Mental Health Association of Central Florida
1998-1999	Editorial Board, *Medicine and Behavior*
1997	Fellow, Academy of Psychosomatic Medicine
1995	Distinguished Service Award, Florida Hospital, Center for Psychiatry, Orlando, FL
1995-1996	Assistant Editor, *Medical Update for Psychiatrists* (Elsevier)
1994	NAMI Effective Legislative Fellow Award, 103rd Congress, Washington, DC
1994	Coordinator, US Senate Working Group on Mental Health, Washington, DC
1994	Legislative Fellow for Health Policy, US Senator Paul Wellstone, 103rd Congress Washington, DC
1994	William Sorum Award for outstanding contribution to Members-in Training American Psychiatric Association
1993-1994	Chief Resident, Dept. of Psychiatric Medicine, University of Virginia Charlottesville, VA
1993-1994	Chair, Member-in-Training Representative Committee, American Psychiatric Association
1992-1993	Member-in-Training Representative, Southeastern US, American Psychiatric Association
1990	PRIDE Award for Outstanding Patient Care, University of Virginia Hospitals Charlottesville, VA
1989	Merck Award for Outstanding Medical Scholarship, University of Virginia, School of Medicine, Charlottesville, VA
1988	Alpha Omega Alpha, Medical Honor Society, University of Virginia, School of Medicine, Charlottesville, VA
1981-1982	Assistant to the President, Haverford College, Haverford, PA
1981-1982	Student Council, Haverford College, Haverford, PA

1980-1983	Resident Advisor, Haverford College, Haverford PA
1979	All-League, Pennsylvania Scholastic Tennis

COMMITTEES:

1998-present	Chair, Peer Review Committee, Lakeside Alternatives, Orlando, FL
1998-present	Chair, Medical Staff Committee, Lakeside Alternatives, Orlando, FL
1998-present	Co-Chair, Pharmacy Committee, Lakeside Alternatives, Orlando, FL
1995-present	Scientific Program Committee, American Psychiatric Association
1995-1998	Joint Commission on Government Relations, American Psychiatric Association
1997	Chair, Early Career Psychiatrist Committee, Florida Psychiatric Society
1995-1997	Corporation for the Advancement of Psychiatry Board
1995-1996	Quality Assurance Committee, Center for Psychiatry, Florida Hospital, Orlando, FL
1995-1996	Medical Executive Committee, Center for Psychiatry, Florida Hospital Orlando, FL
1994-1995	Utilization Review Committee, University of Chicago Hospitals
1994-1995	Quality Assurance Committee, Dept. of Psychiatry, University of Chicago
1994-1995	Residency Training Committee, Dept. of Psychiatry, University of Chicago
1994-1995	Executive Committee, Dept. of Psychiatry, University of Chicago
1995	US Senate Working Group on Mental Health, 103rd Congress
1993-1994	Assembly Executive Committee, American Psychiatric Association
1993-1994	Planning Committee, American Psychiatric Association
1993-1994	Chair, Assembly Member-in-Training Committee, American Psychiatric Association
1992-1993	Membership Committee, American Psychiatric Association
1992-1993	Assembly Member-in-Training Committee, American Psychiatric Association
1988-1991	Admissions Committee, University of Virginia, School of Medicine
1981-1983	Student Council, Haverford College, Haverford, PA

PROFESSIONAL ORGANIZATIONS:

American Psychiatric Association

Florida Psychiatric Society

Association of Geriatric Psychiatry

American Medical Association

Florida Medical Association

Academy of Psychosomatic Medicine, Fellow 11/96

Association of Medicine and Psychiatry

National & Local Alliance for the Mentally Ill.

National & Local Mental Health Association

CERTIFICATION:

National Board of Medical Examiners; July 1, 1990, Diplomate # 377171

American Board of Internal Medicine; December 6, 1993, Diplomate # 150744

American Board of Psychiatry and Neurology; October 30, 1995, Diplomate # 41674

LICENSURE:

Drug Enforcement Agency; 1989, number available upon request

Virginia Medical License; June 29, 1990, # 0101045374

Pennsylvania Medical License; July 24, 1992, # MD-047674-L

Illinois Medical License; July 31, 1994, # 003-036-089225-01 (Inactive)

Florida Medical License; July 3, 1995, # ME-0068720

RESEARCH TRAINING:

1993-1994	A Randomized Comparative Study of Paroxetine in the Treatment of Depression as Used in a Clinical Practice Setting; Anita Clayton, MD and Catherine Leslie, MD, Dept. of Psychiatric Medicine, University of Virginia, Charlottesville, VA
1988-1989	Development of Mesolimbic and Mesocortical Dopamine Systems; James P. Bennett, MD, PhD and Catherine Leslie, MD, Depts. of Neurology, Pharmacology, and Psychiatric Medicine, University of Virginia, Charlottesville, VA

1984	Role of Thromboxane A2 in Renal Vasoconstriction; E. Darracot Vaughn, MD Cornell University, School of Medicine, New York, NY
1982-1983	E. coli 16s rRNA Structure and Function; Dr. Melvin Santer, Haverford College, Haverford, PA

CLINICAL RESEARCH:

Clinical Trials Investigator

1) Double-Blind, Randomized Comparison and Placebo Controlled Studies:

a) Seroquel vs chlorpromazine in the treatment of subjects with treatment-resistant schizophrenia

b) A comparison of the effects on sexual functioning of Wellbutrin SR (bupropion HCl) and sertraline in outpatients with moderate to severe recurrent major depression

c) Safety and efficacy of lamotrigine in the treatment of a major depressive episode in patients with bipolar disorder

d) Safety and efficacy of lamotrigine in the long-term prevention of mood episodes in patients with bipolar disorder with rapid cycling

e) Efficacy and safety of lamotrigine, desipramine, and placebo in outpatients with unipolar depression

f) Aripirazole in the treatment of psychosis

g) Clozaril vs Zyprexa in the reduction of suicidality in patients with schizophrenia and schizoaffective disorder who are at risk for suicide

h) Depakote in the treatment of signs and symtoms of mania in elderly patients with dementia

i) Efficacy and safety of Seroquel, haloperidol, and placebo in elderly subjects residing in nursing homes with Alzheimer's dementia and psychosis or other psychoses

j) Safety and efficacy of lamotrigine compared to placebo and lithium in the treatment of an acute manic or mixed episode in patients who have bipolar disorder

k) Olanzapine vs placebo added to mood stabilizers in the treatment of bipolar disorder

l) Safety and outcome of treatment with oral ziprasidone in subjects with mania who are receiving lithium

m) OPC-14523 vs. Prozac in the treatment of patients with moderate depression

n) Ro 64-0796 used in elderly subjects for the prevention of clinical influenza during influenza season

o) Safety and efficacy of SR 46349B in schizophrenic patients

p) Safety and efficacy of SR 141716B in schizophrenic patients

2) Single-Blind Studies

a) Intramuscular ziprasidone vs haloperidol followed by treatment with oral ziprasidone vs haloperidol in subjects with a diagnosis of psychotic disorder

b) Intramuscular ziprasidone in subjects with psychosis and acute agitation

3) Outcome & Extension Studies

a) Paroxetine in the treatment of depression in a clinical practice setting

b) Seroquel vs usual care health outcomes in subjects with schizophrenia and schizoaffective disorder

c) Risperidone vs haloperidol for prevention of relaspe in subjects with schizophrenia and schizoaffective disorder

d) Safety and efficacy of donepezil in patients with Alzheimer's disease

e) Outcome of oral ziprasidone in the treatment of subjects who have participated in previous ziprasidone clinical trials

f) Long-term safety of aripiprazole in patients with psychosis

g) Flexible-dose continuation study of Lamictal (lamotrigine) in patients with bipolar disorder

h) Safety and outcome of 40-160mg daily of oral ziprasidone in the treatment of subjects with mania

i) Open-label, treatment-switching study from oral antipsychotic monotherapy to oral aripiprazole in the treatment of chronic schizophrenic and schizoaffective patients

j) Open-label, follow-on study of the long-term safety of aripiprazole orally in patients with psychotic disorders or psychotic behaviors of dementia

k) Olanzapine versus placebo in the prevention of relapse in bipolar disorder

l) Cost-effectiveness and functional outcomes.olanzapine in the treatment of schizophrenia in usual clinical practice: a randomized clinical study

PUBLICATIONS:

Cutler, AJ, Goldstein, JM, Tumas, JA: Dosing and switching strategies for quetiapine fumarate. *Clinical Therapeutics* 24(2),209-222, 2002

Tariot PN, Schneider LS, Mintzer JE, Cutler AJ, et al: Safety and tolerability of divalproex sodium in the treatment of signs and symptoms of mania in elderly patients with dementia: results of a double-blind, placebo-controlled trial. *Current Therapeutic Research.* 2001; 62 (1): 51-67

Cutler AJ, Cantillon M, Goldstein JM: Dosing and switching strategies for seroquel (quetiapine fumarate), a new dibenzothiazepine atypical antipsychotic. (Submitted to *Clinical Therapeutics*)

Wallace MB, Lim, J, Cutler, A, Bucci L. Effects of dehydroepiandrosterone vs. androstenedione supplementation in men. *Med Sci Sports Exercise.* 1999 Dec; 31(12):1788-92

Cutler AJ: Domestic violence. *Psychiatry* 25 (11 & 12), 1996 Audio Digest Foundation

Cutler AJ: Sleep apnea. *Medical Update for Psychiatrists* 1(4): 127-130, 1996

Cutler AJ: Asthma: recent trends in diagnosis and management. *Medical Update for Psychiatrists* 1(2):34-40, 1996

Cutler AJ: Recognition and management of hypertension by psychiatric physicians. *Medical Update for Psychiatrists* 1(1):5-12, 1996

Shaffer ER, Cutler AJ, Wellstone PD: Coverage of mental health and substance abuse services under a single-payer health care system. *Hospital and Community Psychiatry* 45:916-919, 1994

Leslie CA, Robertson MW, Cutler AJ, Bennett JP: Postnatal development of D1 dopamine receptors in the medial prefrontal cortex, striatum, and nucleus accumbens of normal and neonatal 6-hydroxydopamine treated rats: a quantitative autoradiographic analysis. *Developmental Brain Research* 62:109-114, 1996

ABSTRACTS:

Tariot P, Schneider L, Mintzer J, Cutler A, et al: Safety and tolerability of divalproex sodium in the treatment of signs and symptoms of mania in elderly patients with dementia: results of a double-blind, placebo-controlled trial. To be presented at the 153rd annual meeting of the American Psychiatric Association; May 2000, Chicago, IL

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PRINT FEATURES:

Internal Medicine News; Psychiatric News; Psychiatric Times; Clinical Psychiatry News, New York Times, Newsweek

OTHER:

1985-1990 Jazz Disc Jockey, WTJU, Charlottesville, VA.

COMMUNITY ACTIVITIES:

1998-present Board Member, Fountainbrook Homeowner's Association

1998-present Board Member, Mental Health Association of Central Florida

1998-present Vice President, Jewish Family Services of Orlando

1997-present Board Member, Jewish Family Services of Orlando

1998-1999 Board Member, Coalition for the Homeless of Central Florida

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Curriculum Vitae

Professional Experience:

February, 2002- present	**Chief Executive Officer,** **Midwest Clinical Research Center. LLC** 9000 North Main Street, Suite 234 Dayton, Ohio 45415
April, 2001-present	**Adjunct Associate Professor of Pharmaceutical Services** College of Pharmacy University of Cincinnati 3223 Eden Avenue Cincinnati, Ohio 45267
March, 2000-July, 2002	**Assistant Director of Clinical Affairs, Mental Health Service Line** Cincinnati VA Medical Center 3200 Vine Street Cincinnati, Ohio 45220
December, 1997-March, 2000	**Director, General Psychiatry Division** Cincinnati VA Medical Center 3200 Vine Street Cincinnati, Ohio 45220
September, 1988-present	**Associate Professor of Clinical Psychiatry** Department of Psychiatry University of Cincinnati College of Medicine 231 Bethesda Avenue Cincinnati, Ohio 45267
May, 1993-December, 1997	**Director, Ambulatory Care Psychiatry** Cincinnati VA Medical Center 3200 Vine Street Cincinnati, Ohio 45220
September, 1991-May, 1993	**Acting Chief of Psychiatry** Cincinnati VA Medical Center 3200 Vine Street Cincinnati, Ohio 45220
July, 1983-June, 1992	**PGY-1 Coordinator**

8/30/02

Department of Psychiatry
University of Cincinnati College of Medicine
231 Bethesda Avenue
Cincinnati, Ohio 45267

January, 1989-September, 1991 — **Director, MHC/HCMI**
Cincinnati VA Medical Center
3200 Vine Street
Cincinnati, Ohio 45220

September, 1987-December, 1988 — **Associate Director, Ambulatory Care Psychiatry**
Cincinnati VA Medical Center
3200 Vine Street
Cincinnati, Ohio 45220

March, 1980-August, 1988 — **Assistant Professor of Clinical Psychiatry**
Department of Psychiatry
University of Cincinnati College of Medicine
231 Bethesda Avenue
Cincinnati, Ohio 45267

March, 1980-June, 1981 — **Medical Director, Psychiatric Evaluation Center**
Cincinnati VA Medical Center
3200 Vine Street
Cincinnati, Ohio 45220

July, 1979-March, 1980 — **Staff Psychiatrist/Instructor**
Rollman Psychiatric Institute
3009 Burnet Avenue
Cincinnati, Ohio 45219

Education and Training:

July, 1976-June, 1979 — Rollman Psychiatric Institute, Cincinnati, Ohio
Psychiatric Residency

December, 1975-May, 1976 — University of Cincinnati Medical College, Cincinnati, Oh
Anesthesia Residency

July, 1974-January, 1975 — Safdarjang Hospital, New Delhi, India
Medicine Residency

July, 1968-June, 1973 — Armed Forces Medical College, Pune, India
Medical Student, lead to MD

Examinations:

- FLEX July, 1977
- ECFMG June, 1975

Board Certification:

November, 1982 American Board of Psychiatry & Neurology

Served as an Examiner for the Board November, 1993 and June, 1995

Licensure:

- Ohio 42602
- Kentucky 19281

Publications:

Book Chapter Baker, D. G., and **D'Souza, B.** (1993).
Treatment of the VA Patient.
In: **Manual of Clinical Psychiatry**, APA Press, Washington, D.C.

Presentations:

- November, 1993. TQI and Use of TQM Tools. Knoxville VA Medical Center, Knoxville, Iowa.
- May, 1993. History of Suicide Attempts: A Trait Variable? (poster). American Psychiatric Association Annual Meeting, San Francisco, California.
- May, 1987. Revamping the Residency Curriculum (workshop). American Psychiatric Association Annual Meeting, Chicago, Illinois.
- April, 1986. Outpatient Treatment of Chronically Mentally Ill Veterans. Allen Park VA Medical Center, Detroit, Michigan.
- November, 1984. Psychopharmacology Review. Armed Forces Medical College, Pune, India.

Grant Writing/Workgroups:

Member of Committee for Homeless Mentally Ill Veterans Program
(Wrote proposal and obtained $500,000 funding for new program)

Member of Task Force for MEDIPP Proposal for Adult Day Health Care Program

VA Consultant for Development of Clinical Indicators
Washington, D.C., April, 1992

Clinical Trials:

- XXX: Phase III, Randomized, Double-blind, Placebo-Controlled study of the Safety and Efficacy of patients with Major Depressive Disorders with psychotic features.
  Sponsor: Corcept Therapeutics Incorporated
- XXX: Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features Who are not Receiving Antidepressants or Antipsychotics.
  Sponsor: Corcept Therapeutics Incorporated
- XXX: A Phase III, Open-Label Study of the Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features Who Have Previously Demonstrated a Rapid Response to either C-1073 or Placebo in Study C-1073-02 or C-1073-03.
  Sponsor: Corcept Therapeutics Incorporated
- Phase I, Double-blind, Randomized, Parallel Group Study of CSF 5-H1AA Concentrations during CP-448, 187 Challenge in Healthy Volunteers.
  Sponsor: Pfizer

- Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in the Prevention of Depression Relapse.
  Sponsor: Forest Laboratories

- Fixed Dose Comparison of the Safety and Efficacy of XXX, Citalopram, and Placebo in the Treatment of Major Depressive Disorder.
  Sponsor: Forest Laboratories

- An Open-Label Follow-on Study of the Long-Term Safety of Aripiprazole in Patients with Chronic Schizophrenia.
  Sponsor: Otsuka America Pharmaceutical, Inc.

- A Multi-Center, Randomized, Double-Blind, Active-Controlled Study to Compare the LongTermMaintenance Effects and Safety of Aripiprazole and Haloperidol Following Acute Relapse in Schizophrenic Patients.
  Sponsor: Otsuka America Pharmaceutical, Inc.

- TAP Holdings, Inc. "Phase II Multicenter Randomized Comparison of XXX Versus Placebo in the Treatment of Subjects with Major Depressive Disorder"

- An Eight-Week, Double-Blind, Placebo-Controlled Study of 2, 20, 50, and 100 mg Flibanserin b.i.d. and Paroxetine q.d. in Patients with Major Depressive Disorder .
  Sponsor: Boehringer-Ingelheim Pharmaceuticals, Inc.

- Double-Blind, Placebo-Controlled Study of Venlafaxine and Fluoxetine in Geriatric Outpatients with Major Depression .
  Sponsor: Wyeth-Ayerst Laboratories

- Safety and Efficacy of Risperidone 8 mg QD and 4 mg QD Compared to Placebo in the Treatment of Schizophrenia .
  Sponsor: Janssen Research Foundation

- Dose-Response Study in the Treatment of Negative Symptoms of Schizophrenia with XXX .
  Sponsor: Boehringer Ingelheim/The Upjohn Company

- A Placebo-Controlled, Double-Blind, Parallel-Group Safety and Efficacy Trial of XXX in Posttraumatic Stress Disorder .
  Sponsor: Ciba-Geigy Corp.

- A Multicenter, Randomized, Double-Blind, Study of XXX Versus Placebo in the Treatment of Acutely Manic Patients with Bipolar Disorder.
  Bristol-Myers Squibb

- An Open-Label Follow-On Study of the Long-Term Safety of XXX in Patients with Psychosis.
  Otsuka America Pharmaceutical

- A Phase III Double-Blind Placebo Controlled Study of XXX in the Treatment of Psychosis.
  Otsuka America Pharmaceutical

- A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Three Fixed Doses of XXX in the Treatment of Patients with Acute Schizophrenia.
  Bristol-Myers Squibb

- A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Two Fixed Doses of XXX in the Treatment of Hospitalized Patients With Acute Mania.
  Bristol-Myers Squibb

- A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of XXX in the Maintenance Treatment of Patients With Bipolar Disorder..
  Bristol-Myers Squibb

- A Double-Blind, Placebo-Controlled, Multicenter Study of the Long-Term Efficacy of XXX in the Maintenance of Antidepressant Effect in Geriatric Outpatients With Major Depressive Disorder.
  Merck

- A Double-Blind, Three-Armed, Fixed-Dose, Placebo-Controlled Dose-Finding Study with Sublingual XXX in Subjects with Acute Phase Schizophrenia..
  Organon

- Long-term Maintenance of Subjects with Schizophrenia with XXX
  Organon

- The Efficacy and Safety of flexible dosage ranges of Risperidone vs. Placebo in the treatment of manic episodes associated with Bipolar I Disorder..
  Janssen Pharmaceutica Products

- A 9-Week, Multicenter, Safety Trial of Flexible Dose Ranges of Risperidone in the Treatment of Manic Episodes Associated with Bipolar I Disorder.
  Janssen Pharmaceutica Products

- A Multicenter, Double-Blind, Randomized Comparison of the Efficacy and Safety of Sustained-release Formulation Quetiapine Fumarate (SEROQUEL™) and Placebo in the Treatment of Patients with Schizophrenia..
  AstraZeneca Pharmaceuticals

Military Experience:

February, 1988	Commissioned as Captain in the US Army Reserves. Colonel in the Air Force Reserve, Medical Corps.
May, 1990	Combat Casualty Care Course Fort McCoy, Wisconsin
December, 1992	Advanced Cardiac Life Support Certification Wright Patterson Air Force Base, Dayton, Ohio
April, 1997	Graduate of Air War College Maxwell Air Force Base, Montgomery, Alabama

Professional Association Memberships:

- American Psychiatric Association
- Ohio Psychiatric Association
- Association of Indian Physicians of Greater Cincinnati
- Association of Military Surgeons of the US
- National Association of VA Physicians

Professional References:

- Jerald Kay, MD
  Chair, Department of Psychiatry
  Wright State University
  Dayton, Ohio 45220
  REDACTED

- J. Randolph Hillard, MD
  Chair, Department of Psychiatry
  University of Cincinnati College of Medicine
  231 Bethesda Avenue
  Cincinnati, Ohio 45267
  REDACTED

- Thomas Geracioti, MD
  Chief, Mental Health Service Line
  Cincinnati VA Medical Center
  3200 Vine Street
  Cincinnati, Ohio 45220
  REDACTED

STATE MEDICAL BOARD OF OHIO
77 S. High St., Columbus, Ohio 43266-0315
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EXPIRES: 04/01/2003 LICENSE NUMBER 35-04-2602-D

Between 01/02/01 and 01/01/03 you must complete and maintain documentation of 100 hours of CME. (40 in Category I)

BERNADETTE B. D'SOUZA,MD

is duly registered and entitled to practice in The State of Ohio until the expiration date. AUDIT # :068778

As a physician or podiatrist practicing in the State of Ohio, you are responsible for:

- Keeping informed of new laws and rules pertaining to your profession.
- Reporting any violations of the Medical Practices Act to our complaint hotline at 1-800-554-7717.
- Notifying the board in writing within 30 days of any change in your address - (residence and principle practice)
- Completing and maintaining documentation of CME.

Access website at **www.state.oh.us/med/** to obtain current information from the board.

Signature

507US/0049:0011

9/11/2002

NARESH PATRICK EMMANUEL M.D.

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Columbia, SC 29201
Phone:(803) 988-0080 Fax: (803) 988-0085
Mobile:REDACTED

HOME ADDRESS:

REDACTED

BIRTHPLACE: Philadelphia, Pennsylvania

MARITAL STATUS: Married, one daughter

MEDICAL SPECIALTY: Medical Specialty: Psychiatry

EDUCATION:

Medical: Karnatak University, Jawarharlal Nheru Medical College, Belgaum, Karnatak State, India.
Degree:Bachelor of Medicine & Bachelor of Surgery (MBBS) 1976-1981.

Internship: State University of New York at Stony Brook Clinical Campus. Nassau County Medical Center, East Meadow. 1986-1987

Residency: State University of New York at Stony Brook Clinical Campus. Nassau County Medical Center, East Meadow. 1987-1990.

Fellowship: Medical University of South Carolina. Clinical Research Program in Anxiety Disorders with James C. Ballenger M.D. & R. Bruce Lydiard Ph.D. M.D. 1990-1992.

MEDICAL LICENSURE:

South Carolina - 14837
New York - 180 498
Virginia - 44985
North Carolina - 39796
Education Commission for Foreign Medical Graduates 1982
Federal Licensing Examination (FLEX)

SPECIALITY CERTIFICATION:

Diplomat, American Board of Psychiatry and Neurology 1998 #45089

FACULTY APPOINTMENTS:

1990-1992	Instructor in Psychiatry, Medical University of South Carolina. July 1990-June 1992
1992-2002	Assistant Professor in Psychiatry, Medical University of South Carolina. July 1992-present
1997-2002	Medical Director - MUSC Clinical Research Associates, 712 Richland Street, Suite J, Columbia, SC 29201.

HOSPITAL APPOINTMENTS:

1990-1992	Clinical and Research Fellow in Psychiatry, Medical University of South Carolina
1992-2002	Attending Physician, Department of Psychiatry, Medical University of South Carolina

MAJOR COMMITTEE ASSIGNMENTS:

2000- 2002	Full Member MUSC IRB Board

PROFESSIONAL MEMBERSHIP:

Member South Carolina Medical Association (SCMA)
Member Drug Information of America (DIA)
Member Association of Clinical Research Professionals (ACRP)

RESEARCH EXPERIENCE:

2000-2002 **Principal investigator,** Forrest Laboratories "Flexible Dose Comparison of the Safety and Efficacy of Lu 26-054, Racemic Citalopram, and Placebo in the treatment of GAD."

2000-2002. **Principal investigator,** Pfizer, "A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Study To Evaluaate The Efficacy And Tolerability Of Sertraline In Subjects Diagnosed With DSM-IV Generalized Anxiety Disorder."

2000-2002 **Principal investigator**, Wyeth-Ayerst Research, Inc., "A six-month, double-blind, placebo-controlled, parallel-group comparison of Venlafaxine ER capsules and placebo in outpatients with Generalized Social Anxiety disorder."

2000-2002 **Principal investigator,** Sanofi-Synthelabo Inc. "DRI 3650: A double-blind, placebo and paroxetine controlled multicenter, dose ranging study evaluating the efficacy and safety of SR142801 in outpatient with Major Depressive Disorder.

1998-2000 **Principal investigator**, Biovail Laboratories "A double-blind, randomized, placebo-controlled, parallel group, fixed-dose study of the safety, tolerability and efficacy of 30 mg and 90 mg buspirone hydrochloride extended release compared to placebo in patients with generalized anxiety disorder."

2000-2001 **Principal investigator**, Biovail Laboratories "A double-blind, randomized, placebo-controlled, parallel group, fixed-dose study of the safety, tolerability and efficacy of 30 mg and 90 mg buspirone hydrochloride extended release compared to placebo in patients with generalized anxiety disorder. A three month extension"

1998-2000 **Principal investigator**, Biovail Laboratories "A double-blind, randomized, placebo-controlled, parallel group, fixed-dose study of the safety, tolerability and efficacy of 30 mg and 90 mg buspirone hydrochloride extended release compared to placebo in patients with generalized anxiety disorder. A nine month extension"

1999-2001 **Principal investigator**, Solvay Pharmaceuticals "A study of low dose flesinoxan, in patients with generalized anxiety disorder (GAD;DSMIV). A randomized double-blind, placebo controlled, parallel-group, multicenter study to assess efficacy and safety."

1999-2000 **Principal Investigator**, Glaxo Wellcome "A Randomized, Multicenter,

Double-blind, Placebo Controlled, Fixed Dose, 7-week Evaluation of the Efficacy and Safety of Lamotrigine in Treatment of a Major Depressive Episode in Unipolar Depressed Patients"

1992-1997 **Principal investigator**, "Imipramine vs.Placebo in the treatment of Social Phobia" Unfunded

1995-1997 **Principal Investigator**, Upjohn Company "Pramipexole vs Placebo in the Treatment of Major Depression"

1997-1998 **Principal Investigator**, Glaxo Wellcome "Wellbutrin-SR open label in the Treatment of Social Phobia"

1998-1999 **Principal Investigator**, Bristol-Myers Squibb, "A double-blind, randomized flexible-dose trial of Buspirone transdermal or alprazolam compared to placebo in the treatment of anxious outpatients.

2000-2002 Co-Investigator, HR 9624, AstraZeneca 5099IL/0041 "A Multicenter, Double-Blind, Randomized Comparison of the Efficacy and Safety of Sustained-Release Formulation Quetiapine Fumarate (Seroquel) and Placebo in the Treatment of Patients with Schizophrenia."

2000- 2002 Co-Investigator, HR 9215, AstraZeneca 5099IL/0099 " A Multicenter, Double-Blind, Randomized, Placebo-controlled Trial of the Safety and Efficacy of Seroquel (Quetiapine Fumarate) as Add-on Therapy with Lithium or Divalproex in the Treatment of Acute Mania"

2000-2002 Co-Investigator, Janssen, Weight Gain, "Effects of Risperidone and Olanzapine on Weight Gain, Physical Health, Outcome in a Community Sample of Severely and Persistently Ill Patients.

2000-2002 Co- Investigator, NIH/NIMH, "Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE)."

2000-2002 Co-Investigator, R.W. Johnson, "A placebo controlled 12 week study of the safety and efficacy of two doses of topiramate versus placebo for the treatment of acute mania or mixed episodes in subjects with bipolar I disorder with optimal open-label extension.

2000-2000 Co-Investigator, GlaxoWellcome, "A multi-center, double-blind, placebo-controlled, randomized, flexible-dose evaluation of the safety and efficacy of lamotrigine in the long-term prevention of relapse and recurrence of mania and/or depression in patients with bipolar I disorder."

2000-2001 Co- Investigator, Warner-Lambert Co., "Placebo-controlled study of Pregabalin and Paroxetine in patients with panic disorder."

2000-2001 Co- Investigator, Pfizer, Co., "A six-week, double-blind, placebo controlled, multi-center study to evaluate the safety and efficacy of 3 doses of CP-448,187 (0.5, 3, and 10 mg) and Fluoxetine in subjects with major depressive disorder."

2000-2002 Co-investigator, NIH (NCCAM) "R-21 Project: Screening Herbs for Drug Interactions." (P.I. John S. Markowitz Pharm.D.)

1999-2002 Co- Investigator, NIH/NIMH, "Systematic Treatment Enhancement Program, Bipolar disorder (STEP BD)."

1999-2001 Co-investigator, Forrest Laboratories "Flexible Dose Comparison of the Safety and Efficacy of Lu 26-054, Racemic Citalopram, and Placebo in theTreatment of Major Depressive Disorder"

1999-2001 Co-investigator, Forrest Laboratories, "Flexible Dose Comparison of the Safety and Efficacy of Lu 26-054, Citalopram, and Placebo in the Treatment of Panic Disorder".

1999-2002 Co-investigator, Glaxo-Wellcome, " Open Label, Safety and Effectiveness of Bupropion-SR for Panic Disorder."

1999-2000 Co-Investigator, Solvay Pharmaceuticals, "A twelve week, randomized, double-blind, placebo-controlled, flexible-dose study Flovoxamine-CR in the treatment of Generalized Social Anxiety Disorder."

1999-2000 Co- Investigator, Bristol Myers Squibb, " An open-label comparison of the efficacy of Serzone vs. Zoloft in patients with generalized anxiety disorder."

1999-2000 Co-Investigator, Solvay Pharmaceuticals, "A study of low dose Flesinoxan in patients with generalized anxiety disorder (GAD; DSM A randomized, double-blind, placebo-controlled, parallel-group, multi center to assess the efficacy and safety."

1999-2000 Co-Investigator, Forest Labs, Inc., "A flexible-dose comparison of the safety and efficacy of LU 26-054, Citalopram, and placebo in the treatment of major depressive disorder."

1999-2000 Co- Investigator, Forest Labs, Inc., "A flexible-dose comparison of the safety and efficacy of LU 26-054, citalopram, and placebo in the treatment of panic disorder."

1999-2000	Co-Investigator, Pharmacia & Upjohn, " Open label reboxetine rescue and continuation therapy."
1999-2001	Co-Investigator, Eli Lilly, "Long term open label treatment with r Fluoxetine for the evaluation of safety."
1999-2000	Co-Investigator, Warner Lambert/Parke Davis, "Pregabalin and paroxetine in patients with panic disorder."
1999-2001	Co-Investigator, Forest Labs, Inc. "LU-26-054 in the prevention of depression relapse."
1999-2002	Co-Investigator, Parke-Davis, "Open-label safety study of Pregabalin (CI-1008) in patients with anxiety disorders."
1999-2003	Co-Investigator, Parke-Davis, "A placebo-controlled study of Pregabalin and Alporazolam in patients with generalized anxiety disorder."
1999- 2000	Co-investigator, Parke-Davis Pharmaceuticals "A Placebo-Controlled Study of Pregabalin and Paroxetine in Patients with Panic Disorder"
1999- 2000	Co-investigator, Parke-Davis Pharmaceuticals "A Placebo-Controlled Study of Pregabalin, Alprazolam and Placebo in Patients with Generalized Anxiety Disorder"
1999-2000	Co-investigator, Pfizer Inc. A Multi-Centered Randomized Double-Blind Placebo Controlled trial of Sertraline for Acute Treatment of DSM-IV Generalized Social Phobia in Outpatients "
1999- 2001	Co-investigator, Solvay Pharmaceuticals." Venlafaxine vs Placebo in the treatment of Social Phobia."
1999-2000	Co-investigator, Eli Lilly & Co. "Open Label R-fluoxetine in the Treatment of Major Depression."
1999-2000	Co-investigator, Pharmacia & Upjohn Inc. " A Placebo-Controlled Study of Reboxetine vs Placebo in the treatment of Major Depression in patients resistant to Fluoxetine."
1999-2001	Co-Investigator, Pharmacia & Upjohn, "Reboxetine vs. placebo in the treatment of major depressive disorder resistant to Fluoxetine."

1999-1999 Co-investigator, Novartis. A Randomized, Double-Blind, Dose-Range Finding, Multicenter, Parallel Group, Active and Placebo Controlled Trial of the Safety and Efficacy of NKP608A in Patients with Moderate to Severe Major Depressive Disorder."

1998-1999 Co-Investigator, Glaxo Wellcome, "A multi-center, double-blind, placebo-controlled, randomized, fixed-dose evaluation of the safety and efficacy of Lamotrigine in the long-term prevention of relapse and recurrence of depression and/or mania in patients with bipolar I disorder."

1998-2000 Co- Investigator, Neurosearch, "A double-blind, randomized, placebo-controlled, safety, tolerability, and pilot efficacy study of NS 2710 (ME3127) Compared to placebo in patients with generalized anxiety disorder."

1998-2000 Co-Investigator, Novartis Pharmaccuticals Corporation. "Safety and efficacy of 4 doses of NKP608A in Social Phobia."

1998-2001 Co- Investigator, Novartis Pharmaceuticals Corporation, "NKP608A in patients with moderate to severe major depressive disorder."

1998-2000 Co-Investigator, SmithKline Beecham Corporation, "Paroxetine vs. placebo treatment of outpatients with IBS."

1998-1999 Co-Investigator, Vanderbilt University, "An eight-week, multi center, parallel-group, double-blind, placebo-controlled study of St. john's wort in outpatients with DSM-IV major depression."

1998- 1999 Co-investigator, Sanofi-Synthelabo SA "Befloxatone vs. Placebo in Outpatients with Moderate to Severe Major Depressive Disorder."

1998- 1999 Co-investigator, Parke-Davis Pharmaceuticals "An Open Label Evaluation of the Efficacy, Safety, and Dosing of Citalopram in Outpatients with Depression."

1998- 1999 Co-investigator, Forest Laboratories "A Placebo-Controlled Study of Pregabalin and Placebo in Patients with Social Phobia."

1998- 1999 Co-investigator, Forest Laboratories "Citalopram Treatment of Depressed Outpatients Discontinued from Paroxetine for Adverse Events."

1998- 1999 Co-investigator, Forest Laboratories "Citalopram Treatment of Depressed Outpatients Discontinued from Fluoxetine for Adverse Events."

1998- 1999 Co-investigator, Forest Laboratories "Citalopram Treatment in Major Depression in Fluoxetine Nonresponders."

1998- 1999 Co-investigator, Forest Laboratories "An Open Label Extension of Citalopram Treatment in Depressed Patients Discontinued from Fluoxetine or Paroxetine."

1997-1998 Co-Investigator, SmithKline Beecham, "A Randomized, Double-Blind, Fixed Dose Comparison of 20, 40, and 60 mg Daily of Paroxetine and Placebo in Generalized Social Phobia."

1997-1998 Co-Investigator, Parke-Davis Pharmaceutical, "Gabapentin Adjunctive Treatment in Patients with Bipolar Disorder."

1997–1998 Co-Investigator, GlaxoWellcome, "Open Label Bupropion Hydrochloride Sustained Release Tablets in Premenstrual Dysphoric Disorder."

1997–1998 Co-Investigator, GlaxoWellcome, "Open Label, Flexible Dosing of Wellbutrin SR in the Treatment of Generalized Social Phobia."

1997-1998 Co-Investigator, Bristol-Myers Squibb, "double-blind, Randomized Trial of Three Fixed Doses of Transdermal Buspirone vs. Placebo in Anxious Outpatients."

1997-1998 Co-Investigator, Organon, Inc., "Double-Blind, Placebo-Controlled, Fixed Dose Response Study to Define the Antidepressant Effectiveness and Sedative Properties of Remeron™ in Outpatients with Major Depression.

1997–1999 Co-Investigator, Bristol-Myers Squibb, "Flexible Dose Nefazodone vs. Placebo in Panic Disorder."

1996-1997 Co-Investigator, GlaxoWellcome. "A Multi-Center, Double-Blind, Placebo Controlled, Fixed Dose Evaluation of the Safety and Efficacy of Lamictal (Lamotrigine) in the Treatment of Major Depressive Episode in Patients Suffering from Bipolar Disorder."

1996-1997 Co-Investigator, Parke-Davis Pharmaceutical. "Placebo-Controlled Trial of Gabapentin in Patients with Panic Disorder."

1996-1998 Co-Investigator, GlaxoWellcome. "An Open, Multi-Center, Flexible Dose Continuation Study of Lamictal (Lamotrigine) in Patients with Bipolar

Disorder."

1992-2000 Co-Investigator, National Institutes of Mental Health. "Drug Treatment of Co-existing Panic and Major Depression."

1996–1997 Co-Investigator, Smith Kline Beecham, "Clinical Effects of Immediate Release Paroxetine and Modified Release Paroxetine in the Treatment of Major Depression."

1996–1997 Co-Investigator, SmithKline Beecham, "Flexible Dosing Trial to Evaluate the Efficacy of Modified Release Paroxetine in the Treatment of Panic Disorder."

1996–1997 Co-Investigator, University of Pittsburgh, "Psychometric Evaluation for the Structured Interview Guide for the Ham A Rating Scale (SIGH-A) in Anxiety Disorder Subjects."

1996–1998 Co-Investigator, Interneuron Pharmaceuticals, Inc., "Placebo Controlled Parallel Groups Trial of Three Doses of Pagaclone in Patients with Panic Disorder."

1996–1998 Co-Investigator, Wyeth Ayerst Research, "Venlafaxine ER in GAD Outpatients."

1996–1998 Co-Investigator, Pfizer, "Double-Blind Placebo Controlled Fixed Dose Sertraline in Premenstrual Syndrome."

1995-1996 Co-Investigator, Bristol-Myers Squibb. "Open-Label Study of Serzone in Outpatients with Depression"

1995-1996 Co-Investigator, Akzo Nobel. "An Eight-Week Placebo-Controlled Study of ORG 4428 in Outpatients with Major Depression"

1995-1996 Co-Investigator, Akzo Nobel. "A Long-Term, Placebo-Controlled Study of ORG 4428 in Outpatients with Major Depression"

1995-1996 Co-Investigator, SmithKline Beecham. "Comparison of Paroxetine and Placebo in the Treatment of Generalized Social Phobia"

1994–1995 Co-Investigator, Parke-Davis. "A Double-Blind, Placebo-Controlled, Six-Week Study of Oral CI-988 in Patients with Panic Disorder."

1994–1995 Co-Investigator, Pfizer, Inc. "Sertraline Treatment Followed by Double-Blind Comparison of Sertraline and Placebo in the Prevention of Relapse in Outpatients with Obsessive Compulsive Disorder"

1994–1995 Co-Investigator, Immunobiology Research Institute. "Basal Levels of

Corticotropin-Releasing Factor and Thymopoietin in Patients with Panic Disorder"

1994–1995 Co-Investigator, Immunobiology Research Institute. "Basal Levels of Corticotropin-Releasing Factor and Thymopoietin in Patients with Depression"

1994–1995 Co-Investigator, Immunobiology Research Institute. "Basal Levels of Corticotropin-Releasing Factor and Thymopoietin in Patients with Generalized Anxiety Disorder"

1994–1995 Co-Investigator, Pfizer, Inc. "12-Week, Double-Blind Comparison of Two Sertraline Dose Regimens in Non-Responder Outpatients with Obsessive Compulsive Disorder"

1994–1996 Co-Investigator, Solvay Pharmaceuticals. "Flesinoxan in the Treatment of Generalized Anxiety Disorder" (M.R. Ware, PI)

1994–1996 Co-Investigator, Pfizer, Inc. "Double-Blind Flexible Dose Parallel Comparison of Placebo and Sertraline (maximum dose 100 mg) in Outpatients with Panic Disorder"

1994–1996 Co-Investigator, Pfizer, Inc. "One Year Open-Label Extension Study of Sertraline Followed by Double-Blind Comparison of Sertraline and Placebo in Outpatients with Panic Disorder"

1994-1996 Co-Investigator, National Institutes of Mental Health. "IBS: Association with Psychiatry Disorders and Trauma."

1994–1997 Co-Investigator, Eli Lilly & Co.. "Fluoxetine *v.* Placebo in the Treatment of Panic Disorder"

1994-1999 Co-Investigator, National Institute on Alcohol Abuse and Alcoholism. "Alcohol and Social Phobia: Treatment of Dual-Diagnosis."

1993–1994 Co-Investigator, Pfizer Inc. "A Double-Blind Comparison of Sertraline vs Paroxetine in Outpatients with Major Depression"

1993–1994 Co-Investigator, Upjohn Company. "Adinazolam in Social Phobia"

1993–1994 Co-Investigator, Solvay Pharmaceuticals. "Fluvoxamine in the Treatment of Depression: A Double-Blind Multicenter Comparison with Sertraline in Outpatients"

1993–1994 Co-Investigator, SmithKline Beecham. "Comparative Study of Paroxetine vs.

Clomipramine and Placebo in the Treatment of OCD"

1993–1994 Co-Investigator, SmithKline Beecham. "Long-term Treatment with Paroxetine of Outpatients with OCD: An Extension of the Comparative Study"

1993–1994 Co-Investigator, SmithKline Beecham. "Fixed Doses of Paroxetine (10 mg, 20 mg, 40 mg) vs. Placebo in Panic Disorder"

1993–1994 Co-Investigator, SmithKline Beecham. "Continuation Study of Fixed Doses of Paroxetine (10 mg, 20 mg, 40 mg) vs. Placebo in the Treatment of Panic Disorder"

1993–95 Co-Investigator, Glaxo. "A Double-Blind, Placebo-Controlled Dose Escalation Study of the Safety and Efficacy of Oral Ondansetron in the Treatment of Patients with Panic Disorder"

1992–1994 Co-Investigator, Roche Inc. "Moclobemide vs Placebo in the Treatment of Social Phobia"

1992–1994 Co-Investigator, Roche Inc. "Moclobemide vs Placebo in the Treatment of Panic Disorder" (J.C. Ballenger, PI)

1992–1993 Co-Investigator, Glaxo, Inc. "Ondansetron vs Placebo in the Treatment of Social Phobia"

1992–1993 Co-Investigator, Ciba-Geigy, Inc. "Brofaramine vs Placebo in the Treatment of Social Phobia"

1992–1995 Co-Investigator, Pfizer, Inc. "Sertraline, Desipramine, and Placebo in the Treatment of Outpatients with Obsessive-Compulsive Disorder and Major Depression"

1992–1994 Co-Investigator, Sandoz, Inc. "Abecarnil and Alprazolam in GAD: Long-term Treatment"

1992–1993 Co-Investigator, E. Lilly, Inc. "Fluoxetine, Amesergide and Placebo in the Treatment of Depressed Outpatients with Normal vs. Short REM Latency"

1992–1994 Co-Investigator, Parke-Davis, Inc. "A Double-Blind, Placebo-Controlled, Study of Oral CI-988 in Patients with Panic Disorder"

1992–1994 Co-Investigator, Glaxo, Inc. "CSF Monoamine Metabolites in Social Phobia"

1992–1995 Co-Investigator, Hoffman-LaRoche, Inc. "Librax vs. Librium, Quarzan and Placebo in the Treatment of Irritable Bowel Syndrome"1988–1990 Co-Investigator, Sandoz Inc., "Safety and Efficacy of ZK112–179 vs Placebo in

the Treatment of Generalized Anxiety"

1990–1991 Co-Investigator, Searle Inc. "Efficacy and Safety of SC-48274 0.25, 1 mg and 5 mg Twice Daily in Patients with Generalized Anxiety Disorder"

1990–1991 Co-Investigator, Upjohn Company. "Evaluation of Xanax SR 4 mg, 6 mg, and placebo in the Treatment of Panic Disorder with Agoraphobia"

1990–1992 Co-Investigator, Wyeth-Ayerst. "Venlafaxine vs. Placebo in Panic Disorder"

1990–present Co-Investigator for substudy, NIH RR01070-15-19 General Clinical Research Center (Scatter Bed Costs) for RO1AA07825. "Imipramine Treatment of Alcoholics with Panic Disorder"

1990–1992 Co-Investigator, Pfizer Inc. "Sertraline, Amitriptyline, and Placebo in Outpatients with Depression"

1990–1992 Co-Investigator, Pfizer Inc. "Sertraline, Clomipramine, and Placebo in Outpatients with Obsessive Compulsive Disorder"

1990–1991 Co-Investigator, Pfizer Inc. "Open Study of Sertraline in Depressed Outpatients Discontinued from Fluoxetine"

1990–1992 Co-Investigator, Pfizer Inc. "Follow-Up Study of Sertraline in Outpatients with Obsessive Compulsive Disorder"

1990–1992 Co-Investigator, Glaxo Inc. "Ondansetron vs. Diazepam and Placebo in the Treatment of Generalized Anxiety Disorder"

1990–1992 Co-Investigator, Bristol-Myers, Inc. "Nefazodone vs Placebo in the Treatment of Depressed Outpatients"

1989–1991 Co-Investigator, Sandoz, Inc. "ZK112–179 Alprazolam and Placebo in the Treatment of Panic Disorder" (J.C. Ballenger, PI)

1989–1991 Co-Investigator, Sandoz, Inc. "ZK112–179 Alprazolam and Placebo in the Treatment of Generalized Anxiety Disorder"

1989–1994 Co-Investigator, NIAAA (RO1AA07825-01A1), "Imipramine Treatment of Alcoholics with Panic Disorder"

1988–1990 Co-Investigator, Pfizer, Inc. "Sertraline vs. Placebo in the Treatment of Obsessive-Compulsive Disorder"

1999-2000 Co-Investigator, GlaxoWellcome, "A randomized, multi-center, double blind, placebo-controlled, fixed-dose 7-week evaluation of the efficacy and safety of Lamotrigine in treatment of a major depressive episode in unipolar depressed patients."

REVIEWER:

Depression & Anxiety
Psychiatric Research
Journal of Clinical Psychiatry

TEACHING ACTIVITIES:

Medical Students:

1992-1997	Small Group Leader- Behavior and Medicine. For medical students.
1993-2002	Anxiety Disorders. Psychiatry Clerkship Lecture Series for medical students.
1992-1994	Introduction to Medicine, Interviewing skills, for medical students
1998	Introduction to Medicine, Interviewing skills, for medical students
2000-2002 (BSMP)	Small Group Leader- Behavioral Sciences in Medical Practice
1999-2002	Small Group Leader- Longitudinal Patient Care Experience (LPCE)

Psychiatry Residents:

1999-onwards	Herbal Remedies- fourth year psychiatry residents
1993-1995 residents.	Cross-Cultural Psychiatry. Lectures to 3rd. year psychiatry
1993-2002	Obsessive-Compulsive Disorder. Anxiety disorders Seminar for third year psychiatry residents.
1994-2002	Obsessive-Compulsive Disorder. Anxiety disorders Seminar for second year psychiatry residents.

Physician Assistant Students:

1994-2002	Anxiety & Somatoform Disorders-Physicians Assistant Course in Psychiatry.

Postgraduate:

1995- 2002	Supervision, Anxiety Disorders Fellows, Department of Psychiatry, Medical University of South Carolina, Charleston, South Carolina

Dental Student:

2000-Summer	Mentor, dental student on Bruxism and anxiety disorders.

Academic Appointment:

2000-2002 Director, Anxiety Disorders Seminar Series for psychiatry residents, Medical University of South Carolina.

CONTINUING MEDICAL EDUCATION:

1997-2001	Weekly Anxiety Disorders Seminar and Journal Club Series, Clinical Psychopharmacology Research Division, Department of Psychiatry, Medical University of South Carolina.

EXTRAMURAL PROFESSIONAL ACTIVITIES:

1997	Speakers Bureau Glaxo-Wellcome Inc. Laboratories
2002	Speakers Bureau Wyeth-Ayerst Laboratories
2000	Speakers Bureau Forrest Pharmaceuticals, Inc.
2001	Speakers Bureau Pfizer Inc.
1999	Speakers Bureau, Projects in Knowledge Inc.

COMMUNITY SERVICES:

1990- onward	Clinical Assessments: National Depression Screening Day
1991- onward	Clinical Assessments: National Anxiety Screening Day

Presentations:

May 8th. 1999	"Stress Management" Vanderhorst Memorial C.M.E. Church. Part of "The Woman in Me" workshop.
December 1St. 1998	"Stress Management" Our Lady of Mercy Community Outreach Center. Johns Island.
April 7th. 1999	"Stress Management" Santee Cooper Health Fair,

PUBLICATIONS:

1. **Emmanuel NP**, Lydiard RB Ballenger JC. "Fluoxetine treatment of exhibitionism" American Journal of Psychiatry, 148 (7): 950, 1991.

2. **Emmanuel NP**, Lydiard RB, Ballenger JC. " Treatment of Social Phobia with Bupropion." Journal of Clinical Psychopharmacology, 11:4,276-277, 1991.

3. **Emmanuel, NP.**, Lydiard RB., & Ballenger, JC. " Blood Groups in Panic Disorder." American Journal of Psychiatry 149 (3): 410,1992.

4. Lydiard RB., Morton WA,, **Emmanuel NP.**, Zealberg JJ,, Laraia MT,, Stuart GW,, O'Neil PM., Ballenger JC. "Preliminary Report: Placebo Controlled, Double-Blind Study of the Clinical and Metabolic Effects of Desipramine in Panic Disorder." Psychopharmacology Bulletin 29: 183-188, 1993.

2. Brawman-Mintzer O, Lydiard RB, **Emmanuel NP**, Payeur R, Johnson M, Roberts J., Jarrell MP., Ballenger JC. "Psychiatric Comorbidity in Patients with Generalized Anxiety Disorder." American Journal of Psychiatry 150:1216-1218, 1993.

3. **Emmanuel NP**, Lydiard RB., Reynolds RD., Roberts J,, Johnson M, Mintzer O, Ballenger JC. "Plasma Pyridoxal Phosphate in Anxiety Disorders." Biological Psychiatry 36:606-608, 1994.

4. Brawman-Mintzer O, Lydiard RB, Crawford MM., **Emmanuel NP**, Payeur R, Johnson M, Knapp RG., Ballenger JC. "Symptoms Distribution in different presentations of generalized Anxiety disorder." American Journal of Psychiatry 151:930-932,1994.

5. Czepowicz VD, MD, Johnson MR, Lydiard RB, **Emmanuel NP**, Ware MR, Mintzer OB, Walsh MD, Ballenger JC. "Sertraline in Social Phobia" Journal of Clinical Psycho- pharmacology.5;15:372-373,1995.

6. Brawman-Mintzer O, Lydiard RB, Phillips KA, Morton A, Czepowicz V, **Emmanuel N**, Villareal G, Johnson M, Ballenger JC: Body dysmorphic disorder in patients with anxiety disorders and major depression: a comorbidity study. Am J Psychiatry 1995; 152(11):1665-1667

7. Ware MR, **Emmanuel N**, Johnson MR, Brawman-Mintzer O, Kapp R, Crawford-Harrison M, Lydiard RB: " Self-reported sexual dysfunctions in anxiety disorder patients'. Psychopharmacology Bulletin, 1996; 32 (3): 530.

8. Rubey RN, Johnson MR, **Emmanuel N**, Lydiard RB. Fluoxetine in the treatment of anger: An open clinical trial. J Clin Psychiatry 57(9):398-401,1996.

9. **Emmanuel NP**, Lydiard RB., Crawford M. "Treatment of Irritable Bowel Syndrome with Fluvoxaine" American Journal of Psychiatry 154:5 711-712, 1997.

10. Brawman-Mintzer O, Lydiard RB, Bradwejn J, Villarreal G, Knapp R, **Emmanuel N**, Ware MR, He Q, Ballenger JC: Effects of the cholecystokinin agonist pentagastrin in patients with generalized anxiety disorder. Am J Psychiatry 1997; 154(5):700-702.

11. Labatte L, Johnson MR, Lydiard RB, Brawman-Mintzer O, **Emmanuel N**, Ballenger JC;" Sleep deprevation in panic disorder and obsessive compulsive disorder". Canadian Journal of Psychiatry. 1997; 42 (9): 982-983.

12. **Emmanuel NP**, Jones C, Lydiard RB: Use of herbal products and symptoms of bipolar disorder. Am J Psychiatry 1998; 155(11):1627.

13. Johnson MR, **Emmanuel N**, Crawford C, Lydiard RB, Villareal G. Treatment of generalized anxiety disorder with venlafaxine: A series of 11 cases. J Clin Psychopharmacol 18(5), 1998(Oct).

14. Johnson MR, Marazziti M, Brawman-Mintzer O, **Emmanuel NP**, Ware MR, Morton WA, Rossi A, Cassano GB, Lydiard RB: "Abnormal peripheral benzodiazepines receptor density associated with generalized social phobia". Biological Psychiatry 1998; 43: 306-309.

15. Labatte L, Johnson MR, Lydiard RB, Brawman-Mintzer O, **Emmanuel N**, Ballenger JC;" Sleep depravation in social phobia and generalized anxiety disorder. Biological psychiatry. 1998; 43 840-842.

16. **Emmanuel NP**, Ware MR, Brawman-Mintzer O, Ballenger JC, Lydiard RB: Once-weekly dosing of fluoxetine in the maintenance of remission in panic disorder. J Clin Psychiatry 1999; 60(5):299-301

17. DeVane CL, Ware MR, **Emmanuel NP**, Brawman-Mintzer O, Morton WA, Villarreal G, Lydiard RB: Evaluation of the efficacy, safety and physiological effects of fluvoxamine in social phobia. Int Clin Psychopharmacol 1999; 14(6):345-351

18. **Emmanuel NP, MD**, Brawman-Mintzer O, MD, Morton WA, Pharm D, Book SW, MD,. Johnson MR, MD, Lorberbaum JP,MD, Ballenger JC, MD, Lydiard RB, PhD, MD. "Bupropion-SR in Treatment of Social Phobia" Depression & Anxiety 12:111-113,200.

19. J.P. Lorberbaum, J.D. Newman, J.R. Dubno, A.R. Horwitz, Z. Nahas, C.C.

Teneback, C.W. Bloomer, D.E. Bohning, D. Vincent, M.R.Johnson, **N. Emmanuel**, O. Brawman-Mintzer, S.W. Book, R.B. Lydiard, J.C. Ballenger, M.S. George. The Feasibility Of Using fMRI To Study Mothers Responding To Infant Cries. Depression and Anxiety, 10 (3):99-1041, 1999.

PUBLISHED ABSTRACTS:

Emmanuel, NP, Mark H. Pollack, , Alexander W. Morton, Naomi M. Simon , Carolyn M. Cosby, John W. Worthington, R. Bruce Lydiard, James C. Ballenger "Bupropion Sustained Release in the Treatment of Panic Disorder" New research poster presentation at NCDEU Annual Meeting, Phoenix, AZ, May 28-31, 2001.

Emmanuel NP, JP Lorberbaum , O Mintzer , R Kapp , M Crawford , A Morton , MR Johnson , SW Book , M Hamner, Z Nahas , GW Arana , JC Ballenger , RB Lydiard , MS George ." r-TMS in GAD Subjects: Testing the Valence Theory of Emotions" Presented at the 153rd. American Psychiatric Association Meeting, May 13-18, Chicago,2000

Emmanuel NP, Michael Ware, Carolyn Cosby, Marsha Crawford, Rebecca Kapp, Olga Mintzer, Michael Johnson, Sarah Book, Alex Morton, , Cathie Jones, James C. Ballenger, R. Bruce Lydiard. "Concomitant Use of Herbal Products in Subjects Applying for Clinical Trials" New research poster presentation at American Psychiatric Association Annual Meeting, Toronto Canada, May, 1998.

Emmanuel NP, Carolyn Cosby, Olga-Brawman Mintzer, Alex Morton, Sarah Book, Michael Johnson, Jeffery Lorberbaum, Marsha Crawford, Rebecca Kapp, Cathie Jones, Bruce Lydiard, James C. Ballenger, R. "Open label Treatment of Social Phobia using Sustained-Released Bupropion" New research poster presentation at NCDEU Annual Meeting, Boca Raton, Fl, June 10-13, 1998.

Emmanuel NP, Michael Ware, Carolyn Cosby, Marsha Crawford, Rebecca Kapp, Olga Mintzer, Michael Johnson, Sarah Book, Alex Morton, , Cathie Jones, James C. Ballenger, R. Bruce Lydiard. "Concomitant Use of Herbal Products in Subjects Applying for Clinical Trials" New research poster presentation at NCDEU Annual Meeting, Boca Raton, Fl, June 10-13, 1998.

Emmanuel NP, Michael Johnson, Gerardo Villareal, Carolyn Cosby, Violetta Czepowicz, Olga Mintzer, Marsha Crawford, Sarah Book, Alex Morton, Robert Rubey, Cynthia Amundsen, John Roberts, Rebecca Kapp, Cathie Jones, R. Bruce Lydiard. " Imipramine in the treatment of social phobia, A double-blind study." New Research poster presented at ACNP Annual meeting, Waikoloa, Hawaii. December 8-12, 1997

Emmanuel NP, Carolyn Cosby C, Olga Mintzer, Michael Johnson, Sarah Book, Alex Morton, Marsha Crawford, James C. Ballenger, R. Bruce Lydiard. "Sertraline in Generalized Anxiety

Disorder, a case series." New research poster presentation at NCDEU Annual Meeting, Boca Raton, Fl, May 27-30, 1997.

Emmanuel NP, Cosby C, Ware MR, Lydiard RB. "The Efficacy of Once a Week Dosing in the Treatment of Panic Disorder." New research poster presentation at NCDEU Annual Meeting, Boca Raton, Fl, May 27-31, 1996.

Emmanuel NP, Cosby C, Ware MR, Lydiard RB. "The Efficacy of Once a Week Dosing of fluoxetine in the Treatment of Panic Disorder." New research poster presentation at American Psychiatric Association Annual Meeting, New York NY, May, 1996.

Emmanuel NP, Czepowicz VD, Villarreal G, Johnson M, Ware MR, Rubey R, Ballenger JC, Lydiard RB. "Venlafaxine in Social Phobia: A Case Series Study." New research poster presentation at American Psychiatric Association Annual Meeting, Miami, FL, May, 1995.

Emmanuel NP, Ware MR, Damewood SB, Ballenger JC, Lydiard RB. "Predicting Patient Dropout in Panic Patients. "New research poster presentation at American Psychiatric Association Annual Meeting, Miami, FL, May, 1995.

Emmanuel NP, Czepowicz VD, Villarreal G, Johnson M, Ware MR, Rubey R, Ballenger JC, Lydiard RB. "Venlafaxine in Social Phobia: A Case Series Study." New research poster presentation at Anxiety Disorders Association of America Annual meeting, Pittsburgh, PA. April 1995.

Emmanuel NP, Ware MR, Damewood SB, Ballenger JC, Lydiard RB. "Predicting Patient Dropout in Panic Patients. "New research poster presentation at Anxiety Disorders Association of America Annual meeting, Pittsburgh, PA. April 1995.

Emmanuel NP, Ware MR, Lydiard RB, Ballenger JC, Brawman-Mintzer O, Czepowicz V, Walsh M, Villarreal G. "Clinical Psychopharmacologic Trials: Cost of Patient Recruitment." New research poster presentation at Anxiety Disorders Association of America Annual Meeting, Santa Monica, CA, March, 1994.

Emmanuel NP, Ware MR, Lydiard RB, Ballenger JC, Brawman-Mintzer O, Czepowicz V, Walsh M, Villarreal G. "Clinical Psychopharmacologic Trials: Cost of Patient Recruitment." New research poster presentation at American Psychiatric Association Annual Meeting, Philadelphia, PA, May, 1994.

Emmanuel NP, Mintzer O, Johnson MR, Morton A, Lydiard RB, Ballenger JC: "Personality Disorders in Social Phobia." Presented at the 13th. National Conference of the Anxiety Disorders Association of America. Charleston SC. March 18-21, 1993.

Emmanuel NP, Mintzer OB, Lydiard RB, Payeur R, Roberts J, Johnson M, Ballenger JC. "Prevalence of Personality Disorders in General Anxiety Disorder". Presented at the

12 th. National Conference of the Anxiety Disorders Association of America, Houston, Texas, April 9-12, 1992.

Emmanuel NP, Lydiard RB, Morton AW, Laraia MT, Zealberg JJ, Stuart GW, Ballenger JC. " Effects of Desipramine on the Resting Metabolic Rate in Panic Disorder." Presented at the 145th. Annual Meeting of the American Psychiatric Association, Washington, DC May 2-6, 1992.

Emmanuel NP, Lydiard RB, Melvin JA, Jolley R, Villeponteaux V, Ballenger JC. "Personality Disorders in Panic Disorder." Presented at the 144th. Annual Meeting of the American Psychiatric Association, New Orleans, LA, May 13-17, 1991.

JP Lorberbaum , **NP Emmanuel** , O Mintzer , R Kapp , MCrawford , A Morton , MR Johnson , SW Book , M Hamner,Z Nahas , GW Arana , JC Ballenger , RB Lydiard , MS George "Changes in Anxiety After Prefrontal r-TMS in Patients with GAD" Society of Biological Psychiatry Annual meeting, May 11-13, 2000, Chicago

Kimberly Coxe, **Naresh Emmanuel**, James Rivers " The Relationship between Bruxism and Anxiety" Presented at Medical University of South Carolina, Annual Students Research Day presentation November 30th.2000.

Michael R. Ware, **Emmanuel NP**, Cathie Jones "Prevalence and Type of Herbal Product Use Among College Students" New research poster presentation at NCDEU Annual Meeting, Boca Raton, Fl, June 10-13, 1998

Johnson MR, **Emmanuel NP**, Brawman-Mintzer O, Book S, Ware M, Morton A, Crawford M, Kapp R, Czepowicz V, Villareal G, Lydiard RB, Ballenger JC.Generalized Social Phobia and Major Depressive Disorder: Increased Disability.New research poster presentation at NCDEU Annual Meeting, Boca Raton, Fl, May 27-30, 1997.

Ware MR, **Emmanuel NP**, Johnson MR, Mintzer OB, Kapp R, Crawford-Harrison M, Lydiard RB. "Self Reported Sexual Dysfunction in Anxiety Disorder Patients" New research poster presentation at American Psychiatric Association Annual Meeting, New York NY, May, 1996.

Johnson MR, **Emmanuel NP**, Ware MR,Brawman-Mintzer O, Book S,Jones C, Kapp R, Crawford M, Morton A, Ballenger JC, Lydiard RB. "Differentiating Generalized from Specific Social Phobia by Response on the Liebowitz Social Anxiety Scale" New research poster presentation at Anxiety Disorders Association of America Annual meeting, Orlando, Fl. March,1996.

Ware MR, **Emmanuel NP**, Czepowicz VD, Johnson MR, Kapp R, Walsh M, Villarreal G, Ruby R, Crawford M, Morton AW, Ballenger JC, Lydiard RB. "Self Report Sexual Dysfunction in Social Phobic Patients. "New research poster presentation at Anxiety Disorders Association of America Annual meeting, Pittsburgh, PA. April 1995.

Ware MR, **Emmanuel NP**, Czepowicz VD, Johnson MR, Kapp R, Walsh M, Villarreal G, Ruby R, Crawford M, Morton AW, Lydiard RB. "Self Report Sexual Dysfunction in Social Phobic Patients. "New research poster presentation at American Psychiatric Association Annual Meeting, Miami, FL, May, 1995.

Villarreal G, **Emmanuel NP**, Lydiard RB, Ballenger JC,. "Venlafaxine in Generalized Anxiety Disorder" New research poster presentation at American Psychiatric Association Annual Meeting, Miami, FL, May, 1995.

Brawman-Mintzer O, **Emmanuel N**, Czepowicz V, Walsh M, Lydiard RB, Villarreal G, Johnson M, Ballenger JC. "Prevalence of Body Dysmorphic Disorder in Different Anxiety Disorders." New research poster presentation at American Psychiatric Association Annual Meeting, Philadelphia, PA, May,1994.

Brawman-Mintzer O, **Emmanuel N**, Czepowicz V, Walsh M, Lydiard RB, Villarreal G, Johnson M, Ballenger JC. "Prevalence of Body Dysmorphic Disorder in Different Anxiety Disorders." New research poster presentation at Anxiety Disorders Association of America Annual Meeting, Santa Monica, CA, March, 1994.

Mintzer OB, **Emmanuel NP**, Lydiard RB Payeur R, Johnson M, Roberts J, Ballenger JC. " Symptom Distribution in Comorbid and Uncomplicated GAD". Presented at the 13th. National Conference of the Anxiety Disorders Association of America. Charleston SC. March 18-21, 1993

Mintzer OB, **Emmanuel NP**, Lydiard RB, Payer R, Johnson M, Roberts J, Ballenger JC: "Validity of Generalized Anxiety Disorder as a diagnostic entity". Presented at the Annual Meeting of the American Psychiatric Association, San Francisco, CA, May 22-27, 1993.

Mintzer OB, **Emmanuel NP**, Lydiard RB, Payeur R, Johnson M, Roberts J, Ballenger JC. "Psychiatric Comorbidity in Generalized Anxiety Disorder." Presented at the 12th. National Conference of the Anxiety Disorders Association of America, Houston, Texas, April 9-12, 1992.

DeVane CL, Ware MR, **Emmanuel NP**, Brawman-Mintzer O, Jones CA, Morton WA, Kapp R, Villareal G, Lydiard RB: "The Evaluation of the Safety, Efficacy, and Physiological Effects of Fluvoxamine in Social Phobia". Presented at the American Psychiatric Association Annual Meeting, New York, NY May 7th. 1996.

DeVane CL, Ware MR, **Emmanuel NP**, Mintzer OB, Johnson MR, Ruby RN, Villarreal G, Lydiard RB. "The Evaluation of the Safety, Efficacy, and Physiological Effects of Fluvoxamine in Social Phobia." New research poster presentation at A.C.N.P. , Puerto Rico, December, 1995.

Johnson MR, Mintzer O, **Emmanuel N**, Morton A, Lydiard RB, Ballenger JC:" The Effect of Personality Disorders on the response to Pharmacologic Treatment of Generalized Anxiety

Disorder". Presented at the 15th. Annual Meeting of the Anxiety Disorders Association of America, Pittsburgh, PA, May 21-26, 1995.

Villarreal G, Johnson M, **Emmanuel N**, Czepowicz V, Walsh M, Brawman-Mintzer O, Ware M, Crawford-Harrison M. "Attributional Style in Social Phobia: Comparison with Major Depression." New research poster presentation at Anxiety Disorders Association of America, Annual Meeting, Santa Monica, CA, March, 1994.

Villarreal G, Johnson M, **Emmanuel N**, Czepowicz V, Walsh M, Brawman-Mintzer O, Ware M, Crawford-Harrison M. "Attributional Style in Social Phobia: Comparison with Major Depression." New research poster presentation at American Psychiatric Association Annual Meeting, Philadelphia, PA, May, 1994.

Irwin C, Lydiard RB, **Emmanuel NP**, Johnson M, Roberts J. "Comorbidity of PTSD and Irritable Bowel Syndrome". Presented at the 13th National Conference of the Anxiety Disorders Association of America. Charleston SC. March 18-21, 1993.

Mintzer O, Lydiard RB, Knapp R, **Emmanuel N**, Johnson M, Morton A, Ballenger JC:"Treatment response in patients with Generalized Anxiety Disorder and a Lifetime History of Major Depression". Presented at the NCDEU Annual Meeting, Boca Raton, Fl, June 10-13, 1998.

Johnson MR, Lydiard RB,Mintzer OB, **Emmanuel NP**, Ware MR, Morton WA, Diamond BI:"Abnormal Peripheral Benzodiazepine Receptors in Social Phobia". Presented at the Society of Biological Psychiatry, New York, NY, May 3, 1996.

Minter O, Lydiard RB, Villareal G, **Emmanuel NP**, Ballenger JC;"Biological Findings in GAD: CCK-B agonist challenge". Presented at the 15th. Annual Meeting of the Anxiety Disorders Association of America, Pittsburgh, PA, April 19-21, 1995.

Lydiard RB, Villarreal G, Knapp RS, **Emmanuel NP**, Ballenger JC. "Pentagastrin Effects in Patients with GAD" New research poster presentation at American Psychiatric Association Annual Meeting, Miami, FL, May, 1995.

Czepowicz VD, MD, Johnson MR, Lydiard RB, **Emmanuel NP**, Ware MR, Mintzer OB, Walsh MD, Ballenger JC. "Sertraline in Social Phobia" New research poster presentation at the Anxiety Disorders Association of America Annual Meeting, Santa Monica, CA, March, 1994.

Czepowicz VD, MD, Johnson MR, Lydiard RB, **Emmanuel NP**, Ware MR, Mintzer OB, Walsh MD, Ballenger JC. "Sertraline in Social Phobia" New research poster presentation at the American Psychiatric Association Annual Meeting, Philadelphia, PA, May, 1994.

Johnson MR, Lydiard RB, Brawman-Mintzer O, **Emmanuel NP**, Ware M, Morton A, Crawford-Harrison M, Walsh M, Czepowicz V, Villarreal G, Amundsen C, Ballenger JC. "Prevalence of Irritable Bowel Syndrome in Anxiety Disorders." New research poster

presentation at Anxiety Disorders Association of America Annual Meeting, Santa Monica, CA, March, 1994.

Johnson M, Lydiard RB, Brawman-Mintzer O, **Emmanuel NP**, Czepowicz V, Villarreal G, Amundsen C, Ballenger JC: "Prevalence of Irritable Bowel Syndrome in Anxiety Disorders". Presented at the 14th. National Conference on Anxiety Disorders, Anxiety Disorders Association of America, Santa Monica, CA, March 17-20, 1994.

Jeffrey P. Lorberbaum, Mark S. George, Michael R. Johnson, **Naresh P. Emmanuel,** Olga Mintzer, Sarah W. Book, Alex Morton, Marsha Crawford-Cisa,Rebecca Kapp, Mark B. Hamner, James C. Ballenger, R. Bruce Lydiard "Brain Activity in Social Phobics Undergoing a Public Speaking Task." ACNP annual meeting December 10-14, 2000 in San Juan, Puerto Rico

Mintzer O, Kapp R, Crawford M, Books S, **Emmanuel NP**, Knapp R, Lydiard RB:"Effects of burpirone on cholecystokinin-B receptor agonist pentagastrin induced anxiety/panic in generalized anxiety disorder. Presented at the 17th. Annual Meeting of the Anxiety Disorders Association of America. New Orleans, LA May 20-23, 1997.

Invited Presentations:

"Stress in the Workplace." Charleston Neonatal Nurses Association. East Cooper Hospital. Charleston. March 18 1993.

"Recent Trends in the Management of Panic Disorder" Department of Psychiatry. S.M.S. Medical College, Jaipur, India. December 29th. 1995.

"Stress in the Workplace." Charleston Area Medical Managers Association. Charleston Hilton Hotel. Charleston. July 18, 1996.

"Anxiety disorders" as part of "ask the experts" public education series. Medical University of South Carolina. April 16th. 1997

"Management of Depression in primary care" for Department of Family Medicine , Medical University of South Carolina. Charleston September 10th. 1997.

"Depression in the Medical Setting" for Department of Internal Medicine , Medical University of South Carolina. Charleston November 6th. 1997.

"Obsessive Compulsiveness; from the perfectionist to the troubles" Mind your health seminar for the lay public. Medical University of South Carolina. Charleston. May 6th 1998

"Update in the treatment of Major Depression" for Savannah Medical Society. Savannah. June 25th 1998

" Anti-anxiety drug update" Faculty Outreach CME-Hilton Head Hospital. July 28, 1998
"Mixed anxiety-depression and related conditions" Florence Medical Society. October 6th. 1998

" Depression- an update" Society of Army Physician Assistants Annual Meeting, April 28th. 1999, Fayetteville NC

"Herbal Remedies-what clinicians need to know and what to tell your patients" June 25th. 1999. MUSC breakfast rounds.

"Anxiety Disorder Complicated by Depression" Glaxo Wellcome Pharmaceutical Preceptorship Depression Education Program. April 6-7th 1999.

"Anxiety disorders and Comorbid Conditions" Dorn VA Medical Center, Columbia Aptil 6th.1999

"Current Research in Alternative Medicine" Day of Discovery Program at Medical University of South Carolina. October 12th. 2000

" Depression- Beyond the Stigma" - March 2nd 2000, Houston Texas, (CME 3 hrs)

"Alternative Treatments in Mental Health" May 25, 2001,Coffee with the Mental Health Pros lecture series: Medical University of South Carolina, Charleston. (CME 1 hr)

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SC Department of Labor, Licensing and Regulation

Board of Medical Examiners

2001-2002

REREGISTRATION CERTIFICATE

PHYSICIAN

EXPIRES 12/31/2002

ALL PHYSICIANS LICENSED BY THIS BOARD ARE REQUIRED TO REREGISTER ANNUALLY. APPLICATIONS ARE MAILED BY MAY 1st EACH YEAR. THIS IS TO CERTIFY THAT THE PHYSICIAN NAMED BELOW HAS REREGISTERED WITH THE BOARD.

DR. NARESH P. EMMANUEL

CERTIFICATE & LICENSE NUMBER 14837

REPORT CHANGES AS REQUIRED:

P.O. Box 11289 • Columbia, SC 29211-1289

CURRICULUM VITAE

October 2002

Personal Data

Name: Frederick W. Reimherr

Business Address: University of Utah School of Medicine
Department of Psychiatry
Mood Disorders Clinic
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E-mail fred.reimherr@hsc.utah.edu

Date of Birth: February 21, 1946

Place of Birth: Yonkers, N.Y.

Citizenship: United States of America

Social Security Number: REDACTED

Medical License: Utah - 156060-1205
State Controlled Substance - 156060-8905

Education

Institution	Degree	Year	Field
Haverford College Haverford, Pennsylvania	B.A.	1964 - 68	Chemistry
Case Western Reserve University School of Medicine Cleveland, Ohio	M.D.	1968 - 72	Medicine
University of Utah College of Medicine	Internship	1972 - 73	Pediatrics
University of Utah College of Medicine	Residency	1973 - 76	Psychiatry

F. Reimherr - 12/15/02

Board Certification

Psychiatry, 1983

Professional Positions

1976 - 1981	Staff Psychiatrist	Sugarhouse Unit Salt Lake City Community Mental Health Center
1981 - 1986	Staff Psychiatrist	Sugarhouse Unit Salt Lake County Mental Health Center
1976 - 1979	Instructor in Psychiatry	College of Medicine University of Utah
1977 - 1980	Psychiatric Consultant	Fremont County Mental Health Center Riverton and Lander, Wyoming
1977 - 1979	Psychiatric Consultant	Public Health Service Wind River Indian Reservation Lander, Wyoming
1978 - 1980	Psychiatric Consultant	Wyoming State Training School Lander, Wyoming
1980 - 1994	Assistant Professor (Clinical)	University of Utah Dep. Of Psychiatry
1985 - present	Director	University of Utah Mood Disorder Clinic Department of Psychiatry
1987 - 1996	Medical Director	United Behavioral Clinics United Health Care Salt Lake City, Utah
1988 - present	Designated Mental Health Examiner	Department of Social Services State of Utah

1994 - present	Associate Professor (Clinical)	Department of Psychiatry

Editorial and Review Experience

Referee	American Journal of Psychiatry Hospital Formulary Journal of Nervous and Mental Disease Medical Letter on Drugs and Therapeutics Biological Psychiatry
Site Visitor	1986 Clinical Research Center Grant National Institute of Health
Grant Review	1988 Office of Orphan Products Development

Research and Grant Awards

Cylert in the Treatment of Adults with Hyperactivity
1975 - 1976
Abbott Research Laboratories
Co-Investigator

Studies of Hyperactivity in Adults
1978 - 1981
National Institute of Mental Health
Co-Investigator

Training Grant in Psychiatry
1980 - 1983
National Institute of Mental Health
Program Director

MK-212 in the Treatment of Patients with Major Depression
1981 - 1982
Merck Sharp and Dohme Research Laboratories
Principal Investigator

12/11/2002

The Use of Fluoxetine in the Treatment of Outpatients with Major Depression, Unipolar Type, Double-Blind Trial with Long-term Open Extension
1981 - 1983
E. Lilly Research Laboratories
Co-Investigator

Studies of Hyperactivity in Adults
1981 - 1984
National Institute of Mental Health
Co-Investigator

The Use of Oxaprotiline in the Treatment of Inpatients with Major Depression; Assessment of Onset of Action, Initial Double-Blind Trial with Long-term Open Extension
1982 - 1983
Ciba-Geigy Corporation
Principal Investigator

Open Evaluation of Tomoxetine in the Treatment of Inpatients with Major Depression, Unipolar Type, Initial Inpatient Trial with Long-term Outpatient Extension
1982 - 1983
E. Lilly Research Laboratories
Co-Investigator

The Use of Oxaprotiline in the Treatment of Outpatients with Major Depression, with Significant Retardation, Initial Double-Blind Trial with Long-term Open Extension
1982 - 1984
Ciba-Geigy Corporation
Co-Investigator

MK-801 in the Treatment of Attention Deficit Disorder, Residual Type
1983 - 1984
Merck Sharp and Dohme Research Laboratories
Principal Investigator

Double-Blind Trial of Tomoxetine in the Treatment of Outpatients with Major Depression, Unipolar Type, Initial Double-Blind Trial with Long-term Double-Blind Extension
1984 - 1985
E. Lilly Research Laboratories
Co-Investigator

12/16/2002

The Use of Multiple Dosage Levels of Fluoxetine in the Treatment of Outpatients with Major Depression, Unipolar Type, Double-Blind Trial with Long-term Open Extension
1984 - 1985
E. Lilly Research Laboratories and International Clinical Research Corporation
Co-Investigator

Double-Blind Trial of Nefazodone at Multiple Dose Levels in the Treatment of Inpatients with Major Depression, Unipolar Type
1984 - 1985
Bristol Myers
Principal Investigator

Double-Blind Trial of Sertraline in the Treatment of Outpatients with Major Depression, Unipolar Type, Initial Double-Blind Trial with Long-term Open Extension
1984 - 1985
Pfizer Central Research
Principal Investigator

Double-Blind Trial of AM versus PM Dosing of Fluoxetine in the Treatment of Outpatients with Major Depression, Unipolar Type
1984 - 1985
E. Lilly Research Laboratories
Co-Investigator

Double-Blind Trial of 5-hydroxytryptophan in the Treatment of Outpatients with Major Depression, Unipolar Type
1985 - 1989
FDA Orphan Drug Division
Principal Investigator

The Assessment of the Risk Associated with Phospholipdosis in Patients Chronically Treated with Fluoxetine, Imipramine or Amiodarone
1986
E. Lilly Research Laboratories
Principal Investigator

Double-Blind Trial of Etoperidone in the Treatment of Outpatients with Major Depression, Unipolar Type, Short-term Double-Blind Trial with Long-term Double-Blind Extension
1986 - 1987
McNeil Pharmaceutical Corporation

Double-Blind Trial of Fluoxetine in the Treatment of Outpatients with Bulimia
1986 - 1987
E. Lilly Research Laboratories
Principal-Investigator

CL-844 in the Treatment of Attention Deficit Disorder, Residual Type
1986 - 1987
Warner Lambert
Principal Investigator

Double-Blind Trial of Fluvoxamine in the Treatment of Outpatients with Major Depression, Unipolar Type, Short-term Double-Blind Trial with Long-term Double-Blind Extension
1986 - 1988
Kali-Duphar
Principal Investigator

Double-Blind Trial of Ipsapirone in the Treatment of Outpatients with Generalized Anxiety Disorder
1987 - 1988
G.H. Besselaar Associates and Bayer
Principal Investigator

Assessment of the Risk of Seizures in Patients with Depression Treated with Bupropion
1987 - 1989
Burroughs Wellcome and International Clinical Research Corporation
Principal Investigator

The Use of Dothiepin in Outpatients with Depression
1987 - 1989
Boots Pharmaceutical, Marion Laboratories, and International Clinical Research Corporation Principal Investigator

Double-Blind Trial of Nefazodone at 2 Dose Levels in the Treatment of Outpatients with Major Depression, Unipolar Type
1987 - 1990
Bristol Myers
Principal Investigator

Double-Blind Trial of Sertraline in the Treatment of Elderly Outpatients with Major Depression, Unipolar Type
1987 - 1990
Pfizer and International Clinical Research Corporation
Principal Investigator

F. Reimherr 12/16/2002

Fluoxetine Versus Placebo: Long term Treatment of Bulimia Nervosa
1988 - 1990
E. Lilly Research Laboratories
Principal Investigator

Randomized, Double-Blind, Comparison of Venlafaxine Amitriptyline and Placebo in Inpatients with Major Depression
1989 - 1990
Wyeth-Ayerst
Principal Investigator

Risperidone (R 64 766) in the Treatment of Chronic Schizophrenic Patients - An International Multicenter Placebo-Controlled Double-Blind Parallel Group Study Versus Haloperidol
1989 - 1991
Janssen Research Foundation
Principal Investigator

A Double-Blind, Multicenter Trial of Gepirone, Imipramine and Placebo in the Treatment of Depressed Outpatients
1989 - 1991
Bristol Myers
Principal Investigator

A Double-Blind Multicenter Trial of Nefazodone, Fluoxetine and Placebo in the Treatment of Depressed Outpatients
1989 - 1992
Bristol Myers
Principal Investigator

An Open Multicenter Trial of Nefazodone in the Treatment of Patients with Mood Disorders
1989 - 1993
Bristol Myers
Principal Investigator

Genetic and Neurobiological Investigation of Schizophrenia
1989 - 1993
NIMH
Co-Investigator

A Double-Blind Multicenter Trial of Gepirone, Fluoxetine and Placebo in the Treatment of Depressed Outpatients
1989
Bristol Myers
Principal Investigator

Fluoxetine Versus Placebo: Long-Term Treatment of Major Depressive Disorder
1990 - 1992
E. Lilly Research Laboratories
Principal Investigator

Open Study of Sertraline in Depressed Outpatients Discontinued From Fluoxetine
1991 - 1992
Pfizer and International Clinical Research Corporation
Principal Investigator

A Prospective Randomized Double-Blind, Placebo-Controlled, Multicenter Parallel-Groups Comparison of The Efficacy and Safety of Abecarnil Low Dose (3.0-9.0 mg) High Dose (7.5 - 22.4) and Buspirone
1991 - 1992
Sandoz Pharmaceuticals Corporation
Principal Investigator

Fixed-Dose, Double-Blind Study Comparing Efficacy and Safety of Xanax SR Tablets Versus Placebo in the Treatment of Panic Disorder Using Once Daily Dosing
1991
Upjohn
Principal Investigator

Double-Blind, Dose Ranging Trial Comparing CGS-18102A to Placebo in Patients with Generalized Anxiety Disorder
1991 - 1993
Ciba-Geigy Corporation
Principal Investigator

A Multicenter Evaluation of the Safety and Efficacy of 150 mg/day and 300 mg/day of Bupropion HCL Sustained-Release Versus Placebo in Depressed Outpatients
1991 - 1993
Burroughs Wellcome
Principal Investigator

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A Prospective, Multicenter, Open-label Study of the Safety of Abecarnil (5.0-17.5 mg.) in Outpatients with Generalized Anxiety Disorder
1991 - 1993
Sandoz Pharmaceuticals Corporation
Principal Investigator

Short and Long-term Discontinuation of Alprazolam in the Treatment of Panic Disorder with Agoraphobia
1992 - 1993
Upjohn
Principal Investigator

A Double-Blind Dose-Response Study to Determine the Safety and Efficacy of Fixed Doses (Range 75 to 900 mg/day) of Moclobemide in Patients with Panic Disorder with or without Agoraphobia
1992 - 1993
Hoffman-La Roche
Principal Investigator

Evaluation of the Safety and Efficacy of 150 mg/day and 300mg/day of Bupropion HCL Sustained-Release vs. Placebo in Depressed Outpatients
1992 - 1993
Burroughs Wellcome
Principal Investigator

A Double-Blind Dose-Response Study to Determine the Safety and Efficacy of Fixed doses (Range 75 to 900 mg/day) of Moclobemide in Patients with Social Phobia
1992 - 1993
Hoffman-La Roche
Principal Investigator

A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Two Doses of Ondansetron Versus Placebo in the Treatment of Social Phobia
1992 - 1994
Glaxo Incorporated
Principal Investigator

Molecular Genetics of Manic-Depression
1992 - 1994
NIMH
Co-Investigator

The Safety and Efficacy of Nefazodone in Preventing Relapse of Patients With Major Depression: A Multicenter, Double-Blind, Placebo-Controlled Discontinuation Study
1992 - 1995
Bristol-Myers
Principal Investigator

Safety Surveillance Study for Wellbutrin Sustained Release
1993
Burroughs Wellcome
Principal Investigator

Double-Blind Comparison of Tandospirone GUTS and Placebo in the Treatment of Outpatients with Major Depression
1993 - 1995
Pfizer and International Clinical Research Corporation
Principal Investigator

A Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Ondansetron in the Treatment of Social Phobia
1993 - 1995
Glaxo, Inc.
Principal Investigator

Olanzapine versus Haloperidol in the Treatment of Schizophrenia and other Psychotic Disorders
1993 - 1996
Lilly Research Laboratories
Principal Investigator

A Multicenter Fixed Dose Study of BMS-181101 in Depressed Patients: A Double-Blind Placebo Controlled Fixed Dose Study of BMS-181101 in Outpatients with Major Depressive Disorder
1994 - 1995
Bristol-Myers
Principal Investigator

Double-Blind, Placebo-Controlled. Parallel-Group. T.I.D. Dose-Finding Study of Adatanserin Hydrochloride Capsules in Outpatients with Generalized Anxiety Disorder
1994 - 1995
Wyeth-Ayerst
Principal Investigator

An Open-Label Trial of the Efficacy of Venlafaxine in Patients with Adult Attention Deficit and Hyperactivity Disorder
1994 - 1995
University of Utah
Department of Psychiatry
Principal Investigator

A Double-Blind, Placebo-Controlled, Fixed Dose Evaluation of the Safety and Efficacy of Oral Ondansetron in the Treatment of Patients with Panic Disorder
1994 - 1995
Glaxo Inc.
Principal Investigator

A Prospective, Multicenter Open-Label Study of Serzone (Nefazodone) in the Management of Depression in General Psychiatric Practices
1994 - 1995
Bristol-Myers
Principal Investigator

Flesinoxan in the Treatment of Generalized Anxiety Disorder: A Multi-center, Double-Blind Parallel Placebo-Controlled Dose Range Study in Outpatients
1995 - 1996
Sylvia Pharmaceuticals
Principal Investigator

An Open-Label Trial of the Efficacy of Serzone in Patients with Generalized Anxiety Disorder
1995 - 1996
University of Utah
Department of Psychiatry
Principal Investigator

A Multicenter Placebo-Controlled Study of Relapse-Prevention by Long-Term Treatment with High or Low Doses of ORG 4428 in Outpatients with Recurrent Major Depressive Episode
1995 - 1996
Pharmaco RS
Principal Investigator

Risperidone QD vs BID Dosing in Schizophrenia
1995 - 1996
Janssen
Principal Investigator

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A Three Month Open Label Study of the Tolerability and Safety of OPAQUE in Schizophrenic Patients
1995 - 1996
Otsuka
Principal Investigator

A Dose-Ranging Study of the Efficacy and Tolerability of OPAQUE in Acutely Relapsed Hospitalized Schizophrenic Patients
1995 - 1996
Otsuka
Principal Investigator

Dose-Ranging Study of Pramipexole in Combination with Maintenance Haloperidol for the Treatment of Negative Symptoms of Schizophrenia
1995 - 1997
Upjohn
Principal Investigator

Double Blind, Placebo Controlled, Parallel-Group Comparison of Venlafaxine Extended-Release Capsules and Buspirone in Outpatients with Generalized Anxiety Disorder
1996 - 1998
Wyeth-Ayerst
Principal Investigator

A Double-Blind, Placebo-Controlled, Study of Venlafaxine and Fluoxetine in Outpatients with Major Depression
1997 - 1997
Wyeth-Ayerst
Principal Investigator

A Double-Blind, Placebo-Controlled, Flexible Dosing Trial to Evaluate the Efficacy of Modified Release Paroxetine in the Treatment of Panic Disorder
1997 - 1998
Eli Lilly
Principal Investigator

Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of LY354740 and Lorazepam in Outpatients with Generalized Anxiety Disorder
1997 - 1998
Eli Lilly
Principal Investigator

A Double-Blind Trial of Three Fixed Doses of Nefazodone and Placebo in the Treatment of Patients with Panic Disorder
1997 - 1999
Bristol-Myers Squibb
Principal Investigator

A Double-Blind, Randomized, Placebo-Controlled Flexible Dose Trial of 30 RM Transdermal Buspirone Patches in Treatment of Anxious Outpatient
1997 - 1999
Bristol-Myers Squibb
Principal Investigator

A Multicenter, Double-Blind, Placebo-Controlled, Randomized, Fixed-Dose Evaluation of the Safety and Efficacy of Lamotrigine in the Long-Term Prevention of Relapse and Recurrence of Depression and/or Mania in Patients with Bipolar I Disorder
1997 - 2001
Glaxo Wellcome
Principal Investigator

A Multicenter, Double-Blind, Double-Dummy, Placebo and Lithium-Controlled, Randomized, Flexible-Dose Evaluation Of The Safety And Efficacy Of Lamotrigine In The Long-Term Prevention Of Relapse And Recurrence Of Mania And/Or Depression In Patients With Bipolar I Disorder
1997 - 2001
Glaxo-Wellcome
Principal Investigator

A Multicenter, Placebo-Controlled Study Of Relapse Prevention By Long-Term Treatment With The Recommended Dose Of Remeron In Outpatients With Major Depressive Episode
1997 - 1999
Organon Inc.
Principal Investigator

A Multicenter, Double-Blind Placebo-Controlled Comparison of the Effects on Sexual Functioning of Wellbutrin (Bupropion Hal) Sustained Release and Sertraline in Outpatients with Moderate to severe Recurrent Major Depression
1997 - 1998
Glaxo Wellcome
Principal Investigator

A Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of SR 2B in Outpatients with Major Depression
January 1998 - July 1998
Sanofi Research Division
Principal Investigator

A Multicenter, Open-label, Long-term, Safety and Efficacy Study of M100907 Tablets Once Daily In Subjects With Schizophrenia Or Other Psychotic Disorders
1998 - 2000
Hoechst Marion Roussel, Inc.
Principal Investigator

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study of Four Oral Doses of 1555U88 (2.5, 5.0, 10, and 20MG per day) in the Treatment of Attention Deficit/Hyperactivity Disorder in Adults
1998 - 1999
Glaxo Wellcome, Inc.
Principal Investigator

A Phase I Study of the Safety and Tolerance of Single Doses of Intranasal PH80
1998 - 2000
Cheri Pharmaceuticals
Co-Investigator

Reboxetine Versus Placebo And Fluoxetine In A Controlled, Randomized, Double-Blind, Multicenter Study Of Treatment In Major Depressive Disorders
1998 - 1999
Pharmacia & Upjohn
Principal Investigator

A Placebo Controlled, 8-Week Clinical Trial of Wellbutrin SR In The Treatment Of Adults With Attention Deficit Hyperactivity Disorder Combined With A Six Month Extension For Treatment Responders
1998 - 2000
Glaxo-Welcome & Mood Disorders Clinic
Principal Investigator

A Double-Blind, Randomized, Multicenter, Parallel Design Study to Evaluate The Efficacy and Safety of Three dose Ranges of EMD 68 843 in Comparison with Placebo and Fluoxetine in Outpatients With Major Depressive Disorder
1998 - 1999
Merck KGaA
Principal Investigator

A Multicenter, Double-Blind, Placebo-Blind, Placebo-Controlled Comparison of the Safety and Efficacy and Effects on Sexual Functioning of Wellbutrin (Bupropion HCL) Sustained Release (SR) and Fluoxetine in Outpatients with Moderate to Severe Recurrent Major Depression
1999 - 2000
Glaxo Wellcome
Principal Investigator

A Double-Blind, Placebo Controlled, Randomized to Determine the Safety and Efficacy of Topiramate in Treating Patients with Bulimia Nervosa
1999 - 2001
Ortho-McNeil Pharmaceuticals
Principal Investigator

The Combination of Olanzapine and Fluoxetine in Treatment Resistant Depression Without Psychotic Features
1999 - 2001
Lilly Research Laboratories
Principal Investigator

Safety of Two Dose Ranges of EMD 128 130 in Comparison with Placebo and Haloperidol in the Treatment of Schizophrenia
1999 - 2000
Merck KGaA
Principal Investigator

A Multicenter, Double-Blind, Placebo Controlled, Randomized Fixed Dose Study of Nefazodone ER in the Treatment of Depressed Patients
1999 - 2001
Bristol Myers Squibb
Principal Investigator

Olanzapine Versus Placebo in the Prevention of Relapse in Bipolar Disorder
1999 - 2001
Lilly/Parexel
Principal Investigator

A Double-Blind, Placebo-Controlled, Study of a Flexible Dose of Venlafaxine ER in Adult Outpatients with Generalized Social Anxiety Disorder
1999 - 2001
Wyeth Ayerst
Principal Investigator

12/12/2002

A Multicenter, Double-Blind, Placebo Controlled, Randomized Fixed Dose Study of Nefazodone ER in the Treatment of Depressed Patients
1999 - 2000
Bristol Myers Squibb
Principal Investigator

Open-Label Safety Study of Pregabalin in Patients with Anxiety Disorders (Panic)
1999 -2001
Warner Lumber Division of Parke Davis
Principal Investigator

A Placebo-Controlled Study of Pregabalin Dosed BID and TID in Patients with Generalized Anxiety Disorder
1999 - 2001
Warner Lumber Division of Parke Davis
Principal Investigator

A Placebo-Controlled Study of Pregabalin and Paroxetine in Patients with Panic Disorder
1999 - 2001
Warner Lumber Division of Parke Davis
Principal Investigator

A Multicenter, Double-Blind, Placebo and Sertraline Controlled, Randomized, Parallel Group Design, Flexible Dose Trial of Nefazodone ER in the Treatment of Depressed Patients -
1999 - 2001
Bristol Myers Squibb
Principal Investigator

Open Label Safety Study of Pregabalin in Patients with Generalized Anxiety Disorder
1999-2001
Warner Lumber Division of Parke Davis
Principal Investigator

A Double-Blind, Multi-Center Extension Trial in Subjects Who Suffer From Major Depressive Disorder with Atypical Features who Participated in the Placebo and Fluoxetine Controlled Study of ORG 33062 ER
2000 - Present
Organon
Principal Investigator

A Double-Blind, Multi-center, Randomized, Placebo-Controlled, Efficacy and Safety Study of ORG 33062 ER and Fluoxetine in Subjects Who Suffer from Major Depressive Disorder with Atypical Features
2000 - Present
Organon
Principal Investigator

Phase III Randomized, double-Blind Comparison of Placebo and Tomoxetine in Adult Outpatients with DSM-IV Attention Deficit/Hyperactivity Disorder
2000 - 2001
Eli Lilly
Principal Investigator

A Long-term, Open-Label Safety Study of Tomoxetine Hydrochloride in Adult Outpatients with DSM-IV Attention-Deficit/Hyperactivity Disorder
2000-Present
Eli Lilly
Principal Investigator

A Multicenter, Parallel, Double-Blind, Placebo-Controlled, 6-Week Randomized Comparison of 3 Fixed Doses of GW650250A (8, 16, and 32mg/day), Fluoxetine 20 mg/day and Placebo for the Outpatient Treatment of Moderate to Severe Recurrent Depression
2000-Present
Glaxo Welcome
Principal Investigator

A Multicenter, Double-Blind, Placebo-Controlled, Fixed-Dose Evaluation of the Safety, Efficacy and Tolerability of Lamictal (Lamotrigine) in the Treatment of a Major Depressive Episode in Patients with Type I Bipolar Disorder
2000-2002
Glaxo SmithKline
Principal Investigator

An Open Assessment of Buspirone in Adult Outpatients with DSM-IV Attention-Deficit/Hyperactivity Disorder (ADHD) for 8 weeks with up to 16 Weeks Extended Observation
2001-Present
University of Utah Health Sciences Center
Mood Disorders Clinic
Principal-Investigator

F. Reimherr 12/11/2002

A Controlled Trial of Olanzapine versus Ziprasidone in the Treatment of Schizophrenia and Schizoaffective Subjects with Comorbid Depression
2001 – Present
Eli Lilly and Company
Principal-Investigator

A Double-Blind, Randomized, Placebo-Controlled 3-Month Clinical Trial of Venlafaxine ER and Sertraline in the Treatment of Posttraumatic Stress Disorder
2001 – Present
Wyeth-Ayerst
Principal-Investigator

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating Efficacy and Safety of SB-659746-A (10 Mg/Day and 20 Mg/Day) and Citalopram (20 Mg/Day) in Patients with Major Depressive Disorder
2002 – Present
SmithKline Beecham
Principal-Investigator

A Randomized, Double-Blind, Multicenter, Placebo-Controlled 12-Week Study of the Safety and Efficacy of Two Doses of Topiramate for the Treatement of Acute Manic or Mixed Episodes in Subjects with Bipolar I Disorder with an Optional Open-Label Extention
2002 – Present
Ingenix
Principal-Investigator

A Randomized, Double-Blind, Placebo-Controlled, Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of CP-601,927 in Adults with Attention Deficit/Hyperactivity Disorder
2002 – Present
Pfizer Inc.
Principal-Investigator

Comparative Effectiveness of Antipsychotic Medications in Patients with Schizophrenia
2002 – Present
University of North Carolina (NIMH)
Principal-Investigator

Efficacy and Tolerability of Olanzapine, Quetiapine and Risperidone in the Treatment of First Episode Psychosis: A Randomized Double Blind 52 Week Comparison
2002 – Present
University of North Carolina (NIMH)
Principal-Investigator

A Double-Blind Study of Treatment Optimization with Atomoxetine Hydrochloride in Adults with DSM-IV Attention-Deficit/Hyperactivity Disorder
2002 – Present
Eli Lilly
Principal-Investigator

F. R. – 12/10/2002

Scholastic Honors

1964 Pennsylvania State Scholarship Winner

Administrative Experience

1976-1979 - Member Research Committee, Salt Lake City Community Mental Health Center

1979-1980 - Director Residency Training, University of Utah Medical Center, Department of Psychiatry

1980-1982 - Chairman - Peer Review and Records Evaluation Committee, Salt Lake County Mental Health Center

1981-1986 - Member, Residency Training Committee, University of Utah Medical Center, Department of Psychiatry

1982-1997 - Member, Pharmacy and Therapeutics Committee, University of Utah Medical Center

1987-1990 - Member, Drug Utilization Review Sub-Committee, Pharmacy and Therapeutics Committee, University of Utah Medical Center

1987-1989 - Member, Ad-hoc Committee to Establish Standards for Psychiatric Hospitalization formed by Utah State Medical Association, Utah Professional Review Organization, and Utah Psychiatric Association

1996-present - Member, Ad-hoc Committee to Review Psychiatric Treatment provided by the Utah State Office of Crime Reparations Association

Professional Organizations

Utah Psychiatric Association - past member

American Psychiatric Association - past member

American Association for the Advancement of Behavior Therapy - past member

American Society for Clinical Trials - past member

American Society of Clinical Psychopharmacology - Current member

12/16/2002

Teaching Responsibilities

Regular lectures in third year medical student rotation in Psychiatry

Periodic lectures in Main Residency Lecture Series

Supervisor of third year residents during year long outpatient rotation at Salt Lake Community Mental Health, 1976-86

Supervise Residents and medical students during elective research rotations
Currently have 2 residents and finishing a medical student elective

While serving as Director of Residency Training, planned new programs in Psychiatry Department of Residency Program:

1. Training in rural psychiatry
2. Service to patients with chronic mental illness
3. Evaluation of teaching performance
4. Evaluation of residency performance
5. Evaluation training sites
6. Developed and implemented residency committee to oversee Residency Training Program

Supervise medical students during 3rd year rotation in Mood Disorder Clinic

Bibliography

Wood, D.R., Reimherr, F.W., Johnson, G., and Wender, P.H.
Diagnosis and treatment of minimal brain dysfunction in adults: A preliminary report.
Archives of General Psychiatry, 33:1453-1461, 1976

Reimherr, F.W., Hill, G., and Wong, K.
Prolongation of muscle relaxant effects by lithium carbonate.
American Journal of Psychiatry, 134:205-206, 1977

Reimherr, F.W., Wood, D.R., and Wender, P.H.
An Open Clinical Trial of L-DOPA and Carbidopa in the Treatment of Adults with Minimal Brain Dysfunction
American Journal of Psychiatry, 137:73-75, 1980

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Strassberg, D.S., Reimherr, F.W., Ward, M.F., Russell, S., and Cole, A.
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Journal of Consulting Clinical Psychology, 49:220-226, 1981

Wender, P.H., Reimherr, F.W., Wood, D.R., and Coyne, T.
Diagnosis and Treatment of Minimal Brain Dysfunction in Adults: A Replication
Archives of General Psychiatry, 38:499-456, 1981

Wood, D.R.; Reimherr, F.W.; Wender, P.H.
Effects of Levodopa on Attention Deficit Disorder, Residual Type (ADD,RT)
Psychiatry Research, 6:13-20, 1982

Wender, P.H., Wood, D.R., Reimherr, F.W., Ward, M.F.
An Open Trial of Pargyline in the Treatment of Attention Deficit Disorder, Residual Type
Psychiatry Research, 9:329-336, 1983

Wood, D.R., Reimherr, F.W.
Minimal Brain Dysfunction (Attention Deficit Disorder) in Adults
New Psychiatric Syndromes, Edited by Akhtar, Aronson, 1983, New York

Wood, D.R., Reimherr, F.W., Wender, P.H.
The Use of L-Deprenyl in the Treatment of Attention Deficit Disorder, Residual Type
Psychopharmacology Bulletin, 19:627-629, 1983

Wood, D.R., Wender, P.H., Reimherr, F.W.
The Prevalence of Attention Deficit Disorder, Residual Type, or Minimal Brain Dysfunction, in a Population of Male Alcoholic Patients
American Journal of Psychiatry, 140:95-98, 1983

Grosser, B.I., Brainard, J., Byerley, W.F., Reimherr, F.W.
Effects of the DST on Plasma Steroids or Melancholic Patients
Neuroendocrinology Letters, Vol 5, #3, 1984

Reimherr, F.W., Wender, P.H., Ebert, M.H., Wood, D.R.
Cerebrospinal Fluid Homovanillic Acid and 5-hydroxyindole Acetic Acid in Adults with Attention Deficit Disorder, Residual Type (ADD,RT)
Psychiatry Research, 11:71-78, 1984

Reimherr, F.W., Wood, D.R., Byerley, W.F., Brainard, J., Grosser, B.I.
Characteristics of Responders to Fluoxetine,
Psychopharmacology Bulletin, 20:70-72, 1984

Wender, P.H., Wood, D.R., Reimherr, F.W.
Studies in Attention Deficit Disorder, Residual Type (Minimal Brain Dysfunction in Adults)
Psychopharmacology Bulletin, 20:18-20, 1984

Wender, P.H., Reimherr, F.W., Wood, D.R., Ward, M.F.
A Controlled Study of Methylphenidate in the Treatment of Attention Deficit Disorder in Adults, Residual Type
American Journal of Psychiatry, 142:547-552, 1985

Wood, D.R., Reimherr, F.W., and Wender, P.H.
The Treatment of Attention Deficit Disorder With DL-Phenylalanine.
Psychiatry Research, 16:21-26, 1985

Wood, D.R., Reimherr, F.W., Wender, P.H.
Amino-acid Acid Precursors in the Treatment of Attention Deficit Disorder, Residual Type
Psychopharmacology Bulletin, 21:146-149, 1985

Reimherr, F.W., Wood, D.R., Wender, P.H.
The Use of MK-801, a Novel Sympathomimetic, in Adults with Attention Deficit Disorder, Residual Type
Psychopharmacology Bulletin, 22:237-242, 1986

Byerley, W.F., Reimherr, F.W., Wood, D.R., Grosser, B.I.
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Journal of Clinical Psychopharmacology, 7:127-137, 1987

Reimherr, F.W., Wender, P.H., Wood, D.R., Ward, M.F.
An Open Trial of l-tyrosine in the Treatment of Attention Deficit Disorder, Residual Type
American Journal of Psychiatry, 144:1071-1074, 1987

Byerley, W.F., Reimherr, F.W., Wood, D.R., Grosser, B.I.
Fluoxetine, A Selective Serotonin Re-uptake Inhibitor For The Treatment of Outpatients With Major Depression
Journal of Clinical Psychopharmacology, 8:112-115, 1988

Reimherr, F., Byerley, W.F., Grosser, B.I.
Sertraline, A Selective Serotonin Re-uptake Blocker for Outpatients With Major Depression
Psychopharmacology Bulletin, 24:200-205, 1988

Reimherr, F.W., Ward, M.F., Byerley, W.F.
The Introductory Placebo Washout: A Retrospective Evaluation
Psychiatry Research, 30:191-199, 1989

Byerley, W.F., Leppert, M., O'Connell, P., Mellon, C., Holik, J., Lubbers, A., Bullen, K., Reimherr, F.W., Wender, P.H., Bunzow, J., Grandy, D., Litt, M., Civelli, O., Lalouel, J.,White, R.
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Psychiatric Genetics, 1:55-62, 1990

Reimherr, F.W., Chouinard, G, Cohn, CK et al
Antidepressant Efficacy of Sertraline: a Double-Blind, Placebo- and Amitriptyline-controlled Multicenter Comparison Study in Outpatients with Major Depression
Journal of Clinical Psychiatry, 51(12, suppl B): 18-27, 1990

Wender, P.H., Reimherr, F.W.,
Bupropion Treatment of Attention Deficit Hyperactivity Disorder in Adults
American Journal of Psychiatry, 147, 1018-1020, 1990

Wender, P.H., Wood, D.R., Reimherr, F.W.
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Reimherr-FW, Hedges-DW, Wender-PH, Strong-RE, Lebegue-BJ, and Halls-C, "The Residual Symptoms of Major Depressive Disorder and the Effects of Treatment with Fluoxetine in a Long Term Placebo-Controlled Study"' Poster Presented at the American college of Neuropsychopharmacology Meeting in San Juan, Puerto Rico, December, 1996

12th 2002

Hedges-DW, Reimherr FW, Wender-PH, Strong-RE and Cameron-M, "The Relationship Between Fluoxetine and Norfluoxetine Plasma Levels and Hamilton Depression Scored During 63 Weeks of Treatment of Major Depression"; Poster Presented at the American College of Neuropsychopharmacology Meeting in San Juan, Puerto Rico, December, 1996

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Wender PH, Reimherr FW, , Czajkowski L, Sanford E, Rogers A, Gardner L and Eden J, "A Longterm Trial of Methylphenidate in the Treatment of ADHD Adults I. APlacebo-Ctontrolled Trial and Six-Month Followup"; Poster Presented at the American College of Neuropsychopharmacology Meeting in San Juan, Puerto Rico, December, 1996

Fawcett J, Zajeck J, Reimherr FW, Kornstein S, Borian F, Ieni J, Jody D, "An Open-Label Study of Nefazodone in the General Psychiatric Practice: Treatment of Depression with a Focus on Anxiety, Sleep, & Sexual Function"; Presented at the American Psychiatric Association, San Diego, California, May, 1997

Reimherr FW, Michelson D, Beasley CM, Wilson M, "Optimal Length of Continuation Therapy: A Prospective Assessment During Fluoxetine Long-term Treatment of Major Depressive Disorder"; Presented at the American Psychiatric Association, San Diego, California, May, 1997

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Brunswick DJ, Amsterdam JD, Fawcett J, Quitkin F, Reimherr F, Rosenbaum J, Beasley C, "Relation of Steady-State Fluoxetine Plasma levels and Relapse-Prevention Outcome." ECDEU, Boca Raton, Florida June, 1998

Brunswick DJ, Amsterdam JD, Fawcett J, Quitkin F, Reimherr F, Rosenbaum J, Beasley C, "What Constitutes an "Adequate" Treatment Period with Fluoxetine." ECDEU, Boca Raton, Florida June, 1998

Amsterdam J, Garcia-Espana F, Fawcett J, Quitkin F, Reimherr F, Rosenbaum J, Beasley C, "Fluoxetine efficacy in menopausal Peri & Postmenoopausal Depressed Women: Effect of Estrogen Replacement Therapy." International College of Neuro-Psychopharmacology, Glasscow, England July, 1998

Amsterdam J, Garcia-Espana F, Fawcett J, Quitkin F, Reimherr F, Rosenbaum J, Beasley C, "Weight Change During Acute and Chronic Fluoxetine Therapy in Patients with Major Depression." International College of Neuro-Psychopharmacology, Glasscow, England July, 1998

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Professional Community Activities

Utah Mental Health Association

Physicians for Social Responsibility

Catalyst - Association of Families of Patients with Chronic Mental Illness

National Association for the Mentally Ill

5077US/0049 : 0014

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
LICENSE

EFFECTIVE DATE: 12/17/2001

EXPIRATION DATE: 01/31/2004

ISSUED TO: **Frederick Reimherr**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

156060-1205	**Physician & Surgeon**
156060-8905	**Physician & Surgeon Controlled Substance**

SIGNATURE OF HOLDER

STATE OF UTAH
DEPARTMENT OF COMMERCE
LICENSE

Frederick Reimherr

EFFECTIVE 12/17/2001

EXPIRATION 01/31/2004

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

Physician & Surgeon
156060-1205

Physician & Surgeon Controlled Substance
156060-8905

SIGNATURE OF HOLDER

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FREDERICK REIMHERR
U OF U MED CTR, DEPT OF PSYCH
50 N MEDICAL DR
SALT LAKE CITY UT 84132

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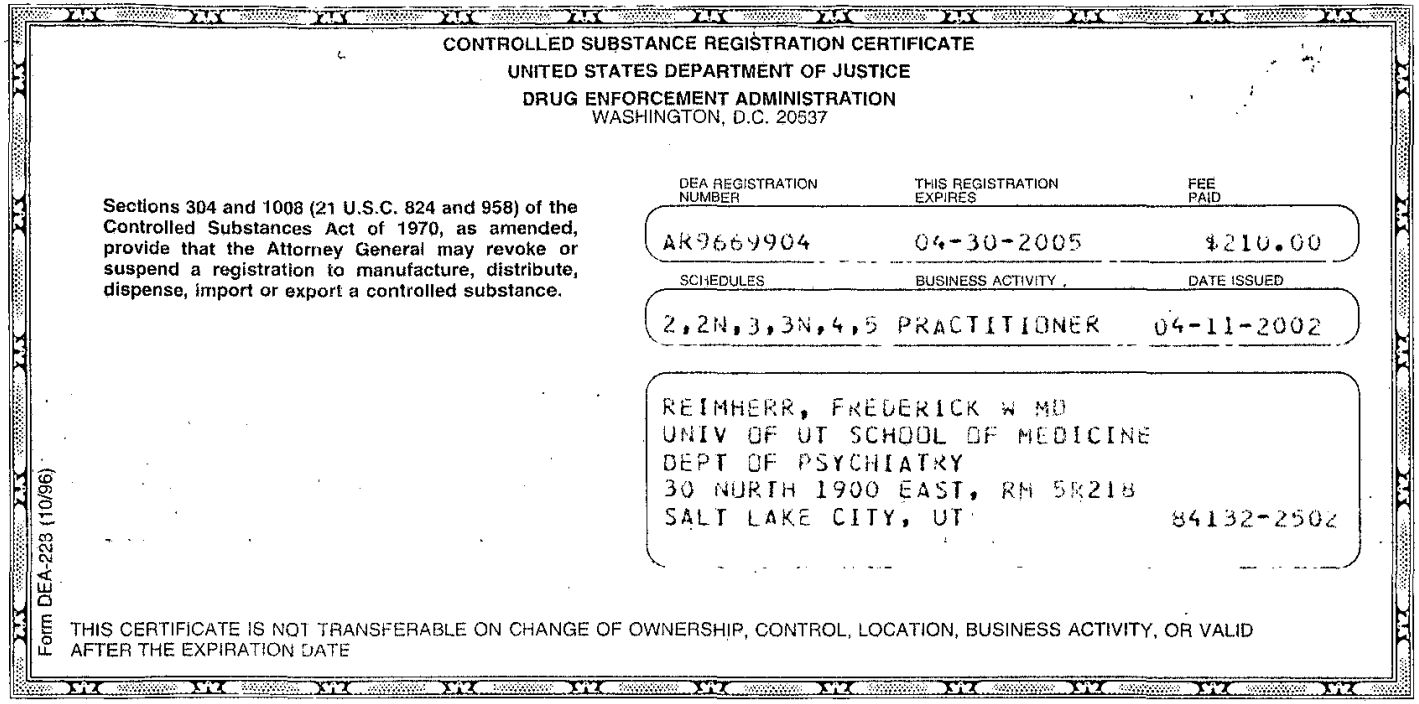

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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2,2N,3,3N,4,5	PRACTITIONER	04-11-2002

REIMHERR, FREDERICK W MD
UNIV OF UT SCHOOL OF MEDICINE
DEPT OF PSYCHIATRY
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Form DEA-223 (10/96)

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CURRICULUM VITAE

Abbey Strauss, M.D.

Comprehensive NeuroScience, Inc.
8200 Jog Road, Suite 101
Boynton Beach, FL 33437
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Education:

1981 - 1985	Beth Israel Medical Center New York, NY Internship and Psychiatric Residency
1981	Medical University of South Carolina Charleston, SC Doctor of Medicine
1972	New York University New York, NY Masters of Social Work
1969	Ohio State University Columbus, Ohio BA in general psychology
	Piqua Central High School Piqua, Ohio

Professional Experience:

Feb 2002 – Present	Investigator Comprehensive NeuroScience, Inc. Boynton Beach, FL
1994 - Jan 2002	Investigator ICSL - Clinical Studies Boynton Beach, FL
1986 - Present	Private Practice Boca Raton, FL Psychopharmacological, forensic and pain control emphasis. Psychiatric Consultant on a number of felony cases associated with cocaine abuse and general psychiatric problems.

Professional Experience:
(cont'd):

1997 - Present	Regional Director (Southeast United States) *Physician's For Social Responsibility* (US Affiliate of the International Physicians for the Prevention of Nuclear War - Winner 1985 Nobel Peace Price),
1992 - 1993	Quality Assurance Committee Fair Oaks Hospital Delray Beach, FL
	Faculty, Fair Oaks Hospital Institute of Advance Studies Delray Beach, Florida
1988	Forensic Evaluator Training University of South Florida
	Professional Speaker for McNeil Laboratories, Sandoz Pharmaceutical and Abbott Laboratories, Cosensys, Wyeth, Lilly, Purdue and other professional organizations
	Many community lectures and Continuing Education Seminars to nursing groups and lay organizations
1987	Substance Abuse Awareness Committee Psychiatric Consultant Boca Raton Community Hospital Boca Raton, FL
1986 - 1988	Executive Committee Fair Oaks Hospital Delray Beach, FL
1986	Reviewer American Journal of Family Therapy
	Psychiatrist Regent's Park Nursing Home Boca Raton, FL

Professional Experience:
(cont'd):

1986 - 1991	Psychiatrist North Broward Detention Center
1984 - 1985	New York University Graduate School of Social Work
1984 - 1985	Gracie Square Hospital New York, NY
1972 - 1976	Pee Dee Mental Health Center Florence, SC
1967 - 1968	Columbus Children's Psychiatric Hospital Columbus, Ohio

Professional Memberships/Organizations:

American Psychiatric Association, General Member
Florida Psychiatric Association
New York Academy of Sciences
American Academy of Psychiatry and the Law
Who's Who in Medicine
American Association of Orthopsychiatry
American Academy of Pain Management
American Sleep Disorders Association

Licenses/Certification:

1988	Board Certified American Board of Psychiatry & Neurology
1982	Diplomat National Board of Medical Examiners
	Florida State Medical License; ME0045950

Research Papers/Presentations:

1982	Propranolol and Anxiety Beth Israel Medical Center (NY) Annual Research Meeting
1985	NMR Study of Human Erythrocyte in Affective Disorders Beth Israel Medical Center (NY) On-Going Research Seminar
1985	NMR Study of Human Erythrocyte in Affective Disorders Grand Rounds Presentation Beth Israel Medical Center (NY)
1985	NMR Study of Human RBC's in Affective Disorders IVth World Congress of Biological Psychiatry Philadelphia
1986	NMR Study of Human RBC's in Affective Disorders New Research Meeting Washington, DC
1985 - 1987	Consultant RBC/NMR and Bipolar Disorders Beth Israel Medical Center (NY)
1988	Interviewed by CBS News "60 Minutes" as the psychiatrist involved with the "Cara" case Aired Autumn

Awards:

1994	Exemplary Psychiatrist Award from the National Alliance for the Mentally Ill Arlington,VA

Publications:

1. Drug Logic, a monthly column in the ADA Journal, Charlotte, NC, directed to high school students; 1974-1975
2. Strauss A: A Physician's Guide to the Treatment of the Overdosed Patient-A Psycho-Medical Approach, Florence County Drug Abuse Team, Florence, SC 1973
3. Strauss A: Several book reviews for The New Physician
4. Strauss A: Communicating with Spanish-Speaking Patients. The New Physician 26:34-36, 1974
5. Strauss A: From Im Morphine to PO Methadone Case Report, Western Journal of Medicine, December 1980, page 520
6. Strauss A: High False Negative Rate for the RPR Syphilis Test (letter) Southern Medical Journal 74:535, March 1981
7. Strauss A: Cimetidine and delirium - Assessment and Management. Psychosomatics 23:57-62, 1982
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10. Strauss A: Shpos. Southern Medical Journal 76:981-984, 1983
11. Strauss A: Psychiatric Services in New York City: A Partial Listing. Committee of Residents NYC APA District Branch, 1984
12. Strauss A: A Social Workers Guide to Psychiatric Drugs. A 100 page unpublished handbook for New York University Graduate Students used in my course, 1984-1985
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Research Experience:

A Thirty Day Open-Label Multicenter Observational Study Assessing the Safety of xxxx Sustained Release (10 mg or 30 mg) Tablets Administered Every Twelve Hours (q12 hours) in Patients Experiencing Chronic Pain

Research Experience:
(cont'd)

A Three Month, Open-Label, Multicenter, Compassionate-Use Study Assessing the Safety of xxxx Sustained Release (10 mg or 30 mg) Tablets Administered Every Twelve Hours (q12 hours) in Patients Experiencing Chronic Pain

A Forty-Eight Week Study to Compare the Efficacy and Safety of xxxx (xxxx) with Placebo in Outpatients with Alzheimer's Disease

A Twenty-Four Week Study to Compare the Efficacy and Safety of xxxx (xxxx) with Placebo in Outpatients with Vascular Dementia

A Double-Blind, Placebo-Controlled, Safety, Tolerability and Efficacy Study of xxxx Following Four-Week, Step-Wise Dose Escalations in Patients with Probable Alzheimer's Disease

An Open-Label, Multicenter, Extended Evaluation of the Safety and Efficacy of xxxx In Patients with Alzheimer's Disease

An Open-Label, Six-Month Extension of xxxx Studies xxxx and xxxx to Prospectively Evaluate the Long-Term Safety, Tolerability, and Efficacy of 1 Through 6 mg B.I.D. (2-12 mg/day) xxxx in Outpatients with Probable Alzheimer's Disease

An Open-Label, Six-Month Extension of xxxx Studies xxxx (U.S. Centers Only), xxxx and xxxx to Prospectively Evaluate the Long-Term Safety, Tolerability, and Efficacy of 1 through 6 mg B.I.D. (2/12 mg/day) xxxx in Outpatients with probable Alzheimer's Disease

A Prospective, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Comparison of the Efficacy and Safety of Three Fixed-Doses of xxxx, 3 mg, 6 mg, and 9 mg per day in Patients with Probable Mild to Moderate Alzheimer's Disease

xxxx Experience with Safety and Tolerability (QUEST) in Schizophrenia.

Research Experience:
(cont'd)

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Safety, Tolerance, and Efficacy Study of 5 and 10 mg of xxxx and 5 mg of xxxx (xxxx) in Elderly Outpatients with Insomnia with an Open-Label Extension Phase for a Maximum Duration of Twelve Months

A Multicenter, Double-Blind, Placebo-Controlled Study of the Cardiovascular Safety and Tolerability of xxxx in Otherwise Healthy Migraineurs

A 15 Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of xxxx in Patients with Alzheimer's Disease

A 30 Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of xxxx in Patients with Alzheimer's Disease

A Randomized, Comparative, Multicenter, Safety and Contraceptive Efficacy Study of Two Cyclophasic xxxx/xxxx Regimens, and One Triphasic xxxx/xxxx Regimens (xxxx) and xxxx 1/20

xxxx Versus xxxx and xxxx in Major Depression:
Comparison of Discontinuation-Emergent Signs and Symptoms

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Single-Dose, Dose-Range-Finding Study to Assess the Efficacy and Tolerability of xxxx in the Acute Treatment of Migraine

Comparison of xxxx, Continuous Combined Hormone Replacement Therapy, and Placebo in Early Postmenopausal Women: Effects on Bone, Endometrium, Menopausal Symptoms and Lipids

A Randomized, Double-Blind, Multicenter, Placebo-Controlled Menopausal Symptom Study of Three Doses of xxxx/xxxx (xxxx) Patches in a Sequential Hormone Replacement Therapy (HRT) Regimen

Research Experience:
(cont'd)

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Dose-Range-Finding Study to Assess the Efficacy, Tolerability and Safety of xxxx (Administered As A Single Dose of 0.5 MG, 2.5 MG, or 5.0 MG) In The Treatment of Acute Migraine

A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of Escalating the Dose of Oral xxxx in Subjects with Acute Migraine

A Multicenter, Randomized, Open-Label, Comparative, Study of the Safety, Toleration and Efficacy of Oral xxxx for Long Term Treatment of Subjects with Acute Migraine

A Randomized, Double-Blind, Parallel Trial Comparing xxxx 5/10 Mg Once Daily, xxxx 5/20 Mg Once Daily, xxxx xxxx 30 Mg Once Daily, and xxxx xxxx 0 Mg Once Daily In Patients Age 1-80 With Essential Hypertension Inadequately Controlled With xxxx xxxx 30 Mg Once Daily Followed By A Single-Blind Extension of xxxx 5/20 Mg Once Daily

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Determine the Efficacy and Safety of xxxx in the Treatment of Osteoporosis in Elderly Women

Evaluation of Endometrial Histology and Bone Mineral Density (BMD) in Post Menopausal Women Receiving xxxx/xxxx Hormone Replacement Therapy (HRT)

A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study Comparing the Efficacy and Safety of Oral Tablets of xxxx/xxxx xxxx as well as xxxx Alone Against Placebo in the Prevention of Osteoporosis in Postmenopausal Women

A Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 3 Dosage Combinations of xxxx xxxx Plus xxxx xxxx for the Treatment of Vasomotor Symptoms of Menopause (Hot Flash Frequency and Intensity)

Research Experience:
(cont'd)

A Randomized, Double-Blind, Active-Controlled, Parallel-Group, Multicenter Study Assessing Menstrual Cycle Control and Ovulation Suppression Associated with Vaginal Administration of 5 Dose-Combinations of xxxx xxxx and xxxx xxxx

Evaluation of the Safety and Efficacy of Adding xxxx xxxx (8 to 16 mg) to xxxx in the Treatment of Patients with Severe (JNC-V) Hypertension: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Design Study with an Open-Label, Long Term Extension

A Randomized, Double-Blind, Placebo-Controlled, Four-Arm Dose-Finding Study Investigating the Efficacy and Safety of Three Doses of xxxx in Patients with Alzheimer's Disease

A Double-Blind, Randomized, Parallel-Group, Multicenter, Dose Finding Study Comparing the Efficacy and Safety of 1 mg xxxx - xxxx in Combination with Low Doses of xxxx xxxx with that of 1 mg xxxx - xxxx Alone on the Endometrium in Postmenopausal Women

Multinational, Multicentre, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Compare xxxx 80 mg o.d. Titrated to 160 mg o.d. with xxxx 50 mg o.d. Titrated to 100 mg o.d. in Patients with Mild to Moderated Essential Hypertension

Randomized, Double-Blind, Double-Dummy, Active-Controlled Multi-Site Crossover Investigation Comparing the Efficacy of xxxx xx (xxxx xx10 mg OR 30 mg Tablets) Administered Every Twelve Hours to xxxx xx (xxxx 5 mg Tablets) Administered Every Six Hours in Patients with Chronic Pain

Double-Blind, Randomized, Placebo-Controlled Evaluation of the Safety, Tolerability, and Pharmacokinetics of xxxx (xxxx) in Patients with Alzheimer's Disease

A Double-Blind, Placebo-Controlled, Randomized, Dose Titration Study to Evaluate the Safety and Efficacy of xxxx

Research Experience:
(cont'd)

An Eight-Week, Multicenter, Parallel-Group, Double-Blind, Placebo-Controlled Study of xxxx in the Treatment of Elderly Outpatients with DSM-IV Major Depression

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of xxxx(xxx xx xx) in the Treatment of Moderate to Severe Vasomotor Symptoms and Atrophic Conditions Associated with the Menopause

A Randomized, Double-Blind, Placebo-Controlled, Eighteen Week, Safety and Efficacy Trial of xxxx (xx-xxx) 1.5 mg/Day with Uptitration to 6 mg/Day as Adjunctive Therapy to Insulin and Compared to Insulin Alone in Type II Diabetes Mellitus Patients (Non-Insulin Dependent Diabetes Mellitus, NIDDM)

A 24 Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Efficacy and Safety of xxxx xxxx (xxxxx) in Patients with Dementia Associated with Cerebrovascular Disease

An Open Label, Randomized Dose Comparative Phase II Study of Low Dose xxxx

An Active Comparator and Placebo-Controlled, Parallel-Group, 6-Week Double Blind Study, Conducted Under In-House Blinding Conditions, to Assess the Efficacy, Safety and Tolerability of xxxx in Patients Aged 80 and Over with Osteoarthritis of the Knee or Hip

An Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of xxxx-xx in Patients with Mild to Moderate Alzheimer's Disease

xxxx (xxxx) Experience with Safety and Tolerability (xxxx) with Outpatients With DSM IV Psychosis

An Open-Label, Non-Comparative, Multicenter, Study to Evaluate Contraceptive Efficacy, Cycle Control and Safety of an One-Compartment All-xxxx Vaginal Ring

Research Experience:
(cont'd)

A Multicenter, Double-Blind, Randomized Comparison of Continuous Oral xxxx-xxxx Combinations and Continuous Oral xxxx, examining the Effect on the Endometrium, Symptoms and Bleeding Patterns in Postmenopausal Women.

A Multicenter, Double-Blind, Controlled, Randomized Study to Determine Efficacy in the Relief of Hot Flushes in Women Receiving xxxx xxxx Compared to Oral Conjugated Estrogens.

A Twelve Month, Double-Blind, Placebo-Controlled, Investigation of the Safety And Efficacy of xxxx Transdermal System (1.0mg/cm^2 x 20 cm^2) in Patients with Dementia of the Alzheimer's Type (Twenty-Four Month Open-Label Extension)

A Twelve Month, Double-Blind, Placebo-Controlled, Investigation of the Safety and Efficacy of xxxx Transdermal System (1.0mg/cm^2 x 20 cm^2) in Patients with Dementia of the Alzheimer's Type.

A Multicenter, Randomized, Double-Blind, Eight Week Comparative Efficacy and Safety Study of xxxx 40 mg and xxxx 20 mg in Study Subjects with Erosive Esophagitis.

A Multicenter, Open-Label Long Term Safety Study of xxxx 40 mg in Subjects with Healed Erosive Esophagitis.

A Multicenter, Double-Blind, Double-Dummy, Randomized, Parallel-Group Trial to Compare the Efficacy and Safety of Three Doses of xxxx (3.75, 7.5, and 15 mg) with Placebo in Patients with Osteoarthritis of the Knee or Hip; and xxxx (100mg) as an Active Control Assess Trial Sensitivity.

A Multicenter, Double-Blind, Double-Dummy, Randomized, Parallel-Group to Compare the Efficacy and Safety of Three Doses of xxxx (7.5, 15, and 22 mg) with xxxx (150 mg) with Placebo in Patients with Rheumatoid Arthritis; and with xxxx (150 mg) as an Active Control to Assess Trial Sensitivity.

Phase II Double-Blind, Placebo-Controlled, 4-Week Multiple Dose Evaluation of xxxx for Its Safety, Toleration and Efficacy for Increasing IGF-1 in Older Normal Men and Women.

Xxxx in the Treatment of Skin/Soft Tissue Infections: An Open Label, Randomized, Dose Comparative Phase II Study of Low Dose xxxx.

Research Experience:
(cont'd)

Safety and Efficacy of Fixed Combination xxxx/xxxx Products as First Line Therapy in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control With Diet and Exercise.

A Triple-Blind, Randomized, Parallel, Pilot Study of xxxx versus xxxx Treatment Regimens in Patients with Mild to Moderate Essential Hypertension

The Comparative Efficacy of xxxx, xxxx, and xxxx for Cognition in Schizophrenia.

Allelic Variation in Schizophrenia.

A Double-Blind, Placebo-Controlled, Parallel-Group Assessment of the Safety and Efficacy of Two Doses of the xxxx Transdermal System (10 mg and 20 mg) in Patients with Major Depression.

A Two-Week, Double-Blind, Placebo-Controlled Trial of the Effects of xxxx 20, 50, and 100 mg BID on Cognitive Tests in Depressed Geriatric Patients.

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate xxxx in Patients with Probable Alzheimer's Disease of Mild to Moderate Severity.

A Randomized, Placebo-Controlled, Parallel-Group, Multiple-Dose Study of the Effects of xxxx and xxxx in Non-Insulin Dependent Diabetic Patients.

The Safety and Activity of Three Doses of xxxx Compared to Acyclovir in the Treatment of Herpes Zoster in Immunocompetent Adults.

A Comparative Efficacy and Safety Study of xxxx 40 mg and xxxx 20 mg in Study Subjects with Erosive Esophagitis

A Multicenter, Double-Blind, Randomized Study of Continuous Transdermal xxxx Combinations, Compared to Continuous Transdermal xxxx, to Examine the Safety and Effect on the Endometrium Symptoms and Bleeding Patterns in Postmenopausal Women.

A Double-Blind, Placebo-Controlled, Ranedomized Trial to Determine the Effects of a Range of Doses of xxxx Novel Oral Dose form (Biphasic Tablet) Administered Either Once or Twice a Day in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control with Diet and Exercise.

Research Experience:
(cont'd)

A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Dose-Ranging Study to Assess the Effect of xxxx on Insulin and Ovarian Androgen Production in Obese Woman with Polycystic Ovary Syndrome (PCOS).

A Double-Blind Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUB's During Chronic Treatment with xxxx or xxxx in Patients with Rheumatoid Arthritis; U.S. Cohort.

A Multicenter, Double-Blind, Randomized Parallel-Group Fixed Dose Study to Prospectively Evaluate the Efficacy, Safety and Tolerability of xxxx Monotherapy, Compared to xxxx Monotherapy in Patients with Type 2 Diabetes Mellitus Inadequately Controlled With Diet.

Multicenter, Randomized, Double-Blind, xxxx Controlled Study of the Efficacy and Safety of xxxx in Subjects with Major Depressive Disorder Who are at Least 65 Years of Age.

A Randomized, Double-Blind, Active-and-Placebo-Controlled, Parallel-Group, Multicenter Study Assessing the Safety and Protective Effect on the Endometrium of 4 Dosage Combinations of xxxx plus xxxx.

A Comparative Trial of xxxx, xxxx and xxxx in Early Postmenopausal Women: A Randomized, Open, Multicenter Study

A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Dose-Finding Study of xxxx in Patients with Essential Hypertension.

A Multicenter, Randomized, Double-Blind, Parallel-Group Study comparing Two 12-Hour xxxx Formulations for the Treatment of Patients with Moderate to Severe Chronic Pain.

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Study of a Novel Formulation of Molecular xxxx for the Treatment of Moderate or Severe, Symptomatic Fibrocystic Breast Disease in Otherwise Healthy, Euthyroid, Premenopausal Woman.

Research Experience:
(cont'd)

Double-Blind, Placebo-Controlled, Parallel-Group Comparison of the Efficacy and Safety of xxxx, xxxx, and Placebo with an Open Label Extension in the Treatment of Osteoarthritis of the Knee and/or Hip.

Evaluation of the Antihypertensive Efficacy of xxxx in Comparison to xxxx: A Multicenter, Double-Blind, Randomized, Parallel-Group, Forced-Titration Study.

A Prospective, Multinational, Multicenter, Double-Blind, Randomized, Active-Controlled Trial in Patients with Essential Hypertension to Compare the Effects of xxxx 80 and 160 mg, with or Without the Addition of xxxx, Once Daily to That of xxxx 5 and 10 mg Once Daily, with or Without the Addition of xxxx, on Cardiovascular Morbidity and Mortality.

An Open-Label Study to Assess the Safety of the xxxx Transdermal System in Patients with Major Depression.

A Multicenter, Randomized, Double-Dummy, Parallel Groups Study of xxxx (xxxx oral extended release capsules) in Patients with Chronic, Moderate to Severe Pain.

A Multicenter, Non-Randomized, Open-Extension Study of xxxx (xxxx oral extended release capsules in Patients with Chronic, Moderate to Severe Pain Who Have Completed a Prior xxxx Clinical Trial.

A 1-Year, Randomized, Placebo- and Active-Comparator-Controlled, Parallel Group, Double-Blind, Two-Part Study to Assess the Safety and Efficacy of xxxx Versus xxxx in Patients with Osteoarthritis.

An Open-Label, Repeated-Dose Trial to Characterize the Efficacy and Safety, and Impact on Quality of Life Measures of xxxx (xxxx) in Patients with Chronic Low Back Pain.

Safety, Efficacy, and Impact on Quality of Life of Long-Term Administration of xxxx (xxxx) in Patients with Chronic Low Back Pain.

A Double-Blind, Placebo and xxxx-Controlled, Multicenter Study Evaluating the Efficacy and Safety of xxxx in Patients with Major Depressive Disorder.

Research Experience:
(cont'd)

A Phase lll Double-Blind Efficacy and Safety Study of One Dose of xxxx (10 mg) Compared to Placebo in Subjects with Primary Hypercholesterolemia.

A Multicenter, Randomized, Controlled Clinical Trial Comparing the Safety and Efficacy of xxxx to xxxx 3.75 mg in Women with Endometriosis-Associated Pain.

A Phase III, Randomized, Multicenter, Placebo-Controlled, Double-Blind Clinical Trial to Study the Efficacy and Safety of xxxx for the Treatment of Hot Flashes Following Surgical or Chemical Castration of Prostate Cancer Patients and its Impact on the Quality of Life in These Patients.

A 24-Week, Randomized, Double-Blind, Multicenter, Trial to Evaluate the Efficacy and Safety of Starting and Maximum Doses of xxxx and xxxx in the Treatment of High Risk Hypercholesterolemic Subjects.

A 12-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of xxxx (5, 10, 20, 40, and 80 mg) in the Treatment of Subjects with Hypertriglyceridemia.

A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy, Safety, and Tolerability of 30 mg and 90 mg xxxx Extended Release Compared to Placebo in Patients with Generalized Anxiety Disorder.

An Open-Label Study of the Safety, Tolerability, and Efficacy of up to 90 mg xxxx Extended Release in Patients with Generalized Anxiety Disorder.

A Multicenter, Randomized, Double-Blind, Active Control Trial to Evaluate the Safety and Efficacy of xxxx as First Line Therapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with Diet and Exercise.

Ninety Day Safety Study of xxxx in Male and Female Parkinson's Patients on xxxx + xxxx.

An Innovative Approach to the Treatment of Post-Herpetic Neuralgia: An Open-Label Study of xxxx.

Research Experience:
(cont'd)

A Double-Blind, Randomized, Placebo-Controlled Clinical Trial in Postmenopausal Women to Demonstrate the Efficacy of Intravaginal Rings Releasing xxxx with Respect to Postmenopausal Vasomotor Symptoms.

Xxxx Versus Placebo and xxxx in the Acute Treatment of Major Depression.

A Prospective, Double-Blind, Randomized, Parallel Efficacy Study of a xxxx Treatment Regimen Versus Placebo in the Treatment of Patients with Isolated Systolic Hypertension.

A Placebo Controlled, Parallel-Group, 4-Week, Trial Conducted Under Double Blind Conditions to Assess the Efficacy and Safety of xxxx in Patients with Chronic Low Back Pain.

A Multicenter, Double-Blind, Placebo-Controlled Study of the Tolerability and Effect of xxxx in Parkinson's subjects with End-of-Dose Wearing off Symptoms Occurring no Earlier than 4 Hours After Their Most Recent xxxx Dose.

Evaluation of Daily Dose of xxxx 7.5 mg Compared to Placebo in the Treatment of Symptomatic Post-Menopausal Women.

Xxxx, Placebo, and xxxx Comparison in Patients with Major Depressive Disorder.

A Single Dose, Double-Blind, Safety and Efficacy Study of xxxx, xxxx and xxxx in Subjects with Acute Migraine Attacks.

Randomized, Multicenter, Multi-Dose, Double-Blind, Double-Dummy, Parallel-Group Study Comparing the Efficacy and Safety of Sustained-Release xxxx to Placebo in the Treatment of Pain Associated with Osteoarthritis.

Long-Term, Open-Label, Safety and Tolerability Study of xxxx in Subjects with Primary Hypercholesterolemia.

A Comparative Efficacy Study of xxxx (40 mg qd) and xxxx (30 mg qd) in Patients with Erosive Esophagitis.

An Open-Label, Multinational, Multicenter, Extension Trial to Assess the Long-Term Safety and Efficacy of xxxx in Subjects in the xxxx Clinical Trial Program.

Research Experience:
(cont'd)

A Multicenter, Randomized, Double-Blind, Active Control Trial to Compare the Safety and Efficacy of a New Formulation of xxxx Tablets (500/1.25mg) to xxxx as First Line Therapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with Diet and Exercise.

Xxxx Cardiovascular Treatment Assessment Versus xxxx.

A Double-Blind Randomized Study to Evaluate the Effects of Fixed Combination xxxx Therapy in Subjects with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Half-Maximum to Maximum of the Labeled Doses of xxxx Monotherapy.

Patient Treatment Preference for and Satisfaction with Migraine Headache Therapy: xxxx Tablets Versus Current xxxx Therapy.

A 13-Week, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel Group Trial of 2 Doses of xxxx (200 and 400 mg qd) in Patients with Rheumatoid Arthritis Using xxxx (200 mg bid) as a Comparator.

A Randomized, Open-Label, Comparative, Multicenter Trial to Evaluate Contraceptive Efficacy, Cycle Control, Safety and Acceptability of a Monophasis xxxx containing 200 µg xxxx and 20 µg xxxx, Compared to a xxxx Containing 100 µg xxxx and 20 µg xxxx.

A Six-Week, Double-Blind, Placebo-Controlled Multicenter Study to Evaluate the Safety and Efficacy of 3 Doses of xxxx (0.5, 3 and 10mg) and xxxx in Subjects with Major Depressive Disorder.

A Randomized, Double-Blind, xxxx and Placebo-Controlled Study of the Efficacy and Safety of xxxx in Outpatients with Generalized Anxiety Disorder.

Open-Label xxxx Continuation Therapy in Patients with Major Depression Disorder.

Pharmacogenomics Blood Sampling Protocol.

A Randomized, Double-Blind, Parallel-Group, Placebo Controlled Evaluation of xxxx and Over-Encapsulated xxxx, Alone and in Combination in the Acute Treatment of a Migraine Attack.

Research Experience:
(cont'd)

A Multicenter, Multinational, Open-Label, Extension Study of Oral xxxx for the Treatment of Opioid-Induced Constipation in Patients with Chronic, Non-Malignant or Malignant Pain.

Open-Label, Multicenter, Multi-Dose Study Evaluating the Long Term Efficacy and Safety of xxxx SR (Titrated Doses) in the Treatment of Pain Associated with Osteoarthritis.

A Double-Blind, Placebo- and xxxx-Controlled, Multicenter, Dose-Ranging Study Evaluating the Efficacy and Safety of xxxx in Outpatients with Major Depressive Disorder.

A Double-Blind, Placebo Controlled, 3-Arm Fixed Dose Study of xxxx CR Continuous Treatment (12.5mg and 25mg/day) for Premenstrual Dysphoric Disorder.

A Double-Blind, Placebo-Controlled, Randomized, Multicenter Study to Investigate the Safety and Efficacy of xxxx in Non-Constipated Patients with Established Irritable Bowel Syndrome.

A Randomized Comparator, Controlled, Double-Blind, Study of the Liver Safety of xxxx Versus xxxx with xxxx and Insulin as Part of Step Therapy in Subjects with Type 2 (Non-Insulin Dependent) Diabetes.

A Multicenter, Randomized, Double-Blind Clinical Trial Comparing the Safety and Efficacy of xxxx Tablets to xxxx Plus xxxx Therapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with xxxx Monotherapy.

A Phase IIB, Six-Week, Double-Blind, Placebo- and xxxx-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Oral xxxx in Outpatients with Major Depressive Disorder.

A Six-Week, Double-Blind, Placebo-Controlled Multicenter Study to Evaluate the Safety and Efficacy of 3 Doses of xxxx (0.5, 3 and 10 mg) and xxxx in Subjects with Major Depressive Disorder.

A 3-Month, Double-Blind, Placebo-Controlled, Fixed Dose, Extension Study of xxxx (12.5mg and 25mg/day) Continuous Treatment for PMDD Patients Completing Studies xxxx, xxxx or xxxx.

Research Experience:
(cont'd)

A Phase II, Randomized, Double-Blind, Vehicle-Controlled, Dose Frequency Response Study of Topical xxxx Gel Applied to Anogential Herpes Lesions Once, Twice or Three Times Per Week for One Recurrence to Prevent Future Recurrences.

A Randomized, Double-Blind, Parallel, Placebo-Controlled, Multicenter Trial to Study the Efficacy, Safety and Steady State Pharmacokinetics of xxxx (dose Levels: 80 mg, 120 mg, 160 mg and 640 mg) in Patients with Essential Hypertension.

Antihypertensive Efficacy of Adding xxxx to xxxx in Comparison to Up-titration of xxxx: A Multicenter Trial using xxxx vs xxxx to Evaluate the Effects on Lowering Blood Pressure.

A 24 Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of xxxx in Patients with Severe Alzheimer's Disease Followed by a 12 Week Open-Label Extension Period.

Placebo Controlled Evaluation of xxxx in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled Release Formulation.

A Randomized, 26 Week, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of xxxx in the Treatment of Dementia Secondary to Cerebrovascular Disease.

A Randomized, Double-Blind, Safety, and Efficacy Pilot Study of xxxx Versus xxxx as First-Line Antihypertensive Therapy in Patients with Type 2 Diabetes Mellitus and Hypertension.

A Placebo-Controlled Dose-Titration Efficacy and Tolerability Study of xxxx in Patients with Probable Alzheimer's Disease.

Multicenter, Randomized, Double-Blind, Active Controlled Trial to Compare the Efficacy and Safety of 104 Weeks of xxxx Plus xxxx vs
xxxx Plus xxxx in Drug Naïve Subjects with Type 2 Diabetes Mellitus who have Inadequate Glycemic Control with Diet and Exercise.

A 52 Week Prospective, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Comparison of the Efficacy, Tolerability and Safety of 3-12 mg/day of xxxx Capsules in Patients with Probable Vascular Dementia.

Research Experience:
(cont'd)

A 13 Week, International, Multicenter, Randomized Double-Blind, Double-Dummy, Placebo-Controlled, Parallel Group Trial Assessing the Safety and Efficacy of 2 Doses xxxx (200 mg and 400 mg od) in Patients with Knee Primary Osteoarthritis, Using xxxx (200 mg od) as a Comparator.

A 26-Week, International, Multicenter, Randomized, Double-Blind, Double-Dummy Parallel Group Active Controlled Endoscopic Study of Gastroduodenal Effects of xxxx (400 mg and 800 mg) in Patients with Rheumatoid Arthritis Using xxxx (800 mg tid) and xxxx (200 mg bid) as Comparators.

A Phase IIB, Seven Week, Double-Blind, Placebo- and xxxx Controlled Multicenter Study to Evaluate the Safety and Efficacy of Oral xxxx in Outpatients with Major Depressive Disorder and Associated Somatic Symptoms.

Preliminary Efficacy Study in Pre-Menopausal Women with Normal or Impaired Sexual Function Due to Acquired Arousal and/or Orgasm Disorder Comparing xxxx 1.0 mg to Placebo: Double-Blind with 8 Week Home Treatment Phase.

Phase III Study of xxxx Subcutaneous Injection in Women with Endometriosis in the US and Canada.

Phase III Contraception Study of xxxx Subcutaneous Injection in Women of Childbearing Potential in the Americas (Including a Bone Mineral Density (BMD) Substudy Comparing the Effects of xxxx and xxxx) Also Including a Return of Ovulation Substudy.

Effects of Oral xxxx on Lipoproteins in Subjects with Type II Diabetes Mellitus Who are Receiving Statin Therapy.

A Phase 2, Multicenter, Double-Blind, Placebo-Controlled, Dose-Finding Study of xxxx in the Treatment of High-Grade Squamous Intra-Epithelial Lesions of the Uterine Cervix.

Prospective, Randomized, Double-Blind Multicenter, Comparative Trial to Evaluate the Efficacy and Safety of xxxx Once-Daily (QD) Modified Release Tablets 1000 Mg Versus Conventional xxxx 500 mg Tablets BID in the 7-14 Day Treatment of Patients with Complicated Urinary Tract Infections (cUTI) or Acute Uncomplicated Pyelonephritis.

Research Experience:
(cont'd)

Open-Label Pilot Study Assessing the Efficacy and Safety of New Formulations of xxxx in the Treatment of Low Back Pain.

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Three Doses of xxxx (0.3 mg, 0.45 mg, and 0.625 mg Modified Release Tablets) Compared with Placebo in Hysterectomixed Postmenopausal Women for the Prevention of Osteoporosis.

Double-Blind, Placebo-Controlled, Parallel Group, Dose Ranging Comparison of the Efficacy and Safety of Extended Release xxxx and Placebo in the Treatment of Osteoarthritis of the Knee and/or Hip.

A Multicenter, Double-Blind, Placebo-Controlled, Randomized Study to Determine Efficacy in the Relief of Hot Flashes in Women Receiving Oral xxxx Tablets.

An Open-Label Extension Trial to Assess the Long-Term Safety of a Controlled Release Formulation of xxxx in the Treatment of Alzheimer's Dementia.

A Double-Blind, Multicenter, Randomized, Placebo-Controlled, Parallel Group Study of the Effects of xxxx on Safety and Efficacy in Patients with Mild to Moderate Hypertension.

A Multinational, Multicenter, Randomized, Double-Blind, Parallel Group, Active Controlled, Comparative Trial, to Assess the Endometrial Histological Profile Following Treatment with xxxx Versus xxxx plus xxxx in Postmenopausal Women.

A Seven-Week, Double-Blind, Extension of xxxx: A Phase IIB, Seven-Week, Double-Blind, Placebo and xxxx-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Oral xxxx in Outpatients with Major Depressive Disorder and Associated Somatic Symptoms.

A Double-Blind Placebo-Controlled, Parallel Group Design Study of Two Doses of xxxx vs. Placebo for the Treatment of Sexual Dysfunction (Hypoactive Desire) in Postmenopausal Women.

A Double-Blind, Placebo-Controlled, Parallel Group Design Study of Two Doses of xxxx vs. Placebo for the Treatment of Sexual Dysfunction (Arousal Disorder) in Postmenopausal Women.

Research Experience:
(cont'd)

A Double-Blind, Randomized, Parallel Group Study of xxxx 10 mg OD Versus Placebo in the Management of Acute Urinary Retention in Patients with a First Episode Due to BPH.

A Randomized, Double-Blind, Dose Ranging, Dose Comparison-Controlled Trial to Determine the Safety and Efficacy of xxxx in Patients with Type 2 Diabetes.

A Phase II Study on Analgesic Efficacy, Safety and Tolerability of xxxx: a Six Week, Randomized, Double-Blind, Placebo-Controlled, Dose-Finding, Multicenter Study Comparing xxxx with xxxx and with xxxx in Subjects with Osteoarthritis of the Knee.

ASS
Abbey Strauss, M.D.

2/27/02
Date

AC#0770874

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/05/2001	**ME 45950**	**64510**

THE **MEDICAL DOCTOR**
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.
EXPIRATION DATE: **JANUARY 31, 2004**

ABBEY STRAUSS
1050 NW 15TH ST #207-A
BOCA RATON, FL 33486-1341

JEB BUSH
GOVERNOR

DISPLAY IF REQUIRED BY LAW

JOHN O. AGWUNOBI, M.D., M.B.A.
SECRETARY

5077US/0049 :0015

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AS3143293	02-29-2003	$210.00

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3,3N,4,5	PRACTITIONER	01-25-2000

STRAUSS, ABBEY MD
1050 NW 15TH STREET
#207A
BOCA RATON, FL 33486

Form DEA-223 (10/96)

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

5077US/0049.0016

CURRICULUM VITAE

William Thiel Granger III, M.D.

Licensure

Nevada Medical License	7492
Texas Medical License	K4443
Arkansas Medical License	C-5059
DEA Number	AG7171616

Associated Sites

American Medical Research Associates
1301 N. McCarron Blvd., Suite 103
Sparks, NV 89431

West Hills Hospital
1240 East Ninth Street
Reno, NV 89512

Research Strategies Inc
3858 Carson Street, Suite 206
Torrance, CA 90503

Research Experience

- Open Label Trials on Anafranil for Obsessive Compulsive Disorder in Adults and Adolescents.
- Open Label Trials on Buspar for Anxiety Disorders in Adults.
- A Multicenter, Double-blind, Randomized Comparison of the Efficacy and Safety of XXX and XXX in the Treatment of Patients with Schizophrenia
- A Controlled Trial of XXX Versus XXX in the Treatment of Schizophrenic and Schizoaffective Subjects with Comorbid Depression.
- A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features Who are not Receiving Antidepressants or Antipsychotics
- A Phase III, Open-Label Study of the Safety and Efficacy of XXX in Patients with Major Depressive Disorder with Psychotic Features Who Have Previously Demonstrated a Rapid Response to either XXX or Placebo.
- A Randomized, Double-Blind, Multiple Dose Study of the Relative Bioavailability and Tolerability of a Slow-Release Formulation and a Medium-Release Formulation of XXX in Patients with Schizophrenia or Schizoaffective Disorder.

MD
20 JAN 03

Education

Internship and Residency in Psychiatry Arkansas State Hospital and University of Arkansas Medical Sciences Campus Little Rock, AR	1979
Doctor of Medicine University of Arkansas Medical Sciences Campus Little Rock, AR	1976
Major-Microbiology; Minor-Chemistry Bachelor of Science University of Arizona Tucson, AZ	1965
Associate of Arts American River College Sacramento, CA	1962

Professional Experience

Private Practice American Medical Research Assoc Sparks, NV	2002-Present
Adult Services Medical Director BHC West Hills Hospital Reno, NV	2000-Present
Associate Medical Director Magellan Behavioral Health Dallas, TX	1999-2000
Consulting Staff South Baldwin County Hospital Foley, AL	1999
Consulting Staff Thomas Hospital Fairhope, AL	1999
Psychiatric Director Bill Nichols State Veteran Home Alexander City, LA	1998-1999

Interim Medical Director Psychiatric Director Wm. F. Green State Veteran Home Bay Minette, AL	Jan-Mar 1998 1998-1999
Associate Staff St. Frances Cabrini Hospital Alexandria, LA	1997
Associate Staff Rapides Regional Medical Center Alexandria, LA	1996-1997
Medical Director Crossroads Regional Hospital Alexandria, LA	1996-1997
Medical Director MCC Behavioral Care Eden Prairie, MN	1995-1996
Medical Review Officer Medical Towers Laboratory Little Rock, AR	1989-1995
Medical Review Officer Air Transport International Little Rock, AR	1989-1995
Reviewer and Senior Reviewer AR PRO (Peer Review Organization); AFMC (Alt Foundation for Medical Care)	1989-1995
Psychiatric Assessor, DAPA Drug & Alcohol Treatment Program Southwest Hospital Little Rock, AR	1988-1989
US Veterans Administration, Compensation & Pension Evaluations North Little Rock, AR Alexandria, LA	 1987-1995 1996-1997
Arkansas Division of Youth Services Alexander & Bluff Units	1986-1987
Credentials Committee Psychiatric Care Committee	1985-1986 1983-1995

Executive Committee	1983-1984 1993-1995
Psychiatry Section Chief	1983-1984 1993-1995
Baptist Medical Center Little Rock, AR	1979-1995
Medical Director, Adolescent Stress Center Baptist Rehabilitation Institute Little Rock, AR	1986-1991 1979-1995
St. Vincent Infirmary Medical Center Little Rock, AR	1979-1995
Doctors Hospital Little Rock, AR	1979-1995
Memorial Hospital North Little Rock, AR	1979-1991
President of Medical Staff Cedarstone Psychiatric Institute North Little Rock, AR	1991-1992 1979-1982
Psychiatric Consultant North Little Rock Public Schools North Little Rock, AR	1979-1995
Private Practice	1979-1995

Professional Affiliations

Diplomate, American Academy of Pain Management	1997-Present
American Society of Military Surgeons	1992-Present
American Association of Medical Review Officers	1992-Present
Southern Medical Association	1991-1993
Pulaski Co (AR) Medical Society	1990-1995
AR Medical Society	1990-1995
American Society of Adolescent Psychiatry	1989-1992
American Medical Association	1985-1987
American Psychiatric Association	1983-Present
AR State Psychiatric Society	1980-1995
American Board of Psychiatry and Neurology	1983-Present

Accreditation and Licensure

Aviation Medical Examiner Federal Aviation Administration	1992-1995

Member and Certified American Association of Medical Review Officers	1992-Present
Member and Certified American Board of Psychiatry and Neurology	1993-Present

Military History

Current Rank-Lieutenant Colonel	1994
USAF Active Reserve	1999-Present
US Army Active Reserve	1992-1999
Retired Reserve USAF	1921-1992
Inactive Reserve USAF	1971-1987
Separation from Active Duty	1971
Promoted to CAPT	1969
Promoted to 1st Lieutenant	1967
Completed Clinical Laboratory Officer training	1966
Commissioned 2nd Lieutenant	1965
Enlisted United States Air Force	1962

20 JAN 03

1

July 12, 2002

CURRICULUM VITAE

LASZLO GYULAI, M.D.

Associate Professor
Departments of Psychiatry and Radiology
University of Pennsylvania

Home Address: REDACTED

Office Address: Division of Mood and Anxiety Disorders

3535 Market Street, Suite 670
Philadelphia, PA 19104-3309
(215) 746-6415

Social Security Number: REDACTED

Education:

1967-73	M.D. Summa Cum Laude Semmelweis Medical University, Budapest, Hungary
1978-80	Philosophy - Post Graduate Training Eotvos L. University, Budapest, Hungary

Postgraduate Training:

2/85-6/85	Intern in Psychiatry University of Pennsylvania Medical Center - Philadelphia
6/85 - 2/86	Intern in Medicine Mercy Catholic Medical Center - Philadelphia
2/86 - 2/89	Resident in Psychiatry University of Pennsylvania Medical Center - Philadelphia

Faculty Appointments:

1973-80	Assistant Professor of Physiology Experimental Research Department, II Institute of Physiology, Semmelweis Medical University,

	Budapest, Hungary
1980-82	Research Associate in Neurology, Cerebrovascular Research Center, University of Pennsylvania Medical Center
1982-85	Research Associate, Johnson Research Foundation Department of Biochemistry and Biophysics, University of Pennsylvania
1985-89	Assistant Instructor, Department of Psychiatry, University of Pennsylvania Medical Center
1989	Instructor, Department of Psychiatry, University of Pennsylvania Medical Center
1989-1999	Assistant Professor of Psychiatry at the University of Pennsylvania Medical Center, Department of Psychiatry, University of Pennsylvania School of Medicine
1999-present	Associate Professor of Psychiatry at the University of Pennsylvania Medical Center, Department of Psychiatry, University of Pennsylvania School of Medicine
1991-present	Associate Professor of Psychiatry in Radiology, Department of Radiology, University of Pennsylvania Medical Center

Hospital and Administrative Appointments:

1976-80	Director, Research Training Program for Medical Students Semmelweis Medical University, Budapest, Hungary
1987-89	House Physician, Northwestern Institute, Fort Washington, Pennsylvania
1988-89	Psychiatric Consultant, Child Guidance Clinic, University of Pennsylvania, Philadelphia
1989-present	Attending Psychiatrist, Hospital of the University of Pennsylvania
1990-91	Co-Director, Bipolar Disorders Unit, Mood and Anxiety Disorders Section, Department of Psychiatry, University of Pennsylvania Medical Center.
1991-present	Director, Bipolar Disorders Program, Mood and Anxiety Disorders Section, Department of Psychiatry, University of Pennsylvania Medical Center.
1998 to 2000	Attending Psychiatrist, Presbyterian Medical Center, University of Pennsylvania Medical Center

Specialty Certification:

1991	American Board of Psychiatry and Neurology

Licensure: Commonwealth of Pennsylvania

Medical Registration: ECFMG, FLEX

Awards, Honors and Membership in Honorary Societies:

1989	National Psychiatric Endowment Fund, Annual Laughlin Award for Merit (N.P.E.F. Fellow)
1990	Young Investigator Award National Alliance for Research in Schizophrenia and Depression
1992	University Research Foundation Award
1994,1995,1996, 2002	Selected as one of the "Best Doctors in Philadelphia" by Philadelphia Magazine
1995	Theodore and Vada Stanley Foundation Research Award
1996-present	Board Examiner for American Board of Psychiatry and Neurology
1997	Patricia Kind Foundation Research Award
1997	University Research Foundation Award
1998,2000	Best Doctors in the US, Woodward/ White Publication
1999	Achievement Award, Jonathan Philip Ford Foundation
2000	Professional of the Year, New Directions/NDMDA Delaware
2001	Selected for inclusion in the Who's Who, Starthmore
2002	Research Award, Jonathan Philip Ford Foundation
2002	

Memberships in Professional and Scientific Societies:

National Societies:

American Psychiatric Association
Society of Nuclear Medicine

Local Societies:

American Suicide Foundation, Member, Scientific Advisory Council for the Greater Philadelphia Chapter

National Scientific Committees:

Member, Reviewer, Institutional Development Grant Program, North Carolina Biotechnology Center, 1997 .
Advisor, Administrator for Special Programs, Office of Vocational Rehabilitation, Commonwealth of Pennsylvania, 1997
Member, Data Monitoring Board for " Reducing the Efficacy-Effectiveness Gap in Bipolar Disorder" (P.I.:Dr. Mark S. Bauer) Department of Veterans Affairs, Washington D.C.,1998-current
Member of Advisory Board, Abbott Laboratories, Glaxo-Wellcome, Bristol-Meyers-Squibb
Grant Reviewer, Department of Veterans Affairs, Washington D.C

Academic Committees at the University of Pennsylvania:

1989-1994	Member, Residency Recruitment Subcommittee, Department of Psychiatry
1991-1994	Member, Research Committee, Department of Psychiatry
1992-1999	Member, Committee on Undergraduate Education
1998-2000	Member, Faculty Senate
1998-2000	Member, Faculty Senate Executive Committee
1998-2000	Observing member, Medical Faculty Senate Steering Committee
1999	Member, Committee on Committees, Faculty Senate Executive Committee
1999-2000	Co-Chair, Ad-Hoc Committee on Parity in Health Insurance for Mental Health, Medical Faculty Senate Steering Committee
1999-current	Program Directors Committee, Department of Psychiatry

Major Teaching and Clinical Responsibilities :

Clinical

1990 to present	In charge of the Clinical Program at the Bipolar Disorders Program
1990 to present	Attending Psychiatrist, Hospital of the University of Pennsylvania
1990 to present	Consultation Service of the Bipolar Disorders Program for psychiatrists and other physicians in the Mid-Atlantic Region, US, and abroad
1998 to 2000	Attending Psychiatrist of the Affective Disorders Team at the Inpatient Service, Department of Psychiatry, UPMC

Teaching:

Residency

1989,1990-91	Course Director, Inpatient Psychotherapy: Course of six lectures for residents, Department of Psychiatry, Hospital of the University of Pennsylvania
1990-97	Course Director, Resident's Bipolar Clinic - a one-year Specialty training program for Residents in Bipolar Disorder
1989-present	Clinical Supervision of residents for outpatient, inpatient care and consultation service
1994-97	Clinical supervision of fellows and psychologists at the Cognitive Therapy Center
1990- present	Lectures on Bipolar Disorders for PGYII., III and IV

	Residents
2000-current	Course Director, Professors' Rounds (Inpatient Program)
2000-current	Module Director, Neuroscience and Psychopharmacology Course, Mood Disorders Module

Medical Students

1974-1980	Lecturer and Instructor on medical physiology for medical students annually, II. Department of Physiology, Semmelweis Medical University, Budapest
1976 - 1980	Course Director, Experimental Methods, Research Scientist Training Program for Medical Students, Semmelweis Medical University, Budapest
1988 -present	Supervision of medical students on Inpatient Unit of the Department of Psychiatry, Hospital of the University of Pennsylvania
1991- 1995	Integrative Neuroscience Course, Leader, Small Group, School of Medicine, University of Pennsylvania
1991,1992,1994,1997,1998,1999,2000,2001	Lectures on Bipolar Disorder and Treatment of Mania Pharmacology 100, University of Pennsylvania
1996-97	Penn Medical Scholars Program, Preceptor
1996-current	Advisor, Medical Student Research Track
1998, 1999	Course Director, the Affective Disorders Panel for the Integrative Neuroscience Course
1996,1997,1998,1999,2000,2001	Lectures on Phenomenology, Diagnosis and Course of Affective Disorders, Integrative Neuroscience Course

Principal Investigator on Grants and contracts:

National Institute of Mental Health:

Systematic Treatment Enhancement Program for Bipolar Disorder, NIMH-98-DS-001, PI at the U. Pennsylvania Site. (PI for the whole project: Gary Sachs M.D., Massachusetts General Hospital, Harvard University)

Thyroid Axis and Episodic Behavior. NIMH 1P01MH44210-01; 7/1/89-6/30/94 (Co-Investigator; PI: Peter C. Whybrow, MD)

A Collaborative Genomic Study of Bipolar Disorder. NIMH 1RO1MH5955301;10/01/98-9/30/99 (Co-Investigator; PI: Wade

Berrettini, MD,PhD)

Foundations:

Treatment of rapid cycling bipolar disorder with thyroid hormones. Stanley Foundation; 7/1/95-6/30/97

Measurement of regional brain lithium concentration in humans in vivo by localized lithium-7 magnetic resonance Spectroscopy. Whitaker Foundation;11/1/89-10/30/92

Brain lithium metabolism in rapid cycling bipolar disorder - An in Vivo 7-lithium magnetic resonance study. NARSAD; 7/1/90-6/30/1992;

Lithium NMR Spectroscopy in Rapid Cycling Bipolar Disorders. Research Foundation, University of Pennsylvania; 5/27/92-5/26/93

Quantitative analysis of daily mood fluctuations in bipolar disorder – methods to improve diagnosis and treatment. University of Pennsylvania Research Foundation. 6/15/97-6/15/98

Pharmaceutical Companies:

Safety and Efficacy of Depakote in the Prevention of Mania in Patients with Bipolar Disorder. Abbott Laboratories; 7/1/93-9/30/96

A Double-Blind, Placebo-Controlled, Comparison of Imipramine and Paroxetine in the Treatment of Bipolar Depression. SmithKline Beecham Pharmaceuticals; 11/1/93-6/30/97

Comparative Cost-Effectiveness Study of Depakote and Usual Care Versus Lithium and Usual Care in the Treatment of Bipolar Disorder. Abbott Laboratories; 5/1/96-6/30/98

Gabapentin adjunctive treatment in patients with bipolar disorder; Parke Davis; 6/15/96-3/31/98

Chronobook data analysis and management study.Parke-Davis; 4/15/97-6/30/98

Lamictal (lamotrigine) in Bipolar Disorder (fixed dose) (605): A multicentre, double-blind, placebo-controlled, randomised, fixed –dose evaluation of the safety and efficacy of lamotrigine in the long-term prevention of relapse and recurrence of depression and/or mania in patients with Bipolar I disorder. Glaxo-Wellcome; 11/1/97-2001

Lamictal (lamotrigine in Rapid Cycling Bipolar Disorder (614): A multicenter, double-blind, placebo-controlled flexible-dose, parallel-group evaluation of the safety and efficacy of lamotrigine in the long-term prevention of mood episodes in patients with bipolar disorder with rapid cycling. Glaxo-Wellcome; 11/1/97-5/28/99

Depakote ER in the Treatment of the manic phase of bipolar disorder: Evaluation of the efficacy and safety of depakote CR in the treatment of the manic phase of bipolar disorder: A placebo-controlled study.Abbott Laboratories; 11/1/98-6/30/99

A multicenter, double-blind, placebo controlled, flexible-dose evaluation of the safety and efficacy of lamictal (lamotrigine) in the long-term treatment of patients who have bipolar disorder with rapid cycling. Glaxo-Wellcome; 2/1/99-6/30/99

A multicenter, randomized, double-blind, placebo-controlled study of two fixed doses of aripiprazole in the treatment of patients with acute mania, Bristol-Myers Squibb Company, 3/1/00-3/1/2001

A multicenter, randomized, double-blind, placebo-controlled study of aripiprazole in the maintenance treatment of patients with bipolar disorder, Bristol-Myers Squibb Company, 3/1/00-3/1/2001

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of the Safety and Efficacy of Seroquel (Quetiapine Fumarate) as Add-On Therapy with Lithium or Divalproex in the Treatment of Acute Mania, Astra-Zeneca, 8/1/00-8/1/2001

A Multicenter, Double-Blind, Placebo-Controlled, Fixed-Dose Evaluation of the Safety, Efficacy and Tolerability of LAMICTAL (Lamotrigine) in the Treatment of a Major Depressive Episode in Patients with Type I Bipolar Disorder, GlaxoSmithKline, 1/30/00-2002

Bipolar Disorder Effectiveness Study (BIDES), Eli Lilly, 2002-

A Multicenter, Randomized, Double-Blind Study of Aripiprazole versus Placebo in the Treatment of Acutely Manic Patients with Bipolar Disorder Bristol-Myers Squibb Company, 2002-

Bibliography:

Research Publications, peer reviewed:

1. Dora, E., Gyulai, l., Kovach, A. G. B., Eke, E.: Die Schutzwirkung einer Durchblutungsfoerdernde Wirkstoffkombination, CRP aur Storgen des Stoffwechsels der Durchblutung und der spontanen kortikalen elektrischen Aktivat des Kortex. Arzneim, Forsh. Drug Res. 27:108-11, 1987.

2. Gyulai, L., Dora, E., Kovach, A.G.B.: NAD/NADH: Redox State Changes on Cat Brain Cortex During Stimulation and Hypercapnia. American *Journal of Physiology* 243:H619-H627, 1982.

3. Haselgrove, J.C., Subramanian, H.V., Leigh, J.S. Jr., Gyulai, L., Chance, B.: In Vivo One Dimensional Imaging of Phosphorus Metabolites by Phosphorus Nuclear Magnetic Resonance. *Science* 220:1170-1173, 1983.

4. Dora, E., Gyulai, L., Kovach, A.G.B.: Determinants of Brain Activation-Induced Cortical NAD/NADH in Vivo. *Brain Research* 299:61-72, 1984.

5. Hilberman, M., Subramanian, H.V., Haselgrove, J.C., Cone, J., Egan, J., Gyulai, L., Chance, B.: In Vivo Time Resolved Brain Phosphorus Nuclear Magnetic Resonance. *Journal of Cerebral Blood Flow and Metabolism* 4:334-342, 1984.

6. Schnall, M., Subramanian, H.V., Leigh, J.S. Jr., Gyulai, L., McLaughlin, A., Chance, B.: A Technique for Simultaneous1H- and 31P-NMR at 2.2 T In Vivo. *Journal of Magnetic Resonance* 63:401-405, 1985.

7. Gyulai, L., Roth, Z., Leigh, J.S. Jr., Chance, B.: Bioenergetic Studies of Mitochondrial Oxidative Phosphorylation Using 31P-Phosphorus NMR. *Journal of Biological Chemistry* R60:3947-3954, 1985.

8. Gyulai, L., Bollinger, L., Leigh, J.S. Jr., Barlow, C., Chance, B.: Phosphorylethanolamine - The Major Constituent of the Phosphomonoester Peak Observed by 31P-NMR on Developing Dog Brain. *FEBS Letters* 178:137-142, 1985.

9. Gyulai, L., Schnall, M., McLaughlin, A., Leigh, J.S. Jr., Chance, B.: Simultaneous 31P and 1H NMR Studies of Hypoxia and Ischemia in the Cat Brain. *Journal Cerebral Blood Flow and Metabolism* 7:543-551, 1987.

10. Gyulai, L., Chance, B., Ligeti, L., McDonald, G., Cone, J.: Correlated in vivo

31P NMR and NADH-Fluorometric Studies on Gerbil Brain in Graded Hypoxia and Hyperoxia. *American Journal Physiology* 254:C699-C708, 1988.

11. Gyulai, L., Wicklund, S.W., Greenstein, R., Bauer, M., Ciccione, P., Whybrow, P.C., Zimmerman, J., Kovachich, J.: Measurement of Tissue Lithium Concentration by Lithium Magnetic Resonance Spectroscopy in Patients with Bipolar Disorder. *Biological Psychiatry* 29:1161-1170, 1991.

12. Whybrow, P.C., Bauer, M.S., Gyulai, L.: Thyroid Axis Considerations in Patients with Rapid Cycling Affective Disorder. *Clinical Neuropharmacology* 15(1):391A-392A, 1992.

13. DiPietro, L., Gyulai, L., Stunkard, S., Whybrow, P.C.: Mood and Body Weight in a Woman with Rapid Cycling Bipolar Disorder. *Psychosomatic Medicine* 55(1):7-10, 1993.

14. Lish, D., Gyulai, L., Resnick, S., Kirtland, A., Amsterdam, J., Whybrow, P.C., Price, R.: A Family History Study of Rapid-Cycling Bipolar Disorder. *Psychiatry Research* 48(1):37-40, 1993.

15. Bauer, M.S., Calabrese, J., Dunner, D., Post, R., Whybrow, P.C., Gyulai, L., Tay, L., Younkin, S., Bynum, D., Lavori, P., Price, R.A.: Multi-Site Data Reanalysis: Validity of Rapid Cycling as a Course Modifier for Bipolar Disorder in DSM-IV. *American Journal of Psychiatry* 151(4):506-15, 1994.

16. Bauer, M.S., Whybrow, P.C., Gyulai, L., Gonnel, J., Yeh, H.S. Testing Definitions of Dysphoric Mania and Hypomania: Prevalence, Clinical Characteristics and Inter-Episode Stability. *Journal of Affective Disorders*. 32:201-211, 1994.

17. Gyulai, L., Alavi, A., Broich, D., Reilley, J., Ball, W., Whybrow, P.C. I-123 Iofetamine (IMP) Single Photon Computed Emission Tomography in Rapid Cycling Bipolar Disorder - A Clinical Study. *Biological Psychiatry* 41:152-161, 1997.

18. Gyulai, L., Jaggi, J., Bauer, M.S., Younkin, S., Rubin, L., Attie, M., and Whybrow, P.C. Bone Mineral Density and L-Thyroxine Treatment in Rapidly Cycling Disorder. *Biological Psychiatry* 41:503-506, 1997.

19. Revicki, D. A., Tohen, M., Gyulai, L., Thompson, C., Pike, S., Davis-Vogel, A., Zarate, C. Telephone versus In-Person Clinical and Health Status Assessment Interviews in Bipolar Disorder Patients. *Harvard Review of Psychiatry* 5:75-81, 1997.

20. Bowden, CL., Swann, AC., Calabrese, JR., McElroy, SL., Morris, D., Petty, F.,

Hirschfeld, RM. and Gyulai, L. Maintenance Clinical Trials in Bipolar Disorder: Design Implications of the Divalproex-Lithium Study. *Psychopharmacology Bulletin* 33(4):693-699, 1997.

21. Hahn, C., Pawlyk A.C., Whybrow, P.C., Gyulai, L.,Tejani-Butt, S.M. Lithium Administration Affects Gene Expression of Thyroid Hormone Receptors in Rat Brain. *Life Sciences*, 64(20):1793-1802,1999

22. Rapaport, M.H., Gyulai,L. Whybrow, P.C. Immune Parameters in Rapid Cycling Bipolar patients Before and After Lithium Treatment *J. Psychiatry Research,* 33:335-340,1999

23. Bowden, C. H., Calabrese, J., McElroy, S., Gyulai, L., Wassef, A., Petty, F., Pope, HG., Chou C-Y., Keck, P., Rhodes, L., Swann, A., Hirschfeld, RM., Wozniak, P. Randomized, Placebo-Controlled Trial of Divalproex Versus Lithium in Maintenance Therapy of Bipolar Disorder *Arch. Gen. Psychiatry*,57:481-489,2000

24. Gyulai, L., Bauer, M., Garcia-Espana, F., Hierholzer, J., Baumgartner, A., Whybrow, P.C. Supressive doses of thyroxine and bone mineral density in pre- and postmenopasual women with affective disorder, *J. of Affective Disorders,* 66:185-191,2001

25. Nemeroff, C., Evans, D., Gyulai, L., Sachs, G., Bowden, C., Young, M., Pitts, C., Oaks, R., Gergel, I. A Double-Blind, Placebo-Controlled comparison of imipramine and paroxetine in the treatment of bipolar depression, *American Journal of Psychiatry,* 158, 906-912, 2001

26. Gyulai, L., Bauer M., Bauer,M.S., Espana-Garcia, F, Whybrow, P.C.Lithium challenge to the thyroid axis in rapid cycling bipolar affective disorder and healthy controlsSubmitted , *Accepted with revisions, Biological Psychiatry*

27. Hahn, C-H, Gyulai, L, Baldassano, C.F, Lenox, R.H., The Current Understanding of Lamotrigine as a Mood Stabilizer, *Submitted, J. Clin. Psychiatry*

28. Young, R. C. , Gyulai, L and. Reynolds, III,C.F,. Treatment of Bipolar Disorders in Late Life—Focus on Pharmacotherapy, *To be submitted to Journal of American Association of Geriatric Psychiatry*

Editorials, Reviews and Book Chapters:

1. Kovach, A.G.B., Hamar, J., Nyary, I., Sandor, P., Reivich, M., Dora, E., Gyulai, L., Eke, A.: Cerebral Blood Flow and Metabolism in Hemorrhagic Shock in the Baboon. In: *Blood Flow Metabolism in the Brain.* Eds. Harper, M., Jennet, B., Miller, D., Rowan, J. Edinburgh, London, New York, Churchill, Livingstone 2:17-19, 1975.

2. Kovach, A.G.B., Eke, E., Dora, E. Gyulai, L.: Correlation Between the Redox State, Electrical Activity and Blood Flow in Cat Brain Cortex during Hemorrhagic Shock In: *Oxygen Transport to Tissues*, Ed: Jurgen Grote D. Reneau and G.Thews, G. New York, London, Plenum Press, 299-305, 1976.

3. Kovach, A.G.B., Dora, E., Eke, E., Gyulai, L.: Effects of Microcirculation on Microfluorometric Measurements. In *Oxygen and Physiologic Function.* Ed.: Frans F. Jobsis, Dallas Tx. Professional Information Library, 111-132, 1977

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6. Mark S. Bauer, Joseph Calabrese, David L. Dunner, Robert Post, Peter C. Whybrow, Laszlo Gyulai, Sharon Younkin, Diane Bynum, Phil Lavori. Multisite Data Reanalysis: Rapid Cycling as a Modifier for Bipolar Disorder *in DSM-IV, DSM-IV Sourcebook*, ed. T.A. Widiger et al., pp 299-314, American Psychiatric Press, Inc., Washington, D.C.,

7. Cory Newman, Noreen Reilly-Harrington, Laszlo Gyulai, Aaron T. Beck Cognitive Therapy of Bipolar Disorder, APA Press, 2001

8. Wade H. Berrettini and Laszlo Gyulai. The Search for Susceptibilty Genes in Bipolar Disorder. In *Genetic Influences on Neuronal and Behavioral Functions,* Ed: Donald. Pfaff, CRC Press, 1999.

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1. Kovach, A.G.B., Dora, E., Gyulai, L., Eke, E.: Cerebrovascular and Metabolic Reactions at the CBF Autoregulatory Level Evoked by Electrical Stimulation of the Cat Brain Cortex. Recent Advances in Basic Microcirculatory Research. Eds. Lewis, D.H., Basel, K. 388-393, 1977.

2. Kovach, A.G.B., Dora, E., Gyulai, Eke, E.: Non-invasive Microreflectometric Local Blood Flow Measurement in Cat Brain Cortex. Recent Advances in Basic Microcirculatory Research, Eds. Lewis, D.H., Basel, K. 376-387, 1977.

3. Gyulai, L., Dora, E., Eke, E., Kovach, A.G.B.: Microvascular Reactions and NAD/NADH Changes in Cat Brain Cortex During Cortical Stimulation Under Normo- and Hypercapnic Conditions. Recent Advances in Basic Microcirculatory Research, Eds: Lewis, D.H., Basel, K. 371-374, 1977.

4. Gyulai, L., Dora., E., Kovach, A.G.B.: Opposite Changes in the Redox State of the Brain Cortex Depending on the Length and Strength of Direct Cortical Stimulation. Adv. In Physiol. Sciences, Vol. 25. Oxygen transport to tissue, Eds. Kovach, A.G.B., Dora, E., Kessler, M., Silver, I.A., Pergamon Press, Akademia Kiado. 1981.

5. Contributor as Expert to: Sachs GS. Printz DJ. Kahn DA. Carpenter D. Docherty JP. The Expert Consensus Guideline Series: Medication Treatment of Bipolar Disorder 2000. Postgraduate Medicine. Spec No:1-104, 2000.

Abstracts of Presentations:

1. Kovach, A.G.B., Dora, E., Hamar, J., Gyulai, L., Eke, A.: The role of catecholamines in anoxic changes of cerebral blood flow metabolism and ultrastructure, pathophysiological biochemical and morphological aspects of cerebra ischemia and arterial hypertension. Abstracts, International Symp. Warsaw, Polish Acad. of Sci. 62m, 1975.

2. Eke, A., Gyulai, L., Dora, E., Hutiray, G., Kovach, A.G.B.: New method for studying cerebral circulation with induced reflectance changes. Acta Biochem. Biophys., Acad. Sci. Hung., 1:183, 1976.

3. Gyulai, L., Dora, E., Eke, A., Kovach, A.G.B.: Effect of direct cortical stimulation on the redox state and blood content of the cerebral cortex during hypotension and hypoxemia. Acta. Biochem. Sci. Hung., 11:182-183, 1976.

4. Eke, A., Hutiray, G., Gyulai, L., Dora, E., Kovach, A.G.B.: NaCl transport across capillary walls monitored by microrelectometry as a new method for measuring local blood flow. Fed. Proc., 35:829, Abstract #3443, 1976.

5. Kovach, A.G.B., Dora, E., Gyulai, L., Eke, A.: Oxido-reduction state, hemoglobin content and blood flow in cat brain cortex during hemorrhagic shock. Fed. Proc., 35:526, Abstract #1762, 1976.

6. Gyulai, L., Dora, E., Eke, A., Kovach, A.G.B.: Microvessel reactions and NAD/NADH changes in cat brain cortex during cortical stimulation under physiologic and hypercapnic conditions, Fed. Proc., 35:52, Abstract #1749, 1976.

7. Kovach, A.G.B., Dora, E., Eke, A., Gyulai, L.: A new method for simultaneous local non-invasive measurement of cerebrocortical blood flow and redox state by microfluororelectrometry and its application in neuropharmacology. Naunlyn-Schmiedelberg Arch. Exp. Pharmak, 293, Suppl. R. 69, 1976.

8. Gyulai, L., Dora, E., Eke, A., Kovach, A.G.B.: Effect of direct cortical stimulation on the redox state and blood content of the cerebral cortex during hypoxia. Acta. Physiol. Acad. Sci. Hung., 49:289, 1977.

9. Gyulai, L., Eke, A., Kovach, A.G.B.: Quantitative aspects of the microvascular and NAD/NADH changes of the cat brain cortex induced by direct cortical stimulation under normal and hypercapnic conditions. Proceedings of the International Union of Physiological Sciences, Vol. 27. Abstracts, Paris 296, 867, 1977.

10. Dora, E., Eke, A., Gyulai, L., Kovach, A.G.B.: Oxidoreduction state and hemoglobin content in the cat cerebral cortex during hemorrhagic shock. Acta. Physiol. Acad. Sci. Hung., 49:272, 1977.

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13. Eke, A., Gyulai, L., Dora, E., Hutiray, G., Kovach, A.G.B.: Correlation of local blood flow and metabolic changes in cat cerebral cortex: A microreflectometric study. Acta. Physiol. Acad. Sci. Hung., 51:119, 1978.

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33. Rapaport M, Gyulai L et al. Immune function in normal volunteers after treatment with lithium, APA Annual Meeting, 1997.

34. Whybrow, P.C., Gyulai, L., Gotschalk, A. Physiological rigidity and behavioral pathology in bipolar illness, American Psychiatric Association Annual Meeting, 1997, San Diego

35. Gyulai, L., Bauer M., Bauer,M.S., Espana-Garcia, F, Whybrow, P.C.Lithium challenge to the thyroid axis in rapid cycling bipolar affective disorder and healthy controls, Lithium-Lexington'99, Meeting of the International Society for Lithium Research

36. Gyulai, L., Bauer, M., Garcia-Espana, F., Hierholzer, J., Baumgartner, A., Whybrow, P.C. Supressive doses of thyroxine and bone mineral density in pre-and post menopasual women with affective disorder, Third International Conference on Bipolar Disorder, Pittsburgh, Pa, 1999

37. Rapaport, M.H., Gyulai, L., Manji, H., Whybrow, P.C. Immune function in rapid cycling bipolar disorder: Effects of lithium, Psychiatric Research Society, 1999 Meeting

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39. Gyulai, L., Bauer M., Bauer,M.S., Espana-Garcia, F, Whybrow, P.C. Thyroid Axis on Rapid Cycling Bipolars and Controls. World Conference of Psychiatry, Hamburg, Germany, 1999

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42. Whybrow, P.C. Gyulai, L., Bauer, M.S., Cnaan, A.L., Bauer, M. Effects of Short-Term Lithium Treatmentto the HPT Axis in Rapid Cycling Bipolar Disorder, ACNP 38th Annual Meeting, 1999.

43. Bauer, M, Berghoefer, A, Baumgartner, A, Gyulai, L, Whybrow, P.C. T4 Enhancement in Bipolar and Unipolar Illness. Neuroopsychopharmacology 23: S68, 2000

44. Kusumakar, P, Greene, P, Asscher, J, Monaghan, E, Smoot, T, Fouche, N, Bowden, C, Clabrese, J, Post, R, Sachs, G, Suppes, T, Gyulai,L, Young, T, Rapaport, M. Mood Stabilization with Lamotrigine in Rapid Cycling Bipolar Disorder: A Double-Blind Placebo-Controlled Study, ECNP Annual Meeting, 2000 Munich, Germany

45. Suppes, P, Ascher, J, Bowden, C, Calabrese, J,Earl, N, Greene, P, Lamotrigine in Rapid-Cycling Bipolar Disorder: Predictors of Response, APA, Annual Meeting 2001

46. Gyulai, L, Suppes , T, Apter, J, Zajecka, J, Ascher, J, Greene, P, Lamotrigine in Rapid Cycling Bipolar Disorder: Predictors of Response, NCDEU Annual Meeting, 2001, Puerto Rico

47. Bauer, M ,. Gyulai, L Glenn, T, Whybrow, PC, A New Clinical and Research Tool for Bipolar Disorder: ChronoRecord Software for Daily Self-Reporting of Mood, Sleep and Medications, Bipolar Disorders Conference, Pittsburgh, 2001

48. Bauer, M,. Gyulai, L Glenn, T, Whybrow, PC ChronoRecord Software for Daily Self-Reporting of Mood: A New Clinical Tool for Bipolar Disorder, APA Annual Meeting, 2001

49. Gyulai, L, Bauer, M, Garcia-Espania, F, Hierholzer, J, Baumgartner, A, Whybrow, PC. Bone Mineral Density in Pre-and Postmenopausal Women with Refractory Affective Disorder Treated with High-Dose Levothyroxine,

Media:(selected)

Business Philadelphia, April 1994
WLYH-TV 15, Lebanon, PA, 1995
National Public Radio, Family Matters, featured guest of Dr. Dan Gottlieb
WHYY 95.7,1995
WCAU-TV 10: Sunday Focus, 1995
TV Channel 57: 1995
Philadelphia Inquirer News December 19,1996
WCAU TV -10: News,1996
WRPN: 1997
WRTI: 1997
WXPN:1997
WXPN:1998
Power 99, WHAT, NPR, WXPN, WRTI: 1999
Daily Local News,West Chester, Pa., 1999 November
Fox News, 2000 March

Film:

Psychiatric consultant to "12 Monkeys" film: advisor to actor Brad Pitt on his role.

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Advanced Study, 1974-1975, Culver City, California,
Advanced Study, 1974-1975

Los Angeles Pierce College, Woodland Hills, California,
EMT Certificate, 1975

University of California, Los Angeles, B.S. Public Health,
Health Services Administration, 1975-1979

Jefferson Medical College, Philadelphia, Pennsylvania,
M.D., 1979-1983

INTERNSHIP & RESIDENCY:

University of Nevada, Reno, Nevada,
Internal Medicine, 1983-1984

Oregon Health Sciences University,
Portland, Oregon, Psychiatry, 1984-1988

CERTIFICATION:

Diplomat, American Board of Psychiatry and Neurology,

#32433, March, 1990

Diplomat, Added Qualifications in Addiction Psychiatry,

ABPN, #587, December, 1994

Diplomat, National Board of Medical Examiners

Eligible, American Medical Records Association, RRA

MEDICAL LICENSURE:

California State Medical Licensure, #G067103, September, 1989

Ohio State Medical Licensure, #56587, April, 1988

Oregon State Medical Licensure, #14018, July, 1984

Washington State Medical Licensure, #30174, September, 1992

Drug Enforcement Administration, #AH2683236

PAST HOSPITAL COMMITTEES/ POSITIONS:

Woodland Park Hospital:
Member-Quality Assurance, Medicine/Pediatrics, Psychiatry Committee, Jan 1994-Jun 1995

Saint Agnes Hospital:
Member, Physical Medicine, Jan 1993-Dec 1993

Cedar Vista Hospital, Fresno, CA:
President, Professional Staff, Jan 1992-Jan 1993
President-Elect, Professional Staff, Jan 1991-Jan 1992
Treasurer, Professional Staff, Jan 1990-Jan 1991
Chairman, Pharmacy and Therapeutics, Jan 1990-Jan 1992, Jan 1993-Mar 1993
Member, Medical Records/UR, Jan 1990-Jan 1992
Member/Chairman, Executive Committee, Jan 1990-Jan 1993

Sacred Heart General Hospital, Eugene, OR:
Medical Records Committee, member, 1988-1989
Emergency Room/Trauma Committee, member, 1988-1989

PROFESSIONAL AFFILIATIONS:

American Psychiatric Association, Member
Oregon Psychiatric Association, Member
OHSU Resident Training Committee, Resident Representative, 1984-1986
OPA Executive Council, Resident Representative, 1987-1988
OMA Public Health and Safety Committee, Member, 1989
FMMS Public Health Committee, Member, 1991-1992

PUBLICATIONS:

Bray, J.D.; Asmann, B.; Helfing, S.; Heide, M; Matsunaga, D.; Garofalo, R.: *Civil Commitment Handbook*; Mental Health Division, State of Oregon: 1987

PUBLIC RELATIONS EXPERIENCE:

"Oregon at Five"; Eugene, OR; Guest Psychiatrist; *"Post-Partum Depression", " Holiday Blues".* November and December, 1998

"Ask an Expert"; Eugene, OR; Talk show guest; *"Anxiety and Obsessive-Compulsive Disorders"*; January and May, 1989

"Sun Up"; Fresno, CA; guest; *"Family Stress During A War"*; December, 1990

"Live at 5"; Fresno, CA; Live guest; *"Winter Depression"*; January, 1991

"Family Forum"; Fresno, CA; Live discussion, panelist; *"Family Values"*; November, 1992

CLINICAL TRIALS EXPERIENCE

Drug, Generalized Anxiety Disorder, Phase III , 1988.

Drug, Obsessive-Compulsive Disorder, Phase IV Open Label Trial, 1989.

Drug, Co-Morbidity, Open Label Panic Trial, 1992.

Drug, Panic Disorder, Double-Blind Phase III, 1992.

Drug, Major Depression, Open Label Phase IV, Pfizer-Roerig, 1991.

Drug, Timed-Release, Major Depression, Phase III Double-Blind, 1996.

Oral *Drug*, Chronic Pain, Phase III Double-Blind, 1997.

Drug, Major Depression, Double-Blind Phase II, 1998.

Drug, Migraine Headache, Phase IV Open Label,1998.

Drug, Posttraumatic Stress Disorder (PTSD), Phase III Double-Blind, 1999.

Drug, Major Depressive Disorder, Phase III Double-Blind, Organon, 1999.

Drug, Generalized Anxiety Disorder, Phase III Double-Blind, 1999.

Drug, Major Depressive Disorder Double-Blind, 1999.

Drug, Major Depressive Disorder Resistant to *Drug*, 1999.

Drug, ADHD, Double Blind, Placebo Controlled Parallel-Group Study, 1999.

Drug, ADHD, Double Blind, Placebo-Controlled Study of Modified Release, 1999

A Placebo-controlled Study of *Drug* Dosed BID and TID in Patients with Generalized Anxiety Disorder, 1999.

A Placebo-Controlled Study of *Drug* and *Drug* in Patients with Panic Disorder, 1999.

A Multicenter Trial to Evaluate the Efficacy, Tolerability and Subject Satisfaction with *Drug* in the Treatment Of Migraine Headache Attacks in Neurology Practices, 1999.

Drug, Placebo, and *Drug* Comparison In Patients with Major Depressive Disorder (M/2020/0046). 2000.

A Double-Blind, Placebo-Controlled, Fixed Dose study of *Drug* or Continuous Treatment (12.5 mg and 25mg) for Premenstrual Dysphoric Disorder. (Protocol 29060/677). 2000.

Three month Double Blind, Placebo-Controlled, Fixed Dose, Extension of *Drug* Continuous Treatment for Premenstrual Dysphoric Disorder for Patients Completing Protocol 29060/667, 668, or 689. 2000.

A Multicenter, Double-Blind, Placebo-controlled, Safety and Efficacy Study of *Drug* Transdermal System in Pediatric patients with Attention Deficit Hyperactivity Disorder. Protocol N17-010. 2000.

A long-term, Open-label Study of *Drug* Transdermal System in Pediatric Patients with Attention Deficit Hyperactivity Disorder Protocol N17-011. 2000.

A Multicenter, Open-Label, Six Month Extension Study to assess the Long-Term Safety of *Drug* in children and

Adolescents with Major depressive Disorder (MDD) or Obsessive Compulsive Disorder (OCD). Protocol 29060/716. 2000.

A 16 Week Double-Blind, Placebo Controlled Study to Investigate the Efficacy And Tolerability of *Drug* in the Treatment of Children and Adolescents With Social Anxiety Disorder/Social Phobia. Protocol 29060/676. 2000.

Drug versus Placebo in Treatment of Major Depression. Protocol H5Z-MC-LUAB(c). 2000.

An Open-Label Evaluation of the Long-term Safety of Oral *Drug* 1 mg Twice Daily as short-Term Prophylactic Treatment for Menstrually-Associated Migraines. Protocol S2W40027. 2000.

Open-Label *Drug* continuation Therapy. Protocol 950E-0005-087. 2000.

A Randomized, Double-blind, placebo-controlled study of *drug* as mono-therapy Assessment of Reducing Cholesterol (MONARCH), 2001.

A Double-Blind, placebo controlled, fixed-dosage study comparing the efficacy and tolerability of *drug* and *drug* to placebo in the treatment of Major Depressive Disorder with anxiety, 2001.

A Well-Controlled Safety and Efficacy Study of *Drug* in Subjects with Mild to Moderate Alzheimer's Disease, 2001.

Multicenter, Randomized, Double-blind, Parallel group, Multiple dose Comparison study of *drug*, *drug*, and placebo in patients with Moderate to Severe Acute Migraine Headache, 2001.

A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of *drug* in Patients with Generalized Anxiety Disorder (GAD), 2001.

A 6-Week, Double-Blind, Randomized, Multicenter, Fixed-Dose, Placebo-Controlled Study of *drug* Dosed Twice a

Day in Patients with Generalized Anxiety Disorder, 2001.

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating Efficacy and Safety of Three doses of *drug* versus Placebo in Patients with Major Depressive Disorder, 2001.

A Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study of *drug* in Adolescent Outpatients with Panic Disorder, 2001.

A Double-Blind, Multicenter, Placebo- and Active-Controlled Acute and Extension study of two doses of *drug* in the treatment of Patients with Major Depressive Disorder, 2001.

A Multicenter, Double-Blind, Placebo-Controlled Safety and Efficacy Study of *drug* in Pediatric Patients with Attention Deficit Hyperactivity Disorder, 2001.

Open Label Study of *drug* in Children with ADHD, 2001.

A 12-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, study to evaluate the efficacy and safety of flexible dosing of *drug* at 500 mg to 1500 mg b.i.d. in the treatment of subjects with painful diabetic neuropathy, 2001.

A 4-Week, Double-Blind, Randomized, Placebo-Contolled, Parallel Study to Evaluate the Efficacy and Safety of *drug* in Children and Adolescents with Attention-Deficit/ Hyperactivity Disorder, Followed by an 8 week Open Label Extension, 2002.

*Drug*30 mg and *Drug* 60 mg once daily versus placebo in Generalized Anxiety Disorder. A Randomized Double-Blind Placebo-Controlled and *drug* controlled Fixed-Dose Parallel Group MultiCenter Study of 10 weeks (Including a 2 week Single Blind Placebo Period), 2002.

A Study to Evaluate the Efficacy, Safety and Maintenance Effect of Risperidone Augmentation of SSRI Monotherapy in Young and Older Adult Patients with Unipolar Treatment-Resistant Depression, 2002. (Janssen Protocol RIS-INT-93)

Drug 60 mg (or 30 mg) once daily in the treatment of Generalized Anxiety Disorder. An Open Label Multicenter Safety Study of 5 months, including a 1-month drug free follow-up period, 2002. (Pharmacia Protocol 3013038)

A Phase III Multi-center, Randomized, Double-blind, Parallel Group Study of drug 20 mg, drug 40 mg and Placebo in Patients with Multiple Moderate or Severe Acute Migraine Headaches, 2002. (Pharmacia Protocol VALA-0513-138)

The Effect of *drug* on Bone Mineral Density in Pediatric Subjects with Anorexia Nervosa: A Double-Blind, Placebo-Controlled Study Protocol CAPSS-169, 2002. (Ortho-McNiel Pharmaceutical, Inc.)

A 6 ½ Month, Multicenter, Randomized, Double-blind, Placebo-Controlled Comparison of 300 mg/day of Extended- release *Drug* and Placebo for the prevention of Seasonal Affective Disorder in Subjects with a History of Seasonal Affective Disorder, 2002.(GlaxoSmithKline Protocol AK 130930/36)

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GEORGE M. JOSEPH, M.D.
CNS HEALTHCARE OF JACKSONVILLE
March 28, 2002

3/28/02

Date of Birth	08/23/1943
Affiliation	**Principal Investigator** Clinical Neuroscience Solutions, Inc. 4063 Salisbury Road, Suite 108, Jacksonville, FL 05/01-Present
Education	Emory University, Atlanta, Georgia; 1961-1964 Emory University School of Medicine; 1964-1968 Madigan Army Medical Center; Internship (Rotating, Internal Medicine Surgery, ObGyn, Pediatrics 1968-1969 Walter Reed Army Medical Center; Residency (Psychiatry)
Professional Training	Forensic Psychiatry Evaluations and Testimony; 1990 - Present Physicians Recovery Network; Evaluator; 1984 – Present United States Army Medical Corps; Major; 1968-1974 Baptist Medical Center Department of Psychiatry; Chairman; 1983-1984 CPC St Johns River Hospital; Medical Director; 1984-1994/1978-1980 Mental Health Resource Center; Staff Psychiatrist; 1995-1997 George M. Joseph, M.D. & Associates; Private Practice 1974-Present
Clinical Trial Experience	2001-Principal Investigator experience in Phase II-IV clinical research. 2002- Continued Principal Investigator/Sub-Investigator experience. Diagnoses include ADHD, general anxiety disorder, depressive disorders, panic disorders, Schizoaffective disorders, Schizophrenia, Migraine, Bipolar disorder, Alzheimer's Industry contracts include: Eli Lilly, Pfizer, Parke-Davis, Forest, GlaxoSmithKline and POZEN
License/ Accreditation	State of Florida Board of Medicine ME# 0015175 State of Georgia Board of Medicine (Inactive) State of Maryland Board of Medicine (Inactive) Drug Enforcement Administration Controlled Substances BJ0563595
Population Experience	*Children & Adolescents:* Twenty eight years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Mental Retardation, Learning Disorders, Motor Skills Disorders, Communication Disorders, Pervasive Dev. Disorders, ADHD & Disruptive Behavior Disorders, Tic Disorders, Elimination Disorders, Substance Abuse/Dependence (adolescents), Psychotic Disorders, Depressive Disorders, Bipolar Disorders, Anxiety Disorders, Sexual & Gender Identity Disorders (adolescents), Eating Disorders (adolescents), Sleep Disorders (adolescents), Impulse-Control Disorders (adolescents), Adjustment Disorders (adolescents), Personality Disorders (adolescents)

Adults: Twenty eight years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Mental Retardation, Learning Disorders, Motor Skills Disorders, Communication Disorders, Pervasive Dev. Disorders, ADHD & Disruptive Behavior Disorders, Tic Disorders, Delirium, Dementia, Amnestic Disorders, Substance Abuse/Dependence, Psychotic Disorders, Depressive Disorders, Bipolar Disorders, Anxiety Disorders, Somatoform Disorders, Factitious Disorders, Dissociative Disorders, Sexual & Gender Identity Disorders, Eating Disorders, Sleep Disorders, Impulse-Control Disorders, Adjustment Disorders, Personality Disorders

Geriatrics: Twenty eight years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Delirium, Dementia, Alzheimer's, Amnestic Disorders, Substance Abuse/Dependence, Psychotic Disorders, Depressive Disorders, Bipolar Disorders, Anxiety Disorders, Somatoform Disorders, Sleep Disorders, Impulse-Control Disorders, Adjustment Disorders, Personality Disorders

Clinical Skills

CPR, ECG interpretation, phlebotomy, physical examinations, and lab interpretations

Ratings Experience

Diagnostic Evaluations: SCID, K-SADS, DICA and MINI

Scales: ADAS, ADCS/ADL scale, ADHD rating scale, AIMS, Barnes, Benten Visual Retention Test, BPRS, Calgary Depression Scale, California Verbal Learning Test, CAPS, CGI, CIBIC, Conners, Continuous Performance Test, Covi Anxiety Scale, Disability Scale, ESRS, Family Impact Scale, Global Assessment Scale, Grooved Pegboard, Hamilton Anxiety Rating Scale, Hamilton Depression Scale, Hospital Anxiety and Depression Scale, MADRS, MMSE, ADAS-COG, ADCS-CGIC, North American Adult Reading Test, PANSS, Quality of Life Assessment, Raskin Depression Scale, Resource Utilization, SADS-C, Simpson-Angus, TODS, Tourette Rage Attack Questionnaire, Tourette Symptom Importance Scale, Trail Making Test, Verbal Fluency Tests, WAIS-III, Wechsler Intelligence Scales, Wisconsin Card Sorting Tests, Yale Global Tic Severity Scale, Y-BOCS, and the Y-MRS

Hospital Appointments

Baptist Medical Center – Beaches; Active Professional
Baptist Medical Center ; Courtesy

Version

March 28, 2002

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STATE OF FLORIDA
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JEB BUSH
GOVERNOR

JOHN O. AGWUNOBI, M.D., M.B.A.
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Center for Emotional Fitness

Focused on Emotional Stability

110 Marter Avenue, Suite 303 • Moorestown, NJ 08057

LEON I. ROSENBERG, M.D.
CURRICULUM VITAE

EDUCATION:

May 1978	Medical School SUNY-Upstate Medical School at Syracuse Doctor of Medicine
June 1974	Undergraduate School Harvard University, Cambridge, Massachusetts Bachelor of Arts Degree cum laude in Biology
June 1970	High School Oceanside Senior High School, Oceanside, New York Regents Graduate

TRAINING:

July 1981 to June 1983	Child Psychiatry Fellowship Division of Child Psychiatry Hahnemann University Hospital Philadelphia, Pennsylvania
July 1979 to June 1981	Adult Psychiatry Residency Department of Psychiatry Hospital of the University of Pennsylvania Philadelphia, Pennsylvania
July 1978 to June 1979	Psychiatric Categorical Internship (Rotating Internship with Emphasis in Psychiatry) Long Island Jewish-Hillside Hospital Glen Oaks, New York

CLINICAL EXPERIENCE:

1983 to Present	Private Practice Center for Emotional Fitness Moorestown, New Jersey Geriatric, Adult, Adolescent and Child Psychiatry Individual, Marital, Family and Group Therapy Forensic Evaluations & Treatment Research Studies in Psychopharmacology
2001 to Present	Privileges Center for Emotional Fitness/South Philadelphia Office Philadelphia, Pennsylvania Research Studies in Pharmacology

Phone: 856-608-8800 • Fax: 856-231-8182 •

July 1983 to January 2000	Memorial Hospital of Burlington County Active Medical Staff - Department of Psychiatry Consultations and In-Patient Care
July 1989 to December 1990	Acting Chairman Department of Psychiatry
January 1985 to 2001	Long-Term Care Consultant to Nursing Homes, Residential Care Facilities and Group Homes
July 1983 to January 1985	Drenk Memorial Guidance Center, Mt. Holly, New Jersey Staff Psychiatrist
July 1982 to June 1984	Private Practice - Part-Time 424 Pine Street, Philadelphia, Pennsylvania Adult Psychiatry

CLINICAL DRUG STUDIES AND RESEARCH PROGRAMS:

3/95 to 4/96	Wyeth-Ayerst PMS Study in association with The University of Pennsylvania Department of Psychiatry, Private Practice Research Group.
3/95 to 9/95	Open-Label Study of Management of Patients with Symptoms of Depression in General Psychiatric Practices, International Clinical Research Corporation.
3/97 to 6/98	Bristol-Myers Squibb Double-Blind Study of Treatment of Children with Attention-Deficit Hyperactivity Disorder.
3/97 to 9/98	Bristol-Myers Squibb Study of Treatment of Children with Attention-Deficit Hyperactivity Disorder. Open-Label, Long-Term Flexible Dose Safety.
9/97 to 3/98	PPD Pharmaco Study of Safety and Tolerability in Psychotic Patients.
10/97 to 11/99	Eli Lilly & Company, Double-Blind, Placebo-Control Study of Geriatric Nursing Home Patients with Major Depression.
11/97 to 7/98	Zeneca Pharmaceuticals Double-Blind, Placebo-Control Study of Geriatric Nursing Home Patients with Alzheimer's Dementia and Psychoses and Other Selected Idiopathic and Organic Psychoses.
12/97 to 12/98	Eli Lilly & Company Study of Management of Behavioral Disturbances and/or Psychosis in Demented Nursing Home Patients.
4/98 to 4/99	Hoechst Marion Roussel, a Multicenter, Placebo and Active Control Randomized Study of Efficacy and Safety in Schizophrenic and Schizoaffective Patients.
4/98 to 9/99	Hoechst Marion Roussel, a Multicenter, Open-Label, Long-Term Follow-up Safety Study of Schizophrenia and Schizoaffective Subjects.
9/98 to 8/00	Eli Lilly & Co, Multicenter, Double Blinded Study of the Treatment of Posttraumatic Stress Disorder.
9/98 to 11/98	Multicenter, Double Blinded Efficacy and Tolerability Study of Depressed Outpatients.

10/98 to 4/99	Roche, A Double-Blind, Randomized, Placebo-Controlled Study of Elderly Subjects for Prevention of Clinical Influenza during the Flu Season.
10/98 to 1/00	Merck, A Double-Blind, Randomized, Placebo-Controlled Evaluation of the Efficacy and Safety of Two Dose Range study Drug in Comparison with Placebo and Haloperidol in the Treatment of Schizophrenia.
5/99 to 4/00	Somerset Pharmaceuticals, A Double-Blind, Placebo-Controlled, Parallel-Group Assessment of the Safety and Efficacy of Two Doses of Study Drug in Patients with Major Depression.
4/99 to 12/00	Medeva Development, Double-Blind, Placebo-Controlled Study of Children with ADHD.
9/99 to 10/00	Somerset Pharmaceuticals, Open-Label Study to Assess the Safety in Patients with Major Depression.
8/99 to 8/01	Eli Lilly & Company, Double-Blind Combination in the Treatment of Resistant Depression Without Psychotic Features
8/99 to 10/01	Eli Lilly & Company, Double-Blind Study of Treatment of Bipolar Disorder
10/99 to 3/01	Parke-Davis, Double-Blind Sustained for Efficacy in Treatment of Social Phobia
10/99 to 2002	Parke-Davis, Open Label for Efficacy in Treatment of Social Phobia
11/99 to 9/00	Organon, Double-Blind in Treatment of Children and Adolescents with Major Depressive Disorder
12/99 to 10/00	Eli Lilly & Company, Double-Blind in the Treatment of Major Depression in Adults
1/00 to 9/00	Novartis, Double-Blind in Children with ADHD
6/00 to 6/01	Eli Lilly & Company Double-Blind Study of Adult Patients with Attention-Deficit/Hyperactivity Disorder
6/00 to Present	Eli Lilly & Company, Open-Label Study of Outpatients with ADHD Ages 6 to 18 Years
6/00 to 4/01	Eli Lilly & Company, Double-Blind Study of Treatment of Bipolar I Depression
6/00 to 10/01	Parke-Davis Double-Blind Study of Patients with Panic Disorder
6/00 to 8/00	Parke-Davis, Double-Blind Study of Elderly Patients with Generalized Anxiety Disorder
7/00 to 6/01	Parke-Davis, Double-Blind Study of Patients with Generalized Anxiety Disorder
11/00 to Present	Eli Lilly & Company, Open-Label Study of ADHD Children Ages 6 to 18

11/00 to 9/01	Wyeth-Ayerst, Double-Blind Study of Children and Adolescents with Major Depressive Disorder
11/00 to 10/01	Wyeth-Ayerst, Double-Blind Study of Children and Adolescents with Generalized Anxiety Disorder
3/00 to Present	Wyeth-Ayerst, Double-Blind Study of Children and Adolescents with Social Anxiety Disorder
8/00 to 2002	Pfizer, Double-Blind Study of Patients with Generalized Anxiety Disorder ages 18 and above
8/00 to Present	Wyeth-Ayerst, Double-Blind Study of the Treatment of Posttraumatic Stress Disorder
8/00 to 2001	Shire Pharmaceutical, Open-Label Study of Children with ADHD
9/01 to Present	Merck Research, Double-Blind, Placebo and Active-Controlled, Acute and Extension Study of 2 Doses in the Treatment of Patients with Major Depressive Disorder
10/01 to Present	Wyeth-Ayerst, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study of Adolescent Outpatients with Panic Disorder
03/02 to Present	Eli Lilly & Company Duloxetine Once-Daily Dosing Versus Placebo in Patient with Major Depression and Pain
04/02 to Present	Eli Lilly & Company The Study of Olanzapine Plus Fluoxetine in Combination for Treatment-Resistant Depression Without Psychotic Features
04/02 to Present	Eli Lilly & Company A Double-Blind Study of Treatment with Optimization with Atomoxetine Hydrochloride In Adults with DSM-IV Attention-Deficit/Hyperactivity Disorder

CERTIFICATIONS:

American Board of Psychiatry and Neurology

Board Certified Psychiatry
June 1986

Board Certified Geriatric Psychiatry
December 1995

Board Certified Forensic Psychiatry
June 1996

Board Eligible Child Psychiatry
June 1983

The American Board of Addiction Medicine
Board Certified December 1993

LICENSURE:

Licensed to Practice Medicine In New Jersey
June 1983 (MA-42361)

Licensed to Practice Medicine in the Commonwealth of Pennsylvania
October 1979 (MD-022896-E)

AFFILIATIONS:

1988 to Present	Center for Emotional Fitness, P.A. President, Medical Director
1983 to 1999	Memorial Hospital of Burlington County Active Medical Staff
1987 to Present	Deborah Heart and Lung Center, Browns Mills, New Jersey Psychiatric Consultant
1994 to Present	Rancocas Hospital, Willingboro, New Jersey Active Medical Staff
2000 to Present	Hampton Hospital, Rancocas, NJ Active Medical Staff

PROFESSIONAL SOCIETIES & BOARDS:

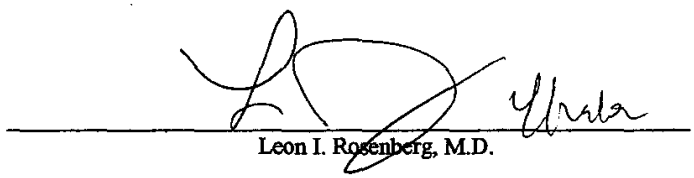
1980 to Present	American Medical Association
1980 to Present	American Psychiatric Association
1984 to Present	Burlington County Medical Society
1983 to Present	New Jersey Psychiatric Society
1990 to Present	American Academy of Psychiatry and Law
1993 to Present	International Society for Traumatic Stress Studies
1996 to Present	Camden County Mental Health Board

PUBLICATIONS AND COPYRIGHTS:

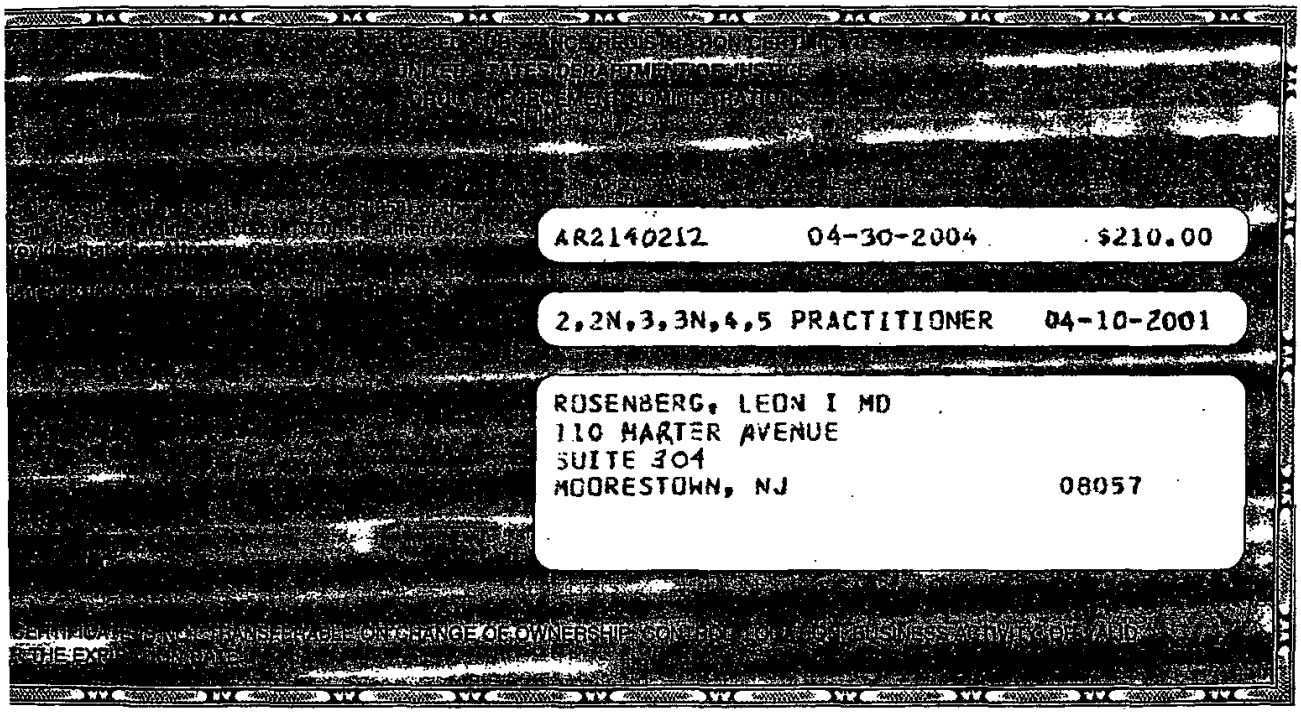
GeriHatTricks, The Journal, Editor, 1997

Mood Mnemonic Manual©, 1999

The Authoritative Guide To Psychiatric Diagnosis©, 2002



Leon I. Rosenberg, M.D.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MOORESTOWN, NJ 08057

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110 MARTER AVE STE 304
MOORESTOWN NJ 08057-3124

FOR PRACTICE IN NEW JERSEY AS A(N): PHYSICIAN - MD

07/01/01 TO 06/30/03
VALID

MA 42361
LICENSE/REGISTRATION/CERTIFICATION #

SIGNATURE OF REGISTRANT

DIRECTOR

5077US/0049 :0021

CURRICULUM VITAE

TERENCE ARTHUR KETTER, M.D.

11/21/02

OFFICE ADDRESS: Department of Psychiatry and Behavioral Sciences
Stanford University School of Medicine
Stanford, California 94305-5723
Telephone: (650) 723-2515
Fax: (650) 723-2507

BORN: April 20, 1950. Toronto, Ontario, Canada

CITIZEN OF: United States of America

MARITAL STATUS: Married, 1984
Wife: REDACTED
REDACTED

EDUCATION AND TRAINING:

1969-1973	University of Toronto, Toronto, Canada B.Sc. (Mathematics) 1973
1974-1976	University of Sydney, Sydney, Australia M.Sc. (Mathematics) 1976
1980-1984	University of Toronto, Toronto, Canada M.D. 1984
1984-1985	University of California, San Francisco Department of Psychiatry, Internship
1985-1988	University of California, San Francisco Department of Psychiatry, Residency
1988-1995	National Institute of Mental Health, Bethesda Intramural Research Program Biological Psychiatry Branch, Senior Staff Fellow

CURRENT POSITIONS:

1997-Present	Associate Professor Department of Psychiatry and Behavioral Sciences Stanford University School of Medicine Stanford, California
1995-Present	Chief, Bipolar Disorders Clinic Department of Psychiatry and Behavioral Sciences Stanford University School of Medicine Stanford, California

PROFESSIONAL EXPERIENCE:

1999-Present	Voting Member Administrative Panel on Human Subjects in Medical Research Stanford University School of Medicine Stanford, California

1995-1996	Acting Associate Professor Department of Psychiatry and Behavioral Sciences Stanford University School of Medicine Stanford, California
1992-1995	Chief, Unit on Brain Imaging Section on Psychobiology Biological Psychiatry Branch National Institute of Mental Health, Bethesda
1990-1995	Chief, 3 West Clinical Research Unit Section on Psychobiology Biological Psychiatry Branch National Institute of Mental Health, Bethesda
1988-1995	Private Medical Practice Pharmacotherapy of Mood and Anxiety Disorders Washington, D.C., and Bethesda, MD
1993-1994	Chair, Physician-Nurse Committee National Institutes of Health Clinical Center, Bethesda
1992-1995	Member, Physician-Nurse Committee National Institutes of Health Clinical Center, Bethesda
1988-1990	Unit Administrator 3 West Clinical Research Unit Section on Psychobiology Biological Psychiatry Branch National Institute of Mental Health, Bethesda
1988-1989	Psychiatric Consultant Clinical Epilepsy Section Medical Neurology Branch National Institute of Neurological Disorders and Stroke, Bethesda
1987-1988	Senior Resident Behavioral Neurosciences Service Langley Porter Psychiatric Institute Department of Psychiatry University of California, San Francisco
1987-1988	Psychiatric Consultant Northern California Epilepsy Center Department of Neurology University of California, San Francisco
1987-1988	Resident Representative Executive Medical Board Department of Psychiatry University of California, San Francisco
1987-1988	Vice-President, Residents' Association Department of Psychiatry University of California, San Francisco

HONORS AND FELLOWSHIPS:

Undergraduate	University of Toronto Varsity Fund Scholarship 1969-73 Governor General's Silver Medal (First standing in graduating class in Erindale College, University of Toronto)
Graduate	Commonwealth of Australia Research Fellowship 1974-76
Pre-medical	Carl Manning Book Prize 1980 (First standing in organic chemistry in Erindale College, University of Toronto)
Medical School	Walter F. Watkins Scholarship 1982
Residency	Creative Resident Award 1987-88 (Creative achievement by a resident in psychiatry, University of California, San Francisco)
Fellowship	American College of Neuropsychopharmacology Mead Johnson Travel Award Fellow 1994

SOCIETY MEMBERSHIPS:

1987 - Present	American Psychiatric Association
1987 - 1988 1996 - Present	Northern California Psychiatric Society
1988 - 1995	Washington Psychiatric Society
1992 - Present	Society of Biological Psychiatry
1992 - Present	International Society for Neuroimaging in Psychiatry
1994 - Present	American Society of Clinical Psychopharmacology
1994 - Present	American Association for the Advancement of Science
1994 - Present	American Academy of Clinical Psychiatrists
1995 - Present	American Epilepsy Society
1996 - Present	Association for Convulsive Therapy
1996 - Present	National Depressive and Manic-Depressive Association
1996 - Present	National Alliance for the Mentally Ill
1996 - Present	West Coast College of Biological Psychiatry
1996 - Present	American Neuropsychiatric Association
1997 - Present	Canadian Psychiatric Association
1998 - Present	International Society for Magnetic Resonance Imaging in Medicine
1999 - Present	International Society for Bipolar Disorders
2001 - Present	Child & Adolescent Bipolar Foundation

MEDICAL LICENSES:

California	March 10, 1986	#G56822
District of Columbia	September 20, 1988	#17541
Maryland	October 13, 1988	#D37533

BOARD CERTIFICATION:

1988 Specialist Certificate in Psychiatry (# 370484)
Royal College of Physicians and Surgeons of Canada

1989 Specialist Certificate in Psychiatry (# 31895)
American Board of Psychiatry and Neurology

1989 Fellow of Royal College of Physicians & Surgeons of Canada (F.R.C.P.C.)

JOURNAL REFEREE:

1991-Present	Neuropsychiatry, Neuropsychology, and Behavioral Neurology
1993-Present	Biochemical Pharmacology
1995-Present	Journal of Clinical Psychopharmacology
1996-Present	Drug Safety
1996-Present	Human Psychopharmacology
1996-Present	Journal of Affective Disorders
1997-Present	Psychiatric Times
1997-Present	Journal of Neuropsychiatry and Clinical Neurosciences
1997-Present	Archives of General Psychiatry
1997 - Present	Psychiatry Research
1997 - Present	Biological Psychiatry
1998-Present	Life Sciences
1998 - Present	Journal of Psychiatric Research
1998 - Present	Journal of Clinical Psychiatry
1998 - Present	Bipolar Disorders
1999 - Present	Harvard Review of Psychiatry
1999 - Present	Expert Opinion on Pharmacotherapy
2000 – Present	Southern Medical Journal
2000 – Present	Depression and Anxiety
2000 – Present	Schizophrenia Research
2000 – Present	Neuropsychopharmacology

EDITORIAL BOARDS

2000-Present	Bipolar Disorders
2000-Present	Journal of Psychiatric Research
2001-Present	Journal of Affective Disorders

EXTERNAL GRANT REVIEWER:

1993-Present	Ontario Mental Health Foundation
1997-Present	Canadian Psychiatric Research Foundation
1997-Present	Department of Veterans Affairs
1998	American Psychiatric Association (1998 Annual Meeting, Research Colloquium for Junior Investigators Applications)
2000-Present	Medical Research Council of Canada
2001-Present	Veterans' Administration Merit Review Committee

BIBLIOGRAPHY OF TERENCE A. KETTER, M.D.

PART I: ABSTRACTS AND PRESENTATIONS

PART II: PUBLICATIONS

PART I: ABSTRACTS AND PRESENTATIONS

1) **Ketter TA**: Complex partial seizures and panic disorder. UCSF symposium: The medical / psychiatric interface of panic. 8th Annual National Conference on Phobias and Related Anxiety Disorders, San Francisco, Oct. 22-25, 1987. Abstract.

2) Kanas N, Deri J, **Ketter T**, and Fein G: Outcome of short-term outpatient groups for schizophrenics. American Group Psychotherapy Association Annual Meeting, San Francisco, Feb. 21-25, 1989. Abstract.

3) Bromfield EB, **Ketter TA**, Balish M, Sato S, Leiderman DB, and Theodore WH: Simple partial status epilepticus with psychosensory and psychoaffective manifestations. American Epilepsy Society Annual Meeting, Boston, December 3-6, 1989. Abstract.

4) **Ketter TA**, Laxer KD: Psychopathology in pseudoepileptic seizures and epilepsy. Pseudoepileptic Seizure Symposium, Fort Lauderdale, March 1-3, 1990. Abstract.

5) Bromfield EB, Altshuler L, Leiderman DB, Balish M, **Ketter TA**, Devinsky O, Post RM, Theodore WH: Cerebral metabolism and depression in patients with complex partial seizures. American Epilepsy Society Annual Meeting, San Diego, November 12-14, 1990. Abstract. Epilepsia 1990;31(5):625-626.

6) **Ketter TA**: Psychiatric aspects of epilepsy. American College of Neuropsychiatrists Spring Meeting, Scottsdale, March 21-24, 1991. Abstract.

7) Post RM, Weiss SR, **Ketter TA**, George MS, Clark M, Rosen J: The temporal lobes and affective disorders. The Temporal Lobes and Limbic System - Basic and Clinical Perspectives. Copenhagen, Denmark, September 19-20, 1991. Abstract.

8) Post RM, Weiss SR, **Ketter TA**, Pazzaglia PJ, Denicoff K: Impact of affective illness on gene expression: rationale for long-term prophylaxis. . 4th European College of Neuropsychopharmacology Congress, Monte Carlo, Monaco, October 6-9, 1991. European Neuropsychopharmacology 1991;1:214-216.

9) Post RM, George MS, **Ketter TA**, Denicoff K, Leverich G, Mikalauskas K: Mechanisms underlying recurrence and cycle acceleration in affective disorders: implications for long-term treatment. British Association for Pharmacology Meeting, London, November 21,1991. Abstract.

10) **Ketter TA**, Barnett J, Schroeder DH, Hinton ML, Chao J, Post RM: Carbamazepine induces bupropion metabolism. 145th Annual Meeting of the American Psychiatric Association, Washington, May 2-7, 1992. Abstract NR563. Page 186.

11) **Ketter TA**, Malow BA, White SR, Post RM, Theodore WH: Anticonvulsant withdrawal-emergent psychopathology. 44th Annual Meeting of the American Academy of Neurology, San Diego, May 3-9, 1992. Abstract 1029P. Neurology 1992;42(Suppl 3):450.

12) Post RM, **Ketter TA**, Pazzaglia PJ, Denicoff K, George MS, Marangell L, Weiss SR: Anticonvulsants in refractory mood disorders. 2nd International Conference on Refractory Depression, The Hague and Amsterdam, June 24-26, 1992. Abstract.

13) **Ketter TA**, Potter WZ: Pharmacologic issues in the treatment of bipolar disorder. 42nd Annual Meeting of the Canadian Psychiatric Association, Montreal, September 16-18,1992. Abstract.

14) Post RM, **Ketter TA**, Pazzaglia PJ, George MS, Marangell L, Weiss SR: Receptor, ion channel, and neuropeptide targets for drug development: implications from the anticonvulsant model. 31st Annual Meeting of the American College of Neuropsychopharmacology, San Juan, Puerto Rico, December 14-18, 1992. Abstract. Page 9.

15) Post RM, **Ketter TA**, Pazzaglia PJ, George MS, Marangell L, Denicoff K: New developments in the use of anticonvulsants as mood stabilizers Symposium on antiepileptic drugs in psychiatry, Freiberg, Germany, January 29-30, 1993. Abstract.

16) **Ketter TA**, Malow BA, Flamini R, White SR, Post RM, Theodore WH: Carbamazepine withdrawal-emergent psychopathology. 45th Annual Meeting of the American Academy of Neurology, New York, April 25-May 1, 1993. Abstract 163S. Neurology 1993;43(Suppl 2):A194.

17) Post RM, **Ketter TA**, George MS: Psychiatric syndromes and the limbic system. 45th Annual Meeting of the American Academy of Neurology, New York, April 25-May 1, 1993. Abstract.

18) **Ketter TA**, Andreason PJ, George MS, Herscovitch P, Post RM: Paralimbic rCBF increases during procaine-induced psychosensory & emotional experiences. 48th Annual Convention and Scientific Program of the Society of Biological Psychiatry, San Francisco, May 19-23, 1993. Abstract 107. Biol Psychiatry 1993;33(Suppl 6A):66A.

19) George MS, **Ketter TA**, Gill D, Herscovitch P, Post RM: The neuroanatomy of facial emotion recognition. 146th Annual Meeting of the American Psychiatric Association, San Francisco, May 22-27, 1993. Abstract NR16. Page 63.

20) **Ketter TA**, Andreason PJ, George MS, Marangell LB, Pazzaglia PJ, Post RM: Reduced resting frontal lobe CBF in mood disorders. 146th Annual Meeting of the American Psychiatric Association, San Francisco, May 22-27, 1993. Abstract NR298. Page 135.

21) George MS, **Ketter TA**, Gill D, Marangell LB, Pazzaglia PJ, Post RM: Blunted CBF with emotion recognition in depression. 146th Annual Meeting of the American Psychiatric Association, San Francisco, May 22-27, 1993. Abstract NR114. Page 88.

22) **Ketter TA**, Andreason PJ, George MS, Pazzaglia PJ, Marangell LB, Post RM: Blunted CBF response to procaine in mood disorders. 146th Annual Meeting of the American Psychiatric Association, San Francisco, May 22-27, 1993. Abstract NR297. Pages 134-135.

23) Pazzaglia PJ, Post RM, **Ketter TA**, George MS, Marangell LB: Nimodipine in affective illness. 146th Annual Meeting of the American Psychiatric Association, San Francisco, May 22-27, 1993. Abstract NR714. Page 239.

24) Post RM, Pazzaglia PJ, **Ketter TA**, George MS, Marangell LB: Carbamazepine and nimodipine in refractory bipolar illness: efficacy and mechanisms. 1st International Congress on Hormones, Brain, and Neuropsychopharmacology, Rhodes, Greece, September 13-17, 1993. Abstract.

25) Parekh P, Spencer J, George MS, Gill DS, **Ketter TA**, Post RM: rCBF correlates of EEG frequencies before and after i.v. procaine. Society of Neuroscience Annual Meeting, November 7-12, 1993. Abstract 501.9, M-46. Page 239.

26) George MS, **Ketter TA**, Parekh PI, Ring, HA, Rosinsky N, Pazzaglia PJ, Marangell LB, Post RM: Differences in performance and regional brain activation in controls and mood disordered subjects while performing a classic and emotional Stroop. 32nd Annual Meeting of the American College of Neurosychophamacology, Honolulu, December 13-17, 1993. Abstract.

27) Post RM, Pazzaglia PJ, **Ketter TA**, Marangell LB, George MS: Efficacy of the L-type calcium channel blocker nimodipine in recurrent affective disorders. 32nd Annual Meeting of the American College of Neurosychophamacology, Honolulu, December 13-17, 1993. Abstract.

28) George MS, **Ketter TA**, Post RM: An overview of brain activation studies in mood disorders. 49th Annual Convention and Scientific Program of the Society of Biological Psychiatry, Philadelphia, May 18-22, 1994. Abstract 157. Biol Psychiatry 1994;35(9):658.

29) **Ketter TA**, George MS, Andreason PJ, Herscovitch P, Post RM: Blunted paralimbic resting & procaine-activated rCBF in healthy females compared to males. 49th Annual Convention and Scientific Program of the Society of Biological Psychiatry, Philadelphia, May 18-22, 1994. Abstract 120. Biol Psychiatry 1994;35(9):648.

30) George MS, **Ketter TA**, Parekh P, Post RM: Regional blood flow correlates of transient self-induced sadness or happiness. 49th Annual Convention and Scientific Program of the Society of Biological Psychiatry, Philadelphia, May 18-22, 1994. Abstract 119. Biol Psychiatry 1994;35(9):647.

31) **Ketter TA**, George MS, Pazzaglia PJ, Marangell LB, Andreason PJ, Post RM: PET activation studies in mood disorders. 147th Annual Meeting of the American Psychiatric Association, Philadelphia, May 21-26, 1994. Abstract. Symposium 105D. Page 184.

32) George MS, **Ketter TA**, Post RM: Brain imaging in mania. 147th Annual Meeting of the American Psychiatric Association, Philadelphia, May 21-26, 1994. Abstract. Symposium 73C. Page 142.

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76) Frye MA, **Ketter TA**, Corá-Locatelli G, Grothe DR, Kimbrell TA, Piscitelli SC, Little JT, Post RM: Gabapentin does not alter lithium pharmacokinetics. 149th Annual Meeting of the American Psychiatric Association, New York, May 4-9, 1996. Abstract NR311. Page 151.

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98) Ali SO, Denicoff K D, **Ketter TA**, Smith-Jackson EE, Post RM: Psychosensory symptoms in patients with bipolar disorder. 150th Annual Meeting of the American Psychiatric Association, San Diego, May 17-22, 1997. Abstract NR423. Pages 182-183.

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100) **Ketter TA**: Clinical pharmacology of carbamazepine. In the course: Anticonvulsants in Child, Adolescent, and Adult Psychiatry. 150th Annual Meeting of the American Psychiatric Association, San Diego, May 17-22, 1997. Course 42.

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107) Frye MA, **Ketter TA**, Osuch EA, Kimbrell T, Speer AM, Dunn RT, Post RM: Gabapentin and lamotrigine monotherapy in mood disorder: an update. In the symposium: New Anticonvulsants in Mood Disorders. 151st Annual Meeting of the American Psychiatric Association, Toronto, May 30 - June 4, 1998. Symposium 77D. Page 150.

108) Kimbrell T, **Ketter TA**, Frye MA, Dunn RM, Speer AM, Osuch EA, Post RM: Neuroimaging of response to lamotrigine and gabapentin . In the symposium: New Anticonvulsants in Mood Disorders. 151st Annual Meeting of the American Psychiatric Association, Toronto, May 30 - June 4, 1998. Symposium 77E. Page 150.

109) **Ketter TA**: Clinical pharmacology of carbamazepine. In the course: Anticonvulsants in Child, Adolescent, and Adult Psychiatry. 151st Annual Meeting of the American Psychiatric Association, Toronto, May 30 - June 4, 1998. Course 41.

110) Chang KD, **Ketter TA**, Steiner H: Psychiatric morbidity in children of bipolar parents. 151st Annual Meeting of the American Psychiatric Association, Toronto, May 30 - June 4, 1998. Abstract NR29. Page 75.

111) Dunn RT, Kimbrell TA, **Ketter TA**, Frye MA, Speer AM, Osuch EA, Post RM: Beck depression inventory and regional cerebral metabolism. 151st Annual Meeting of the American Psychiatric Association, Toronto, May 30 - June 4, 1998. Abstract NR49. Pages 80-81.

112) Winsberg ME, Tate DL, Strong CM, **Ketter TA**: Temperament differences in bipolar disorder patients. 151st Annual Meeting of the American Psychiatric Association, Toronto, May 30 - June 4, 1998. Abstract NR140. Page 106.

113) Chang KD, **Ketter TA**, Santosa CM, Lee BW, Steiner H: Psychiatric phenomenology in children of bipolar parents. Annual Meeting of the American Academy of Child and Adolescent Psychiatry, Anaheim, October 27 - November 1, 1998. Abstract NR-46. Page 97.

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119) **Ketter TA**: Clinical pharmacology of carbamazepine. In the course: Anticonvulsants in Child, Adolescent, and Adult Psychiatry. 152nd Annual Meeting of the American Psychiatric Association, Washington, May 15 - 20, 1999. Course 55.

120) Chang KD, Steiner H, **Ketter TA**: Temperamental characteristics of children and adolescents with bipolar parents. 152nd Annual Meeting of the American Psychiatric Association, Washington, May 15 - 20, 1999. Abstract NR108. Page 91.

121) Santosa CM, Sachs N, Strong CM, Winsberg ME, **Ketter TA**: Differential creativity assessments in patients with bipolar disorder. 152nd Annual Meeting of the American Psychiatric Association, Washington, May 15 - 20, 1999. Abstract NR449. Pages 191-2.

122) **Ketter TA**, Kimbrell TA, George MS, Dunn RT, Speer AM, Willis MW, Benson BE, Frye MA, Post RM: Functional brain imaging studies of treatments for bipolar disorders. 22nd Annual Meeting of the Canadian College of Neuropsychopharmacology, Halifax, June 12-15, 1999. Symposium 7. Abstract. Page 34.

123) Chang KD, Steiner H, **Ketter TA**: Family environment of children and adolescents with bipolar parents. 3rd International Conference on Bipolar Disorder, Pittsburgh, June 17-19, 1999. Abstract 23. Bipolar Disorders 1999;1(Suppl 1):27.

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126) **Ketter TA**, Winsberg ME, Wong PW, Tate DL, Strong CM: Olanzapine in nonpsychotic bipolar disorders. 38th Annual Meeting of the American College of Neuropsychopharmacology, Acapulco, Mexico, December 13-17, 1999. Abstract. Page 166.

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IN PREPARATION

1) George MS, Greenberg BD, Maisog J, Barker C, **Ketter TA**: Statistical parametric mapping (SPM) of brain SPECT images. Eur J Nuc Med (Submitted 12/93)

2) Huggins T, **Ketter TA**, George MS, Reus V, Post RM: Spatial ability in affective illness: cognitive style testing. Neuropsychiatry Neuropsychol Behav Neurol (Submitted 12/93)

3) George MS, Cloninger CR, Kimbrell TA, Willis MW, Parekh PI, Danielson A, **Ketter TA**, Herscovitch P, Post RM: Toward the neurobiological basis of temperament: PET studies of Cloninger's tridimensional scale in healthy adults..

4) **Ketter TA**, Winsberg ME, Dunai M, DeGolia SG, Tate DL, Strong CM: Developing a lithium to divalproex switch algorithm in bipolar disorder patients. Abstract.

5) Little JT, **Ketter TA**, Kimbrell TA, Dunn RT, Danielson, A, Benson BE, Willis MW, Post RM: Changes in regional cerebral blood flow by ^{15}O PET with treatment response to venlafaxine versus bupropion monotherapy in outpatients with unipolar depression.

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Grants, Awards, and Research Experience:

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9/84 - 2/90	Clinical psychopharmacology sub-investigator in depressive disorders, Psychiatric Research Unit, Harborview Medical Center and University of Washington (PI - D. Dunner, MD)
3/85	Principal Investigator, Biomedical Research Support Grant from University of Washington for the study of treatment response to various antidepressants and placebo
8/87	Travel fellowship from the American College of Neuropsychopharmacology (ACNP)
10/88	Principal Investigator, ECT vs. pharmacotherapy in psychotic depression (R01 application, approved, not funded)
1/89-12/89	Co-Investigator, Sleep changes in Early Alzheimer's Disease (PI- Patricia Prinz, PhD, MHR01-33688)
3/91 - 10/91	Principal Investigator, The Washington Institute for Mental Illness Research and Training Grant for TRH in ECT and ECS

1/92 - 12/92	Principal Investigator, The Alcohol and Drug Abuse Institute, University of Washington, Grant for TRH in cognitively impaired alcoholics
6/94	Principal Investigator, Treatment of Depression Using Low-level Electrical Current or Alternating Magnetic Fields (patent filed)
3/90 - Present	*Principal Investigator* *Phase I, II and III Psychopharmacology Studies in depression, anxiety, insomnia, bipolar mood disorder, schizophrenia, Alzheimer's Disease, migraine, irritable bowel syndrome, PTSD, social phobia, pediatric depression, pediatric bipolar mood disorder*
3/01 Present	Extramural Reviewer, SBIR proposals, Ad Hoc committees NIMH

Academic Memberships and Related Activities:

American Medical Association
American Psychiatric Association
American College of Clinical Psychopharmacology
King County Medical Society

Journal Reviewer:

American Journal of Psychiatry
Archives of General Psychiatry
Biological Psychiatry
Convulsive Therapy
International Journal of Neuropsychopharmacology
Journal of Clinical Psychopharmacology
Journal of General Internal Medicine
Journal of Nervous and Mental Disease
Journal of Psychiatric Research
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Publications:

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2. Khan A, Hornblow A and Walshe JWB. Benzodiazepine dependence: a general practice survey. *New Zealand Medical Journal* 94: 19-21, 1981.
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12. Dager S, Khan A, Comess K, Raisys V and Dunner DL. Mitral valve abnormalities and catecholamine activity in anxious patients. *Psychiatry Research* 20: 13-18, 1987.
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14. Dunner DL, Myers J, Khan A, Avery D, Ishiki D and Pyke R. Adinazolam - a new antidepressant: findings of a placebo controlled, double-blind study in outpatients with major depression. *Journal of Clinical Psychopharmacology* 7: 170-172, 1987.
15. Khan A, Cohen S, Stowell M, Capwell R, Avery D and Dunner DL. Treatment options in severe psychotic depression. *Convulsive Therapy* 3: 93-99, 1987.
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21. Solan W, Khan A, Avery D and Cohen S. Psychotic and nonpsychotic depression: comparison of response to ECT. *Journal of Clinical Psychiatry* 49: 97-99, 1988.
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75. Khan A and Leventhal R. Medical aspects of capital punishment executions. *Journal of Forensic Medicine* (In Press, 7/2002).
76. Cohen S, Fitzgerald B, Okos A, Khan S, Khan A. Weight, lipid, glucose and behavioral measures with ziprasidone treatment in a population with mental retardation. *Journal of Clinical Psychiatry* (In Press).
77. Khan A, Khan S, Brown WA. Are placebo controls necessary to test new antidepressants and anxiolytics? *International Journal of Neuropsychopharmacology* (In Press, 9/2002)
78. Khan A, Detke M, Khan S and Mallenkrodt C. Placebo response and outcome among Antidepressant clinical trials. *Journal of Nervous and Mental Disease* (In Press).
79. Storosum J, van Zweiten B, Khan A, Wohlfarth T, de Haan L, van der Brink W. Suicide risk in placebo-controlled trials for schizophrenia. Submitted for publication (October 2001).

Abstracts, Book Reviews, and Other Publications:

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12. Khan A. Acute treatment of psychotic depression. Clinical Advances in the Treatment of Psychiatric Disorders 2; 4: 4, 1988.
13. Khan A and Dunner DL. Study group participant on placebo response at the 27th Annual Meeting of the American College of Neuropsychopharmacology, (Abstract, p. 56), 1988.
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24. Khan A. Book review on "Electroconvulsive Therapy" by Richard Abrams, Second Edition. *Journal of Nervous and Mental Disease* 181: 592, 1993.
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31. Khan A, and Montgomery N. Seizure Inhibition Syndrome. Annual Meeting of the Association for convulsive Therapy, 1995 (Abstract in Convulsive Therapy, p. 70).
32. Khan A. Overall safety profile of venlafaxine: a commentary. An invited abstract for Psychiatry Digest, February, 1997 (Abstract p. 27-28).
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36. Cookson J, Khan A, Asnis P et al . Profile of antidepressant activity of lamotrigine (Lamictal) in Bipolar and Unipolar Depression: Results from double-blind, placebo-controlled studies. 12th Annual meeting of the European College of Neuropsychopharmacology (Abstract), September 1999.
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45. Khan A, Khan SR, Brown WA. Do psychotropics reduce suicide risk? 40th Annual Meeting of the American College of Neuropsychophamacology (#159, p. 186), 2001
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47. Bowden C, Ghaemi N, Gyulai L, Huey L, Khan A, Montgomery P and Ascher, J. lamotrigine delays mood episodes in recently depressed bipolar I patients. Annual meeting of American Psychiatric Association, 2002 (in press)

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September 6, 2002

STATE OF WASHINGTON

HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

THIS CERTIFIES THAT THE PERSON OR ESTABLISHMENT NAMED HEREON IS AUTHORIZED AS PROVIDED BY LAW AS A

PHYSICIAN AND SURGEON

ACTIVE

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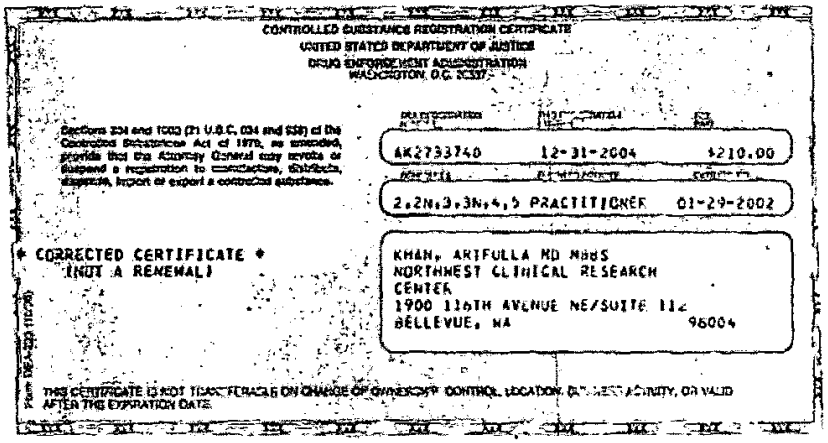
SECRETARY

NUMBER		DATE ISSUED	EXPIRATION DATE
025209	MD00021545	05-09-84	02-03-03



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UNITED STATES DEPARTMENT OF JUSTICE
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CURRICULUM VITAE

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Licensure

Washington Medical License	MD00033603
DEA Number	BK3018579

Associated Sites

Private Practice	BHC Fairfax Hospital
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Kirkland, WA 98033	Kirkland, WA 98034

Research Experience

A Multicenter, Double-blind, Randomized Comparison of the Efficacy and Safety of XXXXX and Placebo in the Treatment of Patients with Schizophrenia

A Placebo-Controlled 12 week Study of the Safety and Efficacy of Two Doses of XXXXX Versus Placebo for the Treatment of Acute Manic or Mixed Episodes in Subjects with Bipolar I Disorder with an Optional Open-Label Extension

A Multicenter, Double-blind, Randomized Comparison of the Efficacy and Safety of XXXXX and XXXXX in the Treatment of Patients with Schizophrenia

A Randomized, Double-Blind, Multiple Dose Study of the Relative Bioavailability And Tolerability of a Slow-Release Formulation of XXXXX in Patients With Schizophrenia or Schizoaffective Disorder

The Effect of XXXXX on Bone Mineral Density in Pediatric Subjects with Anorexia Nervosa: A Double-Blind, Placebo Controlled Study

A Multicenter, Double-Blind, Placebo-Controlled Comparison of the Efficacy and Safety of Extended-Release XXXXX and Placebo Administered for Eight Weeks for the Treatment of Adult Outpatients with Major Depressive Disorder and the Symptoms of Decreased Energy, Pleasure, and Interest

An Open-Label Study Assessing XXXXX with Major Depressive Disorder who Discontinued Treatment with XXXXX or a XXXXX due to Intolerability

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of XXXXX in Children and Adolescents Aged 6-17 with Attention Deficit Hyperactivity Disorder (ADHD)

A Phase III, Open-Label Study of XXXXX in Children and Adolescents (aged 6-17) with Attention Deficit Hyperactivity Disorder (ADHD)

A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Double-Dummy Trial of the Use of XXXXX in the Treatment of Patients with Bipolar Depression

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel, Phase III Study Comparing the Efficacy of XXXXX with Placebo, Utilizing a 6-Week Acute Phase and an Optional 26-Week Open-Label Phase, on Adolescent Patients Age 13-17 Years Who Meet the Diagnostic Criteria for Schizophrenia According to the DSM-IV-TR

A Phase III, Randomized , Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of XXXXX in Adolescents Aged 13-17 with Attention Deficit Hyperactivity Disorder (ADHD)

An assessment of the efficacy and safety of two sublingual doses of XXXXX in subjects with schizophrenia (in an acutely exacerbated state) compared to placebo in a multicenter randomized, double-blind, fixed-dose, 6-week trial with a XXXXX positive control group.

Education

Fellowship: Child and Adolescent Psychiatry — 06/93-06/95
Los Angeles County/University of Southern California Medical Center
Los Angeles, CA

Residency: Adult Psychiatry — 06/90-06/93
Los Angeles County/University of Southern California Medical Center
Los Angeles, CA

Medical School — 09/85-06/90
University of Washington School of Medicine, Seattle, WA

B.A. Zoology — 09/80-06/83
University of Washington, Seattle, WA

Undergraduate — 09/78-06/80
Washington State University, Pullman, WA

Professional Experience

Private Practice — 06/96-Present
512 6th Street South, Suite 101
Kirkland, WA 98033

Consulting Psychiatrist for Behaviorally Disturbed Students — 02/00-Present
Fairfax Hospital-Fairfax School
Kirkland, WA

Medical Director of Child and Adolescent Service — 06/96-03/99
Fairfax Hospital
Kirkland, WA

Attending Physiatrist Van Nuys Psychiatric Hospital Van Nuys, CA	09/95-05/96
Psychiatrist Psychiatric Admissions/Consultant LAC/USC Medical Center	11/91-5/96
Consulting Psychiatrist Optimist Youth Home Los Angeles, CA	06/94-05/96

Certification

American Board of Psychiatry and Neurology — 01/96
Certificate No. 42103

10/28/03

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EDUCATION:

1976–1981	Clinical Clerkships and Medical School Institute of Medicine (I) Burma Degree: M.D.
1973 –1976	Pre-medical Training Institute of Medicine (I) Burma

INTERNSHIP:

1981–1982	Rotating Internship Clinical Intern at the Departments of Medicine, Surgery, Pediatrics, Obstetrics, and Gynecology Rangoon General Hospital, Burma

RESIDENCY:

1992–1993	Psychiatric Chief Resident (PGY IV) Nassau County Medical Center State University of New York, Stonybrook East Meadow, New York
1989–1992	Psychiatric Resident (PGY I-III) Nassau County Medical Center State University of New York, Stonybrook New York, New York
1988–1989	Psychiatric Clinical Research Fellow Albert Einstein College of Medicine / Montefiore Medical Center Bronx, New York

LICENSURE:

California State Physician and Surgeon
License Number: A52179
Expiration Date: January 31, 2003

CERTIFICATION:

American Board of Psychiatry and Neurology: Board Eligible

CURRENT POSITION:

2000 – Present	Principal Investigator/Psychiatry Protocare Trials Irvine Center For Clinical Research Irvine, California
1999 – Present	Sub Investigator/Psychiatry Protocare Trials Irvine Center for Clinical Research Irvine, California

PROFESSIONAL EXPERIENCE:

1995 – 2000	Staff Psychiatrist General Psychiatry (Outpatient) Newport PsychCare Clinic Newport Beach, California
1993 – 1996	Staff Psychiatrist General Psychiatric Unit (In-patient) Orange County Community Hospital Buena Park, California

TEACHING AND ADMINISTRATION:

1992–1993	Member of Council of Chief Residents, Resident Selection Committee, Utilization Review and Quality Assurance, Pertinence Review Committees Nassau County Medical Center, New York
1991–1992	Resident Representative of Hospitality Committee Nassau County Medical Center, New York
1990–1993	Preceptor to junior residents and medical students State University of New York Stonybrook, New York

CLINICAL RESEARCH EXPERIENCE:

1. XXXXX versus Placebo in the Treatment of Generalized Anxiety Disorder.
   Principal Investigator

2. XXXXX versus Placebo in Posttraumatic Stress Disorder.
   Principal Investigator

3. XXXXX versus Placebo in the Treatment of Major Depression. (a)
   Principal Investigator

4. XXXXX Versus Placebo in the Treatment of Major Depression.(b)
   Principal Investigator

5. XXXXX Versus Placebo and XXXXX in the Acute Treatment of Major Depression
   Principal Investigator

6. Efficacy Study of XXXXX in Patient With Panic Disorder
   Subinvestigator

7. Dose Finding Study in Patients With Major Depressive Disorder
   Subinvestigator

8. Monitor Long Term Safety of XXXXX in Major Depressive Disorder
   Subinvestigator

9. XXXXX Versus Placebo in Treatment of Major Depressive Disorder Resistant to XXXXX.
   Principal Investigator

10. Sustained Efficacy Study of XXXXX in Patients With Panic Disorder With or Without Agoraphobia.
    Principal Investigator

11. A Seven-Week, Multicenter Study to Examine Study Drug in Patients with Major Depressive Disorder Receiving XXXXX or XXXXX.
    Principal Investigator

12. Open Label XXXXX Rescue and Continuation Therapy
    Principal Investigator

13. Double Blind, Multicenter, Dose Finding Acute and Extension Study of XXXXX Versus XXXXX and Placebo in the Treatment of Outpatients with Major Depressive Disorder.
    Principal Investigator

14. Multicenter, 10 Week, Randomized, Double Blind, Placebo Controlled Flexible Dose, Outpatient Study of XXXXX in Children and Adolescents with Major Depressive Disorder
    Principal Investigator

15. Multicenter, 24-Week Open Label Extension Study of XXXXX in Children and Adolescent Outpatients Previously Diagnosed with Major Depressive Disorder.
    Principal Investigator

16. XXXXX Versus Placebo in Childhood/Adolescent Depression
    Subinvestigator

17. Double Blind, Placebo Controlled Comparative Efficacy Study of XXXXX and XXXXX in Producing Remission in Outpatients with Major Depressive Disorder.
    Principal Investigator

18. Double Blind, Placebo-Controlled Study of XXXXX in Children and Adolescents with Generalized Anxiety Disorder.
    Sub-Investigator

19. A Randomized, Open Label, Parallel Groups, Outpatient Study To Examine the Long Term Safety and Tolerability of XXXXX for the Acute Treatment of Migraine in Adolescents.

Sub-Investigator

20. A Phase II Randomized, Multicenter, Placebo-And-Active Controlled Study of Oral XXXXX in Subjects With Major Depressive Disorder.
Principal Investigator

21. Phase III Contraception Study of XXXXX Subcutaneous Injection in Women of Childbearing Potential in the Americas (Including a Bone Mineral Density Substudy Comparing the Effects of XXXXX) Also Including a Return of Ovulation Substudy.
Sub-Investigator

22. A Double-Blind, Placebo Controlled, Parallel Group, Flexible-Dose Study of XXXXX Extended Release Capsules in Adult Outpatients with Panic Disorder
Principal Investigator

23. A Multicenter, Randomized, Double-Blind, Placebo Controlled Parallel – Group Trial To Assess the Efficacy of Oral XXXXX 2.5mg in the Acute Treatment of Migraine During the Mild Intensity Phase of an Attack in Patients Highly Disabled by Migraine (MIDAS Grades III or IV)
Sub-Investigator

24. Flexible Dose Comparison of the Safety and Efficacy of XXXXX and Placebo in the Treatment of Generalized Anxiety Disorder. # 3570
Principal Investigator

25. A Randomized, Double-Blind, Placebo Controlled Parallel, Two-Week Efficacy and Safety of XXXXX in Subjects with Primary Insomnia. # 3703
Sub-Investigator

26. A Long Term Extension Study to Evaluate the Safety of Oral XXXXX in Subjects with Major Depressive Disorder. # 2927x1
Principal Investigator

27. A 12 Week Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Flexible Dosing of XXXXX at 500 to 1500 mg B.I.D. in the Treatment of Subjects With Painful Diabetic Neuropathy. #3612
Sub-Investigator

28. A Phase III , Vehicle-Controlled Study of XXXXX XXXXX Applied 2 Times per Week for 1 Week for Each Recurrence of Herpes Genitalis Over 12 Months. # 3685
Sub-Investigator

29. Efficacy and Safety of a Flexible Dose of XXXXX versus Placebo in the Treatment of Psychosis in Alzheimer's Disease (#3583)
Principal Investigator

30. A Well Controlled Safety and Efficacy Study of XXXXX in Subjects with Mild to Moderate Alzheimer's Disease (#3261)
Principal Investigator

31. A Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Effects of XXXXX 200 mg q.d., XXXXX 200 mg b.i.d. and Placebo in Patients With Treated Hypertension. (#3676)
Sub-Investigator

32. A Dose Ranging Study of XXXXX in Patients With Primary Hypercholesterolemia.

(# 3518)
Sub-Investigator

33. A 12-Week, Randomized, Parallel, Double-Blind, Placebo-Controlled, Multicenter Study of the Safety and Efficacy of 4 Doses of XXXXX in Patient With Type 2 Diabetes (#3576)
Sub-Investigator

34. A Randomized, Double-Blind, Multicenter Study Comparing the Glycemic Control Characteristics of XXXXX and XXXXX in Hypertensive Patients with Type II Diabetes Mellitus. (#3535)
Sub-Investigator

35. A Randomized, Double Blind, Placebo Controlled, Parallel Group Study to Evaluate the Safety and Impact on Quality of Life of 12 Weeks of XXXXX Therapy at Dosages of 200 and 300 mg Once Daily as Treatment for Adults With Excessive Sleepiness Associated with Shift Work Sleep Disorder, Followed by a 12-Month Open-Label Extension Period. (# 3643a1)
Principal Investigator

36. A Double Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study Evaluating Three Dose Regimens of XXXXX, A Selective Alpha-Adrenergic Antagonist, In The Treatment of Benign Prostatic Hyperplasia (#3750)
Sub-Investigator

37. A Phase III, Double-Blind, Randomized, Placebo Controlled Study of XXXXX in Severely Obese Subjects. (#3696)
Sub-Investigator

38. An Open-Label Extension Study of the Safety and Efficacy of XXXXX in Patients With Generalized Anxiety Disorder. (#3597)
Principal Investigator

39. A Double-Blind, Randomized, Placebo-Controlled, 3-Month Clinical Trial of XXXXX and XXXXX in the Treatment of Post Traumatic Stress Disorder (#3536)
Principal Investigator

40. A 13-Week, International, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel Group Trial Assessing the Safety and Efficacy of 2 Doses of XXXXX (200 mg and 400mg od) in Patients With Primary Knee Osteoarthritis, Using XXXXX (200 mg od) as a Comparator. (# 3753) Sub-Investigator

41. A Phase III, Double-Blind, Randomized, Parallel Study Evaluating the Efficacy and Safety of XXXXX (xxxxx HCl tablets) Sublingual (2 and 3 mg) In the Treatment of Male Erectile Dysfunction. (#3806) Sub-Investigator

42. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXXX in Subjects With Acute Migraine Attack. (#3844) Sub-Investigator

43. A Double-Blind, Placebo-Controlled, Parallel Group, Dose Response Study to Evaluate the Efficacy and Safety of XXXXX Versus Placebo in the Treatment of Pain Associated with Diabetic Peripheral Polyneuropathy.(#1711) Sub-Investigator

44. Double-Blind, Placebo-Controlled, Parallel Group, Dose Ranging Comparison of the Efficacy and Safety of Controlled Release XXXXX and Placebo in the Treatment of Osteoarthritis of the Knee and/or Hip (#3881) Sub-Investigator

45. A Multicenter, Open-Label Study to Evaluate the Safety and Efficacy of XXXXX/XXXXX as an Oral Contraceptive (#2390) Sub-Investigator

46. Double-Blind, Placebo-Controlled Study of Sustained Release XXXXXX in Subjects with Symptoms of Overactive Bladder of Urgency, Frequency, and Urinary Incontinence (#3641) Sub-Investigator

47. A 6-Week, Double-Blind, Randomized, Multicenter, Fixed-Dose, Placebo-Controlled Study of XXXXX Dosed Once a Day in Patients With Generalized Anxiety Disorder (#3791) Principal Investigator

48. Evaluation of Safety and Efficacy of XXXXX in the Treatment of Chronic Pain in Patients With Painful Diabetic Neuropathy (#3758) Sub-Investigator

49. A Double-Blind, Randomized, Placebo-Controlled, 3-Month Clinical Trial of XXXXX and XXXXX in the Treatment of Post Traumatic Stress Disorder (#3635) Principal Investigator

50. A Double-Blind, Multicenter, Randomized, Parallel Group, Phase III Study to Evaluate the Safety and Efficacy of XXXXX in Comparison to XXXXX in Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM) (#2867) Sub-Investigator

51. A Double-Blind, Randomized, Placebo and Active Controlled, Parallel Group, Dose-Finding Study to Evaluate the Efficacy and Safety of Once Daily Dose Oral Administration of 5 mg, 10 mg, 25 mg and 50 mg of XXXXXX for 8 Weeks in Subjects With Mild to Moderate Essential Hypertension (# 3913) Sub-Investigator

52. A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of XXXXX in Patients With Generalized Anxiety Disorder (GAD) (#3971) Principal Investigator

53. A Phase III, Double-Blind, Randomized, Placebo Controlled Study of XXXXX in Overweight and Obese Subjects With a 12-month Open-Label Extension Phase. (#3696) Sub-Investigator

54. A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Continuation of Benefit of Two Dosages of XXXXX Complex for the Prophylactic Treatment of Migraine Headaches. (#2372x2) Sub-Investigator

55. A Prospective, Multinational, Double-Blind, Randomized, Active Controlled Trial in Patients With Essential Hypertension to Compare the Effect of XXXXX 80 mg and 160 mg, With or Without the Addition of XXXXX, One Daily to That of XXXXX 5 and 10 mg once daily, With or Without the Addition of XXXXX, on Cardiovascular Morbidity and Mortality. (#2338) Sub-Investigator

56. A Multicenter, Prospective, Randomized, Double-Blinded, Parallel Group Study Comparing the Effects of XXXXX (5/20 mg) to XXXXX (5mg) and XXXXX (20mg) on Systolic Blood Pressure and Pulse Pressure in Patients with Systolic Hypertension. (#3980) Sub-Investigator

57. A Multi-Center, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Lipid-Altering Efficacy, Safety and Tolerability of XXXXX When Added to Ongoing Therapy with an HMG-CoA Reductase Inhibitor in Patient With Primary Hypercholesterolemia, Known Heart Disease or Multiple Cardiovascular Risk Factors (#3452) Sub-Investigator

58. A Double-Blind, Multicenter, Placebo- and Active- Controlled Acute and Extension Study of XXXXX in the Treatment of Major Depressive Disorder With Melancholic Features (#3925) Principal Investigator

59. 12 Week, Multinational, Multicenter, Controlled, Open, 1:1:1 Randomized, Parallel Clinical Trial to Assess Noninferiority Between Pre and Post-Meal Administration of XXXXX and Pre-Meal Regular Human Insulin in Subjects With Type 1 Diabetes Mellitus Receiving Insulin XXXXX as the Basal Insulin Therapy (# 3974) Sub-Investigator

60. Clinical Protocol For A Double-Blind, Randomized, Parallel Group Comparison Study of the Safety of XXXXX Vs XXXXX in Treated Hypertensive Patients With Osteoarthritis (# 3871) Sub-Investigator

61. A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of Evaluating Efficacy and Safety of Three Doses of XXXXX (5mg, 10mg, and 20mg) Versus Placebo in Patients With Major Depressive Disorder (# 3920) Principal Investigator

62. A Randomized, Double-Blind, Comparator-Controlled Study of XXXXX Vs XXXXXX in the Treatment of Subjects With Type 2 (Non-Insulin Dependent) Diabetes Mellitus and Mild Cardiac Disease (NYHA1) (#4055) Sub-Investigator

63. A Phase III, Open-Label Safety and Efficacy Study of XXXXX in Outpatients with ADHD, Ages 6 to 18 Years. (#2474) Principal Investigator

64. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study of Weight-Reducing Effect and Safety of XXXXX in Obese Patients With Untreated Dyslipidemia (#3813) Sub-Investigator

65. Systolic and Pulse Pressure Hemodynamic Improvement by Restoring Elasticity (#3783a1) Sub-Investigator

66. A Phase II, Randomized, Double-Blind, Placebo-Controlled Dose Ranging Study to determine the Efficacy, Safety, Tolerability and Pharmacokinetic of XXXXX in Patients With Type 2 Diabetes Mellitus (# 3833) Sub-Investigator

67. A Randomized, Double-Blind, Placebo-Controlled, Single-Attack, Parallel Group Evaluation of the Efficacy of XXXXXX 50 mg Tablets versus Placebo in the Treatment of Self-Described and/or Physician Diagnosed Sinus Headaches that Meet International Headache Society (IHS) Criteria for Migraine Headaches (# 4147) Sub-Investigator

68. Open-Label Extension Study of Sustained Release XXXXX in Subjects With Symptoms of Overactive Bladder (# 3641x1) Sub-Investigator

69. A 52-Week, Open-Label, Multicenter Study of the Long-Term Safety and Efficacy of XXXXX 200 mg T.I.D. in Patients With Constipation-Predominant and Alternating-Type Irritable Bowel Syndrome (# 4159) Sub-Investigator

70. A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel Group, Multicenter Study With a Withdrawal Phase to Investigate the Safety and Efficacy of XXXXX 200 mg T.I.D. or 200 mg B.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome (# 3633) Sub-Investigator

71. Long-Term, Open-Label, Safety Study of XXXXX in Patients 6 Years and Older (# 3552) Principal Investigator

72. Evaluation of Atherosclerotic Outcomes with XXXXXX Therapy (# 3832) Sub-Investigator

73. A Multicenter, Double-Blind, Randomized, Placebo-and Active-Controlled, Parallel Study to Evaluate the Lipid Altering Efficacy and Safety of XXXXX in Patients with Metabolic Syndrome and Dyslipidemia. (#4011) Sub-Investigator

74. Efficacy and Safety of XXXXX in Patient with Probable Alzheimer's Disease (#3822) Principal Investigator

75. Efficacy and Safety of XXXXX in Patients with Mild Cognitive Impairment (#3823) Principal Investigator

76. A Randomized, Double-Blind, Placebo-Controlled, Two-Year Parallel-Group Study to Evaluate the Efficacy and Safety of XXXXX in the Treatment and Modification of Progression of Benign Prostatic Hyperplasia, Followed by a Two-Year Open-Label Treatment Phase. (#2328) Subinvestigator

77. A Phase III/IV Extension – A Phase III, Parallel, Randomized, Multicenter, Open-Label Clinical Study to Evaluate the Safety of XXXXX Extended Oral Contraceptive Therapy – 84-Day Active Cycle (#2745x1) Subinvestigator

78. A Double-Blind, Placebo-Controlled, Parallel Group Design Dose-Ranging Study of Three Doses of XXXXX vs. Placebo for the Treatment of Sexual Dysfunction (Arousal Disorder) in Postmenopausal Women (# 4100) Principal Investigator

79. A Double-Blind, Placebo-Controlled, Parallel Group Design Dose-Ranging Study of Three Doses of XXXXX vs. Placebo for the Treatment of Sexual Dysfunction (Hypoactive Disorder) in Postmenopausal Women (#4101) Principal Investigator

80. A Multicenter, Eight-Week Treatment, Single Step Titration, Open-Label Study Assessing the Percentage of Patients Achieving Low Density Lipoprotein Cholesterol Target with XXXXX Starting Doses of 10 mg, 20 mg, 40 mg, and 80 mg.(# 4168) Sub-Investigator

81. A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of XXXXX Tablets in Patients with Primary Hypercholesterolemia (# 3713) Sub-Investigator

82. A Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXXXX Versus Over-Encapsulated XXXXX in Subjects with Acute Migraine Attacks (#4293) Subinvestigator

83. A Phase III, Multi-Center, Randomized, Double-Blind, Parallel Group Study of XXXXX 20 mg, XXXXX 40 mg and Placebo in Patients with Multiple Moderate or Severe Acute Migraine Headaches (# 3695) Subinvestigator

84. A Randomized, Double-Blind, Dose Ranging, Placebo-Controlled Trial to Determine the Lipid-Lowering Efficacy and Safety of XXXXX Alone and in Combination with XXXXX in Subjects with Mixed Dyslipidemia (# 4204) Subinvestigator

85. A Multi-Center, Eight-Week Treatment, Single Step Titration, Open-Label Study Assessing the Percentage of Patients Achieving Low Density Lipoprotein Cholesterol Target with XXXXX Starting Doses of 10mg, 20mg, 40mg and 80mg (#4168) Sub-Investigator

86. A Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXXXX Versus Over-Encapsulated XXXXX in Subjects with Acute Migraine Headaches (#4293) Sub-Investigator

87. A Phase III, Randomized, Multicenter, Clinical Trial to Evaluate the Efficacy and Safety of Combination Oral Contraceptive Regimens Utilizing Ethinyl Estradiol During the Pill-Free Interval for Prevention of Pregnancy in Women. (#4330) Sub-Investigator

88. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety of the Hormone Replacement Therapy Combination Drug Product XXXXX in Postmenopausal Women with Concomitant Disease and Medication Known to Potentiate the Risk of Hyperkalemia. (#4300) Sub-Investigator

2002

89. A Randomized, Double-Blind, Multi-Center Study to Assess the Safety of Long-Term Administration of Two Dose Levels of XXXXX in Patients with Primary Insomnia. (#3930) Sub-Investigator

90. A Randomized, Double-Blind, Multi-Center, Fixed-Dose, Cross-Over Study to Investigate the Efficacy and Safety of 20mg of XXXXX Given on Demand in Comparison to 100mg of XXXXX Given on Demand in Males with Erectile Dysfunction and a Diagnosis of Diabetes Mellitus and/or Hypertension and/or Hyperlipidemia. (#3521) Sub-Investigator

91. An Open Label Study of Topical XXXXX 0.01% Gel Applied 2 Times per Week for 3 Weeks for Each Recurrence of Herpes Genitalis over 52 Weeks. (#4347) Sub-I

92. Randomized, Double-Blind, Parallel Groups, Multicenter Study to Compare the Efficacy and Safety of Monthly Oral Administration of 100mg and 150mg XXXXX with 2.5 mg Daily Oral XXXXX in Postmenopausal Osteoporosis. (#4267) Sub-I

93. Randomized, Double-Blind, Parallel Groups, Multicenter Study to Compare the Efficacy and Safety of Two IV XXXXX Dose Regimens (2mg q 2 mo., 3mg q 3mo.) with 2.5mg Daily Oral XXXXX in Postmenopausal Osteoporosis. (#4266) Sub-I

94. A Multicenter, Double-Blind, Randomized, Parallel Group, 28-Week Study to Evaluate the Efficacy and Safety of XXXXX and XXXXX Co-Administration Versus XXXXX in Patients with Hypercholesterolemia. (#4223) Sub-I

95. An Open-Label Extension of Study DEX-MD-02A to Investigate the Long-Term Safety and Efficacy of XXXXX 200mg T.I.D. in Female Patients with Constipation-Predominant Irritable Bowel Syndrome. (#3663x1) Sub-I

96. A Multinational, Randomized, Double-Blind, Parallel Group, Placebo Controlled 24 Week Study to Evaluate the Efficacy and Safety of Transdermal Testosterone (300 μg/day) in Women with Hypoactive Sexual Desire Disorder on Concurrent Estrogen Replacement Therapy Who Have Undergone Hysterectomy and Bilateral Oophorectomy. (#1727) Sub-I

97. A Multinational, Randomized, Double-Blind, Parallel Group, Placebo-Controlled 24-Week Study to Evaluate the Efficacy and Safety of Transdermal Testosterone (300μg/day) in Naturally Menopausal Women with Hypoactive Sexual Desire Disorder on Concurrent Oral Hormone Replacement Therapy. (#4337) Sub-I

98. A Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate Two Dose Levels (5mg and 20mg) of XXXXX Nasal Spray in the Acute Treatment of a Single Migraine Attack in Adolescent Migraineurs (12-17 Years of Age). (#4452) Sub-I

99. A Randomized, Double-Blind, Placebo-Controlled Study Evaluating Acetaminophen Extended Release (1950 mg/day and 3900 mg/day) in the Treatment of Osteoarthritis of the Hip or Knee. (#3993) Sub-I

100. A Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of XXXXX Including 3-Months of Initial Drug Dosing, a 9-Month Off-Drug Treatment Period, and a 3-Month Re-Exposure Followed by a 3-Month Crossover in Overweight and Obese Subjects. (#4456) Sub-I

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07/30/1993

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Study Code	5077US/0049
Country	USA
Centre No.	0025

Curriculum Vitae

Please complete this form in English

First and family name	Leon Rubenfaer, MD
Present position	Principal Investigator/Medical Director
Address (Full office address incl. postal/zip code)	33497 23 Mile Rd, Suite #110 New Baltimore, MI 48047
Medical education	
Name of school	Wayne State University-College of Medicine
City, Country	Detroit, MI
Duration of education	4 year(s), month(s)
Degree attained	MD
Education completed in year	1966
Physician's reference/license number (if applicable)	4301027683 Physician License # for State of Michigan
Postgraduate training	
Type of training	Rotating Internship
Name of institution	Sinai Hospital of Detroit
City, Country	Detroit, MI-US
Duration of training	1 year(s), month(s)
Degree attained	
Training completed in year	1967
Type of training	Psychiatric Residency
Name of institution	Sinai Hospital of Detroit
City, Country	Detroit, MI-US
Duration of training	3 year(s), month(s)
Degree attained	
Training completed in year	1970
Type of training	
Name of institution	
City, Country	
Duration of training	year(s), month(s)
Degree attained	
Training completed in year	

Publications
(number of written publications in relevant area(s) of research)

Experience of clinical research 12 studies sponsored by the pharmaceutical industry
(number of clinical studies sponsored by the pharmaceutical industry to which the individual has contributed)

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Curriculum Vitae

Full Name: **David M. Marks, M.D.**
Credentials: **Board-Certified in Psychiatry**
Position Title: **Medical Director/C.E.O.**
Address: **Optimum Health Services**
7200 Parkway Drive, Suite 116
La Mesa, CA 91942
Telephone Number: **619-667-4567**
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Facsimile Number: **619-667-4568**

9/10/02

Education:

Institution & Location	Degree	Year Conferred	Field of Study
University of California at San Diego San Diego, CA	**Fellowship**	**1999 - 2000**	**Consultation and Liaison Psychiatry**
Medical College of Pennsylvania / Clinical Neuroscience Research Unit Philadelphia, PA	**Senior Resident**	**1998 - 1999**	**Psychiatry**
University of California at San Diego San Diego, CA	**Resident**	**1995 - 1998**	**Psychiatry**
University of Texas Medical Branch Galveston, TX	**M.D.**	**1995**	
Rice University Houston, TX	**B.A.**	**1991**	**Psychology**

Research and Professional Experience:

Position	Institution/Employer & Location	Dates of Employment
Medical Director/C.E.O.	**Optimum Health Services, La Mesa, CA**	**10/00 - Present**
Assistant Medical Director	**Behavioral & Medical Research, LLC San Diego, CA**	**04/00 - 01/02**
Secretary/Treasurer of Medical Executive Committee	**Alvarado Parkway Institute La Mesa, CA**	**12/01 - Present**
Clinical Director of Intensive-Care Unit North	**Alvarado Parkway Institute La Mesa, CA**	**10/01 - Present**
Associate Medical Director	**Integrated Insights San Diego, CA**	**10/00 - Present**
Clinical Instructor	**UCSD Department of Psychiatry San Diego, CA**	**07/99 - Present**
Clinical Director of Research	**Alvarado Parkway Institute La Mesa, CA**	**01/01 - 10/01**
Medical Director	**Isis Center Short-term Residential Treatment Program San Diego, CA**	**08/99 - 04/00**
Director of Clinical Education	**Integra Managed Behavioral Health Care Organization San Diego, CA**	**09/98 - 06/99**
Staff Psychiatrist	**Charter Fairmount Institute Philadelphia, PA**	**09/98 - 06/99**

Staff Psychiatrist	**California Psychiatric Coverage San Diego, CA**	**10/97 - 07/98**
Staff Psychiatrist (volunteer position)	**St. Vincent De Paul Village San Diego, CA**	**12/97 - 06/98**
Instructor	**Psychopathology UCSD Medical School San Diego, CA**	**01/97 - 05/97**
Instructor	**DSM-IV for the Novice Practitioner UCSD Extension San Diego, CA**	**04/96**
Instructor	**Introduction to Patient Evaluation UTMB Medical School Galveston, TX**	**09/94 - 05/95**
Research Assistant	**Psychiatric Epidemiology Laboratory, UTMB Galveston, TX**	**05/91 - 08/91**
Research Assistant	**National Institutes of Health Student Research Forum, UTMB Galveston, TX**	**05/92 - 08/92**

Honors and Awards:
Fellowship to Explore Complementary Medicine, 1999
Journal of Clinical Psychiatry Resident Advisory Board, 1998
Commendation for Teaching, UCSD Department of Psychiatry, 1997
UTMB Clinical Pathology Conference Award, 1993; first place out of 200 medical students
National Merit Scholar, Rice University

Publications:
Marks, D.M. and Zisook, S., "Mood Disorders" in Psychiatry: Pearls of Wisdom, Boston Medical Publishing Corporation, 1999.

Clinical Trials Experience:

Principal Investigator on trials

A 6-Week, Double-Blind, Randomized, Fixed-Dose, Parallel-Group study of the Efficacy and Safety of Three Dose Levels of SM-13496 Compared to Placebo and Haloperidaol in Patients with Schizophrenia Who are Experiencing an Acute Exacerbation of Symptoms: Sumitomo Pharmaceuticals America, Ltd.

A Randomized, Open-Label, Dose-Blinded, Multicenter, 6-Month Study of Safety and Tolerability of 3 Dose Levels of SM-13496 in Patients with Schizophrenia: Sumitomo Pharmaceuticals America Ltd.

A Phase III, Three Week, Multicenter, Randomized, Double-Blind, Placebo Controlled, Parallel-Group Safety and Efficacy Study of Extended-Release Carbamazepine in the Treatment of Bipolar I Disorder: Shire Pharmaceutical Development Inc.

Nalfemene in the Treatment of Pathological Gambling. A Placebo-Controlled Dose-Response Study: Oy Contral Pharma Ltd.

Subinvestigator on trials

A Double-Blind, Randomized, Fixed-Dose, Placebo-Controlled, Parallel-Group, Six-Week Efficacy, Safety, and Tolerability Study of Two Dose Levels of SM-13496 in Patients with Schizophrenia by DSM-IV

Criteria who are Experiencing an Acute Exacerbation of Symptoms: Sumitomo Pharmaceuticals America Ltd.

Duloxetine vs. Placebo and Paroxetine in the Acute Treatment of Major Depression: Eli Lilly and Company.

Safety and Efficacy of Depakote as Combination Therapy in the Treatment of Psychosis Associated with Schizophrenia: Abbott.

A Randomized, Double-Blind, Placebo- and Risperidone-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Two Nonoverlapping Dose Ranges of Iloperidone Given b.i.d. for 42 Days to Schizophrenic Patients Followed by a Long-Term Treatment Phase with Iloperidone Given q.d.: Novartis Pharmaceuticals.

An Open-Label Randomized Assessment of The Efficacy and Tolerability of Venlafaxine Extended Release in Serotonin-Selective Reuptake Inhibitor (SSRI)-Failure Patients with Major Depression: Wyeth-Ayerst.

Fixed Dose Comparison of the Safety and Efficacy of LU 26-054, Citalopram, and Placebo in the Treatment of Major Depressive Disorder: Forest Laboratories.

An Open-Label Study of the Safety, Tolerability, and Efficacy of Up to 90 mg Buspirone HydrochlorideExtended Release in Patients with Generalized Anxiety Disorder: Biovail.

A Double-Blind, Placebo-Controlled, Fixed-Dose Study of Paroxetine CR Continuous Treatment (12.5mg and 25mg/day) for Premenstrual Dysphoric Disorder" Issue Date:27 August 1999; Modification No. 1:6 September 1999: Smith Kline Beecham.

A Phase III Randomized, Double-Blind Comparison of Placebo and Tomoxetine Hydrocholoride in Adult Outpatients with DSM-IV Attention-Deficit/Hyperactivity Disorder: Eli Lilly and Company.

A Long-Term, Open-Label Safety Study of Tomoxetine Hydrochloride in Adult Outpatients with DSM-IV Attention-Deficit/Hyperactivity Disorder: Eli Lilly and Company.

A Phase III Open-Label Safety and Efficacy Study of Tomoxetine Hydrochloride in Outpatients with ADHD, Ages 6 to 18 years: Eli Lilly and Company.

A Seven Week, Multi-Center Study to Examine Norepinephrine Transporter Inhibition in Patients with Major Depressive Disorder Receiving Paroxetine or Desipramine: Smith Kline Beecham.

Flexible Dose Comparison of the Safety and Efficacy of Lu 26-054 and Placebo in the Treatment of Generalized Anxiety Disorder: Forest Laboratories.

A Double-Blind, Placebo and Paroxetine Controlled, Multi-Center, Dose Ranging Study Evaluating the Efficacy and Safety of SR142801in Outpatients with Major Depressive Disorder: Sanofi.

A Phase 4, Multicenter, 6-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of PROVIGIL™ (Modafinil) at Individually Titrated Doses of 100, 200, 300, or 400 mg/day as Adjunctive Therapy in Patients With Major Depressive Disorder Who Have Demonstrated a Partial Response to Antidepressant Therapy for a Current Major Depressive Episode: Cephalon.

Evaluation of the Safety and Efficacy of Lu26-054 in the Prevention of Depression Recurrence: Forest Laboratories.

The Efficacy and Safety of Single Dosage Ranges of Risperidone vs. Placebo in the Treatment of Manic Episodes Associated with Bipolar I Disorder: Janssen Research Foundation.

A Nine-Week, Open-Label, Multi-Center, Safety Study of Single Dosage Ranges of Risperidone in the Treatment of Manic Episodes Associated with Bipolar I Disorder: Janssen Research Foundation.

A Phase 3 Open-Label Safety and Efficacy Study of Tomoxetine Hydrochloride in Pediatric Outpatients (6 to 18 Years) with ADHD: Eli Lilly and Company.

A Phase III Multi-Center Randomized Comparison of TAK-637 Versus Placebo in the Treatment of Subjects with Major Depressive Disorder: Tap Holdings, Inc.

A Double-Blind, Multicenter, Randomized, Placebo-Controlled, Parallel Group Study of Efficacy and Safety of ORG 33062 ER and Paroxetine in Subjects who suffer from Major Depressive Disorder with Atypical Features: Organon.

A Double-Blind, Multi-Center Extension Trial in Subjects who suffer from Major Depressive Disorder with Atypical Features who Participated in the Placebo-and Paroxetine-Controlled Study of ORG 33062 ER: Organon.

Placebo-Controlled Olanzapine Monotherapy in the Treatment of Bipolar I Depression: Eli Lilly and Company.

A Phase IIB Seven-Week Double-Blind, Placebo- and Paroxetine-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Oral CP-122,721 in Outpatients with Major Depressive Disorder and Associated Somatic Symptoms: Pfizer.

A Multicenter, Double-blind, Randomized Comparision of the Efficacy and Safety of Sustained-Release Formulation Quetiapine Fumurate (Seroquel TM) and Placebo in the Treatment of Patients with Schizophrenia: Astra Zeneca.

A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Galantamine in Subjects with Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Probable Alzheimer's Disease: Janssen Research Foundation.

A Double-blind, Placebo and Paroxetine Controlled, Multicenter, Dose Ranging Study Evaluating the Efficacy and Safety of SR142801 in Outpatients with Major Depressive Disorder.

Evaluation of the Safety and Efficacy of Escitalopram in the Prevention of Depression Recurrence Protocol SCTMD-11 Fixed Dose Continuation Study of Escitalopram in the Treatment of Depressed Nonresponders: Forest Laboratories.

Placebo-Controlled Olanzapine Monotherapy in the Treatment of Bipolar I Depression: Eli Lilly and Company.

The Assessment of Sibutramine for the Treatment of Olanzapine-Associated Weight Gain in Subjects with Schizophrenia, Schizophreniform Disorder, Schizoaffective Disorder, and Bipolar I Disorder: Eli Lilly and Company.

A Double Blind, Placebo-controlled, Parallel-group, Flexible-dose Study of Venlafaxine ER in Adolescent Outpatients with Social Anxiety Disorder: Wyeth-Ayerst.

A four-week double-blind, placebo and active controlled, dose-ranging study of SL 65.1498-00, 3 doses (5,15, and 50 mg QD) and lorazepam (3mg QD) in outpatients with Generalized Anxiety Disorder (GAD): Sanofi-Synthelabo.

A Randomized, Double-blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Memantine in Patients with Mild to Moderate Dementia of the Alzheimer's Type: Forest Laboratories.

A Multicenter, Randomized, Double-blind, Parallel Group, Multiple Dose Comparison Study of Valdecoxib 20mg, Valdecoxib 40mg, Sumatriptan 50mg and Placebo in Patients with Moderate or Severe Acute Migraine Headache. Pharmacia.

A Phase II, Randomized, Double-Blind, Palcebo-Controlled, Dose-Ranging Study of Fixed-Doses of Oral OPC-14523 and Prozac in the Treatment of Outpatients with Moderate Depression: Otsuka.

Multi-Center, Randomized, Double-Blind, Fluoxetine and Placebo-Controlled Study of the Efficacy and Safety of Remeron Soltab (Mirtazapine) Orally Disintegrating Tablets in Subjects with Major Depressive Disorder: Organon.

Topiramate Versus Placebo as Add-On Treatment of Subjects with Bipolar Disorder in the Outpatient Setting: Ortho-McNeil Pharmaceutical, Inc.

A Double-blind, Parallel-Group, Multicenter, Fixed-dose Study to Evaluate the Safety and Efficacy of Three Doses of INN 00835 in Subjects Diagnosed with Major Depressive Disorder. Innapharma, Inc.

A Phase IIB, Seven Week, Double-Blind, Placebo- and Paroxetine-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Oral CP-122,721 in Outpatients with Major Depressive Disorder and Associated Somatic Symptoms: Pfizer, Inc.

An Open-Label Pilot Study of Modafinil in Patients with Schizophrenia: Cephalon, Inc.

A Randomized, Open-Label, Rater-Blinded Assessment of Optimal Treatment Change Strategy to Risperdone for Patients Intolerant of Olanzapine (Risperdal rescue study): Janssen Pharmaceutica.

A Double-Blind, Placebo-controlled, Multicenter Study of the Long-Term Efficacy of MK-0869 in the Maintenance of Antidepressant Effect in Geriatric Outpatients with Major Depressive Disorder: Merck and Company.

Gregory Warren Mattingly, M.D.
CURRICULUM VITAE

PERSONAL DATA

Birth date:	September 24, 1963
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Greg Mattingly MD
9/19/02

EDUCATION

1981-1985	University of Missouri-Rolla; B.S. in Chemical Engineering
1985-1989	Washington University School of Medicine, St. Louis, Missouri ; M.D.
1989-1993	Resident, Department of Psychiatry Washington University School of Medicine

ACADEMIC DISTINCTIONS

1981-1985	National Merit Scholarship
	President's Scholar, University of Missouri-Rolla
1982-1985	Alpha Chi Sigma Honorary Chemistry Society President, 1984-1985
1985	Summa Cum Laude, B.S. Chemical Engineering

1986-1989	Fulbright Scholarship
1991	Academy of Child and Adolescent Psychiatry National Leadership Award, Charter Fellowship
1992	Upjohn Neuropsychiatry Research Award
1993	Southern Psychiatric Association Research Award

ACADEMIC APPOINTMENTS

1992-present	Journal of Neuropsychiatry and Clinical Neurosciences Reviewer
1993-present	Clinical Faculty, Department of Psychiatry Washington University School of Medicine
1995-present	Psychopharmacology Instructor Washington University School of Medicine

ADMINISTRATIVE APPOINTMENTS

1998-2000	Medical Director, Adolescent Services, St. Joseph Health Center
1998-2000	Regional Director, Adolescent Behavioral Medicine SSM Health Care
1998-present	Medical Director Hobart and Associates EAP
1998-present	Medical Review Board, Blue Cross Blue Shield of Missouri
2000-present	Medical Review Board, Health Link Insurance Corporation
2001-present	Medical Director Adult Behavioral Medicine St. Joseph Health Center
2001-present	SSM Health Care Managed Care Contract Board
2002-present	Chairman, Department of Psychiatry St. Joseph Health Center

BOARD CERTIFICATIONS

1990	Diplomate, National Board of Medical Examiners

1996	Board Certified American Board of Psychiatry and Neurology
1997	Board Certified American Academy of Adolescent Psychiatry

PROFESSIONAL LICENSURE

1989	Missouri Medical License, #MD102964

HOSPITAL AFFILIATIONS

Barnes Hospital; St. Louis, MO
St. John's Mercy Hospital; Creve Coeur, MO
St. Joseph Health Center; St. Charles, MO

PUBLICATIONS

1. Mattingly GW, Figiel GS, Jarvis MR, Zorumski CF. Prospective uses of ECT in the presence of intracranial tumors. J. Neuropsychiatry Clin Neurosciences, 3:459-463, 1991.

2. Figiel GS, Mattingly GW, Zorumski CF. Simultaneous major depression and panic disorder: treatment with electroconvulsive therapy. J. Clin Psychiatry, 53:12-15, 1992.

3. Mattingly GW, Baker K, Figiel GS, Zorumski CF. Multiple Sclerosis and ECT: the potential predictive value of gadolinium enhanced magnetic resonance scans. J. Neuropsychiatry Clin Neurosciences, 4:48-53, 1992.

4. Figiel GS, Mattingly GW. The safety and efficacy of cardiac modified ECT in depressed elderly patients. Convulsive Therapy, 8:72-73, 1992.

5. Figiel GS, Mattingly GW, Zorumski CF. ECT and delirium in Parkinson's disease. J. Neuropsychiatry Clin Neurosciences, 4:231-232, 1992.

6. Martin M, Figiel GS, Mattingly GW, Zorumski CF, Jarvis MR. ECT-induced interictal delirium in patients with a history of CVA. J. Geriatric Psychiatry and Neurology, 5:149-155, 1992.

7. Figiel GS, Zorumski CF, Mattingly GW. Combined use of Labetalol and Nifedipine in controlling cardiovascular response from ECT. J. Geriatric Psychiatry and Neurology, 6:20-24, 1993.

PRESENTATIONS

Cardiac Modified ECT for Geriatric Depression; Academy of Biological Psychiatry. Washington, C.C., 1992.

ECT and Neurological Illness: A Comprehensive Review; Southern Psychiatric Association, Hot Springs, VA, 1992.

Psychiatric Patients and Chronic Fatigue Syndrome. Is There an Overlap? American Psychiatric Association, San Francisco, CA, 1992.

The Interface between PTSD and Borderline Personality Disorder; American Psychiatric Association, San Francisco, CA, 1993.

Neurophysiology of Sleep Disorders; Grand Rounds, Farmington Regional Hospital, Farmington, MO, 1998.

Child and Adolescent Anxiety Disorders; Grand Rounds, St. Luke's Hospital, Town and Country, MO, 1998.

Pediatric Depression; Grand Rounds, St. John's Mercy Health Center, Creve Coeur, MO, 2000.

CLINICAL TRIALS EXPERIENCE

Washington University, Malcolm Bliss Mental Health Center Research Ward-Clinical Rater for 4 Different Double Blind, Placebo Controlled Antipsychotic Trials (1992-1993).

X-Company-An Open-Label, Multi-Center Study to Assess Tolerability, Efficacy and Quality of Life Associated with the Use of Compound A in Children with Attention Deficit Hyperactivity Disorder (ADHD) in a Community Practice Setting, Principal Investigator (2001).

X-Company-A Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Study to Investigate the Safety and Efficacy of Compound A for the Prevention of an Affective Episode in Subjects with Bipolar 1 Disorder, Principal Investigator (2001).

X-Company-A Double Blind, Randomized, Parallel-Group, Placebo-Controlled Study to Investigate the Safety and Efficacy of Compound A for the Treatment of Acute Episodes of Major Depressive disorder, Subinvestigator (2001).

X-Company-A Randomized Open-Label, Parallel-Group, Multi-Center Study to Assess the Efficacy, Cardiac Safety and Side Effect Profile of Two Different Antipsychotics in the Treatment of Schizoprenia and Schizoaffective Disorder, Principal Investigator (2002).

X-Company-A Phase 1 Double Blind, Randomized, Multi-Center Inpatient Study of the Relative Bioavailability and Tolerability of a Slow-Release Formulation and a Medium-Release Formulation of Compound A in Patients with Schizophrenia or Schizoaffective Disorder, Principal Investigator (2002).

X-Company-A Double Blind Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Tolerability of Compound A for Child and Adolescent Depression, Principal Investigator (2002).

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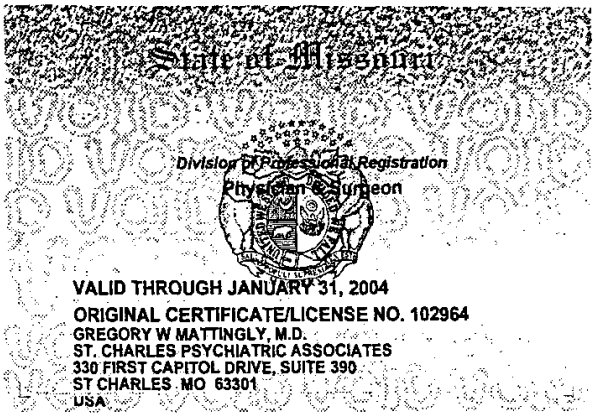
State of Missouri

Division of Professional Registration
Physician & Surgeon

VALID THROUGH JANUARY 31, 2004
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GREGORY W MATTINGLY, M.D.
ST. CHARLES PSYCHIATRIC ASSOCIATES
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GREGORY W MATTINGLY, M.D.
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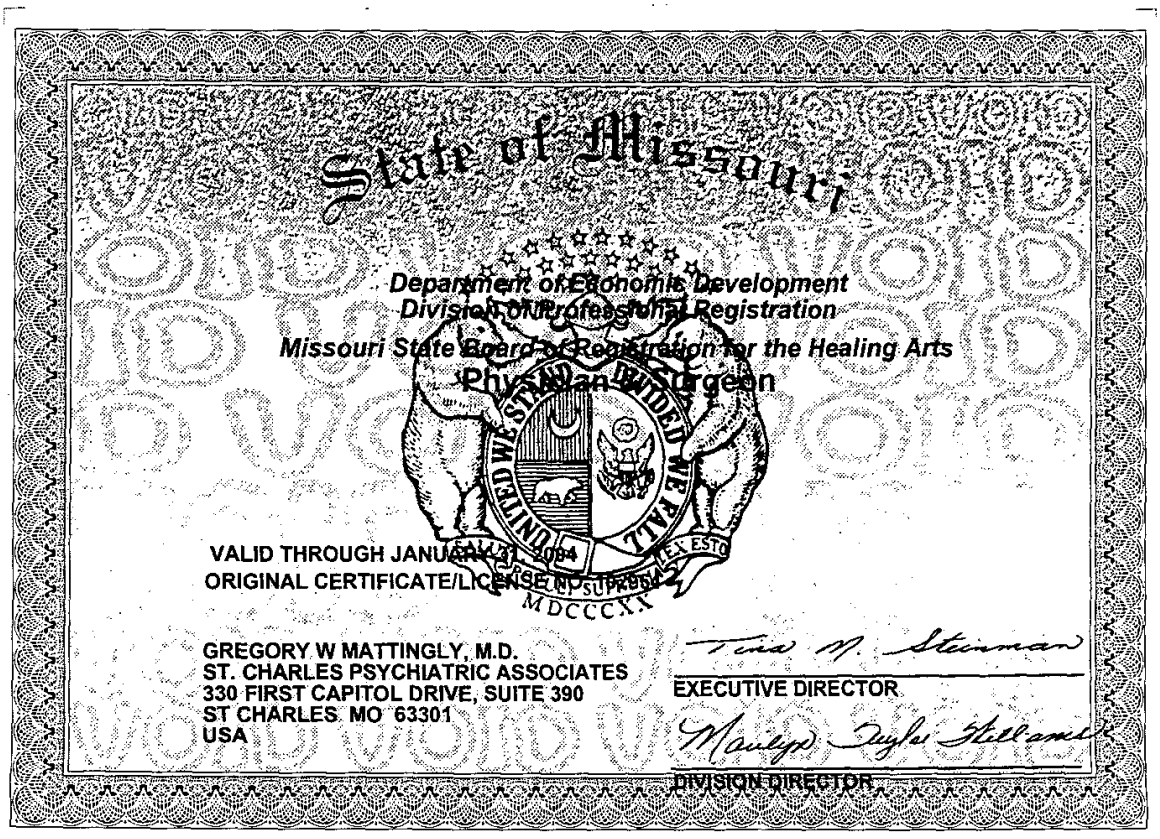
State of Missouri

Department of Economic Development
Division of Professional Registration
Missouri State Board of Registration for the Healing Arts
Physician & Surgeon

VALID THROUGH JANUARY 31, 2004
ORIGINAL CERTIFICATE/LICENSE NO. 102964

GREGORY W MATTINGLY, M.D.
ST. CHARLES PSYCHIATRIC ASSOCIATES
330 FIRST CAPITOL DRIVE, SUITE 390
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EXECUTIVE DIRECTOR

DIVISION DIRECTOR

5077US/0049.0028

CURRICULUM VITAE

Charles H. Merideth, M.D.
Affiliated Research Institute
8989 Rio San Diego Drive, Suite 350
San Diego, CA 92108
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PROFESSIONAL LICENSURE:

California Medical License #C32377
DEA # AM4425802

BOARD CERTIFICATION:

10/1972 American Board of Psychiatry and Neurology

EDUCATION:

1960	DePauw University, Greencastle, Indiana Rector Scholarship, B.A. Summa Cum Laude
1961	Fullbright Scholarship, Anthropology Tuebingen University, Tuebingen, Germany
1965	Washington University School of Medicine, St. Louis, Missouri Jackson-Jackson Fellowship, M.D.

INTERNSHIPS AND RESIDENCIES:

1965-1966	Straight Medicine Internship, Michael Reese Hospital Chicago, Illinois
1966-1969	Psychiatry Residency, Barnes Hospital Washington University School of Medicine, St. Louis, Missouri

EXPERIENCE:

1994-Present	Medical Director, Affiliated Research Institute San Diego, California
1992-1993	Medical Director, Sunrise Recovery San Diego, California
1990-Present	Private Practice, Charles H. Merideth, M.D., Inc.
1971-1990	Private Practice, Psychiatric Centers at San Diego San Diego, California
1985-1989	Director of Research, Alvarado Parkway Institute San Diego, California
1976-1985	Medical Director, Psychiatric Unit, Villa View Community Hospital, San Diego, California
1978-1979	Chief of Staff, Villa View Community Hospital San Diego, California
1970-1971	Consultant, Child Guidance Center, Savannah, Georgia
1969-1971	Consultant, Alcoholism Clinic, Savannah, Georgia
1969-1971	Chief, Mental Hygiene Consultation, Service, U.S. Army Hospital, Fort Stewart, Georgia
1969-1971	Military Service, U.S. Army, Major, Medical Corps
1969	Chief, Consultation Service, Malcolm Bliss Mental Health Center, St. Louis, Missouri
1969	Ward Supervisor, Malcolm Bliss Mental Health Center, St. Louis, Missouri

APPOINTMENTS:

2002	Staff Psychiatrist, Paradise Valley Hospital 2400 E. 4th Street National City, CA 91950

APPOINTMENTS (CONTINUED):

2001	Staff Psychiatrist, Bay View Hospital 330 Moss Street Chula Vista, CA 91911
2000	Clinical Professor of Psychiatry, Loma Linda University, Loma Linda, California
1971-1978	Assistant Clinical Professor of Psychiatry, University of California, San Diego, California

PUBLICATIONS:

Ascher J, Barnett S, Batey S, Ketter T, Merideth CH, Londborg P, West S: Safety and Tolerability of Lamotrigine in Controlled Mood Disorder Trials. Presented at APA in New Orleans 2001.

Merideth, CH: Divalproex Sodium vs. Olanzapine for the treatment of mania in bipolar disorder: Effects on body weight change and related outcomes, 2000

Michael E. Thase, and et al.: Mirtazapine versus Sertraline after SSRI Non-Response. Evaluation of the efficacy and safety of 8 weeks treatment with either Mirtazapine or Sertraline in patients with major depression who had failed to respond to Fluoxetine, Paroxetine, or Citalpram, 2000

Merideth CH, Mahmoud RA, Engdlhart LM, Ramirez L, and the Risperidone Outcome Study & Effectiveness (ROSE) Group: Clinical and quality of life superiority of Risperidone over conventional antipsychotics under usual care conditions: a prospective randomized trial in schizophrenia and schizoaffective disorder, APA, 1998

Ferguson F, Cunningham L, Merideth CH, Apter J, Feighner JP, Ionescu-Pioggia M, Samara B, Johnston JA, Ascher J: Bupropion in Tricyclic Antidepressant Nonresponders with Unipolar Major Depressive Disorder, Annals of Clinical Psychiatry, 6(3), 153-160, 1994

Feighner JP, Boyer WF, Merideth CH, Hendrickson GG: A blind comparison of fluoxetine, imipramine and placebo in outpatients with major depression. International Clinical Psychopharmacology, 4, 127-134, 1989.

Feighner JP, Boyer WF, Merideth CH, Hendrickson GG: An overview of fluoxetine in geriatric depression. Brit J Psychiatry 153 (Supp 3), 105-108, 1988

PUBLICATIONS (CONTINUED):

Feighner JP, Frost NR, Merideth CH, Hendrickson GG, Jacobs RS: A comparative trial of fluoxetine and amitriptyline in outpatients with major depressive disorder. J Clin Psychiatry 46,9.369-372, 1985

Merideth CH, Feighner JP, Hendrickson GG: A blind comparative evaluation of the efficacy and safety of nomifensine, imipramine, and placebo in depressed geriatric outpatients. J Clin Psychiatry 45(4,Pt.2): 73-77, 1984

Feighner JP, Merideth CH, Stern W, Hendrickson GG, Miller LM: A blind study of buproprion and placebo in depression. Am J Psychiatry 141:525-529, 1984

Feighner JP, Merideth CH, Claghorn JL: Multi-center, placebo-controlled evaluation of nomifensive treatment in depressed outpatients. J Clin Psychiatry 45 (4, Pt.2) 47-51, 1984

Merideth CH, Feighner JP: A blind, controlled evaluation of zimelidine, imipramine, and placebo in inpatients with primary affective disorders. Acta Psychiatrica Scandinavica 308: 70-79, 1983

Feighner JP, Merideth CH, Frost NR, Chammas SN, Hendrickson GG: A blind comparison of alprazolam versus imipramine and placebo in the treatment of major depressive disorder. Acta Psychiatrica Scandinavica 68 (4) 223-233, 1983

Feighner JP, Jacobs RS, Jackson RE, Hendrickson GG, Merideth CH, O'Mear P: A Blind Comparative trial with mianserin and amitriptyline in outpatients with major depressive disorder. BR. J. Clin. Pharma. 15:227S-237S, 1983

Feighner JP, Merideth CH, Hendrickson GG: A blind comparison of buspirone and diazepam in outpatients with generalized anxiety disorder. J Clin Psychiatry 43 (12): 103-107, 1982

Feighner JP, Merideth CH, Hendrickson GG: A comparative blind placebo-controlled trial of nomifensine versus imipramine in primary depression. Proceedings of the Collegium Internationale Neuropsycholopharmacologium, Jerusalem, 1982

Feighner JP, Merideth CH, Dutt JE, Hendrickson GG: The comparative evaluation of lofepramine and imipramine for patients with primary depression. Preliminary Report Depressioner. AB Leo, Helsingborg, Sverige, and Acta Psychiatica Scandinavica 66(2): 100-108, 1982

"Maintenance Antidepressant Therapy: A Double-Blind Comparison of Trazadone and Imipramine" Journal of Clinical Psychopharmacology, I - 6, 1981

PUBLICATIONS (CONTINUED):

"Suicide Communication by Adolescents", published by Diseases of the Nervous System, 1971

"The Communication of Suicide Intent in Psychiatric Illness" was presented at a conference on Life History of Research in Psychopathology in St. Louis, Missouri, November 1970

CLINICAL RESEARCH EXPERIENCE:

1974-	Co-Investigator: (Flupenthixol Study) Hoffman-LaRouche Pharmaceutical.
1975-1976	Co-Investigator: (Limbitrol Study) Hoffman-La Roche Pharmaceutical.
1975	Co-Investigator: (Nomifensine Study) Protocol 308. A blind, outpatient, antidepressant study. Hoechst-Roussel Pharmaceutical.
1976-1977	Co-Investigator: (Alprazolam Study) Protocol 63226. A blind, outpatient, antidepressant study. Upjohn Pharmaceutical.
1976-1977	Co-Investigator: (Trazadone Study) Protocol 616. A Blind, Inpatient, Antidepressant Study. Mead Johnson Pharmaceutical.
1976-1977	Co-Investigator: (Trazadone Study) Protocol 63226. A Blind, Inpatient, Antidepressant Study, Mead Johnson Pharmaceutical.
1976	Co-Investigator: (Nomifensine Study) Protocol 3109. A Blind, Inpatient Antidepressant Study. Hoechst-Roussel Pharmaceutical.
1977-1979	Co-Investigator: (Nomifensine Study) Protocol 323. A Double-Blind, Inpatient Geriatric Antidepressant Study. Hoechst-Roussel Pharmaceutical.
1977-1982	Co-Investigator: (Trazadone Study) Protocol 720. A Blind, Long-Term, Outpatient Antidepressant Study. Mead Johnson Pharmaceutical.
1978-1979	Co-Investigator: (Clobazam Study) Protocol 302. A Double-Blind, Outpatient, Anxiolytic Study. Hoechst-Roussel Pharmaceutical.
1978-1979	Co-Investigator: (Lofepramine Study) Protocol 13. A Blind, Outpatient, Antidepressant Study. EM Laboratories.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1978-1979 Co-Investigator: (Nomifensine Study) Protocol 320. A Blind, Geriatric, Outpatient, Antidepressant Study. Hoechst-Roussel Pharmaceutical.

1979-1980 Co-Investigator: (Buspirone Study) Protocol 1049. A Blind, Outpatient, Anxiolytic Study. Mead Johnson Pharmaceutical.

1979-1980 Co-Investigator: (Hydergine Study) Protocol 58. A Blind, Geriatric, Outpatient, Antidepressant Study. Sandoz, Incorporated.

1979-1980 Co-Investigator: (Buspirone Study) Protocol 9966. A Blind, Outpatient, Anxiolytic Study. Mead Johnson Pharmaceutical.

1979-1981 Co-Investigator: (Mianserin Study) Protocols A and B. A Blind, Outpatient, Antidepressant Study with Long-Term Follow Up. Organon Laboratories.

1979-1980 Co-Investigator: (Wellbutrin Study) Protocols 14-01 and 17-01. A Blind Outpatient Antidepressant Study with Long-Term, Open Label Follow Up. Burroughs Wellcome Company.

1980- Co-Investigator: (Fluotracen Study) Protocol 03. A Blind, Outpatient Antidepressant Study. Sandoz Incorporated.

1980-1981 Co-Investigator: (Fluoxetine Study) Protocol 23. A Blind, Outpatient Antidepressant Study. Eli Lilly Pharmaceutical.

1980-1981 Co-Investigator: (Fluvoxamine Study) Protocol 1145510. A Blind, Inpatient Antidepressant Study. Duphar Laboratories.

1980-1982 Co-Investigator: (Zimelidine Study) Protocols 108-411. A Blind , Outpatient, Antidepressant Study with Long-Term Follow Up. Astra Pharmaceutical.

1981-1983 Co-Investigator: (Fluoxetine Study) Protocols 27 and 28. A Blind Outpatient Antidepressant Study with Crossover and Long-Term Options. Eli Lilly Pharmaceutical.

1981-1983 Co-Investigator: (Fluoxetine Study) Protocols 29 and 30. A Double-Blind, Inpatient Antidepressant Study with Crossover and Long-Term Options. Eli Lilly Pharmaceutical.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1981-1983 Co-Investigator: (Fluoxetine Study) Protocols 33 and 34. A Double Blind, Geriatric, Inpatient and Outpatient Antidepressant Study with Crossover and Long-Term Options. Eli Lilly Pharmaceutical.

1982- Co-Investigator: (LY 123508 Study) Protocols 06 and 07.

1982- Co-Investigator: (Trazadone Study) Protocol 1136. A Double-Blind, Outpatient, Antidepressant Study with Long-Term Follow Up. Mead Johnson Pharmaceutical.

1982-1983 Co-Investigator: (Adinazolam Study) Protocols 6309, 6311 and 6312. A Blind, Outpatient, Antidepressant Study with Long-Term Follow Up. Upjohn Pharmaceutical.

1982-1983 Co-Investigator: (Zimelidine Study) Protocol 108-303. A Blind, Geriatric, Inpatient and Outpatient Antidepressant Study. Astra Pharmaceutical.

1982-1989 Co-Investigator: (Wellbutrine Study) Protocol 39. An Open-Label, Humanitarian, Outpatient, Antidepressant Study. Burroughs Wellcome Company.

1983-1984 Co-Investigator: (Oxaprotiline Study) Protocol 14. A Blind, Outpatient, Antidepressant Study in Patients with a History of Alcoholism. Ciba-Geigy Pharmaceutical.

1983-1984 Co-Investigator: (Adinazolam Study) Protocol 6331. A Long-Term, Blind, Outpatient Antidepressant Study. Upjohn Pharmaceutical.

1983-1984 Co-Investigator: (Buspirone Study) Protocol 1604. A Double-Blind, Outpatient Anxiolytic Study. Mead Johnson Pharmaceutical.

1983-1984 Co-Investigator: (Moban (Molindone HCl) Study) A Blind, Outpatient, Anti-psychotic Study. DuPont Pharmaceutical.

1983-1985 Co-Investigator: (Oxaprotiline Study) Protocols 07 and 12. A Double-Blind, Outpatient, Antidepressant Study. Ciba-Geigy Pharmaceutical.

1983-1984 Co-Investigator: (Adinazolam Study) Protocol 6318. A Blind, Outpatient, Antidepressant Study. Upjohn Pharmaceutical.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1983-1984 Co-Investigator: (BW647U Study) Protocol 6318. A Blind, Outpatient, Antidepressant Study. Burroughs Wellcome Company.

1983-1984 Co-Investigator: (Tomoxetine Study) Protocols 5 and 10. A Blind, Outpatient, Antidepressant Study with Long Term Follow Up. Eli Lilly Pharmaceutical.

1984-1985 Co-Investigator: (Fluoxetine Study) Protocol 62. A Blind, Outpatient, Antidepressant Study. Eli Lilly Pharmaceutical.

1985-1986 Co-Investigator: (Fluoxetine Study) Protocol 79. A Blind, outpatient Antidepressant Study. Eli Lilly Pharmaceutical.

1985-1986 Co-Investigator: (Paroxetine Study) Protocol 09. A Fixed Dose, Blind, Outpatient, Antidepressant Study. Beecham Laboratories.

1985-1986 Co-Investigator: (Paroxetine Study) Protocols 03 and 04. A Blind, Outpatient, Antidepressant Study with Long-Term Follow-Up. Beecham Laboratories.

1985-1988 Co-Investigator: (Mianserin Study) Protocols 001-032 and 001-042. A Blind, Outpatient Antidepressant Study with Long-Term Follow Up. Organon Laboratories.

1986-1987 Co-Investigator: (Tomoxetine Study) Protocol B4Z-HFAG. A Blind, Fixed-Dose, Outpatient, Depression Study with Long-Term Extension. Lilly Pharmaceutical.

1987 Co-Investigator: (WY-45, 030 Study) Protocol 600A-204. Intermediate-Term Safety and Clinical Acceptability Study of WY-45, 030 Tablets in Depressed Patients. Wyeth Laboratories.

1987-1988 Co-Investigator: (Buspirone Study) Protocol 03AIL. A Blind, Outpatient, Anxiety Study. Bristol-Myers Company.

1987-1988 Co-Investigator: (Tomoxetine Study) Protocol B4Z-MC-HFAH. A Blind, Fixed Dose, Outpatient Depression Study with Long-Term Extension. Lilly Pharmaceutical.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1987-1988 Co-Investigator: (Wellbutrin Study) Protocol 84A. A Blind, Fixed Dose, Outpatient Depression Study. Burroughs Wellcome Company.

1987-1988 Co-Investigator: (WY 45, 030 Study) Protocol 600A-203. A Blind, Outpatient Depression Study. Wyeth Pharmaceutical.

1987-1988 Co-Investigator: (Wellbutrin Study) Protocol 84A. An Open-Label, Surveillance Study for Depressed Outpatients. Burroughs Wellcome Company.

1987-1988 Co-Investigator: (Dothiepin Study) Protocol BPI 1003. An Open-Label, Multi-Center Trial to Evaluate the Safety and Tolerability of Dothiepin in Doses of 200-300 mg/day for a 6-Week Period in Patients with Depression. The Boots Company.

1987-1988 Co-Investigator: (Dothiepin Study) Protocol BPI 1004. An Open-Label, Long-Term Extension Study of Dothiepin in Patients who have Previously Received Dothiepin for Depression in Study BPI 1003. The Boots Company.

1987-1989 Co-Investigator: (Idazoxan Study) Protocol CR87/026. A Blind, Parallel Group Comparison of Idazoxan and Placebo in Patients with Major Depressive Disorder. Reckitt & Colman.

1987 Co-Investigator: (Buspirone Study) Protocol CN101-006. A Placebo-Controlled Study to Assess a Concurrent Usage Schedule for Switching Patients from Alprazolam to Buspirone. Bristol-Myers Company.

1988 Co-Investigator: (Buspirone Study) Protocol CN101-008. A Placebo-Controlled Study to Assess a Concurrent Usage Schedule for Switching Patients from Alprazolam to Buspirone. Bristol-Myers Company.

1988 Co-Investigator: (Milacemide Study) Protocol IC7-87-02-016. A Multi-Center, Randomized, Blind, Parallel Group Dose Response Study of Milacemide in Patients with Mood Disorders Currently in a Major Depressive Episode. G.D. Searle & Company.

1988-1989 Co-Investigator: (CP-76,593 Study) Protocol 088-101. A Multi-Center, Blind, Placebo Controlled Trial of CP-76, 593 in the Treatment of Outpatients with Major Depressive Disorder. Pfizer, Inc.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1988-1989 Co-Investigator: (Enciprazine Study) Protocol 685-203-US. A Blind, Placebo Controlled, Parallel Group Dose-Determined Study of Enciprazine Tablets in Outpatients with Generalized Anxiety Disorder. Wyeth-Ayerst Research.

1988-1989 Co-Investigator: (Ritanserin Study) Protocol 55667/201E. Ritanserin vs. Placebo in the Treatment of Generalized Anxiety Disorder (GAD), A Blind, Parallel Group Phase II Study. Janssen Research Foundation.

1988-1989 Co-Investigator: (Ritanserin Study) Protocol 55667/201E. Ritanserin in the Treatment of Generalized Anxiety Disorder (GAD), an Open-Label Extension Study. Janssen Research Foundation.

1988-1989 Co-Investigator: (Venlafaxine Study) Protocol 600A-301-US. A Randomized, Blind Comparison of Venlafaxine, Imipramine, and Placebo Capsules in Outpatients with Major Depression. Wyeth-Ayerst Research.

1988-1989 Co-Investigator: (Venlafaxine Study) Protocol 60A-305-US. Long-Term Extension of a Blind Comparison of Venlafaxine, Imipramine, and Placebo Capsules in Outpatients with Major Depression. Wyeth-Ayerst Research.

1988 Co-Investigator: (Buspirone Study) Protocol CN101-016. A Blind Trial of Buspirone, Imipramine and Placebo in the Treatment of Depressed Outpatients. Bristol-Myers Company.

1990-1991 Co-Investigator: (Fluvoxamine Study) Protocol 114.01.06. Fluvoxamine in the Treatment of Depression, A Single Center, Blind, Placebo-Controlled Comparison with Imipramine in Outpatients. Reid-Rowell, Inc.

1989 Principal Investigator: (WY-47,846 Study) Protocol 656A-201-US. Open-Label, Outpatient, Antidepressant Study. Wyeth-Ayerst Research.

1990 Principal Investigator: (WY-47-846 Study) Protocol 656A-202-US. An Open-Label, Outpatient, Anxiolytic Study. Wyeth-Ayerst Research.

1990 Principal Investigator: (Wellbutrin Study) Protocol 88. The Safety and Efficacy of Wellbutrin and Fluoxetine in Depressed Outpatients. Burroughs Wellcome Company.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1992-1993 Principal Investigator: (Wellbutrin SR Study) Protocol 205. A Multi-Center, Dose Response Evaluation of the Safety and Efficacy of Bupropion HCl Sustained-Release Versus Placebo in Depressed Outpatients. Burroughs Wellcome Company.

1992-1993 Principal Investigator: (Wellbutrin Study) Protocol 93. A Multi-Center Evaluation of Bupropion (Wellbutrin) in Depressed Outpatients Non-Responsive to Tricyclic Antidepressants: Amitriptyline, Doxepin, Imipramine, Desipramine, or Nortriptyline. Burroughs Wellcome Company.

1993-1994 Principal Investigator: (DN-2327 Study) Protocol M92-826. A Multi-Center Study Comparing DN-2327 with Placebo in Generalized Anxiety Disorder. Abbott Labs/ Tap Pharmaceuticals Inc./ Besselaar

1993-1994 Principal Investigator: (Wellbutrin SR Study) Protocol 208. An Open-Label, Multi-Site Evaluation of Bupropion HCl Sustained-Release to Determine the Clinical Response, Functional Status and Incidence of Serious Adverse Events. Burroughs Wellcome Company.

1993-1994 Principal Investigator: (Olanzapine Study) Protocol F1D-MC-HGAJ (a). A Multi-Center Evaluation of the Safety and Efficacy of Olanzapine Compared with Haloperidol in the Treatment of Psychotic Disorders. Eli Lilly Company.

1993-1994 Principal Investigator: (DN-2327 Study) Protocol M93-007. An Open- Label, Outpatient Study on Generalized Anxiety Disorder. Abbott Labs/ Tap Pharmaceutical/ Besselaar.

1993-1994 Principal Investigator: (Wellbutrin SR Study) Protocol 212. A Multi-Center Evaluation of Bupropion HCl Sustained-Release Versus Placebo in Depressed Outpatients. Burroughs Wellcome Company.

1994-1995 Principal Investigator: (Sertindole Study) Protocol M93-098. A Double-Blind, Placebo-Controlled, Haldol-Referenced Study of the Safety and Efficacy of Two Doses of Sertindol in Schizophrenia Patients. Abbott Laboratories.

1994-1995 Principal Investigator: (Sertindole Study) Protocol M92-795. An Open-Label Assessment of the Long-Term Safety of Sertindol in the Treatment of Schizophrenic Patients. Abbott Laboratories.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1994-1995 Principal Investigator: (Ziprasidone) Protocol 128-108. A Blind, Haldol-Referenced Study of the Safety and Efficacy of Two Dose Regimens of Ziprasidone in the Maintenance and Treatment of Outpatients with Schizophrenia Disorder. Pfizer Central Laboratories.

1994-1995 Principal Investigator: (Ziprasidone Study) Protocol 128-114. A Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Two Fixed Doses of Ziprasidone in the Acute Exacerbation of Schizophrenia and Schizoaffective Disorder. Pfizer Central Laboratories.

1994-1995 Principal Investigator: (Flesinoxan Study) Protocol 128.2.02. A Blind, Parallel, Placebo Controlled Comparison of Diazepam and Flesinoxan in the Treatment of Generalized Anxiety Disorder. Solvay Pharmaceuticals.

1994-1995 Principal Investigator: (Seroquel Study) Protocol 5077IL/0013. A Blind, Parallel, Multiple Fixed Dose Comparison of Seroquel and Haloperidol in the Treatment of Hospitalized Subjects with Acute Exacerbation of Chronic or Subchronic Schizophrenia. Zeneca Pharmaceuticals.

1994-1995 Principal Investigator: (Propentofylline Study) Protocol US 301. A Forty-Eight Week Efficacy and Safety Study of Propentofylline (HWA 285) in Patients with Alzheimer's Disease. Hoechst-Roussel Pharmaceuticals.

1994-1995 Principal Investigator: (Propentofylline Study) Protocol US 302. A Twenty-Four Week Efficacy and Safety Study of Propentofylline in Patients with Vascular Dementia. Hoechst-Roussel Pharmaceuticals.

1994-1995 Principal Investigator: (Zalaplon Study) A Placebo-Controlled Comparison of Ambien and Zalaplon in the Treatment of Insomnia. American Cyanamid Company.

1995-1996 Principal Investigator: (Sertindole Study) Protocol M94-222. An Open Label Assessment of the Long Term Safety of Sertindole. Abbott Laboratories.

1995-1996 Principal Investigator: (Pramipexole Study) Protocol M/2730/0046. A Dose-Response Study of Pramipexole in Combination with Maintenance Haloperidol for the Treatment of Negative Symptoms of Schizophrenia. The Upjohn Company.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1995-1996 Principal Investigator: (ORG 4428 Study) Protocol 057-004. An Eight-Week, Multi-Center, Active and Placebo-Controlled, Fixed Dose, Efficacy and Safety Study of ORG 4428 in Patients with Major Depression. Organon, Inc.

1995-1996 Principal Investigator: (ORG 4428 Study) Protocol 057-011. A Long Term, Multi-Center, Active and Placebo-Controlled, Fixed Dose Efficacy and Safety Study of ORG 4428 in Outpatients with Major Depression. Organon, Inc.

1995-1996 Principal Investigator: (Fluoxetine Study) Protocol B1Y-MC-HCHG (a). Fluoxetine/Placebo in Panic Disorder. Eli Lilly Laboratories.

1995-1996 Principal Investigator: (MK-462 Study) Protocol 022-012. A Randomized, Triple Blind, Placebo-Controlled, Outpatient Study to Examine the Safety and Efficacy of MK-462 10 mg p.o. and MK-462 5 mg p.o. for the Treatment of Acute Migraine and Migraine Recurrence. Merck & Co, Inc.

1995-1996 Principal Investigator: (L-745,870 Study) Protocol L-745-870. A Blind, Placebo Controlled, Safety, Tolerability and Preliminary Antipsychotic Activity Study of L-745,870 in Hospitalized Schizophrenic Patients. Merck & Co., Inc.

1995-1997 Principal Investigator: (Depakote Study) Protocol M93-111. A Comparative Cost Effectiveness Study of Depakote and Usual Care Versus Lithium and Usual Care in the Treatment of Bi-Polar Disorder. Abbott Laboratories.

1995-1996 Principal Investigator: (Risperdal Study) Protocol RIS-USA-56B. A Randomized Trial to Assess the Outcomes and Costs of Risperdal Versus Conventional Antipsychotic Therapy in Patients with Chronic Schizophrenia. Janssen Research Foundation.

1995-1996 Principal Investigator: (Mazapertine Study) Protocol MAZ-INT-01. Mazapertine Dose Finding Trial, Comparing Three Fixed Dosages of Mazapertine to Risperidone and Placebo: Multi-Center, Blind Parallel-Group Study. Janssen Research Foundation.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1995-1996 Principal Investigator: (Ziprasidone Study) Protocol 128-115. Phase III, Six Week, Blind, Multi-Center, Placebo-Controlled Study Evaluating the Safety and Efficacy of Three Fixed Doses of Oral Ziprasidone (CP-88, Q59-I) (20 mg b.i.d., 60 mg b.i.d., 100 mg b.i.d.) and Haloperidol in the Acute Exacerbation of Schizophrenia or Schizoaffective Disorder. Pfizer Central Laboratories.

1995-1996 Principal Investigator: (Luvox Study) Protocol S1143101. Establishment of the Oral Fluoxetine Dose Effect Relationship for Efficacy and Safety in Outpatients with Major Depressive Disorder. A Randomized, Blind, Placebo and Sertraline Controlled, Parallel Group, Multicenter study. Solvay Pharmaceuticals.

1995-1996 Principal Investigator: (Seroquel Study) Protocol 5077IL/0056. A Multicenter, Open Randomized Comparison of ICI 204, 636 (SEROQUEL) and Usual Care on Health Outcomes in subjects with Schizophrenia and Schizoaffective Disorder. Zeneca Pharmaceuticals.

1995-1996 Principal Investigator: (Wellbutrin Study) Protocol AKIA4003. A Multicenter, Blind, Present Randomized Pilot Study Comparing the Safety and Efficacy of Wellbutrin (Bupropion HCl) Sustained Release and Paroxetine in the Treatment of Elderly Outpatients with Moderate to Severe Recurrent Major Depression. Glaxo Wellcome.

1996- Principal Investigator: (Exelon Study) Protocol ENA-B-452. A Prospective, Multicenter, Open Label Pilot Present Study of the Safety and Efficacy of Exelon in Patients with Moderate to Severe Probable Alzheimer's Disease in a Long-Term Care Setting. Sandoz Pharmaceuticals.

1997- Principal Investigator: (Exelon Study) Protocol ENA-B-356. An Open Label Study to Evaluate the Safety and Efficacy of 1.5 mg b.i.d. through 6 mg b.i.d. of Exelon in Patients with Mild to Severe Probable Alzheimer's Disease in the Community Setting. Sandoz Pharmaceuticals.

1996-1997 Principal Investigator: (NXX-066 Study) Protocol SA-NXX-0013. A Randomized, Placebo-Controlled Present Blind 16 Week Study of the Safety and Tolerability of NXX-066 in Patients with Mild to Moderate Alzheimer's Disease. Astra USA.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1996-1997 Principal Investigator: (Paroxetine Study) Protocol PAR-494. A Blind, Placebo-Controlled Present Flexible Dosing Trial to Evaluate the Efficacy of Modified Release Paroxetine in the Treatment of Panic Disorder. SmithKline Beecham Pharmaceuticals.

1996-1997 Principal Investigator: (Paroxetine Study) Protocol PAR-487. A Blind, Placebo-Controlled Present Trial to Evaluate the Clinical Effects of Immediate Release Paroxetine and Modified Release Paroxetine in the Treatment of Major Depression in Elderly Patients. SmithKline Beecham.

1997 Principal Investigator: (Ziprasidone Study) Protocol 128-126, A Phase III, Randomized Study Comparing 2 Doses of Intramuscular Ziprasidone (2 mg and 20 mg) in Subjects with Psychosis and Acute Agitation. Pfizer, Inc.

1996 Principal Investigator: (Zolmitriptan Study) Protocol 311C11/0071. A Multi-Center, Blind, Randomized Comparison of Zolmitriptan (311C90, ZOMIG) and Sumatriptan in the Acute Treatment of Multiple Migraine Headaches. Zeneca Pharmaceuticals.

1997 Principal Investigator: (Alniditan Study) Protocol ALN-INT-17. A Randomized, Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Alniditan (0.4, 0.8, or 1.4 mg) Given Subcutaneously in the Acute Treatment of Migraine. Janssen Research Foundation.

1997 Principal Investigator: (Alniditan Study) Protocol ALN-USA-18. Open Evaluation of the Long-Term Efficacy, Safety and Tolerability of 1.4 mg SC Alniditan in the Acute Treatment of Migraine Attacks. Janssen Research Foundation.

1997 Principal Investigator: (Propentofylline Study) Protocol HWA285-3018. A 48-Week Study to Compare the Efficacy and Safety of Propentofylline (HWA285) with Placebo in Outpatients with Alzheimer's Disease. Hoechst-Roussel Pharmaceuticals.

1997 Principal Investigator: (Wellbutrin Study) Protocol AK1A4002. A Multi-Center, Blind, Placebo-Controlled Comparison of the Effects of Sexual Functioning of Wellbutrin (Bupropion HCl) Sustained Release of Sertraline in Outpatients with Moderate to Recurrent Major Depression. Glaxo-Wellcome.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1998 Principal Investigator: (Risperdal Study) Protocol RIS-USA-102. The Safety and Efficacy of Risperdal (Risperidone) vs. Placebo vs. Haloperidol as Add on Therapy to Mood Stabilizers in the Treatment of the Manic Phase of Bipolar Disorder. Janssen Research Foundation.

1997 Principal Investigator: (Fluvoxamine Study) Protocol S1143102. A Multicenter, Blind, Placebo-Controlled, Parallel Group Study of the Safety, Tolerability, and Efficacy of Three Fixed Doses of Fluvoxamine vs. Placebo in Outpatients with Major Depressive Disorder. Solvay Pharmaceuticals.

1997-1998 Principal Investigator/Medical Director: (Aripiprazole Study) Protocol 31-97-201. A Phase III Double Blind, Placebo-Controlled Study of Aripiprazole in the Treatment of Psychosis. Otsuka America Pharmaceutical.

1997 Principal Investigator: (Aripiprazole Study) Protocol 31-97-203. An Open-Label, Follow-On Study of the Long Term Safety of Aripiprazole in Patients with Psychosis. Otsuka America Pharmaceutical.

1997 Principal Investigator: (Sertraline Study) Protocol R-0552. An Eight-Week, Multi-Center, Parallel-Group, Blind, Placebo-Controlled Study of Sertraline In Elderly Outpatients With DSM-IV Major Depression. Pfizer Pharmaceuticals.

1997 Principal Investigator: (MDL 100, 907 Study) Protocol 100907PR0015. A Multicenter, Randomized, Blind, Placebo-Controlled Study of MDL 100, 907 in Schizophrenic and Schizoaffective Patients. Hoechst Marion Roussel Pharmaceuticals.

1997 Principal Investigator: (Flibanserine Study) Protocol 511.11. An Eight-Week, Blind, Placebo-Controlled Study of 2, 20, 50 and 100 mg Flibanscrine b.i.d. and Paroxetine q.d. in Patients with Major Depressive Disorder. Boehringer Ingelheim Pharmaceuticals, Inc.

1997 Principal Investigator: (Celecoxib Study) Protocol PR #IQ5-97-02-001. Clinical Protocol for Blind, Randomized, Placebo-Controlled, Comparative Study of Celecoxib (SC-58635) for the Inhibition of Progression of Alzheimer's Disease. G.D. Searle Pharmaceuticals.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1997 Principal Investigator: (L-754-030 Study) Protocol MK-0869 (L-754, 030). A Blind, Multicenter, Dose-Finding Acute and Extension Study of MK-0869 (L-754-030) vs. Fluoxetine Hydrochloride and Placebo in the Treatment of Outpatients with Major Depressive Disorder. Merck & Co., Inc.

1997 Principal Investigator: (EMD 68 843 Study) Protocol EMD 68 843-009. A Blind, Randomized, Multicenter, Parallel Design Study to Evaluate the Efficacy and Safety of Individual Maximum Tolerated Doses of EMD 68 843 in Comparison with Placebo and Fluoxetine in Outpatients with Major Depressive Disorder. Merck Lipha.

1997 Principal Investigator: (M100907 Study) Protocol M100907/3001. A Multicenter, Placebo and Active Control, Blind, Randomized Study of the Efficacy, Safety and Pharmacokinetics of M100907 (10 and 20 mg/ day) in Schizophrenic and Schizoaffective Patients (3001). Hoechst Marion Roussel.

1997 Principal Investigator: (M100907 Study) Long Term Follow-up, Safety Study of M100907 Tablets in Schizophrenic and Schizoaffective Subjects who Participated in Protocol M100907/3001 or M100907/3002. Hoechst Marion Roussel.

1997 Principal Investigator: (ORG 5222 Study) Protocol 041002. A Blind, Five-Armed, Fixed-Dose, Active and Placebo Controlled Dose-Finding Study With Sublingual ORF 5222 in Subjects with Acute Phase Schizophrenia. Organon, Inc.

1997 Principal Investigator: (ORG 5222 Study) Protocol 041500. ORG 5222 for Humanitarian Use. Organon, Inc.

1997 Medical Director: (Sertindole Study) Protocol M95-372. A Double-Blind, Placebo-Controlled, Haldol-Referenced Study of the Safety and Efficacy of Sertindole in Schizophrenic Patients. Abbott Laboratories.

1998 Medical Director: (Flibanserine Study) Protocol 511.12. An Eight-Week, Double-Blind, Placebo-Controlled, Study of 2, 20, 50 and 100 mg Flibanscrine b.i.d. and Paroxetine q.d. in Patients with Major Depressive Disorder. Boehringer Ingelheim.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1998 Principal Investigator: (Lamictal Study) Protocol SCAA2008. A Multicenter, Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Lamictal (Lamotrigine) Compared to Placebo and Lithium in the Treatment of An Acute Manic or Mixed Episode in Patients who have Bi-Polar Disorder: Incorporating Participation in Genotype Research Which is Optional for Both Study Centers and Patients. Glaxo Wellcome Research and Development.

1998 Principal Investigator: (Pregabalin Study) A Placebo-Controlled Study of Pregabalin and Lorazepam in Patients With Generalized Anxiety Disorder (Protocol 1008-025). Parke-Davis Pharmaceutical Research.

1999 Principal Investigator/Medical Director: (Olanzapine (LY170053) Study) Protocol F1D-MC-HGGN. The Comparative Efficacy of Olanzapine, Risperidone, and Haloperidol for Cognition in Schizophrenia. Eli Lilly and Company.

1999 Medical Director: (Lamictal Study) Protocol SCAA2008 (105-609). A Multicenter, Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Lamictal (Lamotrigine) Compared to Placebo in the Treatment of An Acute Manic or Mixed Episode in Patients Who Have Bi-Polar Disorder. Glaxo Wellcome.

1999 Principal Investigator/Medical Director: (Aripiprazole Study) Protocol 31-98-213. An Open-Label Comparison of the Neurocognitive Effects of Aripiprazole to Olanzapine Administered Orally in Patients with Stable Psychosis. Otsuka America Pharmaceutical, Inc.

1998 Principal Investigator: (Aripiprazole Study) Protocol 31-98-217. A Multi-Center, Randomized, Blind, Active-Controlled Study to Compare the Long-term Maintenance Effects and Safety of Aripiprazole and Haloperidol Following Acute Relapse in Schizophrenia Patients. Otsuka America Pharmaceutical, Inc.

1998 Principal Investigator: (Aripiprazole Study) Protocol 31-98-218. Aripiprazole, An Open-Label Follow-up Study of the Long-Term Safety of Aripiprazole in Patients with Chronic Schizophrenia. Otsuka America Pharmaceutical, Inc.

1998 Principal Investigator/Medical Director: (Aripiprazole Study) Protocol 31-98-220. An Open-Label Follow-On Study of the Long-Term Safety of Aripiprazole Administered Orally in Patients with Psychosis. Otsuka America Pharmaceutical, Inc.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1998 Principal Investigator: (Iloperidone Study) Protocol ILP 2001. A Prospective, Randomized, Blind, Multicenter Study of Iloperidone to Evaluate the Safety of Two Titration Schedules and to Compare the Safety and Efficacy of b.i.d. and q.d. Regimens to Haloperidol in Patients with Schizophrenia. Novartis Pharmaceuticals Corporation.

1998 Principal Investigator/Medical Director: (Ziprasidone Study) Protocol R-0548. A Multi-Center, Placebo-Controlled, Double-Blind Study Comparing the Safety and Efficacy of Ziprasidone and Olanzapine in Subjects with Schizophrenia or Schizoaffective Disorder Needing Inpatient Care. Pfizer, Inc.

1998 Principal Investigator: (Selegeline Study) Protocol S9303-E113-98B. A Blind, Placebo-Controlled, Parallel Assessment of the Safety and Efficacy of the Selegiline Transdermal System in Patients with Major Depression. Somerset Pharmaceuticals, Inc.

1998 Principal Investigator: (Memantine Study) Protocol MRZ 90001-9605. Efficacy and Long-term Tolerability of Memantine in Patients with Moderately Severe to Severe Alzheimer's Disease (AD). Merz + Co., GmbH & Co.

1998 Principal Investigator: (MK-0869 Study) Protocol MK-0869. A Blind, Active and Placebo-Controlled, Safety, Tolerability, and Preliminary Antipsychotic Activity Study of MK-0869 in Hospitalized Schizophrenic Patients. Merck & Co., Inc.

1998 Principal Investigator: (Idebinone Study) Protocol CV-2619/PFNP-002. A Blind, 12-Month Safety and Efficacy Extension Study of Idebinone (CV-2619) 120 mg t.i.d., and 360 mg t.i.d. in Patients with Probable Alzheimer's Disease. Takeda America Research & Development Center, Inc.

1998 Principal Investigator: (Paroxetine Study) Protocol BRL 29060/641. A Randomized, Blind, Placebo-Controlled, Fixed Dosage Trial to Evaluate the Efficacy and Tolerability of 20 and 40 mg/day Paroxetine in Patients with Generalized Anxiety Disorder. SmithKline Beecham Pharmaceuticals.

1998 Principal Investigator: (Olanzapine Study) Protocol F1D-MC-HGGU. Olanzapine vs. Risperidone and Placebo in the Treatment of Psychosis and Associated Behavioral Disturbances in Patients with Dementia. Eli Lilly and Company, Inc.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1998 Principal Investigator: (Depakote Study) Protocol M97-696. Evaluation of the Efficacy and Safety of Depakote CR in the treatment of the Manic Phase of Bi-Polar Disorder: A Placebo-Controlled Study. Abbott Laboratories.

1998 Principal Investigator: (Ziprasidone Study) Protocol 128-127E. An Open Extension Study in the Treatment of Schizophrenic Subjects Who Have Participated in Previous Ziprasidone Clinical Trials. Pfizer, Inc.

1998 Principal Investigator: (Propentofylline Study) Protocol HWA285-3019. A 24 Week Study to Compare the Efficacy & Safety of Propentofylline (HWA285) with Placebo in Outpatients with Vascular Dementia. Hoechst-Roussel Pharmaceuticals.

1999 Principal Investigator: (Lamictal Study) Protocol SCAA2010. A Multi-Center, Blind, Placebo-Controlled, Flexible Dose Evaluation of the Safety and Efficacy of Lamictal (Lamotrigine) in the Treatment of a Major Depressive Episode in Patients Suffering from Bipolar Disorder. Glaxo Wellcome.

1998 Principal Investigator: (Galantamine Study) Protocol GAL-USA-10. Placebo Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy Under a Slow-Titration Regimen. Janssen Research.

1998 Medical Director: (Lamictal Study) Protocol SCAA4005. An Evaluation of Lamotrigine vs. Carbamazepime, Phenytoin or Divalproex Sodium as Monotherapy Treatment for Epilepsy Patients who have Failed a Previous Course of Antiepileptic Drug Therapy. Glaxo Wellcome Pharmaceuticals.

2000 Medical Director: (Paroxetine Study) Protocol 29060-651. A Twelve-Week Double-Blind Fixed Dose Comparison of 20 and 40 mg Daily of Paroxetine and Placebo in Patients Suffering from Posttraumatic Stress Disorder. SmithKline Beecham Pharmaceuticals.

1998-1999 Medical Director: (Lamictal Study) Protocol SCAA2010. A Multi-Center, Blind, Placebo-Controlled, Flexible Dose Evaluation of the Safety and Efficacy of Lamictal (Lamotrigine) in the Treatment of a Major Depressive Episode in Patients Suffering from Bi-Polar Disorder. Glaxo Wellcome.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1998-1999 Medical Director: (M100907 Study) Protocol M100907/3001. A Multicenter, Placebo and Active Control, Blind, Randomized Study of the Efficacy, Safety and Pharmacokinetics of M100907 (10 and 20 mg/ day) in Schizophrenic and Schizoaffective Patients (3001). Hoechst Marion Roussel.

1998-1999 Medical Director: (Depakote Study) Protocol M97-696. Evaluation of the Efficacy and Safety of Depakote CR in the treatment of the Manic Phase of Bi-Polar Disorder: A Placebo-Controlled Study. Abbott Laboratories.

1998-1999 Principal Investigator/Medical Director: (Lamictal Study) Protocol SCAA20022. A Randomized, Multicenter, Blind, Placebo Controlled, Fixed Dose, 7 Week Evaluation of the Efficacy and Safety of Lamotrigine in Patients with Major Depression. Glaxo Wellcome.

1998-1999 Principal Investigator/Medical Director: (Iloperidone Study) Protocol ILP 3000. A Prospective, Randomized, Double-Blind, Placebo and Active-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Iloperidone Given b.i.d. for 42 Days to Schizophrenic Patients with Acute or Subacute Exacerbation, Followed by a Double-Blind, Active-Controlled, Flexible Dose, Long-Term, Six-Month Phase with Iloperidone Given q.d. Novartis Pharmaceutical.

1999 Principal Investigator: (Remeron (Mirtazapine) Study) Protocol 003-900. A Multicenter, Randomized, Blind, Sertraline-Controlled Study of the Efficacy and Safety of Remeron (Mirtazapine) in Subjects with Major Depressive Disorder Who Failed on SSRI Treatment Due to Lack of Efficacy. Organon Pharmaceuticals.

1999 Principal Investigator: (MK-0869 Study) Protocol 039-00. A Double-Blind, Parallel, Placebo and Active-Controlled, Multicenter Study to Determine the Safety and Efficacy of MK 869 in Outpatients With Major Depressive Disorder and Anxiety. Merck & Co., Inc.

1999 Principal Investigator: (Galantamine Study) Protocol GAL-USA-11. Safety and Efficacy of Galantamine During Withdrawal in the Treatment of Alzheimer's Disease. Janssen Research Foundation.

1999 Principal Investigator/Medical Director: (Ziprasidone) R-0570. A Double-Blind Six-Month Continuation Protocol for Patients who Successfully Completed Protocol R-0548. Pfizer, Inc.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1999 Principal Investigator: (Belfloxatone Study) Protocol 2918. A Comparison of the Efficacy and Safety of Belfloxatone 2.5 mg OD vs. Placebo in Outpatients With Moderate to Severe Major Depressive Disorders; A Randomized, Double-Blind, 8-Week Multi-Center Phase II Trial. Synthelabo Research, Inc.

1999 Principal Investigator/Medical Director: (Ziprasidone Study) Protocol R-0585. A 52-Week (1 Year), Open Extension Study Evaluating the Safety and Efficacy of Continued Administration of 40-160 mg Daily of Oral Ziprasidone in the Treatment of Schizophrenic Patients Who have Participated in Previous Ziprasidone Clinical Trials. Pfizer, Inc.

1999 Principal Investigator/Medical Director: (Pregabalin Study) Protocol 1008-022. A Placebo-Controlled Study of Pregabalin in Patients with Acute Mania. Parke-Davis.

1999 Principal Investigator: (Paroxetine Study) Protocol 29060/648. A 12 Week, Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Efficacy and Tolerability of Paroxetine in Patients Suffering from Posttraumatic Stress Disorder (PTSD). SmithKline Beecham.

1999 Principal Investigator: (Aripcept and Vitamin E Study) Protocol ADC-008. A Randomized, Blind, Placebo Controlled Trial to Evaluate the Safety and Efficacy of Vitamin E and Donepezil HCl (Aricept) to Delay Clinical Progression from Mild Cognitive Impairment (MCI) to Alzheimer's Disease (AD). Alzheimer's Disease Cooperative Study.

1999 Principal Investigator: (Aripiprazole Study) Protocol 173-98-203. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose Study of Oral OPC-14523 and Prozac in the Treatment of Outpatients with Moderate Depression. Otsuka America Pharmaceutical, Inc.

1999 Principal Investigator: (AIT-082 Study) Protocol 082-99-003. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate AIT-082 in Patients with Probable Alzheimer's Disease of Mild to Moderate Severity. Neotherapeutics.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1999 Principal Investigator/Medical Director: (Selegeline Study) Protocol S9303-P9806. A Double-Blind, Placebo-Controlled, Parallel Group Assessment of the Selegiline Transdermal System in the Prevention of Relapse of Symptoms Associated with Major Depression. Somerset Pharmaceuticals, Inc.

1999 Principal Investigator/Medical Director: (Selegeline Study) Protocol S9303-9918. An Open-Label Study to Assess the Safety of the Selegiline Transdermal System in Patients with Major Depression. Somerset Pharmaceuticals, Inc.

1999 Principal Investigator/ Medical Director: (Pregabalin Study) Protocol 1008-088. A Sustained Efficacy Study of Pregabalin in Patients With Generalized Anxiety Disorder. Parke-Davis Pharmaceutical Research.

1999 Principal Investigator/Medical Director: (Pregabalin Study) Protocol 1008-084. Open-Label Safety Study of Pregabalin (CI-1008) in Patients with Anxiety Disorders. Parke-Davis Pharmaceutical Research.

1999 Principal Investigator: (Org 33062 Study) Protocol 134-002. A Double-Blind, Multicenter, Randomized, Placebo-Controlled, Efficacy and Safety Study of Org 33062 ER in Subjects with Major Depressive Disorder. Organon, Inc.

1999 Principal Investigator: (Org 33062 Study) Protocol 134-501. Open-Label Extension Trial in Subjects with Major Depressive Disorder Who Participated in One of the ORG 33062 ER Efficacy Trials. Organon, Inc.

1999 Principal Investigator: (Depakote Study) Protocol M99-045. Randomized, Double-Blind, Parallel Group, Multi-Center, Comparing the Use of Depakote and Zyprexa in the Treatment of Subjects with Bi-Polar Disorder Type I who are Hospitalized for an Acute Manic Episode. Abbott Laboratories.

1999 Medical Director: (Selegeline Study) Protocol S9303-E114. A Double-Blind, Placebo-Controlled, Parallel-Group Assessment of the Safety and Efficacy of Two Doses of the Selegiline Transdermal System (10 am and 20 mg) in Patients with Major Depression. Somerset Pharmaceuticals.

1999 Principal Investigator/Medical Director: (Org 5222) Protocol 041-002. A Double-Blind Five-Armed, Fixed-Dose, Active and Placebo-Controlled Dose-Finding Study with Sublingual Org 5222 in Subjects with Acute Phase Schizophrenia. Organon Pharmaceuticals.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

1999 Medical Director: (Fluoxetine Study) Protocol B1Y-MC-HCJL. Fluoxetine vs. Placebo in Posttraumatic Stress Disorder. Eli Lilly and Company.

1999 Medical Director: (Wellbutrin Study) Protocol AK1A4007. A Multi-Center, Double-Blind, Placebo-Controlled Comparison of the Safety and Efficacy and Effects on Sexual Functioning of Wellbutrin (Bupropion HCl) Sustained Release (SR) and Fluoxetine in Outpatients with Moderate to Severe Recurrent Major Depression. Glaxo Wellcome Pharmaceuticals.

1999 Medical Director: (Olanzapine Study) Protocol F1D-MC-HGHL. Olanzapine vs. Placebo in the Prevention of Relapse in Bi-Polar Disorder. Eli Lilly Pharmaceuticals.

1999 Medical Director: (Paroxetine Study) Protocol 29060-651. A 12-Week, Double-Blind, Fixed Dose Comparison of 20 and 40 mg Daily of Paroxetine and Placebo in Patients Suffering From Post Traumatic Stress Disorder (PTSD). SmithKline Beecham.

1999 Principal Investigator/Medical Director: (Org 5222 Study) Protocol 041-500. Org 5222 Long-Term Extension to Protocol 041-002. Organon Pharmaceuticals.

1999 Medical Director: (Selegeline Study) Protocol S9303-E113-98B. A Double-Blind, Placebo-Controlled Parallel Assessment of the Safety and Efficacy of the Selegeline Transdermal System in Subjects with Major Depression. Somerset Pharmaceuticals.

2000 Principal Investigator: (Venlafaxine ER) Protocol 0600B4-390-US. A Six-Month, Double-Blind, Placebo-Controlled, Parallel-Group Comparison of Venlafaxine ER Capsules and Placebo in Outpatients with Generalized Social Anxiety Disorder. Wyeth Ayerst.

2000 Principal Investigator/Medical Director: (Iloperidone Study) Protocol ILP3005. A Randomized, Double-Blind, Placebo- and Risperidone-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Two Nonoverlapping Dose Ranges of Iloperidone Given b.i.d. for 42 Days to Schizophrenic Patients Followed by a Long-Term Treatment Phase with Iloperidone given q.d. Novartis Pharmaceuticals.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2000 Medical Director: (L-759274 Study) Protocol 026-00. A Double-Blind, Multicenter Study of Two Doses of L-759274 vs. Paroxetine Hydrochloride and Placebo in the Treatment of Outpatients with Major Depressive Disorder. Merck & Co., Inc.

2000 Medical Director: (Paroxetine Study) Protocol SB29060-701. A Randomized, Multicenter, Eight-Week, Double-Blind, Placebo-Controlled Flexible Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD). SmithKline Beecham.

2000 Principal Investigator/Medical Director: (Lu 26-26-054 Study) Protocol SCT-MD-01. Fixed Dose Comparison of the Safety and Efficacy of Lu 26-054, Citalopram, and Placebo in the Treatment of Major Depressive Disorder. Forest Laboratories, Inc.

2000 Medical Director: (Org 33062 Study) Protocol 134-004. A Double-Blind, Multicenter, Randomized, Placebo-Controlled Efficacy and Safety Study of Org 33062 ER and Fluoxetine in Subjects with Major Depressive Disorder. Organon, Inc.

2000 Medical Director: (Org 33062 Study) Protocol 134-502. A Double-Blind Extension Trial in Subjects with Major Depressive Disorder who Participated in the Placebo-and Fluoxetine Controlled Study of Org 330762 ER (protocol 134-004). Organon, Inc.

2000 Principal Investigator/Medical Director: (Lu 26-26-054 Study) Protocol SCT-MD-05. Flexible Dose Comparison of the Safety and Efficacy of Lu 26-054 and Placebo in the Treatment of Generalized Anxiety Disorder. Forest Laboratories, Inc.

2000 Medical Director: (Paroxetine Study) Protocol 29060/676. A 16-Week Double-Blind, Placebo Controlled Study to Investigate the Efficacy and Tolerability of Paroxetine in the Treatment of Children and Adolescents with Social Anxiety Disorder/Social Phobia. SmithKline Beecham.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2000 Medical Director: Protocol D1050006-P02, A Double-Blind, Randomized, Fixed Dose, Placebo-Controlled, Parallel-Group, 6-Week Efficacy, Safety and Tolerability Study of Two Dose Levels of SM-13496 in Patients with Schizophrenia by DSM-IV Criteria Who are Experiencing an Acute Exacerbation of Symptoms. Sumitomo Pharmaceuticals America, Ltd.

2000 Principal Investigator: (Depakote Study) Protocol M99-010. Safety and Efficacy of Depakote as Combination Therapy in the Treatment of Psychosis Associated with Schizophrenia. Abbott Laboratories.

2000 Principal Investigator/Medical Director: (Org 5222 Study) Protocol 041-013. A Double-Blind, Three-Armed, Fixed-Dose, Placebo-Controlled Dose-Finding Study with Sublingual Org 5222 in Subjects with Acute Phase Schizophrenia. Organon, Inc.

2000 Medical Director: Protocol 29060-716, A Multicenter, Open-Label, Six-Month Extension Study to Assess the Long-Term Safety of Paroxetine in Children and Adolescents with major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). SmithKline Beecham.

2000 Medical Director: Protocol TOPMAT-PHI-374, A Comparative Study of the Steady-State Pharmacokinetics of Lithium Before and During Multiple Oral Daily Topiramate (RWJ-17021) Dosing in Patients with Bipolar Disorder. R.W. Johnson Pharmaceutical research Institute

2000 Principal Investigator/Medical Director: (Org 5222 Study) Protocol 041-505. Long-Term Maintenance of Subjects with Schizophrenia with Org 5222. Organon, Inc.

2000 Principal Investigator: (Galantamine Study) Protocol GAL-USA-18. Open Label Use of Synthetic Galantamine in the Treatment of Alzheimer's Disease. Janssen Research Foundation.

2000 Principal Investigator/Medical Director: (Sertraline Study) Protocol A0501017. A Multicenter, Ten-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible Dose Outpatient Study of Sertraline in Children and Adolescents with Major Depressive Disorder. Pfizer Central Research.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2000 Principal Investigator/Medical Director: (Sertraline Study) Protocol A0501015. A Multicenter, 24-Week, Open-Label Extension Study of Sertraline in Children and Adolescent Outpatients Previously Diagnosed with Major Depressive Disorder. Pfizer Central Research.

2000 Principal Investigator/Medical Director: (LU 26-054 Study) Protocol SCT-MD-04. Flexible Dose Comparison of the Safety and Efficacy of LU 26-054, Citalopram, and Placebo in the Treatment of Panic Disorder. Forest Laboratories.

2000 Principal Investigator/Medical Director: (Seroquel Study) Protocol 0577IL/0099. A Multicenter, Double-Blind, Randomized Placebo-Controlled Trial of the Safety and Efficacy of Seroquel (Quetiapine Fumarate) as Add-On Therapy with Lithium or Divalproex in the Treatment of Acute Mania. Astra Zeneca Pharmaceuticals.

2000 Medical Director: (Rebboxetine Study) Protocol M2020-0047. Reboxetine, Placebo, and Paroxetine Comparison in Patients with Major Depressive Disorder. Pharmacia & Upjohn.

2000 Medical Director: (Reboxetine Study) Protocol 950E-CNS-0005-087. Open-Label Reboxetine Continuation Therapy. Pharmacia & Upjohn.

2000 Principal Investigator/Medical Director: (Buspirone Hydrochloride ER Study) Protocol B99-CT3.005.BUS P02. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy, Safety, and Tolerability of Buspirone Hydrochloride Extended Release Compared to Placebo in Patients with Generalized Anxiety Disorder. Biovail Laboratories, Inc.

2000 Principal Investigator/Medical Director: (Buspirone Hydrochloride ER Study) Protocol B99.CTOL.008.BUS.P02. An Open-Label Study of the Safety , Tolerability, and Efficacy of Up to 90 mg Buspirone Hydrochloride Extended Release in Patients with Generalized Anxiety Disorder. Biovail Laboratories, Inc.

2000 Medical Director: (Venlafaxine Study) Protocol 0600B4-392-US. A Double-Blind, Placebo-Controlled, Parallel-Group Comparison of Venlafaxine Extended-Release Capsules and Paroxetine in Outpatients with Generalized Anxiety Disorder. Wyeth-Ayerst Research.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2000 Medical Director: (Aripiprazole Study) Protocol 173-98-203. A Phase II, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose Study of Oral OPC-14523 and Prozac in the Treatment of Outpatients with Moderate Depression. Otsuka America Pharmaceutical, Inc.

2000 Principal Investigator: Protocol 31-98-213. An Open-Label Comparison of the Neurocognitive Effects of Aripiprazole to Olanzapine Administered Orally in Patients with Stable Psychosis. Otsuka America Pharmaceutical, Inc.

2000 Principal Investigator/Medical Director: Protocol 31-98-220. An Open-Label Follow-On Study of the Long-Term Safety of Aripiprazole Administered Orally in Patients with Psychosis. Otsuka America Pharmaceutical, Inc.

2000 Principal Investigator: (Paroxetine Study) Protocol DRI3650. A Double-Blind, Placebo- and Paroxetine Controlled, Multicenter, Dose Ranging Study Evaluating the Efficacy and Safety of
SRI42801 in Outpatients with Major Depressive Disorder. Sanofi-Synthelabo

2000 Medical Director: (Topiramate Study) Protocol TOPMAT-PDMD-005. A Placebo-Controlled 12-Week Study of the Safety and Efficacy of Two Doses of Topiramate Versus Placebo for the Treatment of Acute Manic or Mixed Episodes In Subjects With Bipolar I Disorder With An Optional Open-Label Extension Protocol. The R.W. Johnson Pharmaceutical Research Institute.

2000 Medical Director: (Depakote Study) Protocol M99-082. A Double-Blind, Placebo-Controlled Study of Depakote® in the Treatment of Behavioral Agitation in Elderly Patients with Dementia. Abbott Laboratories.

2000 Medical Director: (LU 26-054 Study) Protocol SCT-MD-11. Evaluation of the Safety and Efficacy of LU 26-054 in the Prevention of Depression Recurrence. Forest Laboratories, Inc.

2000 Principal Investigator: (LU 26-054 Study) Protocol SCT-MD-17. An Open-Label Extension Study of the Safety and Efficacy of LU 26-054 Patients with Generalized Anxiety Disorder. Forest Laboratories, Inc.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2000 Principal Investigator/Medical Director: (Lamictal Study) Protocol SCA40910. A Multicenter-Double-Blind, Placebo Controlled, Fixed-Dose Evaluation of the Safety, Efficacy, and Tolerability of Lamical (Lamotrigine) in the treatment of a Major Depressive Episode in Patients with Type I Bipolar Disorder. Glaxo Wellcome.

2000 Principal Investigator: (Topiramate Study) Protocol CAPSS-155. A comparison of the Efficacy and Safety of TOPAMAX® (Topiramate) Tablets Versus Placebo for the Prophylaxis of Migraine. Ortho-McNeil Pharmaceutical, Inc.

2000 Principal Investigator: (Galantamine Study) Protocol GAL-INT-10. A Placebo controlled evaluation of galantamine in the treatment of Alzheimer's Disease: Safety and Efficacy of a controlled release formulation. Janssen Research Foundation.

2000 Principal Investigator: (L-830982 Study) Protocol 008-00, A Double-Blind, Multicenter, Placebo-Controlled Study of L-830982 in the Treatment of Outpatients with Generalized Anxiety Disorder. Merck & Co., Inc.

2000 Medical Director: (Fluoxetine Study) Protocol 003048, A Multicenter, Randomized, Double-Blind, Fluoxetine and Placebo controlled Study of the Efficacy and Safety of Remeron Sol Tab (mirtazapine) Orally Disintegrating Tablets in Subjects with Major Depressive Disorder. Organon, Inc.

2001 Principal Investigator: (Seroquel Study) Protocol 5077IL/0099, A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Safety and Efficacy of SEROQUEL (Quetiapine Fumerate) as Add-on Therapy with Lithium or Divalproex in the Treatment of Acute Mania. Astra Zeneca Pharmaceuticals, Inc.

2001 Principal Investigator/Medical Director: (Seroquel Study) Protocol 5077IL/0041, A Multicenter, Double-Blind, Randomized Comparison of the Efficacy and Safety of Sustained-Release Formulation Quetiapine Fumerate (Seroquel ™) and Placebo in the Treatment of Patients with Schizophrenia. Astra Zeneca Pharmaceuticals, Inc.

2001 Principal Investigator/Medical Director: (Org 5222 Study) Protocol 041-013, A Double-Blind, Three-Armed, Fixed-Dose, Placebo Controlled Dose-Finding Study with Sublingual Org 5222 in Subject with Acute Phase Schizophrenia. Organon, Inc.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2001 Medical Director: (L-330932 Study) Protocol 006-01, A Double-Blind, Multicenter Acute Study of Two Doses of L-330932 versus Larazapam and Placebo in the Treatment of Out Patients with Generalized Anxiety Disorder. Merck & Co., Inc.

2001 Principal Investigator: (Risperdal Study) Protocol RIS-USA-240, The Efficacy and Safety of Flexible Dose Ranges of Risperidone vs. Placebo or Divalproex Sodium in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder. Janssen Pharmaceutica Research Foundation.

2001 Principal Investigator: (Risperdal Study) Protocol RIS-USA-241, A 9-Week, Open-Label, Multicenter, Safety Trial of Flexible Dose Ranges of Risperidone in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder. Janssen Pharmaceutica Research Foundation.

2001 Medical Director: (Zopiclone Study) Protocol 190-049, A Twelve-Month, Open-Label Study of the Safety of (S) Zopiclone in Adult Subjects with Insomnia. Sepracor, Inc.

2001 Medical Director: (Risperdal Study) Protocol RIS-USA-209, A Randomized Double Blind Study to Evaluate the Anticholinergic Burden in Subjects with Psychosis of Dementia Treated with Risperidone or Olanzapine. Janssen Pharmaceutica, Inc.

2001 Medical Director/Principal Investigator: Protocol RIS-USA-259, Open Label Trial Exploring a Switching Regimen from Oral Neuroleptics, other than Risperidone, to Risperidone Depot Microspheres. Janssen Research Foundation.

2001 Medical Director/Principal Investigator: Protocol RIS-USA-265, An Open Label, Long Term Trial of Risperidone Long Acting Microspheres in the Treatment of Subjects Diagnosed with Schizophrenia. Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

2001 Medical Director: Protocol 006B-1007-35, A Double-Blind, Randomized, Placebo-Controlled, 3-Month Clinical Trial of Venlafaxine ER and Sertraline in the Treatment of Posttraumatic Stress Disorder. Wyeth-Ayerst Pharmaceuticals.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2001 Medical Director/Principal Investigator: Protocol 059-00, A Double-Blind, Multicenter, Placebo- and Active-Controlled Study of MK-0869 in the Treatment of Patients with Major Depressive Disorder with Melancholic Features. Merck & Company, Inc.

2001 Medical Director: Protocol 0600B-100735, A Double-Blind, Randomized, Placebo-Controlled, 3-Month Clinical Trail of Venlafaxine ER and Sertraline in the Treatment of Posttraumatic Stress Disorder. Wyeth-Ayerst Pharmaceuticals.

2001 Medical Director: Protocol 060-00, A Double-Blind, Multicenter, Placebo- and Active-Controlled Acute and Extension Study of MK-0869 in the Treatment of Patients with Major Depressive Disorder. Merck & Co., Inc.

2001 Medical Director: Protocol B01.CT3.016.BUS P02, Randomized, Double-Blind, Placebo-Controlled Parallel-Group, Fixed Dose Study of the Efficacy, Safety, and Tolerability of 60mg Buspirone Hydrochloride Extended Release Compared to Placebo in Patients with Generalized Anxiety Disorder Who Have Stable Disease Characteristics.

2001 Medical Director: Protocol F1D-US-HGJT, Olanzapine Versus Risperidone in the Treatment of Bipolar I Disorder, Manic or Mixed. Eli Lilly and Company

2001 Medical Director: Protocol 1043-012, A 6-Week, Double-Blind, Rancomized, Multicenter, Fixed-Dose, Placebo-Controlled Study of Pagoclone Dosed Twice a Day in Patients with Generalized Anxiety Disorder. Pfizer, Inc.

2001 Medical Director: Protocol 0600B4-392-US, A Double-Blind, Placebo-Controlled, Parallel Group Comparison of Venlafaxine in Outpatients with Generalized Social Anxiety Disorder. Wyeth-Ayerst Research.

2001 Medical Director: Protocol D10005-P01, A Double-Blind, Randomized, Fixed-Dose, Placebo-Controlled, Parallel Group, 6-Week, Efficacy, Safety and Tolerability of Two Dose Levels of SM-13496 in Patients with Schizophrenia by DSM-IV Criteria who are Experiencing an Acute Exacerbation of Symptoms. Sumitomo Pharmaceuticals

2001 Medical Director: Protocol 134-004 (02), A Double-Blind, Multi-center, Randomized, Placebo-Controlled, Efficacy and Safety Study of ORG 33062 ER and Fluoxetine in Subjects who suffer from Major Depressive Disorder with Atypical Features. Organon, Inc.

CLINICAL RESEARCH EXPERIENCE (CONTINUED):

2001 Medical Director: Protocol 134-502 (02), A Double-Blind, Multi-center Extension Trial in Subjects who shffer from Major Depressive Disorder with Atypical Features who Participated in the Placebo- and Fluoxetine Controlled Study of ORG 33062 ER. Organon, Inc.

2001 Medical Director: Protocol 173-00-221, A Phase II, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging study of Fixed Doses of Oral OPC-14523 and Prozac in the Treatment of Outpatients with Moderate Depression. Otsuke America Pharmaceutical, Inc.

2001 Medical Director: Protocol SB59746-A Study 003, A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of Paroxetine CR in Patients with Generalized Anxiety Disorder (GAD). GlaxoSmithKline.

2001 Medical Director: Protocol 190-048, A Randomized, Double-Blind, Placebo-Controlled Parallel, Two-Week Efficacy and Safety Study of (S)-Zopicione in Elderly Subjects with Primary Insomnia. Sepracor.

2001 Medical Director: Protocol 003-048, Multi-Center, Randomized, Double-Blind, Fluoxetine and Placebo-Controlled Study of the Efficacy and Safety of REMERON Sol Tab (mirtazapine) Orally Disintegrating Tablets in Subjects with major Depressive Disorder. Organon, Inc.

2001 Principal Investigator: Protocol 082-2001-001, A Placebo-Controlled, Dose-Titration, Efficacy and Tolerability Study of Neotrofin™ in Patients with Probable Alzheimer's Disease. NeoTherapeutics Inc.

2001 Medical Director: Protcol TOPMAT-PDMD-005, A Randomized, Double-Blind, Multicenter, Placebo-Controlled 12-Week Study of the Safety and Efficacy of Two Doses of Topirmamte for the Treatment of Acute Manic or Mixed Episodes in Subjects with Bipolar 1 Disorder with an Optional Open-Label Extension . R.W. Johnson Pharmaceutical Research Institute.

2002 Principal Investigator: Protocol 134-501.4, Protocol for the Open-label Extension Trial in Subjects with Major Depressive Disorder who Participated in One of the ORG 33062 ER Efficacy Trials (Amendment 4 Modification: Inclusion of Subjects with major Depressive Disorder Without Prior Participation in ORG 33062 Efficacy Trials) Organon.

STUDIES COMPLETED

STUDY	NUMBER COMPLETED
Acute Mania	9
Adolescent Depression	7
Alcoholism	1
Alzheimer's Disease	15
Bi-Polar Disorder	13
Depression	96
Epilepsy	1
Geriatric Depression	8
Insomnia	3
Migraine	5
Other Dementia	2
Psychosis	19
PTSD	5
Schizophrenia	50
GAD	31
Panic	4
Social Anxiety Disorder	3
Total	271

Consumer Affairs

The Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento, California 95825-3236

PHYSICIAN AND SURGEON

CERTIFICATE NO. C32377 EXPIRATION 01/31/2003

CHARLES HOWARD MERIDETH
8880 RIO SAN DIEGO DRIVE
SUITE 1090
SAN DIEGO CA 92108

ORIGINAL ISSUANCE DATE
06/24/1970

RECEIPT NO.
00092926

JANICE L. MILLER, M.D.
CNS HEALTHCARE OF WEST PALM BEACH
April 9, 2002

Title	**Principal Investigator** Clinical Neuroscience Solutions, Inc. May 1999 to Present
Birth	August 14, 1951
Education	Indian River Community College, Fort Pierce, FL; Associate of Arts, 1969-1971 University of Miami, Coral Gables, FL; Bachelor of Science, Summa Cum Laude, 1971-1972 University of Miami School of Medicine, Miami, FL; Doctor of Medicine, 1972-1976
Professional Training	University of Miami School of Medicine, Miami, FL; Residency in Psychiatry, 1976-1977 Georgetown University Hospital, Washington, DC; Residency in Psychiatry, 1977-1979
License/ Accreditation	Florida ME-0031592 1983 - Diplomate of the American Board of Psychiatry and Neurology 1990 - Certification in Alcoholism & Drug Dependencies, American Society of Addiction Medicine
Population Experience	*Children and Adolescents:* 15 years clinical psychiatric experience, both inpatient and outpatient; diagnoses included ADHD and Disruptive Behaviors disorders, Substance Abuse/ Dependence disorders, Psychotic disorders, Depressive disorders, Bipolar disorders, Anxiety disorders, Eating disorders, Adjustment disorders, and Personality disorders. *Adults:* 22 years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Mental Retardation, ADHD and Disruptive Behaviors disorders, Delirium, Dementia, Substance Abuse/ Dependence disorders, Psychotic disorders, Depressive disorders, Bipolar disorders, Anxiety disorders, Somatoform disorders, Sleep Disturbance disorders, Dissociative disorders, Sexual and Gender Identity disorders, Eating disorders, Adjustment disorders, and Personality disorders. *Geriatrics:* 22 years clinical psychiatric experience, both inpatient and outpatient; diagnoses included Delirium, Dementia, Substance Abuse/Dependence disorders, Psychotic disorders, Depressive disorders, Bipolar disorders, Anxiety disorders, Sleep Disturbance disorders, Eating disorders, Adjustment disorders, and Personality disorders.

CNS Healthcare West Palm Beach Bldg. 2, Suite 210 5601 Corporate Way West Palm Beach, FL 33407
Tel: 561-616-9595 Fax: 561-616-9545
www.cnshealthcare.com/westpalmbeach

Clinical Skills	CPR, vital signs (including orthostatic blood pressure), ECG, venipuncture, height, weight, body mass index, urine dipsticks, urine pregnancy testing, slide preparation, pharmacokinetic sampling and storage, specimen preparation and specimen packaging
Ratings Experience	*Diagnostic Evaluations:* SCID, K-SADS, DICA, MINI and MINI-Kid *Scales:* ADHD rating scale, AIMS, ASEX, Barnes, BPRS, CGI, Conners Continuous Performance Test, Global Assessment Scale, Hamilton Anxiety Rating Scale, Hamilton Depression Scale, MADRS, PANSS (including SCI-PANSS), PGI-Improvement, Quality of Life Assessment, Resource Utilization, SADS-C, Simpson-Angus, Somatic Symptom Inventory, Y-BOCS, Y-MRS, Visual Analog Scales, Stanford Sleepiness Scales, PAAS (Panic and Anticipatory Anxiety Scale, PDSS (Panic Disorder Severity Scale)
Hospital Appointments	Medical Director, Loudoun County Mental Health; Leesburg, Virginia; 1979 – 1980 Medical Staff, Columbia Hospital; West Palm Beach, Florida; 1983 – 1996 Medical Staff, JFK Hospital; Atlantis, Florida; 1982 – 1993 Medical Staff, Savannas Hospital; Port St. Lucie, Florida; 1990 - 2001
Private Practice Experience	Psychiatric Private Practice; Jupiter/West Palm Beach, Florida; 1981 - 2002
Professional Memberships	Association of Clinical Research Professionals (ACRP) December 2000 to Present
Version Date	April 9, 2002

5077US/0049:0029

AC# 0815131

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/26/2002	ME 31592	90140

THE **MEDICAL DOCTOR**
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.
EXPIRATION DATE: **JANUARY 31, 2004**

JANICE L MILLER, MD
5601 CORPORATE WAY
BLDG 2, SUITE 210
WEST PALM BCH, FL 33407

JEB BUSH
GOVERNOR

DISPLAY IF REQUIRED BY LAW

JOHN O. AGWUNOBI, M.D., M.B.A.
SECRETARY

Study Code	5077US/0049
Country	USA
Centre No.	30

Curriculum Vitae

First and family name:	Dennis J. Munjack, M.D.
Present position:	Clinical Professor University of Southern California Department of Psychiatry Los Angeles, CA 1998 - Present Director Southwestern Research, Inc. Beverly Hills, CA 1980 – Present
Address:	Southwestern Research, Inc. 435 North Bedford Drive, Suite 216 Beverly Hills, CA 90210 310-858-7448 Telephone 310-858-7489 Facsimile
Medical education:	Albert Einstein College of Medicine Bronx, New York M.D. 1967
Physician's license number:	Medical Board of California, Physician and Surgeon License Certificate Number G23190
Postgraduate training:	Residency, Psychiatry Temple University Hospital Philadelphia, Pennsylvania 1968 – 1971 Internship Long Island College Hospital Brooklyn, New York 1967 – 1968
Publications *Number of written publications in relevant area(s) of research*	Peer Review Publications 48 Chapters 3 Minor Articles 12
Experience of clinical research *Number of clinical studies sponsored by the pharmaceutical industry to which the individual has contributed*	100

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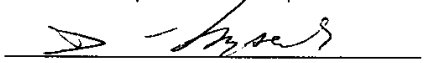
Signature  Date of signature 9/6/02

Dennis J. Munjack, M.D.

Address

Southwestern Research, Inc.
435 North Bedford Drive
Suite 216
Beverly Hills, California 90210
310-858-7448 Telephone
310-858-7489 Facsimile

2031 West Alameda Avenue
Suite 360
Burbank, California 91506

7872 Walker Street
Suite 106
La Palma, California 90623

Education

Temple University Hospital
Philadelphia, Pennsylvania
Psychiatry
1968 – 1971

Long Island College Hospital
Brooklyn, New York
Fellowship
1967 – 1968

Albert Einstein College of Medicine
Bronx, New York
M.D.
1967

Brooklyn College
Brooklyn, New York
B.A.
1963

Medical License

Medical Board of California, Physician and Surgeon License, Certificate Number G23190

Academic Appointments

Clinical Professor
University of Southern California
Department of Psychiatry
Los Angeles, California
7/1/1998 – Present

Associate Professor
University of Southern California
Department of Psychiatry
Los Angeles, California
1980 – 1998

Associate Clinical Professor
University of Southern California
Department of Psychiatry
Los Angeles, California
1977 – 1980

Assistant Professor
University of Southern California
Department of Psychiatry
Los Angles, California
1973 – 1977

Instructor
Temple University Hospital
Department of Psychiatry
Philadelphia, Pennsylvania
1971 –1975

Teaching Appointments

University of Southern California
Los Angeles, California
1973 – 1997

- First Year Medical Students:
  Lecturer and Supervisor
  Sex Education Course
  Sex Therapy Lecture Course
  Summer Fellowship
- Third Year Medical Students:
  Supervisor, Psychiatric Outpatient Clinic
- Third Year Residents:
  Behavior Therapy Lecture Seminar
  Clinical Supervisor, Psychiatric Outpatient Clinic
- Resident Programs:
  Resident Follow-up Group Supervisor
  Resident Clinic Team Leader
  Resident Supervisor, Sex Therapy and Marital Counseling Clinic
  Resident Supervisor, Anxiety Disorders Clinic
  Research Supervisor, Clinical Case Conference and Demonstration

Temple University School of Medicine
Philadelphia, Pennsylvania
1971 – 1973

- Medical Students:
  Supervisor, Psychiatric Outpatient Department
- Third Year Medical Students:
  Behavior Therapy Lecture Seminar
- Second Year Residents:
  Supervisor, Outpatient Psychotherapy Section
- Lecturer:
  Summer Behavior Therapy Institute

Administrative Appointments

University of Southern California School of Medicine
Los Angeles, California
1973 – 1997

- Coordinator, Medical Student Psychiatric Outpatient Clinic Rotation
- Coordinator, Behavior Therapy Unit
- Coordinator, Sex Therapy and Marital Counseling Clinic
- Medical Care Evaluation Committee
- Acting Director, Psychiatric Outpatient Clinic
- Director, Anxiety Disorders Clinic
- Sex Education Committee
- Medical Care Evaluation Committee 1973 – 1978
- Third Year Psychiatry Clerkship Committee 1973 – 1977

Temple University School of Medicine
Philadelphia, Pennsylvania
1971 – 1973

- Coordinator, Third Year Psychiatric Clerkship
- Undergraduate Education Committee

Additional Professional Activities

Member
Harbor View Medical Center
Data Safety Monitoring Board: Protocol Improving Therapy for Panic Disorder in Primary Care.
Peter P. Roy-Byrne, M.D., Principal Investigator
Present

Lecturer
University of Southern California School of Medicine
Postgraduate Education Division
Los Angeles, California
Present

Article Referee
Journal of Anxiety Disorders
1989 – Present

Article Referee
Journal of Clinical Psychopharmacology
1989 – Present

Article Referee
Psychiatry Research
1989 – Present

Lecturer
University of Southern California School of Medicine
Anxiety Disorders Open Forum for the Public
Los Angeles, California
July 17, 1995

Member
Coordination Committee
14th Annual Conference on Anxiety
Los Angeles, California
July 7, 1993
March 1994

Expert Panelist
Human Psychopharmacology
International Study of Expert Judgment on Therapeutic of Benzodiazepines
Vol 8, pp. 253 – 261
1993

Editor
Anxiety Disorders Newsletter
1989 – 1995

Assistant Editor
Anxiety Disorders Newsletter
1986 – 1989

Reviewer
National Institute on Mental Health Treatment Development and Assessment Research Review Committee
1981 – 1982

Director
Southwestern Research, Inc.
Beverly Hills, California
Burbank, California
Los Angeles, California
La Palma, California
1980 – Present

Member
Union of American Physicians and Dentists
Union Negotiating Team
1987

Book Reviewer
Journal of Clinical Psychiatry

Article Reviewer
The Journal of Clinical Review

Article Referee
Journal Nervous and Mental Disease
1980 – Present

Article Referee
Journal of Behavior Therapy
1980 – Present

Article Referee
American Journal of Psychiatry
1980 – Present

NIMH Summer Fellow
Kinsey Institute for Sex Research
1972

Supervisor
Behavior therapy Training Institute

Lieutenant J.G.
United States Navy
Honorable Discharge
1969 – 1971

Consultantships

Wyeth-Ayerst Pharmaceuticals
Investigator's Meeting
San Diego, California
June 1996

DSM-IV Anxiety Disorders Work Group Advisor
1993

Sex Hotline
Los Angeles, California

USC News Service
Los Angeles, California

TAP Pharmaceuticals Corporation
Drug Development conference
Scottsdale, Arizona
December 3-6, 1992

TAP Pharmaceuticals Corporation
New Anxiolytic (DN-2327) Research Protocol Development
1991 – 1993

Editorial Board
Anxiety Disorders Practice Journal
Practice Press
Napa, California
1989 – Present

Consulting Editor
Journal of Sex Education and Therapy

PRN Magazine
Oradell, New Jersey
1982 – Present

Consulting Editor
Journal of Behavior Therapy and Experimental Psychiatry
1980 – 1982

Media

KFWB Radio
Los Angeles, California
Interview, Oklahoma City Bomb Blast
April 19, 1995

Health Connection
KIEV Radio
Los Angeles, California
Interview, Social Phobia
July 1, 1994

Health Connection
KIEV Radio
Los Angeles, California
Interview, Obsessive Compulsive Disorder
May 4, 1994

Health Connection
KIEV Radio
Los Angeles, California
Interview, Recent Advances in Psychiatry
May 1994

USC Transcript
University of Southern California
Los Angeles, California
Interview, Panic Disorder
March 22, 1993

KUNW Radio
Albuquerque, New Mexico
Interview, Anxiety and Depression
September 24, 1992

SELF Magazine
Writer, John Sedgwick
Interview, Panic Attacks
December 1991

Health Connection
KIEV Radio
Los Angeles, California
Interview, Depression
October 2, 1991

Los Angeles Times
Los Angeles, California
Interview, Obsessions and Compulsions
May 1991

Eye On LA
KHJ
Interview, Fears and Phobias
July 7, 1990

Los Angeles Times
Los Angeles, California
Interview, Needle Phobias
June 19, 1990

Los Angeles Magazine
Writer, Tom Johnson
Los Angeles, California
Interview and Quotation, Fear in the City: How Real is the Fear?
September 1988

About You
KNBC Television
Los Angeles, California
Guest Appearance, Fears and Phobias
October 8, 1987

Los Angeles Harold Examiner
Los Angeles, California
Interview, Earthquakes
October 5, 1987

Lifetime Medical Television
Los Angeles, California
Discussant, Panic Attacks and Mitral Valve Prolapse: Diagnostic and Treatment Implications
August 6, 1987

Dr. Ruehl Show
Group W Cable
Los Angeles, California
Interview, Managing Anxiety Disorders
July 14, 1987

Channel 4 News
KNBC Television
Los Angeles, California
Guest Appearance, Phobias and Anxiety
May 25-29, 1987

KFCO Radio
Host, Ted Pane
San Diego, California
Interview, Superstitions and Phobias
February 13, 1987

KVEN Radio
Host, Barry Turnbull
Ventura, California
Interview, Superstition and Phobias
February 13, 1987

KABC Radio
Host, Michael Jackson
Los Angeles, California
Interview, Superstition and Phobias
February 13, 1987

KXL Radio
Host, Jim Bikell
Portland, Oregon
Interview, Superstition and Phobias

Eye On LA
Host, Chuck Henry
KABC Television
Interview, Phobias
February 27, 1986

KGIL Radio
Host, Danielle Sullivan
Los Angeles, California
Interview, Anxiety Disorders
November 1985

KNXT Radio
Host, Lisa Litwiller
Los Angeles, California
Interview, Freeway Phobias
August 14, 1995

Playgirl Magazine
Writer, Catherine Johnson
Los Angeles, California
Interview, Public Passions, Private Thrills
November 1984

AM Los Angeles
KABC
Los Angeles, California
Guest, Anxiety Disorders, Diagnosis and Treatment
November 8, 1984

Lifeline, Educational Television for Physicians
KCET Television
Los Angeles, California
Interview, the Implications of Lactate Induced Panic Attacks for Understanding Panic Disorder
September 6, 1984

Group W Cable Television
Los Angeles, California
Interview, Diagnosis and Treatment of Anxiety Disorders
January 1984

Cable Health Network
Los Angeles, California
Interview, Anxiety Disorders
November 1983

KCBS Radio
San Francisco, California
Interview, Anxiety Disorders
October 1983

Cable Health Network
Los Angeles, California
Interview, Panic Disorders
October 1983

KWBT Radio
South Carolina
Interview, Anxiety and Panic Attacks
August 1983

KRLA Radio
Los Angeles, California
Interview, Anxiety and Panic Attacks
August 1983

Health Connection
KIEV Radio
Los Angeles, California
Interview, Anxiety and Panic Attacks
July 1983

Los Angeles Times
Los Angeles, California
Interview, The Treatment of Panic disorders
March 8, 1983

Women's Day Magazine
Writer, Catherine Houck
Interview, Panic Attacks and Anxiety
February 1983

KZLA Radio
Host, Robert Wilds
Los Angeles, California
Interview, Panic Attacks and Panic Disorder
February 1983

Cable TV Network
Los Angeles, California
Discussant, Phobias
1983

Channel 2 News
KCBS Television
Los Angeles, California
Guest, The Treatment of Phobias
1980

Board Certification

- American Board of Psychiatry and Neurology, October 1974

Other Certification/ Training

SCID Interview Training
Solvay Pharmaceuticals
Atlanta, Georgia
February 26, 1998

HAM-D Anchor Points and Conventions Inter-Rater Training
Solvay Pharmaceuticals
Atlanta, Georgia
February 26, 1998

Professional Memberships

- Southern California Psychiatric Society
- Chairman, Sex Therapy Committee 1977 – 1978
- American Psychiatric Association
- Association for the Advancement of Behavior Therapy
- Society for the Scientific Study of Sex
- American Association of Sex Educators, Counselors, and Therapists
- Behavior therapy Research Society, Charter Clinical Fellow
- The American college of Sexologists
- Anxiety Disorders Association of America, Board of Directors 1980 – 1992, Program Committee 1980 – 1982
- Obsessive-Compulsive Disorders Foundation
- National Anxiety Foundation
- American Society of Clinical Psychopharmacology
- Behavior Therapy and Research Society, Charter Clinical Fellow, 1972

Awards

Teacher of the Year Award
University of Southern California + Los Angeles County Hospital
Los Angeles, California
Presented by: Psychiatric Residency Program
1996

Teacher of the Year Award
University of Southern California + Los Angeles County Hospital
Los Angeles, California
Presented by: Psychiatric Residency Program
1995

Excellence in Teaching Award
University of Southern California + Los Angeles County Hospital
Los Angeles, California
Presented by: The Third Year Class Psychiatric Residency Program
1994

Teacher of the Year Award
University of Southern California + Los Angeles County Hospital
Los Angeles, California
Presented by: The Senior Class Psychiatric Residency Program
1992

Sherwyn M. Woods, M.D. Teaching Award
University of Southern California + Los Angeles County Hospital
Los Angeles, California
Presented by: The Third Year Class Psychiatric Residency Program
1984

Distinguished Teacher Award
University of Southern California + Los Angeles County Hospital
Los Angeles, California
Issued by: Department of Psychiatry, Education division

1983

Outstanding Instructor Award
University of Southern California + Los Angeles County Hospital
Los Angeles, California
Issued by: Department of Psychiatry, Education Division
1981

Contracts and Grants

Inderal in the Treatment of General Anxiety Disorder, Ayerst Laboratories, Protocol No. 81-153-CR

Xanax Regular Tablets Versus Xanax Sustained Release (SR) in the Treatment of Panic Attacks with and without Phobias, The Upjohn Company, Protocol No. 4438

Immediate and Delayed Effects Following Discontinuation of Buspirone or Alprazolam Therapy in Generalized Anxiety Disorder Patients: A Multicenter Study, Bristol-Myers Squibb U.S. Pharmaceutical Group, Protocol No. 05149.

Fluvoxamine in the Treatment of Panic Disorder and Panic Disorder in Agoraphobia: A Multicenter Double-Blind, Placebo-Controlled Study in Outpatients, Kali-Duphar laboratories, Inc., Protocol No. H114.5535/3

A Double-Blind Comparison of the Efficacy of ZK112-119, Alprazolam, and Placebo in Outpatients with Generalized Anxiety Disorder, Sandoz Pharmaceuticals Corporation, Protocol No. B202

A Prospective, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Comparison of the Efficacy and Safety of Abecarnil and Alprazolam in Outpatients with Generalized Anxiety Disorder, Sandoz Pharmaceuticals, Protocol No. B351

A Double-Blind, Placebo-Controlled, Multicenter Trial Comparing 30 MG of Buspar Given Two Times Daily Versus Three Times Daily in Patients with Generalized Anxiety Disorder, Ciba-Geigy, Protocol No. 07

A Double-Blind, 12 Week, Parallel Comparison of Sertraline and Placebo in Outpatients with Obsessive Compulsive Disorder, Pfizer Pharmaceuticals, Protocol No. 91CE21-0546.

A Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of Fluparoxan (0.5, 2 & 8 MG BID) in the Treatment of Secondary (Acquired) Male Erectile Disorder, Glaxo, Inc., Protocol No. ADA-203.

A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Two Doses of Ondansetron Versus Placebo in the Treatment of Social Phobia, Glaxo, Inc., S3A-342.

A Placebo-Controlled, Double-Blind, Parallel Trial of Brofaromine Hydrochloride in Patients with Social Phobia, Ciba-Geigy, Protocol No. 04.

A Double-Blind, Comparison of Three Doses of Tandospirone GITS and Placebo in Outpatients with Major Depression, Pfizer Pharmaceuticals, Protocol No. 93CE30-0611.

Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Finding Study of Venlafaxine Extended Release Capsules in Outpatients with Generalized Anxiety Disorder, Wyeth-Ayerst Research, Protocol No. 0600B2-210-US.

A Double-Blind, Placebo-Controlled Dose Escalation Study of the Safety and Efficacy of Oral Ondansetron in the Treatment of Patients with Panic Disorder, Glaxo, Inc., Protocol No. S3A-323.

Sertraline Treatment Followed by a Double-Blind Comparison of Sertraline and Placebo in the Prevention of Relapse in Outpatients with Obsessive Compulsive Disorder, Pfizer, Inc., Protocol No. 93CE21-0615.

12-Week, Double-Blind, Comparison of Two Sertraline Dose Regimens in "Nonresponder" Outpatients with Obsessive Compulsive Disorder, Pfizer, Inc., Protocol No. 93CE21-0643.

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Safety, Tolerance, and Efficacy Study of 10 and 20 mg Zaleplon, Wyeth-Ayerst Research, Protocol No. 0897A1-307-US.

A Phase III, Multicenter, Long-Term, Open-Label, Safety and Tolerance Study of 10 or 20 mg of Zaleplon Administered Once Daily for a Maximum of 360 Days in Adult Outpatients with Insomnia, Wyeth-Ayerst Research, Protocol No. 0897A1-312-US.

A Phase II, Eight Week, Double-Blind, Placebo-Controlled Multicenter Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Oral CP-93, 393-1 in Outpatients with Major Depressive Disorder, Pfizer, Inc., Protocol No. 129-106.

Double-Blind, Placebo-Controlled Study of Venlafaxine-ER and Venlafaxine OROS[7] in Outpatients with Major Depression, Wyeth-Ayerst Research, Protocol No. 0600C1-217-US.

Six-Month Double-Blind, Placebo-Controlled, Parallel-Group Comparison of Venlafaxine Extended Release Capsules and Placebo in Outpatients with Generalized Anxiety Disorder, Wyeth-Ayerst Research, Protocol No. 0600B2-218-US.

A Double-Blind, Placebo-Controlled Trial to Evaluate the Clinical Effects of Immediate Release Paroxetine and Modified Release Paroxetine in the Treatment of Major Depression, SmithKline Beecham Pharmaceuticals, Protocol No. 29060/448.

A Double-Bind, Placebo-Controlled, Flexible Dosing Trial to Evaluate the Efficacy of Modified Release Paroxetine in the Treatment of Panic Disorder, SmithKline Beecham Pharmaceuticals, Protocol No. 29060/497.

Placebo-Controlled, Parallel Group Trial of Three Doses of Pagoclone in Patients with DSM-IV Panic Disorder, Interneuron Pharmaceuticals Inc., Protocol No. IP456/004.

A Randomized, Double-Blind, Fixed Dose Comparison of 20, 40, and 60 mg Daily of Paroxetine and Placebo in the Treatment of Generalized Social Phobia, SmithKline Beecham Pharmaceuticals, Protocol No. 29060/454.

A Multicenter, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of Single Doses of SB-220453 in the Treatment of Acute Migraine, SmithKline Beecham Pharmaceuticals, Protocol No. 220453/006.

An Eight-Week, Double-Blind, Placebo-Controlled Study of 2, 20, 50, and 100 mg Flibanserin BID and Paroxetine QD in Patients with Major Depressive Disorder, Boehringer Ingelheim, Protocol No. 511.12.

A Double-Blind, Placebo-Controlled, Trial to Evaluate the Clinical Effects of Immediate Release Paroxetine and Modified Release Paroxetine in the Treatment of Major Depression in Elderly Patients, SmithKline Beecham Pharmaceuticals, Protocol No. 29060/487.

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Munjack, D.J.: "Human Sexuality: A health Practitioner's Text, Richard Green (ed), A Book Review", Journal of Clinical Psychiatry, 4:182, 1980.

Munjack, D.J.: "The Role of Drugs in the Treatment of Panic disorders", Fear Breaker: The Newsletter of the Phobia Society of America, Vol 1, 1982.

Munjack, D.J., "Care and cure of Neurosis, Isaac Marks (ed), A book Review", Journal of Clinical Psychiatry, 44:162, 1983.

Munjack, D.J.: "Rush From Judgment", USC Trojan Family, 18(2):11, 1985.

Munjack, D.J.: "A new Look at Panic Disorder and Agoraphobia with Panic Attacks", Anxiety Disorders, V 1, pp. 2-3, Spring/Summer, 1986.

Munjack, D.J., "Biological Theories of Panic Disorder", Anxiety Disorders, Vol 2, p. 3, Spring, 1987.

Munjack, D.J.: "Beyond Exposure Therapy", Anxiety Disorders, Vol 2, p. 3, Fall/Winter, 1987.

Munjack, D.J.: "Book Review: Sexual Aversion, Sexual Phobias, and Panic Disorder", Anxiety disorders, Vol 3, p 4, Spring, 1988.

Munjack, D.J.: "Newer Psychological Theories in the Treatment of Panic Anxiety", Anxiety Disorders, Vol 3, p. 3, Summer, 1988.

Munjack, D.J.: "What is social Phobia?" Anxiety disorders, Vol 3, p 3, Fall, 1988.

Munjack, D.J.: "Alprazolam (Xanax): What is All the Noise About?", Anxiety disorders, Vol 4, p. 4, winter/Spring, 1989.

Munjack, D.J.: "the Relationship between Panic Attacks, Panic Disorder, and Depression", anxiety Disorders, Vol 4, p. 2, Summer/Fall, 1989.

Munjack, D.J.: "Fluoxetine (Prozac) for Panic Disorder and Panic Disorder with Agoraphobia", Anxiety Disorders, Vol 5, No 1, p. 5, Winter/Spring, 1990.

Munjack, D.J.: "The Basics of Behavioral Desensitization for Anxiety and Guilt", anxiety Disorders, Vol 5, No 1, p 6, Winter/Spring, 1990.

Munjack, D.J.: "Panic Disorder and Coronary Artery Disease", Anxiety Disorders, Vol 5, No 2, p 5, Summer/Fall, 1990.

Munjack, D.J.: "Prozac (Fluoxetine): A Practical Note", Anxiety Disorders, Vol 5, No 2, p. 6, Summer/Fall, 1990.

Munjack, D.J.: "External Factors in Panic Disorder", Anxiety Disorders, Vol 6, No 1, p. 4, Winter, 1991.

Munjack, D.J.: "Posttraumatic Stress Disorder", Anxiety Disorders, Vol 6, No 1, p 6, Winter, 1991.

Munjack, D.J.: "Prozac and Panic Disorder", Anxiety Disorders, Vol 6, No 1, p 4, Winter, 1991,

Munjack, D.J.: "Exogenous Factors in Panic Disorder, Part II", Anxiety Disorders, Vol 6, No 2, p 3, summer 1991.

Munjack, D.J.: "Treatment of Posttraumatic Stress Disorder, Part II", Anxiety Disorders, Vol 6, no 2, p 4 , summer, 1991.

Munjack, D.J.: "AIDS Phobia", Anxiety Disorders, Vol 6, No 2, p 4, Summer, 1991.

Munjack, D.J.: "Anafranil", Anxiety Disorders, Vol 6, No 2, p 5, Summer, 1991.

Yent, J., and Munjack, D.J.: "Job Interview Anxiety: Strategies for Successful Coping", Anxiety disorders, Vol 6, No 2, p 7, summer, 1991.

Munjack, D.J.: "Anxiety Disorders in Children", Anxiety Disorders, Vol 6, No 3, p 2, Winter, 1992.

Munjack, D.J.: "What is Placebo?", Anxiety Disorders, Vol 6, No 3, p 3, Winter, 1992.

Munjack, D.J.: "Editor's Column", Anxiety Disorders, Vol 6, No 4, p 2, Spring/Summer, 1992.

Munjack, D.J.: "Obsessive-Compulsive Disorder in Children", Anxiety Disorders, Vol 6, No 4, pp 2-3, Spring/Summer, 1992.

Munjack, D.J.: "Issues in the Pharmacological Treatment of Obsessive-Compulsive Disorder", Anxiety Disorders, Vol 6, No 4, p 3, Spring/Summer, 1992.

Munjack, D.J.: "The Suffocation Alarm Theory of Panic Attacks", Anxiety disorders, Vol 6, No 4, p 4, Spring/Summer, 1992.

Munjack, D.J.: "Medication Discontinuation in Panic Disorder", Anxiety Disorders, Vol 6, No 4, p 5, Spring/summer, 1992.

Munjack, D.J.: " A Random Sampling of Interesting Facts for Individuals with Anxiety Disorders", Anxiety Disorders, Vol 6, No 4, p 6, Spring/Summer, 1992.

Munjack, D.J.: "Avoidant Personality Disorder of Childhood and Adolescence", Anxiety Disorders, Vol 6, No 4, p 7, Spring/Summer, 1992.

Munjack, D.J.: "Can You Believe It?", Anxiety Disorders, Vol 6, No 4, p 7, Spring/Summer, 1992.

VI. Papers Presented

Munjack, D.J.: "The Limitations of Behavior Therapy: Some Proposed Solutions", Eastern Pennsylvania Psychological Association Meeting, Philadelphia, Pennsylvania, July 1969.

Munjack, D.J.: "the Behavioral Treatment of Sex Dysfunctions: Lecture and Videotape Presentation", Temple University – Albert Einstein Hospital Annual Psychotherapy conference, Psychotherapy, Family Therapy, Behavior Therapy, Philadelphia, Pennsylvania, , April 1973.

Munjack, D.J.: "The Treatment of Sex Dysfunction by the Family Practitioner: A Lecture", American Academy of Family Practitioners Meeting, Los Angeles, California, October 1974.

Munjack, D.J.: "Sex Dysfunction: Newer Behavioral Approaches", University of Southern California Psychiatry Alumni Continuing Education Meeting, Los Angeles, California, October 1974.

Munjack, D.J.: "Psychological Characteristics of Frigidity in Sex Clinics", Society for the Scientific Study of Sex, San Diego, California, 1976.

Munjack, D.J.: "Human Sexuality in Medical Practice", Pomona Valley Community Hospital, Pomona, California, October 1976.

Munjack, D.J.: "Male Sexual Problems in Office Practice", Good Samaritan Hospital, Los Angeles, California, November 1976.

Munjack, D.J.: "The Behavioral Treatment of Sex Dysfunction", Harbor General Hospital, Carson, California, December 1976.

Munjack, D.J.: "Sex Dysfunction", USC Department of Psychiatry, Grand Rounds, Los Angeles, California, march 1977.

Munjack, D.J.: "Prognosis in the Treatment of Female Sexual Inhibition", Western Regional Meetings of the Society for the Scientific Study of Sex, Los Angeles, California, October 1977.

Munjack, D.J.: "Males Sexuality", Western Regional Meetings of the Society for the Scientific Study of Sex, Los Angeles, California, October 1977.

Munjack, D.J.: "Sexual complications of Psychiatric Illness", Alcoholism and Illicit Drugs, USC School of Medicine and the Department of Psychiatry, Palm Springs, California, November 1977.

Munjack, D.J.: "The Criteria for Selection for Treatment of Sexual Problems: an Audio-Visual Presentation", Third International Symposium and Workshops on Short-Term Dynamic Psychotherapy, Crisis Theory, and Crisis Intervention, and Short-Term Therapies of Sexual Dysfunctions, Los Angeles, California, November 1977.

Munjack, D.J.: "Principles and Practice of Behavior Therapy", Member of Faculty Panel, American Psychiatric Association Annual Meeting, Atlanta, Georgia, May 10, 1978.

Munjack, D.J.: "A Behavioral Approach to the Evaluation and Treatment of Depression: Comparative Psychiatric Therapies, Diagnosis, and Treatment", USC School of Medicine and the Department of Psychiatry, Maui, Hawaii, June 1979.

Munjack, D.J.: "Male Sexual Dysfunctions", USC School of Medicine and the Department of Psychiatry, USC Medical School Campus, Los Angeles, California, February 1980.

Munjack, D.J.: "The Origins of Phobias", Good Samaritan Hospital, Los Angeles, California, June 1980.

Munjack, D.J.: "The Treatment of Phobias", Good Samaritan Hospital, Los Angeles, California, June 1980.

Munjack, D.J.: "Evaluating Sexual Problems in Office Practice", Panorama City Hospital, Panorama, California, January 1981.

Munjack, D.J.: "The Sex History", family Practice Seminar, LAC+USC Medical Center, Los Angeles, California, June 1981.

Munjack, D.J.: "Evaluating Sexual Problems in Office Practice", Whittier Presbyterian Hospital, Whittier, California, April 1981.

Munjack, D.J.: "Pharmacological Treatment of Agoraphobia", third Annual Phobia Conference, San Francisco, California, October 1981.

Munjack, D.J.: "Panic Disorder", LAC+USC Medical Center, Grand Rounds, Los Angeles, California, September 1981.

Munjack, D.J.: "The Treatment of Panic Disorders", Department of Psychiatry, Postgraduate Education, LAC+USC Medical Center, Los Angeles, California, March 1982.

Munjack, D.J.: "The Treatment of Erectile Failure", Burbank Community Hospital, Burbank, California, March 1982.

Munjack, D.J.: "Panic Disorders: An Overview", Charter Oak Hospital, Covina, California, September 1982.

Munjack, D.J.: "Outcome Studies of Psychological Therapy (by Joseph Wolpe)", Association for the Advancement of Behavior Therapy, Los Angeles, California, November 1982.

Munjack, D.J.: "Panic Disorders and Phobias", La Habra Community Hospital, La Habra Community Hospital, La Habra, California, March 1983.

Munjack, D.J.: "Panic Disorders and Phobias", Guardians of Courage, Hebrew University, Los Angeles, California, May 1983.

Munjack, D.J.: "Anxiety Disorders Clinic", LAC-USC Medical Center, Grand Rounds, Los Angeles, California, July 1983.

Munjack, D.J.: "Clinical Assessment of Depression", USC Department of Psychology, Advanced Graduate Students' Seminars in Psychiatry under Dr. Marston and Dr. Wolpin, USC Department of Psychology, Los Angeles, California, October 1983.

Munjack, D.J.: "Recent Advances in the Treatment of Anxiety Disorders", USC's Salerni Collegium, San Diego, California, September 1983.

Munjack, D.J.: "Recent Advances in the Treatment of Anxiety Disorders", Orange County Psychiatric Society Educational Meeting, Irvine, California, October 1983.

Munjack, D.J.: "Recent Advances in the Treatment of Anxiety Disorders", Del Amo Hospital, Torrance, California, October 1983.

Munjack, D.J.: "Recent Advances in the Treatment of Anxiety Disorders", Pacifica Hospital, Long Beach, California, October 1983.

Munjack, D.J.: "Recent Advances in the Treatment of Anxiety Disorders", Marin County Community Hospital, Marin County, California, October 1983.

Munjack, D.J.: "The Biology of Panic Related Anxiety Disorders", Participant, Conference Sponsored by Upjohn Pharmaceuticals, Boston, Massachusetts, November 1983.

Munjack, D.J.: "Anxiety Disorders – Here Today, Here Tomorrow", Charter Oak Hospital, Covina, California, October 1983.

Munjack, D.J.: "Obsessive-Compulsive Neurosis", LAC+USC Medical Center, Grand Rounds, Los Angeles, California, January 1984.

Munjack, D.J.: "Diagnosis and Treatment of Anxiety Disorders", Kaiser Hospital, Van Nuys, California, January 1984.

Munjack, D.J.: "Agoraphobia", Los Angeles County Department of Mental Health, Human Resources Development Section, Los Angeles, California, February 22 and 29, 1984.

Munjack, D.J.: "The Treatment of Anxiety Disorders: The Present Status", Harbor-UCLA Medical Center, Grand Rounds, Torrance, California, March 5, 1984.

Munjack, D.J.: "Principles and Practices of Behavior therapy: Varieties of Psychotherapy", UCLA Medical Center, Department of Psychiatry, Los Angeles, California, 1984.

Munjack, D.J.: "The Pharmacological Treatment of Generalized Anxiety States", Santa Clara County Psychiatric Society, San Jose, California, March 29, 1984.

Munjack, D.J.: "The Pharmacological Treatment of Generalized States", El Camino Hospital, San Jose, California, March 30, 1984.

Munjack, D.J.: "Panic Disorders", El Centro Community Mental Health Center, Los Angeles, California, April 26, 1984.

Munjack, D.J.: "The Pharmacological Treatment of Panic Disorder", Metropolitan State Hospital, Norwalk, California, April 25, 1984.

Munjack, D.J.: "Panic Disorders", Glendale Adventist Hospital, Glendale, California, May 15, 1984.

Munjack, D.J.: "Anxiety: Symptom or Diagnosis? Rationale for Recognition and Management", Rio Hondo Memorial Hospital, Downey, California, June 18, 1984.

Munjack, D.J.: "Panic Disorder and the Heart Patient", LAC+USC Medical Center, Grand Rounds, Los Angeles, California, July 17, 1984.

Munjack, D.J.: "Clinical Management of Anxiety States", Department of Social Work, LAC+USC Medical Center, Los Angeles, California, August 15, 1984.

Munjack, D.J.: "Psychological Vs. Pharmacological Treatment for Agoraphobia with Panic Attacks", Ingleside Hospital, Rosemead, California, November 1984.

Munjack, D.J.: "Principles and Practices of Behavior Therapy: Varieties of Psychotherapy", UCLA Medical Center, Department of Psychiatry, Los Angeles, California, April 8, 1985.

Munjack, D.J.: "Anxiety Disorders: The Present Status", Hope Community Hospital, San Mateo, California, may 10, 1985.

Munjack, D.J.: "Panic Disorders, Mirtal Valve Prolapse, and Cardiorespiratory Symptoms", The Cypress foundation, Treating the Emotional Aspects of Cardiovascular Disease – Stress, Anxiety, and Depression in the Cardiac Patient, Monterey, California, May 11, 1985.

Munjack, D.J.: "Diagnosis and Treatment of Panic Attacks", Hollywood Mental Health Clinic, Los Angeles, California, June 1985.

Munjack, D.J.: "Panic Attacks: Present Status", Arcadia Methodist Hospital, Arcadia, California, October 1985.

Munjack, D.J.: "Recent Research in the Treatment of Anxiety Disorders", Edgemont Hospital, Los Angeles, California, November 1985.

Munjack, D.J.: "The Current status of Anxiety Disorders", LAC+USC Medical Center, Grand Rounds, Los Angeles, California, November 19, 1985.

Munjack, D.J.: "Overview of Stress/Anxiety and its Effects", Los Angeles Unified School District, Region H, Los Angeles, California, March 19, 1986.

Munjack, D.J.: "Depression: The Other Side of Anxiety", Los Angeles Unified School District, Region H, Los Angeles, California, March 20, 1986.

Munjack, D.J.: "Alprazolam, Propranolol and Placebo in the Treatment of Panic Disorder and Agoraphobia with Panic Attacks", Presented as Anxiety and Anxiety Disorders: Biological Considerations, Sponsored by the Upjohn Company, Panic Disorder Biological Research Workshop, Washington D.C., April 14-16, 1986.

Schneider, L., Munjack, D.J., et al: "Imipramine binding in Panic Disorder and Generalized Anxiety", Presented as a Poster Session, American Psychiatric Association Meeting, Washington, D.C., May 1986.

Munjack, D.J.: "Principles and Practices of Behavior Therapy: Varieties of Psychotherapy", UCLA Medical Center, Department of Psychiatry, Los Angeles, California, August 1986.

Munjack, D.J.: "the role of Medication in the Treatment of Panic and Phobic States", Phobia Society of America National Meeting, New York, New York, October 1986.

Munjack, D.J.: "Sexual Dysfunction", 16th Annual Review Course in Obstetrics and Gynecology, School of Medicine/Postgraduate Division and the Department of Obstetrics and Gynecology, University of Southern California, Pasadena, California, October 21, 1986.

Munjack, D.J.: "The Treatment of Panic Disorders and Agoraphobia with Panic Attacks", Northridge Hospital Medical Center, Northridge, California, October 23, 1986.

Munjack, D.J.: "Sexual Dysfunction", 17th Annual Review Course in Obstetrics and Gynecology, School of Medicine/Postgraduate Division and the Department of Obstetrics and Gynecology, University of Southern California, Pasadena, California, January 15, 1987.

Munjack, D.J.: "Anxiety and panic", Clinical Advances and disorders of Women", University of Southern California Hospital, Marriott Hotel, Los Angeles, California, January 17, 1987.

Munjack, D.J.: "The Role of Medication in the Treatment of Panic and Phobic States", Phobia Society of America National Meeting, San Francisco, California, October 1987.

Munjack, D.J.: "Anxiety Disorders", Los Angeles Unified School District, Region A, Principals and Administrators Stress Management Workshop, Los Angeles, California, April 1988.

Munjack, D.J.: "The Evaluation and Treatment of Anxiety", Arcadia Methodist Hospital, Arcadia, California, June 1988.

Munjack, D.J.: "The Evaluation of Anxiety, The Treatment of Anxiety, The Evaluation of Depression", and "The Treatment of Depression; Plenary Session – An Overview of Depression Disorders", 31st Anniversary Postgraduate Refresher Course, University of Southern California School of Medicine Postgraduate Division, Honolulu and Kauai, Hawaii, August 14-31, 1988.

Munjack, D.J.: "The Evaluation and Treatment of Anxiety", Los Angeles County Medical Women's Association, West Hollywood, California, September 14, 1988.

Munjack, D.J.: "Evaluation of Sexual Problems in Office Practice", Detroit-Macomb Hospital, Detroit, Michigan, October 1988.

Munjack, D.J.: "The Role of Medication in the Treatment of Anxiety Disorders, San Bernardino County Hospital Staff, San Bernardino, California, October 1988.

Munjack, D.J.: "The Present State of Pharmacological Therapy for Anxiety", Phobia Society of America National Meeting, Boston Massachusetts, October 1988.

Munjack, D.J.: "Panic Disorder and Agoraphobia: The Present Status", LAC+USC Medical Center, Grand Rounds, Los Angeles, California, April 25, 1989.

Munjack, D.J.: "The Treatment of Psychiatric Disorders with Behavior Therapy", Harbor-UCLA Medical Center, Psychiatry Residents, Torrance, California, May 4, 1989.

Munjack, D.J.: "Panic Disorders: Management and Treatment", Beyond Depression, Los Angeles Chapter of California Academy of Family Physicians, Marriott Hotel, Los Angeles International Airport, Los Angeles, California, May 6, 1989.

Munjack, D.J.: "Attacking Anxiety", Discussant on Film, American Psychiatric Association, Annual Meeting, San Francisco, California, may 10, 1989.

Munjack, D.J.: "Panic Disorders and Depression in the Latino community: Evaluation, Diagnosis, and Treatment", Depression and Anxiety Disorders Update on the Diagnosis and Treatment as Seen in the Latino Medical Community, Multi-cultural Area Health Education Center (MAHEC), Tamayo Restaurant, Los Angeles, California, June 7, 1989.

Munjack, D.J.: "Clonazepam in the Treatment of Social Phobia: A Pilot Study", Conference on High Potency Benzodiazepines: Emerging Use in Psychiatry, Sponsored by Roche Laboratories, Boston, Massachusetts, January 20, 1990.

Munjack, D.J.: "Panic Disorder and Agoraphobia", Desert Medic al Series, Family Crises in Family Medicine, Sponsored by the Upjohn Company, Annenberg Center for Health Sciences at Eisenhower, Rancho Mirage, California, February 10-11, 1990.

Munjack, D.J.: "Panic Disorder: Disease for the 90's-Psychiatry and Primary Care Interface, Charter Canyon Hospital, Orem, Utah, April 18, 1990.

Munjack, D.J.: "Panic Disorder: Disease for the 90's", Western Institute of Neuropsychiatry, Salt lake City, Utah, April 18, 1990.

Munjack, D.J.: "Panic Disorder: Also a Disorder for the Family Physician", Good Samaritan Hospital, Los Angeles, California, June 11, 1990.

Hoffman, D.L., O'Leary, D.P., Munjack, D.J., and Koek, R.: "Vestibular Autorotation Testing of Panic Disordered Patients", Presented as a Poster Session, Association for Research in Otolaryngology Meeting, St. Petersburg, Florida, February 3-7, 1991.

Munjack, D.J.: "Recent Developments in the Treatment of Panic Disorders", Cedars-Sinai Medical Center, Grand Rounds, Los Angeles, California, October 22, 1990.

Munjack, D.J.: "Panic Disorder: A Diagnosis for the Family Doctor, As Well as the Psychiatrist", Huntington Memorial Hospital, Grand Rounds, Pasadena, California, November 1990.

Munjack, D.J.: "Panic Disorder: The Masquerader of Medical Illness", Torrance Memorial Hospital, Medical Education Conference, Torrance, California, December 5, 1990.

Munjack, D.J.: "Panic Disorder: A Treatable Dilemma", Cigna Hospital (Temple Branch), Health Education Conference, Los Angeles, California, March 14, 1991.

Hoffman, D., O'Leary, D.P., and Munjack, D.J.: "Vestibulo-Ocular Asymmetry and Gain-Phase Abnormalities in Patients with Panic Disorder", Presented as a Poster Session, American Academy of Otolaryngology-Head and Neck Surgery, Kansas City, Missouri, September 23, 1991.

Munjack, D.J.: "Systematic Approach to the Depressed Patient in Primary Care Practice", Sponsored by Eli Lilly and Company, Ma Maison Sofitel Hotel, Los Angeles, California, August 1991.

Munjack, D.J.: "Panic Disorder: Recognition and Treatment", California Medical Center, Family Health Department, Los Angeles, California, February 7, 1992.

Munjack, D.J.: "Results of a Comparative Discontinuation Study of Buspirone Vs. Alprazolam", Visiting Faculty Program by Mead-Johnson Pharmaceuticals, Loews Ventura Canyon Resort, Tucson, Arizona, February 22, 1992.

Munjack, D.J.: "Assessment and Treatment of Panic Attacks and Assessments and Treatment of Acute Depression", Twelfth Annual Mammoth Mountain Emergency Medicine Ski Conference, Mammoth Lakes, California, March 13, 1992.

Munjack, D.J.: "Assessment and Treatment of Panic Attacks", Primary Care Physicians, University of Southern California, Continuing Education Course, Mayer Auditorium, Health Science Campus, Los Angeles, California, March 17, 1992.

Hoffman, D.L,, O'Leary, D.P., and Munjack, D.J.: "Vestibulo-Ocular Asymmetry and Gain-Phase Abnormalities in Panic Disorder", Western Psychological Association, Portland, Oregon, May 2, 1992.

Munjack, D.J.: "Gain-Phase Abnormalities and Vestibular Abnormalities in Relation to Panic Disorder", Pacific Coast OTO-Opthalmological Society, Dona, Hawaii, June 23, 1992.

Hoffman, D.L., O'Leary, D.P., and Munjack, D.J.: "New Possible biological markers for Panic Disorder", LAC+USC Medical Center, Los Angeles, California, June 30, 1992.

Munjack, D.J.: "Recent Advances in the Treatment of Anxiety Disorders", Ingleside Hospital Medical Staff, Rosemead, California, May 20, 1992.

Munjack, D.J.: "Principles and Practice of Behavior Therapy", Psychiatric Residents, Harbor-UCLA Medical Center, Torrance, California, October 28, 1992.

Munjack, D.J., and Hoffman, D.L.: "Vestibular Abnormalities in Panic Disorder and Generalized Anxiety Disorder: Why Are Panic Disorder Patients Dizzy?", Department of Psychiatry, Grand Rounds, LAC+USC Medical Center, Los Angeles, California, November 24, 1992.

Munjack, D.J.: "Vestibular Abnormalities in Panic disorder and Generalized Anxiety Disorder", Biomedical Simulations Resource Site Visit, Seaver Science Building, University of Southern California, Collaborative Project #10 (with Dr. Dennis O'Leary), March 22, 1993.

Munjack, D.J.: "The Evaluation and Treatment of Depression in General Medical Practice", Department of Family Medicine, Harbor-UCLA Medical Center, Sponsored by SmithKline Beecham Pharmaceuticals, April 1993.

Munjack, D.J.: "Obsessive Compulsive disorder", Discussant, Grand Rounds, LAC+USC Medical Center, Los Angeles, California, September 1993.

Munjack, D.J.: "High Frequency Vestibulo-Ocular Reflex (VOR) by Vestibular Autorotation Test in Panic Disorder and GAD", The Anxiety Disorders Association of America, 14th National Conference, Santa Monica, California, March 17-20, 1994.

Munjack, D.J.: "The Suffocation Alarm theory of Panic Disorder", Presenter, Psychiatry Grand Rounds, LAC+USC Medical Center, Department of Psychiatry, Los Angeles, California, March 1994.

Munjack, D.J.: "Panic Disorders", Presenter, Common Problems in Primary Care, 20th Annual Review Course, Post-Graduate Education Course for Primary Care Physicians, Mayer Auditorium, Los Angeles, California, March 22, 1994.

Munjack, D.J.: "Sertraline in Social Phobia", Poster Presentation, CINP Meeting, Washington, D.C., June 1994.

Munjack, D.J., Fertig, D., Flowers,C.: "Sharing of Benzodiazepines in an Outpatient Anxiety Population", Poster Presentation, CINP Meeting, Washington, D.C., June 1994.

Hoehn-Saric, R., Fawcet, J., Munjack, D.J., Roy-Byrne, P.P.: "A Multicenter, Double-Blind, Placebo-Controlled Study of Fluvoxamine in the Treatment of Panic disorder", Poster Presentation, CINP Meeting, Washington, D.C, June 1994.

Munjack, D.J.: "Space Phobia Implications and Treatment", Discussant, Psychiatry Grand Rounds, USC+LAC Medical Center, Los Angeles, California, March 28, 1995.

Munjack, D.J.: "The Pharmacological Treatment of Obsessive Compulsive Disorder: An Update", 19th Annual Psychiatry Symposium – Psychiatric Treatments for the Mid-Nineties, Anaheim, California, September 8, 1995.

Munjack, D.J.: "Medical and Behavioral Aspects of Anxiety Disorders", Workshop, 19th Annual Psychiatry Symposium – Psychiatric Treatments of the Mid-Nineties, Anaheim, California, September 8, 1995.

Munjack, D.J.: "Depression", Family Medicine Comprehensive Review, University of Southern California School of Medicine, Los Angeles, California, June 28, 1996.

Munjack, D.J.: "The Spectrum of Social Anxiety Disorders", Orange County Psychiatric Society, Annual Meeting, Los Angeles, California, July 18, 1999.

Signature

9/6/02
Date

Medical Board of California
Physician and Surgeon License

Munjack, M.D., Dennis

Certificate No.: G23190
Expiration Date: 10/31/02

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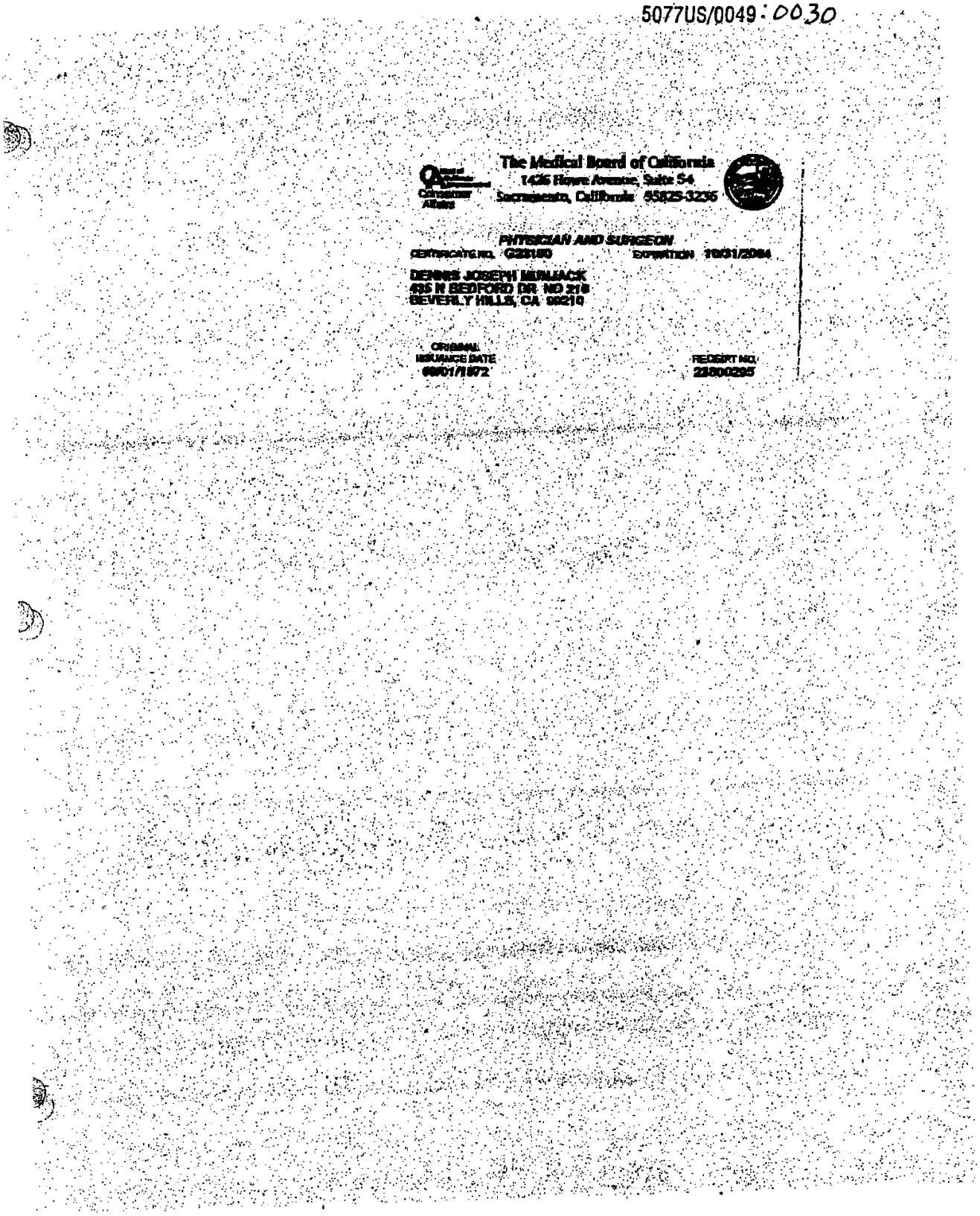

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EDUCATION

Bachelor of Arts, 1980, University of Texas at Austin (Psychology, Microbiology)
Doctor of Medicine, 1984, University of Texas Health Science Center at Houston
Internship in Psychiatry, 1984-1985, St. Mary's Hospital and Medical Center, San Francisco, CA
Residency in Psychiatry, 1985-1988, St. Mary's Hospital and Medical Center, San Francisco, CA
Fellowship in Electroconvulsive Therapy, 1989, Duke University Medical Center, Durham, NC

CERTIFICATION

Certified in Psychiatry by the American Board of Psychiatry and Neurology, July 1992

WORK EXPERIENCE

June 1986 to December 1988 – Contract Psychiatrist, Psychiatric Emergency Service, San Francisco General Hospital
August 1988 to September 1992 – Private Practice, San Francisco, California
November 1989 to September 1992 – Clinical Instructor in Psychopharmacology, University of California at San Francisco Family Practice Residency Program
October 1992 to Present – Private Practice, Austin, Texas
April 1993 to November 1995 – Medical Director, Geriatric Partial Hospitalization Program, St. David's Pavilion, Austin, Texas
July 1996 to April 1997 – Medical Director, Health and Wellness Center, Lockhart, Texas
April 1996 to February 1998 – Contract Psychiatrist, Austin Travis County Mental Health/Mental Retardation (Medication Support Service, Methadone Clinic, Anew/Champs Offender Program, CARE HIV Program, Intake Unit)

7/22/02

March 1998 to May 1999 – Staff Psychiatrist, Austin Travis County Mental Health/Mental Retardation, Director of Psychiatric Emergency Service and Inn/Cornerstone Unit
January 1999 to present – Medical Director for FUTURESEARCH TRIALS.

MEDICAL PRIVILEGES

Texas NeuroRehab Hospital, 1106 W. Dittmar Austin, Texas 78745

Shoal Creek Hospital, 3501 Mills Ave. Austin, Texas 78731

RESEARCH EXPERIENCE

A Multicenter, Double-Blind, Randomized Comparison of the Efficacy and Safety of an Atypical Antipsychotic and Risperidone in the Treatment of Patients with Scizophrenia

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of the Safety and Efficacy of an Atypical Antipsychotic as Add-On Therapy with Lithium or Divalproex in the Treatment of Acute Mania

Double-Blind Comparison of the Safety and Efficacy of an Investigational Antidepressant and Fluoxetine in the Treatment of Fluoxetine Nonresponders

Double-Blind Placebo-Controlled Study of an Investigational Antidepressant in the Treatment of Severe Major Depression

Flexible Dose Comparison of the Safety and Efficacy of an Investigational Antidepressant and Fluoxetine in the Treatment of Major Depressive Disorder

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating Efficacy and Safety of a Novel Antidepressant and Citalopram (20mg/day) in Patients with Major Depressive Disorder

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating Efficacy and Safety of a SSRI Controlled Release Formulation versus Placebo in Patients with Major Depressive Disorder

A Study to Evaluate the Efficacy, Safety and Maintenance Effect of an Atypical Antipsychotic Augmentation of SSRI Monotherapy in Young and Older Adult Patients with Unipolar Treatment-Resistant Depression

A Novel Antidepressant Once-Daily Dosing Versus Placebo in Patients with Major Depression and Pain

MK_1-Receptor Antagonist versus Active and Placebo Controls in Patients with Major Depressive Disorder with Melancholic Features

A Double-Blind, Placebo-Controlled, Multicenter Study of the Long-Term Efficacy of a MK_1-Receptor Antagonist in the Maintenance of Antidepressant Effect in Geriatric Outpatients With Major Depressive Disorder
An Anticonvulsant Versus Placebo as Add-On Treatment in Subjects with Bipolar Disorder in the Outpatient Setting

An Eight Week, Double-Blind, Placebo-Controlled Multicenter Study to Evaluate the Safety and Efficacy of 2 Doses of a 5-HT_{1D} (1.5 and 3MG) and Paroxetine in Subjects with Major Depressive Disorder

A Phase III, Randomized, Placebo-Controlled Study Evaluating the Safety and Outcome of Treatment with Oral Atypical Antipsychotic in Subjects with Mania

A Phase III, Three Week, MultiCenter, Randomized, Double-Blind, Placebo Controlled, Parallel Group Safety and Efficacy Study of an Extended-Release Anticovulsant in Treatment of Bipolar I Disorder

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of an Extended Release Single Ingredient Amphetamine in Adults with Attention Deficit Hyperactivity Disorder

A Four-week Double-blind, Placebo and Active Controlled, Dose-Ranging Study of 3 Doses of a Novel Anxiolytic and Lorazepam (3mg/day) in Outpatients with Generalized Anxiety Disorder

A Flexible Dose Comparison of the Safety and Efficacy of a Novel Antidepressant and Placebo in the Treatment of Generalized Anxiety Disorder

A Double-blind Comparison of a Novel Antidepressant and an SSRI in the Treatment of Generalized Anxiety Disorder

An Atypical Antipsychotic vs. Risperidone and Placebo in the Treatment of Psychosis and Associated Behavioral Disturbances in Patients with Dementia

A Placebo-Controlled 12-Week Study of the Safety and Efficacy of Two Doses of an Anticonvulsant in the Treatment of Acute Manic or Mixed Episodes in Subjects with Bipolar I Disorder with an Optional Open-Label Extension

A Double-Blind, Placebo-Controlled Dose Finding Study Evaluating the Safety and Efficacy of a Novel Antidepressant and a once daily dosing in the Treatment of Major Depressive Disorder

A Double-Blind, Placebo-Controlled Dose Finding Study Evaluating the Safety and Efficacy of a Novel Antidepressant in the Treatment of Major Depressive Disorder

A Double-Blind Inpatient Study of Flexible Doses of a Novel Antipsychotic versus Perphenazine in the Treatment of Patients with Treatment-Resistant Schizophrenia

A Double-Blind, Placebo-Controlled Dose Finding Study Evaluating the Safety and Efficacy of a Novel Antidepressant in the Treatment of Major Depressive Disorder

A Double-Blind Inpatient Study Evaluating the Safety and Efficacy of a Novel Antipsychotic versus Olanzapine in the Treatment of an Acute Episode of Schizophrenia

A Double-Blind Study Evaluating the Safety and Efficacy of a Novel Antidepressant verses Placebo and Paroxetine in the Treatment of Major Depression

A Double-Blind, Placebo Controlled Comparison of the Efficacy and Safety of a Short Acting Intramuscular Antipsychotic, Intramuscular Lorazepam and Intramuscular Placebo in Treating Agitation in Patients with Dementia of the Alzheimer's Type, Vascular Dementia and Mixed Dementia

A Six-Month, Open-Label, Multicenter Study of an Extended-Release Form of a Marketed Anticonvulsant in the Treatment of Patients with Bipolar Disorder

A Three-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Parallel-Group Safety and Efficacy Study of an Extended-Release Form of a Marketed Anticonvulsant in Patients with Bipolar Disorder

The Efficacy of an Atypical Antipsychotic and Adjunctive Lorazepam, as needed, to Treat Acute Behavioral Agitation in Inpatients with Schizophrenia

A Multicenter, Randomized, Double-Blind, Sertraline Controlled Study of the Efficacy and Safety of an Antidepressant in Subjects with Major Depression Disorder Who Failed on SSRI Treatment Due to Lack of Efficacy

An Open-Label Study Evaluating the Prevalence of Hyperprolactinemia in Schizophrenic Patients Taking Antipsychotics

An Open-Label Study Evaluating the Effects of an Antipsychotic on Hyperprolactinemia and Associated Comorbidity in Patients with Schizophrenia and Schizoaffective Disorder

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of the Safety and Efficacy of an atypical antipsychotic as Add-On Therapy with Lithium or Divalproex in the Treatment of Acute Mania

A Double-Blind, Randomized, Parallel Study of the Safety, Tolerability and Preliminary Efficacy of an Anti-Androgen Compared to Placebo in Patients with Anorexia Nervosa

A Dose Ranging, Double-Blind Placebo-Controlled, Safety, Tolerability and Efficacy Study of a Novel Anti-Depressant in Patients with Major Depressive Disorder

A Three Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Safety and Efficacy Study of a Mood Stabilizer in Lithium-Failure Patients with Bipolar Disorder

A Double-Blind, Randomized Comparison of the Efficacy and Safety of Sustained Release Atypical Antipsychotic and Placebo in the Treatment of Patients With Schizophrenia

A Controlled Trial of Atypical Antipsychotics in the Treatment of Schizophrenic and Schizoaffective Subjects with Prominent Negative Symptoms

A Novel Antidepressant Once-Daily Dosing Versus Placebo in the Acute Treatment of Major Depression

Flexible Dose Comparison of the Safety and Efficacy of a Novel SSRI and a marketed SSRI in the Treatment of major Depressive Disorder

PROFESSIONAL AFFILIATIONS

Texas Medical Association
Travis County Medical Association
Association of Clinical Research Professionals

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4200 MARATHON BLVD STE 200
AUSTIN TX 78756-3433

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CURRICULUM VITAE
Javad Razani, MD

Licensure

California Medical License G15084
DEA Number AR8917645

Associated Sites

Research Strategies Inc.
3858 Carson St., Suite 206
Torrance, CA 90503

Glendale Memorial Hospital
1520 South Central Avenue
Glendale, CA 91204

Golden State Behavioral Medical Group
1510 South Central Ave., Suite 320
Glendale, CA 91204

Advanced Psychiatric Group
3907 N. Rosemead Blvd., Suite 130
Rosemead, CA 91770

1510 South Central Ave., Suite 330
Glendale, CA 91204

Research Studies

- An Investigation of Thiothixine and Chlorpromazine on the Cognitive Disorders of the Process and Reactive Schizophrenics.
- A Controlled Comparative Study and Follow-Up of the Treatment of Dependence on Opiates in Iran.
- A Double-Blind Comparison of Tranylcypromine, Nortriptyline and Placebo in Depressed Outpatients.
- Comparative Efficacy and Side Effects of Amitriptyline vs Tranylcypromine vs. Their Combination in Treatment of Acutely Depressed in-patients.
- Family Therapy with Relapsing Schizophrenics.
- A Double-Blind Comparison of Slow Release Lithium (SRLI) and Rapid. Release Lithium (RRLI) with Particular Emphasis on Side Effects.
- Haloperidol Blood Levels in Relation to Clinical Effects.
- Cognitive Therapy vs. Notriptyline in Depression.
- An Open Trial of Deprenyl in MAOI—Responsive Depressive.

10-15-02

Education

Psychiatry Residency Temple University Health Sciences Center Department of Psychiatry Philadelphia, PA	1969-1972
Residency General Surgical Residency University of Colorado Medical Center Denver, CO	1967-1969
Internship University of Colorado Medical Center Denver, CO	1966-1967
B.A./ M.D. Program The John Hopkins University School of Medicine Baltimore, Maryland	1961-1966
Major Premedical Case-Western Reserve University Cleveland, OH	1959-1961

Board Certifications

Certification Added Qualifications in Geriatric Psychiatry Subspecialty Board	04/1994
Certification Added Qualifications in Addiction Psychiatry Subspecialty Board	03/1993
Diplomate American Board of Psychiatry and Neurology, Inc.	1978

Academic Appointments

Clinical Professor of Psychiatry and Behavioral Sciences University of Southern California Keck School of Medicine	08/97-Present
Professor of Clinical Psychiatry and Behavioral Sciences	07/89-08/97

University of Southern California School of Medicine

Associate Professor of Clinical Psychiatry and Behavioral Sciences — 1980-1989
University of Southern California School of Medicine

Assistant Professor of Psychiatry and Behavioral Sciences — 1972-1980
University of Southern California School of Medicine

Other Appointments

Chairman and Medical Director — 1997-Present
Behavioral Health Services
Glendale Memorial Hospital and Health Center
Glendale, CA

Director of Inpatient Geriatric Psychiatry — 1986-1996
University of Southern California School of Medicine
Los Angeles, CA

Acting Director, Division of Geriatric Psychiatry — 1988-1989
University of Southern California School of Medicine
Los Angeles, CA

Chairman, Patient Care Evaluation Committee — 1985-1989
Department of Psychiatry
University of Southern California School of Medicine
Los Angeles, CA

Chairman, Medical Care Review and Quality Assurance Committee — 1983-1989
University of Southern California School of Medicine
Los Angeles, CA

Director, Division of Professional and Staff Development — 1982-1989
Department of Psychiatry
University of Southern California
Los Angeles, CA

Other Post Graduate Training and Workshop

Certificate, Annual Workshop of the Society for Clinical And Experimental Hypnosis — 10/70 & 10/86
Philadelphia, PA

Course in Marital Therapy and Sexual Incompatibility — 02-05/71
Dr. Harold Lief & Staff
Department of Psychiatry
University of Pennsylvania

Certificate of Completion VI Behavior Therapy Institute Temple University	06/1971

Society Memberships

General Member American Psychiatric Association	05/73-Present
General Member Southern California Psychiatric Society	1973-Present
Member, The John Hopkins University Alumni Association	1967-Present
Society for Biological Psychiatry	1976-Present
Member, American Association for Geriatric Psychiatry	1989-Present
Member, American Academy of Addiction Psychiatry	1989-Present
Member, National Geographic Society	1984-Present
Coordinator (President) The Academy of Persian Physicians	1991
Coordinator Elect (President Elect) The Academy of Persian Physicians	1991
Member, Association for Advancement of Behavior Therapy	1980-1989
Member, American Association for the Advancement of Science	1981-1984
Member, Expert Advisory Committee on Drug Dependence and Alcohol Problems World Health Organization Geneva, Switzerland	1977-1981
Iranian Psychiatric Association	1975-1980
Pennsylvania Psychiatric Association	1971-1973
Philadelphia Psychiatric Society	1971-1973
Member Training American Psychiatric Association	1971-1972
Nu Sigma Nu (NEN) Medical Fraternity	1961-1966
Sigma Chi (EX) Fraternity	1959-1961

Other Activities

Faculty Lecturer 02/1988
"Appropriate Use of Neuroleptics on Medical-Surgical Units"
Medical Staff Meeting, Memorial Hospital of Glendale
Glendale, CA

Board Member 1987
University of Southern California Psychiatry and Behavioral
Associates Faculty Practice Plan
Los Angeles, CA

Lecturer 07/30/86
"Depression: The Hidden Illness"
Elder Med Community Education Program
Verdugo Hills Hospital

Chairman, Education Committee, Department of Psychiatry 1982-1985
Brotman Medical Center
Culver City, CA

Member, Executive Committee, Department of Psychiatry 1982-1985
Brotman Medical Center
Culver City

Bibliography

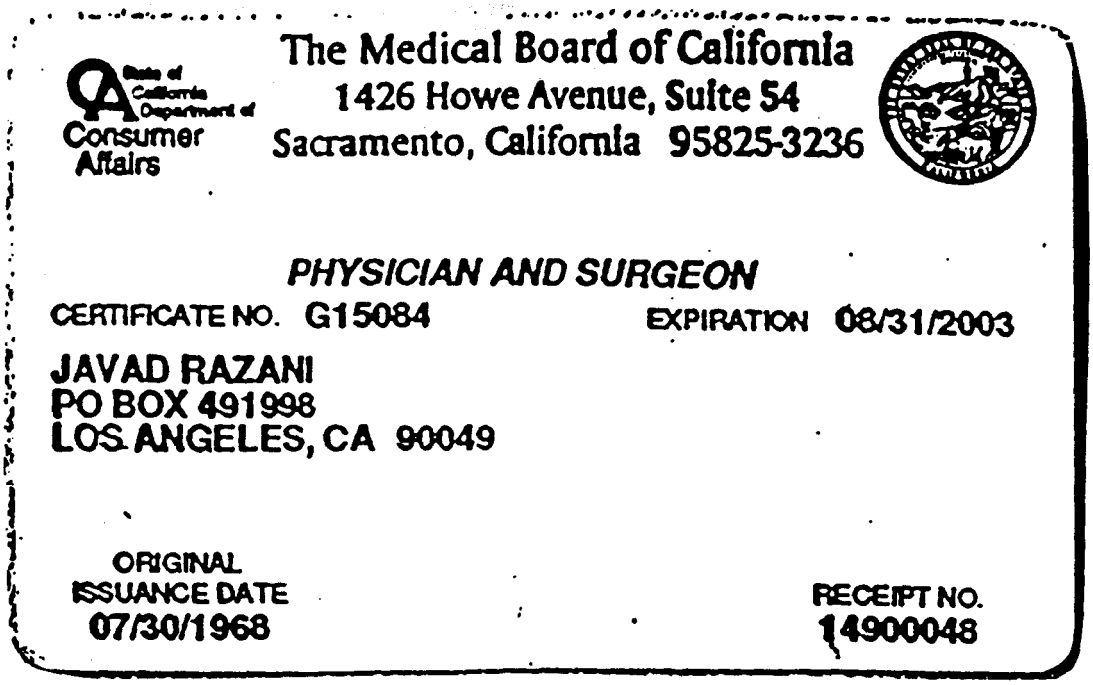
1. Razani, Javad, "Ejaculatory Incompetence Treated by Deconditioning Anxiety" J. Behav. Ther. And Exp Psychiat. 3:65-67, 1972
2. Razani, Javad, " Residents Participation in Curriculum Planning and Execution:, Transactions and Studies of the College of Physicians of Philadelphia, 40(2): 103-105, 1972
3. Razani, Javad, "Treatment of Phobias by Systematic Desensitization: Comparison of Standard vs. Methoexital-Aided Desensitization", Archives of General Psychiatry, 30: 391-393, 1974
4. Munjack, D., Razani, J., "Side Effects of Brevital-Aided Desensitization: Some Clinical impressions", Behavior Therapy, 423-427, 1974
5. Knee, S., Razani, J., "Acute Organic Brain Syndrome, A Complication of Disulfiram Therapy", American Journal of Psychiatry, 131 (11): 286-291, 1974
6. Razani, J., Farina, S., and Stern, R., "Covert Drug Abuse Among Patients Hospitalized in the Psychiatric Ward of a University Hospital." The International Journal of the Addictions, 10(4) : 693-698, 1975.
7. Razani, J., Chisolm, D., Glasser, M., Kappeler, T., "Self-Regulated Methadone Detoxification of Heroin Addicts: An Improved Technique in and Inpatient Setting", Archives of General Psychiatry, 32: 909-911, 1975

8. Maloney, M.P., Sloane, R.B., Whipple, K., Razani, J., and Eaton, E.M., "Auditory Attention in Process and Reactive Schizophrenia", Biological Psychiatry, 11 (3): 325-331, 1976.
9. Razani, Javad, "Status of Drug Abuse and Its Treatment in Iran", Addictive Disease, 3 (1): 69-74, 1977.
10. Razani, Javad, "Current Modalities of Treatment and Follow-Up Approaches of Addicts", presented at Tehran University Symposium on Addiction, Tehran, Iran, Fall 1976. Published in Ravan Pezeshgi (Journal of Psychiatry), Tehran, Iran, 49: 125-131,1977.
11. Strang, J., Falloon, I., Moss, H., Razani, J., and Boyd, J. The Effects of Family Therapy on Treatment Compliance in Schizophrenia. Psychopharmacology Bulletine. 17: 87-8, 1981.
12. Razani, J., White, K., White, J., Simpson, G., Sloane, R. B., Rebal, R., Palmer, R., The Safety and Efficacy of Combined Amitriptyline and Tranylcpromine Antidepressant Treatments: A Controlled Trial. Arch. Gen. Psych. 40: 657-661, 1983.
13. White, K., Razani, J., Cadow, B., Gelfrand, R., Palmer, R., R., Simpson, G., and Sloane R. B. Tranylcypromine vs. Nortriptyline vs. Placebo in Depressed Outpatients: A Controlled Trial. Psychopharmacology 82: 258-262, 1984.
14. White, K., Razani, J., Simpson, G., Rebal, R. Sloane, R.B., O'Leary, J., and Palmer, R. Combined MAOI-Tricyclia Antidepressant Treatment: A Controlled Trial. Psychopharmacology Bulletin 18(1): 179-81, 1982.
15. Falloon, I., Marshal, G., Boyd, J., Razani, J., and Wood, C. Relapse in Schizophrenia: A Review of the Concept and it's Definition. Psychological Medicine, 13(3): 469-77, 1983.
16. White, K., O'Leary, J., Razani, J., Rebal, R., and Palmer, R. MAOI vs. TCA: Electrocardiographic Effects. Journal of Clinical Psychiatry 44: 91-93, 1983.
17. Falloon, I.R.H., Boyd, J., McGill, C., Razani, J., Moss, H., and Golderman, A.. Family Management in the Prevention of Exacerbations of Scizophrenia. A Controlled Study. New England Journal of Medicine, 306: 1437-1440, 1982.
18. Falloon, I.R.H., Boyd, J., McGill, C. Razani, J., et al. Family Management in the Prevention of Morbidity of Schizophrenia. Archives of General Psychiatry, 42 (9): 887-896, 1985.
19. White, J., White, K., Razani, J.: The Influence of Subtype of Depression in Self Rating Scale Validity. National Institute of Education, Resources in Education, University of Michigan, Ann Arbor, 8: 271-274, 1983.
20. White, K., Busk, J., Eaton, E., Gomez, G., Rzaani, J., Sloane, R.B. Dysporic Response to Neuroleptics as a Predictor of Treatment Outcome with Schizophrenics. International Pharmacopsychiatry. 16: 34-38, 1981.
21. Simpson, G., White, K., Pi, E., Razani, J., Sloane, R.B. Monoamine Oxidase Inhibition and Tyramine Sensitivity in Deprenyl Treated Subjects. Psychopharmacology Bulletin 19(3): 93-96, 1983.
22. White, K., McDonald, I., Razani, J., Shih, J., Simpson, G., Sloane, R.B. Platelet MAO Activity in Depression. Comprehensive Psychiatry, 24(5): 453-8, Sept.-Oct.1983.

23. White, J., White, K., Razani, J. Effects of Endogenicity and Severity on Consistency of Standard Depression Rating Scales. J Clin Psychiatry, 45(6): 260-262, 1984.

In Progress:

1. Tuma, A.H., Kline, N., Razani, J., et al. A Report on the Comparative Treatment of Opiate Dependence in Iran. World Health Organization Publications, Geneva, Switzerland.
2. Whipple, K., Eaton, E., Sloane, R.B., Maloney, M. P., Razani, J. World Association Commonality in Schizophrenia: Clinical Correlates and the Process-Reactive Dimension.



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JAVAD RAZANI
PO BOX 491998
LOS ANGELES, CA 90049

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07/30/1968

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14900048

CURRICULUM VITAE
Ari Kiev, M.D.
SOCIAL PSYCHIATRY RESEARCH INSTITUTE

Education:

1950-1954	Harvard College, Cambridge, Massachusetts- A.B., Magna Cum Laude
1954-1958	Cornell Medical College, New York, NY- M.D.
1984-1988	New York Law School, New York, NY- J.D.

Professional Experience:

2001- Present	Social Psychiatry Research Institute, 3044 Coney Island Avenue, Suite 201 Brooklyn, NY 11235- President
1970- Present	Social Psychiatry Research Institute, 150 East 69th Street, Suite 2H New York, NY 10021- President
1994-Present	LifeSpan DevelopMental Systems, 7 Fox Street, Suite 103 Poughkeepsie, NY 12601- Director of Research
1995	Admitted to Practice Before United States Supreme Court
1990	Admitted to New York Bar
1988	Admitted to New Jersey Bar
1978-1980	United States Olympic Council on Sports Medicine New York, NY Chairman, Psychiatry Division
1977	Wilford Hall Hospital, Lackland Air Force Base, Texas Distinguished Visiting Professor
1975-1976	New York University, New York, NY, Adjunct Professor of Psychology
1967-1968	Brandeis University,Waltham, MA- Visiting Professor of Anthropology
1962-1964	Wilford Hall USAF Hospital, Lackland Air force Base, Texas Staff Psychiatrist, Captain USAF, M.D.
1961-1962	The Institute of Psychiatry, Maudsley Hospital, London, England Clinical Assistant, Postdoctoral Research Fellow (NIMH)
1959-1961	Henry Phipps Psychiatric Clinic, The Johns Hopkins Hospital Baltimore, MD- Psychiatric Resident
1958-1959	New York State Medical College (Downstate),Kings County Hospital Center Brooklyn, NY, University Medical Internship

A Kiev
8-20-03

Professional Memberships/Organizations:

American Psychiatric Association (Life Fellow)
American College of Legal Medicine (Fellow)

Academic Affiliations:

1967-1998	Cornell University Medical College, New York, NY Clinical Associate Professor of Psychiatry
1967-1998	New York Hospital, New York, NY- Associate Attending Psychiatrist
1966-1967	College of Physicians and Surgeons, Department of Psychiatry Columbia University, New York, NY Field Station Director • Psychiatric Epidemiology Research Unit
1964-1967	New York State Psychiatric Institute,New York, NY Assistant Attending Psychiatrist
1964-1967	Department of Psychiatry, College of Physicians and Surgeons Columbia University,New York, NY- Research Associate

Licenses/Certification:

Medical Licenses:
New York # 083337
New Jersey # MA20261
New York DEA # AK 1795559
New Jersey DEA # BK 2206630

Certifications:
1965 American Board of Psychiatry and Neurology

Publications: Available upon request.

Recent Research Experience: 2003

A Multi-center, Double-Blind, Randomized, Placebo-Controlled Comparison of the Effects on Sexual Functioning of Extended-Release Bupropion Hydrochloride (300-450mg) and Escitalopram (10-20mg) in Outpatients with Moderate to Severe Major Depression over an Eight-Week Treatment Period AK130926

A four-week double-blind, placebo and active controlled, dose-ranging study of SL 65.1498-00, 3 doses (5, 15, 50mg per day) and lorazepam (3mg/day) in out-patients with Generalized Anxiety Disorder (GAD) DR14390

A Multi-center, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression 5077US/0049

A Double-blind, Multi-center, Extension Trial in Subjects with Major Depressive Disorder who participated in the Placebo-controlled, Efficacy and Safety Trial of Org 22062 ER and Fluoxetine in Subjects with Major Depressive Disorder 134506

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CURRICULUM VITAE

Ramanath Gopalan, MD

Comprehensive NeuroScience of Northern Virginia
6066 Leesburg Pike
Falls Church, VA 22041
703-998-5850

Education:

1983-1985	Arizona Health Sciences Center, Tucson, Arizona Fellowship in Administrative Psychiatry Southern Arizona Mental Health Center and Kino Community Hospital Practical experience
1980-1983	Arizona Health Sciences Center, Tucson, Arizona Psychiatry Residency -- PGY-11-IV
1979-1980	Chicago Medical School, Chicago, Illinois Psychiatry Internship--PGY-I
1975-1976	General Rotating Medical Internship, Bombay, India
1969 – 1975	Topiwala National Medical College, University of Bombay, India – M.B.B.S. (equivalent to MD)
1967-1969	University of Bombay, Bombay, India – Bachelor of Science

Professional Experience:

2001-present	Investigator Comprehensive NeuroScience of Northern Virginia, LLC
1998 – 2002	Principal Investigator ICSL - Clinical Studies Falls Church, VA
1997-1998	Sub-Investigator ICSL - Clinical Studies Falls Church, Virginia

Professional Experience:
(cont'd)

1996-Current	Private Practice in General Psychiatry, 6066 Leesburg Pike Falls Church, Virginia 22041
1996-Current	Psychiatric Consultant at: Burke Health Care Center, Burke, Virginia
1996-Current	Sleepy Hollow Manor Nursing & Convalescent Home Annandale, Virginia
1996-Current	Cherrydale Healthcare Center Arlington, Virginia

Licenses/Certifications:

1994- Current	MD-State of Virginia #0101049249
1985- Current	MD-State of Arizona #15598
1992- Current	American Association of Physicians from India
1982- Current	American Psychiatric Association
1982- Current	Arizona Psychiatric Society
1989- Current	Tucson Psychiatric Society
1979	E.C.F.M.G. Certificate #255-305-5

Admitting Priviledges:

- Dominion Hospital - 2960 Sleepy Hollow Road, Falls Church, VA 22044
- Virginia Hospital Center Arlington - 1701 North George Mason Drive, Arlington, VA 22205
- Northern Virginia Community Hospital - 611 S. Carlin Springs Rd, Arlington, VA 22204

Medical Procedures:

Trained in physical exams, venipuncture, vital signs and administering electrocardiograms.

Proficient In The Following Adult Psychiatric Rating Scales:

Brief Psychiatric Rating Scale (BPRS)
Calgary Depression Scale
Hamilton Anxiety Scale (HAMA)
Hamilton Depression Rating Scale (HAMD)
Leibowitz Social Anxiety Scale (LSAS)
Montgomery and Asberg Depression Rating Scale (MADRS)
Positive and Negative Syndrome Scale for Schizophrenia (PANSS)
Structured Clinical Interview for DSM-IV (SCID)
Structured Clinical Interview for DSM-IV Axis II Disorders (SCID II)
Yale Brown Obsessive Compulsive Scale (YBOCS)
Young Mania Rating Scale (YMRS)

Research Experience:

A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of study medication in the Maintenance Treatment of Patients with Bipolar Disorder

A Multicenter, Randomized, Double-Blind Study of Flexible Doses of study medication Versus Perhenazine In The Treatment of Patients With Acute Schizophrenia

A Multicenter, Double-blind, Randomized Comparison of the Efficacy and Safety of Quetiapine Fumarate (SEROQUEL™) and Risperidone (RISPERDAL™) in the Treatment of Patients with Schizophrenia

Olanzapine versus Risperidone in the Treatment of Bipolar I Disorder, Manic or Mixed

A Multicenter, Randomized, Double-Blind, Study of Aripiprazole Versus Placebo in the Treatment of Acutely Manic Patients with Bipolar Disorder

A randomized, open-label, multicenter, 6-arm, parallel group, safety study evaluating the effect of oral iloperidone at doses of 8 mg b.i.d., 12 mg b.i.d., and 24 mg q.d. on QTc interval duration in the presence and absence of metabolic inhibition, relative to other antipsychotics (Risperidone 4 mg b.i.d., ziprasidone 80 mg b.i.d., and quetiapine 375 mg b.i.d. in the presence and absence of metabolic inhibition), in otherwise healthy patients diagnosed with schizophrenia or schizoaffective disorder

Research Experience:
(cont'd)

A 6½ Month, Multicenter, Randomized, Double-blind, Placebo Controlled Comparison of 150-300mg/day of Extended-release Bupropion hydrochloride and Placebo for the Prevention of Seasonal Affective Disorder in Subjects with a History of Seasonal Affective Disorder

A Double-Blind, Multicenter, Placebo-Controlled Study of MK-0869 in the Treatment of Patients with Major Depressive Disorder

A 12 Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of Donepezil Hydrochloride as Adjunctive Therapy in the Treatment of Cognitive Impairment in Patients with Schizophrenia or Schizoaffective Disorder

An Open-Label, Dose-Blinded, Multicenter, 6-Month Study of Safety and Tolerability of 3 Dose Levels of SM-13496 in Patients with Schizophrenia

A 6-Week, Double-Blind, Randomized, Fixed-Dose, Parallel-
Group Study of the Efficacy and Safety of Three Dose Levels of SM-13496 Compared to Placebo and Haloperidol in Patients with Schizophrenia Who are Experiencing an Acute Exacerbation of Symptoms

A randomized assigned trial of oral XXX versus intramuscular XXX in the emergency treatment of acute psychosis.

XXX cardiovascular treatment assessment versus XXX (XXX).

Safety and efficacy of XXX as combination therapy in the treatment of psychosis associated with schizophrenia.

A multicenter, randomized, double blind study of flexible doses of XXX versus XXX in the treatment of patients with treatment-resistant schizophrenia.

Sustained efficacy study of XXX in patients with panic disorder with or without agoraphobia.

A placebo-controlled 12-week study of the safety and efficacy of two doses of XXX versus XXX for the treatment of acute manic or mixed episodes in subjects with Bipolar I Disorder with an optional open-label extension.

Research Experience:
(cont'd)

A double blind, placebo-controlled dose finding study evaluating the safety and efficacy of XXX/day in the treatment of major depressive disorder.

Safety and efficacy of long-term administration of XXX in the treatment of major depressive disorder. A 4-month double blind extension to study XXX.

Safety of open-label standard antidepressant therapy in the treatment of major depressive disorder. A 1-month follow-up after termination of study XXX.

A 6-week, double blind, placebo-controlled, multicenter study to evaluate the safety and efficacy of 3 doses of XXX and XXX in subjects with major depressive disorder.

A double blind 6-month continuation protocol for patients who successfully completed protocol XXX followed by an optional extension phase of up to a year.

A 364-week (7 year), open extension study evaluating the safety and outcome of XXX daily of oral XXX or XXX BID of oral XXX daily in the treatment of subjects who have participated in previous XXX clinical trials.

A double blind multi-centered study comparing the safety and efficacy of XXX to XXX in patients with schizophrenia or schizoaffective disorder needing in-patient care.

A multicenter, randomized, double blind, placebo-controlled study of flexible doses of XXX in the treatment of hospitalized patients with acute mania.

A multicenter, randomized, double blind, placebo controlled study of XXX in the maintenance treatment of patients with bipolar disorder.

A multicenter, randomized, double blind, placebo controlled study of three fixed doses of XXX in the treatment of patients with acute schizophrenia.

XXX depot (microspheres) vs placebo in the treatment of subjects with schizophrenia.

XXX depot (microspheres) in the treatment of subjects with schizophrenia or schizoaffective disorder.

Research Experience:
(cont'd)

A double blind, placebo and XXX controlled, multicenter study evaluating the safety and efficacy of SR XXX in schizophrenic patients.

A double blind, placebo and XXX controlled, multicenter study evaluating the safety and efficacy of SRXXXXXX in schizophrenic patients.

A randomized, double-blind, placebo and XXX controlled, multicenter study to evaluate the efficacy and safety of two overlapping dose ranges of XXX given b.i.d. for 42 days to schizophrenic patients followed by a long term treatment phase with XXX given q.d.

A double blind, place controlled, parallel group comparison of XXX extended release capsules and XXX in outpatients with generalized social anxiety disorder.

A three-month open label study of the tolerability and safety of XXX in schizophrenic patients.

An open-label follow on study of the long-term safety of XXX in patients with psychosis.

XXX long term extension of Protocol XXX-XXX.

A multi-center, open-label, humanitarian study with sublingual XXX.

A double blind, placebo-controlled study of XXX in the treatment of signs and symptoms of mania in elderly patients with dementia.

XXX in the management of behavioral disturbances and/or psychosis in demented nursing home patients.

Clinical evaluation of efficacy and safety of XXX in the treatment of Alzheimer's disease.

A Phase III randomized study comparing 2 doses of intramuscular XXX in subjects with psychosis and acute agitation.

An open-label study to evaluate the safety and efficacy of XXX through XXX of XXX in patients with mild to severe probable Alzheimer's disease.

A randomized, double blind, placebo-controlled, four-arm dose-finding study.

Research Experience:
(cont'd)

Investigating the efficacy and safety of three doses of XXX in patients with Alzheimer's disease.

A double blind, randomized, comparison of the safety and efficacy of XXX and XXX in treatment resistant schizophrenic patient.
Double blind, haloperidol-controlled, safety and dose finding study in the treatment of schizophrenia.

A double blind, placebo-controlled, haloperidol-referenced study of the safety and efficacy of three doses of XXX administered to schizophrenic patients for 42 days.

An open-label assessment of the long-term safety of XXX.

Long-term safety and efficacy of XXX in the treatment of Alzheimer's disease.

An open-label, long-term, safety study of transdermal XXX in the treatment of anxious outpatients.

An eight-week, multicenter parallel group, double-'blind, placebo-controlled study of XXX in elderly outpatients with DSM-IV major depression.

A multi-center pilot study to examine the clinical effects of cross titration of antipsychotics with XXX in subjects with schizophrenia or schizoaffective disorder followed by an optional open extension phase with continued XXX treatment.

A multi-center pilot study to examine the clinical effects of cross titration of XXX with XXX in subjects with schizophrenia or schizoaffective disorder followed by an optional open extension phase with continued XXX treatment.

The safety and efficacy of XXX vs placebo vs XXX as add-on therapy to mood stabilizers in the treatment of the manic phase of bipolar disorder.

Weekly enteric-coated XXX XXX versus daily XXX or placebo in the continuation treatment of major depressive disorder.

An open-label follow on study of the long-term safety of XXX in patients with psychosis.

XXX added to mood stabilizers in the treatment of bipolar disorder.

Research Experience:
(cont'd)

A phase III double-blind placebo-controlled study of XXX in the treatment of psychosis, with XXX as active control.

A Phase III double-blind placebo-controlled study of XXX in the treatment of psychosis.

A multicenter, double - blind, placebo-controlled evaluation of the safety and efficacy of XXX compared to placebo and XXX in the treatment of an acute manic or mixed episode in patients who have bipolar disorder: Incorporating participation in genotype research which is optional for both study centers and patients.

A double-blind, randomized, active controlled, parallel study comparing ethical XXX XXX 7-day patch 40, 60, 80 ug/day to oral XXX 0.625 mg/day in the treatment of vasomotor symptoms in postmenopausal women.

XXX vs. XXX in the treatment of subjects with schizophrenia.

A multicenter, placebo and active control, double blind, randomized study of the efficacy, safety and pharmacokinetics of XXX (10 and 20mg/day) in schizophrenic and schizoaffective patients.

Multicenter, open-label, long-term follow-up, safety study of XXX tablets in schizophrenic and schizoaffective subjects who participated in protocol XXX or XXX.

A double blind, placebo and haloperidol-controlled, multicenter study evaluating the safety and efficacy of XXX in schizophrenic patients.

A six-week, double-blind, placebo- and fluoxetine-controlled multicenter study to evaluate the safety and efficacy of oral XXX in outpatients with major depressive disorder.

A prospective, randomized, international, parallel-group comparison of XXX/XXX vs XXX in the reduction of suicidality in patients with schizophrenia or schizoaffective disorder who are at risk for suicide.

Safety and efficacy of fixed combination XXX/XXX products as first line therapy in patients with type 2 diabetes mellitus who have inadequate glycemic control with diet and exercise.

Research Experience:
(cont'd)

A multicenter, double-blind, randomized study of continuous transdermal XXX-XXX combinations, compared to continuous XXX XXX, to examine the safety and effect on the endometrium, symptoms and bleeding patterns in postmenopausal women.

Placebo-controlled study of the safety and efficacy of XXX in the treatment of acute manic or mixed episodes in subjects with bipolar I disorder.

A prospective, randomized, double-blind, placebo- and active-controlled, multicenter study to evaluate the efficacy and safety of three fixed doses of XXX (4, 8, and 12 mg/day) given b.i.d. for 42 days to schizophrenic patients with acute or subacute exacerbation, followed by a double-blind, active-controlled, flexible-dose, long-term, 20-week phase with XXX (4, 8, 12 or 16 mg/day) given q.d.

A multicenter, open-label, long-term, safety and efficacy study of XXX tablets once daily in subjects with schizophrenia or other psychotic disorders.

A double blind, multi-center controlled study comparing the safety and efficacy of XXX and XXX to placebo in patients with schizophrenia or schizoaffective disorder needing inpatient care.

XXX versus XXX and placebo in the treatment of psychosis and associated behavioral disturbances in patients with dementia.

A double blind, placebo-controlled parallel-group assessment of the safety and efficacy of two doses of the XXX in patients with major depression.

A randomized, multi-center, double blind, placebo-controlled, fixed-dose seven-week evaluation of the efficacy and safety of XXX in treatment of a major depressive episode in unipolar depressed patients.

A double-blind, randomized, multicenter, parallel group design study to evaluate the efficacy and safety of two dose ranges of XXX in comparison with placebo and haloperidol in the treatment of schizophrenia.

Phase II, six-week, double blind, placebo- and XXX controlled study evaluating the safety and efficacy of oral XXX in schizophrenia and schizoaffective disorder.

Research Experience:
(cont'd)

A double blind, five-armed, fixed-dose active- and placebo-controlled dose-finding study with sublingual XXX in subjects with acute phase schizophrenia.

A multicenter, double blind, placebo-controlled evaluation of the safety and efficacy of XXX compared to placebo in the treatment of an acute manic or mixed episode in patients who have bipolar disorder.

A prospective, randomized, double-blind, placebo- and active controlled, multicenter study to evaluate the efficacy and safety of three fixed doses of XXX given b.i.d. for 42 days to schizophrenic patients with acute or subacute exacerbation, followed by a double-blind, active-controlled, flexible-dose, long-term, 6-month phase with XXX given q.d.

Efficacy of XXX in the treatment of acutely ill non-compliant schizophrenic subjects.

Comparison of the safety and efficacy of XXX and XXX in the treatment of bipolar disorder.

A double blind, multicenter study of two doses of XXX vs. XXX and placebo in the treatment of outpatients with major depressive disorder.

1/27/03

January 27, 2003

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Medical Director, CNS-IPR of Southern California, Inc., a multi site clinical trials program limited to central nervous system diseases.

Board Status:

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Diplomate, Added Qualification in Geriatric Psychiatry, American Board of Psychiatry and Neurology, 1991

Diplomate, Added Qualification in Addiction Psychiatry, American Board of Psychiatry and Neurology, 1994

Diplomate, American Society of Addiction Medicine, 2000

Licensure: California License #G40374

State of California, Department of Industrial Relations, Industrial Medical Council; Qualified Medical Evaluator
- 1993 to present

Education:

B.A. Psychology, Suma Cum Laude, 1974, SUNY at Buffalo, Buffalo, NY
M.D., 1978, Rush Medical College, Chicago, Illinois

Internship:

Psychiatry, UCLA Neuropsychiatric Institute, 1978-1979

Residency:

Psychiatry, UCLA Neuropsychiatric Institute, 1979-1981

Fellowship:

Psychopharmacology, National Institute of Mental Health, Bethesda, Maryland, 1981-1983

Clinical and Administrative Experience

Senior Vice President, Clinical Services,
Aspen Youth Services, Cerritos California, 1998-2001

President and Medical Director,
College Health IPA, a managed behavioral health group practice, Cerritos California, 1993-2001

Senior Medical Director,
College Hospital, Cerritos, California, 1993-1999

Medical Director,
Los Altos Hospital and Mental Health Center, Long Beach, California
August 1987 to August 1993

Chief, Inpatient Unit,
Clinical Psychobiology Branch, National Institute of Mental Health, Bethesda, Maryland
January 1993 to August 1987

Private Practice Experience,
1982 to Present, predominantly in the treatment of patients with affective and anxiety disorders

Emergency Psychiatric Experience,
L.A. County, Olive View Medical Center, Van Nuys, California
December 1979 to June 1981
Prince George's County General Hospital
December 1981 to June 1983

Honors:

1978 – Phi Beta Kappa

PUBLICATIONS

1. Schauf CL, Davis FA, Sack DA, Reed BT, Kesler RL: Neuroelectric blocking factors in human and sera evaluated using the isolated frog spinal chord. *Journal of Neurology, Neurosurgery, and Psychiatry,* 39: 680-685, 1976.

2. Scharfstein SS, Sack DA, Fauci AS: Relationship between alternate day corticosteroid therapy and behavioral abnormalities. *Journal of the American Medical Association,* 248: 2987-2989, 1982

3. Wehr TA, Sack DA, Rosenthal NE, Duncan WK, Gillin JD, Gillin JC: Circadian rhythm disturbances in manic-depressive illness. *Federation Proceedings,* 42: 2809-2814, 1983.

4. Rosenthal NE, Sack DA, Wehr TA: Seasonal Variation in affective disorders, in Wehr TA, Goodwin FK (eds.), *Biological Rhythms in Psychiatry,* Boxwood Press, Pacific Grove, California, 1983, pp. 185-201.

5. Rosenthal NE, Sack DA, Gillin JC, Lewy AJ, Goodwin FK, Davenport Y, Newsome DA, Wehr TA: Seasonal affective disorder: A description of the syndrome and preliminary findings with light therapy. *Archives of General Psychiatry,* 41: 72-80, 1984.

6. Rosenthal NE, Sack DA, Carpenter CJ, Parry BL, Mendelson WB, Wehr TA: Antidepressant effects of light in seasonal affective disorder. *American Journal of Psychiatry,* 142: 06-608, 1985.

7. Wehr TA, Sack DA, Duncan W, Rosenthal NE, Gillin JC, Goodwin FK: Sleep and circadian rhythms in affective patients isolated from external time cues. *Psychiatry Research,* 15: 327-339, 1985

8. Sack DA, Numburger J, Rosenthal NE, Ashburn E, Wehr TA: The potentiation of antidepressant medications by phase-advance of the sleep-wake cycle. *American Journal of Psychiatry,* 142: 606-608, 1985

9. Wehr TA, Rosenthal NE, Sack DA, Gillin JC: Antidepressant effects of sleep deprivation in bright and dim light. *Acta Psychiatrica Scandinavica,* 72: 161-165, 1985.

10. James SP, Wehr TA, Sack DA, Parry BL, Rosenthal NE: Evening light treatment of seasonal affective disorder. *British Journal of Psychiatry,* 147: 424-428, 1985.

11. Strauss GD, Sack DA, Lesser I: Which veterans go to VA psychiatric hospitals for care: a pilot study. *Hospital Community Psychiatry, Sept.* 1985.

12. Golden RN, James SP, Sherer MA, Rodorfer MV, Sack DA, Potter WZ: Psychosis associated with bupropion treatment. *American Journal of Psychiatry, Dec.* 1985

13. Rosenthal NE, Sack DA, Wehr TA: Seasonal effects on mood: The role of light in Adelman G(ed.), *Encyclopedia of Neuroscience,* Birkhauser, Boston.

14. Wehr TA, Sack DA, Rosenthal NE: Antidepressant effects of sleep deprivation and phototherapy. *Acta Psychiatrica Belgica,* 85, 593-602, 1985.

15. Wehr TA, Sack DA, Parry BL, Rosenthal NE: The role of biological rhythms in the biology and treatment of insomnia and depression, in Brodie HKH, Berger PA (eds.), *The American Handbook of Psychiatry.*

16. Rosenthal NE, Sack DA, Jacobsen FM, James SP, Parry BL, Arendt J, Tamarkin L, Wehr TA: The role of melatonin in seasonal affective disorder. *Journal of Neural Transmission.*

17. James SP, Wehr TA, Sack DA, Rosenthal NE, Mendelson WB: Experimental modalities in the treatment of seasonal and non-seasonal affective disorder. *Proceedings of the World Congress of Biological Psychiatry.*

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19. Rosenthal NE, Sack DA, Jacobsen FM, Parry BL, James SP, Tamarkin L, Arendt J, Wehr TA: Consensus and controversy in seasonal affective disorder and phototherapy. *Proceedings of the World Congress of Biological Psychiatry.*

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23. Wehr TA, Jacobsen FM, Sack DA, Arendt J, Tamarkin L, Rosenthal NE: Phototherapy of seasonal affective disorder. Time and day suppression of melatonin are not critical for antidepressant effects. *Arch Gen Psychiatry Sept.* 1986.

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antidepressant effect in seasonal affective disorder. *Archives of General Psychiatry,* 43: 870-875.

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38. Wehr TA, Sack DA, Rosenthal NE: Reverse seasonal affective disorder with spring-summer depression and fall-winter hypomania: possible relationship to environmental

39. Mendelson WB, Sack DA, James SP, Martin JV, Wagner R, Garnett D, Milton J, Wehr TA: Frequency analysis of the sleep EEG in depression. *Psychiatry Research June* 1987.

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45. Golden RN, Morris JE, Sack DA: Combined lithium-tricyclic treatment of obsessive compulsive disorder. *Biological Psychiatry,* in press.

46. Wehr TA, Sack DA: Sleep disruption: A treatment for depression and a cause of mania. *Psychiatric Annals,* in press.

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60. Parry BL, Mendelson WB, Duncan WC, Sack DA, Wehr TA: Longitudinal sleep EEG, temperature, and activity measurements across the menstrual cycle in patients with premenstrual depression and in age-matched controls. *Psychiatry Res,* 1989.

61. Sack DA: "No More Secrets, No More Shame" Understanding Sexual Abuse and Emotional Disorders. *PIA Press, Washington D.C.,* 1990.

Submitted for publication:

62. James SP, Sack DA, Rosenthal NE, Mendleson WB, Wehr TA: The effect of melatonin on polygraphically monitored sleep.

63. Rosenthal NE, Sack DA, Carpenter CJ, Van Sant D, James SP, Wehr TA: The Weekly Mood Inventory: A self-rating scale for the longitudinal evaluation of seasonal affective disorder (SAD).

64. Rosenthal NE, Carpenter CJ, Sack DA, Jacobsen FM, James SP, Wehr TA: The placebo effect and other methodological issues in phototherapy studies of seasonal affective disorder.

ADDENDUM

RECENT CLINICAL RESEARCH EXPERIENCE

1. "Olanzapine Versus Haloperidol in the Treatment of Schizophrenia and Other Psychotic Disorders", Protocol F1D-MC-HGAJ. Sponsored by Lilly Research Laboratories.

2. "A Comparative Cost Effectiveness Study of Depakote and Usual Care versus Lithium and Usual care in the Treatment of Bipolar Disorder", Protocol M93-111. Sponsored by Abbott Laboratories.

3. "Fluoxetine Plus Pindolol Versus Fluoxetine Plus Placebo in the Treatment of Major Depression", Protocol B1Y-MC-HZAA. Sponsored by Lilly Research Laboratories.

4. "Double-Blind, Randomized, Placebo-Controlled Evaluation of the Safety, Tolerability and Parmacokinetics of Dehydoepiandrosterone (DHEA) in Patients with Alzheimer's Disease", Protocol 01. Sponsored by Neurocrine Biosciences.

5. "An Open-Label, Multicenter Clinical Trial Evaluating the Safety and Efficacy of Donepepezil Hydrochloride (E2020) in Patients with Alzheimer's Disease", Protocol E2020-A001-303.

6. "Strategies for Switching from Conventional Antipsychotic Drugs to Olanzapine", Protocol F1D-MC-HGFW. Sponsored by Lilly Research Laboratories.

7. "U-101387G: Double-Blind, Haloperidol-Controlled, Safety and Dose-Finding Study in the treatment of Schizophrenia". ProtocolM/2745/0004. Sponsored by Pharmacia & Upjohn, Inc.

8. "A Phase III Double-Blind Placebo-Controlled Study of Aripiprazole in the Treatment of Psychosis", Protocol 31-97-201. Sponsored by Otsuka Pharmaceuticals.

9. "An Open-label Follow-On Study of the Long-Term Safety of Aripiprazole in Patients with Psychosis", Protocol 31-97-203. Sponsored by Otuska Pharmaceuticals.

10. "Olanzapine Added to Mood Stabilizers in the Treatment of Bipolar Disorder", Protocol F1D-MC-HGFU. Sponsored by Lilly Research Laboratories.

11. "Olanzapine Alone and in Combination with Fluoxetine versus Placebo in Major Depressive Disorder with Psychotic Features", Protocol F1D-MC-HGGA. Sponsored by Lilly Research Laboratories.

12. "A Multicenter, Placebo and Active Control, Double-Blind Randomized Study of the Efficacy and Safety of M100907 (10 & 20 mg/day) in Schizophrenic and Schizoaffective Patients (3002)", Protocol lM100907/3002. Sponsored by Hoechst Marion Roussel.

13. "A Multicenter, Open-Label, Long-Term, Follow-up Safety Study of M100907 Tablets in Schizophrenic and Schizoaffective Subjects Who Participated in Protocol M100907/3001 or Protocol M100907/3002", Protocol M100907/3005. Sponsored by Hoechst Marion Roussel.

14. "A Prospective, Randomized, International, Parallel-Group Comparison of Clozaril/Leponex Vs. Zyprexa in the Reduction of Suicidality in Patients with Schizophrenia and Schizoaffective Disorder Who Are at Risk for Suicide", Protocol ABA 451. Sponsored by Novartis Pharma AG.

15. "A Multicenter Randomized, Double-Blind, Placebo, Controlled Study of Three Fixed Doses of A

16. "A Double-blind, Placebo-Controlled, Parallel- Group Assessment of the Selegiline Transdermal System in the Reappearance of Symptoms Associated with Major Depression." protocol #S9303-P9806, sponsored by Somerset

17. "A Double-blind, Randomized, Multicenter, Parallel Group design Study to Evaluate the Efficacy and Safety of Two Dose Ranges of EMD 128 130 in comparison with Placebo and Haloperidol in the Treatment of Schizophrenia." Sponsored by Mereck

18. "Protocol M/2020/047 , Reboxetine, Placebo, and Paroxetine Comparison in Patients with Major Depressive Disorder." sponsored by Pharmacia Upjohn

19. "A Multi-center Placebo–Controlled Double Blind Study Comparing the Safety and Efficacy of Ziprasidone and Olanzapine in Subjects with Schizophrenia or Schizoaffective Disorder Needing Inpatient Care" Protocol R-548 Sponsored by Pfizer

20. "A 52 Week (1 year), Open Extension Study Evaluating The Safety and Efficacy Of Continued Administration of 40-160 mg Daily Of Oral Ziprasidone In the Treatment Of Subjects Who Have Participated In Previous Ziprasidone Trials" Protocol R-0585, Sponsored by Pfizer

21. "Olanzapine in the Management of Behavioral Disturbance and/or Psychosis in Demented Nursing Home Patients." Protocol F1D-HGGV, Sponsored by Lilly

22. " A Double-Blind Randomized Comparison of the Efficacy and Safety of Short Acting Intramuscular Olanzapine, Short Acting Intramuscular Haloperidol, and Intramuscular Placebo in Patients with Schizophrenia" Protocol HGHB, sponsored by Lilly

23. "The Efficacy of Olanzapine and Adjunctive Lorazepam, as needed, to Treat Acute Behavioral Agitation in Schizophrenia". Sponsored By Lilly.

24. "A Randomized Double-Blind Study to Evaluate the Anticholinergic Burden in Subjects with Psychosis of Dementia Treated with Risperidone of Olanzapine". Sponsored by Janssen.

25. "A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Three Fixed Doses of Aripiprazole in the Treatment of Institutionalized Patients with Psychosis Associated with Dementia of the Alzheimer's Type". Sponsored by Bristol-Myers Squibb.

26. "Risperidone Depot (microspheres) vs. Placebo in the Treatment of Subjects with Schizophrenia or Schizoaffective Disorder". Sponsored by Janssen

27. "A Three-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of Extended-Release Carbamazepine in Patients With Bipolar Disorder". Sponsored by Shire.

28. "The Efficacy and Safety of Flexible Dose Ranges of Risperidone vs. Placebo or Divalproex Sodium in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder". Sponsored by Janssen

29. "A 9-Week, Open-Label, Multicenter, Safety Trial of Flexible Dose Ranges of Risperidone in the Treatment of manic or Mixed Episodes Associated with Bipolar I Disorder". Sponsored by Janssen

30. "A Controlled Trial of Olanzipine versus Quetiapine in the Treatment of Schizophrenic and Schizoaffective Subjects with Prominent Negative Symptoms." Protocol #F1D-US-HJGB Sponsored by Lilly

31. "A Multicenter, Randomized, Double-Blind Study of Flexible Doses of Aripiprazole vs. Perphenzaine in the Treatment of Patients with Treatment-Resistant Schizophrenia". Sponsored by Bristol-Myers Squibb

32. A Multicenter, Randomized, Double-Blind, Placebo Controlled, 26 Week Study of a Fixed Dose of Aripprazole in the Treatment of Stabilized Patients with Chronic Schizophrenia". Sponsored by Bristol-Myers Squibb.

33. "A Multicenter, Randomized, Double-Blind Safety and Tolerability Study of Flexible Doses of Aripiprazole and Olanzapine in the Treatment of Patients with Acute Schizophrenia". Sponsored by Bristol-Myers Squibb.

34. "A Double-Blind, Placebo and Haloperidol-Controlled, Multicenter Study Evaluating the Safety and Efficacy of SR46349B in Schizophrenic patients". Sponsored by Sanofi-Synthelabo.

35. "A Double-Blind, Placebo and Haloperidol-Controlled, Multicenter Study Evaluating the Safety and Efficacy of SR141716 in Schizophrenic Patients". Sponsored by Sanofi-Synthelabo.

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ORIGINAL SUANCE DATE 07/30/1979

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Guy E. Brannon, M.D.

Curriculum Vitae

Education:

Louisiana State University Medical Center, Shreveport, Louisiana
Department of Psychiatry
Chief Resident 1998-1999
Residency Completed: 1995-1999

Louisiana State University Medical Center, Shreveport, Louisiana
Dr. John M. Bick Award (Louisiana Psychiatric Medical Association)
Borroughs Welcome U.S. Psychiatric Congress Fellow
Chairman's Certificate of Award - Psychiatry Department
M.D. Awarded: June 1995

Louisiana State University, Shreveport, Louisiana
Bachelor of Science Degree in Biology (Cum Laude)
Graduation: May 1991

Airline High School, Bossier City, Louisiana
High School Diploma with Honors
Graduation: May 1986

Current Positions:

Principal Investigator
Brentwood Research Institute

Director of Clinical Research
Director of Adult Psychiatric Unit
Director of Chemical Dependency Unit
Brentwood, A Behavioral Health Company

Assistant Clinical Professor of Psychiatry
Teacher of the Year 2001-2002
Department of Psychiatry
Louisiana State University Health Science Center

Adjunct Professor of Psychology
Louisiana State University in Shreveport

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Current Positions: (continued)

Medical Director
First Step Services

Psychiatric Consultant
Family Services Unlimited
Vision Integrated Programs, Inc.
Louisiana Methodist Children's Home
Samaritan Counseling Center
Volunteers of America
Spectrum Rehabilitation Center

Staff Privileges:

Brentwood, A Behavioral Health Company
Christus-Schumpert Medical Center
Louisiana State University Health Science Center

Publications:

Brannon, G.E. Schizoaffective Disorder.
eMedicine Journal - March 2002
Brannon, G.E. Inhalant-Related Psychiatric Disorders.
eMedicine Journal - June 2002
Brannon, G.E. History and Mental Status Exam.
eMedicine Journal - April 2002
Brannon, G.E. Paraphilias.
eMedicine Journal June 2001
Brannon, G.E. and Rolland, P.D. Anorgasmia in a Patient with Bipolar Disorder Type I Treated with Gabapentin.
Journal of Clinical Psychopharmacology - 2000; 20(3):379-381
Brannon, G.E., Rolland, P.D., and Gary, J.M. Use of Mirtazapine as Prophylactic Treatment for Migraine Headache.
Psychosomatics – 2000; 41(2):153-154
Brannon, G.E., Seizure Disorder Presenting as Psychosis -- *In Press*
Rolland, P.D., Kablinger, A.S., **Brannon, G.E.**, and Freeman, A.M. Treatment of Generalized Anxiety Disorder with Venlafaxine XR – A Randomized, Double Blind Trial in Comparison with Buspirone and Placebo.
Clinical Drug Investigations – 2000; 19(2):163-165
Brannon, G.E. Therapeutic Alternatives for Treatment-Resistant Depression.
The Resident Reporter – 1999; 4(9):33-39
Freeman, A.M., Kablinger, A.S., Rolland, P.D. and **Brannon, G.E.** Millon Multiaxial Personality Patterns Differentiate Depressed and Anxious Outpatients.
The Journal of Depression and Anxiety – 1999; 10:73-76

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Publications: (continued)

Brannon, G.E. and Stone, K.D. The Use of Mirtazipine in a Patient with Chronic Pain.
The Journal of Pain and Symptom Management; 18:382-385
Fitz-Gerald, M.J., Pinofsky, H., and **Brannon, G.E.** Olanzapine Induced Mania.
The American Journal of Psychiatry – 1999; 156;7:1114
Brannon, G.E. and Fitz-Gerald, M.J. Psychiatry Pearls of Wisdom.
Substance Abuse. Boston Medical Publishing Corporation – 1999:180-188
Kablinger, A.S. **Brannon, G.E.** Rolland, P.D. and Freeman, A.M. Venlafaxine Versus Buspirone in Treatment of Generalized Anxiety Disorder.
Journal of the American Pharmaceutical Association – 1999; 39 (2):258
Brannon, G.E. Personality Pathology in Depression Ups Costs.
Clinical Psychiatry News – 1999; 27(1):28
Reeves, R.R., McBride, W., and **Brannon, G.E.** Olanzapine Induced Mania.
Journal of American Osteopathic Association – 1998;98(10):549-550
Brannon, G.E. and Kablinger, A.S. When the Depression Won't Go Away.
Annals of Clinical Psychiatry – 1998;10(3):137

Drug Studies:

Abbott Laboratories
A 21-day, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Efficacy and Safety of Depakote ER in the Treatment of the Manic Phase of Bipolar Disorder. March 2003 - present
Bristol-Myers Squibb
A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Two Fixed Doses of an Investigational Medication in the Treatment of Hospitalized Patients with Acute Mania. July 2001-November 2001
Johnson & Johnson Pharmaceutical Research & Development
A Randomized, Double-Blind, Multicenter, Placebo-Controlled 12-week Study of the Safety and Efficacy of Two Doses of an Investigational Medication vs. Placebo for the Treatment of Acute Manic or Mixed Episodes in Subjects with Bipolar I Disorder with an Optional Open-Label Extension.
August 2000 - present
Bristol-Myers Squibb
A Multi-Center, Randomized, Double Blind Safety and Tolerability Study of Flexible Doses of an Investigational Medication in the Treatment of Patients with Acute Schizophrenia. March 2000-February 2001
Bristol-Myers Squibb
A Multi-center, Randomized, Double-Blind, Placebo-Controlled Study of Flexible Doses of an Investigational Medication in the Treatment of Hospitalized Patients with Acute Mania. February 2000 – August 2001

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Drug Studies: (continued)

Bristol-Myers Squibb
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of an Investigational Medication in the Maintenance Treatment of Patients with Bipolar Disorder. February 2000 – Present
anofi~Synthelabo
A Double-Blind, Placebo and Comparator Controlled, Multicenter Study Evaluating the Safety and Efficacy of an Investigational Medication in Schizophrenic Patients. May 1999 – April 2001
Sanofi~Synthelabo
An Investigational Medication as Sole Therapy for Bipolar Disorder. December 1999 – Present
Sanofi~Synthelabo
A Double-Blind, Placebo and Comparator Controlled, Multi-Center Study Evaluating the Safety and Efficacy of an Investigational Medication in Schizophrenic Patients. December 1999 – August 2000
Otsuka America Pharmaceuticals, Inc.
An Open-Label Follow-on Study of the Long Term Safety and Efficacy of Aripiprazole Administered Orally in Patients with Psychotic Disorders or Psychotic Behaviors of Dementia. September 1999 – Present
Glaxo Wellcome
A Multi-Center, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of an Investigational Medication Compared to Placebo in the Treatment of an Acute Manic of Mixed Episode in Patients who have Bipolar Disorder. January 1999 – November 1999
Otsuka America Pharmaceuticals, Inc.
A Phase III, Open-Label, Treatment-Switching Study from Orally Administered Antipsychotic Monotherapy to Orally Administered Aripiprazole Monotherapy on the Treatment of Chronic Paranoid Schizophrenia and Schizoaffective Patients. September 1998 – August 2000
Eli Lilly & Co.
Olanzapine versus Divalproex in the Treatment of Acute Mania. September 1998 – August 2000
Pfizer
A MultiCenter, Placebo-Controlled, Double-Blind Study Comparing the Safety and Efficacy of Ziprasidone and Olanzapine in Subjects with Schizophrenia and Schizoaffective Disorder needing Inpatient Care. June 1998 – Present
Pfizer
A Double-Blind Six Month Continuation Protocol for Subjects who Successfully Completed Protocol #R-0548. June 1998 – August 1999
Pfizer
A 52 Week, Open Extension Study Evaluating the Safety and Efficacy of Continued Administration of 40-160mg Daily of Oral Ziprasidone in the Treatment of Subjects who have participated in Previous Clinical Trials. June 1998 – Present

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Drug Studies: (continued)

Eli Lilly & Co.
The Comparative Efficacy of Olanzapine, Risperidone, and Haloperidol for Cognition in Schizophrenia. June 1998 – November 2000
Abbott Laboratories
Is There a Difference Between Depakote and Valproic Acid in the Treatment of Bipolar Disorder? May 1998 - April 1999
Hoechst Marion Roussel
A Multi-Center Placebo and Active Control Double-Blind Randomized Study of the Efficacy and Safety of M100907 (10mg and 20mg/day) in Schizophrenia and Schizoaffective Patients. May 1998 – March 1999
Hoechst Marion Roussel
A Multi-Center, Long Term Followup Safety Study of M100907 tablets in Schizophrenic and Schizoaffective Subjects who Participated in Protocol M100907/3001 Protocol M100907/3002. March 1998 – March 1999
Sanofi Research Division
A Double-Blind, Placebo-Controlled, MultiCenter Study Evaluation of the Efficacy and Safety of SR 46349B in Outpatients with Major Depression.
October 1997 – October 1998
Zeneca Pharmaceuticals
Quetiapine (SEROQUEL) Experience with Safety and Tolerability (QUEST).
October 1997 – June 1998
Eli Lilly & Co.
Weekly Enteric-Coated Fluoxetine Hydrochloride versus daily Fluoxetine or Placebo in the Continuation Treatment of Major Depressive Disorder.
October 1997 – July 1999
Otsuka America Pharmaceuticals, Inc.
A Phase III Double-Blind Placebo Controlled Study of Aripiprazole in the Treatment of Psychosis. September 1997 – May 1998
Otsuka America Pharmaceuticals, Inc.
An Open-Label, Follow-on Study of the Long-Term Safety of Aripiprazole in Patients with Psychosis. September 1997 – May 1998
Novartis
An Open-Label Study to Evaluate the Safety and Efficacy of 1.5mg b.i.d.(3mg/day) Through 6mg b.i.d. (12mg/day) of Exelon in Patients with Mild to Severe Probable Alzheimer's Disease in the Community Setting. September 1997 – Present
Pfizer
Comparison of Sertraline and Imipramine in Childhood Depression
July 1997 – Present

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David P. Walling, Ph.D.
09/11/02

CURRICULUM VITAE

NAME: David P. Walling, Ph.D. **DATE:** July 2002

PRESENT POSITION:
Chief Executive and Clinical Officer
Collaborative NeuroScience Network
12772 Valley View St. Ste. 3
Garden Grove, CA 92845

HOSPITAL PRIVILEDGES:

Pacific Hospital of Long Beach 2776 Pacific Ave Long Beach, CA 90804	Western Medical Center – Anaheim 1025 S. Anaheim Blvd. Anaheim, CA 92805	Del Amo Hospital 23700 Camino Del Sol Torrance, CA 90505

BIOGRAPHICAL:

Place of Birth: Long Beach, California
Address: REDACTED

Telephone: (714) 799-7799 – office
REDACTED

EDUCATION:

University of Southern California 1989-1993
Ph.D. in Counseling Psychology
APA Accredited

California State University at Fullerton 1987-1989
M.S. in Counseling

California State University at Long Beach 1985-1986
B.A. in Psychology

Golden West College 1983-1985
A.A. in Social Science

Internship:

University of Texas Medical Branch 1992-1993
APA Accredited
Galveston, TX

RESEARCH EXPERIENCE:

Principal Investigator "A Multicenter, Double-blind, Randomized Comparison of the Efficacy and Safety of Two Atypical Antipsychotics in the Treatment of Patients with Schizophrenia (2001 – ongoing).

Principal Investigator " A Phase III, Randomized, Placebo-Controlled Study Evaluating the Safety and Outcome of Treatment with Oral Ziprasidone in Subjects with Mania (A1281083)." Pfizer (2002 – ongoing).

Principal Investigator "A Placebo-Controlled 21-Day Study of the Safety and Efficacy of Topiramate for the Treatment of Treatment-Resistant Bipolar I Disorder with an Optional Open-Label Extension (TOPMAT-PDMD-006)." R.W. Johnson Pharmaceutical Research (2001 – 2002).

Sub-Investigator "A Novel Anxiolytic Versus Placebo in Generalized Anxiety Disorder. A Randomized Double-Blind Placebo and Buspirone Controlled Fixed Dose Parallel Group Multicenter Study of 10 Weeks" (2002 – ongoing).

Sub-Investigator "A Trial of One Atypical Antipsychotic versus Another Atypical Antipsychotic in the Treatment of Schizophrenic and Schizoaffective Subjects with Comorbid Depression." (2001 – ongoing).

Principal Investigator " A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Study Evaluating Efficacy and Safety of SB-29060 Controlled Release (12.5 and 25mg/day) versus Placebo in Patients with Major Depressive Disorder." (29060/810) GlaxoSmithKline (2001-2002).

Principal Investigator "A Three-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of Extended-Release Carbamazepine in Patients with Bipolar Disorder." (Protocol 105.301) Shire Laboratories, Inc. (2000- 2001)

Principal Investigator "A Three-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of Extended-Release Carbamazepine in Lithium-Failure Patients with Bipolar Disorder." (Protocol 105.302) Shire Laboratories, Inc. (2000 - 2001).

Principal Investigator "A Six-Month, Open-Label, Multicenter Study of Extended Release Carbamazepine in Patients with Bipolar Disorder – an Extension of Protocols 105.301 and 105.302." (Protocol 105.303) Shire Laboratories, Inc. (2001)

Co-Investigator "A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of the Safety and Efficacy of Seroquel as Add-on therapy with Lithium or Divalproex in the Treatment of Acute Mania." (Protocol 5077IL/0099) AstraZeneca (2000 – 2001).

RESEARCH EXPERIENCE (Cont.)

Sub-investigator "Risperidone QD vs. BID Dosing in Schizophrenia: A Double-Blind, Parallel Group, Phase III Multicenter Study." (Protocol RIS-USA-60) Janssen Research Foundation (1995).

Sub-investigator: "A Multicenter, Double-Blind, Randomized Comparison of SEROQUEL (ICI 204,636) and chlorpromazine in the Treatment of Hospitalized Subjects with Treatment Resistant Schizophrenia." (Protocol 0031) ZENECA Pharmaceuticals Group (1994-1996).

Sub-investigator/Therapist: "A Prospective, Multicenter Study Comparing the Safety and Efficacy of Nefazodone HCl to Cognitive Behavioral Therapy - Chronic Depression (CBT-CD) and Combined Nefazodone and CBT-CD for the Acute, Continuation and Maintenance Treatment of Chronic Forms of Depression." (Protocol CN104-132) Bristol-Meyers Squibb Company (1996-1999).

Sub-investigator/Therapist: "Serzone and Cognitive Behavior Therapy for the Chronic Depressives: Pilot Study." Bristol-Myers Squibb Company (1995-1996).

Sub-investigator: "A Double-Blind Placebo-Controlled, Dose-Response Comparison of the Safety and Efficacy of Three Doses of SERTINDOLE and Three Doses of Haldol in Schizophrenic Patients." (Protocol M93-113) ABBOTT Laboratories (1994-1995) completed.

Sub-investigator: "An Open-Label Assessment of the Long-Term Safety of SERTINDOLE in the Treatment of Schizophrenic Patients." (Protocol M92-795) ABBOTT Laboratories (1994-1995) completed.

Sub-investigator: "An Open-Label Assessment of the Long-Term Safety of SERTINDOLE." (Protocol M92-222) ABBOTT Laboratories (1994-1995).

Sub-investigator: "A Multicenter, Double-Blind, Placebo-Controlled, Randomized, Multiple Fixed-Dose Comparison of SEROQUEL (ICI 204,636) and Haloperidol in the Treatment of Hospitalized Subjects with Acute Exacerbation of Chronic or Subchronic Schizophrenia." (Protocol 0013) ZENECA Pharmaceuticals (1993-1994) completed.

Sub-investigator: "Fixed-Dose OLANZOPINE Versus Placebo in the Treatment of Schizophrenia." (Protocol FID-MC-HGAP) ELI LILLY and Company (1993-1994) completed.

Sub-investigator: "A Multicenter, Double-Blind, Randomized, Controlled, Multiple Fixed Dose and Dose Regimen Comparison of SEROQUEL (ICI 204,636) and Haloperidol in the Prevention of Psychotic Relapse in Outpatients with Chronic or Subchronic Schizophrenia." (Protocol 0015) ZENECA Pharmaceuticals (1993-1994) completed.

TEACHING EXPERIENCE:

"Introduction to Clinical Hypnosis." One day seminar presented to psychiatry and psychology residents at the University of Texas Medical Branch at Galveston – Department of Psychiatry – 2000.

"Schizophrenia: Theory, Symptoms and Treatment." Seminar presented as a component of Psychiatric Pharmaceutical Care Certificate Program sponsored by the University of Pittsburgh School of Pharmacy – 1999.

"Introduction to Clinical Hypnosis." One day seminar presented to psychiatry and psychology residents at the University of Texas Medical Branch at Galveston – Department of Psychiatry – 1999.

Medical Hypnosis - five week course presented to all third year medical students during psychiatry rotation. University of Texas Medical Branch at Galveston, 1995-1996.

Therapeutic Hypnosis - Thirty week hypnosis training seminar presented to psychology interns at University of Texas Medical Branch at Galveston, 1994.

Faculty and Small Group Facilitator - Introduction to Patient Evaluation. University of Texas Medical Branch at Galveston: Term III, 1995; Term III, 1996.

Faculty and Small Group Facilitator - Community Continuity Experience/Introduction to Patient Evaluation. University of Texas Medical Branch at Galveston: Term II, 1997.

Faculty - Counseling Practicum, School of Education. University of Houston at Clear Lake: Summer Session, 1994.

Faculty - Senior Medical Student Elective: Forensic Psychiatry - Violence Recovery Program.

WORK EXPERIENCE:

Vice President of Clinical Services 1997-2000
Psychiatric Management Resources &
Stadt Solutions Pharmacy Corporation
San Diego, CA

Assistant Professor of Psychiatry and Behavioral Sciences 1995-1997
Dept. of Psychiatry and Behavioral Sciences
University of Texas Medical Branch - Galveston, TX

WORK EXPERIENCE (cont.):

Clinical Director 1993-1997
The Gulf Coast Center
Intensive Treatment Program
Galveston, TX

Research Scientist 1993-1995
Dept. of Psychiatry and Behavioral Sciences
University of Texas Medical Branch - Galveston, TX

College Hospital - Costa Mesa, CA 1992
Crisis Response Clinician

Harbor View Adolescent Center - Long Beach, CA 1990-1992
Primary Therapist

Huntington Psychotherapy - Huntington Beach, CA 1991-1992
Marriage, Family, & Child Counselor

Bellflower Doctors Hospital - Bellflower, CA 1989-1990
Clinical Coordinator

Western Medical Center - Anaheim, CA 1988-1989
Clinical Social Worker/Unit Therapist

PEER REVIEWED PUBLICATIONS:

Bishop, S., Walling, D., Dott, S., Folkes, C., & Bucy, J. (In press) "Refining Quality of Life: Validating a Five Factor Measure for the Severe Mentally Ill. *International Journal for Quality of Life Research.*

Walling, D., Goodwin, J., & Cole, C. (1998) "Prevalence of Dissociative Disorders in a Transsexual Population." *Journal of Sex Education and Therapy 23(2);* 121-123.

Walling, D., Baker, J., & Dott, S. (1998) "Hypnosis Training in Psychology Graduate Programs: A National Survey." *International Journal of Clinical and Experimental Hypnosis,46(2);* 150-156.

Walling, D. and Levine, R. (1997) "Power in the Hypnotic Relationship: Therapeutic or Abusive?" *American Journal of Psychotherapy, 51(1);* 67-76.

Bishop, S., Walling, D., & Walker, B. (1997) "The Emperor's Clothes: Assessing the Validity of the Tennessee Self-Concept Scale." *Educational and Psychological Measurement, 57(1),* 150-163.

PEER REVIEWED PUBLICATIONS (cont.):

Dott, S., Walling, D., Bishop, S, Bucy, J., & Folkes, C. (1996) "The Efficacy of Short-Term Treatment for Improving Quality of Life: A Pilot Study." *Journal of Nervous and Mental Disease,* 507-509.

Walling, D., Baker, J., & Dott, S. (1996) "A National Survey of Hypnosis Training: Its Status in Psychiatric Residencies." *International Journal of Clinical and Experimental Hypnosis, 44,* 184-188.

Walling, D., & Baker, J. (1996) "Hypnosis Training in Psychology Internship Programs." *American Journal of Clinical Hypnosis, 38,(3)* 219-223.

OTHER PUBLICATIONS:

Walling, D. & Marsh, D. (In press) "Relapse Prevention in Serious Mental Illness" In F.J. Frese (Ed.), Psychologists and Serious Mental Illness: New Directions in Mental Health Services. San Francisco: Jossey-Bass.

Walling, D. & Dott, S. (1999) "Contemporary Approaches to the Management of Serious Mental Illness." Book chapter in P. Vega (Ed.) Behavioral Disease Management. Mannisses Communication.

Walling, D. (1997) "Quality of Life in Behavioral Medicine Research" Book Review - *Behavioral Medicine.*

Walling, David (1996) "Standards for Long-Term Psychiatric Residential Care." Book Review - *Psychiatric Services, 47(7),* 772.

Walling, David P. (1993) "Self-Concept in High Achieving Women: A Comparison of Medical and Nursing Educators." Doctoral Dissertation. University of Southern California.

PRESENTATIONS:

"Using Technology to Improve Prescribing Patterns" Presented at Shaping Partnerships for Recovery – 2000 Washington Behavioral Healthcare Conference. Yakima, WA

"Quality of Life: How are we Improving Patient's Lives?" Keynote address given at the Ventura County Department of Mental Health Annual Awards Banquet – Ventura, CA: 1999.

" Partial Hospitalization and the Continuum of Care" Continuing education presentation sponsored by North East Ohio Health Services and Cuyahoga County Community Mental Health Board - Cleveland, Ohio: 1997.

PRESENTATIONS (cont.):

"Strategic Psychotherapy in Practice" Presented to graduate students enrolled in the Psychology Department at the University of Houston - Clear Lake: 1997.

"Suicide and Schizophrenia: Examining the Role of Negative Symptoms." Lecture presented as part of American Suicide Foundation/University of Texas Medical Branch at Galveston series on suicide research.

"Psychological Approaches to the Management of Pain." Lecture presented to second year medical students at the University of Texas Medical Branch - Galveston, 1996.

"Novel Treatment and Current Research in Severe Mental Illness." Invited Speaker: Gulf Coast Alliance for the Mentally Ill. March, 1995.

"Treatment of Sexual Abuse Survivors: Application of Psychotherapy and Hypnotherapy." Presented to graduate students enrolled in the Psychology Department at the University of Houston - Clear Lake: 1993, 1994, 1995 & 1996.

"Treatment Issues in Serious Mental Illness." Invited Speaker: Gulf Coast Alliance for the Mentally Ill. October, 1993.

"Recognition and Treatment of Substance Abuse Disorders." Series of lectures presented to students enrolled in the Physician's Assistant Program at the University of Texas Medical Branch: 1992 & 1993.

ABSTRACTS:

Walling, D.P. "Pharmacologic and Psychosocial Treatment for Serious Mental Illness." Abstract accepted for presentation at the the Institute for Psychiatric Services October 2001 annual meeting: Orlando, FL.

Walling, D., Bisbee, C. & McGurk, S. (Symposium Chair) "Serious Mental Illness:Interventions for Change." Paper: Walling, David "Pharmacologic and Psychosocial Treatment for Serious Mental Illness." Symposium accepted for presentation at the American Psychological Association: August 2001, San Francisco, CA.

Walling, D.P., McGurk, S. & Meltzer, H.Y. "Quality of Life and Service Use in Schizophrenia" Abstract presented at the International Congress on Schizophrenia Research – May 2001; Whistler, B.C. Abstract published in Schizophrenia Research.

McCleery, G., Walling, D.P., Erskine, S. & Bruce, R. "Antipsychotic Usage and Prescriber Reasoning" Abstract presented at the International Congress on Schizophrenia Research – May 2001; Whistler, B.C. Abstract published in Schizophrenia Research.

ABSTRACTS (cont.):

Walling, D., Marsh, D. Scheifler, P. & McGurk, S. (Symposium Chair) "Serious Mental Illness: Providing Hope Through Treatment." Paper: Walling, David & Siry, Deborah. "Pharmacologic Treatment Options for Serious Mental Illness: Providing New Hope" Symposium presented at the American Psychological Association: August 2000, Washington, D.C.

Walling, David "Hypnosis in Medical Treatment: Defining Ethical Boundaries." Paper presented at the American Psychological Association: August 2000, Washington, D.C.

Walling, D., Marsh, D. Scheifler, P. & McGurk, S. (Symposium Chair) "Schizophrenia: Hope for the New Millenium." Paper: Walling, David & Siry, Deborah. "Novel Medications: Changing the Face of Schizophrenia Treatment" Symposium presented at the American Psychological Association; August, 1999 annual conference: Boston, MA.
Walling, D. & Baker, J. "Hypnosis: Education and Training for the Future" Paper presented at the American Psychological Association August, 1999 annual conference: Boston, MA.

Walling, D.P., Klein, C.K., Bishop, S.L. & McCleery, G. "Psychometric Evaluation of a Four Factor Quality of Life Instrument." Paper presented at the National Clinical Drug Evaluation Unit June 1999 annual conference; Boca Raton, FL.

Walling, D., Klein, C. & Bruce, R. Quality of Life: A Measure of Efficacy in Psychosocial Treatment. Paper presented at the International Congress on Schizophrenia Research 1999 biannual conference: Santa Fe, New Mexico.

Walling, D., Klein, C. & Bruce, R. Factor Analysis of the Q-LES-Q: Validating a Quality of Life Measure. Paper presented at the International Congress on Schizophrenia Research 1999 biannual conference: Santa Fe, New Mexico.

Walling, D., Klein, C., Bruce, R., Stephens, J., Erskine, S., Jimenez, R. "Quality of Life in Schizophrenia: The Impact of Symptomatology." Paper presented at the Institute for Psychiatric Services October 1998 annual meeting: Los Angeles, CA.

Walling, D., Klein, C., Bruce, R., Stephens, J., Tepper, A., Jimenez, R. "Validation of the Q-LES-Q for use in Schizophrenia Research and Treatment." Paper presented at the Institute for Psychiatric Services October 1998 annual meeting: Los Angeles, CA.

Walling, D., McGurk, S. Hanson, M., Hollis, J., & Summerfelt, T. (Symposium Chair) "Severe Mental Illness in the Community: Increasing Standards of Care." Paper: Walling, David. "Intensive Outpatient Services for the Severe Mentally Ill: Designing What Works." Symposium presented at the American Psychological Association August, 1998 annual conference: San Francisco, CA.

ABSTRACTS (cont.):

Walling, D. & Goodwin, J. "Sexual Abuse and Hypnosis: Exploring the Relationship to Svengali." Paper presented at the American Psychological Association for August, 1998 annual conference: San Francisco, CA.

Walling, D., & Goodwin, J. "Hypnosis, Sexual Abuse and the Attendant Relationship." Paper presented at the American Society of Clinical Hypnosis March 1998 annual meeting: Dallas, TX.

Dott, S., Walling, D., and Rosales, L. "Quality of Life and Novel Antipsychotics." Paper presented at the American Psychiatric Association's Institute on Psychiatric Services October 1997 annual meeting: Washington, D.C.

Walling, D., Dott, S., & Gaston, C. "Service Delivery in Severe Mental Illness: Training Issues for Psychologists." Paper presented at the American Psychological Association - August 1997 annual meeting, Chicago, Illinois.

Walling, D. (Symposium Chair) "Novel Antipsychotics for the Next Millennium: Treatment Advances in Psychosis" Paper: Dott, S. & Walling, D. "Olanzapine in the Treatment of Schizophrenia: A Novel Antipsychotic." Paper presented at the American Psychological Association - August 1997 annual meeting, Chicago, Illinois.

Walling, D. & Goodyear, R. "Supervision Issues in Hypnosis: Drawing on Counseling Psychology Paradigms." Paper presented at the American Psychological Association - August 1997 annual meeting, Chicago, Illinois.

Bishop, S., Walling, D., Dott, S., & Baker, J. "Sensitivity and Specificity in the Quality of Life Enjoyment and Satisfaction Questionnaire." Paper presented at the American Psychological Association (Div. 5) August 1997 annual meeting, Chicago, Illinois.

Durant, D. & Walling, D. "Recapping the Uses of Hypnosis in the Psychiatric Setting." Paper presented at the American Psychological Association (Div. 30) August 1997 annual meeting, Chicago, Illinois.

Dott, S. & Walling, D. "Quality of Subjective Life Experiences in Schizophrenia-Spectrum Disorders." Paper presented at the International Congress on Schizophrenia Research for April 1997 biennial meeting.

Walling, D. & Dott, S. "Risking it All? Sexual Behavior in Schizophrenia." Paper presented at the American Psychiatric Association May 1997 annual meeting, San Diego, CA.

Dott, S., Walling, D., Cole, C., & Meyer, W. "When Schizophrenia and Gender Dysphoria Coexist." Paper presented at the American Psychiatric Association May 1997 annual meeting, San Diego, CA.

ABSTRACTS (cont.):

Bishop, S., Walling, D., Baker, J., & Dott, S. "Quality of Life Assessment: A Window on Chronic Back Pain Management?" Paper presented at the Society of Behavioral Medicine. April 1997 annual meeting, San Francisco, CA.

Walling, D., Baker, J., & Dott, S. "Hypnosis in Academia: National Status." Paper presented at the Society for Clinical and Experimental Hypnosis. November 1996 annual meeting: Tampa, Florida.

Dott, S., Walling, D., Cole, C., & Meyer, J. "Schizophrenia and Gender Dysphoria: Misdiagnosis, Misconceptions and Realities." Paper presented at the Society for the Scientific Study of Sexuality November 1996 annual meeting: Houston, Texas.

Walling, D. & Dott, S. "Quality of Life: Measurement, Importance, and Validity in Schizophrenia." Paper presented at the International Conference on Schizophrenia: Breaking Down the Barriers. October 1996: Vancouver, Canada.

Dott, S. & Walling, D. "Sexual Attitudes, Beliefs and Behaviors in Schizophrenia-Spectrum Disorders." Paper presented at the International Conference on Schizophrenia: Breaking Down the Barriers. October 1996: Vancouver, Canada.

Dott, S. & Walling, D. "Crisis Interventions in the Community." Paper presented at the American Psychiatric Association's Institute on Psychiatric Services October 1996 annual meeting: Chicago, Illinois.

Durant, D. & Walling, D. "The Schizophrenogenic Mother in Family Therapy?" Paper presented the American Association of Family Therapy for October 1996 annual meeting: Toronto, Canada.

Walling, D., Walker, B., & Bishop, S. "Self-Concept in High Achieving Women." Paper presented at the Northeastern Division Meeting of the American Educational Research Association. October 1996 annual meeting: Ellenville, New York.

Walling, D., Baker, J., & Dott, S. "Hypnosis Training in the U.S.: Results of a National Survey." Paper presented at the American Psychological Association's (Div. 30) August 1996 annual meeting: Toronto, Canada.

Walling, D., Dott, S., Folkes, C., and Glenn, S. "Quality of Life: Measuring the Success of Partial Hospitalization." Paper presented at the Association for Ambulatory Behavioral Healthcare August 1996 annual meeting: Minneapolis, Minnesota.

Dott, S. & Walling, D. "The Ghost of Schizophrenia: Past, Present and Future." Paper presented at the Texas Department of Mental Health and Mental Retardation July 1996 annual meeting: Galveston, Texas.

ABSTRACTS (cont.):

Folkes, C., Dott, S., & Walling, D. "A Collaborative System: Creating a Continuum of Care Within the Community." Paper presented at the Texas Department of Mental Health and Mental Retardation July 1996 annual meeting: Galveston, Texas.

Dott, S. & Walling, D. "An Ounce of Prevention: What Our Patients Don't Know." Paper presented at the 149th annual meeting of the American Psychiatric Association May 1996: New York.

Walling, D. & Wills, S. "Hypnosis, Metaphor and Psychotherapy: Enhancing Treatment Outcomes." Workshop presented at the Southwestern Psychological Association April 1996 annual meeting: Houston, Texas.

Dott, S., Walling, D., & Folkes, C. "Community Based Alternatives to Psychiatric Hospitalization: Efficacy and Outcomes" Paper presented at the American Psychiatric Association's Institute on Psychiatric Services October, 1995: Boston, MA.

Walling, D., Dott, S., & Folkes, C. "Quality of Life in Severe Mental Illness: Does Diagnosis Matter?" Paper presented at the American Psychiatric Association's Institute on Psychiatric Services October, 1995: Boston, MA.

Dott, S., Walling, D., Avery, E., Cole, C., & Meyer, W. "Schizophrenia and Transsexualism: Defining the Boundaries." Paper presented at the Harry Benjamin International Symposium: Transsexualism: State of the Art Treatment. September 1995: Munich, Germany.

Walling, D., Goodwin, J., & Cole, C. "Dissociation and Gender Dysphoria: Exploring the Relationship." Paper presented at the Harry Benjamin International Symposium: Transsexualism: State of the Art Treatment. September 1995: Munich, Germany.

Bishop, S., Walling, D., & Dott, S. "The Quality of Life Enjoyment Scale: Issues of Validity." Paper presented at the American Psychological Association (Div. 5). August 1995: New York.

Dott, S. & Walling, D. "Quality of Life: Exploring How Patients Change." Paper presented at the American Psychiatric Association. May 1995: Miami, FL.

Walker, B., Dott, S., & Walling, D. "Meeting Women's Mental Health Needs: A Challenge to the Primary Care Physician." Paper presented at the Society for Teachers in Family Medicine May 1995: New Orleans, LA.

Walker, B., Walling, D., & Bishop, S. "Women in Academic Medicine: What it Takes to Succeed." Paper presented at the Society for Teachers in Family Medicine. May 1995: New Orleans, LA.

ABSTRACTS (cont.):

Bishop, S., Walling, D., Dott, S., & Folkes, C. "Severe Mental Illness: Exploring Quality of Life Enjoyment Scale Validity (Preliminary Findings)." Paper presented at the Southwestern Psychological Association. April 1995: San Antonio, TX.

Walling, D., Segura, S., & Armsworth, M. "Exploring the Spectrum of Dissociation" (Symposium Chair) Paper: Walling, D., Goodwin, J., & Cole, C. "Dissociation in a Transsexual Population" Paper presented at the Southwestern Psychological Association. April 1995: San Antonio, TX.

Walling, D. & Dott, S. "Beyond Crisis Stabilization: How Are We Improving Quality of Life?" Paper presented at International Conference on Schizophrenia: Schizophrenia. August 1994: Vancouver, Canada.

Dott, S. & Walling, D. "Emerging Treatment Alternatives: A Challenge to Hospital Efficacy." Paper presented at the International Conference on Schizophrenia: Schizophrenia 1994. August 1994: Vancouver, Canada.

Walling, D. & Dott, S. "Quality of Life: A Pilot Study - Comparison of Crisis Stabilization and Psychiatric Hospitalization." Paper presented at New Clinical Drug Evaluation Unit (NCDEU) sponsored by the National Institute of Mental Health - June 1994: Marco Island, FL. Abstract published in *Psychopharmacology Bulletin 30, 725.*

Walling, David. "Symposium on Theories of Metaphor Utilized in the Therapy Process." (Symposium Chair). Paper presented at the Annual Meeting of the Western Psychological Association - May 1992: Portland, OR.

Walling, David. "The Use of Metaphors in Psychotherapy." Presented at the Annual Meeting of the Western Psychological Association - April 1991: San Francisco, CA.

GRANTS:

Walling, D. (Principal Investigator) & Dott, S. "Negative Symptoms as Predictors of Suicide in Schizophrenia: A Prospective Study." Grant funded by the American Suicide Foundation: December 1994 - December 1995 ($8,965.00).

ARTICLES IN SUBMISSION:

Bishop, S.L., Walling, D.P., Dott, S.G., Baker, J. (In submission) *Validating Sensitivity and Specificity in the Quality of Life Enjoyment and Satisfaction Scale (Q-LES-Q).*

Walling, D.P., Klein, C., Bishop, S.L. (In submission) *Validating a Four-Factor Model of Quality of Life in Severe Mental Illness.*

WORK IN PROGRESS...

Walling, David P. *Serious mental illness: A guide to clinical treatment.* Book manuscript in process for Professional Resource Press; Sarasota, FL. (Anticipated publication Spring 2001).

Walling, D. & Goodwin, J. "The Svengali Effect: Sexual Exploitation During Hypnotherapy." In preparation.

Walling, D. & Goodyear, R. "Supervision in Hypnosis Training: Applying Models from Counseling Psychology." In preparation.

"Evaluating the Effectiveness of the Quality of Life Enjoyment and Satisfaction Scale in Medical Populations." In preparation with Sharon G. Dott, M.D. and Sheryl L. Bishop, Ph.D.

"Validating the Quality of Life Enjoyment Scale with Chronic Pain Patients" with Sheryl L. Bishop, Ph.D. and Jeffrey M. Baker, Ph.D.

AFFILIATIONS:

American Psychological Association
- Member – Task Force on Serious Mental Illness (1999 – 2002)
- Member - Division 30: Psychological Hypnosis
- Member - Division 17: Counseling Psychology
  - Member Division 17 Program Committee (1999 – 2002)
  - Vice Chair Hypnosis Special Interest Group (1997-1999)

LICENSES:

1992	California Licensed Marriage, Family & Child Counselor License No. MFC29326
1995	Texas Licensed Psychologist License No. 25348 – License placed on inactive status October 2000
1999	California Licensed Psychologist License No. 16657

CERTIFICATION:

1983	Clinical Hypnotherapist
1996	Cognitive-Behavior Therapy for the Chronic Depressions: The Unipolar Mood Disorders Institute of Virginia Commonwealth University

ADDITIONAL EXPERIENCE:

Special Member of the Faculty: Graduate School of Biomedical Sciences - University of Texas Medical Branch - Galveston (1993-1996).

Member Psychology Internship Program Committee: University of Texas Medical Branch - Galveston (1993-1997).

Reviewer for Psychiatric Services (formerly Hospital and Community Psychiatry)

Reviewer for Psychiatry Research

Reviewer for American Journal of Clinical Hypnosis

Reviewer for Southwestern Psychological Association 1996 annual conference

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CURRICULUM VITAE

Name: Paul E. Keck, Jr., M.D.

Address: University of Cincinnati Medical Center
231 Albert Sabin Way
Cincinnati, OH 45267-0559

Date of Birth: July 22, 1957

Place of Birth: Pittsburgh, Pennsylvania

Education:

1979 A.B. Dartmouth College, Hanover, New Hampshire

1983 M.D. Mount Sinai School of Medicine, New York, New York

Postdoctoral Training:

Internship and Residencies:

1983-1984 Internship in Internal Medicine, Beth Israel Medical Center, New York, New York

1984-1987 Resident in Psychiatry, McLean Hospital
Belmont, Massachusetts

Research Fellowships:

Research Award, National Institute of Arthritis,
Metabolism and Digestive Diseases

1983 Fellowship, Tucker Foundation, Hanover, New Hampshire

1987-1989 Fellowship, Scottish Rite Schizophrenia Program,
Northern Masonic Jurisdiction, USA

Licensure:

1985-1991 Massachusetts License Registration
1991 Ohio License Registration No. 61382
1991 American Board of Psychiatry and Neurology No. 34691
1995 American Board of Forensic Examiners No. 745

3/5/03

1997 American Board of Psychological Specialties No. 2331

Academic Appointments:

1984-1987	Clinical Fellow in Psychiatry, Harvard Medical School, Boston, Massachusetts
1987-1989	Instructor in Psychiatry Harvard Medical School, Boston, Massachusetts
1989-1991	Assistant Professor of Psychiatry Harvard Medical School, Boston, Massachusetts
1991-1998	Associate Professor of Psychiatry, University of Cincinnati College of Medicine, Cincinnati, Ohio
1992-	Associate Professor of Pharmacology and Cell Biophysics (Dual Track), University of Cincinnati College of Medicine, Cincinnati, Ohio
1995-	Adjunct Assistant Professor of Psychology, University of Cincinnati, Cincinnati, Ohio
1997-	Vice Chairman for Research, Department of Psychiatry, University of Cincinnati College of Medicine, Cincinnati Ohio
1998-	Professor of Psychiatry (with tenure), University of Cincinnati College of Medicine, Cincinnati, Ohio

Hospital Appointments:

1986-1987	Chief Resident in Psychiatry, McLean Hospital, Belmont, Massachusetts
1985-1987	Research Fellow in Psychiatry, Laboratories for Psychiatric Research, Mailman Research Center, Belmont, Massachusetts
1987-1990	Assistant Psychiatrist, McLean Hospital, Belmont, Massachusetts
1991-	Attending Psychiatrist, University of Cincinnati Hospital
1992-1993	Consultant, Good Samaritan Hospital, Cincinnati, Ohio
1991-	Attending Psychiatrist, Veterans Administration Medical Center, Cincinnati, Ohio
1992-	Consultant, Children's Hospital Medical Center, Cincinnati, Ohio
1994-	Senior Consulting Psychiatrist Pauline Warfield Lewis Center, Ohio Department of Mental Health, Cincinnati, Ohio
1997-	Attending Psychiatrist, Christ Hospital, Cincinnati, Ohio

Awards and Honors:

1977-1979	New Hampshire Alpha Award for Academic Excellence, Dartmouth College
1979	Phi Beta Kappa Society, Dartmouth College
1979	Magna Cum Laude, Dartmouth College
1983	Alpha Omega Alpha Society, Mount Sinai School of Medicine
1983	M. Ralph Kaufman Award for Excellence in Psychiatry, Mount Sinai School of Medicine
1987	Laughlin Award for Merit, National Psychiatric Endowment Fund
1991	Phillip L. Isenberg Award, Excellence in Teaching McLean Hospital, Harvard Medical School
1993	Exemplary Psychiatrist Award, National Alliance for the Mentally Ill (NAMI)
1994-	Stanley Scholars Program, The Theodore & Vada Stanley Foundation and National Alliance for the Mentally Ill
1994	The Best Mental Health Experts, Good Housekeeping Magazine
1994	Golden Apple Award for Excellence in Teaching Department of Psychiatry, University of Cincinnati College of Medicine
1996	Outstanding Young Men of America
1997	Gerald L Klerman Young Investigator Award, National Depressive and Manic – Depressive Association
1998	Nancy C A Roeske, MD Award for Excellence in Medical Student Education, American Psychiatric Association
1998	Outstanding Young Men of America
1999	Best Doctors in America
1999	Wyeth-Ayerst AADPRT IMG Mentorship Program
1999	Outstanding Physician Partner Award, Postgraduate Institute for Medicine
2000	Crystal Award (2), The Communicator Awards for Continuing Medical Education
2001	Leadership Recognition Award, Neuroleptic Malignant Syndrome Information Service (NMSIS)

Major Committee Assignments:

National and Regional:

Neuroleptic Malignant Syndrome Information Service:

1995- Professional Advisory Council and Director of Scientific Development

U.S. Food and Drug Administration:

2000- Psychopharmacology Drug Advisory Committee (PDAC)

American Psychiatric Association:

1992-1994 APA Practice Guidelines for Bipolar Disorders
Work Group (Formulation of official American Psychiatric Association treatment guidelines for patients with bipolar disorder)

1993-1994 DSM-IV Medication – Induced Movement Disorder
(Formulation of diagnostic criteria for neuroleptic malignant syndrome, akathisia)

2000- APA Institute for Research and Education (Enhance research infrastructure and psychiatric education by fostering collaboration among academic institutions)

2000- APA Practice Guidelines for Bipolar Disorders Work Group (Revise and update treatment guidelines for patients with bipolar disorder)

Local:

McLean Hospital:

1985 Committee on Inpatient Psychotherapy in Residency Training
(Review teaching and supervision of psychotherapy of inpatients by residents)

1986-1987 Committee on Hospital Admissions
(Review problems associated with admission of patients to hospital)

1987 Committee on Residency Training Curriculum and Requirements (Review core residency training curriculum, update and modify in accordance with national standards)

1987-1991 Pharmacy and Therapeutics Committee
(Quality assurance, drug utilization, adverse events)

1990-1991 Hospital Formulary committee
(Review of new drugs for addition to hospital formulary)

University of Cincinnati Hospital:

1991-1997 Hospital Pharmacy and Therapeutics Committee; Chair, Biotechnology Subcommittee, 1993 – (Review of new biotechnology products for submission to hospital formulary committee; involves consultation with experts, cost-benefit analysis)

1998- 2000 Executive Board, Office of Clinical Trials

College of Medicine:

1991-1997	Year II Medical Student Education Committee (Ongoing curriculum review)
1992-1995	Preceptor, Clinical Opportunities Program (Supervision and teaching of medical students wishing to observe clinical care by specialty)
1993-	Medical Student Advisor: David Kriendler, Danielle Kizer
1997-	Dispute Mediation Committee (Assist in mediation of disputes involving faculty)

Department of Psychiatry:

1991-	Medical Student Education Committee (Review department contribution to curriculum of medical school)
1991-1995	Residency Selection Committee (Interview and evaluate resident applicants)
1991-1995	Continuing Education Committee; Chair, 1992-1994 (Coordinate and design Grand Rounds schedule and other CME activities)
1991-	Research Committee; Chair 1997- (Enhance research in department)
1994-1996	Residency Training Committee (Review and improve curriculum, ongoing advisory board to Residency Training Director)
1994-	Steering Committee (Long range resource and personnel planning)
1997-1998	Space Committee (Space allocation for personnel and laboratories)
1999-	Intellectual Property Committee (Assess intellectual property opportunities)
1999-	Community Advisory Committee on Research; Chair (Bioethical considerations of human subjects protocols)
2000-	Appointments and Promotions Committee (Faculty appointments and promotions)

Review and Editorial Boards:

Reviewer:

1987-	Journal of Clinical Psychopharmacology
1988-	Journal of Clinical Psychiatry
1989-	Journal of Neuropsychiatry and Clinical Neurosciences
1989-	American Journal of Psychiatry
1991-	Biological Psychiatry
1991-	Comprehensive Psychiatry
1992-	Journal of Child and Adolescent Psychopharmacology

1992-	Journal of Nervous and Mental Diseases
1993-	Depression
1994-	Drugs
1994-	The Medical Letter
1994-	Harvard Review of Psychiatry
1995-	Anxiety
1995-	Psychiatric Research
1995-	Psychopharmacology
1996-	International Clinical Psychopharmacology
1996-	CNS Drugs
1997-	Journal of Affective Disorders
1998-	Journal of Psychiatric Research
1998-	Critical Reviews in Neurobiology
1999-	Neuro-psychopharmacology & Biological Psychiatry
1999-	Archives of General Psychiatry
1999-	Acta Psychiatrica Scandinavica
1999-	European Neuropsychopharmacology
2000-	Psychosomatic Medicine
2000-	General Hospital Psychiatry
2001-	International Journal of Neuropsychopharmacology
2001-	European Psychiatry

Editorial Boards:

1992-	Psychiatric Annals
1993-	Journal of Clinical Psychiatry
1994-	Psychiatric Times' Bipolar Disorders Letter
1996-1998	Journal of Depressive Disorders: Index and Reviews
1996-	Medscape Mental Health
1996-1998	Journal of Psychotic Disorders
1997-1998	Journal of Bipolar Disorder
1997-	Behavioral Health Advisor, Clinical Reference Systems
1998-	Bipolar Disorder, An International Journal of Psychiatry and Neurosciences
2000-	Journal of Affective Disorders
2000-	Clinical Psychiatry News
2001-	Deputy Editior, Current Psychiatry

Other Professional Activities:

1985-1987	Site interviewer, McLean Hospital, The Structured Clinical Interview for DSM-III-R (SCID), Multisite Test-Retest Reliability Study; Biomedical Research Department, New York State Psychiatric Institute, Arch Gen Psychiatry 1992; 49:630-636
1994	Site participant, University of Cincinnati College of Medicine, DSM-IV General Reliability Field Trial, Expert Phase, American Psychiatric Association

1995	NIMH/NCDEU Workgroup, Assessment of Efficacy in Schizophrenia Clinical Trails
1995	Consensus Panel Expert, The Tri-University (Departments of Psychiatry at Columbia, Cornell and Duke Universities) Consortium, Bipolar Disorder Consensus Evaluation Project
1996	Consensus Panel Expert, The Tri-University (Departments of Psychiatry at Columbia, Cornell and Duke Universities) Consortium, Obsessive Compulsive Disorder Treatment Guidelines
1996	Ad Hoc Consultant, Contracts Review, National Institute of Mental Health, Division of Clinical and Treatment Research, Rockville, MD
1997	Faculty, University Institute for Psychiatry & Law, University of Cincinnati Medical Center
1997	Consultant Veterans Affairs Medical Center Bipolar Disorder Treatment Guidelines
1998	Data Monitoring Board of VA Cooperative Study #430, "Reducing the Efficacy – Effective Gap in Bipolar Disorder"
1998	Consensus Panel Expert, The Tri –University Consortium, Schizophrenia Consensus Evaluation Project
1998	Consensus Panel Expert, The Tri-University Consortium, Posttraumatic Stress Disorder Consensus Evaluation Project
1998-1999	NIMH Intramural Protocols Review Panel
	Consensus Panel Expert Consortium, Health Knowledge Improvement Foundation, Guidelines for Antidepressant Medication in Primary Care
2000	Consultant, American Psychiatric Association Committee on Psychiatric Diagnosis and Assessment, DSM-IV Text Revision Work Group on Mood Disorders
2000	Consultant, NIMH Special Emphasis Panel
2000	Consultant, The Expert Consensus Guideline Series. Medication Treatment of Bipolar Disorder 2000. Postgraduate Medicine Institute
2000	Consultant, Texas Medication Algorithm Project (TMAP), Texas Department of Mental Health and Mental Retardation, Austin, TX

Professional Societies:

1983-1989	American Medical Association
1983-1990	American Psychiatric Association
1989-1991	American Sleep Disorders Association
1991	Society of Biological Psychiatry
1991	American Academy of Clinical Psychiatrist
1991	American Association for the Advancement of Science
1991	Cincinnati Psychiatric Society, Treasurer 1992-1993
1992	Anxiety Disorders Association of America
1993	American Society of Clinical Psychopharmacology
1995	American College of Forensic Examiners, Fellow (1997)
1997	Collegium Internationale Neuro-Psychopharmacologicum
1997	New York Academy of Sciences

1999	International Society for Bipolar Disorders (Councilor)
2001	International Society for Affective Disorders (Fellow)

Major Research Interests:

1. Novel psychopharmacologic agents in the treatment of mood, anxiety, and psychotic disorders
2. Phenomenology, epidemiology, biological abnormalities and treatment of bipolar disorders
3. Neuroleptic malignant syndrome and related side effects of antipsychotic agents

Patent Application: Shapira NA, Goldsmith TD, Keck PE, Jr. Methods of treating obsessive-compulsive spectrum disorders. Filed March 25, 1999.

Principal Clinical and Hospital Service Responsibilities:

McLean Hospital

1987-1988	Clinical and Research Associate, Psychopharmacology Program, McLean Hospital, Belmont, Massachusetts
1988-1991	Psychiatrist-in-Charge, South Belknap I, II (Depression Research, Units McLean Hospital, Belmont Massachusetts)
1989-1990	Assistant Director, Sleep Disorder Center, Neurophysiology Laboratory and Sleep Research Program, McLean Hospital, Belmont, Massachusetts

University Hospital

1991-1996	Co-Director, Biological Psychiatry Program, University of Cincinnati College of Medicine Cincinnati, Ohio
1991-1998	Director, Inpatient Psychobiology Research Unit University Hospital, Cincinnati Ohio

Teaching Experience:

1986-1987	Supervision of medical students and psychiatric residents in emergency psychiatry and psychopharmacology, McLean Hospital
1987-1991	Supervision of residents in psychopharmacology through psychopharmacology program, McLean Hospital
1988-1990	Modern management of acute neuroleptic- induced extrapyramidal syndromes. American Psychiatric Association Annual meeting, Montreal, Canada, May 1-5, 1989; course 90; New York, May 13, 1990; course 26

1988-1999	Supervision of medical students and residents in inpatient psychiatry, McLean Hospital; University Hospital
1989-1995	Neuroleptic malignant syndrome: diagnosis, treatment and aftercare. American Psychiatric Association Annual Meeting, San Francisco, May 9, 1989, W4; New York, May 16, 1990,W47; New Orleans, May 1991; Washington DC, May 1992; San Francisco, 1993; Philadelphia, 1994; Miami, 1995
1990	Side effects of neuroleptics. American Psychiatric Association Annual Meeting, New York, May 17, 1990, PS54
1990	Senior Consultant Psychopharmacology Inpatients Services, McLean Hospital, Belmont, Massachusetts
1991	Visiting Professor, Northeastern Ohio Universities College of Medicine, Akron, Ohio, April, 1991
1991-1993	Integrating research into clinical programs. American Psychiatric Association Annual Meeting, New Orleans, May 1991; Washington DC, 1992; San Francisco, 1993
1993	Visiting Professor, University of Texas Medical Branch at Galveston, Galveston, Texas, February, 1993
1994-1995	Anticonvulsants in Psychiatry. American Psychiatric Association Annual Meeting Philadelphia, May 1994; Miami, 1995
1994	Advances in Treatment of Refractory Depression. American Psychiatric Association Annual Meeting Philadelphia, May 1994
1995	Predictors of Response in Mood Disorder. American Psychiatric Association Annual Meeting Miami, May, 1995
1996	Visiting Professor, McLean Hospital Mini Fellowship in Bipolar Disorder, Belmont, Massachusetts, April 1996
1996	Visiting Professor, Rush-Presbyterian Hospital Mini Fellowship in Bipolar Disorder, Chicago, Illinois, October, 1996
1996	Visiting Professor, Rush-Presbyterian Hospital Mini Fellowship in Bipolar Disorder, Chicago, Illinois, July, 1997
1997	Visiting Professor, New York University Mini Fellowship in Bipolar Disorder, New York, NY, October 1997

Fellowships:

1992 Director, Biological Psychiatry Program Fellowship,

Department of Psychiatry, University of Cincinnati College of Medicine

Fellowship graduates:
- Scott A West, M.D., 1995
- Tammy J. Huber, M.D., 1996
- John M. Hawkins, M.D., 1996
- Cesar A. Soutullo, M.D., 1997
- Vikram Shah, M.D., 1998
- N. Andrew Shapira, M.D., 1999
- Marlene P. Freeman, M.D., 1999
- Shashuka Malhotra, M.D., 2001

Course Developer and Course Director:

1991-1997	Course Director, Psychiatry/Neuroscience Core Curriculum, Second Year Course, University of Cincinnati College of Medicine This integrated course received very high UCCM student evaluations annually since 1991
1992	Designed and organized "Management of Depression in Primary Core Practice," Regional Symposium, April 11, 1992
1992	Designed and organized "Medical Illness and Anxiety Disorders: The Clinical Interface," Regional Symposium, September 24,1992
1993	Designed and organized "Update on the Treatment of Bipolar Disorder," Regional Symposium, October 1, 1993
1993-1999	Course Director, Advanced Psychobiology Clerkship, Fourth Year Course, University of Cincinnati College of Medicine
1999-	Co-Director, Brain and Behavior II, Second Year Course, University of Cincinnati College of Medicine

Course Participant:

1986-1987	Emergency Psychiatry Resident Lecture Series, McLean Hospital
1987-1991	Lecturer in Advanced Psychopharmacology Resident Seminar, McLean Hospital
1987-1991	Lecturer in Affective Disorders Resident Course, McLean Hospital
1990	Course Participant, Comprehensive Update in Clinical Psychiatry, CME Course, McLean Hospital and Harvard Medical School
1991-1993	Lecturer in Psychopharmacology Module, Third Year Clerkship, University of Cincinnati College of Medicine
1991-	Lecturer in Advanced Psychopharmacology Resident Seminar, University of Cincinnati College of Medicine
1991-1999	Lecturer in Psychiatry/Neuroscience Core Curriculum, Second Year, University of Cincinnati College of Medicine
1991-1999	Lecturer in Pharmacology Core Curriculum, Second Year, University of Cincinnati College of Medicine
1992-1998	Lecturer in Introduction to Clinical Practice II Course, Second Year, University of Cincinnati College of Medicine
1999-2001	Lecturer in Forensic Psychiatry Fellowship Didactic Series
1999-	Lecturer in Brain and Behavior II Course, Second Year, University of Cincinnati College of Medicine
2000-	Lecturer in Brain and Behavior I Course, First Year, University of Cincinnati College of Medicine

Invited Lecturer / Grand Rounds:

1987 "Antidepressants in the Treatment of Bulimia"
St. Francis Hospital, Tulsa, OK

1988 "Pharmacologic Treatment of Eating Disorders"
St. Luke's Hospital, St. Louis, MO

1989 "Pharmacologic Approaches to the Treatment of Eating Disorders"
Philadelphia Psychiatric Institute, Philadelphia, PA
"Valproate as a Potential Antimanic Treatment"
University of Massachusetts Medical Center, Worcester, MA
"Diagnosis and Treatment of Neuroleptic Malignant Syndrome"
Massachusetts General Hospital, Boston, MA
"Pharmacologic Treatment of Schizophrenia"
McLean Hospital, Belmont, MA

1990 "Recognition of Sleep Disorders in Psychiatric Practice"
Massachusetts Institute of Technology (MIT), Cambridge, MA
"Why Do We Sleep? Why Do We Study It?"
McLean Hospital, Belmont, MA
"Management of Bipolar Disorder and Comorbid Substance Abuse"
West Virginia University Medical Center, Charleston, WV
"Valproate in the Treatment of Bipolar Disorder"
Canadian Psychiatric Association Annual Meeting, Toronto, Canada
"Valproate in the Treatment of Psychiatric Disorders"
American Academy of Neurology Annual Meeting, Cincinnati, OH
"Anticonvulsants in the Treatment of Bipolar Disorder"
Kings Park Hospital, NY
"Diagnosis and Therapy of Sleep Disorders"
Mount Auburn Hospital, Cambridge, MA
"Anticonvulsants in the Treatment of Bipolar Disorder"
University of Massachusetts Medical Center, Worcester, MA

1991 "Current Research Supporting the Use of Anticonvulsants in Bipolar Disorder"
University of Rochester School of Medicine, Rochester, NY
"Anticonvulsants in the Treatment of Bipolar Disorder:
Jackson-Brook Institute, Portland, MA
"Anticonvulsants as Treatment Alternatives to Lithium in Bipolar Disorder"
University of Toronto School of Medicine, Toronto, Canada
"Pharmacologic Treatment of Bipolar Disorder"
Pembroke Pines Hospital, Ft. Lauderdale, FL
"Pharmacologic Treatment of Bipolar Disorder"
Danvers State Hospital, Danvers, MA
"Anticonvulsants in the Treatment of Bipolar Disorder"

Napa Valley Hospital, Napa, CA
"The Use of Carbamazepine and Valproate in Bipolar Disorder"
Mind, Mountain and Medicine Conference, Portland, OR
"Sleep Disorders and Psychiatric Illness"
University of Winnipeg Hospital, Winnipeg, Canada
"Anticonvulsants in Bipolar Disorder"
Hartford Hospital, Hartford, CT
"Recognition of Sleep Disorders in Children and Adolescents"
North Shore Children's Hospital, Salem, MA
"Advances in the Pharmacologic Treatment of Bipolar Disorder"
Northeast Ohio Universities Medical School, Akron, OH
"Use of Valproate in Bipolar Illness"
Dayton Mental Health Center, Dayton, OH
"Treatment of Bipolar and Schizoaffective Disorders"
Monson Developmental Center, Palmer, MA
"Anticonvulsants in the Treatment of Mania"
The Carrier Foundation, Belle Mead, NJ
"New Developments in the Psychopharmacologic Treatment of Mania"
The Carrier Foundation, Belle Mead, NJ
"Anticonvulsants in the Treatment of Mania:
Walter Reed Army Medical Center, Washington, DC
"Anticonvulsants in the Treatment of Mania"
Beth Israel Medical Center, New York, NY
"Recent Advances in the Use of Valproate in the Treatment of Bipolar Disorders"
Patton State Hospital, Patton, CA
"Valproate in the Treatment of Acute Mania: A Placebo-Controlled Study"
University of Iowa College of Medicine, Iowa City, IA
"Diagnosis and Management of Insomnia and Sleep Disorders"
University of Alabama at Birmingham, Birmingham, AL

1992 "Recent Advances in the Use of Valproate for Bipolar Disorders"
Lutheran Hospital, Park Ridge, IL
"Anticonvulsants in Psychiatry"
Central Ohio Psychiatric Hospital, Columbus, OH
"Diagnosis and Management of Refractory Bipolar Patients"
Heritage Oaks Hospital, Sacramento, CA
"Insomnia"
University of California, Davis, Sacramento, CA
"Management of Bipolar Disorder"
St. Elizabeth's Hospital, Washington, DC
"Treatment of Resistant Bipolar Disorder"
Brookdale Hospital, Brooklyn, NY
"Antiepileptic Drugs in Bipolar Disorder"
University of North Dakota, Fargo, ND
"Valproate in Bipolar Disorder"

Charlotte Mental Health Center, Charlotte, SC
"Assessment and Management of Suicidal Patients and Refractory Depression"
Spring Grove Hospital, Baltimore, MD
"Valproate in Psychiatry"
University of Texas Southwestern Medical Center, Dallas, TX
"New Treatments in Bipolar Disorder:
Oklahoma University College of Medicine, Oklahoma City, OK

1993 "Serotonin Uptake Inhibitors"
Riverside Methodist Hospitals, Columbus, OH
"Recognition and Management of Major Sleep Disorders"
Doctors Hospital, Columbus, OH
"Advances in Antidepressant Therapy"
Dayton Mental Health Center, Dayton, OH
"Organic Mood Syndromes"
Allegheny General Hospital, Pittsburgh, PA
"Diagnosis and Treatment of Panic Disorder"
Kettering Medical Center, Kettering, OH
"Recent Advances in the Treatment of Bipolar Disorder and Schizoaffective Disorder" Menniger Phoenix at St. John's Hospital and Medical Center, Phoenix, AZ
"Recognition and Pharmacologic Treatment of Depression"
Upper Valley Medical Centers, Piqua, OH
"Anticonvulsant Treatment of Bipolar Disorder"
Baylor College of Medicine, Houston, TX
"Insomnia: Treatment Strategies"
Mount Carmel Medical Center, Columbus, OH
"Sleep Disorders and Insomnia"
Dayton VAMC, Dayton, OH
"Pharmacology of Mania"
University of Tennessee Medical Center, Knoxville, TN

1994 "The Atypical Antipsychotics – What's New and When Do You Use Them?"
Upper Valley Medical Centers, Troy, OH
"Treatment of Bipolar Depression"
McLean Hospital, Belmont, MA
"New Management Options in Bipolar Disorders"
Parkside Lutheran Hospital, Park Ridge, IL
"New Management Options in Bipolar Disorder"
Madison Center, South Bend, IN
"New Agents in Acute Mania"
Oregon Health Sciences University, Portland, OR
"Pharmacologic Treatment of Acute Mania"
Henry Ford Hospital, Detroit, MI
"Schizoaffective and Psychotic Mood Disorders"

Harper Hospital/ Wayne State University, Detroit, MI
"Management Options in Bipolar Disorder"
San Francisco General Hospital, University of California, San Francisco, CA
"Pharmacology of Acute Mania"
Harbor UCLA Medical Center, Los Angeles, CA
"Treatment of Bipolar Disorders"
Mount Carmel Health Center, Columbus, OH
"New Management Options in Bipolar Disorder"
St. Louis State Hospital, St. Louis, MO
"Pharmacologic Treatment of Acute Mania"
VAMC Battle Creek, Battle Creek, MI
"Advances in the Pharmacologic Treatment of Acute Mania"
Brigham and Women's Hospital, Boston, MA
"Pharmacologic Treatment of Schizoaffective Disorder"
University of Minnesota School of Medicine, Minneapolis, MN
"Current Ideas on Antidepressant Therapy"
Miami Valley Hospital, Dayton, OH

1995

"Pharmacology of Hypnotic Agents"
Chillecothe VAMC, Chillecothe, OH
"Predictors of Pharmacologic Treatment Response in Acute Mania"
Loyola University Medical Center Chicago, Stritch School of Medicine
"Atypical Antipsychotics in the Treatment of Schizoaffective and Psychotic Mood Disorders"
Wright State University school of Medicine, Dayton, OH
"Diagnosis and Management of Hypochondriasis"
Wright State University School of Medicine, Dayton, OH
"Use of Novel Antipsychotics in Affective Psychoses"
University of Chicago Department of Psychiatry, Chicago, IL
"Acute Treatment of Psychosis in the Emergency Room Setting"
St. Louis University School of Medicine, St. Louis, MO
"Pharmacologic Treatment of Bipolar Disorder"
Ohio University, Athens, OH
"Pharmacologic Treatment of Bipolar Disorder"
Bipolar Disorders Symposium, Stanford University School of Medicine, Stanford, CA
"Bipolar Disorder"
Medical College of Wisconsin, Milwaukee, WI
"Hypochondriasis"
Kettering Medical Center, Kettering, OH
"Pharmacologic Treatment of Acute Mania"
Chicago-Read Hospital, Chicago, IL
"Current advances in the Treatment of Bipolar Disorder"
West Virginia University School of Medicine, Charleston, WV

"Atypical Antipsychotics in the Treatment of Schizophrenia, Schizoaffective Disorder, and Psychotic Mood Disorders"
Mount Sinai School of Medicine, New York, NY

1996 "Treatment – Resistant Depression"
Dayton Mental Health Center, Dayton, OH
"Atypical Antipsychotics in the Treatment of Schizoaffective Disorder and Psychotic Mood Disorders"
University of Southern Florida, Tampa, FL
"Atypical Antipsychotics"
Jewish Hospital, Cincinnati, OH
"Pharmacoeconomics of the Treatment of Bipolar Disorder"
St. Elizabeth's Hospital, Brighton, MA
"Advances in Bipolar Disorder: The Bipolar Spectrum and Pharmacoeconomics"
Ohio State University School of Medicine, Columbus, OH
"The New Antipsychotics: Safety and Efficacy"
Wright State University School of Medicine, Dayton, OH
"Pharmacoeconomics of Bipolar Disorder"
Wayne State University School of Medicine, Detroit, MI
"Advances in the Treatment of Mania Associated with Bipolar Disorder"
Northwestern University Medical School, Chicago, IL
"Definitive Treatment of Acute Mania"
St. Luke's – Roosevelt Medical Center, New York, NY

1997 "Bipolar Disorder: Valproate Loading Strategies"
Massachusetts Mental Health Center, Boston, MA
"Compliance with Maintenance Treatment in Manic-Depressive Illness"
Robert Wood Johnson Medical School, Piscataway, NJ
"Bipolar Disorder"
Cleveland Clinic, Cleveland, OH
"Pharmacology and Therapeutic Efficacy of New Antipsychotics"
University of Louisville School of Medicine, Louisville, KY
" Pharmacology of New Antipsychotics: Implications for Schizoaffective Disorder"
Ohio State University School of Medicine, Columbus, OH
"New Antipsychotics and Affective Psychosis"
University of Mississippi School of Medicine, Jackson, MI
"Therapeutic Potential of New Antipsychotics"
University of California-Davis, Sacramento, CA

1998 "Update on Anticonvulsants in the Treatment of Bipolar Disorder"
University Hospital of Cleveland, Cleveland, OH
"Antipsychotics in the Treatment of Psychotic Mood Disorders" Finch
University of Health Sciences/Chicago Medical School, N. Chicago, IL
"Advances in the Pharmacotherapy of Acute Mania"

Cornell University Medical Center, White Plains, NY
"Pharmacologic Mechanisms of the New Antipsychotics"
University of Rochester, Rochester, NY
"The New Anticonvulsant and Antipsychotic Drugs: what is Their Role in the Treatment of Bipolar Disorder?"
Albert Einstein Medical Center, Philadelphia, PA

1999 "Atypical Antipsychotics: Their Role in the Treatment of Schizoaffective Disorder" St. Vincent's Medical Center, New York, NY
"Antipsychotic and Thymoleptic Actions of Atypical Antipsychotics"
Kevin T. Finnegan Annual Memorial Lecture, University of Utah, Salt Lake City, UT
"Pharmacologic Treatment of Bipolar Disorder – The Future"
University of Cincinnati College of Medicine, Cincinnati, OH
"Alternatives to Lithium in the Treatment of Bipolar Disorder" Lithium – 50th Anniversary in Clinical Medicine Symposium. Lexington, KY
"Atypical Antipsychotics in the Treatment of Acute Mania"
University of Massachusetts, Worcester, MA
"Pharmacotherapy of Schizoaffective Disorder"
McLean Hospital, Belmont, MA
"Principles of Antidepressant Prescribing" Dept. of Internal Medicine, University of Cincinnati Medical Center, Cincinnati, Ohio
"Clinical Update: Antipsychotic and Mood Stabilizer Drug Therapy" Ohio University College of Osteopathic Medicine, Dayton, Ohio

2000 "Why Do We Send Roses? The Neurobiology of Emotion"
University of Cincinnati College of Medicine,
Mini Medical College, Cincinnati, Ohio
"Schizoaffective Disorder" Hillside Hospital – Long Island Jewish Medical Center, Glen Oaks, NY
"Advances in Pharmacotherapy for Bipolar Disorder" University of South Florida, Tampa, FL
"Advances in the Pharmacological Treatment of Bipolar Disorder"
Emory University School of Medicine, Atlanta, GA
"Neurobiology of Bipolar Disorder and Treatment Advances"
University of Southern California School of Medicine, Los Angeles, CA

2001 "Update on Advances in Pharmacotherapy of Bipolar Disorder"
Wright State University School of Medicine, Dayton, OH
"Pharmacologic and Efficacy Comparison of New Atypical Antipsychotic Drugs," Good Samaritan Hospital, Cincinnati, OH
"Latest Treatment Advances for Bipolar Disorder"
St. Elizabeth's Hospital, Washington, DC
"The Many Faces of Bipolar Disorder"
University of Cincinnati College of Medicine
Mini Medical College, Cincinnati, Ohio

2002 "Atypical Antipsychotics: Promise and Controversy"
Jonathan O. Cole Mental Health Consumer Resource Center
McLean Hospital, Belmont, MA
" Recent Advances in the Pharmacological Treatment of Bipolar Disorder"
Massachusetts General Hospital, Boston, MA
"Antiepileptics and Atypical Antipsychotics in the Treatment of Bipolar Disorder" University of Mississippi School of Medicine,
Jackson, MS

Other Teaching Experience and Invited Lectures:

1989 Drug Treatment of Schizophrenia; The Pharmacist and Mental Health Regional Symposium, Northeastern University College of Pharmacy, Waltham, MA
New Advances in the Pharmacologic Treatment of Manic-Depressive Illness, Regional Meeting, National Depressive and Manic Depressive Association, Chattanooga, TN

1990 Recent Research on the Use of Anticonvulsants in Bipolar Disorder; Portraits of Mania Symposium, Third Annual U.S. Psychiatric Congress, San Diego, CA
Clinical Applications of Anticonvulsants in Psychiatric Disorders; Current Trends in the Expanded Use of Anticonvulsants, Ohio Department of Mental Health Conference, Columbus, OH
Recent Research on the Use of Anticonvulsants in Bipolar Disorder; Portraits of Mania, Regional Symposium, Atlanta, GA
The Use of Medications in Treating Psychiatric Illness; Orientation to Mental Health Issues, Pastoral Care and Counseling Symposium, McLean Hospital Belmont, MA
Sleep Disorders and Psychiatric Illness: Diagnosis and Treatment Issues; McLean Hospital Intensive Update in Biological Psychiatry CME Course, Belmont, MA
Differentiating Sleep Disorders from Psychiatric Syndromes; Western Massachusetts Psychiatric Society, Smith College, Northampton, MA
Sleep Disorders; Manic Depressive and Depressive Association of Boston, Boston, MA

1991 Innovative Uses of Anticonvulsants, Henry Ford Hospital Symposium, Dearborn, MI
Pharmacotherapy for Anxiety Disorders; Anxiety Disorders; Recognition, Treatment and Management, Regional Symposium, University of Cincinnati College of Pharmacy, Cincinnati, OH
Alternative Uses of Anticonvulsants; Innovative Uses of Anticonvulsants, Regional Symposium, Case Western Reserve University School of Medicine, Cleveland, OH

Other Possible Uses of Anticonvulsants in Psychiatry; Summit Conference on the Treatment of Bipolar Disorder, National Symposium, School of Medicine, University of Texas Health Science Center at San Antonio, Snowmass, CO

The Clinical Approach to the Differential Diagnosis of Bipolar Disorder; Practical Clinical Guidelines for the Management of Bipolar Disorder, Regional Symposium, Worcester, MA

Rational Use of Traditional Pharmacologic Therapy; Practical Guidelines for the Management of bipolar Disorder, Regional Symposium, Philadelphia, PA

Depression: Recognition and Treatment; Third Annual Mental Health Institute Regional Symposium, Louisville, KY

Reclaiming Lives; Psychiatric Rehabilitation and Clozaril; Third Annual Mental Health Institute Regional Symposium, Louisville, KY

Recent Advances in the Use of Valproate in the Treatment of Bipolar Disorder; Southern California Psychiatric Society, San Bernardino, CA

1992

The Diagnosis of Bipolar II Patients; Bipolar Disorder; Current Progress and Future Directions in Diagnosis and Management; National Symposium, Snowbird, UT

Treatment Refractory Depression, Valley Medical Center, Louisville, KY

Serotonin Reuptake Inhibitor Antidepressants; Charleston Psychiatric Association, Charleston, WV

Traditional Pharmacologic Management for the Treatment of Bipolar Disorder; Bipolar Disorder: Current Progress and Future Directions, Regional Symposium, Chicago, IL

Pharmacologic Treatment of Depression and Panic Disorder; Academy of Medicine, Lima and Allen Counties, OH

Myths of Psychopharmacology; Residency Training Graduation Dinner, Harding Hospital, Columbus, OH

Traditional Pharmacologic Management of Bipolar Disorder; Bipolar Disorder: Current Progress and Future Directions in Diagnosis and Management; Regional Symposium, Detroit, MI

Depression; Association of Indian Psychiatrists, Cincinnati, OH

Depression in Medical Practice: Recognition and Treatment Advances; Current Therapy XXIII, Scioto County 23rd Annual Postgraduate Medical Seminar, Portsmouth, OH

Antiepileptic Drugs in Primary Psychiatric Disorders; Crafts-Farrow State Hospital Eleventh Annual CME Program

New Developments in Sleep Therapy; Central Ohio Academy of Family Practitioners, Columbus, OH

Bipolar Disorder: The Treatment Resistant Patient; Acute Mania: Strategies for Success; Regional Symposium, Ohio State University College of Medicine, Columbus, OH

1993
- Common Pitfalls of Diagnosis; Bipolar Disorder: Meeting the Challenge, National Symposium; Keystone, CO
- Bipolar Disorder; OMEN-TV, Ohio State University, Columbus, OH
- Depression... When the Blues Become More Than Music; Mental Health Association of Franklin County, Columbus, OH

1994
- Management Options in Bipolar disorder; Bipolar Disorder: Diagnostic Challenges, Treatment Optimization; Regional Symposium, Indianapolis, IN
- Lithium, Valproate and Carbamazepine: What Do We Know?; Lithium: The Present and the Future, American Psychiatric Association Symposium, Philadelphia, PA
- Atypical Antipsychotics in Schizophrenia, Schizoaffective Disorder and Psychotic Mood Disorders; Ohio Department of Mental Health Annual Symposium, Columbus, OH
- Management of Bulimia, Body Dysmorphic Disorder and Related Disorders; Diagnosis and Treatment of Depression and Related Disorders: Symposium for Psychiatric Residents; National Symposium, Emory University School of Medicine, Atlanta, GA
- Bipolar Disorder: Case Management; CME Video Symposium, The IMN Group, Psych LINK, Dallas, TX
- Pharmacotherapeutic New Agents in the Treatment of Depression; What's New in Depression? An Update for Clinicians; Regional Symposium, The Ohio State University Medical Center for Continuing Education, Columbus, OH
- Refractory Bipolar Depression and Mania; Complicated and Treatment – Resistant Mood disorders; Regional Symposium, University of Pittsburgh Medical Center, Western Psychiatric Institute and Clinic, Center for Continuing Education in the Health Sciences, Pittsburgh, PA

1995
- The Biology and Treatment of Rapid Cycling Bipolar Disorders; Caribbean Psychopharmacology Congress; National Symposium, CME, Inc., St. Martin, Antilles Francaises
- Treatment of Bipolar Disorder; Bipolar Disorders. Current Breakthroughs in Diagnosis and Treatment; Regional Symposium, University of Miami School of Medicine, Miami, FL
- Treatment of Schizoaffective Disorder. Antipsychotic Drug Therapy: Current Status, Roundtable Symposium. Physicians Postgraduate Press, Inc. New Orleans, LA
- The Promise of New Antipsychotic Medications. Spring Mental Health Conference: Innovations in Mental Health Care in Public Psychiatry. Western Reserve Psychiatric Hospital, Northfield, OH
- Secondary Bipolar Disorder. Comorbidity in Bipolar Disorder, American Psychiatric Association Symposium, Miami, FL
- Practical Perspectives on Bipolar Disorders. CME Library Audio Video. CME, Inc., Santa Ana, CA

Bipolar Disorders, Depressive Disorders, and Psychotic Disorders, Intensive Review of Psychiatry and Neurology CME Inc., Tysons Corner, MD

Human Behavioral and Biochemical Sensitization: Implications for Mood Disorders. American College of Neuropsychopharmacology (ACNP)

Annual Meeting Satellite Symposium – in Honor of Jonathan O. Cole, M.D., San Juan, Puerto Rico

Rapid Stabilization and Treatment of Bipolar Disorder in the Psychiatric Emergency Service. American Psychiatric Association Meeting, Institute on Psychiatric Services, Boston, MA

New Uses of Antidepressants: Social Phobia. Physicians Postgraduate Press, Inc. Roundtable Symposium. Tyson Corner, VA

1996

Clinical Strategies for the Care of Patients with Bipolar Disorder; National Symposium, Co-Chair person. Discovery International, Aspen, CO

New Perspectives on the Treatment of Bipolar Disorder; National Roundtable Symposium, Chairperson. Physicians Postgraduate Press, Inc. Dallas, TX

Strategies for Acute Treatment of Mania; Management of Bipolar Disorder in the Current Environment. American Psychiatric Association Annual Meeting Symposium. New York, NY

Epidemiology and Differential Diagnosis of Bipolar Disorder; Pharmacologic Treatment of Manic-Depressive Illness. Bipolar Disorder Minifellowship, McLean Hospital, Belmont, MA

The Adult Bipolar Patient: Cormorbidity and Treatment; Treating Bipolar Disorder – Comorbidity Issues Throughout the Lifecycle. Massachusetts Psychiatric Society and Cambridge Hospital Symposium. Boston, MA

Health Economic Impact of Bipolar Disorder; Comorbidity and Mixed Mania in Bipolar Disorder - - Cost Effective Strategies, National Symposium Chairperson. Institute on Psychiatric Services, American Psychiatric Association Annual Meeting. Chicago, IL

1997

Role of Antipsychotics in Treating Psychotic Mood Disorders; 4th Annual Psychopharmacology Symposium. Ohio State University School of Medicine. Columbus, OH

Role of Antipsychotics in Treating Mood Disorders; Antipsychotics in Unique Patient Populations. American Psychiatric Association Annual Meeting Symposium, San Diego, CA

Costs and Benefits of Bipolar Pharmacotherapy; Diagnostic and Treatment Advances in Manic Depression. American Psychiatric Association Annual Meeting Symposium. San Diego, CA

Psychopharmacological Treatment of Psychotic Disorders Across the Life Span. American Psychiatric Association Annual Meeting Symposium. San Diego, CA

Treating the Affective Component in Schizophrenia; Depression in Schizophrenia-Expanding Therapeutic Opportunities. World Congress of Biological Psychiatry. Nice, France

The New Antipsychotics and Their Therapeutic Potential; Comprehensive Schizophrenia Update. Alabama Psychiatric Society and the Mississippi Psychiatric Association Annual Meeting, Destin, FL

Pharmacoeconomics of Mood Stabilizers, Acute Manic Phase. International Bipolar Conference. Paris, France

Management of Mixed Mood States and Bipolar Disorder. Mental Health Association of Franklin County Annual Symposium. Columbus, OH

Bipolar Disorder in the Elderly. Institute for Psychiatric Services, American Psychiatric Association Annual Meeting, Washington, DC

Pharmacoeconomics of Bipolar Disorder. Mississippi Psychiatric Society, Jackson, MI

1998

Rapid Pharmacologic Treatment of Acute Mania. Ontario Psychiatric Association, Toronto, Canada

Rapid Loading Strategies in the Treatment of Acute Mania; Pharmacotherapy of Bipolar Disorder: Newest Advances Symposium Chairperson, American Psychiatric Association Annual Meeting, Toronto, Canada

A Biological Basis for Overlap of Mood in Psychotic Disorders; Expanding the Spectrum of Psychoses: The Interface of Affect Symposium. Co-Chairperson, American Psychiatric Association Annual Meeting, Toronto, Canada

Antipsychotics in Schizoaffective Disorder and Mania; Redefining Mood Stabilization: Advances in the Management of Bipolar Disorders. CINP XXIst Congress, Glasgow, Scotland

Making a Difference in Clinical Outcomes – the Profile of IM and Oral Ziprasidone; Making a Difference in Schizophrenia Management. CINP XXIst Congress, Glasgow, Scotland

A Biological Basis for Mood Overlap in Psychotic Disorders; New Advances in the Management of Bipolar Disorder (Chair). 9th Congress of the Association of European Psychiatrists (AEP), Copenhagen, Denmark

Long-term Management of Schizophrenia: The Role of New Antipsychotic; Schizophrenia: Charting a Course Through Mental Illness. Institute on Psychiatric Services Annual Meeting, American Psychiatric Association, Los Angeles, CA

Antipsychotics in Acute Mania: New Findings; Use of Antipsychotics in the management of Bipolar Disorder (Chair). Institute on Psychiatric Services Annual Meeting, American Psychiatric Association Annual Meeting, Los Angeles, CA

Newest Treatment Advances in Bipolar Disorder. U.S. Psychiatric & Mental Health Congress, San Francisco, CA

Atypical Antipsychotics: Efficacy in Treating Affective Symptoms, Hostility and Suicidality in Schizophrenia; Antipsychotic Standard of Care: Redefining the Definition of Atypical Antipsychotics. U.S. Psychiatric & Mental Health Congress, San Francisco, CA

Psychosis and Mood Disorders: Defining Reasonable Expectations for Treatment Outcomes (Chair). Center Net Symposium in conjunction with the Association of Academic Health Centers, Washington, DC

1999

Clinical Assessment of Atypical Antipsychotics: Interpreting the Data. PsychLINK Symposium, Dallas, TX

Update on Clinical Psychopharmacology Research. American Society of Clinical Psychopharmacology Regional Meeting, Cincinnati, OH

Pharmacologic Mechanisms of Mood Stabilization Among Atypical Antipsychotics. Are Atypical Antipsychotics also Mood Stabilizers? (Symposium Chairperson). American Psychiatric Association Annual Meeting, Washington, DC.

Mood Stabilizing Medication. Medication Controversies in Bipolar Disorder Symposium. American Psychiatric Association Annual Meeting, Washington, DC.

Antipsychotics in Schizoaffective Disorder. Global Medical Conference: Focus on Bipolar Disorder. Indianapolis, IN.

Relier L'interface entre les Troubles Psychotiques et les Troubles de l'humeur. Association des Médecins Psychiatres du Quebec. Alymer, Quebec, Canada

The Costs of Treatment of Bipolar Disorder. Bipolar Disorders – 100 years after Kraeplin. Martin Luther Universitat Halle – Wittenburg. Berlin Germany.

Optimizing Outcomes in Bipolar Disorder. Redefining Mood Stabilization: Advances in the Management of Bipolar Disorder. XI World Congress of the World Psychiatric Association. Hamburg, Germany.

Treatment of Psychotic Disorders for the New Century: From Social Containment to Reintegration (Chair). CENTERNET National Videoconference. New York, NY.

Treatment of Bipolar Disorder: Lithium, Anticonvulsants and Atypical Antipsychotics. Advances in Mood Disorders and Schizophrenia: Diagnosis – Biology – Treatment. Palm Beach, Fl.

The Use of Placebo in Studies of Bipolar Disorder: Current Status. Clinical Trials in Mood Disorders. The Use of Placebo, Past, Present and Future. A consensus conference of the National Depressive and Manic-Depressive Association. Washington, DC.

Ask the Doctors. National DMDA Annual Convention. Houston, TX.

New Horizons in Research. National DMDA Annual Convention. Houston, TX.

Clinical Vignettes: Strategies for Psychosis. PsychLink Symposium, Dallas, TX.

Antipsychotics in Acute and Maintenance Treatment of Bipolar Disorder. Role for Antipsychotics in Long-term Mood Stabilization (Program Chair). APA Institute on Psychiatric Services, New Orleans, LA.

Atypical Antipsychotics in the treatment of Mania. Progress in Bipolar Disorders (Program Chair). US Psychiatric & Mental Health congress, CME, Inc. Atlanta, GA.

Filling the Unmet Needs of the Bipolar Patient. Psychlink Symposium, Dallas, TX.

2000

Bipolar Disorder: From Pre-Clinical to Clinical, Facing the New Millenium (Program Chair). Society of Biological Psychiatry, Phoenix, AZ.

Keck PE, Jr. Update on tardive dyskinesia. Tardive dyskinesia in patients with depression including bipolar disorder. J Clin Psychiatry Audiograph Series 2000; 3:1.

Management of Bipolar Disorder for the New Millennium (Program Chair). Provision Medical Education Telecast. Miami, FL.

Thymoleptic mechanisms and activity of atypical antipsychotics. Fifth Annual Psychopharmacology Update. Nevada Association of Psychiatric Physicians. Las Vegas, NV

Rapid stabilization of mood and psychotic symptoms in mania. Defining Bipolar Disorder (Co-Chairman), American Psychiatric Association Annual Meeting. Chicago, IL.

NMS 1960-2000: Forty years of Progress. American Psychiatric Association Annual Meeting. Chicago, IL.

Newest Advances in the Pharmacological Treatment of Psychiatric Illnesses. Wyoming Medical Society Annual Meeting, Jackson Hole, WY

Restoring Balance: Long Term Mood Stabilization in the Bipolar Patient. PsychLink Symposium, Dallas, TX.

Treatment of Bipolar Disorder: Lithium, Anticonvulsants, and Atypical Antipsychotics. Advances in the Diagnosis, Biology and treatment of the Major Psychiatric Disorder. Palm Beach, FL.

Realities of Reintegration: Multidimensional Approaches to Optimize Outcomes in Psychosis and Mood Disorder. Provision Medical Education Telecast. New York, NY.

Redefining Mood Stabilization. The Coming of Age of the Bipolar Spectrum: An International Conference. University of California, San Diego. San Diego, CA.

Interface of Thought, Mood and Behavior. 13th Annual U.S. Psychiatric & Mental Health Congress, San Diego, CA.

Redefining Efficacy in Psychosis and Mood Disorders. 13th Annual U.S. Psychiatric & Mental Health Congress, San Diego, CA.

2001 Update on Treatment Advances in Bipolar Disorder. Sunshine From Darkness, NARSAD Annual Meeting, Sarasota, FL.

Atypical Antipsychotics in the Treatment of Aggressive Behvaviors. Off-Label on the Table: Using New Pharmacological Agents. American Psychiatric Association Annual Meeting, New Orleans, LA.

Manic and Mixed Episodes: The Challenge of Improving Functional Outcome. Providing Complete Treatment for Patients with Bipolar Disorder (Chairperson). American Psychiatric Association Annual Meeting, New Orleans, LA.

New Antiepileptics in the Treatment of Bipolar Disorder. Clinical Issues in Bipolar Disorder: The Stanley Foundation Bipolar Network. American Psychiatric Association Annual Meeting, New Orleans, LA.

Update on Pharmacotherapy and Neuroscience. Fourth International Conference on Bipolar Disorder, Pittsburgh, PA.

What Makes a Drug a Mood-Stabilizer? PsychLink telecast, Interactive Medical Networks, Dallas, TX.

Update on New Treatment Research for Bipolar Disorder. National DMDA 14th Annual Conference, Cleveland, OH.

Bipolar Disorder: An Overview of Diagnosis and Treatment. 150th Annual Meeting of the Kentucky Medical Association, Louisville, KY.

Update on Latest Treatment Advances for Bipolar Disorder. Annual Meeting of the Kentuck Psychiatric Association, Louisville, KY.

Latest Treatment Advances for Bipolar Disorder. Interface of Mood, Thought, and Behavior. U.S. Psychiatric & Mental Health Congress, Boston, MA.

Treating the Acute Phases of Bipolar Disorder: Mania. Progress in Bipolar Disorder. U.S. Psychiatric & Mental Health Congress, Boston , MA.

Acute Efficacy Considerations in Managing Schizophrenia. Redefining Optimal Patients Management in Schizophrenia. U.S. Psychiatric & Mental Health Congress, Boston, MA.

2002

Comprehensive Treatment of Manic-Depressive Illness (Program Chair). Depression Awareness Day: The Latest on Chasing the Blues Away. Albert Sabin Center, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio.

Doctoral Candidate Committee:

1993-1995 Megan G. Murray, "The Measurement of Life Stress in Biplar Disorder," Committee Member for Major Qualifying Exam (MQE) and Dissertation. University of Cincinnati, Department of Psychology

Bibliography:

Science Citation Index 1988-2,001: 14, 252

Original Reports:

1986

1. Pope HG, Jr, Keck PE, Jr, McElroy SL. Frequency and presentation of neuroleptic malignant syndrome in a large psychiatric hospital. Am J Psychiatry 1986; 143:1227-1233.

2. White K, Keck PE, Jr, Lipinski JF. Serotonin uptake inhibitors in obsessive compulsive disorder: a case report. Compr Psychiatry 1989; 27:211-214.

3. Keck PE, Jr, Lipinski JF, White K. An inverse relationship between mania and obsessive compulsive disorder: A case report. J Clin Psychopharm 1986; 6:123-124.

1987

4. McElroy SL, Keck PE, Jr, Pope HG, Jr. Sodium valproate: Its use in primary psychiatric disorders. J Clin Psychopharm 1987; 7:16-24.

5. Keck PE, Jr, Pope HG, Jr, McElroy SL. Frequency and presentation and neuroleptic malignant syndrome: a prospective study. Am J Psychiatry 1987; 144:1344-1346.

6. Keck PE, Jr, Pope HG, Jr, McElroy SL. Frequency of neuroloeptic malignant syndrome, 1963-1986. Psychiatrie and Psychobiologie 1987; 2:59-63

1988

7. Keck PE, Jr, Pope HG, Jr, Hudson JI, McElroy SL, Kulick AR. Lycanthropy: alive and well in the twentieth center. Psychol Med 1988; 18:113-120.

8. Cohen BM, Buonanno F, Keck PE, Jr, Finkelstein S, Benes FM. Comparison of MRI and CT scans in a group of psychiatric patients. Am J Psychiatry 1988; 145:1084-1088.

9. Lipinski JF, Jr, Keck PE, Jr, McElroy SL. Beta-adrenergic antagonists in psychosis: Is improvement due to treatment of neuroleptic-induced akathisia? J Clin Psychopharm 1988; 8:409-416.

10. McElroy SL, Pope HG, Jr, Keck PE, Jr, Hudson JI. Treatment of psychiatric disorders with sodium valproate: A series of 73 cases. Psychiatrie & Psychobiologie 1988; 3:81-85.

11. McElroy SL, Keck PE, Jr, Pope HG, Jr, Hudson JI. Valproate in the treatment of rapid cycling bipolar. J Clin Psychopharm 1988; 8:275-279.

12. Pope HG, Jr, McElroy SL, Satlin A, Hudson JI, Keck PE, Jr, Kalish R. Head injury, bipolar disorder, and response to valproate. Compre Psychiatry 1988; 29:34-38.

1989

13. Pope HG, Jr, McElroy SL, Keck PE, Jr, Hudson JI. Electrophysiologic abnormalities in bulimia and their implications for pharmacotherapy: A reassessment. Int J Eating Disorders 1989; 8:191-201.

14. Pope HG, Jr, Keck PE, Jr, McElroy SL, Hudson JI. A placebo-controlled study of trazodone in bulimia nervosa. J Clin Psychopharm 1989; 9:254-259.

15. Keck PE, Jr, Cohen BM, Baldessarini RJ, McElroy SL. Time course of antipsychotic effects of neuroleptic drugs. Am J Psychiatry 1989; 146:1289-1292.

16. Keck PE, Jr, Sebastianelli J, Pope HG, Jr, McElroy SL. Frequency and presentation of neuroleptic malignant syndrome in a state psychiatric hospital. J Clin Psychiatry 1989; 50:352-355.

17. Keck PE, Jr, Pope HG, Jr, Nierenberg AA. Autoinduction of hypertensive reactions by tranylcypromine? J Clin Psychopharm 1989; 9:48-51.

18. Nierenberg AA, Keck PE, Jr. Management of MAO inhibitor-associated insomnia with trazodone. J Clin Psychopharm 1989; 9:42-45.

19. Keck PE, Jr, Vuckovic A, Pope HG, Jr, Nierenberg AA, Gribble GW, White K. Acute cardiovascular response to monoamine oxidase inhibitors: A prospective assessment. J Clin Psychopharm 1989; 9:203-206.

20. Pope HG, Jr, McElroy SL, Keck PE, Jr, Hudson JI. Long-term pharmacotherapy of bulimia nervosa. J Clin Psychopharm 1989; 9:385-386.

21. Hudson JI, Pope HG, Jr, Keck PE, Jr, McElroy SL. Treatment of bulimia nervosa with trazodone: Short-term response and long-term follow-up. Clinical Neuropharmacology 1989; 12 (Suppl 1): S38-46.

22. Keck PE, Jr, Pope HG, Jr, Cohen BM, McElroy SL, Nierenberg AA. Risk factors for neuroleptic malignant syndrome: a case-control study. Arch Gen Psychiatry 1989; 46:914-918.

23. McElroy SL, Keck PE, Jr, Pope HG, Jr, Hudson JI. Pharmacological treatment of kleptomania and bulimia nervosa. J Clin Psychopharm 1989; 9:358-360.

1990

24. Kulick AR, Pope HG, Jr, Keck PE, Jr, Hudson, JI. Lycanthropy and self-identification in traditional and modern societies. J Nerv Ment Dis 1990; 178:134-137.

25. Vuckovic A, Cohen BM, Keck PE, Jr, Shedlack K. Neuroleptic dosage regimens in psychotic inpatients: A retrospective comparison. J Clin Psychiatry 1990; 51:107-109.

26. Keck PE, Jr, Pope HG, Jr, Hudson JI, McElroy SL, Yurgelun-Todd D, Hundert EM. A controlled study of phenomenology and family history in outpatients with bulimia nervosa. Compr Psychiatry 1990; 31:275-283.

27. Keck PE, Jr, Seeler DC, Pope HG, Jr, McElroy SL. Porcine Stress Syndrome: An animal model for neuroleptic malignant syndrome? Biol Psychiatry 1990;28:58-62.

28. Kando JC, Keck PE, Jr, Wood P. Severe hypotension associated with initiation of pergolide therapy. Drug Intell Clin Pharm, Ann Pharmacotherapy 1990; 24:543.

29. Hudson JI, Lipinski JF, Keck PE, Jr, Lukas SE, Dorsey CM, Rothschild AJ, Aizley HG. Sleep in mania versus unipolar depression. Sleep Res 1990; 19:66.

30. Keck PE, Jr, Hudson JI, Dorsey CM, Matheson JK, Campbell PI. Antiepileptic Drugs. Sleep Res 1990; 19:166.

1991

31. McElroy SL, Hudson JI, Pope HG, Jr, Keck PE, Jr. Kleptomania: clinical characteristics and associated psychopathology. Psychol Med 1991; 21:93-108.

32. Cohen BM, Keck PE, Jr, Satlin A, Cole JO. Prevalence and severity of akathisia in patients on clozapine. Biol Psychiatry 1991; 29:1215-1219.

33. McElroy SL, Keck PE, Jr, Lawrence JM. Treatment of panic disorder and benzodiazepine withdrawal with valproate: A case report. J Neuropsychiatry Clin Neurosci 1991;2:232-233.

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83. Keck PE, Jr, Harrigan E, Reeves K. The efficacy of ziprasidone in the treatment of positive, negative and depressive symptoms of schizophrenia. American Psychiatric Association Annual Meeting, San Diego, CA, May 1997.

84. Keck PE, Jr. Ziprasidone: An overview of efficacy and tolerability in the treatment of patients with an acute exacerbation of schizophrenia or schizoaffective disorder. NCDEU Annual Meeting, Boca Raton, FL, May 1997, NR1; Psychopharmacol Bull 1997; 33: 535.

85. Shapira NA, Keck PE, Jr, Goldsmith TD, McConville BJ, Haggard PJ, McElroy SL. Tramadol for treatment-refractory OCD. American Psychiatric Association Annual Meeting, San Diego, CA, May 1997.

86. Keck PE, Jr, Harrigan E, Reeves K. The efficacy of ziprasidone in schizophrenia and schizoaffective disorder. 6th World Congress of Biological Psychiatry, Nice, France, June1997.

87. Geracioti TD, Ekhator NN, West SA, Hill KK, Baker DG, Bruce AB, Wortman MD, Keck PE, Norman AB. Cerebrospinal fluid dopamine and homovanillic acid concentrations in tobacco smokers and patients with post-traumatic stress disorder. Psychoneuroendocrinology 1997; 22: S204.

88. Baker D, West SA, Orth DN, Hill K Nicholson WE, Ekhator NN, Bruce A Wortman M, Keck PE, Geracioti TD. Elevated cerebrospinal fluid beta-endorphin concentrations in patients with post-traumatic stress disorder. Psychoneuroendocrinology 1997; 22 S212.

1998

89. Soutullo CA, Sorter MT, Foster KD, McElroy SL, Keck PE, Jr. Olanzapine in the treatment of adolescent acute mania: Preliminary report of seven cases. American Psychiatric Association Annual Meeting, June 1, 1998, Toronto, Canada, NR 163.
90. Shapira NA, Goldsmith TD, Keck PE, Jr, Khosla UM, McElroy SL. Psychiatric evaluation of individuals with problematic use of the Internet. American Psychiatric Association Annual Meeting, June 1, 1998, Toronto, Canada, NR 157.

91. Sax KW, Zimmerman ME, DeBello MP, Hawkins JM, Keck PE, Jr, Strakowski SM. Prefrontal corical volume and attentional performance in bipolar disorder. 53rd Annual Meeting of the Society of Biological Psychiatry, Toronto, Canada, May 1998, Biol Psychiatry 1998; 43: 16s

92. Calabrese JR, Shelton MD, Keck PE, Jr, McElroy SL, Werkner JE. Topiramate in severe treatment-refractory mania. American Psychiatric Association Annual Meeting, June 1, 1998, Toronto, Canada, NR 202.

93. McElroy SL, Soutullo CA, Taylor P, Nelson EB, Beckman DA, Keck, PE, Jr, Strakowski SM. Psychiatric features of 30 sex offenders. American Psychiatric Association Annual Meeting, June 2, 1998, Toronto, Canada, NR 424.

94. Hawkins JM, Strakowski, SM, McElroy SL, Sax KW, Keck PE, Jr. First-rank symptoms and outcome in new-onset nonaffective psychosis. American Psychiatric Association Annual Meeting, June 3, 1998, Toronto, Canada, NR 456.

95. Calabrese JR, Shelton MD, Keck PE, McElory SL. Topiramate in severe refractory mania. XXIst CINP Congress, July 13, 1998, Glasgow, Scotland, PM 03032. Int J Neuropsychopharmacol 1999; 2 (Suppl 1): 57.

96. McElory, Kmetz GF, Keck PE, Jr. A pilot trial of adjunctive topiramate in the treatment of bipolar disorder. XXIst CINP Congress, July 13, 1998, Glasgow, Scotland, PM 03006. Int J Neuropsychopharmacol 1999; 2 (Suppl 1): 50.

97. Keck PE, Jr. The efficacy of ziprasidone in the treatment of an acute exacerbation of schizophrenia or schizoaffective disorder. Fifth World Congress of the International association for Emergency Psychiatry, October 15, 1998, Brussels, Belgium.

98. Hirchfeld RMA, Allen MH, Keck PE, Jr, McEvoy J, Fawcett J, Nemeroff CB, Russell J, Bowden CL. Safety and efficacy of rapid-loading divalproex sodium in acutely manic bipolar patients. American College of Neuropsychopharmacology Annual Meeting, December 13-17, 1998, San Juan, Puerto Rico.

99. Sax KW, Strakowski SM, Keck PE, Jr. Attentional improvement and quetiapine fumarate in schizophrenia. Institute on Psychiatric Services Annual Meeting, October 2-6, 1998.

100. Suppes T, Brown ES, McElroy SL, Kmetz GF, Frye MA, Keck PE, Kupka R, Altshuler L, Rochussen J, Hatef J, Leverich GS, Post RM. A pilot trial of adjunctive topiramate in the treatment of bipolar disorder. American College of Neuropsychopharmacology Annual Meeting, Dec 13-17, 1998, San Juan, Puerto Rico.

1999

101. Revicki DA, Hirschfeld RMA, Keck PE, Jr, Weisler RH, Ahearn EP. Cost-effectiveness of divalproex sodium vs lithium in long-term therapy for bipolar disorder. American College of Neuropsychopharmacology Annual Meeting, December 13-17, 1999 San Juan, Puerto Rico.

102. Brown ES, Suppes T, McElroy S, Kmetz G, Frye M, Denicoff K, Keck P, Nolen W, Kupka, Altshuler L, Rochussen J, Hatef J, Leverich G, Post R. A pilot trial of adjunctive topiramate in the treatment of bipolar disorder. Society of Biological Psychiatry Annual Meeting, Washington, DC, May 13-15, 1999, NR 252.

103. Soutullo CA, Del Bello MP, Casuto LS, Lake K, Gramam SM, McDonough-Ryan, McElroy SL, Strakowski SM, Keck PE, Jr. Psychiatric disorders in children of bipolar patients versus controls: preliminary results. American Psychiatric Association Annual Meeting, Washington, DC. May 17, 1999, NR 23.

104. Keck PE, Jr, Reeves KR, Harrigan EP. Ziprasidone treatment of an acute exacerbation of schizoaffective disorder. American Psychiatric Association Annual Meeting, Washington DC. May 18, 1999, NR 283.

105. Del Bello MP, Soutullo CA, Ochsner JE, McElroy SL, Keck PE, Jr, Strakowski, SM. Racial differences in the treatment of adolescents with bipolar disorder. American Psychiatric Association Annual Meeting, Washing, DC. May 18, 1999, NR 379.

106. Keck PE, Jr, Martin J, Thomas JH, Allen MH, Hirschfeld RMA, Aomerville KW. Safety and efficacy of oral loading divalproex sodium in acutely manic bipolar patients. American Psychiatric Association Annual Meeting, Washington, DC. May 19, 1999, NR 451.

107. Calabrese JR, Van Kammen DP, Shelton MD, Keck PE, Jr, McElroy SL. Topiramate in severe treatment-refractory mania. American Psychiatric Association Annual Meeting, Washington, DC. May 20, 1999, NR 680

108. Hirschfeld RMA, Weisler RH, Keck PE, Jr, Ahern E, Revicki S. Cost-effectiveness evaluation of divalproex sodium versus lithium in the treatment of bipolar disorder. American Psychiatric Association Annual Meeting, Washington, DC. May 20, 1999, NR 686.

109. Janicak PG, Keck PE, Jr, Davis JM, Kasckow JW, Tugrul K, Dowd S, Sharma RP. Risperidone versus haloperidol for schizoaffective disorder. American Psychiatric Association Annual Meeting, Washington, DC. May 20, 1999, NR 694.

110. Liang SG, Sadovnick AD, Remick RA, Keck PE, McElroy SL, Luchman HM, Alexander M, Brown JL, Kelsoe JR. Evidence for linkage disequilibrium between bipolar disorder and markers on chromosome 22q. World Congress on Psychiatric Genetics,

111. Kelsoe JR, Spence MA, Loetscher E, Sadovnick AD, Remick RA, Keck PE, McElroy S, Mroczkowski-Parker Z, Shekhtman T, Brown JL, Flodman P, Ungerleider S, Tran H, Rapaport MH, Foquet M, Luebbert H. A genome survey indicates a susceptibility locus for

bipolar disorder on chromosome 22: further support form two additional family sets. World Congress on Psychiatric Genetics,

112. Greenwood TA, Sadovnick AD, Remick RA, Keck PE, McElroy S, Kelsoe JR. Evidence for linkage disequilibrium between the dopamine transporter and bipolar disorder. World Congress on Psychiatric Genetics,

113. Brown ES, Suppes T, McElroy S, Kmetz G, Frye M, Denicoff K, Keck P, Nolen W, Kupka R, Altshuler L, Rochussen J, Haytef J, Leverich GS, Post R. A pilot trial of adjunctive topiramate in the treatment of bipolar disorder. Third International Conference on Bipolar Disorder, Pittsburgh, PA, June 17-19, 1999, Abstract # 17; Bipolar Disorders 1999; 1: 25.

114. Denicoff KD, Brotman MA, Leverich GS, Nolen W, Rush AJ, McElroy SL, Keck PE, Suppes T, Altshuler LL, Kupka R, Frye MA, Post Rm. Validation of the NIMH-Life-Chart Method (NIMH-LCM™). Third International Conference on Bipolar Disorder, Pittsburgh, PA, June 17-19, 1999, Abstract # 29; Bipolar Disorders 1999; 1: 29.

115. Van Kammen DP, Calabrese JR, Shelton MD, Keck PE, McElroy SL. Topiramate in severe treatment refractory mania. Third International Conference on Bipolar Disorder, Pittsburgh, PA, June 17-19, 1999, Abstract # 132; Bipolar Disorders 1999; 1: 56.

116. Soutullo CA, McElroy SL, Del Bello MP, Foster K, Keck PE, Jr, Strakowski SM. Open label olanzapine in the treatment of children and adolescents with acute mania associated with bipolar disorder. American Psychiatric Association Research Colloquium for Junior Investigators. National Institute of Health (NIH), Bethesda, MD, May 16, 1999.

117. Soutullo CA, Sorter MT, Foster KD, McElroy SL, Keck PE, Jr. Olanzapine in the treatment of adolescent acute mania: preliminary report of seven cases. American Psychiatric Association Research Colloquium for Junior Investigators, NIH, Bethesda, MD, May 16, 1999.

118. Mather DB, Bell EM, Bryant-Comstock L, Sullivan SD, Keck PE, Jr. Development of a cost consequences computer simulation model of bipolar disorder. International Society for Pharmacoeconomics and Outcome Research. Crystal City, VA; May 23-26, 1999.

119. McElroy S, Altshuler L, Frye M, Keck P, Kmetz G, Suppes T. A pilot trial of adjunctive topiramate in the treatment of bipolar disorder. XI World Congress of Psychiatry, World Psychiatric Association. Hamburg, Germany, August 7, 1999.

120. Keck PE, Reeves KR, Harrigan EP, Lakshminarayanan M, and the Ziprasidone Study Group. Ziprasidone reduces overall psychopathology and symptoms of depression in the acute treatment of schizoaffective disorder. XI World Congress of Psychiatry, World Psychiatric Association. Hamburg, Germany, August 7, 1999.

121. Friedman LM, Keck PE, Jr, Dewan N, McBride JF, Rothschild AJ. Clinical trials infrastructure in academic psychiatry: a case study. American College of Neuropsychopharmacology. Acapulco, Mexico, December 1999.

2000

122. Hudson JI, Laird NM, Betensky RA, Keck PE, Jr, Pope HG, Jr. Familial aggregation of eating and mood disorders. American Psychiatric Association Annual Meeting, May 13-18, 2000, Chicago, IL.

123. Keck PE, Jr, Ice KN and the Ziprasidine Study Group. Controlled treatment of acute mania with ziprasidone. American Psychiatric Association Annual Meeting, May 13-18, 2000, Chicago, IL.

124. Keck PE, Jr. A three-week, double-blind, randomized trial of ziprasidone with acute treatment of mania. NCDEU Annual Meeting, Boca Raton, FL, May 30 – June 2, 2000.

125. Bryant-Comstock L, Mather DB, Sullivan SD, Keck PE, Jr, Lee TA, Li H. treatment of bipolar depression: clinical and economic outcomes using a computer simulation model. American Psychiatric Association Annual Meeting, May 13-18, 2000, Chicago, IL.

126. Mann SC, Caroff SN, Cabrina-Cambell E, Blerer HR, Fricchime GL. Keck PE, Jr. Malignant catatonia. American Psychiatric Association Annual Meeting, May 13-18, 2000, Chicago, IL.

127. Suppes T, Kupka R, McElroy SL, Altshuler LL, Frye MA, Keck PE, Denicoff KD, Nolen WA, Rochussen J, Leverich GS, Post RM. Incidence of co-occurrence of hypomania and depressive symptoms in the Stanley Foundation Bipolar Network. 2nd European Stanley Foundation Conference on Bipolar Disorder. October, Amsterdam, The Netherlands.

128. Denicoff KD, Leverich GS, Nolen WA, McElroy SL, Keck PE, Jr, Suppes T, Altshuler LL, Kupka R, Frye MA, Pollio C, Post RM. Morbidity in 202 patients followed for one year in the Stanley Foundation Bipolar Network. 2nd European Stanley Foundation Conference on Bipolar Disorder. October, Amsterdam, The Netherlands.

129. Leverich GS, Altshuler LL, McElroy SL, Keck PE, Jr, Suppes T, Denicoff KD, Nolen WA, Rush AJ, Kupka R, Frye MA, Autio KA, Post RM. Prevalence of axis II comorbidity in bipolar disorder: relationship to mood state and course of illness. 2nd European Stanley Foundation Conference on Bipolar Disorder, October, Amsterdam, The Netherlands.

130. Soutullo CA, DelBello MP, Ochsner JE, McElroy SL, Keck PE, Jr. Severity of bipolar illness in hospitalized manic adolescents exposed to stimulants or antidepressants. Spanish Psychiatric Society Fifth Congress, October 18-21, 2000, Zaragoza, Spain.

2001

131. Arnold LM, Hess E, Hudson JI, Keck PE. A double-blind, placebo-controlled, randomized, parallel-group, 12-week trial of fluoxetine in the treatment of fibromyalgia. 41st Annual Meeting of NCDEU, May 28-31, 2001, Phoenix, AZ.

132. Wosnitzer-Smith K, Freeman MP, Kmetz GF, McElroy SL, Keck PE, Jr. Bipolar disorder and the risk of postpartum depressive episodes. American Psychiatric Association Annual Meeting, May 2001, New Orleans, LA.

133. Frye MA, Altshuler LL, Denicoff KD, Keck PE, Jr, McElroy SL, Suppes T. Gender differences in bipolar disorder: alcohol abuse comorbidity. American Psychiatry Association Annual Meeting, May 2001, New Orleans, LA.

134. Welge JA, Keck PE, Jr. Meta-regression of placebo response in antipsychotic trials involving patients with schizophrenia. Society of Biological Psychiatry Annual Meeting, New Orleans, LA, May 3-5, 2001; Biol Psychiatry 2001; 49: 63S.

135. Arnold LM, Hess EV, Hudson JI, Welge JA, Keck PE, Jr. Fluoxetine treatment of fibromyalgia. American College of Rheumatology 65th Annual Meeting, San Francisco, CA, November, 2001.

136. Kupka R, Nolen WA, Post RM, McElroy SL, Altshuler LL, Denicoff KD, Frye MA, Keck PE, Jr, Leverich GS, Rush AJ, Pollio C, Drexhage HA. High rate of autoimmune thyroiditis in bipolar disorder: lack of association with lithium exposure. Fourth International Conference on Bipolar Disorder, Pittsburgh, PA, June 14-16, 2001.

137. Keck PE, Jr. Update on Pharmacotherapy. Fourth International Conference on Bipolar Disorder, Pittsburgh, PA, June 14-16, 2001.

138. McElroy SL, Arnold LM, Shapira NA, Keck PE, Jr, Rosenthal N, Hudson JI. Topiramate in the treatment of binge eating disorder associated with obesity. Annual Meeting of the American Psychiatric Association Psychiatric Services, October 2001.

139. Arnold LM, Hess EV, Hudson JI, Welge JA, Keck PE, Jr. Fluoxetine treatment of fibromyalgia. American College of Rheumatology 65th Annual Meeting.

2002

140. Keck PE, Jr, Saha A, Ali M, Ingenito G, English PA. Aripiprazole vs. placebo in acute mania. American Psychiatric Association Annual Meeting, New Research. Philadelphia, PA, May 13-18, 2002.

141. Keck PE, Hirschfeld RMA, Calabrese J, Reed M, Tierce, Hazard EH. Economic impact of manic symptoms of bipolar spectrum disorder in the United States. New Clinical Drug Evaluation Unit (NCDEU) Annual Meeting. Boca Raton, FL, June 10-13, 2002.

142. Welge JA, Keck PE, Jr, Friedman LM. The Schizophrenia Trial Constorium for modeling placebo response. New Clinical Drug Evaluation Unit (NCDEU) Annual Meeting. Boca Raton, FL, June 10-13, 2002.

Scientific Advisory Boards:

1990-	Abbott Laboratories, National Advisory Board, Depakote[R]
1992-1993	SmithKline Beecham, Regional Advisory Board, Paxil[R]
1993-1994	Janssen, Inc., Regional Advisory Board, Risperdal[R]
1994-	National Depressive and Manic Depressive Association, Vice Chairman (1998-2001)
1994-	Alza Pharmaceutical, CNS Drug Delivery Systems
1994-	Stanley Foundation Bipolar Network Study
1995-	Chairman and Faculty Advisor, Psychiatric Residents National Advisory Board, Abbott Laboratories, Depakote[R]
1995-	Park-Davis, National Advisory Board, Neurontin[R]
1995-	Wyeth-Ayerst, National Advisory Board, CNS Pharmaceutical Development
1996-	Eli Lilly and Company, Regional Advisory Board, Zyprexa[R]
1996-	Zeneca Pharmaceuticals, National Advisory Board, Seroquel[R]
1997-	The R.W. Johnson Pharmaceutical Research Institute, Scientific Consultant
1997-	Solvay Pharmaceuticals, National Advisory Board, Lithobid[R]
1997-	Pfizer, Inc., National Advisory Board, CNS Pharmaceuticals
1999-	Pfizer, Inc., Visiting Professorship Program Advisory Board

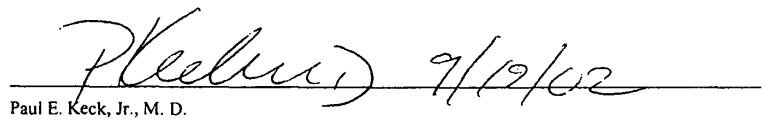
1998-	Quintiles Pacifica, Inc., La Jolla, CA
2001-	GlaxoSmithKline, National Advisory Board, Lamitcal ®

Scientific Consultant:

2001-	Malignant Hyperthermia Association of the United States (MHAUS)

Community Services:

1991-	Speaker, NAMI of Hamilton County
1992-1997	S.A.Y. Soccer Coach, Summit County Day School
1992-1995	Knothole Baseball Coach, Mt. Lookout Knights
1994-1997	Knothole Baseball Coach, Green Monsters Baseball Team
1995-1996	C.Y.O. Baseball Coach, Summit County Day School
1996-	Board of Trustees, Living Arrangements for the Developmentally Disabled, Cincinnati, Ohio
1997	Speaker, Bipolar Support Group, Hamilton County
1999	Speaker, Annual Meeting of PLAN, Hamilton County
1999-2000	C.Y.O. Basketball Coach, Summit Country Day School
2000	M.V.L.A. LACROSSE Coach, Summit Country Day School



Paul E. Keck, Jr., M. D.

Reviewed 9/19/02

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PLACE OF BIRTH: Philadelphia, PA

LICENSURE:
Board Certified by the American Osteopathic Board of Family Practice
Osteopathic Physician and Surgeon, State of California
Osteopathic Physician and Surgeon, State of New Jersey
Osteopathic Physician and Surgeon, State of Pennsylvania

CURRENT STATUS:

1998 – Present	Chief Medical Officer Comprehensive Clinical Research, CNS, P.C.
1994 – 1998	Executive Vice-President, Corporate Development FPA Medical Management, Inc.
1984 – 1993	General Practitioner Family Practice Associates of San Diego, Inc.

EDUCATION:

1979 – 1983	Philadelphia College of Osteopathic Medicine, Philadelphia, Pennsylvania Osteopathic Physician and Surgeon, D.O.
1978 – 1979	Drexel University, Philadelphia, Pennsylvania
1974 – 1978	Fairleigh Dickinson University, Madison, New Jersey B.S.
1983 – 1984	Rotating Internship

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University of Medicine & Dentistry
John F. Kennedy Memorial Hospital
Stratford, Cherry Hill, and Washington Township Divisions, New Jersey

POST GRADUATE TRAINING:

1982 – 1994	University of Pennsylvania, Ongoing Clinical Research Training. Instructor for five years in the Department of Psychiatry at University of Pennsylvania. Worked collaboratively with Karl Rickels, M.D., Chairman of the Department of Psychiatry and President of the Private Practice Research Group
1981 – 1984	W. George Case, M.D., Director, University of Pennsylvania 1240 Hours of Training in the Conduct of Clinical Research

HOSPITAL AND ADMINISTRATIVE APPOINTMENTS:

2001 – 2002	Hampton Behavioral Center, Westhampton NJ
2001 – 2002	Scientific Advisory Group of Organon, Inc. for The New Treatment Option for the Mature Depressed Patient, presenter of Patient Trial Program The Plaza Hotel, New York, NY March 24, 2001
2001 – 2002	Scientific Advisory Group of Organon, Inc. for The New Treatment Option for the Mature Depressed Patient, presenter of Patient Trial Program New York Hilton, New York, NY March 25, 2001
2000 – 2001	Eli Lilly and Company Advisory Board on Tomoxetine for ADD and ADHD Pediatrics, Adolescents, and Adults
1999 – Present	Eli Lilly and Company Advisory Board for Pediatric, Adolescent, and Adult ADHD
1999 – Present	Forest Laboratories Advisory Board for Geriatric Study
1999 – 2000	Eli Lilly and Company Advisory Board on Tomoxetine for ADD and ADHD Pediatrics, Adolescents, and Adults
1998 – 2001	JFK Memorial Hospital, University of Medicine and Dentistry, Stratford NJ
1991 – 1995	Staff Member, Hillside Hospital (Closed)
1990 – 1996	Staff Member, Mercy Hospital
1984 – 1998	Staff Member, Grossmont Hospital
1984 – 1987	Staff Member, Executive Committee, Alvarado Hospital

AWARDS AND HONORS:

1996	Entrepreneur of the Year Award, Ernst & Young
1996	Outstanding Efforts in the Healthcare Community The City of San Diego, Susan Golding, Mayor

1995	San Diego Press Club, Headliner
1982	American College of General Practitioners - Osteopathic Medicine and Surgery Preceptor Program
1980 – 1983	Philadelphia College of Osteopathic Medicine Lambda Omicron Gamma, National Medical Fraternity Award for Outstanding Leadership (three-time recipient)

PUBLICATIONS:

MONOGRAPHS

1999	*Alternative Treatments for Common Conditions*, St. Louis: Quality Medical Publishing, Inc.

ARTICLES

2000	Comparative Study of the Clinical Effectiveness of a Pyrethrin-Based Pediculicide with Combining Versus a Permethrin-Based Pediculide with Combing
2000	Pleconaril Treatment Shortens Duration of Picornavirus Respiratory Illness in Adults; F.G. Hayden; H.A. Hassman; T. Coats; R. Menedez; T. Bock; and the Pleconaril Respiratory Infection Study Group
1998	Clinical Pediatrics Comparative Study of the Clinical Effectiveness of a Pyrethrin-Based Pediculicide with Combining Versus a Permethrin-Based Pediculicide; C.V. Bainbridge, Ph.D.; G.L. Klein, M.D.; S.I. Neibart, M.D.; H. Hassman, D.O.; K. Ellis, D.O.; D. Manring, M.D.; R. Goodyear, R.N.C.; J. Newman, M.D.; S. Micik, M.D.; F. Hoehler, Ph.D.; P. Walicke, M.D.
1998	Journal Of Clinical Psychiatry Buspirone and Imipramine for Treatment of Major Depression in the Elderly; Edward Schweizer, M.D.; Karl Rickels, M.D.; Howard Hassman, D.O.; Felipe Garcia-Espana, Ph.D.
1993	Archives of General Psychiatry Antidepressants for the Treatment of Generalized Anxiety Disorder: A Placebo-Controlled Comparison of Imipramine, Trazodone and Diazepam; Karl Rickels, M.D.; Robert Downing, Ph.D.; Schwizer, M.D.; Howard Hassman D.O.
1991	European Journal Pharmacopsychiatry Adinazolam, Diazepam, Imipramine and Placebo in Major Depressive Disorder, A Controlled Study; K. Rickels; J. London; Ira Fox; H. Hassman; Irma Csanalosi; Ch. Weise; The Psychopharmacology Research and Treatment of Unit and the Private practice Research Group, Department of Psychiatry and The University of Pennsylvania

CLINICAL ABSTRACTS

2001	American Rosuvastatin Trialists Group – Long-Term Efficacy and Safety of Rosuvastatin: Results of a 52-Week Comparator-Controlled Trial Versus Pravastatin and Simvastatin
1999	Hoechst Marion Roussel – A Double-Blind, Multi-Center, Randomized, Active-Controlled, Two-Arm, Parallel-Group Comparative Study of the Efficacy and Safety of Oral HMR3647 Versus Oral Clarithromycin in the Treatment of Community Acquired Pneumonia in Adults

POSTERS

2000	Mirtazapine vs. Sertraline after SSRI Non-Response presented at the ECNP meeting in Munich, Germany September 9-13, 2000
2000	Mirtazapine vs. Paroxetine in Elderly Depressed Patients presented at the ECNP meeting in Munich, Germany September 9-13, 2000

CLINICAL RESEARCH:

CNS STUDIES

1982 – 1983	Rater and Physician, Alprazelam Anxiety Study #2 PPRG
1982 – 1983	Rater and Physician, Abbott Anxiety Study with PPRG
1984 – 1985	University of Pennsylvania Adinazolam Depression Study
1984	Principal Investigator Cheviak Bigasdh Syndrome Study Independently conducted
1985 – 1987	Downing Anxiety Study with PPRG University of Pennsylvania
1989 – 1991	Miles Laboratories Ipsapirone Study, Anxiety Investigational Research University of Pennsylvania
1990 – 1991	Bristol Myers Laboratories Buspirone Study, Depression in the Elderly Research University of Pennsylvania
1990 – 1991	Bristol Myers Laboratories Gepirone Study, Depression Research University of Pennsylvania
1990 – 1991	Bristol Myers Laboratories Gepirone Study, Anxiety Research University of Pennsylvania
1991 – 1992	Sandoz Pharmaceutical Corporation Abecarnil and Diazepam in Outpatients with Generalized Anxiety Disorder Principal Investigator

1991 – 1992	Wyeth Ayerst Laboratories Hydrochloride Study, Depression Research University of Pennsylvania
1991 – 1993	Wyeth Ayerst Laboratories Hydrochloride Study, Anxiety Research University of Pennsylvania
1991 – 1993	Bristol Myers Laboratories, Gepirone Extended Release, Depression Study University of Pennsylvania
1992 – 1994	Bristol Myers-Squibb Lab Open Multi-Center Trial of Nefazodone in the Treatment of Elderly Patients with Mood Disorders Principal Investigator
1992 – 1993	Bristol Myers-Squibb Lab Buspar ER Extended Release in the Treatment of Anxiety Principal Investigator
1993 –1994	TAP Pharmaceuticals, Inc. Double-Blind, Fixed-Dose, Multi-Center Study Comparing DN-2327 (4&8 Mg. Daily) to Buspar (25mg/day) and Placebo in Patients with Generalized Anxiety Disorder Principal Investigator
1999	B4Z-MC-LYAO Eli Lilly and Company ADHD – Adult A Phase III, Randomized, Double-Blind Comparison of Placebo and Tomoxetine Hydrochloride in Adult Outpatients with DSM-IV Attention Deficit Hyperactivity Disorder
1999	B4Z-MC-LYAB Eli Lilly and Company ADHD – Pediatric A Phase III, Open-Label Safety and Efficacy Study of Tomoxetine in Outpatients with ADHD Ages 6 to 18 Years
1999	SCT-MD-05 Forest Laboratories Anxiety Flexible-Dose Comparison of the Safety and Efficacy of LU26-054 and Placebo in the Treatment of Generalized Anxiety Disorder
1999	CN101-124 Bristol-Myers Squibb Anxiety – Adolescent A Double-Blind, Multi-Center, Randomized, Parallel-Group, Placebo-Controlled Study Evaluating the Efficacy and Safety of Two Flexible-Dose Ranges of an Anxiolitic Agent in Children and Adolescents (Ages 6 to 17) with Generalized Anxiety Disorder (GAD). The product is currently marketed for use in adults
1999	0600B2-397 Wyeth-Ayerst Research Anxiety – Pediatric A Double-Blind, Placebo-Controlled Study of Venlafaxine ER in Children and Adolescents with Generalized Anxiety Disorder

1999 003-901 Organon, Inc.
Depression – Elderly
A Double-Blind, Multi-Center, Randomized, Paroxetine-Controlled Study of the Efficacy and Safety of Remeron (mirtazapine) in Subjects with Major Depressive Disorder who are at least 65 Years of Age

1999 134-004 Organon, Inc.
Depression – Gepirone
A Double-Blind, Multi-Center Randomized, Placebo-Controlled Efficacy and Safety Study of ORG 33062 ER and Fluoxetine in Subjects who Suffer from Major Depressive Disorder with Atypical Features

1999 CN104-181 Bristol-Myers Squibb
Depression – Nefazadone
A Multi-Center, Double-Blind, Flexible-Dose Safety Trial Comparing Nefazodone IR to Nefazodone ER in the Treatment of Depressed Patients

1999 CIT-MD3-97-03 Forest Laboratories
Depression – Old
A Randomized, Double-Blind, Placebo-Controlled Trial of Citalopram In Depressed Patients at Least 75 Years of Age

1999 CIT-MD-22 Forest Laboratories
Depression – Old – Extension
Celexa Open-Label Treatment of Depression

1999 31-98-220 Otsuka America Pharmaceuticals, Inc.
Schizophrenia – Extension
Open-Label Follow-Up of the Long Term Safety of Aripiprazole Administered Orally in Patients with Stable Psychosis

1999 CN 138-004-047 Bristol-Myers Squibb
Alzheimer's
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Three Fixed Doses of Aripiprazole in the Treatment of Institutionalized Patients with Psychosis Associated with Dementia of the Alzheimer's Type

2000 0600B1-395 Wyeth-Ayerst Research
Depression – Pediatric
An Open-Label, Long Term Safety Study of Venlafaxine ER in Children and Adolescents with Major Depressive Disorder

2000 CIT-MD-20 Forest Laboratories
Depression – Pediatric – Extension
Open-Label Extension Study of the Safety and Efficacy of Citalopram in Children and Adolescents with Depression

2000 003-045 Organon, Inc.
Depression – Pediatric
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Remeron in Outpatient Children and Adolescents with Major Depressive Disorder

2000	M2020/0046	Pharmacia & Upjohn Corporation
	Depression – Reboxetine	
	Reboxetine, Placebo and Paroxetine Comparison in Patients with Major Depressive Disorder	
2000	SCT-MD-01	Forest Laboratories
	Depression – Son of Celexa	
	Fixed-Dose Comparison of the Safety and Efficacy of LU26-054, Citalopram and Placebo in the Treatment of Major Depressive Disorder	
2000	SCT-MD-03	Forest Laboratories
	Depression – Son of Celexa	
	Placebo-Controlled Evaluation of the Safety and Efficacy of LU26-054 in the Prevention of Depression Relapse	
2000	003-900	Organon, Inc.
	Depression – SSRI Failure	
	Multi-Center, Randomized, Double-Blind, Sertaline-Controlled Study of the Efficacy and Safety of Remeron (mirtazapine) in Subjects with Major Depressive Disorder who Failed on SSRI Treatment Due to Lack of Efficacy	
2000	F1D-MC-HGIE	Eli Lilly and Company
	Depression – Treatment	
	Olanzapine Plus Fluoxetine Combination Therapy in Treatment Resistant Depression: A Dose-Ranging Study	
2000	SCT-MD-04	Forest Laboratories
	Panic Disorder	
	Flexible-Dose Comparison of the Safety and Efficacy of LU26-054, Citalopram and Placebo in the Treatment of Panic Disorder	
2000	31-98-213	Otsuka America Pharmaceuticals, Inc.
	Schizophrenia	
	An Open-Label Comparison of the Neurocognitive effects of Aripiprazole to Olanzapine Administered Orally in Patients with Stable Psychosis	
2000	B1Y-MC-HCKN	Eli Lilly and Company
	Depression – Switching	
	Switching Subjects from Citalopram, Paroxetine, or Sertraline to Once-Weekly Modified-Release Fluoxetine Hydrochloride in Maintenance of Response for Depression	
2000	28105	Organon, Inc.
	Major Depressive Disorder	
	A Double-Blind, Randomized, Placebo- and Paroxetine- Controlled, Multi-Center Dose Finding Trial in Outpatients with Moderate to Severe Major Depressive Disorder	
2000	B4Z-MC-LYBB	Eli Lilly and Company
	ADHD – Pediatric – Extension	
	A Phase III, Open-Label Safety and Efficacy Study of Tomoxetine Hydrochloride in Pediatric Outpatients (6 to 18 Years) with ADHD	
2000	29060/701	SmithKline Beecham

Depression – Pediatric
A Randomized, Multi-Center, 8-Week, Double-Blind, Placebo-Controlled, Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder

2000 SCT-MD-11 Forest Laboratories
Depression – Prophylaxis
An Evaluation of the Safety and Efficacy of LU26-054 in the Prevention of Depression Recurrence

2000 CIT-MD-18 Forest Laboratories
Depression – Pediatric
A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Citalopram in Children and Adolescents with Depression

2000 SCT-MD-17 Forest Laboratories
Anxiety – Extension
An Open-Label Extension Study of the Safety and Efficacy of LU26-054 in Patients with Generalized Anxiety Disorder

2000 134-502 Organon, Inc.
Depression – Gepirone – Extension
A Double-Blind, Multi-Center Extension Trial in Subjects who Suffer from Major Depressive Disorder with Atypical Features who Participated in the Placebo and Fluoxetine Study of ORG33062ER – Protocol 134-004

2000 H5Z-MC-LUAH Eli Lilly and Company
Anxiety
R-Fluoxetine vs. Placebo in the Treatment of Generalized Anxiety Disorder

2000 0600B1-402 Wyeth-Ayerst Research
Major Depressive Disorder
A Double-Blind, Placebo-Controlled Comparative Efficacy Study of Venlafaxine ER and Sertraline in Producing Remission in Outpatients with Major Depressive Disorder

2000 B4Z-MC-LYAI Eli Lilly and Company
ADHD – Pediatric – Extension
Long-Term, Open-Label, Safety Study of Tomoxetine HCL in Patients 6 Years and Older

2000 F1D-MC-HGGY Eli Lilly and Company
Bipolar I Depression
Placebo-Controlled Olanzapine Monotherapy in the Treatment of Bipolar I Depression

2000 F1J-MD-HMBH Eli Lilly and Company
Depression – Adult
Duloxetine Once-Daily Dosing Versus Placebo in the Acute Treatment of Major Depression.

2000 GAL-INT-10 Janssen Research Foundation
Alzheimer's Disease
Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled Release Formulation

2000 GAL-INT-11/18 Janssen Research Foundation

MCI
Galantamine in Patients at Risk for the Development of Alzheimer's Disease

2000 0600B4-389 Wyeth-Ayerst Research
Social Anxiety
A Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study for Venlafaxine ER in Adolescent Outpatients with Social Anxiety Disorder

2000 F1D-MC-HGJJ Eli Lilly and Company
Schizophrenia
The Assessment of Sibutramine for the Treatment of Olanzapine-Associated Weight Gain in Patients with Schizophrenia and Related Disorders and Bipolar Disorder

2000 RIS-USA-240 Janssen Research Foundation
Bipolar I
The Efficacy and Safety of Flexible-Dose Ranges of Risperidone vs. Placebo or Divalproex Sodium in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder

2001 MEM-MD-01, 02, 03 Forest Laboratories
Alzheimer's Disease
A Long-Term Study Evaluating the Safety and Tolerability of Four Memantine Dosing Regimens in Patients with Moderate to Severe Dementia of the Alzheimer's Type

2001 0600B5-353 Wyeth-Ayerst Research
Panic
A Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study of Venlafaxine Extended-Release Capsules in Adult Outpatients With Panic Disorder

2001 003-048 Organon , Inc.
MDD
A Multi-Center, Randomized, Double-Blind, Fluoxetine- and Placebo-Controlled Study of the Efficacy and Safety of REMERON Sol Tab (mirtazapine) Orally Disintegrating Tablets in Subject with Major Depressive Disorder

2001 B1Y-MC-HCLD Eli Lilly and Company
MDD
Continuation Treatment with Once-Weekly Modified-Release Fluoxetine HCl

2001 B4Z-MC-LYAR Eli Lilly and Company
ADHD – Adult – Extension
Long-Term, Open-Label Safety Study of Tomoxetine HCl in Adult Outpatients with DSM-IV ADHD

2001 SCT-MD-06 Forest Laboratories
Panic Disorder
Flexible-Dose Comparison of the Safety and Efficacy of Escitalopram and Placebo in the Treatment of Generalized Anxiety Disorder

2001 5077US/0043 Astra-Zeneca
Schizophrenia

A Multi-Center, Double-Blind, Randomized Comparison of the Efficacy and Safety of Quetiapine Fumarate and Risperidone in the Treatment of Patients with Schizophrenia

2001 GAL-INT-26 Janssen Research Foundation
Vascular Dementia
A Randomized 26-Week, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of Galantamine in the Treatment of Dementia Secondary to Cerebrovascular Disease

2001 C-1073-02 Scirex Corporation
MDD
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Safety and Efficacy of C-1073 in Patients with Major Depressive Disorder With Psychotic Features

IM STUDIES

1992 – 1994 Whitehall Laboratories
Dimetane Extend Tabs vs. Terfenadine, Allergic Rhinitis
Principal Investigator

1992 – 1995 Glaxo, Inc.
Oral GR122311X Compared with Ranitidine, Duodenal, and Benign Gastric Ulcer
Principal Investigator

1992 – 1995 Forest Laboratories
Fosfomycin Tromethamine vs. Ciprofloxin, Uncomplicated Urinary Tract Infection
Principal Investigator

1992 – 1993 Upjohn Company
Insomnia Treatment Study Comparing Triazolam and Temazepam
Principal Investigator

1992 - 1994 Pfizer, Inc.
Randomized Parallel Comparative Study of the Clinical Effectiveness of Two Nit Combs after Treatment with a Pyrethrin-Based Pediculicide
Principal Investigator

1992 –1993 Harris Laboratories/SmithKline Beecham
Safety and Efficacy of Miconazole Nitrate 2% Vaginal Cream (SB) Compared with Miconazole Nitrate 2% Vaginal Cream (Monistat 7) and Placebo in the Treatment of Vulvovaginal Candidiasis
Principal Investigator

1992 –1994 Otsuka Pharmaceutical, Inc.
Protocol 106-92-206, Double-Blind Active-Controlled Efficacy Study of OPC-17116 - Inpatients with Acute Bacterial Exacerbations of Chronic Bronchitis
Principal Investigator

1992 –1993 Otsuka Pharmaceutical, Inc.
Protocol 106-92-201, Double-Blind Active-Controlled Efficacy

Study of OPC 17116 - Inpatients with Community Acquired Pneumonia
Principal Investigator

1993 –1994 Forest Lab, Inc.
Fosfomycin Tromethamine vs. Nitrofuantoin Monohydrate/Macrocrystals in Uncomplicated Urinary Tract Infections, MON-US-03
Principal Investigator

1998 –1999 Tap Holdings, Inc.
A Phase III, Randomized, Double-Blind Comparative Safety and Efficacy of Cefditoren Pivoxil and Cefadroxil Monohydrate in the Treatment of Patients with Uncomplicated Skin or Skin Structure infection
Principal Investigator

1998 –1999 TAP Holdings, Inc.
A Randomized Investigator-Blinded Active-Controlled, Parallel-Group Phase III Study Comparative Safety and Efficacy of Cefditoren Pivoxil and Augmentin (Amoxicillin/Clavulanate Potassium) in the treatment of Patients with Acute Bacterial Sinusitis
Principal Investigator

1998 –1999 ViroPharma
A Double-Blind, Randomized, Placebo-Controlled Trial of Pleconaril in the Treatment of Picornavirus Respiratory Tract Disease
Principal Investigator

1998 –1999 Scirex Corporation
A Multi-Center, Double-Blind, Placebo-Controlled Trial for Safety and Efficacy Evaluation of Study Drug in the Treatment of Viral Syndrome
Principal Investigator

1999 99-0-054 Fujisawa Healthcare Research Institute
Atopic Dermatitis
An Open-Label Study To Evaluate The Safety Of Topically Applied Tacrolimus Ointment For The Treatment Of Atopic Dermatitis

1999 GFXA4004 Glaxo SmithKline Pharmaceutical
Bronchitis – Chronic
A Randomized, Double-Blind, Multi-Center Comparison of the Efficacy and Safety of Grepafloxacin (Raxar) 400mg or 600mg once daily and Clarithromycin (Biaxin) 500mg twice daily in the Treatment of Patients with
Acute Bacterial Exacerbations of Treatment of Patients with Acute Bronchitis

1999 ALLHAT National Heart, Lung and Blood Institute
Heart Attack Prevention
Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial Consisting of a Double-Blinded First-Line Anti-Hypertensive Drug with Chlorthalidone, Amlodipine, Linsinopril or Doxazosin and an
Open-Labeled Second- and Third-Line Anti-Hypertensive Drug with Reserpine, Clonidine, Atenolol or Hydralazine along with a Lipid Lowering Component of Pravastatin vs. Usual Care

1999	265805/049	SmithKline Beecham
	Pneumonia 2	
	A Randomized, Double-Blind, Double-Dummy, Multi-Center, Parallel-Group Study to Asses the Efficacy and Safety of SB-265805, 320mg Oral Dose Once a Day for 7 or 14 Days Compared with Trovafloxacin, 200mg Oral Dose Once a Day for 7 or 14 Days in the Treatment of Bacterial Community Acquired Pneumonia	
2000	CV138-056	Bristol Myers Squibb
	Diabetes – Medication	
	A Multi-Center, Randomized, Double-Blind, Parallel-Group Trial Comparing the Safety and Efficacy of Metformin/Glyburide to Pioglitazone as First Line Therapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with Diet and Exercise	
2000	AGEE-2064	Nova Nordisk
	Diabetes – Open-Label	
	Repaglinide vs. Pioglitazone vs. Combination in Type 2 Diabetes Patients: A 24-Week, Randomized, Controlled Multi-Center Trial	
2000	FLTA4038	Glaxo Wellcome
	Asthma	
	A Randomized, Double-Blind, Parallel-Group Comparison Study of Inhaled fluticasone propionate (88mcg BID) versus Montelukst sodium (10 mg QD) Subjects Currently Receiving Beta agonists Alone	
2000	SC-397-5098	Astra-Zeneca
	COPD 1	
	A 3 Month, Multi-Center, Multinational, Double-Blind, Group Comparative Study to Investigate the Effects of AR-C68397AA via pMDI Compared with Placebo in Adult Patients with Chronic Obstructive Pulmonary Disease COPD	
2000	SC-397-5163	Astra-Zeneca
	COPD 2	
	A Multi-Center, Multi-National Double-Blind, Double-Dummy, Placebo-Controlled, Group Comparative Study to Investigate the Long Term Safety of ARC68397AA via pMDI Compared with Salmeterol in Adult Patients with Chronic Obstructive Pulmonary Disease	
2000	WV15799	Hoffman LaRoche
	Flu – Contacts	
	A Double-Blind, Randomized, Placebo-Controlled study of RO64-0796 (also known as GS4104) Used for the Prevention of Clinical Influenza Post Exposure in Families	
2000	NAI130012	Glaxo Wellcome
	Flu – Elderly Relenza	
	A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicentre Study to Investigate the Efficacy and Safety of Inhaled Zanamivir 10 mg Administered Twice Daily for Five Days in the Treatment of Symptomatic Influenza A and B Viral Infections in Subjects Ages 65 years +	
2000	WV15978	Hoffman LaRoche
	Flu – Elderly Tamiflu	
	A Double-Blind, Stratified, Randomized Placebo-Controlled Study of	

Ro64-0796 in the Treatment of Influenza Infection in Elderly Adults

2000 NAI40012 Glaxo Wellcome
Flu – Relenza Device
An Open-Label, Multi-Center Study of the Patient Instructional Leaflet for Relenza Diskhaler

2000 S1673001 Solvay Pharmaceuticals
Hormone Replacement
A Double-Blind Investigation of the Efficacy and Safety of Continuous Transdermal 1% 17 b-Estradiol in Combination with Levonorgestrel Compared with Continuous Transdermal 1% 17 b-Estradiol Alone for the Prevention of Endometrial Hyperplasia in Postmenopausal Women

2000 S3B30011 Glaxo Wellcome
IBS 1
A Twelve Week Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Tolerability of Hydrochloride 1mg Twice Daily for Control of Bowel Urgency in Females with Diarrhea-predominant Irritable Bowel Syndrome

2000 S3B30020 Glaxo Wellcome
IBS 2
A 24 Week, Randomized, Open-Label Study of Health Care Resource Used Quality of Life and Productivity with Alosetron 1 mg Twice Daily Versus Traditional Therapy in Females with Non-constipated Irritable Bowel Syndrome

2000 P00691 Schering-Plough
Lipids
A Phase III Double-Blind Efficacy and Safety Study of SCH 58235 (10mg) in Addition to Pravastatin Compared to Placebo in Subjects with Primary Hypercholesterolemia

2000 ZD4522IL/0028 Zeneca Pharmaceuticals
Lipids 1
A Randomized Double-Blind Multi-Center Trial to Compare the Short-Term and Long-Term Efficacy and Safety of ZD4522, Simvastatin and Pravastatin in the Treatment of Subjects with Hypercholesterolemia

2000 ZD4522IL/0033 Zeneca Pharmaceuticals
Lipids 2
A 6-week Randomized Double-blind Multi-Center Trial to Evaluate the Safety and Efficacy of ZD4522 (5,10,20,40, and 80 mg) and Atorvastatin (10,20,40 and 80Mg) Across Their Respective Dose Ranges in the Treatment of Subjects With Hypercholesterolemia

2000 ZD4522IL/0034 Zeneca Pharmaceuticals
Lipids 2A
An Open-Label, Multinational, Multi-Center, Extension Trial to Assess the Long-term Safety and Efficacy of ZD4522 in Subjects in the ZD4522 Clinical Trial Program

2000 ZD4522IL/0035 Zeneca Pharmaceuticals
Lipids 3
A 12 Week Multi-Center Randomized Double-blind Placebo-controlled Trial to Evaluate the Efficacy and Safety of ZD4522 (5,10,20,40 and 80 mg) in the Treatment of Subjects with Hypertriglyceridemia

2000 MT100-304 Pozen
Migraine
A Single Dose, Double-Blind, Safety and Efficacy Study of MT 100, Metoclopramide Hydrochloride and Naproxen Sodium in Subjects with Acute Migraine Attacks

2000 N91-99-02-053 Searle
OA – Knee Valdecoxib
Clinical Protocol for a Multi-Center, Double-Blind, Placebo-Controlled, Randomized Comparison Study of the Efficacy and Upper Gastrointestinal Safety of Valdecoxib 5 mg, 10 mg and 20 mg qd and Naproxen 500 mg Bid in Treating the Signs and Symptoms of Osteoarthritis of the Knee

2000 22-163, 302R1 Roberts Laboratories
OA – Ultram
Double-Blind, Placebo-Controlled, Parallel-Group Comparison Of The Efficacy and Safety of Propiram, Tramadol (Ultram), and Placebo With an Open-Label Extension of Pain Associated With Osteoarthritis of the Knee and/or Hip

2000 MK-0663-018 Merck Research Laboratories
OA 1
A 1 year Randomized, Placebo and Active-Comparator-Controlled, Parallel-Group, Double-Blind Two Part Study to Assess the Safety and Efficacy of MK-0663 versus Naproxen in Patients with Osteoarthritis

2000 MK-0663-019 Merck Research Laboratories
OA 2
A 1-Year Randomized, Placebo and Active-Comparator-Controlled, Parallel-Group , Double-Blind, Two Part Study to Access the Safety and Efficacy of MK-0663 Versus Naproxen in Patients with Osteoarthritis

2000 ALX1-11-93001 NPS-Allelix
Osteoporosis
An 18-Month Double-Blind, Placebo-Controlled, Phase III, Trial with a 12-Month Interim Analysis of the Effect of Recombinant Human Parathyroid Hormone (ALX1-11) on Fracture Incidence in Women with Post-Menopausal Osteoporosis

2000 843-023 Viropharma Inc.
Otitis Media
A Double-Blind, Randomized, Placebo-Controlled Evaluation of Pleconaril in the Prevention of Otitis Media in Children with a History of Otitis Media Following Picornavirus Respiratory Tract Infection

2000 HMR3647 Hoechst Marion Roussel
Pneumonia
A Double-Blind, Multi-Center, Randomized, Active-Controlled, Two-Arm Parallel -Group Comparative Study of the Efficacy and Safety of Oral HMR3647 (800mg once daily) Versus Oral Clarithromycin (500mg twice daily) in the Treatment of Community Acquired Pneumonia in Adults

2000 C99-712 Biogen
Psoriasis
A Randomized, Double-Blind, Placebo-Controlled, Dose Comparison Study to Evaluate the Efficacy and Safety of Intramuscular Administration of LFA3TIP (LFA-3/IgG1 Human Fusion Protein) in Subjects with Chronic Plaque Psoriasis

2000 MK-0663-024 Merck Research Laboratories
RA
An Active-Comparator and Placebo-Controlled, Parallel-Group, Double-Blind, 52 - Week Study to Assess the Safety and Efficacy of Mk-0663 in Rheumatoid Arthritis Patients

2000 MK-0966-088 Merck Research Laboratories
RA – GI Outcome
A Double-Blind, Randomized, Stratified, Parallel-Group to Assess the Incidence of PUB's During Chronic Treatment with MK-0966 or Naproxen in Patients with Rheumatoid Arthritis: U.S. Cohort

2000 LAM IV-307 Shire Laboratories
Renal Failure – Chronic
Dose Titration, Open-Label Study to Evaluate Long-Term Safety and Efficacy of Study Drug in Chronic Renal Failure Patients Receiving Hemodialysis

2000 CEF-97-007 Tap Holdings
Sinusitis
Comparative Safety and Efficacy of Cefditoren Pivoxil and Augmentin (Amoxicillin/Clavulanate Potassium) in the Treatment of Patients with Acute Bacterial Sinusitis

2000 M1260/0065 Pharmacia & Upjohn Corporation
Skin Infection – Pediatric
Linezolid vs. Cefadroxil in the Treatment of Skin and Skin Structure Infections in Children

2000 CEF-97-011 Tap Holdings
Skin Infection
Comparative Safety and Efficacy of Cefitoren Pivoxil and Cefadroxil Monohydrate in the Treatment of Patients with Uncomplicated Skin or Skin Structure Infection

2000 843-032 Viropharma Inc.
Viral/Cold Study
A Double-Blind, Randomized, Placebo-Controlled Trial Of A Tablet Formulation of Pleconaril in the Treatment of Viral Respiratory Infection

2000 HMP-3005 Purdue
OA – Pain
A Double-Blind, Randomized, Parallel-Arm, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Hydromorphone Hydrochloride Extended Release 12mg Capsules Compared to Placebo in Patients with Osteoarthritis who have Moderate to Severe Pain

2000 CV138-056 Bristol-Myers Squibb
Diabetes – Medication
A Multi-Center, Randomized, Double-Blind, Parallel-Group Trial Comparing the Safety and Efficacy of Metformin/Glyburide to Pioglitazone as First Line Therapy in Patients with Type 2 Diabetes Mellitus who have Inadequate Glycemic Control with Diet and Exercise

2000	WV16193	Roche Global Development
	Flu – Post Exposure Prevention A Randomized, Controlled Study of Tamiflu Used for the Prevention of Clinical Influenza Post Exposure in Families	
2000	KD98-0601	Purdue
	Diabetes – Type II A Randomized, Double-Blind, Exploratory, Comparison of Titrated Doses of V20001 and Glyburide in Type 2 Diabetic Patients	

PROFESSIONAL AFFILIATIONS AND SOCIETIES:

2001 – 2002	Scientific Advisory Group for Organon, Inc. for The New Treatment Option for the Mature Depressed Patient
2000 – 2001	Advisory Board for Eli Lilly on Tomoxetine for ADD and ADHD Pediatrics, Adolescence, and Adults
1999 – Present	Forest Laboratories Advisory Board for Geriatric Study
1999 – Present	Member, Lilly Advisory Board on ADHD
1997 – 1998	California Board for Devereux California
1994 – 1997	Fellow, American Academy of Disability Evaluative Physicians
1993 – 1998	Qualified Medical Evaluator by Department of Industrial Relations Industrial Medical Council
1991 – 1997	Appointed Instructor of Department of Psychiatry, University of Pennsylvania
1991	Appointed Member of San Diego Advisory Committee for State Insurance Commissioner, John Garamendi
1989 – 1997	Alvarado Hospital Medical Center, San Diego, California Supervisor of Surgery Committee
1987 – 1996	College of Osteopathic Medicine Faculty Council Member
1986 – 1987	Alvarado Hospital Medical Center, San Diego, California Family Practice Supervisory Committee Supervisor of Orthopedic Committee
1986 – 1987	Alvarado Hospital Medical Center, San Diego, California Family Practice Supervisory Committee Supervisor of Orthopedic Committee
1986 – 1987	The Prudential Insurance Company, La Jolla, California Assistant Medical Director
1986 – 1987	Alvarado Medical Center Utilization Review Committee
1986 – 1987	Alvarado Medical Center, Family Practice Sub-Supervisory Committee (1987-1988)

1986 – 1987	Alvarado Medical Center Orthopedics Committee (also appointed 1987-88)
1985 – 1987	Associate Medical Director Pru-Care Plus, San Diego
1984 – 1995	Philadelphia College of Osteopathic Medicine Faculty Council Member
1984 – 1995	Pacific College of Osteopathic Medicine Faculty Council Member
1984	American Osteopathic Association of Osteopathic Physicians and Surgeons of California
1983	American Heart Association
1983	New Jersey Association of Osteopathic Physicians and Surgeons
1982	Osteopathic Physicians and Surgeons of New Jersey
1979	American College of General Practitioners in Osteopathic Medicine and Surgery
1979	Philadelphia College of Osteopathic Medicine, Alumni Association
1979	Lambda Omicron Gamma National Osteopathic Medical Fraternity
1979	Pennsylvania Osteopathic Association

5/22/02

Howard Hassman, D.O. 5/22/02

THE FACE OF THIS DOCUMENT HAS A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES

State Of New Jersey
Department Of Law and Public Safety
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
BOARD OF MEDICAL EXAMINERS

HAS REGISTERED

HOWARD A HASSMAN
130 WHITE HORSE PIKE
CLEMENTON NJ 08021

FOR PRACTICE IN NEW JERSEY AS A(N): PHYSICIAN - DO

07/01/01 TO 06/30/03
VALID

MB 45305
LICENSE/REGISTRATION/CERTIFICATION #

SIGNATURE OF REGISTRANT

DIRECTOR

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BH6062208	10-31-2004	$210.00
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3,3N,4,5	PRACTITIONER	10-02-2001

HASSMAN, HOWARD ADO
130 WHITE HORSE PIKE
CLEMENTON, NJ 08021

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

CURRICULUM VITAE

MICHAEL T. LEVY, M.D.

7/12/03

EDUCATION

Queens College, B.A., Magna Cum Laude, 1965

Washington University, St. Louis, M.D., 1969

Fellow: The Hampstead Clinic, London, with Anna Freud, 1969

Albert Einstein College of Medicine, Medical Internship, 1969-1970

Albert Einstein College of Medicine, Resident in Psychiatry, 1970-1972

Albert Einstein College of Medicine, Chief Resident, 1972-1973

New York Psychoanalytic Institute, 1973-1983. Graduate Psychoanalyst, 1983.

HONORS

Phi Beta Kappa, 1965

Alpha Omega Alpha, 1969

SPECIALTY CERTIFICATE

American Board of Psychiatry & Neurology, Diplomate in Psychiatry, 1976

American Board of Psychiatry & Neurology, Added Qualifications in Geriatric Psychiatry, 1992-2002

New York State License #: 106805-1

PROFESSIONAL POSITIONS

Albert Einstein College of Medicine
Assistant Director Outpatient Clinic - Clinical Instructor, 1973-74

Mt. Sinai
Clinical Instructor, 1974-1976

Gracie Square Hospital
Director, Inpatient Unit, 1975-1978

Coordinated care on inpatient psychiatric unit, developing an extensive network of community outreach consultation services. Linked hospital services to Protective Services for Adults, Jewish Association for Services tot he Aged, New York City Department for the Aging, et. al.

Geriatric Consultation Center, 1973 to date

Created the first private comprehensive psychiatric group practice in New York dedicated to the assessment and treatment of geriatric patients with psychiatric illness. Developed an extensive network of consultation services to community-based agencies throughout the five boroughs providing home visits, education, outpatient assessment and treatment, inpatient care. Trained social workers and mental health aides in the essentials of psychiatric assessment and care through regular lecture series and individual supervision.

PROFESSIONAL POSITIONS (continued)

Private Practice, 1973 to date
General Psychiatry, Psychoanalysis, Psychopharmacology and Geriatric Psychiatry

Long Island College Hospital
Director, Inpatient Psychiatry & Coordinator of Geriatric Psychiatry, 1985-1989
Developed the Geriatric Psychiatry service consisting of an inpatient unit, consultation and liaison, community and nursing home consultation, teaching, and research. Created a unique system of psychiatric consultation in the patient's home working with teams of social workers from the community throughout New York City.

Eger Health Care Center, Staten Island, New York
Director of Psychiatry , 1989 to date

Staten Island University Hospital 450 Seaview Avenue Staten Island, NY 10305
Director of Gerontology & Associate Director, Department of Psychiatry, 1989-1996
Developed and coordinated a fully comprehensive geriatric psychiatry service including a 35 bed inpatient unit, outpatient services, memory disorder clinic, nursing home consultation, community consultation, teaching and research.

Staten Island University Hospital
Chairman, Department of Behavioral Sciences, 1997 to date
450 Seaview Avenue Staten Island, New York 10305

Director, Behavioral Medical Research of Staten Island, PC
1361 Hylan Blvd Staten Island, New York 10305

CONSULTANT IN GERIATRIC PSYCHIATRY TO:

Jewish Association for Services to the Aged, 1980 to date

New York City Department for the aging, 1984 to date

Thomas Jefferson Home for Adults, 1984 to date	650 East 104th St	Brooklyn, NY 11236
Verrazano Nursing Home, 1990 to date	100 Castleton Ave	Staten Island, NY 10310
New Broadview Manor Home for Adults, 1990 to date	70 Father Capadanno Blvd	SI, NY 10305
Lakeside Manor Home for Adults, 1995 to date	797 Brighton Ave	Staten Island, NY 10301
Hylan Manor Home for Adults , 2000 to date	3565 Hylan Blvd	Staten Island, NY 10308
Mermaid Manor Home for Adults	3602 Mermaid Ave	Brooklyn, NY 11224
Golden Gate Health Care Center	191 Bradley Ave.	Staten Island, NY 10314
Staten Island Care	200 Lafayette Ave.	Staten Island, NY 10301

HOSPITAL APPOINTMENTS

Staten Island University Hospital, 1989 to date

777 Seaview Avenue
Staten Island, NY 10305

375 Seguine Avenue
Staten Island, NY 10309

450 Seaview Avenue
Staten Island, NY 10305

392 Seguine Avenue
Staten Island, NY 10309

LECTURE SERIES

- How to be Home bound Without Being Shut In: Improving the Quality of Life for Frail Elders: Lecturer, March 1981.
- Growth in the 80's Enhancing Mental Health in Old Age: Panelist, October 1981.
- The Physiology of the Aging Process. New York State Office of Mental Health, March 1982.

LECTURE SERIES (continued)

- Organic Brain Syndrome, Brooklyn Community Senior Service Network, June 1984.
- Medical/Legal Issues in Aging, Mayor's Conference on Alzheimer's Disease, November 1984.
- Geriatric Medicine. Lutheran Medical Center, November 1985.
- Coping with An Aging Relative. Mental Illness in Later Years: Myths, Realities and Warning Signs, February, 1988.
- The Family Physician and Medication. Alzheimer's Association of Staten Island, March 1990.
- Mothering Mom & Dad. A special Seminar for the "Sandwich Generation". April 1990.
- Update on New Regulations Impacting on Physician Services in Long Term Care Facilities. The Southern New York Residential Health Care Facilities Association. June 1990.
- Come of Age: Coping with Change. Staten Island University Hospital. April 1991.
- Elder Abuse: Working with the Victim and the Abuser. Catholic Charities. April 1991.
- Mayor's Conference on Alzheimer's Disease, Panel Moderator. Sexuality and Aging, 1993.
- Medicine in China: East Meets West in Clinical Practice. Staten Island University Hospital, South, 1993.
- Review of SSRIs: Psychopharmacology, Efficacy, and Side Effect Profile. Staten Island University Hospital, South. Grand Rounds, 1994.
- Olanzapine (Zyprexa): Atypical Antipsychotics; New Directions in Psychopharmacology. Staten Island University Hospital, South. Grand Rounds, 1995.
- Sleep Problems in the Elderly. Staten Island University Hospital, South. Grand Rounds, 1996.
- New Treatments in Schizophrenia: A Review of Atypical Antipsychotics. Staten Island University Hospital, South, 1997.

RESEARCH

- Clinical Investigator: Olanzapine vs. Placebo in the Treatment of Patients with Psychosis Associated with Depression, Eli Lilly, 1994.

- Clinical Investigator: Olanzapine vs. Risperdal in the Treatment of Schizophrenia and Other Psychiatric Disorders, Eli Lilly, 1995.

- Clinical Investigator: Fluoxtine vs. Sertraline vs. Paroxetine in Major Depression, Eli Lilly, 1996 - 1997.

- Clinical Investigator: Seroquel (Quetiapine Fumarate): Comparison with Haldol and Placebo in Nursing Home Patients, Eli Lilly, 1997 - 1998.

- Clinical Investigator: Olanzapine vs. Risperidone and Placebo in the Treatment of Psychosis and Associated Behavioral Disturbances in Patients with Dementia, Eli Lilly, 1999.

- Clinical Investigator: A Double Blind Comparison of the Efficacy and Safety of Short Acting Intramuscular Olanzapine, Lorazepam, and Placebo in Treating Agitation in Patients with Dementia of the Alzheimer's Type, Vascular Dementia and Mixed Dementia, Eli Lilly, 1999.

- Clinical Investigator: Safety and Efficacy of Olanzapine on Cognitive Symptoms in Subjects with Mild to Moderate Alzheimer's Disease without Psychosis, Eli Lilly, 1999.

- Clinical Investigator: A Double Blind Multi - Center Study Comparing the Safety and Efficacy of Ziprasidone to Olanzapine in Patients with Schizophrenia or Schizoaffective Disorder Needing In - Patient Care, Pfizer. Inc., 1999.

- Clinical Investigator: Olanzapine Plus Fluoxetine Combination Therapy in Treatment-Resistant Depression: A Dose Ranging Study, Eli Lilly, 2000.

- Clinical Investigator: Reboxetine, Placebo and Paroxetine Comparison in Patients with Major Depressive Disorder, Pharmacia & Upjohn, 2000.

- Clinical Investigator: A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of Divalproex Sodium Therapy for Agitation in Nursing Home Residents with Dementia, Alzheimer's Disease Cooperative Study, 2000.

- Clinical Investigator: A Multicenter Randomized Double-Blind Study of Flexible Doses of Aripiprazole Versus Perphenazine in the Treatment of Patients with Treatment-Resistant Schizophrenia, Bristol-Myers Squibb Co., 2000.

- Clinical Investigator: Aripiprazole Study of Psychosis Associated with Dementia of the Alzheimer's Type of Nursing Home Residents, Bristol-Myers Squibb Co., 2000.

- Clinical Investigator: A Controlled Trial of the Efficacy of Rapid Initial Dose Escalation of Olanzapine to Treat Acute Behavioral Agitation in Schizophrenia and Bipolar 1 Disorder, Eli Lilly, 2000.

- Clinical Investigator: A Comparative Effectiveness of Antipsychotic Medications in Patients with Schizophrenia,CATIE,2001

- Clinical Investigator: A Comparative Effectiveness of Antipsychotic Medications in Patients with Alzheimer's Disease, CATIE, 2001

- Clinical Investigator: A Randomized, Double-Blind, Placebo-controlled and Open-Label twelve-month study of the safety of (S)-Zopliclone in Adult Subjects with Insomnia, Sepracor, 2001

- Clinical Investigator: A Randomized, Double-Blind, Placebo-controlled and Open-Label twelve-month study of (S)-Zopliclone in Geriatric Subjects with Insomnia, Sepracor, 2001.

RESEARCH (continued)

- A Multicenter, Double-Blind, Randomized, Placebo Controlled, Crossover Study to Evaluate the Efficacy of a Monophasic Oral Contraceptive Preparation, Containing Drospirenone 3 mg/Ethinyl Estradiol 20 g (as Beta-Cyclodextrin Clathrate), in the treatment of Premenstrual Dysphoric Disorder (PMDD), Berlex Laboratories, 2002.

- A Multicenter, Randomized, Double-Blind, Study of Aripiprazole Versus Placebo in the Treatment Acutely Manic Patients with Bipolar Disorder. Bristol Myers Squibb, 2002.

- Randomized, Double-Blind, Dose-Ranging Study of Intramuscular Aripiprazole in the Treatment of Acute Agitation in Patients with a Diagnosis of Schizophrenia, Schizoaffective, or Schizophreniform Disorder. Bristol Myers Squibb, 2002.

- Switching from Oral Neuroleptics to Risperidone Depot Microspheres, Janssen Pharmaceuticals, 2002.

- A Double-Blind, Placebo-Controlled Multicenter Study of the Long-Term Efficacy of MK-0869 in the Maintenance of Antidepressant Effect in Geriatric Outpatients with Major Depressive Disorder. Merck Laboratories, 2002.

- Clinical Investigator: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of NBI-34060 in Adult Patients with Primary Insomnia, Neurocrine Biosciences, Inc., 2002.

- Clinical Investigator: A Double-Blind, Placebo-Controlled, Multicenter Study of the Long-Term Efficacy of MK-0869 in the Maintenance of Antidepressant Effect in Patients with Major Depressive Disorder, Merck Laboratories, 2002.

- Clinical Investigator: Forced Dose Titration, Double-Blind Treatment with Duloxetine Hydrochloride Once Daily Dosing for Evaluation of Safety in Major Depression, Lilly, 2002.

- Clinical Investigator: The Effect of Ortho Tri-Cyclen on Bone Mineral Density in Pediatric Subjects with Anorexia Nervosa: A Double-Blind, Placebo-Controlled Study, Ortho-McNeil Pharmaceutical, Inc., 2002.

PROFESSIONAL ASSOCIATIONS

American Psychiatric Association, 1993

American Association for Geriatric Psychiatry, 1982

The New York Psychoanalytic Society, 1985 - 1992

PUBLICATIONS

"Dynamics of Suicide in Black and White Populations", Archives of General Psychiatry, 1974.

"Depression, Paranoia and Senility in Problems of the Elderly", Health Care News, Vol. 3, 1980.

"What Can You Tell About People From The Way They Dress", Bottom Line, Vol. 2. No. 20, 1981.

"Understanding Aging", Bottom Line, Vol. 5, No. 19, 1984.

"Depression, Myths and Realities", Bottom Line, Vol. 5, No. 19, 1984.

"Psychiatric Assessment of Elderly Patients in the Home: A Survey of 176 Cases", Journal of the American Geriatric Society, 1985.

BOOKS

Parenting Mom & Dad, A Guide for the Grown - Up Children of Aging Parents. N.Y. Prentice - Hall, 1991.

Parenting Mom & Dad, Audiotape, 1992.

Wenn Elfern Alter Werden Der Unfassende Ratgeher Fur Erwadhsene Kinder, Bonn, Bastei Lubee, 1991.
(German Edition)

CUT OFF THIS STRIP

556

The University of the State of New York

THIS IS TO CERTIFY THAT QUALIFICATIONS FOR PROFESSIONAL PRACTICE IN NEW YORK STATE HAVING BEEN APPROVED

THE STATE EDUCATION DEPARTMENT

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LEVY MICHAEL T
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320 CENTRAL PARK WEST
NEW YORK NY 10025-0000

FOR PRACTICE IN NEW YORK STATE AS A (N)

PHYSICIAN

12/31/04
REGISTRATION PERIOD ENDS

106805-1
LICENSE/CERTIFICATE NO.

SIGNATURE OF REGISTRANT

COMMISSIONER OF EDUCATION

REGISTRATION CERTIFICATE --- NOT A LICENSE

ROBERT A. RIESENBERG, MD
CURRICULUM VITAE

DATE OF BIRTH: August 16, 1949

BIRTHPLACE: Memphis, Tennessee

MARITAL STATUS: Married with three children

SOCIAL SECURITY NUMBER: 412-74-5402

CITIZENSHIP: U.S.A.

EDUCATION
*Memphis State University (Memphis, TN) BS (Zoology, Psychology) 1972
*University of Tennessee (Memphis, TN) MD 1975

HOSPITAL AND CLINICAL APPOINTMENTS

Resident in Psychiatry, Washington University School of Medicine (St Louis, MO)
Department of Psychiatry (Barnes Hospital) 1975-1978

Veterans' Administration Hospital (Atlanta, GA) 1978-1979

Consultant in Geriatric Psychiatry, North Dekalb Mental Health Clinic
(Atlanta, GA) 1979-1981

Secretary of the Department of Psychiatry, Dekalb General Hospital (Decatur, GA) 1981-1982

Vice President of the Department of Psychiatry, Dekalb Medical Center
(Decatur, GA) 1994-1996

**Private Practice-Psychiatry, BioBehavioral Associates-811 Juniper St. NE, Atlanta, GA 30308
1979-Present**

**President, Atlanta Center for Medical Research, 811 Juniper St NE, Atlanta, GA 30308
1982-Present**

Designed Behavioral Medicine Unit, Decatur Hospital (Decatur, GA)
Served as Medical Director, 1981-1982

Medical Director
Atlanta Center for Medical Research (Atlanta, GA) 1982-Present
BioBehavioral Associates, P.C. (Atlanta, GA) 1979-Present
T.H.E. Sexual Impotency Center (Decatur, GA) 1986-1996
Weight Control Center (Decatur, GA) 1986-Present
Medical-Psychiatry Unit, Dekalb Medical Center (Decatur, GA) 1992-1993
Central Home Health Care (Atlanta, GA) 1994-1995

09-11-02

ACADEMIC AND STAFF APPOINTMENTS

IRB Advisor/Board member, DeKalb Medical Center IRB, 2701 North Decatur Rd., Decatur, GA 30033
1995 - 2000

Staff Psychiatrist, Full Privileges, Dekalb Medical Center 2701 North Decatur Road, Decatur, GA 30033; 1979-2000

Clinical Assistant Professor of Psychiatry, Emory University
School of Medicine (Atlanta, GA), 1978-1979

Partial Privileges, Decatur Hospital (Decatur, GA) 1994-Present

Partial Privileges, Northside Hospital (Atlanta, GA) 1994-Present

CERTIFICATION

Tennessee Board of Medical Examiners, 1974

FLEX, 1974

LICENSURE

9398 (State of Tennessee)

19589 (State of Georgia)

DEA Number - AR 8246476

PROFESSIONAL MEMBERSHIP

American Psychiatric Association

Georgia Psychiatric Physicians Association

American Medical Association

Dekalb Medical Society

American Academy of Clinical Psychiatrists

Associates of Clinical Pharmacology

Drug Information Association

American Federation for Aging Research

American Geriatric Society

Southern Association for Geriatric Medicine

American Society on Aging

CLINICAL TRIAL EXPERIENCE

Residency - participation in all phases of tricyclic antidepressant and development studies

CIBA-GEIGY 07
Principal Investigator
Phase III of tricyclic short-term study

CIBA-GEIGY 112
Principal Investigator
Phase III of tricyclic long-term study

LILLY 79
Principal Investigator
Phase III of Serotonin re-uptake inhibitor short-term study

BRISTOL-MEYERS 030A2-0004-1982
Principal Investigator
Phase II of second generation antidepressant short-term study

MCNEIL
Principal Investigator
Phase II antidepressant short-term study

MCNEIL
Principal Investigator
Phase II antidepressant long-term study

MCNEIL
Principal Investigator
Phase II antidepressant long-term study

BURROUGHS-WELLCOME
Principal Investigator
Long-term safety study

MCNEIL
Principal Investigator
Phase III antidepressant long-term study

BOOTS
Principal Investigator
Long-term study

WYETH-AYERST
Principal Investigator
Generalized Anxiety Disorder outpatient study

CIBA-GEIGY
Principal Investigator
Obsessive Compulsive Disorder study

BOOTS
Principal Investigator

CLINICAL TRIAL EXPERIENCE

Phase III study

PFIZER
Principal Investigator
Depression/Bipolar inpatient study

PFIZER
Principal Investigator
Generalized Anxiety Disorder outpatient study

PFIZER
Principal Investigator
Panic Disorder outpatient study

MCNEIL
Principal Investigator
Phase III antidepressant study

WYETH-AYERST
Principal Investigator
Phase III long-term antidepressant study

BOOTS
Principal Investigator
Phase III long-term antidepressant study

ICI
Principal Investigator
Phase II antidepressant study

MERRELL DOW
Principal Investigator
Phase II Single-site antidepressant study

PFIZER
Principal Investigator
Outpatient antidepressant study

PFIZER
Principal Investigator
Outpatient antidepressant study

GLAXO
Principal Investigator
Generalized Anxiety Disorder outpatient study

PFIZER
Principal Investigator
Open-Label outpatient depression study

LOREX
Principal Investigator

CLINICAL TRIAL EXPERIENCE

Generalized Anxiety Disorder outpatient study

PFIZER
Principal Investigator
Geriatric Antidepressant outpatient study

UPJOHN
Principal Investigator
Geriatric Panic outpatient study

HOECHST-ROUSSEL
Principal Investigator
Dementia [AAMI] outpatient study

PFIZER
Principal Investigator
Panic outpatient study

PFIZER
Principal Investigator
Obsessive-Compulsive Disorder study

DuPONT
Principal Investigator
Alzheimer's outpatient study

HOECHST-ROUSSEL
Principal Investigator
Alzheimer's outpatient study

WYETH-AYERST
Principal Investigator
Antidepressant outpatient study

TAP ABBOTT
Principal Investigator
Generalized Anxiety Disorder outpatient study

SANDOZ
Principal Investigator
Generalized Anxiety Disorder outpatient study

PFIZER
Principal Investigator
Child & Adolescent Obsessive-Compulsive Disorder study

LILLY
Principal Investigator
Phase I-B Generalized Anxiety Disorder outpatient study

ICI
Principal Investigator

CLINICAL TRIAL EXPERIENCE
Schizophrenia inpatient study

PFIZER
Principal Investigator
Adult Obsessive-Compulsive Disorder study

UPJOHN
Principal Investigator
Generalized Anxiety Disorder outpatient study

CAMBRIDGE NEUROSCIENCE
Principal Investigator
Electroconvulsive Therapy inpatient study

ORGANON
Principal Investigator
Antidepressant outpatient study

UPJOHN
Principal Investigator
Panic outpatient study

MILES
Principal Investigator
Depression open-label outpatient study

BURROUGHS WELLCOME
Principal Investigator
Depression open-label outpatient study

PFIZER
Principal Investigator
Generalized Anxiety Disorder outpatient study

PFIZER
Principal Investigator
Depression outpatient study

LILLY
Principal Investigator
Schizophrenic outpatient study

ZENECA
Principal Investigator
Schizophrenia outpatient study

MILES
Principal Investigator
Alzheimer's outpatient study

SMITHKLINE BEECHAM
Principal Investigator
Panic outpatient study

CLINICAL TRIAL EXPERIENCE

LILLY
Principal Investigator
Depression open-label outpatient study

PFIZER
Principal Investigator
Alzheimer's outpatient study

ABBOTT
Sub-Investigator
Schizophrenic inpatient study

ABBOTT
Sub-Investigator
Schizophrenia open-label outpatient study

WYETH-AYERST
Principal Investigator
Antidepressant outpatient study

WYETH-AYERST
Principal Investigator
Generalized Anxiety Disorder outpatient study

PFIZER 108 and 108E
Principal Investigator
Schizophrenia double-blind outpatient study

MILES
Principal Investigator
Depression outpatient study

BRISTOL-MYERS SQUIBB
Sub-Investigator
Depression open-label outpatient study

MILES
Principal Investigator
Phase III double-blind drug Alzheimer's outpatient study

WYETH -AYERST 341, 335, 208, 211
Principal Investigator
Depression outpatient study

SOLVAY
Principal Investigator
Phase II double-blind drug Generalized Anxiety Disorder outpatient study

BAYER
Principal Investigator

CLINICAL TRIAL EXPERIENCE
Depression outpatient study

DUPONT MERCK
Principal Investigator
Outpatient alcohol dependence study

JANSSEN
Principal Investigator
Inpatient/outpatient Schizophrenia study

JANSSEN
Principal Investigator
Inpatient Schizophrenia study

JANSSEN
Sub-Investigator
Inpatient stroke study

JAPAN TOBACCO
Principal Investigator
Phase II double-blind Inpatient/Outpatient Alzheimer's study

SMITHKLINE
Principal Investigator
Phase III double-blind Outpatient Alzheimer's study

WYETH-AYERST 600B-370-US
Principal Investigator
Outpatient Depression study

WYETH-AYERST 600B-214-US
Principal Investigator
Outpatient Anxiety study

SMITHKLINE 497
Principal Investigator
Outpatient Panic study

SMITHKLINE 449
Principal Investigator
Outpatient Depression study

LILLY B1Y-MC-HZAA
Principal Investigator
Outpatient Depression study

PFIZER 128-121
Principal Investigator
Inpatient 7 day Schizophrenia study

JANSSEN RIS USA 069
Principal Investigator

CLINICAL TRIAL EXPERIENCE
Inpatient Schizophrenia study

WYETH-AYERST 95-016-MA
Principal Investigator
Inpatient Depression study

WYETH-AYERST 95-015-MA
Principal Investigator
Outpatient Geriatric Depression study

PROTODIGM LTD. PDL-1000P
Principal Investigator
Outpatient double-blind Alzheimer's study

PROTODIGM LTD. PDL-1015P
Principal Investigator
Outpatient Open-Label extension Alzheimer's study

PFIZER 128-125
Principal Investigator
Inpatient 24 hour acute psychosis study

PFIZER 128-127E
Principal Investigator
Outpatient psychosis study

GLAXO WELLCOME AK1A4001
Principal Investigator
Outpatient Sexual Functioning in Major Depression study

HOECHST MARION ROUSSEL, INC. 0015
Principal Investigator
Phase IIa Inpatient/outpatient double-blind Schizophrenia study

HOECHST MARION ROUSSEL, INC. 0018
Principal Investigator
Phase IIa Inpatient/outpatient open-label extension Schizophrenia study

EAISI E2020-A001-313
Sub-Investigator
Phase IV Outpatient Alzheimer's study

ZENECA 311CIL/0071
Principal Investigator
Phase II I Outpatient migraine study

LILLY F1D-MC-HGFU
Principal Investigator
Outpatient Bipolar disorder double-blind study

GLAXO WELLCOME

CLINICAL TRIAL EXPERIENCE

Principal Investigator
Phase IV Grant Outpatient geriatric depression open-label study

OTSUKA AMERICA 31-97-202
Principal Investigator
Inpatient/outpatient Schizophrenia double-blind study

OTSUKA AMERICA 31-97-203
Principal Investigator
Outpatient Schizophrenia open-label study

SANOFI DRI2412
Principal Investigator
Outpatient depression double-blind study

ASTRA, INC. 0009/0010/0011
Sub-Investigator
Stroke Inpatient/Outpatient follow up study

GLAXO WELLCOME AK1A4004
Principal Investigator
Outpatient Relapse/Recurrence of Depression study

TAKEDA AMERICA PNFP-004
Principal Investigator
Outpatient double-blind Alzheimer's study

TAKEDA AMERICA PNFP-007
Principal Investigator
Outpatient double-blind co-administered with Aricept Alzheimer's study

ELI LILLY F1D-MC-HGGA
Principal Investigator
Inpatient/Outpatient double-blind Psychotic Depression study

MCNEIL CONSUMER PRODUCTS 97-030
Principal Investigator
Outpatient double-blind Migraine study

PFIZER 128-601
Principal Investigator
Inpatient/Outpatient double-blind Mania study

PFIZER 128-601E
Principal Investigator
Inpatient/Outpatient open-label extension Mania study

MERCK EMD68 843-009
Principal Investigator
Outpatient double-blind Depression study

CLINICAL TRIAL EXPERIENCE

OTSUKA 31-98-213
Principal Investigator
Outpatient open label Schizophrenia study

OTSUKA 31-98-220
Principal Investigator
Outpatient Schizophrenia open label extension study

ELI LILLY B3L-MC-LWA0
Principal Investigator
Outpatient double-blind Generalized Anxiety study

ORGANON 041-002
Principal Investigator
Inpatient double-blind Schizophrenia study

ORGANON 041-500
Principal Investigator
Outpatient Schizophrenia extension

MERCK 128-130-008
Principal Investigator
Inpatient double-blind Schizophrenia study

R.W. JOHNSON TOPMAT PDMD-002
Principal Investigator
Inpatient double-blind bipolar study

R.W. JOHNSON TOPMATPDMD-003
Principal Investigator
Outpatient bipolar open label extension

FOREST CIT-MD3-97-07-000
Principal Investigator
Outpatient double-blind depression study

FOREST CIT-MD3-97-11-000
Principal Investigator
Outpatient double-blind depression study

FOREST CIT-MD3-97-12-000
Principal Investigator
Outpatient double-blind depression study

FOREST CIT-MD3-98-13-000
Principal Investigator
Outpatient depression open label extension study

OTSUKA 31-98-217

CLINICAL TRIAL EXPERIENCE

Principal Investigator
Outpatient double-blind Schizophrenia study

OTSUKA 31-98-218
Principal Investigator
Outpatient Schizophrenia open label extension study

HOECHST MARION ROUSSEL 3001
Principal Investigator
Inpatient double-blind Schizophrenia study

HOECHST MARION ROUSSEL 3005
Principal Investigator
Outpatient Schizophrenia extension study

PFIZER 165-112-5052
Principal Investigator
Outpatient Depression Study

NOVARTIS ILP3000
Principal Investigator
Inpatient/Outpatient Double-Blind Schizophrenia Study

GLAXO WELLCOME AK1A4007
Principal Investigator
Outpatient Sexual Dysfunction Study

SMITHKLINE BEECHAM 29060/641
Principal Investigator
Outpatient Generalized Anxiety Disorder Study

ELI LILLY F1D-MC-HGHB
Principal Investigator
Inpatient Intramuscular Schizophrenia Study

ELI LILLY F1D-MC-HGHQ
Principal Investigator
Inpatient/Outpatient Mania Study

LILLY F1D-MC-HGGU (a)
Principal Investigator
Outpatient Agitated Dementia study ongoing

LILLY H5Z-MC-LUAH
Principal Investigator
Outpatient Adult Generalized Anxiety Disorder

LILLY H5Z-MC-LUAB
Principal Investigator
Outpatient Depression study

CLINICAL TRIAL EXPERIENCE

PHARMACIA AND UPJOHN M/3275/0011
Principal Investigator
Outpatient Migraine Study

FOREST SCT-MD-04
Principal Investigator
Outpatient Panic Study

FOREST SCT-MD-01
Principal Investigator
Outpatient Depression Study

FOREST CIT-MD-20
Principal Investigator
Outpatient Child Depression Study

FOREST SCT-MD-05
Principal Investigator
Outpatient Adult Generalized Anxiety disorder

FOREST CIT-MD-18
Principal Investigator
Outpatient Pediatric Depression

FOREST CIT-MD-20
Principal Investigator
Outpatient Pediatric Extension Study

WYETH-AYERST LABS 0600B1-915
Principal Investigator
Outpatient SSRI failure Depression Study

ORGANON 003-900
Principal Investigator
Outpatient Depression Study

ORGANON 003-901
Principal Investigator
Outpatient Geriatric Depression Study

ORGANON 003-045
Principal Investigator
Outpatient Child/Adolescent Depression Study

ELI LILLY F1D-MC-HGHL
Principal Investigator
Outpatient Bipolar Study

ELI LILLY F1D-MC-HGHZ

CLINICAL TRIAL EXPERIENCE

Principal Investigator
Outpatient treatment resistant depression study

ELI LILLY F1D-MC-HGJA
Principal Investigator
IM antipsychotic (Schizophrenia) study

ELI LILLY B4Z-MC-LYAA
Principal Investigator
Outpatient Adult ADHD study

ELI LILLY B4Z-MC-LYAR
Principal Investigator
Outpatient Open-Label Extension ADULT ADSH Study

ELI LILLY F1D-US-HGIY
Principal Investigator
Inpatient Schizophrenia and Bipolar Study

ELI LILLY F1D-EW-LOBE
Principal Investigator
IM Depo (schizophrenia) Study

PFIZER 128-602
Principal Investigator
Inpatient bipolar with current manic episode study

PFIZER 128-602E
Principal Investigator
Outpatient bipolar extension study

GLAXO AK1A4011
Principal Investigator
Outpatient Smoking Cessation

ABBOTT M99-045
Principal Investigator
Inpatient bipolar with current manic episode study

ABBOTT M99-010
Principal Investigator
Inpatient schizophrenia study

NOVARTIS ILP3004
Principal Investigator
Inpatient Schizophrenia Study

NOVARTIS ILP3005
Principal Investigator
Inpatient Schizophrenia study

CLINICAL TRIAL EXPERIENCE

PFIZER A2721002
Principal Investigator
Outpatient Depression study

GLAXO/SKB 29060/715
Principal Investigator
Outpatient Child Depression & Obsessive Compulsive Disorder PK Study

SUMITOMO D1050006
Principal Investigator
Inpatient/Outpatient Schizophrenia study

PURDUE HCD1002
Principal Investigator
Phase One PK Inpatient Healthy Normal Study

WYETH-AYERST 0600B2-396-US
Principal Investigator
Outpatient Double-Blind Child/Adolescent Anxiety Study

WYETH-AYERST 0600B2-394-US
Principal Investigator
Outpatient Double-Blind Child/Adolescent Depression Study

WYETH-AYERST 0600B4-393-US
Principal Investigator
Outpatient double-Blind Generalized Social Anxiety Disorder

PHARMACIA & UPJOHN M/3275/0008
Principal Investigator
Outpatient double-Blind Adult Migraine Study

ELI LILLY F1D-US-HGJB
Principal Investigator
Outpatient Open-Label Adult Schizophrenia Study

WYETH-AYERST 0600B1-382
Principal Investigator
Outpatient Double-Blind child/Adolescent Depression Study

GLAXO NSD20000004
Principal Investigator
Outpatient Double-Blind Adult Depression Study

TAKEDA ABBOTT PHARMACEUTICALS TAK-637-99-301
Principal Investigator
Outpatient Double-Blind Adult Depression Study

JANSSEN PHARMACEUTICALS INC RIS-USA-235

CLINICAL TRIAL EXPERIENCE

Principal Investigator
Inpatient Open-Label Adult Acute Psychosis Study

PFIZER A1651002
Principal Investigator
Outpatient double-Blind Adult Depression Study

PFIZER A1651007
Principal Investigator
Outpatient Double-Blind Adult Depression Extension Study

FOREST CIT-MD3-97-03-000
Principal Investigator
Outpatient 75 Years and Older Depression Study

ORGANON 041-013
Principal Investigator
Inpatient Schizophrenia study

ORGANON 041-505
Principal Investigator
Outpatient Schizophrenia Extension Study

SEPRACOR 190-049
Principal Investigator
Outpatient double-Blind Adult Insomnia Study

FUJISAWA FA-960-0005
Principal Investigator
Outpatient Double-Blind Adult Alzheimer's Study

WYETH-AYERST 06000B1-402-US
Principal Investigator
Outpatient Double-Blind Adult Depression Study

GLAXO SMITHKLINE 29060/810
Principal Investigator
Outpatient Double-Blind Adult Depression Study

OTSUKA 173-98-203
Principal Investigator
Outpatient Double-Blind Adult Depression Study

PARKE-DAVIS 1008-088
Principal Investigator
Outpatient Double-Blind Generalized Anxiety Disorder Study

PARKE-DAVIS 1008-92
Principal Investigator
Outpatient Double-Blind Adult Panic Disorder Study

CLINICAL TRIAL EXPERIENCE

PHARMACIA & UPJOHN M2020/0047
Principal Investigator
Outpatient Double-Blind Adult Depression Study

PHARMAACIA & UPJOHN M 2020/0046
Principal Investigator
Outpatient Double-Blind Adult Depression Study

PHARMACIA & UPJOHN 378GCNS0069-01
Principal Investigator
Inpatient Double-Blind Schizophrenia Study

SHIRE 105.301
Principal Investigator
Inpatient Double-Blind Bipolar Disorder Study

SHIRE 105.303
Principal Investigator
Inpatient/Outpatient Open-Label bipolar Disorder Study

SMITHKLINE BEECHAM 29060-701
Principal Investigator
Outpatient Double-Blind Pediatric Depression Study

SMITHKLINE BEECHAM 29060/716
Principal Investigator
Outpatient Open-Label Pediatric Depression Study

PUBLICATIONS

Numerous research-related publications

Revised January 2002

5077US/0049.004

BIRMINGHAM PSYCHIATRY PHARMACEUTICAL STUDIES, INC.

Curriculum Vitae
January 10, 2003

Name: H. Edward Logue, M.D.

Position Title: Principal Investigator
Medical Director

Address: Birmingham Psychiatry Pharmaceutical Studies, Inc.
One Independence Plaza, Suite 900
Birmingham, Alabama 35209

Telephone Number: 205-868-4286
Fax Number: 205-868-4293

Education: Medicine AL ML#: 5861

Education:

Institution and Location	Degree	Year Conferred	Field of Study
Medical College of Georgia, Augusta Ga.	*M.D.*	*1963*	*Medicine*
Emory University, Atlanta, Ga.	*B.S.*	*1958*	*Pre-Med*
Emory University, Oxford Georgia	*A.D.*	*1955*	*Science*

Research and Professional Experience:

Position	Institution/Employer and Location	Dates of Employment
Psychiatrist/President/Founder	*Private Practice, Birmingham Psychiatry P.A., Birmingham, Alabama*	*1972 - Present*
Medical Director, Adult Psychiatric Services	*Brookwood Medical Center* *Birmingham, Alabama*	*October 1987-Present*
Founder, Medical Director *Chairman of Board*	*American Behavioral Benefits Managers, Inc.*	*1989 - Present*
Medical Director	*Birmingham Psychiatry Pharmaceutical Studies*, Inc.	*1991 - Present*

President Alabama Psychiatric Society	*State of Alabama*	*1990 - 1991*
Exemplary Psychiatrist Award	*National Alliance for the Mentally Ill* *Birmingham Alliance for the Mentally Ill*	*1998*

Professional Memberships:

(1) American Psychiatric Association

(2) American Medical Association

(3) Alabama Psychiatric Society-District Branch of American Psychiatry Association

(4) Jefferson County Medical Society

(5) Medical Association of State of Alabama

(6) Central Alabama Psychiatric Society

Publications:

Papers presented to Medical Association of Alabama:

1. "Ethics Meets Thanatos" January 1998
2. "Atypical Antipsychotics: What is Here and What is Coming" January 1998

Alabama Medical License Number: 5861

Revised 1-10-2003

Research Experience:

1. Principal Investigator
   "Insomnia treatment study"
   Outpatient study
   The Upjohn Company
   1992

2. Principal Investigator
   "Fluvoxamine vs Placebo in the treatment of Panic Disorder."
   Enrolled: 20 patients (6 months)
   Outpatient study
   The Upjohn Company
   1992-1993

3. Principal Investigator
   "Fluvoxamine vs Placebo in the treatment of Panic Disorder: A long term maintenance, Double Blind study comparing efficacy and safety."
   Enrolled: 20 patients (6 months)
   Outpatient study
   The Upjohn Company
   1993-1994

4. Principal Investigator
   "A Randomized, comparative open-labeled study of Paroxetine in the Treatment of Depression as used in a Clinical Practice Setting."
   Smith-Kline Beecham
   Outpatient study
   Enrolled: 20 patients (3 months)
   1993-1994

5. Principal Investigator
   "Olanzapine versus Haloperidol in the Treatment of Schizophrenia and Other Psychotic Disorders."
   FID-MC-HGAJ
   Enrolled: 44 patients (12 months)
   Inpatient/Outpatient study
   Eli Lilly
   1994-1995

6. Principal Investigator
   "Imitrex Injections in the Treatment of Migraine Headaches."
   Enrolled: 40 patients (2 months)
   Outpatient study
   Glaxo\Pact
   1994

7. Principal Investigator
   "Epidemiologic Survey of Prostep."
   Smoking cessation study
   Enrolled: 20 patients 1993-1994

8. Principal Investigator
" A Double-Blind, Placebo-controlled, dose response comparison of the safety and efficacy of three doses of Sertindole and three doses of Haldol in Schizophrenic Patients."
M93-113
Inpatient Study
Abbott Laboratories
Enrolled: 34 Patients (6 months)
1994-1995

9. Principal Investigator
"An Open-label Assessment of the long-term safety of Sertindole in the treatment of Schizophrenic Patients"
M92-795
Outpatient study
Enrolled: 17 (Continuation Study from M93-113)
Abbott Laboratories
1995

10. Principal Investigator
"An Open-label Assessment of the Safety of Sertindole".
(M94-222)
Enrolled: 15 patients (Continuation Study from M93-113)
Outpatient study
Abbott Laboratories
1995

11. Principal Investigator
"A Phase II comparative study using a single dose of Acetaminophen, Acetaminophen/Cyproheptadine, Cyproheptadine Alone and Placebo in the Treatment of Migraine Headache"
Enrolled: 39 Patients (6 months)
McNeil Laboratories
1994 - 1995

12. Principal Investigator
"A prospective, Multi-center, Open-label study of Serzone (nefazodone) in the Managementof Patients with Symptoms of Depression in Depression in General Psychiatric Practices"
(CN 104-127)
Depression study
Enrolled: 14 patients (3 months)
Bristol-Myers Squibb\ICRC

13. Principal Investigator
"Olanzapine versus Risperidone in the Treatment of Schizophrenia and other Psychotic Disorders"
F1D-MC-HGBG
Enrolled: 49 patients (4 months)
Outpatient study
Eli Lilly 1995

14. Sub Investigator
"A Multi Center, Placebo-Controlled Study of Relapse Prevention By Long-Term Treatment with High or Low Doses of ORG-4428 in Outpatients with Recurrent Major Depressive Episode"
Outpatient study
Organon\Pharmaco Enrolled: 35 patients
1995

15. Principal Investigator
"Open-Label Experience with Olanzapine in Patients Who Have Completed a Previous Olanzapine Clinical Trial" protocol.
Compassionate Use Study
FID-MC-HGDI
Outpatient study
Eli Lilly 1996
Enrolled: 13 patients from previous Olanzapine studies

16. Sub Investigator
"A Randomized Double-Blind, Placebo-Controlled parallel group multicenter, single dose, dose range-finding study to assess the efficacy and tolerability of VML 251 in the acute treatment of migraine."
Outpatient study
April 1996 to June 1996
Vanguard Medica Limited

17. Principal Investigator
"Mazapertine dose finding trial, comparing three fixed dosages of Mazapertine to Risperidone and placebo: multicenter, double-blind parallel group study".
MAZ-INT-01
Janssen Pharmaceutical Research Foundation
March 1996 to July 2, 1996
Inpatient Study Phase II Clinical Trial
Screened: 23 patients Randomized: 20 patients
Janssen Pharmaceutical Research

18. Principal Investigator
"A Comparison of Risperidone and Haloperidol for Prevention of Relapse in subjects with schizophrenia and schizoaffective disorders."
RIS-USA-79 Outpatient Study
Enrolled: 27 patients Janssen Pharmaceutical Research

19. Sub Investigator
"An Open Label, Multicenter Trial Evaluating the Safety and Efficacy of Donepezil Hydrochloride in Patients with Alzheimer's Disease." (E2020)
Outpatient
Pfizer Pharmaceutica

20. Principal Investigator
"A Multicenter Double-Blind, Randomized Comparison of Zolmitriptan and Sumatriptan in The Acute Treatment and of Multiple Migraine Headaches."
Outpatient Zeneca Pharmaceuticals

21. Principal Investigator
"A Multicenter, Double-Blind, Randomized, Placebo Controlled, Parallel Group Study of the Efficacy and Safety of Escalating the Dose of Oral Eletriptan in Subjects with Acute Migraine."
Outpatient
Pfizer

22. Principal Investigator
"A 12-Month Study of VML 251 In the Acute Treatment of Migraine"
Outpatient
Vanguard Medica Ltd.

23. Principal Investigator
"The Safety and Efficacy of Risperdal (Risperidone) vs Placebo vs Haloperidol as Add – On Therapy to Mood Stabilizers in the Treatment of the Manic Phase of Bipolar Disorder"
Inpatient/Outpatient study
Add –On site Enrolled 7 patients

24. Principal Investigator
"A Multi-Center, Randomized, Double-Blind, placebo and active controlled study of MDL 100,907 in Schizophrenic and Schizoaffective Patients."
MDL 100.907 PR0015
Inpatient Study Enrolled 27 Patients Hoechst Marion Roussel, Inc.

25. Principal Investigator
"A Multi-Center, Open-Label, Long-Term Follow-Up, Safety Study of MDL 100,907 In Schizophrenic and Schizoaffective Patients Who Participated in Protocol 100907 PR0015."
MDL 100,907 PR 0018 Inpatient/Outpatient
Hoechst Marion Roussel, Inc.

26. Principal Investigator
"A Phase III, Randomized, Multicenter, Open Label Study Evaluating the Toleration and Safety of 3 Days of Treatment with Intramuscular Ziprasidone (20 to 80 mg. Daily) or Haloperidol (up to 40 mg Daily) Followed by 4 Days of Treatment with Oral Ziprasidone (40 to 200 mg Daily) or Haloperidol in Subjects with a Diagnosis of Psychotic Disorder." (128-121) Inpatient Study
Enrolled 27 Patients Pfizer

27. Principal Investigator
"Risperidone vs Olanzapine in the Treatment of Schizophrenia".
RIS-USA-112 Outpatient Study Janssen Research Foundation

28. Principal Investigator
"Risperidone vs Olanzapine in the Treatment of Schizophrenia".
RIS-USA-113 Outpatient Study Janssen Research Foundation

29. Principal Investigator
"Risperidone vs Olanzapine in the Treatment of Schizophrenia in Elderly Subjects".
RIS-INT-50 Outpatient Study Janssen Research Foundation

30. Principal Investigator
"Fluoxetine Augmentation in Schizophrenic or Schizoaffective Patients with Depressive or Nonresponders to Olanzapine".
FID-MC-HGFT Outpatient Study Eli Lilly

31. Principal Investigator
"Strategies for Switching from Conventional Antipsychotic Drugs to Olanzapine".
FID-MC-HGFW Outpatient Study Eli Lilly

32. Principal Investigator
"Olanzapine Added to Mood Stabilizers in the Treatment of Bipolar Disorder".
FID-MC-HGFU Outpatient Study Eli Lilly

33. Sub-Investigator
"Metrifonate Investigational Nationwide Trial".
(M.I.N.T.) D97-019
Alzheimer' Disease Outpatient Study Bayer Corporation

34. Principal Investigator
"A Phase III, Randomized, Placebo-Controlled Study Evaluating the Safety and Outcome of Treatment with Oral Ziprasidone in subjects with Mania".
128-601 Mania study Inpatient Study Pfizer

35. Principal Investigator
"An Open Extension Study Evaluating the Safety and Outcome of 40-160 mg daily of Ziprasidone in Previous Ziprasidone Clinical Trials".
128-601 Inpatient/Outpatient Study Pfizer

36. Principal investigator
"A Double – Blind, Randomised, Multicenter, Parallel Design Study to Evaluate the Efficacy and Safety of Individual Maximum Tolerated Doses of EMD 68 843 in Comparison with Placebo and Fluoxetine in Outpatients with Major Depressive Disorder"
Merck EMD Outpatient study Merck KGaA

37. Principal investigator
"Phase II, Six-Week, Double-Blind, Placebo and Olanzapine-Controlled Study Evaluating the Safety and Efficacy of Oral CP-361,428 in Schizophrenia and Schizoaffective Disorder"
Schizophrenia study
Pfizer 245-102 Inpatient study Pfizer

38. Principal Investigator
"A double-blind, randomized, multicenter, parallel group design study to evaluate the efficacy and safety of two dosse ranges of EMD 128 130 in comparison with placebo and haloperidol in the treatment of schizophrenia"
EMD 128-130-08
Schizophrenia study Inpatient/Outpatient Study
Merck KgaA Pharmaceutical Co.

39. Principal Investigator
"A prospective, randomized, double-blind, placebo- and active-controlled, multicenter study to evaluate the efficacy and safety of three fixed doses of iloperidone (4, 8, and 12 mg/d) given b.i.d. for 42 days to schizophrenic patients with acute or subacute exacerbation, followed by a double-blind, active-controlled, flexible-dose, long-term, 6-month phase with iloperidone (4, 8, 12, or 16 mg/d) given q.d." ILP 3000
Schizophrenia Inpatient and Outpatient Study Novartis

40. Principal Investigator
Novartis Protocol No.: ABA 451
"A Prospective, Randomized, International Parallel-Group Comparison of Clozaril/Leponex vs. Zyprexa in the Reduction of Suicidality in Patients with Schizophrenia or Schizoaffective Disorder Who are at Risk for Suicide"
Novartis ABA 451
Schizophrenia Outpatient Study Novartis

41. Principal Investigator
"The Assessment of Nizatidine for the Prevention of Olanzapine-Associated Weight Gain in Patients with Schizophrenia"
HGIJ Outpatient Study Eli Lilly

42. Principal Investigator
Protocol: F1D-MC-HGHL
"Olanzapine Versus Placebo in the Prevention of Relapse in Bipolar Disorder
HGHL Outpatient Study Eli Lilly

43. Principal Investigator
"Prevalence of Hyperprolactemia in Schizophrenic Patients Treatees with Antipsychotic Drugs"
Prolactin study HGHC Outpatient study Eli Lilly

44. Principal Investigator
"Allelic Variation in Schizophrenia"
HGGL Outpatient study Eli Lilly

45. Principal Investigator
Protocol: F1D-MC-HGHZ
"The Combination of Olanzapine and Fluoxetine in Treatment Resistant Depression without Psychotic Features"
HGHZ Outpatient study Eli Lilly

46. Principal Investigator
Randomized, double-blind, placebo-controlled multicenter trial to demonstrate the clinical efficacy and safety of two different doses of Ginkgo biloba special extract Egb 761 in patients suffering from Dementia of the Alzheimer's Type according to DSM-IV and NINCDS/ADRA criteria.
Protocol 523001-01-030
Alzheimer's Study Outpatient study Schwabe

47. Principal Investigator
"A Double-Blind, Placebo-Controlled Dose-Finding Study Evaluating the Safety and Efficacy of MKC-242 1.5, 6, and 24 mg/day (0.5. 2, and 8 mg tid) in the Treatment of Major Depressive Disorder."
MKC/A01 Depression study
Outpatient study Mitsubishi

48. Principal Investigator
"Safety and Efficacy of MKC-242 in the treatment of major depressive disorder: A 4 month double-blind extension to study MKC242-A01."
MKC/A02 Depression study
Outpatient study Mitsubishi

49. Principal Investigator
"Safety of open-label standard therapy in the treatment of major depressive disorder: A 1 month follow-up after termination of study MKC-242/A01."
MKC/A03 Depression study
Outpatient study Mitsubishi

50. Principal Investigator
"A Double-Blind, Placebo and Haloperidol-Controlled, Multicenter Study Evaluating the Safety and Efficacy of SR48692 in Schizophrenic Patients"
Schizophrenia study Inpatient study Sanofi

51. Principal Investigator
"A Double-Blind, Placebo and Haloperidol-Controlled, Multicenter Study Evaluating
the Safety and Efficacy of SR141716 in Schizophrenic Patients"
Sanofi 3077 Schizophrenia study Inpatient study

52. Principal Investigator
Abbott M99-010
"Safety and Efficacy of Depakote as Combination Therapy in the Treatment of Psychosis Associated with Schizophrenia"
Inpatient study Abbott Laboratories

53. Principal Investigator
Protocol No. CN138-070 and CN 138-010
"A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Aripiprazole in the Maintenance Treatment of Patients with Bipolar Disorder."
Bristol-Myers Squibb Pharmaceutical Research Institute
Inpatient/Outpatient study

54. Principal Investigator
Protocol No. F1D-MC-HGIJ
"The Assessment of Nizatidine for the Prevention of Olanzapine-Associated Weight Gain in Patients with Schizophrenia"
Outpatient study Sponsor: Eli Lilly

55. Principal Investigator
Protocol No. F1J-MC-HMAT
"Duloxetine Versus Placebo and Paroxetine in the Acute Treatment of Major Depression" Sponsor: Eli Lilly

56. Principal Investigator
Protocol No. F1D-US-HGJB
"A Controlled Trial of Olanzapine Versus Quetiapine in the Treatment of Schizophrenic and Schizoaffective Subjects with Prominent Negative Symptoms"
Outpatient study Sponsor: Eli Lilly

57. Principal Investigator
Protocol No. F1J-MC-HMBH
"Duloxetine Once-Daily Dosing Versus Placebo in the Acute Treatment of Major Depression"
Outpatient Study Sponsor: Eli Lilly

58. Principal Investigator
Protocol No. TAK 637-00-302
"A Phase II Randomized, Multicenter, Placebo- and Active Controlled Study of Oral TAK-637 in Subjects with Major Depressive Disorder"
Outpatient study Sponsor: TAP Pharmaceutical Products, Inc.

59. Principal Investigator
Protocol No. F1D-MC-HGGY
"Placebo – Controlled Olanzapine Monotherapy in the Treatment of Bipolar I Depression"
Outpatient study Sponsor: Eli Lilly

60. Principal Investigator
Protocol No. F1D-MC-HGJN
"The Assessment of Amantadine for the Treatment of Olanzapine – Associated weight Gain in Patients with schizophrenia, Schizophreniform, Schizoaffective and Bipolar I Disorder"
Outpatient Study Sponsor: Eli Lilly

61. Principal Investigator
Protocol No. ILP 3005
"A randomized, Double-Blind, placebo-and risperidone controlled multicenter study to evaluate the efficacy and safety of two nonoverlapping dose ranges of iloperidone given B.I.D. for 42 days to schizophrenic patients followed by a long-term treatment phase with iloperidone given Qd."
Inpatient and outpatient study
Sponsor: Novartis (Inpatient/Outpatient study)

62. Principal Investigator
Protocol No. D105006
"A Double-Blind, Randomized, Fixed Dose, Placebo-Controlled, Placebo-Controlled, Parallel-Group, 6-Week, Efficacy, Safety, and Tolerability Study of Two Dose Levels of SM-13496 in Patients with Schizophrenia by DSM-IV Criteria Who are Experiencing an Acute Exacerbation of Symptoms"
Sponsor: Sumitomo Inpatient/Outpatient study

63. Principal Investigator
Protocol No. 5077US/0043
"A Multicenter, Double-blind, Randomized Comparison of the Efficacy and Safety of Quetiapine Fumarate (SEROQUEL) and Risperidone (RISPERDAL) in the Treatment of Patients with Schizophrenia"
Sponsor: AstraZeneca Inpatient/Outpatient study

64. Principal Investigator
B99.CT3.005.BUS P02
"A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy, Safety, and Tolerability of 60 mg Buspirone Hydrochloride Extended Release Compared to Placebo in Patients with Generalized Anxiety Disorder"
Sponsor: Biovail Outpatient study

65. Principal Investigator
"An Open-Label Study of the Safety, and Tolerability, and Efficacy of Up to 90mg Buspirone Hydrochloride Extended Release in Patients with Generalized Anxiety Disorder"
B99.CT#3.008.BUS P02
Sponsor: Biovail Outpatient study

66. Principal Investigator
Protocol # Biovail B01. 016. BUS PO2
"A Randomized, Double-blind, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy, Safety, and Tolerability of 60 mg Buspirone Hydrochloride Extended Release Compared to Placebo in Patients with Generalized Anxiety Disorder Who Have Stable Disease Characteristics"
Sponsor: Biovail Outpatient study

67. Principal Investigator
Protocol:
"An Acute and Continuation Phase Study of the Comparative Efficacy of Venlafaxine ER (Effexor XR) and Fluoxetine (Prozac) in Achieving and Sustaining Remission (Wellness) in Patients With Recurrent Unipolar Major Depression; Followed by a Long-term Randomized, Placebo-Controlled Maintenance Treatment Study in Patients Treated Initially with Venlafaxine ER"
Sponsor: Wyeth-Ayerst Pharmaceuticals Outpatient Study

68. Principal Investigator
Protocol: "An International, Multicenter, Large Simple Trial (LST) To Compare the Cardiovascular Safety of Ziprasidone and Olanzapine"
Sponsor Pfizer, Inc. Outpatient study

69. Principal Investigator
Protocol: "A 6-Week, Double-Blind, Randomized, Fixed-Dose, Parallel-Group Study of the Efficacy and Safety of Three Dose Levels of SM-13496 Compared to Placebo and Haloperidol in Patients with Schizophrenia Who are Experiencing an Acute Exacerbation of Symptoms "
Sponsor Sumitomo Pharmaceuticals America, Ltd.
Inpatient/Outpatient study

70. Principal Investigator
Protocol:
"A Phase III, Randomised, Placebo-Controlled, Double-Dummy Study Evaluating the Safety and Efficacy of Oral Ziprasidone vs. Haloperidol and Placebo in In-Patients with an Acute Manic Episode"
Sponsor Pfizer Inc. Inpatient/Outpatient study

71. Principal Investigator
Protocol:
"A Phase III, Three-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Safety and Efficacy Study of Extended-Release Carbamazepine in the Treatment of Bipolar Disorder"
Sponsor Shire Pharmaceutical Development Inc.
Inpatient/Outpatient study

72. Principal Investigator
Protocol: "A Pilot Study of the Effect of Hormone Replacement Therapy In Recently Postmenopausal Women with Subjective Complaints"
Sponsor Wyeth Pharmaceuticals Inc. Outpatient study

5077US/0048 : 0042

ALABAMA MEDICAL LICENSURE COMMISSION
P.O. BOX 887
MONTGOMERY, ALABAMA 36101-0887

CERTIFICATE OF REGISTRATION
2003

This is to certify that annual registration has been made and license to practice medicine in the State of Alabama has been granted for the year ending December 31, 2003

License # 00005861 **Amount Paid: $200**
Date Issued: 01/21/1972 **Receipt # 265021**

HARRY EDWARD LOGUE , M.D.
ONE INDEPENDENCE PLAZA
SUITE 900
BIRMINGHAM, AL 35209-5604

Jerry N. Guilley M.D.
CHAIRMAN

Detach along this line . . .

ALABAMA MEDICAL LICENSURE COMMISSION

HARRY EDWARD LOGUE, M.D.
ONE INDEPENDENCE PLAZA
SUITE 900
BIRMINGHAM, AL 35209-5604

Is entitled to practice medicine in Alabama. Registration expires December 31, 2003

Jerry N. Guilley M.D.
CHAIRMAN

LICENSE# 00005861

AstraZeneca

Clinical Study Report: Appendix 12.1.5

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.5
Signatures

Title	Version ID
Main body of document	CNS.000-071-341.2.0
Appendix 12.1 Study information	CNS.000-071-342.2.0
Appendix 12.1.1 Protocol and protocol amendments	CNS.000-071-343.2.0
Appendix 12.1.2 Sample Case Report Form	CNS.000-071-344.3.0
Appendix 12.1.3 Independent Ethics Committees/Institutional Review Boards consulted and sample of written Subject Information and Consent Form	CNS.000-071-345.4.0
Appendix 12.1.4 Participants in the study	CNS.000-071-346.3.0
Appendix 12.1.5 Signatures	CNS.000-071-347.2.0
Appendix 12.1.6 Listing of subjects receiving the various batches of investigational product(s)	CNS.000-071-348.2.0
Appendix 12.1.7 Randomisation scheme and codes	CNS.000-071-349.2.0
Appendix 12.1.8 Audit certificates	CNS.000-071-350.2.0
Appendix 12.1.9 Documentation of statistical methods and supporting statistical analysis	CNS.000-071-351.3.0
Appendix 12.1.10 Documentation of assay-methods, inter-laboratory standardisation methods and related quality assurance procedures	CNS.000-071-352.2.0
Appendix 12.1.11 Publications based on the study	CNS.000-071-353.3.0
Appendix 12.1.12 Important publications referenced in the report	CNS.000-071-354.2.0
Appendix 12.2 Subject data listings	CNS.000-071-355.2.0
Appendix 12.2.1 Disposition of each subject (completion/ discontinuation)	CNS.000-071-356.2.0
Appendix 12.2.2 Protocol deviations	CNS.000-071-357.2.0
Appendix 12.2.3 Subjects and data excluded from efficacy analysis	CNS.000-071-358.2.0
Appendix 12.2.4 Demographic and baseline characteristics	CNS.000-071-359.2.0
Appendix 12.2.5 Treatment compliance (and/or drug concentration data)	CNS.000-071-360.2.0
Appendix 12.2.6 Individual efficacy and pharmacokinetics response data	CNS.000-071-361.2.0
Appendix 12.2.7 Adverse event listing by subject	CNS.000-071-362.2.0
Appendix 12.2.8 Listing of individual laboratory measurements by subject	CNS.000-071-363.2.0
Appendix 12.2.9 Listing of vital signs	CNS.000-071-364.2.0
Appendix 12.2.10 Listing of other safety data	CNS.000-071-365.2.0
Appendix 12.3 Case Report Forms	CNS.000-071-366.2.0
Appendix 12.4 Individual subject data listings	CNS.000-071-367.2.0

SIGNATURE OF SPONSOR'S RESPONSIBLE MEDICAL OFFICER

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study

Signature: Martin Brecher

Martin Brecher, MD, DMSc
Medical Science Director

Date: Jul 21, 2005
(Day Month Year)

SIGNATURE OF SPONSOR'S GLOBAL PRODUCT STATISTICIAN

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL®) in the Treatment of Patients with Bipolar Depression

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study

Signature: Robin P Christ PhD (Information Science Director) July 21st 2005

for Mårten Vågerö, PhL
Global Product Statistician

Date
(Day Month Year)

AstraZeneca

Clinical Study Report: Appendix 12.1.6

Drug Substance	Quetiapine fumarate
Study Code	D1441L00001

Appendix 12.1.6

Listing of subjects receiving the various batches of investigational product(s)

This was a Phase IIIb study in which all active treatments were from production batches of an approved, marketed medication. Therefore, there are no listings of patients receiving different batches of research medication contained in this report. The formulation and lot numbers of the over-encapsulated tablets are given in the following table.

Investigational product or other treatment	**Dosage form and strength**	**Manufacturer**	**Formulation number**	**Lot number**
Quetiapine	tablet, 25 mg	AstraZeneca	F12804	7527F
Quetiapine	tablet, 100 mg	AstraZeneca	F12689	7513H
Quetiapine	tablet, 200 mg	AstraZeneca	F12690	7541F
Placebo	tablet, 25 mg	AstraZeneca	F12636	7553F
Placebo	tablet, 100 mg	AstraZeneca	F12637	7550F
Placebo	tablet, 200 mg	AstraZeneca	F12638	1509C

AstraZeneca

Clinical Study Report: Appendix 12.1.7

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.7
Randomisation scheme and codes

Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001001	0001002	0001003	0001004	0001005	0001006	0001007	0001008	0001009	0001010
0000003	0000001	0000002	0000003	0000001	0000002	0000002	0000003	0000001	0000001
0001011	0001012	0001013	0001014	0001015	0001016	0001017	0001018	0001019	0001020
0000002	0000003	0000002	0000003	0000001	0000001	0000003	0000002	0000002	0000003
0001021	0001022	0001023	0001024	0001025	0001026	0001027	0001028	0001029	0001030
0000001	0000001	0000003	0000002	0000002	0000001	0000003	0000001	0000002	0000003
0001031	0001032	0001033	0001034	0001035	0001036	0001037	0001038	0001039	0001040
0000002	0000001	0000003	0000003	0000002	0000001	0000003	0000001	0000002	0000003
0001041	0001042	0001043	0001044	0001045	0001046	0001047	0001048	0001049	0001050
0000001	0000002	0000002	0000003	0000001	0000002	0000001	0000003	0000002	0000003

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098

Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001051	0001052	0001053	0001054	0001055	0001056	0001057	0001058	0001059	0001060
0000001	0000002	0000003	0000001	0000001	0000002	0000003	0000001	0000002	0000003
0001061	0001062	0001063	0001064	0001065	0001066	0001067	0001068	0001069	0001070
0000001	0000003	0000002	0000001	0000002	0000003	0000002	0000003	0000001	0000003
0001071	0001072	0001073	0001074	0001075	0001076	0001077	0001078	0001079	0001080
0000001	0000002	0000002	0000001	0000003	0000003	0000002	0000001	0000003	0000001
0001081	0001082	0001083	0001084	0001085	0001086	0001087	0001088	0001089	0001090
0000002	0000002	0000001	0000003	0000003	0000001	0000002	0000003	0000001	0000002
0001091	0001092	0001093	0001094	0001095	0001096	0001097	0001098	0001099	0001100
0000002	0000003	0000001	0000001	0000003	0000002	0000003	0000001	0000002	0000001

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098

Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001101	0001102	0001103	0001104	0001105	0001106	0001107	0001108	0001109	0001110
0000003	0000002	0000003	0000002	0000001	0000002	0000001	0000003	0000001	0000003
0001111	0001112	0001113	0001114	0001115	0001116	0001117	0001118	0001119	0001120
0000002	0000003	0000001	0000002	0000002	0000003	0000001	0000002	0000003	0000001
0001121	0001122	0001123	0001124	0001125	0001126	0001127	0001128	0001129	0001130
0000002	0000003	0000001	0000002	0000001	0000003	0000002	0000003	0000001	0000003
0001131	0001132	0001133	0001134	0001135	0001136	0001137	0001138	0001139	0001140
0000002	0000001	0000001	0000003	0000002	0000003	0000001	0000002	0000003	0000001
0001141	0001142	0001143	0001144	0001145	0001146	0001147	0001148	0001149	0001150
0000002	0000001	0000003	0000002	0000002	0000001	0000003	0000002	0000001	0000003

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098

Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001151	0001152	0001153	0001154	0001155	0001156	0001157	0001158	0001159	0001160
0000003	0000001	0000002	0000001	0000002	0000003	0000003	0000002	0000001	0000001
0001161	0001162	0001163	0001164	0001165	0001166	0001167	0001168	0001169	0001170
0000002	0000003	0000001	0000003	0000002	0000002	0000003	0000001	0000003	0000001
0001171	0001172	0001173	0001174	0001175	0001176	0001177	0001178	0001179	0001180
0000002	0000003	0000001	0000002	0000001	0000002	0000003	0000002	0000003	0000001
0001181	0001182	0001183	0001184	0001185	0001186	0001187	0001188	0001189	0001190
0000003	0000001	0000002	0000001	0000003	0000002	0000001	0000003	0000002	0000003
0001191	0001192	0001193	0001194	0001195	0001196	0001197	0001198	0001199	0001200
0000001	0000002	0000002	0000003	0000001	0000001	0000002	0000003	0000001	0000003

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098

Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001201	0001202	0001203	0001204	0001205	0001206	0001207	0001208	0001209	0001210
0000002	0000003	0000001	0000002	0000001	0000002	0000003	0000003	0000002	0000001
0001211	0001212	0001213	0001214	0001215	0001216	0001217	0001218	0001219	0001220
0000003	0000002	0000001	0000001	0000003	0000002	0000002	0000001	0000003	0000002
0001221	0001222	0001223	0001224	0001225	0001226	0001227	0001228	0001229	0001230
0000001	0000003	0000001	0000003	0000002	0000002	0000001	0000003	0000002	0000003
0001231	0001232	0001233	0001234	0001235	0001236	0001237	0001238	0001239	0001240
0000001	0000002	0000003	0000001	0000002	0000001	0000003	0000003	0000001	0000002
0001241	0001242	0001243	0001244	0001245	0001246	0001247	0001248	0001249	0001250
0000001	0000003	0000002	0000001	0000003	0000002	0000003	0000002	0000001	0000001

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098
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Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001251	0001252	0001253	0001254	0001255	0001256	0001257	0001258	0001259	0001260
0000002	0000003	0000002	0000003	0000001	0000001	0000003	0000002	0000003	0000001
0001261	0001262	0001263	0001264	0001265	0001266	0001267	0001268	0001269	0001270
0000002	0000003	0000002	0000001	0000001	0000003	0000002	0000001	0000002	0000003
0001271	0001272	0001273	0001274	0001275	0001276	0001277	0001278	0001279	0001280
0000003	0000002	0000001	0000001	0000003	0000002	0000003	0000002	0000001	0000003
0001281	0001282	0001283	0001284	0001285	0001286	0001287	0001288	0001289	0001290
0000001	0000002	0000001	0000002	0000003	0000002	0000001	0000003	0000002	0000003
0001291	0001292	0001293	0001294	0001295	0001296	0001297	0001298	0001299	0001300
0000001	0000003	0000001	0000002	0000003	0000001	0000002	0000002	0000001	0000003

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098

Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001301	0001302	0001303	0001304	0001305	0001306	0001307	0001308	0001309	0001310
0000002	0000001	0000003	0000003	0000001	0000002	0000003	0000001	0000002	0000002
0001311	*0001312*	*0001313*	*0001314*	*0001315*	*0001316*	*0001317*	*0001318*	*0001319*	*0001320*
0000003	0000001	0000003	0000001	0000002	0000002	0000001	0000003	0000001	0000002
0001321	0001322	0001323	0001324	0001325	0001326	0001327	0001328	0001329	0001330
0000003	0000003	0000001	0000002	0000001	0000003	0000002	0000002	0000003	0000001
0001331	0001332	0001333	0001334	0001335	0001336	0001337	0001338	0001339	0001340
0000002	*0000001*	*0000003*	*0000003*	*0000001*	*0000002*	*0000001*	*0000003*	*0000002*	*0000003*
0001341	0001342	0001343	0001344	0001345	0001346	0001347	0001348	0001349	0001350
0000002	0000001	0000003	0000001	0000002	0000001	0000002	0000003	0000002	0000003

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098

Monday, 26 August 2002

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Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001351	0001352	0001353	0001354	0001355	0001356	0001357	0001358	0001359	0001360
0000001	0000002	0000003	0000001	0000002	0000003	0000001	0000001	0000002	0000003
0001361	0001362	0001363	0001364	0001365	0001366	0001367	0001368	0001369	0001370
0000002	0000003	0000001	0000001	0000002	0000003	0000001	0000002	0000003	0000001
0001371	0001372	0001373	0001374	0001375	0001376	0001377	0001378	0001379	0001380
0000003	0000002	0000002	0000001	0000003	0000002	0000003	0000001	0000002	0000001
0001381	0001382	0001383	0001384	0001385	0001386	0001387	0001388	0001389	0001390
0000003	0000003	0000002	0000001	0000001	0000003	0000002	0000002	0000003	0000001
0001391	0001392	0001393	0001394	0001395	0001396	0001397	0001398	0001399	0001400
0000001	0000003	0000002	0000002	0000003	0000001	0000003	0000002	0000001	0000002

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098
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Monday, 26 August 2002

SCHEDULE NUMBER: 006841
PROTOCOL NUMBER: 5077US/0049

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0001401	0001402	0001403	0001404	0001405	0001406	0001407	0001408	0001409	0001410
0000001	0000003	0000002	0000003	0000001	0000002	0000003	0000001	0000002	0000001
0001411	0001412	0001413	0001414	0001415	0001416	0001417	0001418	0001419	0001420
0000003	0000003	0000002	0000001	0000003	0000001	0000002	0000002	0000001	0000003
0001421	0001422	0001423	0001424	0001425	0001426	0001427	0001428	0001429	0001430
0000001	0000002	0000003	0000002	0000003	0000001	0000002	0000003	0000001	0000003
0001431	0001432	0001433	0001434	0001435	0001436	0001437	0001438	0001439	0001440
0000002	0000001	0000002	0000003	0000001	0000001	0000003	0000002	0000001	0000003
0001441	0001442	0001443	0001444	0001445	0001446	0001447	0001448	0001449	0001450
0000002	0000001	0000003	0000002	0000003	0000002	0000001	0000003	0000001	0000002

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988098

Monday, 26 August 2002

SCHEDULE NUMBER: 006842
PROTOCOL NUMBER: 5077US/0049
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Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002001	0002002	0002003	0002004	0002005	0002006	0002007	0002008	0002009	0002010
0000002	0000003	0000001	0000003	0000002	0000001	0000003	0000001	0000002	0000003
0002011	0002012	0002013	0002014	0002015	0002016	0002017	0002018	0002019	0002020
0000001	0000002	0000002	0000003	0000001	0000002	0000003	0000001	0000002	0000003
0002021	0002022	0002023	0002024	0002025	0002026	0002027	0002028	0002029	0002030
0000001	0000003	0000001	0000002	0000003	0000001	0000002	0000002	0000001	0000003
0002031	0002032	0002033	0002034	0002035	0002036	0002037	0002038	0002039	0002040
0000003	0000001	0000002	0000002	0000001	0000003	0000003	0000002	0000001	0000003
0002041	0002042	0002043	0002044	0002045	0002046	0002047	0002048	0002049	0002050
0000002	0000001	0000001	0000003	0000002	0000001	0000002	0000003	0000001	0000003

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988511

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002051	0002052	0002053	0002054	0002055	0002056	0002057	0002058	0002059	0002060
0000002	0000002	0000001	0000003	0000002	0000003	0000001	0000003	0000001	0000002
0002061	0002062	0002063	0002064	0002065	0002066	0002067	0002068	0002069	0002070
0000002	0000003	0000001	0000002	0000003	0000001	0000002	0000001	0000003	0000001
0002071	0002072	0002073	0002074	0002075	0002076	0002077	0002078	0002079	0002080
0000002	0000003	0000001	0000002	0000003	0000003	0000002	0000001	0000003	0000001
0002081	0002082	0002083	0002084	0002085	0002086	0002087	0002088	0002089	0002090
0000002	0000002	0000003	0000001	0000003	0000001	0000002	0000002	0000001	0000003
0002091	0002092	0002093	0002094	0002095	0002096	0002097	0002098	0002099	0002100
0000002	0000003	0000001	0000001	0000002	0000003	0000003	0000002	0000001	0000002

Statistical Scientist's Initials: MM
Statistical Associate's Initials: TW
Generated by: RAS
Seed: 1345988511
Randomization Design: Randomized Block

Monday, 26 August 2002

SCHEDULE NUMBER: 006842
PROTOCOL NUMBER: 5077US/0049
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Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002101	0002102	0002103	0002104	0002105	0002106	0002107	0002108	0002109	0002110
0000003	0000001	0000001	0000002	0000003	0000002	0000001	0000003	0000003	0000002
0002111	0002112	0002113	0002114	0002115	0002116	0002117	0002118	0002119	0002120
0000001	0000002	0000001	0000003	0000001	0000003	0000002	0000001	0000003	0000002
0002121	0002122	0002123	0002124	0002125	0002126	0002127	0002128	0002129	0002130
0000003	0000001	0000002	0000001	0000002	0000003	0000001	0000003	0000002	0000001
0002131	0002132	0002133	0002134	0002135	0002136	0002137	0002138	0002139	0002140
0000003	0000002	0000002	0000003	0000001	0000003	0000001	0000002	0000002	0000003
0002141	0002142	0002143	0002144	0002145	0002146	0002147	0002148	0002149	0002150
0000001	0000001	0000003	0000002	0000003	0000002	0000001	0000002	0000001	0000003

Statistical Scientist's Initials: MM
Statistical Associate's Initials: TW
Generated by: RAS
Seed: 1345988511
Randomization Design: Randomized Block

Monday, 26 August 2002

SCHEDULE NUMBER: 006842
PROTOCOL NUMBER: 5077US/0049
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Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002151	0002152	0002153	0002154	0002155	0002156	0002157	0002158	0002159	0002160
0000002	0000001	0000003	0000002	0000003	0000001	0000002	0000003	0000001	0000002
0002161	0002162	0002163	0002164	0002165	0002166	0002167	0002168	0002169	0002170
0000001	0000003	0000001	0000003	0000002	0000001	0000002	0000003	0000001	0000003
0002171	0002172	0002173	0002174	0002175	0002176	0002177	0002178	0002179	0002180
0000002	0000002	0000001	0000003	0000001	0000003	0000002	0000002	0000001	0000003
0002181	0002182	0002183	0002184	0002185	0002186	0002187	0002188	0002189	0002190
0000001	0000003	0000002	0000003	0000002	0000001	0000001	0000002	0000003	0000003
0002191	0002192	0002193	0002194	0002195	0002196	0002197	0002198	0002199	0002200
0000001	0000002	0000002	0000003	0000001	0000001	0000002	0000003	0000002	0000001

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988511
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Monday, 26 August 2002

SCHEDULE NUMBER: 006842
PROTOCOL NUMBER: 5077US/0049
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Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002201	0002202	0002203	0002204	0002205	0002206	0002207	0002208	0002209	0002210
0000003	0000003	0000002	0000001	0000001	0000003	0000002	0000001	0000002	0000003
0002211	0002212	0002213	0002214	0002215	0002216	0002217	0002218	0002219	0002220
0000003	0000002	0000001	0000002	0000003	0000001	0000001	0000003	0000002	0000002
0002221	0002222	0002223	0002224	0002225	0002226	0002227	0002228	0002229	0002230
0000001	0000003	0000003	0000001	0000002	0000002	0000001	0000003	0000003	0000001
0002231	0002232	0002233	0002234	0002235	0002236	0002237	0002238	0002239	0002240
0000002	0000003	0000001	0000002	0000001	0000003	0000002	0000001	0000002	0000003
0002241	0002242	0002243	0002244	0002245	0002246	0002247	0002248	0002249	0002250
0000003	0000002	0000001	0000002	0000001	0000003	0000002	0000001	0000003	0000002

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988511

Monday, 26 August 2002

SCHEDULE NUMBER: 006842
PROTOCOL NUMBER: 5077US/0049
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Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002251	0002252	0002253	0002254	0002255	0002256	0002257	0002258	0002259	0002260
0000001	0000003	0000002	0000001	0000003	0000002	0000003	0000001	0000003	0000001
0002261	0002262	0002263	0002264	0002265	0002266	0002267	0002268	0002269	0002270
0000002	0000003	0000002	0000001	0000002	0000003	0000001	0000003	0000002	0000001
0002271	0002272	0002273	0002274	0002275	0002276	0002277	0002278	0002279	0002280
0000002	0000001	0000003	0000002	0000003	0000001	0000001	0000003	0000002	0000001
0002281	0002282	0002283	0002284	0002285	0002286	0002287	0002288	0002289	0002290
0000002	0000003	0000002	0000003	0000001	0000003	0000001	0000002	0000002	0000003
0002291	0002292	0002293	0002294	0002295	0002296	0002297	0002298	0002299	0002300
0000001	0000003	0000002	0000001	0000001	0000002	0000003	0000002	0000001	0000003

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988511
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Monday, 26 August 2002

SCHEDULE NUMBER: 006842
PROTOCOL NUMBER: 5077US/0049
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Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002301	0002302	0002303	0002304	0002305	0002306	0002307	0002308	0002309	0002310
0000002	0000001	0000003	0000002	0000003	0000001	0000001	0000003	0000002	0000002
0002311	0002312	0002313	0002314	0002315	0002316	0002317	0002318	0002319	0002320
0000001	0000003	0000001	0000003	0000002	0000001	0000002	0000003	0000002	0000001
0002321	0002322	0002323	0002324	0002325	0002326	0002327	0002328	0002329	0002330
0000003	0000003	0000002	0000001	0000002	0000003	0000001	0000002	0000003	0000001
0002331	0002332	0002333	0002334	0002335	0002336	0002337	0002338	0002339	0002340
0000001	0000002	0000003	0000002	0000001	0000003	0000002	0000003	0000001	0000001
0002341	0002342	0002343	0002344	0002345	0002346	0002347	0002348	0002349	0002350
0000002	0000003	0000002	0000001	0000003	0000003	0000001	0000002	0000003	0000001

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988511

Monday, 26 August 2002

SCHEDULE NUMBER: 006842
PROTOCOL NUMBER: 5077US/0049
C of 6841

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002351	0002352	0002353	0002354	0002355	0002356	0002357	0002358	0002359	0002360
0000002	0000003	0000001	0000002	0000003	0000001	0000002	0000001	0000002	0000003
0002361	0002362	0002363	0002364	0002365	0002366	0002367	0002368	0002369	0002370
0000003	0000001	0000002	0000003	0000002	0000001	0000003	0000001	0000002	0000003
0002371	0002372	0002373	0002374	0002375	0002376	0002377	0002378	0002379	0002380
0000001	0000002	0000001	0000002	0000003	0000001	0000002	0000003	0000001	0000003
0002381	0002382	0002383	0002384	0002385	0002386	0002387	0002388	0002389	0002390
0000002	0000002	0000003	0000001	0000001	0000002	0000003	0000003	0000002	0000001
0002391	0002392	0002393	0002394	0002395	0002396	0002397	0002398	0002399	0002400
0000003	0000001	0000002	0000002	0000003	0000001	0000001	0000002	0000003	0000002

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988511

Astra Pharmaceuticals, L.P.

UNBLINDED ALLOCATION SCHEDULE

PRODUCT/DRUG NAME: Seroquel

A Multicenter, Double-blind, Randomized, Placebo-c

TREATMENT GROUP 1 : Placebo
TREATMENT GROUP 2 : Seroquel 300 mg
TREATMENT GROUP 3 : Seroquel 600 mg
BLOCKING FACTOR: 3

0002401	0002402	0002403	0002404	0002405	0002406	0002407	0002408	0002409	0002410
0000003	0000001	0000002	0000003	0000001	0000003	0000001	0000002	0000003	0000002
0002411	0002412	0002413	0002414	0002415	0002416	0002417	0002418	0002419	0002420
0000001	0000003	0000002	0000001	0000003	0000002	0000001	0000003	0000002	0000001
0002421	0002422	0002423	0002424	0002425	0002426	0002427	0002428	0002429	0002430
0000002	0000003	0000001	0000002	0000003	0000001	0000001	0000003	0000002	0000002
0002431	0002432	0002433	0002434	0002435	0002436	0002437	0002438	0002439	0002440
0000001	0000003	0000002	0000003	0000001	0000002	0000003	0000001	0000002	0000003
0002441	0002442	0002443	0002444	0002445	0002446	0002447	0002448	0002449	0002450
0000001	0000003	0000001	0000002	0000003	0000001	0000002	0000003	0000002	0000001

Statistical Scientist's Initials: MM
Generated by: RAS
Randomization Design: Randomized Block

Statistical Associate's Initials: TW
Seed: 1345988511

AstraZeneca

Clinical Study Report: Appendix 12.1.8

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.8
Audit certificates

<<Not applicable to this study>>

AstraZeneca

Clinical Study Report: Appendix 12.1.9

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.9
Documentation of statistical methods and supporting statistical analysis

Statistical methods and supporting statistical analysis
Statistical Analysis Plan
Supporting Statistical Analysis

AstraZeneca

Statistical Analysis Plan

Study Code	5077US/0049
Version No.	1.0
Date	11/13/2003

A Multicenter, Double-blind, Randomized, Placebo-controlled, Double-dummy Trial of the Use of Quetiapine Fumarate (SEROQUEL™) in the Treatment of Patients with Bipolar Depression

Study Statistician

Margaret Minkwitz — Date: 11/17/03

Margaret Minkwitz

Global Product Statistician

Martin Jones — Date: 17 Nov 2003

Martin Jones

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LIST OF ABBREVIATIONS

<<Abbreviation>>	*<<Explanation>>*
AE	Adverse Event (definition in Protocol Section 4.4.2.1)
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BP	Bipolar Disorder
BPD	Bipolar Depression
CGI	Clinical Global Impression
CGI-I	Clinical Global Impression – Improvement
CGI-S	Clinical Global Impression – Severity
CMH	Cochran-Mantel Haenszel Test
CRF	Case Report Form
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition
EPS	Extra pyramidal symptoms
ECG	Electrocardiogram
GCP	Good Clinical Practice
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D	Hamilton Rating Scale for Depression
ICTI	Interactive Clinical Technologies, Incorporated
ITT	Intention to Treat Population

IVRS	Interactive Voice Response System
LOCF	Last Observation Carried Forward
MADRS	Montgomery-Asberg Depression Rating Scale
OAE	Other significant adverse event
PP	Per Protocol Population
PSQI	Pittsburgh sleep Quality Index
Qhs	At bedtime
Q-Les-Q	Quality of Life Enjoyment Satisfaction Questionnaire
SAE	Serious adverse event
SAS	Simpson-Angus Scale
SAS®	Statistical Analysis Software, SAS Institute, Cary NC
SSRI	Selective serotonin reuptake inhibitors
UNI	Universal Systems Incorporated
YMRS	Young Mania Rating Scale

1. STUDY DETAILS

1.1 Study Objectives

The primary objectives of the study are to evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks by comparing

1. The change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

2. The percentage of patients with a ≥ 50% reduction from baseline in the MADRS total score at final assessment

3. The change from baseline to each assessment in MADRS total score

4. The change from baseline to each assessment in the total Hamilton Rating Scale for Depression (HAM-D), HAM-D Item 1, and the Clinical Global Impression – Severity (-S), and the Clinical Global Impression – Improvement (-I)

The secondary objectives of the study are:

1. To evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients who meet the criteria for treatment emergent mania on the Young Mania Rating scale (YMRS) or report an adverse event of mania

2. To evaluate the effect of quetiapine on anxiety compared to placebo by

    - The change from baseline to final assessment in the Hamilton Rating scale for Anxiety (HAM-A) total score

    - The change from baseline to each assessment in the HAM-A total score

3. To evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression by

    - The incidence and nature of overall adverse events

    - The incidence and nature of drug related adverse events

    - Patient withdrawal due to adverse events during double-blind treatment

    - The number of patients having clinically significant changes in vital signs from baseline to end of treatment

    - The change in Simpson-Angus Scale (SAS) total score

- The change in Barnes Akathisa Rating Scale (BARS) global assessment
- The incidence of adverse events related to extra pyramidal symptoms during double-blind treatment

Exploratory objectives:

1. To evaluate the efficacy of quetiapine on sleep quality by comparing the change in sleep quality using the Pittsburgh Sleep Quality Index (PSQI) from baseline to end of treatment
2. To evaluate the efficacy of quetiapine on the overall quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-Les-Q) from baseline to end of treatment

1.2 Study Design

This is a double-blind, placebo-controlled, randomized multicenter, 8-week trial evaluating Seroquel at 2 fixed doses as monotherapy in bipolar depression. The randomization is stratified by type of bipolar depression (Bipolar I and Bipolar II).

1.3 Number of Patients

Approximately 530 patients will be enrolled in the trial to obtain 504 evaluable patients.

2. ANALYSIS SETS

2.1 Definition of analysis sets

Data analysis will be based on the following 3 patient populations, defined below.

- The safety population will include all enrolled patients classified according to treatment actually received. Randomized patients who did not receive treatment will be excluded.
- The intention-to-treat (ITT) population will include all evaluable patients in the safety population, classified according to the assigned randomized treatment. It will include all enrolled patients who took study medication and who have a baseline MADRS and at least 1 valid post baseline MADRS assessment. This population will be used to assess the primary efficacy.
- The per-protocol (PP) population will exclude the following; patients with 8 days or less of study treatment, patients who do not meet efficacy related entrance criteria, and patients who do not have a baseline MADRS and at least 1 valid post baseline MADRS assessment. Data will also be excluded based on significant deviations from the protocol (Appendix A details patient/data exclusions).

- Analysis data sets will be developed using the appropriate population designations. Key demographic information will be merged into each analysis data set. This will include, trial, center, patient, age, sex, race, diagnosis, kit number, randomization number, flags for populations (safety, ITT, PP), study treatment start and stop dates, reason for treatment stop, and treatment. Screen failure patients, those without a randomization number, will be flagged and included only in selected demography and safety listings.

Each assessment scale will have an analysis data set created which includes baseline total score, total score, change from baseline total score, % change from baseline total score for MADRS only, an indicator variable for 50% reduction for MADRS only, and similar variables for specified items as appropriate.

Laboratory assessments, including clinical laboratory assessments, vital signs and ECGs will have an analysis data set which includes baseline value, value at visit, change from baseline, and an indicator variables for out of normal range and for potentially clinically significant value based on defined extended normal range criteria for the parameter of interest.

2.2 Violations and deviations

Patients who do not violate the inclusion/exclusion criteria, who are entered into the trial and then do not comply with the protocol are called deviators.

Patients who deviate from the protocol during the course of the trial will be included in the analysis in such a way as to minimize any potential bias; or if this is not possible because of the seriousness of the deviation, they may be excluded from the analysis.

Protocol violations and deviations, which lead to exclusion from analysis data sets, are detailed in Appendix A. In general, protocol violations and deviations, which affect the efficacy of the trial medication, lead to exclusion from the PP population, with continued inclusion in the ITT population. The PP efficacy population will contain all patients randomized to the study who satisfied efficacy inclusion criteria and did not violate efficacy exclusion criteria, detailed in Appendix A, and who did not deviate from the protocol in any way thought to affect the efficacy outcomes. The ITT population will include all patients with data that satisfy the definition of the ITT population in Section 2.1.

After all patients have completed the study, but before the patient data blind is broken, the study team will review all protocol violations and deviations which occurred during the trial and make a determination for each patient regarding inclusion in the PP population.

Certain types of deviation will be handled as defined in sections 2.2.1 through 2.2.6.

2.2.1 Misrandomization

If a patient is randomized to the wrong stratum, the patient will be recoded to the correct stratum based on the actual reported diagnosis for analysis.

If the wrong treatment is administered to a patient then the reason for the incorrect treatment will be fully documented and noted in the report. In the ITT and PP populations, patients will be analyzed as assigned in the original randomization scheme. In the safety population, if a patient went through the entire trial with the incorrect treatment, the patient will be analyzed as treated. Otherwise (e.g., incorrect treatment was administered during part of the trial), the patient will be analyzed as assigned, and the incorrect treatment will be noted.

2.2.2 Patients randomized who fail to receive treatment

If a patient is randomized but fails to receive treatment, the reason for not receiving treatment must be established, and noted in the report. Patients randomized but not receiving treatment will be excluded from Safety, ITT and PP populations, but will be included in patient listings, and enrolment summaries.

2.2.3 Visit compliance

Data will be listed and summarized by visit, providing the visits fall within the following time windows:

Visit	Scheduled Day in relation to first day of randomised treatment	Visit window (days) in relation to first day of randomised treatment
1	Screen	< -1
2	1 (baseline)	-1 to 1
3	8	2 – 12
4	15	13 – 19
5	22	20 – 26
6	29	27 – 33
7	36	34 – 40
8	43	41 – 47
9	50	48 – 54
10	57	55 – *

* last assessment day for completers

If an efficacy measure (MADRS) assessment occurs >4 days after the last dose of study medication the observation will be excluded from the PP analysis.

For observed cases (OC), post baseline data, the following rules will be used: If more than one visit occurs during a visit window, the one closest to the scheduled day will be assigned to the visit for all visits except visit 10, for visit 10 the last visit in the window will be assigned to visit 10. If 2 visits are equidistant from the scheduled day, the later will be assigned to the visit.

For last observation carried forward (LOCF), post baseline data, the following rule will be used: For all missing values, the last available non-missing value, with the exception of baseline, will be used regardless of whether that value was kept for the OC visit under the previous rules.

Baseline data will not be carried forward into the randomized treatment period. If the baseline visit data is missing, the screening assessment will be used as baseline, with the exception of the MADRS which will be set to missing.

All data will be presented in the patient listings. Those assessments, which are dropped from the analysis dataset because of falling outside of the formally defined visit windows, will be indicated as such on the listing.

Visit compliance for the QLESQ and PSQI, which are done monthly will use the following visit windows:

Visit	Scheduled Day in relation to first day of randomised treatment	Visit window (days) in relation to first day of randomised treatment
2	Baseline	≤ 1
6	29	8 – 43
10	57	44 – *

* last assessment day for completers

Visit assignments will follow the same rules for multiple assessments within a window, as those for the weekly assessments but the windows will be larger to capture any post baseline assessment of quality of life.

For assessments of safety and tolerability assessed only at baseline and end of study including, BARS, SAS, ECG and Clinical laboratory data. Post baseline data will be assigned as final visit regardless of visit day. If multiple assessments are made, then the value closest to the date of last dose will be set as the final visit for tabulation, all assessments will be listed regardless of assignment to an analysis visit. If equidistant, the later observation is selected.

Note that record review is also required in selecting the valid visit within a window for vital signs and ECGs, the most complete record within the window should be assigned as the valid and/or carried forward as LOCF.

2.2.4 Compliance with study medication

Individual patient compliance will be assessed based on tablets taken and expected number based on the duration of study participation. The patient will then be classified as fully compliant (≥ 80%), partially compliant (≥ 70% and <80%), or non-compliant < 70%. Non-compliant patients will be excluded from the PP analysis. Patients for whom compliance

cannot be calculated will be indicated as compliant in the listings, and will not be excluded from either the PP or ITT population. Section 4.3.9 describes the computation of compliance; Sections 2.2.6 and 4.5 describes the handling of missing data, and Section 6 details how and why this differs from the protocol.

It should be noted that the calculated compliance is based solely on the prescribed daily number of tablets and count of returned tablets. The duration of treatment will be calculated as the difference between date of last dose and the date of first dose plus one. Compliance will be the number of tablets consumed divided by the total number of expected tablets based on the duration of treatment, converted to a percent. Consequently, a patient who is classified as non-compliant clearly has taken less medication than prescribed (based on number of pills physically returned), while a patient who is classified as compliant may have not actually taken the prescribed medication (e.g., removed but not swallowed, discarded, etc.).

2.2.5 Prior and Concomitant therapy

Prior medication exposure will be tabulated. Selected medications (antidepressants, mood stabilizers, psychotropic medications and hypnotics) will be summarized as the number and percent of patients with 0, 1, 2, 3 or more exposures to the class of medications and also the number and percent of patients receiving 0, 1, 2, 3, or 4 classes of medication.

The use of psychoactive drugs other than those specifically allowed during the trial (i.e., lorazepam and zolpidem tartrate) is restricted. During the first 3 weeks, zolpidem tartrate 5-10 mg at bedtime for insomnia, lorazepam 1-3 mg per day for severe anxiety may be prescribed as long as they do not interfere with any assessments.

Use of these medications after week 3 will be considered a protocol deviation.

Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics are prohibited for 7 to 28 days prior to randomization through the end of study. The wash out periods was specified for each medication based on the drug half-life, these are pecified in the Protocol, Section 4.3 Table 13.

Medications for medical, non-psychiatric illnesses are permitted, as are oral contraceptives and contraceptive devices.

Potent cytochrome P450 3A4 inducers and inhibitors are prohibited during the study.

Concomitant medication will be categorized and reviewed to determine any protocol deviations. These deviations will be reviewed to determine potential impact on efficacy data.

2.2.6 Missing values

Instances of variables with a large proportion of missing values will be documented in the clinical study report. Such variables will be identified before the data is unblinded, and the impact will be assessed and documented by the study statistician.

Imputation of missing data for purposes of analysis is documented in section 4.

3. PRIMARY AND SECONDARY VARIABLES

The primary variable is the change from baseline assessment to final assessment (Day 57 or LOCF) in the MADRS total score

Secondary variables:

- Change from baseline to each assessment (observed cases) MADRS total score
- MADRS total score at each assessment and final assessment
- Response, defined as a decrease from baseline MADRS total score of ≥50% to each assessment and final assessment
- Individual item scores for the MADRS at each assessment and final assessment
- HAM-D total score and change from baseline at each assessment and final assessment
- HAM-D individual item scores and change from baseline at each assessment and final assessment (analysis will key on HAM-D Item 1)
- CGI-S at each assessment and final assessment
- Change from baseline CGI-S to each assessment and final assessment
- CGI-I at each post-baseline assessment and final assessment
- YMRS at each assessment and final assessment
- Change from baseline YMRS to each assessment and final assessment
- YMRS individual item score at each assessment and final assessment
- Presence or absence of treatment emergent mania (YMRS criteria or AE of Mania)
- HAM-A total score at each assessment and final assessment
- Change from baseline HAM-A to each assessment and final assessment
- HAM-A individual item scores at each assessment and final assessment

Quality of Life variables:

- Q-Les-Q at each assessment and final assessment

- Change from baseline Q-Les-Q to each assessment and final assessment
- PSQI at each assessment and final assessment
- Change from baseline PSQI to each assessment and final assessment

Safety variables:

- Adverse events (from randomization to last dose + 30 days)
- Adverse events (considered drug-related)
- Adverse events leading to withdrawal
- Adverse events meeting criteria for a serious event
- SAS at each assessment
- Value at and change from baseline in SAS to each assessment
- BARS at each assessment
- Value at and change from baseline in BARS to each assessment
- Value at and change from baseline in ECG interval data to each assessment
- Classification of clinical significant changes for QT and QTC intervals
- Value at and change from baseline in clinical laboratory assessments to final assessment
- Classification of clinically important changes for AST, ALT, glucose, TSH, free thyroxin
- Value at and change from baseline in vital signs and weight to each assessment
- Classification of clinically important changes for blood pressure, heart rate, orthostatic changes and weight to each assessment

Demographic and baseline characteristic variables:

- Age at study entry
- Sex
- Origin

- Psychiatric diagnosis – stratification variable: Bipolar I and Bipolar II
- Baseline HAM-D assessment (screening and randomization day)

3.1 Definition of efficacy measures

3.1.1 Response rates

Response at a visit is defined as a decrease from baseline MADRS total score of ≥ 50% at the given visit.

3.1.2 Total scores

For MADRS, HAM-D, YMRS, and HAM-A total score will be calculated as the sum of the component items of the scale for each assessment.

3.1.3 Emergent Mania

Emergent mania symptoms will be defined as present for a patient if one of the follow criteria is met: (1) Adverse event of mania requiring hospitalisation, (2) Adverse event of mania leading to withdrawal from study, (3) YMRS total score ≥16 on 2 consecutive assessments at any time during the trial or final assessment ≥ 16 (4) Adverse event of Mania [not included in criteria (1) and (2)].

In addition those whose final YMRS total score is ≥ 16 will be flagged for a separate summary.

3.1.4 Lorazepam use

Daily use of lorazepam during the first 3 weeks of treatment is restricted to 1-3 mg. The MED form will be evaluated for lorazepam use and the presence or absence denoted per study day. Patients taking lorazepam after day 21 will be considered protocol deviators.

3.1.5 PSQI score

The PSQI score will be calculates as follows:

Component 1 (patient sleep quality) = score for question 6

Component 2 (sleep latency)

> If question 2 is: ≤15 then score=0; if 16-30 then score=1; if 31-60 then score=2; if >60 then score=3
>
> Total = Sum of Score for question 2 to Score for 5(a)
>
> Component 2=: 0 if total=0; 1 if total 1-2; 2 if total 3-4; 3 if total 5-6

Component 3 (sleep duration) will be calculated as follows:

If question 4 >7 then score=0; if 6-7 then score=1; if 5-<6 then score=2; if <5 then score=3

Component 4 (habitual sleep efficiency)

Calculate number of hours in bed question 3 – question 1 = number of hours in bed

Calculate habitual sleep efficiency: (question 4 response/hours spent in bed)* 100= habitual sleep efficiency %

Assign component 4 score as follows: sleep efficiency ≥85% then score=0; 75-84% then score=1; 65-74% then score=2; <65% then score=3

Component 5 (sleep disturbances)

Total disturb=sum of questions 5(b) through 5 (J) – 9 items

Assign component 5 score as follows:

If total disturb=0 then score=0; if 1-9 then score=1; if 10-18 then score=2; if 19-27 then score=3

Component 6 (sleep medication)= score for question 7

Component 7 (daytime dysfunction)

Total daydys= sum of question 8 and question 9

Assign component 7 as follows:

If total daydys=0 then score=0; if 1-2 then score=1; if 3-4 then score=2l if 5-6 then score=3

PSQI total score= sum of component 1 through component 7.

3.1.6 The QLESQ total score

The QLESQ total score is the sum of the first 14 items, and this total score is converted to a % maximum score using the following scoring conversion:

Larger values indicate a higher perceived quality of life enjoyment and satisfaction.

The %Maximum score is calculated as follows (Raw total score –14)*(100/56) and rounded to an integer.

3.2 Definition of Safety measures

3.2.1 Total safety scores

SAS total will be calculated as the sum of the component items of the scale for each assessment. Note that for the BARS, the global clinical assessment score will be used for analysis.

3.2.2 Body Mass Index (BMI)

In order to put any changes in weight into perspective, the patient weight data will also be explored as change in body mass index. Patients will be stratified by BMI category to determine changes within and across categories.

Body mass index will be calculated using the following formula:

BMI = weight in kilograms/(height in meters)^2

For cross tabulation the following categorization will be used:

Category	**BMI (kg/m^2)**
Underweight	Under 18.5
Normal weight	18.5 – 24.9
Overweight	25 – 29.9
Obese	30 – 39.9
Severely Obese	40 and over

Changes in body weight and BMI will be computed as Day 57 (OC) and Day 57 (LOCF) measurement minus the baseline measurement. The key endpoint for weight change is whether a patient gained ≥7% over baseline. Weight loss of ≥7% will be presented as well.

3.2.3 Sleep medication

The only sleep medication allowed during the trial is zolpidem tartrate 5-10 mg during the first 3 weeks of the study. Data from the MED form will be classified as presence or absence of sleep medication by study day. A patient will be considered to have deviated from the protocol if this medication was used beyond Day 21.

3.2.4 Study medication

To summarize patient dose in concordance with the intent-to-treat principle, the prescribed daily dose (number of tablets) will be used to measure the daily dose. The prescription record form captures the daily dose of medication based on number of tablets. Investigator could

reduce the dose by 1 tablet per day after day 8 if needed. A patient is considered compliant if they took 75% of the prescribed tablets during treatment. Non-compliant patients will be listed as having deviated from the protocol.

4. ANALYSIS METHODS

The primary analysis of this trial will test whether the mean difference between each quetiapine dose arm and the placebo arm for the change from baseline MADRS total score to final assessment (Day 57 or LOCF) in the ITT population is statistically significant.

4.1 General principles

All statistical tests will be 2-sided. Where appropriate 95% confidence intervals will be presented.

The primary analyses will use last observation carried forward (LOCF) for the time period of interest.

This trial employed a central randomization with a stratification based on diagnosis (bipolar I and bipolar II); therefore diagnosis, not center, will be included as a stratification variable in the analysis models. Center will be included in the ANCOVA model as a random effect.

For the primary analysis a Simes-Hommel step up procedure will be used to adjust for 2 comparisons with placebo. The p-values obtained from the analysis will be ordered as: $P(1) \leq P(2)$. The following rule will be used to assess statistical significance for the primary analysis:

1) If $P(2) \leq 0.05$, then reject both null hypotheses associated with P(2) and P(1): else proceed

2) If $P(1) \leq 0.025$, the reject null hypothesis associated with P(1)

All secondary analyses will be conducted at the nominal significance level of 0.05, with no adjustment for multiple comparisons.

An ITT analysis will be the primary analysis conducted for the primary efficacy variable. The supportive analysis of efficacy will be restricted to those patients who have completed dose titration and have provided one MADRS assessment beyond the titration period (PP).

Although the data were stratified by entry criteria for diagnosis, bipolar I or bipolar II, if a patient's diagnosis on the case report form differed from the stratification group, the patient will be reclassified into the appropriate diagnostic group for analysis.

Patients who were randomized but subsequently were never dosed will be excluded from both efficacy and safety analyses.

4.1.1 Testing of covariates

In general, baseline values in analyses of changes from baseline will be included as a covariate. In the case of tertiary analyses where the baseline for the measure is expected to be low, the MADRS baseline as a surrogate for disease severity will be included as the baseline covariate. Because randomization was stratified by diagnosis, diagnosis stratum will also be included as a covariate where appropriate.

Potential center effects will be evaluated using a mixed model approach to assess the impact of including center as a random effect in the model. It is not expected that all centers will contribute patients to all strata. Thus imbalances are expected both in terms of number randomized and in the distribution across the strata. The expectation is that approximately 1/3 will be bipolar II and 2/3 bipolar I. There is a limit of 70 patients in a center (13 % of the randomized population) but the median is expected to be >12 patients/center.

As appropriate, assumptions of the intended analysis will be explored using blinded data (e.g., using probability plots when testing the assumption of normality). Subsequent to unblinding of the data, model assumptions for consistency of variance will be assessed. If any of the assumptions are found to be violated, an appropriate transformation or a non-parametric technique will be considered to validate the main results.

4.2 Analysis Methods

4.2.1 Primary analysis for MADRS

The primary analysis of change from baseline to final assessment (LOCF) in MADRS total scores will test the superiority of each dose level of quetiapine using an Analysis of Covariance (ANCOVA) with the baseline MADRS as the covariate and including treatment and diagnosis strata as fixed effects and center as a random effect in the model.

As noted in section 4.1, the primary analysis will have the significance of the pairwise comparisons with placebo ordered and compared to the cut off values for the Simes- Himmel step up procedure to preserve the overall experiment wise error rate and conserve power.

The primary analysis will use the ITT population with a second analysis performed on the PP population to assess sensitivity of results to population.

4.2.2 Secondary efficacy analysis

All secondary analyses are made in order to yield supportive evidence that quetiapine is more effective than placebo. These analyses will use the ITT population and will mainly be presented as point estimates with associated 95% confidence intervals for the treatment effects and the difference between groups. The confidence levels and p-values displayed will be nominal with no adjustment for multiplicity issues.

4.2.2.1 Response

Analysis of the MADRS total score will test the differences between treatment and placebo in response rates at each visit assessment and final assessment (LOCF) using a Cochran-Mantel-Haenszel Chi square test across diagnosis strata. Summary statistics (number and % in each treatment group responding) will be presented along with the p-values and estimated odds ratio with 95% confidence interval. The model will be fit using the PROC FREQ procedure in SAS®. The Breslow Day statistic will be used to evaluate homogeneity of response across the bipolar diagnosis strata.

4.2.2.2 HAM-D

Descriptive statistics will be presented for HAM-D total score, HAM-D Item 1 score, change from baseline for HAM-D total score and change from baseline HAM-D Item 1 by visit and final assessment (LOCF). The ANCOVA model will be used with baseline as a covariate and treatment and diagnosis strata as fixed effects.

4.2.2.3 CGI

Descriptive statistics will be presented for the CGI-S, CGI-Improvement and change from baseline in CGI-S by visit and final assessment.

Two approaches to analysis will be evaluated; one approach will handle the data as if it were continuous and analyze the Change from baseline CGI-S and CGI-I using an ANCOVA model with baseline CGI-S as a covariate and treatment and diagnosis strata as fixed effects.

In addition the CGI-I will be dichotomised into a binomial response 1=improved, 0=unchanged or worse. This will be assessed in the same manner as MADRS response.

4.2.2.4 YMRS total score

Descriptive statistics will be presented for the YMRS total score and the change from baseline in YMRS total score by visit and at final assessment. The ANCOVA model will be used with the YMRS baseline as a covariate and treatment and diagnosis strata as fixed effects.

4.2.2.5 HAM-A

Descriptive statistics will be presented for the HAM-A total score and the change from baseline in HAM-A total score by visit and at final assessment. The ANCOVA model will be used with the HAM-A baseline as a covariate and treatment and diagnosis strata as fixed effects.

4.2.2.6 PSQI

The PSQI will have a total score calculated as described in section 3.1.5. Descriptive statistics will be presented for the PSQI total score, change from baseline in PSQI total score and itemized response to each question by assessment visit and final assessment. The ANCOVA model will be used for PSQI change from baseline to each assessment and final visit with the baseline PSQI total score as a covariate and treatment and diagnosis strata as fixed effects.

4.2.2.7 Patient reported outcomes –QLESQ

Descriptive statistics of overall level of satisfaction with general activities will be presented for the QLESQ raw total score (sum of items 1 to 14), QLESQ % maximum total score, change from baseline in QLESQ raw total score, and change from baseline in % maximum total score by assessment visit and final assessment. The ANCOVA model will be used for QLESQ change from baseline for both raw total score and % maximum score to each assessment and final visit with the appropriate baseline QLESQ total score as a covariate and treatment and diagnosis strata as fixed effects.

4.3 Analysis supporting safety and tolerability

When statistical tests are performed, the tests will be 2-tailed with a significance level of 0.05 unless otherwise stated. Where appropriate 95% confidence intervals will be presented. The main analysis will be the final assessment (LOCF) for the time period of interest.

All safety analysis will be based on the safety population, but where change from baseline is the primary focus of the analysis, only patients with both baseline and post baseline data will be included.

4.3.1 Movement disorders

Modified SAS total score and BARS global assessment score, including changes from baseline for each, will be summarized by visit using descriptive statistics. Statistics will include the number and percentage of patients with non-normal scores. The difference between treatment groups in the proportion of patients whose scores are greater than baseline at the final assessment will be tested using a logistic regression model. The odds ratio will be calculated for each treatment arm compared to placebo, together with a 95% confidence interval, using results from PROC GENMOD, and will be used to compare treatments.

4.3.2 Rescue medication use

Number of days and percent of the first 21 days with lorazapam use or sleep medication use will be calculated for each patient. If a patient withdraws early, the percent will be calculated based on the number of days in the trial if less than 21. These data will be summarized by treatment group and diagnosis strata using descriptive statistics.

If the number withdrawing before day 21 is greater than 20% or has an imbalance among treatment groups, descriptive statistics will also be provided broken down by completion status.

4.3.3 Study withdrawals

Differences between treatment groups in overall rate of withdrawal and category of withdrawal will be tested using a CMH test stratified by diagnosis. Withdrawals on or before day 8 will be examined as part of the consideration of balance between treatment groups due to early withdrawal.

For each visit (week of study) withdrawals will be summarized in total and by reason for withdrawal using descriptive statistics.

4.3.4 Adverse events

Adverse events will be classified using MedDRA system of nomenclature. Number of events and crude event rates will be tabulated by system organ class and preferred term. An event that occurs one or more times in a patient after randomised treatment counts as 1 event in the numerator of the crude event rate, the denominator is the number at risk in the group.

Events will also be classified as prior to treatment, during treatment, during follow up period. Tabulation of events will include all events during treatment and events reported within 30 days of the last dose of trial medication. All other events will appear only in patient listings.

Adverse events will have the primary assessment by treatment arm and a secondary reporting by treatment and diagnosis strata.

Incidence rates will be tabulated and presented for the following categories: all adverse events, serious adverse events, drug related adverse events, adverse events leading to death, and adverse events leading to withdrawal of patients from the study.

An additional analysis will include an assessment of events during titration, that is an event that started on Day 1-8 of study treatment. This will descriptively assess the impact of the once daily dosing with relatively rapid titration.

Other adverse events of interest including: suicide attempt, suicide ideation, EPS symptoms, mania, agranulocytosis, cerebrovascular events, diabetes, hyperglycemia, and orthostatic hypertension will be summarized by treatment group to explore potential dose response effects in these events.

No formal statistical testing is planned.

4.3.5 Weight analysis

Descriptive statistics will be used to assess changes in weight. No formal analysis is planned, but the change from baseline in weight and BMI will be reported as will shift table summary statistics for n and percentage of patients shifting into a new category, see section 3.2.2.

4.3.6 Laboratory data

The clinical laboratory data will include only those patients with both a baseline and post baseline assessment for summary tables, all data will appear in the listings. The clinical laboratory summary data to be presented in this section include the value at the baseline, final visit and change from baseline to final assessment for the following variables: total bilirubin, alkaline phosphatase, AST, ALT, sodium, potassium, chloride, glucose, insulin, bicarbonate, total cholesterol, HDL and LDL cholesterol, triglycerides, thyroide functioning (TSH, T3RU, T4), creatinine, hemaglobin, hematocrit, RBC, WBC, differential %, platelets. These test results will be tabulated using descriptive statistics by treatment group. Shift tables will be

provided using the criteria defined in Quetiapine project agreed extended normal ranges to identify potentially clinically significant changes (Appendix B).

4.3.7 Vital signs

Vital signs are measured at each visit in both supine and standing position. The data will be summarized using descriptive statistics by visit and as change from baseline at each visit and final assessment for the following variables: supine pulse, diastolic and systolic blood pressure, standing pulse, diastolic and systolic blood pressure, and change in pulse, diastolic and systolic blood pressure related to change in position.

Shift tables of the data as related to the extended normal range defined in Appendix B, quetiapine project specific agreed extended ranges) will be provided for the blood pressure values at baseline and final assessment by treatment group

For each visit the number and percentage of patients with changes, which meet the criteria for an orthostatic change will be calculated for each treatment group also defined in Appendix B.

4.3.8 ECG data

The ECG variables will be summarized for those patients with both a baseline and final assessment. All ECG assessments will be listed. The ECG summary tables will include atrial and ventricular heart rates, PR interval, QRS interval, QT interval and Fridericia QTc interval at baseline, final assessment and change from baseline to final assessment.

Descriptive statistics will be presented for each treatment group.

Shift tables of the interval data based on the criteria found in Appendix B, quetiapine project specific agreed extended ranges, will be provided for baseline and final assessment by treatment group.

4.3.9 Study medication

Patients will be classified by the nominal dose for the treatment group to which they are assigned.

The number and percentage of patients for whom dose reduction was initiated will be tabulated by treatment group. Compliance will be checked versus the adjusted number of tablets expected for the period.

Compliance will be calculated for the study based on tablet counts. For each patient the overall compliance will be assessed as the total number of tablets taken divided by the total number expected to be taken (adjusted for those with the dose reduction). The patient will then be classified as fully compliant (≥ 80%), partially compliant (≥ 70% and <80%), or non-compliant < 70%.

Descriptive statistics will be provided on the category of compliance by treatment group and diagnosis.

4.4 Descriptive statistics definitions

4.4.1 Standard descriptive statistics

Standard descriptive statistics will be used to summarize all continuous or semi-continuous variables (categorical data analyzed using ANCOVA).

N: Number of patients

Mean: Mean value of the assessment, across the N patients

SD: Standard deviation

Min, Median, Max: percentile information

Descriptive statistics used to summarize discrete data will include the following statistics:

N: Number of patients

#: number of counts in the category (e.g. number of events)

%: #/N*100 or percent of N in the category

Further statistics will be included as appropriate for the scale at hand, including but not limited to:

SE: standard error of mean (inclusion will facilitate informal between group comparisons)

Baseline mean: mean baseline for the N patients (useful when n changing due to drop outs)

% of baseline: mean score divided by the baseline mean, for N patients

%Zero, %Positive, %negative: Percent of N patients for whom the score is zero, etc.

%Minimal: Percent of patients showing the minimum value for the assessment (if other than zero for a scale)

Effect size: mean difference between treatments/pooled standard deviation

Confidence Interval: the lower and upper limits of the region which has 95% probability of containing the parameter of interest given the data

4.4.2 Definition of Normal values for scales

The following is a table of the minimum values for the scales used in this study.

Scale/subscale	Normal/Minimum value

MADRS	= 0
HAM-D	= 0
HAM-D Item 1	= 0
YMRS	= 0
HAM-A	= 0
CGI-S	= 1
BARS	≤ 1
SAS	Item 10 ≤ 2 and Items 1-9 = 0
PSQI	= 0
QLESQ	=70 (maximum)

4.5 Missing Data

4.5.1 MADRS

The MADRS total score will be set to missing for any patient for whom more than 1 item is missing at an assessment. If one item is missing, the MADRS total based on the non-missing items will be multiplied by 10 (total number of items) and then divided by 9 (number non-missing). Imputed values will not be rounded to whole numbers.

If more than one MADRS item is missing at a particular visit the data will be handled as follows:

- If the baseline MADRS is considered missing due to more than one item missing, the patient will be considered non-evaluable as they do not have a satisfactory baseline assessment and no change from baseline can be calculated.

- If it is a post baseline visit, then the visit will be excluded for that patient, but data for all other visits with satisfactory assessments will not be excluded. When using the LOCF approach, any missing MADRS total scores will be replaced with the previous satisfactory assessment.

4.5.2 HAM-D

Eligibility –Screening and randomization

In order to qualify for the trial the unadjusted total score must be ≥ 20 and Item 1 (depressed mood) score ≥ 2.

The HAM-D total score will be set to missing for any patient with more than 1 item missing at an assessment, excluding item 16. If one item, other than item 16, is missing, the HAM-D total will be calculated as follows:

- If the missing item is on a 0-2 scale (items 4, 5, 6, 12, 13, 14, 17); multiply the total of the non-missing values by 17 and divide by 16.
- If the missing item is on a 0-4 scale (items 1, 2, 3, 7, 8, 9, 10, 11,15); multiply the total of the non-missing values by 17 and divide by 14.

4.5.3 YMRS

If more than 1 item is missing the total score is considered missing. If there is one item missing the following rules will be used:

- If the missing item is on a 0-4 scale (items 1-4, 7, 10, 11); multiply the total of the non-missing values by 15 and divide by 14
- If the missing item is on the 0-8 scale (items 5, 6, 8, 9); multiply the total of the non-missing values by 15 and divide by 13

Imputed values will not be rounded to whole numbers

Eligibility – Screening and randomization

In order to qualify the adjusted total score needs to be ≤ 12.

4.5.4 HAM-A

If more than 1 item is missing the total score is considered missing. If there is one item missing then the total score is imputed as follows: multiply the total of the non-missing values by 14 and divide by 13.

4.5.5 SAS

The SAS total score will be taken to be missing for any patient for whom more than one item is missing. If one item is missing, the SAS total score based on the non-missing items will be multiplied by 10 (total number of items) and then divided by 9 (number non-missing). Imputed values will not be rounded to whole numbers.

4.5.6 PSQI

If the data is not available to calculate a component score the component score will be set to missing and the total score will be set to missing.

4.5.7 Q-Les-Q

If more than 1 of the first 14 items is missing the total score is considered missing. If there is one item missing then the total score is imputed as follows: multiply the total of the non-missing values by 14 and divide by 13.

5. INTERIM ANALYSES

No interim analysis is planned for this study.

6. CHANGES OF ANALYSIS FROM PROTOCOL

The definition of the PP population was changed to be a patient with at least one post titration assessment, that is a patient who completed at least 8 days of dosing with study medication. Patients dropping out prior to day 8 of dosing will be handled in the ITT efficacy and the safety and tolerability section.

MADRS assessment obtained > 4 days after the last dose of study medication will not be included in PP population efficacy analysis.

7. REFERENCES

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2. SAS Institute Inc.: SAS/STAT® User's Guide, Version 8; Cary, NC 1999.

3. Simes-Hommel, G: A comparison of two modified Bonferonni procedures. Biometrika 1988; 75: 39-51.

4. Snedecor, GW and Cochran, WG: Statistical Methods, Iowa State University Press; Ames, Iowa 1989.

APPENDIX A. PROTOCOL VIOLATIONS AND DEVIATIONS

Code	Criteria	Computer	Manual	Both	Exclude PP	Exclu
	Inclusion Criteria					
I01	documented ability to provide IC before beginning any study-specific procedures	Yes			Yes	Yes
I02	Male or female patient between 18 & 65 years of age, inclusive	Yes			No	No
I03	Females of childbearing potential, be using reliable method of contraception	Yes			No	No
I04	Women must have negative pregnancy test	Yes			No	No
I05	Meets DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89x), confirmed by SCID	Yes			Yes	No
I06	outpatient status	Yes			No	No
I07	HAM-D (17-item) total score of 20 or greater	Yes			Yes	No
I08	HAM-D item 1 (depressed mood) score >=2	Yes			Yes	No
I09	YMRS total <= 12	Yes			Yes	No
	Exclusion Criteria					
E01	Patients with current Axis I disorder other than bipolar disorder within 6 months of screening	Yes			No	No
E02	Patients whose depression episode exceeds 12 months or is less than 4 weeks			Yes	Yes	Decisi review
E03	History of non-response to an adequate trial (6 weeks) of more than 2 classes of antidepressants during their current episode			Yes	Yes	No
E04	Patients who meet DSM-IV criteria for substance dependence, for any substance except nicotine, within 12 months of screening	Yes			Yes	No
E05	Patients with positive UDS for illicit substances of abuse	Yes			No	No
E06	Patients who are unable to discontinue all psychoactive medications (excluding benzodiazepines) ar least 7 days prior to randomization [fluoxetine 14 days prior; haloperiodol decanoate or fluphenazine decanoate 28 days prior]			Yes	Decision on review	No
E07	Patients who have not discontinued use of potent P450 inhibitors and inducers			Yes	Decision on review	No
E08	Patients who in the investigator's opinion will require initiation of psychotherapy during the study period	Yes			No	No
E09	Patients who in the investigator's judgment pose a serious suicidal or homicidal risk at Visit 1	Yes			No	No
E10	Patients with a history of clinically significant disease	Yes			No	No
E11	Patients who have had an MI within 1 year before Visit 1	Yes			No	No
E12	Patients with clinically significant abnormal laboratory findings	Yes			No	No
E13	Patients with renal impairment (serum creatinine >=1.5 mg/dl) or hepatic impairment (AST or ALT 3 times the ULN)	Yes			No	No

Code	Criteria	Compu ter	Manual	Both	Exclude PP	Exclu
E14	Patients whose TSH is > 10% over the ULN, Patients on thyroid medication must be euthyroid for at least 3 months			Yes	No	No
E15	Patients with clinically significant abnormalities on ECG	Yes			No	No
E16	Women who have positive HCG pregnancy test at Visit 1, lactating or planning to become pregnant during the course of the study	Yes			No	No
E17	Patients who have participated in a clinical trial of an investigational drug within the past 3 months			Yes	Yes	Decisi review
E18	Patients who, in the opinion of the investigator, would be non compliant with visit schedule or study procedures	Yes			No	No
E19	History of orthostatis hypotension or conditions which would predispose them to hypotension (eg dehydration, hypovolemia)			Yes	No	No
E20	Known history of intolerance, hypersensitivity, or lack of response to quetiapine or any of its components	Yes			No	No
	Deviations Leading to Exclusion from the PP Analysis					No
D01	Patients who take more than 10 mg of zolpidem tartrate for insomnia in first 3 weeks	Yes			Decision on review	No
D02	Patients who take more than 3mg/day of lorazepam for severe anxiety in first 3 weeks	Yes			Decision on review	No
D03	Patients who take zolpidem tartrate or lorazepam after Week 3			Yes	Decision on review	No
D04	Patients who take potent cytochrome P450 3A4 inducers	Yes			Decision on review	No
D05	Patients who take potent cytochrome P450 3A4 inhibitors	Yes			Decision on review	No
D06	Patients who take any antipsychotics during treatment			Yes	Decision on review	No
D07	Patients who take any antidepressants, hypnotics, mood stabilizing drugs during treatment			Yes	Decision on review	No
D08	Patients who reduce trial medication by more than 100 mg			Yes	Decision on review	No
D09	Patients who receive any dose reduction before day 8	Yes			Yes	No
D10	Patients who receive less than 70% of prescribed doses	Yes			Yes	No
D11	Patient does not have both baseline & post baseline assessment (MADRS)	Yes			Yes	Yes
D12	Patients who receive <= 8 days of trial therapy	Yes			Yes	No
D13	Patients who fail to receive prescribed trial medication-randomized but not dosed	Yes			Yes	Yes

Code	Criteria	Computer	Manual	Both	Exclude PP	Exclu
D14	Patients who receive incorrect randomized trial medication		Yes		Decision on review	No
D15	Patients who fail to complete visit required assessments	Yes			No	No
D16	Patients who miss 10 cumulative doses or 3 consecutive days of trial medication				No	No
D17	Psychiatric scale data (MADRS) collected >4 days after last dose of study medication	Yes			Yes	No
D18	Documented drug abuse during study	Yes			Yes	No

APPENDIX B. DEFINITIONS OF POTENTIALLY CLINICALLY SIGNIFICANT LABORATORY VALUES, VITAL SIGNS, AND ELECTROCARDIOGRAPHIC DATA

Definition of potentially clinically significant clinical laboratory values

Hematology laboratory parameter		Potentially significant values
Hematocrit		males ≤ 0.37; ≥0.50 vol fraction females ≤ 0.32; ≥0.55 vol fraction
Hemoglobin		males ≤ 11.5 g/dL; ≥ 18.5 g/dL females ≤ 9.5 g/dL; ≥ 16.5 g/dL
RBC		≤ 3 x 10^{12} cells/L; ≥ 6 x 10^{12} cells/L
Platelet count		≤ 75 x 10^{9} cells/L; ≥ 700 x 10^{9} cells/L
WBC		≤ 2.8 x 10^{9} cells/L; ≥ 16.0 x 10^{9} cells/L
Neutrophils	-- percent	≤ 15%
	-- absolute (calculated)	≤ 1.5 x 10^{9} cells/L
Eosinophils	-- percent	≥ 10%
	-- absolute (calculated)	> 450 x 10^{6} cells/L
Basophils		> 3%
Lymphocytes		≤ 10%
Monocytes		> 20%

Chemistry laboratory parameter	Potentially significant values
ALT	≥ 3 x ULN
AST	≥ 3 x ULN
Alkaline phosphatase	≥ 3 x ULN
Total Bilirubin	≥ 2.0mg/dL
Uric acid	females ≥ 8.5mg/dL; males ≥ 10.5mg/dL
Sodium	≤ 129 mmol/L; ≥ 160 mmol/L
Glucose	≤ 50.0mg/dL; ≥ 230.0mg/dL
BUN	≥ 30mg/dL
Creatinine	≥ 2.1mg/dL
Potassium	<3.0mEq/L; >5.5mEq/L
Chloride	<90mEq/L; >120mEq/L
CO_2	<18mEq/L; >30mEq/L
Total cholesterol	> 200 mg/dL
HDL	< 35 mg/dL; > 65 mg/dL
LDL	< 130 mg/dL; > 160 mg/dL
Triglicerides	> 250 mg/dL
Total T4 and Free T4	< 0.8 x LLN; >1.2 x ULN
TSH	> 5 mU/L

Definitions of potentially clinically significant vital signs and weight

Vital sign	Criterion value	Change from baseline
Systolic blood pressure	≥ 180 mm Hg	increase ≥ 20 mm Hg
	≤ 90 mm Hg	decrease ≥ 20 mm Hg
Diastolic blood pressure	≥ 105 mm Hg	increase ≥ 30 mm Hg
	≤ 50 mm Hg	decrease ≥ 20 mm Hg
Pulse	> 120 bpm	increase ≥ 15 bpm
	< 50 bpm	decrease ≥ 15 bpm
Temperature	> 38.3°C	Change≥1.11°C
Weight	--	change ≥ 7% body weight

Orthostatic changes	
Systolic blood pressure or	decrease ≥ 20 mm Hg from supine to standing after 1 min
Diastolic blood pressure	decrease ≥ 15 mm Hg from supine to standing after 1 min
Pulse	increase ≥ 20 bpm from supine to standing after 1 min
Combined	decrease ≥ 20 mm Hg in systolic BP and increase ≥ 20 BPM in pulse rate

Definition of potentially clinically significant electrocardiogram parameters

ECG parameter	Criterion value	Change from baseline
Heart rate	> 120 bpm	increase ≥ 15 bpm
	< 50 bpm	decrease ≥ 15 bpm
PR	≥ 210 msec	
QRS	≤ 50 msec	
	≥ 150 msec	
QT	≥ 500 msec	
	≤ 200 msec	
QT_C (Fridericia Correction)	≥ 450 msec	
PQ	≥ 200 msec	
	≤ 120 msec	

Supporting Statistical Analysis

TABLE OF CONTENTS

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Table 1 of trtseq by complete
Controlling for numcd=1

trtseq complete

Frequency Percent Row Pct Col Pct	0	1	Total
1	35 14.71 29.17 39.77	85 35.71 70.83 56.67	120 50.42
3	53 22.27 44.92 60.23	65 27.31 55.08 43.33	118 49.58
Total	88 36.97	150 63.03	238 100.00

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Statistics for Table 1 of trtseq by complete
Controlling for numcd=1

Statistic	DF	Value	Prob
Chi-Square	1	6.3321	0.0119
Likelihood Ratio Chi-Square	1	6.3657	0.0116
Continuity Adj. Chi-Square	1	5.6744	0.0172
Mantel-Haenszel Chi-Square	1	6.3055	0.0120
Phi Coefficient		-0.1631	
Contingency Coefficient		0.1610	
Cramer's V		-0.1631	

Fisher's Exact Test

Cell (1,1) Frequency (F)	35
Left-sided Pr <= F	0.0085
Right-sided Pr >= F	0.9961
Table Probability (P)	0.0046
Two-sided Pr <= P	0.0155

Sample Size = 238

4

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Table 2 of trtseq by complete
Controlling for numcd=2

trtseq complete

Frequency Percent Row Pct Col Pct	0	1	Total
1	23 19.01 38.98 53.49	36 29.75 61.02 46.15	59 48.76
3	20 16.53 32.26 46.51	42 34.71 67.74 53.85	62 51.24
Total	43 35.54	78 64.46	121 100.00

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Statistics for Table 2 of trtseq by complete
Controlling for numcd=2

Statistic	DF	Value	Prob
Chi-Square	1	0.5968	0.4398
Likelihood Ratio Chi-Square	1	0.5971	0.4397
Continuity Adj. Chi-Square	1	0.3394	0.5602
Mantel-Haenszel Chi-Square	1	0.5919	0.4417
Phi Coefficient		0.0702	
Contingency Coefficient		0.0701	
Cramer's V		0.0702	

Fisher's Exact Test

Cell (1,1) Frequency (F)	23
Left-sided Pr <= F	0.8321
Right-sided Pr >= F	0.2801
Table Probability (P)	0.1122
Two-sided Pr <= P	0.4545

Sample Size = 121

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Summary Statistics for trtseq by complete
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	2.5747	0.1086
2	Row Mean Scores Differ	1	2.5747	0.1086
3	General Association	1	2.5747	0.1086

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.7051	0.4591	1.0830
	Logit	0.7037	0.4555	1.0872
Cohort (Col1 Risk)	Mantel-Haenszel	0.7989	0.6059	1.0533
	Logit	0.8003	0.6052	1.0583
Cohort (Col2 Risk)	Mantel-Haenszel	1.1378	0.9704	1.3341
	Logit	1.1318	0.9648	1.3278

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	4.3820
DF	1
Pr > ChiSq	0.0363

Total Sample Size = 359

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Table 1 of trtseq by complete
Controlling for numcd=1

trtseq complete

Frequency Percent Row Pct Col Pct	0	1	Total
2	52 21.85 43.33 49.52	68 28.57 56.67 51.13	120 50.42
3	53 22.27 44.92 50.48	65 27.31 55.08 48.87	118 49.58
Total	105 44.12	133 55.88	238 100.00

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Statistics for Table 1 of trtseq by complete
Controlling for numcd=1

Statistic	DF	Value	Prob
Chi-Square	1	0.0604	0.8059
Likelihood Ratio Chi-Square	1	0.0604	0.8059
Continuity Adj. Chi-Square	1	0.0133	0.9083
Mantel-Haenszel Chi-Square	1	0.0601	0.8063
Phi Coefficient		-0.0159	
Contingency Coefficient		0.0159	
Cramer's V		-0.0159	

Fisher's Exact Test

Cell (1,1) Frequency (F)	52
Left-sided Pr <= F	0.4541
Right-sided Pr >= F	0.6466
Table Probability (P)	0.1008
Two-sided Pr <= P	0.8962

Sample Size = 238

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Table 2 of trtseq by complete
Controlling for numcd=2

trtseq complete

Frequency Percent Row Pct Col Pct	0	1	Total
2	30 24.59 50.00 60.00	30 24.59 50.00 41.67	60 49.18
3	20 16.39 32.26 40.00	42 34.43 67.74 58.33	62 50.82
Total	50 40.98	72 59.02	122 100.00

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Statistics for Table 2 of trtseq by complete
Controlling for numcd=2

Statistic	DF	Value	Prob
Chi-Square	1	3.9683	0.0464
Likelihood Ratio Chi-Square	1	3.9901	0.0458
Continuity Adj. Chi-Square	1	3.2686	0.0706
Mantel-Haenszel Chi-Square	1	3.9358	0.0473
Phi Coefficient		0.1804	
Contingency Coefficient		0.1775	
Cramer's V		0.1804	

Fisher's Exact Test

Cell (1,1) Frequency (F)	30
Left-sided Pr <= F	0.9854
Right-sided Pr >= F	0.0351
Table Probability (P)	0.0205
Two-sided Pr <= P	0.0653

Sample Size = 122

12.1.9.1.1 Withdrawal Analysis (CMH)

The FREQ Procedure

Summary Statistics for trtseq by complete
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	0.9009	0.3425
2	Row Mean Scores Differ	1	0.9009	0.3425
3	General Association	1	0.9009	0.3425

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	1.2228	0.8065	1.8539
	Logit	1.2205	0.8020	1.8574
Cohort (Col1 Risk)	Mantel-Haenszel	1.1222	0.8839	1.4248
	Logit	1.1104	0.8735	1.4114
Cohort (Col2 Risk)	Mantel-Haenszel	0.9164	0.7645	1.0983
	Logit	0.9150	0.7629	1.0973

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	3.1298
DF	1
Pr > ChiSq	0.0769

Total Sample Size = 360

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/DEM209H.SAS
GENERATED: 14JUL2005 11:40:24 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	509
Observations Used	509
Observations Not Used	0
Total Observations	509

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3449.42724722	
1	3	3435.87288227	0.00017546
2	1	3435.62379301	0.00000963
3	1	3435.61125296	0.00000003
4	1	3435.61120912	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	3.1091
Residual	48.4488

Fit Statistics

-2 Res Log Likelihood	3435.6
AIC (smaller is better)	3439.6
AICC (smaller is better)	3439.6
BIC (smaller is better)	3442.7

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			5.7485	2.0450	464	2.81	0.0051
trtseq		Q300MG	-3.7863	0.7672	500	-4.94	<.0001
trtseq		Q600MG	-3.8949	0.7716	502	-5.05	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.6223	0.7177	435	0.87	0.3864
numcd	2		0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
B_MADRS			-0.3597	0.06223	498	-5.78	<.0001

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.5203	1.6184	12.2	-0.32	0.7533
CENTRE	0002	0.3129	1.3992	21.4	0.22	0.8252
CENTRE	0003	-0.7437	1.3665	23.4	-0.54	0.5914
CENTRE	0004	0.5729	1.3234	26.3	0.43	0.6687
CENTRE	0005	0.2846	1.0869	49.9	0.26	0.7945
CENTRE	0006	1.1441	1.5050	16.2	0.76	0.4581
CENTRE	0007	1.9807	1.3669	23.4	1.45	0.1606
CENTRE	0009	-0.8176	1.3954	21.6	-0.59	0.5640
CENTRE	0010	-1.1040	1.2654	30.8	-0.87	0.3897
CENTRE	0011	-0.02775	1.2870	29	-0.02	0.9829
CENTRE	0013	-1.2142	1.3903	22	-0.87	0.3919
CENTRE	0014	-1.0996	1.2842	29.3	-0.86	0.3988
CENTRE	0015	0.5795	1.5385	14.9	0.38	0.7117
CENTRE	0016	-0.2058	1.5772	13.5	-0.13	0.8981
CENTRE	0018	0.4520	1.3649	23.5	0.33	0.7434
CENTRE	0019	-1.7545	1.0720	51.4	-1.64	0.1078
CENTRE	0020	-0.2820	1.2847	29.2	-0.22	0.8278
CENTRE	0022	1.3064	0.9278	72.1	1.41	0.1634
CENTRE	0023	2.1359	1.0114	60.2	2.11	0.0389
CENTRE	0025	-0.1144	1.6612	11	-0.07	0.9463
CENTRE	0026	-0.8157	1.1967	37.2	-0.68	0.4997
CENTRE	0027	1.1045	1.5799	13.4	0.70	0.4965
CENTRE	0028	1.4556	1.1260	45	1.29	0.2027
CENTRE	0029	1.1548	1.1843	38.5	0.98	0.3356
CENTRE	0030	0.1351	1.3241	26.2	0.10	0.9195
CENTRE	0031	-2.2609	1.1704	39.9	-1.93	0.0605
CENTRE	0033	1.6181	1.3482	24.6	1.20	0.2415
CENTRE	0034	0.1030	1.4733	17.6	0.07	0.9451
CENTRE	0035	-0.01366	1.2301	34	-0.01	0.9912

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0036	-0.02281	1.5782	13.5	-0.01	0.9887
CENTRE	0037	0.006029	1.4422	19.1	0.00	0.9967
CENTRE	0039	-3.0031	1.0882	49.8	-2.76	0.0081
CENTRE	0040	0.5186	1.6629	10.9	0.31	0.7610
CENTRE	0041	-0.3804	1.3914	21.9	-0.27	0.7871
CENTRE	0042	-0.4841	1.6620	11	-0.29	0.7763

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	16.48	<.0001
numcd	1	435	0.75	0.3864
B_MADRS	1	498	33.42	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-8.6723	0.6469	122	-13.41	<.0001	0.05	-9.9529	-7.3918
trtseq	Q600MG	-8.7809	0.6521	122	-13.47	<.0001	0.05	-10.0719	-7.4900
trtseq	P	-4.8860	0.6495	116	-7.52	<.0001	0.05	-6.1724	-3.5997

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.1086	0.7595	490	0.14	0.8863	0.05	-1.3836	1.6008
trtseq	Q300MG	P	-3.7863	0.7672	500	-4.94	<.0001	0.05	-5.2936	-2.2790
trtseq	Q600MG	P	-3.8949	0.7716	502	-5.05	<.0001	0.05	-5.4109	-2.3789

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3606.50755336	
1	2	3598.52467288	0.00000005
2	1	3598.52460096	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	3.5314
Residual	65.3919

Fit Statistics

-2 Res Log Likelihood	3598.5
AIC (smaller is better)	3602.5
AICC (smaller is better)	3602.5
BIC (smaller is better)	3605.6

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			5.0274	2.3574	454	2.13	0.0335
trtseq		Q300MG	-4.7091	0.8891	502	-5.30	<.0001
trtseq		Q600MG	-4.4899	0.8938	504	-5.02	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.2728	0.8269	402	0.33	0.7416
numcd	2		0	.	.	.	.
B_MADRS			-0.4069	0.07178	495	-5.67	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.4842	1.7466	7.95	-0.28	0.7887
CENTRE	0002	0.3888	1.5359	13.2	0.25	0.8041
CENTRE	0003	-0.2706	1.5037	14.3	-0.18	0.8597
CENTRE	0004	-0.8118	1.4606	15.9	-0.56	0.5861
CENTRE	0005	-0.4776	1.2166	30	-0.39	0.6974
CENTRE	0006	1.8583	1.6392	10.2	1.13	0.2828
CENTRE	0007	0.9023	1.5041	14.3	0.60	0.5580
CENTRE	0009	1.1241	1.5323	13.3	0.73	0.4759
CENTRE	0010	1.3186	1.4019	18.5	0.94	0.3590
CENTRE	0011	1.0717	1.4238	17.5	0.75	0.4617
CENTRE	0013	0.6584	1.5273	13.5	0.43	0.6732
CENTRE	0014	-1.7410	1.4210	17.6	-1.23	0.2366
CENTRE	0015	0.7128	1.6713	9.48	0.43	0.6793
CENTRE	0016	0.1687	1.7079	8.69	0.10	0.9235
CENTRE	0018	-0.3517	1.5021	14.3	-0.23	0.8182
CENTRE	0019	-1.3228	1.1934	31.5	-1.11	0.2761
CENTRE	0020	0.3555	1.4214	17.6	0.25	0.8054
CENTRE	0022	0.1317	1.0455	45.2	0.13	0.9004
CENTRE	0023	1.4705	1.1360	36.7	1.29	0.2036
CENTRE	0025	0.3864	1.7863	7.26	0.22	0.8347
CENTRE	0026	0.08000	1.3164	23.2	0.06	0.9521
CENTRE	0027	-0.8516	1.7105	8.64	-0.50	0.6310
CENTRE	0028	0.9326	1.2576	27	0.74	0.4648
CENTRE	0029	0.4721	1.3185	23	0.36	0.7236
CENTRE	0030	-0.4853	1.4613	15.9	-0.33	0.7441
CENTRE	0031	-0.6952	1.3040	23.8	-0.53	0.5989
CENTRE	0033	2.0318	1.4854	14.9	1.37	0.1916
CENTRE	0034	-0.04555	1.6086	11	-0.03	0.9779
CENTRE	0035	-0.4271	1.3658	20.4	-0.31	0.7577
CENTRE	0036	-1.9139	1.7089	8.67	-1.12	0.2928
CENTRE	0037	0.5483	1.5784	11.9	0.35	0.7344
CENTRE	0039	-3.9774	1.2179	29.9	-3.27	0.0027
CENTRE	0040	0.1733	1.7879	7.24	0.10	0.9254
CENTRE	0041	-0.01912	1.5284	13.4	-0.01	0.9902
CENTRE	0042	-0.9107	1.7871	7.25	-0.51	0.6255

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	17.63	<.0001
numcd	1	402	0.11	0.7416
B_MADRS	1	495	32.13	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-11.9215	0.7349	107	-16.22	<.0001	0.05	-13.3784	-10.4645
trtseq	Q600MG	-11.7022	0.7403	106	-15.81	<.0001	0.05	-13.1699	-10.2345
trtseq	P	-7.2123	0.7384	102	-9.77	<.0001	0.05	-8.6770	-5.7477

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.2193	0.8792	490	-0.25	0.8032	0.05	-1.9467	1.5082
trtseq	Q300MG	P	-4.7091	0.8891	502	-5.30	<.0001	0.05	-6.4559	-2.9624
trtseq	Q600MG	P	-4.4899	0.8938	504	-5.02	<.0001	0.05	-6.2460	-2.7338

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3712.00144171	
1	2	3705.45311800	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	3.9070
Residual	81.0054

Fit Statistics

-2 Res Log Likelihood	3705.5
AIC (smaller is better)	3709.5
AICC (smaller is better)	3709.5
BIC (smaller is better)	3712.6

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.3663	2.6149	451	1.67	0.0957
trtseq		Q300MG	-4.7981	0.9887	503	-4.85	<.0001
trtseq		Q600MG	-5.0884	0.9937	505	-5.12	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.2710	0.9162	389	-0.30	0.7675
numcd	2		0	.	.	.	.
B_MADRS			-0.4172	0.07971	493	-5.23	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.7476	1.8506	6.87	-0.40	0.6985
CENTRE	0002	0.5926	1.6444	10.9	0.36	0.7254
CENTRE	0003	0.1808	1.6123	11.8	0.11	0.9126
CENTRE	0004	-1.5207	1.5691	13.1	-0.97	0.3501
CENTRE	0005	0.7514	1.3194	24.2	0.57	0.5743
CENTRE	0006	1.5187	1.7464	8.65	0.87	0.4080
CENTRE	0007	1.3641	1.6128	11.8	0.85	0.4145
CENTRE	0009	0.2574	1.6408	11	0.16	0.8782
CENTRE	0010	1.5404	1.5099	15.1	1.02	0.3237
CENTRE	0011	0.6066	1.5320	14.3	0.40	0.6980
CENTRE	0013	0.04215	1.6359	11.2	0.03	0.9799
CENTRE	0014	-2.1907	1.5292	14.4	-1.43	0.1733
CENTRE	0015	0.9146	1.7777	8.06	0.51	0.6207
CENTRE	0016	-1.0834	1.8132	7.45	-0.60	0.5679
CENTRE	0018	-0.3367	1.6108	11.9	-0.21	0.8380
CENTRE	0019	-0.1624	1.2951	25.5	-0.13	0.9012
CENTRE	0020	1.0577	1.5296	14.4	0.69	0.5003
CENTRE	0022	-0.08693	1.1395	37	-0.08	0.9396
CENTRE	0023	1.5531	1.2350	29.7	1.26	0.2184
CENTRE	0025	0.5304	1.8886	6.33	0.28	0.7878
CENTRE	0026	0.2471	1.4225	18.8	0.17	0.8639
CENTRE	0027	-1.3784	1.8157	7.41	-0.76	0.4712
CENTRE	0028	1.1035	1.3619	21.8	0.81	0.4266
CENTRE	0029	0.9445	1.4247	18.6	0.66	0.5155
CENTRE	0030	-0.07167	1.5699	13.1	-0.05	0.9643
CENTRE	0031	0.1673	1.4098	19.3	0.12	0.9068
CENTRE	0033	0.9479	1.5941	12.3	0.59	0.5629
CENTRE	0034	-0.1761	1.7164	9.26	-0.10	0.9205
CENTRE	0035	0.5145	1.4731	16.6	0.35	0.7313
CENTRE	0036	-1.4958	1.8142	7.44	-0.82	0.4353
CENTRE	0037	-0.4328	1.6866	9.92	-0.26	0.8027
CENTRE	0039	-4.1828	1.3208	24.1	-3.17	0.0041
CENTRE	0040	0.1066	1.8901	6.31	0.06	0.9568
CENTRE	0041	-0.4986	1.6370	11.1	-0.30	0.7663
CENTRE	0042	-0.5768	1.8893	6.32	-0.31	0.7700

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	16.47	<.0001
numcd	1	389	0.09	0.7675
B_MADRS	1	493	27.40	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-13.2581	0.8078	109	-16.41	<.0001	0.05	-14.8590	-11.6572
trtseq	Q600MG	-13.5484	0.8136	108	-16.65	<.0001	0.05	-15.1610	-11.9359
trtseq	P	-8.4600	0.8113	105	-10.43	<.0001	0.05	-10.0688	-6.8513

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.2903	0.9782	490	0.30	0.7668	0.05	-1.6316	2.2123
trtseq	Q300MG	P	-4.7981	0.9887	503	-4.85	<.0001	0.05	-6.7405	-2.8557
trtseq	Q600MG	P	-5.0884	0.9937	505	-5.12	<.0001	0.05	-7.0408	-3.1360

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3751.95004012	
1	2	3741.91530070	0.00000055
2	1	3741.91451996	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	5.9228
Residual	86.2492

Fit Statistics

-2 Res Log Likelihood	3741.9
AIC (smaller is better)	3745.9
AICC (smaller is better)	3745.9
BIC (smaller is better)	3749.0

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			5.6987	2.7285	455	2.09	0.0373
trtseq		Q300MG	-4.9151	1.0231	500	-4.80	<.0001
trtseq		Q600MG	-6.7756	1.0290	503	-6.58	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.2505	0.9588	424	-0.26	0.7940
numcd	2		0	.	.	.	.
B_MADRS			-0.4777	0.08285	499	-5.77	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.7439	2.2216	10	-0.33	0.7447
CENTRE	0002	-0.2321	1.9069	18.1	-0.12	0.9045
CENTRE	0003	2.4104	1.8608	19.9	1.30	0.2100
CENTRE	0004	-2.2125	1.8001	22.4	-1.23	0.2318
CENTRE	0005	0.3052	1.4704	43.3	0.21	0.8366
CENTRE	0006	1.1702	2.0580	13.6	0.57	0.5789
CENTRE	0007	-0.1875	1.8614	19.9	-0.10	0.9208
CENTRE	0009	1.2093	1.9018	18.3	0.64	0.5327
CENTRE	0010	1.9595	1.7186	26.4	1.14	0.2644
CENTRE	0011	-0.4478	1.7489	24.8	-0.26	0.8000
CENTRE	0013	-0.4527	1.8945	18.6	-0.24	0.8138
CENTRE	0014	-2.2977	1.7449	25.1	-1.32	0.1998
CENTRE	0015	1.2466	2.1061	12.4	0.59	0.5646
CENTRE	0016	-1.1591	2.1618	11.2	-0.54	0.6024
CENTRE	0018	-0.3706	1.8586	20	-0.20	0.8440
CENTRE	0019	-1.0368	1.4406	45.2	-0.72	0.4754
CENTRE	0020	2.2486	1.7455	25	1.29	0.2094
CENTRE	0022	-0.1644	1.2521	62.1	-0.13	0.8959
CENTRE	0023	1.2599	1.3664	52.1	0.92	0.3608
CENTRE	0025	0.3116	2.2838	8.97	0.14	0.8945
CENTRE	0026	-0.2165	1.6023	33.5	-0.14	0.8933
CENTRE	0027	-2.0975	2.1659	11.1	-0.97	0.3535
CENTRE	0028	1.2361	1.5243	39	0.81	0.4223
CENTRE	0029	2.7292	1.6053	33.2	1.70	0.0985
CENTRE	0030	0.5782	1.8011	22.4	0.32	0.7512
CENTRE	0031	-0.3308	1.5860	34.5	-0.21	0.8360
CENTRE	0033	2.2548	1.8350	20.9	1.23	0.2328
CENTRE	0034	-1.1848	2.0127	14.8	-0.59	0.5650
CENTRE	0035	0.8959	1.6690	29.3	0.54	0.5955
CENTRE	0036	-2.3734	2.1633	11.1	-1.10	0.2957
CENTRE	0037	0.8554	1.9683	16.1	0.43	0.6696
CENTRE	0039	-4.7880	1.4722	43.1	-3.25	0.0022
CENTRE	0040	0.5759	2.2863	8.93	0.25	0.8068
CENTRE	0041	0.1502	1.8961	18.5	0.08	0.9377
CENTRE	0042	-1.1007	2.2850	8.95	-0.48	0.6416

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	496	23.04	<.0001
numcd	1	424	0.07	0.7940
B_MADRS	1	499	33.25	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-13.8740	0.8696	94.9	-15.95	<.0001	0.05	-15.6004	-12.1475
trtseq	Q600MG	-15.7345	0.8760	94.5	-17.96	<.0001	0.05	-17.4738	-13.9953
trtseq	P	-8.9589	0.8744	90.4	-10.25	<.0001	0.05	-10.6960	-7.2218

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	1.8606	1.0105	488	1.84	0.0662	0.05	-0.1249	3.8460
trtseq	Q300MG	P	-4.9151	1.0231	500	-4.80	<.0001	0.05	-6.9252	-2.9050
trtseq	Q600MG	P	-6.7756	1.0290	503	-6.58	<.0001	0.05	-8.7973	-4.7540

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3786.89243020	
1	2	3781.34442127	0.00000005
2	1	3781.34435516	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	4.2916
Residual	94.2407

Fit Statistics

-2 Res Log Likelihood	3781.3
AIC (smaller is better)	3785.3
AICC (smaller is better)	3785.4
BIC (smaller is better)	3788.5

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.1148	2.8157	448	1.46	0.1446
trtseq		Q300MG	-5.7254	1.0659	503	-5.37	<.0001
trtseq		Q600MG	-6.2007	1.0713	505	-5.79	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.5313	0.9860	380	-0.54	0.5903
numcd	2		0	.	.	.	.
B_MADRS			-0.4293	0.08587	491	-5.00	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.5119	1.9462	6.17	-0.26	0.8011
CENTRE	0002	0.7264	1.7382	9.63	0.42	0.6852
CENTRE	0003	0.2867	1.7056	10.4	0.17	0.8697
CENTRE	0004	-1.5842	1.6614	11.5	-0.95	0.3600
CENTRE	0005	-0.08422	1.4038	21	-0.06	0.9527
CENTRE	0006	1.3322	1.8415	7.69	0.72	0.4908
CENTRE	0007	0.7429	1.7060	10.4	0.44	0.6722
CENTRE	0009	0.9848	1.7345	9.71	0.57	0.5831
CENTRE	0010	0.7379	1.6007	13.2	0.46	0.6523
CENTRE	0011	0.1582	1.6234	12.5	0.10	0.9239
CENTRE	0013	-0.3160	1.7296	9.83	-0.18	0.8587
CENTRE	0014	-1.4656	1.6206	12.6	-0.90	0.3828
CENTRE	0015	0.7248	1.8731	7.19	0.39	0.7100
CENTRE	0016	-1.1269	1.9088	6.67	-0.59	0.5744
CENTRE	0018	0.3685	1.7040	10.4	0.22	0.8330
CENTRE	0019	-1.0992	1.3784	22.1	-0.80	0.4336
CENTRE	0020	0.9623	1.6209	12.6	0.59	0.5633
CENTRE	0022	-0.5705	1.2156	32.3	-0.47	0.6420
CENTRE	0023	0.4094	1.3157	25.8	0.31	0.7582
CENTRE	0025	0.4485	1.9842	5.71	0.23	0.8291
CENTRE	0026	0.3247	1.5107	16.3	0.21	0.8325
CENTRE	0027	-1.0389	1.9113	6.63	-0.54	0.6045
CENTRE	0028	0.7520	1.4479	18.9	0.52	0.6095
CENTRE	0029	3.1399	1.5130	16.2	2.08	0.0542
CENTRE	0030	0.2699	1.6622	11.4	0.16	0.8738
CENTRE	0031	-0.2667	1.4975	16.8	-0.18	0.8608
CENTRE	0033	1.9066	1.6869	10.8	1.13	0.2828
CENTRE	0034	-1.1432	1.8113	8.21	-0.63	0.5451
CENTRE	0035	0.3066	1.5629	14.4	0.20	0.8472
CENTRE	0036	-1.7355	1.9098	6.65	-0.91	0.3952
CENTRE	0037	0.9704	1.7811	8.77	0.54	0.5994
CENTRE	0039	-3.8561	1.4052	20.9	-2.74	0.0122
CENTRE	0040	-0.1926	1.9857	5.69	-0.10	0.9260
CENTRE	0041	0.08537	1.7307	9.81	0.05	0.9616
CENTRE	0042	-0.6467	1.9849	5.7	-0.33	0.7562

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	20.67	<.0001
numcd	1	380	0.29	0.5903
B_MADRS	1	491	24.99	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-14.9349	0.8660	108	-17.25	<.0001	0.05	-16.6515	-13.2183
trtseq	Q600MG	-15.4103	0.8722	107	-17.67	<.0001	0.05	-17.1393	-13.6812
trtseq	P	-9.2095	0.8697	103	-10.59	<.0001	0.05	-10.9343	-7.4848

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.4754	1.0549	490	0.45	0.6525	0.05	-1.5973	2.5480
trtseq	Q300MG	P	-5.7254	1.0659	503	-5.37	<.0001	0.05	-7.8195	-3.6312
trtseq	Q600MG	P	-6.2007	1.0713	505	-5.79	<.0001	0.05	-8.3054	-4.0960

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3794.64432328	
1	3	3791.09264613	0.00000020
2	1	3791.09235893	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	3.0087
Residual	96.8370

Fit Statistics

-2 Res Log Likelihood	3791.1
AIC (smaller is better)	3795.1
AICC (smaller is better)	3795.1
BIC (smaller is better)	3798.2

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			3.7826	2.8256	448	1.34	0.1813
trtseq		Q300MG	-6.1361	1.0774	505	-5.70	<.0001
trtseq		Q600MG	-6.2424	1.0822	506	-5.77	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.9026	0.9851	353	-0.92	0.3601
numcd	2		0	.	.	.	.
B_MADRS			-0.4241	0.08642	485	-4.91	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.5637	1.6607	4.34	-0.34	0.7501
CENTRE	0002	0.2064	1.5281	6.04	0.14	0.8969
CENTRE	0003	0.2900	1.5062	6.4	0.19	0.8533
CENTRE	0004	-0.9634	1.4760	6.92	-0.65	0.5350
CENTRE	0005	0.08299	1.2875	11.6	0.06	0.9497
CENTRE	0006	0.9541	1.5957	5.1	0.60	0.5755
CENTRE	0007	1.1052	1.5065	6.39	0.73	0.4892
CENTRE	0009	0.8411	1.5256	6.08	0.55	0.6011
CENTRE	0010	0.7619	1.4334	7.75	0.53	0.6099
CENTRE	0011	0.2240	1.4494	7.42	0.15	0.8813
CENTRE	0013	0.02323	1.5224	6.14	0.02	0.9883
CENTRE	0014	-0.6418	1.4475	7.47	-0.44	0.6700
CENTRE	0015	0.5655	1.6156	4.85	0.35	0.7410
CENTRE	0016	-0.4738	1.6378	4.59	-0.29	0.7850
CENTRE	0018	0.1901	1.5052	6.42	0.13	0.9034
CENTRE	0019	-0.8612	1.2675	12.2	-0.68	0.5095
CENTRE	0020	1.2054	1.4477	7.46	0.83	0.4309
CENTRE	0022	-0.2272	1.1367	17.7	-0.20	0.8439
CENTRE	0023	0.2189	1.2183	14	0.18	0.8600
CENTRE	0025	0.2120	1.6836	4.11	0.13	0.9057
CENTRE	0026	-0.4426	1.3683	9.25	-0.32	0.7535
CENTRE	0027	-0.3905	1.6393	4.57	-0.24	0.8220
CENTRE	0028	0.9608	1.3213	10.5	0.73	0.4830
CENTRE	0029	1.6321	1.3699	9.21	1.19	0.2633
CENTRE	0030	0.03544	1.4765	6.91	0.02	0.9815
CENTRE	0031	0.3850	1.3584	9.49	0.28	0.7829
CENTRE	0033	1.0006	1.4935	6.61	0.67	0.5256
CENTRE	0034	-0.5970	1.5762	5.35	-0.38	0.7194
CENTRE	0035	-0.3051	1.4064	8.34	-0.22	0.8335
CENTRE	0036	-0.9784	1.6384	4.58	-0.60	0.5786
CENTRE	0037	-0.07207	1.5566	5.62	-0.05	0.9647
CENTRE	0039	-3.5563	1.2887	11.5	-2.76	0.0178
CENTRE	0040	0.1823	1.6844	4.1	0.11	0.9189
CENTRE	0041	-0.5103	1.5232	6.12	-0.34	0.7488
CENTRE	0042	-0.4936	1.6840	4.11	-0.29	0.7837

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	500	21.75	<.0001
numcd	1	353	0.84	0.3601
B_MADRS	1	485	24.08	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-15.7052	0.8477	130	-18.53	<.0001	0.05	-17.3822	-14.0281
trtseq	Q600MG	-15.8114	0.8535	128	-18.53	<.0001	0.05	-17.5002	-14.1226
trtseq	P	-9.5691	0.8507	127	-11.25	<.0001	0.05	-11.2525	-7.8857

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.1063	1.0682	494	0.10	0.9208	0.05	-1.9925	2.2050
trtseq	Q300MG	P	-6.1361	1.0774	505	-5.70	<.0001	0.05	-8.2528	-4.0194
trtseq	Q600MG	P	-6.2424	1.0822	506	-5.77	<.0001	0.05	-8.3686	-4.1161

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3825.26769299	
1	3	3819.55129362	0.00000043
2	1	3819.55066202	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	4.1944
Residual	101.86

Fit Statistics

-2 Res Log Likelihood	3819.6
AIC (smaller is better)	3823.6
AICC (smaller is better)	3823.6
BIC (smaller is better)	3826.7

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			5.0145	2.9191	455	1.72	0.0865
trtseq		Q300MG	-6.6968	1.1073	504	-6.05	<.0001
trtseq		Q600MG	-6.6930	1.1127	505	-6.02	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.5958	1.0211	386	-0.58	0.5599
numcd	2		0	.	.	.	.
B_MADRS			-0.4627	0.08910	491	-5.19	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.3582	1.9349	6.51	-0.19	0.8588
CENTRE	0002	0.02565	1.7429	9.83	0.01	0.9886
CENTRE	0003	-0.01070	1.7123	10.5	-0.01	0.9951
CENTRE	0004	-1.7193	1.6708	11.6	-1.03	0.3245
CENTRE	0005	0.02143	1.4237	20.7	0.02	0.9881
CENTRE	0006	0.9166	1.8390	7.98	0.50	0.6316
CENTRE	0007	1.6591	1.7128	10.5	0.97	0.3544
CENTRE	0009	0.1024	1.7395	9.91	0.06	0.9542
CENTRE	0010	0.8647	1.6132	13.2	0.54	0.6009
CENTRE	0011	-0.4844	1.6347	12.6	-0.30	0.7718
CENTRE	0013	-0.4458	1.7348	10	-0.26	0.8024
CENTRE	0014	-1.0094	1.6321	12.7	-0.62	0.5472
CENTRE	0015	0.6556	1.8680	7.5	0.35	0.7353
CENTRE	0016	-0.6279	1.9008	6.99	-0.33	0.7508
CENTRE	0018	-0.1097	1.7108	10.6	-0.06	0.9501
CENTRE	0019	0.1226	1.3988	21.8	0.09	0.9309
CENTRE	0020	0.9852	1.6324	12.6	0.60	0.5568
CENTRE	0022	-0.5584	1.2387	31.9	-0.45	0.6552
CENTRE	0023	0.8086	1.3376	25.4	0.60	0.5509
CENTRE	0025	0.5358	1.9694	6.07	0.27	0.7946
CENTRE	0026	0.3954	1.5271	16.2	0.26	0.7990
CENTRE	0027	-0.6954	1.9030	6.96	-0.37	0.7257
CENTRE	0028	1.4101	1.4665	18.7	0.96	0.3486
CENTRE	0029	2.7304	1.5293	16.1	1.79	0.0931
CENTRE	0030	0.3628	1.6714	11.6	0.22	0.8320
CENTRE	0031	0.1042	1.5144	16.6	0.07	0.9460
CENTRE	0033	1.8219	1.6948	11	1.08	0.3055
CENTRE	0034	-0.5924	1.8109	8.47	-0.33	0.7515
CENTRE	0035	-1.0429	1.5771	14.4	-0.66	0.5189
CENTRE	0036	-0.8286	1.9016	6.98	-0.44	0.6762
CENTRE	0037	0.2612	1.7829	9.01	0.15	0.8868
CENTRE	0039	-4.2606	1.4251	20.6	-2.99	0.0071
CENTRE	0040	-0.03707	1.9707	6.05	-0.02	0.9856
CENTRE	0041	-0.5399	1.7359	10	-0.31	0.7622
CENTRE	0042	-0.4628	1.9700	6.06	-0.23	0.8220

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	499	24.06	<.0001
numcd	1	386	0.34	0.5599
B_MADRS	1	491	26.96	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-16.0542	0.8913	127	-18.01	<.0001	0.05	-17.8180	-14.2905
trtseq	Q600MG	-16.0505	0.8976	125	-17.88	<.0001	0.05	-17.8269	-14.2741
trtseq	P	-9.3575	0.8949	122	-10.46	<.0001	0.05	-11.1289	-7.5860

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.00373	1.0964	493	-0.00	0.9973	0.05	-2.1579	2.1504
trtseq	Q300MG	P	-6.6968	1.1073	504	-6.05	<.0001	0.05	-8.8722	-4.5213
trtseq	Q600MG	P	-6.6930	1.1127	505	-6.02	<.0001	0.05	-8.8792	-4.5069

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Model Information

Data Set	WORK.MADRSVSTXBL
Dependent Variable	CL_MADRS
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3833.69495852	
1	2	3827.90035048	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	4.6757
Residual	103.34

Fit Statistics

-2 Res Log Likelihood	3827.9
AIC (smaller is better)	3831.9
AICC (smaller is better)	3831.9
BIC (smaller is better)	3835.0

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			0.7939	2.9480	452	0.27	0.7878
trtseq		Q300MG	-6.1294	1.1161	503	-5.49	<.0001
trtseq		Q600MG	-6.4673	1.1217	505	-5.77	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.6462	1.0323	385	-0.63	0.5317
numcd	2		0	.	.	.	.
B_MADRS			-0.3527	0.08991	492	-3.92	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.6602	2.0322	6.55	-0.32	0.7554
CENTRE	0002	0.1568	1.8160	10.2	0.09	0.9328
CENTRE	0003	0.2265	1.7821	11	0.13	0.9012
CENTRE	0004	-1.8062	1.7361	12.1	-1.04	0.3185
CENTRE	0005	0.05033	1.4677	22.2	0.03	0.9730
CENTRE	0006	0.8937	1.9235	8.16	0.46	0.6543
CENTRE	0007	1.7530	1.7825	11	0.98	0.3466
CENTRE	0009	0.7404	1.8122	10.3	0.41	0.6913
CENTRE	0010	0.7154	1.6729	13.9	0.43	0.6754
CENTRE	0011	-1.2500	1.6965	13.2	-0.74	0.4741
CENTRE	0013	0.06953	1.8070	10.4	0.04	0.9700
CENTRE	0014	-1.5513	1.6936	13.3	-0.92	0.3760
CENTRE	0015	0.6619	1.9562	7.63	0.34	0.7442
CENTRE	0016	-0.5031	1.9933	7.08	-0.25	0.8079
CENTRE	0018	0.8054	1.7804	11	0.45	0.6598
CENTRE	0019	0.2279	1.4412	23.3	0.16	0.8757
CENTRE	0020	1.0691	1.6940	13.3	0.63	0.5386
CENTRE	0022	-0.08184	1.2713	34.1	-0.06	0.9490
CENTRE	0023	1.0231	1.3759	27.2	0.74	0.4635
CENTRE	0025	0.4294	2.0717	6.06	0.21	0.8426
CENTRE	0026	0.4410	1.5792	17.2	0.28	0.7834
CENTRE	0027	-1.3213	1.9959	7.04	-0.66	0.5290
CENTRE	0028	1.2184	1.5137	19.9	0.80	0.4304
CENTRE	0029	2.8242	1.5815	17.1	1.79	0.0919
CENTRE	0030	-0.1484	1.7369	12.1	-0.09	0.9333
CENTRE	0031	0.2931	1.5654	17.7	0.19	0.8536
CENTRE	0033	1.9081	1.7626	11.4	1.08	0.3013
CENTRE	0034	-0.8162	1.8920	8.7	-0.43	0.6767
CENTRE	0035	-1.3655	1.6335	15.2	-0.84	0.4161
CENTRE	0036	-1.5495	1.9943	7.06	-0.78	0.4624
CENTRE	0037	-0.01675	1.8606	9.3	-0.01	0.9930
CENTRE	0039	-4.2071	1.4692	22.1	-2.86	0.0090
CENTRE	0040	0.3344	2.0732	6.04	0.16	0.8771
CENTRE	0041	-0.00536	1.8082	10.4	-0.00	0.9977
CENTRE	0042	-0.5591	2.0724	6.05	-0.27	0.7963

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	20.98	<.0001
numcd	1	385	0.39	0.5317
B_MADRS	1	492	15.39	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-16.3874	0.9062	114	-18.08	<.0001	0.05	-18.1826	-14.5921
trtseq	Q600MG	-16.7253	0.9127	113	-18.33	<.0001	0.05	-18.5335	-14.9170
trtseq	P	-10.2580	0.9101	109	-11.27	<.0001	0.05	-12.0616	-8.4543

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.3379	1.1046	491	0.31	0.7598	0.05	-1.8325	2.5082
trtseq	Q300MG	P	-6.1294	1.1161	503	-5.49	<.0001	0.05	-8.3222	-3.9367
trtseq	Q600MG	P	-6.4673	1.1217	505	-5.77	<.0001	0.05	-8.6711	-4.2635

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=3

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	171	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	171	0	-8.53	7.18
		B_MADRS	BL MADRS TOTAL	171	0	30.37	5.00
Q600MG	169	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	169	0	-8.68	7.76
		B_MADRS	BL MADRS TOTAL	169	0	30.32	5.29
P	169	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	169	0	-4.79	7.30
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

WINDOWED VISIT=4

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	172	0	-11.90	8.28
		B_MADRS	BL MADRS TOTAL	172	0	30.32	5.03
Q600MG	170	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	170	0	-11.79	9.29
		B_MADRS	BL MADRS TOTAL	170	0	30.35	5.29
P	169	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	169	0	-7.28	8.05
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

WINDOWED VISIT=5

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	172	0	-13.16	8.69
		B_MADRS	BL MADRS TOTAL	172	0	30.32	5.03
Q600MG	170	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	170	0	-13.52	10.22
		B_MADRS	BL MADRS TOTAL	170	0	30.35	5.29

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=5

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	169	0	-8.54	9.42
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

WINDOWED VISIT=6

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	172	0	-13.84	9.26
		B_MADRS	BL MADRS TOTAL	172	0	30.32	5.03
Q600MG	170	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	170	0	-15.75	10.37
		B_MADRS	BL MADRS TOTAL	170	0	30.35	5.29
P	169	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	169	0	-9.05	10.01
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

WINDOWED VISIT=7

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	172	0	-15.08	9.38
		B_MADRS	BL MADRS TOTAL	172	0	30.32	5.03
Q600MG	170	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	170	0	-15.64	11.03
		B_MADRS	BL MADRS TOTAL	170	0	30.35	5.29
P	169	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	169	0	-9.34	10.01
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
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12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=8

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	172	0	-15.93	9.36
		B_MADRS	BL MADRS TOTAL	172	0	30.32	5.03
Q600MG	170	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	170	0	-16.04	11.14
		B_MADRS	BL MADRS TOTAL	170	0	30.35	5.29
P	169	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	169	0	-9.80	10.12
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

WINDOWED VISIT=9

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	172	0	-16.14	9.55
		B_MADRS	BL MADRS TOTAL	172	0	30.32	5.03
Q600MG	170	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	170	0	-16.16	11.21
		B_MADRS	BL MADRS TOTAL	170	0	30.35	5.29
P	169	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	169	0	-9.56	10.88
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

WINDOWED VISIT=10

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	172	0	-16.45	9.88
		B_MADRS	BL MADRS TOTAL	172	0	30.32	5.03
Q600MG	170	CL_MADRS	CHG_BL_MADRS_TOTAL - LOCF	170	0	-16.78	10.94
		B_MADRS	BL MADRS TOTAL	170	0	30.35	5.29

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.1 MADRS Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	CL_MADRS	CHG_BL MADRS TOTAL - LOCF	169	0	-10.38	10.77
		B_MADRS	BL MADRS TOTAL	169	0	30.59	5.27

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS223H.SAS
GENERATED: 14JUL2005 11:40:26 iceadmn3

12.1.9.2.1.2 MADRS Total Score Change from Baseline (Effect Size - LOCF - ITT)

Obs	ntrtseq	stdd	cl95l	cl95u	d	spool	trtseq	VISIT	$\bar{t}$rtseq	Estimate	residcov	npat	stdev $\bar{t}$rt	stdev $\bar{c}$tr	ncontrol
1	13	0.11031	-0.73924	-0.30684	-0.52304	7.2390	1	3	3	-3.7863	48.4488	171	7.18	7.30	169
2	23	0.11059	-0.73391	-0.30040	-0.51716	7.5314	2	3	3	-3.8949	48.4488	169	7.76	7.30	169
3	13	0.11054	-0.79353	-0.36021	-0.57687	8.1632	1	4	3	-4.7091	65.3919	172	8.28	8.05	169
4	23	0.11042	-0.73292	-0.30007	-0.51649	8.6930	2	4	3	-4.4899	65.3919	170	9.29	8.05	169
5	13	0.11019	-0.74541	-0.31346	-0.52944	9.0627	1	5	3	-4.7981	81.0054	172	8.69	9.42	169
6	23	0.11043	-0.73398	-0.30110	-0.51754	9.8319	2	5	3	-5.0884	81.0054	170	10.22	9.42	169
7	13	0.11006	-0.72573	-0.29430	-0.51002	9.6371	1	6	3	-4.9151	86.2492	172	9.26	10.01	169
8	23	0.11159	-0.88351	-0.44609	-0.66480	10.1920	2	6	3	-6.7756	86.2492	170	10.37	10.01	169
9	13	0.11064	-0.80727	-0.37355	-0.59041	9.6973	1	7	3	-5.7254	94.2407	172	9.38	10.01	169
10	23	0.11095	-0.80614	-0.37120	-0.58867	10.5334	2	7	3	-6.2007	94.2407	170	11.03	10.01	169
11	13	0.11096	-0.84701	-0.41204	-0.62952	9.7472	1	8	3	-6.1361	96.8370	172	9.36	10.12	169
12	23	0.11094	-0.80379	-0.36892	-0.58635	10.6461	2	8	3	-6.2424	96.8370	170	11.14	10.12	169
13	13	0.11117	-0.87264	-0.43684	-0.65474	10.2281	1	9	3	-6.6968	101.86	172	9.55	10.88	169
14	23	0.11109	-0.82363	-0.38816	-0.60590	11.0465	2	9	3	-6.6930	101.86	170	11.21	10.88	169
15	13	0.11067	-0.81020	-0.37639	-0.59330	10.3312	1	10	3	-6.1294	103.34	172	9.88	10.77	169
16	23	0.11101	-0.81349	-0.37833	-0.59591	10.8528	2	10	3	-6.4673	103.34	170	10.94	10.77	169

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS224H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	96 42.29 83.48 48.73	19 8.37 16.52 63.33	115 50.66
P	101 44.49 90.18 51.27	11 4.85 9.82 36.67	112 49.34
Total	197 86.78	30 13.22	227 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	2.2210	0.1361
Likelihood Ratio Chi-Square	1	2.2466	0.1339
Continuity Adj. Chi-Square	1	1.6752	0.1956
Mantel-Haenszel Chi-Square	1	2.2112	0.1370
Phi Coefficient		-0.0989	
Contingency Coefficient		0.0984	
Cramer's V		-0.0989	

Fisher's Exact Test

Cell (1,1) Frequency (F)	96
Left-sided Pr <= F	0.0974
Right-sided Pr >= F	0.9549
Table Probability (P)	0.0523
Two-sided Pr <= P	0.1706

Sample Size = 227

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

nvisit=DAY 8

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	46 40.71 82.14 47.92	10 8.85 17.86 58.82	56 49.56
P	50 44.25 87.72 52.08	7 6.19 12.28 41.18	57 50.44
Total	96 84.96	17 15.04	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.6873	0.4071
Likelihood Ratio Chi-Square	1	0.6901	0.4061
Continuity Adj. Chi-Square	1	0.3202	0.5715
Mantel-Haenszel Chi-Square	1	0.6812	0.4092
Phi Coefficient		-0.0780	
Contingency Coefficient		0.0778	
Cramer's V		-0.0780	

Fisher's Exact Test

Cell (1,1) Frequency (F)	46
Left-sided Pr <= F	0.2861
Right-sided Pr >= F	0.8627
Table Probability (P)	0.1488
Two-sided Pr <= P	0.4417

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	2.8403	0.0919
2	Row Mean Scores Differ	1	2.8403	0.0919
3	General Association	1	2.8403	0.0919

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.5825	0.3097	1.0954
	Logit	0.5828	0.3098	1.0966
Cohort (Col1 Risk)	Mantel-Haenszel	0.9292	0.8532	1.0120
	Logit	0.9289	0.8530	1.0115
Cohort (Col2 Risk)	Mantel-Haenszel	1.5947	0.9215	2.7597
	Logit	1.5921	0.9198	2.7558

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.0552
DF	1
Pr > ChiSq	0.8143

Total Sample Size = 340

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	69 30.26 59.48 42.86	47 20.61 40.52 70.15	116 50.88
P	92 40.35 82.14 57.14	20 8.77 17.86 29.85	112 49.12
Total	161 70.61	67 29.39	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	14.1005	0.0002
Likelihood Ratio Chi-Square	1	14.4229	0.0001
Continuity Adj. Chi-Square	1	13.0296	0.0003
Mantel-Haenszel Chi-Square	1	14.0386	0.0002
Phi Coefficient		-0.2487	
Contingency Coefficient		0.2413	
Cramer's V		-0.2487	

Fisher's Exact Test

Cell (1,1) Frequency (F)	69
Left-sided Pr <= F	1.339E-04
Right-sided Pr >= F	1.0000
Table Probability (P)	9.402E-05
Two-sided Pr <= P	2.471E-04

Sample Size = 228

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	39 34.51 69.64 46.99	17 15.04 30.36 56.67	56 49.56
P	44 38.94 77.19 53.01	13 11.50 22.81 43.33	57 50.44
Total	83 73.45	30 26.55	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.8258	0.3635
Likelihood Ratio Chi-Square	1	0.8275	0.3630
Continuity Adj. Chi-Square	1	0.4840	0.4866
Mantel-Haenszel Chi-Square	1	0.8184	0.3656
Phi Coefficient		-0.0855	
Contingency Coefficient		0.0852	
Cramer's V		-0.0855	

Fisher's Exact Test

Cell (1,1) Frequency (F)	39
Left-sided Pr <= F	0.2435
Right-sided Pr >= F	0.8691
Table Probability (P)	0.1125
Two-sided Pr <= P	0.4001

Sample Size = 113

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	12.9835	0.0003
2	Row Mean Scores Differ	1	12.9835	0.0003
3	General Association	1	12.9835	0.0003

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4119	0.2527	0.6716
	Logit	0.4136	0.2525	0.6774
Cohort (Col1 Risk)	Mantel-Haenszel	0.7807	0.6808	0.8954
	Logit	0.7865	0.6859	0.9019
Cohort (Col2 Risk)	Mantel-Haenszel	1.9053	1.3238	2.7424
	Logit	1.8839	1.3056	2.7182

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	2.0348
DF	1
Pr > ChiSq	0.1537

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	65 28.51 56.03 43.33	51 22.37 43.97 65.38	116 50.88
P	85 37.28 75.89 56.67	27 11.84 24.11 34.62	112 49.12
Total	150 65.79	78 34.21	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	9.9842	0.0016
Likelihood Ratio Chi-Square	1	10.1102	0.0015
Continuity Adj. Chi-Square	1	9.1213	0.0025
Mantel-Haenszel Chi-Square	1	9.9404	0.0016
Phi Coefficient		-0.2093	
Contingency Coefficient		0.2048	
Cramer's V		-0.2093	

Fisher's Exact Test

Cell (1,1) Frequency (F)	65
Left-sided Pr <= F	0.0012
Right-sided Pr >= F	0.9995
Table Probability (P)	7.499E-04
Two-sided Pr <= P	0.0021

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	34 30.09 60.71 44.74	22 19.47 39.29 59.46	56 49.56
P	42 37.17 73.68 55.26	15 13.27 26.32 40.54	57 50.44
Total	76 67.26	37 32.74	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	2.1577	0.1419
Likelihood Ratio Chi-Square	1	2.1672	0.1410
Continuity Adj. Chi-Square	1	1.6090	0.2046
Mantel-Haenszel Chi-Square	1	2.1387	0.1436
Phi Coefficient		-0.1382	
Contingency Coefficient		0.1369	
Cramer's V		-0.1382	

Fisher's Exact Test

Cell (1,1) Frequency (F)	34
Left-sided Pr <= F	0.1022
Right-sided Pr >= F	0.9528
Table Probability (P)	0.0550
Two-sided Pr <= P	0.1639

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	11.7125	0.0006
2	Row Mean Scores Differ	1	11.7125	0.0006
3	General Association	1	11.7125	0.0006

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4491	0.2831	0.7124
	Logit	0.4493	0.2830	0.7133
Cohort (Col1 Risk)	Mantel-Haenszel	0.7662	0.6563	0.8945
	Logit	0.7673	0.6572	0.8957
Cohort (Col2 Risk)	Mantel-Haenszel	1.7076	1.2460	2.3401
	Logit	1.7046	1.2435	2.3367

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.3860
DF	1
Pr > ChiSq	0.5344

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	60 26.32 51.72 43.48	56 24.56 48.28 62.22	116 50.88
P	78 34.21 69.64 56.52	34 14.91 30.36 37.78	112 49.12
Total	138 60.53	90 39.47	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	7.6578	0.0057
Likelihood Ratio Chi-Square	1	7.7170	0.0055
Continuity Adj. Chi-Square	1	6.9262	0.0085
Mantel-Haenszel Chi-Square	1	7.6242	0.0058
Phi Coefficient		-0.1833	
Contingency Coefficient		0.1803	
Cramer's V		-0.1833	

Fisher's Exact Test

Cell (1,1) Frequency (F)	60
Left-sided Pr <= F	0.0041
Right-sided Pr >= F	0.9982
Table Probability (P)	0.0024
Two-sided Pr <= P	0.0067

Sample Size = 228

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	29 25.66 51.79 42.65	27 23.89 48.21 60.00	56 49.56
P	39 34.51 68.42 57.35	18 15.93 31.58 40.00	57 50.44
Total	68 60.18	45 39.82	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	3.2620	0.0709
Likelihood Ratio Chi-Square	1	3.2793	0.0702
Continuity Adj. Chi-Square	1	2.6048	0.1065
Mantel-Haenszel Chi-Square	1	3.2331	0.0722
Phi Coefficient		-0.1699	
Contingency Coefficient		0.1675	
Cramer's V		-0.1699	

Fisher's Exact Test

Cell (1,1) Frequency (F)	29
Left-sided Pr <= F	0.0531
Right-sided Pr >= F	0.9774
Table Probability (P)	0.0305
Two-sided Pr <= P	0.0853

Sample Size = 113

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	10.8416	0.0010
2	Row Mean Scores Differ	1	10.8416	0.0010
3	General Association	1	10.8416	0.0010

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4764	0.3059	0.7419
	Logit	0.4764	0.3059	0.7420
Cohort (Col1 Risk)	Mantel-Haenszel	0.7473	0.6268	0.8910
	Logit	0.7473	0.6268	0.8910
Cohort (Col2 Risk)	Mantel-Haenszel	1.5687	1.1926	2.0633
	Logit	1.5683	1.1923	2.0628

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.0155
DF	1
Pr > ChiSq	0.9009

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	50 21.93 43.10 38.76	66 28.95 56.90 66.67	116 50.88
P	79 34.65 70.54 61.24	33 14.47 29.46 33.33	112 49.12
Total	129 56.58	99 43.42	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	17.4546	<.0001
Likelihood Ratio Chi-Square	1	17.7186	<.0001
Continuity Adj. Chi-Square	1	16.3558	<.0001
Mantel-Haenszel Chi-Square	1	17.3780	<.0001
Phi Coefficient		-0.2767	
Contingency Coefficient		0.2667	
Cramer's V		-0.2767	

Fisher's Exact Test

Cell (1,1) Frequency (F)	50
Left-sided Pr <= F	2.341E-05
Right-sided Pr >= F	1.0000
Table Probability (P)	1.642E-05
Two-sided Pr <= P	3.325E-05

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	34 30.09 60.71 47.22	22 19.47 39.29 53.66	56 49.56
P	38 33.63 66.67 52.78	19 16.81 33.33 46.34	57 50.44
Total	72 63.72	41 36.28	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.4329	0.5106
Likelihood Ratio Chi-Square	1	0.4332	0.5104
Continuity Adj. Chi-Square	1	0.2137	0.6439
Mantel-Haenszel Chi-Square	1	0.4291	0.5124
Phi Coefficient		-0.0619	
Contingency Coefficient		0.0618	
Cramer's V		-0.0619	

Fisher's Exact Test

Cell (1,1) Frequency (F)	34
Left-sided Pr <= F	0.3220
Right-sided Pr >= F	0.8033
Table Probability (P)	0.1253
Two-sided Pr <= P	0.5605

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	14.5157	0.0001
2	Row Mean Scores Differ	1	14.5157	0.0001
3	General Association	1	14.5157	0.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4280	0.2753	0.6654
	Logit	0.4275	0.2736	0.6678
Cohort (Col1 Risk)	Mantel-Haenszel	0.7067	0.5885	0.8487
	Logit	0.7244	0.6036	0.8694
Cohort (Col2 Risk)	Mantel-Haenszel	1.6607	1.2669	2.1767
	Logit	1.6586	1.2631	2.1778

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	3.4596
DF	1
Pr > ChiSq	0.0629

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	50 21.93 43.10 38.17	66 28.95 56.90 68.04	116 50.88
P	81 35.53 72.32 61.83	31 13.60 27.68 31.96	112 49.12
Total	131 57.46	97 42.54	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	19.9007	<.0001
Likelihood Ratio Chi-Square	1	20.2540	<.0001
Continuity Adj. Chi-Square	1	18.7233	<.0001
Mantel-Haenszel Chi-Square	1	19.8134	<.0001
Phi Coefficient		-0.2954	
Contingency Coefficient		0.2833	
Cramer's V		-0.2954	

Fisher's Exact Test

Cell (1,1) Frequency (F)	50
Left-sided Pr <= F	6.472E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	4.696E-06
Two-sided Pr <= P	9.169E-06

Sample Size = 228

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	30 26.55 53.57 45.45	26 23.01 46.43 55.32	56 49.56
P	36 31.86 63.16 54.55	21 18.58 36.84 44.68	57 50.44
Total	66 58.41	47 41.59	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.0686	0.3013
Likelihood Ratio Chi-Square	1	1.0703	0.3009
Continuity Adj. Chi-Square	1	0.7104	0.3993
Mantel-Haenszel Chi-Square	1	1.0591	0.3034
Phi Coefficient		-0.0972	
Contingency Coefficient		0.0968	
Cramer's V		-0.0972	

Fisher's Exact Test

Cell (1,1) Frequency (F)	30
Left-sided Pr <= F	0.1997
Right-sided Pr >= F	0.8897
Table Probability (P)	0.0894
Two-sided Pr <= P	0.3429

Sample Size = 113

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	17.9163	<.0001
2	Row Mean Scores Differ	1	17.9163	<.0001
3	General Association	1	17.9163	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3900	0.2508	0.6063
	Logit	0.3898	0.2496	0.6087
Cohort (Col1 Risk)	Mantel-Haenszel	0.6722	0.5561	0.8125
	Logit	0.6780	0.5607	0.8198
Cohort (Col2 Risk)	Mantel-Haenszel	1.7394	1.3313	2.2726
	Logit	1.7146	1.3106	2.2430

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	3.1415
DF	1
Pr > ChiSq	0.0763

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	48 21.05 41.38 37.80	68 29.82 58.62 67.33	116 50.88
P	79 34.65 70.54 62.20	33 14.47 29.46 32.67	112 49.12
Total	127 55.70	101 44.30	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	19.6315	<.0001
Likelihood Ratio Chi-Square	1	19.9577	<.0001
Continuity Adj. Chi-Square	1	18.4677	<.0001
Mantel-Haenszel Chi-Square	1	19.5454	<.0001
Phi Coefficient		-0.2934	
Contingency Coefficient		0.2816	
Cramer's V		-0.2934	

Fisher's Exact Test

Cell (1,1) Frequency (F)	48
Left-sided Pr <= F	7.490E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	5.400E-06
Two-sided Pr <= P	1.036E-05

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	29 25.66 51.79 43.28	27 23.89 48.21 58.70	56 49.56
P	38 33.63 66.67 56.72	19 16.81 33.33 41.30	57 50.44
Total	67 59.29	46 40.71	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	2.5916	0.1074
Likelihood Ratio Chi-Square	1	2.6022	0.1067
Continuity Adj. Chi-Square	1	2.0117	0.1561
Mantel-Haenszel Chi-Square	1	2.5687	0.1090
Phi Coefficient		-0.1514	
Contingency Coefficient		0.1497	
Cramer's V		-0.1514	

Fisher's Exact Test

Cell (1,1) Frequency (F)	29
Left-sided Pr <= F	0.0779
Right-sided Pr >= F	0.9644
Table Probability (P)	0.0423
Two-sided Pr <= P	0.1276

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	20.6355	<.0001
2	Row Mean Scores Differ	1	20.6355	<.0001
3	General Association	1	20.6355	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3622	0.2326	0.5641
	Logit	0.3622	0.2320	0.5652
Cohort (Col1 Risk)	Mantel-Haenszel	0.6473	0.5331	0.7859
	Logit	0.6537	0.5385	0.7937
Cohort (Col2 Risk)	Mantel-Haenszel	1.7944	1.3780	2.3366
	Logit	1.7875	1.3718	2.3290

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.5743
DF	1
Pr > ChiSq	0.2096

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	44 19.30 37.93 36.97	72 31.58 62.07 66.06	116 50.88
P	75 32.89 66.96 63.03	37 16.23 33.04 33.94	112 49.12
Total	119 52.19	109 47.81	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	19.2499	<.0001
Likelihood Ratio Chi-Square	1	19.5395	<.0001
Continuity Adj. Chi-Square	1	18.1039	<.0001
Mantel-Haenszel Chi-Square	1	19.1655	<.0001
Phi Coefficient		-0.2906	
Contingency Coefficient		0.2790	
Cramer's V		-0.2906	

Fisher's Exact Test

Cell (1,1) Frequency (F)	44
Left-sided Pr <= F	9.215E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	6.586E-06
Two-sided Pr <= P	1.218E-05

Sample Size = 228

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	29 25.66 51.79 46.77	27 23.89 48.21 52.94	56 49.56
P	33 29.20 57.89 53.23	24 21.24 42.11 47.06	57 50.44
Total	62 54.87	51 45.13	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.4257	0.5141
Likelihood Ratio Chi-Square	1	0.4260	0.5140
Continuity Adj. Chi-Square	1	0.2148	0.6431
Mantel-Haenszel Chi-Square	1	0.4220	0.5160
Phi Coefficient		-0.0614	
Contingency Coefficient		0.0613	
Cramer's V		-0.0614	

Fisher's Exact Test

Cell (1,1) Frequency (F)	29
Left-sided Pr <= F	0.3216
Right-sided Pr >= F	0.7999
Table Probability (P)	0.1215
Two-sided Pr <= P	0.5729

Sample Size = 113

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	15.6421	<.0001
2	Row Mean Scores Differ	1	15.6421	<.0001
3	General Association	1	15.6421	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4213	0.2731	0.6498
	Logit	0.4204	0.2711	0.6519
Cohort (Col1 Risk)	Mantel-Haenszel	0.6649	0.5399	0.8188
	Logit	0.6758	0.5484	0.8328
Cohort (Col2 Risk)	Mantel-Haenszel	1.5947	1.2544	2.0274
	Logit	1.5795	1.2407	2.0109

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	4.1367
DF	1
Pr > ChiSq	0.0420

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

nvisit=DAY 8

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	84 37.17 73.68 45.41	30 13.27 26.32 73.17	114 50.44
P	101 44.69 90.18 54.59	11 4.87 9.82 26.83	112 49.56
Total	185 81.86	41 18.14	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	10.3502	0.0013
Likelihood Ratio Chi-Square	1	10.6974	0.0011
Continuity Adj. Chi-Square	1	9.2692	0.0023
Mantel-Haenszel Chi-Square	1	10.3044	0.0013
Phi Coefficient		-0.2140	
Contingency Coefficient		0.2093	
Cramer's V		-0.2140	

Fisher's Exact Test

Cell (1,1) Frequency (F)	84
Left-sided Pr <= F	0.0010
Right-sided Pr >= F	0.9997
Table Probability (P)	7.357E-04
Two-sided Pr <= P	0.0017

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

nvisit=DAY 8

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	44 39.29 80.00 46.81	11 9.82 20.00 61.11	55 49.11
P	50 44.64 87.72 53.19	7 6.25 12.28 38.89	57 50.89
Total	94 83.93	18 16.07	112 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.2365	0.2661
Likelihood Ratio Chi-Square	1	1.2439	0.2647
Continuity Adj. Chi-Square	1	0.7305	0.3927
Mantel-Haenszel Chi-Square	1	1.2255	0.2683
Phi Coefficient		-0.1051	
Contingency Coefficient		0.1045	
Cramer's V		-0.1051	

Fisher's Exact Test

Cell (1,1) Frequency (F)	44
Left-sided Pr <= F	0.1966
Right-sided Pr >= F	0.9150
Table Probability (P)	0.1115
Two-sided Pr <= P	0.3105

Sample Size = 112

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	10.7688	0.0010
2	Row Mean Scores Differ	1	10.7688	0.0010
3	General Association	1	10.7688	0.0010

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3733	0.2046	0.6813
	Logit	0.3762	0.2053	0.6896
Cohort (Col1 Risk)	Mantel-Haenszel	0.8480	0.7673	0.9370
	Logit	0.8510	0.7702	0.9402
Cohort (Col2 Risk)	Mantel-Haenszel	2.2774	1.3635	3.8041
	Logit	2.2511	1.3439	3.7708

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.8808
DF	1
Pr > ChiSq	0.3480

Total Sample Size = 338

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	74 32.74 64.91 44.58	40 17.70 35.09 66.67	114 50.44
P	92 40.71 82.14 55.42	20 8.85 17.86 33.33	112 49.56
Total	166 73.45	60 26.55	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	8.6014	0.0034
Likelihood Ratio Chi-Square	1	8.7339	0.0031
Continuity Adj. Chi-Square	1	7.7405	0.0054
Mantel-Haenszel Chi-Square	1	8.5634	0.0034
Phi Coefficient		-0.1951	
Contingency Coefficient		0.1915	
Cramer's V		-0.1951	

Fisher's Exact Test

Cell (1,1) Frequency (F)	74
Left-sided Pr <= F	0.0026
Right-sided Pr >= F	0.9991
Table Probability (P)	0.0016
Two-sided Pr <= P	0.0041

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	39 34.51 69.64 46.99	17 15.04 30.36 56.67	56 49.56
P	44 38.94 77.19 53.01	13 11.50 22.81 43.33	57 50.44
Total	83 73.45	30 26.55	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.8258	0.3635
Likelihood Ratio Chi-Square	1	0.8275	0.3630
Continuity Adj. Chi-Square	1	0.4840	0.4866
Mantel-Haenszel Chi-Square	1	0.8184	0.3656
Phi Coefficient		-0.0855	
Contingency Coefficient		0.0852	
Cramer's V		-0.0855	

Fisher's Exact Test

Cell (1,1) Frequency (F)	39
Left-sided Pr <= F	0.2435
Right-sided Pr >= F	0.8691
Table Probability (P)	0.1125
Two-sided Pr <= P	0.4001

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	8.4719	0.0036
2	Row Mean Scores Differ	1	8.4719	0.0036
3	General Association	1	8.4719	0.0036

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4818	0.2936	0.7909
	Logit	0.4829	0.2935	0.7946
Cohort (Col1 Risk)	Mantel-Haenszel	0.8260	0.7253	0.9408
	Logit	0.8267	0.7258	0.9416
Cohort (Col2 Risk)	Mantel-Haenszel	1.7179	1.1830	2.4945
	Logit	1.7055	1.1730	2.4798

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.9642
DF	1
Pr > ChiSq	0.3261

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	59 26.11 51.75 40.97	55 24.34 48.25 67.07	114 50.44
P	85 37.61 75.89 59.03	27 11.95 24.11 32.93	112 49.56
Total	144 63.72	82 36.28	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	14.2388	0.0002
Likelihood Ratio Chi-Square	1	14.4586	0.0001
Continuity Adj. Chi-Square	1	13.2139	0.0003
Mantel-Haenszel Chi-Square	1	14.1758	0.0002
Phi Coefficient		-0.2510	
Contingency Coefficient		0.2435	
Cramer's V		-0.2510	

Fisher's Exact Test

Cell (1,1) Frequency (F)	59
Left-sided Pr <= F	1.266E-04
Right-sided Pr >= F	1.0000
Table Probability (P)	8.620E-05
Two-sided Pr <= P	1.831E-04

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	37 32.74 66.07 46.84	19 16.81 33.93 55.88	56 49.56
P	42 37.17 73.68 53.16	15 13.27 26.32 44.12	57 50.44
Total	79 69.91	34 30.09	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.7783	0.3777
Likelihood Ratio Chi-Square	1	0.7795	0.3773
Continuity Adj. Chi-Square	1	0.4584	0.4984
Mantel-Haenszel Chi-Square	1	0.7714	0.3798
Phi Coefficient		-0.0830	
Contingency Coefficient		0.0827	
Cramer's V		-0.0830	

Fisher's Exact Test

Cell (1,1) Frequency (F)	37
Left-sided Pr <= F	0.2493
Right-sided Pr >= F	0.8616
Table Probability (P)	0.1109
Two-sided Pr <= P	0.4169

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	13.0401	0.0003
2	Row Mean Scores Differ	1	13.0401	0.0003
3	General Association	1	13.0401	0.0003

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4310	0.2717	0.6837
	Logit	0.4313	0.2710	0.6864
Cohort (Col1 Risk)	Mantel-Haenszel	0.7521	0.6423	0.8808
	Logit	0.7643	0.6531	0.8943
Cohort (Col2 Risk)	Mantel-Haenszel	1.7499	1.2784	2.3954
	Logit	1.7470	1.2742	2.3953

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	2.0145
DF	1
Pr > ChiSq	0.1558

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
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12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	43 19.03 37.72 35.54	71 31.42 62.28 67.62	114 50.44
P	78 34.51 69.64 64.46	34 15.04 30.36 32.38	112 49.56
Total	121 53.54	105 46.46	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	23.1462	<.0001
Likelihood Ratio Chi-Square	1	23.5747	<.0001
Continuity Adj. Chi-Square	1	21.8806	<.0001
Mantel-Haenszel Chi-Square	1	23.0438	<.0001
Phi Coefficient		-0.3200	
Contingency Coefficient		0.3048	
Cramer's V		-0.3200	

Fisher's Exact Test

Cell (1,1) Frequency (F)	43
Left-sided Pr <= F	1.200E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	8.991E-07
Two-sided Pr <= P	1.535E-06

Sample Size = 226

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	29 25.66 51.79 42.65	27 23.89 48.21 60.00	56 49.56
P	39 34.51 68.42 57.35	18 15.93 31.58 40.00	57 50.44
Total	68 60.18	45 39.82	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	3.2620	0.0709
Likelihood Ratio Chi-Square	1	3.2793	0.0702
Continuity Adj. Chi-Square	1	2.6048	0.1065
Mantel-Haenszel Chi-Square	1	3.2331	0.0722
Phi Coefficient		-0.1699	
Contingency Coefficient		0.1675	
Cramer's V		-0.1699	

Fisher's Exact Test

Cell (1,1) Frequency (F)	29
Left-sided Pr <= F	0.0531
Right-sided Pr >= F	0.9774
Table Probability (P)	0.0305
Two-sided Pr <= P	0.0853

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	24.6765	<.0001
2	Row Mean Scores Differ	1	24.6765	<.0001
3	General Association	1	24.6765	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3278	0.2099	0.5121
	Logit	0.3276	0.2092	0.5129
Cohort (Col1 Risk)	Mantel-Haenszel	0.6125	0.5005	0.7496
	Logit	0.6247	0.5108	0.7639
Cohort (Col2 Risk)	Mantel-Haenszel	1.8720	1.4424	2.4296
	Logit	1.8716	1.4412	2.4305

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.7144
DF	1
Pr > ChiSq	0.1904

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	50 22.12 43.86 38.76	64 28.32 56.14 65.98	114 50.44
P	79 34.96 70.54 61.24	33 14.60 29.46 34.02	112 49.56
Total	129 57.08	97 42.92	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	16.4102	<.0001
Likelihood Ratio Chi-Square	1	16.6409	<.0001
Continuity Adj. Chi-Square	1	15.3394	<.0001
Mantel-Haenszel Chi-Square	1	16.3376	<.0001
Phi Coefficient		-0.2695	
Contingency Coefficient		0.2602	
Cramer's V		-0.2695	

Fisher's Exact Test

Cell (1,1) Frequency (F)	50
Left-sided Pr <= F	4.066E-05
Right-sided Pr >= F	1.0000
Table Probability (P)	2.817E-05
Two-sided Pr <= P	5.563E-05

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	32 28.32 57.14 45.71	24 21.24 42.86 55.81	56 49.56
P	38 33.63 66.67 54.29	19 16.81 33.33 44.19	57 50.44
Total	70 61.95	43 38.05	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.0869	0.2972
Likelihood Ratio Chi-Square	1	1.0888	0.2967
Continuity Adj. Chi-Square	1	0.7204	0.3960
Mantel-Haenszel Chi-Square	1	1.0773	0.2993
Phi Coefficient		-0.0981	
Contingency Coefficient		0.0976	
Cramer's V		-0.0981	

Fisher's Exact Test

Cell (1,1) Frequency (F)	32
Left-sided Pr <= F	0.1981
Right-sided Pr >= F	0.8919
Table Probability (P)	0.0900
Two-sided Pr <= P	0.3361

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	15.2982	<.0001
2	Row Mean Scores Differ	1	15.2982	<.0001
3	General Association	1	15.2982	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4166	0.2675	0.6487
	Logit	0.4164	0.2665	0.6504
Cohort (Col1 Risk)	Mantel-Haenszel	0.6973	0.5793	0.8395
	Logit	0.7077	0.5880	0.8517
Cohort (Col2 Risk)	Mantel-Haenszel	1.6815	1.2841	2.2019
	Logit	1.6774	1.2795	2.1989

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	2.2233
DF	1
Pr > ChiSq	0.1359

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	41 18.14 35.96 33.61	73 32.30 64.04 70.19	114 50.44
P	81 35.84 72.32 66.39	31 13.72 27.68 29.81	112 49.56
Total	122 53.98	104 46.02	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	30.0609	<.0001
Likelihood Ratio Chi-Square	1	30.7983	<.0001
Continuity Adj. Chi-Square	1	28.6152	<.0001
Mantel-Haenszel Chi-Square	1	29.9279	<.0001
Phi Coefficient		-0.3647	
Contingency Coefficient		0.3426	
Cramer's V		-0.3647	

Fisher's Exact Test

Cell (1,1) Frequency (F)	41
Left-sided Pr <= F	3.168E-08
Right-sided Pr >= F	1.0000
Table Probability (P)	2.518E-08
Two-sided Pr <= P	3.918E-08

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	30 26.55 53.57 45.45	26 23.01 46.43 55.32	56 49.56
P	36 31.86 63.16 54.55	21 18.58 36.84 44.68	57 50.44
Total	66 58.41	47 41.59	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.0686	0.3013
Likelihood Ratio Chi-Square	1	1.0703	0.3009
Continuity Adj. Chi-Square	1	0.7104	0.3993
Mantel-Haenszel Chi-Square	1	1.0591	0.3034
Phi Coefficient		-0.0972	
Contingency Coefficient		0.0968	
Cramer's V		-0.0972	

Fisher's Exact Test

Cell (1,1) Frequency (F)	30
Left-sided Pr <= F	0.1997
Right-sided Pr >= F	0.8897
Table Probability (P)	0.0894
Two-sided Pr <= P	0.3429

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	25.7114	<.0001
2	Row Mean Scores Differ	1	25.7114	<.0001
3	General Association	1	25.7114	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3251	0.2087	0.5065
	Logit	0.3241	0.2064	0.5088
Cohort (Col1 Risk)	Mantel-Haenszel	0.6039	0.4921	0.7413
	Logit	0.6241	0.5084	0.7661
Cohort (Col2 Risk)	Mantel-Haenszel	1.8926	1.4567	2.4590
	Logit	1.8614	1.4295	2.4237

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	5.7197
DF	1
Pr > ChiSq	0.0168

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	45 19.91 39.47 36.29	69 30.53 60.53 67.65	114 50.44
P	79 34.96 70.54 63.71	33 14.60 29.46 32.35	112 49.56
Total	124 54.87	102 45.13	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	22.0125	<.0001
Likelihood Ratio Chi-Square	1	22.4091	<.0001
Continuity Adj. Chi-Square	1	20.7760	<.0001
Mantel-Haenszel Chi-Square	1	21.9151	<.0001
Phi Coefficient		-0.3121	
Contingency Coefficient		0.2979	
Cramer's V		-0.3121	

Fisher's Exact Test

Cell (1,1) Frequency (F)	45
Left-sided Pr <= F	2.167E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	1.607E-06
Two-sided Pr <= P	2.814E-06

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	30 26.55 53.57 44.12	26 23.01 46.43 57.78	56 49.56
P	38 33.63 66.67 55.88	19 16.81 33.33 42.22	57 50.44
Total	68 60.18	45 39.82	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	2.0214	0.1551
Likelihood Ratio Chi-Square	1	2.0278	0.1544
Continuity Adj. Chi-Square	1	1.5119	0.2189
Mantel-Haenszel Chi-Square	1	2.0035	0.1569
Phi Coefficient		-0.1337	
Contingency Coefficient		0.1326	
Cramer's V		-0.1337	

Fisher's Exact Test

Cell (1,1) Frequency (F)	30
Left-sided Pr <= F	0.1093
Right-sided Pr >= F	0.9469
Table Probability (P)	0.0563
Two-sided Pr <= P	0.1812

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	21.6199	<.0001
2	Row Mean Scores Differ	1	21.6199	<.0001
3	General Association	1	21.6199	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3534	0.2267	0.5511
	Logit	0.3531	0.2257	0.5524
Cohort (Col1 Risk)	Mantel-Haenszel	0.6379	0.5239	0.7768
	Logit	0.6502	0.5342	0.7914
Cohort (Col2 Risk)	Mantel-Haenszel	1.8153	1.3947	2.3628
	Logit	1.8089	1.3884	2.3569

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	2.4539
DF	1
Pr > ChiSq	0.1172

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	41 18.14 35.96 35.34	73 32.30 64.04 66.36	114 50.44
P	75 33.19 66.96 64.66	37 16.37 33.04 33.64	112 49.56
Total	116 51.33	110 48.67	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by respond50
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	21.7313	<.0001
Likelihood Ratio Chi-Square	1	22.0974	<.0001
Continuity Adj. Chi-Square	1	20.5082	<.0001
Mantel-Haenszel Chi-Square	1	21.6352	<.0001
Phi Coefficient		-0.3101	
Contingency Coefficient		0.2962	
Cramer's V		-0.3101	

Fisher's Exact Test

Cell (1,1) Frequency (F)	41
Left-sided Pr <= F	2.526E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	1.862E-06
Two-sided Pr <= P	3.217E-06

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

trtseq	respond50		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	30 26.55 53.57 47.62	26 23.01 46.43 52.00	56 49.56
P	33 29.20 57.89 52.38	24 21.24 42.11 48.00	57 50.44
Total	63 55.75	50 44.25	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by respond50
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.2140	0.6436
Likelihood Ratio Chi-Square	1	0.2141	0.6436
Continuity Adj. Chi-Square	1	0.0746	0.7847
Mantel-Haenszel Chi-Square	1	0.2121	0.6451
Phi Coefficient		-0.0435	
Contingency Coefficient		0.0435	
Cramer's V		-0.0435	

Fisher's Exact Test

Cell (1,1) Frequency (F)	30
Left-sided Pr <= F	0.3924
Right-sided Pr >= F	0.7427
Table Probability (P)	0.1351
Two-sided Pr <= P	0.7066

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.3 MADRS Response (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Summary Statistics for trtseq by respond50
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	16.5500	<.0001
2	Row Mean Scores Differ	1	16.5500	<.0001
3	General Association	1	16.5500	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4112	0.2663	0.6349
	Logit	0.4097	0.2635	0.6372
Cohort (Col1 Risk)	Mantel-Haenszel	0.6543	0.5295	0.8084
	Logit	0.6731	0.5444	0.8321
Cohort (Col2 Risk)	Mantel-Haenszel	1.6131	1.2693	2.0500
	Logit	1.6002	1.2567	2.0376

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	5.5718
DF	1
Pr > ChiSq	0.0183

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS226H.SAS
GENERATED: 14JUL2005 11:40:31 iceadmn3

12.1.9.2.1.4 MADRS Response - Homogeneity Across Diagnoses (Dreslow-Day Test - LOCF - ITT)

Obs	visit	numcd	Value	LowerCL	UpperCL	trtseq	Chi_Square	DF	Pr___ChiSq	nvisit
1	3		.	.	.	Q300MG VS P	0.055172	1.000000	0.814296	DAY 8
2	3	BIPOLAR I	1.6822	0.8391	3.3723	Q300MG VS P	.	.	.	DAY 8
3	3	BIPOLAR II	1.4541	0.5955	3.5505	Q300MG VS P	.	.	.	DAY 8
4	3		.	.	.	Q600MG VS P	0.880765	1.000000	0.347992	DAY 8
5	3	BIPOLAR I	2.6794	1.4132	5.0802	Q600MG VS P	.	.	.	DAY 8
6	3	BIPOLAR II	1.6286	0.6808	3.8959	Q600MG VS P	.	.	.	DAY 8
7	4		.	.	.	Q300MG VS P	2.034834	1.000000	0.153731	DAY 15
8	4	BIPOLAR I	2.2690	1.4405	3.5738	Q300MG VS P	.	.	.	DAY 15
9	4	BIPOLAR II	1.3310	0.7154	2.4765	Q300MG VS P	.	.	.	DAY 15
10	4		.	.	.	Q600MG VS P	0.964225	1.000000	0.326125	DAY 15
11	4	BIPOLAR I	1.9649	1.2291	3.1412	Q600MG VS P	.	.	.	DAY 15
12	4	BIPOLAR II	1.3310	0.7154	2.4765	Q600MG VS P	.	.	.	DAY 15
13	5		.	.	.	Q300MG VS P	0.385982	1.000000	0.534419	DAY 22
14	5	BIPOLAR I	1.8238	1.2378	2.6870	Q300MG VS P	.	.	.	DAY 22
15	5	BIPOLAR II	1.4929	0.8675	2.5691	Q300MG VS P	.	.	.	DAY 22
16	5		.	.	.	Q600MG VS P	2.014496	1.000000	0.155803	DAY 22
17	5	BIPOLAR I	2.0013	1.3691	2.9254	Q600MG VS P	.	.	.	DAY 22
18	5	BIPOLAR II	1.2893	0.7308	2.2746	Q600MG VS P	.	.	.	DAY 22
19	6		.	.	.	Q300MG VS P	0.015493	1.000000	0.900943	DAY 29
20	6	BIPOLAR I	1.5903	1.1343	2.2295	Q300MG VS P	.	.	.	DAY 29
21	6	BIPOLAR II	1.5268	0.9555	2.4397	Q300MG VS P	.	.	.	DAY 29
22	6		.	.	.	Q600MG VS P	1.714442	1.000000	0.190410	DAY 29
23	6	BIPOLAR I	2.0516	1.4975	2.8106	Q600MG VS P	.	.	.	DAY 29
24	6	BIPOLAR II	1.5268	0.9555	2.4397	Q600MG VS P	.	.	.	DAY 29
25	7		.	.	.	Q300MG VS P	3.459606	1.000000	0.062885	DAY 36
26	7	BIPOLAR I	1.9310	1.3919	2.6791	Q300MG VS P	.	.	.	DAY 36
27	7	BIPOLAR II	1.1786	0.7215	1.9252	Q300MG VS P	.	.	.	DAY 36
28	7		.	.	.	Q600MG VS P	2.223349	1.000000	0.135938	DAY 36
29	7	BIPOLAR I	1.9054	1.3708	2.6484	Q600MG VS P	.	.	.	DAY 36
30	7	BIPOLAR II	1.2857	0.7990	2.0688	Q600MG VS P	.	.	.	DAY 36
31	8		.	.	.	Q300MG VS P	3.141512	1.000000	0.076323	DAY 43
32	8	BIPOLAR I	2.0556	1.4651	2.8842	Q300MG VS P	.	.	.	DAY 43
33	8	BIPOLAR II	1.2602	0.8106	1.9591	Q300MG VS P	.	.	.	DAY 43
34	8		.	.	.	Q600MG VS P	5.719663	1.000000	0.016776	DAY 43
35	8	BIPOLAR I	2.3135	1.6641	3.2163	Q600MG VS P	.	.	.	DAY 43
36	8	BIPOLAR II	1.2602	0.8106	1.9591	Q600MG VS P	.	.	.	DAY 43
37	9		.	.	.	Q300MG VS P	1.574250	1.000000	0.209591	DAY 50
38	9	BIPOLAR I	1.9896	1.4378	2.7530	Q300MG VS P	.	.	.	DAY 50
39	9	BIPOLAR II	1.4464	0.9162	2.2834	Q300MG VS P	.	.	.	DAY 50
40	9		.	.	.	Q600MG VS P	2.453927	1.000000	0.117231	DAY 50
41	9	BIPOLAR I	2.0542	1.4878	2.8364	Q600MG VS P	.	.	.	DAY 50
42	9	BIPOLAR II	1.3929	0.8771	2.2120	Q600MG VS P	.	.	.	DAY 50
43	10		.	.	.	Q300MG VS P	4.136668	1.000000	0.041964	DAY 57
44	10	BIPOLAR I	1.8788	1.3924	2.5352	Q300MG VS P	.	.	.	DAY 57

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS228H.SAS
GENERATED: 14JUL2005 11:40:34 iceadmn3

12.1.9.2.1.4 MADRS Response - Homogeneity Across Diagnoses (Dreslow-Day Test - LOCF - ITT)

Obs	visit	numcd	Value	LowerCL	UpperCL	trtseq	Chi_Square	DF	Pr___ChiSq	nvisit
45	10	BIPOLAR II	1.1451	0.7616	1.7217	Q300MG VS P	.	.	.	DAY 57
46	10		.	.	.	Q600MG VS P	5.571789	1.000000	0.018252	DAY 57
47	10	BIPOLAR I	1.9384	1.4397	2.6097	Q600MG VS P	.	.	.	DAY 57
48	10	BIPOLAR II	1.1027	0.7285	1.6690	Q600MG VS P	.	.	.	DAY 57

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS228H.SAS
GENERATED: 14JUL2005 11:40:34 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	153 45.00 89.47 49.51	18 5.29 10.53 58.06	171 50.29
P	156 45.88 92.31 50.49	13 3.82 7.69 41.94	169 49.71
Total	309 90.88	31 9.12	340 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	126 36.95 73.26 45.99	46 13.49 26.74 68.66	172 50.44
P	148 43.40 87.57 54.01	21 6.16 12.43 31.34	169 49.56
Total	274 80.35	67 19.65	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	112 32.84 65.12 44.62	60 17.60 34.88 66.67	172 50.44
P	139 40.76 82.25 55.38	30 8.80 17.75 33.33	169 49.56
Total	251 73.61	90 26.39	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	108 31.67 62.79 44.08	64 18.77 37.21 66.67	172 50.44
P	137 40.18 81.07 55.92	32 9.38 18.93 33.33	169 49.56
Total	245 71.85	96 28.15	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	101 29.62 58.72 44.30	71 20.82 41.28 62.83	172 50.44
P	127 37.24 75.15 55.70	42 12.32 24.85 37.17	169 49.56
Total	228 66.86	113 33.14	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	87 25.51 50.58 40.65	85 24.93 49.42 66.93	172 50.44
P	127 37.24 75.15 59.35	42 12.32 24.85 33.07	169 49.56
Total	214 62.76	127 37.24	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	83 24.34 48.26 39.90	89 26.10 51.74 66.92	172 50.44
P	125 36.66 73.96 60.10	44 12.90 26.04 33.08	169 49.56
Total	208 61.00	133 39.00	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	81 23.75 47.09 40.10	91 26.69 52.91 65.47	172 50.44
P	121 35.48 71.60 59.90	48 14.08 28.40 34.53	169 49.56
Total	202 59.24	139 40.76	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	146 43.20 86.39 48.34	23 6.80 13.61 63.89	169 50.00
P	156 46.15 92.31 51.66	13 3.85 7.69 36.11	169 50.00
Total	302 89.35	36 10.65	338 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	124 36.58 72.94 45.59	46 13.57 27.06 68.66	170 50.15
P	148 43.66 87.57 54.41	21 6.19 12.43 31.34	169 49.85
Total	272 80.24	67 19.76	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	107 31.56 62.94 43.50	63 18.58 37.06 67.74	170 50.15
P	139 41.00 82.25 56.50	30 8.85 17.75 32.26	169 49.85
Total	246 72.57	93 27.43	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	86 25.37 50.59 38.57	84 24.78 49.41 72.41	170 50.15
P	137 40.41 81.07 61.43	32 9.44 18.93 27.59	169 49.85
Total	223 65.78	116 34.22	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	88 25.96 51.76 40.93	82 24.19 48.24 66.13	170 50.15
P	127 37.46 75.15 59.07	42 12.39 24.85 33.87	169 49.85
Total	215 63.42	124 36.58	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	83 24.48 48.82 39.52	87 25.66 51.18 67.44	170 50.15
P	127 37.46 75.15 60.48	42 12.39 24.85 32.56	169 49.85
Total	210 61.95	129 38.05	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	85 25.07 50.00 40.48	85 25.07 50.00 65.89	170 50.15
P	125 36.87 73.96 59.52	44 12.98 26.04 34.11	169 49.85
Total	210 61.95	129 38.05	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table of trtseq by nremiss12

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	80 23.60 47.06 39.80	90 26.55 52.94 65.22	170 50.15
P	121 35.69 71.60 60.20	48 14.16 28.40 34.78	169 49.85
Total	201 59.29	138 40.71	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	100 44.05 86.96 49.02	15 6.61 13.04 65.22	115 50.66
P	104 45.81 92.86 50.98	8 3.52 7.14 34.78	112 49.34
Total	204 89.87	23 10.13	227 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	2.1696	0.1408
Likelihood Ratio Chi-Square	1	2.2034	0.1377
Continuity Adj. Chi-Square	1	1.5700	0.2102
Mantel-Haenszel Chi-Square	1	2.1600	0.1416
Phi Coefficient		-0.0978	
Contingency Coefficient		0.0973	
Cramer's V		-0.0978	

Fisher's Exact Test

Cell (1,1) Frequency (F)	100
Left-sided Pr <= F	0.1047
Right-sided Pr >= F	0.9558
Table Probability (P)	0.0605
Two-sided Pr <= P	0.1870

Sample Size = 227

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	53 46.90 94.64 50.48	3 2.65 5.36 37.50	56 49.56
P	52 46.02 91.23 49.52	5 4.42 8.77 62.50	57 50.44
Total	105 92.92	8 7.08	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.5007	0.4792
Likelihood Ratio Chi-Square	1	0.5060	0.4769
Continuity Adj. Chi-Square	1	0.1162	0.7332
Mantel-Haenszel Chi-Square	1	0.4963	0.4811
Phi Coefficient		0.0666	
Contingency Coefficient		0.0664	
Cramer's V		0.0666	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	53
Left-sided Pr <= F	0.8586
Right-sided Pr >= F	0.3682
Table Probability (P)	0.2268
Two-sided Pr <= P	0.7165

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	0.8041	0.3699
2	Row Mean Scores Differ	1	0.8041	0.3699
3	General Association	1	0.8041	0.3699

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.7112	0.3371	1.5005
	Logit	0.7086	0.3281	1.5300
Cohort (Col1 Risk)	Mantel-Haenszel	0.9696	0.9065	1.0371
	Logit	0.9781	0.9153	1.0452
Cohort (Col2 Risk)	Mantel-Haenszel	1.3650	0.6888	2.7047
	Logit	1.3751	0.6802	2.7797

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.9052
DF	1
Pr > ChiSq	0.1675

Total Sample Size = 340

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	83 36.40 71.55 45.60	33 14.47 28.45 71.74	116 50.88
P	99 43.42 88.39 54.40	13 5.70 11.61 28.26	112 49.12
Total	182 79.82	46 20.18	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	10.0352	0.0015
Likelihood Ratio Chi-Square	1	10.3309	0.0013
Continuity Adj. Chi-Square	1	9.0167	0.0027
Mantel-Haenszel Chi-Square	1	9.9911	0.0016
Phi Coefficient		-0.2098	
Contingency Coefficient		0.2053	
Cramer's V		-0.2098	

Fisher's Exact Test

Cell (1,1) Frequency (F)	83
Left-sided Pr <= F	0.0012
Right-sided Pr >= F	0.9996
Table Probability (P)	8.319E-04
Two-sided Pr <= P	0.0017

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	43 38.05 76.79 46.74	13 11.50 23.21 61.90	56 49.56
P	49 43.36 85.96 53.26	8 7.08 14.04 38.10	57 50.44
Total	92 81.42	21 18.58	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.5731	0.2098
Likelihood Ratio Chi-Square	1	1.5847	0.2081
Continuity Adj. Chi-Square	1	1.0249	0.3114
Mantel-Haenszel Chi-Square	1	1.5591	0.2118
Phi Coefficient		-0.1180	
Contingency Coefficient		0.1172	
Cramer's V		-0.1180	

Fisher's Exact Test

Cell (1,1) Frequency (F)	43
Left-sided Pr <= F	0.1557
Right-sided Pr >= F	0.9332
Table Probability (P)	0.0889
Two-sided Pr <= P	0.2350

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	10.9820	0.0009
2	Row Mean Scores Differ	1	10.9820	0.0009
3	General Association	1	10.9820	0.0009

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3895	0.2207	0.6873
	Logit	0.3913	0.2212	0.6924
Cohort (Col1 Risk)	Mantel-Haenszel	0.8367	0.7521	0.9309
	Logit	0.8385	0.7537	0.9327
Cohort (Col2 Risk)	Mantel-Haenszel	2.1523	1.3430	3.4491
	Logit	2.1357	1.3306	3.4281

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.6477
DF	1
Pr > ChiSq	0.4209

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	73 32.02 62.93 43.98	43 18.86 37.07 69.35	116 50.88
P	93 40.79 83.04 56.02	19 8.33 16.96 30.65	112 49.12
Total	166 72.81	62 27.19	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	11.6334	0.0006
Likelihood Ratio Chi-Square	1	11.8828	0.0006
Continuity Adj. Chi-Square	1	10.6401	0.0011
Mantel-Haenszel Chi-Square	1	11.5823	0.0007
Phi Coefficient		-0.2259	
Contingency Coefficient		0.2203	
Cramer's V		-0.2259	

Fisher's Exact Test

Cell (1,1) Frequency (F)	73
Left-sided Pr <= F	4.997E-04
Right-sided Pr >= F	0.9998
Table Probability (P)	3.391E-04
Two-sided Pr <= P	9.677E-04

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	39 34.51 69.64 45.88	17 15.04 30.36 60.71	56 49.56
P	46 40.71 80.70 54.12	11 9.73 19.30 39.29	57 50.44
Total	85 75.22	28 24.78	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.8535	0.1734
Likelihood Ratio Chi-Square	1	1.8640	0.1722
Continuity Adj. Chi-Square	1	1.3076	0.2528
Mantel-Haenszel Chi-Square	1	1.8371	0.1753
Phi Coefficient		-0.1281	
Contingency Coefficient		0.1270	
Cramer's V		-0.1281	

Fisher's Exact Test

Cell (1,1) Frequency (F)	39
Left-sided Pr <= F	0.1263
Right-sided Pr >= F	0.9433
Table Probability (P)	0.0696
Two-sided Pr <= P	0.1965

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	12.7725	0.0004
2	Row Mean Scores Differ	1	12.7725	0.0004
3	General Association	1	12.7725	0.0004

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4039	0.2441	0.6683
	Logit	0.4049	0.2442	0.6711
Cohort (Col1 Risk)	Mantel-Haenszel	0.7920	0.6956	0.9018
	Logit	0.7947	0.6981	0.9048
Cohort (Col2 Risk)	Mantel-Haenszel	1.9644	1.3377	2.8848
	Logit	1.9555	1.3303	2.8744

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.7088
DF	1
Pr > ChiSq	0.3998

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	70 30.70 60.34 43.21	46 20.18 39.66 69.70	116 50.88
P	92 40.35 82.14 56.79	20 8.77 17.86 30.30	112 49.12
Total	162 71.05	66 28.95	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	13.1640	0.0003
Likelihood Ratio Chi-Square	1	13.4520	0.0002
Continuity Adj. Chi-Square	1	12.1255	0.0005
Mantel-Haenszel Chi-Square	1	13.1062	0.0003
Phi Coefficient		-0.2403	
Contingency Coefficient		0.2336	
Cramer's V		-0.2403	

Fisher's Exact Test

Cell (1,1) Frequency (F)	70
Left-sided Pr <= F	2.206E-04
Right-sided Pr >= F	0.9999
Table Probability (P)	1.526E-04
Two-sided Pr <= P	4.113E-04

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	38 33.63 67.86 45.78	18 15.93 32.14 60.00	56 49.56
P	45 39.82 78.95 54.22	12 10.62 21.05 40.00	57 50.44
Total	83 73.45	30 26.55	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.7817	0.1819
Likelihood Ratio Chi-Square	1	1.7903	0.1809
Continuity Adj. Chi-Square	1	1.2583	0.2620
Mantel-Haenszel Chi-Square	1	1.7659	0.1839
Phi Coefficient		-0.1256	
Contingency Coefficient		0.1246	
Cramer's V		-0.1256	

Fisher's Exact Test

Cell (1,1) Frequency (F)	38
Left-sided Pr <= F	0.1309
Right-sided Pr >= F	0.9395
Table Probability (P)	0.0704
Two-sided Pr <= P	0.2062

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	13.9602	0.0002
2	Row Mean Scores Differ	1	13.9602	0.0002
3	General Association	1	13.9602	0.0002

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3955	0.2416	0.6475
	Logit	0.3965	0.2416	0.6507
Cohort (Col1 Risk)	Mantel-Haenszel	0.7749	0.6763	0.8880
	Logit	0.7782	0.6792	0.8916
Cohort (Col2 Risk)	Mantel-Haenszel	1.9647	1.3592	2.8400
	Logit	1.9524	1.3491	2.8255

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.9978
DF	1
Pr > ChiSq	0.3179

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	62 27.19 53.45 42.47	54 23.68 46.55 65.85	116 50.88
P	84 36.84 75.00 57.53	28 12.28 25.00 34.15	112 49.12
Total	146 64.04	82 35.96	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	11.4923	0.0007
Likelihood Ratio Chi-Square	1	11.6455	0.0006
Continuity Adj. Chi-Square	1	10.5756	0.0011
Mantel-Haenszel Chi-Square	1	11.4419	0.0007
Phi Coefficient		-0.2245	
Contingency Coefficient		0.2191	
Cramer's V		-0.2245	

Fisher's Exact Test

Cell (1,1) Frequency (F)	62
Left-sided Pr <= F	5.377E-04
Right-sided Pr >= F	0.9998
Table Probability (P)	3.461E-04
Two-sided Pr <= P	8.894E-04

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	39 34.51 69.64 47.56	17 15.04 30.36 54.84	56 49.56
P	43 38.05 75.44 52.44	14 12.39 24.56 45.16	57 50.44
Total	82 72.57	31 27.43	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.4766	0.4900
Likelihood Ratio Chi-Square	1	0.4771	0.4897
Continuity Adj. Chi-Square	1	0.2300	0.6316
Mantel-Haenszel Chi-Square	1	0.4724	0.4919
Phi Coefficient		-0.0649	
Contingency Coefficient		0.0648	
Cramer's V		-0.0649	

Fisher's Exact Test

Cell (1,1) Frequency (F)	39
Left-sided Pr <= F	0.3159
Right-sided Pr >= F	0.8162
Table Probability (P)	0.1321
Two-sided Pr <= P	0.5322

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	10.2737	0.0013
2	Row Mean Scores Differ	1	10.2737	0.0013
3	General Association	1	10.2737	0.0013

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4721	0.2973	0.7497
	Logit	0.4724	0.2966	0.7523
Cohort (Col1 Risk)	Mantel-Haenszel	0.7827	0.6723	0.9112
	Logit	0.7980	0.6865	0.9277
Cohort (Col2 Risk)	Mantel-Haenszel	1.6570	1.2063	2.2761
	Logit	1.6610	1.2076	2.2845

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.7197
DF	1
Pr > ChiSq	0.1897

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	55 24.12 47.41 39.29	61 26.75 52.59 69.32	116 50.88
P	85 37.28 75.89 60.71	27 11.84 24.11 30.68	112 49.12
Total	140 61.40	88 38.60	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	19.5008	<.0001
Likelihood Ratio Chi-Square	1	19.8929	<.0001
Continuity Adj. Chi-Square	1	18.3176	<.0001
Mantel-Haenszel Chi-Square	1	19.4152	<.0001
Phi Coefficient		-0.2925	
Contingency Coefficient		0.2807	
Cramer's V		-0.2925	

Fisher's Exact Test

Cell (1,1) Frequency (F)	55
Left-sided Pr <= F	7.877E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	5.745E-06
Two-sided Pr <= P	1.193E-05

Sample Size = 228

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	32 28.32 57.14 43.24	24 21.24 42.86 61.54	56 49.56
P	42 37.17 73.68 56.76	15 13.27 26.32 38.46	57 50.44
Total	74 65.49	39 34.51	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	3.4197	0.0644
Likelihood Ratio Chi-Square	1	3.4424	0.0635
Continuity Adj. Chi-Square	1	2.7270	0.0987
Mantel-Haenszel Chi-Square	1	3.3894	0.0656
Phi Coefficient		-0.1740	
Contingency Coefficient		0.1714	
Cramer's V		-0.1740	

Fisher's Exact Test

Cell (1,1) Frequency (F)	32
Left-sided Pr <= F	0.0491
Right-sided Pr >= F	0.9800
Table Probability (P)	0.0291
Two-sided Pr <= P	0.0767

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	21.8358	<.0001
2	Row Mean Scores Differ	1	21.8358	<.0001
3	General Association	1	21.8358	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3399	0.2148	0.5378
	Logit	0.3401	0.2146	0.5390
Cohort (Col1 Risk)	Mantel-Haenszel	0.6737	0.5677	0.7995
	Logit	0.6792	0.5725	0.8058
Cohort (Col2 Risk)	Mantel-Haenszel	1.9873	1.4673	2.6915
	Logit	1.9810	1.4617	2.6846

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.0501
DF	1
Pr > ChiSq	0.3055

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	52 22.81 44.83 38.81	64 28.07 55.17 68.09	116 50.88
P	82 35.96 73.21 61.19	30 13.16 26.79 31.91	112 49.12
Total	134 58.77	94 41.23	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	18.9499	<.0001
Likelihood Ratio Chi-Square	1	19.2846	<.0001
Continuity Adj. Chi-Square	1	17.7965	<.0001
Mantel-Haenszel Chi-Square	1	18.8668	<.0001
Phi Coefficient		-0.2883	
Contingency Coefficient		0.2770	
Cramer's V		-0.2883	

Fisher's Exact Test

Cell (1,1) Frequency (F)	52
Left-sided Pr <= F	1.062E-05
Right-sided Pr >= F	1.0000
Table Probability (P)	7.638E-06
Two-sided Pr <= P	1.544E-05

Sample Size = 228

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	31 27.43 55.36 41.89	25 22.12 44.64 64.10	56 49.56
P	43 38.05 75.44 58.11	14 12.39 24.56 35.90	57 50.44
Total	74 65.49	39 34.51	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	5.0401	0.0248
Likelihood Ratio Chi-Square	1	5.0908	0.0241
Continuity Adj. Chi-Square	1	4.1907	0.0406
Mantel-Haenszel Chi-Square	1	4.9955	0.0254
Phi Coefficient		-0.2112	
Contingency Coefficient		0.2066	
Cramer's V		-0.2112	

Fisher's Exact Test

Cell (1,1) Frequency (F)	31
Left-sided Pr <= F	0.0200
Right-sided Pr >= F	0.9930
Table Probability (P)	0.0130
Two-sided Pr <= P	0.0302

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	23.5031	<.0001
2	Row Mean Scores Differ	1	23.5031	<.0001
3	General Association	1	23.5031	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3284	0.2081	0.5181
	Logit	0.3284	0.2080	0.5183
Cohort (Col1 Risk)	Mantel-Haenszel	0.6534	0.5466	0.7809
	Logit	0.6593	0.5520	0.7874
Cohort (Col2 Risk)	Mantel-Haenszel	1.9841	1.4815	2.6572
	Logit	1.9858	1.4826	2.6597

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.3793
DF	1
Pr > ChiSq	0.5380

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	49 21.49 42.24 37.40	67 29.39 57.76 69.07	116 50.88
P	82 35.96 73.21 62.60	30 13.16 26.79 30.93	112 49.12
Total	131 57.46	97 42.54	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	22.3631	<.0001
Likelihood Ratio Chi-Square	1	22.8103	<.0001
Continuity Adj. Chi-Square	1	21.1139	<.0001
Mantel-Haenszel Chi-Square	1	22.2650	<.0001
Phi Coefficient		-0.3132	
Contingency Coefficient		0.2989	
Cramer's V		-0.3132	

Fisher's Exact Test

Cell (1,1) Frequency (F)	49
Left-sided Pr <= F	1.776E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	1.325E-06
Two-sided Pr <= P	2.480E-06

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	32 28.32 57.14 45.07	24 21.24 42.86 57.14	56 49.56
P	39 34.51 68.42 54.93	18 15.93 31.58 42.86	57 50.44
Total	71 62.83	42 37.17	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.5386	0.2148
Likelihood Ratio Chi-Square	1	1.5425	0.2142
Continuity Adj. Chi-Square	1	1.0935	0.2957
Mantel-Haenszel Chi-Square	1	1.5249	0.2169
Phi Coefficient		-0.1167	
Contingency Coefficient		0.1159	
Cramer's V		-0.1167	

Fisher's Exact Test

Cell (1,1) Frequency (F)	32
Left-sided Pr <= F	0.1478
Right-sided Pr >= F	0.9245
Table Probability (P)	0.0724
Two-sided Pr <= P	0.2462

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	21.0257	<.0001
2	Row Mean Scores Differ	1	21.0257	<.0001
3	General Association	1	21.0257	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3565	0.2280	0.5576
	Logit	0.3564	0.2269	0.5597
Cohort (Col1 Risk)	Mantel-Haenszel	0.6587	0.5476	0.7924
	Logit	0.6719	0.5588	0.8080
Cohort (Col2 Risk)	Mantel-Haenszel	1.8615	1.4080	2.4612
	Logit	1.8492	1.3965	2.4485

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	2.9692
DF	1
Pr > ChiSq	0.0849

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	96 42.48 84.21 48.00	18 7.96 15.79 69.23	114 50.44
P	104 46.02 92.86 52.00	8 3.54 7.14 30.77	112 49.56
Total	200 88.50	26 11.50	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	4.1488	0.0417
Likelihood Ratio Chi-Square	1	4.2495	0.0393
Continuity Adj. Chi-Square	1	3.3429	0.0675
Mantel-Haenszel Chi-Square	1	4.1304	0.0421
Phi Coefficient		-0.1355	
Contingency Coefficient		0.1343	
Cramer's V		-0.1355	

Fisher's Exact Test

Cell (1,1) Frequency (F)	96
Left-sided Pr <= F	0.0328
Right-sided Pr >= F	0.9884
Table Probability (P)	0.0213
Two-sided Pr <= P	0.0593

Sample Size = 226

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	50 44.64 90.91 49.02	5 4.46 9.09 50.00	55 49.11
P	52 46.43 91.23 50.98	5 4.46 8.77 50.00	57 50.89
Total	102 91.07	10 8.93	112 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.0035	0.9528
Likelihood Ratio Chi-Square	1	0.0035	0.9528
Continuity Adj. Chi-Square	1	0.0000	1.0000
Mantel-Haenszel Chi-Square	1	0.0035	0.9530
Phi Coefficient		-0.0056	
Contingency Coefficient		0.0056	
Cramer's V		-0.0056	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	50
Left-sided Pr <= F	0.6059
Right-sided Pr >= F	0.6515
Table Probability (P)	0.2574
Two-sided Pr <= P	1.0000

Sample Size = 112

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 8 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	3.0646	0.0800
2	Row Mean Scores Differ	1	3.0646	0.0800
3	General Association	1	3.0646	0.0800

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.5309	0.2595	1.0863
	Logit	0.5358	0.2589	1.1089
Cohort (Col1 Risk)	Mantel-Haenszel	0.9362	0.8695	1.0080
	Logit	0.9417	0.8751	1.0133
Cohort (Col2 Risk)	Mantel-Haenszel	1.7664	0.9238	3.3773
	Logit	1.7493	0.9064	3.3761

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.1541
DF	1
Pr > ChiSq	0.2827

Total Sample Size = 338

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	80 35.40 70.18 44.69	34 15.04 29.82 72.34	114 50.44
P	99 43.81 88.39 55.31	13 5.75 11.61 27.66	112 49.56
Total	179 79.20	47 20.80	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	11.3829	0.0007
Likelihood Ratio Chi-Square	1	11.7260	0.0006
Continuity Adj. Chi-Square	1	10.3038	0.0013
Mantel-Haenszel Chi-Square	1	11.3326	0.0008
Phi Coefficient		-0.2244	
Contingency Coefficient		0.2190	
Cramer's V		-0.2244	

Fisher's Exact Test

Cell (1,1) Frequency (F)	80
Left-sided Pr <= F	5.792E-04
Right-sided Pr >= F	0.9998
Table Probability (P)	4.148E-04
Two-sided Pr <= P	9.357E-04

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	44 38.94 78.57 47.31	12 10.62 21.43 60.00	56 49.56
P	49 43.36 85.96 52.69	8 7.08 14.04 40.00	57 50.44
Total	93 82.30	20 17.70	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.0601	0.3032
Likelihood Ratio Chi-Square	1	1.0655	0.3020
Continuity Adj. Chi-Square	1	0.6132	0.4336
Mantel-Haenszel Chi-Square	1	1.0507	0.3054
Phi Coefficient		-0.0969	
Contingency Coefficient		0.0964	
Cramer's V		-0.0969	

Fisher's Exact Test

Cell (1,1) Frequency (F)	44
Left-sided Pr <= F	0.2170
Right-sided Pr >= F	0.8993
Table Probability (P)	0.1164
Two-sided Pr <= P	0.3340

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 15 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	11.3551	0.0008
2	Row Mean Scores Differ	1	11.3551	0.0008
3	General Association	1	11.3551	0.0008

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3840	0.2176	0.6774
	Logit	0.3866	0.2182	0.6852
Cohort (Col1 Risk)	Mantel-Haenszel	0.8332	0.7481	0.9280
	Logit	0.8385	0.7531	0.9335
Cohort (Col2 Risk)	Mantel-Haenszel	2.1766	1.3584	3.4876
	Logit	2.1540	1.3403	3.4618

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.1593
DF	1
Pr > ChiSq	0.2816

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	66 29.20 57.89 41.51	48 21.24 42.11 71.64	114 50.44
P	93 41.15 83.04 58.49	19 8.41 16.96 28.36	112 49.56
Total	159 70.35	67 29.65	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	17.1208	<.0001
Likelihood Ratio Chi-Square	1	17.5664	<.0001
Continuity Adj. Chi-Square	1	15.9366	<.0001
Mantel-Haenszel Chi-Square	1	17.0450	<.0001
Phi Coefficient		-0.2752	
Contingency Coefficient		0.2654	
Cramer's V		-0.2752	

Fisher's Exact Test

Cell (1,1) Frequency (F)	66
Left-sided Pr <= F	2.708E-05
Right-sided Pr >= F	1.0000
Table Probability (P)	1.994E-05
Two-sided Pr <= P	3.987E-05

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	41 36.28 73.21 47.13	15 13.27 26.79 57.69	56 49.56
P	46 40.71 80.70 52.87	11 9.73 19.30 42.31	57 50.44
Total	87 76.99	26 23.01	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.8940	0.3444
Likelihood Ratio Chi-Square	1	0.8965	0.3437
Continuity Adj. Chi-Square	1	0.5213	0.4703
Mantel-Haenszel Chi-Square	1	0.8861	0.3465
Phi Coefficient		-0.0889	
Contingency Coefficient		0.0886	
Cramer's V		-0.0889	

Fisher's Exact Test

Cell (1,1) Frequency (F)	41
Left-sided Pr <= F	0.2353
Right-sided Pr >= F	0.8789
Table Probability (P)	0.1143
Two-sided Pr <= P	0.3785

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 22 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	15.7717	<.0001
2	Row Mean Scores Differ	1	15.7717	<.0001
3	General Association	1	15.7717	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3689	0.2235	0.6089
	Logit	0.3705	0.2233	0.6149
Cohort (Col1 Risk)	Mantel-Haenszel	0.7659	0.6692	0.8766
	Logit	0.7815	0.6837	0.8932
Cohort (Col2 Risk)	Mantel-Haenszel	2.0853	1.4256	3.0504
	Logit	2.0687	1.4097	3.0357

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	2.3776
DF	1
Pr > ChiSq	0.1231

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	54 23.89 47.37 36.99	60 26.55 52.63 75.00	114 50.44
P	92 40.71 82.14 63.01	20 8.85 17.86 25.00	112 49.56
Total	146 64.60	80 35.40	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	29.8751	<.0001
Likelihood Ratio Chi-Square	1	30.9174	<.0001
Continuity Adj. Chi-Square	1	28.3737	<.0001
Mantel-Haenszel Chi-Square	1	29.7429	<.0001
Phi Coefficient		-0.3636	
Contingency Coefficient		0.3417	
Cramer's V		-0.3636	

Fisher's Exact Test

Cell (1,1) Frequency (F)	54
Left-sided Pr <= F	3.138E-08
Right-sided Pr >= F	1.0000
Table Probability (P)	2.553E-08
Two-sided Pr <= P	4.152E-08

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	32 28.32 57.14 41.56	24 21.24 42.86 66.67	56 49.56
P	45 39.82 78.95 58.44	12 10.62 21.05 33.33	57 50.44
Total	77 68.14	36 31.86	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	6.1864	0.0129
Likelihood Ratio Chi-Square	1	6.2741	0.0123
Continuity Adj. Chi-Square	1	5.2228	0.0223
Mantel-Haenszel Chi-Square	1	6.1317	0.0133
Phi Coefficient		-0.2340	
Contingency Coefficient		0.2278	
Cramer's V		-0.2340	

Fisher's Exact Test

Cell (1,1) Frequency (F)	32
Left-sided Pr <= F	0.0108
Right-sided Pr >= F	0.9966
Table Probability (P)	0.0075
Two-sided Pr <= P	0.0158

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 29 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	34.7486	<.0001
2	Row Mean Scores Differ	1	34.7486	<.0001
3	General Association	1	34.7486	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.2406	0.1478	0.3918
	Logit	0.2411	0.1478	0.3935
Cohort (Col1 Risk)	Mantel-Haenszel	0.6244	0.5292	0.7368
	Logit	0.6305	0.5345	0.7437
Cohort (Col2 Risk)	Mantel-Haenszel	2.6093	1.8426	3.6950
	Logit	2.5861	1.8246	3.6652

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.3049
DF	1
Pr > ChiSq	0.2533

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	54 23.89 47.37 39.13	60 26.55 52.63 68.18	114 50.44
P	84 37.17 75.00 60.87	28 12.39 25.00 31.82	112 49.56
Total	138 61.06	88 38.94	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	18.1418	<.0001
Likelihood Ratio Chi-Square	1	18.4638	<.0001
Continuity Adj. Chi-Square	1	16.9983	<.0001
Mantel-Haenszel Chi-Square	1	18.0616	<.0001
Phi Coefficient		-0.2833	
Contingency Coefficient		0.2726	
Cramer's V		-0.2833	

Fisher's Exact Test

Cell (1,1) Frequency (F)	54
Left-sided Pr <= F	1.627E-05
Right-sided Pr >= F	1.0000
Table Probability (P)	1.167E-05
Two-sided Pr <= P	2.250E-05

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
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12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	34 30.09 60.71 44.16	22 19.47 39.29 61.11	56 49.56
P	43 38.05 75.44 55.84	14 12.39 24.56 38.89	57 50.44
Total	77 68.14	36 31.86	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	2.8211	0.0930
Likelihood Ratio Chi-Square	1	2.8382	0.0920
Continuity Adj. Chi-Square	1	2.1836	0.1395
Mantel-Haenszel Chi-Square	1	2.7961	0.0945
Phi Coefficient		-0.1580	
Contingency Coefficient		0.1561	
Cramer's V		-0.1580	

Fisher's Exact Test

Cell (1,1) Frequency (F)	34
Left-sided Pr <= F	0.0695
Right-sided Pr >= F	0.9704
Table Probability (P)	0.0399
Two-sided Pr <= P	0.1089

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 36 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	19.8609	<.0001
2	Row Mean Scores Differ	1	19.8609	<.0001
3	General Association	1	19.8609	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3555	0.2242	0.5635
	Logit	0.3555	0.2239	0.5644
Cohort (Col1 Risk)	Mantel-Haenszel	0.6895	0.5825	0.8163
	Logit	0.7000	0.5919	0.8278
Cohort (Col2 Risk)	Mantel-Haenszel	1.9387	1.4289	2.6303
	Logit	1.9395	1.4286	2.6330

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.0628
DF	1
Pr > ChiSq	0.3026

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	49 21.68 42.98 36.57	65 28.76 57.02 70.65	114 50.44
P	85 37.61 75.89 63.43	27 11.95 24.11 29.35	112 49.56
Total	134 59.29	92 40.71	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	25.3516	<.0001
Likelihood Ratio Chi-Square	1	25.9493	<.0001
Continuity Adj. Chi-Square	1	24.0064	<.0001
Mantel-Haenszel Chi-Square	1	25.2394	<.0001
Phi Coefficient		-0.3349	
Contingency Coefficient		0.3176	
Cramer's V		-0.3349	

Fisher's Exact Test

Cell (1,1) Frequency (F)	49
Left-sided Pr <= F	3.681E-07
Right-sided Pr >= F	1.0000
Table Probability (P)	2.842E-07
Two-sided Pr <= P	4.817E-07

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	34 30.09 60.71 44.74	22 19.47 39.29 59.46	56 49.56
P	42 37.17 73.68 55.26	15 13.27 26.32 40.54	57 50.44
Total	76 67.26	37 32.74	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	2.1577	0.1419
Likelihood Ratio Chi-Square	1	2.1672	0.1410
Continuity Adj. Chi-Square	1	1.6090	0.2046
Mantel-Haenszel Chi-Square	1	2.1387	0.1436
Phi Coefficient		-0.1382	
Contingency Coefficient		0.1369	
Cramer's V		-0.1382	

Fisher's Exact Test

Cell (1,1) Frequency (F)	34
Left-sided Pr <= F	0.1022
Right-sided Pr >= F	0.9528
Table Probability (P)	0.0550
Two-sided Pr <= P	0.1639

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 43 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	24.8014	<.0001
2	Row Mean Scores Differ	1	24.8014	<.0001
3	General Association	1	24.8014	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3178	0.2007	0.5032
	Logit	0.3177	0.1998	0.5051
Cohort (Col1 Risk)	Mantel-Haenszel	0.6505	0.5452	0.7762
	Logit	0.6700	0.5623	0.7982
Cohort (Col2 Risk)	Mantel-Haenszel	2.0572	1.5219	2.7808
	Logit	2.0493	1.5135	2.7746

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	2.8093
DF	1
Pr > ChiSq	0.0937

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	51 22.57 44.74 38.35	63 27.88 55.26 67.74	114 50.44
P	82 36.28 73.21 61.65	30 13.27 26.79 32.26	112 49.56
Total	133 58.85	93 41.15	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	18.9190	<.0001
Likelihood Ratio Chi-Square	1	19.2434	<.0001
Continuity Adj. Chi-Square	1	17.7614	<.0001
Mantel-Haenszel Chi-Square	1	18.8353	<.0001
Phi Coefficient		-0.2893	
Contingency Coefficient		0.2779	
Cramer's V		-0.2893	

Fisher's Exact Test

Cell (1,1) Frequency (F)	51
Left-sided Pr <= F	1.087E-05
Right-sided Pr >= F	1.0000
Table Probability (P)	7.829E-06
Two-sided Pr <= P	1.476E-05

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	34 30.09 60.71 44.16	22 19.47 39.29 61.11	56 49.56
P	43 38.05 75.44 55.84	14 12.39 24.56 38.89	57 50.44
Total	77 68.14	36 31.86	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	2.8211	0.0930
Likelihood Ratio Chi-Square	1	2.8382	0.0920
Continuity Adj. Chi-Square	1	2.1836	0.1395
Mantel-Haenszel Chi-Square	1	2.7961	0.0945
Phi Coefficient		-0.1580	
Contingency Coefficient		0.1561	
Cramer's V		-0.1580	

Fisher's Exact Test

Cell (1,1) Frequency (F)	34
Left-sided Pr <= F	0.0695
Right-sided Pr >= F	0.9704
Table Probability (P)	0.0399
Two-sided Pr <= P	0.1089

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 50 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	20.5714	<.0001
2	Row Mean Scores Differ	1	20.5714	<.0001
3	General Association	1	20.5714	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3517	0.2226	0.5556
	Logit	0.3515	0.2222	0.5562
Cohort (Col1 Risk)	Mantel-Haenszel	0.6769	0.5686	0.8059
	Logit	0.6916	0.5819	0.8219
Cohort (Col2 Risk)	Mantel-Haenszel	1.9174	1.4276	2.5753
	Logit	1.9218	1.4302	2.5823

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.1244
DF	1
Pr > ChiSq	0.2890

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	47 20.80 41.23 36.43	67 29.65 58.77 69.07	114 50.44
P	82 36.28 73.21 63.57	30 13.27 26.79 30.93	112 49.56
Total	129 57.08	97 42.92	226 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by nremiss12
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	23.5937	<.0001
Likelihood Ratio Chi-Square	1	24.0758	<.0001
Continuity Adj. Chi-Square	1	22.3061	<.0001
Mantel-Haenszel Chi-Square	1	23.4893	<.0001
Phi Coefficient		-0.3231	
Contingency Coefficient		0.3075	
Cramer's V		-0.3231	

Fisher's Exact Test

Cell (1,1) Frequency (F)	47
Left-sided Pr <= F	9.388E-07
Right-sided Pr >= F	1.0000
Table Probability (P)	7.100E-07
Two-sided Pr <= P	1.224E-06

Sample Size = 226

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

trtseq	nremiss12		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	33 29.20 58.93 45.83	23 20.35 41.07 56.10	56 49.56
P	39 34.51 68.42 54.17	18 15.93 31.58 43.90	57 50.44
Total	72 63.72	41 36.28	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by nremiss12
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.1010	0.2940
Likelihood Ratio Chi-Square	1	1.1030	0.2936
Continuity Adj. Chi-Square	1	0.7287	0.3933
Mantel-Haenszel Chi-Square	1	1.0912	0.2962
Phi Coefficient		-0.0987	
Contingency Coefficient		0.0982	
Cramer's V		-0.0987	

Fisher's Exact Test

Cell (1,1) Frequency (F)	33
Left-sided Pr <= F	0.1967
Right-sided Pr >= F	0.8935
Table Probability (P)	0.0902
Two-sided Pr <= P	0.3317

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.5 MADRS Remission (CMH - LOCF - ITT)

---------- nvisit=DAY 57 ----------

The FREQ Procedure

Summary Statistics for trtseq by nremiss12
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	21.0167	<.0001
2	Row Mean Scores Differ	1	21.0167	<.0001
3	General Association	1	21.0167	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3565	0.2277	0.5580
	Logit	0.3560	0.2262	0.5602
Cohort (Col1 Risk)	Mantel-Haenszel	0.6581	0.5464	0.7925
	Logit	0.6772	0.5628	0.8150
Cohort (Col2 Risk)	Mantel-Haenszel	1.8628	1.4083	2.4638
	Logit	1.8517	1.3973	2.4540

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	3.8244
DF	1
Pr > ChiSq	0.0505

Total Sample Size = 339

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS247H.SAS
GENERATED: 14JUL2005 11:40:37 iceadmn3

12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Model Information

Data Set	WORK.MADRS
Dependent Variable	C_MADRS
Covariance Structures	Variance Components, Toeplitz
Subject Effect	PATIENT
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
BPDDESC	2	BIPOLAR I BIPOLAR II
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042
TRTSEQ2	3	1 2 3
VISIT	8	3 4 5 6 7 8 9 10

12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Class Level Information

Class	Levels	Values
PATIENT	511	1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1020 1021 1022 1024 1025 1026 1027 1028 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 1040 1041 1042 1044 1045 1046 1047 1048 1049 1050 1051 1052 1053 1055 1056 1057 1058 1059 1060 1062 1063 1064 1065 1066 1067 1068 1069 1070 1071 1072 1074 1075 1076 1077 1078 1079 1080 1081 1082 1083 1084 1085 1086 1087 1088 1089 1090 1091 1092 1093 1094 1095 1096 1097 1098 1099 1100 1101 1102 1103 1104 1105 1106 1107 1108 1109 1110 1111 1112 1113 1114 1115 1116 1117 1118 1119 1121 1122 1123 1124 1125 1126 1127 1128 1129 1130 1131 1132 1133 1134 1135 1136 1137 1138 1139 1140 1141 1142 1143 1144 1145 1146 1148 1149 1150 1151 1152 1153 1154 1155 1156 1157 1158 1159 1160 1161 1162 1163 1164 1165 1167 1168 1169 1170 1171 1172 1173 1174 1175 1176 1177 1178 1179 1180 1181 1182 1183 1184 1185 1186 1187 1189 1190 1192 1193 1194 1195 1196 1197 1198 1199 1200 1201 1202 1203 1204 1205 1206 1207 1208 1209 1210 1211 1212 1213 1214 1215 1216 1217 1218 1219 1220 1221 1222 1223 1224 1225 1226 1227 1228 1229 1230 1231 1232 1233 1234 1235 1236 1238 1239 1240 1241 1242 1243 1244 1245 1246 1247 1248 1249 1250 1251 1252 1253

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS253H.SAS
GENERATED: 14JUL2005 11:40:40 iceadmn3

12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

1254 1255 1256 1257 1258 1259
1260 1261 1262 1263 1264 1265
1266 1267 1268 1269 1270 1271
1272 1273 1274 1275 1276 1277
1278 1279 1280 1281 1283 1284
1285 1286 1287 1288 1289 1290
1291 1292 1293 1294 1295 1298
1299 1300 1301 1302 1303 1304
1305 1306 1307 1308 1309 1310
1311 1312 1313 1314 1315 1316
1317 1318 1320 1321 1323 1324
1325 1326 1327 1328 1329 1330
1331 1332 1333 1334 1336 1337
1338 1339 1340 1341 1342 1343
1344 1345 1346 1347 1348 1349
1350 1351 1352 1353 1354 1355
2001 2002 2003 2004 2005 2007
2008 2009 2010 2011 2012 2013
2014 2015 2016 2017 2018 2019
2020 2021 2023 2024 2025 2026
2027 2028 2029 2030 2031 2033
2034 2035 2036 2037 2038 2039
2040 2041 2042 2043 2044 2045
2046 2047 2048 2049 2050 2051
2052 2053 2054 2055 2056 2057
2058 2059 2060 2061 2063 2064
2065 2066 2067 2068 2069 2070
2071 2072 2073 2074 2075 2076
2077 2078 2079 2080 2081 2082
2083 2084 2085 2086 2087 2088
2089 2090 2091 2092 2093 2094
2095 2096 2097 2098 2099 2100
2101 2102 2103 2104 2105 2107
2108 2109 2110 2111 2112 2113
2114 2115 2116 2117 2118 2119
2120 2121 2122 2123 2124 2125
2126 2127 2128 2130 2131 2132
2133 2134 2135 2137 2138 2139
2140 2141 2142 2143 2144 2145
2146 2147 2148 2149 2151 2152
2153 2154 2155 2156 2157 2158
2160 2161 2162 2163 2164 2165
2166 2167 2168 2169 2170 2171
2172 2173 2174 2176 2177 2178

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS253H.SAS
GENERATED: 14JUL2005 11:40:40 iceadmn3

12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

2179 2180 2181 2182 2184 2185
2187

Dimensions

Covariance Parameters	9
Columns in X	39
Columns in Z	35
Subjects	1
Max Obs Per Subject	4088
Observations Used	3093
Observations Not Used	995
Total Observations	4088

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	22226.46573985	
1	3	20207.35235027	0.00000754
2	1	20207.29582615	0.00000003
3	1	20207.29563140	0.00000000

Convergence criteria met.

Estimated R Matrix for Subject 1

Row	Col1	Col2	Col3	Col4	Col5	Col6	Col7	Col8
1	74.2354	51.8406	45.0805	40.9334	37.5078	33.4926	31.5253	30.6320
2	51.8406	74.2354	51.8406	45.0805	40.9334	37.5078	33.4926	31.5253
3	45.0805	51.8406	74.2354	51.8406	45.0805	40.9334	37.5078	33.4926
4	40.9334	45.0805	51.8406	74.2354	51.8406	45.0805	40.9334	37.5078
5	37.5078	40.9334	45.0805	51.8406	74.2354	51.8406	45.0805	40.9334
6	33.4926	37.5078	40.9334	45.0805	51.8406	74.2354	51.8406	45.0805
7	31.5253	33.4926	37.5078	40.9334	45.0805	51.8406	74.2354	51.8406
8	30.6320	31.5253	33.4926	37.5078	40.9334	45.0805	51.8406	74.2354

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS253H.SAS
GENERATED: 14JUL2005 11:40:40 iceadmn3

12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Estimated R Correlation Matrix for Subject 1

Row	Col1	Col2	Col3	Col4	Col5	Col6	Col7	Col8
1	1.0000	0.6983	0.6073	0.5514	0.5053	0.4512	0.4247	0.4126
2	0.6983	1.0000	0.6983	0.6073	0.5514	0.5053	0.4512	0.4247
3	0.6073	0.6983	1.0000	0.6983	0.6073	0.5514	0.5053	0.4512
4	0.5514	0.6073	0.6983	1.0000	0.6983	0.6073	0.5514	0.5053
5	0.5053	0.5514	0.6073	0.6983	1.0000	0.6983	0.6073	0.5514
6	0.4512	0.5053	0.5514	0.6073	0.6983	1.0000	0.6983	0.6073
7	0.4247	0.4512	0.5053	0.5514	0.6073	0.6983	1.0000	0.6983
8	0.4126	0.4247	0.4512	0.5053	0.5514	0.6073	0.6983	1.0000

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
CENTRE		2.9105
TOEP(2)	PATIENT	51.8406
TOEP(3)	PATIENT	45.0805
TOEP(4)	PATIENT	40.9334
TOEP(5)	PATIENT	37.5078
TOEP(6)	PATIENT	33.4926
TOEP(7)	PATIENT	31.5253
TOEP(8)	PATIENT	30.6320
Residual		74.2354

Fit Statistics

-2 Res Log Likelihood	20207.3
AIC (smaller is better)	20225.3
AICC (smaller is better)	20225.4
BIC (smaller is better)	20239.3

Information Criteria

Neg2LogLike	Parms	AIC	AICC	HQIC	BIC	CAIC
20207.3	9	20225.3	20225.4	20230.1	20239.3	20248.3

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Solution for Fixed Effects

Effect	BIPOLAR DIAGNOSIS	TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept				0.4663	2.1398	526	0.22	0.8276
B_MADRS				-0.4322	0.06307	501	-6.85	<.0001
BPDDESC	BIPOLAR I			0.09506	0.7250	423	0.13	0.8957
BPDDESC	BIPOLAR II			0	.	.	.	.
TRTSEQ2		1		-5.9724	1.1120	1399	-5.37	<.0001
TRTSEQ2		2		-7.2351	1.1564	1460	-6.26	<.0001
TRTSEQ2		3		0	.	.	.	.
VISIT			3	7.8602	0.8533	447	9.21	<.0001
VISIT			4	4.9223	0.8562	723	5.75	<.0001
VISIT			5	3.4553	0.8447	986	4.09	<.0001
VISIT			6	2.5867	0.8223	1278	3.15	0.0017
VISIT			7	1.8470	0.7924	1564	2.33	0.0199
VISIT			8	0.9260	0.7572	1892	1.22	0.2215
VISIT			9	1.2537	0.6769	2170	1.85	0.0642
VISIT			10	0	.	.	.	.
TRTSEQ2*VISIT		1	3	2.0831	1.1720	423	1.78	0.0762
TRTSEQ2*VISIT		1	4	1.1144	1.1766	697	0.95	0.3439
TRTSEQ2*VISIT		1	5	1.2076	1.1619	967	1.04	0.2989
TRTSEQ2*VISIT		1	6	1.0839	1.1234	1246	0.96	0.3348
TRTSEQ2*VISIT		1	7	0.1651	1.0803	1541	0.15	0.8786
TRTSEQ2*VISIT		1	8	-0.1083	1.0289	1887	-0.11	0.9162
TRTSEQ2*VISIT		1	9	-0.6562	0.9173	2173	-0.72	0.4744
TRTSEQ2*VISIT		1	10	0	.	.	.	.
TRTSEQ2*VISIT		2	3	3.2564	1.2127	449	2.69	0.0075
TRTSEQ2*VISIT		2	4	2.7142	1.2167	724	2.23	0.0260
TRTSEQ2*VISIT		2	5	1.7439	1.2044	994	1.45	0.1479
TRTSEQ2*VISIT		2	6	-0.4774	1.1667	1271	-0.41	0.6825
TRTSEQ2*VISIT		2	7	0.3271	1.1291	1568	0.29	0.7721
TRTSEQ2*VISIT		2	8	0.3918	1.0753	1895	0.36	0.7157
TRTSEQ2*VISIT		2	9	-0.1561	0.9585	2163	-0.16	0.8707
TRTSEQ2*VISIT		2	10	0	.	.	.	.
TRTSEQ2*VISIT		3	3	0	.	.	.	.
TRTSEQ2*VISIT		3	4	0	.	.	.	.
TRTSEQ2*VISIT		3	5	0	.	.	.	.
TRTSEQ2*VISIT		3	6	0	.	.	.	.
TRTSEQ2*VISIT		3	7	0	.	.	.	.
TRTSEQ2*VISIT		3	8	0	.	.	.	.
TRTSEQ2*VISIT		3	9	0	.	.	.	.
TRTSEQ2*VISIT		3	10	0	.	.	.	.

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.9145	1.5820	9.9	-0.58	0.5761
CENTRE	0002	0.1523	1.3732	17.2	0.11	0.9130
CENTRE	0003	0.3043	1.3396	18.9	0.23	0.8228
CENTRE	0004	-1.1150	1.2980	21.2	-0.86	0.4000
CENTRE	0005	0.09529	1.0848	38.8	0.09	0.9305
CENTRE	0006	1.5420	1.4691	13.3	1.05	0.3126
CENTRE	0007	1.3606	1.3590	17.9	1.00	0.3301
CENTRE	0009	0.3179	1.3834	16.7	0.23	0.8211
CENTRE	0010	-0.2837	1.2692	23	-0.22	0.8251
CENTRE	0011	0.3390	1.2613	23.5	0.27	0.7905
CENTRE	0013	-0.3738	1.3726	17.2	-0.27	0.7886
CENTRE	0014	-1.5973	1.2721	22.8	-1.26	0.2219
CENTRE	0015	0.7320	1.5189	11.6	0.48	0.6388
CENTRE	0016	-0.6566	1.5438	10.9	-0.43	0.6789
CENTRE	0018	-0.4470	1.3564	18	-0.33	0.7455
CENTRE	0019	-0.3946	1.0659	40.5	-0.37	0.7132
CENTRE	0020	0.7741	1.2775	22.5	0.61	0.5507
CENTRE	0022	0.3953	0.9169	59.2	0.43	0.6679
CENTRE	0023	1.6279	0.9942	49.3	1.64	0.1079
CENTRE	0025	0.1729	1.6170	9.08	0.11	0.9172
CENTRE	0026	-0.3982	1.1878	29.1	-0.34	0.7399
CENTRE	0027	-0.5002	1.5294	11.3	-0.33	0.7496
CENTRE	0028	1.5260	1.1104	36.1	1.37	0.1778
CENTRE	0029	1.4276	1.1889	28.9	1.20	0.2396
CENTRE	0030	-0.00824	1.3094	20.5	-0.01	0.9950
CENTRE	0031	-0.5728	1.1680	30.7	-0.49	0.6273
CENTRE	0033	1.6797	1.3269	19.5	1.27	0.2204
CENTRE	0034	-0.2017	1.4327	14.6	-0.14	0.8900
CENTRE	0035	-0.3246	1.2173	26.7	-0.27	0.7918
CENTRE	0036	-0.9455	1.5437	10.9	-0.61	0.5528
CENTRE	0037	0.1720	1.4134	15.4	0.12	0.9047
CENTRE	0039	-3.9107	1.0753	39.8	-3.64	0.0008
CENTRE	0040	0.4204	1.6092	9.25	0.26	0.7996
CENTRE	0041	0.2572	1.3572	18	0.19	0.8518
CENTRE	0042	-0.6519	1.6083	9.28	-0.41	0.6944

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
B_MADRS	1	501	46.95	<.0001
BPDDESC	1	423	0.02	0.8957
TRTSEQ2	2	527	35.81	<.0001
VISIT	7	1074	74.89	<.0001
TRTSEQ2*VISIT	14	1070	1.83	0.0302

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Seroquel 300mg-Placebo	-5.3612	0.7899	524	-6.79	<.0001	0.05	-6.9131	-3.8094
Seroquel 600mg-Placebo	-6.2601	0.8004	540	-7.82	<.0001	0.05	-7.8324	-4.6878

Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2	1		-15.0694	0.6555	122	-22.99	<.0001	0.05	-16.3670	-13.7717
TRTSEQ2	2		-15.9682	0.6682	127	-23.90	<.0001	0.05	-17.2905	-14.6460
TRTSEQ2	3		-9.7081	0.6589	117	-14.73	<.0001	0.05	-11.0130	-8.4033
TRTSEQ2*VISIT	1	3	-8.5937	0.7496	209	-11.46	<.0001	0.05	-10.0715	-7.1159
TRTSEQ2*VISIT	1	4	-12.5003	0.7729	233	-16.17	<.0001	0.05	-14.0231	-10.9775
TRTSEQ2*VISIT	1	5	-13.8741	0.7874	250	-17.62	<.0001	0.05	-15.4249	-12.3233
TRTSEQ2*VISIT	1	6	-14.8664	0.7994	264	-18.60	<.0001	0.05	-16.4405	-13.2923
TRTSEQ2*VISIT	1	7	-16.5249	0.8083	274	-20.45	<.0001	0.05	-18.1161	-14.9337
TRTSEQ2*VISIT	1	8	-17.7193	0.8225	293	-21.54	<.0001	0.05	-19.3380	-16.1005
TRTSEQ2*VISIT	1	9	-17.9395	0.8296	302	-21.62	<.0001	0.05	-19.5721	-16.3069
TRTSEQ2*VISIT	1	10	-18.5370	0.8366	311	-22.16	<.0001	0.05	-20.1831	-16.8909
TRTSEQ2*VISIT	2	3	-8.6831	0.7549	208	-11.50	<.0001	0.05	-10.1713	-7.1949
TRTSEQ2*VISIT	2	4	-12.1631	0.7764	231	-15.67	<.0001	0.05	-13.6927	-10.6334
TRTSEQ2*VISIT	2	5	-14.6004	0.7978	257	-18.30	<.0001	0.05	-16.1714	-13.0293
TRTSEQ2*VISIT	2	6	-17.6903	0.8124	274	-21.78	<.0001	0.05	-19.2896	-16.0910
TRTSEQ2*VISIT	2	7	-17.6255	0.8392	309	-21.00	<.0001	0.05	-19.2768	-15.9743
TRTSEQ2*VISIT	2	8	-18.4819	0.8589	334	-21.52	<.0001	0.05	-20.1714	-16.7924
TRTSEQ2*VISIT	2	9	-18.7020	0.8786	360	-21.29	<.0001	0.05	-20.4298	-16.9742

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	2	10	-19.7997	0.8953	380	-22.12	<.0001	0.05	-21.5600	-18.0393
TRTSEQ2*VISIT	3	3	-4.7044	0.7536	200	-6.24	<.0001	0.05	-6.1904	-3.2184
TRTSEQ2*VISIT	3	4	-7.6422	0.7718	220	-9.90	<.0001	0.05	-9.1633	-6.1211
TRTSEQ2*VISIT	3	5	-9.1092	0.7823	232	-11.64	<.0001	0.05	-10.6505	-7.5680
TRTSEQ2*VISIT	3	6	-9.9778	0.8053	258	-12.39	<.0001	0.05	-11.5636	-8.3921
TRTSEQ2*VISIT	3	7	-10.7175	0.8218	278	-13.04	<.0001	0.05	-12.3353	-9.0998
TRTSEQ2*VISIT	3	8	-11.6386	0.8484	312	-13.72	<.0001	0.05	-13.3079	-9.9692
TRTSEQ2*VISIT	3	9	-11.3108	0.8661	335	-13.06	<.0001	0.05	-13.0145	-9.6072
TRTSEQ2*VISIT	3	10	-12.5646	0.8806	353	-14.27	<.0001	0.05	-14.2964	-10.8327

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2	1		2		0.8989	0.7848	519	1.15	0.2526	0.05	-0.6429	2.4406
TRTSEQ2	1		3		-5.3612	0.7899	524	-6.79	<.0001	0.05	-6.9131	-3.8094
TRTSEQ2	2		3		-6.2601	0.8004	540	-7.82	<.0001	0.05	-7.8324	-4.6878
TRTSEQ2*VISIT	1	3	1	4	3.9066	0.5451	2186	7.17	<.0001	0.05	2.8376	4.9755
TRTSEQ2*VISIT	1	3	1	5	5.2804	0.6304	1919	8.38	<.0001	0.05	4.0441	6.5167
TRTSEQ2*VISIT	1	3	1	6	6.2727	0.6814	1575	9.21	<.0001	0.05	4.9362	7.6092
TRTSEQ2*VISIT	1	3	1	7	7.9312	0.7198	1228	11.02	<.0001	0.05	6.5191	9.3433
TRTSEQ2*VISIT	1	3	1	8	9.1256	0.7667	970	11.90	<.0001	0.05	7.6210	10.6302
TRTSEQ2*VISIT	1	3	1	9	9.3458	0.7890	687	11.85	<.0001	0.05	7.7967	10.8950
TRTSEQ2*VISIT	1	3	1	10	9.9433	0.8030	398	12.38	<.0001	0.05	8.3646	11.5221
TRTSEQ2*VISIT	1	3	2	3	0.08939	0.9367	1058	0.10	0.9240	0.05	-1.7486	1.9274
TRTSEQ2*VISIT	1	3	2	4	3.5694	0.9530	1113	3.75	0.0002	0.05	1.6996	5.4392
TRTSEQ2*VISIT	1	3	2	5	6.0067	0.9701	1165	6.19	<.0001	0.05	4.1033	7.9101
TRTSEQ2*VISIT	1	3	2	6	9.0966	0.9815	1190	9.27	<.0001	0.05	7.1710	11.0222
TRTSEQ2*VISIT	1	3	2	7	9.0319	1.0034	1251	9.00	<.0001	0.05	7.0633	11.0004
TRTSEQ2*VISIT	1	3	2	8	9.8882	1.0197	1279	9.70	<.0001	0.05	7.8877	11.8887
TRTSEQ2*VISIT	1	3	2	9	10.1083	1.0363	1304	9.75	<.0001	0.05	8.0753	12.1413
TRTSEQ2*VISIT	1	3	2	10	11.2060	1.0504	1307	10.67	<.0001	0.05	9.1453	13.2666
TRTSEQ2*VISIT	1	3	3	3	-3.8893	0.9437	1065	-4.12	<.0001	0.05	-5.7411	-2.0375
TRTSEQ2*VISIT	1	3	3	4	-0.9515	0.9588	1117	-0.99	0.3212	0.05	-2.8328	0.9298
TRTSEQ2*VISIT	1	3	3	5	0.5155	0.9672	1139	0.53	0.5941	0.05	-1.3822	2.4133
TRTSEQ2*VISIT	1	3	3	6	1.3841	0.9860	1199	1.40	0.1606	0.05	-0.5503	3.3186
TRTSEQ2*VISIT	1	3	3	7	2.1239	0.9999	1233	2.12	0.0339	0.05	0.1621	4.0856

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	1	3	3	8	3.0449	1.0218	1288	2.98	0.0029	0.05	1.0403	5.0495
TRTSEQ2*VISIT	1	3	3	9	2.7171	1.0364	1310	2.62	0.0089	0.05	0.6839	4.7504
TRTSEQ2*VISIT	1	3	3	10	3.9709	1.0489	1312	3.79	0.0002	0.05	1.9131	6.0286
TRTSEQ2*VISIT	1	4	1	5	1.3739	0.5642	2138	2.44	0.0150	0.05	0.2675	2.4802
TRTSEQ2*VISIT	1	4	1	6	2.3661	0.6497	1904	3.64	0.0003	0.05	1.0919	3.6404
TRTSEQ2*VISIT	1	4	1	7	4.0246	0.6980	1553	5.77	<.0001	0.05	2.6555	5.3938
TRTSEQ2*VISIT	1	4	1	8	5.2190	0.7422	1238	7.03	<.0001	0.05	3.7630	6.6751
TRTSEQ2*VISIT	1	4	1	9	5.4392	0.7836	952	6.94	<.0001	0.05	3.9015	6.9770
TRTSEQ2*VISIT	1	4	1	10	6.0367	0.8069	670	7.48	<.0001	0.05	4.4524	7.6211
TRTSEQ2*VISIT	1	4	2	3	-3.8172	0.9544	1117	-4.00	<.0001	0.05	-5.6899	-1.9445
TRTSEQ2*VISIT	1	4	2	4	-0.3372	0.9704	1172	-0.35	0.7283	0.05	-2.2411	1.5668
TRTSEQ2*VISIT	1	4	2	5	2.1001	0.9873	1223	2.13	0.0336	0.05	0.1632	4.0371
TRTSEQ2*VISIT	1	4	2	6	5.1901	0.9984	1248	5.20	<.0001	0.05	3.2313	7.1488
TRTSEQ2*VISIT	1	4	2	7	5.1253	1.0200	1308	5.02	<.0001	0.05	3.1242	7.1263
TRTSEQ2*VISIT	1	4	2	8	5.9816	1.0361	1335	5.77	<.0001	0.05	3.9492	8.0141
TRTSEQ2*VISIT	1	4	2	9	6.2017	1.0524	1359	5.89	<.0001	0.05	4.1372	8.2663
TRTSEQ2*VISIT	1	4	2	10	7.2994	1.0663	1361	6.85	<.0001	0.05	5.2077	9.3911
TRTSEQ2*VISIT	1	4	3	3	-7.7959	0.9616	1125	-8.11	<.0001	0.05	-9.6826	-5.9091
TRTSEQ2*VISIT	1	4	3	4	-4.8580	0.9764	1177	-4.98	<.0001	0.05	-6.7738	-2.9423
TRTSEQ2*VISIT	1	4	3	5	-3.3910	0.9847	1199	-3.44	0.0006	0.05	-5.3230	-1.4591
TRTSEQ2*VISIT	1	4	3	6	-2.5224	1.0031	1258	-2.51	0.0120	0.05	-4.4904	-0.5544
TRTSEQ2*VISIT	1	4	3	7	-1.7827	1.0168	1292	-1.75	0.0798	0.05	-3.7775	0.2121
TRTSEQ2*VISIT	1	4	3	8	-0.8617	1.0384	1346	-0.83	0.4068	0.05	-2.8987	1.1754
TRTSEQ2*VISIT	1	4	3	9	-1.1894	1.0528	1367	-1.13	0.2588	0.05	-3.2546	0.8758
TRTSEQ2*VISIT	1	4	3	10	0.06430	1.0651	1368	0.06	0.9519	0.05	-2.0251	2.1537
TRTSEQ2*VISIT	1	5	1	6	0.9923	0.5798	2150	1.71	0.0871	0.05	-0.1447	2.1293
TRTSEQ2*VISIT	1	5	1	7	2.6508	0.6625	1876	4.00	<.0001	0.05	1.3514	3.9502
TRTSEQ2*VISIT	1	5	1	8	3.8452	0.7169	1570	5.36	<.0001	0.05	2.4391	5.2513
TRTSEQ2*VISIT	1	5	1	9	4.0654	0.7549	1234	5.39	<.0001	0.05	2.5843	5.5465
TRTSEQ2*VISIT	1	5	1	10	4.6629	0.7976	947	5.85	<.0001	0.05	3.0976	6.2281
TRTSEQ2*VISIT	1	5	2	3	-5.1910	0.9661	1150	-5.37	<.0001	0.05	-7.0866	-3.2955
TRTSEQ2*VISIT	1	5	2	4	-1.7110	0.9819	1204	-1.74	0.0817	0.05	-3.6374	0.2153
TRTSEQ2*VISIT	1	5	2	5	0.7263	0.9985	1254	0.73	0.4671	0.05	-1.2327	2.6853
TRTSEQ2*VISIT	1	5	2	6	3.8162	1.0096	1278	3.78	0.0002	0.05	1.8356	5.7968
TRTSEQ2*VISIT	1	5	2	7	3.7514	1.0309	1337	3.64	0.0003	0.05	1.7290	5.7739
TRTSEQ2*VISIT	1	5	2	8	4.6078	1.0468	1362	4.40	<.0001	0.05	2.5543	6.6613
TRTSEQ2*VISIT	1	5	2	9	4.8279	1.0630	1386	4.54	<.0001	0.05	2.7426	6.9131
TRTSEQ2*VISIT	1	5	2	10	5.9256	1.0767	1387	5.50	<.0001	0.05	3.8134	8.0377
TRTSEQ2*VISIT	1	5	3	3	-9.1697	0.9731	1157	-9.42	<.0001	0.05	-11.0789	-7.2605

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	1	5	3	4	-6.2319	0.9877	1208	-6.31	<.0001	0.05	-8.1697	-4.2940
TRTSEQ2*VISIT	1	5	3	5	-4.7649	0.9959	1229	-4.78	<.0001	0.05	-6.7187	-2.8110
TRTSEQ2*VISIT	1	5	3	6	-3.8963	1.0141	1287	-3.84	0.0001	0.05	-5.8858	-1.9068
TRTSEQ2*VISIT	1	5	3	7	-3.1566	1.0277	1320	-3.07	0.0022	0.05	-5.1726	-1.1405
TRTSEQ2*VISIT	1	5	3	8	-2.2355	1.0490	1373	-2.13	0.0333	0.05	-4.2934	-0.1777
TRTSEQ2*VISIT	1	5	3	9	-2.5633	1.0632	1393	-2.41	0.0160	0.05	-4.6490	-0.4775
TRTSEQ2*VISIT	1	5	3	10	-1.3095	1.0754	1393	-1.22	0.2236	0.05	-3.4192	0.8001
TRTSEQ2*VISIT	1	6	1	7	1.6585	0.5868	2130	2.83	0.0048	0.05	0.5078	2.8092
TRTSEQ2*VISIT	1	6	1	8	2.8529	0.6774	1879	4.21	<.0001	0.05	1.5243	4.1815
TRTSEQ2*VISIT	1	6	1	9	3.0731	0.7254	1519	4.24	<.0001	0.05	1.6502	4.4960
TRTSEQ2*VISIT	1	6	1	10	3.6706	0.7652	1210	4.80	<.0001	0.05	2.1693	5.1719
TRTSEQ2*VISIT	1	6	2	3	-6.1833	0.9759	1173	-6.34	<.0001	0.05	-8.0980	-4.2686
TRTSEQ2*VISIT	1	6	2	4	-2.7033	0.9915	1227	-2.73	0.0065	0.05	-4.6485	-0.7581
TRTSEQ2*VISIT	1	6	2	5	-0.2660	1.0080	1277	-0.26	0.7919	0.05	-2.2435	1.7115
TRTSEQ2*VISIT	1	6	2	6	2.8239	1.0189	1298	2.77	0.0057	0.05	0.8250	4.8228
TRTSEQ2*VISIT	1	6	2	7	2.7591	1.0401	1356	2.65	0.0081	0.05	0.7188	4.7995
TRTSEQ2*VISIT	1	6	2	8	3.6155	1.0558	1380	3.42	0.0006	0.05	1.5443	5.6867
TRTSEQ2*VISIT	1	6	2	9	3.8356	1.0719	1402	3.58	0.0004	0.05	1.7329	5.9382
TRTSEQ2*VISIT	1	6	2	10	4.9333	1.0855	1402	4.54	<.0001	0.05	2.8039	7.0626
TRTSEQ2*VISIT	1	6	3	3	-10.1620	0.9827	1179	-10.34	<.0001	0.05	-12.0900	-8.2340
TRTSEQ2*VISIT	1	6	3	4	-7.2242	0.9972	1230	-7.24	<.0001	0.05	-9.1806	-5.2678
TRTSEQ2*VISIT	1	6	3	5	-5.7572	1.0053	1250	-5.73	<.0001	0.05	-7.7294	-3.7849
TRTSEQ2*VISIT	1	6	3	6	-4.8886	1.0234	1307	-4.78	<.0001	0.05	-6.8962	-2.8810
TRTSEQ2*VISIT	1	6	3	7	-4.1489	1.0368	1338	-4.00	<.0001	0.05	-6.1828	-2.1149
TRTSEQ2*VISIT	1	6	3	8	-3.2278	1.0579	1390	-3.05	0.0023	0.05	-5.3032	-1.1525
TRTSEQ2*VISIT	1	6	3	9	-3.5556	1.0721	1408	-3.32	0.0009	0.05	-5.6586	-1.4526
TRTSEQ2*VISIT	1	6	3	10	-2.3018	1.0842	1408	-2.12	0.0339	0.05	-4.4286	-0.1751
TRTSEQ2*VISIT	1	7	1	8	1.1944	0.6009	2152	1.99	0.0470	0.05	0.01604	2.3727
TRTSEQ2*VISIT	1	7	1	9	1.4146	0.6846	1877	2.07	0.0389	0.05	0.07191	2.7573
TRTSEQ2*VISIT	1	7	1	10	2.0121	0.7341	1513	2.74	0.0062	0.05	0.5721	3.4521
TRTSEQ2*VISIT	1	7	2	3	-7.8418	0.9830	1183	-7.98	<.0001	0.05	-9.7704	-5.9132
TRTSEQ2*VISIT	1	7	2	4	-4.3618	0.9985	1237	-4.37	<.0001	0.05	-6.3207	-2.4029
TRTSEQ2*VISIT	1	7	2	5	-1.9245	1.0149	1286	-1.90	0.0581	0.05	-3.9155	0.06653
TRTSEQ2*VISIT	1	7	2	6	1.1654	1.0257	1307	1.14	0.2561	0.05	-0.8469	3.1777
TRTSEQ2*VISIT	1	7	2	7	1.1006	1.0468	1362	1.05	0.2932	0.05	-0.9528	3.1541
TRTSEQ2*VISIT	1	7	2	8	1.9570	1.0624	1384	1.84	0.0657	0.05	-0.1271	4.0411
TRTSEQ2*VISIT	1	7	2	9	2.1771	1.0784	1405	2.02	0.0437	0.05	0.06171	4.2925
TRTSEQ2*VISIT	1	7	2	10	3.2748	1.0919	1403	3.00	0.0028	0.05	1.1329	5.4167
TRTSEQ2*VISIT	1	7	3	3	-11.8205	0.9898	1190	-11.94	<.0001	0.05	-13.7624	-9.8787

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS253H.SAS
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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	1	7	3	4	-8.8827	1.0042	1240	-8.85	<.0001	0.05	-10.8527	-6.9126
TRTSEQ2*VISIT	1	7	3	5	-7.4157	1.0122	1260	-7.33	<.0001	0.05	-9.4015	-5.4298
TRTSEQ2*VISIT	1	7	3	6	-6.5471	1.0301	1316	-6.36	<.0001	0.05	-8.5680	-4.5262
TRTSEQ2*VISIT	1	7	3	7	-5.8073	1.0435	1345	-5.57	<.0001	0.05	-7.8544	-3.7603
TRTSEQ2*VISIT	1	7	3	8	-4.8863	1.0645	1395	-4.59	<.0001	0.05	-6.9745	-2.7981
TRTSEQ2*VISIT	1	7	3	9	-5.2141	1.0785	1411	-4.83	<.0001	0.05	-7.3298	-3.0983
TRTSEQ2*VISIT	1	7	3	10	-3.9603	1.0906	1410	-3.63	0.0003	0.05	-6.0997	-1.8210
TRTSEQ2*VISIT	1	8	1	9	0.2202	0.6082	2110	0.36	0.7173	0.05	-0.9725	1.4129
TRTSEQ2*VISIT	1	8	1	10	0.8177	0.6965	1879	1.17	0.2405	0.05	-0.5482	2.1836
TRTSEQ2*VISIT	1	8	2	3	-9.0362	0.9946	1208	-9.09	<.0001	0.05	-10.9875	-7.0849
TRTSEQ2*VISIT	1	8	2	4	-5.5562	1.0099	1260	-5.50	<.0001	0.05	-7.5375	-3.5750
TRTSEQ2*VISIT	1	8	2	5	-3.1189	1.0261	1309	-3.04	0.0024	0.05	-5.1319	-1.1059
TRTSEQ2*VISIT	1	8	2	6	-0.02899	1.0369	1329	-0.03	0.9777	0.05	-2.0630	2.0051
TRTSEQ2*VISIT	1	8	2	7	-0.09375	1.0577	1382	-0.09	0.9294	0.05	-2.1686	1.9811
TRTSEQ2*VISIT	1	8	2	8	0.7626	1.0732	1402	0.71	0.4774	0.05	-1.3425	2.8678
TRTSEQ2*VISIT	1	8	2	9	0.9827	1.0889	1419	0.90	0.3670	0.05	-1.1534	3.1188
TRTSEQ2*VISIT	1	8	2	10	2.0804	1.1023	1416	1.89	0.0593	0.05	-0.08200	4.2428
TRTSEQ2*VISIT	1	8	3	3	-13.0149	1.0013	1214	-13.00	<.0001	0.05	-14.9794	-11.0504
TRTSEQ2*VISIT	1	8	3	4	-10.0771	1.0156	1264	-9.92	<.0001	0.05	-12.0695	-8.0847
TRTSEQ2*VISIT	1	8	3	5	-8.6101	1.0235	1284	-8.41	<.0001	0.05	-10.6180	-6.6021
TRTSEQ2*VISIT	1	8	3	6	-7.7415	1.0413	1339	-7.43	<.0001	0.05	-9.7842	-5.6987
TRTSEQ2*VISIT	1	8	3	7	-7.0017	1.0545	1366	-6.64	<.0001	0.05	-9.0703	-4.9332
TRTSEQ2*VISIT	1	8	3	8	-6.0807	1.0753	1413	-5.65	<.0001	0.05	-8.1901	-3.9714
TRTSEQ2*VISIT	1	8	3	9	-6.4085	1.0892	1428	-5.88	<.0001	0.05	-8.5451	-4.2718
TRTSEQ2*VISIT	1	8	3	10	-5.1547	1.1012	1424	-4.68	<.0001	0.05	-7.3148	-2.9946
TRTSEQ2*VISIT	1	9	1	10	0.5975	0.6190	2175	0.97	0.3345	0.05	-0.6164	1.8114
TRTSEQ2*VISIT	1	9	2	3	-9.2564	1.0005	1212	-9.25	<.0001	0.05	-11.2194	-7.2934
TRTSEQ2*VISIT	1	9	2	4	-5.7764	1.0158	1264	-5.69	<.0001	0.05	-7.7692	-3.7837
TRTSEQ2*VISIT	1	9	2	5	-3.3391	1.0319	1312	-3.24	0.0012	0.05	-5.3635	-1.3147
TRTSEQ2*VISIT	1	9	2	6	-0.2492	1.0426	1332	-0.24	0.8111	0.05	-2.2945	1.7961
TRTSEQ2*VISIT	1	9	2	7	-0.3140	1.0633	1384	-0.30	0.7678	0.05	-2.3998	1.7719
TRTSEQ2*VISIT	1	9	2	8	0.5424	1.0787	1402	0.50	0.6152	0.05	-1.5736	2.6584
TRTSEQ2*VISIT	1	9	2	9	0.7625	1.0944	1414	0.70	0.4861	0.05	-1.3843	2.9093
TRTSEQ2*VISIT	1	9	2	10	1.8602	1.1077	1407	1.68	0.0933	0.05	-0.3128	4.0331
TRTSEQ2*VISIT	1	9	3	3	-13.2351	1.0071	1218	-13.14	<.0001	0.05	-15.2111	-11.2592
TRTSEQ2*VISIT	1	9	3	4	-10.2973	1.0213	1267	-10.08	<.0001	0.05	-12.3010	-8.2936
TRTSEQ2*VISIT	1	9	3	5	-8.8303	1.0293	1287	-8.58	<.0001	0.05	-10.8495	-6.8111
TRTSEQ2*VISIT	1	9	3	6	-7.9617	1.0469	1341	-7.60	<.0001	0.05	-10.0154	-5.9079
TRTSEQ2*VISIT	1	9	3	7	-7.2220	1.0601	1368	-6.81	<.0001	0.05	-9.3015	-5.1424

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS253H.SAS
GENERATED: 14JUL2005 11:40:40 iceadmn3

12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	1	9	3	8	-6.3009	1.0808	1414	-5.83	<.0001	0.05	-8.4210	-4.1808
TRTSEQ2*VISIT	1	9	3	9	-6.6287	1.0946	1424	-6.06	<.0001	0.05	-8.7759	-4.4814
TRTSEQ2*VISIT	1	9	3	10	-5.3749	1.1065	1416	-4.86	<.0001	0.05	-7.5456	-3.2043
TRTSEQ2*VISIT	1	10	2	3	-9.8539	1.0064	1212	-9.79	<.0001	0.05	-11.8285	-7.8794
TRTSEQ2*VISIT	1	10	2	4	-6.3739	1.0216	1264	-6.24	<.0001	0.05	-8.3781	-4.3698
TRTSEQ2*VISIT	1	10	2	5	-3.9366	1.0377	1312	-3.79	0.0002	0.05	-5.9722	-1.9010
TRTSEQ2*VISIT	1	10	2	6	-0.8467	1.0483	1331	-0.81	0.4194	0.05	-2.9032	1.2098
TRTSEQ2*VISIT	1	10	2	7	-0.9115	1.0689	1382	-0.85	0.3940	0.05	-3.0083	1.1854
TRTSEQ2*VISIT	1	10	2	8	-0.05509	1.0842	1398	-0.05	0.9595	0.05	-2.1820	2.0718
TRTSEQ2*VISIT	1	10	2	9	0.1650	1.0999	1408	0.15	0.8808	0.05	-1.9925	2.3225
TRTSEQ2*VISIT	1	10	2	10	1.2627	1.1131	1388	1.13	0.2568	0.05	-0.9209	3.4462
TRTSEQ2*VISIT	1	10	3	3	-13.8326	1.0131	1219	-13.65	<.0001	0.05	-15.8202	-11.8451
TRTSEQ2*VISIT	1	10	3	4	-10.8948	1.0272	1268	-10.61	<.0001	0.05	-12.9099	-8.8796
TRTSEQ2*VISIT	1	10	3	5	-9.4278	1.0351	1287	-9.11	<.0001	0.05	-11.4583	-7.3972
TRTSEQ2*VISIT	1	10	3	6	-8.5592	1.0526	1341	-8.13	<.0001	0.05	-10.6241	-6.4942
TRTSEQ2*VISIT	1	10	3	7	-7.8194	1.0657	1367	-7.34	<.0001	0.05	-9.9100	-5.7289
TRTSEQ2*VISIT	1	10	3	8	-6.8984	1.0863	1411	-6.35	<.0001	0.05	-9.0294	-4.7675
TRTSEQ2*VISIT	1	10	3	9	-7.2262	1.1001	1418	-6.57	<.0001	0.05	-9.3842	-5.0682
TRTSEQ2*VISIT	1	10	3	10	-5.9724	1.1120	1399	-5.37	<.0001	0.05	-8.1537	-3.7911
TRTSEQ2*VISIT	2	3	2	4	3.4800	0.5453	2179	6.38	<.0001	0.05	2.4106	4.5494
TRTSEQ2*VISIT	2	3	2	5	5.9173	0.6401	1943	9.25	<.0001	0.05	4.6621	7.1726
TRTSEQ2*VISIT	2	3	2	6	9.0072	0.6935	1592	12.99	<.0001	0.05	7.6469	10.3675
TRTSEQ2*VISIT	2	3	2	7	8.9425	0.7517	1306	11.90	<.0001	0.05	7.4678	10.4172
TRTSEQ2*VISIT	2	3	2	8	9.7988	0.8035	1032	12.19	<.0001	0.05	8.2221	11.3755
TRTSEQ2*VISIT	2	3	2	9	10.0189	0.8384	754	11.95	<.0001	0.05	8.3730	11.6648
TRTSEQ2*VISIT	2	3	2	10	11.1166	0.8619	451	12.90	<.0001	0.05	9.4228	12.8104
TRTSEQ2*VISIT	2	3	3	3	-3.9787	0.9481	1066	-4.20	<.0001	0.05	-5.8391	-2.1183
TRTSEQ2*VISIT	2	3	3	4	-1.0409	0.9632	1117	-1.08	0.2801	0.05	-2.9308	0.8490
TRTSEQ2*VISIT	2	3	3	5	0.4261	0.9717	1140	0.44	0.6611	0.05	-1.4803	2.3326
TRTSEQ2*VISIT	2	3	3	6	1.2947	0.9903	1199	1.31	0.1913	0.05	-0.6482	3.2377
TRTSEQ2*VISIT	2	3	3	7	2.0345	1.0043	1233	2.03	0.0430	0.05	0.06413	4.0048
TRTSEQ2*VISIT	2	3	3	8	2.9555	1.0262	1289	2.88	0.0040	0.05	0.9424	4.9686
TRTSEQ2*VISIT	2	3	3	9	2.6277	1.0408	1312	2.52	0.0117	0.05	0.5858	4.6697
TRTSEQ2*VISIT	2	3	3	10	3.8815	1.0535	1315	3.68	0.0002	0.05	1.8148	5.9481
TRTSEQ2*VISIT	2	4	2	5	2.4373	0.5748	2168	4.24	<.0001	0.05	1.3100	3.5646
TRTSEQ2*VISIT	2	4	2	6	5.5272	0.6629	1930	8.34	<.0001	0.05	4.2273	6.8272
TRTSEQ2*VISIT	2	4	2	7	5.4625	0.7305	1619	7.48	<.0001	0.05	4.0296	6.8954
TRTSEQ2*VISIT	2	4	2	8	6.3188	0.7797	1292	8.10	<.0001	0.05	4.7892	7.8484
TRTSEQ2*VISIT	2	4	2	9	6.5389	0.8328	1013	7.85	<.0001	0.05	4.9048	8.1731

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/MADRS253H.SAS
GENERATED: 14JUL2005 11:40:40 iceadmn3

12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	2	4	2	10	7.6366	0.8649	723	8.83	<.0001	0.05	5.9387	9.3345
TRTSEQ2*VISIT	2	4	3	3	-7.4587	0.9643	1121	-7.73	<.0001	0.05	-9.3508	-5.5666
TRTSEQ2*VISIT	2	4	3	4	-4.5209	0.9792	1172	-4.62	<.0001	0.05	-6.4421	-2.5997
TRTSEQ2*VISIT	2	4	3	5	-3.0538	0.9875	1194	-3.09	0.0020	0.05	-4.9913	-1.1164
TRTSEQ2*VISIT	2	4	3	6	-2.1852	1.0059	1253	-2.17	0.0300	0.05	-4.1587	-0.2118
TRTSEQ2*VISIT	2	4	3	7	-1.4455	1.0197	1287	-1.42	0.1565	0.05	-3.4459	0.5549
TRTSEQ2*VISIT	2	4	3	8	-0.5245	1.0412	1342	-0.50	0.6145	0.05	-2.5671	1.5181
TRTSEQ2*VISIT	2	4	3	9	-0.8522	1.0557	1364	-0.81	0.4196	0.05	-2.9232	1.2187
TRTSEQ2*VISIT	2	4	3	10	0.4015	1.0681	1365	0.38	0.7071	0.05	-1.6938	2.4968
TRTSEQ2*VISIT	2	5	2	6	3.0899	0.5939	2154	5.20	<.0001	0.05	1.9253	4.2545
TRTSEQ2*VISIT	2	5	2	7	3.0251	0.6974	1921	4.34	<.0001	0.05	1.6575	4.3928
TRTSEQ2*VISIT	2	5	2	8	3.8815	0.7569	1605	5.13	<.0001	0.05	2.3970	5.3660
TRTSEQ2*VISIT	2	5	2	9	4.1016	0.8073	1287	5.08	<.0001	0.05	2.5178	5.6854
TRTSEQ2*VISIT	2	5	2	10	5.1993	0.8588	998	6.05	<.0001	0.05	3.5140	6.8846
TRTSEQ2*VISIT	2	5	3	3	-9.8960	0.9812	1173	-10.09	<.0001	0.05	-11.8211	-7.9709
TRTSEQ2*VISIT	2	5	3	4	-6.9582	0.9959	1224	-6.99	<.0001	0.05	-8.9120	-5.0044
TRTSEQ2*VISIT	2	5	3	5	-5.4912	1.0040	1244	-5.47	<.0001	0.05	-7.4609	-3.5214
TRTSEQ2*VISIT	2	5	3	6	-4.6226	1.0221	1303	-4.52	<.0001	0.05	-6.6278	-2.6174
TRTSEQ2*VISIT	2	5	3	7	-3.8828	1.0357	1335	-3.75	0.0002	0.05	-5.9146	-1.8511
TRTSEQ2*VISIT	2	5	3	8	-2.9618	1.0569	1389	-2.80	0.0051	0.05	-5.0351	-0.8886
TRTSEQ2*VISIT	2	5	3	9	-3.2896	1.0712	1409	-3.07	0.0022	0.05	-5.3908	-1.1883
TRTSEQ2*VISIT	2	5	3	10	-2.0358	1.0834	1410	-1.88	0.0604	0.05	-4.1611	0.08940
TRTSEQ2*VISIT	2	6	2	7	-0.06476	0.6226	2189	-0.10	0.9172	0.05	-1.2856	1.1561
TRTSEQ2*VISIT	2	6	2	8	0.7916	0.7183	1925	1.10	0.2706	0.05	-0.6171	2.2002
TRTSEQ2*VISIT	2	6	2	9	1.0117	0.7793	1590	1.30	0.1944	0.05	-0.5169	2.5402
TRTSEQ2*VISIT	2	6	2	10	2.1094	0.8279	1262	2.55	0.0110	0.05	0.4852	3.7335
TRTSEQ2*VISIT	2	6	3	3	-12.9859	0.9928	1200	-13.08	<.0001	0.05	-14.9338	-11.0380
TRTSEQ2*VISIT	2	6	3	4	-10.0481	1.0073	1251	-9.98	<.0001	0.05	-12.0243	-8.0719
TRTSEQ2*VISIT	2	6	3	5	-8.5811	1.0154	1271	-8.45	<.0001	0.05	-10.5731	-6.5891
TRTSEQ2*VISIT	2	6	3	6	-7.7125	1.0333	1327	-7.46	<.0001	0.05	-9.7395	-5.6854
TRTSEQ2*VISIT	2	6	3	7	-6.9728	1.0467	1357	-6.66	<.0001	0.05	-9.0260	-4.9195
TRTSEQ2*VISIT	2	6	3	8	-6.0517	1.0676	1408	-5.67	<.0001	0.05	-8.1461	-3.9574
TRTSEQ2*VISIT	2	6	3	9	-6.3795	1.0817	1427	-5.90	<.0001	0.05	-8.5015	-4.2575
TRTSEQ2*VISIT	2	6	3	10	-5.1257	1.0939	1427	-4.69	<.0001	0.05	-7.2715	-2.9800
TRTSEQ2*VISIT	2	7	2	8	0.8564	0.6447	2149	1.33	0.1842	0.05	-0.4079	2.1206
TRTSEQ2*VISIT	2	7	2	9	1.0764	0.7447	1921	1.45	0.1485	0.05	-0.3840	2.5369
TRTSEQ2*VISIT	2	7	2	10	2.1741	0.8045	1571	2.70	0.0070	0.05	0.5962	3.7521
TRTSEQ2*VISIT	2	7	3	3	-12.9212	1.0146	1261	-12.73	<.0001	0.05	-14.9117	-10.9306
TRTSEQ2*VISIT	2	7	3	4	-9.9833	1.0288	1311	-9.70	<.0001	0.05	-12.0016	-7.9650

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	2	7	3	5	-8.5163	1.0367	1330	-8.21	<.0001	0.05	-10.5500	-6.4826
TRTSEQ2*VISIT	2	7	3	6	-7.6477	1.0542	1384	-7.25	<.0001	0.05	-9.7158	-5.5796
TRTSEQ2*VISIT	2	7	3	7	-6.9080	1.0674	1411	-6.47	<.0001	0.05	-9.0018	-4.8142
TRTSEQ2*VISIT	2	7	3	8	-5.9870	1.0879	1458	-5.50	<.0001	0.05	-8.1210	-3.8529
TRTSEQ2*VISIT	2	7	3	9	-6.3147	1.1018	1474	-5.73	<.0001	0.05	-8.4759	-4.1535
TRTSEQ2*VISIT	2	7	3	10	-5.0610	1.1137	1471	-4.54	<.0001	0.05	-7.2455	-2.8765
TRTSEQ2*VISIT	2	8	2	9	0.2201	0.6641	2160	0.33	0.7404	0.05	-1.0823	1.5225
TRTSEQ2*VISIT	2	8	2	10	1.3178	0.7635	1898	1.73	0.0845	0.05	-0.1796	2.8151
TRTSEQ2*VISIT	2	8	3	3	-13.7775	1.0310	1290	-13.36	<.0001	0.05	-15.8002	-11.7549
TRTSEQ2*VISIT	2	8	3	4	-10.8397	1.0450	1339	-10.37	<.0001	0.05	-12.8897	-8.7897
TRTSEQ2*VISIT	2	8	3	5	-9.3727	1.0527	1357	-8.90	<.0001	0.05	-11.4378	-7.3075
TRTSEQ2*VISIT	2	8	3	6	-8.5041	1.0700	1409	-7.95	<.0001	0.05	-10.6030	-6.4051
TRTSEQ2*VISIT	2	8	3	7	-7.7644	1.0829	1433	-7.17	<.0001	0.05	-9.8886	-5.6401
TRTSEQ2*VISIT	2	8	3	8	-6.8433	1.1031	1476	-6.20	<.0001	0.05	-9.0072	-4.6794
TRTSEQ2*VISIT	2	8	3	9	-7.1711	1.1168	1489	-6.42	<.0001	0.05	-9.3617	-4.9804
TRTSEQ2*VISIT	2	8	3	10	-5.9173	1.1285	1482	-5.24	<.0001	0.05	-8.1310	-3.7037
TRTSEQ2*VISIT	2	9	2	10	1.0977	0.6786	2156	1.62	0.1059	0.05	-0.2332	2.4285
TRTSEQ2*VISIT	2	9	3	3	-13.9976	1.0474	1314	-13.36	<.0001	0.05	-16.0525	-11.9428
TRTSEQ2*VISIT	2	9	3	4	-11.0598	1.0612	1363	-10.42	<.0001	0.05	-13.1415	-8.9781
TRTSEQ2*VISIT	2	9	3	5	-9.5928	1.0688	1380	-8.98	<.0001	0.05	-11.6894	-7.4961
TRTSEQ2*VISIT	2	9	3	6	-8.7242	1.0858	1431	-8.03	<.0001	0.05	-10.8541	-6.5942
TRTSEQ2*VISIT	2	9	3	7	-7.9844	1.0985	1453	-7.27	<.0001	0.05	-10.1393	-5.8296
TRTSEQ2*VISIT	2	9	3	8	-7.0634	1.1185	1492	-6.32	<.0001	0.05	-9.2574	-4.8695
TRTSEQ2*VISIT	2	9	3	9	-7.3912	1.1320	1497	-6.53	<.0001	0.05	-9.6115	-5.1708
TRTSEQ2*VISIT	2	9	3	10	-6.1374	1.1435	1485	-5.37	<.0001	0.05	-8.3805	-3.8943
TRTSEQ2*VISIT	2	10	3	3	-15.0953	1.0615	1318	-14.22	<.0001	0.05	-17.1777	-13.0129
TRTSEQ2*VISIT	2	10	3	4	-12.1575	1.0750	1365	-11.31	<.0001	0.05	-14.2664	-10.0485
TRTSEQ2*VISIT	2	10	3	5	-10.6904	1.0826	1382	-9.88	<.0001	0.05	-12.8141	-8.5668
TRTSEQ2*VISIT	2	10	3	6	-9.8218	1.0994	1431	-8.93	<.0001	0.05	-11.9784	-7.6653
TRTSEQ2*VISIT	2	10	3	7	-9.0821	1.1119	1451	-8.17	<.0001	0.05	-11.2632	-6.9010
TRTSEQ2*VISIT	2	10	3	8	-8.1611	1.1316	1487	-7.21	<.0001	0.05	-10.3808	-5.9414
TRTSEQ2*VISIT	2	10	3	9	-8.4888	1.1449	1488	-7.41	<.0001	0.05	-10.7347	-6.2430
TRTSEQ2*VISIT	2	10	3	10	-7.2351	1.1564	1460	-6.26	<.0001	0.05	-9.5034	-4.9668
TRTSEQ2*VISIT	3	3	3	4	2.9378	0.5421	2165	5.42	<.0001	0.05	1.8748	4.0008
TRTSEQ2*VISIT	3	3	3	5	4.4048	0.6246	1896	7.05	<.0001	0.05	3.1798	5.6299
TRTSEQ2*VISIT	3	3	3	6	5.2735	0.6901	1615	7.64	<.0001	0.05	3.9199	6.6270
TRTSEQ2*VISIT	3	3	3	7	6.0132	0.7377	1281	8.15	<.0001	0.05	4.5658	7.4605
TRTSEQ2*VISIT	3	3	3	8	6.9342	0.7981	1042	8.69	<.0001	0.05	5.3681	8.5002
TRTSEQ2*VISIT	3	3	3	9	6.6064	0.8313	756	7.95	<.0001	0.05	4.9746	8.2383

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

The Mixed Procedure

Differences of Least Squares Means

Effect	TRTSEQ2	WINDOWED VISIT	_TRTSEQ2	WINDOWED VISIT	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTSEQ2*VISIT	3	3	3	10	7.8602	0.8533	447	9.21	<.0001	0.05	6.1831	9.5372
TRTSEQ2*VISIT	3	4	3	5	1.4670	0.5593	2145	2.62	0.0088	0.05	0.3701	2.5639
TRTSEQ2*VISIT	3	4	3	6	2.3356	0.6598	1950	3.54	0.0004	0.05	1.0416	3.6297
TRTSEQ2*VISIT	3	4	3	7	3.0753	0.7166	1606	4.29	<.0001	0.05	1.6698	4.4809
TRTSEQ2*VISIT	3	4	3	8	3.9964	0.7744	1308	5.16	<.0001	0.05	2.4772	5.5155
TRTSEQ2*VISIT	3	4	3	9	3.6686	0.8255	1023	4.44	<.0001	0.05	2.0487	5.2885
TRTSEQ2*VISIT	3	4	3	10	4.9223	0.8562	723	5.75	<.0001	0.05	3.2415	6.6032
TRTSEQ2*VISIT	3	5	3	6	0.8686	0.5872	2171	1.48	0.1392	0.05	-0.2830	2.0202
TRTSEQ2*VISIT	3	5	3	7	1.6083	0.6791	1923	2.37	0.0180	0.05	0.2765	2.9401
TRTSEQ2*VISIT	3	5	3	8	2.5293	0.7472	1627	3.38	0.0007	0.05	1.0637	3.9950
TRTSEQ2*VISIT	3	5	3	9	2.2016	0.7956	1290	2.77	0.0057	0.05	0.6407	3.7625
TRTSEQ2*VISIT	3	5	3	10	3.4553	0.8447	986	4.09	<.0001	0.05	1.7977	5.1129
TRTSEQ2*VISIT	3	6	3	7	0.7397	0.6158	2182	1.20	0.2298	0.05	-0.4678	1.9473
TRTSEQ2*VISIT	3	6	3	8	1.6607	0.7184	1967	2.31	0.0209	0.05	0.2518	3.0696
TRTSEQ2*VISIT	3	6	3	9	1.3330	0.7763	1619	1.72	0.0861	0.05	-0.1896	2.8556
TRTSEQ2*VISIT	3	6	3	10	2.5867	0.8223	1278	3.15	0.0017	0.05	0.9736	4.1999
TRTSEQ2*VISIT	3	7	3	8	0.9210	0.6406	2173	1.44	0.1507	0.05	-0.3353	2.1773
TRTSEQ2*VISIT	3	7	3	9	0.5933	0.7357	1933	0.81	0.4201	0.05	-0.8495	2.0361
TRTSEQ2*VISIT	3	7	3	10	1.8470	0.7924	1564	2.33	0.0199	0.05	0.2927	3.4013
TRTSEQ2*VISIT	3	8	3	9	-0.3277	0.6628	2141	-0.49	0.6210	0.05	-1.6275	0.9720
TRTSEQ2*VISIT	3	8	3	10	0.9260	0.7572	1892	1.22	0.2215	0.05	-0.5591	2.4111
TRTSEQ2*VISIT	3	9	3	10	1.2537	0.6769	2170	1.85	0.0642	0.05	-0.07378	2.5812

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12.1.9.2.1.6 MDRS Total Score Change from Baseline (MMRM - ITT & Effect Size)

Obs	EST1	SE1	STDDEV1	ESIZE1	EST2	SE2	STDDEV2	ESIZE2
1	-3.8893	0.9437	9.80259	0.39670	-3.9787	0.9481	9.81333	0.40582
2	-4.8580	0.9764	9.40301	0.51555	-4.5209	0.9792	9.44500	0.47977
3	-4.7649	0.9959	9.28357	0.51336	-5.4912	1.0040	9.20061	0.59161
4	-4.8886	1.0234	9.21970	0.53487	-7.7125	1.0333	9.15510	0.84384
5	-5.8073	1.0435	9.21548	0.64226	-6.9080	1.0674	8.92061	0.76398
6	-6.0807	1.0753	9.12191	0.68032	-6.8433	1.1031	8.88446	0.76564
7	-6.6287	1.0946	9.12596	0.74346	-7.3912	1.1320	8.82961	0.82898
8	-5.9724	1.1120	9.12598	0.66969	-7.2351	1.1564	8.81767	0.81127

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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	509
Observations Used	509
Observations Not Used	0
Total Observations	509

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3123.42228143	
1	3	3109.90771808	0.00014567
2	1	3109.72916355	0.00000679
3	1	3109.72151121	0.00000002
4	1	3109.72149222	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	1.7558
Residual	25.3681

Fit Statistics

-2 Res Log Likelihood	3109.7
AIC (smaller is better)	3113.7
AICC (smaller is better)	3113.7
BIC (smaller is better)	3116.8

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			3.0906	1.8073	496	1.71	0.0879
trtseq		Q300MG	-3.3654	0.5553	499	-6.06	<.0001
trtseq		Q600MG	-3.3026	0.5584	501	-5.91	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.8286	0.5207	435	1.59	0.1123
numcd	2		0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
B_HAMD			-0.3312	0.07011	504	-4.72	<.0001

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.6926	1.2087	11.6	-0.57	0.5776
CENTRE	0002	-0.3797	1.0311	21.4	-0.37	0.7163
CENTRE	0003	-0.3697	1.0112	23	-0.37	0.7180
CENTRE	0004	0.2923	0.9780	25.9	0.30	0.7674
CENTRE	0005	0.5811	0.7971	50	0.73	0.4694
CENTRE	0006	1.5783	1.1193	15.7	1.41	0.1780
CENTRE	0007	1.3813	1.0121	22.9	1.36	0.1856
CENTRE	0009	-0.7885	1.0330	21.2	-0.76	0.4537
CENTRE	0010	-0.7281	0.9356	30.3	-0.78	0.4424
CENTRE	0011	-0.1068	0.9503	28.7	-0.11	0.9113
CENTRE	0013	-0.8674	1.0307	21.4	-0.84	0.4093
CENTRE	0014	-0.3920	0.9514	28.6	-0.41	0.6834
CENTRE	0015	0.7260	1.1457	14.3	0.63	0.5363
CENTRE	0016	0.3321	1.1761	12.9	0.28	0.7821
CENTRE	0018	-0.2970	1.0109	23	-0.29	0.7715
CENTRE	0019	-1.3291	0.7852	51.5	-1.69	0.0966
CENTRE	0020	-0.7719	0.9471	29.1	-0.82	0.4217
CENTRE	0022	0.8883	0.6788	70.9	1.31	0.1949
CENTRE	0023	1.8628	0.7418	59.6	2.51	0.0148
CENTRE	0025	-0.2575	1.2430	10.4	-0.21	0.8399
CENTRE	0026	0.7221	0.8818	37	0.82	0.4181
CENTRE	0027	0.5560	1.1769	12.9	0.47	0.6445
CENTRE	0028	0.3964	0.8279	44.8	0.48	0.6344
CENTRE	0029	1.0589	0.8717	38.3	1.21	0.2319
CENTRE	0030	0.2825	0.9780	26	0.29	0.7749
CENTRE	0031	-0.7623	0.8573	40.3	-0.89	0.3792
CENTRE	0033	0.9055	0.9967	24.2	0.91	0.3725
CENTRE	0034	0.1026	1.0983	16.8	0.09	0.9267
CENTRE	0035	-0.01638	0.9051	34	-0.02	0.9857

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0036	-0.05070	1.1765	12.9	-0.04	0.9663
CENTRE	0037	-0.9847	1.0701	18.6	-0.92	0.3692
CENTRE	0039	-2.2194	0.7997	49.5	-2.78	0.0078
CENTRE	0040	0.6340	1.2437	10.3	0.51	0.6209
CENTRE	0041	-0.6007	1.0303	21.5	-0.58	0.5659
CENTRE	0042	-0.6856	1.2429	10.4	-0.55	0.5929

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	495	23.71	<.0001
numcd	1	435	2.53	0.1123
B_HAMD	1	504	22.32	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-8.0082	0.4727	106	-16.94	<.0001	0.05	-8.9455	-7.0710
trtseq	Q600MG	-7.9454	0.4763	106	-16.68	<.0001	0.05	-8.8897	-7.0012
trtseq	P	-4.6429	0.4748	101	-9.78	<.0001	0.05	-5.5847	-3.7010

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.06281	0.5497	488	-0.11	0.9091	0.05	-1.1429	1.0173
trtseq	Q300MG	P	-3.3654	0.5553	499	-6.06	<.0001	0.05	-4.4565	-2.2743
trtseq	Q600MG	P	-3.3026	0.5584	501	-5.91	<.0001	0.05	-4.3997	-2.2055

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3286.17726042	
1	2	3273.15410741	0.00001105
2	1	3273.14058303	0.00000006
3	1	3273.14051671	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	3.1578
Residual	33.8877

Fit Statistics

-2 Res Log Likelihood	3273.1
AIC (smaller is better)	3277.1
AICC (smaller is better)	3277.2
BIC (smaller is better)	3280.3

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.5528	2.1027	495	0.74	0.4606
trtseq		Q300MG	-3.9267	0.6427	496	-6.11	<.0001
trtseq		Q600MG	-3.6609	0.6466	499	-5.66	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.5352	0.6081	443	0.88	0.3793
numcd	2		0	.	.	.	.
B_HAMD			-0.3273	0.08128	504	-4.03	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.9344	1.5763	11.5	-0.59	0.5648
CENTRE	0002	-0.09302	1.2994	24.2	-0.07	0.9435
CENTRE	0003	-0.06988	1.2701	26.2	-0.06	0.9565
CENTRE	0004	-0.9433	1.2222	29.9	-0.77	0.4463
CENTRE	0005	-0.1540	0.9744	57.6	-0.16	0.8750
CENTRE	0006	3.1509	1.4328	16.8	2.20	0.0422
CENTRE	0007	0.8766	1.2715	26.1	0.69	0.4967
CENTRE	0009	0.9502	1.3023	23.9	0.73	0.4727
CENTRE	0010	1.2671	1.1621	35.4	1.09	0.2829
CENTRE	0011	0.7196	1.1829	33.4	0.61	0.5471
CENTRE	0013	0.6321	1.2987	24.2	0.49	0.6308
CENTRE	0014	-2.3315	1.1843	33.3	-1.97	0.0574
CENTRE	0015	1.3034	1.4743	15	0.88	0.3906
CENTRE	0016	-0.2091	1.5230	13.2	-0.14	0.8929
CENTRE	0018	-0.7052	1.2697	26.3	-0.56	0.5833
CENTRE	0019	-1.0848	0.9523	59.7	-1.14	0.2592
CENTRE	0020	0.07768	1.1783	33.9	0.07	0.9478
CENTRE	0022	0.4006	0.8229	74.5	0.49	0.6278
CENTRE	0023	1.2030	0.9027	66.5	1.33	0.1872
CENTRE	0025	1.3987	1.6335	9.99	0.86	0.4119
CENTRE	0026	-0.03436	1.0727	45.2	-0.03	0.9746
CENTRE	0027	-0.8739	1.5243	13.2	-0.57	0.5761
CENTRE	0028	0.6343	1.0151	52.2	0.62	0.5348
CENTRE	0029	0.9760	1.0740	45	0.91	0.3683
CENTRE	0030	-0.1032	1.2222	30	-0.08	0.9333
CENTRE	0031	-0.04985	1.0547	47.2	-0.05	0.9625
CENTRE	0033	1.5819	1.2491	27.8	1.27	0.2159
CENTRE	0034	-0.3607	1.4006	18.3	-0.26	0.7996
CENTRE	0035	0.3709	1.1197	39.9	0.33	0.7422
CENTRE	0036	-1.9921	1.5236	13.2	-1.31	0.2134
CENTRE	0037	-0.8573	1.3575	20.6	-0.63	0.5346
CENTRE	0039	-3.5843	0.9777	57.1	-3.67	0.0005
CENTRE	0040	0.3060	1.6348	9.96	0.19	0.8553
CENTRE	0041	0.09460	1.2981	24.3	0.07	0.9425
CENTRE	0042	-1.5626	1.6334	10	-0.96	0.3613

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	491	22.95	<.0001
numcd	1	443	0.77	0.3793
B_HAMD	1	504	16.22	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-10.1582	0.5700	70.8	-17.82	<.0001	0.05	-11.2949	-9.0215
trtseq	Q600MG	-9.8925	0.5740	70.9	-17.24	<.0001	0.05	-11.0370	-8.7480
trtseq	P	-6.2316	0.5738	67.6	-10.86	<.0001	0.05	-7.3768	-5.0863

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.2657	0.6341	481	-0.42	0.6754	0.05	-1.5117	0.9803
trtseq	Q300MG	P	-3.9267	0.6427	496	-6.11	<.0001	0.05	-5.1895	-2.6638
trtseq	Q600MG	P	-3.6609	0.6466	499	-5.66	<.0001	0.05	-4.9313	-2.3905

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3379.31625173	
1	2	3374.73528054	0.00000134
2	1	3374.73360961	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	1.8379
Residual	42.3143

Fit Statistics

-2 Res Log Likelihood	3374.7
AIC (smaller is better)	3378.7
AICC (smaller is better)	3378.8
BIC (smaller is better)	3381.8

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			0.9640	2.3109	493	0.42	0.6768
trtseq		Q300MG	-4.0416	0.7137	503	-5.66	<.0001
trtseq		Q600MG	-4.3506	0.7172	505	-6.07	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.1578	0.6595	365	0.24	0.8111
numcd	2		0	.	.	.	.
B_HAMD			-0.3284	0.08996	506	-3.65	0.0003

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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.6220	1.2770	5.19	-0.49	0.6461
CENTRE	0002	-0.09641	1.1407	8.12	-0.08	0.9347
CENTRE	0003	0.3596	1.1241	8.6	0.32	0.7567
CENTRE	0004	-0.9046	1.0958	9.48	-0.83	0.4294
CENTRE	0005	0.5742	0.9283	17.3	0.62	0.5442
CENTRE	0006	1.4147	1.2110	6.42	1.17	0.2842
CENTRE	0007	1.0095	1.1249	8.57	0.90	0.3940
CENTRE	0009	0.4060	1.1422	8.07	0.36	0.7313
CENTRE	0010	0.8067	1.0585	10.8	0.76	0.4623
CENTRE	0011	0.2251	1.0716	10.3	0.21	0.8377
CENTRE	0013	-0.1536	1.1403	8.13	-0.13	0.8961
CENTRE	0014	-1.6627	1.0726	10.3	-1.55	0.1513
CENTRE	0015	0.8991	1.2310	6.02	0.73	0.4926
CENTRE	0016	-0.6849	1.2535	5.59	-0.55	0.6059
CENTRE	0018	-0.5094	1.1239	8.6	-0.45	0.6616
CENTRE	0019	-0.1975	0.9107	18.3	-0.22	0.8307
CENTRE	0020	0.4786	1.0688	10.4	0.45	0.6635
CENTRE	0022	0.1655	0.8056	26.7	0.21	0.8388
CENTRE	0023	0.4429	0.8721	21.2	0.51	0.6168
CENTRE	0025	0.3558	1.3010	4.82	0.27	0.7958
CENTRE	0026	-0.03914	0.9994	13.4	-0.04	0.9693
CENTRE	0027	-0.6817	1.2541	5.58	-0.54	0.6077
CENTRE	0028	0.3501	0.9583	15.5	0.37	0.7198
CENTRE	0029	0.7891	1.0002	13.3	0.79	0.4439
CENTRE	0030	0.2714	1.0958	9.48	0.25	0.8097
CENTRE	0031	0.07908	0.9865	14	0.08	0.9372
CENTRE	0033	0.5047	1.1118	8.96	0.45	0.6606
CENTRE	0034	-0.3111	1.1947	6.77	-0.26	0.8023
CENTRE	0035	0.8468	1.0312	11.9	0.82	0.4277
CENTRE	0036	-0.6735	1.2538	5.59	-0.54	0.6119
CENTRE	0037	-0.5307	1.1724	7.3	-0.45	0.6639
CENTRE	0039	-2.6299	0.9308	17.2	-2.83	0.0116
CENTRE	0040	0.2491	1.3015	4.81	0.19	0.8560
CENTRE	0041	0.1127	1.1400	8.14	0.10	0.9237
CENTRE	0042	-0.6436	1.3010	4.82	-0.49	0.6425

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	22.83	<.0001
numcd	1	365	0.06	0.8111
B_HAMD	1	506	13.32	0.0003

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-11.0762	0.5775	99.6	-19.18	<.0001	0.05	-12.2220	-9.9304
trtseq	Q600MG	-11.3851	0.5814	98.5	-19.58	<.0001	0.05	-12.5388	-10.2315
trtseq	P	-7.0346	0.5799	95.5	-12.13	<.0001	0.05	-8.1857	-5.8834

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.3090	0.7068	489	0.44	0.6622	0.05	-1.0798	1.6978
trtseq	Q300MG	P	-4.0416	0.7137	503	-5.66	<.0001	0.05	-5.4439	-2.6393
trtseq	Q600MG	P	-4.3506	0.7172	505	-6.07	<.0001	0.05	-5.7596	-2.9416

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3414.17427299	
1	2	3400.57586312	0.00001097
2	1	3400.56172997	0.00000005
3	1	3400.56166692	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	3.9769
Residual	43.6237

Fit Statistics

-2 Res Log Likelihood	3400.6
AIC (smaller is better)	3404.6
AICC (smaller is better)	3404.6
BIC (smaller is better)	3407.7

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			0.2448	2.3844	496	0.10	0.9183
trtseq		Q300MG	-4.0998	0.7291	497	-5.62	<.0001
trtseq		Q600MG	-4.9981	0.7335	500	-6.81	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.09425	0.6893	449	0.14	0.8913
numcd	2		0	.	.	.	.
B_HAMD			-0.3237	0.09219	504	-3.51	0.0005

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-1.0490	1.7730	12.8	-0.59	0.5644
CENTRE	0002	-0.5687	1.4654	26.6	-0.39	0.7011
CENTRE	0003	1.6646	1.4327	28.9	1.16	0.2548
CENTRE	0004	-1.6869	1.3792	32.9	-1.22	0.2300
CENTRE	0005	0.4825	1.1012	63	0.44	0.6628
CENTRE	0006	2.5246	1.6140	18.6	1.56	0.1346
CENTRE	0007	0.02448	1.4343	28.7	0.02	0.9865
CENTRE	0009	1.2718	1.4686	26.4	0.87	0.3943
CENTRE	0010	1.9082	1.3120	38.8	1.45	0.1539
CENTRE	0011	-0.2468	1.3352	36.6	-0.18	0.8544
CENTRE	0013	0.1334	1.4646	26.7	0.09	0.9281
CENTRE	0014	-2.3437	1.3368	36.5	-1.75	0.0880
CENTRE	0015	1.8652	1.6601	16.7	1.12	0.2771
CENTRE	0016	-1.1630	1.7140	14.7	-0.68	0.5080
CENTRE	0018	-0.2513	1.4322	28.9	-0.18	0.8619
CENTRE	0019	-0.4353	1.0763	65.4	-0.40	0.6872
CENTRE	0020	1.2469	1.3300	37.2	0.94	0.3545
CENTRE	0022	-0.1454	0.9304	81.8	-0.16	0.8762
CENTRE	0023	-0.2041	1.0205	72.8	-0.20	0.8420
CENTRE	0025	0.4867	1.8362	11.2	0.27	0.7958
CENTRE	0026	-0.3609	1.2117	49.5	-0.30	0.7671
CENTRE	0027	-1.2402	1.7154	14.6	-0.72	0.4811
CENTRE	0028	1.0549	1.1470	57.1	0.92	0.3616
CENTRE	0029	2.1046	1.2131	49.2	1.73	0.0890
CENTRE	0030	0.6402	1.3792	32.9	0.46	0.6456
CENTRE	0031	-0.3611	1.1914	51.6	-0.30	0.7630
CENTRE	0033	0.8917	1.4093	30.5	0.63	0.5316
CENTRE	0034	-1.4136	1.5781	20.2	-0.90	0.3809
CENTRE	0035	1.0935	1.2644	43.7	0.86	0.3919
CENTRE	0036	-1.7710	1.7147	14.7	-1.03	0.3184
CENTRE	0037	0.2036	1.5301	22.7	0.13	0.8953
CENTRE	0039	-4.1841	1.1050	62.5	-3.79	0.0003
CENTRE	0040	0.9661	1.8376	11.1	0.53	0.6094
CENTRE	0041	0.1784	1.4640	26.7	0.12	0.9039
CENTRE	0042	-1.3163	1.8362	11.2	-0.72	0.4882

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	493	26.24	<.0001
numcd	1	449	0.02	0.8913
B_HAMD	1	504	12.33	0.0005

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-11.7706	0.6445	80.2	-18.26	<.0001	0.05	-13.0531	-10.4880
trtseq	Q600MG	-12.6689	0.6490	80.3	-19.52	<.0001	0.05	-13.9603	-11.3775
trtseq	P	-7.6708	0.6488	76.6	-11.82	<.0001	0.05	-8.9627	-6.3789

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.8984	0.7194	484	1.25	0.2124	0.05	-0.5152	2.3119
trtseq	Q300MG	P	-4.0998	0.7291	497	-5.62	<.0001	0.05	-5.5323	-2.6673
trtseq	Q600MG	P	-4.9981	0.7335	500	-6.81	<.0001	0.05	-6.4392	-3.5571

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3475.61118837	
1	2	3468.06750891	0.00000038
2	1	3468.06702408	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	2.8489
Residual	50.5643

Fit Statistics

-2 Res Log Likelihood	3468.1
AIC (smaller is better)	3472.1
AICC (smaller is better)	3472.1
BIC (smaller is better)	3475.2

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			0.6369	2.5390	496	0.25	0.8020
trtseq		Q300MG	-4.5144	0.7818	502	-5.77	<.0001
trtseq		Q600MG	-4.8737	0.7859	504	-6.20	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.1267	0.7283	404	-0.17	0.8620
numcd	2		0	.	.	.	.
B_HAMD			-0.3459	0.09865	506	-3.51	0.0005

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.7695	1.5641	7.89	-0.49	0.6361
CENTRE	0002	-0.2889	1.3634	13.5	-0.21	0.8354
CENTRE	0003	0.1449	1.3400	14.5	0.11	0.9154
CENTRE	0004	-1.2855	1.3006	16.2	-0.99	0.3376
CENTRE	0005	0.2499	1.0779	30.8	0.23	0.8182
CENTRE	0006	2.1086	1.4648	10.2	1.44	0.1799
CENTRE	0007	0.5401	1.3411	14.4	0.40	0.6931
CENTRE	0009	0.9794	1.3655	13.4	0.72	0.4855
CENTRE	0010	0.8548	1.2496	18.7	0.68	0.5023
CENTRE	0011	-0.1975	1.2673	17.8	-0.16	0.8779
CENTRE	0013	-0.02456	1.3628	13.6	-0.02	0.9859
CENTRE	0014	-1.1829	1.2687	17.7	-0.93	0.3637
CENTRE	0015	0.8911	1.4945	9.46	0.60	0.5650
CENTRE	0016	-0.8003	1.5283	8.66	-0.52	0.6136
CENTRE	0018	0.2253	1.3396	14.5	0.17	0.8688
CENTRE	0019	-0.6769	1.0558	32.5	-0.64	0.5259
CENTRE	0020	0.8812	1.2635	18	0.70	0.4945
CENTRE	0022	-0.3438	0.9248	46.1	-0.37	0.7118
CENTRE	0023	-0.3777	1.0070	37.4	-0.38	0.7097
CENTRE	0025	0.3749	1.6012	7.19	0.23	0.8214
CENTRE	0026	0.2188	1.1703	23.6	0.19	0.8533
CENTRE	0027	-0.3670	1.5292	8.64	-0.24	0.8159
CENTRE	0028	0.1748	1.1166	27.5	0.16	0.8767
CENTRE	0029	2.6680	1.1713	23.5	2.28	0.0321
CENTRE	0030	0.5128	1.3006	16.2	0.39	0.6985
CENTRE	0031	-0.2505	1.1535	24.7	-0.22	0.8299
CENTRE	0033	1.0112	1.3228	15.2	0.76	0.4563
CENTRE	0034	-1.0971	1.4410	10.9	-0.76	0.4626
CENTRE	0035	0.6808	1.2126	20.9	0.56	0.5805
CENTRE	0036	-1.1516	1.5288	8.65	-0.75	0.4713
CENTRE	0037	0.2840	1.4086	11.9	0.20	0.8436
CENTRE	0039	-3.4116	1.0811	30.5	-3.16	0.0036
CENTRE	0040	0.1070	1.6020	7.17	0.07	0.9486
CENTRE	0041	0.2290	1.3624	13.6	0.17	0.8690
CENTRE	0042	-0.9111	1.6011	7.19	-0.57	0.5867

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	23.78	<.0001
numcd	1	404	0.03	0.8620
B_HAMD	1	506	12.29	0.0005

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-12.4490	0.6495	101	-19.17	<.0001	0.05	-13.7375	-11.1606
trtseq	Q600MG	-12.8083	0.6539	100	-19.59	<.0001	0.05	-14.1056	-11.5109
trtseq	P	-7.9346	0.6526	96	-12.16	<.0001	0.05	-9.2300	-6.6392

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.3592	0.7733	489	0.46	0.6425	0.05	-1.1602	1.8786
trtseq	Q300MG	P	-4.5144	0.7818	502	-5.77	<.0001	0.05	-6.0505	-2.9784
trtseq	Q600MG	P	-4.8737	0.7859	504	-6.20	<.0001	0.05	-6.4177	-3.3296

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3455.52817579	
1	2	3447.06164473	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	2.8065
Residual	48.4734

Fit Statistics

-2 Res Log Likelihood	3447.1
AIC (smaller is better)	3451.1
AICC (smaller is better)	3451.1
BIC (smaller is better)	3454.2

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			-0.9991	2.4874	496	-0.40	0.6881
trtseq		Q300MG	-4.5617	0.7657	501	-5.96	<.0001
trtseq		Q600MG	-4.7994	0.7697	504	-6.24	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.5444	0.7138	410	-0.76	0.4461
numcd	2		0	.	.	.	.
B_HAMD			-0.2745	0.09662	506	-2.84	0.0047

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.9448	1.5494	8.44	-0.61	0.5581
CENTRE	0002	-0.3011	1.3469	14.6	-0.22	0.8262
CENTRE	0003	0.6481	1.3234	15.6	0.49	0.6311
CENTRE	0004	-1.3164	1.2839	17.5	-1.03	0.3192
CENTRE	0005	0.2296	1.0616	33.5	0.22	0.8301
CENTRE	0006	1.8250	1.4490	11	1.26	0.2339
CENTRE	0007	1.3132	1.3245	15.6	0.99	0.3366
CENTRE	0009	1.1632	1.3490	14.5	0.86	0.4026
CENTRE	0010	0.8144	1.2328	20.3	0.66	0.5163
CENTRE	0011	-0.1290	1.2506	19.2	-0.10	0.9189
CENTRE	0013	0.4334	1.3463	14.6	0.32	0.7520
CENTRE	0014	-0.6643	1.2519	19.2	-0.53	0.6017
CENTRE	0015	1.1755	1.4790	10.2	0.79	0.4449
CENTRE	0016	-0.7064	1.5132	9.28	-0.47	0.6514
CENTRE	0018	0.09106	1.3230	15.6	0.07	0.9460
CENTRE	0019	-0.5961	1.0397	35.2	-0.57	0.5701
CENTRE	0020	0.6347	1.2468	19.5	0.51	0.6164
CENTRE	0022	-0.1608	0.9099	49.7	-0.18	0.8604
CENTRE	0023	-0.5554	0.9912	40.5	-0.56	0.5783
CENTRE	0025	0.4813	1.5870	7.67	0.30	0.7697
CENTRE	0026	-0.5586	1.1536	25.6	-0.48	0.6323
CENTRE	0027	-0.3592	1.5140	9.26	-0.24	0.8176
CENTRE	0028	0.7117	1.1002	29.9	0.65	0.5227
CENTRE	0029	1.8254	1.1547	25.5	1.58	0.1262
CENTRE	0030	0.3183	1.2838	17.5	0.25	0.8071
CENTRE	0031	0.6309	1.1369	26.8	0.55	0.5835
CENTRE	0033	0.4077	1.3061	16.4	0.31	0.7589
CENTRE	0034	-1.0708	1.4250	11.8	-0.75	0.4672
CENTRE	0035	0.3142	1.1958	22.6	0.26	0.7951
CENTRE	0036	-0.9773	1.5136	9.27	-0.65	0.5342
CENTRE	0037	-0.1704	1.3924	12.9	-0.12	0.9045
CENTRE	0039	-3.9096	1.0648	33.1	-3.67	0.0008
CENTRE	0040	0.4858	1.5878	7.66	0.31	0.7678
CENTRE	0041	-0.1723	1.3459	14.7	-0.13	0.8999
CENTRE	0042	-0.9108	1.5870	7.67	-0.57	0.5825

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	24.60	<.0001
numcd	1	410	0.58	0.4461
B_HAMD	1	506	8.07	0.0047

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-12.5853	0.6380	103	-19.73	<.0001	0.05	-13.8507	-11.3200
trtseq	Q600MG	-12.8230	0.6423	102	-19.96	<.0001	0.05	-14.0971	-11.5490
trtseq	P	-8.0236	0.6411	97.9	-12.51	<.0001	0.05	-9.2959	-6.7513

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.2377	0.7572	489	0.31	0.7537	0.05	-1.2501	1.7255
trtseq	Q300MG	P	-4.5617	0.7657	501	-5.96	<.0001	0.05	-6.0660	-3.0574
trtseq	Q600MG	P	-4.7994	0.7697	504	-6.24	<.0001	0.05	-6.3116	-3.2873

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3490.56400493	
1	2	3483.72422847	0.00000001
2	1	3483.72421456	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	2.5138
Residual	52.3627

Fit Statistics

-2 Res Log Likelihood	3483.7
AIC (smaller is better)	3487.7
AICC (smaller is better)	3487.7
BIC (smaller is better)	3490.8

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.1156	2.5755	496	0.43	0.6651
trtseq		Q300MG	-5.1510	0.7946	503	-6.48	<.0001
trtseq		Q600MG	-5.2662	0.7985	505	-6.59	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.03334	0.7365	397	-0.05	0.9639
numcd	2		0	.	.	.	.
B_HAMD			-0.3723	0.1002	506	-3.72	0.0002

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.3566	1.4847	7.38	-0.24	0.8167
CENTRE	0002	-0.8174	1.3143	11.9	-0.62	0.5457
CENTRE	0003	0.3492	1.2939	12.7	0.27	0.7916
CENTRE	0004	-1.2712	1.2593	14	-1.01	0.3298
CENTRE	0005	0.5020	1.0577	26	0.47	0.6391
CENTRE	0006	1.2130	1.4015	9.29	0.87	0.4086
CENTRE	0007	1.4366	1.2949	12.6	1.11	0.2879
CENTRE	0009	0.2342	1.3162	11.9	0.18	0.8618
CENTRE	0010	0.7914	1.2139	16.1	0.65	0.5237
CENTRE	0011	-0.4675	1.2298	15.3	-0.38	0.7091
CENTRE	0013	-0.2517	1.3139	11.9	-0.19	0.8513
CENTRE	0014	-0.5987	1.2310	15.3	-0.49	0.6336
CENTRE	0015	1.0118	1.4267	8.66	0.71	0.4969
CENTRE	0016	-0.4885	1.4550	8	-0.34	0.7457
CENTRE	0018	-0.08716	1.2936	12.7	-0.07	0.9473
CENTRE	0019	0.01629	1.0371	27.5	0.02	0.9876
CENTRE	0020	0.4287	1.2264	15.5	0.35	0.7314
CENTRE	0022	-0.1899	0.9138	39.7	-0.21	0.8364
CENTRE	0023	-0.4208	0.9915	31.7	-0.42	0.6741
CENTRE	0025	0.4867	1.5153	6.8	0.32	0.7577
CENTRE	0026	0.1420	1.1425	20	0.12	0.9023
CENTRE	0027	-0.3276	1.4557	7.99	-0.23	0.8276
CENTRE	0028	0.8526	1.0935	23.3	0.78	0.4434
CENTRE	0029	2.2620	1.1435	20	1.98	0.0619
CENTRE	0030	0.4879	1.2593	14	0.39	0.7042
CENTRE	0031	-0.1126	1.1272	21	-0.10	0.9214
CENTRE	0033	0.9810	1.2788	13.2	0.77	0.4565
CENTRE	0034	-0.8015	1.3812	9.83	-0.58	0.5748
CENTRE	0035	-0.1560	1.1808	17.8	-0.13	0.8964
CENTRE	0036	-0.4838	1.4554	8	-0.33	0.7481
CENTRE	0037	-0.1305	1.3535	10.6	-0.10	0.9250
CENTRE	0039	-3.4773	1.0607	25.8	-3.28	0.0030
CENTRE	0040	0.1282	1.5159	6.79	0.08	0.9350
CENTRE	0041	-0.06300	1.3135	12	-0.05	0.9625
CENTRE	0042	-0.8218	1.5153	6.8	-0.54	0.6049

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	28.27	<.0001
numcd	1	397	0.00	0.9639
B_HAMD	1	506	13.81	0.0002

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-13.2096	0.6491	116	-20.35	<.0001	0.05	-14.4952	-11.9240
trtseq	Q600MG	-13.3248	0.6535	115	-20.39	<.0001	0.05	-14.6193	-12.0304
trtseq	P	-8.0586	0.6520	112	-12.36	<.0001	0.05	-9.3504	-6.7668

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.1152	0.7865	492	0.15	0.8836	0.05	-1.4302	1.6606
trtseq	Q300MG	P	-5.1510	0.7946	503	-6.48	<.0001	0.05	-6.7122	-3.5899
trtseq	Q600MG	P	-5.2662	0.7985	505	-6.59	<.0001	0.05	-6.8351	-3.6974

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMDVSTXBL
Dependent Variable	CL_HAMD
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3502.46144471	
1	2	3494.95152956	0.00000003
2	1	3494.95148491	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	2.8944
Residual	53.3763

Fit Statistics

-2 Res Log Likelihood	3495.0
AIC (smaller is better)	3499.0
AICC (smaller is better)	3499.0
BIC (smaller is better)	3502.1

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			-2.6798	2.6066	496	-1.03	0.3044
trtseq		Q300MG	-4.8394	0.8030	502	-6.03	<.0001
trtseq		Q600MG	-5.2929	0.8072	504	-6.56	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.01472	0.7471	404	0.02	0.9843
numcd	2		0	.	.	.	.
B_HAMD			-0.2387	0.1013	506	-2.36	0.0189

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.7874	1.5807	7.98	-0.50	0.6318
CENTRE	0002	-0.6441	1.3831	13.5	-0.47	0.6489
CENTRE	0003	0.4463	1.3599	14.4	0.33	0.7475
CENTRE	0004	-1.4044	1.3208	16	-1.06	0.3034
CENTRE	0005	0.4275	1.0981	30.4	0.39	0.6998
CENTRE	0006	1.2193	1.4833	10.3	0.82	0.4297
CENTRE	0007	1.5752	1.3610	14.3	1.16	0.2660
CENTRE	0009	0.7608	1.3852	13.4	0.55	0.5919
CENTRE	0010	0.5215	1.2700	18.5	0.41	0.6861
CENTRE	0011	-1.0803	1.2877	17.6	-0.84	0.4128
CENTRE	0013	0.4345	1.3826	13.5	0.31	0.7581
CENTRE	0014	-1.3752	1.2890	17.6	-1.07	0.3005
CENTRE	0015	1.1494	1.5125	9.52	0.76	0.4657
CENTRE	0016	-0.1961	1.5457	8.73	-0.13	0.9019
CENTRE	0018	0.7507	1.3596	14.4	0.55	0.5893
CENTRE	0019	0.5300	1.0759	32.1	0.49	0.6256
CENTRE	0020	0.4004	1.2839	17.8	0.31	0.7588
CENTRE	0022	-0.09535	0.9437	45.7	-0.10	0.9200
CENTRE	0023	-0.1542	1.0267	36.9	-0.15	0.8814
CENTRE	0025	0.4475	1.6170	7.29	0.28	0.7896
CENTRE	0026	0.007232	1.1908	23.3	0.01	0.9952
CENTRE	0027	-0.7901	1.5465	8.71	-0.51	0.6221
CENTRE	0028	0.8007	1.1371	27.2	0.70	0.4873
CENTRE	0029	2.2985	1.1919	23.2	1.93	0.0661
CENTRE	0030	0.3229	1.3208	16	0.24	0.8100
CENTRE	0031	0.05091	1.1740	24.4	0.04	0.9658
CENTRE	0033	0.8492	1.3429	15.1	0.63	0.5366
CENTRE	0034	-1.1069	1.4598	10.9	-0.76	0.4643
CENTRE	0035	-0.3061	1.2331	20.6	-0.25	0.8064
CENTRE	0036	-0.8889	1.5461	8.72	-0.57	0.5799
CENTRE	0037	-0.2268	1.4279	11.9	-0.16	0.8765
CENTRE	0039	-3.6482	1.1013	30.1	-3.31	0.0024
CENTRE	0040	0.3161	1.6177	7.27	0.20	0.8504
CENTRE	0041	0.09824	1.3821	13.5	0.07	0.9444
CENTRE	0042	-0.7028	1.6169	7.29	-0.43	0.6764

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	26.31	<.0001
numcd	1	404	0.00	0.9843
B_HAMD	1	506	5.55	0.0189

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-13.3829	0.6643	107	-20.15	<.0001	0.05	-14.6999	-12.0659
trtseq	Q600MG	-13.8364	0.6688	106	-20.69	<.0001	0.05	-15.1625	-12.5104
trtseq	P	-8.5435	0.6674	102	-12.80	<.0001	0.05	-9.8674	-7.2196

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.4536	0.7944	490	0.57	0.5683	0.05	-1.1073	2.0144
trtseq	Q300MG	P	-4.8394	0.8030	502	-6.03	<.0001	0.05	-6.4171	-3.2617
trtseq	Q600MG	P	-5.2929	0.8072	504	-6.56	<.0001	0.05	-6.8788	-3.7071

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=3

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	171	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	171	0	-7.78	5.24
		B_HAMD	BL TOTAL HAMD SCORE	171	0	24.54	3.00
Q600MG	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-7.78	5.47
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.65	3.51
P	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-4.44	5.24
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

WINDOWED VISIT=4

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	172	0	-10.04	5.95
		B_HAMD	BL TOTAL HAMD SCORE	172	0	24.53	3.00
Q600MG	170	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	170	0	-9.94	6.32
		B_HAMD	BL TOTAL HAMD SCORE	170	0	24.66	3.51
P	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-6.14	6.13
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

WINDOWED VISIT=5

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	172	0	-10.99	6.36
		B_HAMD	BL TOTAL HAMD SCORE	172	0	24.53	3.00
Q600MG	170	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	170	0	-11.39	7.00
		B_HAMD	BL TOTAL HAMD SCORE	170	0	24.66	3.51

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=5

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-7.00	6.76
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

WINDOWED VISIT=6

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	172	0	-11.77	6.62
		B_HAMD	BL TOTAL HAMD SCORE	172	0	24.53	3.00
Q600MG	170	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	170	0	-12.75	7.12
		B_HAMD	BL TOTAL HAMD SCORE	170	0	24.66	3.51
P	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-7.73	7.06
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

WINDOWED VISIT=7

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	172	0	-12.56	6.80
		B_HAMD	BL TOTAL HAMD SCORE	172	0	24.53	3.00
Q600MG	170	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	170	0	-13.01	7.80
		B_HAMD	BL TOTAL HAMD SCORE	170	0	24.66	3.51
P	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-7.98	7.48
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=8

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	172	0	-12.82	6.65
		B_HAMD	BL TOTAL HAMD SCORE	172	0	24.53	3.00
Q600MG	170	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	170	0	-13.08	7.73
		B_HAMD	BL TOTAL HAMD SCORE	170	0	24.66	3.51
P	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-8.15	7.21
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

WINDOWED VISIT=9

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	172	0	-13.27	6.72
		B_HAMD	BL TOTAL HAMD SCORE	172	0	24.53	3.00
Q600MG	170	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	170	0	-13.42	7.98
		B_HAMD	BL TOTAL HAMD SCORE	170	0	24.66	3.51
P	169	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	169	0	-8.09	7.72
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

WINDOWED VISIT=10

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	172	0	-13.42	6.91
		B_HAMD	BL TOTAL HAMD SCORE	172	0	24.53	3.00
Q600MG	170	CL_HAMD	CHG_BL TOTAL HAMD - LOCF	170	0	-13.87	7.93
		B_HAMD	BL TOTAL HAMD SCORE	170	0	24.66	3.51

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
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12.1.9.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	CL_HAMD	CHG BL TOTAL HAMD - LOCF	169	0	-8.56	7.70
		B_HAMD	BL TOTAL HAMD SCORE	169	0	24.60	3.29

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMD204H.SAS
GENERATED: 14JUL2005 11:41:47 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	509
Observations Used	509
Observations Not Used	0
Total Observations	509

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1101.76738820	
1	3	1062.04193229	0.00052235
2	1	1062.00435760	0.00000488
3	1	1062.00402400	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.06898
Residual	0.4266

Fit Statistics

-2 Res Log Likelihood	1062.0
AIC (smaller is better)	1066.0
AICC (smaller is better)	1066.0
BIC (smaller is better)	1069.1

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.3705	0.2743	387	5.00	<.0001
trtseq		Q300MG	-0.3265	0.07250	492	-4.50	<.0001
trtseq		Q600MG	-0.3075	0.07306	494	-4.21	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.05102	0.06989	491	0.73	0.4658
numcd	2		0	.	.	.	.
B_ILLSEV			-0.3709	0.05935	445	-6.25	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1399	0.2169	30.6	-0.64	0.5239
CENTRE	0002	0.1870	0.1667	75.6	1.12	0.2655
CENTRE	0003	-0.3397	0.1621	82.1	-2.09	0.0393
CENTRE	0004	0.04577	0.1547	92.6	0.30	0.7681
CENTRE	0005	-0.1072	0.1213	139	-0.88	0.3785
CENTRE	0006	0.2720	0.1901	49.6	1.43	0.1586
CENTRE	0007	0.2543	0.1620	82.2	1.57	0.1203
CENTRE	0009	-0.2246	0.1669	75.4	-1.35	0.1823
CENTRE	0010	0.09349	0.1469	104	0.64	0.5259
CENTRE	0011	0.1270	0.1498	98.9	0.85	0.3985
CENTRE	0013	0.02234	0.1666	75.7	0.13	0.8937
CENTRE	0014	0.04955	0.1484	103	0.33	0.7392
CENTRE	0015	0.2076	0.1992	41.8	1.04	0.3034
CENTRE	0016	-0.1710	0.2062	37	-0.83	0.4124
CENTRE	0018	0.04787	0.1628	80.4	0.29	0.7696
CENTRE	0019	-0.08019	0.1179	140	-0.68	0.4975
CENTRE	0020	-0.4396	0.1481	103	-2.97	0.0037
CENTRE	0022	-0.07854	0.1011	138	-0.78	0.4386
CENTRE	0023	0.5169	0.1152	142	4.49	<.0001
CENTRE	0025	0.1458	0.2290	24.8	0.64	0.5302
CENTRE	0026	-0.1122	0.1349	123	-0.83	0.4075
CENTRE	0027	0.1751	0.2065	36.8	0.85	0.4020
CENTRE	0028	0.1908	0.1264	132	1.51	0.1334
CENTRE	0029	0.1283	0.1334	125	0.96	0.3381
CENTRE	0030	-0.05161	0.1549	92.5	-0.33	0.7397
CENTRE	0031	-0.09055	0.1312	126	-0.69	0.4913
CENTRE	0033	0.1449	0.1589	86.6	0.91	0.3642
CENTRE	0034	-0.2234	0.1833	56.2	-1.22	0.2281
CENTRE	0035	0.08036	0.1418	111	0.57	0.5721
CENTRE	0036	-0.03823	0.2064	36.9	-0.19	0.8541
CENTRE	0037	0.03538	0.1771	62.7	0.20	0.8423
CENTRE	0039	-0.5040	0.1208	138	-4.17	<.0001
CENTRE	0040	0.06757	0.2291	24.7	0.29	0.7705
CENTRE	0041	-0.08518	0.1678	73.5	-0.51	0.6133
CENTRE	0042	-0.1064	0.2288	24.9	-0.46	0.6461

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	489	12.56	<.0001
numcd	1	491	0.53	0.4658
B_ILLSEV	1	445	39.05	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-0.5826	0.07091	77.5	-8.22	<.0001	0.05	-0.7238	-0.4414
trtseq	Q600MG	-0.5636	0.07145	78.1	-7.89	<.0001	0.05	-0.7058	-0.4213
trtseq	P	-0.2561	0.07147	75.3	-3.58	0.0006	0.05	-0.3984	-0.1137

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.01905	0.07157	483	-0.27	0.7902	0.05	-0.1597	0.1216
trtseq	Q300MG	P	-0.3265	0.07250	492	-4.50	<.0001	0.05	-0.4690	-0.1841
trtseq	Q600MG	P	-0.3075	0.07306	494	-4.21	<.0001	0.05	-0.4510	-0.1639

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1380.12541850	
1	3	1338.63730574	0.00006780
2	1	1338.62290254	0.00000027
3	1	1338.62284820	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.1258
Residual	0.7290

Fit Statistics

-2 Res Log Likelihood	1338.6
AIC (smaller is better)	1342.6
AICC (smaller is better)	1342.6
BIC (smaller is better)	1345.7

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.4435	0.3591	391	4.02	<.0001
trtseq		Q300MG	-0.4187	0.09473	493	-4.42	<.0001
trtseq		Q600MG	-0.4291	0.09548	495	-4.49	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.04242	0.09147	494	0.46	0.6430
numcd	2		0	.	.	.	.
B_ILLSEV			-0.4444	0.07761	451	-5.73	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1433	0.2899	31.4	-0.49	0.6245
CENTRE	0002	0.1411	0.2210	79	0.64	0.5250
CENTRE	0003	-0.2851	0.2148	85.7	-1.33	0.1879
CENTRE	0004	-0.4639	0.2048	96.5	-2.26	0.0258
CENTRE	0005	-0.2331	0.1601	141	-1.46	0.1477
CENTRE	0006	0.4752	0.2528	51.7	1.88	0.0657
CENTRE	0007	0.04579	0.2146	85.9	0.21	0.8315
CENTRE	0009	0.2239	0.2212	78.8	1.01	0.3145
CENTRE	0010	0.1995	0.1942	108	1.03	0.3066
CENTRE	0011	0.3728	0.1982	103	1.88	0.0628
CENTRE	0013	0.08981	0.2209	79.1	0.41	0.6854
CENTRE	0014	-0.05062	0.1963	106	-0.26	0.7970
CENTRE	0015	0.3127	0.2654	43.4	1.18	0.2451
CENTRE	0016	-0.02534	0.2750	38.3	-0.09	0.9271
CENTRE	0018	-0.1205	0.2157	84	-0.56	0.5780
CENTRE	0019	-0.09372	0.1544	142	-0.61	0.5448
CENTRE	0020	-0.3965	0.1959	107	-2.02	0.0454
CENTRE	0022	-0.2585	0.1335	136	-1.94	0.0549
CENTRE	0023	0.5131	0.1520	142	3.38	0.0010
CENTRE	0025	0.2426	0.3067	25.3	0.79	0.4364
CENTRE	0026	0.004229	0.1755	130	0.02	0.9808
CENTRE	0027	0.03302	0.2754	38.1	0.12	0.9052
CENTRE	0028	0.4538	0.1669	134	2.72	0.0074
CENTRE	0029	0.1658	0.1762	129	0.94	0.3486
CENTRE	0030	-0.2339	0.2050	96.4	-1.14	0.2567
CENTRE	0031	0.04106	0.1733	129	0.24	0.8131
CENTRE	0033	0.1765	0.2104	90.3	0.84	0.4038
CENTRE	0034	-0.2523	0.2435	58.6	-1.04	0.3045
CENTRE	0035	0.1630	0.1875	114	0.87	0.3863
CENTRE	0036	-0.3872	0.2753	38.1	-1.41	0.1677
CENTRE	0037	0.2147	0.2351	65.5	0.91	0.3643
CENTRE	0039	-0.6797	0.1595	140	-4.26	<.0001
CENTRE	0040	0.01119	0.3070	25.2	0.04	0.9712
CENTRE	0041	0.01610	0.2225	76.8	0.07	0.9425
CENTRE	0042	-0.2724	0.3066	25.3	-0.89	0.3826

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	490	13.08	<.0001
numcd	1	494	0.22	0.6430
B_ILLSEV	1	451	32.79	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-0.9344	0.09393	72	-9.95	<.0001	0.05	-1.1217	-0.7472
trtseq	Q600MG	-0.9448	0.09460	72.5	-9.99	<.0001	0.05	-1.1333	-0.7562
trtseq	P	-0.5157	0.09478	70.4	-5.44	<.0001	0.05	-0.7047	-0.3267

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.01033	0.09331	483	0.11	0.9119	0.05	-0.1730	0.1937
trtseq	Q300MG	P	-0.4187	0.09473	493	-4.42	<.0001	0.05	-0.6049	-0.2326
trtseq	Q600MG	P	-0.4291	0.09548	495	-4.49	<.0001	0.05	-0.6167	-0.2415

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1511.95156587	
1	3	1475.88825871	0.00000835
2	1	1475.88594112	0.00000001

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.1505
Residual	0.9600

Fit Statistics

-2 Res Log Likelihood	1475.9
AIC (smaller is better)	1479.9
AICC (smaller is better)	1479.9
BIC (smaller is better)	1483.0

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.5972	0.4095	384	3.90	0.0001
trtseq		Q300MG	-0.4590	0.1086	494	-4.23	<.0001
trtseq		Q600MG	-0.5651	0.1095	496	-5.16	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.07590	0.1046	491	-0.73	0.4685
numcd	2		0	.	.	.	.
B_ILLSEV			-0.4965	0.08863	442	-5.60	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1937	0.3219	28.5	-0.60	0.5522
CENTRE	0002	0.2808	0.2485	70.2	1.13	0.2622
CENTRE	0003	-0.1631	0.2417	76.3	-0.67	0.5018
CENTRE	0004	-0.6356	0.2307	86.3	-2.75	0.0072
CENTRE	0005	-0.08338	0.1811	132	-0.46	0.6459
CENTRE	0006	0.4860	0.2828	46	1.72	0.0924
CENTRE	0007	0.1627	0.2414	76.5	0.67	0.5023
CENTRE	0009	0.1938	0.2486	70.1	0.78	0.4383
CENTRE	0010	0.3628	0.2191	97.6	1.66	0.1009
CENTRE	0011	0.3104	0.2235	92.4	1.39	0.1681
CENTRE	0013	0.04116	0.2483	70.3	0.17	0.8688
CENTRE	0014	-0.1224	0.2214	95.8	-0.55	0.5817
CENTRE	0015	0.3281	0.2961	38.8	1.11	0.2748
CENTRE	0016	-0.3950	0.3064	34.4	-1.29	0.2059
CENTRE	0018	-0.2353	0.2427	74.8	-0.97	0.3354
CENTRE	0019	0.09245	0.1746	135	0.53	0.5973
CENTRE	0020	-0.1609	0.2209	96.1	-0.73	0.4680
CENTRE	0022	-0.3212	0.1510	133	-2.13	0.0352
CENTRE	0023	0.5257	0.1719	135	3.06	0.0027
CENTRE	0025	0.1649	0.3394	23.2	0.49	0.6317
CENTRE	0026	0.02808	0.1983	119	0.14	0.8877
CENTRE	0027	-0.08008	0.3067	34.3	-0.26	0.7956
CENTRE	0028	0.3901	0.1886	125	2.07	0.0407
CENTRE	0029	0.2424	0.1991	118	1.22	0.2259
CENTRE	0030	-0.2546	0.2310	86.2	-1.10	0.2733
CENTRE	0031	0.06188	0.1958	119	0.32	0.7525
CENTRE	0033	0.2100	0.2369	80.6	0.89	0.3779
CENTRE	0034	-0.1836	0.2728	52.1	-0.67	0.5038
CENTRE	0035	0.2358	0.2116	104	1.11	0.2676
CENTRE	0036	-0.2406	0.3066	34.3	-0.78	0.4381
CENTRE	0037	0.1139	0.2637	58.1	0.43	0.6673
CENTRE	0039	-0.8245	0.1804	131	-4.57	<.0001
CENTRE	0040	0.02824	0.3397	23.2	0.08	0.9345
CENTRE	0041	-0.1803	0.2501	68.3	-0.72	0.4734
CENTRE	0042	-0.1850	0.3393	23.3	-0.55	0.5908

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	491	14.96	<.0001
numcd	1	491	0.53	0.4685
B_ILLSEV	1	442	31.38	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-1.1121	0.1056	75.8	-10.53	<.0001	0.05	-1.3224	-0.9018
trtseq	Q600MG	-1.2183	0.1064	76.3	-11.45	<.0001	0.05	-1.4301	-1.0065
trtseq	P	-0.6532	0.1065	73.8	-6.13	<.0001	0.05	-0.8654	-0.4409

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.1061	0.1070	484	0.99	0.3219	0.05	-0.1042	0.3165
trtseq	Q300MG	P	-0.4590	0.1086	494	-4.23	<.0001	0.05	-0.6724	-0.2455
trtseq	Q600MG	P	-0.5651	0.1095	496	-5.16	<.0001	0.05	-0.7802	-0.3500

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1568.20857962	
1	3	1531.84735449	0.00028047
2	1	1531.75551863	0.00000613
3	1	1531.75364570	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.1603
Residual	1.0742

Fit Statistics

-2 Res Log Likelihood	1531.8
AIC (smaller is better)	1535.8
AICC (smaller is better)	1535.8
BIC (smaller is better)	1538.9

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.6848	0.4318	382	3.90	0.0001
trtseq		Q300MG	-0.5196	0.1149	495	-4.52	<.0001
trtseq		Q600MG	-0.6815	0.1157	497	-5.89	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.06188	0.1105	489	-0.56	0.5757
numcd	2		0	.	.	.	.
B_ILLSEV			-0.5281	0.09352	439	-5.65	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1504	0.3347	27.6	-0.45	0.6566
CENTRE	0002	0.3263	0.2600	67.1	1.26	0.2138
CENTRE	0003	0.03378	0.2530	72.9	0.13	0.8941
CENTRE	0004	-0.7096	0.2417	82.6	-2.94	0.0043
CENTRE	0005	-0.1808	0.1901	129	-0.95	0.3434
CENTRE	0006	0.3734	0.2951	44.1	1.27	0.2124
CENTRE	0007	-0.1807	0.2527	73	-0.72	0.4768
CENTRE	0009	0.1903	0.2601	66.9	0.73	0.4670
CENTRE	0010	0.4084	0.2296	93.6	1.78	0.0786
CENTRE	0011	0.2620	0.2342	88.6	1.12	0.2662
CENTRE	0013	0.08994	0.2598	67.1	0.35	0.7303
CENTRE	0014	-0.1505	0.2321	91.8	-0.65	0.5182
CENTRE	0015	0.2933	0.3086	37.3	0.95	0.3481
CENTRE	0016	-0.3348	0.3190	33.2	-1.05	0.3016
CENTRE	0018	-0.1784	0.2540	71.5	-0.70	0.4847
CENTRE	0019	-0.00101	0.1833	132	-0.01	0.9956
CENTRE	0020	-0.08580	0.2315	92.1	-0.37	0.7118
CENTRE	0022	-0.4222	0.1585	134	-2.66	0.0087
CENTRE	0023	0.4779	0.1805	133	2.65	0.0091
CENTRE	0025	0.1787	0.3523	22.6	0.51	0.6169
CENTRE	0026	0.007088	0.2081	115	0.03	0.9729
CENTRE	0027	0.07095	0.3194	33	0.22	0.8256
CENTRE	0028	0.4924	0.1979	122	2.49	0.0142
CENTRE	0029	0.2795	0.2089	114	1.34	0.1835
CENTRE	0030	-0.1298	0.2419	82.5	-0.54	0.5930
CENTRE	0031	-0.00140	0.2054	116	-0.01	0.9946
CENTRE	0033	0.09033	0.2480	77	0.36	0.7167
CENTRE	0034	-0.4056	0.2849	49.8	-1.42	0.1608
CENTRE	0035	0.2026	0.2218	99.8	0.91	0.3632
CENTRE	0036	-0.2703	0.3193	33	-0.85	0.4033
CENTRE	0037	0.2310	0.2756	55.5	0.84	0.4055
CENTRE	0039	-0.7997	0.1893	129	-4.22	<.0001
CENTRE	0040	0.1580	0.3525	22.6	0.45	0.6583
CENTRE	0041	0.09857	0.2616	65.3	0.38	0.7075
CENTRE	0042	-0.2633	0.3521	22.7	-0.75	0.4622

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	492	18.82	<.0001
numcd	1	489	0.31	0.5757
B_ILLSEV	1	439	31.89	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-1.2191	0.1106	79	-11.03	<.0001	0.05	-1.4391	-0.9991
trtseq	Q600MG	-1.3809	0.1114	79.5	-12.40	<.0001	0.05	-1.6026	-1.1593
trtseq	P	-0.6995	0.1115	76.8	-6.27	<.0001	0.05	-0.9215	-0.4774

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.1618	0.1132	485	1.43	0.1535	0.05	-0.06060	0.3843
trtseq	Q300MG	P	-0.5196	0.1149	495	-4.52	<.0001	0.05	-0.7453	-0.2939
trtseq	Q600MG	P	-0.6815	0.1157	497	-5.89	<.0001	0.05	-0.9089	-0.4540

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
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12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1623.21044565	
1	3	1605.12579530	0.00005815
2	1	1605.10523084	0.00000033
3	1	1605.10511755	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.1132
Residual	1.2651

Fit Statistics

-2 Res Log Likelihood	1605.1
AIC (smaller is better)	1609.1
AICC (smaller is better)	1609.1
BIC (smaller is better)	1612.2

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.6215	0.4532	335	3.58	0.0004
trtseq		Q300MG	-0.6585	0.1241	499	-5.30	<.0001
trtseq		Q600MG	-0.6743	0.1250	501	-5.39	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.1318	0.1176	456	-1.12	0.2632
numcd	2		0	.	.	.	.
B_ILLSEV			-0.5186	0.09874	380	-5.25	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.08965	0.2998	15.6	-0.30	0.7688
CENTRE	0002	0.2317	0.2482	31.9	0.93	0.3575
CENTRE	0003	-0.1370	0.2428	34.5	-0.56	0.5762
CENTRE	0004	-0.5080	0.2338	39.3	-2.17	0.0359
CENTRE	0005	-0.1343	0.1893	71.9	-0.71	0.4803
CENTRE	0006	0.2717	0.2738	22.2	0.99	0.3317
CENTRE	0007	0.07705	0.2426	34.6	0.32	0.7527
CENTRE	0009	0.1889	0.2483	31.9	0.76	0.4524
CENTRE	0010	0.2654	0.2239	45.1	1.19	0.2420
CENTRE	0011	0.2330	0.2276	42.6	1.02	0.3118
CENTRE	0013	-0.06550	0.2481	32	-0.26	0.7934
CENTRE	0014	-0.1491	0.2260	44	-0.66	0.5128
CENTRE	0015	0.1742	0.2830	19.5	0.62	0.5453
CENTRE	0016	-0.2608	0.2899	17.8	-0.90	0.3802
CENTRE	0018	-0.09971	0.2435	34	-0.41	0.6848
CENTRE	0019	0.06831	0.1829	76.8	0.37	0.7098
CENTRE	0020	-0.1111	0.2255	44.3	-0.49	0.6246
CENTRE	0022	-0.3528	0.1590	94.6	-2.22	0.0289
CENTRE	0023	0.2447	0.1803	78.7	1.36	0.1786
CENTRE	0025	0.06571	0.3104	13.6	0.21	0.8354
CENTRE	0026	0.02288	0.2055	58.7	0.11	0.9117
CENTRE	0027	-0.05498	0.2901	17.8	-0.19	0.8518
CENTRE	0028	0.3751	0.1964	65.3	1.91	0.0605
CENTRE	0029	0.3595	0.2063	58	1.74	0.0867
CENTRE	0030	0.01081	0.2340	39.2	0.05	0.9634
CENTRE	0031	0.02513	0.2030	59.8	0.12	0.9019
CENTRE	0033	0.1227	0.2389	36.5	0.51	0.6107
CENTRE	0034	-0.3608	0.2667	24.5	-1.35	0.1884
CENTRE	0035	0.2126	0.2172	49.2	0.98	0.3326
CENTRE	0036	-0.1597	0.2901	17.8	-0.55	0.5888
CENTRE	0037	0.1259	0.2599	27	0.48	0.6319
CENTRE	0039	-0.6422	0.1886	72.2	-3.41	0.0011
CENTRE	0040	0.04287	0.3105	13.6	0.14	0.8922
CENTRE	0041	0.08183	0.2493	31.2	0.33	0.7450
CENTRE	0042	-0.07431	0.3103	13.6	-0.24	0.8143

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	495	18.89	<.0001
numcd	1	456	1.25	0.2632
B_ILLSEV	1	380	27.59	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-1.4140	0.1094	97.3	-12.92	<.0001	0.05	-1.6311	-1.1968
trtseq	Q600MG	-1.4299	0.1102	97.2	-12.97	<.0001	0.05	-1.6486	-1.2111
trtseq	P	-0.7555	0.1102	93.1	-6.86	<.0001	0.05	-0.9743	-0.5367

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.01590	0.1226	488	0.13	0.8969	0.05	-0.2251	0.2569
trtseq	Q300MG	P	-0.6585	0.1241	499	-5.30	<.0001	0.05	-0.9023	-0.4146
trtseq	Q600MG	P	-0.6743	0.1250	501	-5.39	<.0001	0.05	-0.9199	-0.4288

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1623.47985407	
1	3	1607.78446036	0.00031449
2	1	1607.66726787	0.00000906
3	1	1607.66413740	0.00000001

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.09880
Residual	1.2774

Fit Statistics

-2 Res Log Likelihood	1607.7
AIC (smaller is better)	1611.7
AICC (smaller is better)	1611.7
BIC (smaller is better)	1614.8

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.3837	0.4511	327	3.07	0.0023
trtseq		Q300MG	-0.7025	0.1246	500	-5.64	<.0001
trtseq		Q600MG	-0.6309	0.1254	502	-5.03	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.1398	0.1175	446	-1.19	0.2350
numcd	2		0	.	.	.	.
B_ILLSEV			-0.4685	0.09842	366	-4.76	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1418	0.2840	13.8	-0.50	0.6255
CENTRE	0002	0.2289	0.2392	26.7	0.96	0.3471
CENTRE	0003	-0.08110	0.2343	28.7	-0.35	0.7318
CENTRE	0004	-0.4640	0.2262	32.5	-2.05	0.0484
CENTRE	0005	-0.1082	0.1850	60.1	-0.58	0.5608
CENTRE	0006	0.1983	0.2617	19	0.76	0.4580
CENTRE	0007	0.07831	0.2342	28.8	0.33	0.7405
CENTRE	0009	0.2267	0.2393	26.6	0.95	0.3519
CENTRE	0010	0.2074	0.2172	37.2	0.95	0.3458
CENTRE	0011	0.1729	0.2205	35.3	0.78	0.4382
CENTRE	0013	0.03776	0.2390	26.7	0.16	0.8757
CENTRE	0014	-0.06744	0.2191	36.3	-0.31	0.7600
CENTRE	0015	0.1441	0.2697	16.9	0.53	0.6000
CENTRE	0016	-0.1698	0.2756	15.6	-0.62	0.5466
CENTRE	0018	-0.1186	0.2350	28.3	-0.50	0.6177
CENTRE	0019	0.02210	0.1790	64.8	0.12	0.9021
CENTRE	0020	-0.05648	0.2187	36.5	-0.26	0.7976
CENTRE	0022	-0.3504	0.1560	83.5	-2.25	0.0274
CENTRE	0023	0.1865	0.1765	66.6	1.06	0.2944
CENTRE	0025	0.06029	0.2929	12.2	0.21	0.8403
CENTRE	0026	-0.1128	0.2003	48.5	-0.56	0.5757
CENTRE	0027	0.06934	0.2758	15.5	0.25	0.8048
CENTRE	0028	0.3354	0.1916	54.3	1.75	0.0857
CENTRE	0029	0.2268	0.2009	47.9	1.13	0.2647
CENTRE	0030	-0.05995	0.2264	32.4	-0.26	0.7929
CENTRE	0031	0.1558	0.1979	49.6	0.79	0.4349
CENTRE	0033	0.08846	0.2308	30.3	0.38	0.7042
CENTRE	0034	-0.2768	0.2555	20.8	-1.08	0.2910
CENTRE	0035	0.1694	0.2110	40.7	0.80	0.4268
CENTRE	0036	-0.1464	0.2757	15.5	-0.53	0.6030
CENTRE	0037	0.08421	0.2495	22.7	0.34	0.7389
CENTRE	0039	-0.6623	0.1843	60.5	-3.59	0.0007
CENTRE	0040	0.04577	0.2930	12.2	0.16	0.8784
CENTRE	0041	0.1405	0.2402	26.1	0.58	0.5636
CENTRE	0042	-0.06281	0.2928	12.2	-0.21	0.8337

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	18.98	<.0001
numcd	1	446	1.41	0.2350
B_ILLSEV	1	366	22.66	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-1.4764	0.1076	106	-13.72	<.0001	0.05	-1.6897	-1.2631
trtseq	Q600MG	-1.4049	0.1084	106	-12.96	<.0001	0.05	-1.6198	-1.1900
trtseq	P	-0.7740	0.1083	102	-7.15	<.0001	0.05	-0.9887	-0.5592

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.07156	0.1232	490	-0.58	0.5616	0.05	-0.3136	0.1705
trtseq	Q300MG	P	-0.7025	0.1246	500	-5.64	<.0001	0.05	-0.9472	-0.4577
trtseq	Q600MG	P	-0.6309	0.1254	502	-5.03	<.0001	0.05	-0.8773	-0.3845

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1669.65546608	
1	3	1650.97718674	0.00035544
2	1	1650.83575175	0.00001126
3	1	1650.83160347	0.00000001
4	1	1650.83159876	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.1202
Residual	1.3862

Fit Statistics

-2 Res Log Likelihood	1650.8
AIC (smaller is better)	1654.8
AICC (smaller is better)	1654.9
BIC (smaller is better)	1657.9

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.7250	0.4734	342	3.64	0.0003
trtseq		Q300MG	-0.7351	0.1299	500	-5.66	<.0001
trtseq		Q600MG	-0.6432	0.1308	502	-4.92	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.1225	0.1230	457	-1.00	0.3199
numcd	2		0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
B_ILLSEV			-0.5581	0.1032	384	-5.41	<.0001

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.06765	0.3098	16.3	-0.22	0.8298
CENTRE	0002	0.1280	0.2575	32.9	0.50	0.6223
CENTRE	0003	-0.2293	0.2520	35.5	-0.91	0.3688
CENTRE	0004	-0.5831	0.2428	40.3	-2.40	0.0210
CENTRE	0005	-0.04035	0.1970	73.7	-0.20	0.8382
CENTRE	0006	0.1977	0.2835	23	0.70	0.4927
CENTRE	0007	0.1999	0.2518	35.6	0.79	0.4324
CENTRE	0009	0.03753	0.2576	32.8	0.15	0.8851
CENTRE	0010	0.2072	0.2326	46.3	0.89	0.3777
CENTRE	0011	0.1954	0.2364	43.7	0.83	0.4129
CENTRE	0013	0.05804	0.2573	32.9	0.23	0.8230
CENTRE	0014	-0.06549	0.2347	45.1	-0.28	0.7815
CENTRE	0015	0.1446	0.2928	20.3	0.49	0.6269
CENTRE	0016	-0.1679	0.2998	18.6	-0.56	0.5823
CENTRE	0018	-0.1172	0.2527	35	-0.46	0.6457
CENTRE	0019	0.1097	0.1904	78.8	0.58	0.5662
CENTRE	0020	-0.1806	0.2342	45.4	-0.77	0.4448
CENTRE	0022	-0.3895	0.1656	97.9	-2.35	0.0207
CENTRE	0023	0.3072	0.1877	80.9	1.64	0.1055
CENTRE	0025	0.08207	0.3204	14.3	0.26	0.8015
CENTRE	0026	-0.04337	0.2137	60.1	-0.20	0.8399
CENTRE	0027	-0.02686	0.3001	18.5	-0.09	0.9296
CENTRE	0028	0.3144	0.2043	66.9	1.54	0.1284
CENTRE	0029	0.3796	0.2145	59.4	1.77	0.0819
CENTRE	0030	-0.1036	0.2430	40.2	-0.43	0.6722
CENTRE	0031	0.1251	0.2111	61.3	0.59	0.5556
CENTRE	0033	0.2545	0.2480	37.5	1.03	0.3113
CENTRE	0034	-0.2537	0.2763	25.4	-0.92	0.3671
CENTRE	0035	0.1164	0.2257	50.4	0.52	0.6083

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0036	-0.07349	0.3000	18.5	-0.24	0.8092
CENTRE	0037	0.09871	0.2694	27.8	0.37	0.7168
CENTRE	0039	-0.7336	0.1962	74	-3.74	0.0004
CENTRE	0040	-0.01848	0.3206	14.2	-0.06	0.9548
CENTRE	0041	0.1974	0.2586	32.2	0.76	0.4508
CENTRE	0042	-0.05939	0.3203	14.3	-0.19	0.8555

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	496	18.74	<.0001
numcd	1	457	0.99	0.3199
B_ILLSEV	1	384	29.26	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-1.5582	0.1140	105	-13.67	<.0001	0.05	-1.7842	-1.3322
trtseq	Q600MG	-1.4662	0.1148	105	-12.77	<.0001	0.05	-1.6939	-1.2386
trtseq	P	-0.8231	0.1147	101	-7.17	<.0001	0.05	-1.0507	-0.5955

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.09194	0.1284	490	-0.72	0.4742	0.05	-0.3442	0.1603
trtseq	Q300MG	P	-0.7351	0.1299	500	-5.66	<.0001	0.05	-0.9903	-0.4799
trtseq	Q600MG	P	-0.6432	0.1308	502	-4.92	<.0001	0.05	-0.9002	-0.3862

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGIVSTXBL
Dependent Variable	CLILLSEV
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1703.62079529	
1	3	1687.53764431	0.00014365
2	1	1687.47919332	0.00000215
3	1	1687.47837139	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.1183
Residual	1.4946

Fit Statistics

-2 Res Log Likelihood	1687.5
AIC (smaller is better)	1691.5
AICC (smaller is better)	1691.5
BIC (smaller is better)	1694.6

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.3453	0.4887	330	2.75	0.0062
trtseq		Q300MG	-0.6840	0.1348	500	-5.08	<.0001
trtseq		Q600MG	-0.7154	0.1357	502	-5.27	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.00269	0.1273	448	-0.02	0.9831
numcd	2		0	.	.	.	.
B_ILLSEV			-0.5143	0.1066	370	-4.82	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1558	0.3101	14.4	-0.50	0.6229
CENTRE	0002	0.01631	0.2604	27.9	0.06	0.9505
CENTRE	0003	-0.04365	0.2551	30.1	-0.17	0.8653
CENTRE	0004	-0.5583	0.2462	34.1	-2.27	0.0298
CENTRE	0005	-0.02177	0.2010	63	-0.11	0.9141
CENTRE	0006	0.1513	0.2854	19.8	0.53	0.6020
CENTRE	0007	0.2087	0.2550	30.2	0.82	0.4195
CENTRE	0009	0.2378	0.2606	27.9	0.91	0.3693
CENTRE	0010	0.1328	0.2363	39.1	0.56	0.5774
CENTRE	0011	0.01960	0.2399	37	0.08	0.9353
CENTRE	0013	0.05300	0.2603	28	0.20	0.8402
CENTRE	0014	-0.1594	0.2384	38.2	-0.67	0.5078
CENTRE	0015	0.1586	0.2942	17.6	0.54	0.5966
CENTRE	0016	-0.1391	0.3008	16.2	-0.46	0.6498
CENTRE	0018	0.003206	0.2558	29.7	0.01	0.9901
CENTRE	0019	0.2592	0.1944	67.8	1.33	0.1869
CENTRE	0020	-0.1986	0.2379	38.4	-0.83	0.4091
CENTRE	0022	-0.3038	0.1694	86.7	-1.79	0.0764
CENTRE	0023	0.2822	0.1917	69.7	1.47	0.1455
CENTRE	0025	0.07801	0.3200	12.7	0.24	0.8113
CENTRE	0026	-0.1188	0.2177	50.9	-0.55	0.5877
CENTRE	0027	-0.04860	0.3010	16.1	-0.16	0.8737
CENTRE	0028	0.4680	0.2083	57	2.25	0.0285
CENTRE	0029	0.3238	0.2184	50.3	1.48	0.1445
CENTRE	0030	-0.07026	0.2464	34	-0.29	0.7773
CENTRE	0031	0.06312	0.2151	52.1	0.29	0.7704
CENTRE	0033	0.1371	0.2512	31.8	0.55	0.5891
CENTRE	0034	-0.3177	0.2785	21.8	-1.14	0.2664
CENTRE	0035	0.08971	0.2295	42.7	0.39	0.6978
CENTRE	0036	-0.1063	0.3009	16.2	-0.35	0.7284
CENTRE	0037	0.1410	0.2719	23.8	0.52	0.6089
CENTRE	0039	-0.6707	0.2003	63.3	-3.35	0.0014
CENTRE	0040	0.007357	0.3201	12.7	0.02	0.9820
CENTRE	0041	0.1955	0.2616	27.4	0.75	0.4612
CENTRE	0042	-0.1132	0.3199	12.7	-0.35	0.7291

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	17.69	<.0001
numcd	1	448	0.00	0.9831
B_ILLSEV	1	370	23.28	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-1.6317	0.1168	106	-13.97	<.0001	0.05	-1.8632	-1.4002
trtseq	Q600MG	-1.6630	0.1176	106	-14.14	<.0001	0.05	-1.8962	-1.4298
trtseq	P	-0.9477	0.1175	102	-8.07	<.0001	0.05	-1.1807	-0.7146

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.03136	0.1332	490	0.24	0.8140	0.05	-0.2304	0.2932
trtseq	Q300MG	P	-0.6840	0.1348	500	-5.08	<.0001	0.05	-0.9488	-0.4192
trtseq	Q600MG	P	-0.7154	0.1357	502	-5.27	<.0001	0.05	-0.9820	-0.4488

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=3

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	171	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	171	0	-0.57	0.83
		B_ILLSEV	BL SEVERITY OF ILLNESS	171	0	4.43	0.52
Q600MG	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.59	0.73
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.51	0.62
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.22	0.57
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=4

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	172	0	-0.92	1.01
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	170	0	-1.00	0.95
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.49	0.87
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=5

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	172	0	-1.10	1.06
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	170	0	-1.28	1.15
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=5

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.64	1.03
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=6

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	172	0	-1.22	1.11
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	170	0	-1.45	1.23
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.71	1.08
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=7

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	172	0	-1.43	1.20
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	170	0	-1.51	1.29
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.76	1.12
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=8

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	172	0	-1.51	1.17
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	170	0	-1.49	1.27
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.79	1.17
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=9

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	172	0	-1.58	1.19
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	170	0	-1.55	1.34
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.82	1.26
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=10

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	172	0	-1.62	1.22
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	170	0	-1.70	1.40
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.3 CGI Severity Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	CLILLSEV	CHG BL SEVERITY OF ILLNESS - LOCF	169	0	-0.93	1.28
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI215H.SAS
GENERATED: 14JUL2005 11:41:49 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	509
Observations Used	509
Observations Not Used	0
Total Observations	509

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1266.35144614	
1	3	1245.81086166	0.00014228
2	1	1245.78697944	0.00000093
3	1	1245.78683003	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.06006
Residual	0.6264

Fit Statistics

-2 Res Log Likelihood	1245.8
AIC (smaller is better)	1249.8
AICC (smaller is better)	1249.8
BIC (smaller is better)	1252.9

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			3.4729	0.3211	344	10.81	<.0001
trtseq		Q300MG	-0.3664	0.08749	497	-4.19	<.0001
trtseq		Q600MG	-0.4019	0.08810	499	-4.56	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.06231	0.08310	462	0.75	0.4538
numcd	2		0	.	.	.	.
B_ILLSEV			0.01423	0.06994	389	0.20	0.8388

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1377	0.2168	17.5	-0.64	0.5334
CENTRE	0002	0.1121	0.1780	36.7	0.63	0.5325
CENTRE	0003	-0.02788	0.1740	39.8	-0.16	0.8735
CENTRE	0004	-0.05584	0.1674	45.3	-0.33	0.7402
CENTRE	0005	-0.05740	0.1349	81.8	-0.43	0.6716
CENTRE	0006	0.1433	0.1971	25.3	0.73	0.4740
CENTRE	0007	0.2177	0.1738	39.9	1.25	0.2178
CENTRE	0009	-0.06057	0.1781	36.7	-0.34	0.7357
CENTRE	0010	-0.06027	0.1601	52	-0.38	0.7081
CENTRE	0011	0.05413	0.1628	49.1	0.33	0.7409
CENTRE	0013	0.05073	0.1779	36.8	0.29	0.7771
CENTRE	0014	0.05853	0.1616	50.8	0.36	0.7187
CENTRE	0015	0.07908	0.2040	22.1	0.39	0.7020
CENTRE	0016	-0.05963	0.2092	20.1	-0.29	0.7785
CENTRE	0018	0.1931	0.1745	39.2	1.11	0.2753
CENTRE	0019	-0.1530	0.1313	85.6	-1.17	0.2472
CENTRE	0020	-0.3800	0.1612	51	-2.36	0.0223
CENTRE	0022	-0.04974	0.1131	104	-0.44	0.6610
CENTRE	0023	0.2458	0.1285	88.9	1.91	0.0589
CENTRE	0025	0.09282	0.2248	15.2	0.41	0.6855
CENTRE	0026	-0.04359	0.1487	64.9	-0.29	0.7703
CENTRE	0027	0.1602	0.2094	20.1	0.77	0.4531
CENTRE	0028	0.4192	0.1400	74.5	2.99	0.0037
CENTRE	0029	0.007376	0.1472	66.6	0.05	0.9602
CENTRE	0030	0.02618	0.1675	45.2	0.16	0.8765
CENTRE	0031	-0.2483	0.1448	68.6	-1.71	0.0910
CENTRE	0033	0.1654	0.1711	42.1	0.97	0.3391
CENTRE	0034	-0.1636	0.1917	28.1	-0.85	0.4009
CENTRE	0035	0.1258	0.1552	56.6	0.81	0.4210
CENTRE	0036	-0.1275	0.2094	20.1	-0.61	0.5495
CENTRE	0037	0.09182	0.1867	30.9	0.49	0.6263
CENTRE	0039	-0.4496	0.1343	82	-3.35	0.0012
CENTRE	0040	0.1051	0.2249	15.1	0.47	0.6469
CENTRE	0041	-0.1589	0.1788	35.9	-0.89	0.3802
CENTRE	0042	-0.1151	0.2248	15.2	-0.51	0.6160

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	493	12.71	<.0001
numcd	1	462	0.56	0.4538
B_ILLSEV	1	389	0.04	0.8388

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	3.2010	0.07794	98.4	41.07	<.0001	0.05	3.0464	3.3557
trtseq	Q600MG	3.1656	0.07855	98.6	40.30	<.0001	0.05	3.0097	3.3215
trtseq	P	3.5675	0.07840	93.8	45.51	<.0001	0.05	3.4118	3.7231

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.03545	0.08657	487	0.41	0.6824	0.05	-0.1347	0.2056
trtseq	Q300MG	P	-0.3664	0.08749	497	-4.19	<.0001	0.05	-0.5383	-0.1945
trtseq	Q600MG	P	-0.4019	0.08810	499	-4.56	<.0001	0.05	-0.5750	-0.2288

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1429.03414769	
1	2	1412.26117127	0.00000146
2	1	1412.26081578	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.08477
Residual	0.8615

Fit Statistics

-2 Res Log Likelihood	1412.3
AIC (smaller is better)	1416.3
AICC (smaller is better)	1416.3
BIC (smaller is better)	1419.4

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			2.9713	0.3763	327	7.90	<.0001
trtseq		Q300MG	-0.4544	0.1025	497	-4.43	<.0001
trtseq		Q600MG	-0.4942	0.1032	500	-4.79	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.02293	0.09744	457	-0.24	0.8141
numcd	2		0	.	.	.	.
B_ILLSEV			0.07784	0.08191	377	0.95	0.3426

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.2321	0.2568	14.9	-0.90	0.3804
CENTRE	0002	0.09411	0.2102	31.8	0.45	0.6574
CENTRE	0003	-0.1222	0.2054	34.5	-0.60	0.5557
CENTRE	0004	-0.3262	0.1975	39.4	-1.65	0.1066
CENTRE	0005	-0.00602	0.1589	71.8	-0.04	0.9699
CENTRE	0006	0.3242	0.2331	21.8	1.39	0.1783
CENTRE	0007	0.001455	0.2052	34.6	0.01	0.9944
CENTRE	0009	0.1873	0.2103	31.8	0.89	0.3797
CENTRE	0010	0.06888	0.1888	45.4	0.36	0.7170
CENTRE	0011	0.2836	0.1920	42.8	1.48	0.1471
CENTRE	0013	0.2251	0.2101	31.9	1.07	0.2920
CENTRE	0014	-0.07690	0.1906	44.3	-0.40	0.6886
CENTRE	0015	0.1633	0.2414	19	0.68	0.5070
CENTRE	0016	0.1202	0.2477	17.2	0.49	0.6335
CENTRE	0018	-0.00405	0.2061	34	-0.02	0.9844
CENTRE	0019	0.004466	0.1535	76.2	0.03	0.9769
CENTRE	0020	-0.2046	0.1902	44.5	-1.08	0.2878
CENTRE	0022	-0.1125	0.1332	91.3	-0.84	0.4003
CENTRE	0023	0.1180	0.1512	78	0.78	0.4375
CENTRE	0025	0.1463	0.2666	12.9	0.55	0.5925
CENTRE	0026	-0.07613	0.1728	59	-0.44	0.6612
CENTRE	0027	-0.1020	0.2479	17.2	-0.41	0.6860
CENTRE	0028	0.4545	0.1650	65.3	2.76	0.0076
CENTRE	0029	-0.08137	0.1735	58.4	-0.47	0.6408
CENTRE	0030	-0.07892	0.1977	39.3	-0.40	0.6919
CENTRE	0031	-0.02391	0.1707	60	-0.14	0.8891
CENTRE	0033	0.3192	0.2019	36.6	1.58	0.1226
CENTRE	0034	-0.2099	0.2267	24.2	-0.93	0.3635
CENTRE	0035	-0.00058	0.1830	49.4	-0.00	0.9975
CENTRE	0036	-0.2355	0.2479	17.2	-0.95	0.3552
CENTRE	0037	0.1499	0.2206	26.7	0.68	0.5027
CENTRE	0039	-0.5898	0.1583	71.9	-3.73	0.0004
CENTRE	0040	0.07310	0.2667	12.8	0.27	0.7884
CENTRE	0041	-0.03313	0.2112	31.1	-0.16	0.8764
CENTRE	0042	-0.2178	0.2665	12.9	-0.82	0.4286

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	493	14.08	<.0001
numcd	1	457	0.06	0.8141
B_ILLSEV	1	377	0.90	0.3426

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	2.8523	0.09168	82.5	31.11	<.0001	0.05	2.6699	3.0347
trtseq	Q600MG	2.8124	0.09236	82.5	30.45	<.0001	0.05	2.6287	2.9961
trtseq	P	3.3067	0.09233	79	35.81	<.0001	0.05	3.1229	3.4905

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.03988	0.1012	485	0.39	0.6938	0.05	-0.1590	0.2388
trtseq	Q300MG	P	-0.4544	0.1025	497	-4.43	<.0001	0.05	-0.6558	-0.2530
trtseq	Q600MG	P	-0.4942	0.1032	500	-4.79	<.0001	0.05	-0.6971	-0.2914

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1542.80397066	
1	2	1531.80176422	0.00000067
2	1	1531.80156185	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.07310
Residual	1.1046

Fit Statistics

-2 Res Log Likelihood	1531.8
AIC (smaller is better)	1535.8
AICC (smaller is better)	1535.8
BIC (smaller is better)	1538.9

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			2.5403	0.4154	304	6.12	<.0001
trtseq		Q300MG	-0.5445	0.1157	501	-4.71	<.0001
trtseq		Q600MG	-0.5832	0.1165	503	-5.01	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.04020	0.1086	427	0.37	0.7115
numcd	2		0	.	.	.	.
B_ILLSEV			0.1398	0.09072	340	1.54	0.1243

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.08007	0.2476	10.8	-0.32	0.7525
CENTRE	0002	0.2943	0.2121	19.7	1.39	0.1809
CENTRE	0003	0.09127	0.2082	21.1	0.44	0.6655
CENTRE	0004	-0.4112	0.2015	23.7	-2.04	0.0526
CENTRE	0005	-0.00012	0.1667	44	-0.00	0.9994
CENTRE	0006	0.1973	0.2302	14.4	0.86	0.4055
CENTRE	0007	0.1074	0.2081	21.2	0.52	0.6110
CENTRE	0009	0.02825	0.2122	19.6	0.13	0.8954
CENTRE	0010	-0.00134	0.1940	27.1	-0.01	0.9945
CENTRE	0011	0.1062	0.1968	25.7	0.54	0.5941
CENTRE	0013	0.2016	0.2120	19.7	0.95	0.3531
CENTRE	0014	-0.2022	0.1956	26.4	-1.03	0.3106
CENTRE	0015	0.1479	0.2364	12.9	0.63	0.5424
CENTRE	0016	-0.08281	0.2411	12	-0.34	0.7371
CENTRE	0018	-0.03496	0.2087	20.8	-0.17	0.8686
CENTRE	0019	0.1440	0.1615	47.8	0.89	0.3772
CENTRE	0020	-0.08870	0.1953	26.6	-0.45	0.6533
CENTRE	0022	-0.1198	0.1414	64.4	-0.85	0.3997
CENTRE	0023	0.2526	0.1593	49.3	1.59	0.1192
CENTRE	0025	0.05761	0.2543	9.7	0.23	0.8255
CENTRE	0026	0.01546	0.1798	35.2	0.09	0.9320
CENTRE	0027	-0.1361	0.2412	12	-0.56	0.5829
CENTRE	0028	0.2245	0.1724	39.7	1.30	0.2004
CENTRE	0029	0.02036	0.1804	34.8	0.11	0.9108
CENTRE	0030	-0.1073	0.2017	23.7	-0.53	0.5995
CENTRE	0031	0.02742	0.1777	36.1	0.15	0.8783
CENTRE	0033	0.1087	0.2053	22.2	0.53	0.6019
CENTRE	0034	-0.1145	0.2253	15.6	-0.51	0.6185
CENTRE	0035	0.07880	0.1888	29.6	0.42	0.6795
CENTRE	0036	-0.1404	0.2412	12	-0.58	0.5712
CENTRE	0037	0.05827	0.2205	17	0.26	0.7948
CENTRE	0039	-0.5902	0.1661	44.4	-3.55	0.0009
CENTRE	0040	0.02020	0.2544	9.69	0.08	0.9383
CENTRE	0041	0.003168	0.2129	19.3	0.01	0.9883
CENTRE	0042	-0.07547	0.2543	9.71	-0.30	0.7729

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	15.63	<.0001
numcd	1	427	0.14	0.7115
B_ILLSEV	1	340	2.37	0.1243

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	2.6387	0.09794	106	26.94	<.0001	0.05	2.4446	2.8329
trtseq	Q600MG	2.6001	0.09865	106	26.36	<.0001	0.05	2.4045	2.7957
trtseq	P	3.1832	0.09849	101	32.32	<.0001	0.05	2.9879	3.3786

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.03867	0.1145	490	0.34	0.7357	0.05	-0.1863	0.2636
trtseq	Q300MG	P	-0.5445	0.1157	501	-4.71	<.0001	0.05	-0.7718	-0.3172
trtseq	Q600MG	P	-0.5832	0.1165	503	-5.01	<.0001	0.05	-0.8120	-0.3543

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1588.12975597	
1	3	1577.38808902	0.00000303
2	1	1577.38709758	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.07767
Residual	1.2097

Fit Statistics

-2 Res Log Likelihood	1577.4
AIC (smaller is better)	1581.4
AICC (smaller is better)	1581.4
BIC (smaller is better)	1584.5

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			2.7320	0.4339	303	6.30	<.0001
trtseq		Q300MG	-0.5198	0.1210	501	-4.29	<.0001
trtseq		Q600MG	-0.6750	0.1219	503	-5.54	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.08372	0.1135	425	-0.74	0.4613
numcd	2		0	.	.	.	.
B_ILLSEV			0.09925	0.09478	338	1.05	0.2958

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1287	0.2558	10.5	-0.50	0.6252
CENTRE	0002	0.2964	0.2199	19	1.35	0.1936
CENTRE	0003	0.07030	0.2159	20.3	0.33	0.7480
CENTRE	0004	-0.4455	0.2091	22.9	-2.13	0.0441
CENTRE	0005	-0.01221	0.1734	42.3	-0.07	0.9442
CENTRE	0006	0.1724	0.2383	14	0.72	0.4813
CENTRE	0007	-0.08837	0.2157	20.4	-0.41	0.6864
CENTRE	0009	0.1231	0.2200	18.9	0.56	0.5823
CENTRE	0010	0.1458	0.2014	26	0.72	0.4756
CENTRE	0011	0.07956	0.2042	24.7	0.39	0.7002
CENTRE	0013	0.2436	0.2198	19	1.11	0.2815
CENTRE	0014	-0.1401	0.2031	25.4	-0.69	0.4965
CENTRE	0015	0.08175	0.2446	12.6	0.33	0.7437
CENTRE	0016	-0.1527	0.2493	11.7	-0.61	0.5517
CENTRE	0018	-0.00667	0.2164	20.1	-0.03	0.9757
CENTRE	0019	0.04433	0.1680	46	0.26	0.7930
CENTRE	0020	-0.05591	0.2027	25.6	-0.28	0.7849
CENTRE	0022	-0.2073	0.1472	62.3	-1.41	0.1640
CENTRE	0023	0.1710	0.1657	47.5	1.03	0.3073
CENTRE	0025	0.07003	0.2626	9.5	0.27	0.7954
CENTRE	0026	-0.01463	0.1868	33.8	-0.08	0.9381
CENTRE	0027	-0.1196	0.2494	11.7	-0.48	0.6405
CENTRE	0028	0.2943	0.1792	38.1	1.64	0.1088
CENTRE	0029	0.06757	0.1874	33.4	0.36	0.7207
CENTRE	0030	-0.04140	0.2092	22.8	-0.20	0.8449
CENTRE	0031	-0.07718	0.1847	34.7	-0.42	0.6787
CENTRE	0033	0.1216	0.2129	21.4	0.57	0.5738
CENTRE	0034	-0.1661	0.2333	15.2	-0.71	0.4872
CENTRE	0035	0.1031	0.1961	28.4	0.53	0.6032
CENTRE	0036	0.003369	0.2494	11.7	0.01	0.9894
CENTRE	0037	0.04474	0.2284	16.4	0.20	0.8471
CENTRE	0039	-0.5826	0.1728	42.6	-3.37	0.0016
CENTRE	0040	0.07179	0.2627	9.48	0.27	0.7905
CENTRE	0041	0.03396	0.2207	18.7	0.15	0.8794
CENTRE	0042	0.000285	0.2626	9.51	0.00	0.9992

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	16.77	<.0001
numcd	1	425	0.54	0.4613
B_ILLSEV	1	338	1.10	0.2958

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	2.6126	0.1021	108	25.59	<.0001	0.05	2.4102	2.8149
trtseq	Q600MG	2.4574	0.1028	108	23.90	<.0001	0.05	2.2535	2.6612
trtseq	P	3.1324	0.1027	103	30.51	<.0001	0.05	2.9288	3.3360

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.1552	0.1198	490	1.30	0.1958	0.05	-0.08019	0.3906
trtseq	Q300MG	P	-0.5198	0.1210	501	-4.29	<.0001	0.05	-0.7577	-0.2820
trtseq	Q600MG	P	-0.6750	0.1219	503	-5.54	<.0001	0.05	-0.9144	-0.4356

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1653.07964058	
1	3	1642.99393351	0.00000172
2	1	1642.99331528	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.08476
Residual	1.3789

Fit Statistics

-2 Res Log Likelihood	1643.0
AIC (smaller is better)	1647.0
AICC (smaller is better)	1647.0
BIC (smaller is better)	1650.1

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			2.1569	0.4619	300	4.67	<.0001
trtseq		Q300MG	-0.6529	0.1292	502	-5.05	<.0001
trtseq		Q600MG	-0.5192	0.1300	503	-3.99	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.06521	0.1210	421	-0.54	0.5903
numcd	2		0	.	.	.	.
B_ILLSEV			0.2134	0.1009	334	2.11	0.0352

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1187	0.2681	10.2	-0.44	0.6674
CENTRE	0002	0.2796	0.2315	18	1.21	0.2429
CENTRE	0003	-0.07636	0.2274	19.2	-0.34	0.7407
CENTRE	0004	-0.4224	0.2204	21.6	-1.92	0.0687
CENTRE	0005	-0.1096	0.1834	39.8	-0.60	0.5535
CENTRE	0006	0.1369	0.2503	13.3	0.55	0.5935
CENTRE	0007	0.03932	0.2273	19.3	0.17	0.8644
CENTRE	0009	0.1048	0.2316	17.9	0.45	0.6563
CENTRE	0010	-0.03675	0.2125	24.5	-0.17	0.8641
CENTRE	0011	0.2390	0.2154	23.3	1.11	0.2786
CENTRE	0013	0.1791	0.2314	18	0.77	0.4490
CENTRE	0014	-0.1708	0.2142	23.9	-0.80	0.4331
CENTRE	0015	0.05300	0.2567	12	0.21	0.8399
CENTRE	0016	-0.09195	0.2615	11.2	-0.35	0.7316
CENTRE	0018	0.06082	0.2279	19	0.27	0.7925
CENTRE	0019	0.07710	0.1778	43.3	0.43	0.6666
CENTRE	0020	-0.1645	0.2138	24.1	-0.77	0.4490
CENTRE	0022	-0.1466	0.1559	59.2	-0.94	0.3510
CENTRE	0023	0.2621	0.1754	44.7	1.49	0.1421
CENTRE	0025	0.01837	0.2750	9.18	0.07	0.9482
CENTRE	0026	-0.01279	0.1974	31.8	-0.06	0.9487
CENTRE	0027	-0.1615	0.2616	11.2	-0.62	0.5495
CENTRE	0028	0.2974	0.1895	35.8	1.57	0.1253
CENTRE	0029	0.2117	0.1980	31.4	1.07	0.2931
CENTRE	0030	-0.09799	0.2206	21.5	-0.44	0.6613
CENTRE	0031	-0.05285	0.1952	32.6	-0.27	0.7883
CENTRE	0033	0.1603	0.2244	20.2	0.71	0.4831
CENTRE	0034	-0.1973	0.2452	14.4	-0.80	0.4340
CENTRE	0035	0.08998	0.2070	26.8	0.43	0.6673
CENTRE	0036	-0.01040	0.2616	11.2	-0.04	0.9690
CENTRE	0037	0.1164	0.2403	15.6	0.48	0.6349
CENTRE	0039	-0.5689	0.1827	40.1	-3.11	0.0034
CENTRE	0040	0.03459	0.2751	9.17	0.13	0.9026
CENTRE	0041	0.07517	0.2323	17.7	0.32	0.7501
CENTRE	0042	0.003731	0.2749	9.19	0.01	0.9895

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	14.10	<.0001
numcd	1	421	0.29	0.5903
B_ILLSEV	1	334	4.47	0.0352

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	2.4223	0.1084	111	22.35	<.0001	0.05	2.2075	2.6371
trtseq	Q600MG	2.5560	0.1092	110	23.41	<.0001	0.05	2.3396	2.7724
trtseq	P	3.0752	0.1090	106	28.22	<.0001	0.05	2.8591	3.2913

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.1337	0.1279	491	-1.05	0.2962	0.05	-0.3850	0.1175
trtseq	Q300MG	P	-0.6529	0.1292	502	-5.05	<.0001	0.05	-0.9067	-0.3991
trtseq	Q600MG	P	-0.5192	0.1300	503	-3.99	<.0001	0.05	-0.7747	-0.2637

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1672.11638102	
1	3	1662.67492323	0.00001683
2	1	1662.66858615	0.00000003
3	1	1662.66857471	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.08115
Residual	1.4368

Fit Statistics

-2 Res Log Likelihood	1662.7
AIC (smaller is better)	1666.7
AICC (smaller is better)	1666.7
BIC (smaller is better)	1669.8

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			2.1066	0.4691	299	4.49	<.0001
trtseq		Q300MG	-0.7343	0.1318	502	-5.57	<.0001
trtseq		Q600MG	-0.5777	0.1326	504	-4.36	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.05260	0.1231	416	-0.43	0.6694
numcd	2		0	.	.	.	.
B_ILLSEV			0.2316	0.1026	330	2.26	0.0246

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.1087	0.2640	9.64	-0.41	0.6896
CENTRE	0002	0.2297	0.2299	16.5	1.00	0.3323
CENTRE	0003	0.07402	0.2261	17.6	0.33	0.7472
CENTRE	0004	-0.3683	0.2194	19.7	-1.68	0.1090
CENTRE	0005	-0.1277	0.1838	35.9	-0.69	0.4918
CENTRE	0006	0.1324	0.2475	12.4	0.53	0.6022
CENTRE	0007	0.1741	0.2259	17.7	0.77	0.4512
CENTRE	0009	0.1746	0.2300	16.5	0.76	0.4584
CENTRE	0010	-0.06381	0.2118	22.3	-0.30	0.7660
CENTRE	0011	0.1711	0.2146	21.2	0.80	0.4342
CENTRE	0013	0.2040	0.2298	16.5	0.89	0.3876
CENTRE	0014	-0.04988	0.2135	21.8	-0.23	0.8174
CENTRE	0015	0.04537	0.2535	11.3	0.18	0.8611
CENTRE	0016	-0.03505	0.2579	10.6	-0.14	0.8944
CENTRE	0018	0.06035	0.2265	17.4	0.27	0.7930
CENTRE	0019	0.07491	0.1783	39.2	0.42	0.6766
CENTRE	0020	-0.1226	0.2131	21.9	-0.58	0.5709
CENTRE	0022	-0.1948	0.1568	54.3	-1.24	0.2194
CENTRE	0023	0.1137	0.1759	40.5	0.65	0.5216
CENTRE	0025	0.01575	0.2703	8.78	0.06	0.9548
CENTRE	0026	-0.1575	0.1973	28.7	-0.80	0.4315
CENTRE	0027	-0.05299	0.2580	10.6	-0.21	0.8412
CENTRE	0028	0.2984	0.1897	32.4	1.57	0.1254
CENTRE	0029	0.02020	0.1979	28.4	0.10	0.9194
CENTRE	0030	-0.1579	0.2196	19.6	-0.72	0.4806
CENTRE	0031	0.07927	0.1952	29.5	0.41	0.6876
CENTRE	0033	0.1150	0.2232	18.5	0.52	0.6125
CENTRE	0034	-0.1415	0.2428	13.4	-0.58	0.5696
CENTRE	0035	-0.01900	0.2066	24.3	-0.09	0.9275
CENTRE	0036	0.03921	0.2580	10.6	0.15	0.8820
CENTRE	0037	0.07734	0.2381	14.4	0.32	0.7500
CENTRE	0039	-0.6314	0.1831	36.3	-3.45	0.0014
CENTRE	0040	0.03392	0.2703	8.77	0.13	0.9030
CENTRE	0041	0.1425	0.2307	16.3	0.62	0.5454
CENTRE	0042	-0.04468	0.2702	8.79	-0.17	0.8724

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	17.05	<.0001
numcd	1	416	0.18	0.6694
B_ILLSEV	1	330	5.10	0.0246

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	2.3779	0.1095	118	21.71	<.0001	0.05	2.1611	2.5948
trtseq	Q600MG	2.5346	0.1103	117	22.98	<.0001	0.05	2.3161	2.7531
trtseq	P	3.1123	0.1101	113	28.27	<.0001	0.05	2.8942	3.3303

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.1567	0.1305	492	-1.20	0.2306	0.05	-0.4131	0.09976
trtseq	Q300MG	P	-0.7343	0.1318	502	-5.57	<.0001	0.05	-0.9932	-0.4754
trtseq	Q600MG	P	-0.5777	0.1326	504	-4.36	<.0001	0.05	-0.8383	-0.3171

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1691.88293207	
1	3	1683.26767801	0.00010890
2	1	1683.22395092	0.00000126
3	1	1683.22347209	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.07639
Residual	1.5003

Fit Statistics

-2 Res Log Likelihood	1683.2
AIC (smaller is better)	1687.2
AICC (smaller is better)	1687.2
BIC (smaller is better)	1690.3

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			2.4878	0.4763	295	5.22	<.0001
trtseq		Q300MG	-0.8202	0.1345	503	-6.10	<.0001
trtseq		Q600MG	-0.6560	0.1354	504	-4.84	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.06914	0.1253	409	-0.55	0.5813
numcd	2		0	.	.	.	.
B_ILLSEV			0.1523	0.1042	323	1.46	0.1449

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.04942	0.2579	8.92	-0.19	0.8523
CENTRE	0002	0.1251	0.2269	14.7	0.55	0.5899
CENTRE	0003	-0.1025	0.2234	15.6	-0.46	0.6527
CENTRE	0004	-0.3589	0.2172	17.4	-1.65	0.1164
CENTRE	0005	-0.03675	0.1834	31.2	-0.20	0.8425
CENTRE	0006	0.06703	0.2431	11.3	0.28	0.7877
CENTRE	0007	0.2022	0.2232	15.7	0.91	0.3787
CENTRE	0009	0.03571	0.2270	14.7	0.16	0.8772
CENTRE	0010	-0.07295	0.2101	19.6	-0.35	0.7321
CENTRE	0011	0.2109	0.2127	18.7	0.99	0.3340
CENTRE	0013	0.1284	0.2269	14.7	0.57	0.5800
CENTRE	0014	-0.05872	0.2116	19.1	-0.28	0.7844
CENTRE	0015	0.02586	0.2484	10.3	0.10	0.9191
CENTRE	0016	-0.01958	0.2524	9.72	-0.08	0.9397
CENTRE	0018	-0.01261	0.2238	15.5	-0.06	0.9558
CENTRE	0019	0.1828	0.1781	34.1	1.03	0.3118
CENTRE	0020	-0.09704	0.2113	19.2	-0.46	0.6511
CENTRE	0022	-0.2268	0.1572	47.9	-1.44	0.1556
CENTRE	0023	0.1706	0.1758	35.3	0.97	0.3384
CENTRE	0025	0.02127	0.2635	8.19	0.08	0.9376
CENTRE	0026	-0.00069	0.1964	25	-0.00	0.9972
CENTRE	0027	-0.07710	0.2526	9.69	-0.31	0.7666
CENTRE	0028	0.2559	0.1890	28.2	1.35	0.1866
CENTRE	0029	0.1632	0.1969	24.7	0.83	0.4152
CENTRE	0030	-0.1227	0.2173	17.3	-0.56	0.5795
CENTRE	0031	-0.01900	0.1943	25.7	-0.10	0.9229
CENTRE	0033	0.1438	0.2207	16.4	0.65	0.5236
CENTRE	0034	-0.1053	0.2387	12.1	-0.44	0.6669
CENTRE	0035	-0.05231	0.2051	21.3	-0.26	0.8011
CENTRE	0036	0.09393	0.2525	9.7	0.37	0.7179
CENTRE	0037	0.03866	0.2345	13	0.16	0.8716
CENTRE	0039	-0.5939	0.1828	31.6	-3.25	0.0027
CENTRE	0040	-0.01726	0.2636	8.18	-0.07	0.9494
CENTRE	0041	0.1919	0.2276	14.5	0.84	0.4128
CENTRE	0042	-0.03380	0.2634	8.19	-0.13	0.9010

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	499	20.59	<.0001
numcd	1	409	0.30	0.5813
B_ILLSEV	1	323	2.14	0.1449

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	2.3115	0.1106	126	20.90	<.0001	0.05	2.0926	2.5304
trtseq	Q600MG	2.4757	0.1114	125	22.23	<.0001	0.05	2.2553	2.6962
trtseq	P	3.1317	0.1111	121	28.18	<.0001	0.05	2.9117	3.3517

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.1642	0.1333	493	-1.23	0.2186	0.05	-0.4261	0.09772
trtseq	Q300MG	P	-0.8202	0.1345	503	-6.10	<.0001	0.05	-1.0846	-0.5559
trtseq	Q600MG	P	-0.6560	0.1354	504	-4.84	<.0001	0.05	-0.9221	-0.3900

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Model Information

Data Set	WORK.CGICVSTXBL
Dependent Variable	L_GIMPRO
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	511
Observations Used	511
Observations Not Used	0
Total Observations	511

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1694.75266510	
1	3	1684.81648244	0.00003442
2	1	1684.80297921	0.00000013
3	1	1684.80292928	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.08605
Residual	1.5004

Fit Statistics

-2 Res Log Likelihood	1684.8
AIC (smaller is better)	1688.8
AICC (smaller is better)	1688.8
BIC (smaller is better)	1691.9

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			2.0816	0.4798	303	4.34	<.0001
trtseq		Q300MG	-0.7081	0.1347	502	-5.26	<.0001
trtseq		Q600MG	-0.6032	0.1356	504	-4.45	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.001154	0.1259	419	0.01	0.9927
numcd	2		0	.	.	.	.
B_ILLSEV			0.2002	0.1049	334	1.91	0.0572

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.08496	0.2715	10	-0.31	0.7608
CENTRE	0002	-0.02177	0.2361	17.3	-0.09	0.9276
CENTRE	0003	0.05394	0.2321	18.4	0.23	0.8188
CENTRE	0004	-0.4218	0.2252	20.6	-1.87	0.0754
CENTRE	0005	-0.06049	0.1885	37.7	-0.32	0.7500
CENTRE	0006	0.03992	0.2544	13	0.16	0.8777
CENTRE	0007	0.2290	0.2320	18.5	0.99	0.3364
CENTRE	0009	0.1569	0.2362	17.3	0.66	0.5153
CENTRE	0010	-0.02908	0.2174	23.4	-0.13	0.8947
CENTRE	0011	-0.04608	0.2203	22.2	-0.21	0.8362
CENTRE	0013	0.2111	0.2361	17.3	0.89	0.3835
CENTRE	0014	-0.1425	0.2191	22.8	-0.65	0.5219
CENTRE	0015	-0.00456	0.2606	11.8	-0.02	0.9863
CENTRE	0016	-0.01455	0.2652	11	-0.05	0.9572
CENTRE	0018	0.07440	0.2326	18.3	0.32	0.7527
CENTRE	0019	0.2703	0.1828	41	1.48	0.1467
CENTRE	0020	-0.1015	0.2187	22.9	-0.46	0.6469
CENTRE	0022	-0.1260	0.1607	56.7	-0.78	0.4362
CENTRE	0023	0.1695	0.1804	42.4	0.94	0.3525
CENTRE	0025	0.02782	0.2781	9.12	0.10	0.9225
CENTRE	0026	-0.03508	0.2024	30.1	-0.17	0.8636
CENTRE	0027	-0.07038	0.2653	11	-0.27	0.7957
CENTRE	0028	0.3372	0.1945	34	1.73	0.0921
CENTRE	0029	0.1513	0.2030	29.8	0.75	0.4621
CENTRE	0030	-0.1753	0.2254	20.6	-0.78	0.4457
CENTRE	0031	-0.01559	0.2002	30.9	-0.08	0.9385
CENTRE	0033	0.1371	0.2291	19.3	0.60	0.5565
CENTRE	0034	-0.1451	0.2495	14	-0.58	0.5701
CENTRE	0035	-0.02057	0.2120	25.5	-0.10	0.9235
CENTRE	0036	0.01786	0.2653	11	0.07	0.9475
CENTRE	0037	0.07343	0.2447	15.1	0.30	0.7682
CENTRE	0039	-0.6312	0.1878	38	-3.36	0.0018
CENTRE	0040	0.09998	0.2782	9.11	0.36	0.7274
CENTRE	0041	0.1819	0.2369	17	0.77	0.4533
CENTRE	0042	-0.08520	0.2780	9.13	-0.31	0.7661

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	498	15.91	<.0001
numcd	1	419	0.00	0.9927
B_ILLSEV	1	334	3.64	0.0572

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	2.2661	0.1121	119	20.21	<.0001	0.05	2.0441	2.4881
trtseq	Q600MG	2.3711	0.1129	119	21.00	<.0001	0.05	2.1474	2.5947
trtseq	P	2.9742	0.1127	114	26.39	<.0001	0.05	2.7510	3.1975

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.1049	0.1334	492	-0.79	0.4317	0.05	-0.3670	0.1571
trtseq	Q300MG	P	-0.7081	0.1347	502	-5.26	<.0001	0.05	-0.9727	-0.4435
trtseq	Q600MG	P	-0.6032	0.1356	504	-4.45	<.0001	0.05	-0.8695	-0.3368

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
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12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

WINDOWED VISIT=3

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	171	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	171	0	3.20	0.86
		B_ILLSEV	BL SEVERITY OF ILLNESS	171	0	4.43	0.52
Q600MG	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.15	0.82
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.51	0.62
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.57	0.81
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=4

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	172	0	2.84	0.96
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	170	0	2.78	0.97
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.30	0.98
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=5

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	172	0	2.65	1.03
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	170	0	2.61	1.11
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

WINDOWED VISIT=5

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.18	1.11
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=6

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	172	0	2.59	1.04
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	170	0	2.42	1.19
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.09	1.18
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=7

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	172	0	2.41	1.10
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	170	0	2.54	1.30
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.06	1.24
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

WINDOWED VISIT=8

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	172	0	2.34	1.11
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	170	0	2.50	1.30
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.08	1.30
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=9

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	172	0	2.28	1.14
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	170	0	2.45	1.28
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	3.11	1.35
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

WINDOWED VISIT=10

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	172	0	2.26	1.17
		B_ILLSEV	BL SEVERITY OF ILLNESS	172	0	4.44	0.52
Q600MG	170	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	170	0	2.38	1.29
		B_ILLSEV	BL SEVERITY OF ILLNESS	170	0	4.51	0.62

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.1 CGI Improvement Score (ANCOVA - LOCF- ITT)

WINDOWED VISIT=10

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	169	L_GIMPRO	GLOBAL IMPROVEMENT - LOCF	169	0	2.96	1.33
		B_ILLSEV	BL SEVERITY OF ILLNESS	169	0	4.42	0.60

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI220H.SAS
GENERATED: 14JUL2005 11:41:52 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 8

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency / Percent / Row Pct / Col Pct	0	1	Total
Q300MG	139	32	171
	40.88	9.41	50.29
	81.29	18.71	
	47.77	65.31	
P	152	17	169
	44.71	5.00	49.71
	89.94	10.06	
	52.23	34.69	
Total	291	49	340
	85.59	14.41	100.00

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 15

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	112 32.84 65.12 44.98	60 17.60 34.88 65.22	172 50.44
P	137 40.18 81.07 55.02	32 9.38 18.93 34.78	169 49.56
Total	249 73.02	92 26.98	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 22

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency / Percent / Row Pct / Col Pct	0	1	Total
Q300MG	92	80	172
	26.98	23.46	50.44
	53.49	46.51	
	42.01	65.57	
P	127	42	169
	37.24	12.32	49.56
	75.15	24.85	
	57.99	34.43	
Total	219	122	341
	64.22	35.78	100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 29

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	84 24.63 48.84 42.00	88 25.81 51.16 62.41	172 50.44
P	116 34.02 68.64 58.00	53 15.54 31.36 37.59	169 49.56
Total	200 58.65	141 41.35	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 36 ----------

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	74 21.70 43.02 39.78	98 28.74 56.98 63.23	172 50.44
P	112 32.84 66.27 60.22	57 16.72 33.73 36.77	169 49.56
Total	186 54.55	155 45.45	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 43

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	69 20.23 40.12 37.70	103 30.21 59.88 65.19	172 50.44
P	114 33.43 67.46 62.30	55 16.13 32.54 34.81	169 49.56
Total	183 53.67	158 46.33	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 50

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	65 19.06 37.79 36.11	107 31.38 62.21 66.46	172 50.44
P	115 33.72 68.05 63.89	54 15.84 31.95 33.54	169 49.56
Total	180 52.79	161 47.21	341 100.00

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 57

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	62 18.18 36.05 35.84	110 32.26 63.95 65.48	172 50.44
P	111 32.55 65.68 64.16	58 17.01 34.32 34.52	169 49.56
Total	173 50.73	168 49.27	341 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 8

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	132 39.05 78.11 46.48	37 10.95 21.89 68.52	169 50.00
P	152 44.97 89.94 53.52	17 5.03 10.06 31.48	169 50.00
Total	284 84.02	54 15.98	338 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 15

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	102 30.09 60.00 42.68	68 20.06 40.00 68.00	170 50.15
P	137 40.41 81.07 57.32	32 9.44 18.93 32.00	169 49.85
Total	239 70.50	100 29.50	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 22

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	91 26.84 53.53 41.74	79 23.30 46.47 65.29	170 50.15
P	127 37.46 75.15 58.26	42 12.39 24.85 34.71	169 49.85
Total	218 64.31	121 35.69	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 29

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	78 23.01 45.88 40.21	92 27.14 54.12 63.45	170 50.15
P	116 34.22 68.64 59.79	53 15.63 31.36 36.55	169 49.85
Total	194 57.23	145 42.77	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 36

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	82 24.19 48.24 42.27	88 25.96 51.76 60.69	170 50.15
P	112 33.04 66.27 57.73	57 16.81 33.73 39.31	169 49.85
Total	194 57.23	145 42.77	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 43 ----------

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim	
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	79 23.30 46.47 40.93	91 26.84 53.53 62.33	170 50.15
P	114 33.63 67.46 59.07	55 16.22 32.54 37.67	169 49.85
Total	193 56.93	146 43.07	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 50

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	81 23.89 47.65 41.33	89 26.25 52.35 62.24	170 50.15
P	115 33.92 68.05 58.67	54 15.93 31.95 37.76	169 49.85
Total	196 57.82	143 42.18	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 57

The FREQ Procedure

Table of trtseq by responsegim

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	75 22.12 44.12 40.32	95 28.02 55.88 62.09	170 50.15
P	111 32.74 65.68 59.68	58 17.11 34.32 37.91	169 49.85
Total	186 54.87	153 45.13	339 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 8 ----------

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	92 40.53 80.00 47.42	23 10.13 20.00 69.70	115 50.66
P	102 44.93 91.07 52.58	10 4.41 8.93 30.30	112 49.34
Total	194 85.46	33 14.54	227 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 8

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	5.5980	0.0180
Likelihood Ratio Chi-Square	1	5.7387	0.0166
Continuity Adj. Chi-Square	1	4.7423	0.0294
Mantel-Haenszel Chi-Square	1	5.5733	0.0182
Phi Coefficient		-0.1570	
Contingency Coefficient		0.1551	
Cramer's V		-0.1570	

Fisher's Exact Test

Cell (1,1) Frequency (F)	92
Left-sided Pr <= F	0.0141
Right-sided Pr >= F	0.9951
Table Probability (P)	0.0092
Two-sided Pr <= P	0.0232

Sample Size = 227

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 8

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	47 41.59 83.93 48.45	9 7.96 16.07 56.25	56 49.56
P	50 44.25 87.72 51.55	7 6.19 12.28 43.75	57 50.44
Total	97 85.84	16 14.16	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 8 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.3340	0.5633
Likelihood Ratio Chi-Square	1	0.3346	0.5630
Continuity Adj. Chi-Square	1	0.0949	0.7580
Mantel-Haenszel Chi-Square	1	0.3310	0.5651
Phi Coefficient		-0.0544	
Contingency Coefficient		0.0543	
Cramer's V		-0.0544	

Fisher's Exact Test

Cell (1,1) Frequency (F)	47
Left-sided Pr <= F	0.3793
Right-sided Pr >= F	0.8014
Table Probability (P)	0.1807
Two-sided Pr <= P	0.6001

Sample Size = 113

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 8 ----------

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	5.1270	0.0236
2	Row Mean Scores Differ	1	5.1270	0.0236
3	General Association	1	5.1270	0.0236

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4864	0.2588	0.9144
	Logit	0.4899	0.2592	0.9260
Cohort (Col1 Risk)	Mantel-Haenszel	0.9038	0.8278	0.9868
	Logit	0.9045	0.8284	0.9875
Cohort (Col2 Risk)	Mantel-Haenszel	1.8615	1.0740	3.2263
	Logit	1.8406	1.0578	3.2027

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	0.8510
DF	1
Pr > ChiSq	0.3563

Total Sample Size = 340

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 15 ----------

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	72 31.58 62.07 43.90	44 19.30 37.93 68.75	116 50.88
P	92 40.35 82.14 56.10	20 8.77 17.86 31.25	112 49.12
Total	164 71.93	64 28.07	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	11.3723	0.0007
Likelihood Ratio Chi-Square	1	11.5987	0.0007
Continuity Adj. Chi-Square	1	10.3999	0.0013
Mantel-Haenszel Chi-Square	1	11.3225	0.0008
Phi Coefficient		-0.2233	
Contingency Coefficient		0.2180	
Cramer's V		-0.2233	

Fisher's Exact Test

Cell (1,1) Frequency (F)	72
Left-sided Pr <= F	5.745E-04
Right-sided Pr >= F	0.9998
Table Probability (P)	3.851E-04
Two-sided Pr <= P	0.0011

Sample Size = 228

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 15

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	40 35.40 71.43 47.06	16 14.16 28.57 57.14	56 49.56
P	45 39.82 78.95 52.94	12 10.62 21.05 42.86	57 50.44
Total	85 75.22	28 24.78	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 15 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.8568	0.3546
Likelihood Ratio Chi-Square	1	0.8588	0.3541
Continuity Adj. Chi-Square	1	0.5009	0.4791
Mantel-Haenszel Chi-Square	1	0.8492	0.3568
Phi Coefficient		-0.0871	
Contingency Coefficient		0.0867	
Cramer's V		-0.0871	

Fisher's Exact Test

Cell (1,1) Frequency (F)	40
Left-sided Pr <= F	0.2397
Right-sided Pr >= F	0.8737
Table Probability (P)	0.1134
Two-sided Pr <= P	0.3899

Sample Size = 113

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 15 ----------

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	10.9047	0.0010
2	Row Mean Scores Differ	1	10.9047	0.0010
3	General Association	1	10.9047	0.0010

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4378	0.2668	0.7187
	Logit	0.4392	0.2667	0.7233
Cohort (Col1 Risk)	Mantel-Haenszel	0.8037	0.7048	0.9166
	Logit	0.8090	0.7095	0.9224
Cohort (Col2 Risk)	Mantel-Haenszel	1.8412	1.2666	2.6766
	Logit	1.8296	1.2563	2.6646

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	1.3651
DF	1
Pr > ChiSq	0.2427

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 22 ----------

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	58 25.44 50.00 39.73	58 25.44 50.00 70.73	116 50.88
P	88 38.60 78.57 60.27	24 10.53 21.43 29.27	112 49.12
Total	146 64.04	82 35.96	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 22 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	20.1980	<.0001
Likelihood Ratio Chi-Square	1	20.6705	<.0001
Continuity Adj. Chi-Square	1	18.9764	<.0001
Mantel-Haenszel Chi-Square	1	20.1094	<.0001
Phi Coefficient		-0.2976	
Contingency Coefficient		0.2853	
Cramer's V		-0.2976	

Fisher's Exact Test

Cell (1,1) Frequency (F)	58
Left-sided Pr <= F	5.383E-06
Right-sided Pr >= F	1.0000
Table Probability (P)	3.995E-06
Two-sided Pr <= P	8.525E-06

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 22

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	34 30.09 60.71 46.58	22 19.47 39.29 55.00	56 49.56
P	39 34.51 68.42 53.42	18 15.93 31.58 45.00	57 50.44
Total	73 64.60	40 35.40	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
GENERATED: 14JUL2005 11:41:54 iceadmn3

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 22

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.7337	0.3917
Likelihood Ratio Chi-Square	1	0.7346	0.3914
Continuity Adj. Chi-Square	1	0.4354	0.5094
Mantel-Haenszel Chi-Square	1	0.7272	0.3938
Phi Coefficient		-0.0806	
Contingency Coefficient		0.0803	
Cramer's V		-0.0806	

Fisher's Exact Test

Cell (1,1) Frequency (F)	34
Left-sided Pr <= F	0.2548
Right-sided Pr >= F	0.8539
Table Probability (P)	0.1087
Two-sided Pr <= P	0.4352

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 22 ----------

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	17.2952	<.0001
2	Row Mean Scores Differ	1	17.2952	<.0001
3	General Association	1	17.2952	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3843	0.2432	0.6073
	Logit	0.3852	0.2422	0.6128
Cohort (Col1 Risk)	Mantel-Haenszel	0.7120	0.6040	0.8394
	Logit	0.7173	0.6083	0.8458
Cohort (Col2 Risk)	Mantel-Haenszel	1.8735	1.3746	2.5535
	Logit	1.8297	1.3390	2.5000

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	3.8250
DF	1
Pr > ChiSq	0.0505

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 29

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	54 23.68 46.55 40.60	62 27.19 53.45 65.26	116 50.88
P	79 34.65 70.54 59.40	33 14.47 29.46 34.74	112 49.12
Total	133 58.33	95 41.67	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 29

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	13.4859	0.0002
Likelihood Ratio Chi-Square	1	13.6527	0.0002
Continuity Adj. Chi-Square	1	12.5171	0.0004
Mantel-Haenszel Chi-Square	1	13.4267	0.0002
Phi Coefficient		-0.2432	
Contingency Coefficient		0.2363	
Cramer's V		-0.2432	

Fisher's Exact Test

Cell (1,1) Frequency (F)	54
Left-sided Pr <= F	1.879E-04
Right-sided Pr >= F	0.9999
Table Probability (P)	1.238E-04
Two-sided Pr <= P	2.816E-04

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 29 ----------

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	30 26.55 53.57 44.78	26 23.01 46.43 56.52	56 49.56
P	37 32.74 64.91 55.22	20 17.70 35.09 43.48	57 50.44
Total	67 59.29	46 40.71	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 29 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.5052	0.2199
Likelihood Ratio Chi-Square	1	1.5087	0.2193
Continuity Adj. Chi-Square	1	1.0720	0.3005
Mantel-Haenszel Chi-Square	1	1.4919	0.2219
Phi Coefficient		-0.1154	
Contingency Coefficient		0.1147	
Cramer's V		-0.1154	

Fisher's Exact Test

Cell (1,1) Frequency (F)	30
Left-sided Pr <= F	0.1502
Right-sided Pr >= F	0.9221
Table Probability (P)	0.0724
Two-sided Pr <= P	0.2535

Sample Size = 113

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 29 ----------

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	13.6896	0.0002
2	Row Mean Scores Differ	1	13.6896	0.0002
3	General Association	1	13.6896	0.0002

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.4376	0.2816	0.6800
	Logit	0.4376	0.2811	0.6813
Cohort (Col1 Risk)	Mantel-Haenszel	0.7118	0.5922	0.8554
	Logit	0.7142	0.5941	0.8585
Cohort (Col2 Risk)	Mantel-Haenszel	1.6318	1.2489	2.1322
	Logit	1.6231	1.2415	2.1220

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	1.2859
DF	1
Pr > ChiSq	0.2568

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 36

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	45 19.74 38.79 36.00	71 31.14 61.21 68.93	116 50.88
P	80 35.09 71.43 64.00	32 14.04 28.57 31.07	112 49.12
Total	125 54.82	103 45.18	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 36

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	24.5044	<.0001
Likelihood Ratio Chi-Square	1	25.0039	<.0001
Continuity Adj. Chi-Square	1	23.2044	<.0001
Mantel-Haenszel Chi-Square	1	24.3969	<.0001
Phi Coefficient		-0.3278	
Contingency Coefficient		0.3115	
Cramer's V		-0.3278	

Fisher's Exact Test

Cell (1,1) Frequency (F)	45
Left-sided Pr <= F	5.832E-07
Right-sided Pr >= F	1.0000
Table Probability (P)	4.426E-07
Two-sided Pr <= P	7.736E-07

Sample Size = 228

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 36 ----------

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	29 25.66 51.79 47.54	27 23.89 48.21 51.92	56 49.56
P	32 28.32 56.14 52.46	25 22.12 43.86 48.08	57 50.44
Total	61 53.98	52 46.02	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 36 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.2156	0.6424
Likelihood Ratio Chi-Square	1	0.2157	0.6423
Continuity Adj. Chi-Square	1	0.0760	0.7828
Mantel-Haenszel Chi-Square	1	0.2137	0.6439
Phi Coefficient		-0.0437	
Contingency Coefficient		0.0436	
Cramer's V		-0.0437	

Fisher's Exact Test

Cell (1,1) Frequency (F)	29
Left-sided Pr <= F	0.3915
Right-sided Pr >= F	0.7431
Table Probability (P)	0.1346
Two-sided Pr <= P	0.7074

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 36

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	18.4942	<.0001
2	Row Mean Scores Differ	1	18.4942	<.0001
3	General Association	1	18.4942	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3910	0.2530	0.6044
	Logit	0.3897	0.2500	0.6075
Cohort (Col1 Risk)	Mantel-Haenszel	0.6495	0.5297	0.7964
	Logit	0.6577	0.5357	0.8076
Cohort (Col2 Risk)	Mantel-Haenszel	1.6915	1.3161	2.1742
	Logit	1.6402	1.2735	2.1124

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	6.4900
DF	1
Pr > ChiSq	0.0108

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 43 ----------

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	41 17.98 35.34 33.88	75 32.89 64.66 70.09	116 50.88
P	80 35.09 71.43 66.12	32 14.04 28.57 29.91	112 49.12
Total	121 53.07	107 46.93	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 43

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	29.7896	<.0001
Likelihood Ratio Chi-Square	1	30.5057	<.0001
Continuity Adj. Chi-Square	1	28.3584	<.0001
Mantel-Haenszel Chi-Square	1	29.6590	<.0001
Phi Coefficient		-0.3615	
Contingency Coefficient		0.3399	
Cramer's V		-0.3615	

Fisher's Exact Test

Cell (1,1) Frequency (F)	41
Left-sided Pr <= F	3.652E-08
Right-sided Pr >= F	1.0000
Table Probability (P)	2.889E-08
Two-sided Pr <= P	4.599E-08

Sample Size = 228

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 43 ----------

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	28 24.78 50.00 45.16	28 24.78 50.00 54.90	56 49.56
P	34 30.09 59.65 54.84	23 20.35 40.35 45.10	57 50.44
Total	62 54.87	51 45.13	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 43

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.0621	0.3027
Likelihood Ratio Chi-Square	1	1.0637	0.3024
Continuity Adj. Chi-Square	1	0.7082	0.4001
Mantel-Haenszel Chi-Square	1	1.0527	0.3049
Phi Coefficient		-0.0969	
Contingency Coefficient		0.0965	
Cramer's V		-0.0969	

Fisher's Exact Test

Cell (1,1) Frequency (F)	28
Left-sided Pr <= F	0.2001
Right-sided Pr >= F	0.8888
Table Probability (P)	0.0889
Two-sided Pr <= P	0.3472

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 43 ----------

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	25.4453	<.0001
2	Row Mean Scores Differ	1	25.4453	<.0001
3	General Association	1	25.4453	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3297	0.2124	0.5118
	Logit	0.3287	0.2101	0.5140
Cohort (Col1 Risk)	Mantel-Haenszel	0.5954	0.4819	0.7355
	Logit	0.6091	0.4927	0.7531
Cohort (Col2 Risk)	Mantel-Haenszel	1.8413	1.4316	2.3683
	Logit	1.7982	1.3957	2.3168

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	5.6963
DF	1
Pr > ChiSq	0.0170

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 50 ----------

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	41 17.98 35.34 34.45	75 32.89 64.66 68.81	116 50.88
P	78 34.21 69.64 65.55	34 14.91 30.36 31.19	112 49.12
Total	119 52.19	109 47.81	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 50

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	26.8643	<.0001
Likelihood Ratio Chi-Square	1	27.4349	<.0001
Continuity Adj. Chi-Square	1	25.5073	<.0001
Mantel-Haenszel Chi-Square	1	26.7465	<.0001
Phi Coefficient		-0.3433	
Contingency Coefficient		0.3247	
Cramer's V		-0.3433	

Fisher's Exact Test

Cell (1,1) Frequency (F)	41
Left-sided Pr <= F	1.707E-07
Right-sided Pr >= F	1.0000
Table Probability (P)	1.319E-07
Two-sided Pr <= P	2.155E-07

Sample Size = 228

12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 50 ----------

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	24 21.24 42.86 39.34	32 28.32 57.14 61.54	56 49.56
P	37 32.74 64.91 60.66	20 17.70 35.09 38.46	57 50.44
Total	61 53.98	52 46.02	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 50 ----------

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	5.5313	0.0187
Likelihood Ratio Chi-Square	1	5.5774	0.0182
Continuity Adj. Chi-Square	1	4.6791	0.0305
Mantel-Haenszel Chi-Square	1	5.4824	0.0192
Phi Coefficient		-0.2212	
Contingency Coefficient		0.2160	
Cramer's V		-0.2212	

Fisher's Exact Test

Cell (1,1) Frequency (F)	24
Left-sided Pr <= F	0.0150
Right-sided Pr >= F	0.9946
Table Probability (P)	0.0097
Two-sided Pr <= P	0.0238

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 50 ----------

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	31.0991	<.0001
2	Row Mean Scores Differ	1	31.0991	<.0001
3	General Association	1	31.0991	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.2867	0.1836	0.4479
	Logit	0.2867	0.1832	0.4485
Cohort (Col1 Risk)	Mantel-Haenszel	0.5558	0.4470	0.6910
	Logit	0.5596	0.4500	0.6958
Cohort (Col2 Risk)	Mantel-Haenszel	1.9472	1.5170	2.4995
	Logit	1.9365	1.5082	2.4863

Breslow-Day Test for
Homogeneity of the Odds Ratios

Chi-Square	1.2307
DF	1
Pr > ChiSq	0.2673

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 57

The FREQ Procedure

Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	34 14.91 29.31 30.09	82 35.96 70.69 71.30	116 50.88
P	79 34.65 70.54 69.91	33 14.47 29.46 28.70	112 49.12
Total	113 49.56	115 50.44	228 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

---------- visit=DAY 57 ----------

The FREQ Procedure

Statistics for Table 1 of trtseq by responsegim
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	38.7404	<.0001
Likelihood Ratio Chi-Square	1	39.9176	<.0001
Continuity Adj. Chi-Square	1	37.1088	<.0001
Mantel-Haenszel Chi-Square	1	38.5704	<.0001
Phi Coefficient		-0.4122	
Contingency Coefficient		0.3811	
Cramer's V		-0.4122	

Fisher's Exact Test

Cell (1,1) Frequency (F)	34
Left-sided Pr <= F	3.266E-10
Right-sided Pr >= F	1.0000
Table Probability (P)	2.723E-10
Two-sided Pr <= P	6.421E-10

Sample Size = 228

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 57

The FREQ Procedure

Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

trtseq	responsegim		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	28 24.78 50.00 46.67	28 24.78 50.00 52.83	56 49.56
P	32 28.32 56.14 53.33	25 22.12 43.86 47.17	57 50.44
Total	60 53.10	53 46.90	113 100.00

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 57

The FREQ Procedure

Statistics for Table 2 of trtseq by responsegim
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	0.4277	0.5131
Likelihood Ratio Chi-Square	1	0.4279	0.5130
Continuity Adj. Chi-Square	1	0.2166	0.6416
Mantel-Haenszel Chi-Square	1	0.4239	0.5150
Phi Coefficient		-0.0615	
Contingency Coefficient		0.0614	
Cramer's V		-0.0615	

Fisher's Exact Test

Cell (1,1) Frequency (F)	28
Left-sided Pr <= F	0.3209
Right-sided Pr >= F	0.8002
Table Probability (P)	0.1211
Two-sided Pr <= P	0.5738

Sample Size = 113

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.4.2 CGI Improvement (CMH - LOCF - ITT)

visit=DAY 57

The FREQ Procedure

Summary Statistics for trtseq by responsegim
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	29.7286	<.0001
2	Row Mean Scores Differ	1	29.7286	<.0001
3	General Association	1	29.7286	<.0001

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	0.3059	0.1972	0.4743
	Logit	0.3034	0.1931	0.4766
Cohort (Col1 Risk)	Mantel-Haenszel	0.5500	0.4375	0.6913
	Logit	0.5799	0.4607	0.7301
Cohort (Col2 Risk)	Mantel-Haenszel	1.8645	1.4658	2.3718
	Logit	1.8052	1.4153	2.3025

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	10.1286
DF	1
Pr > ChiSq	0.0015

Total Sample Size = 341

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CGI222H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	508
Observations Used	508
Observations Not Used	0
Total Observations	508

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3051.81551387	
1	3	3033.22778549	0.00027173
2	1	3032.90035354	0.00001824
3	1	3032.88022738	0.00000010
4	1	3032.88012016	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	1.8374
Residual	21.8539

Fit Statistics

-2 Res Log Likelihood	3032.9
AIC (smaller is better)	3036.9
AICC (smaller is better)	3036.9
BIC (smaller is better)	3040.0

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.2484	0.8712	278	4.88	<.0001
trtseq		Q300MG	-1.8550	0.5170	497	-3.59	0.0004
trtseq		Q600MG	-1.1256	0.5200	499	-2.16	0.0309
trtseq		P	0	.	.	.	.
numcd	1		0.2119	0.4871	454	0.44	0.6637
numcd	2		0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
B_HAMA			-0.3767	0.03452	349	-10.91	<.0001

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.6841	1.2154	15.9	-0.56	0.5814
CENTRE	0002	0.09645	1.0140	31.6	0.10	0.9248
CENTRE	0003	-1.1586	0.9930	34.1	-1.17	0.2514
CENTRE	0004	-0.3838	0.9583	38.6	-0.40	0.6910
CENTRE	0005	0.1327	0.7689	73.5	0.17	0.8635
CENTRE	0006	0.4121	1.1123	22.5	0.37	0.7145
CENTRE	0007	0.09676	0.9960	33.6	0.10	0.9232
CENTRE	0009	-0.6603	1.0140	31.6	-0.65	0.5197
CENTRE	0010	-0.1379	0.9136	45.2	-0.15	0.8807
CENTRE	0011	0.5671	0.9265	43.1	0.61	0.5437
CENTRE	0013	-0.01470	1.0126	31.8	-0.01	0.9885
CENTRE	0014	-0.5367	0.9278	43	-0.58	0.5659
CENTRE	0015	0.6238	1.1420	20.3	0.55	0.5908
CENTRE	0016	-1.0981	1.1781	18	-0.93	0.3636
CENTRE	0018	-0.6704	0.9931	34.1	-0.68	0.5042
CENTRE	0019	-1.1356	0.7584	74.5	-1.50	0.1385
CENTRE	0020	0.7757	0.9233	43.7	0.84	0.4054
CENTRE	0022	-1.2162	0.7157	80.1	-1.70	0.0931
CENTRE	0023	2.6281	0.7203	83	3.65	0.0005
CENTRE	0025	-0.5203	1.2558	14	-0.41	0.6849
CENTRE	0026	1.6192	0.8594	54.5	1.88	0.0649
CENTRE	0027	0.7419	1.1779	18	0.63	0.5367
CENTRE	0028	1.6540	0.7993	66.7	2.07	0.0424
CENTRE	0029	0.6682	0.8571	55	0.78	0.4389
CENTRE	0030	-0.3072	0.9564	38.8	-0.32	0.7498
CENTRE	0031	-0.1933	0.8278	60.6	-0.23	0.8161
CENTRE	0033	0.7840	0.9786	35.8	0.80	0.4283
CENTRE	0034	-0.4529	1.0839	24.8	-0.42	0.6797
CENTRE	0035	0.9310	0.8798	51	1.06	0.2949

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=3 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0036	-0.5084	1.1776	18	-0.43	0.6711
CENTRE	0037	-0.01790	1.0581	27.1	-0.02	0.9866
CENTRE	0039	-2.1900	0.8011	63.9	-2.73	0.0081
CENTRE	0040	0.2989	1.2565	14	0.24	0.8154
CENTRE	0041	-0.4375	1.0143	31.6	-0.43	0.6692
CENTRE	0042	0.2942	1.2567	13.9	0.23	0.8183

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	494	6.50	0.0016
numcd	1	454	0.19	0.6637
B_HAMA	1	349	119.12	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-4.5740	0.4510	108	-10.14	<.0001	0.05	-5.4680	-3.6799
trtseq	Q600MG	-3.8445	0.4546	108	-8.46	<.0001	0.05	-4.7457	-2.9433
trtseq	P	-2.7189	0.4545	103	-5.98	<.0001	0.05	-3.6204	-1.8175

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.7295	0.5105	488	-1.43	0.1537	0.05	-1.7326	0.2737
trtseq	Q300MG	P	-1.8550	0.5170	497	-3.59	0.0004	0.05	-2.8709	-0.8392
trtseq	Q600MG	P	-1.1256	0.5200	499	-2.16	0.0309	0.05	-2.1473	-0.1038

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	510
Observations Used	510
Observations Not Used	0
Total Observations	510

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3214.47576333	
1	2	3201.89225722	0.00006299
2	1	3201.81441940	0.00000133
3	1	3201.81288004	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	2.9467
Residual	29.6606

Fit Statistics

-2 Res Log Likelihood	3201.8
AIC (smaller is better)	3205.8
AICC (smaller is better)	3205.8
BIC (smaller is better)	3208.9

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			3.9579	1.0281	237	3.85	0.0002
trtseq		Q300MG	-2.4931	0.6025	495	-4.14	<.0001
trtseq		Q600MG	-1.6982	0.6062	498	-2.80	0.0053
trtseq		P	0	.	.	.	.
numcd	1		0.2901	0.5705	452	0.51	0.6114
numcd	2		0	.	.	.	.
B_HAMA			-0.4258	0.04061	341	-10.49	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-1.0673	1.5127	13.4	-0.71	0.4925
CENTRE	0002	-0.6337	1.2371	28.8	-0.51	0.6124
CENTRE	0003	0.3771	1.2094	31.2	0.31	0.7572
CENTRE	0004	-1.6902	1.1639	35.5	-1.45	0.1552
CENTRE	0005	-0.1818	0.9229	67.5	-0.20	0.8444
CENTRE	0006	1.9697	1.3694	19.8	1.44	0.1660
CENTRE	0007	-0.5101	1.2135	30.7	-0.42	0.6772
CENTRE	0009	0.4346	1.2372	28.8	0.35	0.7279
CENTRE	0010	2.6440	1.1060	41.8	2.39	0.0214
CENTRE	0011	1.2804	1.1227	39.9	1.14	0.2609
CENTRE	0013	0.05192	1.2352	29	0.04	0.9668
CENTRE	0014	-2.0253	1.1243	39.7	-1.80	0.0792
CENTRE	0015	0.3183	1.4101	17.7	0.23	0.8240
CENTRE	0016	-1.4342	1.4603	15.4	-0.98	0.3412
CENTRE	0018	-0.8773	1.2095	31.1	-0.73	0.4737
CENTRE	0019	-0.9033	0.9033	69.1	-1.00	0.3208
CENTRE	0020	1.9821	1.1184	40.5	1.77	0.0839
CENTRE	0022	-1.3107	0.8578	71.9	-1.53	0.1309
CENTRE	0023	0.9795	0.8631	74.9	1.13	0.2600
CENTRE	0025	1.1014	1.5703	11.6	0.70	0.4969
CENTRE	0026	1.8148	1.0223	52.6	1.78	0.0817
CENTRE	0027	-1.1471	1.4600	15.4	-0.79	0.4439
CENTRE	0028	0.9148	0.9609	61.7	0.95	0.3448
CENTRE	0029	0.4037	1.0337	51.1	0.39	0.6978
CENTRE	0030	0.04001	1.1614	35.8	0.03	0.9727
CENTRE	0031	0.7810	0.9967	56.2	0.78	0.4366
CENTRE	0033	1.1777	1.1906	32.8	0.99	0.3298
CENTRE	0034	0.01958	1.3307	22.1	0.01	0.9884
CENTRE	0035	0.2069	1.0626	47.4	0.19	0.8465
CENTRE	0036	-2.1686	1.4596	15.5	-1.49	0.1574
CENTRE	0037	0.4497	1.2960	24.3	0.35	0.7316
CENTRE	0039	-2.0968	0.9636	58.9	-2.18	0.0336
CENTRE	0040	0.2196	1.5714	11.5	0.14	0.8913
CENTRE	0041	-0.4167	1.2376	28.7	-0.34	0.7388
CENTRE	0042	-0.7037	1.5717	11.5	-0.45	0.6626

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
GENERATED: 14JUL2005 11:41:57 iceadmn3

12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=4 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	491	8.86	0.0002
numcd	1	452	0.26	0.6114
B_HAMA	1	341	109.98	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-6.3861	0.5388	74.1	-11.85	<.0001	0.05	-7.4597	-5.3126
trtseq	Q600MG	-5.5912	0.5428	74.4	-10.30	<.0001	0.05	-6.6727	-4.5097
trtseq	P	-3.8930	0.5439	71.5	-7.16	<.0001	0.05	-4.9775	-2.8085

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.7949	0.5933	481	-1.34	0.1810	0.05	-1.9608	0.3709
trtseq	Q300MG	P	-2.4931	0.6025	495	-4.14	<.0001	0.05	-3.6769	-1.3093
trtseq	Q600MG	P	-1.6982	0.6062	498	-2.80	0.0053	0.05	-2.8893	-0.5072

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	510
Observations Used	510
Observations Not Used	0
Total Observations	510

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
GENERATED: 14JUL2005 11:41:57 iceadmn3

12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3323.58810372	
1	2	3320.25177290	0.00001979
2	1	3320.22673706	0.00000017
3	1	3320.22653078	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	1.6858
Residual	38.3736

Fit Statistics

-2 Res Log Likelihood	3320.2
AIC (smaller is better)	3324.2
AICC (smaller is better)	3324.3
BIC (smaller is better)	3327.3

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.1402	1.1003	174	3.76	0.0002
trtseq		Q300MG	-2.2850	0.6808	501	-3.36	0.0008
trtseq		Q600MG	-1.8942	0.6841	504	-2.77	0.0058
trtseq		P	0	.	.	.	.
numcd	1		-0.3428	0.6286	349	-0.55	0.5859
numcd	2		0	.	.	.	.
B_HAMA			-0.4598	0.04383	175	-10.49	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
GENERATED: 14JUL2005 11:41:57 iceadmn3

12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.5826	1.2225	4.36	-0.48	0.6566
CENTRE	0002	-0.1490	1.0907	6.85	-0.14	0.8953
CENTRE	0003	1.0126	1.0752	7.24	0.94	0.3767
CENTRE	0004	-1.5110	1.0490	7.97	-1.44	0.1878
CENTRE	0005	0.2701	0.8872	14.7	0.30	0.7650
CENTRE	0006	0.8936	1.1587	5.4	0.77	0.4729
CENTRE	0007	0.09702	1.0773	7.17	0.09	0.9307
CENTRE	0009	0.04827	1.0907	6.85	0.04	0.9660
CENTRE	0010	0.9756	1.0135	9.07	0.96	0.3607
CENTRE	0011	0.6864	1.0239	8.73	0.67	0.5199
CENTRE	0013	0.3697	1.0898	6.88	0.34	0.7446
CENTRE	0014	-1.4120	1.0249	8.7	-1.38	0.2027
CENTRE	0015	0.3457	1.1778	5.06	0.29	0.7808
CENTRE	0016	-1.3800	1.2003	4.69	-1.15	0.3055
CENTRE	0018	-0.7296	1.0753	7.24	-0.68	0.5186
CENTRE	0019	-0.3154	0.8713	15.4	-0.36	0.7223
CENTRE	0020	0.9867	1.0214	8.82	0.97	0.3598
CENTRE	0022	-0.8197	0.8331	17.2	-0.98	0.3387
CENTRE	0023	0.5652	0.8398	17.4	0.67	0.5098
CENTRE	0025	0.3909	1.2456	4.04	0.31	0.7692
CENTRE	0026	0.9612	0.9585	11.1	1.00	0.3372
CENTRE	0027	-0.6763	1.2001	4.69	-0.56	0.5989
CENTRE	0028	0.8243	0.9153	13.2	0.90	0.3840
CENTRE	0029	0.3644	0.9663	10.8	0.38	0.7134
CENTRE	0030	0.1130	1.0475	8.01	0.11	0.9167
CENTRE	0031	0.2466	0.9407	11.9	0.26	0.7977
CENTRE	0033	0.4756	1.0643	7.52	0.45	0.6676
CENTRE	0034	0.02073	1.1398	5.76	0.02	0.9861
CENTRE	0035	0.6708	0.9858	10.1	0.68	0.5115
CENTRE	0036	-0.9827	1.2000	4.7	-0.82	0.4523
CENTRE	0037	0.08344	1.1221	6.13	0.07	0.9431
CENTRE	0039	-1.5181	0.9148	12.8	-1.66	0.1213
CENTRE	0040	-0.04203	1.2460	4.04	-0.03	0.9747
CENTRE	0041	0.001411	1.0909	6.84	0.00	0.9990
CENTRE	0042	-0.2851	1.2460	4.03	-0.23	0.8302

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
GENERATED: 14JUL2005 11:41:57 iceadmn3

12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=5 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	494	6.37	0.0018
numcd	1	349	0.30	0.5859
B_HAMA	1	175	110.07	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-6.9494	0.5505	84.9	-12.62	<.0001	0.05	-8.0441	-5.8548
trtseq	Q600MG	-6.5585	0.5546	84	-11.83	<.0001	0.05	-7.6614	-5.4557
trtseq	P	-4.6644	0.5545	81.8	-8.41	<.0001	0.05	-5.7675	-3.5613

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.3909	0.6731	485	-0.58	0.5617	0.05	-1.7134	0.9317
trtseq	Q300MG	P	-2.2850	0.6808	501	-3.36	0.0008	0.05	-3.6226	-0.9474
trtseq	Q600MG	P	-1.8942	0.6841	504	-2.77	0.0058	0.05	-3.2381	-0.5502

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	510
Observations Used	510
Observations Not Used	0
Total Observations	510

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
GENERATED: 14JUL2005 11:41:57 iceadmn3

12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3340.81449302	
1	2	3332.17810305	0.00007114
2	1	3332.08462760	0.00000176
3	1	3332.08247803	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	3.1291
Residual	38.6469

Fit Statistics

-2 Res Log Likelihood	3332.1
AIC (smaller is better)	3336.1
AICC (smaller is better)	3336.1
BIC (smaller is better)	3339.2

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.2693	1.1544	223	3.70	0.0003
trtseq		Q300MG	-2.5383	0.6866	497	-3.70	0.0002
trtseq		Q600MG	-2.8615	0.6906	500	-4.14	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.4020	0.6461	429	-0.62	0.5341
numcd	2		0	.	.	.	.
B_HAMA			-0.4799	0.04577	295	-10.48	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
GENERATED: 14JUL2005 11:41:57 iceadmn3

12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.8660	1.5918	10.1	-0.54	0.5982
CENTRE	0002	-0.6810	1.3338	20.1	-0.51	0.6152
CENTRE	0003	2.2180	1.3068	21.6	1.70	0.1040
CENTRE	0004	-2.2175	1.2619	24.5	-1.76	0.0914
CENTRE	0005	0.08289	1.0152	48	0.08	0.9353
CENTRE	0006	1.2574	1.4603	14.2	0.86	0.4035
CENTRE	0007	-0.7447	1.3107	21.3	-0.57	0.5758
CENTRE	0009	1.4391	1.3339	20.1	1.08	0.2935
CENTRE	0010	1.7358	1.2040	28.8	1.44	0.1602
CENTRE	0011	0.2349	1.2207	27.5	0.19	0.8488
CENTRE	0013	-0.00370	1.3321	20.2	-0.00	0.9978
CENTRE	0014	-1.8260	1.2224	27.4	-1.49	0.1467
CENTRE	0015	0.5456	1.4982	12.9	0.36	0.7217
CENTRE	0016	-2.2460	1.5444	11.4	-1.45	0.1728
CENTRE	0018	-0.2648	1.3069	21.6	-0.20	0.8413
CENTRE	0019	-1.3090	0.9943	49.6	-1.32	0.1940
CENTRE	0020	2.3885	1.2165	27.9	1.96	0.0596
CENTRE	0022	-0.6674	0.9451	52.9	-0.71	0.4832
CENTRE	0023	0.006290	0.9515	54.8	0.01	0.9947
CENTRE	0025	0.4039	1.6431	8.93	0.25	0.8114
CENTRE	0026	0.7484	1.1187	36.4	0.67	0.5077
CENTRE	0027	-0.8714	1.5440	11.4	-0.56	0.5834
CENTRE	0028	0.3977	1.0551	43.3	0.38	0.7081
CENTRE	0029	1.7098	1.1304	35.3	1.51	0.1393
CENTRE	0030	0.3277	1.2594	24.7	0.26	0.7969
CENTRE	0031	0.2003	1.0923	39.1	0.18	0.8554
CENTRE	0033	1.3081	1.2882	22.7	1.02	0.3206
CENTRE	0034	-0.5568	1.4238	15.7	-0.39	0.7010
CENTRE	0035	0.7207	1.1600	32.7	0.62	0.5387
CENTRE	0036	-1.6904	1.5437	11.5	-1.09	0.2960
CENTRE	0037	0.4914	1.3907	17.2	0.35	0.7281
CENTRE	0039	-1.9739	1.0571	41.4	-1.87	0.0689
CENTRE	0040	0.1029	1.6440	8.91	0.06	0.9515
CENTRE	0041	-0.1458	1.3343	20	-0.11	0.9141
CENTRE	0042	-0.2548	1.6442	8.9	-0.15	0.8803

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	492	10.23	<.0001
numcd	1	429	0.39	0.5341
B_HAMA	1	295	109.90	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-7.4801	0.5957	77	-12.56	<.0001	0.05	-8.6663	-6.2940
trtseq	Q600MG	-7.8033	0.6001	77.1	-13.00	<.0001	0.05	-8.9983	-6.6082
trtseq	P	-4.9418	0.6010	73.9	-8.22	<.0001	0.05	-6.1393	-3.7443

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.3231	0.6768	482	0.48	0.6333	0.05	-1.0068	1.6530
trtseq	Q300MG	P	-2.5383	0.6866	497	-3.70	0.0002	0.05	-3.8873	-1.1893
trtseq	Q600MG	P	-2.8615	0.6906	500	-4.14	<.0001	0.05	-4.2182	-1.5047

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	510
Observations Used	510
Observations Not Used	0
Total Observations	510

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3398.50170991	
1	2	3393.31492242	0.00000061
2	1	3393.31416131	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	2.0987
Residual	44.2717

Fit Statistics

-2 Res Log Likelihood	3393.3
AIC (smaller is better)	3397.3
AICC (smaller is better)	3397.3
BIC (smaller is better)	3400.4

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.0149	1.1880	208	3.38	0.0009
trtseq		Q300MG	-2.6202	0.7317	501	-3.58	0.0004
trtseq		Q600MG	-2.6394	0.7353	504	-3.59	0.0004
trtseq		P	0	.	.	.	.
numcd	1		-0.1704	0.6771	382	-0.25	0.8015
numcd	2		0	.	.	.	.
B_HAMA			-0.4859	0.04731	215	-10.27	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.4319	1.3579	6.1	-0.32	0.7611
CENTRE	0002	-0.4851	1.2032	9.83	-0.40	0.6955
CENTRE	0003	0.5797	1.1854	10.4	0.49	0.6349
CENTRE	0004	-1.8165	1.1550	11.5	-1.57	0.1429
CENTRE	0005	-0.2375	0.9706	21.4	-0.24	0.8090
CENTRE	0006	0.6407	1.2827	7.66	0.50	0.6315
CENTRE	0007	-0.04935	1.1878	10.3	-0.04	0.9676
CENTRE	0009	0.9264	1.2033	9.83	0.77	0.4595
CENTRE	0010	1.4212	1.1142	13.2	1.28	0.2242
CENTRE	0011	1.2421	1.1261	12.6	1.10	0.2906
CENTRE	0013	-0.02816	1.2022	9.87	-0.02	0.9818
CENTRE	0014	-0.8715	1.1273	12.6	-0.77	0.4537
CENTRE	0015	0.2425	1.3052	7.15	0.19	0.8578
CENTRE	0016	-1.4066	1.3316	6.6	-1.06	0.3280
CENTRE	0018	-0.06085	1.1855	10.4	-0.05	0.9600
CENTRE	0019	-0.9416	0.9528	22.5	-0.99	0.3335
CENTRE	0020	0.9368	1.1233	12.8	0.83	0.4196
CENTRE	0022	-0.7882	0.9101	25.1	-0.87	0.3947
CENTRE	0023	-1.0630	0.9174	25.4	-1.16	0.2574
CENTRE	0025	0.1830	1.3855	5.63	0.13	0.8995
CENTRE	0026	1.2164	1.0513	16.2	1.16	0.2640
CENTRE	0027	-0.1666	1.3314	6.6	-0.13	0.9041
CENTRE	0028	0.4696	1.0023	19.2	0.47	0.6447
CENTRE	0029	1.8437	1.0603	15.8	1.74	0.1015
CENTRE	0030	0.6054	1.1533	11.6	0.52	0.6095
CENTRE	0031	0.1023	1.0311	17.4	0.10	0.9221
CENTRE	0033	0.8082	1.1728	10.8	0.69	0.5052
CENTRE	0034	-0.3056	1.2605	8.21	-0.24	0.8144
CENTRE	0035	0.07874	1.0825	14.7	0.07	0.9430
CENTRE	0036	-0.9801	1.3313	6.61	-0.74	0.4869
CENTRE	0037	0.3768	1.2399	8.75	0.30	0.7683
CENTRE	0039	-1.4856	1.0020	18.7	-1.48	0.1549
CENTRE	0040	-0.1202	1.3859	5.62	-0.09	0.9339
CENTRE	0041	-0.1905	1.2035	9.82	-0.16	0.8774
CENTRE	0042	-0.2449	1.3860	5.62	-0.18	0.8660

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=7 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	496	8.49	0.0002
numcd	1	382	0.06	0.8015
B_HAMA	1	215	105.48	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-7.8140	0.5960	102	-13.11	<.0001	0.05	-8.9962	-6.6317
trtseq	Q600MG	-7.8332	0.6004	101	-13.05	<.0001	0.05	-9.0242	-6.6421
trtseq	P	-5.1938	0.6004	97.9	-8.65	<.0001	0.05	-6.3853	-4.0023

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.01921	0.7231	488	0.03	0.9788	0.05	-1.4016	1.4400
trtseq	Q300MG	P	-2.6202	0.7317	501	-3.58	0.0004	0.05	-4.0577	-1.1826
trtseq	Q600MG	P	-2.6394	0.7353	504	-3.59	0.0004	0.05	-4.0839	-1.1948

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	510
Observations Used	510
Observations Not Used	0
Total Observations	510

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3376.51953465	
1	2	3373.86365054	0.00000012
2	1	3373.86350012	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	1.3458
Residual	42.9684

Fit Statistics

-2 Res Log Likelihood	3373.9
AIC (smaller is better)	3377.9
AICC (smaller is better)	3377.9
BIC (smaller is better)	3381.0

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.0132	1.1395	174	3.52	0.0005
trtseq		Q300MG	-2.9258	0.7186	503	-4.07	<.0001
trtseq		Q600MG	-2.7394	0.7217	505	-3.80	0.0002
trtseq		P	0	.	.	.	.
numcd	1		-0.4665	0.6569	335	-0.71	0.4781
numcd	2		0	.	.	.	.
B_HAMA			-0.4909	0.04535	154	-10.82	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.4517	1.1104	3.43	-0.41	0.7082
CENTRE	0002	-0.4731	1.0179	4.85	-0.46	0.6622
CENTRE	0003	0.3034	1.0066	5.07	0.30	0.7750
CENTRE	0004	-1.4218	0.9870	5.48	-1.44	0.2043
CENTRE	0005	0.01520	0.8590	9.26	0.02	0.9863
CENTRE	0006	0.5367	1.0667	4.03	0.50	0.6411
CENTRE	0007	0.2997	1.0080	5.04	0.30	0.7781
CENTRE	0009	0.6662	1.0179	4.85	0.65	0.5426
CENTRE	0010	1.0932	0.9600	6.1	1.14	0.2976
CENTRE	0011	0.5657	0.9679	5.9	0.58	0.5806
CENTRE	0013	0.1371	1.0173	4.87	0.13	0.8982
CENTRE	0014	-0.6195	0.9687	5.89	-0.64	0.5466
CENTRE	0015	0.4404	1.0800	3.84	0.41	0.7052
CENTRE	0016	-0.8569	1.0954	3.63	-0.78	0.4820
CENTRE	0018	-0.1134	1.0066	5.07	-0.11	0.9146
CENTRE	0019	-0.8257	0.8454	9.72	-0.98	0.3524
CENTRE	0020	0.7592	0.9661	5.95	0.79	0.4621
CENTRE	0022	-0.1180	0.8122	10.9	-0.15	0.8871
CENTRE	0023	-0.8629	0.8189	10.9	-1.05	0.3148
CENTRE	0025	0.1290	1.1258	3.25	0.11	0.9155
CENTRE	0026	0.001476	0.9169	7.26	0.00	0.9988
CENTRE	0027	-0.2951	1.0953	3.63	-0.27	0.8022
CENTRE	0028	0.8704	0.8821	8.39	0.99	0.3514
CENTRE	0029	0.9829	0.9231	7.08	1.06	0.3220
CENTRE	0030	0.3493	0.9858	5.5	0.35	0.7363
CENTRE	0031	0.4515	0.9026	7.69	0.50	0.6309
CENTRE	0033	0.5202	0.9984	5.23	0.52	0.6236
CENTRE	0034	-0.1569	1.0534	4.24	-0.15	0.8884
CENTRE	0035	-0.3470	0.9385	6.66	-0.37	0.7231
CENTRE	0036	-0.6222	1.0952	3.63	-0.57	0.6032
CENTRE	0037	0.1146	1.0407	4.45	0.11	0.9171
CENTRE	0039	-1.0754	0.8808	8.26	-1.22	0.2558
CENTRE	0040	0.1080	1.1261	3.24	0.10	0.9292
CENTRE	0041	0.000858	1.0180	4.85	0.00	0.9994
CENTRE	0042	-0.1053	1.1261	3.24	-0.09	0.9310

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=8 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	10.27	<.0001
numcd	1	335	0.50	0.4781
B_HAMA	1	154	117.18	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-8.3630	0.5650	108	-14.80	<.0001	0.05	-9.4830	-7.2430
trtseq	Q600MG	-8.1765	0.5690	106	-14.37	<.0001	0.05	-9.3047	-7.0484
trtseq	P	-5.4372	0.5688	105	-9.56	<.0001	0.05	-6.5650	-4.3094

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.1864	0.7116	490	-0.26	0.7934	0.05	-1.5845	1.2117
trtseq	Q300MG	P	-2.9258	0.7186	503	-4.07	<.0001	0.05	-4.3377	-1.5139
trtseq	Q600MG	P	-2.7394	0.7217	505	-3.80	0.0002	0.05	-4.1573	-1.3214

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	510
Observations Used	510
Observations Not Used	0
Total Observations	510

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3413.70100573	
1	2	3412.31425812	0.00000167
2	1	3412.31214796	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	1.1102
Residual	46.5788

Fit Statistics

-2 Res Log Likelihood	3412.3
AIC (smaller is better)	3416.3
AICC (smaller is better)	3416.3
BIC (smaller is better)	3419.4

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.2725	1.1680	143	3.66	0.0004
trtseq		Q300MG	-3.3300	0.7469	504	-4.46	<.0001
trtseq		Q600MG	-3.1310	0.7499	505	-4.18	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.7870	0.6775	295	-1.16	0.2464
numcd	2		0	.	.	.	.
B_HAMA			-0.4834	0.04640	115	-10.42	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.3356	1.0188	2.08	-0.33	0.7721
CENTRE	0002	-0.2329	0.9508	2.74	-0.24	0.8237
CENTRE	0003	0.4844	0.9422	2.84	0.51	0.6445
CENTRE	0004	-1.4322	0.9272	3.03	-1.54	0.2193
CENTRE	0005	0.07386	0.8249	4.75	0.09	0.9323
CENTRE	0006	0.2996	0.9871	2.36	0.30	0.7862
CENTRE	0007	0.2606	0.9432	2.83	0.28	0.8013
CENTRE	0009	0.3306	0.9508	2.74	0.35	0.7530
CENTRE	0010	0.8692	0.9062	3.31	0.96	0.4022
CENTRE	0011	-0.09062	0.9124	3.22	-0.10	0.9267
CENTRE	0013	-0.08719	0.9504	2.75	-0.09	0.9332
CENTRE	0014	-0.3765	0.9130	3.22	-0.41	0.7060
CENTRE	0015	0.2196	0.9969	2.27	0.22	0.8439
CENTRE	0016	-0.6684	1.0080	2.17	-0.66	0.5707
CENTRE	0018	-0.2332	0.9422	2.84	-0.25	0.8213
CENTRE	0019	-0.1104	0.8134	4.98	-0.14	0.8973
CENTRE	0020	0.6902	0.9110	3.24	0.76	0.4999
CENTRE	0022	-0.2987	0.7848	5.58	-0.38	0.7176
CENTRE	0023	-0.3241	0.7911	5.52	-0.41	0.6974
CENTRE	0025	0.2623	1.0297	1.99	0.25	0.8228
CENTRE	0026	0.1731	0.8720	3.84	0.20	0.8527
CENTRE	0027	-0.1399	1.0079	2.17	-0.14	0.9015
CENTRE	0028	0.6586	0.8439	4.36	0.78	0.4754
CENTRE	0029	1.2459	0.8770	3.76	1.42	0.2328
CENTRE	0030	0.003456	0.9263	3.04	0.00	0.9973
CENTRE	0031	0.1320	0.8605	4.04	0.15	0.8854
CENTRE	0033	0.4241	0.9359	2.92	0.45	0.6821
CENTRE	0034	-0.1791	0.9773	2.46	-0.18	0.8686
CENTRE	0035	-0.2715	0.8893	3.56	-0.31	0.7771
CENTRE	0036	-0.3960	1.0079	2.17	-0.39	0.7296
CENTRE	0037	0.1180	0.9679	2.55	0.12	0.9119
CENTRE	0039	-1.0105	0.8422	4.32	-1.20	0.2918
CENTRE	0040	0.03078	1.0299	1.99	0.03	0.9789
CENTRE	0041	-0.04909	0.9508	2.74	-0.05	0.9624
CENTRE	0042	-0.04040	1.0299	1.99	-0.04	0.9723

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=9 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	12.38	<.0001
numcd	1	295	1.35	0.2464
B_HAMA	1	115	108.52	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-8.5271	0.5766	102	-14.79	<.0001	0.05	-9.6708	-7.3834
trtseq	Q600MG	-8.3280	0.5805	99.3	-14.35	<.0001	0.05	-9.4799	-7.1762
trtseq	P	-5.1971	0.5804	101	-8.95	<.0001	0.05	-6.3484	-4.0458

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.1991	0.7404	489	-0.27	0.7881	0.05	-1.6538	1.2556
trtseq	Q300MG	P	-3.3300	0.7469	504	-4.46	<.0001	0.05	-4.7974	-1.8627
trtseq	Q600MG	P	-3.1310	0.7499	505	-4.18	<.0001	0.05	-4.6042	-1.6577

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Model Information

Data Set	WORK.HAMAVSTXBL
Dependent Variable	CL_HAMA
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	510
Observations Used	510
Observations Not Used	0
Total Observations	510

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3428.64034152	
1	2	3427.56406886	0.00000107
2	1	3427.56270983	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.9942
Residual	48.1054

Fit Statistics

-2 Res Log Likelihood	3427.6
AIC (smaller is better)	3431.6
AICC (smaller is better)	3431.6
BIC (smaller is better)	3434.7

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			3.2641	1.1780	133	2.77	0.0064
trtseq		Q300MG	-3.0993	0.7584	504	-4.09	<.0001
trtseq		Q600MG	-3.2046	0.7613	505	-4.21	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.4388	0.6855	279	-0.64	0.5226
numcd	2		0	.	.	.	.
B_HAMA			-0.4574	0.04675	102	-9.78	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.2990	0.9682	1.65	-0.31	0.7921
CENTRE	0002	-0.4229	0.9109	2.1	-0.46	0.6862
CENTRE	0003	0.8482	0.9036	2.17	0.94	0.4402
CENTRE	0004	-1.0800	0.8907	2.3	-1.21	0.3352
CENTRE	0005	0.03367	0.8010	3.47	0.04	0.9688
CENTRE	0006	0.2332	0.9418	1.84	0.25	0.8293
CENTRE	0007	0.1463	0.9045	2.16	0.16	0.8854
CENTRE	0009	0.4200	0.9110	2.1	0.46	0.6881
CENTRE	0010	0.5424	0.8726	2.49	0.62	0.5864
CENTRE	0011	-0.3704	0.8779	2.43	-0.42	0.7076
CENTRE	0013	0.08219	0.9106	2.11	0.09	0.9359
CENTRE	0014	-0.5841	0.8785	2.43	-0.66	0.5638
CENTRE	0015	0.1582	0.9500	1.78	0.17	0.8847
CENTRE	0016	-0.5162	0.9593	1.71	-0.54	0.6522
CENTRE	0018	0.09825	0.9036	2.17	0.11	0.9226
CENTRE	0019	-0.2305	0.7906	3.63	-0.29	0.7866
CENTRE	0020	0.4409	0.8767	2.45	0.50	0.6567
CENTRE	0022	-0.1738	0.7647	4.05	-0.23	0.8312
CENTRE	0023	-0.2664	0.7706	4	-0.35	0.7470
CENTRE	0025	0.1055	0.9774	1.59	0.11	0.9261
CENTRE	0026	0.5239	0.8427	2.85	0.62	0.5803
CENTRE	0027	-0.2381	0.9592	1.71	-0.25	0.8305
CENTRE	0028	0.8453	0.8179	3.2	1.03	0.3730
CENTRE	0029	0.8183	0.8472	2.8	0.97	0.4100
CENTRE	0030	0.07150	0.8900	2.3	0.08	0.9424
CENTRE	0031	0.06291	0.8326	2.99	0.08	0.9445
CENTRE	0033	0.3828	0.8982	2.22	0.43	0.7078
CENTRE	0034	-0.2016	0.9335	1.91	-0.22	0.8499
CENTRE	0035	-0.2425	0.8579	2.66	-0.28	0.7979
CENTRE	0036	-0.4368	0.9592	1.71	-0.46	0.7000
CENTRE	0037	0.1283	0.9255	1.97	0.14	0.9026
CENTRE	0039	-0.8988	0.8161	3.18	-1.10	0.3470
CENTRE	0040	0.08858	0.9775	1.58	0.09	0.9379
CENTRE	0041	-0.00930	0.9110	2.1	-0.01	0.9927
CENTRE	0042	-0.06011	0.9775	1.58	-0.06	0.9578

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	497	11.40	<.0001
numcd	1	279	0.41	0.5226
B_HAMA	1	102	95.73	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-8.6426	0.5807	101	-14.88	<.0001	0.05	-9.7946	-7.4907
trtseq	Q600MG	-8.7479	0.5846	98.5	-14.96	<.0001	0.05	-9.9080	-7.5879
trtseq	P	-5.5433	0.5845	101	-9.48	<.0001	0.05	-6.7028	-4.3839

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.1053	0.7522	490	0.14	0.8887	0.05	-1.3725	1.5832
trtseq	Q300MG	P	-3.0993	0.7584	504	-4.09	<.0001	0.05	-4.5892	-1.6093
trtseq	Q600MG	P	-3.2046	0.7613	505	-4.21	<.0001	0.05	-4.7003	-1.7089

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=3

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	171	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	171	0	-4.40	5.30
		B_HAMA	BL HAMA TOTAL	171	0	18.65	7.30
Q600MG	169	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	169	0	-3.80	5.74
		B_HAMA	BL HAMA TOTAL	169	0	18.74	7.34
P	168	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	168	0	-2.73	5.06
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

WINDOWED VISIT=4

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	172	0	-6.21	6.37
		B_HAMA	BL HAMA TOTAL	172	0	18.66	7.28
Q600MG	170	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	170	0	-5.56	6.50
		B_HAMA	BL HAMA TOTAL	170	0	18.73	7.32
P	168	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	168	0	-3.98	5.90
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

WINDOWED VISIT=5

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	172	0	-6.89	6.90
		B_HAMA	BL HAMA TOTAL	172	0	18.66	7.28
Q600MG	170	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	170	0	-6.60	7.67
		B_HAMA	BL HAMA TOTAL	170	0	18.73	7.32

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
GENERATED: 14JUL2005 11:41:57 iceadmn3

12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=5

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	168	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	168	0	-4.82	6.42
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

WINDOWED VISIT=6

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	172	0	-7.51	7.27
		B_HAMA	BL HAMA TOTAL	172	0	18.66	7.28
Q600MG	170	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	170	0	-7.91	7.67
		B_HAMA	BL HAMA TOTAL	170	0	18.73	7.32
P	168	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	168	0	-5.12	6.54
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

WINDOWED VISIT=7

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	172	0	-7.88	7.47
		B_HAMA	BL HAMA TOTAL	172	0	18.66	7.28
Q600MG	170	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	170	0	-7.98	8.09
		B_HAMA	BL HAMA TOTAL	170	0	18.73	7.32
P	168	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	168	0	-5.35	7.07
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

WINDOWED VISIT=8

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	172	0	-8.46	7.53
		B_HAMA	BL HAMA TOTAL	172	0	18.66	7.28
Q600MG	170	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	170	0	-8.31	7.72
		B_HAMA	BL HAMA TOTAL	170	0	18.73	7.32
P	168	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	168	0	-5.60	7.26
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

WINDOWED VISIT=9

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	172	0	-8.63	7.27
		B_HAMA	BL HAMA TOTAL	172	0	18.66	7.28
Q600MG	170	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	170	0	-8.45	8.01
		B_HAMA	BL HAMA TOTAL	170	0	18.73	7.32
P	168	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	168	0	-5.42	7.73
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

WINDOWED VISIT=10

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	172	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	172	0	-8.67	7.68
		B_HAMA	BL HAMA TOTAL	172	0	18.66	7.28
Q600MG	170	CL_HAMA	CHG_BL_HAMA_TOTAL - LOCF	170	0	-8.79	7.88
		B_HAMA	BL HAMA TOTAL	170	0	18.73	7.32

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.1 HAM-A Total Score Change from Baseline (ANCOVA - LOCF - ITT)

---------- WINDOWED VISIT=10 ----------

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	168	CL_HAMA	CHG BL HAMA TOTAL - LOCF	168	0	-5.72	7.52
		B_HAMA	BL HAMA TOTAL	168	0	18.94	7.25

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA202H.SAS
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12.1.9.2.5.2 HAM-A Total Score Change from Baseline (Effect Size - LOCF - ITT)

Obs	ntrtseq	stdd	cl95l	cl95u	d	spool	trtseq	VISIT	trtseq	Estimate	residcov	npat	stdevtrt	stdevctr	ncontrol
1	13	0.10950	-0.57249	-0.14327	-0.35788	5.18345	1	3	3	-1.8550	21.8539	171	5.30	5.06	168
2	23	0.10924	-0.42213	0.00610	-0.20801	5.41103	2	3	3	-1.1256	21.8539	169	5.74	5.06	168
3	13	0.10958	-0.62072	-0.19115	-0.40594	6.14167	1	4	3	-2.4931	29.6606	172	6.37	5.90	168
4	23	0.10930	-0.48775	-0.05932	-0.27353	6.20840	2	4	3	-1.6982	29.6606	170	6.50	5.90	168
5	13	0.10927	-0.55692	-0.12860	-0.34276	6.66652	1	5	3	-2.2850	38.3736	172	6.90	6.42	168
6	23	0.10927	-0.48199	-0.05364	-0.26781	7.07263	2	5	3	-1.8942	38.3736	170	7.67	6.42	168
7	13	0.10938	-0.58107	-0.15230	-0.36669	6.92235	1	6	3	-2.5383	38.6469	172	7.27	6.54	168
8	23	0.10988	-0.61653	-0.18582	-0.40117	7.13269	2	6	3	-2.8615	38.6469	170	7.67	6.54	168
9	13	0.10935	-0.57449	-0.14585	-0.36017	7.27475	1	7	3	-2.6202	44.2717	172	7.47	7.07	168
10	23	0.10960	-0.56220	-0.13255	-0.34738	7.59796	2	7	3	-2.6394	44.2717	170	8.09	7.07	168
11	13	0.10953	-0.61014	-0.18079	-0.39546	7.39842	1	8	3	-2.9258	42.9684	172	7.53	7.26	168
12	23	0.10969	-0.58038	-0.15039	-0.36538	7.49730	2	8	3	-2.7394	42.9684	170	7.72	7.26	168
13	13	0.10980	-0.65921	-0.22879	-0.44400	7.50013	1	9	3	-3.3300	46.5788	172	7.27	7.73	168
14	23	0.10986	-0.61290	-0.18226	-0.39758	7.87497	2	9	3	-3.1310	46.5788	170	8.01	7.73	168
15	13	0.10959	-0.62240	-0.19280	-0.40760	7.60371	1	10	3	-3.0993	48.1054	172	7.68	7.52	168
16	23	0.10996	-0.63147	-0.20043	-0.41595	7.70429	2	10	3	-3.2046	48.1054	170	7.88	7.52	168

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/HAMA205H.SAS
GENERATED: 14JUL2005 11:42:00 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Model Information

Data Set	WORK.QLESSFVSTXBL
Dependent Variable	C_QLESQT
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	463
Observations Used	463
Observations Not Used	0
Total Observations	463

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3353.01362137	
1	2	3352.92717478	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.4345
Residual	82.4950

Fit Statistics

-2 Res Log Likelihood	3352.9
AIC (smaller is better)	3356.9
AICC (smaller is better)	3357.0
BIC (smaller is better)	3360.0

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			22.3682	2.1405	373	10.45	<.0001
trtseq		Q300MG	3.4180	1.0399	457	3.29	0.0011
trtseq		Q600MG	4.7850	1.0398	457	4.60	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.3703	0.9131	184	0.41	0.6855
numcd	2		0	.	.	.	.
B_QLESQT			-0.4869	0.05466	451	-8.91	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	0.05251	0.6542	1	0.08	0.9490
CENTRE	0002	0.02058	0.6446	1	0.03	0.9797
CENTRE	0003	-0.06812	0.6461	1	-0.11	0.9331
CENTRE	0004	0.08649	0.6416	1	0.13	0.9147
CENTRE	0005	-0.1415	0.6220	1	-0.23	0.8576
CENTRE	0006	-0.02891	0.6492	1	-0.04	0.9717
CENTRE	0007	0.009237	0.6415	1	0.01	0.9908
CENTRE	0009	-0.09126	0.6446	1	-0.14	0.9105
CENTRE	0010	-0.02666	0.6386	1	-0.04	0.9734
CENTRE	0011	0.02239	0.6375	1	0.04	0.9776
CENTRE	0013	-0.05635	0.6430	1	-0.09	0.9444
CENTRE	0014	0.1609	0.6371	1	0.25	0.8426
CENTRE	0015	-0.2141	0.6509	1	-0.33	0.7977
CENTRE	0016	0.08845	0.6541	1	0.14	0.9144
CENTRE	0018	-0.1832	0.6414	1	-0.29	0.8229
CENTRE	0019	-0.1647	0.6183	1	-0.27	0.8343
CENTRE	0020	-0.2247	0.6401	1	-0.35	0.7850
CENTRE	0022	-0.01493	0.5970	1	-0.03	0.9841
CENTRE	0023	0.1737	0.6072	1	0.29	0.8226
CENTRE	0025	-0.00848	0.6558	1	-0.01	0.9918
CENTRE	0026	0.2363	0.6301	1	0.38	0.7716
CENTRE	0027	0.1244	0.6525	1	0.19	0.8801
CENTRE	0028	-0.2619	0.6239	1	-0.42	0.7470
CENTRE	0029	-0.4794	0.6314	1	-0.76	0.5866
CENTRE	0030	0.1110	0.6401	1	0.17	0.8907
CENTRE	0031	0.1872	0.6292	1	0.30	0.8159
CENTRE	0033	0.04238	0.6419	1	0.07	0.9580
CENTRE	0034	0.04628	0.6477	1	0.07	0.9546
CENTRE	0035	-0.00250	0.6341	1	-0.00	0.9975
CENTRE	0036	0.2646	0.6525	1	0.41	0.7547
CENTRE	0037	-0.00044	0.6476	1	-0.00	0.9996
CENTRE	0039	0.3648	0.6222	1	0.59	0.6624
CENTRE	0040	-0.04178	0.6558	1	-0.06	0.9595
CENTRE	0041	0.03658	0.6462	1	0.06	0.9640
CENTRE	0042	-0.01887	0.6558	1	-0.03	0.9817

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	452	11.24	<.0001
numcd	1	184	0.16	0.6855
B_QLESQT	1	451	79.36	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	9.0439	0.7627	113	11.86	<.0001	0.05	7.5327	10.5550
trtseq	Q600MG	10.4109	0.7650	108	13.61	<.0001	0.05	8.8945	11.9273
trtseq	P	5.6259	0.7615	120	7.39	<.0001	0.05	4.1181	7.1337

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-1.3670	1.0410	451	-1.31	0.1898	0.05	-3.4129	0.6789
trtseq	Q300MG	P	3.4180	1.0399	457	3.29	0.0011	0.05	1.3744	5.4617
trtseq	Q600MG	P	4.7850	1.0398	457	4.60	<.0001	0.05	2.7416	6.8284

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Model Information

Data Set	WORK.QLESSFVSTXBL
Dependent Variable	C_QLESQT
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	326
Observations Used	326
Observations Not Used	0
Total Observations	326

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	2383.24123101	
1	1	2383.24123101	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0
Residual	89.8762

Fit Statistics

-2 Res Log Likelihood	2383.2
AIC (smaller is better)	2385.2
AICC (smaller is better)	2385.3
BIC (smaller is better)	2386.8

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			26.6991	2.5231	321	10.58	<.0001
trtseq		Q300MG	3.6560	1.2643	321	2.89	0.0041
trtseq		Q600MG	7.1154	1.3350	321	5.33	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.8137	1.1269	321	-0.72	0.4708
numcd	2		0	.	.	.	.
B_QLESQT			-0.5013	0.06471	321	-7.75	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	0	.	.	.	.
CENTRE	0002	0	.	.	.	.
CENTRE	0003	0	.	.	.	.
CENTRE	0004	0	.	.	.	.
CENTRE	0005	0	.	.	.	.
CENTRE	0006	0	.	.	.	.
CENTRE	0007	0	.	.	.	.
CENTRE	0009	0	.	.	.	.
CENTRE	0010	0	.	.	.	.
CENTRE	0011	0	.	.	.	.
CENTRE	0013	0	.	.	.	.
CENTRE	0014	0	.	.	.	.
CENTRE	0015	0	.	.	.	.
CENTRE	0016	0	.	.	.	.
CENTRE	0018	0	.	.	.	.
CENTRE	0019	0	.	.	.	.
CENTRE	0020	0	.	.	.	.
CENTRE	0022	0	.	.	.	.
CENTRE	0023	0	.	.	.	.
CENTRE	0025	0	.	.	.	.
CENTRE	0026	0	.	.	.	.
CENTRE	0027	0	.	.	.	.
CENTRE	0028	0	.	.	.	.
CENTRE	0029	0	.	.	.	.
CENTRE	0030	0	.	.	.	.
CENTRE	0031	0	.	.	.	.
CENTRE	0033	0	.	.	.	.
CENTRE	0034	0	.	.	.	.
CENTRE	0035	0	.	.	.	.
CENTRE	0036	0	.	.	.	.
CENTRE	0037	0	.	.	.	.
CENTRE	0039	0	.	.	.	.
CENTRE	0040	0	.	.	.	.
CENTRE	0041	0	.	.	.	.
CENTRE	0042	0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	321	14.23	<.0001
numcd	1	321	0.52	0.4708
B_QLESQT	1	321	60.02	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	12.4786	0.8924	321	13.98	<.0001	0.05	10.7229	14.2342
trtseq	Q600MG	15.9380	0.9936	321	16.04	<.0001	0.05	13.9832	17.8927
trtseq	P	8.8226	0.9247	321	9.54	<.0001	0.05	7.0034	10.6417

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-3.4594	1.2976	321	-2.67	0.0081	0.05	-6.0122	-0.9066
trtseq	Q300MG	P	3.6560	1.2643	321	2.89	0.0041	0.05	1.1686	6.1434
trtseq	Q600MG	P	7.1154	1.3350	321	5.33	<.0001	0.05	4.4890	9.7418

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Model Information

Data Set	WORK.QLESSFVSTXBL
Dependent Variable	C_QLESQT
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	471
Observations Used	471
Observations Not Used	0
Total Observations	471

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3512.40732381	
1	1	3512.40732381	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0
Residual	103.02

Fit Statistics

-2 Res Log Likelihood	3512.4
AIC (smaller is better)	3514.4
AICC (smaller is better)	3514.4
BIC (smaller is better)	3516.0

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			23.0331	2.3354	466	9.86	<.0001
trtseq		Q300MG	4.3274	1.1515	466	3.76	0.0002
trtseq		Q600MG	5.2743	1.1438	466	4.61	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.04264	0.9987	466	-0.04	0.9660
numcd	2		0	.	.	.	.
B_QLESQT			-0.4766	0.05994	466	-7.95	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	0	.	.	.	.
CENTRE	0002	0	.	.	.	.
CENTRE	0003	0	.	.	.	.
CENTRE	0004	0	.	.	.	.
CENTRE	0005	0	.	.	.	.
CENTRE	0006	0	.	.	.	.
CENTRE	0007	0	.	.	.	.
CENTRE	0009	0	.	.	.	.
CENTRE	0010	0	.	.	.	.
CENTRE	0011	0	.	.	.	.
CENTRE	0013	0	.	.	.	.
CENTRE	0014	0	.	.	.	.
CENTRE	0015	0	.	.	.	.
CENTRE	0016	0	.	.	.	.
CENTRE	0018	0	.	.	.	.
CENTRE	0019	0	.	.	.	.
CENTRE	0020	0	.	.	.	.
CENTRE	0022	0	.	.	.	.
CENTRE	0023	0	.	.	.	.
CENTRE	0025	0	.	.	.	.
CENTRE	0026	0	.	.	.	.
CENTRE	0027	0	.	.	.	.
CENTRE	0028	0	.	.	.	.
CENTRE	0029	0	.	.	.	.
CENTRE	0030	0	.	.	.	.
CENTRE	0031	0	.	.	.	.
CENTRE	0033	0	.	.	.	.
CENTRE	0034	0	.	.	.	.
CENTRE	0035	0	.	.	.	.
CENTRE	0036	0	.	.	.	.
CENTRE	0037	0	.	.	.	.
CENTRE	0039	0	.	.	.	.
CENTRE	0040	0	.	.	.	.
CENTRE	0041	0	.	.	.	.
CENTRE	0042	0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	466	12.08	<.0001
numcd	1	466	0.00	0.9660
B_QLESQT	1	466	63.22	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	10.7676	0.8355	466	12.89	<.0001	0.05	9.1258	12.4094
trtseq	Q600MG	11.7145	0.8292	466	14.13	<.0001	0.05	10.0850	13.3440
trtseq	P	6.4402	0.8257	466	7.80	<.0001	0.05	4.8176	8.0628

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	-0.9469	1.1536	466	-0.82	0.4122	0.05	-3.2139	1.3200
trtseq	Q300MG	P	4.3274	1.1515	466	3.76	0.0002	0.05	2.0647	6.5901
trtseq	Q600MG	P	5.2743	1.1438	466	4.61	<.0001	0.05	3.0267	7.5219

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

WINDOWED VISIT=6

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	156	C_QLESQT	CHG BL QLESQ TOTAL SCORE	156	0	8.47	9.67
		B_QLESQT	BL QLESQ TOTAL SCORE	156	0	36.09	7.86
Q600MG	153	C_QLESQT	CHG BL QLESQ TOTAL SCORE	153	0	10.85	10.68
		B_QLESQT	BL QLESQ TOTAL SCORE	153	0	33.99	8.07
P	154	C_QLESQT	CHG BL QLESQ TOTAL SCORE	154	0	5.96	9.15
		B_QLESQT	BL QLESQ TOTAL SCORE	154	0	34.18	7.45

WINDOWED VISIT=10

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	122	C_QLESQT	CHG BL QLESQ TOTAL SCORE	122	0	11.74	10.42
		B_QLESQT	BL QLESQ TOTAL SCORE	122	0	35.99	8.11
Q600MG	97	C_QLESQT	CHG BL QLESQ TOTAL SCORE	97	0	16.30	10.34
		B_QLESQT	BL QLESQ TOTAL SCORE	97	0	33.78	8.60
P	107	C_QLESQT	CHG BL QLESQ TOTAL SCORE	107	0	8.91	10.12
		B_QLESQT	BL QLESQ TOTAL SCORE	107	0	34.50	7.78

WINDOWED VISIT=99

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	156	C_QLESQT	CHG BL QLESQ TOTAL SCORE	156	0	10.13	10.75
		B_QLESQT	BL QLESQ TOTAL SCORE	156	0	36.08	7.87
Q600MG	157	C_QLESQT	CHG BL QLESQ TOTAL SCORE	157	0	12.03	11.64
		B_QLESQT	BL QLESQ TOTAL SCORE	157	0	34.09	8.21

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.6 QLESQ Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	158	C_QLESQT	CHG BL QLESQ TOTAL SCORE	158	0	6.73	9.93
		B_QLESQT	BL QLESQ TOTAL SCORE	158	0	34.15	7.43

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/QLESQ202H.SAS
GENERATED: 14JUL2005 11:42:03 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Model Information

Data Set	WORK.PSQIVSTXBL
Dependent Variable	C_PSQIT
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	446
Observations Used	446
Observations Not Used	0
Total Observations	446

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	2431.65597730	
1	1	2431.65597730	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0
Residual	13.6211

Fit Statistics

-2 Res Log Likelihood	2431.7
AIC (smaller is better)	2433.7
AICC (smaller is better)	2433.7
BIC (smaller is better)	2435.2

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.5868	0.6567	441	6.98	<.0001
trtseq		Q300MG	-2.4827	0.4300	441	-5.77	<.0001
trtseq		Q600MG	-2.8111	0.4276	441	-6.57	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.4309	0.3725	441	1.16	0.2479
numcd	2		0	.	.	.	.
B_PSQIT			-0.6278	0.04454	441	-14.10	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	0	.	.	.	.
CENTRE	0002	0	.	.	.	.
CENTRE	0003	0	.	.	.	.
CENTRE	0004	0	.	.	.	.
CENTRE	0005	0	.	.	.	.
CENTRE	0006	0	.	.	.	.
CENTRE	0007	0	.	.	.	.
CENTRE	0009	0	.	.	.	.
CENTRE	0010	0	.	.	.	.
CENTRE	0011	0	.	.	.	.
CENTRE	0013	0	.	.	.	.
CENTRE	0014	0	.	.	.	.
CENTRE	0015	0	.	.	.	.
CENTRE	0016	0	.	.	.	.
CENTRE	0018	0	.	.	.	.
CENTRE	0019	0	.	.	.	.
CENTRE	0020	0	.	.	.	.
CENTRE	0022	0	.	.	.	.
CENTRE	0023	0	.	.	.	.
CENTRE	0025	0	.	.	.	.
CENTRE	0026	0	.	.	.	.
CENTRE	0027	0	.	.	.	.
CENTRE	0028	0	.	.	.	.
CENTRE	0029	0	.	.	.	.
CENTRE	0030	0	.	.	.	.
CENTRE	0031	0	.	.	.	.
CENTRE	0033	0	.	.	.	.
CENTRE	0034	0	.	.	.	.
CENTRE	0035	0	.	.	.	.
CENTRE	0036	0	.	.	.	.
CENTRE	0037	0	.	.	.	.
CENTRE	0039	0	.	.	.	.
CENTRE	0040	0	.	.	.	.
CENTRE	0041	0	.	.	.	.
CENTRE	0042	0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	441	25.67	<.0001
numcd	1	441	1.34	0.2479
B_PSQIT	1	441	198.71	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-4.9564	0.3100	441	-15.99	<.0001	0.05	-5.5656	-4.3472
trtseq	Q600MG	-5.2848	0.3075	441	-17.19	<.0001	0.05	-5.8891	-4.6805
trtseq	P	-2.4737	0.3112	441	-7.95	<.0001	0.05	-3.0853	-1.8620

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.3284	0.4273	441	0.77	0.4425	0.05	-0.5113	1.1682
trtseq	Q300MG	P	-2.4827	0.4300	441	-5.77	<.0001	0.05	-3.3279	-1.6376
trtseq	Q600MG	P	-2.8111	0.4276	441	-6.57	<.0001	0.05	-3.6516	-1.9707

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Model Information

Data Set	WORK.PSQIVSTXBL
Dependent Variable	C_PSQIT
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	312
Observations Used	312
Observations Not Used	0
Total Observations	312

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1649.70473343	
1	2	1649.68232103	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.04736
Residual	11.5332

Fit Statistics

-2 Res Log Likelihood	1649.7
AIC (smaller is better)	1653.7
AICC (smaller is better)	1653.7
BIC (smaller is better)	1656.8

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			3.7588	0.7201	238	5.22	<.0001
trtseq		Q300MG	-1.7184	0.4627	307	-3.71	0.0002
trtseq		Q600MG	-2.7584	0.4901	307	-5.63	<.0001
trtseq		P	0	.	.	.	.
numcd	1		-0.02126	0.4159	147	-0.05	0.9593
numcd	2		0	.	.	.	.
B_PSQIT			-0.6522	0.04919	306	-13.26	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.01087	0.2168	1	-0.05	0.9681
CENTRE	0002	-0.01186	0.2143	1	-0.06	0.9648
CENTRE	0003	0.001094	0.2143	1	0.01	0.9967
CENTRE	0004	-0.06932	0.2135	1	-0.32	0.8002
CENTRE	0005	0.02785	0.2116	1	0.13	0.9167
CENTRE	0006	-0.01290	0.2155	1	-0.06	0.9619
CENTRE	0007	0.01024	0.2151	1	0.05	0.9697
CENTRE	0009	-0.02200	0.2159	1	-0.10	0.9354
CENTRE	0010	-0.04403	0.2156	1	-0.20	0.8717
CENTRE	0011	-0.01178	0.2128	1	-0.06	0.9648
CENTRE	0013	0.02071	0.2151	1	0.10	0.9389
CENTRE	0014	-0.04727	0.2139	1	-0.22	0.8615
CENTRE	0015	0.01843	0.2168	1	0.09	0.9460
CENTRE	0016	-0.02123	0.2168	1	-0.10	0.9378
CENTRE	0018	0.005119	0.2155	1	0.02	0.9849
CENTRE	0019	-0.02374	0.2106	1	-0.11	0.9285
CENTRE	0020	0.01749	0.2144	1	0.08	0.9482
CENTRE	0022	0.04327	0.2047	1	0.21	0.8674
CENTRE	0023	-0.04396	0.2063	1	-0.21	0.8663
CENTRE	0025	-0.01288	0.2172	1	-0.06	0.9623
CENTRE	0026	0.05204	0.2135	1	0.24	0.8478
CENTRE	0027	0.008199	0.2159	1	0.04	0.9758
CENTRE	0028	0.1200	0.2124	1	0.57	0.6726
CENTRE	0029	-0.03821	0.2140	1	-0.18	0.8875
CENTRE	0030	-0.00355	0.2143	1	-0.02	0.9895
CENTRE	0031	0.04888	0.2135	1	0.23	0.8567
CENTRE	0033	-0.01232	0.2147	1	-0.06	0.9635
CENTRE	0034	0.000664	0.2151	1	0.00	0.9980
CENTRE	0035	-0.04723	0.2131	1	-0.22	0.8611
CENTRE	0036	-0.01610	0.2168	1	-0.07	0.9528
CENTRE	0037	0.001443	0.2151	1	0.01	0.9957
CENTRE	0039	-0.06833	0.2103	1	-0.32	0.8000
CENTRE	0040	0.03341	0.2168	1	0.15	0.9026
CENTRE	0041	0.07470	0.2147	1	0.35	0.7868
CENTRE	0042	0.03402	0.2168	1	0.16	0.9009

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=10 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	306	16.33	<.0001
numcd	1	147	0.00	0.9593
B_PSQIT	1	306	175.85	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-5.3978	0.3276	84.9	-16.48	<.0001	0.05	-6.0492	-4.7464
trtseq	Q600MG	-6.4379	0.3676	98.7	-17.51	<.0001	0.05	-7.1673	-5.7084
trtseq	P	-3.6794	0.3433	88.2	-10.72	<.0001	0.05	-4.3616	-2.9973

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	1.0401	0.4727	305	2.20	0.0285	0.05	0.1099	1.9702
trtseq	Q300MG	P	-1.7184	0.4627	307	-3.71	0.0002	0.05	-2.6287	-0.8080
trtseq	Q600MG	P	-2.7584	0.4901	307	-5.63	<.0001	0.05	-3.7228	-1.7941

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Model Information

Data Set	WORK.PSQIVSTXBL
Dependent Variable	C_PSQIT
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	Q300MG Q600MG P
numcd	2	1 2
CENTRE	35	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042

Dimensions

Covariance Parameters	2
Columns in X	7
Columns in Z	35
Subjects	1
Max Obs Per Subject	452
Observations Used	452
Observations Not Used	0
Total Observations	452

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	2483.08017986	
1	2	2482.97993917	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.07722
Residual	14.1291

Fit Statistics

-2 Res Log Likelihood	2483.0
AIC (smaller is better)	2487.0
AICC (smaller is better)	2487.0
BIC (smaller is better)	2490.1

Solution for Fixed Effects

Effect	numcd	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			4.0882	0.6712	369	6.09	<.0001
trtseq		Q300MG	-2.2181	0.4356	446	-5.09	<.0001
trtseq		Q600MG	-2.5168	0.4340	446	-5.80	<.0001
trtseq		P	0	.	.	.	.
numcd	1		0.2594	0.3826	231	0.68	0.4985
numcd	2		0	.	.	.	.
B_PSQIT			-0.6178	0.04519	447	-13.67	<.0001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.00298	0.2757	1	-0.01	0.9931
CENTRE	0002	-0.05949	0.2715	1	-0.22	0.8627
CENTRE	0003	0.01815	0.2715	1	0.07	0.9575
CENTRE	0004	-0.1532	0.2696	1	-0.57	0.6710
CENTRE	0005	0.05077	0.2623	1	0.19	0.8783
CENTRE	0006	-0.01691	0.2736	1	-0.06	0.9607
CENTRE	0007	-0.02041	0.2702	1	-0.08	0.9520
CENTRE	0009	0.03660	0.2722	1	0.13	0.9149
CENTRE	0010	0.07007	0.2696	1	0.26	0.8381
CENTRE	0011	-0.07314	0.2684	1	-0.27	0.8306
CENTRE	0013	0.09648	0.2708	1	0.36	0.7821
CENTRE	0014	-0.01757	0.2683	1	-0.07	0.9584
CENTRE	0015	0.05626	0.2742	1	0.21	0.8712
CENTRE	0016	-0.01480	0.2757	1	-0.05	0.9659
CENTRE	0018	0.07902	0.2708	1	0.29	0.8193
CENTRE	0019	0.03224	0.2606	1	0.12	0.9216
CENTRE	0020	0.02718	0.2709	1	0.10	0.9363
CENTRE	0022	-0.09192	0.2509	1	-0.37	0.7764
CENTRE	0023	-0.1010	0.2562	1	-0.39	0.7609
CENTRE	0025	-0.01940	0.2771	1	-0.07	0.9555
CENTRE	0026	0.1126	0.2652	1	0.42	0.7443
CENTRE	0027	-0.00229	0.2750	1	-0.01	0.9947
CENTRE	0028	0.1006	0.2636	1	0.38	0.7679
CENTRE	0029	0.04337	0.2658	1	0.16	0.8970
CENTRE	0030	-0.02143	0.2696	1	-0.08	0.9495
CENTRE	0031	0.05784	0.2659	1	0.22	0.8636
CENTRE	0033	-0.03152	0.2703	1	-0.12	0.9261
CENTRE	0034	-0.02116	0.2728	1	-0.08	0.9507
CENTRE	0035	-0.09272	0.2670	1	-0.35	0.7872
CENTRE	0036	-0.03851	0.2750	1	-0.14	0.9114
CENTRE	0037	0.01502	0.2728	1	0.06	0.9650
CENTRE	0039	-0.1730	0.2613	1	-0.66	0.6277
CENTRE	0040	0.03921	0.2764	1	0.14	0.9103
CENTRE	0041	0.08020	0.2715	1	0.30	0.8172
CENTRE	0042	0.03586	0.2764	1	0.13	0.9179

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	442	19.98	<.0001
numcd	1	231	0.46	0.4985
B_PSQIT	1	447	186.97	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	-5.1587	0.3194	126	-16.15	<.0001	0.05	-5.7908	-4.5267
trtseq	Q600MG	-5.4575	0.3191	117	-17.10	<.0001	0.05	-6.0894	-4.8255
trtseq	P	-2.9407	0.3198	130	-9.20	<.0001	0.05	-3.5733	-2.3081

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	Q300MG	Q600MG	0.2988	0.4334	442	0.69	0.4909	0.05	-0.5529	1.1505
trtseq	Q300MG	P	-2.2181	0.4356	446	-5.09	<.0001	0.05	-3.0741	-1.3620
trtseq	Q600MG	P	-2.5168	0.4340	446	-5.80	<.0001	0.05	-3.3697	-1.6639

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=6 ----------

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	148	C_PSQIT	CHG BL PSQI TOTAL SCORE	148	0	-4.73	4.21
		B_PSQIT	BL PSQI TOTAL SCORE	148	0	11.34	3.78
Q600MG	151	C_PSQIT	CHG BL PSQI TOTAL SCORE	151	0	-5.30	4.89
		B_PSQIT	BL PSQI TOTAL SCORE	151	0	11.74	4.18
P	147	C_PSQIT	CHG BL PSQI TOTAL SCORE	147	0	-2.46	4.18
		B_PSQIT	BL PSQI TOTAL SCORE	147	0	11.68	3.83

---------- WINDOWED VISIT=10 ----------

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	117	C_PSQIT	CHG BL PSQI TOTAL SCORE	117	0	-5.29	4.30
		B_PSQIT	BL PSQI TOTAL SCORE	117	0	11.21	3.70
Q600MG	93	C_PSQIT	CHG BL PSQI TOTAL SCORE	93	0	-6.44	4.33
		B_PSQIT	BL PSQI TOTAL SCORE	93	0	11.39	4.45
P	102	C_PSQIT	CHG BL PSQI TOTAL SCORE	102	0	-3.81	4.14
		B_PSQIT	BL PSQI TOTAL SCORE	102	0	11.59	3.71

---------- WINDOWED VISIT=99 ----------

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
Q300MG	150	C_PSQIT	CHG BL PSQI TOTAL SCORE	150	0	-5.03	4.34
		B_PSQIT	BL PSQI TOTAL SCORE	150	0	11.43	3.82
Q600MG	152	C_PSQIT	CHG BL PSQI TOTAL SCORE	152	0	-5.43	4.82
		B_PSQIT	BL PSQI TOTAL SCORE	152	0	11.61	4.16

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.2.7 PSQI Total Score Change from Baseline (ANCOVA - ITT)

---------- WINDOWED VISIT=99 ----------

The MEANS Procedure

trtseq	N Obs	Variable	Label	N	N Miss	Mean	Std Dev
P	150	C_PSQIT	CHG BL PSQI TOTAL SCORE	150	0	-2.99	4.25
		B_PSQIT	BL PSQI TOTAL SCORE	150	0	11.72	3.82

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/PSQI204H.SAS
GENERATED: 14JUL2005 11:42:06 iceadmn3

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Model Information

Data Set	WORK.GLUC
Dependent Variable	TL_VALUE
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	1 2 3
CENTRE	36	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0017 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042
DIABET_R	3	DIABETIC DIABETIC RISK NON DIABETIC

Dimensions

Covariance Parameters	2
Columns in X	8
Columns in Z	36
Subjects	1
Max Obs Per Subject	456
Observations Used	456
Observations Not Used	0
Total Observations	456

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3965.49743008	

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
1	3	3965.49474859	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.2776
Residual	365.01

Fit Statistics

-2 Res Log Likelihood	3965.5
AIC (smaller is better)	3969.5
AICC (smaller is better)	3969.5
BIC (smaller is better)	3972.7

Solution for Fixed Effects

Effect	trtseq	HISTORY OF DIABETES (RANDOM GLUCOSE)	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			24.1190	6.4340	432	3.75	0.0002
trtseq	1		-0.5494	2.1791	450	-0.25	0.8011
trtseq	2		2.1752	2.2117	450	0.98	0.3259
trtseq	3		0	.	.	.	.
TLBVALUE			-0.2486	0.07313	444	-3.40	0.0007
DIABET_R		DIABETIC	14.9969	5.0951	433	2.94	0.0034
DIABET_R		DIABETIC RISK	3.2154	2.4009	449	1.34	0.1812
DIABET_R		NON DIABETIC	0	.	.	.	.

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12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	0.000703	0.5263	1	0.00	0.9991
CENTRE	0002	0.04186	0.5251	1	0.08	0.9494
CENTRE	0003	-0.01959	0.5250	1	-0.04	0.9763
CENTRE	0004	0.05274	0.5246	1	0.10	0.9362
CENTRE	0005	-0.02257	0.5225	1	-0.04	0.9725
CENTRE	0006	-0.00674	0.5257	1	-0.01	0.9918
CENTRE	0007	0.000407	0.5250	1	0.00	0.9995
CENTRE	0009	-0.01697	0.5253	1	-0.03	0.9794
CENTRE	0010	0.002125	0.5242	1	0.00	0.9974
CENTRE	0011	0.01170	0.5239	1	0.02	0.9858
CENTRE	0013	-0.06065	0.5250	1	-0.12	0.9268
CENTRE	0014	0.002460	0.5243	1	0.00	0.9970
CENTRE	0015	0.05146	0.5261	1	0.10	0.9379
CENTRE	0016	-0.00845	0.5265	1	-0.02	0.9898
CENTRE	0017	-0.01236	0.5267	1	-0.02	0.9851
CENTRE	0018	0.05246	0.5248	1	0.10	0.9366
CENTRE	0019	-0.03104	0.5216	1	-0.06	0.9622
CENTRE	0020	0.000554	0.5240	1	0.00	0.9993
CENTRE	0022	-0.09439	0.5189	1	-0.18	0.8855
CENTRE	0023	0.03059	0.5203	1	0.06	0.9626
CENTRE	0025	-0.06440	0.5265	1	-0.12	0.9225
CENTRE	0026	0.07812	0.5231	1	0.15	0.9056
CENTRE	0027	-0.03388	0.5261	1	-0.06	0.9591
CENTRE	0028	-0.1195	0.5223	1	-0.23	0.8568
CENTRE	0029	0.07548	0.5240	1	0.14	0.9089
CENTRE	0030	0.01313	0.5248	1	0.03	0.9841
CENTRE	0031	-0.07669	0.5233	1	-0.15	0.9074
CENTRE	0033	-0.00873	0.5248	1	-0.02	0.9894
CENTRE	0034	-0.01297	0.5255	1	-0.02	0.9843
CENTRE	0035	0.000298	0.5246	1	0.00	0.9996
CENTRE	0036	0.01715	0.5261	1	0.03	0.9793
CENTRE	0037	0.007505	0.5255	1	0.01	0.9909
CENTRE	0039	0.1592	0.5226	1	0.30	0.8118
CENTRE	0040	-0.00222	0.5265	1	-0.00	0.9973
CENTRE	0041	-0.00308	0.5250	1	-0.01	0.9963
CENTRE	0042	-0.00368	0.5265	1	-0.01	0.9956

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	446	0.85	0.4267
TLBVALUE	1	444	11.55	0.0007
DIABET_R	2	441	4.83	0.0084

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	8.1663	2.2152	296	3.69	0.0003	0.05	3.8067	12.5259
trtseq	2	10.8908	2.2683	290	4.80	<.0001	0.05	6.4264	15.3552
trtseq	3	8.7156	2.2138	296	3.94	0.0001	0.05	4.3588	13.0725

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	2	-2.7245	2.1943	444	-1.24	0.2150	0.05	-7.0370	1.5880
trtseq	1	3	-0.5494	2.1791	450	-0.25	0.8011	0.05	-4.8318	3.7330
trtseq	2	3	2.1752	2.2117	450	0.98	0.3259	0.05	-2.1715	6.5218

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Model Information

Data Set	WORK.INS
Dependent Variable	tl_value
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	1 2 3
CENTRE	36	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0017 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042
DIABET_R	3	DIABETIC DIABETIC RISK NON DIABETIC

Dimensions

Covariance Parameters	2
Columns in X	8
Columns in Z	36
Subjects	1
Max Obs Per Subject	450
Observations Used	450
Observations Not Used	0
Total Observations	450

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	1019.18217144	

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12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
1	3	1019.15814526	0.00000004
2	1	1019.15814094	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0.001193
Residual	0.5454

Fit Statistics

-2 Res Log Likelihood	1019.2
AIC (smaller is better)	1023.2
AICC (smaller is better)	1023.2
BIC (smaller is better)	1026.3

Solution for Fixed Effects

Effect	trtseq	HISTORY OF DIABETES (RANDOM GLUCOSE)	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.1777	0.1191	347	9.89	<.0001
trtseq	1		0.06405	0.08467	444	0.76	0.4498
trtseq	2		0.2357	0.08645	444	2.73	0.0066
trtseq	3		0	.	.	.	.
tlbvalue			0.5446	0.04988	440	10.92	<.0001
DIABET_R		DIABETIC	-0.3155	0.1882	434	-1.68	0.0944
DIABET_R		DIABETIC RISK	0.4045	0.1018	442	3.97	<.0001
DIABET_R		NON DIABETIC	0	.	.	.	.

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12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	-0.00182	0.03442	1	-0.05	0.9663
CENTRE	0002	-0.00620	0.03421	1	-0.18	0.8858
CENTRE	0003	-0.00565	0.03418	1	-0.17	0.8957
CENTRE	0004	0.007075	0.03410	1	0.21	0.8698
CENTRE	0005	0.003980	0.03373	1	0.12	0.9252
CENTRE	0006	-0.00043	0.03432	1	-0.01	0.9920
CENTRE	0007	-0.00439	0.03418	1	-0.13	0.9187
CENTRE	0009	0.004615	0.03424	1	0.13	0.9147
CENTRE	0010	-0.00196	0.03408	1	-0.06	0.9635
CENTRE	0011	0.006397	0.03397	1	0.19	0.8815
CENTRE	0013	0.001216	0.03418	1	0.04	0.9774
CENTRE	0014	0.003792	0.03404	1	0.11	0.9294
CENTRE	0015	0.000035	0.03439	1	0.00	0.9994
CENTRE	0016	-0.00215	0.03446	1	-0.06	0.9603
CENTRE	0017	-0.00277	0.03450	1	-0.08	0.9489
CENTRE	0018	0.006762	0.03417	1	0.20	0.8756
CENTRE	0019	-0.00236	0.03357	1	-0.07	0.9554
CENTRE	0020	0.008577	0.03400	1	0.25	0.8427
CENTRE	0022	-0.01144	0.03309	1	-0.35	0.7881
CENTRE	0023	0.01363	0.03335	1	0.41	0.7530
CENTRE	0025	-0.00099	0.03446	1	-0.03	0.9816
CENTRE	0026	0.006485	0.03385	1	0.19	0.8795
CENTRE	0027	-0.00120	0.03439	1	-0.03	0.9779
CENTRE	0028	-0.00563	0.03372	1	-0.17	0.8947
CENTRE	0029	-0.00288	0.03400	1	-0.08	0.9461
CENTRE	0030	0.001932	0.03414	1	0.06	0.9640
CENTRE	0031	-0.01449	0.03390	1	-0.43	0.7429
CENTRE	0033	-0.00554	0.03414	1	-0.16	0.8977
CENTRE	0034	0.000751	0.03428	1	0.02	0.9861
CENTRE	0035	0.003558	0.03414	1	0.10	0.9339
CENTRE	0036	0.001301	0.03439	1	0.04	0.9759
CENTRE	0037	-0.00325	0.03428	1	-0.09	0.9398
CENTRE	0039	0.000845	0.03378	1	0.03	0.9841
CENTRE	0040	-0.00130	0.03446	1	-0.04	0.9759
CENTRE	0041	0.003112	0.03418	1	0.09	0.9422
CENTRE	0042	0.000401	0.03446	1	0.01	0.9926

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	440	3.96	0.0198
tlbvalue	1	440	119.19	<.0001
DIABET_R	2	439	10.72	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	2.4859	0.08507	275	29.22	<.0001	0.05	2.3184	2.6534
trtseq	2	2.6576	0.08760	279	30.34	<.0001	0.05	2.4852	2.8300
trtseq	3	2.4219	0.08523	298	28.41	<.0001	0.05	2.2541	2.5896

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	2	-0.1717	0.08580	439	-2.00	0.0460	0.05	-0.3403	-0.00307
trtseq	1	3	0.06405	0.08467	444	0.76	0.4498	0.05	-0.1024	0.2305
trtseq	2	3	0.2357	0.08645	444	2.73	0.0066	0.05	0.06584	0.4057

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Model Information

Data Set	WORK.HOMA
Dependent Variable	TL_VALUE
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	1 2 3
CENTRE	36	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0017 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042
DIABET_R	3	DIABETIC DIABETIC RISK NON DIABETIC

Dimensions

Covariance Parameters	2
Columns in X	8
Columns in Z	36
Subjects	1
Max Obs Per Subject	426
Observations Used	426
Observations Not Used	0
Total Observations	426

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3188.05030921	

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
1	1	3188.05030921	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0
Residual	107.52

Fit Statistics

-2 Res Log Likelihood	3188.1
AIC (smaller is better)	3190.1
AICC (smaller is better)	3190.1
BIC (smaller is better)	3191.6

Solution for Fixed Effects

Effect	trtseq	HISTORY OF DIABETES (RANDOM GLUCOSE)	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			1.2772	0.9277	420	1.38	0.1693
trtseq	1		1.6585	1.2238	420	1.36	0.1761
trtseq	2		3.9069	1.2389	420	3.15	0.0017
trtseq	3		0	.	.	.	.
TLBVALUE			0.4344	0.07246	420	5.99	<.0001
DIABET_R		DIABETIC	-4.5781	2.8427	420	-1.61	0.1080
DIABET_R		DIABETIC RISK	4.7425	1.3776	420	3.44	0.0006
DIABET_R		NON DIABETIC	0	.	.	.	.

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12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	0	.	.	.	.
CENTRE	0002	0	.	.	.	.
CENTRE	0003	0	.	.	.	.
CENTRE	0004	0	.	.	.	.
CENTRE	0005	0	.	.	.	.
CENTRE	0006	0	.	.	.	.
CENTRE	0007	0	.	.	.	.
CENTRE	0009	0	.	.	.	.
CENTRE	0010	0	.	.	.	.
CENTRE	0011	0	.	.	.	.
CENTRE	0013	0	.	.	.	.
CENTRE	0014	0	.	.	.	.
CENTRE	0015	0	.	.	.	.
CENTRE	0016	0	.	.	.	.
CENTRE	0017	0	.	.	.	.
CENTRE	0018	0	.	.	.	.
CENTRE	0019	0	.	.	.	.
CENTRE	0020	0	.	.	.	.
CENTRE	0022	0	.	.	.	.
CENTRE	0023	0	.	.	.	.
CENTRE	0025	0	.	.	.	.
CENTRE	0026	0	.	.	.	.
CENTRE	0027	0	.	.	.	.
CENTRE	0028	0	.	.	.	.
CENTRE	0029	0	.	.	.	.
CENTRE	0030	0	.	.	.	.
CENTRE	0031	0	.	.	.	.
CENTRE	0033	0	.	.	.	.
CENTRE	0034	0	.	.	.	.
CENTRE	0035	0	.	.	.	.
CENTRE	0036	0	.	.	.	.
CENTRE	0037	0	.	.	.	.
CENTRE	0039	0	.	.	.	.
CENTRE	0040	0	.	.	.	.
CENTRE	0041	0	.	.	.	.
CENTRE	0042	0	.	.	.	.

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	420	5.00	0.0071
TLBVALUE	1	420	35.94	<.0001
DIABET_R	2	420	8.07	0.0004

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	4.3356	1.2427	420	3.49	0.0005	0.05	1.8929	6.7784
trtseq	2	6.5841	1.2634	420	5.21	<.0001	0.05	4.1007	9.0675
trtseq	3	2.6772	1.2648	420	2.12	0.0349	0.05	0.1911	5.1633

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	2	-2.2484	1.2360	420	-1.82	0.0696	0.05	-4.6779	0.1810
trtseq	1	3	1.6585	1.2238	420	1.36	0.1761	0.05	-0.7470	4.0640
trtseq	2	3	3.9069	1.2389	420	3.15	0.0017	0.05	1.4716	6.3422

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Model Information

Data Set	WORK.QUICKI
Dependent Variable	TL_VALUE
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Satterthwaite

Class Level Information

Class	Levels	Values
trtseq	3	1 2 3
CENTRE	36	0001 0002 0003 0004 0005 0006 0007 0009 0010 0011 0013 0014 0015 0016 0017 0018 0019 0020 0022 0023 0025 0026 0027 0028 0029 0030 0031 0033 0034 0035 0036 0037 0039 0040 0041 0042
DIABET_R	3	DIABETIC DIABETIC RISK NON DIABETIC

Dimensions

Covariance Parameters	2
Columns in X	8
Columns in Z	36
Subjects	1
Max Obs Per Subject	426
Observations Used	426
Observations Not Used	0
Total Observations	426

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	-1493.99907278	

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The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
1	1	-1493.99907278	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
CENTRE	0
Residual	0.001587

Fit Statistics

-2 Res Log Likelihood	-1494.0
AIC (smaller is better)	-1492.0
AICC (smaller is better)	-1492.0
BIC (smaller is better)	-1490.4

Solution for Fixed Effects

Effect	trtseq	HISTORY OF DIABETES (RANDOM GLUCOSE)	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			0.1836	0.01773	420	10.36	<.0001
trtseq	1		-0.00013	0.004720	420	-0.03	0.9784
trtseq	2		-0.00902	0.004757	420	-1.90	0.0586
trtseq	3		0	.	.	.	.
TLBVALUE			0.4480	0.04777	420	9.38	<.0001
DIABET_R		DIABETIC	0.01593	0.01071	420	1.49	0.1379
DIABET_R		DIABETIC RISK	-0.02223	0.005608	420	-3.96	<.0001
DIABET_R		NON DIABETIC	0	.	.	.	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/STAT/CHEM210H.SAS
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12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Solution for Random Effects

Effect	CENTRE	Estimate	Std Err Pred	DF	t Value	Pr > |t|
CENTRE	0001	0	.	.	.	.
CENTRE	0002	0	.	.	.	.
CENTRE	0003	0	.	.	.	.
CENTRE	0004	0	.	.	.	.
CENTRE	0005	0	.	.	.	.
CENTRE	0006	0	.	.	.	.
CENTRE	0007	0	.	.	.	.
CENTRE	0009	0	.	.	.	.
CENTRE	0010	0	.	.	.	.
CENTRE	0011	0	.	.	.	.
CENTRE	0013	0	.	.	.	.
CENTRE	0014	0	.	.	.	.
CENTRE	0015	0	.	.	.	.
CENTRE	0016	0	.	.	.	.
CENTRE	0017	0	.	.	.	.
CENTRE	0018	0	.	.	.	.
CENTRE	0019	0	.	.	.	.
CENTRE	0020	0	.	.	.	.
CENTRE	0022	0	.	.	.	.
CENTRE	0023	0	.	.	.	.
CENTRE	0025	0	.	.	.	.
CENTRE	0026	0	.	.	.	.
CENTRE	0027	0	.	.	.	.
CENTRE	0028	0	.	.	.	.
CENTRE	0029	0	.	.	.	.
CENTRE	0030	0	.	.	.	.
CENTRE	0031	0	.	.	.	.
CENTRE	0033	0	.	.	.	.
CENTRE	0034	0	.	.	.	.
CENTRE	0035	0	.	.	.	.
CENTRE	0036	0	.	.	.	.
CENTRE	0037	0	.	.	.	.
CENTRE	0039	0	.	.	.	.
CENTRE	0040	0	.	.	.	.
CENTRE	0041	0	.	.	.	.
CENTRE	0042	0	.	.	.	.

12.1.9.3.7 Glucose and Insulin Analysis(ANCOVA - Safety)

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtseq	2	420	2.35	0.0963
TLBVALUE	1	420	87.98	<.0001
DIABET_R	2	420	10.05	<.0001

Least Squares Means

Effect	trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	0.3386	0.004808	420	70.43	<.0001	0.05	0.3292	0.3481
trtseq	2	0.3298	0.004859	420	67.87	<.0001	0.05	0.3202	0.3393
trtseq	3	0.3388	0.004780	420	70.88	<.0001	0.05	0.3294	0.3482

Differences of Least Squares Means

Effect	trtseq	_trtseq	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
trtseq	1	2	0.008893	0.004754	420	1.87	0.0621	0.05	-0.00045	0.01824
trtseq	1	3	-0.00013	0.004720	420	-0.03	0.9784	0.05	-0.00940	0.009149
trtseq	2	3	-0.00902	0.004757	420	-1.90	0.0586	0.05	-0.01837	0.000329

12.1.9.3.8.1.5 SAS Total Score Increase from Baseline (Logistic Regression)

The GENMOD Procedure

Model Information

Data Set	WORK.SAS
Distribution	Binomial
Link Function	Logit
Dependent Variable	response
Observations Used	444

Class Level Information

Class	Levels	Values
trtseq	3	P Q300MG Q600MG
numcd	2	1 2

Response Profile

Ordered Value	response	Total Frequency
1	1	49
2	0	395

PROC GENMOD is modeling the probability that response='1'.

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	439	301.8635	0.6876
Scaled Deviance	439	301.8635	0.6876
Pearson Chi-Square	439	439.9540	1.0022
Scaled Pearson X2	439	439.9540	1.0022
Log Likelihood		-150.9318	

Algorithm converged.

12.1.9.3.8.1.5 SAS Total Score Increase from Baseline (Logistic Regression)

The GENMOD Procedure

Analysis Of Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept		1	-1.4834	0.3163	-2.1032	-0.8635	22.00	<.0001
B_SIMP		1	-0.2471	0.1734	-0.5870	0.0927	2.03	0.1541
numcd	1	1	-0.1402	0.3174	-0.7623	0.4819	0.20	0.6587
numcd	2	0	0.0000	0.0000	0.0000	0.0000	.	.
trtseq	P	1	-0.6634	0.3728	-1.3941	0.0673	3.17	0.0752
trtseq	Q300MG	1	-0.6067	0.3656	-1.3233	0.1100	2.75	0.0971
trtseq	Q600MG	0	0.0000	0.0000	0.0000	0.0000	.	.
Scale		0	1.0000	0.0000	1.0000	1.0000		

NOTE: The scale parameter was held fixed.

12.1.9.3.8.1.6 BARS Global Assessment Increase from Baseline (Logistic Regression)

The GENMOD Procedure

Model Information

Data Set	WORK.BARS2
Distribution	Binomial
Link Function	Logit
Dependent Variable	response
Observations Used	447

Class Level Information

Class	Levels	Values
trtseq	3	P Q300MG Q600MG
numcd	2	1 2

Response Profile

Ordered Value	response	Total Frequency
1	1	45
2	0	402

PROC GENMOD is modeling the probability that response='1'.

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	442	289.7446	0.6555
Scaled Deviance	442	289.7446	0.6555
Pearson Chi-Square	442	446.5614	1.0103
Scaled Pearson X2	442	446.5614	1.0103
Log Likelihood		-144.8723	

Algorithm converged.

12.1.9.3.8.1.6 BARS Global Assessment Increase from Baseline (Logistic Regression)

The GENMOD Procedure

Analysis Of Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept		1	-1.7623	0.3289	-2.4069	-1.1176	28.71	<.0001
B_GCLASS		1	0.0209	0.2758	-0.5197	0.5614	0.01	0.9397
numcd	1	1	-0.3122	0.3238	-0.9468	0.3224	0.93	0.3349
numcd	2	0	0.0000	0.0000	0.0000	0.0000	.	.
trtseq	P	1	-0.3943	0.3855	-1.1499	0.3613	1.05	0.3064
trtseq	Q300MG	1	-0.3375	0.3777	-1.0778	0.4027	0.80	0.3715
trtseq	Q600MG	0	0.0000	0.0000	0.0000	0.0000	.	.
Scale		0	1.0000	0.0000	1.0000	1.0000		

NOTE: The scale parameter was held fixed.

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Table of trtseq by emany

trtseq(RANDOM TREATMENT ASSIGNMENT)

	emany		
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	172 47.91 96.09 49.86	7 1.95 3.91 50.00	179 49.86
P	173 48.19 96.11 50.14	7 1.95 3.89 50.00	180 50.14
Total	345 96.10	14 3.90	359 100.00

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Table of trtseq by emany

trtseq(RANDOM TREATMENT ASSIGNMENT)

	emany		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	176 48.89 97.78 50.43	4 1.11 2.22 36.36	180 50.00
P	173 48.06 96.11 49.57	7 1.94 3.89 63.64	180 50.00
Total	349 96.94	11 3.06	360 100.00

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Table 1 of trtseq by emany
Controlling for numcd=BIPOLAR I

trtseq(RANDOM TREATMENT ASSIGNMENT)

	emany	
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	114 47.90 95.00 50.67	6 2.52 5.00 46.15	120 50.42
P	111 46.64 94.07 49.33	7 2.94 5.93 53.85	118 49.58
Total	225 94.54	13 5.46	238 100.00

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Statistics for Table 1 of trtseq by emany
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	0.1001	0.7517
Likelihood Ratio Chi-Square	1	0.1002	0.7516
Continuity Adj. Chi-Square	1	0.0010	0.9751
Mantel-Haenszel Chi-Square	1	0.0997	0.7522
Phi Coefficient		0.0205	
Contingency Coefficient		0.0205	
Cramer's V		0.0205	

Fisher's Exact Test

Cell (1,1) Frequency (F)	114
Left-sided Pr <= F	0.7256
Right-sided Pr >= F	0.4874
Table Probability (P)	0.2130
Two-sided Pr <= P	0.7832

Sample Size = 238

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Table 2 of trtseq by emany
Controlling for numcd=BIPOLAR II

trtseq(RANDOM TREATMENT ASSIGNMENT)

	emany	
Frequency Percent Row Pct Col Pct	0	1	Total
Q300MG	58 47.93 98.31 48.33	1 0.83 1.69 100.00	59 48.76
P	62 51.24 100.00 51.67	0 0.00 0.00 0.00	62 51.24
Total	120 99.17	1 0.83	121 100.00

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Statistics for Table 2 of trtseq by emany
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	1.0596	0.3033
Likelihood Ratio Chi-Square	1	1.4453	0.2293
Continuity Adj. Chi-Square	1	0.0006	0.9801
Mantel-Haenszel Chi-Square	1	1.0508	0.3053
Phi Coefficient		-0.0936	
Contingency Coefficient		0.0932	
Cramer's V		-0.0936	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	58
Left-sided Pr <= F	0.4876
Right-sided Pr >= F	1.0000
Table Probability (P)	0.4876
Two-sided Pr <= P	0.4876

Sample Size = 121

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Summary Statistics for trtseq by emany
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	0.0005	0.9816
2	Row Mean Scores Differ	1	0.0005	0.9816
3	General Association	1	0.0005	0.9816

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	1.0128	0.3461	2.9636
	Logit **	1.0360	0.3593	2.9870
Cohort (Col1 Risk)	Mantel-Haenszel	1.0005	0.9598	1.0429
	Logit	0.9892	0.9605	1.0187
Cohort (Col2 Risk)	Mantel-Haenszel	0.9880	0.3568	2.7357
	Logit **	0.9616	0.3517	2.6297

** These logit estimators use a correction of 0.5 in every cell of those tables that contain a zero.

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	1.1596
DF	1
Pr > ChiSq	0.2816

Total Sample Size = 359

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12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Table 1 of trtseq by emany
Controlling for numcd=BIPOLAR I

trtseq(RANDOM TREATMENT ASSIGNMENT)

	emany		
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	119 50.00 99.17 51.74	1 0.42 0.83 12.50	120 50.42
P	111 46.64 94.07 48.26	7 2.94 5.93 87.50	118 49.58
Total	230 96.64	8 3.36	238 100.00

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Statistics for Table 1 of trtseq by emany
Controlling for numcd=BIPOLAR I

Statistic	DF	Value	Prob
Chi-Square	1	4.7618	0.0291
Likelihood Ratio Chi-Square	1	5.3235	0.0210
Continuity Adj. Chi-Square	1	3.3215	0.0684
Mantel-Haenszel Chi-Square	1	4.7418	0.0294
Phi Coefficient		0.1414	
Contingency Coefficient		0.1401	
Cramer's V		0.1414	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	119
Left-sided Pr <= F	0.9968
Right-sided Pr >= F	0.0311
Table Probability (P)	0.0279
Two-sided Pr <= P	0.0348

Sample Size = 238

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Table 2 of trtseq by emany
Controlling for numcd=BIPOLAR II

trtseq(RANDOM TREATMENT ASSIGNMENT)

	emany	
Frequency Percent Row Pct Col Pct	0	1	Total
Q600MG	57 46.72 95.00 47.90	3 2.46 5.00 100.00	60 49.18
P	62 50.82 100.00 52.10	0 0.00 0.00 0.00	62 50.82
Total	119 97.54	3 2.46	122 100.00

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Statistics for Table 2 of trtseq by emany
Controlling for numcd=BIPOLAR II

Statistic	DF	Value	Prob
Chi-Square	1	3.1782	0.0746
Likelihood Ratio Chi-Square	1	4.3362	0.0373
Continuity Adj. Chi-Square	1	1.4354	0.2309
Mantel-Haenszel Chi-Square	1	3.1521	0.0758
Phi Coefficient		-0.1614	
Contingency Coefficient		0.1593	
Cramer's V		-0.1614	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	57
Left-sided Pr <= F	0.1159
Right-sided Pr >= F	1.0000
Table Probability (P)	0.1159
Two-sided Pr <= P	0.1159

Sample Size = 122

12.1.9.3.8.1.7 Treatment Emergent Mania (CMH)

The FREQ Procedure

Summary Statistics for trtseq by emany
Controlling for numcd

Cochran-Mantel-Haenszel Statistics (Based on Table Scores)

Statistic	Alternative Hypothesis	DF	Value	Prob
1	Nonzero Correlation	1	0.8503	0.3565
2	Row Mean Scores Differ	1	0.8503	0.3565
3	General Association	1	0.8503	0.3565

Estimates of the Common Relative Risk (Row1/Row2)

Type of Study	Method	Value	95% Confidence Limits	
Case-Control (Odds Ratio)	Mantel-Haenszel	1.7579	0.5147	6.0044
	Logit **	1.9478	0.3475	10.9166
Cohort (Col1 Risk)	Mantel-Haenszel	1.0175	0.9801	1.0562
	Logit	1.0104	0.9736	1.0485
Cohort (Col2 Risk)	Mantel-Haenszel	0.5724	0.1706	1.9207
	Logit **	0.5222	0.0956	2.8540

** These logit estimators use a correction of 0.5 in every cell of those tables that contain a zero.

Breslow-Day Test for Homogeneity of the Odds Ratios

Chi-Square	7.6403
DF	1
Pr > ChiSq	0.0057

Total Sample Size = 360

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AstraZeneca

Clinical Study Report: Appendix 12.1.10

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.10

Documentation of assay methods, inter-laboratory standardisation methods and related quality assurance procedures

Not applicable.

AstraZeneca

Clinical Study Report: Appendix 12.1.11.

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.11
Publications based on the study

Publication

Calabrese JR, Keck PE Jr, Macfadden W, Minkwitz M, Ketter TA, Weisler RH, Cutler AJ, McCoy R, Wilson E, Mullen J. A randomised, double-blind, placebo-controlled trial of quetiapine in the treatment of bipolar I or II depression. Am J Psychiatry 2005; 16.

Article

A Randomized, Double-Blind, Placebo-Controlled Trial of Quetiapine in the Treatment of Bipolar I or II Depression

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Paul E. Keck, Jr., M.D.

Wayne Macfadden, M.D.

Margaret Minkwitz, Ph.D.

Terence A. Ketter, M.D.

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Jamie Mullen, M.D.

The BOLDER Study Group

Objective: There is a major unmet need for effective options in the treatment of bipolar depression.

Method: Five hundred forty-two outpatients with bipolar I (N=360) or II (N=182) disorder experiencing a major depressive episode (DSM-IV) were randomly assigned to 8 weeks of quetiapine (600 or 300 mg/day) or placebo. The primary efficacy measure was mean change from baseline to week 8 in the Montgomery-Åsberg Depression Rating Scale total score. Additional efficacy assessments included the Hamilton Depression Rating Scale, Clinical Global Impression of severity and improvement, Hamilton Anxiety Rating Scale, Pittsburgh Sleep Quality Index, and Quality of Life Enjoyment and Satisfaction Questionnaire.

Results: Quetiapine at either dose demonstrated statistically significant improvement in Montgomery-Åsberg Depression Rating Scale total scores compared with placebo from week 1 onward. The proportions of patients meeting response criteria (≥50% Montgomery-Åsberg Depression Rating Scale score improvement) at the final assessment in the groups taking 600 and 300 mg/day of quetiapine were 58.2% and 57.6%, respectively, versus 36.1% for placebo. The proportions of patients meeting remission criteria (Montgomery-Åsberg Depression Rating Scale ≤12) were 52.9% in the groups taking 600 and 300 mg/day of quetiapine versus 28.4% for placebo. Quetiapine at 600 and 300 mg/day significantly improved 9 of 10 and 8 of 10 Montgomery-Åsberg Depression Rating Scale items, respectively, compared to placebo, including the core symptoms of depression. Treatment-emergent mania rates were low and similar for the quetiapine and placebo groups (3.2% and 3.9%, respectively).

Conclusions: Quetiapine monotherapy is efficacious and well tolerated for the treatment of bipolar depression.

(Am J Psychiatry 2005; 162:1351–1360)

Depressive episodes in bipolar I and II disorder are an important source of morbidity and mortality. While symptomatic, patients with bipolar I disorder experience depressive symptoms for about threefold longer than manic symptoms, and the recovery time is considerably longer for depressive than manic episodes (1–4). Symptomatic patients with bipolar II disorder spend almost 40 times longer depressed than hypomanic patients (5). Bipolar depression is associated with high rates of disability (6) and an increased risk of suicide, which occurs in 10% to 20% of patients with bipolar disorder (7).

Although multiple agents, including several atypical antipsychotics, have demonstrated efficacy in the treatment of the manic phase of bipolar I disorder (8), the acute treatment of bipolar depression has not been as well studied (9). Lithium and lamotrigine are recommended as initial treatments for acute bipolar I depression (10, 11). However, the response of bipolar depression to lithium is often incomplete in a substantial proportion of patients (12), and the efficacy of lamotrigine in the treatment of acute bipolar I depression has only been demonstrated in one adequately powered placebo-controlled trial (13).

More recently, the atypical antipsychotic olanzapine was found to be superior to placebo in the treatment of acute bipolar I depression as monotherapy when data were pooled from two 8-week trials (14). Fixed doses of olanzapine in combination with the antidepressant fluoxetine were administered to small groups of patients in these studies and were found to be both superior to placebo and superior to olanzapine monotherapy.

Quetiapine is efficacious in the treatment of acute bipolar mania, both as monotherapy and in combination with other mood stabilizers (15, 16). Preliminary evidence for the efficacy of quetiapine in the treatment of depressive symptoms in a variety of psychotic and mood disorders (including bipolar disorder, rapid-cycling bipolar disorder, and adolescent mania) has been reported in several randomized or open-label studies (17–24).

Based on the need for new treatment options for bipolar depression, the effectiveness of atypical antipsychotics in acute mania, and the emerging evidence for their use in bipolar depression, we evaluated the efficacy and safety of quetiapine compared with placebo in the treatment of depressive episodes in patients with bipolar I or bipolar II disorder.

Method

This double-blind, randomized, fixed-dose, placebo-controlled, parallel-group monotherapy study of quetiapine versus placebo was conducted at 39 centers in the United States between September 2002 and October 2003. After a washout period of at least five half-lives of any prior psychotropic medications, subjects were treated for 8 weeks to evaluate the efficacy, safety, and tolerability of 600 and 300 mg/day of quetiapine and placebo in the treatment of depressive episodes in adult patients with bipolar I or II disorder.

The study was approved by institutional review boards for each site and performed in accordance with the current amendment of the Declaration of Helsinki and the International Conference on Harmonization/Good Clinical Practice guidelines. Written informed consent was obtained from all subjects before participation.

Patient Population

Outpatients ages 18 to 65 years who met DSM-IV criteria for bipolar I or II disorder and were experiencing a major depressive episode were eligible for inclusion in the study. The diagnosis was confirmed with the Structured Clinical Interview for DSM-IV. The patients were required to have a Hamilton Depression Rating Scale 17-item score ≥20 (25), a Hamilton depression scale item 1 score ≥2, and a Young Mania Rating Scale (26) score ≤12 at both the screening and randomization visits. Inclusion criteria were based on the Hamilton depression scale rather than the primary efficacy measure (the Montgomery-Åsberg Depression Rating Scale [27]).

Patients were excluded from the study if they were diagnosed with an axis I disorder other than bipolar disorder that was the primary focus of treatment within 6 months before the screening, if the current episode of depression exceeded 12 months or was less than 4 weeks in duration, or if they had a history of nonresponse to an adequate (6-week) trial of more than two classes of antidepressants during the current episode. Additional exclusion criteria included a diagnosis of substance dependence (DSM-IV) or substance use (except for nicotine) within 12 months before the screening or a clinically significant medical illness. Patients who posed a current serious suicidal or homicidal risk were also excluded. Patients were not permitted to take benzodiazepines during the washout period, and only limited use was permitted during the first 3 weeks after random assignment.

Random assignment was achieved in a non-center-specific manner with an interactive voice-response central randomization service. Random assignment was stratified according to bipolar type (I or II) to ensure a relative balance in the total number of patients among groups (1:1:1). The patients were randomly assigned to one of three groups: quetiapine, 600 mg/day; quetiapine, 300 mg/day; or placebo.

Study Medication

Quetiapine (600 mg/day or 300 mg/day) or placebo was administered orally, in a single dose, once a day at bedtime. Quetiapine was initiated at 50 mg/day and administered to achieve a target dose of 300 mg/day by day 4 or 600 mg/day by week 1. All packaging of treatments was identical, with placebo and active tablets identical in appearance and number.

Prior and Concomitant Medication

Nonpsychotropic medication, including over-the-counter medications taken before entry into the study could be continued. Zolpidem tartrate (5–10 mg/day at bedtime for insomnia) and lorazepam (1–3 mg/day for severe anxiety) were permitted at the discretion of the investigator and only during the first 3 weeks of treatment but were withheld for 8 hours before psychiatric assessments were conducted. The use of all other psychotropic drugs was prohibited during the study.

Efficacy Evaluations

Clinical assessments were conducted at baseline and weekly from weeks 1 to 8. The primary efficacy variable was the mean change in the Montgomery-Åsberg Depression Rating Scale total score from baseline to week 8 (27).

Additional efficacy evaluations included a change from baseline to each assessment on the Montgomery-Åsberg Depression Rating Scale, the proportion of patients who achieved a protocol-defined response (≥50% reduction from baseline score on the Montgomery-Åsberg Depression Rating Scale), the time to response, the proportion of patients who achieved remission (Montgomery-Åsberg Depression Rating Scale score ≤12), the time to remission, as well as a Montgomery-Åsberg Depression Rating Scale item analysis. The change from baseline to each assessment on the Hamilton depression scale, the Clinical Global Impression (CGI) (28) severity of illness score, and the CGI improvement score were also assessed.

The effect of quetiapine on anxiety symptoms was assessed with the Hamilton Anxiety Rating Scale (29). Mean change from baseline to each assessment and at week 8 in the Hamilton anxiety scale total score was determined.

Quality of sleep was assessed with the Pittsburgh Sleep Quality Index, which measures several dimensions of sleep, including quality, latency, duration, efficiency, use of medication, and daytime dysfunction (30).

The 16-item short form of the Quality of Life Enjoyment and Satisfaction Questionnaire was used to measure satisfaction with various areas of daily functioning, such as social relationships, living/housing, physical health, medication, and global satisfaction (31). The Pittsburgh Sleep Quality Index and the Quality of Life Enjoyment and Satisfaction Questionnaire were administered at baseline and at weeks 4 and 8.

Safety and Tolerability Evaluations

Safety and tolerability were evaluated by assessing the incidence and severity of adverse events, as well as withdrawals because of adverse events. Extrapyramidal symptoms were assessed with the Simpson-Angus Rating Scale (32), and akathisia was assessed with the Barnes Rating Scale for Drug-Induced Akathisia (33) at random assignment and at week 8. Measurements of vital signs, including weight and fasting serum glucose levels, were obtained at each study visit. Twelve-lead ECGs, clinical chemistry, and hematology assessments were performed at the screening and at week 8.

The incidence of treatment-emergent mania was evaluated by comparing the percentage of patients in each group who had a total Young Mania Rating Scale score of ≥16 on any two consecutive visits or at the final assessment, or an adverse event of mania or hypomania.

Statistical Analyses

Primary and secondary efficacy analyses were performed on the intent-to-treat population, which included all randomly assigned patients who took at least one dose of study medication and had at least one postbaseline efficacy assessment. A last-observation-carried-forward analysis was used to impute missing data for patients who withdrew during the study. All statistical tests were two-tailed. The primary analysis of change from baseline to final assessment in the Montgomery-Åsberg Depression Rating Scale total scores tested the superiority of each dose of quetiapine in the intent-to-treat group (patients with bipolar I or bipolar II disorder) with an analysis of covariance (ANCOVA) with the baseline Montgomery-Åsberg Depression Rating Scale as the covariate and included treatment and diagnosis strata as fixed ef-

TABLE 1. Baseline Demographic Characteristics of Screened Outpatients With Bipolar I or II Disorder Who Experienced a Major Depressive Episode

	Patients Who Did Not Pass Screening (N=296)		Patients Who Were Randomly Assigned to Treatment (N=539)[a]	
Characteristic	N	%	N	%
Female sex	168	56.8	308	57.1
Caucasian race	227	76.7	438	81.3
Age (years)				
18–39	163	55.1	318	59.0
40–59	122	41.2	310	39.0
≥60	10	3.4	5	0.9

[a] Safety population that excluded three patients who did not receive any dose of study medication.

fects in the model, with adjustment for multiple comparisons. Effect size (improvement of quetiapine over placebo divided by pooled standard deviation) was determined with a mixed-model repeated-measures analysis.

Differences in response rates between treatment and placebo groups and in patients with and without rapid cycling were assessed with a Cochran-Mantel-Haenszel chi-square test across diagnostic strata. Hamilton depression scale, CGI severity and improvement, Young Mania Rating Scale, Hamilton anxiety scale, Pittsburgh Sleep Quality Index, and Quality of Life Enjoyment and Satisfaction Questionnaire scores were tested with ANCOVAs. All secondary analyses were conducted at the nominal significance level of 0.05, with no adjustment for multiple comparisons.

Sample sizes were determined to provide 85% power to detect a difference of 3.6 points on the Montgomery-Åsberg Depression Rating Scale with two-tailed pairwise comparisons between treatment groups and placebo at an alpha level of 0.025 in the intent-to-treat population (patients with bipolar I or bipolar II disorder).

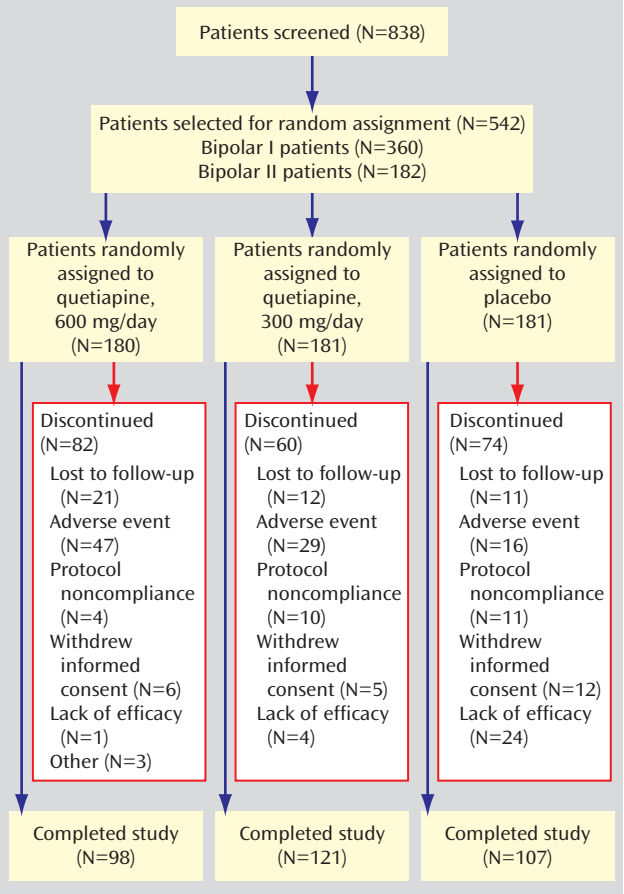
Exploratory analyses were carried out on the bipolar I and II subgroups whose group size was not predetermined to provide power for significance testing. Exploratory analyses were limited to descriptions of the mean changes in primary outcome measure across the three treatment groups, and effect size determinations for the groups taking 600 and 300 mg/day of quetiapine. The repeated measures mixed-effects model included terms for treatment, bipolar diagnosis, treatment-by-bipolar diagnosis, baseline Montgomery-Åsberg Depression Rating Scale total score, visit (week), and treatment-by-visit effects. Several covariance structures were examined, including autoregressive, banded Toeplitz, compound symmetry, and unstructured. The best-fitting covariance structure, the banded Toeplitz, was determined with the Bayesian information criterion.

Results

Patients and Disposition

A total of 838 patients were screened, and 542 patients with bipolar I (N=360) or bipolar II (N=182) disorder were randomly assigned to receive quetiapine, 600 mg/day (N=180); quetiapine, 300 mg/day (N=181); or placebo (N=181). There were no significant differences between the baseline characteristics of patients who did not pass the screening compared with those who were randomly assigned (Table 1). The most common reason for the screening failure was failure to meet eligibility criteria. Figure 1 illustrates the disposition of patients during the study. Of the 542 randomly assigned patients, 539 received at least

FIGURE 1. Disposition of Outpatients with Bipolar I or II Disorder Who Experienced a Major Depressive Episode



one dose of study medication and were included in the safety population. Of these, 511 had at least one postbaseline assessment and were analyzed for efficacy in the intent-to-treat population.

There were no statistically significant differences between treatment groups with respect to any demographic and baseline disease characteristic (Table 2). The mean age was approximately 37 years, and 58.2% of the patients were women. Mean Montgomery-Åsberg Depression Rating Scale scores at baseline were consistent with moderate to severe depression (34).

There were no statistically significant differences between the quetiapine groups and placebo in the proportion of the patients who completed the study: 54% in the 600 mg/day quetiapine group, 67% in the 300 mg/day quetiapine group, and 59% in the placebo group. The most common reasons for withdrawal were related to adverse events in the quetiapine groups (26.1% and 16.0%) and lack of efficacy in the placebo group (13.3%).

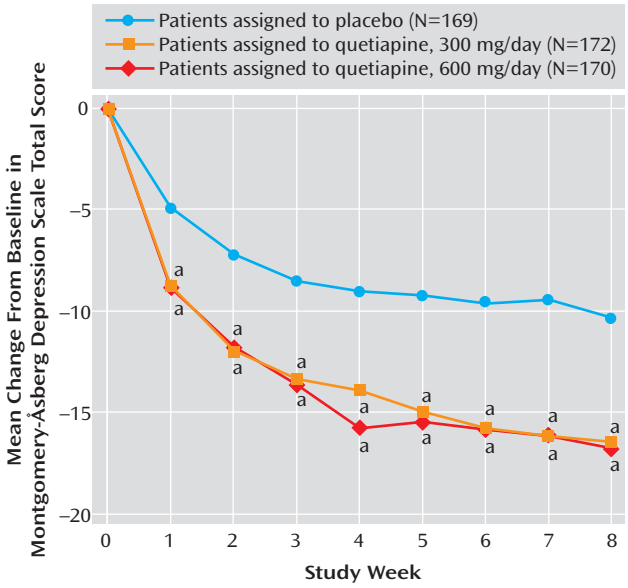
The use of lorazepam and zolpidem (permitted during the first 3 weeks of the study) was generally low across groups. Lorazepam use during the study was 5.6% and 9.5% in the 600 and 300 mg/day quetiapine groups, respectively, compared with 8.3% in the placebo group.

TABLE 2. Baseline Demographic and Clinical Characteristics of Outpatients With Bipolar I or II Disorder Who Experienced a Major Depressive Episode[a]

Characteristic	Patients Taking Quetiapine 600 mg/day (N=170)		Patients Taking Quetiapine 300 mg/day (N=172)		Patients Taking Placebo (N=169)	
	N	%	N	%	N	%
Sex						
Male	71	41.8	79	45.9	64	37.9
Female	99	58.2	93	54.1	105	62.1
Race						
Caucasian	144	84.7	141	82.0	129	76.3
Black	18	10.6	23	13.4	26	15.4
Hispanic	5	2.9	7	4.1	9	5.3
Other	3	1.8	1	0.6	5	2.9
DSM-IV diagnosis						
Bipolar I disorder	114	67.1	116	67.4	112	66.3
Bipolar II disorder	56	32.9	56	32.6	57	33.7
DSM-IV rapid cycling	31	18.2	42	24.4	35	20.7
	Mean	SD	Mean	SD	Mean	SD
Age (years)	37.3	11.4	36.6	11.2	38.3	11.1
Baseline scores						
Montgomery-Åsberg Depression Rating Scale	30.3	5.3	30.4	5.0	30.6	5.3
Hamilton Depression Rating Scale	24.7	3.5	24.5	3.0	24.6	3.3
Hamilton Anxiety Rating Scale	18.7	7.3	18.6	7.3	18.9	7.3

[a] Intent-to-treat analysis.

FIGURE 2. Least-Squares Mean Change From Baseline in Montgomery-Åsberg Depression Rating Scale Total Score at Each Assessment of Outpatients With Bipolar I or II Disorder Who Experienced a Major Depressive Episode[a]



[a] Intent-to-treat, last-observation-carried-forward analyses. Improvement in Montgomery-Åsberg Depression Rating Scale total score with both doses of quetiapine (600 mg/day and 300 mg/day) was significantly greater than placebo at every assessment (p<0.001).

Zolpidem use during the study was 6.7% and 4.5% in the 600 and 300 mg/day quetiapine groups, respectively, compared with 8.3% in the placebo group.

Efficacy

Montgomery-Åsberg Depression Rating Scale. Mean baseline Montgomery-Åsberg Depression Rating Scale scores were 30.3 (SD=5.3), 30.4 (SD=5.0), and 30.6 (SD=5.3) in the 600 mg/day, 300 mg/day, and placebo groups, respectively. Quetiapine at a dose of either 600 or 300 mg/day demonstrated significantly greater mean improvement in Montgomery-Åsberg Depression Rating Scale total scores compared with placebo as early as week 1 and at all time points that followed in the intent-to-treat group of patients with bipolar I or II depression (p<0.001 for both quetiapine doses versus placebo) (Figure 2). The mean change in Montgomery-Åsberg Depression Rating Scale total score from baseline to last assessment was –16.73 in the 600 mg/day group and –16.39 in the 300 mg/day group, compared with –10.26 in the placebo group (p<0.001 for both quetiapine doses versus placebo) (Table 3, Figure 2). The effect sizes were 0.81 for 600 mg/day and 0.67 for 300 mg/day of quetiapine.

Approximately 58% of the patients treated with either dose of quetiapine were responders at the final assessment, and both doses resulted in significantly higher response rates than placebo (36.1%) (p<0.001). Notably, the percentage of patients meeting response criteria with 600 mg/day of quetiapine was significantly higher as early as week 1 (24.3%) versus placebo (10.7%) (p<0.001). In the group taking 300 mg/day of quetiapine, a significantly higher response rate (37.2%) versus placebo (19.5%) was apparent by week 2 (p<0.001). The median time to response was significantly shorter for both 600 mg/day (22 days) and 300 mg/day (22 days) of quetiapine compared with placebo (36 days) (log-rank χ^2=33.1, df=2, p<0.001).

The percentage of patients meeting remission criteria at the final assessment was 52.9% in both the groups taking 600 and 300 mg/day of quetiapine, significantly higher than the placebo rate of 28.4% in each group (p<0.001). The median time to remission was significantly shorter for

TABLE 3. Baseline and Mean Change in Efficacy Measures at the Last Assessment of Outpatients With Bipolar I or II Disorder Who Experienced a Major Depressive Episode[a]

Measure and Treatment	Baseline Score		Change in Score at Last Assessment	Analysis (comparison with placebo)	
	Mean	SD		ANCOVA (df=1)[b]	p
Montgomery-Åsberg Depression Rating Scale					
600 mg/day of quetiapine	30.3	5.3	–16.73	–6.47 (1.12)	<0.001
300 mg/day of quetiapine	30.4	5.0	–16.39	–6.13 (1.12)	<0.001
Placebo	30.6	5.3	–10.26		
Hamilton Depression Scale					
600 mg/day of quetiapine	24.7	3.5	–13.84	–5.29 (0.81)	<0.001
300 mg/day of quetiapine	24.5	3.0	–13.38	–4.84 (0.80)	<0.001
Placebo	24.6	3.3	–8.54		
Hamilton Depression Scale item 1					
600 mg/day of quetiapine	2.9	0.5	–1.68	–0.57 (0.12)	<0.001
300 mg/day of quetiapine	2.9	0.5	–1.65	–0.54 (0.12)	<0.001
Placebo	2.9	0.4	–1.11		
Clinical Global Impression scale					
Improvement					
600 mg/day of quetiapine	4.5	0.6	2.37	–0.60 (0.14)	<0.001
300 mg/day of quetiapine	4.4	0.5	2.27	–0.71 (0.14)	<0.001
Placebo	4.4	0.6	2.97		
Severity					
600 mg/day of quetiapine	4.5	0.6	–1.66	–0.72 (0.14)	<0.001
300 mg/day of quetiapine	4.4	0.5	–1.63	–0.68 (0.14)	<0.001
Placebo	4.4	0.6	–0.95		
Hamilton Anxiety Rating Scale					
600 mg/day of quetiapine	18.7	7.3	–8.75	–3.20 (0.76)	<0.001
300 mg/day of quetiapine	18.6	7.3	–8.64	–3.10 (0.76)	<0.001
Placebo	18.9	7.3	–5.54		
Pittsburgh Sleep Quality Index					
600 mg/day of quetiapine	11.6	4.2	–5.46	–2.52 (0.43)	<0.001
300 mg/day of quetiapine	11.4	3.8	–5.16	–2.22 (0.44)	<0.001
Placebo	11.7	3.8	–2.94		
Quality of Life Enjoyment and Satisfaction Questionnaire					
600 mg/day of quetiapine	34.1	8.2	11.71	5.27 (1.14)	<0.001
300 mg/day of quetiapine	36.1	7.9	10.77	4.33 (1.15)	<0.001
Placebo	34.2	7.4	6.44		

[a] Intent-to-treat, last-observation-carried-forward analyses.
[b] Test, treatment contrast within the framework of the ANCOVA, estimated difference (standard error).

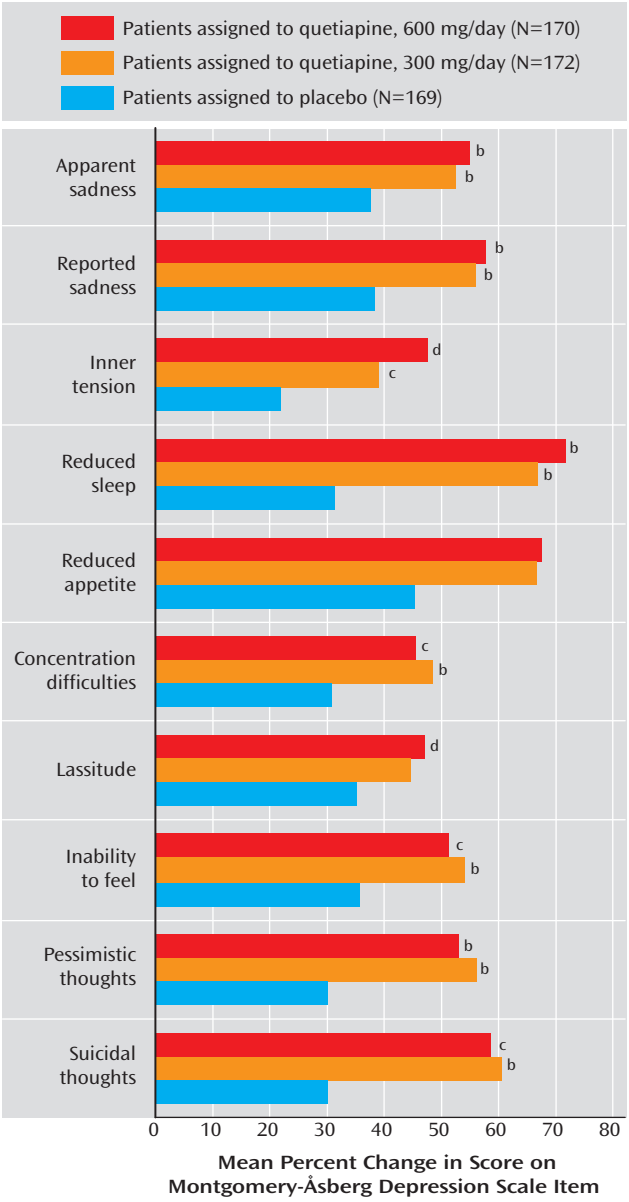
both 600 mg/day (27 days) and 300 mg/day (29 days) of quetiapine compared with placebo (65 days) (log-rank χ^2= 32.8, df=2, p<0.001).

Nine out of 10 Montgomery-Åsberg Depression Rating Scale items were significantly improved from baseline compared with placebo in the 600 mg/day quetiapine group, as were eight items in the 300 mg/day quetiapine group (p<0.05) (Figure 3). With both doses of quetiapine, these items included the core mood symptoms of apparent sadness, reported sadness, inability to feel, pessimistic thoughts, and suicidal thoughts. The core mood symptoms of apparent sadness, reported sadness, and pessimistic thoughts were significantly improved in both quetiapine groups as early as week 1 compared with placebo (p<0.05). An inability to feel and suicidal thoughts were also significantly improved by week 1 in the group taking 600 mg/day of quetiapine compared with placebo (p<0.05). Both doses of quetiapine were more effective than placebo in reducing suicidal thoughts at the final assessment (p≤0.001); the reductions with quetiapine were approximately twice that of placebo.

In the bipolar I subgroup of patients, the mean change in Montgomery-Åsberg Depression Rating Scale total score from baseline to last assessment was –18.05 in the group taking 600 mg/day group of quetiapine and –16.91 in the 300 mg/day group, compared with –9.24 in the placebo group (p<0.001 for both quetiapine doses versus placebo). The effect size in the bipolar I subgroup was 1.09 for those assigned to 600 mg/day and 0.91 for those taking 300 mg/day of quetiapine. In the subgroup of patients with bipolar II disorder, the mean change in Montgomery-Åsberg Depression Rating Scale total score from baseline to last assessment was smaller than in bipolar I patients. Although the change in Montgomery-Åsberg Depression Rating Scale total score from baseline in the patients with bipolar II disorder was statistically superior to placebo at most assessments, it did not reach statistical significance at the final assessment: –14.06 in the group taking 600 mg/day of quetiapine and –14.78 in the group taking 300 mg/day compared with –12.35 in the placebo group. The effect size in the bipolar II subgroup was 0.39 in the 600 mg/day group and 0.28 in the 300 mg/day group.

Significant improvement in Montgomery-Åsberg Depression Rating Scale total scores compared with placebo at the final assessment occurred with quetiapine treatment regardless of the presence of rapid cycling in the intent-to-treat group (patients with bipolar I or II disorder). The mean change in Montgomery-Åsberg Depression Rat-

FIGURE 3. Mean Percent Change From Baseline in Individual Montgomery-Åsberg Depression Rating Scale Items for Outpatients with Bipolar I or II Disorder Experiencing a Major Depressive Episode[a]



[a] Intent-to-treat, last-observation-carried-forward analyses. Nine of 10 and 8 of 10 Montgomery-Åsberg Depression Rating Scale items (including the core mood symptoms of depression [item 1: apparent sadness; item 2: reported sadness; item 8: inability to feel; item 9: pessimistic thoughts; item 10: suicidal thoughts]) were significantly improved from baseline compared to placebo in the groups taking 600 mg/day and 300 mg/day of quetiapine, respectively ($p<0.05$). Apparent sadness, reported sadness, and pessimistic thoughts were significantly improved in both quetiapine groups as early as week 1 compared with placebo ($p<0.05$). Both doses of quetiapine were approximately twice as effective as placebo in reducing suicidal thoughts at the final assessment ($p\leq0.01$).
[b] $p<0.001$ versus placebo.
[c] $p<0.01$.
[d] $p<0.05$.

ing Scale total score at week 8 in the patients with rapid cycling was –17.7 in the 600 mg/day quetiapine group and –18.6 in the 300 mg/day quetiapine group versus –9.9 in the placebo group ($p<0.01$ for both quetiapine doses versus placebo). The mean change in Montgomery-Åsberg Depression Rating Scale total score at week 8 in the patients without rapid cycling was –16.6 in the 600 mg/day group and –15.7 in the 300 mg/day group versus –10.3 in the placebo group ($p<0.001$ for both quetiapine doses versus placebo). A more detailed analysis of patients with and without rapid cycling in this study will be described in a separate report.

In order to explore the role of somnolence or sedation on efficacy, the mean change from baseline in Montgomery-Åsberg Depression Rating Scale total scores in the patients with and without these adverse events were compared. The number of patients in the intent-to-treat group with reported somnolence/sedation was 195 (57%) for the quetiapine groups combined and 24 (14%) for the placebo group. The mean change in the Montgomery-Åsberg Depression Rating Scale total score at week 8 in the patients with somnolence/sedation (either bipolar I or II disorder) was –18.8 in the pooled quetiapine groups (600 or 300 mg/day) versus –18.9 in the placebo group. In the patients without somnolence/sedation, the mean change in the Montgomery-Åsberg Depression Rating Scale total score was –19.3 and –11.7 for in the pooled quetiapine and placebo groups, respectively. The placebo group response was higher in the patients reporting somnolence/sedation, but the results with quetiapine were similar in the patients with or without somnolence/sedation.

Hamilton depression scale. Mean baseline Hamilton depression scale scores were 24.7 (SD=3.5), 24.5 (SD=3.0), and 24.6 (SD=3.3) in the 600 mg/day, 300 mg/day, and placebo groups, respectively (Table 2). Quetiapine at a dose of either 600 or 300 mg/day demonstrated significantly greater mean improvements in Hamilton depression scale total scores compared to placebo as early as week 1 and at all time points that followed in the patients with bipolar I or II depression ($p<0.001$). The mean change from baseline in Hamilton depression scale scores at week 8 was –13.84, –13.38, and –8.54 in the 600 mg/day, 300 mg/day, and placebo groups, respectively ($p<0.001$ for both quetiapine doses versus placebo). At the end of the study, the effect sizes for the group of patients with bipolar I or II disorder with the Hamilton depression scale was 0.93 for 600 mg/day and 0.74 for 300 mg/day of quetiapine.

Significant improvement in the Hamilton depression scale item 1 (depressed mood) was as early as week 1 ($p=0.003$) for both quetiapine doses and continued to be statistically superior to placebo at all time points.

Clinical Global Impression. Quetiapine-treated patients experienced a statistically significant improvement ($p<0.001$) on the CGI severity scale as early as week 1 that was sustained to the end of the study for both quetiapine doses versus placebo. At the final assessment, a larger percentage of patients were rated as "normal, not at all ill," or

TABLE 4. Incidence and Withdrawals Because of Adverse Events Occurring in at Least 10% of the Patients in Any Group of Outpatients with Bipolar I or II Disorder Who Experienced a Major Depressive Episode

	Patients Taking 600 mg/day of Quetiapine (N=180)				Patients Taking 300 mg/day of Quetiapine (N=179)				Patients Taking Placebo (N=180)			
	Incidence		Leading to Withdrawal		Incidence		Leading to Withdrawal		Incidence		Leading to Withdrawal	
Adverse Event	N	%	N	%	N	%	N	%	N	%	N	%
Dry mouth	73	40.6[a]	2	1.1[a]	79	44.1[a]	0	0.0	14	7.8	0	0.0
Sedation	58	32.2[a]	17	9.4[a]	53	29.6[a]	10	5.6[a]	11	6.1	0	0.0
Somnolence	44	24.4[a]	5	2.8[a]	49	27.4[a]	7	3.9[a]	15	8.3	0	0.0
Dizziness	41	22.8[a]	6	3.3[a]	30	16.8[a]	1	0.6[a]	15	8.3	0	0.0
Fatigue	21	11.7	1	0.6	16	8.9	0	0.0	13	7.2	0	0.0
Constipation	20	11.1[a]	1	0.6[a]	21	11.7[a]	0	0.0	8	4.4	0	0.0
Headache	18	10.0	1	0.6[a]	22	12.3	0	0.0	36	20.0	0	0.0
Nausea	6	8.9	0	0.0	14	7.8	3	1.7	23	12.8	0	0.0
Upper respiratory tract infection not otherwise specified	13	7.2	0	0.0	9	5.0	0	0.0	18	10.0	0	0.0

[a] Significantly higher than placebo ($p<0.05$).

"borderline ill" in the 600 mg/day (42.4%) and 300 mg/day quetiapine groups (38.1%) compared with the placebo group (23.7%).

A larger percentage of patients was also rated as "much" or "very much" improved on the CGI improvement scale in the 600 mg/day (55.9%) and 300 mg/day quetiapine groups (64.0%) compared with the placebo group (34.3%) at the final assessment.

Anxiety symptoms. Mean baseline Hamilton anxiety scale scores were 18.7 (SD=7.3), 18.7 (SD=7.3), and 18.9 (SD=7.3) in the 600 mg/day, 300 mg/day, and placebo groups, respectively (Table 2). By the study end, the mean Hamilton anxiety scale total score had decreased by –8.75 in the 600 mg/day group, –8.64 in the 300 mg/day group, and –5.54 in the placebo group ($p<0.001$ for both quetiapine doses versus placebo). A significant improvement in the Hamilton anxiety scale total scores as early as week 1 ($p<0.05$) was maintained to the last assessment ($p<0.001$ for both quetiapine doses versus placebo). Individual items of the Hamilton anxiety scale that most differentiated quetiapine-treated patients from those who received placebo included anxious mood, depressed mood, insomnia, genitourinary symptoms, and tension. A more detailed analysis of the results of the effect of quetiapine on anxiety measures in this study has been presented in a separate report (35).

Quality of sleep. The quality of sleep improved significantly among those treated with either dose of quetiapine compared with placebo. The mean improvement in Pittsburgh Sleep Quality Index scores from baseline in patients treated with 600 mg/day (–5.46) and 300 mg/day (–5.16) of quetiapine was significantly greater with both doses ($p<0.001$) than with placebo (–2.94).

Quality of life. Quetiapine-treated patients also experienced statistically significant improvements in quality of life during the study, as determined by the change from baseline in the Quality of Life Enjoyment and Satisfaction Questionnaire total scores. Mean Quality of Life Enjoyment and Satisfaction Questionnaire total scores improved by 11.71 by the last assessment among patients treated with 600 mg/day of quetiapine and by 10.77 among those treated with 300 mg/day of quetiapine, compared with 6.44 in the placebo group ($p<0.001$ for both quetiapine doses versus placebo).

Safety and Tolerability

Adverse events. Common adverse events (whether or not considered treatment related) occurred in ≥10% of patients, and withdrawals due to common adverse events are shown in Table 4. The overall rate of study discontinuation due to adverse events was 26.1% (N=47) in the 600 mg/day group, 16.0% (N=29) in the 300 mg/day group, and 8.8% (N=16) in the placebo group (Figure 1). There were no significant differences in the rates of serious adverse events across treatment groups, and none was treatment related: 5.0% (N=9) in the 600 mg/day group and 3.4% (N=6) in the 300 mg/day group compared with 8.9% (N=16) in the placebo group. Two patients attempted suicide (one in each of the active treatment groups), but no suicides or deaths occurred during the study.

The rate of discontinuation due to adverse events in the subgroup of patients with bipolar I disorder was 23.3% (N=28) in the 600 mg/day group, 13.1% (N=16) in the 300 mg/day group, and 11.9% (N=14) in the placebo group. The incidence of serious adverse events in the subgroup of patients with bipolar I disorder was 5.0% (N=6) in the 600 mg/day group, 4.2% (N=5) in the 300 mg/day group, and 11.9% (N=14) in the placebo group.

In the subgroup of patients with bipolar II disorder, the rate of discontinuation due to adverse events was 31.7% (N=19) in the 600 mg/day group, 22.0% (N=13) in the 300 mg/day group, and 3.2% (N=2) in the placebo group. The incidence of serious adverse events in the subgroup of patients with bipolar II disorder was 5.0% (N=3) in the 600 mg/day group, 1.7% (N=1) in the 300 mg/day group, and 3.2% (N=2) in the placebo group.

The incidence of treatment-emergent mania was low and not significantly different from placebo at either quetiapine dose: 2.2% with 600 mg/day of quetiapine (Cochran-Mantel-Haenszel, odds ratio=0.57, 95% confidence interval (CI)=0.17–1.91, p=0.35), 3.9% with 300 mg/day of quetiapine (Cochran-Mantel-Haenszel, odds ratio=0.97, 95% CI=0.35–2.68, p=0.95), and 3.9% with placebo.

The mean Simpson-Angus Rating Scale total score decreased in all three groups from baseline to the final assessment by –0.1, –0.2, and –0.3 in the 600 mg/day and 300 mg/day quetiapine groups and the placebo groups, respectively. There was no statistically significant difference in the number of patients with an increase from baseline in Simpson-Angus Rating Scale scores between either of the quetiapine groups and placebo: 15% (logistic regression=0.66, df=3, p<0.08), 9% (logistic regression=0.06, df=3, p=0.89), and 9% in the 600 mg/day and 300 mg/day quetiapine and placebo groups, respectively.

At the last assessment, mean Barnes Rating Scale for Drug-Induced Akathisia scores were low and similar in all groups: 0.3 in the 600 mg/day group, 0.2 in the 300 mg/day group, and 0.1 in the placebo group. There was no statistically significant difference in the number of patients with an increase from baseline in Barnes Rating Scale for Drug-Induced Akathisia score between either of the quetiapine groups and placebo: 12% (logistic regression=0.39, df=3, p=0.31), 9% (logistic regression=0.06, df=3, p=0.89), and 9% in the 600 mg/day and 300 mg/day quetiapine and placebo groups, respectively.

Adverse events considered extrapyramidal symptoms were present in 8.9% of the 600 mg/day group, 6.7% of the 300 mg/day group, and 2.2% of the placebo group; discontinuation rates for extrapyramidal symptoms were 2.8%, 1.1%, and 0.6%, respectively.

Laboratory Results and Vital Signs

No clinically relevant differences between groups were seen in the mean change from baseline for any vital signs, ECGs, hematology, or clinical chemistry parameters.

Patients treated with 600 mg/day of quetiapine experienced a mean weight gain of 1.6 kg by the final assessment compared with 1.0 kg in the 300 mg/kg group and 0.2 kg in the placebo group. At the final assessment, 16 patients (9.0%) treated with 600 mg/day of quetiapine, 15 patients (8.5%) treated with 300 mg/day of quetiapine, and three patients (1.7%) who received placebo had a weight gain of ≥7% of their baseline measurement. No patients withdrew from the study because of weight gain.

Mean fasting serum glucose levels at baseline were 86 (SD=12), 87 (SD=13), and 87 (SD=15) mg/dl in the 600 mg/day and 300 mg/day of quetiapine and placebo groups, respectively. By the final assessment, the mean change in fasting serum glucose was 6 mg/dl (SD=17), 3 mg/dl (SD=13), and 4 mg/dl (SD=26) in the 600 mg/day and 300 mg/day of quetiapine and placebo groups, respectively.

Discussion

To our knowledge, this is the first randomized, parallel-group, placebo-controlled trial to evaluate the efficacy of quetiapine in bipolar depression. It may also be the first published large-scale, controlled study to assess the efficacy of any pharmacological treatment in a group of patients with bipolar I or II depression, and one of few studies to examine an antidepressant effect in patients with rapid cycling.

Quetiapine monotherapy has significant antidepressant efficacy in a group of patients with bipolar I or II depression based on the primary efficacy analysis (mean change in Montgomery-Åsberg Depression Rating Scale total score from baseline to last assessment). The magnitude of the clinical improvement was substantial and evident from the first assessment (week 1) and at each visit thereafter. The rates of response and remission and the time to response and remission were significantly improved in the quetiapine groups compared with placebo. Compared with placebo, evidence of early and sustained efficacy was observed consistently with both doses of quetiapine and in all secondary efficacy analyses from week 1 onward.

In the Montgomery-Åsberg Depression Rating Scale item analysis, both doses of quetiapine produced a significant and early improvement in all of the core mood symptoms of depression, including objective and reported sadness, anhedonia, and pessimistic thoughts. Notably, both doses of quetiapine were approximately twice as effective as placebo in reducing suicidal ideation. These findings provide support for the conclusion that quetiapine has specific antidepressant properties.

In this study, significant antidepressant efficacy was demonstrated for quetiapine dosed once a day in the evening. This has important clinical relevance because once-daily dosing has been associated with enhanced medication adherence (36). Dosing at bedtime may also offer a means of improving tolerability, particularly regarding somnolence or sedation that are sometimes seen with quetiapine and may help treat the sleep disturbance that often accompanies bipolar depression.

Both doses of quetiapine were associated with improvements in quality of sleep and quality of life and were effective in patients with a recent history of rapid-cycling bipolar disorder. Exploratory analyses suggest that the clinical effect of both doses of quetiapine was greater in patients with bipolar I disorder than those with bipolar II disorder.

The most common side effects of quetiapine included dry mouth, sedation, somnolence, dizziness, and constipation. The most common side effects leading to withdrawal from the study were sedation and somnolence, with most discontinuations occurring within the first week. Of importance, changes in weight observed in all three groups were relatively small and did not result in withdrawal from the study. Quetiapine treatment was not associated with treatment-emergent mania. The long-term safety of quetiapine

is being explored in ongoing bipolar disorder maintenance studies. However, data from patients with schizophrenia does not suggest that unexpected adverse effects during long-term treatment should be expected (37).

Several aspects of the design of this study were innovative. First, the inclusion of patients with bipolar II disorder into a large-scale study of acute bipolar depression was novel and enhanced the generalizability of the findings, particularly since there is a higher incidence of bipolar II disorder than bipolar I disorder. The inclusion of patients with rapid cycling was also innovative and enhanced the generalizability of the findings to this difficult-to-treat subgroup. Second, rather than focusing solely on depressive symptoms, this study included sleep quality and health-related quality-of-life measures. Sleep-quality assessments (both patient- and bed-partner-rated) indicated improvements in functioning in addition to symptom severity, including several dimensions of sleep quality and daytime dysfunction. The quality-of-life scale provided novel information regarding the effect of quetiapine on social relationships, living/housing arrangements, physical health, satisfaction with medication, and global satisfaction. Improvements in these measures provide evidence for improved function and overall quality of life in addition to reduction in the symptoms of the illness.

Moreover, the inclusion of analyses that quantify the magnitude of the clinical effect through effect size determinations gives clinicians useful information. Knowing if a significant difference is caused by a small clinical effect (<0.4), a moderately sized clinical effect (0.40–0.79), or a large clinical effect (>0.79) has the potential of helping the clinician make decisions on how to use a new medication (38). The effect sizes reported in the bipolar I depression study by Tohen et al. (14) were 0.32 with olanzapine monotherapy and 0.68 with olanzapine-fluoxetine combination therapy compared with 1.09 in the bipolar I subgroup with 600 mg/day of quetiapine in this study.

This study had several limitations. First, the number of enrolled patients with bipolar II disorder was not sufficient to draw firm conclusions regarding efficacy in this subgroup. For this reason, post hoc analyses conducted in the bipolar II subgroup included effect size determinations, which are less affected by sample size than significance testing. Second, moderate rates of sedation or somnolence were observed in both quetiapine groups, which might have compromised the integrity of the double-blind design. If this were a significant factor in the assessment of efficacy, the reduction in Montgomery-Åsberg Depression Rating Scale total score in patients experiencing sedation or somnolence would have been greater than those in patients not experiencing these adverse events. However, this was not the case, and the improvements observed on the Montgomery-Åsberg Depression Rating Scale were comparable in patients with or without sedation or somnolence. Third, although the study indicated that the two doses used—chosen because of their efficacy in bipolar mania and other disorders—were effective, guidance on the best dosing for most patients or subgroups of patients should be assessed in future studies.

In conclusion, this large, randomized, double-blind, placebo-controlled study provides the first pivotal data demonstrating that quetiapine monotherapy is efficacious and well tolerated for the acute treatment of bipolar depression in a group of patients with bipolar I or II disorder.

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Clinical Study Report: Appendix 12.1.12.

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.1.12
Important publications referenced in the report

Publication

Baldessarini RJ, Tondo L, Hennen J, Viguera AC. Is lithium still worth using? an update of selected recent research. Harv Rev Psychiatry 2002;10:59-75.

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REVIEW

Is Lithium Still Worth Using? An Update of Selected Recent Research

Ross J. Baldessarini, MD, Leonardo Tondo, MD, John Hennen, PhD, and Adele C. Viguera, MD

The treatment of bipolar disorder has seen greater innovation in the past decade than at any other time since the introduction of lithium and the neuroleptics a half-century ago. The place of lithium in contemporary psychiatric therapeutics has become controversial, calling for the present overview of research findings pertaining to its use in treating patients with bipolar disorder. Lithium, by itself, typically is inadequate for rapid control of acute mania; antipsychotics, divalproex, or potent sedatives are commonly used, with or without lithium, for this purpose. The special usefulness of lithium lies in long-term prevention of recurrences of mania and bipolar depression and in reducing risk of suicidal behavior. Lithium also may be beneficial in recurrent unipolar depression and is an effective adjunct for treatment-resistant depression. Expectations that prolonged untreated bipolar illness, multiple episodes, rapid cycling, or retreatment following discontinuation might routinely lead to lithium nonresponsiveness, and the belief that lithium is too toxic for use during pregnancy, have not been borne out by research. Lithium retains a substantial share of prescriptions for bipolar disorder and is inexpensive. No other treatment has performed as well as lithium in as many aspects of long-term care of bipolar disorder patients, and despite some risks and limitations, lithium remains the standard against which all proposed alternatives are compared. (HARVARD REV PSYCHIATRY 2002;10:59–75.)

Preparations of lithium salts (carbonate immediate and slow-release tablets, citrate liquid) have been the mainstay in long-term maintenance treatment for bipolar disorder patients since the 1960s,[1–5] following discovery of the antimanic actions of lithium carbonate by John Cade in Melbourne in 1949.[6] Bipolar disorder affects more than 1% of the general population, and its lifetime prevalence may exceed 5% if both current standard diagnostic subtypes (types I [with mania, usually also with depression] and II [depression with hypomania]), as well as cyclothymia, are considered, and particularly if pediatric, geriatric, and milder forms are included.[2,7–13] Moreover, bipolar and other major affective disorders with psychotic features are the most common idiopathic psychotic illnesses.[7,14]

There is growing recognition of the major therapeutic challenges and pharmaceutical opportunity represented by

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Dr. Baldessarini consults to corporations that market lithium preparations (Solvay and Glaxo-SmithKline) and other antimanic agents (Eli Lilly, Janssen, Protarga).

Some of this material is also presented at a McLean Hospital CME Internet site.

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bipolar disorder. There is also a wish to improve on results obtained with lithium while minimizing the risks attending its use and reducing the need for close medical monitoring to maintain effective serum concentrations of lithium and avoid adverse effects, discussed below.[3,6] Such considerations have stimulated unprecedented innovation in the therapeutics of the disorder over the past decade. This development includes clinically valuable new applications of anticonvulsant, antipsychotic, sedative, and antidepressant drugs.[5,15] Marketing of newer antimanic medicines and proposed mood-stabilizing agents greatly disfavors lithium—an inexpensive, unpatentable inorganic salt. Indeed, many American psychiatrists appear increasingly disinclined to consider lithium as the expert-recommended, first-line option for bipolar disorder patients that it is.[2,5,15,16]

The view that lithium should no longer be considered a primary treatment has been encouraged by evidence that many cases of bipolar disorder involve severe, chronic, disabling illness with clinically unsatisfactory response to any available treatment or combination of treatments.[2,3,5,14,16,17–20] But high risks of treatment failure with lithium and alternative therapies can arise from several sources, including inconsistent adherence to recommended long-term treatment, particularly when symptoms are in apparent remission or the patient has comorbid common substance abuse problems; disinclination to accept adverse effects such as weight gain and minor cognitive dulling; inadequate clinical supervision of treatment with an agent that has an unusually narrow margin of safety, requiring regular medical monitoring and blood testing; and inadequate interpersonal support and encouragement of adherence to long-term treatment.[21–24] Moreover, the proportion of bipolar disorder patients followed at specialized referral centers who have relatively treatment-resistant (or otherwise complex and challenging) illness is probably growing, adding further to the impression that neither lithium nor other treatments for bipolar disorder yield consistently satisfactory results in some individuals.[17,22]

A realistic assessment of current clinical knowledge of the utility of lithium in the treatment of bipolar disorder is needed. This overview aims to provide such an assessment, while emphasizing pertinent results of recent investigations of lithium treatment by the International Consortium for Bipolar Disorder Research.

EFFICACY OF LITHIUM IN ACUTE MANIA

The introduction of lithium carbonate by Cade in 1949 can be considered to have heralded the modern era of psychopharmacology.[6,25] The recent fiftieth anniversary of Cade's discovery stimulated new interest in lithium and provided the occasion for several reviews of research on this agent.[5,26–33] Lithium was introduced for the treatment of acute mania and has continued since the 1970s to be recognized by the U.S. Food and Drug Administration (FDA) only for mania (1970) and unspecified recurrences (presumably, of mania) in bipolar disorder (1974).[34] The short-term efficacy of lithium in acute mania is supported by at least five placebo-controlled trials.[30] However, all but one[35] followed a cross-over design and involved short treatment-exposure times, and recovery rates were only twice the surprisingly high 25–35% associated with placebo and nonspecific clinical management.[29,36]

Comparisons of lithium and antipsychotic drugs in acute mania indicate that clinically useful control of manic behavior is more rapid with antipsychotics, but otherwise lithium and antipsychotics are similar in efficacy.[5,26,27,29,30,36] Rapid response has also been observed with apparently safe loading doses of divalproex,[37] although possibly not with more-conservative dosing.[35,38] Similarly rapid quieting effects can be obtained with high doses of potent benzodiazepines such as lorazepam and clonazepam.[39–41] Whether these early effects with agents other than lithium represent "true antimanic" actions or merely sedation continues to be debated. Nevertheless, the requirement for caution in safe dosing with lithium in acute mania, together with contemporary economic pressures to minimize hospitalization, has strongly encouraged initial use of antipsychotic, anticonvulsant, and sedative agents, with or without lithium, for practical clinical management of acute mania, commonly followed by lithium in a prominent role for aftercare.[5,30]

REVIEW OF LONG-TERM EFFECTIVENESS OF LITHIUM IN BIPOLAR DISORDER

Clinically, the most important application of lithium treatment is to reduce long-term risk of recurrences of illness in bipolar disorder.[5,31] Lithium treatment is usually continued following early recovery from an acute episode of mania or bipolar depression to minimize the high risk of early relapse.[2,5,15–17,22,29,31,42] In addition, it is standard practice to recommend prolonged maintenance or prophylactic treatment and continued psychiatric supervision in most cases after two or more recurrences, particularly when dangerous behavioral dyscontrol, suicide attempts, or hospitalization is involved.[2,3,5,31–33,43] This practice is similar to what is done following several recurrences of major depression[4,44] and is supported by unusually abundant research evidence.[3,5,24,27–29,31–33] To place the available findings in a broad perspective, we carried out a meta-analysis of available research trials of lithium treatment.

Methods

Relevant publications were identified through a computerized *Medline* literature search (search terms: "bipolar disorder," "lithium," "manic-depressive disorder") and by examining the reference lists in the studies thus located and the

reviews cited above. In these studies, we compared the recurrence risks with versus without lithium maintenance treatment in bipolar disorder. Recurrence risk ratios and their standard error estimates were calculated for each study, based on Poisson regression methods with adjustment for exposure time. For studies involving the same subjects on and then off lithium, standard errors for the risk ratios were adjusted for estimated covariance within subjects. Risk ratios were summarized using the meta-analytic methods recommended by DerSimonian and Laird.[45] Interstudy heterogeneity of risk ratios was estimated with Q-statistics.[45] To estimate pooled rates and their 95% confidence intervals (CIs), we used a random-effects estimator employing weights based on the inverse of study variances plus a between-studies variance factor.[45] Rate data are reported as mean ± standard deviation or with CI. Statistical significance required two-tailed $p < 0.05$.

Results

We found a total of 28 pertinent studies with interpretable data[46–73] (see Table 1; when multiple reports have appeared from the same study, only the most recent or largest case series is included here). Many investigations included persons with types I and II bipolar disorder and recurrent, typically melancholic or endogenomorphic, major depression—within the broad syndrome of manic-depressive illness as originally defined by Emil Kraepelin a century ago.[13] The proportion of subjects with bipolar disorder for each study is indicated in the table.

The 28 studies involved a total of 2985 different subjects (some observed both with and without lithium treatment), 59.6% of whom were female. Subjects were exposed for an average of 9.94 ± 4.27 years (5.88 ± 5.26 years in 2351 patients with lithium, and 4.10 ± 3.42 years in 2308 patients without lithium), for a total experience of 23,263 person-years. The great majority of subjects (78.4%) were diagnosed with bipolar disorder. There was no significant tendency for bipolar cases to be more prevalent in more recent studies (Spearman $r_s = 0.28, p = 0.14$). A higher proportion of the 23 studies reporting such information up to 1980 (15/15 = 100%) versus later (2/8 = 25%) selected cases for relatively high or recent morbidity (χ^2 [1 df] = 14.4, $p < 0.0001$). This body of investigation into long-term treatment with or without lithium in bipolar disorder far exceeds—in studies, subjects, and exposure times—that available for any other treatment of the condition.[5]

Numerical results varied substantially among the studies, but in all 28 trials, recurrence risk was lower during lithium treatment; the overall crude risk ratio for recurrence was 3.2-fold lower with lithium than without. Among studies involving at least 1 year of lithium treatment and samples of more than 50 patients mainly with bipolar disorder, the sparing of risk ranged from 96% in an early study[48] to only 20% in a recent trial designed primarily to test for the effectiveness of divalproex.[72] By meta-analysis (see Figure 1) based on recommended random-effects-modeling methods,[45] the computed overall risk ratio, and its CI, without versus with lithium was 3.2 (2.7–3.8), with a great heterogeneity of results across studies (Q [25 df] = 9700, $p < 0.0001$).

Effectiveness of lithium maintenance was quite stable over the entire era represented by the studies analyzed. Even though recent maintenance studies have evidently included fewer severely ill persons, recurrence rates during lithium treatment have not changed significantly since the 1960s ($r_s = 0.20, p = 0.30$). This lack of evidence of a secular change involving loss of treatment effectiveness over the years accords with previous analyses of some of this literature[17,22,73,74] and with studies of outcomes at two European centers for treatment started across several decades.[17,75]

The 28 studies reviewed varied greatly in size (5–375 subjects), duration (0.5–146 months), and design (open studies comparing recurrences before vs. during treatment; randomized, blinded, placebo-controlled, parallel-group trials; and others). However, more than half (57%) involved blinded observations, and 50% included a placebo condition (39% also involved prospective randomization to lithium vs. a placebo in parallel groups). Studies with and without blind assessment showed very similar reductions in recurrence risk (61.4 ± 27.2% [n = 16 trials] vs. 67.6 ± 19.2% [n = 12], respectively; F [1; 26 df] = 0.44, $p = 0.51$), as did trials with or without randomized, parallel-group designs (58.3 ± 25.3% [n = 11] vs. 67.8 ± 22.8% [n = 17], respectively; F [1; 26 df] = 1.07, $p = 0.31$). The weighted-average reduction of recurrence risk by 3.6-fold among the 11 parallel-group trials was similar to both the crude and computed risk ratios found across reports (both 3.2). Another selective, quantitative meta-analysis involving nine randomized, placebo-controlled trials of long-term lithium treatment[32] also found a computed inverse risk ratio of 0.29 (95% CI = 0.09–0.93), or approximately 3.4-fold lower risk with lithium.

At least half of the studies analyzed involved discontinuation of ongoing lithium treatment in some subjects, typically to provide a placebo-control condition. Treatment discontinuation might itself inflate drug-placebo differences in studies of lithium[76–82] and many other treatments,[44,81–85] particularly within the first few months following discontinuation. The clinical impact of treatment discontinuation can be limited substantially by slowly lowering the dose over at least several weeks.[76–83] Such gradual discontinuation of ongoing treatment is rarely included in trial designs.[81–83] However, a recent, well-designed multicenter trial comparing divalproex to lithium and placebo for 52 weeks of maintenance treatment in patients with bipolar I disorder featured an initial dose-tapering period over 2 weeks following treatment of acute mania.

TABLE 1. Summary of Major Studies of Long-term Effectiveness of Lithium Maintenance Treatment in Bipolar Disorder

Study	n	Number		% F	High risk[a]	Bipolar (%)[b]	Study design	Lithium discontinued	Months		Episodes/100 person-years		Risk ratio	% Spared
		On-Li	Off-Li						On	Off	On-Li	Off-Li		
Baastrup & Schou[46]	88	88	88	100.0	Yes	73.9	Open, pre/on	Some (27.3%)	30.0	47.2	20.0	155	7.75	87.1
Angst et al.[47]	244	244	244	80.3	Yes	75.6	Open; pre/on	No	32.8	32.8	35.1	90.2	2.57	61.1
Baastrup et al.[48]	84	45	39	100.0	?	59.5	Blind, d/c to Pbo	Yes	5.0	5.0	0[c]	138[c]	>23.8	95.8
Melia[49]	18	9	9	88.9	?	86.2	Blind, d/c to Pbo	Yes	24.0	24.0	44.4[c]	77.8[c]	1.75	42.9
Coppen et al.[50]	64	28	36	67.7	Yes	59.4	Blind, prospective	Unstated	18.7	18.7	19.9[c]	67.6[c]	3.40	70.6
Small et al.[51]	5	5	5	0	?	80.0	Blind, d/c to Pbo	Yes	36.0	0.83	6.67[c]	1460[c]	219	99.5
Cundall et al.[52]	18	18	17	66.7	Yes	72.2	Blind, d/c to Pbo	Yes	39.8	12.0	31.8	112	3.52	71.6
Hullin et al.[53]	69	69	69	65.2	Yes	66.7	Open, pre/on	No	40.0	40.0	16.8	95.9	5.73	82.5
Persson[54]	66	33	33	60.6	Yes	43.4	Open, matched pairs	No	24.0	72.0	27.3	91.9	3.37	70.3
Prien et al.[55]	205	101	104	35.1	Yes	100.0	Blind, Pbo-control	Yes	24.0	24.0	34.2	54.3	1.59	37.1
Prien et al.[56]	84	45	39	36.1	Yes	36.9	Blind, Pbo-control	Yes	24.0	24.0	26.7	55.1	2.07	51.5
Stallone et al.[57]	52	25	27	51.9	Yes	100.0	Blind, Pbo-control	Some	22.0	8.2	34.8	157	4.51	77.8
Naylor et al.[58]	11	11	11	27.3	Yes[d]	63.6	Blind, cross-over	Some (50%)	9.0	9.0	412	570	1.38	27.7
Prien et al.[59,e]	284	141	143	35.2	Yes	83.1	Blind, Pbo-control	Yes	24.0	24.0	35.8	71.7	2.00	50.1
Fieve et al.[60]	81	38	43	64.2	Yes	65.6	Blind, Pbo-control	Some (<33%)	31.1	16.0	27.4	71.6	2.61	61.7
Fyrö & Petterson[61]	18	9	9	66.7	Yes	100.0	Blind, matched pairs	Yes	54.0	2.7	0	487	>9.00	88.9
Holinger & Wolpert[62]	74	74	74	62.2	Yes	75.7	Open, pre/on	No	ca. 60	39.2	74.1	395	5.33	81.2
Rybakowski et al.[63]	61	61	61	63.9	Yes	100.0	Open, pre/on	No	ca. 54	ca. 54	31.3	110	3.51	71.6

Quitkin et al.[64]	24	11	13	69.4	No	45.8[f]	Blind, Pbo-control	Unstated	11.0	11.0	29.8	93.3	3.13	68.1
Kane et al.[65]	24	11	13	55.9	No	45.8[f]	Blind, Pbo-control	No	12.7	6.7	25.8[c]	152[c]	5.88	83.0
Margo & McMahon[66]	15	15	4	53.3	?	100.0	Open on; d/c to Pbo	Yes	26.3	0.5	30.4[c]	2400[c]	78.9	98.7
Prien et al.[67]	113	79	34	63.5	?	38.9	Blind, Pbo-control[g]	Unstated	24.0	24.0	27.8[c]	35.3[c]	1.27	21.2
Bouman et al.[68]	104	104	104	54.8	Yes	80.8	Open, pre/on	No	109	43.9	27.3	37.4	1.37	27.0
Mander & Loudon[69]	15	15	15	60.0	?	100.0	Open, pre/on[h]	No	118	ca. 60	17.0	50.7	2.98	66.5
Koukopoulos et al.[70]	375	375	375	61.9	No	55.5	Open, pre/on	No	146	ca. 60	45.0	85.0	1.89	47.1
Maj et al.[71]	247	247	247	55.9	No	100.0	Open, pre/on	No	143	60	22.4	57.8	2.59	61.9
Bowden et al.[72]	182	90	92	52.2	No	100.0	Blind, Pbo-control[i]	Some (50%)	12.0	12.0	30.8[c]	38.3[c]	1.24	19.6
Tondo et al.[73]	360	360	360	64.7	No	100.0	Open, pre/on	No	72.0	99.6	81.0	183	2.26	55.7
Totals	2985	2351	2308											
Means	107	84	82	59.6	57.1% yes	78.4	60.7% blind or Pbo	50.0% yes	70.5[j]	49.2[j]	41.7[j]	116.6[j]	3.20[j,k]	54.9[j]

d/c, discontinued; *F,* female; *Pbo,* placebo; *pre/on,* before and during treatment with lithium.
[a]Based on recent history of episodes or hospitalizations.
[b]Bipolar disorder, recurrent mania, or schizoaffective disorder.
[c]Rates based on *persons* with at least one recurrence/100 person-years at risk; otherwise rates are *episodes*/100 person-years at risk.
[d]All subjects were mentally retarded and institutionalized.
[e]May include some subjects from Prien et al.[56]
[f]Bipolar II disorder only.
[g]Placebo controls only for patients with unipolar depression.
[h]Also involved placebo-controlled, 1-month discontinuation with recurrence rate of 720/100 person-years.
[i]Included 187 other subjects maintained on divalproex, at a failure rate of 24.1 episodes/100 person-years.
[j]Weighted by n/study-arm.
[k]Omits two studies[51,66] with less than 1 month observation off-lithium.

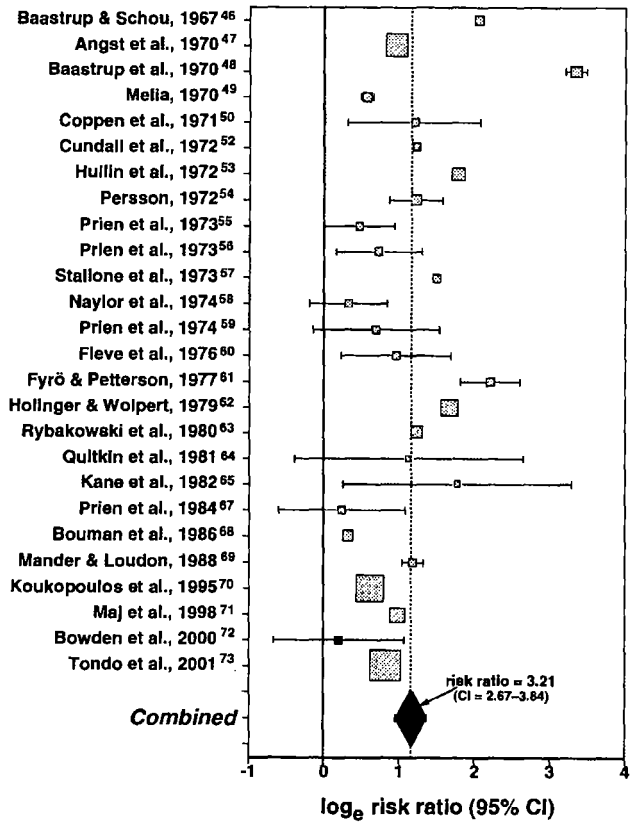

FIGURE 1. Meta-analysis of studies of the ratio of recurrence risk off/on lithium maintenance treatment. Data are the natural logarithm ($\log_e$) of risk ratio and its 95% confidence interval (CI) computed by random-effects modeling, with symbol size (shaded boxes) proportional to weighting by subject count (proportion of n in each study to combined n) and between- vs. within-study variance. The 26 studies included are those summarized in Table 1, minus two small studies having very short observation times off-lithium.[51,66] The computed overall risk ratio (black diamond) of 3.21 (CI = 2.67–3.84) is highly significant (z [25 df] = 12.6, $p < 0.0001$) and similar to the crude average ratio of 3.20 (see Table 1). Findings across studies are highly significantly heterogeneous (Q [25 df] = 9700, $p < 0.0001$).

The phenomenon of excessive early recurrence risk soon after discontinuing or even sharply reducing the dose of lithium, especially if this is done rapidly or abruptly,[81–83] could have had at least a quantitative impact on about half of the trials reviewed, although it seems very unlikely to account for the entire difference in recurrence risk with versus without lithium treatment.[86,87] Among the 25 studies indicating whether discontinuation was involved (n = 14) or not (n = 11), the mean reductions of recurrence risk with versus without lithium treatment are indistinguishable (66.1 ± 28.5% vs. 64.4 ± 16.8%; F [1; 23 df] = 0.03, $p = 0.86$). Of critical importance, even the recurrence rates *off* lithium were not significantly higher in studies involving lithium discontinuation (F [1; 21 df] = 1.62, $p = 0.22$), although they were more variable (418 ± 686 episodes/100 person-years [coefficient of variation, 164%]) than those found in trials apparently not involving lithium discontinuation (123 ± 99.8 episodes/100 person-years [coefficient of variation, 81%]).

Several studies[3,31,53,54,56,63] compared treatment responses in subjects with bipolar and unipolar depression and reported minor or inconsistent outcome differences between these syndromes. Nevertheless, whether lithium is equally effective against recurrences of mania and depression in bipolar disorder and recurrence of nonbipolar depression remains unclear.[2,3,5,24,27,28,31–33] When we divided the 28 studies according to the proportion of subjects in them who had bipolar disorder (15 studies in which at least 75% of subjects had bipolar disorder vs. 13 in which this percentage was lower), we found very similar outcomes. These include sparing of recurrence risk by 63.4 ± 25.5% versus 64.8 ± 22.9%, respectively (F [1; 26 df] = 0.02, $p = 0.88$). Even the five trials involving only a minority of bipolar patients (<50%)[54,56,64,65,67] yielded a similar sparing of recurrences (by 58.8 ± 34.0%).

Although the recurrence-sparing effect associated with long-term lithium treatment was both large and consistent, it was far from complete. The estimated overall reduction of recurrence risk was 54.9%, over 5.9 years of treatment-exposure. This incomplete protection may reflect variable long-term compliance by patients, variable intensity of follow-up and monitoring by treating clinicians, or limitations in effectiveness of the treatment for a severe disorder with a strong tendency toward recurrence.[2,5,15–17,22,24,27–29,31–33,42] It is also important to emphasize that no alternative treatment or combination of treatments has been proved to provide equivalent long-term protection against the risk for recurrences of bipolar disorder.[2,5,15–17,29,31,72]

This large body of diverse investigations is strikingly consistent in showing a substantial, albeit incomplete, lowering of recurrence risk for mania and depression in patients with bipolar disorder or nonbipolar depression. Nevertheless, several important issues remain unresolved in the studies analyzed. These include whether lithium protects against mania more than recurrent depression (in bipolar subtypes or in nonbipolar depressive disorders) and to what extent illness duration and overall morbidity are altered in addition to recurrence frequency.

SARDINIAN STUDIES ON THE EFFECTS OF LITHIUM TREATMENT ON MANIA AND BIPOLAR DEPRESSION

Overall Treatment Effects

Additional information about the relative effectiveness of lithium maintenance treatment in manic and depressive phases in both types I and II bipolar disorder is provided by

TABLE 2. Effects of Lithium Maintenance Treatment in 360 Patients with Bipolar Disorder[a]

Measure	Before treatment	During treatment	% Decrease
All patients			
Duration (y)	8.83 ± 8.38	4.49 ± 4.10	—
Hospitalizations/y	0.33 ± 0.86	0.06 ± 0.22	82
Recurrences/y	1.83 ± 2.14	0.81 ± 1.11	56
% Time ill	45.7 ± 30.6	19.9 ± 21.8	56
Episode duration (mo)	4.03 ± 2.54	3.04 ± 2.45	25
Manias/y	0.99 ± 1.48	0.36 ± 0.53	64
% Time manic	20.9 ± 22.3	8.11 ± 12.8	61
Episode duration (mo)	3.17 ± 2.01	2.48 ± 1.89	22
Depressions/y	0.84 ± 1.03	0.45 ± 0.84	46
% Time depressed	24.8 ± 22.5	11.7 ± 16.7	53
Episode duration (m)	4.80 ± 4.10	3.23 ± 2.57	33
No recurrences (%)		33.1	—
Patients with bipolar I disorder			
Duration (y)	7.94 ± 8.04	4.57 ± 4.13	—
Recurrences/y	1.54 ± 1.64	0.82 ± 0.83	47
% Time ill	43.4 ± 30.3	21.9 ± 21.3	50
Manias or hypomanias/y	1.00 ± 1.56	0.48 ± 0.57	52
% Time manic	23.6 ± 24.5	11.2 ± 14.7	53
Depressions/y	0.54 ± 0.52	0.35 ± 0.49	35
% Time depressed	19.8 ± 21.8	10.8 ± 15.8	45
No recurrences (%)		25.2	—
Patients with bipolar II disorder			
Duration (y)	10.2 ± 8.72	4.37 ± 3.82	—
Recurrences/y	2.28 ± 2.68	0.79 ± 1.47	65
% Time ill	49.3 ± 31.0	16.5 ± 21.0	67
Hypomanias/y	0.98 ± 1.35	0.19 ± 0.51	81
% Time manic	16.7 ± 17.6	3.40 ± 6.76	80
Depressions/y	1.30 ± 1.39	0.60 ± 1.15	54
% Time depressed	32.6 ± 21.4	13.0 ± 18.1	60
No recurrences (%)		45.1	—

[a]Results are based on new data and updated earlier findings presented elsewhere.[72,87] Data are shown as mean ± SD. All differences are significant (all paired t-tests ≥ 4.0, two-tailed $p < 0.001$, with correction for multiple comparisons).

results obtained with 360 patients with these conditions treated at a collaborating Sardinian clinic directed by a coauthor (LT). These subjects, unselected other than for meeting DSM-IV diagnostic criteria for bipolar I or bipolar II disorder, were evaluated for periods before (mean, 8.8 years) and during (mean, 4.5 years) lithium maintenance treatment (see results in Table 2). Lithium was used essentially as a monotherapy. Longitudinal data were acquired in regular clinical follow-up, using detailed, life-chart–based assessments, according to methods detailed previously.[73,88]

Substantial reductions were found in recurrences of bipolar illness with lithium maintenance treatment; these results were very similar to the average for all studies (56% vs. 55% sparing of risk, respectively). Total recurrence rates averaged 1.83 episodes per year before versus 0.81 episodes per year during treatment. This overall reduction in recurrence risk was associated with an even larger (82%; from 0.33 to 0.06/year) sparing of hospitalizations. The recurrence rates for mania or hypomania fell by 64% (from 0.99 to 0.36/year), and those for depression by 46% (from 0.84 to 0.45 episodes/year), suggesting only a moderately smaller benefit against bipolar depression than against mania. These differences are all highly statistically significant (all $p < 0.001$ by paired t-tests corrected for multiple comparisons).[73] Notably, however, full protection (zero recurrences) was attained in only 33% of subjects.[73] This experience accords with rates of full protection reported in other long-term studies of lithium treatment.[24,70,71]

Of the available morbidity measures, data on the proportion of days ill per year during versus before maintenance treatment are particularly important clinically. By this measure, there was an overall 56% reduction of bipolar morbid-

ity, from 45.7 to 19.9% of days ill.[73] For mania and hypomania, the morbidity scores fell by 61%, from 20.9 to 8.11%. For depression, they fell by 53%, from 24.8 to 11.7%, only slightly less than for mania/hypomania.

In addition to reduced recurrence rates and time ill, there was also a 25% reduction in the average duration of episodes among patients who suffered recurrences—from 4.03 months before treatment to 3.04 months during treatment. Episodes of mania/hypomania were shortened by 22%, from 3.17 to 2.48 months, and episodes of bipolar depression by 33%, from 4.80 to 3.23 months. These findings are particularly noteworthy, given the greater average duration of depressive than of manic episodes (4.8 vs. 3.2 months) before treatment, the somewhat higher proportion of time ill with depression than with mania (24.9% vs. 20.9%) before lithium, and the strong association of the depressive phase of bipolar disorder with both subjective distress and suicidal behavior. These results are consistent with data from other studies of the treatment of bipolar depression.[73,88–91]

Effects of Lithium in Bipolar Disorder Subtypes

Previously unpublished Sardinian findings distinguished between patients with type I (n = 218) and type II (n = 142) bipolar disorder. Long-term lithium treatment reduced morbidity in both syndromes. Overall, episode frequency in patients with bipolar I disorder fell by 47%, from 1.54 to 0.82 episodes per year. In patients with type II bipolar disorder, this rate fell even more (by 65%), from 2.28 to 0.79 episodes per year. Moreover, overall percentage of days ill fell by 50% (from 43.4 to 21.9%) in patients with bipolar I disorder, compared to a decrease of 67% (from 49.3 to 16.5%) in those with type II.

The effects of lithium treatment were even greater on recurrences of hypomania in patients with bipolar II disorder than on recurrences of mania/hypomania in those with type I. Recurrence rates fell by 52% (from 1.00 to 0.48 manic or hypomanic episodes/year) in subjects with bipolar I disorder, but by 81% (from 0.98 to 0.19 hypomanic episodes/year) for those with bipolar II disorder. In addition, the proportion of days manic or hypomanic fell by 53% (from 23.6% to 11.2%) in type I patients, whereas proportion of days hypomanic decreased by 80% (from 16.7% to 3.4%) in type II patients.

For bipolar depression, patients with type II bipolar disorder again showed greater improvements than did those with type I illness. The recurrence rate for depression fell by 35% (from 0.54 to 0.35 episodes/year) in type I patients and by 54% (from 1.30 to 0.60 episodes/year) in type II patients. Moreover, the proportion of days depressed decreased by 45% (from 19.8% to 10.8%) in bipolar I patients, compared to 60% (from 32.6% to 13.0%) in type II patients. The proportion of patients remaining completely free of recurrences during lithium maintenance treatment was also much greater in type II patients (45.1%, over an average of 4.4 years) than in type I patients (25.2%, over an average of 4.6 years).

Finally, subtyping by the presence of psychotic features, or of mixed manic-depressive states, in a majority of episodes prior to starting lithium maintenance treatment yielded little difference in morbidity during treatment between these patients and those with "more typical" bipolar disorder. For example, in these subgroups, the proportion of days ill during treatment was 20% (among patients with mainly psychotic features) and 23% (among those with mainly mixed states) versus 24% in patients with less complex illnesses.[73]

LONG-TERM EFFECTIVENESS OF LITHIUM IN RECURRENT MAJOR DEPRESSION

Research on lithium treatment also includes at least ten controlled long-term (average, 1.5 years) trials involving a total of over 400 subjects with recurrent major depressive episodes not considered to represent bipolar disorder.[2,3,19,22,50,54,55,60,64,65,67,92–95] In these trials, recurrence risk for apparently nonbipolar depression was reduced by 78%, on average. This effect is highly significant and is at least as great as that shown against mania and bipolar depression, as just reviewed.

In addition, several randomized, blinded, placebo-controlled trials indicate that lithium serves as an effective adjunct among patients in episodes of nonbipolar depression that have responded poorly to apparently adequate antidepressant trials. Based on meta-analysis, recovery rates were increased more than threefold compared to placebo when lithium was added to an ongoing antidepressant regimen, although fewer than half of the patients with treatment-resistant depression were "rescued" with adjunctive lithium.[96]

It is not clear whether the effects of lithium in nonbipolar depression reflect relatively broad mood-stabilizing effects of this agent or selective benefits in a subgroup of patients with depression. Such a subgroup might include individuals with apparently unipolar depression who have some clinical characteristics of bipolar disorder (such as early age of onset, relatively frequent recurrences, and anergic depressions) and might thus be considered to have "pseudounipolar" depressive illness.[12,13] In any event, a major challenge to any long-term treatment for major affective illnesses is to prevent the recurrence of depression and the substantially increased morbidity, disability, and mortality associated with it. Lithium seems to meet at least some of these requirements by reducing long-term morbidity due to recurrent depression, probably in both bipolar and apparently nonbipolar cases, in addition to its better-accepted benefits against mania and hypomania.

EFFECTIVENESS OF LONG-TERM LITHIUM TREATMENT IN REDUCING SUICIDE RISK

Substantial and quite consistent evidence has accumulated to show that rates of suicide and suicide attempts are markedly lower with long-term lithium maintenance treatment. Indeed, with the possible exception of long-term clozapine in schizophrenia,[97,98] the only medical intervention (including options ranging from psychotherapy to electroconvulsive therapy) for which there is credible evidence of reduction of suicide risk in major psychiatric disorders is lithium in the broad range of manic-depressive disorders, and particularly in bipolar disorder.[99,100] Our recent meta-analysis of relevant studies of lithium indicated consistently lower rates of suicidal acts during long-term treatment with lithium. Based on pooled data from all 22 available studies, which included a total of over 5600 patients with manic-depressive disorder, the computed weighted-average suicide rate was 0.88 (95% CI = 0.63–0.12) suicidal acts per 100 patient-years-at-risk (%/year) without lithium treatment versus only 0.16 (0.11–0.20) during lithium maintenance treatment, for a crude estimate of a 5.5-fold (82%) overall decrease in suicidal acts.[101–106] In a separate meta-analysis limited to the 12 studies involving direct comparisons of suicide rates on and off lithium, we[74] reported a nearly ninefold lower risk of completed suicides during lithium maintenance treatment. A recent case-control study involving 56 matched suicidal/nonsuicidal pairs[107] provides an unusual example of findings not supporting an association of probable ongoing lithium treatment with lack of suicide.

Additional analyses of available data on lithium and suicidal behavior in patients with bipolar disorder suggest other interesting trends.[105] Although the risk of suicidal deaths during lithium treatment was lowered by approximately 82% (to ca. 0.16%, or 160/100,000 per year), even this reduced rate was nearly ten times the average seen in the general population (ca. 0.0165%, or 16.5/100,000 per year).[105,106] This conclusion accords with other recent analyses in which suicide rates among patients with bipolar depression and perhaps also those with unipolar depression assigned (but not necessarily adherent) to long-term lithium treatment were compared to rates in the age- and sex-matched general population to estimate a standardized mortality ratio.[108,109] Although suicide risk was substantially lowered with treatment, the standardized mortality ratio remained elevated among persons assigned to lithium maintenance treatment, indicating that risk was not reduced to the level found in the general population.

There is preliminary evidence that mortality due to causes other than suicide may also be reduced with long-term lithium treatment.[99,109] However, the possibility that mortality associated with presumably stress-sensitive general medical illnesses is increased in bipolar disorder patients remains unsettled.[100]

The impact of lithium treatment on clinically significant suicide *attempts* may be even greater than its impact on suicides, since available data[105] suggest a reduction of attempts among bipolar disorder patients from about 2.83% per year to only 0.12% per year during lithium treatment (a 24-fold, or 96%, reduction). Comparisons to suicide attempt rates in the general population, however, are unreliable, and the ratio of suicide attempts to fatalities is uncertain. The ratio of attempts:suicides in the general population averages 18:1 in published reports[104] but is lower with more-severe attempts. It may be as low as 2:1 or 3:1 among persons with a major affective disorder,[104–106] implying that their suicidal acts are more likely to be lethal[105]—or less likely to be reported—than are those in the general population. If a ratio of 18:1 for attempts:suicides is assumed, then risk of suicide attempts in the general population would be approximately 0.30% per year. If we use this estimate, the attempt rate of about 0.12% per year found during lithium maintenance treatment of patients with bipolar disorder may be even lower than the risk for suicide attempts in the general population, which includes individuals with untreated major affective disorder.

The experience with suicidal behavior among over 350 bipolar I and II disorder patients in the collaborating Sardinian clinic has been consistent with the other published results.[103–105] That is, the risk of suicidal acts (life-threatening severe attempts before treatment, and both fatalities and attempts during treatment, so as to compare risks in the same subjects) was reduced 6.5-fold from an untreated rate of just over 2% per year. Lithium maintenance treatment was electively discontinued in some of these patients because of adverse effects or prolonged stability and refusal to continue; during the first 12 months following discontinuation, rates of suicidal acts increased over treated rates by 20-fold, and several of the patients made multiple attempts.[103–105] This early risk was half as great among those who discontinued lithium gradually (over a minimum of 2 weeks) as among those who did so abruptly, which accords with our previous findings with regard to recurrence risks for bipolar depression as well as mania after discontinuing lithium maintenance treatment.[77–83] Of note, after the patients had not received lithium for at least 12 months, rates of suicidal acts returned to the base rates found before lithium treatment was started.

The reason for the markedly lower suicide risk associated with long-term lithium treatment remains incompletely understood. It may reflect special pharmacodynamic properties of this extraordinarily complex agent.[5,110] Protection against recurrence of bipolar depression, which is particularly strongly associated with suicidal behavior,[103–105] is surely an important contribution. The requirement for close medical

monitoring and clinical follow-up for the safe use of lithium may also contribute to reducing suicide risk.[98,105]

RISKS AND BENEFITS OF LITHIUM TREATMENT AND ITS DISCONTINUATION DURING PREGNANCY

Our earlier research on the phenomenon of high early recurrence risk after discontinuation of lithium was recently extended to a collaborative study of women with bipolar disorder undertaken with colleagues at Massachusetts General Hospital's Perinatal Psychiatry Unit and at the Sardinian clinic. As in our previous studies of patients with bipolar disorder,[76–83] discontinuation proved very risky: women untreated for an equivalent time showed similar recurrence rates (about 55% had new episodes of mania or depression, overall, within 9 months without lithium, whether or not they were pregnant).[111] The risk was much lower among women who were discontinued gradually than among those who were discontinued rapidly, as we had found in broader samples of men and women with bipolar disorder.[77–83]

The lack of a difference in recurrence risk between age-matched pregnant and nonpregnant women after lithium has been stopped for an equivalent time may suggest that pregnancy has little effect on recurrence risk, being neither appreciably protective nor destabilizing.[111,112] An alternative possibility is that the impact of lithium discontinuation, itself, may be a more dominant risk factor. In contrast to the similar, substantial early risk of affective illness after discontinuing lithium maintenance treatment with or without pregnancy, there was an extraordinarily high risk of recurrences during the postpartum period among women who had remained clinically stable during pregnancy that was not found in comparable continued observation of nonpregnant women remaining without lithium for an additional 6 months.[111]

Regarding risks of lithium during pregnancy, cardiac teratogenic effects of early fetal exposure to lithium have proved to be less ominous than originally thought. The most characteristic adverse outcome is Ebstein's anomaly (downward displacement and malformation of the tricuspid valve), often together with an atrial septal defect. The base rate for this anomaly is approximately 1 per 20,000 live births in the general population; with exposure to lithium during the first trimester of pregnancy, the risk is increased to perhaps 1 per 1500 births.[113] This cardiac defect can usually be diagnosed in utero by ultrasonography and can often later be repaired with surgery. In striking contrast, the risk of spina bifida, an incurable and potentially crippling anomaly, may exceed 1 per 100 births among women with epilepsy who are exposed early in pregnancy to mood-stabilizing anticonvulsants, particularly divalproex and perhaps also carbamazepine.[5,114–116] With lithium, however, the risk of spina bifida in women with bipolar disorder does not exceed the spontaneous risk in the general population.[113] These considerations are leading to reassessment of the risks and potential benefits of using lithium late in pregnancy and during the neonatal period.[111,112]

RESPONSE TO RETREATMENT FOLLOWING LITHIUM DISCONTINUATION

Another important question about lithium discontinuation concerns the possibility of regaining previous levels of long-term benefits after stopping and then restarting treatment. The answer remains uncertain since some,[70,117–120] but not other,[121,122] investigators have found evidence that responses to secondary treatment are sometimes less satisfactory than are those in an initial trial of lithium. Our experience at the collaborating Sardinian clinic is more favorable, in that secondary long-term treatment responses were only slightly less robust than those seen in initial trials of lithium.[121] This optimistic outcome was unexpected, particularly in view of a substantial body of epidemiological evidence indicating that the natural history of (untreated) bipolar disorder tends toward a worsening course over time and with repeated episodes.[2,42] To some extent, the observed outcome may reflect selection bias based on over-representation of patients who tolerated and benefited from several years of additional lithium treatment. Yet, despite possible selection bias, the effect is surely not entirely artifactual because it is based on comparing the same subjects during their first and later trials of treatment.[121]

EFFECTS OF TREATMENT LATENCY AND NUMBER OF PRIOR EPISODES

The basis of the reported tendency in bipolar illness toward increasing frequency or severity of episodes remains unexplained, although without sustained long-term treatment a worsening course is to be expected clinically. One hypothesis is that episode count or illness duration may have a neurobiological as well as a clinical impact on individuals with bipolar disorder (the "kindling" hypothesis),[123] and a tendency toward worsening over time is best demonstrated in persons with untreated bipolar disorder.[2,42] However, the hypothesis that a loss of treatment response also occurs after delay of treatment, or after greater number of prior episodes, requires empirical testing.

Recent findings based on a literature review[124] and data from the Sardinian clinic sample[125,126] do not support the prediction that treatment response to long-term lithium maintenance may degrade with longer treatment latency or more episodes of mania or depression. This interpretation appears to hold whether treatment response is assessed as episode

frequency, as proportion of time ill during lithium maintenance treatment, or by survival analysis of time to recurrence during lithium treatment. Indeed, we have found evidence that treatment latency is inversely related to illness severity (measured either as recurrence rate or as proportion of days ill), possibly reflecting clinical indications for earlier therapeutic intervention.[125,126] Paradoxically, this relationship can lead to the misleading impression that a relatively greater *decrease* in morbidity with earlier treatment may suggest that treatment delay is followed by a loss of treatment responsiveness.[125,126]

At the Sardinian clinic, we found that delay in starting regular maintenance treatment was very common among patients with bipolar disorder, averaging nearly 9 years. Treatment delay was longest for women with bipolar II disorder and shortest among men with bipolar I disorder, probably reflecting the important behavioral differences between these subgroups and likely clinical responses to aggressive manic behavior in men compared to withdrawn depressive illness in women.[124,127] Another alarming finding was that the mean latency to a first suicide attempt was at least a year shorter than the mean latency to maintenance therapy.[102,103,105]

These findings encourage earlier diagnosis and earlier clinical intervention with sustained treatment than is often encountered currently in an effort to limit long-term morbidity and premature mortality. However, they fail to support the idea that either delay of treatment or number of pretreatment episodes routinely leads to greater morbidity during long-term maintenance treatment with lithium.

RESPONSES TO LITHIUM AND ALTERNATIVES IN RAPID-CYCLING BIPOLAR DISORDER

An additional factor widely considered to predict poor treatment response in bipolar disorder is rapid cycling. Frequently recurring illness can be severely disruptive and even incapacitating when untreated. Some researchers[123,128,129] have suggested that rapid cycling may be particularly unfavorable for response to lithium and, further, that certain anticonvulsants may yield superior results. However, contrary to expectations, our observations[130] do not support the assumption that rapid cycling precludes beneficial response to treatment. Instead, we found that time to a recurrence during lithium maintenance treatment was indistinguishable between bipolar disorder patients in Sardinia who did (n = 53) or did not (n = 307) experience rapid cycling—defined as involving at least four episodes of mania or depression—either within the 12 months before starting lithium (as required by DSM-IV criteria[131]) or during *any* year before lithium treatment began. Moreover, the average cycling rate (episodes/year) before maintenance treatment began did not correlate with response to lithium treatment.[130] We also found that rapid cycling usually was not a consistent pattern among subjects with untreated bipolar disorder who were evaluated over several years before starting regular maintenance treatment.[130]

In a comparative meta-analysis of studies of treatment responses in rapid- and non-rapid-cycling bipolar disorder patients treated with lithium or antimanic anticonvulsants (J. Hennen et al., unpublished manuscript), lithium was by far the most extensively studied option, in terms of numbers of studies (11/16) and subjects, as well as duration of treatment. In the 16 studies (and 25 treatment arms) included in this meta-analysis of 905 rapid- and 951 non-rapid-cycling subjects, treatment response was most commonly evaluated as the all-or-none risk of any recurrence during treatment. When specific agents were compared, lithium was superior to the alternatives among non-rapid-cycling patients. As expected, responses were, on average, at least moderately inferior with all treatments in rapid-cycling subjects. In comparisons with antimanic or antidepressant anticonvulsants proposed as mood stabilizers, lithium was not inferior to divalproex among rapid-cycling patients, and both agents tended to be superior to carbamazepine. The analysis also included the three available studies of lamotrigine and one of topiramate, with inconclusive results owing to the limited data available for these newer agents.

This analysis of the available, albeit limited, research findings clearly suggests that lithium does not differ significantly from alternative treatments in treatment response among patients with rapid-cycling bipolar disorder. The same result was sustained when broader, clinical ratings of improvement, rather than the reoccurrence of a single episode of illness during treatment, were considered as measures of treatment efficacy.

ADVERSE EFFECTS OF LITHIUM

Lithium presents an unusually narrow margin of safety (therapeutic index), in that serum concentrations only two to three times therapeutic levels can be intoxicating.[3,5] Acute intoxication is characterized by vomiting, diarrhea, coarse tremor, ataxia, nystagmus, coma, and convulsions, typically heralded by nausea, abdominal discomfort, sedation or confusion, and fine tremor. In severe overdoses, effects on the nervous system can include potentially irreversible neurological damage, and coma or death. Lithium also commonly causes electroencephalographic slowing and disorganization.[132]

Less-severe adverse effects, including nausea, daytime drowsiness, mild cognitive dulling, polydipsia, weight gain, fluid retention, and dermatological reactions (e.g., acne) can occur even at therapeutic serum concentrations. Occasional

patients treated with lithium develop benign diffuse, nontender thyroid enlargement, suggestive of compromised thyroid function. Serum thyroxin concentration may decrease, and thyroid-stimulating hormone secretion may be moderately elevated, but clinical hypothyroidism is uncommon.[133]

Transient, mild polyuria often appears early in treatment, and reversible nephrogenic diabetes insipidus is seen in a minority of patients later in maintenance treatment.[134] Chronic inflammatory changes in renal tissue have been found occasionally in patients given lithium for prolonged periods, but progressive impairment of renal function is rare. Nevertheless, these various adverse metabolic effects necessitate regular monitoring of serum concentrations of creatinine, electrolytes, thyroid hormones, and thyroid-stimulating hormone, as well as of the lithium ion itself.[5]

DEFINITION AND TESTING OF INNOVATIVE "MOOD STABILIZERS" AS ALTERNATIVES TO LITHIUM

It is also timely to consider appropriate criteria for a true mood-stabilizing agent, with lithium as the standard for comparison. Minimum criteria should include long-term protective action against at least some aspect of bipolar disorder, without worsening other components of the syndrome. Mood-stabilizing treatments should not only have short-term antimanic effects but also protect against recurrences of bipolar depression and mixed dysphoric-agitated states, as well as mania, over prolonged periods, preferably tested for longer than the common 1-year spontaneous cycling interval.[5,135] Ideally, for an agent to be designated as a "mood stabilizer," it should reduce recurrences of both depression and mania in frequency, duration, and severity. However, credible evidence for this degree of benefit, plus substantial evidence of a suicide risk–reducing effect of long-term treatment, exists only for lithium.

Carbamazepine, divalproex, and other anticonvulsants, as well as various antipsychotics, have been shown to have short-term (weeks) benefits in mania,[5,29,30,35,136] as does lamotrigine in acute bipolar depression.[137] In contrast, however, compelling evidence of long-term prophylactic effects in bipolar disorder (and for both bipolar depression and mania) is very limited for all agents other than lithium. Currently, FDA approval has been granted only to lithium, divalproex, and olanzapine for acute mania.[34] In addition, lithium is FDA approved for "recurrences," presumably of mania, in bipolar disorder.[34] Yet there is widespread use of lithium to protect against all phases of the disorder. And despite very limited evidence for long-term mood-stabilizing effects of agents other than lithium, all of the FDA-approved antimanic agents and several other, similar drugs lacking such approval are widely employed "off-label," either alone or in various inadequately tested combinations, in the long-term treatment of bipolar disorder patients.[5,29]

After lithium, perhaps the second most extensively evaluated mood stabilizer is carbamazepine.[3,5,29,31] Based on several direct comparisons,[138–142] carbamazepine appears to be less effective than lithium in preventing mania, bipolar depression, or suicide. However, the combination of lithium with carbamazepine may be therapeutically superior to either agent given alone.[139]

Randomized, long-term therapeutic comparisons of lithium to other mood stabilizers, and systematic evaluations of other combinations of putative mood-stabilizing agents, are rare. In the single long-term randomized trial of potential mood-stabilizing agent candidates,[5] divalproex was compared to placebo and to lithium for 12 months, following short-term treatment of acute mania.[72] In this unusually well-designed study, there was a nonsignificant prolongation of the latency to a first recurrence on divalproex over the alternatives, based on survival analysis. However, the crude relapse rate was 37.1% lower with divalproex than with placebo (24.1 vs. 38.3 failed cases/100 patient-years; χ^2 [1 df] = 6.18, p = 0.013).

Due to current trends in the experimental therapeutics of bipolar disorder, research evidence for long-term benefits comparable to that reviewed above for lithium is becoming increasingly difficult and expensive to acquire.[135] The design and conduct of long-term trials of any new treatment option in this disorder are becoming more challenging, in part reflecting the partial success of available treatments and a tendency for "off-label" maintenance applications following FDA approval for antimanic efficacy, even without adequate long-term testing. There is also a growing tendency to enroll patients with relatively mild illnesses when a placebo condition is involved, possibly due to emerging appreciation of the potential impact of treatment-discontinuation stress as a contributor to risks associated with placebo treatment. All of these factors combine to make clinical generalizations about treatment effectiveness of proposed mood-stabilizing treatments increasingly risky.[5,29,72,78–81,135,143]

CONCLUSIONS

This overview of contemporary knowledge underlying the use of lithium in the treatment of bipolar disorder suggests several provocative conclusions concerning its clinical utility (see Table 3). Lithium, by itself, is generally inadequate for rapid and safe control of acute mania but can be very useful in aftercare, following short-term interventions with other treatments including divalproex, antipsychotics, and high-potency benzodiazepines.[5] Lithium's major contemporary use is in long-term prevention of recurrences of bipolar illness, not only of mania but also of hypomania. Moreover, its effectiveness against recurrences of bipolar depression and closely associated suicidal behavior is well documented. Lithium may also be useful in many cases of recurrent uni-

TABLE 3. Situations in Which Lithium May Be Effective

Effective
Treatment of acute mania (effective, but slow)*
Prevention of recurrence of mania* and depression in bipolar I disorder
Reduction of suicidal risk in recurrent major affective disorders
Probably effective
Treatment of mania or bipolar disorder variants in children and the elderly
Long-term treatment (alone or with valproate) of rapid-cycling bipolar disorder
Long-term treatment after delay or following multiple bipolar episodes
Long-term retreatment after discontinuation
Prevention of recurrences of depression (and hypomania) in bipolar II disorder
Prevention of recurrences in unipolar or pseudounipolar major depression
Supplementation of antidepressants in major depression
Possibly effective or insufficiently investigated
Treatment of acute major depression (particularly bipolar I or II or pseudounipolar)
Long-term treatment of schizoaffective psychosis
Treatment of personality disorders involving cyclothymia or emotional instability
Treatment of episodic impulsive-aggressive behavior in adults or children (including those with developmental delay or brain damage)
Treatment of stimulant-induced euphoria

*Conditions for which lithium is approved by the Food and Drug Administration and recommended by manufacturers. Empirical clinical use for the other conditions is not unusual, especially when alternatives prove unsuccessful.

polar depression, and it has proved to be an effective adjunctive treatment for treatment-resistant acute major depression. The benefits of lithium do not seem to have degraded, on average, over the past several decades among relatively broadly representative samples of patients with bipolar disorder. The findings reviewed also question widely shared beliefs that several clinical factors are usually associated with nonresponsiveness to lithium. These include mixed manic-depressive states, a history of prolonged untreated bipolar illness, multiple episodes of mania or bipolar depression, and even rapid cycling. Moreover, re-use of lithium after its discontinuation was not routinely met with nonresponsiveness. Recent findings of high clinical risk in women who abruptly discontinue lithium to avoid fetal exposure early in pregnancy encourage reassessment of the broad risk/benefit relationships in continued use of lithium in late pregnancy and after delivery.

It seems fair to conclude that lithium continues to offer many clinical advantages, including highly competitive cost-effectiveness, even allowing for the expense of appropriate medical monitoring. It also has significant risks and liabilities, not least of which is its unusually narrow margin of safety, and the potential risk of irreversible neurotoxic or even fatal effects on overdose; it necessitates repeated blood tests to assure ideal and relatively well-tolerated serum concentrations in the range of 0.6–0.8 mEq/L for long-term use.[5,144] On balance, however, lithium continues to set a standard that has yet to be met by any proposed alternative mood-stabilizing treatments.

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A Rating Scale for Drug-Induced Akathisia

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A rating scale for drug-induced akathisia has been derived that incorporates diagnostic criteria for pseudoakathisia, and mild, moderate, and severe akathisia. It comprises items for rating the observable, restless movements which characterise the condition, the subjective awareness of restlessness, and any distress associated with the akathisia. In addition, there is an item for rating global severity. A standard examination procedure is recommended. The inter-rater reliability for the scale items (Cohen's κ) ranged from 0.738 to 0.955. Akathisia was found in eight of 42 schizophrenic in-patients, and nine had pseudoakathisia, where the typical sense of inner restlessness was not reported.

Akathisia is probably the commonest and one of the more distressing of the movement disorders associated with antipsychotic drugs (Lancet, 1986; Barnes, 1987). Following the original descriptions of drug-induced akathisia (Sigwald *et al*, 1947; Steck, 1954), there was little further work on the phenomenology of akathisia, and no consistent or clear operational definition emerged. The diagnosis of akathisia tended to rest upon systematic questioning regarding a patient's inner restlessness. However, reliance on a patient's subjective report alone does not allow for reliable diagnosis (Van Putten & Marder, 1986, 1987).

The lack of delineation of the associated motor behaviour created difficulty in separating akathisia from other movement disorders seen in drug-treated schizophrenic patients. These include Parkinsonian tremor, dystonia, tardive dyskinesia, tics, stereotypies and mannerisms. The distinction between tardive dyskinesia and akathisia is complicated by the common coexistence of the two conditions (Barnes *et al*, 1983). Descriptions of tardive dyskinesia have consistently mentioned motor restlessness, and subjective distress has been found to correlate rather better with trunk and limb movements than with orofacial movement (Rosen *et al*, 1982).

The lack of diagnostic criteria may partly account for the wide range of prevalence figures reported in the literature (Marsden *et al*, 1985): although a figure of around 20% is commonly accepted (Ayd, 1961; Braude *et al*, 1983), Freyhan (1958), for example, found a prevalence of only 12.5%, while Van Putten (1975) recorded a figure of 45%. Furthermore, in a sample of drug-free schizophrenic patients who received haloperidol (10 mg) at bedtime for seven days, Van Putten *et al* (1984) found that 75% experienced akathisia.

In addition, the absence of a precise clinical definition might be partly responsible for the failure of clinicians to recognise the condition consistently (Weiden *et al*, 1987). It may also contribute to the common misinterpretation of motor phenomena of akathisia as the signs and symptoms of psychiatric illness (Van Putten, 1975; Braude *et al*, 1983). If akathisia is misdiagnosed as an exacerbation of agitation or psychotic excitement, this error may prompt an increase in antipsychotic drug dose, which would almost certainly aggravate the problem.

Validity of the scale

The validity of the rating scale (see Appendix) derives from its basis in signs and symptoms found to be characteristic of the condition in our previous studies of both acute psychiatric admissions receiving antipsychotic medication (Braude *et al*, 1983) and schizophrenic out-patients on maintenance medication (Barnes & Braude, 1985).

Subjective item

These studies found that against the background of a relatively non-specific sense of inner restlessness or mental unease, sufferers were often particularly aware of tension and discomfort in their limbs, sometimes with paraesthesia and unpleasant pulling or drawing sensations in their legs. These complaints are akin to symptoms found in the 'restless legs', or Ekbom's, syndrome (Blom & Ekbom, 1961; Lancet, 1986).

In addition, the patients with akathisia would typically experience a desire to move, an awareness that they were unable to keep their legs still, or a compulsion to move which was often particularly referable to the legs. Many patients complained that the condition was least tolerable when they were required to stand still, for example when queueing for meals or medication on the ward, waiting at the supermarket checkout, or standing in the kitchen

while cooking. These symptoms constitute the subjective diagnostic criteria for akathisia included in the item 'awareness of restlessness' of the scale.

The inner restlessness and emotional unease experienced by patients with akathisia is often distressing for patients, and may lead them to refuse further medication. The importance of akathisia as a cause of poor compliance with antipyschotic drugs has been emphasised by Van Putten (1974). The overwhelming and intense nature of the subjective experience in severe cases is illustrated by reports where akathisia has been thought to have contributed to violent, aggressive behaviour (Kekich, 1978; Kumar, 1979; Schulte, 1985) or impulsive suicidal behaviour (Shear *et al*, 1983; Schulte, 1985; Drake & Erlich, 1985; Shaw *et al*, 1986). An item for distress related to restlessness was included in the scale. Any distress associated with akathisia can usually be elicited without difficulty, and is commonly complained of spontaneously.

Objective criterion

The study by Braude *et al* (1983) and a similar investigation by Gibb & Lees (1986) also found that particular patterns of restless leg movements were observed in association with the subjective experience of akathisia. The most characteristic signs that emerged were rocking from foot to foot or walking on the spot when standing. Van Putten & Marder (1987) agree that these foot movements are easily recognisable, and are present in all patients with moderate or severe akathisia. Braude *et al* (1983) observed other patterns of restless movement in seated patients, which accompanied the typical subjective experience of akathisia. They described these as shuffling or tramping of the legs. With severe akathisia, patients appeared to be unable to stand without walking or pacing. Gibb & Lees (1986) generally confirmed these findings, and suggested further that fast walking and swinging of one leg when sitting should also be considered as part of the akathisia syndrome.

These motor phenomena were considered to be observable diagnostic criteria for akathisia, and are included in the 'objective' item of the rating scale.

Global item

The rating of 'absent' refers to the failure of the rater to elicit any subjective awareness or complaint of restlessness. However, in the absence of any report of a sense of inner restlessness or a compulsion to move, some patients may manifest obvious, complex, repetitive movements resembling those seen in akathisia (Barnes & Braude, 1985). A common feature is rocking from foot to foot while standing. These movements seem to be of a volitional rather than choreic nature, and appear to represent motor restlessness. This syndrome has been called pseudo-akathisia (Munetz & Cornes, 1982; Barnes & Braude, 1985), and its relationship with akathisia and tardive dyskinesia is a matter for speculation (Barnes & Braude, 1985; Stahl, 1985; Munetz, 1986).

The signs of motor restlessness are not invariably present in mild cases of acute akathisia (Braude *et al*, 1983). The typical subjective experience of akathisia in the absence of restless movements has been referred to as 'subjective akathisia' (Van Putten & Marder, 1986). In practice, it may be difficult to differentiate between this condition and subtle manifestations of anxiety or emotional distress unrelated to akathisia. This difficulty is acknowledged by the 'questionable' rating in the global item of the scale, and the existence of subjective akathisia is reflected in the 'mild akathisia' rating, as it does not demand the presence of the characteristic restless phenomena.

The ratings for moderate, marked, and severe akathisia reflect increasing degrees of subjective distress and the desire or compulsion to move, an increasing inability to remain sitting comfortably, and an increasing amount of time spent exhibiting restless movements, such as rocking from foot to foot when standing, and pacing up and down.

Reliability

Patients and method

Forty-two chronic in-patients, all of whom fulfilled DSM–III criteria (American Psychiatric Association, 1980) for schizophrenia, and were receiving antipsychotic medication, were each assessed by two raters during the same examination period using the rating scale (Barnes & Halstead, 1988). The age range of the sample was 32–65 (median 52) years, and 13 were women.

Examination procedure

Each patient was observed seated for at least five minutes while consent to take part in the study was obtained and the patient completed a self-rating scale for anxiety, modified from the Leeds Anxiety Scale (Snaith *et al*, 1976). The patient was then asked to stand up, and was examined for evidence of Parkinsonism using the Extrapyramidal Rating Scale (Simpson & Angus, 1970). Still standing, patients were then engaged in conversation on neutral topics for several minutes while being observed, and finally were asked specific questions about inner restlessness, and awareness of the features of akathisia. For example, inquiry was made as to whether they experienced a sense of inner restlessness, and whether restless, fidgety feelings could

TABLE I
Inter-rater reliability

Rating scale item	*Linearly weighted Cohen's κ*
Objective	0.738
Subjective	
Awareness of restlessness	0.827
Distress related to restlessness	0.901
Global clinical assessment	0.955

be localised to any part of their body. Further, they were asked if they had any awareness of difficulty sitting comfortably for long periods, an increasing restlessness and tension when required to stand still, or a compulsive desire to move.

If akathisia was present, additional information was collected regarding any diurnal variation of symptoms, and whether the patient was aware of any particular situations which seemed to provoke or exacerbate the restlessness and any associated distress.

Inter-rater reliability

The agreement between the two raters on the akathisia scale was calculated. There was high inter-rater reliability on the scores for the four items, expressed in terms of Cohen's κ (Table I).

There was complete agreement between the two raters on the presence of akathisia, that is a rating of two or more on the global clinical assessment item. There was disagreement between the raters on the scores for the severity of akathisia in only two patients. The scores differed by one in both cases.

According to the global rating, akathisia was found in eight (19%) of 42 patients. The condition was rated as being of mild or moderate severity in six patients, and marked or severe in only two. Five (12%) of the 42 patients received a rating of 'questionable' akathisia. They manifested non-specific restless movements and described a vague sense of inner tension, but these features were unconvincing for a diagnosis of akathisia.

Nine (21%) patients were rated as having pseudo-akathisia. These patients exhibited akathisic movements, that is, they scored one or more on the 'objective' item, but did not apparently experience any associated inner restlessness or desire to move their legs, that is, they scored 0 on the 'subjective' item.

Discussion

In this small reliability study, the rating scale was found to be viable and practical, and a high level of inter-rater reliability was achieved. The results confirm both the relatively high prevalence of akathisia in chronic schizophrenic patients receiving maintenance antipsychotic drugs, and the existence in a proportion of such patients of pseudoakathisia, where the characteristic movements of akathisia are observed in the absence of the subjective symptoms.

It is envisaged that the rating on the global item alone should be sufficient for diagnostic purposes, and for measuring change in the overall severity of akathisia in response to treatment. Nevertheless, to rate the global item accurately the elements of the three other items need to be taken into account, and these items should be completed first.

The individual ratings on the two subjective items, 'awareness of restlessness' and 'distress related to restlessness', and the 'objective' item may be of value if an investigator wishes to detect whether the objective and subjective components of akathisia are differentially affected by particular drug treatments, or change independently over time. Also, when assessing a patient with pseudoakathisia, either over time or in the context of a treatment trial, the main measure of the condition is the rating on the 'objective' item. However, the emergence of a score for the 'awareness of restlessness' item might warrant a change in diagnosis to akathisia.

It is recommended that the scale is completed after observation of the patient in more than one setting. Preferably, the patient should be unobtrusively watched in a natural setting, for example while involved in activity on the ward, as well as during a formal interview. Experience with the assessment of patients with akathisia suggests that the situation in which the characteristic restless movements of rocking from foot to foot or treading on the spot are most likely to be observed is when the patient is standing with the rater, engaged in casual conversation on some neutral topic.

We are currently using this scale in a placebo-controlled study of β-adrenoceptor-blocking drugs in akathisia, and in a prevalence study in a population of chronic schizophrenic in-patients. The scale is also being employed in studies by other research groups in the UK and internationally. We plan to examine the reliability of the scale further in these studies, and also hope to test the validity of the scale by using an electronic movement meter to quantify the restless activity of patients, to provide an objective measure of the condition.

Appendix: Rating scale for drug-induced akathisia

Patient name:
Patient research no.:
Hospital no.:
Ward:
Rater:

Patients should be observed while they are seated, and then standing while engaged in neutral conversation (for a

minimum of two minutes in each position). Symptoms observed in other situations, for example, while engaged in activity on the ward, may also be rated. Subsequently, the subjective phenomena should be elicited by direct questioning.

Objective

0 Normal, occasional fidgety movements of the limbs
1 Presence of characteristic restless movements: shuffling or tramping movements of the legs/feet, or swinging of one leg, while sitting, *and/or* rocking from foot to foot or 'walking on the spot' when standing, *but* movements present for less than half the time observed
2 Observed phenomena, as described in (1) above, which are present for at least half the observation period
3 The patient is constantly engaged in characteristic restless movements, *and/or* has the inability to remain seated or standing without walking or pacing, during the time observed.

Subjective

Awareness of restlessness

0 Absence of innser restlessness
1 Non-specific sense of inner restlessness
2 The patient is aware of an inability to keep the legs still, or a desire to move the legs, *and/or* complains of inner restlessness aggravated specifically by being required to stand still
3 Awareness of an intense compulsion to move most of the time *and/or* reports a strong desire to walk or pace most of the time

Distress related to restlessness

0 No distress
1 Mild
2 Moderate
3 Severe

Global clinical assessment of akathisia

0 Absent
No evidence of awareness of restlessness. Observation of characteristic movements of akathisia in the absence of a subjective report of inner restlessness or compulsive desire to move the legs should be classified as pseudoakathisia
1 Questionable
Non-specific inner tension and fidgety movements
2 Mild akathisia
Awareness of restlessness in the legs *and/or* inner restlessness worse when required to stand still. Fidgety movements present, but characteristic restless movements of akathisia not necessarily observed. Condition causes little or no distress
3 Moderate akathisia
Awareness of restlessness as described for mild akathisia above, combined with characteristic restless movements such as rocking from foot to foot when standing. Patient finds the condition distressing
4 Marked akathisia
Subjective experience of restlessness includes a compulsive desire to walk or pace. However, the patient is able to remain seated for at least five minutes. The condition is obviously distressing
5 Severe akathisia
The patient reports a strong compulsion to pace up and down most of the time. Unable to sit or lie down for more than a few minutes. Constant restlessness which is associated with intense distress and insomnia

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The Pittsburgh Sleep Quality Index: A New Instrument for Psychiatric Practice and Research

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Abstract. Despite the prevalence of sleep complaints among psychiatric patients, few questionnaires have been specifically designed to measure sleep quality in clinical populations. The Pittsburgh Sleep Quality Index (PSQI) is a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. Nineteen individual items generate seven "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these seven components yields one global score. Clinical and clinimetric properties of the PSQI were assessed over an 18-month period with "good" sleepers (healthy subjects, $n = 52$) and "poor" sleepers (depressed patients, $n = 54$; sleep-disorder patients, $n = 62$). Acceptable measures of internal homogeneity, consistency (test-retest reliability), and validity were obtained. A global PSQI score > 5 yielded a diagnostic sensitivity of 89.6% and specificity of 86.5% (kappa $= 0.75$, $p < 0.001$) in distinguishing good and poor sleepers. The clinimetric and clinical properties of the PSQI suggest its utility both in psychiatric clinical practice and research activities.

Key Words. Sleep, sleep quality, depression, sleep disorders.

"Sleep quality" is an important clinical construct for two major reasons. First, complaints about sleep quality are common; epidemiological surveys indicate that 15-35% of the adult population complain of frequent sleep quality disturbance, such as difficulty falling asleep or difficulty maintaining sleep (Karacan et al., 1976, 1983; Bixler et al., 1979; Lugaresi et al., 1983; Welstein et al., 1983; Mellinger et al., 1985). Second, poor sleep quality can be an important symptom of many sleep and medical disorders. One frequently measured component of sleep quality, sleep duration, may even have a direct association with mortality (Kripke et al., 1979).

Sleep quality complaints are particularly relevant to psychiatry. Factors relating to anxiety and stress are one of the most important concomitants of sleep complaints in the general population (Karacan et al., 1983), and insomnia associated with psychiatric disorders is the most prevalent type of insomnia seen in sleep disorders centers, accounting for 35% of diagnoses (Coleman, 1983). Furthermore, sleep

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quality disturbances are frequently reported in essentially all psychiatric disorders, including depression, schizophrenia, anxiety disorders, and psychoactive substance use disorders.

Although sleep quality is a readily accepted clinical construct, it represents a complex phenomenon that is difficult to define and measure objectively. "Sleep quality" includes quantitative aspects of sleep, such as sleep duration, sleep latency, or number of arousals, as well as more purely subjective aspects, such as "depth" or "restfulness" of sleep. However, the exact elements that compose sleep quality, and their relative importance, may vary between individuals. Furthermore, because sleep quality is largely subjective, sleep laboratory measures may correlate with perceived sleep quality, but they cannot define it. Finally, the measurement of sleep quality is affected by the type of study in which it is being examined. Large-scale population surveys generally focus on a few general questions about habitual sleep quality and types of sleep disturbances (e.g., Bixler et al., 1979; Karacan et al., 1983). Studies that examine the previous night's sleep (drug efficacy studies, for example) may focus on more subjective, comparative aspects of sleep quality, such as depth of sleep, restfulness, and feelings upon awakening (e.g., Frankel et al., 1976; Webb et al., 1976; Parrott and Hindmarch, 1978).

Given the importance of the construct and the inherent difficulties in its definition and quantification, it is important to have a clinical instrument that measures sleep quality. It is also necessary, however, to assess the "clinimetric" properties (i.e., properties such as sensibility, accuracy, comprehensibility, and reproducibility) of the instrument, all of which are essential to the description and valid measurement of complex clinical phenomena (Feinstein, 1987). Although many sleep questionnaires have been described in previous studies, they share several general difficulties. First, very few of them have used specified time intervals for assessment. Second, previous questionnaires have not been designed to yield a simple, global score to facilitate comparisons between groups or individuals. Third, few of these studies have directly assessed clinimetric properties of the questionnaires. Finally, previous questionnaires have been used primarily with unselected population samples or nonclinical control subjects.

The Pittsburgh Sleep Quality Index was developed with several goals: (1) to provide a reliable, valid, and standardized measure of sleep quality; (2) to discriminate between "good" and "poor" sleepers; (3) to provide an index that is easy for subjects to use and for clinicians and researchers to interpret; and (4) to provide a brief, clinically useful assessment of a variety of sleep disturbances that might affect sleep quality. This article describes the instrument and its clinimetric properties, including internal homogeneity, performance consistency, and validity.

Methods

Instrument Development and Description (Appendix). Items in the Pittsburgh Sleep Quality Index (PSQI) were derived from three sources: clinical intuition and experience with sleep disorder patients; a review of previous sleep quality questionnaires reported in the literature; and clinical experience with the instrument during 18 months of field testing.

The PSQI assesses sleep quality during the previous month. This is a time frame intermediate between postsleep inventories (which assess only the previous night's sleep) and

survey-type questionnaires (which assess difficulties over the previous year or more). A postsleep questionnaire may reflect more accurately the night-to-night variations that occur in sleep quality, but it does not provide information about the frequency or duration of specific problems that may lead a patient to seek help. On the other hand, survey-type questionnaires may not indicate the severity of a particular problem at the present time. In addition, a duration of 2-3 weeks is often used clinically to differentiate transient from persistent sleep-wake disorders (Consensus Conference on Insomnia, 1984). Therefore, administering the PSQI on two occasions separated by approximately 1 month allows for the discrimination of most transient and persistent disturbances.

The PSQI consists of 19 self-rated questions and five questions rated by the bedpartner or roommate. The latter five questions are used for clinical information only, are not tabulated in the scoring of the PSQI, and are not reported on in this article. The 19 self-rated questions assess a wide variety of factors relating to sleep quality, including estimates of sleep duration and latency and of the frequency and severity of specific sleep-related problems. These 19 items are grouped into seven component scores, each weighted equally on a 0-3 scale. The seven component scores are then summed to yield a global PSQI score, which has a range of 0-21; higher scores indicate worse sleep quality.

The seven components of the PSQI are standardized versions of areas routinely assessed in clinical interviews of patients with sleep/wake complaints. These components are subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction. Scoring of each component is illustrated in the Appendix. Subject instructions for the PSQI are contained in the text. The entire index requires 5-10 min for the subject to complete, and 5 min to score.

Subjects. The PSQI was administered to three groups of subjects during an 18-month study period. Group 1 consisted of "good" sleepers: 52 healthy control subjects without sleep complaints, recruited for participation in research studies of sleep and aging (MH-37869), nocturnal penile tumescence (MH-40023), and sleep in depression (MH-40023, MH-30915). Group 2 consisted of "poor" sleepers: 34 patients with major depressive disorder, who were again recruited for participation in research protocols relating to sleep, aging, depression, and nocturnal penile tumescence. This group included 24 outpatients and 10 inpatients at the Western Psychiatric Institute and Clinic. Group 3, also consisting of "poor" sleepers, was a clinical sample of 62 physician-referred outpatients at the Sleep Evaluation Center (SEC) of the Western Psychiatric Institute and Clinic. Patients are referred to the SEC for assessment of a variety of sleep/wake complaints, but only patients with Disorder of Initiating and Maintaining Sleep (DIMS, $n = 45$) or Disorders of Excessive Somnolence (DOES, $n = 17$) (Association of Sleep Disorders Centers-ASDC, 1979) were included in this study, since the number of patients with other disorders was too small to permit statistical analysis.

Subjects were not matched for age or sex ratio because of the different requirements for each research protocol, and the absence of any age criteria for the clinical sleep disorders sample. The mean ages for subject groups were as follows: controls 59.9 years (range: 24-83); depressives 50.9 years (range: 21-80); DIMS 44.8 years (range: 20-80); and DOES 42.2 years (range: 19-57). Analysis of variance (ANOVA) indicated a significant difference in age between groups ($F = 5.20, p < 0.001$), with post hoc differences between control subjects and DIMS and DOES patients. Male/female ratios were as follows: controls 40/12; depressives 25/9; DIMS 16/29; and DOES 8/9 ($\chi^2 = 21.2, p < 0.001$). Male subjects had a lower mean age (46.5 years; SD = 16.7) than female subjects (55.4 years; SD = 18.9) ($t = -3.01, p < 0.005$). Many of the male subjects were involved in studies of nocturnal penile tumescence in depression, while female subjects were participating mainly in studies of sleep, aging, and depression.

Evaluation for all subjects included a complete medical history and physical examination. Depressives and controls were excluded from research involvement (and therefore, from the current study) for any medical conditions that would prevent a 2-week medication-free interval, as well as for the presence of known central nervous system disease such as

seizure disorder, cerebrovascular disease, or dementia. No specific exclusion criteria were used for the clinic sample of sleep-disorder patients. All depressed patients and healthy controls were assessed with the Schedule for Affective Disorders and Schizophrenia-Lifetime version (SADS-L) (Endicott and Spitzer, 1978), and diagnosed according to Research Diagnostic Criteria (Spitzer et al., 1978); all depressed patients met criteria for definite or probable current major depressive disorder. Severity of depressive symptoms was assessed with the Hamilton Rating Scale for Depression (Hamilton, 1960); the mean Hamilton score for depressed patients was 21.3 (SD = 4.65). Sleep-disorder patients were evaluated as described elsewhere (Jacobs et al., 1988), and given preliminary diagnoses according to ASDC nosology (ASDC, 1979). Sleep-disorder patients meeting criteria for *DSM-III* (American Psychiatric Association, 1980) major depression were excluded from the current study. All subjects completed a 2-week sleep/wake diary and a sleep habits questionnaire.

All subjects were further evaluated with routine polysomnography following a medication-free interval of at least 2 weeks. For depressed and sleep-disorder patients, this interval followed withdrawal from psychotropic and sedative-hypnotic medications. All subjects were studied with a routine sleep montage, including electroencephalographic (C4, referenced to tied mastoids), electro-oculographic (EOG), and electromyographic (submental) leads. Most subjects had additional monitoring for sleep apnea, myoclonus, or nocturnal penile tumescence, dictated by clinical indications or research protocol involvement. All sleep records were scored in 1-min epochs according to standard criteria (Rechtschaffen and Kales, 1968), using Stage 2 sleep onset, and standard convention for definition of sleep efficiency (time spent asleep/total recording period).

Final diagnoses for depressed and sleep-disorder patients were based on results of clinical and structured interviews, sleep questionnaires, and diaries. In addition, polysomnographic findings were considered in the final diagnoses of the sleep-disorder patients (Jacobs et al., 1988).

All 148 subjects completed the PSQI on at least one occasion (T_1) during the course of their clinical and research evaluation. For the majority of subjects (n = 107), the PSQI was completed before sleep studies. For some subjects with stable sleep/wake complaints (n = 41), the PSQI was completed after sleep studies. A subgroup of 91 subjects (43 controls, 22 depressives, and 26 sleep-disorder patients) completed the index a second time (T_2), an average of 28.2 days later (range: 1-265 days). The second PSQI was completed before any pharmacological treatment began.

Statistical Analyses. Descriptive statistics and ANOVA were used to contrast clinical and demographic features of the patient groups.

Internal homogeneity of separate items was assessed using Cronbach's α statistic and corrected component-total correlation coefficients (Cronbach, 1951). Pearson product-moment correlations were also used to correlate component and item scores with the PSQI global score.

Test-retest reliability (consistency) was assessed with paired t tests and Pearson product-moment correlations for PSQI global score, component scores, and individual items, at Time 1 (T_1) versus Time 2 (T_2). This was done for the entire subject pool, as well as for separate subject groups (except DOES patients, since only five patients had complete questionnaires on two occasions).

As the primary analysis of *validity*, we assessed the degree to which the index detected differences between groups recognized clinically as distinct. This assumes that the index measures differences between groups at the same time point as a clinical "gold standard." In this case, the relevant "gold standard" diagnoses were based on a combination of clinical interviews, structured interviews, and polysomnographic data. For this analysis, an analysis of covariance (ANCOVA) was used to compare patient groups for PSQI global and component scores, and the Student-Neuman-Keul's procedure was used for pairwise comparisons. Age and sex were used as covariates because of group differences in age and sex ratio. A multiple ANCOVA (MANCOVA) was performed for the PSQI global score, again using age and sex as covariates.

As a secondary analysis of validity, we compared PSQI scores with polysomnographic results, being cognizant of the fact that PSQI scores reflect the experience of sleep during the previous month, while polysomnographic data were limited to 2 or 3 nights. PSQI estimates of sleep latency, sleep duration, and sleep efficiency were compared to their homologous polysomnographic measures, using both *t* tests and Pearson product-moment correlations. Global PSQI scores were also compared to polysomnographic variables selected a priori as being likely to correlate with overall sleep quality, again using Pearson correlations. The specific variables selected were REM %, delta %, sleep latency, sleep efficiency, and sleep duration. Finally, group differences for these polysomnographic variables were assessed using one-way ANOVAs.

Results

General Results. Subjects found the PSQI easy to use and understand. Ten subjects out of an original pool of 158 failed to give complete responses to all items, and were therefore omitted from any further analyses; nine of these 10 were DOES patients.

The PSQI global score has a possible range of 0-21 points. Actual scores ranged from 0 to 20 points, with an overall group mean of 7.4, median of 6.0, and SD of 5.1. For individual components, each with a possible range of 0-3, the observed ranges were 0-3.

Age was negatively correlated with the subjective sleep quality ($r = -0.22, p < 0.05$) and daytime dysfunction ($r = -0.29, p < 0.02$) component scores in the healthy controls. The PSQI global score and other component scores (sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, and use of sleeping medications) were not significantly correlated with age.

Internal Homogeneity. The seven *component* scores of the PSQI had an overall reliability coefficient (Cronbach's α) of 0.83, indicating a high degree of internal consistency. In other words, each of the seven components appears to measure a particular aspect of the same overall construct, viz., sleep quality. The largest component-total correlation coefficients were found for habitual sleep efficiency and subjective sleep quality (0.76 for each), and the smallest correlation coefficient was found for sleep disturbances (0.35). The mean component-total correlation coefficient was 0.58. Pearson product-moment correlations between component scores and the PSQI global score were also calculated for the entire group, as well as each group separately (Table 1). Once again, the strongest correlations were seen for habitual sleep efficiency and subjective sleep quality.

Individual *items* were also strongly correlated with each other, indicated by a reliability coefficient (Cronbach's α) of 0.83. Item-total correlation coefficients ranged from 0.66 for question #9 (enthusiasm to get things done) to 0.20 for item #8 (difficulty staying awake). Pearson product-moment correlations between individual items and the global score ranged from 0.83 (subjective sleep quality) to 0.07 (cough or snore during sleep) (Table 2).

Performance Consistency (Test-Retest Reliability). Ninety-one patients completed the PSQI on two separate occasions. Paired *t* tests for the global PSQI score, as well as the seven individual component scores, showed no significant

differences between T_1 and T_2. Two differences were noted for depressed patients, who showed a reduction in sleep disturbances ($t = 2.32$, $p = 0.03$) and daytime dysfunction ($t = 3.46$, $p = 0.002$) at T_2.

Table 1. Component-global Pittsburgh Sleep Quality Index (PSQI) score correlations[1]

	All groups ($n = 48$)		Controls ($n = 52$)		Depressives ($n = 34$)		DIMS[2] ($n = 45$)		DOES[3] ($n = 17$)	
Component	*r*	*p*	*r*	*p*	*r*	*p*	*r*	*p*	*r*	*p*
Sleep quality	0.83	0.001	0.64	0.001	0.71	0.001	0.68	0.001	0.57	0.01
Sleep latency	0.72	0.001	0.58	0.001	0.64	0.001	0.67	0.001	0.69	0.001
Sleep duration	0.80	0.001	0.44	0.001	0.68	0.001	0.79	0.001	0.60	0.01
Habitual sleep efficiency	0.85	0.001	0.57	0.001	0.83	0.001	0.75	0.001	0.76	0.001
Sleep disturbance	0.46	0.001	0.70	0.001	0.19	—	0.31	0.02	0.38	—
Use of sleeping medication	0.62	0.001	0.20	—	0.69	0.001	0.51	0.001	0.33	—
Daytime dysfunction	0.63	0.001	0.53	0.001	0.38	0.01	0.53	0.001	0.38	0.001

1. Pearson product-moment correlations.
2. DIMS = Disorders of Initiating and Maintaining Sleep.
3. DOES = Disorders of Excessive Somnolence.

Pearson product-moment correlations again demonstrated stability in global and component scores. For the entire subgroup in which T_1 and T_2 measures were obtained, the T_1-T_2 correlation coefficient for global PSQI scores was 0.85 ($p < 0.001$). Component scores had coefficients ranging from 0.84 (sleep latency) to 0.65 (medication use) ($p < 0.001$ for each component score). Global PSQI scores for each diagnostic group were also significantly correlated between the two testing times, with r's > 0.40 ($p < 0.005$) for each group. Component scores within each subject group showed more variability across time, but all of these scores were significantly correlated (r's > 0.35, $p < 0.05$). The single exception was medication use in control subjects, which showed no correlation between the two testing times.

Validity. (Table 3, Figs. 1, 2). Global PSQI scores differed significantly between subject groups, using an ANCOVA with age and sex as covariates (Table 3). Control subjects differed from all patient groups (Student-Neuman-Keul's procedure). Furthermore, DIMS and depressed patients had significantly higher scores than DOES patients. Control subjects differed from DIMS and depressed patients on all individual component scores; controls also differed from DOES patients on three components (sleep disturbances, daytime dysfunction, and sleep quality). DOES and DIMS patients had significantly different scores on all components except sleep disturbances, and DOES and depressives patients differed on all components except sleep disturbance and daytime dysfunction.

Group differences resulted in distinctive component and global score profiles, shown in Fig. 1. Depressed and DIMS patients showed similar profiles, which differed from those of DOES patients and control subjects. These differences were further substantiated with a significant MANCOVA for component scores across groups (Hotelling's $T^2 = 2.62$, $p < 0.001$).

Age was a significant covariate only for the daytime dysfunction component; but contrary to expectations, these factors were *inversely* correlated, i.e., reported severity of daytime dysfunction tended to be greater in younger than in older subjects. Sex was a significant covariate for use of sleeping medications and habitual sleep efficiency, with males showing higher scores for each of these components. Age and sex were *both* significant covariates for the PSQI global score, but group differences were highly statistically significant even after covarying for these factors.

The distribution of global PSQI scores also differed between groups (Fig. 2). A post hoc cutoff score of 5 correctly identified 88.5% (131/148) of all patients and controls (kappa = 0.75, $p < 0.001$). This represents a sensitivity of 89.6% and a specificity of 86.5%. The same cutoff score correctly identified 84.4% (38/45) of DIMS patients, 88% (15/17) of DOES patients, and 97% (33/34) of depressives.

Group differences in PSQI global scores were also substantiated by polysomnographic results, which showed significant group differences for sleep latency ($F = 4.53$, $p < 0.001$), sleep efficiency ($F = 5.78$, $p < 0.001$), sleep duration ($F = 4.82$, $p < 0.003$), and number of arousals ($F = 2.87$, $p < 0.04$). Significant group differences were not found for rapid eye movement (REM) % or delta sleep %.

Validity of the PSQI was further examined by comparing PSQI estimates of sleep variables with those obtained by polysomnography. *T* tests showed no differences between PSQI estimates and laboratory findings for sleep latency, but PSQI estimates of the past month's usual sleep duration and efficiency were greater than

Table 2. Item-global Pittsburgh Sleep Quality Index (PSQI) score correlations[1]

	All groups ($n = 148$)		Controls ($n = 52$)		Depressives ($n = 34$)		DIMS[3] ($n = 45$)		DOES[4] ($n = 17$)	
Item[2]	*r*	*p*	*r*	*p*	*r*	*p*	*r*	*p*	*r*	*p*
Q5A	0.71	0.001	0.63	0.001	0.56	0.001	0.64	0.001	0.68	0.001
Q5B	0.52	0.001	0.52	0.001	0.38	0.01	0.49	0.001	0.55	0.01
Q5C	0.24	0.001	0.29	0.02	0.31	0.04	0.33	0.01	0.14	—
Q5D	0.17	0.02	0.12	—	0.07	—	0.08	—	-0.07	—
Q5E	0.07	—	0.34	0.007	-0.17	—	-0.10	—	0.29	—
Q5F	0.29	0.001	0.03	—	0.03	—	0.23	—	-0.03	—
Q5G	0.18	0.01	0.26	0.03	0.02	—	0.07	—	-0.00	—
Q5H	0.20	0.007	0.31	0.01	0.25	—	-0.21	—	-0.03	—
Q5I	0.24	0.002	0.54	0.001	0.06	—	-0.02	—	0.33	—
Q5J	0.32	0.001	0.37	0.004	0.17	—	0.22	—	-0.13	—
Q8	0.19	0.009	0.21	—	-0.08	—	0.28	0.03	0.14	—
Q6	0.83	0.001	0.37	0.003	0.71	0.001	0.69	0.001	0.57	0.008
Q2	0.66	0.001	0.64	0.001	0.56	0.001	0.64	0.001	0.72	0.001
Q4	0.80	0.001	0.44	0.001	0.68	0.001	0.79	0.001	0.57	0.008
Q7	0.62	0.001	0.19	—	0.69	0.001	0.49	0.001	0.31	—
Q9	0.69	0.001	0.55	0.001	0.44	0.005	0.53	0.001	0.30	—

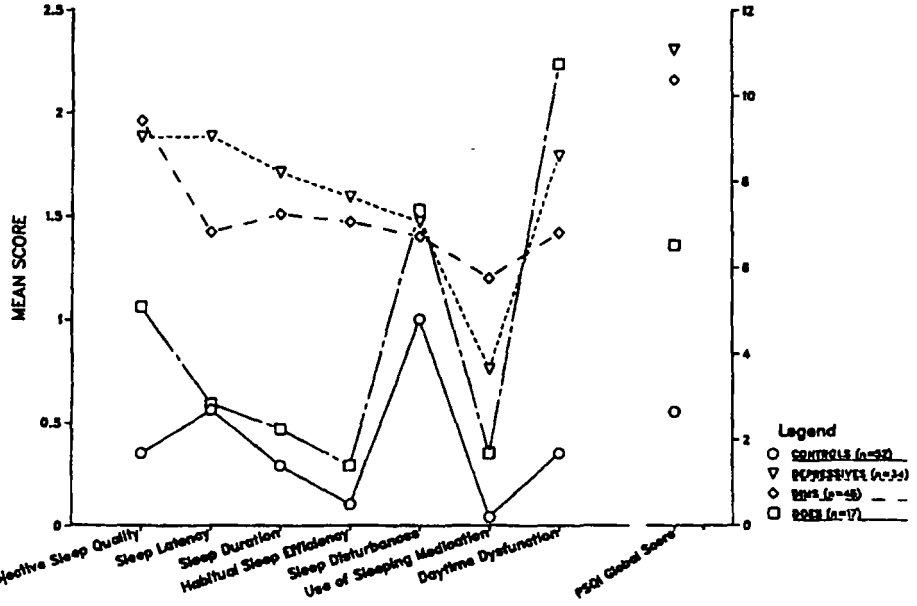
1. Pearson product-moment correlations.
2. Refer to questionnaire in Appendix.
3. DIMS = Disorders of Initiating and Maintaining Sleep.
4. DOES = Disorders of Excessive Somnolence.

Table 3. Pittsburgh Sleep Quality Index (PSQI) comparisons between diagnostic groups[1]

Component	Mean score ± SD (adjusted mean) Controls ($n = 52$)	Depressives ($n = 34$)	DIMS ($n = 45$)	DOES ($n = 17$)	ANCOVA F	ANCOVA p	Significant Student-Neuman-Keuls' comparisons
Subjective sleep quality	0.35 ± 0.48 (0.40)	1.88 ± 0.88 (1.92)	1.96 ± 0.93 (1.91)	1.06 ± 0.75 (1.02)	35.9	0.0001	Controls vs. depressives, DIMS, DOES; DOES vs. depressives, DIMS
Sleep latency	0.56 ± 0.73 (0.70)	1.88 ± 1.15 (1.96)	1.42 ± 1.01 (1.31)	0.59 ± 0.87 (0.49)	15.3	0.0001	Controls vs. depressives, DIMS; DOES vs. depressives, DIMS
Sleep duration	0.29 ± 0.50 (0.31)	1.71 ± 1.14 (1.74)	1.51 ± 1.20 (1.46)	0.47 ± 0.80 (0.46)	20.4	0.0001	Controls vs. depressives, DIMS; DOES vs. depressives, DIMS
Habitual sleep efficiency	0.10 ± 0.30 (0.11)	1.59 ± 1.18 (1.63)	1.47 ± 1.24 (1.41)	0.29 ± 0.77 (0.30)	25.2[2]	0.0001	Controls vs. depressives, DIMS; DOES vs. depressives, DIMS
Sleep disturbances	1.00 ± 0.40 (0.95)	1.47 ± 0.51 (1.45)	1.40 ± 0.62 (1.43)	1.53 ± 0.72 (1.56)	8.4	0.0001	Controls vs. depressives, DIMS, DOES
Use of sleeping medication	0.04 ± 0.28 (0.12)	0.76 ± 1.21 (0.84)	1.20 ± 1.31 (1.09)	0.35 ± 1.00 (0.31)	7.9[2]	0.0001	Controls vs. depressives, DIMS; DOES vs. depressives, DIMS
Daytime dysfunction	0.35 ± 0.48 (0.44)	1.79 ± 0.69 (1.83)	1.42 ± 0.94 (1.37)	2.24 ± 0.90 (2.16)	33.2[3]	0.0001	Controls vs. depressives, DIMS, DOES; DOES vs. DIMS
PSQI global score	2.67 ± 1.70	11.09 ± 4.31	10.38 ± 4.57	6.53 ± 2.98	45.1[4]	0.001	Controls vs. depressives, DIMS, DOES; DOES vs. depressives, DIMS

1. DIMS = Disorders of Initiating and Maintaining Sleep. DOES = Disorders of Excessive Somnolence.
2. Significant effect of sex as covariate.
3. Significant effect of age as covariate.
4. Significant effect of age and sex as covariates.

Fig. 1. Pittsburgh Sleep Quality Index (PSQI): Mean component score profiles



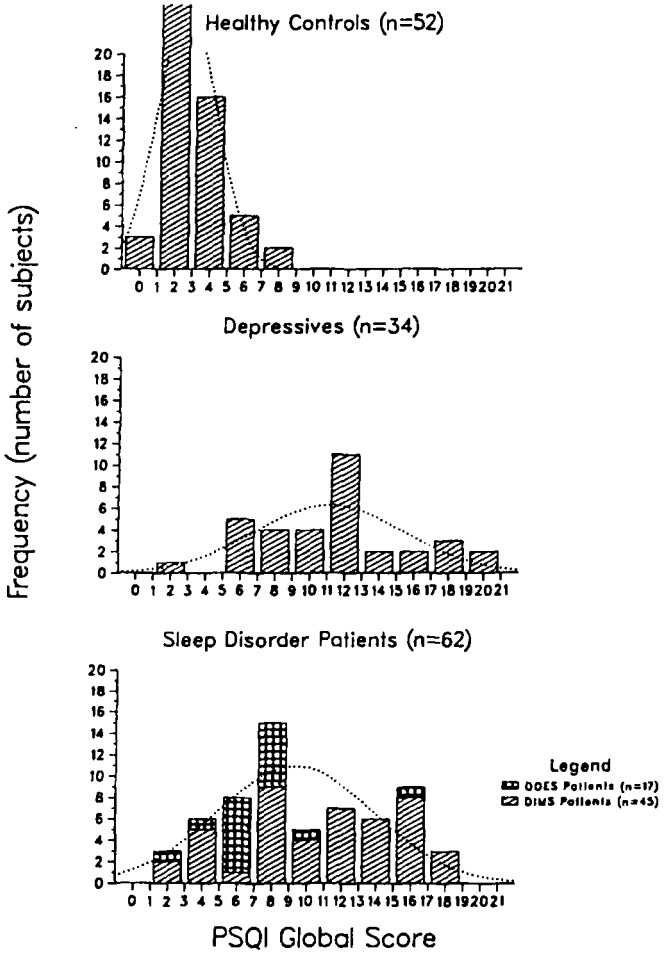
Depressed patients and patients with Disorders of Initiating and Maintaining Sleep (DIMS) have different components score profiles than do control subjects. Patients with Disorders of Excessive Somnolence (DOES) have a profile more similar to controls, but with expected elevations in subjective sleep quality, sleep disturbances, and daytme dysfunction. Significant group differences for individual components and overall profiles were substantiated with analyses of variance and multiple analyses of covariance (Table 3).

those obtained during polysomnography ($t = 9.98$ and 4.50, respectively; both p's < 0.001). This pattern was true for the total subject pool as well as individual subject groups. Pearson correlations demonstrated no significant positive correlations between PSQI estimates and polysomnographic results, except in sleep latency for the total subject pool ($r = 0.33$, $p < 0.001$) and for the depressive subgroup ($r = 0.37$, $p < 0.02$). Similarly, the global PSQI score was compared with several polysomnographic measures which we selected a priori as being likely to correlate with perceived sleep quality. For all subjects, the global score was weakly correlated only with objective sleep latency ($r = 0.20$, $p < 0.01$). For individual subject groups, the global PSQI score correlated only with REM % in controls ($r = 0.34$, $p < 0.006$) and number of arousals in depressives ($r = 0.47$, $p < 0.002$).

Discussion

Eighteen months of field testing with the PSQI have demonstrated that (1) subjects and patients find the index easy to use; (2) the seven major components of the index, as well as the 19 individual questions, are internally consistent; (3) the global scores, component scores, and individual question responses are stable across time; (4) the validity of the index is supported by its ability to discriminate patients from controls, and, to a more limited degree, by concurrent polysomnographic findings. We will

Fig. 2. Pittsburgh Sleep Quality Index (PSQI) global scores



PSQI global scores showed different distributions for control subjects, depressed patients, and sleep-disorder patients. A global score cutoff of > 5 correctly identified 88.5% of all controls and patients, yielding a sensitivity of 89.6% and a specificity of 86.5% (Kappa = 0.75, $p < 0.001$).

further discuss the format and clinimetric properties of the PSQI in relation to previous sleep questionnaires in the literature. We will also discuss possible applications for the PSQI in psychiatric clinical practice and research studies.

Questionnaire Format. A number of previous studies have reported on the use of self-rated or interviewer-administered sleep-quality questionnaires. In general, these instruments are of three types: habitual (i.e., "usual") sleep questionnaires for population surveys; habitual ("usual") sleep questionnaires for clinical investigations; and postsleep inventories.

The first type of questionnaire is used in epidemiological surveys of habitual or usual sleep habits, sleep difficulties, and sleep quality (e.g., McGhie and Russell,

1962; Karacan et al., 1976, 1983; Bixler et al., 1979; Johnson and Spinweber, 1983; Lugaresi et al., 1983; Welstein et al., 1983; Mellinger et al., 1985). The questions are usually few in number and general in scope, typically focusing on sleep duration, the presence of insomnia, and the use of medications for sleep. Habitual sleep questionnaires have also been used in clinical studies, most often to compare subjective reports with polysomnographic correlates (e.g., Monroe, 1969; Baekeland and Roy, 1971; Mendelson et al., 1984, 1986) or to examine differences between groups of subjects (McGhie, 1966; Beutler et al., 1978; Domino et al., 1984). These questionnaires are often more detailed than those used in large-scale surveys, and they include subjective estimates of sleep quality; however, their main focus is again on quantitative measures. The final type of questionnaire found in the literature is postsleep inventories (e.g., Samuel, 1964; Lewis, 1969; Frankel et al., 1973, 1976; Carskadon et al., 1976; Webb et al., 1976; Parrott and Hindmarch, 1978, 1980; Ellis et al., 1981; Mendelson et al., 1984). These instruments ask a variety of quantitative and qualitative questions about the previous night's sleep. They vary considerably in format, and in the number and type of questions. Postsleep inventories have been used to examine differences between subjective reports and objective polysomnographic findings, to study "good" and "bad" sleep, and to assess medication effects on sleep.

The PSQI has some similarities to these other questionnaires, but also has some important differences. The first comparison is in time interval of assessment. Most habitual sleep questionnaires do not specify a particular time frame, although there are some exceptions to this generalization (e.g., McGhie, 1966; Mendelson et al., 1986). The PSQI assesses a 1-month interval, which, as mentioned above, is clinically and scientifically useful. While postsleep inventories are unambiguous in their assessment of a single night's sleep, they are not as useful for detecting patterns of dysfunction, as noted previously.

A second comparison regards the type of questions included in the questionnaire. The PSQI is similar to many of the habitual sleep questionnaires in the type of questions included, e.g., estimates of sleep latency and duration, and frequency and severity estimates of problems. The PSQI's combination of quantitative and qualitative information is not found, however, in some of the more carefully studied questionnaires, such as those of Domino et al. (1984) and Webb et al. (1976).

The use of "component" scores in the PSQI is also similar to several other questionnaires, which have generated between 4 and 11 "factors" relating to sleep quality (Webb et al., 1976; Beutler et al., 1978; Parrott and Hindmarch, 1978; Domino et al., 1984). One major difference is that other questionnaires have more often included factors concerning mental activity before and during sleep. Another difference is that these other questionnaires have used factor analysis to generate specific factors, while the PSQI components are empirical and clinical in origin, rather than statistical.

A third comparison between the PSQI and other questionnaires regards scoring methods. The PSQI assigns ordinal scores to quantitative and qualitative information, allowing for the generation of component scores and a single global score. Except for McGhie (1966) and Beutler et al. (1978), previous questionnaires

do not use numerical scores for components or global scores. In the latter questionnaire, standard scores were determined by transforming the actual values of eight differently weighted "factors," and assigning an arbitrary value of "50" to the control mean. The PSQI global score has the advantages of giving a single overall assessment of sleep quality, being simple to calculate, and allowing for direct comparisons of individual patients or groups.

Finally, the PSQI was designed to assess clinical samples, while most previous questionnaires have been designed to assess normal sleep habits or entire populations. Although some questionnaires have been applied to patients with insomnia diagnosed by ASDC criteria (Mendelson et al., 1984, 1986), most have used patient samples that were not diagnosed according to current sleep disorders or psychiatric nomenclature.

Clinical Properties: Homogeneity and Consistency. The Cronbach's α of 0.83 obtained for PSQI components indicates a high degree of internal homogeneity (Feinstein, 1987). In other words, each of the components measures part of a coherent overall construct. Subjective sleep quality (item #6) showed one of the highest component-total correlation coefficients, which further supports this notion. The low component-total correlation coefficient seen for sleep disturbances may be the result of the large number of items that make up this component, as well as the fact that these items may be particularly susceptible to variation between individuals and over time. The sleep disturbance component also showed the least difference between diagnostic groups.

Data about internal homogeneity have been reported for three other sleep questionnaires, each of which used factor-analytic techniques. Domino et al. (1984) reported a factor analysis which yielded seven factors accounting for 71.7% of the total variance in the questionnaire. Cronbach's α was computed for these factors, with a median α of 0.82. Beutler et al. (1978) analyzed their 186-item questionnaire and found eight factors accounting for 59% of the total variance. The number of questions contributing to each factor ranged between 4 and 17. Finally, the postsleep inventory of Webb et al. (1976) had seven factors accounting for 54.5% of the total variance; specific questions with inter-item correlations higher than 0.65 were deliberately excluded. It is difficult to compare the PSQI with these questionnaires, due to differences in time frame of assessment, number of total questions, and subject populations tested. Most important, components of the PSQI were selected on purely clinical grounds, and not on the basis of factor analysis.

Overall consistency (test-retest reliability) of the PSQI was better for the entire subject pool than for any specific group. Of particular interest is the finding that DIMS patients had the highest correlations across time, while the control subjects had the lowest correlations. One possible explanation for the lower stability in the control subjects' scores is their low scores on all components, and particularly medication use. For both control subjects and DIMS patients, component correlations were highest for sleep latency and sleep duration, two "quantitative" variables. Correlation coefficients were lower for daytime dysfunction and sleep quality, two of the more "qualitative" components, as well as for the sleep disturbances component, which may include items that are variable between individuals and across time.

Consistency for the PSQI is lower than that reported by Domino et al. (1984), who administered their questionnaire on two occasions separated by 10 weeks, and found Pearson correlations for the seven factors of their questionnaire ranging from 0.68 to 0.79. However, this sample did not include patients with sleep or psychiatric disorders.

Clinimetric Properties: Validity. The identification of "good" and "poor" sleepers for research studies relies on subjective assessments of sleep quality, clinical interviews, and polysomnographic studies. The PSQI provides a standardized, quantitative measure of sleep quality that quickly identifies good and poor sleepers, and compares favorably with the "gold standard" of clinical and laboratory diagnosis. In the current study, good and poor sleepers consisted of healthy control subjects and depressed or sleep-disordered patients. A global PSQI score > 5 provided a sensitive and specific measure of poor sleep quality, relative to clinical and laboratory measures. Age and sex did not strongly correlate with PSQI component scores, but they were significant covariates for the global score. Given the differences in mean age and sex ratio between groups (with good sleepers being older than poor sleepers), the current results are likely to underestimate the PSQI's ability to identify good and poor sleepers.

Distinct component score profiles emerged for controls, DOES patients, and DIMS/depressed patients. The PSQI did *not* differentiate DIMS and depressed patients. This is not surprising, since the sleep disturbance of depressives is most often a sleep onset and maintenance insomnia. In fact, the current study lends validity to the classification of depressive sleep disturbance as a DIMS in the ASDC classification.

The PSQI is primarily intended to measure sleep quality and to identify good and bad sleepers, not to provide accurate clinical diagnoses. Nevertheless, responses to specific questions can point the clinician toward areas for further investigation. This is particularly true for the "sleep disturbances" component, which may guide clinical evaluations for specific patients, even though mean scores do not discriminate between groups. Furthermore, a PSQI global score > 5 indicates that a subject is having severe difficulties in at least two areas, or moderate difficulties in more than three areas. The global score is therefore "transparent," i.e., it conveys information about the severity of the subject's problem, and the number of problems present, through a single simple measure (Feinstein, 1987).

A number of other studies have also validated their sleep questionnaires by comparing different subject populations. For example, Domino et al. (1984) validated their scale by administering it to patients with and without complaints of sleep disturbance at a family physician's office, and to patients with and without depressive symptoms at a community mental health center. In each case, the patient groups differed significantly on a number of the questionnaire's scales. Beutler et al. (1978) used a stepwise discriminant function analysis to identify self-proclaimed insomniacs and controls. Their discriminant model, including subject age and three of the eight factors in their questionnaire, correctly identified 93% (86/92) of subjects. A separate discriminant analysis correctly identified 86% (37/43) of insomniacs who used or did not use medications. Mendelson et al. (1984, 1986)

found statistically significant differences on self-report sleep questionnaires for insomniacs versus controls. McGhie (1966) compared depressed and nondepressed psychiatric patients, and found no differences on the total sleep disturbance scale of his questionnaire. Finally, Webb et al. (1976) found differences between "good" and "bad" sleep episodes, and between high school and elderly subjects, with their postsleep inventory. Like these previous questionnaires, the PSQI separates patients with different diagnoses, but differs in that control subjects and patients in this study were diagnosed according to current research and clinical criteria. In addition, except for Beutler et al. (1978), previous reports have not indicated the sensitivity and specificity of their scales.

A number of other studies have reported on the use of polysomnography to validate subjective sleep reports (e.g., Lewis, 1969; Monroe, 1969; Baekeland and Hoy, 1971; Bixler et al., 1973; Frankel et al., 1973, 1976; Carskadon et al., 1976; Mendelson et al., 1984, 1986; Hoch et al., 1987). Several consistent findings emerge from these reports. First, subjects with and without insomnia are not "accurate" in their subjective report of variables such as sleep latency, sleep duration, and number of arousals. However, while control subjects tend to overestimate their ability to sleep, insomniacs tend to underestimate it, perhaps because they misperceive the experience of being asleep (W. Mendelson, personal communication, April 15, 1988). Second, while subjective estimates and objective measures of sleep differ in actual amount, they are often strongly and positively correlated. Finally, postsleep questionnaires yield more accurate subjective estimates that are more strongly correlated with polysomnographic findings. The current findings using the PSQI did not replicate these general findings, as PSQI responses were not found to correlate with polysomnographic measures. It is not surprising that subjects differed in subjective and polysomnographic variables, since the PSQI asks for a global estimate spanning 1 month, and is not sensitive to daily variability.

Applications. The PSQI's simplicity and its ability to identify different groups of patients suggest several clinical and research applications in psychiatry and general medical settings. Most fundamentally, it may be used as a simple screening measure to identify cases and controls, or "good" and "poor" sleepers. In a general clinical setting, the PSQI could be used to screen patients for the presence of significant sleep disturbance. In psychiatric settings, the PSQI may identify patients who are likely to have a sleep disturbance concomitant with their psychiatric symptoms. In addition, it may direct the clinican to specific areas of dysfunction that require further investigation. The PSQI could also be used in clinical research and epidemiological studies to identify groups that differ in the quality of their sleep.

The PSQI may also have several longitudinal applications in clinical practice and research. For example, it could be used to examine the course and natural history of sleep/wake disorders. It could also be used to monitor the progression of sleep disturbances and their interaction with other symptoms during the course of psychiatric illnesses such as depression. Rodin et al. (1988) recently published one of the few studies to examine the interaction between depressive symptoms and sleep disturbance longitudinally. The PSQI may be helpful in future studies of this type, providing more detailed information about types and severity of sleep disturbances

over time. Further, the PSQI could be useful in studying the relation between sleep quality and other variables, such as age, gender, health status, medical and psychiatric conditions, and performance on other psychological variables. Finally, the PSQI could be used to examine the longitudinal effects of specific therapeutic interventions for psychiatric disorders or sleep disorders. For example, sleep quality could be monitored during maintenance treatment of depression with medications or psychotherapy. Used in this way, the PSQI might also detect relapses heralded by the onset or reemergence of sleep disturbance.

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Appendix. Pittsburgh Sleep Quality Index (PSQI)

Name _____ ID # _____ Date _____ Age _____

Instructions:

The following questions relate to your usual sleep habits during the past month *only*. Your answers should indicate the most accurate reply for the *majority* of days and nights in the past month. Please answer all questions.

1. During the past month, when have you usually gone to bed at night?

   USUAL BED TIME _____

2. During the past month, how long (in minutes) has it usually take you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, when have you usually gotten up in the morning?

   USUAL GETTING UP TIME _____

4. During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer *all* questions.

5. During the past month, how often have you had trouble sleeping because you...

   (a) Cannot get to sleep within 30 minutes

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (b) Wake up in the middle of the night or early morning

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (c) Have to get up to use the bathroom

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (d) Cannot breathe comfortably

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (e) Cough or snore loudly

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (f) Feel too cold

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (g) Feel too hot

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (h) Had bad dreams

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

   (i) Have pain

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

(j) Other reason(s), please describe _____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

6. During the past month, how would you rate your sleep quality overall?
   - Very good ____
   - Fairly good ____
   - Fairly bad ____
   - Very bad ____
7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?
   - No problem at all ____
   - Only a very slight problem ____
   - Somewhat of a problem ____
   - A very big problem ____
10. Do you have a bed partner or roommate?
    - No bed partner or roommate ____
    - Partner/roommate in other room ____
    - Partner in same room, but not same bed ____
    - Partner in same bed ____

If you have a roommate or bed partner, ask him/her how often in the past month you have had...

(a) Loud snoring

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

(b) Long pauses between breaths while asleep

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

(c) Legs twitching or jerking while you sleep

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

(d) Episodes of disorientation or confusion during sleep

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

(e) Other restlessness while you sleep; please describe _____

_____

Not during the past month ____	Less than once a week ____	Once or twice a week ____	Three or more times a week ____

Scoring Instructions for the Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) contains 19 self-rated questions and 5 questions rated by the bed partner or roommate (if one is available). Only self-rated questions are included in the scoring. The 19 self-rated items are combined to form seven "component" scores, each of which has a range of 0-3 points. In all cases, a score of "0" indicates no difficulty, while a score of "3" indicates severe difficulty. The seven component scores are then added to yield one "global" score, with a range of 0-21 points, "0" indicating no difficulty and "21" indicating severe difficulties in all areas.

Scoring proceeds as follows:

Component 1: Subjective sleep quality

Examine question #6, and assign scores as follows:

Response	Component 1 score
"Very good"	0
"Fairly good"	1
"Fairly bad"	2
"Very bad"	3

Component 1 score: _____

Component 2: Sleep latency

1. Examine question #2, and assign scores as follows:

Response	Score
≤ 15 minutes	0
16-30 minutes	1
31-60 minutes	2
> 60 minutes	3

Question #2 score: _____

2. Examine question #5a, and assign scores as follows:

Response	Score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Question #5a score: _____

3. Add #2 score and #5a score

Sum of #2 and #5a: _____

4. Assign component 2 score as follows:

Sum of #2 and #5a	Component 2 score
0	0
1-2	1
3-4	2
5-6	3

Component 2 score: _____

Component 3: Sleep duration

Examine question #4, and assign scores as follows:

Response	Component 3 score
> 7 hours	0
6-7 hours	1
5-6 hours	2
< 5 hours	3

Component 3 score: _____

Component 4: Habitual sleep efficiency

(1) Write the number of hours slept (question # 4) here: _____

(2) Calculate the number of hours spent in bed:

Getting up time (question # 3): _____

− Bedtime (question # 1): _____

Number of hours spent in bed: _____

(3) Calculate habitual sleep efficiency as follows:

(Number of hours slept/Number of hours spent in bed) × 100 = Habitual sleep efficiency (%)

(_____/_____) × 100 = _____%

(4) Assign component 4 score as follows:

Habitual sleep efficiency %	Component 4 score
> 85%	0
75-84%	1
65-74%	2
< 65%	3

Component 4 score: _____

Component 5: Sleep disturbances

(1) Examine questions # 5b-5j, and assign scores for *each* question as follows:

Response	Score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

#5b score _____
c score _____
d score _____
e score _____
f score _____
g score _____
h score _____
i score _____
j score _____

(2) Add the scores for questions # 5b-5j:

Sum of # 5b-5j: _____

(3) Assign component 5 score as follows:

Sum of # 5b-5j	Component 5 score
0	0
1-9	1
10-18	2
19-27	3

Component 5 score: _____

Component 6: Use of sleeping medication

Examine question # 7 and assign scores as follows:

Response	Component 6 score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Component 6 score: _____

Component 7: Daytime dysfunction

(1) Examine question # 8, and assign scores as follows:

Response	Score
Never	0
Once or twice	1
Once or twice each week	2
Three or more times each week	3

Question # 8 score: _____

(2) Examine question # 9, and assign scores as follows:

Response	Score
No problem at all	0
Only a very slight problem	1
Somewhat of a problem	2
A very big problem	3

Question # 9 score: _____

(3) Add the scores for question # 8 and # 9:

Sum of #8 and #9: _____

(4) Assign component 7 score as follows:

Sum of # 8 and #9	Component 7 score
0	0
1-2	1
3-4	2
5-6	3

Component 7 score: _____

Global PSQI Score

Add the seven component scores together:

Global PSQI Score: _____

A Double-Blind Placebo-Controlled Study of Lamotrigine Monotherapy in Outpatients With Bipolar I Depression

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Background: More treatment options for bipolar depression are needed. Currently available antidepressants may increase the risk of mania and rapid cycling, and mood stabilizers appear to be less effective in treating depression than mania. Preliminary data suggest that lamotrigine, an established antiepileptic drug, may be effective for both the depression and mania associated with bipolar disorder. This is the first controlled multicenter study evaluating lamotrigine monotherapy in the treatment of bipolar I depression.

Method: Outpatients with bipolar I disorder experiencing a major depressive episode (DSM-IV, N = 195) received lamotrigine (50 or 200 mg/day) or placebo as monotherapy for 7 weeks. Psychiatric evaluations, including the Hamilton Rating Scale for Depression (HAM-D), the Montgomery-Asberg Depression Rating Scale (MADRS), Mania Rating Scale, and the Clinical Global Impressions scale for Severity (CGI-S) and Improvement (CGI-I) were completed at each weekly visit.

Results: Lamotrigine 200 mg/day demonstrated significant antidepressant efficacy on the 17-item HAM-D, HAM-D Item 1, MADRS, CGI-S, and CGI-I compared with placebo. Improvements were seen as early as week 3. Lamotrigine 50 mg/day also demonstrated efficacy compared with placebo on several measures. The proportions of patients exhibiting a response on CGI-I were 51%, 41%, and 26% for lamotrigine 200 mg/day, lamotrigine 50 mg/day, and placebo groups, respectively. Adverse events and other safety results were similar across treatment groups, except for a higher rate of headache in the lamotrigine groups.

Conclusion: Lamotrigine monotherapy is an effective and well-tolerated treatment for bipolar depression.

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A complete list of the members of the Lamictal Study 602 Group is given at the end of this article.

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More effective treatments for the depressive episodes of bipolar disorder are needed. Currently available mood stabilizers, including lithium, are effective in the treatment of mania but appear to be less effective in the treatment of bipolar depression.[1] The adjunctive use of antidepressant medications is common, but this practice can put patients with bipolar disorder at increased risk for the development of hypomania, mania, or cycle acceleration.[2] During the development of the antiepileptic compound lamotrigine, the drug was observed to improve mood, alertness, and social interactions in some patients.[3] These early observations in patients with epilepsy stimulated interest in the evaluation of lamotrigine as an antidepressant and mood stabilizer. Open-label clinical reports involving over 200 patients suggest that lamotrigine may possess a broad spectrum of mood stabilizing efficacy in bipolar I and II disorder when given as adjunct treatment or as monotherapy.[4–18]

A series of controlled studies has been initiated to evaluate the efficacy and safety of lamotrigine in the various phases of bipolar I and II disorder. This report presents data from the first study in this series, which compared 2 doses of lamotrigine with placebo in the treatment

of a major depressive episode in patients with bipolar I disorder.

METHOD

Patients

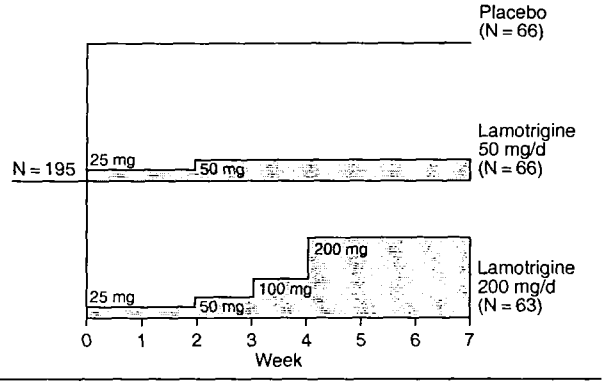
Men and women at least 18 years of age were eligible for the study if they were diagnosed with bipolar I disorder, as defined by DSM-IV criteria, and had at least 2 previous mood episodes during the past 10 years, at least 1 of which was a manic or mixed episode. The diagnosis was confirmed by the Structural Clinical Interview for DSM-IV. Eligible patients were currently experiencing a major depressive episode with a duration ≥ 2 weeks but ≤ 12 months. A minimum score of 18 on the 17-item Hamilton Rating Scale for Depression (HAM-D)[19,20] was required at study entry. Patients with rapid-cycling bipolar disorder; abnormal thyroid function tests; a diagnosis of or treatment for panic disorder, obsessive-compulsive disorder, social phobia, or bulimia nervosa in the previous 12 months; a history of substance dependence (previous year) or abuse (previous month) or with a positive toxicological screen; a chronic cardiac, renal, or hepatic condition or an unstable medical condition; or epilepsy were excluded. Pregnant or lactating women and patients who were actively suicidal were also excluded. Patients with worsening of psychiatric status such that symptoms constituted a danger to them or to others were to be discontinued. Patients must have discontinued any psychoactive drug within a time equal to 5 elimination half-lives prior to randomization.

Study Design and Procedures

This randomized, double-blind, parallel-group, multicenter study (Glaxo Wellcome Protocol 105-602) was conducted to compare the efficacy and safety of lamotrigine monotherapy and placebo in the treatment of bipolar I depression. Careful consideration was given to the use of placebo in this trial. Institutional review board (United States) and ethics committee (outside the United States) approvals were obtained, and patients provided written, informed consent. After screening and baseline assessments confirmed that entry criteria were met, equivalent numbers of patients were randomly assigned to treatment with a target dose of either lamotrigine 50 mg/day (25 mg b.i.d., N = 66), lamotrigine 200 mg/day (100 mg b.i.d., N = 63), or placebo tablets (b.i.d., N = 66) (Figure 1). To balance the effects of recent use of lithium, randomization was stratified according to intensity of treatment with lithium (presence or absence of plasma levels of ≥ 0.4 mmol/L or dosing of ≥ 600 mg/day for ≥ 1 month) during the 5 months preceding study entry.

Patients randomly assigned to lamotrigine 50 or lamotrigine 200 mg/day received active lamotrigine as 25-mg chewable, dispersible tablets. The lamotrigine dose was

Figure 1. Flow Diagram of Study Design and Dose Escalation Schedule



escalated according to the following schedule to reach a target of 50 mg/day (weeks 1–2, 25 mg q.d.; weeks 3–7, 25 mg b.i.d.) or 200 mg/day (weeks 1–2, 25 mg q.d.; week 3, 25 mg b.i.d.; week 4, 50 mg b.i.d.; weeks 5–7, 100 mg b.i.d.) as shown in Figure 1. Placebo tablets were identical in appearance to the active drug. The number of placebo tablets was adjusted at each week and for each lamotrigine dose so that the total number of tablets administered per day (lamotrigine plus placebo) was always 8. Patients were provided with blister cards containing each week's medication. Compliance with the prescribed dosing regimen was determined by returned tablet counts at each treatment visit. The only other psychoactive drugs permitted were chloral hydrate, lorazepam, temazepam, or oxazepam as needed for control of agitation, insomnia, and hostile behaviors during the first 3 weeks of the treatment phase.

Clinic visits were conducted at screening (within 14 days prior to treatment), baseline (the day prior to the start of treatment), on the fourth day of treatment, and the end of every week for the 7-week duration of treatment. At the screening visit, patients underwent the following assessments: demographic characteristics, a modified version of the Structured Clinical Interview for DSM-IV (SCID),[21] psychiatric history (including age at onset of affective symptoms), physical examination, skin rash history, clinical laboratory tests (including thyroid function tests), urinalysis, urine screen for illicit drugs, electrocardiogram, and psychiatric rating scales including the HAM-D, the Montgomery-Asberg Depression Rating Scale (MADRS),[22] the Mania Rating Scale (first 11 items from the Schedule for Affective Disorders and Schizophrenia, Change Version; MRS),[23] and the Clinical Global Impressions scale for Severity (CGI-S).[24] At the baseline visit and each treatment visit, the following assessments were completed: HAM-D, MADRS, MRS, CGI-S, and Clinical Global Impressions scale for Improvement (CGI-I, day 4 onward)[24]; adverse event assessment by standardized verbal probe; and record of study and other

Table 1. Patient Disposition

Event	Placebo N	Placebo %	Lamotrigine 50 mg/day N	Lamotrigine 50 mg/day %	Lamotrigine 200 mg/day N	Lamotrigine 200 mg/day %
Randomized	66		66		63	
Withdrawn prematurely	19	29	23	35	18	29
Adverse event	10	15	12	18	10	16
Death	1	2	0	0	0	0
Inadequate response	2	3	0	0	1	2
Protocol violation	1	2	1	2	2	3
Other	5	8	10	15	5	8
Completed	47	71	43	65	45	71
Received ≥ 1 dose of study drug (safety population)	65		66		63	
Had baseline and ≥ 1 post-randomization assessment (efficacy population)	65		64		63	

medications. The investigators' reports of clinically significant manifestations of manic, hypomanic, or mixed episodes were recorded as adverse events whether or not they met full DSM-IV criteria. Patients who developed a rash were withdrawn unless the rash was clearly unrelated to use of the study drug. At the last treatment visit (day 50 or discontinuation), patients were given physical examinations and clinical laboratory tests.

Blood samples for determination of trough lamotrigine plasma concentrations were drawn at screening, 2 and 4 weeks after the start of treatment, and at the last treatment visit (day 50 or discontinuation). The potential correlation between plasma concentrations and response will be the subject of a future report.

Patients who completed this 7-week study could elect to enter a 1-year open-label continuation study. Patients who withdrew prematurely or chose not to enter the continuation study discontinued lamotrigine dosing without taper. They returned 2 weeks after study treatment for a follow-up visit with psychiatric assessments and reporting of adverse events and concomitant medications. Patients who elected to participate in the continuation trial were initiated (placebo patients) or continued (lamotrigine patients) on lamotrigine treatment during a blinded transition period.

Data Analysis

Efficacy. The study was powered to detect a 5.0-point difference between lamotrigine and placebo on 17-item HAM-D change from baseline scores, estimating mean ± SD placebo change from baseline scores of 6.0 ± 7.0, a 2-sided alpha level of .05, and a power of 0.90. Based on these assumptions, approximately 60 patients were enrolled to provide 40 completed patients per treatment group. All patients who completed baseline assessments and at least 1 postrandomization efficacy assessment were included in the efficacy analyses. In addition to analysis of observed data at each time point, efficacy variables were assessed using last-observation-carried-forward (LOCF) scores. CGI-I scores and change from baseline scores for the other overall efficacy scales (17-item HAM-D, 31-item HAM-D, HAM-D item 1, MADRS, MRS, and CGI-S) were tested for treatment group differences at each week using analysis of variance (ANOVA). Significant differences in change scores were determined for each visit using a 2-tailed comparison alpha level of .05. In addition, a responder analysis was performed on the last observed 17-item HAM-D, MADRS, and CGI-I scores comparing the rate of response among treatment groups by a stratum-adjusted Cochran-Mantel-Haenszel chi-square analysis. A response was categorically defined as 50% or more reduction on the 17-item HAM-D or MADRS scales or a rating of very much improved or much improved on the CGI-I scale.

Medication compliance. All patients who received at least 1 dose of study medication and had dosing records were included in the compliance analyses. Medication compliance during the 50-day treatment phase was assessed from compliance records (tablets taken/tablets prescribed), and the percentage of patients with greater than 70% compliance was calculated.

Safety. All patients who received at least 1 dose of study drug were included in the safety analysis. The incidence of patients reporting a treatment-emergent adverse event (one emerging or worsening after beginning study drug treatment) was summarized. To compare the incidence of adverse events between treatment groups, 95% confidence intervals were determined. For clinical laboratory tests and vital signs, all patients with clinically significant changes, i.e., values or changes from baseline outside predetermined ranges, were listed.

RESULTS

Sample Composition

One hundred ninety-five patients (66 placebo, 66 lamotrigine 50 mg/day, and 63 lamotrigine 200 mg/day) were randomized to treatment at 15 centers in the United States and 6 centers in the United Kingdom, France, and Australia. Approximately 30% of the patients withdrew prematurely from the trial, most frequently for adverse events or other reasons (e.g., lost to follow-up or withdrawn consent, Table 1). Four patients were withdrawn for protocol violations (noncompliance with scheduled visits in 3 cases and continued use of disallowed psychotropic medications in the other). The rate of withdrawals and completions and the specific reasons for withdrawal were similar across the 3 treatment groups. All patients but one on placebo (who was immediately lost to follow-up and had no record of study drug administration) were included in the safety analyses. The 192 patients who received at least 1 dose of study medication and completed the baseline and at least 1 postrandomization assessment were included in the efficacy analyses.

Table 2. Patient Characteristics[a]

Characteristic	Placebo (N = 66)	Lamotrigine 50 mg/day (N = 66)	Lamotrigine 200 mg/day (N = 63)
Sex, N (%)			
Male	27 (41)	22 (33)	28 (44)
Female	39 (59)	44 (67)	35 (56)
Age, y			
Mean	42	41	42
Range	21–71	19–75	21–66
Age at onset of affective symptoms, y			
Mean	21	22	21
Range	5–50	4–68	6–53
No. mood episodes in last 12 mo per patient, mean ± SD	2.2 ± 0.8	2.2 ± 0.8	2.2 ± 0.9
No. mood episodes in lifetime per patient,[b] mean ± SD	17.4 ± 16.0	17.2 ± 18.1	15.9 ± 16.1
Duration of current episode, N (%)			
2–8 wk	19 (29)	26 (39)	23 (37)
> 8–24 wk	28 (42)	29 (44)	26 (41)
> 24 wk	19 (29)	11 (17)	14 (22)
Intensity of depression,[c] N (%)			
Mild	0 (0)	3 (5)	2 (3)
Moderate	40 (61)	38 (58)	34 (54)
Severe	23 (35)	23 (35)	24 (38)
Severe with psychosis	3 (5)	2 (3)	3 (5)
CGI-S score at baseline, N (%)			
Normal	0 (0)	0 (0)	0 (0)
Borderline mentally ill	0 (0)	0 (0)	0 (0)
Mildly ill	1 (2)	2 (3)	6 (10)
Moderately ill	43 (65)	42 (64)	32 (51)
Markedly ill	15 (28)	15 (23)	19 (30)
Severely ill	7 (11)	7 (11)	6 (10)
Extremely ill	0 (0)	0 (0)	0 (0)
Melancholic features, N (%)	33 (50)	26 (39)	25 (40)
Prior hospitalization for mood episode, N (%)	41 (62)	29 (44)	32 (51)
Prior suicide attempts, N (%)	24 (36)	21 (32)	20 (32)
Lithium use in last 5 mo according to study criteria,[d] N (%)	15 (23)	15 (23)	12 (19)

[a]Abbreviation: CGI-S = Clinical Global Impressions scale for Severity.
[b]Excluding patients with episodes too numerous to count.
[c]Based on Structured Clinical Interview for DSM-IV.
[d]Plasma levels ≥ 0.4 mmol/L or dosing of ≥ 600 mg/day for ≥ 1 month.

Patient Characteristics

The gender, age, psychiatric history, and baseline illness of the patients were similar across treatment groups (Table 2). Approximately 60% of patients in each treatment group were women, and the mean age was approximately 40 years. Over 50% of the patients had been previously hospitalized, and over 30% had attempted suicide. For the majority of patients, the current depressive episode had lasted for at least 8 weeks prior to enrollment. Other indications of their baseline severity (CGI-S, SCID, melancholia) suggest that these patients were moderately to markedly ill when enrolled in the study. Randomization was stratified to balance the groups for the use of lithium at minimally active levels in the 5 months prior to study entry.

Table 3. Previous Treatment for Bipolar Disorder (N = 178)

Treatment	Patients With Prior Treatment[a]	Responders[b] (%)	Intolerant[b] (%)
Antidepressants	85	52	73
Lithium	65	59	34
Valproate	37	45	29
Neuroleptics	28	55	33
Carbamazepine	22	36	44
Electroconvulsive therapy	7	67	25

[a]Percentage based on total number of patients with any prior treatment.
[b]Percentage based on total number of patients with prior treatment in each drug category.

One hundred seventy-eight (91%) of 195 patients had been previously treated for bipolar disorder. Table 3 describes the prior medication history of this patient population, including the percentage responding to and the percentage unable to tolerate individual medications. The incidence of prior treatment described in Table 3 was similar across treatment groups.

Efficacy Results

Observed and LOCF results for all efficacy scales at the last treatment visit are provided in Table 4.

HAM-D scores. 17-Item HAM-D. The mean ± SD baseline 17-item HAM-D score was 24 ± 4 in each treatment group. Both lamotrigine groups demonstrated a mean 13-point improvement in 17-item HAM-D scores over the course of treatment, which was significantly greater than the 9-point improvement in placebo group scores (Table 4; observed scores). Significant improvement for lamotrigine 200 mg/day, but not lamotrigine 50 mg/day, compared with placebo was first noted at week 5 (Figure 2). LOCF results were qualitatively similar, reaching a trend ($p = .084$) at endpoint for the lamotrigine 200-mg/day group only.

HAM-D Item 1. Mean scores for HAM-D item 1 (depressed mood) were reduced over the treatment period by at least 1.1 points in each of the lamotrigine groups versus at least 0.6 points in the placebo group (observed and LOCF scores; see Table 4 and Figure 2). Significant differences compared with placebo were observed by the third week of treatment and continued throughout treatment.

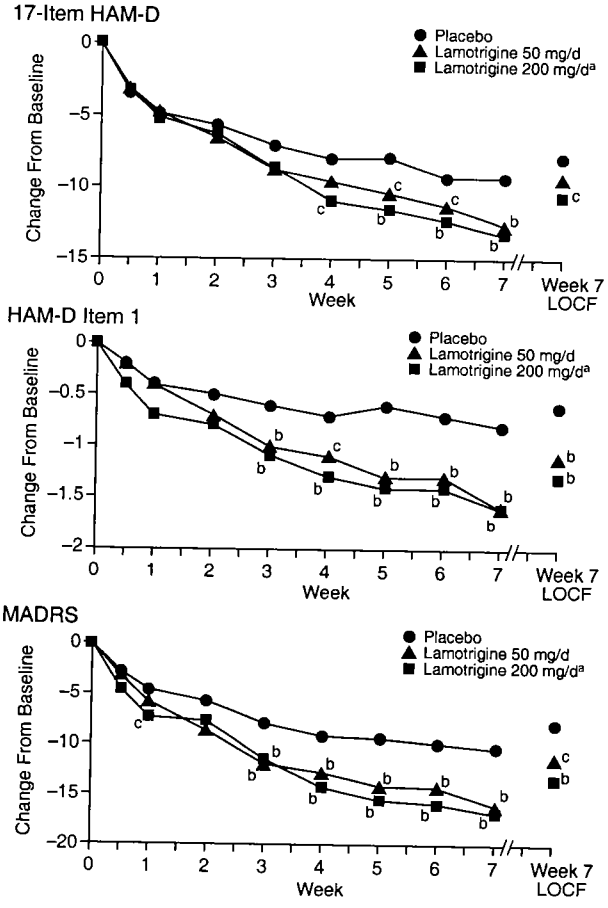
31-Item HAM-D. Mean reductions in 31-item HAM-D of 19.1 in the lamotrigine 50-mg/day and lamotrigine 200-mg/day groups approached significance compared with placebo ($p = .072$ and $p = .086$, respectively, for observed scores; see Table 4). At week 4 only, the mean observed score for the lamotrigine 200-mg/day group was

Table 4. Baseline and Change From Baseline Scores (mean ± SD) on Efficacy Scales at Week 7[a]

	Placebo						Lamotrigine 50 mg/day						Lamotrigine 200 mg/day					
	Baseline Score (N = 65)		Observed Change (N = 47)		LOCF Change (N = 65)		Baseline Score (N = 64)		Observed Change (N = 43)		LOCF Change (N = 64)		Baseline Score (N = 63)		Observed Change (N = 45)		LOCF Change (N = 63)	
Scale	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
17-Item HAM-D	24.3	3.9	−9.3	6.9	−7.8	7.9	23.7	4.4	−12.6[b]	7.7	−9.3	8.9	23.8	3.9	−13.2[b]	7.4	−10.5[c]	8.1
HAM-D item 1	2.8	0.5	−0.8	1.1	−0.6	1.0	2.8	0.6	−1.6[b]	1.1	−1.1[b]	1.3	2.8	0.6	−1.6[b]	1.1	−1.3[b]	1.2
31-Item HAM-D	35.8	5.6	−14.7	11.4	−12.1	12.8	35.1	7.4	−19.1[c]	11.8	−14.2	13.9	34.5	6.8	−19.1[c]	11.2	−15.7	12.2
MADRS	28.9	5.9	−10.2	9.0	−7.8	10.4	28.0	6.5	−16.1[b]	9.8	−11.2[c]	12.6	28.9	6.5	−16.7[b]	10.6	−13.3[b]	11.4
CGI-S	4.4	0.7	−0.9	1.1	−0.7	1.1	4.4	0.7	−1.5[b]	1.3	−1.0[c]	1.4	4.4	0.8	−1.6[b]	1.3	−1.2[b]	1.4
CGI-I	NA		3.0	1.1	3.3	1.2	NA		2.5[b]	1.2	3.0	1.5	NA		2.1[b]	1.0	2.6[b]	1.3
MRS	2.0	2.9	−0.6	4.0	−0.5	3.5	2.0	3.3	1.3[b]	6.0	0.9[c]	5.3	2.7	3.2	−0.8[d]	3.6	0.3	6.0

[a]Abbreviations: CGI-I = Clinical Global Impressions scale for Improvement, HAM-D = Hamilton Rating Scale for Depression, LOCF = last observation carried forward, MADRS = Montgomery-Asberg Depression Rating Scale, MRS = Mania Rating Scale, NA = not applicable.
[b]$p < .05$ vs. placebo.
[c]$p < .1$ vs. placebo.
[d]$p < .1$ vs. lamotrigine 50 mg/day.

Figure 2. Change From Baseline in Observed Scores at Each Treatment Visit Plus Week 7 LOCF Scores for 17-Item Hamilton Rating Scale for Depression (HAM-D), Item 1 (Depressed Mood) of the HAM-D, and MADRS



[a]Dose > 50 mg/day in lamotrigine 200-mg/d group only after week 3.
[b]$p < .05$ vs. placebo.
[c]$p < .1$ vs. placebo.

significantly reduced compared with placebo. LOCF scores were not significantly different from placebo for either active treatment dose.

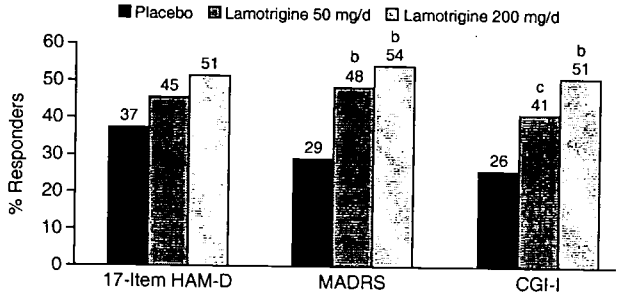
MADRS scores. Mean baseline MADRS scores were 28–29 ± 6–7 across treatment groups. Both lamotrigine 50-mg/day and lamotrigine 200-mg/day treatment resulted in mean 16- to 17-point reductions compared with the placebo reduction of 10 points (observed scores; see Table 4 and Figure 2). Improvement was significant by the third week of treatment and throughout the remainder of the study. LOCF analysis demonstrated statistically significant differences between lamotrigine 200 mg/day and placebo scores beginning at week 5; differences between lamotrigine 50 mg/day and placebo scores at the end of treatment approached significance ($p = .058$).

CGI-S scores. The mean ± SD baseline CGI-S score was 4.4 ± 0.7–0.8 (moderately to markedly ill) in each treatment group. CGI-S scores were significantly reduced compared with placebo by the end of treatment in the lamotrigine 200-mg/day group (observed and LOCF scores) and in the lamotrigine 50-mg/day group (observed scores) (see Table 4).

CGI-I scores. Mean CGI-I scores improved steadily with lamotrigine treatment; statistically significant differences in observed scores between both lamotrigine groups and placebo were observed by the third week and continued to the end of treatment (see Table 4). LOCF scores during weeks 4, 5, and 7 of treatment were significantly lower in the lamotrigine 200-mg/day group, but not the lamotrigine 50-mg/day group, compared with placebo.

Combined week 3 analysis. Since both lamotrigine groups received the same dosing for the first 3 weeks of treatment (≤ 50 mg/day), the first 3 weeks of data were analyzed comparing the entire population receiving lamotrigine (N = 127) with placebo. The lamotrigine-treated patients demonstrated significant improvements by week

Figure 3. Percentage of Patients Showing a Response to Treatment at Endpoint[a]



[a]Response defined as ≥ 50% reduction on the 17-Item HAM-D or MADRS scales or a rating of very much improved or much improved on the CGI-I scale.
[b]$p < .05$ vs. placebo.
[c]$p < .1$ vs. placebo.

3 ($p < .05$) on the following scales: HAM-D Item 1 (observed and LOCF scores), MADRS (observed and LOCF scores), CGI-I (observed scores), and CGI-S (observed scores).

Subgroup analysis. Results of each efficacy measure (17-item HAM-D, HAM-D Item 1, 31-item HAM-D, MADRS, CGI-S, and CGI-I) were compared between the 2 subgroups: patients with recent lithium use at minimally active levels (≥ 0.4 mmol/L or dosing of ≥ 600 mg/day for 1 month) during the 5 months preceding study entry and patients without such lithium use. There were no significant differences between the 2 subgroups on any of the efficacy measures. Furthermore, there was no significant effect of recent lithium use on the treatment group differences for any of the efficacy measures.

Responder analysis. Over 50% of the patients in the lamotrigine 200-mg/day group met the criteria for response to treatment by each of the following scales: 17-item HAM-D, MADRS, and CGI-I (Figure 3). The rate of response to lamotrigine 200 mg/day was statistically significant compared with placebo for both MADRS and CGI-I, whereas the rate of response to lamotrigine 50 mg/day was significantly higher than placebo only on the MADRS.

MRS scores. Mean ± SD baseline MRS scores were 2.0 ± 2.9 for the placebo group, 2.0 ± 3.3 for the lamotrigine 50-mg/day group, and 2.7 ± 3.2 for the lamotrigine 200-mg/day group. During treatment, mean changes in score were small and moved in both positive and negative directions. During treatment, groups did not differ significantly, with the exception that the placebo and lamotrigine 50-mg/day group observed scores demonstrated a reduction of 0.6 and a gain of 1.3, respectively, in MRS score on day 50 (see Table 4).

There were no significant differences between lamotrigine dose groups in efficacy scale change scores or responder rates at any treatment time.

Table 5. Most Common (≥ 5%) Adverse Events[a]

Adverse Event	Placebo (N = 65) N	Placebo (N = 65) %	Lamotrigine 50 mg/day (N = 66) N	Lamotrigine 50 mg/day (N = 66) %	Lamotrigine 200 mg/day[b] (N = 63) N	Lamotrigine 200 mg/day[b] (N = 63) %
Headache	11	17	23	35[c]	20	32[c]
Nausea	10	15	11	17	10	16
Pain	5	8	5	8	7	11
Rash	7	11	9	14	7	11
Dizziness	9	14	6	9	6	10
Accidental injury	2	3	1	2	6	10
Xerostomia	6	9	5	8	5	8
Manic/hypomanic/ mixed episodes	3	5	2	3	5	8[d]
Infection	9	14	4	6	4	6
Constipation	5	8	1	2	4	6
Diarrhea	10	15	3	5	3	5
Somnolence	8	12	3	5	3	5
Pruritus	4	6	7	11	3	5
Insomnia	6	9	5	8	2	3
Rhinitis	6	9	2	3	2	3
Influenza	4	6	1	2	2	3
Dyspepsia	4	6	3	5	1	2
Fatigue	4	6	3	5	1	2
Worsening of depression	1	2	4	6	0	0

[a]Patients reporting adverse events.
[b]Lamotrigine 200-mg/day group dose > 50 mg/day only after day 28.
[c]$p < .05$ vs. placebo.
[d]All but one event occurred during 25–50 mg/day dosing phase.

Compliance

In the placebo, lamotrigine 50-mg/day, and lamotrigine 200-mg/day dose groups, the majority (97%, 91%, and 97%, respectively) of the patients were over 70% compliant with medication dosing.

Adverse Events and Other Safety Data

Adverse events that emerged during the treatment phase and were experienced by 5% or more of patients in any treatment group are listed in Table 5. Ninety-two percent of placebo-treated patients reported any adverse event compared with 79% of patients in each lamotrigine group. The most common adverse event was headache, which was the only event observed significantly more frequently in the lamotrigine groups than the placebo group. Other common events were nausea, pain, rash, and dizziness. A smaller percentage of patients had any adverse events that were considered by investigators to be reasonably associated with study drug treatment (placebo, 60%; lamotrigine 50 mg/day, 54%; lamotrigine 200 mg/day, 51%).

There was one death in the placebo group on day 21 owing to probable suicide. Thirty-two other patients withdrew for adverse events (10 placebo, 12 lamotrigine 50 mg/day, and 10 lamotrigine 200 mg/day; see Table 1), including all of the serious adverse events described below. The adverse events accounting for more than one withdrawal included rash (2 placebo, 3 lamotrigine 50 mg/day, 4 lamotrigine 200 mg/day), a worsening of psychiatric de-

pression (1 placebo, 3 lamotrigine 50 mg/day), pruritus (1 placebo, 1 lamotrigine 200 mg/day), suicidal ideation (1 lamotrigine 50 mg/day, 1 lamotrigine 200 mg/day), suicide attempt (1 placebo, 1 lamotrigine 50 mg/day), and mania (2 lamotrigine 200 mg/day).

Nine patients experienced serious adverse events. Most of these events were related to bipolar disorder, including suicide (1 placebo), attempted suicide (1 placebo, 1 lamotrigine 50 mg/day), suicidal ideation (1 lamotrigine 50 mg/day, 1 lamotrigine 200 mg/day), worsening depression (1 lamotrigine 50 mg/day), and a psychotic episode (1 lamotrigine 50 mg/day). The illness-related events of 3 of the 4 patients in the lamotrigine 50-mg/day group (all but the attempted suicide) were the only serious adverse events considered to be possibly drug related. The other 2 events included a ruptured disk (placebo) and a myocardial infarction (lamotrigine 200 mg/day).

Rash was reported by 11% to 14% of patients in each treatment group (see Table 5). Rash led to withdrawal in 9 cases as noted above; the timing of these withdrawals ranged from 4 to 31 days after the start of treatment. None of the cases of rash were considered serious or resulted in hospitalization.

Manic, hypomanic, or mixed episodes were reported as adverse events in 10 patients (3 placebo [2 hypomania, 1 mixed], 2 lamotrigine 50 mg/day [1 hypomania, 1 mixed], 5 lamotrigine 200 mg/day [4 mania, 1 hypomania]; see Table 5), 2 of which led to withdrawal and none to hospitalization. In all but 1 of the 7 lamotrigine patients, these episodes occurred during the first 3 weeks of treatment when both lamotrigine groups were receiving 50 mg/day or less. The seventh patient's episode occurred on day 24, 3 days after the dose was increased to 100 mg/day. Overall, 7 (5.4%) of 129 patients on lamotrigine versus 3 (4.6%) of 65 patients on placebo developed these episodes ($p = .81$).

There were no apparent treatment group differences in clinical laboratory results postrandomization nor were there any patients with clinically significant changes in systolic blood pressure, diastolic blood pressure, pulse, or weight in any treatment group. Mean ± SD body weight at screening in the placebo, lamotrigine 50 mg/day, and lamotrigine 200 mg/day groups was 78.6 ± 16.0, 76.5 ± 17.6, and 82.2 ± 18.9 kg, respectively, and the mean change from screening to day 50 (LOCF scores) was 0.2, –0.4, and 0.0 kg, respectively.

DISCUSSION

This is the first randomized, parallel-group, placebo-controlled trial to evaluate any monotherapy treatment in bipolar I depression. The study results demonstrate that lamotrigine has significant antidepressant efficacy in bipolar I depression and that clinical improvement becomes evident as early as the third week of treatment.

Lamotrigine was significantly more effective than placebo on most, but not all, outcome measures. Patients receiving 200 mg daily exhibited significant improvement on all efficacy endpoints using both LOCF and observed case analyses, except the LOCF analysis of the 17-item HAM-D and both analyses of the 31-item HAM-D total score. Over 50% of patients given 200 mg daily met response criteria on the 17-item HAM-D, MADRS, and CGI-I. For MADRS and CGI-I, this rate of improvement was significantly higher and nearly twice that observed for those given placebo. Compared with the lamotrigine 200-mg/day group, the lamotrigine 50-mg/day group showed significant efficacy on fewer measures and the proportion of responders was somewhat lower.

These placebo-controlled data are consistent with the findings of earlier uncontrolled clinical reports of lamotrigine's efficacy in bipolar depression.[4–18] The largest of these previous studies[18] evaluated 40 depressed patients with either bipolar I or II disorder treated with lamotrigine as add-on therapy or monotherapy over 48 weeks. In it, Corn et al. reported a significant decrease in 17-item HAM-D scores over time compared with baseline and a 48% rate of marked response to lamotrigine.

The design of the current study provides significant advantages over previous studies of lamotrigine and other treatments for bipolar I depression. Published reports of other treatments for bipolar I depression include 9 studies (177 patients) of lithium,[25–33] one study (24 patients) of carbamazepine,[34] and 9 studies (466 patients) of marketed antidepressants.[25,35–42] Although most of these early innovative lithium studies suggest at least modest efficacy in bipolar depression, methodological problems limit interpretation of these data. Most of the studies did not limit enrollment to patients with bipolar depression, nor did the studies employ random assignment to parallel groups. The only efficacy analyses were of observed data (i.e., none employed LOCF analysis). Also, the use of lithium/placebo crossover designs may have confounded early estimates of lithium's antidepressant efficacy.[28,43] In the only double-blind study evaluating the antidepressant efficacy of carbamazepine, Post and colleagues[34] demonstrated significant improvement compared with placebo using a crossover design in a mixed cohort of bipolar and unipolar patients. Although the studies of marketed antidepressants used random assignment to parallel groups, they too had some methodological limitations. Only 6 limited enrollment to patients with bipolar disorder.[25,37,39–42] In contrast to the current study, 3 of these 6 studies permitted concurrent use of mood stabilizers[37,40,42] (2 standardized their use[40,42]), and most efficacy analyses were limited to observed data. These studies provided evidence for the efficacy of several classes of antidepressants, including nonselective monoamine reuptake inhibitors (imipramine, desipramine, bupropion),[25,39–41] selective serotonin reuptake inhibitors (fluoxetine, parox-

etine),[37,42] and MAO inhibitors (tranylcypromine, moclobemide)[38,39,41] when given alone or in combination with mood stabilizers.

Both lamotrigine treatment groups received the same doses of lamotrigine during the first 3 weeks of the study and first showed significant improvement over placebo during the third week when receiving 50 mg/day. Similar time to onset of antidepressant response has been reported for fluoxetine, tranylcypromine, and imipramine.[37,39] Comparisons with the rate of antidepressant response to lithium in bipolar I depression are not possible since the early lithium studies employed crossover designs rather than random assignment to a parallel placebo group.[25–33] Moreover, direct comparison studies would be needed to draw meaningful conclusions about onset of activity for lamotrigine relative to antidepressants or lithium.

Since this trial represents the first randomized, parallel-group, placebo-controlled trial to evaluate monotherapy treatment in bipolar I depression, there was no information available on placebo response rates in this population; the use of placebo was considered essential. The percentage of placebo patients with a response on the 17-item HAM-D in the current study (37%) is similar to that observed in the only other study of bipolar I depression employing random assignment to a parallel placebo group (38%).[37] The placebo-response rates for the MADRS and the CGI-I in our study were 29% and 26%, respectively; there are no previous reports using these 2 rating scales in a placebo-controlled bipolar depression trial. These rates of placebo response are roughly comparable to recently published unipolar depression studies[44,45] and will provide valuable benchmark data for future controlled studies in bipolar depression.

Lamotrigine was well tolerated in this study, and serious drug-related adverse events were uncommon. There was no difference between placebo and either dose of lamotrigine in the number of patients withdrawing from the study due to adverse events. The incidence of headache was higher in the lamotrigine groups compared with placebo; however, only 1 lamotrigine-treated patient was discontinued due to headache, one of several reasons given for discontinuation of this patient. The rates of other adverse events were similar to placebo for both doses of lamotrigine. The types of reported adverse events in this study are consistent with those previously reported for bipolar disorder patients by Corn and colleagues[18] as well as patients who received adjunctive or monotherapy lamotrigine for treatment of epilepsy.[46,47] Across the dose range tested there was no evidence of a dose-response relationship for adverse experiences. It is of interest to note that total adverse events and many of the reported CNS-related adverse events occurred numerically less frequently in the lamotrigine groups than in the placebo group.

The incidence of rash (11%–14%) was similar across placebo and lamotrigine groups and similar to that observed on lamotrigine treatment in open-label and placebo-controlled epilepsy clinical trials.[47,48] In 7 cases (5.4%), rash led to the discontinuation of lamotrigine. This frequency of rash-related withdrawal was similar to the rate for lamotrigine (6.1%) and lower than the rate for carbamazepine (8.9%) in previously reported lamotrigine active-control studies in epilepsy.[47] None of the rashes in the current study was considered serious or required hospitalization. In patients with epilepsy, the incidence of serious rash requiring hospitalization and discontinuation of treatment with lamotrigine has been reported to be approximately 3 in 1000 adults (1 in 100 in children ≤ 16 years old). These rashes usually occur within 8 weeks of the initiation of treatment.[48] There are suggestions, yet to be proven, that the risk of rash may be increased by coadministrating it with valproate, exceeding the recommended initial dose of lamotrigine, or exceeding the recommended dose escalation for lamotrigine.[48] Strict adherence to the recommended dose escalation schedule may diminish the likelihood of rash.

The current monotherapy study reported the rate of development of combined manic, hypomanic, or mixed episodes according to adverse event reports. The frequency of these combined mood episodes was not significantly different between lamotrigine and placebo groups. The event rate of 4.6%–5.4% in the current study that allowed no concurrent psychoactive medications compared favorably to the placebo switch rate of 3.3% in a study allowing concurrent lithium use.[37] In contrast, tricyclic antidepressants and MAO inhibitors evaluated in controlled monotherapy studies of the depressive phase of bipolar disorder suggest a higher rate of switching, as much as 25% for imipramine and 21% for tranylcypromine.[39] Direct comparison studies would be needed to draw meaningful conclusions about switch rates for lamotrigine relative to other antidepressants.

The design of this study had some limitations that could confound interpretation of the data. The fixed-dose titration schedule in this study resulted in both active treatment groups receiving the same dose for the first 3 weeks of the study. Hence, the 200-mg/day group reached target dose 2 weeks after the 50-mg/day group, and the groups had different durations of treatment at target dose (lamotrigine 50 mg/day: 5 weeks; lamotrigine 200 mg/day: 3 weeks). A longer duration for the blinded phase of the study would have lessened the impact of this difference and provided further information on the continued course of antidepressant response to lamotrigine. The ongoing open-label continuation phase of this study should help to address this limitation.

The MADRS appeared to separate efficacy differences between placebo and lamotrigine more robustly than the 17-item HAM-D. The 17-item HAM-D scale is weighted toward somatic symptomatology relative to the MADRS. These results suggest that effects on bipolar depression

(versus unipolar depression) may be more sensitively and reliably measured by scales that focus on nonsomatic depressive symptoms rather than those containing somatic items. Alternatively, effects of lamotrigine (versus other antidepressants) may be more sensitively and reliably measured by such scales.

The data from this first double-blind, placebo-controlled trial of lamotrigine monotherapy in bipolar disorder demonstrate that lamotrigine possesses significant antidepressant efficacy in bipolar I depression. In addition, the use of lamotrigine in patients with bipolar I depression was well tolerated, with a side effect profile similar to that of placebo.

Drug names: bupropion (Wellbutrin, Zyban), carbamazepine (Tegretol and others), chloral hydrate (Noctec), desipramine (Norpramin and others), fluoxetine (Prozac), imipramine (Tofranil and others), lamotrigine (Lamictal), lorazepam (Ativan and others), oxazepam (Serax and others), paroxetine (Paxil), temazepam (Restoril and others), tranylcypromine (Parnate).

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Original Research

A Random-Assignment, Double-Blind, Clinical Trial of Once- vs Twice-Daily Administration of Quetiapine Fumarate in Patients with Schizophrenia or Schizoaffective Disorder: A Pilot Study

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Objective: To evaluate the efficacy and safety of administering quetiapine once vs twice daily.

Method: Utilizing a double-blind design, 21 hospitalized adult men or women with DSM-IV schizophrenia or schizoaffective disorder, who had received unchanged doses (for 2 weeks) of either 400 or 600 mg daily of quetiapine administered in 2 doses, were randomly assigned to once- or twice-daily administration for 4 weeks and then crossed over to the opposite dosing regimen for an additional 4 weeks. Standard psychopathology and safety measures were used in the study.

Results: Nearly 70% (15/21) of the subjects met the a priori efficacy responder criteria with no statistical differences in response between those assigned to once- or twice-daily quetiapine administration. Statistical analyses confirmed that most subjects maintained efficacy during the switch to once- or twice-daily administration with quetiapine. A minority (15%) did experience worsening of symptoms or orthostatic hypotension during the crossover. Quetiapine was generally well tolerated at either twice- or once-daily administration.

Conclusions: These pilot data suggest that it is clinically feasible to switch most quetiapine-treated subjects receiving a therapeutic twice-daily dosing schedule to a once-daily regimen. A minority may experience worsening of symptoms or orthostatic hypotension during the switch. This strategy of administering quetiapine entirely at bedtime may promote improved adherence to treatment.

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Clinical Implications

- In many patients who are receiving a therapeutic dosage of quetiapine fumarate, it is possible to switch a twice-daily dosage schedule to a once-daily regimen.
- Clinical monitoring for orthostatic effects, worsening of symptoms due to cholinergic rebound or possible supersensitivity psychoses, or unmasking of tardive dyskinesia may be prudent in the first few weeks following the switch to once-daily administration; a minority of patients experience worsening symptoms.
- Once-daily administration of quetiapine at bedtime may be convenient for some patients and may promote increased adherence to long-term treatment.

Limitations

- This is a pilot study with a small sample size.
- Switch to a once-daily regimen was tested after a therapeutic dosage was reached rather than at initiation.
- A longer-acting formulation of quetiapine may provide additional data of clinical utility, especially if that formulation can be administered once-daily right at the initiation of treatment.

***Key Words**: quetiapine, once-daily dosing, twice-daily dosing, schizophrenia, schizoaffective disorder, adherence*

Quetiapine, a second-generation antipsychotic agent, has shown efficacy and safety in the treatment of patients with schizophrenia experiencing an acute exacerbation of their illness (1,2). Further, pharmacokinetic data suggest quetiapine has a plasma half-life of nearly 6 hours, which is slightly increased with multiple dosing. Thus, in spite of an elimination half-life that averages 6 hours (range 5.8 to 6.8 hours [3]), quetiapine has been shown to be therapeutically equivalent when dosed at either 2 or 3 times daily (4).

Among the key pharmacokinetic variables that guide dosing of a drug are its plasma elimination half-life, the presence or absence of active metabolites, whether the drug exhibits linear pharmacokinetics, and the time taken to achieve steady-state levels of the drug. Therefore, quetiapine, which exhibits a linear pharmacokinetic profile over its therapeutic dosage range (150 to 750 mg daily), reaches steady-state plasma levels in 2 days. To maintain these steady-state plasma levels, it would follow that quetiapine needs to be administered 2 or 3 times daily. However, there is no known one-to-one correspondence between plasma levels of a drug and its levels in the central nervous system (CNS) or, for that matter, between plasma levels and drug-receptor occupancy. Further, recent positron emission tomography (PET) data suggest that neither high rates of dopamine (D_2) receptor occupancy nor sustained blockade of these receptors is necessary for antipsychotic efficacy (5). These new PET data have led to the concepts of tight (for example, haloperidol) vs loose (for example, clozapine and quetiapine) D_2 receptor binding and sustained (for example, haloperidol) vs transient and surmountable (for example, clozapine and quetiapine) blockade of D_2 receptors to explain the rationale for the efficacy of the second-generation antipsychotic agents, such as clozapine and quetiapine. One corollary to this hypothesis would be to test the dosing frequency of drugs such as clozapine and quetiapine at less frequent intervals than predicted by their pharmacologic half-lives. If quetiapine, with a relatively short elimination half-life, could be dosed as a single daily dose, it might result in a greater adherence to treatment by patients in the long term. The objective of this study was to evaluate whether quetiapine fumarate dosed once a day was therapeutically equivalent to twice-daily dosing in subjects who had reached a stable therapeutic dose.

Methods

Study Design

The trial comprised 3 phases, each of 4 weeks' duration. The first phase (from baseline, time 0, to visit 4 , week 4) involved withdrawal of the previous antipsychotic agent (over 7 to 14 days) as quetiapine was initiated (50 to 100 mg daily) and increased to either 400 or 600 mg daily during the next 7 to 10 days. Once the target dose was achieved (either 400 or 600 mg), quetiapine was administered as 200 mg twice daily (400 mg daily) or 200 mg in the morning and 400 mg in the evening (600 mg daily) for an additional 2 weeks. The second phase of the study (from visit 4, week 4, to visit 8, week 8) was double blind and involved the random assignment (1:1 ratio) to either once- or twice-daily treatment with quetiapine. The once-daily group received either 400 mg or 600 mg at bedtime and one placebo tablet in the morning. The twice-daily group received 200 mg twice daily (along with a placebo tablet at bedtime) for the 400 mg daily group or 200 mg and 400 mg (and a placebo) at bedtime for the 600 mg daily group. This phase lasted 4 weeks. The next phase was also double-blind (from visit 8, week 8, to visit 10, week 12) and involved a crossover for 4 additional weeks. The once-daily group was crossed over to twice daily and vice versa. At the end of this double-blind phase, subjects were dosed openly with quetiapine at either 400 or 600 mg given as a single bedtime dose (or twice daily if they so chose) until they were discharged.

Baseline screening assessments, medical history, and psychiatric history were recorded after written informed consent was obtained from participants. Patients with a diagnosis of schizoaffective disorder were permitted to continue mood stabilizers, either lithium, valproate, or antidepressant medications, unchanged in dosage throughout the double-blind phase. Lorazepam (up to 4 mg daily) was permitted for episodic agitation on an as-needed basis, as were hypnotic agents for insomnia. After the withdrawal of routine antiparkinsonian agents (1 week following the last dosage of the previous antipsychotic agent), their use was permitted only for newly emergent extrapyramidal symptoms (EPS) based on clinical judgement and after ratings for EPS were completed.

Patient Population

Eligible subjects were men and women of any ethnicity aged 18 to 65 years with DSM-IV (6) diagnoses of either schizophrenia (except the catatonic subtype) or schizoaffective disorder who had provided informed consent. They were required to have a Positive and Negative Symptom Scale (PANSS) (7) total score of ≥ 60 but ≤ 120 and a Clinical Global Impression (CGI) severity score ≥ 4 (8); to pass laboratory screening, ECG, slit-lamp ophthalmological, and physical examinations; and to be clinically appropriate candidates for quetiapine treatment. These subjects were referred by their attending psychiatrists, as the current antipsychotic treatments were ineffective (6 to 8 weeks of prior treatment) for these subjects.

Pregnant or lactating women or women of reproductive age without adequate contraception were excluded, as were subjects considered to be actively suicidal or homicidal. Those

Table 1 Demographic characteristics of cohort

Demographic variable	*n*	%
Total subjects	21	
Men	13	62
Women	8	38
DSM-IV diagnoses (6)		
Chronic schizophrenia	7	33
Schizoaffective disorder	14	67
Ethnicity		
White	13	62
African American	8	38
	Mean (SD)	
Age (years)	38 (8.4)	
Duration of illness (years)	15 (7.0)	

receiving injectable long-acting neuroleptic agents (or within one injection cycle of study entry) were excluded.

Assessments

Psychopathology and its severity was assessed at scheduled intervals starting at the baseline through week 12, using the PANSS, CGI Scale, and the 21 item Hamilton Depression Rating Scale (HDRS; 9). EPS, akathisia, and tardive dyskinesia (TD) were assessed at the same time points as the psychopathology measures, using the Simpson Angus Neurological Rating Scale, Barnes Akathisia Scale (BA), and Abnormal Involuntary Movement Scale (AIMS), respectively (10–12). General Assessment of Functioning (GAF; DSM-IV, Axis V) scores were assessed at baseline and exit from the double-blind phase. Adverse events, whether spontaneously reported or in response to an open-ended question, were recorded, and orthostatic blood pressure and pulse were recorded at each visit. Body weight was recorded at quetiapine initiation (that is, baseline) and at the end of the double-blind study.

Statistical Analysis

The primary outcome of the study was to examine the differences, if any, in the therapeutic efficacy between once- vs twice-daily quetiapine administration regimens. A priori, the primary efficacy measure was defined as a $\geq 30\%$ reduction in the total PANSS score from baseline to the last visit in the double-blind phase. The differences between the proportion of subjects meeting the a priori response criteria were compared in the two quetiapine dosing administration groups, using contingency statistics.

A 1-way repeated-measures analysis of variance (ANOVA) was used to examine the relation between successive PANSS total scores and subscale scores at weeks 0, 4, 8, and 12 in the study sample as a whole, as well as in the groups assigned to once- or twice-daily administration separately. If the main effect was significant, post hoc pairwise differences between visit mean changes were examined using Bonferroni's adjustment for multiple comparisons. Subsequently, a mixed-model, repeated-measures ANOVA with the clinical measures (PANSS total or subscale scores) as the within-subject factor and the randomly assigned (once or twice daily) as the between-subject factor was performed to examine the interaction between the 2 factors.

PANSS subscale change scores, as well as change scores for the HDRS, CGI severity, and GAF, were analyzed for the entire group using the last observation carried forward (LOCF) method rather than a "completers" analysis. However, it is pertinent to note that only 2 of 21 randomized subjects dropped out at the penultimate visit of the double-blind phase of the study and that their data were carried forward to the last visit.

Results

Baseline Characteristics

The demography and illness characteristics for the 21 subjects are summarized in Table 1. In terms of switching from the previous antipsychotic agents, 13 were switched from first-generation agents, 4 were switched from risperidone, and 4 were switched from olanzapine. Among the 14 subjects with schizoaffective disorder, 2 were receiving lithium, 8 were receiving valproic acid, and 5 were receiving antidepressants.

Patient Disposition

Four subjects were titrated and stabilized at a daily dosage of 400 mg of quetiapine; the 17 remaining subjects achieved the daily dosage of 600 mg. Nineteen of these 21 subjects completed the 2-month double-blind phase, whereas 1 subject in each of those assigned to either the once- or twice-daily treatment arms reached the penultimate visit and was dropped from the study owing to worsening of their illness during the crossover phase (Figures 1 and 2). Another subject assigned initially to the twice-daily dosing had not shown clinical improvement and also worsened at the crossover point to once-daily dosing but completed the double-blind phase (Figure 2).

Efficacy Analyses

There were no statistically significant differences between the number of patients who met the PANSS response criteria in the once-daily quetiapine administration group (8/10 subjects) when compared with the group treated with twice-daily quetiapine (7/11 subjects). Three of the 4 subjects stabilized at 400 mg daily met the response criteria, and 12 of 17 subjects stabilized at 600 mg daily met the response criteria. In the group as a whole, 15 of 21 subjects (70%) met the response criteria.

Figure 1 Patients (n = 10) who were assigned to once-daily quetiapine administration at week 4

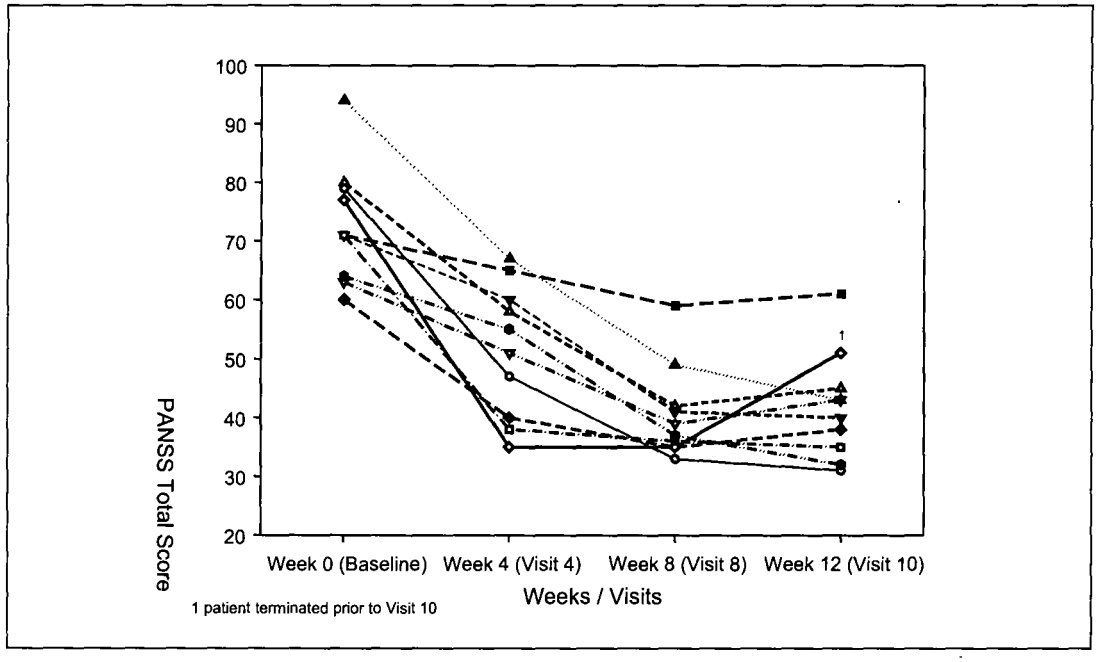
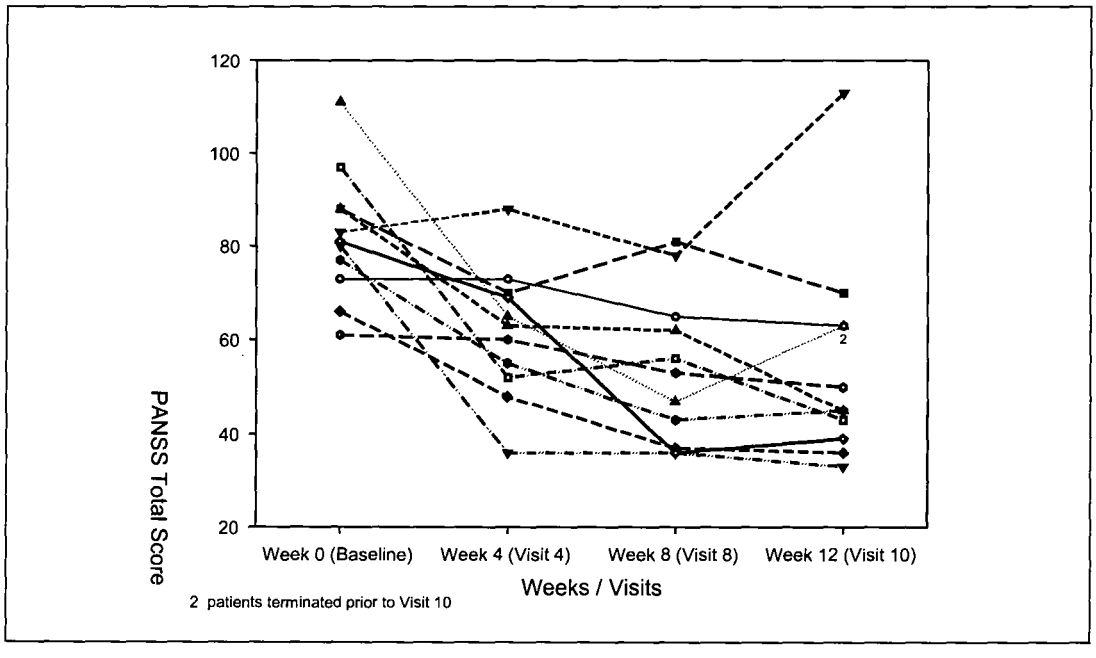


Figure 2 Patients (n = 11) who were assigned to twice-daily quetiapine administration at week 4



Secondary Analyses

PANSS total scores in the group as a whole showed significant improvement on quetiapine treatment (F = 40.6, df 2.2, 46.9, $P < 0.0005$) with Huynh–Feldt correction. Post hoc pairwise comparisons were all significant ($P < 0.05$ to $P < 0.0005$), except for the difference between week 8 and week 12; that is, most of the improvement had occurred by week 8. Similar results were obtained when the data for PANSS total scores were analyzed separately for those assigned to once- vs twice-daily dosing with quetiapine (Table 2).

The total and subscale change scores of PANSS and other efficacy assessments are presented in Tables 2 and 3 for the entire

Table 2 Baseline to endpoint change scores for PANSS and other scales, based on whether patients were first randomized to once-daily (OD) (group 1) or to twice-daily (BID) (group 2) administration with quetiapine

Scale or variable	Group 1 (n = 10)				Group 2 (n = 11)			
	BID at baseline[a] Mean (SD)	OD at week 4[b] Mean (SD)	BID at week 8[c] Mean (SD)	Week 12[d] Mean (SD)	BID at baseline Mean (SD)	BID at week 4 Mean (SD)	OD at week 8 Mean (SD)	Week 12 Mean (SD)
PANSS scores[e]								
Total	73.0 (10.0)	51.6 (11.3)	40.6 (7.9)	41.9 (9.0)	82.3 (14.0)	61.7 (13.9)	54.0 (16.0	54.5 (22.9)
Positive	23.6 (4.5)	16.3 (4.8)	11.4 (4.3)	11.0 (4.4)	20.0 (5.2)	22.3 (5.7)	18.4 (6.9	18.1 (8.3)
Negative	19.3 (4.7)	12.7 (4.2)	10.5 (3.1)	11.7 (3.7)	20.8 (3.3)	14.8 (4.8)	12.1 (4.0)	12.4 (6.0)
General psychophathology	30.1 (4.6)	22.6 (3.8)	18.7 (1.8)	19.0 (3.8)	34.5 (7.9)	24.6 (4.7)	23.6 (6.2)	24.1 (9.6)
CGI-severity[f]	4.2 (0.4)	3.4 (0.5)	2.7 (0.7)	2.6 (0.8)	4.7 (0.7)	4.0 (0.6)	3.3 (0.8)	3.3 (0.9)
HDRS[g]	7.7 (3.5)	4.6 (2.1)	1.6 (1.9)	3.2 (3.3)	8.2 (5.2)	4.4 (2.7)	4.3 (2.8)	3.8 (3.7)
GAF[h]	44.7 (9.0)	—	—	71 (5.0)	40.6 (8.0)	—	—	57.6 (14.2)

[a]Initiation, titration, and stable target dosing of quetiapine; [b]Random assignment to either once- or twice-daily administration, blinded; [c]Switch from once-daily to twice daily or vice versa, depending on original randomization at week 4; [d]End of double-blind administration; [e]Positive and Negative Syndrome Scale (7); [f]Clinical Global Impression of Severity (8); [g]Hamilton Depression Rating Scale (9); [h]Global Assessment of Functioning Scale (Axis V of DSM-IV (6)).

group as well as for those assigned to either once- or twice-daily dosing with quetiapine. The LOCF analyses for the entire group showed a significant improvement in the PANSS total and subscale scores, as well as the CGI severity scores, HDRS scores, and GAF scores.

Safety Analyses

Clinical Course at the Study Switchover Points, Including Study Withdrawals. The initial dosing switch occurred from the twice-daily (open) phase to the randomization (double-blind) phase. At this switch point, 10 of the 21 subjects were switched to once daily, and 11 subjects continued on the twice-daily regimen. None of the 10 subjects randomized to the once-daily dosing worsened at this switch point as can be noted in Figure 1. The next switch point occurred 4 weeks later and involved a crossover of the dosing regimen. At this point, 3 subjects showed worsening of clinical symptoms. Two subjects who switched from twice daily to once daily (2/11, 18%) evidenced worsening of symptoms, and one subject switched from once- to the twice-daily dosing regimen (1/10, 10%) deteriorated clinically.

The final switchover point occurred at the end of the double-blind phase. Among 15 responding subjects, 14 voluntarily chose the once-daily open treatment, and 1 subject chose the twice-daily regimen. None of the 15 subjects worsened at this switch point.

Additional Safety Evaluation. Adverse effects elicited or reported during the titration and stable administration periods and the double-blind period, at a rate of at least 1 subject (that is, 5%) or more were somnolence (5/21, 24%), headache (4/21, 19%), dizziness (3/21, 14%), constipation (1/21, 5%), urinary incontinence (1/21, 5%), and insomnia (1/21, 5%). These adverse effects were noted mostly in the first 4 to 8 weeks of treatment and were of mild-to-moderate severity. These events did not lead to withdrawal from the study, either resolved in time or with symptomatic treatment, and did not reoccur during the crossover phase, except for somnolence in 1 subject, intermittent headache in 1 subject, and constipation in 1 subject. Symptomatic postural hypotension was noted in 4 subjects (19%) during the titration phase of the study. For 2 of these 4 subjects, symptomatic postural hypotension recurred in the crossover phase of the blinded study. These events occurred during the crossover from once- to twice-daily dosing or vice versa.

Five subjects experienced akathisia at baseline, and 5 subjects evidenced EPS at baseline. Four subjects had TD (using research diagnostic criteria for TD [13]) at baseline. Akathisia resolved in all subjects by 4 weeks of quetiapine treatment, and EPS resolved in 6 to 8 weeks of treatment. No new cases of akathisia or other EPS were noted in the double-blind phases of the study. Two of the 4 subjects with TD showed evidence of worsening (withdrawal dyskinesia) for up to 6 weeks but, by the end of the double-blind study, had AIMS scores lower than at baseline. The other 2 subjects with TD at baseline showed a gradual and steady improvement of the scores during the study. All 4 subjects had lower AIMS scores by the end of the study (data not shown).

The mean body weight for the entire group was 87.7 kg (SD 17.3) at baseline and increased by a mean of 3.1 kg (SD 4.8) toward the end of the double-blind phase of the study

Table 3 Baseline to endpoint change scores of the PANSS[a] and other efficacy scales among all patients in the quetiapine administration trial

Scale or variable	Baseline Mean (SD)	Change in LOCF[b] Mean (SD)	Statistics[c]
PANSS scores			
Total	78.0 (13.0)	−29.3 (19.3)	$t = 7.0$, df 20, $P < 0.001$
Positive	25.4 (5.1)	−10.7 (9.0)	$t = 5.5$, df 20, $P < 0.001$
Negative	20.1 (4.0)	−8.1 (4.6)	$t = 8.1$, df 20, $P < 0.001$
General psychophathology	32.4 (6.8)	−10.6 (7.7)	$t = 6.3$, df 20, $P < 0.001$
CGI - severity[d]	4.5 (0.6)	−1.5 (1.0)	$t = 7.10$, df 20, $P < 0.001$
HDRS[e]	8.0 (4.4)	−4.4 (4.6)	$t = 4.5$, df 20, $P < 0.001$
GAF[f]	43.0 (8.7)	21.4 (13.2)	$t = 7.5$, df 20, $P < 0.001$

[a]Positive and Negative Syndrome Scale (7); [b]Last observation carried forward; [c]All tests remained significant even after applying the Bonferroni correction for multiple comparisons ; [d]Clinical Global Impression of Severity (8); [e]Hamilton Depression Rating Scale (9); [f]Global Assessment of Functioning Scale (Axis V of DSM-IV [6]).

($t = 2.9$, df 20, $P = 0.008$). The weight gain was noted over a duration of 11 to 12 weeks of quetiapine treatment, and it is important to note all subjects with schizoaffective disorders were also receiving either mood stabilizers or antidepressant medicines as concomitant therapy.

During the double-blind phase, there were 27 doses of lorazepam dispensed for episodic agitation or anxiety. These differences were not statistically significant between the once- and twice-daily administration groups and occurred mainly in the first 4 weeks of treatment. There were only 3 instances of anticholinergic use for EPS: once in a person receiving once-daily treatment and twice in subjects assigned to twice-daily dosing. These instances occurred shortly after the switch from the previous antipsychotic agents during the open-titration and stabilization phase.

Adherence to Medications

As all subjects were inpatients, study tablets and other medications were dispensed by nursing staff, and pill counts revealed > 98% adherence to treatment.

Discussion

These preliminary data suggest that most subjects who had reached a therapeutic dose of quetiapine fumarate (400 or 600 mg daily) on a twice-daily administration schedule were switched to the once-daily regimen without significant difficulty. A minority (3/21, 15%) of subjects worsened clinically during the switch, and so it would be clinically prudent to closely monitor subjects for the first 2 to 4 weeks after the switch to once-daily administration.

Just prior to the initiation of the double-blind randomization phase, all subjects were receiving the twice-daily regimen, and 10 subjects were randomized to the once-daily regimen, whereas 11 continued on the twice-daily regimen. None of the 10 subjects randomized to once-daily administration at this point experienced any worsening of symptoms. Four weeks later, at the crossover point, 2 subjects showed evidence of worsening after initial improvement. Based on the initial improvement and worsening shortly following the switch, it is likely that the temporal deterioration in these 2 subjects was associated with the change in the administration schedule. One occurred in a subject crossing from the once- to twice-daily regimen (1/10, 10%) and another in a subject moving from twice- to once-daily regimen (1/11, 9%). Is it possible that supersensitivity has a role to play in these patients (14)? Subjects who had received the previous oral antipsychotic agents for 6 to 8 weeks were tapered off their medicines in 1 to 2 weeks, and the phenomena were noted within 6 weeks (15). Thus, in sensitive individuals who have shown the need for escalating dosages of first-generation neuroleptic agents in the recent past, have increased psychotic symptoms just before a depot neuroleptic injection, or have symptoms of schizophrenia that are different from earlier exacerbations on medication withdrawal may show deterioration in the switching over to quetiapine. In such individuals a slower switch may be appropriate. Interestingly, and similar to the experience of Chouinard and others (16) in treating supersensitivity psychoses, we too noted significant improvement with clozapine in 2 patients who worsened at the switchover point in the current study.

A third subject assigned to the twice-daily regimen, who had not improved through the first 4 weeks of double-blind treatment, worsened at the crossover but stayed the course through the next 4 weeks. While it is possible that the worsening of symptoms in this last subject was caused by the switch in administration schedule, it is also likely that this clinical worsening was associated with the natural course of the illness.

In some subjects, attention to sedation and postural hypotension is clinically advisable both during the titration phase and following the switch to once-daily administration, especially among those subjects who are treated with antihypertensive medicines or have diabetes mellitus. However, in most subjects, administration of the entire dose of quetiapine at bedtime may help minimize the risk of orthostatic hypotension and sedation, as patients are more likely to be recumbent during the peak plasma concentrations of the drug.

It is possible that some subjects switching from agents with an anticholinergic profile to quetiapine could experience a cholinergic rebound, and perhaps a longer taper of the anticholinergic agent may be useful (17). In some subjects, worsening of the preexisting TD may have been caused by unmasking of TD occurring during a switch from a potent and tight D_2 receptor antagonist (first-generation agents) to

quetiapine. However, with the passage of time, the symptoms of TD diminished considerably on continued quetiapine treatment to less than the prequetiapine baseline.

Emerging data sets from PET studies in patients with schizophrenia have begun to suggest that D_2 receptor occupancy by antipsychotic agents need not be very high; further, the question has arisen whether such receptor blockade needs to be sustained continuously (18). The PET data from patients treated with depot haloperidol injections or oral clozapine and quetiapine-treated subjects would argue otherwise (19,20).

A second set of questions raised by recent PET data regarding quetiapine specifically suggest that transiently high D_2 occupancy rates (58% to 64%) may be adequate for treatment response (18). More recently, the same group also noted that first-episode patients who responded to quetiapine did not differ from those who did not, simply based on peak and trough D_2 receptor occupancy rates (20).

A third line of support for once-daily administration of relatively short half-life drugs comes from clinical experience in clozapine clinics. Subsets of subjects who have achieved steady-state drug levels and reached stable target dosages of clozapine (that is, those who are not also encumbered by dosage-related adverse effects: seizures, sedation, and postural hypotension) can be switched to a once-daily dosing regimen (mainly for patient convenience and to increase adherence to treatment) without loss of antipsychotic efficacy. These converging lines of evidence provide the rationale for the dosing of quetiapine fumarate as a single daily dose in subjects who have already reached a stable target dosage.

Nonetheless, these preliminary, random-assignment, double-blind clinical data suggest that bedtime administration of quetiapine among patients stabilized at their therapeutic dosage is clinically feasible. A switch to once-daily quetiapine administration can be considered both for the convenience of the subject and to improve adherence to long-term treatment. However, it must be emphasized that these data do not suggest "drug holidays" are good clinical practice but really that administration frequency based on plasma half-lives may not necessarily be valid for all antipsychotic agents.

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Résumé : Essai clinique à répartition aléatoire et à double insu sur l'administration une ou deux fois par jour de fumarate de quétiapine chez les patients souffrant de schizophrénie ou de trouble schizo-affectif : une étude pilote

Objectif : Évaluer l'efficacité et l'innocuité de l'administration de quétiapine une ou deux fois par jour.

Méthode : Au moyen d'une méthode à double insu, 21 hommes ou femmes hospitalisés souffrant de schizophrénie ou de trouble schizo-affectif conforme aux critères du *DSM-IV* qui avaient reçu des doses inchangées (pendant 2 semaines) de soit 400 mg, soit 600 mg par jour de quétiapine administrée deux fois par jour, ont été affectés au hasard à l'administration une ou deux fois par jour pendant 4 semaines puis, ont croisé pour la dose opposée pendant 4 autres semaines. La psychopathologie d'usage et des mesures de sécurité ont été utilisées durant l'étude.

Résultats : Presque 70 % (15/21) des sujets ont satisfait aux critères de réponse efficace a priori, sans différences statistiques dans la réponse entre ceux qui étaient affectés à l'administration de quétiapine une fois par jour et ceux qui la recevaient deux fois par jour. Les analyses statistiques ont confirmé que la majorité des sujets maintenaient l'efficacité durant la transition à l'administration une ou deux fois par jour de quétiapine. Une minorité (15 %) a connu une aggravation des symptômes ou une hypotension orthostatique durant le croisement. La quétiapine était généralement bien tolérée, qu'elle soit administrée une ou deux fois par jour.

Conclusions : Ces données pilotes indiquent qu'il est cliniquement faisable de changer la dose biquotidienne de la majorité des sujets traités à la quétiapine pour un régime quotidien. Une minorité peut connaître une aggravation des symptômes ou une hypotension orthostatique durant la substitution. Cette stratégie consistant à administrer la quétiapine entièrement au coucher peut favoriser l'adhésion au traitement.

Quality of Life Enjoyment and Satisfaction Questionnaire: A New Measure[1]

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Abstract

The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) is a self-report measure designed to enable investigators to easily obtain sensitive measures of the degree of enjoyment and satisfaction experienced by subjects in various areas of daily functioning. The summary scores were found to be reliable and valid measures of these dimensions in a group of depressed outpatients. The Q-LES-Q measures were related to, but not redundant with, measures of overall severity of illness or severity of depression within this sample. These findings suggest that the Q-LES-Q measures may be sensitive to important differences among depressed patients that are not detected by the measures usually employed.

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Introduction

Patients with mental disorders frequently experience little enjoyment or satisfaction in many aspects of their life. This is particularly true for patients with mood disorders. Investigators and clinicians who are considering different forms of treatment for various mental disorders have traditionally focused on the need to document partial or complete relief of the major symptoms of the disorder and improvement in functioning in social roles. There is growing recognition that treatments may differ in their effects on other important aspects of a patient's functioning as well. The capacity to obtain pleasure and to feel satisfied with one's ability to function in multiple life activities has been recognized to be as important to many patients as is the absence of signs and symptoms used to define the disorders.

There has been an increased recognition of the need to assess "quality of life" in patients, although there are wide variations in what is covered by this term. Although some measures focus on symptoms, resources, and opportunities, clinicians generally are interested in patients' own assessments of how they feel about what they have, how they are functioning, and their ability to derive pleasure from their life activities. Many measures have been developed for evaluation of the effects of specific physical disabilities or illnesses on quality of life; these were recently reviewed in *Medical Care* (Nelson et al. 1981). Over the past two decades a number of procedures have been developed to help assess these variables in patients with mental disorders as well (e.g., Baker & Intagliata 1982; Bigelow et al. 1991; Heinrichs et al. 1984; Lehman 1988; Malm et al. 1981). However, none of the measures have been widely used or accepted as a standard, most require the use of a trained interviewer, many are quite lengthy, the content of many is closely tied to the specific symptoms of a disorder, and the psychometric properties of some are troublesome or unknown. Furthermore, at times the content is not distinct from the symptoms of the clinical syndromes under study.

The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) was developed by the authors to enable investigators and clinicians to easily obtain sensitive self-report measures of the degree of enjoyment and satisfaction experienced by subjects in various areas of daily functioning. The intent was to use a format and content applicable for assessment of subjects with a wide variety of mental and medical disorders. An effort was made to avoid items that primarily measured

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symptoms of one or more particular disorders. Although an effort was made to keep the language simple, it may be necessary to read the items to some patients who are severely ill or who have limited reading ability.

The Q-LES-Q consists of 93 items, 91 of which can be grouped into eight summary scales that were rationally derived and reflect the organization of the questionnaire. Five of these summary scales are scored for all subjects: Physical Health (13 items), Subjective Feelings (14 items), Leisure Time Activities (6 items), Social Relationships (11 items), and General Activities (14 items). Three are also scored for those subjects for whom the activities are applicable: Work (13 items), Household Duties (10 items), and School/Course Work (10 items). If a subject is expected to be involved in one or more of these three activities but is completely unable to perform them because of being "too upset emotionally," the most severe score possible is used as the summary score. Each of the 93 questions is scored on a 5-point scale that indicates the degree of enjoyment or satisfaction achieved during the past week relative to the particular activity or feeling described in the item. Higher scores are indicative of greater enjoyment or satisfaction. The raw summary scores are converted to and expressed as a percentage of the maximum score possible to facilitate comparisons across areas of functioning within the same subject or groups of subjects. In addition to the eight summary scale scores, there are two individual items that are scored separately: One measures satisfaction with medication (if any is being taken) and the other is a single measure of "overall life satisfaction and contentment." (Examples of items on the questionnaire are shown in Table 1.)

If a procedure is to be useful for the discrimination of differences among groups of subjects or within the same subject over time, it must have demonstrated reliability and validity for these tasks. The reliability of a procedure is an index of the likelihood that the derived scores would consistently discriminate the placement of an individual subject among a group of subjects when the subjects have not changed in their degree of severity relative to each other on the dimension of interest. The validity of a procedure is dependent on the degree to which it provides "meaningful" data that distinguish a subject or group of subjects from others.

TABLE 1. Examples of Quality of Life Enjoyment and Satisfaction Questionnaire Items.

During the past week, how often have you . . .
. . . been pleased with your work accomplishments?
. . . kept your room/apartment/house cleaned to your satisfaction?
. . . shopped for food or other household items to your satisfaction?
. . . had a feeling of accomplishment with regard to household activities?
. . . enjoyed talking with or being with friends or relatives?
. . . looked forward to getting together with friends or relatives?
. . . enjoyed talking with co-workers or neighbors?
. . . joked or laughed with other people?

If the Q-LES-Q is to be used as an outcome measure for the study of patients in treatment for various disorders, it must be shown to discriminate among subjects with the disorder, to be related to the severity of the disorder, and to be sensitive to changes in the severity of the disorder. At the same time, it should not correlate so highly with other measures generally used in such studies as to be essentially redundant and wasteful.

Many measures that can discriminate reliably and validly among subjects with a very wide range of severity of illness, from well to extremely or severely ill, do not perform well with more homogeneous samples. In this report we assess the performance characteristics of the Q-LES-Q among patients who were seeking treatment for depression in an outpatient setting. This sample was selected to provide a very stringent test of the procedure. The range of severity would be restricted and the type of symptoms of primary focus would be those most likely to be correlated with lowered enjoyment and satisfaction in daily activities. Thus we could test the procedure's ability to demonstrate reliability with a sample with restricted variance, as well as its degree of redundancy with the major measures of outcome.

Methods

The Depression Evaluation Service of the New York State Psychiatric Institute is an outpatient

facility that has a number of studies of the treatment of depressive disorders going on at any given time. The Q-LES-Q was added to the intake and outcome portions of several ongoing studies to obtain a large number of evaluations completed during different phases of treatment. Each of these study protocols included one or more visits during the screening phase, a placebo washout phase prior to the prerandomization visit, and outcome evaluations made at various points after randomization. The Clinical Global Impressions (CGI) Severity of Illness and Global Improvement scales (National Institute of Mental Health 1985) and the Hamilton Rating Scale for Depression (HAM-D; Hamilton 1960) were completed by the clinicians at various visits during the studies. The patients also completed the Beck Depression Inventory (BDI; Beck & Beamesderfer 1974) and the Symptom Check List-90 (SCL-90; Derogatis et al. 1973) during some of the visits.

Subjects

The data from patients were used for the Q-LES-Q reliability and validity analyses if the patient met the *DSM-III-R* (American Psychiatric Association 1987) criteria for major depressive disorder at the time of intake. All patients were in good physical health and, for the most part, were free of current comorbid mental disorders, with the exception of a group of subjects in a specific protocol who had a diagnosis of alcoholism. Ninety-five subjects completed at least one Q-LES-Q evaluation. The mean age was 39.1 years (SD = 10.7, range = 18–63); 59 percent were female.

Data Analysis and Results

Subsets of the data were analyzed for the reliability and validity of the procedure. Two types of reliability analyses were performed: the first for test–retest reliability and the second for an assessment of the internal consistency of the summary scale scores.

Test–Retest Reliability

Fifty-four of the subjects who completed two Q-LES-Q evaluations during the prerandomization phase of the studies met criteria for test–retest reliability evaluations. We wished to test the reliability of the Q-LES-Q in a setting where the patients had not changed greatly in severity of illness between occasions. Therefore, the CGI evaluations of severity made at the second visit had to indicate no clinically significant change in the patients' condition and the patients still had to meet the criteria for major depressive disorder.

This selection procedure resulted in a sample of subjects (n = 54) in relatively stable clinical condition, that is, they continued to be moderately to severely ill with a major depressive disorder during the period under study for both Q-LES-Q evaluations. The homogeneity of the sample thus poses a very stringent test of the test–retest reliability of the Q-LES-Q summary scale scores, because none of the subjects were well (or even only slightly ill) and none were so severely ill as to warrant inpatient care.

The second column of Table 2 lists the intraclass coefficients of test–retest reliability for the eight summary scale scores. Even within a very homogeneous sample of depressed patients, these coefficients are quite high and are indicative of a consistent pattern of discrimination among the subjects.

Internal Consistency Reliability

We used a larger sample (n = 83) to test the degree to which the individual items used in the summary scales were measuring the same underlying dimension. We used the alpha internal consistency coefficient of reliability for this task (Kuder & Richardson 1937). To more adequately assess this index, we needed to ensure some variability in severity of illness of the subjects; therefore, we used the Q-LES-Q for the last visit for which we had data for each subject. Approximately 60 percent of these visits occurred before randomization and the other 40 percent were visits after treatment had begun and, in many instances, after improvement would have occurred.

The fourth column of Table 2 indicates that the items assigned to the various summary scales were highly internally consistent. These item sets are "reliably" assessing the same dimension and the underlying dimensions are quite coherent.

TABLE 2. Coefficients of Reliability of Summary Scale Scores of Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) Among Patients With Major Depressive Disorder.[a]

Q-LES-Q Scores	Test-Retest[b]		Internal Consistency[c]	
	n	*r*	*n*	α
Physical Health	54	.82	83	.92
Subjective Feelings	54	.66	83	.91
Work[d]	39	.73	61	.96
Household Duties[d]	52	.73	82	.92
School/Course Work[d]	6	.89	10	.93
Leisure Time Activities	54	.63	83	.92
Social Relationships	54	.82	83	.93
General Activities	54	.74	83	.90

[a]Subjects were patients who sought treatment for depressive symptoms; all met *DSM-III-R* criteria for major depressive disorder.
[b]Intraclass coefficients of reliability. Q-LES-Q was completed twice (during screening and visit 1 or visit 2) before start of active treatment ($n = 54$).
[c]Alpha coefficient of internal consistency ($n = 83$).
[d]Scored only if applicable, i.e., if activities would ordinarily be expected of the subject. If subject was unable to perform these activities at all because of psychopathology, the most severe score possible was assigned.

TABLE 3. Correlations of Summary Scale Scores of Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) with the Clinical Global Impressions Severity of Illness Ratings ($n = 85$).

Q-LES-Q Scores	*r*
Overall Life Enjoyment and Satisfaction	−.62
Physical Health	−.60
Subjective Feelings	−.68
Work ($n = 69$)[a]	−.45
Household Duties ($n = 84$)[a]	−.34
School/Course Work ($n = 15$)[a]	−.34
Leisure Time Activities	−.54
Social Relationships	−.51
General Activities	−.66

NOTE: Subjects were patients who sought treatment for depressive symptoms. All met *DSM-III-R* criteria for major depressive disorder. Mean age = 39.1 yrs (SD = 10.7); 41% male. Sixty-two percent of the questionnaires were completed during visits 1 or 2 (pretreatment visits); 14% during visits 3–10, 24% during visits 11 or 12. Visits 3 and later occurred during treatment with either drug or placebo.
[a]Scored only if applicable, i.e., if activities would ordinarily be expected of the subject. If subject was unable to perform these activities at all because of psychopathology, the most severe score was assigned.

Validity

Several kinds of evidence of the validity of the Q-LES-Q summary scale scores were examined. The concurrent validity of the Q-LES-Q as a measure of the severity of illness was assessed by examining the correlation of the scale scores with the primary measures of severity of illness used in these studies. The ability of the scale scores to assess change in clinical status was also assessed. Both analyses also allowed an evaluation of the degree to which the Q-LES-Q scores were redundant with the other measures or were measuring some aspects of patient functioning that were relatively independent of the other measures.

Correlations of the Q-LES-Q summary scale scores and the CGI Severity of Illness ratings. Table 3 lists the correlations of the Q-LES-Q summary scale scores with the CGI Severity of Illness ratings made at the time of the visit. The same data set used to test internal consistency reliability was used to ensure some variability in severity of illness. The correlations are high enough that we can conclude that the Q-LES-Q scores have validity as measures of severity of illness (range −.34 to −.68). However, the index of shared variance between the two measures (r^2) suggests that the Q-LES-Q and the CGI Severity of Illness as used in this study are also assessing different dimensions of severity. This is further demonstrated by the fact that even at the highest correlation, for Subjective Feelings, only 46 percent of the variance is shared.

Correlations of the Q-LES-Q summary scale scores with measures of depression. Some investigators and clinicians have contended that the ability to enjoy activities or to be satisfied with aspects of daily living represent simply an absence of depression. To assess this assumption, we correlated the Q-LES-Q summary scale scores with the HAM-D total scores and the self-report questionnaire measures of depression. In each set of correlations we used the last evaluations for which both sets of data were available to ensure greater variability of scores than would be manifested at intake. Table 4 lists the correlations of the two types of measures, clinical ratings (HAM-D) and self-report (SCL-90 and BDI). The correlations ranged from −.29 to −.72, indicating that the Q-LES-Q does reflect differences in severity of depression. However, many of the correlations indicate that the Q-LES-Q scores are not simply

TABLE 4. Correlations of Summary Scale Scores of Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) with Measures of Depression.

Q-LES-Q Scores	HAM-D[a] (*n* = 82) *r*	SCL-90[b] (*n* = 73) *r*	BDI[c] (*n* = 33) *r*
Overall Life Enjoyment and Satisfaction	−.61	−.67	−.36
Physical Health	−.56	−.74	−.62
Subjective Feelings	−.69	−.72	−.68
Work[d]	−.44	−.55	−.49
Household Duties[d]	−.36	−.29	−.56
School/Course Work[d]	−.33	−.70	−.73
Leisure Time Activities	−.48	−.53	−.34
Social Relationships	−.49	−.63	−.67
General Activities	−.64	−.64	−.67

NOTES: Subjects were patients who sought treatment for depressive symptoms. All met *DSM-III-R* criteria for major depressive disorder.
[a]Hamilton Rating Scale for Depression.
[b]Symptom Check List–90.
[c]Beck Depression Inventory.
[d]Scored only if applicable, i.e., if activities would ordinarily be expected of the subject. If subject was unable to perform these activities at all because of psychopathology, the lowest score was assigned.

TABLE 5. Correlations of Changes in Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) Summary Scale Scores With Clinical Global Impressions (CGI) of Global Improvement Ratings After Intake and With Changes in Hamilton Rating Scale for Depression (HAM-D) Scores.

Q-LES-Q Scores	CGI Global Improvement (*n* = 41)	HAM-D (*n* = 31)
Physical Health	−.48	−.54
Subjective Feelings	−.54	−.40
Work[a]	−.30	−.34
Household Duties[a]	−.38	−.39
School/Course Work[a,b]	—	—
Leisure Time Activities	−.54	−.42
Social Relationships	−.44	−.46
General Activities	−.50	−.41

NOTES: Subjects were patients with major depressive disorder who received treatment with drug or placebo. CGI Global Improvement scores and changes in HAM-D and Q-LES-Q scores were based on contrasts between intake evaluations and those made at various points after randomization.
[a]Scored only if applicable, i.e., if activities would ordinarily be expected of the subject. If subject was unable to perform these activities at all because of psychopathology, the lowest score was assigned.
[b]Number of subjects who completed this summary scale was insufficient to be included in the analysis.

reflecting the absence of depression and are therefore not totally redundant with measures of depression. This is particularly the case for those scores focused more on activities (e.g., Leisure Time Activities, Social Relationships).

Assessment of the Q-LES-Q summary scale scores as measures of change or improvement. We were able to obtain two measures of change in clinical condition for subsets of subjects in this setting: the CGI Global Improvement and pre–post HAM-D change scores. CGI Global Improvement scores were available for 41 subjects and pre–post HAM-D change scores could be calculated for 31 subjects. Q-LES-Q change scores were calculated for these two patient subsets. Table 5 shows the high degree of correlation between the CGI Global Improvement rating and the change scores (between the intake Q-LES-Q and the Q-LES-Q evaluations done at the same visit as the CGI Global Improvement rating). These results demonstrate that the Q-LES-Q scores are sensitive to changes in clinical state but, again, are not simply redundant with the primary measure of change used in many studies. Table 5 also shows the correlation between the change scores on the Q-LES-Q and change scores on the HAM-D. Again, the results demonstrate that the Q-LES-Q summary scale scores are sensitive to changes in level of depressive symptoms but that they are not totally redundant with them.

Conclusions

The analyses summarized in this report indicate that the Q-LES-Q summary scale scores are reliable and valid measures of aspects of quality of life in a group of depressed outpatients. The scores discriminated among the patients and were shown to be sensitive to change. The sample selected for these analyses posed a tough test of the procedure by virtue of its homogeneity and limited variance. The analyses also indicated that the Q-LES-Q scores were measures of important dimensions of illness that are not reflected in the measures of severity and symptoms generally used in studies of treatment for depression. The findings presented here indicate that there is a possibility that these Q-LES-Q measures are capable of detecting differences in

the efficacy of contrasted treatments for depressed patients that would not be reflected in the CGI or measures of depression such as the HAM-D, the SCL-90, or the BDI.

The Q-LES-Q has also been used with a sample of nonpatients in the community and found to have good test-retest reliability and to discriminate between those who were found to meet criteria for a current mental disorder and those who did not (paper in preparation). The procedure is currently being used in a number of studies involving patients with alcoholic, schizophrenic, and anxiety disorders as well as with women who have severe premenstrual depression. Its performance characteristics in these samples is yet to be determined.

The correlation of the Q-LES-Q scores with those of other measures of quality of life have not yet been determined, nor has its prognostic value for predicting response to treatment or relapse. As with all new procedures, its value for a number of specific purposes will be more clearly established as it is used in a variety of studies.

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ECDEU ASSESSMENT MANUAL FOR PSYCHOPHARMACOLOGY Revised, 1976

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047 BPRS
BRIEF
PSYCHIATRIC
RATING SCALE

MH-9—47
6-73

BRIEF PSYCHIATRIC RATING SCALE (Overall and Gorham)

BPRS

INSTRUCTIONS: *Insert General Scoring Sheet and Code 01 Under Sheet Number.*

This form consists of 18 symptom constructs, each to be rated on a 7—point scale of severity ranging from "not present" to "extremely severe". If a specific symptom is not rated, mark "0" = Not Assessed.

Mark the column headed by the term which best describes the patient's present condition.

USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE.

NOT ASSESSED	NOT PRESENT	VERY MILD	MILD	MODERATE	MODERATELY SEVERE	SEVERE	EXTREMELY SEVERE
0	1	2	3	4	5	6	7

Mark on right half of scoring sheet on row specified			ROW NO.
1.	SOMATIC CONCERN	Degree of concern over present bodily health. Rate the degree to which physical health is perceived as a problem by the patient, whether complaints have a realistic basis or not.	1
2.	ANXIETY	Worry, fear, or over-concern for present or future. Rate solely on the basis of verbal report of patient's own subjective experiences. Do not infer anxiety from physical signs or from neurotic defense mechanisms.	2
3.	EMOTIONAL WITHDRAWAL	Deficiency in relating to the interviewer and to the interview situation. Rate only the degree to which the patient gives the impression of failing to be in emotional contact with other people in the interview situation.	3
4.	CONCEPTUAL DISORGANIZATION	Degree to which the thought processes are confused, disconnected or disorganized. Rate on the basis of integration of the verbal products of the patient; do not rate on the basis of patient's subjective impression of his own level of functioning.	4
5.	GUILT FEELINGS	Over-concern or remorse for past behavior. Rate on the basis of the patient's subjective experiences of guilt as evidenced by verbal report with appropriate affect; do not infer guilt feelings from depression, anxiety or neurotic defenses.	5
6.	TENSION	Physical and motor manifestations of tension, "nervousness," and heightened activation level. Tension should be rated solely on the basis of physical signs and motor behavior and not on the basis of subjective experiences of tension reported by the patient.	6
7.	MANNERISMS AND POSTURING	Unusual and unnatural motor behavior, the type of motor behavior which causes certain mental patients to stand out in a crowd of normal people. Rate only abnormality of movements; do not rate simple heightened motor activity here.	7
8.	GRANDIOSITY	Exaggerated self-opinion, conviction of unusual ability or powers. Rate only on the basis of patient's statements about himself or self-in-relation-to-others, not on the basis of his demeanor in the interview situation.	8
9.	DEPRESSIVE MOOD	Despondency in mood, sadness. Rate only degree of despondency; do not rate on the basis of inferences concerning depression based upon general retardation and somatic complaints.	9
10.	HOSTILITY	Animosity, contempt, belligerence, disdain for other people outside the interview situation. Rate solely on the basis of the verbal report of feelings and actions of the patient toward others; do not infer hostility from neurotic defenses, anxiety nor somatic complaints. *(Rate attitude toward interviewer under "uncooperativeness".)*	10
11.	SUSPICIOUSNESS	Belief *(delusional or otherwise)* that others have now, or have had in the past, malicious or discriminatory intent toward the patient. On the basis of verbal report, rate only those suspicions which are currently held whether they concern past or present circumstances.	11

Continue marking on right half of scoring sheet on row specified			ROW NO.
12.	HALLUCINATORY BEHAVIOR	Perceptions without normal external stimulus correspondence. Rate only those experiences which are reported to have occurred within the last week and which are described as distinctly different from the thought and imagery processes of normal people.	12
13.	MOTOR RETARDATION	Reduction in energy level evidenced in slowed movements. Rate on the basis of observed behavior of the patient only; do not rate on basis of patient's subjective impression of own energy level	13
14.	UNCOOPERATIVENESS	Evidence of resistance, unfriendliness, resentment, and lack of readiness to cooperate with the interviewer. Rate only on the basis of the patient's attitude and responses to the interviewer and the interview situation; do not rate on basis of reported resentment or uncooperativeness outside the interview situation.	14
15.	UNUSUAL THOUGHT CONTENT	Unusual, odd, strange, or bizarre thought content. Rate here the degree of unusualness, not the degree of disorganization of thought processes.	15
16.	BLUNTED AFFECT	Reduced emotional tone, apparent lack of normal feeling or involvement.	16
17.	EXCITEMENT	Heightened emotional tone, agitation, increased reactivity.	17
18.	DISORIENTATION	Confusion or lack of proper association for person, place or time.	18

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Developed by Overall and Gorham, the Brief Psychiatric Rating Scale (BPRS) is formatted for use with the General Scoring Sheet and consists of the 18-item version of the scale. Developed from the longer Lorr Multidimensional Scale for Rating Psychiatric Patients (MSRPP) and Lorr Inpatient Multidimensional Psychiatric Scale (IMPS), the BPRS provides a rapid and efficient evaluation of treatment response in both clinical drug trials and routine clinical settings. Its focus is primarily inpatient psychopathology. It has been employed in outpatient settings to assess levels of anxiety and depression and to distinguish neurotic from more severely disturbed patients; but the authors caution that the BPRS was not designed to represent the fine distinctions between types of neurotic patients.

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1. Overall, J. E. and Gorham, D. R., The Brief Psychiatric Rating Scale, Psychol. Rep., 10:799-812, 1962.

2. Overall, J. E., The Brief Psychiatric Rating Scale in Psychopharmacology Research, Psychometric Laboratory Reports, No. 29, University of Texas, Galveston, June, 1972.

APPLICABILITY — Primarily for adult inpatient populations.

UTILIZATION — Once at pretreatment; at least one post-treatment assessment. The number and spacing of post-treatment assessments are at the discretion of the investigator.

TIME SPAN RATED — At a maximum, the interval since the last assessment. At pretreatment, a span of one week is suggested.

CARD FORMAT - ITEMS CARD 01 = 19x, 1811)

Item	Column	Item	Column
1. Somatic Concern	20	10. Hostility	29
2. Anxiety	21	11. Suspiciousness	30
3. Emotional Withdrawal	22	12. Hallucinatory Behavior	31
4. Conceptual Disorganization	23	13. Motor Retardation	32
5. Guilt Feelings	24	14. Uncooperativeness	33
6. Tension	25	15. Unusual Thought Content	34
7. Mannerisms	26	16. Blunted Affect	35
8. Grandiosity	27	17. Excitement	36
9. Depressive Mood	28	18. Disorientation	37

CARD FORMAT - FACTORS

CARD 51 = (19x, 5F6.2, F4.0)

Code "5" in Column 18 indicates card containing factor, cluster or derived scores.

Factor	Columns
I	20-25
II	26-31
III	32-37
IV	38-43
V	44-49
Total Score	50-53

Factor score = $\frac{\text{Sum of composite items}}{\text{No. of composite items}}$ Factor score range = 1 - 7

Total score = Sum of all items Total score range = 18 - 126

FACTOR COMPOSITION This factor structure is based on a 1974 analysis of the pretreatment scores of 3596 subjects with diagnoses of schizophrenia. (Table 8).

I. Anxiety-Depression (ANDP)

1. Somatic Concern
2. Anxiety
5. Guilt Feelings
9. Depressive Mood

II. Anergia (ANER)

3. Emotional Withdrawal
13. Motor Retardation
16. Blunted Affect
18. Disorientation

III. Thought Disturbance (THOT)

4. Conceptual Disorganization
8. Grandiosity
12. Hallucinatory Behavior
15. Unusual Thought Content

IV. Activitation (ACTV)

6. Tension
7. Mannerisms & Posturing
17. Excitement

V. Hostile-Suspiciousness (HOST)

10. Hostility
11. Suspiciousness
14. Uncooperativeness

TABLE 8

5-FACTOR VARIMAX SOLUTION OF 18-ITEM BRIEF PSYCHIATRIC RATING SCALE

Guy, W., Cleary, P. and Bonato, R. R., Methodological Implications of a Large Central Data System, published in Proceedings of IXth Congress, CINP, Excerpta Medica, Amsterdam, 1975.

ITEM	I	II	III	IV	V	Communalities
Somatic Concern	-627	066	-164	030	014	425
Anxiety	-746	115	-073	293	127	677
Emotional Withdrawal	156	-808	-139	157	073	726
Conceptual Disorganization	019	-344	-640	280	052	610
Guilt Feelings	-694	014	-055	013	074	491
Tensions	-381	-040	-064	732	161	712
Mannerisms	023	-463	-216	568	-082	591
Grandiosity	004	208	-536	-027	441	526
Depressive Mood	-784	-116	099	-008	124	653
Hostility	-208	036	-156	195	778	712
Suspiciousness	-346	078	-376	-020	650	689
Hallucinatory Behavior	-081	-147	-711	156	003	558
Motor Retardation	-337	-635	125	-198	039	573
Uncooperativeness	078	-451	044	301	641	713
Unusual Thought Content	159	-027	-797	049	286	745
Blunted Affect	015	-793	-094	-077	-032	645
Excitement	-030	172	-210	744	319	729
Disorientation	227	-475	-330	300	-208	519
Contribution of factor (V_p)	2.58	2.48	2.30	1.89	1.94	11.29
% Total Variance	14.3	13.8	12.8	10.5	10.8	62.7
% Common Variance	22.8	21.1	20.3	16.7	17.1	

SPECIAL INSTRUCTIONS

Brief instructions for rating each item are printed on the scale itself. To increase the degree of communality in interpretation, the items are defined below in greater detail by Overall and Gorham, and the rater is urged to confine his responses within these contexts.

A. Ratings Based Upon Observation of Patient

3. Emotional Withdrawal - This construct is defined solely in terms of the ability of the patient to relate in the interpersonal interview situation. Thus, an attempt is made to distinguish between motor aspects of general retardation, which are rated as "motor retardation" and the more mental-emotional aspects of withdrawal, even though ratings in the two areas may be expected to covary to some extent. In the factor analyses of change in psychiatric ratings, a "general retardation" factor has emerged in several different analyses, and this general retardation factor has included both emotional and motor retardation items. It is difficult to identify the basis for rating of "ability to relate"; however, initial work has indicated that raters achieve reasonably high agreement in rating this quality. Emotional withdrawal is represented by the feeling on the part of the rater that an invisible barrier exists between the patient and other persons in the interview situation. It is suspected that eyes, facial expression, voice quality and variability, and expressive movements all enter into the evaluation of this important, but nebulous, quality of the patients.

6. Tension - It should be noted that the construct "tension" is restricted in the Brief Scale to physical and motor signs commonly associated with anxiety. Tension does not involve the subjective experience or mental state of the patient. Although research psychologists in an effort to attain a high degree of objectivity frequently define anxiety in terms of physical signs, in the Brief Scale observable physical signs of tension and subjective experiences of anxiety are rated separately. Although anxiety and tension tend to vary together, developmental research with an earlier form of the Brief Scale indicated that the degree of pathology in the two areas may be quite different in specific patients. A patient, especially when under the influence of a drug, may report extreme apprehension but give no external evidence of tension whatsoever, or vice versa. In rating the degree of tension, the rater should attend to the number and nature of signs of abnormally heightened activation level such as nervousness, fidgeting, tremors, twitches, sweating, frequent changing of posture, hypertonicity of movements, and heightened muscle tone.

7. Mannerisms and posturing - This symptom area includes the unusual and bizarre motor behavior by which a mentally ill person can often be identified in a crowd of normal persons. The severity of manneristic behavior depends both upon the nature and number of unusual motor responses. However, it is the "unusualness", and not simply the amount of movement, which is to be rated. Odd, indirect, repetitive movements, or movements lacking normal coordination and integration, are rated on this scale. Strained, distorted, abnormal postures which are maintained for extended periods are rated. Grimaces and unusual movements of lips, tongue, or eyes are considered here also. Tics and twitches which are rated as signs of tension are not rated as manneristic behavior.

13. Motor retardation - Motor retardation involves the general slowing down and weakening of voluntary motor responses. Symptomatology in this area is represented by behavior which might be attributed to the loss of energy and vigor necessary to perform voluntary acts in a normal manner. Voluntary acts which are especially affected by reduced energy level include those related to speech as well as gross muscular behavior. With increased "motor retardation" speech is slowed, weakened in volume, and reduced in amount. Voluntary movements are slowed, weakened, and less frequent.

14. Uncooperativeness - This is the term adopted to represent signs of hostility and resistance to the interviewer and interview situation. It should be noted that "uncooperativeness" is judged on the basis of response of the patient to the interview situation while "hostility" is rated on the basis of verbal reports of hostile feelings or behavior toward others outside the interview situation. It was found necessary to separate the two areas because of an occasional patient who refrained from any reference to hostile feelings and who even denies them, while evidencing strong hostility toward the interviewer.

B. Ratings Based Primarily Upon Verbal Report

1. Somatic concern - The severity of physical complaints should be rated solely on the number and nature of complaints of bodily illness or malfunction, or suspiciousness of same, alleged during the interview period. The evaluation is of the degree to which the patient perceives or suspects physical ailments to play an important part in his total lack of well-being. No consideration of the probability of true organic basis for the complaints is required. Only the frequency and severity of complaints are rated.

2. Anxiety - Anxiety is a term restricted to the subjective experience of worry, overconcern, apprehension or fear. Rating of degree of anxiety should be based upon verbal responses reporting such subjective experiences on the part of the patient. Care should be taken to exclude from consideration in rating anxiety the physical signs which are included in the concept of tension, as defined in the scale. The sincerity of the report and the strength of the experience as indicated by the involvement of the patient may be important in evaluating degree of anxiety.

4. Conceptual disorganization - Conceptual disorganization involves the disruption of normal thought processes and is evidenced in confusion, irrelevance, inconsistency, disconnectedness, disjointedness, blocking, confabulation, autism, and unusual chain of associating. Ratings should be based upon the patient's spontaneous verbal products, especially those longer, spontaneous response sequences which are likely to be elicited during the initial, non-directive portion of the interview. Attention to the facial expression of the patient during the verbal response may be helpful in evaluating the degree of confusion or blocking.

5. Guilt feelings - The strength of guilt feelings should be judged from the frequency and intensity of reported experiences of remorse for past behavior. The strength of the guilt feelings must be judged in part from the involvement evidenced by the patient in reporting such experiences. Care should be exercised not to infer guilt feelings from signs of depression or generalized anxiety. Guilt feelings relate to specific past behavior which the patient now believes to have been wrong and the memory of which is a source of conscious concern.

8. Grandiosity - Grandiosity involves the reported feeling of unusual ability, power, wealth, importance, or superiority. The degree of pathology should be rated relative to the discrepancy between self-appraisal and reality. The verbal report of the patient and not his demeanor in the interview situation should provide the basis for evaluation of grandiosity. Care should be taken not to infer grandiosity from suspicions of persecution or other unfounded beliefs where no explicit reference to personal superiority as the basis for persecution has been elicited. Ratings should be based upon opinions currently held by the patient, even though the unfounded superiority may be claimed to have existed in the past.

9. Depressive mood - Depressive mood includes only the affective component of depression. It should be rated on the basis of expressions of discouragement, pessimism, sadness, hopelessness, helplessness, and gloomy thema. Facial expression, weeping, moaning and other modes of communicating mood should be considered, but motor retardation, guilt, and somatic complaints, which are commonly associated with the psychiatric syndrome of depression, should not be considered in rating depressive mood.

10. Hostility - Hostility is a term reserved for reported feelings of animosity, belligerence, contempt, or hatred toward other people outside the interview situation. The rater may attend to the sincerity and affect present in reporting of such experiences when he attempts to evaluate the severity of pathology in the symptom area. It should be noted that evidences of hostility toward the interviewer in the interview situation should be rated on the "Uncooperativeness" item and should not be considered in rating hostility as defined here.

11. Suspiciousness - Suspiciousness is a term which is used to designate a wide range of mental experience in which the patient believes himself to have been wronged by another person or believes that another person has, or has had, intent to wrong. Since no information is usually available as a basis for evaluating the objectivity of the more plausible suspicions, the term "accusations" might be a more appropriate characterization of this area. The rating should reflect the degree to which the patient tends to project blame and to accuse other people or forces of malicious or discriminatory intent. The pathology in this symptom area may range from mild suspiciousness through delusions of persecution or ideas of reference.

12. Hallucinatory behavior - The evaluation of hallucinatory experiences frequently requires judgment on the part of the rater as to whether the reported experience represents hallucination or merely vivid mental imagery. In general, unless the rater is quite convinced that the experiences reported represent true deviations from normal thought and imagery processes, hallucinatory behavior should be rated as "not present".

15. Unusual thought content - This symptom area is concerned solely with the CONTENT of the patient's verbalization; the extent to which it is unusual, odd, strange, or bizarre. Notice that a delusional or paranoid patient may present bizarre or unbelievable ideas in a perfectly straightforward, clear, and organized fashion. Rate only unusualness of content for this item, not degree of organization or disorganization.

16. Blunted affect - This symptom area is recognized by reduced emotional tone and apparent lack of normal feeling or involvement. Emotional expressions are apt to

be absent or of marked indifference and apathy. Attempted expressions of feeling may appear to be mimetic and without sincerity.

DOCUMENTATION:

a. Raw score printout
b. Factor score printout
c. Means and standard deviations
d. Cross tabulations
e. Variance analyses

COMMENTS OF THE AUTHOR

THE BRIEF PSYCHIATRIC RATING SCALE IN PSYCHOPHARMACOLOGIC RESEARCH

John E. Overall, Ph.D.

The Brief Psychiatric Rating Scale (BPRS) was originally developed to provide an efficient and clinically valid means of assessing efficacy in psychopharmacologic research.[1] Later research demonstrated its utility for descriptive classification of psychiatric patients according to profile pattern.[2,3] The BPRS consists of 18 (originally 16) symptom constructs, each to be rated on a 7-point scale of severity. The ratings are coded 0-6* for the 7 categories of severity ranging from "not present" to "extremely severe".

In most clinical research applications, the BPRS is completed immediately prior to the start of drug treatment and again after a fixed period of time, usually 4 to 6 weeks. Ratings are based on information obtained in a clinical interview of about 20 minutes duration. It is recommended that each patient be interviewed and rated independently by two professional observers to enhance the reliability of ratings, although the advantage gained from duplicate independent ratings is not now considered to be as great as it once was. A minimum of 35 to 40 patients in each treatment group should be included in any study in which the BPRS is used with two independent raters, or approximately 45 to 50 patients per group if a single rater is used.[4] These estimates of sample size do not appear restricted to the BPRS and can be readily calculated for any particular research setting.[5]

The BPRS pre-treatment ratings can be used to describe the patient sample and to classify patients into phenomenological homogeneous sub-types. Profile classification has been found useful in reducing within-treatment variability and in the study of specific indications of psychotherapeutic drugs. Although earlier efforts at profile classification using the BPRS were attempts to provide more objective methods for assigning patients among standard diagnostic categories,[6,7,8] more recent efforts have centered about the use of cluster analysis and related empirical methods to identify the most frequently occurring and thus most representative profile patterns.[9,10] The results of these studies have produced a classification system consisting of six types described as anxious depression, hostile depression, withdrawn-retarded depression, paranoid hostile-suspiciousness syndrome, withdrawn-disorganized thinking disturbance and florid thinking disorder.[11] Most psychiatric patients can be recognized as having symptom patterns fitting closely one of these six types. The six BPRS prototype patterns, which depend upon only the original 16 items, are as follows.

ANXIOUS DEPRESSION

2.6	2.8	1.1	0.5	0.8	0.2	0.2	2.5	0.8	0.4	0.1	1.0	0.3	0.4	1.0

HOSTILE DEPRESSION

0.6	2.7	1.1	1.1	2.0	1.8	0.3	0.3	2.5	2.9	2.2	0.2	0.5	1.0	0.7	0.7

* The ECDEU version of the BPRS is coded 1 - 7 rather than 0 - 6.

WITHDRAWN-RETARDED DEPRESSION

1.4	1.7	3.0	1.2	0.7	1.1	0.6	0.1	3.4	0.5	0.5	0.3	2.2	0.8	0.4	2.7

PARANOID HOSTILE-SUSPICIOUSNESS SYNDROME

1.4	1.5	1.0	1.4	0.4	1.4	0.4	1.0	0.5	3.4	2.6	0.1	0.4	1.6	1.2	0.7

WITHDRAWN-DISORGANIZED THINKING DISTURBANCE

0.7	0.8	3.1	3.4	0.1	1.1	1.3	0.2	0.5	0.4	1.0	1.5	1.8	1.2	2.2	3.6

FLORID THINKING DISORDER

0.7	1.3	2.4	3.9	0.2	2.0	1.5	1.4	0.8	1.4	3.0	3.5	0.7	1.6	4.2	2.6

Patients can be classified among the six phenomenological sub-groups by simply calculating the sum of squared differences between individual profile elements (scored 0-6 for single rater or average of two raters) and the corresponding prototype values, with the patient then being assigned to the group for which the simple d^2 is smallest.[12] For studies involving only pre-screened clinically depressed patients, only the first three profile patterns need be considered. Several more complex profile analysis methods have been programmed for computer to classify patients among the six types and can be obtained from J. E. Overall (University of Texas Medical Branch, Galveston). Dr. Overall also has the facilities to process profiles sent to him in punched cards and has agreed to do so for any ECDEU investigator.

Several composite scores derived from the BPRS are frequently used in evaluating treatment effects. Numerous factor analyses of BPRS ratings have consistently revealed the presence of four major higher order factors which have been described as thinking disturbance, withdrawal-retardation, hostile-suspiciousness and anxious depression.[13] Factor scores are obtained by summing ratings on the three BPRS items most highly related to each factor.

THINKING DISTURBANCE - Conceptual Disorganization, Hallucinatory Behavior and Unusual Thought Content.

WITHDRAWAL-RETARDATION - Emotional Withdrawal, Motor Retardation and Blunted Affect.

HOSTILE-SUSPICIOUSNESS - Hostility, Suspiciousness and Uncooperativeness.

ANXIOUS DEPRESSION - Anxiety, Guilt Feelings, and Depressive Mood.

In addition to the four higher order factor scores, a "total pathology" score is used to represent the total deviation from normality and to evaluate total change during treatment. The total pathology score is the sum of ratings on all 18 rating constructs, each scored on a 0-6 scale. Where patients have been grouped into distinctively different profile types, the total pathology score is recommended for evaluation of treatment outcome because specific symptom factors tend to be too highly related to profile group.

[illegible] has gone into the identification of extrinsic factors which influence BPRS ratings. It is considered that these non-drug factors produce variability in symptom patterns and treatment responses which should be controlled experimentally or statistically in order to improve the precision of clinical psychopharmacologic research. Differences in initial symptom patterns are significantly related to age, race, sex, age of onset, previous course of illness, marital status, education, work achievement and a variety of other less important factors.[14, 15, 16] Differences in treatment outcome have been found to depend significantly on pretreatment level and type of symptomatology, age of onset, previous hospitalizations and/or course of illness, marital status, presence of identifiable precipitating stress and race.[17, 18] Where several different raters are involved in a project, systematic rater differences are often very important.

While work is continuing along these lines, it appears obvious that a variety of factors do influence BPRS evaluations of symptom pattern and treatment outcome, and the above appear to be among the potentially most important. It is recommended that these extrinsic factors be carefully recorded and that their effects then should be removed by using somewhat more complex statistical analyses than have been used in the past.[17] Experimental control can be achieved by holding certain of the extrinsic factors constant, such as age or sex, but this tends to restrict the generality of conclusions that can be drawn.

A completely adequate experimental design involving BPRS evaluations should take into account (a) pre-treatment profile type, (b) pre-treatment level of severity, (c) demographic and sociocultural background characteristics of the patient which may influence outcome independently of drugs, (d) experimentally introduced systematic effects such as hospital differences, rater differences and the like, and (e) drug treatments. Where patients are classified into distinct profile groups, the broad measure of change in total pathology is recommended for evaluation of outcome with differences in pre-treatment level of severity partialled out. In this brief summary, an attempt has been made to provide the investigator with essential information concerning sample size, scoring, patient classification and control variables that will enable him to use the BPRS in as effective a manner as current methodology permits.

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A RATING SCALE FOR DEPRESSION

BY

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The appearance of yet another rating scale for measuring symptoms of mental disorder may seem unnecessary, since there are so many already in existence and many of them have been extensively used. Unfortunately, it cannot be said that perfection has been achieved, and indeed, there is considerable room for improvement.

Types of Rating Scale

The value of this one, and its limitations, can best be considered against its background, so it is useful to consider the limitations of the various rating scales extant. They can be classified into four groups, the first of which has been devised for use on normal subjects. Patients suffering from mental disorders score very highly on some of the variables and these high scores serve as a measure of their illness. Such scales can be very useful, but have two defects: many symptoms are not found in normal persons; and less obviously, but more important, there is a qualitative difference between symptoms of mental illness and normal variations of behaviour. The difference between the two is not a philosophical problem but a biological one. There is always a loss of function in illness, with impaired efficiency.

Self-rating scales are popular because they are easy to administer. Aside from the notorious unreliability of self-assessment, such scales are of little use for semiliterate patients and are no use for seriously ill patients who are unable to deal with them.

Many rating scales for behaviour have been devised for assessing the social adjustment of patients and their behaviour in the hospital ward. They are very useful for their purpose but give little or no information about symptoms.

Finally, a number of scales have been devised specifically for rating symptoms of mental illness. They cover the whole range of symptoms, but such all-inclusiveness has its disadvantages. In the first place, it is extremely difficult to differentiate some symptoms, *e.g.*, apathy, retardation, stupor. These three look alike, but they are quite different and appear in different settings. Other symptoms are difficult to define, except in terms of their settings, *e.g.*, mild agitation and derealization. A more serious difficulty lies in the fallacy of naming. For example, the term "delusions" covers schizophrenic, depressive, hypochrondriacal, and paranoid delusions. They are all quite different and should be clearly distinguished. Another difficulty may be summarized by saying that the weights given to symptoms should not be linear. Thus, in schizophrenia, the amount of anxiety is of no importance, whereas in anxiety states it is fundamental. Again, a schizophrenic patient who has delusions is not necessarily worse than one who has not, but a depressive patient who has, is much worse. Finally, although rating scales are not used for making a diagnosis, they should have some relation to it. Thus the schizophrenic patients should have a high score on schizophrenia and comparatively small scores on other syndromes. In practice, this does not occur.

The present scale has been devised for use only on patients already diagnosed as suffering from affective disorder of depressive type. It is used for quantifying the results of an interview, and its value depends entirely on the skill of the interviewer in eliciting the necessary information. The interviewer may, and should, use all information available to help him with his interview and in making the final assessment. The scale has undergone a number of changes since it was first tried out, and although there is room for further improvement, it will be found efficient and simple in use. It has been found to be of great practical value in assessing results of treatment.

Description of the Rating Scale

The scale contains 17 variables (see Appendix I). Some are defined in terms of a series of categories of increasing intensity, while others are defined by a number of equal-valued terms (see Appendix II). The form on which ratings are recorded also includes four additional variables: Diurnal variation, derealization, paranoid symptoms, obsessional symp-

toms. These are excluded from the scale because the first is not a measure of depression or of its intensity, but defines the type of depression. The other three occur so infrequently that there is no point in including them.

The variables are measured either on five-point or three-point scales, the latter being used where quantification of the variable is either difficult or impossible. No distinction is made between intensity and frequency of symptom, the rater having to give due weight to both of them in making his judgment.

Various problems are to be found with specific symptoms. Thus considerable difficulty is found with the depressive triad: depressive mood, guilt, and suicidal tendencies. These are so closely linked in description and judgment as to be very difficult to separate. It is very important to avoid the halo effect by automatically giving all of them high or low scores, as the case may be.

Depressed Mood.—This tends to have a narrow range of scores, for no diagnosed patients will score zero and few will score 1 or 4. The most useful indicator for depressed mood is the tendency to weep, but it must always be considered against the cultural background, and patients may also "go beyond weeping".

Suicide.—An attempt at suicide scores 4, but such an attempt may sometimes occur suddenly against a background of very little suicidal tendency; in such cases it should be scored as 3. There will be great difficulty sometimes in differentiating between a real attempt at suicide and a demonstrative attempt; the rater must use his judgment.

Work and Loss of Interest.—Difficulties at work and loss of interest in hobbies and social activities are both included. The patient who has given up work solely because of his illness is rated 4.

Retardation.—A grade 4 patient is completely mute, and is therefore unsuitable for rating on the scale. Grade 3 patients need much care and patience to rate, but it can be done.

Agitation.—This is defined as restlessness associated with anxiety. Unfortunately, a five-point scale was found impracticable, and therefore this variable is rated on a three-point scale. The mildest degrees of agitation cause considerable difficulty.

Gastro-intestinal Symptoms.—These occur in connexion with both anxiety and depression. Considerable clinical experience is required to evaluate them satisfactorily. The definitions given have been found very useful in practice.

General Somatic Symptoms.—In depressions these are characteristically vague and ill defined, and it is extremely difficult to get a satisfactory description of them from the patient.

Hypochondriasis.—This is easy to rate when it is obviously present, but difficulties arise with mild hypochondriacal preoccupations. Phobias of specific disease can cause difficulties. A phobia of venereal disease or of cancer will sometimes be rated under "guilt" by the nature of the symptom, but other cases may give rise to much doubt and judgment requires care. Fortunately, phobias are not common, but the whole subject of hypochondriasis could well repay clinical investigation.

Insight.—This must always be considered in relation to the patient's thinking and background of knowledge. It is important to distinguish between a patient who has no insight and one who is reluctant to admit that he is "mental".

Loss of Weight.—Ideally this would be measured in pounds or kilograms, but few patients know their normal weight and keep a check on it. It was therefore necessary to use a three-point scale.

After recovery from depression, some patients sometimes show a brief hypomanic reaction, during which the exuberantly cheerful patient will deny that he has any symptoms whatever, though he is obviously not to be regarded as normal. In such cases, the rating scale is inapplicable and should be delayed until the patient has fully recovered.

Scoring

It is particularly useful to have two raters independently scoring a patient at the same interview, since this gives data for calculating the inter-physician reliability. The score for the patient is obtained by summing the scores of the two physicians. This is, of course, the best way of learning how to use the scale, Where only one rater uses the scale, the scores should be doubled so as to make them comparable. With sufficient experience, a skilled rater can learn to give half-points.

Results

For two raters, the correlation between summed scores for the first 10 patients was 0·84. Adding successively 10 patients at a time, the correlation changed to 0·84, 0·88, 0·89, 0·89, 0·90, 0·90. The last correlation is therefore total for 70 patients.

Product-moment correlations were calculated for the 17 variables on the first 49 male patients (Table I). The correlation matrix was then factor-analysed by extracting the latent roots and vectors (Table II). As the intercorrelations are in general low because of the intense selection of patients, the latent roots (variances extracted by factors) diminish

TABLE I

CORRELATION MATRIX OF THE SCALE FOR DEPRESSION

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)
1	Depressed mood	1·0	0·491	0·373	0·082	0·236	0·140	0·362	0·590	−0·055	−0·198	−0·224	−0·032	0·014	0·370	−0·024	0·341
2	Guilt		1·0	0·522	−0·049	−0·048	0·121	0·358	0·370	0·027	−0·167	−0·151	0·071	−0·063	0·426	0·113	0·419
3	Suicide			1·0	0·043	0·098	−0·073	0·016	0·335	−0·068	−0·216	−0·065	−0·087	−0·115	0·304	−0·042	0·201
4	Insomnia, initial				1·0	0·199	0·309	0·130	−0·115	0·191	−0·001	−0·036	0·438	0·169	−0·044	0·152	0·179
5	,, middle					1·0	0·054	0·035	0·200	0·126	0·003	0·095	0·308	0·278	0·111	0·067	0·146
6	,, delayed						1·0	0·17	0·126	0·022	−0·180	−0·162	0·376	−0·038	0·142	0·171	0·012
7	Work and interests							1·0	0·230	0·183	0·017	−0·045	0·285	0·094	−0·058	−0·020	0·313
8	Retardation								1·0	−0·305	−0·365	−0·356	0·067	0·127	0·269	−0·208	0·232
9	Agitation									1·0	0·274	0·329	0·199	−0·107	0·045	0·001	0·217
10	Anxiety, psychic										1·0	0·370	−0·146	−0·058	−0·026	0·043	−0·159
11	,, somatic											1·0	−0·082	0·060	0·033	−0·014	−0·310
12	Somatic, gastro-intestinal												1·0	0·248	−0·115	0·135	0·074
13	Somatic general													1·0	0·048	0·137	−0·024
14	,, genital														1·0	0·199	0·254
15	Hypochondriasis															1·0	0·275
16	Insight																1·0
17	Loss of weight																

TABLE II

FACTOR SATURATIONS AND LATENT ROOTS

Condition	Factor 1	Factor 2	Factor 3	Factor 4
(1) Depressed mood	0·763	−0·172	0·103	0·151
(2) Guilt	0·728	−0·156	0·341	−0·138
(3) Suicide	0·531	−0·311	0·283	0·122
(4) Insomnia, initial	0·207	0·614	−0·208	−0·025
(5) ,, middle	0·284	0·363	−0·081	0·639
(6) ,, delayed	0·338	0·371	−0·304	−0·340
(7) Work and interests	0·458	0·275	0·043	−0·134
(8) Retardation	0·683	−0·371	−0·253	0·224
(9) Agitation	−0·034	0·539	0·503	−0·032
(10) Anxiety, psychic	−0·373	0·326	0·557	0·072
(11) ,, somatic	−0·403	0·250	0·480	0·421
(12) Somatic, gastro-intestinal	0·282	0·674	−0·395	−0·010
(13) ,, general	0·087	0·245	−0·356	0·628
(14) Genital	0·474	−0·139	0·397	0·225
(15) Hypochondriasis	0·157	0·367	0·117	−0·144
(16) Insight	0·603	0·107	0·204	−0·173
(17) Loss of weight	0·353	0·439	0·214	−0·192
Latent root	3·4358	2·3439	1·7496	1·3658

slowly. Out of the total variance of 17, the first six roots take up 3·44, 2·34, 1·75, 1·37, 1·28, 1·07, 0·99. The first four factors were used for calculating factor measurements for the patients, in the form of T-scores.

For the interest of those factorists who have a taste for factors rotated to give simple structure, the first three factors were rotated by an orthogonal rotation matrix (Table III) to give the results shown in Table IV. The fourth factor was left as it is, as it already has a fair number of near-zero saturations. The final saturations give a good approximation to simple structure and still retain the advantage of orthogonality.

TABLE III

ORTHOGONAL ROTATION MATRIX

Factor	Matrix		
F_1	0·7377	0·4932	−0·4610
F_2	−0·4182	0·8699	0·2614
F_3	0·5300	0	0·8480

TABLE IV

SATURATIONS OF ROTATED FACTORS

Condition	Factor 1	Factor 2	Factor 3	Factor 4
(3) Suicide	0·672	−0·009	−0·086	0·122
(14) Genital	0·618	0·113	0·081	0·225
(2) Guilt	0·783	0·224	−0·087	−0·138
(8) Retardation	0·525	0·014	−0·626	0·224
(1) Depressed mood	0·690	0·227	−0·309	0·151
(12) Somatic, gastro-intestinal	−0·283	0·725	−0·288	−0·010
(16) Loss of insight	0·508	0·401	−0·077	−0·173
(4) Insomnia, initial	−0·214	0·637	−0·111	−0·025
(5) ,, middle	0·015	0·456	−0·105	0·639
(7) Work and interests	0·245	0·466	−0·102	−0·134
(15) Hypochondriasis	0·024	0·397	0·123	−0·144
(17) Loss of weight	0·190	0·556	0·133	−0·192
(6) Insomnia, delayed	−0·067	0·490	−0·317	−0·340
(9) Agitation	0·016	0·453	0·583	−0·032
(10) Anxiety, psychic	−0·117	0·100	0·730	0·072
(11) ,, somatic	−0·148	−0·019	0·658	0·421
(13) Somatic, general	−0·227	0·256	−0·278	0·628

Factor Saturations.—It is customary to examine the factor saturations in order to give an appropriate name to the factors. When all the variables are positively correlated, the general factor may be regarded as an overall average of the items; but when, as in this case, a group of the variables is negatively correlated with the rest, this notion of an average becomes a little tenuous. Be that as it may, there would be little objection to the proposal to call the first factor "retarded depression" on the basis of its factor saturations. The important ones are, in descending order, depressed mood 0·76, guilt 0·73, retardation 0·68, loss of insight 0·60, suicide 0·53, genital symptoms (loss of libido) 0·47, work and interest 0·46, anxiety (somatic) 0·40, anxiety (psychic) 0·37, loss of weight 0·35, and insomnia (delayed) 0·34. The correspondence with the classical descriptions is remarkably close. The saturations in the second factor are: Somatic symptoms (gastro-intestinal) 0·67, insomnia (initial) 0·61,

agitation 0·54, loss of weight 0·44, retardation 0·37, insomnia (delayed) 0·37, insomnia (middle) 0·36, hypochondriasis 0·37, anxiety (psychic) 0·33, and suicide 0·31. It might be said to be vaguely like agitated depression, which clinically shows anxiety and agitation, together with disturbed sleep (particularly initial insomnia), but the factor is deficient in depression, the first factor having taken out most of the depressive variance. The third factor might be called some sort of anxiety reaction, with saturations of anxiety (psychic) 0·56, agitation 0·50, anxiety (somatic) 0·50, genital (loss of libido) symptoms 0·40, gastrointestinal symptoms — 0·39, general somatic symptoms — 0·36, guilt 0·34, and insomnia (delayed) — 0·30. The fourth factor has saturations of insomnia (middle) 0·64, general somatic symptoms 0·63, anxiety (somatic) 0·42, and insomnia (delayed) — 0·34. It is difficult to attach any label to the third and fourth factors, as they do not bring any clinical pattern to mind.

The situation is no better with the rotated factors. Factor I is still very much like retarded depression, but the negative saturation for gastrointestinal symptoms strikes a most incongruous note. Factor II shows many somatic symptoms and disturbed sleep, but the presence in the factor of agitation without anxiety is disturbing. It cannot be regarded as a factor of objective symptoms, as opposed to subjective, since it includes loss of interest and insight. Factor III could be named "anxiety reaction", but the negative saturations of depression and loss of insight must disqualify any attempt to relate it to clinical syndromes. The fourth factor has been left unrotated.

It is not surprising that the classical clinical syndromes have not appeared from the factor analysis, since this technique is incapable of demonstrating them. It would appear from the literature that psychologists have hoped that factor analysis would elicit the classical syndromes, and perhaps even additional ones, but in practice this does not occur. The clinical syndromes are mutually exclusive, *i.e.*, a patient can be ill with endogenous depression, or reactive depression, or schizophrenia, etc., but not from two or more. Of course, there are always patients who diagnostically are doubtful in-betweens. On the other hand, factors are orthogonal, and any individual patient can have high scores in two or more factors, or conversely, low scores. The discrepancy between clinical syndromes and factors is even greater when correlated factors are obtained by non-orthogonal rotations, for with such factors, patients will tend to score high or low in all factors simultaneously.

The appropriate statistical technique for describing the clinical syndromes in terms of quantified variables is that of discriminant functions. These divide the multidimensional space into regions, the centres of which characterize the typical case, and the meeting of the regions, the "interfaces", are the sites where are located the atypical, anomalous, or half-way cases. Since this procedure requires the initial establishment of criterion groups, already diagnosed, it cannot therefore be used to find syndromes. It can be used to test the (null) hypothesis that the syndromes are not distinct, and to identify new cases.

Factor Measurements

Another way of investigating the nature of the factors is to consider the individuals who have high scores on the factors:—

Factor 1.—A man aged 39 years (Case 39) had factor scores of F_1 76, F_2 37, F_3 49, and F_4 52.

This patient was admitted to hospital after two attempts at suicide, first by electrocution, and, when this failed, by an overdose of phenobarbitone. No psychological precipitating factors were found. On admission he was severely depressed and still actively suicidal. He had strong feelings of guilt, and feared that he had acquired venereal disease and was infecting others with it. He was markedly retarded and showed loss of insight. His sleep was disturbed in all three phases, he had no interest in anything and had complete loss of libido since the onset of his illness four months previously. His symptoms cleared with six courses of electroshock treatment (E.C.T.). Two weeks later he suddenly relapsed and attempted to cut his wrists with a broken tumbler. He again recovered with a further course of E.C.T. and has remained well ever since.

This case was one of classical endogenous depression.

Case 24.—A man aged 54 had factor scores of F_1 64, F_2 51, F_3 44, and F_4 50.

This patient developed symptoms of anxiety two years ago, accompanied by impotence. As a result of physical illness, he had to change his job to one much less satisfactory and with less pay. He worried excessively over this and over his health, and became very depressed. He was given E.C.T. as an out-patient, improved and returned to work for three months. He was twice admitted to hospital, refused E.C.T., and discharged himself. Eventually he agreed to accept E.C.T. but committed suicide just before he was due to attend for treatment. When in hospital he was deeply depressed, had some guilt feelings, suicidal thoughts, and moderate retardation. He had difficulty in falling asleep and woke in the early hours. He showed loss of interest and of libido. He lacked insight, had lost weight, and complained of vague bodily symptoms. He showed little anxiety but was preoccupied with his health and his future prospects.

Psychological precipitating factors cannot be excluded, but the overall picture is that of endogenous depression.

Factor 2.—A man aged 62 years (Case 61) had factor scores of F_1 32, F_2 54, F_3 37, and F_4 38.

This patient had been off work for 11 years for "bad nerves" following an accident at work. He had many hypochondriacal complaints and had undergone many fruitless investigations. Four years ago, he was admitted to hospital for severe depression with delusions and hallucinations. This cleared after E.C.T. He was readmitted a year ago, diagnosed as a case of reactive depression, and improved slowly under general treatment. He was discharged after three months. His condition fluctuated and eventually he was readmitted, given six courses of E.C.T. and showed marked improvement. He was discharged and remained well. His symptoms were of moderate depression, without feelings of guilt or suicidal ideas. He had difficulty in falling asleep and awoke early. He showed moderate loss of interest, anxiety, both psychic and somatic, and suffered from poor appetite and constipation. He was diagnosed as a case of reactive depression, but the relation of the illness to psychological precipitating factors is not certain.

Case 17.—A man aged 72 years had factor scores of F_1 48, F_2 65, F_3 43, and F_4 45.

There was a long history of abdominal complaints, but investigations found nothing to account for them. A year ago the patient became obviously depressed and was admitted to hospital. He showed moderate depression, guilt, and some suicidal preoccupations. His sleep was disturbed in all three phases. He showed loss of interest, some agitation, severe hypochondriasis, and considerable anxiety. His appetite was poor, his bowels were constipated, and he had lost weight. Because of the poor state of his heart, he was not given E.C.T. He improved slowly, finally discharging himself against advice. Eventually he was admitted to a general hospital and died from cancer of the lung.

The clinical picture is that of reactive depression, but the psychological precipitating factors are doubtful.

Factor 3.—A man aged 61 years (Case 2) had factor scores of F_1 41, F_2 38, F_3 63, and F_4 44.

The patient had a history of several attacks of depression, the last one precipitated by the deaths of his wife and daughter. The course of the illness was fluctuating, and the patient showed a poor response to E.C.T. He showed marked depression, guilt, suicidal thinking, retardation, loss of interest, and grossly disturbed sleep. Eventually he recovered and has remained well.

Case 45.—A man aged 53 years had factor scores of F_1 60, F_2 55, F_3 78, and F_4 52.

The patient had had one previous attack of depression four years before. Two years ago, the patient again fell ill, and his symptoms have fluctuated considerably. In hospital he showed much depression, guilt, and loss of interest, much anxiety and agitation, loss of libido and loss of insight. He is a rather inadequate personality and his present illness began when he was offered a post which involved greater responsibility.

Both of these patients have had previous attacks of depression, characteristic of an endogenous type of disorder, but in both cases, there were obvious psychological stresses to account for the onset of the present attack. In the first, the symptoms were of the endogenous (retarded) type, and in the second of the reactive (agitated) type. Clinically, these patients are very unlike, but the factor scores pick them out on account of their resemblance; what this is, is not clear.

Since the factors are derived from a limited number of cases, the fourth factor is of very doubtful stability. (The question of statistical significance is ignored for the moment.) Nevertheless, it is of considerable interest. Both of the following patients showed depression with much anxiety, disturbance of sleep and many somatic symptoms, but it is the background to the illness that is noteworthy.

Factor 4.—A man aged 51 years (Case 62) had factor scores of F_1 39, F_2 41, F_3 56, and F_4 71.

This patient was a hard worker, but could not restrain his heavy drinking and gambled heavily. These caused considerable marital discord. When temporarily out of work after an accident, he stole money from his daughter to continue his "hobbies". He went off to London, stayed in a hotel and decamped without paying. When he eventually returned home, he heard that the theft had been reported to the police. He became desperate, and after a few days attempted to gas himself and was admitted to hospital. His condition cleared after E.C.T.

Case 7.—A man aged 44 years had factor scores of F_1 34, F_2 44, F_3 58, and F_4 71.

This patient came from a disturbed parental home where he had been rejected and deprived. He has always been an odd personality with marked neurotic traits and paranoid attitudes. He served in the Royal Air Force for nine years, during which he was repeatedly delinquent and resistant to authority. Eventually he was discharged for "psychoneurosis". His subsequent occupational history is irregular, with frequent loss of jobs because of quarrelling. He always feels that others are against him. He has not worked for years, has shown much anxiety and in the last six months became depressed, being finally admitted to hospital. He improved a little after E.C.T. but relapsed, subsequently recovering spontaneously.

Both of these patients have obviously abnormal personalities, although it would be an exaggeration to describe them as psychopathic personalities. It has long been recognized that abnormal personalities, particularly of the hysterical type, are liable to attacks of depression, and it is of great interest that such patients should be picked out by reason of the pattern of symptoms of their depression. Nevertheless, the present findings should not be regarded as more than suggestive and worthy of further investigation.

Another way of tackling the relation between factors and clinical syndromes is to take groups of clinically identified patients and compare their mean

factor measurements. Since this is purely a clinical problem and involves other matters, it is reported elsewhere (Hamilton and White, 1959).

Tests of significance have not been applied to these factors. It seems likely that even the smallest factor would become statistically significant if a sufficient number of patients were tested, and the ratings were repeated often enough to make the individual variables highly reliable. The value of factors lies in their use. In this connexion, although the data for the factor analysis were derived from 49 patients, the regression equations were used on the ratings obtained from 64 patients investigated for other purposes. Of these 64 patients, 49 were followed up after treatment (not the same 49). The correlation between factor measurements and total crude score after treatment is for F_1 0·23, for F_2 0·17, for F_3 0·27, and for F_4 — 0·09. Although F_3 has no obvious clinical or psychological meaning, it is the only one of the factors to be correlated with outcome after treatment at a significance level of just over 5%. This is not much, but a large correlation with outcome is not to be expected in such a highly selected group of patients (Hamilton and White, 1959). Furthermore, 16 out of the 49 cases followed up are new cases, so that some of the shrinkage to be expected in a cross-validation group has already occurred. (The situation is not quite the same as when a multiple correlation is calculated, but F_3 has been picked out because it has the highest correlation with outcome. Herein lies the interest of this factor.)

Summary

A rating scale is described for use in assessing the symptoms of patients diagnosed as suffering from depressive states. The first four latent vectors of the intercorrelation matrix obtained from 49 male patients are of interest, as shown by (*a*) the factor saturations, (*b*) the case histories of patients scoring highly in the factors, and (*c*) the correlation between factor scores and outcome after treatment. The general problem of the relationship between clinical syndromes and factors extracted from the intercorrelations of symptoms is discussed.

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APPENDIX I

ASSESSMENT OF DEPRESSION

Item No.	Score Range	Symptom	Score
1	0-4	Depressed mood	
2	0-4	Guilt	
3	0-4	Suicide	
4	0-2	Insomnia, initial	
5	0-2	,, middle	
6	0-2	,, delayed	
7	0-4	Work and interests	
8	0-4	Retardation	
9	0-2	Agitation	
10	0-4	Anxiety, psychic	
11	0-4	,, somatic	
12	0-2	Somatic symptoms, gastrointestinal	
13	0-2	,, ,, general	
14	0-2	Genital symptoms	
15	0-4	Hypochondriasis	
16	0-2	Loss of insight	
17	0-2	,, ,, weight	
18	0-2	Diurnal variation {M / E}	
19	0-4	Depersonalization, etc.	
20	0-4	Paranoid symptoms	
21	0-2	Obsessional symptoms	

Grading	
0	Absent
1	Mild or trivial
2 } 3	Moderate
4	Severe
0	Absent
1	Slight or doubtful
2	Clearly present

APPENDIX II

CHECK LIST OF SYMPTOMS OF DEPRESSIVE STATES

Item No.	Range of Scores	Symptom
1.	0-4	*Depressed Mood* Gloomy attitude, pessimism about the future Feeling of sadness Tendency to weep Sadness, etc ..... 1 Occasional weeping .. 2 Frequent weeping ..... 3 Extreme symptoms 4
2	0-4	*Guilt* Self-reproach, feels he has let people down Ideas of guilt Present illness is a punishment Delusions of guilt Hallucinations of guilt
3	0-4	*Suicide* Feels life is not worth living Wishes he were dead Suicidal ideas Attempts at suicide
4	0-2	*Insomnia, initial* Difficulty in falling asleep
5	0-2	*Insomnia, middle* Patient restless and disturbed during the night Waking during the night
6	0-2	*Insomnia, delayed* Waking in early hours of the morning and unable to fall asleep again
7	0-4	*Work and Interests* Feelings of incapacity Listlessness, indecision and vacillation Loss of interest in hobbies Decreased social activities Productivity decreased Unable to work Stopped working because of present illness only ..... 4 (Absence from work after treatment or recovery may rate a lower score.)
8	0-4	*Retardation* Slowness of thought, speech, and activity Apathy Stupor Slight retardation at interview .. 1 Obvious retardation at interview 2 Interview difficult ..... 3 Complete stupor 4
9	0-2	*Agitation* Restlessness associated with anxiety
10	0-4	*Anxiety, psychic* Tension and irritability Worrying about minor matters Apprehensive attitude Fears
11	0	*Anxiety, somatic* Gastrointestinal, wind, indigestion Cardiovascular, palpitations, headaches Respiratory, genito-urinary, etc.
12	0-2	*Somatic Symptoms, Gastrointestinal* Loss of appetite Heavy feelings in abdomen Constipation
13	0-2	*Somatic Symptoms, General* Heaviness in limbs, back, or head Diffuse backache Loss of energy and fatiguability
14	0-2	*Genital Symptoms* Loss of libido Menstrual disturbances
15	0-4	*Hypochondriasis* Self-absorption (bodily) Preoccupation with health Querulous attitude Hypochondriacal delusions
16	0-2	*Loss of Weight*
17	2-0	*Insight* Loss of insight ..... 2 Partial or doubtful loss ..... 1 No loss ..... 0 (Insight must be interpreted in terms of patient's understanding and background.)
18	0-2	*Diurnal Variation* Symptoms worse in morning or evening. Note which it is.
19	0-4	*Depersonalization and Derealization* Feelings of unreality } Specify Nihilistic ideas } Specify
20	0-4	*Paranoid Symptoms* Suspicious Ideas of reference Delusions of reference and persecution Hallucinations, persecutory } Not with a depressive quality
21	0-2	*Obsessional Symptoms* Obsessive thoughts and compulsions, against which the patient struggles

THE ASSESSMENT OF ANXIETY STATES BY RATING

By MAX HAMILTON*

In the last decade many scales have been devised for the assessment of psychiatric symptoms. Most have been designed for use with patients in mental hospitals and have therefore concentrated chiefly on behaviour in the ward and in hospital activities. Not many of the items are concerned with symptoms, and these are chiefly those of schizophrenia and the depressive psychoses. Even less attention is paid to neurotic symptoms, especially anxiety states, despite the fact that the scales are intended generally to cover the full range of psychiatric syndromes. These scales have been designed to enable the research worker to obtain a quantified measure of the patient's clinical status, e.g. for use in clinical trials of treatment. In them, the separate items are summed in groups and a set of scores or 'profile' is obtained for each patient. This 'profile' is often used as a diagnostic aid, although this is not the primary purpose of the scale. Users are generally warned not to use the scale for making a diagnosis.

In practice, these scales have two other functions of great importance. The first is that the investigator can describe precisely certain characteristics of his group of patients using the mean score and standard deviation. The description and definition of the population from which a sample is drawn is of fundamental importance and is one of the difficult problems that faces research in psychiatry. For this purpose diagnostic categories are notoriously unreliable and rating scales are invaluable. The second function is that they help to define syndromes and subsyndromes, and in a manner which permits of reproduction in another enquiry.

The present scale was designed along different lines. It is intended for use with patients already diagnosed as suffering from neurotic anxiety states, not for assessing anxiety in patients suffering from other disorders. Anxiety in greater or lesser degree is found in agitated depression and obsessional states particularly, and also in such states as organic dementia, hysteria and schizophrenia, but it must be clearly emphasized that the scale is not intended to cope with these conditions.

The usual methods for scale design were used. A series of symptoms were assembled which were considered to cover the condition adequately. These were then grouped together according to their nature, or where clinical experiences indicated that they were associated. It was decided that for practical purposes twelve groupings were sufficient. Together with the patient's behaviour at interview, these formed the thirteen variables of the scale. They are: anxious mood (a continued state of apprehension), tension (including irritability), fears (of specific or phobic type), insomnia, cognitive changes (difficulty in concentration and forgetfulness), depression, somatic symptoms of a general type, cardiovascular, respiratory, gastro-intestinal, genito-urinary, and general autonomic symptoms, the latter consisting chiefly of headaches and sweating. Each of the variables was defined in a series of brief statements, headed by the name of the variable, printed on a sheet which faced the interviewer during the interview with the patient (see Appendix 1).

Assessments were made on a five-point scale (see Appendix 2). In practice, the last grade is very rarely used for out-patients, and serves more as a marker, a method of delimiting

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the range, rather than as a grade of practical use. In order to determine the reliability of the scale the patients were seen by two interviewers simultaneously. The principal interviewer conducted the interview and endeavoured to obtain information regarding the patient's symptoms. The second interviewer made his ratings independently of the first and could add his own questions if he thought he had not had sufficient information.

Table 1. *Correlations and t tests between raters*

		Raters I	Raters II	Raters III	
I	*t* test	—	0·30	0·54	First interview
	Correlation	—	0·93	0·39	
	No. of subjects	—	8	8	
II	*t* test	0·07	—	0·63	
	Correlation	0·83	—	0·91	
	No. of subjects	8	—	10	
III	*t* test	0·64	1·30	—	
	Correlation	0·95	0·93	—	
	No. of subjects	8	10	—	
		Second interview			

The initial testing of the scale involved three psychiatrists. Preliminary discussions eliminated many of the difficulties in the first version of the definitions of the variables. The rating scale was then tried on a number of patients and the discrepancies and agreements between psychiatrists carefully considered in detail, in an endeavour to eliminate difficulties. The scale was then tried on a group of patients and this paper is concerned with the results. An identical procedure was followed throughout. Each patient was assessed by two raters and the results recorded. Afterwards the results were compared and any discrepancies noted and discussed. Nevertheless, once a rating had been made it was not altered. The measure of reliability was based on the sum of crude scores for each patient. Product-moment correlations were calculated between each pair of physicians, and since the patients were interviewed on two occasions for purposes of a drug trial, two such correlations between each pair of physicians is available. The results are to be seen in Table 1. The weighted mean of these correlations, using the z transformation, is 0·89. This is remarkably high and illustrates the reliability of psychiatric assessments under suitable conditions. Since the reliability coefficient does not give information on the bias of raters towards high or low scores, t tests were calculated between pairs of raters in the same way (see Table 1). The weighted mean of these t tests is 0·61 and shows that very little bias is to be found.

The relations between the variables were then examined. Product-moment correlations were calculated between the variables and the resultant matrix factor-analysed by the method of Simple Summation (the matrix of correlations is available on request). Communalities were estimated by five iterations of the process. This is very easily done using the shortened method of Burt (1949). A general and one bipolar factor were extracted. The general factor is clearly a general factor of anxiety and the bipolar divides the symptoms into two groups: The first contains psychic symptoms consisting of tension, fears, insomnia, anxiety, intellectual (cognitive) changes, depression, and behaviour at interview. This was contrasted with a group of somatic symptoms consisting of gastro-intestinal, genito-urinary, respiratory, cardiovascular, somatic general and autonomic symptoms (Table 2).

When the factor saturations are plotted it may be seen that the vectors lie almost completely within a right angle. In other words it is possible to rotate the saturations to give two orthogonal group factors. The variance of the general factor constitutes 27 %, of the bipolar 18 %, giving a total of 45 % of the total variance. This total was probably reduced by selection.

Table 2. *Saturations for centroid and rotated factors*

	G	BP	I	II
Tension	0·60	0·26	0·36	0·54
Fears	0·29	0·37	0·04	0·46
Insomnia	0·79	0·32	0·48	0·70
Anxious mood	0·43	0·75	−0·06	0·86
Cognitive changes	0·56	0·07	0·42	0·37
Depression	0·38	0·52	0·02	0·64
Behaviour	0·37	0·22	0·18	0·39
Gastro-intestinal symptoms	0·41	0·00	0·34	0·22
Genito-urinary symptoms	0·43	−0·34	0·55	−0·05
Respiratory symptoms	0·31	−0·54	0·56	−0·27
Cardiovascular symptoms	0·34	−0·62	0·62	−0·33
Somatic (general) symptoms	0·48	−0·31	0·57	0·01
Autonomic symptoms	0·56	−0·10	0·52	23
Communality	2·93	2·09	—	—
Communality as percentage	23	16	—	—

DISCUSSION

This particular matrix of correlations can be resolved either into a general factor of anxiety and a bipolar factor of psychic versus somatic symptoms, or alternatively, into two orthogonal group factors of 'psychic anxiety' and 'somatic anxiety'. Since both factorizations give orthogonal factors, there is no advantage in one over the other. On general grounds, we know that had there been less selection of subjects, so that they extended through the full range from those with trivial symptoms to those severely ill, then in the centroid analysis, the general factor would have had a greater variance, the bipolar factor still being orthogonal to it. In the group factor analysis, the two group factors would have been positively correlated, this implying a general second order factor. The British school of factorists, following Burt, emphasize the value of orthogonality. The American school, following Thurstone, emphasize the value of being able to identify the same factors regardless of the problems introduced by selection. In this particular case, the group factor analysis has the advantage of orthogonality as well.

Despite the apparent advantage of the group factor approach over the general factor approach, it must not be forgotten that mathematically, the two have an equivalence, since the one can be converted into the other by a simple transformation, in this case, the simplest of all, an orthogonal rotation. No new information can appear from such a transformation. (In fact, factor analysis, except for the method of principal components with full variance, actually loses information. Its great advantage is that it makes information clearer and more comprehensible.) The choice between general and group factor analysis must depend on other considerations.

In this case, the selection of patients is based on the fact that they all suffer from anxiety neurosis, and this condition shows itself as a general factor, i.e. a dimension to which all the variables are positively correlated, or on which they all have positive non-zero projections. It may be that, in other circumstances, the division into group factors may be preferred. For example, the response to treatment, or the effects of some drug, may show as a change in one or other of the group factors. Even if this should be so, it would only mean that whereas for such a situation, the group factor is appropriate, for the present situation, i.e. for diagnosis, the general factor is the appropriate one.

It is interesting to compare this rating scale with the factor analysis of the Taylor scale by O'Connor, Lorr & Stafford (1956). Although the present scale is concerned with general symptoms, whereas the Taylor scale deals with specific statements, the two factors A and B correspond roughly with the present general and bipolar factors. Factors A and B correlate 0·068, so they too are orthogonal.

Both the Taylor scale and the scales of Dixon, de Monchaux & Sandler (1957*a*, *b*) differ from the present one in that they are concerned with the content of the patient's

symptoms, rather than the form. This is also true of the Taylor scale. Although in the course of treatment the specific nature of a patient's fears and anxieties may change, it does so much less readily than the intensity. The assessment of both these kinds of changes is of practical and theoretical importance, and therefore the two kinds of scale are complementary.

The present scale obviously invites comparison with that designed by Buss, Wiener, Durkee & Baer (1955). It is important to recognize the difference between the two. The present scale is designed for the rating of anxiety neurosis as a syndrome, not for the rating of anxiety. Until the contrary is proved, it must be regarded as invalid for the rating of anxiety in any other setting. This limits the range of usefulness of the scale but, within these limits, patients can be compared meaningfully. It places great emphasis on the patient's subjective state. (This follows from the medical bias of the author, for in treatment the patient's subjective state takes first place both as a criterion of illness, which brings the patient for treatment, and as a criterion of improvement.) The various symptoms are rated separately, the somatic ones being given equal place with the psychic. This is because in outpatient practice patients place great emphasis on somatic symptoms, and a large number go first to the general medical departments for investigation of these. The scale of Buss *et al.* was used for rating anxiety on all types of patient except those suffering from cerebral damage. It therefore has a wider range of application. This is counter-balanced by the fact that the comparison of scores for anxiety, e.g. schizophrenia, depression and anxiety neuroses, has no clear meaning. It assembles symptoms into fewer groups. It gives less weight to somatic symptoms, or alternatively, gives more weight to psychic symptoms. Both scales group many single items under a limited number of headings, and it would be clearly desirable to investigate the appropriateness and usefulness of this procedure. Both show high reliability in use. I do not intend to suggest that either scale is better than the other. Only practical use will determine which is the more useful, and it is to be hoped that both will be superseded by something better.

The scale can by no means be considered to be in its final state. Ideally, each of the items listed under the heading of a variable should be handled separately for purposes of full item analysis. The sheer labour of doing this in a rating scale (as opposed to a questionnaire) will delay this for a long time. Some of the variables are obviously a rag-bag of oddments and need further investigation. Further work is being done in which the general somatic symptoms are separated into two variables: muscular and sensory.

Experience has shown that grade 2 can be split up into two grades without increasing the difficulty of rating. In practice, grade 4 is almost never used because the rater is reluctant to give the maximum score to subjects who could obviously be much worse. An additional grade would probably be rarely or never used, but would encourage the rater to subdivide grade 3, shifting some of his ratings to the higher grade.

Summary

A rating scale for the symptoms of anxiety neurosis has been prepared as an aid to the quantification of symptoms. It was used on thirty-five patients by three physicians working in pairs. The reliability of the scale, as shown by correlations and *t* tests between raters, is high. The correlations between variables can be factorized into a general factor of anxiety and a bipolar factor contrasting psychic with somatic symptoms; or into two orthogonal group factors of 'psychic' and 'somatic' anxiety.

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Appendix 1

Symptoms of anxiety states

Anxious mood
- Worries
- Anticipation of the worst
- Apprehension (fearful anticipation)
- Irritability

Tension
- Feelings of tension
- Fatiguability
- Inability to relax
- Startle response
- Moved to tears easily
- Trembling
- Feelings of restlessness

Fears
- Of Dark
- Strangers
- Being left alone
- Large animals, etc.
- Traffic
- Crowds

Insomnia
- Difficulty in falling asleep
- Broken sleep
- Unsatisfying sleep and fatigue on waking
- Dreams
- Nightmares
- Night terrors

Intellectual (cognitive)
- Difficulty in concentration
- Poor memory

Depressed mood
- Loss of interest
- Lack of pleasure in hobbies
- Depression
- Early waking
- Diurnal swing

General somatic (muscular)
- Muscular pains and aches
- Muscular stiffness
- Muscular twitchings
- Clonic jerks
- Grinding of teeth
- Unsteady voice

General somatic (sensory)
- Tinnitus
- Blurring of vision
- Hot and cold flushes
- Feelings of weakness
- Pricking sensations

Cardiovascular symptoms
- Tachycardia
- Palpitations
- Pain in chest
- Throbbing of vessels
- Fainting feelings
- Missing beat

Respiratory symptoms
- Pressure or constriction in chest
- Choking feelings
- Sighings
- Dyspnoea

Gastro-intestinal symptoms
- Difficulty in swallowing
- Wind
- Dyspepsia:
  - pain before and after meals
  - burning sensations
  - fullness
  - waterbrash
  - nausea
  - vomiting
  - sinking feelings
- 'Working' in abdomen
- Borborygmi
- Looseness of bowels
- Loss of weight
- Constipation

Genito-urinary symptoms
- Frequency of micturition
- Urgency of micturition
- Amenorrhea / Menorrhagia / Development of frigidity
- Ejaculatio praecox / Loss of erection / Impotence

Autonomic symptoms
- Dry mouth
- Flushing
- Pallor
- Tendency to sweat
- Giddiness
- Tension headache
- Raising of hair

Behaviour at interview (general)
- Tense, not relaxed
- Fidgetting: hands, picking fingers, clenching, tics, handkerchief
- Restlessness: pacing
- Tremor of hands
- Furrowed brow
- Strained face
- Increased muscular tone
- Sighing respirations
- Facial pallor

Behaviour (physiological)
- Swallowing
- Belching
- High resting pulse rate
- Respiration rate over 20/min.
- Brisk tendon jerks
- Tremor
- Dilated pupils
- Exophthalmos
- Sweating
- Eye-lid twitching

APPENDIX 2

Date				
Anxious mood				
Tension				
Fears				
Insomnia				
Intellect				
Depressed mood				
Somatic general (muscular and sensory)				
Cardiovascular system				
Respiratory system				
Gastro-intestinal system				
Genito-urinary system				
Autonomic system				
Behaviour at interview				

General comments:

Grades
0 is none
1 is mild
2 is moderate
3 is severe
4 is very severe, grossly disabling

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A New Depression Scale Designed to be Sensitive to Change

By STUART A. MONTGOMERY and MARIE ÅSBERG

SUMMARY The construction of a depression rating scale designed to be particularly sensitive to treatment effects is described. Ratings of 54 English and 52 Swedish patients on a 65 item comprehensive psychopathology scale were used to identify the 17 most commonly occurring symptoms in primary depressive illness in the combined sample.

Ratings on these 17 items for 64 patients participating in studies of four different antidepressant drugs were used to create a depression scale consisting of the 10 items which showed the largest changes with treatment and the highest correlation to overall change.

The inter-rater reliability of the new depression scale was high. Scores on the scale correlated significantly with scores on a standard rating scale for depression, the Hamilton Rating Scale (HRS), indicating its validity as a general severity estimate. Its capacity to differentiate between responders and non-responders to antidepressant treatment was better than the HRS, indicating greater sensitivity to change. The practical and ethical implications in terms of smaller sample sizes in clinical trials are discussed.

Introduction

The most common use of psychiatric rating scales is probably for comparison of effects of new drugs to standard treatment. In most trials of antidepressant drugs a difference can be demonstrated between pharmacologically active compounds and placebo (Morris and Beck, 1974) but only rarely are consistent differences found between active drugs even when they are known to have different mechanisms of action.

One possible explanation is that the standard rating scales are not sensitive enough to pick up such differences (Angst, 1972) which is not surprising if the scales were not designed specifically for that purpose. The result has often been that the scales reflect diagnostic features rather than being sensitive to change. We therefore decided to construct a rating scale for depressive illness where sensitivity and accuracy of change estimates were to be major criteria for the inclusion of items. This work was made possible by the recent introduction of a new, comprehensive psychopathological rating scale or CPRS (Åsberg *et al*, 1978). The CPRS is composed of 65 scaled items covering a wide range of psychiatric symptoms.

Patients and Ratings

The selection of items for the depression scale was based on ratings on the CPRS of 106 depressed patients, 33 men and 73 women, participating in clinical trials of antidepressant drugs. Thirty-three were out-patients and 73 in-patients. In the majority of cases, two raters participated in the interview. Only patients with a primary depressive illness (Feighner *et al*,

1972) were included. Inventories (Gurney *et al*, 1972) were applied to ensure diagnostic and descriptive uniformity. Within this group, a wide variation in patient characteristics was sought and the sample includes endogenous and reactive, psychotic and non-psychotic, bipolar and unipolar out-patients and in-patients from a wide age range (18–69 years). Patients from two countries (England n = 54, and Sweden n = 52) were included in order to reduce cultural bias in the selection of items.

CPRS scores after four weeks therapy with four antidepressant drugs with different pharmacological profiles were used to study change with treatment. The drugs were mianserin, amitriptyline, maprotiline and clomipramine. Amitriptyline (Tuck and Punell, 1973), maprotiline (Maitre *et al*, 1971) and clomipramine (Hamberger and Tuck, 1973) block neuronal reuptake of noradrenaline, directly or by means of endogenously formed metabolites. Clomipramine is also a potent serotonin uptake blocker (Åsberg *et al*, 1977). Amitriptyline may also affect serotoninergic neurones (Tuck and Punell, 1973) and has pronounced anticholinergic effects (Mass, 1975); it is also thought to have a stronger sedative effect than the other drugs (Silverstone and Turner, 1974). Mianserin appears to lack uptake inhibiting effects (Ferl *et al*, 1973) as well as anticholinergic effects (Coppen *et al*, 1976) and its mechanism of action is not clear.

Of the 64 patients for whom scores were available from before and after four weeks of treatment 35 were simultaneously rated on the Hamilton Rating Scale (HRS) (Hamilton, 1967) and on a 7-point scale for global severity of illness.

Construction of the Scale

Parametric statistical methods were used except when dealing with ranked data as recommended by Anderson (1961) and Boneau (1961). The difference between pre-treatment scores has been used as an estimate of change, both for individual and sums of items.

Preliminary item selection

The frequency of scores above zero on all of the 65 items as well as the ranking by inci-

TABLE I

Frequency of scores above zero and correlation between English and Swedish raters on the 17 most commonly scored items of the CPRS

Item	Frequency of scores above zero in per cent (both samples combined, n = 106)	Interrater reliability between English and Swedish rater (n = 11)
Reported sadness	100	0.96
Apparent sadness	99	0.90
Lassitude	96	0.78
Inner tension	95	0.90
Pessimistic thoughts	94	0.53
Inability to feel	93	0.41
Worrying over trifles	91	0.78
Concentration difficulties	88	0.80
Observed muscular tension	88	0.74
Suicidal thoughts	87	0.71
Fatiguability	86	0.89
Reduced sleep	83	0.76
Indecision	81	0.27
Reported autonomic disturbances	79	0.72
Reported muscular tension	74	0.59
Reduced appetite	73	0.95
Agitation	73	0.62

dence were remarkably similar in the Swedish and the English samples (r = +.88, rho = +.88, P for both <0.001 (Montgomery *et al*, 1978a). Since the agreement between ratings of English patients by English and Swedish raters was generally high (Table I) it was decided to merge the two samples in the further calculations.

An arbitrary cut-off point of 70 per cent occurrence was used to identify the 17 most common items (Table I) in the total sample of patients. The sum of scores on these 17 items was used as a preliminary estimate of severity of the illness. This estimate was significantly correlated with the HRS scores (r = +.94, P <0.001) and also with the global scores (r = +.89, P <0.001) during the fourth treatment week. Before treatment these correlations were slightly lower as would be expected from the more restricted range of scores (HRS, r = +.73, Global, r = +.61, P for both <0.001).

TABLE II

Mean change (regardless of direction), and correlation between change on each item and sum of change on the preliminary 17 item scale (n = 64). The items are ranked in order of descending sensitivity on both estimates combined

Item	Mean change	Correlation to total change
Apparent sadness	2.12	0.84
Reported sadness	2.19	0.73
Inability to feel	1.98	0.75
Inner tension	1.79	0.73
Suicidal thoughts	2.03	0.64
Lassitude	1.61	0.79
Concentration difficulties	1.79	0.69
Reduced sleep	2.45	0.49
Reduced appetite	1.78	0.63
Pessimistic thoughts	1.69	0.64
Worrying over trifles	1.88	0.46
Fatiguability	1.73	0.58
Muscular tension (reported)	1.41	0.56
Muscular tension (observed)	1.22	0.49
Indecision	1.57	0.44
Autonomic disturbances	1.60	0.40
Agitation	0.99	0.34

Selecting items for sensitivity

Two different estimates of sensitivity were used (Table II). Firstly the mean changes of scores (absolute values) on each of the 17 items after four weeks of treatment were calculated and ranked. The second estimate was the correlation between change on each item and the overall change on the preliminary 17 item scale over the four weeks. These estimates reflect different aspects of sensitivity to change. Ideally, an item should both yield large changes (that can be reliably rated) and be strongly correlated to general amelioration of depression. This is not always the case.

For example, reduced sexual interest yielded large changes but was less well correlated to general outcome. Inclusion of an item like this in a scale might spuriously inflate the change scores.

The summed ranks on both estimates were used to select the 10 most sensitive items for the final depression rating scale, which is shown in the Appendix.

Reliability and Validity of the New Depression Scale

Interrater reliability

Data from the conjoint interviews were used to compute interrater correlations. Comparisons between two English raters, two Swedish raters and one English and one Swedish rater, rating English patients, are given in Table III. The interrater reliability in the simultaneously performed HRS ratings is shown for comparison. The interrater correlations are satisfactory for both scales, for raw scores as well as for difference scores.

To test the robustness of the instrument in the hands of untrained raters, ratings were also performed by a trained psychiatrist and a general practitioner or a psychiatric nurse (a detailed account of the procedure is given elsewhere; Montgomery *et al*, 1978). Also in this setting the interrater correlations were high (Table III).

Validity studies

To test the validity of a scale which estimates the severity of depression a comparison must

TABLE III

Interrater reliability of the new depression scale with different rater pairs. Interrater correlation between simultaneously performed Hamilton scale ratings are shown within brackets for comparison. All correlations are highly significant ($P < 0.001$)

Rater pair	r	n
Two English raters		
before treatment	0.89 (HRS: 0.89)	30 (HRS: 25)
during treatment	0.95 (HRS: 0.98)	20 (HRS: 14)
difference	0.90 (HRS: 0.91)	13 (HRS: 12)
Two Swedish raters		
before treatment	0.95	22
One English, one Swedish rater		
various stages of treatment	0.97	11
Psychiatrist and general practitioner		
various stages of treatment	0.97	17
Psychiatrist and nurse		
various stages of treatment	0.93	12

be made with an independent measure. An experienced clinician's global judgement as to whether the patient has responded or not is the criterion against which depression scales should be judged. As a preliminary validation of this scale's capacity to identify responders and non-responders to treatment we compared the scale scores with a clinician's global judgement in a sample where there was a clear cut differentiation between responders (18 patients) and non-responders (17 patients).

Point biserial correlations between response category and change scores were calculated for the preliminary 17-item scale, the final 10-item depression scale and the Hamilton Rating Scale. All correlations were highly significant. The correlations were used to determine which of the three scales differentiated better between responders and non-responders to treatment. The best correlation was achieved with the 10-item depression scale ($r = +.70$), the next best was with the 17-item preliminary scale ($r = +.67$). Of the three the HRS was the least able to discriminate ($r = +.59$). Converted into approximate patient numbers needed to achieve equivalent significance at different levels, for a point biserial correlation of this order 28 patients would have been needed to reach a significance at the 0.001 probability level with the HRS, compared with 19 patients on the 10 item scale.

Discussion

The major requirements of a rating scale for antidepressant treatment effects is that it should be short and easy to apply in a clinical setting, relevant for depressive illness, and provide a sensitive and accurate estimate of change (Hamilton, 1976; Carroll *et al*, 1973; Åsberg *et al*, 1973).

It would of course be possible to use a very extensive rating scale covering all aspects of depressive illness. A scale of this type might be more likely to pick up unexpected differences in the spectrum of action of drugs. However, the presence of a large number of items that were scored in only a few patients would tend to introduce and increase the random error. More important, the ratings would be cumbersome and time-consuming to undertake. Unskilled raters might have difficulties in covering a large number of items in a single interview. Repeated asking of questions which appear irrelevant to the patient might also be detrimental to clinical rapport and reduce the validity of the information provided.

When reducing the number of items, it is important that those included are relevant to

the illness and indeed occur in the majority of cases. An item may be both of diagnostic importance and likely to change with treatment but because it occurs so infrequently it might diminish the overall sensitivity of the scale. Examples of this type which failed to meet our frequency criterion for consideration are Ideas of Persecution and Compulsive Thoughts. Similar items were included in the initial version of the Hamilton Rating Scale (Hamilton, 1960) but excluded later (Hamilton, 1967).

Sensitivity of the scale in this context refers to its capacity to measure change. Change will be most sensitively recorded on items which are not restricted in range, but when the full width of the scales are used for the ratings. Restriction of the range might occur if a positive score on an item reflects a personality trait which is unlikely to change with short term treatment, rather than a symptom of an illness. It might also occur as a result of central tendency error, in which raters tend to avoid using the extreme ends of the scales (Guilford, 1954).

Change estimates should also be accurate and reflect a change in general severity of depressive illness. Some items may show a high degree of change without this being related to the illness as such. Hospitalization would be expected to have effects, for instance, on sexual interest and general levels of activity. Increased severity of some symptoms (for instance autonomic disturbances) may be side-effects of an antidepressant drug treatment.

The 10 items included in the new depression scale are all core symptoms of depressive illness. A few characteristic symptoms are, however, not included. Motor retardation (called Slowness of Movement in the full CPRS) is perhaps the most conspicuous omission. It was excluded from the primary selection, since it occurred in relatively few patients (63 per cent of the English patients and 69 per cent of the Swedish patients). Clinical experience shows that motor retardation only occurs in a proportion of patients and this is indeed the background of one of the classifications of depressive illness into retarded and non-retarded forms. In any case the mean change in Slowness of Movement was smaller than for any item included in the scale and the correlation of change to overall amelioration was comparatively low ($r = +.57$).

The large number of rating scales available to clinical investigators is a problem in psychiatric research (Pichot, 1972) and the comparability between scales is rarely known. It is therefore important that a new rating scale should be shown to have clear advantages over existing instruments before it is accepted for research purposes. Our scale appears to have certain advantages, even when compared to the most widely used depression rating scale, the Hamilton Rating Scale.

Our depression scale has fewer items to score than the HRS (10 vs 17) and a reduction in reliability might be expected. However, we have demonstrated equally high reliabilities with the HRS and the 10 item scale. The scale can be used by trained nurses and psychologists as well as by psychiatrists (Montgomery *et al*, 1978b). It appears to be a more precise measure of change than the HRS. This means that significant differences between treatments may be revealed with smaller numbers of patients. In clinical trials this is important for ethical reasons, since fewer patients need to be exposed to possibly inferior treatments.

There is a definite need for simple, clinically oriented rating scales to measure treatment effects in other psychiatric syndromes such as mania, schizophrenia and anxiety states. To our knowledge, the strategy we employed for arriving at an empirically founded scale has not previously been used and should prove valuable in constructing further scales.

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APPENDIX

Montgomery and Åsberg (MADRS) Depression Rating Scale.

The rating should be based on a clinical interview moving from broadly phrased questions about symptoms to more detailed ones which allow a precise rating of severity. The rater must decide whether the rating lies on the defined scale steps (0, 2, 4, 6) or between them (1, 3, 5).

It is important to remember that it is only on rare occasions that a depressed patient is encountered who cannot be rated on the items in the scale. If definite answers cannot be elicited from the patient all relevant clues as well as information from other sources should be used as a basis for the rating in line with customary clinical practice.

The scale may be used for any time interval between ratings, be it weekly or otherwise but this must be recorded.

Item List

1. Apparent sadness
2. Reported sadness
3. Inner tension
4. Reduced sleep
5. Reduced appetite
6. Concentration difficulties
7. Lassitude
8. Inability to feel
9. Pessimistic thoughts
10. Suicidal thoughts

1. *Apparent Sadness*

Representing despondency, gloom and despair, (more than just ordinary transient low spirits)

reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

0 No sadness.
1
2 Looks dispirited but does brighten up without difficulty.
3
4 Appears sad and unhappy most of the time.
5
6 Looks miserable all the time. Extremely despondent.

---

2. *Reported sadness*

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope.

Rate according to intensity, duration and the extent to which the mood is reported to be influenced by events.

0 Occasional sadness in keeping with the circumstances.
1
2 Sad or low but brightens up without difficulty.
3
4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.
5
6 Continuous or unvarying sadness, misery or despondency.

---

3. *Inner tension*

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread or anguish.

Rate according to intensity, frequency, duration and the extent of reassurance called for.

0 Placid. Only fleeting inner tension.
1
2 Occasional feelings of edginess and ill-defined discomfort.
3
4 Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.
5
6 Unrelenting dread or anguish. Overwhelming panic.

---

4. *Reduced sleep*

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

0 Sleeps as usual.
1
2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep.
3
4 Sleep reduced or broken by at least two hours.
5
6 Less than two or three hours sleep.

---

5. *Reduced appetite*

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

0 Normal or increased appetite.
1
2 Slightly reduced appetite.
3
4 No appetite. Food is tasteless.
5
6 Needs persuasion to eat at all.

---

6. *Concentration difficulties*

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.

Rate according to intensity, frequency, and degree of incapacity produced.

0 No difficulties in concentrating.
1
2 Occasional difficulties in collecting one's thoughts.
3
4 Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.
5
6 Unable to read or converse without great difficulty.

---

7. *Lassitude*

Representing a difficulty getting started or slowness initiating and performing everyday activities.

0 Hardly any difficulty in getting started. No sluggishness.
1
2 Difficulties in starting activities.

3

4 Difficulties in starting simple routine activities which are carried out with effort.

5

6 Complete lassitude. Unable to do anything without help.

8. *Inability to feel*

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

0 Normal interest in the surroundings and in other people.

1

2 Reduced ability to enjoy usual interests.

3

4 Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.

5

6 The experience of being emotionally paralysed, inability to feel anger, grief or pleasure and a complete or even painful failure to feel for close relatives and friends.

9. *Pessimistic thoughts*

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

0 No pessimistic thoughts.

1

2 Fluctuating ideas of failure, self-reproach or self depreciation.

3

4 Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.

5

6 Delusions of ruin, remorse or unredeemable sin. Self-accusations which are absurd and unshakable.

10. *Suicidal thoughts*

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.

Suicidal attempts should not in themselves influence the rating.

0 Enjoys life or takes it as it comes.

1

2 Weary of life. Only fleeting suicidal thoughts.

3

4 Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.

5

6 Explicit plans for suicide when there is an opportunity. Active preparations for suicide.

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Evaluation of 10 QT Prediction Formulas in 881 Middle-aged Men From the Seven Countries Study: Emphasis on the Cubic Root Fridericia's Equation

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SUMMARY

In 881 middle-aged men from one Italian cohort of the Seven Countries Study, QT and RR intervals were measured in lead 2 from resting ECGs (25 mm/sec) and fitted separately with 10 mathematically different QT prediction formulas. The relative accuracy of fit to data was assessed from the minimum mean-squared residual and the minimum Akaike Information Criterion values. Using the Minnesota code, 588 men had normal (group 1) and 293 had abnormal (group 2) ECGs. A better fit to QT–RR data by all formulas was observed in group 1, compared with group 2. Among one-parameter equations in both groups, the cubic root Fridericia's formula is better suited to fit the data than the Bazett's square root or other formulas. The former compares favorably with multiparameter equations or with the inverse relation and gives the best fit in group 2. Thus the cubic root equation might be more accurate than the square root or several complex formulas for correcting measured QT intervals for cardiac cycle length in middle-aged men.

None[1] of several QT prediction formulas[2–17] used during the past 65 years has been derived from or validated in a residential cohort. Indeed, in most studies data were collected in few normal resting subjects,[1] which leaves a major range of heart rate insufficiently addressed. This may explain, at least in part, why interest in QT has waxed and waned historically among cardiologists.[13,18–21] Even so, corrected QT (QTc), derived from Bazett's formula[4] by dividing the measured QT by the square root of the measured RR, has been reported to predict the onset of life-threatening arrhythmias for values exceeding 440 units in disparate clinical situations.[1,20–23]

The methods required to measure QT interval have been fully detailed,[18,21,24–27] but the best method for correcting the meticulously measured QT for cardiac cycle length, with either curvilinear or linear formulas, remains a crucial and not completely solved problem.[1,16,17,22,26] Yet the best fit to data in the field of human QT–RR relation has been examined only occasionally, and then incompletely.[13,16,19,28]

We compared four previously proposed formulas (square root, cubic root, logarithmic, and linear)[3,4,8,11] relative to four closely related formulas,[16,29] to a more recently described exponential equation,[16] and to a formula derived from equations for the conservation of energy for the heart as a pump and the first law of thermodynamics,[17] to characterize human QT–RR relation under resting conditions in middle-aged men. We believed that the results might provide an accurate

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method for obtaining heart rate-corrected QT. Such a method would be applicable in the field of QT-driven pacemakers[1,16] and might improve our ability to predict sudden death, using QT interval calculations, in clinical practice.[1,20–23]

MATERIALS AND METHODS

The Seven Countries Study is an ongoing longitudinal investigation on natural history, epidemiology, and etiology of adult cardiovascular diseases in seven countries, including Italy.[30,31]

The cohort used in this study involves men from Crevalcore, an agricultural district near Bologna. In 1960, there were about 12,000 inhabitants in that area; the entry data include 98.12% (993 of 1,012) of all men then 40–59 years old.[30] The data collected included a resting 12-lead ECG, recorded using the standard methods adopted and described by the Research Group on Epidemiology of Heart Disease.[32] In 1962, an interim study was carried out, with the aim of determining the willingness of the initial study population to participate in follow-up visits, eight-hundred eighty-one men (88.72% of those seen in 1960) were examined and form the study group for this report.

ECG Analysis

Resting supine 12-lead ECGs were recorded on a three-channel inkjet electrocardiograph (Siemens-Elema B31) at 25 mm/sec paper speed. Calibration (10 mm = 1 mV) was performed before the ECG was recorded in any subject. Paper speed was controlled every 25th ECG. One observer coded all ECGs according to the Minnesota code,[33] a reference method developed mainly for epidemiologic purposes and aimed at a standardized and analytic description of ECGs based principally on measurements.

The QT and RR intervals were measured (in msec) in lead 2 by a second observer. The measurements were made manually, with the aid of a caliper and a magnifying device with a grid,[33] from the beginning of the QRS complex to the end of the T wave, where its terminal limb joined the baseline. Intervals preceded by premature beats were not measured, nor were U waves in the QT intervals included.[18] To avoid respiratory influences, we used three to five nonconsecutive QRST complexes to derive average data for both QT and RR intervals, although minimal complex-to-complex variability of both QT and RR intervals might be appreciated. In the presence of atrial fibrillation, 10 nonconsecutive QRST complexes were considered. The measurements were taken to the nearest 0.50 mm (20 msec).

Data Analysis

The QT–RR data from each subject were fitted separately using the following 10 formulas (F1–F10) by means of an IBM 4341 computer using BMDP statistical programs[26]:

$$QT = A1 \cdot \sqrt{RR} \quad (F1)$$

$$QT = A2 \cdot \sqrt{RR} + B2 \quad (F2)$$

$$QT = A3 \cdot \sqrt[3]{RR} \quad (F3)$$

$$QT = A4 \cdot \sqrt[3]{RR} + B4 \quad (F4)$$

$$QT = A5 \cdot \log(RR) \quad (F5)$$

$$QT = A6 \cdot \log(RR) + B6 \quad (F6)$$

$$QT = A7 \cdot RR \quad (F7)$$

$$QT = A8 \cdot RR + B8 \quad (F8)$$

$$QT = A9 + B9 \cdot \mathrm{Exp}(-k9 \cdot RR) \quad (F9)$$

$$QT = A10 + B10 \cdot (RR)^{-1} \quad (F10)$$

where A, B, and k are regression parameters. F1 is the square root Bazett's formula[4]; F3 is the cubic root Fridericia's formula[3]; F6 is the logarithmic Ashman's formula[11]; F8 is the linear formula originally proposed by Adams[9]; F9 is the exponential formula of Sarma et al.[16]; and F10 is the inverse Kovacs' formula.[17] F2, F4, F5, and F7 are related to F1, F3, F6, and F8, respectively, but differ by one parameter each. F1–F6 and F9 and F10 were fitted by nonlinear regression analysis, whereas linear regression analysis was used for F7 and F8.

The relative accuracy of fit to data by the 10 formulas was assessed[10] in two ways. (1) It was assessed from the mean-squared residual (MSR) values, which provide an appropriate and objective means of comparing formulas with differing numbers of observations, using the following equation:

$$MSR = RSS/(N - P) \quad (E1)$$

where RSS is the residual sum of squares, N is the number of observations, and P is the number of parameters in the formula used. The equation with minimum MSR is considered the best representation of a given plot of data, therefore no further statistical analysis is required. (2) It was assessed using the Akaike Information Criterion (AIC) to account for the differences in the number of parameters among the 10 formulas. Akaike[34] and Tanabe[35] defined AIC by the following equation, assuming that the random errors obey Gaussian distribution:

$$AIC = N \cdot \ln(RSS) + 2P \quad (E2)$$

where N is the number of observations, ln is the natural logarithm, RSS is the residual sum of squares, and P is the number of parameters in the formula used. AIC was derived in relation to the maximum likelihood estimation, which is essentially equivalent to estimating the parameters so as to minimize "Kullbach–Leiblers mean information."[34,35] Because the equation with minimum AIC is regarded as the best representation of a given plot of data, this statistical method is called

"minimum AIC estimation" (MAICE). When the RSSs are almost equal for different models, MAICE chooses the model with the smaller number of parameters, according to the principle of parsimony. Therefore, the level of significance and the F table are not required when using MAICE. AIC is also directly related to the number of observations, N; therefore, AICs from groups with different numbers of observations may not be compared. Thus in this study, we used AIC to assess only the relative intragroup accuracy of fit in the QT–RR relation by different formulas.

Accuracy and Repeatability of QT and RR Measurements

Because inspection of the data (Figs. 1, 2) indicates that most of the measurements are multiples of 20 msec, suggesting that there might have been a systematic error in the measurements, we attempted to check the accuracy of these measurements. To this end, we assessed the relative accuracy of fit to data by the 10 formulas on all grouped 881 subjects, based on the methods delineated above. After selecting the "best" fit between QT and RR, we performed a separate MSR analysis on quartiles of the entire population.

To check intraobserver variability,[27] we made duplicate measurements of QT and RR intervals in 25 selected (nonrandom) ECGs. We used the same series to appreciate interobserver variability in selected ECGs. In addition, a third observer measured both QT and RR intervals on all 881 ECGs as a routine part of another study, during which she was unaware of the results from the present investigation; this interobserver variability was also measured. Variability was computed by calculating the technical error (coefficient of variability) for duplicate QT or RR interval measurements with the formula[33]:

$$\sigma = \sqrt{\frac{\sum (X_1 - X_2)^2}{2n - 1}}$$

and expressed as a fraction of the mean from all duplicate observations.

RESULTS

Of the entire population of 881 men aged 42–61 years in 1962, 588 had a normal ECG (Minnesota code 1.0) (group 1) and 293 had an ECG with codable items (Minnesota codes different from 1.0) (group 2). Codable Q waves (code 1.1) were present in one subject. Complete left (code 7.1) or right (code 7.2) bundle branch blocks were observed in 3 and 21 subjects, respectively. Frequent ventricular premature beats (10% or more of record complexes) (code 8.1) were seen in eight subjects. Atrial fibrillation (code 8.3) was present in five subjects. The range of RR intervals was 540–1,180 msec (mean, 846 ± 127 msec; ie, 111–51 beats/min) in group 1 (Fig. 1) and 420–1,280 msec (mean, 812 ± 163 msec) (ie, 143–47 beats/min) in group 2 ($p < 0.002$, one-way analysis of variance) (Fig. 2). However, only nine subjects from group 2 (3.07%) had a resting heart rate greater than 110 beats/min, and two of these nine presented with atrial fibrillation. The range of QT intervals was 300–460 msec (mean, 383 ± 30 msec) in group 1 (Fig. 1) and 300–480 msec (mean, 388 ± 35 msec) in group 2 ($p < 0.05$, one-way analysis of variance) (Fig. 2).

The values of MSR, RSS, and AIC are shown in Table I and of the estimated regression parameters in Table II.

Regression fits by F6–F10 to QT–RR data are depicted in Figures 1 and 2 for groups 1 and 2, respectively. The corresponding plots of residuals against RR interval are also shown in the figures. The data points in these figures are circles representative of a certain number of observations considered during the calculation process but not actually shown. The scatter of QT–RR data and the scatter of residuals against the independent variable RR are greater in group 2 than in group 1. Accordingly, the mean-squared residuals from group 2 are greater than those calculated in group 1, by all formulas.

It is noteworthy that in both groups approximately equivalent QT predictions are reached by either complex multiparameter formulas (Figs. 1, 2),[8,11,15,17,29] including the logarithmic formula of Ashman,[11] the exponential formula of Sarma et al.,[16] and the inverse formula of Kovacs,[17] or the simpler one-parameter cubic root equation of Fridericia.[3] Indeed, with the above-mentioned QT prediction formulas, the residuals against the independent variable RR are randomly distributed about the zero line. In contrast, the other one-parameter equations do not provide accurate predictions. In particular, Bazett's formula,[4] especially in group 2, overcorrects QT interval at high heart rates (positive residuals at short RR intervals) and undercorrects it at low heart rates (negative residuals at long RR intervals).

The MSR and AIC analyses performed on all grouped 881 individuals confirmed these results. All two-parameter equations performed well (MSR: 613, 612, 634, and 617 for F2, F4, F6, and F8, respectively), similar to more complex formulas (MSR: 614 and 617 for F9 and F10, respectively). On the other hand, one-parameter equations provided a less accurate fit to the data (MSR: 764, 779, and 2557 for F1, F5, and F7, respectively), with the notable exception of Fridericia's equation (F3), which provided the best fit

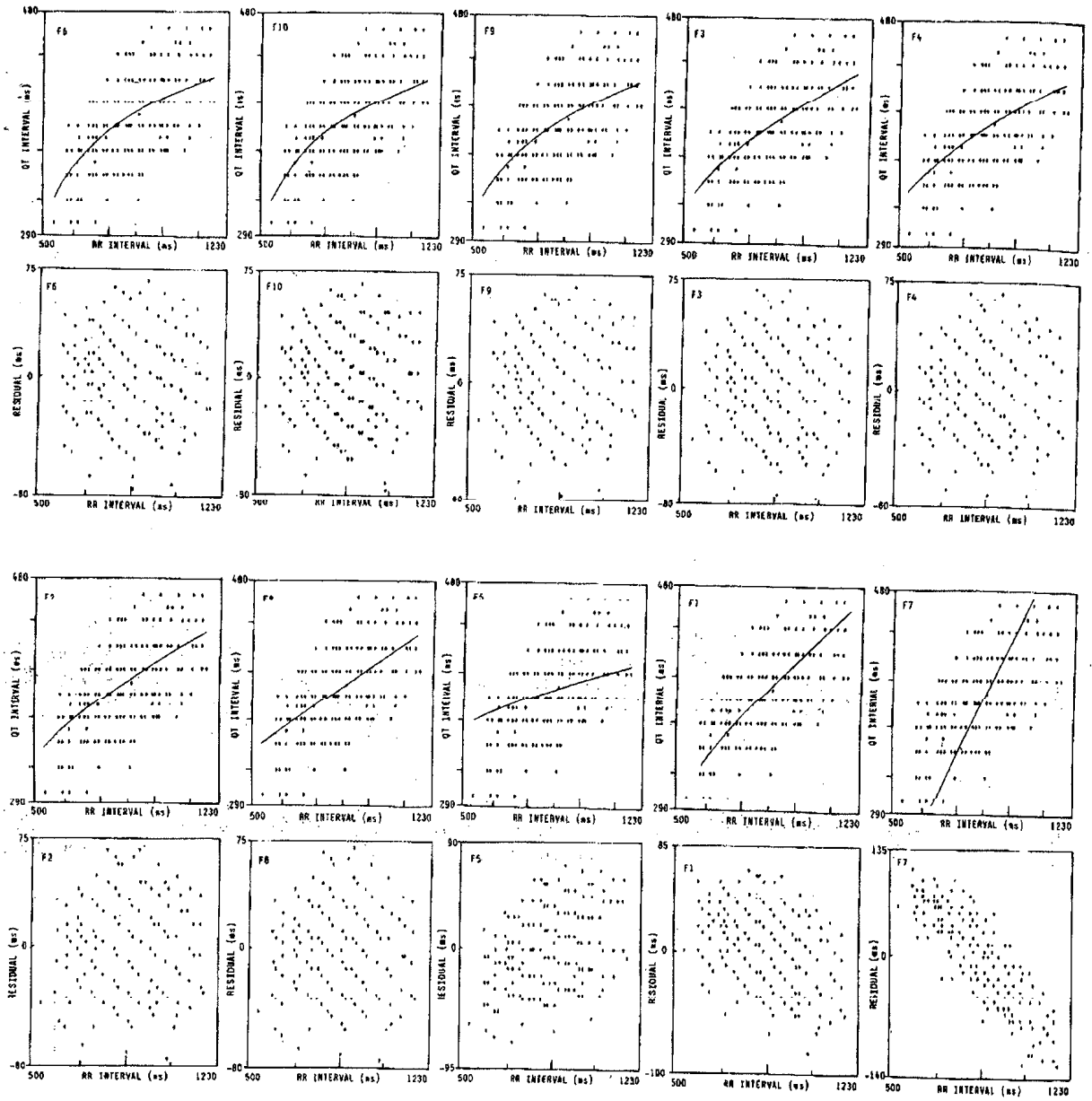

Fig. 1. Pooled QT–RR plots for all group 1 subjects (rows 1 and 3). The least-squared fit of data points are shown for formulas 1–10 (F1–F10), ranked left to right from best to worst, using the results shown in Table I. The residuals corresponding to the same least-squared curves are plotted in rows 2 and 4. Note the differences in the Y axis scales and the apparent dependence of residuals on RR intervals of the plots of residuals corresponding to the last three formulas.

(MSR: 614) also relative to F9 (AIC: 3516 and 3520 for F3 and F9, respectively).

The accuracy of QT relative to RR measurements was therefore assessed assuming Fridericia's equation[3] provided the best fit. Four quartiles of the population were formed based on RR data: 420–720 msec (n = 218), 740–820 msec (n = 221), 840–920 msec (n = 228), and 940–1,280 msec (n = 214). The MSRs were, respectively: 553, 609, 584, and 692. Since the numerical composition of quartiles was similar, this might be interpreted as providing some evidence of independency of QT interval measurement accuracy from RR interval with the Fridericia's equation.

The technical error (coefficient of variability) for duplicate QT and RR measurements was, respectively: 4.77% (±18 msec) and 1.64% (±14 msec), intraindividually (2n = 50); and 6.86%

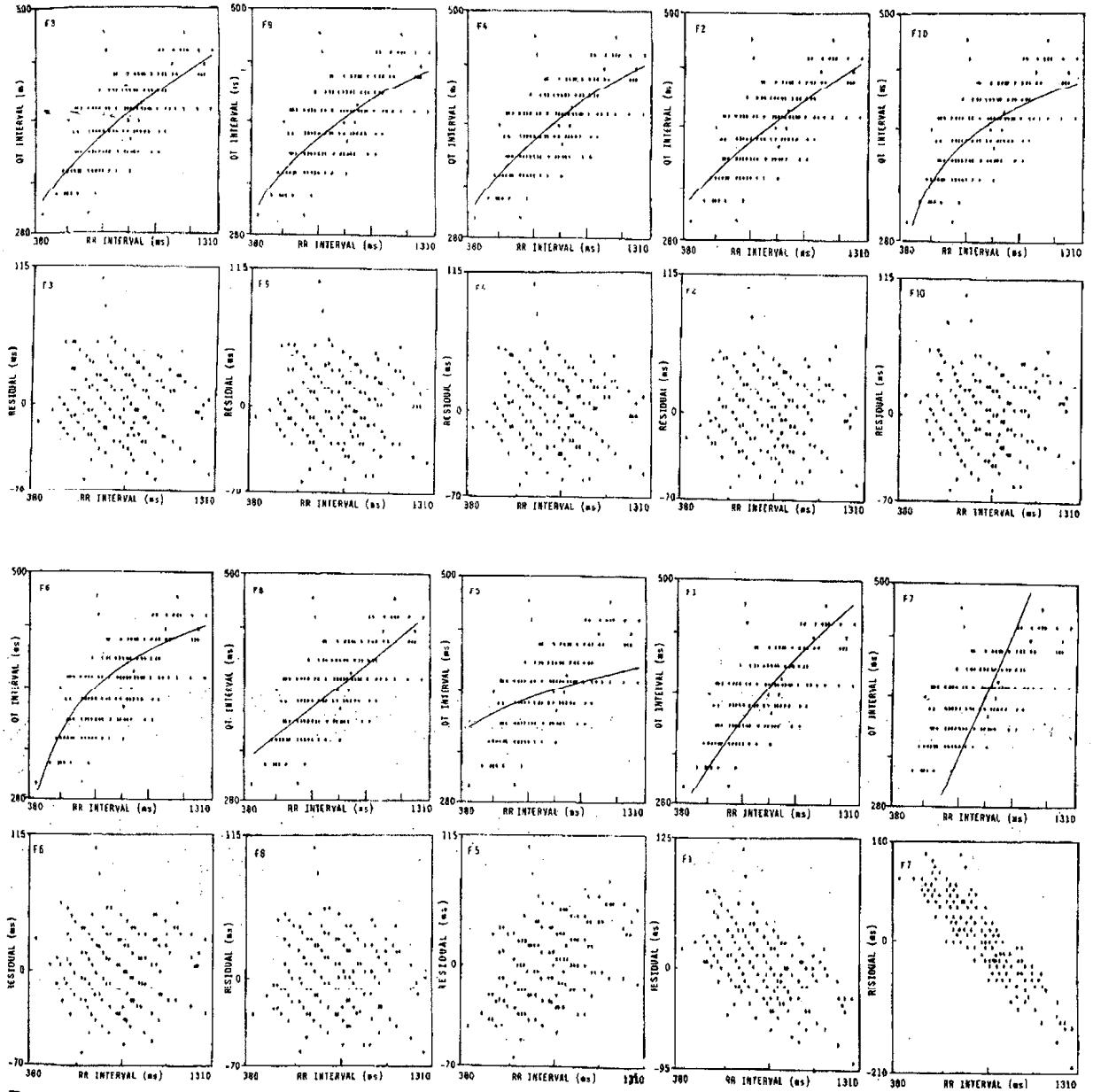

Fig. 2. Pooled QT–RR plots for all group 2 subjects (rows 1 and 3). The least-squared fit of data points are shown for formulas 1–10 (F1–F10), ranked left to right from best to worst, using the results shown in Table I. The plots of residuals corresponding to the same least-squared curves are shown in rows 2 and 4. Note the differences in Y axis scales of the last two plots and the apparent dependence of residuals on RR intervals of the plots of residuals corresponding to the last three formulas.

(±25 msec) and 2.34% (±20 msec) (2n = 50) and 8.90% (±34 msec) and 2.66% (±22 msec) inter-individually (2n = 1,762).

DISCUSSION

This investigation is the first to examine the relative accuracy of fit to QT–RR data by several QT prediction formulas in a residential cohort of middle-aged men. In contrast to previous reports,[2–16] we observed a wider range (47–143 beats/min) of resting heart rate. Since a potentially important application of this investigation relates to the use of QT prediction formulas in subjects at risk for life-threatening arrhythmias,[1,19–23,26] we used the Minnesota code[33] to subdivide the total cohort into subjects with normal (group 1) or abnormal (group 2) ECG. In ad-

TABLE I
Mean-squared Residuals, Residual Sums of Squares, and Akaike Information Criterion Values in 881 Men Aged 42–61 Years

	Group 1 (N = 588)			Group 2 (N = 293)		
No. of Parameters	**MSR**	**RSS**	**AIC**	**MSR**	**RSS**	**AIC**
Direct relation between QT and RR ($QT \propto \beta RR$)						
1						
F1	681	399,719	7,586	822	239,996	3,632
F3	565	331,962	7,477	634	185,092	3,556
F5	653	383,099	7,561	818	238,778	3,630
F7	2,094	1,229,170	8,247	3,325	970,968	4,041
2						
F2	566	331,814	7,479	638	185,583	3,558
F4	565	331,149	7,478	636	184,952	3,557
F6	560	328,453	7,473	641	186,393	3,560
F8	570	334,266	7,483	648	188,464	3,563
3						
F9	562	329,000	7,476	635	184,254	3,558
Inverse relation between QT and RR ($QT \propto \beta(RR)^{-1}$)						
2						
F10	561	328,703	7,473	640	186,162	3,559

F1, square root Bazett's formula[4]; F2, corrected square root formula [26]; F3, cubic root Fridericia's formula[3]; F4, corrected cubic root formula[26]; F5, logarithmic one-parameter formula[26]; F6, logarithmic Ashman's formula[11]; F7, linear one-parameter formula[26]; F8, linear Adam's formula,[8]; F9, exponential Sarma's formula[16]; F10, inverse Kovacs' formula.[17]

TABLE II
Regression Parameters (± Asymptotic Standard Deviation) Estimated Using the 10 Formulas in 881 Men Aged 42–61 Years

No. of Parameters	**Group 1 (N = 588)**	**Group 2 (N = 293)**
Direct relation between QT and RR ($QT \propto \beta RR$)		
1		
A1	13.18 ± 0.03	13.64 ± 0.05
A3	40.62 ± 0.10	41.78 ± 0.15
A5	131.23 ± 0.36	133.95 ± 0.57
A7	0.44 ± 0.002	0.46 ± 0.004
2		
A2	8.27 ± 0.45	8.88 ± 0.51
B2	143.42 ± 13.09	136.31 ± 14.75
A4	38.14 ± 2.07	40.67 ± 2.36
B4	23.46 ± 19.56	10.32 ± 22
A6	144.71 ± 1.07	147.08 ± 1.15
B6	−383.33 ± 7.96	−345.92 ± 7.54
A8	0.14 ± 0.007	0.15 ± 0.009
B8	263.63 ± 6.65	262.9 ± 7.56
3		
A9	445.79 ± 20.04	495.57 ± 42.41
B9	−431.84 ± 126.29	−352.38 ± 30.84
k9	0.0023 ± 0.0007	0.0014 ± 0.0005
Inverse relation between QT and RR ($QT \propto \beta(RR)^{-1}$)		
2		
A10	501.72 ± 6.45	510.58 ± 7.31
B10	−98,063.19 ± 5,271.22	−95,447.97 ± 5,582.06

Parameters A, B, and k refer to formulas 1–10 (see Table I), respectively (measurements in msec).

dition, we justified the latter subdivision to derive information applicable in the field of QT-driven pacemakers,[1,16] a device used in subjects who often present with an ECG abnormality.

A better fit to QT–RR data by all formulas was seen in group 1. This may be accounted for by the composition of the groups and by the larger range of RR intervals in group 2. Yet there is evidence that QT prediction equations may be used also in presence of ECG abnormalities. Moreover, it appears that among one-parameter equations, in both groups 1 and 2, the cubic root Fridericia's formula[3] provides the best fit to the QT–RR relation, whereas the logarithmic and the square root Bazett's[4] formulas provided the poorest fit and the straight-line formula is unsuitable. In addition, the fit provided by Fridericia's formula compares favorably with multiparameter equations[8,11,16,17] and in both groups is not improved by a second regression parameter as occurs for the square root, logarithmic, and straight-line one-parameter formulas. Finally, in group 2 the best fit is provided by Fridericia's equation.

It has been pointed out[17] that the commonly cited formulas[3,4,8,11,14–16] for predicting human QT duration have not been derived from basic principles, that rather they result from the approximate fit of an arbitrarily selected algebraic function to a set of data with wide scatter. However, the results from this study suggest that the relation between QT and RR interval is better expressed, in middle-aged men, by the simpler one-parameter cubic root formula derived empirically from 50 normal subjects by Fridericia as early as 1920[3] and almost ignored thereafter.[9,18] This conclusion is not coincidental: the robustness of the statistical method used[16,29] permitted an objective, comparative, and exhaustive analysis, which emphasizes that more sophisticated QT prediction equations are no more accurate.[11,16,17] Nevertheless, no more than one couple of points from a single individual was obtained to derive the QT–RR relation in this study. Therefore caution must be used in interpreting these conclusions or adapting them to different populations.

For example it may be that if QT–RR interval relationships were determined for individual subjects, using multiparameter formulas, many different slopes would be obtained intraindividually.[16] Although these slopes might reside within the scatter of the data described here, it is important to stress that the overall (interindividual) slope may not apply to any single subject. Clearly, further study is needed to clarify these issues.

QT Interval

In most studies, QT and RR intervals have been measured in lead II,[1,4,26] and Lepeschkin[18] has stated that the QT duration is longest in lead II. However, using multiple measurements in four different leads (LI, LII, V_1, and V_6), Ahnve observed that the longest QT interval is not always in lead II.[36] On the other hand, Wanderman et al.,[37] using multiple simultaneous recordings, showed that analysis of time intervals based on mean values in large groups of subjects is little affected by electrocardiographic lead choice. Therefore, the data presented here are from a single lead. We chose lead II to facilitate comparison with most of the previous studies that either assess the accuracy of fit to QT–RR data by various formulas[8,13,19] or provide evidence for QT interval as a risk index for life-threatening arrhythmias.[1,20–23,26]

Although it may be preferable to measure QT and RR intervals at 50[24,27] or 100[16] mm/sec paper speed, most available data on QT–RR relation were obtained from 25 mm/sec tracings.[1] The ECGs from this investigation were recorded in 1962 for epidemiologic purposes, and we had no choice but to use the available records. We tried to improve the readability of 25-mm/sec ECG tracings by using a magnifying device with a grid, to permit measurement to the nearest 0.25 mm (10 msec), but it was more practical to round up to the nearest 0.50 mm (20 msec). Although this may have introduced a systematic error in the data collection, we stress that only one observer was responsible for QT and RR measurements. Indeed, the intrareader variability in QT interval measurements is similar to that in previous reports using 25-mm/sec ECG recordings,[27] and the measurement accuracy seems not to be influenced by heart rate over a large range. Nevertheless, it may be worth repeating this study on new high-quality, high-speed ECG records from other residential cohorts. It might also be of interest to retrieve the existing data of digitized ECGs from the Seven Countries Study and record them on paper at high speed, to determine whether the measurement accuracy of QT interval could be improved and the present results confirmed.

The QT–RR Relation

During the past 65 years, both curvilinear and linear relations have been proposed to fit QT–RR data.[3–18] Most of these relations were derived from selected and generally scanty groups of normal subjects.[1,26] In 1920, Bazett derived, from

only 20 men,[4] an empirical equation where QT = K $\sqrt{RR}$, later used[1,17,18,21,22] to correct measured QT for cycle length in individual cases, based on the assumption that corrected QT = measured QT/$\sqrt{\text{measured RR}}$. Thus Bazett's correction has remained the most frequently used method to derive heart rate corrected QT (QTc).[1,18,22] Even so, Adams, in 1936, found that the QT duration (in seconds) from 50 presumably normal men might be accurately predicted by the formula QT = 0.1536(RR) + 0.2462.[8] However, no statistical analysis supported Adams' conclusion that this straight-line formula better fits the data than curvilinear equations.[8] Later, use of the Bazett's formula was recommended by Hegglin and Holtzmann, based on 700 normal subjects of both sexes,[9] and by Lepeschkin, based on his compiled data from about 5,000 cases from the literature and his own 1,100 cases.[18] In contrast, Fridericia's cubic root formula, also proposed in 1920 from a scanty series of 50 subjects, was considered less suitable for correcting measured QT interval by the same authorities who recommended use of Bazett's formula.[9,18]

Beginning in 1962, Bazett's formula has been criticized.[13,26,28,38–43] In particular, it has been stressed that the square root formula overcorrects the measured QT interval at high heart rates and undercorrects it at low heart rates.[26,28,39,43] Indeed, as shown in the plots of residuals from groups 1 and 2 (Figs. 1, 2), Bazett's formula inaccurately predicts QT duration for a wide range of low and high heart rates. However, dealing with 160 acute myocardial infarction patients, Ahnve recently observed that Bazett's formula fits the relationship between QT interval and heart rate rather well[22]; although the reported range of heart rate appears to be relatively large, no statistical analysis is provided to support his contention.

The "Best" Fit for QT–RR

Finding the "best" empirical formula to fit a set of observations is generally difficult.[16,17] In the field of human QT–RR relation, there is a lack of studies dealing with either a residential cohort or multiple testing of mathematically different equations.[13,16,17,19,28,42,44]

From an analysis of ECGs recorded in 649 men aged 20–59 years, Simonson et al.[13] proposed, in 1962, a straight-line formula (QT duration in sec), where QT = 0.140 (RR) + 0.2423 + 0.0003 (age). In the range of heart rate of 56–115 beats/min, there was an agreement between upper (97.5%) and lower (2.5%) normal limits determined from the percentile distribution and predicted from linear regression equation. However, no extensive statistical analysis demonstrates the best fit for the proposed formula compared with the square root, logarithmic, or two other related formulas.[13]

The mathematical relationship between QT and RR intervals was studied in 1969 by Susmano et al.[19] in eight patients with complete AV block during cardiac pacing at multiple ventricular rates. The results suggest, within the range of heart rate of 35–130 beats/min, that expressing the QT interval as a linear, square root, cubic root, or logarithmic function of the RR interval will provide equivalently valid predictions. However, due to the large variations observed between individuals, no method is suggested to correct the QT duration for a given heart rate.[10]

Preliminary data to reevaluate the QT–heart rate relation were presented in 1983 by Hodges et al.[28] based on 607 normal men and women equally distributed across age decades from 20s to 80s. Compared with Bazett's equation, both linear and logarithmic regressions were shown to fit the QT–heart rate data better. However, for convenience the use of the linear model, where QT = 496 − 1.75 (heart rate), was proposed. The results obtained in this study are in keeping with the findings from the latter study.[28]

In 1983, Staniforth[42] investigated 547 sets of QT–RR data from 27 healthy young men. It was found from pooled data that with the subject in resting supine position, the square root formula gave an unsatisfactory correction for the QT interval following atropine and hyoscine, over a wide heart rate range. Givens that log QT = log K + n log RR,[42] the best n value was 0.35, which is very close to the cube root correction of Fridericia.[4] That there was an optimum value of n in a one-parameter correction formula was also seen[44] when plots of the mean-squared residuals were made for a range of values of n (0.1–0.7) for each subject. In this way, a set of parabolas was produced, with minima centering around 0.3. Although these studies[42,44] indicated that Fridericia's equation is more adequate than Bazett's correction, they failed to test comparatively more complex formulas and therefore need be considered important only for having called attention to the almost neglected cubic root correction.[9,13,18]

In 1984, Sarma et al.[16] analyzed data obtained from 16 disparate subjects who were either exercised on a stationary bicycle to a heart rate of 160 or 180 beats/min or paced until the ventricular rate was progressively increased to 130 beats/

min. They demonstrated that the QT–RR relation is better expressed by a newly proposed exponential formula than by Bazett's formula or two other closely related formulas. They also used an estimate of mean-squared residual values and the AIC,[34,35] as was done in this investigation, to assess the accuracy of fit to QT–RR data. With Bazett's and the exponential formulas in pooled data from sinus-driven subjects, they found values much like those reported here.[16] Although meticulous statistical analysis provided proof that an exponential equation is more suitable for representing the human QT–RR relation than is Bazett's formula,[16] which is in accordance with our results, these conclusions may not be generalized to logarithmic, cubic root, straight-line, or related formulas, which were not comparatively tested in that study.

More recently, Kovacs[17] presented a graphic comparison of the major algebraic classes of formulas (exclusive of exponential equations[16]) for the QT as a function of RR interval and showed the approximate overlap of all curves. In addition, to derive an expression for QT as a function of RR and thereby attempt to resolve the ambiguity among the disparate expressions for QT, Kovacs presented a thermodynamic and conservation of energy argument applied to the normal heart, where $QT \propto K'1 + K'2/RR$. However, the inverse RR dependence (denoted as $(RR)^{-1}$) is incorrectly claimed to be derived from the first principle. In fact, Kovacs' "derivation" is heavily dependent on the empirical relation between the systolic time interval QS_2 and QT,[15] as well as several other empirical assumptions,[17] and should therefore also be considered essentially empirical.[45] More important, no objective measurement is provided to support the author's contention that the inverse relation delineates the nature of the algebraic dependence of QT as a function of RR for the normal heart operating in the physiologic range, as opposed to several other formulas, including Fridericia's and Bazett's equations, therefore Kovacs' conclusion[17] must be regarded as a hypothesis, which is not confirmed by our results.

Implications

The results of this investigation in 881 men aged 42–61 years demonstrate that over a wide range of resting heart rate a better fit to QT–RR relation is achieved using Fridericia's one-parameter cubic root formula[8] than by the Bazett's square root formula.[4] The performance of the former formula is not improved by adding a second regression parameter and compares favorably with more complex formulas,[8,11,29] particularly with those recently proposed by Sarma et al.[16] and by Kovacs.[17] In addition, Fridericia's formula provides the best fit in subjects with any kind of ECG abnormality according to the Minnesota code.[33] These observations may have potentially useful implications, since the cubic root equation is simple and therefore potentially directly applicable for correcting single measurements.[42,44]

Application of the cubic root relation might be useful in the field of rate-adaptive pacemakers, because it may favor the development of a more compliant device.[1,16] Another potentially useful application of this investigation relates to the proposal to use heart rate-corrected QT (QTc) to predict life-threatening arrhythmias and sudden death.[1,20–23,26] For those purposes, it would be appropriate to use a formula whose performance has been successfully tested in a large residential cohort with age ranges related to high incidence rates of the index events. We suggest that Fridericia's simple cubic root equation might be compared with more complex multiparameter formulas or the popular and abundantly adopted Bazett's square root formula to determine whether prediction might be improved.

We have provided evidence that QT is overcorrected by Bazett's formula for a wide range of high heart rate. As a result, more cases may lie above the accepted limit of normalcy than with Fridericia's cubic root correction. This warrants further studies to compare the sensitivity, specificity, and predictive accuracy of these formulas in the prediction of life-threatening arrhythmias and sudden death, reevaluating accordingly the limit of normalcy for heart rate-corrected QT (QTc) duration in humans.

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50. REBOXETINE VS VENLAFAXINE IN THE TREATMENT OF SEVERE MAJOR DEPRESSION

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Approximately one-third of outpatients with major depressive disorder (MDD) meet the requirements for severe illness (symptom intensity, diagnostic subtype and/or degree of functional impairment) while patients receiving inpatient care are, by definition, more severely ill. The present study was conducted to assess the efficacy and tolerability of the selective norepinephrine reuptake inhibitor (selective NRI) reboxetine in the treatment of adults with severe MDD compared with venlafaxine.

Adult patients (18-65 years) with a confirmed diagnosis of MDD were randomized to receive either reboxetine (8-10 mg/day) or venlafaxine (225-375 mg/day) for up to 8 weeks in this double-blind, parallel group trial. Only patients with severe symptomatology as defined by a HAM-D 17-item total score ≥25 points were included in the study. Clinical efficacy was assessed at weekly intervals using the HAM-D 17-item rating scale. Secondary measures included the Clinical Global Impression Severity (CGI-S) and Improvement (CGI-I) scales and the Social Adaptation Self-evaluation Scale (SASS). Response to treatment was defined as a ≥50% decrease in the HAM-D 17-item total score and remission was defined as a HAM-D 17-item total score of ≤8 points. Adverse events were recorded by direct observation and spontaneous reporting.

The mean HAM-D 17-item total score decreased markedly from baseline to Week 8 in both treatment groups (reboxetine 28.6 ±3.1 to 13.4 ±8.1; venlafaxine 28.8 ±2.8 to 12.2 ±7.7). After 8 weeks of treatment 56% of patients treated with reboxetine were classed as responders compared with 54% of patients in the venlafaxine group. Twenty-four per cent of patients in each treatment group were classed as being in remission after 8 weeks of treatment. A week-by-week analysis of remission rates revealed that by Week 4, a markedly greater proportion of patients treated with reboxetine achieved symptomatic remission compared with those in the venlafaxine group, although by Week 8 remission rates were comparable. Marked improvements were also seen on the secondary efficacy measures.

The results of the present study demonstrate that reboxetine 8-10 mg/day is as effective as venlafaxine 225-375 mg/day in the treatment of severe MDD in adults and is well tolerated.

51. DIVALPROEX VERSUS PLACEBO FOR THE TREATMENT OF BIPOLAR DEPRESSION

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Objective: This pilot study sought to evaluate the use of divalproex as treatment for acute bipolar depression.

Methods: A double-blind, multi-center, parallel-group, placebo-controlled trial was carried out as a pilot study of the effect of divalproex on the treatment of acute bipolar depression. Eligible subjects met DSM-IV criteria for bipolar disorder, Types I or II, and criteria for current major depression. A single-blind, placebo lead-in phase lasting up to 14 days was followed by an 8-week double-blind treatment phase and then an open-treatment phase of up to 8 weeks. During the double-blind treatment phase, study drug was initiated at 250 mg QHS and was titrated over a two week period based on safety and efficacy. The primary efficacy measure was recovery, which was defined as the absence of hypomania (YMRS<10) with ≥50% improvement on the HAM-D (26 item). Secondary efficacy measures included mean change from baseline in the HAM-D and YMRS.

Results: A total of 45 subjects were randomized in the double-blind phase of the trial. The mean maximum daily dose of divalproex was 1391 mg. In the intent-to-treat analysis of 43 subjects, 9 of 21 subjects (43%) treated with divalproex met criteria for recovery at the final assessment compared to 6 of 22 subjects (27%) treated with placebo ($p<0.4$). The divalproex-treated subjects had an improvement in the HAM-D depressed mood item that was numerically superior to placebo at every follow-up assessment and this difference reached statistical significance on weeks two, four and five (all p-values <0.05). Among those subjects with bipolar II disorder, 4 of 9 subjects (44%) treated with divalproex and 2 of 9 subjects (22%) treated with placebo met criteria for recovery ($p<0.7$). No statistically significant difference between groups was observed in the incidence or severity of adverse events.

Discussion: The findings of this pilot study are encouraging, although the results from planned analyses did not reach statistical significance. In this study, divalproex-treated subjects were almost twice as likely to meet the recovery criteria than placebo-treated subjects. Improvement found in the depressed mood item score is consistent with specific antidepressant activity, which is of interest given the increased risk of manic episode onset or cycle acceleration that may be associated with standard antidepressants. Results from this small pilot study should be interpreted with caution. A larger, multi-center, placebo-controlled study is required to confirm these data. A power analysis indicates that a sample size of 151 subjects in each group (alpha=0.05, power 0.80) would be required to confirm this difference of improved rate of recovery in the divalproex-treated subjects (43%) versus placebo-treated subjects (27%).

Quetiapine Alone and Added to a Mood Stabilizer for Serious Mood Disorders

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Background: Use of antipsychotic medication intermittently or over the long term may be necessary in treating patients with bipolar disorder whose symptoms have responded suboptimally to standard mood-stabilizing agents. Quetiapine fumarate is an effective novel antipsychotic with mixed serotonergic (5-HT_2) and dopaminergic (D_2) activity. This is an open-label, 12-week prospective study to assess the efficacy and tolerability of quetiapine in the treatment of patients with bipolar and schizoaffective disorder who were suboptimally responsive to mood stabilizers alone.

Method: Participants in the study were inpatients or outpatients with a DSM-IV diagnosis of bipolar or schizoaffective disorder. Baseline psychopathology was evaluated with the Brief Psychiatric Rating Scale (BPRS), the Young Mania Rating Scale (YMRS), and the Hamilton Rating Scale for Depression (HAM-D). Involuntary movements were rated with the Simpson-Angus Neurologic Rating Scale. Quetiapine was added on an open-label basis and increased to optimum clinical dosage. Psychopathology and Abnormal Involuntary Movement Scale ratings were repeated weekly for the first 4 weeks and then again at weeks 8 and 12.

Results: Ten individuals with bipolar disorder and 10 with schizoaffective disorder received quetiapine therapy. Overall, patients improved, with significant improvement in BPRS ($p < .001$), YMRS ($p = .043$), and HAM-D scores ($p = .002$). Simpson-Angus score also significantly decreased ($p = .02$). Overall, quetiapine was well tolerated by patients in this group with serious mood disorders. The mean ± SD quetiapine dose was 202.9 ± 124.3 mg/day (range, 50–400 mg/day). Mean weight gain was 10.9 lb (4.9 kg).

Conclusion: Although limited by its small size, open-label design, and relative gender homogeneity, this study suggests that quetiapine therapy may be useful in the treatment of individuals with serious mood disorders who are suboptimally responsive to mood stabilizers alone. These preliminary findings should be explored in larger, controlled trials.

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Bipolar disorder is a major public health problem with significant morbidity and mortality.[1] In 1990, the economic burden of bipolar disorder in the United States was estimated to be $15.5 billion in diminished or lost productivity in work performance alone,[2] while approximately 11% of individuals with bipolar disorder die by suicide.[3] While 1 or more episodes of acute mood disorder are not generally associated with the personality deterioration that occurs in psychotic illnesses such as schizophrenia, many individuals with bipolar disorder experience persistent symptoms and poor outcome.[4] These patients often have severe impairment in functioning and frequent or long hospitalizations and many times require a complex medication regimen with multiple mood stabilizers. Use of antipsychotic medication intermittently or over the long term may also be necessary in treating patients whose symptoms have responded suboptimally to standard mood-stabilizing agents.[5,6] These patients are frequently maintained on chronic neuroleptic treatment,[7] and combining lithium with other medications, including anti-

psychotics, may provide greater prophylaxis in bipolar disorder.[8]

Individuals with schizoaffective disorder have a prominent affective component in addition to chronic psychosis and usually require maintenance antipsychotic medication along with psychotropic medication for affective symptoms. The use of chronic neuroleptic therapy in seriously ill mood disorder patients often creates additional new problems. These patients may be at greater risk of developing tardive dyskinesia (TD) compared with patients with schizophrenia,[9] and often experience other extrapyramidal adverse effects or central nervous system (CNS) side effects associated with conventional neuroleptics such as sedation. Mukherjee et al.[10] reported that up to 73% of patients meeting criteria for bipolar disorder remained on long-term neuroleptic treatment (average = 8.7 years), whereas the prevalence of TD in individuals with bipolar disorder has been reported to range from 19% to 44%.[11–13]

Quetiapine fumarate is an effective novel antipsychotic with mixed serotonergic (5-HT_2) and dopaminergic (D_2) activity.[14] Clinically, it appears to be generally well tolerated with a low extrapyramidal adverse effect profile.[15] Given the greater risk of neurologic adverse effects of patients with mood disorder compared with patients with schizophrenia, the novel antipsychotics may prove to be a particularly important therapy for individuals who have significant mood disorder and who require antipsychotic medication. This is an open-label, 12-week prospective study to assess efficacy and tolerability of quetiapine in the treatment of patients with serious mood disorders suboptimally responsive to mood stabilizers alone.

METHOD

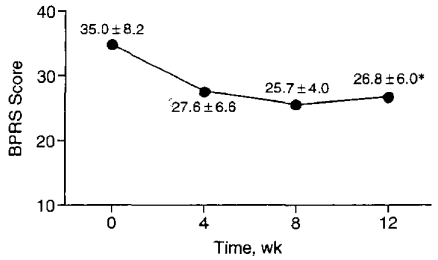
Eligible participants in the study were inpatients or outpatients with a DSM-IV[16] diagnosis of bipolar or schizoaffective disorder at a large, urban Veterans Affairs (VA) Medical Center. All participants had been taking an antipsychotic medication for at least 6 months with documented inability to wean off of neuroleptic treatment. Inability to successfully stop neuroleptic treatment was manifested by clinical worsening with neuroleptic reduction or discontinuation. Participants who were taking mood stabilizers must have been maintained on a stable and therapeutic dosage of the mood stabilizer (lithium or valproic acid). Individuals with significant or acutely worsening medical illness were excluded, as were individuals with significant alcohol or drug use within the previous 3 months. Baseline psychopathology was evaluated with the Brief Psychiatric Rating Scale (BPRS),[17] the Young Mania Rating Scale (YMRS),[18] and the Hamilton Rating Scale for Depression (HAM-D).[19] Involuntary movements were rated at baseline using the Abnormal Involuntary Movement Scale (AIMS)[20] and the Simpson-Angus Neurologic Rating Scale.[21] Subjective response to antipsychotic medication was rated with the Drug Attitude Inventory (DAI) developed by Awad.[22] Patients who agreed to study participation and met entry criteria were begun on quetiapine, 25 mg b.i.d., on an add-on, open-label basis. Quetiapine was increased as clinically tolerated to therapeutic dosage (possible range, 25–800 mg/day). Conventional antipsychotic medication was incrementally tapered and eventually discontinued as tolerated during the first 4 weeks of the study. This discontinuation was done at the discretion of the treating psychiatrist on the basis of patient clinical status. Patients were permitted to receive lorazepam, 1 mg orally p.r.n., for sleep or agitation and/or anticholinergic medications if required for acute extrapyramidal symptoms. No other new psychotropic drugs were permitted. Quetiapine therapy was continued for a total of 12 weeks. Psychopathology and abnormal involuntary movement ratings were repeated weekly for the first 4 weeks, then again at weeks 8 and 12 (end of study). Data were analyzed using paired t tests comparing baseline psychopathology and abnormal movement scores with endpoint scores. All endpoint scores utilized last observation carried forward (LOCF). This prospective protocol was approved by the local VA Institutional Review Board (Cleveland, Ohio), and appropriate written informed consent was obtained from all study participants.

RESULTS

Twenty individuals (10 with bipolar disorder and 10 with schizoaffective disorder) received quetiapine therapy. Mean ± SD age of the group was 47.8 ± 10.2 years (range, 34–74 years). Not surprisingly, this veteran sample was predominantly male, with 19 men and 1 woman. Racial composition of the group was 14 white individuals (70%) and 6 African American individuals (30%). There were no statistically significant differences between individuals with bipolar disorder and those with schizoaffective disorder in terms of demographic characteristics or baseline psychopathology rating scale scores or movement rating scale scores. Study participants generally had persistent mild-to-moderate psychotic and depressive symptoms at study entry that, by history, had not responded optimally to mood stabilizers alone. Five individuals were maintained on lithium treatment (mean ± SD dosage = 1125 ± 248.8 mg/day), and 8 individuals were maintained on valproate treatment (mean ± SD dosage = 1468.8 ± 471.3 mg/day). Mean ± SD serum levels were 82.0 ± 17.0 μg/mL for valproate and 0.74 ± 0.15 mEq/L for lithium. Seven individuals were not taking a mood stabilizer, and no individual was taking more than 1 mood stabilizer.

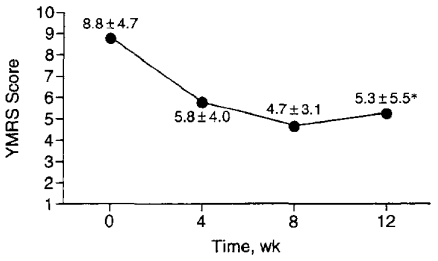
Overall, patients improved on quetiapine therapy, with significant improvement in BPRS score ($p < .001$), YMRS score ($p = .043$), and HAM-D score ($p = .002$). Figures 1 through 3 illustrate changes from baseline to

Figure 1. Brief Psychiatric Rating Scale (BPRS) Score (mean ± SD) for Patients With Serious Mood Disorders on Quetiapine Therapy[a]



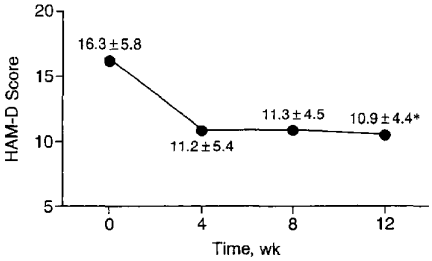
[a]All analyses used last-observation-carried-forward methodology.
*t = 1.7, df = 35, p < .001 vs. baseline.

Figure 2. Young Mania Rating Scale (YMRS) Score (mean ± SD) for Patients With Serious Mood Disorders on Quetiapine Therapy[a]



[a]All analyses used last-observation-carried-forward methodology.
*t = 1.7, df = 37, p = .043 vs. baseline.

Figure 3. Hamilton Rating Scale for Depression (HAM-D) Score (mean ± SD) for Patients With Serious Mood Disorders on Quetiapine Therapy[a]



[a]All analyses used last-observation-carried-forward methodology.
*t = 1.7, df = 35, p = .002 vs. baseline.

endpoint (using LOCF) on these psychopathology scales. There were no statistically significant differences between the bipolar and schizoaffective groups in response on any scale. There were also no significant differences in treatment response between individuals treated with quetiapine alone and individuals treated with quetiapine in combination with a mood stabilizer. Item analysis of the BPRS suggests that the items evaluating conceptual disorganization and suspiciousness changed the most, whereas the items evaluating guilt feelings, tension, hallucinatory behavior, uncooperativeness, excitement, and disorientation changed the least. However, comparing these items, the amount of change between items was not significant at a = .05. Mean ± SD Simpson-Angus scale score also significantly decreased from a baseline of 5.5 ± 4.9 to an endpoint score of 1.9 ± 3.8 (t = 1.7, df = 34, p = .02). There was no statistically significant change in AIMS score or in DAI score.

Overall, quetiapine was well tolerated by patients in this group with serious mood disorders. Three individuals dropped out within 1 week of beginning the study. These included 1 individual who began abusing alcohol within a few days after study initiation, 1 individual who was noncompliant with study medication, and 1 individual who reported the development of agitation, which resolved on quetiapine discontinuation. Mean ± SD quetiapine dose was 202.9 ± 124.3 mg/day (range, 50–400 mg/day) for the 17 individuals who completed the study and 178.8 ± 28.6 mg/day (range, 50–400 mg/day) for the entire sample. Mean ± SD weight gain over the course of the study was 10.9 ± 12.9 lb (4.9 ± 5.8 kg). Of note were 2 individuals who had nutrition/dietician consultation and follow-up at study entry. These 2 individuals had a small amount of weight loss (3 and 4 lb [1.4 and 1.8 kg], respectively) during the study course.

DISCUSSION

Long-term or intermittent use of antipsychotic medication may be deemed necessary for some individuals with serious mood disorders when mood or behavioral symptoms have not adequately responded to mood-stabilizer therapy.[5,7] In individuals with persistent mood symptoms and chronic psychosis, the combination of lithium and antipsychotics appears to be more efficacious than an antipsychotic alone.[23] However, the utilization of antipsychotic medication in individuals with chronic, serious mood disorders presents a number of clinical challenges. Some investigators have suggested that neuroleptics may exacerbate postmanic major depressive episodes and induce rapid cycling in some bipolar persons.[24] Additionally, individuals with primary mood disorders may be particularly vulnerable to the development of TD associated with neuroleptic therapy.[25] Other adverse effects, such as sedation, associated with some antipsychotic medications may reduce quality of life. Finally, suboptimal antipsychotic medication response may be associated with persistent behavioral symptoms and long-term functional impairment. The atypical antipsychotic clozapine has been reported to be beneficial, and may have mood-stabilizing

properties, in the treatment of patients with serious mood disorders.[26,27] A recently reported meta-analysis involving primarily retrospective and open-label studies of clozapine suggested that patients with manic or psychotic phases of schizoaffective or bipolar disorder were significantly more likely to respond to clozapine than patients with schizophrenia.[28] The atypical antipsychotic medication olanzapine has been demonstrated to be effective in acute mania,[29] and it has been reported that the atypical antipsychotic risperidone is as effective as lithium or haloperidol in the treatment of acute mania,[30] as well as being effective in adjunctive treatment with mood stabilizers for patients with bipolar and schizoaffective disorder.[31] Published data on the use of quetiapine therapy in serious mood disorders are extremely limited.

Although limited by its small size, open-label design, lack of a control group, and relative gender homogeneity, this study suggests that quetiapine may be a useful agent in the treatment of individuals with serious mood disorders who are suboptimally responsive to mood stabilizers alone. Overall, patients in the study sample did well on quetiapine therapy, with significant improvements in BPRS, YMRS, and HAM-D scores. Improvements were similarly noted by McConville et al.[32] in both positive and negative symptoms in 10 adolescents with psychotic mood disorders (3 individuals with bipolar disorders and 7 individuals with schizoaffective disorder). Most individuals in the study reported here had persistent depressive symptoms. HAM-D improvements were seen here without the addition of antidepressant medication. In a recent report on affective symptoms in individuals with schizophrenia,[33] quetiapine was superior to placebo and haloperidol in improvements in mood symptom items (depressive mood, guilt feelings, somatic concern, and anxiety) on the BPRS.

It must be noted that the results here at 4 weeks reflected a combined effect of quetiapine and neuroleptic, due to the fact that conventional neuroleptic was tapered over the first 4 weeks of the study. It is not clear how the presence of the neuroleptic might have affected dosage of and/or symptom response to the atypical antipsychotic. It is possible that combined therapy may have contributed to the relatively rapid symptom response and may possibly explain the relatively low mean quetiapine dosage in this study (approximately 200 mg/day). The modest quetiapine dosage might also have been due to the use of a concomitant mood stabilizer for most of the patients in this study or to the older age of some of the study participants. However, it is also possible that effective dose of quetiapine required in individuals with mood disorders may be lower than effective doses that have been reported for individuals with schizophrenia.[34] In clinical practice, combination therapy of an antipsychotic plus a mood stabilizer is frequently utilized in the management of serious mood disorders and may enhance clinical outcomes.[35]

Quetiapine was generally well tolerated in this study population, with only 1 dropout due to adverse effect of medication. This finding is consistent with safety and tolerability reports of quetiapine therapy suggesting that most patients, even the elderly, tolerate quetiapine quite well and that incidence of extrapyramidal effects is minimal.[36,37] Kalali et al.[38] reported on 129 patients who received quetiapine therapy and were assessed for patient satisfaction. The majority of individuals (98%) reported being satisfied with their medication treatment, most commonly identifying improved tolerability and improved general well-being compared with previous conventional antipsychotic agents. Quality of life was generally reported to be improved.

There was a mean weight gain of 10.9 lb (4.9 kg) in this trial. This greater-than-expected weight gain may be at least partially due to combined use of quetiapine plus mood-stabilizing medication, both of which may be associated with weight gain. Guille et al.[39] recently reported that individuals with bipolar disorder receiving mood-stabilizing medication plus atypical antipsychotic medication experience weight gain ranging from a mean of 16.1 lb (7.2 kg) with olanzapine to a mean of 7.8 lb (3.5 kg) with risperidone. Guille et al.[39] also reported a trend for less weight gain among patients receiving a novel antipsychotic with lithium than those receiving other mood-stabilizing agents ($p = .06$). Patients receiving prophylactic dietary consultation in the trial presented here did not gain weight.

In conclusion, quetiapine may be beneficial for some individuals with serious mood disorders. These preliminary findings should be explored in larger, controlled trials.

Drug names: clozapine (Clozaril and others), haloperidol (Haldol and others), lorazepam (Ativan and others), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperdal), valproic acid (Depakene and others).

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Efficacy of Quetiapine and Risperidone Against Depressive Symptoms in Outpatients With Psychosis

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Background: The treatment of psychotic symptoms in patients with mood disorders is a complex challenge. Antipsychotic medications in these individuals may be associated with extrapyramidal symptoms (EPS), worsening of depression, and functional impairment. Atypical antipsychotics such as quetiapine and risperidone are associated with a decreased incidence of adverse events such as EPS. The objective of this study was to compare the efficacy and tolerability of quetiapine and risperidone for the treatment of depressive symptoms in outpatients with psychosis.

Method: In this 4-month, multicenter, open-label trial, patients were randomly assigned in a 3:1 ratio of quetiapine to risperidone, and both drugs were flexibly dosed. Eligible patients had psychoses and demonstrated 1 of several DSM-IV diagnoses, including schizoaffective disorder, bipolar I disorder, major depressive disorder, delusional disorder, Alzheimer's dementia, schizophreniform disorder, vascular dementia, and substance abuse dementia. Patients were classified as mood disordered if they had bipolar disorder, major depressive disorder, or schizoaffective disorder. Efficacy was assessed using the Positive and Negative Syndrome Scale and the Clinical Global Impressions scale. The Hamilton Rating Scale for Depression (HAM-D) was used to assess the level of depressive symptoms. The primary tolerability assessment was presence or absence of substantial EPS, defined as EPS severe enough to require an alteration in treatment.

Results: A total of 554 patients were randomly assigned to quetiapine and 175 to risperidone. Mean doses at 16 weeks were 318 mg for quetiapine and 4.4 mg for risperidone. Although both agents produced improvements in mean HAM-D scores, quetiapine produced a greater improvement than risperidone in all patients ($p = .0015$). Within the mood-diagnosed population, incidences of both substantial EPS ($p = .001$) and at least moderate EPS ($p = .0373$) occurred significantly less frequently among patients taking quetiapine. For patients with non-mood diagnoses, incidences of substantial EPS were fewer for patients taking quetiapine than for those taking risperidone ($p = .062$); however, this was not statistically significant.

Conclusion: These results suggest that quetiapine may be a useful agent in the management of depressive symptoms in patients with psychosis.

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Depressive symptoms are common in patients with schizophrenia and may contribute to the 20-fold higher incidence of suicide in this population compared with the general population.[1] Affective disorders in patients with schizophrenia are generally associated with poor outcome, with an increased risk of relapse and a high rate of suicide.[1] In serious mood disorders, such as bipolar depression, the suicide rate is 30 times higher than that of the general population.[2] Thus, treatment of coexisting affective and psychotic symptoms is a complex clinical challenge.

Antipsychotics are commonly added to the treatment regimen for patients with psychotic mood disorders.[3,4] However, antipsychotic medications in these individuals may be associated with extrapyramidal symptoms (EPS), possible worsening of depression, and functional impairment.[5–7]

Recent evidence suggests that atypical antipsychotics may produce an antidepressant effect that could be beneficial in the treatment of depressive symptoms in patients with schizophrenia.[1,8] Compared with conventional antipsychotics, atypical antipsychotics may have superior efficacy for the treatment of schizophrenia with mood symptoms.[9] Additionally, preliminary evidence supports the usefulness of atypical antipsychotics in treating depressive symptoms associated with psychotic and depressive disorders.[10] Because atypical antipsychotics are associated with a decreased incidence of EPS,[11] these medications may have more overall advantages compared with typical antipsychotics.[9,12,13] Quetiapine, in particular,

appears to have low potential for EPS at all dosing ranges[14] and in all populations, including the elderly[15–17] and adolescents.[18]

Quetiapine and risperidone are 2 atypical antipsychotics currently used in the United States for the treatment of patients with schizophrenia and other psychotic disorders. The objective of the present study was to compare the efficacy and tolerability of quetiapine and risperidone for the treatment of depressive symptoms in outpatients with psychotic disorders. This is a subanalysis of data on mood symptoms from the quetiapine experience with safety and tolerability (QUEST) study. The results of the analysis of primary endpoints on psychosis, tolerability, and EPS from the QUEST study are described in another article.[19]

METHOD

Study Design

In this 4-month, multicenter, open-label trial, patients were randomly assigned in a 3:1 ratio of quetiapine to risperidone. Patients completed 7 office visits at weeks 0, 1, 2, 4, 8, 12, and 16.

Both quetiapine and risperidone were flexibly dosed. Patients randomly assigned to quetiapine began with a total daily dose of 50 mg, with upward titration in 50-mg to 100-mg increments every 1 to 2 days. The maximum dose of quetiapine was 800 mg/day.

Patients randomly assigned to risperidone began with 1 mg b.i.d. with increases in increments of 1 mg b.i.d. on days 2 and 3 as tolerated, to a target dose of 3 mg b.i.d. Further dose adjustments, if indicated, occurred at intervals of not less than 1 week.

For both drugs, investigators were instructed to adjust dosage to meet the clinical needs and response of individual patients. Investigators were also instructed to discontinue previous antipsychotic agents within 1 month of trial entry. Patients who failed to stabilize on either quetiapine or risperidone monotherapy were permitted to return to their original antipsychotics.

Patients

Patients were included if they had psychoses and 1 of the following DSM-IV[20] diagnoses: schizoaffective disorder, bipolar I disorder, major depressive disorder, delusional disorder, Alzheimer's dementia, schizophreniform disorder, vascular dementia, or substance abuse dementia. Diagnoses were made based on clinical interviews administered by site investigators. Other eligibility criteria included no evidence of medically significant disorders, no current treatment with clozapine or history of nonresponsiveness to clozapine, and no history of drug-induced agranulocytosis. Patients were classified as having a mood disorder if they had 1 of the following diagnoses: (1) bipolar disorder, (2) major depressive disorder, or (3) schizoaffective disorder. Patients with schizoaffective disorder were grouped with patients with mood disorders because their pharmacologic treatment was more like that of patients with bipolar disorder or psychotic major depressive disorder (i.e., mood medication plus antipsychotic medication) than that of patients with schizophrenia (i.e., usually antipsychotic monotherapy).

Concurrent Medications

Patients could receive concomitant medications that were deemed clinically indicated by the investigator. Another antipsychotic agent was to be prescribed only after attempts to stabilize the patient on quetiapine or risperidone monotherapy failed over a 1-month period. Long-acting injectable antipsychotics (haloperidol or fluphenazine) and clozapine or olanzapine were prohibited during the study period.

Patients who were taking prescribed mood stabilizers and antidepressants were allowed to continue with those medications if they had been on a stable dose for at least 2 weeks before randomization. Rescue medication (e.g., intramuscular haloperidol, benzodiazepines, or anti-EPS agents) for situations such as extreme agitation, acute psychosis, and EPS was permitted at the discretion of the investigator. EPS assessments were not completed within 24 hours after administration of rescue medication.

Efficacy Assessments

The Positive and Negative Syndrome Scale (PANSS)[21] and the Clinical Global Impressions (CGI) scale[22] were used to evaluate efficacy against psychotic symptoms. The Hamilton Rating Scale for Depression (HAM-D)[23] was used to assess the level of depressive symptoms at weeks 0, 8, and 16. The following HAM-D factors were assessed: factor 1—anxiety/somatization (anxiety psychic, anxiety somatic, somatic symptoms gastrointestinal, somatic symptoms general, hypochondriasis, and insight); factor 2—weight (loss of weight); factor 3—cognitive disturbance (feelings of guilt, suicide, agitation, depersonalization and derealization, paranoid symptoms, obsessive and compulsive symptoms); factor 4—diurnal variation (morning or afternoon severity); factor 5—retardation (depressed mood, work and activities retardation, genital symptoms); and factor 6—sleep disturbance (insomnia early, insomnia middle, and insomnia late).

Two domains on the HAM-D were also assessed: (1) vegetative symptoms (insomnia early, insomnia middle, insomnia late; retardation, agitation, anxiety somatic, somatic symptoms gastrointestinal, somatic symptoms general, genital symptoms, weight loss, diurnal variation present, diurnal variation severity) and (2) nonvegetative symptoms (depressed mood, guilt, suicide, work and activities, anxiety psychic, hypochondriasis, insight, depersonalization and derealization, paranoid symptoms, and obsessional and compulsive symptoms).

EPS Assessments

The primary assessment for tolerability was the presence or absence of EPS to a substantial degree. *Substantial EPS* is defined as requiring 1 or more of the following alterations in treatment: (1) prescription of an anti-EPS medication, (2) reduction in dose of randomized treatment, or (3) discontinuation of the randomized treatment. EPS event information was determined from a symptom checklist created by AstraZeneca (available from AstraZeneca upon request).

Statistical Analysis

The overall differences between treatment with quetiapine and treatment with risperidone in postbaseline last-observation-carried-forward (LOCF) HAM-D score were evaluated using an analysis of covariance (ANCOVA). Treatment differences over time according to diagnosis (mood versus non-mood disorders) were assessed using a repeated-measures ANCOVA. Treatment differences over time stratified by baseline HAM-D score (i.e., < 10, 10 to 19, and ≥ 20) were assessed using a repeated-measures ANCOVA within mood and non-mood diagnostic groups.

HAM-D factor scores were summarized with descriptive statistics. Differences in dose of quetiapine or risperidone at 4 months were analyzed using Dunnett's t test. Incidence of EPS was analyzed using generalized estimating equations and included maximum baseline EPS severity and time as covariate factors.

RESULTS

Patient Demographics

The characteristics of the patients randomly assigned to quetiapine (N = 554) or risperidone (N = 175) are shown in Table 1. Both groups of patients showed similar demographics with mean ages of 45 and 46 years for quetiapine and risperidone, respectively. No statistically significant differences between treatments were found for age, sex, or race. The male/female ratio was 50:50 for quetiapine and 54:46 for risperidone. Mood disorders were diagnosed in 316 (57%) of quetiapine patients and 103 (59%) of risperidone patients.

On study entry, 33.7% of patients were using mood stabilizers, 33.7% were taking antidepressants, 26.5% were taking anxiolytics (including benzodiazepines), 13.6% were taking atypical antipsychotics, and 36%, typical antipsychotics. No significant differences in the continuing use of prior medications were found between treatment groups (p = .17).

Dosing

The dosing of quetiapine over time for the different diagnostic groups is shown in Figure 1. The mean dose received by all the patients at week 16 was 318 mg; however, patients with schizophrenia used significantly more quetiapine at all time periods after 2 weeks than patients with mood disorders (p = .036). At 16 weeks, patients with bipolar disorder used less quetiapine (mean difference = −74 mg, p = .062) than patients with schizophrenia. At 16 weeks, patients with major depressive disorder or schizoaffective disorder used 54 mg and 28 mg, respectively, less than patients with schizophrenia; however, this was not statistically significant (p > .25).

Table 1. Demographic Details

Characteristic	Quetiapine Group (N = 554)	Risperidone Group (N = 175)
Age, mean, y	45.1	46.2
Race, N (%)		
White	402 (73)	131 (75)
African American	94 (17)	28 (16)
Other	58 (10)	16 (9)
Sex, N (%)		
Women	277 (50)	80 (46)
Men	277 (50)	95 (54)
Diagnosis, N (%)		
Bipolar disorder	83 (15)	20 (11)
Major depressive disorder	75 (14)	26 (15)
Schizoaffective disorder	158 (29)	57 (32)
Schizophrenia	218 (39)	67 (38)
All mood diagnoses	316 (57)	103 (59)
All non-mood diagnoses	238 (43)	72 (41)

The dosing of risperidone over time for the different diagnostic groups is shown in Figure 2. The mean dose received by all of the patients was 4.4 mg at week 16, and, as with quetiapine, patients with mood disorders required lower doses of risperidone than did patients with schizophrenia (p < .011).

Efficacy Against Psychotic Symptoms

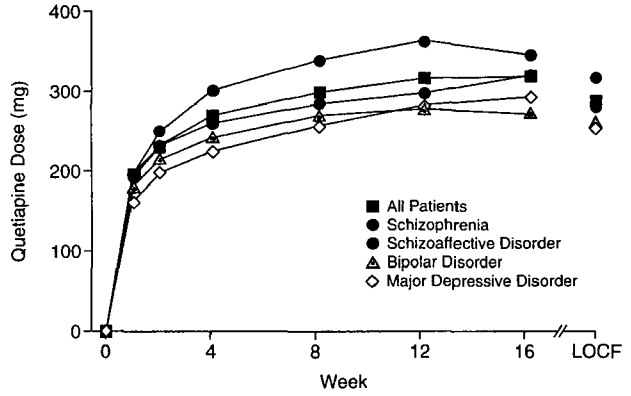
Efficacy against psychotic symptoms was assessed using the PANSS and the CGI. Both quetiapine and risperidone groups showed increasing improvement in clinical condition throughout the trial, according to CGI scores. At trial completion, no significant difference was seen between treatment groups on CGI scores or on PANSS positive scale, negative scale, or total score. These results are reported in full elsewhere.[19]

HAM-D Scores

There was no significant difference in baseline HAM-D scores between quetiapine- and risperidone-treated patients. The mean change from baseline to postbaseline observation in HAM-D score at week 16 (LOCF) was slightly greater (p = .028) in the quetiapine group than in the risperidone group (Figure 3).

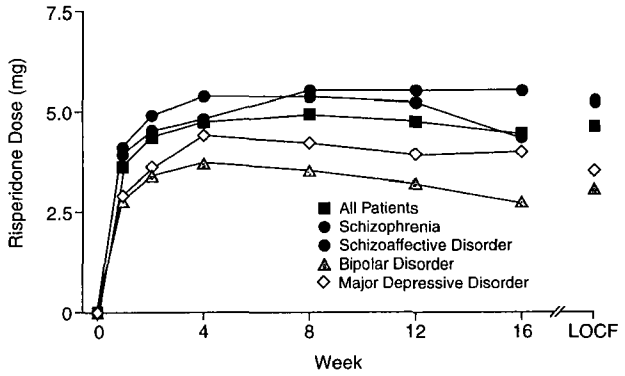
The percentages of changes from baseline for the different diagnostic groups are shown in Table 2. Quetiapine produced a greater improvement in HAM-D scores than did risperidone, both in patients with primary mood disorders and in patients with non-mood disorders.

Figure 1. Mean Quetiapine Dose by Diagnosis[a]



[a]Abbreviation: LOCF = last observation carried forward.

Figure 2. Mean Risperidone Dose by Diagnosis[a]



[a]Abbreviation: LOCF = last observation carried forward.

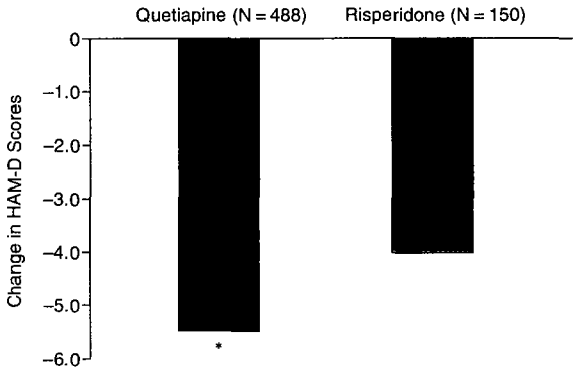
The changes in mean HAM-D scores for patients with and without mood disorders were examined with respect to baseline HAM-D score. In patients with mood disorders and a high baseline HAM-D score (≥ 20), quetiapine produced a significantly greater reduction in HAM-D score than risperidone (–47% vs. –34%, p = .0051, Figure 4A). For patients with mood disorders who had moderate HAM-D scores at baseline (scores of 10 to 19), both drugs were equally effective (–38% vs. –43%, p = .54). For patients with mood disorders who had low baseline HAM-D scores (< 10), neither drug produced a significant improvement or deterioration (–0.1% ± 16.1% vs. –15.2% ± 25.4%, p = .59, for quetiapine and risperidone, respectively).

The changes in HAM-D scores for non-mood disordered patients were similar to the changes seen in mood disordered patients (Figure 4B). For patients with non-mood disorders who had low or moderate baseline HAM-D scores (< 20), there were no significant differences in the improvements produced by quetiapine or risperidone. However, for patients with non-mood disorders and high baseline HAM-D scores (≥ 20), quetiapine produced a significantly greater reduction in mean HAM-D scores than risperidone (p = .008).

The mean changes from baseline for individual HAM-D factor scores are shown in Figure 5. The largest treatment differences (at least 5% of baseline) were in favor of quetiapine over risperidone—these were for HAM-D factors 4 (diurnal variation), 5 (retardation), and 6 (sleep disturbance) and in the vegetative symptom domain. Little difference between quetiapine and risperidone was observed for the HAM-D factors of anxiety/somatization, weight, and cognitive disturbance and in the nonvegetative domain items.

For the group as a whole, patients in the quetiapine group scored significantly better on the retardation, sleep disturbance, and vegetative domain items. Mood disordered patients on quetiapine scored significantly better on

Figure 3. Mean Change in HAM-D Scores for All Patients (baseline to postbaseline, last observation carried forward)[a]



[a]Abbreviation: HAM-D = Hamilton Rating Scale for Depression.
*p = .028.

retardation and vegetative domains. In patients diagnosed with non-mood disorders, and in patients with factor scores of 0 at baseline, differences were not statistically significant.

EPS Assessments

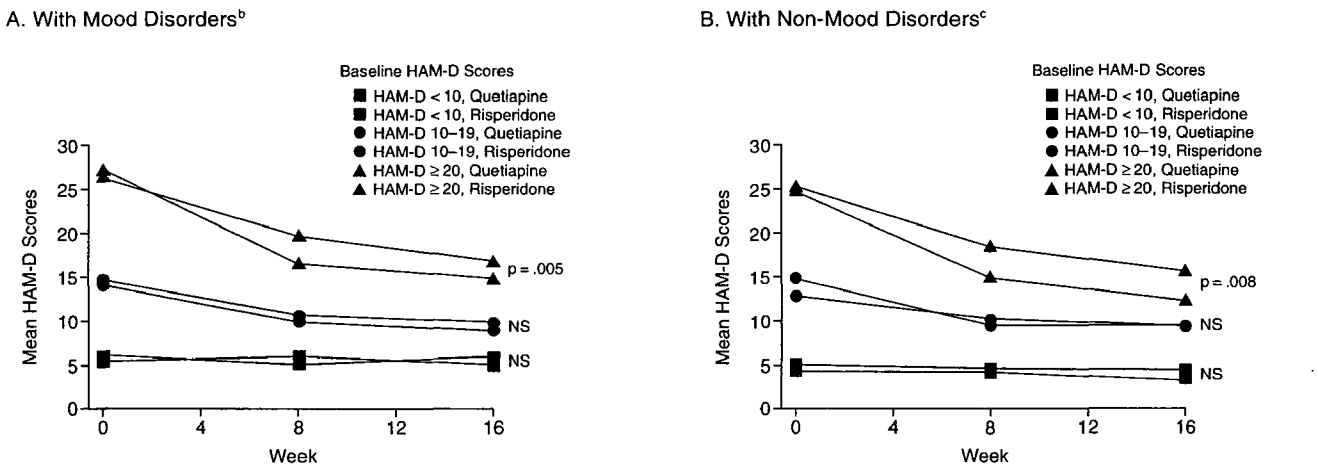
The safety and tolerability of quetiapine and risperidone were compared by examining the incidence of EPS to a substantial degree in the patients diagnosed with either mood disorders (Figure 6) or non-mood disorders. Over the trial period, substantial EPS occurred less frequently among quetiapine-treated patients in both the mood (p < .001) and non-mood (p = .063) diagnosed patients. More of the patients diagnosed with mood disorders and treated with risperidone reported substantial EPS at week 1 (8.3%) compared with the patients with mood disorders treated with quetiapine (1.4%). The incidence of substantial EPS at LOCF was also lower for patients treated with quetiapine (2.9%) compared with patients treated with risperidone (10.1%).

Table 2. Percentages of Change From Baseline HAM-D Scores[a]

Diagnosis	Quetiapine N	Quetiapine Mean Baseline Score	Quetiapine Change (%)	Risperidone N	Risperidone Mean Baseline Score	Risperidone Change (%)	p Value of Difference
All patients	554	15.50	–44.6	175	15.07	–34.4	.0015
All mood diagnoses	316	16.86	–44.1	103	16.58	–35.7	.0364
All non-mood diagnoses	238	13.71	–45.6	72	12.93	–31.1	.0083
Bipolar disorder	83	16.28	–50.4	20	14.60	–33.2	.0956
Major depressive disorder	75	19.11	–42.2	26	20.08	–39.7	.7100
Schizoaffective disorder	158	16.10	–41.6	57	15.74	–34.6	.2149
Schizophrenia	218	13.46	–41.6	67	13.16	–31.4	.0694
Other non-mood[b]	20	16.45	–65.4	5	9.80	–31.1	.0447

[a]Repeated-measures analysis of 2- and 4-month results. Abbreviation: HAM-D = Hamilton Rating Scale for Depression.
[b]A p value is not reliable for this small number of patients with varying diagnoses, including Alzheimer's dementia, delusional disorder, and substance abuse dementia.

Figure 4. Mean HAM-D Scores for Patients With Psychosis From Baseline to Week 16 for Quetiapine and Risperidone[a]



[a]Abbreviations: HAM-D = Hamilton Rating Scale for Depression, NS = nonsignificant.
[b]Mood diagnoses include bipolar disorder, major depressive disorder, and schizoaffective disorder.
[c]Non-mood diagnoses include delusional disorder, Alzheimer's dementia, schizophreniform disorder, vascular dementia, and substance abuse dementia.

In patients diagnosed with mood disorders, the incidence of substantial EPS and at least moderate EPS was significantly less frequent in patients taking quetiapine than in patients taking risperidone ($p < .001$ for substantial EPS, $p = .037$ for moderate EPS).

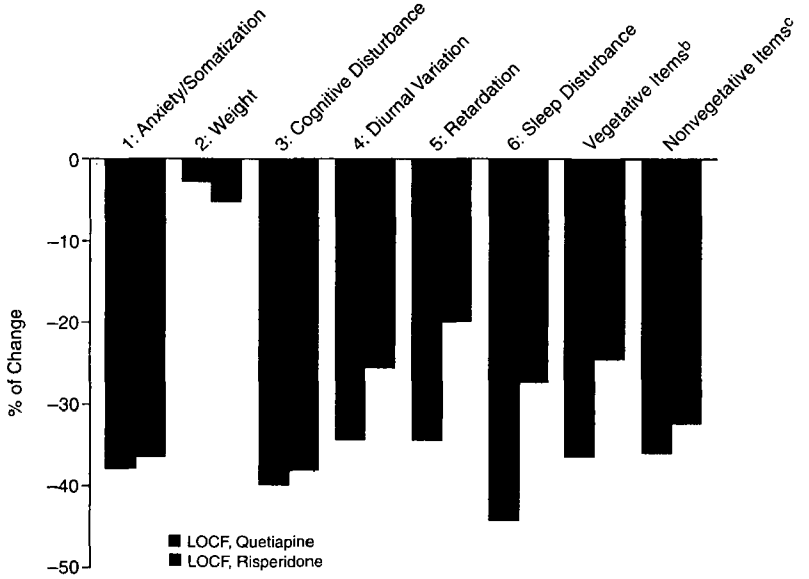
In the subgroup of patients diagnosed with non-mood disorders, substantial EPS was present at week 1 in 2.9% of the patients treated with risperidone, the incidence increased to a peak of 7.8% at month 2, and the overall incidence at LOCF was 4.2%. For quetiapine-treated patients, substantial EPS was present at week 1 in 1.3% of the patients, the incidence subsequently increased to a peak value of 3.5% at month 1, and the overall incidence at LOCF was 3.4% ($p = .063$).

The occurrence of at least moderate hypokinesia or akinesia was rare for both diagnostic groups (3.3% for quetiapine, 9.9% for risperidone). Changes in hypokinesia/akinesia severity and changes in HAM-D scores were found to be correlated and reflected the fact that, on average, both kinesia and mood symptoms improved throughout the study. To rule out a causal link between EPS condition and HAM-D scores, a subset ANCOVA examined patients who had at worst mild akinesia, hypokinesia, or akathisia at baseline and experienced no change in the severity of those 3 symptoms; quetiapine patients still scored significantly better on HAM-D ($p = .017$). No significant difference was found between mood and non-mood diagnoses groups ($p > .40$).

DISCUSSION

This study compared the safety and efficacy of quetiapine and risperidone for the treatment of depressive symptoms in psychotic patients. While both agents produced improvements in mean HAM-D scores, quetiapine produced a greater improvement than did risperidone in

Figure 5. Mean Change From Baseline in HAM-D Composite Factor Scores for Quetiapine and Risperidone[a]



[a]Abbreviations: HAM-D = Hamilton Rating Scale for Depression, LOCF = last observation carried forward.
[b]Includes insomnia early, middle, late; retardation; agitation; anxiety somatic; somatic symptoms gastrointestinal; somatic symptoms general; genital symptoms; weight loss; diurnal variation present; and diurnal variation severity.
[c]Includes depressed mood, guilt, suicide, work and activities, anxiety (psychic), hypochondriasis, insight, depersonalization and derealization, paranoid symptoms, and obsessional and compulsive symptoms.

all patients ($p = .0015$), in patients with primary mood disorders ($p = .036$), and in patients with non-mood disorders ($p = .008$). Quetiapine produced a statistically greater effect than risperidone in treating depressive symptoms in those patients with higher initial HAM-D scores. The clinical significance of the changes produced by treatment with quetiapine is not known. The incidence of substantial EPS was lower in patients treated with quetiapine than in patients treated with risperidone. This was statistically significant for mood diagnoses and showed a trend for non-mood diagnoses ($p = .062$). Both substantial and moderate EPS occurred statistically significantly less frequently among those mood-diagnosed patients who were taking quetiapine.

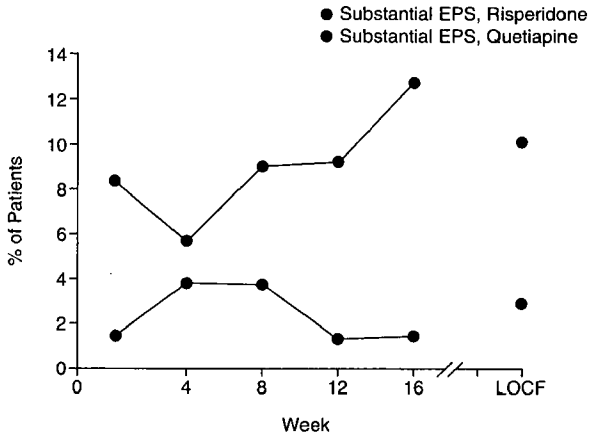
Other groups of investigators have reported that quetiapine and risperidone exhibit efficacy in the treatment of depressive symptoms in patients.[10,24] Sajatovic et al.[25] reported significant improvement on HAM-D scores in 20 individuals with bipolar or schizoaffective disorder who received open-label quetiapine therapy. In a case series of 6 patients with treatment-resistant bipolar disorder treated with quetiapine, 2 patients showed evidence of moderate-to-marked improvement on the Clinical Global Impressions scale modified for bipolar disorder.[26] Sedation was the main side effect noted in the Ghaemi and Katzow report,[26] and the investigators concluded that quetiapine may be a useful treatment for some patients with treatment-resistant bipolar disorder.

A number of open-label studies have investigated the use of risperidone to treat mood disorders with promising results.[27-32] Ostroff and Nelson[29] examined the use of risperidone to augment selective serotonin reuptake inhibitor (SSRI) antidepressants in 8 patients who had not responded to SSRI therapy. The 8 patients showed improvement within 1 week of the addition of risperidone. Vieta et al.[24] reported significant reductions in HAM-D scores for 8 of 10 patients with refractory rapid-cycling bipolar disorder who received open-label risperidone therapy. One double-blind study found risperidone to be as effective as lithium or haloperidol in the treatment of acute mania.[33] Finally, Guille et al.[32] reported that risperidone was as effective as clozapine and olanzapine in the treatment of bipolar disorder.

Induction of mania has been associated with a number of atypical antipsychotics such as risperidone, olanzapine, sertindole, quetiapine, and amisulpride.[34-39] Mania induction was not reported in this study; however, all the patients who were receiving mood stabilizers were permitted to continue this treatment as per protocol. In this analysis and in the larger QUEST study,[19] no mania scale was used; thus, instances of mood induction might not have been detected. Our conclusion of no identified mania induction in this study and in the larger QUEST study, then, is qualified by the small sample size in this study and the limited methodology in the QUEST study.

This study had a flexible-dose design, which allowed clinicians to titrate medications for maximum efficacy and minimum side effects depending upon the needs of each patient. At the time of the trial, risperidone was a U.S. Food and Drug Administration–approved medication and thus had a package insert that specified dosage. Quetiapine was still an investigational drug with optimal dose yet to be determined. Instructions to investigators were identical for both drugs: to titrate dosage according to patients' clinical needs. This dosing plan mirrors what generally occurs in clinical practice and thus provides insight into how study compounds will be used under such conditions. The limitations of this study include the following: (1) this was an open-label clinical trial, with the possibility of investigator and/or patient bias; (2) the trial involved a relatively small number of patients, with correspondingly small numbers of patients with mood and

Figure 6. Incidence of Extrapyramidal Symptoms (EPS) to a Substantial Degree in Patients Diagnosed With Mood Disorders[a]



[a]Substantial EPS is defined as requiring 1 or more of the following alterations in treatment: prescription of an anti-EPS medication, reduction in dose of randomized treatment, a discontinuation of randomized treatment.

non-mood disorders; (3) no standardized diagnostic instrument was used to assign diagnoses to patients; (4) no measurement was made of mania; (5) all patients were psychotic, thus no conclusions can be drawn about patients with bipolar disorder without psychoses; (6) elderly patients were also examined with the HAM-D, although it has been suggested that another scale might be more appropriate (e.g., the Geriatric Depression Screening Scale[40]); and (7) patients were allowed to continue the use of antidepressants and mood medications, thus efficacy and side effects might have been influenced by the concomitant medications.

In conclusion, in this trial, quetiapine produced a greater overall improvement in HAM-D scores compared with risperidone—this was true whether patients had mood or non-mood disorders. Patients with high baseline HAM-D scores improved more than did individuals with lower baseline HAM-D scores. The incidences of substantial EPS were fewer in patients treated with quetiapine compared with patients treated with risperidone. These results suggest that quetiapine may be a useful agent in the management of depressive symptoms in patients with psychotic disorders.

Drug names: clozapine (Clozaril and others), fluphenazine (Prolixin, Permitil, and others), haloperidol (Haldol and others), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperdal).

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DRUG INDUCED EXTRAPYRAMIDAL DISORDERS

Controlled studies of the relationship
between the behavioural change and the extrapyramidal
symptoms produced by psychotropic drugs

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MUNKSGAARD
COPENHAGEN 1970

A RATING SCALE FOR EXTRAPYRAMIDAL SIDE EFFECTS

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SUMMARY

A modification of an earlier rating scale for extrapyramidal system disturbance is described, and evidence for the validity and reliability of the scale is presented. The usefulness of the scale in studies of neuroleptic drugs is discussed. By its application it is possible to quantify extrapyramidal side effects and to separate them into four principal factors.

INTRODUCTION

The discovery of phenothiazines as useful agents in the treatment of mental disorder was shortly followed by discoveries of their adverse reactions, particularly those affecting the extrapyramidal system (3). This led to claims that side effects were part and parcel of their usefulness (4), and to counter-claims that they were undesirable side effects (6). The extensive studies of Haase (5), who claims that minimal extrapyramidal signs, as demonstrated in handwriting changes, are the "sine qua non" for optimal treatment, represent a somewhat intermediate position in this controversy.

This whole area has been thoroughly reviewed in two recent publications by Bishop, et al. (1) and by Ching-Piao and DiMascio (2). The latter point out that part of the confusion in this area may be related to differences in classification, and that too many investigators use extrapyramidal system disturbance as if it were a unity. We use this term throughout to describe the factors we are actually measuring. We see the difficulty not so much one of classification, but of defining and quantifying what is being observed. Thus, infrequent dystonic reactions and the slightly more frequent akathisia have been omitted from this study. We also feel that the differences between Haase and, for example, the French investigators are not semantic ones or a problem of classification, but merely that a proper comparison or study remains to be done.

We have elsewhere stated our opinion on this point (7, 9), namely that the presence of minimal extrapyramidal side effects seem to be associated with therapeutic improvement, excess extrapyramidal effects with less improvement. Further discussion on this subject would be outside the scope of

the present paper, but it is mentioned merely to highlight the point that all neuroleptic agents, irrespective of their chemical structure, possess two things in common: (1) an effect on psychotic behavior, and (2) an effect on the extrapyramidal system. Within limits, the potency of the drugs seems to be proportional to their propensity for producing extrapyramidal symptoms. If this is so, it is important to have an instrument for assessing accurately the amount of extrapyramidal system disorder produced, a quantitative measure rather than a qualitative description of these side effects.

In a previous investigation a rating scale for measuring extrapyramidal system disorder produced by neuroleptic drugs was described (7), and since that time it has been routinely used in this research unit. This scale was shown to have both clinical validity and high inter-rater reliability, but later attempts at more precise studies of extrapyramidal system disorder led to the need for its revision. Factors such as Salivation and Tremor, which were difficult to quantify, had not been included in the old scale, but in various studies, scores on the scale were diluted by their absence. Thus, zero scores occurred despite obvious tremor or disturbing salivation which frequently required the use of antiparkinson medication. It was, therefore, decided to expand the rating scale to include these factors. It is the purpose of this paper to present this rating instrument with a discussion of its potential usefulness in the field of clinical research.

The original rating scale contained nine items, all of which were common clinical signs, used in the diagnosis of Parkinson's Disease in clinical practice. One of these items, the evaluation of the state of the trunk muscles—a sign which can be of considerable diagnostic importance—was found difficult to quantify and was dropped from the scale. The other eight items were retained and, with the addition of Tremor and Salivation, make up the ten-item scale shown in Table 1. Each item is rated on a 5-point scale, with 0 meaning the complete absence of the condition, and 4 meaning the presence of the condition in extreme form. Each point on the scale was defined and is shown in the appendix. The score on the scale is obtained by adding the items and dividing by 10.

TABLE 1

Neurological Rating Scale for Extrapyramidal Effects

1. Gait	6. Leg Pendulousness
2. Arm Dropping	7. Head Dropping
3. Shoulder Shaking	8. Glabella Tap
4. Elbow Rigidity	9. Tremor
5. Wrist Rigidity	10. Salivation

Two questions of concern in any rating scale involve validity and reliability, and these questions were answered reasonably well in the studies on the

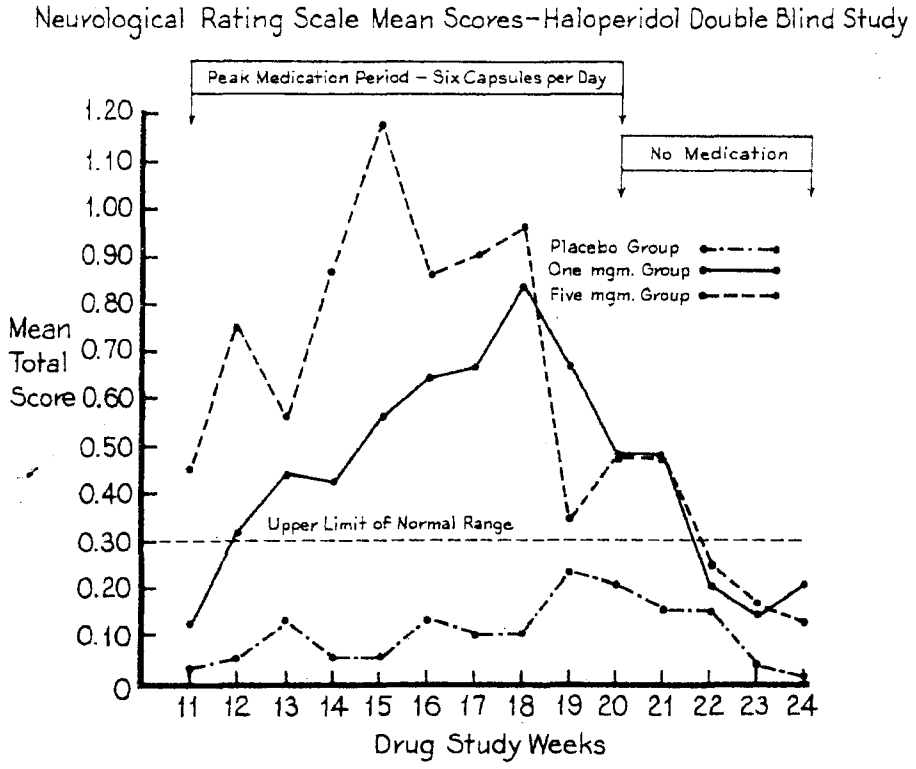

Fig. 1

previous scale (7). The reliability of the present scale was tested during a double-blind study involving two dose levels of the potent neuroleptic haloperidol and a placebo (8). Striking evidence for the validity of the scale was also obtained from the same trial.

METHOD

Fourteen patients who had been off all drugs for four weeks, were treated with identical capsules containing placebo, 1 mg and 5 mg of haloperidol respectively. The regime was fixed so that all patients received one capsule daily during the first week, and an increase of daily dosage by one capsule each week to a maximum of six. The daily dosage was maintained at this level for a further ten weeks, and, following withdrawal of medication, the patients were studied for another four weeks. When the code was broken, four patients had received placebo, five the 1 mg capsule (6 mg/day), and five the 5 mg capsule (30 mg/day).

The graph (Fig. 1) depicts the mean weekly rating on the scale for each group during the period on maximum medication and for the four weeks following withdrawal of medication, all ratings having been made by one physician. It can be seen that the scale satisfactorily separates the three groups. At Week 15 a t-test indicated that the difference between the placebo group and the 1 mg group was statistically significant ($p < 0.01$). The difference between the 5 mg and 1 mg groups just fails to be statistically significant ($p > 0.05$).

Two points should be made. We consider scores of up to 0.3 to be within the "normal range," and we found, on breaking the code, that three patients in the high dose group had been given benztropine mesylate for clinically troublesome side effects, whereas only one in the low dose group received it. This may account for the fall in the scores of the high dose group during the latter part of the drug period, and would certainly have diminished the difference between the 1 mg and 5 mg group mean scores.

In order to test inter-rater reliability, the patients were examined by two doctors during Weeks 11 to 18 of the trial. The patients were examined and rated at the same time of day each week and were seen by the second doctor immediately after examination by the first. Separate examining rooms were used, and the doctors were unaware of each other's ratings and of their own ratings made in previous weeks. There was no discussion or analysis of the data until the study had been completed. Correlation coefficients between raters for each item in each of the seven weeks were obtained and are shown in Table 2.

In our early clinical drug studies and in previous investigations, the total score on the neurological rating scale was the one used most frequently. This is obtained by summing the score for all the rated items and dividing

TABLE 2

Correlation Coefficients Between Raters

Item	Mean	Range
1. Gait	0.52	0.22–0.78
2. Arm Dropping	0.73	0.58–0.89
3. Shoulder Shaking	0.78	0.69–0.94
4. Elbow Rigidity	0.73	0.67–0.92
5. Wrist Rigidity	0.59	0.20–0.89
6. Leg Pendulousness	0.75	0.62–0.78
7. Head Dropping	0.70	0.62–0.78
8. Glabella Tap	0.87	0.60–1.0
9. Tremor	0.56	0.29–0.94
10. Salivation	0.59	0.16–1.0
Total Score	0.87	0.71–0.96

the total by the number of items. Correlations for the total scores between the two investigators ranged from 0.71 to 0.96.

In general, there was a good correlation between the two raters, but in one week, poor correlations were obtained on four items. Otherwise, the ten items rated on seven weeks, that is, seventy correlations, were all of a high order. All the low correlations were recorded in the third week of the study; this included Wrist Rigidity, Salivation, Gait, and Tremor. No explanation can be given for this at this time.

A principal component factor analysis, followed by a normalized Varimax rotation of the four resulting principal components was carried out. The factor loadings for these components are shown in Table 3. The first factor has high loadings on the items Shoulder-shaking, Elbow rigidity, Wrist rigidity, and Leg pendulousness and is obviously a factor involving rigidity. This factor accounted for 34 % of the total variance. The second factor places greatest weight on the items Gait, Salivation, and Head-dropping and accounted for 15 % of the total variance. The item Head-dropping is a difficult one to score, and we expected it to be included in the first factor to which it does contribute. That it should cluster with Gait is not particularly surprising, but no clinical explanation can be given for Salivation being included in this factor. We consider it a statistical artifact. The third factor was Glabella tap, which explained just over 10 % of the variance. Tremor emerged as a fourth factor, accounting for over 9 % of the variance. It would appear, therefore, that in using this scale to study extrapyramidal effects or antiparkinson agents, four factors, which in this study accounted for 68 % of the variance, could be considered: Rigidity, Salivation, Glabella tap, and Tremor.

Because seven of the items in the scale are measurements of rigidity, and because the latter accounted for a major part of the variance, we sepa-

TABLE 3

Factor Loadings for Four Principal Components

	I	II	III	IV
1. Gait	0.216	0.740	0.032	0.106
2. Arm Dropping	0.200	0.260	0.043	0.666
3. Shoulder shaking	0.818	0.262	0.069	0.047
4. Elbow Rigidity	0.799	0.227	0.121	0.140
5. Wrist Rigidity	0.792	0.004	0.249	0.207
6. Leg Pendulousness	0.702	0.231	0.067	0.213
7. Head Dropping	0.441	0.575	0.264	0.053
8. Glabella Tap	0.086	0.037	0.959	0.065
9. Tremor	0.088	0.046	0.119	0.819
10. Salivation	0.185	0.762	0.009	0.170

rated out the rigidity scores for the three groups. As might be expected, they ran parallel to the total score, although the fit was not exact. The discrimination between the placebo group and the drug groups remained, but that between the two drug groups was diminished.

DISCUSSION

There have been many attempts to quantify the phenomena of parkinsonism and its response to treatment. Unfortunately, the scales often contain many items, or the assessment involves time-consuming procedures, such as sorting tests or handwriting. We believe that we have devised a valid, reliable scale that is simple and rapidly applied and requires no equipment other than an examining couch. In addition, the method can be quickly taught to a nurse or research assistant. Its application does not require specialized medical knowledge.

The items on the scale have a certain face validity in that they are commonly used signs in the clinical evaluation of parkinsonism. A further attestation to the validity of the scale was its ability to separate in a double-blind trial not only patients receiving placebo from those receiving potent neuroleptic medications, but also two dose levels of the medication. The relatively high correlations on each item between raters, and the high correlation on the total score, indicate that the scale is reliable. Like every other scale, its use has to be learned, and it is advisable for raters to rate the same patients from time to time, in order to check shifts in definition.

As most of the items are concerned with the measurement of rigidity, it is no surprise that such a factor accounts for a large part of the variance and separates out from Salivation, Tremor, and Glabella tap. Nevertheless, the retention of the latter three items appears to be justified, because the mean total score proved better at separating the two drug groups than the rigidity score alone. The grouping of items in the scale according to these factors might be used to bring greater precision to the assessment of neuroleptic drugs or the use of drugs for treating extrapyramidal symptoms.

We are using the scale routinely both in the work of early clinical drug evaluation and in the investigation of extrapyramidal side effects. It is possible that others, working in psychopharmacology, might find it of value and possible, too, that it may be of interest to neurologists in assessing the treatment of parkinsonism.

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APPENDIX

1. *Gait*—The patient is examined as he walks into the examining room, his gait, the swing of his arms, his general posture, all form the basis for an overall score for this item. This is rated as follows:

0 – normal
1 – diminution in swing while the patient is walking
2 – marked diminution in swing with obvious rigidity in the arm
3 – stiff gait with arms held rigidly before the abdomen
4 – stooped shuffling gait with propulsion and retropulsion

2. *Arm Dropping*—The patient and the examiner both raise their arms to shoulder height and let them fall to their sides. In a normal subject a stout slap is heard as the arms hit the sides. In the patient with extreme Parkinson's syndrome the arms falls very slowly:

0 – normal, free fall with loud slap and rebound
1 – fall slowed slightly with less audible contact and little rebound
2 – fall slowed, no rebound
3 – marked slowing, no slap at all
4 – arms fall as though against resistance; as though through glue

3. *Shoulder Shaking*.—The subject's arms are bent at a right angle at the elbow and are taken one at a time by the examiner who grasps one hand and also clasps the other around the patient's elbow. The subject's upper arm is pushed to and fro and the humerus is externally rotated. The degree of resistance from normal to extreme rigidity is scored as follows:

0 – normal
1 – slight stiffness and resistance
2 – moderate stiffness and resistance
3 – marked rigidity with difficulty in passive movement
4 – extreme stiffness and rigidity with almost a frozen shoulder

4. *Elbow Rigidity*—The elbow joints are separately bent at right angles and passively extended and flexed, with the subject's biceps observed and simultaneously palpated. The resistance to this procedure is rated. (The presence of cogwheel rigidity is noted separately.) Scoring is from 0–4 as in Shoulder Shaking test.

5. Fixation of position or *Wrist Rigidity*—The wrist is held in one hand and the fingers held by the examiner's other hand, with the wrist moved to extension flexion and both ulner and radial deviation. The resistance to this procedure is rated as in Items 3 and 4.

6. *Leg Pendulousness*—The patient sits on a table with his legs hanging down and swinging free. The ankle is grasped by the examiner and raised until the knee is partially extended. It is then allowed to fall. The resistance to falling and the lack of swinging form the basis for the score on this item:

0 – the legs swing freely
1 – slight diminution in the swing of the legs
2 – moderate resistance to swing
3 – marked resistance and damping of swing
4 – complete absence of swing

7. *Head Dropping*—The patient lies on a well-padded examining table and his head is raised by the examiner's hand. The hand is then withdrawn and the head allowed to drop. In the normal subject the head will fall upon the table. The movement is delayed in extrapyramidal system disorder, and in extreme parkinsonism it is absent. The neck muscles are rigid and the head does not reach the examining table. Scoring is as follows:

0 – the head falls completely with a good thump as it hits the table
1 – slight slowing in fall, mainly noted by lack of slap as head meets the table
2 – moderate slowing in the fall quite noticeable to the eye
3 – head falls stiffly and slowly
4 – head does not reach examining table

8. *Glabella Tap*—Subject is told to open his eyes wide and not to blink. The glabella region is tapped at a steady, rapid speed. The number of times patient blinks in succession is noted:

0 – 0–5 blinks
1 – 6–10 blinks
2 – 11–15 blinks
3 – 16–20 blinks
4 – 21 and more blinks

9. *Tremor*—Patient is observed walking into examining room and then is re-examined for this item:

0 – normal
1 – mild finger tremor, obvious to sight and touch

2 – tremor of hand or arm occurring spasmodically
3 – persistent tremor or one or more limbs
4 – whole body tremor

10. *Salivation*—Patient is observed while talking and then asked to open his mouth and elevate his tongue. The following ratings are given:

0 – normal
1 – excess salivation to the extent that pooling takes place if the mouth is open and the tongue raised
2 – when excess salivation is present and might occasionally result in difficulty in speaking
3 – speaking with difficulty because of excess salivation
4 – frank drooling

ORIGINAL ARTICLE

Efficacy of Olanzapine and Olanzapine-Fluoxetine Combination in the Treatment of Bipolar I Depression

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Background: Despite the longer duration of the depressive phase in bipolar disorder and the frequent clinical use of antidepressants combined with antipsychotics or mood stabilizers, relatively few controlled studies have examined treatment strategies for bipolar depression.

Objective: To examine the use of olanzapine and olanzapine-fluoxetine combination in the treatment of bipolar I depression.

Design: Double-blind, 8-week, randomized controlled trial.

Setting: Eighty-four sites (inpatient and outpatient) in 13 countries.

Patients: A total of 833 randomized adults with bipolar I depression with a Montgomery-Åsberg Depression Rating Scale (MADRS) score of at least 20.

Intervention: Patients were randomly assigned to receive placebo (n=377); olanzapine, 5 to 20 mg/d (n=370); or olanzapine-fluoxetine combination, 6 and 25, 6 and 50, or 12 and 50 mg/d (n=86).

Main Outcome Measure: Changes in MADRS total scores using mixed-effects model repeated-measures analyses.

Results: During all 8 study weeks, the olanzapine and olanzapine-fluoxetine groups showed statistically significant improvement in depressive symptoms vs the placebo group ($P<.001$ for all). The olanzapine-fluoxetine group also showed statistically greater improvement than the olanzapine group at weeks 4 through 8. At week 8, MADRS total scores were lower than at baseline by 11.9, 15.0, and 18.5 points in the placebo, olanzapine, and olanzapine-fluoxetine groups, respectively. Remission criteria were met by 24.5% (87/355) of the placebo group, 32.8% (115/351) of the olanzapine group, and 48.8% (40/82) of the olanzapine-fluoxetine group. Treatment-emergent mania (Young Mania Rating Scale score <15 at baseline and ≥15 subsequently) did not differ among groups (placebo, 6.7% [23/345]; olanzapine, 5.7% [19/335]; and olanzapine-fluoxetine, 6.4% [5/78]). Adverse events for olanzapine-fluoxetine therapy were similar to those for olanzapine therapy but also included higher rates of nausea and diarrhea.

Conclusions: Olanzapine is more effective than placebo, and combined olanzapine-fluoxetine is more effective than olanzapine and placebo in the treatment of bipolar I depression without increased risk of developing manic symptoms.

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BIPOLAR DEPRESSION, or the depressive phase of bipolar disorder, represents a difficult-to-treat and disabling form of depression. However, relative to its impact, an insufficient number of studies have explored its treatment. Studies indicate that patients with bipolar disorder spend more time in and take longer to recover from the depressive phase than the manic phase. Judd et al[1] reported that patients with bipolar disorder experience depressive symptoms more than 3 times longer than they experience manic symptoms. Keller et al,[2] using a naturalistic study design, found that the median time to recovery from the depressive phase was 9 weeks but from the manic phase was 5 weeks and that 22% of patients in the depressive phase but only 7% in the manic phase remained ill for at least 1 year. Moreover, Hlastala et al,[3] in a controlled study of maintenance therapies, found that the median time to full remission was 16.8 weeks for a manic episode but 40.0 weeks for a depressive episode. In addition to being longer and more persistent, the depressive phase of bipolar disorder is associated with higher rates of morbidity and mortality. Dilsaver et al[4] reported the relative risk of suicidality among patients with bipolar depression to be 34.9 times greater than that among patients with pure mania. Depres-

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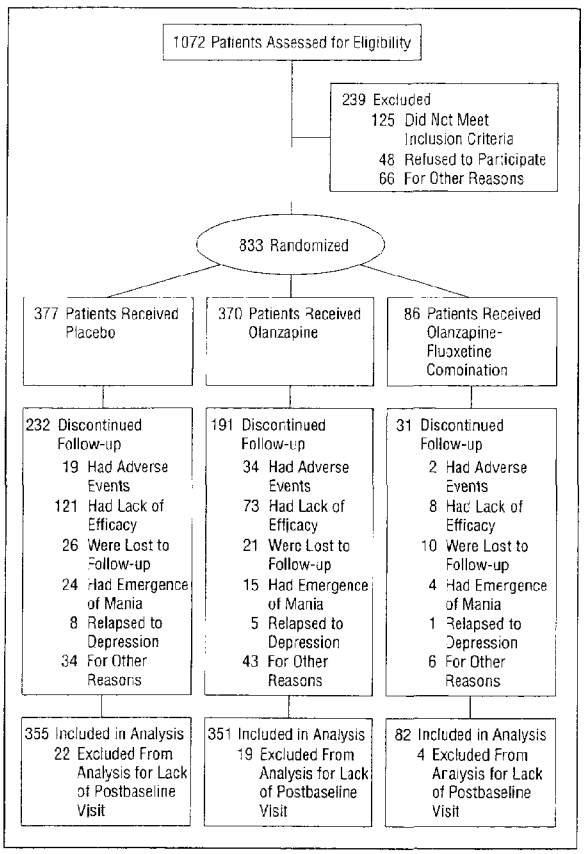

Figure 1. Flow diagram of patient progress through phases of the study.

sive symptoms have also been found to be a strong predictor of disability in patients with bipolar disorder.[5]

Nevertheless, despite the clear clinical and public health implications of these findings, treatment of bipolar depression remains an understudied area, as clinicians and researchers have historically focused more on treatment of mania.[6] Although a wide range of mood-stabilizing medications is available, treatment options for bipolar depression remain more limited, and no medication has been formally approved for this indication. At present, the 2002 treatment guidelines from the American Psychiatric Association recommend either lithium or lamotrigine as first-line treatment.[7] Although reviews[8,9] of clinical trials have concluded that there is evidence of lithium's acute efficacy for bipolar depression, patients in those clinical trials frequently did not achieve a full response.[10] Anticonvulsants such as lamotrigine and valproate sodium have also been used to treat bipolar depression.[11,12] However, although Calabrese and colleagues[11] reported the antidepressant efficacy of lamotrigine therapy in a placebo-controlled trial of patients with bipolar depression, lamotrigine requires a slow upward titration to avoid the risk of rash.[11,13] Other common treatments include the adjunctive use of antidepressants with a mood stabilizer. However, some antidepressants, particularly tricyclics, are problematic for their potential to induce mania or hypomania or to accelerate cycling.[14,15] Thus, alternative effective and safe treatment options are needed.

Olanzapine has demonstrated efficacy in the treatment of acute bipolar mania[16-18] and has been found to improve depressive symptoms in patients with schizophrenia.[19] The present study was thus designed to test the antidepressant efficacy of olanzapine in treating the depressive phase of bipolar I disorder. For exploratory purposes, a small group of patients was treated with olanzapine combined with the selective serotonin reuptake inhibitor fluoxetine. The olanzapine-fluoxetine combination was previously found to be effective in a small sample of patients with treatment-resistant unipolar depression.[20] The present study represents the first controlled trial, to our knowledge, of an atypical antipsychotic agent alone or combined with an antidepressant for the treatment of bipolar depression.

METHODS

STUDY DESIGN

The primary objective of this 8-week, randomized, double-blind, parallel study was to compare the efficacy and safety of olanzapine monotherapy and placebo in the treatment of bipolar I disorder, depressed. An olanzapine-fluoxetine combination treatment arm was also included concurrently for exploratory purposes. Qualified patients who completed a 2- to 14-day screening and washout period were therefore randomized in a 4:4:1 allocation, as specified in the protocol, to receive olanzapine, 5 to 20 mg/d (n=370); placebo (n=377); or olanzapine-fluoxetine combination, 6 and 25, 6 and 50, or 12 and 50 mg/d (n=86) in a flexible dosing schedule. Olanzapine monotherapy was initiated at 5 mg and could be adjusted upward in increments of 5 mg/d. Olanzapine-fluoxetine combination therapy was initiated at 6 and 25 mg/d but could be administered at 6 and 50 or 12 and 50 mg/d after at least 1 day at each dose. No other dose combinations were allowed. Combination dosing was based on the positive findings from a study[20] of patients with treatment-resistant depression. Olanzapine and fluoxetine were administered as separate capsules, taken together once daily in the evening. Patients receiving placebo or olanzapine monotherapy also received 2 pills per day. Randomization was stratified by site and used a blinded voice response system. All clinical and statistical investigators, site personnel, and patients were blinded to treatment.

Patients were permitted adjunctive use of benzodiazepines (up to 2 mg of lorazepam equivalents per day) throughout the screening and acute therapy phases of the study. Anticholinergic therapy (benztropine mesylate or biperiden, ≤6 mg/d, or trihexyphenidyl, ≤12 mg/d) was permitted throughout the study for treatment of extrapyramidal symptoms but not for prophylaxis. Use of other psychotropic drugs was not permitted, and all such medication was tapered during the 2- to 14-day screening period at the discretion of the investigator and was completed at least 1 day before randomization.

PATIENTS

All patients were 18 years or older and met *DSM-IV*[21] criteria for bipolar I disorder, depressed. A total of 1072 patients were recruited from the inpatient and outpatient services of 84 study sites in 13 countries between June 1, 2000, and December 31, 2001 (**Figure 1**). Diagnosis was confirmed by the *Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Patient Version*.[22] Patients were required to have a Montgomery-Åsberg Depression Rating Scale (MADRS)[23] total score of at least 20 at the screening visit and at the time of

Table 1. Patient and Illness Characteristics at Baseline

Characteristic	Placebo Group (n = 377)	Olanzapine Group (n = 370)	OFC Group (n = 86)	Total (N = 833)	P Value
Age, mean (SD), y	41.7 (12.4)	42.2 (12.5)	40.3 (13.0)	41.8 (12.5)	.91*
Women, %	62.6	62.4	67.4	63.0	.68
White, %	82.2	84.1	77.9	82.6	.52
Inpatients, %	13.3	13.8	9.3	13.1	.57
Psychotic features, %	12.7	13.5	7.0	12.5	.25
Melancholic features, %	67.9	66.5	62.8	66.7	.68
Atypical features, %	7.7	9.2	7.0	8.3	.89
Rapid cycling course, %†	35.0	38.4	39.5	37.0	.82
Manic or mixed episode in the past 12 mo, %‡	77.8	83.5	80.5	80.7	.20
Length of current depressive episode, median, d	82	63	81	73	.006§

Abbreviation: OFC, olanzapine-fluoxetine combination.
*$F_{2,809} = 0.1$.
†Rapid cycling was defined as more than 4 mood episodes (depressive, manic, or mixed) in the past 12 months.
‡Based on available data (placebo group, n = 302; olanzapine group, n = 310; and OFC group, n = 66).
§$X^2_2 = 10.38$.

randomization. Patients were also required to have a history of at least 1 previous manic or mixed episode of sufficient severity to require treatment with a mood stabilizer or an antipsychotic agent. Exclusion criteria included a history of alcohol or substance dependence within the previous 3 months, suicidal behavior within the previous 3 months, or an unstable or untreated medical disorder. For safety reasons, any patient with worsening of manic symptoms, as verified by a score of 15 or greater on the Young Mania Rating Scale (YMRS)[24] during weeks 1 to 3 of treatment, was discontinued from the study. Before participation, all patients provided written informed consent; the study was approved by the institutional review board at each site.

ASSESSMENTS

Clinical visits were conducted at baseline and at weeks 1, 2, 3, 4, 6, and 8. The protocol-defined primary measure of efficacy was the change in MADRS total score from baseline to week 8. Secondary efficacy measures included the Clinical Global Impressions Bipolar Version–Severity of Depression scale (CGI-BP-S),[25] the YMRS, and the Hamilton Anxiety Rating scale (HAM-A).[26] Rates of and time to response and remission were also assessed. Response was defined as 50% or greater improvement in the MADRS total score from baseline to an end point and completion of at least 4 weeks of study. Remission was defined as a MADRS total score of 12 or less at an end point and completion of at least 4 weeks of study.

Screening included a standard history and physical examination, psychiatric examination, laboratory profile, and electrocardiogram. Adverse events were recorded at each visit and were coded using the *Coding Symbol for Thesaurus of Adverse Reaction Terms*.[27] Extrapyramidal symptoms were assessed using the Simpson-Angus Rating Scale[28] and the Abnormal Involuntary Movement Scale.[29] Adverse events or abnormal values that originally occurred or worsened in severity during double-blind therapy were considered treatment emergent.

STATISTICAL ANALYSIS

All analyses were conducted on an intent-to-treat basis and were performed using statistical software (SAS version 6.09; SAS Institute Inc, Cary, NC). Treatment effects were tested at a 2-tailed α level of .05. Interaction effects were tested at a 2-tailed α level of .10. As specified a priori, analysis of the primary measure of efficacy was performed using a mixed-effects model repeated-measures (MMRM) method, which has been shown to provide highly accurate modeling of treatment outcome while accounting for nonrandom missing data (ie, patient dropout).[30,31] Initially, an unstructured covariance matrix was used to model within-patient error. Independent factors included in this model were treatment, investigator, treatment × investigator interaction, visit, and treatment × visit interaction, with the treatment × investigator interaction excluded if not statistically significant. Next, the best-fit covariance structure for each analysis was determined using a maximum Schwartz's Bayesian criterion and is reported in the tables. Possible structures included autoregressive, banded Toeplitz, compound symmetric with or without heterogeneous variances, spatial power, and unstructured. Treatment differences for each visit were tested using a single *df* contrast, based on least squares means from the final model. Inference from the repeated-measures analyses was based on the restricted maximum likelihood solution and on approximated F tests and *t* tests using *df*'s estimated by Satterthwaite's approximation. The MADRS items and secondary efficacy measures were similarly analyzed, except for the HAM-A, which used an analysis of variance (ANOVA) model due to assessments being taken only at baseline and an end point on that measure. Thus, all reported MADRS, MADRS item, CGI-BP-S, and YMRS mean change scores represent least squares means. The MMRM analyses were performed using the SAS PROC MIXED procedure, version 6.09 (SAS Institute Inc, Cary, NC).

The ANOVA models were also used to evaluate safety data, using mean change from baseline to end point based on a last-observation-carried-forward strategy. These models included terms for treatment and country plus treatment × country interaction if statistically significant. The Kruskal-Wallis test was used to analyze baseline length of the current episode because of the presence of outliers. The Fisher exact test was used to analyze treatment differences for categorical patient and illness characteristics. Odds ratios (and 95% confidence intervals [CI]) characterize group differences in clinical response. Kaplan-Meier analysis and the log-rank test were used to compare treatment groups for time-to-event data.

RESULTS

PATIENTS

A total of 833 patients were enrolled and randomized to treatment groups. The baseline characteristics of each group are given in **Table 1**. All of the groups were mod-

Table 2. Patient Disposition

Variable	Placebo Group (n = 377)	Olanzapine Group (n = 370)	OFC Group (n = 86)	*P* Value: Placebo vs Olanzapine	*P* Value: Placebo vs OFC	*P* Value: OFC vs Olanzapine
Weeks completed, No. (%)						
2	317 (84.1)	304 (82.2)	76 (88.4)	NA	NA	NA
4	200 (53.1)	233 (63.0)	65 (75.6)	NA	NA	NA
8	145 (38.5)	179 (48.4)	55 (64.0)	.006	.001	.01
Discontinued treatment, No. (%)						
Adverse events	19 (5.0)	34 (9.2)	2 (2.3)	.03	.39	.04
Lack of efficacy	121 (32.1)	73 (19.7)	8 (9.3)	.001	.001	.03
Lost to follow-up	26 (6.9)	21 (5.7)	10 (11.6)	.55	.18	.06
Emergence of mania	24 (6.4)	15 (4.1)	4 (4.7)	.19	.80	.77
Relapse to depression	8 (2.1)	5 (1.4)	1 (1.2)	.58	>.99	>.99
Other reasons	34 (9.0)	43 (11.6)	6 (7.0)	.28	.67	.25
Subtotal	**232** (61.5)	**191** (51.6)	**31** (36.0)			
Time to discontinuation, median (mean ± SE), d*	41 (43.1 ± 1.2)	56 (45.8 ± 1.2)	65 (53.2 ± 2.3)	.02	<.001	.006

Abbreviations: NA, not applicable; OFC, olanzapine-fluoxetine combination.
*Time to discontinuation uses Kaplan-Meier survival analysis, with curves compared using the log-rank test.

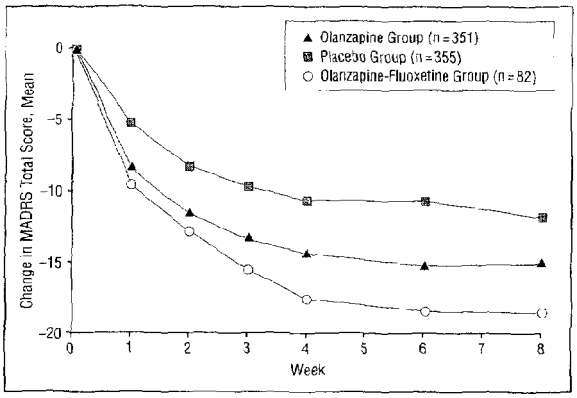

Figure 2. Least squares mean change in Montgomery-Åsberg Depression Rating Scale (MADRS) total scores during the 8-week study. Improvement in MADRS scores with use of olanzapine and the olanzapine-fluoxetine combination was significantly greater than with use of placebo throughout the study ($P<.001$). Improvement in MADRS scores with use of olanzapine-fluoxetine combination was significantly greater than with use of olanzapine at weeks 4 to 8 ($P<.02$).

erately to severely depressed, with baseline mean MADRS scores of 31.3, 32.6, and 30.8 for the placebo, olanzapine, and olanzapine-fluoxetine groups, respectively. Length of current depressive episode was statistically significantly shorter for the olanzapine group.

Mean modal drug dose for the olanzapine monotherapy group was 9.7 mg/d. Mean drug dose for the combination group was 7.4 mg/d for olanzapine and 39.3 mg/d for fluoxetine. The percentage of patients who used benzodiazepines at least once during the study was not statistically significantly different among groups (placebo group, 43.5%; olanzapine group, 43.0%; olanzapine-fluoxetine group, 36.0%; overall $P=.44$).

PATIENT DISPOSITION

Rates of study completion and reasons for discontinuation are reported in **Table 2**. Patients taking olanzapine-fluoxetine had the highest rates of completion (64.0%) and were less likely to discontinue due to lack of efficacy or adverse events. The most frequent adverse event resulting in discontinuation from the olanzapine monotherapy group was somnolence. There were no differences among groups in the rate of discontinuation due to emergence of mania. Three patients (all in the placebo group) died during the study: 1 was a homicide victim and 2 committed suicide.

Times to study discontinuation are also reported in Table 2. Median estimated times to discontinuation for any reason were 41, 56, and 65 days for the placebo, olanzapine, and olanzapine-fluoxetine groups, respectively, with patients in the placebo group discontinuing significantly earlier than those in the olanzapine group (log-rank test $\chi^2_1=5.06$; $P=.02$) or the olanzapine-fluoxetine group (log-rank test $\chi^2_1=17.02$; $P<.001$) and with those in the olanzapine group discontinuing earlier than those in the olanzapine-fluoxetine group (log-rank test $\chi^2_1=7.68$; $P=.006$).

EFFICACY

Mean ± SD baseline MADRS scores ranged from 30.8 ± 6.1 to 32.6 ± 6.2. The MMRM analyses of visitwise mean changes in MADRS scores are depicted in **Figure 2**. There were significant main effects for treatment ($F_{2,806}=25.14$; $P<.001$) and for visit ($F_{5,1036}=55.91$; $P<.001$), with no significant treatment × visit interaction ($F_{10,1044}=1.01$; $P=.43$). Between-group comparisons for visitwise MADRS mean change scores are given in **Table 3**. Starting as early as week 1 and continuing throughout the study, the olanzapine and olanzapine-fluoxetine groups demonstrated significantly greater mean improvements in MADRS total scores than those receiving placebo. Starting at week 4 and continuing to week 8, the olanzapine-fluoxetine group also demonstrated significantly greater mean improvement in MADRS total scores than the olanzapine monotherapy group. The therapeutic effect sizes for olanzapine and olanzapine-fluoxetine were 0.32 and 0.68, respectively. Due to the differences among groups in epi-

Table 3. Visitwise MADRS Mean Change Scores (MMRM Analysis)*

Treatment Group	Change in MADRS Score, Mean ± SE (95% CI)	vs Placebo			vs Olanzapine		
		t Test	*df*	*P* Value	*t* Test	*df*	*P* Value
Week 1							
Placebo	−5.2 ± 0.5 (−6.2 to −4.2)	NA	NA	NA	NA	NA	NA
Olanzapine	−8.5 ± 0.5 (−9.5 to −7.5)	−5.19	896	<.001	NA	NA	NA
OFC	−9.6 ± 0.9 (−11.5 to −7.8)	−4.27	896	<.001	−1.09	896	.28
Week 2							
Placebo	−8.3 ± 0.6 (−9.4 to −7.1)	NA	NA	NA	NA	NA	NA
Olanzapine	−11.5 ± 0.6 (−12.6 to −10.3)	−4.42	858	<.001	NA	NA	NA
OFC	−12.8 ± 1.1 (−14.9 to −10.7)	−3.92	841	<.001	−1.17	843	.24
Week 3							
Placebo	−9.6 ± 0.6 (−10.8 to −8.5)	NA	NA	NA	NA	NA	NA
Olanzapine	−13.3 ± 0.6 (−14.5 to −12.2)	−4.77	819	<.001	NA	NA	NA
OFC	−15.5 ± 1.1 (−17.7 to −13.3)	−4.71	808	<.001	−1.74	810	.08
Week 4							
Placebo	−10.7 ± 0.6 (−11.9 to −9.5)	NA	NA	NA	NA	NA	NA
Olanzapine	−14.3 ± 0.6 (−15.5 to −13.0)	−4.36	807	<.001	NA	NA	NA
OFC	−17.5 ± 1.2 (−19.9 to −15.2)	−5.21	794	<.001	−2.49	797	.01
Week 6							
Placebo	−10.7 ± 0.7 (−12.1 to −9.4)	NA	NA	NA	NA	NA	NA
Olanzapine	−15.1 ± 0.7 (−16.5 to −13.8)	−4.89	726	<.001	NA	NA	NA
OFC	−18.5 ± 1.3 (−21.0 to −16.0)	−5.56	696	<.001	−2.41	689	.02
Week 8							
Placebo	−11.9 ± 0.8 (−13.4 to −10.4)	NA	NA	NA	NA	NA	NA
Olanzapine	−15.0 ± 0.7 (−16.4 to −13.6)	−3.13	596	.002	NA	NA	NA
OFC	−18.5 ± 1.3 (−21.1 to −16.0)	−4.53	577	<.001	−2.46	571	.01

Abbreviations: CI, confidence interval; MADRS, Montgomery-Åsberg Depression Rating Scale; MMRM, mixed-effects model repeated-measures; NA, not applicable; OFC, olanzapine-fluoxetine combination.

*Baseline MADRS scores, mean ± SE: placebo group, 31.3 ± 0.3; olanzapine group, 32.6 ± 0.3; OFC group, 30.8 ± 0.7. The MMRM analysis used a heterogeneous banded Toeplitz structure for the within-patient error covariance structure.

sode length, this variable was subsequently entered into the MMRM model. After adjustment for episode length, week 8 MADRS mean ± SE change scores were −11.9 ± 0.8, −15.0 ± 0.7, and −18.6 ± 1.3 for the placebo, olanzapine, and olanzapine-fluoxetine groups, respectively. Because episode length was not a significant predictor of MADRS change score in this model ($F_{1,864} = 0.06$; $P = .81$) and resulted in negligible adjustment to the scores, Table 3 reports the MADRS mean change scores without this adjustment.

The response rate for the olanzapine group was 39.0% (137/351), which was significantly higher than the rate for the placebo group of 30.4% (108/355; $P = .02$; odds ratio, 1.46; 95% CI, 1.07-2.00). The response rate for the olanzapine-fluoxetine group was 56.1% (46/82), which was significantly higher than that for the placebo ($P < .001$; odds ratio, 2.92; 95% CI, 1.79-4.80) and olanzapine ($P = .006$; odds ratio, 2.00; 95% CI, 1.23-3.26) groups. Median times to response for the placebo, olanzapine, and olanzapine-fluoxetine groups were 59, 55, and 21 days, respectively (**Figure 3**). Time to response was significantly shorter for the olanzapine group compared with the placebo group (log-rank test $\chi^2_1 = 6.62$; $P = .01$) and shorter still for the olanzapine-fluoxetine group compared with the placebo (log-rank test $\chi^2_1 = 23.78$; $P < .001$) and olanzapine (log-rank test $\chi^2_1 = 7.93$; $P = .005$) groups.

The remission rate for the olanzapine group was 32.8% (115/351), which was significantly higher than the rate for the placebo group of 24.5% (87/355; $P = .02$). The remission rate for the olanzapine-fluoxetine group was 48.8% (40/82), which was significantly higher than that for the placebo ($P < .001$) and olanzapine ($P = .007$) groups. Median estimated times to remission for the placebo, olanzapine, and combination groups were 59, 57, and 42 days, respectively. Time to remission was significantly shorter for the olanzapine group compared with the placebo group

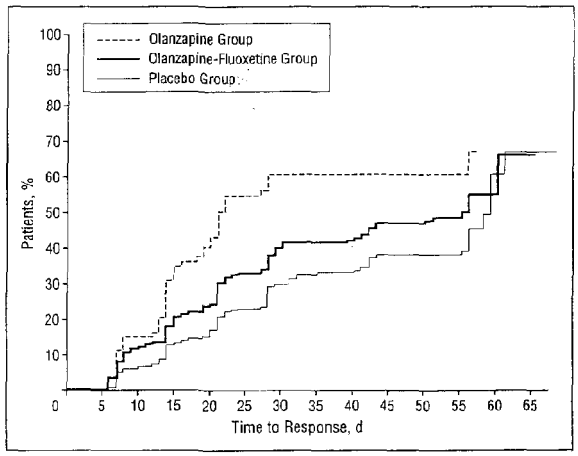

Figure 3. Kaplan-Meier estimates of time to response. Response is defined as a decrease in Montgomery-Åsberg Depression Rating Scale total score of 50% or more after at least 4 weeks of treatment. Median time to response for the olanzapine group (55 days) was significantly earlier compared with the placebo group (59 days). Median time to response for the combined olanzapine-fluoxetine combination group (21 days) was significantly earlier than for the olanzapine and placebo groups.

Table 4. Change in MADRS Item Scores Between Baseline and Week 8 (MMRM Analysis)*

Item and Treatment Group	Baseline Score, Mean ± SE	Change in Item Score, Mean ± SE (95% CI)	vs Placebo			vs Olanzapine		
			t Test	*df*	*P* Value	*t* Test	*df*	*P* Value
1. Apparent sadness								
Placebo	3.5 ± 0.1	−1.3 ± 0.1 (−1.5 to −1.1)	NA	NA	NA	NA	NA	NA
Olanzapine	3.8 ± 0.1	−1.5 ± 0.1 (−1.7 to −1.3)	−1.74	2439	.08	NA	NA	NA
OFC	3.6 ± 0.1	−2.1 ± 0.2 (−2.4 to −1.7)	−3.69	2122	<.001	−2.56	2034	.01
2. Reported sadness								
Placebo	4.0 ± 0.1	−1.5 ± 0.1 (−1.8 to −1.3)	NA	NA	NA	NA	NA	NA
Olanzapine	4.1 ± 0.1	−1.8 ± 0.1 (−2.0 to −1.5)	−1.48	550	.14	NA	NA	NA
OFC	3.8 ± 0.1	−2.2 ± 0.2 (−2.6 to −1.8)	−2.98	537	.003	−2.01	532	.045
3. Inner tension								
Placebo	3.3 ± 0.1	−1.0 ± 0.1 (−1.2 to −0.8)	NA	NA	NA	NA	NA	NA
Olanzapine	3.4 ± 0.1	−1.4 ± 0.1 (−1.5 to −1.2)	−2.56	2522	.01	NA	NA	NA
OFC	3.2 ± 0.1	−1.7 ± 0.2 (−2.0 to −1.4)	−3.46	2240	<.001	−1.75	2153	.08
4. Reduced sleep								
Placebo	3.1 ± 0.1	−1.3 ± 0.1 (−1.6 to −1.0)	NA	NA	NA	NA	NA	NA
Olanzapine	3.2 ± 0.1	−2.0 ± 0.1 (−2.3 to −1.8)	−4.05	2298	<.001	NA	NA	NA
OFC	3.2 ± 0.2	−2.3 ± 0.2 (−2.8 to −1.9)	−3.83	1986	<.001	−1.12	1903	.26
5. Reduced appetite								
Placebo	1.8 ± 0.1	−0.7 ± 0.1 (−1.0 to −0.5)	NA	NA	NA	NA	NA	NA
Olanzapine	2.0 ± 0.1	−1.4 ± 0.1 (−1.6 to −1.1)	−3.98	1938	<.001	NA	NA	NA
OFC	1.6 ± 0.2	−1.2 ± 0.2 (−1.7 to −0.8)	−2.09	1643	.04	0.55	1577	.58
6. Concentration difficulties								
Placebo	3.4 ± 0.1	−1.4 ± 0.1 (−1.7 to −1.2)	NA	NA	NA	NA	NA	NA
Olanzapine	3.4 ± 0.1	−1.7 ± 0.1 (−1.9 to −1.5)	−1.59	554	.11	NA	NA	NA
OFC	3.3 ± 0.1	−1.6 ± 0.2 (−2.0 to −1.2)	−0.72	538	.47	0.36	533	.72
7. Lassitude								
Placebo	3.5 ± 0.1	−1.5 ± 0.1 (−1.7 to −1.2)	NA	NA	NA	NA	NA	NA
Olanzapine	3.5 ± 0.1	−1.5 ± 0.1 (−1.7 to −1.2)	−0.01	2388	.99	NA	NA	NA
OFC	3.7 ± 0.1	−2.1 ± 0.2 (−2.5 to −1.6)	−2.48	2063	.01	−2.51	1976	.01
8. Inability to feel								
Placebo	3.6 ± 0.1	−1.6 ± 0.1 (−1.9 to −1.4)	NA	NA	NA	NA	NA	NA
Olanzapine	3.6 ± 0.1	−1.6 ± 0.1 (−1.9 to −1.4)	−0.13	2469	.90	NA	NA	NA
OFC	3.5 ± 0.1	−2.3 ± 0.2 (−2.7 to −1.9)	−3.13	2157	.002	−3.10	2069	.002
9. Pessimistic thoughts								
Placebo	3.3 ± 0.1	−1.3 ± 0.1 (−1.5 to −1.1)	NA	NA	NA	NA	NA	NA
Olanzapine	3.3 ± 0.1	−1.4 ± 0.1 (−1.6 to −1.2)	−1.07	2471	.29	NA	NA	NA
OFC	3.2 ± 0.1	−2.0 ± 0.2 (−2.3 to −1.6)	−3.35	2140	<.001	−2.67	2050	.008
10. Suicidal thoughts								
Placebo	1.9 ± 0.1	−0.9 ± 0.1 (−1.1 to −0.7)	NA	NA	NA	NA	NA	NA
Olanzapine	2.0 ± 0.1	−1.1 ± 0.1 (−1.3 to −0.9)	−1.68	2149	.09	NA	NA	NA
OFC	1.8 ± 0.1	−1.2 ± 0.2 (−1.5 to −0.9)	−1.69	1830	.09	−0.57	1753	.57

Abbreviations: CI, confidence interval; MADRS, Montgomery-Åsberg Depression Rating Scale; MMRM, mixed-effects model repeated-measures; NA, not applicable; OFC, olanzapine-fluoxetine combination.

*The MMRM analysis used a banded Toeplitz structure for the within-patient error covariance structure based on maximum Schwartz's Bayesian criterion for items 1, 3, 4, 5, 7, 8, 9, and 10 and a heterogeneous banded Toeplitz structure for the within-patient error covariance structure based on maximum Schwartz's Bayesian criterion for items 2 and 6.

(log-rank test $\chi^2_1=5.05$; $P=.02$) and again significantly shorter for the olanzapine-fluoxetine group compared with the placebo (log-rank test $\chi^2_1=17.95$; $P<.001$) and olanzapine (log-rank test $\chi^2_1=6.01$; $P=.01$) groups.

Analyses of the individual MADRS items are given in **Table 4**. The olanzapine and olanzapine-fluoxetine groups showed statistically significant improvements on inner tension, reduced sleep, and reduced appetite compared with the placebo group. In addition, the olanzapine-fluoxetine group showed statistically significant improvement on core mood items, including apparent sadness, reported sadness, lassitude, inability to feel, and pessimistic thoughts, compared with the olanzapine and placebo groups.

Analyses of the secondary measures of efficacy are given in **Table 5**. The olanzapine group showed greater mean improvement on the CGI-BP-S than the placebo group, and the olanzapine-fluoxetine group showed greater mean improvement than the placebo and olanzapine groups. In addition, the olanzapine and olanzapine-fluoxetine groups showed greater mean improvement on the HAM-A than the placebo group but were not significantly different from each other.

TREATMENT-EMERGENT MANIA

Treatment-emergent mania was defined as a YMRS score less than 15 at baseline and 15 or greater at any time thereafter. In all 3 groups, the incidence of treatment-emergent mania was low, and there were no statistically significant differences among groups ($P=.86$). Rates of treatment-emergent mania were 6.7% (23/345) for the

Table 5. Change in Scores From Baseline for Secondary Measures of Efficacy

Item and Treatment Group	Patients, No.	Mean ± SD Baseline Score	Change in Score, Mean ± SE (95% CI)	vs Placebo			vs Olanzapine		
				t Test	*df*	*P* Value	*t* Test	*df*	*P* Value
YMRS*									
Placebo	355	4.8 ± 4.6	−0.1 ± 0.3 (−0.8 to 0.6)	NA	NA	NA	NA	NA	NA
Olanzapine	351	5.0 ± 4.8	−1.4 ± 0.3 (−2.0 to −0.8)	−3.04	2170	.002	NA	NA	NA
OFC	82	5.0 ± 4.8	−1.9 ± 0.6 (−3.0 to −0.8)	−2.91	1868	.004	−0.88	1791	.38
CGI-BP-S*									
Placebo	355	4.8 ± 0.8	−1.2 ± 0.1 (−1.4 to −1.0)	NA	NA	NA	NA	NA	NA
Olanzapine	351	4.9 ± 0.8	−1.6 ± 0.1 (−1.8 to −1.4)	−2.90	575	.004	NA	NA	NA
OFC	82	4.8 ± 0.7	−2.2 ± 0.2 (−2.5 to −1.8)	−4.49	559	<.001	−2.57	553	.01
HAM-A†									
Placebo	315	16.7 ± 0.4	−3.5 ± 0.4 (−4.4 to −2.7)	NA	NA	NA	NA	NA	NA
Olanzapine	309	17.1 ± 0.4	−5.5 ± 0.4 (−6.4 to −4.6)	F = 31.1	1,685	.002	NA	NA	NA
OFC	71	15.8 ± 1.0	−7.0 ± 1.0 (−9.0 to −4.9)	F = 11.3	1,685	<.001	F = 2.0	1,685	.16

Abbreviations: CI, confidence interval; CGI-BP-S, Clinical Global Impressions Bipolar Version–Severity of Depression; HAM-A, Hamilton Anxiety Rating Scale; NA, not applicable; YMRS, Young Mania Rating Scale.

*Analyses use mixed-effects model repeated-measures (MMRM) and report mean change at week 8. The MMRM analysis used a banded Toeplitz structure for the YMRS and a heterogeneous banded Toeplitz for the CGI-BP-S for the within-patient error covariance structure based on maximum Schwartz's Bayesian Criterion for each.

†These data were collected at baseline and end point only; therefore, analyses use analysis of variance and report mean change at the patient's end point.

Table 6. Treatment-Emergent Adverse Events Reported by 10% or More of Patients in Any Group

Adverse Event	Patients, %			*P* Value		
	Olanzapine Group (n = 370)	OFC Group (n = 86)	Placebo Group (n = 377)	Olanzapine vs Placebo	OFC vs Placebo	Olanzapine vs OFC
Somnolence	28.1	20.9	12.5	<.001	.06	.22
Weight gain	17.3	17.4	2.7	<.001	<.001	>.99
Increased appetite	13.5	12.8	5.0	<.001	.01	>.99
Headache	12.4	14.0	18.6	.03	.35	.72
Dry mouth	11.1	16.3	6.1	.02	.004	.20
Nervousness	10.5	9.3	8.0	.26	.66	.84
Asthenia	9.7	12.8	3.2	<.001	<.001	.43
Insomnia	8.4	9.3	15.1	.005	.23	.83
Diarrhea	6.5	18.6	6.6	>.99	.001	.001
Nausea	4.3	11.6	8.8	.02	.41	.02

Abbreviation: OFC, olanzapine-fluoxetine combination.

placebo group, 5.7% (19/335) for the olanzapine group, and 6.4% (5/78) for the olanzapine-fluoxetine group. Mean change scores on the YMRS are reported in Table 5. Mean mania scores decreased significantly in the olanzapine and olanzapine-fluoxetine groups compared with the placebo group, with no significant difference between the olanzapine and olanzapine-fluoxetine groups.

SAFETY

Adverse events that emerged during the study or that were present at baseline and then worsened in severity were considered treatment emergent. **Table 6** lists treatment-emergent adverse events reported by 10% or more of patients in any treatment group. The adverse event profile for olanzapine-fluoxetine combination therapy was similar to that for olanzapine monotherapy but also included statistically significantly higher rates of nausea and diarrhea.

Mean change in and emergence of extrapyramidal symptoms were low, with no statistically significant differences across treatment groups. The percentage of patients who used anticholinergic medications at least once during the trial was statistically significantly greater in the olanzapine-fluoxetine group (8.1% [7/86]) compared with the olanzapine group (2.8% [10/360]; $P=.03$) but not the placebo group (3.7% [14/377]; $P=.09$).

Mean±SD weight gain was higher in treated patients than in those who received placebo (olanzapine vs placebo: 2.59±3.24 kg vs −0.47±2.62 kg, $F_{1,774}=194.36$, $P<.001$; olanzapine-fluoxetine vs placebo: 2.79±3.23 kg vs −0.47±2.62 kg, $F_{1,774}=80.87$, $P<.001$). Weight gain was not significantly different between the olanzapine and olanzapine-fluoxetine groups ($F_{1,774}=0.16$; $P=.69$). In addition, the percentage of patients who had a potentially clinically significant change in weight, defined as a 7% or greater increase from baseline, was significantly greater for the olanzapine (18.7% [65/347]) and olanzapine-fluoxetine (19.5% [16/82]) groups compared with the placebo group (0.3% [1/355]) ($P<.001$ for all) but did not differ between the olanzapine and olanzapine-fluoxetine groups ($P=.88$). In the olanzapine-fluoxetine group, 7.3% (6/82) of the patients had potentially clinically relevant orthostatic hypo-

tension, defined as a 30 mm Hg or greater decrease in systolic blood pressure from supine to standing. This percentage was significantly greater than that in the placebo (1.4% [5/352]; $P=.008$) and olanzapine (1.4% [5/346]; $P=.009$) groups. In addition, 4.9% (4/82) of the olanzapine-fluoxetine group had a potentially clinically relevant increase in high supine systolic blood pressure (≥180 mm Hg with an increase ≥20 mm Hg); this percentage was significantly greater than that in the olanzapine group (0.6% [2/349]; $P=.01$) but not that in the placebo group (1.7% [6/354]; $P=.10$). There were no clinically relevant QT prolongations. Only 2 women (1 in the placebo group and 1 in the olanzapine group) had treatment-emergent QTc intervals of 470 milliseconds or greater, and no men had treatment-emergent QTc of 450 milliseconds or greater (Fridericia corrected).

Mean±SD baseline cholesterol levels were high across all groups (207±47 mg/dL [5.35±1.21 mmol/L] for placebo, 206±46 mg/dL [5.34±1.18 mmol/L] for olanzapine, and 207±68 mg/dL [5.36±1.75 mmol/L] for olanzapine-fluoxetine) but increased significantly at the end point for the olanzapine (6±31 mg/dL [0.16±0.80 mmol/L]; $F_{1,667}=16.66$; $P<.001$) and olanzapine-fluoxetine (10±67 mg/dL [0.27±1.74 mmol/L]; $F_{1,667}=11.54$; $P<.001$) groups compared with the placebo group (−6±30 mg/dL (−0.15±0.78 mmol/L]), with no significant difference between the olanzapine and olanzapine-fluoxetine groups ($F_{1,667}=0.82$; $P=.37$). Mean±SD changes in nonfasting glucose levels were significantly higher for the olanzapine (4±30 mg/dL [0.2±1.7 mmol/L]; $F_{1,658}=5.41$; $P=.02$) and olanzapine-fluoxetine (6±40 mg/dL [0.3±2.2 mmol/L]; $F_{1,658}=9.99$; $P=.002$) groups compared with the placebo group (−4±26 mg/dL (−0.2±1.5 mmol/L]), with no significant difference between the olanzapine and olanzapine-fluoxetine groups ($F_{1,658}=0.16$; $P=.69$). The incidence of treatment-emergent glucose elevation of 200 mg/dL or greater (≥11.1 mmol/L) was 0.3% (1/298) for the placebo group, 1.4% (4/289) for the olanzapine group, and 1.5% (1/65) for the olanzapine-fluoxetine group. These percentages were not significantly different (overall $P=.30$).

COMMENT

To our knowledge, this is the first placebo-controlled trial comparing the use of an antipsychotic or mood-stabilizing agent alone and in combination with an antidepressant agent. Results indicate that olanzapine therapy significantly improved depressive symptoms in patients with bipolar depression and that the olanzapine-fluoxetine combination had an even more robust antidepressant effect without a greater risk of switch into mania. The reduction in depressive symptoms by both therapies was evident by week 1 of acute therapy and was maintained throughout the 8-week trial. The olanzapine-fluoxetine combination was statistically significantly superior in all efficacy measures of depression compared with olanzapine monotherapy, including higher completion rates, lower discontinuation rates due to adverse events, higher rates of response and remission, and quicker times to response and remission. Analysis of the individual items on the MADRS indicated that the olanzapine-fluoxetine combination, but not olanzapine, was effective at reducing core mood symptoms of depression.

Despite some methodological and sample differences, the present findings may be compared with those of a recent double-blind, placebo-controlled, 7-week study of lamotrigine therapy for bipolar I depression.[11] In that study, patients receiving lamotrigine had MADRS response rates of 48% to 54%, depending on dose, with a placebo response rate of 29%. The present study had response rates of 39% for olanzapine and 56% for olanzapine-fluoxetine, with a placebo response rate of 30%. Note, however, that the present study required at least 4 weeks of treatment to be eligible for response. Also, comparison of baseline illness characteristics indicates that the lamotrigine sample may have been less symptomatic, as indicated by fewer melancholic patients, no inpatients, and no patients with a rapid cycling course.

Divalproex sodium, another anticonvulsant agent known to be effective in treating bipolar mania,[32,33] has also been studied in bipolar depression. In an 8-week, double-blind pilot study of bipolar I and II patients with major depression, Sachs and collaborators[34] found that patients treated with divalproex had a recovery rate of 43% compared with the placebo rate of 27%, with recovery defined as a 50% improvement on the Hamilton Depression Rating Scale and a YMRS score less than 10. However, this difference was not statistically significant.

Regarding the possibility of treatment-emergent mania, the present findings indicate no additional risk when fluoxetine was added to olanzapine therapy. Mean ratings of manic symptoms, which were low at baseline, showed small (not clinically meaningful) but statistically significant improvement in patients treated with olanzapine and olanzapine-fluoxetine compared with placebo. Moreover, there were no significant differences in the incidences of treatment-emergent mania among the 3 groups. Lastly, the rates of treatment-emergent mania reported in this study approximate those reported previously for placebo[11,35] and are lower than rates reported with tricyclic antidepressant use.[35]

In terms of safety, the olanzapine adverse event profile was consistent with previously reported findings,[36,37] whereas the olanzapine-fluoxetine profile was similar to that of olanzapine, except for higher rates of nausea and diarrhea. Mean weight increases of 2.6 and 2.8 kg were noted in patients treated with olanzapine and olanzapine-fluoxetine, respectively, and small but statistically significant mean increases in glucose and cholesterol levels were also seen.

One question raised by the present findings is whether similar results could be achieved by using other atypical antipsychotic agents, such as risperidone or quetiapine, in combination with a selective serotonin reuptake inhibitor or other antidepressants. Controlled clinical trials are needed to determine the therapeutic efficacy of different combinations. The safety of such combinations must be considered as well.

Limitations of the present study should be noted when interpreting the results. One limitation was the high overall dropout rate. Although the present rates were in line with those of a previous 6-week study[38] of bipolar depression, which reported a placebo group completion

rate of 34% (compared with 38.5% in the present 8-week study), this is in direct contrast to the placebo group completion rate of 71% in the 7-week lamotrigine study,[11] which may have had a less severe and more stable population given that rapid cyclers were excluded. Nevertheless, examination of the current between-group differences in dropout due to lack of efficacy is informative. The higher rate of dropout due to lack of antidepressant efficacy with olanzapine monotherapy suggests that although this treatment may be effective for some patients, the addition of an appropriately tested antidepressant drug may be warranted for others. Another limitation was the lack of a fluoxetine monotherapy comparison arm because of concerns regarding possible induction of mania. Future studies might also more thoroughly address the issue of patients' baseline proneness to mania. For example, the present finding that the addition of fluoxetine did not increase the risk of mania would be further strengthened by similar findings in a bipolar I depressed population specifically selected for recent manic episodes. Studies with longer durations are necessary to evaluate maintenance of response and to determine the safety and efficacy of olanzapine monotherapy after treatment with olanzapine-fluoxetine combination therapy. Also, head-to-head controlled trials would be useful to establish how the efficacy of this combination compares with that of lamotrigine or other putative combination treatments for bipolar depression.

In summary, the results of this study suggest that although olanzapine may be effective in the treatment of bipolar depression, these effects are significantly enhanced with the coadministration of fluoxetine. In addition, patients receiving such combination therapy did not demonstrate any higher likelihood of treatment-emergent mania. The roles of olanzapine and olanzapine-fluoxetine, as well as other combinations of antidepressants with lithium, anticonvulsants, or atypical antipsychotics, in the longer-term treatment of patients with bipolar disorder should be further evaluated in controlled studies.

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A Rating Scale for Mania: Reliability, Validity and Sensitivity*

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SUMMARY An eleven item clinician-administered Mania Rating Scale (MRS) is introduced, and its reliability, validity and sensitivity are examined. There was a high correlation between the scores of two independent clinicians on both the total score (0.93) and the individual item scores (0.66 to 0.92). The MRS score correlated highly with an independent global rating, and with scores of two other mania rating scales administered concurrently. The score also correlated with the number of days of subsequent stay in hospital. It was able to differentiate statistically patients before and after two weeks of treatment and to distinguish levels of severity based on the global rating.

Introduction

While several rating scales are available to quantitate the severity of depression (Hamilton, 1960, 1976), there is a less satisfactory choice of instruments for the rating of mania. Treatment studies of mania frequently employ a global rating combined with a non-specific scale such as the Brief Psychiatric Rating Scale (Overall and Gorham, 1962). Dissatisfaction with the results of this type of rating procedure has been expressed (Shopsin *et al*, 1975).

Attempts to devise a specific scale for quantitating the severity of mania have been limited. Beigel *et al* (1971) reported a ward behaviour rating scale for mania (Beigel Scale) intended to be completed by nursing personnel. This scale consists of twenty-six items. A frequency score (0 to 5) and an intensity score (1 to 5) are assigned separately, and the individual item score is the product of these ratings. The reliability and validity of the scale have been examined in detail by its developers (Beigel and Murphy, 1971; Murphy *et al*, 1974). Bech *et al* (1975) reported on its use both as a ward rating scale and as a clinician-administered interview scale. It has also been utilized in a treatment study (Murphy and Beigel, 1974). Blackburn *et al* (1977) have recently modified the Beigel Scale for interview use, expanding it to twenty-eight items.

Petterson *et al* (1973) reported a clinician-administered interview scale for mania (Petterson Scale) consisting of seven items, each scored on a one to five scale of severity. The Petterson Scale evaluates a more narrow range of abnormal signs and symptoms than the Beigel Scale but gives explicit definitions for the various grades of severity within each item. The Petterson Scale appears to sacrifice breadth for potentially greater inter-rater agreement, particularly between centres.

Experience with these scales has indicated the need for a clinician-administered interview scale with broader scope and greater sensitivity than the Petterson Scale, but shorter and more explicit in its rating of item severity than the Beigel Scale. The Mania Rating Scale (MRS) reported here (Appendix) consists of eleven items, each with five explicitly defined grades of severity. The choice of items was made on the basis of published descriptions of the core symptoms of the manic phase of bipolar affective disorder (Winokur *et al*, 1969; Carlson and Goodwin, 1973) and includes those abnormalities which were felt to exist over the entire range

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of illness from mild to severe. Depressive symptoms, although frequently present in mania, were omitted, since previous reports (Beigel *et al*, 1971; Blackburn *et al*, 1977) have shown them to be poorly correlated with the severity of mania.

The MRS follows the style of the Hamilton Rating Scale for depression (Hamilton, 1960) and is intended to be administered by a trained clinician during a fifteen- to thirty-minute interview. A severity rating is assigned to each of the eleven items, based on the patient's subjective report of his or her condition over the previous forty-eight hours and the clinician's behavioural observations during the interview, with the emphasis on the latter. Four items (5, 6, 8 and 9) are given twice the weight of the remaining seven in order to compensate for poor cooperation from severely ill patients. This report introduces the MRS and examines its reliability, validity and sensitivity.

Method

The MRS was examined by paired evaluations of manic patients on several measures during an eight-hour period. Two psychiatrists (R.Y. and J.B.) trained in the use of the MRS and the Petterson Scale administered both scales independently during a joint fifteen- to thirty-minute semi-structured interview with the patient. Two independent psychiatrists (V.Z. and D.M.) assigned a global rating after a joint unstructured interview of similar duration. An eight-point global rating was used (euthymic 0, 1; hypomanic, 2, 3; manic, 4, 5; severely manic, 6, 7). Members of the hospital nursing staff were trained in the use of the Beigel Scale, and on the day of evaluation two nurses completed this scale independently, based on their observations over an eight-hour period. The training period for the two psychiatrists who administered the MRS and the Petterson Scale consisted of six practice interviews, each followed by a discussion between the interviewers of the ratings assigned.

During a three-month period, all adult patients admitted to Renard Hospital, the teaching hospital of Washington University, were evaluated. Consecutive patients meeting research criteria for the diagnosis of mania (Feighner *et al*, 1972) were asked to participate in the study. No patient refused to participate. Twenty patients were evaluated during their first week in hospital, and fifteen of these were re-evaluated two weeks after the initial interview. In the interval, patients were treated in an uncontrolled manner by their individual psychiatrists, who were unaware of the scores. The usual treatment consisted of a combination of lithium carbonate and neuroleptics. A total of thirty-five sets of ratings was obtained. The number of days from each rating to discharge was noted, and thirty days after discharge the patient was followed up to determine if re-admission had been necessary.

Since rating scales yield ordinal level measures, non-parametric statistics (Spearman rank-order correlation coefficient, Kruskal-Wallis one-way analysis of variance, and the Mann-Whitney U Test) were used throughout the analysis (Siegel, 1956). All probabilities are two-tailed.

Results

Reliability

The inter-rater reliability of the MRS was examined by comparing the scores assigned by the two physicians independently administering the scale during a joint interview. These correlations for the total score and the individual item scores of the MRS are given in Table I along with the inter-rater reliability of the global rating, the Petterson Scale, and the Beigel Scale. The lower correlation between the two nurses completing the Beigel Scale is expected, since 12 members of the nursing staff participated in the study, thus introducing more variation in the completion of the scale. The correlation between the total scores on the MRS was 0.93 and ranged from 0.66 for item 9, disruptive-aggressive behaviour, to 0.95 for item 4, sleep. All correlations were significant at the 0.001 level.

Validity

The concurrent validity was examined by correlating the mean score of the two raters completing each scale with the mean scores of the other scales. These correlations are given in Table II. All were significant at the 0.001 level. The total scores on the MRS correlated

TABLE I

Interrater reliability. Spearman rank-order correlation coefficient (r_s) between the two raters for each scale and for the individual items of the MRS ($N = 35$)

Scale	Correlation (r_s)*
Global rating	0.77
Beigel scale	0.60
Petterson scale	0.88
Mania rating scale	0.93
Individual items of MRS	
1. Mood	0.80
2. Energy	0.72
3. Sexual interest	0.92
4. Sleep	0.95
5. Irritability	0.75
6. Speech	0.83
7. Language-Thought disorder	0.72
8. Content	0.92
9. Disruptive-Aggressive behaviour	0.66
10. Appearance	0.67
11. Insight	0.92

*P < 0.001 for all correlations

highly with the global rating (0.88) and the Petterson Scale (0.89). The correlation with the Beigel scale, although of a lower magnitude (0.71), was acceptable. The correlation between the global rating and the MRS score for the twenty initial interviews was 0.86 (P < 0.001) and for the fifteen repeated interviews was 0.53 (P < 0.05). The lower correlation for the repeated interviews is a reflection of the more narrow range of scores.

TABLE II

Spearman rank-order correlation coefficient between the various rating scales ($N = 35$)

Ratings	Global	Beigel	Petterson
Mania rating scale	0.88	0.71	0.89
Petterson scale	0.80	0.65	—
Beigel scale	0.66	—	—

P < 0.001 for all correlations

The correlations between the change in the global rating and the changes in the various scales were calculated for the fifteen patients rated on two occasions. This correlation was 0.76 (P < 0.05) for the MRS, 0.80 (P < 0.01) for the Petterson Scale, and 0.54 (P < 0.05) for the Beigel Scale.

The correlations between the individual items of the MRS and the total MRS score and the global rating are given in Table III. The correlations between the item scores and the total score ranged from 0.41 for item 10, appearance, to 0.85 for item 7, language-thought disorder. The correlations between the item scores and the global rating ranged from 0.32 for item 10, appearance, to 0.85 for item 7, language-thought disorder.

TABLE III

Spearman rank-order correlation coefficient (r_s) of the individual items of the Mania Rating Scale (MRS) with the total score and the global rating ($N = 35$)

Individual MRS item with:	Total MRS score*	Global score*
1. Mood	0.76	0.75
2. Energy	0.84	0.79
3. Sexual interest	0.69	0.67
4. Sleep	0.59	0.61
5. Irritability	0.56	0.39
6. Speech	0.64	0.60
7. Language-Thought disorder	0.85	0.85
8. Content	0.84	0.77
9. Disruptive-Aggressive behaviour	0.64	0.43
10. Appearance	0.41	0.32
11. Insight	0.57	0.40

*$r_s \geq 0.35$, P < 0.050 $r_s \geq 0.45$, P < 0.01; $r_s \geq 0.56$, P < 0.001

The predictive validity of the various scales was examined by correlating the scores with the number of days of continued stay in hospital following completion of the scale. This correlation was 0.66 (P < 0.001) for the MRS, 0.58 (P < 0.001) for the Beigel Scale and 0.50 (P < 0.01) for the Petterson Scale. Two of the three patients with total MRS scores greater than 15.0 who were discharged within one week of being rated were readmitted within thirty days. None of the patients with lower MRS scores, discharged within one week, were re-admitted during this interval.

Sensitivity

The sensitivity of the various scales was examined by comparing the scores before and after two weeks of treatment, for the 15 patients on whom these ratings were available, by the Mann-Whitney U Test. The MRS differentiated the pre-treatment and post-treatment scores at the 0.005 level, as did the Petterson Scale and the Beigel Scale. The pre-treatment and post-treatment scores on the three scales were not significantly correlated (MRS, 0.05; Petterson, 0.31; Beigel, 0.35).

A more rigorous test of sensitivity of the MRS was undertaken by dividing the 35 sets of ratings into four groups based on the severity of the global rating, with sample sizes as equal as possible. The ability of the MRS to differentiate these four groups overall and from adjacent severity levels was then examined and compared to that of the Petterson and Beigel Scales. The median scores on each of the four severity groups and the results of the Kruskal-Wallis one-way analysis of variance are given in Table IV. The distributions of all three scales were significant at the 0.001 level. The ability of each scale to differentiate each severity level from adjacent levels by the Mann-Whitney U Test was then examined. These results are given in Table V. The Petterson Scale did poorly in the mild range and the Beigel Scale in the mid-severity range. The MRS was the most consistent of the three scales over the entire range of severity.

TABLE V

Sensitivity of the three scales in differentiating a severity level based on the global rating, from adjacent levels

Severity levels to be differentiated (Global)	Probability of the differentiation	
	Scale	p*
I (0 to 1.5) from II (2.0 to 2.5)	Mania rating scale	<0.070
	Petterson scale	<0.960
	Beigel scale	<0.016
II (2.0 to 2.5) from III (3.0 to 4.0)	Mania rating scale	<0.021
	Petterson scale	<0.012
	Beigel scale	<0.562
III (3.0 to 4.0) from IV (>4.0)	Mania rating scale	<0.003
	Petterson scale	<0.004
	Beigel scale	<0.004

*By the Mann-Whitney U test.

To examine the effect of weighting four (5, 6, 8 and 9) of the eleven items of the MRS twice as heavily as the remaining items, the analysis presented was repeated without the weighting. Only minor variations occurred, none of which affected the reliability, validity or sensitivity of the MRS. This was because only a few of the patients rated in this study were severely agitated. If more had fallen into this category the advantage of the weighted items would have become evident. This is based on experience during the development of the scale, when a minority of patients with acute mania

TABLE IV

Median rating scale scores of the patients grouped by the global severity and the probabilities of the distributions

	Severity by global rating				
	I	II	III	IV	
Global Rating	0—1.5	2.0—2.5	3.0—4.0	>4.0	
N	11	7	11	6	p*
Mania rating scale	12.5	19.3	25.5	37.9	<0.001
Petterson scale	12.5	11.8	16.5	22.0	<0.001
Beigel scale	31.0	80.0	59.3	161.8	<0.001

* By the Kruskal-Wallis one-way analysis of variance.

were found to be so severely agitated that the usual semi-structured interview was impossible. The weighting allowed these patients to be rated in an abbreviated manner while still yielding scores representative of the severity of mania present.

Discussion

The MRS was found to be a reliable, valid and sensitive rating scale to measure the severity of mania by the criteria for psychiatric rating scales discussed by Hamilton (1974). The scale appears to function over the entire range of severity and is sensitive to differences in severity in sample sizes similar to those found in treatment or biological studies. The scale is not intended to be used as a diagnostic instrument. It appears to measure the manic 'state', as opposed to traits, since there was virtually no correlation between scores in individuals rated before and after two weeks of treatment.

The MRS should have a high degree of inter-centre reliability, since specific instructions are given for scoring the severity of each item. In a separate procedure this characteristic was examined. Nine psychiatric residents participated in one of two group interviews with the same patient on the same day. Each completed the MRS without exposure to the scale prior to the interview. The scores assigned by the nine residents ranged from 10 to 22 with a mean of 14.5 and a standard deviation of 3.3. These results were felt to support the communicability of the MRS.

There has been a limited selection of rating scales with which to evaluate mania. While the two existing mania scales function reasonably well, the MRS adds a broader and more sensitive instrument than the Petterson Scale and is both shorter and more explicitly defined than the Beigel Scale or its modified versions.

The usual practice in psychopharmacological studies has been to use a number of different scales with a central focus to measure various aspects of behaviour, such as the use of both self-rating and clinician-administered scales in depression studies. In studies where the quantification of the severity of mania is required, the combined use of a ward behaviour scale, such as the Beigel Scale, and a clinician-administered interview scale is recommended.

Acknowledgements

We wish to express our appreciation to the nursing staff of Renard Hospital and to Ms Patricia Stanfield, R.N., in particular, for their assistance in this project.

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Appendix: Mania Rating Scale

Guide for Scoring Items—The purpose of each item is to rate the severity of that abnormality in the patient. When several keys are given for a particular grade of severity, the presence of only one is required to qualify for that rating.

The keys provided are guides. One can ignore the keys if that is necessary to indicate severity, although this should be the exception rather than the rule.

Scoring between the points given (whole or half points) is possible and encouraged after experience with the scale is acquired. This is particularly useful when severity of a particular item in a patient does not follow the progression indicated by the keys.

1. *Elevated Mood*
   0. Absent
   1. Mildly or possibly increased on questioning
   2. Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content
   3. Elevated, inappropriate to content; humorous
   4. Euphoric; inappropriate laughter; singing

2. *Increased Motor Activity-Energy*
   0. Absent
   1. Subjectively increased
   2. Animated; gestures increased
   3. Excessive energy; hyperactive at times; restless (can be calmed)
   4. Motor excitement; continuous hyperactivity (cannot be calmed)

3. *Sexual Interest*
   0. Normal; not increased
   1. Mildly or possibly increased
   2. Definite subjective increase on questioning
   3. Spontaneous sexual content; elaborates on sexual matters; hypersexual by self-report
   4. Overt sexual acts (toward patients, staff, or interviewer)

4. *Sleep*
   0. Reports no decrease in sleep
   1. Sleeping less than normal amount by up to one hour
   2. Sleeping less than normal by more than one hour
   3. Reports decreased need for sleep
   4. Denies need for sleep

5. *Irritability*
   0. Absent
   2. Subjectively increased
   4. Irritable at times during interview; recent episodes of anger or annoyance on ward
   6. Frequently irritable during interview; short, curt throughout
   8. Hostile, unco-operative; interview impossible.

6. *Speech (Rate and Amount)*
   0. No increase
   2. Feels talkative
   4. Increased rate or amount at times, verbose at times
   6. Push; consistently increased rate and amount; difficult to interrupt
   8. Pressured; uninterruptible, continuous speech

7. *Language-Thought Disorder*
   0. Absent
   1. Circumstantial; mild distractibility; quick thoughts
   2. Distractible; loses goal of thought; changes topics frequently; racing thoughts
   3. Flight of ideas; tangentiality; difficult to follow; rhyming, echolalia
   4. Incoherent; communication impossible

8. *Content*
   0. Normal
   2. Questionable plans, new interests
   4. Special project(s); hyperreligious
   6. Grandiose or paranoid ideas; ideas of reference
   8. Delusions; hallucinations

9. *Disruptive-Aggressive Behaviour*
   0. Absent, co-operative
   2. Sarcastic; loud at times, guarded
   4. Demanding; threats on ward
   6. Threatens interviewer; shouting; interview difficult
   8. Assaultive; destructive; interview impossible

10. *Appearance*
    0. Appropriate dress and grooming
    1. Minimally unkempt
    2. Poorly groomed; moderately dishevelled; overdressed
    3. Dishevelled; partly clothed; garish make-up
    4. Completely unkempt; decorated; bizarre garb

11. *Insight*
    0. Present; admits illness; agrees with need for treatment
    1. Possibly ill
    2. Admits behaviour change, but denies illness
    3. Admits possible change in behaviour, but denies illness
    4. Denies any behaviour change

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AstraZeneca

Clinical Study Report: Appendix 12.2

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.2
Subject data listings

Appendix 12.2 Subject Data Listings

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Clinical Study Report: Appendix 12.2.1

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.1
Disposition of each subject

Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0001003	PROTOCOL/NONCOMPLIANCE	
	E0002002	PROTOCOL/NONCOMPLIANCE	
	E0002005	PROTOCOL/NONCOMPLIANCE	
	E0002013	PROTOCOL/NONCOMPLIANCE	
	E0002014	PROTOCOL/NONCOMPLIANCE	
	E0002017	OTHER	
	E0003001	PROTOCOL/NONCOMPLIANCE	
	E0003003	PROTOCOL/NONCOMPLIANCE	
	E0003006	PROTOCOL/NONCOMPLIANCE	
	E0003012	INFORMED CONSENT WITHDRAW	REASON FOR STUDY TERMINATION SIC PAGE 213
	E0003013	PROTOCOL/NONCOMPLIANCE	
	E0003014	PROTOCOL/NONCOMPLIANCE	
	E0003017	PROTOCOL/NONCOMPLIANCE	
	E0003021	LOST TO FOLLOW-UP	
	E0004008	LOST TO FOLLOW-UP	
	E0004010	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0004011	PROTOCOL/NONCOMPLIANCE	
	E0004014	PROTOCOL/NONCOMPLIANCE	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM100.SAS
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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0004017	PROTOCOL/NONCOMPLIANCE	
	E0004022	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0004023	PROTOCOL/NONCOMPLIANCE	
	E0005001	LOST TO FOLLOW-UP	
	E0005015	PROTOCOL/NONCOMPLIANCE	
	E0005018	PROTOCOL/NONCOMPLIANCE	
	E0005021	INFORMED CONSENT WITHDRAW	
	E0005028	PROTOCOL/NONCOMPLIANCE	
	E0005032	PROTOCOL/NONCOMPLIANCE	
	E0005035	LOST TO FOLLOW-UP	
	E0006011	PROTOCOL/NONCOMPLIANCE	
	E0007002	PROTOCOL/NONCOMPLIANCE	
	E0007014	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0009005	LOST TO FOLLOW-UP	DATE SIC DATE OF LAST CONTACT WITH SUBJECT. PAGE 213
	E0010001	INFORMED CONSENT WITHDRAW	
	E0010003	INFORMED CONSENT WITHDRAW	INFORMED CONSENT SIC PAGE 213
	E0010007	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0010011	PROTOCOL/NONCOMPLIANCE	
	E0010013	PROTOCOL/NONCOMPLIANCE	
	E0010022	LOST TO FOLLOW-UP	
	E0010025	PROTOCOL/NONCOMPLIANCE	
	E0010030	LOST TO FOLLOW-UP	
	E0010031	LOST TO FOLLOW-UP	
	E0010033	OTHER	
	E0011003	PROTOCOL/NONCOMPLIANCE	
	E0011005	PROTOCOL/NONCOMPLIANCE	
	E0011006	INFORMED CONSENT WITHDRAW	INFORMED CONSENT SIC PAGE 213
	E0011017	PROTOCOL/NONCOMPLIANCE	
	E0013004	PROTOCOL/NONCOMPLIANCE	
	E0013010	INFORMED CONSENT WITHDRAW	
	E0014003	PROTOCOL/NONCOMPLIANCE	
	E0014008	PROTOCOL/NONCOMPLIANCE	
	E0015009	PROTOCOL/NONCOMPLIANCE	
	E0015010	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0016002	ADVERSE EVENT	
	E0018004	PROTOCOL/NONCOMPLIANCE	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0018008	PROTOCOL/NONCOMPLIANCE	
	E0018011	PROTOCOL/NONCOMPLIANCE	
	E0018016	PROTOCOL/NONCOMPLIANCE	
	E0018017	PROTOCOL/NONCOMPLIANCE	
	E0018018	INFORMED CONSENT WITHDRAW	
	E0019001	LOST TO FOLLOW-UP	
	E0019023	LOST TO FOLLOW-UP	
	E0020003	LOST TO FOLLOW-UP	
	E0020005	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN PATIENT MOVED TO ANOTHER STATE. PAGE 213
	E0020008	PROTOCOL/NONCOMPLIANCE	
	E0020009	PROTOCOL/NONCOMPLIANCE	
	E0020012	LOST TO FOLLOW-UP	
	E0020016	LOST TO FOLLOW-UP	
	E0020018	INFORMED CONSENT WITHDRAW	
	E0022002	INFORMED CONSENT WITHDRAW	
	E0022009	PROTOCOL/NONCOMPLIANCE	
	E0022013	OTHER	
	E0022014	PROTOCOL/NONCOMPLIANCE	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0022021	INFORMED CONSENT WITHDRAW	
	E0022026	INFORMED CONSENT WITHDRAW	
	E0022028	INFORMED CONSENT WITHDRAW	INFORMED CONSENT SIC PAGE 213
	E0022037	LOST TO FOLLOW-UP	
	E0022040	PROTOCOL/NONCOMPLIANCE	
	E0022049	INFORMED CONSENT WITHDRAW	
	E0022050	INFORMED CONSENT WITHDRAW	
	E0022055	PROTOCOL/NONCOMPLIANCE	
	E0022057	LOST TO FOLLOW-UP	
	E0022066	PROTOCOL/NONCOMPLIANCE	
	E0022067	PROTOCOL/NONCOMPLIANCE	
	E0022072	INFORMED CONSENT WITHDRAW	
	E0022074	LOST TO FOLLOW-UP	
	E0023005	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0023024	LOST TO FOLLOW-UP	
	E0023026	LOST TO FOLLOW-UP	
	E0024001	PROTOCOL/NONCOMPLIANCE	
	E0025003	INFORMED CONSENT WITHDRAW	REASON FOR STUDY TERMINATION SIC PAGE 213

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0026011	PROTOCOL/NONCOMPLIANCE	
	E0026026	PROTOCOL/NONCOMPLIANCE	
	E0027001	PROTOCOL/NONCOMPLIANCE	
	E0027002	PROTOCOL/NONCOMPLIANCE	
	E0027009	LOST TO FOLLOW-UP	
	E0027010	ADVERSE EVENT	
	E0027012	PROTOCOL/NONCOMPLIANCE	
	E0027014	LOST TO FOLLOW-UP	
	E0027015	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW - UP SUBJECT WAS SCHEDULED FOR RETURN VISIT FOR URINE DRUG SCREEN BUT WAS SUBSEQUENTLY LOST TO FOLLOW - UP PAGE 213
	E0028002	PROTOCOL/NONCOMPLIANCE	
	E0028013	LOST TO FOLLOW-UP	SUBJECT DID NOT COMPLETE SCREEN-SUBJECT DID NOT RETURN FOR REPEAT UDS
	E0028014	LOST TO FOLLOW-UP	SUBJECT DID NOT COMPLETE SCREEN VISIT - SUBJECT DID NOT RETURN FOR REPEAT UDS
	E0028018	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SUBJECT DID NOT COMPLETE SCREEN; DID NOT RETURN FOR REPEAT UDS PAGE 213
	E0028020	LOST TO FOLLOW-UP	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM100.SAS
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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0028021	PROTOCOL/NONCOMPLIANCE	
	E0028022	PROTOCOL/NONCOMPLIANCE	
	E0028024	LOST TO FOLLOW-UP	
	E0028026	PROTOCOL/NONCOMPLIANCE	
	E0028036	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW - UP SIC, PT TESTED POSITIVE FOR CANNABINOIDS AND DID NOT RETURN FOR RETEST PAGE 213
	E0028040	LOST TO FOLLOW-UP	
	E0028042	LOST TO FOLLOW-UP	
	E0029006	PROTOCOL/NONCOMPLIANCE	
	E0029007	PROTOCOL/NONCOMPLIANCE	
	E0029010	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0029022	PROTOCOL/NONCOMPLIANCE	
	E0029027	PROTOCOL/NONCOMPLIANCE	
	E0029029	PROTOCOL/NONCOMPLIANCE	
	E0029034	PROTOCOL/NONCOMPLIANCE	
	E0030002	PROTOCOL/NONCOMPLIANCE	
	E0030004	PROTOCOL/NONCOMPLIANCE	
	E0030010	LOST TO FOLLOW-UP	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0030012	PROTOCOL/NONCOMPLIANCE	
	E0030013	PROTOCOL/NONCOMPLIANCE	
	E0030018	PROTOCOL/NONCOMPLIANCE	
	E0030023	OTHER	
	E0031007	LOST TO FOLLOW-UP	
	E0031012	PROTOCOL/NONCOMPLIANCE	
	E0031014	PROTOCOL/NONCOMPLIANCE	
	E0031025	PROTOCOL/NONCOMPLIANCE	
	E0031026	PROTOCOL/NONCOMPLIANCE	
	E0033017	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0033020	LOST TO FOLLOW-UP	
	E0035008	LOST TO FOLLOW-UP	
	E0035012	PROTOCOL/NONCOMPLIANCE	
	E0035017	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW - UP SIC PAGE 213
	E0035018	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0035019	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0035025	PROTOCOL/NONCOMPLIANCE	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0036003	PROTOCOL/NONCOMPLIANCE	
	E0036004	PROTOCOL/NONCOMPLIANCE	
	E0037001	PROTOCOL/NONCOMPLIANCE	
	E0037008	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE213
	E0037010	LOST TO FOLLOW-UP	
	E0039002	PROTOCOL/NONCOMPLIANCE	
	E0039005	PROTOCOL/NONCOMPLIANCE	
	E0039008	OTHER	
	E0039009	PROTOCOL/NONCOMPLIANCE	
	E0039010	ADVERSE EVENT	
	E0039013	PROTOCOL/NONCOMPLIANCE	
	E0039014	PROTOCOL/NONCOMPLIANCE	
	E0039016	PROTOCOL/NONCOMPLIANCE	DATE SIC PAGE 213
	E0039017	INFORMED CONSENT WITHDRAW	
	E0039020	PROTOCOL/NONCOMPLIANCE	
	E0039021	PROTOCOL/NONCOMPLIANCE	
	E0039027	PROTOCOL/NONCOMPLIANCE	
	E0039029	PROTOCOL/NONCOMPLIANCE	
	E0039033	PROTOCOL/NONCOMPLIANCE	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR I)	E0039035	PROTOCOL/NONCOMPLIANCE	
	E0039036	PROTOCOL/NONCOMPLIANCE	
	E0039039	PROTOCOL/NONCOMPLIANCE	
	E0039045	PROTOCOL/NONCOMPLIANCE	
	E0039048	PROTOCOL/NONCOMPLIANCE	
	E0039049	LOST TO FOLLOW-UP	
	E0039050	PROTOCOL/NONCOMPLIANCE	DATE STUDY COMPLETED SIC PAGE 213
	E0039054	PROTOCOL/NONCOMPLIANCE	DATE STUDY COMPLETED SIC PAGE 213
	E0039055	OTHER	
	E0039058	PROTOCOL/NONCOMPLIANCE	
	E0039060	OTHER	
	E0041006	LOST TO FOLLOW-UP	

Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR II)	E0001001	PROTOCOL/NONCOMPLIANCE	
	E0001005	PROTOCOL/NONCOMPLIANCE	
	E0005020	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0005029	PROTOCOL/NONCOMPLIANCE	DATE STUDY COMPLETED SIC PAGE 213
	E0006009	PROTOCOL/NONCOMPLIANCE	
	E0007007	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0007011	PROTOCOL/NONCOMPLIANCE	
	E0009003	PROTOCOL/NONCOMPLIANCE	
	E0009013	PROTOCOL/NONCOMPLIANCE	
	E0010006	LOST TO FOLLOW-UP	DATE SIC PAGE 213
	E0010026	LOST TO FOLLOW-UP	TERMAW SUBJECT TESTED POSITIVE FOR CANNABINOIDS, SUBSEQUENTLY WAS LOST TO FOLLOW - UP PRIOR TO OBTAINING RETEST. PAGE 213
	E0011012	INFORMED CONSENT WITHDRAW	INFORMED CONSENT SIC PAGE 213
	E0011015	LOST TO FOLLOW-UP	SUBJECT HAD POSITIVE UDS FOR COCAINE AND OPIATES BUT WAS LOST TO FOLLOW - UP BEFORE REPEAT UDS COULD BE PERFORMED.
	E0011019	PROTOCOL/NONCOMPLIANCE	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR II)	E0011023	INFORMED CONSENT WITHDRAW	
	E0011026	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0013002	INFORMED CONSENT WITHDRAW	
	E0013011	LOST TO FOLLOW-UP	
	E0013015	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0015006	PROTOCOL/NONCOMPLIANCE	
	E0015007	INFORMED CONSENT WITHDRAW	STUDY TERMINATION REASON 5, SIC PAGE 213
	E0017001	LOST TO FOLLOW-UP	
	E0019006	LOST TO FOLLOW-UP	
	E0019013	PROTOCOL/NONCOMPLIANCE	
	E0019017	PROTOCOL/NONCOMPLIANCE	
	E0019029	PROTOCOL/NONCOMPLIANCE	
	E0019030	PROTOCOL/NONCOMPLIANCE	
	E0019044	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0019050	PROTOCOL/NONCOMPLIANCE	
	E0020002	INFORMED CONSENT WITHDRAW	
	E0020019	PROTOCOL/NONCOMPLIANCE	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR II)	E0021001	PROTOCOL/NONCOMPLIANCE	
	E0022003	LOST TO FOLLOW-UP	
	E0022024	PROTOCOL/NONCOMPLIANCE	
	E0022045	ADVERSE EVENT	
	E0023004	LOST TO FOLLOW-UP	
	E0023032	PROTOCOL/NONCOMPLIANCE	
	E0023035	LOST TO FOLLOW-UP	
	E0023042	INFORMED CONSENT WITHDRAW	
	E0023048	PROTOCOL/NONCOMPLIANCE	
	E0026008	LOST TO FOLLOW-UP	
	E0026016	LOST TO FOLLOW-UP	
	E0027007	INFORMED CONSENT WITHDRAW	
	E0027011	INFORMED CONSENT WITHDRAW	
	E0027013	PROTOCOL/NONCOMPLIANCE	
	E0027017	PROTOCOL/NONCOMPLIANCE	
	E0027019	PROTOCOL/NONCOMPLIANCE	
	E0028012	PROTOCOL/NONCOMPLIANCE	
	E0028015	INFORMED CONSENT WITHDRAW	SUBJECT DID NOT COMPLETE SCREEN
	E0029017	LOST TO FOLLOW-UP	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR II)	E0029025	PROTOCOL/NONCOMPLIANCE	
	E0029031	PROTOCOL/NONCOMPLIANCE	
	E0029035	PROTOCOL/NONCOMPLIANCE	
	E0030005	PROTOCOL/NONCOMPLIANCE	
	E0030017	INFORMED CONSENT WITHDRAW	
	E0030019	LOST TO FOLLOW-UP	
	E0031009	PROTOCOL/NONCOMPLIANCE	
	E0031024	LOST TO FOLLOW-UP	
	E0031028	PROTOCOL/NONCOMPLIANCE	
	E0033003	INFORMED CONSENT WITHDRAW	
	E0033005	LOST TO FOLLOW-UP	
	E0033008	LOST TO FOLLOW-UP	
	E0033011	INFORMED CONSENT WITHDRAW	
	E0033018	PROTOCOL/NONCOMPLIANCE	
	E0033019	PROTOCOL/NONCOMPLIANCE	
	E0034005	PROTOCOL/NONCOMPLIANCE	
	E0034010	PROTOCOL/NONCOMPLIANCE	
	E0037011	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW - UP SIC PAGE 213
	E0039001	ADVERSE EVENT	DATE SIC PAGE 213

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM100.SAS
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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE (BIPOLAR II)	E0039004	PROTOCOL/NONCOMPLIANCE	
	E0041001	ADVERSE EVENT	

Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE ( )	E0002007	PROTOCOL/NONCOMPLIANCE	
	E0003009	PROTOCOL/NONCOMPLIANCE	
	E0004004	PROTOCOL/NONCOMPLIANCE	
	E0004005	PROTOCOL/NONCOMPLIANCE	
	E0004007	PROTOCOL/NONCOMPLIANCE	
	E0004019	PROTOCOL/NONCOMPLIANCE	
	E0004020	PROTOCOL/NONCOMPLIANCE	
	E0005016	PROTOCOL/NONCOMPLIANCE	
	E0005040	PROTOCOL/NONCOMPLIANCE	
	E0006001	PROTOCOL/NONCOMPLIANCE	
	E0006002	PROTOCOL/NONCOMPLIANCE	
	E0006003	PROTOCOL/NONCOMPLIANCE	
	E0006004	PROTOCOL/NONCOMPLIANCE	
	E0006006	PROTOCOL/NONCOMPLIANCE	
	E0006007	PROTOCOL/NONCOMPLIANCE	
	E0006008	PROTOCOL/NONCOMPLIANCE	
	E0006010	PROTOCOL/NONCOMPLIANCE	
	E0006012	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0006013	PROTOCOL/NONCOMPLIANCE	

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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE ( )	E0006014	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0006017	PROTOCOL/NONCOMPLIANCE	
	E0010016	PROTOCOL/NONCOMPLIANCE	
	E0010019	INFORMED CONSENT WITHDRAW	
	E0010020	PROTOCOL/NONCOMPLIANCE	
	E0010021	PROTOCOL/NONCOMPLIANCE	
	E0011002	PROTOCOL/NONCOMPLIANCE	
	E0015002	PROTOCOL/NONCOMPLIANCE	
	E0018014	PROTOCOL/NONCOMPLIANCE	
	E0018019	PROTOCOL/NONCOMPLIANCE	
	E0019010	PROTOCOL/NONCOMPLIANCE	
	E0019012	PROTOCOL/NONCOMPLIANCE	
	E0019028	PROTOCOL/NONCOMPLIANCE	
	E0019037	PROTOCOL/NONCOMPLIANCE	
	E0023020	INFORMED CONSENT WITHDRAW	
	E0026001	OTHER	
	E0026004	PROTOCOL/NONCOMPLIANCE	
	E0026022	PROTOCOL/NONCOMPLIANCE	
	E0027004	OTHER	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM100.SAS
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Listing 12.2.1.1 Patient Disposition-Screen Failures

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	REASON FOR WITHDRAWAL	COMMENT
SCREEN FAILURE ( )	E0027006	PROTOCOL/NONCOMPLIANCE	
	E0027008	INFORMED CONSENT WITHDRAW	
	E0027020	INFORMED CONSENT WITHDRAW	
	E0028019	INFORMED CONSENT WITHDRAW	
	E0028028	LOST TO FOLLOW-UP	
	E0028041	PROTOCOL/NONCOMPLIANCE	
	E0028044	PROTOCOL/NONCOMPLIANCE	
	E0029016	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0029028	PROTOCOL/NONCOMPLIANCE	
	E0029036	PROTOCOL/NONCOMPLIANCE	
	E0029037	PROTOCOL/NONCOMPLIANCE	
	E0030006	PROTOCOL/NONCOMPLIANCE	
	E0030007	PROTOCOL/NONCOMPLIANCE	
	E0036001	PROTOCOL/NONCOMPLIANCE	
	E0039012	PROTOCOL/NONCOMPLIANCE	
	E0039040	OTHER	
	E0040002	LOST TO FOLLOW-UP	
	E0040005	PROTOCOL/NONCOMPLIANCE	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM100.SAS
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	1138	58	57	COMPLETED TREATMENT PERIOD	
	E0002010	1229	29	15	LACK OF EFFICACY	
	E0002012	1246	59	56	COMPLETED TREATMENT PERIOD	DATE STUDY COMPLETED SIC PAGE 213
	E0002015	1297	23	9	INFORMED CONSENT WITHDRAW	
	E0002018	1355	15	3	ADVERSE EVENT	
	E0003004	1073	22	9	PROTOCOL/NONCOMPLIANCE	
	E0003005	1082	58	57	COMPLETED TREATMENT PERIOD	
	E0003007	1096	57	56	COMPLETED TREATMENT PERIOD	
	E0003015	1263	59	58	COMPLETED TREATMENT PERIOD	
	E0004002	1006	57	56	COMPLETED TREATMENT PERIOD	
	E0004013	1102	23	22	ADVERSE EVENT	
	E0004018	1206	56	55	COMPLETED TREATMENT PERIOD	
	E0004021	1276	57	56	COMPLETED TREATMENT PERIOD	
	E0005002	1011	54	53	COMPLETED TREATMENT PERIOD	
	E0005004	1007	43	21	ADVERSE EVENT	DATE STUDY COMPLETED SIC PAGE 213

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0005013	1029	44	4	ADVERSE EVENT	DATE STUDY COMPLETED SIC PAGE 213
	E0005024	1148	59	57	COMPLETED TREATMENT PERIOD	
	E0005027	1193	24	19	ADVERSE EVENT	
	E0005037	1267	71	56	COMPLETED TREATMENT PERIOD	DATE STUDY COMPLETED SIC PAGE 213
	E0005042	1320	56	55	COMPLETED TREATMENT PERIOD	
	E0006005	1059	57	56	COMPLETED TREATMENT PERIOD	
	E0006018	1197	12	4	ADVERSE EVENT	
	E0007013	1306	56	55	COMPLETED TREATMENT PERIOD	
	E0010004	1065	58	58	COMPLETED TREATMENT PERIOD	
	E0010012	1099	58	57	COMPLETED TREATMENT PERIOD	
	E0010024	1261	59	58	COMPLETED TREATMENT PERIOD	
	E0010032	1339	8	6	ADVERSE EVENT	
	E0011025	1324	58	57	COMPLETED TREATMENT PERIOD	
	E0013007	1209	19	9	ADVERSE EVENT	
	E0013009	1225	58	58	COMPLETED TREATMENT PERIOD	
	E0014006	1217	65	57	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM101.SAS
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	1248	57	56	COMPLETED TREATMENT PERIOD	
	E0016001	1115	57	56	COMPLETED TREATMENT PERIOD	
	E0016004	2052	9	8	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC SUBJECT DID NOT WANT TO CONTINUE IN THE STUDY PAGE 213
	E0018001	1024	57	56	COMPLETED TREATMENT PERIOD	
	E0018006	1077	59	58	COMPLETED TREATMENT PERIOD	
	E0019004	1031	43	41	ADVERSE EVENT	
	E0019011	1046	57	56	COMPLETED TREATMENT PERIOD	
	E0019025	1144	57	56	COMPLETED TREATMENT PERIOD	
	E0019026	1166	43	9	LOST TO FOLLOW-UP	DATE SIC PAGE 213
	E0019043	1294	57	56	COMPLETED TREATMENT PERIOD	
	E0020001	1025	53	52	COMPLETED TREATMENT PERIOD	
	E0020006	1072	24	18	PROTOCOL/NONCOMPLIANCE	
	E0020007	1106	70	16	PROTOCOL/NONCOMPLIANCE	
	E0020011	1174	57	56	COMPLETED TREATMENT PERIOD	
	E0020013	1183	21	12	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM101.SAS
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	1035	57	57	COMPLETED TREATMENT PERIOD	
	E0022017	1081	57	56	COMPLETED TREATMENT PERIOD	
	E0022018	1067	62	56	COMPLETED TREATMENT PERIOD	
	E0022022	1091	60	45	ADVERSE EVENT	
	E0022027	1145	57	56	COMPLETED TREATMENT PERIOD	
	E0022030	1153	29	29	INFORMED CONSENT WITHDRAW	DATE STUDY COMPLETED DATE OF LAST CONTACT PAGE 213
	E0022031	1155	57	56	COMPLETED TREATMENT PERIOD	
	E0022032	1158	60	55	COMPLETED TREATMENT PERIOD	
	E0022035	1161	23	5	ADVERSE EVENT	
	E0022036	1171	57	56	COMPLETED TREATMENT PERIOD	
	E0022056	1243	54	22	LACK OF EFFICACY	
	E0022060	1258	56	55	COMPLETED TREATMENT PERIOD	
	E0022063	1269	50	44	LOST TO FOLLOW-UP	
	E0023008	1131	54	53	COMPLETED TREATMENT PERIOD	
	E0023013	1176	8	3	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM101.SAS
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023015	1192	57	56	COMPLETED TREATMENT PERIOD	
	E0023034	1301	58	49	PROTOCOL/NONCOMPLIANCE	
	E0023037	1316	59	58	COMPLETED TREATMENT PERIOD	
	E0023038	1327	59	58	COMPLETED TREATMENT PERIOD	
	E0023044	1347	28	25	ADVERSE EVENT	
	E0023045	1349	61	57	COMPLETED TREATMENT PERIOD	
	E0025002	1232	57	56	COMPLETED TREATMENT PERIOD	
	E0026010	1114	9	5	ADVERSE EVENT	
	E0026017	1186	16	9	PROTOCOL/NONCOMPLIANCE	STUDY TERMINATION SIC VISIT WINDOW FAILURE PAGE 213
	E0026018	1212	57	56	COMPLETED TREATMENT PERIOD	
	E0026025	1272	56	55	COMPLETED TREATMENT PERIOD	
	E0026029	2177	20	16	PROTOCOL/NONCOMPLIANCE	
	E0026030	1336	57	56	COMPLETED TREATMENT PERIOD	
	E0026031	1352	57	56	COMPLETED TREATMENT PERIOD	
	E0027003	1124	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	1003	10	8	INFORMED CONSENT WITHDRAW	REASON FOR STUDY TERMINATION SIC SUBJECT MOVED OUT OF TOWN PAGE 213
	E0028006	1013	62	61	COMPLETED TREATMENT PERIOD	
	E0028008	1019	57	56	COMPLETED TREATMENT PERIOD	
	E0028009	1018	59	58	COMPLETED TREATMENT PERIOD	
	E0028016	1039	57	56	COMPLETED TREATMENT PERIOD	
	E0028017	1043	1		PROTOCOL/NONCOMPLIANCE	
	E0028027	1111	39	39	LOST TO FOLLOW-UP	
	E0028029	1141	60	58	COMPLETED TREATMENT PERIOD	
	E0028034	1220	63	62	COMPLETED TREATMENT PERIOD	
	E0028038	1253	55	54	COMPLETED TREATMENT PERIOD	
	E0028043	1298	55	54	COMPLETED TREATMENT PERIOD	DATE STUDY COMPLETED SIC PAGE 213
	E0028045	1315	86	21	ADVERSE EVENT	
	E0029005	1052	56	55	COMPLETED TREATMENT PERIOD	
	E0030001	1042	59	58	COMPLETED TREATMENT PERIOD	
	E0030008	1104	64	63	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM101.SAS
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	1121	57	56	COMPLETED TREATMENT PERIOD	
	E0030015	1165	61	60	COMPLETED TREATMENT PERIOD	
	E0030022	1310	60	59	COMPLETED TREATMENT PERIOD	
	E0031002	2019	57	56	COMPLETED TREATMENT PERIOD	
	E0031003	1063	57	56	COMPLETED TREATMENT PERIOD	
	E0033015	1235	63	54	COMPLETED TREATMENT PERIOD	DATE SIC - DATE OF LAST CONTACT WITH SUBJECT REGARDING ADVERSE EVENT FOLLOW - UP. PAGE 213
	E0034002	1216	23	21	ADVERSE EVENT	
	E0034003	1251	57	56	COMPLETED TREATMENT PERIOD	
	E0034006	1278	56	55	COMPLETED TREATMENT PERIOD	
	E0034008	1289	60	58	COMPLETED TREATMENT PERIOD	
	E0035003	1049	50	49	LOST TO FOLLOW-UP	
	E0035005	1056	50	50	LOST TO FOLLOW-UP	
	E0035014	1135	57	56	COMPLETED TREATMENT PERIOD	
	E0035024	1286	58	56	COMPLETED TREATMENT PERIOD	
	E0036005	1328	58	57	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	1087	57	56	COMPLETED TREATMENT PERIOD	
	E0037005	1189	57	56	COMPLETED TREATMENT PERIOD	
	E0037006	1201	57	56	COMPLETED TREATMENT PERIOD	
	E0039006	1090	57	56	COMPLETED TREATMENT PERIOD	
	E0039015	1118	57	56	COMPLETED TREATMENT PERIOD	
	E0039024	1178	58	56	COMPLETED TREATMENT PERIOD	DATE STUDY COMPLETED SIC PAGE213
	E0039025	1204	71	56	COMPLETED TREATMENT PERIOD	
	E0039041	1240	58	56	COMPLETED TREATMENT PERIOD	
	E0039044	1284	63	48	PROTOCOL/NONCOMPLIANCE	
	E0039046	1282	14		PROTOCOL/NONCOMPLIANCE	
	E0039051	1309	58	57	COMPLETED TREATMENT PERIOD	
	E0039053	1341	60	58	COMPLETED TREATMENT PERIOD	
	E0039057	1345	58	57	COMPLETED TREATMENT PERIOD	
	E0041003	1127	57	56	COMPLETED TREATMENT PERIOD	
	E0041008	1226	65	56	COMPLETED TREATMENT PERIOD	
	E0042001	1331	56	55	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	2082	57	56	COMPLETED TREATMENT PERIOD	
	E0003018	2139	57	56	COMPLETED TREATMENT PERIOD	
	E0005011	2001	50	50	LOST TO FOLLOW-UP	
	E0005030	2100	22	22	LOST TO FOLLOW-UP	
	E0005036	2133	22	7	ADVERSE EVENT	
	E0006015	2060	57	56	COMPLETED TREATMENT PERIOD	
	E0006016	2064	61	60	COMPLETED TREATMENT PERIOD	
	E0007008	2117	76	7	ADVERSE EVENT	
	E0009002	2012	58	57	COMPLETED TREATMENT PERIOD	
	E0009006	2045	57	56	COMPLETED TREATMENT PERIOD	
	E0009009	2081	13	10	ADVERSE EVENT	
	E0010015	2071	55	54	COMPLETED TREATMENT PERIOD	
	E0011004	2027	57	56	COMPLETED TREATMENT PERIOD	
	E0011007	2024	57	56	COMPLETED TREATMENT PERIOD	
	E0011018	2148	57	56	COMPLETED TREATMENT PERIOD	
	E0011024	2165	59	58	COMPLETED TREATMENT PERIOD	
	E0015003	2016	8	7	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	2013	57	56	COMPLETED TREATMENT PERIOD	
	E0019007	2009	56	55	COMPLETED TREATMENT PERIOD	
	E0019014	2033	14	4	ADVERSE EVENT	
	E0019018	2047	57	56	COMPLETED TREATMENT PERIOD	
	E0019022	2051	57	56	COMPLETED TREATMENT PERIOD	
	E0019027	2074	8	3	ADVERSE EVENT	
	E0019032	2104	71	56	COMPLETED TREATMENT PERIOD	
	E0019034	2091	38	22	LOST TO FOLLOW-UP	
	E0019036	2095	92	44	LOST TO FOLLOW-UP	
	E0019039	2129	8	3	ADVERSE EVENT	
	E0019041	2146	57	55	COMPLETED TREATMENT PERIOD	
	E0019049	2178	61	56	COMPLETED TREATMENT PERIOD	
	E0022052	2110	57	56	COMPLETED TREATMENT PERIOD	
	E0022064	2132	57	56	COMPLETED TREATMENT PERIOD	
	E0022073	2167	57	56	COMPLETED TREATMENT PERIOD	
	E0023002	2005	36	33	LACK OF EFFICACY	
	E0023017	2098	59	58	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	2123	56	55	COMPLETED TREATMENT PERIOD	
	E0023027	2144	55	54	COMPLETED TREATMENT PERIOD	
	E0023030	2154	58	57	COMPLETED TREATMENT PERIOD	
	E0023040	2172	65	64	COMPLETED TREATMENT PERIOD	
	E0026014	2067	29	28	LACK OF EFFICACY	
	E0026019	2087	57	57	COMPLETED TREATMENT PERIOD	
	E0027005	2028	57	55	COMPLETED TREATMENT PERIOD	
	E0029009	2038	58	57	COMPLETED TREATMENT PERIOD	
	E0029021	2088	71	58	COMPLETED TREATMENT PERIOD	
	E0029026	2112	58	57	COMPLETED TREATMENT PERIOD	
	E0029030	2151	58	57	COMPLETED TREATMENT PERIOD	
	E0031008	2077	56	55	COMPLETED TREATMENT PERIOD	
	E0031020	2120	23	22	ADVERSE EVENT	
	E0031021	2125	56	54	COMPLETED TREATMENT PERIOD	
	E0031029	2157	21	14	ADVERSE EVENT	
	E0033002	2034	57	56	COMPLETED TREATMENT PERIOD	
	E0033006	2041	21	16	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	2171	50	44	PROTOCOL/NONCOMPLIANCE	
	E0035013	2055	7	3	ADVERSE EVENT	
	E0035015	2061	8	5	ADVERSE EVENT	
	E0035016	2106	8	8	LOST TO FOLLOW-UP	
	E0035023	2138	36	36	LOST TO FOLLOW-UP	
	E0039052	2160	18	13	ADVERSE EVENT	DATE STUDY COMPLETED SIC PAGE 213
	E0039056	2183	10	9	LOST TO FOLLOW-UP	
	E0040003	2185	57	55	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	1181	61	60	COMPLETED TREATMENT PERIOD	
	E0002011	1254	58	57	COMPLETED TREATMENT PERIOD	
	E0003010	1136	57	55	COMPLETED TREATMENT PERIOD	
	E0003011	2054	31	31	LOST TO FOLLOW-UP	
	E0003016	1285	23	21	ADVERSE EVENT	
	E0003019	2170	56	55	COMPLETED TREATMENT PERIOD	
	E0003020	1353	57	56	COMPLETED TREATMENT PERIOD	
	E0004001	1004	37	31	ADVERSE EVENT	
	E0004009	1084	82	55	COMPLETED TREATMENT PERIOD	
	E0004012	1103	57	56	COMPLETED TREATMENT PERIOD	
	E0004015	1162	55	54	COMPLETED TREATMENT PERIOD	
	E0005003	1008	93	55	COMPLETED TREATMENT PERIOD	DATE STUDY COMPLETED DATE OF LAST LABORATORY RE - TEST. PAGE 213
	E0005005	1001	11	9	LOST TO FOLLOW-UP	
	E0005007	1014	98	56	COMPLETED TREATMENT PERIOD	
	E0005008	1017	58	57	COMPLETED TREATMENT PERIOD	
	E0005009	1023	8	4	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	1020	64	57	COMPLETED TREATMENT PERIOD	
	E0005012	1040	55	54	COMPLETED TREATMENT PERIOD	
	E0005014	1037	64	54	COMPLETED TREATMENT PERIOD	DATE SIC PAGE 213
	E0005022	1128	42	33	ADVERSE EVENT	DATE STUDY COMPLETED SIC PAGE 213
	E0005025	1177	36	35	ADVERSE EVENT	
	E0006019	1230	58	57	COMPLETED TREATMENT PERIOD	
	E0007005	1134	71	56	COMPLETED TREATMENT PERIOD	
	E0007015	1348	57	56	COMPLETED TREATMENT PERIOD	
	E0009001	1033	112	57	LOST TO FOLLOW-UP	
	E0010002	1050	8	1	ADVERSE EVENT	
	E0010009	1085	56	55	COMPLETED TREATMENT PERIOD	
	E0010010	1092	15	14	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0010014	1122	57	56	COMPLETED TREATMENT PERIOD	
	E0010017	1169	57	56	COMPLETED TREATMENT PERIOD	
	E0010023	1242	15	11	ADVERSE EVENT	
	E0010027	1307	16	13	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0010029	1318	15	9	INFORMED CONSENT WITHDRAW	
	E0011022	1300	58	57	COMPLETED TREATMENT PERIOD	
	E0013006	1198	12	8	ADVERSE EVENT	
	E0013012	1266	57	56	COMPLETED TREATMENT PERIOD	
	E0013014	1295	28	20	ADVERSE EVENT	
	E0014005	1194	57	56	COMPLETED TREATMENT PERIOD	
	E0014007	1224	22	17	ADVERSE EVENT	
	E0014011	1275	57	56	COMPLETED TREATMENT PERIOD	
	E0014012	1290	29	28	ADVERSE EVENT	
	E0015001	1053	53	50	INFORMED CONSENT WITHDRAW	
	E0015008	1079	50	44	OTHER	
	E0016003	1119	55	51	INFORMED CONSENT WITHDRAW	SIC SUBJECT DID NOT WANT TO CONTINUE IN THE STUDY
	E0016005	1172	67	56	COMPLETED TREATMENT PERIOD	
	E0018007	1088	15	4	ADVERSE EVENT	
	E0019005	1027	67	58	COMPLETED TREATMENT PERIOD	
	E0019015	1095	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	1062	45	44	LACK OF EFFICACY	
	E0020010	1143	57	56	COMPLETED TREATMENT PERIOD	
	E0020014	1202	56	55	COMPLETED TREATMENT PERIOD	
	E0020021	1280	57	56	COMPLETED TREATMENT PERIOD	
	E0020023	1311	57	55	COMPLETED TREATMENT PERIOD	
	E0022007	1030	33	32	LOST TO FOLLOW-UP	
	E0022010	1048	57	56	COMPLETED TREATMENT PERIOD	
	E0022012	1060	57	56	COMPLETED TREATMENT PERIOD	
	E0022019	1066	58	57	COMPLETED TREATMENT PERIOD	
	E0022025	1126	8	7	ADVERSE EVENT	
	E0022033	1157	57	56	COMPLETED TREATMENT PERIOD	
	E0022034	1156	57	55	COMPLETED TREATMENT PERIOD	
	E0022038	1179	43	41	ADVERSE EVENT	
	E0022039	1185	57	56	COMPLETED TREATMENT PERIOD	
	E0022046	1211	58	57	COMPLETED TREATMENT PERIOD	
	E0022048	1222	78	61	LOST TO FOLLOW-UP	
	E0022051	1233	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022053	1237	14	9	LOST TO FOLLOW-UP	
	E0022058	1247	32	31	ADVERSE EVENT	
	E0022061	1257	58	57	COMPLETED TREATMENT PERIOD	
	E0022062	1262	19	16	ADVERSE EVENT	
	E0022068	1288	15	14	LOST TO FOLLOW-UP	
	E0022069	1303	57	55	COMPLETED TREATMENT PERIOD	
	E0022071	1326	57	56	COMPLETED TREATMENT PERIOD	
	E0023003	1076	57	56	COMPLETED TREATMENT PERIOD	
	E0023006	1075	57	56	COMPLETED TREATMENT PERIOD	
	E0023010	1139	56	55	COMPLETED TREATMENT PERIOD	
	E0023025	1277	57	56	COMPLETED TREATMENT PERIOD	
	E0023039	1329	57	56	COMPLETED TREATMENT PERIOD	
	E0026002	1034	59	58	COMPLETED TREATMENT PERIOD	
	E0026007	1108	56	55	COMPLETED TREATMENT PERIOD	
	E0026013	1151	61	56	COMPLETED TREATMENT PERIOD	
	E0028007	1012	42	41	ADVERSE EVENT	
	E0028023	1110	158	48	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	1101	15	12	ADVERSE EVENT	
	E0028033	1219	57	56	COMPLETED TREATMENT PERIOD	
	E0028035	1228	57	56	COMPLETED TREATMENT PERIOD	
	E0028037	1304	58	56	COMPLETED TREATMENT PERIOD	
	E0028039	1271	29	27	INFORMED CONSENT WITHDRAW	
	E0028046	1322	1	1	LOST TO FOLLOW-UP	
	E0028048	1350	55	55	LOST TO FOLLOW-UP	
	E0029008	1070	8	5	ADVERSE EVENT	
	E0029011	1112	24	23	LOST TO FOLLOW-UP	
	E0029012	1150	36	35	ADVERSE EVENT	
	E0029015	1167	16	10	ADVERSE EVENT	
	E0029018	1188	2	2	LOST TO FOLLOW-UP	
	E0030014	1164	61	58	COMPLETED TREATMENT PERIOD	
	E0030020	1292	27	27	OTHER	
	E0030024	1343	8	5	ADVERSE EVENT	
	E0030025	1340	40	39	ADVERSE EVENT	
	E0031027	2153	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM101.SAS
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	1321	59	58	COMPLETED TREATMENT PERIOD	
	E0033012	1147	11	9	LOST TO FOLLOW-UP	
	E0034001	1208	57	56	COMPLETED TREATMENT PERIOD	
	E0034004	1245	57	56	COMPLETED TREATMENT PERIOD	
	E0035001	1044	56	55	COMPLETED TREATMENT PERIOD	
	E0035006	1068	57	56	COMPLETED TREATMENT PERIOD	
	E0035021	1252	57	56	COMPLETED TREATMENT PERIOD	
	E0036002	1313	58	27	ADVERSE EVENT	
	E0036006	1334	57	55	COMPLETED TREATMENT PERIOD	
	E0036007	1333	21	13	ADVERSE EVENT	
	E0037009	2143	56	55	COMPLETED TREATMENT PERIOD	
	E0039011	1097	62	57	LOST TO FOLLOW-UP	
	E0039018	1116	56	37	LOST TO FOLLOW-UP	
	E0039026	1190	57	55	COMPLETED TREATMENT PERIOD	DATE STUDY COMPLETED SIC PAGE 213
	E0039028	1215	107	51	ADVERSE EVENT	
	E0039032	1200	22	10	PROTOCOL/NONCOMPLIANCE	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
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** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	1207	57	56	COMPLETED TREATMENT PERIOD	
	E0039042	1270	57	56	COMPLETED TREATMENT PERIOD	
	E0041004	1130	61	59	COMPLETED TREATMENT PERIOD	
	E0041009	1259	47	42	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0042002	1338	56	55	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	2180	15	5	ADVERSE EVENT	
	E0003002	2002	56	56	COMPLETED TREATMENT PERIOD	
	E0005031	2105	93	48	LOST TO FOLLOW-UP	
	E0005033	2114	43	19	ADVERSE EVENT	
	E0005038	2140	23	22	ADVERSE EVENT	
	E0007009	2116	12	5	ADVERSE EVENT	
	E0009010	2085	21	21	LOST TO FOLLOW-UP	
	E0009011	2131	71	58	COMPLETED TREATMENT PERIOD	
	E0010005	2022	2	2	OTHER	
	E0011016	2121	57	56	COMPLETED TREATMENT PERIOD	
	E0011020	2136	8	2	ADVERSE EVENT	
	E0018002	2020	55	54	COMPLETED TREATMENT PERIOD	
	E0018003	2017	15	12	ADVERSE EVENT	
	E0018013	2044	8	4	ADVERSE EVENT	
	E0019002	2007	8	8	LOST TO FOLLOW-UP	
	E0019008	2014	138	37	LOST TO FOLLOW-UP	
	E0019009	2010	27	27	LOST TO FOLLOW-UP	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	2031	57	56	COMPLETED TREATMENT PERIOD	
	E0019020	2040	64	56	COMPLETED TREATMENT PERIOD	
	E0019021	2048	33	18	PROTOCOL/NONCOMPLIANCE	
	E0019024	2050	134	9	ADVERSE EVENT	DATE STUDY S.I.C. PAGE 213
	E0019031	2083	13	4	ADVERSE EVENT	
	E0019035	2090	38	30	ADVERSE EVENT	
	E0019040	2145	59	58	COMPLETED TREATMENT PERIOD	
	E0019042	2155	17	14	ADVERSE EVENT	
	E0019045	2168	21	12	PROTOCOL/NONCOMPLIANCE	
	E0020024	2162	59	58	COMPLETED TREATMENT PERIOD	
	E0022044	2092	56	54	COMPLETED TREATMENT PERIOD	
	E0023007	2036	59	56	COMPLETED TREATMENT PERIOD	
	E0023011	2056	57	56	COMPLETED TREATMENT PERIOD	
	E0023014	2072	64	62	COMPLETED TREATMENT PERIOD	
	E0023019	2108	58	57	COMPLETED TREATMENT PERIOD	
	E0023022	2119	56	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	2126	7	3	ADVERSE EVENT	
	E0023029	2150	48	3	ADVERSE EVENT	DATE STUDY COMPLETED DATE OF LAST CONTACT PAGE 213
	E0023031	2164	57	56	COMPLETED TREATMENT PERIOD	
	E0023041	2176	59	58	COMPLETED TREATMENT PERIOD	
	E0023043	2182	58	57	COMPLETED TREATMENT PERIOD	
	E0026003	1057	62	57	COMPLETED TREATMENT PERIOD	STUDY TERMINATION SIC - VISIT WINDOW FAILURE PAGE 213
	E0026005	2030	8	7	ADVERSE EVENT	
	E0026009	2037	7	4	ADVERSE EVENT	
	E0026015	2076	58	57	COMPLETED TREATMENT PERIOD	
	E0026023	2128	59	56	COMPLETED TREATMENT PERIOD	
	E0027016	2109	56	55	COMPLETED TREATMENT PERIOD	
	E0027018	2097	59	58	COMPLETED TREATMENT PERIOD	
	E0028032	2096	74	56	COMPLETED TREATMENT PERIOD	
	E0029003	2004	57	56	COMPLETED TREATMENT PERIOD	
	E0029020	2079	36	7	LOST TO FOLLOW-UP	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	2025	57	56	COMPLETED TREATMENT PERIOD	
	E0031006	2065	57	56	COMPLETED TREATMENT PERIOD	
	E0031010	2069	16	14	ADVERSE EVENT	
	E0031011	2075	57	56	COMPLETED TREATMENT PERIOD	
	E0031015	2101	7	6	ADVERSE EVENT	
	E0031031	2174	52	28	PROTOCOL/NONCOMPLIANCE	
	E0033009	2062	7	7	ADVERSE EVENT	
	E0034009	2158	61	58	COMPLETED TREATMENT PERIOD	
	E0037007	1238	43	16	LOST TO FOLLOW-UP	
	E0037012	2184	55	54	COMPLETED TREATMENT PERIOD	
	E0039019	2058	57	56	COMPLETED TREATMENT PERIOD	
	E0039043	2134	63	37	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0002001	1093	59	58	COMPLETED TREATMENT PERIOD	
	E0002003	1113	56	55	COMPLETED TREATMENT PERIOD	DATE STUDY COMPLETED SIC PAGE 213
	E0002004	1120	34	9	ADVERSE EVENT	
	E0002008	1173	58	57	COMPLETED TREATMENT PERIOD	
	E0002016	1354	56	55	COMPLETED TREATMENT PERIOD	
	E0003008	1123	35	27	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0004003	1015	22	16	INFORMED CONSENT WITHDRAW	REASON OF TERMINATION SIC PAGE 213
	E0004006	1026	64	63	COMPLETED TREATMENT PERIOD	
	E0004016	1160	58	57	COMPLETED TREATMENT PERIOD	
	E0004024	1332	57	56	COMPLETED TREATMENT PERIOD	
	E0005006	1009	20	20	INFORMED CONSENT WITHDRAW	
	E0005017	1089	65	61	COMPLETED TREATMENT PERIOD	
	E0005019	1105	10	7	ADVERSE EVENT	
	E0005026	1187	28	19	LACK OF EFFICACY	
	E0005039	1283	56	55	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0005043	1337	57	56	COMPLETED TREATMENT PERIOD	
	E0006020	1274	59	56	COMPLETED TREATMENT PERIOD	
	E0007001	1094	70	53	COMPLETED TREATMENT PERIOD	
	E0007003	1129	62	26	ADVERSE EVENT	
	E0007006	1184	23	23	ADVERSE EVENT	
	E0009004	1051	23	22	LACK OF EFFICACY	
	E0009012	1323	28	1	ADVERSE EVENT	
	E0010008	1078	29	29	LOST TO FOLLOW-UP	
	E0010018	1205	57	53	PROTOCOL/NONCOMPLIANCE	
	E0010028	1312	30	28	ADVERSE EVENT	
	E0011008	1133	15	11	ADVERSE EVENT	
	E0011009	1086	57	56	COMPLETED TREATMENT PERIOD	
	E0011010	1146	38	35	LACK OF EFFICACY	
	E0013001	1038	58	56	COMPLETED TREATMENT PERIOD	
	E0013003	1036	56	55	COMPLETED TREATMENT PERIOD	
	E0013005	1154	57	56	COMPLETED TREATMENT PERIOD	
	E0013013	1264	28	21	LACK OF EFFICACY	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0014002	1175	44	38	LACK OF EFFICACY	
	E0014004	1196	35	19	ADVERSE EVENT	
	E0014009	1249	24	7	LACK OF EFFICACY	DATE STUDY COMPLETED SIC PAGE 213
	E0014015	1314	52	17	LOST TO FOLLOW-UP	
	E0014017	1325	54	53	COMPLETED TREATMENT PERIOD	
	E0014018	1330	58	57	COMPLETED TREATMENT PERIOD	
	E0015005	1055	17	16	LACK OF EFFICACY	
	E0017002	1296	11	9	PROTOCOL/NONCOMPLIANCE	
	E0018009	1098	9	9	LACK OF EFFICACY	
	E0018010	1107	57	56	COMPLETED TREATMENT PERIOD	
	E0018015	1125	59	58	COMPLETED TREATMENT PERIOD	
	E0020015	1218	58	57	COMPLETED TREATMENT PERIOD	
	E0020017	1227	62	56	COMPLETED TREATMENT PERIOD	
	E0020020	1273	12	11	LACK OF EFFICACY	
	E0020022	1308	57	56	COMPLETED TREATMENT PERIOD	
	E0022001	1022	60	58	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0022004	1021	57	56	COMPLETED TREATMENT PERIOD	
	E0022005	1032	57	56	COMPLETED TREATMENT PERIOD	
	E0022011	1054	7	7	ADVERSE EVENT	
	E0022015	1064	59	58	COMPLETED TREATMENT PERIOD	
	E0022016	1074	57	56	COMPLETED TREATMENT PERIOD	
	E0022020	1069	43	35	PROTOCOL/NONCOMPLIANCE	
	E0022023	1083	59	57	COMPLETED TREATMENT PERIOD	
	E0022029	1159	55	54	COMPLETED TREATMENT PERIOD	
	E0022041	1203	57	55	COMPLETED TREATMENT PERIOD	
	E0022042	1195	62	57	COMPLETED TREATMENT PERIOD	
	E0022043	1210	54	54	COMPLETED TREATMENT PERIOD	
	E0022054	1239	55	44	LOST TO FOLLOW-UP	
	E0022059	1265	64	60	COMPLETED TREATMENT PERIOD	
	E0022065	1268	57	56	COMPLETED TREATMENT PERIOD	
	E0022070	1305	7	6	PROTOCOL/NONCOMPLIANCE	
	E0023001	1041	61	61	COMPLETED TREATMENT PERIOD	
	E0023009	1149	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0023028	1291	54	53	COMPLETED TREATMENT PERIOD	
	E0023033	1299	8	7	LACK OF EFFICACY	
	E0023047	1351	57	56	COMPLETED TREATMENT PERIOD	
	E0025001	1231	23	22	LACK OF EFFICACY	
	E0026012	1163	57	56	COMPLETED TREATMENT PERIOD	
	E0026020	1221	22	21	LACK OF EFFICACY	
	E0026024	1260	33	33	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW - UP PATIENT LOST TO FOLLOW - UP, DUE TO FAMILY EMERGENCY PAGE 213
	E0026028	1319	34	25	ADVERSE EVENT	
	E0028001	1016	55	54	COMPLETED TREATMENT PERIOD	
	E0028003	1002	58	57	COMPLETED TREATMENT PERIOD	
	E0028005	1010	29	10	LACK OF EFFICACY	
	E0028010	1028	57	56	COMPLETED TREATMENT PERIOD	
	E0028011	1061	57	56	COMPLETED TREATMENT PERIOD	
	E0028030	1182	58	57	COMPLETED TREATMENT PERIOD	
	E0028031	1191	38	23	ADVERSE EVENT	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0028047	1344	58	57	COMPLETED TREATMENT PERIOD	
	E0029001	1005	26	17	LOST TO FOLLOW-UP	DATE STUDY COMPLETED THIS WAS DATE PATIENT RECEIVED CERTIFIED LETTER ASKING TO RETURN FOR TERMINATION VISIT.
	E0029014	1137	57	56	COMPLETED TREATMENT PERIOD	
	E0029023	1234	64	60	COMPLETED TREATMENT PERIOD	
	E0029032	1302	22	10	LACK OF EFFICACY	
	E0029033	1293	29	28	LACK OF EFFICACY	
	E0029039	1346	14	13	ADVERSE EVENT	
	E0030003	1071	9	7	INFORMED CONSENT WITHDRAW	
	E0030009	1117	56	55	COMPLETED TREATMENT PERIOD	
	E0030016	1180	51	46	LACK OF EFFICACY	
	E0030021	1281	29	29	LOST TO FOLLOW-UP	
	E0031001	1047	33	33	INFORMED CONSENT WITHDRAW	
	E0031017	1223	29	28	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0031018	1236	42	23	PROTOCOL/NONCOMPLIANCE	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0031023	1255	57	56	COMPLETED TREATMENT PERIOD	
	E0033001	1100	22	21	LACK OF EFFICACY	DATE SIC PAGE 213
	E0033004	1109	57	56	COMPLETED TREATMENT PERIOD	
	E0033010	1142	82	47	ADVERSE EVENT	DATE STUDY COMPLETED SIC - LAST DATE OF CONTACT W/SUBJECT. DATE SUBJECT SIGNED FOR AND RECEIVED CERTIFIED LETTER ASKING FOR THE RETURN OF THE STUDY DRUG TO THE CLINIC PAGE 213
	E0033014	2093	90	40	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213
	E0035002	1045	27	27	INFORMED CONSENT WITHDRAW	
	E0035007	1080	55	54	COMPLETED TREATMENT PERIOD	
	E0035011	1140	57	56	COMPLETED TREATMENT PERIOD	
	E0035020	1244	57	56	COMPLETED TREATMENT PERIOD	
	E0037003	1132	22	21	LACK OF EFFICACY	
	E0037004	1152	57	56	COMPLETED TREATMENT PERIOD	
	E0039007	1058	57	56	COMPLETED TREATMENT PERIOD	
	E0039022	1170	59	58	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR I)	E0039023	1168	19	16	LOST TO FOLLOW-UP	
	E0039030	1214	68	56	COMPLETED TREATMENT PERIOD	
	E0039031	1213	58	57	COMPLETED TREATMENT PERIOD	
	E0039037	1241	107	59	COMPLETED TREATMENT PERIOD	
	E0039038	1250	59	45	PROTOCOL/NONCOMPLIANCE	
	E0039047	1279	66	56	COMPLETED TREATMENT PERIOD	
	E0039059	1342	57	56	COMPLETED TREATMENT PERIOD	
	E0041007	1199	57	56	COMPLETED TREATMENT PERIOD	
	E0041010	1256	45	42	ADVERSE EVENT	
	E0041011	1287	57	56	COMPLETED TREATMENT PERIOD	
	E0041012	1317	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR II)	E0001004	2130	63	57	COMPLETED TREATMENT PERIOD	
	E0005023	2057	56	56	COMPLETED TREATMENT PERIOD	
	E0005034	2113	56	55	COMPLETED TREATMENT PERIOD	
	E0005041	2163	56	55	COMPLETED TREATMENT PERIOD	
	E0007004	2049	15	13	LACK OF EFFICACY	
	E0007010	2118	60	58	COMPLETED TREATMENT PERIOD	
	E0007012	2141	49	46	LACK OF EFFICACY	
	E0009007	2053	29	28	LACK OF EFFICACY	
	E0009008	2063	56	55	COMPLETED TREATMENT PERIOD	
	E0011001	2003	56	54	COMPLETED TREATMENT PERIOD	
	E0011011	2070	56	55	COMPLETED TREATMENT PERIOD	
	E0011013	2115	57	56	COMPLETED TREATMENT PERIOD	
	E0011014	2107	32	16	INFORMED CONSENT WITHDRAW	
	E0011021	2147	61	58	COMPLETED TREATMENT PERIOD	
	E0013008	2099	55	54	COMPLETED TREATMENT PERIOD	
	E0014001	2073	35	34	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC PAGE 213

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR II)	E0014013	2152	58	57	COMPLETED TREATMENT PERIOD	
	E0014014	2156	58	57	COMPLETED TREATMENT PERIOD	
	E0015004	2021	59	58	COMPLETED TREATMENT PERIOD	
	E0018005	2026	57	56	COMPLETED TREATMENT PERIOD	
	E0018012	2043	34	33	LACK OF EFFICACY	
	E0019019	2042	26	23	INFORMED CONSENT WITHDRAW	
	E0019033	2089	60	58	COMPLETED TREATMENT PERIOD	
	E0019038	2124	57	55	COMPLETED TREATMENT PERIOD	
	E0019046	2166	57	56	COMPLETED TREATMENT PERIOD	
	E0019047	2173	59	58	COMPLETED TREATMENT PERIOD	
	E0019048	2179	56	55	COMPLETED TREATMENT PERIOD	
	E0022006	2008	57	56	COMPLETED TREATMENT PERIOD	
	E0022047	2103	57	56	COMPLETED TREATMENT PERIOD	
	E0022075	2175	58	57	COMPLETED TREATMENT PERIOD	
	E0023012	2059	58	57	COMPLETED TREATMENT PERIOD	
	E0023016	2149	57	56	COMPLETED TREATMENT PERIOD	
	E0023018	2102	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZA-TION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR II)	E0023036	2161	55	54	COMPLETED TREATMENT PERIOD	
	E0023046	2187	56	55	COMPLETED TREATMENT PERIOD	
	E0026006	2032	43	43	LOST TO FOLLOW-UP	
	E0026021	2122	20	19	PROTOCOL/NONCOMPLIANCE	
	E0026027	2159	22	5	ADVERSE EVENT	
	E0029002	2006	8		PROTOCOL/NONCOMPLIANCE	
	E0029004	2011	59	58	COMPLETED TREATMENT PERIOD	
	E0029013	2066	51	51	LOST TO FOLLOW-UP	
	E0029019	2078	15	14	LACK OF EFFICACY	
	E0029024	2086	65	64	COMPLETED TREATMENT PERIOD	
	E0029038	1335	36	7	ADVERSE EVENT	
	E0031004	2023	58	57	COMPLETED TREATMENT PERIOD	
	E0031013	2084	57	56	COMPLETED TREATMENT PERIOD	
	E0031016	2094	23	21	LACK OF EFFICACY	
	E0031019	2111	32	31	INFORMED CONSENT WITHDRAW	INFORMED CONSENT WITHDRAWN SIC - SUBJECT MOVED TO FLORIDA PAGE 213
	E0031022	2127	45	36	PROTOCOL/NONCOMPLIANCE	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.2 Patient Disposition-Randomized Patients

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZATION CODE	DUR IN TRIAL (DAYS)*	DUR ON TREATMENT (DAYS)**	REASON FOR WITHDRAWAL	COMMENT
PLACEBO (BIPOLAR II)	E0033007	2046	57	56	COMPLETED TREATMENT PERIOD	
	E0033013	2068	57	56	COMPLETED TREATMENT PERIOD	
	E0033016	2135	56	55	COMPLETED TREATMENT PERIOD	
	E0033022	2181	60	59	COMPLETED TREATMENT PERIOD	
	E0034007	2142	60	59	COMPLETED TREATMENT PERIOD	
	E0035004	2018	8	7	LOST TO FOLLOW-UP	
	E0035009	2029	55	53	COMPLETED TREATMENT PERIOD	
	E0035010	2035	56	55	COMPLETED TREATMENT PERIOD	
	E0035022	2137	60	58	COMPLETED TREATMENT PERIOD	
	E0039003	2015	39	23	PROTOCOL/NONCOMPLIANCE	
	E0040001	2169	57	56	COMPLETED TREATMENT PERIOD	
	E0040004	2186	14	9	LOST TO FOLLOW-UP	
	E0041002	2039	50	44	PROTOCOL/NONCOMPLIANCE	
	E0041005	2080	57	56	COMPLETED TREATMENT PERIOD	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
Subject E0034001 was assigned to center 0004 instead of center 0034 in the study database.
* DURATION IN STUDY CALCULATED FROM RANDOMIZATION DATE TO LAST DATE OF STUDY DRUG INCLUSIVE.
** DURATION ON TREATMENT CALCULATED FROM FIRST DATE OF STUDY DRUG TO LAST DATE OF STUDY DRUG INCLUSIVE.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	14JAN2003	04FEB2003	1138	04FEB2003	01APR2003	02APR2003
	E0002010	25MAR2003	04APR2003	1229	04APR2003	18APR2003	02MAY2003
	E0002012	16APR2003	21APR2003	1246	21APR2003	15JUN2003	18JUN2003
	E0002015	21MAY2003	04JUN2003	1297	04JUN2003	12JUN2003	26JUN2003
	E0002018	09JUL2003	24JUL2003	1355	24JUL2003	26JUL2003	07AUG2003
	E0003004	03DEC2002	17DEC2002	1073	17DEC2002	25DEC2002	07JAN2003
	E0003005	16DEC2002	23DEC2002	1082	23DEC2002	17FEB2003	18FEB2003
	E0003007	19DEC2002	02JAN2003	1096	02JAN2003	26FEB2003	27FEB2003
	E0003015	28APR2003	05MAY2003	1263	05MAY2003	01JUL2003	02JUL2003
	E0004002	24SEP2002	01OCT2002	1006	01OCT2002	25NOV2002	26NOV2002
	E0004013	08JAN2003	14JAN2003	1102	14JAN2003	04FEB2003	05FEB2003
	E0004018	12MAR2003	19MAR2003	1206	19MAR2003	12MAY2003	13MAY2003
	E0004021	07MAY2003	14MAY2003	1276	14MAY2003	08JUL2003	09JUL2003
	E0005002	23SEP2002	03OCT2002	1011	03OCT2002	24NOV2002	25NOV2002
	E0005004	24SEP2002	01OCT2002	1007	01OCT2002	21OCT2002	12NOV2002
	E0005013	29OCT2002	07NOV2002	1029	07NOV2002	10NOV2002	20DEC2002
	E0005024	05JAN2003	10FEB2003	1148	10FEB2003	07APR2003	09APR2003
	E0005027	21FEB2003	11MAR2003	1193	11MAR2003	29MAR2003	03APR2003
	E0005037	30APR2003	07MAY2003	1267	07MAY2003	01JUL2003	16JUL2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM102.SAS
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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	19JUN2003	24JUN2003	1320	24JUN2003	17AUG2003	18AUG2003
	E0006005	25NOV2002	05DEC2002	1059	05DEC2002	29JAN2003	30JAN2003
	E0006018	06MAR2003	13MAR2003	1197	13MAR2003	16MAR2003	24MAR2003
	E0007013	06JUN2003	13JUN2003	1306	13JUN2003	06AUG2003	07AUG2003
	E0010004	04DEC2002	11DEC2002	1065	11DEC2002	06FEB2003	06FEB2003
	E0010012	30DEC2002	07JAN2003	1099	07JAN2003	04MAR2003	05MAR2003
	E0010024	23APR2003	05MAY2003	1261	05MAY2003	01JUL2003	02JUL2003
	E0010032	03JUL2003	10JUL2003	1339	10JUL2003	15JUL2003	17JUL2003
	E0011025	20JUN2003	26JUN2003	1324	26JUN2003	21AUG2003	22AUG2003
	E0013007	13MAR2003	20MAR2003	1209	20MAR2003	28MAR2003	07APR2003
	E0013009	26MAR2003	02APR2003	1225	02APR2003	29MAY2003	29MAY2003
	E0014006	11MAR2003	25MAR2003	1217	25MAR2003	20MAY2003	28MAY2003
	E0014010	15APR2003	22APR2003	1248	22APR2003	16JUN2003	17JUN2003
	E0016001	02JAN2003	22JAN2003	1115	22JAN2003	18MAR2003	19MAR2003
	E0016004	27JAN2003	03FEB2003	2052	03FEB2003	10FEB2003	11FEB2003
	E0018001	22OCT2002	29OCT2002	1024	29OCT2002	23DEC2002	24DEC2002
	E0018006	10DEC2002	17DEC2002	1077	17DEC2002	12FEB2003	13FEB2003
	E0019004	30OCT2002	07NOV2002	1031	07NOV2002	17DEC2002	19DEC2002
	E0019011	12NOV2002	21NOV2002	1046	21NOV2002	15JAN2003	16JAN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM102.SAS
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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	30JAN2003	06FEB2003	1144	06FEB2003	02APR2003	03APR2003
	E0019026	10FEB2003	24FEB2003	1166	24FEB2003	04MAR2003	07APR2003
	E0019043	21MAY2003	03JUN2003	1294	03JUN2003	28JUL2003	29JUL2003
	E0020001	08OCT2002	29OCT2002	1025	29OCT2002	19DEC2002	20DEC2002
	E0020006	26NOV2002	16DEC2002	1072	16DEC2002	02JAN2003	08JAN2003
	E0020007	19DEC2002	15JAN2003	1106	15JAN2003	30JAN2003	25MAR2003
	E0020011	19FEB2003	26FEB2003	1174	26FEB2003	22APR2003	23APR2003
	E0020013	25FEB2003	05MAR2003	1183	05MAR2003	16MAR2003	25MAR2003
	E0022008	05NOV2002	12NOV2002	1035	12NOV2002	07JAN2003	07JAN2003
	E0022017	03DEC2002	19DEC2002	1081	19DEC2002	12FEB2003	13FEB2003
	E0022018	04DEC2002	12DEC2002	1067	12DEC2002	05FEB2003	11FEB2003
	E0022022	16DEC2002	30DEC2002	1091	30DEC2002	12FEB2003	27FEB2003
	E0022027	23JAN2003	06FEB2003	1145	06FEB2003	02APR2003	03APR2003
	E0022030	07FEB2003	14FEB2003	1153	14FEB2003	14MAR2003	14MAR2003
	E0022031	10FEB2003	18FEB2003	1155	18FEB2003	14APR2003	15APR2003
	E0022032	11FEB2003	18FEB2003	1158	18FEB2003	13APR2003	18APR2003
	E0022035	11FEB2003	19FEB2003	1161	19FEB2003	23FEB2003	13MAR2003
	E0022036	13FEB2003	25FEB2003	1171	25FEB2003	21APR2003	22APR2003
	E0022056	09APR2003	17APR2003	1243	17APR2003	08MAY2003	09JUN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM102.SAS
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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	23APR2003	30APR2003	1258	30APR2003	23JUN2003	24JUN2003
	E0022063	28APR2003	07MAY2003	1269	07MAY2003	19JUN2003	25JUN2003
	E0023008	23JAN2003	30JAN2003	1131	30JAN2003	23MAR2003	24MAR2003
	E0023013	13FEB2003	27FEB2003	1176	27FEB2003	01MAR2003	06MAR2003
	E0023015	04MAR2003	11MAR2003	1192	11MAR2003	05MAY2003	06MAY2003
	E0023034	03JUN2003	09JUN2003	1301	09JUN2003	27JUL2003	05AUG2003
	E0023037	11JUN2003	18JUN2003	1316	18JUN2003	14AUG2003	15AUG2003
	E0023038	20JUN2003	30JUN2003	1327	30JUN2003	26AUG2003	27AUG2003
	E0023044	08JUL2003	16JUL2003	1347	16JUL2003	09AUG2003	12AUG2003
	E0023045	10JUL2003	17JUL2003	1349	17JUL2003	11SEP2003	15SEP2003
	E0025002	27MAR2003	03APR2003	1232	03APR2003	28MAY2003	29MAY2003
	E0026010	15JAN2003	22JAN2003	1114	22JAN2003	26JAN2003	30JAN2003
	E0026017	26FEB2003	06MAR2003	1186	06MAR2003	14MAR2003	21MAR2003
	E0026018	06MAR2003	20MAR2003	1212	20MAR2003	14MAY2003	15MAY2003
	E0026025	01MAY2003	09MAY2003	1272	09MAY2003	02JUL2003	03JUL2003
	E0026029	02JUL2003	09JUL2003	2177	09JUL2003	24JUL2003	28JUL2003
	E0026030	02JUL2003	09JUL2003	1336	09JUL2003	02SEP2003	03SEP2003
	E0026031	10JUL2003	21JUL2003	1352	21JUL2003	14SEP2003	15SEP2003
	E0027003	11DEC2002	28JAN2003	1124	28JAN2003	24MAR2003	25MAR2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM102.SAS
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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	27SEP2002	30SEP2002	1003	30SEP2002	07OCT2002	09OCT2002
	E0028006	01OCT2002	04OCT2002	1013	04OCT2002	03DEC2002	04DEC2002
	E0028008	08OCT2002	15OCT2002	1019	15OCT2002	09DEC2002	10DEC2002
	E0028009	10OCT2002	15OCT2002	1018	15OCT2002	11DEC2002	12DEC2002
	E0028016	07NOV2002	14NOV2002	1039	14NOV2002	08JAN2003	09JAN2003
	E0028017	12NOV2002	19NOV2002	1043			19NOV2002
	E0028027	14JAN2003	21JAN2003	1111	21JAN2003	28FEB2003	28FEB2003
	E0028029	28JAN2003	04FEB2003	1141	04FEB2003	02APR2003	04APR2003
	E0028034	20MAR2003	01APR2003	1220	01APR2003	01JUN2003	02JUN2003
	E0028038	18APR2003	25APR2003	1253	25APR2003	17JUN2003	18JUN2003
	E0028043	29MAY2003	05JUN2003	1298	05JUN2003	28JUL2003	29JUL2003
	E0028045	09JUN2003	18JUN2003	1315	18JUN2003	08JUL2003	11SEP2003
	E0029005	14NOV2002	27NOV2002	1052	27NOV2002	20JAN2003	21JAN2003
	E0030001	12NOV2002	19NOV2002	1042	19NOV2002	15JAN2003	16JAN2003
	E0030008	07JAN2003	14JAN2003	1104	14JAN2003	17MAR2003	18MAR2003
	E0030011	16JAN2003	27JAN2003	1121	27JAN2003	23MAR2003	24MAR2003
	E0030015	13FEB2003	21FEB2003	1165	21FEB2003	21APR2003	22APR2003
	E0030022	06JUN2003	16JUN2003	1310	16JUN2003	13AUG2003	14AUG2003
	E0031002	20NOV2002	27NOV2002	2019	27NOV2002	21JAN2003	22JAN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	03DEC2002	10DEC2002	1063	10DEC2002	03FEB2003	04FEB2003
	E0033015	03APR2003	10APR2003	1235	10APR2003	02JUN2003	11JUN2003
	E0034002	14MAR2003	25MAR2003	1216	25MAR2003	14APR2003	16APR2003
	E0034003	11APR2003	24APR2003	1251	24APR2003	18JUN2003	19JUN2003
	E0034006	25APR2003	16MAY2003	1278	16MAY2003	09JUL2003	10JUL2003
	E0034008	15MAY2003	23MAY2003	1289	24MAY2003	20JUL2003	21JUL2003
	E0035003	15NOV2002	22NOV2002	1049	22NOV2002	09JAN2003	10JAN2003
	E0035005	26NOV2002	03DEC2002	1056	03DEC2002	21JAN2003	21JAN2003
	E0035014	28JAN2003	03FEB2003	1135	03FEB2003	30MAR2003	31MAR2003
	E0035024	15MAY2003	22MAY2003	1286	23MAY2003	17JUL2003	18JUL2003
	E0036005	24JUN2003	01JUL2003	1328	01JUL2003	26AUG2003	27AUG2003
	E0037002	18DEC2002	26DEC2002	1087	26DEC2002	19FEB2003	20FEB2003
	E0037005	26FEB2003	06MAR2003	1189	06MAR2003	30APR2003	01MAY2003
	E0037006	06MAR2003	14MAR2003	1201	14MAR2003	08MAY2003	09MAY2003
	E0039006	08NOV2002	30DEC2002	1090	30DEC2002	23FEB2003	24FEB2003
	E0039015	02JAN2003	23JAN2003	1118	23JAN2003	19MAR2003	20MAR2003
	E0039024	05FEB2003	27FEB2003	1178	27FEB2003	23APR2003	25APR2003
	E0039025	26FEB2003	18MAR2003	1204	18MAR2003	12MAY2003	27MAY2003
	E0039041	07APR2003	15APR2003	1240	15APR2003	09JUN2003	11JUN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	05MAY2003	22MAY2003	1284	22MAY2003	08JUL2003	23JUL2003
	E0039046	06MAY2003	21MAY2003	1282			03JUN2003
	E0039051	22MAY2003	16JUN2003	1309	16JUN2003	11AUG2003	12AUG2003
	E0039053	16JUN2003	11JUL2003	1341	11JUL2003	06SEP2003	08SEP2003
	E0039057	02JUL2003	14JUL2003	1345	14JUL2003	08SEP2003	09SEP2003
	E0041003	16JAN2003	28JAN2003	1127	28JAN2003	24MAR2003	25MAR2003
	E0041008	26MAR2003	07APR2003	1226	07APR2003	01JUN2003	10JUN2003
	E0042001	17JUN2003	02JUL2003	1331	02JUL2003	25AUG2003	26AUG2003
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	26FEB2003	12MAR2003	2082	12MAR2003	06MAY2003	07MAY2003
	E0003018	06MAY2003	13MAY2003	2139	13MAY2003	07JUL2003	08JUL2003
	E0005011	16OCT2002	24OCT2002	2001	24OCT2002	12DEC2002	12DEC2002
	E0005030	18MAR2003	26MAR2003	2100	26MAR2003	16APR2003	16APR2003
	E0005036	28APR2003	06MAY2003	2133	06MAY2003	12MAY2003	27MAY2003
	E0006015	06FEB2003	11FEB2003	2060	11FEB2003	07APR2003	08APR2003
	E0006016	07FEB2003	17FEB2003	2064	17FEB2003	17APR2003	18APR2003
	E0007008	07APR2003	18APR2003	2117	18APR2003	24APR2003	02JUL2003
	E0009002	29OCT2002	19NOV2002	2012	19NOV2002	14JAN2003	15JAN2003
	E0009006	22JAN2003	28JAN2003	2045	28JAN2003	24MAR2003	25MAR2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR II)	E0009009	27FEB2003	12MAR2003	2081	12MAR2003	21MAR2003	24MAR2003
	E0010015	29JAN2003	20FEB2003	2071	20FEB2003	14APR2003	15APR2003
	E0011004	05DEC2002	24DEC2002	2027	24DEC2002	17FEB2003	18FEB2003
	E0011007	12DEC2002	19DEC2002	2024	19DEC2002	12FEB2003	13FEB2003
	E0011018	24APR2003	22MAY2003	2148	22MAY2003	16JUL2003	17JUL2003
	E0011024	17JUN2003	24JUN2003	2165	24JUN2003	20AUG2003	21AUG2003
	E0015003	13NOV2002	25NOV2002	2016	25NOV2002	01DEC2002	02DEC2002
	E0019003	29OCT2002	21NOV2002	2013	21NOV2002	15JAN2003	16JAN2003
	E0019007	06NOV2002	13NOV2002	2009	13NOV2002	06JAN2003	07JAN2003
	E0019014	17DEC2002	09JAN2003	2033	09JAN2003	12JAN2003	22JAN2003
	E0019018	14JAN2003	30JAN2003	2047	30JAN2003	26MAR2003	27MAR2003
	E0019022	23JAN2003	30JAN2003	2051	30JAN2003	26MAR2003	27MAR2003
	E0019027	13FEB2003	27FEB2003	2074	27FEB2003	01MAR2003	06MAR2003
	E0019032	06MAR2003	01APR2003	2104	01APR2003	26MAY2003	10JUN2003
	E0019034	10MAR2003	18MAR2003	2091	18MAR2003	08APR2003	24APR2003
	E0019036	18MAR2003	25MAR2003	2095	25MAR2003	07MAY2003	24JUN2003
	E0019039	17APR2003	01MAY2003	2129	01MAY2003	03MAY2003	08MAY2003
	E0019041	14MAY2003	21MAY2003	2146	21MAY2003	14JUL2003	16JUL2003
	E0019049	03JUL2003	10JUL2003	2178	10JUL2003	03SEP2003	08SEP2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	01APR2003	10APR2003	2110	10APR2003	04JUN2003	05JUN2003
	E0022064	29APR2003	06MAY2003	2132	06MAY2003	30JUN2003	01JUL2003
	E0022073	19JUN2003	26JUN2003	2167	26JUN2003	20AUG2003	21AUG2003
	E0023002	25OCT2002	05NOV2002	2005	05NOV2002	07DEC2002	10DEC2002
	E0023017	14MAR2003	25MAR2003	2098	25MAR2003	21MAY2003	22MAY2003
	E0023021	10APR2003	23APR2003	2123	23APR2003	16JUN2003	17JUN2003
	E0023027	07MAY2003	16MAY2003	2144	16MAY2003	08JUL2003	09JUL2003
	E0023030	16MAY2003	03JUN2003	2154	03JUN2003	29JUL2003	30JUL2003
	E0023040	25JUN2003	03JUL2003	2172	03JUL2003	04SEP2003	05SEP2003
	E0026014	12FEB2003	19FEB2003	2067	19FEB2003	18MAR2003	19MAR2003
	E0026019	10MAR2003	17MAR2003	2087	17MAR2003	12MAY2003	12MAY2003
	E0027005	16DEC2002	26DEC2002	2028	26DEC2002	18FEB2003	20FEB2003
	E0029009	13JAN2003	20JAN2003	2038	20JAN2003	17MAR2003	18MAR2003
	E0029021	03MAR2003	18MAR2003	2088	18MAR2003	14MAY2003	27MAY2003
	E0029026	07APR2003	14APR2003	2112	14APR2003	09JUN2003	10JUN2003
	E0029030	13MAY2003	27MAY2003	2151	27MAY2003	22JUL2003	23JUL2003
	E0031008	31JAN2003	28FEB2003	2077	28FEB2003	23APR2003	24APR2003
	E0031020	14APR2003	21APR2003	2120	21APR2003	12MAY2003	13MAY2003
	E0031021	18APR2003	25APR2003	2125	25APR2003	17JUN2003	19JUN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 300 MG (BIPOLAR II)	E0031029	05JUN2003	18JUN2003	2157	18JUN2003	01JUL2003	08JUL2003
	E0033002	19DEC2002	10JAN2003	2034	10JAN2003	06MAR2003	07MAR2003
	E0033006	13JAN2003	23JAN2003	2041	23JAN2003	07FEB2003	12FEB2003
	E0033021	18JUN2003	02JUL2003	2171	02JUL2003	14AUG2003	20AUG2003
	E0035013	27JAN2003	04FEB2003	2055	04FEB2003	06FEB2003	10FEB2003
	E0035015	03FEB2003	11FEB2003	2061	11FEB2003	15FEB2003	18FEB2003
	E0035016	10MAR2003	04APR2003	2106	04APR2003	11APR2003	11APR2003
	E0035023	06MAY2003	13MAY2003	2138	13MAY2003	17JUN2003	17JUN2003
	E0039052	29MAY2003	20JUN2003	2160	20JUN2003	02JUL2003	07JUL2003
	E0039056	01JUL2003	14JUL2003	2183	15JUL2003	23JUL2003	23JUL2003
	E0040003	09JUL2003	18JUL2003	2185	19JUL2003	11SEP2003	12SEP2003
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	04FEB2003	03MAR2003	1181	03MAR2003	01MAY2003	02MAY2003
	E0002011	12APR2003	29APR2003	1254	29APR2003	24JUN2003	25JUN2003
	E0003010	27JAN2003	03FEB2003	1136	03FEB2003	29MAR2003	31MAR2003
	E0003011	28JAN2003	04FEB2003	2054	04FEB2003	06MAR2003	06MAR2003
	E0003016	01MAY2003	22MAY2003	1285	22MAY2003	11JUN2003	13JUN2003
	E0003019	19JUN2003	27JUN2003	2170	27JUN2003	20AUG2003	21AUG2003
	E0003020	24JUN2003	23JUL2003	1353	23JUL2003	16SEP2003	17SEP2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	23SEP2002	30SEP2002	1004	30SEP2002	30OCT2002	05NOV2002
	E0004009	17DEC2002	26DEC2002	1084	26DEC2002	18FEB2003	17MAR2003
	E0004012	07JAN2003	14JAN2003	1103	14JAN2003	10MAR2003	11MAR2003
	E0004015	06FEB2003	20FEB2003	1162	20FEB2003	14APR2003	15APR2003
	E0005003	23SEP2002	02OCT2002	1008	02OCT2002	25NOV2002	02JAN2003
	E0005005	24SEP2002	30SEP2002	1001	30SEP2002	08OCT2002	10OCT2002
	E0005007	02OCT2002	09OCT2002	1014	09OCT2002	03DEC2002	14JAN2003
	E0005008	08OCT2002	15OCT2002	1017	15OCT2002	10DEC2002	11DEC2002
	E0005009	09OCT2002	29OCT2002	1023	29OCT2002	01NOV2002	05NOV2002
	E0005010	14OCT2002	21OCT2002	1020	21OCT2002	16DEC2002	23DEC2002
	E0005012	23OCT2002	14NOV2002	1040	14NOV2002	06JAN2003	07JAN2003
	E0005014	05NOV2002	13NOV2002	1037	13NOV2002	05JAN2003	15JAN2003
	E0005022	23JAN2003	29JAN2003	1128	29JAN2003	02MAR2003	11MAR2003
	E0005025	20FEB2003	27FEB2003	1177	27FEB2003	02APR2003	03APR2003
	E0006019	26MAR2003	07APR2003	1230	07APR2003	02JUN2003	03JUN2003
	E0007005	27JAN2003	31JAN2003	1134	31JAN2003	27MAR2003	11APR2003
	E0007015	09JUL2003	16JUL2003	1348	16JUL2003	09SEP2003	10SEP2003
	E0009001	29OCT2002	12NOV2002	1033	12NOV2002	07JAN2003	03MAR2003
	E0010002	14NOV2002	25NOV2002	1050	25NOV2002	25NOV2002	02DEC2002

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	18DEC2002	26DEC2002	1085	26DEC2002	18FEB2003	19FEB2003
	E0010010	20DEC2002	30DEC2002	1092	30DEC2002	12JAN2003	13JAN2003
	E0010014	14JAN2003	28JAN2003	1122	28JAN2003	24MAR2003	25MAR2003
	E0010017	05FEB2003	25FEB2003	1169	25FEB2003	21APR2003	22APR2003
	E0010023	10APR2003	17APR2003	1242	17APR2003	27APR2003	01MAY2003
	E0010027	05JUN2003	16JUN2003	1307	16JUN2003	28JUN2003	01JUL2003
	E0010029	10JUN2003	19JUN2003	1318	19JUN2003	27JUN2003	03JUL2003
	E0011022	02JUN2003	09JUN2003	1300	09JUN2003	04AUG2003	05AUG2003
	E0013006	05MAR2003	13MAR2003	1198	13MAR2003	20MAR2003	24MAR2003
	E0013012	28APR2003	07MAY2003	1266	07MAY2003	01JUL2003	02JUL2003
	E0013014	08MAY2003	03JUN2003	1295	03JUN2003	22JUN2003	30JUN2003
	E0014005	04MAR2003	11MAR2003	1194	11MAR2003	05MAY2003	06MAY2003
	E0014007	25MAR2003	01APR2003	1224	01APR2003	17APR2003	22APR2003
	E0014011	06MAY2003	13MAY2003	1275	13MAY2003	07JUL2003	08JUL2003
	E0014012	19MAY2003	27MAY2003	1290	27MAY2003	23JUN2003	24JUN2003
	E0015001	08NOV2002	29NOV2002	1053	29NOV2002	17JAN2003	20JAN2003
	E0015008	13DEC2002	19DEC2002	1079	19DEC2002	31JAN2003	06FEB2003
	E0016003	10JAN2003	24JAN2003	1119	24JAN2003	15MAR2003	19MAR2003
	E0016005	20FEB2003	25FEB2003	1172	25FEB2003	21APR2003	02MAY2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR I)	E0018007	16DEC2002	27DEC2002	1088	27DEC2002	30DEC2002	10JAN2003
	E0019005	30OCT2002	05NOV2002	1027	05NOV2002	01JAN2003	10JAN2003
	E0019015	19DEC2002	02JAN2003	1095	02JAN2003	26FEB2003	27FEB2003
	E0020004	21NOV2002	09DEC2002	1062	09DEC2002	21JAN2003	22JAN2003
	E0020010	28JAN2003	05FEB2003	1143	05FEB2003	01APR2003	02APR2003
	E0020014	11MAR2003	18MAR2003	1202	18MAR2003	11MAY2003	12MAY2003
	E0020021	09MAY2003	19MAY2003	1280	19MAY2003	13JUL2003	14JUL2003
	E0020023	09JUN2003	16JUN2003	1311	17JUN2003	10AUG2003	11AUG2003
	E0022007	01NOV2002	07NOV2002	1030	07NOV2002	08DEC2002	09DEC2002
	E0022010	14NOV2002	21NOV2002	1048	21NOV2002	15JAN2003	16JAN2003
	E0022012	21NOV2002	05DEC2002	1060	05DEC2002	29JAN2003	30JAN2003
	E0022019	04DEC2002	11DEC2002	1066	11DEC2002	05FEB2003	06FEB2003
	E0022025	08JAN2003	28JAN2003	1126	28JAN2003	03FEB2003	04FEB2003
	E0022033	11FEB2003	18FEB2003	1157	18FEB2003	14APR2003	15APR2003
	E0022034	11FEB2003	18FEB2003	1156	18FEB2003	13APR2003	15APR2003
	E0022038	20FEB2003	28FEB2003	1179	28FEB2003	09APR2003	11APR2003
	E0022039	27FEB2003	06MAR2003	1185	06MAR2003	30APR2003	01MAY2003
	E0022046	13MAR2003	20MAR2003	1211	20MAR2003	15MAY2003	16MAY2003
	E0022048	25MAR2003	01APR2003	1222	01APR2003	31MAY2003	17JUN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	31MAR2003	07APR2003	1233	07APR2003	01JUN2003	02JUN2003
	E0022053	04APR2003	11APR2003	1237	11APR2003	19APR2003	24APR2003
	E0022058	11APR2003	21APR2003	1247	21APR2003	21MAY2003	22MAY2003
	E0022061	24APR2003	30APR2003	1257	30APR2003	25JUN2003	26JUN2003
	E0022062	25APR2003	05MAY2003	1262	05MAY2003	20MAY2003	23MAY2003
	E0022068	14MAY2003	22MAY2003	1288	23MAY2003	05JUN2003	05JUN2003
	E0022069	03JUN2003	10JUN2003	1303	10JUN2003	03AUG2003	05AUG2003
	E0022071	16JUN2003	30JUN2003	1326	30JUN2003	24AUG2003	25AUG2003
	E0023003	08NOV2002	17DEC2002	1076	17DEC2002	10FEB2003	11FEB2003
	E0023006	10DEC2002	17DEC2002	1075	17DEC2002	10FEB2003	11FEB2003
	E0023010	28JAN2003	04FEB2003	1139	04FEB2003	30MAR2003	31MAR2003
	E0023025	01MAY2003	15MAY2003	1277	15MAY2003	09JUL2003	10JUL2003
	E0023039	24JUN2003	01JUL2003	1329	01JUL2003	25AUG2003	26AUG2003
	E0026002	05NOV2002	12NOV2002	1034	12NOV2002	08JAN2003	09JAN2003
	E0026007	06JAN2003	16JAN2003	1108	16JAN2003	11MAR2003	12MAR2003
	E0026013	05FEB2003	13FEB2003	1151	13FEB2003	09APR2003	14APR2003
	E0028007	01OCT2002	04OCT2002	1012	04OCT2002	13NOV2002	14NOV2002
	E0028023	17DEC2002	21JAN2003	1110	21JAN2003	09MAR2003	27JUN2003
	E0028025	08JAN2003	13JAN2003	1101	13JAN2003	24JAN2003	27JAN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	18MAR2003	27MAR2003	1219	27MAR2003	21MAY2003	22MAY2003
	E0028035	27MAR2003	03APR2003	1228	03APR2003	28MAY2003	29MAY2003
	E0028037	17APR2003	12JUN2003	1304	13JUN2003	07AUG2003	08AUG2003
	E0028039	02MAY2003	08MAY2003	1271	09MAY2003	04JUN2003	05JUN2003
	E0028046	17JUN2003	25JUN2003	1322	25JUN2003	25JUN2003	25JUN2003
	E0028048	11JUL2003	17JUL2003	1350	17JUL2003	09SEP2003	09SEP2003
	E0029008	09DEC2002	16DEC2002	1070	16DEC2002	20DEC2002	23DEC2002
	E0029011	14JAN2003	21JAN2003	1112	22JAN2003	13FEB2003	13FEB2003
	E0029012	04FEB2003	11FEB2003	1150	11FEB2003	17MAR2003	18MAR2003
	E0029015	11FEB2003	24FEB2003	1167	24FEB2003	05MAR2003	11MAR2003
	E0029018	26FEB2003	06MAR2003	1188	06MAR2003	07MAR2003	07MAR2003
	E0030014	12FEB2003	21FEB2003	1164	21FEB2003	19APR2003	22APR2003
	E0030020	13MAY2003	29MAY2003	1292	29MAY2003	24JUN2003	24JUN2003
	E0030024	17JUN2003	11JUL2003	1343	11JUL2003	15JUL2003	18JUL2003
	E0030025	24JUN2003	11JUL2003	1340	11JUL2003	18AUG2003	19AUG2003
	E0031027	27MAY2003	03JUN2003	2153	03JUN2003	28JUL2003	29JUL2003
	E0031030	17JUN2003	24JUN2003	1321	24JUN2003	20AUG2003	21AUG2003
	E0033012	05FEB2003	10FEB2003	1147	10FEB2003	18FEB2003	20FEB2003
	E0034001	13MAR2003	20MAR2003	1208	20MAR2003	14MAY2003	15MAY2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	11APR2003	21APR2003	1245	21APR2003	15JUN2003	16JUN2003
	E0035001	12NOV2002	20NOV2002	1044	20NOV2002	13JAN2003	14JAN2003
	E0035006	03DEC2002	12DEC2002	1068	12DEC2002	05FEB2003	06FEB2003
	E0035021	18APR2003	25APR2003	1252	25APR2003	19JUN2003	20JUN2003
	E0036002	10JUN2003	17JUN2003	1313	17JUN2003	13JUL2003	13AUG2003
	E0036006	24JUN2003	03JUL2003	1334	03JUL2003	26AUG2003	28AUG2003
	E0036007	26JUN2003	03JUL2003	1333	03JUL2003	15JUL2003	23JUL2003
	E0037009	09MAY2003	16MAY2003	2143	16MAY2003	09JUL2003	10JUL2003
	E0039011	16DEC2002	02JAN2003	1097	02JAN2003	27FEB2003	04MAR2003
	E0039018	14JAN2003	23JAN2003	1116	23JAN2003	28FEB2003	19MAR2003
	E0039026	26FEB2003	07MAR2003	1190	07MAR2003	30APR2003	02MAY2003
	E0039028	03MAR2003	24MAR2003	1215	24MAR2003	13MAY2003	08JUL2003
	E0039032	07MAR2003	14MAR2003	1200	14MAR2003	23MAR2003	04APR2003
	E0039034	12MAR2003	19MAR2003	1207	19MAR2003	13MAY2003	14MAY2003
	E0039042	24APR2003	07MAY2003	1270	07MAY2003	01JUL2003	02JUL2003
	E0041004	22JAN2003	30JAN2003	1130	30JAN2003	29MAR2003	31MAR2003
	E0041009	22APR2003	01MAY2003	1259	01MAY2003	11JUN2003	16JUN2003
	E0042002	02JUL2003	09JUL2003	1338	09JUL2003	01SEP2003	02SEP2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	23JUN2003	11JUL2003	2180	11JUL2003	15JUL2003	25JUL2003
	E0003002	22OCT2002	29OCT2002	2002	29OCT2002	23DEC2002	23DEC2002
	E0005031	26MAR2003	02APR2003	2105	02APR2003	19MAY2003	03JUL2003
	E0005033	08APR2003	16APR2003	2114	16APR2003	04MAY2003	28MAY2003
	E0005038	05MAY2003	14MAY2003	2140	14MAY2003	04JUN2003	05JUN2003
	E0007009	09APR2003	17APR2003	2116	17APR2003	21APR2003	28APR2003
	E0009010	27FEB2003	13MAR2003	2085	13MAR2003	02APR2003	02APR2003
	E0009011	28APR2003	06MAY2003	2131	06MAY2003	02JUL2003	15JUL2003
	E0010005	04DEC2002	18DEC2002	2022	18DEC2002	19DEC2002	19DEC2002
	E0011016	14APR2003	21APR2003	2121	21APR2003	15JUN2003	16JUN2003
	E0011020	01MAY2003	08MAY2003	2136	08MAY2003	09MAY2003	15MAY2003
	E0018002	13NOV2002	29NOV2002	2020	29NOV2002	21JAN2003	22JAN2003
	E0018003	19NOV2002	26NOV2002	2017	26NOV2002	07DEC2002	10DEC2002
	E0018013	17JAN2003	24JAN2003	2044	24JAN2003	27JAN2003	31JAN2003
	E0019002	29OCT2002	12NOV2002	2007	12NOV2002	19NOV2002	19NOV2002
	E0019008	06NOV2002	21NOV2002	2014	21NOV2002	27DEC2002	07APR2003
	E0019009	28OCT2002	14NOV2002	2010	14NOV2002	10DEC2002	10DEC2002
	E0019016	30DEC2002	06JAN2003	2031	06JAN2003	02MAR2003	03MAR2003
	E0019020	16JAN2003	23JAN2003	2040	23JAN2003	19MAR2003	27MAR2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	16JAN2003	30JAN2003	2048	30JAN2003	16FEB2003	03MAR2003
	E0019024	23JAN2003	30JAN2003	2050	30JAN2003	07FEB2003	12JUN2003
	E0019031	06MAR2003	13MAR2003	2083	13MAR2003	16MAR2003	25MAR2003
	E0019035	11MAR2003	18MAR2003	2090	18MAR2003	16APR2003	24APR2003
	E0019040	08MAY2003	20MAY2003	2145	20MAY2003	16JUL2003	17JUL2003
	E0019042	20MAY2003	04JUN2003	2155	04JUN2003	17JUN2003	20JUN2003
	E0019045	19JUN2003	26JUN2003	2168	26JUN2003	07JUL2003	16JUL2003
	E0020024	11JUN2003	23JUN2003	2162	23JUN2003	19AUG2003	20AUG2003
	E0022044	11MAR2003	18MAR2003	2092	18MAR2003	10MAY2003	12MAY2003
	E0023007	07JAN2003	14JAN2003	2036	14JAN2003	10MAR2003	13MAR2003
	E0023011	28JAN2003	04FEB2003	2056	04FEB2003	31MAR2003	01APR2003
	E0023014	14FEB2003	21FEB2003	2072	21FEB2003	23APR2003	25APR2003
	E0023019	21MAR2003	07APR2003	2108	07APR2003	02JUN2003	03JUN2003
	E0023022	10APR2003	18APR2003	2119	18APR2003	12JUN2003	12JUN2003
	E0023023	17APR2003	25APR2003	2126	25APR2003	27APR2003	01MAY2003
	E0023029	16MAY2003	23MAY2003	2150	23MAY2003	25MAY2003	09JUL2003
	E0023031	22MAY2003	24JUN2003	2164	24JUN2003	18AUG2003	19AUG2003
	E0023041	02JUL2003	09JUL2003	2176	09JUL2003	04SEP2003	05SEP2003
	E0023043	07JUL2003	14JUL2003	2182	14JUL2003	08SEP2003	09SEP2003

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	25NOV2002	04DEC2002	1057	04DEC2002	29JAN2003	03FEB2003
	E0026005	23DEC2002	30DEC2002	2030	30DEC2002	05JAN2003	06JAN2003
	E0026009	10JAN2003	15JAN2003	2037	15JAN2003	18JAN2003	21JAN2003
	E0026015	20FEB2003	27FEB2003	2076	27FEB2003	24APR2003	25APR2003
	E0026023	23APR2003	30APR2003	2128	30APR2003	24JUN2003	27JUN2003
	E0027016	19MAR2003	09APR2003	2109	09APR2003	02JUN2003	03JUN2003
	E0027018	21MAR2003	25MAR2003	2097	25MAR2003	21MAY2003	22MAY2003
	E0028032	13MAR2003	25MAR2003	2096	25MAR2003	19MAY2003	06JUN2003
	E0029003	28OCT2002	04NOV2002	2004	04NOV2002	29DEC2002	30DEC2002
	E0029020	25FEB2003	04MAR2003	2079	05MAR2003	11MAR2003	08APR2003
	E0031005	06DEC2002	20DEC2002	2025	20DEC2002	13FEB2003	14FEB2003
	E0031006	29JAN2003	18FEB2003	2065	18FEB2003	14APR2003	15APR2003
	E0031010	12FEB2003	19FEB2003	2069	19FEB2003	04MAR2003	06MAR2003
	E0031011	18FEB2003	27FEB2003	2075	27FEB2003	23APR2003	24APR2003
	E0031015	13MAR2003	26MAR2003	2101	26MAR2003	31MAR2003	01APR2003
	E0031031	01JUL2003	08JUL2003	2174	08JUL2003	04AUG2003	28AUG2003
	E0033009	22JAN2003	12FEB2003	2062	12FEB2003	18FEB2003	18FEB2003
	E0034009	10JUN2003	19JUN2003	2158	19JUN2003	15AUG2003	18AUG2003
	E0037007	04APR2003	11APR2003	1238	11APR2003	26APR2003	23MAY2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	09JUL2003	16JUL2003	2184	16JUL2003	07SEP2003	08SEP2003
	E0039019	20JAN2003	06FEB2003	2058	06FEB2003	02APR2003	03APR2003
	E0039043	25APR2003	08MAY2003	2134	08MAY2003	13JUN2003	09JUL2003
PLACEBO (BIPOLAR I)	E0002001	13DEC2002	30DEC2002	1093	30DEC2002	25FEB2003	26FEB2003
	E0002003	21DEC2002	22JAN2003	1113	22JAN2003	17MAR2003	18MAR2003
	E0002004	24DEC2002	25JAN2003	1120	25JAN2003	02FEB2003	27FEB2003
	E0002008	29JAN2003	25FEB2003	1173	25FEB2003	22APR2003	23APR2003
	E0002016	09JUL2003	24JUL2003	1354	24JUL2003	16SEP2003	17SEP2003
	E0003008	21JAN2003	28JAN2003	1123	28JAN2003	23FEB2003	03MAR2003
	E0004003	02OCT2002	10OCT2002	1015	10OCT2002	25OCT2002	31OCT2002
	E0004006	28OCT2002	04NOV2002	1026	04NOV2002	05JAN2003	06JAN2003
	E0004016	12FEB2003	19FEB2003	1160	19FEB2003	16APR2003	17APR2003
	E0004024	25JUN2003	03JUL2003	1332	03JUL2003	27AUG2003	28AUG2003
	E0005006	24SEP2002	03OCT2002	1009	03OCT2002	22OCT2002	22OCT2002
	E0005017	11DEC2002	30DEC2002	1089	30DEC2002	28FEB2003	04MAR2003
	E0005019	19DEC2002	15JAN2003	1105	15JAN2003	21JAN2003	24JAN2003
	E0005026	26FEB2003	06MAR2003	1187	06MAR2003	24MAR2003	02APR2003
	E0005039	15MAY2003	22MAY2003	1283	22MAY2003	15JUL2003	16JUL2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR I)	E0005043	01JUL2003	09JUL2003	1337	09JUL2003	02SEP2003	03SEP2003
	E0006020	02MAY2003	13MAY2003	1274	13MAY2003	07JUL2003	10JUL2003
	E0007001	10DEC2002	31DEC2002	1094	31DEC2002	21FEB2003	10MAR2003
	E0007003	03JAN2003	30JAN2003	1129	30JAN2003	24FEB2003	01APR2003
	E0007006	21FEB2003	05MAR2003	1184	05MAR2003	27MAR2003	27MAR2003
	E0009004	11NOV2002	26NOV2002	1051	26NOV2002	17DEC2002	18DEC2002
	E0009012	16JUN2003	25JUN2003	1323	25JUN2003	25JUN2003	22JUL2003
	E0010008	11DEC2002	18DEC2002	1078	18DEC2002	15JAN2003	15JAN2003
	E0010018	26FEB2003	19MAR2003	1205	19MAR2003	10MAY2003	14MAY2003
	E0010028	09JUN2003	16JUN2003	1312	16JUN2003	13JUL2003	15JUL2003
	E0011008	17DEC2002	30JAN2003	1133	30JAN2003	09FEB2003	13FEB2003
	E0011009	19DEC2002	26DEC2002	1086	27DEC2002	20FEB2003	20FEB2003
	E0011010	03FEB2003	10FEB2003	1146	10FEB2003	16MAR2003	19MAR2003
	E0013001	24OCT2002	14NOV2002	1038	14NOV2002	08JAN2003	10JAN2003
	E0013003	06NOV2002	12NOV2002	1036	12NOV2002	05JAN2003	06JAN2003
	E0013005	11FEB2003	18FEB2003	1154	18FEB2003	14APR2003	15APR2003
	E0013013	01MAY2003	06MAY2003	1264	06MAY2003	26MAY2003	02JUN2003
	E0014002	19FEB2003	26FEB2003	1175	26FEB2003	04APR2003	10APR2003
	E0014004	04MAR2003	12MAR2003	1196	12MAR2003	30MAR2003	15APR2003

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR I)	E0014009	15APR2003	23APR2003	1249	23APR2003	29APR2003	16MAY2003
	E0014015	11JUN2003	18JUN2003	1314	18JUN2003	04JUL2003	08AUG2003
	E0014017	17JUN2003	27JUN2003	1325	27JUN2003	18AUG2003	19AUG2003
	E0014018	24JUN2003	01JUL2003	1330	01JUL2003	26AUG2003	27AUG2003
	E0015005	25NOV2002	02DEC2002	1055	02DEC2002	17DEC2002	18DEC2002
	E0017002	06MAY2003	03JUN2003	1296	03JUN2003	11JUN2003	13JUN2003
	E0018009	17DEC2002	06JAN2003	1098	06JAN2003	14JAN2003	14JAN2003
	E0018010	09JAN2003	16JAN2003	1107	16JAN2003	12MAR2003	13MAR2003
	E0018015	21JAN2003	28JAN2003	1125	28JAN2003	26MAR2003	27MAR2003
	E0020015	18MAR2003	27MAR2003	1218	27MAR2003	22MAY2003	23MAY2003
	E0020017	27MAR2003	03APR2003	1227	03APR2003	28MAY2003	03JUN2003
	E0020020	07MAY2003	12MAY2003	1273	12MAY2003	22MAY2003	23MAY2003
	E0020022	09JUN2003	16JUN2003	1308	16JUN2003	10AUG2003	11AUG2003
	E0022001	07OCT2002	28OCT2002	1022	28OCT2002	24DEC2002	26DEC2002
	E0022004	17OCT2002	28OCT2002	1021	28OCT2002	22DEC2002	23DEC2002
	E0022005	17OCT2002	08NOV2002	1032	08NOV2002	02JAN2003	03JAN2003
	E0022011	20NOV2002	29NOV2002	1054	29NOV2002	05DEC2002	05DEC2002
	E0022015	29NOV2002	10DEC2002	1064	10DEC2002	05FEB2003	06FEB2003
	E0022016	03DEC2002	17DEC2002	1074	17DEC2002	10FEB2003	11FEB2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR I)	E0022020	05DEC2002	12DEC2002	1069	12DEC2002	15JAN2003	23JAN2003
	E0022023	19DEC2002	24DEC2002	1083	25DEC2002	19FEB2003	20FEB2003
	E0022029	05FEB2003	19FEB2003	1159	19FEB2003	13APR2003	14APR2003
	E0022041	04MAR2003	18MAR2003	1203	18MAR2003	11MAY2003	13MAY2003
	E0022042	05MAR2003	12MAR2003	1195	12MAR2003	07MAY2003	12MAY2003
	E0022043	10MAR2003	20MAR2003	1210	20MAR2003	12MAY2003	12MAY2003
	E0022054	04APR2003	11APR2003	1239	11APR2003	24MAY2003	04JUN2003
	E0022059	22APR2003	06MAY2003	1265	06MAY2003	04JUL2003	08JUL2003
	E0022065	30APR2003	07MAY2003	1268	07MAY2003	01JUL2003	02JUL2003
	E0022070	05JUN2003	12JUN2003	1305	12JUN2003	17JUN2003	18JUN2003
	E0023001	24OCT2002	15NOV2002	1041	15NOV2002	14JAN2003	14JAN2003
	E0023009	24JAN2003	11FEB2003	1149	11FEB2003	07APR2003	08APR2003
	E0023028	16MAY2003	29MAY2003	1291	29MAY2003	20JUL2003	21JUL2003
	E0023033	30MAY2003	05JUN2003	1299	05JUN2003	11JUN2003	12JUN2003
	E0023047	11JUL2003	18JUL2003	1351	18JUL2003	11SEP2003	12SEP2003
	E0025001	25MAR2003	01APR2003	1231	01APR2003	22APR2003	23APR2003
	E0026012	05FEB2003	20FEB2003	1163	20FEB2003	16APR2003	17APR2003
	E0026020	28MAR2003	01APR2003	1221	01APR2003	21APR2003	22APR2003
	E0026024	25APR2003	02MAY2003	1260	02MAY2003	03JUN2003	03JUN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR I)	E0026028	06JUN2003	20JUN2003	1319	20JUN2003	14JUL2003	23JUL2003
	E0028001	20SEP2002	10OCT2002	1016	10OCT2002	02DEC2002	03DEC2002
	E0028003	23SEP2002	30SEP2002	1002	30SEP2002	25NOV2002	26NOV2002
	E0028005	30SEP2002	03OCT2002	1010	03OCT2002	12OCT2002	31OCT2002
	E0028010	15OCT2002	05NOV2002	1028	05NOV2002	30DEC2002	31DEC2002
	E0028011	16OCT2002	05DEC2002	1061	05DEC2002	29JAN2003	30JAN2003
	E0028030	26FEB2003	04MAR2003	1182	04MAR2003	29APR2003	30APR2003
	E0028031	06MAR2003	11MAR2003	1191	11MAR2003	02APR2003	17APR2003
	E0028047	08JUL2003	14JUL2003	1344	14JUL2003	08SEP2003	09SEP2003
	E0029001	24SEP2002	01OCT2002	1005	01OCT2002	17OCT2002	26OCT2002
	E0029014	28JAN2003	04FEB2003	1137	04FEB2003	31MAR2003	01APR2003
	E0029023	11MAR2003	08APR2003	1234	08APR2003	06JUN2003	10JUN2003
	E0029032	22MAY2003	10JUN2003	1302	10JUN2003	19JUN2003	01JUL2003
	E0029033	27MAY2003	02JUN2003	1293	02JUN2003	29JUN2003	30JUN2003
	E0029039	10JUL2003	15JUL2003	1346	15JUL2003	27JUL2003	28JUL2003
	E0030003	03DEC2002	16DEC2002	1071	16DEC2002	22DEC2002	24DEC2002
	E0030009	10JAN2003	23JAN2003	1117	23JAN2003	18MAR2003	19MAR2003
	E0030016	21FEB2003	03MAR2003	1180	03MAR2003	17APR2003	22APR2003
	E0030021	13MAY2003	20MAY2003	1281	20MAY2003	17JUN2003	17JUN2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR I)	E0031001	14NOV2002	21NOV2002	1047	21NOV2002	23DEC2002	23DEC2002
	E0031017	25MAR2003	01APR2003	1223	01APR2003	28APR2003	29APR2003
	E0031018	01APR2003	10APR2003	1236	10APR2003	02MAY2003	21MAY2003
	E0031023	21APR2003	29APR2003	1255	29APR2003	23JUN2003	24JUN2003
	E0033001	19DEC2002	09JAN2003	1100	09JAN2003	29JAN2003	30JAN2003
	E0033004	08JAN2003	17JAN2003	1109	17JAN2003	13MAR2003	14MAR2003
	E0033010	22JAN2003	04FEB2003	1142	04FEB2003	22MAR2003	26APR2003
	E0033014	12MAR2003	19MAR2003	2093	19MAR2003	27APR2003	16JUN2003
	E0035002	14NOV2002	21NOV2002	1045	21NOV2002	17DEC2002	17DEC2002
	E0035007	13DEC2002	19DEC2002	1080	19DEC2002	10FEB2003	11FEB2003
	E0035011	09JAN2003	04FEB2003	1140	04FEB2003	31MAR2003	01APR2003
	E0035020	11APR2003	18APR2003	1244	18APR2003	12JUN2003	13JUN2003
	E0037003	22JAN2003	30JAN2003	1132	30JAN2003	19FEB2003	20FEB2003
	E0037004	06FEB2003	13FEB2003	1152	13FEB2003	09APR2003	10APR2003
	E0039007	25NOV2002	04DEC2002	1058	04DEC2002	28JAN2003	29JAN2003
	E0039022	04FEB2003	25FEB2003	1170	25FEB2003	23APR2003	24APR2003
	E0039023	05FEB2003	24FEB2003	1168	24FEB2003	11MAR2003	14MAR2003
	E0039030	04MAR2003	24MAR2003	1214	24MAR2003	18MAY2003	30MAY2003
	E0039031	05MAR2003	24MAR2003	1213	24MAR2003	19MAY2003	20MAY2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR I)	E0039037	26MAR2003	16APR2003	1241	16APR2003	13JUN2003	31JUL2003
	E0039038	26MAR2003	23APR2003	1250	23APR2003	06JUN2003	20JUN2003
	E0039047	12MAY2003	19MAY2003	1279	19MAY2003	13JUL2003	23JUL2003
	E0039059	03JUL2003	11JUL2003	1342	11JUL2003	04SEP2003	05SEP2003
	E0041007	05MAR2003	13MAR2003	1199	13MAR2003	07MAY2003	08MAY2003
	E0041010	23APR2003	30APR2003	1256	30APR2003	10JUN2003	13JUN2003
	E0041011	15MAY2003	22MAY2003	1287	22MAY2003	16JUL2003	17JUL2003
	E0041012	05JUN2003	19JUN2003	1317	19JUN2003	13AUG2003	14AUG2003
PLACEBO (BIPOLAR II)	E0001004	23APR2003	01MAY2003	2130	01MAY2003	26JUN2003	02JUL2003
	E0005023	28JAN2003	05FEB2003	2057	05FEB2003	01APR2003	01APR2003
	E0005034	08APR2003	15APR2003	2113	15APR2003	08JUN2003	09JUN2003
	E0005041	17JUN2003	24JUN2003	2163	24JUN2003	17AUG2003	18AUG2003
	E0007004	24JAN2003	30JAN2003	2049	30JAN2003	11FEB2003	13FEB2003
	E0007010	11APR2003	18APR2003	2118	18APR2003	14JUN2003	16JUN2003
	E0007012	02MAY2003	16MAY2003	2141	16MAY2003	30JUN2003	03JUL2003
	E0009007	27JAN2003	03FEB2003	2053	03FEB2003	02MAR2003	03MAR2003
	E0009008	04FEB2003	12FEB2003	2063	12FEB2003	07APR2003	08APR2003
	E0011001	25OCT2002	01NOV2002	2003	01NOV2002	24DEC2002	26DEC2002

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR II)	E0011011	12FEB2003	20FEB2003	2070	20FEB2003	15APR2003	16APR2003
	E0011013	25MAR2003	17APR2003	2115	17APR2003	11JUN2003	12JUN2003
	E0011014	31MAR2003	07APR2003	2107	07APR2003	22APR2003	08MAY2003
	E0011021	15MAY2003	22MAY2003	2147	22MAY2003	18JUL2003	21JUL2003
	E0013008	19MAR2003	26MAR2003	2099	26MAR2003	18MAY2003	19MAY2003
	E0014001	18FEB2003	26FEB2003	2073	26FEB2003	31MAR2003	01APR2003
	E0014013	20MAY2003	27MAY2003	2152	27MAY2003	22JUL2003	23JUL2003
	E0014014	03JUN2003	10JUN2003	2156	10JUN2003	05AUG2003	06AUG2003
	E0015004	25NOV2002	02DEC2002	2021	02DEC2002	28JAN2003	29JAN2003
	E0018005	10DEC2002	20DEC2002	2026	20DEC2002	13FEB2003	14FEB2003
	E0018012	17JAN2003	24JAN2003	2043	24JAN2003	25FEB2003	26FEB2003
	E0019019	14JAN2003	23JAN2003	2042	23JAN2003	14FEB2003	17FEB2003
	E0019033	10MAR2003	18MAR2003	2089	18MAR2003	14MAY2003	16MAY2003
	E0019038	10APR2003	24APR2003	2124	24APR2003	17JUN2003	19JUN2003
	E0019046	19JUN2003	26JUN2003	2166	26JUN2003	20AUG2003	21AUG2003
	E0019047	26JUN2003	08JUL2003	2173	08JUL2003	03SEP2003	04SEP2003
	E0019048	03JUL2003	10JUL2003	2179	10JUL2003	02SEP2003	03SEP2003
	E0022006	21OCT2002	12NOV2002	2008	12NOV2002	06JAN2003	07JAN2003
	E0022047	21MAR2003	28MAR2003	2103	28MAR2003	22MAY2003	23MAY2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR II)	E0022075	25JUN2003	08JUL2003	2175	08JUL2003	02SEP2003	03SEP2003
	E0023012	31JAN2003	06FEB2003	2059	06FEB2003	03APR2003	04APR2003
	E0023016	15MAY2003	22MAY2003	2149	22MAY2003	16JUL2003	17JUL2003
	E0023018	18MAR2003	27MAR2003	2102	27MAR2003	21MAY2003	22MAY2003
	E0023036	10JUN2003	20JUN2003	2161	20JUN2003	12AUG2003	13AUG2003
	E0023046	11JUL2003	23JUL2003	2187	23JUL2003	15SEP2003	16SEP2003
	E0026006	31DEC2002	08JAN2003	2032	08JAN2003	19FEB2003	19FEB2003
	E0026021	14APR2003	23APR2003	2122	23APR2003	11MAY2003	12MAY2003
	E0026027	05JUN2003	19JUN2003	2159	19JUN2003	23JUN2003	10JUL2003
	E0029002	24OCT2002	12NOV2002	2006			19NOV2002
	E0029004	13NOV2002	19NOV2002	2011	19NOV2002	15JAN2003	16JAN2003
	E0029013	27JAN2003	19FEB2003	2066	19FEB2003	10APR2003	10APR2003
	E0029019	24FEB2003	03MAR2003	2078	03MAR2003	16MAR2003	17MAR2003
	E0029024	11MAR2003	17MAR2003	2086	17MAR2003	19MAY2003	20MAY2003
	E0029038	30JUN2003	07JUL2003	1335	07JUL2003	13JUL2003	11AUG2003
	E0031004	12DEC2002	19DEC2002	2023	19DEC2002	13FEB2003	14FEB2003
	E0031013	06MAR2003	13MAR2003	2084	13MAR2003	07MAY2003	08MAY2003
	E0031016	17MAR2003	24MAR2003	2094	24MAR2003	13APR2003	15APR2003
	E0031019	03APR2003	11APR2003	2111	11APR2003	11MAY2003	12MAY2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.3 Study Dates

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	CONSENT	RANDOMIZATION	RANDOMIZATION CODE	FIRST DOSE	LAST DOSE	TRIAL COMPLETION
PLACEBO (BIPOLAR II)	E0031022	21APR2003	28APR2003	2127	28APR2003	02JUN2003	11JUN2003
	E0033007	13JAN2003	28JAN2003	2046	28JAN2003	24MAR2003	25MAR2003
	E0033013	31JAN2003	19FEB2003	2068	19FEB2003	15APR2003	16APR2003
	E0033016	14APR2003	08MAY2003	2135	08MAY2003	01JUL2003	02JUL2003
	E0033022	25JUN2003	14JUL2003	2181	14JUL2003	10SEP2003	11SEP2003
	E0034007	06MAY2003	16MAY2003	2142	16MAY2003	13JUL2003	14JUL2003
	E0035004	22NOV2002	27NOV2002	2018	27NOV2002	03DEC2002	04DEC2002
	E0035009	20DEC2002	27DEC2002	2029	27DEC2002	17FEB2003	19FEB2003
	E0035010	06JAN2003	10JAN2003	2035	10JAN2003	05MAR2003	06MAR2003
	E0035022	01MAY2003	09MAY2003	2137	09MAY2003	05JUL2003	07JUL2003
	E0039003	06NOV2002	25NOV2002	2015	25NOV2002	17DEC2002	02JAN2003
	E0040001	18JUN2003	27JUN2003	2169	27JUN2003	21AUG2003	22AUG2003
	E0040004	11JUL2003	18JUL2003	2186	18JUL2003	26JUL2003	31JUL2003
	E0041002	13JAN2003	21JAN2003	2039	21JAN2003	05MAR2003	11MAR2003
	E0041005	24FEB2003	05MAR2003	2080	05MAR2003	29APR2003	30APR2003

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	NO	YES	YES	YES	
	E0002010	NO	YES	YES	YES	
	E0002012	NO	YES	YES	YES	
	E0002015	NO	YES	NO	NO	
	E0002018	NO	YES	YES	NO	
	E0003004	NO	YES	NO	NO	
	E0003005	NO	YES	YES	YES	
	E0003007	NO	YES	YES	YES	
	E0003015	NO	YES	YES	YES	
	E0004002	NO	YES	YES	YES	
	E0004013	NO	YES	YES	YES	
	E0004018	NO	YES	YES	YES	
	E0004021	NO	YES	YES	YES	
	E0005002	NO	YES	YES	YES	
	E0005004	NO	YES	YES	YES	
	E0005013	NO	YES	NO	NO	
	E0005024	NO	YES	YES	YES	
	E0005027	NO	YES	YES	YES	24

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
*BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS DAY FORWARD.

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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	NO	YES	YES	YES	
	E0005042	NO	YES	YES	YES	
	E0006005	NO	YES	YES	YES	
	E0006018	NO	YES	YES	NO	
	E0007013	NO	YES	YES	YES	
	E0010004	NO	YES	YES	YES	
	E0010012	NO	YES	YES	YES	
	E0010024	NO	YES	YES	YES	
	E0010032	NO	YES	YES	NO	
	E0011025	NO	YES	YES	YES	
	E0013007	NO	YES	YES	YES	19
	E0013009	NO	YES	YES	YES	
	E0014006	NO	YES	YES	YES	
	E0014010	NO	YES	YES	YES	
	E0016001	NO	YES	YES	YES	
	E0016004	NO	YES	YES	NO	
	E0018001	NO	YES	YES	YES	
	E0018006	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	NO	YES	YES	YES	
	E0019011	NO	YES	YES	YES	
	E0019025	NO	YES	YES	YES	
	E0019026	NO	YES	NO	NO	
	E0019043	NO	YES	YES	YES	
	E0020001	NO	YES	YES	YES	
	E0020006	NO	YES	YES	YES	
	E0020007	NO	YES	YES	YES	
	E0020011	NO	YES	YES	YES	
	E0020013	NO	YES	YES	YES	
	E0022008	NO	YES	YES	YES	
	E0022017	NO	YES	YES	YES	
	E0022018	NO	YES	YES	YES	
	E0022022	NO	YES	YES	YES	60
	E0022027	NO	YES	YES	YES	
	E0022030	NO	YES	YES	YES	
	E0022031	NO	YES	YES	YES	54
	E0022032	NO	YES	YES	YES	60

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR I)	E0022035	NO	YES	YES	NO	
	E0022036	NO	YES	YES	YES	
	E0022056	NO	YES	YES	YES	
	E0022060	NO	YES	YES	YES	
	E0022063	NO	YES	YES	YES	
	E0023008	NO	YES	YES	YES	
	E0023013	NO	YES	YES	NO	
	E0023015	NO	YES	YES	YES	
	E0023034	NO	YES	YES	YES	58
	E0023037	NO	YES	YES	YES	
	E0023038	NO	YES	YES	YES	
	E0023044	NO	YES	YES	YES	
	E0023045	NO	YES	YES	YES	
	E0025002	NO	YES	YES	YES	
	E0026010	NO	YES	YES	NO	
	E0026017	NO	YES	YES	NO	
	E0026018	NO	YES	YES	YES	
	E0026025	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR I)	E0026029	NO	YES	YES	YES	
	E0026030	NO	YES	YES	YES	
	E0026031	NO	YES	YES	YES	
	E0027003	NO	YES	YES	NO	
	E0028004	NO	YES	YES	NO	
	E0028006	NO	YES	YES	YES	
	E0028008	NO	YES	YES	YES	
	E0028009	NO	YES	YES	YES	
	E0028016	NO	YES	YES	YES	
	E0028017	YES	NO	NO	NO	
	E0028027	NO	YES	YES	YES	
	E0028029	NO	YES	YES	YES	
	E0028034	NO	YES	YES	YES	
	E0028038	NO	YES	YES	YES	
	E0028043	NO	YES	YES	YES	
	E0028045	NO	YES	YES	NO	
	E0029005	NO	YES	YES	YES	
	E0030001	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	NO	YES	YES	YES	
	E0030011	NO	YES	YES	YES	
	E0030015	NO	YES	YES	YES	
	E0030022	NO	YES	YES	YES	
	E0031002	NO	YES	YES	YES	
	E0031003	NO	YES	YES	YES	
	E0033015	NO	YES	YES	YES	
	E0034002	NO	YES	YES	YES	
	E0034003	NO	YES	YES	YES	
	E0034006	NO	YES	YES	YES	
	E0034008	NO	YES	YES	YES	
	E0035003	NO	YES	YES	YES	
	E0035005	NO	YES	YES	YES	
	E0035014	NO	YES	YES	YES	
	E0035024	NO	YES	YES	YES	
	E0036005	NO	YES	YES	YES	
	E0037002	NO	YES	YES	YES	
	E0037005	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	NO	YES	YES	YES	
	E0039006	NO	YES	YES	YES	
	E0039015	NO	YES	YES	YES	
	E0039024	NO	YES	YES	YES	
	E0039025	NO	YES	YES	YES	
	E0039041	NO	YES	YES	YES	
	E0039044	NO	YES	YES	YES	
	E0039046	YES	NO	NO	NO	
	E0039051	NO	YES	YES	YES	
	E0039053	NO	YES	YES	YES	
	E0039057	NO	YES	YES	YES	
	E0041003	NO	YES	YES	YES	
	E0041008	NO	YES	YES	YES	
	E0042001	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	NO	YES	YES	YES	
	E0003018	NO	YES	YES	YES	
	E0005011	NO	YES	YES	YES	
	E0005030	NO	YES	YES	YES	
	E0005036	NO	YES	YES	NO	
	E0006015	NO	YES	YES	YES	
	E0006016	NO	YES	YES	YES	
	E0007008	NO	YES	YES	NO	
	E0009002	NO	YES	YES	YES	
	E0009006	NO	YES	YES	YES	
	E0009009	NO	YES	YES	YES	
	E0010015	NO	YES	YES	YES	
	E0011004	NO	YES	YES	YES	
	E0011007	NO	YES	YES	YES	
	E0011018	NO	YES	YES	YES	
	E0011024	NO	YES	YES	YES	
	E0015003	NO	YES	YES	NO	
	E0019003	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR II)	E0019007	NO	YES	YES	YES	
	E0019014	NO	YES	YES	NO	
	E0019018	NO	YES	YES	YES	
	E0019022	NO	YES	YES	YES	
	E0019027	NO	YES	YES	NO	
	E0019032	NO	YES	YES	YES	
	E0019034	NO	YES	YES	YES	
	E0019036	NO	YES	YES	YES	
	E0019039	NO	YES	NO	NO	
	E0019041	NO	YES	YES	YES	
	E0019049	NO	YES	YES	YES	61
	E0022052	NO	YES	YES	YES	
	E0022064	NO	YES	YES	YES	
	E0022073	NO	YES	YES	YES	
	E0023002	NO	YES	YES	YES	
	E0023017	NO	YES	YES	YES	
	E0023021	NO	YES	YES	YES	
	E0023027	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	NO	YES	YES	YES	
	E0023040	NO	YES	YES	YES	
	E0026014	NO	YES	YES	YES	
	E0026019	NO	YES	YES	YES	
	E0027005	NO	YES	YES	YES	
	E0029009	NO	YES	YES	YES	
	E0029021	NO	YES	YES	YES	
	E0029026	NO	YES	YES	YES	
	E0029030	NO	YES	YES	YES	
	E0031008	NO	YES	YES	NO	
	E0031020	NO	YES	YES	YES	
	E0031021	NO	YES	YES	YES	
	E0031029	NO	YES	YES	YES	
	E0033002	NO	YES	YES	YES	
	E0033006	NO	YES	YES	YES	
	E0033021	NO	YES	YES	YES	
	E0035013	NO	YES	YES	NO	
	E0035015	NO	YES	YES	NO	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 300 MG (BIPOLAR II)	E0035016	NO	YES	NO	NO	
	E0035023	NO	YES	YES	YES	
	E0039052	NO	YES	YES	NO	
	E0039056	NO	YES	NO	NO	
	E0040003	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	NO	YES	YES	YES	
	E0002011	NO	YES	YES	YES	
	E0003010	NO	YES	YES	YES	
	E0003011	NO	YES	YES	YES	
	E0003016	NO	YES	YES	YES	
	E0003019	NO	YES	YES	YES	
	E0003020	NO	YES	YES	YES	
	E0004001	NO	YES	YES	NO	
	E0004009	NO	YES	YES	YES	
	E0004012	NO	YES	YES	YES	
	E0004015	NO	YES	YES	YES	
	E0005003	NO	YES	YES	YES	
	E0005005	NO	YES	NO	NO	
	E0005007	NO	YES	YES	YES	
	E0005008	NO	YES	YES	YES	
	E0005009	NO	YES	NO	NO	
	E0005010	NO	YES	YES	YES	
	E0005012	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	NO	YES	YES	YES	
	E0005022	NO	YES	YES	YES	
	E0005025	NO	YES	YES	YES	
	E0006019	NO	YES	YES	YES	
	E0007005	NO	YES	YES	YES	
	E0007015	NO	YES	YES	YES	
	E0009001	NO	YES	YES	YES	
	E0010002	NO	YES	YES	NO	
	E0010009	NO	YES	YES	YES	
	E0010010	NO	YES	YES	YES	
	E0010014	NO	YES	YES	YES	
	E0010017	NO	YES	YES	YES	
	E0010023	NO	YES	YES	YES	
	E0010027	NO	YES	YES	YES	
	E0010029	NO	YES	YES	YES	
	E0011022	NO	YES	YES	YES	
	E0013006	NO	YES	YES	NO	
	E0013012	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
*BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS DAY FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM103.SAS
GENERATED: 12JUL2005 17:41:38 iceadmn3

Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR I)	E0013014	NO	YES	YES	YES	28
	E0014005	NO	YES	YES	YES	
	E0014007	NO	YES	YES	NO	
	E0014011	NO	YES	YES	YES	
	E0014012	NO	YES	YES	YES	
	E0015001	NO	YES	YES	YES	
	E0015008	NO	YES	YES	YES	
	E0016003	NO	YES	YES	NO	
	E0016005	NO	YES	YES	YES	
	E0018007	NO	YES	YES	NO	
	E0019005	NO	YES	YES	YES	
	E0019015	NO	YES	YES	NO	
	E0020004	NO	YES	YES	YES	
	E0020010	NO	YES	YES	YES	
	E0020014	NO	YES	YES	YES	
	E0020021	NO	YES	YES	YES	
	E0020023	NO	YES	YES	YES	
	E0022007	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:41:38 iceadmn3

Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	NO	YES	YES	YES	
	E0022012	NO	YES	YES	YES	
	E0022019	NO	YES	YES	YES	
	E0022025	NO	YES	YES	NO	
	E0022033	NO	YES	YES	YES	
	E0022034	NO	YES	YES	YES	
	E0022038	NO	YES	YES	YES	
	E0022039	NO	YES	YES	YES	
	E0022046	NO	YES	YES	YES	
	E0022048	NO	YES	YES	YES	
	E0022051	NO	YES	YES	YES	
	E0022053	NO	YES	NO	NO	
	E0022058	NO	YES	YES	YES	
	E0022061	NO	YES	YES	YES	
	E0022062	NO	YES	YES	YES	
	E0022068	NO	YES	YES	YES	
	E0022069	NO	YES	YES	YES	
	E0022071	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	NO	YES	YES	YES	
	E0023006	NO	YES	YES	YES	
	E0023010	NO	YES	YES	YES	
	E0023025	NO	YES	YES	YES	
	E0023039	NO	YES	YES	YES	
	E0026002	NO	YES	YES	YES	
	E0026007	NO	YES	YES	YES	
	E0026013	NO	YES	YES	YES	
	E0028007	NO	YES	YES	YES	38
	E0028023	NO	YES	YES	NO	
	E0028025	NO	YES	YES	YES	
	E0028033	NO	YES	YES	YES	
	E0028035	NO	YES	YES	YES	
	E0028037	NO	YES	YES	YES	
	E0028039	NO	YES	YES	YES	
	E0028046	NO	YES	NO	NO	
	E0028048	NO	YES	YES	YES	
	E0029008	NO	YES	YES	NO	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	NO	YES	YES	YES	
	E0029012	NO	YES	YES	YES	
	E0029015	NO	YES	YES	YES	16
	E0029018	NO	YES	NO	NO	
	E0030014	NO	YES	YES	YES	
	E0030020	NO	YES	YES	YES	
	E0030024	NO	YES	YES	NO	
	E0030025	NO	YES	YES	YES	
	E0031027	NO	YES	YES	YES	
	E0031030	NO	YES	YES	YES	
	E0033012	NO	YES	NO	NO	
	E0034001	NO	YES	YES	YES	
	E0034004	NO	YES	YES	YES	
	E0035001	NO	YES	YES	YES	
	E0035006	NO	YES	YES	YES	
	E0035021	NO	YES	YES	YES	
	E0036002	NO	YES	YES	YES	
	E0036006	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	NO	YES	YES	YES	
	E0037009	NO	YES	YES	YES	
	E0039011	NO	YES	YES	YES	
	E0039018	NO	YES	YES	YES	
	E0039026	NO	YES	YES	YES	
	E0039028	NO	YES	YES	NO	
	E0039032	NO	YES	YES	YES	
	E0039034	NO	YES	YES	YES	
	E0039042	NO	YES	YES	YES	
	E0041004	NO	YES	YES	YES	
	E0041009	NO	YES	YES	YES	
	E0042002	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	NO	YES	YES	NO	
	E0003002	NO	YES	YES	YES	
	E0005031	NO	YES	YES	YES	
	E0005033	NO	YES	YES	YES	
	E0005038	NO	YES	YES	YES	
	E0007009	NO	YES	YES	NO	
	E0009010	NO	YES	YES	YES	
	E0009011	NO	YES	YES	YES	
	E0010005	NO	YES	NO	NO	
	E0011016	NO	YES	YES	YES	
	E0011020	NO	YES	NO	NO	
	E0018002	NO	YES	YES	YES	
	E0018003	NO	YES	YES	YES	
	E0018013	NO	YES	YES	NO	
	E0019002	NO	YES	YES	NO	
	E0019008	NO	YES	YES	YES	
	E0019009	NO	YES	YES	YES	
	E0019016	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	NO	YES	YES	YES	64
	E0019021	NO	YES	YES	YES	33
	E0019024	NO	YES	YES	YES	
	E0019031	NO	YES	YES	NO	
	E0019035	NO	YES	YES	YES	
	E0019040	NO	YES	YES	YES	
	E0019042	NO	YES	YES	YES	
	E0019045	NO	YES	YES	YES	12
	E0020024	NO	YES	YES	YES	
	E0022044	NO	YES	YES	YES	
	E0023007	NO	YES	YES	YES	
	E0023011	NO	YES	YES	YES	
	E0023014	NO	YES	YES	YES	
	E0023019	NO	YES	YES	YES	
	E0023022	NO	YES	YES	YES	
	E0023023	NO	YES	YES	NO	
	E0023029	NO	YES	NO	NO	
	E0023031	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	NO	YES	YES	YES	
	E0023043	NO	YES	YES	YES	
	E0026003	NO	YES	YES	NO	
	E0026005	NO	YES	YES	NO	
	E0026009	NO	YES	YES	NO	
	E0026015	NO	YES	YES	YES	
	E0026023	NO	YES	YES	YES	
	E0027016	NO	YES	YES	YES	
	E0027018	NO	YES	YES	YES	
	E0028032	NO	YES	YES	YES	
	E0029003	NO	YES	YES	YES	
	E0029020	NO	YES	YES	NO	
	E0031005	NO	YES	YES	YES	
	E0031006	NO	YES	YES	YES	
	E0031010	NO	YES	YES	YES	
	E0031011	NO	YES	YES	YES	
	E0031015	NO	YES	YES	NO	
	E0031031	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
QUETIAPINE 600 MG (BIPOLAR II)	E0033009	NO	YES	NO	NO	
	E0034009	NO	YES	YES	YES	
	E0037007	NO	YES	YES	YES	
	E0037012	NO	YES	YES	YES	
	E0039019	NO	YES	YES	YES	
	E0039043	NO	YES	YES	YES	25

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR I)	E0002001	NO	YES	YES	YES	
	E0002003	NO	YES	YES	YES	
	E0002004	NO	YES	NO	NO	
	E0002008	NO	YES	YES	YES	
	E0002016	NO	YES	YES	YES	
	E0003008	NO	YES	YES	YES	
	E0004003	NO	YES	YES	YES	
	E0004006	NO	YES	YES	YES	
	E0004016	NO	YES	YES	YES	
	E0004024	NO	YES	YES	YES	
	E0005006	NO	YES	YES	YES	
	E0005017	NO	YES	YES	YES	
	E0005019	NO	YES	YES	NO	
	E0005026	NO	YES	YES	YES	
	E0005039	NO	YES	YES	YES	
	E0005043	NO	YES	YES	YES	
	E0006020	NO	YES	YES	YES	
	E0007001	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR I)	E0007003	NO	YES	YES	YES	40
	E0007006	NO	YES	YES	YES	
	E0009004	NO	YES	YES	YES	
	E0009012	NO	YES	YES	NO	
	E0010008	NO	YES	YES	YES	
	E0010018	NO	YES	YES	YES	
	E0010028	NO	YES	YES	YES	
	E0011008	NO	YES	YES	YES	
	E0011009	NO	YES	YES	YES	
	E0011010	NO	YES	YES	YES	
	E0013001	NO	YES	YES	YES	
	E0013003	NO	YES	YES	YES	
	E0013005	NO	YES	YES	NO	
	E0013013	NO	YES	YES	YES	
	E0014002	NO	YES	YES	YES	44
	E0014004	NO	YES	YES	YES	35
	E0014009	NO	YES	YES	NO	
	E0014015	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR I)	E0014017	NO	YES	YES	YES	
	E0014018	NO	YES	YES	YES	
	E0015005	NO	YES	YES	YES	
	E0017002	NO	YES	NO	NO	
	E0018009	NO	YES	YES	YES	
	E0018010	NO	YES	YES	YES	
	E0018015	NO	YES	YES	YES	
	E0020015	NO	YES	YES	YES	
	E0020017	NO	YES	YES	YES	
	E0020020	NO	YES	YES	YES	
	E0020022	NO	YES	YES	YES	
	E0022001	NO	YES	YES	YES	
	E0022004	NO	YES	YES	YES	
	E0022005	NO	YES	YES	NO	
	E0022011	NO	YES	NO	NO	
	E0022015	NO	YES	YES	YES	
	E0022016	NO	YES	YES	YES	
	E0022020	NO	YES	YES	YES	43

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR I)	E0022023	NO	YES	YES	YES	
	E0022029	NO	YES	YES	YES	
	E0022041	NO	YES	YES	YES	
	E0022042	NO	YES	YES	YES	62
	E0022043	NO	YES	YES	YES	
	E0022054	NO	YES	YES	YES	
	E0022059	NO	YES	YES	YES	
	E0022065	NO	YES	YES	YES	
	E0022070	NO	YES	YES	NO	
	E0023001	NO	YES	YES	NO	
	E0023009	NO	YES	YES	NO	
	E0023028	NO	YES	YES	YES	
	E0023033	NO	YES	YES	NO	
	E0023047	NO	YES	YES	YES	
	E0025001	NO	YES	YES	YES	
	E0026012	NO	YES	YES	YES	
	E0026020	NO	YES	YES	YES	
	E0026024	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR I)	E0026028	NO	YES	NO	NO	
	E0028001	NO	YES	YES	YES	
	E0028003	NO	YES	YES	YES	
	E0028005	NO	YES	YES	YES	29
	E0028010	NO	YES	YES	YES	
	E0028011	NO	YES	NO	NO	
	E0028030	NO	YES	YES	YES	
	E0028031	NO	YES	NO	NO	
	E0028047	NO	YES	YES	YES	
	E0029001	NO	YES	YES	YES	
	E0029014	NO	YES	YES	YES	
	E0029023	NO	YES	YES	NO	
	E0029032	NO	YES	YES	YES	22
	E0029033	NO	YES	YES	YES	
	E0029039	NO	YES	YES	YES	
	E0030003	NO	YES	YES	NO	
	E0030009	NO	YES	YES	YES	
	E0030016	NO	YES	YES	YES	51

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR I)	E0030021	NO	YES	YES	YES	
	E0031001	NO	YES	YES	NO	
	E0031017	NO	YES	YES	YES	
	E0031018	NO	YES	YES	YES	
	E0031023	NO	YES	YES	YES	
	E0033001	NO	YES	YES	YES	
	E0033004	NO	YES	YES	YES	
	E0033010	NO	YES	YES	YES	
	E0033014	NO	YES	YES	YES	
	E0035002	NO	YES	YES	YES	
	E0035007	NO	YES	YES	YES	
	E0035011	NO	YES	YES	YES	
	E0035020	NO	YES	YES	YES	
	E0037003	NO	YES	YES	YES	
	E0037004	NO	YES	YES	YES	
	E0039007	NO	YES	YES	YES	
	E0039022	NO	YES	YES	YES	
	E0039023	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR I)	E0039030	NO	YES	YES	YES	
	E0039031	NO	YES	YES	YES	
	E0039037	NO	YES	YES	YES	
	E0039038	NO	YES	YES	YES	18
	E0039047	NO	YES	YES	YES	
	E0039059	NO	YES	YES	YES	
	E0041007	NO	YES	YES	YES	
	E0041010	NO	YES	YES	YES	
	E0041011	NO	YES	YES	YES	
	E0041012	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR II)	E0001004	NO	YES	YES	YES	
	E0005023	NO	YES	YES	YES	
	E0005034	NO	YES	YES	YES	
	E0005041	NO	YES	YES	YES	
	E0007004	NO	YES	YES	YES	
	E0007010	NO	YES	YES	YES	
	E0007012	NO	YES	YES	YES	
	E0009007	NO	YES	YES	YES	
	E0009008	NO	YES	YES	YES	
	E0011001	NO	YES	YES	YES	
	E0011011	NO	YES	YES	YES	
	E0011013	NO	YES	YES	NO	
	E0011014	NO	YES	YES	YES	
	E0011021	NO	YES	YES	YES	
	E0013008	NO	YES	YES	YES	
	E0014001	NO	YES	YES	YES	
	E0014013	NO	YES	YES	YES	
	E0014014	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR II)	E0015004	NO	YES	YES	YES	
	E0018005	NO	YES	YES	YES	
	E0018012	NO	YES	YES	YES	
	E0019019	NO	YES	YES	YES	
	E0019033	NO	YES	YES	YES	
	E0019038	NO	YES	YES	YES	
	E0019046	NO	YES	YES	YES	
	E0019047	NO	YES	YES	YES	
	E0019048	NO	YES	YES	YES	
	E0022006	NO	YES	YES	YES	
	E0022047	NO	YES	YES	YES	
	E0022075	NO	YES	NO	NO	
	E0023012	NO	YES	YES	YES	
	E0023016	NO	YES	YES	YES	
	E0023018	NO	YES	YES	YES	
	E0023036	NO	YES	YES	YES	
	E0023046	NO	YES	YES	YES	
	E0026006	NO	YES	NO	NO	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR II)	E0026021	NO	YES	YES	NO	
	E0026027	NO	YES	NO	NO	
	E0029002	YES	NO	NO	NO	
	E0029004	NO	YES	YES	YES	
	E0029013	NO	YES	YES	YES	
	E0029019	NO	YES	YES	YES	
	E0029024	NO	YES	YES	YES	
	E0029038	NO	YES	NO	NO	
	E0031004	NO	YES	YES	YES	
	E0031013	NO	YES	YES	YES	
	E0031016	NO	YES	YES	YES	
	E0031019	NO	YES	YES	YES	
	E0031022	NO	YES	YES	YES	
	E0033007	NO	YES	YES	YES	
	E0033013	NO	YES	YES	YES	
	E0033016	NO	YES	YES	YES	
	E0033022	NO	YES	YES	YES	
	E0034007	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
*BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS DAY FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM103.SAS
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Listing 12.2.1.4 Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	RANDOMIZED NO DOSE	SAFETY	INTENT -TO-TREAT	PER-PROTOCOL	EXCLUDE DAY*
PLACEBO (BIPOLAR II)	E0035004	NO	YES	YES	NO	
	E0035009	NO	YES	YES	YES	
	E0035010	NO	YES	YES	YES	
	E0035022	NO	YES	YES	YES	
	E0039003	NO	YES	YES	YES	
	E0040001	NO	YES	YES	YES	
	E0040004	NO	YES	NO	NO	
	E0041002	NO	YES	YES	YES	
	E0041005	NO	YES	YES	YES	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
*BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS DAY FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM103.SAS
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AstraZeneca

Clinical Study Report: Appendix 12.2.2

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.2
Protocol deviations

Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	NONE	NO EXCLUSIONS			
	E0002010	NONE	NO EXCLUSIONS			
	E0002012	NONE	NO EXCLUSIONS			
	E0002015	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT			
	E0002018	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (3) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (6 DAYS)			
	E0003004	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT			
	E0003005	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0003007	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (DIFLUCAN FROM DAY 50 TO DAY 50)		Y	PROJECT PHYSICIAN APPROVED - 1 DOSE ONLY
	E0003015	NONE	NO EXCLUSIONS			
	E0004002	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0004018	NONE	NO EXCLUSIONS			
	E0004021	NONE	NO EXCLUSIONS			
	E0005002	NONE	NO EXCLUSIONS			
	E0005004	NONE	NO EXCLUSIONS			
	E0005013	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4) ZOLPIDEM USE >10 MG (20MG)IN FIRST 3 WEEKS (DAY 1 TO DAY 4)			
	E0005024	NONE	NO EXCLUSIONS			
	E0005027	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)	24		
	E0005037	NONE	NO EXCLUSIONS			
	E0005042	NONE	NO EXCLUSIONS			
	E0006005	NONE	NO EXCLUSIONS			
	E0006018	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0006018		MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (8 DAYS)			
	E0007013	NONE	NO EXCLUSIONS			
	E0010004	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (1MG) AFTER WEEK 3 (DAY 1 TO DAY 24)		Y	PROJECT PHYSICIAN APPROVED
	E0010012	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (1MG) AFTER WEEK 3 (DAY 1 TO DAY 22)		Y	PROJECT PHYSICIAN APPROVED
	E0010024	NONE	NO EXCLUSIONS			
	E0010032	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (6)			
	E0011025	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0013007	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (10 DAYS)	19		
	E0013009	NONE	NO EXCLUSIONS			
	E0014006	NONE	NO EXCLUSIONS			
	E0014010	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	NONE	NO EXCLUSIONS			
	E0016004	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (8)			
	E0018001	NONE	NO EXCLUSIONS			
	E0018006	NONE	NO EXCLUSIONS			
	E0019004	NONE	NO EXCLUSIONS			
	E0019011	NONE	NO EXCLUSIONS			
	E0019025	NONE	NO EXCLUSIONS			
	E0019026	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT			
	E0019043	NONE	NO EXCLUSIONS			
	E0020001	NONE	NO EXCLUSIONS			
	E0020006	NONE	NO EXCLUSIONS			
	E0020007	NONE	NO EXCLUSIONS			
	E0020011	NONE	NO EXCLUSIONS			
	E0020013	NONE	NO EXCLUSIONS			
	E0022008	NONE	NO EXCLUSIONS			
	E0022017	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	NONE	NO EXCLUSIONS			
	E0022022	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (15 DAYS)	60		
	E0022027	NONE	NO EXCLUSIONS			
	E0022030	NONE	NO EXCLUSIONS			
	E0022031	PP*	DOCUMENTED DRUG ABUSE DURING STUDY (DAY 54)	54		
	E0022032	PP*	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)	60	Y	PATIENT COMPLIANT
	E0022035	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5)			
	E0022036	NONE	NO EXCLUSIONS			
	E0022056	NONE	NO EXCLUSIONS			
	E0022060	NONE	NO EXCLUSIONS			
	E0022063	NONE	NO EXCLUSIONS			
	E0023008	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023008		PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ZOLOFT - 3 DAYS)			
	E0023013	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (3) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)			
	E0023015	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (DEPAKOTE - 5 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (LITHOBID - 5 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ZOLOFT - 2 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0023034	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (9 DAYS)	58		
	E0023037	NONE	NO EXCLUSIONS			
	E0023038	NONE	NO EXCLUSIONS			
	E0023044	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (EFFEXOR-XR - 6 DAYS)		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023044		PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (LAMOTRIGINE - 6 DAYS)			
	E0023045	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (PAXIL - 5 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0025002	NONE	NO EXCLUSIONS			
	E0026010	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5)			
	E0026017	PP	NO POST-BASELINE ASSESSMENT AFTER DATA EXCLUSIONS ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (ESCITALOPRAM FROM DAY 8 TO DAY 9) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (LITHIUMCARBONATE FROM DAY 8 TO DAY 9) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (7 DAYS)			
	E0026018	NONE	NO EXCLUSIONS			
	E0026025	NONE	NO EXCLUSIONS			
	E0026029	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	NONE	NO EXCLUSIONS			
	E0026031	NONE	NO EXCLUSIONS			
	E0027003	PP	NO POST-BASELINE ASSESSMENT AFTER DATA EXCLUSIONS ZOLPIDEM USE >10 MG (20MG)IN FIRST 3 WEEKS (DAY 1 TO DAY 56) LORAZEPAM USE (3MG) AFTER WEEK 3 (DAY 1 TO DAY 56) ZOLPIDEM USE (20MG)AFTER WEEK 3 (DAY 1 TO DAY 56)			
	E0028004	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (8)			
	E0028006	NONE	NO EXCLUSIONS			
	E0028008	NONE	NO EXCLUSIONS			
	E0028009	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0028016	NONE	NO EXCLUSIONS			
	E0028017	SAFETY\ITT\PP	RANDOMIZED, NO DOSE USE OF PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION YMRS TOTAL SCORE >12 AT BASELINE VISIT			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	NONE	NO EXCLUSIONS			
	E0028029	NONE	NO EXCLUSIONS			
	E0028034	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0028038	NONE	NO EXCLUSIONS			
	E0028043	NONE	NO EXCLUSIONS			
	E0028045	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ARIPIPRAZOLE - 0 DAYS) ANTIPSYCHOTIC USE DURING STUDY (ARIPIPRAZOLE FROM DAY 1 TO DAY 21) DOCUMENTED DRUG ABUSE DURING STUDY (DAY 45)			
	E0029005	NONE	NO EXCLUSIONS			
	E0030001	NONE	NO EXCLUSIONS			
	E0030008	NONE	NO EXCLUSIONS			
	E0030011	NONE	NO EXCLUSIONS			
	E0030015	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 44 TO DAY 49)		Y	PROJECT PHYSICIAN APPROVED
	E0031002	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (DIPHENHYDRAMINE FROM DAY 55 TO DAY 55)		Y	PROJECT PHYSICIAN APPROVED
	E0031003	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (DOXEPIN - 5 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0033015	NONE	NO EXCLUSIONS			
	E0034002	NONE	NO EXCLUSIONS			
	E0034003	NONE	NO EXCLUSIONS			
	E0034006	NONE	NO EXCLUSIONS			
	E0034008	NONE	NO EXCLUSIONS			
	E0035003	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (BENADRYL "WARNER-LAMBERT" /		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0035003		ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 1			
	E0035005	NONE	NO EXCLUSIONS			
	E0035014	NONE	NO EXCLUSIONS			
	E0035024	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0036005	NONE	NO EXCLUSIONS			
	E0037002	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0037005	NONE	NO EXCLUSIONS			
	E0037006	NONE	NO EXCLUSIONS			
	E0039006	NONE	NO EXCLUSIONS			
	E0039015	NONE	NO EXCLUSIONS			
	E0039024	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0039024		ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 21			
	E0039025	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0039041	NONE	NO EXCLUSIONS			
	E0039044	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (3MG) AFTER WEEK 3 (DAY 38 TO DAY 48)		Y	PROJECT PHYSICIAN APPROVED
	E0039046	SAFETY\ITT\PP	RANDOMIZED, NO DOSE			
	E0039051	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (EFFEXOR - 6 DAYS) SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PROJECT PHYSICIAN APPROVED
	E0039053	NONE	NO EXCLUSIONS			
	E0039057	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0041003	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	NONE	NO EXCLUSIONS			
	E0042001	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	NONE	NO EXCLUSIONS			
	E0003018	NONE	NO EXCLUSIONS			
	E0005011	NONE	NO EXCLUSIONS			
	E0005030	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0005036	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7) SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8			
	E0006015	NONE	NO EXCLUSIONS			
	E0006016	NONE	NO EXCLUSIONS			
	E0007008	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7) SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSE (40)			
	E0009002	NONE	NO EXCLUSIONS			
	E0009006	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0009006		ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (NICOTINE FROM DAY 40 TO DAY 56)			
	E0009009	NONE	NO EXCLUSIONS			
	E0010015	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (3MG) AFTER WEEK 3 (DAY 1 TO DAY 22)		Y	PROJECT PHYSICIAN APPROVED
	E0011004	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 28 TO DAY 28) POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 29 TO DAY 33)		Y	PROJECT PHYSICIAN APPROVED
	E0011007	NONE	NO EXCLUSIONS			
	E0011018	NONE	NO EXCLUSIONS			
	E0011024	NONE	NO EXCLUSIONS			
	E0015003	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0019003	NONE	NO EXCLUSIONS			
	E0019007	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (8 DAYS)			
	E0019018	NONE	NO EXCLUSIONS			
	E0019022	NONE	NO EXCLUSIONS			
	E0019027	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ZOLOFT - 6 DAYS) SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (3) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)			
	E0019032	NONE	NO EXCLUSIONS			
	E0019034	NONE	NO EXCLUSIONS			
	E0019036	NONE	NO EXCLUSIONS			
	E0019039	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (3)			
	E0019041	NONE	NO EXCLUSIONS			
	E0019049	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)	61		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	NONE	NO EXCLUSIONS			
	E0022064	NONE	NO EXCLUSIONS			
	E0022073	NONE	NO EXCLUSIONS			
	E0023002	NONE	NO EXCLUSIONS			
	E0023017	NONE	NO EXCLUSIONS			
	E0023021	NONE	NO EXCLUSIONS			
	E0023027	NONE	NO EXCLUSIONS			
	E0023030	NONE	NO EXCLUSIONS			
	E0023040	NONE	NO EXCLUSIONS			
	E0026014	NONE	NO EXCLUSIONS			
	E0026019	NONE	NO EXCLUSIONS			
	E0027005	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE >3 MG (4MG)IN FIRST 3 WEEKS (DAY 1 TO DAY 55) LORAZEPAM USE (4MG) AFTER WEEK 3 (DAY 1 TO DAY 55) ZOLPIDEM USE (10MG)AFTER WEEK 3 (DAY 1 TO DAY 55)		Y	PROJECT PHYSICIAN APPROVED
	E0029009	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	NONE	NO EXCLUSIONS			
	E0029026	NONE	NO EXCLUSIONS			
	E0029030	NONE	NO EXCLUSIONS			
	E0031008	PP	HISTORY OF SUBSTANCE DEPENDENCE			
	E0031020	NONE	NO EXCLUSIONS			
	E0031021	NONE	NO EXCLUSIONS			
	E0031029	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0033002	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0033006	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0033021	NONE	NO EXCLUSIONS			
	E0035013	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (RISPERDAL - 3 DAYS)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0035013		SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (3)			
	E0035015	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5)			
	E0035016	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (8)			
	E0035023	NONE	NO EXCLUSIONS			
	E0039052	PP	SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSE (64.1)			
	E0039056	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSE (60.87)			
	E0040003	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	NONE	NO EXCLUSIONS			
	E0002011	NONE	NO EXCLUSIONS			
	E0003010	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ZOLPIDEM USE (1TAB)AFTER WEEK 3 (DAY 40 TO DAY 40)		Y	PROJECT PHYSICIAN APPROVED
	E0003011	NONE	NO EXCLUSIONS			
	E0003016	NONE	NO EXCLUSIONS			
	E0003019	NONE	NO EXCLUSIONS			
	E0003020	NONE	NO EXCLUSIONS			
	E0004001	PP	SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG YMRS TOTAL SCORE >12 AT BASELINE VISIT			
	E0004009	NONE	NO EXCLUSIONS			
	E0004012	NONE	NO EXCLUSIONS			
	E0004015	NONE	NO EXCLUSIONS			
	E0005003	NONE	NO EXCLUSIONS			
	E0005005	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	NONE	NO EXCLUSIONS			
	E0005008	NONE	NO EXCLUSIONS			
	E0005009	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4)			
	E0005010	NONE	NO EXCLUSIONS			
	E0005012	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (0.5MG) AFTER WEEK 3 (DAY 22 TO DAY 22)		Y	PROJECT PHYSICIAN APPROVED-SUFF WASHOUT
	E0005014	NONE	NO EXCLUSIONS			
	E0005022	NONE	NO EXCLUSIONS			
	E0005025	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0006019	NONE	NO EXCLUSIONS			
	E0007005	NONE	NO EXCLUSIONS			
	E0007015	NONE	NO EXCLUSIONS			
	E0009001	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0010002	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (1) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (7 DAYS)			
	E0010009	NONE	NO EXCLUSIONS			
	E0010010	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0010014	NONE	NO EXCLUSIONS			
	E0010017	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0010023	NONE	NO EXCLUSIONS			
	E0010027	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0010029	NONE	NO EXCLUSIONS			
	E0011022	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (VISTARIL - 0 DAYS)		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0011022		ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (VISTARIL FROM DAY 1 TO DAY 1)			
	E0013006	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (8) SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSE (27.78) SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG			
	E0013012	NONE	NO EXCLUSIONS			
	E0013014	PP*	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (SONATA - 1 DAYS) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (8 DAYS)	28	Y	PROJECT PHYSICIAN APPROVED
	E0014005	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0014007	PP	SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSE (61.22) SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0014007		MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)			
	E0014011	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0014012	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 19		Y	PROJECT PHYSICIAN APPROVED
	E0015001	NONE	NO EXCLUSIONS			
	E0015008	NONE	NO EXCLUSIONS			
	E0016003	PP	DEPRESSION EPISODE >12 MONTHS OR <4 WEEKS			
	E0016005	NONE	NO EXCLUSIONS			
	E0018007	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (11 DAYS)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	NONE	NO EXCLUSIONS			
	E0019015	PP	SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG			
	E0020004	NONE	NO EXCLUSIONS			
	E0020010	NONE	NO EXCLUSIONS			
	E0020014	NONE	NO EXCLUSIONS			
	E0020021	NONE	NO EXCLUSIONS			
	E0020023	NONE	NO EXCLUSIONS			
	E0022007	NONE	NO EXCLUSIONS			
	E0022010	NONE	NO EXCLUSIONS			
	E0022012	NONE	NO EXCLUSIONS			
	E0022019	NONE	NO EXCLUSIONS			
	E0022025	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0022033	NONE	NO EXCLUSIONS			
	E0022034	NONE	NO EXCLUSIONS			
	E0022038	NONE	NO EXCLUSIONS			
	E0022039	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	NONE	NO EXCLUSIONS			
	E0022048	NONE	NO EXCLUSIONS			
	E0022051	NONE	NO EXCLUSIONS			
	E0022053	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT			
	E0022058	NONE	NO EXCLUSIONS			
	E0022061	NONE	NO EXCLUSIONS			
	E0022062	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (DIPHENHYDRAMINEHYDROCHLORIDE FROM DAY 11		Y	PROJECT PHYSICIAN APPROVED
	E0022068	NONE	NO EXCLUSIONS			
	E0022069	NONE	NO EXCLUSIONS			
	E0022071	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (1MG) AFTER WEEK 3 (DAY 46 TO DAY 46)		Y	PROJECT PHYSICIAN APPROVED
	E0023003	NONE	NO EXCLUSIONS			
	E0023006	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0023006		PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (LAMOTRIGINE - 3 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (PAXIL - 4 DAYS) SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8			
	E0023010	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (CLONAZEPAM - 3 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0023025	NONE	NO EXCLUSIONS			
	E0023039	NONE	NO EXCLUSIONS			
	E0026002	NONE	NO EXCLUSIONS			
	E0026007	NONE	NO EXCLUSIONS			
	E0026013	NONE	NO EXCLUSIONS			
	E0028007	PP*	DOCUMENTED DRUG ABUSE DURING STUDY (DAY 38)	38		
	E0028023	PP	- E04: HISTORY OF SUBSTANCE DEPENDENCE HISTORY OF SUBSTANCE DEPENDENCE ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (ZOLOFT FROM DAY 48 TO DAY 48)			SUBSTANCE DEPENDENCE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (MELATONIN - 1 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0028033	NONE	NO EXCLUSIONS			
	E0028035	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (VALERIANROOT FROM DAY 40 TO DAY 40)		Y	PROJECT PHYSICIAN APPROVED
	E0028037	NONE	NO EXCLUSIONS			
	E0028039	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0028046	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (1)			
	E0028048	NONE	NO EXCLUSIONS			
	E0029008	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5)			
	E0029011	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (NICODERM - 0 DAYS) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (NICODERM FROM DAY 1 TO DAY 7)		Y	PROJECT PHYSICIAN APPROVED
	E0029015	PP*	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (SONATA - 6 DAYS) SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (6 DAYS)	16	Y	PROJECT PHYSICIAN APPROVED
	E0029018	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (2)			
	E0030014	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (DIAMOX - 0 DAYS) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (DIAMOX FROM DAY 1 TO DAY 58)		Y	PROJECT PHYSICIAN APPROVED
	E0030020	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0030024	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5)			
	E0030025	NONE	NO EXCLUSIONS			
	E0031027	NONE	NO EXCLUSIONS			
	E0031030	NONE	NO EXCLUSIONS			
	E0033012	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT			
	E0034001	NONE	NO EXCLUSIONS			
	E0034004	NONE	NO EXCLUSIONS			
	E0035001	NONE	NO EXCLUSIONS			
	E0035006	NONE	NO EXCLUSIONS			
	E0035021	NONE	NO EXCLUSIONS			
	E0036002	NONE	NO EXCLUSIONS			
	E0036006	NONE	NO EXCLUSIONS			
	E0036007	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0037009	NONE	NO EXCLUSIONS			
	E0039011	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0039018	NONE	NO EXCLUSIONS			
	E0039026	NONE	NO EXCLUSIONS			
	E0039028	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (LITHIUM - 0 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (RISPERDAL - 0 DAYS) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (LITHIUM FROM DAY 1 TO DAY 51) ANTIPSYCHOTIC USE DURING STUDY (RISPERDAL FROM DAY 1 TO DAY 51) DOCUMENTED DRUG ABUSE DURING STUDY (DAY 46)			
	E0039032	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0039034	NONE	NO EXCLUSIONS			
	E0039042	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0041004	NONE	NO EXCLUSIONS			
	E0041009	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5)			
	E0003002	NONE	NO EXCLUSIONS			
	E0005031	NONE	NO EXCLUSIONS			
	E0005033	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0005038	NONE	NO EXCLUSIONS			
	E0007009	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (7 DAYS)			
	E0009010	NONE	NO EXCLUSIONS			
	E0009011	NONE	NO EXCLUSIONS			
	E0010005	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (2)			
	E0011016	NONE	NO EXCLUSIONS			
	E0011020	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (2)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	NONE	NO EXCLUSIONS			
	E0018003	NONE	NO EXCLUSIONS			
	E0018013	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4)			
	E0019002	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (8)			
	E0019008	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0019009	NONE	NO EXCLUSIONS			
	E0019016	NONE	NO EXCLUSIONS			
	E0019020	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (8 DAYS)	64		
	E0019021	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (15 DAYS)	33		
	E0019024	NONE	NO EXCLUSIONS			
	E0019031	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (9 DAYS)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019035	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (ZITHROMAXZ-PACK FROM DAY 18 TO DAY 22)		Y	PROJECT PHYSICIAN APPROVED
	E0019040	NONE	NO EXCLUSIONS			
	E0019042	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0019045	PP*	ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (WELLBUTRIN FROM DAY 12 TO DAY 12) DOCUMENTED DRUG ABUSE DURING STUDY (DAY 12)	12		
	E0020024	NONE	NO EXCLUSIONS			
	E0022044	NONE	NO EXCLUSIONS			
	E0023007	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (LAMOTRIGINE - 2 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0023011	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (LAMOTRIGINE - 4 DAYS)		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023011		PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (LITHIUM - 4 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (NEURONTIN - 4 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (PAXIL - 4 DAYS)			
	E0023014	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ZOLOFT - 2 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0023019	NONE	NO EXCLUSIONS			
	E0023022	NONE	NO EXCLUSIONS			
	E0023023	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (SERZONE - 6 DAYS) SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (3)			
	E0023029	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (3)			
	E0023031	NONE	NO EXCLUSIONS			
	E0023041	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	NONE	NO EXCLUSIONS			
	E0026003	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ELAVIL - 0 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (KEPPRA - 0 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (NEURONTIN - 0 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (TOPAMAX - 0 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (WELLBUTRIN - 0 DAYS) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (ELAVIL FROM DAY 1 TO DAY 57) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (KEPPRA FROM DAY 1 TO DAY 57) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (NEURONTIN FROM DAY 1 TO DAY 57) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (TOPAMAX FROM DAY 1 TO DAY 57) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (WELLBUTRIN FROM DAY 1 TO DAY 57)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0026003		POTENT P450 INHIBITOR USE (KALETRA FROM DAY 1 TO DAY 57) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)			
	E0026005	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (PAXIL - 5 DAYS) SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0026009	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (4)			
	E0026015	NONE	NO EXCLUSIONS			
	E0026023	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (AZITHROMYCIN FROM DAY 1 TO DAY 4)		Y	PROJECT PHYSICIAN APPROVED
	E0027016	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 25 TO DAY 30)		Y	PROJECT PHYSICIAN APPROVED
	E0027018	NONE	NO EXCLUSIONS			
	E0028032	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0028032		ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (SINEQUAN FROM DAY 55 TO DAY 56)			
	E0029003	NONE	NO EXCLUSIONS			
	E0029020	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7) SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8			
	E0031005	NONE	NO EXCLUSIONS			
	E0031006	NONE	NO EXCLUSIONS			
	E0031010	NONE	NO EXCLUSIONS			
	E0031011	NONE	NO EXCLUSIONS			
	E0031015	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (6)			
	E0031031	NONE	NO EXCLUSIONS			
	E0033009	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0034009	NONE	NO EXCLUSIONS			
	E0037007	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN		Y	PATIENT COMPLIANT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0037007		SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8			
	E0037012	NONE	NO EXCLUSIONS			
	E0039019	NONE	NO EXCLUSIONS			
	E0039043	PP*	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 DOCUMENTED DRUG ABUSE DURING STUDY (DAY 25)	25	Y	PATIENT COMPLIANT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0002001	NONE	NO EXCLUSIONS			
	E0002003	NONE	NO EXCLUSIONS			
	E0002004	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (BENADRYL "WARNER-LAMBERT" / PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (KLONOPIN - 5 DAYS) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 1			
	E0002008	NONE	NO EXCLUSIONS			
	E0002016	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (.UNK) AFTER WEEK 3 (DAY 24 TO DAY 24)		Y	PROJECT PHYSICIAN APPROVED
	E0003008	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 13 POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 17 TO DAY 27)		Y	PROJECT PHYSICIAN APPROVED - 1 DOSE ONLY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0004003	NONE	NO EXCLUSIONS			
	E0004006	NONE	NO EXCLUSIONS			
	E0004016	NONE	NO EXCLUSIONS			
	E0004024	NONE	NO EXCLUSIONS			
	E0005006	NONE	NO EXCLUSIONS			
	E0005017	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0005019	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0005026	NONE	NO EXCLUSIONS			
	E0005039	NONE	NO EXCLUSIONS			
	E0005043	NONE	NO EXCLUSIONS			
	E0006020	NONE	NO EXCLUSIONS			
	E0007001	NONE	NO EXCLUSIONS			
	E0007003	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (14 DAYS)	40		
	E0007006	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0009004	NONE	NO EXCLUSIONS			
	E0009012	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (1) MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (8 DAYS)			
	E0010008	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (0.5MG) AFTER WEEK 3 (DAY 16 TO DAY 22)		Y	PROJECT PHYSICIAN APPROVED
	E0010018	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (3MG) AFTER WEEK 3 (DAY 1 TO DAY 22)		Y	PROJECT PHYSICIAN APPROVED
	E0010028	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN LORAZEPAM USE (3MG) AFTER WEEK 3 (DAY 16 TO DAY 23) ZOLPIDEM USE (10MG)AFTER WEEK 3 (DAY 1 TO DAY 23)		Y	PROJECT PHYSICIAN APPROVED
	E0011008	NONE	NO EXCLUSIONS			
	E0011009	NONE	NO EXCLUSIONS			
	E0011010	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0011010		ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (XANAX FROM DAY 4 TO DAY 4)			
	E0013001	NONE	NO EXCLUSIONS			
	E0013003	NONE	NO EXCLUSIONS			
	E0013005	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (PROZAC - 7 DAYS)			
	E0013013	NONE	NO EXCLUSIONS			
	E0014002	PP*	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (BENADRYL "WARNER-LAMBERT" / ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 14 MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (6 DAYS)	44	Y	PROJECT PHYSICIAN APPROVED
	E0014004	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (16 DAYS)	35		
	E0014009	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0014015	NONE	NO EXCLUSIONS			
	E0014017	NONE	NO EXCLUSIONS			
	E0014018	NONE	NO EXCLUSIONS			
	E0015005	NONE	NO EXCLUSIONS			
	E0017002	ITT\PP	NO BASELINE MADRS ASSESSMENT NO POST-BASELINE MADRS ASSESSMENT			
	E0018009	NONE	NO EXCLUSIONS			
	E0018010	NONE	NO EXCLUSIONS			
	E0018015	NONE	NO EXCLUSIONS			
	E0020015	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0020017	NONE	NO EXCLUSIONS			
	E0020020	NONE	NO EXCLUSIONS			
	E0020022	NONE	NO EXCLUSIONS			
	E0022001	NONE	NO EXCLUSIONS			
	E0022004	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0022005	PP	- E14: TSH >10% OVER THE ULN AT SCREEN/BASELINE			TSH > 10% over ULN
	E0022011	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (VALIUM FROM DAY 2 TO DAY 2) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (VERSED FROM DAY 2 TO DAY 2)			
	E0022015	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0022016	NONE	NO EXCLUSIONS			
	E0022020	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (8 DAYS)	43		
	E0022023	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ZOLPIDEM USE (10MG)AFTER WEEK 3 (DAY 9 TO DAY 23) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (NYQUIL FROM DAY 24 TO DAY 30)		Y	PROJECT PHYSICIAN APPROVED
	E0022029	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0022041	NONE	NO EXCLUSIONS			
	E0022042	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)	62		
	E0022043	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 15		Y	PROJECT PHYSICIAN APPROVED
	E0022054	NONE	NO EXCLUSIONS			
	E0022059	NONE	NO EXCLUSIONS			
	E0022065	NONE	NO EXCLUSIONS			
	E0022070	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (6) SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSE (58.33)			
	E0023001	PP	- E14: TSH >10% OVER THE ULN AT SCREEN/BASELINE			TSH > 10% over ULN
	E0023009	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (PROZAC - 13 DAYS)			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0023009		SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8			
	E0023028	NONE	NO EXCLUSIONS			
	E0023033	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0023047	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ZYPREXA - 5 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0025001	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (DEPAKOTE - SLOW RELEASE - 6 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (WELLBUTRIN - SLOW RELEASE - 6 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ZYPREXA - 6 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0026012	NONE	NO EXCLUSIONS			
	E0026020	NONE	NO EXCLUSIONS			
	E0026024	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0026028	ITT\PP	- E17: MULTIPLE CENTER STUDY PARTICIPATION SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (ESCITALOPRAM FROM DAY 22 TO DAY 25) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (KLONOPIN FROM DAY 22 TO DAY 22) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (NEURONTIN FROM DAY 22 TO DAY 25) ANTIPSYCHOTIC USE DURING STUDY (RISPERDAL FROM DAY 22 TO DAY 25) ANTIPSYCHOTIC USE DURING STUDY (SEROQUEL FROM DAY 22 TO DAY 25) POTENT P450 INDUCER USE (TRILEPTAL"NOVARTIS" FROM DAY 22 TO DAY 22) ZOLPIDEM USE (10MG)AFTER WEEK 3 (DAY 22 TO DAY 23) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (KLONOPIN FROM DAY 23 TO DAY 25) POTENT P450 INDUCER USE (TRILEPTAL"NOVARTIS" FROM DAY 23 TO DAY 25)			Multiple Center Study Participation

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0026028		ZOLPIDEM USE (5MG)AFTER WEEK 3 (DAY 24 TO DAY 24)			
	E0028001	NONE	NO EXCLUSIONS			
	E0028003	NONE	NO EXCLUSIONS			
	E0028005	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (19 DAYS)	29		
	E0028010	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (BENADRYL "WARNER-LAMBERT" / SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8 ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 1		Y	PROJECT PHYSICIAN APPROVED
	E0028011	ITT\PP	- E17: MULTIPLE CENTER STUDY PARTICIPATION SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8			Multiple Center Study Participation
	E0028030	NONE	NO EXCLUSIONS			
	E0028031	ITT\PP	- E17: MULTIPLE CENTER STUDY PARTICIPATION			Multiple Center Study Participation

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0028031		ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (KLONOPIN FROM DAY 20 TO DAY 23) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (LITHIUM FROM DAY 20 TO DAY 23) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (NEURONTIN FROM DAY 20 TO DAY 23) ANTIPSYCHOTIC USE DURING STUDY (RISPERDAL FROM DAY 20 TO DAY 23)			
	E0028047	NONE	NO EXCLUSIONS			
	E0029001	NONE	NO EXCLUSIONS			
	E0029014	NONE	NO EXCLUSIONS			
	E0029023	PP	DEPRESSION EPISODE >12 MONTHS OR <4 WEEKS PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (BENADRYL "WARNER-LAMBERT" / ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (NYQUIL FROM DAY 18 TO DAY 19)			
	E0029032	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (12 DAYS)	22		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0029033	NONE	NO EXCLUSIONS			
	E0029039	NONE	NO EXCLUSIONS			
	E0030003	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0030009	NONE	NO EXCLUSIONS			
	E0030016	PP*	MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION (5 DAYS)	51		
	E0030021	NONE	NO EXCLUSIONS			
	E0031001	PP	PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (KLONOPIN - 0 DAYS) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (KLONOPIN FROM DAY 1 TO DAY 33) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 12 ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (KLONOPIN FROM DAY 14 TO DAY 14)			
	E0031017	NONE	NO EXCLUSIONS			
	E0031018	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0031023	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0033001	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 5		Y	PROJECT PHYSICIAN APPROVED
	E0033004	NONE	NO EXCLUSIONS			
	E0033010	NONE	NO EXCLUSIONS			
	E0033014	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (BENADRYL "WARNER-LAMBERT" /		Y	PROJECT PHYSICIAN APPROVED
	E0035002	NONE	NO EXCLUSIONS			
	E0035007	NONE	NO EXCLUSIONS			
	E0035011	NONE	NO EXCLUSIONS			
	E0035020	NONE	NO EXCLUSIONS			
	E0037003	NONE	NO EXCLUSIONS			
	E0037004	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0039007	NONE	NO EXCLUSIONS			
	E0039022	NONE	NO EXCLUSIONS			
	E0039023	NONE	NO EXCLUSIONS			
	E0039030	NONE	NO EXCLUSIONS			
	E0039031	NONE	NO EXCLUSIONS			
	E0039037	NONE	NO EXCLUSIONS			
	E0039038	PP*	MANUAL OVERRIDE BY PROJECT CLINICIAN ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 13 ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (DIAZEPAM FROM DAY 13 TO DAY 15) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (CELEXA FROM DAY 18 TO DAY 45) POTENT P450 INHIBITOR USE (AZITHROMYCIN FROM DAY 18 TO DAY 45)	18	Y	PROJECT PHYSICIAN APPROVED
	E0039047	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 22 TO DAY 22)		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR I)	E0039047		POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 23 TO DAY 26)			
	E0039059	NONE	NO EXCLUSIONS			
	E0041007	NONE	NO EXCLUSIONS			
	E0041010	NONE	NO EXCLUSIONS			
	E0041011	NONE	NO EXCLUSIONS			
	E0041012	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (BIAXIN FROM DAY 20 TO DAY 30)		Y	PROJECT PHYSICIAN APPROVED

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	EXCLUSION FROM ANALYSIS: POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR II)	E0001004	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO RECEIVE DOSE REDUCTION BEFORE DAY 8		Y	PATIENT COMPLIANT
	E0005023	NONE	NO EXCLUSIONS			
	E0005034	NONE	NO EXCLUSIONS			
	E0005041	NONE	NO EXCLUSIONS			
	E0007004	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (ZOLOFT - 6 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0007010	NONE	NO EXCLUSIONS			
	E0007012	NONE	NO EXCLUSIONS			
	E0009007	NONE	NO EXCLUSIONS			
	E0009008	NONE	NO EXCLUSIONS			
	E0011001	NONE	NO EXCLUSIONS			
	E0011011	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN SUBJECTS WHO REDUCE STUDY MEDICATION MORE THAN 100 MG		Y	PATIENT COMPLIANT
	E0011013	PP	- E14: TSH >10% OVER THE ULN AT SCREEN/BASELINE			TSH > 10% over ULN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIODV100.SAS
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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR II)	E0011014	NONE	NO EXCLUSIONS			
	E0011021	NONE	NO EXCLUSIONS			
	E0013008	NONE	NO EXCLUSIONS			
	E0014001	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (ZITHROMAX"PFIZER" FROM DAY 22 TO DAY 25)		Y	PROJECT PHYSICIAN APPROVED
	E0014013	NONE	NO EXCLUSIONS			
	E0014014	NONE	NO EXCLUSIONS			
	E0015004	NONE	NO EXCLUSIONS			
	E0018005	NONE	NO EXCLUSIONS			
	E0018012	NONE	NO EXCLUSIONS			
	E0019019	NONE	NO EXCLUSIONS			
	E0019033	NONE	NO EXCLUSIONS			
	E0019038	NONE	NO EXCLUSIONS			
	E0019046	NONE	NO EXCLUSIONS			
	E0019047	NONE	NO EXCLUSIONS			
	E0019048	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR II)	E0022006	NONE	NO EXCLUSIONS			
	E0022047	NONE	NO EXCLUSIONS			
	E0022075	ITT\PP	NO BASELINE MADRS ASSESSMENT PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (BENADRYL "WARNER-LAMBERT" / ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 1 ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 30			
	E0023012	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (DEPAKOTE - 2 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (EFFEXOR-XR - 2 DAYS) PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (NEURONTIN - 2 DAYS)		Y	PROJECT PHYSICIAN APPROVED
	E0023016	NONE	NO EXCLUSIONS			
	E0023018	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR II)	E0023036	NONE	NO EXCLUSIONS			
	E0023046	NONE	NO EXCLUSIONS			
	E0026006	ITT\PP	- E17: MULTIPLE CENTER STUDY PARTICIPATION			Multiple Center Study Participation
	E0026021	PP	- E02: DEPRESSION EPISODE >12 MONTHS OR <4 WEEKS			DEPRESSED EPISODE 18 MONTHS
	E0026027	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (5)			
	E0029002	SAFETY\ITT\PP	RANDOMIZED, NO DOSE YMRS TOTAL SCORE >12 AT BASELINE VISIT			
	E0029004	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (DIFLUCAN FROM DAY 13 TO DAY 16) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (BENADRYL"WARNER-LAMBERT"/USA/ FROM DAY 52		Y	PROJECT PHYSICIAN APPROVED
	E0029013	NONE	NO EXCLUSIONS			
	E0029019	NONE	NO EXCLUSIONS			
	E0029024	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR II)	E0029038	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0031004	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION (SONATA - 0 DAYS) ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY (SONATA FROM DAY 1 TO DAY 57)		Y	PROJECT PHYSICIAN APPROVED
	E0031013	NONE	NO EXCLUSIONS			
	E0031016	NONE	NO EXCLUSIONS			
	E0031019	NONE	NO EXCLUSIONS			
	E0031022	NONE	NO EXCLUSIONS			
	E0033007	NONE	MANUAL OVERRIDE BY PROJECT CLINICIAN POTENT P450 INHIBITOR USE (ULTRACET FROM DAY 1 TO DAY 21)		Y	PROJECT PHYSICIAN APPROVED
	E0033013	NONE	NO EXCLUSIONS			
	E0033016	NONE	NO EXCLUSIONS			
	E0033022	NONE	NO EXCLUSIONS			
	E0034007	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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Listing 12.2.2 Major Protocol Violations and Deviations Leading to Exclusion from Patient Populations

		EXCLUSION FROM ANALYSIS				
TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	POPULATION EXCLUDED FROM	REASON FOR EXCLUSION	DAY*	OVER-RIDE	COMMENT
PLACEBO (BIPOLAR II)	E0035004	PP	SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY (7)			
	E0035009	NONE	NO EXCLUSIONS			
	E0035010	NONE	NO EXCLUSIONS			
	E0035022	NONE	NO EXCLUSIONS			
	E0039003	NONE	NO EXCLUSIONS			
	E0040001	NONE	NO EXCLUSIONS			
	E0040004	ITT\PP	NO POST-BASELINE MADRS ASSESSMENT			
	E0041002	NONE	NO EXCLUSIONS			
	E0041005	NONE	NO EXCLUSIONS			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* DAY TO BEGIN EXCLUDING PER-PROTOCOL DATA FROM THIS POINT FORWARD.

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AstraZeneca

Clinical Study Report: Appendix 12.2.3

Drug Substance	Quetiapine fumarate
Study Code	5077US0049

Appendix 12.2.3
Subject and data excluded from efficacy analysis

Not applicable to this study.

AstraZeneca

Clinical Study Report: Appendix 12.2.4

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.4
Demographic and baseline characteristics

Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	57	FEMALE	CAUCASIAN	170	89	30.8
	E0002010	32	MALE	CAUCASIAN	183	159	47.5
	E0002012	31	MALE	CAUCASIAN	183	70	20.9
	E0002015	40	MALE	CAUCASIAN	166	64	23.2
	E0002018	48	MALE	CAUCASIAN	188	148	41.9
	E0003004	20	MALE	CAUCASIAN	175	103	33.6
	E0003005	37	FEMALE	CAUCASIAN	160	79	30.9
	E0003007	25	FEMALE	CAUCASIAN	170	81	28
	E0003015	20	FEMALE	CAUCASIAN	158	57	22.8
	E0004002	24	FEMALE	CAUCASIAN	156	65	26.7
	E0004013	24	FEMALE	CAUCASIAN	157	84	34.1
	E0004018	24	MALE	CAUCASIAN	178	65	20.5
	E0004021	53	MALE	CAUCASIAN	173	89	29.7
	E0005002	48	MALE	CAUCASIAN	173	60	20
	E0005004	36	FEMALE	CAUCASIAN	165	73	26.8
	E0005013	43	FEMALE	CAUCASIAN	168	71	25.2
	E0005024	19	FEMALE	CAUCASIAN	170	105	36.3
	E0005027	41	MALE	CAUCASIAN	180	90	27.8
	E0005037	56	FEMALE	CAUCASIAN	165	138	50.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
GENERATED: 12JUL2005 17:41:40 iceadmn3

Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	50	MALE	CAUCASIAN	188	118	33.4
	E0006005	37	FEMALE	CAUCASIAN	158	101	40.5
	E0006018	57	MALE	CAUCASIAN	180	95	29.3
	E0007013	60	FEMALE	CAUCASIAN	152	53	22.9
	E0010004	57	FEMALE	HISPANIC	158	68	27.2
	E0010012	51	FEMALE	CAUCASIAN	173	122	40.8
	E0010024	39	MALE	CAUCASIAN	170	98	33.9
	E0010032	38	FEMALE	CAUCASIAN	171	87	29.8
	E0011025	47	FEMALE	CAUCASIAN	152	54	23.4
	E0013007	49	MALE	CAUCASIAN	180	90	27.8
	E0013009	44	FEMALE	CAUCASIAN	173	104	34.7
	E0014006	18	FEMALE	CAUCASIAN	158	101	40.5
	E0014010	40	FEMALE	CAUCASIAN	170	103	35.6
	E0016001	32	MALE	CAUCASIAN	161	69	26.6
	E0016004	36	MALE	CAUCASIAN	173	91	30.4
	E0018001	24	FEMALE	CAUCASIAN	168	93	33
	E0018006	42	MALE	CAUCASIAN	180	94	29
	E0019004	32	FEMALE	CAUCASIAN	163	62	23.3
	E0019011	50	FEMALE	HISPANIC	151	93	40.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
GENERATED: 12JUL2005 17:41:40 iceadmn3

Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	30	FEMALE	CAUCASIAN	165	62	22.8
	E0019026	18	FEMALE	CAUCASIAN	158	100	40.1
	E0019043	54	MALE	CAUCASIAN	170	67	23.2
	E0020001	48	FEMALE	CAUCASIAN	168	79	28
	E0020006	52	FEMALE	CAUCASIAN	166	114	41.4
	E0020007	26	FEMALE	CAUCASIAN	155	47	19.6
	E0020011	21	FEMALE	CAUCASIAN	170	99	34.3
	E0020013	23	MALE	CAUCASIAN	173	81	27.1
	E0022008	37	MALE	CAUCASIAN	175	84	27.4
	E0022017	41	MALE	CAUCASIAN	193	96	25.8
	E0022018	41	MALE	CAUCASIAN	188	123	34.8
	E0022022	23	FEMALE	CAUCASIAN	159	50	19.8
	E0022027	45	MALE	CAUCASIAN	186	121	35
	E0022030	22	MALE	CAUCASIAN	173	140	46.8
	E0022031	36	MALE	CAUCASIAN	177	86	27.5
	E0022032	21	FEMALE	CAUCASIAN	170	66	22.8
	E0022035	20	FEMALE	CAUCASIAN	157	73	29.6
	E0022036	22	MALE	CAUCASIAN	183	74	22.1
	E0022056	41	FEMALE	CAUCASIAN	163	78	29.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
GENERATED: 12JUL2005 17:41:40 iceadmn3

Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	24	MALE	CAUCASIAN	182	76	22.9
	E0022063	35	FEMALE	BLACK	177	85	27.1
	E0023008	35	FEMALE	CAUCASIAN	170	64	22.1
	E0023013	40	FEMALE	CAUCASIAN	163	66	24.8
	E0023015	43	FEMALE	CAUCASIAN	173	64	21.4
	E0023034	18	FEMALE	CAUCASIAN	163	60	22.6
	E0023037	39	MALE	CAUCASIAN	188	86	24.3
	E0023038	59	MALE	CAUCASIAN	170	100	34.6
	E0023044	44	FEMALE	CAUCASIAN	168	115	40.7
	E0023045	29	MALE	CAUCASIAN	178	64	20.2
	E0025002	46	FEMALE	CAUCASIAN	168	100	35.4
	E0026010	31	MALE	CAUCASIAN	180	94	29
	E0026017	27	MALE	CAUCASIAN	173	85	28.4
	E0026018	39	FEMALE	CAUCASIAN	168	109	38.6
	E0026025	41	MALE	CAUCASIAN	173	74	24.7
	E0026029	22	FEMALE	CAUCASIAN	157	158	64.1
	E0026030	29	MALE	BLACK	185	89	26
	E0026031	41	MALE	BLACK	188	86	24.3
	E0027003	50	FEMALE	CAUCASIAN	163	76	28.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	30	MALE	CAUCASIAN	198	82	20.9
	E0028006	40	FEMALE	CAUCASIAN	163	64	24.1
	E0028008	36	MALE	CAUCASIAN	183	112	33.4
	E0028009	21	FEMALE	CAUCASIAN	168	90	31.9
	E0028016	28	MALE	CAUCASIAN	183	95	28.4
	E0028017	39	FEMALE	CAUCASIAN	165	91	33.4
	E0028027	58	MALE	HISPANIC	178	89	28.1
	E0028029	39	MALE	HISPANIC	181	96	29.3
	E0028034	39	MALE	CAUCASIAN	168	86	30.5
	E0028038	50	MALE	CAUCASIAN	173	138	46.1
	E0028043	51	MALE	CAUCASIAN	168	86	30.5
	E0028045	46	MALE	CAUCASIAN	183	72	21.5
	E0029005	30	FEMALE	BLACK	168	96	34
	E0030001	41	FEMALE	CAUCASIAN	172	63	21.3
	E0030008	40	MALE	CAUCASIAN	183	90	26.9
	E0030011	21	MALE	CAUCASIAN	170	108	37.4
	E0030015	21	MALE	CAUCASIAN	185	91	26.6
	E0030022	39	MALE	CAUCASIAN	155	92	38.3
	E0031002	18	FEMALE	CAUCASIAN	166	59	21.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	33	MALE	CAUCASIAN	176	72	23.2
	E0033015	34	FEMALE	CAUCASIAN	168	60	21.3
	E0034002	55	MALE	CAUCASIAN	170	98	33.9
	E0034003	49	MALE	CAUCASIAN	173	77	25.7
	E0034006	35	FEMALE	CAUCASIAN	173	150	50.1
	E0034008	34	MALE	BLACK	175	85	27.8
	E0035003	28	MALE	CAUCASIAN	188	108	30.6
	E0035005	48	FEMALE	CAUCASIAN	170	81	28
	E0035014	35	FEMALE	BLACK	155	66	27.5
	E0035024	41	FEMALE	BLACK	165	114	41.9
	E0036005	19	FEMALE	CAUCASIAN	152	97	42
	E0037002	28	FEMALE	CAUCASIAN	168	77	27.3
	E0037005	27	FEMALE	CAUCASIAN	165	95	34.9
	E0037006	50	FEMALE	CAUCASIAN	156	57	23.4
	E0039006	32	FEMALE	BLACK	152	65	28.1
	E0039015	41	MALE	BLACK	183	79	23.6
	E0039024	35	FEMALE	CAUCASIAN	173	98	32.7
	E0039025	47	MALE	BLACK	179	96	30
	E0039041	35	MALE	BLACK	178	75	23.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	44	MALE	CAUCASIAN	173	82	27.4
	E0039046	36	FEMALE	BLACK	152	101	43.7
	E0039051	40	FEMALE	BLACK	165	82	30.1
	E0039053	40	MALE	BLACK	183	87	26
	E0039057	38	MALE	BLACK	178	97	30.6
	E0041003	36	FEMALE	BLACK	163	96	36.1
	E0041008	32	FEMALE	CAUCASIAN	167	70	25.1
	E0042001	59	FEMALE	CAUCASIAN	168	87	30.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	47	FEMALE	BLACK	158	68	27.2
	E0003018	33	FEMALE	BLACK	166	56	20.3
	E0005011	26	MALE	CAUCASIAN	178	83	26.2
	E0005030	19	FEMALE	CAUCASIAN	167	59	21.2
	E0005036	40	FEMALE	CAUCASIAN	142	90	44.6
	E0006015	36	FEMALE	CAUCASIAN	163	76	28.6
	E0006016	43	MALE	CAUCASIAN	180	87	26.9
	E0007008	42	FEMALE	CAUCASIAN	168	125	44.3
	E0009002	47	MALE	CAUCASIAN	182	103	31.1
	E0009006	20	MALE	CAUCASIAN	185	78	22.8
	E0009009	23	FEMALE	CAUCASIAN	177	85	27.1
	E0010015	42	MALE	HISPANIC	178	112	35.3
	E0011004	32	MALE	CAUCASIAN	178	91	28.7
	E0011007	47	FEMALE	CAUCASIAN	161	95	36.6
	E0011018	23	MALE	CAUCASIAN/FILIPINO MIXED	170	76	26.3
	E0011024	36	FEMALE	BLACK	165	96	35.3
	E0015003	54	FEMALE	CAUCASIAN	152	64	27.7
	E0019003	27	FEMALE	CAUCASIAN	161	78	30.1
	E0019007	39	FEMALE	CAUCASIAN	171	64	21.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	24	MALE	CAUCASIAN	178	63	19.9
	E0019018	34	MALE	CAUCASIAN	173	104	34.7
	E0019022	24	FEMALE	CAUCASIAN	163	97	36.5
	E0019027	26	FEMALE	HISPANIC	163	96	36.1
	E0019032	28	FEMALE	CAUCASIAN	166	66	24
	E0019034	33	FEMALE	CAUCASIAN	161	95	36.6
	E0019036	27	MALE	CAUCASIAN	173	74	24.7
	E0019039	35	MALE	CAUCASIAN	181	70	21.4
	E0019041	22	FEMALE	CAUCASIAN	165	68	25
	E0019049	33	FEMALE	CAUCASIAN	170	83	28.7
	E0022052	46	FEMALE	BLACK	173	92	30.7
	E0022064	19	MALE	CAUCASIAN	190	70	19.4
	E0022073	25	FEMALE	CAUCASIAN	157	61	24.7
	E0023002	19	FEMALE	CAUCASIAN	170	82	28.4
	E0023017	18	MALE	CAUCASIAN	178	63	19.9
	E0023021	49	MALE	CAUCASIAN	185	135	39.4
	E0023027	25	FEMALE	CAUCASIAN	173	113	37.8
	E0023030	40	FEMALE	CAUCASIAN	160	87	34
	E0023040	32	FEMALE	BLACK	170	94	32.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	57	MALE	CAUCASIAN	175	78	25.5
	E0026019	39	FEMALE	BLACK	168	77	27.3
	E0027005	58	FEMALE	CAUCASIAN	170	75	26
	E0029009	44	MALE	CAUCASIAN	183	103	30.8
	E0029021	38	FEMALE	CAUCASIAN	164	80	29.7
	E0029026	65	MALE	CAUCASIAN	183	100	29.9
	E0029030	31	MALE	CAUCASIAN	160	63	24.6
	E0031008	31	FEMALE	CAUCASIAN	157	70	28.4
	E0031020	44	MALE	CAUCASIAN	178	87	27.5
	E0031021	27	MALE	BLACK	185	90	26.3
	E0031029	24	MALE	CAUCASIAN	183	81	24.2
	E0033002	59	MALE	CAUCASIAN	168	86	30.5
	E0033006	38	MALE	CAUCASIAN	175	76	24.8
	E0033021	27	FEMALE	CAUCASIAN	163	62	23.3
	E0035013	28	FEMALE	CAUCASIAN	158	86	34.4
	E0035015	33	FEMALE	HISPANIC	162	132	50.3
	E0035016	25	FEMALE	CAUCASIAN	168	117	41.5
	E0035023	41	MALE	CAUCASIAN	180	88	27.2
	E0039052	37	FEMALE	BLACK	188	136	38.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 300 MG (BIPOLAR II)	E0039056	46	MALE	BLACK	183	95	28.4
	E0040003	50	FEMALE	CAUCASIAN	165	65	23.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	42	FEMALE	CAUCASIAN	152	81	35.1
	E0002011	35	FEMALE	CAUCASIAN	173	74	24.7
	E0003010	54	FEMALE	CAUCASIAN	163	60	22.6
	E0003011	26	FEMALE	CAUCASIAN	165	109	40
	E0003016	33	FEMALE	CAUCASIAN	168	74	26.2
	E0003019	51	MALE	CAUCASIAN	184	88	26
	E0003020	34	MALE	CAUCASIAN	175	108	35.3
	E0004001	33	FEMALE	HISPANIC	160	44	17.2
	E0004009	22	FEMALE	CAUCASIAN	155	64	26.6
	E0004012	20	FEMALE	ASIAN/AMERICAN	157	50	20.3
	E0004015	47	MALE	CAUCASIAN	188	117	33.1
	E0005003	48	MALE	CAUCASIAN	185	101	29.5
	E0005005	32	MALE	CAUCASIAN			
	E0005007	44	FEMALE	CAUCASIAN	163	80	30.1
	E0005008	43	MALE	CAUCASIAN	170	124	42.9
	E0005009	24	MALE	CAUCASIAN	183	87	26
	E0005010	20	FEMALE	CAUCASIAN	183	156	46.6
	E0005012	54	MALE	CAUCASIAN	180	86	26.5
	E0005014	30	MALE	CAUCASIAN	188	85	24

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR I)	E0005022	25	MALE	CAUCASIAN	183	93	27.8
	E0005025	40	FEMALE	CAUCASIAN	158	72	28.8
	E0006019	42	MALE	CAUCASIAN	183	83	24.8
	E0007005	34	FEMALE	CAUCASIAN	167	80	28.7
	E0007015	58	FEMALE	CAUCASIAN	160	65	25.4
	E0009001	36	FEMALE	BLACK	160	93	36.3
	E0010002	46	MALE	CAUCASIAN	173	81	27.1
	E0010009	58	FEMALE	CAUCASIAN	171	79	27
	E0010010	35	FEMALE	CAUCASIAN	155	53	22.1
	E0010014	38	FEMALE	CAUCASIAN	173	87	29.1
	E0010017	32	MALE	CAUCASIAN	183	95	28.4
	E0010023	28	FEMALE	CAUCASIAN	165	73	26.8
	E0010027	32	MALE	CAUCASIAN	173	76	25.4
	E0010029	44	MALE	CAUCASIAN	170	129	44.6
	E0011022	35	FEMALE	CAUCASIAN	161	87	33.6
	E0013006	28	FEMALE	CAUCASIAN	183	126	37.6
	E0013012	58	FEMALE	BLACK	160	95	37.1
	E0013014	48	MALE	CAUCASIAN	183	72	21.5
	E0014005	44	FEMALE	CAUCASIAN	160	69	27

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	22	FEMALE	CAUCASIAN	155	60	25
	E0014011	39	MALE	CAUCASIAN	183	89	26.6
	E0014012	55	FEMALE	CAUCASIAN	165	72	26.4
	E0015001	54	MALE	CAUCASIAN	187	106	30.3
	E0015008	41	MALE	CAUCASIAN	183	73	21.8
	E0016003	22	FEMALE	CAUCASIAN	165	127	46.6
	E0016005	47	FEMALE	CAUCASIAN	168	75	26.6
	E0018007	42	FEMALE	CAUCASIAN	165	85	31.2
	E0019005	50	FEMALE	CAUCASIAN	163	66	24.8
	E0019015	24	FEMALE	CAUCASIAN	173	81	27.1
	E0020004	61	MALE	CAUCASIAN	170	91	31.5
	E0020010	31	FEMALE	CAUCASIAN	160	64	25
	E0020014	43	FEMALE	BLACK	165	54	19.8
	E0020021	47	MALE	BLACK	173	143	47.8
	E0020023	46	MALE	CAUCASIAN	173	99	33.1
	E0022007	31	FEMALE	CAUCASIAN	158	82	32.8
	E0022010	21	MALE	CAUCASIAN	184	80	23.6
	E0022012	27	FEMALE	CAUCASIAN	177	108	34.5
	E0022019	30	MALE	CAUCASIAN	181	102	31.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	46	FEMALE	CAUCASIAN	160	72	28.1
	E0022033	45	FEMALE	CAUCASIAN	162	74	28.2
	E0022034	42	MALE	CAUCASIAN	178	104	32.8
	E0022038	39	MALE	CAUCASIAN	188	101	28.6
	E0022039	31	FEMALE	BLACK	168	134	47.5
	E0022046	54	FEMALE	CAUCASIAN	158	75	30
	E0022048	26	FEMALE	ORIENTAL	157	55	22.3
	E0022051	41	FEMALE	CAUCASIAN	164	80	29.7
	E0022053	28	FEMALE	CAUCASIAN	160	86	33.6
	E0022058	43	MALE	CAUCASIAN	179	82	25.6
	E0022061	22	FEMALE	CAUCASIAN	167	73	26.2
	E0022062	63	MALE	CAUCASIAN	180	110	34
	E0022068	44	FEMALE	CAUCASIAN	169	89	31.2
	E0022069	27	FEMALE	CAUCASIAN	175	68	22.2
	E0022071	57	MALE	CAUCASIAN	180	76	23.5
	E0023003	19	MALE	CAUCASIAN	185	87	25.4
	E0023006	39	MALE	CAUCASIAN	175	69	22.5
	E0023010	46	MALE	CAUCASIAN	185	102	29.8
	E0023025	19	MALE	CAUCASIAN	188	77	21.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	48	FEMALE	CAUCASIAN	163	79	29.7
	E0026002	62	MALE	CAUCASIAN	175	84	27.4
	E0026007	59	FEMALE	CAUCASIAN	168	103	36.5
	E0026013	28	FEMALE	CAUCASIAN	170	81	28
	E0028007	22	FEMALE	CAUCASIAN	155	41	17.1
	E0028023	54	MALE	BLACK	170	72	24.9
	E0028025	27	MALE	CAUCASIAN	178	75	23.7
	E0028033	44	FEMALE	CAUCASIAN	170	83	28.7
	E0028035	57	MALE	CAUCASIAN	180	106	32.7
	E0028037	61	MALE	CAUCASIAN	180	95	29.3
	E0028039	28	MALE	CAUCASIAN	178	71	22.4
	E0028046	33	FEMALE	BLACK	170	93	32.2
	E0028048	18	FEMALE	HISPANIC	158	67	26.8
	E0029008	22	FEMALE	CAUCASIAN	141	57	28.7
	E0029011	26	MALE	CAUCASIAN	193	122	32.8
	E0029012	39	FEMALE	CAUCASIAN	170	99	34.3
	E0029015	45	FEMALE	CAUCASIAN	168	64	22.7
	E0029018	22	MALE	CAUCASIAN	173	81	27.1
	E0030014	32	FEMALE	CAUCASIAN	168	60	21.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	20	MALE	CAUCASIAN	191	120	32.9
	E0030024	30	FEMALE	CAUCASIAN	158	61	24.4
	E0030025	63	FEMALE	BLACK	168	82	29.1
	E0031027	38	MALE	CAUCASIAN	173	64	21.4
	E0031030	35	FEMALE	CAUCASIAN	164	70	26
	E0033012	39	MALE	CAUCASIAN	175	76	24.8
	E0034001	55	FEMALE	CAUCASIAN	165	73	26.8
	E0034004	46	MALE	CAUCASIAN	183	97	29
	E0035001	40	FEMALE	BLACK	168	132	46.8
	E0035006	37	FEMALE	HISPANIC	168	66	23.4
	E0035021	29	FEMALE	HISPANIC	160	82	32
	E0036002	32	FEMALE	CAUCASIAN	175	79	25.8
	E0036006	38	MALE	CAUCASIAN	173	101	33.7
	E0036007	35	FEMALE	CAUCASIAN	163	64	24.1
	E0037009	34	FEMALE	HISPANIC	163	77	29
	E0039011	34	FEMALE	BLACK	180	97	29.9
	E0039018	34	FEMALE	BLACK	150	62	27.6
	E0039026	45	FEMALE	BLACK	160	66	25.8
	E0039028	39	MALE	BLACK	185	158	46.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	26	FEMALE	BLACK	160	127	49.6
	E0039034	29	FEMALE	CAUCASIAN	163	94	35.4
	E0039042	35	FEMALE	BLACK	152	67	29
	E0041004	35	MALE	CAUCASIAN	183	101	30.2
	E0041009	46	FEMALE	BLACK	163	36	13.5
	E0042002	26	MALE	CAUCASIAN	168	97	34.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	29	MALE	CAUCASIAN	180	95	29.3
	E0003002	37	MALE	CAUCASIAN	180	67	20.7
	E0005031	29	FEMALE	CAUCASIAN	157	60	24.3
	E0005033	33	FEMALE	CAUCASIAN	165	64	23.5
	E0005038	31	FEMALE	CAUCASIAN	163	103	38.8
	E0007009	29	FEMALE	CAUCASIAN	165	65	23.9
	E0009010	31	MALE	CAUCASIAN	185	79	23.1
	E0009011	62	MALE	CAUCASIAN	188	88	24.9
	E0010005	18	MALE	CAUCASIAN	191	159	43.6
	E0011016	40	MALE	CAUCASIAN	181	97	29.6
	E0011020	33	MALE	CAUCASIAN	182	71	21.4
	E0018002	53	MALE	CAUCASIAN	175	95	31
	E0018003	27	FEMALE	CAUCASIAN	163	127	47.8
	E0018013	44	MALE	CAUCASIAN	178	110	34.7
	E0019002	22	FEMALE	CAUCASIAN	174	77	25.4
	E0019008	35	FEMALE	CAUCASIAN	155	86	35.8
	E0019009	22	FEMALE	CAUCASIAN	153	50	21.4
	E0019016	26	FEMALE	CAUCASIAN	152	100	43.3
	E0019020	35	FEMALE	CAUCASIAN	159	56	22.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	41	MALE	CAUCASIAN	173	81	27.1
	E0019024	26	MALE	CAUCASIAN	172	101	34.1
	E0019031	47	MALE	CAUCASIAN	188		
	E0019035	34	FEMALE	CAUCASIAN	155	104	43.3
	E0019040	49	MALE	BLACK	180	123	38
	E0019042	27	FEMALE	CAUCASIAN	173	75	25.1
	E0019045	32	FEMALE	CAUCASIAN	161	61	23.5
	E0020024	18	MALE	CAUCASIAN	176	73	23.6
	E0022044	34	FEMALE	CAUCASIAN	173	61	20.4
	E0023007	23	FEMALE	CAUCASIAN	170	72	24.9
	E0023011	50	FEMALE	CAUCASIAN	163	75	28.2
	E0023014	40	MALE	CAUCASIAN	175	93	30.4
	E0023019	32	MALE	CAUCASIAN	177	72	23
	E0023022	21	MALE	CAUCASIAN	180	73	22.5
	E0023023	35	FEMALE	CAUCASIAN	160	54	21.1
	E0023029	46	FEMALE	HISPANIC	163	60	22.6
	E0023031	49	FEMALE	CAUCASIAN	163	107	40.3
	E0023041	40	FEMALE	CAUCASIAN	161	80	30.9
	E0023043	48	MALE	CAUCASIAN	185	64	18.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	46	MALE	CAUCASIAN	175	81	26.4
	E0026005	57	FEMALE	CAUCASIAN	168	63	22.3
	E0026009	43	FEMALE	CAUCASIAN	152	56	24.2
	E0026015	47	FEMALE	CAUCASIAN	163	57	21.5
	E0026023	20	MALE	CAUCASIAN	185	96	28
	E0027016	24	FEMALE	CAUCASIAN	150	87	38.7
	E0027018	23	FEMALE	CAUCASIAN	163	79	29.7
	E0028032	36	MALE	CAUCASIAN	180	78	24.1
	E0029003	20	MALE	CAUCASIAN	191	134	36.7
	E0029020	33	MALE	CAUCASIAN	183	91	27.2
	E0031005	44	FEMALE	CAUCASIAN	178	92	29
	E0031006	41	MALE	CAUCASIAN	201	119	29.5
	E0031010	37	FEMALE	ITALIAN/NATIVE AMERICAN	167	75	26.9
	E0031011	46	MALE	CAUCASIAN	173	79	26.4
	E0031015	27	FEMALE	CAUCASIAN	163	74	27.9
	E0031031	33	FEMALE	CAUCASIAN	168	87	30.8
	E0033009	46	FEMALE	CAUCASIAN	163	62	23.3
	E0034009	44	MALE	BLACK	189	93	26
	E0037007	23	FEMALE	CAUCASIAN	170	67	23.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	21	MALE	CAUCASIAN	163	54	20.3
	E0039019	35	FEMALE	BLACK	150	100	44.4
	E0039043	20	MALE	CAUCASIAN	178	74	23.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR I)	E0002001	49	FEMALE	BLACK	140	53	27
	E0002003	22	FEMALE	CAUCASIAN	155	60	25
	E0002004	33	FEMALE	CAUCASIAN	165	98	36
	E0002008	41	MALE	CAUCASIAN	178	90	28.4
	E0002016	56	FEMALE	CAUCASIAN	163	78	29.4
	E0003008	35	FEMALE	CAUCASIAN	168	64	22.7
	E0004003	22	MALE	CAUCASIAN	168	86	30.5
	E0004006	37	FEMALE	CAUCASIAN	165	91	33.4
	E0004016	20	FEMALE	HISPANIC	160	55	21.5
	E0004024	39	FEMALE	CAUCASIAN	155	85	35.4
	E0005006	35	MALE	CAUCASIAN	180	77	23.8
	E0005017	41	FEMALE	CAUCASIAN	168	76	26.9
	E0005019	22	FEMALE	CAUCASIAN	170	77	26.6
	E0005026	29	FEMALE	CAUCASIAN	168	52	18.4
	E0005039	39	FEMALE	CAUCASIAN	170	142	49.1
	E0005043	58	MALE	CAUCASIAN	191	135	37
	E0006020	38	MALE	CAUCASIAN	183	86	25.7
	E0007001	46	MALE	CAUCASIAN	180	89	27.5
	E0007003	53	MALE	CAUCASIAN	173	63	21

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR I)	E0007006	39	MALE	BLACK	183	113	33.7
	E0009004	36	MALE	CAUCASIAN	175	85	27.8
	E0009012	28	MALE	CAUCASIAN	177	84	26.8
	E0010008	30	FEMALE	CAUCASIAN	163	56	21.1
	E0010018	37	FEMALE	ORIENTAL	155	49	20.4
	E0010028	32	FEMALE	HISPANIC	163	66	24.8
	E0011008	23	MALE	CAUCASIAN	177	61	19.5
	E0011009	57	MALE	CAUCASIAN	180	95	29.3
	E0011010	49	FEMALE	CAUCASIAN	168	83	29.4
	E0013001	34	MALE	CAUCASIAN	183	107	32
	E0013003	55	FEMALE	CAUCASIAN	165	130	47.8
	E0013005	40	MALE	CAUCASIAN	175	68	22.2
	E0013013	22	FEMALE	CAUCASIAN	175	70	22.9
	E0014002	43	FEMALE	CAUCASIAN	163	67	25.2
	E0014004	29	FEMALE	CAUCASIAN	173	75	25.1
	E0014009	28	FEMALE	CAUCASIAN	155	95	39.5
	E0014015	23	MALE	CAUCASIAN	173	74	24.7
	E0014017	23	FEMALE	CAUCASIAN	166	75	27.2
	E0014018	24	MALE	CAUCASIAN	178	73	23

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR I)	E0015005	49	MALE	CAUCASIAN	185	70	20.5
	E0017002	34	FEMALE	CAUCASIAN	156	80	32.9
	E0018009	27	MALE	CAUCASIAN	180	85	26.2
	E0018010	47	MALE	CAUCASIAN	178	88	27.8
	E0018015	50	MALE	CAUCASIAN	178	80	25.2
	E0020015	35	MALE	CAUCASIAN	173	78	26.1
	E0020017	41	FEMALE	CAUCASIAN	165	58	21.3
	E0020020	36	FEMALE	CAUCASIAN	163	50	18.8
	E0020022	49	FEMALE	CAUCASIAN	152	84	36.4
	E0022001	52	MALE	CAUCASIAN	175	74	24.2
	E0022004	30	FEMALE	CAUCASIAN	172	95	32.1
	E0022005	46	FEMALE	CAUCASIAN	167	110	39.4
	E0022011	28	MALE	CAUCASIAN	179	90	28.1
	E0022015	19	FEMALE	CAUCASIAN	165	71	26.1
	E0022016	32	FEMALE	CAUCASIAN	140	81	41.3
	E0022020	18	FEMALE	CAUCASIAN	158	44	17.6
	E0022023	50	MALE	CAUCASIAN	167	79	28.3
	E0022029	25	MALE	CAUCASIAN	179	146	45.6
	E0022041	51	FEMALE	CAUCASIAN	152	81	35.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR I)	E0022042	46	MALE	CAUCASIAN	197	109	28.1
	E0022043	43	FEMALE	CAUCASIAN	167	79	28.3
	E0022054	25	MALE	CAUCASIAN	178	92	29
	E0022059	40	FEMALE	BLACK	167	79	28.3
	E0022065	32	FEMALE	CAUCASIAN	168	100	35.4
	E0022070	59	MALE	CAUCASIAN	178	96	30.3
	E0023001	31	FEMALE	CAUCASIAN	168	104	36.8
	E0023009	62	FEMALE	CAUCASIAN	158	60	24
	E0023028	53	FEMALE	CAUCASIAN	158	64	25.6
	E0023033	53	MALE	CAUCASIAN	172	90	30.4
	E0023047	26	MALE	CAUCASIAN	191	111	30.4
	E0025001	31	FEMALE	CAUCASIAN	165	149	54.7
	E0026012	44	MALE	BLACK	173	80	26.7
	E0026020	28	MALE	ASIAN PACIFIC ISLANDER	175	80	26.1
	E0026024	44	FEMALE	ORIENTAL	165	71	26.1
	E0026028	35	MALE	CAUCASIAN	173	112	37.4
	E0028001	53	MALE	CAUCASIAN	188	130	36.8
	E0028003	53	FEMALE	CAUCASIAN	165	105	38.6
	E0028005	49	FEMALE	CAUCASIAN	175	63	20.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR I)	E0028010	28	FEMALE	CAUCASIAN	170	54	18.7
	E0028011	36	MALE	CAUCASIAN	173	63	21
	E0028030	33	MALE	CAUCASIAN	175	76	24.8
	E0028031	35	MALE	CAUCASIAN	173	118	39.4
	E0028047	50	FEMALE	BLACK	178	114	36
	E0029001	35	MALE	CAUCASIAN	183	86	25.7
	E0029014	34	FEMALE	CAUCASIAN	163	75	28.2
	E0029023	41	FEMALE	CAUCASIAN	157	79	32
	E0029032	52	MALE	CAUCASIAN	170	91	31.5
	E0029033	36	MALE	CAUCASIAN	179	98	30.6
	E0029039	30	FEMALE	HISPANIC	157	47	19.1
	E0030003	39	FEMALE	BLACK	165	84	30.9
	E0030009	55	MALE	CAUCASIAN	178	69	21.8
	E0030016	49	MALE	CAUCASIAN	180	93	28.7
	E0030021	25	MALE	CAUCASIAN	168	55	19.5
	E0031001	44	FEMALE	CAUCASIAN	171	125	42.7
	E0031017	42	MALE	CAUCASIAN	186	104	30.1
	E0031018	24	FEMALE	CAUCASIAN	150	110	48.9
	E0031023	25	FEMALE	CAUCASIAN	168	145	51.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR I)	E0033001	42	MALE	CAJUN - CREOLE	188	95	26.9
	E0033004	37	FEMALE	CAUCASIAN	160	68	26.6
	E0033010	26	FEMALE	BLACK	173	74	24.7
	E0033014	53	MALE	CAUCASIAN	183	95	28.4
	E0035002	46	MALE	CAUCASIAN	180	92	28.4
	E0035007	41	FEMALE	NATIVE AMERICAN INDIAN	188	99	28
	E0035011	50	FEMALE	HISPANIC	168	146	51.7
	E0035020	47	FEMALE	BLACK	152	81	35.1
	E0037003	38	FEMALE	HISPANIC	168	70	24.8
	E0037004	44	FEMALE	CAUCASIAN	163	110	41.4
	E0039007	39	MALE	HISPANIC	175	65	21.2
	E0039022	33	FEMALE	BLACK	170	70	24.2
	E0039023	44	MALE	BLACK	178	77	24.3
	E0039030	52	FEMALE	CAUCASIAN	152	122	52.8
	E0039031	34	FEMALE	CAUCASIAN	170	68	23.5
	E0039037	33	FEMALE	CAUCASIAN	165	58	21.3
	E0039038	40	FEMALE	BLACK	157	93	37.7
	E0039047	32	FEMALE	BLACK	160	96	37.5
	E0039059	55	FEMALE	BLACK	163	93	35

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR I)	E0041007	35	MALE	BLACK	188	73	20.7
	E0041010	32	MALE	CAUCASIAN	175	86	28.1
	E0041011	38	FEMALE	BLACK	163	115	43.3
	E0041012	47	FEMALE	BLACK	168	117	41.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR II)	E0001004	25	FEMALE	CAUCASIAN	158	67	26.8
	E0005023	29	FEMALE	BLACK	168	69	24.4
	E0005034	25	FEMALE	CAUCASIAN	165	92	33.8
	E0005041	52	FEMALE	CAUCASIAN	155	73	30.4
	E0007004	31	FEMALE	CAUCASIAN	156	94	38.6
	E0007010	59	FEMALE	CAUCASIAN	178	113	35.7
	E0007012	40	MALE	CAUCASIAN	163	65	24.5
	E0009007	31	MALE	CAUCASIAN	188	93	26.3
	E0009008	55	MALE	CAUCASIAN	188	93	26.3
	E0011001	53	FEMALE	CAUCASIAN	159	64	25.3
	E0011011	28	FEMALE	BLACK	163	52	19.6
	E0011013	54	FEMALE	CAUCASIAN	164	86	32
	E0011014	34	FEMALE	BLACK	163	93	35
	E0011021	38	FEMALE	CAUCASIAN	173	68	22.7
	E0013008	33	FEMALE	CAUCASIAN	165	118	43.3
	E0014001	25	FEMALE	CAUCASIAN	165	61	22.4
	E0014013	31	FEMALE	CAUCASIAN	165	55	20.2
	E0014014	38	MALE	CAUCASIAN	183	92	27.5
	E0015004	32	FEMALE	CAUCASIAN	170	102	35.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR II)	E0018005	24	MALE	CAUCASIAN	183	68	20.3
	E0018012	33	FEMALE	CAUCASIAN	173	85	28.4
	E0019019	22	FEMALE	CAUCASIAN	168	116	41.1
	E0019033	58	MALE	CAUCASIAN	176	70	22.6
	E0019038	19	MALE	CAUCASIAN	185	79	23.1
	E0019046	35	FEMALE	CAUCASIAN	175	66	21.6
	E0019047	23	MALE	CAUCASIAN	174	77	25.4
	E0019048	34	FEMALE	CAUCASIAN	161	57	22
	E0022006	20	FEMALE	CAUCASIAN	156	71	29.2
	E0022047	51	MALE	CAUCASIAN	180	87	26.9
	E0022075	51	FEMALE	CAUCASIAN	157	53	21.5
	E0023012	42	FEMALE	CAUCASIAN	170	102	35.3
	E0023016	42	FEMALE	CAUCASIAN	175	60	19.6
	E0023018	18	MALE	CAUCASIAN	173	92	30.7
	E0023036	25	FEMALE	CAUCASIAN	173	73	24.4
	E0023046	62	FEMALE	BLACK	165	98	36
	E0026006	37	MALE	CAUCASIAN	173	60	20
	E0026021	35	FEMALE	CAUCASIAN	163	53	19.9
	E0026027	40	FEMALE	CAUCASIAN	160	59	23

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DEM104.SAS
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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR II)	E0029002	54	FEMALE	CAUCASIAN	160	55	21.5
	E0029004	34	FEMALE	BLACK	168	82	29.1
	E0029013	39	FEMALE	CAUCASIAN	180	113	34.9
	E0029019	56	MALE	CAUCASIAN	170	91	31.5
	E0029024	48	FEMALE	CAUCASIAN	160	51	19.9
	E0029038	61	MALE	CAUCASIAN	172	86	29.1
	E0031004	37	FEMALE	CAUCASIAN	155	67	27.9
	E0031013	33	FEMALE	CAUCASIAN	152	109	47.2
	E0031016	24	MALE	CAUCASIAN	178	74	23.4
	E0031019	47	MALE	CAUCASIAN	170	71	24.6
	E0031022	36	FEMALE	HISPANIC	165	96	35.3
	E0033007	58	FEMALE	CAUCASIAN	160	69	27
	E0033013	29	FEMALE	CAUCASIAN	152	59	25.5
	E0033016	34	FEMALE	HISPANIC	160	60	23.4
	E0033022	20	FEMALE	CAUCASIAN	160	95	37.1
	E0034007	43	FEMALE	CAUCASIAN	155	50	20.8
	E0035004	43	MALE	HISPANIC	183	103	30.8
	E0035009	24	MALE	BLACK	188	71	20.1
	E0035010	57	FEMALE	BLACK	158	96	38.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.1 Demography and Other Patient Characteristics at Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE AT ENTRY	SEX	RACE	HEIGHT (CM)	WEIGHT (KG)	BODY MASS INDEX
PLACEBO (BIPOLAR II)	E0035022	48	FEMALE	BLACK	155	56	23.3
	E0039003	34	FEMALE	BLACK	170	95	32.9
	E0040001	38	FEMALE	CAUCASIAN	163	65	24.5
	E0040004	21	MALE	HISPANIC	178	56	17.7
	E0041002	47	MALE	BLACK	173	90	30.1
	E0041005	49	MALE	CAUCASIAN	180	98	30.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	Past	HYSTERECTOMY 1991
		Current	ALLERGIES - SEASONAL
		Current	ALLERGY TO PENICILLIN
	E0002010	Past	APPENDECTOMY
		Current	BACK/NECK INJURY (STRAIN) FROM CAR ACCIDENT
	E0002012	Past	EYE SURGERY TO CORRECT WEAK MUSCLES
		Past	FOREARM FRACTURE
	E0002018	Current	ARTHRITIS
	E0003004	Past	APPENDECTOMY 1994
		Past	MIGRAINES
		Past	SEASONAL ALLERGIES
		Current	ALLERGY TO PENICILLIN
		Current	HEMORRHOIDS
		Current	SHINGLES, NECK & HEAD
	E0003005	Current	BACK PAIN
		Current	GENERAL BODY PAIN
		Current	HEADACHES
		Current	HYPOTHYROIDISM
	E0003007	Past	ASTHMA
		Past	CONSTIPATION
		Past	HEARTBURN
		Current	HEADACHES
	E0003015	Past	GASTRITIS
		Past	HYPOGLYCEMIA
		Past	STILLBORN BIRTH
		Current	HEADACHES
		Current	MENSTRUAL CRAMPS
		Current	MIGRAINE HEADACHES
	E0004002	Past	HISTORY OF 3 ABORTIONS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	Past	RASH FROM USE OF TRAZADONE
		Current	ACID REFLUX
		Current	ALLERGY TO SULFA
	E0004013	Past	TUBAL LIGATION
		Current	ASTHMA
		Current	SLIGHTLY OBESE
	E0004018	Current	COLD SYMPTOMS
		Current	LEFT KNEE LIGAMENT DAMAGE
	E0004021	Past	ASTHMA
		Past	DEVIATED SEPTUM
		Past	HYPERLIPIDEMIA
		Past	INGUINAL HERNIA
		Current	ENLARGED PROSTATE
		Current	ENVIRONMENTAL ALLERGIES
		Current	LACTOSE INTOLERANCE
		Current	SINUS HEADACHES
	E0005002	Current	CLUSTER HEADACHES
		Current	HEARTBURN
	E0005004	Past	ANEMIA, IRON - DEFICIENCY
		Past	ROSACEA
		Past	SUICIDE ATTEMPT
		Past	TUBAL LIGATION
		Current	ALLERGIC TO CODEINE
		Current	ALLERGIC TO PERCOCET
		Current	HEART MURMUR
		Current	SHORTNESS OF BREATH
	E0005013	Past	GALLSTONES
		Current	ALLERGIC TO SULFA DRUGS
		Current	CONSTIPATION
		Current	INDIGESTION
		Current	INSOMNIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0005013	Current	NAUSEA
		Current	NECK PAIN, RECURRENT
		Current	RHINITUS/SINUSITIS
		Current	SINUS HEADACHES
	E0005024	Current	ASTHMA
		Current	RECURRENT DIARRHEA
		Current	SEASONAL ALLERGIES
		Current	STRESS HEADACHES
	E0005027	Past	VASECTOMY
		Past	WRIST SURGERY
		Current	EXERCISE INDUCED ASTHMA
		Current	HYPERLIPIDEMIA
		Current	INDIGESTION
		Current	SEASONAL ALLERGIES
		Current	SINUS HEADACHES
		Current	VERTIGO
	E0005037	Past	BACK SURGERY
		Past	CANCER OF CERVIX
		Past	DRY SKIN
		Past	HYSTERECTOMY
		Current	"NERVOUS" HIVES
		Current	ALLERGY TO CODEINE
		Current	ALLERGY TO SULFA DRUGS
		Current	ARTHRITIS - KNEES & BACK
		Current	HYPERTENSION
		Current	RECURRENT DIARRHEA
		Current	RECURRENT HEARTBURN
		Current	YEAR LONG ALLERGIES
	E0005042	Current	ARTHRITIS
		Current	GOUT - INTERMITTENT
		Current	NON - SPECIFIC PSORISIS
	E0006005	Past	LAZY EYE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	Current	HEAVY MENSTRUAL BLEEDING RULE OUT FIBROID TUMOR
		Current	OCCASIONAL HEADACHES
		Current	PAINFUL MENSTRUAL CRAMPS
		Current	SEASONAL ALLERGIES
		Current	TINNITIUS BILATERAL
	E0006018	Current	ARTHRITIC BACK
		Current	ELEVATED BLOOD PRESSURE
		Current	ELEVATED CHOLESTEROL
	E0007013	Current	GASTROESOPHAGEAL REFLUX
		Current	HEADACHE
		Current	HYPERTENSION
		Current	MIGRAINE HEADACHE
	E0010004	Past	BILATERAL TUBAL LIGATION
	E0010012	Past	ALCOHOL DEPENDENCE IN REMISSION (2000)
		Past	TUBAL LIGATION (1992)
		Current	OBESITY
	E0010024	Past	ALCOHOL ABUSE (1999)
		Past	HERNIA REPAIR
		Current	HYPERTENSION
		Current	INSOMNIA
		Current	OVERWEIGHT
		Current	STRABISMUS
		Current	TYPE II, DIABETES MELLITUS
	E0010032	Current	MILD PHARINGEAL HYPERHEMIA
		Current	SULFA ALLERGY
	E0013007	Current	DIABETES TYPE II
		Current	HIGH CHOLESTEROL
	E0013009	Past	BLOOD CLOT LEFT CALF
		Past	PARTIAL HYSTERECTOMY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	Past	TUBAL LIGATION
		Current	ARTHRITIS
	E0014006	Past	TEETH GRINDING
		Current	ALLERGIC TO MILK
		Current	ASTHMA
		Current	HAYFEVER
		Current	HEADACHES
		Current	UPPER BACK PAIN
	E0014010	Past	ABDOMINAL PAIN
		Past	ANEMIA
		Past	BACK PAIN
		Past	BODY STREP
		Past	CHOLECYSECTOMY
		Past	DRUG ABUSE
		Past	PARTIAL HYSTERECTOMY
		Past	PLURACY
		Past	SUICIDE ATTEMPT
		Past	WALKING PNEUMONIA
		Current	ALLERGIC - IODINE
		Current	CHRONIC FATIGUE SYNDROME
		Current	HAY FEVER
		Current	HEADCHES
		Current	HYPERINSULINEMIA
		Current	JOINT PAIN
		Current	OVERWEIGHT
		Current	PALPITATIONS
		Current	PELVIC PAIN
	E0016001	Past	HEART MURMURS
		Current	INSOMNIA
		Current	VISUAL HALLUCINATIONS (INTERMITTANT)
	E0018001	Past	DECREASED LIBIDO
		Past	LATEX ALLERGY
		Past	POLY SUBSTANCE ABUSE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	Past	SEASONAL ALLERGIES
		Past	TOBACCO USE
		Current	DECREASED LIBIDO
		Current	DEGENERATIVE JOINT DISEASE
		Current	GASTRO INTESTINAL REFLUX DISEASE
		Current	HYDROCODONE ALLERGY
		Current	LATEX ALLERGY
		Current	OXY CODONE ALLERGY
		Current	PENICILLIN ALLERGY
		Current	SEASONAL ALLERGIES
	E0018006	Past	KNEE ARTHROSCOPY
		Past	SEASONAL ALLERGIES
		Current	SEASONAL ALLERGIES
	E0019004	Past	MIGRAINES
		Current	ANXIETY
	E0019011	Current	HYPERGLYCEMIA
		Current	STRESS INCONTINENCE
	E0019025	Current	TENSION HEADACHES
	E0019026	Current	MODERATELY OBESE
	E0019043	Past	GASTRIC ULCERS
		Past	INTERMITTENT DIARRHEA
		Past	PROSTITITUS
		Current	ACID REFLUX
		Current	ENVIRONMENTAL ALLERGIES
		Current	OVERACTIVE BLADDER
	E0020001	Past	DETACHED RETINA
		Past	PNEUMONIA
		Past	RIGHT EYE SURGURY FOR DETACHED RETINA
		Current	INTERMITTENT ABDOMINAL DISCOMFORT
		Current	INTERMITTENT NAUSEA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	Current	SINUS HEADACHES
	E0020006	Past	BILATERAL CARPAL TUNNEL
		Past	BILATERAL CARPAL TUNNEL REPAIR
		Past	PARTIAL HYSTERECTOMY
		Past	RIGHT KNEE SURGERY, TORN MENISCUS
		Past	SUICIDE ATTEMPT - OVERDOSE
		Past	TOTAL RIGHT KNEE REPLACEMENT
		Current	ANXIETY SYMPTOMS
		Current	GASTRO ESOPHAGEAL REFLUX DISEASE
		Current	HERNIATED DISC, THORACIC AREA
		Current	HYPERTENSION
		Current	INTERMITTENT HEADACHES
		Current	INTERMITTENT THORACIC & LUMBAR AREA PAIN
		Current	LEFT HAND SCAR (DUE TO PAST INJURY)
		Current	LEFT KNEE SCAR (DUE TO PAST INJURY)
		Current	MENOPAUSE
		Current	RIGHT BUNDLE BRANCH BLOCK
	E0020007	Past	OVERDOSE ON ASPIRIN
		Past	PNEUMONIA
		Current	ALLERGIC TO PENICILLIN
		Current	INTERMITTENT HEADACHES
	E0020011	Current	ANEMIA
		Current	ANXIETY SYMPTOMS
		Current	IRREGULAR MENSES
	E0022008	Past	CARPAL TUNNEL SURGERY
		Past	THROAT CANCER, SURGERY, RADIATION
		Current	FLU LIKE SYMPTOMS
		Current	HEADACHES
	E0022017	Current	ASTHMA
		Current	CHRONIC BACK PAIN
		Current	ERECTILE DYSFUNCTION
		Current	HEADACHES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	Current	ASTHMA
		Current	GASTROESOPHAGEAL REFLUX
		Current	HEADACHES
	E0022022	Past	POLYSUBSTANCE ABUSE
		Current	ALLERGIC RHINITIS
		Current	ASTHMA
		Current	CONSTIPATION
		Current	DENTAIL CARIES
		Current	GASTRIC REFLUX
		Current	HEADACHES
		Current	INGROWN TOE NAIL PAIN
		Current	ORTHOSTATIC DIZZINESS
	E0022027	Current	HEADACHES
		Current	MUSCULOSKELATAL PAIN
	E0022030	Current	HEADACHES
	E0022031	Past	ASTHMA
		Current	BURSITIS RIGHT SHOULDER
		Current	DIARRHEA
		Current	HEADACHES
	E0022032	Past	LEFT URETERAL ANOMALY
		Past	NEPHROLITHIOSIS
		Current	HEADACHES
	E0022036	Current	ABDOMINAL PAIN
		Current	CONSTIPATION
		Current	DIARRHEA
		Current	HEADACHES
	E0022056	Past	THYROID DISEASE
		Past	TUBAL LIGATION 1987
		Current	HEARTBURN/GASTRIC REFLUX
		Current	MILD ANEMIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	Current	HEADACHES
		Current	MITRAL VALVE PROLAPSE
	E0022063	Past	CHOLECYSTECTOMY
		Past	CHOLELITHIASIS
		Past	RESECTION OF SUPRAMAMMARY GLAND
		Current	GASTROESOPHAGEAL REFLUX
		Current	HEADACHES
	E0023013	Current	HEADACHES
	E0023015	Past	HYSTERECTOMY
		Current	NECK PAIN
		Current	SHOULDER PAIN
	E0023037	Past	BILATERAL ANTERIOR CRUCIATE LIGAMENT REPAIR
	E0023038	Past	TONSILLECTOMY
		Current	CONSTIPATION
		Current	HIGH CHOLESTEROL
		Current	INGUINAL HERNIA
	E0023044	Past	ADENOIDECTOMY
		Past	SPONDYLOLITHESIS (SURGICAL REPAIR)
		Past	TONSILLECTOMY
		Current	ASTHMA
		Current	HAYFEVER (SEASONAL ALLERGIES)
	E0023045	Past	JAW SURGERY
	E0025002	Past	HYSTERECTOMY
		Past	TRANS ISCHEMIC ATTACK
		Current	ASTHMA
		Current	ESOPHAGEAL SPASMS
	E0026010	Past	MARIJUANA
		Past	PNEUMONIA 1977

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0026010	Current	ALLERGIES 1980 - FISH OIL
		Current	HEADACHES 1970'S
		Current	INSOMNIA 1999
		Current	TMJ 1989
	E0026017	Past	BLUNT TRAUMA TO HAND IN 2002
		Current	GAS SINCE 2001
		Current	HEADACHES SINCE 1997
		Current	INSOMNIA SINCE 3-6-07 2001
		Current	LEFT EAR HEARING LOSS SINCE 1999
		Current	MIGRAINE HEADACHES SINCE 1999
		Current	WEIGHT PROBLEMS (LOSS) SINCE 2002
	E0026018	Past	C - SECTION SINCE 1982
		Past	COCAINE ABUSE
		Past	ETOH ABUSE
		Past	TACHEOSTOMY
		Past	TUBAL LIGATION SINCE 1982
		Current	HEADACHES SINCE 1970
		Current	HEARTBURN SINCE 1985
		Current	HEPATITIS "C" SINCE 1980
		Current	INSOMNIA SINCE 1990
		Current	IRREGULAR PERIOS SINCE 1990
		Current	MOOD CHANGES WITH PERIOD SINCE 1990
		Current	OBESE SINCE 1970
	E0026025	Past	LEFT EYE LID INJURY
		Past	LEFT SHOULDER ANTERIOR CRUCIATE LIGAMENT REPAIR
		Past	SALIVA GLAND EXCISION
		Current	DEGENERATIVE JOINT DISEASE
		Current	HEADACHES
		Current	INSOMNIA
	E0026029	Past	ALCOHOL ABUSE
		Past	BULEMIA
		Past	METHAMPHETAMINE ABUSE
		Current	EMESIS WITH ANXIETY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0026029	Current	FATIGUE
		Current	HEADACHES
		Current	INSOMNIA
		Current	LOWER BACK PAIN
		Current	NAUSEA WITH ANXIETY
	E0026030	Current	HAY FEVER
		Current	HEADACHES
		Current	INSOMNIA
	E0026031	Past	FACIAL RECONSTRUCTION
		Past	SUBSTANCE ABUSE
		Current	HEADACHES
		Current	HYPERTENSION
		Current	INSOMNIA
		Current	MIGRAINE HEADACHES
		Current	OSTEOARTHRITIS, LEFT HIP.
		Current	PENICILLIN ALLERGY
		Current	SUMMER WEIGHT LOSS
	E0027003	Past	ALCOHOL ABUSE
		Past	APPENDECTOMY
		Past	BENZODIOZEPINE ABUSE
		Past	CHRONIC PANCREATITIS
		Past	ECT TREATMENTS
		Past	LEFT ANKLE FRACTURE
		Past	SUBDURAL HEMATOMA
		Current	ARTHRITIS
		Current	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
		Current	COLON POLYPS
		Current	GASTRIC REFLUX
		Current	INSOMNIA
		Current	MIGRAINE HEADACHES
		Current	TUBAL LIGATION
	E0028006	Past	BREAST AUGMENTATION
		Current	ALLERGY TO PCN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	Current	ANXIETY
		Current	ARTHRITIS
		Current	IUD IMPLANT
		Current	SEASONAL ALLERGIES
	E0028008	Past	MILD CONCUSSION
		Current	ASTHMA
		Current	DIARRHEA
		Current	GERD
		Current	GLAUCOMA
		Current	HIATAL HERNIA
		Current	INSOMNIA
		Current	MIGRAINES
		Current	OBESITY
	E0028009	Past	KIDNEY INFECTION, 1999
		Current	OCCASIONAL BACK ACHES
	E0028016	Past	MARIJUANA USE
		Current	INSOMNIA
	E0028017	Past	ADENOIDECTOMY
		Past	APPENDECTOMY
		Past	CANCER IN SITU OF CERVIX
		Past	SEIZURES (SECONDARY TO HALDOL ALLERGY
		Past	TONSILECTOMY
		Current	GI DISTRESS
		Current	HEPATITIS C
		Current	HYPOTHYROIDISM
		Current	KNEE PAIN
		Current	OBESITY
		Current	RASH ON NOSE
		Current	TENSION HEADACHES
	E0028027	Current	INSOMNIA
		Current	SEASONAL HAY FEVER

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	Current	HAY FEVER
	E0028038	Past	EAR INFECTION
		Current	GASTRIC REFLUX DISEASE
		Current	HYPERDIPIDEMIA
		Current	OBESITY
		Current	PAIN IN FEET
		Current	PROSTATIC HYPERTROPHY
		Current	SEASONAL ALLERGIES
	E0028043	Past	ADENOIDECTOMY
		Past	TONSILECTOMY
		Current	OCCASIONAL BACK PAIN
	E0028045	Past	ANEMIA
		Past	BROKEN LEG
		Past	CONCUSSION
		Past	ESOPHAGEAL TEAR
		Past	POST TRAUMATIC STRESS DISORDER
		Past	SUBSTANCE DEPENDENCE
		Current	ABSENT LOWER TEETH
		Current	DRY MOUTH
		Current	HEPATITIS C
		Current	HYPOTHYROIDISM
		Current	INSULIN RESISTANCE
	E0029005	Current	ASTHMA - MODERATE, SINCE 1977
		Current	DUST ALLERGY - MODERATE, SINCE 1972
		Current	FELINE ALLERGY - MODERATE, SINCE 1972
	E0030001	Past	ABORTION - 1997
		Past	ACNE - 2001
		Past	ANEMIA - 1982
		Past	ANOREXIA - 1982
		Past	BRONCHITIS - 2001
		Past	GENERALIZED ANXIETY DISORDER - 1996
		Past	RIGHT TOE FRACTURES (2 TIMES) - 1976, 2001

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	Past	SKIN RASH, - 2001
		Past	URINARY TRACT INFECTION - 1992
		Current	ALLERGIES (WOOL, ENVIRONMENTAL)
		Current	ASTYGMATISM
		Current	CRAMPS (MENSTRUAL CYCLE)
		Current	HEADACHES (INTERMITTENT, SINUS)
		Current	LOWER BACK PAIN
		Current	RESTING AND INTENTIONAL TREMOR
		Current	SACRO - ILLIAC PAIN
		Current	SINUS CONGESTION
	E0030008	Past	COMPOUND FRACTURE - 1978
		Past	FRACTURE LEFT ARM - 1967
		Past	ORTHO - KNEE SURGERY 1996
		Current	ACUTE ANEMIA - SINCE 1995
		Current	ARTHRITIS SINCE 2000 (BILATERAL KNEES AND BILATERAL ANKLES)
		Current	BACK PAIN SINCE 1974
	E0030011	Past	DIABETES
		Past	FRACTURED LEFT 5TH METACARPAL - 1989
		Past	HIATAL HERNIA SURGERY - 1982
		Past	KIDNEY INFECTION
		Past	SUBSTANCE ABUSE
		Past	VON WILLINBRAND DISEASE
		Current	HEADACHE
		Current	SINUS CONGESTION
	E0030015	Past	LEG INJURY - 1992
		Past	PNEUMONIA - 1987
		Current	HEADACHES
		Current	MYOPIA - DX 1996
	E0030022	Past	APENDECTOMY - 1976
		Past	ASTHMA - 1993
		Past	FRACTURED NOSE - 1984, 1986, 1987
		Past	INCISIONAL HERNIA (SURGERY) - 2000

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	Past	KNEE SURGEY - LEFT
		Past	ROOT CANAL - 3/03
		Past	SPLEENECTOMY - 1976
		Current	ALLERGIES - 1993
		Current	ARTHRITIS - LEFT KNEE
		Current	GASTRO ESOPHAGEAL REFLUX DISEASE
		Current	HIGH BLOOD PRESSURE
		Current	HIGH CHOLESTEROL
		Current	MYOPIA
	E0031002	Current	MIGRAINES
	E0031003	Past	BLOOD IN STOOL
		Current	HEPATITIS C
		Current	PROLIXIN ALLERGY
	E0033015	Past	APPENDICITIS W/RESULTING APPENDECTOMY 1990
		Past	HERNIA, 1991
		Past	THYROID DISEASE (HYPOTHYROID) 1998
		Past	TONSILLITIS W/RESULTING TONSILLECTOMY 1993
	E0034002	Past	BACK SURGERY
		Past	CHOLECYSTECTOMY
		Past	POLYP REMOVED FROM COLON
		Past	PROLAPSE OF INTERVERTEBRAL DISC L5-S1
		Past	RIGHT ROTATOR CUFF INJURY
		Current	LOWER BACK PAIN
		Current	MUSCLE SPASMS
		Current	SEASONAL ALLERGIES
	E0034003	Past	INGUINAL HERNIA OPERATION(S)
		Current	GASTROESOPHAGEAL REFLUX DISEASE
		Current	HEADACHES
		Current	SEASONAL ALLERGIES
	E0034006	Past	APPENDECTOMY
		Past	CERVICAL DYSPLASIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	Past	GALLBLADDER REMOVED
		Past	STOMACH STAPLING
		Past	URINARY TRACT INFECTIONS
		Current	ABDOMINAL PAIN
		Current	ACID REFLUX DISEASE
		Current	BACKPAIN FROM DEGENERATIVE DISK DISEASE
		Current	HEADACHES
		Current	INTERMITTENT DIZZINESS
		Current	SLEEP APNEA
		Current	SULPHA ALLERGY
	E0034008	Current	ASTHMA
	E0035003	Past	TOE INJURY
		Current	ELEVATED CHOLESTEROL
		Current	ENVIRONMENTAL ALLERGIES
		Current	REFRACTION ERROR (WEARS GLASSES)
	E0035005	Past	GASTROPLASTRY FOR OBESITY
		Past	HYSTERECTOMY
		Past	TONSILECTOMY
		Current	DENTAL PAIN
	E0035014	Past	BRONCHITIS WITH ENLARGED LYMPH NODES
		Past	TONSILS REMOVED
		Past	TUBAL PREGNANCY
		Current	IRREGULAR HEAVY MENSTRUAL PERIODS WITH CRAMPING
	E0035024	Past	HISTORY OF DRUG USE
		Past	REPEATED EAR INFECTIONS
		Current	ENVIRONMENTAL ALLERGIES
		Current	FREQUENCY URINATION
		Current	POOR BLADDER CONTROL
	E0036005	Current	HEADACHES - OCCASIONAL NON - SPECIFIC
		Current	OBESITY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	Current	CARPAL TUNNEL SYNDROME
		Current	LEFT HAND TREMOR
		Current	MIGRAINE HEADACHES
	E0037005	Past	HEADACHE
		Current	SEASONAL ALLERGIES
		Current	WRIST PAIN
	E0037006	Past	APPENDECTOMY
		Past	ENDOMETRIOSIS
		Past	HYSTERECTOMY
		Current	HEADACHE
		Current	IRRITABLE BOWEL SYNDROME
		Current	NECK PAIN
		Current	SINUS CONGESTION
	E0039006	Past	ENDOMETRIOSIS
		Current	AMENORRHEA
		Current	HEADACHES
		Current	INSOMNIA
	E0039015	Past	GUNSHOT WOUND TO HEAD (DID NOT PENETRATE SKULL)
		Past	WISDOM TOOTH EXTRACTION
		Current	BAD DREAMS
	E0039024	Past	EROSION OF ESOPHAGUS
		Current	BOWEL IRRITATION
		Current	GASTRIC ULCERS
		Current	HIATAL HERNIA
		Current	MIGRAINES
		Current	POLYPS IN COLON
		Current	POLYPS IN STOMACH
		Current	SEASONAL ALLERGIES
	E0039025	Current	INSOMNIA
	E0039041	Current	INSOMNIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	Current	SEASONAL ALLERGIES
	E0039044	Past	ARRHYTHMIA
		Past	EPSTEIN - BARR VIRUS
		Past	INTERMITTENT NASAL CONGESTION
		Current	NAIL FUNGUS BILATERAL THUMBS
	E0039046	Past	MIGRAINE
		Past	PNEUMONIA
		Current	HEADACHES
		Current	HERNIATED DISC
		Current	INSOMNIA
		Current	OBESITY
	E0039051	Past	FACIAL STAB WOUND
		Past	TUBAL LIGATION
		Current	CONSTIPATION
		Current	HEADACHES
		Current	INSOMNIA
	E0039053	Past	BACK PAIN DUE TO MOTOR VEHICLE ACCIDENT
		Current	INTERMITTENT CONSTIPATION
		Current	PLATE IN RIGHT HAND
		Current	SEASONAL ALLERGIES
	E0039057	Current	INSOMNIA
	E0041003	Current	FIBROMYLASIA SINCE 12/2002
		Current	HYPERTENSION SINCE 2000
		Current	INTERMITTENT ACID REFLUX SINCE 2001
		Current	INTERMITTENT CONSTIPATION SINCE 2002
		Current	INTERMITTENT COUGH SINCE 1970
		Current	INTERMITTENT DIARRHEA SINCE 1998
		Current	INTERMITTENT HEADACHE SINCE 1985
		Current	INTERMITTENT INDIGESTION SINCE 1998
		Current	INTERMITTENT INSOMNIA SINCE 1992
		Current	INTERMITTENT MENSTRUAL CRAMPING SINCE 1978

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	Current	INTERMITTENT NAUSEA SINCE 1998
		Current	INTERMITTENT SINUSITIS SINCE 1993
		Current	INTERMITTENT URINARY INCONTINENCE SINCE 1998
		Current	INTERMITTENT VOMITTING SINCE 1998
	E0041008	Past	ALCOHOL ABUSE IN 03/00 - 12/01
		Past	BLOOD TRANSFUSION IN 1999
		Past	C - SECTION IN 1998
		Past	ENDOMETRIOSIS IN 1999
		Past	EXTRAPYRAMIDAL SYMPTOMS IN 09/17/02 - 10/10/02
		Past	HAIR LOSS IN 2001
		Past	HYSTERECTOMY IN 1999
		Past	MISCARRIAGE IN 1989
		Past	TONSILLECTOMY IN 1978
		Current	HYPOTHYROIDISM SINCE 1997
		Current	INTERMITTENT ACID REFLUX SINCE 2000
		Current	INTERMITTENT AGITATION SINCE 2001
		Current	INTERMITTENT ANXIETY SINCE 1998
		Current	INTERMITTENT DIZZINESS SINCE 2000
		Current	INTERMITTENT HEADACHE SINCE 1997
		Current	INTERMITTENT INDIGESTION SINCE 2000
		Current	INTERMITTENT INSOMNIA SINCE 1998
		Current	INTERMITTENT MIGRAINES SINCE 1997
		Current	INTERMITTENT NAUSEA SINCE 2000
		Current	INTERMITTENT SINUSITIS SINCE 1998
		Current	IRREGULAR HEARTBEAT SINCE 1994
	E0042001	Current	ANXIETY DUE TO BIPOLAR DEPRESSION
		Current	CONSTIPATION
		Current	GASTROESOPHAGEAL REFLUX
		Current	HYPERTENSION
		Current	SEASONAL RHINITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	Past	DIVERTICULOSIS
		Past	GENERALIZED ANXIETY
		Past	RIGHT ANKLE INJURY
		Current	ARTHRITIC CHANGED IN RIGHT ANKLE
		Current	HYPERTENSION
	E0003018	Past	MISCARRIAGE
		Current	DIFFICULTY SLEEPING
		Current	HEADACHES
		Current	MENSTRUAL CRAMPS
		Current	MUSCLE STIFFNESS, HIPS & NECK
		Current	SINUS DRAINAGE, SEASONAL
		Current	SINUS HEADACHE, SEASONAL
	E0005030	Current	ACNE
		Current	MIGRAINE HEADACHES
		Current	PAINFUL MEASES
	E0005036	Past	TUBAL LIGATION
		Current	ELEVATED CHOLESTEROL
		Current	RECURRENT DIARRHEA
		Current	STRESS HEADACHES
	E0006015	Current	BENIGN BREAST CYST
		Current	HYPERLIPIDEMIA
		Current	MIGRAINE HEADACHES
	E0006016	Past	TOOTH INFECTION
		Current	GENITAL HERPES
		Current	GOUT (RULE OUT) - FOOT/ANKLE PAIN
		Current	RIGHT KNEE PAIN
	E0007008	Past	CESAREAN SECTION 1993 1994
		Past	HYPERTHYROIDISM HYPERTHYROIDISM (GRAVES) DISEASE 1996
		Past	STATUS POST CHOLECYSTECTOMY
		Current	HYPOTHYROIDISM (ONSET 1997)

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	Current	LEFT VESTIBULAR IMBALANCE (ONSET 2001)
	E0009002	Past	ENLARGED PROSTATE 1996
		Past	GASH ABOVE RIGHT EYE 3/98, STITCHES ABOVE RIGHT EYE 3/98
		Past	LOSS OF CONSCIOUSNESS, NO SEQUALAE (10 - 15 MIN) 3/98
		Current	ACID REFLUX 3/99 - ONG
		Current	GRAVE'S DISEASE 3/99 - ONG
		Current	HEADACHES 1969 - ONG
		Current	HIGH CHOLESTERAL 2001 - ONG
		Current	LOW TESTOSTERONE
	E0009006	Past	TONSILLECTOMY 1984
		Past	TONSILLITIS 1984
		Current	ASTHMA 1984 -
		Current	HEADACHES 1996 -
	E0009009	Past	(LOSS OF CONSCIOUSNESS) X10 SECONDS, NO SEQUALAE 8/1/97
		Current	GALLSTONE 12/01
		Current	HEADACHES 2001
		Current	HEARTBURN 12/01
		Current	INSOMNIA 1995
		Current	TOOTHACHE 2002
	E0010015	Past	1985 - NASAL POLYPS
		Past	CHOLECYSTECTOMY
		Past	HYPOGLYCEMIA EPISODES
		Past	VITILIGO
		Current	INSOMNIA
		Current	OVERWEIGHT
	E0011004	Past	TOOTH ABSCESS
		Current	2 HERNIATED DISCS
		Current	ASTHMA
		Current	CHRONIC COUGH

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	Current	LIPOMAS
	E0011007	Past	HISTORY OF BREAST BIOPSY - NEGATIVE
		Past	HISTORY OF CHOLECYSTECTOMY
		Past	HISTORY OF HYSTERECTOMY
		Past	HISTORY OF TONSILLITIS
		Past	HISTORY OF UPPER PARTIAL PALATE PLATE
		Past	HISTORY OF UTERINE PROLAPSE
		Current	BACKACHES
		Current	FIBROCYSTIC DISEASE OF BREAST
		Current	HEADACHES
		Current	SINUS INFECTION
	E0011018	Current	CIGARETTE SMOKER
		Current	HEADACHE
	E0015003	Past	BASAL CELL CARCINOMA REMOVED RIGHT CHEEK
		Current	CONSTIPATION
		Current	POST MENOPAUSAL
	E0019003	Past	KIDNEY STONE
		Past	TUBAL LIGATION
		Current	ACNE WITH MENSTRUAL CYCLE
		Current	ASTHMA WITH EXERTION
		Current	FOOD ALLERGIES (SHELLFISH, CHERRIES, MUSTARD SEED)
		Current	GERD (GASTRO ESOPHAGIAL REFLUX DISEASE)
		Current	HEADACHES (TENSION)
		Current	HIATAL HERNIA
	E0019007	Past	GASTROINTESTINAL BYPASS SURGERY
		Past	GENITO - URINARY - HYSTERECTOMY
		Current	IRRITABLE BOWEL SYNDROME
		Current	MIGRAINES HEADACHE
	E0019014	Past	UPPER GASTRO - INTESTIONAL DISCOMFORT
		Current	DIARRHEA
		Current	INFLUENZA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	Current	STOMACH CRAMPS
	E0019018	Past	CARDIOVASCULAR - IRREGULAR HEART BEAT
		Past	TONISILLECTOMY
		Current	HIATAL HERNIA
		Current	HYPOGLYCEMIA
		Current	TENSION HEADACHE
		Current	TOOTHACHE
		Current	ULCERS GASTROINTESTINAL
	E0019022	Past	GASTROENTERITIS
		Past	HYSTERECTOMY
		Past	RUPTURED OVARY
		Current	HERNIATED NUCLEUS PROPULSUS L4 - L5
		Current	INDIGESTION
		Current	MITRAL VALVE PROLAPSE
		Current	TENSION HEADACHES
	E0019027	Past	ANXIETY
		Past	CHILDHOOD ASTHMA
		Past	DIABETIC RETINOPATHY
		Past	TENDINITUS (KNEES & ANKLES)
		Current	ACNE
		Current	ALLERGIES [ENVIRONMENTAL]
		Current	CHRONIC EAR INFECTIONS
		Current	DECREASED HORMONE LEVELS
		Current	HEART MURMOR
		Current	IDDM (INSULIN PUMP) INSULIN DEPENDENT DIABETES MELLITUS
	E0019032	Past	CHRONIC NEPHRITIS
		Past	INTERSTITIAL CYSTITIS
		Past	SEPTOPLASTY
	E0019034	Current	MYOPIA
		Current	TENSION HEADACHES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0019036	Past	ASTHMA
		Past	CARPAL TUNNEL IN WRISTS
		Past	KIDNEY STONES
		Past	SEASONAL ALLERGIES
		Past	SUBSTANCE ABUSE
		Current	ACID REFLUX
		Current	HEART MURMUR
		Current	MIGRAINES
		Current	TENSION HEADACHES
	E0019039	Current	CERVICAL "PINCHED NERVE"
		Current	ENVIRONMENTAL ALLERGIES
		Current	NECK PAIN
	E0019041	Past	ACID REFLUX
		Past	DEFICIENT IN PROGESTERONE
		Past	STREP THROAT
		Current	ALLERGIES - DUSTMITES, DANDER
	E0019049	Past	APPENDECTOMY
		Past	CESAREAN (BIRTH) OF CHILD
		Past	LAPAROSCOPY
		Past	PNEUMONIA
		Past	SEASONAL ALLERGIC RHINITUS
		Past	TOTAL ABDOMINAL HYSTERECTOMY
		Current	GERD (REFLUX DISEASE)
		Current	RIGHT LEG PAIN
		Current	STRESS FRACTURE (RIGHT FIBULA)
	E0022052	Past	HYSTERECTOMY
		Past	UTERINE FIBROIDS
		Current	ASTHMA
		Current	DIARRHEA
		Current	HEADACHES
		Current	MUSCULOSKELETAL PAIN
	E0022064	Current	BACK PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	Current	HEADACHES
	E0022073	Current	ALLERGIC RHINITIS
		Current	ASTHMA
		Current	DYSMENORRHEA
		Current	GASTROESOPHAGEAL REFLUX
		Current	HEADACHES
	E0023021	Current	OBESITY
	E0023027	Current	ASTHMA
		Current	ESOPHAGEAL REFLUX
		Current	HYPERTENSION
		Current	HYPOTHYROIDISM
		Current	OBESITY
	E0023030	Current	OBESITY
	E0026014	Past	ETOH DEPENDENCE
		Current	HAND TREMORS (BOTH) SINCE 1970
		Current	HEADACHES SINCE 1965
		Current	HYPERTENSION SINCE 1978
		Current	INSOMNIA SINCE 1980
		Current	LOSS OF APPETITE 1996
		Current	TINNITUS
	E0026019	Past	TUBAL LIGATION 1982
		Current	BODY STIFFNESS 1996
		Current	HEADACHES 1992
		Current	HYPERLIPIDEMIA
		Current	INSOMNIA 1989
	E0027005	Past	AGORAPHOBIA
		Past	ANXIETY DISORDER
		Past	CHRONIC FATIGUE
		Past	ECT TREATMENT
		Past	LENS IMPLANTS/CATARACTS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0027005	Past	POLYSUBSTANCE ABUSE
		Past	TONSILLECTOMY
		Current	ARTHRITIS
		Current	GASTRITIS
		Current	GASTROESOPHAGEAL REFLUX DISEASE
		Current	HYPERCHOLESTEROLEMIA/HYPERLIPIDEMIA
		Current	HYPERTENSION
		Current	MENOPAUSE
		Current	MIGRAINE HEADACHES
		Current	OSTEOPOMA
		Current	TUBAL LIGITION
		Current	ULCER
	E0029009	Past	VERTEBRAL FRACTURE (C7)
		Current	CODEINE HYPERSENSITIVITY
		Current	HEARTBURN
		Current	NECK PAIN
	E0029021	Current	BODY ACHES
		Current	HEADACHES
		Current	PTURIGIUM
		Current	SCOLIOSIS
		Current	SEASONAL ALLERGIES
	E0029026	Past	BACK SURGERY
		Past	ELEVATED PROSTATE SPEICIFIC ANTIGEN (PSA) LEVEL
		Current	ARTHRITIS IN LEFT KNEE
		Current	HEADACHE
	E0029030	Past	HEPATITIS C
		Current	ALLERGIC RHINITIS
		Current	COUGH
		Current	HEADACHE
		Current	LOW BACK PAIN
	E0031008	Past	ADDENOIDECTOMY
		Past	BREAST REDUCTION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0031008	Past	FEBRILE SEIZURES
		Past	FIBIA REPAIR SURGERY
		Past	GANGLION CYSTECTOMY
		Past	LEG FRACTURE
		Past	OVARIAN CYSTS
		Past	TONSILECTOMY
		Current	ALLERGIC TO GEODON
		Current	ALLERGIC TO SULFA
		Current	ASTHMA
		Current	EATING DISORDER
		Current	FIBROMYALGIA
		Current	HEART MURMUR
		Current	HERPES GENITALIS
		Current	MIGRAINES
		Current	POST TRAUMATIC STRESS DISORDER
		Current	SEASONAL ALLERGIES
		Current	SUBSTANCE DEPENDENCE
	E0031020	Past	BRONCHITIS
		Past	CHICKEN POX
		Past	MEASLES
		Past	MUMPS
		Past	SKULL FRACTURE
		Current	ACID REFLUX
		Current	ASTHMA
		Current	HEARING LOSS
		Current	SEASONAL ALLERGIES
		Current	SPINAL COLUMN INJURY
	E0031021	Past	CHICKEN POX
		Current	CHRONIC BACK PAIN
		Current	LITHIUM ALLERGY
	E0031029	Past	ADHD
		Past	BACK PAIN
		Past	CONCUSSION
		Past	HIATAL HERNIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0031029	Past	LEG CRAMP
		Past	MUSCLE ACHES
		Current	MIGRAINES
		Current	TOOTHACHE
	E0033002	Past	KIDNEY STONES
		Past	PNEUMONIA
		Current	ARTHRITIS
		Current	HEADACHES
		Current	INSOMNIA
		Current	NECK PAIN
	E0033021	Past	URINARY TRACT INFECTION, 2002
		Current	LOW BLOOD PRESSURE
		Current	NERVE DAMAGE IN NECK, 2002
		Current	SEASONAL ALLERGIES, UNK START DATE
	E0035013	Past	TUBAL LIGATION
		Past	TUMOR CYSTS ON OVERIES REMOVED
		Current	BLADDER INFECTION
		Current	HYPERCHOLESTEREMIA
	E0035015	Current	ASTHMA
		Current	CARPAL TUNNEL SYNDROME
		Current	WEATHER ALLERGIES
	E0035016	Past	DRUG ABUSE HISTORY
		Past	ENDOMETRIOSIS
		Past	TUBAL LIGATION
		Current	ALLERGY TO COMPAZINE
		Current	SEVERE MENTRUAL CRAMPS
	E0035023	Past	BROKEN LEFT WRIST - BONE GRAFT
		Past	ETOH ABUSE
		Current	HISTORY OF PEPTIC ULCER DISEASE
	E0039052	Past	FUNGAL INFECTION BOTH FEET

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 300 MG (BIPOLAR II)	E0039052	Past	UMBILICAL HERNIA
		Current	ASTHMA
		Current	ECZEMA
		Current	INSOMNIA
		Current	NON INSULIN DEPENDENT DIABETES MELLITUS
		Current	OBESITY
		Current	SEASONAL ALLERGIES
	E0039056	Past	HEPATITIS B
		Past	HEPATITIS C
		Past	ULCER
	E0040003	Past	CHOLECYSTECTOMY
		Past	SEASONAL ALLERGIES
		Current	ASTHMA
		Current	OSTEOARTHRITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	Past	GALL BLADDER REMOVED 1995
		Current	ASTHMA
		Current	HIATAL HERNIA
	E0002011	Past	ABORTION
		Current	UTERINE FIBROID (MASS)
	E0003010	Past	HYSTERECTOMY
		Past	SULFA ALLERGY
	E0003011	Past	C - SECTION
		Past	CHOLECYSTECTOMY
		Past	FRACTURE OF RIGHT ARM
		Past	TONSILLECTOMY
		Past	TUBAL LIGATION
		Current	GASTROESPHAGEAL REFLUX
		Current	HEADACHES
		Current	PSORIASIS
	E0003016	Past	ANXIETY
		Past	COUGH
		Past	NERVE ENTRAPMENT RELEASE RIGHT ARM
		Past	RIGHT PAROTID GLAND ARM REPAIR
		Past	SINUS CONGESTION
		Past	TUBAL LIGATION
		Current	FREQUENT HEARTBURN
	E0003019	Past	ANAL WARTS
	E0003020	Past	ALCOHOL ABUSE
		Past	HYPOTHYROIDISM
		Current	AVASCULAR NECROSIS, BILATERAL HIPS
	E0004001	Past	LAPARASCOPY
		Past	LEFT KNEE ARTHRO SCOPIC SURGERY
		Current	DYSMENORRHEA
		Current	FREQUENT HEADACHES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	Current	IRRITABLE BOWEL SYNDROME
		Current	OCCASIONAL NAUSEA SINCE MARCH/02
	E0004009	Current	OCCASIONAL LEG CRAMPS AT NIGHT
	E0004012	Current	BREAST IMPLANTS 12/2002
		Current	ENVIRONMENTAL ALLERGIES SINCE 1985
		Current	NIGHT TIME GRINDING OF TEETH
	E0004015	Past	HYPERTENSION
		Past	LIPOMA REMOVED FROM BACK
		Past	TONSILLECTOMY
		Current	ALLERGY TO PENICILLIN
	E0005003	Past	JOINT PAIN
		Current	HYPERTENSION
	E0005005	Past	LOWER ABDOMINAL HERNIA
		Current	ACNE
	E0005007	Past	URINARY TRACT INFECTION
		Current	ARTHRITIS
		Current	CHEST PAIN SECONDARY TO ANXIETY
		Current	INSOMNIA
		Current	INTERMITTENT CONSTIPATION
		Current	INTERMITTENT DIARRHEA
		Current	INTERMITTENT TENSION HEADACHES
		Current	MIGRAINE HEADACHES
		Current	STOMACH ULCER
		Current	TENDONITIS IN HANDS
		Current	TUBAL LIGATION
	E0005008	Current	BACK PAIN - BACK INJURY
		Current	CARPAL TUNNEL
		Current	HEARTBURN
		Current	KNEE PAIN - INJURY
		Current	SHOULDER PAIN - INJURY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0005009	Past	HEARTBURN
		Past	MIGRAINE HA (HEADACHE)
		Current	HEARTBURN
		Current	MIGRAINE HA (HEADACHE)
		Current	SINUSITIS
	E0005010	Current	OBESITY
	E0005012	Past	BILATERAL INGUINAL HERNIA
		Past	DUPUYTREN'S CONTRACTURE
		Past	HEARTBURN
		Past	INTERMITTENT GI PAIN
		Past	RECURRENT CONSTIPATION
		Past	RECURRENT DIARRHEA
		Past	RECURRENT JOINT PAIN
		Past	SEASONAL ALLERGIC RHINITIS
		Past	STRESS HA
		Current	HEADACHES
	E0005014	Current	ALLERGY - NAPROXEN
		Current	IRRITABLE BOWEL SYNDROME
		Current	POOR CIRCULATION - HANDS AND FEET
		Current	RECURRENT BACK PAIN
	E0005022	Current	JOINT PAIN (LEFT KNEE)
	E0005025	Past	HX BRONCHITIS ANUALLY
		Current	CHRONIC NECK & BACK PAIN
		Current	HYPOTHYROIDISM
		Current	INTERMITTENT HEADACHES
	E0006019	Current	HYPOTHYROIDISM
		Current	OSTEOPEROSIS
		Current	SEASONAL ALLERGIES
	E0007005	Current	ALLERGIC TO ERYTHROMYCIN
		Current	HERPES GENITALIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	Past	ACNE
		Past	ALLERGIC RHINITIS
		Past	HERPES GENITALIA
		Past	PNEUMOTHORAX
		Past	TUBAL LIGATION 1976
		Current	CONTACT DERMATITIS
		Current	ECZEMA
		Current	HYPERLIPIDEMIA
		Current	OSTEOPENIA
		Current	POST MENOPAUSE
	E0009001	Past	BROKE 2 PHALANGES LEFT HAND 7/20/01
		Past	BRUISED COLLARBONE 7/20/01
		Past	FRACTURED RIGHT ANKLE 7/20/01
		Past	HERNIORHAPHY 1999
		Past	HERNIORRHAPHY 1975
		Past	INGUINAL HERNIA 1975
		Past	OVERACTIVE BLADDER 7/20/01
		Past	UMBILICAL HERNIA 1999 - 1999
		Current	CUBAN BLUE CHEESE ALLERGY 1990 - ONG
		Current	HEADACHES 7/01 - ONG
		Current	HYPERTENSION 1996 - ONG
		Current	INSOMNIA 1970 - ONG
		Current	MIGRAINES 1970 - ONG
		Current	OBESITY 1990 - ONG
	E0010002	Current	ASTHMA
		Current	INSOMNIA (MODERATE)
	E0010009	Past	HEAVINESS IN LEGS
		Past	MENOPAUSE
		Past	SURGERY FOR LESION IN AORTA (1992)
		Current	HISTORY OF ELEVATED CHOLESTEROL
		Current	HYPOACUSSIS - USES HEARING AIDS
		Current	SODIUM PENTATHAL ALLERGY
	E0010010	Past	CONGENITAL DYSFUNCTIONAL KIDNEY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0010010	Past	JIDNEY INFECTION
		Past	RIGHT SHIN FRACTURE
		Current	ACUTE ASTHMATIC BRONCHITIS
		Current	ALLERGIES : HAYFEVER, POLLEN, DUST
		Current	SCALY ECZEMATOUS SKIN ON POSTERIER SCALP
		Current	SPASMODIC DYSPHONIA
	E0010014	Past	APPENDECTOMY
		Past	CHOLECYSTECTOMY
		Past	ELEVATED BLOOD SUGAR
		Past	INCARCERATED HERNIA REPAIR
		Past	OBESITY
		Past	UNILATERAL OOPHORECTOMY
		Current	HYPERTENSION
		Current	INSOMNIA (MILD)
	E0010017	Past	APPENDECTOMY
		Current	INSOMNIA (MILD)
	E0010023	Past	TUBAL LIGATION
		Current	MUSCLE PAINS
	E0010027	Past	SUBSTANCE ABUSE
	E0010029	Past	ALCOHOLISM
		Past	COLON POLYPS
		Past	SUBSTANCE ABUSE
		Current	ABDOMEN PAIN (LOWER RIGHT)
		Current	DIABETES MELLITUS, TYPE II
		Current	HEPATITIS B
		Current	HYPERTENSION
		Current	OBESITY
	E0011022	Past	CARPAL TUNNEL SURGERY
		Past	CARPAT TUNNEL SYNDROME
		Past	CERVICAL CANCER
		Past	CHOLECYSTECTOMY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	Past	CHOLELITHIASIS
		Past	HYSTERECTOMY WITH RIGHT OOPHORECTOMY
		Past	TRANSIENT ISCHEMIC ATTACK
		Current	ALLERGIC TO PENICILLIN, ERYTHROMYCIN, TETRACYCLINE, CODEINE, SULFA, CLOZAPINE
		Current	ASTHMA
		Current	HEADACHES
		Current	HYPERTENSION
		Current	INDIGESTION
		Current	LEFT OVARIAN CYST
		Current	MIGRAINES
		Current	RIGHT ROTATOR CUFF INJURY
		Current	SEASONAL ALLERGIES
		Current	TEMPOROMANDIBULAR JOINT PAIN
	E0013006	Current	HEADACHES
		Current	IBS (IRRITABLE BOWEL SYNDROME)
		Current	MITRAL VALUE PROLAPSE
		Current	POLYP ON GALL BLADDER
	E0013012	Current	ANAEMIA
		Current	HYPERLIPIDEMIA
		Current	HYPOTHYROIDISM
	E0014005	Past	BREAST CANCER-AGE 33
		Past	BREAST RECONSTRUCTIVE SURGERY
		Past	CONE BIOPSY
		Past	TUBAL LIGATION
		Current	BACK PAIN
		Current	CHEST PAIN - MUSCULO - SKELETAL - LEFTSIDE
		Current	DYSLIPIDEMIA
		Current	HEADACHES
		Current	JOINT PAIN
		Current	LATERAL EPI CONDYLITIS (TENNIS ELBOW)
		Current	MUSCLE SPASMS OF THE NECK
		Current	NECK PAIN
		Current	PELVIC PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	Past	URINARY TRACT INFECTIONS
		Current	(HEADACHE) - FREQUENT
		Current	MUSCLE ACHES AND PAINS
	E0014011	Past	CONCUSSION
		Current	ACID REFLUX
		Current	ARTHRITIS
		Current	HEADACHES
		Current	MUSCULO - SKELETAL PAIN - SHOULDER
		Current	POLLEN ALLERGIES (HAY FEVER)
	E0014012	Past	ASTHMA
		Past	BACK PAIN
		Past	HAYFEVER
		Past	LOSS OF CONSCOUISNESS
		Past	SUICIDE ATTEMPTS
		Past	TONSILECTOMY
		Past	TUBAL LIGATION
		Past	ULCERS
		Current	ABDOMINAL PAIN
		Current	HEADACHES (MIGRAINES)
		Current	JOINT PAIN
		Current	TREMORS ON HANDS AND HEAD
	E0015001	Current	HYPOTHYROID
		Current	OCCASIONAL DIZZINESS
	E0016003	Current	RIGHT EYE LATERAL NYSTAGMUS
	E0016005	Past	MITRAL VALVE PROLAPSE
	E0018007	Past	ALCOHOL ABUSE
		Past	ANKLE OPEN REDUCTION INTERNAL FICSATION
		Past	APPENDECTOMY
		Past	CHOLECYSTECTOMY
		Past	DEEP VEIN THROMBOSIS
		Past	HYSTERECTOMY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0018007	Past	LAMINECTOMY
		Past	MISCARRIAGE
		Past	POLYSUBSTANCE ABUSE
		Current	ALLERGY TO PENNICILLIN
		Current	ALLERGY TO SULFA
		Current	ARTHRITIS
		Current	ASTHMA
		Current	CHRONIC BRONCHITITS
		Current	DEGENERATIVE JOINT DISEASE
		Current	INTERMITTENT LEG PAIN
		Current	MIGRAINES
		Current	SEASONAL ALLERGIES
	E0019005	Past	BROKEN PELVIS
		Past	CERVICAL CANCER
		Past	ENLARGED PITUITARY
	E0019015	Past	RECURRENT UTI
	E0020004	Past	BORDERLINE HYPERGLYCEMIA
		Past	LIPOMA BILATERAL ARMS AND LEGS (EXCISED)
		Past	PROSTATE CANCER
		Past	PROSTATECTOMY
		Current	BORDERLINE DIABETES
		Current	HYPERCHOLESTEROLEMIA
		Current	HYPERTENSION
		Current	INTERMITTENT LEFT KNEE PAIN
		Current	PENICILLIN ALLERGY
	E0020010	Past	DILATATION AND EVACUATION
		Past	PNEUMONIA
		Past	SPONTANEOUS ABORTION
		Current	ASTHMA
		Current	INTERMITTENT CONSTIPATION
		Current	INTERMITTENT DIARRHEA
		Current	SEASONAL ALLERGIES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	Past	LUMPECTOMY RIGHT BREAST BENIGN MASS
		Current	INTERMITTENT LUMBAR AREA DISCOMFORT
		Current	OVERACTIVE BLADDER
		Current	SEASONAL ALLERGIES
		Current	UPPER RESPIRATORY INFECTION
	E0020021	Past	ATTENTION DEFICIT HYPERACTIVE DISORDER SYMPTOMS
		Past	HISTORY OF BULEMIA
		Past	HOSPITALIZED FOR MORBID OBESITY
		Current	BODERLINE HYPERTENSION
		Current	OBESITY
		Current	SEASONAL ALLERGIES
		Current	SLEEP APNEA
	E0020023	Past	LUMBAR LAMINECTOMY (L4 - L5)
		Past	TONSILLECTOMY
		Current	ALLERGIC TO LORABID
		Current	BORDERLINE HYPERCHOLESTEROLEMIA
		Current	HYPERTENSION
		Current	HYPOGLYCEMIA
		Current	INTERMITTENT LEFT HAND TREMORS
		Current	INTERMITTENT LUMBER AREA PAIN
		Current	REFLUX
		Current	SEASONAL ALLERGIES
	E0022007	Past	PEPTIC ULCER HEALED
		Current	HEADACHES
		Current	POLYCYSTIC OVARIES
	E0022012	Current	HEADACHES
		Current	HEARTBURN
	E0022019	Current	HEADACHES
	E0022025	Past	CHELECYSTECTOMY
		Past	IRON DEFICIENCY ANEMIA
		Past	TUBAL LIGATION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	Current	HEADACHES, OCCASI0NAL
		Current	HYPERTENSION
		Current	IRRITABLE BOWEL SYNDROME
		Current	MENSTRUAL CRAMPS
		Current	MUSCULOSKELETAL PAIN
		Current	RESTLESS LEG SYNDROME
	E0022033	Past	CHOLECYSTECTOMY
		Past	PERITONITIS
		Past	THROMBOPHLEBITIS
		Past	TUBAL LIGATIM
		Current	HADACHES
		Current	INSOMNIA
	E0022034	Past	LEFT KNEE SURGERY
	E0022038	Past	RIGHT KNEE SURGERY
		Current	LUMBAR DISC DISEASE
		Current	RIGHT KNEE PAIN
	E0022039	Current	ALLERGIC RHINITIS
		Current	ASTHMA
		Current	CHEST WALL PAIN
		Current	HEADACHES
		Current	VERTIGO
	E0022046	Past	CHOLECYSTECTOMY
		Past	CHOLECYSTITIS
		Past	EXCISION OF TOXIC THYROID ADENOMA
		Past	HYPERTHYROIDISM
		Current	HEADACHES
		Current	HYPERLIPIDEMIA
	E0022048	Current	FOOD ALLERGIES
	E0022051	Past	HYSTERECTOMY
		Past	OVARIAN CYST, BENIGN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	Current	GASTRO ESOPHAGEAL REFLUX
		Current	HEADACHES
		Current	POSTMENOPAUSAL STATUS
	E0022053	Current	HEADACHES, ONSET 1991
	E0022058	Past	DIVERTICULITIS
		Past	PARTIAL BOWEL REFECTION
		Current	HEADACHES
	E0022061	Current	HEADACHES
		Current	RECURRENT URINARY TRACT INFECTIONS
	E0022062	Past	CHOLECYSTECTOMY 1965
		Past	NEPHROLITHIASIS, 1958
		Past	SURGICAL REPAIR - SPORTS INJURY, LEFT KNEE 1993
		Past	SURGICAL REPAIR SPORTS INJURY, RIGHT KNEE, 1988
		Current	ALLERGIC RHINITIS - 1/2001
		Current	ERECTILE DYSFUNCTION, ONSET 01/03
		Current	HEADACHES, 1/2002
		Current	HYPERTENSION, 1/1983
		Current	SLEEP APNEA
	E0022068	Past	LEFT KNEE LIGAMENT REPAIR
		Past	MISCARRIAGE
		Past	RIGHT KNEE LIGAMENT REPAIR
		Current	OCCASIONAL HEADACHE
	E0022069	Past	TUBAL LIGATION
		Current	DYSMENORRHEA
		Current	HEADACHES
		Current	INDIGESTION
	E0022071	Past	PANIC ATTACKS
		Past	PEPTIC ULCER DISEASE
		Past	TONSILLECTOMY
		Current	ANXIETY, SECONDARY TO DEPRESSED EPISODE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	Current	GILBERT'S SYNDROME
		Current	HYPERCHOLESTEROLEMIA
	E0023003	Current	HEADACHES
	E0023006	Current	ASTHMA
	E0026002	Past	LEFT NECK CYST REMOVAL
		Current	HEADACHES
		Current	INSOMNIA
	E0026007	Past	HERNIATED DISK
		Past	HIGH CHOLESTEROL SINCE 2001
		Past	HYPERTENSION SINCE 2001
		Past	HYSTERECTOMY
		Current	ARRYTHMIA
		Current	HEADACHES SINCE 1970
		Current	INCONTINENCE
		Current	INSOMINIA SINCE 1995
		Current	MIGRAINE HEADACHES SINCE 1970
		Current	OBESE SINCE 1970
		Current	OSTEOARTHRITIS BACK AND NECK SINCE 1990
		Current	TINNITIS SINCE 1985
	E0026013	Current	ALLERGIC TO BENADRYL SINCE 1998
		Current	ASTHMA SINCE 1999
		Current	HEADACHES SINCE 1989
		Current	INSOMNIA SINCE 1995
		Current	NAUSEA WITH ANXIETY
		Current	RT EYE CATARACT SINCE 1974
		Current	VOMITING WITH ANXIETY
	E0028007	Past	POLYSUBSTANCE ABUSE
		Current	ALLERGIC TO PCN
		Current	OCCASIONAL HEADACHES
	E0028023	Past	MYOCARDIAL INFARCTION (1993)

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	Past	STROKE
		Current	ALLERGIC TO EGGS, PROCARDIA; NEOSYNEPHRINE
		Current	CHRONIC BACK PAIN (SECONDARY TO ARTHRITIS)
		Current	CORONARY ARTERY DISEASE
		Current	ETOH ABUSE
		Current	HEPATITIS C
		Current	HYPERTENSION
		Current	HYPOTHYROIDISM
		Current	POLYSUBSTANCE DEPENDENCE
		Current	SEIZURE DISORDER (SECONDARY TO HEAD TRAUMA)
	E0028025	Past	RIGHT ROTATOR CUFF SURGERY 1998
		Past	WOLF PARKINSON WHITE SYNDROME
		Current	FOOD ALLERGIES
		Current	GAS
		Current	HAY FEVER
		Current	HEADACHES
		Current	INSOMNIA
	E0028033	Past	HYSTERECTOMY
		Past	OCCASIONAL BRONCHITIS
		Current	ALLERGIES
		Current	ASTHMA
		Current	OBESITY
		Current	SULFA ALLERGY
	E0028035	Current	DRUG ALLERGY (TERRAMYCIN/ACHROMYCIN)
		Current	ERECTILE DYSFUNCTION
		Current	OCCOSIONAL HEARTBURN
	E0028037	Past	HYPERLIPIDEMIA
		Current	DIABETES MELLITUS
		Current	OBESITY
		Current	OCCASIONAL MIGRAINES
	E0028039	Past	APPENDECTOMY 2002
		Past	LEFT KNEE SURGERY 1997

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	Current	CODEINE ALLERGY
		Current	PENICILLIN ALLERGY
	E0028046	Past	ARTHRITIS
		Past	ASTHMA
		Past	TUBAL LIGATION
		Current	ALLERGY TO PETS
		Current	ALLERGY TO POLLEN
		Current	OBESITY
	E0028048	Current	DUST ALLERGY
		Current	PENICILLIN ALLERGY
		Current	POLLEN ALLERGY
	E0029008	Past	BRONCHITIS
		Past	LAPANOTOMY
		Current	ABDOMINAL PAIN
		Current	ALLERGIC RHINITIS
		Current	ENDOMETRIOSIS
		Current	HEADACHES
		Current	HYDROCODONE ALLERGY
		Current	IRON DEFICIENT ANEMIA
		Current	LOWER RIGHT QUADRANT TENDERNESS
	E0029011	Past	ASTHMA - 2000
		Past	NASOPHARYNGEAL SURGERY - 2001
		Past	SLEEP APNEA, 1976 - 2001
		Current	BACK ACHES, MODERATE - 2000 - SEES CHIROPRACTOR
		Current	CHEST ACHES - MODERATE
		Current	HEADACHES, MODERATE - 2000
	E0029012	Past	TUBAL LIGATION
		Current	ACID REFLUX - IN SUPINE ONLY
		Current	HEADACHE
		Current	MILD ACNE
	E0029015	Past	FIBROID BREAST CYSTS - BILATERAL

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0029015	Past	HYPOTHYROIDISM
		Past	TUBAL LIGATION
		Current	ALLERGY TO SULFA DRUGS
		Current	HEADACHES
		Current	HEARTBURN
		Current	LOWER BACK PAIN
		Current	OVER - ACTIVE BLADDER
	E0029018	Past	HEADACHES
		Past	MULTIPLE BONE FRACTURES
		Past	PARALYSIS
		Current	BACK PAIN
		Current	HEPATITIS C
		Current	HIP PAIN
		Current	MITRAL VALVE PROLAPSE
	E0030014	Past	BLADDER INFECITON 1975
		Past	COLLAPSED LUNG - 1988
		Past	ESTROPIA SURGERY - 1975, 1984
		Past	KNEE INJURY - 1996
		Past	KNEE SURGERY
		Past	MOLE REMOVAL - 1997
		Past	PNEUMONIA - 1972, 2002
		Past	RIGHT ARM FRACTURE
		Past	URETHRAL STENOSIS 1975
		Current	ASTIGMATISM
		Current	DRUG ALLERGY PENICILLIN - SKIN RASH
		Current	FOOD ALLERGY
		Current	HEADACHE
		Current	HYPERIMNA (RIGHT EYE)
		Current	HYPOGLYCEMIA
		Current	MITRAL VALVE PROLAPSE
		Current	MYOTONIC DYSTROPHY (HYPERKULEMIC PERIODIC PARALYSIS)
		Current	SCOLIOSIS
		Current	SEASONAL ALLERGY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	Past	ALCOHOLISM
		Past	CRYSTAL METH ABUSE
		Past	DIFFICUTL BREATHING - 1999
		Past	SPIDER BITE - BROWN RECLUSE - 12/02
		Current	ENVIRONMENTAL ALLERGIES
		Current	HEADACHES
		Current	HEARTBURN - 2X/MONTH
		Current	LOWER BACK PAIN
		Current	MYOPIA
		Current	SINUS CONGESTION (ALLERGY) - 2X/MONTH
		Current	SKIN RASH (ALLERGY)
		Current	STYES - ONCE PER YEAR
	E0030024	Past	ANXIETY - (1994, 1997)
		Past	BLADDER INFECTIONS
		Past	BURN LEFT SIDE OF BODY 30% OF BODY
		Past	GESTATIONAL HYPOGLYCEMIA
		Past	KIDNEY INFECTION
		Past	MARIJUANA DPENDENCE - 1995 - 1996
		Past	SINUS INFECTION
		Current	ANEMIA
		Current	ARTHRITIS LEFT ANKLE/FOOT
		Current	CHEST PAIN
		Current	DRUG ALLERGY - SULFA: HIVES
		Current	HEADACHES
		Current	MYOPIA
		Current	PRESSURE IN HEAD
		Current	SINUS CONGESTION
	E0030025	Past	ANEMIA - 2001
		Past	LEFT LEG INFECTION - 1/02
		Past	MISCARRIAGE - 1963
		Past	NVD - 1961 (NATURAL VAGINAL DELIVERY)
		Past	TUBAL LIGATION - 1978
		Current	ARTHRITIS - BACK
		Current	BACK PAIN DUE TO SLIPPED DISC
		Current	DRUG ALLERGY: CLYNDAMYACIN - SKIN RASH

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0030025	Current	DRUG ALLERGY: KEFLEX - SKIN RASH
		Current	DRUG ALLERGY: PENICILLIN - SKIN RASH
		Current	MYOPIA
	E0031027	Past	BRONCHITIS
		Past	CHEST PAIN
		Past	HEAD INJURY
		Past	HEARTBURN
		Past	HYPERTENSION
		Past	MEMORY LOSS
		Past	WRIST FRACTURE
		Current	EMPHYSEMA
		Current	INTERMITTENT HEADACHES
	E0031030	Current	BODERLINE HYPERCHOLESTEROLEMIA
	E0034001	Past	ENDOMETRIOSIS
		Past	URINARY TRACT INFECTIONS
		Current	CONSTIPATION
		Current	HEADACHES
		Current	INDIGESTION, GAS
	E0034004	Past	FRACTURED SKULL
		Past	THROAT SURGERY (2 TIMES)
		Current	ALLERGIES
		Current	BACK PAIN
		Current	HEADACHES
		Current	INDIGESTION
		Current	STIFF JOINTS
	E0035001	Past	APPENDECTOMY SURGERY
		Past	GALL BLADDER SURGERY
		Past	TUBAL LIGATION IN SEPT. 1991
		Current	ALLERGIC TO PENICILLIN
		Current	HYPERTENSION CONTROLLLED WITH MEDICATION
	E0035006	Past	C - SECTION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	Past	HISTORY OF SUBSTANCE ABUSE SOBER > 2 YRS.
	E0036002	Past	TUBAL LIGATION - 1988
		Current	DRUG ALLERGIES: PENICILLIN
		Current	INTERMITTENT MIGRAINE HEADACHES
		Current	INTERMITTENT NON - SPECIFIC HEADACHES
	E0036006	Current	ASTHMA
		Current	GASTROESOPHAGEAL REFLUX DISEASE
		Current	HYPERLIPIDEMIA
		Current	SULPHA ALLERGIES
	E0036007	Past	TUBAL LIGATION - 1992
		Current	INTERMITTENT MIGRAINE HEADACHES
		Current	SEASONAL ALLERGIES
	E0037009	Current	INTERMITTENT HEADACHES
	E0039011	Past	INSULIN - DEPENDENT DIABETES
		Current	DIET CONTROLLED DIABETES
	E0039018	Past	RECURRENT SINUS INFECTIONS
		Current	HEADACHES
		Current	HOT AND COLD FLASHES
		Current	INSOMNIA
		Current	INTERMITTENT ABDOMINAL CRAMPS
		Current	LOWER BACK PAIN
		Current	MENSTRUAL CRAMPS
		Current	NECK PAIN
		Current	NIGHT SWEATS
		Current	PERIPHERAL VASOCONSTRICTION
	E0039026	Past	FIBROID CYSTS (UTERUS)
		Current	ASTHMA
		Current	INTERMITTENT CONSTIPATION
	E0039028	Current	ACID REFLUX

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0039028	Current	ANGINA
		Current	HYPERTENSION
		Current	OBESITY
		Current	PAIN IN NECK
		Current	PAIN IN SHOULDERS
	E0039032	Past	CESAREAN SECTION
		Past	CESAREAN SECTION
		Past	DILATATION AND CURETTAGE
		Current	OBESITY
	E0039034	Past	CESAREAN SECTION
		Past	OVARIAN CYST REMOVAL
		Past	SUBDURAL HEMATOMA
		Past	TOOTH EXTRACTION
		Past	TUBAL PREGNANCY
		Current	ARACHNOID CYST
		Current	MIGRAINES DURING MENSTRUATION
		Current	OBESITY
	E0039042	Past	TUBAL LIGATION
		Past	UTERINE ABCESS
		Current	ASTHMA
		Current	CONSTIPATION
		Current	HEADACHES
		Current	INSOMNIA
	E0041004	Past	WALKING PNEUMONIA IN 1990
		Current	INTERMITTENT HEADACHES SINE 12/2002
		Current	INTERMITTENT INDIGESTION SINCE 1997
		Current	INTERMITTENT INSOMNIA SINCE 1982
		Current	INTERMITTENT LEFT EARACHES SINCE 1972
		Current	PENICILLIN ALLERGY SINCE 1973
	E0041009	Past	C - SECTION IN 1987, 1990, AND 1992
		Past	EXTRAPYRAMADAL SYMPTOMS IN 1978 - 1979
		Past	HYPERTHYROIDISM IN 2000

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	Past	LEFT RING FINGER BROKEN IN 1990
		Past	RIGHT LEG BROKEN IN 1999
		Past	URINARY TRACT INFECTION IN 2002
		Current	INTERMITTENT AGITATION SINCE 1992
		Current	INTERMITTENT ANXIETY SINCE 1992
		Current	INTERMITTENT BILATERAL LEG PAIN SINCE 1999
		Current	INTERMITTENT CONSTIPATION SINCE 1999
		Current	INTERMITTENT HEADACHE SINCE 1987
		Current	INTERMITTENT INSOMNIA SINCE 1992
		Current	INTERMITTENT IRREGULAR MENSTRUAL CYCLES SINCE 12/02
		Current	INTERMITTENT MIGRAINES SINCE 1987
		Current	INTERMITTENT SINUSITIS SINCE 1982
		Current	POLLEN ALLERGY SINCE 1982
	E0042002	Current	ENVIRONMENTAL ALLERGIES
		Current	HYPERTENSION
		Current	TENDONITIS. KNEES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	Past	BROKEN CLAVICLE
		Past	SLEEP APNEA
		Current	ASTHMA
		Current	SEASONAL ALLERGIES
	E0003002	Current	RESTLESS LEGS
	E0005031	Current	INTERMITTENT CHEST PAIN SECONDARY TO ANXIETY
		Current	INTERMITTENT CONSTIPATION
		Current	INTERMITTENT HEADACHES
		Current	INTERMITTENT PALPITATIONS SECONDARY TO ANXIETY
		Current	RECURRENT NECK PAIN
		Current	SEASONAL ALLERGIES
	E0005033	Past	MIGRAINES
		Current	FOLLICULITIS
	E0005038	Current	ASTHMA
		Current	CONSTIPATION
		Current	GALL BLADDER REMOVED
		Current	INTERMITTENT HEADACHES
		Current	MENSTRUAL CRAMPS
		Current	OBESITY
	E0009010	Past	TONSILECTOMY
		Past	TONSILITIS
		Current	HIGH CHOLESTEROL
		Current	HIGH TRIGLYCERIDES
		Current	INDIGESTION
	E0009011	Past	HERNIA
		Past	HERNIORRHAPHY
		Past	TONSILECTOMY
		Past	TONSILITIS
	E0010005	Past	REYE'S SYNDROME
		Past	SURGICAL REMOVAL OF LEFT BIG TOE INGROWN NAIL

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0010005	Current	OBESE
	E0011016	Past	LEFT KNEE TORN LIGAMENT AND CARTILAGE
		Current	BACK STRAIN
		Current	GASTRIC ULCER
		Current	HEADACHES
		Current	LEFT EYE IS LEGALLY BLIND
	E0011020	Past	MALIGNANT MELANOMA
		Current	CIGARETTE SMOKER
		Current	MIGRAINES
		Current	SINUS HEADACHES
		Current	TINNITUS
	E0018002	Past	ALLERGY TO AMPICILLIN
		Past	ARTHRITIS
		Past	PROSTATE INFECTIONS
		Past	SEASONAL ALLERGIES
		Current	ALLERGY TO AMPICILLIN
		Current	ARTHRITIS
		Current	OCCASSIONAL ALCOHOL USE
		Current	SEASONAL ALLERGIES
	E0018003	Past	KIDNEY STONES
		Past	MIGRAINES
		Past	OBESITY
		Current	MIGRAINES
		Current	OBESITY
		Current	SEASONAL ALLERGIES
	E0018013	Past	ALCOHOL ABUSE
		Past	ALLERGY TO CODEINE
		Past	ALLERGY TO DIPHENHYDRAMINE
		Past	ALLERGY TO IBUPROFEN
		Past	ALLERGY TO VICODIN
		Past	BROKEN LEG
		Current	ALLERGY TO CODEINE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	Current	ALLERGY TO DIPHENHYDRAMINE
		Current	ALLERGY TO IBUPROFEN
		Current	ALLERGY TO VICODIN
		Current	CONTACT DERMATITIS
		Current	HEADACHES
		Current	INSOMNIA
	E0019002	Past	BACK SURGERY (3 TIMES)
		Current	INDIGESTION
		Current	MIGRAINE HEADACHES
		Current	SCOLIOSIS
		Current	SEASONAL ALLERGIES
		Current	SINUS CONGESTION
		Current	STOMACH CRAMPS
	E0019008	Current	ENVIRONMENTAL ALLERGIES
		Current	HEADACHES
		Current	HYPOTHYROIDSM
	E0019009	Past	DERMATOLOGICAL (ACNE)
		Past	INTERMITTENT - NAUSEA
		Past	RESPIRATORY (LUNG COLLAPSE)
		Past	URINARY TRACT INFECTION
		Current	ALLERGY - SEASONAL
	E0019016	Past	BLADDER INFECTION
		Past	KIDNEY INFECTION
		Current	ALLERGY - INSECTS
		Current	BOWEL INCONTINENCE - MILD
		Current	OCCASIONAL HEADACHES
		Current	OCCASIONAL HEARTBURN
		Current	PRICKLY HEAT RASH
		Current	URINARY INCONTINENCE - MILD
	E0019020	Current	HEARTBURN
		Current	MIGRAINES
		Current	SEASONAL ALLERGIES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	Current	SINUS CONGESTION
		Current	TENSION HEADACHES
	E0019021	Past	ACHALASIA SURGERY
		Past	BRONCHITIS
		Past	SURGERY - LOWER BACK (HERNIATED DISK)
	E0019024	Past	TONSILLECTOMY
		Current	AMOXICILLIN ALLERGY
		Current	CERVICAL HERNIATED DISKS
		Current	CHRONIC COUGH
		Current	PENICILLIN ALLERGY
		Current	SINUS ALLERGY
	E0019035	Current	ARTHRITIS (HANDS)
		Current	TENSION HEADACHE
	E0019040	Past	SUBSTANCE ABUSE
		Current	ACID REFLUX
		Current	BACKACHE
		Current	OBESITY
		Current	SLEEP APNEA
	E0019042	Past	MIGRATORY ARTHRITIS
		Past	REMOVAL OF BONE SPURS IN PINKY.
		Current	ALLERGIC TO LAUNDRY DETERGENTS
		Current	MIGRAINE HEADACHES
		Current	TENSIM HEADACHES
	E0019045	Past	BROKEN LEFT ARM
		Past	PNEUMONIA
		Past	STREP THROAT
		Past	SUBSTANCE DEPENDANCE
		Past	TUBAL LIGATION
		Past	URINARY TRACT INFECTION
		Current	ASTIGMATISM
		Current	CONSTIPATION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	Past	HOSPITALIZED FOR BIPOLAR
		Past	PAST SUBSTANCE ABUSE/REHAB. SOBER
		Current	INTERMITTENT BILATERAL LEG CRAMPS
		Current	INTERMITTENT CALF CRAMPS
		Current	INTERMITTENT CRAMPS BILATERAL FEET (ARCH AREA)
	E0022044	Current	ALLERGIC RHINITIS
		Current	ASTHMA
		Current	DIARRHEA
		Current	HEADACHES
		Current	INDIGESTION
		Current	ORTHSTATIC DIZZINESS
		Current	SCOLIOSIS
	E0023007	Current	IRREGULAR PERIODS
	E0023011	Current	ALLERGIES
		Current	HYPOTHYROIDISM
		Current	IBS
	E0023014	Current	SHOULDER PAIN
	E0023019	Past	APPENDECTOMY
		Past	LEFT INGUINAL HERNIA
		Past	SCOLIOSIS
		Past	SPINAL SURGERY SECONDARY TO SCOLIOSIS
	E0023023	Past	FIBROID SURGERY
		Past	STATUS POST HYSTERECTOMY
		Current	IRRITABLE BOWEL SYNDROME
	E0023031	Past	PLEURISY
		Past	RIGHT OVARY REMOVAL
		Current	HYPERTENSION
		Current	LAMICTAL ALLERGY
		Current	OBESITY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	Current	ALLERGY TO PENICILLIN
		Current	ALLERGY TO SULFA
	E0023043	Past	LEFT THUMB SURGICAL REPAIR
	E0026003	Past	ADENOIDECTOMY
		Past	HYPERTENSION
		Past	PERIPHERAL NEUROPATHY
		Past	SEIZURE DISORDER
		Past	TONSILLECTOMY
		Past	TRANSIENT ISCHEONIC ATTACK
		Current	ALLERGIES TO DEMEROL, OXYCONTIN/HIVES, RASH
		Current	H. I. V.
		Current	HEARTBURN
		Current	HEPATITIS B
		Current	INSOMNIA
		Current	NON - HODGKINS LYMPHOMA
		Current	OCCASIONAL HEADACHES
		Current	RIGHT SHOULDER/PINCHED NERVE
	E0026005	Past	HEMORROIDECTOMY
		Past	HYSTERECTOMY
		Past	LOSS OF CONSCIOUSNESS
		Past	MASTECTOMY BREAST CANCER (RIGHT BREAST) RIGHT BREAST REMOVED 1986
		Current	HEAD TREMOR
		Current	HEARTBURN
		Current	HYPERTENSION
		Current	INSOMNIA
		Current	IRRITABLE BOWEL SYNDROME
		Current	OCCASIONAL HEADACHES
		Current	OSTEOARTHRITIS
		Current	PENNICILLIN ALLERGY
		Current	SEASONAL ALLERGIES
	E0026009	Past	TUBAL LIGATION 1991
		Current	ALLERGIES 1965 - PCN, ASA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0026009	Current	ALLERGIES 2000 - LAMICTAL
	E0026015	Current	ALLERGIES TO DHE 43
		Current	ALLERGIES TO NEBANE, IMMITREX, PEN
		Current	BODY ACHES SINCE 1994
		Current	HEADACHES SINCE 1969
		Current	HEARTBURN SINCE 1980
		Current	INSOMNIA SINCE 1960
		Current	MIGRAINE HEADACHES SINCE 1965
		Current	PRESSURE IN CHEST - NCS SINCE 2000
		Current	RHEUMATOID ARTHRITIS RIGHT HAND AND RIGHT SHOULDER BLADE
		Current	SINUS INFECTION
		Current	SPINAL DISK DISEASE
		Current	TUBAL LIGATION SINCE 1989
	E0026023	Past	ALCOHOL ABUSE
		Current	HEADACHES
		Current	HEARTBURN
		Current	INSOMNIA
		Current	KYPHOSCOLIOSIS
		Current	OSTEROARTHRITIS LEFT KNEE
	E0027016	Current	CHLAMYDIA
		Current	HEADACHES
		Current	OBESITY
		Current	PINCHED NERVE
	E0027018	Current	ASTHMA
	E0029003	Past	ALCOHOL ABUSE
		Past	DRUG ABUSE
		Current	HEADACHES
		Current	HEARTBURN
	E0029020	Current	MIGRAINE HEADACHES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	Past	BURNED TENDONS IN LEFT HIP
		Current	BURSITIS IN BOTH SHOULDERS
		Current	DOXYCYCLINE ALLERGY
		Current	ENVIRONMENTAL ALLERGIES
		Current	HYPERCHOLESTEROLEMIA
		Current	INSOMNIA
		Current	LEFT HIP PAIN
		Current	REFLUX
		Current	SULFA ALLERGY
	E0031006	Past	RUPTURED SPLEEN
		Past	SPLEENECTOMY
		Current	ALLERGIC TO PENICILLIN
		Current	ALLERGIC TO TETNUS
		Current	ARTHRITIS IN ANKLES
		Current	ARTHRITIS IN FEET
		Current	BIPEDAL DISTAL NEUROPATHY
		Current	CHEST PAIN
		Current	HEART PALPITATIONS
		Current	HYPERTENSION
		Current	INSOMNIA
		Current	IRREGULAR HEART BEAT
		Current	JOINT ACHES
		Current	OBESE
		Current	TYPE II DIABETES
	E0031010	Past	CHICKEN POX
		Current	ALLERGIC TO AMITRYPTILINE
		Current	ALLERGIC TO NAPROXEN
		Current	ALLERGIC TO OXYCOCET
		Current	BACK PAIN
		Current	CARPAL TUNNEL SYNDROME
		Current	JOINT ACHES
		Current	LACTOSE INTOLERANT
		Current	LEG CRAMPS
		Current	MUSCLE ACHES
		Current	NECK PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0031010	Current	PNEUMONIA
		Current	SHOULDER PAIN
		Current	STOMACH ACHES
	E0031011	Current	HEADACHES
		Current	HIATAL HERNIA
	E0031015	Current	ALLERGIC TO MONOCYCLINES
		Current	ALLERGIC TO PENICILLIN
		Current	ALLERGIC TO TETRACYCLINES
		Current	BACK PAIN
		Current	LEG CRAMPS
	E0031031	Past	CHICKEN POX
		Past	TRANSMANDIBULAR JOINT DISEASE
		Past	TUBAL LIGATION
		Current	ERYTHROMYCIN ALLERGY
		Current	GENITAL HERPES
		Current	MIGRAINES
		Current	SINUS HEADACHES
	E0033009	Current	ASTHMA
		Current	CHRONIC BRONCHITIS
		Current	HEADACHES
	E0034009	Past	SHOULDER PAIN
		Current	PSORIASIS
	E0037007	Current	HEADACHES
	E0037012	Past	METHAMPHETAMINE ABUSE
		Current	BACKACHES
		Current	HEADACHES
		Current	SHIN PAIN
	E0039019	Past	DIABETES MELLITUS
		Past	HYPERTENSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	Current	GLAUCOMA
		Current	INSOMNIA
		Current	OBESITY
	E0039043	Past	ALCOHOL ABUSE
		Past	COCAINE ABUSE
		Past	SUICIDE ATTEMPT
		Current	DAYTIME LETHARGY
		Current	HEADACHES
		Current	INSOMNIA
		Current	MIGRAINES
		Current	SEASONAL ALLERGIES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0002001	Past	SEASONAL AFFECTIVE DISORDER
		Current	GRAVE'S DISEASE
		Current	TINNITUS
		Current	TUMER'S SYNDROME
	E0002003	Past	BLADDER TUCK
		Past	HAND SURGERY
		Past	SPHINCTER SURGERY (RELATED TO PREGNANCY)
		Past	TUMOR ON UTERUS REMOVED
		Current	SEVERE JUVENILE RHEUMATOID ARTHRITIS
		Current	TMJ
	E0002004	Past	APPENDECTOMY
		Past	FIBROID TUMOR REMOVED
		Past	GALLBLADDER REMOVED
		Past	HYPOGLYCEMIA
		Past	HYSTERECTOMY
		Past	MULTIPLE OVARIAN CYSTS REMOVED
		Past	SURGERY FOR BROKEN BONES RIGHT HAND
		Past	TUBAL LIGATION
	E0002008	Past	CONCUSSION 1980
		Past	SCOLIOSIS - BACKBRACE 1975 - 1978
		Past	URINARY TRACT- SURGERY
	E0002016	Current	ADULT ACNE
		Current	ASTHMA
		Current	EMPHYSEMA
		Current	HIGH CHOLESTEROL
		Current	HYPERTENSION
		Current	IRREGULARITY
	E0003008	Past	APPENDECTOMY
		Past	ATTENTION DEFICIT DISORDER
		Past	BROKEN RIGHT ANKLE 1997
		Past	DILATATION & CURETTAGE
		Past	TUBAL LIGATION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0003008	Current	ASTHMA
		Current	SEASONAL ALLERGIES
		Current	SINUS DRAINAGE RELATED TO ALLERGIES
		Current	SWOLLEN LYMPH GLANDS - NECK
	E0004003	Past	1990 LEFT FOOT SURGERY
		Past	1991 INGUINAL HERNIA REPAIR
		Past	1997 ARTHROSCOPIC SURGERY LEFT KNEE
		Current	2002 STRAINED BACK MUSCLE
	E0004006	Past	HISTORY POSSIBLE LOU GEHRIG'S DISEASE RESOLVED
		Past	PARTIAL HYSTERECTOMY 1998
		Current	ALLERGY TO PENICILLIN & SULFA & BETADINE
		Current	MILD FAMILIAL TREMOR OF HANDS
	E0004016	Past	BREAST AUGMENTATION 12-2000
		Past	SEVERE ACNE
	E0004024	Past	2 MISCARRIAGES 1988 & 1989
		Past	ACNE 1998
		Past	BELLS PALSY 1993
		Current	FREQUENT INDIGESTION
		Current	RIGHT FACIAL DROOP
	E0005006	Past	HEART ATTACK (MINOR INFARCTION)
		Current	GI REFLUX (CURRENTLY MANAGED)
		Current	HYPERCHOLESTEROLEMIA (CURRENTLY MANAGED)
		Current	HYPERTRIGLYCERIDEMIA
	E0005017	Current	BORDERLINE HIGH BLOOD PRESSURE
		Current	HEARTBURN
		Current	JOINT PAIN (SI JOINT)
		Current	SEASONAL ALLERGIES
		Current	STRESS HEADACHES
	E0005019	Current	ALLERGIC TO PENICILLIN
		Current	HIP PAIN - SECONDARY TO SHATTERED PELVIS 1998

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0005026	Past	HX OF STOMACH ULCER
		Current	CHRONIC NECK AND BACK PAIN
		Current	INTERMITTENT HEADACHES
	E0005039	Past	POSITIVE TUBERCULOSIS TEST
		Past	TUBAL LIGATION
		Current	HEARTBURN
		Current	MIGRAINE/STRESS HEADACHES
		Current	SEASONAL ALLERGIES
	E0005043	Current	OBESITY
	E0007001	Current	HEADACHE
		Current	TENDONITIS LEFT ELBOW
	E0007003	Past	ANEMIA 7/02
		Past	EXCISION CYSTIC MASS LEFT SUBMENTAL AREA OF NECK 7/02
		Past	GUN SHOT WOUND LEFT FOREARM 1966
		Past	HYPERLIPIDEMIA
		Past	HYPOKALEMIA SECONDARY TO HYDROCHLORTHIAZIDE 7/02
		Past	HYPONATREMIA 7/02
		Past	METATARSALGIA
		Past	PEPTIC ULCER DISEASE 1993
		Past	STATUS POST CARDIAC STENT 1998
		Current	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
		Current	CHRONIC RECURRENT BACK PAIN
		Current	CORONARY ARTERY DISEASE
		Current	HYPERTENSION
	E0009004	Past	BROKEN LEFT WRIST 1976
		Past	BROKEN LEFT WRIST 1979
		Past	BROKEN NOSE 1979, 1980, 1981, 1982, 1983, 1984
		Past	BROKEN RIGHT WRIST 1978
		Past	DAMAGED LEFT KNEE 1983
		Past	LACERATION FROM EYEBROW TO BELOW RIGHT EYE
		Past	PNEUMONIA 1966

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0009004	Current	BROKEN JAW 4/02 - ONGOING
	E0009012	Past	APPENDECTOMY
		Past	APPENDICITIS
		Current	HEADACHES
		Current	HEARTBURN
	E0010008	Past	CHOLECYSTECTOMY
		Past	TUBAL LIGATION
		Current	HEADACHES
		Current	INSOMNIA
	E0010018	Past	ALCOHOL ABUSE
		Past	HISTORY OF PEPTIC ULCER DISEASE
		Past	LAPROSCOPY
		Past	OVARIAN CYST
		Current	BACK PAIN (FROM RECENT CAR ACCIDENT)
	E0010028	Current	GENITAL HERPES
		Current	INSOMNIA
	E0011008	Past	BURN ON LEFT ARM
		Past	SCALP INJURY
		Current	CIGARETTE SMOKING
	E0011009	Past	HISTORY OF KIDNEY STONES
		Past	HISTORY OF VENTRAL HERNIA
		Current	HEADACHES
		Current	LIPOMAS
		Current	SCOLIOSIS
		Current	TENDON CONTRACTURE OF LEFT RING FINGER
	E0011010	Past	HISTORY OF ASTHMA
		Current	ALLERGIC TO PENICILLIN
		Current	HEADACHES
		Current	POSTMENOPAUSAL

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0013003	Past	CHOLECYSTECTOMY 1982
		Past	GASTRIC BYPASS SURGERY 1967
		Past	REVERSAL OF GASTRIC BYPASS SURGERY 1977
		Current	ALLERGIES (SEASONAL & MOLD)
		Current	HEADACHES 1998
		Current	INSOMNIA
		Current	INTERMITTENT ELEVATED BP
		Current	MENOPAUSE (2001)
		Current	OBESITY
	E0013005	Current	HEARING LOSS (RIGHT EAR)
	E0013013	Current	DYSPEPSIA
		Current	HEADACHES
	E0014002	Past	ATTENTION DEFICIT DISORDER
		Past	C - SECTION
		Past	C - SECTION
		Past	CHOLECYSTECTOMY
		Past	CONCUSSION WITH LOSS OF CONSCIOUSNESS
		Past	HYSTERECTOMY
		Past	RHEUMATIC FEVER
		Past	SINUS SURGERY
		Past	TONSILECTOMY
		Current	HAY FEVER
		Current	HIP PAIN
		Current	MIGRAINE HEADACHES
		Current	SLIGHT HEART MURMUR
	E0014004	Past	BLADDER REPAIR
		Past	CAESAREAN SECTION
		Past	CHOLECYSECTOMY
		Past	CHRONIC BRONCHITIS
		Past	DRUG ABUSE
		Past	HYSTERECTOMY
		Past	UTERINE AND CERVICAL CANCER
		Past	VIRAL HEPATITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0014004	Current	ALLERGIC - IBUPROFEN
		Current	ALLERGIC - PERCOCET
		Current	BACK PAIN
		Current	HEADACHES
		Current	HEARING PROBLEMS - CERUMEN PLUG/RIGHT EAR
		Current	IRRITABLE BOWEL SYNDROME
		Current	JOINT PAIN
		Current	NECK PAIN
		Current	STOMACH PAIN
	E0014009	Past	BULIMIA
		Past	SUICIDE ATTEMPTS
		Past	TUBAL LIGATION
		Current	ALLERGIC - PENICILLIN
		Current	HEADACHES
		Current	HYPERTENSION
		Current	KNEE PAIN
		Current	STOMACH PAIN
	E0014017	Past	KNEE SURGERY
		Past	THREE SUICIDE ATTEMPTS
		Current	ALLERGIC TO CATS
		Current	ASTHMA
		Current	DIARRHEA
		Current	HEADACHES
		Current	IRRITABLE BOWEL SYNDROME
		Current	SWEATY HANDS
		Current	TIGHTNESS IN CHEST
	E0014018	Current	ALLERGIC TO MILK PRODUCTS
		Current	ECZEMA
		Current	HAY FEVER
		Current	HEADACHES
		Current	SINUS PROBLEMS
		Current	STOMACH PAIN
	E0017002	Current	UPPER AIRWAY REISTANCE SYNDROME

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0018009	Past	POLYSUBSTANCE ABUSE
	E0018010	Past	ERYTHROMYCIN ALLERGY
		Past	MIGRAINES
		Current	ERYTHROMYCIN ALLERGY
		Current	IRRITABLE BOWEL SYNDROME
		Current	MIGRAINES
		Current	PENDENTAL PROBLEMS
		Current	SINUS HEADACHES
	E0018015	Past	ARTHRITIS
		Past	KIDNEY STONES
		Past	ROSACES
		Current	ARTHRITIS
		Current	DEGENERATIVE JOINT DISEASE
		Current	ROSACES
	E0020015	Past	LEFT KNEE SURGERY (MENISCAL TEAR)
		Past	UMBILICAL HERNAI REPAIR X2
		Current	ABNORMAL GAIT (DUE TO HERNIATED DISC L5)
		Current	ALLERGY TO CODEINE
		Current	ARTHRITIS (BACK AREA)
		Current	ARTHRITIS (BILATERAL HIPS)
		Current	HERNIATED DISC (L5)
	E0020017	Past	BREAST AUGMENTATION SURGERY
		Past	PAST ALCOHOL ABUSE
		Past	SUICIDE ATTEMPT
		Past	TUBAL LIGATION
		Current	GASTRIC ESOPHAGEAL REFLUX DISORDER
		Current	HIATAL HERNIA
		Current	INTERMITTENT HEADACHES
		Current	INTERMITTENT LUMBAR AREA DISCOMFORT
		Current	INTERMITTENT RIGHT CERVICAL AREA DISCOMFORT (NECK)
		Current	SEASONAL ALLERGIES
	E0020020	Past	ELECTRICAL CONVULSANT THERAPY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0020020	Past	HISTORY OF ALCOHOL AND SUBSTANCE ABUSE
		Past	HISTORY OF ANOREXIA
		Past	HISTORY OF BULIMIA
		Past	JAW RECONSTRUCTIVE SURGERY
		Past	OVERDOSE ATTEMPTS
		Current	ALLERGIC TO AMPICILLIN
		Current	ALLERGIC TO GEODON
		Current	IRREGULAR MENSES
		Current	PSORIASIS
	E0020022	Past	BREAST REDUCTION
		Past	CHOLECYSTECTOMY
		Past	SPHINCTER MUSCLE REPAIR
		Current	ALLERGIC TO CHOCOLATE
		Current	ALLERGIC TO EGGS
		Current	ALLERGIC TO STRAWBERRIES
		Current	INTERMITTENT MUSCLE ACHES (ALL OVER)
		Current	POST MENOPAUSAL
	E0022001	Current	GASTRIC REFLUX
		Current	HEADACHES
		Current	HEMORRHOIDS
		Current	HYPERTENSION
	E0022004	Past	BILATERAL OOPHERECTEMY
		Past	HYSTERECTOMY
		Past	OVARIAN CYSTS
		Past	RECURRENT URINARY TRACT INFECTION
		Current	ALLERGIC RHINITIS
		Current	ENDOMETRIOSIS
		Current	FOOD ALLERGIES - BANANAS, KIWI, NUTS
		Current	GASTRIC REFLUX
		Current	HEADACHES - MIGRAINES
		Current	LACTOSE INTOLERANCE
	E0022005	Past	FRACTURED LEFT ANKLE
		Past	FRACTURED RIGHT FOOT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0022005	Past	GALL BLADDER REMOVED
		Past	GANGLIAN CYST REMOVED
		Current	ALLERGIC RHINITIS
		Current	ASTHMA
		Current	GASTRIC REFLUX
		Current	HEADACHES
		Current	HYPOTHYRODISM
		Current	MENSTRUAL CRAMPS
		Current	MIGRAINES
		Current	VERTIGO 1999
	E0022011	Past	BILATERAL BUNIECTOMY
		Past	BULLET INJURY IN SERVICE
		Past	MENINGITIS AT BIRTH
		Current	HEADACHES.
	E0022015	Current	CHRONIC BACK PAIN
		Current	DYSMENORHEA
		Current	HEADACHE
		Current	SHOULDER PAIN
	E0022016	Current	CHRONIC BACK PAIN
		Current	HEADACHES
		Current	HEARTBURN
		Current	LEFT ARM PAIN
	E0022020	Current	ASTHMA
		Current	HEADACHES
		Current	MIGRAINE HEADACHES
		Current	MUSCULOSKELETAL CHEST PAIN
	E0022023	Past	(EXERCISE INDUCED ASTHMA)
		Current	HEADACHES
	E0022029	Current	HEADACHES
	E0022041	Past	CHOLECYSTECTOMY - 1997

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0022041	Past	PEPTIC ULCER DISEASE. 1994
		Past	TUBAL LIGATION, 1975
		Current	ALLERGIC TO TETRACYCLINE (RASH)
		Current	FIBROMYALGIA
		Current	HEADACHES
		Current	INGROWN TOENAIL
		Current	INSOMNIA
		Current	OCCASIONAL HEARTBURN, ONSET 1973
		Current	RECURRENT URINARY TRACT INFECTIONS, ONSET 1993
	E0022043	Past	BENIGN OVARIAN CYSTS
		Past	BENIGN RECTAL POLYPS
		Past	UTERINE FIBROIDS
		Current	ALLERGIC RHINITIS
		Current	CONGENITAL NYSTAGMUS
		Current	GASTROESOPHAGEAL REFLUX
		Current	HEADACHES
		Current	HEART MURMUR
		Current	IRRITABLE BOWEL SYNDROME
		Current	URINARY PAIN
	E0022054	Current	ALLERGIC RHINITIS, ONSET 1993
		Current	CONGENITAL ABSENCE OF KIDNEY (SOLITARY KIDNEY)
		Current	OCCASIONAL HEADACHES, ONSET 1997
		Current	OCCASIONAL HEART BURN, ONSET 2000
		Current	OCCASIONAL NECK PAIN, ONSET 1997
		Current	RIGHT ANKLE SPRAIN ONSET 10/2/77
	E0022059	Past	TUBAL LIGATION 1989
		Current	ALLERGIC RHINITIS - SINCE 1995
		Current	ASTHMA - SINCE 2000
		Current	CHRONIC BACK PAIN SINCE 1978
		Current	HEADACHES SINCE 1980
	E0022065	Past	ENDOMETRIOSIS
		Past	HYSTERECTOMY
		Past	PROLAPSED UTERUS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0022065	Past	TUBAL LIGATION
		Current	ALLERGIC RHINITIS
		Current	DIZZINESS
		Current	GASTROESOPHAGEAL REFLUX
		Current	HEADACHES
		Current	INDIGESTION
	E0022070	Past	AORTIC ANEURYSM REPAIR OF RUPTURED AORTA
		Past	CEREBROVASCULAR ACCIDENT
		Past	HEART VALVE REPAIR
		Past	MYOCARDIAL INFARCT
		Past	NEPHROLITHIASIS - SURGICAL REMOVAL
		Current	GASTROINTESTINAL REFLUX
		Current	GOUT
		Current	HEADACHES
		Current	HYPERLIPIDEMIA
		Current	HYPERTENSION
		Current	LOOSE STOOLS
		Current	POST SURGICAL CHEST WALL PAIN
	E0023001	Current	HYPOTHYROID
	E0023028	Past	TUBAL LIGATION
		Current	HEADACHES
	E0025001	Current	CHRONIC URINARY TRACT INFECTIONS
		Current	GASTRIC ESOPHAGEAL REFLUX DISORDER
		Current	HERNIATED DISC
		Current	NON INSULIN DEPENDENT DIABETES MELLITUS
		Current	SEASONAL ALLERGIES
	E0026012	Past	ETOH ABUSE
		Past	RIGHT ANKLE INJURY
		Past	SUBSTANCE ABUSE
		Current	INSOMNIA
		Current	LEFT KNEE PAIN
		Current	OCC. HEADACHES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0026012	Current	RIGHT SHOULDER PAIN
		Current	TENDONITIS TO LEFT KNEE
	E0026020	Past	APPENDECTOMY
		Past	BLURRED VISION
		Current	HEADACHES
		Current	INSOMNIA
		Current	LOWER BACK PAIN
		Current	TINNITIS BOTH EARS
	E0026024	Past	MIGRAINE HEADACHES
		Past	ULCER
		Current	ALLERGIC TO ASPIRIN
		Current	ASTHMA
		Current	HEADACHES
		Current	HEARTBURN
		Current	HYPOTHYROIDISM
		Current	INSOMNIA
		Current	TUBAL LIGATION
		Current	WEIGHT GAIN
	E0026028	Current	GASTROESOPHAGEL REFLUX
		Current	HEADACHES
		Current	HYPERCHOLESTEROLEMIA
		Current	HYPERTENSION (MILD)
		Current	INSOMNIA
		Current	NAUSEA WITH DIETING
		Current	OBESE
		Current	PENICILLIN ALLERGY
		Current	SHOULDER INJURY
		Current	SPIDER BITE TO LEFT ARM
	E0028001	Past	CHOLECYSTECTOMY 1985
		Past	OSTEOPLASTY OF THE LEFT METACARPAL
		Current	ANXIETY
		Current	DECREASED LIBIDO
		Current	DIABETES MELLITUS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0028001	Current	DIARRHEA
		Current	HYPERCHOLESTEREMIA
		Current	INSOMNIA
		Current	INTERMITTENT HIGH BLOOD PRESSURE
		Current	OBESE
	E0028003	Past	CHOLECYSTITIS
		Past	MELANOMA
		Past	MELANOMA EXCISION
		Past	POST MENOPAUSAL
		Current	ALLERGIES TO PCN, ERYTHROMYCIN, AND ALOE GEL
		Current	BORDERLINE DIABETES MELLITUS
		Current	DEGENERATIVE ARTHRITIS
		Current	DEPRESSIVE ANXIETY
		Current	OBESITY
		Current	OCCASIONAL HEADACHES
		Current	WATER RETENTION
	E0028005	Past	HEAD TRAUMA WITHOUT SEQUELAE
		Current	CONSTIPATION
	E0028010	Past	ALCOHOL & DRUG DEPENDENCE
		Past	BREAST IMPLANTS
		Past	FRACTURE LEFT RADIUS PROXIMAL
		Past	HEAD TRAUMA
		Past	LASER EYE SURGERY
		Past	SEIZURE (DRUG INDUCED)
		Current	BREAST TENDERNESS
		Current	CONSTIPATION
		Current	DRY MOUTH
		Current	DUST MITES ALLERGY
		Current	HEADACHES
		Current	INSOMNIA
		Current	WEEKLY HEADACHES
	E0028011	Current	DIARRHEA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0028030	Current	ALOPECIA
		Current	LEFT INGUINAL HERNIA
		Current	SINUSITUS
	E0028031	Current	ACID REFLUX
		Current	PENICILLIN
	E0028047	Past	COCCIDIOIDOMYCOSIS
		Past	PARTIAL LEFT LUNG LOBECTOMY
		Past	POST MENOPAUSAL
		Current	ARTHRITIS
		Current	DIABETES MELLITUS TYPE II
		Current	HEADACHES
		Current	HYPERTENSION
		Current	OBESE
		Current	PENICILLIN ALLERGY
	E0029001	Past	HEAD INJURY - 1983
	E0029014	Current	ALLERGIC RHINITIS
		Current	BILATERAL KNEE PAIN
		Current	ECZEMA
		Current	IODINC HYPERSENSITIVITY
		Current	MENSTRUAL CRAMPS
		Current	POLLEN ALLERGY
		Current	ROSACEA
	E0029023	Current	CONSTIPATION
		Current	HEARTBURN
		Current	MEMSTRUAL CRAMPS
	E0029032	Past	AMPUTATED LEFT PINKY DIGIT
		Past	HEART MURMUR
		Past	SEIZURES
		Current	EMPHYSEMA
		Current	LEG PAIN
		Current	LOWER BACK PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0029032	Current	MIGRAINE HEADACHE
		Current	TENSION HEADACHE
		Current	TRANSIENT STOMACH PAIN
	E0029033	Past	ADENOIDECTOMY
		Past	CERVICAL FUSION SURGERY
		Past	MYRINGOTOMIES
		Past	TONSILLECTOMY
		Current	COMMON COLD
		Current	HERNIATED CERVICAL DISKS
		Current	MIGRAINE HEADACHES
		Current	POSTERIOR NECK TENDERNESS
	E0029039	Past	ANEMIA 1988
		Past	RIGHT OVARIAN CYST NOVEMBER 2002
		Current	ALLERGY - BANANAS MODERATE REACTION 2001
		Current	ALLERGY - BEE STINGS SEVERE REACTION 1983
		Current	MIGRAINE HEADACHES - SEVERE 1990
		Current	RIGHT SHOULDER PAIN 2001
		Current	TENSION HEADACHES 1995
		Current	UTERINE FIBROID DISEASE NOVEMBER 2002
	E0030003	Past	ABORTION - 1979
		Past	D&C (MISCARRIAGE) - 1984
		Past	GALL STONES REMOVED - 1997
		Current	ALLERGY (DUST)
		Current	HEADACHE
		Current	HYPEROPIA
		Current	LOWER BACK PAIN
		Current	SINUS PRESSURE
	E0030009	Past	HERNIA - 1969
		Past	RIGHT KNEE SURGERY - 1986
		Past	RIGHT SHOULDER SURGERY - 1995
		Current	HEADACHES
		Current	MIGRAINES
		Current	POLYCYSTIC KIDNEY DISORDER LEFT KIDNEY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0030009	Current	PRESBYOPIA
		Current	SERUM HEPATITIS
	E0030016	Past	RIGHT PATELLA RECONSTRUCTION - 1972
		Past	TONSILECTOMY - 1960
		Current	PRESBYCPIA
		Current	URINARY FREQUENCY
	E0030021	Past	LEFT INDEX FINGER FRACTURE - 2001
		Past	LEFT KNEE SURGERY - 1989
		Past	SURGERY LEFT INDEX FINGER - 2001
	E0031001	Past	FRACTURED RIGHT LEG 1995
		Past	GALL BLADDER REMOVAL 1996
		Past	HYSTERECTOMY 1991
		Past	INTERNAL FIXATION REMOVAL 1999
		Current	ALLERGIES SEASONAL 1995
		Current	ASPIRIN ALLERGY
	E0031017	Past	ARTHROSCOPIC KNEE SURGERY
		Past	BRONCHITIS
		Past	GASTROESOPHOGEAL REFLUX DISEASE
		Past	MEMORY LOST
		Past	MYOCARDIAL INFARCTION
		Past	PYLES
		Past	TREMORS
		Past	URINARY TRACT BLOCKAGE
		Current	HYPERCHOLESTEROLEMIA
		Current	HYPERTENSION
		Current	INSOMNIA
		Current	JOINT ACHES
		Current	SEASONAL ALLERGIES
		Current	SINUS INFECTIONS
		Current	TENDONITIS IN RIGHT ELBOW
		Current	ULCERS
	E0031018	Past	BRONCHITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0031018	Past	CHICKEN POX
		Past	MEASLES
		Past	MUMPS
		Current	ASTHMA
		Current	CHEST PAIN
		Current	HIGH BLOOD PRESSURE
		Current	LEG CRAMPS
		Current	MIGRAINES
	E0031023	Past	CHICKEN POX
		Past	MEMORY LOSS
		Current	BACK PAIN
		Current	EASY BRUISING
		Current	GASTROESOPHAGEAL REFLUX DISEASE
		Current	HIGH TRYGLYCERIDES
		Current	NECK PAIN
		Current	SEASONAL ALLERGIES
	E0033001	Past	BLADDER INFECTION
		Past	TORN LIGAMENTS LEFT KNEE
		Current	ALLERGIES
	E0033004	Current	HYPOTHYROIDISM
		Current	NAUSEA
		Current	WEAKNESS
	E0033010	Past	ANEMIA
		Past	UMBILICAL HERNIA
		Past	URINARY TRACT INFECTION
	E0033014	Past	SPASTIC COLON
		Current	HERNIATED SPINAL DISC
		Current	SINUS ALLERGIES
	E0035002	Past	GALL BLADDER SURGERY
		Past	PAST HX. OF ETOH AND COCAINE ABUSE IN REMISSION X3 MONTHS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0035007	Past	KNEE SURGERY
		Past	TONSILECTOMY
		Current	ALLERGIC TO SULFA
	E0035011	Past	C - SECTION
		Past	CONCUSSION TO THE HEAD
		Past	PARTIAL HYSTERECTOMY
		Past	PAST HX OF ALCOHOL
		Past	TUBAL LIGATION
		Past	TUBAL PREGNANCY
		Current	DIABETES
		Current	HYPOTHYROID STABLE
	E0035020	Past	PARTIAL HYSTERECTOMY
		Past	TORN LIGAMENTS ON BOTH KNEES
		Past	TWO BACK SURGERIES
		Current	ALLERGY TO ASPIRIN
		Current	ALLERGY TO CODEINE
		Current	ALLERGY TO PENICILLIN
		Current	ALLERGY TO VALIUM
		Current	ALLERGY TO VICODIN
		Current	ALLERGY TO ZESTORIL
		Current	OCCASIONAL HEADACHES
		Current	OCCASIONAL MIGRAINES
	E0037003	Past	GALLBLADDER DISEASE
		Past	LEFT BREAST BIOPSY
		Current	RHEUMATOID ARTHRITIS
	E0037004	Past	GASTRIC BYPASS
		Current	FEVER BLISTERS
		Current	MIGRAINES
		Current	SEASONAL ALLERGIES
	E0039022	Current	BILATERAL EAR INFECTION
	E0039023	Past	CYST REMOVAL FROM BACK

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0039023	Current	HERNIATED DISCS
	E0039030	Past	MEMOPAUSE
		Current	ARTHRITIS
		Current	HEPATITIS C
		Current	INSOMNIA
		Current	OBESITY
	E0039031	Past	ASTHMA
		Past	ENDOMETRIAL ABLATION
		Current	ACNE
		Current	FIBROIDS
		Current	HEADACHES
		Current	INSOMNIA
		Current	OCCASIONAL MIGRAINES
		Current	PAIN LOWER LEFT BACK
		Current	RECURRENT NASAL CONGESTION
	E0039037	Past	ABUSE OF PERCOCET
		Past	WISDOM TOOTH EXTRACTION
		Current	ARTHRITIS IN NECK
		Current	BULGING DISK
		Current	DEGENERATIVE DISK
		Current	HEADACHES
		Current	HERNIATED DISK
		Current	INSOMNIA
		Current	MIGRAINES
	E0039038	Past	LEFT HIP FRACTURE
		Past	RIGHT HIP FRACTURE
		Current	ASTHMA
		Current	HIRSUTISM
		Current	INSULIN DEPENDENT DIABETES MELLITUS
		Current	OBESITY
	E0039047	Current	AMOXICILLIN ALLERGY
		Current	ASTHMA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0039047	Current	INTERMITTENT LEG PAIN
		Current	OVARIAN CYSTS
	E0039059	Past	BOILS ON BUTTOCKS
		Past	BOILS ON INNER THIGHS
	E0041007	Past	GONORRHEA IN 1988
		Current	INTERMITTENT AGITATION SINCE 1990
		Current	INTERMITTENT ANXIETY SINCE 1990
		Current	INTERMITTENT FACIAL ACNE SINCE 1999
		Current	INTERMITTENT HEADACHE SINCE 1992
		Current	INTERMITTENT INSOMNIA SINCE 1978
		Current	INTERMITTENT RIGHT AND LEFT TINNITIS SINCE 1999
	E0041010	Current	INTERMITTENT AGITATION SINCE 1986
		Current	INTERMITTENT ANXIETY SINCE 1986
		Current	INTERMITTENT BILATERAL KNEE PAIN SINCE 1986
		Current	INTERMITTENT HEADACHE SINCE 1985
		Current	INTERMITTENT INDIGESTION SINCE 2002
		Current	INTERMITTENT INSOMNIA SINCE 1986
		Current	INTERMITTENT MIGRAINE SINCE 1992
		Current	INTERMITTENT SINUSITIS SINCE 1984
	E0041011	Past	BILATERAL TUBAL LIGATION IN 1986
		Past	CESAREAN SECTION IN 1986
		Current	INTERMITTENT ABDOMINAL PAIN SINCE 10/02
		Current	INTERMITTENT AGITATION SINCE 1980
		Current	INTERMITTENT ANXIETY SINCE 1980
		Current	INTERMITTENT BACK PAIN SINCE 2000
		Current	INTERMITTENT BILATERAL EARACHES SINCE 1974
		Current	INTERMITTENT CONSTIPATION SINCE 10/02
		Current	INTERMITTENT COUGH SINCE 08/02
		Current	INTERMITTENT DIARRHEA SINCE 10/02
		Current	INTERMITTENT GASTRITIS SINCE 2000
		Current	INTERMITTENT HEADACHES SINCE 04/02
		Current	INTERMITTENT INDIGESTION SINCE 01/02
		Current	INTERMITTENT INSOMNIA SINCE 04/02

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR I)	E0041011	Current	INTERMITTENT NAUSEA SINCE 04/02
		Current	INTERMITTENT RIGHT ARM PAIN SINCE 02/03
		Current	INTERMITTENT RIGHT LEG PAIN SINCE 2000
		Current	INTERMITTENT SINUSITIS SINCE 10/02
		Current	INTERMITTENT TINNITUS SINCE 1980
		Current	INTERMITTENT URGENCY IN URINATION SINCE 04/02
	E0041012	Past	GALL STONES WITH REMOVAL IN 1997
		Past	GONORRHEA IN 1976
		Past	HEMORRHOIDS IN 1993
		Past	PNEUMONIA 05/18/03 - 05/23/03
		Past	PULMONARY EMBOLISMS 1989
		Past	SYPHILLIS IN 1991
		Past	TONSILLITIS WITH TONSILLECTOMY IN 1963
		Current	INTERMITTENT ABDOMINAL PAIN SINCE 1973
		Current	INTERMITTENT ACID REFLUX SINCE 1973
		Current	INTERMITTENT AGITATION SINCE 1973
		Current	INTERMITTENT ANXIETY SINCE 1973
		Current	INTERMITTENT BACK PAIN SINCE 1995
		Current	INTERMITTENT BILATERAL EARACHES SINCE 1960
		Current	INTERMITTENT BILATERAL KNEE PAIN SINCE 1999
		Current	INTERMITTENT BILATERAL LEG PAIN SINCE 2000
		Current	INTERMITTENT BILATERAL TINNITUS SINCE 1960
		Current	INTERMITTENT CONSTIPATION SINCE 1990
		Current	INTERMITTENT DIARRHEA SINCE 1973
		Current	INTERMITTENT HEADACHES SINCE 1968
		Current	INTERMITTENT HYPERLIPIDEMIA SINCE 1994
		Current	INTERMITTENT HYPERTENSION SINCE 1989
		Current	INTERMITTENT INDIGESTION SINCE 1973
		Current	INTERMITTENT INSOMNIA SINCE 1973
		Current	INTERMITTENT NAUSEA SINCE 04/2003
		Current	INTERMITTENT NECK PAIN SINCE 1995
		Current	INTERMITTENT SINUSITIS SINCE 1956

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0001004	Past	KIDNEY STONES/CRYSTALS - 2
		Past	RECURRENT URINARY TRACT INFECTIONS
		Current	CIGARETTE SMOKING
	E0005023	Current	HEADACHES, STRESS
	E0005034	Past	TUBAL LIGATION
		Current	HYPOTHYROIDISM
		Current	RECURRENT BACK PAIN
		Current	STRESS HEADACHES
	E0005041	Past	TUBAL LIGATION
		Current	ASTHMA
		Current	INTERMITTENT JOINT PAIN
	E0007004	Past	C - SECTION
		Past	CONCUSSION
		Past	RIGHT LABRINTHECTOMY
		Past	SURGICAL POST CHOLECYSTECTOMY
		Current	HYPERCHOLESTEROLEMIA
		Current	HYPERLIPIDEMIA
		Current	HYPOTHYROIDISM
	E0007010	Past	BRONCHIAL ASTHMA
		Past	HYSTERECTOMY 1982
	E0007012	Past	HEADACHE
		Current	ALLERGIC RHINITIS
		Current	BELL'S PALSY LEFT SIDE FACE
	E0009007	Past	BROKEN RIGHT THUMB 1987
		Past	EAR PAIN 1977
		Past	TONSILECTOMY 1977
		Past	TONSILITIS 1977
		Past	TUBES IN EARS 1977
		Current	BACK PAIN 1995
		Current	INSOMNIA 1995

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HISM100.SAS
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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0009007	Current	MIGRAINES 1995
	E0009008	Past	CHRONIC HICCUPS
		Current	BENIGN CYST ON FOREHEAD
		Current	HEADACHES
		Current	INSOMNIA
	E0011001	Past	STILLBIRTH - 1965
		Current	DENTURES
		Current	SINUS INFECTION
	E0011011	Past	ELECTIVE ABORTION
		Current	HEADACHES
		Current	IRON DEFICIENCY ANEMIA
	E0011013	Past	CHOLESCYSTITIS (2000)
		Past	FUNGAL EYE INFECTION
		Past	GOITER (1970)
		Current	ARTHRITIS
		Current	HEADACHES
		Current	HYPERTENSION
		Current	HYPOTHYROIDISM
		Current	SEASONAL ALLERGIES
	E0011014	Past	CESEREAN SECTION
		Past	GESTATIONAL DIABETES
		Past	TUBAL LIGATION
	E0011021	Past	CESEREAN SECTIONS
		Past	TUBAL LIGATION
		Past	URINARY TRACT INFECTIONS
		Current	HEADACHE
		Current	IRON DEFICIENCY ANEMIA
	E0013008	Current	ASTHMA
		Current	HEADACHES

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0014001	Past	C - SECTION
		Past	CHOLECYSTECTOMY
		Past	HYSTERECTOMY
		Past	KIDNEY/RENAL FAILURE
		Past	SHOULDER SURGERY
		Current	ALLERGIC TO MORPHINE
		Current	BACK PAIN
		Current	HAYFEVER
		Current	JOINT PAIN
		Current	MODERATE HEADACHES
		Current	NECK PAIN
		Current	OSTEO - ARTHRITIS
		Current	PELVIC PAIN
	E0014013	Past	ANEMIA
		Past	DRUG ABUSE
		Past	OVARIAN CERVICAL CANCER
		Past	SUICIDE ATTEMPT
		Past	URINARY TRACT INFECTIONS
		Current	ALLERGIC TO CODEINE
		Current	ALLERGIC TO LORTAB
		Current	HAYFEVER
		Current	IRREGULAR PERIODS
		Current	MIGRAINE HEADACHES
		Current	PELVIC PAIN
	E0014014	Past	HEPATITIS B
		Past	KNEE SURGERY
		Past	SINUS ALLERGIES
		Current	JOINT PAIN
		Current	NECK PAIN
	E0015004	Past	BILATERAL TUBAL LIGATION
		Past	HERNIATED L4 - L5 DISCS
	E0018005	Past	RIGHT KNEE SURGERY
		Current	BACK PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0018005	Current	KNEE PAIN
	E0018012	Past	APPENDECTOMY
		Past	CHOLECYSTITIS
		Past	CHRONIC BRONCHITIS
		Past	COLITIS
		Past	SEASONAL ALLERGIES
		Past	TONSILLECTOMY
		Current	GENITAL WARTS
		Current	HEPATITIS A+
		Current	REACTIVE AIRWAY DISEASE
		Current	SEASONAL ALLERGIES
	E0019019	Current	ACNE
		Current	ALLERGIC - CECLOR, VICXIN, AUGMENTIN
		Current	AMBLIOPIA
		Current	ASTHMA
		Current	HEMOPHILIAC
		Current	LAX TENDON
		Current	LAZY EYE
		Current	LOWER BACK PAIN
	E0019033	Past	HERNIORRHAPHY
	E0019038	Past	COLONOSCOPY
		Past	EXERCISE INDUCED ASTHMA
		Current	BACK PAIN
		Current	INDEGESTION
		Current	NECK PAIN
		Current	SEASONAL ALLERGIES
	E0019046	Past	BREAST AUGMENTATION
		Past	COLON RESECTION
		Past	ENDOMETRIOSIS
		Past	HYSTERECTOMY
		Past	MIGRAINE HEADACHES
		Past	PLASTIC SURGERY - BILLATERAL EARS

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0019046	Current	ALLERGY - AUGMENTIN
		Current	SCOLIOSIS
	E0019047	Current	ALLERGIES [DUST, POLLEN, DANDER]
	E0019048	Past	MIGRAINES
		Current	ALLERGIC TO PENICILLIN
		Current	ANEMIA
		Current	FLUID IN EARS
		Current	HEART MURMUR
		Current	INFLAMATION OF JOINTS
		Current	LOW BACK PAIN
		Current	RECEEDING GUM LINE
		Current	SCOLIOSIS
		Current	SEASONAL ALLERGIES
	E0022006	Current	ACNE
		Current	ALLERGIC RHINITIS
		Current	ASTHMA
		Current	HEADACHES
		Current	SULFA ALLERGY
	E0022047	Current	ALLERGIC RHINITIS
		Current	ASTHMA
		Current	HEADACHES
	E0022075	Past	DYSLEXIA
		Current	ALLERGIC RHINITIS
		Current	DRY SKIN
		Current	ESOPHAGEAL REFLUX
		Current	HEADACHES
		Current	HIP PAIN
		Current	KNEE PAIN
		Current	OSTEOPOROSIS
		Current	POST MENOPAUSAL STATUS
	E0023016	Past	APPENDECTOMY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.2 Medical History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0023016	Past	EYE SURGERY
		Past	GALL BLADDER SURGERY
		Current	NECK PAIN
		Current	SHOULDER PAIN
	E0023036	Current	INSOMNIA
	E0023046	Current	ARTHRITIS - RHEUMATOID
		Current	ENLARGED BILATERAL SUB - MANDIBULAR NODES
		Current	HYPTERTENSION
		Current	POST - MENOPAUSAL
		Current	SJOGRENS SYNDROME
	E0026006	Past	TONSILLECTOMY
		Current	HEADACHES SINCE 1970
	E0026021	Current	ADULT ACNE
		Current	HEADACHES
		Current	INSOMNIA
	E0026027	Past	BASAL CELL CARCINOMNA TO CENTER BACK
		Past	SEIZURES (SUBJECT DID NOT REPORT THE HISTORY OF SEIZURE AT SCREEN VISIT.)
		Current	DRUG ALLERGY PENICILLIN
		Current	HEADACHE
		Current	INSOMNIA
		Current	MILD BRONCHITIS
	E0029002	Past	DYSPLASIS 1989
		Past	HYSTERECTOMY - (1989)
		Past	INVASIVE CANCEROUS TUMOR ON VULVA REMOVED
		Past	LYMPH NODES IN GROIN AREA REMOVED
		Past	OVARIAN CYST REMOVED & LEFT OVARY REMOVED 1979
		Past	THYROIDECTOMY (- 1976)
		Current	CODEINE ALLERGY (SINCE 1972)
		Current	DORMANT ECZEMA - 1972
		Current	DORMANT HPV - 1968

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0029002	Current	DORMANT PSORIASIS - 1972
		Current	HEADACHES (SINCE 1998)
		Current	HYPOTHYROIDISM (SINCE 1976)
		Current	JAW PAIN (SINCE 2002)
		Current	METAL ALLERGY (1962)
		Current	OCCASIONAL HEART PALPITATION (1962)
	E0029004	Past	ASTHMA - 1972
		Past	BENIGN TUMOR REMOVED FROM SPINE 1994
		Past	ECZEMA - 1978
		Past	HERNIA REPAIR - 1996
		Past	ULCERS - 1996
		Current	BILATERAL CARPAL TUNNEL - 2000
		Current	BILATERAL FINGER JOINT PAIN - 2000
		Current	BILATERAL KNEE PAIN - 1999
		Current	GERD - 1997
		Current	HEADACHES - 1985
		Current	LEFT EYE TWITCHES 1999
		Current	MIGRAINES - 1985
		Current	SEASONAL ALLERGIES - 1970
	E0029013	Current	HEADACHES
		Current	LOWER BACK PAIN
		Current	OBESITY
		Current	SCARS ON RIGHT SIDE OF FACE & ARM
	E0029019	Past	CALCIFIED BRAIN
		Past	KIDNEY STONES
		Past	TONSILLECTOMY
		Current	ARTHRITIS
		Current	HEADACHE
		Current	HYPERCHOLESTEROLEMIA
	E0029024	Current	HEADACHES
		Current	HYPOTHYROIDISM
		Current	POST - MENOPAUSAL

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0029038	Past	TONSILLECTOMY
	E0031004	Past	ATTENTION DEFICIT DISORDER
		Past	RIGHT KNEE ARTHROSCOPY SURGERY
		Past	TRICHOTILLOMANIA
		Current	ENVIRONMENTAL ALLERGIES
		Current	GASTROESOPHAGEAL REFLUX DISEASE
		Current	HYPERCHOLESTOLEMIA
		Current	INSOMNIA
		Current	MILD ASTHMA
		Current	RESTLESS LEG SYNDROME
	E0031013	Past	TUBAL LIGATION
		Current	ACID REFLUX
		Current	CHRONIC BROCHITIS
		Current	ENVIRONMENTAL ALLERGIES
		Current	HYPERTENSION
		Current	URINAL URGENCY
	E0031016	Past	CHICKEN POX
		Current	HEART MURMUR
	E0031019	Past	BROKEN BACK L1
		Past	BROKEN JAW
		Past	BROKEN NECK C4 AND C5
		Past	BROKEN RIGHT ANKLE
		Past	CHICKEN POX
		Past	KNEE SURGERY, LEFT KNEE, ARTHROSCOPIC
		Past	MEASLES
		Past	MEMORY LOSS
		Past	MUMPS
		Past	ROTATOR CUFF SURGERY, BOTH SHOULDERS
		Past	SKULL FRACTURE
		Current	ARTHRITIS
		Current	HEARTBURN
		Current	JOINT ACHES
		Current	LOWER BACK PAIN

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0031019	Current	MIGRAINES
		Current	MUSCLE ACHES
		Current	SHOULDER PAIN
	E0031022	Past	GROIN SURGERY
		Past	OVARIAN TUMORS REMOVED
		Current	INSOMNIA
		Current	INTERMITTENT HEADACHES
		Current	JOINT ACHES
		Current	MIGRAINES
		Current	MUSCLE ACHES
		Current	SEASONAL ALLERGIES
	E0033007	Past	APPENDIX REMOVED
		Past	BASAL CELL CARCINOMA
		Past	HYSTERECTOMY (UTERUS ONLY)
		Past	PIN IN LEG (THROUGH FEMUR) DUE TO CAR ACCIDENT
		Past	TONSILS REMOVED
		Past	TUBERCULOSIS (NOT MANIFESTED, BUT TESTED POSITIVE FOR IT)
		Current	ARTHRITIS
		Current	FIBROMYALGIA
	E0033016	Past	HEMORRHOIDS
		Current	ANEMIA
		Current	LOW BLOOD PRESSURE
	E0033022	Past	KIDNEY STONES, 1999, 2000
		Past	NEUROCARDIOGENIC SYNCOPE, 2001
		Past	URINARY TRACT INFECTION, UNKNOWN DATE
		Current	BRONCHIOASTHMA, UNKNOWN DATE
		Current	KNEE PAIN, 1998
		Current	OBESITY, UNKNOWN DATE
	E0034007	Past	APPENDECTOMY
		Past	BREAST MASS REMOVED
		Past	KIDNEY STONES

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0034007	Past	OVARIAN CYST REMOVED
		Current	HEADACHES
		Current	HYPERTENSION
		Current	SEASONAL ALLERGIES
	E0035004	Current	POSSIBLE EARLY SIGNS OF GLAUCOMA
	E0035010	Past	GALLBLADDER SURGERY
		Past	HISTORY OF ALCOHOL
		Current	ALLERGY: PENICILLIN
		Current	ARTHRITIS
		Current	C - SECTION,
		Current	HYPERTENSION (ON MEDS)
		Current	HYSTERECTOMY
		Current	REFRACTION ERROR
	E0035022	Past	TUBAL LIGATION
		Current	ALLERGY TO PENICILLIN
	E0039003	Past	BACK INJURY
		Past	NECK INJURY
		Current	ANEMIA
		Current	BILATERAL CYSTS ON INNER AND OUTER CANTHUS BOTH EYES AND EYELIDS
	E0041002	Current	HYPERTENSION SINCE 2001
		Current	INTERMITTENT AGITATION SINCE 03/2002
		Current	INTERMITTENT BACK PAIN SINCE 1996
		Current	INTERMITTENT HEADACHE SINCE 2001
		Current	INTERMITTENT INSOMNIA SINCE 2002
		Current	INTERMITTENT LEFT TINNITUS SINCE 2002
		Current	INTERMITTENT NECK PAIN SINCE 1996
		Current	INTERMITTENT SINUSITIS SINCE 2000
	E0041005	Past	APPENDITICITIS WITH APPENDECTOMY IN 1975
		Past	BRONCHITIS IN 1970 - 1990
		Past	DEVIATED SEPTUM WITH SURGERY IN 1990

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	PAST OR CURRENT	CONDITION
PLACEBO (BIPOLAR II)	E0041005	Past	HEMORRHOIDS WITH REMOVAL IN 1999
		Past	HIATAL HERNIA WITH REPAIR IN 1957
		Past	INTERMITTENT SINUSITIS 1970 - 1990
		Past	KIDNEY STONES IN 1997
		Past	KNEE SURGERY IN 1978
		Past	LEFT WRIST BROKEN IN 1973
		Past	SPINAL INJURY IN 02/2001
		Past	TONSILLITIS WITH TONSILLECTOMY IN 1960
		Current	INTERMITTENT ABDOMINAL PAIN SINCE 2002
		Current	INTERMITTENT ANXIETY SINCE 1999
		Current	INTERMITTENT ARM PAIN SINCE 02/2001
		Current	INTERMITTENT BACK PAIN SINCE 02/2001
		Current	INTERMITTENT CONSTIPATION SINCE 1999
		Current	INTERMITTENT COUGH SINCE 1972
		Current	INTERMITTENT DECREASED TESTOSTERONE SINCE 03/2002
		Current	INTERMITTENT DIARRHEA SINCE 1978
		Current	INTERMITTENT HEADACHES SINCE 1980
		Current	INTERMITTENT HYPERTENSION SINCE 2000
		Current	INTERMITTENT INDIGESTION SINCE 2002
		Current	INTERMITTENT INSOMNIA SINCE 1994
		Current	INTERMITTENT KNEE PAIN SINCE 1978
		Current	INTERMITTENT LEG PAIN SINCE 02/2001
		Current	INTERMITTENT NAUSEA SINCE 1980
		Current	INTERMITTENT NECK PAIN SINCE 02/2001

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Listing 12.2.4.3 Physical Examination

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	SCREEN	04APR2003	Yes	CARDIOVASCULAR	HIGH BLOOD PRESSURE, NEEDS TO HAVE BLOOD PRESSURE MONITORED. START ON BP MED BEFORE STARTING STUDY
	E0002015	SCREEN	28MAY2003	Yes	MUSCULOSKELETAL/EXTREMITIES	TENDERNESS OVER LOWER LEFT RIB
	E0003004	SCREEN	03DEC2002	Yes	LUNGS	NON PRODUCTIVE COUGH
					SKIN	HEALING SHINGLES ON LEFT SIDE OF NECK
		FINAL	07JAN2003		HEAD AND NECK	INSIDE LEFT EAR, IRROTATED DUE TO Q-TIP NCII BED
	E0003007	SCREEN	19DEC2002	Yes	SKIN	SPIDER ANGIOMA ON UPPER STERNUM, LEFT HAND & FOREARM (LIFELONG)
	E0004013	SCREEN	08JAN2003	Yes	GENERAL APPEARANCE	SLIGHTLY OBESE
					SKIN	2 TATOOS, LEFTLEG & STOMACH
		FINAL	05FEB2003		ABDOMEN	IN DURATION LEFT BREAST MEDIUM TO NIPPLE WITH TENDERNESS
	E0005002	SCREEN	23SEP2002	Yes	SKIN	TATOOS
	E0005004	SCREEN	24SEP2002	Yes	CARDIOVASCULAR	HEART MURMUR
					HEAD AND NECK	DECREASED VISUAL ACUITY (WEARS CORRECTIVE LENSES)
	E0005024	SCREEN	05FEB2003	Yes	GENERAL APPEARANCE	OVERWEIGHT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.3 Physical Examination

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	SCREEN	03MAR2003	Yes	SKIN	TATTOO ON L FOREARM AND SLIGHT ? RASH ON NECK AT BACK ON HIS CHEST.
	E0005037	SCREEN	30APR2003	Yes	GENERAL APPEARANCE	OBESE
					MUSCULOSKELETAL/EXTREMITIES	POST BACK SURGERY
					NEUROLOGICAL	NUMBNESS IN RIGHT FOOT WITH MILD RIGHT LEG WEAKNESS
		FINAL	02JUL2003		MUSCULOSKELETAL/EXTREMITIES	RIGHT KNEE TENDERNESS SECONDARY TO ARTHRITIS
	E0005042	SCREEN	19JUN2003	Yes	SKIN	PSORASIS ON HANDS
	E0006005	SCREEN	25NOV2002	Yes	HEAD AND NECK	BILATERAL TONSILS SLIGHTLY ENLARGED RIGHT EAR MEMBRANE DULL
	E0006018	SCREEN	06MAR2003	Yes	HEAD AND NECK	BILATERAL OCCLUSION/BOTH EARS.
					SKIN	FACIAL ROSACEA/BOTH CHEEKS
	E0010012	FINAL	05MAR2003		HEAD AND NECK	RIGHT EXTERNAL OTITIS PROGRESSIVELY RESOLVING WITH TREATMENT
	E0010024	SCREEN	23APR2003	Yes	GENERAL APPEARANCE	SLIGHTLY OVERWEIGHT
	E0010032	SCREEN	03JUL2003	Yes	HEAD AND NECK	MILD PHARINGEAL HYPERHEMIA
	E0013009	SCREEN	26MAR2003	Yes	ABDOMEN	"MILD" TENDERNESS IN EPIGASTRIC REGION
	E0014006	SCREEN	11MAR2003	Yes	GENERAL APPEARANCE	MORBIDLY OBESE

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	FINAL	21MAY2003		LYMPH NODES	RED THROAT; INCREASED SUBMANDULAR GLANDS
	E0014010	SCREEN	15APR2003	Yes	ABDOMEN	MILD, TENDER LEFT, UPPER QUADRANT UMBILICAL HERNIA, SURGICAL SCARS
					GENERAL APPEARANCE	OVERWEIGHT
					LUNGS	DECREASED BREATH SOUNDS
	E0019004	SCREEN	30OCT2002	Yes	SKIN	TATTOOS LEFT SHOULDER, LOW BACK
	E0019026	SCREEN	10FEB2003	Yes	GENERAL APPEARANCE	MODERATELY OBESE
	E0020006	SCREEN	26NOV2002	Yes	GENERAL APPEARANCE	LEFT HAND SCAR LEFT KNEE SCAR
	E0020007	SCREEN	19DEC2002	Yes	HEAD AND NECK	RIGHT EAR CERUMEN. LEFT EAR POSSIBLE SCARRING.
	E0022008	SCREEN	05NOV2002	Yes	CARDIOVASCULAR	ABSENT LEFT RADIAL PULSE
					HEAD AND NECK	ABSENT MUSCLE MASS LEFT SIDE OF NECK WELL HEALED SURGICAL SCARS LEFT RIGHT NECK AND ANTERIOR ON NECK
					SKIN	WELL HEALED SURGICAL SCAR LEFT FOREARM PART OF LEFT SIDE OF TONGUE RESECTED
	E0022022	FINAL	27FEB2003		GENERAL APPEARANCE	IN WHEEL CHAIR DUE TO CONVERSION DISORDER

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	FINAL	27FEB2003		MUSCULOSKELETAL/EXTREMITIES	CONVERSION DISORDER VIBRATION, SOFT TOUCH ABSENT IN LOWER MOTOR ABSENT IN LOWER EXTREMITIES
					NEUROLOGICAL	VIBRATION, SOFT TOUCH ABSENT IN LOWER EXTREMITY. (DUE TO CONVERSION DISORDER)
	E0022032	SCREEN	11FEB2003	Yes	ABDOMEN	WELL HEALED SURGICAL SCAR - ABDOMEN
	E0022035	SCREEN	11FEB2003	Yes	MUSCULOSKELETAL/EXTREMITIES	MILD TREMOR
	E0022063	SCREEN	30APR2003	Yes	ABDOMEN SKIN	SURGICAL SCAR SURGICAL SCAR LEFT AXILLA
	E0023008	SCREEN	23JAN2003	Yes	ABDOMEN	APPENDECTOMY SCAR - 1994
	E0023034	FINAL	05AUG2003		ABDOMEN	OVARIAN CYST
	E0023037	SCREEN	11JUN2003	Yes	SKIN	TATTOO ON LEFT ARM
	E0023044	SCREEN	08JUL2003	Yes	SKIN	SCAR LUMBAR AREA
	E0026018	SCREEN	06MAR2003	Yes	GENERAL APPEARANCE HEAD AND NECK	OBESE TRACHEOSTAMY SCAR
	E0026029	SCREEN	02JUL2003	Yes	ABDOMEN	RIGHT LOWER QUADRANT SCAR STATUS POST LIVER BIOPSY
	E0027003	FINAL	25MAR2003		LUNGS	WHEEZES IN R LUNG
	E0028008	SCREEN	08OCT2002	Yes	ABDOMEN	OBESE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	SCREEN	10OCT2002	Yes	ABDOMEN	OBESE
	E0028017	SCREEN	12NOV2002	Yes	ABDOMEN SKIN	OBESE RASH ON NOSE
	E0028038	SCREEN	18APR2003	Yes	ABDOMEN	OBESE
	E0028045	SCREEN	09JUN2003	Yes	HEAD AND NECK	ABSENT LOWER TEETH
	E0030001	SCREEN	12NOV2002	Yes	NEUROLOGICAL	RESTING AND INTENTIONAL TREMOR
	E0030008	SCREEN	07JAN2003	Yes	SKIN	MULTIPLE TATTOOS ARM, BACK, NECK
	E0030011	SCREEN	16JAN2003	Yes	HEAD AND NECK SKIN	TONGUE PIERCED HEAD, NECK, BACK EACH ARM TATTOOS LEFT AND RIGHT ARM
	E0030022	SCREEN	06JUN2003	Yes	SKIN	WELL HEALED ABDOMINAL SCAR AND LEFT KNEE SCAR
	E0033015	SCREEN	10APR2003	Yes	SKIN	RIGHT HERNIA & APPENDECTOMY SURGERY ABDOMINAL SCARS - WELL - HEALED
	E0034002	SCREEN	14MAR2003	Yes	GENERAL APPEARANCE SKIN	OBESE MALE MIDLINE SCAR 3 ON BACK (SURGICAL)
	E0034003	SCREEN	11APR2003	Yes	SKIN	2 SCARS FROM INGUINAL HERNIA SURGERY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	SCREEN	25APR2003	Yes	ABDOMEN	4" SCAR BELOW UMBILICUS 8" VERTICAL MIDLINE SURGICAL SCAR NCS
					GENERAL APPEARANCE	OBESE
					SKIN	2 TATTOOS
	E0035003	SCREEN	15NOV2002	Yes	MUSCULOSKELETAL/EXTREMITIES	RECENT INJURY TO RT MIDDLE TOE REDDEMED, TOENAIL FELL OFF
	E0035005	SCREEN	26NOV2002	Yes	ABDOMEN	SCAR OF GASTROPLASTY
	E0037006	SCREEN	06MAR2003	Yes	HEAD AND NECK	THROAT IRRITATION
	E0039025	SCREEN	26FEB2003	Yes	SKIN	SCAR ANTERIOR CHEST SECONDARY TO LACERATION
	E0039044	SCREEN	05MAY2003	Yes	MUSCULOSKELETAL/EXTREMITIES	BILATERAL NAIL FUNGUS
	E0039046	SCREEN	06MAY2003	Yes	GENERAL APPEARANCE	OBESE
	E0039051	SCREEN	22MAY2003	Yes	SKIN	SCAR RIGHT CHEEK AREA
		FINAL	12AUG2003		HEAD AND NECK	BROKEN TOOTH LOWER RIGHT NUMBER 5
	E0039057	FINAL	09SEP2003		MUSCULOSKELETAL/EXTREMITIES	PULLED HAMSTRING LEFT THIGH DUE TO BASKETBALL INJURY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	SCREEN	26FEB2003	Yes	CARDIOVASCULAR	HYPERTENSION - TREATED ADEQUATELY
					MUSCULOSKELETAL/EXTREMITIES	STARTING CARPEL TUNNEL SYNDROME
	E0003018	SCREEN	06MAY2003	Yes	HEAD AND NECK	RIGHT TYMPANIC MEMBRANE OBSCURED BY WAX
	E0005011	SCREEN	16OCT2002	Yes	SKIN	TATTOO SHOULDER - RIGHT
	E0007008	SCREEN	07APR2003	Yes	GENERAL APPEARANCE	OBESITY QUADRANT W. H. S. S. R UPPER QUADRANT Q ABDOMEN
					SKIN	W. H. S. S. HORIZONTAL LOWER ABDOMENT (WELL HEALED SURGICAL SCAR)
	E0009009	SCREEN	27FEB2003	Yes	LUNGS	MILD INSPIRATORY WHEEZING
	E0011004	SCREEN	17DEC2002	Yes	SKIN	MULTIPLE LIPOMAS
	E0011007	SCREEN	12DEC2002	Yes	ABDOMEN	HEALED CHOLECYSTECTOMY SCAR
					GENERAL APPEARANCE	MODERATELY OBESE
	E0011018	SCREEN	15MAY2003	Yes	GENERAL APPEARANCE	MULTIPLE BODY PIERCINGS
	E0011024	SCREEN	17JUN2003	Yes	SKIN	TATTOO ON RIGHT UPPER ARM
	E0019007	FINAL	07JAN2003		GENERAL APPEARANCE	BRUISES DUE TO FALLING OFF BIKE (RACING MOTORCYCLE)
	E0019049	SCREEN	03JUL2003	Yes	MUSCULOSKELETAL/EXTREMITIES	BELOW THE KNEE CAST ON RIGHT LEG

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	SCREEN	01APR2003	Yes	MUSCULOSKELETAL/EXTREMITIES	TENDERNESS TO PALPATION LEFT NECK AND SHOULDER DECREASED LEFT UPPER EXTREMITY STRENGTH DUE TO PAIN
	E0023027	SCREEN	07MAY2003	Yes	ABDOMEN	OBESITY
	E0026014	SCREEN	12FEB2003	Yes	NEUROLOGICAL	HAND TREMORS R+ > LEFT
	E0026019	SCREEN	10MAR2003	Yes	ABDOMEN	MIDLINE SCAR FROM TUBAL LIGATION
	E0029030	SCREEN	13MAY2003	Yes	HEAD AND NECK	MANY DECAYED AND ROTTEN TEETH
	E0031008	SCREEN	05FEB2003	Yes	ABDOMEN	TENDER R & LLQ, HISTORY OVARIN CYSTS
	E0031021	FINAL	19JUN2003		HEAD AND NECK SKIN	SUTURES IN PLACE SUTURES IN PLACE
	E0035023	SCREEN	06MAY2003	Yes	MUSCULOSKELETAL/EXTREMITIES	SCAR OF OPERATION ON LEFT HAND WRIST (BONE GRADT & PIN IMPLANT)
	E0039052	SCREEN	29MAY2003	Yes	GENERAL APPEARANCE	OBESITY
	E0039056	SCREEN	01JUL2003	Yes	ABDOMEN	MIDLINE VERTICAL SURGICAL SCAR
	E0040003	SCREEN	09JUL2003	Yes	SKIN	RIGHT ARM CHEMICAL BURNS

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	FINAL	31MAR2003		HEAD AND NECK	COMPLAINS OF BLURRED VISION INCREASED AT A DISTANCE
	E0003011	SCREEN	28JAN2003	Yes	HEAD AND NECK	RETRACKED TEMPANIC MEMBRANE
					SKIN	PSORIASIS, MULTIPLE SITES
	E0003016	SCREEN	01MAY2003	Yes	HEAD AND NECK	SWELLING - RIGHT CHEEK; POST - SURGICAL
	E0003019	SCREEN	19JUN2003	Yes	THYROID	SOFT ENLARGEMENT IN LEFT LOBE NOT TENDER
	E0003020	SCREEN	24JUN2003	Yes	CARDIOVASCULAR	LOW RATE
					MUSCULOSKELETAL/EXTREMITIES	STIFFNESS IN GAIT
	E0004001	SCREEN	23SEP2002	Yes	ABDOMEN	TATOO ABOVE UMBILICUS
					HEAD AND NECK	RIGHT TYMPANIC MEMBRANE BLOCKED BY SERUM
		FINAL	05NOV2002		MUSCULOSKELETAL/EXTREMITIES	PAIN ON PERCUSSION BILATERAL FLANKS
	E0004009	SCREEN	17DEC2002	Yes	HEAD AND NECK	PIERCED TONGUE
					SKIN	ACNE FACIAL SCARS
	E0004012	SCREEN	07JAN2003	Yes	ABDOMEN	PIERCED BELLYBUTTON
	E0004015	SCREEN	06FEB2003	Yes	HEAD AND NECK	WEARS GLASSES, PRESBYOPIA
					NEUROLOGICAL	SLIGHT ASSYMETRY, RIGHT SIDE OF MOUTH SLIGHTLY LOWER
	E0005005	SCREEN	24SEP2002	Yes	GENERAL APPEARANCE	MILD ACNE ON FACE
	E0005007	SCREEN	02OCT2002	Yes	SKIN	TATTOO LEFT SHOULDER

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	FINAL	04DEC2002		MUSCULOSKELETAL/EXTREMITIES	RIGHT KNEE PATELLOR TENDERNESS
	E0005008	SCREEN	08OCT2002	Yes	GENERAL APPEARANCE	OVERWEIGHT
					MUSCULOSKELETAL/EXTREMITIES	LUMBAR TENDERNESS DUE TO BACK INJURY IN 1996
		FINAL	11DEC2002		LUNGS	MILD BRONCHIAL CONGESTION
	E0005009	SCREEN	09OCT2002	Yes	SKIN	MULTIPLE TATOOS ON BACK & ARM
	E0005010	SCREEN	14OCT2002	Yes	GENERAL APPEARANCE	OBESITY
	E0005014	SCREEN	05NOV2002	Yes	SKIN	FOLLICULITIS BARBAE
	E0007015	SCREEN	09JUL2003	Yes	SKIN	LINEAR RASH SCATTERED LOWER EXTREMITY MODERATE
	E0009001	SCREEN	29OCT2002	Yes	GENERAL APPEARANCE	MODERATELY OBESE
					SKIN	MIDLINE ABDOMINAL SCAR
	E0010002	SCREEN	14NOV2002	Yes	HEAD AND NECK	MILD HYPEREMIA LEFT EAR CANAL AND TIMPANIC MEMBRANE
	E0010009	SCREEN	18DEC2002	Yes	HEAD AND NECK	HYPOACUSSIS - USES HEARING AIDS
					SKIN	WELL HEALED MID - LINE TOVACO ABDOMINAL, WELL HEALED CICATRIX
	E0010010	SCREEN	20DEC2002	Yes	SKIN	PATCH OF DRY SCALY ECZEMATOUS SKIN POSTERIOR SCALP
	E0010014	SCREEN	14JAN2003	Yes	GENERAL APPEARANCE	OVERWEIGHT

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	SCREEN	14JAN2003		SKIN	THERE ARE HOWEVER WELL HEALED SURGICAL CICATRICES, NCS
	E0010029	SCREEN	10JUN2003	Yes	ABDOMEN	PROMINENT - MILD PAIN OR DEEP PALPATION RLQ
					GENERAL APPEARANCE	SOMEWHAT OBESE
					SKIN	SKIN GRAFT ABOVE LEFT ANKLE (THIS UNS RECONSTRUCTIVE SURGERY FOR OLD BURN)
	E0011022	SCREEN	02JUN2003	Yes	ABDOMEN	HEALED SURGICAL SCAR
					SKIN	THREE TATTOOS
	E0014012	SCREEN	19MAY2003	Yes	NEUROLOGICAL	FINE TREMOR - HANDS AND NECK
	E0018007	FINAL	10JAN2003		MUSCULOSKELETAL/EXTREMITIES	DEEPVEIN THOMBOSIS LEFT LEG INCREASED CIRCUMFRENCE SECONDARY TO ABOVE DVT LEFT LEG
	E0019015	SCREEN	19DEC2002	Yes	MUSCULOSKELETAL/EXTREMITIES	TRAUMATIC AMPUTATION LEFT HAND
	E0020021	SCREEN	09MAY2003	Yes	GENERAL APPEARANCE	OBESE
		FINAL	14JUL2003		MUSCULOSKELETAL/EXTREMITIES	BILATERAL EDEMA
	E0022025	SCREEN	08JAN2003	Yes	ABDOMEN	WELL HEALED CHOLECYSTECTOMY SURGICAL SCAR
	E0022033	SCREEN	11FEB2003	Yes	ABDOMEN	WELL - HEALED SURGICAL SCAR

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	SCREEN	20FEB2003	Yes	NEUROLOGICAL	MILD BILATERAL HAND TREMOR
	E0022039	SCREEN	27FEB2003	Yes	THYROID	MILDLY ENLARGED THYROID (1.5 - 2 X)
	E0022058	SCREEN	11APR2003	Yes	ABDOMEN	SURGICAL SCAR
	E0022062	SCREEN	25APR2003	Yes	ABDOMEN	WELL HEALED SURGICAL SCAR
	E0023006	FINAL	11FEB2003		LUNGS	BILATERAL WHEEZE SECONDARY TO ASTHMA
	E0026002	SCREEN	05NOV2002	Yes	HEAD AND NECK	SURGICAL SCAR LEFT NECK S/P FAT INCISION
	E0026007	SCREEN	06JAN2003	Yes	GENERAL APPEARANCE	OBESE - NCS
	E0028023	SCREEN FINAL	14JAN2003 27JUN2003	Yes	HEAD AND NECK GENERAL APPEARANCE	UPPER & LOWER DENTURES EDENTULOUS
	E0028025	SCREEN	08JAN2003	Yes	MUSCULOSKELETAL/EXTREMITIES	SCAR RIGHT ROTATOR CUFF PINPOINT SCAR RIGHT GROIN - CARDIAC CATHETER
	E0028033	SCREEN	18MAR2003	Yes	GENERAL APPEARANCE	OBESE
	E0028037	SCREEN	09JUN2003	Yes	GENERAL APPEARANCE	OBESE; MARKED PSYCHOMOTOR RETARDATION
	E0028039	SCREEN	02MAY2003	Yes	ABDOMEN MUSCULOSKELETAL/EXTREMITIES	APPENDECTOMY SCAR SCAR ON LEFT KNEE
	E0028046	SCREEN	17JUN2003	Yes	GENERAL APPEARANCE	OBESE
	E0029008	SCREEN	09DEC2002	Yes	ABDOMEN	LOWER RIGHT QUADRANT TENDERNESS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	SCREEN	14JAN2003	Yes	MUSCULOSKELETAL/EXTREMITIES	MUSCLES BESIDE SPINE ACHE
	E0029012	SCREEN	04FEB2003	Yes	SKIN	PIMPLES ON CHEST, FACE & BACK - NCS
	E0029015	SCREEN	11FEB2003	Yes	MUSCULOSKELETAL/EXTREMITIES	SORE RIGHT SHOULDER
	E0030014	SCREEN	14FEB2003	Yes	MUSCULOSKELETAL/EXTREMITIES	DEFORMITY LEFT ARM AT ELBOW SECONDARY TO FRACTURE
	E0030024	SCREEN	17JUN2003	Yes	SKIN	BURN SCARS ON LEFT SIDE OF BODY
	E0031030	FINAL	21AUG2003		NEUROLOGICAL	3+ HYPER REFLEXIC BILATERAL
	E0035001	SCREEN	12NOV2002	Yes	ABDOMEN	SCARS OF APPENDECTOMY AND GALL BLADDER SURGERY
					GENERAL APPEARANCE	OVERWEIGHT
	E0035006	SCREEN	03DEC2002	Yes	ABDOMEN	SCAR FROM C - SECTION
	E0039026	FINAL	02MAY2003		MUSCULOSKELETAL/EXTREMITIES	PLUS 2 PITTING EDEMA SECONDARY TO FLUID RETENTION, WHICH IS CAUSING WEIGHT GAIN
	E0039028	SCREEN	03MAR2003	Yes	GENERAL APPEARANCE	OBESITY
	E0039032	SCREEN	07MAR2003	Yes	GENERAL APPEARANCE	CENTRAL OBESITY
	E0039034	SCREEN	12MAR2003	Yes	GENERAL APPEARANCE	OBESITY

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	SCREEN	22OCT2002	Yes	NEUROLOGICAL	NUMBNESS IN ARMS DURING SLEEP
	E0005031	SCREEN	26MAR2003	Yes	SKIN	TATOO RIGHT ANKLE
	E0005033	SCREEN	08APR2003	Yes	SKIN	TATOO LOWER BACK
	E0005038	SCREEN	05MAY2003	Yes	ABDOMEN GENERAL APPEARANCE	MARKED PURPLE STRIA OBESE
	E0007009	FINAL	28APR2003		SKIN	CIRCUMSCRIBED ERTHEMATOUS ANNULAR LESION LEFT SIDE NECK
	E0010005	SCREEN	10DEC2002	Yes	GENERAL APPEARANCE	OBESE
	E0011016	SCREEN	14APR2003	Yes	MUSCULOSKELETAL/EXTREMITIES	SURGICAL SCAR ON LEFT KNEE
	E0011020	SCREEN	01MAY2003	Yes	SKIN	MULTIPLE MOLES ON BACK, NECK, UPPER ARMS. SCAR ON LEFT SHOULDER.
	E0018003	SCREEN	19NOV2002	Yes	GENERAL APPEARANCE	OBESITY
	E0018013	SCREEN	17JAN2003	Yes	SKIN	CONTACT DERMATITIS
	E0019016	SCREEN	30DEC2002	Yes	GENERAL APPEARANCE	EXOGENOUS OBESITY
	E0019035	SCREEN	11MAR2003	Yes	GENERAL APPEARANCE	MILDLY OBESE
	E0019040	SCREEN	08MAY2003	Yes	GENERAL APPEARANCE	OBESITY
	E0022044	SCREEN	11MAR2003	Yes	MUSCULOSKELETAL/EXTREMITIES	THORACIC SCOLIOSIS
	E0023011	SCREEN	28JAN2003	Yes	ABDOMEN THYROID	GALLBLADDER SCAR HYPOTHYROIDISM

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	SCREEN	22MAY2003	Yes	ABDOMEN	OBESITY
	E0026003	SCREEN	25NOV2002	Yes	MUSCULOSKELETAL/EXTREMITIES	PAIN RIGHT SHOULDER WITH PALPATION
		FINAL	03FEB2003		ABDOMEN	DIFFUSELY TENDER, CAUSE ACUTE PROSTATITIS
	E0026005	SCREEN	23DEC2002	Yes	LYMPH NODES	S/P LYMPH NODE DISECTION
					MUSCULOSKELETAL/EXTREMITIES	S/P RIGHT MASTECTOMY
					NEUROLOGICAL	MILD HEAD TREMOR
	E0026009	SCREEN	10JAN2003	Yes	ABDOMEN	FAINT C - SECTION SCAR
	E0026023	SCREEN	23APR2003	Yes	MUSCULOSKELETAL/EXTREMITIES	KYPHOSCOLIOSIS
	E0027016	SCREEN	19MAR2003	Yes	ABDOMEN	OBESE
	E0031005	SCREEN	13DEC2002	Yes	GENERAL APPEARANCE	OBESE
	E0031006	SCREEN	31JAN2003	Yes	GENERAL APPEARANCE	OBESE
		FINAL	15APR2003		NEUROLOGICAL	BIPEDAL DISTAL NEUROPATHY DUE TO TYPE II DIABETES
					SKIN	ABRASIONS
	E0034009	SCREEN	10JUN2003	Yes	SKIN	TATTOO ON LEFT ARM AND AROUND ANKLE
	E0039019	SCREEN	20JAN2003	Yes	GENERAL APPEARANCE	OBESITY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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PLACEBO (BIPOLAR I)	E0002003	SCREEN	03JAN2003	Yes	MUSCULOSKELETAL/EXTREMITIES	JOINT ABNORMALITIES SECONDARY TO RHEUMATOID ARTHRITIS
	E0002004	SCREEN	17JAN2003	Yes	HEAD AND NECK	ERRYTHEMA NASAL MUCASA ERRYTHEMA PHARYNX WITH COBBLESTONE APPEARANCE
					LUNGS	HAVING PLURITIC CHEST PAIN
	E0003008	SCREEN	21JAN2003	Yes	HEAD AND NECK	POST NASAL DRIP, CONGESTION
					LYMPH NODES	LEFT NODE TENDER - NECK
					NEUROLOGICAL	DECREASED REFLEX BILATERAL
	E0004003	SCREEN	02OCT2002	Yes	ABDOMEN	WELL HEALED SURGICAL SCAR
	E0004006	SCREEN	28OCT2002	Yes	GENERAL APPEARANCE	SLIGHTLY OBESE
					NEUROLOGICAL	MILD TREMOR HANDS
					SKIN	WELL HEALED SURGICAL SCAR
	E0004024	SCREEN	25JUN2003	Yes	NEUROLOGICAL	RIGHT FACIAL DROOP
	E0005006	SCREEN	24SEP2002	Yes	SKIN	TATTOO LEFT ARM
	E0005019	SCREEN	19DEC2002	Yes	MUSCULOSKELETAL/EXTREMITIES	S/P PELVIC FRACTURE & SURGICAL REPAIR X 4
		FINAL	23JAN2003		SKIN	MINOR ABRASION RIGHT FIST
	E0005026	SCREEN	26FEB2003	Yes	SKIN	TATTOO ON LEFT WRIST, SHOULDER , NECK
	E0005039	SCREEN	15MAY2003	Yes	GENERAL APPEARANCE	OBESITY
	E0005043	SCREEN	01JUL2003	Yes	GENERAL APPEARANCE	OBESITY

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PLACEBO (BIPOLAR I)	E0007006	FINAL	26MAR2003		SKIN	RASH - EXTREMITIES, THORAX & SCALP
	E0009004	FINAL	18DEC2002		SKIN	ECCHYMOSIS LEFT SHOULDER (SCAPULAR AREA) AND LEFT CHEEK BONE
	E0009012	SCREEN	16JUN2003	Yes	SKIN	APPENDECTOMY SCAR LOWER RIGHT QUADRANT
	E0010028	SCREEN	09JUN2003	Yes	GENERAL APPEARANCE	2 TATOOS: RIGHT UPPER BACK AND LOWER BACK
					MUSCULOSKELETAL/EXTREMITIES	BILATERAL BREAST IMPLANT
		FINAL	15JUL2003		HEAD AND NECK	SHALLOW ULCERATION LEFT CHEEK
	E0011008	SCREEN	23JAN2003	Yes	SKIN	MULTIPLE TATOOS BURN SCAR LEFT ARM.
	E0011009	SCREEN	19DEC2002	Yes	ABDOMEN	HEALED LOWER RIGHT SURGICAL SCAR
					MUSCULOSKELETAL/EXTREMITIES	CONTRACTURE OF LEFT RING FINGER; SCOLIOSIS
					SKIN	3 MOLES ON BACK; 3 SMALL LIPOMAS
	E0013003	SCREEN	07NOV2002	Yes	ABDOMEN	GALLBLADDER INCISION SCAR 1982 INTESTINAL BYPASS INCISION SCAR 1967
					GENERAL APPEARANCE	OBESE
	E0013013	SCREEN	01MAY2003	Yes	SKIN	TATTOO RT SHOULDER & BOTH ANKLES
	E0014004	SCREEN	04MAR2003	Yes	ABDOMEN	TENDER HYPOGASTRIUM
					HEAD AND NECK	DECREASED HEARING; CERUMEN PLUG RIGHT EAR

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.3 Physical Examination

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
PLACEBO (BIPOLAR I)	E0014004	SCREEN	04MAR2003		LUNGS	DECREASED BREATH SOUNDS
					NEUROLOGICAL	DECREASED STRENGTH UPPER EXTREMITY BILATERAL
	E0014009	FINAL	16MAY2003		HEAD AND NECK	RIGHT EARDRUM RETRACTED - NO INFECTION
	E0018015	SCREEN	21JAN2003	Yes	SKIN	ROSACEA
	E0020015	SCREEN	18MAR2003	Yes	MUSCULOSKELETAL/EXTREMITIES	ABNORMAL GAIT DUE TO L5 HERNIATION
	E0020017	SCREEN	27MAR2003	Yes	HEAD AND NECK	RIGHT EAR CERUMEN
	E0020020	SCREEN	07MAY2003	Yes	GENERAL APPEARANCE	THIN
					SKIN	PSORIASIS
	E0022005	SCREEN	17OCT2002	Yes	ABDOMEN	WELL HEALED CHOLECYSTECTOMY SCAR
	E0022011	SCREEN	20NOV2002	Yes	MUSCULOSKELETAL/EXTREMITIES	BILATERAL BUNIONECTOMY SCARS
					SKIN	SCAR LEFT TIBIA REGION - WELL HEALED
	E0022043	SCREEN	10MAR2003	Yes	NEUROLOGICAL	HORIZONTAL NYSTAGMUS
	E0022054	SCREEN	04APR2003	Yes	MUSCULOSKELETAL/EXTREMITIES	SPRAIN IN RIGHT ANKLE
	E0022070	SCREEN	05JUN2003	Yes	NEUROLOGICAL	SLIGHT DECREASE IN STRENGTH RIGHT UPPER & LOWER EXTREMITIES
					SKIN	WELL HEALED STERNOTOMY SCAR
	E0023001	SCREEN	24OCT2002	Yes	ABDOMEN	C-SECTION SCAR

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.3 Physical Examination

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
PLACEBO (BIPOLAR I)	E0023001	SCREEN	24OCT2002		THYROID	HYPOTHYROID
	E0026012	SCREEN	05FEB2003	Yes	MUSCULOSKELETAL/EXTREMITIES	VERTICAL SCAR RIGHT ANKLE
	E0026020	SCREEN	28MAR2003	Yes	ABDOMEN	APPENDECTOMY SCAR.
	E0026024	SCREEN	25APR2003	Yes	ABDOMEN	MIDLINE SCAR STATUS POST LAPAROTOMY, EROSIVE ULCER
	E0026028	SCREEN	06JUN2003	Yes	GENERAL APPEARANCE	OBESE, NCS
	E0028001	SCREEN	20SEP2002	Yes	ABDOMEN	OBESE
	E0028003	SCREEN	23SEP2002	Yes	GENERAL APPEARANCE	OBESE
					MUSCULOSKELETAL/EXTREMITIES	DEGENERATIVE ARTHRITIS BOTH KNEES
					SKIN	MELANOMA EXCISION SCAR
		FINAL	26NOV2002		ABDOMEN	CHOLECYSTECTOMY SCAR
					HEAD AND NECK	TENDER @ C6
	E0028010	SCREEN	15OCT2002	Yes	MUSCULOSKELETAL/EXTREMITIES	BREAST IMPLANTS
	E0028030	SCREEN	26FEB2003	Yes	ABDOMEN	LEFT INGUINAL HERNIA
	E0028031	SCREEN	06MAR2003	Yes	GENERAL APPEARANCE	OBESE
	E0028047	SCREEN	08JUL2003	Yes	GENERAL APPEARANCE	OBESE
					LUNGS	SLIGHT DECREASED BREATH SOUNDS LEFT LOWER LOBE
					SKIN	SCAR LEFT CHEST ANTERIOR & POSTERIOR
	E0029014	SCREEN	28JAN2003	Yes	MUSCULOSKELETAL/EXTREMITIES	BILATERAL KNEE TENDERNESS - NCS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
PLACEBO (BIPOLAR I)	E0029014	SCREEN	28JAN2003		SKIN	ROSACEA AROUND NOSE AND MOUTH; ECZEMA OF HANDS AND FEET
	E0029032	SCREEN	22MAY2003	Yes	MUSCULOSKELETAL/EXTREMITIES	AMPUTATED LEFT PINKY
	E0029033	SCREEN	27MAY2003	Yes	HEAD AND NECK	POSTERIOR TENDERNESS
	E0029039	SCREEN	10JUL2003	Yes	SKIN	VERTICAL SCAR RIGHT FOREHEAD & CHEEK
	E0030003	FINAL	24DEC2002		LUNGS	RHONCHI BILATERAL
	E0030009	SCREEN	10JAN2003	Yes	NEUROLOGICAL	RIGHT PATELLAR REFLEX DECREASED
					SKIN	LEFT AND RIGHT ARM SCARS SECONDARY TO LASER TATTOO REMOVAL
	E0030016	SCREEN	21FEB2003	Yes	MUSCULOSKELETAL/EXTREMITIES	RIGHT PATELLA 1/2 NORMAL SIZE
					SKIN	RIGHT KNEE SURGICAL SCAR
	E0031001	SCREEN	14NOV2002	Yes	GENERAL APPEARANCE	OBESE
	E0031018	SCREEN	01APR2003	Yes	GENERAL APPEARANCE	OBESE
	E0031023	SCREEN	21APR2003	Yes	GENERAL APPEARANCE	OBESE
	E0033010	FINAL	26MAR2003		SKIN	POST - SURGICAL SUPRAPUBIC INCISION, WELL - HEALED
	E0035002	SCREEN	14NOV2002	Yes	ABDOMEN	SMALL SCAR OF GALLBLADDER SURGERY
	E0035007	SCREEN	13DEC2002	Yes	MUSCULOSKELETAL/EXTREMITIES	SMALL SCAR ON RIGHT KNEE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.3 Physical Examination

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
PLACEBO (BIPOLAR I)	E0035011	SCREEN	09JAN2003	Yes	MUSCULOSKELETAL/EXTREMITIES	FUNGAL INFECTION OF TOES
	E0035020	SCREEN	11APR2003	Yes	ABDOMEN	SCAR OF HYSTERECTOMY
	E0037004	SCREEN	06FEB2003	Yes	ABDOMEN	HEALED SCAR, OBESE
	E0039030	SCREEN	12MAR2003	Yes	ABDOMEN GENERAL APPEARANCE MUSCULOSKELETAL/EXTREMITIES	GLOBULAR ABDOMINAL OBESITY STATUS POST BILATERAL TOTAL KNEE REPLACEMENT
	E0039038	SCREEN	27MAR2003	Yes	GENERAL APPEARANCE SKIN	CENTRAL OBESITY HIRSUTISM
	E0039047	SCREEN	12MAY2003	Yes	GENERAL APPEARANCE	CENTRAL OBESITY
	E0039059	SCREEN	03JUL2003	Yes	SKIN	HIRSUTISM

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.3 Physical Examination

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
PLACEBO (BIPOLAR II)	E0005034	SCREEN	08APR2003	Yes	SKIN	INGROWN TOENAIL SURGERY - BILATERAL
	E0007004	SCREEN	24JAN2003	Yes	ABDOMEN	WELL HEALED SURGICAL SCAR LOWER ABODMEN HORIZONTAL
					HEAD AND NECK	WELL HEALED SURGICAL SCAR BEHIND RIGHT EAR HEARING LOSS RIGHT EAR WEBER BONE > AIR
	E0007010	SCREEN	11APR2003	Yes	GENERAL APPEARANCE SKIN	OBESITY WHSS ABDOMINAL SCAR MIDLINE (WELL HEALED SURGICAL SCAR)
	E0007012	SCREEN	02MAY2003	Yes	NEUROLOGICAL	DECREASED MOTOR STRENGTH LEFT LOWER FACE (BELLS PALSY)
	E0011001	SCREEN	25OCT2002	Yes	SKIN	SKIN TAG ON NECK
	E0011013	SCREEN	25MAR2003	Yes	ABDOMEN MUSCULOSKELETAL/EXTREMITIES	THREE LAPAROSCOPIC SCARS DISCOLORED LEFT BIG TOE NAIL; HEALED SCAR RIGHT THUMB
					SKIN	HEALED THYROIDECTOMY SCAR
	E0011014	SCREEN	31MAR2003	Yes	ABDOMEN	HEALED MIDLINE CESEREAN SECTION SCAR
	E0011021	SCREEN	15MAY2003	Yes	ABDOMEN	HEALED SUPRAPUBIC SCAR
	E0015004	SCREEN	25NOV2002	Yes	ABDOMEN	MODERATE ABDOMENAL OBESITY
	E0019019	SCREEN	14JAN2003	Yes	SKIN	FACIAL ACNE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.3 Physical Examination

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	VISIT	DATE	OPHTHAL-MOSCOPIC EXAM PERFORMED	BODY AREA	DESCRIPTION OF ABNORMALITY
PLACEBO (BIPOLAR II)	E0019048	SCREEN	03JUL2003	Yes	CARDIOVASCULAR	HEART MURMUR
					MUSCULOSKELETAL/EXTREMITIES	SCOLIOSIS RIGHT SCAPULA AREA ELEVATED
	E0022047	FINAL	23MAY2003		SKIN	INSECT BITES ON ARM, CHEST & ABDOMEN
	E0023012	SCREEN	31JAN2003	Yes	SKIN	PT HAS 3 TATOOS - 2 ON ANKLES, 1 ON CHEST
	E0023046	SCREEN	11JUL2003	Yes	HEAD AND NECK	SUBMANDIBULAR NODE PRESENT BILAT. WITH RECENT CHANGE IN SIZE/SHAPE
	E0026021	SCREEN	14APR2003	Yes	SKIN	FACIAL CYSTIC ACNE - NCS
	E0026027	SCREEN	05JUN2003	Yes	SKIN	SMALL SCARE ON CENTER BACK
	E0029002	SCREEN	05NOV2002	Yes	THYROID	ABSENT - DUE TO SURGERY
	E0029013	SCREEN	27JAN2003	Yes	SKIN	SCAR RIGHT FACE & ARM
	E0034007	SCREEN	06MAY2003	Yes	SKIN	2 SURGICAL INCISIONS BY BREAST; 3" SCAR BY KIDNEY
	E0035010	SCREEN	06JAN2003	Yes	ABDOMEN	SCARS OF CHOLECYSTECTOMY & C - SECTION
					MUSCULOSKELETAL/EXTREMITIES	SCAR OF OPERATION RIGHT KNEE (POST SURGERY)
	E0039003	SCREEN	06NOV2002	Yes	HEAD AND NECK	MULTIPLE CYSTIC LESIONS IN INNER AND OUTER CANTHUS OF BOTH EYES AND EYELIDS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	296.5	NO	24	9	1	19	5	0
	E0002010	296.5	NO	16	11	2	8	2	0
	E0002012	296.5	YES	10	12	2	10	20	3
	E0002015	296.5	YES	28	24	5	29	9	4
	E0002018	296.5	NO	3		0	3	30	2
	E0003004	296.5	YES	8	14	2	6	180	36
	E0003005	296.5	NO	21	8	1	4	2	1
	E0003007	296.5	YES	16	74	9	8	35	5
	E0003015	296.5	YES	9	50	5	4	20	4
	E0004002	296.5	NO	13	12	1	13	13	0
	E0004013	296.5	YES	13	50	4	9	30	3
	E0004018	296.5	NO	9	11	1	7	12	1
	E0004021	296.5	NO	39	29	1	39	15	1
	E0005002	296.5	NO	39		2	33		1
	E0005004	296.5	YES	22		3			1
	E0005013	296.5	NO	10	3	0	5	2	0
	E0005024	296.5	NO	9	2	0	4	4	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DSMIV100.SAS
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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	296.5	NO	28		2	18		0
	E0005037	296.5	NO	44		1	44		1
	E0005042	296.5	NO	38		0	36		1
	E0006005	296.5	NO	12	6	2	18	2	0
	E0006018	296.5	NO	35	3	0	36	5	1
	E0007013	296.5	NO	47		0	3		0
	E0010004	296.5	NO	43	4	1	20	2	0
	E0010012	296.5	NO	33	4	0	38	2	0
	E0010024	296.5	NO	17	1	0	8	2	1
	E0010032	296.5	NO	15	2	0	15	2	1
	E0011025	296.5	NO	21	9	0	31	10	0
	E0013007	296.5	NO	38	30	1	27	30	1
	E0013009	296.5	NO	28	29	1	29	50	2
	E0014006	296.5	NO	6	6	0	5	6	1
	E0014010	296.5	NO	15	9	1	14	4	1
	E0016001	296.5	YES	2	1	1	2	3	3
	E0016004	296.5	YES	19	60	2	26		3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	296.5	NO	4	2	1	5	4	1
	E0018006	296.5	YES	18	17	2	15	20	4
	E0019004	296.5	YES	20		2	20	15	2
	E0019011	296.5	NO	8		2	38	3	1
	E0019025	296.5	NO	9	2	1	9	1	0
	E0019026	296.5	NO	10	5	1	8	4	1
	E0019043	296.5	NO	19	4	0	18	6	1
	E0020001	296.5	NO	34	7	1	13	4	1
	E0020006	296.5	NO	40	4	0	1	1	1
	E0020007	296.5	YES	10		4	8		2
	E0020011	296.5	YES	8		1	8		4
	E0020013	296.5	NO	6	3	0	7	10	2
	E0022008	296.5	NO	2	1	0	28	3	1
	E0022017	296.5	NO	12	9	1	9	5	0
	E0022018	296.5	NO	24	5	1	7	2	0
	E0022022	296.5	NO	9	8	0	6	11	1
	E0022027	296.5	NO	22	5	1	17	4	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0022030	296.5	NO	6	2	0	6	3	0
	E0022031	296.5	NO	18	3	0	3	1	0
	E0022032	296.5	NO	8	2	0	8	6	1
	E0022035	296.5	NO	8	7	1	6	2	0
	E0022036	296.5	NO	3	1	0	4	2	1
	E0022056	296.5	NO	28	7	0	5	4	1
	E0022060	296.5	NO	7	4	0	6	5	1
	E0022063	296.5	NO	17	8	0	6	2	0
	E0023008	296.5	NO	19	6	1	4	3	1
	E0023013	296.5	NO	7	2	0	5	2	0
	E0023015	296.5	NO	11	3	0	10	4	0
	E0023034	296.5	NO	5	3	1	4	1	0
	E0023037	296.5	NO	31	7	1	23	2	0
	E0023038	296.5	NO	25	9	2	18	3	0
	E0023044	296.5	NO	29	6	1	24	3	1
	E0023045	296.5	NO	16	6	0	12	4	0
	E0025002	296.5	YES	31		5	31		6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0026010	296.5	NO	13	19	1	14	26	2
	E0026017	296.5	YES	4	5	2	3	8	2
	E0026018	296.5	NO	31	49	2	5		0
	E0026025	296.5	YES	29	35	2	29	99	4
	E0026029	296.5	NO	10	8	1	7	12	2
	E0026030	296.5	NO	15	13	0	13	20	1
	E0026031	296.5	NO	31	19	0	24	15	1
	E0027003	296.5	YES	24	21	4	24	20	1
	E0028004	296.5	NO	7	3	0	4	3	1
	E0028006	296.5	NO	19	4	0	17	4	0
	E0028008	296.5	NO	4	3	0	4	4	1
	E0028009	296.5	NO	9	6	1	5	4	1
	E0028016	296.5	NO	14	4	1	14	3	0
	E0028017	296.5	NO	21	7	0	21	7	0
	E0028027	296.5	NO	40	5	0	35	4	0
	E0028029	296.5	NO	23	3	0	16	3	0
	E0028034	296.5	NO	21	4	1	6	3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	296.5	NO	33	5	1	33	4	0
	E0028043	296.5	NO	28	25	0	28	5	0
	E0028045	296.5	NO	35	6	1	17	4	0
	E0029005	296.5	YES	18	7	1	19	1	8
	E0030001	296.5	YES	27		1	6		6
	E0030008	296.5	YES	4	3	2	9	25	4
	E0030011	296.5	YES	15		5	13		2
	E0030015	296.5	YES	9	12	4	6	8	3
	E0030022	296.5	NO	17	15	1	12	6	1
	E0031002	296.5	NO	2	2	1	1	1	1
	E0031003	296.5	NO	12	2	0	15	3	0
	E0033015	296.5	NO	8	1	0	10	1	0
	E0034002	296.5	NO	32		1	3		1
	E0034003	296.5	NO	30		1	31	5	1
	E0034006	296.5	NO	12	5	1	4	2	1
	E0034008	296.5	NO	27		0	20		0
	E0035003	296.5	YES	17	14	2	11	10	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0035005	296.5	NO	36	24	1	16	4	0
	E0035014	296.5	YES	8	10	3	10	6	1
	E0035024	296.5	NO	22	14	2	26	4	0
	E0036005	296.5	YES	5	4	2	5	5	2
	E0037002	296.5	NO	19	19	1	11	10	1
	E0037005	296.5	NO	5	3	0	7	3	0
	E0037006	296.5	NO	26	15	1	24	8	1
	E0039006	296.5	NO	9	8	1	8	5	1
	E0039015	296.5	NO	36		2	33	3	0
	E0039024	296.5	YES	25		6	24		4
	E0039025	296.5	NO	31		2	30	9	1
	E0039041	296.5	YES	11		3	22		4
	E0039044	296.5	NO	25	29	1	25	15	0
	E0039046	296.5	NO	8	7	1	8	4	0
	E0039051	296.5	NO	11	6	0	10	5	1
	E0039053	296.5	NO	12	20	1	11	15	2
	E0039057	296.5	NO	31	3	0	23	4	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DSMIV100.SAS
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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	296.5	NO	12	4	0	6	6	0
	E0041008	296.5	NO	15	3	0	15	7	1
	E0042001	296.5	YES	19		4	19	24	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	296.89	NO	37		1	33	60	1
	E0003018	296.89	YES	20	99	4	20	99	2
	E0005011	296.89	YES	11		2	12		5
	E0005030	296.89	NO	9		1	2		
	E0005036	296.89	YES	26		2	26		6
	E0006015	296.89	YES	9	3	1	23	22	3
	E0006016	296.89	NO	29	7	2	4	3	1
	E0007008	296.89	NO	25		0	23		0
	E0009002	296.89	YES	32		2	33	30	4
	E0009006	296.89	NO	6		1			
	E0009009	296.89	NO	11			10		
	E0010015	296.89	NO	19	6	1	10	3	1
	E0011004	296.89	NO	19	35	0	16	30	2
	E0011007	296.89	YES	13	36	2	13	24	3
	E0011018	296.89	NO	9	11	1	7	5	0
	E0011024	296.89	NO	6	11	1	6	12	1
	E0015003	296.89	NO	43	2	0	43		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	296.89	YES	16		2	16	6	2
	E0019007	296.89	NO	16	7	0	3	5	2
	E0019014	296.89	NO	13	9	1	13	5	1
	E0019018	296.89	NO	21		1	12	8	0
	E0019022	296.89	NO	11	3	0	8	4	0
	E0019027	296.89	NO	12	11	0	11	6	1
	E0019032	296.89	NO	16		0	14	10	0
	E0019034	296.89	NO	16		1	15	12	0
	E0019036	296.89	NO	16		0	14	20	0
	E0019039	296.89	YES	8	74	1	7	20	3
	E0019041	296.89	YES	11		5	9	20	1
	E0019049	296.89	NO	11	12	0	10	15	0
	E0022052	296.89	NO	5	4	0	6	5	1
	E0022064	296.89	NO	3	3	1	4	4	1
	E0022073	296.89	NO	11	2	0	10	25	2
	E0023002	296.89	NO	8	3	0	2	3	2
	E0023017	296.89	NO	17	4	1	5	4	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	296.89	NO	39	7	0	34	4	0
	E0023027	296.89	NO	13	11	1	6	4	0
	E0023030	296.89	NO	25	5	0	22	3	0
	E0023040	296.89	NO	25	7	0	16	3	0
	E0026014	296.89	YES	38	99	4	36	7	1
	E0026019	296.89	NO	9	12	2	9		1
	E0027005	296.89	NO	37	24	3	15	8	0
	E0029009	296.89	YES	14	199	12	19	60	4
	E0029021	296.89	YES	5	46	11	5	24	6
	E0029026	296.89	YES	21	39	2	21	40	2
	E0029030	296.89	NO	25	19	1	16	30	1
	E0031008	296.89	NO	24	19	1	18	20	2
	E0031020	296.89	NO	27	29	0	28	20	0
	E0031021	296.89	YES	18	29	5	18	10	0
	E0031029	296.89	YES	6	19	3	6	10	3
	E0033002	296.89	YES		3	2			2
	E0033006	296.89	YES	16		3	12	10	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	296.89	NO	13			13		
	E0035013	296.89	NO	18	11	1	8	4	0
	E0035015	296.89	NO	18	3	1	9	7	2
	E0035016	296.89	YES	9	5	1	14	10	3
	E0035023	296.89	NO	17	9	1	13	20	0
	E0039052	296.89	NO	8	11	1	8	4	0
	E0039056	296.89	YES	24		3	20		4
	E0040003	296.89	NO	7	10	1	3	3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	296.5	YES	31	49	7	29	11	4
	E0002011	296.5	NO	9	2	0	19	4	0
	E0003010	296.5	NO	38	35	0	40	50	1
	E0003011	296.5	YES	12	30	4	15	13	3
	E0003016	296.5	YES	16	99	5	10	99	3
	E0003019	296.5	YES	17		2	28		2
	E0003020	296.5	YES	26		2	16	28	2
	E0004001	296.5	NO	18	5	2	9	4	1
	E0004009	296.5	YES	8	40	4	7	10	2
	E0004012	296.5	YES	14	48	3	4	5	1
	E0004015	296.5	YES	25		3	25	18	1
	E0005003	296.5	NO	11	4	1	31		0
	E0005005	296.5	NO	17			17		
	E0005007	296.5	NO	28		0	28		1
	E0005008	296.5	NO	8		1	18		1
	E0005009	296.5	NO	5		1	11		1
	E0005010	296.5	NO	11					

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0005012	296.5	NO	43		1	22		0
	E0005014	296.5	NO	14		0	11		1
	E0005022	296.5	NO	11	3	0	12	4	0
	E0005025	296.5	NO	18	6	0	26		1
	E0006019	296.5	NO	34	7	1	12	2	0
	E0007005	296.5	NO	12		1	11		1
	E0007015	296.5	NO	29		0	29		1
	E0009001	296.5	YES	25		2	2	4	2
	E0010002	296.5	NO	13	3	1	8	2	1
	E0010009	296.5	NO	34		0	9	6	0
	E0010010	296.5	NO	17	42	0	15	14	1
	E0010014	296.5	NO	27	5	1	11	3	1
	E0010017	296.5	NO	19	5	1	13	2	0
	E0010023	296.5	NO	13	14	0	13		1
	E0010027	296.5	NO	12	9	0	18	4	0
	E0010029	296.5	NO	9	2	0	9	3	1
	E0011022	296.5	NO	20	29	1	20	20	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	296.5	NO	10	9	1	11	15	2
	E0013012	296.5	NO	43	50	1	41	50	2
	E0013014	296.5	NO	29	26	1	29	20	1
	E0014005	296.5	NO	34	19	0	32	3	1
	E0014007	296.5	NO	16	29	1	10	23	0
	E0014011	296.5	NO	24	49	1	24	35	2
	E0014012	296.5	YES	45	61	2	41	27	2
	E0015001	296.5	NO	43		2	37	5	0
	E0015008	296.5	YES	18		4			1
	E0016003	296.5	YES	21		5	19	30	3
	E0016005	296.5	YES	13		6	31		5
	E0018007	296.5	NO	27	9	1	28	10	0
	E0019005	296.5	NO	11	8	1	3	2	1
	E0019015	296.5	NO	7	1	0	9	3	1
	E0020004	296.5	NO	17	3	0	12	3	1
	E0020010	296.5	NO	11	9	0	5	1	0
	E0020014	296.5	NO	40		1	31		2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	296.5	NO	35	3	1	13	5	1
	E0020023	296.5	NO	31	5	0	31	1	0
	E0022007	296.5	NO	21	17	0	21	18	1
	E0022010	296.5	NO	4	1	1	4	3	0
	E0022012	296.5	NO	5	7	1	4	5	2
	E0022019	296.5	NO	4	6	1	19	16	1
	E0022025	296.5	YES	33		3	32		4
	E0022033	296.5	NO	14	3	0	11	2	1
	E0022034	296.5	NO	19	2	1	19	8	2
	E0022038	296.5	NO	20	3	1	18	9	1
	E0022039	296.5	NO	20	4	1	14	4	1
	E0022046	296.5	NO	27	4	0	12	2	0
	E0022048	296.5	NO	11	3	1	5	2	1
	E0022051	296.5	NO	31	4	0	31	5	1
	E0022053	296.5	NO	14	12	1	11	10	0
	E0022058	296.5	NO	22	4	1	22	5	1
	E0022061	296.5	NO	3	1	0	11	3	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	296.5	NO	29	27	1	33	32	1
	E0022068	296.5	NO	2	0	0	32	3	0
	E0022069	296.5	NO	21	8	0	15	5	1
	E0022071	296.5	NO	37	19	1	11	20	2
	E0023003	296.5	NO	9	5	0	11	4	1
	E0023006	296.5	NO	34	10	0	26	3	1
	E0023010	296.5	NO	24	8	1	7	2	0
	E0023025	296.5	NO	10	5	0	6	3	1
	E0023039	296.5	NO	39	9	1	30	6	0
	E0026002	296.5	NO	23		1	23		1
	E0026007	296.5	NO	20		1	20	10	1
	E0026013	296.5	NO	19		2	15	7	1
	E0028007	296.5	NO	5	2	0	5	3	0
	E0028023	296.5	NO	25	6	0	24	7	0
	E0028025	296.5	NO	12	3	0	8	3	0
	E0028033	296.5	NO	34	7	1	13	4	0
	E0028035	296.5	NO	24	6	0	24	5	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	296.5	NO	25	3	0	25	3	0
	E0028039	296.5	NO	13	4	0	14	3	1
	E0028046	296.5	NO	14	4	0	4	3	0
	E0028048	296.5	NO	4	3	1	3	1	0
	E0029008	296.5	NO	8	19	1	8	20	2
	E0029011	296.5	YES	16		3	15		10
	E0029012	296.5	NO	32	59	2	24	30	1
	E0029015	296.5	NO	7	5	1	8	10	1
	E0029018	296.5	YES	10	49	1	12	25	3
	E0030014	296.5	YES	29		4	24		4
	E0030020	296.5	NO	11	14	2	9	15	1
	E0030024	296.5	NO	24	49	0	7	15	3
	E0030025	296.5	NO	43		1	43	10	0
	E0031027	296.5	NO	18	1	0	15	2	1
	E0031030	296.5	NO	24	39	1	24	20	1
	E0033012	296.5	NO	23		1			1
	E0034001	296.5	NO	17	5	1	8	2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	296.5	NO	30		1	22	10	1
	E0035001	296.5	NO	21	14	1	10	5	1
	E0035006	296.5	NO	3	1	0	2	1	0
	E0035021	296.5	NO	5	5	2	3	5	1
	E0036002	296.5	YES	20	23	5	19	24	6
	E0036006	296.5	NO	4	3	1	4	2	0
	E0036007	296.5	NO	5	4	2	4	3	1
	E0037009	296.5	NO	20	15	0	20	10	1
	E0039011	296.5	NO	25		0	8	2	0
	E0039018	296.5	NO	12		1	10	7	1
	E0039026	296.5	NO	30	9	1	30	15	1
	E0039028	296.5	NO	3	3	2	3	6	1
	E0039032	296.5	NO	6	11	1	6	8	2
	E0039034	296.5	NO	7		2	7	5	1
	E0039042	296.5	NO	31		1	19	5	0
	E0041004	296.5	NO	22	4	0	22	5	0
	E0041009	296.5	NO	28	3	0	26	5	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	296.5	YES	10	19	4	10	50	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DSMIV100.SAS
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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	296.89	YES	22		2	22		4
	E0003002	296.89	YES	20	456	24	16	60	4
	E0005031	296.89	NO	19		0	13		1
	E0005033	296.89	YES	15		0	15		5
	E0005038	296.89	YES	21	7	0	13		20
	E0007009	296.89	NO	7	2	0	7	2	1
	E0009010	296.89	YES	17	99	2	16	99	4
	E0009011	296.89	NO	23		2	13		1
	E0010005	296.89	NO	1	2	1	2	2	2
	E0011016	296.89	NO	30	59	1	23	40	0
	E0011020	296.89	YES	14	103	8	13	24	2
	E0018002	296.89	NO	5	1	0	5	3	0
	E0018003	296.89	NO	11	2	1	6	3	0
	E0018013	296.89	NO	11	2	1	8	5	0
	E0019002	296.89	NO	6	1	0	6	2	1
	E0019008	296.89	NO	6	7	1	3	3	1
	E0019009	296.89	NO	8	5	1	8	4	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DSMIV100.SAS
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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	296.89	NO	5	1	0	13		1
	E0019020	296.89	NO	24		2	19	12	1
	E0019021	296.89	NO	6	9	1	4	8	1
	E0019024	296.89	NO	15		1	15		1
	E0019031	296.89	NO	2	1	1	2	2	2
	E0019035	296.89	NO	17		0	15		0
	E0019040	296.89	NO	9	6	1	7	5	0
	E0019042	296.89	NO	20	4	1	13	2	0
	E0019045	296.89	NO	11	11	0	11	15	0
	E0020024	296.89	NO	7		1	7		1
	E0022044	296.89	NO	3	1	0	11	3	1
	E0023007	296.89	YES	6	7	3	6	4	1
	E0023011	296.89	NO	44	6	0	27	2	0
	E0023014	296.89	NO	17	5	0	22	3	0
	E0023019	296.89	NO	19	6	0	14	3	0
	E0023022	296.89	NO	11	3	0	8	3	0
	E0023023	296.89	NO	26	3	1	14	3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR II)	E0023029	296.89	NO	15	6	1	14	3	0
	E0023031	296.89	NO	28	5	1	24	4	1
	E0023041	296.89	NO	25	4	1	24	4	1
	E0023043	296.89	NO	6	1	0	3	1	0
	E0026003	296.89	NO	39		1	20	5	0
	E0026005	296.89	NO	28	15	1	11	99	0
	E0026009	296.89	NO	22		0	22	99	2
	E0026015	296.89	YES	21	29	2	38		5
	E0026023	296.89	NO	9		1	9	3	0
	E0027016	296.89	YES	16	48	6	16	32	3
	E0027018	296.89	YES	9	50	10	9	50	10
	E0028032	296.89	NO	20	5	1	20	4	0
	E0029003	296.89	YES	5	3	2	5	8	2
	E0029020	296.89	NO	27	21	1	15	6	0
	E0031005	296.89	NO	7	4	0	4	3	2
	E0031006	296.89	YES	35	29	2	18	35	3
	E0031010	296.89	NO	3	1	0	3	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	296.89	YES	10	14	0	10	30	15
	E0031015	296.89	NO	5	2	0	5	1	0
	E0031031	296.89	YES	19	59	5	11	15	1
	E0033009	296.89	NO	11		0	10		1
	E0034009	296.89	NO	33		0	26		1
	E0037007	296.89	NO	13	7	1	8	5	0
	E0037012	296.89	NO	9	6	1	6	5	1
	E0039019	296.89	NO	16		0	17	6	1
	E0039043	296.89	NO	16	9	1	4	2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR I)	E0002001	296.5	NO	15	59	0	10	2	1
	E0002003	296.5	YES	4	39		4	39	6
	E0002004	296.5	NO	6	6	1	6	9	
	E0002008	296.5	YES	31	29	2	30	84	3
	E0002016	296.5	NO	24		2	38	4	0
	E0003008	296.5	NO	32		2	17		1
	E0004003	296.5	YES	11	19	2	11	20	3
	E0004006	296.5	YES	13	40	2	7	18	3
	E0004016	296.5	YES	8	11	2	2	3	3
	E0004024	296.5	NO	27	29	1	24	20	2
	E0005006	296.5	NO			1		3	1
	E0005017	296.5	NO	18		3	6		0
	E0005019	296.5	NO	13		1	11		0
	E0005026	296.5	NO	24		0	15		1
	E0005039	296.5	NO	15		1	21		1
	E0005043	296.5	NO	19		0	49		0
	E0006020	296.5	NO	24	5	0	13	3	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR I)	E0007001	296.5	NO	20	6	1	21	3	0
	E0007003	296.5	NO	14	3	1	15	1	0
	E0007006	296.5	NO	12		0	12	3	0
	E0009004	296.5	NO	8	3	1	21		1
	E0009012	296.5	NO	7		1	7		1
	E0010008	296.5	NO	15	2	0	16	2	0
	E0010018	296.5	NO	16	3	1	12	2	0
	E0010028	296.5	NO	17	2	1	6	2	1
	E0011008	296.5	NO	11	20	0	7	5	0
	E0011009	296.5	NO	22	3	0	18	3	0
	E0011010	296.5	NO	37	70	1	28	52	2
	E0013001	296.5	NO	16	5	0	17	6	1
	E0013003	296.5	NO	7	11	0	36	70	1
	E0013005	296.5	NO	22	6	0	26	20	1
	E0013013	296.5	NO	11	14	0	11	15	1
	E0014002	296.5	NO	23	29	0	37	40	1
	E0014004	296.5	YES	17	29	2	7	18	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR I)	E0014009	296.5	YES	18	49	2	16	45	3
	E0014015	296.5	NO	11	19	1	4	11	2
	E0014017	296.5	YES	12	37	3	10	30	1
	E0014018	296.5	YES	9	27	2	3	6	3
	E0015005	296.5	NO	40			3		
	E0017002	296.5	NO	17	5	1	18	4	1
	E0018009	296.5	NO	10	4	1	7	4	1
	E0018010	296.5	NO	16	5	0	14	6	1
	E0018015	296.5	NO	15	13	1	16	15	1
	E0020015	296.5	NO	26	29	2	19	10	1
	E0020017	296.5	NO	34	10	1	22	5	1
	E0020020	296.5	NO	28		0	20		1
	E0020022	296.5	NO	13		1	11		1
	E0022001	296.5	NO	29	55	1	29	29	1
	E0022004	296.5	NO	5	2	0	5	4	1
	E0022005	296.5	NO	34	3	0	7	2	0
	E0022011	296.5	NO	18	6	1	17	5	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR I)	E0022015	296.5	YES	5	11	2	3	3	2
	E0022016	296.5	NO	9	3	0	6	4	0
	E0022020	296.5	NO	6	3	1	1	1	1
	E0022023	296.5	NO	38	6	1	18	2	1
	E0022029	296.5	NO	9	2	1	8	4	1
	E0022041	296.5	NO	38	8	0	35	6	0
	E0022042	296.5	NO	28	5	1	17	6	1
	E0022043	296.5	NO	3	3	1	3	3	0
	E0022054	296.5	NO	13	6	1	14	10	1
	E0022059	296.5	NO	13	4	0	13	3	0
	E0022065	296.5	NO	15	8	1	14	10	1
	E0022070	296.5	NO	13	4	0	54	9	0
	E0023001	296.5	NO	25	7	0	12	3	1
	E0023009	296.5	NO	33	5	1	13	3	0
	E0023028	296.5	NO	23	3	0	24	5	1
	E0023033	296.5	NO	36	5	0	26	2	0
	E0023047	296.5	NO	8	4	1	8	4	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR I)	E0025001	296.5	YES	18		23	18		24
	E0026012	296.5	NO	26	4	1	3	1	0
	E0026020	296.5	NO	8	4	0	8	3	1
	E0026024	296.5	NO	22		1	8	4	0
	E0026028	296.5	NO	23	2	0	23		3
	E0028001	296.5	NO	36	15	1	36	5	1
	E0028003	296.5	NO	35	10	0	13	5	0
	E0028005	296.5	NO	7	4	0	7	3	1
	E0028010	296.5	NO	11	4	0	11	5	1
	E0028011	296.5	NO	15	3	0	15	3	1
	E0028030	296.5	NO	27	6	0	20	3	0
	E0028031	296.5	NO	16	4	1	16	4	1
	E0028047	296.5	NO	21	3	1	21	3	0
	E0029001	296.5	NO	11	5	0	19	8	0
	E0029014	296.5	NO	12	9	0	12	20	2
	E0029023	296.5	YES	11	24	14	2	10	10
	E0029032	296.5	NO	29	200	1	29	75	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR I)	E0029033	296.5	YES	22	99	4	29	120	5
	E0029039	296.5	NO	14	22	0	13	12	0
	E0030003	296.5	NO	23		0	25	2	0
	E0030009	296.5	YES	29		4	29		4
	E0030016	296.5	YES	32		6	24	21	1
	E0030021	296.5	NO	8	3	2	2	1	1
	E0031001	296.5	NO	26	3	1	19	2	1
	E0031017	296.5	NO	10	2	0	4	2	0
	E0031018	296.5	NO	8	2	0	4	2	1
	E0031023	296.5	NO	14	2	0	14	4	1
	E0033001	296.5	NO			0			1
	E0033004	296.5	NO	2	0	0	18		0
	E0033010	296.5	NO	11		1	7		1
	E0033014	296.5	NO	35		1	33		0
	E0035002	296.5	YES	9	19	3	8	10	1
	E0035007	296.5	NO	17	9	1	17	6	1
	E0035011	296.5	NO	29	9	1	15	6	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR I)	E0035020	296.5	YES	33	19	2	33	10	5
	E0037003	296.5	NO	21	9	1	4	6	1
	E0037004	296.5	NO	22	14	0	8	4	1
	E0039007	296.5	NO	3	2	1	3	1	0
	E0039022	296.5	YES	9	7	2	7	6	2
	E0039023	296.5	NO	11		0	11	12	2
	E0039030	296.5	YES	14		3	14		1
	E0039031	296.5	YES	5	9	2	5	4	2
	E0039037	296.5	YES	11	9	0	11	10	5
	E0039038	296.5	YES	8	9	3	8	3	1
	E0039047	296.5	YES	18		3	16	15	1
	E0039059	296.5	NO	41		2	35		0
	E0041007	296.5	NO	26	3	1	23	9	2
	E0041010	296.5	NO	23	4	1	21	7	1
	E0041011	296.5	NO	23	5	0	15	6	1
	E0041012	296.5	NO	31	17	0	17	52	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR II)	E0001004	296.89	NO	9			3		
	E0005023	296.89	NO	25	2	0	3	3	2
	E0005034	296.89	NO	12		1	5		1
	E0005041	296.89	NO	3	3	0			2
	E0007004	296.89	NO	19		1	13		1
	E0007010	296.89	NO	29		0	8		1
	E0007012	296.89	NO	7		0	4		0
	E0009007	296.89	NO	8			13		
	E0009008	296.89	NO	25		1	8		0
	E0011001	296.89	NO	8	4	0	3	2	1
	E0011011	296.89	NO	8	6	0	6	4	2
	E0011013	296.89	YES	35	135	3	25	46	2
	E0011014	296.89	NO	23	29	0	10	9	1
	E0011021	296.89	NO	24	32	1	24	33	2
	E0013008	296.89	NO	22	23	0	18	30	2
	E0014001	296.89	NO	9	19	1	5	15	2
	E0014013	296.89	YES	22	46	2	21	50	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR II)	E0014014	296.89	NO	21	39	1	26	41	1
	E0015004	296.89	YES	20		3	15		4
	E0018005	296.89	NO	3	4	0	4	5	1
	E0018012	296.89	NO	8	2	1	10	8	2
	E0019019	296.89	NO	12	20	2	9	6	0
	E0019033	296.89	NO	35	3	0	10	3	0
	E0019038	296.89	NO	6	4	0	4	5	1
	E0019046	296.89	NO	10	5	0	10	12	0
	E0019047	296.89	NO	5	2	0	5	5	1
	E0019048	296.89	NO	25	9	0	9	20	2
	E0022006	296.89	NO	7	13	1	7	10	1
	E0022047	296.89	NO	39	4	0	32	3	1
	E0022075	296.89	NO	28	5	1	21	20	1
	E0023012	296.89	NO	22	5	1	20	3	0
	E0023016	296.89	NO	24	3	0	22	3	0
	E0023018	296.89	NO	11	4	0	6	3	1
	E0023036	296.89	NO	13	6	0	7	2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR II)	E0023046	296.89	NO	55	5	0	41	4	0
	E0026006	296.89	NO	12		1	1		1
	E0026021	296.89	NO	21	1	0	18	25	0
	E0026027	296.89	YES	12		2	7		5
	E0029002	296.89	YES	42		6	37		5
	E0029004	296.89	YES	6	5	1	17	90	5
	E0029013	296.89	YES	5		36	5		36
	E0029019	296.89	YES	31	89	2	34	45	2
	E0029024	296.89	NO	28	3	1	28	60	0
	E0029038	296.89	YES	46	91	2	42	123	2
	E0031004	296.89	NO	5	1	0	1	1	1
	E0031013	296.89	YES	5	19	5	3	20	5
	E0031016	296.89	NO	7	9	0	7	10	1
	E0031019	296.89	YES	39	29	2	11	30	3
	E0031022	296.89	NO	34	9	0	24	10	0
	E0033007	296.89	NO	44	29	0	41	28	1
	E0033013	296.89	YES	16		12	16		6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/DSMIV100.SAS
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Listing 12.2.4.4 DSM-IV Diagnosis and Psychiatric History

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DSM-IV*	RAPID CYCLER	PRIOR DEPRESSED EPISODES			PRIOR MANIC/HYPOMANIC EPISODES		
				YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR	YEARS SINCE FIRST	TOTAL OVER LIFETIME	TOTAL OVER THE PAST YEAR
PLACEBO (BIPOLAR II)	E0033016	296.89	NO	20	4	0	18		2
	E0033022	296.89	NO	2			2		
	E0034007	296.89	NO	30		0	21	5	0
	E0035004	296.89	NO	13	4	0	25	10	0
	E0035009	296.89	NO	12	5	0	4	2	1
	E0035010	296.89	YES	34	10	1	27	4	3
	E0035022	296.89	YES	39	19	1	41	8	3
	E0039003	296.89	NO	11		0	7	6	0
	E0040001	296.89	YES	6	10	2	9	40	5
	E0040004	296.89	YES	4	8	3	4	25	10
	E0041002	296.89	NO	29	4	1	19	4	1
	E0041005	296.89	NO	34	10	1	26	6	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* 296.5 = bipolar I disorder, most recent episode depressed, 296.89=bipolar II DISORDER.

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AstraZeneca

Clinical Study Report: Appendix 12.2.5

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.5
Treatment compliance

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					
		11FEB2003	8		0	4					CAME IN FOR VISIT - 2/12/03 EXTENDED VISIT INTERVAL
		12FEB2003	9	4	0	4					
		13FEB2003	10	4	0	4					
		14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	0	4					
		18FEB2003	15	4	0	4					
		19FEB2003	16	4	0	4					
		20FEB2003	17	4	0	4					
		21FEB2003	18	4	0	4					
		22FEB2003	19	4	0	4					
		23FEB2003	20	4	0	4					
		24FEB2003	21	4	0	4					
		25FEB2003	22	4	0	4					
		26FEB2003	23	4	0	4					
		27FEB2003	24	4	0	4					
		28FEB2003	25	4	0	4					
		01MAR2003	26	4	0	4					
		02MAR2003	27	4	0	4					
		03MAR2003	28	4	0	4					
		04MAR2003	29	4	0	4					
		05MAR2003	30	4	0	4					
		06MAR2003	31	4	0	4					
		07MAR2003	32	4	0	4					
		08MAR2003	33	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	09MAR2003	34	4	0	4					
		10MAR2003	35	4	0	4					
		11MAR2003	36	4	1	3					SEEN AT VISIT 7 ON 3/11/03
		11MAR2003	36	4	1	3					DOSE REDUCTION DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		12MAR2003	37	4	1	3					DID NOT TAKE 1ST PILL AE (DIZZINESS)
		13MAR2003	38	4	1	3					DID NOT TAKE 1ST PILL A. E. DIZZINESS)
		14MAR2003	39	4	1	3					DID NOT TAKE 1ST PILL AE. (DIZZINESS)
		15MAR2003	40	4	1	3					DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		16MAR2003	41	4	1	3					DID NOT TAKE 1ST PILL AE (DIZZINESS
		17MAR2003	42	4	1	3					DID NOT TAKE 1ST PILL AE (DIZZINESS
		18MAR2003	43	4	1	3					DOSE REDUCTION DID NOT TAKE 1ST PILL A. E (DIZZINESS)
		19MAR2003	44	4	1	3					DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		20MAR2003	45	4	1	3					DID NOT TAKE 1ST PILL AE. (DIZZINESS)
		21MAR2003	46	4	1	3					DID NOT TAKE 1ST PILL A. E (DIZZINESS)
		22MAR2003	47	4	1	3					DID NOT TAKE 1ST PILL A. E (DIZZINESS)
		23MAR2003	48	4	1	3					DID NOT TAKE 1ST PILL AE (DIZZINESS)
		24MAR2003	49	4	1	3					DID NOT TAKE 1ST PILL A. E (DIZZINESS0

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	25MAR2003	50	4	1	3					DOSE REDUCTION DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		26MAR2003	51	4	1	3					DID NOT TAKE 1ST PILL A. E (DIZZINESS)
		27MAR2003	52	4	1	3					DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		28MAR2003	53	4	1	3					DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		29MAR2003	54	4	1	3					DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		30MAR2003	55	4	1	3					DID NOT TAKE 1ST PILL A. E. (DIZZINESS)
		31MAR2003	56	4	1	3					DID NOT TAKE 1ST PILL A. E (DIZZINESS)
		01APR2003	57		1	3	YES	251.8	57	100	DOSE REDUCTION DID NOT TAKE 1ST PILL AE (DIZZINESS) CAME INTO VISIT ON 4/2/03
	E0002010	04APR2003	1	2	0	2					
		05APR2003	2	1	0	1					
		06APR2003	3	1	0	1					
		07APR2003	4	2	0	2					
		08APR2003	5	3	0	3					
		09APR2003	6	3	0	3					
		10APR2003	7	4	0	4					VISIT V3 ON 4/10/03 SHORT VISIT INFORMAL
		10APR2003	7	4	0	4					DID NOT BRING BLISTER CARD BACK
		11APR2003	8	4	0	4					
		12APR2003	9	4	0	4					
		13APR2003	10	4	0	4					
		14APR2003	11	4	0	4					
		15APR2003	12	4	0	4					
		16APR2003	13	4	0	4					

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	17APR2003	14		0	4					UNKNOWN DID NOT BRING BLISTER CARD BACK
		18APR2003	15		0	4	NO	263.3	15	102	DID NOT BRING BLISTER CARD BACK
	E0002012	21APR2003	1	2	0	2					
		22APR2003	2	1	0	1					
		23APR2003	3	1	0	1					
		24APR2003	4	2	0	2					
		25APR2003	5	3	0	3					
		26APR2003	6	3	0	3					
		27APR2003	7	3	0	3					
		28APR2003	8		0	4					TOOK EXTRA DAY EXTENDED VISIT INTERVAL
		29APR2003	9	4	0	4					
		30APR2003	10	4	0	4					
		01MAY2003	11	4	0	4					
		02MAY2003	12	4	0	4					
		03MAY2003	13	4	0	4					
		04MAY2003	14	4	0	4					
		05MAY2003	15	4	0	4					
		06MAY2003	16	4	0	4					
		07MAY2003	17	4	0	4					
		08MAY2003	18	4	0	4					
		09MAY2003	19	4	0	4					
		10MAY2003	20	4	0	4					
		11MAY2003	21	4	0	4					
		12MAY2003	22	4	0	4					
		13MAY2003	23		0	4					TOOK EXTRA DAY EXTENDED VISIT INTERVAL
		14MAY2003	24		0	4					TOOK EXTRA DAY
		15MAY2003	25	4	0	4					
		16MAY2003	26	4	0	4					
		17MAY2003	27	4	0	4					
		18MAY2003	28	4	0	4					
		19MAY2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0002012	20MAY2003	30	4	0	4					
		21MAY2003	31	4	0	4					SAW FOR VISIT 6 ON 5/21/03
		22MAY2003	32	4	0	4					
		23MAY2003	33	4	0	4					
		24MAY2003	34	4	0	4					
		25MAY2003	35	4	0	4					
		26MAY2003	36	4	0	4					
		27MAY2003	37	4	0	4					
		28MAY2003	38	4	0	4					
		29MAY2003	39	4	0	4					
		30MAY2003	40	4	0	4					
		31MAY2003	41	4	0	4					
		01JUN2003	42	4	0	4					
		02JUN2003	43	4	0	4					
		03JUN2003	44	4	0	4					
		04JUN2003	45	4	0	4					
		05JUN2003	46	4	0	4					
		06JUN2003	47	4	0	4					
		07JUN2003	48	4	0	4					
		08JUN2003	49	4	0	4					
		09JUN2003	50	4	0	4					
		10JUN2003	51	4	0	4					
		11JUN2003	52	4	0	4					
		12JUN2003	53	4	0	4					
		13JUN2003	54	4	0	4					
		14JUN2003	55	4	0	4					
		15JUN2003	56	4	0	4					
		16JUN2003									SAW FOR VISIT 10 ON 6/16/03
		17JUN2003					NO	290.2	56	100	SAW FOR VISIT 10 ON 6/16/03
	E0002015	04JUN2003	1	2	0	2					PATIENT DID NOT RETURN BLISTER PACK
		05JUN2003	2	1	0	1					
		06JUN2003	3	1	0	1					
		07JUN2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0002015	08JUN2003	5	3	0	3					
		09JUN2003	6	3	0	3					
		10JUN2003	7	3	0	3					
		11JUN2003	8		0	4					EXTRA DAY DOSES UNKNOWN PATIENT DID NOT RETURN BLISTER PACK
		12JUN2003	9		0	4	NO	238.9	9	100	
	E0002018	24JUL2003	1	2	0	2					
		25JUL2003	2	1	0	1					
		26JUL2003	3	1	0	1					
		27JUL2003									DID NOT TAKE MEDS DUE TO ADVERSE EVENT DROWSINESS
		28JUL2003									DID NOT TAKE MEDS DUE TO ADVERSE EVENT DROWSINESS
		29JUL2003									DID NOT TAKE MEDS DUE TO ADVERSE EVENT DROWSINESS
		30JUL2003					NO	116.7	3	100	DID NOT TAKE MEDS DUE TO ADVERSE EVENT DROWSINESS
	E0003004	17DEC2002	1	2	0	2					
		18DEC2002	2	1	0	1					
		19DEC2002	3	1	0	1					
		20DEC2002	4	2	0	2					
		21DEC2002	5	3	0	3					
		22DEC2002	6	3	0	3					
		23DEC2002	7	3	0	3					
		24DEC2002	8		0	4					
		25DEC2002	9		0	4	NO	238.9	9	100	
	E0003005	23DEC2002	1	2	0	2					
		24DEC2002	2	1	0	1					
		25DEC2002	3	1	1	0					PATIENT TOOK DOSE ON 12/26/02
		26DEC2002	4	2	1	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	27DEC2002	5	3	0	3					
		28DEC2002	6	3	0	3					
		29DEC2002	7	3	0	3					
		30DEC2002	8	4	0	4					
		31DEC2002	9	4	0	4					.
		01JAN2003	10	4	0	4					
		02JAN2003	11	4	0	4					
		03JAN2003	12	4	0	4					
		04JAN2003	13	4	0	4					
		05JAN2003	14	4	0	4					
		06JAN2003	15	4	0	4					
		07JAN2003	16	4	0	4					
		08JAN2003	17	4	0	4					
		09JAN2003	18	4	0	4					
		10JAN2003	19	4	0	4					
		11JAN2003	20	4	0	4					
		12JAN2003	21	4	0	4					
		13JAN2003	22		0	4					
		14JAN2003	23	4	0	4					
		15JAN2003	24	4	0	4					
		16JAN2003	25	4	0	4					
		17JAN2003	26	4	0	4					
		18JAN2003	27	4	0	4					
		19JAN2003	28	4	0	4					
		20JAN2003	29	4	0	4					
		21JAN2003	30	4	0	4					
		22JAN2003	31	4	0	4					
		23JAN2003	32	4	0	4					
		24JAN2003	33	4	0	4					
		25JAN2003	34	4	0	4					
		26JAN2003	35	4	0	4					
		27JAN2003	36	4	0	4					
		28JAN2003	37	4	0	4					
		29JAN2003	38	4	0	4					
		30JAN2003	39	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	31JAN2003	40	4	0	4					
		01FEB2003	41	4	0	4					
		02FEB2003	42	4	0	4					
		03FEB2003	43	4	0	4					
		04FEB2003	44	4	0	4					
		05FEB2003	45	4	0	4					
		06FEB2003	46	4	0	4					
		07FEB2003	47	4	0	4					
		08FEB2003	48	4	0	4					
		09FEB2003	49	4	0	4					
		10FEB2003	50	4	0	4					
		11FEB2003	51	4	0	4					
		12FEB2003	52	4	0	4					
		13FEB2003	53	4	0	4					
		14FEB2003	54	4	0	4					
		15FEB2003	55	4	0	4					
		16FEB2003	56	4	0	4					
		17FEB2003	57	4	0	4	NO	281.6	56	99.1	
	E0003007	02JAN2003	1	2	0	2					
		03JAN2003	2	1	0	1					
		04JAN2003	3	1	0	1					
		05JAN2003	4	2	0	2					
		06JAN2003	5	3	0	3					
		07JAN2003	6	3	0	3					
		08JAN2003	7	3	0	3					
		09JAN2003	8	4	0	4					
		10JAN2003	9	4	0	4					
		11JAN2003	10	4	0	4					
		12JAN2003	11	4	0	4					
		13JAN2003	12	4	0	4					
		14JAN2003	13	4	0	4					
		15JAN2003	14	4	0	4					
		16JAN2003	15	4	0	4					
		17JAN2003	16	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	18JAN2003	17	4	0	4					
		19JAN2003	18	4	0	4					
		20JAN2003	19	4	0	4					
		21JAN2003	20	4	0	4					
		22JAN2003	21	4	0	4					
		23JAN2003	22	4	0	4					
		24JAN2003	23	4	0	4					
		25JAN2003	24	4	0	4					
		26JAN2003	25	4	0	4					
		27JAN2003	26	4	0	4					
		28JAN2003	27	4	0	4					
		29JAN2003	28	4	0	4					
		30JAN2003	29	4	0	4					
		31JAN2003	30	4	0	4					
		01FEB2003	31	4	0	4					
		02FEB2003	32	4	0	4					
		03FEB2003	33	4	0	4					
		04FEB2003	34	4	0	4					
		05FEB2003	35	4	0	4					
		06FEB2003	36		0	4					
		07FEB2003	37	4	0	4					
		08FEB2003	38	4	0	4					
		09FEB2003	39	4	0	4					
		10FEB2003	40	4	0	4					
		11FEB2003	41	4	0	4					
		12FEB2003	42	4	0	4					
		13FEB2003	43	4	0	4					
		14FEB2003	44	4	0	4					
		15FEB2003	45	4	0	4					
		16FEB2003	46	4	0	4					
		17FEB2003	47	4	0	4					
		18FEB2003	48	4	0	4					
		19FEB2003	49	4	0	4					
		20FEB2003	50	4	0	4					
		21FEB2003	51	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	22FEB2003	52	4	0	4					
		23FEB2003	53	4	0	4					
		24FEB2003	54	4	0	4					
		25FEB2003	55	4	0	4					
		26FEB2003	56	4	0	4	NO	290.2	56	100	
	E0003015	05MAY2003	1	2	0	2					
		06MAY2003	2	1	0	1					
		07MAY2003	3	1	0	1					
		08MAY2003	4	2	0	2					
		09MAY2003	5	3	0	3					
		10MAY2003	6	3	0	3					
		11MAY2003	7	3	0	3					
		12MAY2003	8		0	4					PATIENT'S VISIT INTERVAL WAS 8 DAYS SO SHE TOOK THESE DOSES FROM THIS CARD
		13MAY2003	9	4	0	4					
		14MAY2003	10	4	0	4					
		15MAY2003	11	4	0	4					
		16MAY2003	12	4	0	4					
		17MAY2003	13	4	0	4					
		18MAY2003	14	4	0	4					
		19MAY2003	15	4	0	4					PT. HAD VISIT IN 6 DAYS DUE TO WORK SCHEDULE.
		20MAY2003	16	4	0	4					
		21MAY2003	17	4	0	4					
		22MAY2003	18	4	0	4					
		23MAY2003	19	4	0	4					
		24MAY2003	20	4	0	4					
		25MAY2003	21	4	0	4					
		26MAY2003	22		0	4					8 DAY VISIT INTERVAL SO THIS DOSE TAKEN FROM THIS CARD
		27MAY2003	23	4	0	4					
		28MAY2003	24	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	29MAY2003	25	4	0	4					
		30MAY2003	26	4	0	4					
		31MAY2003	27	4	0	4					
		01JUN2003	28	4	0	4					
		02JUN2003	29	4	0	4					
		03JUN2003	30		0	4					8 DAY VISIT INTERVAL SO DRUG TAKEN OUT OF THIS CARD
		04JUN2003	31	4	0	4					
		05JUN2003	32	4	0	4					
		06JUN2003	33	4	0	4					
		07JUN2003	34	4	0	4					
		08JUN2003	35	4	0	4					
		09JUN2003	36	4	0	4					
		10JUN2003	37	4	0	4					6 DAY VISIT INTERVAL DOSE NOT TAKEN FROM THIS CARD.
		11JUN2003	38	4	0	4					
		12JUN2003	39	4	0	4					
		13JUN2003	40	4	0	4					
		14JUN2003	41	4	0	4					
		15JUN2003	42	4	0	4					
		16JUN2003	43	4	0	4					
		17JUN2003	44	4	0	4					
		18JUN2003	45	4	0	4					
		19JUN2003	46	4	0	4					
		20JUN2003	47	4	0	4					
		21JUN2003	48	4	0	4					
		22JUN2003	49	4	0	4					
		23JUN2003	50	4	0	4					
		24JUN2003	51	4	0	4					
		25JUN2003	52	4	0	4					
		26JUN2003	53	4	0	4					
		27JUN2003	54	4	0	4					
		28JUN2003	55	4	0	4					
		29JUN2003	56	4	0	4					
		30JUN2003	57	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	01JUL2003	58		0	4	NO	290.5	58	100	8 DAY INTERVAL, THIS DAY STUDY DRUG TAKEN FROM THIS CARD
	E0004002	01OCT2002	1	2	0	2					
		02OCT2002	2	1	0	1					
		03OCT2002	3	1	0	1					
		04OCT2002	4	2	0	2					
		05OCT2002	5	3	0	3					
		06OCT2002	6	3	0	3					
		07OCT2002	7	3	0	3					
		08OCT2002	8		0	4					
		09OCT2002	9		0	4					
		10OCT2002	10	4	0	4					
		11OCT2002	11	4	0	4					
		12OCT2002	12	4	0	4					
		13OCT2002	13	4	0	4					
		14OCT2002	14	4	0	4					
		15OCT2002	15	4	0	4					
		16OCT2002	16	4	0	4					
		17OCT2002	17	4	0	4					
		18OCT2002	18	4	0	4					
		19OCT2002	19	4	0	4					
		20OCT2002	20	4	0	4					
		21OCT2002	21	4	0	4					
		22OCT2002	22	4	0	8					
		23OCT2002	23	4	0	8					
		24OCT2002	24	4	0	4					
		25OCT2002	25	4	0	4					
		26OCT2002	26	4	0	4					
		27OCT2002	27	4	0	4					
		28OCT2002	28	4	0	4					
		29OCT2002	29	4	0	4					
		30OCT2002	30	4	0	4					
		31OCT2002	31	4	0	4					
		01NOV2002	32	4	0	4					
		02NOV2002	33	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	03NOV2002	34	4	0	4					
		04NOV2002	35	4	0	4					
		05NOV2002	36	4	0	4					
		06NOV2002	37	4	0	4					
		07NOV2002	38	4	0	4					
		08NOV2002	39	4	0	4					
		09NOV2002	40	4	0	4					
		10NOV2002	41	4	0	4					
		11NOV2002	42	4	0	4					
		12NOV2002	43	4	0	4					
		13NOV2002	44	4	0	4					
		14NOV2002	45	4	0	4					
		15NOV2002	46	4	0	4					
		16NOV2002	47	4	0	4					
		17NOV2002	48	4	0	4					
		18NOV2002	49	4	0	4					
		19NOV2002	50	4	0	4					
		20NOV2002	51	4	0	4					
		21NOV2002	52	4	0	4					
		22NOV2002	53	4	0	4					
		23NOV2002	54	4	0	4					
		24NOV2002	55	4	0	4					
		25NOV2002	56	4	0	4	NO	300.9	56	104	
	E0004013	14JAN2003	1	2	0	2					
		15JAN2003	2	1	0	1					
		16JAN2003	3	1	0	1					
		17JAN2003	4	2	2	0					MISSED DOSE ON 1-17-03 THIS DOSE TAKEN 1-18-03
		18JAN2003	5	3	1	2					THIS DOSE TAKE 1-19-03
		19JAN2003	6	3	0	3					THIS DOSE TAKEN 1-20-03
		20JAN2003	7	3	0	3					
		21JAN2003	8	4	0	4					
		22JAN2003	9	4	0	4					
		23JAN2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	24JAN2003	11	4	0	4					
		25JAN2003	12	4	0	4					
		26JAN2003	13	4	0	4					
		27JAN2003	14	4	0	4					
		28JAN2003	15		0	4					
		29JAN2003	16		0	4					
		30JAN2003	17	4	0	4					
		31JAN2003	18	4	0	4					
		01FEB2003	19	4	0	4					
		02FEB2003	20	4	0	4					
		03FEB2003	21	4	0	4					
		04FEB2003	22	4	0	4	NO	247.7	21	96	
	E0004018	19MAR2003	1	2	0	2					
		20MAR2003	2	1	0	1					
		21MAR2003	3	1	0	1					
		22MAR2003	4	2	0	2					
		23MAR2003	5	3	0	3					
		24MAR2003	6	3	0	3					
		25MAR2003	7	3	0	3					
		26MAR2003	8	4	0	4					
		27MAR2003	9	4	0	4					MISSED DOSE ON 3-17-03 TOOK FROM CARD CONSECUTIVELY
		28MAR2003	10	4	0	4					
		29MAR2003	11	4	0	4					
		30MAR2003	12	4	0	4					
		31MAR2003	13	4	0	4					
		01APR2003	14	4	4	0					THAT DOSE WAS MISSED ON 3-27-03. BUT PATIENT TOOK CONSECUTIVELY FROM CARD
		02APR2003	15	4	0	4					
		03APR2003	16	4	0	4					
		04APR2003	17	4	0	4					
		05APR2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	06APR2003	19	4	0	4					
		07APR2003	20	4	0	4					
		08APR2003	21	4	0	4					
		09APR2003	22	4	0	4					
		10APR2003	23	4	0	4					
		11APR2003	24	4	0	4					
		12APR2003	25	4	0	4					
		13APR2003	26	4	0	4					
		14APR2003	27	4	0	4					
		15APR2003	28	4	0	4					
		16APR2003	29	4	0	4					
		17APR2003	30	4	4	0					SKIPPED DOSE
		18APR2003	31	4	0	4					
		19APR2003	32	4	0	4					
		20APR2003	33	4	0	4					
		21APR2003	34	4	0	4					
		22APR2003	35	4	0	4					
		23APR2003	36	4	0	4					
		24APR2003	37	4	0	4					
		25APR2003	38	4	0	4					
		26APR2003	39	4	0	4					
		27APR2003	40	4	0	4					
		28APR2003	41	4	0	4					
		29APR2003	42	4	0	4					
		30APR2003	43	4	0	4					
		01MAY2003	44	4	0	4					
		02MAY2003	45	4	0	4					
		03MAY2003	46	4	0	4					
		04MAY2003	47	4	4	0					MISSED DOSE
		05MAY2003	48	4	0	4					
		06MAY2003	49	4	0	4					
		07MAY2003	50	4	0	4					
		08MAY2003	51	4	0	4					
		09MAY2003	52	4	0	4					
		10MAY2003	53	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	11MAY2003	54	4	0	4					
		12MAY2003	55	4	0	4	NO	273.6	52	94.2	
	E0004021	14MAY2003	1	2	0	2					
		15MAY2003	2	1	0	1					
		16MAY2003	3	1	0	1					
		17MAY2003	4	2	0	2					
		18MAY2003	5	3	0	3					
		19MAY2003	6	3	0	3					
		20MAY2003	7	3	0	3					
		21MAY2003	8	4	0	4					
		22MAY2003	9	4	0	4					
		23MAY2003	10	4	0	4					
		24MAY2003	11	4	0	4					
		25MAY2003	12	4	0	4					
		26MAY2003	13	4	0	4					
		27MAY2003	14	4	0	4					
		28MAY2003	15	4	0	4					
		29MAY2003	16	4	0	4					
		30MAY2003	17	4	0	4					
		31MAY2003	18	4	0	4					
		01JUN2003	19	4	0	4					
		02JUN2003	20	4	0	4					
		03JUN2003	21	4	0	4					
		04JUN2003	22	4	0	4					
		05JUN2003	23	4	0	4					
		06JUN2003	24	4	0	4					
		07JUN2003	25	4	0	4					
		08JUN2003	26	4	0	4					
		09JUN2003	27	4	0	4					
		10JUN2003	28	4	0	4					
		11JUN2003	29	4	0	4					
		12JUN2003	30	4	0	4					
		13JUN2003	31	4	0	4					
		14JUN2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	15JUN2003	33	4	0	4					
		16JUN2003	34	4	0	4					
		17JUN2003	35	4	0	4					
		18JUN2003	36	4	0	4					
		19JUN2003	37	4	0	4					
		20JUN2003	38	4	0	4					
		21JUN2003	39	4	0	4					
		22JUN2003	40	4	0	4					
		23JUN2003	41	4	0	4					
		24JUN2003	42	4	0	4					
		25JUN2003	43	4	0	4					
		26JUN2003	44	4	0	4					
		27JUN2003	45	4	0	4					
		28JUN2003	46	4	0	4					
		29JUN2003	47	4	0	4					
		30JUN2003	48	4	0	4					
		01JUL2003	49	4	0	4					
		02JUL2003	50	4	0	4					
		03JUL2003	51	4	0	4					
		04JUL2003	52	4	0	4					
		05JUL2003	53	4	0	4					
		06JUL2003	54	4	0	4					
		07JUL2003	55	4	0	4					
		08JUL2003	56	4	0	4	NO	290.2	56	100	
	E0005002	03OCT2002	1	2	0	2					
		04OCT2002	2	1	0	1					
		05OCT2002	3	1	0	1					
		06OCT2002	4	2	0	2					
		07OCT2002	5	3	0	3					
		08OCT2002	6	3	0	3					REDISPENSED AT VISIT 3
		09OCT2002	7	3	0	3					REDISPENSED AT VISIT 3
		10OCT2002	8	4	0	4					
		11OCT2002	9	4	0	4					
		12OCT2002	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	13OCT2002	11	4	0	4					
		14OCT2002	12	4	0	4					
		15OCT2002	13	4	0	4					
		16OCT2002	14	4	0	4					
		17OCT2002	15	4	0	4					DOSES FOR 10-8-03 AND 10-9-03 TAKEN FROM PREVIOUS CARD
		18OCT2002	16	4	0	4					
		19OCT2002	17	4	0	4					
		20OCT2002	18	4	0	4					
		21OCT2002	19	4	0	4					
		22OCT2002	20	4	0	4					
		23OCT2002	21	4	0	4					
		24OCT2002	22	4	0	4					
		25OCT2002	23	4	0	4					
		26OCT2002	24	4	0	4					
		27OCT2002	25	4	0	4					
		28OCT2002	26	4	0	5					LOST PILL, TOOK EXTRA
		29OCT2002	27	4	0	4					
		30OCT2002	28	4	0	4					
		31OCT2002	29	4	0	4					
		01NOV2002	30	4	4	0					MISSED DOSE
		02NOV2002	31	4	0	4					
		03NOV2002	32	4	0	4					
		04NOV2002	33	4	0	4					
		05NOV2002	34	4	0	4					
		06NOV2002	35	4	0	4					
		07NOV2002	36	4	0	4					
		08NOV2002	37	4	0	4					
		09NOV2002	38	4	0	4					
		10NOV2002	39	4	0	4					
		11NOV2002	40		0	4					
		12NOV2002	41		0	4					
		13NOV2002	42	4	0	4					
		14NOV2002	43	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	15NOV2002	44	4	0	4					
		16NOV2002	45	4	0	4					
		17NOV2002	46	4	0	4					
		18NOV2002	47	4	0	4					
		19NOV2002	48	4	0	4					
		20NOV2002	49	4	0	4					
		21NOV2002	50	4	0	4					
		22NOV2002	51	4	0	4					
		23NOV2002	52	4	0	4					
		24NOV2002	53	4	0	4	NO	284	52	98.5	
	E0005004	01OCT2002	1	2	0	2					
		02OCT2002	2	1	0	1					
		03OCT2002	3	1	0	1					
		04OCT2002	4	2	0	2					
		05OCT2002	5	3	0	3					
		06OCT2002	6	3	0	3					
		07OCT2002	7	3	0	3					
		08OCT2002	8		0	4					
		09OCT2002	9		0	4					
		10OCT2002	10	4	0	4					
		11OCT2002	11	4	0	4					
		12OCT2002	12	4	0	4					
		13OCT2002	13	4	0	4					
		14OCT2002	14	4	0	4					
		15OCT2002	15	4	1	3					REDUCED DOSE TO 3 PILLS PER PI
		16OCT2002	16	4	1	3					
		17OCT2002	17	4	1	3					- UNK - CARD NOT RETURNED
		18OCT2002	18	4	1	3					
		19OCT2002	19	4	1	3					
		20OCT2002	20	4	1	3					
		21OCT2002	21	4	1	3					LAST DOSE TAKEN (PM) PER SUBJ REPORT
		22OCT2002					YES	240.5	21	100	- UNK - CARD NOT RETURNED

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005013	07NOV2002	1	2	0	2					
		08NOV2002	2	1	0	1					
		09NOV2002	3	1	0	1					
		10NOV2002	4	2	0	2	NO	162.5	4	100	STUDY MEDS D/C AE
	E0005024	10FEB2003	1	2	0	2					
		11FEB2003	2	1	0	1					
		12FEB2003	3	1	0	1					
		13FEB2003	4	2	0	2					
		14FEB2003	5	3	0	3					
		15FEB2003	6	3	0	3					
		16FEB2003	7	3	0	3					
		17FEB2003	8		0	4					
		18FEB2003	9	4	0	4					
		19FEB2003	10	4	0	4					
		20FEB2003	11	4	0	4					
		21FEB2003	12	4	4	0					OUT OF TOWN FORGOT PILLS
		22FEB2003	13	4	4	0					OUT OF TOWN FORGOT PILLS
		23FEB2003	14	4	0	4					
		24FEB2003	15	4	0	4					
		25FEB2003	16		0	4					
		26FEB2003	17	4	0	4					
		27FEB2003	18	4	0	4					
		28FEB2003	19	4	0	4					
		01MAR2003	20	4	0	4					
		02MAR2003	21	4	0	4					
		03MAR2003	22	4	0	4					
		04MAR2003	23	4	0	4					
		05MAR2003	24		0	4					
		06MAR2003	25	4	0	4					
		07MAR2003	26	4	0	4					
		08MAR2003	27	4	0	4					
		09MAR2003	28	4	0	4					
		10MAR2003	29	4	0	4					
		11MAR2003	30	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	12MAR2003	31	4	0	4					
		13MAR2003	32	4	0	4					
		14MAR2003	33	4	0	4					
		15MAR2003	34	4	0	4					
		16MAR2003	35	4	0	4					
		17MAR2003	36	4	0	4					
		18MAR2003	37	4	0	4					
		19MAR2003	38	4	0	4					
		20MAR2003	39	4	0	4					
		21MAR2003	40	4	0	4					
		22MAR2003	41	4	0	4					
		23MAR2003	42	4	0	4					
		24MAR2003	43	4	0	4					
		25MAR2003	44	4	4	0					MISSED THIS DOSE, TOOK IT ON 3/26/03
		26MAR2003	45	4	0	4					
		27MAR2003	46	4	0	4					3/28/03
		28MAR2003	47	4	0	4					3/29/03
		29MAR2003	48	4	0	4					3/30/03
		30MAR2003	49	4	0	4					3/31/03
		31MAR2003	50	4	0	4					04/01/03
		01APR2003	51		4	0					
		02APR2003	52	4	0	4					
		03APR2003	53	4	0	4					
		04APR2003	54	4	0	4					
		05APR2003	55	4	0	4					
		06APR2003	56	4	0	4					
		07APR2003	57	4	0	4					
		08APR2003					NO	269.3	53	92.6	MISSED THIS DOSE
	E0005027	11MAR2003	1	2	0	2					
		12MAR2003	2	1	0	1					
		13MAR2003	3	1	0	1					
		14MAR2003	4	2	0	2					
		15MAR2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	16MAR2003	6	3	0	3					
		17MAR2003	7	3	0	3					
		18MAR2003	8		4	0					MISSED THIS NIGHT
		19MAR2003	9	4	0	4					
		20MAR2003	10	4	0	4					
		21MAR2003	11	4	0	4					
		22MAR2003	12	4	0	4					
		23MAR2003	13	4	0	4					
		24MAR2003	14	4	0	4					
		25MAR2003	15	4	0	4					
		26MAR2003	16	4	1	3					
		27MAR2003	17	4	1	3					
		28MAR2003	18	4	1	3					
		29MAR2003	19	4	1	3	YES	234.2	18	93.2	
	E0005037										CARD NOT DISPENSED MISSED VISIT 8
		07MAY2003	1	2	0	2					
		08MAY2003	2	1	0	1					
		09MAY2003	3	1	0	1					
		10MAY2003	4	2	0	2					
		11MAY2003	5	3	0	3					
		12MAY2003	6	3	0	3					
		13MAY2003	7	3	0	3					
		14MAY2003	8		0	4					
		15MAY2003	9	4	0	4					
		16MAY2003	10	4	0	4					
		17MAY2003	11	4	0	4					
		18MAY2003	12	4	0	4					
		19MAY2003	13	4	0	4					
		20MAY2003	14	4	0	4					
		21MAY2003	15	4	0	4					
		22MAY2003	16	4	0	4					
		23MAY2003	17	4	0	4					
		24MAY2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	25MAY2003	19	4	0	4					
		26MAY2003	20	4	0	4					
		27MAY2003	21	4	0	4					
		28MAY2003	22	4	0	4					
		29MAY2003	23	4	0	4					
		30MAY2003	24	4	0	4					
		31MAY2003	25	4	0	4					
		01JUN2003	26	4	0	4					
		02JUN2003	27	4	0	4					
		03JUN2003	28	4	4	0					MISSED DOSE
		04JUN2003	29		4	0					MISSED DOSE
		05JUN2003	30	4	0	4					
		06JUN2003	31	4	0	4					
		07JUN2003	32	4	0	4					
		08JUN2003	33	4	0	4					
		09JUN2003	34	4	0	4					
		10JUN2003	35	4	0	4					
		11JUN2003	36	4	0	4					
		12JUN2003	37	4	0	4					
		13JUN2003	38	4	0	4					
		14JUN2003	39	4	0	4					
		15JUN2003	40	4	0	4					
		16JUN2003	41	4	0	4					
		17JUN2003	42	4	0	4					
		18JUN2003	43	4	0	4					
		19JUN2003	44		0	4					
		20JUN2003	45		0	4					
		21JUN2003	46			0					
		22JUN2003	47			0					
		23JUN2003	48			0					
		24JUN2003	49			0					
		25JUN2003	50	4	0	4					
		26JUN2003	51	4	0	4					
		27JUN2003	52	4	0	4					
		28JUN2003	53	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	29JUN2003	54	4	0	4					
		30JUN2003	55	4	0	4					
		01JUL2003	56	4	0	4	NO	258	50	88.6	
	E0005042	24JUN2003	1	2	0	2					
		25JUN2003	2	1	0	1					
		26JUN2003	3	1	0	1					
		27JUN2003	4	2	0	2					
		28JUN2003	5	3	0	3					
		29JUN2003	6	3	0	3					
		30JUN2003	7	3	0	3					
		01JUL2003	8		0	4					
		02JUL2003	9	4	0	4					
		03JUL2003	10	4	0	4					
		04JUL2003	11	4	0	4					
		05JUL2003	12	4	0	4					
		06JUL2003	13	4	0	4					
		07JUL2003	14	4	0	4					
		08JUL2003	15	4	0	4					
		09JUL2003	16	4	0	4					
		10JUL2003	17	4	0	4					
		11JUL2003	18	4	0	4					
		12JUL2003	19	4	0	4					
		13JUL2003	20	4	0	4					
		14JUL2003	21	4	0	4					
		15JUL2003	22	4	0	4					
		16JUL2003	23	4	0	4					
		17JUL2003	24	4	0	4					
		18JUL2003	25	4	0	4					
		19JUL2003	26	4	0	4					
		20JUL2003	27	4	0	4					
		21JUL2003	28	4	0	4					
		22JUL2003	29	4	0	4					
		23JUL2003	30	4	0	4					
		24JUL2003	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	25JUL2003	32	4	0	4					
		26JUL2003	33	4	0	4					
		27JUL2003	34	4	0	4					
		28JUL2003	35	4	0	4					
		29JUL2003	36	4	0	4					
		30JUL2003	37	4	0	4					
		31JUL2003	38	4	0	4					
		01AUG2003	39	4	0	4					
		02AUG2003	40	4	0	4					
		03AUG2003	41	4	0	4					
		04AUG2003	42	4	0	4					
		05AUG2003	43	4	0	4					
		06AUG2003	44	4	0	4					
		07AUG2003	45	4	0	4					
		08AUG2003	46	4	0	4					
		09AUG2003	47	4	0	4					
		10AUG2003	48	4	0	4					
		11AUG2003	49	4	0	4					
		12AUG2003	50	4	0	4					
		13AUG2003	51	4	0	4					
		14AUG2003	52	4	0	4					
		15AUG2003	53	4	0	4					
		16AUG2003	54	4	0	4					
		17AUG2003	55	4	0	4	NO	290	55	100	
	E0006005	05DEC2002	1	2	0	2					
		06DEC2002	2	1	0	1					
		07DEC2002	3	1	0	1					
		08DEC2002	4	2	0	2					
		09DEC2002	5	3	0	3					
		10DEC2002	6	3	0	3					
		11DEC2002	7	3	0	3					
		12DEC2002	8	4	0	4					
		13DEC2002	9	4	0	4					
		14DEC2002	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	15DEC2002	11	4	0	4					
		16DEC2002	12	4	0	4					
		17DEC2002	13	4	0	4					
		18DEC2002	14	4	0	4					
		19DEC2002	15		0	4					REDISPENSED ON 12/20/02 DUE TO HOLIDAY SCHEDULE
		20DEC2002	16		0	4					SUBJECT TOOK THIS DOSE ON 12/20/02
		21DEC2002	17	4	0	4					
		22DEC2002	18	4	0	4					
		23DEC2002	19	4	0	4					
		24DEC2002	20	4	0	4					
		25DEC2002	21	4	0	4					
		26DEC2002	22	4	0	4					
		27DEC2002	23	4	0	4					
		28DEC2002	24		0	4					
		29DEC2002	25		0	4					
		30DEC2002	26	4	0	4					
		31DEC2002	27	4	0	4					
		01JAN2003	28	4	0	4					
		02JAN2003	29	4	0	4					
		03JAN2003	30	4	0	4					SUBJECT DID NOT TAKED DUE TO HOLIDAY SCHEDULE CHANGE. PT TOOK MEDS DAILY VISIT SCHEDULED WAS ALTERED DUE ABOVE MENTIONED REASON.
		04JAN2003	31	4	0	4					
		05JAN2003	32	4	0	4					
		06JAN2003	33	4	0	4					
		07JAN2003	34	4	0	4					
		08JAN2003	35	4	0	4					
		09JAN2003	36	4	0	4					PT VISIT DATE CHANGED. TOOK ON ALT CARD. DID NOT MISS DOSE.

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	10JAN2003	37	4	0	4					
		11JAN2003	38	4	0	4					
		12JAN2003	39	4	0	4					
		13JAN2003	40	4	0	4					
		14JAN2003	41	4	0	4					
		15JAN2003	42	4	0	4					
		16JAN2003	43	4	0	4					
		17JAN2003	44	4	0	4					
		18JAN2003	45	4	0	4					
		19JAN2003	46	4	0	4					
		20JAN2003	47	4	0	4					
		21JAN2003	48	4	0	4					
		22JAN2003	49	4	0	4					
		23JAN2003	50	4	0	4					
		24JAN2003	51	4	0	4					
		25JAN2003	52	4	0	4					
		26JAN2003	53	4	0	4					
		27JAN2003	54	4	0	4					
		28JAN2003	55	4	0	4					
		29JAN2003	56	4	0	4	NO	290.2	56	100	
	E0006018	13MAR2003	1	2	0	2					
		14MAR2003	2	1	0	1					
		15MAR2003	3	1	0	1					
		16MAR2003	4	2	0	2					
		17MAR2003					NO	162.5	4	100	INVESTIGATOR STOPPED THE STUDY DRUG AND SUBJECT DID NOT TAKE DOSE ON 3/17 3/18 3/19.
	E0007013	13JUN2003	1	2	0	2					
		14JUN2003	2	1	0	1					
		15JUN2003	3	1	0	1					
		16JUN2003	4	2	0	2					
		17JUN2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0007013	18JUN2003	6	3	0	3					
		19JUN2003	7	3	0	3					
		20JUN2003	8	4	0	4					
		21JUN2003	9	4	0	4					
		22JUN2003	10	4	0	4					
		23JUN2003	11	4	0	4					
		24JUN2003	12	4	0	4					
		25JUN2003	13	4	0	4					
		26JUN2003	14	4	0	4					CAME IN 1 DAY EARLY
		27JUN2003	15	4	0	4					
		28JUN2003	16	4	0	4					
		29JUN2003	17	4	0	4					
		30JUN2003	18	4	0	4					
		01JUL2003	19	4	0	4					
		02JUL2003	20	4	0	4					
		03JUL2003	21	4	0	4					
		04JUL2003	22	4	0	4					
		05JUL2003	23	4	0	4					
		06JUL2003	24	4	0	4					
		07JUL2003	25	4	0	4					
		08JUL2003	26	4	0	4					
		09JUL2003	27	4	0	4					
		10JUL2003	28	4	0	4					
		11JUL2003	29	4	0	4					
		12JUL2003	30	4	0	4					
		13JUL2003	31	4	0	4					
		14JUL2003	32	4	0	4					
		15JUL2003	33	4	0	4					
		16JUL2003	34	4	0	4					
		17JUL2003	35	4	0	4					
		18JUL2003	36	4	0	4					
		19JUL2003	37	4	0	4					
		20JUL2003	38	4	0	4					
		21JUL2003	39	4	0	4					
		22JUL2003	40	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0007013	23JUL2003	41	4	0	4					
		24JUL2003	42	4	0	4					
		25JUL2003	43	4	0	4					
		26JUL2003	44	4	0	4					
		27JUL2003	45	4	0	4					
		28JUL2003	46	4	0	4					
		29JUL2003	47	4	0	4					
		30JUL2003	48	4	0	4					
		31JUL2003	49		0	4					PT RETURN 1 DAY LATER
		01AUG2003	50	4	0	4					
		02AUG2003	51	4	0	4					
		03AUG2003	52	4	0	4					
		04AUG2003	53	4	0	4					
		05AUG2003	54	4	0	4					
		06AUG2003	55	4	0	4	NO	290	55	100	
	E0010004										CARD NOT DISPENSED - VISIT 6 SKIPPED AS SUBJECT WAS OUT OF VISIT WINDOW - VISIT 7 PERFORMED INSTEAD. APPROVED BY BRYAN PROCTOR.
		11DEC2002	1	2	0	2					
		12DEC2002	2	1	0	1					
		13DEC2002	3	1	0	1					
		14DEC2002	4	2	0	2					
		15DEC2002	5	3	0	3					
		16DEC2002	6	3	0	3					
		17DEC2002	7	3	0	3					
		18DEC2002	8	4	0	4					
		19DEC2002	9	4	0	4					
		20DEC2002	10	4	0	4					
		21DEC2002	11	4	0	4					
		22DEC2002	12	4	0	4					
		23DEC2002	13	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	24DEC2002	14	4	0	4					
		25DEC2002	15		0	4					
		26DEC2002	16	4	0	4					
		27DEC2002	17	4	0	4					
		28DEC2002	18	4	0	4					
		29DEC2002	19	4	0	4					
		30DEC2002	20	4	0	4					
		31DEC2002	21	4	0	4					
		01JAN2003	22	4	0	4					
		02JAN2003	23	4	0	4					
		03JAN2003	24	4	0	4					
		04JAN2003	25	4	0	4					
		05JAN2003	26	4	0	4					
		06JAN2003	27	4	0	4					
		07JAN2003	28	4	0	4					
		08JAN2003	29	4	0	4					
		09JAN2003	30		0	4					
		10JAN2003	31		4	0					SUBJECT CHOSE TO TAKE THIS DOSE ON 30-JAN-2003 SUBJECT MISSED DOSING ON 11/JAN/2003 AND 12/JAN/2003.
		11JAN2003	32			0					
		12JAN2003	33			0					
		13JAN2003	34	4	0	4					01/10/03, 1/11/03 AND 1/12/03 SUBJECT MISSED DOSE.
		14JAN2003	35	4	0	4					
		15JAN2003	36	4	0	4					
		16JAN2003	37	4	0	4					
		17JAN2003	38	4	0	4					
		18JAN2003	39	4	0	4					
		19JAN2003	40	4	0	4					
		20JAN2003	41		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	21JAN2003	42	4	0	4					SUBJECT STATES SHE HAS 4 TABLETS REMAINING AT HOME
		22JAN2003	43	4	0	4					
		23JAN2003	44	4	0	4					
		24JAN2003	45	4	0	4					
		25JAN2003	46	4	0	4					
		26JAN2003	47	4	0	4					
		27JAN2003	48	4	0	4					
		28JAN2003	49		0	4					
		29JAN2003	50		0	4					
		30JAN2003	51			0					
		31JAN2003	52	4	0	4					
		01FEB2003	53	4	0	4					
		02FEB2003	54	4	0	4					
		03FEB2003	55	4	0	4					
		04FEB2003	56	4	0	4					
		05FEB2003	57	4	0	4					
		06FEB2003	58	4	0	4	NO	269.8	54	92.7	
	E0010012	07JAN2003	1	2	0	2					
		08JAN2003	2	1	0	1					
		09JAN2003	3	1	0	1					
		10JAN2003	4	2	0	2					
		11JAN2003	5	3	0	3					
		12JAN2003	6	3	0	3					
		13JAN2003	7	3	0	3					THE BLISTERCARD WAS NOT RETURNED
		14JAN2003	8	4	0	4					NO DOSE TAKEN
		15JAN2003	9	4	0	4					NO DOSE TAKEN
		16JAN2003	10	4	0	4					
		17JAN2003	11	4	0	4					
		18JAN2003	12	4	0	4					
		19JAN2003	13	4	0	4					
		20JAN2003	14	4	0	4					
		21JAN2003	15	4	0	4					SHE USED AN EXTRA BECAUSE 1 TABLET FELL IN THE SINK

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	22JAN2003	16	4	0	4					
		23JAN2003	17	4	0	4					
		24JAN2003	18	4	0	4					
		25JAN2003	19	4	0	4					
		26JAN2003	20	4	0	4					
		27JAN2003	21	4	0	4					
		28JAN2003	22	4	0	4					
		29JAN2003	23	4	0	4					
		30JAN2003	24	4	0	4					
		31JAN2003	25	4	0	4					
		01FEB2003	26	4	0	4					
		02FEB2003	27	4	0	4					
		03FEB2003	28	4	0	4					
		04FEB2003	29	4	0	4					
		05FEB2003	30	4	0	4					
		06FEB2003	31	4	0	4					
		07FEB2003	32	4	0	4					
		08FEB2003	33	4	0	4					
		09FEB2003	34	4	0	4					
		10FEB2003	35	4	0	4					
		11FEB2003	36	4	0	4					
		12FEB2003	37	4	0	4					
		13FEB2003	38	4	0	4					
		14FEB2003	39	4	0	4					
		15FEB2003	40	4	0	4					
		16FEB2003	41	4	0	4					
		17FEB2003	42	4	0	4					
		18FEB2003	43	4	0	4					
		19FEB2003	44	4	0	4					
		20FEB2003	45	4	0	4					
		21FEB2003	46	4	0	4					
		22FEB2003	47	4	0	4					
		23FEB2003	48	4	0	4					
		24FEB2003	49	4	0	4					
		25FEB2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	26FEB2003	51	4	0	4					
		27FEB2003	52	4	0	4					
		28FEB2003	53	4	0	4					
		01MAR2003	54	4	0	4					
		02MAR2003	55	4	0	4					
		03MAR2003	56	4	0	4					
		04MAR2003	57		0	4	NO	290.4	57	100	
	E0010024	05MAY2003	1	2	0	2					
		06MAY2003	2	1	0	1					
		07MAY2003	3	1	0	1					
		08MAY2003	4	2	0	2					
		09MAY2003	5	3	0	3					
		10MAY2003	6	3	0	3					
		11MAY2003	7	3	0	3					
		12MAY2003	8	4	0	4					
		13MAY2003	9	4	0	4					
		14MAY2003	10	4	0	4					
		15MAY2003	11	4	0	4					
		16MAY2003	12	4	0	4					
		17MAY2003	13	4	0	4					
		18MAY2003	14	4	0	4					
		19MAY2003	15	4	0	4					
		20MAY2003	16	4	0	4					
		21MAY2003	17	4	0	4					
		22MAY2003	18	4	0	4					
		23MAY2003	19	4	0	4					
		24MAY2003	20	4	0	4					
		25MAY2003	21	4	0	4					
		26MAY2003	22		0	4					
		27MAY2003	23	4	0	4					
		28MAY2003	24	4	0	4					
		29MAY2003	25	4	0	4					
		30MAY2003	26	4	0	4					
		31MAY2003	27	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	01JUN2003	28	4	0	4					
		02JUN2003	29	4	0	4					
		03JUN2003	30		0	4					
		04JUN2003	31	4	0	4					
		05JUN2003	32	4	0	4					
		06JUN2003	33	4	0	4					
		07JUN2003	34	4	0	4					
		08JUN2003	35	4	0	4					
		09JUN2003	36	4	0	4					
		10JUN2003	37	4	0	4					
		11JUN2003	38	4	0	4					
		12JUN2003	39	4	0	4					
		13JUN2003	40	4	0	4					
		14JUN2003	41	4	0	4					
		15JUN2003	42	4	0	4					
		16JUN2003	43	4	0	4					
		17JUN2003	44	4	0	4					
		18JUN2003	45	4	0	4					
		19JUN2003	46	4	0	4					
		20JUN2003	47	4	0	4					
		21JUN2003	48	4	0	4					
		22JUN2003	49	4	0	4					
		23JUN2003	50	4	0	4					
		24JUN2003	51	4	0	4					
		25JUN2003	52	4	0	4					
		26JUN2003	53	4	0	4					
		27JUN2003	54	4	0	4					
		28JUN2003	55	4	0	4					
		29JUN2003	56	4	0	4					
		30JUN2003	57	4	0	4					
		01JUL2003	58	4	0	4	NO	290.5	58	100	
	E0010032	10JUL2003	1	2	0	2					
		11JUL2003	2	1	0	1					
		12JUL2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0010032	13JUL2003	4	2	0	2					
		14JUL2003	5	3	0	3					
		15JUL2003	6	3	0	3					
		16JUL2003					NO	208.3	6	100	SUBJECT STOPPED DUE TO INTOLERANCE OF AE
	E0011025	26JUN2003	1	2	0	2					
		27JUN2003	2	1	0	1					
		28JUN2003	3	1	0	1					
		29JUN2003	4	2	0	2					
		30JUN2003	5	3	0	3					
		01JUL2003	6	3	1	2					DID NOT TAKE 1 TAB BECAUSE FELT SLUGGISHNESS & TIRED.
		02JUL2003	7	4	0	4					DID NOT TAKE BECAUSE VISITED ON 7/2/03
		03JUL2003	8	4	0	4					
		04JUL2003	9	4	0	4					
		05JUL2003	10	4	0	4					
		06JUL2003	11	4	0	4					
		07JUL2003	12	4	0	4					
		08JUL2003	13	4	0	4					
		09JUL2003	14		0	4					HAD VISIT ON 7/10/03.
		10JUL2003	15	4	0	4					
		11JUL2003	16	4	0	4					
		12JUL2003	17	4	0	4					
		13JUL2003	18	4	0	4					
		14JUL2003	19	4	0	4					
		15JUL2003	20	4	0	4					
		16JUL2003	21	4	0	4					
		17JUL2003	22	4	0	4					
		18JUL2003	23	4	0	4					
		19JUL2003	24	4	0	4					
		20JUL2003	25	4	0	4					
		21JUL2003	26	4	4	0					SUBJECT FORGOT TO TAKE DOSE.

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	22JUL2003	27	4	0	4					SUBJECT CAME FOR VISIT - 6 ON 7/22/03.
		23JUL2003	28	4	0	4					
		24JUL2003	29	4	0	4					
		25JUL2003	30	4	0	4					
		26JUL2003	31	4	0	4					
		27JUL2003	32	4	0	4					
		28JUL2003	33	4	0	4					
		29JUL2003	34		0	4					TOOK EXTRA DOSE AS VISIT WAS ON 7/30/03.
		30JUL2003	35	4	0	4					PATIENT LOST THIS BLISTER CARD STATES REGULAR GOOD COMPLIANCE WITH STUDY DRUG.
		31JUL2003	36	4	0	4					
		01AUG2003	37	4	0	4					
		02AUG2003	38	4	0	4					
		03AUG2003	39	4	0	4					
		04AUG2003	40	4	0	4					
		05AUG2003	41	4	0	4					
		06AUG2003	42		0	4					UNKNOWN, SUBJECT DID NOT RETURN BLISTER CARD
		07AUG2003	43	4	0	8					
		08AUG2003	44	4	0	4					
		09AUG2003	45	4	0	4					
		10AUG2003	46	4	0	4					
		11AUG2003	47	4	0	4					
		12AUG2003	48	4	0	4					
		13AUG2003	49	4	0	4					
		14AUG2003	50	4	0	4					
		15AUG2003	51	4	0	4					
		16AUG2003	52	4	0	4					
		17AUG2003	53	4	0	4					
		18AUG2003	54	4	0	4					
		19AUG2003	55	4	0	4					
		20AUG2003	56	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	21AUG2003	57		0	4	NO	285.1	56	100	TOOK EXTRA DOSE DUE TO EXTENDED VISIT INTERVAL.
	E0013007	20MAR2003	1	2	0	2					
		21MAR2003	2	1	0	1					
		22MAR2003	3	1	0	1					
		23MAR2003	4	2	0	2					
		24MAR2003	5	3	0	3					
		25MAR2003	6	3	0	3					
		26MAR2003	7	3	0	3					
		27MAR2003	8	4	0	4					
		28MAR2003	9	4	0	4					
		29MAR2003					NO	238.9	9	100	PT. STOPPED MEDICATION ON HIS OWN. 3/29/03
	E0013009	02APR2003	1	2	0	2					
		03APR2003	2	1	0	1					
		04APR2003	3	1	0	1					
		05APR2003	4	2	0	2					
		06APR2003	5	3	0	3					
		07APR2003	6	3	0	3					
		08APR2003	7	3	0	3					
		09APR2003	8	4	0	4					
		10APR2003	9	4	0	4					
		11APR2003	10	4	0	4					
		12APR2003	11	4	4	0					
		13APR2003	12	4	0	4					
		14APR2003	13	4	0	4					
		15APR2003	14	4	4	0					MISSED DOSE ON 12APR03 TOOK DAY 4 DOSE ON 13 APR 03
		16APR2003	15	4	0	4					
		17APR2003	16	4	0	4					
		18APR2003	17	4	0	4					
		19APR2003	18	4	0	4					
		20APR2003	19	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	21APR2003	20	4	0	4					
		22APR2003	21	4	0	4					
		23APR2003	22		0	4					
		24APR2003	23	4	0	4					
		25APR2003	24	4	0	4					
		26APR2003	25	4	4	0					MISSED DOSE
		27APR2003	26	4	0	4					
		28APR2003	27	4	0	4					
		29APR2003	28	4	0	4					
		30APR2003	29	4	0	4					
		01MAY2003	30	4	0	4					
		02MAY2003	31	4	0	4					
		03MAY2003	32	4	0	4					
		04MAY2003	33	4	0	4					
		05MAY2003	34	4	0	4					
		06MAY2003	35	4	0	4					
		07MAY2003	36	4	0	4					
		08MAY2003	37	4	0	4					
		09MAY2003	38	4	0	4					
		10MAY2003	39	4	0	4					
		11MAY2003	40	4	0	4					
		12MAY2003	41	4	0	4					
		13MAY2003	42	4	0	4					
		14MAY2003	43		0	4					
		15MAY2003	44		0	4					
		16MAY2003	45	4	0	4					
		17MAY2003	46	4	0	4					
		18MAY2003	47	4	0	4					
		19MAY2003	48	4	0	4					
		20MAY2003	49	4	0	4					
		21MAY2003	50	4	4	4					SIC PATIENT TOOK THIS DOSE ON DAY OF VISIT 9 5-21-03
		21MAY2003	50	4	4	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/22

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	22MAY2003	51	4	0	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/23
		23MAY2003	52	4	0	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/24
		24MAY2003	53	4	0	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/25
		25MAY2003	54	4	0	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/26
		26MAY2003	55	4	0	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/27
		27MAY2003	56	4	0	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/28
		28MAY2003	57		0	4					PATIENT TOOK STUDY DRUG AS FOLLOWS 5/29
		29MAY2003	58		0	4	NO	275	55	94.5	PATIENT TOOK STUDY DRUG AS FOLLOWS 5/30
	E0014006	25MAR2003	1	2	0	2					
		26MAR2003	2	1	0	1					
		27MAR2003	3	1	0	1					
		28MAR2003	4	2	0	2					
		29MAR2003	5	3	0	3					
		30MAR2003	6	3	0	3					
		31MAR2003	7	3	0	3					
		01APR2003	8		0	4					
		02APR2003	9	4	0	4					
		03APR2003	10	4	0	4					
		04APR2003	11	4	0	4					
		05APR2003	12	4	0	4					
		06APR2003	13	4	0	4					
		07APR2003	14	4	0	4					
		08APR2003	15	4	0	4					
		09APR2003	16	4	0	4					
		10APR2003	17	4	0	4					
		11APR2003	18	4	0	4					
		12APR2003	19	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	13APR2003	20	4	0	4					
		14APR2003	21	4	0	4					
		15APR2003	22	4	0	4					
		16APR2003	23	4	0	4					
		17APR2003	24	4	0	4					
		18APR2003	25	4	0	4					
		19APR2003	26	4	0	4					
		20APR2003	27	4	0	4					
		21APR2003	28	4	0	4					
		22APR2003	29	4	0	4					
		23APR2003	30	4	0	4					
		24APR2003	31	4	0	4					
		25APR2003	32	4	0	4					
		26APR2003	33	4	0	4					
		27APR2003	34	4	0	4					
		28APR2003	35	4	0	4					
		29APR2003	36	4	0	4					
		30APR2003	37	4	0	4					
		01MAY2003	38	4	0	4					
		02MAY2003	39	4	0	4					
		03MAY2003	40	4	0	4					
		04MAY2003	41	4	0	4					
		05MAY2003	42	4	0	4					
		06MAY2003	43	4	0	4					
		07MAY2003	44	4	0	4					
		08MAY2003	45	4	0	4					
		09MAY2003	46	4	0	4					
		10MAY2003	47	4	0	4					
		11MAY2003	48	4	0	4					
		12MAY2003	49	4	0	4					
		13MAY2003	50	4	0	4					
		14MAY2003	51	4	0	4					
		15MAY2003	52	4	0	4					
		16MAY2003	53	4	0	4					
		17MAY2003	54	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	18MAY2003	55	4	0	4					
		19MAY2003	56	4	0	4					
		20MAY2003	57	4	0	4	NO	290.4	57	100	
	E0014010	22APR2003	1	2	0	2					
		23APR2003	2	1	0	1					
		24APR2003	3	1	0	1					
		25APR2003	4	2	0	2					
		26APR2003	5	3	0	3					
		27APR2003	6	3	0	3					
		28APR2003	7	3	0	3					
		29APR2003	8		0	4					
		30APR2003	9	4	0	4					
		01MAY2003	10	4	1	3					DOSE REDUCED BY 100MG
		02MAY2003	11	4	1	3					
		03MAY2003	12	4	1	3					
		04MAY2003	13	4	1	3					
		05MAY2003	14	4	1	3					
		06MAY2003	15	4	1	3					
		07MAY2003	16	4	1	3					
		08MAY2003	17	4	1	3					
		09MAY2003	18	4	1	3					
		10MAY2003	19	4	1	3					
		11MAY2003	20	4	1	3					
		12MAY2003	21	4	1	3					
		13MAY2003	22	4	1	3					
		14MAY2003	23	4	1	3					
		15MAY2003	24	4	1	3					
		16MAY2003	25	4	1	3					
		17MAY2003	26	4	1	3					
		18MAY2003	27	4	1	3					
		19MAY2003	28	4	1	3					
		20MAY2003	29	4	1	3					
		21MAY2003	30	4	1	3					
		22MAY2003	31	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	23MAY2003	32	4	1	3					
		24MAY2003	33	4	1	3					
		25MAY2003	34	4	1	3					
		26MAY2003	35	4	1	3					
		27MAY2003	36	4	1	3					
		28MAY2003	37		1	3					"SIC" BLISTER CARD RETURNED ON 5/29/03. SUBJECT TOOK EXTRA DRUG DOSE ON EVENING OF 5/28/03, AFTER VISIT 7.
		29MAY2003	38	4	1	3					
		30MAY2003	39	4	1	3					
		31MAY2003	40	4	1	3					
		01JUN2003	41	4	1	3					
		02JUN2003	42	4	1	3					
		03JUN2003	43	4	1	3					
		04JUN2003	44	4	1	3					
		05JUN2003	45	4	1	3					
		06JUN2003	46	4	1	3					
		07JUN2003	47	4	1	3					
		08JUN2003	48	4	1	3					
		09JUN2003	49	4	1	3					
		10JUN2003	50		1	3					
		11JUN2003	51	4	1	3					
		12JUN2003	52	4	1	3					
		13JUN2003	53	4	1	3					
		14JUN2003	54	4	1	3					
		15JUN2003	55	4	1	3					
		16JUN2003	56	4	1	3	YES	206.3	56	100	
	E0016001	22JAN2003	1	2	0	2					
		23JAN2003	2	1	0	1					
		24JAN2003	3	1	0	1					
		25JAN2003	4	2	0	2					
		26JAN2003	5	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	27JAN2003	6	3	0	3					
		28JAN2003	7	3	0	3					
		29JAN2003	8	4	0	4					
		30JAN2003	9	4	0	4					
		31JAN2003	10	4	0	4					
		01FEB2003	11	4	0	4					
		02FEB2003	12	4	0	4					
		03FEB2003	13	4	0	4					
		04FEB2003	14	4	0	4					
		05FEB2003	15	4	1	3					TAB IN LAST COLUMN NOT TAKEN
		06FEB2003	16	4	1	3					TAB IN LAST COLUMN NOTTAKEN
		07FEB2003	17	4	1	3					TAB IN LAST COLUMN NOTTAKEN
		08FEB2003	18	4	1	3					TAB IN LAST COLUMN NOTTAKEN
		09FEB2003	19	4	1	3					TAB IN LAST COLUMN NOTTAKEN
		10FEB2003	20	4	0	4					
		11FEB2003	21	4	0	4					
		12FEB2003	22	4	0	4					
		13FEB2003	23	4	0	4					
		14FEB2003	24	4	0	4					
		15FEB2003	25	4	0	4					
		16FEB2003	26	4	0	4					
		17FEB2003	27	4	0	4					
		18FEB2003	28	4	0	4					
		19FEB2003	29	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		20FEB2003	30	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		21FEB2003	31	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		22FEB2003	32	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		23FEB2003	33	4	1	3					TABLET IN LAST COLUMN NOT TAKEN

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	24FEB2003	34	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		25FEB2003	35	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		26FEB2003	36	4	0	4					
		27FEB2003	37	4	0	4					
		28FEB2003	38	4	0	4					
		01MAR2003	39	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		02MAR2003	40	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		03MAR2003	41	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		04MAR2003	42	4	0	4					
		05MAR2003	43	4	1	3					TABLET NOT TAKEN IN LAST COLUMN
		06MAR2003	44	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		07MAR2003	45	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		08MAR2003	46	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		09MAR2003	47	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		10MAR2003	48	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		11MAR2003	49	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		12MAR2003	50	4	1	3					TABLETS NOT TAKEN IN LAST COLUMN
		13MAR2003	51	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		14MAR2003	52	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		15MAR2003	53	4	1	3					TABLET IN LAST COLUMN NOT TAKEN

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	16MAR2003	54	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		17MAR2003	55	4	1	3					TABLET IN LAST COLUMN NOT TAKEN
		18MAR2003	56	4	1	3	YES	238.4	56	100	TABLET IN LAST COLUMN NOT TAKEN
	E0016004	03FEB2003	1	2	0	2					
		04FEB2003	2	1	0	1					
		05FEB2003	3	1	0	1					
		06FEB2003	4	2	0	2					
		07FEB2003	5	3	0	3					
		08FEB2003	6	3	0	3					
		09FEB2003	7	3	0	3					
		10FEB2003	8	4	0	4					
		11FEB2003					NO	231.3	8	100	SUBJECT STOP MED' S, DISCONTINUED IN STUDY
	E0018001	29OCT2002	1	2	0	2					
		30OCT2002	2	1	0	1					
		31OCT2002	3	1	0	1					
		01NOV2002	4	2	0	2					
		02NOV2002	5	3	0	3					
		03NOV2002	6	3	0	3					
		04NOV2002	7	3	0	3					
		05NOV2002	8	4	0	4					
		06NOV2002	9	4	0	4					
		07NOV2002	10	4	0	4					
		08NOV2002	11	4	0	4					
		09NOV2002	12	4	0	4					
		10NOV2002	13	4	0	4					
		11NOV2002	14	4	0	4					
		12NOV2002	15		0	4					
		13NOV2002	16	4	0	4					
		14NOV2002	17	4	0	4					
		15NOV2002	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	16NOV2002	19	4	0	4					
		17NOV2002	20	4	0	4					
		18NOV2002	21	4	0	4					
		19NOV2002	22	4	0	4					
		20NOV2002	23	4	0	4					
		21NOV2002	24	4	0	4					
		22NOV2002	25	4	0	4					
		23NOV2002	26	4	0	4					
		24NOV2002	27	4	0	4					
		25NOV2002	28	4	0	4					
		26NOV2002	29	4	0	4					
		27NOV2002	30	4	0	4					
		28NOV2002	31	4	0	4					
		29NOV2002	32	4	0	4					
		30NOV2002	33	4	0	4					
		01DEC2002	34	4	0	4					
		02DEC2002	35	4	0	4					
		03DEC2002	36	4	0	4					
		04DEC2002	37	4	0	4					
		05DEC2002	38	4	0	4					
		06DEC2002	39	4	0	4					
		07DEC2002	40	4	0	4					
		08DEC2002	41	4	0	4					
		09DEC2002	42	4	0	4					
		10DEC2002	43	4	0	4					
		11DEC2002	44	4	0	4					
		12DEC2002	45	4	0	4					
		13DEC2002	46	4	0	4					
		14DEC2002	47	4	0	4					
		15DEC2002	48	4	0	4					
		16DEC2002	49	4	0	4					
		17DEC2002	50	4	0	4					
		18DEC2002	51	4	0	4					
		19DEC2002	52	4	0	4					
		20DEC2002	53	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	21DEC2002	54	4	0	4					
		22DEC2002	55	4	0	4					
		23DEC2002	56	4	0	4	NO	290.2	56	100	
	E0018006	17DEC2002	1	2	0	2					
		18DEC2002	2	1	0	1					
		19DEC2002	3	1	0	1					
		20DEC2002	4	2	0	2					
		21DEC2002	5	3	0	3					
		22DEC2002	6	3	0	3					
		23DEC2002	7	3	0	3					
		24DEC2002	8	4	0	4					
		25DEC2002	9	4	0	4					
		26DEC2002	10	4	0	4					
		27DEC2002	11	4	0	4					
		28DEC2002	12	4	0	4					
		29DEC2002	13	4	0	4					
		30DEC2002	14	4	0	4					
		31DEC2002	15	4	0	4					
		01JAN2003	16	4	0	4					
		02JAN2003	17	4	0	4					
		03JAN2003	18	4	0	4					
		04JAN2003	19	4	0	4					
		05JAN2003	20	4	0	4					
		06JAN2003	21	4	0	4					
		07JAN2003	22	4	0	4					
		08JAN2003	23	4	0	4					
		09JAN2003	24	4	0	4					
		10JAN2003	25	4	0	4					
		11JAN2003	26	4	0	4					
		12JAN2003	27	4	0	4					
		13JAN2003	28	4	0	4					
		14JAN2003	29	4	0	4					
		15JAN2003	30	4	0	4					
		16JAN2003	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	17JAN2003	32	4	0	4					
		18JAN2003	33	4	0	4					
		19JAN2003	34	4	0	4					PATIENT TOOK EXTRA DAY MEDS
		20JAN2003	35	4	0	4					PATIENT TOOK EXTRA DAY MEDS.
		21JAN2003	36	4	0	4					TAKEN 20030119
		22JAN2003	37	4	0	4					TAKEN 20030120
		23JAN2003	38	4	0	4					
		24JAN2003	39	4	0	4					
		25JAN2003	40	4	0	4					
		26JAN2003	41	4	0	4					
		27JAN2003	42	4	0	4					
		28JAN2003	43	4	0	4					DOSE TAKEN
		29JAN2003	44	4	0	4					DOSE TAKEN
		30JAN2003	45	4	0	4					DOSE TAKEN
		31JAN2003	46	4	0	4					DOSE TAKEN
		01FEB2003	47	4	0	4					DOSE TAKEN
		02FEB2003	48	4	0	4					DOSE TAKEN
		03FEB2003	49	4	0	4					DOSE TAKEN
		04FEB2003	50		4	0					DOSE MISSED
		05FEB2003	51		4	0					DOSE MISSED
		06FEB2003	52	4	0	4					
		07FEB2003	53	4	0	4					
		08FEB2003	54	4	0	4					
		09FEB2003	55	4	0	4					
		10FEB2003	56	4	0	4					
		11FEB2003	57	4	0	4					
		12FEB2003	58	4	0	4	NO	280.2	56	96.4	
	E0019004	07NOV2002	1	2	0	2					
		08NOV2002	2	1	0	1					
		09NOV2002	3	1	0	1					
		10NOV2002	4	2	0	2					
		11NOV2002	5	3	0	3					
		12NOV2002	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	13NOV2002	7	3	0	3					
		14NOV2002	8	4	0	4					
		15NOV2002	9	4	0	4					
		16NOV2002	10	4	0	4					
		17NOV2002	11	4	0	4					
		18NOV2002	12	4	0	4					
		19NOV2002	13	4	0	4					
		20NOV2002	14	4	0	4					
		21NOV2002	15	4	0	4					
		22NOV2002	16	4	0	4					
		23NOV2002	17	4	0	4					
		24NOV2002	18	4	0	4					
		25NOV2002	19	4	0	4					
		26NOV2002	20	4	0	4					
		27NOV2002	21	4	0	4					
		28NOV2002	22	4	0	4					
		29NOV2002	23	4	0	4					
		30NOV2002	24	4	0	4					
		01DEC2002	25	4	0	4					
		02DEC2002	26	4	0	4					
		03DEC2002	27		0	4					
		04DEC2002	28		0	4					
		05DEC2002	29	4	0	4					
		06DEC2002	30	4	4	0					SKIPPED DOSE 02/12/06 HOWEVER TOOK THIS ROW ON 02/12/18
		07DEC2002	31	4	0	4					
		08DEC2002	32	4	0	4					
		09DEC2002	33	4	0	4					
		10DEC2002	34	4	0	4					
		11DEC2002	35	4	4	0					SKIPPED DOSE 02/12/11
		12DEC2002	36	4	0	4					
		13DEC2002	37	4	0	4					
		14DEC2002	38	4	0	4					
		15DEC2002	39	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	16DEC2002	40	4	0	4					
		17DEC2002	41	4	0	4					
		18DEC2002					NO	272	39	94.7	TOOK TABLETS FROM BLISTER CARD #5 (DOSE 02/12/06)
	E0019011	21NOV2002	1	2	0	2					
		22NOV2002	2	1	0	1					
		23NOV2002	3	1	0	1					
		24NOV2002	4	2	0	2					
		25NOV2002	5	3	0	3					
		26NOV2002	6	3	0	3					
		27NOV2002	7	3	0	3					
		28NOV2002	8	4	0	4					
		29NOV2002	9	4	0	4					
		30NOV2002	10	4	0	4					
		01DEC2002	11	4	0	4					
		02DEC2002	12	4	0	4					
		03DEC2002	13	4	0	4					
		04DEC2002	14	4	0	4					
		05DEC2002	15	4	0	4					
		06DEC2002	16	4	0	4					
		07DEC2002	17	4	0	4					
		08DEC2002	18	4	0	4					
		09DEC2002	19	4	0	4					
		10DEC2002	20	4	0	4					
		11DEC2002	21	4	0	4					
		12DEC2002	22	4	0	4					
		13DEC2002	23	4	0	4					
		14DEC2002	24	4	0	4					
		15DEC2002	25	4	0	4					
		16DEC2002	26	4	0	4					
		17DEC2002	27	4	0	4					
		18DEC2002	28	4	0	4					
		19DEC2002	29	4	0	4					
		20DEC2002	30	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0019011	21DEC2002	31	4	0	4					
		22DEC2002	32	4	0	4					
		23DEC2002	33	4	0	4					
		24DEC2002	34	4	0	4					
		25DEC2002	35	4	0	4					
		26DEC2002	36	4	0	4					PT. LOST CARD
		27DEC2002	37	4	0	4					
		28DEC2002	38	4	0	4					
		29DEC2002	39	4	0	4					
		30DEC2002	40	4	0	4					
		31DEC2002	41	4	0	4					
		01JAN2003	42	4	0	4					
		02JAN2003	43	4	0	4					PT. REPORTED THAT SHE DID NOT TAKE EXTRA "AND REPORTED DOSE COMPLIANCE."
		03JAN2003	44	4	0	4					
		04JAN2003	45	4	0	4					
		05JAN2003	46	4	0	4					
		06JAN2003	47	4	0	4					
		07JAN2003	48	4	0	4					
		08JAN2003	49	4	4	0					PT. MISSED DOSE
		09JAN2003	50	4	0	4					
		10JAN2003	51	4	0	4					
		11JAN2003	52	4	0	4					
		12JAN2003	53	4	0	4					
		13JAN2003	54	4	0	4					
		14JAN2003	55	4	0	4					
		15JAN2003	56	4	0	4	NO	284.8	55	98.1	
	E0019025	06FEB2003	1	2	0	2					
		07FEB2003	2	1	0	1					
		08FEB2003	3	1	0	1					
		09FEB2003	4	2	0	2					
		10FEB2003	5	3	0	3					
		11FEB2003	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	12FEB2003	7	3	0	3					
		13FEB2003	8	4	0	4					
		14FEB2003	9	4	0	4					
		15FEB2003	10	4	0	4					
		16FEB2003	11	4	0	4					
		17FEB2003	12	4	0	4					
		18FEB2003	13	4	4	0					MISSED DOSE
		19FEB2003	14	4	0	4					
		20FEB2003	15	4	0	4					
		21FEB2003	16	4	0	4					
		22FEB2003	17	4	0	4					
		23FEB2003	18	4	0	4					
		24FEB2003	19	4	0	4					
		25FEB2003	20	4	0	4					
		26FEB2003	21	4	0	4					
		27FEB2003	22	4	0	4					
		28FEB2003	23	4	0	4					
		01MAR2003	24	4	0	4					
		02MAR2003	25	4	0	4					
		03MAR2003	26	4	0	4					
		04MAR2003	27	4	0	4					
		05MAR2003	28	4	0	4					
		06MAR2003	29	4	0	4					
		07MAR2003	30	4	0	4					
		08MAR2003	31	4	0	4					
		09MAR2003	32	4	0	4					
		10MAR2003	33	4	0	4					
		11MAR2003	34	4	0	4					
		12MAR2003	35	4	4	0					MISSED DOSE
		13MAR2003	36	4	0	4					
		14MAR2003	37	4	0	4					
		15MAR2003	38	4	0	4					
		16MAR2003	39	4	0	4					
		17MAR2003	40	4	0	4					
		18MAR2003	41	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	19MAR2003	42	4	0	4					
		20MAR2003	43	4	0	4					
		21MAR2003	44	4	0	4					
		22MAR2003	45	4	0	4					
		23MAR2003	46	4	0	4					
		24MAR2003	47	4	0	4					
		25MAR2003	48	4	4	0					MISSED DOSE
		26MAR2003	49	4	0	4					
		27MAR2003	50	4	0	4					
		28MAR2003	51	4	4	0					MISSED DOSE
		29MAR2003	52	4	0	4					
		30MAR2003	53	4	0	4					
		31MAR2003	54	4	4	0					MISSED DOSE
		01APR2003	55	4	0	4					
		02APR2003	56	4	0	4	NO	263.4	51	90.5	
	E0019026	24FEB2003	1	2	0	2					SUBJECT DID NOT RETURN BLISTER CARD
		25FEB2003	2	1	0	1					
		26FEB2003	3	1	0	1					
		27FEB2003	4	2	0	2					
		28FEB2003	5	3	0	3					
		01MAR2003	6	3	0	3					
		02MAR2003	7	3	0	3					
		03MAR2003	8		0	4					UNKNOWN
		04MAR2003	9		0	4	NO	238.9	9	100	
	E0019043	03JUN2003	1	2	0	2					
		04JUN2003	2	1	0	1					
		05JUN2003	3	1	0	1					
		06JUN2003	4	2	0	2					
		07JUN2003	5	3	0	3					
		08JUN2003	6	3	0	3					
		09JUN2003	7	3	0	3					
		10JUN2003	8	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	11JUN2003	9	4	0	4					
		12JUN2003	10	4	0	4					
		13JUN2003	11	4	0	4					
		14JUN2003	12	4	0	4					
		15JUN2003	13	4	0	4					
		16JUN2003	14	4	0	4					
		17JUN2003	15	4	0	4					
		18JUN2003	16	4	0	4					
		19JUN2003	17	4	0	4					
		20JUN2003	18	4	0	4					
		21JUN2003	19	4	0	4					
		22JUN2003	20	4	0	4					
		23JUN2003	21	4	0	4					
		24JUN2003	22	4	1	3					SUBJECT TITRATED DOWN ROW #1 SKIPPED
		25JUN2003	23	4	1	3					
		26JUN2003	24	4	1	3					
		27JUN2003	25	4	1	3					
		28JUN2003	26	4	1	3					
		29JUN2003	27	4	1	3					
		30JUN2003	28	4	1	3					
		01JUL2003	29	4	1	3					SUBJECT TITRATED DOWN 100MG ROW #1 SKIPPED
		02JUL2003	30	4	1	3					
		03JUL2003	31	4	1	3					
		04JUL2003	32	4	1	3					
		05JUL2003	33	4	1	3					
		06JUL2003	34	4	1	3					
		07JUL2003	35	4	1	3					
		08JUL2003	36	4	1	3					SUBJECT TITRATED DOWN 100MG ROW #1 SKIPPED
		09JUL2003	37	4	1	3					
		10JUL2003	38	4	1	3					
		11JUL2003	39	4	1	3					
		12JUL2003	40	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	13JUL2003	41	4	1	3					
		14JUL2003	42	4	1	3					
		15JUL2003	43	4	1	3					SUBJECT TITRATED DOWN 100MG ROW #1 SKIPPED
		16JUL2003	44	4	1	3					
		17JUL2003	45	4	1	3					
		18JUL2003	46	4	1	3					
		19JUL2003	47	4	1	3					
		20JUL2003	48	4	1	3					
		21JUL2003	49	4	1	3					
		22JUL2003	50	4	1	3					
		23JUL2003	51	4	1	3					
		24JUL2003	52	4	1	3					
		25JUL2003	53	4	1	3					
		26JUL2003	54	4	1	3					SUBJECT LOST 1 TAB (COLUMN 2)
		27JUL2003	55	4	1	3					
		28JUL2003	56	4	1	3	YES	227.7	56	100	
	E0020001	29OCT2002	1	2	0	2					
		30OCT2002	2	1	0	1					
		31OCT2002	3	1	0	1					
		01NOV2002	4	2	0	2					
		02NOV2002	5	3	0	3					
		03NOV2002	6	3	0	3					
		04NOV2002	7	3	0	3					
		05NOV2002	8	4	0	4					
		06NOV2002	9	4	0	4					
		07NOV2002	10	4	0	4					
		08NOV2002	11	4	0	4					
		09NOV2002	12	4	0	4					
		10NOV2002	13	4	0	4					
		11NOV2002	14	4	0	4					
		12NOV2002	15	4	0	4					
		13NOV2002	16	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	14NOV2002	17	4	0	4					
		15NOV2002	18	4	0	4					
		16NOV2002	19	4	0	4					
		17NOV2002	20	4	0	4					
		18NOV2002	21	4	0	4					
		19NOV2002	22	4	0	4					
		20NOV2002	23	4	0	4					
		21NOV2002	24	4	0	4					
		22NOV2002	25	4	0	4					
		23NOV2002	26	4	0	4					
		24NOV2002	27	4	0	4					
		25NOV2002	28	4	0	4					
		26NOV2002	29	4	0	4					
		27NOV2002	30	4	0	4					
		28NOV2002	31	4	0	4					
		29NOV2002	32	4	0	4					
		30NOV2002	33	4	0	4					
		01DEC2002	34	4	0	4					
		02DEC2002	35		4	4					SIC ON 12/02/02 PATIENT TOOK 1 EXTRA TABLET AS; 1 DAY 7 TABLET FELL OUT AND COULD NOT LOCATE.
		03DEC2002	36	4	0	4					
		04DEC2002	37	4	0	4					
		05DEC2002	38	4	0	4					
		06DEC2002	39	4	0	4					
		07DEC2002	40	4	0	4					
		08DEC2002	41	4	0	4					
		09DEC2002	42	4	0	4					
		10DEC2002	43	4	0	4					
		11DEC2002	44	4	0	4					
		12DEC2002	45	4	0	4					
		13DEC2002	46	4	0	4					
		14DEC2002	47	4	0	4					
		15DEC2002	48	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	16DEC2002	49	4	0	8					
		17DEC2002	50	4	0	4					
		18DEC2002	51	4	0	4					
		19DEC2002	52	4	0	4	NO	295.2	52	102	
	E0020006	16DEC2002	1	2	0	2					
		17DEC2002	2	1	0	1					
		18DEC2002	3	1	0	1					
		19DEC2002	4	2	0	2					
		20DEC2002	5	3	0	3					
		21DEC2002	6	3	0	3					
		22DEC2002	7	3	0	3					
		23DEC2002	8	4	0	4					
		24DEC2002	9	4	0	4					
		25DEC2002	10	4	0	4					
		26DEC2002	11	4	0	4					
		27DEC2002	12	4	0	4					
		28DEC2002	13	4	0	4					
		29DEC2002	14	4	0	4					
		30DEC2002	15		0	4					
		31DEC2002	16		0	4					
		01JAN2003	17		0	4					
		02JAN2003	18		0	4	NO	269.4	18	100	
	E0020007	15JAN2003	1	2	0	2					
		16JAN2003	2	1	0	1					
		17JAN2003	3	1	0	1					
		18JAN2003	4	2	0	2					
		19JAN2003	5	3	0	3					
		20JAN2003	6	3	0	3					
		21JAN2003	7	3	0	3					
		22JAN2003	8	4	0	4					
		23JAN2003	9	4	0	4					
		24JAN2003	10	4	0	4					
		25JAN2003	11	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0020007	26JAN2003	12	4	0	4					
		27JAN2003	13	4	0	4					
		28JAN2003	14	4	0	4					
		29JAN2003	15		0	4					
		30JAN2003	16		0	4	NO	265.6	16	100	
	E0020011	26FEB2003	1	2	0	2					
		27FEB2003	2	1	0	1					
		28FEB2003	3	1	0	1					
		01MAR2003	4	2	0	2					
		02MAR2003	5	3	0	3					
		03MAR2003	6	3	0	3					
		04MAR2003	7	3	0	3					
		05MAR2003	8	4	0	4					
		06MAR2003	9	4	0	4					
		07MAR2003	10	4	0	4					
		08MAR2003	11	4	0	4					
		09MAR2003	12	4	0	4					
		10MAR2003	13	4	0	4					
		11MAR2003	14	4	0	4					
		12MAR2003	15	4	0	4					
		13MAR2003	16	4	0	4					
		14MAR2003	17	4	0	4					
		15MAR2003	18	4	0	4					
		16MAR2003	19	4	0	4					
		17MAR2003	20	4	0	4					
		18MAR2003	21	4	0	4					
		19MAR2003	22		0	4					
		20MAR2003	23	4	0	4					
		21MAR2003	24	4	0	4					
		22MAR2003	25	4	0	4					
		23MAR2003	26	4	0	4					
		24MAR2003	27	4	0	4					
		25MAR2003	28	4	0	4					
		26MAR2003	29	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	27MAR2003	30	4	0	4					
		28MAR2003	31	4	0	4					
		29MAR2003	32	4	0	4					
		30MAR2003	33	4	0	4					
		31MAR2003	34	4	0	4					
		01APR2003	35	4	0	4					
		02APR2003	36	4	0	4					
		03APR2003	37	4	0	4					
		04APR2003	38	4	0	4					
		05APR2003	39	4	0	4					
		06APR2003	40	4	0	4					
		07APR2003	41	4	0	4					
		08APR2003	42	4	0	4					
		09APR2003	43	4	0	4					
		10APR2003	44	4	0	4					
		11APR2003	45	4	0	4					
		12APR2003	46	4	0	4					
		13APR2003	47	4	0	4					
		14APR2003	48	4	0	4					
		15APR2003	49	4	0	4					
		16APR2003	50	4	0	4					
		17APR2003	51	4	0	4					
		18APR2003	52	4	0	4					
		19APR2003	53	4	0	4					
		20APR2003	54	4	0	4					
		21APR2003	55	4	0	4					
		22APR2003	56	4	0	4	NO	290.2	56	100	
	E0020013	05MAR2003	1	2	0	2					
		06MAR2003	2	1	0	1					
		07MAR2003	3	1	0	1					
		08MAR2003	4	2	0	2					
		09MAR2003	5	3	0	3					
		10MAR2003	6	3	0	3					
		11MAR2003	7	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0020013	12MAR2003	8	4	0	4					PER PATIENT REPORT
		13MAR2003	9	4	0	4					PER PATIENT REPORT
		14MAR2003	10	4	0	4					PER PATIENT REPORT
		15MAR2003	11	4	0	4					PER PATIENT REPORT
		16MAR2003	12	4	0	4					PER PATIENT REPORT
		17MAR2003									NOT TAKEN
		18MAR2003									NOT TAKEN
		19MAR2003									NOT TAKEN
		20MAR2003					NO	254.2	12	100	NOT TAKEN BLISTERCARD NOT RETURNED. PAGE COMPLETED PER PATIENT REPORT.
	E0022008	12NOV2002	1	2	0	2					
		13NOV2002	2	1	0	1					
		14NOV2002	3	1	0	1					
		15NOV2002	4	2	0	2					
		16NOV2002	5	3	0	3					
		17NOV2002	6	3	0	3					
		18NOV2002	7	3	0	3					
		19NOV2002	8	4	0	4					
		20NOV2002	9	4	0	4					
		21NOV2002	10	4	0	4					
		22NOV2002	11	4	0	4					
		23NOV2002	12	4	0	4					
		24NOV2002	13	4	0	4					
		25NOV2002	14	4	0	4					
		26NOV2002	15	4	0	4					
		27NOV2002	16	4	0	4					
		28NOV2002	17	4	0	4					
		29NOV2002	18	4	0	4					
		30NOV2002	19	4	0	4					
		01DEC2002	20	4	0	4					
		02DEC2002	21	4	0	4					
		03DEC2002	22	4	0	4					
		04DEC2002	23	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	05DEC2002	24	4	0	4					
		06DEC2002	25	4	0	4					
		07DEC2002	26	4	0	4					
		08DEC2002	27	4	0	4					
		09DEC2002	28	4	0	4					
		10DEC2002	29		0	4					
		11DEC2002	30		0	4					
		12DEC2002	31	4	0	4					
		13DEC2002	32	4	0	4					
		14DEC2002	33	4	0	4					
		15DEC2002	34	4	0	4					
		16DEC2002	35	4	0	4					
		17DEC2002	36	4	0	4					
		18DEC2002	37	4	0	4					
		19DEC2002	38	4	0	4					
		20DEC2002	39	4	0	4					
		21DEC2002	40	4	0	4					
		22DEC2002	41	4	0	4					
		23DEC2002	42	4	0	4					
		24DEC2002	43	4	0	4					
		25DEC2002	44	4	0	4					
		26DEC2002	45	4	0	4					
		27DEC2002	46	4	0	4					
		28DEC2002	47	4	0	4					
		29DEC2002	48	4	0	4					
		30DEC2002	49	4	0	4					
		31DEC2002	50	4	0	4					
		01JAN2003	51	4	0	4					
		02JAN2003	52	4	0	4					
		03JAN2003	53	4	0	4					
		04JAN2003	54	4	0	4					
		05JAN2003	55	4	0	4					
		06JAN2003	56	4	0	4					B/P PACK NOT RETURNED PT REPORTS 100% COMPLIANCE
		07JAN2003	57		0	4	NO	290.4	57	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	19DEC2002	1	2	0	2					
		20DEC2002	2	1	0	1					
		21DEC2002	3	1	0	1					
		22DEC2002	4	2	0	2					
		23DEC2002	5	3	0	3					
		24DEC2002	6	3	0	3					
		25DEC2002	7	3	0	3					
		26DEC2002	8	4	0	4					
		27DEC2002	9	4	0	4					
		28DEC2002	10	4	0	4					
		29DEC2002	11	4	0	4					
		30DEC2002	12	4	0	4					
		31DEC2002	13	4	0	4					
		01JAN2003	14	4	0	4					
		02JAN2003	15		0	4					
		03JAN2003	16	4	0	4					
		04JAN2003	17	4	0	4					
		05JAN2003	18	4	0	4					
		06JAN2003	19	4	0	4					
		07JAN2003	20	4	0	4					
		08JAN2003	21	4	0	4					
		09JAN2003	22	4	0	4					
		10JAN2003	23	4	0	4					
		11JAN2003	24	4	0	4					
		12JAN2003	25	4	0	4					
		13JAN2003	26	4	0	4					
		14JAN2003	27	4	0	4					
		15JAN2003	28	4	0	4					
		16JAN2003	29		0	4					
		17JAN2003	30	4	0	4					
		18JAN2003	31	4	0	4					
		19JAN2003	32	4	0	4					
		20JAN2003	33	4	0	4					
		21JAN2003	34	4	0	4					
		22JAN2003	35	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	23JAN2003	36	4	0	4					
		24JAN2003	37	4	0	4					
		25JAN2003	38	4	0	4					
		26JAN2003	39	4	0	4					
		27JAN2003	40	4	0	4					
		28JAN2003	41	4	0	4					
		29JAN2003	42		0	4					
		30JAN2003	43		0	4					
		31JAN2003	44	4	0	4					
		01FEB2003	45	4	0	4					
		02FEB2003	46	4	0	4					
		03FEB2003	47	4	0	4					
		04FEB2003	48	4	0	4					
		05FEB2003	49	4	0	4					
		06FEB2003	50	4	0	4					
		07FEB2003	51	4	0	4					
		08FEB2003	52	4	0	4					
		09FEB2003	53	4	0	4					
		10FEB2003	54	4	0	4					
		11FEB2003	55	4	0	4					
		12FEB2003	56	4	0	4	NO	290.2	56	100	
	E0022018	12DEC2002	1	2	0	2					
		13DEC2002	2	1	0	1					
		14DEC2002	3	1	0	1					
		15DEC2002	4	2	0	2					
		16DEC2002	5	3	0	3					
		17DEC2002	6	3	0	3					
		18DEC2002	7	3	0	3					
		19DEC2002	8	4	0	4					
		20DEC2002	9	4	0	4					
		21DEC2002	10	4	0	4					
		22DEC2002	11	4	0	4					
		23DEC2002	12	4	0	4					
		24DEC2002	13	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	25DEC2002	14	4	0	4					
		26DEC2002	15	4	0	4					
		27DEC2002	16	4	0	4					
		28DEC2002	17	4	0	4					
		29DEC2002	18	4	0	4					
		30DEC2002	19	4	0	4					
		31DEC2002	20	4	0	4					
		01JAN2003	21	4	0	4					
		02JAN2003	22	4	0	4					
		03JAN2003	23	4	0	4					
		04JAN2003	24	4	0	4					
		05JAN2003	25	4	0	4					
		06JAN2003	26	4	0	4					
		07JAN2003	27	4	0	4					
		08JAN2003	28	4	0	4					
		09JAN2003	29	4	0	4					
		10JAN2003	30	4	0	4					
		11JAN2003	31	4	0	4					
		12JAN2003	32	4	0	4					
		13JAN2003	33	4	0	4					
		14JAN2003	34	4	0	4					
		15JAN2003	35	4	0	4					
		16JAN2003	36	4	0	4					
		17JAN2003	37	4	0	4					
		18JAN2003	38	4	0	4					
		19JAN2003	39	4	0	4					
		20JAN2003	40	4	0	4					
		21JAN2003	41	4	0	4					
		22JAN2003	42	4	0	4					
		23JAN2003	43	4	0	4					
		24JAN2003	44	4	0	4					
		25JAN2003	45	4	0	4					
		26JAN2003	46	4	0	4					
		27JAN2003	47	4	0	4					
		28JAN2003	48	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	29JAN2003	49	4	0	4					
		30JAN2003	50	4	0	4					
		31JAN2003	51	4	0	4					
		01FEB2003	52	4	0	4					
		02FEB2003	53	4	0	4					
		03FEB2003	54	4	0	4					
		04FEB2003	55	4	0	4					
		05FEB2003	56	4	0	4	NO	290.2	56	100	
	E0022022	30DEC2002	1	2	0	2					
		31DEC2002	2	1	0	1					
		01JAN2003	3	1	0	1					
		02JAN2003	4	2	0	2					
		03JAN2003	5	3	0	3					
		04JAN2003	6	3	0	3					
		05JAN2003	7	3	0	3					
		06JAN2003	8	4	0	4					
		07JAN2003	9	4	0	4					
		08JAN2003	10	4	0	4					
		09JAN2003	11	4	0	4					
		10JAN2003	12	4	0	4					
		11JAN2003	13	4	0	4					
		12JAN2003	14	4	0	4					
		13JAN2003	15		0	4					
		14JAN2003	16	4	0	4					
		15JAN2003	17	4	0	4					
		16JAN2003	18	4	0	4					
		17JAN2003	19	4	0	4					
		18JAN2003	20	4	0	4					
		19JAN2003	21	4	0	4					
		20JAN2003	22	4	0	4					
		21JAN2003	23	4	0	4					
		22JAN2003	24	4	0	4					
		23JAN2003	25	4	0	4					
		24JAN2003	26	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	25JAN2003	27	4	0	4					
		26JAN2003	28	4	0	4					
		27JAN2003	29	4	0	4					
		28JAN2003	30	4	0	4					
		29JAN2003	31	4	0	4					
		30JAN2003	32	4	0	4					
		31JAN2003	33	4	0	4					
		01FEB2003	34	4	0	4					
		02FEB2003	35	4	0	4					
		03FEB2003	36	4	0	4					
		04FEB2003	37	4	0	4					
		05FEB2003	38	4	0	4					
		06FEB2003	39	4	0	4					
		07FEB2003	40	4	0	4					
		08FEB2003	41	4	0	4					
		09FEB2003	42	4	0	4					
		10FEB2003	43	4	0	4					
		11FEB2003	44		0	4					
		12FEB2003	45		0	4	NO	287.8	45	100	
	E0022027	06FEB2003	1	2	0	2					
		07FEB2003	2	1	0	1					
		08FEB2003	3	1	0	1					
		09FEB2003	4	2	0	2					
		10FEB2003	5	3	0	3					
		11FEB2003	6	3	0	3					20030212
		12FEB2003	7	3	0	3					
		13FEB2003	8	4	0	4					
		14FEB2003	9	4	0	4					
		15FEB2003	10	4	0	4					
		16FEB2003	11	4	0	4					
		17FEB2003	12	4	0	4					
		18FEB2003	13	4	0	4					
		19FEB2003	14	4	0	4					
		20FEB2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	21FEB2003	16	4	0	4					
		22FEB2003	17	4	0	4					
		23FEB2003	18	4	0	4					
		24FEB2003	19	4	0	4					
		25FEB2003	20	4	0	4					
		26FEB2003	21	4	0	4					
		27FEB2003	22	4	0	4					
		28FEB2003	23	4	0	4					
		01MAR2003	24	4	0	4					
		02MAR2003	25	4	0	4					
		03MAR2003	26	4	0	4					
		04MAR2003	27	4	0	4					
		05MAR2003	28	4	0	4					
		06MAR2003	29	4	0	4					
		07MAR2003	30	4	0	4					
		08MAR2003	31	4	0	4					
		09MAR2003	32	4	0	4					
		10MAR2003	33	4	0	4					
		11MAR2003	34	4	0	4					
		12MAR2003	35	4	0	4					
		13MAR2003	36	4	0	4					
		14MAR2003	37	4	0	4					
		15MAR2003	38	4	0	4					
		16MAR2003	39	4	0	4					
		17MAR2003	40	4	0	4					
		18MAR2003	41	4	0	4					
		19MAR2003	42	4	0	4					
		20MAR2003	43	4	0	4					
		21MAR2003	44	4	0	4					
		22MAR2003	45	4	0	4					
		23MAR2003	46	4	0	4					
		24MAR2003	47	4	0	4					
		25MAR2003	48	4	0	4					
		26MAR2003	49	4	0	4					
		27MAR2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	28MAR2003	51	4	0	4					
		29MAR2003	52	4	0	4					
		30MAR2003	53	4	0	4					
		31MAR2003	54	4	0	4					
		01APR2003	55	4	0	4					
		02APR2003	56	4	0	4	NO	290.2	56	100	
	E0022030	14FEB2003	1	2	0	2					
		15FEB2003	2	1	0	1					
		16FEB2003	3	1	0	1					
		17FEB2003	4	2	0	2					
		18FEB2003	5	3	0	3					
		19FEB2003	6	3	0	3					
		20FEB2003	7	3	0	3					
		21FEB2003	8	4	0	4					SIC
		22FEB2003	9	4	0	4					
		23FEB2003	10	4	0	4					
		24FEB2003	11	4	0	4					
		25FEB2003	12	4	0	4					
		26FEB2003	13	4	0	4					
		27FEB2003	14	4	0	4					
		28FEB2003	15	4	0	4					
		01MAR2003	16	4	0	4					
		02MAR2003	17	4	0	4					
		03MAR2003	18	4	0	4					
		04MAR2003	19	4	0	4					
		05MAR2003	20	4	0	4					
		06MAR2003	21	4	0	4					
		07MAR2003	22	4	0	4					PT. DID NOT RETURN THESE MEDS.
		08MAR2003	23	4	0	4					
		09MAR2003	24	4	0	4					
		10MAR2003	25	4	0	4					
		11MAR2003	26	4	0	4					
		12MAR2003	27	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)		14MAR2003	29		0	4	NO	281	29	100	UNKNOWN
	E0022031	18FEB2003	1	2	0	2					
		19FEB2003	2	1	0	1					
		20FEB2003	3	1	0	1					
		21FEB2003	4	2	0	2					
		22FEB2003	5	3	0	3					
		23FEB2003	6	3	0	3					
		24FEB2003	7	3	0	3					
		25FEB2003	8	4	0	4					
		26FEB2003	9	4	0	4					
		27FEB2003	10	4	0	4					
		28FEB2003	11	4	0	4					
		01MAR2003	12	4	0	4					
		02MAR2003	13	4	0	4					
		03MAR2003	14	4	0	4					
		04MAR2003	15	4	0	4					
		05MAR2003	16	4	0	4					
		06MAR2003	17	4	0	4					
		07MAR2003	18	4	0	4					
		08MAR2003	19	4	0	4					
		09MAR2003	20	4	0	4					
		10MAR2003	21	4	0	4					
		11MAR2003	22	4	1	3					DOSE REDUCED TO 3 TABS PRN
		12MAR2003	23	4	1	3					
		13MAR2003	24	4	1	3					
		14MAR2003	25	4	1	3					
		15MAR2003	26	4	1	3					
		16MAR2003	27	4	1	3					
		17MAR2003	28	4	1	3					
		18MAR2003	29	4	1	3					PT TAKES ONLY 3 PRN
		19MAR2003	30	4	1	3					
		20MAR2003	31	4	1	3					
		21MAR2003	32	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022031	22MAR2003	33	4	1	3					
		23MAR2003	34	4	1	3					
		24MAR2003	35	4	1	3					
		25MAR2003	36	4	1	3					
		26MAR2003	37	4	1	3					
		27MAR2003	38	4	1	3					
		28MAR2003	39	4	1	3					
		29MAR2003	40	4	1	3					
		30MAR2003	41	4	1	3					
		31MAR2003	42	4	1	3					
		01APR2003	43	4	1	3					
		02APR2003	44	4	1	3					
		03APR2003	45	4	1	3					
		04APR2003	46	4	1	3					
		05APR2003	47	4	1	3					
		06APR2003	48	4	1	3					
		07APR2003	49	4	1	3					
		08APR2003	50	4	4	0					PT FORGOT DOSE
		09APR2003	51	4	1	3					
		10APR2003	52	4	1	3					
		11APR2003	53	4	1	3					
		12APR2003	54	4	4	0					PT FORGOT DOSE
		13APR2003	55	4	1	3					
		14APR2003	56	4	1	3	YES	220.5	54	95.5	
	E0022032	18FEB2003	1	2	0	2					
		19FEB2003	2	1	0	1					
		20FEB2003	3	1	0	1					
		21FEB2003	4	2	0	2					PT. TOOK ON 2/22/03
		22FEB2003	5	3	1	2					PT. TOOK ON 2/23/03
		23FEB2003	6	3	0	3					PT. TOOK ON 2/24/03
		24FEB2003	7	3	0	3					PT. TOOK ON 2/25/03
		25FEB2003	8		1	3					PT. TOOK ON 2/26/03
		26FEB2003	9		0	4					PT. TOOK ON 2/27/03
		27FEB2003	10			0					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	28FEB2003	11	4	0	4					SIC
		01MAR2003	12	4	0	4					
		02MAR2003	13	4	0	4					
		03MAR2003	14	4	0	4					
		04MAR2003	15	4	0	4					
		05MAR2003	16	4	0	4					
		06MAR2003	17	4	0	4					
		07MAR2003	18	4	0	4					
		08MAR2003	19	4	0	4					
		09MAR2003	20	4	0	4					
		10MAR2003	21	4	0	4					
		11MAR2003	22	4	0	4					
		12MAR2003	23	4	0	4					
		13MAR2003	24	4	0	4					
		14MAR2003	25	4	0	4					
		15MAR2003	26	4	0	4					
		16MAR2003	27	4	0	4					
		17MAR2003	28	4	0	4					
		18MAR2003	29		0	4					
		19MAR2003	30		0	4					PT. MISSED DOSE ON 3/20/03
		20MAR2003	31			0					
		21MAR2003	32	4	0	4					SIC
		22MAR2003	33	4	0	4					
		23MAR2003	34	4	0	4					
		24MAR2003	35	4	0	4					
		25MAR2003	36	4	0	4					
		26MAR2003	37	4	0	4					
		27MAR2003	38	4	0	4					
		28MAR2003	39	4	0	4					
		29MAR2003	40	4	0	4					
		30MAR2003	41	4	0	4					
		31MAR2003	42	4	0	4					
		01APR2003	43	4	0	4					
		02APR2003	44	4	0	4					
		03APR2003	45	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	04APR2003	46	4	0	4					
		05APR2003	47	4	0	4					
		06APR2003	48	4	0	4					
		07APR2003	49	4	0	4					
		08APR2003	50	4	0	4					
		09APR2003	51	4	0	4					
		10APR2003	52	4	0	4					
		11APR2003	53	4	0	4					
		12APR2003	54	4	0	4					
		13APR2003	55	4	0	4					
		14APR2003					NO	271.8	53	95.6	PATIENT STOPPED MEDS EARLY LAST DOSE 04/13/03
	E0022035	19FEB2003	1	2	0	2					
		20FEB2003	2	1	0	1					
		21FEB2003	3	1	0	1					
		22FEB2003	4	2	0	2					
		23FEB2003	5	3	0	3					
		24FEB2003									LAST DAY WAS DAY 5 2/23/03 PT. STOPPED MEDS ALTOGETHER.
		25FEB2003									LAST DAY WAS DAY 5 2/23/03 PT. STOPPED MEDS ALTOGETHER.
		26FEB2003					NO	190	5	100	TOOK 1 PILL TO REPLACE LOST PILL
	E0022036	25FEB2003	1	2	0	2					
		26FEB2003	2	1	0	1					
		27FEB2003	3	1	0	1					
		28FEB2003	4	2	0	2					
		01MAR2003	5	3	0	3					
		02MAR2003	6	3	0	3					
		03MAR2003	7	3	0	3					
		04MAR2003	8	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	05MAR2003	9	4	0	4					
		06MAR2003	10	4	0	4					
		07MAR2003	11	4	0	4					
		08MAR2003	12	4	0	4					
		09MAR2003	13	4	0	4					
		10MAR2003	14	4	0	4					
		11MAR2003	15	4	0	4					
		12MAR2003	16	4	0	4					
		13MAR2003	17	4	0	4					
		14MAR2003	18	4	0	4					
		15MAR2003	19	4	0	4					
		16MAR2003	20	4	0	4					
		17MAR2003	21		0	4					
		18MAR2003	22	4	0	4					
		19MAR2003	23	4	0	4					
		20MAR2003	24	4	0	4					
		21MAR2003	25	4	0	4					
		22MAR2003	26	4	0	4					
		23MAR2003	27	4	0	4					
		24MAR2003	28	4	0	4					
		25MAR2003	29	4	0	4					
		26MAR2003	30	4	0	4					
		27MAR2003	31	4	0	4					
		28MAR2003	32	4	0	4					
		29MAR2003	33	4	0	4					
		30MAR2003	34	4	0	4					
		31MAR2003	35	4	0	4					
		01APR2003	36	4	0	4					
		02APR2003	37	4	0	4					
		03APR2003	38	4	0	4					
		04APR2003	39	4	0	4					
		05APR2003	40	4	0	4					
		06APR2003	41	4	0	4					
		07APR2003	42	4	0	4					
		08APR2003	43	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	09APR2003	44	4	0	4					
		10APR2003	45	4	0	4					
		11APR2003	46	4	0	4					
		12APR2003	47	4	0	4					
		13APR2003	48	4	0	4					
		14APR2003	49	4	0	4					
		15APR2003	50	4	0	4					
		16APR2003	51	4	0	4					
		17APR2003	52	4	0	4					
		18APR2003	53	4	0	4					
		19APR2003	54	4	0	4					
		20APR2003	55	4	0	4					
		21APR2003	56	4	0	4	NO	290.2	56	100	
	E0022056	17APR2003	1	2	0	2					
		18APR2003	2	1	0	1					
		19APR2003	3	1	0	1					
		20APR2003	4	2	0	2					
		21APR2003	5	3	0	3					
		22APR2003	6	3	0	3					
		23APR2003	7	3	0	3					
		24APR2003	8	4	0	4					
		25APR2003	9	4	0	4					
		26APR2003	10	4	0	4					
		27APR2003	11	4	0	4					
		28APR2003	12	4	0	4					
		29APR2003	13	4	0	4					
		30APR2003	14	4	0	4					
		01MAY2003	15	4	0	4					
		02MAY2003	16	4	0	4					
		03MAY2003	17	4	0	4					
		04MAY2003	18	4	0	4					
		05MAY2003	19	4	4	0					PT FORGOT DOSE
		06MAY2003	20	4	0	4					
		07MAY2003	21	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022056	08MAY2003	22	4	0	4	NO	261.4	21	94.7	PT WAS ET LAST DOSE 5-8-03
	E0022060	30APR2003	1	2	0	2					
		01MAY2003	2	1	0	1					
		02MAY2003	3	1	0	1					
		03MAY2003	4	2	0	2					
		04MAY2003	5	3	0	3					
		05MAY2003	6	3	0	3					
		06MAY2003	7	3	0	3					
		07MAY2003	8	4	0	4					
		08MAY2003	9	4	4	0					MISSED DOSE
		09MAY2003	10	4	0	4					
		10MAY2003	11	4	0	4					
		11MAY2003	12	4	0	4					
		12MAY2003	13	4	1	3					PT. SCHEDULED EARLY DUE TO WORK SCHEDULE.
		12MAY2003	13	4	1	3					TAKING 3 TABS DUE TO AE
		13MAY2003	14	4	1	3					SIC
		14MAY2003	15	4	1	3					SIC
		15MAY2003	16	4	1	3					SIC
		16MAY2003	17	4	1	3					SIC
		17MAY2003	18	4	4	0					MISSED DOSE IN ERROR
		18MAY2003	19	4	4	0					MISSED DOSE IN ERROR
		19MAY2003	20	4	1	3					
		20MAY2003	21	4	1	3					
		21MAY2003	22	4	1	3					
		22MAY2003	23	4	1	3					
		23MAY2003	24	4	1	3					
		24MAY2003	25	4	1	3					
		25MAY2003	26	4	1	3					
		26MAY2003	27		1	3					
		27MAY2003	28		1	3					
		28MAY2003	29	4	0	4					SIC DOSE INCREASED IN ERROR
		29MAY2003	30	4	0	4					
		30MAY2003	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	31MAY2003	32	4	0	4					
		01JUN2003	33	4	0	4					
		02JUN2003	34	4	0	4					
		03JUN2003	35	4	0	4					
		04JUN2003	36	4	0	4					
		05JUN2003	37	4	0	4					
		06JUN2003	38	4	0	4					
		07JUN2003	39	4	0	4					
		08JUN2003	40	4	0	4					
		09JUN2003	41		0	4					
		10JUN2003	42	4	4	4					
		11JUN2003	43	4	0	4					
		12JUN2003	44	4	0	4					
		13JUN2003	45	4	0	4					
		14JUN2003	46	4	0	4					
		15JUN2003	47	4	0	4					
		16JUN2003	48	4	0	4					
		17JUN2003	49	4	0	4					
		18JUN2003	50	4	0	4					
		19JUN2003	51	4	0	4					
		20JUN2003	52	4	0	4					
		21JUN2003	53	4	0	4					
		22JUN2003	54	4	0	4					
		23JUN2003	55	4	0	4	YES	248.2	52	93.8	
	E0022063	07MAY2003	1	2	0	2					
		08MAY2003	2	1	0	1					
		09MAY2003	3	1	0	1					
		10MAY2003	4	2	0	2					
		11MAY2003	5	3	0	3					
		12MAY2003	6	3	0	3					
		13MAY2003	7	3	0	3					
		14MAY2003	8	4	0	4					
		15MAY2003	9	4	0	4					
		16MAY2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	17MAY2003	11	4	0	4					
		18MAY2003	12	4	0	4					
		19MAY2003	13	4	0	4					
		20MAY2003	14	4	0	4					
		21MAY2003	15	4	0	4					
		22MAY2003	16	4	0	4					
		23MAY2003	17	4	0	4					
		24MAY2003	18	4	0	4					
		25MAY2003	19	4	0	4					
		26MAY2003	20	4	0	4					
		27MAY2003	21	4	0	4					
		28MAY2003	22	4	0	4					
		29MAY2003	23	4	0	4					
		30MAY2003	24	4	0	4					
		31MAY2003	25	4	0	4					
		01JUN2003	26	4	0	4					
		02JUN2003	27	4	0	4					
		03JUN2003	28	4	0	4					
		04JUN2003	29	4	0	4					
		05JUN2003	30	4	0	4					
		06JUN2003	31	4	0	4					
		07JUN2003	32	4	0	4					
		08JUN2003	33	4	0	4					
		09JUN2003	34	4	0	4					
		10JUN2003	35	4	0	4					
		11JUN2003	36	4	0	4					PATIENT LOST OT FOLLOW MEDS NOT RETURNED.
		12JUN2003	37	4	0	4					
		13JUN2003	38	4	0	4					
		14JUN2003	39	4	0	4					
		15JUN2003	40	4	0	4					
		16JUN2003	41	4	0	4					
		17JUN2003	42	4	0	4					
		18JUN2003	43		0	4					UNK
		19JUN2003	44		0	4	NO	287.5	44	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8	4	0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4					
		12FEB2003	14	4	0	4					
		13FEB2003	15	4	1	3					DECREASED DOSE
		14FEB2003	16	4	1	3					
		15FEB2003	17	4	1	3					
		16FEB2003	18	4	1	3					
		17FEB2003	19	4	1	3					
		18FEB2003	20	4	0	4					TOOK FULL DOSE
		19FEB2003	21	4	1	3					
		20FEB2003	22	4	1	3					DOSE DECREASED FOR REST OF STUDY
		21FEB2003	23	4	0	4					INADVERTENTLY TOOK ALL 4 TABS
		22FEB2003	24	4	1	3					
		23FEB2003	25	4	1	3					
		24FEB2003	26	4	1	3					
		25FEB2003	27	4	1	3					DOSE DECREASED FOR REST OF STUDY
		26FEB2003	28	4	1	3					
		27FEB2003	29	4	1	3					
		28FEB2003	30	4	1	3					
		01MAR2003	31	4	1	3					
		02MAR2003	32	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	03MAR2003	33	4	1	3					
		04MAR2003	34		1	3					
		05MAR2003	35		1	3					
		06MAR2003	36	4	1	3					DOSE DECREASED FOR REST OF STUDY
		07MAR2003	37	4	1	3					
		08MAR2003	38	4	1	3					
		09MAR2003	39	4	1	3					
		10MAR2003	40	4	1	3					
		11MAR2003	41	4	1	3					DOSE DECREASED FOR REST OF STUDY
		12MAR2003	42	4	1	3					
		13MAR2003	43	4	1	3					
		14MAR2003	44	4	1	3					
		15MAR2003	45	4	1	3					
		16MAR2003	46	4	1	3					
		17MAR2003	47	4	1	3					
		18MAR2003	48	4	1	3					DOSE DECREASED FOR REST OF STUDY
		19MAR2003	49	4	1	3					
		20MAR2003	50	4	1	3					
		21MAR2003	51	4	1	3					
		22MAR2003	52	4	1	3					
		23MAR2003	53	4	1	3	YES	219.8	53	100	
	E0023013	27FEB2003	1	2	0	2					
		28FEB2003	2	1	0	1					
		01MAR2003	3	1	0	1					
		02MAR2003					NO	116.7	3	100	PT STOPPED MEDS ON OWN PRIOR TO EARLY TERMINATION DATE
	E0023015	11MAR2003	1	2	0	2					
		12MAR2003	2	1	0	1					
		13MAR2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023015	14MAR2003	4	2	0	2					
		15MAR2003	5	3	0	3					
		16MAR2003	6	3	0	3					
		17MAR2003	7	3	0	3					
		18MAR2003	8	4	0	4					
		19MAR2003	9	4	0	4					
		20MAR2003	10	4	0	4					
		21MAR2003	11	4	0	4					
		22MAR2003	12	4	0	4					
		23MAR2003	13	4	0	4					
		24MAR2003	14	4	0	4					
		25MAR2003	15	4	0	4					
		26MAR2003	16	4	0	4					
		27MAR2003	17	4	0	4					
		28MAR2003	18	4	0	4					
		29MAR2003	19	4	0	4					
		30MAR2003	20	4	0	4					
		31MAR2003	21	4	0	4					
		01APR2003	22	4	0	4					
		02APR2003	23	4	0	4					
		03APR2003	24	4	0	4					
		04APR2003	25	4	0	4					
		05APR2003	26	4	0	4					
		06APR2003	27	4	0	4					
		07APR2003	28	4	0	4					
		08APR2003	29	4	1	3					DOSE DECREASED FOR REST OF STUDY
		09APR2003	30	4	1	3					
		10APR2003	31	4	1	3					
		11APR2003	32	4	1	3					
		12APR2003	33	4	1	3					
		13APR2003	34	4	1	3					
		14APR2003	35	4	1	3					
		15APR2003	36		4	0					
		16APR2003	37	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023015	17APR2003	38	4	1	3					
		18APR2003	39	4	1	3					
		19APR2003	40	4	1	3					
		20APR2003	41	4	1	3					
		21APR2003	42	4	1	3					
		22APR2003	43	4	1	6					
		23APR2003	44	4	1	3					
		24APR2003	45	4	1	3					
		25APR2003	46	4	1	3					
		26APR2003	47	4	1	3					
		27APR2003	48	4	1	3					
		28APR2003	49	4	1	3					
		29APR2003	50	4	1	3					
		30APR2003	51	4	1	3					
		01MAY2003	52	4	1	3					
		02MAY2003	53	4	1	3					
		03MAY2003	54	4	1	3					
		04MAY2003	55	4	1	3					
		05MAY2003	56	4	1	3	YES	240.2	55	98.9	
	E0023034	09JUN2003	1	2	0	2					
		10JUN2003	2	1	0	1					
		11JUN2003	3	1	0	1					
		12JUN2003	4	2	0	2					
		13JUN2003	5	3	0	3					
		14JUN2003	6	3	0	3					
		15JUN2003	7	3	0	3					
		16JUN2003	8	4	0	4					
		17JUN2003	9	4	0	4					
		18JUN2003	10	4	0	4					
		19JUN2003	11	4	0	4					
		20JUN2003	12	4	0	4					
		21JUN2003	13	4	0	4					
		22JUN2003	14	4	0	4					
		23JUN2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	24JUN2003	16	4	0	4					
		25JUN2003	17	4	0	4					
		26JUN2003	18	4	0	4					
		27JUN2003	19	4	0	4					
		28JUN2003	20	4	0	4					
		29JUN2003	21	4	0	4					
		30JUN2003	22	4	0	4					
		01JUL2003	23	4	0	4					
		02JUL2003	24	4	0	4					
		03JUL2003	25	4	0	4					
		04JUL2003	26	4	0	4					
		05JUL2003	27	4	0	4					
		06JUL2003	28	4	0	4					
		07JUL2003	29	4	0	4					
		08JUL2003	30	4	0	4					
		09JUL2003	31	4	0	4					
		10JUL2003	32	4	0	4					
		11JUL2003	33	4	0	4					
		12JUL2003	34	4	4	0					MISSED DOSE
		13JUL2003	35	4	0	4					
		14JUL2003	36	4	0	4					
		15JUL2003	37	4	0	4					
		16JUL2003	38	4	0	4					
		17JUL2003	39	4	0	4					
		18JUL2003	40	4	0	4					
		19JUL2003	41	4	0	4					
		20JUL2003	42	4	0	4					
		21JUL2003	43		4	0					
		22JUL2003	44	4	0	4					MISSED DOSE ON 7-21-03
		23JUL2003	45	4	0	4					
		24JUL2003	46	4	0	4					
		25JUL2003	47	4	0	4					
		26JUL2003	48	4	0	4					
		27JUL2003	49	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	28JUL2003					NO	276.5	47	95.6	INADVERTENTLY NOT TAKEN BY PATIENT - PT COUNSELLED
	E0023037	18JUN2003	1	2	0	2					
		19JUN2003	2	1	0	1					
		20JUN2003	3	1	0	1					
		21JUN2003	4	2	0	2					
		22JUN2003	5	3	0	3					
		23JUN2003	6	3	0	3					
		24JUN2003	7	3	0	3					
		25JUN2003	8	4	0	4					
		26JUN2003	9	4	0	4					
		27JUN2003	10	4	0	4					
		28JUN2003	11	4	0	4					
		29JUN2003	12	4	0	4					
		30JUN2003	13	4	0	4					
		01JUL2003	14	4	0	4					
		02JUL2003	15		0	4					
		03JUL2003	16		0	4					
		04JUL2003	17	4	0	4					
		05JUL2003	18	4	0	4					
		06JUL2003	19	4	0	4					
		07JUL2003	20	4	0	4					
		08JUL2003	21	4	0	4					
		09JUL2003	22	4	0	4					
		10JUL2003	23	4	0	4					
		11JUL2003	24		0	4					
		12JUL2003	25		0	4					
		13JUL2003	26			0					
		14JUL2003	27	4	0	4					PT MISSED DOSE ON 7/13/03
		15JUL2003	28	4	0	4					
		16JUL2003	29	4	0	4					
		17JUL2003	30	4	0	4					
		18JUL2003	31	4	0	4					
		19JUL2003	32	4	0	4					
		20JUL2003	33	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023037	21JUL2003	34	4	0	4					
		22JUL2003	35	4	0	4					
		23JUL2003	36	4	0	4					
		24JUL2003	37	4	0	4					
		25JUL2003	38	4	0	4					
		26JUL2003	39	4	0	4					
		27JUL2003	40	4	0	4					
		28JUL2003	41	4	0	4					
		29JUL2003	42	4	0	4					
		30JUL2003	43	4	0	4					
		31JUL2003	44	4	0	4					
		01AUG2003	45	4	0	4					
		02AUG2003	46	4	0	4					
		03AUG2003	47	4	0	4					
		04AUG2003	48	4	0	4					
		05AUG2003	49	4	0	4					
		06AUG2003	50	4	0	4					
		07AUG2003	51	4	0	4					
		08AUG2003	52	4	0	4					
		09AUG2003	53	4	0	4					
		10AUG2003	54	4	0	4					
		11AUG2003	55	4	0	4					
		12AUG2003	56	4	0	4					
		13AUG2003	57	4	0	4					
		14AUG2003	58	4	0	4	NO	285.3	57	98.2	COMPLETED TREATMENT
	E0023038	30JUN2003	1	2	0	2					
		01JUL2003	2	1	0	1					
		02JUL2003	3	1	0	1					
		03JUL2003	4	2	0	2					
		04JUL2003	5	3	0	3					
		05JUL2003	6	3	0	3					
		06JUL2003	7	3	0	3					
		07JUL2003	8		0	4					
		08JUL2003	9		0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023038	09JUL2003	10	4	0	4					
		10JUL2003	11	4	0	4					
		11JUL2003	12	4	0	4					
		12JUL2003	13	4	0	4					
		13JUL2003	14	4	0	4					
		14JUL2003	15	4	0	4					
		15JUL2003	16	4	0	4					VISIT 4 DATE
		16JUL2003	17	4	0	4					
		17JUL2003	18	4	0	4					
		18JUL2003	19	4	0	4					
		19JUL2003	20	4	0	4					
		20JUL2003	21	4	0	4					
		21JUL2003	22	4	0	4					VISIT 5 DATE
		22JUL2003	23	4	0	4					
		23JUL2003	24	4	0	4					
		24JUL2003	25	4	0	4					
		25JUL2003	26	4	0	4					
		26JUL2003	27	4	0	4					
		27JUL2003	28	4	0	4					
		28JUL2003	29	4	0	4					
		29JUL2003	30	4	0	4					
		30JUL2003	31	4	0	4					
		31JUL2003	32	4	0	4					
		01AUG2003	33	4	0	4					
		02AUG2003	34	4	0	4					
		03AUG2003	35	4	0	4					
		04AUG2003	36		0	4					
		05AUG2003	37		0	4					
		06AUG2003	38			0					
		07AUG2003	39	4	0	4					PT MISSED DOSE ON 8/6/03
		08AUG2003	40	4	0	4					
		09AUG2003	41	4	0	4					
		10AUG2003	42	4	0	4					
		11AUG2003	43	4	0	4					
		12AUG2003	44	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023038	13AUG2003	45	4	0	4					VISIT 8 DATE
		14AUG2003	46	4	0	4					SIC
		15AUG2003	47	4	0	4					LOST TAB
		16AUG2003	48	4	0	4					
		17AUG2003	49	4	0	4					
		18AUG2003	50	4	0	4					
		19AUG2003	51	4	0	4					
		20AUG2003	52		0	4					
		21AUG2003	53	4	1	3					PT REDUCED DOSE WITHOUT SITE KNOWLEDGE
		22AUG2003	54	4	1	3					
		23AUG2003	55	4	1	3					
		24AUG2003	56	4	1	3					
		25AUG2003	57	4	1	3					
		26AUG2003	58	4	1	3					
		27AUG2003					YES	275	57	98.1	COMPLETED TREATMENT
	E0023044	16JUL2003	1	2	0	2					
		17JUL2003	2	1	0	1					
		18JUL2003	3	1	0	1					
		19JUL2003	4	2	0	2					
		20JUL2003	5	3	0	3					
		21JUL2003	6	3	0	3					
		22JUL2003	7	3	0	3					
		23JUL2003	8	4	0	8					WALLET NOT RETURNED
		24JUL2003	9	4	0	8					
		25JUL2003	10	4	0	4					
		26JUL2003	11	4	0	4					
		27JUL2003	12	4	0	4					
		28JUL2003	13	4	0	4					
		29JUL2003	14	4	0	4					
		30JUL2003	15	4	0	4					
		31JUL2003	16	4	0	4					
		01AUG2003	17	4	0	4					
		02AUG2003	18	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023044	03AUG2003	19	4	0	4					
		04AUG2003	20	4	0	4					
		05AUG2003	21	4	4	0					MISSED DOSE
		06AUG2003	22	4	0	4					
		07AUG2003	23	4	4	0					MISSED DOSE
		08AUG2003	24	4	0	4					
		09AUG2003	25	4	0	4	NO	278	23	100	LAST DOSE TAKEN CARD NOT RETURNED ALL INFO PER PT. REPORT
	E0023045	17JUL2003	1	2	0	2					
		18JUL2003	2	1	0	1					
		19JUL2003	3	1	0	1					
		20JUL2003	4	2	0	2					
		21JUL2003	5	3	0	3					
		22JUL2003	6	3	0	3					
		23JUL2003	7	3	0	3					
		24JUL2003	8	4	0	4					
		25JUL2003	9	4	0	4					
		26JUL2003	10	4	0	4					
		27JUL2003	11	4	0	4					
		28JUL2003	12	4	0	4					
		29JUL2003	13	4	0	4					
		30JUL2003	14	4	0	4					
		31JUL2003	15	4	0	4					
		01AUG2003	16	4	0	4					
		02AUG2003	17	4	0	4					
		03AUG2003	18	4	0	4					
		04AUG2003	19	4	0	4					
		05AUG2003	20	4	0	4					
		06AUG2003	21	4	0	4					
		07AUG2003	22	4	0	4					
		08AUG2003	23	4	0	4					
		09AUG2003	24	4	0	4					
		10AUG2003	25	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	11AUG2003	26	4	0	4					
		12AUG2003	27	4	0	4					
		13AUG2003	28	4	0	4					
		14AUG2003	29	4	0	4					
		15AUG2003	30	4	0	4					
		16AUG2003	31	4	0	4					
		17AUG2003	32	4	0	4					
		18AUG2003	33	4	0	4					
		19AUG2003	34	4	0	4					
		20AUG2003	35	4	0	4					
		21AUG2003	36	4	0	4					
		22AUG2003	37	4	0	4					
		23AUG2003	38	4	0	4					
		24AUG2003	39	4	0	4					
		25AUG2003	40	4	0	4					
		26AUG2003	41	4	0	4					
		27AUG2003	42	4	0	4					
		28AUG2003	43	4	0	4					
		29AUG2003	44	4	0	4					
		30AUG2003	45	4	0	4					
		31AUG2003	46			0					
		01SEP2003	47	4	0	4					
		02SEP2003	48	4	0	4					
		03SEP2003	49	4	0	4					
		04SEP2003	50	4	0	4					
		05SEP2003	51	4	0	4					
		06SEP2003	52	4	0	4					
		07SEP2003	53	4	0	4					
		08SEP2003	54	4	0	4					
		09SEP2003	55	4	0	4					
		10SEP2003	56	4	0	4					
		11SEP2003	57	4	0	4	NO	285.1	56	98.1	
	E0025002	03APR2003	1	2	0	2					
		04APR2003	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	05APR2003	3	1	0	1					
		06APR2003	4	2	0	2					
		07APR2003	5	3	0	3					
		08APR2003	6	3	0	3					
		09APR2003	7	3	0	3					
		10APR2003	8	4	0	4					
		11APR2003	9	4	1	3					DOSE REDUCED
		12APR2003	10	4	1	3					
		13APR2003	11	4	1	3					
		14APR2003	12	4	1	3					
		15APR2003	13	4	1	3					
		16APR2003	14	4	1	3					
		17APR2003	15	4	0	4					DOSE INCREASED
		18APR2003	16	4	0	4					
		19APR2003	17	4	0	4					
		20APR2003	18	4	0	4					
		21APR2003	19	4	0	4					
		22APR2003	20	4	0	4					
		23APR2003	21	4	0	4					
		24APR2003	22	4	0	4					
		25APR2003	23	4	0	4					
		26APR2003	24	4	0	4					
		27APR2003	25	4	0	4					
		28APR2003	26	4	0	4					
		29APR2003	27	4	0	4					
		30APR2003	28	4	0	4					
		01MAY2003	29	4	0	4					
		02MAY2003	30	4	0	4					
		03MAY2003	31	4	0	4					
		04MAY2003	32	4	0	4					
		05MAY2003	33	4	0	4					
		06MAY2003	34	4	0	4					
		07MAY2003	35	4	0	4					
		08MAY2003	36	4	0	4					
		09MAY2003	37	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	10MAY2003	38	4	0	4					
		11MAY2003	39	4	0	4					
		12MAY2003	40	4	0	4					
		13MAY2003	41	4	0	4					
		14MAY2003	42	4	0	4					
		15MAY2003	43	4	0	4					
		16MAY2003	44	4	0	4					
		17MAY2003	45	4	0	4					
		18MAY2003	46	4	0	4					
		19MAY2003	47	4	0	4					
		20MAY2003	48	4	0	4					
		21MAY2003	49	4	0	4					
		22MAY2003	50	4	0	4					
		23MAY2003	51	4	0	4					
		24MAY2003	52	4	0	4					
		25MAY2003	53	4	0	4					
		26MAY2003	54	4	0	4					
		27MAY2003	55	4	0	4					
		28MAY2003	56	4	0	4	YES	279.5	56	100	
	E0026010	22JAN2003	1	2	0	2					
		23JAN2003	2	1	0	1					
		24JAN2003	3	1	0	1					
		25JAN2003	4	2	0	2					
		26JAN2003	5	3	0	3					
		27JAN2003									PT. STOPPED DUE TO AES
		28JAN2003					NO	190	5	100	PT. STOPPED DUE TO AE'S
	E0026017	06MAR2003	1	2	0	2					PATIENT LOST BLISTER CARD
		07MAR2003	2	1	0	1					
		08MAR2003	3	1	0	1					
		09MAR2003	4	2	0	2					
		10MAR2003	5	3	0	3					
		11MAR2003	6	3	0	3					
		12MAR2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026017	13MAR2003	8		0	4					PATIENT LOST BLISTER CARD, REPORTED 100% COMPLIANCE. DOSING CANNOT BE VERIFIED, CANNOT VERIFY DATE AND LAST DOSE.
		14MAR2003	9		0	4	NO	238.9	9	100	
	E0026018	20MAR2003	1	2	0	2					
		21MAR2003	2	1	0	1					
		22MAR2003	3	1	0	1					
		23MAR2003	4	2	0	2					
		24MAR2003	5	3	0	3					
		25MAR2003	6	3	0	3					
		26MAR2003	7	3	0	3					
		27MAR2003	8	4	0	4					
		28MAR2003	9	4	0	4					
		29MAR2003	10	4	0	4					
		30MAR2003	11	4	0	4					
		31MAR2003	12	4	0	4					
		01APR2003	13	4	0	4					
		02APR2003	14	4	0	4					
		03APR2003	15	4	0	4					
		04APR2003	16	4	0	4					
		05APR2003	17	4	0	4					
		06APR2003	18	4	0	4					
		07APR2003	19	4	0	4					
		08APR2003	20	4	0	4					
		09APR2003	21	4	0	4					
		10APR2003	22	4	0	4					
		11APR2003	23	4	0	4					
		12APR2003	24	4	0	4					
		13APR2003	25	4	0	4					
		14APR2003	26	4	0	4					
		15APR2003	27	4	0	4					
		16APR2003	28	4	0	4					
		17APR2003	29	4	0	4					
		18APR2003	30	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	19APR2003	31	4	0	4					
		20APR2003	32	4	0	4					
		21APR2003	33	4	0	4					
		22APR2003	34	4	0	4					
		23APR2003	35	4	0	4					
		24APR2003	36	4	0	4					
		25APR2003	37	4	0	4					
		26APR2003	38	4	0	4					
		27APR2003	39	4	0	4					
		28APR2003	40	4	0	4					
		29APR2003	41	4	0	4					
		30APR2003	42	4	0	4					
		01MAY2003	43	4	0	4					
		02MAY2003	44	4	0	4					
		03MAY2003	45	4	0	4					
		04MAY2003	46	4	0	4					
		05MAY2003	47	4	0	4					
		06MAY2003	48	4	0	4					
		07MAY2003	49	4	0	4					
		08MAY2003	50	4	0	4					
		09MAY2003	51	4	0	4					
		10MAY2003	52	4	0	4					
		11MAY2003	53	4	0	4					
		12MAY2003	54	4	0	4					
		13MAY2003	55	4	0	4					
		14MAY2003	56	4	0	4	NO	290.2	56	100	
	E0026025	09MAY2003	1	2	0	2					
		10MAY2003	2	1	0	1					
		11MAY2003	3	1	0	1					
		12MAY2003	4	2	0	2					
		13MAY2003	5	3	0	3					
		14MAY2003	6	3	0	3					
		15MAY2003	7	4	0	4					
		16MAY2003	8	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	17MAY2003	9	4	0	4					
		18MAY2003	10	4	0	4					
		19MAY2003	11	4	0	4					
		20MAY2003	12	4	0	4					
		21MAY2003	13	4	0	4					
		22MAY2003	14	4	0	4					
		23MAY2003	15	4	0	4					
		24MAY2003	16	4	0	4					
		25MAY2003	17	4	0	4					
		26MAY2003	18	4	0	4					
		27MAY2003	19	4	0	4					
		28MAY2003	20	4	0	4					
		29MAY2003	21	4	0	4					
		30MAY2003	22	4	0	4					
		31MAY2003	23	4	0	4					
		01JUN2003	24	4	0	4					
		02JUN2003	25	4	0	4					
		03JUN2003	26	4	0	4					
		04JUN2003	27	4	0	4					
		05JUN2003	28	4	0	4					
		06JUN2003	29	4	0	4					
		07JUN2003	30	4	0	4					
		08JUN2003	31	4	0	4					
		09JUN2003	32	4	0	4					
		10JUN2003	33	4	0	4					
		11JUN2003	34	4	0	4					
		12JUN2003	35		0	4					
		13JUN2003	36	4	0	4					
		14JUN2003	37	4	0	4					
		15JUN2003	38	4	0	4					
		16JUN2003	39	4	0	4					
		17JUN2003	40	4	0	4					
		18JUN2003	41	4	0	4					
		19JUN2003	42	4	0	4					
		20JUN2003	43	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	21JUN2003	44	4	0	4					
		22JUN2003	45	4	0	4					
		23JUN2003	46	4	0	4					
		24JUN2003	47	4	0	4					
		25JUN2003	48	4	0	4					
		26JUN2003	49	4	0	4					
		27JUN2003	50	4	0	4					
		28JUN2003	51	4	0	4					
		29JUN2003	52	4	0	4					
		30JUN2003	53	4	0	4					
		01JUL2003	54	4	0	4					
		02JUL2003	55	4	0	4	NO	290	55	100	
	E0026029	09JUL2003	1	2	0	2					
		10JUL2003	2	1	0	1					
		11JUL2003	3	1	0	1					
		12JUL2003	4	2	0	2					
		13JUL2003	5	3	0	3					
		14JUL2003	6	3	0	3					
		15JUL2003	7	3	0	3					
		16JUL2003	8	4	0	4					
		17JUL2003	9	4	0	4					
		18JUL2003	10	4	0	4					TOOK ON 7/19/03
		19JUL2003	11	4	0	4					SIC - SUBJECT DOUBLE - DOSED ON 7/19/03
		20JUL2003	12	4	0	4					
		21JUL2003	13	4	0	4					
		22JUL2003	14	4	0	4					
		23JUL2003	15		0	4					
		24JUL2003	16		0	4	NO	265.6	16	100	
	E0026030	09JUL2003	1	2	0	2					
		10JUL2003	2	1	0	1					
		11JUL2003	3	1	0	1					
		12JUL2003	4	2	0	2					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	13JUL2003	5	3	0	3					
		14JUL2003	6	3	0	3					
		15JUL2003	7	3	0	3					
		16JUL2003	8	4	0	4					
		17JUL2003	9	4	0	4					
		18JUL2003	10	4	0	4					
		19JUL2003	11	4	1	3					DOSE REDUCED
		20JUL2003	12	4	1	3					
		21JUL2003	13	4	1	3					
		22JUL2003	14	4	1	3					
		23JUL2003	15	4	1	3					
		24JUL2003	16	4	1	3					
		25JUL2003	17	4	1	3					
		26JUL2003	18	4	1	3					
		27JUL2003	19	4	1	3					
		28JUL2003	20	4	1	3					
		29JUL2003	21	4	1	3					
		30JUL2003	22	4	1	3					
		31JUL2003	23	4	1	3					
		01AUG2003	24	4	1	3					
		02AUG2003	25	4	1	3					
		03AUG2003	26	4	1	3					
		04AUG2003	27	4	1	3					
		05AUG2003	28	4	1	3					
		06AUG2003	29	4	1	3					
		07AUG2003	30	4	1	3					
		08AUG2003	31	4	1	3					
		09AUG2003	32	4	1	3					
		10AUG2003	33	4	1	3					
		11AUG2003	34		1	3					
		12AUG2003	35	4	1	3					
		13AUG2003	36	4	1	3					
		14AUG2003	37	4	1	3					
		15AUG2003	38	4	1	3					
		16AUG2003	39	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	17AUG2003	40	4	1	3					
		18AUG2003	41	4	1	3					
		19AUG2003	42	4	1	3					
		20AUG2003	43	4	1	3					
		21AUG2003	44	4	1	3					
		22AUG2003	45	4	1	3					
		23AUG2003	46	4	1	3					
		24AUG2003	47	4	1	3					
		25AUG2003	48	4	1	3					
		26AUG2003	49	4	1	3					
		27AUG2003	50	4	1	3					
		28AUG2003	51	4	1	3					
		29AUG2003	52	4	1	3					
		30AUG2003	53	4	1	3					
		31AUG2003	54	4	1	3					
		01SEP2003	55	4	1	3					
		02SEP2003	56		1	3	YES	208	56	100	
	E0026031	21JUL2003	1	2	0	2					
		22JUL2003	2	1	0	1					
		23JUL2003	3	1	0	1					
		24JUL2003	4	2	0	2					
		25JUL2003	5	3	0	3					
		26JUL2003	6	3	0	3					
		27JUL2003	7	3	0	3					
		28JUL2003	8	4	0	4					
		29JUL2003	9	4	0	4					
		30JUL2003	10	4	0	4					
		31JUL2003	11	4	0	4					
		01AUG2003	12	4	0	4					
		02AUG2003	13	4	0	4					
		03AUG2003	14	4	0	4					
		04AUG2003	15	4	0	4					
		05AUG2003	16	4	0	4					
		06AUG2003	17	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026031	07AUG2003	18	4	0	4					
		08AUG2003	19	4	0	4					
		09AUG2003	20	4	0	4					
		10AUG2003	21	4	0	4					
		11AUG2003	22	4	0	4					
		12AUG2003	23	4	0	4					
		13AUG2003	24	4	0	4					
		14AUG2003	25	4	0	4					
		15AUG2003	26	4	0	4					
		16AUG2003	27	4	0	4					
		17AUG2003	28	4	0	4					
		18AUG2003	29	4	0	4					
		19AUG2003	30	4	0	4					
		20AUG2003	31	4	0	4					
		21AUG2003	32	4	0	4					
		22AUG2003	33	4	0	4					
		23AUG2003	34	4	0	4					
		24AUG2003	35	4	0	4					
		25AUG2003	36	4	0	4					
		26AUG2003	37	4	0	4					
		27AUG2003	38	4	0	4					
		28AUG2003	39	4	0	4					
		29AUG2003	40	4	0	4					
		30AUG2003	41	4	0	4					
		31AUG2003	42	4	0	4					
		01SEP2003	43		0	4					
		02SEP2003	44	4	0	4					
		03SEP2003	45	4	0	4					
		04SEP2003	46	4	0	4					
		05SEP2003	47	4	0	4					
		06SEP2003	48	4	0	4					
		07SEP2003	49	4	0	4					
		08SEP2003	50	4	0	4					
		09SEP2003	51	4	0	4					
		10SEP2003	52	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0026031	11SEP2003	53	4	0	4					
		12SEP2003	54	4	0	4					
		13SEP2003	55	4	0	4					
		14SEP2003	56	4	0	4	NO	290.2	56	100	
	E0027003	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					
		30JAN2003	3	1	0	1					
		31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					
		03FEB2003	7	3	0	3					
		04FEB2003	8		0	4					
		05FEB2003	9		0	4					
		06FEB2003	10	4	0	4					
		07FEB2003	11	4	0	4					
		08FEB2003	12	4	0	4					
		09FEB2003	13	4	0	4					
		10FEB2003	14	4	0	4					
		11FEB2003	15	4	0	4					
		12FEB2003	16	4	0	4					
		13FEB2003	17	4	0	4					
		14FEB2003	18	4	0	4					
		15FEB2003	19	4	0	4					
		16FEB2003	20	4	0	4					
		17FEB2003	21	4	0	4					
		18FEB2003	22	4	0	4					
		19FEB2003	23	4	0	4					
		20FEB2003	24	4	0	4					
		21FEB2003	25	4	0	4					
		22FEB2003	26	4	0	4					
		23FEB2003	27	4	0	4					
		24FEB2003	28	4	0	4					
		25FEB2003	29	4	0	4					
		26FEB2003	30		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0027003	27FEB2003	31	4	0	4					
		28FEB2003	32	4	0	4					
		01MAR2003	33	4	0	4					
		02MAR2003	34	4	0	4					
		03MAR2003	35	4	0	4					
		04MAR2003	36	4	0	4					
		05MAR2003	37	4	0	4					
		06MAR2003	38	4	0	4					
		07MAR2003	39	4	0	4					
		08MAR2003	40	4	0	4					
		09MAR2003	41	4	0	4					
		10MAR2003	42	4	0	4					
		11MAR2003	43	4	0	4					
		12MAR2003	44	4	0	4					
		13MAR2003	45	4	0	4					
		14MAR2003	46	4	0	4					
		15MAR2003	47	4	0	4					
		16MAR2003	48	4	0	4					
		17MAR2003	49	4	0	4					
		18MAR2003	50	4	0	4					
		19MAR2003	51	4	0	4					
		20MAR2003	52	4	0	4					
		21MAR2003	53	4	0	4					
		22MAR2003	54	4	0	4					
		23MAR2003	55	4	0	4					
		24MAR2003	56	4	0	4	NO	290.2	56	100	
	E0028004	30SEP2002	1	2	0	2					
		01OCT2002	2	1	0	1					
		02OCT2002	3	1	0	1					
		03OCT2002	4	2	0	2					
		04OCT2002	5	3	0	3					
		05OCT2002	6	3	0	3					
		06OCT2002	7	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	07OCT2002	8	4	0	4	NO	231.3	8	100	PT. REPORTED LAST DOSE WAS 10/7/02. PT. ALSO REPORTED MED CARD STOLEN EVENING OF 10/08/02. BLISTERCARD NOT RETURNED.
	E0028006	04OCT2002	1	2	0	2					
		05OCT2002	2	1	0	1					
		06OCT2002	3	1	0	1					
		07OCT2002	4	2	0	2					
		08OCT2002	5	3	0	3					
		09OCT2002	6	3	0	3					
		10OCT2002	7	3	0	3					
		11OCT2002	8	4	0	4					
		12OCT2002	9	4	0	4					
		13OCT2002	10	4	0	4					
		14OCT2002	11	4	0	4					
		15OCT2002	12	4	0	4					
		16OCT2002	13	4	0	4					
		17OCT2002	14	4	0	4					
		18OCT2002	15	4	0	4					
		19OCT2002	16	4	0	4					
		20OCT2002	17	4	0	4					
		21OCT2002	18	4	0	4					
		22OCT2002	19	4	0	4					
		23OCT2002	20	4	1	3					DOSE REDUCED DUE TO AE OF PARASTHESIA
		24OCT2002	21	4	1	3					
		25OCT2002	22	4	1	3					
		26OCT2002	23	4	1	3					
		27OCT2002	24	4	1	3					
		28OCT2002	25	4	1	3					
		29OCT2002	26	4	1	3					
		30OCT2002	27		1	3					
		31OCT2002	28	4	1	3					
		01NOV2002	29	4	1	3					
		02NOV2002	30	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	03NOV2002	31	4	1	3					
		04NOV2002	32	4	1	3					
		05NOV2002	33	4	1	3					
		06NOV2002	34	4	1	3					
		07NOV2002	35	4	1	3					
		08NOV2002	36	4	1	3					
		09NOV2002	37	4	1	3					
		10NOV2002	38	4	1	3					
		11NOV2002	39	4	1	3					
		12NOV2002	40	4	1	3					
		13NOV2002	41	4	1	3					
		14NOV2002	42	4	1	3					
		15NOV2002	43	4	1	3					
		16NOV2002	44	4	1	3					
		17NOV2002	45	4	1	3					
		18NOV2002	46	4	1	3					
		19NOV2002	47	4	1	3					
		20NOV2002	48	4	1	3					
		21NOV2002	49		1	3					
		22NOV2002	50		1	3					
		23NOV2002	51		1	3					REDISPENSED ON 11/21/02 AND RETURNED ON 12/4/02
		24NOV2002	52		1	3					REDISPENSED ON 11/21/02 AND RETURNED ON 12/4/02
		25NOV2002	53	4	1	3					
		26NOV2002	54	4	1	3					
		27NOV2002	55	4	1	3					
		28NOV2002	56	4	1	3					
		29NOV2002	57	4	1	3					
		30NOV2002	58	4	1	3					
		01DEC2002	59	4	1	3					
		02DEC2002	60		1	3					
		03DEC2002	61		1	3	YES	222.1	61	100	
	E0028008	15OCT2002	1	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	16OCT2002	2	1	0	1					
		17OCT2002	3	1	0	1					
		18OCT2002	4	2	0	2					
		19OCT2002	5	3	0	3					
		20OCT2002	6	3	0	3					
		21OCT2002	7	3	0	3					
		22OCT2002	8		0	4					SUBJECT TOOK STUDY MED IN A.M.
		23OCT2002	9	4	0	4					
		24OCT2002	10	4	0	4					
		25OCT2002	11	4	0	4					
		26OCT2002	12	4	0	4					
		27OCT2002	13	4	0	4					
		28OCT2002	14	4	0	4					
		29OCT2002	15	4	0	4					SUBJECT TOOK STUDY MED IN AM
		30OCT2002	16	4	0	4					
		31OCT2002	17	4	0	4					
		01NOV2002	18	4	0	4					
		02NOV2002	19	4	0	4					
		03NOV2002	20	4	0	4					
		04NOV2002	21	4	0	4					
		05NOV2002	22	4	0	4					
		06NOV2002	23		0	4					
		07NOV2002	24	4	0	4					
		08NOV2002	25	4	0	4					
		09NOV2002	26	4	0	4					
		10NOV2002	27	4	0	4					
		11NOV2002	28	4	0	4					
		12NOV2002	29	4	0	4					
		13NOV2002	30	4	0	4					
		14NOV2002	31		0	4					SUBJECT TOOK STUDY MED IN AM
		15NOV2002	32	4	0	4					
		16NOV2002	33	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	17NOV2002	34	4	0	4					
		18NOV2002	35	4	0	4					
		19NOV2002	36	4	0	4					
		20NOV2002	37	4	0	4					
		21NOV2002	38	4	0	4					
		22NOV2002	39	4	0	4					
		23NOV2002	40	4	0	4					
		24NOV2002	41	4	0	4					
		25NOV2002	42	4	0	4					
		26NOV2002	43	4	0	4					
		27NOV2002	44	4	0	4					
		28NOV2002	45	4	0	4					
		29NOV2002	46	4	0	4					
		30NOV2002	47	4	0	4					
		01DEC2002	48	4	0	4					
		02DEC2002	49	4	0	4					
		03DEC2002	50	4	0	4					
		04DEC2002	51	4	0	4					
		05DEC2002	52	4	0	4					
		06DEC2002	53	4	0	4					
		07DEC2002	54	4	0	4					
		08DEC2002	55	4	0	4					
		09DEC2002	56	4	0	4	NO	290.2	56	100	
	E0028009	15OCT2002	1	2	0	2					
		16OCT2002	2	1	0	1					
		17OCT2002	3	1	1	0					PT. MISSED DAY 3 DOSE ON 10/17 & TOOK ON 10/18
		18OCT2002	4	2	0	2					
		19OCT2002	5	3	0	3					
		20OCT2002	6	3	0	3					
		21OCT2002	7			0					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	22OCT2002	8		4	0					1 EXTRA PILL TAKEN ON UNKNOWN DATE TO REPLACE 1 DROPPED PILL SIC EXTRA DAY DOSES DATED AS WERE ORIGINALLY PRESCRIBED. DAY 7S DOSE WAS REDISPENSED ON 10/23/02 TO ACHIEVE FULL TITRATION
		23OCT2002	9		4	3					PT. MISSED DAY 7 DOSE ON 10/22/02
		24OCT2002	10	4	0	4					
		25OCT2002	11	4	0	4					
		26OCT2002	12	4	0	4					
		27OCT2002	13	4	0	4					
		28OCT2002	14	4	0	4					
		29OCT2002	15	4	0	4					
		30OCT2002	16	4	0	4					
		31OCT2002	17	4	0	4					
		01NOV2002	18	4	0	4					
		02NOV2002	19	4	0	4					
		03NOV2002	20	4	0	4					
		04NOV2002	21	4	0	4					
		05NOV2002	22	4	0	4					
		06NOV2002	23	4	0	4					
		07NOV2002	24	4	0	4					
		08NOV2002	25	4	0	4					
		09NOV2002	26	4	0	4					
		10NOV2002	27	4	0	4					
		11NOV2002	28	4	0	4					
		12NOV2002	29	4	0	4					
		13NOV2002	30	4	4	0					PT. FORGOT TO TAKE DOSE
		14NOV2002	31	4	0	4					
		15NOV2002	32	4	0	4					
		16NOV2002	33	4	0	4					
		17NOV2002	34	4	0	4					
		18NOV2002	35	4	0	4					
		19NOV2002	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	20NOV2002	37	4	0	4					
		21NOV2002	38	4	0	4					
		22NOV2002	39	4	0	4					
		23NOV2002	40	4	0	4					
		24NOV2002	41	4	0	4					
		25NOV2002	42	4	0	4					
		26NOV2002	43	4	0	4					
		27NOV2002	44	4	0	4					
		28NOV2002	45	4	0	4					
		29NOV2002	46	4	0	4					
		30NOV2002	47	4	0	4					
		01DEC2002	48	4	0	4					
		02DEC2002	49	4	0	4					
		03DEC2002	50	4	0	4					
		04DEC2002	51	4	0	4					
		05DEC2002	52	4	0	4					
		06DEC2002	53	4	0	4					
		07DEC2002	54	4	0	4					
		08DEC2002	55	4	0	4					
		09DEC2002	56	4	0	4					
		10DEC2002	57		0	4					
		11DEC2002	58		0	4	NO	269.8	54	94.5	
	E0028016	14NOV2002	1	2	0	2					
		15NOV2002	2	1	0	1					
		16NOV2002	3	1	0	1					
		17NOV2002	4	2	0	2					
		18NOV2002	5	3	0	3					
		19NOV2002	6	3	0	3					
		20NOV2002	7	3	0	3					
		21NOV2002	8	4	0	4					
		22NOV2002	9	4	0	4					
		23NOV2002	10	4	0	4					
		24NOV2002	11	4	0	4					
		25NOV2002	12	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	26NOV2002	13	4	0	4					
		27NOV2002	14	4	0	4					
		28NOV2002	15	4	0	4					
		29NOV2002	16	4	0	4					
		30NOV2002	17	4	0	4					
		01DEC2002	18	4	0	4					
		02DEC2002	19	4	0	4					
		03DEC2002	20		0	4					
		04DEC2002	21		0	4					
		05DEC2002	22	4	0	4					
		06DEC2002	23	4	0	4					
		07DEC2002	24	4	0	4					
		08DEC2002	25	4	0	4					
		09DEC2002	26	4	0	4					
		10DEC2002	27	4	0	4					
		11DEC2002	28	4	0	4					
		12DEC2002	29	4	0	4					
		13DEC2002	30	4	0	4					
		14DEC2002	31	4	0	4					
		15DEC2002	32	4	0	4					
		16DEC2002	33	4	0	4					
		17DEC2002	34	4	0	4					
		18DEC2002	35	4	0	4					
		19DEC2002	36	4	0	4					
		20DEC2002	37	4	0	4					
		21DEC2002	38	4	0	4					
		22DEC2002	39	4	0	4					
		23DEC2002	40	4	0	4					
		24DEC2002	41	4	0	4					
		25DEC2002	42	4	0	4					
		26DEC2002	43	4	0	4					
		27DEC2002	44	4	0	4					
		28DEC2002	45	4	0	4					
		29DEC2002	46	4	0	4					
		30DEC2002	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	31DEC2002	48	4	0	4					
		01JAN2003	49	4	0	4					
		02JAN2003	50	4	0	4					
		03JAN2003	51	4	0	4					
		04JAN2003	52	4	0	4					
		05JAN2003	53	4	0	4					
		06JAN2003	54	4	0	4					
		07JAN2003	55	4	0	4					
		08JAN2003	56	4	0	4	NO	290.2	56	100	
	E0028027	21JAN2003	1	2	0	2					
		22JAN2003	2	1	0	1					
		23JAN2003	3	1	0	1					
		24JAN2003	4	2	0	2					
		25JAN2003	5	3	0	3					
		26JAN2003	6	3	0	3					
		27JAN2003	7	3	0	3					
		28JAN2003	8	4	0	4					
		29JAN2003	9	4	0	4					
		30JAN2003	10	4	0	4					
		31JAN2003	11	4	0	4					
		01FEB2003	12	4	4	0					MISSED DOSE
		02FEB2003	13	4	4	0					MISSED DOSE
		03FEB2003	14	4	0	4					
		04FEB2003	15	4	0	4					
		05FEB2003	16	4	0	4					
		06FEB2003	17	4	0	4					
		07FEB2003	18	4	0	4					
		08FEB2003	19	4	0	4					
		09FEB2003	20	4	0	4					
		10FEB2003	21	4	0	4					
		11FEB2003	22	4	0	4					
		12FEB2003	23	4	0	4					
		13FEB2003	24	4	0	4					
		14FEB2003	25	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	15FEB2003	26	4	0	4					
		16FEB2003	27	4	0	4					
		17FEB2003	28	4	0	4					
		18FEB2003	29		0	4					
		19FEB2003	30		4	0					MISSED DOSE
		20FEB2003	31	4	0	4					
		21FEB2003	32	4	0	4					
		22FEB2003	33	4	0	4					
		23FEB2003	34	4	0	4					
		24FEB2003	35	4	0	4					
		25FEB2003	36	4	0	4					
		26FEB2003	37	4	0	4					
		27FEB2003	38		0	4					
		28FEB2003	39	4	0	4					PATIENT IS LOST TO FOLLOW - UP. BLISTER CARD WAS NOT RETURNED
		07MAR2003					NO	262.8	36	91.6	UNK
	E0028029	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					
		11FEB2003	8	4	0	4					
		12FEB2003	9	4	0	4					
		13FEB2003	10	4	0	4					
		14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	1	3					DOSE REDUCED TO 3 TABS DUE TO EXTENDED VISIT, INTERVAL BLISTERCARD WAS RE-DISPENSED ON 2/17/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	18FEB2003	15	4	1	3					DATE SIC DUE TO EXTENDED VISIT INTERVAL BLISTER CARD WAS REDISPENSED ON 2/17/03
		19FEB2003	16	4	1	3					
		20FEB2003	17	4	1	3					
		21FEB2003	18	4	1	3					
		22FEB2003	19	4	1	3					
		23FEB2003	20	4	1	3					
		24FEB2003	21	4	1	3					
		25FEB2003	22		1	3					
		26FEB2003	23		1	3					
		27FEB2003	24	4	1	3					
		28FEB2003	25	4	1	3					
		01MAR2003	26	4	1	3					
		02MAR2003	27	4	1	3					
		03MAR2003	28	4	1	3					
		04MAR2003	29	4	1	3					
		05MAR2003	30	4	1	3					
		06MAR2003	31	4	1	3					
		07MAR2003	32	4	1	3					
		08MAR2003	33	4	1	3					
		09MAR2003	34	4	1	3					
		10MAR2003	35	4	1	3					
		11MAR2003	36	4	1	3					
		12MAR2003	37	4	1	3					
		13MAR2003	38	4	1	3					
		14MAR2003	39	4	1	3					
		15MAR2003	40	4	1	3					
		16MAR2003	41	4	1	3					
		17MAR2003	42	4	1	3					
		18MAR2003	43	4	1	3					
		19MAR2003	44	4	1	3					
		20MAR2003	45	4	1	3					
		21MAR2003	46	4	1	3					
		22MAR2003	47	4	1	3					
		23MAR2003	48	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	24MAR2003	49	4	1	3					
		25MAR2003	50	4	1	3					
		26MAR2003	51	4	1	3					
		27MAR2003	52	4	1	3					
		28MAR2003	53	4	1	3					
		29MAR2003	54	4	1	3					
		30MAR2003	55	4	1	3					
		31MAR2003	56	4	1	3					
		01APR2003	57	4	1	3					
		02APR2003	58	4	1	3	YES	212.9	58	100	
	E0028034	01APR2003	1	2	0	2					
		02APR2003	2	1	0	1					
		03APR2003	3	1	1	0					MISSED DOSE
		04APR2003	4	2	0	2					
		05APR2003	5	3	3	0					DOSE TAKEN ON 4/8
		06APR2003	6	3	3	0					DOSE TAKE ON 4/9
		07APR2003	7	3	0	3					
		08APR2003	8		1	3					SIC, PT WAS TOLD TO HOLD 4/5 & 4/6 DOSES DUE TO DRY MOUTH, CONFUSION & ANXIETY. PT. RESUMED DOSING ON 4/7/03 BY TAKING DAY 7 DOSE, THEN TAKING DAY 5 DOSE ON 4/8/03 & DAY 6 DOSE ON 4/9/03.
		09APR2003	9		1	3					
		10APR2003	10	4	0	4					
		11APR2003	11	4	0	4					
		12APR2003	12	4	4	0					PT. FORGOT TO TAKE 4/12 DOSE
		13APR2003	13	4	0	4					
		14APR2003	14	4	0	4					
		15APR2003	15	4	0	4					
		16APR2003	16	4	4	0					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	17APR2003	17	4	0	4					
		18APR2003	18	4	0	4					
		19APR2003	19	4	0	4					
		20APR2003	20	4	0	4					
		21APR2003	21	4	0	4					
		22APR2003	22	4	0	4					
		23APR2003	23	4	0	4					
		24APR2003	24	4	0	4					
		25APR2003	25	4	0	4					
		26APR2003	26	4	0	4					
		27APR2003	27	4	0	4					
		28APR2003	28	4	0	4					
		29APR2003	29		0	4					
		30APR2003	30		0	4					
		01MAY2003	31	4	0	4					
		02MAY2003	32	4	0	4					
		03MAY2003	33	4	0	4					
		04MAY2003	34	4	0	4					
		05MAY2003	35	4	0	4					
		06MAY2003	36	4	0	4					
		07MAY2003	37	4	0	4					
		08MAY2003	38	4	0	4					
		09MAY2003	39	4	0	4					
		10MAY2003	40	4	0	4					
		11MAY2003	41	4	0	4					
		12MAY2003	42	4	0	4					
		13MAY2003	43	4	0	4					
		14MAY2003	44	4	0	4					
		15MAY2003	45	4	0	4					
		16MAY2003	46	4	0	4					
		17MAY2003	47	4	0	4					
		18MAY2003	48	4	0	4					
		19MAY2003	49	4	0	4					
		20MAY2003	50		0	4					
		21MAY2003	51		4	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	22MAY2003	52		0	4					REDISPENSED ON 5/21/03, SIC DAY 2 TABS & BOTH EXTRA DAY TABS WERE ORIGINALLY RETURNED BY PT, THER REPRESCRIBED FOR 5/21, 5/22, & 5/23.
		23MAY2003	53		0	4					RETURNED ON 6/2/03
		24MAY2003	54	4	0	4					
		25MAY2003	55	4	4	0					PT. MISSED DOSE
		26MAY2003	56	4	0	4					
		27MAY2003	57	4	2	2					PT. TOOK "1/2 DOSE"
		28MAY2003	58	4	0	4					
		29MAY2003	59	4	0	4					
		30MAY2003	60	4	0	4					
		31MAY2003	61		0	4					
		01JUN2003	62		0	4	YES	255.6	56	91.4	
	E0028038	25APR2003	1	2	0	2					
		26APR2003	2	1	0	1					
		27APR2003	3	1	0	1					
		28APR2003	4	2	0	2					
		29APR2003	5	3	0	3					
		30APR2003	6	3	0	3					
		01MAY2003	7	3	0	3					
		02MAY2003	8	4	0	4					
		03MAY2003	9	4	0	4					
		04MAY2003	10	4	0	4					
		05MAY2003	11	4	0	4					
		06MAY2003	12	4	0	4					
		07MAY2003	13	4	0	4					
		08MAY2003	14	4	0	4					
		09MAY2003	15	4	4	0					SUBJECT MISSED STUDY DOSE
		10MAY2003	16	4	0	4					
		11MAY2003	17	4	0	4					
		12MAY2003	18	4	0	4					
		13MAY2003	19	4	0	4					
		14MAY2003	20	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	15MAY2003	21	4	0	4					
		16MAY2003	22	4	0	4					
		17MAY2003	23	4	0	4					
		18MAY2003	24	4	0	4					
		19MAY2003	25	4	0	4					
		20MAY2003	26	4	0	4					
		21MAY2003	27	4	0	4					
		22MAY2003	28	4	0	4					
		23MAY2003	29	4	0	4					BLISTER CARD DISPENSED AT V4 TO ACCOMMODATE FOR SUBJECTS NEED FOR AN EXTENDED INTERVAL BETWEEN STUDY VISITS.
		24MAY2003	30	4	0	4					
		25MAY2003	31	4	0	4					
		26MAY2003	32	4	0	4					
		27MAY2003	33	4	0	4					
		28MAY2003	34	4	0	4					
		29MAY2003	35		0	4					
		30MAY2003	36	4	0	4					
		31MAY2003	37	4	0	4					
		01JUN2003	38	4	0	4					
		02JUN2003	39	4	0	4					
		03JUN2003	40	4	0	4					
		04JUN2003	41	4	0	4					
		05JUN2003	42	4	0	4					
		06JUN2003	43	4	0	4					
		07JUN2003	44	4	0	4					
		08JUN2003	45	4	0	4					
		09JUN2003	46	4	0	4					
		10JUN2003	47	4	0	4					
		11JUN2003	48	4	0	4					
		12JUN2003	49	4	0	4					
		13JUN2003	50	4	0	4					
		14JUN2003	51	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	15JUN2003	52	4	0	4					
		16JUN2003	53	4	0	4					
		17JUN2003	54	4	0	4	NO	284.3	53	98	
	E0028043	05JUN2003	1	2	0	2					
		06JUN2003	2	1	0	1					
		07JUN2003	3	1	0	1					
		08JUN2003	4	2	0	2					
		09JUN2003	5	3	0	3					
		10JUN2003	6	3	0	3					
		11JUN2003	7	3	0	3					
		12JUN2003	8	4	0	4					
		13JUN2003	9	4	0	4					
		14JUN2003	10	4	0	4					
		15JUN2003	11	4	0	4					
		16JUN2003	12	4	0	4					
		17JUN2003	13	4	0	4					
		18JUN2003	14	4	0	4					
		19JUN2003	15	4	0	4					
		20JUN2003	16	4	0	4					
		21JUN2003	17	4	0	4					
		22JUN2003	18	4	0	4					
		23JUN2003	19	4	0	4					
		24JUN2003	20	4	0	4					
		25JUN2003	21	4	0	4					
		26JUN2003	22	4	0	4					
		27JUN2003	23	4	0	4					
		28JUN2003	24	4	0	4					
		29JUN2003	25	4	0	4					
		30JUN2003	26	4	0	4					
		01JUL2003	27	4	0	4					
		02JUL2003	28	4	0	4					
		03JUL2003	29	4	0	4					
		04JUL2003	30	4	0	4					
		05JUL2003	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	06JUL2003	32	4	0	4					
		07JUL2003	33	4	0	4					
		08JUL2003	34	4	0	4					
		09JUL2003	35	4	0	4					
		10JUL2003	36	4	0	4					
		11JUL2003	37	4	0	4					
		12JUL2003	38	4	0	4					
		13JUL2003	39	4	0	4					
		14JUL2003	40	4	0	4					
		15JUL2003	41	4	0	4					
		16JUL2003	42	4	0	4					
		17JUL2003	43	4	0	4					
		18JUL2003	44	4	0	4					
		19JUL2003	45	4	0	4					
		20JUL2003	46	4	0	4					
		21JUL2003	47	4	0	4					
		22JUL2003	48	4	0	4					
		23JUL2003	49	4	0	4					
		24JUL2003	50	4	0	4					
		25JUL2003	51	4	0	4					
		26JUL2003	52	4	0	4					
		27JUL2003	53	4	0	4					
		28JUL2003	54	4	0	4	NO	289.8	54	100	
	E0028045	18JUN2003	1	2	0	2					
		19JUN2003	2	1	0	1					
		20JUN2003	3	1	0	1					
		21JUN2003	4	2	0	2					
		22JUN2003	5	3	0	3					
		23JUN2003	6	3	0	3					
		24JUN2003	7	3	0	3					
		25JUN2003	8	4	1	3					IN ERROR, PT. ONLY DOSE 3 TABS ON 6/25/03.
		26JUN2003	9	4	0	4					
		27JUN2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0028045	28JUN2003	11	4	0	4					
		29JUN2003	12	4	0	4					
		30JUN2003	13	4	0	4					SUBJECT DID NOT RETURN BLISTERCARD AND CAN NOT REMEMBER WHEN HE LAST DOSED
		01JUL2003	14	4	0	4					
		02JUL2003	15	4	0	4					
		03JUL2003	16	4	0	4					
		04JUL2003	17	4	0	4					
		05JUL2003	18	4	0	4					
		06JUL2003	19	4	0	4					
		07JUL2003	20		0	4					UNK
		08JUL2003	21		0	4	NO	269	21	100	
	E0029005	27NOV2002	1	2	0	2					BLISTER PACK #1 WAS REDISPENSED ON 12/03/02 AT VISIT 3 AND BLISTER PACK 2 WAS ALSO DISPENSED AT THIS TIME.
		28NOV2002	2	1	0	1					
		29NOV2002	3	1	0	1					
		30NOV2002	4	2	0	2					
		01DEC2002	5	3	0	3					
		02DEC2002	6	3	0	3					
		03DEC2002	7	3	0	3					
		04DEC2002	8	4	0	4					
		05DEC2002	9	4	0	4					
		06DEC2002	10	4	0	4					
		07DEC2002	11	4	0	4					
		08DEC2002	12	4	0	4					
		09DEC2002	13	4	0	4					
		10DEC2002	14	4	0	4					
		11DEC2002	15	4	0	4					
		12DEC2002	16	4	0	4					
		13DEC2002	17	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	14DEC2002	18	4	0	4					
		15DEC2002	19	4	0	4					
		16DEC2002	20	4	0	4					
		17DEC2002	21	4	0	4					
		18DEC2002	22	4	0	4					
		19DEC2002	23	4	0	4					
		20DEC2002	24	4	0	4					
		21DEC2002	25	4	0	4					
		22DEC2002	26	4	0	4					
		23DEC2002	27	4	0	4					
		24DEC2002	28	4	0	4					
		25DEC2002	29	4	0	4					
		26DEC2002	30	4	0	4					
		27DEC2002	31	4	0	4					
		28DEC2002	32	4	0	4					
		29DEC2002	33	4	0	4					
		30DEC2002	34	4	0	4					
		31DEC2002	35	4	0	4					
		01JAN2003	36	4	0	4					
		02JAN2003	37	4	0	4					
		03JAN2003	38	4	0	4					
		04JAN2003	39	4	0	4					
		05JAN2003	40	4	0	4					
		06JAN2003	41		0	4					
		07JAN2003	42	4	0	4					
		08JAN2003	43	4	0	4					
		09JAN2003	44	4	0	4					
		10JAN2003	45	4	0	4					
		11JAN2003	46	4	0	4					
		12JAN2003	47	4	0	4					
		13JAN2003	48	4	0	4					
		14JAN2003	49	4	0	4					
		15JAN2003	50	4	0	4					
		16JAN2003	51	4	0	4					
		17JAN2003	52	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	18JAN2003	53	4	0	4					
		19JAN2003	54	4	0	4					
		20JAN2003	55	4	0	4	NO	290	55	100	
	E0030001	19NOV2002	1	2	0	2					
		20NOV2002	2	1	0	1					
		21NOV2002	3	1	0	1					
		22NOV2002	4	2	0	2					
		23NOV2002	5	3	0	3					
		24NOV2002	6	3	0	3					
		25NOV2002	7	3	0	3					
		26NOV2002	8	4	0	4					
		27NOV2002	9	4	0	4					
		28NOV2002	10	4	0	4					
		29NOV2002	11	4	0	4					
		30NOV2002	12	4	0	4					
		01DEC2002	13	4	0	4					
		02DEC2002	14	4	4	0					MISSED DOSE
		03DEC2002	15	4	0	8					TOOK DOSE IN AM; ON 12/3/02 SUBJECT TOOK AM DOSE DUE TO MISSING DOSE ON 12/2/02.
		04DEC2002	16	4	0	4					
		05DEC2002	17	4	0	4					
		06DEC2002	18	4	0	4					
		07DEC2002	19	4	0	4					
		08DEC2002	20	4	0	4					
		09DEC2002	21	4	0	4					
		10DEC2002	22	4	4	0					MISSED DOSE
		11DEC2002	23	4	0	4					
		12DEC2002	24	4	0	4					
		13DEC2002	25	4	0	4					
		14DEC2002	26	4	0	4					
		15DEC2002	27	4	0	4					
		16DEC2002	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	17DEC2002	29	4	0	8					SUBJECT TOOK 2 DOSES OF MEDICATION ON 12/11/02 DUE TO MISSING DOSE ON 12/10/02.
		18DEC2002	30	4	0	4					
		19DEC2002	31	4	0	4					
		20DEC2002	32	4	0	4					
		21DEC2002	33	4	0	4					
		22DEC2002	34	4	0	4					
		23DEC2002	35	4	0	4					
		24DEC2002	36		0	4					
		25DEC2002	37		0	4					
		26DEC2002	38	4	0	4					
		27DEC2002	39	4	0	4					
		28DEC2002	40	4	0	4					
		29DEC2002	41	4	0	4					
		30DEC2002	42	4	0	4					
		31DEC2002	43	4	0	4					
		01JAN2003	44	4	0	4					
		02JAN2003	45	4	0	4					
		03JAN2003	46	4	0	4					
		04JAN2003	47	4	0	4					
		05JAN2003	48	4	0	4					
		06JAN2003	49	4	0	4					
		07JAN2003	50	4	0	4					
		08JAN2003	51	4	0	4					
		09JAN2003	52	4	0	4					
		10JAN2003	53	4	0	4					
		11JAN2003	54	4	0	4					
		12JAN2003	55	4	0	4					
		13JAN2003	56	4	0	4					
		14JAN2003	57	4	0	4					
		15JAN2003	58	4	0	4	NO	290.5	56	100	
	E0030008	14JAN2003	1	2	0	2					
		15JAN2003	2	1	0	1					
		16JAN2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	17JAN2003	4	2	0	2					
		18JAN2003	5	3	0	3					
		19JAN2003	6	3	0	3					
		20JAN2003	7	3	0	3					
		21JAN2003	8		0	4					
		22JAN2003	9		0	4					
		23JAN2003	10	4	0	4					
		24JAN2003	11	4	0	4					
		25JAN2003	12	4	0	4					
		26JAN2003	13	4	0	4					
		27JAN2003	14	4	0	4					
		28JAN2003	15	4	0	4					
		29JAN2003	16	4	0	4					
		30JAN2003	17	4	0	4					
		31JAN2003	18	4	0	4					
		01FEB2003	19	4	0	4					
		02FEB2003	20	4	0	4					
		03FEB2003	21	4	0	4					
		04FEB2003	22	4	0	4					
		05FEB2003	23	4	0	4					
		06FEB2003	24		0	4					
		07FEB2003	25	4	0	4					
		08FEB2003	26	4	0	4					
		09FEB2003	27	4	0	4					
		10FEB2003	28	4	0	4					
		11FEB2003	29	4	0	4					
		12FEB2003	30	4	0	4					
		13FEB2003	31	4	0	4					
		14FEB2003	32	4	0	4					
		15FEB2003	33	4	0	4					
		16FEB2003	34	4	0	4					
		17FEB2003	35	4	0	4					
		18FEB2003	36	4	0	4					
		19FEB2003	37	4	0	4					
		20FEB2003	38	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	21FEB2003	39	4	0	4					
		22FEB2003	40	4	0	4					
		23FEB2003	41	4	0	4					
		24FEB2003	42	4	0	4					
		25FEB2003	43	4	0	4					
		26FEB2003	44	4	0	4					
		27FEB2003	45	4	0	4					
		28FEB2003	46		0	4					
		01MAR2003	47		0	4					MISSED DOSE TOOK THIS DOSE FOR 3/2/03
		02MAR2003	48			0					
		03MAR2003	49	4	0	4					
		04MAR2003	50	4	0	4					
		05MAR2003	51	4	0	4					
		06MAR2003	52	4	0	4					
		07MAR2003	53	4	0	4					
		08MAR2003	54	4	0	4					
		09MAR2003	55	4	0	4					
		10MAR2003	56		0	4					
		11MAR2003	57	4	0	4					
		12MAR2003	58	4	0	4					
		13MAR2003	59	4	0	4					
		14MAR2003	60	4	0	4					
		15MAR2003	61	4	0	4					
		16MAR2003	62	4	0	4					
		17MAR2003	63	4	0	4	NO	286.5	62	98.3	
	E0030011	27JAN2003	1	2	0	2					
		28JAN2003	2	1	0	1					
		29JAN2003	3	1	0	1					
		30JAN2003	4	2	0	2					
		31JAN2003	5	3	0	3					
		01FEB2003	6	3	0	3					
		02FEB2003	7	3	0	3					
		03FEB2003	8	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	04FEB2003	9	4	0	4					
		05FEB2003	10	4	0	4					
		06FEB2003	11	4	0	4					
		07FEB2003	12	4	0	4					
		08FEB2003	13	4	0	4					
		09FEB2003	14	4	0	4					
		10FEB2003	15	4	0	4					
		11FEB2003	16	4	0	4					
		12FEB2003	17	4	0	4					
		13FEB2003	18	4	0	4					
		14FEB2003	19	4	0	4					
		15FEB2003	20	4	0	4					
		16FEB2003	21	4	0	4					
		17FEB2003	22		0	4					
		18FEB2003	23	4	0	4					
		19FEB2003	24	4	0	4					
		20FEB2003	25	4	0	4					
		21FEB2003	26	4	0	4					
		22FEB2003	27	4	0	4					
		23FEB2003	28	4	0	4					
		24FEB2003	29	4	0	4					
		25FEB2003	30	4	0	4					
		26FEB2003	31	4	0	4					
		27FEB2003	32	4	0	4					
		28FEB2003	33	4	0	4					
		01MAR2003	34	4	0	4					
		02MAR2003	35	4	0	4					
		03MAR2003	36	4	0	4					
		04MAR2003	37	4	0	4					
		05MAR2003	38	4	0	4					
		06MAR2003	39	4	0	4					
		07MAR2003	40	4	0	4					
		08MAR2003	41	4	0	4					
		09MAR2003	42	4	0	4					
		10MAR2003	43	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	11MAR2003	44	4	0	4					
		12MAR2003	45	4	0	4					
		13MAR2003	46	4	0	4					
		14MAR2003	47	4	0	4					
		15MAR2003	48	4	0	4					
		16MAR2003	49	4	0	4					
		17MAR2003	50	4	0	4					
		18MAR2003	51	4	0	4					
		19MAR2003	52	4	0	4					
		20MAR2003	53	4	0	4					
		21MAR2003	54	4	0	4					
		22MAR2003	55	4	0	4					
		23MAR2003	56	4	0	4	NO	290.2	56	100	
	E0030015	21FEB2003	1	2	0	2					DOSE TAKEN 2/22/03 SUBJECT MISSED DOSE
		22FEB2003	2	1	0	1					DOSE TAKEN 02/23/03
		23FEB2003	3	1	0	1					DOSE TAKEN 2/24/03
		24FEB2003	4	2	0	2					DOSE TAKEN 2/25/03
		25FEB2003	5	3	0	3					DOSE TAKEN 2/26/03
		26FEB2003	6	3	0	3					DOSE TAKEN 2/27/03
		27FEB2003	7	3	0	3					DOSE TAKEN 2/28/03
		28FEB2003	8		0	4					DOSE TAKEN 3/1/03
		01MAR2003	9		0	4					DOSE TAKEN 3/2/03 SIC - SUBJECT MISSED DOSE ON 2/21/03 AND STARTED MEDICATION ON 2/22/03
		02MAR2003	10			0					
		03MAR2003	11	4	0	4					
		04MAR2003	12	4	0	4					
		05MAR2003	13	4	0	4					
		06MAR2003	14	4	0	4					
		07MAR2003	15	4	0	4					
		08MAR2003	16	4	0	4					
		09MAR2003	17	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	10MAR2003	18		0	4					
		11MAR2003	19	4	0	4					
		12MAR2003	20	4	0	4					
		13MAR2003	21	4	0	4					
		14MAR2003	22	4	0	4					
		15MAR2003	23	4	0	4					
		16MAR2003	24	4	0	4					
		17MAR2003	25	4	0	4					
		18MAR2003	26		0	4					
		19MAR2003	27	4	0	4					
		20MAR2003	28	4	0	4					
		21MAR2003	29	4	0	4					
		22MAR2003	30	4	0	4					
		23MAR2003	31	4	0	4					
		24MAR2003	32	4	0	4					
		25MAR2003	33	4	0	4					
		26MAR2003	34	4	0	4					
		27MAR2003	35	4	0	4					
		28MAR2003	36	4	0	4					
		29MAR2003	37	4	0	4					
		30MAR2003	38	4	0	4					
		31MAR2003	39	4	0	4					
		01APR2003	40	4	0	4					
		02APR2003	41	4	0	4					
		03APR2003	42	4	4	0					MISSED DOSE
		04APR2003	43	4	0	4					
		05APR2003	44	4	0	4					
		06APR2003	45	4	0	4					
		07APR2003	46	4	0	4					
		08APR2003	47	4	0	4					
		09APR2003	48	4	0	4					
		10APR2003	49	4	0	4					
		11APR2003	50	4	0	4					
		12APR2003	51	4	0	4					
		13APR2003	52	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	14APR2003	53	4	0	4					
		15APR2003	54	4	0	4					
		16APR2003	55		0	4					
		17APR2003	56	4	0	4					
		18APR2003	57	4	0	4					
		19APR2003	58	4	0	4					
		20APR2003	59	4	0	4					
		21APR2003	60	4	0	4	NO	280.8	58	96.5	
	E0030022	16JUN2003	1	2	0	2					PATIENT LOST BLISTER CARD.
		17JUN2003	2	1	0	1					
		18JUN2003	3	1	0	1					
		19JUN2003	4	2	0	2					
		20JUN2003	5	3	0	3					
		21JUN2003	6	4	0	7					DAY 1 DATE DOES NOT EQUAL VISIT 3 DATE DUE TO SUBJECT TAKING 6/20/03 DOSE FROM BLISTERCARD 1.
		22JUN2003	7	4	0	4					NO DOSE TAKEN
		23JUN2003	8	4	0	4					NO DOSE TAKEN AS PER PATIENT REPORT.
		24JUN2003	9	4	0	4					NO DOSE TAKEN
		25JUN2003	10	4	0	4					
		26JUN2003	11	4	4	0					NOTE PER SUBJECT REPORT NO DOSE WAS TAKEN ON 6/26/03. SUBJECT REPORTED DISCARDING THE PILLS FROM THAT DAY.
		27JUN2003	12	4	0	4					
		28JUN2003	13		0	4					
		29JUN2003	14		0	4					
		30JUN2003	15	4	0	4					
		01JUL2003	16	4	0	4					
		02JUL2003	17	4	0	4					
		03JUL2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	04JUL2003	19	4	0	4					
		05JUL2003	20	4	0	4					
		06JUL2003	21	4	0	4					
		07JUL2003	22	4	0	4					
		08JUL2003	23	4	0	4					
		09JUL2003	24	4	0	4					
		10JUL2003	25	4	0	4					
		11JUL2003	26	4	0	4					
		12JUL2003	27	4	0	4					
		13JUL2003	28	4	0	4					
		14JUL2003	29	4	0	4					
		15JUL2003	30	4	0	4					
		16JUL2003	31	4	0	4					
		17JUL2003	32	4	0	4					
		18JUL2003	33	4	0	4					
		19JUL2003	34	4	0	4					
		20JUL2003	35	4	0	4					
		21JUL2003	36	4	1	3					DOSAGE DECREASED FOR REMAINDER OF STUDY
		22JUL2003	37	4	1	3					
		23JUL2003	38	4	1	3					
		24JUL2003	39	4	1	3					
		25JUL2003	40	4	1	3					
		26JUL2003	41	4	1	3					
		27JUL2003	42	4	4	0					ON 7/27/03, SUBJECT MISSED DOSE.
		28JUL2003	43		4	0					
		29JUL2003	44	4	1	3					(DOSAGE DECREASED FOR REMAINDER OF STUDY)
		30JUL2003	45	4	1	3					
		31JUL2003	46	4	1	3					
		01AUG2003	47	4	1	3					
		02AUG2003	48	4	1	3					
		03AUG2003	49	4	1	3					
		04AUG2003	50	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	05AUG2003	51	4	1	6					(DOSAGE DECREASED FOR REMAINDER OF STUDY)
		06AUG2003	52	4	1	3					
		07AUG2003	53	4	1	3					
		08AUG2003	54	4	1	3					
		09AUG2003	55	4	1	3					
		10AUG2003	56	4	1	3					
		11AUG2003	57	4	1	3					
		12AUG2003	58		1	3					
		13AUG2003	59		1	3	YES	241.5	56	97.5	
	E0031002	27NOV2002	1	2	0	2					
		28NOV2002	2	1	0	1					
		29NOV2002	3	1	0	1					
		30NOV2002	4	2	0	2					
		01DEC2002	5	3	0	3					
		02DEC2002	6	3	0	3					
		03DEC2002	7	3	0	3					
		04DEC2002	8		0	4					
		05DEC2002	9		0	4					
		06DEC2002	10	4	0	4					
		07DEC2002	11	4	0	4					
		08DEC2002	12	4	0	4					
		09DEC2002	13	4	0	4					
		10DEC2002	14	4	0	4					
		11DEC2002	15	4	0	4					
		12DEC2002	16	4	0	4					
		13DEC2002	17	4	0	4					
		14DEC2002	18	4	0	4					
		15DEC2002	19	4	0	4					
		16DEC2002	20	4	0	4					
		17DEC2002	21	4	0	4					
		18DEC2002	22	4	0	4					
		19DEC2002	23	4	0	4					
		20DEC2002	24	4	0	4					
		21DEC2002	25	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	22DEC2002	26	4	0	4					
		23DEC2002	27	4	0	4					
		24DEC2002	28	4	0	4					
		25DEC2002	29	4	0	4					
		26DEC2002	30	4	0	4					
		27DEC2002	31	4	0	4					
		28DEC2002	32	4	0	4					
		29DEC2002	33	4	0	4					
		30DEC2002	34	4	0	4					
		31DEC2002	35	4	0	4					
		01JAN2003	36	4	0	4					
		02JAN2003	37	4	0	4					
		03JAN2003	38		0	4					
		04JAN2003	39	4	0	4					
		05JAN2003	40	4	0	4					
		06JAN2003	41	4	0	4					
		07JAN2003	42	4	0	4					
		08JAN2003	43	4	0	4					
		09JAN2003	44	4	0	4					
		10JAN2003	45	4	0	4					
		11JAN2003	46		0	4					
		12JAN2003	47		0	4					
		13JAN2003	48	4	0	4					
		14JAN2003	49	4	0	4					
		15JAN2003	50	4	0	4					
		16JAN2003	51	4	0	4					
		17JAN2003	52	4	0	4					TABLETS WERE REMOVED FROM PACK BUT NOT TAKEN ON 1/17/03. TABS WERE RETURNED.
		18JAN2003	53	4	0	4					
		19JAN2003	54	4	0	4					
		20JAN2003	55	4	0	4					
		21JAN2003	56	4	0	4	NO	290.2	56	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	10DEC2002	1	2	0	2					
		11DEC2002	2	1	0	1					
		12DEC2002	3	1	0	1					
		13DEC2002	4	2	0	2					
		14DEC2002	5	3	0	3					
		15DEC2002	6	3	0	3					
		16DEC2002	7	3	0	3					
		17DEC2002	8	4	0	4					
		18DEC2002	9	4	0	4					
		19DEC2002	10	4	0	4					
		20DEC2002	11	4	0	4					
		21DEC2002	12	4	0	4					
		22DEC2002	13	4	0	4					
		23DEC2002	14	4	0	4					
		24DEC2002	15	4	0	4					
		25DEC2002	16	4	0	4					
		26DEC2002	17	4	0	4					
		27DEC2002	18	4	0	4					
		28DEC2002	19	4	0	4					
		29DEC2002	20	4	0	4					
		30DEC2002	21		0	4					
		31DEC2002	22	4	0	4					
		01JAN2003	23	4	0	4					
		02JAN2003	24	4	0	4					
		03JAN2003	25	4	0	4					
		04JAN2003	26	4	0	4					
		05JAN2003	27	4	0	4					
		06JAN2003	28	4	0	4					
		07JAN2003	29	4	0	4					
		08JAN2003	30	4	0	4					
		09JAN2003	31	4	0	4					
		10JAN2003	32	4	0	4					
		11JAN2003	33	4	0	4					
		12JAN2003	34	4	0	4					
		13JAN2003	35	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	14JAN2003	36		0	4					
		15JAN2003	37	4	0	4					
		16JAN2003	38	4	0	4					
		17JAN2003	39	4	0	4					
		18JAN2003	40	4	0	4					
		19JAN2003	41	4	0	4					
		20JAN2003	42	4	0	4					
		21JAN2003	43	4	0	4					
		22JAN2003	44	4	0	4					
		23JAN2003	45	4	0	4					
		24JAN2003	46	4	0	4					
		25JAN2003	47	4	0	4					
		26JAN2003	48	4	0	4					
		27JAN2003	49	4	0	4					
		28JAN2003	50		0	4					
		29JAN2003	51		0	4					
		30JAN2003	52	4	0	4					
		31JAN2003	53	4	0	4					
		01FEB2003	54	4	0	4					
		02FEB2003	55	4	0	4					
		03FEB2003	56	4	0	4	NO	290.2	56	100	
	E0033015	10APR2003	1	2	0	2					
		11APR2003	2	1	0	1					
		12APR2003	3	1	0	1					
		13APR2003	4	2	0	2					
		14APR2003	5	3	0	3					
		15APR2003	6	3	0	3					
		16APR2003	7	3	0	3					
		17APR2003	8	4	0	4					
		18APR2003	9	4	0	4					
		19APR2003	10	4	0	4					
		20APR2003	11	4	0	4					
		21APR2003	12	4	0	4					
		22APR2003	13	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	23APR2003	14	4	0	4					
		24APR2003	15	4	0	4					
		25APR2003	16	4	0	4					
		26APR2003	17	4	0	4					
		27APR2003	18	4	0	4					
		28APR2003	19	4	0	4					
		29APR2003	20	4	0	4					
		30APR2003	21	4	0	4					
		01MAY2003	22	4	0	4					
		02MAY2003	23	4	0	4					
		03MAY2003	24	4	0	4					
		04MAY2003	25	4	0	4					
		05MAY2003	26		0	4					
		06MAY2003	27	4	0	4					
		07MAY2003	28	4	0	4					
		08MAY2003	29	4	0	4					
		09MAY2003	30	4	0	4					
		10MAY2003	31	4	0	4					
		11MAY2003	32	4	0	4					
		12MAY2003	33	4	0	4					
		13MAY2003	34	4	0	4					
		14MAY2003	35	4	0	4					
		15MAY2003	36	4	0	4					
		16MAY2003	37	4	0	4					
		17MAY2003	38	4	0	4					
		18MAY2003	39	4	0	4					
		19MAY2003	40	4	0	4					
		20MAY2003	41	4	1	3					DOSAGE DECREASED - 100% COMPLIANT
		21MAY2003	42	4	1	3					
		22MAY2003	43	4	1	3					
		23MAY2003	44	4	1	3					
		24MAY2003	45	4	1	3					
		25MAY2003	46	4	1	3					
		26MAY2003	47	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	27MAY2003	48	4	1	3					DOSAGE DECREASED - 100% COMPLIANT
		28MAY2003	49	4	1	3					
		29MAY2003	50	4	1	3					
		30MAY2003	51	4	1	3					
		31MAY2003	52	4	1	3					
		01JUN2003	53	4	1	3					
		02JUN2003	54	4	1	3					
		03JUN2003					YES	263.9	54	100	PT DID NOT TAKE P.M. DOSE PRIOR TO LAST APPT
	E0034002	25MAR2003	1	2	0	2					
		26MAR2003	2	1	0	1					
		27MAR2003	3	1	0	1					
		28MAR2003	4	2	0	2					
		29MAR2003	5	3	0	3					
		30MAR2003	6	3	0	3					
		31MAR2003	7	3	0	3					
		01APR2003	8	4	0	4					
		02APR2003	9	4	0	4					
		03APR2003	10	4	0	4					
		04APR2003	11	4	0	4					
		05APR2003	12	4	0	4					
		06APR2003	13	4	0	4					
		07APR2003	14	4	0	4					
		08APR2003	15	4	0	4					
		09APR2003	16	4	0	4					
		10APR2003	17	4	0	4					
		11APR2003	18	4	0	4					
		12APR2003	19	4	0	4					
		13APR2003	20	4	0	4					
		14APR2003	21	4	0	4	NO	273.8	21	100	
	E0034003	24APR2003	1	2	0	2					
		25APR2003	2	1	0	1					
		26APR2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	27APR2003	4	2	0	2					
		28APR2003	5	3	0	3					
		29APR2003	6	3	0	3					
		30APR2003	7	3	0	3					
		01MAY2003	8	4	0	4					
		02MAY2003	9	4	0	4					
		03MAY2003	10	4	0	4					
		04MAY2003	11	4	0	4					
		05MAY2003	12	4	0	4					
		06MAY2003	13	4	0	4					
		07MAY2003	14	4	0	4					
		08MAY2003	15	4	0	4					
		09MAY2003	16	4	0	4					
		10MAY2003	17	4	0	4					
		11MAY2003	18	4	0	4					
		12MAY2003	19	4	0	4					
		13MAY2003	20	4	0	4					
		14MAY2003	21	4	0	4					
		15MAY2003	22	4	0	4					
		16MAY2003	23	4	0	4					
		17MAY2003	24	4	0	4					
		18MAY2003	25	4	0	4					
		19MAY2003	26	4	0	4					
		20MAY2003	27	4	0	4					
		21MAY2003	28	4	0	4					
		22MAY2003	29	4	0	4					
		23MAY2003	30	4	0	4					
		24MAY2003	31	4	0	4					
		25MAY2003	32	4	0	4					
		26MAY2003	33	4	0	4					
		27MAY2003	34	4	0	4					
		28MAY2003	35	4	0	4					
		29MAY2003	36	4	0	4					
		30MAY2003	37	4	0	4					
		31MAY2003	38	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	01JUN2003	39	4	0	4					
		02JUN2003	40	4	0	4					
		03JUN2003	41	4	0	4					
		04JUN2003	42	4	0	4					
		05JUN2003	43	4	0	4					
		06JUN2003	44	4	0	4					
		07JUN2003	45	4	0	4					
		08JUN2003	46	4	0	4					
		09JUN2003	47	4	0	4					
		10JUN2003	48	4	0	4					
		11JUN2003	49	4	0	4					
		12JUN2003	50	4	0	4					
		13JUN2003	51	4	0	4					
		14JUN2003	52	4	0	4					
		15JUN2003	53	4	0	4					
		16JUN2003	54	4	0	4					
		17JUN2003	55	4	0	4					
		18JUN2003	56	4	0	4	NO	290.2	56	100	
	E0034006	16MAY2003	1	2	0	2					SUBJECT DID NOT RETURN BLISTER CARD, ENDORSES COMPLIANCE. TO ADHERE TO VISIT SCHEDULE PT. WAS PRESCRIBED ALL TABLETS INCLUDING EXTRA DOSES. SUBJ. SAYS DOG ATE BLISTER CARD
		17MAY2003	2	1	0	1					
		18MAY2003	3	1	0	1					
		19MAY2003	4	2	0	2					
		20MAY2003	5	3	0	3					
		21MAY2003	6	3	0	3					
		22MAY2003	7	3	0	3					
		23MAY2003	8		0	4					
		24MAY2003	9		0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	25MAY2003	10	4	0	4					SIC
		26MAY2003	11	4	0	4					
		27MAY2003	12	4	0	4					
		28MAY2003	13	4	0	4					
		29MAY2003	14	4	0	4					
		30MAY2003	15	4	0	4					
		31MAY2003	16	4	0	4					
		01JUN2003	17		0	4					
		02JUN2003	18	4	0	4					
		03JUN2003	19	4	0	4					
		04JUN2003	20	4	0	4					
		05JUN2003	21	4	0	4					
		06JUN2003	22	4	0	4					
		07JUN2003	23	4	0	4					
		08JUN2003	24	4	0	4					
		09JUN2003	25	4	0	4					
		10JUN2003	26	4	0	4					
		11JUN2003	27	4	0	4					
		12JUN2003	28	4	0	4					
		13JUN2003	29	4	0	4					NOT PRESCRIBED DAYS 5 - 7
		14JUN2003	30	4	0	4					
		15JUN2003	31	4	0	4					
		16JUN2003	32	4	0	4					
		17JUN2003	33	4	0	4					
		18JUN2003	34	4	0	4					
		19JUN2003	35	4	0	4					
		20JUN2003	36	4	0	4					
		21JUN2003	37	4	4	0					PT MISSED THIS DOSE
		22JUN2003	38	4	0	4					
		23JUN2003	39	4	0	4					
		24JUN2003	40	4	0	4					
		25JUN2003	41	4	0	4					
		26JUN2003	42	4	0	4					
		27JUN2003	43	4	0	4					
		28JUN2003	44	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	29JUN2003	45	4	0	4					
		30JUN2003	46	4	0	4					
		01JUL2003	47	4	0	4					
		02JUL2003	48	4	0	4					
		03JUL2003	49	4	0	4					PT. NOT PRESCRIBED THIS DOSE
		04JUL2003	50	4	0	4					
		05JUL2003	51	4	4	0					PT MISSED THIS DOSE
		06JUL2003	52	4	0	4					
		07JUL2003	53	4	0	4					
		08JUL2003	54	4	0	4					
		09JUL2003	55	4	0	4	NO	279.1	53	96.1	
	E0034008	24MAY2003	1	2	0	2					PER LRA APPROVAL SUBJ. DOSED DAY AFTER VISIT SO SUBJ. WOULD HAVE ENOUGH MEDS UNTIL NEXT VISIT.
		25MAY2003	2	1	0	1					
		26MAY2003	3	1	0	1					
		27MAY2003	4	2	0	2					
		28MAY2003	5	3	0	3					
		29MAY2003	6	3	0	3					
		30MAY2003	7	3	0	3					
		31MAY2003	8		0	4					
		01JUN2003	9		0	4					
		02JUN2003	10	4	0	4					
		03JUN2003	11	4	0	4					
		04JUN2003	12	4	0	4					
		05JUN2003	13	4	0	4					
		06JUN2003	14	4	0	4					PT. NOT PRESCRIBED THIS DOSE FROM THIS CARD.
		07JUN2003	15	4	0	4					
		08JUN2003	16	4	0	4					
		09JUN2003	17	4	0	4					
		10JUN2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	11JUN2003	19	4	0	4					
		12JUN2003	20	4	0	4					SIC
		13JUN2003	21	4	0	4					TOOK THIS DOSE ON 6/12 IN ERROR.
		14JUN2003	22	4	0	4					
		15JUN2003	23	4	0	4					
		16JUN2003	24	4	0	4					
		17JUN2003	25	4	0	4					
		18JUN2003	26	4	0	4					
		19JUN2003	27	4	0	4					
		20JUN2003	28	4	0	4					
		21JUN2003	29	4	0	4					
		22JUN2003	30	4	0	4					
		23JUN2003	31	4	0	4					
		24JUN2003	32	4	0	4					
		25JUN2003	33	4	0	4					
		26JUN2003	34	4	0	4					
		27JUN2003	35	4	0	4					
		28JUN2003	36	4	0	4					
		29JUN2003	37	4	0	4					
		30JUN2003	38	4	0	4					
		01JUL2003	39	4	0	4					
		02JUL2003	40	4	0	4					
		03JUL2003	41	4	0	4					
		04JUL2003	42		0	4					
		05JUL2003	43		0	4					
		06JUL2003	44			0					
		07JUL2003	45	4	0	4					SIC MISSED DOSE ON 7/6/03 DUE TO RUNNING OUT OF STUDY DRUG.
		08JUL2003	46	4	0	4					
		09JUL2003	47	4	0	4					
		10JUL2003	48	4	0	4					
		11JUL2003	49	4	0	4					
		12JUL2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	13JUL2003	51	4	0	4					
		14JUL2003	52	4	0	4					
		15JUL2003	53	4	0	4					
		16JUL2003	54	4	0	4					
		17JUL2003	55	4	0	4					
		18JUL2003	56	4	0	4					
		19JUL2003	57	4	0	4					
		20JUL2003	58	4	0	4	NO	285.3	57	98.2	
	E0035003										NOT TAKEN NOT TAKEN NOT TAKEN NOT TAKEN
		22NOV2002	1	2	0	2					
		23NOV2002	2	1	0	1					
		24NOV2002	3	1	0	1					
		25NOV2002	4	2	0	2					
		26NOV2002	5	3	0	3					
		27NOV2002	6	3	0	3					
		28NOV2002	7	3	0	3					
		29NOV2002	8		0	4					
		30NOV2002	9		0	4					
		01DEC2002	10		0	4					
		02DEC2002	11		0	4					
		03DEC2002	12	4	0	4					
		04DEC2002	13	4	0	4					
		05DEC2002	14	4	0	4					
		06DEC2002	15	4	0	4					
		07DEC2002	16	4	0	4					
		08DEC2002	17	4	0	4					
		09DEC2002	18	4	0	4					
		10DEC2002	19	4	0	4					
		11DEC2002	20	4	0	4					
		12DEC2002	21	4	0	4					
		13DEC2002	22	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	14DEC2002	23	4	0	4					
		15DEC2002	24	4	0	4					
		16DEC2002	25	4	0	4					
		17DEC2002	26	4	0	4					
		18DEC2002	27	4	0	4					
		19DEC2002	28	4	0	4					
		20DEC2002	29	4	0	4					
		21DEC2002	30	4	0	4					
		22DEC2002	31	4	0	4					
		23DEC2002	32	4	0	4					
		24DEC2002	33	4	0	4					
		25DEC2002	34	4	0	4					
		26DEC2002	35	4	0	4					
		27DEC2002	36	4	0	4					
		28DEC2002	37	4	0	4					
		29DEC2002	38	4	0	4					
		30DEC2002	39	4	0	4					
		31DEC2002	40	4	0	4					
		01JAN2003	41	4	0	4					
		02JAN2003	42	4	0	4					
		03JAN2003	43	4	0	4					
		04JAN2003	44	4	0	4					
		05JAN2003	45	4	0	4					
		06JAN2003	46	4	0	4					
		07JAN2003	47	4	0	4					
		08JAN2003	48	4	0	4					
		09JAN2003	49	4	0	4	NO	288.8	49	100	
	E0035005	03DEC2002	1	2	0	2					
		04DEC2002	2	1	0	1					
		05DEC2002	3	1	0	1					
		06DEC2002	4	2	0	2					
		07DEC2002	5	3	0	3					
		08DEC2002	6	3	0	3					
		09DEC2002	7	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0035005	10DEC2002	8		0	4					
		11DEC2002	9		0	4					
		12DEC2002	10	4	0	4					
		13DEC2002	11	4	0	4					
		14DEC2002	12	4	0	4					
		15DEC2002	13	4	0	4					
		16DEC2002	14	4	0	4					
		17DEC2002	15	4	0	4					
		18DEC2002	16	4	0	4					
		19DEC2002	17	4	0	4					
		20DEC2002	18	4	0	4					
		21DEC2002	19	4	0	4					
		22DEC2002	20	4	0	4					
		23DEC2002	21	4	0	4					
		24DEC2002	22	4	0	4					
		25DEC2002	23	4	0	4					
		26DEC2002	24	4	0	4					
		27DEC2002	25	4	0	4					
		28DEC2002	26	4	0	4					
		29DEC2002	27	4	0	4					
		30DEC2002	28	4	0	4					
		31DEC2002	29	4	0	4					
		01JAN2003	30	4	0	4					
		02JAN2003	31	4	0	4					
		03JAN2003	32	4	0	4					
		04JAN2003	33	4	0	4					
		05JAN2003	34	4	0	4					
		06JAN2003	35	4	0	4					
		07JAN2003	36	4	0	4					
		08JAN2003	37	4	0	4					
		09JAN2003	38	4	0	4					
		10JAN2003	39	4	0	4					
		11JAN2003	40	4	0	4					
		12JAN2003	41	4	0	4					
		13JAN2003	42	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0035005	14JAN2003	43	4	0	4					
		15JAN2003	44	4	0	4					
		16JAN2003	45	4	0	4					
		17JAN2003	46	4	0	4					
		18JAN2003	47	4	0	4					
		19JAN2003	48	4	0	4					
		20JAN2003	49	4	0	4					
		21JAN2003	50	4	0	4					CARD NOT RETURNED CAN NOT CONFIRM DOSING FOR DAYS 6 & 7 PLUS EXTRA DAYS.
		23JAN2003					NO	289	50	100	NOT KNOWN
	E0035014	03FEB2003	1	2	0	2					
		04FEB2003	2	1	0	1					
		05FEB2003	3	1	0	1					
		06FEB2003	4	2	0	2					
		07FEB2003	5	3	0	3					
		08FEB2003	6	3	0	3					
		09FEB2003	7	3	0	3					
		10FEB2003	8	4	0	4					
		11FEB2003	9	4	0	4					
		12FEB2003	10	4	0	4					
		13FEB2003	11	4	0	4					
		14FEB2003	12	4	0	4					
		15FEB2003	13	4	0	4					
		16FEB2003	14	4	0	4					
		17FEB2003	15	4	0	4					
		18FEB2003	16	4	0	4					
		19FEB2003	17	4	0	4					
		20FEB2003	18	4	0	4					
		21FEB2003	19	4	0	4					
		22FEB2003	20	4	0	4					
		23FEB2003	21	4	0	4					
		24FEB2003	22	4	0	4					
		25FEB2003	23	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	26FEB2003	24	4	0	4					
		27FEB2003	25	4	0	4					
		28FEB2003	26	4	0	4					
		01MAR2003	27	4	0	4					
		02MAR2003	28	4	0	4					
		03MAR2003	29	4	0	4					
		04MAR2003	30	4	0	4					
		05MAR2003	31	4	0	4					
		06MAR2003	32	4	0	4					
		07MAR2003	33	4	0	4					
		08MAR2003	34	4	0	4					
		09MAR2003	35	4	0	4					
		10MAR2003	36	4	0	4					
		11MAR2003	37	4	0	4					
		12MAR2003	38	4	0	4					
		13MAR2003	39	4	0	4					
		14MAR2003	40	4	0	4					
		15MAR2003	41	4	0	4					
		16MAR2003	42	4	0	4					
		17MAR2003	43	4	0	4					
		18MAR2003	44	4	0	4					
		19MAR2003	45	4	0	4					
		20MAR2003	46	4	0	4					
		21MAR2003	47	4	0	4					
		22MAR2003	48	4	0	4					
		23MAR2003	49	4	0	4					
		24MAR2003	50	4	0	4					
		25MAR2003	51	4	0	4					
		26MAR2003	52	4	0	4					
		27MAR2003	53	4	0	4					
		28MAR2003	54	4	0	4					
		29MAR2003	55	4	0	4					
		30MAR2003	56	4	0	4	NO	290.2	56	100	
	E0035024	22MAY2003	0	2	2	0					PT. MISSED DOSE

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	23MAY2003	1	1	0	1					
		24MAY2003	2	1	0	1					
		25MAY2003	3	2	0	2					
		26MAY2003	4	3	0	3					
		27MAY2003	5	3	0	3					
		28MAY2003	6	3	0	3					
		29MAY2003	7	4	0	4					
		30MAY2003	8	4	0	4					
		31MAY2003	9	4	0	4					
		01JUN2003	10	4	0	4					
		02JUN2003	11	4	0	4					
		03JUN2003	12	4	0	4					
		04JUN2003	13	4	0	4					
		05JUN2003	14	4	0	5					PT. POPPED OUT PILL ON ACCIDENT AND THREW IT AWAY.
		06JUN2003	15	4	0	4					
		07JUN2003	16	4	0	4					
		08JUN2003	17	4	0	4					
		09JUN2003	18	4	0	4					
		10JUN2003	19	4	0	4					
		11JUN2003	20	4	0	4					
		12JUN2003	21		0	4					
		13JUN2003	22	4	0	4					
		14JUN2003	23	4	0	4					
		15JUN2003	24	4	0	4					
		16JUN2003	25	4	0	4					
		17JUN2003	26	4	0	4					
		18JUN2003	27	4	0	4					
		19JUN2003	28	4	0	4					
		20JUN2003	29	4	0	4					
		21JUN2003	30	4	0	4					
		22JUN2003	31	4	0	4					
		23JUN2003	32	4	0	4					
		24JUN2003	33	4	0	4					
		25JUN2003	34	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	26JUN2003	35		0	4					
		27JUN2003	36	4	0	4					
		28JUN2003	37	4	0	4					
		29JUN2003	38	4	0	4					
		30JUN2003	39	4	0	4					
		01JUL2003	40	4	0	4					
		02JUL2003	41	4	0	4					
		03JUL2003	42	4	0	4					
		04JUL2003	43	4	0	4					
		05JUL2003	44	4	0	4					
		06JUL2003	45	4	0	4					
		07JUL2003	46	4	0	4					
		08JUL2003	47	4	0	4					
		09JUL2003	48	4	0	4					
		10JUL2003	49	4	0	4					
		11JUL2003	50	4	0	4					
		12JUL2003	51	4	0	4					
		13JUL2003	52	4	0	4					
		14JUL2003	53	4	0	4					
		15JUL2003	54	4	0	4					
		16JUL2003	55	4	0	4					
		17JUL2003	56		0	4	NO	285.1	56	101	
	E0036005	01JUL2003	1	2	0	2					
		02JUL2003	2	1	0	1					
		03JUL2003	3	1	0	1					
		04JUL2003	4	2	0	2					
		05JUL2003	5	3	0	3					
		06JUL2003	6	3	0	3					
		07JUL2003	7	3	0	3					
		08JUL2003	8	4	0	4					
		09JUL2003	9	4	0	4					
		10JUL2003	10	4	0	4					
		11JUL2003	11	4	0	4					
		12JUL2003	12	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	13JUL2003	13	4	0	4					
		14JUL2003	14	4	0	4					
		15JUL2003	15	4	0	4					
		16JUL2003	16	4	0	4					
		17JUL2003	17	4	0	4					
		18JUL2003	18	4	0	4					
		19JUL2003	19	4	0	4					
		20JUL2003	20	4	0	4					
		21JUL2003	21	4	0	4					
		22JUL2003	22		0	4					
		23JUL2003	23	4	0	4					
		24JUL2003	24	4	0	4					
		25JUL2003	25	4	0	4					
		26JUL2003	26	4	0	4					
		27JUL2003	27	4	0	4					
		28JUL2003	28	4	0	4					
		29JUL2003	29	4	0	4					LOST TABLETS
		30JUL2003	30	4	0	4					
		31JUL2003	31	4	0	4					
		01AUG2003	32	4	0	4					
		02AUG2003	33	4	0	4					
		03AUG2003	34	4	0	4					
		04AUG2003	35	4	0	4					
		05AUG2003	36	4	0	4					
		06AUG2003	37	4	0	4					
		07AUG2003	38	4	0	4					
		08AUG2003	39	4	0	4					
		09AUG2003	40	4	0	4					
		10AUG2003	41	4	0	4					
		11AUG2003	42	4	0	4					
		12AUG2003	43	4	0	4					
		13AUG2003	44	4	0	4					
		14AUG2003	45	4	0	4					
		15AUG2003	46	4	0	4					
		16AUG2003	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	17AUG2003	48	4	0	4					
		18AUG2003	49	4	0	4					
		19AUG2003	50	4	0	4					
		20AUG2003	51	4	0	4					
		21AUG2003	52	4	0	4					
		22AUG2003	53	4	0	4					
		23AUG2003	54	4	0	4					
		24AUG2003	55	4	0	4					
		25AUG2003	56	4	0	4					
		26AUG2003	57		0	4	NO	290.4	57	100	
	E0037002	26DEC2002	1	2	0	2					
		27DEC2002	2	1	0	1					
		28DEC2002	3	1	1	0					PT SKIPPED THIS LINE OF MEDICATION
		29DEC2002	4	2	0	2					PT TOOK 12/28/02
		30DEC2002	5	3	0	3					PT TOOK 12/29/02
		31DEC2002	6	3	0	3					PT TOOK 12/30/02
		01JAN2003	7	3	0	3					PT TOOK 12/31/02
		02JAN2003	8		0	4					PT TOOK 1/1/03
		03JAN2003	9	4	0	8					PT TOOK 1/2/03
		04JAN2003	10	4	0	4					
		05JAN2003	11	4	0	4					
		06JAN2003	12	4	0	4					
		07JAN2003	13	4	0	4					
		08JAN2003	14	4	0	4					
		09JAN2003	15	4	0	4					
		10JAN2003	16	4	0	4					
		11JAN2003	17	4	0	4					
		12JAN2003	18	4	0	4					
		13JAN2003	19	4	0	4					
		14JAN2003	20	4	0	4					
		15JAN2003	21	4	0	4					
		16JAN2003	22		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	17JAN2003	23		0	4					PT TOOK 1/17/03 WHEN SHE FORGOT TO RETURN MEDICATION PACKAGE
		18JAN2003	24	4	0	4					
		19JAN2003	25	4	0	4					
		20JAN2003	26	4	0	4					
		21JAN2003	27	4	0	4					
		22JAN2003	28	4	0	4					
		23JAN2003	29	4	0	4					
		24JAN2003	30	4	0	4					
		25JAN2003	31	4	0	4					
		26JAN2003	32	4	0	4					
		27JAN2003	33	4	0	4					
		28JAN2003	34	4	0	4					PT LOST COLUMN 1 PILL
		29JAN2003	35	4	0	4					
		30JAN2003	36	4	0	4					
		31JAN2003	37	4	1	3					1/28/03 PT TOOK COLUMN ONE PILL
		31JAN2003	37	4	1	3					STARTING 1/31/03 DOSE DECREASED.
		01FEB2003	38	4	1	3					
		02FEB2003	39	4	1	3					
		03FEB2003	40	4	1	3					
		04FEB2003	41	4	1	3					
		05FEB2003	42	4	1	3					
		06FEB2003	43	4	1	3					
		07FEB2003	44	4	1	3					DOSE DECREASED
		08FEB2003	45	4	1	3					
		09FEB2003	46	4	1	3					
		10FEB2003	47	4	1	3					
		11FEB2003	48	4	1	3					
		12FEB2003	49	4	1	3					
		13FEB2003	50	4	1	3					
		14FEB2003	51	4	1	3					DOSE DECREASED.
		15FEB2003	52	4	1	3					
		16FEB2003	53	4	1	3					
		17FEB2003	54	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	18FEB2003	55	4	1	3					
		19FEB2003	56	4	1	3	YES	256.3	55	102	
	E0037005	06MAR2003	1	2	0	2					
		07MAR2003	2	1	0	1					
		08MAR2003	3	1	0	1					
		09MAR2003	4	2	0	2					
		10MAR2003	5	3	0	3					
		11MAR2003	6	3	0	3					
		12MAR2003	7	3	0	3					
		13MAR2003	8	4	0	4					
		14MAR2003	9	4	0	4					
		15MAR2003	10	4	0	4					
		16MAR2003	11	4	0	4					
		17MAR2003	12	4	0	4					
		18MAR2003	13	4	0	4					
		19MAR2003	14	4	0	4					
		20MAR2003	15	4	0	4					
		21MAR2003	16	4	0	4					
		22MAR2003	17	4	0	4					
		23MAR2003	18	4	0	4					
		24MAR2003	19	4	0	4					
		25MAR2003	20	4	0	4					
		26MAR2003	21	4	0	4					
		27MAR2003	22	4	0	4					
		28MAR2003	23	4	0	4					
		29MAR2003	24	4	0	4					
		30MAR2003	25	4	0	4					
		31MAR2003	26	4	0	4					
		01APR2003	27	4	0	4					
		02APR2003	28	4	0	4					
		03APR2003	29	4	0	4					
		04APR2003	30	4	0	4					
		05APR2003	31	4	0	4					
		06APR2003	32	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	07APR2003	33	4	0	4					
		08APR2003	34	4	0	4					
		09APR2003	35	4	0	4					
		10APR2003	36	4	0	4					
		11APR2003	37	4	0	4					
		12APR2003	38	4	0	4					
		13APR2003	39	4	0	4					
		14APR2003	40	4	0	4					
		15APR2003	41	4	0	4					
		16APR2003	42	4	0	4					
		17APR2003	43	4	0	4					
		18APR2003	44	4	0	4					
		19APR2003	45	4	0	4					
		20APR2003	46	4	0	4					
		21APR2003	47	4	0	4					
		22APR2003	48	4	0	4					
		23APR2003	49	4	0	4					
		24APR2003	50	4	0	4					
		25APR2003	51	4	0	4					
		26APR2003	52	4	0	4					
		27APR2003	53	4	0	4					
		28APR2003	54	4	0	4					
		29APR2003	55	4	0	4					
		30APR2003	56	4	0	4	NO	290.2	56	100	
	E0037006	14MAR2003	1	2	0	2					
		15MAR2003	2	1	0	1					
		16MAR2003	3	1	0	1					
		17MAR2003	4	2	0	2					
		18MAR2003	5	3	0	3					
		19MAR2003	6	3	0	3					
		20MAR2003	7	3	0	3					
		21MAR2003	8	4	0	4					
		22MAR2003	9	4	0	4					
		23MAR2003	10	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	24MAR2003	11	4	0	4					
		25MAR2003	12	4	0	4					
		26MAR2003	13	4	0	4					
		27MAR2003	14	4	0	4					
		28MAR2003	15	4	0	4					
		29MAR2003	16	4	0	4					
		30MAR2003	17	4	0	4					
		31MAR2003	18	4	0	4					
		01APR2003	19	4	0	4					
		02APR2003	20	4	0	4					
		03APR2003	21	4	0	4					
		04APR2003	22	4	0	4					
		05APR2003	23	4	0	4					
		06APR2003	24	4	0	4					
		07APR2003	25	4	0	4					
		08APR2003	26	4	0	4					
		09APR2003	27	4	0	4					
		10APR2003	28	4	0	4					
		11APR2003	29	4	0	4					
		12APR2003	30	4	0	4					
		13APR2003	31	4	0	4					
		14APR2003	32	4	0	4					
		15APR2003	33	4	0	4					
		16APR2003	34	4	0	4					
		17APR2003	35	4	0	4					
		18APR2003	36	4	0	4					
		19APR2003	37	4	0	4					
		20APR2003	38	4	4	0					PT FELL ASLEEP - FORGOT TO TAKE
		21APR2003	39	4	0	4					
		22APR2003	40	4	0	4					
		23APR2003	41	4	0	4					
		24APR2003	42	4	0	4					
		25APR2003	43	4	0	4					
		26APR2003	44	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	27APR2003	45	4	0	4					
		28APR2003	46	4	0	4					
		29APR2003	47	4	0	4					
		30APR2003	48	4	0	4					
		01MAY2003	49	4	0	4					
		02MAY2003	50	4	0	4					
		03MAY2003	51	4	0	4					
		04MAY2003	52	4	0	4					
		05MAY2003	53	4	0	4					
		06MAY2003	54	4	0	4					
		07MAY2003	55	4	0	4					
		08MAY2003	56		0	4	NO	284.8	55	98.1	
	E0039006	30DEC2002	1	2	0	2					
		31DEC2002	2	1	0	1					
		01JAN2003	3	1	0	1					
		02JAN2003	4	2	0	2					
		03JAN2003	5	3	0	3					
		04JAN2003	6	3	0	3					
		05JAN2003	7	3	0	3					
		06JAN2003	8	4	0	4					
		07JAN2003	9	4	0	4					
		08JAN2003	10	4	0	4					
		09JAN2003	11	4	0	4					
		10JAN2003	12	4	0	4					
		11JAN2003	13	4	0	4					
		12JAN2003	14	4	0	4					
		13JAN2003	15	4	0	4					
		14JAN2003	16	4	0	4					
		15JAN2003	17	4	0	4					
		16JAN2003	18	4	0	4					
		17JAN2003	19	4	0	4					
		18JAN2003	20	4	0	4					
		19JAN2003	21	4	0	4					
		20JAN2003	22	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	21JAN2003	23	4	0	4					
		22JAN2003	24	4	0	4					
		23JAN2003	25	4	0	4					
		24JAN2003	26	4	0	4					
		25JAN2003	27	4	0	4					
		26JAN2003	28	4	0	4					
		27JAN2003	29		0	4					
		28JAN2003	30	4	0	4					
		29JAN2003	31	4	0	4					
		30JAN2003	32	4	0	4					
		31JAN2003	33	4	0	4					
		01FEB2003	34	4	0	4					
		02FEB2003	35	4	0	4					
		03FEB2003	36	4	0	4					
		04FEB2003	37	4	0	4					
		05FEB2003	38	4	0	4					
		06FEB2003	39	4	0	4					
		07FEB2003	40	4	0	4					
		08FEB2003	41	4	0	4					
		09FEB2003	42	4	0	4					
		10FEB2003	43	4	0	4					
		11FEB2003	44	4	0	4					
		12FEB2003	45	4	0	4					
		13FEB2003	46	4	0	4					
		14FEB2003	47	4	0	4					
		15FEB2003	48	4	0	4					
		16FEB2003	49	4	0	4					
		17FEB2003	50		0	4					
		18FEB2003	51	4	0	4					
		19FEB2003	52	4	0	4					
		20FEB2003	53	4	0	4					
		21FEB2003	54	4	0	4					
		22FEB2003	55	4	0	4					
		23FEB2003	56	4	0	4	NO	290.2	56	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039015	23JAN2003	1	2	0	2					
		24JAN2003	2	1	0	1					
		25JAN2003	3	1	0	1					
		26JAN2003	4	2	0	2					
		27JAN2003	5	3	0	3					
		28JAN2003	6	3	0	3					
		29JAN2003	7	3	0	3					
		30JAN2003	8	4	0	4					
		31JAN2003	9	4	0	4					
		01FEB2003	10	4	0	4					
		02FEB2003	11	4	0	4					
		03FEB2003	12	4	0	4					
		04FEB2003	13	4	0	4					
		05FEB2003	14	4	0	4					
		06FEB2003	15	4	0	4					
		07FEB2003	16	4	0	4					
		08FEB2003	17	4	0	4					
		09FEB2003	18	4	0	4					
		10FEB2003	19	4	0	4					
		11FEB2003	20	4	0	4					
		12FEB2003	21	4	0	4					
		13FEB2003	22		0	4					
		14FEB2003	23	4	0	4					
		15FEB2003	24	4	0	4					
		16FEB2003	25	4	0	4					
		17FEB2003	26	4	0	4					
		18FEB2003	27	4	0	4					
		19FEB2003	28	4	0	4					
		20FEB2003	29	4	0	4					
		21FEB2003	30	4	0	4					
		22FEB2003	31	4	0	4					
		23FEB2003	32	4	0	4					
		24FEB2003	33	4	0	4					
		25FEB2003	34	4	0	4					
		26FEB2003	35	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039015	27FEB2003	36	4	0	4					
		28FEB2003	37	4	0	4					
		01MAR2003	38	4	0	4					
		02MAR2003	39	4	0	4					
		03MAR2003	40	4	0	4					
		04MAR2003	41	4	0	4					
		05MAR2003	42	4	0	4					
		06MAR2003	43	4	0	4					
		07MAR2003	44	4	0	4					
		08MAR2003	45	4	0	4					
		09MAR2003	46	4	0	4					
		10MAR2003	47	4	0	4					
		11MAR2003	48	4	0	4					
		12MAR2003	49	4	0	4					
		13MAR2003	50		0	4					
		14MAR2003	51	4	0	4					
		15MAR2003	52	4	0	4					
		16MAR2003	53	4	0	4					
		17MAR2003	54	4	0	4					
		18MAR2003	55	4	0	4					
		19MAR2003	56	4	0	4	NO	290.2	56	100	
	E0039024	27FEB2003	1	2	0	2					THE SUBJECT TOOK DOSE ON 2/28/203
		28FEB2003	2	1	0	1					THE SUBJECT TOOK DOSE ON 3/1/03
		01MAR2003	3	1	0	1					THE SUBJECT TOOK DOSE ON 3/2/03
		02MAR2003	4	2	0	2					THE SUBJECT TOOK DOSE ON 3/3/03
		03MAR2003	5	3	0	3					THE SUBJECT TOOK DOSE ON 3/4/03
		04MAR2003	6	3	3	0					THE SUBJECT DID NOT TAKE THIS DOSE.
		05MAR2003	7	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	06MAR2003	8	4	0	4					
		07MAR2003	9	4	0	4					
		08MAR2003	10	4	0	4					
		09MAR2003	11	4	0	4					
		10MAR2003	12	4	0	4					
		11MAR2003	13	4	1	3					THE SUBJECT DOSE HAS BEEN REDUCED TO 3 TABLETS PER NIGHT.
		12MAR2003	14	4	1	3					
		13MAR2003	15	4	1	3					
		14MAR2003	16	4	1	3					
		15MAR2003	17	4	1	3					
		16MAR2003	18	4	1	3					
		17MAR2003	19	4	1	3					
		18MAR2003	20		1	3					
		19MAR2003	21		4	0					MISSED ONE DOSE
		20MAR2003	22	4	1	3					THE SUBJECT DOSE HAS BEEN REDUCED TO 3 TABLETS PER NIGHT.
		21MAR2003	23	4	1	3					
		22MAR2003	24	4	1	3					
		23MAR2003	25	4	1	3					
		24MAR2003	26	4	1	3					
		25MAR2003	27	4	1	3					
		26MAR2003	28	4	1	3					
		27MAR2003	29	4	1	3					THE SUBJECT'S DOSE WAS REDUCED TO 3 TABLETS PER NIGHT.
		28MAR2003	30	4	1	3					
		29MAR2003	31	4	1	3					
		30MAR2003	32	4	1	3					
		31MAR2003	33	4	1	3					
		01APR2003	34	4	1	3					
		02APR2003	35	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	03APR2003	36	4	1	3					THE SUBJECT DOSE WAS REDUCED TO 3 TABLETS PER NIGHT.
		04APR2003	37	4	1	3					
		05APR2003	38	4	1	3					
		06APR2003	39	4	1	3					
		07APR2003	40	4	1	3					
		08APR2003	41	4	1	3					
		09APR2003	42	4	1	3					
		10APR2003	43	4	1	3					THE DOSE WAS REDUCED TO 3 TABLETS PER NIGHT.
		11APR2003	44	4	1	3					
		12APR2003	45	4	1	3					
		13APR2003	46	4	1	3					
		14APR2003	47	4	1	3					
		15APR2003	48	4	1	3					
		16APR2003	49	4	1	3					
		17APR2003	50	4	1	3					THE SUBJECT DOSE WAS REDUCED TO 3 TABLETS PER NIGHT
		18APR2003	51	4	1	3					
		19APR2003	52	4	1	3					
		20APR2003	53	4	1	3					
		21APR2003	54	4	1	3					
		22APR2003	55	4	1	3					
		23APR2003	56	4	1	3	YES	202.7	54	96.4	
	E0039025	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					
		20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8	4	0	4					
		26MAR2003	9	4	0	4					
		27MAR2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039025	28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					
		02APR2003	16	4	2	2					THE SUBJECT FORGOT 2 TAKE 2 TABLETS.
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	4					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	0	4					
		08APR2003	22		0	4					
		09APR2003	23		0	4					
		10APR2003	24	4	0	4					
		11APR2003	25	4	0	4					
		12APR2003	26	4	0	4					
		13APR2003	27	4	0	4					
		14APR2003	28	4	0	4					
		15APR2003	29	4	0	8					
		16APR2003	30	4	0	8					
		17APR2003	31	4	0	4					
		18APR2003	32	4	0	4					
		19APR2003	33	4	0	4					
		20APR2003	34	4	0	4					
		21APR2003	35	4	0	4					
		22APR2003	36	4	0	4					
		23APR2003	37	4	0	4					
		24APR2003	38	4	0	4					
		25APR2003	39	4	0	4					
		26APR2003	40	4	0	4					
		27APR2003	41	4	0	4					
		28APR2003	42	4	0	4					
		29APR2003	43	4	0	4					
		30APR2003	44	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039025	01MAY2003	45	4	0	4					
		02MAY2003	46	4	0	4					
		03MAY2003	47	4	0	4					
		04MAY2003	48	4	0	4					
		05MAY2003	49	4	0	4					
		06MAY2003	50	4	0	4					
		07MAY2003	51	4	0	4					
		08MAY2003	52	4	0	4					
		09MAY2003	53	4	0	4					
		10MAY2003	54	4	0	4					
		11MAY2003	55	4	0	4					
		12MAY2003	56	4	0	4	NO	295.5	56	103	
	E0039041	15APR2003	1	2	0	2					
		16APR2003	2	1	0	1					
		17APR2003	3	1	0	1					
		18APR2003	4	2	0	2					
		19APR2003	5	3	0	3					
		20APR2003	6	3	0	3					
		21APR2003	7	3	0	3					
		22APR2003	8	4	0	4					
		23APR2003	9	4	0	4					
		24APR2003	10	4	0	4					
		25APR2003	11	4	0	4					
		26APR2003	12	4	0	4					
		27APR2003	13	4	0	4					
		28APR2003	14	4	0	4					
		29APR2003	15	4	0	4					CARD NOT RETURNED, SUBJECT REPORTED NOT TAKING EXTRA DOSES.
		30APR2003	16	4	0	4					
		01MAY2003	17	4	0	4					
		02MAY2003	18	4	0	4					
		03MAY2003	19	4	0	4					
		04MAY2003	20	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	05MAY2003	21	4	0	4					
		06MAY2003	22	4	0	8					CARD WAS NOT RETURNED.
		07MAY2003	23	4	0	8					
		08MAY2003	24	4	0	4					
		09MAY2003	25	4	0	4					
		10MAY2003	26	4	0	4					
		11MAY2003	27	4	0	4					
		12MAY2003	28	4	0	4					
		13MAY2003	29	4	0	8					THE CARD WAS NOT RETURNED. THE SUBJECT REPORTED NOT TAKING EXTRA DOSES.
		13MAY2003	29	4	0	8					THE CARD WAS NOT RETURNED.
		14MAY2003	30	4	0	8					
		15MAY2003	31	4	0	4					
		16MAY2003	32	4	0	4					
		17MAY2003	33	4	0	4					
		18MAY2003	34	4	0	4					
		19MAY2003	35	4	0	4					
		20MAY2003	36	4	0	8					THE SUBJECT REPORTED NOT TAKING EXTRA DOSES.
		20MAY2003	36	4	0	8					THE CARD WAS NOT RETURNED.
		21MAY2003	37	4	0	8					
		22MAY2003	38	4	0	4					
		23MAY2003	39	4	0	4					
		24MAY2003	40	4	0	4					
		25MAY2003	41	4	0	4					
		26MAY2003	42	4	0	4					
		27MAY2003	43	4	0	8					THE SUBJECT REPORTED NOT TAKING EXTRA DOSES.
		28MAY2003	44	4	0	8					
		29MAY2003	45	4	0	4					
		30MAY2003	46	4	0	4					
		31MAY2003	47	4	0	4					
		01JUN2003	48	4	0	4					
		02JUN2003	49	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	03JUN2003	50	4	0	8					THE CARD WAS NOT RETURNED.
		04JUN2003	51	4	0	8					THE SUBJECT REPORTED NOT TAKING EXTRA DOSES.
		05JUN2003	52	4	0	4					
		06JUN2003	53	4	0	4					
		07JUN2003	54	4	0	4					
		08JUN2003	55	4	0	4					
		09JUN2003	56	4	0	4					
		10JUN2003					NO	343.8	56	119	THE SUBJECT MISSED ONE DOSE
	E0039044	22MAY2003	1	2	0	2					
		23MAY2003	2	1	0	1					
		24MAY2003	3	1	0	1					
		25MAY2003	4	2	0	2					
		26MAY2003	5	3	0	3					
		27MAY2003	6	3	0	3					
		28MAY2003	7	3	0	3					
		29MAY2003	8	4	0	4					
		30MAY2003	9	4	0	4					
		31MAY2003	10	4	0	4					
		01JUN2003	11	4	0	4					
		02JUN2003	12	4	0	4					
		03JUN2003	13	4	0	4					
		04JUN2003	14	4	0	4					
		05JUN2003	15	4	0	4					
		06JUN2003	16	4	0	4					
		07JUN2003	17	4	0	4					
		08JUN2003	18	4	0	4					
		09JUN2003	19	4	0	4					
		10JUN2003	20	4	0	4					
		11JUN2003	21	4	0	4					
		12JUN2003	22	4	0	4					
		13JUN2003	23	4	0	4					
		14JUN2003	24	4	0	4					
		15JUN2003	25	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	16JUN2003	26	4	0	4					
		17JUN2003	27	4	0	4					
		18JUN2003	28	4	0	4					
		19JUN2003	29	4	0	4					
		20JUN2003	30	4	0	4					
		21JUN2003	31	4	0	4					
		22JUN2003	32	4	0	4					
		23JUN2003	33	4	0	4					
		24JUN2003	34	4	0	4					
		25JUN2003	35		4	0					MISSED DOSE
		26JUN2003	36	4	0	4					
		27JUN2003	37	4	0	4					
		28JUN2003	38	4	0	4					
		29JUN2003	39	4	0	4					
		30JUN2003	40	4	0	4					
		01JUL2003	41	4	0	4					
		02JUL2003	42	4	0	8					IT IS UNKNOWN WHAT HAPPENED TO THIS DOSE. SUBJECT DID NOT REPORT TAKING 2 DOSES ON 7/2/03.
		03JUL2003	43	4	0	4					
		04JUL2003	44	4	0	4					
		05JUL2003	45	4	0	4					
		06JUL2003	46	4	0	4					
		07JUL2003	47	4	0	4					
		08JUL2003	48	4	0	4	NO	288.5	47	100	
	E0039046	21MAY2003					NO				SUBJECT NEVER TOOK STUDY DRUG.
	E0039051	16JUN2003	1	2	0	2					
		17JUN2003	2	1	0	1					
		18JUN2003	3	1	0	1					
		19JUN2003	4	2	0	2					
		20JUN2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	21JUN2003	6	3	0	3					
		22JUN2003	7	3	0	3					
		23JUN2003	8	4	0	4					
		24JUN2003	9	4	0	4					
		25JUN2003	10	4	0	4					
		26JUN2003	11	4	0	4					
		27JUN2003	12	4	0	4					
		28JUN2003	13	4	0	4					
		29JUN2003	14	4	0	4					
		30JUN2003	15	4	0	4					
		01JUL2003	16	4	0	4					
		02JUL2003	17	4	0	4					
		03JUL2003	18	4	0	4					
		04JUL2003	19	4	0	4					
		05JUL2003	20	4	0	4					
		06JUL2003	21	4	1	3					SUBJECT MISSED 1 TABLET ON 7/6/03.
		07JUL2003	22	4	0	4					
		08JUL2003	23	4	2	2					SUBJECT FORGOT TO TAKE 2 TABS.
		09JUL2003	24	4	0	4					
		10JUL2003	25	4	0	4					
		11JUL2003	26	4	0	4					
		12JUL2003	27	4	0	4					
		13JUL2003	28	4	0	4					
		14JUL2003	29	4	0	4					
		15JUL2003	30	4	0	4					
		16JUL2003	31	4	0	4					
		17JUL2003	32	4	0	4					
		18JUL2003	33	4	0	4					
		19JUL2003	34	4	0	4					
		20JUL2003	35	4	0	4					
		21JUL2003	36		0	4					
		22JUL2003	37	4	0	4					
		23JUL2003	38	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	24JUL2003	39	4	0	4					
		25JUL2003	40	4	0	4					
		26JUL2003	41	4	0	4					
		27JUL2003	42	4	0	4					
		28JUL2003	43	4	0	4					
		29JUL2003	44	4	0	4					
		30JUL2003	45	4	0	4					
		31JUL2003	46	4	0	4					
		01AUG2003	47	4	0	4					
		02AUG2003	48	4	0	4					
		03AUG2003	49	4	0	4					
		04AUG2003	50	4	0	4					
		05AUG2003	51	4	0	4					
		06AUG2003	52	4	0	4					
		07AUG2003	53	4	0	4					
		08AUG2003	54	4	0	4					
		09AUG2003	55	4	0	4					
		10AUG2003	56	4	0	4					
		11AUG2003	57		0	4	NO	283.3	57	99.5	
	E0039053	11JUL2003	1	2	0	2					
		12JUL2003	2	1	0	1					
		13JUL2003	3	1	0	1					
		14JUL2003	4	2	0	2					
		15JUL2003	5	3	0	3					
		16JUL2003	6	3	0	3					
		17JUL2003	7	3	0	3					
		18JUL2003	8	4	0	4					
		19JUL2003	9	4	0	4					
		20JUL2003	10	4	0	4					
		21JUL2003	11	4	0	4					
		22JUL2003	12	4	0	4					
		23JUL2003	13	4	0	4					
		24JUL2003	14	4	0	4					
		25JUL2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	26JUL2003	16	4	0	4					
		27JUL2003	17	4	0	4					
		28JUL2003	18	4	0	4					
		29JUL2003	19	4	0	4					
		30JUL2003	20	4	0	4					
		31JUL2003	21	4	0	4					
		01AUG2003	22	4	0	4					
		02AUG2003	23	4	0	4					
		03AUG2003	24	4	0	4					
		04AUG2003	25	4	0	4					
		05AUG2003	26	4	0	4					
		06AUG2003	27	4	0	4					
		07AUG2003	28	4	0	4					SUBJECT RETURNED FOR VISIT 6 TODAY
		08AUG2003	29	4	0	4					
		09AUG2003	30	4	0	4					
		10AUG2003	31	4	0	4					
		11AUG2003	32	4	0	4					
		12AUG2003	33	4	0	4					
		13AUG2003	34	4	0	4					
		14AUG2003	35	4	0	4					
		15AUG2003	36	4	0	4					
		16AUG2003	37	4	0	4					
		17AUG2003	38	4	0	4					
		18AUG2003	39	4	0	4					
		19AUG2003	40	4	0	4					
		20AUG2003	41	4	0	4					
		21AUG2003	42	4	0	4					
		22AUG2003	43	4	0	4					
		23AUG2003	44	4	0	4					
		24AUG2003	45	4	0	4					
		25AUG2003	46	4	0	4					
		26AUG2003	47	4	0	4					
		27AUG2003	48	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	28AUG2003	49		4	0					THE SUBJECT MISSED A DOSE ON 8/28/03
		29AUG2003	50	4	0	4					THE SUBJECT DID NOT HAVE A DOSE OF STUDY MEDICATION ON 9/7/03. THE SUBJECT COMPLETED STUDY ON 9/8/03.
		30AUG2003	51	4	0	4					
		31AUG2003	52	4	0	4					
		01SEP2003	53	4	0	4					
		02SEP2003	54	4	0	4					
		03SEP2003	55	4	0	4					
		04SEP2003	56	4	0	4					
		05SEP2003	57		0	4					
		06SEP2003	58		0	4	NO	285.3	57	98.2	
	E0039057	14JUL2003	1	2	0	2					
		15JUL2003	2	1	0	1					
		16JUL2003	3	1	0	1					
		17JUL2003	4	2	0	2					
		18JUL2003	5	3	0	3					
		19JUL2003	6	3	0	3					
		20JUL2003	7	3	0	3					
		21JUL2003	8		0	4					
		22JUL2003	9	4	0	4					
		23JUL2003	10	4	0	4					
		24JUL2003	11	4	0	4					
		25JUL2003	12	4	0	4					
		26JUL2003	13	4	0	4					
		27JUL2003	14	4	0	4					
		28JUL2003	15	4	0	4					SUBJECT RETURNED ON 7/28/03 FOR VISIT 4, SEE PG. 201
		29JUL2003	16	4	0	4					
		30JUL2003	17	4	0	4					
		31JUL2003	18	4	0	4					
		01AUG2003	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039057	02AUG2003	20	4	0	4					
		03AUG2003	21	4	0	4					
		04AUG2003	22	4	0	4					
		05AUG2003	23	4	0	4					
		06AUG2003	24	4	0	4					
		07AUG2003	25	4	0	4					
		08AUG2003	26	4	0	4					
		09AUG2003	27	4	0	4					
		10AUG2003	28	4	0	4					
		11AUG2003	29		0	4					
		12AUG2003	30	4	0	4					THE SUBJECT IS NOW WORKING THE NIGHT SHIFT AND IS TAKING HIS DOSE OF MEDICATION FROM BLISTERCARD PRIOR TO EACH VISIT DAY.
		13AUG2003	31	4	0	4					
		14AUG2003	32	4	0	4					
		15AUG2003	33	4	0	4					
		16AUG2003	34	4	0	4					
		17AUG2003	35	4	0	4					
		18AUG2003	36	4	0	5					THE SUBJECT MISSED 3 TABLETS.
		18AUG2003	36	4	0	5					SUBJECT TOOK DOSE ON 8/19/03.
		19AUG2003	37	4	0	4					SUBJECT TOOK DOSE ON 8/20/03.
		20AUG2003	38	4	0	4					SUBJECT TOOK DOSE ON 8/21/03.
		21AUG2003	39	4	0	4					SUBJECT TOOK DOSE ON 8/22/03.
		22AUG2003	40	4	0	4					SUBJECT TOOK DOSE ON 8/23/03.
		23AUG2003	41	4	0	4					SUBJECT TOOK DOSE ON 8/24/03.

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0039057	24AUG2003	42	4	0	4					SUBJECT TOOK DOSE ON 8/25/03.
		25AUG2003	43		2	2					THE SUBJECT MISSED 2 TABLETS ON 8/26/03
		26AUG2003	44	4	0	4					THE SUBJECT TOOK DOSE ON 8/27/03.
		27AUG2003	45	4	0	4					THE SUBJECT TOOK DOSE ON 8/28/03.
		28AUG2003	46	4	0	4					THE SUBJECT TOOK DOSE ON 8/29/03.
		29AUG2003	47	4	0	4					THE SUBJECT TOOK DOSE ON 8/30/03.
		30AUG2003	48	4	0	4					THE SUBJECT TOOK DOSE ON 08/31/03.
		31AUG2003	49	4	0	4					THE SUBJECT TOOK DOSE ON 9/1/03.
		01SEP2003	50	4	1	3					THE SUBJECT MISSED ONE TABLET ON 9/2/03.
		02SEP2003	51	4	0	4					THE SUBJECT TOOK DOSE ON 9/3/03.
		03SEP2003	52	4	0	4					THE SUBJECT TOOK DOSE ON 9/4/03.
		04SEP2003	53	4	0	4					THE SUBJECT TOOK DOSE ON 9/5/03.
		05SEP2003	54	4	0	4					THE SUBJECT TOOK DOSE ON 9/6/03.
		06SEP2003	55	4	0	4					THE SUBJECT TOOK DOSE ON 9/7/03.
		07SEP2003	56	4	0	4					THE SUBJECT TOOK DOSE ON 9/8/03.
		08SEP2003	57	4	0	4	NO	283.3	57	100	THE SUBJECT TOOK DOSE ON 9/9/03.
	E0041003	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					
		30JAN2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					
		03FEB2003	7	3	0	3					
		04FEB2003	8	4	0	4					
		05FEB2003	9	4	0	4					
		06FEB2003	10	4	0	4					
		07FEB2003	11	4	0	4					
		08FEB2003	12	4	0	4					
		09FEB2003	13	4	0	4					
		10FEB2003	14	4	0	4					
		11FEB2003	15	4	0	4					
		12FEB2003	16	4	0	4					
		13FEB2003	17	4	0	4					
		14FEB2003	18	4	0	4					
		15FEB2003	19	4	0	4					
		16FEB2003	20	4	0	4					
		17FEB2003	21	4	0	4					
		18FEB2003	22	4	0	4					
		19FEB2003	23	4	0	4					
		20FEB2003	24	4	0	4					
		21FEB2003	25	4	0	4					
		22FEB2003	26	4	0	4					
		23FEB2003	27	4	0	4					
		24FEB2003	28	4	0	4					
		25FEB2003	29	4	0	4					
		26FEB2003	30	4	0	4					
		27FEB2003	31	4	0	4					
		28FEB2003	32	4	0	4					
		01MAR2003	33	4	0	4					
		02MAR2003	34	4	0	4					
		03MAR2003	35	4	0	4					
		04MAR2003	36	4	0	4					
		05MAR2003	37	4	0	4					
		06MAR2003	38	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	07MAR2003	39	4	0	4					
		08MAR2003	40	4	0	4					
		09MAR2003	41	4	0	4					
		10MAR2003	42	4	0	4					
		11MAR2003	43	4	0	4					
		12MAR2003	44	4	0	4					
		13MAR2003	45	4	0	4					
		14MAR2003	46	4	0	4					
		15MAR2003	47	4	0	4					
		16MAR2003	48	4	0	4					
		17MAR2003	49	4	0	4					
		18MAR2003	50	4	0	4					
		19MAR2003	51	4	0	4					
		20MAR2003	52	4	0	4					
		21MAR2003	53	4	0	4					
		22MAR2003	54	4	0	4					
		23MAR2003	55	4	0	4					
		24MAR2003	56	4	0	4	NO	290.2	56	100	
	E0041008	07APR2003	1	2	0	2					
		08APR2003	2	1	0	1					
		09APR2003	3	1	0	1					
		10APR2003	4	2	0	2					
		11APR2003	5	3	0	3					
		12APR2003	6	3	0	3					
		13APR2003	7	3	0	3					
		14APR2003	8	4	0	4					
		15APR2003	9	4	0	4					
		16APR2003	10	4	0	4					
		17APR2003	11	4	0	4					
		18APR2003	12	4	0	4					
		19APR2003	13	4	0	4					
		20APR2003	14	4	0	4					
		21APR2003	15		0	4					
		22APR2003	16	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	23APR2003	17	4	0	4					
		24APR2003	18	4	0	4					
		25APR2003	19	4	0	4					
		26APR2003	20	4	0	4					
		27APR2003	21	4	0	4					
		28APR2003	22	4	0	4					
		29APR2003	23	4	0	4					
		30APR2003	24	4	0	4					
		01MAY2003	25	4	0	4					
		02MAY2003	26	4	0	4					
		03MAY2003	27	4	0	4					
		04MAY2003	28	4	0	4					
		05MAY2003	29	4	0	4					
		06MAY2003	30	4	0	4					
		07MAY2003	31	4	0	4					
		08MAY2003	32	4	0	4					
		09MAY2003	33	4	0	4					
		10MAY2003	34	4	0	4					
		11MAY2003	35	4	0	4					
		12MAY2003	36	4	0	4					
		13MAY2003	37	4	0	4					
		14MAY2003	38	4	0	4					
		15MAY2003	39	4	0	4					
		16MAY2003	40	4	0	4					
		17MAY2003	41	4	0	4					
		18MAY2003	42	4	0	4					
		19MAY2003	43		0	4					
		20MAY2003	44		0	4					
		21MAY2003	45	4	0	4					
		22MAY2003	46	4	0	4					
		23MAY2003	47	4	0	4					
		24MAY2003	48	4	0	4					
		25MAY2003	49	4	0	4					
		26MAY2003	50	4	0	4					
		27MAY2003	51	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	28MAY2003	52	4	0	4					
		29MAY2003	53	4	0	4					
		30MAY2003	54	4	0	4					
		31MAY2003	55	4	0	4					
		01JUN2003	56	4	0	4					
		02JUN2003					NO	290.2	56	100	DUE TO A SCHEDULING CONFLICT, PATIENT'S V8 OCCURED ON ACTUAL DAY 45. PATIENT WAS SCHEDULED FOR V9 1 DAY EARLY TO GET SUBJECT IN WINDOW.
	E0042001	02JUL2003	1	2	0	2					
		03JUL2003	2	1	0	1					
		04JUL2003	3	1	0	1					
		05JUL2003	4	2	0	2					
		06JUL2003	5	3	0	3					
		07JUL2003	6	3	0	3					
		08JUL2003	7	3	0	3					
		09JUL2003	8	4	0	4					
		10JUL2003	9	4	0	4					
		11JUL2003	10	4	0	4					
		12JUL2003	11	4	0	4					
		13JUL2003	12	4	0	4					
		14JUL2003	13	4	0	4					
		15JUL2003	14	4	0	4					SCHEDULED VISIT EXTENDED VISIT INTERVAL
		16JUL2003	15	4	0	4					
		17JUL2003	16	4	0	4					
		18JUL2003	17	4	0	4					
		19JUL2003	18	4	0	4					
		20JUL2003	19	4	0	4					
		21JUL2003	20	4	0	4					
		22JUL2003	21	4	0	4					
		23JUL2003	22	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR I)	E0042001	24JUL2003	23	4	0	4					
		25JUL2003	24	4	0	4					
		26JUL2003	25	4	0	4					
		27JUL2003	26	4	0	4					
		28JUL2003	27	4	0	4					
		29JUL2003	28	4	0	4					
		30JUL2003	29	4	0	4					
		31JUL2003	30	4	0	4					
		01AUG2003	31	4	0	4					
		02AUG2003	32	4	0	4					
		03AUG2003	33	4	0	4					
		04AUG2003	34	4	0	4					
		05AUG2003	35	4	0	4					
		06AUG2003	36	4	0	4					
		07AUG2003	37	4	0	4					
		08AUG2003	38	4	0	4					
		09AUG2003	39	4	0	4					
		10AUG2003	40	4	0	4					
		11AUG2003	41	4	0	4					
		12AUG2003	42	4	0	4					
		13AUG2003	43	4	0	4					
		14AUG2003	44	4	0	4					
		15AUG2003	45	4	0	4					
		16AUG2003	46	4	0	4					
		17AUG2003	47	4	0	4					
		18AUG2003	48	4	0	4					
		19AUG2003	49	4	0	4					
		20AUG2003	50	4	0	4					
		21AUG2003	51	4	0	4					
		22AUG2003	52	4	0	4					
		23AUG2003	53	4	0	4					
		24AUG2003	54	4	0	4					
		25AUG2003	55	4	0	4	NO	290	55	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	12MAR2003	1	2	0	2					
		13MAR2003	2	1	0	1					
		14MAR2003	3	1	0	1					
		15MAR2003	4	2	0	2					
		16MAR2003	5	3	0	3					
		17MAR2003	6	3	0	3					
		18MAR2003	7	3	0	3					
		19MAR2003	8	4	0	4					
		20MAR2003	9	4	0	4					
		21MAR2003	10	4	0	4					
		22MAR2003	11	4	0	4					
		23MAR2003	12	4	0	4					
		24MAR2003	13	4	0	4					
		25MAR2003	14	4	0	4					
		26MAR2003	15	4	0	4					
		27MAR2003	16	4	0	4					
		28MAR2003	17	4	0	4					
		29MAR2003	18	4	0	4					
		30MAR2003	19	4	0	4					
		31MAR2003	20	4	0	4					
		01APR2003	21	4	0	4					
		02APR2003	22	4	0	4					
		03APR2003	23	4	0	4					
		04APR2003	24	4	0	4					
		05APR2003	25	4	0	4					
		06APR2003	26	4	0	4					
		07APR2003	27	4	0	4					
		08APR2003	28	4	0	4					
		09APR2003	29	4	0	4					
		10APR2003	30	4	0	4					
		11APR2003	31	4	0	4					
		12APR2003	32	4	0	4					
		13APR2003	33	4	0	4					
		14APR2003	34	4	0	4					
		15APR2003	35	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	16APR2003	36	4	0	4					
		17APR2003	37	4	0	4					
		18APR2003	38	4	0	4					
		19APR2003	39	4	0	4					
		20APR2003	40	4	0	4					
		21APR2003	41	4	0	4					
		22APR2003	42	4	0	4					
		23APR2003	43	4	0	4					
		24APR2003	44	4	0	4					
		25APR2003	45	4	0	4					
		26APR2003	46	4	0	4					
		27APR2003	47	4	0	4					
		28APR2003	48	4	0	4					
		29APR2003	49	4	0	4					
		30APR2003	50	4	0	4					
		01MAY2003	51	4	0	4					
		02MAY2003	52	4	0	4					
		03MAY2003	53	4	0	4					
		04MAY2003	54	4	0	4					
		05MAY2003	55	4	0	4					
		06MAY2003	56	4	0	4	NO	290.2	56	100	
	E0003018	13MAY2003	1	2	0	2					
		14MAY2003	2	1	0	1					
		15MAY2003	3	1	0	1					
		16MAY2003	4	2	0	2					
		17MAY2003	5	3	0	3					
		18MAY2003	6	3	0	3					
		19MAY2003	7	3	0	3					
		20MAY2003	8	4	0	4					
		21MAY2003	9	4	0	4					
		22MAY2003	10	4	0	4					
		23MAY2003	11	4	0	4					
		24MAY2003	12	4	0	4					
		25MAY2003	13	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	26MAY2003	14	4	0	4					
		27MAY2003	15	4	0	4					
		28MAY2003	16	4	0	4					
		29MAY2003	17	4	0	4					
		30MAY2003	18	4	0	4					
		31MAY2003	19	4	0	4					
		01JUN2003	20	4	0	4					
		02JUN2003	21	4	0	4					
		03JUN2003	22	4	0	4					
		04JUN2003	23	4	0	4					
		05JUN2003	24	4	0	4					
		06JUN2003	25	4	0	4					
		07JUN2003	26	4	0	4					
		08JUN2003	27	4	0	4					
		09JUN2003	28	4	0	4					
		10JUN2003	29	4	0	4					
		11JUN2003	30	4	0	4					
		12JUN2003	31	4	0	4					
		13JUN2003	32	4	0	4					
		14JUN2003	33	4	0	4					
		15JUN2003	34	4	0	4					
		16JUN2003	35	4	0	4					
		17JUN2003	36	4	0	4					
		18JUN2003	37	4	0	4					
		19JUN2003	38	4	0	4					
		20JUN2003	39	4	0	4					
		21JUN2003	40	4	0	4					
		22JUN2003	41	4	0	4					
		23JUN2003	42	4	0	4					
		24JUN2003	43	4	0	4					
		25JUN2003	44	4	0	4					
		26JUN2003	45	4	0	4					
		27JUN2003	46	4	0	4					
		28JUN2003	47	4	0	4					
		29JUN2003	48	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	30JUN2003	49	4	0	4					
		01JUL2003	50		0	4					PATIENT HAD 8 DAY WEEK VISIT SO HAD TO TAKE FROM EXTRA
		02JUL2003	51	4	0	4					
		03JUL2003	52	4	0	4					
		04JUL2003	53	4	0	4					
		05JUL2003	54	4	0	4					
		06JUL2003	55	4	0	4					
		07JUL2003	56	4	0	4					
		08JUL2003					NO	290.2	56	100	6 DAY WEEK, SO PATIENT HAD THIS VISIT ON 7/8/03 & DID NOT TAKE DOSE FROM CARD
	E0005011	24OCT2002	1	2	0	2					
		25OCT2002	2	1	0	1					
		26OCT2002	3	1	0	1					
		27OCT2002	4	2	0	2					
		28OCT2002	5	3	0	3					
		29OCT2002	6	3	0	3					
		30OCT2002	7	3	0	3					
		31OCT2002	8	4	0	4					
		01NOV2002	9	4	0	4					
		02NOV2002	10	4	0	4					
		03NOV2002	11	4	0	4					
		04NOV2002	12	4	0	4					
		05NOV2002	13	4	0	4					
		06NOV2002	14	4	0	4					
		07NOV2002	15	4	0	4					
		08NOV2002	16	4	0	4					
		09NOV2002	17	4	0	4					
		10NOV2002	18	4	0	4					
		11NOV2002	19	4	0	4					
		12NOV2002	20	4	0	4					
		13NOV2002	21	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0005011	14NOV2002	22	4	0	4					
		15NOV2002	23	4	0	4					
		16NOV2002	24	4	0	4					
		17NOV2002	25	4	0	4					
		18NOV2002	26	4	0	4					
		19NOV2002	27	4	0	4					
		20NOV2002	28	4	0	4					
		21NOV2002	29	4	0	4					
		22NOV2002	30	4	0	4					
		23NOV2002	31	4	0	4					
		24NOV2002	32	4	0	4					
		25NOV2002	33	4	0	4					
		26NOV2002	34	4	0	4					
		27NOV2002	35	4	0	4					
		28NOV2002	36	4	0	4					
		29NOV2002	37	4	0	4					
		30NOV2002	38	4	0	4					
		01DEC2002	39	4	0	4					
		02DEC2002	40	4	4	0					SKIPPED DOSE
		03DEC2002	41	4	0	4					PATIENT FAILED TO RETURN CARD - REPORTS 100% COMPLIANCE
		04DEC2002	42	4	0	4					
		05DEC2002	43	4	0	4					
		06DEC2002	44	4	0	4					
		07DEC2002	45	4	0	4					
		08DEC2002	46	4	0	4					
		09DEC2002	47	4	0	4					
		10DEC2002	48		0	4					
		11DEC2002	49		0	4					
		12DEC2002	50	4	0	4					PATIENT LOST TO FOLLOWUP DID NOT RETURN CARD
		19DEC2002					NO	283	49	97.9	UNK
	E0005030	26MAR2003	1	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0005030	27MAR2003	2	1	0	1					
		28MAR2003	3	1	1	0					PT. MISSED
		29MAR2003	4	2	0	2					
		30MAR2003	5	3	0	3					
		31MAR2003	6	3	0	3					
		01APR2003	7	3	0	3					
		02APR2003	8	4	4	4					SUBJECT CONTINUED TO DOSE FROM THIS CARD AT VISIT 3
		02APR2003	8	4	4	4					TOOK FROM PREVIOUS CARD
		03APR2003	9	4	4	4					TOOK FROM PREVIOUS CARD
		04APR2003	10	4	0	4					
		05APR2003	11	4	0	4					
		06APR2003	12	4	0	4					
		07APR2003	13	4	0	4					
		08APR2003	14	4	0	4					
		09APR2003	15	4	0	4					CARD NOT RETURNED
		10APR2003	16	4	0	4					
		11APR2003	17	4	0	4					
		12APR2003	18	4	0	4					
		13APR2003	19	4	0	4					
		14APR2003	20	4	0	4					
		15APR2003	21	4	0	4					
		16APR2003	22	4	0	8					UNK
		16APR2003	22	4	0	8					CARD NOT RETURNED
		23APR2003					NO	279.5	21	104	UNK
	E0005036	06MAY2003	1	2	0	2					
		07MAY2003	2	1	0	1					
		08MAY2003	3	1	0	1					
		09MAY2003	4	2	0	2					
		10MAY2003	5	3	3	0					MISSED DOSE, SEDATION
		11MAY2003	6	3	0	3					
		12MAY2003	7	3	0	3					
		14MAY2003					NO	178.6	6	80	STOPPED DOSE ON 5/12/03 DUE TO SEDATION

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	11FEB2003	1	2	0	2					
		12FEB2003	2	1	0	1					
		13FEB2003	3	1	0	1					
		14FEB2003	4	2	0	2					
		15FEB2003	5	3	0	3					
		16FEB2003	6	3	0	3					
		17FEB2003	7	3	0	3					
		18FEB2003	8	4	0	4					
		19FEB2003	9	4	0	4					
		20FEB2003	10	4	0	4					
		21FEB2003	11	4	0	4					
		22FEB2003	12	4	0	4					
		23FEB2003	13	4	0	4					
		24FEB2003	14	4	0	4					
		25FEB2003	15	4	0	4					
		26FEB2003	16	4	0	4					
		27FEB2003	17	4	0	4					
		28FEB2003	18	4	0	4					
		01MAR2003	19	4	0	4					
		02MAR2003	20	4	0	4					
		03MAR2003	21	4	0	4					
		04MAR2003	22	4	0	4					
		05MAR2003	23	4	0	4					
		06MAR2003	24	4	0	4					
		07MAR2003	25	4	0	4					
		08MAR2003	26	4	0	4					
		09MAR2003	27	4	0	4					
		10MAR2003	28	4	0	4					
		11MAR2003	29	4	0	4					
		12MAR2003	30	4	0	4					
		13MAR2003	31	4	0	4					
		14MAR2003	32	4	0	4					
		15MAR2003	33	4	0	4					
		16MAR2003	34	4	0	4					
		17MAR2003	35	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	18MAR2003	36	4	0	4					SUBJECT VOMITTED 3-15-03 DOSE TOOK EXTRA DAY DOSES TO REPLACE.
		19MAR2003	37	4	0	4					
		20MAR2003	38	4	0	4					
		21MAR2003	39	4	0	4					
		22MAR2003	40	4	0	4					
		23MAR2003	41	4	0	4					
		24MAR2003	42	4	0	4					
		25MAR2003	43	4	0	4					
		26MAR2003	44	4	0	4					
		27MAR2003	45	4	0	4					
		28MAR2003	46	4	0	4					
		29MAR2003	47	4	0	4					
		30MAR2003	48	4	0	4					
		31MAR2003	49	4	0	4					
		01APR2003	50	4	0	4					
		02APR2003	51	4	0	4					
		03APR2003	52	4	0	4					
		04APR2003	53	4	0	4					
		05APR2003	54	4	0	4					
		06APR2003	55	4	0	4					
		07APR2003	56	4	0	4	NO	290.2	56	100	
	E0006016	17FEB2003	1	2	0	2					
		18FEB2003	2	1	0	1					
		19FEB2003	3	1	0	1					
		20FEB2003	4	2	0	2					
		21FEB2003	5	3	0	3					
		22FEB2003	6	3	0	3					
		23FEB2003	7	3	0	3					
		24FEB2003	8	4	0	4					
		25FEB2003	9	4	0	4					
		26FEB2003	10	4	0	4					
		27FEB2003	11	4	0	4					
		28FEB2003	12	4	0	4					
		01MAR2003	13	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	02MAR2003	14	4	0	4					
		03MAR2003	15	4	0	4					
		04MAR2003	16	4	4	0					MISSED DOSE, SUBJECT FELL ASLEEP EARLY AND DID NOT TAKE THE MEDICATION FOR 3/4/03
		05MAR2003	17	4	0	4					
		06MAR2003	18	4	0	4					
		07MAR2003	19	4	0	4					
		08MAR2003	20	4	0	4					
		09MAR2003	21	4	0	4					
		10MAR2003	22	4	0	4					
		11MAR2003	23	4	0	4					
		12MAR2003	24	4	0	4					
		13MAR2003	25	4	0	4					
		14MAR2003	26	4	0	4					
		15MAR2003	27	4	0	4					
		16MAR2003	28	4	0	4					
		17MAR2003	29	4	0	4					
		18MAR2003	30	4	0	4					
		19MAR2003	31	4	0	4					
		20MAR2003	32	4	0	4					
		21MAR2003	33	4	4	0					SUBJECT WENT OUT OF TOWN 3-21 AND 3-22 - FORGOT TO TAKE MEDICATION
		22MAR2003	34	4	4	0					SUBJECT WENT OUT OF TOWN 3-21 AND 3-22 - FORGOT TO TAKE MEDICATION
		23MAR2003	35	4	0	4					
		24MAR2003	36		0	4					SUBJECT TOOK EXTRA 3-24 AND 3-25 BECAUSE THE SCHEDULED VISIT DATE WAS EXTENDED 2 DAYS.

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	25MAR2003	37		0	4					SUBJECT MISSED OFFICE VISIT DAY ON 3-26-03 AND CAME IN ON 3-27-03
		26MAR2003	38			0					
		27MAR2003	39	4	1	3					DOSE REDUCTION OF ONE PILL FOR EACH DAY THIS WEEK.
		28MAR2003	40	4	1	3					
		29MAR2003	41	4	1	3					
		30MAR2003	42	4	1	3					
		31MAR2003	43	4	1	3					
		01APR2003	44	4	1	3					
		02APR2003	45	4	1	3					
		03APR2003	46	4	1	3					DOSE REDUCTION OF 1 PILL CONTINUED THIS WEEK.
		04APR2003	47	4	1	3					
		05APR2003	48	4	1	3					
		06APR2003	49	4	1	3					
		07APR2003	50	4	1	3					
		08APR2003	51	4	1	3					
		09APR2003	52	4	1	3					
		10APR2003	53	4	1	3					DOSE REDUCTION OF 1 PILL CONTINUED THIS WEEK.
		11APR2003	54	4	1	3					
		12APR2003	55	4	1	3					
		13APR2003	56	4	1	3					
		14APR2003	57	4	1	3					
		15APR2003	58	4	1	3					
		16APR2003	59	4	1	3					
		17APR2003	60		1	3	YES	234.2	56	92.2	SUBJECT TOOK EXTRA DOSE ON HIS OWN. SUBJECT SCHEDULED VISIT WAS EXTENDED BY ONE DAY AND SUBJECT TOOK ONE EXTRA DOSE.
	E0007008	18APR2003	1	2	0	2					
		19APR2003	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	20APR2003	3	1	0	1					
		21APR2003	4	2	1	1					TOOK ONE PILL ONLY
		22APR2003	5	3	3	0					SKIPPED THE DOSES
		23APR2003	6	3	3	0					SKIPPED THE DOSES
		24APR2003	7	3	2	1	NO	50	5	40	PT TOOK ONE PILL ONLY
	E0009002	19NOV2002	1	2	0	2					
		20NOV2002	2	1	0	1					
		21NOV2002	3	1	0	1					
		22NOV2002	4	2	0	2					
		23NOV2002	5	3	0	3					
		24NOV2002	6	3	0	3					
		25NOV2002	7	3	0	3					
		26NOV2002	8	4	0	4					
		27NOV2002	9	4	0	4					
		28NOV2002	10	4	0	4					
		29NOV2002	11	4	0	4					
		30NOV2002	12	4	0	4					
		01DEC2002	13	4	0	4					
		02DEC2002	14	4	0	4					
		03DEC2002	15	4	0	4					
		04DEC2002	16	4	0	4					
		05DEC2002	17	4	0	4					
		06DEC2002	18	4	0	4					
		07DEC2002	19	4	0	4					
		08DEC2002	20	4	0	4					
		09DEC2002	21	4	0	4					
		10DEC2002	22	4	0	4					
		11DEC2002	23	4	0	4					
		12DEC2002	24	4	0	4					
		13DEC2002	25	4	0	4					
		14DEC2002	26	4	0	4					
		15DEC2002	27	4	0	4					
		16DEC2002	28	4	0	4					
		17DEC2002	29		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0009002	18DEC2002	30	4	0	4					
		19DEC2002	31	4	0	4					
		20DEC2002	32	4	0	4					
		21DEC2002	33	4	0	4					
		22DEC2002	34	4	0	4					
		23DEC2002	35	4	0	4					NEW CARD DISPENSED AT APPT.
		24DEC2002	36	4	0	4					NEW CARD DISPENSED AT APPT.
		25DEC2002	37	4	0	4					
		26DEC2002	38	4	0	4					
		27DEC2002	39	4	0	4					
		28DEC2002	40	4	0	4					
		29DEC2002	41	4	0	4					
		30DEC2002	42	4	0	4					
		31DEC2002	43	4	0	4					
		01JAN2003	44	4	0	4					
		02JAN2003	45	4	0	4					
		03JAN2003	46	4	0	4					
		04JAN2003	47	4	0	4					
		05JAN2003	48	4	0	4					
		06JAN2003	49		0	4					
		07JAN2003	50	4	0	4					
		08JAN2003	51	4	0	4					
		09JAN2003	52	4	0	4					
		10JAN2003	53	4	0	4					
		11JAN2003	54	4	0	4					
		12JAN2003	55	4	0	4					
		13JAN2003	56	4	0	4					
		14JAN2003	57		0	4	NO	290.4	57	100	
	E0009006	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					
		30JAN2003	3	1	0	1					
		31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	03FEB2003	7	3	0	3					
		04FEB2003	8	4	0	4					
		05FEB2003	9	4	0	4					
		06FEB2003	10	4	0	4					
		07FEB2003	11	4	0	4					
		08FEB2003	12	4	0	4					
		09FEB2003	13	4	0	4					PT. INADVERTENTLY TOOK MEDICATION FROM EXTRA DAYS ON 2/9/03 & 2/10/03
		10FEB2003	14	4	0	4					PT. INADVERTENTLY TOOK MEDICATION FROM EXTRA DAYS ON 2/9/03 & 2/10/03
		11FEB2003	15	4	0	4					PT. INADVERTENTLY TOOK EXTRA DAYS MEDICATION ON 2/9/03 AND 2/10/03
		12FEB2003	16	4	0	4					
		13FEB2003	17	4	0	4					
		14FEB2003	18	4	0	4					
		15FEB2003	19	4	0	4					
		16FEB2003	20	4	0	4					
		17FEB2003	21	4	0	4					
		18FEB2003	22	4	0	4					
		19FEB2003	23	4	0	4					
		20FEB2003	24	4	0	4					
		21FEB2003	25	4	0	4					
		22FEB2003	26	4	0	4					
		23FEB2003	27	4	0	4					
		24FEB2003	28	4	0	4					
		25FEB2003	29	4	0	4					
		26FEB2003	30	4	0	4					
		27FEB2003	31	4	0	4					
		28FEB2003	32	4	0	4					
		01MAR2003	33	4	0	4					
		02MAR2003	34	4	0	4					
		03MAR2003	35	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	04MAR2003	36	4	0	4					TOOK DOSE FROM EXTRA DAY
		05MAR2003	37	4	0	4					TOOK DOSE FROM EXTRA DAY
		06MAR2003	38	4	0	4					
		07MAR2003	39	4	0	4					
		08MAR2003	40	4	0	4					
		09MAR2003	41	4	0	4					
		10MAR2003	42	4	0	4					
		11MAR2003	43	4	0	4					DOSE TAKEN 3/4/03
		12MAR2003	44	4	0	4					DOSE TAKEN 3/5/03
		13MAR2003	45	4	0	4					
		14MAR2003	46	4	0	4					
		15MAR2003	47	4	0	4					
		16MAR2003	48	4	0	4					
		17MAR2003	49	4	0	4					
		18MAR2003	50	4	0	4					
		19MAR2003	51	4	0	4					
		20MAR2003	52	4	0	4					
		21MAR2003	53	4	0	4					
		22MAR2003	54	4	0	4					
		23MAR2003	55	4	0	4					
		24MAR2003	56	4	0	4	NO	290.2	56	100	
	E0009009	12MAR2003	1	2	0	2					
		13MAR2003	2	1	0	1					
		14MAR2003	3	1	0	1					
		15MAR2003	4	2	0	2					
		16MAR2003	5	3	0	3					
		17MAR2003	6	3	0	3					
		18MAR2003	7	3	0	3					
		19MAR2003	8	4	0	4					
		20MAR2003	9	4	0	4					
		21MAR2003	10	4	0	4					
		22MAR2003					NO	245	10	100	PT. DISCONTINUED DUE TO A.E. OF DROWSINESS ON 3/22/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	20FEB2003	1	2	0	2					
		21FEB2003	2	1	0	1					
		22FEB2003	3	1	0	1					
		23FEB2003	4	2	0	2					
		24FEB2003	5	3	0	3					
		25FEB2003	6	3	0	3					
		26FEB2003	7	3	0	3					
		27FEB2003	8	4	0	4					
		28FEB2003	9	4	0	4					
		01MAR2003	10	4	0	4					
		02MAR2003	11	4	0	4					
		03MAR2003	12	4	0	4					
		04MAR2003	13	4	0	4					
		05MAR2003	14	4	0	4					
		06MAR2003	15	4	0	4					
		07MAR2003	16	4	0	4					
		08MAR2003	17	4	0	4					
		09MAR2003	18	4	0	4					
		10MAR2003	19	4	0	4					
		11MAR2003	20	4	0	4					
		12MAR2003	21	4	0	4					
		13MAR2003	22	4	0	4					
		14MAR2003	23	4	0	4					
		15MAR2003	24	4	0	4					
		16MAR2003	25	4	0	4					
		17MAR2003	26	4	0	4					
		18MAR2003	27	4	0	4					
		19MAR2003	28	4	0	4					
		20MAR2003	29	4	0	4					
		21MAR2003	30	4	0	4					
		22MAR2003	31	4	0	4					
		23MAR2003	32	4	0	4					
		24MAR2003	33	4	0	4					
		25MAR2003	34	4	0	4					
		26MAR2003	35	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	27MAR2003	36	4	0	4					
		28MAR2003	37	4	0	4					
		29MAR2003	38	4	0	4					
		30MAR2003	39	4	0	4					
		31MAR2003	40	4	0	4					
		01APR2003	41	4	0	4					
		02APR2003	42	4	0	4					
		03APR2003	43	4	0	4					
		04APR2003	44	4	0	4					
		05APR2003	45	4	0	4					
		06APR2003	46	4	0	4					
		07APR2003	47	4	0	4					
		08APR2003	48	4	0	4					
		09APR2003	49	4	0	4					
		10APR2003	50	4	0	4					
		11APR2003	51	4	0	4					
		12APR2003	52	4	0	4					
		13APR2003	53	4	0	4					
		14APR2003	54	4	0	4					
		15APR2003					NO	289.8	54	100	SUBJECTS END OF STUDY VISIT WAS 15/APR/2003. THIS DOSE WAS MISSED.
	E0011004	24DEC2002	1	2	0	2					
		25DEC2002	2	1	0	1					
		26DEC2002	3	1	0	1					
		27DEC2002	4	2	0	2					
		28DEC2002	5	3	0	3					
		29DEC2002	6	3	0	3					
		30DEC2002	7	3	0	3					TOP HALF OF BLISTERCARD NOT RETURNED, MAY HAVE BEEN DISCARDED ACCIDENTALLY; SUBJECT TOOK ALL REQUIRED DOSAGES.
		31DEC2002	8	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	01JAN2003	9	4	0	4					
		02JAN2003	10	4	0	4					
		03JAN2003	11	4	0	4					
		04JAN2003	12	4	0	4					
		05JAN2003	13	4	0	4					
		06JAN2003	14	4	0	4					TOP HALF OF BLISTERCARD NOT RETURNED, MAY HAVE BEEN ACCIDENTALLY DISCARDED; SUBJECT TOOK ALL REQUIRED DOSES.
		07JAN2003	15	4	0	4					
		08JAN2003	16	4	0	4					
		09JAN2003	17	4	0	4					
		10JAN2003	18	4	0	4					
		11JAN2003	19	4	0	4					
		12JAN2003	20	4	0	4					
		13JAN2003	21	4	0	4					
		14JAN2003	22	4	0	4					
		15JAN2003	23	4	0	4					
		16JAN2003	24	4	0	4					
		17JAN2003	25	4	0	4					
		18JAN2003	26	4	0	4					
		19JAN2003	27	4	0	4					
		20JAN2003	28	4	0	4					
		21JAN2003	29	4	0	4					
		22JAN2003	30	4	0	4					
		23JAN2003	31	4	0	4					
		24JAN2003	32	4	0	4					
		25JAN2003	33	4	0	4					
		26JAN2003	34	4	0	4					
		27JAN2003	35	4	0	4					
		28JAN2003	36	4	0	4					
		29JAN2003	37	4	0	4					
		30JAN2003	38	4	0	4					
		31JAN2003	39	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	01FEB2003	40	4	0	4					
		02FEB2003	41	4	0	4					
		03FEB2003	42	4	0	4					
		04FEB2003	43	4	0	4					
		05FEB2003	44	4	0	4					
		06FEB2003	45	4	0	4					
		07FEB2003	46	4	0	4					
		08FEB2003	47	4	0	4					
		09FEB2003	48	4	0	4					
		10FEB2003	49	4	0	4					
		11FEB2003	50	4	0	4					
		12FEB2003	51	4	0	4					
		13FEB2003	52	4	0	4					
		14FEB2003	53	4	0	4					
		15FEB2003	54	4	0	4					
		16FEB2003	55	4	0	4					
		17FEB2003	56	4	0	4	NO	290.2	56	100	
	E0011007	19DEC2002	1	2	0	2					
		20DEC2002	2	1	0	1					
		21DEC2002	3	1	0	1					
		22DEC2002	4	2	0	2					
		23DEC2002	5	3	0	3					
		24DEC2002	6	3	0	3					
		25DEC2002	7	3	0	3					
		26DEC2002	8	4	0	4					
		27DEC2002	9	4	0	4					
		28DEC2002	10	4	0	4					
		29DEC2002	11	4	0	4					
		30DEC2002	12	4	0	4					
		31DEC2002	13	4	0	4					
		01JAN2003	14	4	0	4					
		02JAN2003	15	4	0	4					
		03JAN2003	16	4	0	4					
		04JAN2003	17	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	05JAN2003	18	4	0	4					
		06JAN2003	19	4	0	4					
		07JAN2003	20	4	0	4					
		08JAN2003	21	4	0	4					
		09JAN2003	22	4	0	4					
		10JAN2003	23	4	0	4					
		11JAN2003	24	4	0	4					
		12JAN2003	25	4	0	4					
		13JAN2003	26	4	0	4					
		14JAN2003	27	4	0	4					
		15JAN2003	28	4	0	4					
		16JAN2003	29		0	4					APPT RESCHEDULED FOR 1 DAY LATER BECAUSE OF INCLEMENT WEATHER
		17JAN2003	30	4	0	4					
		18JAN2003	31	4	0	4					
		19JAN2003	32	4	0	4					
		20JAN2003	33	4	0	4					
		21JAN2003	34	4	0	4					
		22JAN2003	35	4	0	4					
		23JAN2003	36	4	0	4					PATIENT PICKED UP BLISTERCARD ONE DAY EARLY. PATIENT HAS TAKEN DOSAGE EVERY DAY.
		24JAN2003	37	4	0	4					
		25JAN2003	38	4	0	4					
		26JAN2003	39	4	0	4					
		27JAN2003	40	4	0	4					
		28JAN2003	41	4	0	4					
		29JAN2003	42	4	0	4					
		30JAN2003	43	4	0	4					
		31JAN2003	44	4	0	4					
		01FEB2003	45	4	0	4					
		02FEB2003	46	4	0	4					
		03FEB2003	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	04FEB2003	48	4	0	4					
		05FEB2003	49	4	0	4					
		06FEB2003	50	4	0	4					
		07FEB2003	51	4	0	4					
		08FEB2003	52	4	0	4					
		09FEB2003	53	4	0	4					
		10FEB2003	54	4	0	4					
		11FEB2003	55	4	0	4					
		12FEB2003	56	4	0	4	NO	290.2	56	100	
	E0011018	22MAY2003	1	2	0	2					
		23MAY2003	2	1	0	1					
		24MAY2003	3	1	0	1					
		25MAY2003	4	2	0	2					
		26MAY2003	5	3	0	3					
		27MAY2003	6	3	0	3					
		28MAY2003	7	3	0	3					
		29MAY2003	8		4	0					PT FORGOT TO TAKE THIS DOSE. NO DOSE TAKEN ON 5-29-03
		30MAY2003	9	4	0	4					
		31MAY2003	10	4	0	4					
		01JUN2003	11	4	0	4					
		02JUN2003	12	4	0	4					
		03JUN2003	13	4	0	4					
		04JUN2003	14	4	0	4					
		05JUN2003	15	4	0	4					
		06JUN2003	16		0	4					SUBJECT DID NOT TAKE DOSES FOR 06-08-2003 AND 06-09-2003 SUBJECT HAD AN EXTENDED VISIT INTERVAL AND RAN OUT OF STUDY MEDICATION.
		07JUN2003	17		0	4					
		08JUN2003	18			0					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	09JUN2003	19			0					
		10JUN2003	20	4	1	3					DOSE REDUCTION BY 100MG (1 TAB)
		11JUN2003	21	4	1	3					
		12JUN2003	22	4	1	3					
		13JUN2003	23	4	1	3					DOSE REDUCTION BY 100MG (1 TAB) SUBJECT CAME IN FOR VISIT 5 ON 6-13-03. WHEN PT ARRIVED FOR THIS VISIT THE 6-13-2003 DOSE WAS MISSING. PT CAN NOT REMEMBER IF THIS DOSE WAS TAKEN OR MISPLACED
		14JUN2003	24	4	1	3					SIC DOSE REDUCTION BY 100MG (1 TAB)
		15JUN2003	25	4	1	3					PT CAME INTO OFFICE FOR VISIT 5 ON 6-13-03
		16JUN2003	26	4	1	3					
		17JUN2003	27	4	1	3					
		18JUN2003	28	4	1	3					
		19JUN2003	29	4	1	3					
		20JUN2003	30	4	0	4					PATIENT CAME IN FOR VISIT 6 ON 6-20-03
		20JUN2003	30	4	0	4					SUPPOSED TO BE A DOSE REDUCTION BUT PATIENT VOLUNTARILY TOOK ALL PILLS.
		21JUN2003	31	4	0	4					DUE TO 6-13-03 PILLS MISSING, PATIENT INSTRUCTED TO START DOSE 6-14-03.
		22JUN2003	32	4	0	4					
		23JUN2003	33	4	0	4					
		24JUN2003	34	4	0	4					
		25JUN2003	35	4	0	4					
		26JUN2003	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	27JUN2003	37		4	0					SUBJECT FORGOT TO TAKE DOSE ON 6-27-03
		28JUN2003	38	4	1	3					DOSE REDUCTION BY 100MG (1 TAB)
		29JUN2003	39	4	1	3					
		30JUN2003	40	4	1	3					
		01JUL2003	41	4	1	3					
		02JUL2003	42	4	1	3					
		03JUL2003	43	4	1	3					SUBJECT CAME IN FOR VISIT 8 ON 7-3-03
		03JUL2003	43	4	1	3					DOSE REDUCTION BY 100MG (1 TAB)
		04JUL2003	44	4	1	3					
		05JUL2003	45	4	1	3					
		06JUL2003	46	4	1	3					
		07JUL2003	47	4	1	3					
		08JUL2003	48	4	1	3					
		09JUL2003	49	4	1	3					
		10JUL2003	50	4	1	3					DOSE REDUCTION BY 100MG (1 TAB)
		11JUL2003	51	4	1	3					
		12JUL2003	52	4	1	3					
		13JUL2003	53	4	1	3					
		14JUL2003	54	4	1	3					
		15JUL2003	55	4	1	3					
		16JUL2003	56	4	1	3	YES	217	52	91.2	
	E0011024	24JUN2003	1	2	0	2					
		25JUN2003	2	1	0	1					
		26JUN2003	3	1	0	1					
		27JUN2003	4	2	0	2					
		28JUN2003	5	3	0	3					
		29JUN2003	6	3	0	3					
		30JUN2003	7	3	0	3					
		01JUL2003	8	4	0	4					
		02JUL2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	03JUL2003	10	4	0	4					
		04JUL2003	11	4	0	4					
		05JUL2003	12	4	0	4					
		06JUL2003	13	4	0	4					
		07JUL2003	14	4	0	4					
		08JUL2003	15	4	1	3					1 TAB PER DAY WAS REDUCED DUE TO REPORTED SEDATION, SO PATIENT TOOK 3 TAB PER DAY.
		09JUL2003	16	4	1	3					
		10JUL2003	17	4	1	3					
		11JUL2003	18	4	1	3					
		12JUL2003	19	4	1	3					
		13JUL2003	20	4	1	3					
		14JUL2003	21	4	1	3					
		15JUL2003	22	4	1	3					DOSE REDUCTION BY 1 TAB PER DAY.
		16JUL2003	23	4	1	3					
		17JUL2003	24	4	1	3					
		18JUL2003	25	4	1	3					
		19JUL2003	26	4	1	3					
		20JUL2003	27	4	1	3					
		21JUL2003	28	4	1	3					LOST 1 TAB FROM 2ND ROW. DOSE REDUCTION 1 TAB PER DAY
		22JUL2003	29	4	1	3					TOOK 1 TAB FROM 7/22/03 DOSE TO REPLACE TAB LOST ON 7/21/03.
		22JUL2003	29	4	1	3					DOSE REDUCTION 1 TAB PER DAY.
		23JUL2003	30	4	1	3					
		24JUL2003	31	4	1	3					
		25JUL2003	32	4	1	3					
		26JUL2003	33	4	1	3					
		27JUL2003	34	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	28JUL2003	35	4	1	3					
		29JUL2003	36		1	3					TOOK EXTRA DOSE DUE TO AN EXTENDED VISIT INTERVAL PERIOD. DOSE REDUCTION BY 1 TAB PER DAY.
		30JUL2003	37	4	1	3					DOSE REDUCTION 1 TAB PER DAY
		31JUL2003	38	4	1	3					
		01AUG2003	39	4	1	3					
		02AUG2003	40	4	1	3					
		03AUG2003	41	4	1	3					
		04AUG2003	42	4	1	3					
		05AUG2003	43	4	1	3					
		06AUG2003	44	4	1	3					VISIT WAS ON 8/5/03 BUT PATIENT HAD POPPED OUT DRUG FOR 8/5/03 FROM HER VISIT 7, WEEK 6 BLISTER CARD, SO THE VISIT WAS ON 8/5/03 BUT MEDICATION STARTED ON 8/6/03 WITH THIS BLISTER CARD.
		07AUG2003	45	4	1	3					DOSE REDUCTION 1 TAB PER DAY.
		08AUG2003	46	4	1	3					
		09AUG2003	47	4	1	3					
		10AUG2003	48	4	1	3					
		11AUG2003	49	4	1	3					
		12AUG2003	50	4	1	3					PATIENT DID NOT TAKE BECAUSE HAD VISIT ON 8/12/03
		12AUG2003	50	4	1	3					DOSE REDUCTION 1 TAB PER DAY
		13AUG2003	51	4	1	3					
		14AUG2003	52	4	1	3					
		15AUG2003	53	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	16AUG2003	54	4	1	3					
		17AUG2003	55	4	1	3					
		18AUG2003	56	4	1	3					
		19AUG2003	57		1	3					EXTRA DOSE TAKEN WITH REDUCTION OF 1 TAB PER DAY.
		20AUG2003	58		1	3	YES	214.7	58	100	
	E0015003	25NOV2002	1	2	0	2					
		26NOV2002	2	1	0	1					
		27NOV2002	3	1	0	1					
		28NOV2002	4	2	0	2					
		29NOV2002	5	3	0	3					
		30NOV2002	6	3	0	3					
		01DEC2002	7	3	0	3	NO	221.4	7	100	
	E0019003	21NOV2002	1	2	0	2					
		22NOV2002	2	1	0	1					
		23NOV2002	3	1	0	1					
		24NOV2002	4	2	0	2					
		25NOV2002	5	3	0	3					
		26NOV2002	6	3	0	3					
		27NOV2002	7	3	0	3					
		28NOV2002	8	4	0	8					MED TAKEN ON 2002/12/08
		28NOV2002	8	4	0	8					PT. MISSED DOSE ON 12/07/02
		29NOV2002	9	4	0	4					
		30NOV2002	10	4	0	4					
		01DEC2002	11	4	0	4					
		02DEC2002	12	4	0	4					
		03DEC2002	13	4	0	4					
		04DEC2002	14	4	0	4					
		05DEC2002	15		0	4					
		06DEC2002	16		0	4					
		07DEC2002	17			0					
		08DEC2002	18			0					
		09DEC2002	19	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	10DEC2002	20	4	0	4					
		11DEC2002	21	4	0	4					
		12DEC2002	22	4	0	4					
		13DEC2002	23	4	0	4					
		14DEC2002	24	4	0	4					
		15DEC2002	25	4	0	4					
		16DEC2002	26	4	0	4					
		17DEC2002	27	4	0	4					
		18DEC2002	28	4	0	4					
		19DEC2002	29	4	0	4					
		20DEC2002	30	4	0	4					
		21DEC2002	31	4	0	4					
		22DEC2002	32	4	0	4					
		23DEC2002	33		0	4					
		24DEC2002	34	4	0	4					
		25DEC2002	35	4	0	4					
		26DEC2002	36	4	0	4					
		27DEC2002	37	4	0	4					
		28DEC2002	38	4	0	4					
		29DEC2002	39	4	0	4					
		30DEC2002	40	4	0	4					
		31DEC2002	41	4	0	4					
		01JAN2003	42	4	0	4					
		02JAN2003	43	4	0	4					
		03JAN2003	44	4	0	4					
		04JAN2003	45	4	0	4					
		05JAN2003	46	4	0	4					
		06JAN2003	47	4	0	4					
		07JAN2003	48	4	0	4					
		08JAN2003	49	4	0	4					
		09JAN2003	50	4	0	4					
		10JAN2003	51	4	0	4					
		11JAN2003	52	4	0	4					
		12JAN2003	53	4	0	4					
		13JAN2003	54		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	14JAN2003	55	4	0	4					
		15JAN2003	56	4	0	4	NO	284.8	54	98.1	
	E0019007	13NOV2002	1	2	0	2					
		14NOV2002	2	1	0	1					
		15NOV2002	3	1	0	1					
		16NOV2002	4	2	0	2					
		17NOV2002	5	3	0	3					
		18NOV2002	6	3	0	3					
		19NOV2002	7	3	0	3					
		20NOV2002	8		0	4					
		21NOV2002	9	4	0	4					
		22NOV2002	10	4	0	4					
		23NOV2002	11	4	0	4					
		24NOV2002	12	4	0	4					
		25NOV2002	13	4	0	4					
		26NOV2002	14	4	0	4					
		27NOV2002	15	4	0	4					
		28NOV2002	16	4	0	4					
		29NOV2002	17	4	0	4					
		30NOV2002	18	4	0	4					
		01DEC2002	19	4	0	4					
		02DEC2002	20	4	0	4					
		03DEC2002	21	4	0	4					
		04DEC2002	22		0	4					
		05DEC2002	23	4	0	4					
		06DEC2002	24	4	0	4					
		07DEC2002	25	4	0	4					
		08DEC2002	26	4	0	4					
		09DEC2002	27	4	0	4					
		10DEC2002	28	4	0	4					
		11DEC2002	29	4	0	4					
		12DEC2002	30	4	0	4					
		13DEC2002	31	4	0	4					
		14DEC2002	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019007	15DEC2002	33	4	0	4					
		16DEC2002	34	4	0	4					
		17DEC2002	35	4	0	4					
		18DEC2002	36	4	0	4					
		19DEC2002	37	4	0	4					
		20DEC2002	38	4	0	4					
		21DEC2002	39	4	0	4					
		22DEC2002	40	4	0	4					
		23DEC2002	41	4	0	4					
		24DEC2002	42	4	0	4					
		25DEC2002	43	4	0	4					
		26DEC2002	44	4	0	4					
		27DEC2002	45	4	0	4					
		28DEC2002	46	4	0	4					
		29DEC2002	47	4	0	4					
		30DEC2002	48	4	0	4					
		31DEC2002	49	4	0	4					
		01JAN2003	50	4	0	4					
		02JAN2003	51	4	0	4					
		03JAN2003	52	4	0	4					
		04JAN2003	53	4	0	4					
		05JAN2003	54	4	0	4					
		06JAN2003	55		0	4	NO	290	55	100	
	E0019014	09JAN2003	1	2	0	2					
		10JAN2003	2	1	0	1					
		11JAN2003	3	1	0	1					
		12JAN2003	4	2	0	2					
		13JAN2003					NO	162.5	4	100	SUBJECT DID NOT DOSE DUE TO AE'S
	E0019018	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019018	03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8	4	0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4					
		12FEB2003	14	4	0	4					
		13FEB2003	15	4	0	4					
		14FEB2003	16	4	0	4					
		15FEB2003	17	4	0	4					
		16FEB2003	18	4	0	4					
		17FEB2003	19	4	0	4					
		18FEB2003	20	4	0	4					
		19FEB2003	21	4	0	4					
		20FEB2003	22	4	0	4					
		21FEB2003	23	4	0	4					
		22FEB2003	24	4	0	4					
		23FEB2003	25	4	0	4					
		24FEB2003	26	4	0	4					
		25FEB2003	27	4	0	4					
		26FEB2003	28	4	0	4					
		27FEB2003	29	4	0	4					
		28FEB2003	30	4	0	4					
		01MAR2003	31	4	0	4					
		02MAR2003	32	4	0	4					
		03MAR2003	33	4	0	4					
		04MAR2003	34	4	0	4					
		05MAR2003	35	4	0	4					
		06MAR2003	36	4	0	4					
		07MAR2003	37	4	0	4					
		08MAR2003	38	4	0	4					
		09MAR2003	39	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019018	10MAR2003	40	4	0	4					
		11MAR2003	41	4	0	4					
		12MAR2003	42	4	0	4					
		13MAR2003	43	4	0	4					
		14MAR2003	44	4	0	4					
		15MAR2003	45	4	0	4					
		16MAR2003	46	4	0	4					
		17MAR2003	47	4	0	4					
		18MAR2003	48	4	0	4					
		19MAR2003	49	4	0	4					
		20MAR2003	50	4	0	4					
		21MAR2003	51	4	0	4					
		22MAR2003	52	4	0	4					
		23MAR2003	53	4	0	4					
		24MAR2003	54	4	0	4					
		25MAR2003	55	4	0	4					
		26MAR2003	56	4	0	4	NO	290.2	56	100	
	E0019022	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8	4	0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4					
		12FEB2003	14	4	0	4					
		13FEB2003	15	4	0	4					
		14FEB2003	16	4	0	4					
		15FEB2003	17	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	16FEB2003	18	4	0	4					
		17FEB2003	19	4	0	4					
		18FEB2003	20	4	4	0					PATIENT TOOK MEDS OUT OF BLISTERCARD, BUT DID NOT TAKE MEDS.
		19FEB2003	21	4	0	4					
		20FEB2003	22	4	0	4					
		21FEB2003	23	4	0	4					
		22FEB2003	24	4	0	4					
		23FEB2003	25	4	0	4					
		24FEB2003	26	4	0	4					
		25FEB2003	27	4	0	4					
		26FEB2003	28	4	0	4					
		27FEB2003	29	4	0	4					
		28FEB2003	30	4	0	4					
		01MAR2003	31	4	0	4					
		02MAR2003	32	4	0	4					
		03MAR2003	33	4	0	4					
		04MAR2003	34	4	0	4					
		05MAR2003	35	4	0	4					
		06MAR2003	36	4	0	4					
		07MAR2003	37	4	0	4					
		08MAR2003	38	4	0	4					
		09MAR2003	39	4	0	4					
		10MAR2003	40	4	0	4					
		11MAR2003	41	4	0	4					
		12MAR2003	42	4	0	4					
		13MAR2003	43	4	0	4					
		14MAR2003	44	4	0	4					
		15MAR2003	45	4	0	4					
		16MAR2003	46	4	0	4					
		17MAR2003	47	4	0	4					
		18MAR2003	48	4	0	4					
		19MAR2003	49	4	0	4					
		20MAR2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	21MAR2003	51	4	0	4					
		22MAR2003	52	4	0	4					
		23MAR2003	53	4	0	4					
		24MAR2003	54	4	0	4					
		25MAR2003	55	4	0	4					
		26MAR2003	56	4	0	4	NO	284.8	55	98.1	
	E0019027	27FEB2003	1	2	0	2					
		28FEB2003	2	1	0	1					
		01MAR2003	3	1	0	1					
		02MAR2003					NO	116.7	3	100	PT. DISCONTINUED MEDICATION AFTER 3RD DOSE.
	E0019032	01APR2003	1	2	0	2					
		02APR2003	2	1	0	1					
		03APR2003	3	1	0	1					
		04APR2003	4	2	0	2					
		05APR2003	5	3	0	3					
		06APR2003	6	3	0	3					
		07APR2003	7	3	0	3					
		08APR2003	8	4	0	4					
		09APR2003	9	4	0	4					
		10APR2003	10	4	0	4					
		11APR2003	11	4	0	4					
		12APR2003	12	4	0	4					
		13APR2003	13	4	0	4					
		14APR2003	14	4	0	4					
		15APR2003	15	4	0	4					
		16APR2003	16	4	0	4					
		17APR2003	17	4	0	4					
		18APR2003	18	4	0	4					
		19APR2003	19	4	0	4					
		20APR2003	20	4	0	4					
		21APR2003	21	4	0	4					
		22APR2003	22	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	23APR2003	23	4	0	4					
		24APR2003	24	4	0	4					
		25APR2003	25	4	0	4					
		26APR2003	26	4	0	4					
		27APR2003	27	4	0	4					
		28APR2003	28		0	4					
		29APR2003	29	4	0	4					
		30APR2003	30	4	0	4					
		01MAY2003	31	4	0	4					
		02MAY2003	32	4	0	4					
		03MAY2003	33	4	0	4					
		04MAY2003	34	4	0	4					
		05MAY2003	35	4	0	4					
		06MAY2003	36		0	4					
		07MAY2003	37	4	0	4					
		08MAY2003	38	4	0	4					
		09MAY2003	39	4	0	4					
		10MAY2003	40	4	0	4					
		11MAY2003	41	4	0	4					
		12MAY2003	42	4	0	4					
		13MAY2003	43	4	0	4					
		14MAY2003	44	4	0	4					
		15MAY2003	45	4	0	4					
		16MAY2003	46	4	0	4					
		17MAY2003	47	4	0	4					
		18MAY2003	48	4	0	4					
		19MAY2003	49	4	0	4					
		20MAY2003	50	4	0	4					
		21MAY2003	51	4	0	4					
		22MAY2003	52	4	0	4					
		23MAY2003	53	4	0	4					
		24MAY2003	54	4	0	4					
		25MAY2003	55	4	0	4					
		26MAY2003	56	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	27MAY2003					NO	290.2	56	100	NO DRUG TAKEN 5/27/03 4 TABS RETURNED.
	E0019034	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					
		20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8	4	0	4					
		26MAR2003	9	4	0	4					
		27MAR2003	10	4	0	4					
		28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					BLISTER CARD NOT RETURNED
		02APR2003	16	4	0	4					
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	4					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	0	4					
		08APR2003	22		0	8	NO	288.6	22	105	UNKNOWN
	E0019036	25MAR2003	1	2	0	2					
		26MAR2003	2	1	0	1					
		27MAR2003	3	1	0	1					
		28MAR2003	4	2	0	2					
		29MAR2003	5	3	0	3					
		30MAR2003	6	3	0	3					
		31MAR2003	7	3	0	3					
		01APR2003	8	4	0	4					
		02APR2003	9	4	0	4					
		03APR2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019036	04APR2003	11	4	0	4					
		05APR2003	12	4	0	4					
		06APR2003	13	4	0	4					
		07APR2003	14	4	0	4					
		08APR2003	15		0	4					
		09APR2003	16		0	4					
		10APR2003	17	4	0	4					
		11APR2003	18	4	0	4					
		12APR2003	19	4	0	4					
		13APR2003	20	4	0	4					
		14APR2003	21	4	0	4					
		15APR2003	22	4	0	4					
		16APR2003	23	4	0	4					
		17APR2003	24	4	0	4					
		18APR2003	25	4	0	4					
		19APR2003	26	4	0	4					
		20APR2003	27	4	0	4					
		21APR2003	28	4	0	4					
		22APR2003	29	4	0	4					
		23APR2003	30	4	0	4					
		24APR2003	31	4	0	4					
		25APR2003	32	4	0	4					
		26APR2003	33	4	0	4					
		27APR2003	34	4	0	4					
		28APR2003	35	4	0	4					
		29APR2003	36	4	0	4					
		30APR2003	37	4	0	4					
		01MAY2003	38	4	0	4					
		02MAY2003	39	4	0	4					
		03MAY2003	40	4	0	4					
		04MAY2003	41	4	0	4					
		05MAY2003	42	4	0	4					
		06MAY2003	43		0	4					UNK. CARD NOT RETURNED
		07MAY2003	44		0	4	NO	287.5	44	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019039	01MAY2003	1	2	0	2					
		02MAY2003	2	1	0	1					
		03MAY2003	3	1	0	1					
		04MAY2003					NO	116.7	3	100	PT. DISCONTINUED MEDICATION DUE TO AES
	E0019041	21MAY2003	1	2	0	2					
		22MAY2003	2	1	0	1					
		23MAY2003	3	1	0	1					
		24MAY2003	4	2	0	2					
		25MAY2003	5	3	0	3					
		26MAY2003	6	3	0	3					
		27MAY2003	7	3	0	3					
		28MAY2003	8	4	0	4					
		29MAY2003	9	4	0	4					
		30MAY2003	10	4	0	4					
		31MAY2003	11	4	0	4					
		01JUN2003	12	4	0	4					
		02JUN2003	13	4	0	4					
		03JUN2003	14	4	0	4					
		04JUN2003	15	4	0	4					
		05JUN2003	16	4	0	4					
		06JUN2003	17	4	0	4					
		07JUN2003	18	4	0	4					
		08JUN2003	19	4	0	4					
		09JUN2003	20	4	0	4					
		10JUN2003	21	4	0	4					
		11JUN2003	22		0	4					
		12JUN2003	23	4	0	4					
		13JUN2003	24	4	0	4					
		14JUN2003	25	4	0	4					
		15JUN2003	26	4	0	4					
		16JUN2003	27	4	0	4					
		17JUN2003	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	18JUN2003	29	4	0	4					SUBJECT CAME IN FOR VISIT 6 ON 6/18/03 (ONE DAY EARLY) THEREFORE DID NOT DOSE (DAY 7) OF (WEEKLY) BLISTER CARD.
		19JUN2003	30	4	0	4					
		20JUN2003	31	4	0	4					
		21JUN2003	32	4	0	4					
		22JUN2003	33	4	0	4					
		23JUN2003	34	4	0	4					
		24JUN2003	35	4	0	4					
		25JUN2003	36	4	0	4					
		26JUN2003	37	4	0	4					
		27JUN2003	38	4	0	4					
		28JUN2003	39	4	0	4					
		29JUN2003	40	4	0	4					
		30JUN2003	41	4	0	4					
		01JUL2003	42	4	0	4					
		02JUL2003	43	4	0	4					
		03JUL2003	44	4	0	4					
		04JUL2003	45	4	0	4					
		05JUL2003	46	4	0	4					
		06JUL2003	47	4	0	4					
		07JUL2003	48	4	0	4					
		08JUL2003	49	4	0	4					
		09JUL2003	50	4	0	4					
		10JUL2003	51	4	0	4					
		11JUL2003	52	4	0	4					
		12JUL2003	53	4	0	4					
		13JUL2003	54	4	0	4					
		14JUL2003	55	4	0	4					
		15JUL2003					NO	290	55	100	SUBJECT MISSED DOSE ON 7/15/03
	E0019049	10JUL2003	1	2	0	2					BLISTER CARD RETURNED 7/24/03
		11JUL2003	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	12JUL2003	3	1	0	1					
		13JUL2003	4	2	0	2					
		14JUL2003	5	3	0	3					
		15JUL2003	6	3	0	3					
		16JUL2003	7	3	0	3					
		17JUL2003	8	4	0	4					
		18JUL2003	9	4	0	4					
		19JUL2003	10	4	4	0					SUBJECT FORGOT DOSE
		20JUL2003	11	4	0	4					
		21JUL2003	12	4	0	4					
		22JUL2003	13	4	0	4					
		23JUL2003	14	4	0	4					
		24JUL2003	15	4	0	4					
		25JUL2003	16	4	0	4					
		26JUL2003	17	4	0	4					
		27JUL2003	18	4	0	4					
		28JUL2003	19	4	0	4					
		29JUL2003	20	4	0	4					
		30JUL2003	21	4	0	4					
		31JUL2003	22	4	0	4					
		01AUG2003	23	4	0	4					
		02AUG2003	24	4	0	4					
		03AUG2003	25	4	0	4					
		04AUG2003	26	4	0	4					
		05AUG2003	27	4	0	4					
		06AUG2003	28	4	0	4					
		07AUG2003	29	4	0	4					
		08AUG2003	30	4	0	4					
		09AUG2003	31	4	0	4					
		10AUG2003	32	4	0	4					
		11AUG2003	33	4	0	4					
		12AUG2003	34	4	0	4					
		13AUG2003	35	4	0	4					
		14AUG2003	36	4	0	4					TOOK ON 8/23/03 MISSED DOSE ON 8/14/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	15AUG2003	37	4	0	4					
		16AUG2003	38	4	0	4					
		17AUG2003	39	4	0	4					SUBJECT HAD TO LEAVE TOWN ON FAMILY EMERGENCY - COULD NOT COME IN FOR VISIT 8 UNTIL 8/26/03.
		18AUG2003	40	4	0	4					
		19AUG2003	41	4	0	4					
		20AUG2003	42	4	0	4					
		21AUG2003	43		0	4					
		22AUG2003	44		0	4					
		23AUG2003	45			0					
		24AUG2003	46			0					
		25AUG2003	47			0					
		26AUG2003	48	4	0	4					BLISTER CARD NOT RETURNED SUBJECT REPORTS MISSING DOSES (DATES UNKNOWN)
		27AUG2003	49	4	0	4					
		28AUG2003	50	4	0	4					
		29AUG2003	51	4	0	4					
		30AUG2003	52	4	0	4					
		31AUG2003	53	4	0	4					
		01SEP2003	54	4	0	4					
		02SEP2003	55		0	4					
		03SEP2003	56		0	4	NO	268.8	52	92.4	SUBJECT REPORTS TAKING ON 9/5/2003
	E0022052	10APR2003	1	2	0	2					
		11APR2003	2	1	0	1					
		12APR2003	3	1	0	1					
		13APR2003	4	2	0	2					
		14APR2003	5	3	0	3					
		15APR2003	6	3	0	3					
		16APR2003	7	3	0	3					
		17APR2003	8	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	18APR2003	9	4	0	4					
		19APR2003	10	4	0	4					
		20APR2003	11	4	0	4					
		21APR2003	12	4	0	4					
		22APR2003	13	4	0	4					
		23APR2003	14	4	0	4					
		24APR2003	15	4	0	4					
		25APR2003	16	4	0	4					
		26APR2003	17	4	0	4					
		27APR2003	18	4	0	4					
		28APR2003	19	4	0	4					
		29APR2003	20	4	0	4					
		30APR2003	21	4	0	4					
		01MAY2003	22	4	0	4					
		02MAY2003	23	4	0	4					
		03MAY2003	24	4	0	4					
		04MAY2003	25	4	0	4					
		05MAY2003	26	4	0	4					
		06MAY2003	27	4	0	4					
		07MAY2003	28	4	0	4					
		08MAY2003	29	4	0	4					
		09MAY2003	30	4	0	4					
		10MAY2003	31	4	0	4					
		11MAY2003	32	4	0	4					
		12MAY2003	33	4	0	4					
		13MAY2003	34	4	0	4					
		14MAY2003	35	4	0	4					
		15MAY2003	36	4	0	4					
		16MAY2003	37	4	0	4					
		17MAY2003	38	4	0	4					
		18MAY2003	39	4	0	4					
		19MAY2003	40	4	0	4					
		20MAY2003	41	4	0	4					
		21MAY2003	42	4	0	4					
		22MAY2003	43	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	23MAY2003	44	4	0	4					
		24MAY2003	45	4	0	4					
		25MAY2003	46	4	0	4					
		26MAY2003	47	4	0	4					
		27MAY2003	48	4	0	4					
		28MAY2003	49	4	0	4					
		29MAY2003	50	4	0	4					
		30MAY2003	51	4	0	4					
		31MAY2003	52	4	0	4					
		01JUN2003	53	4	0	4					
		02JUN2003	54	4	0	4					
		03JUN2003	55	4	0	4					LOST 1 TAB, TOOK EXTRA
		04JUN2003	56	4	0	4					
		05JUN2003					NO	290.2	56	100	EXTRA TAB TAKEN 6-3-03
	E0022064	06MAY2003	1	2	0	2					
		07MAY2003	2	1	0	1					
		08MAY2003	3	1	0	1					
		09MAY2003	4	2	0	2					
		10MAY2003	5	3	0	3					
		11MAY2003	6	3	0	3					
		12MAY2003	7	3	0	3					
		13MAY2003	8	4	0	4					
		14MAY2003	9	4	0	4					
		15MAY2003	10	4	0	4					
		16MAY2003	11	4	0	4					
		17MAY2003	12	4	0	4					
		18MAY2003	13	4	0	4					
		19MAY2003	14	4	0	4					
		20MAY2003	15	4	0	4					
		21MAY2003	16	4	0	4					
		22MAY2003	17	4	0	4					
		23MAY2003	18	4	0	4					
		24MAY2003	19	4	0	4					
		25MAY2003	20	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	26MAY2003	21	4	0	4					
		27MAY2003	22	4	0	4					
		28MAY2003	23	4	0	4					
		29MAY2003	24	4	0	4					
		30MAY2003	25	4	0	4					
		31MAY2003	26	4	4	0					PT. LOST PILLS - MISSED DOSE
		01JUN2003	27	4	0	4					
		02JUN2003	28	4	4	0					PATIENT MISSED DOSE
		03JUN2003	29	4	0	4					
		04JUN2003	30	4	0	4					
		05JUN2003	31	4	0	4					
		06JUN2003	32	4	0	4					
		07JUN2003	33	4	0	4					
		08JUN2003	34	4	0	4					
		09JUN2003	35	4	0	4					
		10JUN2003	36	4	0	4					
		11JUN2003	37	4	0	4					
		12JUN2003	38	4	0	4					
		13JUN2003	39	4	0	4					
		14JUN2003	40	4	0	4					
		15JUN2003	41	4	0	4					
		16JUN2003	42	4	0	4					
		17JUN2003	43	4	0	4					
		18JUN2003	44	4	0	4					
		19JUN2003	45	4	0	4					
		20JUN2003	46	4	0	4					
		21JUN2003	47	4	0	4					
		22JUN2003	48	4	0	4					
		23JUN2003	49	4	0	4					
		24JUN2003	50	4	0	4					PT. TOOK FROM EXTRA DAY
		25JUN2003	51	4	0	4					PT. TOOK FROM EXTRA DAY
		26JUN2003	52	4	0	4					
		27JUN2003	53	4	0	4					
		28JUN2003	54	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	29JUN2003	55	4	0	4					
		30JUN2003	56	4	0	4					
		01JUL2003									PT. TOOK 6 - 24
		02JUL2003					NO	279.5	54	96.2	PT. TOOK 6 - 25
	E0022073	26JUN2003	1	2	0	2					
		27JUN2003	2	1	0	1					
		28JUN2003	3	1	0	1					
		29JUN2003	4	2	0	2					
		30JUN2003	5	3	0	3					
		01JUL2003	6	3	0	3					
		02JUL2003	7	3	0	3					
		03JUL2003	8	4	0	4					
		04JUL2003	9	4	0	4					
		05JUL2003	10	4	0	4					
		06JUL2003	11	4	0	4					
		07JUL2003	12	4	0	4					
		08JUL2003	13	4	0	4					
		09JUL2003	14	4	0	4					
		10JUL2003	15	4	0	4					
		11JUL2003	16	4	0	4					
		12JUL2003	17	4	0	4					
		13JUL2003	18	4	0	4					
		14JUL2003	19	4	0	4					
		15JUL2003	20	4	0	4					
		16JUL2003	21	4	0	4					
		17JUL2003	22	4	0	4					
		18JUL2003	23	4	0	4					
		19JUL2003	24	4	0	4					
		20JUL2003	25	4	0	4					
		21JUL2003	26	4	0	4					
		22JUL2003	27	4	0	4					
		23JUL2003	28	4	0	4					
		24JUL2003	29	4	0	4					
		25JUL2003	30	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0022073	26JUL2003	31	4	0	4					
		27JUL2003	32	4	0	4					
		28JUL2003	33	4	0	4					
		29JUL2003	34	4	0	4					
		30JUL2003	35	4	0	4					
		31JUL2003	36	4	0	4					
		01AUG2003	37	4	0	4					
		02AUG2003	38	4	0	4					
		03AUG2003	39	4	0	4					
		04AUG2003	40	4	0	4					
		05AUG2003	41	4	0	4					
		06AUG2003	42	4	0	4					
		07AUG2003	43	4	0	4					
		08AUG2003	44	4	0	4					
		09AUG2003	45	4	0	4					
		10AUG2003	46	4	0	4					
		11AUG2003	47	4	0	4					
		12AUG2003	48	4	0	4					
		13AUG2003	49	4	0	4					
		14AUG2003	50	4	0	4					
		15AUG2003	51	4	0	4					
		16AUG2003	52	4	0	4					
		17AUG2003	53	4	0	4					
		18AUG2003	54	4	0	4					
		19AUG2003	55	4	0	4					
		20AUG2003	56	4	0	4	NO	290.2	56	100	
	E0023002	05NOV2002	1	2	0	2					
		06NOV2002	2	1	0	1					
		07NOV2002	3	1	0	1					
		08NOV2002	4	2	0	2					
		09NOV2002	5	3	0	3					
		10NOV2002	6	3	0	3					
		11NOV2002	7	3	0	3					
		12NOV2002	8	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	13NOV2002	9	4	0	4					
		14NOV2002	10	4	0	4					
		15NOV2002	11	4	0	4					
		16NOV2002	12	4	0	4					
		17NOV2002	13	4	0	4					
		18NOV2002	14	4	0	4					
		19NOV2002	15	4	0	4					
		20NOV2002	16	4	0	4					
		21NOV2002	17	4	1	3					DOSE REDUCED
		22NOV2002	18	4	1	3					DOSE REDUCED
		23NOV2002	19	4	1	3					DOSE REDUCED
		24NOV2002	20	4	4	0					MISSED DOSING
		25NOV2002	21	4	1	3					DOSE REDUCED
		26NOV2002	22	4	1	3					REDUCED DOSE
		27NOV2002	23	4	1	3					REDUCED DOSE
		28NOV2002	24	4	1	3					REDUCED DOSE
		29NOV2002	25	4	1	3					REDUCED DOSE
		30NOV2002	26	4	1	3					REDUCED DOSE
		01DEC2002	27	4	1	3					REDUCED DOSE
		02DEC2002	28	4	1	3					REDUCED DOSE
		03DEC2002	29	4	1	3					REDUCED DOSE
		04DEC2002	30	4	1	3					REDUCED DOSE
		05DEC2002	31	4	4	0					SKIPPED DOSING
		06DEC2002	32	4	4	0					SKIPPED DOSING
		07DEC2002	33	4	1	3					REDUCED DOSING
		08DEC2002									PT STOPPED DOSING
		09DEC2002					YES	213.6	30	88.6	STOPPED DOSING
	E0023017	25MAR2003	1	2	0	2					
		26MAR2003	2	1	0	1					
		27MAR2003	3	1	0	1					
		28MAR2003	4	2	0	2					
		29MAR2003	5	3	0	3					
		30MAR2003	6	3	0	3					
		31MAR2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	01APR2003	8		0	4					
		02APR2003	9		0	4					
		03APR2003	10	4	0	4					
		04APR2003	11	4	0	4					
		05APR2003	12	4	0	4					
		06APR2003	13	4	0	4					
		07APR2003	14	4	0	4					
		08APR2003	15	4	0	4					
		09APR2003	16	4	0	4					
		10APR2003	17	4	0	4					
		11APR2003	18	4	0	4					
		12APR2003	19	4	0	4					
		13APR2003	20	4	0	4					
		14APR2003	21	4	0	4					
		15APR2003	22	4	0	4					
		16APR2003	23	4	0	4					
		17APR2003	24		0	4					
		18APR2003	25	4	0	4					
		19APR2003	26	4	0	4					
		20APR2003	27	4	0	4					
		21APR2003	28	4	0	4					
		22APR2003	29	4	0	4					
		23APR2003	30	4	0	4					
		24APR2003	31	4	0	4					
		25APR2003	32	4	0	4					
		26APR2003	33	4	0	4					
		27APR2003	34	4	0	4					
		28APR2003	35	4	0	4					
		29APR2003	36	4	0	4					
		30APR2003	37	4	0	4					
		01MAY2003	38	4	1	3					DOSE REDUCED
		02MAY2003	39	4	1	3					
		03MAY2003	40	4	1	3					
		04MAY2003	41	4	1	3					
		05MAY2003	42	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	06MAY2003	43	4	1	3					
		07MAY2003	44	4	1	3					
		08MAY2003	45	4	1	3					
		09MAY2003	46	4	1	3					
		10MAY2003	47	4	1	3					
		11MAY2003	48	4	1	3					
		12MAY2003	49	4	1	3					
		13MAY2003	50	4	1	3					
		14MAY2003	51	4	1	3					
		15MAY2003	52	4	1	3					
		16MAY2003	53	4	1	3					
		17MAY2003	54	4	1	3					
		18MAY2003	55	4	1	3					
		19MAY2003	56	4	1	3					
		20MAY2003	57	4	1	3					
		21MAY2003	58	4	1	3	YES	254.3	58	100	
	E0023021	23APR2003	1	2	0	2					
		24APR2003	2	1	0	1					
		25APR2003	3	1	0	1					
		26APR2003	4	2	0	2					
		27APR2003	5	3	0	3					
		28APR2003	6	3	0	3					
		29APR2003	7	3	0	3					
		30APR2003	8	4	0	4					
		01MAY2003	9	4	0	4					
		02MAY2003	10	4	0	4					
		03MAY2003	11	4	0	4					
		04MAY2003	12	4	0	4					
		05MAY2003	13	4	0	4					
		06MAY2003	14	4	0	4					
		07MAY2003	15	4	0	4					
		08MAY2003	16	4	0	4					
		09MAY2003	17	4	0	4					
		10MAY2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	11MAY2003	19	4	0	4					
		12MAY2003	20	4	0	4					
		13MAY2003	21	4	0	4					
		14MAY2003	22	4	0	4					
		15MAY2003	23	4	0	4					
		16MAY2003	24	4	0	4					
		17MAY2003	25	4	0	4					
		18MAY2003	26	4	0	4					
		19MAY2003	27	4	0	4					
		20MAY2003	28	4	0	4					
		21MAY2003	29	4	0	4					
		22MAY2003	30	4	0	4					
		23MAY2003	31	4	0	4					
		24MAY2003	32	4	0	4					
		25MAY2003	33	4	0	4					
		26MAY2003	34	4	0	4					
		27MAY2003	35		0	4					
		28MAY2003	36		0	4					
		29MAY2003	37	4	0	4					
		30MAY2003	38	4	0	4					
		31MAY2003	39	4	0	4					
		01JUN2003	40	4	0	4					
		02JUN2003	41	4	0	4					
		03JUN2003	42	4	0	4					
		04JUN2003	43	4	0	4					
		05JUN2003	44	4	0	4					
		06JUN2003	45	4	0	4					
		07JUN2003	46	4	0	4					
		08JUN2003	47	4	0	4					
		09JUN2003	48	4	0	4					
		10JUN2003	49	4	0	4					
		11JUN2003	50	4	0	4					
		12JUN2003	51	4	0	4					
		13JUN2003	52	4	0	4					
		14JUN2003	53	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	15JUN2003	54	4	0	4					
		16JUN2003	55	4	0	4	NO	290	55	100	
	E0023027	16MAY2003	1	2	0	2					
		17MAY2003	2	1	0	1					
		18MAY2003	3	1	0	1					
		19MAY2003	4	2	0	2					
		20MAY2003	5	3	0	3					
		21MAY2003	6	3	0	3					
		22MAY2003	7	3	0	3					
		23MAY2003	8	4	0	4					
		24MAY2003	9	4	0	4					
		25MAY2003	10	4	0	4					
		26MAY2003	11	4	0	4					
		27MAY2003	12	4	0	4					
		28MAY2003	13	4	0	4					
		29MAY2003	14	4	0	4					
		30MAY2003	15	4	1	3					REDUCED DOSE
		31MAY2003	16	4	1	3					
		01JUN2003	17	4	1	3					
		02JUN2003	18	4	1	3					
		03JUN2003	19	4	1	3					
		04JUN2003	20	4	1	3					
		05JUN2003	21	4	1	3					
		06JUN2003	22	4	1	3					
		07JUN2003	23	4	1	3					
		08JUN2003	24	4	1	3					
		09JUN2003	25	4	1	3					
		10JUN2003	26	4	1	3					
		11JUN2003	27	4	1	3					
		12JUN2003	28	4	1	3					
		13JUN2003	29	4	1	3					
		14JUN2003	30	4	1	3					
		15JUN2003	31	4	1	3					
		16JUN2003	32	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	17JUN2003	33	4	1	3					
		18JUN2003	34	4	1	3					
		19JUN2003	35	4	1	3					
		20JUN2003	36	4	1	3					
		21JUN2003	37	4	1	3					
		22JUN2003	38	4	1	3					
		23JUN2003	39	4	1	3					
		24JUN2003	40	4	1	3					
		25JUN2003	41		1	3					
		26JUN2003	42		1	3					
		27JUN2003	43	4	1	3					
		28JUN2003	44	4	1	3					
		29JUN2003	45	4	1	3					
		30JUN2003	46	4	1	3					
		01JUL2003	47	4	1	3					
		02JUL2003	48	4	1	3					
		03JUL2003	49	4	1	3					
		04JUL2003	50	4	1	3					
		05JUL2003	51	4	1	3					
		06JUL2003	52	4	1	3					
		07JUL2003	53	4	1	3					
		08JUL2003	54	4	1	3	YES	215.7	54	100	
	E0023030	03JUN2003	1	2	0	2					
		04JUN2003	2	1	0	1					
		05JUN2003	3	1	0	1					
		06JUN2003	4	2	0	2					
		07JUN2003	5	3	0	3					
		08JUN2003	6	3	0	3					
		09JUN2003	7	3	0	3					
		10JUN2003	8	4	0	4					
		11JUN2003	9	4	0	4					
		12JUN2003	10	4	0	4					
		13JUN2003	11	4	0	4					
		14JUN2003	12	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	15JUN2003	13	4	0	4					
		16JUN2003	14	4	0	4					
		17JUN2003	15	4	0	4					
		18JUN2003	16	4	0	4					
		19JUN2003	17	4	0	4					
		20JUN2003	18	4	0	4					
		21JUN2003	19	4	0	4					
		22JUN2003	20	4	0	4					
		23JUN2003	21	4	0	4					
		24JUN2003	22	4	0	4					
		25JUN2003	23	4	0	4					
		26JUN2003	24	4	0	4					
		27JUN2003	25	4	0	4					
		28JUN2003	26	4	0	4					
		29JUN2003	27	4	0	4					
		30JUN2003	28	4	0	4					
		01JUL2003	29	4	0	4					
		02JUL2003	30	4	0	4					
		03JUL2003	31	4	0	4					
		04JUL2003	32	4	0	4					
		05JUL2003	33	4	0	4					
		06JUL2003	34	4	0	4					
		07JUL2003	35	4	0	4					
		08JUL2003	36	4	0	4					
		09JUL2003	37	4	0	4					
		10JUL2003	38	4	0	4					
		11JUL2003	39	4	0	4					
		12JUL2003	40	4	0	4					
		13JUL2003	41	4	0	4					
		14JUL2003	42	4	0	4					
		15JUL2003	43	4	0	4					
		16JUL2003	44	4	0	4					
		17JUL2003	45	4	0	4					
		18JUL2003	46	4	0	4					
		19JUL2003	47	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	20JUL2003	48	4	0	4					
		21JUL2003	49	4	0	4					
		22JUL2003	50	4	0	4					
		23JUL2003	51	4	0	4					
		24JUL2003	52	4	0	4					
		25JUL2003	53	4	0	4					
		26JUL2003	54	4	0	4					
		27JUL2003	55	4	0	4					
		28JUL2003	56		0	4					
		29JUL2003	57		0	4	NO	290.4	57	100	
	E0023040	03JUL2003	1	2	0	2					
		04JUL2003	2	1	0	1					
		05JUL2003	3	1	0	1					
		06JUL2003	4	2	0	2					
		07JUL2003	5	3	0	3					
		08JUL2003	6	3	0	3					
		09JUL2003	7	3	0	3					
		10JUL2003	8		0	4					
		11JUL2003	9		0	4					
		12JUL2003	10	4	0	4					
		13JUL2003	11	4	0	4					
		14JUL2003	12	4	0	4					
		15JUL2003	13	4	0	4					
		16JUL2003	14	4	0	4					
		17JUL2003	15	4	0	4					VISIT 4 DATE
		18JUL2003	16	4	0	4					
		19JUL2003	17	4	0	4					
		20JUL2003	18	4	0	4					
		21JUL2003	19	4	0	4					
		22JUL2003	20	4	0	4					
		23JUL2003	21	4	0	4					
		24JUL2003	22		4	0					MISSED DOSE
		25JUL2003	23	4	0	4					
		26JUL2003	24	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023040	27JUL2003	25	4	0	4					
		28JUL2003	26	4	0	4					
		29JUL2003	27	4	0	4					
		30JUL2003	28	4	0	4					
		31JUL2003	29	4	0	4					
		01AUG2003	30		0	4					
		02AUG2003	31		0	4					
		03AUG2003	32			0					
		04AUG2003	33			0					
		05AUG2003	34	4	0	4					MISSED DOSE 8/3/03 & 8/4/03
		06AUG2003	35	4	0	4					
		07AUG2003	36	4	0	4					
		08AUG2003	37	4	0	4					VISIT 6 DATE
		09AUG2003	38	4	0	4					
		10AUG2003	39	4	0	4					
		11AUG2003	40	4	0	4					
		12AUG2003	41	4	0	4					
		13AUG2003	42	4	0	4					
		14AUG2003	43	4	0	4					
		15AUG2003	44		0	4					
		16AUG2003	45		0	4					
		17AUG2003	46			0					
		18AUG2003	47	4	0	4					MISSED DOSE ON 8-17-03
		19AUG2003	48	4	0	4					
		20AUG2003	49	4	0	4					
		21AUG2003	50	4	0	4					
		22AUG2003	51	4	0	4					
		23AUG2003	52	4	0	4					
		24AUG2003	53	4	0	4					
		25AUG2003	54		0	4					
		26AUG2003	55		0	4					
		27AUG2003	56			0					
		28AUG2003	57	4	0	4					MISSED DOSE 8-27-03
		29AUG2003	58	4	0	4					
		30AUG2003	59	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0023040	31AUG2003	60	4	0	4					
		01SEP2003	61	4	0	4					
		02SEP2003	62	4	0	4					
		03SEP2003	63	4	0	4					
		04SEP2003	64		0	4	NO	268	59	91.8	
	E0026014	19FEB2003	1	2	0	2					
		20FEB2003	2	1	0	1					
		21FEB2003	3	1	0	1					
		22FEB2003	4	2	0	2					
		23FEB2003	5	3	0	3					
		24FEB2003	6	3	0	3					
		25FEB2003	7	3	0	3					
		26FEB2003	8	4	0	4					
		27FEB2003	9	4	0	4					
		28FEB2003	10	4	0	4					
		01MAR2003	11	4	0	4					
		02MAR2003	12	4	0	4					
		03MAR2003	13	4	0	4					
		04MAR2003	14	4	0	4					
		05MAR2003	15	4	0	4					
		06MAR2003	16	4	0	4					
		07MAR2003	17	4	0	4					
		08MAR2003	18	4	0	4					
		09MAR2003	19	4	0	4					
		10MAR2003	20	4	0	4					
		11MAR2003	21	4	0	4					
		12MAR2003	22	4	0	4					
		13MAR2003	23	4	0	4					
		14MAR2003	24	4	0	4					
		15MAR2003	25	4	0	4					
		16MAR2003	26	4	0	4					
		17MAR2003	27	4	0	4					
		18MAR2003	28	4	0	4	NO	280.4	28	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0026019	17MAR2003	1	2	0	2					
		18MAR2003	2	1	0	1					
		19MAR2003	3	1	0	1					
		20MAR2003	4	2	0	2					
		21MAR2003	5	3	0	3					
		22MAR2003	6	3	0	3					
		23MAR2003	7	3	0	3					
		24MAR2003	8	4	0	6					DUE TO OVERSIGHT, PT TOOK 2 PILLS EXTRA 3-23-03
		25MAR2003	9	4	0	4					
		26MAR2003	10	4	0	4					
		27MAR2003	11	4	0	4					
		28MAR2003	12	4	0	4					
		29MAR2003	13	4	0	4					
		30MAR2003	14	4	0	4					
		31MAR2003	15	4	0	4					
		01APR2003	16	4	0	4					
		02APR2003	17	4	0	4					
		03APR2003	18	4	0	4					
		04APR2003	19	4	0	4					
		05APR2003	20	4	0	4					
		06APR2003	21	4	0	4					
		07APR2003	22	4	0	4					
		08APR2003	23	4	0	4					
		09APR2003	24	4	0	4					
		10APR2003	25	4	0	4					
		11APR2003	26	4	0	4					
		12APR2003	27	4	0	4					
		13APR2003	28	4	0	4					
		14APR2003	29	4	0	7					PT TOOK 3 EXTRA DOSES DUE TO OVERSIGHT
		15APR2003	30	4	0	4					
		16APR2003	31	4	0	4					
		17APR2003	32	4	0	4					
		18APR2003	33	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0026019	19APR2003	34	4	0	4					
		20APR2003	35	4	0	4					
		21APR2003	36	4	0	4					
		22APR2003	37	4	0	4					
		23APR2003	38	4	0	4					
		24APR2003	39	4	0	4					
		25APR2003	40	4	0	4					
		26APR2003	41	4	0	4					
		27APR2003	42	4	0	4					
		28APR2003	43	4	0	4					
		29APR2003	44	4	0	4					
		30APR2003	45	4	0	4					
		01MAY2003	46	4	0	4					
		02MAY2003	47	4	0	4					
		03MAY2003	48	4	0	4					
		04MAY2003	49	4	0	4					
		05MAY2003	50	4	0	4					
		06MAY2003	51	4	0	4					
		07MAY2003	52	4	0	4					
		08MAY2003	53	4	0	4					
		09MAY2003	54	4	0	4					
		10MAY2003	55	4	0	4					
		11MAY2003	56	4	0	4					
		12MAY2003	57		3	1	NO	286.8	57	101	PT LOST ONE PILL.
	E0027005	26DEC2002	1	2	0	2					
		27DEC2002	2	1	0	1					
		28DEC2002	3	1	0	1					
		29DEC2002	4	2	0	2					
		30DEC2002	5	3	0	3					
		31DEC2002	6	3	0	3					
		01JAN2003	7	3	0	3					
		02JAN2003	8	4	0	4					
		03JAN2003	9	4	0	4					
		04JAN2003	10	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0027005	05JAN2003	11	4	0	4					
		06JAN2003	12	4	0	4					
		07JAN2003	13	4	0	4					
		08JAN2003	14	4	0	4					
		09JAN2003	15	4	0	4					
		10JAN2003	16	4	0	4					
		11JAN2003	17	4	0	4					
		12JAN2003	18	4	0	4					
		13JAN2003	19	4	0	4					
		14JAN2003	20	4	0	4					
		15JAN2003	21	4	0	4					
		16JAN2003	22	4	0	4					
		17JAN2003	23	4	0	4					
		18JAN2003	24	4	0	4					
		19JAN2003	25	4	0	4					
		20JAN2003	26	4	0	4					
		21JAN2003	27	4	0	4					
		22JAN2003	28	4	0	4					
		23JAN2003	29	4	0	4					
		24JAN2003	30	4	0	4					
		25JAN2003	31	4	0	4					
		26JAN2003	32	4	0	4					
		27JAN2003	33	4	0	4					
		28JAN2003	34	4	0	4					
		29JAN2003	35	4	0	4					
		30JAN2003	36	4	0	4					
		31JAN2003	37	4	0	4					
		01FEB2003	38	4	0	4					
		02FEB2003	39	4	0	4					
		03FEB2003	40	4	0	4					
		04FEB2003	41	4	0	4					
		05FEB2003	42	4	0	4					
		06FEB2003	43	4	0	4					
		07FEB2003	44	4	0	4					
		08FEB2003	45	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0027005	09FEB2003	46	4	0	4					
		10FEB2003	47	4	0	4					
		11FEB2003	48	4	0	4					
		12FEB2003	49	4	0	4					
		13FEB2003	50	4	0	4					
		14FEB2003	51	4	0	4					
		15FEB2003	52	4	0	4					
		16FEB2003	53	4	0	4					
		17FEB2003	54	4	0	4					
		18FEB2003	55	4	0	4					
		20FEB2003					NO	290	55	100	PT TOOK LAST ROW OF BLISTER CARD (4 PILLS). THUS LEAVING 1 ROW (4 PILLS) OF 9 UNUSED FOR VISIT 9.
	E0029009	20JAN2003	1	2	0	2					
		21JAN2003	2	1	0	1					
		22JAN2003	3	1	0	1					
		23JAN2003	4	2	0	2					
		24JAN2003	5	3	0	3					
		25JAN2003	6	3	0	3					
		26JAN2003	7	3	0	3					
		27JAN2003	8	4	0	4					
		28JAN2003	9	4	0	4					
		29JAN2003	10	4	0	4					
		30JAN2003	11	4	0	4					
		31JAN2003	12	4	0	4					
		01FEB2003	13	4	0	4					
		02FEB2003	14	4	0	4					
		03FEB2003	15	4	0	4					
		04FEB2003	16	4	0	4					
		05FEB2003	17	4	0	4					
		06FEB2003	18	4	0	4					
		07FEB2003	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	08FEB2003	20	4	0	4					
		09FEB2003	21	4	0	4					
		10FEB2003	22		0	4					
		11FEB2003	23	4	0	4					
		12FEB2003	24	4	0	4					
		13FEB2003	25	4	0	4					
		14FEB2003	26	4	0	4					
		15FEB2003	27	4	0	4					
		16FEB2003	28	4	0	4					
		17FEB2003	29	4	0	4					
		18FEB2003	30	4	0	4					
		19FEB2003	31	4	0	4					
		20FEB2003	32	4	0	4					
		21FEB2003	33	4	0	4					
		22FEB2003	34	4	0	4					
		23FEB2003	35	4	0	4					
		24FEB2003	36	4	0	4					
		25FEB2003	37	4	0	4					
		26FEB2003	38	4	0	4					
		27FEB2003	39	4	0	4					
		28FEB2003	40	4	0	4					
		01MAR2003	41	4	0	4					
		02MAR2003	42	4	0	4					
		03MAR2003	43	4	0	4					
		04MAR2003	44	4	0	4					
		05MAR2003	45	4	0	4					
		06MAR2003	46	4	0	4					
		07MAR2003	47	4	0	4					
		08MAR2003	48	4	0	4					
		09MAR2003	49	4	0	4					
		10MAR2003	50		0	4					
		11MAR2003	51	4	0	4					
		12MAR2003	52	4	0	4					
		13MAR2003	53	4	0	4					
		14MAR2003	54	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	15MAR2003	55	4	0	4					
		16MAR2003	56	4	0	4					
		17MAR2003	57	4	0	4	NO	290.4	57	100	
	E0029021	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					
		20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8	4	0	4					
		26MAR2003	9	4	0	4					
		27MAR2003	10	4	0	4					
		28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					
		02APR2003	16	4	0	4					
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	4					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	0	4					
		08APR2003	22	4	0	4					
		09APR2003	23	4	0	4					
		10APR2003	24	4	0	4					
		11APR2003	25	4	0	4					
		12APR2003	26	4	0	4					
		13APR2003	27	4	0	4					
		14APR2003	28		0	4					
		15APR2003	29	4	0	4					
		16APR2003	30	4	0	4					
		17APR2003	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	18APR2003	32	4	0	4					
		19APR2003	33	4	0	4					
		20APR2003	34	4	0	4					
		21APR2003	35	4	0	4					
		22APR2003	36	4	0	4					
		23APR2003	37	4	0	4					
		24APR2003	38	4	0	4					
		25APR2003	39	4	0	4					
		26APR2003	40	4	0	4					
		27APR2003	41	4	0	4					
		28APR2003	42	4	0	4					
		29APR2003	43	4	0	4					
		30APR2003	44	4	0	4					
		01MAY2003	45	4	0	4					
		02MAY2003	46	4	0	4					
		03MAY2003	47	4	0	4					
		04MAY2003	48	4	0	4					
		05MAY2003	49	4	0	4					
		06MAY2003	50	4	0	4					SUBJECT DID NOT TAKE THE EXTRA DAY DOSES.
		07MAY2003	51	4	0	4					
		08MAY2003	52	4	0	4					
		09MAY2003	53	4	0	4					
		10MAY2003	54	4	0	4					
		11MAY2003	55	4	0	4					
		12MAY2003	56	4	0	4					
		13MAY2003	57		0	4					
		14MAY2003	58		0	4	NO	290.5	58	100	
	E0029026	14APR2003	1	2	0	2					
		15APR2003	2	1	0	1					
		16APR2003	3	1	0	1					
		17APR2003	4	2	0	2					
		18APR2003	5	3	0	3					
		19APR2003	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	20APR2003	7	3	0	3					
		21APR2003	8	4	1	3					DOSE REDUCED TO 3 TABS HS
		22APR2003	9	4	1	3					
		23APR2003	10	4	1	3					
		24APR2003	11	4	1	3					
		25APR2003	12	4	1	3					
		26APR2003	13	4	1	3					
		27APR2003	14	4	1	3					
		28APR2003	15	4	1	3					
		29APR2003	16	4	1	3					
		30APR2003	17	4	1	3					
		01MAY2003	18	4	1	3					
		02MAY2003	19	4	1	3					
		03MAY2003	20	4	1	3					
		04MAY2003	21	4	1	3					
		05MAY2003	22	4	1	3					
		06MAY2003	23	4	1	3					
		07MAY2003	24	4	1	3					
		08MAY2003	25	4	1	3					
		09MAY2003	26	4	1	3					
		10MAY2003	27	4	1	3					
		11MAY2003	28	4	1	3					
		12MAY2003	29	4	1	3					
		13MAY2003	30	4	1	3					
		14MAY2003	31	4	1	3					
		15MAY2003	32	4	1	3					
		16MAY2003	33	4	1	3					
		17MAY2003	34	4	1	3					
		18MAY2003	35	4	1	3					
		19MAY2003	36	4	1	3					
		20MAY2003	37	4	1	3					
		21MAY2003	38	4	1	3					
		22MAY2003	39	4	1	3					
		23MAY2003	40	4	1	3					
		24MAY2003	41	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	25MAY2003	42	4	1	3					
		26MAY2003	43		1	3					
		27MAY2003	44		1	3					
		28MAY2003	45	4	1	3					
		29MAY2003	46	4	1	3					
		30MAY2003	47	4	1	3					
		31MAY2003	48	4	1	3					
		01JUN2003	49	4	1	3					
		02JUN2003	50	4	1	3					
		03JUN2003	51	4	1	3					
		04JUN2003	52	4	1	3					
		05JUN2003	53	4	1	3					
		06JUN2003	54	4	1	3					
		07JUN2003	55	4	1	3					
		08JUN2003	56	4	1	3					
		09JUN2003	57		1	3	YES	202.6	57	100	
	E0029030	27MAY2003	1	2	0	2					
		28MAY2003	2	1	0	1					
		29MAY2003	3	1	0	1					
		30MAY2003	4	2	0	2					
		31MAY2003	5	3	0	3					
		01JUN2003	6	3	0	3					
		02JUN2003	7	3	0	3					
		03JUN2003	8	4	0	4					
		04JUN2003	9	4	0	4					
		05JUN2003	10	4	0	4					
		06JUN2003	11	4	0	4					
		07JUN2003	12	4	0	4					
		08JUN2003	13	4	0	4					
		09JUN2003	14	4	0	4					
		10JUN2003	15	4	0	4					
		11JUN2003	16	4	0	4					
		12JUN2003	17	4	0	4					
		13JUN2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	14JUN2003	19	4	0	4					
		15JUN2003	20	4	0	4					
		16JUN2003	21	4	0	4					
		17JUN2003	22	4	0	4					
		18JUN2003	23	4	0	4					
		19JUN2003	24	4	0	4					
		20JUN2003	25	4	0	4					
		21JUN2003	26	4	0	4					
		22JUN2003	27	4	0	4					
		23JUN2003	28	4	0	4					
		24JUN2003	29		0	4					
		25JUN2003	30		0	4					
		26JUN2003	31	4	0	4					MISSED DOSE ON 6/28/03, BUT CONTINUED TO TAKE STUDY DRUG CONSECUTIVELY AS IT WAS LABELED ON THE STUDY DRUG CARD. LAST DOSE WAS TAKEN ON 07/01/2003.
		27JUN2003	32	4	0	4					
		28JUN2003	33	4	4	0					
		29JUN2003	34	4	0	4					
		30JUN2003	35	4	0	4					
		01JUL2003	36	4	0	4					
		02JUL2003	37	4	0	4					
		03JUL2003	38	4	0	4					
		04JUL2003	39	4	0	4					
		05JUL2003	40	4	0	4					
		06JUL2003	41	4	0	4					
		07JUL2003	42	4	0	4					
		08JUL2003	43	4	0	4					
		09JUL2003	44	4	0	4					
		10JUL2003	45	4	0	4					
		11JUL2003	46	4	0	4					
		12JUL2003	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	13JUL2003	48	4	0	4					
		14JUL2003	49	4	0	4					
		15JUL2003	50	4	0	4					
		16JUL2003	51	4	0	4					
		17JUL2003	52	4	0	4					
		18JUL2003	53	4	0	4					
		19JUL2003	54	4	0	4					
		20JUL2003	55	4	0	4					
		21JUL2003	56	4	0	4					
		22JUL2003	57	4	0	4	NO	285.1	56	98.1	
	E0031008	28FEB2003	1	2	0	2					
		01MAR2003	2	1	0	1					
		02MAR2003	3	1	0	1					
		03MAR2003	4	2	0	2					
		04MAR2003	5	3	0	3					
		05MAR2003	6	3	0	3					
		06MAR2003	7	3	0	3					
		07MAR2003	8	4	0	4					
		08MAR2003	9	4	0	4					
		09MAR2003	10	4	0	4					
		10MAR2003	11	4	0	4					
		11MAR2003	12	4	0	4					
		12MAR2003	13	4	0	4					
		13MAR2003	14	4	0	4					
		14MAR2003	15	4	0	4					
		15MAR2003	16	4	0	4					
		16MAR2003	17	4	0	4					
		17MAR2003	18	4	0	4					
		18MAR2003	19	4	0	4					
		19MAR2003	20	4	0	4					
		20MAR2003	21		0	4					
		21MAR2003	22	4	0	4					
		22MAR2003	23	4	0	4					
		23MAR2003	24	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0031008	24MAR2003	25	4	0	4					
		25MAR2003	26	4	0	4					
		26MAR2003	27	4	0	4					
		27MAR2003	28	4	0	4					
		28MAR2003	29	4	0	4					
		29MAR2003	30	4	0	4					
		30MAR2003	31	4	0	4					
		31MAR2003	32	4	0	4					
		01APR2003	33	4	0	4					
		02APR2003	34	4	0	4					
		03APR2003	35	4	0	4					
		04APR2003	36	4	0	4					
		05APR2003	37	4	0	4					
		06APR2003	38	4	0	4					
		07APR2003	39	4	0	4					
		08APR2003	40	4	0	4					
		09APR2003	41	4	0	4					
		10APR2003	42	4	0	4					
		11APR2003	43	4	0	4					
		12APR2003	44	4	0	4					
		13APR2003	45	4	0	4					
		14APR2003	46	4	0	4					
		15APR2003	47	4	0	4					
		16APR2003	48	4	0	4					
		17APR2003	49	4	0	4					
		18APR2003	50	4	0	4					
		19APR2003	51	4	0	4					
		20APR2003	52	4	0	4					
		21APR2003	53	4	0	4					
		22APR2003	54	4	0	4					
		23APR2003	55	4	0	4	NO	290	55	100	
	E0031020	21APR2003	1	2	0	2					
		22APR2003	2	1	0	1					
		23APR2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	24APR2003	4	2	0	2					
		25APR2003	5	3	0	3					
		26APR2003	6	3	0	3					
		27APR2003	7	3	0	3					
		28APR2003	8	4	0	4					
		29APR2003	9	4	0	4					
		30APR2003	10	4	0	4					
		01MAY2003	11	4	0	4					
		02MAY2003	12	4	0	4					
		03MAY2003	13	4	0	4					
		04MAY2003	14	4	0	4					
		05MAY2003	15	4	0	4					
		06MAY2003	16	4	0	4					
		07MAY2003	17	4	0	4					
		08MAY2003	18	4	0	4					
		09MAY2003	19	4	0	4					
		10MAY2003	20	4	0	4					
		11MAY2003	21	4	0	4					
		12MAY2003	22		0	4	NO	275	22	100	
	E0031021	25APR2003	1	2	0	2					
		26APR2003	2	1	0	1					
		27APR2003	3	1	0	1					
		28APR2003	4	2	0	2					
		29APR2003	5	3	0	3					
		30APR2003	6	3	0	3					
		01MAY2003	7	3	0	3					
		02MAY2003	8	4	0	4					
		03MAY2003	9	4	0	4					
		04MAY2003	10	4	0	4					
		05MAY2003	11	4	0	4					
		06MAY2003	12	4	0	4					
		07MAY2003	13	4	0	4					
		08MAY2003	14	4	0	4					
		09MAY2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	10MAY2003	16	4	0	4					
		11MAY2003	17	4	0	4					
		12MAY2003	18	4	0	4					
		13MAY2003	19	4	0	4					
		14MAY2003	20	4	0	4					
		15MAY2003	21	4	0	4					
		16MAY2003	22	4	0	4					
		17MAY2003	23	4	0	4					
		18MAY2003	24	4	0	4					
		19MAY2003	25	4	0	4					
		20MAY2003	26	4	0	4					
		21MAY2003	27	4	0	4					
		22MAY2003	28	4	0	4					
		23MAY2003	29	4	0	4					
		24MAY2003	30	4	0	4					
		25MAY2003	31	4	0	4					
		26MAY2003	32	4	0	4					
		27MAY2003	33	4	0	4					
		28MAY2003	34	4	0	4					
		29MAY2003	35	4	0	4					
		30MAY2003	36	4	0	4					
		31MAY2003	37	4	0	4					
		01JUN2003	38	4	0	4					
		02JUN2003	39	4	0	4					
		03JUN2003	40	4	0	4					
		04JUN2003	41	4	0	4					
		05JUN2003	42		4	0					PT MISSED DOSE
		06JUN2003	43	4	0	4					
		07JUN2003	44	4	0	4					
		08JUN2003	45	4	0	4					
		09JUN2003	46	4	0	4					
		10JUN2003	47	4	0	4					
		11JUN2003	48	4	0	4					
		12JUN2003	49	4	0	4					
		13JUN2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	14JUN2003	51	4	0	4					
		15JUN2003	52	4	0	4					
		16JUN2003	53	4	0	4					
		17JUN2003	54		0	4					
		18JUN2003					NO	284.3	53	98	MISSED DOSE
	E0031029	18JUN2003	1	2	0	2					
		19JUN2003	2	1	0	1					
		20JUN2003	3	1	0	1					
		21JUN2003	4	2	0	2					
		22JUN2003	5	3	0	3					
		23JUN2003	6	3	0	3					
		24JUN2003	7	3	0	3					
		25JUN2003	8	4	0	4					SIC - DAY 1 DATE DOES NOT EQUAL VISIT 3 DATE DUE TO BLISTERCARD 1 BEING REDISPENSED FOR FULL TITRATION.
		26JUN2003	9	4	0	4					
		27JUN2003	10	4	0	4					
		28JUN2003	11	4	2	2					PATIENT DID NOT TAKE 2 TABS 6/28 AND 6/29
		29JUN2003	12	4	2	2					
		30JUN2003	13	4	1	3					DOSE WAS REDUCED TO 3 TABS 6/30
		01JUL2003	14	4	1	3	YES	203.6	14	94.9	
	E0033002										SUBJECT TOOK DAY 5 DOSE ON 2/26/03 SUBJECT TOOK DAY 6 DOSE ON 2/27/03 SUBJECT TOOK DAY 7 DOSE ON 2/27/03
		10JAN2003	1	2	0	2					SUBJECT TOOK DOSE ON 1/11/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0033002	11JAN2003	2	1	0	1					SUBJECT TOOK DOSE ON 1/12/03
		12JAN2003	3	1	0	1					SUBJECT TOOK DOSE ON 1/13/03
		13JAN2003	4	2	0	2					SUBJECT TOOK DOSE ON 1/14/03
		14JAN2003	5	3	3	0					MISSED DOSE ON 1/15/03.
		15JAN2003	6	3	3	0					
		16JAN2003	7	4	0	4					
		17JAN2003	8	4	0	5					PT TOOK LAST IN ROW FROM EACH EXTRA ROW BY MISTAKE FOR DOSE ONE ON 1/10/03.
		18JAN2003	9	4	0	5					
		19JAN2003	10	4	0	4					
		20JAN2003	11	4	0	4					
		21JAN2003	12	4	0	4					
		22JAN2003	13	4	0	4					
		23JAN2003	14		0	4					
		24JAN2003	15	4	0	4					
		25JAN2003	16	4	0	4					
		26JAN2003	17	4	0	4					
		27JAN2003	18	4	0	4					
		28JAN2003	19	4	0	4					
		29JAN2003	20	4	0	4					
		30JAN2003	21	4	0	4					
		31JAN2003	22	4	0	4					
		01FEB2003	23	4	0	4					
		02FEB2003	24	4	0	4					
		03FEB2003	25	4	0	4					
		04FEB2003	26	4	0	4					
		05FEB2003	27	4	0	4					
		06FEB2003	28	4	0	4					PT DID NOT TAKE THESE BUT LOST CARD ON SUBWAY
		07FEB2003	29	4	0	4					PT DID NOT TAKE THESE BUT LOST CARD ON SUBWAY
		08FEB2003	30	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0033002	09FEB2003	31	4	0	4					
		10FEB2003	32	4	0	4					
		11FEB2003	33	4	0	4					
		12FEB2003	34	4	0	4					
		13FEB2003	35	4	0	4					
		14FEB2003	36	4	0	4					
		15FEB2003	37	4	0	4					
		16FEB2003	38	4	0	4					
		17FEB2003	39	4	0	4					
		18FEB2003	40	4	0	4					
		19FEB2003	41	4	0	4					
		20FEB2003	42		0	4					
		21FEB2003	43		0	4					SUBJECT TOOK DOSE ON 2/22/03 (SKIPPED DOSE ON 2/21/03)
		22FEB2003	44			0					
		23FEB2003	45			0					
		24FEB2003	46	4	0	4					PT DID NOT TAKE STUDY MEDS ON 2/23/03
		25FEB2003	47	4	0	4					
		26FEB2003	48	4	0	4					SUBJECT TOOK DAY 3 DOSE ON 2/25/03
		27FEB2003	49	4	0	4					SUBJECT TOOK DAY 4 DOSE ON 2/26/03
		28FEB2003	50	4	0	4					
		01MAR2003	51	4	0	4					
		02MAR2003	52	4	0	4					
		03MAR2003	53	4	0	4					
		04MAR2003	54	4	0	4					
		05MAR2003	55	4	0	4					
		06MAR2003	56	4	0	4	NO	268.8	52	94.8	
	E0033006	23JAN2003	1	2	0	2					
		24JAN2003	2	1	0	1					
		25JAN2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0033006	26JAN2003	4	2	0	2					
		27JAN2003	5	3	0	3					
		28JAN2003	6	3	0	3					
		29JAN2003	7	3	3	0					PATIENT DID NOT TAKE DAY 7 DOSE BECAUSE OF AES
		30JAN2003	8	4	0	4					SUBJECT DISCARDED OF BLISTER PACK, BUT REPORTS ONLY HAVING TAKEN THE DAY 1 AND DAY 2 DOSES.
		31JAN2003	9	4	0	4					
		01FEB2003	10	4	0	4					
		02FEB2003	11	4	0	4					
		03FEB2003	12	4	0	4					
		04FEB2003	13	4	0	4					
		05FEB2003	14	4	0	4					
		06FEB2003	15		0	4					SIC PER PT. REPORT SUBJECT DISCARDED OF BLISTER PACK
		07FEB2003	16		0	4	NO	246.9	15	94.1	
	E0033021	02JUL2003	1	2	0	2					
		03JUL2003	2	1	0	1					
		04JUL2003	3	1	0	1					
		05JUL2003	4	2	0	2					
		06JUL2003	5	3	0	3					
		07JUL2003	6	3	0	3					
		08JUL2003	7	3	0	3					
		09JUL2003	8		0	4					
		10JUL2003	9		0	4					
		11JUL2003	10	4	0	4					
		12JUL2003	11	4	0	4					
		13JUL2003	12	4	0	4					
		14JUL2003	13	4	0	4					
		15JUL2003	14	4	0	4					
		16JUL2003	15	4	0	4					
		17JUL2003	16	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	18JUL2003	17		0	4					
		19JUL2003	18		4	0					PT MISSED DOSE PATIENT MISSED DOSE ON 7/20/03
		20JUL2003	19			0					
		21JUL2003	20	4	0	4					
		22JUL2003	21	4	0	4					
		23JUL2003	22	4	0	4					
		24JUL2003	23	4	0	4					
		25JUL2003	24	4	1	3					SUBJECT RETURNED TO CLINIC ON 7/25/03 & WAS DISPENSED NEXT BLISTERED CARD. SEE PAGE 202.
		25JUL2003	24	4	1	3					DOSAGE REDUCED BY 1 TABLET PER EVENING
		26JUL2003	25	4	1	3					
		27JUL2003	26	4	1	3					
		28JUL2003	27	4	1	3					
		29JUL2003	28	4	1	3					
		30JUL2003	29	4	1	3					
		31JUL2003	30	4	1	3					
		01AUG2003	31	4	1	3					DOSAGE DECREASED BY 1 TABLET/DAY
		02AUG2003	32	4	1	3					
		03AUG2003	33	4	1	3					
		04AUG2003	34	4	1	3					
		05AUG2003	35	4	0	4					PT MISSED DOSE PT TOOK ON 8/5/03 IN ERROR
		06AUG2003	36	4	1	6					DOSAGE DECREASED BY 1 TABLET
		07AUG2003	37	4	1	3					
		08AUG2003	38	4	1	3					
		09AUG2003	39	4	1	3					
		10AUG2003	40	4	1	3					
		11AUG2003	41	4	1	3					
		12AUG2003	42	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	13AUG2003	43		1	3					
		14AUG2003	44		1	3	YES	233	42	95.8	SUBJECT DID NOT TAKE STUDY MEDICATION ON 8/15/03, 8/16/03, 8/17/03. THE SUBJECT RETURNED TO THE CLINIC FOR EARLY TERMINATION ON 8/18/03.
	E0035013	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003									PT. STOPPED TAKING MEDS DUE TO AE.
		09FEB2003					NO	116.7	3	100	DAYS 4 - 9 PILLS WERE RETURNED
	E0035015	11FEB2003	1	2	0	2					
		12FEB2003	2	1	0	1					
		13FEB2003	3	1	0	1					
		14FEB2003	4	2	0	2					
		15FEB2003	5	3	0	3					
		16FEB2003					NO	190	5	100	PT NO LONGER WANTED TO TAKE STUDY MEDS
	E0035016	04APR2003	1	2	0	2					PT WAS LOST TO FOLLOW
		05APR2003	2	1	0	1					
		06APR2003	3	1	0	1					
		07APR2003	4	2	0	2					
		08APR2003	5	3	0	3					
		09APR2003	6	3	0	3					
		10APR2003	7	3	0	3					
		11APR2003	8		0	4	NO	231.3	8	100	UNKNOWN PT WAS LOST TO FOLLOW
	E0035023	13MAY2003	1	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0035023	14MAY2003	2	1	0	1					
		15MAY2003	3	1	0	1					
		16MAY2003	4	2	0	2					
		17MAY2003	5	3	0	3					
		18MAY2003	6	3	0	3					
		19MAY2003	7	3	0	3					
		20MAY2003	8	4	0	4					
		21MAY2003	9	4	1	3					DOSE REDUCED THRU END TO STUDY
		22MAY2003	10	4	1	3					
		23MAY2003	11	4	1	3					
		24MAY2003	12	4	1	3					
		25MAY2003	13	4	1	3					
		26MAY2003	14	4	1	3					
		27MAY2003	15		1	3					
		28MAY2003	16		1	3					
		29MAY2003	17	4	1	3					
		30MAY2003	18	4	1	3					
		31MAY2003	19	4	1	3					
		01JUN2003	20	4	1	3					
		02JUN2003	21	4	1	3					
		03JUN2003	22	4	1	6					
		04JUN2003	23	4	1	6					
		05JUN2003	24	4	1	3					
		06JUN2003	25	4	1	3					
		07JUN2003	26	4	1	3					
		08JUN2003	27	4	1	3					
		09JUN2003	28	4	1	3					
		10JUN2003	29	4	0	4					CARD NOT RETURNED
		11JUN2003	30	4	0	4					
		12JUN2003	31	4	0	4					
		13JUN2003	32	4	0	4					
		14JUN2003	33	4	0	4					
		15JUN2003	34	4	0	4					
		16JUN2003	35	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)		17JUN2003	36		0	4	YES	240.3	36	104	
	E0039052	20JUN2003	1	2	0	2					
		21JUN2003	2	1	0	1					
		22JUN2003	3	1	1	0					MISSED A DOSE
		23JUN2003	4	2	0	2					
		24JUN2003	5	3	3	0					MISSED A DOSE
		25JUN2003	6	3	1	2					MISSED A DOSE
		26JUN2003	7	3	1	2					MISSED A DOSE
		27JUN2003	8	4	0	4					
		28JUN2003	9	4	0	4					
		29JUN2003	10	4	4	0					MISSED DOSE
		30JUN2003	11	4	0	4					
		01JUL2003	12	4	4	0					MISSED DOSE
		02JUL2003	13	4	0	4					
		03JUL2003					NO	126.9	9	64.1	SUBJECT DID NOT TAKE DOSE BECAUSE VISIT 4 WAS ON 2003/07/03.
	E0039056	14JUL2003	0	2	2	0					FORGOT TO TAKE DOSE
		15JUL2003	1	1	0	1					
		16JUL2003	2	1	0	1					
		17JUL2003	3	2	0	2					
		18JUL2003	4	3	0	3					
		19JUL2003	5	3	0	3					
		20JUL2003	6	3	3	0					DID NOT TAKE DOSE
		21JUL2003	7		4	0					DID NOT TAKE DOSE
		22JUL2003	8		4	0					DID NOT TAKE DOSE
		23JUL2003	9	4	0	4					SUBJECT DID NOT RETURN THIS BLISTERCARD; THEREFORE IT IS UNKNOWN WHAT STUDY MEDICATION THE SUBJECT TOOK.
		30JUL2003					NO	125	6	60.9	UNKNOWN SIC

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	18JUL2003	0	2	2	0					MISSED DOSE
		19JUL2003	1	1	0	1					
		20JUL2003	2	1	0	1					
		21JUL2003	3	2	0	2					
		22JUL2003	4	3	0	3					
		23JUL2003	5	3	0	3					
		24JUL2003	6	3	0	3					
		25JUL2003	7	4	0	4					
		26JUL2003	8	4	0	4					
		27JUL2003	9	4	0	4					
		28JUL2003	10	4	0	4					
		29JUL2003	11	4	0	4					
		30JUL2003	12	4	0	4					
		31JUL2003	13	4	0	4					
		01AUG2003	14	4	0	4					
		02AUG2003	15	4	0	4					
		03AUG2003	16	4	0	4					
		04AUG2003	17	4	0	4					
		05AUG2003	18	4	0	4					
		06AUG2003	19	4	0	4					
		07AUG2003	20	4	0	4					
		08AUG2003	21	4	0	4					
		09AUG2003	22	4	0	4					
		10AUG2003	23	4	0	4					
		11AUG2003	24	4	0	4					
		12AUG2003	25	4	0	4					
		13AUG2003	26	4	0	4					
		14AUG2003	27	4	0	4					
		15AUG2003	28	4	0	4					
		16AUG2003	29	4	0	4					
		17AUG2003	30	4	0	4					
		18AUG2003	31	4	0	4					
		19AUG2003	32	4	0	4					
		20AUG2003	33	4	0	4					
		21AUG2003	34	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	22AUG2003	35	4	0	4					SUBJECT BEGAN TAKING STUDY MEDICATION FROM THE BOTTOM OF BLISTERCARD.
		23AUG2003	36	4	4	0					
		24AUG2003	37	4	0	4					TAKEN ON 8/28/03
		25AUG2003	38	4	0	4					TAKEN ON 8/27/03
		26AUG2003	39	4	0	4					TAKEN ON 8/26/03
		27AUG2003	40	4	0	4					TAKEN ON 8/25/03
		28AUG2003	41	4	0	4					TAKEN ON 8/24/03
		29AUG2003	42	4	4	0					TAKEN ON 08/23/03
		29AUG2003	42	4	4	0					MISSED 4 TABLETS
		30AUG2003	43	4	4	0					TAKEN ON 08/22/03
		30AUG2003	43	4	4	0					MISSED 4 TABLETS
		31AUG2003	44	4	0	4					
		01SEP2003	45	4	0	4					
		02SEP2003	46	4	0	4					
		03SEP2003	47	4	0	4					
		04SEP2003	48	4	0	4					
		05SEP2003	49	4	0	4					
		06SEP2003	50	4	0	4					
		07SEP2003	51	4	0	4					
		08SEP2003	52	4	0	4					
		09SEP2003	53	4	0	4					
		10SEP2003	54	4	0	4					
		11SEP2003	55	4	0	4	NO	268.8	52	95.2	
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	03MAR2003	1	2	0	2					
		04MAR2003	2	1	0	1					
		05MAR2003	3	1	0	1					
		06MAR2003	4	2	0	2					
		07MAR2003	5	3	0	3					
		08MAR2003	6	3	0	3					
		09MAR2003	7	3	0	3					
		10MAR2003	8		0	4					VISIT INTERVAL WAS 8 DAYS
		11MAR2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	12MAR2003	10	4	0	4					
		13MAR2003	11	4	0	4					
		14MAR2003	12	4	0	4					
		15MAR2003	13	4	0	4					
		16MAR2003	14	4	0	4					
		17MAR2003	15	4	0	4					
		18MAR2003	16	4	0	4					
		19MAR2003	17	4	0	4					
		20MAR2003	18	4	0	4					
		21MAR2003	19	4	0	4					
		22MAR2003	20	4	0	4					
		23MAR2003	21	4	0	4					
		24MAR2003	22	4	0	4					
		25MAR2003	23	4	0	4					
		26MAR2003	24	4	0	4					
		27MAR2003	25	4	0	4					
		28MAR2003	26	4	0	4					
		29MAR2003	27	4	0	4					
		30MAR2003	28	4	0	4					
		31MAR2003	29	4	0	4					
		01APR2003	30	4	0	4					
		02APR2003	31	4	0	4					
		03APR2003	32	4	0	4					
		04APR2003	33	4	0	4					
		05APR2003	34	4	0	4					
		06APR2003	35	4	0	4					
		07APR2003	36	4	0	4					
		08APR2003	37	4	1	3					DOSE REDUCTION DID NOT TAKE 1ST PILL. A. E. - WEAKNESS.
		09APR2003	38	4	1	3					DID NOT TAKE 1ST PILL A. E. - WEAKNESS
		10APR2003	39	4	1	3					DID NOT TAKE 1ST PILL A. E. WEAKNESS

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION		TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE		COMMENTS
				DISPENSE	RETURN (ADJUSTED)				NO. DAYS STUDY DRUG	%	
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	11APR2003	40	4	1	3					DID NOT TAKE 1ST PILL AE - WEAKNESS
		12APR2003	41	4	1	3					DID NOT TAKE 1ST PILL A. E - WEAKNESS
		13APR2003	42	4	1	3					DID NOT TAKE 1ST PILL A. E. WEAKNESS
		14APR2003	43	4	1	3					DID NOT TAKE 1ST PILL A. E. WEAKNESS
		15APR2003	44	4	1	3					DOSE REDUCTION DIDNT TAKE 1ST PILL A. E. WEAKNESS
		16APR2003	45	4	1	3					DIDN'T TAKE 1ST PILL AE WEAKNESS
		17APR2003	46	4	1	3					DIDNT TAKE 1ST PILL A. E. WEAKNESS
		18APR2003	47	4	1	3					DIDNT TAKE 1ST PILL A. E. WEAKNESS
		19APR2003	48	4	1	3					DIDN'T TAKE 1ST PILL AE. WEAKNESS
		20APR2003	49	4	1	3					DIDNT TAKE 1ST PILL A. E. WEAKNESS
		21APR2003	50	4	1	3					DIDNT TAKE 1ST PILL A. E. WEAKNESS
		22APR2003	51		1	3					DOSE REDUCTION DIDN'T TAKE 1ST PILL AE WEAKNESS
		23APR2003	52		1	3					DIDNT TAKE 1ST PILL AE. WEAKNESS
		24APR2003	53	4	1	3					DOSE REDUCTION DIDN'T TAKE 1ST PILL AE WEAKNESS
		25APR2003	54	4	1	3					DIDNT TAKE 1ST PILL AE WEAKNESS
		26APR2003	55	4	1	3					DIDN'T TAKE 1ST PILL AE. WEAKNESS
		27APR2003	56	4	1	3					DIDN'T TAKE 1ST PILL A. E. WEAKNESS
		28APR2003	57	4	1	3					DIDNT TAKE 1ST PILL A. E. WEAKNESS

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	29APR2003	58	4	1	3					DIDNT TAKE 1ST PILL A. E. WEAKNESS
		30APR2003	59	4	1	3					DIDNT TAKE 1 ST PILL A. E. WEAKNESS
		01MAY2003	60		1	3					DOSE REDUCTION DIDNT TAKE 1ST PILL A. E. WEAKNESS
		02MAY2003					YES	520.8	60	100	NO EXTRA DAY VISIT INTERVAL WAS 8 DAYS
	E0002011	29APR2003	1	2	0	2					
		30APR2003	2	1	0	1					
		01MAY2003	3	1	0	1					
		02MAY2003	4	2	0	2					
		03MAY2003	5	3	0	3					
		04MAY2003	6	3	0	3					
		05MAY2003	7	3	0	3					
		06MAY2003	8		0	4					EXTRA DAY EXTENDED VISIT INTERVAL. PATIENT TOOK EXTRA DOSES
		07MAY2003	9		0	4					EXTRA DAY
		08MAY2003	10	4	0	4					
		09MAY2003	11	4	0	4					
		10MAY2003	12	4	0	4					
		11MAY2003	13	4	0	4					
		12MAY2003	14	4	0	4					
		13MAY2003	15	4	0	4					
		14MAY2003	16	4	0	4					
		15MAY2003	17	4	0	4					
		16MAY2003	18	4	0	4					
		17MAY2003	19	4	0	4					
		18MAY2003	20	4	0	4					
		19MAY2003	21	4	0	4					
		20MAY2003	22	4	0	4					
		21MAY2003	23	4	0	4					
		22MAY2003	24	4	0	4					
		23MAY2003	25	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0002011	24MAY2003	26	4	0	4					
		25MAY2003	27	4	0	4					
		26MAY2003	28	4	0	4					
		27MAY2003	29	4	0	4					
		28MAY2003	30	4	0	4					
		29MAY2003	31	4	0	4					
		30MAY2003	32	4	0	4					
		31MAY2003	33	4	0	4					
		01JUN2003	34	4	0	4					
		02JUN2003	35	4	0	4					
		03JUN2003	36	4	0	4					
		04JUN2003	37	4	0	4					
		05JUN2003	38	4	0	4					
		06JUN2003	39	4	0	4					
		07JUN2003	40	4	0	4					
		08JUN2003	41	4	0	4					
		09JUN2003	42	4	0	4					
		10JUN2003	43	4	0	4					
		11JUN2003	44	4	0	4					
		12JUN2003	45	4	0	4					
		13JUN2003	46	4	0	4					
		14JUN2003	47	4	0	4					
		15JUN2003	48	4	0	4					
		16JUN2003	49	4	0	4					
		17JUN2003	50	4	0	4					
		18JUN2003	51	4	0	4					
		19JUN2003	52	4	0	4					
		20JUN2003	53	4	0	4					
		21JUN2003	54	4	0	4					
		22JUN2003	55	4	0	4					
		23JUN2003	56	4	0	4					
		24JUN2003	57	4	0	4					
		25JUN2003					NO	558.8	57	100	VISIT INTERVAL WAS 6 DAYS VISIT 10 - 06/25/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	03FEB2003	1	2	0	2					
		04FEB2003	2	1	0	1					
		05FEB2003	3	1	0	1					
		06FEB2003	4	2	0	2					
		07FEB2003	5	3	0	3					
		08FEB2003	6	3	0	3					
		09FEB2003	7	3	0	3					
		10FEB2003	8	4	0	4					
		11FEB2003	9	4	0	4					
		12FEB2003	10	4	0	4					
		13FEB2003	11	4	0	4					
		14FEB2003	12	4	0	4					
		15FEB2003	13	4	0	4					
		16FEB2003	14	4	0	4					
		17FEB2003	15		0	4					
		18FEB2003	16		0	4					
		19FEB2003	17	4	0	4					
		20FEB2003	18	4	0	4					
		21FEB2003	19	4	0	4					
		22FEB2003	20	4	0	4					
		23FEB2003	21	4	0	4					
		24FEB2003	22	4	0	4					
		25FEB2003	23	4	0	4					
		26FEB2003	24		0	4					
		27FEB2003	25	4	0	4					
		28FEB2003	26	4	0	4					
		01MAR2003	27	4	0	4					
		02MAR2003	28	4	0	4					
		03MAR2003	29	4	0	4					
		04MAR2003	30	4	0	4					
		05MAR2003	31	4	0	4					
		06MAR2003	32	4	0	4					
		07MAR2003	33	4	0	4					
		08MAR2003	34	4	0	4					
		09MAR2003	35	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	10MAR2003	36		0	4					
		11MAR2003	37		0	4					
		12MAR2003	38			0					
		13MAR2003	39			0					
		14MAR2003	40	4	0	4					DID NOT DOSE 3/12/03 & 3/13/03.
		15MAR2003	41	4	0	4					
		16MAR2003	42	4	0	4					
		17MAR2003	43	4	0	4					
		18MAR2003	44	4	0	4					
		19MAR2003	45	4	0	4					
		20MAR2003	46	4	0	4					
		21MAR2003	47	4	0	4					
		22MAR2003	48	4	0	4					
		23MAR2003	49	4	0	4					
		24MAR2003	50	4	0	4					
		25MAR2003	51	4	0	4					
		26MAR2003	52	4	0	4					
		27MAR2003	53	4	0	4					
		28MAR2003	54	4	0	4					
		29MAR2003	55	4	0	4					
		30MAR2003									TOOK FROM DAY 7 LINE IN ERROR
		31MAR2003					NO	535.5	53	96.1	TOOK ON 3/30/03
	E0003011	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					
		11FEB2003	8	4	0	4					
		12FEB2003	9	4	0	4					
		13FEB2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	0	4					
		18FEB2003	15	4	0	4					
		19FEB2003	16	4	0	4					
		20FEB2003	17	4	0	4					
		21FEB2003	18	4	0	4					
		22FEB2003	19	4	0	4					
		23FEB2003	20	4	0	4					
		24FEB2003	21	4	0	4					
		25FEB2003	22		0	4					
		26FEB2003	23		0	4					
		27FEB2003	24			0					
		28FEB2003	25			0					
		01MAR2003	26	4	0	4					SUBJECT NEVER RETURNED THIS BLISTER CARD. THROWN AWAY BY PT.
		02MAR2003	27	4	0	4					
		03MAR2003	28	4	0	4					
		04MAR2003	29	4	0	4					
		05MAR2003	30	4	0	4					
		06MAR2003	31	4	0	4					
		08MAR2003					NO	485.5	29	92.8	UNKNOWN
	E0003016	22MAY2003	1	2	0	2					
		23MAY2003	2	1	0	1					
		24MAY2003	3	1	0	1					
		25MAY2003	4	2	0	2					
		26MAY2003	5	3	0	3					
		27MAY2003	6	3	0	3					
		28MAY2003	7	3	0	3					
		29MAY2003	8	4	0	4					
		30MAY2003	9	4	0	4					
		31MAY2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003016	01JUN2003	11	4	0	4					
		02JUN2003	12	4	0	4					
		03JUN2003	13	4	0	4					
		04JUN2003	14	4	0	4					
		05JUN2003	15	4	0	4					
		06JUN2003	16	4	0	4					
		07JUN2003	17	4	0	4					
		08JUN2003	18	4	0	4					
		09JUN2003	19	4	0	4					
		10JUN2003	20	4	0	4					
		11JUN2003	21	4	0	4	NO	488.1	21	100	
	E0003019	27JUN2003	1	2	0	2					
		28JUN2003	2	1	0	1					
		29JUN2003	3	1	0	1					
		30JUN2003	4	2	0	2					
		01JUL2003	5	3	0	3					
		02JUL2003	6	3	0	3					
		03JUL2003	7	4	0	4					PATIENT DID NOT TAKE THIS DOSE BECAUSE VISIT 3 WAS ON 7/3/03
		04JUL2003	8	4	0	4					
		05JUL2003	9	4	0	4					
		06JUL2003	10	4	0	4					
		07JUL2003	11	4	0	4					
		08JUL2003	12	4	0	4					
		09JUL2003	13	4	0	4					
		10JUL2003	14	4	0	4					
		11JUL2003	15	4	0	4					
		12JUL2003	16	4	0	4					
		13JUL2003	17	4	0	4					
		14JUL2003	18	4	0	4					
		15JUL2003	19	4	0	4					PATIENT DID NOT TAKE THESE 2 DOSES BECAUSE HE CAME IN FOR VISIT 5 ON 7/15/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	16JUL2003	20	4	0	4					PATIENT DID NOT TAKE THESE 2 DOSES BECAUSE HE CAME IN FOR VISIT 5 ON 7/15/03
		17JUL2003	21	4	0	4					
		18JUL2003	22	4	0	4					
		19JUL2003	23	4	0	4					
		20JUL2003	24	4	0	4					
		21JUL2003	25	4	0	4					
		22JUL2003	26		0	4					PATIENT TOOK THESE EXTRA DOSES DUE TO AN EXTENDED VISIT INTERVAL
		23JUL2003	27	4	4	4					PATIENT TOOK THESE EXTRA DOSES DUE TO AN EXTENDED VISIT INTERVAL
		23JUL2003	27	4	4	4					THE SUBJECT DID NOT HAVE VISIT 6 BUT STUDY DRUG WAS DISPENSED. PATIENT TOOK 7/23/03 DOSE FROM WEEK 4 BLISTER CARD
		24JUL2003	28	4	0	4					
		25JUL2003	29	4	0	4					
		26JUL2003	30	4	0	4					
		27JUL2003	31	4	0	4					
		28JUL2003	32	4	0	4					
		29JUL2003	33	4	0	4					PATIENT DID NOT TAKE DOSE BECAUSE PATIENT HAD VISIT 7 ON 7/29/03
		30JUL2003	34	4	0	4					
		31JUL2003	35	4	0	4					
		01AUG2003	36	4	0	4					
		02AUG2003	37	4	0	4					
		03AUG2003	38	4	0	4					
		04AUG2003	39	4	0	4					
		05AUG2003	40		0	4					PATIENT TOOK THESE EXTRA DOSES DUE TO AN EXTENDED VISIT INTERVAL

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	06AUG2003	41		0	4					PATIENT TOOK THESE EXTRA DOSES DUE TO AN EXTENDED VISIT INTERVAL
		07AUG2003	42	4	0	4					
		08AUG2003	43	4	0	4					
		09AUG2003	44	4	0	4					
		10AUG2003	45	4	0	4					
		11AUG2003	46	4	0	4					
		12AUG2003	47	4	0	4					
		13AUG2003	48	4	0	4					
		14AUG2003	49	4	0	4					
		15AUG2003	50	4	0	4					
		16AUG2003	51	4	0	4					
		17AUG2003	52	4	0	4					
		18AUG2003	53	4	0	4					
		19AUG2003	54	4	0	4					
		20AUG2003	55	4	0	4	NO	560.9	55	100	
	E0003020	23JUL2003	1	2	0	2					
		24JUL2003	2	1	0	1					
		25JUL2003	3	1	0	1					
		26JUL2003	4	2	0	2					
		27JUL2003	5	3	0	3					
		28JUL2003	6	3	0	3					
		29JUL2003	7	4	0	4					PATIENT HAD A VISIT INTERVAL OF 6 DAYS
		30JUL2003	8	4	0	4					
		31JUL2003	9	4	0	4					
		01AUG2003	10	4	0	4					
		02AUG2003	11	4	0	4					
		03AUG2003	12	4	0	4					
		04AUG2003	13	4	0	4					
		05AUG2003	14		0	4					PATIENT TOOK THIS DOSE FROM THIS CARD BECAUSE VISIT 4 DID NOT OCCUR UNTIL 8/6/03
		06AUG2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	07AUG2003	16	4	0	4					
		08AUG2003	17	4	0	4					
		09AUG2003	18	4	0	4					
		10AUG2003	19	4	0	4					
		11AUG2003	20	4	0	4					
		12AUG2003	21	4	0	4					
		13AUG2003	22	4	0	4					
		14AUG2003	23	4	0	4					
		15AUG2003	24	4	0	4					
		16AUG2003	25	4	0	4					
		17AUG2003	26	4	0	4					
		18AUG2003	27	4	0	4					
		19AUG2003	28	4	0	4					
		20AUG2003	29	4	0	4					
		21AUG2003	30	4	0	4					
		22AUG2003	31	4	0	4					
		23AUG2003	32	4	0	4					
		24AUG2003	33	4	0	4					
		25AUG2003	34	4	0	4					
		26AUG2003	35	4	0	4					
		27AUG2003	36	4	0	4					
		28AUG2003	37	4	0	4					
		29AUG2003	38	4	0	4					
		30AUG2003	39	4	0	4					
		31AUG2003	40	4	0	4					
		01SEP2003	41	4	0	4					
		02SEP2003	42	4	0	4					
		03SEP2003	43	4	0	4					
		04SEP2003	44	4	0	4					
		05SEP2003	45	4	0	4					
		06SEP2003	46	4	0	4					
		07SEP2003	47	4	0	4					
		08SEP2003	48	4	0	4					
		09SEP2003	49	4	0	4					
		10SEP2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	11SEP2003	51	4	0	4					
		12SEP2003	52	4	0	4					
		13SEP2003	53	4	0	4					
		14SEP2003	54	4	0	4					
		15SEP2003	55	4	0	4					
		16SEP2003	56	4	0	4	NO	561.6	56	100	
	E0004001	30SEP2002	1	2	0	2					
		01OCT2002	2	1	0	1					
		02OCT2002	3	1	0	1					
		03OCT2002	4	2	0	2					
		04OCT2002	5	3	0	3					
		05OCT2002	6	3	2	1					DID NOT WANT TO BE TOO SEDATED TO WORK
		06OCT2002	7	3	0	3					
		07OCT2002	8	4	0	4					
		08OCT2002	9	4	0	4					
		09OCT2002	10	4	0	4					
		10OCT2002	11	4	2	2					DECREASED DUE TO AE OF SEDATION
		11OCT2002	12	4	2	2					DECREASED DUE TO AE OF SEDATION BY PATIENT
		12OCT2002	13	4	4	0					SKIPPED DOSE ON PLANE
		13OCT2002	14	4	2	2					DECREASED DUE TO SEDATION
		14OCT2002	15		2	2					DECREASED DUE TO SEDATION
		15OCT2002	16		2	2					DECREASED DUE TO SEDATION
		16OCT2002	17	4	4	0					SKIPPED DOSE ON AIRPLANE
		17OCT2002	18	4	2	2					DECREASED DUE TO SEDATION
		18OCT2002	19	4	2	2					DECREASED DUE TO SEDATION
		19OCT2002	20	4	2	2					DECREASED DUE TO SEDATION
		20OCT2002	21	4	2	2					DECREASED DUE TO SEDATION
		21OCT2002	22	4	1	3					DOSE REDUCTION
		22OCT2002	23	4	1	3					
		23OCT2002	24	4	1	3					
		24OCT2002	25	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	25OCT2002	26	4	1	3					
		26OCT2002	27	4	1	3					
		27OCT2002	28	4	1	3					
		28OCT2002	29	4	1	3					
		29OCT2002	30	4	1	3					
		30OCT2002	31	4	1	3					
		31OCT2002					YES	266.1	29	79.4	STOPPED DRUG DUE TO TAKING LORTAB FOR PAIN KIDNEY STONE
	E0004009	26DEC2002	1	2	0	2					
		27DEC2002	2	1	0	1					
		28DEC2002	3	1	0	1					
		29DEC2002	4	2	0	2					
		30DEC2002	5	3	0	3					
		31DEC2002	6	3	0	3					
		01JAN2003	7	3	0	3					
		02JAN2003	8	4	0	4					
		03JAN2003	9	4	0	4					
		04JAN2003	10	4	0	4					
		05JAN2003	11	4	0	4					
		06JAN2003	12	4	0	4					
		07JAN2003	13	4	0	4					
		08JAN2003	14	4	0	8					
		09JAN2003	15	4	0	4					
		10JAN2003	16	4	0	4					
		11JAN2003	17	4	0	4					
		12JAN2003	18	4	0	4					
		13JAN2003	19	4	0	4					
		14JAN2003	20	4	0	4					
		15JAN2003	21	4	0	4					
		16JAN2003	22	4	0	4					
		17JAN2003	23	4	0	4					
		18JAN2003	24	4	0	4					
		19JAN2003	25	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0004009	20JAN2003	26	4	0	4					
		21JAN2003	27	4	0	4					
		22JAN2003	28	4	0	4					
		23JAN2003	29	4	0	4					
		24JAN2003	30	4	0	4					
		25JAN2003	31	4	0	4					
		26JAN2003	32	4	0	4					
		27JAN2003	33	4	0	4					
		28JAN2003	34	4	0	4					
		29JAN2003	35	4	0	4					
		30JAN2003	36	4	0	4					
		31JAN2003	37	4	0	4					
		01FEB2003	38	4	0	4					
		02FEB2003	39	4	0	4					
		03FEB2003	40	4	0	4					
		04FEB2003	41	4	0	4					
		05FEB2003	42	4	0	4					
		06FEB2003	43	4	0	4					
		07FEB2003	44	4	0	4					
		08FEB2003	45	4	0	4					
		09FEB2003	46	4	0	4					
		10FEB2003	47	4	0	4					
		11FEB2003	48	4	0	4					
		12FEB2003	49	4	0	4					
		13FEB2003	50	4	0	4					
		14FEB2003	51	4	0	4					
		15FEB2003	52	4	0	4					
		16FEB2003	53	4	0	4					
		17FEB2003	54	4	0	4					
		18FEB2003	55	4	0	4	NO	568.2	55	102	
	E0004012	14JAN2003	1	2	0	2					
		15JAN2003	2	1	0	1					
		16JAN2003	3	1	0	1					
		17JAN2003	4	2	0	2					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	18JAN2003	5	3	0	3					
		19JAN2003	6	3	0	3					
		20JAN2003	7	3	0	3					
		21JAN2003	8	4	0	4					
		22JAN2003	9	4	0	4					
		23JAN2003	10	4	0	4					
		24JAN2003	11	4	0	4					
		25JAN2003	12	4	0	4					
		26JAN2003	13	4	0	4					
		27JAN2003	14	4	0	4					
		28JAN2003	15	4	0	4					
		29JAN2003	16	4	0	4					
		30JAN2003	17	4	0	4					
		31JAN2003	18	4	0	4					
		01FEB2003	19	4	0	4					
		02FEB2003	20	4	0	4					
		03FEB2003	21	4	0	4					
		04FEB2003	22	4	0	4					
		05FEB2003	23	4	0	4					
		06FEB2003	24	4	0	4					
		07FEB2003	25	4	0	4					
		08FEB2003	26	4	0	4					
		09FEB2003	27	4	0	4					
		10FEB2003	28	4	0	4					
		11FEB2003	29	4	0	4					
		12FEB2003	30	4	0	4					
		13FEB2003	31	4	0	4					
		14FEB2003	32	4	0	4					
		15FEB2003	33	4	0	4					
		16FEB2003	34	4	0	4					
		17FEB2003	35	4	0	4					
		18FEB2003	36	4	0	4					
		19FEB2003	37	4	0	4					
		20FEB2003	38	4	0	4					
		21FEB2003	39	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	22FEB2003	40	4	0	4					
		23FEB2003	41	4	0	4					
		24FEB2003	42	4	0	4					
		25FEB2003	43	4	0	4					
		26FEB2003	44	4	0	4					
		27FEB2003	45	4	0	4					
		28FEB2003	46	4	0	4					
		01MAR2003	47	4	0	4					
		02MAR2003	48	4	0	4					
		03MAR2003	49	4	0	4					
		04MAR2003	50	4	0	4					
		05MAR2003	51	4	0	4					
		06MAR2003	52	4	0	4					
		07MAR2003	53	4	0	4					
		08MAR2003	54	4	0	4					
		09MAR2003	55	4	0	4					
		10MAR2003	56	4	0	4	NO	558	56	100	
	E0004015	20FEB2003	1	2	0	2					
		21FEB2003	2	1	0	1					
		22FEB2003	3	1	0	1					
		23FEB2003	4	2	0	2					
		24FEB2003	5	3	0	3					
		25FEB2003	6	3	0	3					DAY 6 & 7 WERE RE - DISPENSED
		26FEB2003	7	3	0	3					MISSED DOSE ON 2-26-03, TOOK ON 2-27-03
		27FEB2003	8		1	3					
		28FEB2003	9	4	0	4					
		01MAR2003	10	4	0	4					
		02MAR2003	11	4	0	4					
		03MAR2003	12	4	0	4					
		04MAR2003	13	4	0	4					
		05MAR2003	14	4	0	4					
		06MAR2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	07MAR2003	16	4	0	4					
		08MAR2003	17	4	0	4					
		09MAR2003	18	4	0	4					
		10MAR2003	19	4	0	4					
		11MAR2003	20	4	1	3					DOSE DECREASED BY 1 TAB PER PROTOCOL
		12MAR2003	21	4	1	3					
		13MAR2003	22	4	1	3					
		14MAR2003	23	4	1	3					
		15MAR2003	24	4	1	3					
		16MAR2003	25	4	1	3					
		17MAR2003	26	4	1	3					
		18MAR2003	27	4	1	3					
		19MAR2003	28	4	4	0					FORGOT TO TAKE DOSE
		20MAR2003	29	4	1	3					
		21MAR2003	30	4	1	3					
		22MAR2003	31	4	1	3					
		23MAR2003	32	4	1	3					
		24MAR2003	33	4	1	3					
		25MAR2003	34	4	0	4					TOOK EXTRA TAB FROM COLUMN 1 ON 3-28-03
		26MAR2003	35	4	1	3					
		27MAR2003	36	4	1	3					
		28MAR2003	37	4	1	3					DROPPED 1 TAB DOWN DRAIN
		29MAR2003	38	4	1	3					
		30MAR2003	39	4	1	3					
		31MAR2003	40	4	1	3					
		01APR2003	41	4	1	3					
		02APR2003	42	4	1	3					
		03APR2003	43	4	1	3					
		04APR2003	44	4	1	3					
		05APR2003	45	4	1	3					
		06APR2003	46	4	4	0					MISSED THIS DOSE
		07APR2003	47	4	1	3					
		08APR2003	48	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	09APR2003	49	4	1	3					
		10APR2003	50	4	1	3					
		11APR2003	51	4	1	3					
		12APR2003	52	4	4	0					MISSED THIS DOSE
		13APR2003	53	4	1	3					
		14APR2003	54	4	1	3	YES	463.9	51	93	
	E0005003	02OCT2002	1	2	0	2					
		03OCT2002	2	1	0	1					
		04OCT2002	3	1	0	1					
		05OCT2002	4	2	0	2					
		06OCT2002	5	3	0	3					
		07OCT2002	6	3	0	3					
		08OCT2002	7	3	0	3					
		09OCT2002	8	4	0	4					
		10OCT2002	9	4	0	4					
		11OCT2002	10	4	0	4					
		12OCT2002	11	4	0	4					
		13OCT2002	12	4	0	4					
		14OCT2002	13	4	0	4					
		15OCT2002	14	4	0	4					
		16OCT2002	15	4	0	4					
		17OCT2002	16	4	0	4					
		18OCT2002	17	4	0	4					
		19OCT2002	18	4	0	4					
		20OCT2002	19	4	0	4					
		21OCT2002	20	4	0	4					
		22OCT2002	21	4	0	4					
		23OCT2002	22	4	1	3					DOSE REDUCED BEGINNING 10/23/03
		24OCT2002	23	4	1	3					
		25OCT2002	24	4	1	3					
		26OCT2002	25	4	1	3					
		27OCT2002	26	4	1	3					
		28OCT2002	27	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	29OCT2002	28	4	1	3					
		30OCT2002	29	4	1	3					SUBJECT SKIPPED DOSE
		31OCT2002	30	4	1	3					
		01NOV2002	31	4	1	3					
		02NOV2002	32	4	1	3					
		03NOV2002	33	4	1	3					
		04NOV2002	34	4	1	3					
		05NOV2002	35	4	1	3					
		06NOV2002	36	4	1	3					
		07NOV2002	37	4	1	3					
		08NOV2002	38	4	1	3					
		09NOV2002	39	4	1	3					
		10NOV2002	40	4	1	3					
		11NOV2002	41	4	1	3					
		12NOV2002	42	4	1	3					
		13NOV2002	43		1	3					
		14NOV2002	44	4	1	3					
		15NOV2002	45	4	1	3					
		16NOV2002	46	4	1	3					
		17NOV2002	47	4	1	3					
		18NOV2002	48	4	1	3					
		19NOV2002	49	4	1	3					
		20NOV2002	50	4	1	3					
		21NOV2002	51	4	1	3					
		22NOV2002	52	4	1	3					
		23NOV2002	53	4	1	3					
		24NOV2002	54	4	1	3					
		25NOV2002	55	4	1	3	YES	495.5	55	100	
	E0005005	30SEP2002	1	2	0	2					
		01OCT2002	2	1	0	1					
		02OCT2002	3	1	0	1					
		03OCT2002	4	2	0	2					
		04OCT2002	5	3	0	3					
		05OCT2002	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	06OCT2002	7	3	0	3					
		07OCT2002	8		0	4					- UNKN - BLISTER CARD NOT RETURNED
		08OCT2002	9		0	4	NO	338.9	9	100	
	E0005007	09OCT2002	1	2	0	2					
		10OCT2002	2	1	0	1					
		11OCT2002	3	1	0	1					
		12OCT2002	4	2	0	2					
		13OCT2002	5	3	0	3					
		14OCT2002	6	3	0	3					
		15OCT2002	7	3	0	3					
		16OCT2002	8	4	0	4					
		17OCT2002	9	4	0	4					
		18OCT2002	10	4	0	4					
		19OCT2002	11	4	0	4					
		20OCT2002	12	4	0	4					
		21OCT2002	13	4	0	4					
		22OCT2002	14	4	0	4					
		23OCT2002	15	4	0	4					
		24OCT2002	16	4	0	4					
		25OCT2002	17	4	0	4					
		26OCT2002	18	4	0	4					
		27OCT2002	19	4	0	4					
		28OCT2002	20	4	0	4					
		29OCT2002	21	4	0	4					
		30OCT2002	22	4	0	4					
		31OCT2002	23	4	0	4					
		01NOV2002	24	4	0	4					
		02NOV2002	25	4	0	4					
		03NOV2002	26	4	0	4					
		04NOV2002	27	4	0	4					
		05NOV2002	28	4	0	4					
		06NOV2002	29	4	0	4					
		07NOV2002	30	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	08NOV2002	31	4	0	4					
		09NOV2002	32	4	0	4					
		10NOV2002	33	4	0	4					
		11NOV2002	34	4	0	4					
		12NOV2002	35	4	0	4					
		13NOV2002	36		0	4					
		14NOV2002	37	4	0	4					
		15NOV2002	38	4	0	4					
		16NOV2002	39	4	0	4					
		17NOV2002	40	4	0	4					
		18NOV2002	41	4	0	4					
		19NOV2002	42	4	0	4					
		20NOV2002	43	4	0	4					NEW BLISTER CARD DISPENSED ON 11/20 (VISIT #8) - ONLY 6 DAYS BETWEEN VISITS
		21NOV2002	44	4	0	4					
		22NOV2002	45	4	0	4					
		23NOV2002	46	4	0	4					
		24NOV2002	47	4	0	4					
		25NOV2002	48	4	0	4					
		26NOV2002	49	4	0	4					NEW BLISTER CARD DISPENSED ON 11/26/02 (VISIT #9) - ONLY 6 DAYS BETWEEN VISITS
		27NOV2002	50	4	0	4					
		28NOV2002	51	4	0	4					
		29NOV2002	52	4	0	4					
		30NOV2002	53	4	0	4					
		01DEC2002	54	4	0	4					
		02DEC2002	55	4	0	4					
		03DEC2002	56		0	4	NO	558	56	100	
	E0005008	15OCT2002	1	2	0	2					
		16OCT2002	2	1	0	1					
		17OCT2002	3	1	0	1					
		18OCT2002	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	19OCT2002	5	3	0	3					
		20OCT2002	6	3	0	3					
		21OCT2002	7	3	0	3					
		22OCT2002	8	4	0	4					
		23OCT2002	9	4	0	4					
		24OCT2002	10	4	0	4					
		25OCT2002	11	4	0	4					
		26OCT2002	12	4	0	4					
		27OCT2002	13	4	0	4					
		28OCT2002	14	4	0	4					
		29OCT2002	15	4	0	4					
		30OCT2002	16	4	0	4					
		31OCT2002	17	4	0	4					
		01NOV2002	18	4	0	4					
		02NOV2002	19	4	0	4					
		03NOV2002	20	4	0	4					
		04NOV2002	21	4	0	4					
		05NOV2002	22		0	4					
		06NOV2002	23	4	0	4					
		07NOV2002	24	4	0	4					
		08NOV2002	25	4	0	4					
		09NOV2002	26	4	0	4					
		10NOV2002	27	4	0	4					
		11NOV2002	28	4	0	4					
		12NOV2002	29	4	0	4					
		13NOV2002	30	4	0	4					
		14NOV2002	31	4	0	4					
		15NOV2002	32	4	0	4					
		16NOV2002	33	4	0	4					
		17NOV2002	34	4	0	4					
		18NOV2002	35	4	0	4					
		19NOV2002	36	4	0	4					
		20NOV2002	37	4	0	4					
		21NOV2002	38	4	0	4					
		22NOV2002	39	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	23NOV2002	40	4	0	4					
		24NOV2002	41	4	0	4					
		25NOV2002	42	4	0	4					
		26NOV2002	43	4	0	4					
		27NOV2002	44	4	0	4					
		28NOV2002	45	4	0	4					
		29NOV2002	46	4	0	4					
		30NOV2002	47	4	0	4					
		01DEC2002	48	4	0	4					
		02DEC2002	49	4	0	4					
		03DEC2002	50	4	0	4					
		04DEC2002	51	4	0	4					
		05DEC2002	52	4	0	4					
		06DEC2002	53	4	0	4					
		07DEC2002	54	4	0	4					
		08DEC2002	55	4	0	4					
		09DEC2002	56		0	4					
		10DEC2002	57		0	4	NO	558.8	57	100	
	E0005009	29OCT2002	1	2	0	2					
		30OCT2002	2	1	0	1					
		31OCT2002	3	1	0	1					
		01NOV2002	4	2	0	2					- LAST DOSE (EARLY DISCONT.)
		05NOV2002									PER SUBJECT REPORT AS BLISTER CARD NOT RETURNED
		06NOV2002					NO	162.5	4	100	* NON - COMPLIANT WITH RETURN OF INVESTIGATIONAL BLISTER CARD
	E0005010	21OCT2002	1	2	0	2					
		22OCT2002	2	1	0	1					
		23OCT2002	3	1	0	1					
		24OCT2002	4	2	0	2					
		25OCT2002	5	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	26OCT2002	6	3	0	3					
		27OCT2002	7	3	0	3					
		28OCT2002	8	4	0	4					
		29OCT2002	9	4	0	4					
		30OCT2002	10	4	0	4					
		31OCT2002	11	4	0	4					
		01NOV2002	12	4	0	4					
		02NOV2002	13	4	0	4					
		03NOV2002	14	4	0	4					
		04NOV2002	15	4	0	8					SUBJECT TOOK 8 PILLS ON 11/4/03. WAS SICK TO STOMACH & VOMITED FIRST SET OF PILLS, THEN TOOK FROM EXTRA DUE TO VOMITING.
		05NOV2002	16	4	0	4					
		06NOV2002	17	4	0	4					
		07NOV2002	18	4	0	4					
		08NOV2002	19	4	0	4					
		09NOV2002	20	4	0	4					
		10NOV2002	21	4	0	4					
		11NOV2002	22		0	4					
		12NOV2002	23		0	4					
		13NOV2002	24	4	0	4					
		14NOV2002	25	4	0	4					
		15NOV2002	26	4	0	4					
		16NOV2002	27	4	0	4					
		17NOV2002	28	4	0	4					
		18NOV2002	29	4	0	4					
		19NOV2002	30	4	0	8					
		20NOV2002	31	4	0	4					
		21NOV2002	32	4	0	4					
		22NOV2002	33	4	0	4					
		23NOV2002	34	4	0	4					
		24NOV2002	35	4	0	4					
		25NOV2002	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	26NOV2002	37	4	0	4					
		27NOV2002	38	4	0	4					
		28NOV2002	39	4	0	4					
		29NOV2002	40	4	0	4					
		30NOV2002	41	4	0	4					
		01DEC2002	42	4	0	4					
		02DEC2002	43	4	0	4					
		03DEC2002	44	4	0	4					
		04DEC2002	45	4	0	4					
		05DEC2002	46	4	0	4					
		06DEC2002	47	4	0	4					
		07DEC2002	48	4	0	4					
		08DEC2002	49	4	0	4					
		09DEC2002	50	4	0	4					
		10DEC2002	51	4	0	4					
		11DEC2002	52	4	0	4					
		12DEC2002	53	4	0	4					
		13DEC2002	54	4	0	4					
		14DEC2002	55	4	0	4					
		15DEC2002	56	4	0	4					
		16DEC2002	57		0	4	NO	579.8	57	104	
	E0005012	14NOV2002	1	2	0	2					
		15NOV2002	2	1	0	1					
		16NOV2002	3	1	0	1					
		17NOV2002	4	2	0	2					
		18NOV2002	5	3	0	3					
		19NOV2002	6	3	0	3					
		20NOV2002	7	4	0	4					
		21NOV2002	8	4	0	4					
		22NOV2002	9	4	0	4					
		23NOV2002	10	4	0	4					
		24NOV2002	11	4	0	4					
		25NOV2002	12	4	0	4					
		26NOV2002	13	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005012	27NOV2002	14	4	0	4					
		28NOV2002	15	4	0	4					
		29NOV2002	16	4	0	4					
		30NOV2002	17	4	0	4					
		01DEC2002	18	4	0	4					
		02DEC2002	19	4	0	4					
		03DEC2002	20		0	4					
		04DEC2002	21		0	4					
		05DEC2002	22			0					
		06DEC2002	23	4	0	4					MISSED 12/5 DOSE
		07DEC2002	24	4	0	4					
		08DEC2002	25	4	0	4					
		09DEC2002	26	4	0	4					
		10DEC2002	27	4	0	4					
		11DEC2002	28	4	0	4					
		12DEC2002	29	4	0	4					
		13DEC2002	30	4	0	4					
		14DEC2002	31	4	0	4					
		15DEC2002	32	4	0	4					
		16DEC2002	33	4	0	4					
		17DEC2002	34		0	4					
		18DEC2002	35	4	0	4					
		19DEC2002	36	4	0	4					
		20DEC2002	37	4	0	4					
		21DEC2002	38	4	0	4					
		22DEC2002	39	4	0	4					
		23DEC2002	40	4	0	4					
		24DEC2002	41	4	0	4					
		25DEC2002	42	4	0	4					
		26DEC2002	43	4	0	4					
		27DEC2002	44	4	0	4					
		28DEC2002	45	4	0	4					
		29DEC2002	46	4	0	4					
		30DEC2002	47		0	4					
		31DEC2002	48		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005012	01JAN2003	49			0					
		02JAN2003	50	4	0	4					
		03JAN2003	51	4	0	4					
		04JAN2003	52	4	0	4					
		05JAN2003	53	4	0	4					
		06JAN2003	54	4	0	4	NO	538	52	96.6	
	E0005014	13NOV2002	1	2	0	2					
		14NOV2002	2	1	0	1					
		15NOV2002	3	1	0	1					
		16NOV2002	4	2	0	2					
		17NOV2002	5	3	0	3					
		18NOV2002	6	3	0	3					
		19NOV2002	7	3	0	3					
		20NOV2002	8	4	0	4					
		21NOV2002	9	4	0	4					
		22NOV2002	10	4	0	4					
		23NOV2002	11	4	0	4					
		24NOV2002	12	4	0	4					
		25NOV2002	13	4	0	4					
		26NOV2002	14	4	0	4					
		27NOV2002	15	4	0	4					
		28NOV2002	16	4	0	4					
		29NOV2002	17	4	0	4					
		30NOV2002	18	4	0	4					
		01DEC2002	19	4	0	4					
		02DEC2002	20	4	0	4					
		03DEC2002	21	4	1	3					PATIENT TAKING X3 PILLS DAILY
		04DEC2002	22	4	1	3					
		05DEC2002	23	4	1	3					
		06DEC2002	24	4	1	3					
		07DEC2002	25	4	1	3					
		08DEC2002	26	4	1	3					
		09DEC2002	27	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	10DEC2002	28		1	3					
		11DEC2002	29	4	1	3					
		12DEC2002	30	4	1	3					
		13DEC2002	31	4	1	3					
		14DEC2002	32	4	1	3					
		15DEC2002	33	4	1	3					
		16DEC2002	34	4	1	3					
		17DEC2002	35	4	1	3					
		18DEC2002	36	4	1	3					
		19DEC2002	37	4	1	3					
		20DEC2002	38	4	1	3					
		21DEC2002	39	4	1	3					
		22DEC2002	40	4	1	3					
		23DEC2002	41	4	1	3					
		24DEC2002	42	4	1	3					
		25DEC2002	43	4	1	3					
		26DEC2002	44	4	1	3					
		27DEC2002	45	4	1	3					
		28DEC2002	46	4	1	3					
		29DEC2002	47	4	1	3					
		30DEC2002	48	4	1	3					
		31DEC2002	49	4	1	3					
		01JAN2003	50	4	1	3					
		02JAN2003	51	4	1	3					
		03JAN2003	52	4	1	3					
		04JAN2003	53	4	1	3					
		05JAN2003	54	4	1	3	YES	493.5	54	100	
	E0005022	29JAN2003	1	2	0	2					
		30JAN2003	2	1	0	1					
		31JAN2003	3	1	0	1					
		01FEB2003	4	2	0	2					
		02FEB2003	5	3	0	3					
		03FEB2003	6	3	0	3					
		04FEB2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005022	05FEB2003	8	4	0	4					
		06FEB2003	9	4	0	4					
		07FEB2003	10	4	0	4					
		08FEB2003	11	4	0	4					
		09FEB2003	12	4	0	4					
		10FEB2003	13	4	0	4					
		11FEB2003	14	4	0	4					TOOK ON 2/19/03
		12FEB2003	15	4	0	8					TOOK ON 2/20/03
		13FEB2003	16	4	0	4					TOOK 1 - LOST PILL
		14FEB2003	17	4	0	4					
		15FEB2003	18	4	0	4					
		16FEB2003	19	4	0	4					
		17FEB2003	20	4	0	4					
		18FEB2003	21		0	4					
		19FEB2003	22		0	4					
		20FEB2003	23			0					
		21FEB2003	24	4	1	3					DOSE REDUCTION
		22FEB2003	25	4	1	3					DOSE REDUCTION
		23FEB2003	26	4	1	3					DOSE REDUCTION
		24FEB2003	27	4	1	3					DOSE REDUCTION
		25FEB2003	28	4	1	3					DOSE REDUCTION
		26FEB2003	29	4	1	3					DOSE REDUCTION
		27FEB2003	30	4	1	3					DOSE REDUCTION
		28FEB2003	31	4	1	3					DOSE REDUCTION
		01MAR2003	32	4	4	0					MISSED DOSE
		02MAR2003	33	4	1	3	YES	483.3	31	96.4	DOSE REDUCTION
	E0005025	27FEB2003	1	2	0	2					
		28FEB2003	2	1	0	1					
		01MAR2003	3	1	0	1					
		02MAR2003	4	2	0	2					
		03MAR2003	5	3	0	3					
		04MAR2003	6	3	0	3					
		05MAR2003	7	3	0	3					
		06MAR2003	8	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0005025	07MAR2003	9	4	0	4					
		08MAR2003	10	4	0	4					
		09MAR2003	11	4	0	4					
		10MAR2003	12	4	0	4					
		11MAR2003	13	4	0	4					
		12MAR2003	14	4	0	4					
		13MAR2003	15		1	3					SUBJECT DECREASED OWN DOSE, OMITTED COLUMN 4 PAGE 200
		14MAR2003	16	4	1	3					BEGAN DOSE REDUCTION - OMMITTED COLUMN I
		15MAR2003	17	4	1	3					
		16MAR2003	18	4	1	3					
		17MAR2003	19	4	1	3					
		18MAR2003	20	4	1	3					
		19MAR2003	21	4	1	3					
		20MAR2003	22	4	1	3					
		21MAR2003	23	4	2	2					MISSED ONE PILL COLUMN II
		22MAR2003	24	4	4	0					SKIPPED DOSE
		23MAR2003	25	4	1	3					
		24MAR2003	26	4	1	3					
		25MAR2003	27	4	1	3					
		26MAR2003	28	4	4	0					SKIPPED DOSE
		27MAR2003	29	4	1	3					
		28MAR2003	30	4	1	3					
		29MAR2003	31	4	1	3					
		30MAR2003	32	4	1	3					
		31MAR2003	33	4	1	3					
		01APR2003	34	4	1	3					
		02APR2003	35	4	1	3	YES	430	33	91.7	
	E0006019	07APR2003	1	2	0	2					
		08APR2003	2	1	0	1					
		09APR2003	3	1	0	1					
		10APR2003	4	2	0	2					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	11APR2003	5	3	0	3					
		12APR2003	6	3	0	3					
		13APR2003	7	3	0	3					
		14APR2003	8	4	0	4					
		15APR2003	9	4	0	4					
		16APR2003	10	4	0	4					
		17APR2003	11	4	0	4					
		18APR2003	12	4	0	4					
		19APR2003	13	4	0	4					
		20APR2003	14	4	0	4					
		21APR2003	15	4	0	4					
		22APR2003	16	4	0	4					
		23APR2003	17	4	0	4					
		24APR2003	18	4	0	4					
		25APR2003	19	4	0	4					
		26APR2003	20	4	0	4					
		27APR2003	21	4	0	4					
		28APR2003	22	4	0	4					
		29APR2003	23	4	0	4					
		30APR2003	24	4	0	4					
		01MAY2003	25	4	0	4					
		02MAY2003	26	4	0	4					
		03MAY2003	27	4	0	4					
		04MAY2003	28	4	0	4					
		05MAY2003	29	4	0	4					
		06MAY2003	30	4	0	4					
		07MAY2003	31	4	0	4					
		08MAY2003	32	4	0	4					
		09MAY2003	33	4	0	4					
		10MAY2003	34	4	0	4					
		11MAY2003	35	4	0	4					
		12MAY2003	36	4	0	4					
		13MAY2003	37	4	0	4					
		14MAY2003	38	4	0	4					
		15MAY2003	39	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	16MAY2003	40	4	0	4					
		17MAY2003	41	4	0	4					
		18MAY2003	42	4	0	4					
		19MAY2003	43	4	0	4					
		20MAY2003	44	4	0	4					
		21MAY2003	45	4	0	4					
		22MAY2003	46	4	0	4					
		23MAY2003	47	4	0	4					
		24MAY2003	48	4	0	4					
		25MAY2003	49	4	0	4					
		26MAY2003	50		0	4					REGULARLY SCHEDULED VISIT THIS DAY, BUT THE OFFICE WAS CLOSED ON THE 26TH MEMORIAL DAY.
		27MAY2003	51	4	0	4					
		28MAY2003	52	4	0	4					
		29MAY2003	53	4	0	4					
		30MAY2003	54	4	0	4					
		31MAY2003	55	4	0	4					
		01JUN2003	56	4	0	4					
		02JUN2003	57	4	0	4	NO	558.8	57	100	
	E0007005	31JAN2003	1	2	0	2					
		01FEB2003	2	1	0	1					
		02FEB2003	3	1	0	1					
		03FEB2003	4	2	0	2					
		04FEB2003	5	3	0	3					
		05FEB2003	6	3	0	3					
		06FEB2003	7	3	0	3					
		07FEB2003	8	4	0	4					
		08FEB2003	9	4	0	4					
		09FEB2003	10	4	0	4					
		10FEB2003	11	4	0	4					
		11FEB2003	12	4	0	4					
		12FEB2003	13	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	13FEB2003	14	4	0	4					
		14FEB2003	15	4	0	4					ACCIDENTALLY DISPENSED BLISTER PACK FOR DAYS 50 - 56
		15FEB2003	16	4	0	4					
		16FEB2003	17	4	0	4					
		17FEB2003	18	4	0	4					
		18FEB2003	19	4	0	4					
		19FEB2003	20	4	0	4					
		20FEB2003	21	4	0	4					
		21FEB2003	22		0	4					
		22FEB2003	23	4	0	4					ACCIDENTALLY DISPENSED BLISTER PACK FOR DAYS 15 - 21
		23FEB2003	24	4	0	4					
		24FEB2003	25	4	0	4					
		25FEB2003	26	4	0	4					
		26FEB2003	27	4	0	4					
		27FEB2003	28	4	0	4					
		28FEB2003	29	4	0	4					
		01MAR2003	30		0	4					
		02MAR2003	31		0	4					
		03MAR2003	32	4	0	4					ACCIDENTALLY DISPENSED BLISTER PACK FOR DAYS 22 - 28
		04MAR2003	33	4	0	4					
		05MAR2003	34	4	0	4					
		06MAR2003	35	4	0	4					
		07MAR2003	36	4	0	4					
		08MAR2003	37	4	0	4					
		09MAR2003	38	4	0	4					
		10MAR2003	39	4	0	4					ACCIDENTALLY DISPENSED BLISTER PACK FOR DAYS 29 - 35
		11MAR2003	40	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	12MAR2003	41	4	0	4					
		13MAR2003	42	4	0	4					
		14MAR2003	43	4	0	4					ACCIDENTALLY DISPENSED BLISTER PACK FOR DAYS 36 - 42
		15MAR2003	44	4	0	4					
		16MAR2003	45	4	0	4					
		17MAR2003	46	4	0	4					
		18MAR2003	47	4	0	4					
		19MAR2003	48	4	0	4					
		20MAR2003	49	4	0	4					
		21MAR2003	50	4	0	4					ACCIDENTALLY DISPENSED BLISTER PACK FOR DAYS 43 - 49
		22MAR2003	51	4	0	4					
		23MAR2003	52	4	0	4					
		24MAR2003	53	4	0	4					
		25MAR2003	54	4	0	4					
		26MAR2003	55	4	0	4					
		27MAR2003	56	4	0	4	NO	558	56	100	
	E0007015	16JUL2003	1	2	0	2					
		17JUL2003	2	1	0	1					
		18JUL2003	3	1	0	1					
		19JUL2003	4	2	0	2					
		20JUL2003	5	3	0	3					
		21JUL2003	6	3	0	3					
		22JUL2003	7	3	0	3					
		23JUL2003	8	4	0	4					
		24JUL2003	9	4	0	4					
		25JUL2003	10	4	0	4					
		26JUL2003	11	4	0	4					
		27JUL2003	12	4	0	4					
		28JUL2003	13	4	0	4					
		29JUL2003	14	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	30JUL2003	15		0	4					PT RETURNED TWO DAYS LATER THAN NORMAL
		31JUL2003	16		0	4					
		01AUG2003	17	4	0	4					
		02AUG2003	18	4	0	4					
		03AUG2003	19	4	0	4					
		04AUG2003	20	4	0	4					
		05AUG2003	21	4	0	4					
		06AUG2003	22	4	0	4					
		07AUG2003	23	4	0	4					
		08AUG2003	24	4	0	4					
		09AUG2003	25	4	0	4					
		10AUG2003	26	4	0	4					
		11AUG2003	27	4	0	4					
		12AUG2003	28	4	0	4					
		13AUG2003	29	4	0	4					
		14AUG2003	30	4	0	4					
		15AUG2003	31	4	0	4					
		16AUG2003	32	4	0	4					
		17AUG2003	33	4	0	4					
		18AUG2003	34	4	0	4					
		19AUG2003	35	4	0	4					
		20AUG2003	36	4	1	3					DECREASED DOSE
		21AUG2003	37	4	1	3					DECREASED DOSE
		22AUG2003	38	4	1	3					DECREASED DOSE
		23AUG2003	39	4	1	3					DECREASED DOSE
		24AUG2003	40	4	1	3					DECREASED DOSE
		25AUG2003	41	4	1	3					DECREASED DOSE
		26AUG2003	42	4	1	3					DECREASED DOSE
		27AUG2003	43	4	1	3					DECREASED DOSE
		28AUG2003	44	4	1	3					DECREASED DOSE
		29AUG2003	45	4	1	3					DECREASED DOSE
		30AUG2003	46	4	1	3					DECREASED DOSE
		31AUG2003	47	4	1	3					DECREASED DOSE
		01SEP2003	48	4	1	3					DECREASED DOSE
		02SEP2003	49	4	1	3					DECREASED DOSE

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	03SEP2003	50	4	1	3					DECREASED DOSE
		04SEP2003	51	4	1	3					DECREASED DOSE
		05SEP2003	52	4	1	3					DECREASED DOSE
		06SEP2003	53	4	1	3					DECREASED DOSE
		07SEP2003	54	4	1	3					DECREASED DOSE
		08SEP2003	55	4	1	3					DECREASED DOSE
		09SEP2003	56	4	1	3	YES	520.5	56	100	DECREASED DOSE
	E0009001	12NOV2002	1	2	0	2					
		13NOV2002	2	1	0	1					
		14NOV2002	3	1	0	1					
		15NOV2002	4	2	0	2					
		16NOV2002	5	3	0	3					
		17NOV2002	6	3	0	3					
		18NOV2002	7	3	0	3					
		19NOV2002	8		0	4					
		20NOV2002	9		0	4					
		21NOV2002	10	4	0	4					
		22NOV2002	11	4	0	4					
		23NOV2002	12	4	0	4					
		24NOV2002	13	4	0	4					
		25NOV2002	14	4	0	4					
		26NOV2002	15	4	0	4					
		27NOV2002	16	4	0	8					
		28NOV2002	17	4	0	4					
		29NOV2002	18	4	0	4					
		30NOV2002	19	4	0	4					
		01DEC2002	20	4	0	4					
		02DEC2002	21	4	0	4					
		03DEC2002	22	4	0	4					
		04DEC2002	23	4	0	4					
		05DEC2002	24	4	0	4					
		06DEC2002	25	4	0	4					
		07DEC2002	26	4	0	4					
		08DEC2002	27	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	09DEC2002	28	4	0	4					
		10DEC2002	29	4	0	4					
		11DEC2002	30	4	0	4					
		12DEC2002	31	4	0	4					
		13DEC2002	32	4	0	4					
		14DEC2002	33	4	0	4					
		15DEC2002	34	4	0	4					
		16DEC2002	35	4	0	4					
		17DEC2002	36	4	0	4					
		18DEC2002	37	4	0	4					
		19DEC2002	38	4	0	4					
		20DEC2002	39	4	0	4					
		21DEC2002	40	4	0	4					
		22DEC2002	41	4	0	4					
		23DEC2002	42	4	0	4					NEW CARD DISPENSED AT APPOINTMENT
		24DEC2002	43	4	0	4					
		25DEC2002	44	4	0	4					
		26DEC2002	45	4	0	4					
		27DEC2002	46	4	0	4					
		28DEC2002	47	4	0	4					
		29DEC2002	48	4	0	4					
		30DEC2002	49	4	0	4					BLISTER CARD NOT RETURNED
		31DEC2002	50	4	0	4					BLISTER CARD NOT RETURNED
		01JAN2003	51	4	0	4					BLISTER CARD NOT RETURNED
		02JAN2003	52	4	0	4					BLISTER CARD NOT RETURNED
		03JAN2003	53	4	0	4					BLISTER CARD NOT RETURNED
		04JAN2003	54	4	0	4					BLISTER CARD NOT RETURNED
		05JAN2003	55	4	0	4					BLISTER CARD NOT RETURNED
		06JAN2003	56		0	4					PT. REPORTED MED'S WERE DISCONTINUED ON 1/6/03, HOWEVER, HER MEDICATION WAS NOT RETURNED TO CONFIRM THIS TO BE TRUE.
		07JAN2003	57		0	4	NO	569.3	57	102	BLISTER CARD NOT RETURNED

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0010002	25NOV2002	1	2	0	2	NO	50	1	100	SUBJECT TOOK STUDY DRUG 1 NIGHT DATE OF LAST DOSE = 11/25/2002
	E0010009	26DEC2002	1	2	0	2					
		27DEC2002	2	1	0	1					
		28DEC2002	3	1	0	1					
		29DEC2002	4	2	0	2					
		30DEC2002	5	3	0	3					
		31DEC2002	6	3	0	3					
		01JAN2003	7	3	0	3					
		02JAN2003	8	4	0	4					
		03JAN2003	9	4	0	4					
		04JAN2003	10	4	0	4					
		05JAN2003	11	4	0	4					
		06JAN2003	12	4	0	4					
		07JAN2003	13	4	0	4					
		08JAN2003	14	4	0	4					
		09JAN2003	15	4	0	4					
		10JAN2003	16	4	0	4					
		11JAN2003	17	4	0	4					
		12JAN2003	18	4	0	4					
		13JAN2003	19	4	0	4					
		14JAN2003	20	4	0	4					
		15JAN2003	21	4	0	4					
		16JAN2003	22		0	4					
		17JAN2003	23	4	0	4					
		18JAN2003	24	4	0	4					
		19JAN2003	25	4	0	4					
		20JAN2003	26	4	0	4					
		21JAN2003	27	4	0	4					
		22JAN2003	28	4	0	4					SUBJECT SEEN FOR VISIT ON 22/JAN/2003
		23JAN2003	29	4	0	4					
		24JAN2003	30	4	0	4					
		25JAN2003	31	4	0	4					
		26JAN2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	27JAN2003	33	4	0	4					
		28JAN2003	34	4	0	4					
		29JAN2003	35		0	4					
		30JAN2003	36	4	0	4					
		31JAN2003	37	4	0	4					
		01FEB2003	38	4	0	4					
		02FEB2003	39	4	0	4					
		03FEB2003	40	4	0	4					
		04FEB2003	41	4	0	4					
		05FEB2003	42	4	0	4					
		06FEB2003	43	4	0	4					
		07FEB2003	44	4	0	4					
		08FEB2003	45	4	0	4					
		09FEB2003	46	4	0	4					
		10FEB2003	47	4	0	4					
		11FEB2003	48	4	0	4					
		12FEB2003	49		0	4					
		13FEB2003	50	4	0	4					
		14FEB2003	51	4	0	4					
		15FEB2003	52	4	0	4					
		16FEB2003	53	4	0	4					
		17FEB2003	54	4	0	4					
		18FEB2003	55	4	0	4	NO	557.3	55	100	
	E0010010	30DEC2002	1	2	0	2					
		31DEC2002	2	1	0	1					
		01JAN2003	3	1	0	1					
		02JAN2003	4	2	0	2					
		03JAN2003	5	3	0	3					
		04JAN2003	6	3	3	0					SUBJECT MISSED DOSE ON 2003/01/04 SHE TOOK TWO DOSES ON 2003/01/05
		05JAN2003	7	3	0	3					
		06JAN2003	8	4	0	4					
		07JAN2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0010010	08JAN2003	10	4	0	4					
		09JAN2003	11	4	0	4					
		10JAN2003	12	4	0	4					
		11JAN2003	13	4	0	4					
		12JAN2003	14	4	0	4	NO	403.6	13	93	
	E0010014	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					
		30JAN2003	3	1	0	1					
		31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					
		03FEB2003	7	3	0	3					
		04FEB2003	8	4	0	4					
		05FEB2003	9	4	0	4					
		06FEB2003	10	4	0	4					
		07FEB2003	11	4	0	4					
		08FEB2003	12	4	0	4					
		09FEB2003	13	4	0	4					
		10FEB2003	14	4	0	4					
		11FEB2003	15	4	0	4					
		12FEB2003	16	4	0	4					
		13FEB2003	17	4	0	4					
		14FEB2003	18	4	0	4					
		15FEB2003	19	4	0	4					
		16FEB2003	20	4	0	4					
		17FEB2003	21	4	0	4					
		18FEB2003	22	4	0	4					
		19FEB2003	23	4	0	4					
		20FEB2003	24	4	0	4					
		21FEB2003	25	4	0	4					
		22FEB2003	26	4	0	4					
		23FEB2003	27	4	0	4					
		24FEB2003	28	4	0	4					
		25FEB2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	26FEB2003	30	4	0	4					
		27FEB2003	31	4	0	4					
		28FEB2003	32	4	0	4					
		01MAR2003	33	4	0	4					
		02MAR2003	34	4	0	4					
		03MAR2003	35	4	0	4					
		04MAR2003	36	4	0	4					
		05MAR2003	37	4	0	4					
		06MAR2003	38	4	0	4					
		07MAR2003	39	4	0	4					
		08MAR2003	40	4	0	4					
		09MAR2003	41	4	0	4					
		10MAR2003	42	4	0	4					
		11MAR2003	43	4	0	4					
		12MAR2003	44	4	0	4					
		13MAR2003	45	4	0	4					
		14MAR2003	46	4	0	4					
		15MAR2003	47	4	0	4					
		16MAR2003	48	4	0	4					
		17MAR2003	49	4	0	4					
		18MAR2003	50	4	0	4					
		19MAR2003	51	4	0	4					
		20MAR2003	52	4	0	4					
		21MAR2003	53	4	0	4					
		22MAR2003	54	4	0	4					
		23MAR2003	55	4	0	4					
		24MAR2003	56	4	0	4	NO	558	56	100	
	E0010017	25FEB2003	1	2	0	2					
		26FEB2003	2	1	0	1					
		27FEB2003	3	1	0	1					
		28FEB2003	4	2	0	2					
		01MAR2003	5	3	0	3					
		02MAR2003	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	03MAR2003	7	3	3	0					CARD WAS REDISPENSED ON 3/03/03 FOR SUBJECT TO COMPLETE TITRATION; HOWEVER, SUBJECT MISSED DOSE ON 3/3/03
		04MAR2003	8	4	0	4					SIC DAY 1 DOES NOT EQUAL VISIT 3 DATE DUE TO BLISTERCARD 1 BEING REDISPENSED FOR SUBJECT TO COMPLETE TITRATION ON 3/3/03
		05MAR2003	9	4	0	4					
		06MAR2003	10	4	0	4					
		07MAR2003	11	4	0	4					
		08MAR2003	12	4	0	4					
		09MAR2003	13	4	0	4					
		10MAR2003	14	4	0	4					
		11MAR2003	15	4	0	4					
		12MAR2003	16	4	0	4					
		13MAR2003	17	4	0	4					
		14MAR2003	18	4	0	4					
		15MAR2003	19	4	0	4					
		16MAR2003	20	4	0	4					
		17MAR2003	21		0	4					
		18MAR2003	22	4	0	4					
		19MAR2003	23	4	0	4					
		20MAR2003	24	4	0	4					
		21MAR2003	25	4	0	4					
		22MAR2003	26	4	0	4					
		23MAR2003	27	4	0	4					
		24MAR2003	28	4	0	4					
		25MAR2003	29	4	0	4					
		26MAR2003	30	4	0	4					
		27MAR2003	31	4	0	4					
		28MAR2003	32	4	4	0					MISSED DOSE
		29MAR2003	33	4	0	4					
		30MAR2003	34	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	31MAR2003	35	4	0	4					
		01APR2003	36	4	0	4					
		02APR2003	37	4	0	4					
		03APR2003	38	4	0	4					
		04APR2003	39	4	0	4					
		05APR2003	40	4	0	4					
		06APR2003	41	4	0	4					
		07APR2003	42	4	0	4					
		08APR2003	43	4	0	4					
		09APR2003	44	4	0	4					
		10APR2003	45	4	0	4					
		11APR2003	46	4	0	4					
		12APR2003	47	4	0	4					
		13APR2003	48	4	0	4					
		14APR2003	49	4	0	4					
		15APR2003	50	4	0	4					
		16APR2003	51	4	0	4					
		17APR2003	52	4	0	4					
		18APR2003	53	4	0	4					
		19APR2003	54	4	0	4					
		20APR2003	55	4	0	4					
		21APR2003	56	4	0	4	NO	540.2	54	96.7	
	E0010023	17APR2003	1	2	0	2					
		18APR2003	2	1	0	1					
		19APR2003	3	1	0	1					
		20APR2003	4	2	0	2					
		21APR2003	5	3	0	3					
		22APR2003	6	3	0	3					
		23APR2003	7	3	0	3					
		24APR2003	8	4	0	4					
		25APR2003	9	4	0	4					
		26APR2003	10	4	0	4					
		27APR2003	11	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0010023	28APR2003					NO	386.4	11	100	SUBJECT STOPPED MEDICATION ON HER OWN. DAYS 5-7 WERE MISSED.
	E0010027	16JUN2003	1	2	0	2					
		17JUN2003	2	1	0	1					
		18JUN2003	3	1	0	1					
		19JUN2003	4	2	0	2					
		20JUN2003	5	3	0	3					
		21JUN2003	6	3	0	3					
		22JUN2003	7	3	3	0					MISSED DOSE
		23JUN2003	8	4	0	4					
		24JUN2003	9	4	0	4					
		25JUN2003	10	4	0	4					
		26JUN2003	11	4	0	4					
		27JUN2003	12	4	0	4					
		28JUN2003	13	4	0	4					
		29JUN2003					NO	388.5	12	92.3	SUBJECT DID NOT TAKE DAY 7 DOSE. REASON NOT KNOWN.
	E0010029	19JUN2003	1	2	0	2					
		20JUN2003	2	1	0	1					
		21JUN2003	3	1	0	1					
		22JUN2003	4	2	0	2					
		23JUN2003	5	3	0	3					
		24JUN2003	6	3	0	3					
		25JUN2003	7	3	0	3					
		26JUN2003	8	4	0	4					SIC - SUBJECT TOOK MEDICATION FROM BLISTERCARD 1 ON 06/25/2003 IN ORDER TO ACHIEVE FULL TITRATION.
		27JUN2003	9	4	0	4					
		28JUN2003					NO	338.9	9	100	SUBJECT STOPPED MEDICATION ON HIS OWN
	E0011022	09JUN2003	1	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	10JUN2003	2	1	0	1					
		11JUN2003	3	1	0	1					
		12JUN2003	4	2	0	2					
		13JUN2003	5	3	0	3					
		14JUN2003	6	3	0	3					
		15JUN2003	7	3	0	3					
		16JUN2003	8	4	0	4					
		17JUN2003	9	4	1	3					PATIENT HAD A REDUCED DOSE BY 100MG (1 TAB) STARTING ON 6-17-03
		18JUN2003	10	4	1	3					
		19JUN2003	11	4	1	3					
		20JUN2003	12	4	1	3					
		21JUN2003	13	4	1	3					
		22JUN2003	14	4	1	3					
		23JUN2003	15		1	3					PATIENT HAD A DOSE REDUCTION BY 100MG (1 TAB). PATIENT TOOK EXTRA DOSE DUE TO NEXT VISIT DATE WAS 6-24-03
		24JUN2003	16	4	1	3					PATIENT REDUCED DOSE BY 100MG (1 TAB)
		25JUN2003	17	4	1	3					
		26JUN2003	18	4	1	3					
		27JUN2003	19	4	1	3					
		28JUN2003	20	4	1	3					
		29JUN2003	21	4	1	3					
		30JUN2003	22	4	1	3					
		01JUL2003	23	4	1	3					PATIENT HAD A DOSE REDUCTION OF 100MG (1 TAB)
		02JUL2003	24	4	1	3					
		03JUL2003	25	4	1	3					
		04JUL2003	26	4	1	3					
		05JUL2003	27	4	1	3					
		06JUL2003	28	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	07JUL2003	29	4	1	3					
		08JUL2003	30	4	1	3					PATIENT HAD A DOSE REDUCTION OF 100MG (1 TAB)
		09JUL2003	31	4	1	3					
		10JUL2003	32	4	1	3					
		11JUL2003	33	4	1	3					
		12JUL2003	34	4	1	3					
		13JUL2003	35	4	1	3					
		14JUL2003	36	4	1	3					
		15JUL2003	37	4	1	3					PATIENT HAD A DOSE REDUCTION OF 100MG (1 TAB)
		16JUL2003	38	4	1	3					
		17JUL2003	39	4	1	3					
		18JUL2003	40	4	1	3					
		19JUL2003	41	4	1	3					
		20JUL2003	42	4	1	3					
		21JUL2003	43	4	1	3					
		22JUL2003	44		1	3					PATIENT HAD A DOSE REDUCTION OF 100MG (1 TAB). TOOK EXTRA DOSE DUE TO NEXT VISIT BEING ON 7-24-03
		23JUL2003	45		1	3					PATIENT HAD A DOSE REDUCTION OF 100MG (1 TAB) TOOK EXTRA DOSE DUE TO NEXT VISIT BEING ON 7-24-03
		24JUL2003	46	4	1	3					PATIENT HAD A DOSE REDUCTION OF 100MG (1 TAB)
		25JUL2003	47	4	1	3					
		26JUL2003	48	4	1	3					
		27JUL2003	49	4	1	3					
		28JUL2003	50	4	1	3					
		29JUL2003	51	4	1	3					
		30JUL2003	52	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	31JUL2003	53	4	1	3					PATIENT HAD A DOSE REDUCTION OF 100MG (1 TAB)
		01AUG2003	54	4	1	3					
		02AUG2003	55	4	1	3					
		03AUG2003	56	4	1	3					
		04AUG2003	57	4	1	3					
		05AUG2003					YES	472.8	57	100	PATIENTS APPOINTMENT WAS ON 05-AUG-2003
	E0013006	13MAR2003	1	2	0	2					-SUBJECT DID NOT DOSE ON 3/14/03 TO 3/17/03 SUBJECT DOSE FROM DAY 2 ON 3/18/03 SUBJECT DOSED FROM DAY 3 ON 3/19/03 SUBJECT DOSED FROM DAY 4 ON 3/20/03
		14MAR2003	2	1	1	0					-BECAUSE OF MISSED DOSES SUBJECT WAS GIVEN APPROVAL BY LRA TO DOSE WITH DAY 4 STUDY DRUG ON 3/20/03. -DUE TO AE SUBJECT DISCONTINUED STUDY DRUG ON 3/21/03.
		15MAR2003	3	1	0	1					
		16MAR2003	4			0					
		17MAR2003	5			0					
		18MAR2003	6			0					
		19MAR2003	7			0					
		20MAR2003	8	2	0	2	NO	31.25	3	27.8	
	E0013012	07MAY2003	1	2	0	2					
		08MAY2003	2	1	0	1					
		09MAY2003	3	1	0	1					
		10MAY2003	4	2	0	2					
		11MAY2003	5	3	0	3					
		12MAY2003	6	3	0	3					
		13MAY2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	14MAY2003	8		0	4					
		15MAY2003	9		0	4					
		16MAY2003	10	4	0	4					
		17MAY2003	11	4	0	4					
		18MAY2003	12	4	1	3					MISSED 1 TAB
		19MAY2003	13	4	0	4					
		20MAY2003	14	4	0	4					
		21MAY2003	15	4	0	4					
		22MAY2003	16	4	0	4					
		23MAY2003	17	4	0	4					
		24MAY2003	18	4	0	4					
		25MAY2003	19	4	0	4					
		26MAY2003	20	4	1	3					PT STARTED TAKING 3 TABLETS EVERY PM ON 2003/05/26 THRU 2003/05/28 BECAUSE SHE FELT LESS DROWSINESS ON 3 TABLETS.
		27MAY2003	21	4	1	3					
		28MAY2003	22	4	1	3					
		29MAY2003	23		0	4					
		30MAY2003	24	4	0	4					
		31MAY2003	25	4	1	3					PT TRIED TO TAKE 4 TABLETS EVERY PM (ON 5/30/03, 6/2/03 & 6/3/03). SHE WENT BACK TO 3 TABLETS EVERY PM BECAUSE OF DROWSINESS
		01JUN2003	26	4	1	3					
		02JUN2003	27	4	0	4					
		03JUN2003	28	4	0	4					
		04JUN2003	29	4	1	3					
		05JUN2003	30	4	1	3					DOSE REDUCED DUE TO AE
		06JUN2003	31	4	1	3					
		07JUN2003	32	4	1	3					
		08JUN2003	33	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	09JUN2003	34	4	1	3					
		10JUN2003	35	4	1	3					
		11JUN2003	36	4	1	3					
		12JUN2003	37	4	1	3					
		13JUN2003	38	4	1	3					
		14JUN2003	39	4	1	3					
		15JUN2003	40	4	1	3					
		16JUN2003	41	4	1	3					
		17JUN2003	42	4	1	3					
		18JUN2003	43	4	1	3					
		19JUN2003	44	4	1	3					
		20JUN2003	45	4	1	3					
		21JUN2003	46	4	1	3					
		22JUN2003	47	4	1	3					
		23JUN2003	48	4	1	3					
		24JUN2003	49	4	1	3					
		25JUN2003	50	4	1	3					
		26JUN2003	51	4	1	3					
		27JUN2003	52	4	1	3					
		28JUN2003	53	4	1	3					
		29JUN2003	54	4	1	3					
		30JUN2003	55	4	1	3					
		01JUL2003	56	4	1	3	YES	497.3	56	100	
	E0013014	03JUN2003	1	2	0	2					
		04JUN2003	2	1	0	1					
		05JUN2003	3	1	0	1					
		06JUN2003	4	2	0	2					
		07JUN2003	5	3	0	3					
		08JUN2003	6	3	0	3					
		09JUN2003	7	3	0	3					
		10JUN2003	8	4	0	4					
		11JUN2003	9	4	0	4					
		12JUN2003	10	4	0	4					
		13JUN2003	11	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0013014	14JUN2003	12	4	0	4					
		15JUN2003	13	4	0	4					
		16JUN2003	14	4	0	4					
		17JUN2003	15		0	4					
		18JUN2003	16		0	4					
		19JUN2003	17	4	0	4					
		20JUN2003	18	4	0	4					
		21JUN2003	19	4	0	4					
		22JUN2003	20	4	0	4					
		23JUN2003					NO	482.5	20	100	PT STATES REMOVED TABLET FROM BLISTER PACK, BUT DID NOT TAKE, DISCARDED TABS
	E0014005	11MAR2003	1	2	0	2					
		12MAR2003	2	1	0	1					
		13MAR2003	3	1	0	1					
		14MAR2003	4	2	0	2					
		15MAR2003	5	3	0	3					
		16MAR2003	6	3	0	3					
		17MAR2003	7	3	0	3					
		18MAR2003	8	4	0	4					
		19MAR2003	9	4	1	3					DECREASED DUE TO A/E
		20MAR2003	10	4	1	3					
		21MAR2003	11	4	1	3					
		22MAR2003	12	4	1	3					
		23MAR2003	13	4	1	3					
		24MAR2003	14	4	1	3					
		25MAR2003	15	4	1	3					
		26MAR2003	16	4	1	3					
		27MAR2003	17	4	1	3					
		28MAR2003	18	4	1	3					
		29MAR2003	19	4	1	3					
		30MAR2003	20	4	1	3					
		31MAR2003	21	4	1	3					
		01APR2003	22	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	02APR2003	23	4	1	3					
		03APR2003	24	4	1	3					
		04APR2003	25	4	1	3					
		05APR2003	26	4	1	3					
		06APR2003	27	4	1	3					
		07APR2003	28	4	3	1					MISSED ONE IN ERROR
		08APR2003	29	4	1	3					
		09APR2003	30	4	1	3					
		10APR2003	31	4	1	3					
		11APR2003	32	4	1	3					
		12APR2003	33	4	1	3					
		13APR2003	34	4	1	3					
		14APR2003	35	4	1	3					
		15APR2003	36		1	3					
		16APR2003	37	4	1	3					
		17APR2003	38	4	1	3					
		18APR2003	39	4	1	3					
		19APR2003	40	4	1	3					
		20APR2003	41	4	1	3					
		21APR2003	42	4	1	3					
		22APR2003	43	4	1	3					
		23APR2003	44	4	4	0					HELD DUE TO A/E'S THEN TITRATED TO 3/DAY
		24APR2003	45	4	3	1					
		25APR2003	46	4	2	2					
		26APR2003	47	4	2	2					
		27APR2003	48	4	1	3					
		28APR2003	49	4	1	3					
		29APR2003	50	4	1	3					
		30APR2003	51	4	1	3					
		01MAY2003	52	4	1	3					
		02MAY2003	53	4	1	3					
		03MAY2003	54	4	1	3					
		04MAY2003	55	4	1	3					
		05MAY2003	56	4	1	3	YES	427.7	55	92.8	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	01APR2003	1	2	0	2					
		02APR2003	2	1	0	1					
		03APR2003	3	1	0	1					
		04APR2003	4	2	0	2					
		05APR2003	5	3	0	3					
		06APR2003	6	3	0	3					
		07APR2003	7	3	0	3					
		08APR2003	8	4	3	1					HELD DOSES PER PHYSICIAN DUE TO A/E'S
		09APR2003	9	4	2	2					
		10APR2003	10	4	2	2					
		11APR2003	11	4	2	2					
		12APR2003	12	4	2	2					
		13APR2003	13	4	4	0					
		14APR2003	14	4	1	3					
		15APR2003	15	4	2	2					HELD DUE TO A/E
		16APR2003	16	4	4	0					
		17APR2003	17	4	3	1	YES	138.2	15	61.2	HELD DUE TO A/E
	E0014011	13MAY2003	1	2	0	2					
		14MAY2003	2	1	0	1					
		15MAY2003	3	1	0	1					
		16MAY2003	4	2	0	2					
		17MAY2003	5	3	0	3					
		18MAY2003	6	3	0	3					
		19MAY2003	7	3	0	3					
		20MAY2003	8	4	0	4					
		21MAY2003	9	4	0	4					
		22MAY2003	10	4	0	4					
		23MAY2003	11	4	4	0					HELD PER DR. STRONG
		24MAY2003	12	4	2	2					REDUCED DOSE
		25MAY2003	13	4	1	3					
		26MAY2003	14	4	1	3					
		27MAY2003	15	4	1	3					
		28MAY2003	16	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	29MAY2003	17	4	1	3					
		30MAY2003	18	4	1	3					
		31MAY2003	19	4	1	3					
		01JUN2003	20	4	1	3					
		02JUN2003	21	4	1	3					
		03JUN2003	22		1	3					
		04JUN2003	23	4	1	3					
		05JUN2003	24	4	1	3					
		06JUN2003	25	4	1	3					
		07JUN2003	26	4	1	3					
		08JUN2003	27	4	1	3					
		09JUN2003	28	4	1	3					
		10JUN2003	29	4	1	3					
		11JUN2003	30	4	1	3					
		12JUN2003	31	4	1	3					
		13JUN2003	32	4	1	3					
		14JUN2003	33	4	1	3					
		15JUN2003	34	4	1	3					
		16JUN2003	35	4	1	3					
		17JUN2003	36	4	1	3					
		18JUN2003	37	4	1	3					
		19JUN2003	38	4	1	3					
		20JUN2003	39	4	1	3					
		21JUN2003	40	4	1	3					
		22JUN2003	41	4	1	3					
		23JUN2003	42	4	1	3					
		24JUN2003	43		1	3					
		25JUN2003	44		1	3					
		26JUN2003	45	4	1	3					
		27JUN2003	46	4	1	3					
		28JUN2003	47	4	1	3					
		29JUN2003	48	4	1	3					
		30JUN2003	49	4	1	3					
		01JUL2003	50	4	1	3					
		02JUL2003	51	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	03JUL2003	52	4	1	3					
		04JUL2003	53	4	1	3					
		05JUL2003	54	4	1	3					
		06JUL2003	55	4	1	3					
		07JUL2003	56	4	1	3	YES	458	55	97	
	E0014012	27MAY2003	1	2	0	2					
		28MAY2003	2	1	0	1					
		29MAY2003	3	1	0	1					
		30MAY2003	4	2	0	2					
		31MAY2003	5	3	3	0					HELD DUE TO A/E
		01JUN2003	6	3	0	3					
		02JUN2003	7	3	0	3					
		03JUN2003	8	4	2	2					
		04JUN2003	9	4	1	3					DOSE REDUCED TO AE, AKATHISIA.
		05JUN2003	10	4	1	3					
		06JUN2003	11	4	1	3					
		07JUN2003	12	4	1	3					
		08JUN2003	13	4	1	3					
		09JUN2003	14	4	1	3					
		10JUN2003	15	4	1	3					
		11JUN2003	16	4	1	3					
		12JUN2003	17	4	1	3					
		13JUN2003	18	4	1	3					
		14JUN2003	19	4	1	3					
		15JUN2003	20	4	1	3					
		16JUN2003	21	4	1	3					
		17JUN2003	22	4	1	3					
		18JUN2003	23	4	1	3					
		19JUN2003	24	4	1	3					
		20JUN2003	25	4	1	3					
		21JUN2003	26	4	1	3					
		22JUN2003	27	4	1	3					
		23JUN2003	28	4	1	3	YES	408.9	27	94.9	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	29NOV2002	1	2	0	2					
		30NOV2002	2	1	0	1					
		01DEC2002	3	1	0	1					
		02DEC2002	4	2	0	2					
		03DEC2002	5	3	0	3					
		04DEC2002	6	3	0	3					
		05DEC2002	7	3	0	3					
		06DEC2002	8	4	0	4					
		07DEC2002	9	4	0	4					
		08DEC2002	10	4	0	4					
		09DEC2002	11	4	0	4					
		10DEC2002	12	4	0	4					
		11DEC2002	13	4	0	4					
		12DEC2002	14	4	0	4					
		13DEC2002	15	4	0	4					
		14DEC2002	16	4	0	4					
		15DEC2002	17	4	0	4					
		16DEC2002	18	4	0	4					
		17DEC2002	19	4	0	4					PT LOST/DROPPED USED REPLACEMENT 1ST EXTRA ROW TO DOSE 12/17/02
		18DEC2002	20	4	0	4					SUBJECT CONTINUED USING THE EXTRA ROW TO DOSE ON 12/18/02. DAY 6 AND DAY 7 ROWS WERE THEREFORE UNUSED WHEN SUBJ. RETURNED BLISTER CARD AT VISIT = 5.
		19DEC2002	21	4	0	4					
		20DEC2002	22	4	0	8					
		21DEC2002	23	4	0	8					
		22DEC2002	24	4	0	4					
		23DEC2002	25	4	0	4					
		24DEC2002	26	4	0	4					
		25DEC2002	27	4	0	4					
		26DEC2002	28		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	27DEC2002	29	4	0	4					
		28DEC2002	30	4	0	4					
		29DEC2002	31	4	0	4					
		30DEC2002	32	4	0	4					
		31DEC2002	33	4	0	4					
		01JAN2003	34	4	0	4					
		02JAN2003	35	4	0	4					
		03JAN2003	36	4	0	4					
		04JAN2003	37	4	0	4					
		05JAN2003	38	4	0	4					
		06JAN2003	39	4	0	4					
		07JAN2003	40	4	0	4					
		08JAN2003	41	4	0	4					
		09JAN2003	42	4	0	4					
		10JAN2003	43	4	0	4					
		11JAN2003	44	4	0	4					
		12JAN2003	45	4	0	4					
		13JAN2003	46	4	0	4					
		14JAN2003	47	4	0	4					
		15JAN2003	48	4	0	4					
		16JAN2003	49		0	4					
		17JAN2003	50		0	4	NO	577	50	104	
	E0015008	19DEC2002	1	2	0	2					
		20DEC2002	2	1	0	1					
		21DEC2002	3	1	0	1					
		22DEC2002	4	2	0	2					
		23DEC2002	5	3	0	3					
		24DEC2002	6	3	0	3					
		25DEC2002	7	3	0	3					
		26DEC2002	8		0	4					
		27DEC2002	9	4	0	4					
		28DEC2002	10	4	0	4					
		29DEC2002	11	4	0	4					
		30DEC2002	12	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0015008	31DEC2002	13	4	0	4					
		01JAN2003	14	4	0	4					
		02JAN2003	15	4	0	4					
		03JAN2003	16	4	0	4					
		04JAN2003	17	4	0	4					
		05JAN2003	18	4	0	4					
		06JAN2003	19	4	0	4					
		07JAN2003	20	4	0	4					
		08JAN2003	21	4	0	4					
		09JAN2003	22	4	0	4					
		10JAN2003	23	4	0	4					
		11JAN2003	24	4	0	4					
		12JAN2003	25	4	0	4					
		13JAN2003	26	4	0	4					
		14JAN2003	27	4	0	4					
		15JAN2003	28	4	0	4					
		16JAN2003	29	4	0	4					
		17JAN2003	30	4	0	4					
		18JAN2003	31	4	0	4					
		19JAN2003	32	4	0	4					
		20JAN2003	33	4	0	4					
		21JAN2003	34	4	0	4					
		22JAN2003	35	4	0	4					
		23JAN2003	36	4	0	4					PT. DID NOT RETURN BLISTER CARD/PT. INCARCERATED
		24JAN2003	37	4	0	4					
		25JAN2003	38	4	0	4					
		26JAN2003	39	4	0	4					
		27JAN2003	40	4	0	4					
		28JAN2003	41	4	0	4					
		29JAN2003	42	4	0	4					
		30JAN2003	43		0	4					NA
		31JAN2003	44		0	4	NO	546.6	44	100	
	E0016003	24JAN2003	1	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0016003	25JAN2003	2	1	0	1					
		26JAN2003	3	1	0	1					
		27JAN2003	4	2	0	2					
		28JAN2003	5	3	0	3					
		29JAN2003	6	3	0	3					
		30JAN2003	7	3	0	3					
		31JAN2003	8	4	0	4					
		01FEB2003	9	4	0	4					
		02FEB2003	10	4	0	4					
		03FEB2003	11	4	0	4					
		04FEB2003	12	4	0	4					
		05FEB2003	13	4	0	4					
		06FEB2003	14	4	0	4					
		07FEB2003	15	4	0	4					
		08FEB2003	16	4	0	4					
		09FEB2003	17	4	0	4					
		10FEB2003	18	4	0	4					
		11FEB2003	19	4	0	4					
		12FEB2003	20	4	0	4					
		13FEB2003	21	4	0	4					
		14FEB2003	22	4	0	4					
		15FEB2003	23	4	0	4					
		16FEB2003	24	4	0	4					
		17FEB2003	25	4	0	4					
		18FEB2003	26	4	0	4					
		19FEB2003	27	4	0	4					
		20FEB2003	28	4	0	4					
		21FEB2003	29	4	0	4					
		22FEB2003	30	4	0	4					
		23FEB2003	31	4	0	4					
		24FEB2003	32	4	0	4					
		25FEB2003	33	4	0	4					
		26FEB2003	34	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0016003	27FEB2003	35	4	1	3					3 TABS REDISPENSED ON 2/27/03 DUE TO DOSE REDUCTION
		28FEB2003	36	4	1	3					DOSE REDUCTION DONE INCORRECTLY BY LEAVING ONE TABLET IN COLUMN FOUR FROM ALL BLISTER CARDS (DAYS 1 - 7)
		01MAR2003	37	4	1	3					
		02MAR2003	38	4	1	3					
		03MAR2003	39	4	1	3					
		04MAR2003	40	4	1	3					
		05MAR2003	41	4	1	3					
		06MAR2003	42	4	1	3					
		07MAR2003	43	4	0	4					CARD NOT RETURNED AND SUBJECT CAN NOT REMEMBER SINCE SHE THREW CARD AWAY
		08MAR2003	44	4	0	4					
		09MAR2003	45	4	0	4					
		10MAR2003	46	4	0	4					
		11MAR2003	47	4	0	4					
		12MAR2003	48	4	0	4					
		13MAR2003	49	4	0	4					
		14MAR2003	50		0	4					UNK - SIC
		15MAR2003	51		0	4	YES	538.2	51	100	
	E0016005	25FEB2003	1	2	0	2					
		26FEB2003	2	1	0	1					
		27FEB2003	3	1	0	1					
		28FEB2003	4	2	0	2					
		01MAR2003	5	3	0	3					
		02MAR2003	6	3	0	3					
		03MAR2003	7	3	0	3					
		04MAR2003	8	4	0	4					BLISTER CARD WAS NOT RETURNED PATIENT REPORTED COMPLIANCE WITH STUDY DRUG DOSING

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	05MAR2003	9	4	0	4					
		06MAR2003	10	4	0	4					
		07MAR2003	11	4	0	4					
		08MAR2003	12	4	0	4					
		09MAR2003	13	4	0	4					
		10MAR2003	14	4	0	4					
		11MAR2003	15	4	0	8					UNK - SIC
		12MAR2003	16	4	0	8					
		13MAR2003	17	4	0	4					
		14MAR2003	18	4	0	4					
		15MAR2003	19	4	0	4					
		16MAR2003	20	4	0	4					
		17MAR2003	21	4	0	4					
		18MAR2003	22	4	0	4					
		19MAR2003	23	4	0	4					
		20MAR2003	24	4	0	4					
		21MAR2003	25	4	0	4					
		22MAR2003	26	4	0	4					
		23MAR2003	27	4	0	4					
		24MAR2003	28	4	0	4					
		25MAR2003	29	4	0	4					
		26MAR2003	30	4	0	4					
		27MAR2003	31	4	0	4					
		28MAR2003	32	4	0	4					
		29MAR2003	33	4	0	4					
		30MAR2003	34	4	0	4					
		31MAR2003	35	4	0	4					
		01APR2003	36	4	0	4					
		02APR2003	37	4	0	4					
		03APR2003	38	4	0	4					
		04APR2003	39	4	0	4					
		05APR2003	40	4	0	4					
		06APR2003	41	4	0	4					
		07APR2003	42	4	0	4					
		08APR2003	43	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	09APR2003	44	4	0	4					
		10APR2003	45	4	0	4					
		11APR2003	46	4	0	4					
		12APR2003	47	4	0	4					
		13APR2003	48	4	0	4					
		14APR2003	49	4	0	4					
		15APR2003	50		0	4					
		16APR2003	51		0	4					
		17APR2003	52	4	0	4					
		18APR2003	53	4	0	4					
		19APR2003	54	4	0	4					
		20APR2003	55	4	0	4					
		21APR2003	56	4	0	4					
		22APR2003					NO	579.5	56	104	SUBJECT RETURNED FOR DAY 57 VISIT ON 4/22/03
	E0018007	27DEC2002	1	2	0	2					
		28DEC2002	2	1	0	1					
		29DEC2002	3	1	0	1					
		30DEC2002	4	2	0	2					
		31DEC2002					NO	162.5	4	100	SAE DRUG STOPPED PERMANENTLY
	E0019005	05NOV2002	1	2	0	2					
		06NOV2002	2	1	0	1					
		07NOV2002	3	1	0	1					
		08NOV2002	4	2	0	2					
		09NOV2002	5	3	0	3					
		10NOV2002	6	3	0	3					
		11NOV2002	7	3	0	3					
		12NOV2002	8	4	0	4					
		13NOV2002	9	4	0	4					
		14NOV2002	10	4	0	4					
		15NOV2002	11	4	0	4					
		16NOV2002	12	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	17NOV2002	13	4	0	4					
		18NOV2002	14	4	0	4					
		19NOV2002	15	4	0	4					
		20NOV2002	16	4	0	4					
		21NOV2002	17	4	0	4					
		22NOV2002	18	4	0	4					
		23NOV2002	19	4	0	4					
		24NOV2002	20	4	0	4					
		25NOV2002	21	4	0	4					
		26NOV2002	22	4	0	4					
		27NOV2002	23	4	0	4					
		28NOV2002	24	4	0	4					
		29NOV2002	25	4	0	4					
		30NOV2002	26	4	0	4					
		01DEC2002	27	4	0	4					
		02DEC2002	28	4	0	4					
		03DEC2002	29		0	4					
		04DEC2002	30		0	4					
		05DEC2002	31	4	0	4					
		06DEC2002	32	4	0	4					
		07DEC2002	33	4	0	4					
		08DEC2002	34	4	0	4					
		09DEC2002	35	4	0	4					
		10DEC2002	36	4	0	4					
		11DEC2002	37	4	0	4					
		12DEC2002	38	4	0	4					
		13DEC2002	39	4	0	4					
		14DEC2002	40	4	0	4					
		15DEC2002	41	4	0	4					
		16DEC2002	42	4	0	4					
		17DEC2002	43	4	0	4					
		18DEC2002	44	4	0	4					
		19DEC2002	45	4	0	4					
		20DEC2002	46	4	0	4					
		21DEC2002	47	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	22DEC2002	48	4	0	4					
		23DEC2002	49	4	0	4					
		24DEC2002	50	4	0	4					
		25DEC2002	51	4	0	4					
		26DEC2002	52	4	0	4					
		27DEC2002	53	4	0	4					
		28DEC2002	54	4	0	4					
		29DEC2002	55	4	0	4					
		30DEC2002	56	4	0	4					
		31DEC2002	57	4	0	4					
		01JAN2003	58	4	0	4	NO	559.5	58	100	
	E0019015	02JAN2003	1	2	0	2					PT. DISCARDED BLISTER CARD #1 UNKNOWINGLY. INFORMATION WAS VERIFIED BY COORDINATOR @ VISIT 3.
		03JAN2003	2	1	0	1					
		04JAN2003	3	1	0	1					
		05JAN2003	4	2	0	2					
		06JAN2003	5	3	0	3					
		07JAN2003	6	3	0	3					
		08JAN2003	7	3	0	3					
		09JAN2003	8	4	0	4					
		10JAN2003	9	4	0	4					
		11JAN2003	10	4	0	4					
		12JAN2003	11	4	0	4					
		13JAN2003	12	4	0	4					
		14JAN2003	13	4	0	4					
		15JAN2003	14	4	0	4					
		16JAN2003	15	4	0	4					
		17JAN2003	16	4	0	4					
		18JAN2003	17	4	0	4					
		19JAN2003	18	4	0	4					
		20JAN2003	19	4	0	4					
		21JAN2003	20	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	22JAN2003	21	4	0	4					
		23JAN2003	22	4	0	4					
		24JAN2003	23	4	0	4					
		25JAN2003	24	4	0	4					
		26JAN2003	25	4	0	4					
		27JAN2003	26	4	0	4					
		28JAN2003	27	4	0	4					
		29JAN2003	28	4	0	4					
		30JAN2003	29	4	0	4					
		31JAN2003	30	4	0	4					
		01FEB2003	31	4	0	4					
		02FEB2003	32	4	0	4					
		03FEB2003	33	4	0	4					
		04FEB2003	34	4	0	4					
		05FEB2003	35	4	0	4					
		06FEB2003	36	4	2	2					PT. WAS ADVISED BY DR. JOSEPH TO ONLY TAKE COLUMN 1 & 4 (DOSE REDUCTION) DUE TO AE.
		07FEB2003	37	4	2	2					
		08FEB2003	38	4	2	2					
		09FEB2003	39	4	2	2					
		10FEB2003	40	4	2	2					
		11FEB2003	41	4	2	2					
		12FEB2003	42	4	2	2					
		13FEB2003	43	4	2	2					
		14FEB2003	44	4	2	2					
		15FEB2003	45	4	2	2					
		16FEB2003	46	4	2	2					
		17FEB2003	47	4	2	2					
		18FEB2003	48	4	2	2					
		19FEB2003	49	4	2	2					
		20FEB2003	50	4	2	2					
		21FEB2003	51	4	2	2					
		22FEB2003	52	4	2	2					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	23FEB2003	53	4	2	2					
		24FEB2003	54	4	2	2					
		25FEB2003	55	4	2	2					
		26FEB2003	56	4	2	2	YES	333	56	89	
	E0020004	09DEC2002	1	2	0	2					
		10DEC2002	2	1	0	1					
		11DEC2002	3	1	0	1					
		12DEC2002	4	2	0	2					
		13DEC2002	5	3	0	3					
		14DEC2002	6	3	0	3					
		15DEC2002	7	3	0	3					
		16DEC2002	8	4	0	4					
		17DEC2002	9	4	0	4					
		18DEC2002	10	4	0	4					
		19DEC2002	11	4	0	4					
		20DEC2002	12	4	0	4					REDISPENSED DAY 5, 6, AND 7 MEDS ON 12/20/02. BROUGHT BACK ON 12/31/02 WITH NO TABLETS. EXCEPT FOR EXTRA DAYS TABLETS.
		21DEC2002	13	4	0	4					
		22DEC2002	14	4	0	4					
		23DEC2002	15	4	0	4					
		24DEC2002	16	4	0	4					
		25DEC2002	17	4	0	4					
		26DEC2002	18	4	0	4					
		27DEC2002	19	4	0	4					
		28DEC2002	20	4	0	4					
		29DEC2002	21	4	0	4					
		30DEC2002	22		0	4					
		31DEC2002	23	4	0	4					
		01JAN2003	24	4	0	4					
		02JAN2003	25	4	0	4					
		03JAN2003	26	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	04JAN2003	27	4	0	4					
		05JAN2003	28	4	0	4					
		06JAN2003	29	4	0	4					
		07JAN2003	30	4	0	4					
		08JAN2003	31	4	0	4					
		09JAN2003	32	4	0	4					
		10JAN2003	33	4	0	4					
		11JAN2003	34	4	0	4					
		12JAN2003	35	4	0	4					
		13JAN2003	36	4	0	4					
		14JAN2003	37	4	0	4					
		15JAN2003	38	4	0	4					
		16JAN2003	39	4	0	4					
		17JAN2003	40	4	0	4					
		18JAN2003	41	4	0	4					
		19JAN2003	42	4	0	4					
		20JAN2003	43	4	0	4					
		21JAN2003	44		0	4	NO	546.6	44	100	
	E0020010	05FEB2003	1	2	0	2					
		06FEB2003	2	1	0	1					
		07FEB2003	3	1	0	1					
		08FEB2003	4	2	0	2					
		09FEB2003	5	3	0	3					
		10FEB2003	6	3	0	3					
		11FEB2003	7	3	0	3					
		12FEB2003	8	4	0	4					
		13FEB2003	9	4	0	4					
		14FEB2003	10	4	0	4					
		15FEB2003	11	4	0	4					
		16FEB2003	12	4	0	4					
		17FEB2003	13	4	0	4					
		18FEB2003	14	4	0	4					
		19FEB2003	15	4	0	4					
		20FEB2003	16	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020010	21FEB2003	17	4	0	4					
		22FEB2003	18	4	0	4					
		23FEB2003	19	4	0	4					
		24FEB2003	20	4	0	4					
		25FEB2003	21	4	0	4					
		26FEB2003	22	4	0	4					
		27FEB2003	23	4	0	4					
		28FEB2003	24	4	0	4					
		01MAR2003	25	4	0	4					
		02MAR2003	26	4	0	4					
		03MAR2003	27	4	0	4					
		04MAR2003	28	4	0	4					
		05MAR2003	29	4	0	4					
		06MAR2003	30	4	0	4					
		07MAR2003	31	4	0	4					
		08MAR2003	32	4	0	4					
		09MAR2003	33	4	0	4					
		10MAR2003	34	4	0	4					
		11MAR2003	35	4	0	4					
		12MAR2003	36	4	0	4					
		13MAR2003	37	4	0	4					
		14MAR2003	38	4	0	4					
		15MAR2003	39	4	0	4					
		16MAR2003	40	4	0	4					
		17MAR2003	41	4	0	4					
		18MAR2003	42	4	0	4					
		19MAR2003	43	4	0	4					
		20MAR2003	44	4	0	4					
		21MAR2003	45	4	0	4					
		22MAR2003	46	4	0	4					
		23MAR2003	47	4	0	4					
		24MAR2003	48		0	4					
		25MAR2003	49	4	0	4					
		26MAR2003	50	4	0	4					
		27MAR2003	51	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020010	28MAR2003	52	4	0	4					
		29MAR2003	53	4	0	4					
		30MAR2003	54	4	0	4					
		31MAR2003	55	4	0	4					
		01APR2003	56		0	4	NO	558	56	100	
	E0020014	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					
		20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8	4	0	4					
		26MAR2003	9	4	0	4					
		27MAR2003	10	4	0	4					
		28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					
		02APR2003	16	4	0	4					
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	4					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	4	0					SUBJECT INADVERTENTLY MISSED DOSE.
		08APR2003	22	4	0	4					
		09APR2003	23	4	0	4					
		10APR2003	24	4	0	4					
		11APR2003	25	4	0	4					
		12APR2003	26	4	0	4					
		13APR2003	27	4	0	4					
		14APR2003	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	15APR2003	29	4	0	4					
		16APR2003	30	4	0	4					
		17APR2003	31	4	0	4					
		18APR2003	32	4	0	4					
		19APR2003	33	4	0	4					
		20APR2003	34	4	0	4					
		21APR2003	35	4	0	4					
		22APR2003	36	4	0	4					
		23APR2003	37	4	0	4					
		24APR2003	38	4	0	4					
		25APR2003	39	4	0	4					
		26APR2003	40	4	0	4					
		27APR2003	41	4	0	4					
		28APR2003	42	4	0	4					
		29APR2003	43	4	0	4					
		30APR2003	44	4	0	4					
		01MAY2003	45	4	0	4					
		02MAY2003	46	4	0	4					
		03MAY2003	47	4	0	4					
		04MAY2003	48	4	0	4					
		05MAY2003	49	4	0	4					
		06MAY2003	50	4	0	4					
		07MAY2003	51	4	0	4					
		08MAY2003	52	4	0	4					
		09MAY2003	53	4	0	4					
		10MAY2003	54	4	0	4					
		11MAY2003	55	4	0	4	NO	546.4	54	98.1	
	E0020021	19MAY2003	1	2	0	2					
		20MAY2003	2	1	0	1					
		21MAY2003	3	1	0	1					
		22MAY2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	23MAY2003	5	3	0	3					REDISPENSED DAY 5,6,7 MEDS ON 5/23/03. BROUGHT BACK ON 6/2/03 WITH NO TABLETS EXCEPT FOR EXTRA DAYS TABLETS.
		24MAY2003	6	3	0	3					
		25MAY2003	7	3	0	3					
		26MAY2003	8	4	0	4					
		27MAY2003	9	4	0	4					
		28MAY2003	10	4	0	4					
		29MAY2003	11	4	0	4					
		30MAY2003	12	4	0	4					
		31MAY2003	13	4	0	4					
		01JUN2003	14	4	0	4					
		02JUN2003	15	4	0	4					
		03JUN2003	16	4	0	4					
		04JUN2003	17	4	0	4					
		05JUN2003	18	4	0	4					
		06JUN2003	19	4	0	4					
		07JUN2003	20	4	0	4					
		08JUN2003	21	4	4	0					PATIENT INADVERTENTLY MISSED DOSE.
		09JUN2003	22		4	0					PATIENT INADVERTENTLY MISSED DOSE.
		10JUN2003	23	4	0	4					
		11JUN2003	24	4	0	4					
		12JUN2003	25	4	0	4					
		13JUN2003	26	4	0	4					
		14JUN2003	27	4	0	4					
		15JUN2003	28	4	4	0					PATIENT INADVERTENTLY FORGOT DOSE. COUNSELED PT.
		16JUN2003	29	4	0	4					
		17JUN2003	30	4	0	4					
		18JUN2003	31	4	0	4					
		19JUN2003	32	4	0	4					
		20JUN2003	33	4	0	4					
		21JUN2003	34	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	22JUN2003	35	4	0	4					
		23JUN2003	36	4	0	4					
		24JUN2003	37	4	0	4					
		25JUN2003	38	4	0	4					
		26JUN2003	39	4	0	4					
		27JUN2003	40	4	0	4					
		28JUN2003	41	4	0	4					
		29JUN2003	42	4	0	4					
		30JUN2003	43	4	0	4					
		01JUL2003	44	4	0	4					
		02JUL2003	45	4	0	4					
		03JUL2003	46	4	0	4					
		04JUL2003	47	4	0	4					
		05JUL2003	48	4	0	4					
		06JUL2003	49	4	0	4					
		07JUL2003	50	4	0	4					
		08JUL2003	51	4	0	4					
		09JUL2003	52	4	0	4					
		10JUL2003	53	4	0	4					
		11JUL2003	54	4	0	4					
		12JUL2003	55	4	0	4					
		13JUL2003	56	4	0	4	NO	525.9	53	94.3	
	E0020023	17JUN2003	1	2	0	2					PATIENT IS TO TAKE STUDY MEDICATION ON 6/17/03 AS PATIENT WORKS NIGHT SHIFT. DAY SIC PAGE 199
		18JUN2003	2	1	0	1					
		19JUN2003	3	1	0	1					
		20JUN2003	4	2	0	2					
		21JUN2003	5	3	0	3					
		22JUN2003	6	3	0	3					
		23JUN2003	7	3	0	3					
		24JUN2003	8	4	0	4					
		25JUN2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	26JUN2003	10	4	0	4					
		27JUN2003	11	4	0	4					
		28JUN2003	12	4	0	4					
		29JUN2003	13	4	0	4					
		30JUN2003	14	4	0	4					
		01JUL2003	15	4	0	4					
		02JUL2003	16	4	0	4					
		03JUL2003	17	4	0	4					
		04JUL2003	18	4	0	4					
		05JUL2003	19	4	0	4					
		06JUL2003	20	4	0	4					
		07JUL2003	21	4	0	4					
		08JUL2003	22	4	0	4					
		09JUL2003	23	4	0	4					
		10JUL2003	24	4	0	4					
		11JUL2003	25	4	0	4					
		12JUL2003	26	4	0	4					
		13JUL2003	27	4	0	4					
		14JUL2003	28	4	0	4					
		15JUL2003	29	4	0	4					
		16JUL2003	30	4	0	4					
		17JUL2003	31	4	0	4					
		18JUL2003	32	4	0	4					
		19JUL2003	33	4	0	4					
		20JUL2003	34	4	0	4					
		21JUL2003	35	4	0	4					
		22JUL2003	36	4	0	4					
		23JUL2003	37	4	0	4					
		24JUL2003	38	4	0	4					
		25JUL2003	39	4	0	4					
		26JUL2003	40	4	0	4					
		27JUL2003	41	4	0	4					
		28JUL2003	42	4	0	4					
		29JUL2003	43	4	0	4					
		30JUL2003	44	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	31JUL2003	45	4	0	4					
		01AUG2003	46	4	0	4					
		02AUG2003	47	4	0	4					
		03AUG2003	48	4	0	4					
		04AUG2003	49	4	0	4					
		05AUG2003	50	4	0	4					
		06AUG2003	51	4	0	4					
		07AUG2003	52	4	0	4					
		08AUG2003	53	4	0	4					
		09AUG2003	54	4	0	4					
		10AUG2003	55	4	0	4	NO	557.3	55	100	
	E0022007	07NOV2002	1	2	0	2					STUDY MEDS NOT RETURNED PATIENT REPORTED 100% COMPLIANCE
		08NOV2002	2	1	0	1					
		09NOV2002	3	1	0	1					
		10NOV2002	4	2	0	2					
		11NOV2002	5	3	0	3					
		12NOV2002	6	3	0	3					
		13NOV2002	7	3	0	3					
		14NOV2002	8	4	0	8					
		15NOV2002	9	4	0	8					
		16NOV2002	10	4	0	4					
		17NOV2002	11	4	0	4					
		18NOV2002	12	4	0	4					
		19NOV2002	13	4	0	4					
		20NOV2002	14	4	0	4					
		21NOV2002	15		0	4					
		22NOV2002	16	4	0	4					
		23NOV2002	17	4	0	4					
		24NOV2002	18	4	0	4					
		25NOV2002	19	4	0	4					
		26NOV2002	20	4	0	4					
		27NOV2002	21	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022007	28NOV2002	22	4	0	4					
		29NOV2002	23		0	4					
		30NOV2002	24		0	4					
		01DEC2002	25			0					
		02DEC2002	26	4	0	4					PT. MISSED DOSE 12/1
		03DEC2002	27	4	0	4					
		04DEC2002	28	4	0	4					
		05DEC2002	29	4	0	4					
		06DEC2002	30	4	0	4					
		07DEC2002	31	4	0	4					
		08DEC2002	32	4	0	4	NO	545.3	31	103	
	E0022010										CARD NOT DISPENSED DUE TO PATIENT TAKING PERSONS EXTRA DOSES FROM OLD CARDS
		21NOV2002	1	2	0	2					
		22NOV2002	2	1	0	1					
		23NOV2002	3	1	0	1					
		24NOV2002	4	2	0	2					
		25NOV2002	5	3	0	3					
		26NOV2002	6	3	0	3					
		27NOV2002	7	3	0	3					
		28NOV2002	8		0	8					PT. TOOK BOTH EXTRA ROWS 11 - 28 - 02 IN ERROR
		29NOV2002	9	4	0	4					
		30NOV2002	10	4	0	4					
		01DEC2002	11	4	0	4					
		02DEC2002	12	4	0	4					
		03DEC2002	13	4	0	4					
		04DEC2002	14	4	0	4					
		05DEC2002	15	4	0	4					
		06DEC2002	16	4	0	4					
		07DEC2002	17	4	0	4					
		08DEC2002	18	4	0	4					
		09DEC2002	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	10DEC2002	20	4	0	4					
		11DEC2002	21	4	0	4					
		12DEC2002	22	4	0	4					
		13DEC2002	23	4	0	4					
		14DEC2002	24	4	0	4					
		15DEC2002	25	4	0	4					
		16DEC2002	26	4	0	4					
		17DEC2002	27	4	0	4					
		18DEC2002	28	4	0	4					
		19DEC2002	29		0	4					
		20DEC2002	30		0	4					
		21DEC2002	31			0					
		22DEC2002	32	4	0	4					PATIENT MISSED DOSE 12 - 21 - 02
		23DEC2002	33		0	4					
		24DEC2002	34		0	4					PATIENT MISSED DOSE 12 - 25 - 02
		25DEC2002	35			0					
		26DEC2002	36	4	0	4					
		27DEC2002	37	4	0	4					
		28DEC2002	38	4	0	4					
		29DEC2002	39	4	0	4					
		30DEC2002	40	4	0	4					
		31DEC2002	41	4	0	4					
		01JAN2003	42	4	0	4					
		02JAN2003	43	4	0	4					
		03JAN2003	44	4	0	4					
		04JAN2003	45	4	0	4					
		05JAN2003	46	4	0	4					
		06JAN2003	47	4	0	4					
		07JAN2003	48	4	0	4					
		08JAN2003	49	4	0	4					
		09JAN2003	50	4	0	4					
		10JAN2003	51	4	0	4					
		11JAN2003	52	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	12JAN2003	53	4	0	4					
		13JAN2003	54	4	0	4					
		14JAN2003	55	4	0	4					
		15JAN2003	56	4	0	4	NO	547.3	54	98.1	
	E0022012	05DEC2002	1	2	0	2					
		06DEC2002	2	1	0	1					
		07DEC2002	3	1	0	1					
		08DEC2002	4	2	0	2					
		09DEC2002	5	3	0	3					
		10DEC2002	6	3	0	3					
		11DEC2002	7	3	0	3					
		12DEC2002	8	4	0	4					
		13DEC2002	9	4	0	4					
		14DEC2002	10	4	0	4					
		15DEC2002	11	4	0	4					
		16DEC2002	12	4	0	4					
		17DEC2002	13	4	0	4					
		18DEC2002	14	4	0	4					
		19DEC2002	15	4	0	4					PATIENT CONTINUED DOSING FROM CARD #3 AFTER VISIT 5 ON 12/23/02
		20DEC2002	16	4	0	4					
		21DEC2002	17	4	0	4					
		22DEC2002	18	4	0	4					
		23DEC2002	19	4	0	4					
		24DEC2002	20	4	0	4					
		25DEC2002	21	4	0	4					
		26DEC2002	22	4	0	4					PATIENT BEGAN CARD #4 ON 12/26, NOT VISIT 5 DATE OF 12/23/02.
		27DEC2002	23	4	4	0					MISSED DOSE
		28DEC2002	24	4	0	4					
		29DEC2002	25	4	0	4					
		30DEC2002	26	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022012	31DEC2002	27	4	0	4					
		01JAN2003	28	4	0	4					
		02JAN2003	29	4	0	4					
		03JAN2003	30	4	0	4					
		04JAN2003	31	4	0	4					
		05JAN2003	32	4	0	4					
		06JAN2003	33	4	0	4					
		07JAN2003	34	4	0	4					
		08JAN2003	35	4	0	4					
		09JAN2003	36	4	0	4					
		10JAN2003	37	4	0	4					
		11JAN2003	38	4	0	4					
		12JAN2003	39	4	0	4					
		13JAN2003	40	4	0	4					
		14JAN2003	41	4	0	4					
		15JAN2003	42	4	0	4					
		16JAN2003	43	4	0	4					
		17JAN2003	44	4	0	4					
		18JAN2003	45	4	0	4					
		19JAN2003	46	4	0	4					
		20JAN2003	47	4	0	4					
		21JAN2003	48	4	0	4					
		22JAN2003	49	4	0	4					
		23JAN2003	50	4	0	4					PT. LOST MEDS
		24JAN2003	51	4	0	4					PT. LOST MEDS
		25JAN2003	52	4	0	4					
		26JAN2003	53	4	0	4					
		27JAN2003	54	4	0	4					
		28JAN2003	55	4	0	4					
		29JAN2003	56	4	0	4					
		30JAN2003									PT. LOST MEDS
		31JAN2003					NO	547.3	55	98.1	PT. LOST MEDS
	E0022019	11DEC2002	1	2	0	2					
		12DEC2002	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022019	13DEC2002	3	1	0	1					
		14DEC2002	4	2	0	2					
		15DEC2002	5	3	0	3					
		16DEC2002	6	3	0	3					
		17DEC2002	7	3	0	3					
		18DEC2002	8		0	4					
		19DEC2002	9	4	0	4					
		20DEC2002	10	4	0	4					
		21DEC2002	11	4	0	4					
		22DEC2002	12	4	0	4					
		23DEC2002	13	4	0	4					
		24DEC2002	14	4	0	4					
		25DEC2002	15	4	0	4					
		26DEC2002	16	4	0	4					
		27DEC2002	17	4	0	4					
		28DEC2002	18	4	0	4					
		29DEC2002	19	4	0	4					
		30DEC2002	20	4	0	4					
		31DEC2002	21	4	0	4					
		01JAN2003	22	4	0	4					
		02JAN2003	23		0	4					
		03JAN2003	24	4	0	4					
		04JAN2003	25	4	0	4					
		05JAN2003	26	4	0	4					
		06JAN2003	27	4	0	4					
		07JAN2003	28	4	0	4					
		08JAN2003	29	4	0	4					
		09JAN2003	30	4	0	4					
		10JAN2003	31	4	0	4					
		11JAN2003	32	4	0	4					
		12JAN2003	33	4	0	4					
		13JAN2003	34	4	0	4					
		14JAN2003	35	4	0	4					
		15JAN2003	36	4	0	4					
		16JAN2003	37		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022019	17JAN2003	38	4	0	4					
		18JAN2003	39	4	0	4					
		19JAN2003	40	4	0	4					
		20JAN2003	41	4	0	4					
		21JAN2003	42	4	0	4					
		22JAN2003	43	4	0	4					
		23JAN2003	44	4	4	0					PT FORGOT DOSE
		24JAN2003	45	4	0	4					
		25JAN2003	46	4	0	4					
		26JAN2003	47	4	0	4					
		27JAN2003	48	4	0	4					
		28JAN2003	49	4	0	4					
		29JAN2003	50	4	0	4					
		30JAN2003	51	4	0	4					
		31JAN2003	52	4	0	4					
		01FEB2003	53	4	0	4					
		02FEB2003	54	4	0	4					
		03FEB2003	55	4	0	4					
		04FEB2003	56	4	0	4					
		05FEB2003	57	4	0	4	NO	548.2	56	98.1	
	E0022025	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					
		30JAN2003	3	1	0	1					
		31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					
		03FEB2003	7	3	0	3	NO	264.3	7	100	
	E0022033	18FEB2003	1	2	0	2					
		19FEB2003	2	1	0	1					
		20FEB2003	3	1	0	1					
		21FEB2003	4	2	0	2					
		22FEB2003	5	3	0	3					
		23FEB2003	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	24FEB2003	7	3	0	3					
		25FEB2003	8	4	0	4					
		26FEB2003	9	4	0	4					
		27FEB2003	10	4	0	4					
		28FEB2003	11	4	0	4					
		01MAR2003	12	4	0	4					
		02MAR2003	13	4	0	4					
		03MAR2003	14	4	0	4					
		04MAR2003	15	4	0	4					
		05MAR2003	16	4	0	4					
		06MAR2003	17	4	0	4					
		07MAR2003	18	4	0	4					
		08MAR2003	19	4	0	4					
		09MAR2003	20	4	0	4					
		10MAR2003	21	4	0	4					
		11MAR2003	22	4	0	4					
		12MAR2003	23	4	0	4					
		13MAR2003	24	4	0	4					
		14MAR2003	25	4	0	4					
		15MAR2003	26	4	0	4					
		16MAR2003	27	4	0	4					
		17MAR2003	28	4	0	4					
		18MAR2003	29	4	0	4					
		19MAR2003	30	4	0	4					
		20MAR2003	31	4	0	4					
		21MAR2003	32	4	0	4					
		22MAR2003	33	4	0	4					
		23MAR2003	34	4	0	4					
		24MAR2003	35	4	0	4					
		25MAR2003	36		0	4					
		26MAR2003	37		0	4					
		27MAR2003	38	4	0	4					
		28MAR2003	39	4	0	4					
		29MAR2003	40	4	0	4					
		30MAR2003	41	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	31MAR2003	42	4	0	4					
		01APR2003	43	4	0	4					
		02APR2003	44	4	0	4					
		03APR2003	45	4	0	4					
		04APR2003	46	4	0	4					
		05APR2003	47	4	0	4					
		06APR2003	48	4	0	4					
		07APR2003	49	4	0	4					
		08APR2003	50	4	0	4					
		09APR2003	51	4	0	4					
		10APR2003	52	4	0	4					
		11APR2003	53	4	0	4					
		12APR2003	54	4	0	4					
		13APR2003	55	4	0	4					
		14APR2003	56	4	0	4	NO	558	56	100	
	E0022034	18FEB2003	1	2	0	2					
		19FEB2003	2	1	0	1					
		20FEB2003	3	1	0	1					
		21FEB2003	4	2	0	2					
		22FEB2003	5	3	0	3					
		23FEB2003	6	3	0	3					
		24FEB2003	7	3	0	3					
		25FEB2003	8	4	0	4					
		26FEB2003	9	4	0	4					
		27FEB2003	10	4	0	4					
		28FEB2003	11	4	0	4					
		01MAR2003	12	4	0	4					
		02MAR2003	13	4	0	4					
		03MAR2003	14	4	0	4					
		04MAR2003	15	4	0	4					
		05MAR2003	16	4	0	4					
		06MAR2003	17	4	0	4					
		07MAR2003	18	4	0	4					
		08MAR2003	19	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	09MAR2003	20	4	0	4					
		10MAR2003	21	4	0	4					
		11MAR2003	22	4	0	4					
		12MAR2003	23	4	0	4					
		13MAR2003	24	4	0	4					
		14MAR2003	25	4	0	4					
		15MAR2003	26	4	0	4					
		16MAR2003	27	4	0	4					
		17MAR2003	28	4	0	4					
		18MAR2003	29	4	0	4					
		19MAR2003	30	4	3	1					PT. TOOK ONLY 1 TAB, MISSED 3 IN ERROR.
		20MAR2003	31	4	0	4					
		21MAR2003	32	4	0	4					
		22MAR2003	33	4	0	4					
		23MAR2003	34	4	0	4					
		24MAR2003	35	4	0	4					
		25MAR2003	36	4	0	4					
		26MAR2003	37	4	0	4					
		27MAR2003	38	4	0	4					
		28MAR2003	39	4	0	4					
		29MAR2003	40	4	0	4					
		30MAR2003	41	4	0	4					
		31MAR2003	42	4	0	4					
		01APR2003	43	4	0	8					SIC PT. LOST PILLS FROM EXTRA ROW - DID NOT TAKE THEM.
		02APR2003	44	4	0	4					
		03APR2003	45	4	0	4					
		04APR2003	46	4	0	4					
		05APR2003	47	4	0	4					
		06APR2003	48	4	0	4					
		07APR2003	49	4	0	4					PT. RETURNED FOR VISIT 1 DAY EARLY.
		08APR2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	09APR2003	51	4	0	4					
		10APR2003	52	4	0	4					
		11APR2003	53	4	0	4					
		12APR2003	54	4	0	4					
		13APR2003	55	4	0	4					
		14APR2003					NO	557.3	55	100	PT. MISSED DOSE IN ERROR.
	E0022038	28FEB2003	1	2	0	2					
		01MAR2003	2	1	0	1					
		02MAR2003	3	1	0	1					
		03MAR2003	4	2	0	2					
		04MAR2003	5	3	0	3					
		05MAR2003	6	3	0	3					
		06MAR2003	7	3	0	3					
		07MAR2003	8	4	0	4					
		08MAR2003	9	4	0	4					
		09MAR2003	10	4	0	4					
		10MAR2003	11	4	0	4					
		11MAR2003	12	4	1	3					PT DOSE DECREASED TO 3 TABS
		12MAR2003	13	4	1	3					PT DOSE DECREASED TO 3 TABS
		13MAR2003	14	4	1	3					PT DOSE DECREASED TO 3 TABS
		14MAR2003	15	4	1	3					PT DOSE 3 QPM
		15MAR2003	16	4	1	3					
		16MAR2003	17	4	1	3					
		17MAR2003	18	4	1	3					
		18MAR2003	19	4	1	3					
		19MAR2003	20	4	1	3					
		20MAR2003	21	4	1	3					
		21MAR2003	22	4	1	3					PT TAKES 3 QPM
		22MAR2003	23	4	1	3					
		23MAR2003	24	4	1	3					
		24MAR2003	25	4	1	3					
		25MAR2003	26	4	1	3					
		26MAR2003	27	4	1	3					
		27MAR2003	28	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	28MAR2003	29	4	1	3					
		29MAR2003	30	4	1	3					
		30MAR2003	31	4	1	3					
		31MAR2003	32	4	1	3					
		01APR2003	33	4	1	3					
		02APR2003	34	4	1	3					
		03APR2003	35	4	1	3					
		04APR2003	36	4	1	3					
		05APR2003	37	4	1	3					
		06APR2003	38	4	1	3					
		07APR2003	39	4	1	3					
		08APR2003	40	4	1	3					
		09APR2003	41	4	1	3					
		10APR2003					YES	469.5	41	100	PT DID NOT TAKE DOSE ON 4-10-03 (ET)
	E0022039	06MAR2003	1	2	0	2					
		07MAR2003	2	1	0	1					
		08MAR2003	3	1	0	1					
		09MAR2003	4	2	0	2					
		10MAR2003	5	3	0	3					
		11MAR2003	6	3	0	3					
		12MAR2003	7	3	0	3					
		13MAR2003	8	4	0	4					
		14MAR2003	9	4	0	4					
		15MAR2003	10	4	0	4					
		16MAR2003	11	4	0	4					
		17MAR2003	12	4	0	4					
		18MAR2003	13	4	0	4					
		19MAR2003	14	4	4	0					PT FORGOT DOSE ON 3-19-03
		20MAR2003	15	4	1	3					PT DOSE DECREASED TO 3 TABS QPM STARTING 3-20-03
		21MAR2003	16	4	1	3					
		22MAR2003	17	4	1	3					
		23MAR2003	18	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	24MAR2003	19	4	1	3					
		25MAR2003	20	4	1	3					
		26MAR2003	21	4	1	3					
		27MAR2003	22	4	1	3					
		28MAR2003	23	4	1	3					
		29MAR2003	24	4	1	3					
		30MAR2003	25	4	1	3					
		31MAR2003	26	4	1	3					
		01APR2003	27	4	1	3					
		02APR2003	28	4	1	3					
		03APR2003	29		1	3					
		04APR2003	30	4	1	3					
		05APR2003	31	4	1	3					
		06APR2003	32	4	1	3					
		07APR2003	33	4	1	3					
		08APR2003	34	4	4	0					PT FORGOT DOSE
		09APR2003	35	4	1	3					
		10APR2003	36	4	1	6					
		11APR2003	37	4	1	3					
		12APR2003	38	4	1	3					
		13APR2003	39	4	1	3					
		14APR2003	40			0					
		15APR2003	41	4	1	3					
		16APR2003	42	4	1	3					
		17APR2003	43	4	1	3					
		18APR2003	44	4	1	6					
		19APR2003	45	4	1	3					
		20APR2003	46	4	1	3					
		21APR2003	47	4	1	3					
		22APR2003	48	4	1	3					
		23APR2003	49	4	1	3					
		24APR2003	50	4	1	6					
		25APR2003	51	4	1	3					
		26APR2003	52	4	1	3					
		27APR2003	53	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	28APR2003	54	4	1	3					
		29APR2003	55	4	1	3					
		30APR2003	56	4	1	3	YES	481.3	53	96.6	
	E0022046	20MAR2003	1	2	0	2					
		21MAR2003	2	1	0	1					
		22MAR2003	3	1	0	1					
		23MAR2003	4	2	0	2					
		24MAR2003	5	3	0	3					
		25MAR2003	6	3	0	3					
		26MAR2003	7	3	0	3					
		27MAR2003	8	4	0	4					
		28MAR2003	9	4	0	4					
		29MAR2003	10	4	0	4					
		30MAR2003	11	4	0	4					
		31MAR2003	12	4	0	4					
		01APR2003	13	4	0	4					
		02APR2003	14	4	0	4					
		03APR2003	15		0	4					
		04APR2003	16	4	0	4					
		05APR2003	17	4	0	4					
		06APR2003	18	4	0	4					
		07APR2003	19	4	0	4					
		08APR2003	20	4	0	4					
		09APR2003	21	4	0	4					
		10APR2003	22	4	0	4					
		11APR2003	23	4	0	4					
		12APR2003	24	4	0	4					
		13APR2003	25	4	0	4					
		14APR2003	26	4	0	4					
		15APR2003	27	4	0	4					
		16APR2003	28	4	0	4					
		17APR2003	29	4	0	4					
		18APR2003	30	4	0	4					
		19APR2003	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	20APR2003	32	4	0	4					
		21APR2003	33	4	0	4					
		22APR2003	34	4	0	4					
		23APR2003	35	4	0	4					
		24APR2003	36	4	0	4					PT DISCARDED BLISTER PACK WITH 12 TABS
		25APR2003	37	4	0	4					PATIENT DISCARDED BLISTER PACK WITH 12 TABS
		26APR2003	38	4	0	4					
		27APR2003	39	4	0	4					
		28APR2003	40	4	0	4					
		29APR2003	41	4	0	4					
		30APR2003	42	4	0	4					
		01MAY2003	43		0	4					PATIENT DISCARDED EMPTY BLISTER PACK
		02MAY2003	44		0	4					
		03MAY2003	45	4	0	4					
		04MAY2003	46	4	0	4					
		05MAY2003	47	4	0	4					
		06MAY2003	48	4	0	4					
		07MAY2003	49	4	0	4					
		08MAY2003	50	4	0	4					
		09MAY2003	51	4	0	4					
		10MAY2003	52		0	4					
		11MAY2003	53		0	4					
		12MAY2003	54	4	0	4					
		13MAY2003	55	4	0	4					
		14MAY2003	56	4	0	4					
		15MAY2003	57	4	0	4	NO	558.8	57	100	
	E0022048	01APR2003	1	2	0	2					
		02APR2003	2	1	0	1					
		03APR2003	3	1	0	1					
		04APR2003	4	2	0	2					
		05APR2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022048	06APR2003	6	3	0	3					
		07APR2003	7	3	0	3					
		08APR2003	8	4	0	4					
		09APR2003	9	4	0	4					
		10APR2003	10	4	0	4					
		11APR2003	11	4	0	4					
		12APR2003	12	4	0	4					
		13APR2003	13	4	0	4					
		14APR2003	14	4	0	4					PT LOST THESE PILLS
		15APR2003	15	4	1	3					PT TOOK THESE FOR 4-14-04 DOSE
		15APR2003	15	4	1	3					SIC PT DECREASED TO 3 TABS PER DAY DUE TO SUMMER
		16APR2003	16	4	1	3					
		17APR2003	17	4	1	3					
		18APR2003	18	4	1	3					
		19APR2003	19	4	1	3					
		20APR2003	20	4	1	3					
		21APR2003	21	4	1	3					
		22APR2003	22		1	3					
		23APR2003	23		1	3					
		24APR2003	24	4	1	3					
		25APR2003	25	4	1	3					
		26APR2003	26	4	1	3					
		27APR2003	27	4	1	3					
		28APR2003	28	4	1	3					
		29APR2003	29	4	1	3					
		30APR2003	30	4	1	3					
		01MAY2003	31		1	3					
		02MAY2003	32	4	1	3					
		03MAY2003	33	4	1	3					
		04MAY2003	34	4	1	3					
		05MAY2003	35	4	1	3					
		06MAY2003	36	4	1	3					
		07MAY2003	37	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022048	08MAY2003	38	4	1	3					
		09MAY2003	39	4	1	3					
		10MAY2003	40	4	1	3					
		11MAY2003	41	4	1	3					
		12MAY2003	42	4	1	3					
		13MAY2003	43	4	1	3					
		14MAY2003	44	4	1	3					
		15MAY2003	45	4	1	3					
		16MAY2003	46	4	1	3					
		17MAY2003	47	4	1	3					
		18MAY2003	48	4	1	3					
		19MAY2003	49	4	1	3					
		20MAY2003	50		1	3					PT MISSED 5-20-03 DOSE TOOK 5-21-03 DOSE THIS DAY
		21MAY2003	51		1	3					PT TOOK 5-22-03 DOSE THIS DAY
		22MAY2003	52			0					
		23MAY2003	53	4	0	4					PT DID NOT RETURN MEDS - LTFU
		24MAY2003	54	4	0	4					
		25MAY2003	55	4	0	4					
		26MAY2003	56	4	0	4					
		27MAY2003	57	4	0	4					
		28MAY2003	58	4	0	4					
		29MAY2003	59	4	0	4					
		30MAY2003	60		0	4					
		31MAY2003	61		0	4	YES	491	60	97.9	
	E0022051	07APR2003	1	2	0	2					
		08APR2003	2	1	0	1					
		09APR2003	3	1	0	1					
		10APR2003	4	2	0	2					
		11APR2003	5	3	0	3					
		12APR2003	6	3	0	3					
		13APR2003	7	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	14APR2003	8	4	0	4					
		15APR2003	9	4	0	4					
		16APR2003	10	4	0	4					
		17APR2003	11	4	0	4					
		18APR2003	12	4	0	4					
		19APR2003	13	4	0	4					
		20APR2003	14	4	0	4					
		21APR2003	15	4	0	4					
		22APR2003	16	4	0	4					
		23APR2003	17	4	0	4					
		24APR2003	18	4	0	4					
		25APR2003	19	4	0	4					
		26APR2003	20	4	0	4					
		27APR2003	21	4	0	4					
		28APR2003	22	4	0	4					
		29APR2003	23	4	0	4					
		30APR2003	24	4	0	4					
		01MAY2003	25	4	0	4					
		02MAY2003	26	4	0	4					
		03MAY2003	27	4	0	4					
		04MAY2003	28	4	0	4					
		05MAY2003	29	4	0	4					
		06MAY2003	30	4	0	4					
		07MAY2003	31	4	0	4					
		08MAY2003	32	4	0	4					
		09MAY2003	33	4	0	4					
		10MAY2003	34	4	0	4					
		11MAY2003	35	4	0	4					
		12MAY2003	36	4	0	4					
		13MAY2003	37	4	0	4					
		14MAY2003	38	4	0	4					
		15MAY2003	39	4	0	4					
		16MAY2003	40	4	0	4					
		17MAY2003	41	4	0	4					
		18MAY2003	42	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	19MAY2003	43	4	0	4					
		20MAY2003	44	4	0	4					
		21MAY2003	45	4	0	4					
		22MAY2003	46	4	0	4					
		23MAY2003	47	4	0	4					
		24MAY2003	48	4	0	4					
		25MAY2003	49	4	0	4					
		26MAY2003	50		0	4					
		27MAY2003	51		0	4					
		28MAY2003	52	4	0	4					
		29MAY2003	53	4	0	4					
		30MAY2003	54	4	0	4					
		31MAY2003	55	4	0	4					
		01JUN2003	56	4	0	4	NO	558	56	100	
	E0022053	11APR2003	1	2	0	2					MEDS NOT RETURNED
		12APR2003	2	1	0	1					
		13APR2003	3	1	0	1					
		14APR2003	4	2	0	2					
		15APR2003	5	3	0	3					
		16APR2003	6	3	0	3					
		17APR2003	7	3	0	3					
		18APR2003	8		0	4					
		19APR2003	9		0	4	NO	338.9	9	100	
	E0022058	21APR2003	1	2	0	2					
		22APR2003	2	1	0	1					
		23APR2003	3	1	0	1					
		24APR2003	4	2	0	2					
		25APR2003	5	3	0	3					
		26APR2003	6	3	0	3					
		27APR2003	7	3	0	3					
		28APR2003	8	4	0	4					
		29APR2003	9	4	0	4					
		30APR2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022058	01MAY2003	11	4	0	4					
		02MAY2003	12	4	0	4					
		03MAY2003	13	4	0	4					
		04MAY2003	14	4	0	4					
		05MAY2003	15	4	1	3					PT SWITCHED TO 3 TABS QD AS OF 5-5-03
		06MAY2003	16	4	1	3					
		07MAY2003	17	4	1	3					
		08MAY2003	18	4	1	3					
		09MAY2003	19	4	1	3					
		10MAY2003	20	4	1	3					
		11MAY2003	21	4	4	0					PT FORGOT DOSE THIS DAY
		12MAY2003	22	4	1	3					
		13MAY2003	23	4	1	3					
		14MAY2003	24	4	1	3					
		15MAY2003	25	4	1	3					
		16MAY2003	26	4	1	3					
		17MAY2003	27	4	1	3					
		18MAY2003	28	4	1	3					
		19MAY2003	29	4	1	3					
		20MAY2003	30	4	1	3					
		21MAY2003	31	4	1	3					
		22MAY2003					YES	453.2	30	95.8	PT STOPPED STUDY
	E0022061	30APR2003	1	2	0	2					
		01MAY2003	2	1	0	1					
		02MAY2003	3	1	0	1					
		03MAY2003	4	2	0	2					
		04MAY2003	5	3	0	3					
		05MAY2003	6	3	0	3					
		06MAY2003	7	3	0	3					
		07MAY2003	8	4	0	4					
		08MAY2003	9	4	0	4					
		09MAY2003	10	4	0	4					
		10MAY2003	11	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	11MAY2003	12	4	0	4					
		12MAY2003	13	4	0	4					
		13MAY2003	14	4	0	4					
		14MAY2003	15	4	0	4					
		15MAY2003	16	4	0	4					
		16MAY2003	17	4	0	4					
		17MAY2003	18	4	0	4					
		18MAY2003	19	4	0	4					
		19MAY2003	20	4	0	4					
		20MAY2003	21	4	0	4					
		21MAY2003	22		0	4					PT TOOK 5-21-03 DOSE FROM EXTRA
		22MAY2003	23	4	0	8					PT TOOK 5-27-03 DOSE FROM EXTRA
		23MAY2003	24	4	0	4					
		24MAY2003	25	4	0	4					
		25MAY2003	26	4	0	4					
		26MAY2003	27	4	0	4					
		27MAY2003	28	4	4	0					PT TOOK 5-27-03 DOSE FROM PREVIOUS PACK.
		28MAY2003	29	4	0	4					
		29MAY2003	30	4	0	4					
		30MAY2003	31	4	0	4					
		31MAY2003	32	4	0	4					
		01JUN2003	33	4	0	4					
		02JUN2003	34	4	0	4					
		03JUN2003	35	4	0	4					
		04JUN2003	36	4	0	4					DOSE TAKEN ON 6/17/03
		05JUN2003	37	4	0	4					
		06JUN2003	38	4	0	4					
		07JUN2003	39	4	0	4					
		08JUN2003	40	4	0	4					
		09JUN2003	41	4	0	4					
		10JUN2003	42	4	0	4					
		11JUN2003	43	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	12JUN2003	44	4	0	4					
		13JUN2003	45	4	0	4					
		14JUN2003	46	4	0	4					
		15JUN2003	47	4	0	4					
		16JUN2003	48	4	0	4					
		17JUN2003	49	4	0	4					TAKEN FROM EXTRA DAY FOR V6
		18JUN2003	50	4	0	4					
		19JUN2003	51	4	0	4					
		20JUN2003	52	4	0	4					
		21JUN2003	53	4	0	4					
		22JUN2003	54	4	0	4					
		23JUN2003	55	4	0	4					
		24JUN2003	56	4	0	4					
		25JUN2003	57		0	4	NO	558.8	56	100	
	E0022062	05MAY2003	1	2	0	2					
		06MAY2003	2	1	0	1					
		07MAY2003	3	1	0	1					
		08MAY2003	4	2	0	2					
		09MAY2003	5	3	0	3					
		10MAY2003	6	3	0	3					
		11MAY2003	7	3	0	3					
		12MAY2003	8	4	0	4					
		13MAY2003	9	4	0	4					
		14MAY2003	10	4	0	4					
		15MAY2003	11	4	0	4					
		16MAY2003	12	4	0	4					
		17MAY2003	13	4	0	4					
		18MAY2003	14	4	0	4					
		19MAY2003	15	4	0	4					
		20MAY2003	16	4	0	4					
		21MAY2003					NO	453.1	16	100	PT STOPPED STUDY MEDS

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022068	23MAY2003	1	2	0	2					BASELINE PROCEDURES AND DRUG DISPENSING OCCURRED ON DIFFERENT DAYS
		24MAY2003	2	1	0	1					
		25MAY2003	3	1	0	1					
		26MAY2003	4	2	0	2					
		27MAY2003	5	3	0	3					
		28MAY2003	6	3	0	3					
		29MAY2003	7	3	0	3					
		30MAY2003	8	4	0	4					
		31MAY2003	9	4	1	3					DOSE REDUCED THROUGH END OF STUDY.
		01JUN2003	10	4	1	3					
		02JUN2003	11	4	1	3					
		03JUN2003	12	4	1	3					
		04JUN2003	13	4	1	3					
		05JUN2003	14	4	0	4					CARD NOT RETURNED
		12JUN2003									UNKNOWN
		12JUN2003									CARD NOT RETURNED
		19JUN2003					YES	396.4	14	100	UNKNOWN
	E0022069	10JUN2003	1	2	0	2					
		11JUN2003	2	1	0	1					
		12JUN2003	3	1	0	1					
		13JUN2003	4	2	0	2					
		14JUN2003	5	3	0	3					
		15JUN2003	6	3	0	3					
		16JUN2003	7	3	0	3					
		17JUN2003	8	4	0	4					
		18JUN2003	9	4	0	4					
		19JUN2003	10	4	0	4					
		20JUN2003	11	4	0	4					
		21JUN2003	12	4	0	4					
		22JUN2003	13	4	0	4					
		23JUN2003	14	4	0	4					
		24JUN2003	15	4	0	4					
		25JUN2003	16	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	26JUN2003	17	4	0	4					
		27JUN2003	18	4	0	4					
		28JUN2003	19	4	0	4					
		29JUN2003	20	4	0	4					
		30JUN2003	21	4	0	4					
		01JUL2003	22	4	4	0					PT. LOST PILLS, MISSED DOSE 7-1-03
		02JUL2003	23	4	0	4					
		03JUL2003	24	4	0	4					
		04JUL2003	25	4	0	4					LOST 2 PILLS TOOK EXTRA
		05JUL2003	26	4	0	4					LOST 2 PILLS TOOK EXTRA
		06JUL2003	27	4	0	4					
		07JUL2003	28	4	0	4					
		08JUL2003	29	4	0	4					TOOK 2 7-4-03
		09JUL2003	30	4	0	4					TOOK 2 7-5-03
		10JUL2003	31	4	0	4					
		11JUL2003	32	4	0	4					
		12JUL2003	33	4	0	4					
		13JUL2003	34	4	0	4					
		14JUL2003	35	4	0	4					
		15JUL2003	36	4	0	4					
		16JUL2003	37	4	0	4					
		17JUL2003	38	4	0	4					
		18JUL2003	39	4	0	4					
		19JUL2003	40	4	0	4					
		20JUL2003	41	4	0	4					
		21JUL2003	42	4	0	4					
		22JUL2003	43	4	0	4					
		23JUL2003	44	4	0	4					
		24JUL2003	45	4	0	4					
		25JUL2003	46	4	0	4					
		26JUL2003	47	4	0	4					
		27JUL2003	48	4	0	4					
		28JUL2003	49	4	0	4					
		29JUL2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	30JUL2003	51	4	0	4					
		31JUL2003	52	4	0	4					
		01AUG2003	53	4	0	4					
		02AUG2003	54	4	0	4					PT. MISSED DOSE 8-2-03 DID NOT SKIP ROW AND TOOK ON 8-3-03
		03AUG2003	55	4	0	4	NO	546.4	54	98.1	TOOK THIS DOSE 8-4-03
	E0022071	30JUN2003	1	2	0	2					
		01JUL2003	2	1	0	1					
		02JUL2003	3	1	0	1					
		03JUL2003	4	2	0	2					
		04JUL2003	5	3	0	3					
		05JUL2003	6	3	0	3					
		06JUL2003	7	3	0	3					
		07JUL2003	8	4	0	4					
		08JUL2003	9	4	0	4					
		09JUL2003	10	4	0	4					
		10JUL2003	11	4	0	4					
		11JUL2003	12	4	0	4					
		12JUL2003	13	4	0	4					
		13JUL2003	14	4	0	4					
		14JUL2003	15	4	0	4					
		15JUL2003	16	4	0	4					
		16JUL2003	17	4	0	4					
		17JUL2003	18	4	0	4					
		18JUL2003	19	4	0	4					
		19JUL2003	20	4	0	4					
		20JUL2003	21	4	0	4					
		21JUL2003	22	4	0	4					
		22JUL2003	23	4	0	4					
		23JUL2003	24	4	0	4					
		24JUL2003	25	4	0	4					
		25JUL2003	26	4	0	4					
		26JUL2003	27	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	27JUL2003	28	4	0	4					
		28JUL2003	29	4	0	4					
		29JUL2003	30	4	0	4					
		30JUL2003	31	4	0	4					
		31JUL2003	32	4	0	4					
		01AUG2003	33	4	0	4					
		02AUG2003	34	4	0	4					
		03AUG2003	35	4	0	4					
		04AUG2003	36	4	0	4					
		05AUG2003	37	4	0	4					
		06AUG2003	38	4	0	4					
		07AUG2003	39	4	0	4					
		08AUG2003	40	4	0	4					
		09AUG2003	41	4	0	4					
		10AUG2003	42	4	0	4					
		11AUG2003	43	4	0	4					
		12AUG2003	44	4	0	4					
		13AUG2003	45	4	0	4					
		14AUG2003	46	4	0	4					
		15AUG2003	47	4	0	4					
		16AUG2003	48	4	0	4					
		17AUG2003	49	4	0	4					
		18AUG2003	50	4	0	4					
		19AUG2003	51	4	0	4					
		20AUG2003	52	4	0	4					
		21AUG2003	53	4	0	4					
		22AUG2003	54	4	0	4					
		23AUG2003	55	4	0	4					
		24AUG2003	56	4	0	4	NO	558	56	100	
	E0023003	17DEC2002	1	2	0	2					
		18DEC2002	2	1	0	1					
		19DEC2002	3	1	0	1					
		20DEC2002	4	2	0	2					
		21DEC2002	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	22DEC2002	6	3	0	3					
		23DEC2002	7	3	0	3					BLISTER PACK REDISPENSED ON V3 (12-23-02) IN ORDER FOR PT TO TAKE D. 7 MED.
		24DEC2002	8	4	0	4					CARD NOT RETURNED
		25DEC2002	9	4	0	4					
		26DEC2002	10	4	0	4					
		27DEC2002	11	4	0	4					
		28DEC2002	12	4	0	4					
		29DEC2002	13	4	0	4					
		30DEC2002	14	4	0	4					UNK IF TAKEN
		31DEC2002	15	4	0	8					UNK IF TAKEN
		01JAN2003	16	4	0	8					UNK IF TAKEN
		02JAN2003	17	4	0	4					
		03JAN2003	18	4	0	4					
		04JAN2003	19	4	0	4					
		05JAN2003	20	4	0	4					
		06JAN2003	21	4	0	4					
		07JAN2003	22	4	0	4					
		08JAN2003	23	4	0	4					
		09JAN2003	24	4	0	4					
		10JAN2003	25	4	0	4					
		11JAN2003	26	4	0	4					
		12JAN2003	27	4	0	4					
		13JAN2003	28	4	0	4					
		14JAN2003	29		0	4					
		15JAN2003	30		0	4					
		16JAN2003	31	4	0	4					
		17JAN2003	32	4	0	4					
		18JAN2003	33	4	0	4					
		19JAN2003	34	4	0	4					
		20JAN2003	35	4	0	4					
		21JAN2003	36	4	3	1					
		22JAN2003	37	4	0	4					
		23JAN2003	38	4	0	8					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	24JAN2003	39	4	0	8					
		25JAN2003	40	4	0	4					
		26JAN2003	41	4	0	4					
		27JAN2003	42	4	4	0					
		28JAN2003	43	4	0	4					
		29JAN2003	44	4	0	4					
		30JAN2003	45	4	0	4					LOST DOSE AFTER TAKING MEDICATION OUT - DID NOT TAKE
		31JAN2003	46	4	0	4					
		01FEB2003	47	4	0	4					
		02FEB2003	48	4	0	4					
		03FEB2003	49	4	0	4					
		04FEB2003	50	4	0	4					
		05FEB2003	51	4	0	4					
		06FEB2003	52	4	0	4					PT LOST DOSE
		07FEB2003	53	4	0	4					
		08FEB2003	54	4	0	4					
		09FEB2003	55	4	0	4					
		10FEB2003	56	4	0	4					
		11FEB2003					NO	579.5	55	104	PT TERMINATED STUDY AT V. 10
	E0023006	17DEC2002	1	2	0	2					
		18DEC2002	2	1	0	1					
		19DEC2002	3	1	0	1					
		20DEC2002	4	2	0	2					
		21DEC2002	5	3	0	3					
		22DEC2002	6	3	0	3					
		23DEC2002	7	3	3	0					
		24DEC2002	8	4	0	4					
		25DEC2002	9	4	0	4					
		26DEC2002	10	4	0	4					
		27DEC2002	11	4	0	4					
		28DEC2002	12	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	29DEC2002	13	4	0	4					
		30DEC2002	14	4	4	0					PT. MISSED DOSE
		31DEC2002	15		4	0					PT. MISSED DOSE
		01JAN2003	16		4	0					PT. MISSED DOSE
		02JAN2003	17	4	0	4					
		03JAN2003	18	4	0	4					
		04JAN2003	19	4	0	4					
		05JAN2003	20	4	0	4					
		06JAN2003	21	4	0	4					
		07JAN2003	22	4	0	4					
		08JAN2003	23	4	0	4					
		09JAN2003	24	4	0	4					
		10JAN2003	25	4	0	4					
		11JAN2003	26	4	0	4					
		12JAN2003	27	4	0	4					
		13JAN2003	28	4	0	4					
		14JAN2003	29	4	0	4					
		15JAN2003	30	4	0	4					
		16JAN2003	31	4	0	4					
		17JAN2003	32	4	0	4					
		18JAN2003	33	4	0	4					
		19JAN2003	34	4	0	4					
		20JAN2003	35	4	0	4					
		21JAN2003	36	4	1	3					DAY 6: DOSE REDUCED
		22JAN2003	37	4	1	3					DOSE REDUCED THROUGH END OF STUDY
		23JAN2003	38	4	1	3					
		24JAN2003	39	4	1	3					
		25JAN2003	40	4	1	3					
		26JAN2003	41	4	1	3					
		27JAN2003	42	4	1	3					
		28JAN2003	43	4	1	3					DOSE REDUCED THROUGH END OF STUDY
		29JAN2003	44	4	1	3					
		30JAN2003	45	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	31JAN2003	46	4	1	3					
		01FEB2003	47	4	1	3					
		02FEB2003	48	4	1	3					
		03FEB2003	49	4	1	3					
		04FEB2003	50	4	1	3					DOSE REDUCED THROUGH END OF STUDY
		05FEB2003	51	4	1	3					
		06FEB2003	52	4	1	3					
		07FEB2003	53	4	1	3					
		08FEB2003	54	4	1	3					
		09FEB2003	55	4	1	3					
		10FEB2003	56	4	1	3	YES	481.3	52	92.1	
	E0023010	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					
		11FEB2003	8	4	0	4					
		12FEB2003	9	4	0	4					
		13FEB2003	10	4	0	4					
		14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	0	4					
		18FEB2003	15	4	0	4					
		19FEB2003	16	4	0	4					
		20FEB2003	17	4	0	4					
		21FEB2003	18	4	0	4					
		22FEB2003	19	4	0	4					
		23FEB2003	20	4	0	4					
		24FEB2003	21	4	0	4					
		25FEB2003	22	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	26FEB2003	23	4	0	4					
		27FEB2003	24	4	0	4					
		28FEB2003	25	4	0	4					
		01MAR2003	26	4	0	4					
		02MAR2003	27	4	0	4					
		03MAR2003	28	4	0	4					
		04MAR2003	29	4	1	3					DOSE REDUCED
		05MAR2003	30	4	1	3					
		06MAR2003	31	4	1	3					
		07MAR2003	32	4	1	3					
		08MAR2003	33	4	1	3					
		09MAR2003	34	4	1	3					
		10MAR2003	35	4	1	3					
		11MAR2003	36	4	1	3					DOSE REDUCED
		12MAR2003	37	4	1	3					
		13MAR2003	38	4	1	3					
		14MAR2003	39	4	1	3					
		15MAR2003	40	4	1	3					
		16MAR2003	41	4	4	0					MISSED DOSE
		17MAR2003	42	4	1	3					
		18MAR2003	43	4	1	3					
		19MAR2003	44	4	1	3					
		20MAR2003	45	4	1	3					
		21MAR2003	46	4	1	3					
		22MAR2003	47	4	1	3					
		23MAR2003	48	4	1	3					
		24MAR2003	49	4	1	3					
		25MAR2003	50	4	1	3					
		26MAR2003	51	4	1	3					
		27MAR2003	52	4	1	3					
		28MAR2003	53	4	1	3					
		29MAR2003	54	4	1	3					
		30MAR2003	55	4	1	3					
		31MAR2003					YES	499.1	54	97.8	CAME IN 1 D EARLY

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023025	15MAY2003	1	2	0	2					
		16MAY2003	2	1	0	1					
		17MAY2003	3	1	0	1					
		18MAY2003	4	2	0	2					
		19MAY2003	5	3	0	3					
		20MAY2003	6	3	0	3					
		21MAY2003	7	3	0	3					
		22MAY2003	8	4	0	4					
		23MAY2003	9	4	0	4					
		24MAY2003	10	4	0	4					
		25MAY2003	11	4	0	4					
		26MAY2003	12	4	0	4					
		27MAY2003	13	4	0	4					
		28MAY2003	14	4	0	4					
		29MAY2003	15	4	0	4					
		30MAY2003	16	4	0	4					
		31MAY2003	17	4	0	4					
		01JUN2003	18	4	0	4					
		02JUN2003	19	4	0	4					
		03JUN2003	20	4	0	4					
		04JUN2003	21	4	0	4					
		05JUN2003	22	4	0	4					
		06JUN2003	23	4	0	4					
		07JUN2003	24	4	0	4					
		08JUN2003	25	4	0	4					
		09JUN2003	26	4	0	4					
		10JUN2003	27	4	0	4					
		11JUN2003	28	4	0	4					
		12JUN2003	29	4	0	4					
		13JUN2003	30	4	0	4					
		14JUN2003	31	4	0	4					
		15JUN2003	32	4	0	4					
		16JUN2003	33	4	0	4					
		17JUN2003	34	4	0	4					
		18JUN2003	35	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023025	19JUN2003	36	4	0	4					
		20JUN2003	37	4	0	4					
		21JUN2003	38	4	0	4					
		22JUN2003	39	4	0	4					
		23JUN2003	40	4	0	4					
		24JUN2003	41	4	0	4					
		25JUN2003	42	4	0	4					
		26JUN2003	43		0	4					
		27JUN2003	44	4	0	4					
		28JUN2003	45	4	0	4					
		29JUN2003	46	4	0	4					
		30JUN2003	47	4	0	4					
		01JUL2003	48	4	0	4					
		02JUL2003	49	4	0	4					
		03JUL2003	50	4	0	4					PT APPT 7/3 AM
		04JUL2003	51	4	0	4					
		05JUL2003	52	4	0	4					
		06JUL2003	53	4	0	4					
		07JUL2003	54	4	0	4					
		08JUL2003	55	4	0	4					
		09JUL2003	56	4	0	4	NO	558	56	100	
	E0023039	01JUL2003	1	2	0	2					
		02JUL2003	2	1	0	1					
		03JUL2003	3	1	0	1					
		04JUL2003	4	2	0	2					
		05JUL2003	5	3	0	3					
		06JUL2003	6	3	0	3					
		07JUL2003	7	3	0	3					
		08JUL2003	8	4	0	4					
		09JUL2003	9	4	0	4					
		10JUL2003	10	4	0	4					
		11JUL2003	11	4	0	4					
		12JUL2003	12	4	0	4					
		13JUL2003	13	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	14JUL2003	14	4	0	4					
		15JUL2003	15	4	0	4					
		16JUL2003	16	4	0	4					
		17JUL2003	17	4	0	4					
		18JUL2003	18	4	0	4					
		19JUL2003	19	4	0	4					
		20JUL2003	20	4	0	4					
		21JUL2003	21	4	0	4					
		22JUL2003	22	4	0	4					
		23JUL2003	23	4	0	4					
		24JUL2003	24	4	0	4					
		25JUL2003	25	4	0	4					
		26JUL2003	26	4	0	4					
		27JUL2003	27	4	0	4					
		28JUL2003	28	4	0	4					
		29JUL2003	29	4	0	4					
		30JUL2003	30	4	0	4					
		31JUL2003	31	4	0	4					
		01AUG2003	32	4	0	4					
		02AUG2003	33	4	0	4					
		03AUG2003	34	4	0	4					
		04AUG2003	35	4	0	4					
		05AUG2003	36	4	0	4					
		06AUG2003	37	4	0	4					
		07AUG2003	38	4	0	4					
		08AUG2003	39	4	0	4					
		09AUG2003	40	4	0	4					
		10AUG2003	41	4	4	0					PT FORGOT DOSE
		11AUG2003	42	4	0	4					
		12AUG2003	43	4	0	4					
		13AUG2003	44	4	0	4					
		14AUG2003	45	4	0	4					
		15AUG2003	46	4	0	4					
		16AUG2003	47	4	0	4					
		17AUG2003	48	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	18AUG2003	49	4	0	4					
		19AUG2003	50	4	0	4					
		20AUG2003	51	4	0	4					
		21AUG2003	52	4	0	4					
		22AUG2003	53	4	0	4					
		23AUG2003	54	4	0	4					
		24AUG2003	55	4	0	4					
		25AUG2003	56	4	0	4	NO	547.3	55	98.1	
	E0026002	12NOV2002	1	2	0	2					
		13NOV2002	2	1	0	1					
		14NOV2002	3	1	0	1					
		15NOV2002	4	2	0	2					
		16NOV2002	5	3	0	3					
		17NOV2002	6	3	0	3					
		18NOV2002	7	3	0	3					
		19NOV2002	8	4	0	4					
		20NOV2002	9	4	0	4					
		21NOV2002	10	4	0	4					
		22NOV2002	11	4	0	4					
		23NOV2002	12	4	0	4					
		24NOV2002	13	4	0	4					
		25NOV2002	14	4	0	4					
		26NOV2002	15	4	0	4					
		27NOV2002	16	4	0	4					
		28NOV2002	17	4	0	4					
		29NOV2002	18	4	0	4					
		30NOV2002	19	4	0	4					
		01DEC2002	20	4	0	4					
		02DEC2002	21	4	0	4					
		03DEC2002	22	4	0	4					
		04DEC2002	23	4	0	4					
		05DEC2002	24	4	0	4					
		06DEC2002	25	4	0	4					
		07DEC2002	26	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	08DEC2002	27	4	0	4					
		09DEC2002	28	4	0	4					
		10DEC2002	29		0	4					
		11DEC2002	30	4	0	4					
		12DEC2002	31	4	0	4					
		13DEC2002	32	4	0	4					
		14DEC2002	33	4	0	4					
		15DEC2002	34	4	0	4					
		16DEC2002	35	4	0	4					
		17DEC2002	36	4	0	4					
		18DEC2002	37	4	0	4					
		19DEC2002	38	4	0	4					
		20DEC2002	39	4	0	4					
		21DEC2002	40	4	0	4					
		22DEC2002	41	4	0	4					
		23DEC2002	42	4	0	4					
		24DEC2002	43	4	0	4					
		25DEC2002	44		0	4					
		26DEC2002	45	4	0	4					
		27DEC2002	46	4	0	4					
		28DEC2002	47	4	0	4					
		29DEC2002	48	4	0	4					
		30DEC2002	49	4	0	4					
		31DEC2002	50	4	0	4					
		01JAN2003	51	4	0	4					
		02JAN2003	52	4	0	4					
		03JAN2003	53	4	0	4					
		04JAN2003	54	4	0	4					
		05JAN2003	55	4	0	4					
		06JAN2003	56	4	0	4					
		07JAN2003	57	4	0	4					
		08JAN2003	58	4	0	4	NO	559.5	58	100	
	E0026007	16JAN2003	1	2	0	2					
		17JAN2003	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0026007	18JAN2003	3	1	0	1					
		19JAN2003	4	2	0	2					
		20JAN2003	5	3	0	3					
		21JAN2003	6	3	0	3					
		22JAN2003	7	3	0	3					
		23JAN2003	8	4	0	4					
		24JAN2003	9	4	0	4					
		25JAN2003	10	4	0	4					
		26JAN2003	11	4	0	4					
		27JAN2003	12	4	0	4					
		28JAN2003	13	4	0	4					
		29JAN2003	14	4	0	4					
		30JAN2003	15	4	0	4					
		31JAN2003	16	4	0	4					
		01FEB2003	17	4	0	4					
		02FEB2003	18	4	0	4					
		03FEB2003	19	4	0	4					
		04FEB2003	20	4	0	4					
		05FEB2003	21	4	0	4					
		06FEB2003	22	4	0	4					
		07FEB2003	23	4	0	4					
		08FEB2003	24	4	0	4					
		09FEB2003	25	4	0	4					
		10FEB2003	26	4	0	4					
		11FEB2003	27	4	0	4					
		12FEB2003	28	4	0	4					
		13FEB2003	29	4	0	4					
		14FEB2003	30	4	0	4					
		15FEB2003	31	4	0	4					
		16FEB2003	32	4	0	4					
		17FEB2003	33	4	0	4					
		18FEB2003	34	4	0	4					
		19FEB2003	35	4	0	4					PT ONE DAY EARLY DUE TO FUNERAL.
		20FEB2003	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0026007	21FEB2003	37	4	0	4					
		22FEB2003	38	4	0	4					
		23FEB2003	39	4	0	4					
		24FEB2003	40	4	0	4					
		25FEB2003	41	4	0	4					
		26FEB2003	42	4	0	4					
		27FEB2003	43	4	0	4					
		28FEB2003	44	4	0	4					
		01MAR2003	45	4	0	4					
		02MAR2003	46	4	0	4					
		03MAR2003	47	4	0	4					
		04MAR2003	48	4	0	4					
		05MAR2003	49	4	0	4					
		06MAR2003	50	4	0	4					
		07MAR2003	51	4	0	4					
		08MAR2003	52	4	0	4					
		09MAR2003	53	4	0	4					
		10MAR2003	54	4	0	4					
		11MAR2003	55	4	0	4	NO	557.3	55	100	
	E0026013	13FEB2003	1	2	0	2					
		14FEB2003	2	1	0	1					
		15FEB2003	3	1	0	1					
		16FEB2003	4	2	0	2					
		17FEB2003	5	3	0	3					
		18FEB2003	6	3	0	3					
		19FEB2003	7	3	0	3					
		20FEB2003	8	4	0	4					
		21FEB2003	9	4	0	4					
		22FEB2003	10	4	0	4					
		23FEB2003	11	4	0	4					
		24FEB2003	12	4	0	4					
		25FEB2003	13	4	0	4					
		26FEB2003	14	4	0	4					
		27FEB2003	15	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	28FEB2003	16	4	0	4					
		01MAR2003	17	4	0	4					
		02MAR2003	18	4	0	4					
		03MAR2003	19	4	0	4					
		04MAR2003	20	4	0	4					
		05MAR2003	21	4	0	4					
		06MAR2003	22	4	0	4					
		07MAR2003	23	4	0	4					
		08MAR2003	24	4	0	4					
		09MAR2003	25	4	0	4					
		10MAR2003	26	4	0	4					
		11MAR2003	27	4	0	4					
		12MAR2003	28	4	0	4					
		13MAR2003	29	4	0	4					
		14MAR2003	30	4	0	4					
		15MAR2003	31	4	0	4					
		16MAR2003	32	4	0	4					
		17MAR2003	33	4	0	4					
		18MAR2003	34	4	0	4					
		19MAR2003	35	4	0	4					
		20MAR2003	36	4	0	4					
		21MAR2003	37	4	0	4					
		22MAR2003	38	4	0	4					
		23MAR2003	39	4	0	4					
		24MAR2003	40	4	0	4					
		25MAR2003	41	4	0	4					
		26MAR2003	42	4	0	4					
		27MAR2003	43	4	0	4					
		28MAR2003	44	4	0	4					
		29MAR2003	45	4	0	4					
		30MAR2003	46	4	0	4					
		31MAR2003	47	4	0	4					
		01APR2003	48	4	0	4					
		02APR2003	49	4	0	4					
		03APR2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	04APR2003	51	4	0	4					
		05APR2003	52	4	0	4					
		06APR2003	53	4	0	4					
		07APR2003	54	4	0	4					
		08APR2003	55	4	0	4					
		09APR2003	56	4	0	4	NO	558	56	100	
	E0028007	04OCT2002	1	2	0	2					
		05OCT2002	2	1	0	1					
		06OCT2002	3	1	0	1					
		07OCT2002	4	2	0	2					
		08OCT2002	5	3	0	3					
		09OCT2002	6	3	0	3					
		10OCT2002	7	3	0	3					
		11OCT2002	8	4	0	4					
		12OCT2002	9	4	0	4					
		13OCT2002	10	4	0	4					
		14OCT2002	11	4	0	4					
		15OCT2002	12	4	0	4					
		16OCT2002	13	4	0	4					
		17OCT2002	14	4	0	4					
		18OCT2002	15	4	4	0					FORGOT DOSE
		19OCT2002	16	4	0	4					
		20OCT2002	17	4	0	4					
		21OCT2002	18	4	0	4					
		22OCT2002	19	4	0	4					
		23OCT2002	20	4	0	4					
		24OCT2002	21	4	0	4					
		25OCT2002	22	4	0	4					
		26OCT2002	23	4	0	4					
		27OCT2002	24	4	0	4					
		28OCT2002	25	4	0	4					
		29OCT2002	26	4	0	4					
		30OCT2002	27		0	4					
		31OCT2002	28	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	01NOV2002	29	4	0	4					
		02NOV2002	30	4	0	4					
		03NOV2002	31	4	0	4					
		04NOV2002	32	4	0	4					
		05NOV2002	33	4	0	4					
		06NOV2002	34	4	0	4					
		07NOV2002	35	4	0	4					
		08NOV2002	36	4	0	4					
		09NOV2002	37	4	0	4					
		10NOV2002	38	4	0	4					
		11NOV2002	39	4	0	4					PT. TOOK 8 TABS ON 11/11/02 SEE SAE REPORT.
		12NOV2002	40	4	0	4					0 TABS TAKEN ON 11/12/02. TAM
		13NOV2002	41	4	0	4	NO	528	40	97.4	
	E0028023	21JAN2003	1	2	0	2					PT. LOST BLISTER CARD BUT REPORTS USING ALL STUDY MEDICATION.
		22JAN2003	2	1	0	1					
		23JAN2003	3	1	0	1					
		24JAN2003	4	2	0	2					
		25JAN2003	5	3	0	3					
		26JAN2003	6	3	0	3					
		27JAN2003	7	3	0	3					
		28JAN2003	8		0	4					
		29JAN2003	9		0	4					
		30JAN2003	10	4	0	4					
		31JAN2003	11	4	0	4					
		01FEB2003	12	4	0	4					
		02FEB2003	13	4	0	4					
		03FEB2003	14	4	0	4					
		04FEB2003	15	4	0	4					
		05FEB2003	16	4	0	4					
		06FEB2003	17	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	07FEB2003	18	4	0	4					
		08FEB2003	19	4	0	4					
		09FEB2003	20	4	0	4					
		10FEB2003	21	4	0	4					
		11FEB2003	22	4	0	4					
		12FEB2003	23	4	0	4					
		13FEB2003	24	4	0	4					
		14FEB2003	25	4	0	4					
		15FEB2003	26	4	0	4					
		16FEB2003	27	4	0	4					
		17FEB2003	28	4	1	3					REDUCED DOSE BLISTER CARD REDISPENSED ON 2/17/03 DUE TO A PLANNED EXTENDED VISIT INTERVAL
		18FEB2003	29	4	1	3					SIC DAY 1 DOES NOT EQUAL VISIT 6 DATE DUE TO PREVIOUS BLISTER CARD BEING REDISPENSED
		19FEB2003	30	4	1	3					
		20FEB2003	31	4	1	3					
		21FEB2003	32	4	1	3					
		22FEB2003	33	4	1	3					
		23FEB2003	34	4	1	3					
		24FEB2003	35	4	1	3					
		25FEB2003	36		1	3					
		26FEB2003	37		1	3					
		27FEB2003	38	4	1	3					
		28FEB2003	39	4	1	3					
		01MAR2003	40	4	1	3					
		02MAR2003	41	4	1	3					
		03MAR2003	42	4	1	3					
		04MAR2003	43	4	1	3					
		05MAR2003	44	4	1	3					
		06MAR2003	45	4	1	3					
		07MAR2003	46	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	08MAR2003	47	4	1	3					
		09MAR2003	48	4	1	3					
		10MAR2003									SIC NO DOSE TAKEN
		11MAR2003					YES	507.3	48	100	LAST KNOWN DOSE OF STUDY MED IS 3/9/03 PER PT. REPORT.
	E0028025	13JAN2003	1	2	0	2					
		14JAN2003	2	1	0	1					
		15JAN2003	3	1	0	1					
		16JAN2003	4	2	0	2					
		17JAN2003	5	3	0	3					
		18JAN2003	6	3	0	3					
		19JAN2003	7	3	0	3					
		20JAN2003	8	4	0	4					
		21JAN2003	9	4	0	4					
		22JAN2003	10	4	0	4					
		23JAN2003	11	4	0	4					
		24JAN2003	12	4	0	4					
		25JAN2003									PT. MISSED DOSE ON 01/25
		26JAN2003					NO	404.2	12	100	PT. MISSED DOSE ON 01/26
	E0028033	27MAR2003	1	2	0	2					
		28MAR2003	2	1	0	1					
		29MAR2003	3	1	0	1					
		30MAR2003	4	2	0	2					
		31MAR2003	5	3	0	3					
		01APR2003	6	3	0	3					
		02APR2003	7	3	0	3					
		03APR2003	8	4	0	4					
		04APR2003	9	4	0	4					
		05APR2003	10	4	0	4					
		06APR2003	11	4	0	4					
		07APR2003	12	4	0	4					
		08APR2003	13	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	09APR2003	14	4	0	4					
		10APR2003	15	4	0	4					
		11APR2003	16	4	0	4					
		12APR2003	17	4	0	4					
		13APR2003	18	4	0	4					
		14APR2003	19	4	0	4					
		15APR2003	20	4	0	4					
		16APR2003	21	4	0	4					
		17APR2003	22	4	0	4					
		18APR2003	23	4	0	4					
		19APR2003	24	4	0	4					
		20APR2003	25	4	0	4					
		21APR2003	26	4	0	4					
		22APR2003	27	4	0	4					
		23APR2003	28	4	0	4					
		24APR2003	29	4	4	0					MISSED DOSE "FORGOT"
		25APR2003	30	4	0	4					
		26APR2003	31	4	0	4					
		27APR2003	32	4	0	4					
		28APR2003	33	4	0	4					
		29APR2003	34	4	0	4					
		30APR2003	35	4	0	4					
		01MAY2003	36	4	0	4					
		02MAY2003	37	4	0	4					
		03MAY2003	38	4	4	0					SUBJECT FORGOT STUDY DOSE
		04MAY2003	39	4	0	4					
		05MAY2003	40	4	0	4					
		06MAY2003	41	4	0	4					
		07MAY2003	42	4	0	4					
		08MAY2003	43	4	0	4					
		09MAY2003	44	4	0	4					
		10MAY2003	45	4	0	4					
		11MAY2003	46	4	4	0					SUBJECT FORGOT STUDY DOSE
		12MAY2003	47	4	0	4					
		13MAY2003	48	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	14MAY2003	49	4	0	4					
		15MAY2003	50	4	0	4					
		16MAY2003	51	4	0	4					
		17MAY2003	52	4	0	4					
		18MAY2003	53	4	0	4					
		19MAY2003	54	4	0	4					
		20MAY2003	55	4	0	4					
		21MAY2003	56	4	0	4	NO	525.9	53	94.3	
	E0028035	03APR2003	1	2	0	2					
		04APR2003	2	1	0	1					
		05APR2003	3	1	0	1					
		06APR2003	4	2	0	2					
		07APR2003	5	3	0	3					
		08APR2003	6	3	0	3					
		09APR2003	7	3	0	3					
		10APR2003	8	4	0	4					1 PILLED DROPPED, 1 EXTRA PILL USED
		11APR2003	9	4	0	4					
		12APR2003	10	4	0	4					
		13APR2003	11	4	0	4					
		14APR2003	12	4	0	4					
		15APR2003	13	4	0	4					
		16APR2003	14	4	0	4					
		17APR2003	15	4	0	4					
		18APR2003	16	4	0	4					
		19APR2003	17	4	0	4					
		20APR2003	18	4	0	4					
		21APR2003	19	4	0	4					
		22APR2003	20	4	0	4					
		23APR2003	21	4	0	4					
		24APR2003	22	4	0	4					
		25APR2003	23	4	4	0					PT. DID NOT TAKE 4/25 DOSE - HE THREW IT AWAY
		26APR2003	24	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	27APR2003	25	4	0	4					
		28APR2003	26	4	0	4					
		29APR2003	27	4	0	4					
		30APR2003	28	4	0	4					
		01MAY2003	29	4	0	4					
		02MAY2003	30	4	0	4					
		03MAY2003	31	4	0	4					
		04MAY2003	32	4	0	4					
		05MAY2003	33	4	0	4					
		06MAY2003	34	4	0	4					
		07MAY2003	35	4	0	4					
		08MAY2003	36	4	0	4					
		09MAY2003	37	4	0	4					
		10MAY2003	38	4	0	4					
		11MAY2003	39	4	0	4					
		12MAY2003	40	4	0	4					
		13MAY2003	41	4	0	4					
		14MAY2003	42	4	0	4					
		15MAY2003	43	4	0	4					
		16MAY2003	44	4	0	4					
		17MAY2003	45	4	0	4					
		18MAY2003	46	4	0	4					
		19MAY2003	47	4	0	4					
		20MAY2003	48	4	0	4					
		21MAY2003	49	4	0	4					
		22MAY2003	50	4	0	4					
		23MAY2003	51	4	0	4					
		24MAY2003	52	4	0	4					
		25MAY2003	53	4	0	4					
		26MAY2003	54	4	0	4					
		27MAY2003	55	4	0	4					
		28MAY2003	56	4	0	4	NO	547.3	55	98.1	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	13JUN2003	1	2	0	2					DAY 1 DATE DOES NOT EQUAL VISIT 2 DATE DUE TO SUBJECT NEEDING TO COMPLETE WASHOUT PERIOD. NO DOSE TAKEN ON 6/12/03 AS PRESCRIBED
		14JUN2003	2	1	0	1					
		15JUN2003	3	1	0	1					
		16JUN2003	4	2	0	2					
		17JUN2003	5	3	0	3					
		18JUN2003	6	3	0	3					
		19JUN2003	7	3	0	3					
		20JUN2003	8	4	0	4					
		21JUN2003	9	4	0	4					
		22JUN2003	10	4	0	4					
		23JUN2003	11	4	0	4					
		24JUN2003	12	4	0	4					
		25JUN2003	13	4	0	4					
		26JUN2003	14	4	0	4					
		27JUN2003	15	4	0	4					
		28JUN2003	16	4	0	4					
		29JUN2003	17	4	0	4					
		30JUN2003	18	4	0	4					
		01JUL2003	19	4	0	4					
		02JUL2003	20	4	0	4					
		03JUL2003	21	4	0	4					
		04JUL2003	22	4	0	4					
		05JUL2003	23	4	0	4					
		06JUL2003	24	4	0	4					
		07JUL2003	25	4	0	4					
		08JUL2003	26	4	0	4					
		09JUL2003	27	4	0	4					
		10JUL2003	28	4	0	4					
		11JUL2003	29	4	0	4					
		12JUL2003	30	4	0	4					
		13JUL2003	31	4	0	4					
		14JUL2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	15JUL2003	33		0	4					
		16JUL2003	34	4	0	4					
		17JUL2003	35	4	0	4					
		18JUL2003	36	4	0	4					
		19JUL2003	37	4	0	4					
		20JUL2003	38	4	0	4					
		21JUL2003	39	4	0	4					
		22JUL2003	40	4	0	4					
		23JUL2003	41	4	0	4					
		24JUL2003	42	4	0	4					
		25JUL2003	43	4	0	4					
		26JUL2003	44	4	0	4					
		27JUL2003	45	4	0	4					
		28JUL2003	46	4	0	4					
		29JUL2003	47	4	0	4					
		30JUL2003	48	4	0	4					
		31JUL2003	49	4	0	4					
		01AUG2003	50	4	0	4					
		02AUG2003	51	4	0	4					
		03AUG2003	52	4	0	4					
		04AUG2003	53	4	0	4					
		05AUG2003	54	4	0	4					
		06AUG2003	55		0	4					
		07AUG2003	56		0	4	NO	558	56	100	
	E0028039	08MAY2003	0	2	2	0					DOSE TAKEN 5/9/03 SIC - SUBJECT MISSED DOSES OF STUDY MEDICATION ON 5/8/03 AND 5/15/03. BLISTERCARD WAS RE - DISPENSED IN ORDER TO ACHIEVE FULL TITRATION.
		09MAY2003	1	1	0	1					DOSE TAKEN 5/10/03
		10MAY2003	2	1	0	1					DOSE TAKEN 5/11/03
		11MAY2003	3	2	1	1					DOSE TAKEN 5/12/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	12MAY2003	4	3	1	2					DOSE TAKEN 5/13/03
		13MAY2003	5	3	0	3					DOSE TAKEN 5/14/03
		14MAY2003	6	3	0	3					DOSE TAKEN 5/16/03
		15MAY2003	7		4	0					
		16MAY2003	8		1	3					
		17MAY2003	9	4	0	4					BLISTERCARD #1 WAS REDISPENSED FOR 5/16/03 DOSE. THEREFORE, SUBJECT STARTED BLISTERCARD #2 ON 05/17/2003
		18MAY2003	10	4	0	4					
		19MAY2003	11	4	0	4					
		20MAY2003	12	4	0	4					
		21MAY2003	13	4	4	0					MISSED DOSE
		22MAY2003	14	4	1	3					DOSE REDUCED
		23MAY2003	15	4	1	3					
		24MAY2003	16	4	1	3					
		25MAY2003	17	4	1	3					
		26MAY2003	18	4	1	3					
		27MAY2003	19	4	1	3					
		28MAY2003	20	4	1	3					
		29MAY2003	21	4	1	3					
		30MAY2003	22	4	1	3					
		31MAY2003	23	4	1	3					
		01JUN2003	24	4	1	3					
		02JUN2003	25	4	1	3					
		03JUN2003	26	4	1	3					
		04JUN2003	27	4	1	3	YES	387.5	25	90	
	E0028046	25JUN2003	1	2	0	2					SIC DRUG NOT RETURNED
		02JUL2003					NO	50	1	100	UNK
	E0028048	17JUL2003	1	2	0	2					
		18JUL2003	2	1	0	1					
		19JUL2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	20JUL2003	4	2	0	2					
		21JUL2003	5	3	0	3					
		22JUL2003	6	3	0	3					
		23JUL2003	7	3	0	3					PT. LOST 7/23 DOSE & TOOK 7/24 DOSE ON 7/23
		24JUL2003	8	4	1	7					DOSE TAKEN ON 7/23
		24JUL2003	8	4	1	7					DOSE REDUCED TO 3 TABS DUE TO DIZZINESS
		25JUL2003	9	4	1	3					
		26JUL2003	10	4	1	3					
		27JUL2003	11	4	1	3					
		28JUL2003	12	4	1	3					
		29JUL2003	13	4	1	3					
		30JUL2003	14	4	1	3					
		31JUL2003	15	4	1	3					
		01AUG2003	16	4	1	3					
		02AUG2003	17	4	1	3					
		03AUG2003	18	4	1	3					
		04AUG2003	19	4	1	3					
		05AUG2003	20	4	1	3					
		06AUG2003	21	4	1	3					
		07AUG2003	22	4	1	3					
		08AUG2003	23	4	1	3					
		09AUG2003	24	4	1	3					
		10AUG2003	25	4	1	3					
		11AUG2003	26	4	1	3					PT. TOOK COLUMN 2 & 3 ON 8/11 & COLUMN 4 ON 8/12
		12AUG2003	27	4	1	3					PT TOOK COLUMN 2 ON 8/12 & COLUMN 3 & 4 ON 8/13
		13AUG2003	28		4	0					
		14AUG2003	29	4	1	3					
		15AUG2003	30	4	1	3					
		16AUG2003	31	4	1	3					
		17AUG2003	32	4	1	3					
		18AUG2003	33	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	19AUG2003	34	4	1	3					
		20AUG2003	35	4	1	3					
		21AUG2003	36	4	0	4					PT. DISCARDED 3 TABS
		21AUG2003	36	4	0	4					CARD NOT RETURNED, PAGE COMPLETED PER SUBJECT REPORT
		22AUG2003	37	4	0	4					PT. DISCARDED 4 TABS
		23AUG2003	38	4	0	4					
		24AUG2003	39	4	0	4					
		25AUG2003	40	4	0	4					
		26AUG2003	41	4	0	4					
		27AUG2003	42	4	0	4					
		28AUG2003	43		0	4					UNK SIC
		29AUG2003	44	4	0	4					DOSE NOT TAKEN PER SUBJECT REPORT
		29AUG2003	44	4	0	4					CARD NOT RETURNED, PAGE COMPLETED PER SUBJECT REPORT
		30AUG2003	45	4	0	4					
		31AUG2003	46	4	0	4					
		01SEP2003	47	4	0	4					
		02SEP2003	48	4	0	4					
		03SEP2003	49	4	0	4					
		04SEP2003	50	4	0	4					
		05SEP2003	51		0	4					UNK SIC
		06SEP2003	52		0	4					V9 OUT OF WINDOW. PT. MISSED DOSES ON 9/7/03 & 9/8/03
		07SEP2003	53			0					
		08SEP2003	54			0					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	09SEP2003	55	4	0	4					CARD NOT RETURNED, SUBJECT LOST TO FOLLOW - UP SUBJECT LATE FOR VISIT DUE TO WORK SCHEDULE, NO MEDS TAKEN ON 9/7/03 AND 9/8/03 PER SUBJECT REPORT.
		16SEP2003					YES	477.3	52	95	UNK SIC
	E0029008	16DEC2002	1	2	0	2					
		17DEC2002	2	1	0	1					
		18DEC2002	3	1	0	1					
		19DEC2002	4	2	0	2					
		20DEC2002	5	3	0	3					
		21DEC2002					NO	210	5	100	MEDS WERE RETURNED 12/23/03 AND SUBJECT TOOK MEDS 12/16-12/20/02
	E0029011	22JAN2003	1	2	0	2					6AM SUBJECT ALTERNATELY WORKS NIGHTS AND DAYS. IN ORDER TO AVOID SEDATION AT WORK, DOSE TIMES VARY AND SUBJECT OCCASIONALLY TAKES DRUG 18-36 HOURS APART FOR LENGTH OF TRIAL.
		23JAN2003	2	1	0	1					6AM
		24JAN2003	3	1	0	1					6AM
		25JAN2003	4	2	0	2					10PM - ACTUALLY TOOK ON 1/24/03
		26JAN2003	5	3	0	3					1AM
		27JAN2003	6	3	0	3					10PM - ACTUALLY TOOK ON 1/26/03
		28JAN2003	7	3	0	3					6AM
		29JAN2003	8	4	0	4					PATIENT WORKS NIGHTS AND DOES NOT WANT TO TAKE SEDATING MED BEFORE GOING TO WORK
		29JAN2003	8	4	0	4					6AM

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	30JAN2003	9	4	0	4					7AM
		31JAN2003	10	4	0	4					ACTUALLY TOOK ON 2/1/03 @ 3:30AM - PATIENT MISSED DOSE ON 1/31/03
		01FEB2003	11	4	0	4					11PM
		02FEB2003	12	4	0	4					10:30PM
		03FEB2003	13	4	0	4					6AM - ACTUALLY TOOK ON 2/4/03
		04FEB2003	14	4	4	0					REPRESENTS MISSED DOSE ON 1/31/03 SUBJECT MISSED DOSE ON 1/31/03 & DIDN'T SKIP THAT ROW; ROW AT BOTTOM WAS LEFT INSTEAD
		05FEB2003	15	4	0	4					
		06FEB2003	16	4	0	4					
		07FEB2003	17	4	0	4					
		08FEB2003	18	4	0	4					
		09FEB2003	19	4	0	4					
		10FEB2003	20	4	0	4					ACTUALLY TOOK ON 2/11 MISSED DOSE ON 2/10/03
		11FEB2003	21	4	0	4					ACTUALLY TOOK ON 2/12/03
		12FEB2003	22		0	4					ACTUALLY TOOK ON 2/13/03
		13FEB2003	23		4	0					
		14FEB2003									VISIT ON 2/13/03 DOSE REDUCED ON 2/15 AT 6:30AM
		15FEB2003									ACTUALLY TOOK ON TOOK AT 23:45
		16FEB2003									TOOK AT 23:30
		17FEB2003									ACTUALLY TOOK AT 2/18 @ 6:30
		18FEB2003									ACTUALLY TOOK AT 2/19 @ 6:45
		19FEB2003									DIDN'T TAKE

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	20FEB2003					NO	445.7	21	89.9	DIDN'T TAKE SUBJECT LOST TO FOLLOW-UP. RETURNED DRUG VIA FEDEX. APPEARS TO HAVE MISSED DOSE ON 2/14/03 (AND TOOK 2/13/03'S DOSE FROM LAST BLISTER PACK IN EARLY AM BEFORE THAT VISIT)
	E0029012	11FEB2003	1	2	0	2					
		12FEB2003	2	1	0	1					
		13FEB2003	3	1	0	1					
		14FEB2003	4	2	0	2					
		15FEB2003	5	3	0	3					
		16FEB2003	6	3	0	3					
		17FEB2003	7	3	0	3					
		18FEB2003	8		0	4					
		19FEB2003	9	4	0	4					
		20FEB2003	10	4	0	4					
		21FEB2003	11	4	0	4					
		22FEB2003	12	4	0	4					
		23FEB2003	13	4	0	4					
		24FEB2003	14	4	0	4					
		25FEB2003	15	4	0	4					
		26FEB2003	16	4	1	3					DOSE REDUCED BY 100MG
		27FEB2003	17	4	1	3					
		28FEB2003	18	4	1	3					
		01MAR2003	19	4	1	3					
		02MAR2003	20	4	1	3					
		03MAR2003	21	4	1	3					
		04MAR2003	22	4	1	3					
		05MAR2003	23	4	1	3					
		06MAR2003	24	4	4	0					MISSED DOSE
		07MAR2003	25	4	1	3					
		08MAR2003	26	4	1	3					
		09MAR2003	27	4	1	3					
		10MAR2003	28		1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	11MAR2003	29	4	1	3					
		12MAR2003	30	4	1	3					
		13MAR2003	31	4	1	3					
		14MAR2003	32	4	0	4					DROPPED 1 WHITE PILL
		15MAR2003	33	4	1	3					
		16MAR2003	34	4	1	3					
		17MAR2003	35	4	1	3					
		18MAR2003					YES	464.3	34	96.3	DROPPED 1 WHITE PILL 3/14 TOOK FROM EXTRA DAY
	E0029015	24FEB2003	1	2	0	2					
		25FEB2003	2	1	0	1					
		26FEB2003	3	1	0	1					
		27FEB2003	4	2	0	2					
		28FEB2003	5	3	0	3					
		01MAR2003	6	3	0	3					
		02MAR2003	7	3	0	3					
		03MAR2003	8	4	1	3					PT. WAS NON - COMPLIANT WITH MEDICATION, NOT TAKING THE DOSES IN THE MANNER PRESCRIBED/DIRECTED.
		04MAR2003	9	4	2	2					PT. WAS NON - COMPLIANT WITH MEDICATION, NOT TAKING THE DOSES IN THE MANNER PRESCRIBED/DIRECTED.
		05MAR2003	10	4	2	2	YES	235	10	91.7	PT. STOPPED MEDS.
	E0029018	06MAR2003	1	2	0	2					MEDICATIONS WERE NOT RETURNED
		07MAR2003	2	1	0	1					
		13MAR2003					NO	75	2	100	UNKNOWN
	E0030014	21FEB2003	1	2	0	2					
		22FEB2003	2	1	0	1					
		23FEB2003	3	1	0	1					

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	24FEB2003	4	2	0	2					
		25FEB2003	5	3	0	3					
		26FEB2003	6	3	0	3					
		27FEB2003	7	3	0	3					
		28FEB2003	8	4	1	3					DOSAGE DECREASED THROUGH REMAINDER OF THE STUDY
		01MAR2003	9	4	1	3					
		02MAR2003	10	4	1	3					
		03MAR2003	11	4	1	3					
		04MAR2003	12	4	1	3					
		05MAR2003	13	4	1	3					
		06MAR2003	14	4	1	3					
		07MAR2003	15	4	1	3					
		08MAR2003	16	4	1	3					
		09MAR2003	17	4	1	3					
		10MAR2003	18	4	1	3					
		11MAR2003	19	4	1	3					
		12MAR2003	20	4	1	3					
		13MAR2003	21	4	1	3					
		14MAR2003	22	4	1	3					
		15MAR2003	23	4	1	3					
		16MAR2003	24	4	1	3					
		17MAR2003	25	4	1	3					
		18MAR2003	26	4	1	3					
		19MAR2003	27	4	1	3					
		20MAR2003	28	4	1	3					
		21MAR2003	29	4	1	3					
		22MAR2003	30	4	1	3					
		23MAR2003	31	4	1	3					
		24MAR2003	32	4	1	3					
		25MAR2003	33	4	1	3					
		26MAR2003	34	4	1	3					
		27MAR2003	35	4	1	3					
		28MAR2003	36	4	1	3					
		29MAR2003	37	4	1	3					

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	30MAR2003	38	4	1	3					
		31MAR2003	39	4	1	3					
		01APR2003	40	4	1	3					
		02APR2003	41	4	1	3					
		03APR2003	42		1	3					
		04APR2003	43	4	1	3					
		05APR2003	44	4	1	3					
		06APR2003	45	4	4	0					PT. FORGOT DAY'S DOSE
		07APR2003	46	4	1	3					
		08APR2003	47	4	1	3					
		09APR2003	48	4	1	3					
		10APR2003	49	4	1	3					
		11APR2003	50	4	1	6					TAKEN 04/20/03
		12APR2003	51	4	1	6					TAKEN 04/21/03
		13APR2003	52	4	1	3					
		14APR2003	53	4	1	3					
		15APR2003	54	4	1	3					
		16APR2003	55	4	1	3					
		17APR2003	56	4	1	3					
		18APR2003	57		1	3					
		19APR2003	58		1	3	YES	480.2	57	100	
	E0030020	29MAY2003	1	2	0	2					
		30MAY2003	2	1	0	1					
		31MAY2003	3	1	0	1					
		01JUN2003	4	2	0	2					
		02JUN2003	5	3	0	3					
		03JUN2003	6	3	0	3					
		04JUN2003	7	3	0	3					
		05JUN2003	8	4	0	4					
		06JUN2003	9	4	0	4					
		07JUN2003	10	4	0	4					
		08JUN2003	11	4	0	4					
		09JUN2003	12	4	0	4					
		10JUN2003	13	4	0	4					

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	11JUN2003	14	4	0	4					
		12JUN2003	15	4	0	4					BLISTER CARD WAS NOT RETURNED
		13JUN2003	16	4	0	4					
		14JUN2003	17	4	0	4					
		15JUN2003	18	4	0	4					
		16JUN2003	19	4	0	4					
		17JUN2003	20	4	0	8					BLISTER CARD WAS NOT RETURNED
		18JUN2003	21	4	0	8					
		19JUN2003	22	4	0	8					UNKN.
		20JUN2003	23	4	0	8					
		21JUN2003	24	4	0	4					
		22JUN2003	25	4	0	4					
		23JUN2003	26	4	0	4					
		24JUN2003	27	4	0	8					UNKNOWN
		24JUN2003	27	4	0	8					BLISTER CARD NOT RETURNED
		01JUL2003					NO	624.1	27	121	UNKNOWN
	E0030024	11JUL2003	1	2	0	2					BLISTER CARD WAS NOT RETURNED
		12JUL2003	2	1	0	1					
		13JUL2003	3	1	0	1					
		14JUL2003	4	2	0	2					
		15JUL2003	5	3	0	3					
		16JUL2003									NO DOSE TAKEN
		17JUL2003									NO DOSE TAKEN
		18JUL2003									NO DOSE TAKEN
		19JUL2003					NO	210	5	100	NO DOSE TAKEN
	E0030025	11JUL2003	1	2	0	2					
		12JUL2003	2	1	0	1					
		13JUL2003	3	1	0	1					
		14JUL2003	4	2	0	2					
		15JUL2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0030025	16JUL2003	6	3	0	3					
		17JUL2003	7	3	0	3					
		18JUL2003	8	4	0	4					
		19JUL2003	9	4	0	4					
		20JUL2003	10	4	0	4					
		21JUL2003	11	4	0	4					
		22JUL2003	12	4	0	4					
		23JUL2003	13	4	0	4					
		24JUL2003	14	4	0	4					
		25JUL2003	15	4	0	4					
		26JUL2003	16	4	0	4					
		27JUL2003	17	4	0	4					
		28JUL2003	18	4	0	4					
		29JUL2003	19	4	0	4					
		30JUL2003	20	4	4	0					PT. CAME IN 2 DAYS EARLY.
		31JUL2003	21	4	0	4					
		01AUG2003	22	4	0	4					
		02AUG2003	23	4	0	4					
		03AUG2003	24	4	0	4					
		04AUG2003	25	4	0	4					
		05AUG2003	26	4	0	4					
		06AUG2003	27	4	0	4					
		07AUG2003	28		0	4					
		08AUG2003	29		0	4					
		09AUG2003	30			0					
		10AUG2003	31			0					
		11AUG2003	32	4	0	4					SIC - PT. MISSED DOSES ON 8/9/03 AND 8/10/03
		12AUG2003	33	4	0	4					
		13AUG2003	34	4	0	4					
		14AUG2003	35	4	0	4					
		15AUG2003	36	4	0	4					
		16AUG2003	37	4	0	4					
		17AUG2003	38	4	0	4					
		18AUG2003	39		0	4	NO	493.6	36	91.6	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0031027	03JUN2003	1	2	0	2					
		04JUN2003	2	1	0	1					
		05JUN2003	3	1	0	1					
		06JUN2003	4	2	0	2					
		07JUN2003	5	3	0	3					
		08JUN2003	6	3	0	3					
		09JUN2003	7	3	0	3					
		10JUN2003	8	4	0	6					PT TOOK 2 EXTRA TABS ON 6/9/03
		11JUN2003	9	4	0	4					
		12JUN2003	10	4	0	4					
		13JUN2003	11	4	0	4					
		14JUN2003	12	4	0	4					
		15JUN2003	13	4	0	4					
		16JUN2003	14	4	0	4					
		17JUN2003	15	4	0	4					
		18JUN2003	16	4	0	4					
		19JUN2003	17	4	0	4					
		20JUN2003	18	4	0	4					
		21JUN2003	19	4	0	4					
		22JUN2003	20	4	0	4					
		23JUN2003	21	4	0	4					
		24JUN2003	22	4	0	4					
		25JUN2003	23	4	0	4					
		26JUN2003	24	4	0	4					
		27JUN2003	25	4	0	4					
		28JUN2003	26	4	0	4					
		29JUN2003	27	4	0	4					
		30JUN2003	28	4	0	4					
		01JUL2003	29	4	0	4					
		02JUL2003	30	4	0	4					
		03JUL2003	31	4	0	4					
		04JUL2003	32	4	0	4					
		05JUL2003	33	4	0	4					
		06JUL2003	34	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0031027	07JUL2003	35	4	0	4					
		08JUL2003	36		0	4					
		09JUL2003	37	4	0	4					
		10JUL2003	38	4	0	4					
		11JUL2003	39	4	0	4					
		12JUL2003	40	4	0	4					
		13JUL2003	41	4	0	4					
		14JUL2003	42	4	0	4					
		15JUL2003	43	4	0	4					
		16JUL2003	44	4	0	4					
		17JUL2003	45	4	0	4					
		18JUL2003	46	4	0	4					
		19JUL2003	47	4	0	4					
		20JUL2003	48	4	0	4					
		21JUL2003	49	4	0	4					
		22JUL2003	50	4	0	4					
		23JUL2003	51	4	0	4					
		24JUL2003	52	4	0	4					
		25JUL2003	53	4	0	4					
		26JUL2003	54	4	0	4					
		27JUL2003	55	4	0	4					
		28JUL2003	56	4	0	4	NO	565.2	56	101	
	E0031030	24JUN2003	1	2	0	2					
		25JUN2003	2	1	0	1					
		26JUN2003	3	1	0	1					
		27JUN2003	4	2	0	2					
		28JUN2003	5	3	0	3					
		29JUN2003	6	3	0	3					
		30JUN2003	7	3	0	3					
		01JUL2003	8	4	0	4					
		02JUL2003	9	4	0	4					
		03JUL2003	10	4	0	4					
		04JUL2003	11	4	0	4					
		05JUL2003	12	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	06JUL2003	13	4	0	4					
		07JUL2003	14	4	0	4					
		08JUL2003	15	4	0	4					
		09JUL2003	16	4	0	4					
		10JUL2003	17	4	0	4					
		11JUL2003	18	4	0	4					
		12JUL2003	19	4	0	4					
		13JUL2003	20	4	0	4					
		14JUL2003	21	4	0	4					
		15JUL2003	22		0	4					
		16JUL2003	23	4	0	4					
		17JUL2003	24	4	0	4					
		18JUL2003	25	4	0	4					
		19JUL2003	26	4	0	4					
		20JUL2003	27	4	0	4					
		21JUL2003	28	4	0	4					
		22JUL2003	29	4	0	4					
		23JUL2003	30	4	0	4					
		24JUL2003	31	4	0	4					
		25JUL2003	32	4	0	4					
		26JUL2003	33	4	0	4					
		27JUL2003	34	4	0	4					
		28JUL2003	35	4	0	4					
		29JUL2003	36	4	0	4					
		30JUL2003	37		0	4					
		31JUL2003	38	4	0	4					
		01AUG2003	39	4	0	4					
		02AUG2003	40	4	0	4					
		03AUG2003	41	4	0	4					
		04AUG2003	42	4	0	4					
		05AUG2003	43	4	0	4					
		06AUG2003	44	4	0	4					
		07AUG2003	45		0	4					
		08AUG2003	46	4	0	4					
		09AUG2003	47	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	10AUG2003	48	4	0	4					
		11AUG2003	49	4	0	4					
		12AUG2003	50	4	0	4					
		13AUG2003	51	4	0	4					
		14AUG2003	52	4	0	4					
		15AUG2003	53	4	0	4					
		16AUG2003	54	4	0	4					
		17AUG2003	55	4	0	4					
		18AUG2003	56	4	0	4					
		19AUG2003	57	4	0	4					
		20AUG2003	58	4	0	4	NO	559.5	58	100	
	E0033012	10FEB2003	1	2	0	2					SUBJECT LOST - TO - FOLLOW - UP. TABLETS TAKEN COULD NOT BE DETERMINED.
		11FEB2003	2	1	0	1					
		12FEB2003	3	1	0	1					
		13FEB2003	4	2	0	2					
		14FEB2003	5	3	0	3					
		15FEB2003	6	3	0	3					
		16FEB2003	7	3	0	3					
		17FEB2003	8		0	4					UNKNOWN SUBJECT LOST TO FOLLOW - UP. BLISTER CARD NOT RETURNED.
		18FEB2003	9		0	4	NO	338.9	9	100	
	E0034001	20MAR2003	1	2	0	2					
		21MAR2003	2	1	0	1					
		22MAR2003	3	1	0	1					
		23MAR2003	4	2	0	2					
		24MAR2003	5	3	0	3					
		25MAR2003	6	3	0	3					
		26MAR2003	7	3	0	3					
		27MAR2003	8	4	0	4					
		28MAR2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	29MAR2003	10	4	0	4					
		30MAR2003	11	4	0	4					
		31MAR2003	12	4	0	4					
		01APR2003	13	4	0	4					
		02APR2003	14	4	0	4					
		03APR2003	15	4	0	4					
		04APR2003	16	4	0	4					
		05APR2003	17	4	0	4					
		06APR2003	18	4	0	4					
		07APR2003	19	4	0	4					
		08APR2003	20	4	0	4					
		09APR2003	21	4	0	4					
		10APR2003	22	4	0	4					
		11APR2003	23	4	0	4					
		12APR2003	24	4	0	4					
		13APR2003	25	4	0	4					
		14APR2003	26	4	0	4					
		15APR2003	27	4	0	4					
		16APR2003	28	4	0	4					
		17APR2003	29	4	0	4					
		18APR2003	30	4	0	4					
		19APR2003	31	4	0	4					
		20APR2003	32	4	0	4					
		21APR2003	33	4	0	4					
		22APR2003	34	4	0	4					
		23APR2003	35	4	0	4					
		24APR2003	36	4	0	4					
		25APR2003	37	4	0	4					
		26APR2003	38	4	0	4					
		27APR2003	39	4	0	4					
		28APR2003	40	4	0	4					
		29APR2003	41	4	0	4					
		30APR2003	42	4	0	4					
		01MAY2003	43	4	0	4					
		02MAY2003	44	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	03MAY2003	45	4	0	4					
		04MAY2003	46	4	0	4					
		05MAY2003	47	4	0	4					
		06MAY2003	48	4	0	4					
		07MAY2003	49	4	0	4					
		08MAY2003	50	4	0	4					
		09MAY2003	51	4	0	4					
		10MAY2003	52	4	0	4					
		11MAY2003	53	4	0	4					
		12MAY2003	54	4	0	4					
		13MAY2003	55	4	0	4					
		14MAY2003	56	4	0	4	NO	558	56	100	
	E0034004	21APR2003	1	2	0	2					
		22APR2003	2	1	0	1					
		23APR2003	3	1	0	1					
		24APR2003	4	2	0	2					
		25APR2003	5	3	0	3					
		26APR2003	6	3	0	3					
		27APR2003	7	3	0	3					
		28APR2003	8		0	4					
		29APR2003	9		0	4					
		30APR2003	10	4	0	4					
		01MAY2003	11	4	0	4					
		02MAY2003	12	4	0	4					
		03MAY2003	13	4	0	4					
		04MAY2003	14	4	0	4					
		05MAY2003	15	4	0	4					NOT PRESCRIBED DAY 6 & 7 FROM THIS CARD DUE TO CHANGE IN VISIT SCHEDULE.
		06MAY2003	16	4	0	4					
		07MAY2003	17	4	0	4					
		08MAY2003	18	4	0	4					
		09MAY2003	19	4	0	4					
		10MAY2003	20	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	11MAY2003	21	4	0	4					
		12MAY2003	22		0	4					
		13MAY2003	23	4	0	4					
		14MAY2003	24	4	0	4					
		15MAY2003	25	4	0	4					
		16MAY2003	26	4	0	4					
		17MAY2003	27	4	0	4					
		18MAY2003	28	4	0	4					
		19MAY2003	29	4	0	4					NOT PRESCRIBED DAY 7 DOSE DUE TO CHANGE IN VISIT SCHEDULE
		19MAY2003	29	4	0	4					CARD RE - DISPENSED ON 5-23-03
		20MAY2003	30	4	0	4					
		21MAY2003	31	4	0	4					
		22MAY2003	32	4	0	4					
		23MAY2003	33	4	0	4					
		24MAY2003	34	4	0	4					
		25MAY2003	35	4	0	4					
		26MAY2003	36		0	4					
		27MAY2003	37		0	4					
		28MAY2003	38	4	0	4					SIC
		29MAY2003	39	4	0	4					
		30MAY2003	40	4	0	4					
		31MAY2003	41	4	0	4					
		01JUN2003	42	4	0	4					
		02JUN2003	43	4	0	4					NOT PRESCRIBED THIS DOSE
		03JUN2003	44	4	0	4					NOT PRESCRIBED THIS DOSE
		04JUN2003	45	4	0	4					
		05JUN2003	46	4	0	4					
		06JUN2003	47	4	0	4					
		07JUN2003	48	4	0	4					
		08JUN2003	49	4	0	4					
		09JUN2003	50	4	0	4					
		10JUN2003	51	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	11JUN2003	52	4	0	4					
		12JUN2003	53	4	0	4					
		13JUN2003	54	4	0	4					
		14JUN2003	55	4	0	4					
		15JUN2003	56	4	0	4	NO	558	56	100	
	E0035001	20NOV2002	1	2	0	2					
		21NOV2002	2	1	0	1					
		22NOV2002	3	1	0	1					
		23NOV2002	4	2	0	2					
		24NOV2002	5	3	0	3					
		25NOV2002	6	3	0	3					
		26NOV2002	7		4	3					
		27NOV2002	8	4	0	4					
		28NOV2002	9	4	0	4					
		29NOV2002	10	4	0	4					
		30NOV2002	11	4	0	4					
		01DEC2002	12	4	0	4					
		02DEC2002	13	4	0	4					
		03DEC2002	14	4	0	4					
		04DEC2002	15	4	0	4					
		05DEC2002	16	4	0	4					
		06DEC2002	17	4	0	4					
		07DEC2002	18	4	0	4					
		08DEC2002	19	4	0	4					
		09DEC2002	20	4	0	4					
		10DEC2002	21	4	0	4					
		11DEC2002	22		0	4					
		12DEC2002	23	4	0	4					
		13DEC2002	24	4	0	4					
		14DEC2002	25	4	0	4					
		15DEC2002	26	4	0	4					
		16DEC2002	27	4	0	4					
		17DEC2002	28	4	0	4					
		18DEC2002	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0035001	19DEC2002	30	4	0	4					
		20DEC2002	31	4	0	4					
		21DEC2002	32	4	0	4					
		22DEC2002	33	4	0	4					
		23DEC2002	34	4	0	4					
		24DEC2002	35	4	0	4					
		25DEC2002	36	4	0	4					
		26DEC2002	37	4	0	4					
		27DEC2002	38	4	0	4					
		28DEC2002	39	4	0	4					
		29DEC2002	40	4	0	4					
		30DEC2002	41	4	0	4					
		31DEC2002	42	4	0	4					
		01JAN2003	43	4	0	4					
		02JAN2003	44	4	0	4					
		03JAN2003	45	4	0	4					
		04JAN2003	46	4	0	4					
		05JAN2003	47	4	0	4					
		06JAN2003	48	4	0	4					
		07JAN2003	49	4	0	4					
		08JAN2003	50	4	0	4					
		09JAN2003	51	4	0	4					
		10JAN2003	52	4	0	4					
		11JAN2003	53	4	0	4					
		12JAN2003	54	4	0	4					
		13JAN2003	55	4	0	4	NO	559.1	55	100	
	E0035006	12DEC2002	1	2	0	2					
		13DEC2002	2	1	0	1					
		14DEC2002	3	1	0	1					
		15DEC2002	4	2	0	2					
		16DEC2002	5	3	0	3					
		17DEC2002	6	3	0	3					
		18DEC2002	7		0	7					PT MISPLACED STUDY MEDS THEREFORE TAKING EXTRA DAY

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	19DEC2002	8	4	0	4					
		20DEC2002	9	4	0	4					
		21DEC2002	10	4	0	4					
		22DEC2002	11	4	0	4					
		23DEC2002	12	4	0	4					
		24DEC2002	13	4	0	4					
		25DEC2002	14	4	0	4					
		26DEC2002	15		0	4					
		27DEC2002	16	4	0	4					
		28DEC2002	17	4	0	4					
		29DEC2002	18	4	0	4					
		30DEC2002	19	4	0	4					
		31DEC2002	20	4	0	4					
		01JAN2003	21	4	0	4					
		02JAN2003	22	4	0	4					
		03JAN2003	23	4	0	4					
		04JAN2003	24	4	0	4					
		05JAN2003	25	4	0	4					
		06JAN2003	26	4	0	4					
		07JAN2003	27	4	0	4					
		08JAN2003	28	4	0	4					
		09JAN2003	29	4	0	4					
		10JAN2003	30	4	0	4					
		11JAN2003	31	4	0	4					
		12JAN2003	32	4	0	4					
		13JAN2003	33	4	0	4					
		14JAN2003	34	4	0	4					
		15JAN2003	35	4	0	4					
		16JAN2003	36	4	0	4					
		17JAN2003	37	4	0	4					
		18JAN2003	38	4	0	4					
		19JAN2003	39	4	0	4					
		20JAN2003	40	4	0	4					
		21JAN2003	41	4	0	4					
		22JAN2003	42	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	23JAN2003	43	4	0	4					
		24JAN2003	44	4	0	4					FOR DAY 1 THROUGH BOTH EXTRA DAYS, THEY CAN NOT BE ACCOUNTED FOR DUE TO PT. THREW OUT BLISTER CARD. PT. STATED THAT SHE WAS MED COMPLIANT AND TOOK HER DOSES.
		25JAN2003	45	4	0	4					
		26JAN2003	46	4	0	4					
		27JAN2003	47	4	0	4					
		28JAN2003	48	4	0	4					
		29JAN2003	49	4	0	4					
		30JAN2003	50	4	0	4					
		31JAN2003	51	4	0	4					FOR DAY 1 THROUGH BOTH EXTRA DAYS THEY ARE UNACCOUNTED FOR SINCE PT THREW OUT BLISTER CARD BUT STATES WAS COMPLIANT.
		01FEB2003	52	4	0	4					
		02FEB2003	53	4	0	4					
		03FEB2003	54	4	0	4					
		04FEB2003	55	4	0	4					
		05FEB2003	56	4	0	4	NO	561.6	56	102	
	E0035021	25APR2003	1	2	0	2					
		26APR2003	2	1	0	1					
		27APR2003	3	1	0	1					
		28APR2003	4	2	0	2					
		29APR2003	5	3	0	3					
		30APR2003	6	3	0	3					
		01MAY2003	7	4	0	4					STUDY MEDS WERE GIVEN ON 5/1/03 FOR DAY 1 FOR WK 2.
		02MAY2003	8	4	0	4					
		03MAY2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	04MAY2003	10	4	0	4					
		05MAY2003	11	4	0	4					
		06MAY2003	12	4	0	4					
		07MAY2003	13	4	0	4					
		08MAY2003	14		0	4					
		09MAY2003	15	4	0	4					
		10MAY2003	16	4	0	4					
		11MAY2003	17	4	0	4					
		12MAY2003	18	4	0	4					
		13MAY2003	19	4	0	4					
		14MAY2003	20	4	0	4					
		15MAY2003	21	4	0	4					
		16MAY2003	22	4	0	4					
		17MAY2003	23	4	0	4					
		18MAY2003	24	4	0	4					
		19MAY2003	25	4	0	4					
		20MAY2003	26	4	0	4					
		21MAY2003	27	4	0	4					
		22MAY2003	28		0	4					
		23MAY2003	29	4	0	4					
		24MAY2003	30	4	0	4					
		25MAY2003	31	4	0	4					
		26MAY2003	32	4	0	4					
		27MAY2003	33	4	0	4					
		28MAY2003	34	4	0	4					
		29MAY2003	35	4	0	4					
		30MAY2003	36	4	0	4					
		31MAY2003	37	4	0	4					
		01JUN2003	38	4	0	4					
		02JUN2003	39	4	0	4					
		03JUN2003	40	4	0	4					
		04JUN2003	41	4	0	4					
		05JUN2003	42	4	0	4					
		06JUN2003	43		0	4					
		07JUN2003	44		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	08JUN2003	45			0					
		09JUN2003	46	4	0	4					DAY 1 SIC PT MISSED DOSE ON 6-8-03
		10JUN2003	47	4	0	4					
		11JUN2003	48	4	0	4					
		12JUN2003	49	4	0	4					
		13JUN2003	50	4	0	4					
		14JUN2003	51	4	0	4					
		15JUN2003	52	4	0	4					
		16JUN2003	53	4	0	4					
		17JUN2003	54	4	0	4					
		18JUN2003	55	4	0	4					
		19JUN2003	56	4	0	4	NO	550.9	55	98.6	
	E0036002	17JUN2003	1	2	0	2					
		18JUN2003	2	1	0	1					
		19JUN2003	3	1	0	1					
		20JUN2003	4	2	0	2					
		21JUN2003	5	3	0	3					
		22JUN2003	6	3	0	3					
		23JUN2003	7	3	0	3					
		24JUN2003	8	4	0	4					
		25JUN2003	9	4	0	4					
		26JUN2003	10	4	0	4					
		27JUN2003	11	4	0	4					
		28JUN2003	12	4	0	4					
		29JUN2003	13	4	0	4					
		30JUN2003	14	4	0	4					PT. SEEN IN CLINIC FOR VISIT 4 ON THIS DATE.
		01JUL2003	15	4	0	4					
		02JUL2003	16	4	0	4					
		03JUL2003	17	4	0	4					
		04JUL2003	18	4	0	4					
		05JUL2003	19	4	0	4					
		06JUL2003	20	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	07JUL2003	21		0	4					
		08JUL2003	22	4	0	4					
		09JUL2003	23	4	0	4					
		10JUL2003	24	4	0	4					
		11JUL2003	25	4	0	4					
		12JUL2003	26	4	0	4					
		13JUL2003	27	4	0	4					
		14JUL2003					NO	513	27	100	PT. CAME IN FOR VISIT TODAY
	E0036006	03JUL2003	1	2	0	2					
		04JUL2003	2	1	0	1					
		05JUL2003	3	1	0	1					
		06JUL2003	4	2	0	2					
		07JUL2003	5	3	0	3					
		08JUL2003	6	3	0	3					
		09JUL2003	7	3	0	3					
		10JUL2003	8	4	0	4					
		11JUL2003	9	4	0	4					
		12JUL2003	10	4	0	4					
		13JUL2003	11	4	0	4					
		14JUL2003	12	4	0	4					
		15JUL2003	13	4	0	4					
		16JUL2003	14	4	0	4					
		17JUL2003	15		0	4					
		18JUL2003	16	4	0	4					
		19JUL2003	17	4	0	4					
		20JUL2003	18	4	0	4					
		21JUL2003	19	4	0	4					
		22JUL2003	20	4	0	4					
		23JUL2003	21	4	0	4					
		24JUL2003	22	4	0	4					
		25JUL2003	23	4	0	4					
		26JUL2003	24	4	0	4					
		27JUL2003	25	4	0	4					
		28JUL2003	26	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	29JUL2003	27	4	0	4					
		30JUL2003	28	4	0	4					
		31JUL2003	29	4	0	4					
		01AUG2003	30	4	0	4					
		02AUG2003	31	4	0	4					
		03AUG2003	32	4	0	4					
		04AUG2003	33	4	0	4					
		05AUG2003	34	4	0	4					
		06AUG2003	35	4	0	4					
		07AUG2003	36	4	0	4					
		08AUG2003	37	4	0	4					
		09AUG2003	38	4	0	4					
		10AUG2003	39	4	0	4					
		11AUG2003	40	4	0	4					
		12AUG2003	41	4	0	4					
		13AUG2003	42	4	0	4					SUBJECT CAME IN FOR VISIT 8 ON 8/13/03 - SEE P. 205
		14AUG2003	43	4	0	4					
		15AUG2003	44	4	0	4					
		16AUG2003	45	4	0	4					
		17AUG2003	46	4	0	4					
		18AUG2003	47	4	0	4					
		19AUG2003	48	4	0	4					
		20AUG2003	49	4	0	4					
		21AUG2003	50	4	0	4					
		22AUG2003	51	4	0	4					
		23AUG2003	52	4	0	4					
		24AUG2003	53	4	0	4					
		25AUG2003	54	4	0	4					
		26AUG2003	55	4	0	4	NO	557.3	55	100	
	E0036007	03JUL2003	1	2	0	2					
		04JUL2003	2	1	0	1					
		05JUL2003	3	1	0	1					
		06JUL2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	07JUL2003	5	3	0	3					
		08JUL2003	6	3	0	3					DAY 6 & DAY 7 STUDY DRUG RE - DISPENSED ON 7/8/03 TO COMPLETE TITRATION SCHEDULE
		09JUL2003	7	3	0	3					DAY 6 & DAY 7 STUDY DRUG RE - DISPENSED ON 7/8/03 TO COMPLETE TITRATION SCHEDULE
		10JUL2003	8	4	0	4					
		11JUL2003	9	4	1	3					SUBJECT REDUCED DOSE BY ONE TABLET ON 7/11/03 DUE TO SEVERE SEDATION.
		12JUL2003	10	4	2	2					SUBJECT REDUCED DOSE BY 2 TABS
		13JUL2003	11	4	2	2					SUBJECT REDUCED DOSE BY 2 TABS
		14JUL2003	12	4	1	3					SUBJECT REDUCED DOSE BY 1 TAB
		15JUL2003	13	4	1	3					SUBJECT REDUCED DOSE BY 1 TAB
		16JUL2003					YES	303.8	13	94.1	SUBJECT STOPPED TAKING STUDY MEDS DUE TO SEVERE SEDATION.
	E0037009	16MAY2003	1	2	0	2					
		17MAY2003	2	1	0	1					
		18MAY2003	3	1	0	1					
		19MAY2003	4	2	0	2					
		20MAY2003	5	3	0	3					
		21MAY2003	6	3	0	3					
		22MAY2003	7	3	0	3					
		23MAY2003	8	4	0	4					SIC PT THREW AWAY
		23MAY2003	8	4	0	4					SIC
		24MAY2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0037009	25MAY2003	10	4	0	4					
		26MAY2003	11	4	0	4					
		27MAY2003	12	4	0	4					
		28MAY2003	13	4	0	4					
		29MAY2003	14	4	0	4					
		30MAY2003	15	4	0	4					
		31MAY2003	16	4	0	4					
		01JUN2003	17	4	0	4					
		02JUN2003	18	4	0	4					
		03JUN2003	19	4	0	4					
		04JUN2003	20	4	0	4					
		05JUN2003	21	4	0	4					
		06JUN2003	22	4	0	4					
		07JUN2003	23	4	0	4					
		08JUN2003	24	4	0	4					
		09JUN2003	25	4	0	4					
		10JUN2003	26	4	0	4					
		11JUN2003	27	4	0	4					
		12JUN2003	28	4	1	3					DR. DECREASED DOSAGE AS OF 6/12/03.
		13JUN2003	29	4	1	3					
		14JUN2003	30	4	1	3					
		15JUN2003	31	4	1	3					
		16JUN2003	32	4	1	3					
		17JUN2003	33	4	1	3					
		18JUN2003	34	4	4	0					PT MISSED DOSE
		19JUN2003	35	4	1	3					DR. DECREASED DOSAGE AS OF 6/12/03.
		20JUN2003	36	4	1	3					
		21JUN2003	37	4	1	3					
		22JUN2003	38	4	1	3					
		23JUN2003	39	4	1	3					
		24JUN2003	40	4	1	3					
		25JUN2003	41	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0037009	26JUN2003	42	4	1	3					DR. DECREASED DOSAGE AS OF 6/12/03.
		27JUN2003	43	4	1	3					
		28JUN2003	44	4	1	3					
		29JUN2003	45	4	1	3					
		30JUN2003	46	4	1	3					
		01JUL2003	47	4	1	3					
		02JUL2003	48	4	1	3					
		03JUL2003	49	4	1	3					DR. DECREASED DOSAGE AS OF 6/12/03.
		04JUL2003	50	4	1	3					
		05JUL2003	51	4	1	3					
		06JUL2003	52	4	1	3					
		07JUL2003	53	4	1	3					
		08JUL2003	54	4	1	3					
		09JUL2003	55	4	1	3	YES	497.3	54	97.8	
	E0039011	02JAN2003	1	2	0	2					
		03JAN2003	2	1	0	1					
		04JAN2003	3	1	0	1					
		05JAN2003	4	2	0	2					
		06JAN2003	5	3	0	3					
		07JAN2003	6	3	0	3					
		08JAN2003	7	3	0	3					
		09JAN2003	8	4	0	4					
		10JAN2003	9	4	0	4					
		11JAN2003	10	4	0	4					
		12JAN2003	11	4	0	4					
		13JAN2003	12	4	0	4					
		14JAN2003	13	4	0	4					
		15JAN2003	14	4	0	4					
		16JAN2003	15	4	0	4					
		17JAN2003	16	4	0	4					
		18JAN2003	17	4	0	4					
		19JAN2003	18	4	0	4					
		20JAN2003	19	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039011	21JAN2003	20	4	0	4					
		22JAN2003	21	4	0	4					
		23JAN2003	22	4	0	4					
		24JAN2003	23	4	0	4					
		25JAN2003	24	4	0	4					
		26JAN2003	25	4	0	4					
		27JAN2003	26	4	0	4					
		28JAN2003	27	4	0	4					
		29JAN2003	28	4	0	4					
		30JAN2003	29		0	4					
		31JAN2003	30		0	4					SUBJECT DID NOT TAKE DRUG ON 2/1/03 & 2/2/03
		01FEB2003	31			0					
		02FEB2003	32			0					
		03FEB2003	33	4	0	4					SIC
		04FEB2003	34	4	0	4					
		05FEB2003	35	4	0	4					
		06FEB2003	36	4	0	4					
		07FEB2003	37	4	0	4					
		08FEB2003	38	4	0	4					
		09FEB2003	39	4	0	4					
		10FEB2003	40	4	0	4					
		11FEB2003	41	4	0	4					
		12FEB2003	42	4	0	4					
		13FEB2003	43	4	0	8					SUBJECT DID NOT RETURN BLISTERCARD. SIC 100% COMPLIANCE PER SUBJECT REPORT
		14FEB2003	44	4	0	8					SUBJECT DID NOT RETURN BLISTERCARD.
		15FEB2003	45	4	0	4					
		16FEB2003	46	4	0	4					
		17FEB2003	47	4	0	4					
		18FEB2003	48	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039011	19FEB2003	49	4	0	4					SUBJECT DID NOT RETURN BLISTERCARD.
		19FEB2003	49	4	0	4					SUBJECT WAS LOST TO FOLLOW UP AND BLISTERCARD WAS NOT RETURNED. CANNOT CONFIRM ACTUAL COMPLIANCE WITH DRUG.
		20FEB2003	50	4	0	4					SUBJECT DID NOT RETURN BLISTERCARD. SIC 100% COMPLIANCE PER SUBJ. REPORT.
		21FEB2003	51	4	0	4					SUBJECT DID NOT RETURN BLISTERCARD.
		22FEB2003	52	4	0	4					
		23FEB2003	53	4	0	4					
		24FEB2003	54	4	0	4					
		25FEB2003	55	4	0	4					
		26FEB2003	56		0	4					UNK (SUBJECT IS LOST TO FOLLOW UP.)
		27FEB2003	57		0	4	NO	558.8	55	100	UNK (SUBJECT IS LOST TO FOLLOW UP.)
	E0039018	23JAN2003	1	2	0	2					
		24JAN2003	2	1	0	1					
		25JAN2003	3	1	0	1					
		26JAN2003	4	2	0	2					
		27JAN2003	5	3	0	3					
		28JAN2003	6	3	0	3					
		29JAN2003	7	3	0	3					
		30JAN2003	8	4	0	8					TOOK 2 EXTRA TABLETS ON 1/25/03 1/26/03 1/27/03 AND 1/29/03
		31JAN2003	9	4	0	8					
		01FEB2003	10	4	0	4					
		02FEB2003	11	4	0	4					
		03FEB2003	12	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039018	04FEB2003	13	4	0	4					
		05FEB2003	14	4	0	4					
		06FEB2003	15	4	0	4					RETURNED 2/13/03
		07FEB2003	16	4	0	4					RETURNED 2/13/03
		08FEB2003	17	4	0	4					
		09FEB2003	18	4	0	4					
		10FEB2003	19	4	0	4					
		11FEB2003	20	4	0	4					
		12FEB2003	21	4	0	4					
		13FEB2003	22	4	0	4					
		14FEB2003	23	4	0	4					
		15FEB2003	24	4	0	4					
		16FEB2003	25	4	0	4					
		17FEB2003	26	4	0	4					
		18FEB2003	27	4	0	4					
		19FEB2003	28	4	0	4					
		20FEB2003	29	4	0	4					THE CARD WAS NEVER RETURNED. THE SUBJECT WAS LOST TO FOLLOW-UP.
		21FEB2003	30	4	0	4					
		22FEB2003	31	4	0	4					
		23FEB2003	32	4	0	4					
		24FEB2003	33	4	0	4					
		25FEB2003	34	4	0	4					
		26FEB2003	35	4	0	4					
		27FEB2003	36		0	4					UNK CAN'T CONFIRM IF TOOK ANY DOSES OR EXTRA DAY DOSES
		28FEB2003	37		0	4	NO	568.9	37	106	
	E0039026	07MAR2003	1	2	0	2					
		08MAR2003	2	1	0	1					
		09MAR2003	3	1	0	1					
		10MAR2003	4	2	0	2					
		11MAR2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	12MAR2003	6	3	0	3					
		13MAR2003	7	3	0	3					
		14MAR2003	8	4	0	4					
		15MAR2003	9	4	0	4					
		16MAR2003	10	4	0	4					
		17MAR2003	11	4	0	4					
		18MAR2003	12	4	0	4					
		19MAR2003	13	4	0	4					
		20MAR2003	14	4	0	4					
		21MAR2003	15	4	0	4					
		22MAR2003	16	4	0	4					
		23MAR2003	17	4	0	4					
		24MAR2003	18	4	0	4					
		25MAR2003	19	4	0	4					
		26MAR2003	20		0	4					
		27MAR2003	21		0	4					
		28MAR2003	22	4	0	4					
		29MAR2003	23	4	0	4					
		30MAR2003	24	4	0	4					
		31MAR2003	25	4	0	4					
		01APR2003	26	4	0	4					
		02APR2003	27	4	0	4					
		03APR2003	28	4	0	4					
		04APR2003	29	4	0	4					
		05APR2003	30	4	0	4					
		06APR2003	31	4	0	4					
		07APR2003	32	4	0	4					
		08APR2003	33	4	0	4					
		09APR2003	34	4	0	4					
		10APR2003	35	4	0	4					
		11APR2003	36	4	0	4					
		12APR2003	37	4	0	4					
		13APR2003	38	4	0	4					
		14APR2003	39	4	0	4					
		15APR2003	40	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	16APR2003	41	4	0	4					
		17APR2003	42	4	0	4					
		18APR2003	43	4	0	4					
		19APR2003	44	4	0	4					
		20APR2003	45	4	0	4					
		21APR2003	46	4	0	4					
		22APR2003	47	4	0	4					
		23APR2003	48	4	0	4					
		24APR2003	49	4	0	4					
		25APR2003	50	4	0	4					
		26APR2003	51	4	0	4					
		27APR2003	52	4	0	4					
		28APR2003	53	4	0	4					
		29APR2003	54	4	0	4					
		30APR2003	55	4	0	4					
		01MAY2003					NO	557.3	55	100	THE SUBJECT'S VISIT 10 WAS DONE ON 5-01-03, THEREFORE THE DOSE WAS NOT TAKEN ON 5-01-03.
	E0039028	24MAR2003	1	2	0	2					
		25MAR2003	2	1	0	1					
		26MAR2003	3	1	0	1					
		27MAR2003	4	2	0	2					
		28MAR2003	5	3	0	3					
		29MAR2003	6	3	0	3					
		30MAR2003	7	3	0	3					
		31MAR2003	8	4	0	4					
		01APR2003	9	4	0	4					
		02APR2003	10	4	0	4					
		03APR2003	11	4	0	4					
		04APR2003	12	4	0	4					
		05APR2003	13	4	0	4					
		06APR2003	14	4	0	4					
		07APR2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039028	08APR2003	16	4	0	4					
		09APR2003	17	4	0	4					
		10APR2003	18	4	0	4					
		11APR2003	19	4	0	4					
		12APR2003	20	4	0	4					
		13APR2003	21	4	0	4					
		14APR2003	22	4	0	4					
		15APR2003	23	4	0	4					
		16APR2003	24	4	0	4					
		17APR2003	25	4	0	4					
		18APR2003	26	4	0	4					
		19APR2003	27	4	0	4					
		20APR2003	28	4	0	4					
		21APR2003	29	4	0	4					
		22APR2003	30	4	0	4					
		23APR2003	31	4	0	4					
		24APR2003	32	4	0	4					
		25APR2003	33	4	0	4					
		26APR2003	34	4	0	4					
		27APR2003	35	4	0	4					
		28APR2003	36	4	0	4					
		29APR2003	37	4	0	4					
		30APR2003	38	4	0	4					
		01MAY2003	39	4	0	4					
		02MAY2003	40	4	0	4					
		03MAY2003	41	4	0	4					
		04MAY2003	42	4	0	4					
		05MAY2003	43	4	0	4					SIC EXTRA DAY DOSES WERE NOT TAKEN ON 5/5/03 AND 5/6/03. IT IS UNKNOWN (SIC) UNOBTAINABLE) WHAT DATES THE SUBJECT TOOK THESE DOSES. DOUBLE DOSING IS NOT SUSPECTED.
		06MAY2003	44	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039028	07MAY2003	45	4	0	4					
		08MAY2003	46	4	0	4					
		09MAY2003	47	4	0	4					
		10MAY2003	48	4	0	4					
		11MAY2003	49	4	0	4					
		12MAY2003	50		0	4					
		13MAY2003	51		0	4	NO	553.9	51	100	
	E0039032	14MAR2003	1	2	0	2					
		15MAR2003	2	1	0	1					
		16MAR2003	3	1	0	1					
		17MAR2003	4	2	0	2					
		18MAR2003	5	3	2	1					SUBJECT TOOK ONLY ONE TABLET TO PREVENT DROWSINESS
		19MAR2003	6	4	0	4					THE SUBJECT RETURNED ON THE 19TH FOR VISIT 3
		20MAR2003	7	4	0	4					THE SUBJECT RETURNED ON THE 19TH. FOR VISIT 3
		21MAR2003	8	4	0	4					
		22MAR2003	9	4	0	4					
		23MAR2003	10	4	0	4					
		24MAR2003									SUBJECT DID NOT TAKE STUDY DRUG NONCOMPLIANCE
		25MAR2003									NON - COMPLIANCE
		26MAR2003									NON - COMPLIANCE
		27MAR2003					NO	365	10	100	NON - COMPLIANCE
	E0039034	19MAR2003	1	2	0	2					
		20MAR2003	2	1	0	1					
		21MAR2003	3	1	0	1					
		22MAR2003	4	2	0	2					
		23MAR2003	5	3	0	3					
		24MAR2003	6	3	0	3					
		25MAR2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	26MAR2003	8	4	0	4					
		27MAR2003	9	4	0	4					
		28MAR2003	10	4	0	4					
		29MAR2003	11	4	0	4					
		30MAR2003	12	4	0	4					
		31MAR2003	13	4	0	4					
		01APR2003	14	4	0	4					
		02APR2003	15	4	0	4					
		03APR2003	16	4	0	4					
		04APR2003	17	4	0	4					
		05APR2003	18	4	0	4					
		06APR2003	19	4	0	4					
		07APR2003	20	4	0	4					
		08APR2003	21	4	0	4					
		09APR2003	22	4	0	4					
		10APR2003	23	4	0	4					
		11APR2003	24	4	0	4					
		12APR2003	25	4	0	4					
		13APR2003	26	4	0	4					
		14APR2003	27	4	0	4					
		15APR2003	28	4	0	4					
		16APR2003	29	4	0	4					
		17APR2003	30	4	0	4					
		18APR2003	31	4	0	4					
		19APR2003	32	4	0	4					
		20APR2003	33	4	0	4					
		21APR2003	34	4	0	4					
		22APR2003	35	4	0	4					
		23APR2003	36		0	4					
		24APR2003	37	4	0	4					
		25APR2003	38	4	0	4					
		26APR2003	39	4	0	4					
		27APR2003	40	4	0	4					
		28APR2003	41	4	0	4					
		29APR2003	42	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	30APR2003	43	4	0	4					
		01MAY2003	44	4	0	4					
		02MAY2003	45	4	0	4					
		03MAY2003	46	4	0	4					
		04MAY2003	47	4	0	4					
		05MAY2003	48	4	0	4					
		06MAY2003	49	4	0	4					
		07MAY2003	50		0	4					
		08MAY2003	51		0	4					
		09MAY2003	52	4	0	4					
		10MAY2003	53	4	0	4					
		11MAY2003	54	4	0	4					
		12MAY2003	55	4	0	4					
		13MAY2003	56	4	0	4	NO	558	56	100	
	E0039042	07MAY2003	1	2	0	2					
		08MAY2003	2	1	0	1					
		09MAY2003	3	1	0	1					
		10MAY2003	4	2	0	2					
		11MAY2003	5	3	0	3					
		12MAY2003	6	3	0	3					
		13MAY2003	7	3	3	0					THE SUBJECT THREW OUT THIS DOSE.
		14MAY2003	8	4	0	4					
		15MAY2003	9	4	0	4					
		16MAY2003	10	4	0	4					
		17MAY2003	11	4	0	4					
		18MAY2003	12	4	0	4					
		19MAY2003	13	4	0	4					
		20MAY2003	14	4	0	4					
		21MAY2003	15	4	0	4					
		22MAY2003	16	4	0	4					
		23MAY2003	17	4	0	4					
		24MAY2003	18	4	0	4					
		25MAY2003	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	26MAY2003	20	4	0	4					
		27MAY2003	21	4	0	4					
		28MAY2003	22	4	0	4					
		29MAY2003	23	4	0	4					
		30MAY2003	24	4	0	4					
		31MAY2003	25	4	0	4					
		01JUN2003	26	4	0	4					
		02JUN2003	27	4	0	4					
		03JUN2003	28	4	0	4					
		04JUN2003	29		0	4					
		05JUN2003	30	4	0	4					
		06JUN2003	31	4	0	4					
		07JUN2003	32	4	0	4					
		08JUN2003	33	4	0	4					
		09JUN2003	34	4	0	4					
		10JUN2003	35	4	0	4					
		11JUN2003	36	4	0	4					
		12JUN2003	37	4	0	4					
		13JUN2003	38	4	0	4					
		14JUN2003	39	4	0	4					
		15JUN2003	40	4	0	4					
		16JUN2003	41	4	0	4					
		17JUN2003	42	4	0	4					
		18JUN2003	43	4	0	4					
		19JUN2003	44	4	0	4					
		20JUN2003	45	4	0	4					
		21JUN2003	46	4	0	4					
		22JUN2003	47	4	0	4					
		23JUN2003	48	4	0	4					
		24JUN2003	49	4	4	0					THE SUBJECT FORGOT TO TAKE THE DOSE 2003/06/24.
		25JUN2003	50	4	0	4					
		26JUN2003	51	4	0	4					
		27JUN2003	52	4	0	4					
		28JUN2003	53	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	29JUN2003	54	4	0	4					
		30JUN2003	55	4	0	4					
		01JUL2003	56	4	0	4	NO	540.2	54	96.7	
	E0041004	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					TOOK MEDS ON 02/04/03 PATIENT MISSED DOSE ON 02/03/03
		04FEB2003	6	3	0	3					TOOK MEDS ON 02/05/03
		05FEB2003	7	3	0	3					TOOK MEDS ON 02/06/03
		06FEB2003	8		0	4					SIC TOOK MEDS ON 02/07/03
		07FEB2003	9		0	4					SIC TOOK MEDS ON 02/08/03 PATIENT MISSED DOSE ON 02/09/03
		08FEB2003	10			0					
		09FEB2003	11			0					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4					
		12FEB2003	14	4	0	4					
		13FEB2003	15	4	0	4					
		14FEB2003	16	4	0	4					
		15FEB2003	17	4	0	4					
		16FEB2003	18	4	0	4					
		17FEB2003	19	4	0	4					
		18FEB2003	20	4	0	4					
		19FEB2003	21	4	0	4					
		20FEB2003	22	4	0	4					
		21FEB2003	23	4	0	4					
		22FEB2003	24	4	0	4					
		23FEB2003	25	4	0	4					
		24FEB2003	26	4	0	4					
		25FEB2003	27	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	26FEB2003	28	4	0	4					
		27FEB2003	29	4	0	4					
		28FEB2003	30	4	0	4					
		01MAR2003	31	4	0	4					
		02MAR2003	32	4	0	4					
		03MAR2003	33	4	0	4					
		04MAR2003	34	4	0	4					
		05MAR2003	35	4	0	4					
		06MAR2003	36		0	4					
		07MAR2003	37	4	0	4					
		08MAR2003	38	4	0	4					
		09MAR2003	39	4	0	4					
		10MAR2003	40	4	0	4					
		11MAR2003	41	4	0	4					
		12MAR2003	42	4	0	4					
		13MAR2003	43	4	0	4					
		14MAR2003	44	4	0	4					
		15MAR2003	45	4	0	4					
		16MAR2003	46	4	0	4					
		17MAR2003	47	4	0	4					
		18MAR2003	48	4	0	4					
		19MAR2003	49	4	0	4					
		20MAR2003	50	4	0	4					
		21MAR2003	51	4	0	4					SUBJECT COULD NOT LOCATE BLISTER CARD AND THEREFORE DID NOT RETURN IT.
		22MAR2003	52	4	0	4					
		23MAR2003	53	4	0	4					
		24MAR2003	54	4	0	4					
		25MAR2003	55	4	0	4					
		26MAR2003	56	4	0	4					
		27MAR2003	57	4	0	4					
		28MAR2003	58		0	4					SIC PER PATIENT REPORT
		29MAR2003	59		0	4	NO	539.8	57	96.4	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	01MAY2003	1	2	0	2					
		02MAY2003	2	1	0	1					
		03MAY2003	3	1	0	1					
		04MAY2003	4	2	0	2					
		05MAY2003	5	3	0	3					
		06MAY2003	6	3	0	3					
		07MAY2003	7	3	0	3					
		08MAY2003	8	4	0	4					
		09MAY2003	9	4	0	4					
		10MAY2003	10	4	0	4					
		11MAY2003	11	4	0	4					
		12MAY2003	12	4	0	4					
		13MAY2003	13	4	0	4					
		14MAY2003	14	4	0	4					
		15MAY2003	15	4	0	4					
		16MAY2003	16	4	0	4					
		17MAY2003	17	4	0	4					
		18MAY2003	18	4	0	4					
		19MAY2003	19	4	0	4					
		20MAY2003	20	4	0	4					
		21MAY2003	21	4	0	4					
		22MAY2003	22	4	0	5					PT. LOST 1 TAB, USED 1 EXTRA YELLOW ON 5/21/03
		23MAY2003	23	4	0	4					
		24MAY2003	24	4	0	4					
		25MAY2003	25	4	0	4					
		26MAY2003	26	4	0	4					
		27MAY2003	27	4	0	4					
		28MAY2003	28	4	0	4					
		29MAY2003	29		0	4					
		30MAY2003	30		0	4					SUBJECT WAS OUT OF STUDY MEDS AND DID NOT TAKE STUDY MEDS ON 05/31/03, 06/1/03, AND 06/02/03
		31MAY2003	31			0					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	01JUN2003	32			0					
		02JUN2003	33			0					
		03JUN2003	34	4	0	4					
		04JUN2003	35	4	0	4					
		05JUN2003	36	4	0	4					
		06JUN2003	37	4	0	4					
		07JUN2003	38	4	0	4					
		08JUN2003	39	4	0	4					
		09JUN2003	40	4	0	4					
		10JUN2003	41		0	4					
		11JUN2003	42		0	4	NO	501.2	39	92.9	SUBJECTS LAST DOSE OF STUDY MEDICATION PRIOR TO 06/16/03 EARLY TERMINATION
	E0042002	09JUL2003	1	2	0	2					
		10JUL2003	2	1	0	1					
		11JUL2003	3	1	0	1					
		12JUL2003	4	2	0	2					
		13JUL2003	5	3	0	3					
		14JUL2003	6	3	0	3					
		15JUL2003	7	3	0	3					1. DOSE REDISPENSED 2. VISIT 3 ON THIS DATE, 7-15-03
		16JUL2003	8	4	0	4					
		17JUL2003	9	4	0	4					
		18JUL2003	10	4	0	4					
		19JUL2003	11	4	0	4					
		20JUL2003	12	4	0	4					
		21JUL2003	13	4	0	4					
		22JUL2003	14	4	0	4					SUBJECT DID NOT TAKE THIS DOSE DUE TO SHORT VISIT INTERVAL
		23JUL2003	15	4	0	4					
		24JUL2003	16	4	0	4					
		25JUL2003	17	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	26JUL2003	18	4	0	4					
		27JUL2003	19	4	0	4					
		28JUL2003	20	4	0	4					
		29JUL2003	21	4	0	4					
		30JUL2003	22	4	0	4					
		31JUL2003	23	4	0	4					
		01AUG2003	24	4	0	4					
		02AUG2003	25	4	0	4					
		03AUG2003	26	4	0	4					
		04AUG2003	27	4	0	4					
		05AUG2003	28	4	0	4					
		06AUG2003	29	4	0	4					
		07AUG2003	30	4	0	4					
		08AUG2003	31	4	0	4					
		09AUG2003	32	4	0	4					
		10AUG2003	33	4	0	4					
		11AUG2003	34	4	0	4					
		12AUG2003	35	4	0	4					
		13AUG2003	36	4	0	4					
		14AUG2003	37	4	0	4					
		15AUG2003	38	4	0	4					
		16AUG2003	39	4	0	4					
		17AUG2003	40	4	0	4					
		18AUG2003	41	4	0	4					
		19AUG2003	42	4	0	4					
		20AUG2003	43	4	0	4					
		21AUG2003	44	4	0	4					
		22AUG2003	45	4	0	4					
		23AUG2003	46	4	0	4					
		24AUG2003	47	4	0	4					
		25AUG2003	48	4	0	4					
		26AUG2003	49	4	0	4					
		27AUG2003	50	4	0	4					
		28AUG2003	51	4	0	4					
		29AUG2003	52	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	30AUG2003	53	4	0	4					
		31AUG2003	54	4	0	4					
		01SEP2003	55	4	0	4	NO	557.3	55	100	
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	11JUL2003	1	2	0	2					
		12JUL2003	2	1	0	1					
		13JUL2003	3	1	0	1					
		14JUL2003	4	2	0	2					
		15JUL2003	5	3	0	3					
		16JUL2003					NO	210	5	100	PATIENT DID NOT TAKE DOSE DUE TO ADVERSE EVENTS
	E0003002	29OCT2002	1	2	0	2					
		30OCT2002	2	1	0	1					
		31OCT2002	3	1	0	1					
		01NOV2002	4	2	0	2					
		02NOV2002	5	3	0	3					
		03NOV2002	6	3	0	3					
		04NOV2002	7	3	0	3					
		05NOV2002	8	4	0	4					
		06NOV2002	9	4	0	4					
		07NOV2002	10	4	0	4					
		08NOV2002	11	4	0	4					
		09NOV2002	12	4	0	4					
		10NOV2002	13	4	0	4					
		11NOV2002	14	4	0	4					
		12NOV2002	15		0	4					
		13NOV2002	16		0	4					
		14NOV2002	17	4	0	4					
		15NOV2002	18	4	0	4					
		16NOV2002	19	4	0	4					
		17NOV2002	20	4	0	4					
		18NOV2002	21	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	19NOV2002	22	4	0	4					PT. ERROR, PUNCHED OUT BUT NOT TAKEN, THROWN AWAY
		20NOV2002	23	4	0	4					
		21NOV2002	24	4	0	4					
		22NOV2002	25	4	0	4					
		23NOV2002	26	4	0	4					
		24NOV2002	27	4	0	4					
		25NOV2002	28	4	0	4					
		26NOV2002	29	4	0	4					
		27NOV2002	30	4	0	4					
		28NOV2002	31	4	0	4					
		29NOV2002	32	4	0	4					
		30NOV2002	33	4	0	4					
		01DEC2002	34	4	0	4					
		02DEC2002	35	4	0	4					
		03DEC2002	36	4	0	4					
		04DEC2002	37	4	0	4					
		05DEC2002	38	4	0	4					
		06DEC2002	39	4	0	4					
		07DEC2002	40	4	0	4					
		08DEC2002	41	4	0	4					
		09DEC2002	42	4	0	4					
		10DEC2002	43	4	0	4					PT. STARTED DOSES IN WRONG ORDER - INTAKE CORRECT
		11DEC2002	44	4	0	4					PT. STARTED DOSES IN WRONG ORDER - INTAKE CORRECT
		12DEC2002	45	4	0	4					
		13DEC2002	46	4	0	4					
		14DEC2002	47	4	0	4					
		15DEC2002	48	4	0	4					
		16DEC2002	49	4	0	4					
		17DEC2002	50	4	0	4					THE "EXTRA" DOSES TAKEN ON 12/10/02 AND 12/11/02
		18DEC2002	51	4	0	4					
		19DEC2002	52	4	0	4					
		20DEC2002	53	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	21DEC2002	54	4	0	4					
		22DEC2002	55	4	0	4					
		23DEC2002	56	4	0	4	NO	558	56	100	
	E0005031	02APR2003	1	2	0	2					
		03APR2003	2	1	0	1					
		04APR2003	3	1	0	1					
		05APR2003	4	2	0	2					
		06APR2003	5	3	0	3					
		07APR2003	6	3	0	3					
		08APR2003	7	3	0	3					
		09APR2003	8	4	0	4					
		10APR2003	9	4	0	4					
		11APR2003	10	4	0	4					
		12APR2003	11	4	0	4					
		13APR2003	12	4	0	4					
		14APR2003	13	4	0	4					
		15APR2003	14	4	0	4					
		16APR2003	15	4	0	4					CARD NOT RETURNED
		17APR2003	16	4	0	4					
		18APR2003	17	4	0	4					
		19APR2003	18	4	0	4					
		20APR2003	19	4	0	4					
		21APR2003	20	4	0	4					
		22APR2003	21	4	0	4					
		23APR2003	22		0	4					PER SUBJECT REPORT SIC
		24APR2003	23	4	0	8					
		25APR2003	24	4	0	4					
		26APR2003	25	4	0	4					
		27APR2003	26	4	0	4					
		28APR2003	27	4	0	4					
		29APR2003	28	4	0	4					
		30APR2003	29	4	0	4					
		01MAY2003	30	4	0	4					
		02MAY2003	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0005031	03MAY2003	32	4	0	4					
		04MAY2003	33	4	0	4					
		05MAY2003	34	4	4	0					PATIENT MISSED DOSE
		06MAY2003	35	4	4	0					MISSED DOSE
		07MAY2003	36	4	0	4					CARD NOT RETURNED
		08MAY2003	37	4	0	4					
		09MAY2003	38	4	0	4					
		10MAY2003	39	4	0	4					
		11MAY2003	40	4	0	4					
		12MAY2003	41	4	0	4					
		13MAY2003	42	4	0	4					
		14MAY2003	43	4	0	8					UNK
		15MAY2003	44	4	0	8					
		16MAY2003	45	4	0	4					
		17MAY2003	46	4	0	4					
		18MAY2003	47	4	0	4					
		19MAY2003	48	4	0	4					
		20MAY2003					NO	563.5	46	102	SKIPPED DOSE
	E0005033	16APR2003	1	2	0	2					PT NOT RANDOMIZED UNTIL 4/16/03
		17APR2003	2	1	0	1					
		18APR2003	3	1	0	1					
		19APR2003	4	2	0	2					
		20APR2003	5	3	0	3					
		21APR2003	6	3	0	3					
		22APR2003	7	4	0	4					
		23APR2003	8	4	0	4					
		24APR2003	9	4	0	4					
		25APR2003	10	4	0	4					
		26APR2003	11	4	1	3					SKIPPED 1 PILL
		27APR2003	12	4	2	2					SKIPPED 2 PILLS
		28APR2003	13	4	2	2					SKIPPED 2 PILLS
		29APR2003	14		4	0					SKIPPED DOSE
		30APR2003	15	4	1	3					DOSE REDUCED BY 1 TAB.

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0005033	01MAY2003	16	4	1	3					
		02MAY2003	17	4	1	3					
		03MAY2003	18	4	1	3					
		04MAY2003	19	4	1	3					
		05MAY2003									SKIPPED DOSE
		06MAY2003					YES	360.5	18	90.9	SUBJ DOSES AT NIGHT. NOT TAKEN BECAUSE DATE FALLS ON VISIT 10.
	E0005038	14MAY2003	1	2	0	2					
		15MAY2003	2	1	0	1					
		16MAY2003	3	1	0	1					
		17MAY2003	4	2	0	2					
		18MAY2003	5	3	0	3					
		19MAY2003	6	3	0	3					
		20MAY2003	7	3	0	3					
		21MAY2003	8		0	4					
		22MAY2003	9	4	0	4					
		23MAY2003	10	4	0	4					
		24MAY2003	11	4	0	4					
		25MAY2003	12	4	0	4					
		26MAY2003	13	4	0	4					
		27MAY2003	14	4	0	4					
		28MAY2003	15	4	0	4					
		29MAY2003	16	4	1	3					DOSE REDUCED
		30MAY2003	17	4	1	3					
		31MAY2003	18	4	1	3					
		01JUN2003	19	4	1	3					
		02JUN2003	20	4	1	3					
		03JUN2003	21	4	1	3					
		04JUN2003	22	4	1	3	YES	461.4	22	100	
	E0007009	17APR2003	1	2	0	2					
		18APR2003	2	1	0	1					
		19APR2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0007009	20APR2003	4	2	0	2					
		21APR2003	5	3	0	3					
		22APR2003					NO	210	5	100	PT BEGAN SEDATION AND STOPPED MEDICATION
	E0009010	13MAR2003	1	2	0	2					PT. DID NOT RETURN MEDICATION
		14MAR2003	2	1	0	1					
		15MAR2003	3	1	0	1					
		16MAR2003	4	2	0	2					
		17MAR2003	5	3	0	3					
		18MAR2003	6	3	0	3					
		19MAR2003	7	3	0	3					
		20MAR2003	8	4	0	8					SIC UNKNOWN - SIC
		20MAR2003	8	4	0	8					SIC
		21MAR2003	9	4	0	8					SIC
		21MAR2003	9	4	0	8					SIC
		22MAR2003	10	4	0	4					
		23MAR2003	11	4	0	4					
		24MAR2003	12	4	0	4					
		25MAR2003	13	4	0	4					
		26MAR2003	14	4	0	4					PT. DID NOT RETURN MEDICATION.
		27MAR2003	15	4	0	4					
		28MAR2003	16	4	0	4					
		29MAR2003	17	4	0	4					
		30MAR2003	18	4	0	4					
		31MAR2003	19	4	0	4					
		01APR2003	20	4	0	4					
		02APR2003	21	4	0	4					PT. DID NOT RETURN MEDICATION.
		03APR2003									SIC
		07APR2003									SIC UNKNOWN - SIC
		09APR2003					NO	545.2	21	111	UNKNOWN SIC

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0009011	06MAY2003	1	2	0	2					
		07MAY2003	2	1	0	1					
		08MAY2003	3	1	0	1					
		09MAY2003	4	2	0	2					
		10MAY2003	5	3	0	3					
		11MAY2003	6	3	0	3					
		12MAY2003	7	4	0	4					
		13MAY2003	8	4	0	4					
		14MAY2003	9	4	0	4					
		15MAY2003	10	4	0	4					
		16MAY2003	11	4	0	4					
		17MAY2003	12	4	0	4					
		18MAY2003	13	4	0	4					
		19MAY2003	14	4	0	4					
		20MAY2003	15	4	0	4					
		21MAY2003	16	4	0	4					
		22MAY2003	17	4	0	4					
		23MAY2003	18	4	0	4					
		24MAY2003	19	4	0	4					
		25MAY2003	20	4	0	4					
		26MAY2003	21		0	4					
		27MAY2003	22	4	0	4					
		28MAY2003	23	4	0	4					
		29MAY2003	24	4	0	4					
		30MAY2003	25	4	0	4					
		31MAY2003	26	4	0	4					
		01JUN2003	27	4	0	4					
		02JUN2003	28	4	0	4					
		03JUN2003	29	4	0	4					
		04JUN2003	30	4	0	4					
		05JUN2003	31	4	0	4					
		06JUN2003	32	4	0	4					
		07JUN2003	33	4	0	4					
		08JUN2003	34	4	0	4					
		09JUN2003	35	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0009011	10JUN2003	36	4	0	4					
		11JUN2003	37	4	0	4					
		12JUN2003	38	4	0	4					
		13JUN2003	39	4	0	4					
		14JUN2003	40	4	0	4					
		15JUN2003	41	4	0	4					
		16JUN2003	42	4	0	4					
		17JUN2003	43	4	0	4					
		18JUN2003	44	4	0	4					
		19JUN2003	45	4	0	4					
		20JUN2003	46	4	0	4					
		21JUN2003	47	4	0	4					
		22JUN2003	48	4	0	4					
		23JUN2003	49	4	0	4					
		24JUN2003	50	4	0	4					
		25JUN2003	51	4	0	4					
		26JUN2003	52	4	0	4					
		27JUN2003	53	4	0	4					
		28JUN2003	54	4	0	4					
		29JUN2003	55	4	0	4					
		30JUN2003	56	4	0	4					
		01JUL2003	57		0	4					
		02JUL2003	58		0	4	NO	562.9	58	100	
	E0010005	18DEC2002	1	2	0	2					SUBJECT DID NOT RETURN BLISTERCARD - UNABLE TO CONFIRM DOSAGE TAKEN.
		19DEC2002	2	1	0	1	NO	75	2	100	
	E0011016	21APR2003	1	2	0	2					
		22APR2003	2	1	0	1					
		23APR2003	3	1	0	1					
		24APR2003	4	2	0	2					
		25APR2003	5	3	0	3					
		26APR2003	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	27APR2003	7	3	0	3					
		28APR2003	8	4	0	4					
		29APR2003	9	4	0	4					
		30APR2003	10	4	0	4					
		01MAY2003	11	4	0	4					
		02MAY2003	12	4	0	4					
		03MAY2003	13	4	0	4					
		04MAY2003	14	4	0	4					
		05MAY2003	15	4	0	4					
		06MAY2003	16	4	0	4					
		07MAY2003	17	4	0	4					
		08MAY2003	18	4	0	4					
		09MAY2003	19	4	0	4					
		10MAY2003	20	4	0	4					
		11MAY2003	21	4	0	4					
		12MAY2003	22	4	0	4					
		13MAY2003	23	4	0	4					
		14MAY2003	24	4	0	4					
		15MAY2003	25	4	0	4					
		16MAY2003	26	4	0	4					
		17MAY2003	27	4	0	4					
		18MAY2003	28	4	0	4					
		19MAY2003	29	4	0	4					
		20MAY2003	30	4	0	4					
		21MAY2003	31	4	0	4					
		22MAY2003	32	4	0	4					
		23MAY2003	33	4	0	4					
		24MAY2003	34	4	0	4					
		25MAY2003	35	4	0	4					
		26MAY2003	36		0	4					PATIENT TOOK EXTRA DAY DOSE BECAUSE CAME IN ONE DAY LATER SINCE HOLIDAY ON THIS DATE.
		27MAY2003	37	4	0	4					
		28MAY2003	38	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	29MAY2003	39	4	0	4					
		30MAY2003	40	4	0	4					
		31MAY2003	41	4	0	4					
		01JUN2003	42	4	0	4					
		02JUN2003	43	4	0	4					PATIENT RETURNED FOR APPOINTMENT AFTER 6 DAYS.
		03JUN2003	44	4	0	4					
		04JUN2003	45	4	0	4					
		05JUN2003	46	4	0	4					
		06JUN2003	47	4	0	4					
		07JUN2003	48	4	0	4					
		08JUN2003	49	4	0	4					
		09JUN2003	50	4	0	4					
		10JUN2003	51	4	0	4					
		11JUN2003	52	4	0	4					
		12JUN2003	53	4	0	4					
		13JUN2003	54	4	0	4					
		14JUN2003	55	4	0	4					
		15JUN2003	56	4	0	4	NO	558	56	100	
	E0011020	08MAY2003	1	2	0	2					
		09MAY2003	2	1	0	1					
		10MAY2003					NO	75	2	100	PATIENT STOPPED TAKING STUDY MEDICATION DUE TO ADVERSE EVENTS.
	E0018002	29NOV2002	1	2	0	2					
		30NOV2002	2	1	0	1					
		01DEC2002	3	1	0	1					
		02DEC2002	4	2	0	2					
		03DEC2002	5	3	0	3					
		04DEC2002	6	3	0	3					
		05DEC2002	7	3	0	3					
		06DEC2002	8	4	0	4					
		07DEC2002	9	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	08DEC2002	10	4	0	4					
		09DEC2002	11	4	0	4					
		10DEC2002	12	4	0	4					
		11DEC2002	13	4	0	4					
		12DEC2002	14	4	0	4					
		13DEC2002	15	4	0	4					
		14DEC2002	16	4	0	4					
		15DEC2002	17	4	0	4					
		16DEC2002	18	4	0	4					
		17DEC2002	19	4	0	4					
		18DEC2002	20	4	0	4					
		19DEC2002	21	4	0	4					
		20DEC2002	22	4	0	4					
		21DEC2002	23	4	0	4					
		22DEC2002	24	4	0	4					
		23DEC2002	25	4	0	4					
		24DEC2002	26	4	0	4					
		25DEC2002	27	4	0	4					
		26DEC2002	28	4	0	4					
		27DEC2002	29	4	0	4					
		28DEC2002	30	4	0	4					
		29DEC2002	31	4	0	4					
		30DEC2002	32	4	0	4					
		31DEC2002	33		0	4					
		01JAN2003	34		0	4					
		02JAN2003	35	4	0	4					
		03JAN2003	36	4	0	4					
		04JAN2003	37	4	0	4					
		05JAN2003	38	4	0	4					
		06JAN2003	39	4	0	4					
		07JAN2003	40	4	0	4					
		08JAN2003	41	4	0	4					
		09JAN2003	42	4	0	4					
		10JAN2003	43	4	0	4					
		11JAN2003	44	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	12JAN2003	45	4	0	4					
		13JAN2003	46	4	0	4					
		14JAN2003	47	4	0	4					
		15JAN2003	48	4	0	4					
		16JAN2003	49	4	4	0					MISSED DOSE
		17JAN2003	50	4	0	4					
		18JAN2003	51	4	0	4					
		19JAN2003	52	4	0	4					
		20JAN2003	53	4	0	4					
		21JAN2003	54	4	0	4	NO	545.4	53	98	
	E0018003	26NOV2002	1	2	0	2					
		27NOV2002	2	1	0	1					
		28NOV2002	3	1	0	1					
		29NOV2002	4	2	0	2					
		30NOV2002	5	3	0	3					
		01DEC2002	6	3	0	3					
		02DEC2002	7	3	0	3					
		03DEC2002	8	4	0	4					
		04DEC2002	9	4	0	4					
		05DEC2002	10	4	0	4					
		06DEC2002	11	4	0	4					
		07DEC2002	12	4	0	4					
		08DEC2002									NOT TAKEN
		09DEC2002					NO	404.2	12	100	NOT TAKEN
	E0018013	24JAN2003	1	2	0	2					
		25JAN2003	2	1	0	1					
		26JAN2003	3	1	0	1					
		27JAN2003	4	2	0	2					
		28JAN2003					NO	162.5	4	100	PT. DISCONTINUED MEDICATION PAGE 199
	E0019002	12NOV2002	1	2	0	2					
		13NOV2002	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019002	14NOV2002	3	1	0	1					
		15NOV2002	4	2	0	2					
		16NOV2002	5	3	0	3					
		17NOV2002	6	3	0	3					
		18NOV2002	7	3	0	3					
		19NOV2002	8	4	0	4					PT. DID NOT RETURN CARD
		26NOV2002					NO	306.3	8	100	UNK
	E0019008	21NOV2002	1	2	0	2					
		22NOV2002	2	1	0	1					
		23NOV2002	3	1	0	1					
		24NOV2002	4	2	0	2					
		25NOV2002	5	3	3	0					MISSED DOSE
		26NOV2002	6	3	0	3					
		27NOV2002	7	3	0	3					CARD ONE WAS REDISPENSED ON 11/27/02 BECAUSE OF TITRATION. CARD ONE WAS ALSO DISPENSED ON THIS DATE.
		28NOV2002	8	4	0	8					TOOK ON 11/30/02.
		29NOV2002	9	4	4	4					PT. SKIPPED TO GET ON CORRECT DATE
		30NOV2002	10	4	0	4					
		01DEC2002	11	4	0	4					
		02DEC2002	12	4	4	0					MISSED DOSE
		03DEC2002	13	4	0	4					
		04DEC2002	14	4	0	4					
		05DEC2002	15	4	0	4					
		06DEC2002	16	4	0	4					
		07DEC2002	17	4	0	4					
		08DEC2002	18	4	0	4					
		09DEC2002	19	4	0	4					
		10DEC2002	20	4	0	4					
		11DEC2002	21	4	0	4					
		12DEC2002	22	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019008	13DEC2002	23	4	0	4					
		14DEC2002	24	4	0	4					
		15DEC2002	25	4	0	4					
		16DEC2002	26	4	0	4					
		17DEC2002	27	4	0	4					
		18DEC2002	28	4	0	4					
		19DEC2002	29	4	0	4					BLISTER CARD NOT RETURNED
		20DEC2002	30	4	0	4					
		21DEC2002	31	4	0	4					
		22DEC2002	32	4	0	4					
		23DEC2002	33	4	0	4					
		24DEC2002	34	4	0	4					
		25DEC2002	35	4	0	4					
		26DEC2002	36		0	4					UNKNOWN
		27DEC2002	37		0	4	NO	525.7	35	97.8	
	E0019009	14NOV2002	1	2	0	2					
		15NOV2002	2	1	0	1					
		16NOV2002	3	1	0	1					
		17NOV2002	4	2	0	2					
		18NOV2002	5	3	0	3					
		19NOV2002	6	3	0	3					
		20NOV2002	7	3	0	3					
		21NOV2002	8	4	4	4					SUBJECT DID NOT RETURN CARD #1 ON 11/21/03 AND TOOK EXTRA DOSE ON 11/21/03 FROM THIS CARD.
		21NOV2002	8	4	4	4					TOOK DOSE FROM PREVOUS CARD
		22NOV2002	9	4	0	4					
		23NOV2002	10	4	0	4					
		24NOV2002	11	4	0	4					
		25NOV2002	12	4	4	0					SKIPPED DOSE
		26NOV2002	13	4	4	0					SKIPPED DOSE
		27NOV2002	14	4	1	3					DOSE REDUCTION 100MG
		28NOV2002	15	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019009	29NOV2002	16	4	1	3					
		30NOV2002	17	4	1	3					
		01DEC2002	18	4	1	3					
		02DEC2002	19	4	1	3					
		03DEC2002	20	4	1	3					
		04DEC2002	21		1	3					
		05DEC2002	22	4	1	3					
		06DEC2002	23	4	1	3					
		07DEC2002	24	4	1	3					
		08DEC2002	25	4	1	3					
		09DEC2002	26	4	1	3					
		10DEC2002	27	4	0	4					CARD NOT RETURNED
		17DEC2002					YES	420.4	25	90.2	UNK
	E0019016	06JAN2003	1	2	0	2					
		07JAN2003	2	1	0	1					
		08JAN2003	3	1	0	1					
		09JAN2003	4	2	0	2					
		10JAN2003	5	3	0	3					
		11JAN2003	6	3	0	3					
		12JAN2003	7	3	0	3					
		13JAN2003	8	4	0	4					
		14JAN2003	9	4	0	4					
		15JAN2003	10	4	0	4					
		16JAN2003	11	4	0	4					
		17JAN2003	12	4	0	4					
		18JAN2003	13	4	0	4					
		19JAN2003	14	4	0	4					
		20JAN2003	15	4	0	4					
		21JAN2003	16	4	0	4					
		22JAN2003	17	4	0	4					
		23JAN2003	18	4	0	4					
		24JAN2003	19	4	0	4					
		25JAN2003	20	4	0	4					
		26JAN2003	21	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	27JAN2003	22	4	0	4					
		28JAN2003	23	4	0	4					
		29JAN2003	24	4	0	4					
		30JAN2003	25	4	0	4					
		31JAN2003	26	4	0	4					
		01FEB2003	27	4	0	4					
		02FEB2003	28	4	0	4					
		03FEB2003	29	4	0	4					
		04FEB2003	30	4	0	4					
		05FEB2003	31	4	0	4					
		06FEB2003	32	4	0	4					
		07FEB2003	33	4	0	4					
		08FEB2003	34	4	0	4					
		09FEB2003	35	4	0	4					
		10FEB2003	36	4	0	4					
		11FEB2003	37	4	0	4					
		12FEB2003	38	4	0	4					
		13FEB2003	39	4	0	4					
		14FEB2003	40	4	0	4					
		15FEB2003	41	4	0	4					
		16FEB2003	42	4	0	4					
		17FEB2003	43		0	4					
		18FEB2003	44		0	4					
		19FEB2003	45	4	0	4					PT. TOOK DOSE ON 2/17/03 AND 2/18/03 FROM "EXTRA" ON PREVIOUS CARD.
		20FEB2003	46	4	0	4					
		21FEB2003	47	4	0	4					
		22FEB2003	48	4	0	4					
		23FEB2003	49	4	0	4					
		24FEB2003	50	4	0	4					
		25FEB2003	51	4	0	4					
		26FEB2003	52		0	4					
		27FEB2003	53	4	0	4					
		28FEB2003	54	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	01MAR2003	55	4	0	4					
		02MAR2003	56	4	0	4	NO	558	56	100	
	E0019020	23JAN2003	1	2	0	2					ONLY A PORTION OF CARD WAS RETURNED - COULD ONLY VERIFY ACTUAL TABLET COUNT FOR DAY 6, 7, AND "EXTRA" DAYS.
		24JAN2003	2	1	0	1					
		25JAN2003	3	1	0	1					
		26JAN2003	4	2	0	2					
		27JAN2003	5	3	0	3					
		28JAN2003	6	3	0	3					
		29JAN2003	7	3	0	3					
		30JAN2003	8	4	0	4					
		31JAN2003	9	4	0	4					
		01FEB2003	10	4	0	4					
		02FEB2003	11	4	0	4					
		03FEB2003	12	4	0	4					
		04FEB2003	13	4	0	4					
		05FEB2003	14	4	0	4					
		06FEB2003	15	4	0	4					
		07FEB2003	16	4	0	4					
		08FEB2003	17	4	0	4					
		09FEB2003	18	4	0	4					
		10FEB2003	19	4	0	4					
		11FEB2003	20	4	0	4					
		12FEB2003	21	4	0	4					
		13FEB2003	22	4	0	4					
		14FEB2003	23	4	0	4					
		15FEB2003	24	4	0	4					
		16FEB2003	25	4	0	4					
		17FEB2003	26	4	0	4					
		18FEB2003	27	4	0	4					
		19FEB2003	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	20FEB2003	29	4	0	4					
		21FEB2003	30	4	0	4					
		22FEB2003	31	4	0	4					
		23FEB2003	32	4	0	4					
		24FEB2003	33	4	0	4					
		25FEB2003	34	4	0	4					
		26FEB2003	35	4	0	4					
		27FEB2003	36	4	0	4					
		28FEB2003	37	4	0	4					
		01MAR2003	38	4	0	4					
		02MAR2003	39	4	0	4					
		03MAR2003	40	4	0	4					
		04MAR2003	41	4	0	4					
		05MAR2003	42	4	0	4					
		06MAR2003	43	4	0	4					
		07MAR2003	44	4	0	4					
		08MAR2003	45	4	0	4					
		09MAR2003	46	4	0	4					
		10MAR2003	47	4	0	4					
		11MAR2003	48	4	0	4					
		12MAR2003	49	4	0	4					
		13MAR2003	50	4	0	4					
		14MAR2003	51	4	0	4					
		15MAR2003	52	4	0	4					
		16MAR2003	53	4	0	4					
		17MAR2003	54	4	0	4					
		18MAR2003	55	4	0	4					
		19MAR2003	56	4	0	4					
		20MAR2003									TOOK ON 3/13/03
		21MAR2003					NO	558	56	100	TOOK ON 3/14/03
	E0019021	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8	4	0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4					
		12FEB2003	14	4	0	4					
		13FEB2003	15		0	4					
		14FEB2003	16		0	4					
		15FEB2003	17		0	4					TOOK ON 2/15/03
		16FEB2003	18		0	4	NO	469.4	18	100	TOOK ON 2/16/03
	E0019024	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8		0	4					UNK BLISTER CARD NOT RETURNED
		07FEB2003	9		0	4	NO	338.9	9	100	
	E0019031	13MAR2003	1	2	0	2					
		14MAR2003	2	1	0	1					
		15MAR2003	3	1	0	1					
		16MAR2003	4	2	0	2					
		17MAR2003					NO	162.5	4	100	PATIENT DISCONTINUED MEDS DUE TO AES.
	E0019035	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019035	20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8		0	4					
		26MAR2003	9		0	4					
		27MAR2003	10	4	0	4					
		28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					DROPPED COLUMN #1 & #2 DOWN SINK. REPLACED WITH EXTRA DOSE. ON 03/30/03 DOSE.
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					
		02APR2003	16	4	0	4					
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	6					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	0	4					
		08APR2003	22	4	0	4					
		09APR2003	23	4	0	4					
		10APR2003	24	4	0	4					
		11APR2003	25	4	0	4					
		12APR2003	26	4	0	4					
		13APR2003	27	4	0	4					
		14APR2003	28	4	0	4					
		15APR2003	29	4	0	4					
		16APR2003	30	4	0	4	NO	535	30	102	
	E0019040	20MAY2003	1	2	0	2					
		21MAY2003	2	1	0	1					
		22MAY2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	23MAY2003	4	2	0	2					
		24MAY2003	5	3	0	3					
		25MAY2003	6	3	0	3					
		26MAY2003	7	3	0	3					
		27MAY2003	8		0	4					
		28MAY2003	9		4	0					MISSED DOSE
		29MAY2003	10	4	0	4					
		30MAY2003	11	4	0	4					
		31MAY2003	12	4	0	4					
		01JUN2003	13	4	0	4					
		02JUN2003	14	4	0	4					
		03JUN2003	15	4	0	4					
		04JUN2003	16	4	0	4					
		05JUN2003	17	4	0	4					
		06JUN2003	18	4	0	4					
		07JUN2003	19	4	0	4					
		08JUN2003	20	4	0	4					
		09JUN2003	21	4	0	4					
		10JUN2003	22	4	0	4					
		11JUN2003	23	4	0	4					
		12JUN2003	24	4	0	4					
		13JUN2003	25	4	0	4					
		14JUN2003	26	4	0	4					
		15JUN2003	27	4	0	4					
		16JUN2003	28	4	0	4					
		17JUN2003	29	4	0	4					
		18JUN2003	30	4	0	4					
		19JUN2003	31	4	0	4					
		20JUN2003	32	4	0	4					
		21JUN2003	33	4	0	4					
		22JUN2003	34	4	0	4					
		23JUN2003	35	4	0	4					
		24JUN2003	36	4	0	4					
		25JUN2003	37		0	4					
		26JUN2003	38	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	27JUN2003	39	4	0	4					
		28JUN2003	40	4	0	4					
		29JUN2003	41	4	0	4					
		30JUN2003	42	4	0	4					
		01JUL2003	43	4	0	4					
		02JUL2003	44	4	0	4					
		03JUL2003	45	4	0	4					
		04JUL2003	46	4	0	4					
		05JUL2003	47	4	0	4					
		06JUL2003	48	4	0	4					
		07JUL2003	49	4	0	4					
		08JUL2003	50	4	0	4					
		09JUL2003	51	4	0	4					
		10JUL2003	52	4	0	4					
		11JUL2003	53	4	0	4					
		12JUL2003	54	4	0	4					
		13JUL2003	55	4	0	4					
		14JUL2003	56	4	0	4					
		15JUL2003	57	4	0	4					
		16JUL2003	58	4	0	4	NO	549.1	57	98.2	
	E0019042	04JUN2003	1	2	0	2					
		05JUN2003	2	1	0	1					
		06JUN2003	3	1	0	1					
		07JUN2003	4	2	0	2					
		08JUN2003	5	3	0	3					
		09JUN2003	6	3	0	3					
		10JUN2003	7	3	0	3					
		11JUN2003	8		0	4					
		12JUN2003	9	4	0	4					
		13JUN2003	10	4	0	4					
		14JUN2003	11	4	0	4					
		15JUN2003	12	4	2	2					SUBJECT TOOK COLUMN 1 & 3 (REDUCED DOSE ON OWN ACCORD)

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	16JUN2003	13	4	0	4					
		17JUN2003	14	4	1	3					DOSE REDUCTION BY DR. PAI
		18JUN2003					NO	382.1	14	97.6	SUBJECT MISSED DOSE
	E0019045	26JUN2003	1	2	0	2					
		27JUN2003	2	1	0	1					
		28JUN2003	3	1	0	1					
		29JUN2003	4	2	0	2					
		30JUN2003	5	3	0	3					
		01JUL2003	6	3	0	3					
		02JUL2003	7	3	0	3					
		03JUL2003	8	4	0	4					
		04JUL2003	9	4	0	4					
		05JUL2003	10	4	0	4					
		06JUL2003	11	4	0	4					
		07JUL2003	12	4	0	4	NO	404.2	12	100	SUBJECTS LAST DOSE D/C'D BECAUSE OF INCREASED DEPRESSION
	E0020024	23JUN2003	1	2	0	2					
		24JUN2003	2	1	0	1					
		25JUN2003	3	1	0	1					
		26JUN2003	4	2	0	2					
		27JUN2003	5	3	0	3					
		28JUN2003	6	3	0	3					
		29JUN2003	7	3	0	3					
		30JUN2003	8	4	0	4					
		01JUL2003	9	4	0	4					
		02JUL2003	10	4	0	4					
		03JUL2003	11	4	0	4					
		04JUL2003	12	4	0	4					
		05JUL2003	13	4	4	0					PATIENT INADVERTENTLY FORGOT
		06JUL2003	14	4	0	4					
		07JUL2003	15	4	1	3					P. I. REDUCED PT'S DOSE

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	08JUL2003	16	4	0	4					
		09JUL2003	17	4	0	4					
		10JUL2003	18	4	0	4					
		11JUL2003	19	4	0	4					
		12JUL2003	20	4	0	4					
		13JUL2003	21	4	0	4					
		14JUL2003	22		0	4					
		15JUL2003	23	4	1	3					DOSE REDUCED PER P. I.
		16JUL2003	24	4	1	3					DOSE REDUCED PER P. I.
		17JUL2003	25	4	1	3					DOSE REDUCED PER P. I.
		18JUL2003	26	4	1	3					DOSE REDUCED PER P. I.
		19JUL2003	27	4	1	3					DOSE REDUCED PER P. I.
		20JUL2003	28	4	1	3					DOSE REDUCED PER P. I.
		21JUL2003	29	4	1	3					P. I. REDUCED DOSE
		22JUL2003	30	4	1	3					P. I. REDUCED DOSE
		23JUL2003	31	4	1	3					P. I. REDUCED DOSE
		24JUL2003	32	4	1	3					P. I. REDUCED DOSE
		25JUL2003	33	4	1	3					P. I. REDUCED DOSE
		26JUL2003	34	4	1	3					P. I. REDUCED DOSE
		27JUL2003	35	4	1	3					P. I. REDUCED DOSE
		28JUL2003	36	4	1	3					PI REDUCED DOSE
		29JUL2003	37	4	1	3					PI REDUCED DOSE
		30JUL2003	38	4	1	3					PI REDUCED DOSE
		31JUL2003	39	4	1	3					PI REDUCED DOSE
		01AUG2003	40	4	1	3					PI REDUCED DOSE
		02AUG2003	41	4	1	3					PI REDUCED DOSE
		03AUG2003	42	4	1	3					PI REDUCED DOSE
		04AUG2003	43	4	1	3					PI REDUCED DOSE
		05AUG2003	44	4	1	3					PI REDUCED DOSE
		06AUG2003	45	4	1	3					PI REDUCED DOSE
		07AUG2003	46	4	1	3					PI REDUCED DOSE
		08AUG2003	47	4	1	3					PI REDUCED DOSE
		09AUG2003	48	4	1	3					PI REDUCED DOSE
		10AUG2003	49	4	1	3					PI REDUCED DOSE
		11AUG2003	50		1	3					PI REDUCED DOSE

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	12AUG2003	51	4	1	3					PI REDUCED DOSE
		13AUG2003	52	4	1	3					PI REDUCED DOSE
		14AUG2003	53	4	1	3					PI REDUCED DOSE
		15AUG2003	54	4	1	3					PI REDUCED DOSE
		16AUG2003	55	4	1	3					PI REDUCED DOSE
		17AUG2003	56	4	1	3					PI REDUCED DOSE
		18AUG2003	57	4	1	3					PI REDUCED DOSE
		19AUG2003	58		1	3	YES	485.3	57	97.8	PI REDUCED DOSE
	E0022044	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					
		20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8	4	0	4					
		26MAR2003	9	4	0	4					
		27MAR2003	10	4	0	4					
		28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					
		02APR2003	16	4	0	4					
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	4					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	0	4					
		08APR2003	22	4	0	4					
		09APR2003	23	4	0	4					
		10APR2003	24	4	0	4					
		11APR2003	25	4	0	4					
		12APR2003	26	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0022044	13APR2003	27	4	0	4					
		14APR2003	28	4	0	4					
		15APR2003	29	4	0	4					
		16APR2003	30	4	0	4					
		17APR2003	31	4	0	4					
		18APR2003	32	4	0	4					
		19APR2003	33	4	0	4					
		20APR2003	34	4	0	4					
		21APR2003	35	4	0	4					
		22APR2003	36	4	0	4					PT LOST 1 PILL & TOOK FROM EXTRA
		23APR2003	37	4	0	4					
		24APR2003	38	4	0	4					
		25APR2003	39	4	0	4					
		26APR2003	40	4	0	4					
		27APR2003	41	4	0	4					
		28APR2003	42	4	0	4					
		29APR2003	43	4	0	4					
		30APR2003	44	4	0	4					
		01MAY2003	45	4	0	4					
		02MAY2003	46	4	0	4					
		03MAY2003	47	4	0	4					
		04MAY2003	48	4	0	4					
		05MAY2003	49	4	0	4					
		06MAY2003	50	4	0	4					
		07MAY2003	51	4	0	4					
		08MAY2003	52	4	0	4					
		09MAY2003	53	4	0	4					
		10MAY2003	54	4	0	4					
		11MAY2003					NO	556.5	54	100	PT FORGOT DOSE THIS PM
	E0023007	14JAN2003	1	2	0	2					
		15JAN2003	2	1	0	1					
		16JAN2003	3	1	0	1					
		17JAN2003	4	2	0	2					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	18JAN2003	5	3	0	3					
		19JAN2003	6	3	0	3					
		20JAN2003	7	3	0	3					
		21JAN2003	8	4	0	4					
		22JAN2003	9	4	0	4					
		23JAN2003	10	4	4	0					PT MISSED DOSE
		24JAN2003	11	4	0	4					
		25JAN2003	12	4	0	4					
		26JAN2003	13	4	0	4					
		27JAN2003	14	4	0	4					
		28JAN2003	15	4	1	3					PT. DECREASED DOSE
		29JAN2003	16	4	1	3					
		30JAN2003	17	4	1	3					
		31JAN2003	18	4	1	3					
		01FEB2003	19	4	1	3					
		02FEB2003	20	4	1	3					
		03FEB2003	21	4	1	3					
		04FEB2003	22		1	3					
		05FEB2003	23		1	3					PT. MISSED DOSE ON 2-6-03
		06FEB2003	24			0					
		07FEB2003	25	4	1	3					SIC
		08FEB2003	26	4	1	3					
		09FEB2003	27	4	1	3					
		10FEB2003	28	4	1	3					
		11FEB2003	29	4	1	3					
		12FEB2003	30	4	1	3					
		13FEB2003	31	4	1	3					
		14FEB2003	32	4	1	3					
		15FEB2003	33	4	1	3					
		16FEB2003	34	4	1	3					
		17FEB2003	35	4	1	3					PT. TOOK EXTRA DOSE INSTEAD OF DOSE 2-17-03
		18FEB2003	36	4	1	3					
		19FEB2003	37	4	1	3					PT. TOOK EXTRA DOSE INSTEAD OF 2-17-03 DOSE

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	20FEB2003	38	4	1	3					
		21FEB2003	39	4	1	3					
		22FEB2003	40	4	1	3					
		23FEB2003	41	4	1	3					
		24FEB2003	42	4	1	3					
		25FEB2003	43	4	1	3					
		26FEB2003	44	4	1	3					
		27FEB2003	45	4	1	3					
		28FEB2003	46	4	1	3					
		01MAR2003	47	4	1	3					
		02MAR2003	48	4	4	0					MISSED DOSE
		03MAR2003	49	4	4	0					MISSED DOSE
		04MAR2003	50	4	1	3					
		05MAR2003	51	4	1	3					
		06MAR2003	52	4	1	3					
		07MAR2003	53	4	1	3					
		08MAR2003	54	4	1	3					
		09MAR2003	55	4	1	3					
		10MAR2003	56	4	1	3	YES	445.5	52	90.7	
	E0023011	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					
		11FEB2003	8		0	4					
		12FEB2003	9		0	4					
		13FEB2003	10	4	0	4					
		14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	0	4					
		18FEB2003	15	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	19FEB2003	16	4	0	4					
		20FEB2003	17		0	4					
		21FEB2003	18	4	0	4					
		22FEB2003	19	4	0	4					
		23FEB2003	20	4	0	4					
		24FEB2003	21	4	0	4					
		25FEB2003	22	4	0	8					
		26FEB2003	23	4	0	8					
		27FEB2003	24	4	0	8					
		28FEB2003	25	4	0	4					
		01MAR2003	26	4	0	4					
		02MAR2003	27	4	0	4					
		03MAR2003	28	4	0	4					
		04MAR2003	29	4	0	4					
		05MAR2003	30	4	0	4					
		06MAR2003	31	4	0	4					
		07MAR2003	32	4	0	4					
		08MAR2003	33	4	0	4					
		09MAR2003	34	4	0	4					
		10MAR2003	35	4	0	4					
		11MAR2003	36	4	0	4					
		12MAR2003	37	4	0	4					
		13MAR2003	38	4	0	4					
		14MAR2003	39	4	0	4					
		15MAR2003	40	4	0	4					
		16MAR2003	41	4	0	4					
		17MAR2003	42	4	0	4					
		18MAR2003	43	4	0	4					
		19MAR2003	44	4	0	4					
		20MAR2003	45	4	0	4					
		21MAR2003	46	4	0	4					
		22MAR2003	47	4	0	4					
		23MAR2003	48	4	0	4					
		24MAR2003	49	4	0	4					
		25MAR2003	50		0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	26MAR2003	51		0	4					
		27MAR2003	52	4	0	4					
		28MAR2003	53	4	0	4					
		29MAR2003	54	4	0	4					
		30MAR2003	55	4	0	4					
		31MAR2003	56	4	0	4	NO	590.2	56	106	
	E0023014	21FEB2003	1	2	0	2					
		22FEB2003	2	1	0	1					
		23FEB2003	3	1	0	1					
		24FEB2003	4	2	0	2					
		25FEB2003	5	3	0	3					
		26FEB2003	6	3	0	3					
		27FEB2003	7	3	0	3					
		28FEB2003	8		0	4					
		01MAR2003	9		0	4					
		02MAR2003	10	4	0	4					
		03MAR2003	11	4	0	4					
		04MAR2003	12	4	0	4					
		05MAR2003	13	4	0	4					
		06MAR2003	14	4	0	8					TABS TAKEN 03-15-03
		07MAR2003	15	4	0	8					TABS TAKEN 03-16-03
		08MAR2003	16	4	0	8					TABS TAKEN 03-17-03
		09MAR2003	17	4	0	4					
		10MAR2003	18	4	0	4					
		11MAR2003	19	4	0	4					
		12MAR2003	20	4	0	4					
		13MAR2003	21		0	4					
		14MAR2003	22		0	4					
		15MAR2003	23			0					
		16MAR2003	24			0					
		17MAR2003	25			0					
		18MAR2003	26	4	0	4					
		19MAR2003	27	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023014	20MAR2003	28	4	1	3					PT REDUCED DOSE FOR REMAINDER OF STUDY
		21MAR2003	29	4	1	3					
		22MAR2003	30	4	1	3					
		23MAR2003	31	4	4	0					PATIENT MISSED DOSE
		24MAR2003	32	4	4	0					PATIENT MISSED DOSE
		25MAR2003	33	4	1	3					PT REDUCED DOSE FOR REMAINDER OF STUDY
		26MAR2003	34	4	1	3					
		27MAR2003	35	4	1	3					
		28MAR2003	36	4	1	3					
		29MAR2003	37	4	1	3					
		30MAR2003	38	4	1	3					
		31MAR2003	39	4	1	3					
		01APR2003	40	4	1	3					PT REDUCED DOSE FOR REMAINDER OF STUDY
		02APR2003	41	4	1	3					
		03APR2003	42	4	1	3					
		04APR2003	43	4	1	3					
		05APR2003	44	4	1	3					
		06APR2003	45	4	1	3					
		07APR2003	46	4	1	3					
		08APR2003	47		1	3					
		09APR2003	48	4	1	3					PT REDUCED DOSE
		10APR2003	49	4	1	3					
		11APR2003	50	4	1	3					
		12APR2003	51	4	1	3					
		13APR2003	52	4	1	3					
		14APR2003	53	4	1	3					
		15APR2003	54	4	1	3					PT REDUCED DOSE
		16APR2003	55	4	1	3					
		17APR2003	56	4	1	3					
		18APR2003	57	4	1	3					
		19APR2003	58	4	1	3					
		20APR2003	59	4	1	3					
		21APR2003	60	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023014	22APR2003	61		1	3					
		23APR2003	62		1	3	YES	489.5	57	96	PT DID NOT DOSE 4/24/03
	E0023019	07APR2003	1	2	0	2					
		08APR2003	2	1	0	1					
		09APR2003	3	1	0	1					
		10APR2003	4	2	0	2					
		11APR2003	5	3	0	3					
		12APR2003	6	3	0	3					
		13APR2003	7	3	0	3					
		14APR2003	8		1	3					MISSED 1
		15APR2003	9	4	0	4					
		16APR2003	10	4	0	4					
		17APR2003	11	4	0	4					
		18APR2003	12	4	0	4					
		19APR2003	13	4	0	4					
		20APR2003	14	4	0	4					
		21APR2003	15	4	0	4					
		22APR2003	16	4	0	4					
		23APR2003	17	4	0	4					
		24APR2003	18	4	0	4					
		25APR2003	19	4	0	4					
		26APR2003	20	4	0	4					
		27APR2003	21	4	0	4					
		28APR2003	22	4	0	4					
		29APR2003	23		0	4					
		30APR2003	24		0	4					
		01MAY2003	25			0					
		02MAY2003	26	4	0	4					MISSED DOSE ON 5-1-03
		03MAY2003	27	4	0	4					
		04MAY2003	28	4	0	4					
		05MAY2003	29	4	0	4					
		06MAY2003	30	4	4	0					MISSED DOSE
		07MAY2003	31	4	0	4					
		08MAY2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023019	09MAY2003	33	4	0	4					
		10MAY2003	34	4	0	4					
		11MAY2003	35	4	0	4					
		12MAY2003	36	4	0	4					
		13MAY2003	37	4	0	4					
		14MAY2003	38	4	0	4					
		15MAY2003	39	4	0	4					
		16MAY2003	40	4	0	4					
		17MAY2003	41	4	0	4					
		18MAY2003	42	4	0	4					
		19MAY2003	43	4	0	4					
		20MAY2003	44	4	0	4					TOOK FOR DAY 1 WEEK 7
		20MAY2003	44	4	0	4					TOOK EXTRA DAY FROM WK 6
		21MAY2003	45	4	0	4					PT TOOK ON 5/23/03
		22MAY2003	46	4	0	4					
		23MAY2003	47	4	0	4					TOOK EXTRA DAY FROM WK 6
		24MAY2003	48	4	0	4					
		25MAY2003	49	4	0	4					
		26MAY2003	50	4	0	4					
		27MAY2003	51		0	4					
		28MAY2003	52		0	4					
		29MAY2003	53	4	0	4					
		30MAY2003	54	4	0	4					
		31MAY2003	55	4	0	4					
		01JUN2003	56	4	0	4					
		02JUN2003	57	4	0	4					
		03JUN2003					NO	536	55	96.3	STUDY TERM.
	E0023022	18APR2003	1	2	0	2					
		19APR2003	2	1	0	1					
		20APR2003	3	1	0	1					
		21APR2003	4	2	0	2					
		22APR2003	5	3	0	3					
		23APR2003	6	3	0	3					
		24APR2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023022	25APR2003	8	4	0	4					
		26APR2003	9	4	0	4					
		27APR2003	10	4	0	4					
		28APR2003	11	4	0	4					
		29APR2003	12	4	0	4					
		30APR2003	13	4	0	4					
		01MAY2003	14	4	0	4					
		02MAY2003	15	4	0	4					
		03MAY2003	16	4	4	0					PT MISSED DOSE THIS DAY
		04MAY2003	17	4	4	0					PT MISSED DOSE THIS DAY.
		05MAY2003	18	4	0	4					
		06MAY2003	19	4	0	4					
		07MAY2003	20	4	0	4					
		08MAY2003	21	4	0	4					
		09MAY2003	22	4	0	4					
		10MAY2003	23	4	0	4					
		11MAY2003	24	4	0	4					
		12MAY2003	25	4	0	4					
		13MAY2003	26	4	0	4					
		14MAY2003	27	4	0	4					
		15MAY2003	28	4	0	4					
		16MAY2003	29	4	0	4					
		17MAY2003	30	4	0	4					
		18MAY2003	31	4	0	4					
		19MAY2003	32	4	0	4					
		20MAY2003	33	4	0	4					
		21MAY2003	34	4	0	4					
		22MAY2003	35	4	0	4					
		23MAY2003	36	4	0	4					
		24MAY2003	37	4	0	4					
		25MAY2003	38	4	0	4					
		26MAY2003	39	4	0	4					
		27MAY2003	40	4	0	4					
		28MAY2003	41	4	0	4					
		29MAY2003	42		0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023022	30MAY2003	43	4	0	4					
		31MAY2003	44	4	0	4					
		01JUN2003	45	4	0	4					
		02JUN2003	46	4	0	4					
		03JUN2003	47	4	0	4					
		04JUN2003	48	4	0	4					
		05JUN2003	49	4	0	4					
		06JUN2003	50	4	0	4					
		07JUN2003	51	4	0	4					
		08JUN2003	52	4	0	4					
		09JUN2003	53	4	0	4					
		10JUN2003	54	4	0	4					
		11JUN2003	55	4	0	4					
		12JUN2003	56	4	0	4	NO	536.6	54	96.2	
	E0023023	25APR2003	1	2	0	2					
		26APR2003	2	1	0	1					
		27APR2003	3	1	0	1					
		28APR2003					NO	116.7	3	100	PT DISCONTIUED DUE TO AE
	E0023029	23MAY2003	1	2	0	2					
		24MAY2003	2	1	0	1					
		25MAY2003	3	1	0	1					
		26MAY2003					NO	116.7	3	100	PT STOPPED MEDICATION, WITH REASON AS ADVERSE EVENT
	E0023031	24JUN2003	1	2	0	2					
		25JUN2003	2	1	0	1					
		26JUN2003	3	1	0	1					
		27JUN2003	4	2	0	2					
		28JUN2003	5	3	0	3					
		29JUN2003	6	3	0	3					
		30JUN2003	7	3	0	3					
		01JUL2003	8	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	02JUL2003	9	4	0	4					
		03JUL2003	10	4	0	4					
		04JUL2003	11	4	0	4					
		05JUL2003	12	4	0	4					
		06JUL2003	13	4	0	4					
		07JUL2003	14	4	0	4					
		08JUL2003	15	4	0	4					
		09JUL2003	16	4	0	4					
		10JUL2003	17	4	0	4					
		11JUL2003	18	4	0	4					
		12JUL2003	19	4	0	4					
		13JUL2003	20	4	0	4					
		14JUL2003	21	4	0	4					
		15JUL2003	22	4	0	4					
		16JUL2003	23	4	0	4					
		17JUL2003	24	4	0	4					
		18JUL2003	25	4	0	4					
		19JUL2003	26	4	0	4					
		20JUL2003	27	4	0	4					
		21JUL2003	28	4	0	4					
		22JUL2003	29	4	0	4					
		23JUL2003	30	4	0	4					
		24JUL2003	31	4	0	4					
		25JUL2003	32	4	0	4					
		26JUL2003	33	4	0	4					
		27JUL2003	34	4	0	4					
		28JUL2003	35	4	0	4					
		29JUL2003	36	4	0	4					
		30JUL2003	37	4	0	4					
		31JUL2003	38	4	0	4					
		01AUG2003	39	4	0	4					
		02AUG2003	40	4	0	4					
		03AUG2003	41	4	0	4					
		04AUG2003	42	4	0	4					
		05AUG2003	43	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	06AUG2003	44	4	0	4					
		07AUG2003	45	4	0	4					
		08AUG2003	46	4	0	4					
		09AUG2003	47	4	0	4					
		10AUG2003	48	4	0	4					
		11AUG2003	49	4	0	4					
		12AUG2003	50	4	0	4					
		13AUG2003	51	4	0	4					
		14AUG2003	52	4	0	4					
		15AUG2003	53	4	0	4					
		16AUG2003	54	4	0	4					
		17AUG2003	55	4	0	4					
		18AUG2003	56	4	0	4	NO	558	56	100	
	E0023041	09JUL2003	1	2	0	2					
		10JUL2003	2	1	0	1					
		11JUL2003	3	1	0	1					
		12JUL2003	4	2	0	2					
		13JUL2003	5	3	0	3					
		14JUL2003	6	3	0	3					
		15JUL2003	7	3	0	3					
		16JUL2003	8	4	0	4					
		17JUL2003	9	4	0	4					
		18JUL2003	10	4	0	4					
		19JUL2003	11	4	0	4					
		20JUL2003	12	4	0	4					
		21JUL2003	13	4	0	4					
		22JUL2003	14	4	0	4					
		23JUL2003	15		0	4					
		24JUL2003	16	4	0	4					
		25JUL2003	17	4	0	4					
		26JUL2003	18	4	0	4					
		27JUL2003	19	4	0	4					
		28JUL2003	20	4	0	4					
		29JUL2003	21	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	30JUL2003	22	4	0	4					VISIT 5 DATE
		31JUL2003	23	4	0	4					
		01AUG2003	24	4	0	4					
		02AUG2003	25	4	0	4					
		03AUG2003	26	4	0	4					
		04AUG2003	27	4	0	4					
		05AUG2003	28	4	0	4					
		06AUG2003	29	4	0	4					
		07AUG2003	30	4	0	4					
		08AUG2003	31	4	0	4					
		09AUG2003	32	4	0	4					
		10AUG2003	33	4	0	4					
		11AUG2003	34	4	0	4					
		12AUG2003	35	4	0	4					
		13AUG2003	36	4	0	4					
		14AUG2003	37	4	0	4					
		15AUG2003	38	4	0	4					
		16AUG2003	39	4	0	4					
		17AUG2003	40	4	0	4					
		18AUG2003	41	4	0	4					
		19AUG2003	42	4	0	4					
		20AUG2003	43	4	0	4					
		21AUG2003	44	4	0	4					
		22AUG2003	45	4	0	4					
		23AUG2003	46	4	0	4					
		24AUG2003	47	4	0	4					
		25AUG2003	48	4	0	4					
		26AUG2003	49	4	0	4					
		27AUG2003	50	4	0	4					
		28AUG2003	51	4	0	4					
		29AUG2003	52	4	0	4					
		30AUG2003	53	4	0	4					
		31AUG2003	54	4	0	4					
		01SEP2003	55	4	0	4					
		02SEP2003	56	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	03SEP2003	57		0	4					
		04SEP2003	58		0	4	NO	559.5	58	100	
	E0023043	14JUL2003	1	2	0	2					
		15JUL2003	2	1	0	1					
		16JUL2003	3	1	0	1					
		17JUL2003	4	2	0	2					
		18JUL2003	5	3	0	3					
		19JUL2003	6	3	0	3					
		20JUL2003	7	3	0	3					
		21JUL2003	8		0	4					
		22JUL2003	9		0	4					
		23JUL2003	10	4	0	4					
		24JUL2003	11	4	0	4					
		25JUL2003	12	4	0	4					
		26JUL2003	13	4	0	4					
		27JUL2003	14	4	0	4					
		28JUL2003	15	4	0	4					VISIT 4 DATE
		29JUL2003	16	4	0	4					
		30JUL2003	17	4	0	4					
		31JUL2003	18	4	0	4					
		01AUG2003	19	4	0	4					
		02AUG2003	20	4	0	4					
		03AUG2003	21	4	0	4					
		04AUG2003	22		0	4					
		05AUG2003	23	4	0	4					
		06AUG2003	24	4	0	4					
		07AUG2003	25	4	0	4					
		08AUG2003	26	4	0	4					
		09AUG2003	27	4	0	4					
		10AUG2003	28	4	0	4					
		11AUG2003	29	4	0	4					
		12AUG2003	30	4	0	4					
		13AUG2003	31	4	0	4					
		14AUG2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	15AUG2003	33	4	0	4					
		16AUG2003	34	4	0	4					
		17AUG2003	35	4	0	4					
		18AUG2003	36	4	0	4					
		19AUG2003	37	4	0	4					
		20AUG2003	38	4	0	4					
		21AUG2003	39	4	0	4					
		22AUG2003	40	4	0	4					
		23AUG2003	41	4	0	4					
		24AUG2003	42	4	0	4					
		25AUG2003	43	4	0	4					
		26AUG2003	44	4	0	4					
		27AUG2003	45	4	0	4					
		28AUG2003	46	4	0	4					
		29AUG2003	47	4	0	4					
		30AUG2003	48	4	0	4					
		31AUG2003	49	4	0	4					
		01SEP2003	50	4	0	4					
		02SEP2003	51	4	0	4					
		03SEP2003	52	4	0	4					
		04SEP2003	53	4	0	4					
		05SEP2003	54	4	0	4					
		06SEP2003	55	4	0	4					
		07SEP2003	56	4	0	4					
		08SEP2003	57	4	0	4	NO	558.8	57	100	
	E0026003	04DEC2002	1	2	0	2					
		05DEC2002	2	1	0	1					
		06DEC2002	3	1	0	1					
		07DEC2002	4	2	0	2					
		08DEC2002	5	3	0	3					
		09DEC2002	6	3	0	3					
		10DEC2002	7	3	0	3					
		11DEC2002	8		0	4					
		12DEC2002	9	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	13DEC2002	10	4	0	4					
		14DEC2002	11	4	0	4					
		15DEC2002	12	4	0	4					
		16DEC2002	13	4	0	4					
		17DEC2002	14	4	0	4					
		18DEC2002	15	4	0	4					
		19DEC2002	16	4	0	4					
		20DEC2002	17	4	0	4					
		21DEC2002	18	4	0	4					
		22DEC2002	19	4	0	4					
		23DEC2002	20	4	0	4					
		24DEC2002	21	4	0	4					
		25DEC2002	22	4	0	4					
		26DEC2002	23	4	0	4					
		27DEC2002	24	4	0	4					
		28DEC2002	25	4	0	4					
		29DEC2002	26	4	0	4					
		30DEC2002	27	4	0	4					
		31DEC2002	28	4	0	4					
		01JAN2003	29	4	0	4					
		02JAN2003	30	4	0	4					
		03JAN2003	31	4	0	4					
		04JAN2003	32	4	0	4					
		05JAN2003	33	4	0	4					
		06JAN2003	34	4	0	4					
		07JAN2003	35	4	0	4					
		08JAN2003	36	4	0	4					
		09JAN2003	37	4	0	4					
		10JAN2003	38	4	0	4					
		11JAN2003	39	4	0	4					
		12JAN2003	40	4	0	4					
		13JAN2003	41	4	0	4					
		14JAN2003	42	4	0	4					
		15JAN2003	43	4	0	4					
		16JAN2003	44	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	17JAN2003	45	4	0	4					
		18JAN2003	46	4	0	4					
		19JAN2003	47	4	0	4					
		20JAN2003	48	4	0	4					
		21JAN2003	49	4	0	4					
		22JAN2003	50	4	0	4					
		23JAN2003	51	4	0	4					
		24JAN2003	52	4	0	4					
		25JAN2003	53	4	0	4					
		26JAN2003	54	4	0	4					
		27JAN2003	55	4	0	4					
		28JAN2003	56	4	0	4					
		29JAN2003	57	4	0	4	NO	558.8	57	100	
	E0026005	30DEC2002	1	2	0	2					
		31DEC2002	2	1	0	1					
		01JAN2003	3	1	0	1					
		02JAN2003	4	2	0	2					
		03JAN2003	5	3	0	3					
		04JAN2003	6	3	0	3					
		05JAN2003	7	3	0	3	NO	264.3	7	100	
	E0026009	15JAN2003	1	2	0	2					
		16JAN2003	2	1	0	1					
		17JAN2003	3	1	0	1					
		18JAN2003	4	2	0	2					SUBJECT DISCONTINUED STUDY MED DUE TO AE.
		19JAN2003									MISSED DOSE
		20JAN2003					NO	162.5	4	100	MISSED DOSE
	E0026015	27FEB2003	1	2	0	2					
		28FEB2003	2	1	0	1					
		01MAR2003	3	1	0	1					
		02MAR2003	4	2	0	2					
		03MAR2003	5	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	04MAR2003	6	3	0	3					
		05MAR2003	7	3	0	3					
		06MAR2003	8		0	4					
		07MAR2003	9	4	0	4					
		08MAR2003	10	4	0	4					
		09MAR2003	11	4	0	4					
		10MAR2003	12	4	0	4					
		11MAR2003	13	4	0	4					
		12MAR2003	14	4	0	4					
		13MAR2003	15	4	0	4					NO DOSE TAKEN
		14MAR2003	16	4	0	4					NO DOSE TAKEN
		15MAR2003	17	4	0	4					NO DOSE TAKEN ABOVE DOSES LOST PER PATIENT.
		16MAR2003	18	4	0	4					
		17MAR2003	19	4	0	4					
		18MAR2003	20	4	0	4					
		19MAR2003	21	4	0	4					
		20MAR2003	22	4	0	4					
		21MAR2003	23	4	0	4					
		22MAR2003	24	4	0	4					
		23MAR2003	25	4	0	4					
		24MAR2003	26	4	0	4					
		25MAR2003	27	4	0	4					
		26MAR2003	28	4	0	4					
		27MAR2003	29	4	0	4					
		28MAR2003	30	4	0	4					
		29MAR2003	31	4	0	4					
		30MAR2003	32	4	0	4					
		31MAR2003	33	4	0	4					
		01APR2003	34	4	0	4					
		02APR2003	35	4	0	4					
		03APR2003	36	4	0	4					
		04APR2003	37	4	0	4					
		05APR2003	38	4	0	4					
		06APR2003	39	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	07APR2003	40	4	0	4					
		08APR2003	41	4	0	4					
		09APR2003	42	4	0	4					
		10APR2003	43	4	0	4					
		11APR2003	44	4	0	4					
		12APR2003	45	4	0	4					
		13APR2003	46	4	0	4					
		14APR2003	47	4	0	4					
		15APR2003	48	4	0	4					
		16APR2003	49	4	0	4					
		17APR2003	50	4	0	4					
		18APR2003	51	4	0	4					
		19APR2003	52	4	0	4					
		20APR2003	53	4	0	4					
		21APR2003	54	4	0	4					
		22APR2003	55	4	0	4					
		23APR2003	56	4	0	4					
		24APR2003	57		0	4	NO	558.8	57	100	
	E0026023	30APR2003	1	2	0	2					
		01MAY2003	2	1	0	1					
		02MAY2003	3	1	0	1					
		03MAY2003	4	2	0	2					
		04MAY2003	5	3	0	3					
		05MAY2003	6	3	0	3					
		06MAY2003	7	3	0	3					
		07MAY2003	8	4	0	4					PER SUBJECT REPORT NO DOSE TAKEN
		08MAY2003	9	4	0	4					NO DOSE TAKEN PATIENT LOST BLISTER CARD.
		09MAY2003	10	4	0	4					
		10MAY2003	11	4	0	4					
		11MAY2003	12	4	0	4					
		12MAY2003	13	4	0	4					
		13MAY2003	14	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0026023	14MAY2003	15	4	0	4					
		15MAY2003	16	4	0	4					
		16MAY2003	17	4	0	4					
		17MAY2003	18	4	0	4					
		18MAY2003	19	4	0	4					
		19MAY2003	20	4	0	4					
		20MAY2003	21	4	0	4					
		21MAY2003	22	4	0	4					
		22MAY2003	23	4	0	4					
		23MAY2003	24	4	0	4					
		24MAY2003	25	4	0	4					
		25MAY2003	26	4	0	4					
		26MAY2003	27	4	0	4					
		27MAY2003	28	4	0	4					
		28MAY2003	29	4	0	4					
		29MAY2003	30	4	0	4					
		30MAY2003	31	4	0	4					
		31MAY2003	32	4	0	4					
		01JUN2003	33	4	0	4					
		02JUN2003	34	4	0	4					
		03JUN2003	35	4	0	4					
		04JUN2003	36	4	0	4					
		05JUN2003	37	4	0	4					
		06JUN2003	38	4	0	4					
		07JUN2003	39	4	0	4					
		08JUN2003	40	4	0	4					
		09JUN2003	41	4	0	4					
		10JUN2003	42	4	0	4					
		11JUN2003	43	4	0	4					
		12JUN2003	44	4	0	4					
		13JUN2003	45	4	0	4					
		14JUN2003	46	4	0	4					
		15JUN2003	47	4	0	4					
		16JUN2003	48	4	0	4					
		17JUN2003	49	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0026023	18JUN2003	50	4	0	4					
		19JUN2003	51	4	0	4					
		20JUN2003	52	4	0	4					
		21JUN2003	53	4	0	4					
		22JUN2003	54	4	0	4					
		23JUN2003	55	4	0	4					
		24JUN2003	56	4	0	4					
		25JUN2003									PER SUBJECT REPORT NO DOSE TAKEN
		26JUN2003					NO	558	56	100	PATIENT LOST BLISTER CARD. NO DOSE TAKEN
	E0027016	09APR2003	1	2	0	2					
		10APR2003	2	1	0	1					
		11APR2003	3	1	0	1					
		12APR2003	4	2	0	2					
		13APR2003	5	3	0	3					
		14APR2003	6	4	0	4					SIC SUBJECT DID NOT TITRATE PER PROTOCOL
		15APR2003	7	4	0	4					
		16APR2003	8	4	0	4					
		17APR2003	9	4	0	4					
		18APR2003	10	4	0	4					
		19APR2003	11	4	0	4					
		20APR2003	12	4	0	4					
		21APR2003	13		0	4					
		22APR2003	14	4	0	4					
		23APR2003	15	4	0	4					
		24APR2003	16	4	0	4					
		25APR2003	17	4	0	4					
		26APR2003	18	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	27APR2003	19	4	2	2					PATIENT REPORTED ONLY TAKING 2 PILLS THAT DAY WHICH WAS CONFIRMED WHEN SHE BROUGHT BACK HER BLISTER PACK ON 2003/04/27
		28APR2003	20	4	0	4					
		29APR2003	21	4	0	4					
		30APR2003	22	4	0	4					
		01MAY2003	23	4	0	4					
		02MAY2003	24	4	0	4					
		03MAY2003	25	4	0	4					
		04MAY2003	26	4	0	4					
		05MAY2003	27	4	0	4					
		06MAY2003	28	4	0	4					
		07MAY2003	29	4	0	4					
		08MAY2003	30	4	0	4					
		09MAY2003	31	4	0	4					
		10MAY2003	32	4	0	4					
		11MAY2003	33	4	0	4					
		12MAY2003	34		0	4					
		13MAY2003	35		0	4					
		14MAY2003	36	4	4	0					MISSED DOSE DUE TO COORDINATOR OMITTING 5-14 ON BLISTER CARD
		15MAY2003	37	4	0	4					
		16MAY2003	38	4	0	4					
		17MAY2003	39	4	0	4					
		18MAY2003	40	4	0	4					
		19MAY2003	41	4	0	4					
		20MAY2003	42	4	0	4					
		21MAY2003	43	4	0	4					
		22MAY2003	44	4	0	4					
		23MAY2003	45	4	0	4					
		24MAY2003	46	4	0	4					
		25MAY2003	47	4	0	4					
		26MAY2003	48		0	4					
		27MAY2003	49	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	28MAY2003	50	4	0	4					
		29MAY2003	51	4	0	4					
		30MAY2003	52	4	0	4					
		31MAY2003	53	4	0	4					
		01JUN2003	54	4	0	4					
		02JUN2003	55	4	0	4	NO	542.7	54	98.5	
	E0027018	25MAR2003	1	2	0	2					
		26MAR2003	2	1	0	1					
		27MAR2003	3	1	0	1					
		28MAR2003	4	2	0	2					
		29MAR2003	5	3	0	3					
		30MAR2003	6	3	0	3					
		31MAR2003	7	3	0	3					
		01APR2003	8		0	4					
		02APR2003	9	4	0	4					
		03APR2003	10	4	0	4					
		04APR2003	11	4	0	4					
		05APR2003	12	4	0	4					
		06APR2003	13	4	0	4					
		07APR2003	14	4	0	4					
		08APR2003	15	4	0	4					
		09APR2003	16	4	0	4					
		10APR2003	17	4	0	4					
		11APR2003	18	4	0	4					
		12APR2003	19	4	0	4					
		13APR2003	20	4	0	4					
		14APR2003	21	4	0	4					
		15APR2003	22	4	0	4					
		16APR2003	23	4	0	4					
		17APR2003	24	4	0	4					
		18APR2003	25	4	0	4					
		19APR2003	26	4	0	4					
		20APR2003	27	4	0	4					
		21APR2003	28	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	22APR2003	29	4	0	4					
		23APR2003	30	4	0	4					
		24APR2003	31	4	0	4					
		25APR2003	32	4	0	4					
		26APR2003	33	4	0	4					
		27APR2003	34	4	0	4					
		28APR2003	35	4	0	4					
		29APR2003	36	4	0	4					
		30APR2003	37	4	0	4					
		01MAY2003	38	4	0	4					
		02MAY2003	39	4	0	4					
		03MAY2003	40	4	0	4					
		04MAY2003	41	4	0	4					
		05MAY2003	42	4	0	4					
		06MAY2003	43	4	0	4					
		07MAY2003	44	4	0	4					
		08MAY2003	45	4	0	4					
		09MAY2003	46	4	0	4					
		10MAY2003	47	4	0	4					
		11MAY2003	48	4	0	4					
		12MAY2003	49		0	4					
		13MAY2003	50	4	0	4					
		14MAY2003	51	4	0	4					
		15MAY2003	52	4	0	4					
		16MAY2003	53	4	0	4					
		17MAY2003	54	4	0	4					
		18MAY2003	55	4	0	4					
		19MAY2003	56	4	0	4					
		20MAY2003	57		0	4					
		21MAY2003	58		0	4	NO	559.5	58	100	
	E0028032	25MAR2003	1	2	0	2					
		26MAR2003	2	1	0	1					
		27MAR2003	3	1	0	1					
		28MAR2003	4	2	0	2					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	29MAR2003	5	3	0	3					
		30MAR2003	6	3	0	3					
		31MAR2003	7	3	0	3					
		01APR2003	8	4	0	4					
		02APR2003	9	4	0	4					
		03APR2003	10	4	0	4					
		04APR2003	11	4	0	4					
		05APR2003	12	4	0	4					
		06APR2003	13	4	0	4					
		07APR2003	14	4	0	4					
		08APR2003	15	4	0	4					
		09APR2003	16	4	0	4					
		10APR2003	17	4	0	4					
		11APR2003	18	4	0	4					
		12APR2003	19	4	0	4					
		13APR2003	20	4	0	4					
		14APR2003	21	4	0	4					
		15APR2003	22	4	0	4					
		16APR2003	23	4	0	4					
		17APR2003	24	4	0	4					
		18APR2003	25	4	0	4					
		19APR2003	26	4	0	4					
		20APR2003	27	4	0	4					
		21APR2003	28	4	0	4					
		22APR2003	29	4	0	4					
		23APR2003	30	4	0	4					
		24APR2003	31	4	0	4					
		25APR2003	32	4	0	4					
		26APR2003	33	4	0	4					
		27APR2003	34	4	0	4					
		28APR2003	35	4	0	4					
		29APR2003	36		0	4					
		30APR2003	37	4	0	4					
		01MAY2003	38	4	0	4					
		02MAY2003	39	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	03MAY2003	40	4	0	4					
		04MAY2003	41	4	0	4					
		05MAY2003	42	4	0	4					
		06MAY2003	43	4	0	4					
		07MAY2003	44	4	0	4					
		08MAY2003	45	4	0	4					
		09MAY2003	46	4	0	4					
		10MAY2003	47	4	0	4					
		11MAY2003	48	4	0	4					
		12MAY2003	49	4	0	4					
		13MAY2003	50	4	0	4					
		14MAY2003	51	4	0	4					
		15MAY2003	52	4	0	4					
		16MAY2003	53	4	0	4					
		17MAY2003	54	4	0	4					
		18MAY2003	55	4	0	4					
		19MAY2003	56	4	0	4	NO	558	56	100	
	E0029003	04NOV2002	1	2	0	2					
		05NOV2002	2	1	0	1					
		06NOV2002	3	1	0	1					
		07NOV2002	4	2	0	2					
		08NOV2002	5	3	0	3					
		09NOV2002	6	3	0	3					
		10NOV2002	7	3	0	3					LOST TABLET FROM COLUMN 1
		11NOV2002	8	4	0	4					USED TABLET FROM COLUMN 1 TO COMPLETE DOSE ON 11/10/02
		12NOV2002	9	4	0	4					
		13NOV2002	10	4	0	4					
		14NOV2002	11	4	0	4					
		15NOV2002	12	4	0	4					
		16NOV2002	13	4	0	4					
		17NOV2002	14	4	0	4					
		18NOV2002	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	19NOV2002	16	4	0	4					
		20NOV2002	17	4	0	4					
		21NOV2002	18	4	0	4					
		22NOV2002	19	4	4	0					MISSED DOSE
		23NOV2002	20	4	0	4					
		24NOV2002	21	4	0	4					
		25NOV2002	22	4	0	4					
		26NOV2002	23	4	0	4					
		27NOV2002	24	4	0	4					
		28NOV2002	25	4	0	4					
		29NOV2002	26	4	0	4					
		30NOV2002	27	4	0	4					
		01DEC2002	28	4	0	4					
		02DEC2002	29	4	0	4					
		03DEC2002	30	4	0	4					
		04DEC2002	31	4	0	4					
		05DEC2002	32	4	0	4					
		06DEC2002	33	4	0	4					
		07DEC2002	34	4	0	4					
		08DEC2002	35	4	0	4					
		09DEC2002	36	4	0	4					
		10DEC2002	37	4	0	4					
		11DEC2002	38	4	0	4					
		12DEC2002	39	4	0	4					
		13DEC2002	40	4	0	4					
		14DEC2002	41	4	0	4					
		15DEC2002	42	4	0	4					
		16DEC2002	43	4	0	4					
		17DEC2002	44	4	0	4					
		18DEC2002	45	4	0	4					
		19DEC2002	46	4	0	4					
		20DEC2002	47	4	0	4					
		21DEC2002	48	4	0	4					
		22DEC2002	49	4	0	4					
		23DEC2002	50	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	24DEC2002	51	4	0	4					
		25DEC2002	52	4	0	4					
		26DEC2002	53	4	0	4					
		27DEC2002	54	4	0	4					
		28DEC2002	55	4	0	4					
		29DEC2002	56	4	0	4	NO	547.3	55	98.1	
	E0029020	05MAR2003	1	2	0	2					PATIENT DID NOT START STUDY MED UNTIL 3/5/03. FORGOT TO START 3/4/03
		06MAR2003	2	1	0	1					
		07MAR2003	3	1	0	1					
		08MAR2003	4	2	2	0					TOOK DOSE ON 3/9/03. MISSED DOSE ON 3/8/03 DUE TO SEDATION
		09MAR2003	5	3	1	2					TOOK DOSE ON 3/10/03
		10MAR2003	6	3	0	3					
		11MAR2003	7	4	1	3	NO	178.6	6	80	PATIENT SKIPPED COLUMN 1
	E0031005	20DEC2002	1	2	0	2					
		21DEC2002	2	1	0	1					
		22DEC2002	3	1	0	1					
		23DEC2002	4	2	0	2					
		24DEC2002	5	3	0	3					
		25DEC2002	6	3	0	3					
		26DEC2002	7	3	0	3					
		27DEC2002	8	4	0	4					
		28DEC2002	9	4	0	4					
		29DEC2002	10	4	0	4					
		30DEC2002	11	4	0	4					
		31DEC2002	12	4	0	4					
		01JAN2003	13	4	0	4					
		02JAN2003	14	4	0	4					
		03JAN2003	15	4	0	4					
		04JAN2003	16	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	05JAN2003	17	4	0	4					
		06JAN2003	18	4	0	4					
		07JAN2003	19	4	0	4					
		08JAN2003	20	4	0	4					
		09JAN2003	21	4	0	4					
		10JAN2003	22	4	0	4					
		11JAN2003	23	4	0	4					
		12JAN2003	24	4	0	4					
		13JAN2003	25	4	0	4					
		14JAN2003	26	4	0	4					
		15JAN2003	27	4	0	4					
		16JAN2003	28	4	0	4					
		17JAN2003	29	4	0	4					
		18JAN2003	30	4	0	4					
		19JAN2003	31	4	0	4					
		20JAN2003	32	4	0	4					
		21JAN2003	33	4	0	4					
		22JAN2003	34	4	0	4					
		23JAN2003	35	4	0	4					
		24JAN2003	36	4	0	4					
		25JAN2003	37	4	0	4					
		26JAN2003	38	4	0	4					
		27JAN2003	39	4	0	4					
		28JAN2003	40	4	0	4					
		29JAN2003	41	4	0	4					
		30JAN2003	42	4	0	4					
		31JAN2003	43	4	0	4					
		01FEB2003	44	4	0	4					
		02FEB2003	45	4	0	4					
		03FEB2003	46	4	0	4					
		04FEB2003	47	4	0	4					
		05FEB2003	48	4	0	4					
		06FEB2003	49		0	4					
		07FEB2003	50	4	0	4					
		08FEB2003	51	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	09FEB2003	52	4	0	4					
		10FEB2003	53	4	0	4					
		11FEB2003	54	4	0	4					
		12FEB2003	55	4	0	4					
		13FEB2003	56	4	0	4	NO	558	56	100	
	E0031006	18FEB2003	1	2	0	2					
		19FEB2003	2	1	0	1					
		20FEB2003	3	1	0	1					
		21FEB2003	4	2	0	2					
		22FEB2003	5	3	0	3					
		23FEB2003	6	3	0	3					
		24FEB2003	7	3	0	3					
		25FEB2003	8		0	4					
		26FEB2003	9	4	0	4					
		27FEB2003	10	4	0	4					
		28FEB2003	11	4	0	4					
		01MAR2003	12	4	0	4					
		02MAR2003	13	4	0	4					
		03MAR2003	14	4	0	4					
		04MAR2003	15	4	0	4					
		05MAR2003	16	4	0	4					
		06MAR2003	17	4	0	4					
		07MAR2003	18	4	0	4					
		08MAR2003	19	4	0	4					
		09MAR2003	20	4	0	4					
		10MAR2003	21	4	0	4					
		11MAR2003	22	4	0	4					
		12MAR2003	23	4	0	4					
		13MAR2003	24	4	0	4					
		14MAR2003	25	4	0	4					
		15MAR2003	26	4	0	4					
		16MAR2003	27	4	0	4					
		17MAR2003	28	4	0	4					
		18MAR2003	29	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0031006	19MAR2003	30	4	0	4					
		20MAR2003	31	4	0	4					
		21MAR2003	32	4	0	4					
		22MAR2003	33	4	0	4					
		23MAR2003	34	4	0	4					
		24MAR2003	35	4	0	4					
		25MAR2003	36	4	0	4					
		26MAR2003	37	4	0	4					
		27MAR2003	38	4	0	4					
		28MAR2003	39	4	0	4					
		29MAR2003	40	4	0	4					
		30MAR2003	41	4	0	4					
		31MAR2003	42	4	0	4					
		01APR2003	43		0	4					
		02APR2003	44	4	0	4					
		03APR2003	45	4	0	4					
		04APR2003	46	4	0	4					
		05APR2003	47	4	0	4					
		06APR2003	48	4	0	4					
		07APR2003	49	4	0	4					
		08APR2003	50	4	0	4					
		09APR2003	51	4	0	4					
		10APR2003	52	4	0	4					
		11APR2003	53	4	0	4					
		12APR2003	54	4	0	4					
		13APR2003	55	4	0	4					
		14APR2003	56		0	4	NO	558	56	100	
	E0031010	19FEB2003	1	2	0	2					
		20FEB2003	2	1	0	1					
		21FEB2003	3	1	0	1					
		22FEB2003	4	2	0	2					
		23FEB2003	5	3	0	3					
		24FEB2003	6	3	0	3					
		25FEB2003	7	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0031010	26FEB2003	8	4	0	4					
		27FEB2003	9	4	1	3					DOSE REDUCED THROUGH END
		28FEB2003	10	4	1	3					
		01MAR2003	11	4	1	3					
		02MAR2003	12	4	1	3					
		03MAR2003	13	4	1	3					
		04MAR2003	14	4	1	3	YES	389.3	14	100	
	E0031011	27FEB2003	1	2	0	2					
		28FEB2003	2	1	0	1					
		01MAR2003	3	1	0	1					
		02MAR2003	4	2	0	2					
		03MAR2003	5	3	0	3					
		04MAR2003	6	3	0	3					
		05MAR2003	7	3	0	3					
		06MAR2003	8	4	0	4					
		07MAR2003	9	4	0	4					
		08MAR2003	10	4	0	4					
		09MAR2003	11	4	0	4					
		10MAR2003	12	4	0	4					
		11MAR2003	13	4	0	4					
		12MAR2003	14	4	0	4					
		13MAR2003	15	4	0	4					
		14MAR2003	16	4	0	4					
		15MAR2003	17	4	0	4					
		16MAR2003	18	4	0	4					
		17MAR2003	19	4	0	4					
		18MAR2003	20	4	0	4					
		19MAR2003	21	4	0	4					
		20MAR2003	22	4	0	4					
		21MAR2003	23	4	0	4					
		22MAR2003	24	4	0	4					
		23MAR2003	25	4	0	4					
		24MAR2003	26	4	0	4					
		25MAR2003	27	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	26MAR2003	28	4	0	4					
		27MAR2003	29	4	0	4					
		28MAR2003	30	4	0	4					
		29MAR2003	31	4	0	4					
		30MAR2003	32	4	0	4					
		31MAR2003	33	4	0	4					
		01APR2003	34	4	0	4					
		02APR2003	35	4	0	4					
		03APR2003	36	4	0	4					
		04APR2003	37	4	0	4					
		05APR2003	38	4	0	4					
		06APR2003	39	4	0	4					
		07APR2003	40	4	0	4					
		08APR2003	41	4	0	4					
		09APR2003	42	4	0	4					
		10APR2003	43		0	4					
		11APR2003	44	4	0	4					
		12APR2003	45	4	0	4					
		13APR2003	46	4	0	4					
		14APR2003	47	4	0	4					
		15APR2003	48	4	0	4					
		16APR2003	49	4	0	4					
		17APR2003	50	4	0	4					
		18APR2003	51	4	0	4					
		19APR2003	52	4	0	4					
		20APR2003	53	4	0	4					
		21APR2003	54	4	0	4					
		22APR2003	55	4	0	4					
		23APR2003	56	4	0	4	NO	558	56	100	
	E0031015	26MAR2003	1	2	0	2					
		27MAR2003	2	1	0	1					
		28MAR2003	3	1	0	1					
		29MAR2003	4	2	0	2					
		30MAR2003	5	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	31MAR2003	6	3	0	3	NO	241.7	6	100	
	E0031031	08JUL2003	1	2	0	2					
		09JUL2003	2	1	0	1					
		10JUL2003	3	1	0	1					
		11JUL2003	4	2	0	2					
		12JUL2003	5	3	0	3					
		13JUL2003	6	3	0	3					
		14JUL2003	7	3	0	3					
		15JUL2003	8	4	0	4					
		16JUL2003	9	4	0	4					
		17JUL2003	10	4	0	4					
		18JUL2003	11	4	0	4					
		19JUL2003	12	4	0	4					
		20JUL2003	13	4	0	4					
		21JUL2003	14	4	0	4					
		22JUL2003	15	4	0	4					
		23JUL2003	16	4	0	4					
		24JUL2003	17	4	0	4					
		25JUL2003	18	4	0	4					
		26JUL2003	19	4	0	4					
		27JUL2003	20	4	0	4					
		28JUL2003	21	4	0	4					
		29JUL2003	22	4	0	4					
		30JUL2003	23	4	0	4					
		31JUL2003	24	4	0	4					
		01AUG2003	25	4	0	4					
		02AUG2003	26	4	0	4					
		03AUG2003	27	4	0	4					
		04AUG2003	28	4	0	4	NO	516.1	28	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0033009	12FEB2003	1	2	0	2					SUBJECT DID NOT RETURN THIS BLISTER CARD. SUBJECT REFUSED TO RETURN FOR EARLY TERMINATION VISIT. ACTUAL DOSAGES SUBJECT TOOK CANNOT BE CONFIRMED
		13FEB2003	2	1	0	1					
		14FEB2003	3	1	0	1					
		15FEB2003	4	2	0	2					
		16FEB2003	5	3	0	3					
		17FEB2003	6	3	0	3					
		18FEB2003	7	3	0	3					
		19FEB2003					NO	264.3	7	100	UNK
	E0034009	19JUN2003	1	2	0	2					
		20JUN2003	2	1	0	1					
		21JUN2003	3	1	0	1					
		22JUN2003	4	2	0	2					
		23JUN2003	5	3	0	3					
		24JUN2003	6	3	0	3					
		25JUN2003	7	3	0	3					
		26JUN2003	8		0	4					
		27JUN2003	9	4	0	4					
		28JUN2003	10	4	0	4					
		29JUN2003	11	4	0	4					
		30JUN2003	12	4	0	4					
		01JUL2003	13	4	0	4					
		02JUL2003	14	4	0	4					
		03JUL2003	15	4	0	4					PT. NOT PRESCRIBED THIS DOSE ON THIS BLISTER CARD.
		04JUL2003	16	4	0	4					
		05JUL2003	17	4	0	4					
		06JUL2003	18	4	0	4					
		07JUL2003	19	4	0	4					
		08JUL2003	20	4	0	4					
		09JUL2003	21	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0034009	10JUL2003	22	4	0	4					
		11JUL2003	23	4	0	4					
		12JUL2003	24	4	0	4					
		13JUL2003	25	4	0	4					
		14JUL2003	26	4	0	4					
		15JUL2003	27	4	0	4					
		16JUL2003	28	4	0	4					
		17JUL2003	29		0	4					
		18JUL2003	30	4	1	3					DOSE DECREASED BY 1 PILL DUE TO A/E'S. 3 PILLS DISPENSED ONLY ON THIS DATE & UNTIL END OF STUDY.
		19JUL2003	31	4	1	3					
		20JUL2003	32	4	1	3					
		21JUL2003	33	4	1	3					
		22JUL2003	34	4	1	3					
		23JUL2003	35	4	1	3					
		24JUL2003	36	4	1	3					
		25JUL2003	37	4	1	3					SIC
		26JUL2003	38	4	1	3					
		27JUL2003	39	4	1	3					
		28JUL2003	40	4	1	3					
		29JUL2003	41	4	1	3					
		30JUL2003	42	4	1	3					
		31JUL2003	43	4	1	3					NOT PRESCRIBED THIS DOSE
		31JUL2003	43	4	1	3					SIC
		01AUG2003	44	4	1	3					
		02AUG2003	45	4	1	3					
		03AUG2003	46	4	1	3					
		04AUG2003	47	4	1	3					
		05AUG2003	48	4	1	3					
		06AUG2003	49	4	1	3					
		07AUG2003	50	4	1	3					
		08AUG2003	51	4	1	3					
		09AUG2003	52	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0034009	10AUG2003	53	4	1	3					
		11AUG2003	54	4	1	3					
		12AUG2003	55	4	1	3					
		13AUG2003	56	4	1	3					
		14AUG2003	57		1	3					
		15AUG2003	58		1	3	YES	509.5	58	100	LAST DOSE TAKEN @ 10P.M. RATINGS PERFORMED < 72 HRS POST LAST DOSE
	E0037007	11APR2003	1	2	0	2					CARD NOT RETURNED CANNOT CONFIRM DOSING
		12APR2003	2	1	0	1					
		13APR2003	3	1	0	1					
		14APR2003	4	2	0	2					
		15APR2003	5	3	3	0					PT REPORTED SKIPPING DOSE
		16APR2003	6	3	3	0					PT REPORTED SKIPPING DOSE
		17APR2003	7	3	0	3					
		18APR2003	8	4	0	8					UNKNOWN
		18APR2003	8	4	0	8					CARD NOT RETURNED. CANNOT CONFIRM DOSING
		19APR2003	9	4	0	8					
		20APR2003	10	4	0	4					
		21APR2003	11	4	0	4					
		22APR2003	12	4	0	4					
		23APR2003	13	4	0	4					
		24APR2003	14	4	0	4					
		25APR2003	15		0	4					UNKNOWN
		26APR2003	16		0	4	NO	478.1	14	104	
	E0037012	16JUL2003	1	2	0	2					
		17JUL2003	2	1	0	1					
		18JUL2003	3	1	0	1					
		19JUL2003	4	2	0	2					
		20JUL2003	5	3	0	3					
		21JUL2003	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	22JUL2003	7	3	0	3					
		23JUL2003	8		0	4					LOST 7/23/03 DOSE
		24JUL2003	9	4	4	0					TOOK ON 7/23/03
		24JUL2003	9	4	4	0					SIC PT DID NOT TAKE DUE TO NAUSEA
		25JUL2003	10	4	0	4					
		26JUL2003	11	4	0	4					
		27JUL2003	12	4	0	4					
		28JUL2003	13	4	0	4					
		29JUL2003	14	4	0	4					
		30JUL2003	15	4	0	4					
		31JUL2003	16		0	4					
		01AUG2003	17	4	1	3					DOSE DECREASED
		02AUG2003	18	4	1	3					
		03AUG2003	19	4	1	3					
		04AUG2003	20	4	1	3					
		05AUG2003	21	4	1	3					
		06AUG2003	22	4	1	3					
		07AUG2003	23	4	1	3					NOTE PT LOST COLUMN 2 TAB.
		08AUG2003	24	4	1	3					PT TOOK EXTRA COLUMN 2 TAB ON 8/7/03
		08AUG2003	24	4	1	3					DOSE DECREASED
		09AUG2003	25	4	1	3					
		10AUG2003	26	4	1	3					
		11AUG2003	27	4	4	0					PT FORGOT DOSE
		12AUG2003	28	4	1	3					
		13AUG2003	29	4	1	3					
		14AUG2003	30	4	1	3					
		15AUG2003	31	4	1	3					DOSE DECREASED
		16AUG2003	32	4	1	3					
		17AUG2003	33	4	1	3					
		18AUG2003	34	4	1	3					
		19AUG2003	35	4	1	3					
		20AUG2003	36	4	1	3					
		21AUG2003	37	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	22AUG2003	38	4	1	3					DOSE DECREASED
		23AUG2003	39	4	1	3					
		24AUG2003	40	4	1	3					
		25AUG2003	41	4	1	3					
		26AUG2003	42	4	1	3					
		27AUG2003	43	4	1	3					
		28AUG2003	44	4	1	3					
		29AUG2003	45	4	1	3					DOSE DECREASED
		30AUG2003	46	4	1	3					
		31AUG2003	47	4	1	3					
		01SEP2003	48	4	1	3					
		02SEP2003	49	4	1	3					
		03SEP2003	50	4	1	3					
		04SEP2003	51	4	1	3					
		05SEP2003	52	4	1	3					DOSE DECREASED
		06SEP2003	53	4	1	3					
		07SEP2003	54	4	1	3					
		08SEP2003					YES	465.7	52	95.2	STUDY COMPLETED
	E0039019	06FEB2003	1	2	0	2					
		07FEB2003	2	1	0	1					
		08FEB2003	3	1	0	1					
		09FEB2003	4	2	0	2					
		10FEB2003	5	3	0	3					
		11FEB2003	6	3	0	3					
		12FEB2003	7	3	0	3					
		13FEB2003	8	4	0	4					
		14FEB2003	9	4	0	4					
		15FEB2003	10	4	0	4					
		16FEB2003	11	4	0	4					
		17FEB2003	12	4	0	4					
		18FEB2003	13	4	0	4					
		19FEB2003	14	4	0	4					
		20FEB2003	15	4	0	4					
		21FEB2003	16	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	22FEB2003	17	4	0	4					
		23FEB2003	18	4	0	4					
		24FEB2003	19	4	0	4					
		25FEB2003	20	4	0	4					
		26FEB2003	21	4	0	4					
		27FEB2003	22	4	0	4					
		28FEB2003	23	4	0	4					
		01MAR2003	24	4	0	4					
		02MAR2003	25	4	0	4					
		03MAR2003	26	4	0	4					
		04MAR2003	27	4	0	4					
		05MAR2003	28	4	0	4					
		06MAR2003	29		0	4					
		07MAR2003	30	4	0	4					
		08MAR2003	31	4	0	4					
		09MAR2003	32	4	0	4					
		10MAR2003	33	4	0	4					
		11MAR2003	34	4	0	4					
		12MAR2003	35	4	0	4					
		13MAR2003	36	4	0	4					
		14MAR2003	37	4	0	4					
		15MAR2003	38	4	0	4					
		16MAR2003	39	4	0	4					
		17MAR2003	40	4	0	4					
		18MAR2003	41	4	0	4					
		19MAR2003	42	4	0	4					
		20MAR2003	43	4	0	4					
		21MAR2003	44	4	0	4					
		22MAR2003	45	4	0	4					
		23MAR2003	46	4	0	4					
		24MAR2003	47	4	0	4					
		25MAR2003	48	4	0	4					
		26MAR2003	49	4	0	4					
		27MAR2003	50	4	0	4					
		28MAR2003	51	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	29MAR2003	52	4	0	4					
		30MAR2003	53	4	0	4					
		31MAR2003	54	4	0	4					
		01APR2003	55	4	0	4					
		02APR2003	56	4	0	4	NO	558	56	100	
	E0039043	08MAY2003	1	2	0	2					
		09MAY2003	2	1	0	1					
		10MAY2003	3	1	0	1					
		11MAY2003	4	2	0	2					
		12MAY2003	5	3	3	0					DOSE NOT TAKEN, TABS LOST
		13MAY2003	6	3	0	3					TABS TAKEN ON 5/12/03
		14MAY2003	7	3	0	3					TABS TAKEN ON 5/13/03
		15MAY2003	8	4	0	8					TABS WERE TAKEN 5/14/03
		16MAY2003	9	4	0	4					
		17MAY2003	10	4	0	4					
		18MAY2003	11	4	0	4					
		19MAY2003	12	4	0	4					
		20MAY2003	13	4	0	4					
		21MAY2003	14	4	0	4					
		22MAY2003	15		0	4					
		23MAY2003	16	4	0	4					
		24MAY2003	17	4	0	4					
		25MAY2003	18	4	0	4					
		26MAY2003	19	4	0	4					
		27MAY2003	20	4	0	4					
		28MAY2003	21	4	0	4					
		29MAY2003	22	4	0	4					
		30MAY2003	23	4	0	4					
		31MAY2003	24	4	0	4					
		01JUN2003	25	4	0	4					
		02JUN2003	26	4	0	4					
		03JUN2003	27	4	0	4					
		04JUN2003	28	4	0	4					
		05JUN2003	29	4	0	4					CARD NOT RETURNED

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
QUETIAPINE 600 MG (BIPOLAR II)	E0039043	06JUN2003	30	4	0	4					
		07JUN2003	31	4	0	4					
		08JUN2003	32	4	0	4					
		09JUN2003	33	4	0	4					
		10JUN2003	34	4	0	4					
		11JUN2003	35	4	0	4					
		12JUN2003	36		0	4					UNKNOWN - SIC
		13JUN2003	37		0	4	NO	541.9	36	101	
PLACEBO (BIPOLAR I)	E0002001	30DEC2002	1	2	0	2					THIS PART OF BLISTER CARD WAS NOT RETURNED SUBJECT REPORTED TAKING ALL DOSE
		31DEC2002	2	1	0	1					THIS PART OF BLISTER CARD WAS NOT RETURNED SUBJECT REPORTED TAKING ALL DOSE
		01JAN2003	3	1	0	1					THIS PART OF BLISTER CARD WAS NOT RETURNED SUBJECT REPORTED TAKING ALL DOSE
		02JAN2003	4	2	0	2					THIS PART OF BLISTER CARD WAS NOT RETURNED SUBJECT REPORTED TAKING ALL DOSE
		03JAN2003	5	3	0	3					THIS PART OF BLISTER CARD WAS NOT RETURNED SUBJECT REPORTED TAKING ALL DOSE
		04JAN2003	6	3	0	3					
		05JAN2003	7	3	0	3					
		06JAN2003	8	4	0	4					
		07JAN2003	9	4	0	4					
		08JAN2003	10	4	0	4					
		09JAN2003	11	4	0	4					
		10JAN2003	12	4	0	4					
		11JAN2003	13	4	0	4					
		12JAN2003	14	4	0	4					
		13JAN2003	15		0	4					TOOK EXTRA DOSE
		14JAN2003	16	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0002001	15JAN2003	17	4	0	4					
		16JAN2003	18	4	0	4					
		17JAN2003	19	4	0	4					
		18JAN2003	20	4	0	4					
		19JAN2003	21	4	0	4					
		20JAN2003	22	4	0	4					
		21JAN2003	23	4	0	4					
		22JAN2003	24	4	0	4					
		23JAN2003	25	4	0	4					
		24JAN2003	26	4	0	4					
		25JAN2003	27	4	0	4					
		26JAN2003	28	4	0	4					
		27JAN2003	29	4	0	4					
		28JAN2003	30		0	4					TOOK EXTRA DOSE
		29JAN2003	31	4	0	4					
		30JAN2003	32	4	0	4					
		31JAN2003	33	4	0	4					
		01FEB2003	34	4	0	4					
		02FEB2003	35	4	0	4					
		03FEB2003	36	4	0	4					
		04FEB2003	37	4	0	4					
		05FEB2003	38	4	0	4					
		06FEB2003	39	4	0	4					
		07FEB2003	40	4	0	4					
		08FEB2003	41	4	0	4					
		09FEB2003	42	4	0	4					
		10FEB2003	43	4	0	4					
		11FEB2003	44	4	0	4					
		12FEB2003	45	4	0	4					
		13FEB2003	46	4	0	4					
		14FEB2003	47	4	0	4					
		15FEB2003	48	4	0	4					
		16FEB2003	49	4	0	4					
		17FEB2003	50	4	0	4					
		18FEB2003	51	4	0	4					
		19FEB2003	52	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0002001	20FEB2003	53	4	0	4					
		21FEB2003	54	4	0	4					
		22FEB2003	55	4	0	4					
		23FEB2003	56	4	0	4					
		24FEB2003	57	4	0	4					
		25FEB2003	58	4	0	4	NO	0	58	100	
	E0002003	22JAN2003	1	2	0	2					
		23JAN2003	2	1	0	1					
		24JAN2003	3	1	0	1					
		25JAN2003	4	2	0	2					
		26JAN2003	5	3	0	3					
		27JAN2003	6	3	0	3					
		28JAN2003	7	3	0	3					
		29JAN2003	8	4	0	4					
		30JAN2003	9	4	0	4					
		31JAN2003	10	4	0	4					
		01FEB2003	11	4	0	4					
		02FEB2003	12	4	0	4					
		03FEB2003	13	4	0	4					
		04FEB2003	14	4	0	4					
		05FEB2003	15	4	0	4					
		06FEB2003	16	4	0	4					
		07FEB2003	17	4	0	4					
		08FEB2003	18	4	0	4					
		09FEB2003	19	4	0	4					
		10FEB2003	20	4	0	4					
		11FEB2003	21	4	0	4					
		12FEB2003	22	4	0	4					
		13FEB2003	23	4	0	4					
		14FEB2003	24	4	0	4					
		15FEB2003	25	4	0	4					
		16FEB2003	26	4	4	0					FORGOT TO TAKE DOSE
		17FEB2003	27	4	0	4					
		18FEB2003	28	4	0	4					
		19FEB2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0002003	20FEB2003	30	4	0	4					
		21FEB2003	31	4	0	4					
		22FEB2003	32	4	0	4					
		23FEB2003	33	4	0	4					
		24FEB2003	34	4	0	4					
		25FEB2003	35	4	0	4					
		26FEB2003	36	4	0	4					
		27FEB2003	37	4	0	4					
		28FEB2003	38	4	0	4					
		01MAR2003	39	4	0	4					
		02MAR2003	40	4	0	4					
		03MAR2003	41	4	0	4					
		04MAR2003	42	4	0	4					
		05MAR2003	43	4	4	0					FORGOT TO TAKE MEDICATION
		06MAR2003	44	4	0	4					
		07MAR2003	45	4	0	4					
		08MAR2003	46	4	4	0					FORGOT TO TAKE MEDICATION
		09MAR2003	47	4	0	4					
		10MAR2003	48	4	0	4					
		11MAR2003	49	4	0	4					SEEN AT VISIT 9 SUBJECT HAD NEXT VISIT ON 3/11/03
		12MAR2003	50	4	0	4					
		13MAR2003	51	4	0	4					
		14MAR2003	52	4	0	4					
		15MAR2003	53	4	0	4					
		16MAR2003	54	4	0	4					
		17MAR2003	55	4	0	4	NO	0	52	94.2	
	E0002004	25JAN2003	1	2	0	2					SUBJECT DID NOT RETURN BLISTER CARD UNKNOWN IF ANY DOSE WERE TAKEN
		26JAN2003	2	1	0	1					
		27JAN2003	3	1	0	1					
		28JAN2003	4	2	0	2					
		29JAN2003	5	3	0	3					
		30JAN2003	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0002004	31JAN2003	7	3	0	3					
		01FEB2003	8		0	4					UNKNOWN SUBJECT DID NOT RETURN BLISTER CARD UNKNOWN IF ANY DOSES WERE TAKEN
		02FEB2003	9		0	4	NO	0	9	100	
	E0002008	25FEB2003	1	2	0	2					
		26FEB2003	2	1	0	1					
		27FEB2003	3	1	0	1					
		28FEB2003	4	2	0	2					
		01MAR2003	5	3	0	3					
		02MAR2003	6	3	0	3					
		03MAR2003	7	3	0	3					
		04MAR2003	8		0	4					VISIT INTERVAL WAS 6 DAYS
		05MAR2003	9	4	0	4					
		06MAR2003	10	4	0	4					
		07MAR2003	11	4	0	4					
		08MAR2003	12	4	0	4					
		09MAR2003	13	4	0	4					
		10MAR2003	14	4	0	4					
		11MAR2003	15	4	0	4					
		12MAR2003	16		0	4					TOOK EXTRA DOSE VISIT INTERVAL WAS 6 DAYS
		13MAR2003	17	4	0	4					
		14MAR2003	18	4	0	4					
		15MAR2003	19	4	0	4					
		16MAR2003	20	4	0	4					
		17MAR2003	21	4	0	4					
		18MAR2003	22	4	0	4					
		19MAR2003	23	4	0	4					
		20MAR2003	24	4	0	4					
		21MAR2003	25	4	0	4					
		22MAR2003	26	4	0	4					
		23MAR2003	27	4	0	4					
		24MAR2003	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0002008	25MAR2003	29	4	0	4					
		26MAR2003	30	4	0	4					
		27MAR2003	31	4	0	4					
		28MAR2003	32	4	0	4					
		29MAR2003	33	4	0	4					
		30MAR2003	34	4	0	4					
		31MAR2003	35	4	0	4					
		01APR2003	36	4	0	4					
		02APR2003	37	4	0	4					
		03APR2003	38	4	0	4					
		04APR2003	39	4	0	4					
		05APR2003	40	4	0	4					
		06APR2003	41	4	0	4					
		07APR2003	42	4	0	4					
		08APR2003	43	4	0	4					
		09APR2003	44	4	0	4					
		10APR2003	45		0	4					VISIT INTERVAL WAS 6 DAYS
		11APR2003	46	4	0	4					
		12APR2003	47	4	0	4					
		13APR2003	48	4	0	4					
		14APR2003	49	4	0	4					
		15APR2003	50	4	0	4					
		16APR2003	51	4	0	4					SUBJECT HAD VISIT 9 ON 4/16/03
		17APR2003	52	4	0	4					
		18APR2003	53	4	0	4					
		19APR2003	54	4	0	4					
		20APR2003	55	4	0	4					
		21APR2003	56	4	0	4					
		22APR2003	57	4	0	4	NO	0	57	100	
	E0002016	24JUL2003	1	2	0	2					
		25JUL2003	2	1	0	1					
		26JUL2003	3	1	0	1					
		27JUL2003	4	2	0	2					
		28JUL2003	5	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0002016	29JUL2003	6	3	0	3					
		30JUL2003	7	4	0	4					SUBJECT DID NOT TAKE DOSE BECAUSE VISIT 3 WAS ON - 07/30/03
		31JUL2003	8	4	0	4					
		01AUG2003	9	4	0	4					
		02AUG2003	10	4	0	4					
		03AUG2003	11	4	0	4					
		04AUG2003	12	4	0	4					
		05AUG2003	13	4	0	4					
		06AUG2003	14	4	0	4					
		07AUG2003	15	4	0	4					
		08AUG2003	16	4	0	4					
		09AUG2003	17	4	0	4					
		10AUG2003	18	4	0	4					
		11AUG2003	19	4	0	4					
		12AUG2003	20	4	0	4					
		13AUG2003	21	4	0	4					
		14AUG2003	22	4	0	4					
		15AUG2003	23	4	0	4					
		16AUG2003	24	4	0	4					
		17AUG2003	25	4	0	4					
		18AUG2003	26	4	0	4					
		19AUG2003	27	4	0	4					
		20AUG2003	28		0	4					SUBJECT TOOK EXTRA DOSE ON 8-20-03 BECAUSE VISIT 6 - 8-21-03
		21AUG2003	29	4	0	4					
		22AUG2003	30	4	0	4					
		23AUG2003	31	4	0	4					
		24AUG2003	32	4	0	4					
		25AUG2003	33	4	0	4					
		26AUG2003	34	4	4	0					SUBJECT DID NOT TAKE DOSE ON 8-26-03 BECAUSE VISIT 7 WAS ON 8/27/03
		27AUG2003	35	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0002016	28AUG2003	36	4	0	4					
		29AUG2003	37	4	0	4					
		30AUG2003	38	4	0	4					
		31AUG2003	39	4	0	4					
		01SEP2003	40	4	0	4					
		02SEP2003	41	4	0	4					
		03SEP2003	42	4	0	4					
		04SEP2003	43	4	0	4					
		05SEP2003	44	4	0	4					
		06SEP2003	45	4	0	4					
		07SEP2003	46	4	0	4					
		08SEP2003	47	4	0	4					
		09SEP2003	48	4	0	4					
		10SEP2003	49		0	4					PATIENT TOOK EXTRA DOSE BECAUSE VISIT 9 - 9/11/03
		11SEP2003	50	4	0	4					
		12SEP2003	51	4	0	4					
		13SEP2003	52	4	0	4					
		14SEP2003	53	4	0	4					
		15SEP2003	54	4	0	4					
		16SEP2003	55	4	0	4					
		17SEP2003					NO	0	54	98.6	PATIENT DID NOT TAKE DOSE 9/17 BECAUSE VISIT 10 WAS ON 9/17/03
	E0003008	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					
		30JAN2003	3	1	0	1					
		31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					
		03FEB2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0003008	04FEB2003	8	4	0	4					PER PATIENT REPORT: SHE TOOK ALL MEDS AS PRECRIBED BUT RETURNED ONLY THE BOTTOM PART OF THE BLISTER CARD.
		05FEB2003	9	4	0	4					
		06FEB2003	10	4	0	4					
		07FEB2003	11	4	0	4					
		08FEB2003	12	4	0	4					
		09FEB2003	13	4	0	4					
		10FEB2003	14	4	0	4					
		11FEB2003	15	4	0	4					PT. DROPPED A PILL & TOOK A REPLACEMENT FROM EXTRAS
		12FEB2003	16	4	0	4					
		13FEB2003	17	4	0	4					
		14FEB2003	18	4	0	4					
		15FEB2003	19	4	0	4					
		16FEB2003	20	4	0	4					
		17FEB2003	21	4	0	4					
		18FEB2003	22	4	0	4					
		19FEB2003	23	4	0	4					
		20FEB2003	24	4	4	0					PT. MISSED - ERROR
		21FEB2003	25	4	0	4					
		22FEB2003	26	4	0	4					
		23FEB2003	27	4	0	4					
		24FEB2003					NO	0	26	95.8	PT. MISSED - ERROR
	E0004003	10OCT2002	1	2	0	2					
		11OCT2002	2	1	0	1					
		12OCT2002	3	1	0	1					
		13OCT2002	4	2	0	2					
		14OCT2002	5	3	0	3					
		15OCT2002	6	3	0	3					
		16OCT2002	7	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0004003	17OCT2002	8	4	0	4					SUBJ. W/DREW CONSENT 10/31/02.CERTIFIED LETTER SENT TO SUBJ. ON 12/3/02 CONFIRMING W/DRAWAL & REQUESTING RETURN OF STUDY MEDS.SUBJ. NEVER RESPONDED & NEVER RETURNED STUDY MEDS. DT OF LAST DOSE IS UNK
		18OCT2002	9	4	0	4					
		19OCT2002	10	4	0	4					
		20OCT2002	11	4	0	4					
		21OCT2002	12	4	0	4					
		22OCT2002	13	4	0	4					
		23OCT2002	14	4	0	4					
		24OCT2002	15		0	4					
		25OCT2002	16		0	4	NO	0	16	100	
	E0004006	04NOV2002	1	2	0	2					
		05NOV2002	2	1	0	1					
		06NOV2002	3	1	0	1					
		07NOV2002	4	2	0	2					
		08NOV2002	5	3	0	3					
		09NOV2002	6	3	0	3					
		10NOV2002	7	3	0	3					
		11NOV2002	8	4	0	4					
		12NOV2002	9	4	0	4					
		13NOV2002	10	4	0	4					
		14NOV2002	11	4	0	4					
		15NOV2002	12	4	0	4					
		16NOV2002	13	4	0	4					
		17NOV2002	14	4	0	4					
		18NOV2002	15	4	0	4					
		19NOV2002	16	4	0	4					
		20NOV2002	17	4	0	4					
		21NOV2002	18	4	0	4					
		22NOV2002	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0004006	23NOV2002	20	4	0	4					
		24NOV2002	21	4	0	4					
		25NOV2002	22	4	0	4					
		26NOV2002	23	4	0	4					
		27NOV2002	24	4	0	4					
		28NOV2002	25	4	0	4					
		29NOV2002	26	4	0	4					
		30NOV2002	27	4	0	4					
		01DEC2002	28	4	0	4					
		02DEC2002	29	4	0	4					
		03DEC2002	30	4	0	4					
		04DEC2002	31	4	0	4					
		05DEC2002	32	4	0	4					
		06DEC2002	33	4	0	4					
		07DEC2002	34	4	0	4					
		08DEC2002	35	4	0	4					
		09DEC2002	36	4	0	4					
		10DEC2002	37	4	0	4					
		11DEC2002	38	4	0	4					
		12DEC2002	39	4	0	4					
		13DEC2002	40	4	0	4					
		14DEC2002	41	4	0	4					
		15DEC2002	42	4	0	4					
		16DEC2002	43		0	4					THE TWO EXTRA ROWS WERE RETURNED AND REDISPENSED ON 12/08/02 TO COVER SUBJECT WHEN OUT OF TOWN. SUBJECT WILL TAKE THOSE TWO ROWS ON 12/16/02 & 12/17/02. APPROVAL PER S. LARUE/K. ABERNATHY W LRA.
		17DEC2002	44		0	4					SUBJECT CONFIRMED PILLS TAKEN, EXTRA DOSE WELLS RETURNED EMPTY.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0004006	18DEC2002	45		0	4					THE TWO EXTRA ROWS WERE RETURNED AND REDISPENSED ON 12/08/02 TO COVER SUBJECT WHEN OUT OF TOWN. SUBJECT WILL TAKE THOSE TWO ROWS ON 12/18/02 & 12/19/02. APPROVAL PER S. LARUE/K. ABERNATHY W/LRA.
		19DEC2002	46		0	4					SUBJECT CONFIRMED PILLS TAKEN EXTRA DOSE WELLS RETURNED EMPTY.
		20DEC2002	47	4	0	4					
		21DEC2002	48	4	0	4					
		22DEC2002	49	4	0	4					
		23DEC2002	50	4	0	4					
		24DEC2002	51	4	0	4					
		25DEC2002	52	4	0	4					
		26DEC2002	53	4	0	4					
		27DEC2002	54		0	4					
		28DEC2002	55		0	4					
		29DEC2002	56	4	0	4					
		30DEC2002	57	4	0	4					
		31DEC2002	58	4	0	4					
		01JAN2003	59	4	0	4					
		02JAN2003	60	4	0	4					
		03JAN2003	61	4	0	4					
		04JAN2003	62	4	0	4					
		05JAN2003	63		0	4	NO	0	63	100	
	E0004016	19FEB2003	1	2	0	2					
		20FEB2003	2	1	0	1					
		21FEB2003	3	1	0	1					
		22FEB2003	4	2	0	2					
		23FEB2003	5	3	0	3					
		24FEB2003	6	3	0	3					
		25FEB2003	7	3	0	3					
		26FEB2003	8	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0004016	27FEB2003	9	4	4	0					MISSED DOSE
		28FEB2003	10	4	0	4					
		01MAR2003	11	4	0	4					
		02MAR2003	12	4	0	4					
		03MAR2003	13	4	0	4					
		04MAR2003	14	4	0	4					
		05MAR2003	15	4	0	4					
		06MAR2003	16	4	0	4					
		07MAR2003	17	4	0	4					
		08MAR2003	18	4	0	4					
		09MAR2003	19	4	0	4					
		10MAR2003	20	4	0	4					
		11MAR2003	21	4	0	4					
		12MAR2003	22		4	0					MISSED THIS DOSE
		13MAR2003	23	4	0	4					
		14MAR2003	24	4	1	3					MISSED 1 TABLET
		15MAR2003	25	4	0	4					
		16MAR2003	26	4	0	4					
		17MAR2003	27	4	0	4					
		18MAR2003	28	4	4	0					MISSED THIS DOSE
		19MAR2003	29	4	0	4					
		20MAR2003	30	4	0	4					
		21MAR2003	31	4	0	4					
		22MAR2003	32	4	0	4					
		23MAR2003	33	4	0	4					
		24MAR2003	34	4	0	4					
		25MAR2003	35	4	4	0					MISSED THIS DOSE
		26MAR2003	36	4	0	4					
		27MAR2003	37	4	0	4					
		28MAR2003	38	4	0	4					
		29MAR2003	39	4	0	4					
		30MAR2003	40	4	0	4					
		31MAR2003	41	4	0	4					
		01APR2003	42	4	0	4					
		02APR2003	43		0	4					
		03APR2003	44	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0004016	04APR2003	45	4	0	4					
		05APR2003	46	4	0	4					
		06APR2003	47	4	0	4					
		07APR2003	48	4	0	4					
		08APR2003	49	4	0	4					
		09APR2003	50	4	0	4					
		10APR2003	51	4	0	4					THIS DOSE USED TO REPLACE 1 LOST DOSE ON 4-3-03
		11APR2003	52	4	0	4					
		12APR2003	53	4	0	4					
		13APR2003	54	4	0	4					
		14APR2003	55	4	0	4					
		15APR2003	56	4	0	4					
		16APR2003	57	4	0	4	NO	0	53	92.5	
	E0004024	03JUL2003	1	2	0	2					
		04JUL2003	2	1	0	1					
		05JUL2003	3	1	0	1					
		06JUL2003	4	2	0	2					
		07JUL2003	5	3	0	3					
		08JUL2003	6	3	0	3					
		09JUL2003	7	3	0	3					
		10JUL2003	8	4	0	4					
		11JUL2003	9	4	0	4					
		12JUL2003	10	4	0	4					
		13JUL2003	11	4	0	4					
		14JUL2003	12	4	0	4					
		15JUL2003	13	4	0	4					
		16JUL2003	14	4	0	4					
		17JUL2003	15	4	0	4					
		18JUL2003	16	4	0	4					
		19JUL2003	17	4	0	4					
		20JUL2003	18	4	0	4					
		21JUL2003	19	4	0	4					
		22JUL2003	20	4	0	4					
		23JUL2003	21	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0004024	24JUL2003	22	4	0	4					
		25JUL2003	23	4	0	4					
		26JUL2003	24	4	0	4					
		27JUL2003	25	4	0	4					
		28JUL2003	26	4	0	4					
		29JUL2003	27	4	0	4					
		30JUL2003	28	4	0	4					
		31JUL2003	29	4	0	4					
		01AUG2003	30	4	0	4					
		02AUG2003	31	4	0	4					
		03AUG2003	32	4	0	4					
		04AUG2003	33	4	0	4					
		05AUG2003	34	4	0	4					
		06AUG2003	35	4	0	4					
		07AUG2003	36	4	0	4					
		08AUG2003	37	4	0	4					
		09AUG2003	38	4	0	4					
		10AUG2003	39	4	0	4					
		11AUG2003	40	4	0	4					
		12AUG2003	41	4	0	4					
		13AUG2003	42	4	0	4					
		14AUG2003	43	4	0	4					
		15AUG2003	44	4	0	4					
		16AUG2003	45	4	0	4					
		17AUG2003	46	4	0	4					
		18AUG2003	47	4	0	4					
		19AUG2003	48	4	0	4					
		20AUG2003	49	4	0	4					
		21AUG2003	50	4	0	4					
		22AUG2003	51	4	0	4					
		23AUG2003	52	4	0	4					
		24AUG2003	53	4	0	4					
		25AUG2003	54	4	0	4					
		26AUG2003	55	4	0	4					
		27AUG2003	56	4	0	4	NO	0	56	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0005006	03OCT2002	1	2	0	2					
		04OCT2002	2	1	0	1					
		05OCT2002	3	1	0	1					
		06OCT2002	4	2	0	2					
		07OCT2002	5	3	0	3					
		08OCT2002	6	3	0	3					
		09OCT2002	7	3	0	3					
		10OCT2002	8		4	0					FORGOT
		11OCT2002	9		0	4					MISSED DOSES ON 10/12 & 10/13/03
		12OCT2002	10			0					
		13OCT2002	11			0					
		14OCT2002	12	4	0	4					
		15OCT2002	13	4	0	4					
		16OCT2002	14	4	0	4					
		17OCT2002	15	4	0	4					
		18OCT2002	16	4	0	4					
		19OCT2002	17	4	0	4					
		20OCT2002	18	4	0	4					
		21OCT2002	19		0	4					UNKNOWN CARD NOT RETURNED
		22OCT2002	20		0	4	NO	0	17	82.1	
	E0005017	30DEC2002	1	2	0	2					
		31DEC2002	2	1	1	0					LOST TABLET
		01JAN2003	3	1	0	1					
		02JAN2003	4	2	0	2					
		03JAN2003	5	3	0	3					
		04JAN2003	6	3	0	3					
		05JAN2003	7	3	0	3					
		06JAN2003	8	4	0	4					
		07JAN2003	9	4	0	4					TOOK TO REPLACE ONE LOST ON 12-31-02
		08JAN2003	10	4	0	4					
		09JAN2003	11	4	0	4					
		10JAN2003	12	4	0	4					
		11JAN2003	13	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0005017	12JAN2003	14	4	0	4					
		13JAN2003	15		0	4					
		14JAN2003	16	4	0	4					
		15JAN2003	17	4	0	4					
		16JAN2003	18	4	0	4					
		17JAN2003	19	4	0	4					
		18JAN2003	20	4	0	4					
		19JAN2003	21	4	0	4					
		20JAN2003	22	4	0	4					
		21JAN2003	23		0	4					
		22JAN2003	24	4	0	4					
		23JAN2003	25	4	0	4					
		24JAN2003	26	4	0	4					
		25JAN2003	27	4	0	4					
		26JAN2003	28	4	0	4					
		27JAN2003	29	4	0	4					
		28JAN2003	30	4	0	4					
		29JAN2003	31		0	4					
		30JAN2003	32	4	0	4					
		31JAN2003	33	4	0	4					
		01FEB2003	34	4	0	4					
		02FEB2003	35	4	0	4					
		03FEB2003	36	4	0	4					
		04FEB2003	37	4	0	4					
		05FEB2003	38	4	0	4					
		06FEB2003	39	4	0	4					
		07FEB2003	40	4	0	4					
		08FEB2003	41	4	0	4					
		09FEB2003	42	4	0	4					
		10FEB2003	43	4	0	4					
		11FEB2003	44		0	4					
		12FEB2003	45		0	4					
		13FEB2003	46	4	0	4					
		14FEB2003	47	4	0	4					
		15FEB2003	48	4	0	4					
		16FEB2003	49	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0005017	17FEB2003	50	4	0	4					
		18FEB2003	51	4	0	4					
		19FEB2003	52	4	0	4					
		20FEB2003	53	4	0	4					
		21FEB2003	54	4	0	4					
		22FEB2003	55	4	0	4					
		23FEB2003	56	4	0	4					
		24FEB2003	57	4	0	4					
		25FEB2003	58	4	0	4					
		26FEB2003	59	4	0	4					
		27FEB2003	60		0	4					
		28FEB2003	61		0	4	NO	0	60	99.6	
	E0005019	15JAN2003	1	2	0	2					
		16JAN2003	2	1	0	1					
		17JAN2003	3	1	0	1					
		18JAN2003	4	2	0	2					
		19JAN2003	5	3	0	3					
		20JAN2003	6	3	0	3					
		21JAN2003	7	3	0	3	NO	0	7	100	
	E0005026	06MAR2003	1	2	0	2					
		07MAR2003	2	1	0	1					
		08MAR2003	3	1	0	1					
		09MAR2003	4	2	0	2					
		10MAR2003	5	3	0	3					
		11MAR2003	6	3	0	3					
		12MAR2003	7	3	0	3					
		13MAR2003	8	4	0	4					
		14MAR2003	9	4	0	4					
		15MAR2003	10	4	0	4					
		16MAR2003	11	4	0	4					
		17MAR2003	12	4	0	4					
		18MAR2003	13	4	0	4					
		19MAR2003	14	4	4	0					DID NOT TAKE
		20MAR2003	15	4	4	0					MISSED 3/20/03 DOSE

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0005026	21MAR2003	16	4	0	4					
		22MAR2003	17	4	0	4					
		23MAR2003	18	4	0	4					
		24MAR2003	19	4	0	4					
		25MAR2003					NO	0	17	87.3	VISIT DATE
	E0005039	22MAY2003	1	2	0	2					
		23MAY2003	2	1	0	1					
		24MAY2003	3	1	0	1					
		25MAY2003	4	2	0	2					
		26MAY2003	5	3	0	3					
		27MAY2003	6	3	0	3					
		28MAY2003	7	3	0	3					
		29MAY2003	8	4	0	4					DOSE FOR 5/28/03 WAS REDISPENSED FROM VISIT 2 CARD
		30MAY2003	9	4	0	4					
		31MAY2003	10	4	0	4					
		01JUN2003	11	4	0	4					
		02JUN2003	12	4	0	4					
		03JUN2003	13	4	0	4					
		04JUN2003	14	4	0	4					
		05JUN2003	15	4	0	4					
		06JUN2003	16	4	0	4					
		07JUN2003	17	4	0	4					
		08JUN2003	18	4	0	4					
		09JUN2003	19	4	0	4					
		10JUN2003	20	4	0	4					
		11JUN2003	21	4	0	4					
		12JUN2003	22	4	0	4					
		13JUN2003	23	4	0	4					
		14JUN2003	24	4	0	4					
		15JUN2003	25	4	0	4					
		16JUN2003	26	4	0	4					
		17JUN2003	27	4	0	4					
		18JUN2003	28	4	0	8					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0005039	19JUN2003	29	4	0	4					
		20JUN2003	30	4	0	4					
		21JUN2003	31	4	0	4					
		22JUN2003	32	4	0	4					
		23JUN2003	33	4	0	4					
		24JUN2003	34	4	0	4					
		25JUN2003	35	4	0	4					
		26JUN2003	36	4	0	4					
		27JUN2003	37	4	0	4					
		28JUN2003	38	4	4	0					FORGOT
		29JUN2003	39	4	0	4					
		30JUN2003	40	4	0	4					
		01JUL2003	41		0	4					
		02JUL2003	42		0	4					
		03JUL2003	43	4	0	4					
		04JUL2003	44	4	0	4					
		05JUL2003	45	4	0	4					
		06JUL2003	46	4	0	4					
		07JUL2003	47	4	0	4					
		08JUL2003	48	4	0	4					
		09JUL2003	49	4	0	4					
		10JUL2003	50	4	0	4					
		11JUL2003	51	4	0	4					
		12JUL2003	52	4	0	4					
		13JUL2003	53	4	0	4					
		14JUL2003	54	4	0	4					
		15JUL2003	55	4	0	4					
		16JUL2003					NO	0	54	100	07/16/2003 WAS THE DAY OF HER VISIT 10.
	E0005043	09JUL2003	1	2	0	2					
		10JUL2003	2	1	0	1					
		11JUL2003	3	1	0	1					
		12JUL2003	4	2	0	2					
		13JUL2003	5	3	0	3					
		14JUL2003	6	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0005043	15JUL2003	7	3	0	3					
		16JUL2003	8		0	4					
		17JUL2003	9	4	0	4					
		18JUL2003	10	4	0	4					
		19JUL2003	11	4	0	4					
		20JUL2003	12	4	0	4					
		21JUL2003	13	4	0	4					
		22JUL2003	14	4	0	4					
		23JUL2003	15	4	0	4					
		24JUL2003	16	4	0	4					
		25JUL2003	17	4	0	4					
		26JUL2003	18	4	0	4					
		27JUL2003	19	4	0	4					
		28JUL2003	20	4	0	4					
		29JUL2003	21	4	0	4					
		30JUL2003	22	4	0	4					
		31JUL2003	23	4	0	4					
		01AUG2003	24	4	0	4					
		02AUG2003	25	4	0	4					
		03AUG2003	26	4	0	4					
		04AUG2003	27	4	0	4					
		05AUG2003	28	4	0	4					
		06AUG2003	29	4	0	4					
		07AUG2003	30	4	0	4					
		08AUG2003	31	4	0	4					
		09AUG2003	32	4	0	4					
		10AUG2003	33	4	0	4					
		11AUG2003	34	4	0	4					
		12AUG2003	35	4	0	4					
		13AUG2003	36	4	0	4					
		14AUG2003	37	4	0	4					
		15AUG2003	38	4	0	4					
		16AUG2003	39	4	0	4					
		17AUG2003	40	4	0	4					
		18AUG2003	41	4	0	4					
		19AUG2003	42	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0005043	20AUG2003	43	4	0	4					
		21AUG2003	44	4	0	4					
		22AUG2003	45	4	0	4					
		23AUG2003	46	4	0	4					
		24AUG2003	47	4	0	4					
		25AUG2003	48	4	0	4					
		26AUG2003	49	4	0	4					
		27AUG2003	50	4	0	4					
		28AUG2003	51	4	0	4					
		29AUG2003	52	4	0	4					
		30AUG2003	53	4	0	4					
		31AUG2003	54	4	0	4					
		01SEP2003	55	4	0	4					
		02SEP2003	56	4	0	4	NO	0	56	100	
	E0006020	13MAY2003	1	2	0	2					
		14MAY2003	2	1	0	1					
		15MAY2003	3	1	0	1					
		16MAY2003	4	2	0	2					
		17MAY2003	5	3	0	3					
		18MAY2003	6	3	0	3					
		19MAY2003	7	3	0	3					
		20MAY2003	8	4	0	4					
		21MAY2003	9	4	0	4					
		22MAY2003	10	4	0	4					
		23MAY2003	11	4	0	4					
		24MAY2003	12	4	0	4					
		25MAY2003	13	4	0	4					
		26MAY2003	14	4	0	4					
		27MAY2003	15	4	0	4					
		28MAY2003	16	4	0	4					
		29MAY2003	17	4	0	4					
		30MAY2003	18	4	0	4					
		31MAY2003	19	4	0	4					
		01JUN2003	20	4	0	4					
		02JUN2003	21	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0006020	03JUN2003	22	4	0	4					
		04JUN2003	23	4	0	4					
		05JUN2003	24	4	0	4					
		06JUN2003	25	4	0	4					
		07JUN2003	26	4	0	4					
		08JUN2003	27	4	0	4					
		09JUN2003	28	4	0	4					
		10JUN2003	29	4	0	4					
		11JUN2003	30	4	0	4					
		12JUN2003	31	4	0	4					
		13JUN2003	32	4	0	4					
		14JUN2003	33	4	0	4					
		15JUN2003	34	4	0	4					
		16JUN2003	35	4	0	4					
		17JUN2003	36	4	0	4					
		18JUN2003	37	4	0	4					
		19JUN2003	38	4	0	4					
		20JUN2003	39	4	0	4					
		21JUN2003	40	4	0	4					
		22JUN2003	41	4	0	4					
		23JUN2003	42	4	0	4					
		24JUN2003	43	4	0	4					
		25JUN2003	44	4	0	4					
		26JUN2003	45	4	0	4					
		27JUN2003	46	4	0	4					
		28JUN2003	47	4	0	4					
		29JUN2003	48	4	0	4					
		30JUN2003	49	4	0	4					
		01JUL2003	50	4	0	4					
		02JUL2003	51	4	0	4					
		03JUL2003	52	4	0	4					
		04JUL2003	53	4	0	4					
		05JUL2003	54	4	0	4					
		06JUL2003	55	4	0	4					
		07JUL2003	56	4	0	4	NO	0	56	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0007001	31DEC2002	1	2	0	2					
		01JAN2003	2	1	0	1					
		02JAN2003	3	1	0	1					
		03JAN2003	4	2	0	2					
		04JAN2003	5	3	0	3					
		05JAN2003	6	3	0	3					
		06JAN2003	7	3	0	3					
		07JAN2003	8	4	0	4					
		08JAN2003	9	4	0	4					
		09JAN2003	10	4	0	4					
		10JAN2003	11	4	0	4					
		11JAN2003	12	4	0	4					
		12JAN2003	13	4	0	4					
		13JAN2003	14	4	0	4					
		14JAN2003	15	4	0	4					
		15JAN2003	16	4	0	4					
		16JAN2003	17	4	0	4					
		17JAN2003	18	4	0	4					
		18JAN2003	19	4	0	4					
		19JAN2003	20	4	0	4					
		20JAN2003	21	4	0	4					
		21JAN2003	22	4	0	4					
		22JAN2003	23	4	0	4					
		23JAN2003	24	4	0	4					
		24JAN2003	25	4	0	4					
		25JAN2003	26	4	0	4					
		26JAN2003	27	4	0	4					
		27JAN2003	28	4	0	4					
		28JAN2003	29	4	0	4					
		29JAN2003	30	4	0	4					
		30JAN2003	31	4	0	4					
		31JAN2003	32	4	0	4					
		01FEB2003	33	4	0	4					
		02FEB2003	34	4	0	4					
		03FEB2003	35	4	0	4					
		04FEB2003	36	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0007001	05FEB2003	37	4	0	4					
		06FEB2003	38	4	0	4					
		07FEB2003	39	4	0	4					
		08FEB2003	40	4	0	4					
		09FEB2003	41	4	0	4					
		10FEB2003	42	4	0	4					
		11FEB2003	43	4	0	4					
		12FEB2003	44	4	0	4					
		13FEB2003	45	4	0	4					
		14FEB2003	46	4	0	4					
		15FEB2003	47	4	0	4					
		16FEB2003	48	4	0	4					
		17FEB2003	49	4	0	4					
		18FEB2003	50	4	0	4					
		19FEB2003	51	4	0	4					
		20FEB2003	52	4	0	4					
		21FEB2003	53	4	0	4					
		22FEB2003					NO	0	53	100	SIC SUBJECT 100% COMPLIANT DATE OF DISCONTINUATION 2/22/03
	E0007003	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8	4	0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4					
		12FEB2003	14	4	0	4					
		13FEB2003	15		0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0007003	14FEB2003	16	4	0	4					
		15FEB2003	17	4	0	4					
		16FEB2003	18	4	0	4					
		17FEB2003	19	4	0	4					
		18FEB2003	20	4	0	4					
		19FEB2003	21	4	0	4					
		20FEB2003	22	4	0	4					
		21FEB2003	23		0	4					
		22FEB2003	24	4	0	4					
		23FEB2003	25	4	0	4					
		24FEB2003	26	4	0	4					
		25FEB2003					NO	0	26	100	SUBJECT HAD SAE WENT TO HOSPITAL AND STOPPED MEDICATION
	E0007006	05MAR2003	1	2	0	2					
		06MAR2003	2	1	0	1					
		07MAR2003	3	1	0	1					
		08MAR2003	4	2	0	2					
		09MAR2003	5	3	0	3					
		10MAR2003	6	3	0	3					
		11MAR2003	7	3	0	3					
		12MAR2003	8	4	4	0					LEFT DRUG IN OTHER CAR
		13MAR2003	9	4	0	4					
		14MAR2003	10	4	0	4					
		15MAR2003	11	4	0	4					
		16MAR2003	12	4	0	4					
		17MAR2003	13	4	0	4					
		18MAR2003	14	4	0	4					
		19MAR2003	15	4	0	4					DRUG CARD NOT RETURNED
		20MAR2003	16	4	0	4					
		21MAR2003	17	4	0	4					
		22MAR2003	18	4	0	4					
		23MAR2003	19	4	0	4					
		24MAR2003	20	4	0	4					
		25MAR2003	21	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0007006	26MAR2003	22		0	4					UNKNOWN SIC
		27MAR2003	23		0	4	NO	0	22	94.9	
	E0009004	26NOV2002	1	2	0	2					
		27NOV2002	2	1	0	1					
		28NOV2002	3	1	0	1					
		29NOV2002	4	2	0	2					
		30NOV2002	5	3	0	3					
		01DEC2002	6	3	0	3					
		02DEC2002	7	3	0	3					
		03DEC2002	8		4	0					PT. MISSED 12/3/02 DOSE
		04DEC2002	9	4	0	4					
		05DEC2002	10	4	0	4					
		06DEC2002	11	4	0	4					
		07DEC2002	12	4	4	0					PT. MISSED DOSE
		08DEC2002	13	4	0	4					
		09DEC2002	14	4	0	4					
		10DEC2002	15	4	0	4					
		11DEC2002	16	4	0	4					
		12DEC2002	17	4	0	4					
		13DEC2002	18	4	4	0					PT. MISSED DOSE
		14DEC2002	19	4	0	4					
		15DEC2002	20	4	0	4					
		16DEC2002	21	4	0	4					
		17DEC2002	22	4	0	4	NO	0	19	84	
	E0009012	25JUN2003	1	2	0	2	NO	0	1	100	SUBJECT TOOK DAY 1 DOSE AND THEN STOPPED TAKING DUE TO ADVERSE EVENT ON CRF PG. 212
	E0010008	18DEC2002	1	2	0	2					
		19DEC2002	2	1	0	1					
		20DEC2002	3	1	0	1					
		21DEC2002	4	2	0	2					
		22DEC2002	5	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0010008	23DEC2002	6	3	0	3					
		24DEC2002	7	3	0	3					
		25DEC2002	8		0	4					
		26DEC2002	9	4	0	4					
		27DEC2002	10	4	0	4					
		28DEC2002	11	4	0	4					
		29DEC2002	12	4	0	4					
		30DEC2002	13	4	0	4					
		31DEC2002	14	4	0	4					
		01JAN2003	15	4	0	4					
		02JAN2003	16	4	4	0					MISSED DOSE
		03JAN2003	17	4	0	4					
		04JAN2003	18	4	0	4					
		05JAN2003	19	4	0	4					
		06JAN2003	20	4	0	4					
		07JAN2003	21	4	0	4					
		08JAN2003	22	4	0	4					
		09JAN2003	23	4	0	4					
		10JAN2003	24	4	0	4					
		11JAN2003	25	4	0	4					
		12JAN2003	26	4	0	4					
		13JAN2003	27	4	0	4					
		14JAN2003	28	4	0	4					
		15JAN2003	29	4	0	4					
		22JAN2003					NO	0	28	96.1	THE BLISTERCARD WAS NOT RETURNED. SUBJECT IS LOST TO FOLLOW
	E0010018	19MAR2003	1	2	0	2					
		20MAR2003	2	1	0	1					
		21MAR2003	3	1	0	1					
		22MAR2003	4	2	0	2					
		23MAR2003	5	3	0	3					
		24MAR2003	6	3	0	3					
		25MAR2003	7	3	0	3					
		26MAR2003	8	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0010018	27MAR2003	9	4	0	4					
		28MAR2003	10	4	0	4					
		29MAR2003	11	4	4	0					SUBJECT FORGOT
		30MAR2003	12	4	4	0					SUBJECT FORGOT
		31MAR2003	13	4	0	4					
		01APR2003	14	4	0	4					
		02APR2003	15	4	0	4					
		03APR2003	16	4	0	4					
		04APR2003	17	4	0	4					
		05APR2003	18	4	0	4					
		06APR2003	19	4	0	4					
		07APR2003	20	4	0	4					
		08APR2003	21	4	0	4					
		09APR2003	22	4	0	4					
		10APR2003	23	4	0	4					SUBJECT TOOK ON 4/6/03
		11APR2003	24	4	0	4					
		12APR2003	25	4	0	4					
		13APR2003	26	4	0	4					
		14APR2003	27	4	0	4					
		15APR2003	28	4	0	4					
		16APR2003	29	4	0	4					
		17APR2003	30	4	0	4					
		18APR2003	31	4	0	4					
		19APR2003	32	4	0	4					
		20APR2003	33	4	0	4					
		21APR2003	34	4	0	4					
		22APR2003	35	4	0	4					
		23APR2003	36	4	0	4					
		24APR2003	37	4	0	4					
		25APR2003	38	4	0	4					
		26APR2003	39	4	0	4					
		27APR2003	40	4	0	4					
		28APR2003	41	4	0	4					
		29APR2003	42	4	0	4					
		30APR2003	43		4	0					MISSED DOSE
		01MAY2003	44	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0010018	02MAY2003	45	4	0	4					
		03MAY2003	46	4	0	4					
		04MAY2003	47	4	0	4					
		05MAY2003	48			0					
		06MAY2003	49	4	0	4					
		07MAY2003	50	4	0	4					
		08MAY2003	51	4	0	4					
		09MAY2003	52		0	4					
		10MAY2003	53		0	4	NO	0	49	92	
	E0010028	16JUN2003	1	2	0	2					
		17JUN2003	2	1	0	1					
		18JUN2003	3	1	0	1					
		19JUN2003	4	2	0	2					
		20JUN2003	5	3	0	3					
		21JUN2003	6	3	0	3					
		22JUN2003	7	3	0	3					
		23JUN2003	8		0	4					
		24JUN2003	9	4	0	4					
		25JUN2003	10	4	0	4					
		26JUN2003	11	4	0	4					
		27JUN2003	12	4	0	4					
		28JUN2003	13	4	0	4					
		29JUN2003	14	4	0	4					
		30JUN2003	15	4	0	4					
		01JUL2003	16	4	0	4					
		02JUL2003	17	4	0	4					
		03JUL2003	18	4	0	4					
		04JUL2003	19	4	0	4					
		05JUL2003	20	4	0	4					
		06JUL2003	21	4	0	4					
		07JUL2003	22	4	0	4					
		08JUL2003	23	4	0	4					
		09JUL2003	24	4	0	4					
		10JUL2003	25	4	0	4					
		11JUL2003	26	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0010028	12JUL2003	27	4	0	4					
		13JUL2003	28	4	0	4					
		14JUL2003					NO	0	28	100	SUBJECT STOPPED MEDICATION ON HER OWN
	E0011008	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8	4	0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003					NO	0	11	100	PATIENT STOPPED MEDS. DUE TO ADVERSE EVENTS EXPERIENCED.
	E0011009	27DEC2002	1	2	0	2					PT'S NIGHT IS ACTUALLY IN THE MORNING B/C HE WORKS NIGHT SHIFT SO PT. DID TAKE FIRST DOSE EARLY MORNING ON 2002/12/27.
		28DEC2002	2	1	0	1					
		29DEC2002	3	1	0	1					
		30DEC2002	4	2	0	2					
		31DEC2002	5	3	0	3					
		01JAN2003	6	3	0	3					
		02JAN2003	7	3	0	3					
		03JAN2003	8	4	0	4					
		04JAN2003	9	4	0	4					
		05JAN2003	10	4	0	4					
		06JAN2003	11	4	0	4					
		07JAN2003	12	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0011009	08JAN2003	13	4	0	4					
		09JAN2003	14	4	0	4					
		10JAN2003	15	4	0	4					
		11JAN2003	16	4	0	4					
		12JAN2003	17	4	0	4					
		13JAN2003	18	4	0	4					
		14JAN2003	19	4	0	4					
		15JAN2003	20	4	0	4					
		16JAN2003	21	4	0	4					
		17JAN2003	22	4	0	4					
		18JAN2003	23	4	0	4					
		19JAN2003	24	4	0	4					
		20JAN2003	25	4	0	4					
		21JAN2003	26	4	0	4					
		22JAN2003	27	4	0	4					
		23JAN2003	28	4	0	4					
		24JAN2003	29	4	0	4					
		25JAN2003	30	4	0	4					
		26JAN2003	31	4	0	4					
		27JAN2003	32	4	0	4					
		28JAN2003	33	4	0	4					
		29JAN2003	34	4	0	4					
		30JAN2003	35	4	0	4					
		31JAN2003	36	4	0	4					
		01FEB2003	37	4	0	4					
		02FEB2003	38	4	0	4					
		03FEB2003	39	4	0	4					
		04FEB2003	40	4	0	4					
		05FEB2003	41	4	0	4					
		06FEB2003	42	4	0	4					
		07FEB2003	43	4	0	4					
		08FEB2003	44	4	0	4					
		09FEB2003	45	4	0	4					
		10FEB2003	46	4	0	4					
		11FEB2003	47	4	0	4					
		12FEB2003	48	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0011009	13FEB2003	49	4	0	4					
		14FEB2003	50	4	0	4					
		15FEB2003	51	4	0	4					
		16FEB2003	52	4	0	4					
		17FEB2003	53	4	0	4					
		18FEB2003	54	4	0	4					
		19FEB2003	55	4	0	4					
		20FEB2003	56	4	0	4	NO	0	56	100	
	E0011010	10FEB2003	1	2	0	2					
		11FEB2003	2	1	0	1					
		12FEB2003	3	1	0	1					
		13FEB2003	4	2	0	2					
		14FEB2003	5	3	0	3					
		15FEB2003	6	3	0	3					
		16FEB2003	7	3	0	3					
		17FEB2003	8	4	0	4					
		18FEB2003	9	4	4	0					PATIENT MISSED DOSAGE
		19FEB2003	10	4	0	4					
		20FEB2003	11	4	0	4					
		21FEB2003	12	4	0	4					
		22FEB2003	13	4	0	4					
		23FEB2003	14	4	0	4					
		24FEB2003	15	4	0	4					
		25FEB2003	16	4	0	4					
		26FEB2003	17	4	0	4					
		27FEB2003	18	4	0	4					
		28FEB2003	19	4	0	4					
		01MAR2003	20	4	0	4					
		02MAR2003	21	4	0	4					
		03MAR2003	22	4	0	4					
		04MAR2003	23	4	0	4					
		05MAR2003	24	4	0	4					
		06MAR2003	25	4	4	0					PATIENT MISSED DOSAGE.
		07MAR2003	26	4	0	4					
		08MAR2003	27	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0011010	09MAR2003	28	4	4	0					PATIENT MISSED DOSAGE.
		10MAR2003	29	4	0	4					
		11MAR2003	30	4	0	4					
		12MAR2003	31	4	0	4					
		13MAR2003	32	4	0	4					
		14MAR2003	33	4	2	2					PATIENT DID NOT WANT TO TAKE FULL DOSAGE
		15MAR2003	34	4	2	2					PATIENT DID NOT WANT TO TAKE FULL DOSAGE.
		16MAR2003	35	4	2	2	YES	0	32	87.9	PATIENT DID NOT WANT TO TAKE FULL DOSAGE.
	E0013001	14NOV2002	1	2	0	2					
		15NOV2002	2	1	0	1					
		16NOV2002	3	1	0	1					
		17NOV2002	4	2	0	2					
		18NOV2002	5	3	0	3					
		19NOV2002	6	3	0	3					
		20NOV2002	7	3	0	3					
		21NOV2002	8	4	0	4					
		22NOV2002	9	4	0	4					
		23NOV2002	10	4	0	4					
		24NOV2002	11	4	0	4					
		25NOV2002	12	4	0	4					
		26NOV2002	13	4	0	4					
		27NOV2002	14	4	0	4					
		28NOV2002	15	4	0	4					
		29NOV2002	16	4	0	4					
		30NOV2002	17	4	0	4					
		01DEC2002	18	4	0	4					
		02DEC2002	19	4	0	4					
		03DEC2002	20	4	0	4					
		04DEC2002	21		0	4					
		05DEC2002	22		4	0					MISSED DOSE
		06DEC2002	23	4	0	4					
		07DEC2002	24	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0013001	08DEC2002	25	4	0	4					
		09DEC2002	26	4	0	4					
		10DEC2002	27	4	0	4					
		11DEC2002	28	4	0	4					
		12DEC2002	29	4	0	4					
		13DEC2002	30	4	0	4					
		14DEC2002	31	4	0	4					
		15DEC2002	32	4	0	4					
		16DEC2002	33	4	0	4					
		17DEC2002	34	4	0	4					
		18DEC2002	35	4	0	4					
		19DEC2002	36	4	0	4					
		20DEC2002	37	4	0	4					
		21DEC2002	38	4	0	4					
		22DEC2002	39	4	0	4					
		23DEC2002	40	4	0	4					
		24DEC2002	41	4	0	4					
		25DEC2002	42		0	4					
		26DEC2002	43		0	4					
		27DEC2002	44	4	0	4					
		28DEC2002	45	4	0	4					
		29DEC2002	46	4	0	4					
		30DEC2002	47	4	0	4					
		31DEC2002	48	4	0	4					
		01JAN2003	49	4	0	4					
		02JAN2003	50	4	0	4					
		03JAN2003	51	4	0	4					
		04JAN2003	52	4	0	4					
		05JAN2003	53	4	0	4					
		06JAN2003	54	4	0	4					
		07JAN2003	55	4	0	4					
		08JAN2003	56	4	0	4					
		09JAN2003					NO	0	55	98.1	SUBJECT SHOULD HAVE TAKEN 1/9/03 DOSE REPORTED MISSED DOSE

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0013003	12NOV2002	1	2	0	2					
		13NOV2002	2	1	0	1					
		14NOV2002	3	1	0	1					
		15NOV2002	4	2	0	2					
		16NOV2002	5	3	0	3					
		17NOV2002	6	3	0	3					
		18NOV2002	7	3	0	3					
		19NOV2002	8	4	0	4					
		20NOV2002	9	4	0	4					
		21NOV2002	10	4	0	4					
		22NOV2002	11	4	0	4					
		23NOV2002	12	4	0	4					
		24NOV2002	13	4	0	4					PT LOST 1 TAB REPLACE WITH 1 EXTRA TAB
		25NOV2002	14	4	0	4					
		26NOV2002	15	4	0	4					
		27NOV2002	16	4	0	4					USED 1 TAB TO REPLACE LOST TAB 11/24
		28NOV2002	17	4	0	4					
		29NOV2002	18	4	0	4					
		30NOV2002	19	4	0	4					
		01DEC2002	20	4	0	4					
		02DEC2002	21	4	0	4					
		03DEC2002	22	4	0	4					
		04DEC2002	23	4	0	4					
		05DEC2002	24	4	0	4					
		06DEC2002	25	4	0	4					
		07DEC2002	26	4	0	4					
		08DEC2002	27	4	0	4					
		09DEC2002	28	4	0	4					
		10DEC2002	29		0	4					
		11DEC2002	30	4	0	4					
		12DEC2002	31	4	0	4					
		13DEC2002	32	4	0	4					
		14DEC2002	33	4	0	4					
		15DEC2002	34	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0013003	16DEC2002	35	4	0	4					
		17DEC2002	36	4	0	4					
		18DEC2002	37	4	0	4					
		19DEC2002	38	4	0	4					
		20DEC2002	39	4	0	4					
		21DEC2002	40	4	0	4					
		22DEC2002	41	4	0	4					
		23DEC2002	42	4	0	4					
		24DEC2002	43	4	0	4					
		25DEC2002	44	4	0	4					
		26DEC2002	45	4	0	4					
		27DEC2002	46	4	0	4					
		28DEC2002	47	4	0	4					
		29DEC2002	48	4	4	0					MISSED DOSE
		30DEC2002	49	4	0	4					
		31DEC2002	50	4	0	4					
		01JAN2003	51	4	0	4					
		02JAN2003	52	4	0	4					
		03JAN2003	53	4	0	4					
		04JAN2003	54	4	0	4					
		05JAN2003	55	4	0	4	NO	0	54	98.1	
	E0013005	18FEB2003	1	2	0	2					
		19FEB2003	2	1	0	1					
		20FEB2003	3	1	0	1					
		21FEB2003	4	2	0	2					
		22FEB2003	5	3	0	3					
		23FEB2003	6	3	0	3					
		24FEB2003	7	3	0	3					
		25FEB2003	8	4	0	4					
		26FEB2003	9	4	0	4					
		27FEB2003	10	4	0	4					
		28FEB2003	11	4	0	4					
		01MAR2003	12	4	0	4					
		02MAR2003	13	4	0	4					
		03MAR2003	14	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0013005	04MAR2003	15	4	0	4					
		05MAR2003	16	4	0	4					
		06MAR2003	17	4	0	4					
		07MAR2003	18	4	0	4					
		08MAR2003	19	4	0	4					1 TAB WAS LOST
		09MAR2003	20	4	0	4					
		10MAR2003	21	4	0	4					
		11MAR2003	22	4	0	4					PT. DROPPED 1 TAB IN DRAIN ON 3/08/03 REPLACE FROM FROM EXTRA DAY
		12MAR2003	23	4	0	4					
		13MAR2003	24	4	0	4					
		14MAR2003	25	4	0	4					
		15MAR2003	26	4	0	4					
		16MAR2003	27	4	0	4					
		17MAR2003	28	4	0	4					
		18MAR2003	29		0	4					
		19MAR2003	30	4	0	4					DAY 50 - 56 BLISTER CARD WAS DISPENSED IN ERROR, AT VISIT 6 3/19/03
		20MAR2003	31	4	0	4					
		21MAR2003	32	4	0	4					
		22MAR2003	33	4	0	4					
		23MAR2003	34	4	0	4					
		24MAR2003	35	4	0	4					
		25MAR2003	36	4	0	4					SIC SUBJECT TOOK DAY 7 DOSE IN THE EVENING AFTER VISIT 7 3/25/03
		26MAR2003	37	4	0	4					SIC DAY 29 - 35 BLISTER CARD WAS DISPENSED AT VISIT 7 3/25/03
		27MAR2003	38	4	0	4					
		28MAR2003	39	4	0	4					
		29MAR2003	40	4	0	4					
		30MAR2003	41	4	0	4					
		31MAR2003	42	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0013005	01APR2003	43	4	0	4					
		02APR2003	44	4	0	4					DAY 36 - 42 BLISTER CARD DISPENSED AT VISIT 8 ON 4-2-03
		03APR2003	45	4	0	4					
		04APR2003	46	4	0	4					
		05APR2003	47	4	0	4					
		06APR2003	48	4	0	4					
		07APR2003	49	4	0	4					
		08APR2003	50	4	0	4					SUBJECT REMOVED DAY 7 TABS, BUT DID NOT TAKE. DAY 7 TABS WAS LOST 4-8-03
		08APR2003	50	4	0	4					DAY 43 - 49 BLISTER CARD WAS DISPENSED AT VISIT 9 ON 4-8-03
		09APR2003	51	4	0	4					
		10APR2003	52	4	0	4					
		11APR2003	53	4	0	4					
		12APR2003	54	4	0	4					
		13APR2003	55	4	0	4					
		14APR2003	56	4	0	4	NO	0	56	100	
	E0013013	06MAY2003	1	2	0	2					
		07MAY2003	2	1	0	1					
		08MAY2003	3	1	0	1					
		09MAY2003	4	2	0	2					
		10MAY2003	5	3	0	3					
		11MAY2003	6	3	0	3					
		12MAY2003	7	4	0	4					
		13MAY2003	8	4	0	4					
		14MAY2003	9	4	0	4					
		15MAY2003	10	4	0	4					
		16MAY2003	11	4	0	4					
		17MAY2003	12	4	0	4					
		18MAY2003	13	4	0	4					
		19MAY2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0013013	20MAY2003	15	4	0	4					
		21MAY2003	16	4	0	4					
		22MAY2003	17	4	0	4					
		23MAY2003	18	4	0	4					
		24MAY2003	19	4	0	4					
		25MAY2003	20	4	0	4					
		26MAY2003	21		0	4					
		27MAY2003					NO	0	21	101	NO TABLETS TAKEN FROM THIS BLISTER CARD
	E0014002	26FEB2003	1	2	0	2					
		27FEB2003	2	1	0	1					
		28FEB2003	3	1	0	1					
		01MAR2003	4	2	0	2					
		02MAR2003	5	3	0	3					
		03MAR2003	6	3	0	3					
		04MAR2003	7	3	0	3					
		05MAR2003	8	4	0	4					
		06MAR2003	9	4	0	4					
		07MAR2003	10	4	0	4					
		08MAR2003	11	4	0	4					
		09MAR2003	12	4	0	4					
		10MAR2003	13	4	0	4					
		11MAR2003	14	4	0	4					
		12MAR2003	15	4	0	4					
		13MAR2003	16	4	0	4					
		14MAR2003	17	4	0	4					
		15MAR2003	18	4	0	4					
		16MAR2003	19	4	0	4					
		17MAR2003	20	4	0	4					
		18MAR2003	21	4	0	4					
		19MAR2003	22		0	4					
		20MAR2003	23	4	0	4					
		21MAR2003	24	4	0	4					
		22MAR2003	25	4	0	4					
		23MAR2003	26	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0014002	24MAR2003	27	4	0	4					
		25MAR2003	28	4	0	4					
		26MAR2003	29	4	0	4					
		27MAR2003	30	4	0	4					PER VERBAL REPORT - SON THREW OUT EMPTY BLISTER PAK.
		28MAR2003	31	4	0	4					
		29MAR2003	32	4	0	4					
		30MAR2003	33	4	0	4					
		31MAR2003	34	4	0	4					
		01APR2003	35	4	0	4					
		02APR2003	36	4	0	4					
		03APR2003	37		0	4					
		04APR2003	38		0	4	NO	0	38	100	
	E0014004	12MAR2003	1	2	0	2					
		13MAR2003	2	1	0	1					
		14MAR2003	3	1	0	1					
		15MAR2003	4	2	0	2					PT. DID NOT TAKE MEDS 3-16-03 THROUGH 3-19-03. MEDICATION WAS REDISPENSED ON 3-17-03.
		16MAR2003	5			0					
		17MAR2003	6			0					
		18MAR2003	7			0					
		19MAR2003	8			0					
		20MAR2003	9	3	0	3					
		21MAR2003	10	3	0	3					
		22MAR2003	11	3	0	3					
		23MAR2003	12		0	4					
		24MAR2003	13		0	4					
		25MAR2003	14	4	0	4					
		26MAR2003	15	4	0	4					
		27MAR2003	16	4	0	4					
		28MAR2003	17	4	0	4					
		29MAR2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0014004	30MAR2003	19	4	0	4					
		31MAR2003					YES	0	15	78.3	HELD DOSE PER DR. REIMHERR
	E0014009	23APR2003	1	2	0	2					
		24APR2003	2	1	0	1					
		25APR2003	3	1	0	1					
		26APR2003	4	2	0	2					
		27APR2003	5	3	0	3					
		28APR2003	6	3	0	3					
		29APR2003	7	3	0	3	NO	0	7	100	
	E0014015	18JUN2003	1	2	0	2					BLISTER CARD NEVER RETURNED - SUBJECT IS LOST TO FOLLOW - UP
		19JUN2003	2	1	0	1					
		20JUN2003	3	1	0	1					
		21JUN2003	4	2	0	2					
		22JUN2003	5	3	0	3					
		23JUN2003	6	3	0	3					
		24JUN2003	7	3	0	3					
		25JUN2003	8		0	4					UNKNOWN - SIC
		26JUN2003	9	4	0	8					BLISTER CARD NEVER RETURNED - PATIENT LOST TO FOLLOW - UP.
		27JUN2003	10	4	0	4					
		28JUN2003	11	4	0	4					
		29JUN2003	12	4	0	4					
		30JUN2003	13	4	0	4					
		01JUL2003	14	4	0	4					
		02JUL2003	15	4	0	4					
		03JUL2003	16		0	4					UNKNOWN - SIC
		04JUL2003	17		0	4	NO	0	17	107	
	E0014017	27JUN2003	1	2	0	2					
		28JUN2003	2	1	0	1					
		29JUN2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0014017	30JUN2003	4	2	0	2					
		01JUL2003	5	3	0	3					
		02JUL2003	6	4	1	3					SUBJECT INSTRUCTED TO TAKE ONLY 3 TABS 7/2 & 7/3 TO CONTINUE TITRATION
		03JUL2003	7	4	1	3					
		04JUL2003	8	4	0	4					
		05JUL2003	9	4	4	0					PT MISSED DOSE ON 7/5 - OUT OF TOWN & FORGOT MEDS
		06JUL2003	10	4	0	4					
		07JUL2003	11	4	0	4					
		08JUL2003	12	4	0	4					
		09JUL2003	13	4	0	4					
		10JUL2003	14	4	0	4					
		11JUL2003	15	4	0	4					
		12JUL2003	16	4	0	4					
		13JUL2003	17	4	0	4					
		14JUL2003	18	4	0	4					
		15JUL2003	19	4	0	4					
		16JUL2003	20	4	0	4					
		17JUL2003	21	4	0	4					
		18JUL2003	22	4	0	4					
		19JUL2003	23	4	0	4					
		20JUL2003	24	4	0	4					
		21JUL2003	25	4	0	4					
		22JUL2003	26	4	0	4					
		23JUL2003	27	4	0	4					
		24JUL2003	28	4	0	4					
		25JUL2003	29	4	0	4					
		26JUL2003	30	4	0	4					
		27JUL2003	31	4	0	4					
		28JUL2003	32	4	0	4					
		29JUL2003	33	4	0	4					
		30JUL2003	34	4	0	4					
		31JUL2003	35	4	0	4					
		01AUG2003	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0014017	02AUG2003	37	4	0	4					
		03AUG2003	38	4	0	4					
		04AUG2003	39	4	0	4					
		05AUG2003	40	4	0	4					
		06AUG2003	41	4	0	4					
		07AUG2003	42	4	0	4					
		08AUG2003	43	4	0	4					
		09AUG2003	44	4	0	4					
		10AUG2003	45	4	0	4					
		11AUG2003	46	4	0	4					
		12AUG2003	47	4	0	4					
		13AUG2003	48	4	0	4					
		14AUG2003	49	4	0	4					
		15AUG2003	50	4	0	4					
		16AUG2003	51	4	4	0					MISSED DOSE
		17AUG2003	52	4	0	4					
		18AUG2003	53	4	0	4	NO	0	51	96	
	E0014018	01JUL2003	1	2	0	2					
		02JUL2003	2	1	0	1					
		03JUL2003	3	1	0	1					
		04JUL2003	4	2	0	2					
		05JUL2003	5	3	0	3					
		06JUL2003	6	3	0	3					
		07JUL2003	7	3	0	3					
		08JUL2003	8		0	4					
		09JUL2003	9	4	0	4					
		10JUL2003	10	4	0	4					
		11JUL2003	11	4	0	4					
		12JUL2003	12	4	0	4					
		13JUL2003	13	4	0	4					
		14JUL2003	14	4	0	4					
		15JUL2003	15	4	0	4					
		16JUL2003	16	4	0	4					
		17JUL2003	17	4	0	4					
		18JUL2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0014018	19JUL2003	19	4	0	4					
		20JUL2003	20	4	0	4					
		21JUL2003	21	4	0	4					
		22JUL2003	22	4	0	4					
		23JUL2003	23	4	0	4					
		24JUL2003	24	4	0	4					
		25JUL2003	25	4	0	4					
		26JUL2003	26	4	0	4					
		27JUL2003	27	4	0	4					
		28JUL2003	28	4	0	4					
		29JUL2003	29	4	0	4					
		30JUL2003	30	4	0	4					
		31JUL2003	31	4	0	4					
		01AUG2003	32	4	0	4					
		02AUG2003	33	4	0	4					
		03AUG2003	34	4	0	4					
		04AUG2003	35	4	0	4					
		05AUG2003	36	4	0	4					
		06AUG2003	37	4	0	4					
		07AUG2003	38	4	0	4					
		08AUG2003	39	4	0	4					
		09AUG2003	40	4	0	4					
		10AUG2003	41	4	0	4					
		11AUG2003	42	4	0	4					
		12AUG2003	43	4	0	4					
		13AUG2003	44	4	0	4					
		14AUG2003	45	4	0	4					
		15AUG2003	46	4	0	4					
		16AUG2003	47	4	0	4					
		17AUG2003	48	4	0	4					
		18AUG2003	49	4	0	4					
		19AUG2003	50	4	0	4					
		20AUG2003	51	4	0	4					
		21AUG2003	52	4	0	4					
		22AUG2003	53	4	0	4					
		23AUG2003	54	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0014018	24AUG2003	55	4	0	4					
		25AUG2003	56	4	0	4					
		26AUG2003	57		0	4	NO	0	57	100	
	E0015005	02DEC2002	1	2	0	2					
		03DEC2002	2	1	0	1					
		04DEC2002	3	1	0	1					
		05DEC2002	4	2	0	2					
		06DEC2002	5	3	0	3					
		07DEC2002	6	3	0	3					
		08DEC2002	7	3	0	3					
		09DEC2002	8		0	4					
		10DEC2002	9		0	4					
		11DEC2002	10	4	0	4					
		12DEC2002	11	4	0	4					
		13DEC2002	12	4	0	4					
		14DEC2002	13	4	0	4					
		15DEC2002	14	4	0	4					
		16DEC2002	15	4	0	4					
		17DEC2002	16	4	0	4	NO	0	16	100	
	E0017002	03JUN2003	1	2	0	2					BLISTER CARD NOT RETURNED BY SUBJ. PT. REPORT- PT. MOVED & LOST PILL PACK. PT. REPORTED TAKING 2 PILLS PRESCRIBED FOR DAY 1 & SINGLE PILL PRESCIBED FOR DAY 2. NO PILLS WERE TAKEN, NOR EXTRA DAY DOSES.
		04JUN2003	2	1	0	1					
		05JUN2003	3	1	0	1					
		06JUN2003	4	2	0	2					
		07JUN2003	5	3	0	3					
		08JUN2003	6	3	0	3					
		09JUN2003	7	3	0	3					
		10JUN2003	8		0	4					UNKNOWN - SIC

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0017002	11JUN2003	9		0	4	NO	0	9	100	
	E0018009	06JAN2003	1	2	0	2					
		07JAN2003	2	1	0	1					
		08JAN2003	3	1	0	1					
		09JAN2003	4	2	0	2					
		10JAN2003	5	3	0	3					
		11JAN2003	6	3	0	3					
		12JAN2003	7	3	0	3					
		13JAN2003	8	4	0	4					PATIENT LOST BLISTER CARD
		14JAN2003	9	4	0	4					
		20JAN2003					NO	0	9	100	SIC
	E0018010	16JAN2003	1	2	0	2					
		17JAN2003	2	1	0	1					
		18JAN2003	3	1	0	1					
		19JAN2003	4	2	0	2					
		20JAN2003	5	3	0	3					
		21JAN2003	6	3	0	3					
		22JAN2003	7	3	0	3					
		23JAN2003	8	4	0	4					
		24JAN2003	9	4	0	4					
		25JAN2003	10	4	0	4					
		26JAN2003	11	4	0	4					
		27JAN2003	12	4	0	4					
		28JAN2003	13	4	0	4					
		29JAN2003	14	4	0	4					
		30JAN2003	15	4	0	4					
		31JAN2003	16	4	0	4					
		01FEB2003	17	4	0	4					
		02FEB2003	18	4	0	4					
		03FEB2003	19	4	0	4					
		04FEB2003	20	4	4	0					PT. MISSED DOSE PAGE 201
		05FEB2003	21	4	0	4					
		06FEB2003	22	4	0	4					
		07FEB2003	23	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0018010	08FEB2003	24	4	0	4					
		09FEB2003	25	4	0	4					
		10FEB2003	26	4	0	4					
		11FEB2003	27	4	0	4					
		12FEB2003	28	4	0	4					
		13FEB2003	29	4	0	4					
		14FEB2003	30	4	0	4					
		15FEB2003	31	4	0	4					
		16FEB2003	32	4	0	4					
		17FEB2003	33	4	0	4					
		18FEB2003	34	4	0	4					
		19FEB2003	35	4	0	4					
		20FEB2003	36	4	0	4					
		21FEB2003	37	4	0	4					
		22FEB2003	38	4	0	4					
		23FEB2003	39	4	0	4					
		24FEB2003	40	4	0	4					
		25FEB2003	41	4	0	4					
		26FEB2003	42	4	0	4					
		27FEB2003	43	4	0	4					
		28FEB2003	44	4	0	4					
		01MAR2003	45	4	0	4					
		02MAR2003	46	4	0	4					
		03MAR2003	47	4	0	4					
		04MAR2003	48	4	0	4					
		05MAR2003	49		0	4					
		06MAR2003	50	4	0	4					
		07MAR2003	51	4	0	4					
		08MAR2003	52	4	0	4					
		09MAR2003	53	4	4	0					MISSED DOSE
		10MAR2003	54	4	0	4					
		11MAR2003	55	4	0	4					
		12MAR2003	56	4	0	4	NO	0	54	96.2	
	E0018015	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0018015	30JAN2003	3	1	0	1					
		31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					
		03FEB2003	7	3	0	3					
		04FEB2003	8	4	0	4					
		05FEB2003	9	4	0	4					
		06FEB2003	10	4	0	4					
		07FEB2003	11	4	4	0					PT. MISSED DOSE
		08FEB2003	12	4	0	4					
		09FEB2003	13	4	0	4					
		10FEB2003	14	4	0	4					
		11FEB2003	15		0	4					
		12FEB2003	16		0	4					
		13FEB2003	17	4	0	4					
		14FEB2003	18	4	0	4					
		15FEB2003	19	4	0	4					
		16FEB2003	20	4	0	4					
		17FEB2003	21	4	0	4					
		18FEB2003	22	4	0	4					
		19FEB2003	23	4	0	4					
		20FEB2003	24	4	0	4					
		21FEB2003	25	4	0	4					
		22FEB2003	26	4	0	4					
		23FEB2003	27	4	0	4					
		24FEB2003	28	4	0	4					
		25FEB2003	29	4	0	4					
		26FEB2003	30	4	0	4					
		27FEB2003	31	4	0	4					
		28FEB2003	32	4	0	4					
		01MAR2003	33	4	0	4					
		02MAR2003	34	4	0	4					
		03MAR2003	35	4	0	4					
		04MAR2003	36	4	0	4					
		05MAR2003	37		0	4					
		06MAR2003	38	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0018015	07MAR2003	39	4	0	4					
		08MAR2003	40	4	0	4					
		09MAR2003	41	4	0	4					
		10MAR2003	42	4	0	4					
		11MAR2003	43	4	0	4					
		12MAR2003	44	4	0	4					
		13MAR2003	45	4	0	4					
		14MAR2003	46	4	0	4					
		15MAR2003	47	4	0	4					
		16MAR2003	48	4	0	4					
		17MAR2003	49	4	0	4					
		18MAR2003	50	4	0	4					
		19MAR2003	51	4	0	4					
		20MAR2003	52	4	0	4					
		21MAR2003	53	4	0	4					
		22MAR2003	54	4	0	4					
		23MAR2003	55	4	0	4					
		24MAR2003	56	4	0	4					
		25MAR2003	57	4	0	4					
		26MAR2003	58	4	0	4	NO	0	57	98.2	
	E0020015	27MAR2003	1	2	0	2					
		28MAR2003	2	1	0	1					
		29MAR2003	3	1	0	1					
		30MAR2003	4	2	0	2					
		31MAR2003	5	3	3	0					PATIENT INADVERTENLLY FORGOT TO TAKE
		01APR2003	6	3	0	3					
		02APR2003	7	3	0	3					
		03APR2003	8	4	0	4					
		04APR2003	9	4	0	4					
		05APR2003	10	4	0	4					
		06APR2003	11	4	0	4					
		07APR2003	12	4	0	4					
		08APR2003	13	4	0	4					
		09APR2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0020015	10APR2003	15	4	0	4					
		11APR2003	16	4	0	4					
		12APR2003	17	4	0	4					
		13APR2003	18	4	0	4					
		14APR2003	19	4	0	4					
		15APR2003	20	4	0	4					
		16APR2003	21	4	0	4					
		17APR2003	22	4	0	4					
		18APR2003	23	4	0	4					
		19APR2003	24	4	0	4					
		20APR2003	25	4	0	4					
		21APR2003	26	4	0	4					
		22APR2003	27	4	0	4					
		23APR2003	28	4	0	4					
		24APR2003	29	4	0	4					
		25APR2003	30	4	0	4					
		26APR2003	31	4	0	4					
		27APR2003	32	4	0	4					
		28APR2003	33	4	0	4					
		29APR2003	34	4	0	4					
		30APR2003	35	4	0	4					
		01MAY2003	36	4	0	4					
		02MAY2003	37	4	0	4					
		03MAY2003	38	4	0	4					
		04MAY2003	39	4	0	4					
		05MAY2003	40	4	0	4					
		06MAY2003	41	4	0	4					
		07MAY2003	42		0	4					
		08MAY2003	43	4	0	4					
		09MAY2003	44	4	0	4					
		10MAY2003	45	4	0	4					
		11MAY2003	46	4	0	4					
		12MAY2003	47	4	0	4					
		13MAY2003	48	4	0	4					
		14MAY2003	49	4	0	4					
		15MAY2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0020015	16MAY2003	51	4	0	4					
		17MAY2003	52	4	0	4					
		18MAY2003	53	4	0	4					
		19MAY2003	54	4	0	4					
		20MAY2003	55	4	0	4					
		21MAY2003	56	4	0	4					
		22MAY2003	57		0	4	NO	0	56	98.6	
	E0020017	03APR2003	1	2	0	2					
		04APR2003	2	1	0	1					
		05APR2003	3	1	0	1					
		06APR2003	4	2	0	2					
		07APR2003	5	3	0	3					
		08APR2003	6	3	0	3					
		09APR2003	7	3	0	3					
		10APR2003	8	4	0	4					
		11APR2003	9	4	0	4					
		12APR2003	10	4	0	4					
		13APR2003	11	4	0	4					
		14APR2003	12	4	0	4					
		15APR2003	13	4	0	4					
		16APR2003	14	4	0	4					
		17APR2003	15	4	0	4					
		18APR2003	16	4	0	4					
		19APR2003	17	4	0	4					
		20APR2003	18	4	0	4					
		21APR2003	19	4	0	4					
		22APR2003	20	4	0	4					
		23APR2003	21	4	0	4					
		24APR2003	22	4	0	4					
		25APR2003	23	4	0	4					
		26APR2003	24	4	0	4					
		27APR2003	25	4	0	4					
		28APR2003	26	4	0	4					
		29APR2003	27	4	0	4					
		30APR2003	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0020017	01MAY2003	29	4	0	4					
		02MAY2003	30	4	0	4					
		03MAY2003	31	4	0	4					
		04MAY2003	32	4	0	4					
		05MAY2003	33	4	0	4					
		06MAY2003	34	4	0	4					
		07MAY2003	35	4	0	4					
		08MAY2003	36	4	0	4					
		09MAY2003	37	4	0	4					
		10MAY2003	38	4	0	4					
		11MAY2003	39	4	0	4					
		12MAY2003	40	4	0	4					
		13MAY2003	41	4	0	4					
		14MAY2003	42	4	0	4					
		15MAY2003	43	4	0	4					
		16MAY2003	44	4	0	4					
		17MAY2003	45	4	0	4					
		18MAY2003	46	4	0	4					
		19MAY2003	47		0	4					
		20MAY2003	48	4	0	4					
		21MAY2003	49	4	0	4					
		22MAY2003	50	4	0	4					
		23MAY2003	51	4	0	4					
		24MAY2003	52	4	0	4					
		25MAY2003	53	4	0	4					
		26MAY2003	54	4	0	4					
		27MAY2003	55		0	4					
		28MAY2003	56		0	4	NO	0	56	100	
	E0020020	12MAY2003	1	2	0	2					
		13MAY2003	2	1	0	1					
		14MAY2003	3	1	0	1					
		15MAY2003	4	2	0	2					
		16MAY2003	5	3	0	3					
		17MAY2003	6	3	0	3					
		18MAY2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0020020	19MAY2003	8	4	0	4					
		20MAY2003	9	4	0	4					
		21MAY2003	10	4	0	4					
		22MAY2003	11	4	0	4					
		23MAY2003					NO	0	11	100	PATIENT DISCONTINUED FROM STUDY
	E0020022	16JUN2003	1	2	0	2					
		17JUN2003	2	1	0	1					
		18JUN2003	3	1	0	1					
		19JUN2003	4	2	0	2					
		20JUN2003	5	3	0	3					
		21JUN2003	6	3	0	3					
		22JUN2003	7	3	0	3					
		23JUN2003	8	4	0	4					
		24JUN2003	9	4	0	4					
		25JUN2003	10	4	0	4					
		26JUN2003	11	4	0	4					
		27JUN2003	12	4	0	4					
		28JUN2003	13	4	0	4					
		29JUN2003	14	4	0	4					
		30JUN2003	15	4	0	4					
		01JUL2003	16	4	0	4					
		02JUL2003	17	4	0	4					
		03JUL2003	18	4	0	4					
		04JUL2003	19	4	0	4					
		05JUL2003	20	4	0	4					
		06JUL2003	21	4	0	4					
		07JUL2003	22	4	0	4					
		08JUL2003	23	4	0	4					
		09JUL2003	24	4	0	4					
		10JUL2003	25	4	0	4					
		11JUL2003	26	4	0	4					
		12JUL2003	27	4	0	4					
		13JUL2003	28	4	0	4					
		14JUL2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0020022	15JUL2003	30	4	0	4					
		16JUL2003	31	4	0	4					
		17JUL2003	32	4	0	4					
		18JUL2003	33	4	0	4					
		19JUL2003	34	4	0	4					
		20JUL2003	35	4	0	4					
		21JUL2003	36	4	0	4					
		22JUL2003	37	4	0	4					
		23JUL2003	38	4	0	4					
		24JUL2003	39	4	0	4					
		25JUL2003	40	4	0	4					
		26JUL2003	41	4	0	4					
		27JUL2003	42	4	0	4					
		28JUL2003	43	4	0	4					
		29JUL2003	44	4	0	4					
		30JUL2003	45	4	0	4					
		31JUL2003	46	4	0	4					
		01AUG2003	47	4	0	4					
		02AUG2003	48	4	0	4					
		03AUG2003	49	4	0	4					
		04AUG2003	50	4	0	4					
		05AUG2003	51	4	0	4					
		06AUG2003	52	4	0	4					
		07AUG2003	53	4	0	4					
		08AUG2003	54	4	0	4					
		09AUG2003	55	4	0	4					
		10AUG2003	56	4	0	4	NO	0	56	100	
	E0022001	28OCT2002	1	2	0	2					
		29OCT2002	2	1	0	1					
		30OCT2002	3	1	0	1					
		31OCT2002	4	2	0	2					
		01NOV2002	5	3	0	3					
		02NOV2002	6	3	0	3					
		03NOV2002	7	3	0	3					
		04NOV2002	8	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022001	05NOV2002	9	4	0	4					
		06NOV2002	10	4	0	4					
		07NOV2002	11	4	0	4					
		08NOV2002	12	4	0	4					
		09NOV2002	13	4	0	4					
		10NOV2002	14	4	0	4					
		11NOV2002	15	4	0	4					
		12NOV2002	16	4	0	4					
		13NOV2002	17	4	0	4					
		14NOV2002	18	4	0	4					
		15NOV2002	19	4	0	4					
		16NOV2002	20	4	0	4					
		17NOV2002	21	4	0	4					
		18NOV2002	22	4	0	4					
		19NOV2002	23	4	0	4					
		20NOV2002	24	4	0	4					
		21NOV2002	25	4	0	4					
		22NOV2002	26	4	0	4					
		23NOV2002	27	4	0	4					
		24NOV2002	28	4	0	4					
		25NOV2002	29		0	4					
		26NOV2002	30	4	0	4					
		27NOV2002	31	4	0	4					
		28NOV2002	32	4	0	4					
		29NOV2002	33	4	0	4					TOOK 1 EXTRA PILL FROM DAY 7
		30NOV2002	34	4	0	4					TOOK 1 EXTRA PILL FROM DAY 7
		01DEC2002	35	4	0	4					TOOK 1 EXTRA PILL FROM DAY 7
		02DEC2002	36	4	0	7					PATIENT DID NOT TAKE ANY DOSES THIS DATE
		03DEC2002	37	4	0	4					
		04DEC2002	38	4	0	4					
		05DEC2002	39	4	0	4					
		06DEC2002	40	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022001	07DEC2002	41	4	0	4					
		08DEC2002	42	4	0	4					
		09DEC2002	43	4	0	4					
		10DEC2002	44	4	0	4					
		11DEC2002	45	4	0	4					
		12DEC2002	46	4	0	4					
		13DEC2002	47	4	0	4					
		14DEC2002	48	4	0	4					
		15DEC2002	49	4	0	4					
		16DEC2002	50	4	0	4					
		17DEC2002	51	4	0	4					
		18DEC2002	52	4	0	4					
		19DEC2002	53	4	0	4					
		20DEC2002	54	4	0	4					
		21DEC2002	55	4	0	4					
		22DEC2002	56	4	0	4					
		23DEC2002	57		0	4					
		24DEC2002	58		0	4	NO	0	58	101	
	E0022004	28OCT2002	1	2	0	2					PT DISCARDED USED PORTION OF BLISTER PACK.
		29OCT2002	2	1	0	1					
		30OCT2002	3	1	0	1					
		31OCT2002	4	2	0	2					
		01NOV2002	5	3	0	3					
		02NOV2002	6	3	0	3					
		03NOV2002	7	3	0	3					
		04NOV2002	8	4	0	4					
		05NOV2002	9	4	0	4					
		06NOV2002	10	4	0	4					
		07NOV2002	11	4	0	4					
		08NOV2002	12	4	0	4					
		09NOV2002	13	4	0	4					
		10NOV2002	14	4	0	4					
		11NOV2002	15	4	0	4					
		12NOV2002	16	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022004	13NOV2002	17	4	0	4					
		14NOV2002	18	4	0	4					
		15NOV2002	19	4	0	4					
		16NOV2002	20	4	0	4					
		17NOV2002	21	4	0	4					
		18NOV2002	22		4	0					PT FORGOT DOSE
		19NOV2002	23	4	0	4					
		20NOV2002	24	4	0	4					
		21NOV2002	25	4	0	4					
		22NOV2002	26	4	0	4					
		23NOV2002	27	4	0	4					
		24NOV2002	28	4	0	4					
		25NOV2002	29	4	0	4					
		26NOV2002	30	4	0	4					
		27NOV2002	31	4	0	4					
		28NOV2002	32	4	0	4					
		29NOV2002	33	4	0	4					
		30NOV2002	34	4	0	4					
		01DEC2002	35	4	0	4					
		02DEC2002	36	4	0	4					
		03DEC2002	37	4	0	4					
		04DEC2002	38	4	0	4					
		05DEC2002	39	4	0	4					
		06DEC2002	40	4	0	4					
		07DEC2002	41	4	0	4					
		08DEC2002	42	4	0	4					
		09DEC2002	43		0	4					
		10DEC2002	44	4	0	4					
		11DEC2002	45	4	4	0					PT WENT OUT OF TOWN FORGOT TO TAKE MEDS.
		12DEC2002	46	4	0	4					
		13DEC2002	47	4	0	4					
		14DEC2002	48	4	0	4					
		15DEC2002	49	4	0	4					
		16DEC2002	50	4	0	4					
		17DEC2002	51	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022004	18DEC2002	52	4	0	4					
		19DEC2002	53	4	0	4					
		20DEC2002	54	4	0	4					
		21DEC2002	55	4	0	4					
		22DEC2002	56	4	0	4	NO	0	54	96.2	
	E0022005	08NOV2002	1	2	0	2					
		09NOV2002	2	1	0	1					
		10NOV2002	3	1	0	1					
		11NOV2002	4	2	0	2					
		12NOV2002	5	3	0	3					
		13NOV2002	6	3	0	3					
		14NOV2002	7	3	0	3					
		15NOV2002	8	4	0	4					
		16NOV2002	9	4	0	4					
		17NOV2002	10	4	0	4					
		18NOV2002	11	4	0	4					
		19NOV2002	12	4	0	4					
		20NOV2002	13	4	0	4					
		21NOV2002	14	4	0	4					
		22NOV2002	15	4	0	4					
		23NOV2002	16	4	0	4					
		24NOV2002	17	4	0	4					
		25NOV2002	18	4	0	4					
		26NOV2002	19	4	0	4					
		27NOV2002	20	4	0	4					
		28NOV2002	21	4	0	4					
		29NOV2002	22	4	0	4					
		30NOV2002	23	4	0	4					
		01DEC2002	24	4	0	4					
		02DEC2002	25	4	0	4					
		03DEC2002	26	4	0	4					
		04DEC2002	27	4	0	4					
		05DEC2002	28	4	0	4					
		06DEC2002	29	4	0	4					
		07DEC2002	30	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022005	08DEC2002	31	4	0	4					
		09DEC2002	32	4	0	4					
		10DEC2002	33	4	0	4					
		11DEC2002	34	4	0	4					
		12DEC2002	35	4	0	4					
		13DEC2002	36	4	0	4					
		14DEC2002	37	4	0	4					
		15DEC2002	38	4	0	4					
		16DEC2002	39	4	0	4					
		17DEC2002	40	4	0	4					
		18DEC2002	41	4	0	4					
		19DEC2002	42	4	0	4					
		20DEC2002	43	4	0	4					
		21DEC2002	44	4	0	4					
		22DEC2002	45	4	0	4					
		23DEC2002	46	4	0	4					
		24DEC2002	47	4	0	4					
		25DEC2002	48	4	0	4					
		26DEC2002	49	4	0	4					
		27DEC2002	50	4	0	4					
		28DEC2002	51	4	0	4					
		29DEC2002	52	4	0	4					
		30DEC2002	53	4	0	4					
		31DEC2002	54	4	0	4					
		01JAN2003	55	4	0	4					
		02JAN2003	56	4	0	4	NO	0	56	100	
	E0022011	29NOV2002	1	2	0	2					STUDY MEDS NOT RETURNED UNK IF ANY TAKEN ONE DOSE TAKEN BY PT REPORT ON 11/29/02 ONLY DOSE TAKEN
		30NOV2002	2	1	0	1					
		01DEC2002	3	1	0	1					
		02DEC2002	4	2	0	2					
		03DEC2002	5	3	0	3					
		04DEC2002	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022011	05DEC2002	7	3	0	3	NO	0	7	100	
	E0022015	10DEC2002	1	2	0	2					
		11DEC2002	2	1	1	0					MISSED DOSE
		12DEC2002	3	1	0	1					
		13DEC2002	4	2	0	2					
		14DEC2002	5	3	0	3					
		15DEC2002	6	3	0	3					
		16DEC2002	7	3	0	3					
		17DEC2002	8	4	0	4					
		18DEC2002	9	4	0	4					
		19DEC2002	10	4	4	0					MISSED DOSE
		20DEC2002	11	4	0	4					
		21DEC2002	12	4	0	4					
		22DEC2002	13	4	0	4					
		23DEC2002	14	4	0	4					
		24DEC2002	15		0	8					REDISPENSED TAKEN 12/24/02
		24DEC2002	15		0	8					DOSE TAKEN FROM PREVIOUS PACK
		25DEC2002	16		4	0					MISSED DOSE
		26DEC2002	17	4	0	4					
		27DEC2002	18	4	0	4					
		28DEC2002	19	4	0	4					
		29DEC2002	20	4	0	4					
		30DEC2002	21	4	0	4					
		31DEC2002	22	4	0	4					
		01JAN2003	23	4	0	4					
		02JAN2003	24	4	0	4					
		03JAN2003	25	4	0	4					
		04JAN2003	26	4	0	4					
		05JAN2003	27	4	0	4					
		06JAN2003	28	4	0	4					
		07JAN2003	29	4	0	4					
		08JAN2003	30	4	0	4					
		09JAN2003	31	4	0	4					
		10JAN2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022015	11JAN2003	33	4	0	4					
		12JAN2003	34	4	0	4					
		13JAN2003	35	4	0	4					
		14JAN2003	36	4	0	4					
		15JAN2003	37	4	0	4					
		16JAN2003	38	4	0	4					
		17JAN2003	39	4	0	4					
		18JAN2003	40	4	0	4					
		19JAN2003	41	4	0	4					
		20JAN2003	42	4	0	4					
		21JAN2003	43	4	0	4					
		22JAN2003	44	4	0	4					
		23JAN2003	45	4	0	4					
		24JAN2003	46	4	0	4					
		25JAN2003	47	4	0	4					
		26JAN2003	48	4	0	4					
		27JAN2003	49	4	0	4					
		28JAN2003	50	4	0	4					
		29JAN2003	51	4	0	4					
		30JAN2003	52	4	0	4					
		31JAN2003	53	4	0	4					
		01FEB2003	54	4	0	4					
		02FEB2003	55	4	0	4					
		03FEB2003	56	4	0	4					
		04FEB2003	57	4	0	4					
		05FEB2003	58	4	0	4	NO	0	55	97.7	
	E0022016	17DEC2002	1	2	0	2					
		18DEC2002	2	1	0	1					
		19DEC2002	3	1	0	1					
		20DEC2002	4	2	0	2					
		21DEC2002	5	3	0	3					
		22DEC2002	6	3	0	3					
		23DEC2002	7	3	0	3					
		24DEC2002	8		0	4					
		25DEC2002	9		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022016	26DEC2002	10	4	0	4					
		27DEC2002	11	4	0	4					
		28DEC2002	12	4	0	4					
		29DEC2002	13	4	0	4					
		30DEC2002	14	4	0	4					
		31DEC2002	15	4	0	4					
		01JAN2003	16	4	0	4					
		02JAN2003	17	4	0	4					
		03JAN2003	18	4	0	4					
		04JAN2003	19	4	0	4					
		05JAN2003	20	4	0	4					
		06JAN2003	21	4	0	4					
		07JAN2003	22	4	0	4					
		08JAN2003	23	4	0	4					
		09JAN2003	24	4	0	4					
		10JAN2003	25	4	0	4					
		11JAN2003	26	4	0	4					
		12JAN2003	27	4	4	0					PT FORGOT DOSE
		13JAN2003	28	4	0	4					
		14JAN2003	29	4	0	4					
		15JAN2003	30	4	0	4					
		16JAN2003	31	4	0	4					
		17JAN2003	32	4	0	4					
		18JAN2003	33	4	0	4					
		19JAN2003	34	4	0	4					
		20JAN2003	35		0	4					
		21JAN2003	36	4	0	4					
		22JAN2003	37	4	0	4					
		23JAN2003	38	4	0	4					
		24JAN2003	39	4	0	4					
		25JAN2003	40	4	0	4					
		26JAN2003	41	4	0	4					
		27JAN2003	42	4	0	4					
		28JAN2003	43		0	4					
		29JAN2003	44		0	4					
		30JAN2003	45	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022016	31JAN2003	46	4	0	4					
		01FEB2003	47	4	0	4					
		02FEB2003	48	4	0	4					
		03FEB2003	49	4	0	4					
		04FEB2003	50	4	0	4					
		05FEB2003	51	4	0	4					
		06FEB2003	52	4	0	4					
		07FEB2003	53	4	0	4					
		08FEB2003	54	4	0	4					
		09FEB2003	55	4	0	4					
		10FEB2003	56	4	0	4	NO	0	55	98.1	
	E0022020	12DEC2002	1	2	0	2					
		13DEC2002	2	1	0	1					
		14DEC2002	3	1	0	1					
		15DEC2002	4	2	0	2					
		16DEC2002	5	3	0	3					
		17DEC2002	6	3	0	3					
		18DEC2002	7	3	0	3					
		19DEC2002	8	4	0	4					
		20DEC2002	9	4	0	4					
		21DEC2002	10	4	0	4					
		22DEC2002	11	4	4	0					MISSED DOSE
		23DEC2002	12	4	0	4					
		24DEC2002	13	4	0	4					
		25DEC2002	14	4	0	4					
		26DEC2002	15	4	0	4					
		27DEC2002	16	4	0	4					
		28DEC2002	17	4	4	0					MISSED DOSE
		29DEC2002	18	4	0	4					
		30DEC2002	19	4	0	4					
		31DEC2002	20	4	0	4					
		01JAN2003	21	4	0	4					
		02JAN2003	22	4	0	4					
		03JAN2003	23	4	0	4					
		04JAN2003	24	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022020	05JAN2003	25	4	0	4					
		06JAN2003	26	4	0	4					
		07JAN2003	27	4	0	4					
		08JAN2003	28	4	0	4					
		09JAN2003	29		0	4					PT RESCHEDULED FOR 1 - 10 - 03 & TOOK THIS ON 1 - 9 - 03
		10JAN2003	30	4	0	4					
		11JAN2003	31	4	0	4					
		12JAN2003	32	4	0	4					
		13JAN2003	33	4	0	4					
		14JAN2003	34	4	0	4					
		15JAN2003	35	4	0	4					
		16JAN2003					NO	0	33	93.7	PT DID NOT TAKE ANY DOSE THIS PACK RETURNED FULL PACK.
	E0022023	25DEC2002	1	2	0	2					DAY 1 DATE SIC PAGE 199 MEDS STARTED DAY AFTER VISIT 2.
		26DEC2002	2	1	0	1					
		27DEC2002	3	1	0	1					
		28DEC2002	4	2	0	2					
		29DEC2002	5	3	0	3					
		30DEC2002	6	3	0	3					
		31DEC2002	7	3	0	3					
		01JAN2003	8		0	4					
		02JAN2003	9	4	0	4					
		03JAN2003	10	4	0	4					
		04JAN2003	11	4	0	4					
		05JAN2003	12	4	0	4					
		06JAN2003	13	4	0	4					
		07JAN2003	14	4	0	4					
		08JAN2003	15	4	0	4					
		09JAN2003	16	4	0	4					
		10JAN2003	17	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022023	11JAN2003	18	4	0	4					
		12JAN2003	19	4	0	4					
		13JAN2003	20	4	0	4					
		14JAN2003	21	4	0	4					
		15JAN2003	22	4	0	4					
		16JAN2003	23	4	0	4					
		17JAN2003	24	4	0	4					
		18JAN2003	25	4	0	4					
		19JAN2003	26	4	0	4					
		20JAN2003	27	4	0	4					
		21JAN2003	28	4	0	4					
		22JAN2003	29	4	0	4					
		23JAN2003	30	4	0	4					
		24JAN2003	31	4	0	4					
		25JAN2003	32	4	0	4					
		26JAN2003	33	4	0	4					
		27JAN2003	34	4	0	4					
		28JAN2003	35	4	0	4					
		29JAN2003	36	4	4	0					PT. TOOK ROW OF EXTRA PILLS ON THIS DAY.
		30JAN2003	37	4	0	4					
		31JAN2003	38	4	0	8					PT. TOOK EXTRA PILLS 1-29-03
		01FEB2003	39	4	0	4					
		02FEB2003	40	4	0	4					
		03FEB2003	41	4	0	4					
		04FEB2003	42	4	0	4					
		05FEB2003	43	4	0	4					PT. TOOK EXTRA PILLS ON THIS DAY
		06FEB2003	44	4	0	4					
		07FEB2003	45	4	0	4					PT. TOOK THESE PILLS ON 2-5-03
		08FEB2003	46	4	0	4					
		09FEB2003	47	4	0	4					
		10FEB2003	48	4	0	4					
		11FEB2003	49	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022023	12FEB2003	50	4	0	4					
		13FEB2003	51	4	0	4					
		14FEB2003	52	4	0	4					
		15FEB2003	53	4	0	4					
		16FEB2003	54	4	0	4					
		17FEB2003	55	4	0	4					
		18FEB2003	56	4	0	4					
		19FEB2003	57	4	0	4	NO	0	56	100	
	E0022029	19FEB2003	1	2	0	2					
		20FEB2003	2	1	0	1					
		21FEB2003	3	1	0	1					
		22FEB2003	4	2	0	2					
		23FEB2003	5	3	0	3					
		24FEB2003	6	3	0	3					
		25FEB2003	7	3	0	3					
		26FEB2003	8	4	0	4					
		27FEB2003	9	4	0	4					
		28FEB2003	10	4	0	4					
		01MAR2003	11	4	0	4					
		02MAR2003	12	4	0	4					
		03MAR2003	13	4	0	4					
		04MAR2003	14	4	0	4					
		05MAR2003	15	4	0	4					
		06MAR2003	16	4	0	4					
		07MAR2003	17	4	0	4					
		08MAR2003	18	4	0	4					
		09MAR2003	19	4	0	4					
		10MAR2003	20		0	4					
		11MAR2003	21		0	4					
		12MAR2003	22	4	0	4					
		13MAR2003	23	4	0	4					
		14MAR2003	24	4	0	4					
		15MAR2003	25	4	0	4					
		16MAR2003	26	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022029	17MAR2003	27	4	4	0					SIC PT. STATES DOG ATE PILLS - ROWS 6 THROUGH EXTRA ROWS PARTIAL PILLS REMAIN 1/2
		18MAR2003	28	4	0	4					SIC PT. STATES DOG ATE PILLS - ROWS 6 THROUGH EXTRA ROWS PARTIAL PILLS REMAIN 1TAB + 2-1/2 TABS
		18MAR2003	28	4	0	4					PT. MISSED 3/17/03 DOSE
		19MAR2003	29	4	0	4					PT. LAST DOSE ON THIS CARD 3-16-03. 2- 1/2 TABS
		20MAR2003	30	4	0	4					SIC 3 - 1/2 TABS
		21MAR2003	31	4	0	4					
		22MAR2003	32	4	0	4					
		23MAR2003	33	4	0	4					
		24MAR2003	34			0					
		25MAR2003	35		0	8					PT. TOOK EXTRA DAY TO RETURN TO WINDOW
		26MAR2003	36	4	0	4					
		27MAR2003	37	4	0	4					
		28MAR2003	38	4	0	4					
		29MAR2003	39	4	0	4					
		30MAR2003	40	4	0	4					
		31MAR2003	41	4	0	4					
		01APR2003	42	4	4	0					SIC 1 TAB & 2 PARTIAL TABS PT. MISSED DOSE 4-1-03, AS DOG DESTROYED PILLS, PARTIAL PILLS REMAIN.
		02APR2003	43	4	0	4					SIC 2 PARTIAL TABS REMAIN SIC PT. LAST DOSE ON THIS CARD 3-31-03
		02APR2003	43	4	0	4					PT. MISSED 4/1/03 DOSE
		03APR2003	44	4	0	4					1 TAB + 2 PARTIAL TABS REMAIN SIC
		04APR2003	45	4	0	4					
		05APR2003	46	4	0	4					
		06APR2003	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022029	07APR2003	48	4	0	4					PT. RETURNED FOR VISIT EARLY DUE TO SCHEDULE
		08APR2003	49	4	0	4					
		09APR2003	50	4	0	4					
		10APR2003	51	4	0	4					
		11APR2003	52	4	0	4					
		12APR2003	53	4	0	4					
		13APR2003	54	4	0	4	NO	0	51	96.1	
	E0022041	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					
		20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8	4	0	4					
		26MAR2003	9	4	0	4					
		27MAR2003	10	4	0	4					
		28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					
		02APR2003	16	4	0	4					
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	4					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	0	4					
		08APR2003	22	4	0	4					
		09APR2003	23	4	0	4					
		10APR2003	24	4	0	4					
		11APR2003	25	4	0	4					
		12APR2003	26	4	0	4					
		13APR2003	27	4	0	4					
		14APR2003	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022041	15APR2003	29	4	0	4					
		16APR2003	30	4	0	4					
		17APR2003	31	4	0	4					
		18APR2003	32	4	0	4					
		19APR2003	33	4	0	4					
		20APR2003	34	4	0	4					
		21APR2003	35	4	0	4					
		22APR2003	36	4	0	4					
		23APR2003	37	4	0	4					
		24APR2003	38	4	0	4					
		25APR2003	39	4	0	4					
		26APR2003	40	4	0	4					
		27APR2003	41	4	0	4					
		28APR2003	42		0	4					
		29APR2003	43	4	0	4					
		30APR2003	44	4	0	4					
		01MAY2003	45	4	0	4					
		02MAY2003	46	4	0	4					
		03MAY2003	47	4	4	0					PT. MISSED DOSE ON 5/3/03. TOOK 5/3/03 DOSE ON 5/4/03
		04MAY2003	48	4	0	4					THIS DOSE TAKEN 05/05/03
		05MAY2003	49	4	0	4					
		06MAY2003	50	4	0	4					SIC
		07MAY2003	51	4	0	4					
		08MAY2003	52	4	0	4					
		09MAY2003	53	4	0	4					
		10MAY2003	54	4	0	4					
		11MAY2003	55	4	0	4					
		12MAY2003									THIS DOSE TAKEN FROM EXTRA DAY LINE
		14MAY2003					NO	0	54	98.1	DOSE TAKEN ON 5/12/03
	E0022042	12MAR2003	1	2	0	2					
		13MAR2003	2	1	0	1					
		14MAR2003	3	1	0	1					
		15MAR2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022042	16MAR2003	5	3	0	3					
		17MAR2003	6	3	0	3					
		18MAR2003	7	3	0	3					
		19MAR2003	8	4	0	4					
		20MAR2003	9	4	0	4					
		21MAR2003	10	4	0	4					
		22MAR2003	11	4	0	4					
		23MAR2003	12	4	0	4					
		24MAR2003	13	4	0	4					
		25MAR2003	14	4	0	4					
		26MAR2003	15		4	0					PT MISSED DOSE ON 3-26-03 (FORGOT)
		27MAR2003	16	4	0	4					
		28MAR2003	17	4	0	4					
		29MAR2003	18	4	0	4					
		30MAR2003	19	4	0	4					
		31MAR2003	20	4	0	4					
		01APR2003	21	4	0	4					
		02APR2003	22	4	0	4					
		03APR2003	23	4	0	4					
		04APR2003	24	4	0	4					
		05APR2003	25	4	0	4					
		06APR2003	26	4	0	4					
		07APR2003	27	4	0	4					
		08APR2003	28	4	0	4					
		09APR2003	29		0	4					TOOK EXTRA DOSE DUE TO SCHEDULING
		10APR2003	30	4	0	4					
		11APR2003	31	4	0	4					
		12APR2003	32	4	0	4					
		13APR2003	33	4	0	4					
		14APR2003	34	4	0	4					
		15APR2003	35	4	0	4					
		16APR2003	36	4	4	0					PT. MISSED DOSE IN ERROR
		17APR2003	37	4	0	4					
		18APR2003	38	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022042	19APR2003	39	4	0	4					
		20APR2003	40	4	0	4					
		21APR2003	41	4	0	4					
		22APR2003	42	4	0	4					
		23APR2003	43	4	0	4					
		24APR2003	44	4	0	4					
		25APR2003	45	4	0	4					
		26APR2003	46	4	0	4					
		27APR2003	47	4	0	4					
		28APR2003	48	4	0	4					
		29APR2003	49	4	0	4					
		30APR2003	50	4	0	4					
		01MAY2003	51	4	0	4					
		02MAY2003	52	4	0	4					
		03MAY2003	53	4	0	4					
		04MAY2003	54	4	0	4					
		05MAY2003	55	4	0	4					
		06MAY2003	56	4	0	4					
		07MAY2003	57	4	0	4	NO	0	55	96.3	LAST DOSE 5-7 DID NOT RETURN FOR VISIT 10 UNTIL 5-12.
	E0022043	20MAR2003	1	2	0	2					
		21MAR2003	2	1	0	1					
		22MAR2003	3	1	0	1					
		23MAR2003	4	2	0	2					
		24MAR2003	5	3	0	3					
		25MAR2003	6	3	0	3					
		26MAR2003	7	3	0	3					
		27MAR2003	8	4	0	4					
		28MAR2003	9	4	0	4					
		29MAR2003	10	4	0	4					
		30MAR2003	11	4	0	4					
		31MAR2003	12	4	0	4					
		01APR2003	13	4	0	4					
		02APR2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022043	03APR2003	15	4	0	4					
		04APR2003	16	4	0	4					
		05APR2003	17	4	0	4					
		06APR2003	18	4	0	4					
		07APR2003	19	4	0	4					
		08APR2003	20	4	0	4					
		09APR2003	21	4	0	4					
		10APR2003	22	4	0	4					
		11APR2003	23	4	0	4					
		12APR2003	24	4	0	4					
		13APR2003	25	4	0	4					
		14APR2003	26	4	0	4					
		15APR2003	27	4	0	4					
		16APR2003	28	4	0	4					
		17APR2003	29	4	0	4					
		18APR2003	30	4	0	4					
		19APR2003	31	4	0	4					
		20APR2003	32	4	0	4					
		21APR2003	33	4	0	4					
		22APR2003	34	4	0	4					
		23APR2003	35	4	0	4					
		24APR2003	36	4	0	4					
		25APR2003	37	4	0	4					
		26APR2003	38	4	0	4					
		27APR2003	39	4	0	4					
		28APR2003	40	4	0	4					
		29APR2003	41	4	0	4					
		30APR2003	42	4	0	4					
		01MAY2003	43	4	0	4					
		02MAY2003	44	4	0	4					
		03MAY2003	45	4	0	4					
		04MAY2003	46	4	0	4					
		05MAY2003	47	4	0	4					
		06MAY2003	48	4	0	4					
		07MAY2003	49	4	0	4					
		08MAY2003	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022043	09MAY2003	51	4	0	4					
		10MAY2003	52	4	0	4					
		11MAY2003	53	4	0	4					
		12MAY2003	54	4	0	4	NO	0	54	100	FINAL DOSE 5 - 12, PATIENT RETURNED EARLY FOR VISIT 10
	E0022054	11APR2003	1	2	0	2					
		12APR2003	2	1	0	1					
		13APR2003	3	1	0	1					
		14APR2003	4	2	0	2					
		15APR2003	5	3	0	3					
		16APR2003	6	3	0	3					
		17APR2003	7	3	0	3					
		18APR2003	8	4	0	4					
		19APR2003	9	4	0	4					
		20APR2003	10	4	0	4					
		21APR2003	11	4	0	4					
		22APR2003	12	4	0	4					
		23APR2003	13	4	0	4					
		24APR2003	14	4	0	4					
		25APR2003	15		0	4					
		26APR2003	16		0	4					PATIENT MISSED 4/26/03 DOSE PT TOOK MISSED 4/26/03 DOSE ON 4/27/03.
		27APR2003	17			0					
		28APR2003	18	4	0	4					
		29APR2003	19	4	0	4					
		30APR2003	20	4	0	4					
		01MAY2003	21	4	0	4					
		02MAY2003	22	4	0	4					
		03MAY2003	23	4	0	4					
		04MAY2003	24	4	0	4					
		05MAY2003	25	4	0	4					
		06MAY2003	26	4	0	4					
		07MAY2003	27	4	0	4					PT TOOK DOSE OF 5/8/03
		08MAY2003	28	4	0	4					PT TOOK DOSE OF 5/9/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022054	09MAY2003	29	4	0	4					PT TOOK DOSE OF 5/10/03
		10MAY2003	30	4	0	4					PT TOOK DOSE OF 5/11/03
		11MAY2003	31		4	0					
		12MAY2003	32	4	1	3					SIC DOSE REDUCED THROUGH END OF STUDY
		13MAY2003	33	4	1	3					
		14MAY2003	34	4	1	3					
		15MAY2003	35	4	1	3					
		16MAY2003	36	4	0	4					MED NOT RETURNED - ACTUAL DOSEAGE FOR THIS PERIOD IS UNKNOWN
		17MAY2003	37	4	0	4					
		18MAY2003	38	4	0	4					
		19MAY2003	39	4	0	4					
		20MAY2003	40	4	0	4					
		21MAY2003	41	4	0	4					
		22MAY2003	42	4	0	4					
		23MAY2003	43		0	4					UNK
		24MAY2003	44		0	4	YES	0	42	95	
	E0022059	06MAY2003	1	2	0	2					
		07MAY2003	2	1	0	1					
		08MAY2003	3	1	0	1					
		09MAY2003	4	2	0	2					
		10MAY2003	5	3	0	3					
		11MAY2003	6	3	0	3					
		12MAY2003	7	3	0	3					
		13MAY2003	8	4	0	4					PT TOOK THIS DOSE ON 5-15-03
		14MAY2003	9	4	0	4					
		15MAY2003	10	4	0	4					PT TOOK THIS DOSE FROM BLISTER CARD 1 EXTRA DOSE
		16MAY2003	11	4	0	4					
		17MAY2003	12	4	0	4					
		18MAY2003	13	4	0	4					
		19MAY2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022059	20MAY2003	15	4	0	4					
		21MAY2003	16	4	0	4					
		22MAY2003	17	4	0	4					
		23MAY2003	18	4	0	4					
		24MAY2003	19	4	0	4					
		25MAY2003	20	4	0	4					
		26MAY2003	21	4	0	4					PT REDISPENSED THE DAY 7 & EXTRA DOSES FOR V9 - V10 EXTENSION
		27MAY2003	22	4	4	4					PT FORGOT DOSE
		28MAY2003	23	4	0	8					
		29MAY2003	24	4	0	4					
		30MAY2003	25	4	0	4					
		31MAY2003	26	4	0	4					
		01JUN2003	27	4	0	4					
		02JUN2003	28	4	0	4					
		03JUN2003	29	4	0	4					
		04JUN2003	30	4	0	4					
		05JUN2003	31	4	0	4					
		06JUN2003	32	4	0	4					
		07JUN2003	33	4	0	4					
		08JUN2003	34	4	0	4					
		09JUN2003	35	4	0	4					
		10JUN2003	36	4	0	4					
		11JUN2003	37	4	0	4					
		12JUN2003	38	4	0	4					
		13JUN2003	39	4	0	4					
		14JUN2003	40	4	0	4					
		15JUN2003	41	4	0	4					
		16JUN2003	42	4	0	4					
		17JUN2003	43	4	0	4					
		18JUN2003	44	4	0	4					
		19JUN2003	45	4	0	4					
		20JUN2003	46	4	0	4					
		21JUN2003	47	4	0	4					
		22JUN2003	48	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022059	23JUN2003	49	4	0	4					
		24JUN2003	50		0	4					PT USED EXTRA DOSES FOR EXTENDED VISIT V9 - V10
		25JUN2003	51		0	4					
		26JUN2003	52	4	0	4					
		27JUN2003	53	4	0	4					
		28JUN2003	54	4	0	4					
		29JUN2003	55	4	0	4					
		30JUN2003	56	4	0	4					
		01JUL2003	57	4	0	4					
		02JUL2003	58	4	0	4					
		03JUL2003	59		0	4					PT USED EXTRA DOSES FOR EXTENDED VISIT V9 - V10
		04JUL2003	60		0	4	NO	0	60	102	
	E0022065	07MAY2003	1	2	0	2					
		08MAY2003	2	1	0	1					
		09MAY2003	3	1	0	1					
		10MAY2003	4	2	0	2					
		11MAY2003	5	3	0	3					
		12MAY2003	6	3	0	3					
		13MAY2003	7	3	0	3					
		14MAY2003	8	4	0	4					
		15MAY2003	9	4	0	4					
		16MAY2003	10	4	0	4					
		17MAY2003	11	4	0	4					
		18MAY2003	12	4	0	4					
		19MAY2003	13	4	0	4					
		20MAY2003	14	4	0	4					
		21MAY2003	15	4	0	4					
		22MAY2003	16	4	0	4					
		23MAY2003	17	4	0	4					
		24MAY2003	18	4	0	4					
		25MAY2003	19	4	0	4					
		26MAY2003	20	4	0	4					
		27MAY2003	21	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022065	28MAY2003	22	4	0	4					
		29MAY2003	23	4	0	4					
		30MAY2003	24	4	0	4					
		31MAY2003	25	4	0	4					
		01JUN2003	26	4	0	4					
		02JUN2003	27	4	0	4					
		03JUN2003	28	4	0	4					
		04JUN2003	29	4	0	4					
		05JUN2003	30	4	0	4					
		06JUN2003	31	4	0	4					
		07JUN2003	32	4	0	4					
		08JUN2003	33	4	0	4					
		09JUN2003	34	4	0	4					
		10JUN2003	35	4	0	4					
		11JUN2003	36	4	0	4					
		12JUN2003	37	4	0	4					
		13JUN2003	38	4	0	4					
		14JUN2003	39	4	0	4					
		15JUN2003	40	4	0	4					
		16JUN2003	41	4	0	4					
		17JUN2003	42	4	0	4					
		18JUN2003	43	4	0	4					
		19JUN2003	44	4	0	4					
		20JUN2003	45	4	0	4					
		21JUN2003	46	4	0	4					
		22JUN2003	47	4	0	4					
		23JUN2003	48	4	0	4					
		24JUN2003	49	4	0	4					
		25JUN2003	50	4	0	4					
		26JUN2003	51	4	0	4					
		27JUN2003	52	4	0	4					
		28JUN2003	53	4	0	4					
		29JUN2003	54	4	0	4					
		30JUN2003	55	4	0	4					
		01JUL2003	56	4	0	4	NO	0	56	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0022070	12JUN2003	1	2	0	2					
		13JUN2003	2	1	0	1					
		14JUN2003	3	1	0	1					
		15JUN2003	4	2	1	1					PT DOSING ERROR
		16JUN2003	5	3	2	1					PT DOSING ERROR
		17JUN2003	6	3	2	1	NO	0	6	58.3	PT DOSING ERROR
	E0023001	15NOV2002	1	2	0	2					
		16NOV2002	2	1	0	1					
		17NOV2002	3	1	0	1					
		18NOV2002	4	2	0	2					
		19NOV2002	5	3	0	3					
		20NOV2002	6	3	0	3					
		21NOV2002	7	3	0	3					
		22NOV2002	8	4	0	4					
		23NOV2002	9	4	0	4					
		24NOV2002	10	4	0	4					
		25NOV2002	11	4	0	4					
		26NOV2002	12	4	0	4					
		27NOV2002	13	4	0	4					
		28NOV2002	14	4	0	4					
		29NOV2002	15	4	0	4					
		30NOV2002	16	4	0	4					
		01DEC2002	17	4	0	4					
		02DEC2002	18	4	0	4					
		03DEC2002	19	4	0	4					
		04DEC2002	20	4	0	4					
		05DEC2002	21	4	0	4					
		06DEC2002	22	4	0	4					
		07DEC2002	23	4	0	4					
		08DEC2002	24	4	0	4					
		09DEC2002	25	4	0	4					
		10DEC2002	26	4	0	4					
		11DEC2002	27	4	0	4					
		12DEC2002	28	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0023001	13DEC2002	29		0	4					PT CAME TO VISIT AT D.9 THIS TOOK 2 EXTRA DOSE = 100% COMPLIANCE
		14DEC2002	30		0	4					
		15DEC2002	31	4	0	4					
		16DEC2002	32	4	0	4					
		17DEC2002	33	4	0	4					
		18DEC2002	34	4	0	4					
		19DEC2002	35	4	0	4					
		20DEC2002	36	4	0	4					
		21DEC2002	37	4	0	4					
		22DEC2002	38		0	4					PT CAME TO V.7 AT DAY 9 THIS TOOK 2 EXTRA DAYS
		23DEC2002	39		0	4					
		24DEC2002	40	4	0	4					
		25DEC2002	41	4	0	4					
		26DEC2002	42	4	0	4					
		27DEC2002	43	4	0	4					
		28DEC2002	44	4	0	4					
		29DEC2002	45	4	0	4					
		30DEC2002	46	4	0	4					
		31DEC2002	47	4	0	4					
		01JAN2003	48	4	0	4					
		02JAN2003	49	4	0	4					
		03JAN2003	50	4	0	4					
		04JAN2003	51	4	0	4					
		05JAN2003	52	4	0	4					
		06JAN2003	53	4	0	4					
		07JAN2003	54		0	4					
		08JAN2003	55	4	0	4					
		09JAN2003	56	4	0	4					
		10JAN2003	57	4	0	4					
		11JAN2003	58	4	0	4					
		12JAN2003	59	4	0	4					
		13JAN2003	60	4	0	4					
		14JAN2003	61	4	0	4	NO	0	61	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0023009	11FEB2003	1	2	0	2					
		12FEB2003	2	1	0	1					
		13FEB2003	3	1	0	1					
		14FEB2003	4	2	0	2					
		15FEB2003	5	3	1	2					PT STATED SHE COULD NOT GET 1 PILL OUT OF BLISTER PACK
		16FEB2003	6	3	0	3					
		17FEB2003	7	3	0	3					
		18FEB2003	8	4	0	4					
		19FEB2003	9	4	0	4					
		20FEB2003	10	4	0	4					
		21FEB2003	11	4	0	4					
		22FEB2003	12	4	0	4					
		23FEB2003	13	4	0	4					
		24FEB2003	14	4	0	4					
		25FEB2003	15		0	4					TOOK EXTRA DAY
		26FEB2003	16		0	4					TOOK EXTRA DAY
		27FEB2003	17	4	0	4					
		28FEB2003	18	4	0	4					
		01MAR2003	19	4	0	4					
		02MAR2003	20	4	0	4					
		03MAR2003	21	4	0	4					
		04MAR2003	22	4	0	4					STARTED NEW PACK
		05MAR2003	23	4	0	4					
		06MAR2003	24	4	0	4					
		07MAR2003	25	4	0	4					
		08MAR2003	26	4	0	4					
		09MAR2003	27	4	0	4					
		10MAR2003	28	4	0	4					
		11MAR2003	29	4	0	4					
		12MAR2003	30	4	0	4					
		13MAR2003	31	4	0	4					
		14MAR2003	32	4	0	4					
		15MAR2003	33	4	0	4					
		16MAR2003	34	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0023009	17MAR2003	35	4	0	4					
		18MAR2003	36	4	0	4					
		19MAR2003	37	4	0	4					
		20MAR2003	38	4	0	4					
		21MAR2003	39	4	0	4					
		22MAR2003	40	4	0	4					
		23MAR2003	41	4	0	4					
		24MAR2003	42	4	0	4					
		25MAR2003	43	4	1	3					DOSE DECREASED THROUGH END OF STUDY
		26MAR2003	44	4	1	3					
		27MAR2003	45	4	1	3					
		28MAR2003	46	4	1	3					
		29MAR2003	47	4	1	3					
		30MAR2003	48	4	1	3					
		31MAR2003	49	4	1	3					
		01APR2003	50		4	0					FORGOT DOSE
		02APR2003	51		1	3					
		03APR2003	52	4	1	3					
		04APR2003	53	4	1	3					
		05APR2003	54	4	1	3					
		06APR2003	55	4	1	3					
		07APR2003	56	4	1	3					"SIC" LOST ONE PILL
		09APR2003					YES	0	55	97.5	TOOK 1 PILL FOR LOST PILL ON 4/7/03.
	E0023028	29MAY2003	1	2	0	2					
		30MAY2003	2	1	0	1					
		31MAY2003	3	1	0	1					
		01JUN2003	4	2	0	2					
		02JUN2003	5	3	0	3					
		03JUN2003	6	3	0	3					
		04JUN2003	7	3	0	3					
		05JUN2003	8	4	0	4					
		06JUN2003	9	4	0	4					
		07JUN2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0023028	08JUN2003	11	4	0	4					
		09JUN2003	12	4	0	4					
		10JUN2003	13	4	0	4					
		11JUN2003	14	4	0	4					
		12JUN2003	15	4	0	4					
		13JUN2003	16	4	0	4					
		14JUN2003	17	4	0	4					
		15JUN2003	18	4	0	4					
		16JUN2003	19	4	0	4					
		17JUN2003	20	4	0	4					
		18JUN2003	21	4	0	4					
		19JUN2003	22	4	0	4					
		20JUN2003	23	4	0	4					
		21JUN2003	24	4	0	4					
		22JUN2003	25	4	0	4					
		23JUN2003	26	4	0	4					
		24JUN2003	27	4	0	4					
		25JUN2003	28	4	0	4					
		26JUN2003	29	4	0	4					
		27JUN2003	30	4	0	4					
		28JUN2003	31	4	0	4					
		29JUN2003	32	4	0	4					
		30JUN2003	33	4	0	4					
		01JUL2003	34	4	0	4					
		02JUL2003	35	4	0	4					
		03JUL2003	36	4	0	4					
		04JUL2003	37	4	0	4					
		05JUL2003	38	4	0	4					
		06JUL2003	39	4	0	4					
		07JUL2003	40	4	0	4					
		08JUL2003	41	4	0	4					
		09JUL2003	42	4	0	4					
		10JUL2003	43	4	0	4					
		11JUL2003	44	4	0	4					
		12JUL2003	45	4	0	4					
		13JUL2003	46	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0023028	14JUL2003	47	4	0	4					
		15JUL2003	48	4	0	4					
		16JUL2003	49	4	0	4					
		17JUL2003	50	4	0	4					
		18JUL2003	51	4	0	4					
		19JUL2003	52	4	0	4					
		20JUL2003	53	4	0	4					
		21JUL2003					NO	0	53	100	COMPLETED STUDY
	E0023033	05JUN2003	1	2	0	2					
		06JUN2003	2	1	0	1					
		07JUN2003	3	1	0	1					
		08JUN2003	4	2	0	2					
		09JUN2003	5	3	0	3					
		10JUN2003	6	3	0	3					
		11JUN2003	7	3	0	3	NO	0	7	100	EARLY TERMINATION
	E0023047	18JUL2003	1	2	0	2					
		19JUL2003	2	1	0	1					
		20JUL2003	3	1	0	1					
		21JUL2003	4	2	0	2					
		22JUL2003	5	3	0	3					
		23JUL2003	6	3	0	3					
		24JUL2003	7	3	0	3					
		25JUL2003	8	4	0	4					
		26JUL2003	9	4	0	4					
		27JUL2003	10	4	0	4					
		28JUL2003	11	4	0	4					
		29JUL2003	12	4	0	4					
		30JUL2003	13	4	0	4					
		31JUL2003	14	4	0	4					
		01AUG2003	15	4	0	4					
		02AUG2003	16	4	0	4					
		03AUG2003	17	4	0	4					
		04AUG2003	18	4	0	4					
		05AUG2003	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0023047	06AUG2003	20	4	0	4					
		07AUG2003	21		0	4					
		08AUG2003	22	4	0	4					
		09AUG2003	23	4	0	4					
		10AUG2003	24	4	0	4					
		11AUG2003	25	4	0	4					
		12AUG2003	26	4	0	4					
		13AUG2003	27	4	0	4					
		14AUG2003	28	4	0	4					
		15AUG2003	29	4	0	4					
		16AUG2003	30	4	0	4					
		17AUG2003	31	4	0	4					
		18AUG2003	32	4	0	4					
		19AUG2003	33	4	0	4					
		20AUG2003	34	4	0	4					
		21AUG2003	35	4	0	4					
		22AUG2003	36	4	0	4					
		23AUG2003	37	4	0	4					
		24AUG2003	38	4	0	4					
		25AUG2003	39	4	0	4					
		26AUG2003	40	4	0	4					
		27AUG2003	41	4	0	4					
		28AUG2003	42		0	4					
		29AUG2003	43	4	0	4					
		30AUG2003	44	4	0	4					
		31AUG2003	45	4	0	4					
		01SEP2003	46	4	0	4					
		02SEP2003	47	4	0	4					
		03SEP2003	48	4	0	4					
		04SEP2003	49	4	0	4					
		05SEP2003	50	4	0	4					
		06SEP2003	51	4	0	4					
		07SEP2003	52	4	0	4					
		08SEP2003	53	4	0	4					
		09SEP2003	54	4	0	4					
		10SEP2003	55	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0023047	11SEP2003	56	4	0	4	NO	0	56	100	
	E0025001	01APR2003	1	2	0	2					
		02APR2003	2	1	0	1					
		03APR2003	3	1	0	1					
		04APR2003	4	2	0	2					
		05APR2003	5	3	0	3					
		06APR2003	6	3	0	3					
		07APR2003	7	3	0	3					
		08APR2003	8		0	4					
		09APR2003	9		0	4					
		10APR2003	10	4	0	4					
		11APR2003	11	4	0	4					
		12APR2003	12	4	0	4					
		13APR2003	13	4	0	4					
		14APR2003	14	4	0	4					
		15APR2003	15	4	0	4					
		16APR2003	16	4	0	4					
		17APR2003	17	4	0	4					
		18APR2003	18	4	0	4					
		19APR2003	19	4	0	4					
		20APR2003	20	4	0	4					
		21APR2003	21	4	0	4					
		22APR2003	22	4	0	4	NO	0	22	100	
	E0026012	20FEB2003	1	2	0	2					
		21FEB2003	2	1	0	1					
		22FEB2003	3	1	0	1					
		23FEB2003	4	2	0	2					
		24FEB2003	5	3	0	3					
		25FEB2003	6	3	0	3					
		26FEB2003	7	3	0	3					
		27FEB2003	8	4	0	4					
		28FEB2003	9	4	0	4					
		01MAR2003	10	4	0	4					
		02MAR2003	11	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0026012	03MAR2003	12	4	0	4					
		04MAR2003	13	4	0	4					
		05MAR2003	14	4	0	4					
		06MAR2003	15	4	0	4					
		07MAR2003	16	4	0	4					
		08MAR2003	17	4	0	4					
		09MAR2003	18	4	0	4					
		10MAR2003	19	4	0	4					
		11MAR2003	20	4	0	4					
		12MAR2003	21	4	0	4					
		13MAR2003	22	4	0	4					
		14MAR2003	23	4	0	4					
		15MAR2003	24	4	0	4					
		16MAR2003	25	4	0	4					
		17MAR2003	26	4	0	4					
		18MAR2003	27	4	0	4					
		19MAR2003	28	4	0	4					
		20MAR2003	29	4	0	4					
		21MAR2003	30	4	0	4					
		22MAR2003	31	4	0	4					
		23MAR2003	32	4	0	4					
		24MAR2003	33	4	0	4					
		25MAR2003	34	4	0	4					
		26MAR2003	35	4	0	4					
		27MAR2003	36	4	0	4					
		28MAR2003	37	4	0	4					
		29MAR2003	38	4	0	4					
		30MAR2003	39	4	0	4					
		31MAR2003	40	4	0	4					
		01APR2003	41	4	0	4					
		02APR2003	42	4	0	4					
		03APR2003	43	4	0	4					
		04APR2003	44	4	0	4					
		05APR2003	45	4	0	4					
		06APR2003	46	4	0	4					
		07APR2003	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0026012	08APR2003	48	4	0	4					
		09APR2003	49	4	0	4					
		10APR2003	50	4	0	4					
		11APR2003	51	4	0	4					
		12APR2003	52	4	0	4					
		13APR2003	53	4	0	4					
		14APR2003	54	4	0	4					
		15APR2003	55	4	0	4					
		16APR2003	56	4	0	4	NO	0	56	100	
	E0026020	01APR2003	1	2	0	2					
		02APR2003	2	1	0	1					
		03APR2003	3	1	0	1					
		04APR2003	4	2	0	2					
		05APR2003	5	3	0	3					
		06APR2003	6	3	0	3					
		07APR2003	7	3	0	3					
		08APR2003	8	4	0	4					
		09APR2003	9	4	0	4					
		10APR2003	10	4	0	4					
		11APR2003	11	4	0	4					
		12APR2003	12	4	0	4					
		13APR2003	13	4	0	4					
		14APR2003	14	4	0	4					
		15APR2003	15	4	0	4					
		16APR2003	16	4	0	4					
		17APR2003	17	4	0	4					
		18APR2003	18	4	0	4					
		19APR2003	19	4	0	4					
		20APR2003	20	4	0	4					
		21APR2003	21	4	0	4	NO	0	21	100	
	E0026024	02MAY2003	1	2	0	2					
		03MAY2003	2	1	0	1					
		04MAY2003	3	1	0	1					
		05MAY2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0026024	06MAY2003	5	3	0	3					
		07MAY2003	6	3	0	3					
		08MAY2003	7	3	0	3					
		09MAY2003	8	4	0	4					
		10MAY2003	9	4	0	4					
		11MAY2003	10	4	0	4					
		12MAY2003	11	4	0	4					
		13MAY2003	12	4	0	4					
		14MAY2003	13	4	0	4					
		15MAY2003	14	4	0	4					
		16MAY2003	15	4	0	4					
		17MAY2003	16	4	0	4					
		18MAY2003	17	4	0	4					
		19MAY2003	18	4	0	4					
		20MAY2003	19	4	0	4					
		21MAY2003	20	4	0	4					
		22MAY2003	21	4	0	4					
		23MAY2003	22	4	0	4					
		24MAY2003	23	4	0	4					
		25MAY2003	24	4	0	4					
		26MAY2003	25	4	0	4					
		27MAY2003	26	4	0	4					
		28MAY2003	27	4	0	4					
		29MAY2003	28	4	0	4					
		30MAY2003	29	4	0	4					PATIENT DID NOT RETURN BLISTER CARD
		31MAY2003	30		4	0					
		01JUN2003	31	4	0	4					
		02JUN2003	32	4	0	4					
		03JUN2003	33	4	0	4					
		07JUN2003					NO	0	32	96.6	UNKNOWN
	E0026028	20JUN2003	1	2	0	2					
		21JUN2003	2	1	0	1					
		22JUN2003	3	1	1	0					NO DOSE TAKEN
		23JUN2003	4	2	2	0					NO DOSE TAKEN

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0026028	24JUN2003	5	3	0	3					
		25JUN2003	6	3	0	3					
		26JUN2003	7	3	0	3					
		27JUN2003	8	4	0	4					TAKEN ON 6/25/03
		28JUN2003	9	4	0	4					TAKEN ON 6/26/03
		29JUN2003	10	4	0	4					
		30JUN2003	11	4	0	4					
		01JUL2003	12	4	0	4					
		02JUL2003	13	4	0	4					
		03JUL2003	14	4	0	4					
		04JUL2003	15	4	0	4					
		05JUL2003	16	4	0	4					
		06JUL2003	17	4	0	4					
		07JUL2003	18	4	0	4					
		08JUL2003	19	4	0	4					
		09JUL2003	20	4	0	4					
		10JUL2003	21	4	0	4					
		11JUL2003	22	4	0	4					
		12JUL2003	23	4	0	4					
		13JUL2003	24	4	0	4					
		14JUL2003	25	4	0	4	NO	0	23	96.6	
	E0028001	10OCT2002	1	2	0	2					
		11OCT2002	2	1	0	1					
		12OCT2002	3	1	0	1					
		13OCT2002	4	2	0	2					
		14OCT2002	5	3	0	3					
		15OCT2002	6	3	0	3					
		16OCT2002	7	4	0	4					
		17OCT2002	8	4	0	4					
		18OCT2002	9	4	0	4					
		19OCT2002	10	4	0	4					
		20OCT2002	11	4	0	4					
		21OCT2002	12	4	0	4					
		22OCT2002	13	4	0	4					
		23OCT2002	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028001	24OCT2002	15	4	0	4					
		25OCT2002	16	4	0	4					
		26OCT2002	17	4	0	4					
		27OCT2002	18	4	0	4					
		28OCT2002	19	4	0	4					
		29OCT2002	20	4	0	4					
		30OCT2002	21	4	0	4					
		31OCT2002	22	4	0	4					
		01NOV2002	23	4	0	4					
		02NOV2002	24	4	0	4					
		03NOV2002	25	4	0	4					
		04NOV2002	26	4	0	4					
		05NOV2002	27	4	0	4					
		06NOV2002	28	4	0	4					
		07NOV2002	29	4	0	4					
		08NOV2002	30	4	0	4					
		09NOV2002	31	4	0	4					
		10NOV2002	32	4	0	4					
		11NOV2002	33	4	0	4					
		12NOV2002	34	4	0	4					
		13NOV2002	35	4	0	4					
		14NOV2002	36	4	0	4					
		15NOV2002	37	4	0	4					
		16NOV2002	38	4	0	4					
		17NOV2002	39	4	0	4					
		18NOV2002	40	4	0	4					
		19NOV2002	41	4	0	4					
		20NOV2002	42	4	0	4					
		21NOV2002	43	4	0	4					
		22NOV2002	44	4	0	4					
		23NOV2002	45	4	0	4					
		24NOV2002	46	4	0	4					
		25NOV2002	47	4	0	4					
		26NOV2002	48	4	0	4					
		27NOV2002	49	4	0	4					
		28NOV2002	50	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028001	29NOV2002	51	4	0	4					
		30NOV2002	52	4	0	4					
		01DEC2002	53	4	0	4					
		02DEC2002	54	4	0	4	NO	0	54	100	
	E0028003	30SEP2002	1	2	0	2					
		01OCT2002	2	1	0	1					
		02OCT2002	3	1	0	1					
		03OCT2002	4	2	0	2					
		04OCT2002	5	3	0	3					
		05OCT2002	6	3	0	3					
		06OCT2002	7	3	0	3					
		07OCT2002	8	4	0	4					
		08OCT2002	9	4	0	4					
		09OCT2002	10	4	0	4					
		10OCT2002	11	4	0	4					
		11OCT2002	12	4	0	4					
		12OCT2002	13	4	0	4					
		13OCT2002	14	4	0	4					
		14OCT2002	15		0	4					
		15OCT2002	16		0	4					
		16OCT2002	17	4	0	4					
		17OCT2002	18	4	0	4					
		18OCT2002	19	4	0	4					
		19OCT2002	20	4	0	4					
		20OCT2002	21	4	0	4					
		21OCT2002	22	4	0	4					
		22OCT2002	23	4	0	4					
		23OCT2002	24	4	0	4					
		24OCT2002	25	4	0	4					
		25OCT2002	26	4	0	4					
		26OCT2002	27	4	0	4					
		27OCT2002	28	4	0	4					
		28OCT2002	29	4	0	4					
		29OCT2002	30	4	0	4					
		30OCT2002	31	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028003	31OCT2002	32	4	0	4					
		01NOV2002	33	4	0	4					
		02NOV2002	34	4	0	4					
		03NOV2002	35	4	0	4					
		04NOV2002	36	4	0	4					
		05NOV2002	37		0	4					
		06NOV2002	38		0	4					
		07NOV2002	39	4	0	4					
		08NOV2002	40	4	0	4					
		09NOV2002	41	4	0	4					
		10NOV2002	42	4	0	4					
		11NOV2002	43	4	0	4					
		12NOV2002	44	4	0	4					
		13NOV2002	45	4	0	4					
		14NOV2002	46	4	0	4					
		15NOV2002	47	4	0	4					
		16NOV2002	48	4	0	4					
		17NOV2002	49	4	0	4					
		18NOV2002	50	4	0	4					
		19NOV2002	51	4	0	4					
		20NOV2002	52	4	0	4					
		21NOV2002	53	4	0	4					
		22NOV2002	54	4	0	4					
		23NOV2002	55	4	0	4					
		24NOV2002	56	4	0	4					
		25NOV2002	57	4	0	4	NO	0	57	100	
	E0028005	03OCT2002	1	2	0	2					
		04OCT2002	2	1	0	1					
		05OCT2002	3	1	0	1					
		06OCT2002	4	2	0	2					
		07OCT2002	5	3	0	3					
		08OCT2002	6	3	0	3					
		09OCT2002	7	3	0	3					
		10OCT2002	8		4	0					PT. FORGOT TO TAKE DOSE
		11OCT2002	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028005	12OCT2002	10	4	0	4	NO	0	9	85.2	LAST DOSE TAKEN ON 10/12
	E0028010	05NOV2002	1	2	0	2					
		06NOV2002	2	1	0	1					
		07NOV2002	3	1	0	1					
		08NOV2002	4	2	0	2					
		09NOV2002	5	3	3	0					11/09 DOSE NOT TAKEN, ACCIDENTALLY DISCARDED
		10NOV2002	6	3	0	3					
		11NOV2002	7	3	0	3					
		12NOV2002	8	4	0	4					
		13NOV2002	9	4	0	4					
		14NOV2002	10	4	1	3					11/14 1 TAB ACCIDENTALLY NOT TAKEN
		15NOV2002	11	4	0	4					
		16NOV2002	12	4	1	3					11/16 1 TAB NOT TAKEN, DOSE REDUCED
		17NOV2002	13	4	4	0					11/17 DOSE NOT TAKEN
		18NOV2002	14	4	4	0					11/18 DOSE NOT TAKEN
		19NOV2002	15	4	1	3					DOSE REDUCED TO 3 TABS QHS
		20NOV2002	16	4	1	3					
		21NOV2002	17	4	1	3					
		22NOV2002	18	4	1	3					
		23NOV2002	19	4	1	3					
		24NOV2002	20	4	1	3					
		25NOV2002	21	4	1	3					
		26NOV2002	22	4	1	3					
		27NOV2002	23	4	1	3					
		28NOV2002	24	4	1	3					
		29NOV2002	25	4	1	3					
		30NOV2002	26	4	1	3					
		01DEC2002	27	4	1	3					
		02DEC2002	28		4	0					12/02 DOSE ACCIDENTALLY NOT TAKEN
		03DEC2002	29	4	1	3					
		04DEC2002	30	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028010	05DEC2002	31	4	1	3					
		06DEC2002	32	4	1	3					
		07DEC2002	33	4	1	3					
		08DEC2002	34	4	1	3					
		09DEC2002	35	4	1	3					
		10DEC2002	36	4	1	3					
		11DEC2002	37	4	1	3					
		12DEC2002	38	4	1	3					
		13DEC2002	39	4	1	3					
		14DEC2002	40	4	1	3					
		15DEC2002	41	4	1	3					
		16DEC2002	42	4	1	3					
		17DEC2002	43	4	1	3					
		18DEC2002	44	4	1	3					
		19DEC2002	45	4	1	3					
		20DEC2002	46	4	1	3					
		21DEC2002	47	4	1	3					
		22DEC2002	48	4	1	3					
		23DEC2002	49	4	1	3					
		24DEC2002	50	4	1	3					
		25DEC2002	51	4	1	3					
		26DEC2002	52	4	1	3					
		27DEC2002	53	4	1	3					
		28DEC2002	54	4	1	3					
		29DEC2002	55	4	1	3					
		30DEC2002	56		1	3	YES	0	52	91.1	
	E0028011	05DEC2002	1	2	0	2					BLISTER CARD LOST. PT. REPORTS TAKING ALL STUDY MED AS INDICATED UNTIL 12/10/02.
		06DEC2002	2	1	0	1					
		07DEC2002	3	1	0	1					
		08DEC2002	4	2	0	2					
		09DEC2002	5	3	0	3					
		10DEC2002	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028011	11DEC2002	7	3	3	0					MISSED DOSE
		12DEC2002	8	4	0	4					NO DOSE TAKEN
		13DEC2002	9	4	0	4					NO DOSE TAKEN
		14DEC2002	10	4	0	4					
		15DEC2002	11	4	0	4					
		16DEC2002	12	4	0	4					
		17DEC2002	13	4	0	4					
		18DEC2002	14	4	0	4					
		19DEC2002	15	4	0	4					
		20DEC2002	16	4	0	4					
		21DEC2002	17	4	0	4					
		22DEC2002	18	4	0	4					
		23DEC2002	19	4	0	4					
		24DEC2002	20	4	0	4					
		25DEC2002	21	4	0	4					
		26DEC2002	22	4	0	4					PT. LOST BLISTER CARD. HE REPORTS TAKING STUDY MED EVERY DAY THROUGH 01/01/03.
		27DEC2002	23	4	0	4					
		28DEC2002	24	4	0	4					
		29DEC2002	25	4	0	4					
		30DEC2002	26	4	0	4					
		31DEC2002	27	4	0	4					
		01JAN2003	28	4	0	4					
		02JAN2003	29	4	0	4					NO DOSE TAKEN
		03JAN2003	30	4	0	4					NO DOSE TAKEN
		04JAN2003	31	4	0	4					
		05JAN2003	32	4	0	4					
		06JAN2003	33	4	0	4					
		07JAN2003	34	4	0	4					
		08JAN2003	35	4	0	4					
		09JAN2003	36	4	0	4					ON 1 UNKNOWN DAY PT. DROPPED 1 PILL, THEN THREW AWAY ALL 4 PILLS FOR THAT DAY & TOOK 4 EXTRA PILLS.
		10JAN2003	37	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028011	11JAN2003	38	4	0	4					
		12JAN2003	39	4	0	4					
		13JAN2003	40	4	0	4					
		14JAN2003	41	4	0	4					
		15JAN2003	42	4	0	4					
		16JAN2003	43	4	0	4					NO DOSE TAKEN
		17JAN2003	44	4	0	4					
		18JAN2003	45	4	0	4					
		19JAN2003	46	4	0	4					
		20JAN2003	47	4	0	4					
		21JAN2003	48	4	0	4					
		22JAN2003	49	4	0	4					
		23JAN2003	50	4	0	4					
		24JAN2003	51	4	0	4					
		25JAN2003	52	4	0	4					
		26JAN2003	53	4	0	4					
		27JAN2003	54	4	0	4					
		28JAN2003	55	4	0	4					
		29JAN2003	56	4	0	4					
		31JAN2003					NO	0	55	98.6	1 PILL DROPPED AND REPLACED WITH 1 EXTRA
	E0028030	04MAR2003	1	2	0	2					DOSE TAKEN 3/5/03
		05MAR2003	2	1	0	1					DOSE TAKEN 3/6/03
		06MAR2003	3	1	0	1					DOSE TAKEN 3/7/03
		07MAR2003	4	2	0	2					DOSE TAKEN 3/8/03
		08MAR2003	5	3	0	3					DOSE TAKEN 3/9/03
		09MAR2003	6	3	0	3					DOSE TAKEN 3/10/03
		10MAR2003	7	3	0	3					BLISTER CARD REDISPENSED ON 3/11/03 SO PATIENT WOULD TAKE FULL 7 DAYS OF DOSES.
		11MAR2003	8		4	0					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028030	12MAR2003	9	4	0	4					DATE SIC 3-11-03 DOSE TAKEN FROM BLISTER CARD # 1 IN ORDER TO ACHIEVE FULL TITRATION
		13MAR2003	10	4	0	4					
		14MAR2003	11	4	0	4					
		15MAR2003	12	4	0	4					
		16MAR2003	13	4	0	4					
		17MAR2003	14	4	0	4					
		18MAR2003	15	4	0	4					
		19MAR2003	16	4	0	4					
		20MAR2003	17	4	0	4					
		21MAR2003	18	4	0	4					
		22MAR2003	19	4	0	4					
		23MAR2003	20	4	0	4					
		24MAR2003	21	4	0	4					
		25MAR2003	22	4	0	4					
		26MAR2003	23	4	0	4					
		27MAR2003	24	4	0	4					
		28MAR2003	25	4	0	4					
		29MAR2003	26	4	0	4					
		30MAR2003	27	4	0	4					
		31MAR2003	28	4	0	4					
		01APR2003	29	4	0	4					
		02APR2003	30	4	0	4					
		03APR2003	31	4	0	4					
		04APR2003	32	4	0	4					
		05APR2003	33	4	0	4					
		06APR2003	34	4	0	4					
		07APR2003	35	4	0	4					
		08APR2003	36	4	0	4					
		09APR2003	37	4	0	4					
		10APR2003	38	4	0	4					
		11APR2003	39	4	0	4					
		12APR2003	40	4	0	4					
		13APR2003	41	4	0	4					
		14APR2003	42	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028030	15APR2003	43		0	4					
		16APR2003	44		0	4					
		17APR2003	45	4	0	4					
		18APR2003	46	4	0	4					
		19APR2003	47	4	0	4					
		20APR2003	48	4	0	4					
		21APR2003	49	4	0	4					
		22APR2003	50	4	0	4					
		23APR2003	51	4	0	4					
		24APR2003	52	4	0	4					
		25APR2003	53	4	0	4					
		26APR2003	54	4	0	4					
		27APR2003	55	4	0	4					
		28APR2003	56	4	0	4					
		29APR2003	57		0	4	NO	0	56	98.1	
	E0028031	11MAR2003	1	2	0	2					
		12MAR2003	2	1	0	1					
		13MAR2003	3	1	0	1					
		14MAR2003	4	2	0	2					
		15MAR2003	5	3	0	3					
		16MAR2003	6	3	0	3					
		17MAR2003	7	3	0	3					
		18MAR2003	8	4	0	4					
		19MAR2003	9	4	0	4					
		20MAR2003	10	4	0	4					
		21MAR2003	11	4	0	4					
		22MAR2003	12	4	0	4					
		23MAR2003	13	4	0	4					
		24MAR2003	14	4	0	4					
		25MAR2003	15	4	0	4					LAST DOSE OF STUDY MEDICATION WAS 3/26/03. PT. LOST BLISTER CARD.
		26MAR2003	16	4	0	4					
		27MAR2003	17	4	0	4					
		28MAR2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028031	29MAR2003	19	4	0	4					
		30MAR2003	20	4	0	4					
		31MAR2003	21	4	0	4					
		01APR2003	22		0	4					UNKNOWN
		02APR2003	23		0	4	NO	0	23	100	
	E0028047	14JUL2003	1	2	0	2					
		15JUL2003	2	1	0	1					
		16JUL2003	3	1	0	1					
		17JUL2003	4	2	0	2					
		18JUL2003	5	3	0	3					
		19JUL2003	6	3	0	3					
		20JUL2003	7	3	0	3					
		21JUL2003	8	4	0	4					
		22JUL2003	9	4	0	4					
		23JUL2003	10	4	0	4					
		24JUL2003	11	4	0	4					
		25JUL2003	12	4	0	4					
		26JUL2003	13	4	0	4					
		27JUL2003	14	4	0	4					
		28JUL2003	15		0	4					
		29JUL2003	16	4	0	4					
		30JUL2003	17	4	0	4					
		31JUL2003	18	4	0	4					
		01AUG2003	19	4	0	4					
		02AUG2003	20	4	0	4					
		03AUG2003	21	4	0	4					
		04AUG2003	22	4	0	4					
		05AUG2003	23	4	0	4					
		06AUG2003	24	4	0	4					
		07AUG2003	25	4	0	4					
		08AUG2003	26	4	0	4					
		09AUG2003	27	4	0	4					
		10AUG2003	28	4	0	4					
		11AUG2003	29	4	0	4					
		12AUG2003	30	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0028047	13AUG2003	31	4	0	4					
		14AUG2003	32	4	0	4					
		15AUG2003	33	4	0	4					
		16AUG2003	34	4	0	4					
		17AUG2003	35	4	0	4					
		18AUG2003	36	4	0	4					
		19AUG2003	37	4	0	4					
		20AUG2003	38	4	0	4					
		21AUG2003	39	4	0	4					
		22AUG2003	40	4	0	4					
		23AUG2003	41	4	0	4					
		24AUG2003	42	4	0	4					
		25AUG2003	43	4	0	4					
		26AUG2003	44	4	0	4					
		27AUG2003	45	4	0	4					
		28AUG2003	46	4	0	4					
		29AUG2003	47	4	0	4					
		30AUG2003	48	4	0	4					
		31AUG2003	49	4	0	4					
		01SEP2003	50	4	0	4					
		02SEP2003	51	4	0	4					
		03SEP2003	52	4	0	4					
		04SEP2003	53	4	0	4					
		05SEP2003	54	4	0	4					
		06SEP2003	55	4	0	4					
		07SEP2003	56	4	0	4					
		08SEP2003	57	4	0	4	NO	0	57	100	
	E0029001	01OCT2002	1	2	0	2					
		02OCT2002	2	1	0	1					
		03OCT2002	3	1	0	1					
		04OCT2002	4	2	0	2					
		05OCT2002	5	3	0	3					
		06OCT2002	6	3	0	3					
		07OCT2002	7	3	0	3					
		08OCT2002	8		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0029001	09OCT2002	9	4	0	4					UNABLE TO ASSESS. PATIENT DID NOT RETURN STUDY DRUG.
		10OCT2002	10	4	0	4					
		11OCT2002	11	4	0	4					
		12OCT2002	12	4	0	4					
		13OCT2002	13	4	0	4					
		14OCT2002	14	4	0	4					
		15OCT2002	15	4	0	4					
		16OCT2002	16		0	4					
		17OCT2002	17		0	4	NO	0	17	100	
	E0029014	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					
		11FEB2003	8	4	0	4					
		12FEB2003	9	4	0	4					
		13FEB2003	10	4	0	4					
		14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	0	4					
		18FEB2003	15	4	0	4					
		19FEB2003	16	4	0	4					
		20FEB2003	17	4	0	4					
		21FEB2003	18	4	0	4					
		22FEB2003	19	4	0	4					
		23FEB2003	20	4	0	4					
		24FEB2003	21	4	0	4					
		25FEB2003	22	4	0	4					DAYS 29 -35 DRUG WALLET WAS INADVERTENTLY DISPENSED ON VISIT 5, WEKK 4 VISIT DATE
		26FEB2003	23	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0029014	27FEB2003	24	4	0	4					
		28FEB2003	25	4	0	4					
		01MAR2003	26	4	0	4					
		02MAR2003	27	4	0	4					
		03MAR2003	28	4	0	4					
		04MAR2003	29		0	4					
		05MAR2003	30		0	4					
		06MAR2003	31	4	0	4					VISIT 5, WEEK 4 STUDY MEDICATION DISPENSED AT VISIT 6, WEEK 5 DUE TO EARLIER DISPENSING ERROR
		07MAR2003	32	4	0	4					
		08MAR2003	33	4	0	4					
		09MAR2003	34	4	0	4					
		10MAR2003	35	4	0	4					
		11MAR2003	36	4	0	4					
		12MAR2003	37	4	0	4					
		13MAR2003	38	4	0	4					
		14MAR2003	39	4	0	4					
		15MAR2003	40	4	0	4					
		16MAR2003	41	4	0	4					
		17MAR2003	42	4	0	4					
		18MAR2003	43		0	4					
		19MAR2003	44		0	4					
		20MAR2003	45	4	0	4					
		21MAR2003	46	4	0	4					
		22MAR2003	47	4	0	4					
		23MAR2003	48	4	0	4					
		24MAR2003	49	4	0	4					
		25MAR2003	50	4	0	4					
		26MAR2003	51	4	0	4					
		27MAR2003	52	4	0	4					
		28MAR2003	53	4	0	4					
		29MAR2003	54	4	0	4					
		30MAR2003	55	4	0	4					
		31MAR2003	56	4	0	4	NO	0	56	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0029023	08APR2003	1	2	0	2					
		09APR2003	2	1	0	1					
		10APR2003	3	1	0	1					
		11APR2003	4	2	0	2					
		12APR2003	5	3	0	3					
		13APR2003	6	3	0	3					
		14APR2003	7	3	0	3					
		15APR2003	8	4	0	8					PT. TOOK ALL THESE DOSES BUT COULD NOT SPECIFY WHEN- SHE DID NOT RETURN THE PACKAGE UNTIL 4/22/03 SO THE 8 TABS WERE TAKEN OVER THE COURSE OF 2 WEEKS (1-2 EACH DAY TO HELP HER SLEEP)
		16APR2003	9	4	0	8					
		17APR2003	10	4	0	4					
		18APR2003	11	4	0	4					
		19APR2003	12	4	0	4					
		20APR2003	13	4	0	4					
		21APR2003	14	4	0	4					
		22APR2003	15	4	0	4					
		23APR2003	16	4	0	4					
		24APR2003	17	4	0	4					
		25APR2003	18	4	0	4					
		26APR2003	19	4	0	4					
		27APR2003	20	4	0	4					
		28APR2003	21	4	0	4					
		29APR2003	22		0	4					
		30APR2003	23		0	4					
		01MAY2003	24	4	0	4					
		02MAY2003	25	4	0	4					
		03MAY2003	26	4	0	4					
		04MAY2003	27	4	0	4					
		05MAY2003	28	4	0	4					
		06MAY2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0029023	07MAY2003	30	4	0	4					
		08MAY2003	31		0	4					
		09MAY2003	32		0	4					
		10MAY2003	33			0					
		11MAY2003	34			0					
		12MAY2003	35	4	0	4					SUBJECT MISSED DOSES ON 5/10, 5/11, 5/15/03
		13MAY2003	36	4	0	4					
		14MAY2003	37	4	0	4					
		15MAY2003	38	4	4	0					TOOK ON 5/16
		16MAY2003	39	4	0	4					TOOK ON 5/17
		17MAY2003	40	4	0	4					TOOK ON 5/18
		18MAY2003	41	4	0	4					TOOK ON 5/19
		19MAY2003	42		0	4					
		20MAY2003	43	4	0	4					
		21MAY2003	44	4	0	4					
		22MAY2003	45	4	0	4					
		23MAY2003	46	4	0	4					
		24MAY2003	47	4	0	4					
		25MAY2003	48	4	0	4					
		26MAY2003	49	4	0	4					
		27MAY2003	50		0	4					
		28MAY2003	51		0	4					
		29MAY2003	52	4	0	4					
		30MAY2003	53	4	0	4					
		31MAY2003	54	4	0	4					
		01JUN2003	55	4	0	4					
		02JUN2003	56	4	0	4					
		03JUN2003	57	4	0	4					
		04JUN2003	58	4	0	4					
		05JUN2003	59		0	4					
		06JUN2003	60		0	4	NO	0	57	98.2	
	E0029032	10JUN2003	1	2	0	2					
		11JUN2003	2	1	0	1					
		12JUN2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0029032	13JUN2003	4	2	0	2					
		14JUN2003	5	3	0	3					
		15JUN2003	6	3	0	3					
		16JUN2003	7	3	0	3					
		17JUN2003	8	4	0	4					
		18JUN2003	9	4	0	4					
		19JUN2003	10	4	0	4	NO	0	10	100	LAST DOSE PT TOOK
	E0029033	02JUN2003	1	2	0	2					
		03JUN2003	2	1	0	1					
		04JUN2003	3	1	0	1					
		05JUN2003	4	2	0	2					
		06JUN2003	5	3	0	3					
		07JUN2003	6	3	0	3					
		08JUN2003	7	3	0	3					
		09JUN2003	8	4	0	4					
		10JUN2003	9	4	0	4					
		11JUN2003	10	4	0	4					
		12JUN2003	11	4	0	4					
		13JUN2003	12	4	0	4					
		14JUN2003	13	4	0	4					
		15JUN2003	14	4	0	4					
		16JUN2003	15	4	0	4					
		17JUN2003	16	4	0	4					
		18JUN2003	17	4	0	4					
		19JUN2003	18	4	0	4					
		20JUN2003	19	4	0	4					
		21JUN2003	20	4	0	4					
		22JUN2003	21	4	0	4					
		23JUN2003	22	4	0	4					
		24JUN2003	23	4	0	4					
		25JUN2003	24	4	0	4					
		26JUN2003	25	4	0	4					
		27JUN2003	26	4	0	4					
		28JUN2003	27	4	0	4					
		29JUN2003	28	4	0	4	NO	0	28	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0029039	15JUL2003	1	2	0	2					
		16JUL2003	2	1	0	1					
		17JUL2003	3	1	0	1					
		18JUL2003	4	2	0	2					
		19JUL2003	5	3	0	3					
		20JUL2003	6	3	0	3					
		21JUL2003	7	3	0	3					
		22JUL2003	8		0	4					
		23JUL2003	9	4	0	4					
		24JUL2003	10	4	0	4					
		25JUL2003	11	4	0	4					
		26JUL2003	12	4	0	4					
		27JUL2003	13	4	0	4	NO	0	13	100	LAST DOSE TAKEN
	E0030003	16DEC2002	1	2	0	2					PT DISCARDED BLISTER PACK, PT REPORTS BEING 100% COMPLIANT.
		17DEC2002	2	1	0	1					
		18DEC2002	3	1	0	1					
		19DEC2002	4	2	0	2					
		20DEC2002	5	3	0	3					
		21DEC2002	6	3	0	3					
		22DEC2002	7	3	0	3					
		23DEC2002									NO DOSE TAKEN
		23DEC2002									MISSED DOSE
		24DEC2002					NO	0	7	100	NO DOSE TAKEN
	E0030009	23JAN2003	1	2	0	2					
		24JAN2003	2	1	0	1					
		25JAN2003	3	1	0	1					
		26JAN2003	4	2	0	2					
		27JAN2003	5	3	0	3					
		28JAN2003	6	3	0	3					
		29JAN2003	7	3	0	3					11 PILLS FROM BLISTER CARD 1 REDISPENSED AT V3
		30JAN2003	8	4	0	8					DOSE TAKEN 2/16/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0030009	30JAN2003	8	4	0	8					BLISTER CARD 1 WAS REDISPENSED TO ACHIEVE FULL TITRATION SUBJECT TOOK DOSE FROM BLISTER CARD 1 ON 1/29/03
		31JAN2003	9	4	0	8					DOSE TAKEN 2/17/03
		01FEB2003	10	4	0	4					
		02FEB2003	11	4	0	4					
		03FEB2003	12	4	0	4					
		04FEB2003	13	4	0	4					
		05FEB2003	14	4	0	4					
		06FEB2003	15		0	4					
		07FEB2003	16	4	0	4					SIC 2/18/03 - 2/20/03 MISSED DOSES 2/16/03 AND 2/17/03 DOSES WERE TAKEN FROM BLISTER CARD 1
		08FEB2003	17	4	0	4					
		09FEB2003	18	4	0	4					
		10FEB2003	19	4	0	4					
		11FEB2003	20	4	0	4					
		12FEB2003	21	4	0	4					
		13FEB2003	22	4	0	4					
		14FEB2003	23		0	4					
		15FEB2003	24		0	4					
		16FEB2003	25			0					
		17FEB2003	26			0					
		18FEB2003	27			0					
		19FEB2003	28			0					
		20FEB2003	29			0					
		21FEB2003	30	4	0	4					SIC - V5 BLISTER CARD DISPENSED IN ERROR. V5 WAS NOT DONE DUE TO VISIT WINDOW FAILURE. V6 BLISTERCARD SHOULD HAVE BEEN DISPENSED ON 2/21/03.
		22FEB2003	31	4	0	4					
		23FEB2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0030009	24FEB2003	33	4	0	4					
		25FEB2003	34	4	0	4					
		26FEB2003	35	4	0	4					
		27FEB2003	36	4	0	4					
		28FEB2003	37	4	0	4					
		01MAR2003	38	4	0	4					
		02MAR2003	39	4	0	4					
		03MAR2003	40	4	0	4					
		04MAR2003	41	4	0	4					
		05MAR2003	42	4	0	4					
		06MAR2003	43	4	0	4					
		07MAR2003	44	4	0	4					
		08MAR2003	45	4	0	4					
		09MAR2003	46	4	0	4					
		10MAR2003	47	4	4	0					MISSED DOSE
		11MAR2003	48	4	0	4					
		12MAR2003	49	4	0	4					
		13MAR2003	50	4	4	0					MISSED DOSE
		14MAR2003	51	4	0	4					
		15MAR2003	52	4	0	4					
		16MAR2003	53	4	0	4					
		17MAR2003	54	4	0	4					
		18MAR2003	55	4	0	4	NO	0	48	90.3	
	E0030016	03MAR2003	1	2	0	2					
		04MAR2003	2	1	0	1					
		05MAR2003	3	1	0	1					
		06MAR2003	4	2	0	2					
		07MAR2003	5	3	0	3					
		08MAR2003	6	3	0	3					
		09MAR2003	7	3	0	3					
		10MAR2003	8	4	0	4					
		11MAR2003	9	4	0	4					
		12MAR2003	10	4	0	4					
		13MAR2003	11	4	0	4					
		14MAR2003	12	4	0	4					

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0030016	15MAR2003	13	4	0	4					
		16MAR2003	14	4	0	4					
		17MAR2003	15	4	0	4					
		18MAR2003	16	4	0	4					
		19MAR2003	17	4	0	4					
		20MAR2003	18	4	0	4					
		21MAR2003	19	4	0	4					
		22MAR2003	20	4	0	4					
		23MAR2003	21	4	0	4					
		24MAR2003	22		0	4					
		25MAR2003	23	4	0	4					
		26MAR2003	24	4	0	4					
		27MAR2003	25	4	0	4					
		28MAR2003	26	4	0	4					
		29MAR2003	27	4	0	4					
		30MAR2003	28	4	0	4					
		31MAR2003	29	4	0	4					
		01APR2003	30		0	4					
		02APR2003	31	4	0	4					
		03APR2003	32	4	0	4					
		04APR2003	33	4	0	4					
		05APR2003	34	4	0	4					
		06APR2003	35	4	0	4					
		07APR2003	36	4	0	4					
		08APR2003	37	4	0	4					
		09APR2003	38	4	0	4					
		10APR2003	39	4	0	4					
		11APR2003	40	4	0	4					
		12APR2003	41	4	0	4					
		13APR2003	42	4	0	4					
		14APR2003	43	4	0	4					
		15APR2003	44	4	0	4					
		16APR2003	45		0	4					
		17APR2003	46		0	4	NO	0	46	100	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0030021	20MAY2003	1	2	0	2					PT DID NOT RETURN THE BLISTER CARD
		21MAY2003	2	1	0	1					
		22MAY2003	3	1	0	1					
		23MAY2003	4	2	0	2					
		24MAY2003	5	3	0	3					
		25MAY2003	6	3	0	3					
		26MAY2003	7	3	0	3					
		27MAY2003	8	4	0	4					AS PER PATIENT REPORT NO DOSE TAKEN
		28MAY2003	9	4	0	4					BLISTER CARD NOT RETURNED NO DOSE TAKEN
		29MAY2003	10	4	0	4					
		30MAY2003	11	4	1	3					FORGOT TO DOSE
		31MAY2003	12	4	0	4					
		01JUN2003	13	4	1	3					DID NOT TAKE DUE TO NON SERIOUS AE
		02JUN2003	14	4	1	3					NON SERIOUS AE
		03JUN2003	15	4	0	4					PT DID NOT RETURN BLISTER CARD
		04JUN2003	16	4	0	6					ACCIDENTALLY POPPED OUT
		05JUN2003	17	4	0	4					
		06JUN2003	18	4	0	4					
		07JUN2003	19	4	0	4					
		08JUN2003	20	4	0	4					
		09JUN2003	21	4	0	4					
		10JUN2003	22	4	0	8					AS PER PATIENT REPORT
		11JUN2003	23	4	0	8					BLISTER CARD NOT RETURNED
		12JUN2003	24	4	0	4					
		13JUN2003	25	4	0	4					
		14JUN2003	26	4	0	4					
		15JUN2003	27	4	0	4					
		16JUN2003	28	4	0	4					
		17JUN2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DRUG TABLET ADMINISTRATION DAY	DISPENSE	RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE NO. DAYS STUDY DRUG	%	COMMENTS
PLACEBO (BIPOLAR I)	E0030021	18JUN2003									PT. ACCIDENTALLY TOOK 2003/06/18 DOSE FOR 2003/06/16, PT DISCARDED THE FIRST TAB OF EACH ROW.
		24JUN2003									EXTRA DAY DOSES UNKNOWN
		25JUN2003					YES	0	29	110	BLISTER CARD NOT RETURNED
	E0031001	21NOV2002	1	2	0	2					
		22NOV2002	2	1	0	1					
		23NOV2002	3	1	0	1					
		24NOV2002	4	2	0	2					
		25NOV2002	5	3	0	3					
		26NOV2002	6	3	0	3					
		27NOV2002	7	3	0	3					
		28NOV2002	8	4	0	4					
		29NOV2002	9	4	0	4					PATIENT REPORTED DOG EATING ONE TAB
		30NOV2002	10	4	0	4					
		01DEC2002	11	4	0	4					
		02DEC2002	12	4	0	4					
		03DEC2002	13	4	0	4					
		04DEC2002	14	4	0	4					
		05DEC2002	15	4	0	4					CARD WAS NOT RETURNED.
		06DEC2002	16	4	0	4					
		07DEC2002	17	4	0	4					
		08DEC2002	18	4	0	4					
		09DEC2002	19	4	0	4					
		10DEC2002	20	4	0	4					
		11DEC2002	21	4	0	4					
		12DEC2002	22	4	0	8					UNKNOWN. CARD NOT RETURNED.
		12DEC2002	22	4	0	8					CARD WAS NOT RETURNED
		13DEC2002	23	4	0	8					
		14DEC2002	24	4	0	4					
		15DEC2002	25	4	0	4					
		16DEC2002	26	4	0	4					
		17DEC2002	27	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0031001	18DEC2002	28	4	0	4					
		19DEC2002	29		0	4					UNKNOWN. CARD NOT RETURNED
		20DEC2002	30	4	0	8					CARD WAS NOT RETURNED.
		21DEC2002	31	4	0	4					
		22DEC2002	32	4	0	4					
		23DEC2002	33	4	0	4					
		27DEC2002					NO	0	33	110	UNKNOWN. CARD NOT RETURNED.
	E0031017	01APR2003	1	2	0	2					
		02APR2003	2	1	0	1					
		03APR2003	3	1	0	1					
		04APR2003	4	2	0	2					
		05APR2003	5	3	0	3					
		06APR2003	6	3	0	3					
		07APR2003	7	3	0	3					
		08APR2003	8	4	0	4					
		09APR2003	9	4	0	4					
		10APR2003	10	4	0	4					
		11APR2003	11	4	0	4					
		12APR2003	12	4	0	4					
		13APR2003	13	4	0	4					
		14APR2003	14	4	0	4					
		15APR2003	15	4	0	4					
		16APR2003	16	4	0	4					
		17APR2003	17	4	0	4					
		18APR2003	18	4	0	4					
		19APR2003	19	4	0	4					
		20APR2003	20	4	0	4					
		21APR2003	21	4	0	4					
		22APR2003	22	4	0	4					
		23APR2003	23	4	0	4					
		24APR2003	24	4	0	4					
		25APR2003	25	4	0	4					
		26APR2003	26	4	0	4					
		27APR2003	27	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0031017	28APR2003	28	4	0	4	NO	0	28	100	
	E0031018	10APR2003	1	2	0	2					
		11APR2003	2	1	0	1					
		12APR2003	3	1	0	1					
		13APR2003	4	2	0	2					
		14APR2003	5	3	0	3					
		15APR2003	6	3	0	3					
		16APR2003	7	3	0	3					
		17APR2003	8	4	0	4					TABS FOR DAY 1 TAKEN FROM LINE 9
		18APR2003	9	4	0	4					
		19APR2003	10	4	0	4					
		20APR2003	11	4	0	4					
		21APR2003	12	4	0	4					
		22APR2003	13	4	0	4					
		23APR2003	14	4	0	4					
		24APR2003	15	4	0	4					MEDICATION NOT RETURNED. SUBJECT LOST TO FOLLOW - UP.
		25APR2003	16	4	0	4					TAKEN ON DAY 1
		26APR2003	17	4	0	4					
		27APR2003	18	4	0	4					
		28APR2003	19	4	0	4					
		29APR2003	20	4	0	4					
		30APR2003	21	4	0	4					
		01MAY2003	22		0	4					UNKNOWN
		02MAY2003	23		0	4	NO	0	23	100	
	E0031023	29APR2003	1	2	0	2					
		30APR2003	2	1	1	0					MISSED DOSE
		01MAY2003	3	1	1	0					MISSED DOSE
		02MAY2003	4	2	0	2					
		03MAY2003	5	3	0	3					
		04MAY2003	6	3	0	3					
		05MAY2003	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0031023	06MAY2003	8		0	4					
		07MAY2003	9	4	0	4					
		08MAY2003	10	4	0	4					
		09MAY2003	11	4	0	4					
		10MAY2003	12	4	0	4					
		11MAY2003	13	4	0	4					
		12MAY2003	14	4	0	4					
		13MAY2003	15	4	0	4					
		14MAY2003	16	4	0	4					
		15MAY2003	17	4	0	4					
		16MAY2003	18	4	0	4					
		17MAY2003	19	4	0	4					
		18MAY2003	20	4	0	4					
		19MAY2003	21	4	0	4					
		20MAY2003	22	4	0	4					
		21MAY2003	23	4	0	4					
		22MAY2003	24	4	0	4					
		23MAY2003	25	4	0	4					
		24MAY2003	26	4	0	4					
		25MAY2003	27	4	0	4					
		26MAY2003	28	4	0	4					
		27MAY2003	29	4	0	4					
		28MAY2003	30	4	0	4					
		29MAY2003	31	4	0	4					
		30MAY2003	32	4	0	4					
		31MAY2003	33	4	0	4					
		01JUN2003	34	4	0	4					
		02JUN2003	35	4	0	4					
		03JUN2003	36		0	4					
		04JUN2003	37	4	0	4					
		05JUN2003	38	4	0	4					
		06JUN2003	39	4	0	4					
		07JUN2003	40	4	0	4					
		08JUN2003	41	4	0	4					
		09JUN2003	42	4	0	4					
		10JUN2003	43	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0031023	11JUN2003	44	4	0	4					
		12JUN2003	45	4	0	4					
		13JUN2003	46	4	0	4					
		14JUN2003	47	4	0	4					
		15JUN2003	48	4	0	4					
		16JUN2003	49	4	0	4					
		17JUN2003	50	4	0	4					
		18JUN2003	51	4	0	4					
		19JUN2003	52	4	0	4					
		20JUN2003	53	4	0	4					
		21JUN2003	54	4	0	4					
		22JUN2003	55	4	0	4					
		23JUN2003	56	4	0	4	NO	0	54	99.1	
	E0033001	09JAN2003	1	2	0	2					
		10JAN2003	2	1	0	1					
		11JAN2003	3	1	0	1					
		12JAN2003	4	2	0	2					
		13JAN2003	5	3	0	3					
		14JAN2003	6	3	0	3					
		15JAN2003	7	3	0	3					
		16JAN2003	8	4	0	4					
		17JAN2003	9	4	0	4					
		18JAN2003	10	4	0	4					
		19JAN2003	11	4	0	4					
		20JAN2003	12	4	0	4					
		21JAN2003	13	4	0	4					
		22JAN2003	14	4	0	4					
		23JAN2003	15	4	0	4					
		24JAN2003	16	4	0	4					
		25JAN2003	17	4	0	4					
		26JAN2003	18	4	0	4					
		27JAN2003	19	4	0	4					
		28JAN2003	20	4	0	4					
		29JAN2003	21	4	0	4	NO	0	21	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0033004	17JAN2003	1	2	0	2					
		18JAN2003	2	1	0	1					
		19JAN2003	3	1	0	1					
		20JAN2003	4	2	0	2					
		21JAN2003	5	3	0	3					
		22JAN2003	6	3	0	3					
		23JAN2003	7	3	0	3					
		24JAN2003	8	4	0	4					
		25JAN2003	9	4	0	4					
		26JAN2003	10	4	0	4					
		27JAN2003	11	4	0	4					
		28JAN2003	12	4	0	4					
		29JAN2003	13	4	0	4					
		30JAN2003	14	4	0	4					
		31JAN2003	15	4	0	4					
		01FEB2003	16	4	0	4					
		02FEB2003	17	4	0	4					
		03FEB2003	18	4	0	4					
		04FEB2003	19	4	0	4					
		05FEB2003	20	4	0	4					
		06FEB2003	21	4	0	4					
		07FEB2003	22	4	0	4					
		08FEB2003	23	4	0	4					
		09FEB2003	24	4	0	4					
		10FEB2003	25	4	0	4					
		11FEB2003	26	4	0	4					
		12FEB2003	27	4	0	4					
		13FEB2003	28	4	0	4					
		14FEB2003	29	4	0	4					
		15FEB2003	30	4	0	4					
		16FEB2003	31	4	0	4					
		17FEB2003	32	4	0	4					
		18FEB2003	33	4	0	4					
		19FEB2003	34	4	0	4					
		20FEB2003	35	4	0	4					
		21FEB2003	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0033004	22FEB2003	37	4	0	4					
		23FEB2003	38	4	0	4					
		24FEB2003	39	4	0	4					
		25FEB2003	40	4	0	4					
		26FEB2003	41	4	0	4					
		27FEB2003	42	4	0	4					
		28FEB2003	43	4	0	4					
		01MAR2003	44	4	0	4					
		02MAR2003	45	4	0	4					
		03MAR2003	46	4	0	4					
		04MAR2003	47	4	0	4					
		05MAR2003	48	4	0	4					
		06MAR2003	49	4	0	4					
		07MAR2003	50	4	0	4					
		08MAR2003	51	4	0	4					
		09MAR2003	52	4	0	4					
		10MAR2003	53	4	0	4					
		11MAR2003	54	4	0	4					
		12MAR2003	55	4	0	4					
		13MAR2003	56	4	0	4	NO	0	56	100	
	E0033010	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					
		11FEB2003	8	4	0	4					
		12FEB2003	9	4	0	4					
		13FEB2003	10	4	0	4					
		14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	0	4					
		18FEB2003	15		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0033010	19FEB2003	16		0	4					
		20FEB2003	17	4	0	4					
		21FEB2003	18	4	0	4					
		22FEB2003	19	4	0	4					
		23FEB2003	20	4	0	4					
		24FEB2003	21	4	0	4					
		25FEB2003	22	4	0	4					
		26FEB2003	23	4	0	4					
		27FEB2003	24	4	0	4					
		28FEB2003	25	4	0	4					
		01MAR2003	26	4	0	4					
		02MAR2003	27	4	0	4					
		03MAR2003	28	4	0	4					
		04MAR2003	29	4	0	4					
		05MAR2003	30	4	0	4					
		06MAR2003	31	4	0	4					
		07MAR2003	32	4	0	4					
		08MAR2003	33	4	0	4					
		09MAR2003	34	4	0	4					
		10MAR2003	35	4	0	4					
		11MAR2003	36		0	4					
		12MAR2003	37		0	4					SUBJECT DID NOT TAKE STUDY MEDICATION ON 3/13/03 BECAUSE NO STUDY MEDS REMAINED IN BLISTER CARD.
		13MAR2003	38			0					
		14MAR2003	39	4	0	4					
		15MAR2003	40	4	0	4					
		16MAR2003	41	4	0	4					
		17MAR2003	42	4	0	4					
		18MAR2003	43	4	0	4					LAST KNOWN DOSE OF STUDY MEDICATION WAS 2003/03/18
		19MAR2003	44	4	0	4					
		20MAR2003	45	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0033010	21MAR2003	46		0	4					"UNKNOWN - SIC - UNOBTAINABLE SINCE SUBJECT DID NOT RETURN BLISTER - CARD"
		22MAR2003	47		0	4	NO	0	46	97.7	SUBJECT DID NOT RETURN BLISTERCARD AT LAST VISIT, THEREFORE, THE # OF TABLETS LEFT ON BLISTER CARD COULD NOT BE DETERMINED AND IS UNOBTAINABLE.
	E0033014	19MAR2003	1	2	0	2					
		20MAR2003	2	1	0	1					
		21MAR2003	3	1	0	1					
		22MAR2003	4	2	0	2					
		23MAR2003	5	3	0	3					
		24MAR2003	6	3	0	3					
		25MAR2003	7	3	0	3					
		26MAR2003	8	4	0	4					
		27MAR2003	9	4	0	4					
		28MAR2003	10	4	0	4					
		29MAR2003	11	4	0	4					
		30MAR2003	12	4	0	4					
		31MAR2003	13	4	0	4					
		01APR2003	14	4	0	4					
		02APR2003	15		0	4					
		03APR2003	16	4	0	4					
		04APR2003	17	4	0	4					
		05APR2003	18	4	0	4					
		06APR2003	19	4	0	4					
		07APR2003	20	4	0	4					
		08APR2003	21	4	0	4					
		09APR2003	22	4	0	4					
		10APR2003	23		0	4					
		11APR2003	24	4	0	4					
		12APR2003	25	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0033014	13APR2003	26	4	0	4					
		14APR2003	27	4	0	4					
		15APR2003	28	4	0	4					
		16APR2003	29	4	0	4					
		17APR2003	30	4	0	4					
		18APR2003	31	4	0	4					
		19APR2003	32	4	0	4					
		20APR2003	33	4	0	4					
		21APR2003	34	4	0	4					
		22APR2003	35	4	0	4					
		23APR2003	36	4	0	4					
		24APR2003	37	4	0	4					
		25APR2003	38	4	0	4					
		26APR2003	39	4	0	4					
		27APR2003	40	4	0	4	NO	0	40	100	
	E0035002	21NOV2002	1	2	0	2					
		22NOV2002	2	1	0	1					
		23NOV2002	3	1	0	1					
		24NOV2002	4	2	0	2					
		25NOV2002	5	3	0	3					
		26NOV2002	6	3	0	3					
		27NOV2002	7	3	0	3					
		28NOV2002	8	4	0	4					
		29NOV2002	9	4	0	4					
		30NOV2002	10	4	0	4					
		01DEC2002	11	4	0	4					
		02DEC2002	12	4	0	4					
		03DEC2002	13	4	0	4					
		04DEC2002	14	4	0	4					
		05DEC2002	15	4	0	4					
		06DEC2002	16	4	0	4					
		07DEC2002	17	4	0	4					
		08DEC2002	18	4	0	4					
		09DEC2002	19	4	0	4					
		10DEC2002	20	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0035002	11DEC2002	21	4	0	4					
		12DEC2002	22	4	0	4					NO TABLETS RETURNED
		13DEC2002	23	4	0	4					
		14DEC2002	24	4	0	4					
		15DEC2002	25	4	0	4					
		16DEC2002	26	4	0	4					
		17DEC2002	27	4	0	4					LAST KNOWN DOSE OF STUDY MEDICATION WAS 2002/12/17
		19DEC2002					NO	0	27	100	UNK
	E0035007	19DEC2002	1	2	0	2					
		20DEC2002	2	1	0	1					
		21DEC2002	3	1	0	1					
		22DEC2002	4	2	0	2					
		23DEC2002	5	3	0	3					
		24DEC2002	6	3	0	3					
		25DEC2002	7	3	0	3					
		26DEC2002	8	4	0	4					
		27DEC2002	9	4	0	4					
		28DEC2002	10	4	0	4					
		29DEC2002	11	4	0	4					
		30DEC2002	12	4	0	4					
		31DEC2002	13	4	0	4					
		01JAN2003	14	4	0	4					
		02JAN2003	15	4	0	4					
		03JAN2003	16	4	0	4					
		04JAN2003	17	4	0	4					
		05JAN2003	18	4	0	4					
		06JAN2003	19	4	0	4					
		07JAN2003	20	4	0	4					
		08JAN2003	21	4	0	4					
		09JAN2003	22	4	0	4					
		10JAN2003	23	4	0	4					
		11JAN2003	24	4	0	4					
		12JAN2003	25	4	0	4					
		13JAN2003	26	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0035007	14JAN2003	27	4	0	4					
		15JAN2003	28	4	0	4					
		16JAN2003	29		0	4					
		17JAN2003	30	4	0	4					
		18JAN2003	31	4	0	4					
		19JAN2003	32	4	0	4					
		20JAN2003	33	4	0	4					
		21JAN2003	34	4	0	4					
		22JAN2003	35	4	0	4					
		23JAN2003	36	4	0	4					
		24JAN2003	37	4	0	4					
		25JAN2003	38	4	0	4					
		26JAN2003	39	4	0	4					
		27JAN2003	40	4	0	4					
		28JAN2003	41	4	0	4					
		29JAN2003	42	4	0	4					
		30JAN2003	43	4	0	4					
		31JAN2003	44	4	0	4					
		01FEB2003	45	4	0	4					
		02FEB2003	46	4	0	4					
		03FEB2003	47	4	0	4					
		04FEB2003	48	4	0	4					
		05FEB2003	49	4	0	4					
		06FEB2003	50	4	0	4					
		07FEB2003	51	4	0	4					
		08FEB2003	52	4	0	4					
		09FEB2003	53	4	0	4					
		10FEB2003	54	4	0	4	NO	0	54	100	
	E0035011	04FEB2003	1	2	0	2					
		05FEB2003	2	1	0	1					
		06FEB2003	3	1	0	1					
		07FEB2003	4	2	0	2					
		08FEB2003	5	3	0	3					
		09FEB2003	6	3	0	3					
		10FEB2003	7	3	0	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0035011	11FEB2003	8	4	0	4					
		12FEB2003	9	4	0	4					
		13FEB2003	10	4	0	4					
		14FEB2003	11	4	0	4					
		15FEB2003	12	4	0	4					
		16FEB2003	13	4	0	4					
		17FEB2003	14	4	0	4					
		18FEB2003	15	4	0	4					
		19FEB2003	16	4	0	4					
		20FEB2003	17	4	0	4					
		21FEB2003	18	4	0	4					
		22FEB2003	19	4	0	4					
		23FEB2003	20	4	0	4					
		24FEB2003	21	4	0	4					
		25FEB2003	22	4	0	4					
		26FEB2003	23	4	0	4					
		27FEB2003	24	4	0	4					
		28FEB2003	25	4	0	4					
		01MAR2003	26	4	0	4					
		02MAR2003	27	4	0	4					
		03MAR2003	28	4	0	4					
		04MAR2003	29	4	0	4					
		05MAR2003	30	4	0	4					
		06MAR2003	31	4	0	4					
		07MAR2003	32	4	0	4					
		08MAR2003	33	4	0	4					
		09MAR2003	34	4	0	4					
		10MAR2003	35	4	0	4					
		11MAR2003	36	4	0	4					
		12MAR2003	37	4	0	4					
		13MAR2003	38	4	0	4					
		14MAR2003	39	4	0	4					
		15MAR2003	40	4	0	4					
		16MAR2003	41	4	0	4					
		17MAR2003	42	4	0	4					
		18MAR2003	43	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0035011	19MAR2003	44	4	0	4					
		20MAR2003	45	4	0	4					
		21MAR2003	46	4	0	4					
		22MAR2003	47	4	0	4					
		23MAR2003	48	4	0	4					
		24MAR2003	49	4	0	4					
		25MAR2003	50	4	0	4					
		26MAR2003	51	4	0	4					
		27MAR2003	52	4	0	4					
		28MAR2003	53	4	0	4					
		29MAR2003	54	4	0	4					
		30MAR2003	55	4	0	4					
		31MAR2003	56	4	0	4	NO	0	56	100	
	E0035020	18APR2003	1	2	0	2					
		19APR2003	2	1	0	1					
		20APR2003	3	1	0	1					
		21APR2003	4	2	0	2					
		22APR2003	5	3	0	3					
		23APR2003	6	3	0	3					
		24APR2003	7	3	0	3					
		25APR2003	8	4	0	4					PT MISPLACED TABLET PT DID NOT TAKE TAB.
		26APR2003	9	4	0	4					PT MISPLACED TABLET BUT DID NOT TAKE TABLET.
		27APR2003	10	4	0	4					
		28APR2003	11	4	0	4					
		29APR2003	12	4	0	4					
		30APR2003	13	4	0	4					
		01MAY2003	14	4	0	4					
		02MAY2003	15	4	0	4					
		03MAY2003	16	4	0	4					
		04MAY2003	17	4	0	4					
		05MAY2003	18	4	0	4					
		06MAY2003	19	4	0	4					
		07MAY2003	20	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0035020	08MAY2003	21		0	4					
		09MAY2003	22	4	0	4					
		10MAY2003	23	4	0	4					
		11MAY2003	24	4	0	4					
		12MAY2003	25	4	0	4					
		13MAY2003	26	4	0	4					
		14MAY2003	27	4	0	4					
		15MAY2003	28	4	0	4					
		16MAY2003	29	4	0	4					
		17MAY2003	30	4	0	4					
		18MAY2003	31	4	0	4					
		19MAY2003	32	4	0	4					
		20MAY2003	33	4	0	4					
		21MAY2003	34	4	0	4					
		22MAY2003	35		0	4					
		23MAY2003	36	4	0	4					
		24MAY2003	37	4	0	4					
		25MAY2003	38	4	0	4					
		26MAY2003	39	4	0	4					
		27MAY2003	40	4	0	4					
		28MAY2003	41	4	0	4					
		29MAY2003	42	4	0	4					
		30MAY2003	43	4	0	4					
		31MAY2003	44	4	0	4					
		01JUN2003	45	4	0	4					
		02JUN2003	46	4	0	4					
		03JUN2003	47	4	0	4					
		04JUN2003	48	4	0	4					
		05JUN2003	49	4	0	4					
		06JUN2003	50	4	0	4					
		07JUN2003	51	4	0	4					
		08JUN2003	52	4	0	4					
		09JUN2003	53	4	0	4					
		10JUN2003	54	4	0	4					
		11JUN2003	55	4	0	4					
		12JUN2003	56	4	0	4	NO	0	56	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0037003	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					
		04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8	4	0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4					
		12FEB2003	14	4	0	4					
		13FEB2003	15	4	0	4					
		14FEB2003	16	4	0	4					
		15FEB2003	17	4	0	4					
		16FEB2003	18	4	0	4					
		17FEB2003	19	4	0	4					
		18FEB2003	20	4	0	4					
		19FEB2003	21	4	0	4	NO	0	21	100	
	E0037004	13FEB2003	1	2	0	2					
		14FEB2003	2	1	0	1					
		15FEB2003	3	1	0	1					
		16FEB2003	4	2	0	2					
		17FEB2003	5	3	0	3					
		18FEB2003	6	3	0	3					
		19FEB2003	7	3	0	3					
		20FEB2003	8		0	4					
		21FEB2003	9	4	0	4					
		22FEB2003	10	4	0	4					
		23FEB2003	11	4	0	4					
		24FEB2003	12	4	0	4					
		25FEB2003	13	4	0	4					
		26FEB2003	14	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0037004	27FEB2003	15	4	0	4					
		28FEB2003	16	4	0	4					
		01MAR2003	17	4	0	4					
		02MAR2003	18	4	0	4					
		03MAR2003	19	4	0	4					
		04MAR2003	20	4	0	4					
		05MAR2003	21	4	0	4					
		06MAR2003	22	4	0	4					
		07MAR2003	23	4	0	4					
		08MAR2003	24	4	0	4					
		09MAR2003	25	4	0	4					
		10MAR2003	26	4	0	4					
		11MAR2003	27	4	0	4					
		12MAR2003	28	4	0	4					
		13MAR2003	29	4	0	4					
		14MAR2003	30	4	0	4					
		15MAR2003	31	4	0	4					
		16MAR2003	32	4	4	0					PT FORGOT TO TAKE MEDS
		17MAR2003	33	4	0	4					
		18MAR2003	34	4	0	4					
		19MAR2003	35	4	0	4					
		20MAR2003	36	4	0	4					
		21MAR2003	37	4	0	4					
		22MAR2003	38	4	0	4					
		23MAR2003	39	4	0	4					
		24MAR2003	40	4	0	4					
		25MAR2003	41	4	0	4					
		26MAR2003	42	4	0	4					
		27MAR2003	43		0	4					
		28MAR2003	44	4	0	4					
		29MAR2003	45	4	0	4					
		30MAR2003	46	4	0	4					
		31MAR2003	47	4	0	4					
		01APR2003	48	4	0	4					
		02APR2003	49	4	0	4					
		03APR2003	50	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0037004	04APR2003	51	4	0	4					PT DIDN'T USE - THREW AWAY IN ERROR.
		05APR2003	52	4	0	4					
		06APR2003	53	4	0	4					
		07APR2003	54	4	0	4					
		08APR2003	55	4	0	4					
		09APR2003	56	4	0	4	NO	0	55	98.1	
	E0039007	04DEC2002	1	2	0	2					
		05DEC2002	2	1	0	1					
		06DEC2002	3	1	0	1					
		07DEC2002	4	2	0	2					
		08DEC2002	5	3	0	3					
		09DEC2002	6	3	0	3					
		10DEC2002	7	3	0	3					
		11DEC2002	8	4	0	4					
		12DEC2002	9	4	0	4					
		13DEC2002	10	4	0	4					
		14DEC2002	11	4	0	4					
		15DEC2002	12	4	0	4					
		16DEC2002	13	4	0	4					
		17DEC2002	14	4	0	4					
		18DEC2002	15	4	0	4					
		19DEC2002	16	4	0	4					
		20DEC2002	17	4	0	4					
		21DEC2002	18	4	0	4					
		22DEC2002	19	4	0	4					
		23DEC2002	20	4	0	4					
		24DEC2002	21	4	0	4					
		25DEC2002	22	4	0	4					
		26DEC2002	23	4	0	4					
		27DEC2002	24	4	0	4					
		28DEC2002	25	4	0	4					
		29DEC2002	26	4	0	4					
		30DEC2002	27	4	0	4					
		31DEC2002	28	4	0	4					
		01JAN2003	29	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039007	02JAN2003	30	4	0	4					
		03JAN2003	31	4	0	4					
		04JAN2003	32	4	0	4					
		05JAN2003	33	4	0	4					
		06JAN2003	34		0	4					
		07JAN2003	35		0	4					
		08JAN2003	36	4	0	4					
		09JAN2003	37	4	0	4					
		10JAN2003	38	4	0	4					
		11JAN2003	39	4	0	4					
		12JAN2003	40	4	0	4					
		13JAN2003	41	4	0	4					
		14JAN2003	42	4	0	4					
		15JAN2003	43	4	0	4					
		16JAN2003	44	4	0	4					
		17JAN2003	45	4	0	4					
		18JAN2003	46	4	0	4					
		19JAN2003	47	4	0	4					
		20JAN2003	48	4	0	4					
		21JAN2003	49	4	0	4					
		22JAN2003	50	4	0	4					
		23JAN2003	51	4	0	4					
		24JAN2003	52	4	0	4					
		25JAN2003	53	4	0	4					
		26JAN2003	54	4	0	4					
		27JAN2003	55	4	0	4					
		28JAN2003	56	4	0	4	NO	0	56	100	
	E0039022	25FEB2003	1	2	0	2					
		26FEB2003	2	1	0	1					
		27FEB2003	3	1	0	1					
		28FEB2003	4	2	0	2					
		01MAR2003	5	3	0	3					
		02MAR2003	6	3	0	3					
		03MAR2003	7	3	0	3					
		04MAR2003	8		1	3					MISSED 1 TABLET

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039022	05MAR2003	9		1	3					MISSED 1 TABLET
		06MAR2003	10	4	0	4					
		07MAR2003	11	4	0	4					
		08MAR2003	12	4	0	4					
		09MAR2003	13	4	0	4					
		10MAR2003	14	4	0	4					
		11MAR2003	15	4	0	4					
		12MAR2003	16	4	0	4					
		13MAR2003	17	4	0	4					
		14MAR2003	18	4	0	4					
		15MAR2003	19	4	0	4					
		16MAR2003	20	4	0	4					
		17MAR2003	21	4	0	4					
		18MAR2003	22	4	0	4					
		19MAR2003	23	4	0	4					
		20MAR2003	24	4	4	0					FORGOT 1 DOSE
		21MAR2003	25	4	0	4					
		22MAR2003	26	4	0	4					
		23MAR2003	27	4	0	4					
		24MAR2003	28	4	0	4					
		25MAR2003	29	4	0	4					
		26MAR2003	30	4	0	4					
		27MAR2003	31	4	0	4					
		28MAR2003	32	4	0	4					
		29MAR2003	33	4	0	4					
		30MAR2003	34	4	0	4					
		31MAR2003	35	4	0	4					
		01APR2003	36	4	0	4					
		02APR2003	37	4	0	4					
		03APR2003	38	4	0	4					
		04APR2003	39	4	0	4					
		05APR2003	40	4	0	4					
		06APR2003	41	4	0	4					
		07APR2003	42	4	0	4					
		08APR2003	43	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039022	09APR2003	44	4	4	0					THE SUBJECT MISSED ONE DOSE.
		10APR2003	45	4	0	4					
		11APR2003	46	4	0	4					
		12APR2003	47	4	0	4					
		13APR2003	48	4	0	4					
		14APR2003	49		0	4					
		15APR2003	50	4	0	4					
		16APR2003	51	4	0	4					
		17APR2003	52	4	0	4					
		18APR2003	53	4	0	4					
		19APR2003	54	4	0	4					
		20APR2003	55	4	0	4					
		21APR2003	56	4	0	4					
		22APR2003	57		0	4					
		23APR2003	58		0	4	NO	0	56	96.3	
	E0039023	24FEB2003	1	2	0	2					
		25FEB2003	2	1	0	1					
		26FEB2003	3	1	0	1					
		27FEB2003	4	2	0	2					
		28FEB2003	5	3	0	3					
		01MAR2003	6	3	0	3					
		02MAR2003	7	3	0	3					
		03MAR2003	8	4	0	4					THE SITE CANNOT CONFIRM IF SUBJECT TOOK EXTRA DAY DOSES OR ANY DOSES SINCE SUBJECT WAS LOST TO FOLLOW UP AND BLISTER CARD WAS NOT RETURNED.
		04MAR2003	9	4	0	4					
		05MAR2003	10	4	0	4					
		06MAR2003	11	4	0	4					
		07MAR2003	12	4	0	4					
		08MAR2003	13	4	0	4					
		09MAR2003	14	4	0	4					
		10MAR2003	15		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039023	11MAR2003	16		0	4	NO	0	16	100	
	E0039030	24MAR2003	1	2	0	2					
		25MAR2003	2	1	0	1					
		26MAR2003	3	1	0	1					
		27MAR2003	4	2	0	2					
		28MAR2003	5	3	0	3					
		29MAR2003	6	3	0	3					
		30MAR2003	7	3	0	3					
		31MAR2003	8	4	0	4					
		01APR2003	9	4	0	4					
		02APR2003	10	4	0	4					
		03APR2003	11	4	0	4					
		04APR2003	12	4	0	4					
		05APR2003	13	4	0	4					
		06APR2003	14	4	0	4					
		07APR2003	15	4	0	4					
		08APR2003	16	4	0	4					
		09APR2003	17	4	0	4					
		10APR2003	18	4	0	4					
		11APR2003	19	4	0	4					
		12APR2003	20	4	0	4					
		13APR2003	21	4	0	4					
		14APR2003	22	4	0	4					
		15APR2003	23	4	0	4					
		16APR2003	24	4	0	4					
		17APR2003	25	4	0	4					
		18APR2003	26	4	0	4					
		19APR2003	27	4	0	4					
		20APR2003	28		4	4					
		21APR2003	29	4	0	4					
		22APR2003	30	4	0	4					
		23APR2003	31	4	0	4					
		24APR2003	32	4	0	4					
		25APR2003	33	4	0	4					
		26APR2003	34	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039030	27APR2003	35	4	0	4					
		28APR2003	36	4	0	4					
		29APR2003	37	4	0	4					
		30APR2003	38	4	0	4					
		01MAY2003	39	4	0	4					
		02MAY2003	40	4	0	4					
		03MAY2003	41	4	0	4					
		04MAY2003	42	4	0	4					
		05MAY2003	43	4	0	4					
		06MAY2003	44	4	0	4					
		07MAY2003	45	4	0	4					
		08MAY2003	46	4	0	4					
		09MAY2003	47	4	0	4					
		10MAY2003	48	4	0	4					
		11MAY2003	49	4	0	4					
		12MAY2003	50		0	4					
		13MAY2003	51	4	0	4					
		14MAY2003	52	4	0	4					
		15MAY2003	53	4	0	4					
		16MAY2003	54	4	0	4					
		17MAY2003	55	4	0	4					
		18MAY2003	56	4	0	4					
		19MAY2003					NO	0	56	100	THE SUBJECT TOOK THIS DOSE ON 5/16/03 IN ADDITION TO THE SUBJECT'S NORMAL DOSE ON 5/16/03
	E0039031	24MAR2003	1	2	0	2					
		25MAR2003	2	1	0	1					
		26MAR2003	3	1	0	1					
		27MAR2003	4	2	0	2					
		28MAR2003	5	3	0	3					
		29MAR2003	6	3	0	3					
		30MAR2003	7	3	0	3					
		31MAR2003	8	4	0	4					
		01APR2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039031	02APR2003	10	4	0	4					
		03APR2003	11	4	0	4					
		04APR2003	12	4	0	4					
		05APR2003	13	4	0	4					
		06APR2003	14	4	0	4					
		07APR2003	15	4	0	4					
		08APR2003	16	4	0	4					
		09APR2003	17	4	0	4					
		10APR2003	18	4	0	4					
		11APR2003	19	4	0	4					
		12APR2003	20	4	0	4					
		13APR2003	21	4	0	4					
		14APR2003	22		0	4					THE SUBJECT TOOK AN EXTRA DAY DOSE DUE TO VISITS BEING 8 DAYS APART.
		15APR2003	23	4	0	4					
		16APR2003	24	4	0	4					
		17APR2003	25	4	0	4					
		18APR2003	26	4	0	4					
		19APR2003	27	4	0	4					
		20APR2003	28	4	0	4					
		21APR2003	29	4	0	4					THE SUBJECT DID NOT TAKE DOSE ON 4/21/03 BECAUSE THE VISIT WAS SCHEDULED ONE DAY EARLY.
		22APR2003	30	4	0	4					
		23APR2003	31	4	0	4					
		24APR2003	32	4	0	4					
		25APR2003	33	4	0	4					
		26APR2003	34	4	0	4					
		27APR2003	35	4	0	4					
		28APR2003	36	4	0	4					
		29APR2003	37	4	0	4					
		30APR2003	38	4	0	4					
		01MAY2003	39	4	0	4					
		02MAY2003	40	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039031	03MAY2003	41	4	0	4					
		04MAY2003	42	4	0	4					
		05MAY2003	43	4	0	4					
		06MAY2003	44	4	0	4					
		07MAY2003	45	4	0	4					
		08MAY2003	46	4	0	4					
		09MAY2003	47	4	0	4					
		10MAY2003	48	4	0	4					
		11MAY2003	49	4	0	4					
		12MAY2003	50		0	4					THE EXTRA DAY DOSE WAS TAKEN BECAUSE IT WAS 8 DAYS BETWEEN VISITS.
		13MAY2003	51	4	0	4					
		14MAY2003	52	4	0	4					
		15MAY2003	53	4	0	4					
		16MAY2003	54	4	0	4					
		17MAY2003	55	4	0	4					
		18MAY2003	56	4	0	4					
		19MAY2003	57	4	0	4	NO	0	57	100	
	E0039037	16APR2003	1	2	0	2					
		17APR2003	2	1	0	1					
		18APR2003	3	1	0	1					
		19APR2003	4	2	0	2					
		20APR2003	5	3	0	3					
		21APR2003	6	3	0	3					
		22APR2003	7	3	0	3					
		23APR2003	8	4	0	4					
		24APR2003	9	4	0	4					
		25APR2003	10	4	0	4					
		26APR2003	11	4	0	4					
		27APR2003	12	4	0	4					
		28APR2003	13	4	0	4					
		29APR2003	14	4	0	4					
		30APR2003	15		0	4					
		01MAY2003	16	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039037	02MAY2003	17	4	0	4					
		03MAY2003	18	4	0	4					
		04MAY2003	19	4	0	4					
		05MAY2003	20	4	0	4					
		06MAY2003	21	4	0	4					
		07MAY2003	22	4	0	4					
		08MAY2003	23	4	0	4					
		09MAY2003	24	4	0	4					
		10MAY2003	25	4	0	4					
		11MAY2003	26	4	0	4					
		12MAY2003	27	4	0	4					
		13MAY2003	28	4	0	4					
		14MAY2003	29		4	0					MISSED DOSE
		15MAY2003	30	4	0	4					
		16MAY2003	31	4	0	4					
		17MAY2003	32	4	0	4					
		18MAY2003	33	4	0	4					
		19MAY2003	34	4	0	4					
		20MAY2003	35	4	0	4					
		21MAY2003	36	4	0	4					
		22MAY2003	37	4	0	4					
		23MAY2003	38	4	0	4					
		24MAY2003	39	4	0	4					
		25MAY2003	40	4	0	4					
		26MAY2003	41	4	0	4					
		27MAY2003	42	4	0	4					
		28MAY2003	43	4	0	4					
		29MAY2003	44	4	0	4					
		30MAY2003	45	4	0	4					
		31MAY2003	46	4	0	4					
		01JUN2003	47	4	0	4					
		02JUN2003	48	4	0	4					
		03JUN2003	49	4	0	4					
		04JUN2003	50		0	4					
		05JUN2003	51	4	0	4					THE SUBJECT DID NOT RETURN THE BLISTERCARD

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039037	06JUN2003	52	4	0	4					
		07JUN2003	53	4	0	4					
		08JUN2003	54	4	0	4					
		09JUN2003	55	4	0	4					
		10JUN2003	56	4	0	4					
		11JUN2003	57	4	0	4					
		12JUN2003	58		0	4					UNKNOWN SIC
		13JUN2003	59		0	4	NO	0	58	98.2	
	E0039038										THIS BLISTERCARD WAS NOT DISPENSED AS PER SPONSOR.
		23APR2003	1	2	0	2					
		24APR2003	2	1	0	1					
		25APR2003	3	1	0	1					
		26APR2003	4	2	0	2					
		27APR2003	5	3	0	3					
		28APR2003	6	3	0	3					
		29APR2003	7	3	0	3					
		30APR2003	8	4	0	4					
		01MAY2003	9	4	0	4					
		02MAY2003	10	4	0	4					
		03MAY2003	11	4	0	4					
		04MAY2003	12	4	0	4					
		05MAY2003	13	4	0	4					
		06MAY2003	14	4	0	4					THE SUBJECT TOOK THIS ON MAY 5, 2003 (ACCIDENTAL OVERDOSE)
		07MAY2003	15		0	4					AS PER BLISTER CARD THE DOSE WAS TAKEN 5/9/03
		08MAY2003	16		0	4					AS PER BLISTER CARD, THE DOSE WAS TAKEN 5/10/03
		09MAY2003	17			0					
		10MAY2003	18			0					
		11MAY2003	19			0					
		12MAY2003	20			0					
		13MAY2003	21			0					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039038	14MAY2003	22			0					
		15MAY2003	23	4	0	4					
		16MAY2003	24	4	0	4					
		17MAY2003	25	4	0	4					
		18MAY2003	26	4	0	4					
		19MAY2003	27	4	0	4					
		20MAY2003	28	4	0	4					
		21MAY2003	29	4	0	4					
		22MAY2003	30	4	0	4					
		23MAY2003	31	4	0	4					
		24MAY2003	32	4	0	4					
		25MAY2003	33	4	0	4					
		26MAY2003	34	4	0	4					
		27MAY2003	35	4	0	4					
		28MAY2003	36		4	0					THE SUBJECT FORGOT TO TAKE THIS DOSE.
		29MAY2003	37	4	0	4					
		30MAY2003	38	4	0	4					
		31MAY2003	39	4	0	4					
		01JUN2003	40	4	0	4					
		02JUN2003	41	4	0	4					
		03JUN2003	42	4	0	4					
		04JUN2003	43	4	0	4					
		05JUN2003	44		0	4					
		06JUN2003	45		0	4	NO	0	38	83.2	
	E0039047	19MAY2003	1	2	0	2					
		20MAY2003	2	1	0	1					
		21MAY2003	3	1	0	1					
		22MAY2003	4	2	0	2					
		23MAY2003	5	3	0	3					
		24MAY2003	6	3	0	3					
		25MAY2003	7	3	0	3					
		26MAY2003	8		0	4					
		27MAY2003	9	4	0	4					
		28MAY2003	10	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	COMPLIANCE: MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039047	29MAY2003	11	4	0	4					
		30MAY2003	12	4	0	4					
		31MAY2003	13	4	0	4					
		01JUN2003	14	4	0	4					
		02JUN2003	15	4	0	4					
		03JUN2003	16	4	0	4					
		04JUN2003	17	4	0	4					
		05JUN2003	18	4	0	4					
		06JUN2003	19	4	0	4					
		07JUN2003	20	4	0	4					
		08JUN2003	21	4	0	4					
		09JUN2003	22	4	0	4					
		10JUN2003	23	4	0	4					
		11JUN2003	24	4	0	4					
		12JUN2003	25	4	0	4					
		13JUN2003	26	4	0	4					
		14JUN2003	27	4	0	4					
		15JUN2003	28	4	0	4					
		16JUN2003	29	4	0	4					
		17JUN2003	30	4	0	4					
		18JUN2003	31	4	0	4					
		19JUN2003	32	4	0	4					
		20JUN2003	33	4	0	4					
		21JUN2003	34	4	0	4					
		22JUN2003	35	4	0	4					
		23JUN2003	36	4	0	4					
		24JUN2003	37	4	0	4					
		25JUN2003	38	4	0	4					
		26JUN2003	39	4	0	4					
		27JUN2003	40	4	0	4					
		28JUN2003	41	4	0	4					
		29JUN2003	42	4	0	4					
		30JUN2003	43	4	0	4					
		01JUL2003	44	4	0	4					
		02JUL2003	45	4	0	4					
		03JUL2003	46	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039047	04JUL2003	47	4	0	4					
		05JUL2003	48	4	0	4					
		06JUL2003	49	4	0	4					
		07JUL2003	50	4	0	4					
		08JUL2003	51	4	0	4					
		09JUL2003	52	4	0	4					
		10JUL2003	53	4	0	4					
		11JUL2003	54	4	0	4					
		12JUL2003	55	4	0	4					
		13JUL2003	56	4	0	4	NO	0	56	100	
	E0039059	11JUL2003	1	2	0	2					
		12JUL2003	2	1	0	1					
		13JUL2003	3	1	0	1					
		14JUL2003	4	2	0	2					
		15JUL2003	5	3	0	3					
		16JUL2003	6	3	0	3					
		17JUL2003	7	3	0	3					
		18JUL2003	8	4	0	4					
		19JUL2003	9	4	0	4					
		20JUL2003	10	4	0	4					
		21JUL2003	11	4	0	4					
		22JUL2003	12	4	0	4					
		23JUL2003	13	4	0	4					
		24JUL2003	14	4	0	4					
		25JUL2003	15	4	0	4					
		26JUL2003	16	4	0	4					
		27JUL2003	17	4	0	4					
		28JUL2003	18	4	0	4					
		29JUL2003	19	4	0	4					
		30JUL2003	20	4	0	4					
		31JUL2003	21	4	0	4					
		01AUG2003	22	4	0	4					
		02AUG2003	23	4	0	4					
		03AUG2003	24	4	0	4					
		04AUG2003	25	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0039059	05AUG2003	26	4	0	4					
		06AUG2003	27	4	0	4					
		07AUG2003	28	4	0	4					THE SUBJECT RETURNED FOR VISIT 6. SEE PG. 203
		08AUG2003	29	4	0	4					
		09AUG2003	30	4	0	4					
		10AUG2003	31	4	0	4					
		11AUG2003	32	4	0	4					
		12AUG2003	33	4	0	4					
		13AUG2003	34	4	0	4					
		14AUG2003	35		0	4					
		15AUG2003	36	4	0	4					
		16AUG2003	37	4	0	4					
		17AUG2003	38	4	0	4					
		18AUG2003	39	4	0	4					
		19AUG2003	40	4	0	4					
		20AUG2003	41	4	0	4					
		21AUG2003	42	4	0	4					SUBJECT RETURNED FOR VISIT 8. SEE PAGE 205.
		22AUG2003	43	4	0	4					
		23AUG2003	44	4	0	4					
		24AUG2003	45	4	0	4					
		25AUG2003	46	4	0	4					
		26AUG2003	47	4	0	4					
		27AUG2003	48	4	0	4					
		28AUG2003	49		0	4					
		29AUG2003	50	4	0	4					
		30AUG2003	51	4	0	4					
		31AUG2003	52	4	0	4					
		01SEP2003	53	4	0	4					
		02SEP2003	54	4	0	4					
		03SEP2003	55	4	0	4					
		04SEP2003	56	4	0	4	NO	0	56	100	
	E0041007	13MAR2003	1	2	0	2					
		14MAR2003	2	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0041007	15MAR2003	3	1	0	1					
		16MAR2003	4	2	0	2					
		17MAR2003	5	3	0	3					
		18MAR2003	6	3	0	3					
		19MAR2003	7	3	0	3					
		20MAR2003	8	4	0	4					
		21MAR2003	9	4	0	4					
		22MAR2003	10	4	0	4					
		23MAR2003	11	4	0	4					
		24MAR2003	12	4	0	4					
		25MAR2003	13	4	0	4					
		26MAR2003	14	4	0	4					
		27MAR2003	15	4	0	4					
		28MAR2003	16	4	0	4					
		29MAR2003	17	4	0	4					
		30MAR2003	18	4	0	4					
		31MAR2003	19	4	0	4					
		01APR2003	20	4	0	4					
		02APR2003	21	4	0	4					
		03APR2003	22	4	0	4					
		04APR2003	23	4	0	4					
		05APR2003	24	4	0	4					
		06APR2003	25	4	0	4					
		07APR2003	26	4	0	4					
		08APR2003	27	4	0	4					
		09APR2003	28	4	0	4					
		10APR2003	29	4	0	4					
		11APR2003	30	4	0	4					
		12APR2003	31	4	0	4					
		13APR2003	32	4	0	4					
		14APR2003	33	4	0	4					
		15APR2003	34	4	0	4					
		16APR2003	35	4	0	4					
		17APR2003	36	4	0	4					
		18APR2003	37	4	0	4					
		19APR2003	38	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0041007	20APR2003	39	4	0	4					
		21APR2003	40	4	0	4					
		22APR2003	41	4	0	4					
		23APR2003	42	4	0	4					
		24APR2003	43		0	4					
		25APR2003	44	4	0	4					
		26APR2003	45	4	0	4					
		27APR2003	46	4	0	4					
		28APR2003	47	4	0	4					
		29APR2003	48	4	0	4					
		30APR2003	49	4	0	4					
		01MAY2003	50	4	0	4					SIC - PATIENT TOOK THESE TABS ON 04/27/03 BECAUSE HE DROPPED THAT DAY'S DOSE
		01MAY2003	50	4	0	4					SIC SEE PAGE 205 FOR COMMENT DAY 7
		02MAY2003	51	4	0	4					
		03MAY2003	52	4	0	4					
		04MAY2003	53	4	0	4					
		05MAY2003	54	4	0	4					
		06MAY2003	55	4	0	4					
		07MAY2003	56	4	0	4	NO	0	56	100	
	E0041010	30APR2003	1	2	0	2					
		01MAY2003	2	1	0	1					
		02MAY2003	3	1	0	1					
		03MAY2003	4	2	0	2					
		04MAY2003	5	3	0	3					
		05MAY2003	6	3	0	3					
		06MAY2003	7	3	0	3					
		07MAY2003	8		0	4					
		08MAY2003	9	4	0	4					
		09MAY2003	10	4	0	4					
		10MAY2003	11	4	0	4					
		11MAY2003	12	4	0	4					
		12MAY2003	13	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0041010	13MAY2003	14	4	0	4					
		14MAY2003	15	4	0	4					
		15MAY2003	16	4	0	4					
		16MAY2003	17	4	0	4					
		17MAY2003	18	4	0	4					
		18MAY2003	19	4	0	4					
		19MAY2003	20	4	0	4					
		20MAY2003	21	4	0	4					
		21MAY2003	22	4	0	4					
		22MAY2003	23	4	0	4					
		23MAY2003	24	4	0	4					
		24MAY2003	25	4	0	4					
		25MAY2003	26	4	0	4					
		26MAY2003	27	4	0	4					
		27MAY2003	28	4	0	4					
		28MAY2003	29	4	0	8					PT. DROPPED DAY 5'S TABS, THEREFORE TOOK EXTRA DOSE FROM EXTRA DAY ROW ON 05/25/03
		29MAY2003	30	4	0	4					
		30MAY2003	31	4	0	4					
		31MAY2003	32	4	0	4					
		01JUN2003	33	4	0	4					
		02JUN2003	34	4	0	4					
		03JUN2003	35	4	0	4					
		04JUN2003	36	4	0	4					
		05JUN2003	37	4	0	4					
		06JUN2003	38	4	0	4					
		07JUN2003	39	4	0	4					
		08JUN2003	40	4	0	4					
		09JUN2003	41	4	0	4					
		10JUN2003	42	4	0	4	NO	0	42	103	
	E0041011	22MAY2003	1	2	0	2					
		23MAY2003	2	1	0	1					
		24MAY2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0041011	25MAY2003	4	2	0	2					
		26MAY2003	5	3	0	3					
		27MAY2003	6	3	0	3					
		28MAY2003	7	3	0	3					
		29MAY2003	8	4	0	4					STUDY MEDS DISPENSED TO SUBJECT VIA SUBJECTS SISTER ON 05/29/03 PRIOR TO SUBJECTS VISIT 3 ON 06/02/03
		30MAY2003	9	4	0	4					
		31MAY2003	10	4	0	4					
		01JUN2003	11	4	0	4					
		02JUN2003	12	4	0	4					
		03JUN2003	13	4	0	4					
		04JUN2003	14	4	0	4					
		05JUN2003	15		0	4					
		06JUN2003	16	4	0	4					
		07JUN2003	17	4	0	4					
		08JUN2003	18	4	0	4					
		09JUN2003	19	4	0	4					
		10JUN2003	20	4	0	4					
		11JUN2003	21	4	0	4					
		12JUN2003	22	4	0	4					
		13JUN2003	23		0	4					SUBJECT DID NOT TAKE STUDY MEDS ON 06/13/03 SUBJECT TOOK MEDS ON 06/14/03
		14JUN2003	24		0	4					SUBJECT TOOK MEDS ON 06/15/03
		15JUN2003	25			0					
		16JUN2003	26	4	0	4					
		17JUN2003	27	4	0	4					
		18JUN2003	28	4	0	4					
		19JUN2003	29	4	0	4					
		20JUN2003	30	4	0	4					
		21JUN2003	31	4	0	4					
		22JUN2003	32	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0041011	23JUN2003	33	4	0	4					
		24JUN2003	34	4	0	4					
		25JUN2003	35	4	0	4					
		26JUN2003	36	4	0	4					
		27JUN2003	37	4	0	4					
		28JUN2003	38	4	0	4					
		29JUN2003	39	4	0	4					
		30JUN2003	40	4	0	4					
		01JUL2003	41	4	0	4					
		02JUL2003	42	4	0	4					
		03JUL2003	43	4	0	4					
		04JUL2003	44	4	0	4					
		05JUL2003	45	4	0	4					
		06JUL2003	46	4	0	4					
		07JUL2003	47	4	0	4					
		08JUL2003	48	4	0	4					
		09JUL2003	49	4	0	4					
		10JUL2003	50	4	0	4					
		11JUL2003	51	4	0	4					
		12JUL2003	52	4	0	4					
		13JUL2003	53	4	0	4					
		14JUL2003	54	4	0	4					
		15JUL2003	55	4	0	4					
		16JUL2003	56	4	0	4	NO	0	55	98.1	
	E0041012	19JUN2003	1	2	0	2					
		20JUN2003	2	1	0	1					
		21JUN2003	3	1	0	1					
		22JUN2003	4	2	0	2					
		23JUN2003	5	3	0	3					
		24JUN2003	6	3	0	3					
		25JUN2003	7	3	0	3					
		26JUN2003	8	4	0	4					
		27JUN2003	9	4	0	4					
		28JUN2003	10	4	0	4					
		29JUN2003	11	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0041012	30JUN2003	12	4	0	4					
		01JUL2003	13	4	0	4					
		02JUL2003	14	4	0	4					
		03JUL2003	15	4	0	4					
		04JUL2003	16	4	0	4					
		05JUL2003	17	4	0	4					
		06JUL2003	18	4	0	4					
		07JUL2003	19	4	0	4					
		08JUL2003	20	4	0	4					
		09JUL2003	21	4	0	4					
		10JUL2003	22	4	0	4					
		11JUL2003	23	4	0	4					
		12JUL2003	24	4	0	4					
		13JUL2003	25	4	0	4					
		14JUL2003	26	4	0	4					
		15JUL2003	27	4	0	4					
		16JUL2003	28	4	0	4					
		17JUL2003	29	4	0	4					
		18JUL2003	30	4	0	4					
		19JUL2003	31	4	0	4					
		20JUL2003	32	4	0	4					
		21JUL2003	33	4	0	4					
		22JUL2003	34	4	0	4					
		23JUL2003	35	4	0	4					
		24JUL2003	36	4	0	4					
		25JUL2003	37	4	0	4					
		26JUL2003	38	4	0	4					
		27JUL2003	39	4	0	4					
		28JUL2003	40	4	0	4					
		29JUL2003	41	4	0	4					
		30JUL2003	42	4	0	4					
		31JUL2003	43	4	0	4					
		01AUG2003	44	4	0	4					
		02AUG2003	45	4	0	4					
		03AUG2003	46	4	0	4					
		04AUG2003	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR I)	E0041012	05AUG2003	48	4	0	4					
		06AUG2003	49	4	0	4					
		07AUG2003	50	4	0	4					
		08AUG2003	51	4	0	4					
		09AUG2003	52	4	0	4					
		10AUG2003	53	4	0	4					
		11AUG2003	54	4	0	4					
		12AUG2003	55	4	0	4					
		13AUG2003	56	4	0	4	NO	0	56	100	
PLACEBO (BIPOLAR II)	E0001004	01MAY2003	1	2	0	2					
		02MAY2003	2	1	1	0					PATIENT FORGOT TO TAKE DOSE ON 5/2, BUT TOOK 5/2 TABS ON 5/3
		03MAY2003	3	1	0	1					TOOK 5/3 TABS ON 5/4/03
		04MAY2003	4	2	1	1					TOOK 5/4 TABS ON 5/5/03
		05MAY2003	5	3	1	2					TOOK 5/5 TABS ON 5/6/03
		06MAY2003	6	3	0	3					TOOK 5/6 TABS ON 5/7/03
		07MAY2003	7	3	0	3					TOOK 5/7 TABS ON 5/8/03
		08MAY2003	8		1	3					TOOK DOSE PRESCRIBED ON 5/7/03 ON 5/8/03.
		09MAY2003	9	4	0	4					
		10MAY2003	10	4	0	4					
		11MAY2003	11	4	0	4					
		12MAY2003	12	4	0	4					
		13MAY2003	13	4	0	4					
		14MAY2003	14	4	0	4					
		15MAY2003	15	4	0	4					
		16MAY2003	16	4	0	4					
		17MAY2003	17	4	0	4					
		18MAY2003	18	4	0	4					
		19MAY2003	19	4	0	4					
		20MAY2003	20	4	4	0					PATIENT FORGOT TO TAKE DOSE ON THIS DATE
		21MAY2003	21	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0001004	22MAY2003	22	4	0	4					
		23MAY2003	23	4	0	8					
		24MAY2003	24	4	0	8					
		25MAY2003	25	4	0	4					
		26MAY2003	26	4	0	4					
		27MAY2003	27	4	0	4					
		28MAY2003	28	4	0	4					
		29MAY2003	29	4	0	4					PATIENT HAD VISIT 6 ON 5/29/03.
		30MAY2003	30	4	0	4					
		31MAY2003	31	4	0	4					
		01JUN2003	32	4	0	4					
		02JUN2003	33	4	0	4					
		03JUN2003	34	4	0	4					
		04JUN2003	35	4	4	0					MISSED 6/4, TOOK 6/4'S DOSE ON 6/5/03
		05JUN2003	36		0	4					TOOK DOSE PRESCRIBED FOR 6/4/03 ON 6/5/03.
		06JUN2003	37	4	0	4					
		07JUN2003	38	4	0	4					
		08JUN2003	39	4	0	4					
		09JUN2003	40	4	0	4					
		10JUN2003	41	4	0	4					
		11JUN2003	42	4	0	4					
		12JUN2003	43	4	0	4					PATIENT HAD VISIT 8 ON 6/12/03.
		13JUN2003	44	4	0	4					
		14JUN2003	45	4	0	4					
		15JUN2003	46	4	0	4					
		16JUN2003	47	4	0	4					
		17JUN2003	48	4	0	4					
		18JUN2003	49	4	0	4					
		19JUN2003	50		0	4					PATIENT TOOK EXTRA DOSE AS VISIT 9 WAS ON 6/20/03.
		20JUN2003	51	4	0	4					
		21JUN2003	52	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0001004	22JUN2003	53	4	0	4					
		23JUN2003	54	4	0	4					
		24JUN2003	55	4	0	4					
		25JUN2003	56	4	0	4					
		26JUN2003	57	4	0	4	NO	0	54	98.6	
	E0005023	05FEB2003	1	2	0	2					
		06FEB2003	2	1	0	1					
		07FEB2003	3	1	0	1					
		08FEB2003	4	2	0	2					
		09FEB2003	5	3	0	3					
		10FEB2003	6	3	0	3					
		11FEB2003	7	3	0	3					
		12FEB2003	8		0	4					
		13FEB2003	9	4	0	4					
		14FEB2003	10	4	0	4					
		15FEB2003	11	4	0	4					
		16FEB2003	12	4	0	4					
		17FEB2003	13	4	0	4					
		18FEB2003	14	4	0	4					
		19FEB2003	15	4	0	4					
		20FEB2003	16	4	0	4					
		21FEB2003	17	4	0	4					
		22FEB2003	18	4	0	4					
		23FEB2003	19	4	0	4					
		24FEB2003	20	4	0	4					
		25FEB2003	21	4	0	4					
		26FEB2003	22	4	0	4					
		27FEB2003	23	4	0	4					
		28FEB2003	24	4	0	4					
		01MAR2003	25	4	0	4					
		02MAR2003	26	4	0	4					
		03MAR2003	27	4	0	4					
		04MAR2003	28	4	0	4					
		05MAR2003	29	4	0	4					
		06MAR2003	30	4	1	3					DOSE REDUCTION

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0005023	07MAR2003	31	4	1	3					
		08MAR2003	32	4	1	3					
		09MAR2003	33	4	1	3					
		10MAR2003	34	4	1	3					
		11MAR2003	35	4	1	3					
		12MAR2003	36	4	1	3					
		13MAR2003	37	4	1	3					
		14MAR2003	38	4	1	3					
		15MAR2003	39	4	1	3					
		16MAR2003	40	4	1	3					
		17MAR2003	41	4	1	3					
		18MAR2003	42	4	1	3					
		19MAR2003	43	4	1	3					
		20MAR2003	44	4	1	3					
		21MAR2003	45	4	1	3					
		22MAR2003	46	4	1	3					
		23MAR2003	47	4	1	3					
		24MAR2003	48	4	1	3					
		25MAR2003	49		1	3					
		26MAR2003	50	4	1	3					
		27MAR2003	51	4	1	3					
		28MAR2003	52	4	1	3					
		29MAR2003	53	4	1	3					
		30MAR2003	54	4	1	3					
		31MAR2003	55	4	1	3					
		01APR2003	56	4	1	3	YES	0	56	100	
	E0005034	15APR2003	1	2	0	2					
		16APR2003	2	1	0	1					
		17APR2003	3	1	0	1					
		18APR2003	4	2	0	2					
		19APR2003	5	3	0	3					
		20APR2003	6	3	0	3					
		21APR2003	7	3	0	3					
		22APR2003	8		0	4					
		23APR2003	9	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0005034	24APR2003	10	4	0	4					
		25APR2003	11	4	0	4					
		26APR2003	12	4	0	4					
		27APR2003	13	4	0	4					
		28APR2003	14	4	0	4					
		29APR2003	15	4	0	4					
		30APR2003	16		0	4					
		01MAY2003	17	4	0	4					
		02MAY2003	18	4	0	4					
		03MAY2003	19	4	0	4					
		04MAY2003	20	4	0	4					
		05MAY2003	21	4	0	4					
		06MAY2003	22	4	0	4					
		07MAY2003	23	4	0	4					
		08MAY2003	24	4	0	4					
		09MAY2003	25	4	0	4					
		10MAY2003	26	4	0	4					
		11MAY2003	27	4	0	4					
		12MAY2003	28	4	0	4					
		13MAY2003	29	4	0	4					
		14MAY2003	30	4	0	4					
		15MAY2003	31	4	0	4					
		16MAY2003	32	4	0	4					
		17MAY2003	33	4	0	4					
		18MAY2003	34	4	0	4					
		19MAY2003	35	4	0	4					
		20MAY2003	36		0	4					
		21MAY2003	37		0	4					
		22MAY2003	38	4	0	4					
		23MAY2003	39	4	0	4					
		24MAY2003	40	4	0	4					
		25MAY2003	41	4	0	4					
		26MAY2003	42	4	0	4					
		27MAY2003	43	4	0	4					
		28MAY2003	44	4	0	4					
		29MAY2003	45	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0005034	30MAY2003	46	4	0	4					
		31MAY2003	47	4	0	4					
		01JUN2003	48	4	0	4					
		02JUN2003	49	4	0	4					
		03JUN2003	50	4	0	4					
		04JUN2003	51		0	4					
		05JUN2003	52	4	0	4					
		06JUN2003	53	4	0	4					
		07JUN2003	54	4	0	4					
		08JUN2003	55	4	0	4	NO	0	55	100	
	E0005041	24JUN2003	1	2	0	2					
		25JUN2003	2	1	0	1					
		26JUN2003	3	1	0	1					
		27JUN2003	4	2	0	2					
		28JUN2003	5	3	0	3					
		29JUN2003	6	3	0	3					
		30JUN2003	7	3	0	3					
		01JUL2003	8	4	0	4					
		02JUL2003	9	4	0	4					
		03JUL2003	10	4	0	4					
		04JUL2003	11	4	0	4					
		05JUL2003	12	4	0	4					
		06JUL2003	13	4	0	4					
		07JUL2003	14	4	0	4					
		08JUL2003	15	4	0	4					
		09JUL2003	16	4	0	4					
		10JUL2003	17	4	0	4					
		11JUL2003	18	4	0	4					
		12JUL2003	19	4	0	4					
		13JUL2003	20	4	0	4					
		14JUL2003	21	4	0	4					
		15JUL2003	22		0	4					
		16JUL2003	23	4	0	4					
		17JUL2003	24	4	0	4					
		18JUL2003	25	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0005041	19JUL2003	26	4	0	4					
		20JUL2003	27	4	0	4					
		21JUL2003	28	4	0	4					
		22JUL2003	29	4	0	4					
		23JUL2003	30	4	0	4					
		24JUL2003	31	4	0	4					
		25JUL2003	32	4	0	4					
		26JUL2003	33	4	0	4					
		27JUL2003	34	4	0	4					
		28JUL2003	35	4	0	4					
		29JUL2003	36	4	0	4					
		30JUL2003	37	4	0	4					
		31JUL2003	38	4	0	4					
		01AUG2003	39	4	0	4					
		02AUG2003	40	4	0	4					
		03AUG2003	41	4	0	4					
		04AUG2003	42	4	0	4					
		05AUG2003	43	4	0	4					
		06AUG2003	44	4	0	4					
		07AUG2003	45	4	0	4					
		08AUG2003	46	4	0	4					
		09AUG2003	47	4	0	4					
		10AUG2003	48	4	4	0					MISSED DOSE
		11AUG2003	49	4	0	4					
		12AUG2003	50	4	0	4					
		13AUG2003	51	4	0	4					
		14AUG2003	52	4	0	4					
		15AUG2003	53	4	0	4					
		16AUG2003	54	4	0	4					
		17AUG2003	55	4	0	4	NO	0	54	98.1	
	E0007004	30JAN2003	1	2	0	2					
		31JAN2003	2	1	0	1					
		01FEB2003	3	1	0	1					
		02FEB2003	4	2	0	2					
		03FEB2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0007004	04FEB2003	6	3	0	3					
		05FEB2003	7	3	0	3					
		06FEB2003	8		0	4					
		07FEB2003	9	4	0	4					
		08FEB2003	10	4	0	4					
		09FEB2003	11	4	0	4					
		10FEB2003	12	4	0	4					
		11FEB2003	13	4	0	4	NO	0	13	100	
	E0007010	18APR2003	1	2	0	2					
		19APR2003	2	1	0	1					
		20APR2003	3	1	0	1					
		21APR2003	4	2	0	2					
		22APR2003	5	3	0	3					
		23APR2003	6	3	0	3					
		24APR2003	7	3	0	3					
		25APR2003	8	4	0	4					
		26APR2003	9	4	0	4					
		27APR2003	10	4	0	4					
		28APR2003	11	4	0	4					
		29APR2003	12	4	0	4					
		30APR2003	13	4	0	4					
		01MAY2003	14	4	0	4					
		02MAY2003	15	4	0	4					
		03MAY2003	16	4	0	4					
		04MAY2003	17	4	0	4					
		05MAY2003	18	4	0	4					
		06MAY2003	19	4	0	4					
		07MAY2003	20	4	0	4					
		08MAY2003	21	4	0	4					
		09MAY2003	22	4	0	4					
		10MAY2003	23	4	0	4					
		11MAY2003	24	4	0	4					
		12MAY2003	25	4	0	4					
		13MAY2003	26	4	0	4					
		14MAY2003	27	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0007010	15MAY2003	28	4	1	3					TOOK FROM WRONG DAY TOOK ONE PILL FROM LAST COLUMN IN EXTRA DAY. INSTEAD IN ERROR
		16MAY2003	29	4	0	5					TOOK FROM WRONG DAY TOOK ONE PILL FROM LAST COLUMN ON 5/15/03
		17MAY2003	30	4	0	4					
		18MAY2003	31	4	0	4					
		19MAY2003	32	4	0	4					
		20MAY2003	33	4	0	4					
		21MAY2003	34	4	0	4					
		22MAY2003	35	4	0	4					
		23MAY2003	36	4	0	4					
		24MAY2003	37	4	0	4					
		25MAY2003	38	4	0	4					
		26MAY2003	39	4	0	4					
		27MAY2003	40	4	0	4					
		28MAY2003	41	4	0	4					
		29MAY2003	42	4	0	4					
		30MAY2003	43	4	0	4					
		31MAY2003	44	4	0	4					
		01JUN2003	45	4	0	4					
		02JUN2003	46	4	0	4					
		03JUN2003	47	4	4	0					6-3-03 0 TABS WERE RETURNED 4 TABS RETURNED FOR 6-5-03. PT MISSED DOSE ON 6-3-03 TOOK ON 6-4-03 ON 6-4-03 TOOK ON 6-5-03
		04JUN2003	48	4	0	4					
		05JUN2003	49		0	4					6-3-03 0 TABS WERE RETURNED 4 TABS RETURNED FOR 6-5-03. PT MISSED DOSE ON 6-3-03 TOOK ON 6-4-03 ON 6-4-03 TOOK ON 6-5-03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0007010	06JUN2003	50	4	0	4					
		07JUN2003	51	4	0	4					
		08JUN2003	52	4	0	4					
		09JUN2003	53	4	0	4					
		10JUN2003	54	4	0	4					
		11JUN2003	55	4	0	4					
		12JUN2003	56	4	4	0					
		13JUN2003	57		0	4					SUBJECT RETURNED 2 DAYS LATER THAN SCHEDULE
		14JUN2003	58		0	4	NO	0	56	96.8	SUBJECT MISSED DOSE ON 6-12-03, TOOK 6-12-03 DOSE ON 6-13-03 TOOK 6-13-03 DOSE ON 6-14-03 TOOK 6-14-03 DOSE ON 6-15-03 LAST DOSE OF STUDY DRUG TAKEN ON 6/15/03
	E0007012	16MAY2003	1	2	0	2					
		17MAY2003	2	1	0	1					
		18MAY2003	3	1	0	1					
		19MAY2003	4	2	0	2					
		20MAY2003	5	3	0	3					
		21MAY2003	6	3	0	3					
		22MAY2003	7	3	0	3					
		23MAY2003	8	4	0	4					
		24MAY2003	9	4	0	4					
		25MAY2003	10	4	0	4					
		26MAY2003	11	4	0	4					
		27MAY2003	12	4	0	4					
		28MAY2003	13	4	0	4					
		29MAY2003	14	4	4	0					CAME ONE DAY EARLY
		29MAY2003	14	4	4	0					LEFT DRUG IN OTHER CAR - MISSED DOSE
		30MAY2003	15	4	0	4					
		31MAY2003	16	4	0	4					
		01JUN2003	17	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0007012	02JUN2003	18	4	0	4					
		03JUN2003	19	4	0	4					
		04JUN2003	20	4	0	4					
		05JUN2003	21		0	4					
		06JUN2003	22	4	0	4					
		07JUN2003	23	4	0	4					
		08JUN2003	24	4	0	4					
		09JUN2003	25	4	0	4					
		10JUN2003	26	4	0	4					
		11JUN2003	27	4	0	4					
		12JUN2003	28	4	0	4					
		13JUN2003	29	4	0	4					
		14JUN2003	30	4	0	4					
		15JUN2003	31	4	0	4					
		16JUN2003	32	4	0	4					
		17JUN2003	33	4	0	4					
		18JUN2003	34	4	0	4					
		19JUN2003	35	4	4	0					MISSED DOSE
		20JUN2003	36	4	0	4					
		21JUN2003	37	4	0	4					
		22JUN2003	38	4	0	4					
		23JUN2003	39	4	0	4					
		24JUN2003	40	4	0	4					
		25JUN2003	41	4	0	4					PT RETURNED EARLY
		26JUN2003	42	4	0	4					
		27JUN2003	43	4	0	4					
		28JUN2003	44	4	0	4					
		29JUN2003	45	4	0	4					
		30JUN2003	46	4	0	4					
		01JUL2003					NO	0	44	95.3	EARLY TERM
	E0009007	03FEB2003	1	2	0	2					
		04FEB2003	2	1	0	1					
		05FEB2003	3	1	0	1					
		06FEB2003	4	2	0	2					
		07FEB2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0009007	08FEB2003	6	3	0	3					
		09FEB2003	7	3	0	3					
		10FEB2003	8	4	0	4					
		11FEB2003	9	4	0	4					
		12FEB2003	10	4	0	4					
		13FEB2003	11	4	0	4					
		14FEB2003	12	4	0	4					
		15FEB2003	13	4	0	4					
		16FEB2003	14	4	0	4					
		17FEB2003	15	4	0	4					NOTE THAT DAY 15 - 21 BLISTERCARD WAS NOT DISPENSED INADVERTENTLY, DAYS 22 - 28 BLISTER CARD DISPENSED AT THIS VISIT.
		18FEB2003	16	4	0	4					
		19FEB2003	17	4	0	4					
		20FEB2003	18	4	4	0					PT. MISSED DOSING ON 2/20/03, TOOK ON 2/21/03
		21FEB2003	19	4	0	4					PT. TOOK 2/22/03 DOSE
		22FEB2003	20	4	0	4					PT. TOOK 2/23/03 DOSE
		23FEB2003	21	4	0	4					PT. TOOK 2/24/03 DOSE
		24FEB2003	22		0	4					
		25FEB2003	23	4	0	4					BLISTER CARD DAYS 22 - 28 WAS DISPENSED ON 2/17/03. DAYS 29 - 35 BLISTER CARD WAS DISPENSED AT THIS VISIT ON 2/25/03.
		26FEB2003	24	4	0	4					
		27FEB2003	25	4	0	4					
		28FEB2003	26	4	0	4					
		01MAR2003	27	4	0	4					
		02MAR2003	28	4	0	4	NO	0	27	96	
	E0009008	12FEB2003	1	2	0	2					
		13FEB2003	2	1	0	1					
		14FEB2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0009008	15FEB2003	4	2	0	2					
		16FEB2003	5	3	0	3					
		17FEB2003	6	3	0	3					
		18FEB2003	7	3	0	3					
		19FEB2003	8	4	0	4					
		20FEB2003	9	4	0	4					
		21FEB2003	10	4	0	4					
		22FEB2003	11	4	0	4					
		23FEB2003	12	4	0	4					
		24FEB2003	13	4	0	4					
		25FEB2003	14	4	0	4					
		26FEB2003	15	4	0	4					
		27FEB2003	16	4	0	4					
		28FEB2003	17	4	0	4					
		01MAR2003	18	4	0	4					
		02MAR2003	19	4	0	4					
		03MAR2003	20	4	0	4					
		04MAR2003	21	4	0	4					
		05MAR2003	22	4	0	4					
		06MAR2003	23	4	0	4					
		07MAR2003	24	4	0	4					
		08MAR2003	25	4	0	4					
		09MAR2003	26	4	0	4					
		10MAR2003	27	4	0	4					
		11MAR2003	28	4	0	4					
		12MAR2003	29	4	0	4					
		13MAR2003	30	4	0	4					
		14MAR2003	31	4	0	4					
		15MAR2003	32	4	0	4					
		16MAR2003	33	4	0	4					
		17MAR2003	34	4	0	4					
		18MAR2003	35	4	0	4					
		19MAR2003	36	4	0	4					
		20MAR2003	37	4	0	4					
		21MAR2003	38	4	0	4					
		22MAR2003	39	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0009008	23MAR2003	40	4	0	4					
		24MAR2003	41	4	0	4					
		25MAR2003	42		0	4					
		26MAR2003	43	4	0	4					
		27MAR2003	44	4	0	4					
		28MAR2003	45	4	0	4					
		29MAR2003	46	4	0	4					
		30MAR2003	47	4	0	4					
		31MAR2003	48	4	0	4					
		01APR2003	49	4	0	4					
		02APR2003	50		0	4					
		03APR2003	51	4	0	5					PT TOOK ONE TAB BECAUSE PT. DROPPED 1 TAB ON 4/2/03 AND TRASHED IT.
		04APR2003	52	4	0	4					
		05APR2003	53	4	0	4					
		06APR2003	54	4	0	4					
		07APR2003	55	4	0	4	NO	0	55	100	
	E0011001	01NOV2002	1	2	0	2					
		02NOV2002	2	1	0	1					
		03NOV2002	3	1	0	1					
		04NOV2002	4	2	0	2					
		05NOV2002	5	3	0	3					
		06NOV2002	6	3	0	3					
		07NOV2002	7	3	0	3					
		08NOV2002	8	4	0	4					PT. TOOK DOSAGE FROM EXTRA DAY 2.
		09NOV2002	9	4	0	4					
		10NOV2002	10	4	0	4					
		11NOV2002	11	4	0	4					
		12NOV2002	12	4	0	4					
		13NOV2002	13	4	0	4					
		14NOV2002	14	4	0	4					PT. TOOK DOSAGE FROM EXTRA DAY 2.
		15NOV2002	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011001	16NOV2002	16	4	0	4					TOOK DOSAGE ON 11/08/02 FROM EXTRA DAY INSTEAD OF FIRST DAY'S DOSAGE OF THE WEEK 2. (IN ERROR)
		17NOV2002	17	4	0	4					
		18NOV2002	18	4	0	4					
		19NOV2002	19	4	0	4					
		20NOV2002	20	4	0	4					
		21NOV2002	21	4	0	4					
		22NOV2002	22	4	0	4					TOOK THIS DOSAGE AS FIRST DAY'S DOSAGE OF WEEK 3 (IN ERROR)
		23NOV2002	23	4	0	4					
		24NOV2002	24	4	0	4					
		25NOV2002	25	4	0	4					
		26NOV2002	26	4	0	4					CARD REDISPENSED BECAUSE PATIENT RETURNED ONE DAY EARLY FOR VISIT.
		27NOV2002	27	4	0	4					
		28NOV2002	28	4	0	4					
		29NOV2002	29	4	0	4					
		30NOV2002	30	4	0	4					
		01DEC2002	31	4	0	4					
		02DEC2002	32	4	0	4					
		03DEC2002	33	4	0	4					
		04DEC2002	34	4	0	4					
		05DEC2002	35	4	0	4					
		06DEC2002	36	4	0	4					
		07DEC2002	37	4	0	4					
		08DEC2002	38	4	0	4					
		09DEC2002	39	4	0	4					
		10DEC2002	40	4	0	4					
		11DEC2002	41	4	0	4					
		12DEC2002	42	4	0	4					
		13DEC2002	43	4	0	4					
		14DEC2002	44	4	0	4					
		15DEC2002	45	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011001	16DEC2002	46	4	0	4					
		17DEC2002	47	4	0	4					
		18DEC2002	48	4	0	4					
		19DEC2002	49	4	0	4					
		20DEC2002	50	4	0	4					
		21DEC2002	51	4	0	4					
		22DEC2002	52	4	0	4					
		23DEC2002	53	4	0	4					
		24DEC2002	54	4	0	4					
		25DEC2002					NO	0	54	100	PT. MISSED DOSAGE
	E0011011	20FEB2003	1	2	0	2					
		21FEB2003	2	1	0	1					
		22FEB2003	3	1	0	1					
		23FEB2003	4	2	0	2					
		24FEB2003	5	3	0	3					
		25FEB2003	6	3	0	3					
		26FEB2003	7	4	0	4					PATIENT CAME IN ONE DAY EARLY FOR APPOINTMENT
		27FEB2003	8	4	0	4					
		28FEB2003	9	4	0	4					
		01MAR2003	10	4	0	4					
		02MAR2003	11	4	0	4					
		03MAR2003	12	4	0	4					
		04MAR2003	13	4	2	2					PATIENT FORGOT TO TAKE SECOND HALF OF DOSAGE
		05MAR2003	14	4	0	4					
		06MAR2003	15	4	0	4					
		07MAR2003	16	4	0	4					
		08MAR2003	17	4	0	4					
		09MAR2003	18	4	0	4					
		10MAR2003	19	4	0	4					
		11MAR2003	20	4	0	4					
		12MAR2003	21	4	0	4					
		13MAR2003	22	4	0	4					
		14MAR2003	23	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011011	15MAR2003	24	4	0	4					
		16MAR2003	25	4	0	4					
		17MAR2003	26	4	0	4					
		18MAR2003	27	4	0	4					
		19MAR2003	28	4	0	4					
		20MAR2003	29	4	0	4					
		21MAR2003	30	4	0	4					
		22MAR2003	31	4	0	4					
		23MAR2003	32	4	0	4					
		24MAR2003	33	4	0	4					
		25MAR2003	34	4	0	4					
		26MAR2003	35	4	0	4					
		27MAR2003	36	4	0	4					
		28MAR2003	37	4	0	4					
		29MAR2003	38	4	0	4					
		30MAR2003	39	4	0	4					
		31MAR2003	40	4	0	4					
		01APR2003	41	4	0	4					
		02APR2003	42	4	0	4					
		03APR2003	43	4	0	4					
		04APR2003	44	4	0	4					
		05APR2003	45	4	0	4					
		06APR2003	46	4	0	4					
		07APR2003	47	4	0	4					
		08APR2003	48	4	0	4					
		09APR2003	49	4	0	4					
		10APR2003	50	4	0	4					
		11APR2003	51	4	0	4					
		12APR2003	52	4	0	4					
		13APR2003	53	4	0	4					
		14APR2003	54	4	0	4					
		15APR2003	55	4	0	4	NO	0	55	100	
	E0011013	17APR2003	1	2	0	2					
		18APR2003	2	1	0	1					
		19APR2003	3	1	0	1					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011013	20APR2003	4	2	0	2					
		21APR2003	5	3	0	3					
		22APR2003	6	3	0	3					
		23APR2003	7	3	0	3					
		24APR2003	8	4	0	4					
		25APR2003	9	4	0	4					
		26APR2003	10	4	0	4					
		27APR2003	11	4	0	4					
		28APR2003	12	4	0	4					
		29APR2003	13	4	0	4					
		30APR2003	14	4	0	4					
		01MAY2003	15	4	0	4					
		02MAY2003	16	4	0	4					
		03MAY2003	17	4	0	4					
		04MAY2003	18	4	0	4					
		05MAY2003	19	4	0	4					
		06MAY2003	20	4	0	4					
		07MAY2003	21	4	0	4					
		08MAY2003	22	4	0	4					
		09MAY2003	23	4	0	4					
		10MAY2003	24	4	0	4					
		11MAY2003	25	4	0	4					
		12MAY2003	26	4	0	4					
		13MAY2003	27	4	0	4					
		14MAY2003	28	4	0	4					
		15MAY2003	29	4	0	4					
		16MAY2003	30	4	0	4					
		17MAY2003	31	4	0	4					
		18MAY2003	32	4	0	4					
		19MAY2003	33	4	0	4					
		20MAY2003	34	4	0	4					
		21MAY2003	35	4	0	4					
		22MAY2003	36	4	0	4					
		23MAY2003	37	4	0	4					
		24MAY2003	38	4	0	4					
		25MAY2003	39	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011013	26MAY2003	40	4	0	4					
		27MAY2003	41	4	0	4					
		28MAY2003	42	4	0	4					
		29MAY2003	43	4	0	4					
		30MAY2003	44	4	0	4					
		31MAY2003	45	4	0	4					
		01JUN2003	46	4	0	4					
		02JUN2003	47	4	0	4					
		03JUN2003	48	4	0	4					
		04JUN2003	49	4	0	4					
		05JUN2003	50	4	0	4					
		06JUN2003	51	4	0	4					
		07JUN2003	52	4	0	4					
		08JUN2003	53	4	0	4					
		09JUN2003	54	4	0	4					
		10JUN2003	55	4	0	4					
		11JUN2003	56	4	0	4	NO	0	56	100	
	E0011014	07APR2003	1	2	0	2					
		08APR2003	2	1	0	1					
		09APR2003	3	1	0	1					
		10APR2003	4	2	0	2					
		11APR2003	5	3	0	3					
		12APR2003	6	3	0	3					
		13APR2003	7	3	0	3					
		14APR2003	8	4	0	4					BLISTER CARD NOT RETURNED. SUBJECT REPORTED TAKING ALL DOSES.
		15APR2003	9	4	0	4					
		16APR2003	10	4	0	4					
		17APR2003	11	4	0	4					
		18APR2003	12	4	0	4					
		19APR2003	13	4	0	4					
		20APR2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011014	21APR2003	15		0	4					UNKNOWN SIC BLISTER CARD NOT RETURNED. SUBJECT REPORTED TAKING ALL DOSES.
		22APR2003	16		0	4	NO	0	16	100	
	E0011021	22MAY2003	1	2	0	2					
		23MAY2003	2	1	0	1					
		24MAY2003	3	1	0	1					
		25MAY2003	4	2	0	2					
		26MAY2003	5	3	0	3					
		27MAY2003	6	3	0	3					
		28MAY2003	7	3	0	3					
		29MAY2003	8	4	0	4					
		30MAY2003	9	4	0	4					
		31MAY2003	10	4	0	4					
		01JUN2003	11	4	0	4					
		02JUN2003	12	4	0	4					
		03JUN2003	13	4	0	4					
		04JUN2003	14	4	0	4					PATIENT DROPPED 1 YELLOW AND ONE WHITE PILL IN SINK. PATIENT TOOK CORRESPONDING PILLS FROM 6/6/03 DOSE.
		05JUN2003	15	4	0	4					
		06JUN2003	16	4	0	4					PATIENT TOOK ONE YELLOW AND ONE WHITE PILL TO REPLACE LOST PILLS ON 6/4/03.
		07JUN2003	17	4	0	4					
		08JUN2003	18	4	0	4					
		09JUN2003	19	4	4	0					PATIENT FORGOT TO TAKE DOSAGE.
		10JUN2003	20	4	0	4					
		11JUN2003	21	4	0	4					
		12JUN2003	22	4	0	4					
		13JUN2003	23	4	0	4					
		14JUN2003	24	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011021	15JUN2003	25	4	0	4					
		16JUN2003	26	4	0	4					
		17JUN2003	27	4	0	4					
		18JUN2003	28	4	0	4					
		19JUN2003	29		0	4					PATIENT TOOK THIS DOSE BECAUSE HER VISIT 6 WAS ON 6-20-03.
		20JUN2003	30	4	0	4					
		21JUN2003	31	4	0	4					
		22JUN2003	32	4	0	4					
		23JUN2003	33	4	0	4					
		24JUN2003	34	4	0	4					
		25JUN2003	35	4	0	4					
		26JUN2003	36	4	0	4					
		27JUN2003	37	4	0	4					
		28JUN2003	38	4	0	4					
		29JUN2003	39	4	0	4					
		30JUN2003	40	4	0	4					
		01JUL2003	41	4	0	4					PATIENT TOOK THE 7-2-03 DOSE ON 7-1-03
		02JUL2003	42	4	0	4					
		03JUL2003	43	4	0	4					PATIENT DID NOT TAKE THE 7-3-03 DOSE BECAUSE PATIENT'S VISIT WAS ON 7-2-03
		04JUL2003	44	4	0	4					
		05JUL2003	45	4	0	4					
		06JUL2003	46	4	0	4					
		07JUL2003	47	4	0	4					
		08JUL2003	48	4	0	4					
		09JUL2003	49		0	4					
		10JUL2003	50	4	0	4					
		11JUL2003	51	4	0	4					
		12JUL2003	52	4	0	4					
		13JUL2003	53	4	0	4					
		14JUL2003	54	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0011021	15JUL2003	55	4	0	4					
		16JUL2003	56	4	0	4					
		17JUL2003	57		0	4					
		18JUL2003	58		1	3	NO	0	57	98.2	PATIENT THOUGHT SHE TOOK ALL FOUR PILLS BUT ONE REMAINS
	E0013008	26MAR2003	1	2	0	2					
		27MAR2003	2	1	0	1					
		28MAR2003	3	1	0	1					
		29MAR2003	4	2	0	2					
		30MAR2003	5	3	0	3					
		31MAR2003	6	3	0	3					
		01APR2003	7	3	0	3					
		02APR2003	8	4	0	4					
		03APR2003	9	4	0	4					
		04APR2003	10	4	0	4					
		05APR2003	11	4	0	4					
		06APR2003	12	4	0	4					
		07APR2003	13	4	0	4					
		08APR2003	14	4	0	4					
		09APR2003	15	4	0	4					
		10APR2003	16	4	0	4					
		11APR2003	17	4	0	4					
		12APR2003	18	4	0	4					
		13APR2003	19	4	0	4					
		14APR2003	20	4	0	4					
		15APR2003	21	4	0	4					
		16APR2003	22		0	4					
		17APR2003	23	4	0	4					
		18APR2003	24	4	0	4					
		19APR2003	25	4	0	4					
		20APR2003	26	4	0	4					
		21APR2003	27	4	0	4					
		22APR2003	28	4	0	4					
		23APR2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0013008	24APR2003	30	4	0	4					
		25APR2003	31	4	0	4					
		26APR2003	32	4	0	4					
		27APR2003	33	4	0	4					
		28APR2003	34	4	0	4					
		29APR2003	35	4	0	4					
		30APR2003	36	4	0	4					
		01MAY2003	37	4	0	4					
		02MAY2003	38	4	0	4					
		03MAY2003	39	4	0	4					
		04MAY2003	40	4	0	4					
		05MAY2003	41	4	0	4					
		06MAY2003	42	4	0	4					
		07MAY2003	43	4	0	4					
		08MAY2003	44	4	0	4					
		09MAY2003	45	4	0	4					
		10MAY2003	46	4	0	4					
		11MAY2003	47	4	0	4					
		12MAY2003	48	4	0	4					
		13MAY2003	49	4	0	4					
		14MAY2003	50	4	0	4					
		15MAY2003	51	4	0	4					
		16MAY2003	52	4	0	4					
		17MAY2003	53	4	0	4					
		18MAY2003	54	4	0	4	NO	0	54	100	
	E0014001	26FEB2003	1	2	0	2					
		27FEB2003	2	1	0	1					
		28FEB2003	3	1	0	1					
		01MAR2003	4	2	0	2					
		02MAR2003	5	3	0	3					
		03MAR2003	6	3	0	3					
		04MAR2003	7	3	0	3					
		05MAR2003	8	4	0	4					
		06MAR2003	9	4	0	4					
		07MAR2003	10	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0014001	08MAR2003	11	4	0	4					
		09MAR2003	12	4	0	4					
		10MAR2003	13	4	0	4					
		11MAR2003	14	4	0	4					
		12MAR2003	15	4	0	4					
		13MAR2003	16	4	0	4					
		14MAR2003	17	4	0	4					
		15MAR2003	18	4	0	4					
		16MAR2003	19	4	0	4					
		17MAR2003	20	4	0	4					
		18MAR2003	21	4	0	4					
		19MAR2003	22	4	0	4					
		20MAR2003	23	4	0	4					
		21MAR2003	24	4	0	4					
		22MAR2003	25	4	0	4					
		23MAR2003	26	4	0	4					
		24MAR2003	27	4	0	4					
		25MAR2003	28	4	0	4					
		26MAR2003	29	4	4	0					HELD WHILE IN HOSPITAL
		27MAR2003	30	4	4	0					
		28MAR2003	31	4	4	0					
		29MAR2003	32	4	0	4					
		30MAR2003	33	4	0	4					
		31MAR2003	34	4	0	4	NO	0	31	90.2	
	E0014013	27MAY2003	1	2	0	2					
		28MAY2003	2	1	0	1					
		29MAY2003	3	1	0	1					
		30MAY2003	4	2	0	2					
		31MAY2003	5	3	0	3					
		01JUN2003	6	3	0	3					
		02JUN2003	7	3	0	3					
		03JUN2003	8		0	4					
		04JUN2003	9	4	0	4					
		05JUN2003	10	4	0	4					
		06JUN2003	11	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0014013	07JUN2003	12	4	0	4					
		08JUN2003	13	4	0	4					
		09JUN2003	14	4	0	4					
		10JUN2003	15	4	0	4					
		11JUN2003	16		0	4					
		12JUN2003	17		0	4					
		13JUN2003	18	4	0	4					
		14JUN2003	19	4	0	4					
		15JUN2003	20	4	0	4					
		16JUN2003	21	4	0	4					
		17JUN2003	22	4	0	4					
		18JUN2003	23	4	0	4					
		19JUN2003	24	4	4	0					FORGOT
		20JUN2003	25	4	0	4					
		21JUN2003	26	4	0	4					
		22JUN2003	27	4	0	4					
		23JUN2003	28	4	0	4					
		24JUN2003	29	4	0	4					
		25JUN2003	30	4	0	4					
		26JUN2003	31	4	0	4					
		27JUN2003	32	4	0	4					
		28JUN2003	33	4	0	4					
		29JUN2003	34	4	0	4					
		30JUN2003	35	4	0	4					
		01JUL2003	36	4	0	4					
		02JUL2003	37	4	0	4					
		03JUL2003	38	4	0	4					
		04JUL2003	39	4	0	4					
		05JUL2003	40	4	0	4					
		06JUL2003	41	4	0	4					
		07JUL2003	42	4	0	4					
		08JUL2003	43	4	0	4					
		09JUL2003	44		4	0					FORGOT DOSE
		10JUL2003	45	4	4	0					FORGOT DOSE
		11JUL2003	46	4	0	4					
		12JUL2003	47	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0014013	13JUL2003	48	4	0	4					
		14JUL2003	49	4	0	4					
		15JUL2003	50	4	0	4					
		16JUL2003	51	4	0	4					
		17JUL2003	52	4	0	4					
		18JUL2003	53	4	0	4					
		19JUL2003	54	4	0	4					
		20JUL2003	55	4	0	4					
		21JUL2003	56	4	0	4					
		22JUL2003	57	4	0	4	NO	0	54	94.4	
	E0014014										WEEK 7 CARD NOT DISPENSED
		10JUN2003	1	2	0	2					
		11JUN2003	2	1	0	1					
		12JUN2003	3	1	0	1					
		13JUN2003	4	2	0	2					
		14JUN2003	5	3	0	3					
		15JUN2003	6	3	0	3					
		16JUN2003	7	3	0	3					
		17JUN2003	8		0	4					
		18JUN2003	9	4	4	4					PATIENT FORGOT STUDY MEDS AT VISIT 2 AND DIDN'T RETURN THEM UNTIL VISIT 3.
		18JUN2003	9	4	4	4					PT POPPED 4 TABS 6/18 FROM DAYS 8 - 14 BLISTER PAK W/GLASS OF MILK. MILK WAS SOUR & HE SPIT EVERYTHING OUT INCLUDING PILLS & THEY WENT DOWN THE SINK. HE TOOK EXTRA FROM DAY 1-7 PAK (LAST ROW) INSTEAD!
		19JUN2003	10	4	0	4					
		20JUN2003	11	4	0	4					
		21JUN2003	12	4	0	4					
		22JUN2003	13	4	0	4					
		23JUN2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0014014	24JUN2003	15	4	0	4					
		25JUN2003	16	4	0	4					
		26JUN2003	17	4	0	4					
		27JUN2003	18	4	0	4					
		28JUN2003	19	4	0	4					
		29JUN2003	20	4	0	4					
		30JUN2003	21	4	0	4					
		01JUL2003	22		0	4					
		02JUL2003	23		0	4					
		03JUL2003	24	4	0	4					
		04JUL2003	25	4	4	0					FORGOT
		05JUL2003	26	4	0	4					
		06JUL2003	27	4	0	4					
		07JUL2003	28	4	0	4					
		08JUL2003	29	4	0	4					
		09JUL2003	30	4	0	4					
		10JUL2003	31	4	0	4					
		11JUL2003	32	4	0	4					
		12JUL2003	33	4	0	4					
		13JUL2003	34	4	0	4					
		14JUL2003	35	4	0	4					
		15JUL2003	36	4	0	4					
		16JUL2003	37	4	0	4					
		17JUL2003	38		0	4					
		18JUL2003	39	4	0	4					TOOK FROM THIS CARD WHEN DAYS 36 - 42 RAN OUT. TOOK ON 7/29/03.
		19JUL2003	40	4	0	4					
		20JUL2003	41	4	0	4					
		21JUL2003	42	4	0	4					
		22JUL2003	43	4	0	4					
		23JUL2003	44	4	0	4					
		24JUL2003	45	4	4	0					PT. MISSED 7/24 AND 7/26 DOSES. TOOK ON 7/25/03
		25JUL2003	46		0	4					TOOK ON 7/27/03
		26JUL2003	47		4	0					TOOK ON 7/28/03

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0014014	27JUL2003	48			0					
		28JUL2003	49			0					
		29JUL2003	50			0					
		30JUL2003	51	4	0	4					
		31JUL2003	52	4	0	4					
		01AUG2003	53	4	0	4					
		02AUG2003	54	4	0	4					
		03AUG2003	55	4	0	4					
		04AUG2003	56	4	0	4					
		05AUG2003	57	4	0	4	NO	0	51	88.8	
	E0015004	02DEC2002	1	2	0	2					
		03DEC2002	2	1	0	1					
		04DEC2002	3	1	0	1					
		05DEC2002	4	2	0	2					
		06DEC2002	5	3	0	3					
		07DEC2002	6	3	0	3					
		08DEC2002	7	3	0	3					
		09DEC2002	8		0	4					
		10DEC2002	9		0	4					
		11DEC2002	10	4	0	4					
		12DEC2002	11	4	0	4					
		13DEC2002	12	4	0	4					
		14DEC2002	13	4	0	4					
		15DEC2002	14	4	0	4					
		16DEC2002	15	4	0	4					
		17DEC2002	16	4	0	4					
		18DEC2002	17	4	0	4					
		19DEC2002	18	4	0	4					
		20DEC2002	19	4	0	4					
		21DEC2002	20	4	0	4					
		22DEC2002	21	4	0	4					
		23DEC2002	22	4	0	4					
		24DEC2002	23	4	0	4					
		25DEC2002	24		0	4					
		26DEC2002	25		0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0015004	27DEC2002	26	4	0	4					
		28DEC2002	27	4	0	4					
		29DEC2002	28	4	0	4					
		30DEC2002	29	4	0	4					
		31DEC2002	30	4	0	4					
		01JAN2003	31	4	0	4					
		02JAN2003	32	4	0	4					
		03JAN2003	33		0	4					
		04JAN2003	34		0	4					PT. MISSED DOSE ON 1/05/03 BECAUSE SHE RAN OUT OF STUDY MEDICATION PRIOR TO RETURNING TO CLINIC ON 01/06/03
		05JAN2003	35			0					
		06JAN2003	36	4	0	4					
		07JAN2003	37	4	0	4					
		08JAN2003	38	4	0	4					
		09JAN2003	39	4	0	4					
		10JAN2003	40	4	0	4					
		11JAN2003	41	4	0	4					
		12JAN2003	42	4	0	4					
		13JAN2003	43	4	0	4					
		14JAN2003	44	4	0	4					
		15JAN2003	45	4	0	4					
		16JAN2003	46		0	4					
		17JAN2003	47	4	0	4					
		18JAN2003	48	4	0	4					
		19JAN2003	49	4	0	4					
		20JAN2003	50	4	0	4					
		21JAN2003	51	4	0	4					
		22JAN2003	52	4	0	4					
		23JAN2003	53	4	0	4					
		24JAN2003	54	4	0	4					
		25JAN2003	55	4	0	4					
		26JAN2003	56	4	0	4					
		27JAN2003	57	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0015004	28JAN2003	58	4	0	4	NO	0	57	98.2	
	E0018005	20DEC2002	1	2	0	2					
		21DEC2002	2	1	0	1					
		22DEC2002	3	1	0	1					
		23DEC2002	4	2	0	2					
		24DEC2002	5	3	0	3					
		25DEC2002	6	3	0	3					
		26DEC2002	7	3	0	3					
		27DEC2002	8	4	0	4					
		28DEC2002	9	4	0	4					
		29DEC2002	10	4	0	4					
		30DEC2002	11	4	0	4					
		31DEC2002	12	4	0	4					
		01JAN2003	13	4	0	4					
		02JAN2003	14	4	0	4					
		03JAN2003	15	4	0	4					
		04JAN2003	16	4	0	4					
		05JAN2003	17	4	0	4					
		06JAN2003	18	4	0	4					
		07JAN2003	19	4	0	4					
		08JAN2003	20	4	0	4					
		09JAN2003	21	4	0	4					
		10JAN2003	22	4	0	4					
		11JAN2003	23	4	0	4					
		12JAN2003	24	4	0	4					
		13JAN2003	25	4	0	4					
		14JAN2003	26	4	0	4					
		15JAN2003	27	4	0	4					
		16JAN2003	28	4	0	4					
		17JAN2003	29	4	0	4					
		18JAN2003	30	4	0	4					
		19JAN2003	31	4	0	4					
		20JAN2003	32	4	0	4					
		21JAN2003	33	4	0	4					
		22JAN2003	34	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0018005	23JAN2003	35	4	0	4					
		24JAN2003	36	4	0	4					
		25JAN2003	37	4	0	4					
		26JAN2003	38	4	0	4					
		27JAN2003	39	4	0	4					
		28JAN2003	40	4	0	4					
		29JAN2003	41	4	0	4					
		30JAN2003	42	4	0	4					
		31JAN2003	43	4	0	4					
		01FEB2003	44	4	0	4					
		02FEB2003	45	4	0	4					
		03FEB2003	46	4	0	4					
		04FEB2003	47	4	0	4					
		05FEB2003	48	4	0	4					
		06FEB2003	49	4	0	4					
		07FEB2003	50	4	0	4					
		08FEB2003	51	4	0	4					
		09FEB2003	52	4	0	4					
		10FEB2003	53	4	0	4					
		11FEB2003	54	4	0	4					
		12FEB2003	55	4	0	4					
		13FEB2003	56	4	0	4	NO	0	56	100	
	E0018012	24JAN2003	1	2	0	2					
		25JAN2003	2	1	0	1					
		26JAN2003	3	1	0	1					
		27JAN2003	4	2	0	2					
		28JAN2003	5	3	0	3					
		29JAN2003	6	3	0	3					
		30JAN2003	7	3	0	3					
		31JAN2003	8	4	0	4					
		01FEB2003	9	4	4	0					PT. MISSED DOSE
		02FEB2003	10	4	0	4					
		03FEB2003	11	4	0	4					
		04FEB2003	12	4	0	4					
		05FEB2003	13	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0018012	06FEB2003	14	4	0	4					
		07FEB2003	15	4	0	4					
		08FEB2003	16	4	0	4					
		09FEB2003	17	4	0	4					
		10FEB2003	18	4	0	4					
		11FEB2003	19	4	0	4					
		12FEB2003	20	4	0	4					
		13FEB2003	21	4	0	4					
		14FEB2003	22	4	0	4					
		15FEB2003	23	4	0	4					
		16FEB2003	24	4	0	4					
		17FEB2003	25	4	0	4					
		18FEB2003	26	4	0	4					
		19FEB2003	27	4	0	4					
		20FEB2003	28	4	0	4					
		21FEB2003	29	4	0	4					
		22FEB2003	30	4	0	4					
		23FEB2003	31	4	0	4					
		24FEB2003	32	4	0	4					
		25FEB2003	33	4	0	4	NO	0	32	96.6	
	E0019019	23JAN2003	1	2	0	2					
		24JAN2003	2	1	0	1					
		25JAN2003	3	1	0	1					
		26JAN2003	4	2	0	2					
		27JAN2003	5	3	0	3					
		28JAN2003	6	3	0	3					
		29JAN2003	7	3	0	3					
		30JAN2003	8	4	4	4					DOSE TAKEN FROM PREVIOUS CARD
		31JAN2003	9	4	4	4					DOSE TAKEN FROM PREVIOUS CARD
		01FEB2003	10	4	0	4					
		02FEB2003	11	4	0	4					
		03FEB2003	12	4	0	4					
		04FEB2003	13	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019019	05FEB2003	14	4	0	4					
		06FEB2003	15	4	0	4					CARD NOT RETURNED - UNABLE TO VERIFY INFORMATION
		07FEB2003	16	4	0	4					
		08FEB2003	17	4	0	4					
		09FEB2003	18	4	0	4					
		10FEB2003	19	4	0	4					
		11FEB2003	20	4	0	4					
		12FEB2003	21	4	0	4					
		13FEB2003	22		0	4					UNKNOWN
		14FEB2003	23		0	4	NO	0	23	100	
	E0019033	18MAR2003	1	2	0	2					
		19MAR2003	2	1	0	1					
		20MAR2003	3	1	0	1					
		21MAR2003	4	2	0	2					
		22MAR2003	5	3	0	3					
		23MAR2003	6	3	0	3					
		24MAR2003	7	3	0	3					
		25MAR2003	8		0	4					
		26MAR2003	9		0	4					
		27MAR2003	10	4	0	4					
		28MAR2003	11	4	0	4					
		29MAR2003	12	4	0	4					
		30MAR2003	13	4	0	4					
		31MAR2003	14	4	0	4					
		01APR2003	15	4	0	4					
		02APR2003	16	4	0	4					
		03APR2003	17	4	0	4					
		04APR2003	18	4	0	4					
		05APR2003	19	4	0	4					
		06APR2003	20	4	0	4					
		07APR2003	21	4	0	4					
		08APR2003	22	4	0	4					
		09APR2003	23	4	0	4					
		10APR2003	24	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019033	11APR2003	25	4	0	4					
		12APR2003	26	4	0	4					
		13APR2003	27	4	0	4					
		14APR2003	28	4	0	4					
		15APR2003	29	4	0	4					
		16APR2003	30	4	0	4					
		17APR2003	31	4	0	4					
		18APR2003	32	4	0	4					
		19APR2003	33	4	0	4					
		20APR2003	34	4	0	4					
		21APR2003	35		0	4					
		22APR2003	36	4	0	4					
		23APR2003	37	4	0	4					
		24APR2003	38	4	0	4					
		25APR2003	39	4	0	4					
		26APR2003	40	4	0	4					
		27APR2003	41	4	0	4					
		28APR2003	42	4	0	4					
		29APR2003	43		0	4					
		30APR2003	44		0	4					
		01MAY2003	45	4	0	4					
		02MAY2003	46	4	0	4					
		03MAY2003	47	4	0	4					
		04MAY2003	48	4	0	4					
		05MAY2003	49	4	0	4					
		06MAY2003	50	4	0	4					
		07MAY2003	51	4	0	4					
		08MAY2003	52	4	0	4					
		09MAY2003	53	4	0	4					
		10MAY2003	54	4	0	4					
		11MAY2003	55	4	0	4					
		12MAY2003	56	4	0	4					
		13MAY2003	57	4	0	4					
		14MAY2003	58	4	0	4	NO	0	58	100	
	E0019038	24APR2003	1	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019038	25APR2003	2	1	0	1					
		26APR2003	3	1	0	1					
		27APR2003	4	2	0	2					
		28APR2003	5	3	0	3					
		29APR2003	6	3	0	3					
		30APR2003	7	3	0	3					
		01MAY2003	8	4	0	4					
		02MAY2003	9	4	0	4					
		03MAY2003	10	4	0	4					
		04MAY2003	11	4	0	4					
		05MAY2003	12	4	0	4					
		06MAY2003	13	4	0	4					
		07MAY2003	14	4	0	8					S. I. C. "POSSIBLE UNINTENTIONAL OVERDOSE"
		08MAY2003	15	4	0	4					
		09MAY2003	16	4	0	4					
		10MAY2003	17	4	0	4					
		11MAY2003	18	4	0	4					
		12MAY2003	19	4	0	4					
		13MAY2003	20	4	0	4					
		14MAY2003	21	4	0	4					
		15MAY2003	22	4	0	4					
		16MAY2003	23	4	0	4					
		17MAY2003	24	4	0	4					
		18MAY2003	25	4	0	4					
		19MAY2003	26	4	0	4					
		20MAY2003	27	4	0	4					
		21MAY2003	28	4	0	4					
		22MAY2003	29	4	0	4					
		23MAY2003	30	4	0	4					
		24MAY2003	31	4	0	4					
		25MAY2003	32	4	0	4					
		26MAY2003	33	4	0	4					
		27MAY2003	34	4	0	4					
		28MAY2003	35	4	0	4					
		29MAY2003	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019038	30MAY2003	37	4	0	4					
		31MAY2003	38	4	0	4					
		01JUN2003	39	4	0	4					
		02JUN2003	40	4	0	4					
		03JUN2003	41	4	0	4					
		04JUN2003	42	4	0	4					
		05JUN2003	43	4	0	4					
		06JUN2003	44	4	0	4					
		07JUN2003	45	4	0	4					
		08JUN2003	46	4	0	4					
		09JUN2003	47	4	0	4					
		10JUN2003	48	4	0	4					
		11JUN2003	49	4	0	4					
		12JUN2003	50	4	0	4					
		13JUN2003	51	4	0	4					
		14JUN2003	52	4	0	4					
		15JUN2003	53	4	0	4					
		16JUN2003	54	4	0	4					
		17JUN2003	55	4	0	4	NO	0	55	102	
	E0019046	26JUN2003	1	2	0	2					
		27JUN2003	2	1	0	1					
		28JUN2003	3	1	0	1					
		29JUN2003	4	2	0	2					
		30JUN2003	5	3	0	3					
		01JUL2003	6	3	0	3					
		02JUL2003	7	3	0	3					
		03JUL2003	8	4	0	4					
		04JUL2003	9	4	0	4					
		05JUL2003	10	4	0	4					
		06JUL2003	11	4	0	4					
		07JUL2003	12	4	0	4					
		08JUL2003	13	4	0	4					
		09JUL2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019046	10JUL2003	15	4	1	7					SUBJECT STATES SHE REMOVED TABS TO KEEP IN PURSE IN CASE SHE "SPENDS NIGHT OUT" AWAY FROM BLISTER PACK. MEDICATION NOT RETURNED FROM 07/10/03.
		10JUL2003	15	4	1	7					DOSE TITRATED DOWN 100MG DUE TO AE - COLUMN 1 SKIPPED.
		11JUL2003	16	4	1	3					
		12JUL2003	17	4	1	3					
		13JUL2003	18	4	1	3					
		14JUL2003	19	4	1	3					
		15JUL2003	20	4	1	3					REPLACED WITH "EXTRA"
		16JUL2003	21	4	1	3					
		17JUL2003	22	4	1	3					DOSED WITH EXTRA ON 7/15/03 BECAUSE DAY 7/15/03 MEDS GOT WET & WERE DISPOSED OF.
		18JUL2003	23	4	1	3					DOSE TITRATED DOWN 100MG
		19JUL2003	24	4	1	3					
		20JUL2003	25	4	1	3					
		21JUL2003	26	4	1	3					
		22JUL2003	27	4	1	3					
		23JUL2003	28	4	1	3					
		24JUL2003	29	4	1	3					
		25JUL2003	30	4	1	3					DOSE TITRATED DOWN 100MG
		26JUL2003	31	4	1	3					
		27JUL2003	32	4	1	3					
		28JUL2003	33	4	1	3					
		29JUL2003	34	4	1	3					
		30JUL2003	35	4	1	3					SUBJECT IN FOR VISIT 7 ONE DAY EARLY
		31JUL2003	36	4	1	3					DOSE TITRATED DOWN 100MG
		01AUG2003	37	4	1	3					
		02AUG2003	38	4	1	3					
		03AUG2003	39	4	1	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019046	04AUG2003	40	4	1	3					
		05AUG2003	41	4	1	3					
		06AUG2003	42	4	1	3					
		07AUG2003	43	4	1	3					DOSE TITRATED DOWN 100MG
		08AUG2003	44	4	1	3					
		09AUG2003	45	4	1	3					
		10AUG2003	46	4	1	3					
		11AUG2003	47	4	1	3					
		12AUG2003	48	4	1	3					
		13AUG2003	49		1	3					
		14AUG2003	50	4	1	3					
		15AUG2003	51	4	1	3					DOSE TITRATED DOWN 100MG
		16AUG2003	52	4	1	3					
		17AUG2003	53	4	1	3					
		18AUG2003	54	4	1	3					
		19AUG2003	55	4	1	3					
		20AUG2003	56	4	1	3	YES	0	56	102	
	E0019047	08JUL2003	1	2	0	2					
		09JUL2003	2	1	0	1					
		10JUL2003	3	1	0	1					
		11JUL2003	4	2	0	2					
		12JUL2003	5	3	0	3					
		13JUL2003	6	3	0	3					
		14JUL2003	7	3	0	3					
		15JUL2003	8		0	4					
		16JUL2003	9		0	4					
		17JUL2003	10	4	0	4					
		18JUL2003	11	4	0	4					
		19JUL2003	12	4	0	4					
		20JUL2003	13	4	0	4					
		21JUL2003	14	4	0	4					
		22JUL2003	15	4	0	4					
		23JUL2003	16	4	0	4					
		24JUL2003	17	4	0	4					
		25JUL2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019047	26JUL2003	19	4	0	4					
		27JUL2003	20	4	0	4					
		28JUL2003	21	4	0	4					
		29JUL2003	22	4	0	4					
		30JUL2003	23	4	0	4					
		31JUL2003	24	4	0	4					
		01AUG2003	25	4	0	4					
		02AUG2003	26	4	0	4					
		03AUG2003	27	4	0	4					
		04AUG2003	28	4	0	4					
		05AUG2003	29	4	0	4					
		06AUG2003	30	4	0	4					
		07AUG2003	31	4	0	4					
		08AUG2003	32	4	0	4					
		09AUG2003	33	4	0	4					
		10AUG2003	34	4	0	4					
		11AUG2003	35	4	0	4					
		12AUG2003	36	4	0	4					
		13AUG2003	37	4	0	4					
		14AUG2003	38	4	0	4					
		15AUG2003	39	4	0	4					
		16AUG2003	40	4	0	4					
		17AUG2003	41	4	0	4					
		18AUG2003	42	4	0	4					
		19AUG2003	43	4	0	4					
		20AUG2003	44	4	0	4					
		21AUG2003	45	4	0	4					
		22AUG2003	46	4	0	4					
		23AUG2003	47	4	0	4					
		24AUG2003	48	4	0	4					
		25AUG2003	49	4	0	4					
		26AUG2003	50	4	0	4					
		27AUG2003	51	4	0	4					
		28AUG2003	52	4	0	4					
		29AUG2003	53	4	0	4					
		30AUG2003	54	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019047	31AUG2003	55	4	0	4					
		01SEP2003	56	4	0	4					
		02SEP2003	57	4	0	4					
		03SEP2003	58	4	0	4	NO	0	58	100	
	E0019048	10JUL2003	1	2	0	2					
		11JUL2003	2	1	0	1					
		12JUL2003	3	1	0	1					
		13JUL2003	4	2	0	2					
		14JUL2003	5	3	0	3					
		15JUL2003	6	3	0	3					
		16JUL2003	7	3	0	3					
		17JUL2003	8	4	0	4					
		18JUL2003	9	4	0	4					
		19JUL2003	10	4	0	4					
		20JUL2003	11	4	0	4					SUBJECT IN FOR VISIT 4 ON 7/22/03 DUE TO VACATION 7/23/03.
		21JUL2003	12	4	0	4					
		22JUL2003	13	4	0	4					
		23JUL2003	14	4	0	4					
		24JUL2003	15	4	0	4					
		25JUL2003	16	4	0	4					
		26JUL2003	17	4	0	4					
		27JUL2003	18	4	0	4					
		28JUL2003	19	4	0	4					
		29JUL2003	20		0	4					
		30JUL2003	21		0	4					
		31JUL2003	22	4	0	4					
		01AUG2003	23	4	0	4					
		02AUG2003	24	4	0	4					
		03AUG2003	25	4	0	4					
		04AUG2003	26	4	0	4					
		05AUG2003	27	4	0	4					
		06AUG2003	28	4	0	4					
		07AUG2003	29	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0019048	08AUG2003	30	4	0	4					
		09AUG2003	31	4	0	4					
		10AUG2003	32	4	0	4					
		11AUG2003	33	4	0	4					
		12AUG2003	34	4	0	4					
		13AUG2003	35	4	0	4					
		14AUG2003	36	4	0	4					
		15AUG2003	37	4	0	4					
		16AUG2003	38	4	0	4					
		17AUG2003	39	4	0	4					
		18AUG2003	40	4	0	4					
		19AUG2003	41	4	0	4					
		20AUG2003	42	4	4	0					SUBJECT FORGOT TO DOSE ON 8/20/03
		21AUG2003	43	4	0	4					
		22AUG2003	44	4	0	4					
		23AUG2003	45	4	0	4					
		24AUG2003	46	4	0	4					
		25AUG2003	47	4	0	4					
		26AUG2003	48	4	0	4					
		27AUG2003	49	4	0	4					
		28AUG2003	50	4	0	4					
		29AUG2003	51	4	0	4					
		30AUG2003	52	4	0	4					
		31AUG2003	53	4	0	4					
		01SEP2003	54	4	0	4					
		02SEP2003	55	4	0	4	NO	0	54	98.1	SUBJECT IN FOR VISIT 10 ONE DAY EARLY
	E0022006	12NOV2002	1	2	0	2					
		13NOV2002	2	1	0	1					
		14NOV2002	3	1	0	1					
		15NOV2002	4	2	0	2					
		16NOV2002	5	3	0	3					
		17NOV2002	6	3	0	3					
		18NOV2002	7	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0022006	19NOV2002	8	4	0	4					
		20NOV2002	9	4	0	4					
		21NOV2002	10	4	0	4					
		22NOV2002	11	4	0	4					
		23NOV2002	12	4	0	4					
		24NOV2002	13	4	0	4					
		25NOV2002	14	4	0	4					
		26NOV2002	15	4	0	4					
		27NOV2002	16	4	0	4					
		28NOV2002	17	4	0	4					
		29NOV2002	18	4	0	4					
		30NOV2002	19	4	0	4					
		01DEC2002	20	4	0	4					
		02DEC2002	21	4	0	4					
		03DEC2002	22	4	0	4					
		04DEC2002	23	4	0	4					
		05DEC2002	24	4	0	4					
		06DEC2002	25	4	0	4					
		07DEC2002	26	4	0	4					
		08DEC2002	27	4	0	4					
		09DEC2002	28	4	0	4					
		10DEC2002	29	4	4	0					MISSED DOSE
		11DEC2002	30	4	0	4					
		12DEC2002	31	4	0	4					
		13DEC2002	32	4	0	4					
		14DEC2002	33	4	0	4					
		15DEC2002	34	4	0	4					
		16DEC2002	35	4	0	4					
		17DEC2002	36		0	4					MISSED DOSE ON 12-10 TOOK ON 12-17-02 (REDISPENSED.)
		18DEC2002	37	4	0	4					
		19DEC2002	38	4	0	4					
		20DEC2002	39	4	0	4					
		21DEC2002	40	4	0	4					
		22DEC2002	41	4	0	4					
		23DEC2002	42	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0022006	24DEC2002	43	4	0	4					REDISPENSED
		25DEC2002	44	4	0	4					
		26DEC2002	45	4	0	4					
		27DEC2002	46	4	0	4					
		28DEC2002	47	4	0	4					
		29DEC2002	48	4	0	4					
		30DEC2002	49	4	0	4					
		31DEC2002	50	4	0	4					REDISPENSED
		01JAN2003	51	4	0	4					
		02JAN2003	52	4	0	4					
		03JAN2003	53	4	0	4					
		04JAN2003	54	4	0	4					
		05JAN2003	55	4	0	4					
		06JAN2003	56	4	0	4					
		07JAN2003					NO	0	55	98.1	PATIENT REMOVED DOSE FROM CARD - DID NOT TAKE - LOST.
	E0022047	28MAR2003	1	2	0	2					
		29MAR2003	2	1	0	1					
		30MAR2003	3	1	0	1					
		31MAR2003	4	2	0	2					
		01APR2003	5	3	0	3					
		02APR2003	6	3	0	3					
		03APR2003	7	3	0	3					
		04APR2003	8	4	0	4					
		05APR2003	9	4	0	4					
		06APR2003	10	4	0	4					
		07APR2003	11	4	0	4					
		08APR2003	12	4	0	4					
		09APR2003	13	4	0	4					
		10APR2003	14	4	0	4					
		11APR2003	15	4	0	4					
		12APR2003	16	4	0	4					
		13APR2003	17	4	0	4					
		14APR2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0022047	15APR2003	19	4	0	4					
		16APR2003	20	4	0	4					
		17APR2003	21	4	0	4					
		18APR2003	22	4	0	4					
		19APR2003	23	4	0	4					
		20APR2003	24	4	0	4					
		21APR2003	25	4	0	4					
		22APR2003	26	4	0	4					
		23APR2003	27	4	0	4					
		24APR2003	28		0	4					
		25APR2003	29	4	0	4					
		26APR2003	30	4	0	4					
		27APR2003	31	4	0	4					
		28APR2003	32	4	0	4					
		29APR2003	33	4	0	4					
		30APR2003	34	4	0	4					
		01MAY2003	35	4	0	4					
		02MAY2003	36	4	0	4					
		03MAY2003	37	4	0	4					
		04MAY2003	38	4	0	4					
		05MAY2003	39	4	0	4					
		06MAY2003	40	4	0	4					
		07MAY2003	41	4	0	4					
		08MAY2003	42	4	0	4					
		09MAY2003	43	4	0	4					
		10MAY2003	44	4	0	4					
		11MAY2003	45	4	0	4					
		12MAY2003	46	4	0	4					
		13MAY2003	47	4	0	4					
		14MAY2003	48	4	0	4					
		15MAY2003	49	4	0	4					
		16MAY2003	50	4	0	4					
		17MAY2003	51	4	0	4					
		18MAY2003	52	4	0	4					
		19MAY2003	53	4	0	4					
		20MAY2003	54	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0022047	21MAY2003	55	4	0	4					
		22MAY2003	56	4	0	4	NO	0	56	100	
	E0022075	08JUL2003	1	2	0	2					
		09JUL2003	2	1	0	1					
		10JUL2003	3	1	0	1					
		11JUL2003	4	2	0	2					
		12JUL2003	5	3	0	3					
		13JUL2003	6	3	0	3					
		14JUL2003	7	3	0	3					
		15JUL2003	8	4	0	4					
		16JUL2003	9	4	0	4					
		17JUL2003	10	4	0	4					
		18JUL2003	11	4	0	4					
		19JUL2003	12	4	0	4					
		20JUL2003	13	4	0	4					
		21JUL2003	14	4	0	4					
		22JUL2003	15	4	0	4					
		23JUL2003	16	4	0	4					
		24JUL2003	17	4	0	4					
		25JUL2003	18	4	0	4					
		26JUL2003	19	4	0	4					
		27JUL2003	20	4	0	4					
		28JUL2003	21	4	0	4					
		29JUL2003	22	4	0	4					
		30JUL2003	23	4	0	4					
		31JUL2003	24	4	0	4					
		01AUG2003	25	4	0	4					
		02AUG2003	26	4	0	4					
		03AUG2003	27	4	0	4					
		04AUG2003	28	4	0	4					
		05AUG2003	29	4	0	4					
		06AUG2003	30	4	0	4					
		07AUG2003	31	4	0	4					
		08AUG2003	32	4	0	4					
		09AUG2003	33	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0022075	10AUG2003	34	4	0	4					
		11AUG2003	35	4	0	4					
		12AUG2003	36	4	0	4					
		13AUG2003	37	4	0	4					
		14AUG2003	38	4	0	4					
		15AUG2003	39	4	0	4					
		16AUG2003	40	4	0	4					
		17AUG2003	41	4	0	4					
		18AUG2003	42	4	0	4					
		19AUG2003	43	4	0	4					
		20AUG2003	44	4	0	4					
		21AUG2003	45	4	0	4					
		22AUG2003	46	4	0	4					
		23AUG2003	47	4	0	4					
		24AUG2003	48	4	0	4					
		25AUG2003	49	4	0	4					
		26AUG2003	50	4	0	4					
		27AUG2003	51	4	0	4					
		28AUG2003	52	4	0	4					
		29AUG2003	53	4	0	4					
		30AUG2003	54	4	0	4					
		31AUG2003	55	4	0	4					
		01SEP2003	56	4	0	4					
		02SEP2003	57		0	4	NO	0	57	100	TOOK EXTRA DAY ON SCHEDULE
	E0023012	06FEB2003	1	2	0	2					
		07FEB2003	2	1	0	1					
		08FEB2003	3	1	0	1					
		09FEB2003	4	2	0	2					
		10FEB2003	5	3	0	3					
		11FEB2003	6	3	0	3					
		12FEB2003	7	3	0	3					
		13FEB2003	8	4	0	4					
		14FEB2003	9	4	0	4					
		15FEB2003	10	4	0	4					
		16FEB2003	11	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023012	17FEB2003	12	4	0	4					
		18FEB2003	13	4	0	4					
		19FEB2003	14	4	0	4					
		20FEB2003	15	4	0	4					
		21FEB2003	16	4	0	4					
		22FEB2003	17	4	0	4					
		23FEB2003	18	4	0	4					
		24FEB2003	19	4	0	4					
		25FEB2003	20	4	0	4					
		26FEB2003	21	4	0	4					
		27FEB2003	22		0	4					
		28FEB2003	23	4	0	4					
		01MAR2003	24	4	0	4					
		02MAR2003	25	4	0	4					
		03MAR2003	26	4	0	4					
		04MAR2003	27	4	0	4					
		05MAR2003	28	4	0	4					
		06MAR2003	29	4	0	4					
		07MAR2003	30	4	0	4					
		08MAR2003	31	4	0	4					
		09MAR2003	32	4	0	4					
		10MAR2003	33	4	0	4					
		11MAR2003	34	4	0	4					
		12MAR2003	35	4	0	4					
		13MAR2003	36	4	4	0					MISSED DOSE
		14MAR2003	37	4	0	4					
		15MAR2003	38	4	0	4					
		16MAR2003	39	4	0	4					
		17MAR2003	40	4	0	4					
		18MAR2003	41	4	0	4					
		19MAR2003	42	4	0	4					
		20MAR2003	43	4	0	4					
		21MAR2003	44	4	0	4					
		22MAR2003	45	4	0	4					
		23MAR2003	46	4	0	4					
		24MAR2003	47	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023012	25MAR2003	48	4	0	4					
		26MAR2003	49	4	0	4					
		27MAR2003	50	4	4	0					PT " FORGOT"
		28MAR2003	51	4	0	4					
		29MAR2003	52	4	0	4					
		30MAR2003	53	4	0	4					
		31MAR2003	54	4	0	4					
		01APR2003	55	4	0	4					
		02APR2003	56	4	0	4					
		03APR2003	57	4	0	4	NO	0	55	96.3	
	E0023016	22MAY2003	1	2	0	2					
		23MAY2003	2	1	0	1					
		24MAY2003	3	1	0	1					
		25MAY2003	4	2	0	2					
		26MAY2003	5	3	0	3					
		27MAY2003	6	3	0	3					
		28MAY2003	7	3	0	3					
		29MAY2003	8	4	0	4					
		30MAY2003	9	4	0	4					
		31MAY2003	10	4	0	4					
		01JUN2003	11	4	0	4					
		02JUN2003	12	4	0	4					
		03JUN2003	13	4	0	4					
		04JUN2003	14	4	0	4					
		05JUN2003	15	4	0	4					
		06JUN2003	16	4	0	4					
		07JUN2003	17	4	0	4					
		08JUN2003	18	4	0	4					
		09JUN2003	19	4	0	4					
		10JUN2003	20	4	0	4					
		11JUN2003	21	4	0	4					
		12JUN2003	22	4	0	4					
		13JUN2003	23	4	0	4					
		14JUN2003	24	4	0	4					
		15JUN2003	25	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023016	16JUN2003	26	4	0	4					
		17JUN2003	27	4	0	4					
		18JUN2003	28	4	0	4					
		19JUN2003	29	4	0	4					
		20JUN2003	30	4	0	4					
		21JUN2003	31	4	0	4					
		22JUN2003	32	4	0	4					
		23JUN2003	33	4	0	4					
		24JUN2003	34	4	0	4					
		25JUN2003	35	4	0	4					
		26JUN2003	36	4	0	4					
		27JUN2003	37	4	0	4					
		28JUN2003	38	4	0	4					
		29JUN2003	39	4	0	4					
		30JUN2003	40	4	0	4					
		01JUL2003	41	4	0	4					
		02JUL2003	42	4	0	4					
		03JUL2003	43	4	0	4					
		04JUL2003	44	4	0	4					
		05JUL2003	45	4	0	4					
		06JUL2003	46	4	0	4					
		07JUL2003	47	4	0	4					
		08JUL2003	48		0	4					
		09JUL2003	49		0	4					
		10JUL2003	50	4	0	4					
		11JUL2003	51	4	0	4					
		12JUL2003	52	4	0	4					
		13JUL2003	53	4	0	4					
		14JUL2003	54	4	0	4					
		15JUL2003	55	4	0	4					
		16JUL2003	56	4	0	4	NO	0	56	100	
	E0023018	27MAR2003	1	2	0	2					
		28MAR2003	2	1	0	1					
		29MAR2003	3	1	0	1					
		30MAR2003	4	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023018	31MAR2003	5	3	0	3					
		01APR2003	6	3	0	3					
		02APR2003	7	3	0	3					
		03APR2003	8	4	0	4					
		04APR2003	9	4	0	4					
		05APR2003	10	4	0	4					
		06APR2003	11	4	0	4					
		07APR2003	12	4	0	4					
		08APR2003	13	4	0	4					
		09APR2003	14	4	0	4					
		10APR2003	15	4	0	4					
		11APR2003	16	4	0	4					
		12APR2003	17	4	0	4					
		13APR2003	18	4	0	4					
		14APR2003	19	4	0	4					
		15APR2003	20	4	0	4					
		16APR2003	21	4	0	8					
		17APR2003	22	4	0	4					
		18APR2003	23	4	0	4					
		19APR2003	24	4	0	4					
		20APR2003	25	4	0	4					
		21APR2003	26	4	0	4					
		22APR2003	27	4	0	4					
		23APR2003	28		0	4					
		24APR2003	29	4	0	4					
		25APR2003	30	4	0	4					
		26APR2003	31	4	0	4					
		27APR2003	32	4	0	4					
		28APR2003	33	4	0	4					
		29APR2003	34	4	0	4					
		30APR2003	35	4	0	4					
		01MAY2003	36		0	4					
		02MAY2003	37	4	0	4					
		03MAY2003	38	4	0	4					
		04MAY2003	39	4	0	4					
		05MAY2003	40	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023018	06MAY2003	41	4	0	4					
		07MAY2003	42	4	0	4					
		08MAY2003	43	4	0	4					
		09MAY2003	44		0	4					
		10MAY2003	45		0	4					
		11MAY2003	46			0					
		12MAY2003	47	4	0	4					SIC PT MISSED 1 DOSE ON 5/11/03
		13MAY2003	48	4	0	4					
		14MAY2003	49	4	0	4					
		15MAY2003	50	4	0	4					
		16MAY2003	51	4	0	4					
		17MAY2003	52	4	0	4					
		18MAY2003	53	4	0	4					
		19MAY2003	54	4	0	4					
		20MAY2003	55	4	0	4					
		21MAY2003	56	4	0	4	NO	0	55	100	
	E0023036	20JUN2003	1	2	0	2					
		21JUN2003	2	1	0	1					
		22JUN2003	3	1	0	1					
		23JUN2003	4	2	0	2					
		24JUN2003	5	3	0	3					
		25JUN2003	6	3	0	3					
		26JUN2003	7	3	0	3					
		27JUN2003	8	4	0	4					
		28JUN2003	9	4	0	4					
		29JUN2003	10	4	0	4					
		30JUN2003	11	4	0	4					
		01JUL2003	12	4	0	4					
		02JUL2003	13	4	0	4					
		03JUL2003	14	4	0	4					
		04JUL2003	15	4	0	4					
		05JUL2003	16	4	0	4					
		06JUL2003	17	4	0	4					
		07JUL2003	18	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023036	08JUL2003	19	4	0	4					
		09JUL2003	20	4	0	4					
		10JUL2003	21	4	0	4					
		11JUL2003	22	4	0	4					
		12JUL2003	23	4	0	4					
		13JUL2003	24	4	0	4					
		14JUL2003	25	4	0	4					
		15JUL2003	26	4	0	4					
		16JUL2003	27	4	0	4					
		17JUL2003	28	4	0	4					
		18JUL2003	29	4	0	4					
		19JUL2003	30	4	0	4					
		20JUL2003	31	4	0	4					
		21JUL2003	32	4	0	4					
		22JUL2003	33	4	0	4					
		23JUL2003	34	4	0	4					
		24JUL2003	35	4	0	4					
		25JUL2003	36	4	0	4					
		26JUL2003	37	4	0	4					
		27JUL2003	38	4	0	4					
		28JUL2003	39	4	0	4					
		29JUL2003	40	4	0	4					
		30JUL2003	41	4	0	4					
		31JUL2003	42	4	0	4					
		01AUG2003	43	4	0	4					
		02AUG2003	44	4	0	4					
		03AUG2003	45	4	0	4					
		04AUG2003	46	4	0	4					
		05AUG2003	47	4	0	4					
		06AUG2003	48	4	0	4					
		07AUG2003	49	4	0	4					
		08AUG2003	50	4	0	4					
		09AUG2003	51	4	0	4					
		10AUG2003	52	4	0	4					
		11AUG2003	53	4	0	4					
		12AUG2003	54		0	4	NO	0	54	100	

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023046	23JUL2003	1	2	0	2					
		24JUL2003	2	1	0	1					
		25JUL2003	3	1	0	1					
		26JUL2003	4	2	0	2					
		27JUL2003	5	3	0	3					
		28JUL2003	6	3	0	3					
		29JUL2003	7	3	0	3					
		30JUL2003	8		0	4					
		31JUL2003	9		0	4					
		01AUG2003	10	4	0	4					
		02AUG2003	11	4	0	4					
		03AUG2003	12	4	0	4					
		04AUG2003	13	4	0	4					
		05AUG2003	14	4	0	4					
		06AUG2003	15	4	0	4					
		07AUG2003	16	4	0	4					
		08AUG2003	17	4	0	4					
		09AUG2003	18	4	0	4					
		10AUG2003	19	4	0	4					
		11AUG2003	20	4	0	4					
		12AUG2003	21	4	1	3					PT FORGOT TO TAKE 1 TAB
		13AUG2003	22	4	0	4					
		14AUG2003	23	4	0	4					
		15AUG2003	24	4	0	4					
		16AUG2003	25	4	0	4					
		17AUG2003	26	4	0	4					
		18AUG2003	27	4	0	4					
		19AUG2003	28	4	0	4					
		20AUG2003	29	4	0	4					
		21AUG2003	30		0	4					
		22AUG2003	31	4	0	4					
		23AUG2003	32	4	0	4					
		24AUG2003	33	4	0	4					
		25AUG2003	34	4	0	4					
		26AUG2003	35	4	0	4					
		27AUG2003	36	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0023046	28AUG2003	37	4	0	4					
		29AUG2003	38	4	0	4					
		30AUG2003	39	4	0	4					
		31AUG2003	40	4	0	4					
		01SEP2003	41	4	0	4					
		02SEP2003	42	4	0	4					
		03SEP2003	43	4	0	4					
		04SEP2003	44	4	0	4					
		05SEP2003	45	4	0	4					
		06SEP2003	46	4	0	4					
		07SEP2003	47	4	0	4					
		08SEP2003	48	4	0	4					
		09SEP2003	49	4	0	4					
		10SEP2003	50	4	0	4					
		11SEP2003	51	4	0	4					
		12SEP2003	52	4	0	4					
		13SEP2003	53	4	0	4					
		14SEP2003	54	4	0	4					
		15SEP2003	55	4	0	4	NO	0	55	100	COMPLETED TREATMENT
	E0026006	08JAN2003	1	2	0	2					
		09JAN2003	2	1	0	1					
		10JAN2003	3	1	0	1					
		11JAN2003	4	2	0	2					
		12JAN2003	5	3	0	3					
		13JAN2003	6	3	0	3					
		14JAN2003	7	3	0	3					
		15JAN2003	8	4	0	4					
		16JAN2003	9	4	0	4					PT. LOST 1 PILL - TOOK FROM EXTRA 1-23-03
		17JAN2003	10	4	0	4					
		18JAN2003	11	4	0	4					
		19JAN2003	12	4	0	4					
		20JAN2003	13	4	0	4					
		21JAN2003	14	4	0	4					
		22JAN2003	15	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0026006	23JAN2003	16	4	0	4					
		24JAN2003	17	4	0	4					
		25JAN2003	18	4	0	4					
		26JAN2003	19	4	0	4					
		27JAN2003	20	4	0	4					
		28JAN2003	21	4	0	4					
		29JAN2003	22	4	0	4					SUBJECT LOST BLISTER CARD. REPORTED TAKING STUDY MED 1/29/03 THRU 2/4/03
		30JAN2003	23	4	0	4					
		31JAN2003	24	4	0	4					
		01FEB2003	25	4	0	4					
		02FEB2003	26	4	0	4					
		03FEB2003	27	4	0	4					
		04FEB2003	28	4	0	4					
		05FEB2003	29	4	0	4					NO DOSE TAKEN
		06FEB2003	30	4	0	4					NO DOSE TAKEN
		07FEB2003	31	4	0	4					
		08FEB2003	32	4	0	4					
		09FEB2003	33	4	0	4					
		10FEB2003	34	4	0	4					
		11FEB2003	35	4	0	4					
		12FEB2003	36	4	0	4					
		13FEB2003	37	4	0	4					
		14FEB2003	38	4	0	4					
		15FEB2003	39	4	0	4					
		16FEB2003	40	4	0	4					
		17FEB2003	41	4	1	3					TOOK EXTRA DOSE 2-19-03 BY MISTAKE
		18FEB2003	42	4	1	3					TOOK EXTRA DOSE 2-20-03 BY MISTAKE
		19FEB2003	43	4	0	4					
		26FEB2003									SIC - UNK SUBJECT LOST TO FOLLOW - UP, BLISTER CARD WAS NOT - RETURNED.
		27FEB2003					NO	0	43	100	SIC - UNK

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0026021	23APR2003	1	2	0	2					
		24APR2003	2	1	0	1					
		25APR2003	3	1	0	1					
		26APR2003	4	2	0	2					
		27APR2003	5	3	0	3					
		28APR2003	6	3	0	3					
		29APR2003	7	3	0	3					DAY 7 SIC, DAY 7 DURING V - 3 V - 4 INTERVAL IN ORDER TO ACHIEVE FULL TITRATION.
		30APR2003	8	4	0	4					DAY 1 SIC DAY 1 DOES NOT EQUAL VISIT 3 VISIT DATE DUE TO SUBJECT TAKING 4/29/03 DOSE FROM BLISTER CARD #1
		01MAY2003	9	4	0	4					
		02MAY2003	10	4	0	4					
		03MAY2003	11	4	0	4					
		04MAY2003	12	4	0	4					
		05MAY2003	13	4	0	4					
		06MAY2003	14	4	0	4					
		07MAY2003	15		0	4					
		08MAY2003	16	4	0	8					PT TOOK 4 EXTRA DOSES DUE TO OVERSIGHT
		09MAY2003	17	4	0	4					
		10MAY2003	18	4	0	4					
		11MAY2003	19	4	0	4	NO	0	19	106	
	E0026027	19JUN2003	1	2	0	2					
		20JUN2003	2	1	0	1					
		21JUN2003	3	1	0	1					
		22JUN2003	4	2	0	2					
		23JUN2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DRUG TABLET ADMINISTRATION DAY	DISPENSE	RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE NO. DAYS STUDY DRUG	%	COMMENTS
PLACEBO (BIPOLAR II)	E0026027	24JUN2003					NO	0	5	100	PATIENT ASKED TO STOP TAKING MEDICATION BY 8/1/03 STUDY STAFF, DUE TO SAE
	E0029002	12NOV2002					NO				SUBJECT RANDOMIZED IN ERROR
	E0029004	19NOV2002	1	2	0	2					
		20NOV2002	2	1	0	1					
		21NOV2002	3	1	0	1					
		22NOV2002	4	2	0	2					
		23NOV2002	5	3	0	3					
		24NOV2002	6	3	0	3					
		25NOV2002	7	3	0	3					
		26NOV2002	8	4	0	4					
		27NOV2002	9	4	0	4					
		28NOV2002	10	4	0	4					
		29NOV2002	11	4	0	4					
		30NOV2002	12	4	0	4					
		01DEC2002	13	4	0	4					
		02DEC2002	14	4	0	4					
		03DEC2002	15		0	4					
		04DEC2002	16	4	4	0					ON 12/4/02, THE SUBJECT MISSED A DOSE BECAUSE SHE WAS WASHING OFF AN EXCLUDED MED PER D. RIDGEWAY. APPROVAL TO CONTINUE IN STUDY ON 12/4/02. PATIENT SKIPPED STUDY MED IN ERROR ON 12/7/02.
		05DEC2002	17	4	0	4					
		06DEC2002	18	4	0	4					

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0029004	07DEC2002	19	4	4	0					PATIENT DID NOT NECESSARILY TAKE EACH DAY'S DOSE FROM THE CARD IN THE RIGHT ORDER - SHE WOULD TAKE A SKIPPED DOSE THE NEXT DAY AND DISREGARDED DATES WRITTEN ON CARD.
		08DEC2002	20	4	0	4					
		09DEC2002	21	4	0	4					
		10DEC2002	22	4	4	0					
		11DEC2002	23		4	0					
		12DEC2002	24	4	0	4					
		13DEC2002	25	4	0	4					
		14DEC2002	26	4	0	4					
		15DEC2002	27	4	0	4					
		16DEC2002	28	4	0	4					
		17DEC2002	29	4	0	4					
		18DEC2002	30	4	0	4					
		19DEC2002	31		0	4					
		20DEC2002	32		0	4					
		21DEC2002	33			0					
		22DEC2002	34			0					
		23DEC2002	35			0					
		24DEC2002	36	4	0	4					SUBJECT MISSED APPT. ON 12/18, SHE RAN OUT OF STUDY DRUG ON 12/21. SUBJECT OFF STUDY MED 12/21-12/23. SUBJECT CAME BY SITE AND PICKED UP VISIT 6 CARD TO DOSE FROM ON 12/24 & 12/25 UNTIL APPT.

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0029004	25DEC2002	37	4	0	4					ON 12/26 WHEN DOCTOR COULD SEE HER. K. ABERNATHY APPROVED SITE TO SKIP V6 ON 12/26 AND DO VISIT 7 INSTEAD. V6 BLISTERCARD RETURNED 12/26. V7 CARD DISPENSED FOR 12/26 TO GET SUBJECT BACK ON TRACK.
		26DEC2002	38	4	0	4					
		27DEC2002	39	4	0	4					
		28DEC2002	40	4	0	4					
		29DEC2002	41	4	0	4					
		30DEC2002	42	4	0	4					
		31DEC2002	43	4	0	4					
		01JAN2003	44	4	0	4					
		02JAN2003	45	4	0	4					
		03JAN2003	46	4	0	4					
		04JAN2003	47	4	0	4					
		05JAN2003	48	4	0	4					
		06JAN2003	49	4	0	4					
		07JAN2003	50	4	0	4					
		08JAN2003	51	4	0	4					
		09JAN2003	52	4	0	4					
		10JAN2003	53	4	0	4					
		11JAN2003	54	4	4	0					FORGOT DOSE
		12JAN2003	55	4	0	4					
		13JAN2003	56	4	0	4					
		14JAN2003	57	4	0	4					
		15JAN2003	58	4	0	4	NO	0	50	85.4	
	E0029013	19FEB2003	1	2	0	2					
		20FEB2003	2	1	0	1					
		21FEB2003	3	1	0	1					
		22FEB2003	4	2	0	2					
		23FEB2003	5	3	0	3					
		24FEB2003	6	3	0	3					
		25FEB2003	7	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0029013	26FEB2003	8	4	0	4					
		27FEB2003	9	4	0	4					
		28FEB2003	10	4	0	4					
		01MAR2003	11	4	0	4					
		02MAR2003	12	4	0	4					
		03MAR2003	13	4	0	4					
		04MAR2003	14	4	0	4					
		05MAR2003	15	4	0	4					
		06MAR2003	16	4	0	4					
		07MAR2003	17	4	0	4					
		08MAR2003	18	4	0	4					
		09MAR2003	19	4	0	4					
		10MAR2003	20	4	0	4					
		11MAR2003	21		0	4					
		12MAR2003	22		0	4					
		13MAR2003	23	4	0	4					
		14MAR2003	24	4	0	4					
		15MAR2003	25	4	0	4					
		16MAR2003	26	4	0	4					
		17MAR2003	27	4	0	4					
		18MAR2003	28	4	0	4					
		19MAR2003	29	4	0	4					
		20MAR2003	30	4	1	3					REDUCED DOSE BY 100 MG
		21MAR2003	31	4	1	3					
		22MAR2003	32	4	1	3					
		23MAR2003	33	4	1	3					
		24MAR2003	34	4	1	3					
		25MAR2003	35	4	1	3					
		26MAR2003	36	4	1	3					
		27MAR2003	37	4	1	3					
		28MAR2003	38	4	1	3					
		29MAR2003	39	4	1	3					
		30MAR2003	40	4	1	3					
		31MAR2003	41	4	1	3					
		01APR2003	42	4	1	3					
		02APR2003	43	4	1	3					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0029013	03APR2003	44	4	1	3					
		04APR2003	45	4	1	3					
		05APR2003	46	4	1	3					
		06APR2003	47	4	1	3					
		07APR2003	48		1	3					
		08APR2003	49		1	3					PT. RAN OUT OF MED. - DOSE NOT TAKEN 4/9/03
		09APR2003	50			0					
		10APR2003	51	4	0	4					CARD NOT RETURNED - WOULD NOT VERIFY COUNT
		17APR2003					YES	0	50	98.3	UNK
	E0029019	03MAR2003	1	2	0	2					
		04MAR2003	2	1	0	1					
		05MAR2003	3	1	0	1					
		06MAR2003	4	2	0	2					
		07MAR2003	5	3	0	3					
		08MAR2003	6	3	0	3					
		09MAR2003	7	3	0	3					
		10MAR2003	8	4	0	4					
		11MAR2003	9	4	0	4					
		12MAR2003	10	4	0	4					
		13MAR2003	11	4	0	4					
		14MAR2003	12	4	0	4					
		15MAR2003	13	4	0	4					
		16MAR2003	14	4	0	4	NO	0	14	100	
	E0029024	17MAR2003	1	2	0	2					
		18MAR2003	2	1	0	1					
		19MAR2003	3	1	0	1					
		20MAR2003	4	2	0	2					
		21MAR2003	5	3	0	3					
		22MAR2003	6	3	0	3					
		23MAR2003	7	3	0	3					
		24MAR2003	8		0	4					
		25MAR2003	9	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0029024	26MAR2003	10	4	0	4					
		27MAR2003	11	4	0	4					
		28MAR2003	12	4	0	4					
		29MAR2003	13	4	0	4					
		30MAR2003	14	4	0	4					
		31MAR2003	15	4	0	4					
		01APR2003	16		0	4					
		02APR2003	17	4	0	4					
		03APR2003	18	4	0	4					
		04APR2003	19	4	0	4					
		05APR2003	20	4	0	4					
		06APR2003	21	4	0	4					
		07APR2003	22	4	0	4					
		08APR2003	23	4	0	4					
		09APR2003	24	4	0	4					
		10APR2003	25	4	0	4					
		11APR2003	26	4	0	4					
		12APR2003	27	4	0	4					
		13APR2003	28	4	0	4					
		14APR2003	29	4	0	4					
		15APR2003	30	4	0	4					
		16APR2003	31		0	4					
		17APR2003	32	4	0	4					
		18APR2003	33	4	0	4					
		19APR2003	34	4	0	4					
		20APR2003	35	4	0	4					
		21APR2003	36	4	0	4					
		22APR2003	37	4	0	4					
		23APR2003	38	4	0	4					
		24APR2003	39	4	0	4					
		25APR2003	40	4	0	4					
		26APR2003	41	4	0	4					
		27APR2003	42	4	0	4					
		28APR2003	43	4	0	4					
		29APR2003	44	4	0	4					
		30APR2003	45	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0029024	01MAY2003	46		0	4					PT MISSED DOSES ON 5/3/03 & 5/4/03 BECAUSE SHE MISSED HER APPOINTMENT & RAN OUT OF STUDY DRUG
		02MAY2003	47		0	4					
		03MAY2003	48			0					
		04MAY2003	49			0					
		05MAY2003	50	4	0	4					
		06MAY2003	51	4	0	4					
		07MAY2003	52	4	0	4					
		08MAY2003	53	4	0	4					
		09MAY2003	54	4	0	4					
		10MAY2003	55	4	0	4					
		11MAY2003	56	4	0	4					
		12MAY2003	57	4	0	4					
		13MAY2003	58	4	0	4					
		14MAY2003	59	4	0	4					
		15MAY2003	60	4	0	4					
		16MAY2003	61	4	0	4					
		17MAY2003	62	4	0	4					
		18MAY2003	63	4	0	4					
		19MAY2003	64		0	4	NO	0	62	96.7	
	E0029038	07JUL2003	1	2	0	2					
		08JUL2003	2	1	0	1					
		09JUL2003	3	1	0	1					
		10JUL2003	4	2	0	2					
		11JUL2003	5	3	0	3					
		12JUL2003	6	3	0	3					
		13JUL2003	7	3	0	3	NO	0	7	100	
	E0031004	19DEC2002	1	2	0	2					
		20DEC2002	2	1	0	1					
		21DEC2002	3	1	0	1					
		22DEC2002	4	2	0	2					
		23DEC2002	5	3	0	3					
		24DEC2002	6	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0031004	25DEC2002	7	3	0	3					
		26DEC2002	8		0	4					
		27DEC2002	9	4	0	4					
		28DEC2002	10	4	0	4					
		29DEC2002	11	4	0	4					
		30DEC2002	12	4	0	4					
		31DEC2002	13	4	0	4					
		01JAN2003	14	4	0	4					
		02JAN2003	15	4	0	4					
		03JAN2003	16	4	0	4					
		04JAN2003	17	4	0	4					
		05JAN2003	18	4	0	4					
		06JAN2003	19	4	0	4					
		07JAN2003	20	4	0	4					
		08JAN2003	21	4	0	4					
		09JAN2003	22	4	0	4					
		10JAN2003	23	4	0	4					
		11JAN2003	24	4	0	4					
		12JAN2003	25	4	0	4					
		13JAN2003	26	4	0	4					
		14JAN2003	27	4	0	4					
		15JAN2003	28	4	0	4					
		16JAN2003	29	4	0	4					
		17JAN2003	30	4	0	4					
		18JAN2003	31	4	0	4					
		19JAN2003	32	4	0	4					
		20JAN2003	33	4	0	4					
		21JAN2003	34	4	0	4					
		22JAN2003	35	4	0	4					
		23JAN2003	36	4	0	4					
		24JAN2003	37	4	0	4					
		25JAN2003	38	4	0	4					
		26JAN2003	39	4	0	4					
		27JAN2003	40	4	0	4					
		28JAN2003	41	4	0	4					
		29JAN2003	42	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0031004	30JAN2003	43	4	0	4					
		31JAN2003	44	4	0	4					
		01FEB2003	45	4	0	4					
		02FEB2003	46	4	0	4					
		03FEB2003	47	4	0	4					
		04FEB2003	48	4	0	4					
		05FEB2003	49	4	0	4					
		06FEB2003	50	4	0	4					
		07FEB2003	51	4	0	4					
		08FEB2003	52	4	0	4					
		09FEB2003	53	4	0	4					
		10FEB2003	54	4	0	4					
		11FEB2003	55	4	0	4					
		12FEB2003	56	4	0	4					
		13FEB2003	57		0	4	NO	0	57	100	
	E0031013	13MAR2003	1	2	0	2					
		14MAR2003	2	1	0	1					
		15MAR2003	3	1	0	1					
		16MAR2003	4	2	0	2					
		17MAR2003	5	3	0	3					
		18MAR2003	6	3	0	3					
		19MAR2003	7	3	0	3					
		20MAR2003	8	4	0	4					
		21MAR2003	9	4	0	4					
		22MAR2003	10	4	0	4					
		23MAR2003	11	4	0	4					
		24MAR2003	12	4	0	4					
		25MAR2003	13	4	0	4					
		26MAR2003	14	4	0	4					
		27MAR2003	15	4	0	4					
		28MAR2003	16	4	0	4					
		29MAR2003	17	4	0	4					
		30MAR2003	18	4	0	4					
		31MAR2003	19	4	0	4					
		01APR2003	20	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0031013	02APR2003	21	4	0	4					
		03APR2003	22		0	4					
		04APR2003	23	4	0	4					
		05APR2003	24	4	0	4					
		06APR2003	25	4	0	4					
		07APR2003	26	4	0	4					
		08APR2003	27	4	0	4					
		09APR2003	28	4	0	4					
		10APR2003	29	4	0	4					
		11APR2003	30	4	0	4					
		12APR2003	31	4	0	4					
		13APR2003	32	4	0	4					
		14APR2003	33	4	0	4					
		15APR2003	34	4	0	4					
		16APR2003	35	4	0	4					
		17APR2003	36	4	0	4					
		18APR2003	37	4	0	4					
		19APR2003	38	4	0	4					
		20APR2003	39	4	0	4					
		21APR2003	40	4	0	4					
		22APR2003	41	4	0	4					
		23APR2003	42	4	0	4					
		24APR2003	43	4	0	4					
		25APR2003	44	4	0	4					
		26APR2003	45	4	0	4					
		27APR2003	46	4	0	4					
		28APR2003	47	4	0	4					
		29APR2003	48	4	0	4					
		30APR2003	49	4	0	4					
		01MAY2003	50	4	0	4					
		02MAY2003	51	4	0	4					
		03MAY2003	52	4	0	4					
		04MAY2003	53	4	0	4					
		05MAY2003	54	4	0	4					
		06MAY2003	55	4	0	4					
		07MAY2003	56	4	0	4	NO	0	56	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0031016	24MAR2003	1	2	0	2					
		25MAR2003	2	1	0	1					
		26MAR2003	3	1	0	1					
		27MAR2003	4	2	0	2					
		28MAR2003	5	3	0	3					
		29MAR2003	6	3	0	3					
		30MAR2003	7	3	0	3					
		31MAR2003	8	4	0	4					
		01APR2003	9	4	0	4					
		02APR2003	10	4	0	4					
		03APR2003	11	4	0	4					
		04APR2003	12	4	0	4					
		05APR2003	13	4	0	4					
		06APR2003	14	4	0	4					
		07APR2003	15	4	0	4					
		08APR2003	16	4	0	4					
		09APR2003	17	4	0	4					
		10APR2003	18	4	0	4					
		11APR2003	19	4	0	4					
		12APR2003	20	4	0	4					
		13APR2003	21	4	0	4	NO	0	21	100	
	E0031019	11APR2003	1	2	0	2					
		12APR2003	2	1	0	1					
		13APR2003	3	1	0	1					
		14APR2003	4	2	0	2					
		15APR2003	5	3	0	3					
		16APR2003	6	3	0	3					
		17APR2003	7	3	0	3					
		18APR2003	8	4	0	4					
		19APR2003	9	4	0	4					
		20APR2003	10	4	0	4					
		21APR2003	11	4	0	4					
		22APR2003	12	4	0	4					
		23APR2003	13	4	0	4					
		24APR2003	14	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0031019	25APR2003	15	4	0	4					
		26APR2003	16	4	0	4					
		27APR2003	17	4	0	4					
		28APR2003	18	4	0	4					
		29APR2003	19	4	0	4					
		30APR2003	20	4	0	4					
		01MAY2003	21	4	0	4					
		02MAY2003	22	4	0	4					
		03MAY2003	23	4	0	4					
		04MAY2003	24	4	0	4					
		05MAY2003	25	4	0	4					
		06MAY2003	26	4	0	4					
		07MAY2003	27	4	0	4					
		08MAY2003	28	4	0	4					
		09MAY2003	29	4	0	4					
		10MAY2003	30	4	0	4					
		11MAY2003	31	4	0	4	NO	0	31	100	
	E0031022	28APR2003	1	2	0	2					
		29APR2003	2	1	0	1					
		30APR2003	3	1	0	1					
		01MAY2003	4	2	0	2					
		02MAY2003	5	3	0	3					
		03MAY2003	6	3	0	3					
		04MAY2003	7	3	0	3					
		05MAY2003	8		1	3					PT DID NOT TAKE LAST PILL
		06MAY2003	9	4	0	4					MED PACK NOT RETURNED LOST BY PATIENT
		07MAY2003	10	4	0	4					
		08MAY2003	11	4	0	4					
		09MAY2003	12	4	0	4					
		10MAY2003	13	4	0	4					
		11MAY2003	14	4	0	4					
		12MAY2003	15	4	0	4					
		13MAY2003	16	4	0	8					UNKNOWN
		14MAY2003	17	4	0	8					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0031022	15MAY2003	18	4	0	4					
		16MAY2003	19	4	0	4					
		17MAY2003	20	4	0	4					
		18MAY2003	21	4	0	4					
		19MAY2003	22	4	0	4					
		20MAY2003	23	4	0	4					
		21MAY2003	24	4	0	4					
		22MAY2003	25	4	0	4					
		23MAY2003	26	4	0	4					
		24MAY2003	27	4	0	4					
		25MAY2003	28	4	0	4					
		26MAY2003	29	4	0	4					
		27MAY2003	30	4	0	4					
		28MAY2003	31	4	0	4					
		29MAY2003	32	4	0	4					
		30MAY2003	33	4	0	4					
		31MAY2003	34	4	0	4					
		01JUN2003	35	4	0	4					
		02JUN2003	36	4	0	4	NO	0	36	106	
	E0033007	28JAN2003	1	2	0	2					
		29JAN2003	2	1	0	1					
		30JAN2003	3	1	0	1					
		31JAN2003	4	2	0	2					
		01FEB2003	5	3	0	3					
		02FEB2003	6	3	0	3					
		03FEB2003	7	3	0	3					
		04FEB2003	8	4	0	4					
		05FEB2003	9	4	0	4					
		06FEB2003	10	4	0	4					
		07FEB2003	11	4	0	4					
		08FEB2003	12	4	0	4					
		09FEB2003	13	4	0	4					
		10FEB2003	14	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033007	11FEB2003	15		0	4					PT. WAS SICK AND HAD TO RESCHEDULE VISIT 4 APPOINTMENT
		12FEB2003	16	4	0	4					
		13FEB2003	17	4	0	4					
		14FEB2003	18	4	0	4					
		15FEB2003	19	4	0	4					
		16FEB2003	20	4	0	4					
		17FEB2003	21	4	0	4					
		18FEB2003	22	4	0	4					
		19FEB2003	23		0	4					PT. HAD TO RESCHEDULE VISIT 5 APPOINTMENT DUE TO WEATHER CONDITIONS
		20FEB2003	24	4	0	4					
		21FEB2003	25	4	0	4					
		22FEB2003	26	4	0	4					
		23FEB2003	27	4	0	4					
		24FEB2003	28	4	0	4					
		25FEB2003	29	4	0	4					
		26FEB2003	30	4	0	4					
		27FEB2003	31	4	0	4					
		28FEB2003	32	4	0	4					
		01MAR2003	33	4	0	4					
		02MAR2003	34	4	0	4					
		03MAR2003	35	4	0	4					
		04MAR2003	36	4	0	4					
		05MAR2003	37	4	0	4					
		06MAR2003	38	4	0	4					
		07MAR2003	39	4	0	4					
		08MAR2003	40	4	0	4					
		09MAR2003	41	4	0	4					
		10MAR2003	42	4	0	4					
		11MAR2003	43		0	4					
		12MAR2003	44		0	4					
		13MAR2003	45	4	0	4					
		14MAR2003	46	4	0	4					
		15MAR2003	47	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033007	16MAR2003	48	4	0	4					
		17MAR2003	49	4	0	4					
		18MAR2003	50	4	0	4					
		19MAR2003	51	4	0	4					
		20MAR2003	52	4	0	4					
		21MAR2003	53	4	0	4					
		22MAR2003	54	4	0	4					
		23MAR2003	55	4	0	4					
		24MAR2003	56	4	0	4	NO	0	56	100	
	E0033013	19FEB2003	1	2	0	2					
		20FEB2003	2	1	0	1					
		21FEB2003	3	1	0	1					
		22FEB2003	4	2	0	2					
		23FEB2003	5	3	0	3					
		24FEB2003	6	3	0	3					
		25FEB2003	7	3	0	3					
		26FEB2003	8	4	0	4					
		27FEB2003	9	4	0	4					
		28FEB2003	10	4	0	4					
		01MAR2003	11	4	0	4					
		02MAR2003	12	4	0	4					
		03MAR2003	13	4	0	4					
		04MAR2003	14	4	0	4					
		05MAR2003	15	4	0	4					
		06MAR2003	16	4	0	4					
		07MAR2003	17	4	0	4					
		08MAR2003	18	4	0	4					
		09MAR2003	19	4	0	4					
		10MAR2003	20	4	0	4					
		11MAR2003	21	4	0	4					
		12MAR2003	22		0	4					
		13MAR2003	23	4	0	4					
		14MAR2003	24	4	0	4					
		15MAR2003	25	4	0	4					
		16MAR2003	26	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033013	17MAR2003	27	4	0	4					
		18MAR2003	28	4	0	4					
		19MAR2003	29	4	0	4					
		20MAR2003	30	4	0	4					
		21MAR2003	31	4	0	4					
		22MAR2003	32	4	0	4					
		23MAR2003	33	4	0	4					
		24MAR2003	34	4	0	4					
		25MAR2003	35	4	0	4					
		26MAR2003	36		0	4					
		27MAR2003	37	4	0	4					
		28MAR2003	38	4	0	4					
		29MAR2003	39	4	0	4					
		30MAR2003	40	4	0	4					
		31MAR2003	41	4	0	4					
		01APR2003	42	4	0	4					
		02APR2003	43	4	0	4					
		03APR2003	44	4	0	4					
		04APR2003	45	4	0	4					
		05APR2003	46	4	0	4					
		06APR2003	47	4	0	4					
		07APR2003	48	4	0	4					
		08APR2003	49		0	4					
		09APR2003	50		0	4					
		10APR2003	51	4	0	4					
		11APR2003	52	4	0	4					
		12APR2003	53	4	0	4					
		13APR2003	54	4	0	4					
		14APR2003	55	4	0	4					
		15APR2003	56	4	0	4	NO	0	56	100	
	E0033016	08MAY2003	1	2	0	2					
		09MAY2003	2	1	0	1					
		10MAY2003	3	1	0	1					
		11MAY2003	4	2	0	2					
		12MAY2003	5	3	0	3					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033016	13MAY2003	6	4	0	4					SUBJECT RETURNED FOR VISIT 3 ON 05/13/03 AND WAS DISPENSED THE WEEK 2 BLISTERCARD. SEE PAGE 200.
		14MAY2003	7	4	0	4					
		15MAY2003	8	4	0	4					
		16MAY2003	9	4	0	4					
		17MAY2003	10	4	0	4					
		18MAY2003	11	4	0	4					
		19MAY2003	12	4	0	4					
		20MAY2003	13	4	0	4					
		21MAY2003	14	4	0	4					
		22MAY2003	15	4	0	4					
		23MAY2003	16	4	0	4					
		24MAY2003	17	4	0	4					
		25MAY2003	18	4	0	4					
		26MAY2003	19	4	0	4					
		27MAY2003	20		0	4					
		28MAY2003	21	4	0	4					SUBJECT DID NOT TAKE STUDY MEDICATION ON 06/04/03 AND 06/06/03 AND 06/08/03 BECAUSE THE PATIENT COULD NOT MAKE STUDY VISIT
		29MAY2003	22	4	0	4					
		30MAY2003	23	4	0	4					
		31MAY2003	24	4	0	4					
		01JUN2003	25	4	0	4					
		02JUN2003	26	4	0	4					
		03JUN2003	27	4	0	4					
		04JUN2003	28		0	4					AS PER ABBY WEAR AT LINEBERRY, SUBJECT TOOK ON 06/05/03 PT INSTRUCTED TO TAKE STUDY MEDS (EXTRA) EVERY OTHER DAY

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033016	05JUN2003	29		0	4					AS PER ABBY WEAR AT LINEBERRY, PT INSTRUCTED TO TAKE EXTRA STUDY MEDS EVERY OTHER DAY SUBJECT TOOK ON 06/07/03
		06JUN2003	30			0					
		07JUN2003	31			0					
		08JUN2003	32			0					
		09JUN2003	33	4	0	4					
		10JUN2003	34	4	0	4					
		11JUN2003	35	4	0	4					
		12JUN2003	36	4	0	4					
		13JUN2003	37	4	0	4					
		14JUN2003	38	4	0	4					
		15JUN2003	39	4	0	4					
		16JUN2003	40		0	4					
		17JUN2003	41	4	0	4					
		18JUN2003	42	4	0	4					
		19JUN2003	43	4	0	4					
		20JUN2003	44	4	0	4					
		21JUN2003	45	4	0	4					
		22JUN2003	46	4	0	4					
		23JUN2003	47	4	0	8					SUBJECT TOOK THIS DOSE ON 06/22/03 IN ADDITION TO DAY 6 DOSE.
		24JUN2003	48	4	0	4					
		25JUN2003	49	4	0	4					
		26JUN2003	50	4	0	4					
		27JUN2003	51	4	0	4					SUBJECT RETURNED ON 06/27/03 FOR VISIT 9 AND WAS DISPENSED WEEK 8 BLISTERCARD. SEE PAGE 206.
		28JUN2003	52	4	0	4					
		29JUN2003	53	4	0	4					
		30JUN2003	54	4	0	4					
		01JUL2003	55	4	0	4					
		02JUL2003					NO	0	52	97.1	PT COMPLETED STUDY

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033022	14JUL2003	1	2	0	2					
		15JUL2003	2	1	0	1					
		16JUL2003	3	1	0	1					
		17JUL2003	4	2	0	2					
		18JUL2003	5	3	0	3					
		19JUL2003	6	3	0	3					
		20JUL2003	7	3	0	3					
		21JUL2003	8		0	4					
		22JUL2003	9		0	4					
		23JUL2003	10	4	0	4					INADVERTENTLY DISPENSED DAY 50 - 56 BLISTERCARD AT THIS VISIT
		24JUL2003	11	4	0	4					
		25JUL2003	12	4	0	4					
		26JUL2003	13	4	0	4					
		27JUL2003	14	4	0	4					
		28JUL2003	15	4	0	4					
		29JUL2003	16	4	0	4					
		30JUL2003	17	4	0	4					
		31JUL2003	18	4	0	4					
		01AUG2003	19	4	0	4					
		02AUG2003	20	4	0	4					
		03AUG2003	21	4	0	4					
		04AUG2003	22	4	0	4					
		05AUG2003	23	4	0	4					
		06AUG2003	24	4	0	4					INADVERTENTLY DISPENSED DAY 8 - 14 BLISTERCARD AT THIS VISIT
		07AUG2003	25	4	0	4					
		08AUG2003	26	4	0	4					
		09AUG2003	27	4	0	4					
		10AUG2003	28	4	0	4					
		11AUG2003	29	4	0	4					SUBJECT RETURNED FOR VISIT 6 ON THIS DATE - SEE PAGE 203.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033022	11AUG2003	29	4	0	4					INADVERTENTLY DISPENSED DAY 22 - 28 BLISTERCARD AT THIS VISIT.
		12AUG2003	30	4	0	4					
		13AUG2003	31	4	0	4					
		14AUG2003	32	4	0	4					
		15AUG2003	33	4	0	4					
		16AUG2003	34	4	0	4					
		17AUG2003	35	4	0	4					
		18AUG2003	36	4	0	4					INADVERTENTLY DISPENSED DAY 29 - 35 BLISTERCARD AT THIS VISIT.
		19AUG2003	37	4	0	4					
		20AUG2003	38	4	0	4					
		21AUG2003	39	4	0	4					
		22AUG2003	40	4	0	4					
		23AUG2003	41	4	0	4					
		24AUG2003	42	4	0	4					
		25AUG2003	43		0	4					
		26AUG2003	44	4	0	4					INADVERTENTLY DISPENSED DAY 36 - 42 BLISTERCARD AT THIS VISIT.
		27AUG2003	45	4	0	4					
		28AUG2003	46	4	0	4					
		29AUG2003	47	4	0	4					
		30AUG2003	48	4	0	4					
		31AUG2003	49	4	0	4					
		01SEP2003	50	4	0	4					
		02SEP2003	51		0	4					
		03SEP2003	52		0	4					
		04SEP2003	53	4	0	4					INADVERTENTLY DISPENSED DAY 43 - 46 BLISTERCARD AT THIS VISIT.
		05SEP2003	54	4	0	4					
		06SEP2003	55	4	0	4					
		07SEP2003	56	4	0	4					
		08SEP2003	57	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0033022	09SEP2003	58	4	0	4					
		10SEP2003	59	4	0	4	NO	0	59	100	
	E0034007	16MAY2003	1	2	0	2					
		17MAY2003	2	1	0	1					
		18MAY2003	3	1	0	1					
		19MAY2003	4	2	0	2					
		20MAY2003	5	3	0	3					
		21MAY2003	6	3	0	3					
		22MAY2003	7	3	0	3					
		23MAY2003	8		0	4					
		24MAY2003	9	4	0	4					
		25MAY2003	10	4	0	4					
		26MAY2003	11	4	0	4					
		27MAY2003	12	4	0	4					
		28MAY2003	13	4	0	4					
		29MAY2003	14	4	0	4					
		30MAY2003	15	4	0	4					
		31MAY2003	16		0	4					
		01JUN2003	17		0	4					
		02JUN2003	18	4	0	4					
		03JUN2003	19	4	0	4					
		04JUN2003	20	4	0	4					
		05JUN2003	21	4	0	4					
		06JUN2003	22	4	0	4					
		07JUN2003	23	4	0	4					
		08JUN2003	24	4	0	4					
		09JUN2003	25	4	0	4					
		10JUN2003	26	4	0	4					
		11JUN2003	27	4	0	4					
		12JUN2003	28	4	0	4					
		13JUN2003	29	4	0	4					
		14JUN2003	30	4	0	4					
		15JUN2003	31	4	0	4					
		16JUN2003	32	4	0	4					
		17JUN2003	33	4	0	4					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0034007	18JUN2003	34	4	0	4					
		19JUN2003	35	4	0	4					
		20JUN2003	36	4	0	4					CARD RE - DISPENSED
		21JUN2003	37	4	0	4					
		22JUN2003	38	4	0	4					
		23JUN2003	39		0	4					
		24JUN2003	40		0	4					
		25JUN2003	41	4	0	4					SIC
		26JUN2003	42	4	0	4					
		27JUN2003	43	4	0	4					
		28JUN2003	44	4	0	4					
		29JUN2003	45	4	0	4					
		30JUN2003	46	4	0	4					NOT PRESCRIBED THIS DOSE
		01JUL2003	47	4	0	4					NOT PRESCRIBED THIS DOSE
		02JUL2003	48	4	0	4					
		03JUL2003	49	4	0	4					
		04JUL2003	50	4	0	4					
		05JUL2003	51	4	0	4					
		06JUL2003	52	4	0	4					
		07JUL2003	53	4	0	4					
		08JUL2003	54	4	0	4					
		09JUL2003	55	4	0	4					
		10JUL2003	56	4	0	4					
		11JUL2003	57	4	0	4					
		12JUL2003	58	4	0	4					
		13JUL2003	59	4	0	4	NO	0	59	100	
	E0035004	27NOV2002	1	2	0	2					
		28NOV2002	2	1	0	1					
		29NOV2002	3	1	0	1					
		30NOV2002	4	2	0	2					
		01DEC2002	5	3	0	3					
		02DEC2002	6	3	0	3					
		03DEC2002	7	3	0	3	NO	0	7	100	
	E0035009	27DEC2002	1	2	0	2					

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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0035009	28DEC2002	2	1	0	1					
		29DEC2002	3	1	0	1					
		30DEC2002	4	2	0	2					
		31DEC2002	5	3	0	3					
		01JAN2003	6	3	0	3					
		02JAN2003	7	3	0	3					
		03JAN2003	8	4	0	4					
		04JAN2003	9	4	0	4					
		05JAN2003	10	4	0	4					
		06JAN2003	11	4	0	4					
		07JAN2003	12	4	0	4					
		08JAN2003	13	4	0	4					
		09JAN2003	14	4	0	4					
		10JAN2003	15	4	0	4					
		11JAN2003	16	4	0	4					
		12JAN2003	17	4	0	4					
		13JAN2003	18	4	0	4					
		14JAN2003	19	4	0	4					
		15JAN2003	20	4	0	4					
		16JAN2003	21	4	0	4					
		17JAN2003	22	4	0	4					
		18JAN2003	23	4	0	4					
		19JAN2003	24	4	0	4					
		20JAN2003	25	4	0	4					
		21JAN2003	26	4	0	4					
		22JAN2003	27	4	0	4					
		23JAN2003	28	4	0	4					
		24JAN2003	29	4	0	4					
		25JAN2003	30	4	0	4					
		26JAN2003	31	4	0	4					
		27JAN2003	32	4	0	4					
		28JAN2003	33	4	0	4					
		29JAN2003	34	4	0	4					
		30JAN2003	35	4	0	4					
		31JAN2003	36	4	0	4					
		01FEB2003	37	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0035009	02FEB2003	38	4	0	4					
		03FEB2003	39	4	0	4					
		04FEB2003	40	4	0	4					
		05FEB2003	41	4	0	4					CARD NOT RETURNED
		06FEB2003	42	4	0	4					CANNOT CONFIRM DOSES.
		07FEB2003	43	4	0	4					
		08FEB2003	44	4	0	4					
		09FEB2003	45	4	0	4					
		10FEB2003	46	4	0	4					
		11FEB2003	47	4	0	4					
		12FEB2003	48	4	0	8					UNKNOWN
		13FEB2003	49	4	0	8					
		14FEB2003	50	4	0	4					
		15FEB2003	51	4	0	4					
		16FEB2003	52	4	0	4					
		17FEB2003	53	4	0	4	NO	0	53	104	
	E0035010	10JAN2003	1	2	0	2					
		11JAN2003	2	1	0	1					
		12JAN2003	3	1	0	1					
		13JAN2003	4	2	0	2					
		14JAN2003	5	3	0	3					
		15JAN2003	6	3	0	3					
		16JAN2003	7	3	0	3					
		17JAN2003	8	4	0	4					
		18JAN2003	9	4	0	4					
		19JAN2003	10	4	0	4					
		20JAN2003	11	4	0	4					
		21JAN2003	12	4	0	4					
		22JAN2003	13	4	0	4					
		23JAN2003	14	4	0	4					
		24JAN2003	15	4	0	4					
		25JAN2003	16	4	0	4					
		26JAN2003	17	4	0	4					
		27JAN2003	18	4	0	4					
		28JAN2003	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0035010	29JAN2003	20	4	0	4					
		30JAN2003	21	4	0	4					
		31JAN2003	22	4	0	4					
		01FEB2003	23	4	0	4					
		02FEB2003	24	4	0	4					
		03FEB2003	25	4	4	0					PT. SKIPPED DOSES ON DAY 4 - 6
		04FEB2003	26	4	4	0					
		05FEB2003	27	4	4	0					
		06FEB2003	28	4	0	4					
		07FEB2003	29	4	0	4					
		08FEB2003	30	4	0	4					
		09FEB2003	31	4	0	4					
		10FEB2003	32	4	0	4					
		11FEB2003	33	4	0	4					
		12FEB2003	34	4	0	4					
		13FEB2003	35	4	0	4					
		14FEB2003	36	4	0	4					
		15FEB2003	37	4	0	4					
		16FEB2003	38	4	0	4					
		17FEB2003	39	4	0	4					
		18FEB2003	40	4	0	4					
		19FEB2003	41	4	0	4					
		20FEB2003	42	4	0	4					
		21FEB2003	43		0	4					
		22FEB2003	44		0	4					
		23FEB2003	45			0					
		24FEB2003	46	4	0	4					
		25FEB2003	47	4	0	4					
		26FEB2003	48	4	0	4					
		27FEB2003	49	4	0	4					
		28FEB2003	50	4	0	4					PT. WAS DISPENSED A NEW BLISTER CARD FOR 2-28-03.
		01MAR2003	51	4	0	4					
		02MAR2003	52	4	0	4					
		03MAR2003	53	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0035010	04MAR2003	54	4	0	4					
		05MAR2003	55	4	0	4	NO	0	51	92.3	
	E0035022	09MAY2003	1	2	0	2					
		10MAY2003	2	1	0	1					
		11MAY2003	3	1	0	1					
		12MAY2003	4	2	0	2					
		13MAY2003	5	3	0	3					
		14MAY2003	6	3	0	3					
		15MAY2003	7	4	0	4					
		16MAY2003	8	4	0	4					
		17MAY2003	9	4	0	4					
		18MAY2003	10	4	0	4					
		19MAY2003	11	4	0	4					
		20MAY2003	12	4	0	4					
		21MAY2003	13	4	0	4					
		22MAY2003	14		0	4					
		23MAY2003	15	4	0	4					
		24MAY2003	16	4	0	4					
		25MAY2003	17	4	0	4					
		26MAY2003	18	4	0	4					
		27MAY2003	19	4	0	4					
		28MAY2003	20	4	0	4					
		29MAY2003	21	4	0	4					
		30MAY2003	22	4	0	4					
		31MAY2003	23	4	0	4					
		01JUN2003	24	4	0	4					
		02JUN2003	25	4	0	4					
		03JUN2003	26	4	0	4					
		04JUN2003	27	4	0	4					
		05JUN2003	28	4	0	4					
		06JUN2003	29	4	0	4					
		07JUN2003	30	4	0	4					
		08JUN2003	31	4	0	4					
		09JUN2003	32	4	0	4					
		10JUN2003	33	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0035022	11JUN2003	34	4	0	4					
		12JUN2003	35	4	0	4					
		13JUN2003	36	4	0	4					
		14JUN2003	37	4	0	4					
		15JUN2003	38	4	0	4					
		16JUN2003	39	4	0	4					
		17JUN2003	40	4	0	4					
		18JUN2003	41	4	0	4					
		19JUN2003	42	4	0	4					
		20JUN2003	43	4	0	4					
		21JUN2003	44	4	0	4					
		22JUN2003	45	4	0	4					
		23JUN2003	46	4	0	4					
		24JUN2003	47	4	0	4					
		25JUN2003	48	4	0	4					
		26JUN2003	49	4	0	4					
		27JUN2003	50	4	0	4					
		28JUN2003	51	4	0	4					
		29JUN2003	52	4	0	4					
		30JUN2003	53	4	0	4					
		01JUL2003	54	4	0	4					
		02JUL2003	55	4	0	4					
		03JUL2003	56	4	0	4					
		04JUL2003	57		0	4					
		05JUL2003	58		0	4	NO	0	58	100	PT DID NOT DOSE ON 07-06-2003
	E0039003	25NOV2002	1	2	0	2					
		26NOV2002	2	1	0	1					
		27NOV2002	3	1	0	1					
		28NOV2002	4	2	0	2					
		29NOV2002	5	3	0	3					
		30NOV2002	6	3	0	3					
		01DEC2002	7	3	0	3					
		02DEC2002	8	4	0	4					
		03DEC2002	9	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0039003	04DEC2002	10	4	0	4					
		05DEC2002	11	4	0	4					
		06DEC2002	12	4	0	4					
		07DEC2002	13	4	0	4					
		08DEC2002	14	4	0	4					
		09DEC2002	15	4	0	4					
		10DEC2002	16	4	0	4					
		11DEC2002	17	4	0	4					
		12DEC2002	18	4	0	4					
		13DEC2002	19	4	0	4					
		14DEC2002	20	4	0	4					
		15DEC2002	21	4	0	4					
		16DEC2002	22		0	4					
		17DEC2002	23		0	4	NO	0	23	100	
	E0040001	27JUN2003	1	2	0	2					
		28JUN2003	2	1	0	1					
		29JUN2003	3	1	0	1					
		30JUN2003	4	2	0	2					
		01JUL2003	5	3	0	3					
		02JUL2003	6	3	0	3					
		03JUL2003	7	3	0	3					BLISTERCARD REDISPENSED TO ALLOW SUBJECT TO COMPLETE TITRATION.
		04JUL2003	8	4	0	4					
		05JUL2003	9	4	0	4					
		06JUL2003	10	4	0	4					
		07JUL2003	11	4	0	4					
		08JUL2003	12	4	0	4					
		09JUL2003	13	4	0	4					
		10JUL2003	14	4	0	4					
		11JUL2003	15	4	0	4					
		12JUL2003	16	4	0	4					
		13JUL2003	17	4	0	4					
		14JUL2003	18	4	0	4					
		15JUL2003	19	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0040001	16JUL2003	20	4	0	4					
		17JUL2003	21	4	0	4					
		18JUL2003	22	4	0	4					
		19JUL2003	23	4	0	4					
		20JUL2003	24	4	0	4					
		21JUL2003	25	4	0	4					
		22JUL2003	26	4	0	4					
		23JUL2003	27	4	0	4					
		24JUL2003	28	4	0	4					
		25JUL2003	29	4	0	4					
		26JUL2003	30	4	0	4					
		27JUL2003	31	4	0	4					
		28JUL2003	32	4	0	4					
		29JUL2003	33	4	0	4					
		30JUL2003	34	4	0	4					
		31JUL2003	35	4	0	4					
		01AUG2003	36	4	0	4					
		02AUG2003	37	4	0	4					
		03AUG2003	38	4	0	4					
		04AUG2003	39	4	0	4					
		05AUG2003	40	4	0	4					
		06AUG2003	41	4	0	4					
		07AUG2003	42	4	0	4					
		08AUG2003	43	4	0	4					
		09AUG2003	44	4	0	4					
		10AUG2003	45	4	0	4					
		11AUG2003	46	4	0	4					
		12AUG2003	47	4	0	4					
		13AUG2003	48	4	0	4					
		14AUG2003	49	4	0	4					
		15AUG2003	50	4	0	4					
		16AUG2003	51	4	0	4					
		17AUG2003	52	4	0	4					
		18AUG2003	53	4	0	4					
		19AUG2003	54	4	0	4					
		20AUG2003	55	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0040001	21AUG2003	56	4	0	4	NO	0	56	100	
	E0040004	18JUL2003	1	2	0	2					PT. DIDN'T BRING BACK STUDY MEDS. SUBJECT LOST TO FOLLOW - UP. BLISTERCARD WASN'T RETURNED.
		19JUL2003	2	1	0	1					
		20JUL2003	3	1	0	1					
		21JUL2003	4	2	0	2					
		22JUL2003	5	3	0	3					
		23JUL2003	6	3	0	3					
		24JUL2003	7	3	0	3					
		25JUL2003	8		0	4					UNKNOWN
		26JUL2003	9		0	4	NO	0	9	100	
	E0041002	21JAN2003	1	2	0	2					
		22JAN2003	2	1	0	1					
		23JAN2003	3	1	0	1					
		24JAN2003	4	2	0	2					
		25JAN2003	5	3	0	3					
		26JAN2003	6	3	0	3					
		27JAN2003	7	3	0	3					
		28JAN2003	8	4	1	3					PATIENT FORGOT ONE TAB
		29JAN2003	9	4	0	4					
		30JAN2003	10	4	0	4					
		31JAN2003	11	4	0	4					
		01FEB2003	12	4	0	4					
		02FEB2003	13	4	0	4					
		03FEB2003	14	4	0	4					
		04FEB2003	15	4	0	4					
		05FEB2003	16	4	0	4					
		06FEB2003	17	4	0	4					
		07FEB2003	18	4	0	4					
		08FEB2003	19	4	0	4					
		09FEB2003	20	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
GENERATED: 12JUL2005 17:45:41 iceadmn3

Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0041002	10FEB2003	21	4	0	4					
		11FEB2003	22	4	0	4					
		12FEB2003	23	4	0	4					
		13FEB2003	24	4	0	4					
		14FEB2003	25	4	0	4					
		15FEB2003	26	4	0	4					
		16FEB2003	27	4	0	4					
		17FEB2003	28	4	0	4					
		18FEB2003	29	4	0	4					
		19FEB2003	30	4	0	4					
		20FEB2003	31	4	0	4					
		21FEB2003	32	4	0	4					
		22FEB2003	33	4	0	4					
		23FEB2003	34	4	0	4					
		24FEB2003	35	4	0	4					
		25FEB2003	36	4	0	4					LATE ENTRY - JAP 03/25/03 SUBJECT LOST BLISTERCARD AND IT WAS NOT RETURNED. PER THE SUBJECTS REPORT, HE HAD TAKEN ALL DOSES FROM THIS CARD AND HIS LAST DOSE WAS ON 03/05/03 (4 TABS).
		26FEB2003	37	4	0	4					
		27FEB2003	38	4	0	4					
		28FEB2003	39	4	0	4					
		01MAR2003	40	4	0	4					
		02MAR2003	41	4	0	4					
		03MAR2003	42	4	0	4					
		04MAR2003	43		0	4					
		05MAR2003	44		0	4	NO	0	44	100	
	E0041005	05MAR2003	1	2	0	2					
		06MAR2003	2	1	0	1					
		07MAR2003	3	1	0	1					
		08MAR2003	4	2	0	2					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0041005	09MAR2003	5	3	0	3					
		10MAR2003	6	3	0	3					
		11MAR2003	7	3	0	3					3 TABLETS REDISPENSED TO SUBJECT ON 03/11/03.
		12MAR2003	8	4	0	4					SIC VISIT 3 TOOK PLACE ON 03/11/03, BUT SUBJECT WAS REDISPENSED MEDICATION ON THIS DATE FROM WEEK 1 BLISTER CARD. SEE PAGE 199.
		13MAR2003	9	4	0	4					
		14MAR2003	10	4	0	4					
		15MAR2003	11	4	0	4					
		16MAR2003	12	4	0	4					
		17MAR2003	13	4	0	4					
		18MAR2003	14	4	0	4					
		19MAR2003	15	4	0	4					
		20MAR2003	16	4	0	4					
		21MAR2003	17	4	0	4					
		22MAR2003	18	4	0	4					
		23MAR2003	19	4	0	4					
		24MAR2003	20	4	0	4					
		25MAR2003	21	4	0	4					
		26MAR2003	22	4	0	4					
		27MAR2003	23	4	0	4					
		28MAR2003	24	4	0	4					
		29MAR2003	25	4	0	4					
		30MAR2003	26	4	0	4					
		31MAR2003	27	4	0	4					
		01APR2003	28	4	0	4					
		02APR2003	29	4	0	4					
		03APR2003	30	4	0	4					
		04APR2003	31	4	0	4					
		05APR2003	32	4	0	4					
		06APR2003	33	4	0	4					
		07APR2003	34	4	0	4					

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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Listing 12.2.5 Study Compliance and Exposure

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	DATE	DAY	DRUG TABLET ADMINISTRATION: DISPENSE	DRUG TABLET ADMINISTRATION: RETURN (ADJUSTED)	TABLETS TAKEN	DOSE REDUCTION?	MEAN DAILY DOSE	COMPLIANCE: NO. DAYS STUDY DRUG	COMPLIANCE: %	COMMENTS
PLACEBO (BIPOLAR II)	E0041005	08APR2003	35	4	0	4					
		09APR2003	36	4	0	4					
		10APR2003	37	4	0	4					
		11APR2003	38	4	0	4					
		12APR2003	39	4	0	4					
		13APR2003	40	4	0	4					
		14APR2003	41	4	0	4					
		15APR2003	42	4	0	4					
		16APR2003	43	4	0	4					
		17APR2003	44	4	0	4					
		18APR2003	45	4	0	4					
		19APR2003	46	4	0	4					
		20APR2003	47	4	0	4					
		21APR2003	48	4	0	4					
		22APR2003	49	4	0	4					
		23APR2003	50	4	0	4					
		24APR2003	51	4	0	4					
		25APR2003	52	4	0	4					
		26APR2003	53	4	0	4					
		27APR2003	54	4	0	4					
		28APR2003	55	4	0	4					
		29APR2003	56	4	0	4	NO	0	56	100	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PRESN100.SAS
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AstraZeneca

Clinical Study Report: Appendix 12.2.6

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.6
Individual efficacy and pharmacokinetic response data

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1		04FEB2003	1	PP			30		3	4	4	2	3	2	3	4	4	1
		DAY 8		12FEB2003	9	PP	-53	NO	14	-16	2	2	1	0	3	1	1	2	2	0
		DAY 15		19FEB2003	16	PP	-53	NO	14	-16	2	1	1	0	2	1	2	2	2	1
		DAY 22		26FEB2003	23	PP	-77	YES	7	-23	1	0	0	0	2	0	1	2	1	0
		DAY 29		05MAR2003	30	PP	-83	YES	5	-25	1	0	0	0	1	0	0	2	1	0
		DAY 36		11MAR2003	36	PP	-77	YES	7	-23	1	0	2	0	0	0	2	2	0	0
		DAY 43		18MAR2003	43	PP	-87	YES	4	-26	1	0	0	0	0	0	1	2	0	0
		DAY 50		25MAR2003	50	PP	-90	YES	3	-27	0	0	1	0	0	0	0	2	0	0
		DAY 57		02APR2003	58	PP	-80	YES	6	-24	1	0	2	0	0	0	3	0	0	0
	E0002010	DAY 1		04APR2003	1	PP			32		3	3	5	3	2	3	3	4	3	3
		DAY 8		10APR2003	7	PP	0	NO	32	0	3	3	4	1	3	3	4	4	4	3
	E0002012	DAY 1		21APR2003	1	PP			24		3	3	3	2	1	2	2	2	4	2
		DAY 8		29APR2003	9	PP	-21	NO	19	-5	2	3	1	2	3	2	1	2	2	1
		DAY 15		06MAY2003	16	PP	-29	NO	17	-7	2	2	2	2	0	2	2	2	2	1
		DAY 22		15MAY2003	25	PP	-42	NO	14	-10	2	2	2	0	0	2	2	1	2	1
		DAY 29		21MAY2003	31	PP	-33	NO	16	-8	3	2	2	0	2	1	2	1	2	1
		DAY 36		28MAY2003	38	PP	-54	YES	11	-13	2	2	2	1	1	1	0	0	2	0
		DAY 43		04JUN2003	45	PP	-54	YES	11	-13	3	3	2	0	0	0	0	0	2	1
		DAY 50		11JUN2003	52	PP	-79	YES	5	-19	1	1	1	0	0	0	1	0	1	0
		DAY 57		16JUN2003	57	PP	-79	YES	5	-19	1	1	2	0	0	0	1	0	0	0
	E0002015	DAY 1		04JUN2003	1	SAFETY			19		2	2	3	0	0	3	2	2	3	2
	E0002018	DAY 1		24JUL2003	1	ITT			13		1	1	2	0	0	2	3	2	1	1
		DAY 8	*	30JUL2003	7	ITT	-8	YES	12	-1	1	1	2	0	0	2	2	2	1	1
		DAY 8		01AUG2003	9	ITT	-39	YES	8	-5	1	1	0	0	0	1	2	2	1	0

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0003004	DAY 1	17DEC2002	1	SAFETY			34		3	4	4	4	0	6	5	3	2	3
	E0003005	DAY 1	23DEC2002	1	PP			26		4	1	3	2	2	3	3	4	2	2
		DAY 8	30DEC2002	8	PP	-19	NO	21	-5	3	4	3	0	3	1	2	1	3	1
		DAY 15	06JAN2003	15	PP	-23	NO	20	-6	2	1	3	0	3	2	3	3	3	0
		DAY 22	14JAN2003	23	PP	-50	NO	13	-13	0	0	3	1	2	2	2	1	2	0
		DAY 29	21JAN2003	30	PP	-15	NO	22	-4	3	4	4	0	0	3	1	3	3	1
		DAY 36	28JAN2003	37	PP	-8	NO	24	-2	3	3	4	0	3	2	2	3	3	1
		DAY 43	04FEB2003	44	PP	0	NO	26	0	3	3	4	1	2	2	1	4	4	2
		DAY 50	11FEB2003	51	PP	-27	NO	19	-7	2	1	5	2	0	2	2	0	4	1
		DAY 57	18FEB2003	58	PP	-23	NO	20	-6	3	1	3	3	0	3	2	2	2	1
	E0003007	DAY 1	02JAN2003	1	PP			31		3	4	3	4	5	4	2	4	2	0
		DAY 8	09JAN2003	8	PP	-55	NO	14	-17	1	2	3	1	3	1	2	0	1	0
		DAY 15	16JAN2003	15	PP	-48	NO	16	-15	1	1	2	1	3	1	4	0	2	1
		DAY 22	23JAN2003	22	PP	-52	NO	15	-16	1	1	2	1	3	1	3	1	2	0
		DAY 29	30JAN2003	29	PP	-19	NO	25	-6	3	4	3	0	4	4	4	1	2	0
		DAY 36	07FEB2003	37	PP	-84	YES	5	-26	0	1	0	0	3	0	0	0	1	0
		DAY 43	13FEB2003	43	PP	-84	YES	5	-26	2	0	2	0	0	0	1	0	0	0
		DAY 50	20FEB2003	50	PP	-81	YES	6	-25	1	0	0	3	0	0	1	1	0	0
		DAY 57	27FEB2003	57	PP	-90	YES	3	-28	0	0	2	0	0	0	1	0	0	0
	E0003015	DAY 1	05MAY2003	1	PP			25		3	3	3	4	0	0	3	4	3	2
		DAY 8	13MAY2003	9	PP	16	NO	29	4	3	3	4	3	0	3	3	4	3	3
		DAY 15	19MAY2003	15	PP	-16	NO	21	-4	3	3	3	0	2	2	2	3	2	1
		DAY 22	27MAY2003	23	PP	-84	YES	4	-21	2	1	1	0	0	0	0	0	0	0
		DAY 29	04JUN2003	31	PP	-56	YES	11	-14	1	1	3	2	0	2	1	0	1	0
		DAY 36	10JUN2003	37	PP	-100	YES	0	-25	0	0	0	0	0	0	0	0	0	0
		DAY 43	17JUN2003	44	PP	-84	YES	4	-21	0	0	2	1	0	0	0	0	1	0

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	DAY 50	24JUN2003	51	PP	-84	YES	4	-21	1	0	1	0	0	0	0	1	1	0
		DAY 57	02JUL2003	59	PP	-24	NO	19	-6	0	0	4	5	2	4	2	0	2	0
	E0004002	DAY 1	01OCT2002	1	PP			29		4	4	4	0	0	4	4	4	5	0
		DAY 8	10OCT2002	10	PP	-28	NO	21	-8	2	3	3	0	1	3	2	3	4	0
		DAY 15	17OCT2002	17	PP	-52	NO	14	-15	1	1	2	0	0	2	2	2	4	0
		DAY 22	22OCT2002	22	PP	-62	YES	11	-18	1	1	1	0	0	3	0	1	4	0
		DAY 29	29OCT2002	29	PP	-66	YES	10	-19	2	2	2	0	0	1	0	0	3	0
		DAY 36	05NOV2002	36	PP	-72	YES	8	-21	1	1	1	0	0	1	1	0	2	1
		DAY 43	12NOV2002	43	PP	-38	NO	18	-11	3	3	2	1	0	2	3	2	1	1
		DAY 50	19NOV2002	50	PP	-69	YES	9	-20	1	1	2	0	0	1	2	1	1	0
		DAY 57	26NOV2002	57	PP	-79	YES	6	-23	0	1	3	1	0	0	0	0	1	0
	E0004013	DAY 1	14JAN2003	1	PP			34		4	4	3	4	3	4	3	4	4	1
		DAY 8	21JAN2003	8	PP	-15	NO	29	-5	4	3	3	2	2	3	3	4	4	1
		DAY 15	30JAN2003	17	PP	-32	NO	23	-11	3	2	3	4	0	3	3	4	1	0
		DAY 22	05FEB2003	23	PP	-18	NO	28	-6	3	4	4	0	2	3	5	4	3	0
	E0004018	DAY 1	19MAR2003	1	PP			33		3	4	3	3	2	4	4	4	4	2
		DAY 8	26MAR2003	8	PP	-24	NO	25	-8	3	3	0	2	2	3	4	4	4	0
		DAY 15	02APR2003	15	PP	-9	NO	30	-3	3	4	3	2	3	3	4	4	3	1
		DAY 22	09APR2003	22	PP	-30	NO	23	-10	2	2	2	4	3	2	4	2	2	0
		DAY 29	16APR2003	29	PP	-58	NO	14	-19	2	1	2	4	2	0	1	0	2	0
		DAY 36	23APR2003	36	PP	-61	NO	13	-20	2	1	2	4	2	0	1	0	1	0
		DAY 43	30APR2003	43	PP	-79	YES	7	-26	1	0	1	2	1	0	1	0	1	0
		DAY 50	06MAY2003	49	PP	-73	YES	9	-24	2	1	0	0	2	0	2	2	0	0
		DAY 57	13MAY2003	56	PP	-67	YES	11	-22	2	1	0	3	3	0	2	0	0	0
	E0004021	DAY 1	14MAY2003	1	PP			29		3	4	3	3	0	4	4	4	3	1

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QUETIAPINE 300 MG (BIPOLAR I)	E0004021	DAY 8		21MAY2003	8	PP	-35	NO	19	-10	2	1	4	2	0	2	2	3	3	0
		DAY 15		28MAY2003	15	PP	-55	NO	13	-16	1	2	2	0	0	3	1	2	1	1
		DAY 22		04JUN2003	22	PP	-69	YES	9	-20	1	1	1	2	0	0	1	1	2	0
		DAY 29		11JUN2003	29	PP	-66	YES	10	-19	1	1	2	2	0	2	1	1	0	0
		DAY 36		18JUN2003	36	PP	-79	YES	6	-23	0	1	0	2	0	2	1	0	0	0
		DAY 43		25JUN2003	43	PP	-69	YES	9	-20	1	0	1	2	0	2	2	1	0	0
		DAY 50		02JUL2003	50	PP	-79	YES	6	-23	0	1	2	0	0	2	0	1	0	0
		DAY 57		09JUL2003	57	PP	-83	YES	5	-24	1	0	0	1	0	2	1	0	0	0
	E0005002	DAY 1		03OCT2002	1	PP			31		4	5	4	4	0	4	4	3	2	1
		DAY 8		08OCT2002	6	PP	3	NO	32	1	4	4	2	5	0	4	3	4	4	2
		DAY 8	*	14OCT2002	12	PP	-55	NO	14	-17	3	2	2	2	0	0	2	1	2	0
		DAY 15		21OCT2002	19	PP	-61	YES	12	-19	1	1	2	3	0	2	1	1	1	0
		DAY 22		28OCT2002	26	PP	-77	YES	7	-24	0	0	2	4	0	0	0	0	1	0
		DAY 29		04NOV2002	33	PP	-74	YES	8	-23	1	0	0	3	0	0	1	2	1	0
		DAY 43		13NOV2002	42	PP	-58	NO	13	-18	0	1	2	3	2	1	2	1	1	0
		DAY 43	*	18NOV2002	47	PP	-84	YES	5	-26	0	0	0	2	2	0	0	0	1	0
		DAY 50		25NOV2002	54	PP	-90	YES	3	-28	0	0	0	2	0	0	1	0	0	0
	E0005004	DAY 1		01OCT2002	1	PP			31		4	4	4	5	0	4	3	3	3	1
		DAY 8		10OCT2002	10	PP	-48	NO	16	-15	0	1	2	0	0	4	2	3	3	1
		DAY 15		15OCT2002	15	PP	-65	YES	11	-20	2	1	2	0	0	3	3	0	0	0
	E0005013	DAY 1		07NOV2002	1	SAFETY			37		4	4	4	4	3	4	4	4	4	2
	E0005024	DAY 1		10FEB2003	1	PP			36		4	5	4	4	3	4	4	4	3	1
		DAY 8		18FEB2003	9	PP	-50	NO	18	-18	2	3	2	0	2	2	2	2	2	1
		DAY 15		26FEB2003	17	PP	-83	YES	6	-30	1	1	0	0	0	2	1	1	0	0
		DAY 22		06MAR2003	25	PP	-94	YES	2	-34	0	0	0	0	0	2	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	DAY 29	13MAR2003	32	PP	-94	YES	2	-34	0	0	0	0	0	2	0	0	0	0
		DAY 36	20MAR2003	39	PP	-94	YES	2	-34	0	0	0	0	0	2	0	0	0	0
		DAY 43	25MAR2003	44	PP	-94	YES	2	-34	0	0	0	0	0	2	0	0	0	0
		DAY 50	02APR2003	52	PP	-86	YES	5	-31	0	0	3	0	0	2	0	0	0	0
		DAY 57	09APR2003	59	PP	-92	YES	3	-33	0	0	1	0	0	2	0	0	0	0
	E0005027	DAY 1	11MAR2003	1	PP (24)			33		4	5	4	3	0	4	3	4	4	2
		DAY 8	19MAR2003	9	PP (24)	0	NO	33	0	5	5	4	0	0	4	4	4	4	3
		DAY 15	26MAR2003	16	PP (24)	-12	NO	29	-4	4	4	4	0	0	4	4	4	3	2
		DAY 22	03APR2003	24	PP (24)	-15	NO	28	-5	4	4	3	1	0	4	4	4	3	1
	E0005037	DAY 1	07MAY2003	1	PP			37		4	4	4	5	2	4	4	4	4	2
		DAY 8	15MAY2003	9	PP	-22	NO	29	-8	4	4	4	0	2	4	3	4	3	1
		DAY 15	22MAY2003	16	PP	-16	NO	31	-6	4	4	3	4	3	3	4	3	2	1
		DAY 22	27MAY2003	21	PP	-11	NO	33	-4	4	4	3	4	3	4	4	4	2	1
		DAY 29	05JUN2003	30	PP	-27	NO	27	-10	3	3	3	3	3	3	3	3	2	1
		DAY 36	12JUN2003	37	PP	-32	NO	25	-12	2	3	2	2	1	3	4	4	3	1
		DAY 57	02JUL2003	57	PP	-27	NO	27	-10	2	3	3	2	2	3	4	4	3	1
	E0005042	DAY 1	24JUN2003	1	PP			28		4	4	3	2	0	4	4	3	3	1
		DAY 8	02JUL2003	9	PP	-46	NO	15	-13	2	1	2	0	0	3	2	2	2	1
		DAY 15	09JUL2003	16	PP	-57	YES	12	-16	1	1	2	0	0	2	2	1	2	1
		DAY 22	16JUL2003	23	PP	-50	NO	14	-14	1	2	2	0	0	2	2	2	2	1
		DAY 29	23JUL2003	30	PP	-57	YES	12	-16	1	1	2	0	0	2	2	1	2	1
		DAY 36	30JUL2003	37	PP	-61	YES	11	-17	0	1	2	0	0	2	2	2	2	0
		DAY 43	06AUG2003	44	PP	-57	YES	12	-16	1	1	3	0	0	2	2	1	2	0
		DAY 50	12AUG2003	50	PP	-64	YES	10	-18	0	0	2	0	0	2	2	1	2	1
		DAY 57	18AUG2003	56	PP	-79	YES	6	-22	0	0	2	0	0	2	1	1	0	0

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 1	05DEC2002	1	PP			37		5	5	4	4	3	4	4	3	3	2
		DAY 8	12DEC2002	8	PP	-24	NO	28	-9	4	4	3	1	1	3	4	3	4	1
		DAY 15	20DEC2002	16	PP	-16	NO	31	-6	4	4	3	3	2	2	4	4	4	1
		DAY 22	30DEC2002	26	PP	-16	NO	31	-6	5	5	2	0	3	4	4	1	5	2
		DAY 29	03JAN2003	30	PP	-57	NO	16	-21	2	2	2	0	0	0	1	0	5	4
		DAY 36	09JAN2003	36	PP	-22	NO	29	-8	3	4	4	3	1	2	4	3	3	2
		DAY 43	16JAN2003	43	PP	-32	NO	25	-12	4	3	3	0	2	2	3	4	3	1
		DAY 50	23JAN2003	50	PP	-24	NO	28	-9	3	3	3	3	3	2	4	3	2	2
		DAY 57	30JAN2003	57	PP	-38	NO	23	-14	3	3	2	3	0	1	4	3	3	1
	E0006018	DAY 1	13MAR2003	1	ITT			30		4	4	3	2	1	5	3	3	4	1
		DAY 8	24MAR2003	12	ITT	-27	NO	22	-8	4	4	2	2	1	1	3	2	2	1
	E0007013	DAY 1	13JUN2003	1	PP			27		4	4	2	3	0	3	3	4	3	1
		DAY 8	20JUN2003	8	PP	-4	NO	26	-1	4	4	2	4	0	2	3	4	2	1
		DAY 15	26JUN2003	14	PP	-19	NO	22	-5	3	3	1	5	0	2	2	3	2	1
		DAY 22	03JUL2003	21	PP	-19	NO	22	-5	3	3	2	5	0	2	2	3	1	1
		DAY 29	10JUL2003	28	PP	-44	NO	15	-12	2	2	1	5	0	1	1	2	0	1
		DAY 36	17JUL2003	35	PP	-52	NO	13	-14	2	2	2	3	0	1	1	1	0	1
		DAY 43	24JUL2003	42	PP	-56	YES	12	-15	2	1	2	3	0	1	1	1	0	1
		DAY 50	01AUG2003	50	PP	-70	YES	8	-19	1	0	1	3	0	1	1	1	0	0
		DAY 57	07AUG2003	56	PP	-56	YES	12	-15	1	1	1	3	0	1	2	2	0	1
	E0010004	DAY 1	11DEC2002	1	PP			30		3	2	4	4	0	4	4	4	3	2
		DAY 8	18DEC2002	8	PP	-30	NO	21	-9	2	4	2	1	0	4	2	4	1	1
		DAY 15	26DEC2002	16	PP	-43	NO	17	-13	1	2	4	0	0	4	2	3	1	0
		DAY 22	02JAN2003	23	PP	17	NO	35	5	4	4	4	4	2	4	4	4	3	2
		DAY 36	13JAN2003	34	PP	-53	NO	14	-16	1	1	2	1	2	0	2	3	2	0
		DAY 43	21JAN2003	42	PP	-60	YES	12	-18	1	2	3	0	0	0	2	2	2	0

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	DAY 50	31JAN2003	52	PP	-27	NO	22	-8	2	3	4	0	3	3	1	3	3	0
		DAY 57	06FEB2003	58	PP	-60	YES	12	-18	2	2	2	0	0	2	0	2	2	0
	E0010012	DAY 1	07JAN2003	1	PP			36		3	3	4	5	4	4	4	4	3	2
		DAY 8	14JAN2003	8	PP	-17	NO	30	-6	4	3	4	1	2	4	3	4	3	2
		DAY 15	21JAN2003	15	PP	-56	NO	16	-20	2	2	2	0	3	2	2	1	2	0
		DAY 22	28JAN2003	22	PP	-67	YES	12	-24	1	2	2	0	2	0	2	1	2	0
		DAY 29	04FEB2003	29	PP	-67	YES	12	-24	2	2	2	0	2	0	2	0	2	0
		DAY 36	11FEB2003	36	PP	-69	YES	11	-25	0	1	2	0	2	0	2	2	2	0
		DAY 43	18FEB2003	43	PP	-75	YES	9	-27	0	2	1	0	2	0	1	1	2	0
		DAY 50	25FEB2003	50	PP	-89	YES	4	-32	0	0	1	0	2	0	1	0	0	0
		DAY 57	05MAR2003	58	PP	-94	YES	2	-34	0	0	2	0	0	0	0	0	0	0
	E0010024	DAY 1	05MAY2003	1	PP			28		3	4	3	4	0	2	4	4	2	2
		DAY 8	12MAY2003	8	PP	-29	NO	20	-8	3	3	3	0	0	1	3	3	2	2
		DAY 15	19MAY2003	15	PP	-18	NO	23	-5	2	3	2	1	0	2	4	3	3	3
		DAY 22	27MAY2003	23	PP	-25	NO	21	-7	2	3	2	0	0	2	4	3	2	3
		DAY 29	04JUN2003	31	PP	-14	NO	24	-4	3	3	2	1	0	2	4	3	3	3
		DAY 36	11JUN2003	38	PP	-39	NO	17	-11	2	3	2	0	0	3	1	1	2	3
		DAY 43	18JUN2003	45	PP	-32	NO	19	-9	1	2	2	0	0	2	3	4	2	3
		DAY 50	25JUN2003	52	PP	-21	NO	22	-6	2	3	2	0	0	2	4	4	2	3
		DAY 57	02JUL2003	59	PP	-43	NO	16	-12	1	2	2	0	0	1	3	3	2	2
	E0010032	DAY 1	10JUL2003	1	ITT			35		4	4	3	4	2	4	4	4	4	2
		DAY 8	17JUL2003	8	ITT	-26	NO	26	-9	4	4	3	0	0	3	4	4	2	2
	E0011025	DAY 1	26JUN2003	1	PP			31		4	3	4	2	3	4	4	2	3	2
		DAY 8	02JUL2003	7	PP	-3	NO	30	-1	4	3	4	2	2	4	4	2	2	3
		DAY 15	10JUL2003	15	PP	-19	NO	25	-6	3	2	4	1	0	3	4	3	2	3

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	DAY 22	17JUL2003	22	PP	-19	NO	25	-6	3	2	4	1	0	3	4	3	2	3
		DAY 29	22JUL2003	27	PP	-29	NO	22	-9	2	2	4	1	0	2	4	3	2	2
		DAY 36	30JUL2003	35	PP	-32	NO	21	-10	2	2	4	0	0	2	4	3	2	2
		DAY 43	07AUG2003	43	PP	-48	NO	16	-15	2	2	3	0	0	2	3	2	1	1
		DAY 50	14AUG2003	50	PP	-58	NO	13	-18	1	2	2	1	0	1	3	2	1	0
		DAY 57	22AUG2003	58	PP	-68	YES	10	-21	1	1	2	1	0	1	2	2	0	0
	E0013007	DAY 1	20MAR2003	1	PP (19)			29		2	4	3	3	3	4	2	3	2	3
		DAY 8	27MAR2003	8	PP (19)	-31	NO	20	-9	2	3	2	0	2	3	2	3	1	2
		DAY 15	07APR2003	19	PP (19)	-3	NO	28	-1	3	3	3	3	3	3	3	2	2	3
	E0013009	DAY 1	02APR2003	1	PP			25		3	3	3	4	0	3	3	3	2	1
		DAY 8	09APR2003	8	PP	-28	NO	18	-7	2	3	2	0	3	2	2	2	1	1
		DAY 15	16APR2003	15	PP	-28	NO	18	-7	2	2	2	0	2	3	2	2	2	1
		DAY 22	24APR2003	23	PP	-68	YES	8	-17	1	1	1	0	0	3	1	0	1	0
		DAY 29	01MAY2003	30	PP	-68	YES	8	-17	0	0	2	0	0	3	2	1	0	0
		DAY 36	07MAY2003	36	PP	-84	YES	4	-21	1	1	0	0	0	0	1	0	0	1
		DAY 43	16MAY2003	45	PP	-84	YES	4	-21	0	0	1	0	0	2	0	0	0	1
		DAY 50	21MAY2003	50	PP	-72	YES	7	-18	1	1	1	0	0	2	0	1	1	0
		DAY 57	29MAY2003	58	PP	-80	YES	5	-20	0	0	2	0	0	1	0	1	1	0
	E0014006	DAY 1	25MAR2003	1	PP			25		2	4	3	3	0	2	2	3	4	2
		DAY 8	02APR2003	9	PP	-4	NO	24	-1	2	4	3	1	0	3	3	3	3	2
		DAY 15	09APR2003	16	PP	-8	NO	23	-2	2	3	2	2	0	3	3	3	3	2
		DAY 22	16APR2003	23	PP	-68	YES	8	-17	0	1	1	0	1	1	1	2	0	1
		DAY 29	23APR2003	30	PP	-88	YES	3	-22	0	0	0	0	0	0	1	2	0	0
		DAY 36	30APR2003	37	PP	-92	YES	2	-23	0	1	0	0	0	0	0	0	0	1
		DAY 43	07MAY2003	44	PP	-96	YES	1	-24	1	0	0	0	0	0	0	0	0	0
		DAY 50	14MAY2003	51	PP	-76	YES	6	-19	1	1	1	1	0	0	0	2	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	DAY 57	21MAY2003	58	PP	-96	YES	1	-24	0	0	0	0	0	0	0	1	0	0
	E0014010	DAY 1	22APR2003	1	PP			31		4	4	3	3	0	3	4	4	3	3
		DAY 8	30APR2003	9	PP	-36	NO	20	-11	2	3	3	0	2	2	3	3	1	1
		DAY 15	07MAY2003	16	PP	-52	NO	15	-16	1	1	2	2	0	3	3	2	1	0
		DAY 22	14MAY2003	23	PP	-61	YES	12	-19	1	1	2	2	0	2	1	1	2	0
		DAY 29	21MAY2003	30	PP	-58	NO	13	-18	1	1	2	0	1	2	2	3	1	0
		DAY 36	28MAY2003	37	PP	-74	YES	8	-23	1	1	2	0	0	1	1	1	1	0
		DAY 43	03JUN2003	43	PP	-26	NO	23	-8	2	2	3	4	0	2	3	3	2	2
		DAY 50	11JUN2003	51	PP	-32	NO	21	-10	3	3	3	2	1	2	1	1	3	2
		DAY 57	17JUN2003	57	PP	-39	NO	19	-12	2	2	3	2	1	2	2	1	2	2
	E0016001	DAY 1	22JAN2003	1	PP			28		3	3	4	4	0	3	4	4	3	0
		DAY 8	29JAN2003	8	PP	-43	NO	16	-12	2	2	2	2	0	2	2	2	2	0
		DAY 15	05FEB2003	15	PP	-68	YES	9	-19	1	1	2	2	1	1	0	1	0	0
		DAY 22	12FEB2003	22	PP	-82	YES	5	-23	0	0	2	0	0	0	2	0	1	0
		DAY 29	19FEB2003	29	PP	-68	YES	9	-19	0	0	1	2	1	0	2	1	1	1
		DAY 36	26FEB2003	36	PP	-96	YES	1	-27	0	0	0	0	0	0	1	0	0	0
		DAY 43	05MAR2003	43	PP	-89	YES	3	-25	0	0	0	0	0	1	1	1	0	0
		DAY 50	12MAR2003	50	PP	-89	YES	3	-25	1	0	1	0	0	0	1	0	0	0
		DAY 57	19MAR2003	57	PP	-96	YES	1	-27	1	0	0	0	0	0	0	0	0	0
	E0016004	DAY 1	03FEB2003	1	ITT			31		4	4	3	2	2	4	4	3	4	1
		DAY 8	10FEB2003	8	ITT	-52	NO	15	-16	2	3	2	2	0	2	2	2	0	0
	E0018001	DAY 1	29OCT2002	1	PP			31		4	4	3	3	2	4	4	3	3	1
		DAY 8	05NOV2002	8	PP	-13	NO	27	-4	4	4	4	0	0	4	4	3	4	0
		DAY 15	13NOV2002	16	PP	-77	YES	7	-24	1	1	1	0	0	1	1	1	1	0
		DAY 22	20NOV2002	23	PP	-87	YES	4	-27	0	0	2	0	0	2	0	0	0	0

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	DAY 29	27NOV2002	30	PP	-94	YES	2	-29	0	0	1	0	0	1	0	0	0	0
		DAY 36	04DEC2002	37	PP	-97	YES	1	-30	0	0	1	0	0	0	0	0	0	0
		DAY 43	11DEC2002	44	PP	-90	YES	3	-28	0	0	1	0	0	1	1	0	0	0
		DAY 50	18DEC2002	51	PP	-74	YES	8	-23	0	0	1	0	1	2	2	1	1	0
		DAY 57	24DEC2002	57	PP	-94	YES	2	-29	0	0	0	2	0	0	0	0	0	0
	E0018006	DAY 1	17DEC2002	1	PP			34		4	4	4	4	3	4	4	3	3	1
		DAY 8	23DEC2002	7	PP	-29	NO	24	-10	3	3	3	0	2	3	3	3	3	1
		DAY 15	31DEC2002	15	PP	-50	NO	17	-17	3	3	3	0	0	3	2	2	1	0
		DAY 22	07JAN2003	22	PP	-38	NO	21	-13	2	2	2	0	2	4	4	3	2	0
		DAY 29	14JAN2003	29	PP	-68	YES	11	-23	1	1	1	0	0	2	2	2	2	0
		DAY 36	21JAN2003	36	PP	-56	NO	15	-19	2	2	2	0	0	3	2	2	2	0
		DAY 43	28JAN2003	43	PP	-65	YES	12	-22	1	1	2	0	2	2	2	1	1	0
		DAY 50	06FEB2003	52	PP	-74	YES	9	-25	1	1	2	0	0	2	1	1	1	0
		DAY 57	13FEB2003	59	PP	-38	NO	21	-13	2	3	3	0	0	3	4	3	3	0
	E0019004	DAY 1	07NOV2002	1	PP			30		3	2	4	5	0	3	4	4	4	1
		DAY 8	14NOV2002	8	PP	-70	YES	9	-21	1	0	3	4	0	0	0	1	0	0
		DAY 15	21NOV2002	15	PP	-40	NO	18	-12	2	2	4	1	0	2	4	2	1	0
		DAY 22	26NOV2002	20	PP	-63	YES	11	-19	2	0	2	6	0	0	0	0	1	0
		DAY 29	05DEC2002	29	PP	-27	NO	22	-8	4	1	3	2	0	3	4	4	1	0
		DAY 36	12DEC2002	36	PP	-47	NO	16	-14	2	2	3	4	0	1	2	1	0	1
		DAY 43	19DEC2002	43	PP	-13	NO	26	-4	4	3	3	5	0	3	4	4	0	0
	E0019011	DAY 1	21NOV2002	1	PP			38		5	5	4	3	2	4	5	5	5	0
		DAY 8	27NOV2002	7	PP	-24	NO	29	-9	4	4	3	2	2	2	4	4	4	0
		DAY 15	05DEC2002	15	PP	-42	NO	22	-16	2	2	2	2	0	3	4	4	3	0
		DAY 22	12DEC2002	22	PP	-24	NO	29	-9	5	4	2	3	1	3	3	3	4	1
		DAY 29	19DEC2002	29	PP	-45	NO	21	-17	2	2	2	2	0	3	4	3	3	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0019011	DAY 43	02JAN2003	43	PP	-37	NO	24	-14	3	2	2	2	0	4	4	3	4	0
		DAY 50	09JAN2003	50	PP	-29	NO	27	-11	4	4	3	2	1	2	4	3	4	0
		DAY 57	16JAN2003	57	PP	-47	NO	20	-18	2	2	2	0	2	2	4	2	4	0
	E0019025	DAY 1	06FEB2003	1	PP			29		4	3	3	2	4	3	4	4	2	0
		DAY 8	13FEB2003	8	PP	-31	NO	20	-9	3	3	3	1	3	1	4	2	0	0
		DAY 15	20FEB2003	15	PP	-52	NO	14	-15	2	2	1	1	4	0	2	2	0	0
		DAY 22	27FEB2003	22	PP	-48	NO	15	-14	3	1	0	1	4	0	2	3	1	0
		DAY 29	06MAR2003	29	PP	-62	YES	11	-18	3	1	0	0	2	0	4	1	0	0
		DAY 36	13MAR2003	36	PP	-55	NO	13	-16	1	0	2	2	3	2	0	3	0	0
		DAY 43	20MAR2003	43	PP	-66	YES	10	-19	2	1	0	2	2	0	2	1	0	0
		DAY 50	27MAR2003	50	PP	-69	YES	9	-20	2	0	0	2	2	0	2	1	0	0
		DAY 57	03APR2003	57	PP	-72	YES	8	-21	2	0	0	1	2	0	1	1	1	0
	E0019026	DAY 1	24FEB2003	1	SAFETY			25		3	5	2	0	0	4	4	4	2	1
	E0019043	DAY 1	03JUN2003	1	PP			37		5	4	0	5	5	4	4	4	4	2
		DAY 8	10JUN2003	8	PP	-30	NO	26	-11	4	4	0	2	3	3	2	4	3	1
		DAY 15	17JUN2003	15	PP	-51	NO	18	-19	3	2	3	1	0	2	3	2	2	0
		DAY 22	24JUN2003	22	PP	-14	NO	32	-5	4	4	3	0	3	4	4	4	4	2
		DAY 29	01JUL2003	29	PP	-54	NO	17	-20	4	2	2	0	2	2	2	2	1	0
		DAY 36	08JUL2003	36	PP	-27	NO	27	-10	4	2	3	3	2	4	4	3	2	0
		DAY 43	15JUL2003	43	PP	-43	NO	21	-16	4	2	2	2	2	2	3	2	2	0
		DAY 50	22JUL2003	50	PP	-51	NO	18	-19	3	2	3	2	2	0	2	2	2	0
		DAY 57	29JUL2003	57	PP	-43	NO	21	-16	4	2	2	2	2	2	2	4	1	0
	E0020001	DAY 1	29OCT2002	1	PP			27		3	5	3	3	0	4	4	3	2	0
		DAY 8	05NOV2002	8	PP	-41	NO	16	-11	2	2	2	0	0	2	3	3	2	0
		DAY 15	12NOV2002	15	PP	11	NO	30	3	4	3	3	2	0	5	4	4	4	1

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	DAY 22		19NOV2002	22	PP	-56	YES	12	-15	2	1	3	0	0	1	2	0	0	3
		DAY 29		26NOV2002	29	PP	-7	NO	25	-2	3	4	3	2	0	2	3	4	4	0
		DAY 36		03DEC2002	36	PP	-15	NO	23	-4	2	4	3	3	2	3	3	0	2	1
		DAY 43		10DEC2002	43	PP	-26	NO	20	-7	4	3	3	4	0	3	1	0	2	0
		DAY 50		16DEC2002	49	PP	-37	NO	17	-10	1	2	2	3	2	3	0	2	2	0
		DAY 50	*	20DEC2002	53	PP	-41	NO	16	-11	2	3	3	3	0	3	0	0	2	0
	E0020006	DAY 1		16DEC2002	1	PP			30		4	4	3	3	4	2	4	3	2	1
		DAY 8		20DEC2002	5	PP	0	NO	30	0	3	3	3	3	3	4	4	3	2	2
	E0020007	DAY 1		15JAN2003	1	PP			34		3	4	3	4	3	4	4	5	2	2
		DAY 8		22JAN2003	8	PP	-44	NO	19	-15	2	2	2	0	1	3	2	4	2	1
	E0020011	DAY 1		26FEB2003	1	PP			26		4	4	2	2	0	4	4	3	2	1
		DAY 8		05MAR2003	8	PP	-39	NO	16	-10	3	4	2	0	0	4	2	0	1	0
		DAY 15		12MAR2003	15	PP	-92	YES	2	-24	0	0	0	1	0	0	0	0	1	0
		DAY 22		20MAR2003	23	PP	-42	NO	15	-11	2	1	3	2	1	3	2	1	0	0
		DAY 29		26MAR2003	29	PP	-65	YES	9	-17	0	0	0	4	0	3	0	0	2	0
		DAY 36		02APR2003	36	PP	-77	YES	6	-20	0	0	2	0	0	3	1	0	0	0
		DAY 43		09APR2003	43	PP	-39	NO	16	-10	2	4	4	0	0	0	3	3	0	0
		DAY 50		16APR2003	50	PP	-77	YES	6	-20	0	0	0	2	0	4	0	0	0	0
		DAY 57		23APR2003	57	PP	-96	YES	1	-25	0	0	0	0	0	0	1	0	0	0
	E0020013	DAY 1		05MAR2003	1	PP			26		3	4	3	2	0	4	4	4	1	1
		DAY 8		12MAR2003	8	PP	-100	YES	0	-26	0	0	0	0	0	0	0	0	0	0
	E0022008	DAY 1		12NOV2002	1	PP			32		4	4	3	4	0	4	4	4	3	2
		DAY 8		19NOV2002	8	PP	-41	NO	19	-13	3	3	3	0	0	2	2	2	2	2
		DAY 15		26NOV2002	15	PP	-84	YES	5	-27	1	1	1	0	0	0	2	0	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 22	03DEC2002	22	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 29	12DEC2002	31	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 36	17DEC2002	36	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 43	24DEC2002	43	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 50	31DEC2002	50	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	57	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
	E0022017	DAY 1	19DEC2002	1	PP			27		4	4	0	4	0	4	4	4	3	0
		DAY 8	26DEC2002	8	PP	0	NO	27	0	4	4	4	2	0	4	2	2	3	2
		DAY 15	03JAN2003	16	PP	-7	NO	25	-2	3	3	2	3	0	4	3	2	3	2
		DAY 22	09JAN2003	22	PP	-19	NO	22	-5	2	3	4	0	0	4	4	1	2	2
		DAY 29	17JAN2003	30	PP	-48	NO	14	-13	2	3	3	0	2	1	1	0	2	0
		DAY 36	22JAN2003	35	PP	-78	YES	6	-21	1	0	2	0	0	2	0	0	1	0
		DAY 43	31JAN2003	44	PP	-37	NO	17	-10	3	0	3	4	0	2	2	2	1	0
		DAY 50	06FEB2003	50	PP	-74	YES	7	-20	0	0	2	1	0	0	2	1	1	0
		DAY 57	13FEB2003	57	PP	-93	YES	2	-25	0	0	0	1	0	0	1	0	0	0
	E0022018	DAY 1	12DEC2002	1	PP			38		4	4	3	4	2	5	4	4	4	4
		DAY 8	19DEC2002	8	PP	-3	NO	37	-1	4	4	4	3	2	5	4	4	4	3
		DAY 15	26DEC2002	15	PP	-13	NO	33	-5	3	3	3	3	2	4	3	4	4	4
		DAY 22	02JAN2003	22	PP	-18	NO	31	-7	3	3	3	3	3	4	2	4	3	3
		DAY 29	09JAN2003	29	PP	-16	NO	32	-6	3	4	2	3	3	4	3	4	4	2
		DAY 36	16JAN2003	36	PP	-24	NO	29	-9	4	4	3	2	2	3	2	4	3	2
		DAY 43	23JAN2003	43	PP	-26	NO	28	-10	3	3	3	3	2	4	2	3	3	2
		DAY 50	30JAN2003	50	PP	-32	NO	26	-12	2	4	3	2	2	4	3	2	3	1
		DAY 57	06FEB2003	57	PP	-21	NO	30	-8	3	4	3	2	2	4	4	4	3	1
	E0022022	DAY 1	30DEC2002	1	PP (60)			44		5	5	4	5	5	5	4	3	4	4
		DAY 8	06JAN2003	8	PP (60)	-23	NO	34	-10	5	5	3	0	0	4	5	4	4	4

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	DAY 15	14JAN2003	16	PP (60)	-18	NO	36	-8	4	4	4	0	4	4	5	3	4	4
		DAY 22	21JAN2003	23	PP (60)	-16	NO	37	-7	4	4	4	6	0	4	5	4	4	2
		DAY 29	28JAN2003	30	PP (60)	-14	NO	38	-6	4	4	4	6	4	3	5	3	4	1
		DAY 36	04FEB2003	37	PP (60)	-34	NO	29	-15	2	3	2	4	4	0	4	3	3	4
		DAY 57	27FEB2003	60	PP (60)	-11	NO	39	-5	4	5	3	4	4	4	5	2	4	4
	E0022027	DAY 1	06FEB2003	1	PP			30		4	4	4	4	0	3	4	4	2	1
		DAY 8	13FEB2003	8	PP	-23	NO	23	-7	3	3	2	2	0	4	3	3	2	1
		DAY 15	20FEB2003	15	PP	-53	NO	14	-16	2	2	2	0	0	2	2	2	2	0
		DAY 22	27FEB2003	22	PP	-40	NO	18	-12	3	3	2	0	0	2	2	3	2	1
		DAY 29	06MAR2003	29	PP	-73	YES	8	-22	0	0	2	0	0	2	2	2	0	0
		DAY 36	13MAR2003	36	PP	-80	YES	6	-24	0	0	1	0	0	1	2	1	1	0
		DAY 43	20MAR2003	43	PP	-90	YES	3	-27	0	0	0	0	0	0	0	1	2	0
		DAY 50	27MAR2003	50	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 57	03APR2003	57	PP	-93	YES	2	-28	0	0	0	0	0	2	0	0	0	0
	E0022030	DAY 1	14FEB2003	1	PP			35		5	4	4	4	0	4	4	4	2	4
		DAY 8	20FEB2003	7	PP	-43	NO	20	-15	2	2	2	0	0	2	4	4	2	2
		DAY 15	28FEB2003	15	PP	-51	NO	17	-18	2	2	2	0	0	2	4	2	2	1
		DAY 22	07MAR2003	22	PP	-89	YES	4	-31	2	2	0	0	0	0	0	0	0	0
	E0022031	DAY 1	18FEB2003	1	PP (54)			38		4	4	4	4	2	4	4	4	4	4
		DAY 8	25FEB2003	8	PP (54)	-40	NO	23	-15	3	2	2	0	0	4	4	4	2	2
		DAY 15	04MAR2003	15	PP (54)	-21	NO	30	-8	4	4	2	2	0	4	4	4	2	4
		DAY 22	11MAR2003	22	PP (54)	-26	NO	28	-10	2	4	3	2	0	4	3	4	2	4
		DAY 29	18MAR2003	29	PP (54)	-47	NO	20	-18	2	2	2	2	0	2	2	4	2	2
		DAY 36	25MAR2003	36	PP (54)	-55	NO	17	-21	2	2	2	2	0	2	2	2	2	1
		DAY 43	01APR2003	43	PP (54)	-55	NO	17	-21	2	2	2	2	0	2	2	2	2	1
		DAY 50	08APR2003	50	PP (54)	-50	NO	19	-19	2	2	2	2	0	2	3	2	2	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%@	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0022031	DAY 57	15APR2003	57	PP (54)	-66	NO	13	-25	1	1	0	2	0	2	2	2	2	1
	E0022032	DAY 1	18FEB2003	1	PP (60)			36		4	4	3	5	3	4	4	4	3	2
		DAY 8	28FEB2003	11	PP (60)	-22	NO	28	-8	4	4	2	0	2	4	4	4	3	1
		DAY 15	04MAR2003	15	PP (60)	-67	YES	12	-24	2	1	0	0	5	2	1	0	1	0
		DAY 22	11MAR2003	22	PP (60)	-56	NO	16	-20	2	2	2	0	2	3	3	2	0	0
		DAY 29	21MAR2003	32	PP (60)	-50	NO	18	-18	2	2	1	2	2	3	2	2	1	1
		DAY 36	27MAR2003	38	PP (60)	-69	YES	11	-25	1	1	0	0	3	0	2	1	2	1
		DAY 43	03APR2003	45	PP (60)	-75	YES	9	-27	0	0	0	0	2	2	3	2	0	0
		DAY 50	10APR2003	52	PP (60)	-81	YES	7	-29	1	1	0	0	0	2	2	1	0	0
		DAY 57	18APR2003	60	PP (60)	-64	NO	13	-23	2	2	0	0	2	3	2	2	0	0
	E0022035	DAY 1	19FEB2003	1	ITT			24		3	4	3	3	0	2	4	3	2	0
		DAY 8	26FEB2003	8	ITT	-8	NO	22	-2	3	3	3	3	0	2	3	3	2	0
	E0022036	DAY 1	25FEB2003	1	PP			28		4	3	2	2	2	4	2	3	2	4
		DAY 8	03MAR2003	7	PP	-4	NO	27	-1	4	3	2	2	0	4	2	4	2	4
		DAY 15	10MAR2003	14	PP	-46	NO	15	-13	2	2	2	2	0	2	0	2	2	1
		DAY 22	18MAR2003	22	PP	-14	NO	24	-4	3	3	3	2	2	2	3	3	2	1
		DAY 29	25MAR2003	29	PP	-39	NO	17	-11	3	3	2	3	0	0	2	2	1	1
		DAY 36	01APR2003	36	PP	-14	NO	24	-4	3	3	2	2	0	2	2	4	2	4
		DAY 43	08APR2003	43	PP	-25	NO	21	-7	3	3	2	2	0	1	2	2	2	4
		DAY 50	15APR2003	50	PP	-18	NO	23	-5	3	3	2	1	2	2	2	2	2	4
		DAY 57	22APR2003	57	PP	-14	NO	24	-4	4	3	2	2	0	2	3	3	2	3
	E0022056	DAY 1	17APR2003	1	PP			33		4	4	2	5	4	2	4	2	4	2
		DAY 8	24APR2003	8	PP	-3	NO	32	-1	4	4	3	2	4	4	4	3	2	2
		DAY 15	01MAY2003	15	PP	-6	NO	31	-2	4	4	3	2	3	2	4	4	3	2
		DAY 22	08MAY2003	22	PP	3	NO	34	1	4	4	4	3	2	4	4	3	2	4

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QUETIAPINE 300 MG (BIPOLAR I)	E0022060	DAY 1		30APR2003	1	PP			28		3	4	4	3	3	3	2	2	3	1
		DAY 8		05MAY2003	6	PP	-11	NO	25	-3	3	3	4	1	2	4	2	1	3	2
		DAY 15		12MAY2003	13	PP	-18	NO	23	-5	3	4	4	0	3	3	2	0	2	2
		DAY 22		19MAY2003	20	PP	-29	NO	20	-8	2	2	4	2	2	3	2	1	2	0
		DAY 29		28MAY2003	29	PP	-7	NO	26	-2	4	4	5	0	3	3	2	2	3	0
		DAY 36		02JUN2003	34	PP	-7	NO	26	-2	4	4	4	0	2	2	3	3	3	1
		DAY 43		10JUN2003	42	PP	-39	NO	17	-11	2	2	3	0	2	3	1	1	3	0
		DAY 50		17JUN2003	49	PP	-21	NO	22	-6	3	4	3	0	2	3	3	2	2	0
		DAY 57		24JUN2003	56	PP	-68	YES	9	-19	0	0	2	0	2	2	1	0	2	0
	E0022063	DAY 1		07MAY2003	1	PP			25		3	4	4	3	0	2	2	2	4	1
		DAY 8		12MAY2003	6	PP	-20	NO	20	-5	3	4	4	1	0	2	2	2	2	0
		DAY 15		21MAY2003	15	PP	-32	NO	17	-8	2	2	3	0	0	3	2	2	3	0
		DAY 22		28MAY2003	22	PP	-60	YES	10	-15	1	1	2	1	0	2	0	1	2	0
		DAY 29		04JUN2003	29	PP	-60	YES	10	-15	1	2	1	0	0	2	1	1	2	0
		DAY 36		11JUN2003	36	PP	-72	YES	7	-18	0	0	0	1	0	2	0	2	2	0
	E0023008	DAY 1		30JAN2003	1	PP			33		4	4	3	4	4	3	2	3	4	2
		DAY 8		06FEB2003	8	PP	6	NO	35	2	6	6	4	0	0	4	4	4	5	2
		DAY 15		13FEB2003	15	PP	-12	NO	29	-4	5	5	3	0	0	4	3	4	4	1
		DAY 22		20FEB2003	22	PP	-3	NO	32	-1	5	4	5	3	0	3	2	3	4	3
		DAY 29		25FEB2003	27	PP	-12	NO	29	-4	4	5	4	0	0	3	2	4	4	3
		DAY 36		06MAR2003	36	PP	-3	NO	32	-1	5	5	5	0	0	4	2	4	4	3
		DAY 43		11MAR2003	41	PP	-21	NO	26	-7	4	5	5	1	0	3	2	2	2	2
		DAY 50		18MAR2003	48	PP	-18	NO	27	-6	5	5	5	0	0	3	2	2	3	2
		DAY 50	*	24MAR2003	54	PP	-6	NO	31	-2	5	5	5	0	3	3	2	3	3	2
	E0023013	DAY 1		27FEB2003	1	ITT			35		4	4	4	2	2	5	4	4	4	2
		DAY 8		06MAR2003	8	ITT	-9	NO	32	-3	4	4	4	2	2	3	4	4	4	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0023015	DAY 1		11MAR2003	1	PP			28		6	5	1	0	1	5	0	5	4	1
		DAY 8		18MAR2003	8	PP	-50	NO	14	-14	2	1	3	0	0	4	1	1	1	1
		DAY 15		25MAR2003	15	PP	-61	YES	11	-17	2	1	3	0	0	4	0	0	1	0
		DAY 22		01APR2003	22	PP	-61	YES	11	-17	2	2	3	0	0	3	0	0	1	0
		DAY 29		08APR2003	29	PP	-61	YES	11	-17	2	2	3	0	0	3	0	0	1	0
		DAY 36		15APR2003	36	PP	-96	YES	1	-27	0	0	0	0	0	1	0	0	0	0
		DAY 43		22APR2003	43	PP	-93	YES	2	-26	0	0	1	0	0	1	0	0	0	0
		DAY 50		29APR2003	50	PP	-93	YES	2	-26	0	0	1	0	0	1	0	0	0	0
		DAY 57		06MAY2003	57	PP	-86	YES	4	-24	1	1	2	0	0	0	0	0	0	0
	E0023034	DAY 1		09JUN2003	1	PP (58)			27		4	3	3	4	0	3	4	3	2	1
		DAY 8		16JUN2003	8	PP (58)	-11	NO	24	-3	2	3	3	4	0	3	3	3	1	2
		DAY 15		23JUN2003	15	PP (58)	-4	NO	26	-1	3	3	4	4	0	3	3	3	1	2
		DAY 22		30JUN2003	22	PP (58)	-26	NO	20	-7	2	2	3	3	0	3	2	3	1	1
		DAY 29		07JUL2003	29	PP (58)	4	NO	28	1	3	4	3	4	0	4	3	4	2	1
		DAY 36		14JUL2003	36	PP (58)	-44	NO	15	-12	2	2	2	1	0	2	2	2	1	1
		DAY 43		22JUL2003	44	PP (58)	-56	YES	12	-15	1	1	1	1	2	2	1	2	1	0
		DAY 57		05AUG2003	58	PP (58)	-56	YES	12	-15	1	1	1	1	2	2	1	2	1	0
	E0023037	DAY 1		18JUN2003	1	PP			36		4	4	3	5	3	4	4	5	3	1
		DAY 8		24JUN2003	7	PP	-42	NO	21	-15	2	2	2	2	1	2	3	3	2	2
		DAY 15		01JUL2003	14	PP	-78	YES	8	-28	1	1	0	1	0	2	1	1	0	1
		DAY 29	*	14JUL2003	27	PP	-83	YES	6	-30	1	1	0	0	0	1	0	3	0	0
		DAY 29		18JUL2003	31	PP	-94	YES	2	-34	0	0	0	0	0	0	0	2	0	0
		DAY 36		25JUL2003	38	PP	-94	YES	2	-34	0	0	0	0	0	0	0	2	0	0
		DAY 43		01AUG2003	45	PP	-94	YES	2	-34	0	0	0	0	0	0	0	2	0	0
		DAY 50		08AUG2003	52	PP	-94	YES	2	-34	0	0	0	0	0	0	0	2	0	0
		DAY 57		15AUG2003	59	PP	-89	YES	4	-32	1	1	0	0	0	0	0	2	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0023038	DAY 1	30JUN2003	1	PP			34		4	4	3	4	1	4	4	4	4	2
		DAY 8	09JUL2003	10	PP	-32	NO	23	-11	2	2	3	2	0	4	3	3	3	1
		DAY 15	15JUL2003	16	PP	-53	NO	16	-18	1	1	2	1	0	4	2	2	2	1
		DAY 22	21JUL2003	22	PP	-47	NO	18	-16	1	1	3	0	0	4	3	2	3	1
		DAY 29	28JUL2003	29	PP	-53	NO	16	-18	1	1	3	0	0	3	3	2	2	1
		DAY 36	07AUG2003	39	PP	-50	NO	17	-17	2	2	2	0	0	2	4	2	2	1
		DAY 43	13AUG2003	45	PP	-59	NO	14	-20	2	2	1	0	0	1	3	2	2	1
		DAY 50	21AUG2003	53	PP	-44	NO	19	-15	3	3	1	0	1	3	3	2	2	1
		DAY 57	27AUG2003	59	PP	-44	NO	19	-15	3	3	1	0	2	3	3	2	1	1
	E0023044	DAY 1	16JUL2003	1	PP			33		2	4	4	3	3	4	4	4	3	2
		DAY 8	22JUL2003	7	PP	3	NO	34	1	4	4	4	4	2	4	4	4	2	2
		DAY 15	29JUL2003	14	PP	0	NO	33	0	3	3	4	4	3	4	4	4	2	2
		DAY 22	05AUG2003	21	PP	3	NO	34	1	3	4	4	4	3	4	4	4	2	2
		DAY 29	12AUG2003	28	PP	15	NO	38	5	3	4	4	4	3	4	5	5	3	3
	E0023045	DAY 1	17JUL2003	1	PP			37		5	5	4	4	0	4	4	5	4	2
		DAY 8	24JUL2003	8	PP	-14	NO	32	-5	4	4	4	2	0	4	4	4	4	2
		DAY 15	31JUL2003	15	PP	-19	NO	30	-7	4	4	4	0	0	4	4	4	4	2
		DAY 22	07AUG2003	22	PP	-43	NO	21	-16	3	3	3	0	2	3	2	2	2	1
		DAY 29	14AUG2003	29	PP	-38	NO	23	-14	3	3	3	2	2	3	2	2	2	1
		DAY 36	21AUG2003	36	PP	-60	NO	15	-22	2	2	2	2	0	1	1	2	2	1
		DAY 43	28AUG2003	43	PP	-60	NO	15	-22	2	2	2	2	0	1	1	2	2	1
		DAY 50	04SEP2003	50	PP	-81	YES	7	-30	1	1	1	0	0	1	0	1	1	1
		DAY 57	11SEP2003	57	PP	-78	YES	8	-29	1	1	1	0	0	2	0	1	1	1
	E0025002	DAY 1	03APR2003	1	PP			30		4	4	3	3	0	3	4	4	3	2
		DAY 8	10APR2003	8	PP	-47	NO	16	-14	2	2	2	0	0	2	4	2	1	1
		DAY 15	17APR2003	15	PP	-37	NO	19	-11	3	3	2	2	1	2	0	2	3	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%@	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	DAY 22	24APR2003	22	PP	-57	NO	13	-17	2	2	2	0	0	0	2	2	2	1
		DAY 29	01MAY2003	29	PP	-83	YES	5	-25	0	0	1	0	0	1	2	0	0	1
		DAY 36	08MAY2003	36	PP	-70	YES	9	-21	2	2	0	0	0	1	2	1	0	1
		DAY 43	15MAY2003	43	PP	-87	YES	4	-26	0	0	0	0	0	1	2	0	0	1
		DAY 50	22MAY2003	50	PP	-63	YES	11	-19	2	2	1	0	0	0	4	0	1	1
		DAY 57	29MAY2003	57	PP	-80	YES	6	-24	0	0	1	0	0	0	3	0	1	1
	E0026010	DAY 1	22JAN2003	1	ITT			28		4	3	2	4	3	2	4	3	3	0
		DAY 8	30JAN2003	9	ITT	-75	YES	7	-21	0	0	2	5	0	0	0	0	0	0
	E0026017	DAY 1	06MAR2003	1	ITT			22		4	3	2	2	0	2	4	2	3	0
		DAY 15	21MAR2003	16	ITT	-86	YES	3	-19	1	0	2	0	0	0	0	0	0	0
	E0026018	DAY 1	20MAR2003	1	PP			32		4	5	0	3	5	4	2	4	4	1
		DAY 8	27MAR2003	8	PP	-56	NO	14	-18	1	0	2	2	0	2	0	2	4	1
		DAY 15	03APR2003	15	PP	-31	NO	22	-10	2	2	3	2	0	4	4	0	0	5
		DAY 22	10APR2003	22	PP	-75	YES	8	-24	0	0	2	3	0	2	1	0	0	0
		DAY 29	17APR2003	29	PP	-63	YES	12	-20	1	2	2	2	0	1	1	1	1	1
		DAY 36	24APR2003	36	PP	-75	YES	8	-24	2	2	1	0	0	1	0	1	0	1
		DAY 43	01MAY2003	43	PP	-88	YES	4	-28	1	0	0	3	0	0	0	0	0	0
		DAY 50	08MAY2003	50	PP	-84	YES	5	-27	1	0	1	3	0	0	0	0	0	0
		DAY 57	15MAY2003	57	PP	-91	YES	3	-29	0	0	0	3	0	0	0	0	0	0
	E0026025	DAY 1	09MAY2003	1	PP			36		4	5	1	2	4	4	5	4	4	3
		DAY 8	15MAY2003	7	PP	-33	NO	24	-12	3	3	3	0	2	2	3	2	4	2
		DAY 15	22MAY2003	14	PP	-25	NO	27	-9	4	3	3	0	2	3	3	4	3	2
		DAY 22	29MAY2003	21	PP	-36	NO	23	-13	3	2	3	0	1	3	2	4	3	2
		DAY 29	05JUN2003	28	PP	-53	NO	17	-19	2	2	3	0	1	2	1	3	2	1
		DAY 36	13JUN2003	36	PP	-64	NO	13	-23	3	2	3	0	0	1	1	2	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	DAY 43	20JUN2003	43	PP	-75	YES	9	-27	2	1	2	0	0	1	1	1	1	0
		DAY 50	27JUN2003	50	PP	-67	YES	12	-24	1	0	1	4	0	3	1	1	1	0
		DAY 57	03JUL2003	56	PP	-67	YES	12	-24	1	0	1	4	0	5	0	0	1	0
	E0026029	DAY 1	09JUL2003	1	PP			38		5	4	3	5	3	5	5	4	3	1
		DAY 8	16JUL2003	8	PP	-18	NO	31	-7	2	3	4	4	3	5	4	3	2	1
	E0026030	DAY 1	09JUL2003	1	PP			34		3	4	3	4	3	4	3	4	3	3
		DAY 8	16JUL2003	8	PP	-29	NO	24	-10	1	3	3	2	2	3	1	3	3	3
		DAY 15	23JUL2003	15	PP	-29	NO	24	-10	4	3	2	1	2	1	3	3	2	3
		DAY 22	30JUL2003	22	PP	-47	NO	18	-16	4	1	3	1	2	2	1	2	1	1
		DAY 29	04AUG2003	27	PP	-50	NO	17	-17	3	2	2	1	2	2	2	1	1	1
		DAY 36	12AUG2003	35	PP	-88	YES	4	-30	0	1	1	0	1	0	0	0	0	1
		DAY 43	19AUG2003	42	PP	-91	YES	3	-31	1	0	0	0	0	0	1	0	0	1
		DAY 50	26AUG2003	49	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 57	03SEP2003	57	PP	-94	YES	2	-32	0	0	1	1	0	0	0	0	0	0
	E0026031	DAY 1	21JUL2003	1	PP			23		3	3	1	4	0	3	2	3	3	1
		DAY 8	28JUL2003	8	PP	-48	YES	12	-11	1	2	1	0	0	4	1	1	1	1
		DAY 15	04AUG2003	15	PP	4	NO	24	1	2	4	2	0	1	3	5	3	3	1
		DAY 22	11AUG2003	22	PP	-39	NO	14	-9	1	3	1	1	0	4	1	1	1	1
		DAY 29	18AUG2003	29	PP	-35	NO	15	-8	2	3	0	2	2	3	1	1	0	1
		DAY 36	25AUG2003	36	PP	-9	NO	21	-2	1	3	2	2	3	0	4	3	2	1
		DAY 43	02SEP2003	44	PP	-30	NO	16	-7	1	3	1	2	3	0	3	2	0	1
		DAY 50	08SEP2003	50	PP	-26	NO	17	-6	1	1	1	2	3	0	4	4	0	1
		DAY 57	15SEP2003	57	PP	-35	NO	15	-8	1	2	2	0	0	0	3	4	2	1
	E0027003	DAY 1	23JAN2003	-5	ITT			35		4	5	5	4	0	4	4	4	3	2
		DAY 8	06FEB2003	10	ITT	-11	NO	31	-4	4	4	3	4	0	4	4	3	3	2

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QUETIAPINE 300 MG (BIPOLAR I)	E0027003	DAY 15		13FEB2003	17	ITT	-37	NO	22	-13	3	3	2	2	0	3	4	2	2	1
		DAY 22		19FEB2003	23	ITT	-69	YES	11	-24	1	0	2	2	0	1	2	1	2	0
		DAY 29		27FEB2003	31	ITT	-51	NO	17	-18	1	1	2	1	0	3	4	2	2	1
		DAY 36		06MAR2003	38	ITT	-57	NO	15	-20	2	1	3	2	0	2	2	0	2	1
		DAY 43		13MAR2003	45	ITT	-43	NO	20	-15	3	3	3	2	0	2	2	2	2	1
		DAY 50		20MAR2003	52	ITT	-60	NO	14	-21	3	2	0	2	0	2	1	1	2	1
		DAY 57		25MAR2003	57	ITT	-80	YES	7	-28	1	0	1	0	0	2	1	0	2	0
	E0028004	DAY 1		30SEP2002	1	ITT			36		5	5	1	5	4	4	4	3	4	1
		DAY 8		07OCT2002	8	ITT	-33	NO	24	-12	4	4	0	0	4	4	2	4	2	0
		DAY 8	*	09OCT2002	10	ITT	-25	NO	27	-9	4	5	0	3	4	4	2	4	1	0
	E0028006	DAY 1		04OCT2002	1	PP			34		4	4	3	4	2	4	3	4	4	2
		DAY 8		11OCT2002	8	PP	-12	NO	30	-4	4	4	4	4	2	2	2	2	2	4
		DAY 15		16OCT2002	13	PP	-56	NO	15	-19	2	2	2	1	0	2	2	2	2	0
		DAY 22		23OCT2002	20	PP	-50	NO	17	-17	3	2	2	2	0	2	2	2	2	0
		DAY 29		31OCT2002	28	PP	-53	NO	16	-18	1	2	2	1	2	2	2	2	2	0
		DAY 36		07NOV2002	35	PP	-29	NO	24	-10	2	4	2	2	4	2	2	2	4	0
		DAY 43		14NOV2002	42	PP	-29	NO	24	-10	4	4	4	2	0	2	4	2	2	0
		DAY 50		21NOV2002	49	PP	-41	NO	20	-14	2	4	3	1	0	2	2	2	2	2
		DAY 57		04DEC2002	62	PP	-38	NO	21	-13	2	3	2	1	0	4	4	3	2	0
	E0028008	DAY 1		15OCT2002	1	PP			22		4	2	0	2	0	2	4	4	4	0
		DAY 8		22OCT2002	8	PP	5	NO	23	1	4	3	4	4	0	2	2	2	2	0
		DAY 15		29OCT2002	15	PP	14	NO	25	3	2	3	2	4	2	3	4	3	2	0
		DAY 22		07NOV2002	24	PP	-9	NO	20	-2	4	4	3	3	0	3	0	0	3	0
		DAY 29		14NOV2002	31	PP	-5	NO	21	-1	2	4	3	4	0	3	1	2	2	0
		DAY 36		21NOV2002	38	PP	-14	NO	19	-3	2	2	3	0	0	4	0	4	4	0
		DAY 43		26NOV2002	43	PP	0	NO	22	0	4	2	4	4	0	2	2	2	2	0

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	DAY 50	03DEC2002	50	PP	-9	NO	20	-2	3	4	1	0	0	4	0	4	4	0
		DAY 57	10DEC2002	57	PP	46	NO	32	10	4	3	3	6	0	6	4	4	2	0
	E0028009	DAY 1	15OCT2002	1	PP			19		3	2	0	2	2	2	4	2	2	0
		DAY 8	23OCT2002	9	PP	-79	YES	4	-15	0	2	0	0	0	0	0	0	2	0
		DAY 15	31OCT2002	17	PP	-68	YES	6	-13	2	2	0	0	2	0	0	0	0	0
		DAY 22	07NOV2002	24	PP	-100	YES	0	-19	0	0	0	0	0	0	0	0	0	0
		DAY 29	14NOV2002	31	PP	-100	YES	0	-19	0	0	0	0	0	0	0	0	0	0
		DAY 36	19NOV2002	36	PP	-100	YES	0	-19	0	0	0	0	0	0	0	0	0	0
		DAY 43	26NOV2002	43	PP	-100	YES	0	-19	0	0	0	0	0	0	0	0	0	0
		DAY 50	03DEC2002	50	PP	-68	YES	6	-13	2	2	0	0	0	0	0	2	0	0
		DAY 57	12DEC2002	59	PP	-95	YES	1	-18	0	0	0	0	0	0	1	0	0	0
	E0028016	DAY 1	14NOV2002	1	PP			36		4	4	4	4	0	4	4	4	4	4
		DAY 8	21NOV2002	8	PP	-8	NO	33	-3	4	4	3	0	2	4	3	5	4	4
		DAY 15	26NOV2002	13	PP	-39	NO	22	-14	3	3	2	0	0	2	2	4	3	3
		DAY 22	05DEC2002	22	PP	8	NO	39	3	5	5	4	4	0	4	4	5	4	4
		DAY 29	12DEC2002	29	PP	-28	NO	26	-10	3	3	2	0	0	3	2	5	4	4
		DAY 36	19DEC2002	36	PP	-58	NO	15	-21	2	2	0	2	0	2	4	2	1	0
		DAY 43	26DEC2002	43	PP	-39	NO	22	-14	2	2	3	3	0	4	4	2	1	1
		DAY 50	02JAN2003	50	PP	-33	NO	24	-12	2	3	4	3	0	4	4	2	1	1
		DAY 57	09JAN2003	57	PP	-75	YES	9	-27	0	0	2	2	0	2	2	1	0	0
	E0028017	*	19NOV2002		NODOSE			23		3	3	4	4	0	1	2	3	3	0
	E0028027	DAY 1	21JAN2003	1	PP			34		4	4	4	4	0	4	4	2	4	4
		DAY 8	28JAN2003	8	PP	-18	NO	28	-6	2	4	2	0	0	4	4	4	4	4
		DAY 15	04FEB2003	15	PP	-44	NO	19	-15	2	4	0	0	0	0	4	4	3	2
		DAY 22	11FEB2003	22	PP	-32	NO	23	-11	3	4	0	0	0	0	4	4	4	4

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	DAY 29	20FEB2003	31	PP	-35	NO	22	-12	2	3	3	1	0	3	2	2	3	3
		DAY 36	28FEB2003	39	PP	-21	NO	27	-7	4	3	4	0	0	4	4	4	2	2
	E0028029	DAY 1	04FEB2003	1	PP			28		2	4	0	4	2	4	4	4	4	0
		DAY 8	11FEB2003	8	PP	-46	NO	15	-13	4	2	0	1	0	0	4	2	2	0
		DAY 15	17FEB2003	14	PP	-50	NO	14	-14	2	2	0	0	0	0	4	4	2	0
		DAY 22	27FEB2003	24	PP	-57	YES	12	-16	2	2	0	0	0	0	3	3	2	0
		DAY 29	06MAR2003	31	PP	-25	NO	21	-7	2	3	4	0	2	4	4	2	0	0
		DAY 36	13MAR2003	38	PP	-86	YES	4	-24	0	2	0	0	0	0	2	0	0	0
		DAY 43	20MAR2003	45	PP	-79	YES	6	-22	0	0	0	2	0	2	2	0	0	0
		DAY 50	27MAR2003	52	PP	-89	YES	3	-25	0	1	0	0	0	0	0	0	2	0
		DAY 57	03APR2003	59	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
	E0028034	DAY 1	01APR2003	1	PP			23		2	4	3	4	0	2	2	2	4	0
		DAY 8	08APR2003	8	PP	48	NO	34	11	4	4	4	4	0	2	4	4	4	4
		DAY 15	15APR2003	15	PP	-44	NO	13	-10	2	2	0	2	0	1	2	2	2	0
		DAY 22	22APR2003	22	PP	-87	YES	3	-20	0	1	0	2	0	0	0	0	0	0
		DAY 29	01MAY2003	31	PP	-78	YES	5	-18	0	1	2	2	0	0	0	0	0	0
		DAY 36	06MAY2003	36	PP	-83	YES	4	-19	0	0	0	2	0	0	2	0	0	0
		DAY 43	13MAY2003	43	PP	-78	YES	5	-18	0	0	1	2	0	0	2	0	0	0
		DAY 50	21MAY2003	51	PP	-91	YES	2	-21	0	0	0	2	0	0	0	0	0	0
		DAY 57	02JUN2003	63	PP	-83	YES	4	-19	0	1	2	1	0	0	0	0	0	0
	E0028038	DAY 1	25APR2003	1	PP			25		2	3	2	2	0	4	4	4	2	2
		DAY 8	02MAY2003	8	PP	-44	NO	14	-11	2	3	1	2	0	2	2	2	0	0
		DAY 15	08MAY2003	14	PP	-24	NO	19	-6	2	4	2	1	0	2	2	2	2	2
		DAY 29	22MAY2003	28	PP	-20	NO	20	-5	1	1	2	2	0	3	4	3	2	2
		DAY 36	30MAY2003	36	PP	-40	NO	15	-10	1	1	2	1	0	2	2	2	2	2
		DAY 43	05JUN2003	42	PP	-28	NO	18	-7	2	2	2	1	0	2	4	3	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	DAY 50	12JUN2003	49	PP	-28	NO	18	-7	2	2	2	2	0	2	2	2	2	2
		DAY 57	18JUN2003	55	PP	-24	NO	19	-6	2	3	2	2	0	2	3	3	2	0
	E0028043	DAY 1	05JUN2003	1	PP			22		4	4	4	2	0	2	2	2	2	0
		DAY 8	12JUN2003	8	PP	18	NO	26	4	4	4	4	3	0	3	4	2	2	0
		DAY 15	19JUN2003	15	PP	0	NO	22	0	4	2	4	4	0	2	2	2	2	0
		DAY 22	26JUN2003	22	PP	-18	NO	18	-4	2	2	2	4	0	2	2	2	2	0
		DAY 29	01JUL2003	27	PP	-18	NO	18	-4	2	2	2	2	2	2	2	2	2	0
		DAY 36	08JUL2003	34	PP	-41	NO	13	-9	1	1	1	2	1	2	2	1	2	0
		DAY 43	15JUL2003	41	PP	-27	NO	16	-6	2	2	2	2	0	2	2	2	2	0
		DAY 50	22JUL2003	48	PP	-32	NO	15	-7	1	2	2	4	0	2	2	0	2	0
		DAY 57	29JUL2003	55	PP	-36	NO	14	-8	2	2	2	2	0	2	2	0	2	0
	E0028045	DAY 1	18JUN2003	1	ITT			38		4	4	4	4	4	4	4	4	2	4
		DAY 8	25JUN2003	8	ITT	0	NO	38	0	4	4	4	4	4	4	4	4	4	2
		DAY 15	30JUN2003	13	ITT	-11	NO	34	-4	4	4	4	2	4	4	4	2	4	2
	E0029005	DAY 1	27NOV2002	1	PP			32		4	4	2	4	4	4	4	2	4	0
		DAY 8	03DEC2002	7	PP	-28	NO	23	-9	2	2	2	3	4	2	2	2	4	0
		DAY 15	09DEC2002	13	PP	-31	NO	22	-10	1	3	2	3	2	3	2	3	2	1
		DAY 22	16DEC2002	20	PP	-56	NO	14	-18	1	2	2	0	2	2	2	1	2	0
		DAY 29	23DEC2002	27	PP	-53	NO	15	-17	2	1	2	2	2	2	2	0	2	0
		DAY 36	30DEC2002	34	PP	-56	NO	14	-18	3	3	2	0	0	2	2	0	2	0
		DAY 43	07JAN2003	42	PP	-63	YES	12	-20	0	2	2	1	1	2	2	0	2	0
		DAY 50	14JAN2003	49	PP	-41	NO	19	-13	3	2	2	2	2	2	4	0	2	0
		DAY 57	21JAN2003	56	PP	-53	NO	15	-17	2	2	2	2	2	1	0	2	2	0
	E0030001	DAY 1	19NOV2002	1	PP			33		4	4	3	3	0	4	4	4	4	3
		DAY 8	26NOV2002	8	PP	-21	NO	26	-7	3	4	3	3	0	4	2	3	2	2

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	DAY 15		03DEC2002	15	PP	-42	NO	19	-14	3	3	2	2	0	3	1	1	2	2
		DAY 22		10DEC2002	22	PP	-33	NO	22	-11	3	3	3	2	0	2	4	1	2	2
		DAY 29		17DEC2002	29	PP	-46	NO	18	-15	3	3	2	1	0	2	2	1	2	2
		DAY 43		02JAN2003	45	PP	-79	YES	7	-26	2	1	2	1	0	0	0	0	1	0
		DAY 50		09JAN2003	52	PP	-55	NO	15	-18	2	2	2	1	0	2	2	2	1	1
		DAY 57		16JAN2003	59	PP	-52	NO	16	-17	2	2	2	1	0	2	2	1	2	2
	E0030008	DAY 1		14JAN2003	1	PP			26		3	3	2	4	0	4	4	2	3	1
		DAY 8		23JAN2003	10	PP	8	NO	28	2	4	4	2	1	3	3	4	4	2	1
		DAY 15		30JAN2003	17	PP	0	NO	26	0	4	2	2	5	2	1	4	4	2	0
		DAY 22		07FEB2003	25	PP	8	NO	28	2	3	4	3	4	0	4	4	4	2	0
		DAY 29		14FEB2003	32	PP	15	NO	30	4	4	4	3	2	2	4	4	4	2	1
		DAY 36		21FEB2003	39	PP	4	NO	27	1	3	3	2	4	0	4	3	4	3	1
		DAY 50		03MAR2003	49	PP	-27	NO	19	-7	3	2	1	0	3	3	2	2	2	1
		DAY 57	*	11MAR2003	57	PP	-27	NO	19	-7	2	2	2	2	2	2	2	2	2	1
		DAY 57		18MAR2003	64	PP	-19	NO	21	-5	4	2	2	4	0	2	2	2	2	1
	E0030011	DAY 1		27JAN2003	1	PP			41		5	5	4	5	5	4	5	4	2	2
		DAY 8		03FEB2003	8	PP	-78	YES	9	-32	0	0	2	0	2	2	2	1	0	0
		DAY 15		10FEB2003	15	PP	-88	YES	5	-36	1	1	0	0	0	2	0	0	1	0
		DAY 22		18FEB2003	23	PP	-100	YES	0	-41	0	0	0	0	0	0	0	0	0	0
		DAY 29		24FEB2003	29	PP	-100	YES	0	-41	0	0	0	0	0	0	0	0	0	0
		DAY 36		03MAR2003	36	PP	-93	YES	3	-38	0	2	1	0	0	0	0	0	0	0
		DAY 43		10MAR2003	43	PP	-100	YES	0	-41	0	0	0	0	0	0	0	0	0	0
		DAY 50		17MAR2003	50	PP	-100	YES	0	-41	0	0	0	0	0	0	0	0	0	0
		DAY 57		24MAR2003	57	PP	-100	YES	0	-41	0	0	0	0	0	0	0	0	0	0
	E0030015	DAY 1		21FEB2003	1	PP			28		4	4	2	3	0	3	4	4	3	1
		DAY 8		03MAR2003	11	PP	-4	NO	27	-1	4	4	3	0	0	3	4	3	3	3

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	DAY 15		11MAR2003	19	PP	-50	NO	14	-14	2	2	1	3	0	0	1	2	2	1
		DAY 29		19MAR2003	27	PP	-46	NO	15	-13	2	2	1	2	0	1	2	2	2	1
		DAY 36		26MAR2003	34	PP	-75	YES	7	-21	1	1	2	0	0	0	1	1	0	1
		DAY 43		02APR2003	41	PP	-79	YES	6	-22	1	1	1	0	0	0	0	0	2	1
		DAY 50		09APR2003	48	PP	-79	YES	6	-22	0	0	0	0	0	0	2	2	2	0
		DAY 57	*	17APR2003	56	PP	-93	YES	2	-26	0	0	0	0	0	0	1	1	0	0
		DAY 57		22APR2003	61	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
	E0030022	DAY 1		16JUN2003	1	PP			24		2	4	2	3	0	2	4	4	2	1
		DAY 8		20JUN2003	5	PP	13	NO	27	3	4	4	3	0	2	3	3	4	3	1
		DAY 15		30JUN2003	15	PP	-54	YES	11	-13	2	1	2	0	0	0	1	1	3	1
		DAY 22		07JUL2003	22	PP	-46	NO	13	-11	2	2	2	0	0	2	1	2	2	0
		DAY 29		14JUL2003	29	PP	-42	NO	14	-10	1	3	2	0	0	0	2	2	3	1
		DAY 36		21JUL2003	36	PP	-50	YES	12	-12	2	1	1	1	0	2	2	1	2	0
		DAY 43		29JUL2003	44	PP	-79	YES	5	-19	2	0	1	0	0	0	1	1	0	0
		DAY 50		05AUG2003	51	PP	-29	NO	17	-7	2	2	2	2	1	0	2	3	3	0
		DAY 57		14AUG2003	60	PP	-71	YES	7	-17	2	2	2	0	0	0	0	0	1	0
	E0031002	DAY 1		27NOV2002	1	PP			32		4	4	4	3	4	4	4	4	1	0
		DAY 8		06DEC2002	10	PP	-63	YES	12	-20	1	1	2	0	0	2	1	2	3	0
		DAY 15		12DEC2002	16	PP	-38	NO	20	-12	2	3	4	2	2	2	2	1	2	0
		DAY 22		19DEC2002	23	PP	-59	NO	13	-19	2	1	2	0	2	3	0	0	3	0
		DAY 29		27DEC2002	31	PP	-44	NO	18	-14	2	2	2	1	2	3	2	2	2	0
		DAY 36		02JAN2003	37	PP	-72	YES	9	-23	0	0	2	1	2	2	2	0	0	0
		DAY 50	*	13JAN2003	48	PP	-94	YES	2	-30	0	0	2	0	0	0	0	0	0	0
		DAY 50		17JAN2003	52	PP	-81	YES	6	-26	0	0	2	0	0	2	2	0	0	0
		DAY 57		22JAN2003	57	PP	-66	YES	11	-21	0	0	3	0	0	0	2	4	2	0
	E0031003	DAY 1		10DEC2002	1	PP			31		4	5	3	3	0	3	3	5	4	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	DAY 8		17DEC2002	8	PP	-42	NO	18	-13	3	4	0	2	0	2	3	2	2	0
		DAY 15		23DEC2002	14	PP	-65	YES	11	-20	1	1	0	2	0	2	3	2	0	0
		DAY 22		31DEC2002	22	PP	-23	NO	24	-7	3	3	2	6	2	2	0	4	2	0
		DAY 29		07JAN2003	29	PP	-3	NO	30	-1	4	4	3	4	6	3	2	1	2	1
		DAY 36		15JAN2003	37	PP	-26	NO	23	-8	2	3	3	5	0	2	1	4	2	1
		DAY 43		21JAN2003	43	PP	-45	NO	17	-14	2	2	2	2	0	1	2	4	2	0
		DAY 50		30JAN2003	52	PP	-48	NO	16	-15	3	2	0	2	0	3	2	1	3	0
		DAY 57		04FEB2003	57	PP	-42	NO	18	-13	3	3	2	2	0	2	2	2	2	0
	E0033015	DAY 1		10APR2003	1	PP			28		3	3	3	3	3	3	3	3	2	2
		DAY 8		17APR2003	8	PP	-11	NO	25	-3	3	3	4	2	0	3	3	3	2	2
		DAY 15		22APR2003	13	PP	-25	NO	21	-7	2	3	3	2	0	2	3	3	2	1
		DAY 15	*	28APR2003	19	PP	-43	NO	16	-12	3	2	2	0	0	2	2	2	2	1
		DAY 29		06MAY2003	27	PP	-36	NO	18	-10	2	1	2	0	2	2	2	4	2	1
		DAY 36		13MAY2003	34	PP	-46	NO	15	-13	2	2	2	1	0	2	2	2	1	1
		DAY 43		20MAY2003	41	PP	-64	YES	10	-18	2	1	2	0	0	2	1	0	1	1
		DAY 50		27MAY2003	48	PP	-79	YES	6	-22	2	1	0	0	0	2	0	1	0	0
		DAY 57		04JUN2003	56	PP	-61	YES	11	-17	2	1	2	0	0	2	1	1	1	1
	E0034002	DAY 1		25MAR2003	1	PP			28		4	3	4	5	1	3	4	2	2	0
		DAY 8		01APR2003	8	PP	-57	YES	12	-16	2	2	2	0	0	1	4	1	0	0
		DAY 15		08APR2003	15	PP	-75	YES	7	-21	1	0	2	0	0	1	3	0	0	0
		DAY 22		15APR2003	22	PP	-75	YES	7	-21	1	1	2	0	0	0	3	0	0	0
	E0034003	DAY 1		24APR2003	1	PP			28		4	4	3	4	2	2	4	3	2	0
		DAY 8		01MAY2003	8	PP	-64	YES	10	-18	1	2	2	0	2	1	2	0	0	0
		DAY 15		08MAY2003	15	PP	-82	YES	5	-23	0	2	0	0	1	0	2	0	0	0
		DAY 22		15MAY2003	22	PP	-89	YES	3	-25	0	1	0	0	0	0	2	0	0	0
		DAY 29		22MAY2003	29	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	DAY 36	29MAY2003	36	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
		DAY 43	05JUN2003	43	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
		DAY 50	12JUN2003	50	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
		DAY 57	19JUN2003	57	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
	E0034006	DAY 1	16MAY2003	1	PP			41		4	5	5	4	4	5	4	4	3	3
		DAY 8	23MAY2003	8	PP	-12	NO	36	-5	4	5	5	1	4	5	4	4	2	2
		DAY 15	02JUN2003	18	PP	-7	NO	38	-3	4	5	5	4	4	4	4	4	2	2
		DAY 22	09JUN2003	25	PP	-15	NO	35	-6	4	5	5	4	2	4	3	4	2	2
		DAY 29	13JUN2003	29	PP	-20	NO	33	-8	4	4	5	4	0	4	4	4	2	2
		DAY 36	20JUN2003	36	PP	-17	NO	34	-7	4	5	5	4	0	4	4	4	2	2
		DAY 43	27JUN2003	43	PP	-15	NO	35	-6	4	5	5	4	0	5	4	4	2	2
		DAY 50	03JUL2003	49	PP	-5	NO	39	-2	4	5	5	4	4	4	4	4	3	2
		DAY 57	10JUL2003	56	PP	-7	NO	38	-3	4	5	4	4	4	4	4	4	3	2
	E0034008	DAY 1	23MAY2003	-1	PP			30		3	4	3	3	3	4	3	3	4	0
		DAY 8	02JUN2003	10	PP	-17	NO	25	-5	3	4	4	0	0	4	3	3	4	0
		DAY 15	06JUN2003	14	PP	-17	NO	25	-5	4	4	4	0	0	4	3	3	3	0
		DAY 22	13JUN2003	21	PP	10	NO	33	3	4	5	4	0	2	5	4	3	4	2
		DAY 29	20JUN2003	28	PP	-63	YES	11	-19	2	2	3	0	0	1	1	2	0	0
		DAY 36	27JUN2003	35	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 43	07JUL2003	45	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 50	14JUL2003	52	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 57	21JUL2003	59	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
	E0035003	DAY 1	22NOV2002	1	PP			28		3	4	3	4	3	3	2	3	2	1
		DAY 8	27NOV2002	6	PP	-36	NO	18	-10	2	2	3	0	3	2	2	3	1	0
		DAY 15	04DEC2002	13	PP	-46	NO	15	-13	2	2	2	0	2	2	2	2	1	0
		DAY 22	13DEC2002	22	PP	-39	NO	17	-11	2	2	2	2	0	2	2	3	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	DAY 29	20DEC2002	29	PP	-64	YES	10	-18	1	1	2	2	0	1	1	2	0	0
		DAY 36	27DEC2002	36	PP	-68	YES	9	-19	1	1	2	3	0	0	1	1	0	0
		DAY 43	03JAN2003	43	PP	-71	YES	8	-20	1	1	3	3	0	0	0	0	0	0
		DAY 50	10JAN2003	50	PP	-82	YES	5	-23	1	1	2	1	0	0	0	0	0	0
	E0035005	DAY 1	03DEC2002	1	PP			25		3	3	3	4	2	3	0	2	3	2
		DAY 8	12DEC2002	10	PP	-52	YES	12	-13	2	2	2	0	0	2	0	2	2	0
		DAY 15	17DEC2002	15	PP	-64	YES	9	-16	2	2	2	0	0	2	0	1	0	0
		DAY 22	24DEC2002	22	PP	-76	YES	6	-19	1	1	2	0	0	1	0	0	1	0
		DAY 29	31DEC2002	29	PP	-72	YES	7	-18	1	1	3	0	0	1	0	1	0	0
		DAY 36	07JAN2003	36	PP	-64	YES	9	-16	2	2	2	0	0	1	0	1	1	0
		DAY 43	14JAN2003	43	PP	-76	YES	6	-19	2	1	1	1	0	0	0	0	1	0
		DAY 50	21JAN2003	50	PP	-68	YES	8	-17	2	1	2	1	0	0	0	1	1	0
	E0035014	DAY 1	03FEB2003	1	PP			23		3	3	3	2	2	2	0	4	4	0
		DAY 8	10FEB2003	8	PP	0	NO	23	0	3	3	3	0	0	2	2	4	4	2
		DAY 15	17FEB2003	15	PP	-65	YES	8	-15	2	2	1	0	0	2	0	1	0	0
		DAY 22	24FEB2003	22	PP	-26	NO	17	-6	2	2	1	3	4	1	2	2	0	0
		DAY 29	03MAR2003	29	PP	-39	NO	14	-9	1	1	3	0	2	0	4	1	2	0
		DAY 36	10MAR2003	36	PP	-44	NO	13	-10	2	2	2	2	0	1	0	0	4	0
		DAY 43	17MAR2003	43	PP	-87	YES	3	-20	1	1	1	0	0	0	0	0	0	0
		DAY 50	24MAR2003	50	PP	-83	YES	4	-19	1	1	2	0	0	0	0	0	0	0
		DAY 57	31MAR2003	57	PP	-78	YES	5	-18	1	1	2	0	0	1	0	0	0	0
	E0035024	DAY 1	22MAY2003	-1	PP			29		4	3	3	5	0	2	4	3	4	1
		DAY 8	29MAY2003	7	PP	10	NO	32	3	4	4	4	4	0	2	4	4	4	2
		DAY 15	05JUN2003	14	PP	-3	NO	28	-1	3	4	3	1	0	3	4	4	4	2
		DAY 22	13JUN2003	22	PP	-14	NO	25	-4	2	3	3	1	0	2	4	4	4	2
		DAY 29	19JUN2003	28	PP	-3	NO	28	-1	4	4	4	0	0	2	4	4	4	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	DAY 36	27JUN2003	36	PP	-7	NO	27	-2	4	4	4	0	0	2	4	4	4	1
		DAY 43	03JUL2003	42	PP	7	NO	31	2	4	4	4	3	0	2	4	4	4	2
		DAY 50	10JUL2003	49	PP	10	NO	32	3	5	4	4	4	0	3	4	3	4	1
		DAY 57	18JUL2003	57	PP	-17	NO	24	-5	3	3	3	4	0	2	2	1	4	2
	E0036005	DAY 1	01JUL2003	1	PP			26		4	4	3	0	2	4	2	4	3	0
		DAY 8	08JUL2003	8	PP	-12	NO	23	-3	3	3	3	1	2	4	3	3	1	0
		DAY 15	15JUL2003	15	PP	-58	YES	11	-15	0	0	1	2	3	4	1	0	0	0
		DAY 22	23JUL2003	23	PP	-27	NO	19	-7	2	2	2	0	3	4	3	1	2	0
		DAY 29	29JUL2003	29	PP	-65	YES	9	-17	1	1	1	0	2	0	2	0	2	0
		DAY 36	05AUG2003	36	PP	-69	YES	8	-18	2	1	1	0	2	0	1	0	1	0
		DAY 43	12AUG2003	43	PP	-42	NO	15	-11	4	2	1	0	2	2	2	0	1	1
		DAY 50	19AUG2003	50	PP	0	NO	26	0	4	4	0	0	2	4	3	4	2	3
		DAY 57	27AUG2003	58	PP	-69	YES	8	-18	3	1	1	0	3	0	0	0	0	0
	E0037002	DAY 1	26DEC2002	1	PP			31		2	3	3	4	2	4	3	3	4	3
		DAY 8	03JAN2003	9	PP	-26	NO	23	-8	3	3	3	0	0	4	3	2	3	2
		DAY 15	09JAN2003	15	PP	-52	NO	15	-16	2	1	3	0	0	3	1	2	2	1
		DAY 22	17JAN2003	23	PP	-68	YES	10	-21	1	2	2	0	0	0	0	2	2	1
		DAY 29	24JAN2003	30	PP	-23	NO	24	-7	2	3	2	2	2	4	2	2	3	2
		DAY 36	31JAN2003	37	PP	-29	NO	22	-9	2	3	1	3	0	4	2	3	2	2
		DAY 43	07FEB2003	44	PP	-81	YES	6	-25	0	0	2	0	0	1	0	1	2	0
		DAY 50	13FEB2003	50	PP	-65	YES	11	-20	0	0	2	0	2	2	0	3	2	0
		DAY 57	20FEB2003	57	PP	-71	YES	9	-22	0	0	2	0	2	4	1	0	0	0
	E0037005	DAY 1	06MAR2003	1	PP			29		3	3	2	3	0	4	4	4	4	2
		DAY 8	13MAR2003	8	PP	-38	NO	18	-11	2	1	2	0	0	4	3	4	2	0
		DAY 15	20MAR2003	15	PP	-28	NO	21	-8	2	3	2	0	0	3	3	4	2	2
		DAY 22	27MAR2003	22	PP	-45	NO	16	-13	2	2	3	0	0	4	2	1	2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	DAY 29	03APR2003	29	PP	-38	NO	18	-11	2	2	3	0	0	3	2	3	2	1
		DAY 36	10APR2003	36	PP	-48	NO	15	-14	1	1	3	0	0	3	1	3	3	0
		DAY 43	17APR2003	43	PP	-41	NO	17	-12	1	1	3	0	0	3	2	4	2	1
		DAY 50	24APR2003	50	PP	-41	NO	17	-12	1	1	3	0	0	3	2	4	2	1
		DAY 57	01MAY2003	57	PP	-35	NO	19	-10	2	2	2	0	0	4	3	4	2	0
	E0037006	DAY 1	14MAR2003	1	PP			19		2	4	2	0	0	3	3	2	3	0
		DAY 8	21MAR2003	8	PP	-21	NO	15	-4	2	0	2	0	0	3	3	2	3	0
		DAY 15	28MAR2003	15	PP	-42	YES	11	-8	1	2	0	0	0	2	2	1	2	1
		DAY 22	04APR2003	22	PP	-37	YES	12	-7	2	2	0	0	0	0	1	2	3	2
		DAY 29	11APR2003	29	PP	-37	YES	12	-7	2	1	2	0	0	2	1	1	2	1
		DAY 36	18APR2003	36	PP	0	NO	19	0	2	2	2	0	0	2	3	3	3	2
		DAY 43	25APR2003	43	PP	-32	NO	13	-6	2	2	1	1	0	2	0	2	2	1
		DAY 50	01MAY2003	49	PP	-42	YES	11	-8	1	1	1	1	0	2	0	2	2	1
		DAY 57	09MAY2003	57	PP	-74	YES	5	-14	0	0	2	0	0	0	0	1	2	0
	E0039006	DAY 1	30DEC2002	1	PP			28		4	4	2	4	3	3	1	4	2	1
		DAY 8	06JAN2003	8	PP	14	NO	32	4	4	4	3	5	2	3	3	4	2	2
		DAY 15	13JAN2003	15	PP	14	NO	32	4	4	4	3	5	2	3	3	4	2	2
		DAY 22	20JAN2003	22	PP	-4	NO	27	-1	3	4	1	3	2	1	4	4	3	2
		DAY 29	28JAN2003	30	PP	11	NO	31	3	3	4	2	4	1	3	4	4	4	2
		DAY 36	04FEB2003	37	PP	11	NO	31	3	4	4	1	4	1	3	4	4	4	2
		DAY 43	10FEB2003	43	PP	-79	YES	6	-22	1	0	1	1	0	1	0	1	1	0
		DAY 50	18FEB2003	51	PP	-79	YES	6	-22	1	0	1	1	0	1	0	1	1	0
		DAY 57	24FEB2003	57	PP	-79	YES	6	-22	1	1	1	0	0	1	1	1	0	0
	E0039015	DAY 1	23JAN2003	1	PP			30		4	3	3	5	2	2	3	3	3	2
		DAY 8	30JAN2003	8	PP	-60	YES	12	-18	1	1	2	1	0	1	2	2	2	0
		DAY 15	06FEB2003	15	PP	-83	YES	5	-25	1	0	1	0	0	1	0	1	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0039015	DAY 22	14FEB2003	23	PP	-77	YES	7	-23	1	1	1	1	0	0	1	1	1	0
		DAY 29	20FEB2003	29	PP	-87	YES	4	-26	1	0	1	0	0	1	0	1	0	0
		DAY 36	27FEB2003	36	PP	-87	YES	4	-26	0	0	2	0	0	1	0	1	0	0
		DAY 43	06MAR2003	43	PP	-77	YES	7	-23	1	1	2	0	0	1	1	1	0	0
		DAY 50	14MAR2003	51	PP	-90	YES	3	-27	0	0	1	0	0	1	0	1	0	0
		DAY 57	20MAR2003	57	PP	-80	YES	6	-24	1	1	1	0	0	1	1	1	0	0
	E0039024	DAY 1	27FEB2003	1	PP			26		3	4	3	4	2	0	3	3	2	2
		DAY 8	05MAR2003	7	PP	-65	YES	9	-17	2	1	2	2	0	1	0	1	0	0
		DAY 15	11MAR2003	13	PP	-77	YES	6	-20	0	0	1	1	1	1	1	1	0	0
		DAY 22	20MAR2003	22	PP	-65	YES	9	-17	1	1	2	2	2	0	0	1	0	0
		DAY 29	27MAR2003	29	PP	-23	NO	20	-6	4	4	0	4	0	3	2	3	0	0
		DAY 36	03APR2003	36	PP	-27	NO	19	-7	3	3	0	4	0	3	2	3	0	1
		DAY 43	10APR2003	43	PP	-31	NO	18	-8	2	2	2	1	1	1	3	4	1	1
		DAY 50	17APR2003	50	PP	-89	YES	3	-23	0	0	2	0	0	0	0	1	0	0
		DAY 57	24APR2003	57	PP	-96	YES	1	-25	0	0	1	0	0	0	0	0	0	0
	E0039025	DAY 1	18MAR2003	1	PP			25		3	4	2	4	2	2	0	3	3	2
		DAY 8	25MAR2003	8	PP	-32	NO	17	-8	2	2	2	1	0	2	3	3	2	0
		DAY 15	01APR2003	15	PP	-64	YES	9	-16	1	0	3	0	0	2	1	1	1	0
		DAY 22	10APR2003	24	PP	-96	YES	1	-24	0	0	1	0	0	0	0	0	0	0
		DAY 29	15APR2003	29	PP	-100	YES	0	-25	0	0	0	0	0	0	0	0	0	0
		DAY 36	22APR2003	36	PP	-92	YES	2	-23	0	0	1	0	0	1	0	0	0	0
		DAY 43	29APR2003	43	PP	-96	YES	1	-24	0	0	0	0	0	0	0	1	0	0
		DAY 50	06MAY2003	50	PP	-100	YES	0	-25	0	0	0	0	0	0	0	0	0	0
	E0039041	DAY 1	15APR2003	1	PP			25		3	3	2	4	2	3	2	2	2	2
		DAY 8	22APR2003	8	PP	-12	NO	22	-3	3	3	3	4	0	1	2	3	2	1
		DAY 15	29APR2003	15	PP	-60	YES	10	-15	2	2	1	0	0	2	1	1	1	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 22		06MAY2003	22	PP	-92	YES	2	-23	1	0	1	0	0	0	0	0	0	0
		DAY 29		13MAY2003	29	PP	-36	NO	16	-9	2	2	2	3	0	1	2	1	2	1
		DAY 36		20MAY2003	36	PP	-84	YES	4	-21	1	0	1	0	0	1	1	0	0	0
		DAY 43		27MAY2003	43	PP	-52	YES	12	-13	1	1	1	3	2	0	1	2	1	0
		DAY 50		03JUN2003	50	PP	-68	YES	8	-17	1	1	1	0	1	1	1	1	1	0
		DAY 57		11JUN2003	58	PP	-92	YES	2	-23	0	0	1	1	0	0	0	0	0	0
	E0039044	DAY 1		22MAY2003	1	PP			26		3	3	3	3	1	2	3	4	2	2
		DAY 8		29MAY2003	8	PP	-81	YES	5	-21	1	1	1	0	0	1	1	0	0	0
		DAY 15		04JUN2003	14	PP	-89	YES	3	-23	0	0	2	0	0	0	0	1	0	0
		DAY 22		11JUN2003	21	PP	-96	YES	1	-25	0	0	1	0	0	0	0	0	0	0
		DAY 29		18JUN2003	28	PP	-100	YES	0	-26	0	0	0	0	0	0	0	0	0	0
		DAY 36		26JUN2003	36	PP	-92	YES	2	-24	0	0	2	0	0	0	0	0	0	0
		DAY 43		02JUL2003	42	PP	-92	YES	2	-24	0	0	2	0	0	0	0	0	0	0
		DAY 50		09JUL2003	49	PP	-96	YES	1	-25	0	0	0	0	0	1	0	0	0	0
	E0039046		*	21MAY2003		NODOSE			29		4	4	3	4	2	2	1	4	3	2
	E0039051	DAY 1		16JUN2003	1	PP			23		3	3	3	3	0	2	2	3	2	2
		DAY 8		23JUN2003	8	PP	-17	NO	19	-4	2	2	2	2	2	3	1	2	2	1
		DAY 15		30JUN2003	15	PP	-44	NO	13	-10	2	2	3	0	0	0	2	2	2	0
		DAY 22		07JUL2003	22	PP	-44	NO	13	-10	0	2	3	0	0	2	3	1	2	0
		DAY 29		14JUL2003	29	PP	-52	YES	11	-12	1	2	2	2	0	0	2	1	1	0
		DAY 36		22JUL2003	37	PP	-57	YES	10	-13	2	1	2	0	0	2	0	2	1	0
		DAY 43		28JUL2003	43	PP	-96	YES	1	-22	0	0	1	0	0	0	0	0	0	0
		DAY 50		04AUG2003	50	PP	-61	YES	9	-14	1	1	2	0	2	1	0	1	1	0
		DAY 57		12AUG2003	58	PP	-65	YES	8	-15	1	1	2	0	0	0	2	1	1	0
	E0039053	DAY 1		11JUL2003	1	PP			32		4	4	3	4	1	3	4	4	3	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	DAY 8	18JUL2003	8	PP	-28	NO	23	-9	2	2	3	2	2	2	4	2	2	2
		DAY 15	25JUL2003	15	PP	-22	NO	25	-7	3	3	3	4	3	3	2	2	1	1
		DAY 22	01AUG2003	22	PP	-44	NO	18	-14	2	3	2	3	2	1	2	1	2	0
		DAY 29	07AUG2003	28	PP	-69	YES	10	-22	2	1	1	2	0	1	1	1	1	0
		DAY 36	14AUG2003	35	PP	-72	YES	9	-23	2	1	0	2	0	1	1	1	1	0
		DAY 43	21AUG2003	42	PP	-84	YES	5	-27	2	1	1	0	0	0	0	1	0	0
		DAY 50	29AUG2003	50	PP	-91	YES	3	-29	1	0	1	0	0	0	1	0	0	0
		DAY 57	08SEP2003	60	PP	-53	NO	15	-17	2	2	3	0	1	1	2	2	2	0
	E0039057	DAY 1	14JUL2003	1	PP			29		3	4	3	4	2	3	3	4	2	1
		DAY 8	22JUL2003	9	PP	-86	YES	4	-25	1	0	1	0	0	0	0	1	1	0
		DAY 15	28JUL2003	15	PP	-97	YES	1	-28	0	0	1	0	0	0	0	0	0	0
		DAY 22	04AUG2003	22	PP	-86	YES	4	-25	1	0	1	0	0	0	1	1	0	0
		DAY 29	12AUG2003	30	PP	-100	YES	0	-29	0	0	0	0	0	0	0	0	0	0
		DAY 36	18AUG2003	36	PP	-100	YES	0	-29	0	0	0	0	0	0	0	0	0	0
		DAY 43	26AUG2003	44	PP	-90	YES	3	-26	0	0	1	0	0	0	0	1	1	0
		DAY 50	02SEP2003	51	PP	-79	YES	6	-23	1	2	2	0	0	0	0	1	0	0
		DAY 57	09SEP2003	58	PP	-79	YES	6	-23	1	0	1	0	0	0	1	2	1	0
	E0041003	DAY 1	28JAN2003	1	PP			29		3	4	3	4	2	3	4	3	3	0
		DAY 8	04FEB2003	8	PP	-48	NO	15	-14	2	2	0	2	0	0	3	3	3	0
		DAY 15	11FEB2003	15	PP	-76	YES	7	-22	1	2	0	2	0	0	2	0	0	0
		DAY 22	18FEB2003	22	PP	-86	YES	4	-25	1	1	0	2	0	0	0	0	0	0
		DAY 29	25FEB2003	29	PP	-72	YES	8	-21	1	2	0	1	0	0	0	2	2	0
		DAY 36	04MAR2003	36	PP	-83	YES	5	-24	1	1	0	1	0	0	0	1	1	0
		DAY 43	11MAR2003	43	PP	-76	YES	7	-22	1	1	0	1	0	0	0	2	2	0
		DAY 50	18MAR2003	50	PP	-76	YES	7	-22	1	1	0	1	0	0	0	2	2	0
		DAY 57	25MAR2003	57	PP	-76	YES	7	-22	2	2	0	0	0	0	0	1	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	DAY 1	07APR2003	1	PP			30		3	3	3	4	3	3	4	4	3	0
		DAY 8	14APR2003	8	PP	-10	NO	27	-3	2	3	3	4	2	3	3	4	3	0
		DAY 15	22APR2003	16	PP	-33	NO	20	-10	2	3	2	3	0	3	3	2	2	0
		DAY 22	28APR2003	22	PP	-27	NO	22	-8	3	3	3	3	3	2	3	2	0	0
		DAY 29	05MAY2003	29	PP	-20	NO	24	-6	2	2	3	3	4	3	4	3	0	0
		DAY 36	12MAY2003	36	PP	-17	NO	25	-5	2	2	3	3	3	3	4	3	2	0
		DAY 43	21MAY2003	45	PP	-50	NO	15	-15	0	0	3	3	3	2	4	0	0	0
		DAY 50	27MAY2003	51	PP	-33	NO	20	-10	2	2	2	3	3	2	3	3	0	0
		DAY 57	02JUN2003	57	PP	-27	NO	22	-8	2	2	4	3	3	2	3	3	0	0
	E0042001	DAY 1	02JUL2003	1	PP			26		4	4	3	3	1	3	3	2	3	0
		DAY 8	09JUL2003	8	PP	-35	NO	17	-9	2	3	2	3	0	2	2	1	2	0
		DAY 15	15JUL2003	14	PP	-73	YES	7	-19	2	1	1	0	0	1	1	0	1	0
		DAY 22	22JUL2003	21	PP	-69	YES	8	-18	2	2	1	1	0	0	1	0	1	0
		DAY 29	29JUL2003	28	PP	-81	YES	5	-21	0	1	1	0	0	1	1	0	1	0
		DAY 36	05AUG2003	35	PP	-81	YES	5	-21	0	1	1	0	0	1	1	0	1	0
		DAY 43	12AUG2003	42	PP	-92	YES	2	-24	1	1	0	0	0	0	0	0	0	0
		DAY 50	19AUG2003	49	PP	-73	YES	7	-19	0	1	1	1	0	1	2	0	1	0
		DAY 57	26AUG2003	56	PP	-85	YES	4	-22	0	1	0	1	0	0	2	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	PP			39		3	5	3	5	5	4	4	5	4	1
		DAY 8	19MAR2003	8	PP	-36	NO	25	-14	3	5	0	1	3	4	4	3	2	0
		DAY 15	26MAR2003	15	PP	-49	NO	20	-19	2	3	1	0	2	3	3	3	2	1
		DAY 22	02APR2003	22	PP	-67	NO	13	-26	0	2	2	1	2	1	2	2	1	0
		DAY 29	09APR2003	29	PP	-64	NO	14	-25	0	1	3	1	2	2	2	2	1	0
		DAY 36	16APR2003	36	PP	-85	YES	6	-33	0	1	1	0	0	2	0	2	0	0
		DAY 43	23APR2003	43	PP	-85	YES	6	-33	0	0	1	1	1	1	1	0	1	0
		DAY 50	30APR2003	50	PP	-90	YES	4	-35	0	0	1	1	0	0	1	1	0	0
		DAY 57	07MAY2003	57	PP	-87	YES	5	-34	0	0	0	0	0	2	1	1	1	0
	E0003018	DAY 1	13MAY2003	1	PP			28		3	3	3	3	2	4	3	3	2	2
		DAY 8	20MAY2003	8	PP	-7	NO	26	-2	3	3	3	1	2	3	2	4	3	2
		DAY 15	27MAY2003	15	PP	-18	NO	23	-5	3	3	3	2	0	3	3	0	3	3
		DAY 22	03JUN2003	22	PP	0	NO	28	0	3	3	3	3	1	3	3	3	3	3
		DAY 29	10JUN2003	29	PP	21	NO	34	6	3	3	3	3	0	4	5	5	4	4
		DAY 36	17JUN2003	36	PP	-29	NO	20	-8	3	3	3	2	0	3	2	1	3	0
		DAY 43	24JUN2003	43	PP	-36	NO	18	-10	3	3	3	2	0	2	1	2	2	0
		DAY 50	02JUL2003	51	PP	-32	NO	19	-9	3	2	3	2	0	2	2	1	2	2
		DAY 57	08JUL2003	57	PP	-32	NO	19	-9	2	2	3	2	0	2	3	2	2	1
	E0005011	DAY 1	24OCT2002	1	PP			33		4	4	2	4	3	4	4	4	3	1
		DAY 8	31OCT2002	8	PP	-21	NO	26	-7	4	4	1	0	3	3	4	4	2	1
		DAY 15	07NOV2002	15	PP	-46	NO	18	-15	3	3	0	0	0	2	4	3	2	1
		DAY 22	14NOV2002	22	PP	-58	NO	14	-19	2	2	2	0	0	0	2	4	1	1
		DAY 29	21NOV2002	29	PP	-64	YES	12	-21	2	2	2	0	0	0	2	2	1	1
		DAY 36	26NOV2002	34	PP	-76	YES	8	-25	1	1	2	0	0	0	2	1	1	0
		DAY 43	03DEC2002	41	PP	-82	YES	6	-27	1	1	0	0	0	0	2	2	0	0
		DAY 50	12DEC2002	50	PP	-82	YES	6	-27	1	1	0	0	0	0	2	2	0	0

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QUETIAPINE 300 MG (BIPOLAR II)	E0005030	DAY 1	26MAR2003	1	PP			35		4	5	4	4	3	4	4	4	2	1
		DAY 8	02APR2003	8	PP	-23	NO	27	-8	3	3	4	0	3	3	2	4	3	2
		DAY 15	09APR2003	15	PP	-63	NO	13	-22	1	2	2	2	2	2	0	2	0	0
		DAY 22	16APR2003	22	PP	-11	NO	31	-4	3	4	4	4	0	2	4	4	4	2
	E0005036	DAY 1	06MAY2003	1	ITT			27		3	4	3	4	0	3	4	3	2	1
		DAY 8	12MAY2003	7	ITT	-37	NO	17	-10	2	2	2	3	0	3	2	1	1	1
	E0006015	DAY 1	11FEB2003	1	PP			30		4	4	3	3	0	4	5	4	3	0
		DAY 8	18FEB2003	8	PP	-10	NO	27	-3	3	3	3	3	0	4	5	3	3	0
		DAY 15	25FEB2003	15	PP	7	NO	32	2	4	4	3	3	2	5	5	4	1	1
		DAY 22	04MAR2003	22	PP	-3	NO	29	-1	4	4	2	2	2	4	5	4	1	1
		DAY 29	11MAR2003	29	PP	-7	NO	28	-2	4	4	2	1	2	4	5	4	1	1
		DAY 36	18MAR2003	36	PP	-10	NO	27	-3	4	4	2	1	2	3	5	4	1	1
		DAY 43	25MAR2003	43	PP	0	NO	30	0	4	4	3	2	2	4	5	4	1	1
		DAY 50	01APR2003	50	PP	-27	NO	22	-8	1	3	2	3	1	3	3	3	2	1
		DAY 57	08APR2003	57	PP	-30	NO	21	-9	1	3	2	2	1	3	3	3	2	1
	E0006016	DAY 1	17FEB2003	1	PP			32		4	4	3	3	2	4	4	2	3	3
		DAY 8	24FEB2003	8	PP	-9	NO	29	-3	3	3	4	2	2	4	2	3	4	2
		DAY 15	03MAR2003	15	PP	-16	NO	27	-5	3	3	4	1	2	3	3	3	3	2
		DAY 22	10MAR2003	22	PP	-25	NO	24	-8	3	3	3	2	1	3	3	2	3	1
		DAY 29	17MAR2003	29	PP	-34	NO	21	-11	3	3	3	2	1	2	1	2	3	1
		DAY 36	27MAR2003	39	PP	-44	NO	18	-14	3	2	3	1	1	3	1	1	2	1
		DAY 43	03APR2003	46	PP	-44	NO	18	-14	1	3	1	2	1	3	2	2	2	1
		DAY 50	10APR2003	53	PP	-56	NO	14	-18	2	2	2	1	1	2	1	1	1	1
		DAY 57	18APR2003	61	PP	-66	YES	11	-21	2	2	2	0	1	2	1	1	0	0
	E0007008	DAY 1	18APR2003	1	ITT			29		4	4	2	4	2	2	2	4	4	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	DAY 8	25APR2003	8	ITT	-10	NO	26	-3	4	4	2	0	2	2	3	4	4	1
	E0009002	DAY 1	19NOV2002	1	PP			39		4	4	5	5	3	5	5	4	3	1
		DAY 8	26NOV2002	8	PP	-67	NO	13	-26	2	0	2	0	0	3	3	2	1	0
		DAY 15	03DEC2002	15	PP	-21	NO	31	-8	5	5	3	4	0	3	4	4	2	1
		DAY 22	10DEC2002	22	PP	-33	NO	26	-13	4	5	3	0	0	3	4	4	2	1
		DAY 29	18DEC2002	30	PP	-69	YES	12	-27	1	2	2	0	0	2	2	3	0	0
		DAY 36	23DEC2002	35	PP	-54	NO	18	-21	2	2	2	0	0	4	3	3	2	0
		DAY 43	30DEC2002	42	PP	-46	NO	21	-18	2	3	2	3	0	2	3	3	2	1
		DAY 50	07JAN2003	50	PP	-69	YES	12	-27	0	3	2	0	0	1	3	3	0	0
		DAY 57	15JAN2003	58	PP	-31	NO	27	-12	3	4	3	0	0	4	5	4	3	1
	E0009006	DAY 1	28JAN2003	1	PP			32		3	3	3	5	3	3	4	3	3	2
		DAY 8	04FEB2003	8	PP	-22	NO	25	-7	4	3	3	0	2	3	2	2	4	2
		DAY 15	11FEB2003	15	PP	-41	NO	19	-13	3	3	3	1	0	2	2	2	3	0
		DAY 22	18FEB2003	22	PP	-31	NO	22	-10	3	3	3	3	0	2	0	3	3	2
		DAY 29	25FEB2003	29	PP	-41	NO	19	-13	3	3	3	2	4	1	1	1	1	0
		DAY 36	04MAR2003	36	PP	-38	NO	20	-12	3	3	2	1	0	2	2	2	3	2
		DAY 43	11MAR2003	43	PP	-44	NO	18	-14	3	3	3	2	0	3	1	1	2	0
		DAY 50	18MAR2003	50	PP	-38	NO	20	-12	3	3	3	2	0	3	0	2	3	1
		DAY 57	25MAR2003	57	PP	-41	NO	19	-13	3	3	2	4	0	1	2	1	2	1
	E0009009	DAY 1	12MAR2003	1	PP			31		3	4	3	4	4	2	4	4	2	1
		DAY 8	19MAR2003	8	PP	-48	NO	16	-15	3	2	2	0	0	2	1	3	2	1
		DAY 15	24MAR2003	13	PP	-55	NO	14	-17	2	2	2	0	0	2	1	2	2	1
	E0010015	DAY 1	20FEB2003	1	PP			39		5	5	3	6	2	4	4	4	3	3
		DAY 8	27FEB2003	8	PP	-77	YES	9	-30	1	1	0	3	0	2	0	2	0	0
		DAY 15	06MAR2003	15	PP	3	NO	40	1	4	5	4	6	3	3	4	4	4	3

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	DAY 22	13MAR2003	22	PP	-15	NO	33	-6	4	4	3	6	0	4	4	4	2	2
		DAY 29	20MAR2003	29	PP	-56	NO	17	-22	3	3	0	5	0	2	3	1	0	0
		DAY 36	26MAR2003	35	PP	-64	NO	14	-25	1	0	2	5	0	2	3	1	0	0
		DAY 43	02APR2003	42	PP	-72	YES	11	-28	1	0	0	6	0	1	3	0	0	0
		DAY 50	09APR2003	49	PP	-80	YES	8	-31	1	0	0	5	0	0	2	0	0	0
		DAY 57	15APR2003	55	PP	-80	YES	8	-31	0	0	0	5	0	1	2	0	0	0
	E0011004	DAY 1	24DEC2002	1	PP			29		3	4	3	4	4	3	3	2	1	2
		DAY 8	31DEC2002	8	PP	-38	NO	18	-11	2	2	3	4	2	2	2	1	0	0
		DAY 15	07JAN2003	15	PP	-48	NO	15	-14	2	2	3	3	0	1	1	1	1	1
		DAY 22	14JAN2003	22	PP	-66	YES	10	-19	1	2	0	3	0	2	0	1	0	1
		DAY 29	21JAN2003	29	PP	-69	YES	9	-20	2	1	0	2	0	1	1	1	1	0
		DAY 36	28JAN2003	36	PP	-45	NO	16	-13	2	3	3	3	0	1	1	1	1	1
		DAY 43	04FEB2003	43	PP	-41	NO	17	-12	1	2	2	4	0	2	1	2	2	1
		DAY 50	11FEB2003	50	PP	-90	YES	3	-26	0	0	0	0	0	0	0	2	1	0
		DAY 57	18FEB2003	57	PP	-93	YES	2	-27	0	1	0	0	0	0	0	0	1	0
	E0011007	DAY 1	19DEC2002	1	PP			22		2	4	2	3	2	2	1	2	2	2
		DAY 8	26DEC2002	8	PP	-36	NO	14	-8	1	2	1	2	0	1	2	2	2	1
		DAY 15	02JAN2003	15	PP	18	NO	26	4	3	4	3	4	0	2	4	2	3	1
		DAY 22	09JAN2003	22	PP	-50	YES	11	-11	1	2	2	0	0	2	1	1	2	0
		DAY 29	17JAN2003	30	PP	-50	YES	11	-11	1	1	2	0	0	0	2	2	2	1
		DAY 36	23JAN2003	36	PP	-27	NO	16	-6	1	1	3	3	0	2	1	2	2	1
		DAY 43	30JAN2003	43	PP	-50	YES	11	-11	1	1	2	1	0	1	1	2	2	0
		DAY 50	06FEB2003	50	PP	-82	YES	4	-18	1	1	0	2	0	0	0	0	0	0
		DAY 57	13FEB2003	57	PP	-96	YES	1	-21	0	0	0	0	0	0	0	0	1	0
	E0011018	DAY 1	22MAY2003	1	PP			31		4	3	3	3	3	3	4	3	3	2
		DAY 8	30MAY2003	9	PP	-36	NO	20	-11	2	2	2	1	0	2	3	2	3	3

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	DAY 22	*	10JUN2003	20	PP	-23	NO	24	-7	2	3	2	2	2	2	2	2	3	4
		DAY 22		13JUN2003	23	PP	-71	YES	9	-22	2	0	1	0	0	1	2	1	2	0
		DAY 29		20JUN2003	30	PP	-74	YES	8	-23	1	0	2	0	0	2	2	0	1	0
		DAY 36		28JUN2003	38	PP	-81	YES	6	-25	1	0	2	0	0	2	1	0	0	0
		DAY 43		03JUL2003	43	PP	-87	YES	4	-27	1	0	1	0	0	1	1	0	0	0
		DAY 50		10JUL2003	50	PP	-87	YES	4	-27	1	0	0	0	0	0	2	0	0	1
		DAY 57		17JUL2003	57	PP	-77	YES	7	-24	2	0	1	0	0	2	1	0	0	1
	E0011024	DAY 1		24JUN2003	1	PP			28		4	3	3	4	2	3	2	3	3	1
		DAY 8		01JUL2003	8	PP	-21	NO	22	-6	3	2	4	0	0	2	4	3	3	1
		DAY 15		08JUL2003	15	PP	-25	NO	21	-7	3	2	4	0	0	1	4	3	3	1
		DAY 22		15JUL2003	22	PP	-18	NO	23	-5	3	2	4	0	0	2	4	3	3	2
		DAY 29		22JUL2003	29	PP	-29	NO	20	-8	2	2	4	0	0	1	4	3	2	2
		DAY 36		30JUL2003	37	PP	-46	NO	15	-13	2	2	3	0	0	1	3	2	1	1
		DAY 43		05AUG2003	43	PP	-57	YES	12	-16	2	1	3	0	0	1	2	2	0	1
		DAY 50		12AUG2003	50	PP	-64	YES	10	-18	2	1	2	0	0	1	1	2	0	1
		DAY 57		21AUG2003	59	PP	-64	YES	10	-18	2	1	1	0	1	1	1	2	0	1
	E0015003	DAY 1		25NOV2002	1	ITT			29		3	3	3	4	2	3	4	4	2	1
		DAY 8		02DEC2002	8	ITT	-24	NO	22	-7	3	3	2	0	0	3	4	4	2	1
	E0019003	DAY 1		21NOV2002	1	PP			38		5	5	5	5	0	3	4	4	4	3
		DAY 8		27NOV2002	7	PP	-66	NO	13	-25	1	1	2	0	0	2	4	2	1	0
		DAY 15		09DEC2002	19	PP	-84	YES	6	-32	1	0	0	0	0	2	2	1	0	0
		DAY 22		16DEC2002	26	PP	-76	YES	9	-29	2	2	3	0	0	0	0	0	2	0
		DAY 36		24DEC2002	34	PP	-63	NO	14	-24	1	3	2	2	0	1	2	1	2	0
		DAY 36	*	30DEC2002	40	PP	-82	YES	7	-31	1	1	2	0	0	0	2	0	1	0
		DAY 43		06JAN2003	47	PP	-84	YES	6	-32	1	0	1	0	1	1	1	1	0	0
		DAY 57	*	14JAN2003	55	PP	-95	YES	2	-36	0	0	0	0	0	2	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	DAY 57	16JAN2003	57	PP	-84	YES	6	-32	2	0	2	0	0	0	2	0	0	0
	E0019007	DAY 1	13NOV2002	1	PP			37		4	5	4	5	3	2	4	4	4	2
		DAY 8	21NOV2002	9	PP	-35	NO	24	-13	1	3	2	0	2	3	4	3	4	2
		DAY 15	27NOV2002	15	PP	-60	NO	15	-22	1	2	2	1	0	2	2	2	2	1
		DAY 22	05DEC2002	23	PP	-78	YES	8	-29	1	1	2	1	0	0	1	0	1	1
		DAY 29	12DEC2002	30	PP	-70	YES	11	-26	1	2	2	0	0	2	1	1	1	1
		DAY 36	17DEC2002	35	PP	-49	NO	19	-18	1	3	1	3	0	2	2	1	4	2
		DAY 43	24DEC2002	42	PP	-60	NO	15	-22	1	2	2	2	0	2	2	1	2	1
		DAY 50	30DEC2002	48	PP	-22	NO	29	-8	3	3	3	2	2	3	4	4	3	2
		DAY 57	07JAN2003	56	PP	-5	NO	35	-2	4	4	3	4	3	3	4	4	4	2
	E0019014	DAY 1	09JAN2003	1	ITT			31		3	3	4	4	2	2	4	3	4	2
		DAY 8	20JAN2003	12	ITT	-48	NO	16	-15	2	2	2	2	1	1	2	1	2	1
	E0019018	DAY 1	30JAN2003	1	PP			39		4	5	4	4	3	4	5	4	4	2
		DAY 8	06FEB2003	8	PP	-13	NO	34	-5	4	5	3	0	4	4	5	4	4	1
		DAY 15	13FEB2003	15	PP	-51	NO	19	-20	2	2	2	0	0	2	4	4	3	0
		DAY 22	20FEB2003	22	PP	-49	NO	20	-19	3	3	3	0	1	2	2	2	2	2
		DAY 29	27FEB2003	29	PP	-54	NO	18	-21	3	2	3	0	0	2	2	3	3	0
		DAY 36	06MAR2003	36	PP	-10	NO	35	-4	5	4	4	3	2	3	5	4	3	2
		DAY 43	13MAR2003	43	PP	-18	NO	32	-7	4	4	4	0	3	4	4	4	3	2
		DAY 50	20MAR2003	50	PP	-28	NO	28	-11	4	4	3	0	0	4	4	4	4	1
		DAY 57	27MAR2003	57	PP	-28	NO	28	-11	4	4	3	0	0	4	4	4	4	1
	E0019022	DAY 1	30JAN2003	1	PP			28		4	4	3	3	2	3	4	2	3	0
		DAY 8	06FEB2003	8	PP	14	NO	32	4	4	5	3	2	3	4	4	4	3	0
		DAY 15	13FEB2003	15	PP	-25	NO	21	-7	4	2	3	0	0	3	4	2	3	0
		DAY 22	20FEB2003	22	PP	-25	NO	21	-7	2	2	2	2	2	4	4	1	2	0

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 29	27FEB2003	29	PP	-25	NO	21	-7	2	2	2	2	2	4	3	2	2	0
		DAY 36	06MAR2003	36	PP	-61	YES	11	-17	2	1	2	0	2	1	1	1	1	0
		DAY 43	13MAR2003	43	PP	-68	YES	9	-19	1	1	2	0	1	2	2	0	0	0
		DAY 50	20MAR2003	50	PP	-39	NO	17	-11	2	2	1	2	2	0	3	2	3	0
		DAY 57	27MAR2003	57	PP	-46	NO	15	-13	2	1	2	3	3	2	2	0	0	0
	E0019027	DAY 1	27FEB2003	1	ITT			33		4	4	3	4	3	3	4	3	3	2
		DAY 8	06MAR2003	8	ITT	-46	NO	18	-15	2	1	2	2	2	2	2	3	1	1
	E0019032	DAY 1	01APR2003	1	PP			34		4	4	3	5	1	4	4	3	4	2
		DAY 8	08APR2003	8	PP	-32	NO	23	-11	2	3	4	2	0	3	3	3	3	0
		DAY 15	15APR2003	15	PP	-41	NO	20	-14	3	2	2	1	0	4	4	3	1	0
		DAY 22	21APR2003	21	PP	-29	NO	24	-10	2	2	3	2	2	4	4	4	0	1
		DAY 29	29APR2003	29	PP	-56	NO	15	-19	3	1	0	2	0	3	3	3	0	0
		DAY 36	07MAY2003	37	PP	-56	NO	15	-19	4	1	3	0	0	3	2	2	0	0
		DAY 43	14MAY2003	44	PP	-62	NO	13	-21	4	1	1	1	0	2	2	1	1	0
		DAY 50	21MAY2003	51	PP	-44	NO	19	-15	5	1	4	2	0	3	2	2	0	0
		DAY 57	27MAY2003	57	PP	-56	NO	15	-19	4	1	5	0	0	4	0	1	0	0
	E0019034	DAY 1	18MAR2003	1	PP			38		4	4	3	6	4	4	4	4	3	2
		DAY 8	25MAR2003	8	PP	-53	NO	18	-20	2	3	0	0	0	3	2	3	3	2
		DAY 15	01APR2003	15	PP	-82	YES	7	-31	1	0	0	0	0	0	3	0	3	0
	E0019036	DAY 1	25MAR2003	1	PP			30		3	4	4	4	0	3	4	2	4	2
		DAY 8	31MAR2003	7	PP	-50	NO	15	-15	1	1	2	0	2	3	2	2	2	0
		DAY 15	10APR2003	17	PP	-63	YES	11	-19	3	2	2	0	0	1	1	1	1	0
		DAY 22	15APR2003	22	PP	-67	YES	10	-20	2	1	3	0	0	1	1	2	0	0
		DAY 29	22APR2003	29	PP	-90	YES	3	-27	1	0	1	0	0	0	0	0	1	0
		DAY 36	29APR2003	36	PP	-87	YES	4	-26	2	0	2	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0019039	DAY 1	01MAY2003	1	SAFETY			36		4	5	4	4	2	4	5	4	3	1
	E0019041	DAY 1	21MAY2003	1	PP			28		3	2	4	4	2	4	3	4	2	0
		DAY 8	28MAY2003	8	PP	-46	NO	15	-13	2	1	2	0	0	2	4	2	2	0
		DAY 15	04JUN2003	15	PP	-21	NO	22	-6	4	2	3	0	0	4	2	2	4	1
		DAY 22	12JUN2003	23	PP	-39	NO	17	-11	3	2	2	2	0	2	2	2	2	0
		DAY 29	18JUN2003	29	PP	-54	NO	13	-15	3	1	1	2	0	1	2	1	2	0
		DAY 36	25JUN2003	36	PP	-39	NO	17	-11	2	2	2	2	0	0	3	2	3	1
		DAY 43	02JUL2003	43	PP	-68	YES	9	-19	2	1	0	2	0	0	1	1	2	0
		DAY 50	09JUL2003	50	PP	-64	YES	10	-18	4	1	0	2	0	0	1	0	2	0
		DAY 57	16JUL2003	57	PP	-57	YES	12	-16	3	1	1	3	0	0	2	0	2	0
	E0019049	DAY 1	10JUL2003	1	PP (61)			35		5	4	3	5	4	4	4	4	0	2
		DAY 8	17JUL2003	8	PP (61)	-46	NO	19	-16	2	2	3	0	4	0	2	4	2	0
		DAY 15	24JUL2003	15	PP (61)	-14	NO	30	-5	4	4	3	3	4	2	4	4	2	0
		DAY 22	31JUL2003	22	PP (61)	-20	NO	28	-7	4	4	2	4	4	2	4	2	2	0
		DAY 29	07AUG2003	29	PP (61)	-29	NO	25	-10	4	2	4	4	4	0	2	1	4	0
		DAY 36	14AUG2003	36	PP (61)	-37	NO	22	-13	4	4	3	4	0	0	1	2	3	1
		DAY 50	26AUG2003	48	PP (61)	-26	NO	26	-9	4	3	3	2	0	2	4	4	3	1
		DAY 57	08SEP2003	61	PP (61)	-29	NO	25	-10	4	4	3	4	0	4	2	2	2	0
	E0022052	DAY 1	10APR2003	1	PP			38		4	4	4	5	2	4	4	4	4	3
		DAY 8	17APR2003	8	PP	-32	NO	26	-12	4	4	3	0	0	3	3	3	4	2
		DAY 15	24APR2003	15	PP	-37	NO	24	-14	3	2	3	2	2	3	2	2	3	2
		DAY 22	01MAY2003	22	PP	-16	NO	32	-6	4	4	4	4	0	3	3	3	4	3
		DAY 29	08MAY2003	29	PP	-11	NO	34	-4	4	4	4	4	0	4	4	4	4	2
		DAY 36	15MAY2003	36	PP	-3	NO	37	-1	4	4	5	4	0	4	4	4	4	4
		DAY 43	22MAY2003	43	PP	-3	NO	37	-1	4	4	4	4	2	3	4	4	4	4
		DAY 50	29MAY2003	50	PP	-21	NO	30	-8	4	3	3	4	0	3	3	4	4	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	DAY 57	05JUN2003	57	PP	-13	NO	33	-5	4	4	4	5	0	4	3	3	3	3
	E0022064	DAY 1	06MAY2003	1	PP			31		4	4	3	3	3	3	3	3	3	2
		DAY 8	12MAY2003	7	PP	-52	NO	15	-16	2	2	2	0	2	2	1	2	2	0
		DAY 15	20MAY2003	15	PP	-65	YES	11	-20	2	1	1	0	2	3	1	0	1	0
		DAY 22	27MAY2003	22	PP	-74	YES	8	-23	1	1	1	1	0	2	0	0	2	0
		DAY 29	03JUN2003	29	PP	-77	YES	7	-24	0	1	1	0	0	3	0	0	1	1
		DAY 36	10JUN2003	36	PP	-87	YES	4	-27	0	0	1	1	0	2	0	0	0	0
		DAY 43	17JUN2003	43	PP	-94	YES	2	-29	0	0	0	0	0	2	0	0	0	0
		DAY 50	24JUN2003	50	PP	-90	YES	3	-28	0	0	0	0	0	3	0	0	0	0
		DAY 57	01JUL2003	57	PP	-94	YES	2	-29	0	0	0	0	0	2	0	0	0	0
	E0022073	DAY 1	26JUN2003	1	PP			28		4	4	3	3	0	3	4	2	3	2
		DAY 8	03JUL2003	8	PP	-43	NO	16	-12	2	2	2	0	0	2	2	3	3	0
		DAY 15	10JUL2003	15	PP	-71	YES	8	-20	2	1	1	0	0	1	1	0	2	0
		DAY 22	17JUL2003	22	PP	-75	YES	7	-21	2	0	2	0	0	1	2	0	0	0
		DAY 29	24JUL2003	29	PP	-61	YES	11	-17	3	2	2	0	0	2	1	0	1	0
		DAY 36	31JUL2003	36	PP	-64	YES	10	-18	2	1	2	2	0	2	1	0	0	0
		DAY 43	07AUG2003	43	PP	-64	YES	10	-18	2	1	1	1	0	2	1	0	2	0
		DAY 50	14AUG2003	50	PP	-57	YES	12	-16	2	2	1	1	0	2	1	1	2	0
		DAY 57	21AUG2003	57	PP	-57	YES	12	-16	2	2	0	3	0	2	1	1	1	0
	E0023002	DAY 1	05NOV2002	1	PP			26		4	3	3	0	2	4	4	2	3	1
		DAY 8	12NOV2002	8	PP	4	NO	27	1	4	3	3	0	2	4	4	3	3	1
		DAY 15	19NOV2002	15	PP	15	NO	30	4	4	4	3	1	2	4	4	3	3	2
		DAY 22	25NOV2002	21	PP	-4	NO	25	-1	4	3	3	0	1	4	4	3	2	1
		DAY 29	03DEC2002	29	PP	0	NO	26	0	4	3	3	0	2	4	4	3	2	1
		DAY 36	10DEC2002	36	PP	0	NO	26	0	4	4	3	0	0	3	4	4	2	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	DAY 1	25MAR2003	1	PP			29		4	4	3	2	2	4	4	2	4	0
		DAY 8	03APR2003	10	PP	-14	NO	25	-4	4	4	3	0	0	5	3	2	4	0
		DAY 15	10APR2003	17	PP	-72	YES	8	-21	1	1	2	0	0	1	1	1	0	1
		DAY 22	18APR2003	25	PP	-86	YES	4	-25	1	0	0	0	0	1	2	0	0	0
		DAY 29	24APR2003	31	PP	-48	NO	15	-14	2	2	0	4	0	4	0	1	1	1
		DAY 36	01MAY2003	38	PP	-93	YES	2	-27	1	0	0	0	0	0	1	0	0	0
		DAY 43	08MAY2003	45	PP	-93	YES	2	-27	0	0	0	0	0	2	0	0	0	0
		DAY 50	15MAY2003	52	PP	-93	YES	2	-27	0	0	0	0	0	1	1	0	0	0
		DAY 57	22MAY2003	59	PP	-86	YES	4	-25	0	0	0	1	0	2	1	0	0	0
	E0023021	DAY 1	23APR2003	1	PP			30		4	4	3	4	2	2	3	4	2	2
		DAY 8	29APR2003	7	PP	-7	NO	28	-2	4	4	3	1	2	2	4	4	2	2
		DAY 15	06MAY2003	14	PP	-27	NO	22	-8	3	3	3	1	0	2	4	3	2	1
		DAY 22	13MAY2003	21	PP	-27	NO	22	-8	3	3	3	1	0	2	4	3	2	1
		DAY 29	20MAY2003	28	PP	-30	NO	21	-9	3	3	3	0	2	1	3	2	2	2
		DAY 36	29MAY2003	37	PP	-3	NO	29	-1	4	4	4	2	2	1	3	3	3	3
		DAY 43	03JUN2003	42	PP	-27	NO	22	-8	3	4	2	2	2	1	3	2	2	1
		DAY 50	10JUN2003	49	PP	-10	NO	27	-3	4	4	3	3	1	2	3	3	2	2
		DAY 57	17JUN2003	56	PP	-10	NO	27	-3	4	4	3	4	1	2	3	3	2	1
	E0023027	DAY 1	16MAY2003	1	PP			29		4	4	3	3	0	3	3	4	3	2
		DAY 8	21MAY2003	6	PP	0	NO	29	0	4	4	3	0	0	3	4	4	3	4
		DAY 15	30MAY2003	15	PP	-24	NO	22	-7	3	3	2	0	0	3	3	4	3	1
		DAY 22	05JUN2003	21	PP	-10	NO	26	-3	2	2	2	3	2	3	4	4	3	1
		DAY 29	11JUN2003	27	PP	-7	NO	27	-2	3	4	2	2	4	2	2	4	3	1
		DAY 36	18JUN2003	34	PP	-21	NO	23	-6	4	3	2	2	3	2	2	3	1	1
		DAY 43	27JUN2003	43	PP	-24	NO	22	-7	2	2	3	2	2	2	3	3	2	1
		DAY 50	02JUL2003	48	PP	-14	NO	25	-4	2	2	3	4	2	3	3	3	2	1
		DAY 57	09JUL2003	55	PP	21	NO	35	6	4	4	4	4	3	3	4	4	3	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	DAY 1		03JUN2003	1	PP			29		3	4	3	2	3	3	3	4	2	2
		DAY 8		10JUN2003	8	PP	-14	NO	25	-4	3	4	3	0	2	4	4	4	1	0
		DAY 15		17JUN2003	15	PP	-38	NO	18	-11	2	3	2	0	2	2	2	4	1	0
		DAY 22		24JUN2003	22	PP	-41	NO	17	-12	2	2	2	0	2	3	2	1	2	1
		DAY 29		01JUL2003	29	PP	-62	YES	11	-18	1	2	2	0	0	3	1	1	1	0
		DAY 36		08JUL2003	36	PP	-76	YES	7	-22	1	1	0	0	0	2	1	1	1	0
		DAY 43		15JUL2003	43	PP	-93	YES	2	-27	0	0	0	0	0	1	1	0	0	0
		DAY 50		21JUL2003	49	PP	-93	YES	2	-27	0	0	0	0	0	1	1	0	0	0
		DAY 57		30JUL2003	58	PP	-93	YES	2	-27	0	0	0	0	0	1	1	0	0	0
	E0023040	DAY 1		03JUL2003	1	PP			29		4	4	3	4	0	3	3	4	2	2
		DAY 8		12JUL2003	10	PP	-21	NO	23	-6	3	4	2	3	2	3	1	2	1	2
		DAY 15		17JUL2003	15	PP	-35	NO	19	-10	2	3	2	2	2	2	1	2	1	2
		DAY 22		25JUL2003	23	PP	-55	NO	13	-16	1	2	2	1	2	1	1	2	1	0
		DAY 36	*	05AUG2003	34	PP	-38	NO	18	-11	3	3	3	1	2	1	1	3	1	0
		DAY 36		08AUG2003	37	PP	-38	NO	18	-11	2	3	3	1	2	2	1	3	1	0
		DAY 43		18AUG2003	47	PP	-62	YES	11	-18	1	1	1	1	2	2	1	2	0	0
		DAY 57	*	28AUG2003	57	PP	-45	NO	16	-13	1	2	2	4	0	2	1	3	1	0
		DAY 57		05SEP2003	65	PP	-52	NO	14	-15	1	1	3	2	0	3	1	2	1	0
	E0026014	DAY 1		19FEB2003	1	PP			31		4	4	2	5	6	2	0	3	4	1
		DAY 8		26FEB2003	8	PP	-52	NO	15	-16	2	2	0	0	2	1	2	2	2	2
		DAY 15		05MAR2003	15	PP	-74	YES	8	-23	0	0	0	0	4	0	4	0	0	0
		DAY 22		12MAR2003	22	PP	-45	NO	17	-14	2	4	2	0	4	0	0	2	2	1
		DAY 29		19MAR2003	29	PP	3	NO	32	1	5	4	2	0	4	2	4	5	4	2
	E0026019	DAY 1		17MAR2003	1	PP			30		4	4	3	5	0	4	0	4	5	1
		DAY 8		24MAR2003	8	PP	-13	NO	26	-4	4	3	4	0	0	4	4	2	4	1
		DAY 15		31MAR2003	15	PP	-63	YES	11	-19	1	1	2	0	0	1	3	1	2	0

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QUETIAPINE 300 MG (BIPOLAR II)	E0026019	DAY 22	07APR2003	22	PP	-23	NO	23	-7	3	4	3	2	0	3	0	3	4	1
		DAY 29	14APR2003	29	PP	-53	NO	14	-16	2	2	4	0	0	1	0	1	4	0
		DAY 36	21APR2003	36	PP	-63	YES	11	-19	1	1	3	2	0	2	0	0	1	1
		DAY 43	28APR2003	43	PP	-17	NO	25	-5	4	3	3	3	0	4	0	4	3	1
		DAY 50	05MAY2003	50	PP	-7	NO	28	-2	5	4	4	4	0	4	1	4	1	1
		DAY 57	12MAY2003	57	PP	-17	NO	25	-5	3	3	4	4	0	4	2	2	2	1
	E0027005	DAY 1	26DEC2002	1	PP			45		6	6	3	5	5	5	4	4	4	3
		DAY 8	02JAN2003	8	PP	-36	NO	29	-16	4	3	3	1	3	4	4	3	3	1
		DAY 15	09JAN2003	15	PP	-44	NO	25	-20	3	3	3	1	1	3	3	3	3	2
		DAY 22	16JAN2003	22	PP	-56	NO	20	-25	1	1	3	1	2	3	3	3	2	1
		DAY 29	23JAN2003	29	PP	-76	YES	11	-34	1	0	2	0	0	3	1	1	2	1
		DAY 36	30JAN2003	36	PP	-58	NO	19	-26	1	1	1	4	4	4	0	1	2	1
		DAY 43	06FEB2003	43	PP	-36	NO	29	-16	4	4	3	4	3	2	3	3	2	1
		DAY 50	12FEB2003	49	PP	-49	NO	23	-22	4	3	3	3	1	2	2	2	2	1
		DAY 57	20FEB2003	57	PP	-56	NO	20	-25	1	2	3	1	2	2	4	2	2	1
	E0029009	DAY 1	20JAN2003	1	PP			28		3	4	4	4	2	4	3	0	2	2
		DAY 8	27JAN2003	8	PP	-21	NO	22	-6	1	2	4	2	2	2	4	2	3	0
		DAY 15	03FEB2003	15	PP	-82	YES	5	-23	0	0	1	2	0	2	0	0	0	0
		DAY 22	11FEB2003	23	PP	-79	YES	6	-22	0	2	2	0	0	2	0	0	0	0
		DAY 29	17FEB2003	29	PP	-43	NO	16	-12	2	2	4	0	0	2	2	1	3	0
		DAY 36	24FEB2003	36	PP	-18	NO	23	-5	3	3	5	0	0	3	2	3	3	1
		DAY 43	03MAR2003	43	PP	-71	YES	8	-20	1	1	0	1	0	2	1	2	0	0
		DAY 50	11MAR2003	51	PP	-75	YES	7	-21	0	0	3	1	0	1	1	1	0	0
		DAY 57	18MAR2003	58	PP	-79	YES	6	-22	1	0	2	0	0	0	2	0	1	0
	E0029021	DAY 1	18MAR2003	1	PP			27		4	4	4	2	0	3	4	4	2	0
		DAY 8	25MAR2003	8	PP	-30	NO	19	-8	2	3	2	0	0	3	4	2	2	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%@	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	DAY 15	01APR2003	15	PP	-30	NO	19	-8	2	4	2	0	0	3	4	2	2	0
		DAY 22	07APR2003	21	PP	-52	NO	13	-14	1	2	2	0	0	2	2	2	2	0
		DAY 29	15APR2003	29	PP	-52	NO	13	-14	1	2	2	0	0	2	2	2	2	0
		DAY 36	22APR2003	36	PP	-22	NO	21	-6	3	3	3	2	0	3	3	2	1	1
		DAY 43	29APR2003	43	PP	-74	YES	7	-20	1	2	0	0	0	2	2	0	0	0
		DAY 50	06MAY2003	50	PP	-56	YES	12	-15	1	2	2	0	0	2	2	2	1	0
		DAY 57	15MAY2003	59	PP	-56	YES	12	-15	1	3	4	0	0	0	2	0	2	0
	E0029026	DAY 1	14APR2003	1	PP			28		4	4	0	4	2	4	4	4	2	0
		DAY 8	21APR2003	8	PP	-39	NO	17	-11	4	4	0	0	2	0	4	3	0	0
		DAY 15	28APR2003	15	PP	-68	YES	9	-19	2	2	0	0	1	0	2	2	0	0
		DAY 22	05MAY2003	22	PP	-93	YES	2	-26	2	0	0	0	0	0	0	0	0	0
		DAY 29	12MAY2003	29	PP	-86	YES	4	-24	2	0	0	0	0	0	1	1	0	0
		DAY 36	19MAY2003	36	PP	-86	YES	4	-24	2	0	0	0	0	0	2	0	0	0
		DAY 43	28MAY2003	45	PP	-86	YES	4	-24	2	0	1	0	0	0	1	0	0	0
		DAY 50	02JUN2003	50	PP	-79	YES	6	-22	1	0	2	2	0	0	1	0	0	0
		DAY 57	10JUN2003	58	PP	-93	YES	2	-26	1	0	0	0	0	0	1	0	0	0
	E0029030	DAY 1	27MAY2003	1	PP			33		4	3	3	3	4	3	4	4	3	2
		DAY 8	03JUN2003	8	PP	-30	NO	23	-10	2	2	3	0	3	3	4	1	4	1
		DAY 15	10JUN2003	15	PP	-67	YES	11	-22	1	1	2	1	0	2	2	0	2	0
		DAY 22	17JUN2003	22	PP	-64	YES	12	-21	2	3	2	0	0	0	2	0	3	0
		DAY 29	26JUN2003	31	PP	-94	YES	2	-31	0	0	0	0	0	1	0	0	1	0
		DAY 36	02JUL2003	37	PP	-94	YES	2	-31	0	0	0	0	0	2	0	0	0	0
		DAY 43	09JUL2003	44	PP	-85	YES	5	-28	1	0	3	0	0	0	0	0	1	0
		DAY 50	16JUL2003	51	PP	-85	YES	5	-28	0	0	2	0	2	0	0	0	1	0
		DAY 57	23JUL2003	58	PP	-94	YES	2	-31	0	0	1	0	0	0	0	0	1	0
	E0031008	DAY 1	28FEB2003	1	ITT			29		3	4	3	5	3	2	0	3	4	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0031008	DAY 8		07MAR2003	8	ITT	0	NO	29	0	3	4	3	1	2	4	4	3	4	1
		DAY 15		13MAR2003	14	ITT	-3	NO	28	-1	5	4	3	1	0	2	4	3	4	2
		DAY 22		21MAR2003	22	ITT	-24	NO	22	-7	2	2	3	3	0	3	2	2	4	1
		DAY 29		28MAR2003	29	ITT	-41	NO	17	-12	2	2	2	2	2	0	0	2	4	1
		DAY 36		04APR2003	36	ITT	-28	NO	21	-8	1	2	2	3	0	2	4	3	2	2
		DAY 43		10APR2003	42	ITT	-66	YES	10	-19	1	3	0	0	0	2	0	1	3	0
		DAY 50		17APR2003	49	ITT	-24	NO	22	-7	2	2	2	5	0	4	2	2	2	1
		DAY 57		24APR2003	56	ITT	-7	NO	27	-2	4	4	3	0	3	2	2	3	4	2
	E0031020	DAY 1		21APR2003	1	PP			20		1	3	2	5	0	2	2	2	2	1
		DAY 8		28APR2003	8	PP	-70	YES	6	-14	0	1	0	0	0	3	0	0	0	2
		DAY 15		05MAY2003	15	PP	-30	NO	14	-6	1	3	2	0	0	2	2	2	0	2
		DAY 22		13MAY2003	23	PP	-40	YES	12	-8	1	2	2	0	0	3	2	2	0	0
	E0031021	DAY 1		25APR2003	1	PP			26		4	4	0	5	2	0	4	3	2	2
		DAY 8		02MAY2003	8	PP	-62	YES	10	-16	0	1	2	0	0	0	2	2	3	0
		DAY 15		09MAY2003	15	PP	-100	YES	0	-26	0	0	0	0	0	0	0	0	0	0
		DAY 22		16MAY2003	22	PP	-73	YES	7	-19	1	1	0	0	0	0	1	2	2	0
		DAY 29		23MAY2003	29	PP	-62	YES	10	-16	1	1	2	0	0	2	2	0	2	0
		DAY 36		29MAY2003	35	PP	-62	YES	10	-16	1	1	2	0	0	0	2	2	2	0
		DAY 43		06JUN2003	43	PP	-31	NO	18	-8	4	3	2	5	2	0	0	1	0	1
		DAY 43	*	10JUN2003	47	PP	-81	YES	5	-21	0	0	2	0	0	0	0	2	1	0
		DAY 57		19JUN2003	56	PP	-62	YES	10	-16	2	1	2	2	0	0	2	1	0	0
	E0031029	DAY 1		18JUN2003	1	PP			36		4	4	3	5	3	4	4	4	4	1
		DAY 8		23JUN2003	6	PP	-47	NO	19	-17	2	2	2	0	2	4	2	3	2	0
	E0033002	DAY 1		10JAN2003	1	PP			32		3	4	4	5	0	2	4	4	3	3
		DAY 8		16JAN2003	7	PP	-9	NO	29	-3	3	4	3	0	2	4	3	4	2	4

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0033002	DAY 15		24JAN2003	15	PP	-16	NO	27	-5	4	3	2	0	3	3	4	4	2	2
		DAY 22		30JAN2003	21	PP	-28	NO	23	-9	2	3	3	4	0	3	0	3	3	2
		DAY 29		06FEB2003	28	PP	-38	NO	20	-12	2	3	3	2	0	2	2	2	2	2
		DAY 36		13FEB2003	35	PP	-34	NO	21	-11	2	3	2	2	3	3	1	2	2	1
		DAY 43		24FEB2003	46	PP	-63	YES	12	-20	2	2	2	0	0	3	1	1	1	0
		DAY 50		28FEB2003	50	PP	-59	NO	13	-19	2	2	2	0	0	2	2	1	1	1
		DAY 57		07MAR2003	57	PP	-88	YES	4	-28	1	1	0	0	0	1	0	0	0	1
	E0033006	DAY 1		23JAN2003	1	PP			34		4	5	3	4	3	4	4	3	3	1
		DAY 8		30JAN2003	8	PP	9	NO	37	3	4	4	4	2	5	4	4	5	4	1
	E0033021	DAY 1		02JUL2003	1	PP			32		3	3	4	4	0	4	4	4	4	2
		DAY 8		11JUL2003	10	PP	-13	NO	28	-4	2	3	3	3	0	4	4	4	3	2
		DAY 22	*	21JUL2003	20	PP	-22	NO	25	-7	3	3	3	2	0	3	3	3	3	2
		DAY 22		25JUL2003	24	PP	-41	NO	19	-13	2	2	2	1	0	3	3	2	2	2
		DAY 29		01AUG2003	31	PP	-50	NO	16	-16	2	2	3	2	0	2	2	1	2	0
		DAY 36		06AUG2003	36	PP	-47	NO	17	-15	2	2	3	2	0	1	2	2	2	1
	E0035013	DAY 1		04FEB2003	1	ITT			23		3	3	2	4	2	1	1	3	4	0
		DAY 8		10FEB2003	7	ITT	-9	NO	21	-2	4	4	2	0	0	3	2	2	4	0
	E0035015	DAY 1		11FEB2003	1	ITT			21		2	2	2	3	0	2	2	4	4	0
		DAY 8		18FEB2003	8	ITT	-29	NO	15	-6	2	2	2	0	0	2	5	2	0	0
	E0035016	DAY 1		04APR2003	1	SAFETY			25		3	3	3	2	0	3	4	4	3	0
	E0035023	DAY 1		13MAY2003	1	PP			30		3	2	3	4	2	2	4	4	4	2
		DAY 8		20MAY2003	8	PP	-27	NO	22	-8	2	2	2	1	2	3	2	4	4	0
		DAY 15		29MAY2003	17	PP	-20	NO	24	-6	2	2	2	1	2	2	4	3	4	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0035023	DAY 22	03JUN2003	22	PP	-23	NO	23	-7	2	2	2	2	3	2	4	2	4	0
		DAY 29	10JUN2003	29	PP	-47	NO	16	-14	2	3	2	1	0	2	2	2	2	0
	E0039052	DAY 1	20JUN2003	1	ITT			30		4	4	3	5	0	3	3	3	3	2
		DAY 8	27JUN2003	8	ITT	-57	NO	13	-17	2	2	2	0	0	2	2	1	2	0
		DAY 15	03JUL2003	14	ITT	-77	YES	7	-23	1	1	1	0	0	0	2	1	1	0
	E0039056	DAY 1	14JUL2003	-1	SAFETY			28		3	4	2	5	2	3	2	4	2	1
	E0040003	DAY 1	18JUL2003	-1	PP			23		3	3	3	3	2	2	3	3	0	1
		DAY 8	25JUL2003	7	PP	-4	NO	22	-1	3	3	3	3	2	2	3	2	0	1
		DAY 15	01AUG2003	14	PP	-39	NO	14	-9	2	1	2	1	2	2	2	2	0	0
		DAY 22	08AUG2003	21	PP	-52	YES	11	-12	2	1	2	0	2	2	1	1	0	0
		DAY 29	15AUG2003	28	PP	-26	NO	17	-6	2	2	2	4	0	3	2	2	0	0
		DAY 36	22AUG2003	35	PP	-61	YES	9	-14	1	1	2	0	1	2	1	1	0	0
		DAY 43	29AUG2003	42	PP	-35	NO	15	-8	2	1	3	4	0	2	2	1	0	0
		DAY 50	05SEP2003	49	PP	-52	YES	11	-12	0	0	3	4	0	2	1	0	1	0
		DAY 57	12SEP2003	56	PP	-30	NO	16	-7	2	0	2	4	1	2	3	2	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	PP			25		1	4	2	3	3	2	2	2	3	3
		DAY 8	11MAR2003	9	PP	0	NO	25	0	2	4	0	0	2	3	4	4	4	2
		DAY 15	18MAR2003	16	PP	-32	NO	17	-8	2	2	2	0	0	3	3	2	1	2
		DAY 22	25MAR2003	23	PP	-44	NO	14	-11	2	2	1	0	0	3	3	2	0	1
		DAY 29	01APR2003	30	PP	-36	NO	16	-9	2	2	2	0	2	1	3	2	1	1
		DAY 36	08APR2003	37	PP	-52	YES	12	-13	2	2	2	0	1	1	1	1	1	1
		DAY 43	15APR2003	44	PP	-60	YES	10	-15	1	1	2	0	0	2	1	1	1	1
		DAY 50	24APR2003	53	PP	-32	NO	17	-8	2	2	4	0	1	3	2	0	2	1
		DAY 57	02MAY2003	61	PP	-56	YES	11	-14	1	0	2	0	1	2	1	2	1	1
	E0002011	DAY 1	29APR2003	1	PP			16		2	2	2	0	0	2	3	2	2	1
		DAY 8	08MAY2003	10	PP	-19	NO	13	-3	1	1	2	0	0	1	3	2	2	1
		DAY 15	15MAY2003	17	PP	19	NO	19	3	2	2	3	1	0	3	3	2	2	1
		DAY 22	22MAY2003	24	PP	19	NO	19	3	3	3	3	1	0	2	2	2	2	1
		DAY 29	29MAY2003	31	PP	-81	YES	3	-13	1	1	1	0	0	0	0	0	0	0
		DAY 36	05JUN2003	38	PP	13	NO	18	2	2	2	2	0	0	1	4	2	3	2
		DAY 43	12JUN2003	45	PP	-13	NO	14	-2	2	2	3	0	0	0	2	2	2	1
		DAY 50	19JUN2003	52	PP	-56	YES	7	-9	2	2	2	1	0	0	0	0	0	0
		DAY 57	25JUN2003	58	PP	-19	NO	13	-3	2	2	3	1	0	3	0	0	2	0
	E0003010	DAY 1	03FEB2003	1	PP			35		3	4	5	6	0	4	4	4	3	2
		DAY 8	10FEB2003	8	PP	-77	YES	8	-27	1	1	2	0	0	0	1	1	2	0
		DAY 15	19FEB2003	17	PP	-100	YES	0	-35	0	0	0	0	0	0	0	0	0	0
		DAY 22	27FEB2003	25	PP	-40	NO	21	-14	4	5	2	3	0	2	1	1	3	0
		DAY 29	03MAR2003	29	PP	-69	YES	11	-24	1	2	2	0	0	2	1	1	2	0
		DAY 36	14MAR2003	40	PP	-86	YES	5	-30	1	0	1	2	0	0	0	0	1	0
		DAY 43	20MAR2003	46	PP	-60	NO	14	-21	0	1	3	3	0	2	3	0	2	0
		DAY 50	25MAR2003	51	PP	-89	YES	4	-31	0	0	0	2	0	2	0	0	0	0
		DAY 57	31MAR2003	57	PP	-100	YES	0	-35	0	0	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	DAY 1		04FEB2003	1	PP			30		4	3	4	2	1	3	4	4	3	2
		DAY 8		11FEB2003	8	PP	-53	NO	14	-16	2	0	2	1	2	0	0	3	3	1
		DAY 15		18FEB2003	15	PP	-40	NO	18	-12	2	2	2	2	1	3	2	2	2	0
	E0003016	DAY 1		22MAY2003	1	PP			45		5	6	5	2	5	5	5	5	5	2
		DAY 8		29MAY2003	8	PP	-16	NO	38	-7	3	4	4	3	3	5	5	4	5	2
		DAY 15		05JUN2003	15	PP	-36	NO	29	-16	2	3	3	4	3	3	4	4	3	0
		DAY 22		12JUN2003	22	PP	-31	NO	31	-14	0	1	5	5	0	6	5	4	4	1
	E0003019	DAY 1		27JUN2003	1	PP			27		3	3	0	5	0	4	2	4	4	2
		DAY 8		03JUL2003	7	PP	-37	NO	17	-10	1	3	3	0	0	3	3	0	3	1
		DAY 15		10JUL2003	14	PP	-19	NO	22	-5	3	3	2	2	0	3	3	3	2	1
		DAY 15	*	15JUL2003	19	PP	-33	NO	18	-9	1	2	3	2	0	3	3	2	2	0
		DAY 29		29JUL2003	33	PP	0	NO	27	0	3	3	5	0	0	4	2	3	4	3
		DAY 43		07AUG2003	42	PP	0	NO	27	0	3	3	3	0	0	4	4	3	4	3
		DAY 50		14AUG2003	49	PP	-7	NO	25	-2	3	3	2	2	0	4	4	3	2	2
		DAY 57		21AUG2003	56	PP	-11	NO	24	-3	2	3	2	2	0	3	4	3	2	3
	E0003020	DAY 1		23JUL2003	1	PP			32		4	4	4	4	0	0	4	5	3	4
		DAY 8		29JUL2003	7	PP	-59	NO	13	-19	1	2	2	0	0	1	2	1	2	2
		DAY 15		06AUG2003	15	PP	-31	NO	22	-10	3	3	3	0	0	1	2	4	4	2
		DAY 22		13AUG2003	22	PP	-50	NO	16	-16	1	2	2	3	0	2	2	1	2	1
		DAY 29		20AUG2003	29	PP	-16	NO	27	-5	4	4	3	4	0	3	1	4	3	1
		DAY 36		27AUG2003	36	PP	-22	NO	25	-7	3	4	3	4	0	3	1	2	3	2
		DAY 43		03SEP2003	43	PP	-53	NO	15	-17	1	2	0	1	1	2	1	2	4	1
		DAY 50		10SEP2003	50	PP	-53	NO	15	-17	1	2	1	1	1	1	1	2	4	1
		DAY 57		17SEP2003	57	PP	-63	YES	12	-20	1	1	1	1	1	0	1	2	3	1
	E0004001	DAY 1		30SEP2002	1	ITT			39		5	4	4	4	4	4	4	4	3	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	DAY 8	07OCT2002	8	ITT	-28	NO	28	-11	4	4	4	0	3	3	3	3	2	2
		DAY 22	21OCT2002	22	ITT	-56	NO	17	-22	3	3	3	0	0	2	2	2	2	0
		DAY 29	28OCT2002	29	ITT	-69	YES	12	-27	2	2	2	0	0	2	1	2	1	0
	E0004009	DAY 1	26DEC2002	1	PP			30		3	4	3	2	3	4	4	4	2	1
		DAY 8	02JAN2003	8	PP	-30	NO	21	-9	2	2	3	3	1	3	2	3	1	1
		DAY 15	08JAN2003	14	PP	-63	YES	11	-19	1	1	2	0	2	3	0	2	0	0
		DAY 22	15JAN2003	21	PP	-77	YES	7	-23	1	0	0	1	2	1	1	1	0	0
		DAY 29	22JAN2003	28	PP	-77	YES	7	-23	2	1	0	0	1	0	0	1	1	1
		DAY 36	29JAN2003	35	PP	-83	YES	5	-25	1	1	2	0	0	0	0	1	0	0
		DAY 43	05FEB2003	42	PP	-83	YES	5	-25	1	0	2	0	0	2	0	0	0	0
		DAY 50	12FEB2003	49	PP	-90	YES	3	-27	0	0	2	0	0	0	0	1	0	0
		DAY 57	19FEB2003	56	PP	-97	YES	1	-29	0	0	0	0	0	0	0	1	0	0
	E0004012	DAY 1	14JAN2003	1	PP			31		4	4	2	4	3	3	3	4	3	1
		DAY 8	21JAN2003	8	PP	-7	NO	29	-2	4	4	3	3	3	3	4	4	1	0
		DAY 15	28JAN2003	15	PP	-48	NO	16	-15	3	3	1	1	0	3	2	3	0	0
		DAY 22	04FEB2003	22	PP	-58	NO	13	-18	1	2	1	0	0	3	2	4	0	0
		DAY 29	11FEB2003	29	PP	-68	YES	10	-21	1	2	1	0	0	2	2	2	0	0
		DAY 36	18FEB2003	36	PP	-77	YES	7	-24	1	1	0	0	0	2	2	1	0	0
		DAY 43	25FEB2003	43	PP	-77	YES	7	-24	1	1	1	0	0	0	2	2	0	0
		DAY 50	04MAR2003	50	PP	-74	YES	8	-23	1	1	2	0	0	2	1	1	0	0
		DAY 57	11MAR2003	57	PP	-65	YES	11	-20	2	2	2	0	0	2	2	1	0	0
	E0004015	DAY 1	20FEB2003	1	PP			29		4	4	2	4	2	3	4	3	2	1
		DAY 8	25FEB2003	6	PP	-3	NO	28	-1	4	4	0	4	2	3	4	3	3	1
		DAY 15	04MAR2003	13	PP	-41	NO	17	-12	2	2	2	3	0	2	3	1	2	0
		DAY 22	11MAR2003	20	PP	-79	YES	6	-23	0	1	0	0	0	0	4	0	1	0
		DAY 29	18MAR2003	27	PP	-90	YES	3	-26	0	1	0	0	0	0	2	0	0	0

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	DAY 36	25MAR2003	34	PP	-93	YES	2	-27	0	1	0	0	0	0	1	0	0	0
		DAY 43	01APR2003	41	PP	-90	YES	3	-26	0	1	0	0	0	0	1	0	1	0
		DAY 50	08APR2003	48	PP	-90	YES	3	-26	0	1	1	0	0	0	1	0	0	0
		DAY 57	15APR2003	55	PP	-100	YES	0	-29	0	0	0	0	0	0	0	0	0	0
	E0005003	DAY 1	02OCT2002	1	PP			27		4	5	5	0	2	0	0	5	4	2
		DAY 8	09OCT2002	8	PP	-7	NO	25	-2	4	5	3	4	0	0	3	4	2	0
		DAY 15	16OCT2002	15	PP	-56	YES	12	-15	1	3	0	2	2	0	0	2	2	0
		DAY 22	23OCT2002	22	PP	-22	NO	21	-6	4	4	0	0	0	0	4	4	4	1
		DAY 29	30OCT2002	29	PP	-52	NO	13	-14	2	3	1	1	0	0	2	2	2	0
		DAY 36	06NOV2002	36	PP	-70	YES	8	-19	2	3	0	0	0	0	0	2	1	0
		DAY 43	14NOV2002	44	PP	-70	YES	8	-19	2	2	2	0	0	0	0	2	0	0
		DAY 50	21NOV2002	51	PP	-78	YES	6	-21	0	1	2	0	0	0	0	1	2	0
		DAY 57	26NOV2002	56	PP	-70	YES	8	-19	2	2	2	0	0	0	0	2	0	0
	E0005005	DAY 1	30SEP2002	1	SAFETY			30		4	4	3	4	3	4	2	3	3	0
	E0005007	DAY 1	09OCT2002	1	PP			44		5	5	4	6	4	5	4	4	4	3
		DAY 8	16OCT2002	8	PP	-14	NO	38	-6	4	4	4	4	4	5	4	4	4	1
		DAY 15	23OCT2002	15	PP	-5	NO	42	-2	5	5	4	5	5	4	4	4	4	2
		DAY 22	30OCT2002	22	PP	-39	NO	27	-17	3	3	2	4	2	4	3	3	2	1
		DAY 29	06NOV2002	29	PP	-46	NO	24	-20	2	3	2	4	2	4	3	2	2	0
		DAY 36	14NOV2002	37	PP	-48	NO	23	-21	2	2	3	4	2	3	2	2	2	1
		DAY 43	20NOV2002	43	PP	-36	NO	28	-16	4	3	2	5	2	3	4	2	2	1
		DAY 50	26NOV2002	49	PP	-46	NO	24	-20	3	3	2	4	2	4	2	2	2	0
		DAY 57	04DEC2002	57	PP	-59	NO	18	-26	1	2	2	2	2	3	2	2	2	0
	E0005008	DAY 1	15OCT2002	1	PP			32		4	5	3	4	0	4	4	4	2	2
		DAY 8	22OCT2002	8	PP	-41	NO	19	-13	2	2	2	0	2	3	3	3	1	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	DAY 15		29OCT2002	15	PP	-6	NO	30	-2	4	4	3	0	3	4	4	4	3	1
		DAY 22		06NOV2002	23	PP	-9	NO	29	-3	4	5	3	0	3	3	4	4	2	1
		DAY 29		13NOV2002	30	PP	-72	YES	9	-23	1	0	0	0	3	1	1	2	1	0
		DAY 36		18NOV2002	35	PP	-72	YES	9	-23	0	0	0	0	3	1	2	2	1	0
		DAY 43		25NOV2002	42	PP	-75	YES	8	-24	0	1	0	0	3	1	1	1	1	0
		DAY 50		02DEC2002	49	PP	-78	YES	7	-25	0	0	0	0	3	1	2	1	0	0
		DAY 57		11DEC2002	58	PP	-84	YES	5	-27	0	0	0	0	3	1	0	1	0	0
	E0005009	DAY 1		29OCT2002	1	SAFETY			31		4	4	4	3	0	4	3	3	4	2
	E0005010	DAY 1		21OCT2002	1	PP			33		4	4	4	4	4	4	3	4	2	0
		DAY 8		28OCT2002	8	PP	-52	NO	16	-17	2	2	2	0	3	2	2	2	1	0
		DAY 15		04NOV2002	15	PP	-49	NO	17	-16	2	2	3	2	0	3	2	2	1	0
		DAY 22		13NOV2002	24	PP	-55	NO	15	-18	1	1	2	5	3	1	1	1	0	0
		DAY 29		19NOV2002	30	PP	-88	YES	4	-29	0	0	0	0	3	1	0	0	0	0
		DAY 36		26NOV2002	37	PP	-88	YES	4	-29	0	0	0	0	3	1	0	0	0	0
		DAY 43		03DEC2002	44	PP	-91	YES	3	-30	0	0	0	0	3	0	0	0	0	0
		DAY 50		09DEC2002	50	PP	-91	YES	3	-30	0	0	0	0	3	0	0	0	0	0
		DAY 57		17DEC2002	58	PP	-100	YES	0	-33	0	0	0	0	0	0	0	0	0	0
	E0005012	DAY 1		14NOV2002	1	PP			37		4	4	4	5	3	4	4	4	3	2
		DAY 8		20NOV2002	7	PP	-14	NO	32	-5	4	4	4	4	0	4	4	4	3	1
		DAY 15		26NOV2002	13	PP	-41	NO	22	-15	2	1	4	3	0	4	3	3	2	0
		DAY 22		06DEC2002	23	PP	-68	YES	12	-25	1	1	2	1	0	1	2	2	2	0
		DAY 29		10DEC2002	27	PP	-70	YES	11	-26	0	0	2	1	2	1	2	1	2	0
		DAY 36		18DEC2002	35	PP	-51	NO	18	-19	1	3	2	3	2	2	2	2	1	0
		DAY 36	*	23DEC2002	40	PP	-46	NO	20	-17	1	3	2	4	3	2	2	2	1	0
		DAY 50		02JAN2003	50	PP	-68	YES	12	-25	1	1	2	4	0	1	2	1	0	0
		DAY 57		07JAN2003	55	PP	-57	NO	16	-21	2	1	2	4	2	1	3	0	1	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 1	13NOV2002	1	PP			37		4	4	4	5	3	4	4	4	4	1
		DAY 8	20NOV2002	8	PP	-24	NO	28	-9	3	3	4	1	0	4	4	4	4	1
		DAY 15	27NOV2002	15	PP	-49	NO	19	-18	2	1	2	1	0	4	4	2	3	0
		DAY 22	03DEC2002	21	PP	-49	NO	19	-18	2	1	3	0	0	4	4	2	3	0
		DAY 29	11DEC2002	29	PP	-62	NO	14	-23	1	1	2	0	0	3	4	1	2	0
		DAY 36	17DEC2002	35	PP	-62	NO	14	-23	1	1	2	0	0	3	4	1	2	0
		DAY 43	23DEC2002	41	PP	-57	NO	16	-21	1	1	4	0	0	4	2	1	3	0
		DAY 50	30DEC2002	48	PP	-43	NO	21	-16	2	2	4	1	0	4	2	2	4	0
		DAY 57	06JAN2003	55	PP	-46	NO	20	-17	2	2	4	0	0	4	2	2	4	0
	E0005022	DAY 1	29JAN2003	1	PP			30		3	4	4	2	3	4	4	3	2	1
		DAY 8	04FEB2003	7	PP	-3	NO	29	-1	3	4	3	2	3	4	3	3	2	2
		DAY 15	11FEB2003	14	PP	-13	NO	26	-4	3	4	2	2	3	4	3	3	1	1
		DAY 22	21FEB2003	24	PP	-3	NO	29	-1	3	3	4	2	3	4	4	4	1	1
		DAY 29	26FEB2003	29	PP	-77	YES	7	-23	0	0	1	2	2	2	0	0	0	0
		DAY 36	06MAR2003	37	PP	-80	YES	6	-24	0	0	0	0	2	2	2	0	0	0
	E0005025	DAY 1	27FEB2003	1	PP			34		4	4	4	4	4	0	5	5	4	0
		DAY 8	06MAR2003	8	PP	-68	YES	11	-23	1	1	0	2	0	2	3	2	0	0
		DAY 15	14MAR2003	16	PP	-97	YES	1	-33	0	0	0	0	0	0	1	0	0	0
		DAY 22	20MAR2003	22	PP	-94	YES	2	-32	0	0	0	0	0	0	2	0	0	0
		DAY 29	27MAR2003	29	PP	-59	NO	14	-20	4	3	0	1	0	0	4	2	0	0
		DAY 36	03APR2003	36	PP	-82	YES	6	-28	0	0	0	2	0	0	2	2	0	0
	E0006019	DAY 1	07APR2003	1	PP			28		4	4	2	4	2	3	3	3	2	1
		DAY 8	14APR2003	8	PP	7	NO	30	2	4	4	3	4	2	3	4	3	2	1
		DAY 15	21APR2003	15	PP	-4	NO	27	-1	4	3	3	4	1	2	4	3	2	1
		DAY 22	28APR2003	22	PP	-21	NO	22	-6	3	3	2	4	0	2	3	2	2	1
		DAY 29	05MAY2003	29	PP	-25	NO	21	-7	3	3	2	3	0	2	3	2	2	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 36	12MAY2003	36	PP	-18	NO	23	-5	4	3	2	3	0	2	4	2	2	1
		DAY 43	19MAY2003	43	PP	-21	NO	22	-6	4	3	1	3	0	2	4	2	2	1
		DAY 50	27MAY2003	51	PP	-25	NO	21	-7	3	3	1	3	0	2	4	2	2	1
		DAY 57	03JUN2003	58	PP	-11	NO	25	-3	3	4	4	3	0	3	3	2	2	1
	E0007005	DAY 1	31JAN2003	1	PP			32		5	5	0	5	2	3	3	5	3	1
		DAY 8	07FEB2003	8	PP	-6	NO	30	-2	4	4	2	4	2	3	2	5	3	1
		DAY 15	14FEB2003	15	PP	-31	NO	22	-10	4	4	2	0	0	2	2	4	3	1
		DAY 22	22FEB2003	23	PP	-31	NO	22	-10	4	3	2	2	0	2	2	4	2	1
		DAY 29	03MAR2003	32	PP	-53	NO	15	-17	3	3	1	0	0	1	1	3	2	1
		DAY 36	10MAR2003	39	PP	-31	NO	22	-10	4	4	2	0	0	2	2	4	3	1
		DAY 43	14MAR2003	43	PP	-59	NO	13	-19	3	2	1	0	0	1	1	3	1	1
		DAY 50	21MAR2003	50	PP	-6	NO	30	-2	4	4	3	4	2	2	2	4	4	1
		DAY 57	28MAR2003	57	PP	-25	NO	24	-8	4	4	2	2	0	2	2	4	3	1
	E0007015	DAY 1	16JUL2003	1	PP			24		5	5	2	0	0	0	3	4	4	1
		DAY 8	23JUL2003	8	PP	17	NO	28	4	5	5	2	0	1	2	4	4	4	1
		DAY 15	01AUG2003	17	PP	0	NO	24	0	4	4	2	1	0	3	3	4	2	1
		DAY 22	06AUG2003	22	PP	-4	NO	23	-1	4	4	2	0	0	2	2	4	4	1
		DAY 29	13AUG2003	29	PP	-88	YES	3	-21	0	1	2	0	0	0	0	0	0	0
		DAY 36	20AUG2003	36	PP	-21	NO	19	-5	3	3	2	0	0	2	2	3	3	1
		DAY 43	27AUG2003	43	PP	-13	NO	21	-3	4	4	2	0	0	0	2	4	4	1
		DAY 50	03SEP2003	50	PP	-25	NO	18	-6	3	3	2	0	0	1	2	3	3	1
		DAY 57	10SEP2003	57	PP	-8	NO	22	-2	4	4	1	0	0	2	2	4	4	1
	E0009001	DAY 1	12NOV2002	1	PP			36		4	3	3	5	4	3	4	4	4	2
		DAY 8	21NOV2002	10	PP	-11	NO	32	-4	4	3	4	0	4	3	4	4	4	2
		DAY 15	26NOV2002	15	PP	-6	NO	34	-2	3	4	3	2	4	4	4	4	4	2
		DAY 22	04DEC2002	23	PP	-44	NO	20	-16	1	3	3	4	0	3	2	2	2	0

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QUETIAPINE 600 MG (BIPOLAR I)	E0009001	DAY 29	10DEC2002	29	PP	-33	NO	24	-12	2	3	2	6	0	2	2	2	4	1
		DAY 36	17DEC2002	36	PP	-25	NO	27	-9	2	3	4	4	4	2	2	2	4	0
		DAY 43	23DEC2002	42	PP	-47	NO	19	-17	3	2	3	4	2	2	2	0	1	0
		DAY 50	30DEC2002	49	PP	-53	NO	17	-19	2	2	2	3	2	2	2	2	0	0
	E0010002	DAY 1	25NOV2002	1	ITT			27		2	3	3	4	3	2	4	3	1	2
		DAY 8	02DEC2002	8	ITT	-15	NO	23	-4	3	5	4	2	0	1	2	2	1	3
	E0010009	DAY 1	26DEC2002	1	PP			24		3	4	2	3	0	4	2	4	2	0
		DAY 8	02JAN2003	8	PP	-67	YES	8	-16	1	0	1	0	0	2	3	0	1	0
		DAY 15	09JAN2003	15	PP	-63	YES	9	-15	1	1	0	0	0	3	0	3	1	0
		DAY 22	17JAN2003	23	PP	-25	NO	18	-6	2	3	2	0	0	2	5	3	1	0
		DAY 29	22JAN2003	28	PP	-54	YES	11	-13	1	2	2	0	0	2	2	1	1	0
		DAY 36	30JAN2003	36	PP	-67	YES	8	-16	0	2	1	0	0	2	0	2	1	0
		DAY 43	05FEB2003	42	PP	-63	YES	9	-15	2	2	2	0	0	2	0	1	0	0
		DAY 50	13FEB2003	50	PP	-79	YES	5	-19	0	2	0	0	0	0	1	2	0	0
		DAY 57	19FEB2003	56	PP	-75	YES	6	-18	0	2	2	0	0	0	0	2	0	0
	E0010010	DAY 1	30DEC2002	1	PP			27		3	3	3	0	4	3	2	2	5	2
		DAY 8	06JAN2003	8	PP	26	NO	34	7	3	5	4	4	2	4	4	2	4	2
		DAY 15	13JAN2003	15	PP	15	NO	31	4	3	4	3	4	3	2	4	3	3	2
	E0010014	DAY 1	28JAN2003	1	PP			34		4	4	5	4	0	4	4	4	3	2
		DAY 8	04FEB2003	8	PP	-85	YES	5	-29	1	1	0	0	1	0	1	0	1	0
		DAY 15	11FEB2003	15	PP	-82	YES	6	-28	1	0	3	0	0	0	0	0	2	0
		DAY 22	18FEB2003	22	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 29	25FEB2003	29	PP	-94	YES	2	-32	1	0	1	0	0	0	0	0	0	0
		DAY 36	04MAR2003	36	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 43	11MAR2003	43	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	DAY 50	18MAR2003	50	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 57	25MAR2003	57	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
	E0010017	DAY 1	25FEB2003	1	PP			34		3	4	3	5	3	4	4	4	4	0
		DAY 8	03MAR2003	7	PP	-32	NO	23	-11	2	3	3	2	3	2	4	2	2	0
		DAY 15	10MAR2003	14	PP	-71	YES	10	-24	1	1	2	0	0	2	2	0	2	0
		DAY 22	18MAR2003	22	PP	-77	YES	8	-26	0	2	1	0	3	0	2	0	0	0
		DAY 29	25MAR2003	29	PP	-94	YES	2	-32	0	0	0	0	0	0	2	0	0	0
		DAY 36	01APR2003	36	PP	-91	YES	3	-31	1	1	0	0	0	0	1	0	0	0
		DAY 43	08APR2003	43	PP	-88	YES	4	-30	0	0	1	0	0	0	2	1	0	0
		DAY 50	15APR2003	50	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	57	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
	E0010023	DAY 1	17APR2003	1	PP			34		4	5	4	3	0	4	4	4	4	2
		DAY 8	24APR2003	8	PP	-62	NO	13	-21	1	2	2	0	0	2	3	1	2	0
		DAY 15	01MAY2003	15	PP	-27	NO	25	-9	2	3	4	3	0	0	3	4	4	2
	E0010027	DAY 1	16JUN2003	1	PP			29		2	3	2	4	4	4	4	4	2	0
		DAY 8	23JUN2003	8	PP	-31	NO	20	-9	1	2	2	0	2	4	4	3	2	0
		DAY 15	01JUL2003	16	PP	-21	NO	23	-6	2	2	3	4	3	0	2	4	2	1
	E0010029	DAY 1	19JUN2003	1	PP			26		3	3	2	4	0	4	0	4	3	3
		DAY 8	25JUN2003	7	PP	4	NO	27	1	3	3	4	3	0	2	1	4	4	3
	E0011022	DAY 1	09JUN2003	1	PP			33		4	4	4	4	0	4	4	3	3	3
		DAY 8	16JUN2003	8	PP	-3	NO	32	-1	4	4	4	2	2	4	4	3	4	1
		DAY 15	24JUN2003	16	PP	-21	NO	26	-7	4	3	3	2	2	1	4	3	3	1
		DAY 22	01JUL2003	23	PP	-9	NO	30	-3	4	3	4	4	0	2	4	4	4	1
		DAY 29	08JUL2003	30	PP	-46	NO	18	-15	5	4	2	1	0	0	1	1	3	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	DAY 36	15JUL2003	37	PP	-15	NO	28	-5	3	4	4	3	0	3	4	4	2	1
		DAY 43	24JUL2003	46	PP	-3	NO	32	-1	5	5	4	0	0	1	4	5	4	4
		DAY 50	31JUL2003	53	PP	-3	NO	32	-1	5	4	2	1	0	2	5	5	4	4
		DAY 57	05AUG2003	58	PP	-27	NO	24	-9	4	4	3	0	0	1	2	4	4	2
	E0013006	DAY 1	13MAR2003	1	ITT			27		3	4	4	4	0	5	2	2	2	1
		DAY 8	24MAR2003	12	ITT	-70	YES	8	-19	1	2	0	3	0	0	0	2	0	0
	E0013012	DAY 1	07MAY2003	1	PP			34		4	5	3	5	2	4	4	3	2	2
		DAY 8	16MAY2003	10	PP	-82	YES	6	-28	1	1	0	0	0	2	1	1	0	0
		DAY 15	22MAY2003	16	PP	-79	YES	7	-27	1	1	0	1	0	1	2	1	0	0
		DAY 22	30MAY2003	24	PP	-79	YES	7	-27	1	1	2	0	0	1	1	1	0	0
		DAY 29	05JUN2003	30	PP	-77	YES	8	-26	1	1	0	2	0	2	2	0	0	0
		DAY 36	12JUN2003	37	PP	-85	YES	5	-29	0	1	0	1	0	1	1	1	0	0
		DAY 43	19JUN2003	44	PP	-82	YES	6	-28	1	1	0	0	0	1	1	1	1	0
		DAY 50	25JUN2003	50	PP	-91	YES	3	-31	0	0	0	1	0	0	1	1	0	0
		DAY 57	02JUL2003	57	PP	-97	YES	1	-33	0	1	0	0	0	0	0	0	0	0
	E0013014	DAY 1	03JUN2003	1	PP (28)			24		4	4	2	3	0	3	2	2	2	2
		DAY 8	10JUN2003	8	PP (28)	17	NO	28	4	3	3	3	4	0	4	4	2	2	3
		DAY 15	19JUN2003	17	PP (28)	0	NO	24	0	3	3	3	3	2	3	3	2	1	1
		DAY 29	30JUN2003	28	PP (28)	-71	YES	7	-17	1	1	0	3	0	0	0	1	0	1
	E0014005	DAY 1	11MAR2003	1	PP			41		6	6	5	3	0	5	5	4	5	2
		DAY 8	18MAR2003	8	PP	-61	NO	16	-25	2	2	3	0	0	1	1	2	3	2
		DAY 15	25MAR2003	15	PP	-85	YES	6	-35	1	1	1	0	0	1	1	0	0	1
		DAY 22	01APR2003	22	PP	-98	YES	1	-40	0	0	0	0	0	0	0	0	0	1
		DAY 29	08APR2003	29	PP	-88	YES	5	-36	0	0	1	0	0	3	0	0	1	0
		DAY 36	16APR2003	37	PP	-78	YES	9	-32	1	1	2	0	0	3	1	0	1	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	DAY 43	23APR2003	44	PP	-93	YES	3	-38	0	1	2	0	0	0	0	0	0	0
		DAY 50	29APR2003	50	PP	-98	YES	1	-40	0	0	0	0	0	0	1	0	0	0
		DAY 57	06MAY2003	57	PP	-93	YES	3	-38	1	1	1	0	0	0	0	0	0	0
	E0014007	DAY 1	01APR2003	1	ITT			29		2	4	3	4	0	3	5	4	3	1
		DAY 8	08APR2003	8	ITT	-45	NO	16	-13	2	2	3	0	0	4	2	2	1	0
		DAY 15	15APR2003	15	ITT	3	NO	30	1	5	3	4	3	1	5	4	3	2	0
		DAY 22	22APR2003	22	ITT	0	NO	29	0	4	3	1	6	1	4	3	4	3	0
	E0014011	DAY 1	13MAY2003	1	PP			33		4	4	4	4	3	2	4	3	3	2
		DAY 8	20MAY2003	8	PP	-64	YES	12	-21	2	2	2	0	0	1	2	2	0	1
		DAY 15	27MAY2003	15	PP	-42	NO	19	-14	2	2	2	0	2	2	3	3	2	1
		DAY 22	04JUN2003	23	PP	-76	YES	8	-25	1	1	2	0	0	1	1	1	1	0
		DAY 29	10JUN2003	29	PP	-73	YES	9	-24	1	1	2	0	0	2	1	1	1	0
		DAY 36	17JUN2003	36	PP	-79	YES	7	-26	1	1	1	0	0	1	1	1	1	0
		DAY 43	26JUN2003	45	PP	-85	YES	5	-28	0	1	1	0	0	0	2	1	0	0
		DAY 50	02JUL2003	51	PP	-94	YES	2	-31	0	0	2	0	0	0	0	0	0	0
		DAY 57	08JUL2003	57	PP	-100	YES	0	-33	0	0	0	0	0	0	0	0	0	0
	E0014012	DAY 1	27MAY2003	1	PP			48		6	6	6	6	5	4	5	4	5	1
		DAY 8	03JUN2003	8	PP	-15	NO	41	-7	5	5	6	1	5	4	5	4	5	1
		DAY 15	10JUN2003	15	PP	-35	NO	31	-17	3	3	4	3	3	3	3	4	4	1
		DAY 22	17JUN2003	22	PP	-44	NO	27	-21	3	3	4	3	0	3	3	3	4	1
		DAY 29	24JUN2003	29	PP	-42	NO	28	-20	3	3	4	3	0	3	3	3	4	2
	E0015001	DAY 1	29NOV2002	1	PP			30		3	4	3	4	0	4	4	3	3	2
		DAY 8	06DEC2002	8	PP	-20	NO	24	-6	3	4	3	0	0	3	4	3	2	2
		DAY 15	13DEC2002	15	PP	-33	NO	20	-10	3	3	2	0	0	3	3	3	2	1
		DAY 22	19DEC2002	21	PP	-33	NO	20	-10	3	3	2	0	0	3	3	3	2	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	DAY 29	27DEC2002	29	PP	-40	NO	18	-12	3	3	2	0	0	3	1	4	1	1
		DAY 36	03JAN2003	36	PP	-27	NO	22	-8	3	2	3	0	2	2	3	3	2	2
		DAY 43	09JAN2003	42	PP	-50	NO	15	-15	2	2	2	0	0	3	1	2	2	1
		DAY 50	20JAN2003	53	PP	-57	NO	13	-17	0	1	2	0	2	2	2	2	1	1
	E0015008	DAY 1	19DEC2002	1	PP			31		3	4	3	4	2	4	4	4	2	1
		DAY 8	27DEC2002	9	PP	-26	NO	23	-8	3	4	2	0	0	3	4	4	2	1
		DAY 15	03JAN2003	16	PP	-42	NO	18	-13	2	2	2	0	2	2	3	2	2	1
		DAY 22	10JAN2003	23	PP	-48	NO	16	-15	2	2	2	0	0	2	3	2	2	1
		DAY 29	16JAN2003	29	PP	-58	NO	13	-18	1	0	3	0	1	2	3	1	1	1
		DAY 36	23JAN2003	36	PP	-71	YES	9	-22	0	0	2	0	2	1	2	1	0	1
	E0016003	DAY 1	24JAN2003	1	ITT			30		3	4	4	2	1	4	4	2	5	1
		DAY 8	31JAN2003	8	ITT	7	NO	32	2	4	4	3	3	1	4	4	4	4	1
		DAY 15	07FEB2003	15	ITT	17	NO	35	5	4	5	4	5	0	4	4	4	4	1
		DAY 22	14FEB2003	22	ITT	-50	NO	15	-15	3	1	1	1	1	2	2	3	1	0
		DAY 29	21FEB2003	29	ITT	-57	NO	13	-17	2	2	1	3	0	1	2	1	1	0
		DAY 36	27FEB2003	35	ITT	-60	YES	12	-18	2	2	1	0	0	2	2	2	1	0
		DAY 43	07MAR2003	43	ITT	-40	NO	18	-12	2	2	2	2	0	3	2	2	2	1
	E0016005	DAY 1	25FEB2003	1	PP			28		3	4	3	4	1	3	3	3	3	1
		DAY 8	04MAR2003	8	PP	-36	NO	18	-10	3	3	1	0	0	3	2	2	3	1
		DAY 15	11MAR2003	15	PP	-39	NO	17	-11	3	1	2	0	0	4	1	2	4	0
		DAY 22	18MAR2003	22	PP	-89	YES	3	-25	1	1	1	0	0	0	0	0	0	0
		DAY 29	25MAR2003	29	PP	-96	YES	1	-27	0	1	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	36	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
		DAY 43	08APR2003	43	PP	-96	YES	1	-27	0	0	0	0	0	1	0	0	0	0
		DAY 50	17APR2003	52	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	57	PP	-86	YES	4	-24	1	0	1	0	0	1	1	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0018007	DAY 1		27DEC2002	1	ITT			29		4	4	4	4	0	4	3	3	3	0
		DAY 8		31DEC2002	5	ITT	-31	NO	20	-9	3	3	2	0	1	4	3	2	2	0
		DAY 15		10JAN2003	15	ITT	0	NO	29	0	4	4	4	5	0	4	3	3	2	0
	E0019005	DAY 1		05NOV2002	1	PP			35		3	4	4	3	4	3	4	4	4	2
		DAY 8		12NOV2002	8	PP	-37	NO	22	-13	2	2	3	1	3	3	3	3	2	0
		DAY 15		19NOV2002	15	PP	-63	NO	13	-22	1	1	2	2	0	3	2	2	0	0
		DAY 22		26NOV2002	22	PP	-49	NO	18	-17	2	2	2	2	0	2	4	4	0	0
		DAY 29		05DEC2002	31	PP	-69	YES	11	-24	2	0	2	3	2	0	1	0	1	0
		DAY 36		12DEC2002	38	PP	-83	YES	6	-29	0	0	0	0	0	3	0	2	1	0
		DAY 43		19DEC2002	45	PP	-63	NO	13	-22	2	2	1	2	0	2	1	1	2	0
		DAY 57	*	30DEC2002	56	PP	-46	NO	19	-16	4	2	1	2	0	0	3	4	2	1
		DAY 57		02JAN2003	59	PP	-60	NO	14	-21	3	1	0	2	0	0	3	4	1	0
	E0019015	DAY 1		02JAN2003	1	ITT			29		3	3	4	4	0	2	5	4	4	0
		DAY 8		09JAN2003	8	ITT	-62	YES	11	-18	1	1	2	0	2	2	1	2	0	0
		DAY 15		16JAN2003	15	ITT	-59	YES	12	-17	2	1	0	2	1	0	3	3	0	0
		DAY 22		23JAN2003	22	ITT	-83	YES	5	-24	2	0	1	0	0	2	0	0	0	0
		DAY 29		30JAN2003	29	ITT	-83	YES	5	-24	3	0	0	0	0	1	0	1	0	0
		DAY 36		06FEB2003	36	ITT	-90	YES	3	-26	0	0	0	1	0	2	0	0	0	0
		DAY 43		13FEB2003	43	ITT	-93	YES	2	-27	1	0	0	0	0	0	1	0	0	0
		DAY 50		20FEB2003	50	ITT	-83	YES	5	-24	2	1	0	0	0	0	0	2	0	0
		DAY 57		27FEB2003	57	ITT	-83	YES	5	-24	3	0	2	0	0	0	0	0	0	0
	E0020004	DAY 1		09DEC2002	1	PP			25		4	4	2	5	2	4	1	3	0	0
		DAY 8		16DEC2002	8	PP	-4	NO	24	-1	4	3	2	2	0	4	4	4	1	0
		DAY 8	*	20DEC2002	12	PP	-36	NO	16	-9	3	3	2	1	0	3	4	0	0	0
		DAY 22		31DEC2002	23	PP	20	NO	30	5	4	4	4	3	2	3	4	4	2	0
		DAY 29		07JAN2003	30	PP	8	NO	27	2	4	3	3	0	0	4	4	4	3	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	DAY 36	14JAN2003	37	PP	20	NO	30	5	4	5	3	2	3	0	4	4	4	1
		DAY 43	22JAN2003	45	PP	36	NO	34	9	5	5	3	1	4	1	5	5	4	1
	E0020010	DAY 1	05FEB2003	1	PP			32		3	4	5	6	0	4	1	4	4	1
		DAY 8	12FEB2003	8	PP	-22	NO	25	-7	4	3	2	2	0	4	2	4	4	0
		DAY 15	19FEB2003	15	PP	-66	YES	11	-21	2	0	1	1	0	4	1	0	2	0
		DAY 22	26FEB2003	22	PP	-72	YES	9	-23	0	0	1	2	0	4	2	0	0	0
		DAY 29	05MAR2003	29	PP	3	NO	33	1	4	4	4	3	0	5	4	4	4	1
		DAY 36	10MAR2003	34	PP	-44	NO	18	-14	2	2	2	0	0	4	4	4	0	0
		DAY 43	17MAR2003	41	PP	-63	YES	12	-20	0	0	0	2	0	4	0	4	2	0
		DAY 50	25MAR2003	49	PP	-72	YES	9	-23	1	0	1	1	0	3	2	1	0	0
		DAY 57	02APR2003	57	PP	-88	YES	4	-28	0	0	0	2	0	1	0	0	1	0
	E0020014	DAY 1	18MAR2003	1	PP			23		2	2	2	1	2	4	4	4	2	0
		DAY 8	25MAR2003	8	PP	0	NO	23	0	3	2	3	3	0	4	4	1	2	1
		DAY 15	01APR2003	15	PP	-26	NO	17	-6	2	2	2	4	0	3	1	1	2	0
		DAY 22	08APR2003	22	PP	-35	NO	15	-8	2	2	2	5	0	2	0	0	2	0
		DAY 29	15APR2003	29	PP	-35	NO	15	-8	2	2	2	3	0	2	2	0	2	0
		DAY 36	22APR2003	36	PP	-48	YES	12	-11	2	2	2	2	0	2	0	0	2	0
		DAY 43	29APR2003	43	PP	-78	YES	5	-18	0	0	0	0	2	2	1	0	0	0
		DAY 50	06MAY2003	50	PP	-48	YES	12	-11	2	2	2	1	0	2	1	0	2	0
		DAY 57	12MAY2003	56	PP	-78	YES	5	-18	1	1	0	0	0	2	0	0	1	0
	E0020021	DAY 1	19MAY2003	1	PP			25		3	4	3	4	0	3	4	2	0	2
		DAY 8	23MAY2003	5	PP	-32	NO	17	-8	1	2	2	0	0	2	4	0	4	2
		DAY 15	02JUN2003	15	PP	-24	NO	19	-6	2	2	0	5	0	2	4	3	0	1
		DAY 22	10JUN2003	23	PP	-36	NO	16	-9	2	2	0	4	0	2	2	4	0	0
		DAY 29	16JUN2003	29	PP	-64	YES	9	-16	2	1	0	0	0	2	2	0	0	2
		DAY 36	23JUN2003	36	PP	-16	NO	21	-4	2	2	0	4	2	0	4	2	3	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	DAY 43	30JUN2003	43	PP	-4	NO	24	-1	2	4	3	4	0	0	4	3	2	2
		DAY 50	07JUL2003	50	PP	-32	NO	17	-8	2	2	0	0	3	2	4	0	2	2
		DAY 57	14JUL2003	57	PP	-16	NO	21	-4	2	2	0	4	0	3	4	3	2	1
	E0020023	DAY 1	16JUN2003	-1	PP			26		2	4	3	2	0	3	4	4	4	0
		DAY 8	24JUN2003	8	PP	-19	NO	21	-5	3	3	2	0	1	2	2	4	3	1
		DAY 15	30JUN2003	14	PP	0	NO	26	0	2	4	3	3	3	3	2	4	0	2
		DAY 22	07JUL2003	21	PP	12	NO	29	3	3	4	3	3	2	3	4	4	1	2
		DAY 29	14JUL2003	28	PP	23	NO	32	6	2	4	3	4	2	3	4	4	4	2
		DAY 36	21JUL2003	35	PP	-39	NO	16	-10	1	2	3	2	0	2	1	3	2	0
		DAY 43	28JUL2003	42	PP	-15	NO	22	-4	2	2	2	2	0	3	1	4	4	2
		DAY 50	04AUG2003	49	PP	-19	NO	21	-5	2	2	3	2	2	2	1	4	2	1
		DAY 57	11AUG2003	56	PP	-15	NO	22	-4	2	2	2	2	0	2	2	5	3	2
	E0022007	DAY 1	07NOV2002	1	PP			30		3	4	3	5	0	3	4	4	3	1
		DAY 8	14NOV2002	8	PP	-40	NO	18	-12	2	2	2	2	0	2	3	3	2	0
		DAY 15	22NOV2002	16	PP	-43	NO	17	-13	2	2	2	1	0	2	3	3	2	0
		DAY 22	02DEC2002	26	PP	-40	NO	18	-12	2	2	3	0	0	2	2	3	3	1
		DAY 29	09DEC2002	33	PP	-40	NO	18	-12	2	1	2	2	0	3	3	3	2	0
	E0022010	DAY 1	21NOV2002	1	PP			29		4	4	3	3	0	4	2	4	4	1
		DAY 8	29NOV2002	9	PP	-28	NO	21	-8	2	2	2	2	0	4	4	2	3	0
		DAY 15	06DEC2002	16	PP	-83	YES	5	-24	0	0	1	2	0	0	0	0	1	1
		DAY 22	12DEC2002	22	PP	-79	YES	6	-23	0	1	2	0	0	0	1	1	1	0
		DAY 36	26DEC2002	36	PP	-83	YES	5	-24	0	0	2	1	0	2	0	0	0	0
		DAY 43	02JAN2003	43	PP	-83	YES	5	-24	0	0	2	0	0	2	0	0	1	0
		DAY 50	09JAN2003	50	PP	-93	YES	2	-27	0	0	0	1	0	1	0	0	0	0
		DAY 57	16JAN2003	57	PP	-86	YES	4	-25	0	0	1	1	0	2	0	0	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0022012	DAY 1		05DEC2002	1	PP			30		4	4	2	5	0	4	3	4	3	1
		DAY 8		12DEC2002	8	PP	-50	NO	15	-15	2	2	2	1	1	2	2	2	1	0
		DAY 15		19DEC2002	15	PP	-80	YES	6	-24	1	1	1	0	0	2	1	0	0	0
		DAY 15	*	23DEC2002	19	PP	-80	YES	6	-24	0	1	2	0	0	2	1	0	0	0
		DAY 29		02JAN2003	29	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 36		09JAN2003	36	PP	-90	YES	3	-27	0	0	0	0	0	2	1	0	0	0
		DAY 43		16JAN2003	43	PP	-90	YES	3	-27	1	0	0	0	0	1	1	0	0	0
		DAY 50		23JAN2003	50	PP	-87	YES	4	-26	1	0	1	0	0	2	0	0	0	0
		DAY 57		30JAN2003	57	PP	-93	YES	2	-28	0	0	0	1	0	1	0	0	0	0
	E0022019	DAY 1		11DEC2002	1	PP			30		4	4	2	4	0	4	3	4	3	2
		DAY 8		19DEC2002	9	PP	-70	YES	9	-21	2	1	2	0	0	0	2	0	2	0
		DAY 15		26DEC2002	16	PP	-83	YES	5	-25	2	2	0	0	0	0	1	0	0	0
		DAY 22		03JAN2003	24	PP	-93	YES	2	-28	0	0	0	0	0	0	2	0	0	0
		DAY 29		09JAN2003	30	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 36		17JAN2003	38	PP	-93	YES	2	-28	0	0	0	0	0	0	2	0	0	0
		DAY 43		24JAN2003	45	PP	-73	YES	8	-22	0	0	0	4	2	0	2	0	0	0
		DAY 50		30JAN2003	51	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 57		06FEB2003	58	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
	E0022025	DAY 1		28JAN2003	1	ITT			37		4	4	5	5	0	4	4	4	4	3
		DAY 8		04FEB2003	8	ITT	0	NO	37	0	4	4	5	5	0	5	4	4	5	1
	E0022033	DAY 1		18FEB2003	1	PP			25		2	2	3	4	0	4	2	4	2	2
		DAY 8		25FEB2003	8	PP	-12	NO	22	-3	4	3	2	1	0	2	4	2	2	2
		DAY 15		04MAR2003	15	PP	-48	NO	13	-12	2	2	2	0	0	2	2	2	0	1
		DAY 22		11MAR2003	22	PP	-84	YES	4	-21	1	0	2	0	0	0	0	0	1	0
		DAY 29		18MAR2003	29	PP	-88	YES	3	-22	0	0	2	0	0	0	0	1	0	0
		DAY 36		27MAR2003	38	PP	-96	YES	1	-24	0	0	0	0	0	0	1	0	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	DAY 43	01APR2003	43	PP	-92	YES	2	-23	1	0	0	0	0	1	0	0	0	0
		DAY 50	08APR2003	50	PP	-80	YES	5	-20	0	0	2	0	0	0	2	0	1	0
		DAY 57	15APR2003	57	PP	-96	YES	1	-24	0	0	0	0	0	0	0	0	1	0
	E0022034	DAY 1	18FEB2003	1	PP			30		4	4	4	4	0	3	3	4	3	1
		DAY 8	25FEB2003	8	PP	-30	NO	21	-9	4	3	3	0	0	2	2	4	2	1
		DAY 15	04MAR2003	15	PP	-47	NO	16	-14	3	3	2	0	0	1	3	2	2	0
		DAY 22	11MAR2003	22	PP	-13	NO	26	-4	4	4	3	0	0	4	4	4	2	1
		DAY 29	18MAR2003	29	PP	-43	NO	17	-13	3	3	3	0	0	1	2	3	2	0
		DAY 36	25MAR2003	36	PP	-57	NO	13	-17	3	2	2	0	0	1	2	1	2	0
		DAY 43	01APR2003	43	PP	-67	YES	10	-20	0	1	2	0	0	2	1	1	2	1
		DAY 50	07APR2003	49	PP	-67	YES	10	-20	1	1	2	0	0	2	1	1	1	1
		DAY 57	15APR2003	57	PP	-67	YES	10	-20	1	1	2	0	0	2	2	1	1	0
	E0022038	DAY 1	28FEB2003	1	PP			34		4	4	2	4	2	4	4	4	4	2
		DAY 8	07MAR2003	8	PP	-41	NO	20	-14	2	2	2	0	2	4	2	2	2	2
		DAY 15	14MAR2003	15	PP	-24	NO	26	-8	3	2	3	0	2	4	3	3	2	4
		DAY 22	21MAR2003	22	PP	-44	NO	19	-15	3	2	2	2	0	4	3	2	0	1
		DAY 29	28MAR2003	29	PP	-50	NO	17	-17	1	1	2	2	2	2	2	2	2	1
		DAY 36	04APR2003	36	PP	-41	NO	20	-14	2	2	2	2	1	4	2	2	2	1
		DAY 43	11APR2003	43	PP	-41	NO	20	-14	2	2	2	0	2	4	2	2	2	2
	E0022039	DAY 1	06MAR2003	1	PP			27		3	3	2	4	0	4	3	4	2	2
		DAY 8	13MAR2003	8	PP	4	NO	28	1	3	3	3	4	2	2	3	4	2	2
		DAY 15	20MAR2003	15	PP	-41	NO	16	-11	2	2	2	2	0	2	2	2	1	1
		DAY 22	27MAR2003	22	PP	-41	NO	16	-11	2	2	1	2	0	0	3	3	1	2
		DAY 29	04APR2003	30	PP	-82	YES	5	-22	0	0	3	0	0	0	0	0	2	0
		DAY 36	10APR2003	36	PP	-93	YES	2	-25	0	0	0	0	0	0	0	2	0	0
		DAY 43	18APR2003	44	PP	-89	YES	3	-24	0	0	0	0	1	0	0	0	2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	DAY 50	24APR2003	50	PP	-82	YES	5	-22	1	0	2	0	0	0	0	0	2	0
		DAY 57	01MAY2003	57	PP	-93	YES	2	-25	0	0	1	0	0	0	1	0	0	0
	E0022046	DAY 1	20MAR2003	1	PP			41		5	5	2	5	4	4	5	5	3	3
		DAY 8	27MAR2003	8	PP	-12	NO	36	-5	4	4	3	3	4	4	5	4	3	2
		DAY 15	04APR2003	16	PP	-44	NO	23	-18	2	2	2	2	0	3	3	4	2	3
		DAY 22	11APR2003	23	PP	-54	NO	19	-22	1	0	2	2	2	2	4	3	2	1
		DAY 29	18APR2003	30	PP	-54	NO	19	-22	3	3	0	0	4	3	3	3	0	0
		DAY 36	24APR2003	36	PP	-42	NO	24	-17	3	3	2	2	2	2	3	3	2	2
		DAY 43	02MAY2003	44	PP	-44	NO	23	-18	3	3	3	0	2	3	3	3	2	1
		DAY 50	12MAY2003	54	PP	-54	NO	19	-22	2	2	2	1	0	3	4	3	1	1
		DAY 57	16MAY2003	58	PP	-42	NO	24	-17	3	3	3	0	2	3	3	4	2	1
	E0022048	DAY 1	01APR2003	1	PP			30		4	4	2	4	0	4	4	4	2	2
		DAY 8	08APR2003	8	PP	-47	NO	16	-14	2	2	2	0	0	3	4	2	0	1
		DAY 15	15APR2003	15	PP	-50	NO	15	-15	2	2	1	1	0	2	2	4	0	1
		DAY 22	24APR2003	24	PP	-77	YES	7	-23	2	0	2	2	0	0	1	0	0	0
		DAY 29	02MAY2003	32	PP	-77	YES	7	-23	1	1	1	0	0	0	2	0	1	1
		DAY 36	06MAY2003	36	PP	-93	YES	2	-28	0	0	0	0	0	0	2	0	0	0
		DAY 43	13MAY2003	43	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
		DAY 50	23MAY2003	53	PP	-100	YES	0	-30	0	0	0	0	0	0	0	0	0	0
	E0022051	DAY 1	07APR2003	1	PP			40		5	4	3	3	4	4	5	4	4	4
		DAY 8	14APR2003	8	PP	-38	NO	25	-15	3	3	2	2	2	3	3	3	2	2
		DAY 15	21APR2003	15	PP	-63	NO	15	-25	2	3	0	0	0	3	4	3	0	0
		DAY 22	28APR2003	22	PP	-83	YES	7	-33	1	1	0	0	0	1	2	2	0	0
		DAY 29	05MAY2003	29	PP	-88	YES	5	-35	1	1	1	0	0	1	1	0	0	0
		DAY 36	12MAY2003	36	PP	-85	YES	6	-34	0	0	0	3	0	3	0	0	0	0
		DAY 43	19MAY2003	43	PP	-85	YES	6	-34	1	1	2	0	0	2	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	DAY 50		28MAY2003	52	PP	-100	YES	0	-40	0	0	0	0	0	0	0	0	0	0
		DAY 57		02JUN2003	57	PP	-98	YES	1	-39	0	0	0	0	0	0	1	0	0	0
	E0022053	DAY 1		11APR2003	1	SAFETY			34		4	4	3	5	0	4	4	4	4	2
	E0022058	DAY 1		21APR2003	1	PP			27		4	4	2	1	0	3	3	4	2	4
		DAY 8		28APR2003	8	PP	-26	NO	20	-7	2	2	2	0	0	2	4	4	2	2
		DAY 15		05MAY2003	15	PP	-78	YES	6	-21	1	1	0	0	0	0	1	2	0	1
		DAY 22		12MAY2003	22	PP	-82	YES	5	-22	0	0	2	0	0	2	1	0	0	0
		DAY 29		19MAY2003	29	PP	-85	YES	4	-23	0	0	0	0	0	2	2	0	0	0
		DAY 29	*	22MAY2003	32	PP	-63	YES	10	-17	0	0	2	0	0	4	2	0	2	0
	E0022061	DAY 1		30APR2003	1	PP			27		3	3	4	2	0	3	4	4	3	1
		DAY 8		07MAY2003	8	PP	-41	NO	16	-11	2	2	2	0	0	2	3	3	2	0
		DAY 15		14MAY2003	15	PP	-63	YES	10	-17	2	0	2	0	0	2	2	2	0	0
		DAY 22		22MAY2003	23	PP	-96	YES	1	-26	0	0	1	0	0	0	0	0	0	0
		DAY 29		28MAY2003	29	PP	-96	YES	1	-26	0	0	1	0	0	0	0	0	0	0
		DAY 36		04JUN2003	36	PP	-93	YES	2	-25	0	0	2	0	0	0	0	0	0	0
		DAY 50		18JUN2003	50	PP	-96	YES	1	-26	0	0	1	0	0	0	0	0	0	0
		DAY 57		26JUN2003	58	PP	-93	YES	2	-25	0	0	2	0	0	0	0	0	0	0
	E0022062	DAY 1		05MAY2003	1	PP			28		4	4	2	3	2	4	2	2	4	1
		DAY 8		12MAY2003	8	PP	-4	NO	27	-1	3	3	2	4	0	5	2	4	2	2
		DAY 15		19MAY2003	15	PP	14	NO	32	4	4	4	3	4	3	4	2	4	2	2
		DAY 15	*	23MAY2003	19	PP	18	NO	33	5	4	4	2	4	2	5	2	4	4	2
	E0022068	DAY 1		22MAY2003	-1	PP			23		3	3	3	3	0	3	3	2	3	0
		DAY 8		29MAY2003	7	PP	22	NO	28	5	3	3	3	2	0	4	4	4	3	2
		DAY 15		05JUN2003	14	PP	22	NO	28	5	3	3	3	0	2	4	4	4	3	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	DAY 1	10JUN2003	1	PP			33		4	4	3	4	2	4	3	4	2	3
		DAY 8	17JUN2003	8	PP	-30	NO	23	-10	4	4	2	0	0	2	2	4	3	2
		DAY 15	24JUN2003	15	PP	-27	NO	24	-9	4	3	2	0	2	3	2	3	2	3
		DAY 22	01JUL2003	22	PP	-67	YES	11	-22	2	1	2	0	2	2	1	1	0	0
		DAY 29	08JUL2003	29	PP	-64	YES	12	-21	3	2	1	2	0	1	0	3	0	0
		DAY 36	15JUL2003	36	PP	-94	YES	2	-31	0	0	0	0	0	2	0	0	0	0
		DAY 43	22JUL2003	43	PP	-91	YES	3	-30	1	0	1	0	0	0	0	1	0	0
		DAY 50	29JUL2003	50	PP	-88	YES	4	-29	0	0	2	0	0	2	0	0	0	0
		DAY 57	05AUG2003	57	PP	-88	YES	4	-29	1	0	2	0	0	1	0	0	0	0
	E0022071	DAY 1	30JUN2003	1	PP			43		6	6	4	4	4	4	5	4	3	3
		DAY 8	07JUL2003	8	PP	-9	NO	39	-4	5	5	3	5	3	4	5	4	3	2
		DAY 15	14JUL2003	15	PP	-21	NO	34	-9	4	4	4	0	4	4	5	4	3	2
		DAY 22	21JUL2003	22	PP	-21	NO	34	-9	4	4	4	3	2	4	4	4	3	2
		DAY 29	28JUL2003	29	PP	-26	NO	32	-11	4	4	4	0	3	4	4	4	3	2
		DAY 36	04AUG2003	36	PP	-28	NO	31	-12	4	4	3	0	3	4	4	4	3	2
		DAY 43	11AUG2003	43	PP	-19	NO	35	-8	4	4	3	3	3	4	4	4	3	3
		DAY 50	18AUG2003	50	PP	-30	NO	30	-13	4	4	3	0	3	3	4	4	3	2
		DAY 57	25AUG2003	57	PP	-21	NO	34	-9	4	4	3	0	3	4	4	4	4	4
	E0023003	DAY 1	17DEC2002	1	PP			30		3	4	3	4	2	3	3	4	2	2
		DAY 8	23DEC2002	7	PP	7	NO	32	2	4	4	4	4	2	3	3	4	2	2
		DAY 15	30DEC2002	14	PP	-7	NO	28	-2	3	2	3	4	1	3	4	4	2	2
		DAY 22	07JAN2003	22	PP	0	NO	30	0	3	2	4	4	1	3	4	4	3	2
		DAY 29	16JAN2003	31	PP	-27	NO	22	-8	2	1	4	2	1	2	2	3	3	2
		DAY 36	21JAN2003	36	PP	-40	NO	18	-12	3	3	3	0	0	2	2	2	2	1
		DAY 43	28JAN2003	43	PP	-40	NO	18	-12	2	2	3	1	1	2	2	2	2	1
		DAY 50	06FEB2003	52	PP	-43	NO	17	-13	2	1	2	2	1	2	2	1	2	2
		DAY 57	11FEB2003	57	PP	-50	NO	15	-15	3	3	2	0	0	2	2	1	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	DAY 1	17DEC2002	1	PP			23		3	3	2	0	0	3	4	4	2	2
		DAY 8	23DEC2002	7	PP	35	NO	31	8	4	4	3	2	2	4	4	4	2	2
		DAY 15	02JAN2003	17	PP	-26	NO	17	-6	2	2	2	2	0	2	3	3	1	0
		DAY 22	07JAN2003	22	PP	-65	YES	8	-15	2	1	0	0	1	0	2	1	1	0
		DAY 29	16JAN2003	31	PP	-74	YES	6	-17	1	1	0	0	2	0	1	1	0	0
		DAY 36	21JAN2003	36	PP	-61	YES	9	-14	1	1	1	1	2	1	1	1	0	0
		DAY 43	28JAN2003	43	PP	-57	YES	10	-13	1	2	1	0	2	2	1	1	0	0
		DAY 50	04FEB2003	50	PP	-65	YES	8	-15	1	1	1	0	1	2	1	1	0	0
		DAY 57	11FEB2003	57	PP	-70	YES	7	-16	1	1	1	0	0	2	1	1	0	0
	E0023010	DAY 1	04FEB2003	1	PP			31		4	4	4	4	0	3	3	4	3	2
		DAY 8	11FEB2003	8	PP	-32	NO	21	-10	3	3	3	1	0	2	3	4	1	1
		DAY 15	18FEB2003	15	PP	-36	NO	20	-11	3	3	3	0	0	3	3	4	1	0
		DAY 22	25FEB2003	22	PP	-39	NO	19	-12	3	3	3	0	0	3	2	4	1	0
		DAY 29	04MAR2003	29	PP	-45	NO	17	-14	3	3	2	0	0	2	2	4	1	0
		DAY 36	11MAR2003	36	PP	-58	NO	13	-18	3	2	1	1	0	1	2	2	1	0
		DAY 43	18MAR2003	43	PP	-65	YES	11	-20	3	2	1	0	0	1	1	2	1	0
		DAY 50	25MAR2003	50	PP	-52	NO	15	-16	3	3	3	2	0	0	1	1	2	0
		DAY 57	31MAR2003	56	PP	-65	YES	11	-20	2	2	1	1	0	1	2	2	0	0
	E0023025	DAY 1	15MAY2003	1	PP			24		2	3	2	2	1	4	2	3	2	3
		DAY 8	22MAY2003	8	PP	4	NO	25	1	4	3	3	0	0	4	3	3	3	2
		DAY 15	29MAY2003	15	PP	-4	NO	23	-1	4	3	4	0	0	4	3	3	1	1
		DAY 22	05JUN2003	22	PP	-21	NO	19	-5	3	3	4	0	0	3	2	2	1	1
		DAY 29	12JUN2003	29	PP	-54	YES	11	-13	1	1	2	0	0	2	2	0	2	1
		DAY 36	19JUN2003	36	PP	-46	NO	13	-11	1	1	2	2	0	2	2	0	2	1
		DAY 43	27JUN2003	44	PP	-42	NO	14	-10	2	2	3	0	0	2	2	0	2	1
		DAY 50	03JUL2003	50	PP	-46	NO	13	-11	1	1	2	0	0	3	2	1	2	1
		DAY 57	10JUL2003	57	PP	-46	NO	13	-11	2	2	2	2	0	2	2	1	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	DAY 1	01JUL2003	1	PP			32		4	4	3	4	2	3	4	4	2	2
		DAY 8	08JUL2003	8	PP	-53	NO	15	-17	2	2	1	2	0	2	2	2	1	1
		DAY 15	15JUL2003	15	PP	-56	NO	14	-18	2	2	1	0	0	2	3	2	1	1
		DAY 22	22JUL2003	22	PP	-75	YES	8	-24	1	1	1	0	0	1	2	1	1	0
		DAY 29	29JUL2003	29	PP	-56	NO	14	-18	3	3	2	0	0	1	2	1	1	1
		DAY 36	05AUG2003	36	PP	-69	YES	10	-22	1	2	2	0	0	1	2	1	1	0
		DAY 43	12AUG2003	43	PP	-78	YES	7	-25	0	0	2	0	0	1	2	1	1	0
		DAY 50	19AUG2003	50	PP	-81	YES	6	-26	0	0	1	0	0	1	2	1	1	0
		DAY 57	26AUG2003	57	PP	-81	YES	6	-26	0	0	1	0	0	1	2	1	1	0
	E0026002	DAY 1	12NOV2002	1	PP			29		4	5	2	3	2	4	1	4	3	1
		DAY 8	19NOV2002	8	PP	-21	NO	23	-6	3	4	1	0	0	4	4	4	2	1
		DAY 15	26NOV2002	15	PP	-35	NO	19	-10	4	4	0	0	0	4	0	5	2	0
		DAY 22	03DEC2002	22	PP	-66	YES	10	-19	0	0	0	0	0	4	0	6	0	0
		DAY 29	11DEC2002	30	PP	-76	YES	7	-22	0	0	0	3	0	4	0	0	0	0
		DAY 36	18DEC2002	37	PP	-41	NO	17	-12	2	4	2	2	0	4	1	0	1	1
		DAY 43	26DEC2002	45	PP	-97	YES	1	-28	0	0	0	0	0	1	0	0	0	0
		DAY 50	02JAN2003	52	PP	10	NO	32	3	3	4	0	3	3	4	4	6	4	1
		DAY 57	09JAN2003	59	PP	-41	NO	17	-12	3	0	0	0	2	3	1	6	1	1
	E0026007	DAY 1	16JAN2003	1	PP			27		2	4	2	6	2	2	0	3	4	2
		DAY 8	23JAN2003	8	PP	-41	NO	16	-11	2	2	2	0	4	0	0	1	4	1
		DAY 15	30JAN2003	15	PP	-67	YES	9	-18	0	1	0	4	4	0	0	0	0	0
		DAY 22	06FEB2003	22	PP	-74	YES	7	-20	0	0	0	1	6	0	0	0	0	0
		DAY 29	13FEB2003	29	PP	-96	YES	1	-26	0	0	0	1	0	0	0	0	0	0
		DAY 36	19FEB2003	35	PP	-100	YES	0	-27	0	0	0	0	0	0	0	0	0	0
		DAY 43	26FEB2003	42	PP	-96	YES	1	-26	0	0	1	0	0	0	0	0	0	0
		DAY 50	05MAR2003	49	PP	-96	YES	1	-26	0	0	0	0	0	0	1	0	0	0
		DAY 57	12MAR2003	56	PP	-93	YES	2	-25	0	0	2	0	0	0	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR I)	E0026013	DAY 1	13FEB2003	1	PP			31		3	4	3	3	4	3	3	3	4	1
		DAY 8	20FEB2003	8	PP	0	NO	31	0	4	4	3	2	4	3	3	3	4	1
		DAY 15	27FEB2003	15	PP	-7	NO	29	-2	4	4	3	0	2	3	3	4	3	3
		DAY 22	06MAR2003	22	PP	32	NO	41	10	4	4	4	4	6	3	4	4	4	4
		DAY 29	13MAR2003	29	PP	-48	NO	16	-15	1	2	2	0	2	2	0	2	4	1
		DAY 36	20MAR2003	36	PP	36	NO	42	11	6	6	4	0	6	5	3	4	4	4
		DAY 43	27MAR2003	43	PP	-55	NO	14	-17	2	2	1	0	2	2	0	2	2	1
		DAY 50	03APR2003	50	PP	-61	YES	12	-19	1	1	2	0	0	2	0	2	3	1
	E0028007	DAY 1	04OCT2002	1	PP (38)			32		4	3	2	4	4	4	4	4	2	1
		DAY 8	11OCT2002	8	PP (38)	-69	YES	10	-22	2	2	2	0	0	0	2	0	2	0
		DAY 15	16OCT2002	13	PP (38)	-81	YES	6	-26	0	0	2	0	2	2	0	0	0	0
		DAY 22	23OCT2002	20	PP (38)	-75	YES	8	-24	0	1	2	0	0	1	2	2	0	0
		DAY 29	31OCT2002	28	PP (38)	-88	YES	4	-28	0	2	2	0	0	0	0	0	0	0
		DAY 36	07NOV2002	35	PP (38)	-94	YES	2	-30	0	0	2	0	0	0	0	0	0	0
		DAY 43	14NOV2002	42	PP (38)	-75	YES	8	-24	2	2	0	0	0	2	0	0	2	0
	E0028023	DAY 1	21JAN2003	1	ITT			27		4	4	4	4	0	2	3	2	4	0
		DAY 8	30JAN2003	10	ITT	4	NO	28	1	4	4	4	0	0	2	4	4	4	2
		DAY 15	04FEB2003	15	ITT	-11	NO	24	-3	2	4	2	4	0	4	4	4	0	0
		DAY 22	11FEB2003	22	ITT	7	NO	29	2	4	4	2	4	0	2	3	4	4	2
		DAY 29	17FEB2003	28	ITT	-33	NO	18	-9	4	2	0	4	0	4	0	0	0	4
		DAY 36	27FEB2003	38	ITT	-85	YES	4	-23	1	1	0	2	0	0	0	0	0	0
		DAY 43	04MAR2003	43	ITT	-100	YES	0	-27	0	0	0	0	0	0	0	0	0	0
	E0028025	DAY 1	13JAN2003	1	PP			30		2	4	4	4	4	2	2	2	2	4
		DAY 8	17JAN2003	5	PP	-70	YES	9	-21	0	2	0	1	0	2	2	2	0	0
		DAY 15	27JAN2003	15	PP	-37	NO	19	-11	2	1	1	4	1	2	2	4	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	DAY 1		27MAR2003	1	PP			18		2	2	1	2	2	3	2	2	2	0
		DAY 8		03APR2003	8	PP	11	NO	20	2	2	2	2	3	0	3	3	3	2	0
		DAY 15		10APR2003	15	PP	-6	NO	17	-1	2	1	1	1	1	3	3	3	2	0
		DAY 22		17APR2003	22	PP	-33	YES	12	-6	2	1	1	2	0	2	2	1	1	0
		DAY 29		24APR2003	29	PP	-50	YES	9	-9	1	1	1	2	0	2	1	1	0	0
		DAY 36		01MAY2003	36	PP	-11	NO	16	-2	3	3	2	2	0	2	2	2	0	0
		DAY 43		08MAY2003	43	PP	39	NO	25	7	3	3	3	4	1	3	3	3	2	0
		DAY 50		15MAY2003	50	PP	-11	NO	16	-2	2	2	2	2	0	4	2	0	2	0
		DAY 57		22MAY2003	57	PP	-61	YES	7	-11	1	1	0	2	0	1	1	1	0	0
	E0028035	DAY 1		03APR2003	1	PP			32		4	4	2	4	0	2	4	4	4	4
		DAY 8		10APR2003	8	PP	-16	NO	27	-5	4	3	2	4	0	2	4	2	4	2
		DAY 15		17APR2003	15	PP	-25	NO	24	-8	4	4	0	0	0	2	4	4	4	2
		DAY 22		24APR2003	22	PP	-25	NO	24	-8	3	4	1	0	0	3	3	4	4	2
		DAY 29		01MAY2003	29	PP	-81	YES	6	-26	0	0	0	0	0	2	2	0	2	0
		DAY 36		08MAY2003	36	PP	-38	NO	20	-12	2	2	4	0	0	4	4	2	2	0
		DAY 43		15MAY2003	43	PP	-75	YES	8	-24	0	0	2	4	0	2	0	0	0	0
		DAY 50		22MAY2003	50	PP	-28	NO	23	-9	2	3	2	0	0	4	4	2	4	2
		DAY 57		29MAY2003	57	PP	-44	NO	18	-14	2	2	4	2	0	2	2	2	2	0
	E0028037	DAY 1		12JUN2003	-1	PP			26		4	2	4	4	0	4	4	2	2	0
		DAY 8		20JUN2003	8	PP	-39	NO	16	-10	2	2	4	0	0	0	0	2	4	2
		DAY 15		25JUN2003	13	PP	-54	YES	12	-14	2	2	2	0	0	2	0	2	2	0
		DAY 15	*	01JUL2003	19	PP	-77	YES	6	-20	2	1	3	0	0	0	0	0	0	0
		DAY 22		08JUL2003	26	PP	-81	YES	5	-21	0	0	1	0	0	2	0	0	2	0
		DAY 36		16JUL2003	34	PP	-81	YES	5	-21	0	1	2	0	0	0	0	0	2	0
		DAY 43		23JUL2003	41	PP	-85	YES	4	-22	0	0	2	2	0	0	0	0	0	0
		DAY 50		30JUL2003	48	PP	-85	YES	4	-22	0	1	1	0	0	0	0	0	0	2
		DAY 57		08AUG2003	57	PP	-92	YES	2	-24	0	0	2	0	0	0	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 1	08MAY2003	-1	PP			31		3	3	3	4	4	3	3	3	2	3
		DAY 8	16MAY2003	8	PP	-10	NO	28	-3	2	2	4	2	4	2	2	2	4	4
		DAY 15	22MAY2003	14	PP	-19	NO	25	-6	3	3	3	1	4	4	1	1	3	2
		DAY 22	29MAY2003	21	PP	-23	NO	24	-7	3	3	3	1	3	3	3	2	1	2
		DAY 29	05JUN2003	28	PP	-39	NO	19	-12	2	2	2	2	2	3	2	2	2	0
	E0028046	DAY 1	25JUN2003	1	SAFETY			34		4	4	4	4	2	4	4	4	2	2
	E0028048	DAY 1	17JUL2003	1	PP			28		4	4	4	4	2	2	2	4	2	0
		DAY 8	24JUL2003	8	PP	-25	NO	21	-7	4	4	1	0	0	4	4	4	0	0
		DAY 15	31JUL2003	15	PP	-71	YES	8	-20	2	2	2	0	0	2	0	0	0	0
		DAY 22	06AUG2003	21	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
		DAY 29	14AUG2003	29	PP	-93	YES	2	-26	0	0	0	0	0	0	2	0	0	0
		DAY 36	21AUG2003	36	PP	-93	YES	2	-26	0	0	0	0	0	0	2	0	0	0
		DAY 43	29AUG2003	44	PP	-71	YES	8	-20	2	0	0	0	0	2	2	2	0	0
		DAY 57	09SEP2003	55	PP	-57	YES	12	-16	2	0	2	0	0	2	4	2	0	0
	E0029008	DAY 1	16DEC2002	1	ITT			32		4	4	2	3	3	4	4	5	2	1
		DAY 8	23DEC2002	8	ITT	9	NO	35	3	5	5	4	2	3	4	4	6	2	0
	E0029011	DAY 1	21JAN2003	-1	PP			34		4	4	4	2	3	4	4	5	2	2
		DAY 8	28JAN2003	7	PP	-15	NO	29	-5	3	4	4	4	2	2	4	2	3	1
		DAY 15	04FEB2003	14	PP	-15	NO	29	-5	3	4	4	3	2	3	2	4	4	0
		DAY 22	13FEB2003	23	PP	-21	NO	27	-7	4	4	2	0	4	3	3	4	3	0
	E0029012	DAY 1	11FEB2003	1	PP			33		5	5	4	4	0	2	2	4	2	5
		DAY 8	19FEB2003	9	PP	-21	NO	26	-7	4	4	2	1	0	3	4	4	1	3
		DAY 15	26FEB2003	16	PP	-24	NO	25	-8	2	5	2	0	0	4	4	3	1	4
		DAY 22	03MAR2003	21	PP	-33	NO	22	-11	3	3	3	0	0	2	3	4	2	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	DAY 29	11MAR2003	29	PP	12	NO	37	4	6	5	3	2	0	4	4	4	4	5
		DAY 36	18MAR2003	36	PP	15	NO	38	5	6	6	4	0	0	4	4	5	4	5
	E0029015	DAY 1	24FEB2003	1	PP (16)			29		3	4	4	2	1	4	4	3	3	1
		DAY 8	03MAR2003	8	PP (16)	-28	NO	21	-8	2	2	6	4	0	3	2	0	1	1
		DAY 15	11MAR2003	16	PP (16)	0	NO	29	0	3	3	4	4	3	2	4	3	3	0
	E0029018	DAY 1	06MAR2003	1	SAFETY			27		4	4	2	5	0	4	4	4	0	0
	E0030014	DAY 1	21FEB2003	1	PP			40		4	5	2	5	5	4	4	4	4	3
		DAY 8	28FEB2003	8	PP	-45	NO	22	-18	1	1	1	0	4	4	4	4	2	1
		DAY 15	07MAR2003	15	PP	-43	NO	23	-17	3	3	2	0	2	4	2	4	2	1
		DAY 22	14MAR2003	22	PP	-58	NO	17	-23	2	2	2	0	0	4	2	2	2	1
		DAY 29	21MAR2003	29	PP	-63	NO	15	-25	1	2	3	0	0	2	2	2	2	1
		DAY 36	27MAR2003	35	PP	-68	NO	13	-27	1	2	2	2	0	0	2	2	2	0
		DAY 43	04APR2003	43	PP	-50	NO	20	-20	1	3	3	2	0	2	2	2	2	3
		DAY 50	11APR2003	50	PP	-65	NO	14	-26	0	2	2	1	1	2	1	1	2	2
		DAY 57	22APR2003	61	PP	-75	YES	10	-30	1	1	1	0	2	0	1	2	2	0
	E0030020	DAY 1	29MAY2003	1	PP			32		4	4	3	3	3	1	4	4	3	3
		DAY 8	05JUN2003	8	PP	-31	NO	22	-10	3	3	3	0	0	3	3	3	4	0
		DAY 15	12JUN2003	15	PP	-72	YES	9	-23	1	0	1	0	0	1	2	1	3	0
		DAY 22	17JUN2003	20	PP	-75	YES	8	-24	1	1	2	0	1	0	0	1	2	0
		DAY 29	24JUN2003	27	PP	-88	YES	4	-28	0	0	0	1	0	3	0	0	0	0
	E0030024	DAY 1	11JUL2003	1	ITT			30		4	3	4	4	4	0	4	4	2	1
		DAY 8	18JUL2003	8	ITT	-20	NO	24	-6	2	3	3	3	2	4	2	3	1	1
	E0030025	DAY 1	11JUL2003	1	PP			42		5	4	4	6	3	4	4	5	4	3

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0030025	DAY 8	18JUL2003	8	PP	-26	NO	31	-11	4	4	2	4	2	4	2	4	4	1
		DAY 15	25JUL2003	15	PP	-62	NO	16	-26	2	2	2	2	3	0	1	1	2	1
		DAY 22	31JUL2003	21	PP	-60	NO	17	-25	3	1	1	2	2	3	1	2	1	1
		DAY 29	11AUG2003	32	PP	-52	NO	20	-22	3	3	1	0	3	2	2	3	2	1
		DAY 36	19AUG2003	40	PP	-21	NO	33	-9	5	3	4	2	4	2	3	4	4	2
	E0031027	DAY 1	03JUN2003	1	PP			22		2	3	2	3	3	2	2	2	3	0
		DAY 8	11JUN2003	9	PP	-18	NO	18	-4	2	3	3	4	3	0	2	1	0	0
		DAY 15	17JUN2003	15	PP	-9	NO	20	-2	2	4	3	3	2	0	1	2	3	0
		DAY 22	24JUN2003	22	PP	-46	YES	12	-10	0	1	2	5	2	0	1	1	0	0
		DAY 29	01JUL2003	29	PP	-14	NO	19	-3	2	2	3	4	3	2	2	1	0	0
		DAY 36	09JUL2003	37	PP	-59	YES	9	-13	0	2	2	1	1	1	1	1	0	0
		DAY 43	15JUL2003	43	PP	-96	YES	1	-21	0	1	0	0	0	0	0	0	0	0
		DAY 50	22JUL2003	50	PP	-82	YES	4	-18	0	0	2	2	0	0	0	0	0	0
		DAY 57	29JUL2003	57	PP	-100	YES	0	-22	0	0	0	0	0	0	0	0	0	0
	E0031030	DAY 1	24JUN2003	1	PP			28		3	4	1	5	2	2	4	3	2	2
		DAY 8	01JUL2003	8	PP	-54	NO	13	-15	1	2	2	2	0	2	0	2	2	0
		DAY 15	08JUL2003	15	PP	-57	YES	12	-16	0	0	2	5	0	3	1	1	0	0
		DAY 22	16JUL2003	23	PP	-68	YES	9	-19	0	0	2	3	2	1	0	1	0	0
		DAY 29	23JUL2003	30	PP	-89	YES	3	-25	0	0	0	2	0	1	0	0	0	0
		DAY 36	31JUL2003	38	PP	-93	YES	2	-26	0	0	0	2	0	0	0	0	0	0
		DAY 43	08AUG2003	46	PP	-86	YES	4	-24	0	0	0	4	0	0	0	0	0	0
		DAY 50	14AUG2003	52	PP	-25	NO	21	-7	2	2	2	4	4	1	2	2	2	0
		DAY 57	21AUG2003	59	PP	-75	YES	7	-21	1	0	2	3	0	0	1	0	0	0
	E0033012	DAY 1	10FEB2003	1	SAFETY			41		4	5	4	4	4	4	4	4	4	4
	E0034001	DAY 1	20MAR2003	1	PP			30		4	4	3	4	0	4	4	3	4	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	DAY 8		27MAR2003	8	PP	-10	NO	27	-3	4	3	3	2	0	4	4	3	4	0
		DAY 15		03APR2003	15	PP	-70	YES	9	-21	1	2	2	0	0	2	2	0	0	0
		DAY 22		10APR2003	22	PP	-70	YES	9	-21	2	2	2	0	0	0	3	0	0	0
		DAY 29		17APR2003	29	PP	-67	YES	10	-20	2	2	2	0	0	0	3	0	1	0
		DAY 36		24APR2003	36	PP	-73	YES	8	-22	2	2	2	0	0	0	2	0	0	0
		DAY 43		01MAY2003	43	PP	-70	YES	9	-21	3	2	2	0	0	0	2	0	0	0
		DAY 50		08MAY2003	50	PP	-70	YES	9	-21	3	2	2	0	0	0	2	0	0	0
		DAY 57		15MAY2003	57	PP	-80	YES	6	-24	2	2	0	0	0	0	2	0	0	0
	E0034004	DAY 1		21APR2003	1	PP			32		4	4	3	4	0	4	4	3	3	3
		DAY 8		30APR2003	10	PP	-31	NO	22	-10	3	3	2	0	0	2	4	3	3	2
		DAY 15		05MAY2003	15	PP	-56	NO	14	-18	2	2	2	2	0	1	2	1	1	1
		DAY 22		13MAY2003	23	PP	-91	YES	3	-29	1	1	0	0	0	0	1	0	0	0
		DAY 29		19MAY2003	29	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 29	*	23MAY2003	33	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 43		02JUN2003	43	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 50		09JUN2003	50	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
		DAY 57		16JUN2003	57	PP	-100	YES	0	-32	0	0	0	0	0	0	0	0	0	0
	E0035001	DAY 1		20NOV2002	1	PP			25		3	3	3	4	5	2	2	0	2	1
		DAY 8		27NOV2002	8	PP	-44	NO	14	-11	2	2	2	1	2	2	1	0	2	0
		DAY 15		03DEC2002	14	PP	-48	NO	13	-12	2	2	2	1	2	2	0	0	2	0
		DAY 22		12DEC2002	23	PP	-52	YES	12	-13	2	2	2	1	2	2	0	0	1	0
		DAY 29		18DEC2002	29	PP	-68	YES	8	-17	1	1	2	0	1	2	0	0	1	0
		DAY 36		23DEC2002	34	PP	-72	YES	7	-18	1	1	2	0	0	2	0	0	1	0
		DAY 43		30DEC2002	41	PP	-80	YES	5	-20	1	1	2	0	0	1	0	0	0	0
		DAY 50		07JAN2003	49	PP	-80	YES	5	-20	1	1	2	0	0	1	0	0	0	0
		DAY 57		14JAN2003	56	PP	-96	YES	1	-24	0	0	0	1	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 1	12DEC2002	1	PP			30		3	3	3	4	3	3	3	3	3	2
		DAY 8	19DEC2002	8	PP	7	NO	32	2	4	4	3	4	3	3	2	3	3	3
		DAY 15	26DEC2002	15	PP	17	NO	35	5	4	4	3	5	4	3	2	4	3	3
		DAY 22	02JAN2003	22	PP	3	NO	31	1	4	4	3	3	4	3	1	3	3	3
		DAY 29	09JAN2003	29	PP	7	NO	32	2	4	4	3	4	4	3	3	2	2	3
		DAY 36	16JAN2003	36	PP	27	NO	38	8	4	4	4	5	5	3	3	4	3	3
		DAY 43	24JAN2003	44	PP	23	NO	37	7	4	4	4	3	5	3	4	3	4	3
		DAY 50	30JAN2003	50	PP	23	NO	37	7	4	4	4	4	6	3	0	4	4	4
		DAY 57	06FEB2003	57	PP	-33	NO	20	-10	3	3	2	4	4	3	0	1	0	0
	E0035021	DAY 1	25APR2003	1	PP			28		4	4	3	4	0	2	4	3	4	0
		DAY 8	01MAY2003	7	PP	-50	NO	14	-14	1	2	2	0	2	2	2	1	2	0
		DAY 15	09MAY2003	15	PP	-75	YES	7	-21	1	0	0	0	3	0	3	0	0	0
		DAY 22	15MAY2003	21	PP	-61	YES	11	-17	2	2	2	0	2	0	1	0	2	0
		DAY 29	23MAY2003	29	PP	-68	YES	9	-19	1	2	2	0	2	0	0	0	2	0
		DAY 36	30MAY2003	36	PP	-32	NO	19	-9	3	2	0	0	4	2	4	0	4	0
		DAY 43	09JUN2003	46	PP	-93	YES	2	-26	1	0	0	0	0	0	1	0	0	0
		DAY 50	13JUN2003	50	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
		DAY 57	20JUN2003	57	PP	-71	YES	8	-20	1	2	0	0	2	1	0	0	2	0
	E0036002	DAY 1	17JUN2003	1	PP			41		4	4	4	5	5	4	5	4	4	2
		DAY 8	24JUN2003	8	PP	-20	NO	33	-8	3	3	4	0	4	4	4	5	4	2
		DAY 15	30JUN2003	14	PP	-46	NO	22	-19	2	3	2	0	2	3	4	3	3	0
		DAY 22	08JUL2003	22	PP	-66	NO	14	-27	0	1	4	0	0	3	1	3	2	0
		DAY 29	14JUL2003	28	PP	-73	YES	11	-30	0	0	4	2	0	5	0	0	0	0
	E0036006	DAY 1	03JUL2003	1	PP			34		4	4	4	4	0	5	4	4	4	1
		DAY 8	10JUL2003	8	PP	-71	YES	10	-24	1	0	0	0	0	3	4	2	0	0
		DAY 15	18JUL2003	16	PP	-88	YES	4	-30	0	0	0	0	0	2	2	0	0	0

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	DAY 22	25JUL2003	23	PP	-94	YES	2	-32	0	0	0	1	0	0	1	0	0	0
		DAY 29	31JUL2003	29	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 36	07AUG2003	36	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 43	13AUG2003	42	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 50	20AUG2003	49	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 57	27AUG2003	56	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
	E0036007	DAY 1	03JUL2003	1	PP			34		4	4	3	4	3	4	4	4	3	1
		DAY 8	08JUL2003	6	PP	-12	NO	30	-4	3	3	3	5	0	4	4	5	2	1
		DAY 15	18JUL2003	16	PP	-91	YES	3	-31	1	0	2	0	0	0	0	0	0	0
	E0037009	DAY 1	16MAY2003	1	PP			27		4	4	2	4	1	2	4	2	2	2
		DAY 8	23MAY2003	8	PP	-19	NO	22	-5	4	4	2	2	0	2	4	0	2	2
		DAY 15	29MAY2003	14	PP	-33	NO	18	-9	3	3	2	2	0	2	3	0	2	1
		DAY 22	05JUN2003	21	PP	-48	NO	14	-13	2	2	2	3	0	0	3	0	2	0
		DAY 29	12JUN2003	28	PP	-30	NO	19	-8	3	3	0	4	0	1	3	1	2	2
		DAY 36	19JUN2003	35	PP	-37	NO	17	-10	2	2	2	2	0	3	2	0	2	2
		DAY 43	26JUN2003	42	PP	-59	YES	11	-16	2	2	1	0	0	3	1	0	2	0
		DAY 50	03JUL2003	49	PP	-41	NO	16	-11	2	2	2	2	0	2	2	0	2	2
		DAY 57	10JUL2003	56	PP	-48	NO	14	-13	1	2	2	2	0	1	3	0	2	1
	E0039011	DAY 1	02JAN2003	1	PP			33		4	4	3	5	2	3	4	4	3	1
		DAY 8	09JAN2003	8	PP	-55	NO	15	-18	2	1	2	0	1	1	2	2	3	1
		DAY 15	16JAN2003	15	PP	-30	NO	23	-10	3	2	4	2	1	1	2	2	4	2
		DAY 22	23JAN2003	22	PP	-49	NO	17	-16	2	2	2	3	0	2	1	2	2	1
		DAY 29	03FEB2003	33	PP	-100	YES	0	-33	0	0	0	0	0	0	0	0	0	0
		DAY 36	06FEB2003	36	PP	-100	YES	0	-33	0	0	0	0	0	0	0	0	0	0
		DAY 43	13FEB2003	43	PP	-97	YES	1	-32	0	0	1	0	0	0	0	0	0	0
		DAY 50	19FEB2003	49	PP	-97	YES	1	-32	0	0	1	0	0	0	0	0	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0039018	DAY 1	23JAN2003	1	PP			33		4	5	3	5	1	3	3	4	3	2
		DAY 8	30JAN2003	8	PP	-64	YES	12	-21	2	2	1	1	0	1	1	2	2	0
		DAY 15	06FEB2003	15	PP	-46	NO	18	-15	3	2	4	2	0	2	0	2	2	1
		DAY 22	13FEB2003	22	PP	-76	YES	8	-25	2	1	2	0	0	1	0	1	0	1
		DAY 29	20FEB2003	29	PP	-88	YES	4	-29	1	0	2	0	0	0	1	0	0	0
	E0039026	DAY 1	07MAR2003	1	PP			31		4	4	3	3	1	4	4	4	3	1
		DAY 8	14MAR2003	8	PP	-71	YES	9	-22	1	1	2	0	0	2	2	1	0	0
		DAY 15	19MAR2003	13	PP	-87	YES	4	-27	0	0	2	0	0	1	0	1	0	0
		DAY 22	28MAR2003	22	PP	-87	YES	4	-27	0	1	1	0	0	1	1	0	0	0
		DAY 29	04APR2003	29	PP	-87	YES	4	-27	0	1	1	0	0	1	1	0	0	0
		DAY 36	11APR2003	36	PP	-71	YES	9	-22	1	1	2	0	0	2	2	1	0	0
		DAY 43	18APR2003	43	PP	-81	YES	6	-25	0	0	2	0	0	1	2	1	0	0
		DAY 50	25APR2003	50	PP	-90	YES	3	-28	0	0	0	0	0	1	1	0	1	0
		DAY 57	01MAY2003	56	PP	-94	YES	2	-29	0	0	0	0	0	1	1	0	0	0
	E0039028	DAY 1	24MAR2003	1	ITT			28		4	4	3	4	0	2	3	4	2	2
		DAY 8	31MAR2003	8	ITT	-54	NO	13	-15	1	1	3	0	0	2	2	3	1	0
		DAY 15	07APR2003	15	ITT	-57	YES	12	-16	2	2	2	0	0	1	1	2	2	0
		DAY 22	14APR2003	22	ITT	-82	YES	5	-23	0	1	2	0	0	1	0	1	0	0
		DAY 29	21APR2003	29	ITT	-21	NO	22	-6	3	3	3	3	1	1	1	3	2	2
		DAY 36	28APR2003	36	ITT	-43	NO	16	-12	2	3	3	0	0	2	2	2	1	1
		DAY 43	05MAY2003	43	ITT	-82	YES	5	-23	1	0	1	0	0	2	0	1	0	0
	E0039032	DAY 1	14MAR2003	1	PP			33		4	4	3	5	2	3	3	4	3	2
		DAY 8	19MAR2003	6	PP	-70	YES	10	-23	0	0	3	0	3	0	2	2	0	0
	E0039034	DAY 1	19MAR2003	1	PP			25		3	4	3	3	1	3	3	3	2	0
		DAY 8	26MAR2003	8	PP	-76	YES	6	-19	1	1	2	0	0	1	0	1	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	DAY 15	02APR2003	15	PP	-68	YES	8	-17	2	2	2	0	0	0	2	0	0	0
		DAY 22	09APR2003	22	PP	-84	YES	4	-21	0	0	1	0	0	1	1	1	0	0
		DAY 29	16APR2003	29	PP	-88	YES	3	-22	0	0	2	0	0	0	0	1	0	0
		DAY 36	24APR2003	37	PP	-88	YES	3	-22	0	0	1	0	0	1	1	0	0	0
		DAY 43	30APR2003	43	PP	-96	YES	1	-24	0	0	1	0	0	0	0	0	0	0
		DAY 50	09MAY2003	52	PP	-92	YES	2	-23	0	0	2	0	0	0	0	0	0	0
		DAY 57	14MAY2003	57	PP	-100	YES	0	-25	0	0	0	0	0	0	0	0	0	0
	E0039042	DAY 1	07MAY2003	1	PP			33		4	4	3	5	2	2	4	4	3	2
		DAY 8	14MAY2003	8	PP	-55	NO	15	-18	2	2	3	0	0	2	2	2	2	0
		DAY 15	21MAY2003	15	PP	-73	YES	9	-24	1	1	2	0	0	0	1	1	2	1
		DAY 22	28MAY2003	22	PP	-88	YES	4	-29	1	1	0	0	0	1	1	0	0	0
		DAY 29	05JUN2003	30	PP	-97	YES	1	-32	0	0	1	0	0	0	0	0	0	0
		DAY 36	11JUN2003	36	PP	-97	YES	1	-32	0	0	0	1	0	0	0	0	0	0
		DAY 43	18JUN2003	43	PP	-100	YES	0	-33	0	0	0	0	0	0	0	0	0	0
		DAY 50	25JUN2003	50	PP	-82	YES	6	-27	2	1	1	0	0	0	0	1	1	0
		DAY 57	02JUL2003	57	PP	-97	YES	1	-32	0	0	1	0	0	0	0	0	0	0
	E0041004	DAY 1	30JAN2003	1	PP			26		3	3	3	3	3	2	3	3	3	0
		DAY 8	10FEB2003	12	PP	-58	YES	11	-15	2	2	2	0	0	0	3	2	0	0
		DAY 15	14FEB2003	16	PP	-81	YES	5	-21	0	0	3	0	0	0	0	2	0	0
		DAY 22	20FEB2003	22	PP	-85	YES	4	-22	0	0	2	0	2	0	0	0	0	0
		DAY 29	27FEB2003	29	PP	-65	YES	9	-17	1	1	2	3	2	0	0	0	0	0
		DAY 36	07MAR2003	37	PP	-81	YES	5	-21	0	0	1	0	2	0	2	0	0	0
		DAY 43	14MAR2003	44	PP	-92	YES	2	-24	0	0	2	0	0	0	0	0	0	0
		DAY 50	21MAR2003	51	PP	-81	YES	5	-21	0	0	2	0	0	0	3	0	0	0
		DAY 57	31MAR2003	61	PP	-81	YES	5	-21	0	0	2	0	0	0	2	0	1	0
	E0041009	DAY 1	01MAY2003	1	PP			31		4	4	4	4	2	2	4	3	4	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	DAY 8	08MAY2003	8	PP	-42	NO	18	-13	2	2	0	3	0	2	3	3	3	0
		DAY 15	15MAY2003	15	PP	-26	NO	23	-8	2	3	3	4	0	2	3	3	3	0
		DAY 22	22MAY2003	22	PP	-81	YES	6	-25	0	0	0	2	0	2	2	0	0	0
	E0042002	DAY 1	09JUL2003	1	PP			20		4	3	2	3	0	3	2	1	2	0
		DAY 8	15JUL2003	7	PP	-55	YES	9	-11	2	1	2	0	0	2	1	0	1	0
		DAY 15	22JUL2003	14	PP	-85	YES	3	-17	0	0	1	1	0	1	0	0	0	0
		DAY 22	29JUL2003	21	PP	-80	YES	4	-16	0	0	1	0	0	1	1	0	1	0
		DAY 29	05AUG2003	28	PP	-100	YES	0	-20	0	0	0	0	0	0	0	0	0	0
		DAY 36	12AUG2003	35	PP	-95	YES	1	-19	0	1	0	0	0	0	0	0	0	0
		DAY 43	19AUG2003	42	PP	-95	YES	1	-19	0	1	0	0	0	0	0	0	0	0
		DAY 50	26AUG2003	49	PP	-95	YES	1	-19	0	0	0	0	0	0	0	1	0	0
		DAY 57	02SEP2003	56	PP	-100	YES	0	-20	0	0	0	0	0	0	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	ITT			34		4	4	5	1	0	5	6	4	4	1
		DAY 8	18JUL2003	8	ITT	-21	NO	27	-7	3	4	4	0	0	4	4	4	4	0
	E0003002	DAY 1	29OCT2002	1	PP			39		5	5	3	4	4	4	5	4	4	1
		DAY 8	05NOV2002	8	PP	-44	NO	22	-17	3	2	2	0	0	3	4	4	3	1
		DAY 15	14NOV2002	17	PP	-72	YES	11	-28	3	3	2	0	0	0	0	2	1	0
		DAY 22	19NOV2002	22	PP	-64	NO	14	-25	3	2	1	0	1	1	1	2	2	1
		DAY 29	26NOV2002	29	PP	-72	YES	11	-28	2	1	0	2	0	0	0	2	3	1
		DAY 36	03DEC2002	36	PP	-82	YES	7	-32	1	1	1	0	0	0	0	2	2	0
		DAY 43	10DEC2002	43	PP	-100	YES	0	-39	0	0	0	0	0	0	0	0	0	0
		DAY 50	17DEC2002	50	PP	-95	YES	2	-37	1	0	0	0	0	0	0	0	1	0
		DAY 57	23DEC2002	56	PP	-100	YES	0	-39	0	0	0	0	0	0	0	0	0	0
	E0005031	DAY 1	02APR2003	1	PP			29		4	3	4	2	2	4	3	3	4	0
		DAY 8	09APR2003	8	PP	-55	NO	13	-16	1	1	2	1	2	4	0	0	2	0
		DAY 15	16APR2003	15	PP	-69	YES	9	-20	0	0	1	0	1	3	1	1	1	1
		DAY 22	24APR2003	23	PP	-45	NO	16	-13	0	3	2	0	0	3	3	2	2	1
		DAY 29	01MAY2003	30	PP	-35	NO	19	-10	1	2	2	0	0	4	4	3	2	1
		DAY 36	07MAY2003	36	PP	-66	YES	10	-19	1	1	2	0	0	2	2	2	0	0
		DAY 43	14MAY2003	43	PP	-66	YES	10	-19	0	1	2	0	0	4	0	1	2	0
	E0005033	DAY 1	15APR2003	-1	PP			38		4	4	4	4	2	4	4	4	4	4
		DAY 8	22APR2003	7	PP	-13	NO	33	-5	4	4	4	1	2	4	4	4	4	2
		DAY 15	30APR2003	15	PP	-21	NO	30	-8	4	4	4	0	0	4	4	4	4	2
		DAY 22	06MAY2003	21	PP	-16	NO	32	-6	4	4	4	2	0	4	4	4	4	2
	E0005038	DAY 1	14MAY2003	1	PP			35		4	4	3	4	2	4	4	4	4	2
		DAY 8	22MAY2003	9	PP	-9	NO	32	-3	4	4	3	3	2	2	4	4	4	2
		DAY 15	28MAY2003	15	PP	-6	NO	33	-2	4	4	4	4	0	3	4	4	4	2

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# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
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Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0005038	DAY 22		05JUN2003	23	PP	-6	NO	33	-2	4	4	3	3	2	2	4	4	4	3
	E0007009	DAY 1		17APR2003	1	ITT			26		4	4	2	0	2	3	2	4	4	1
		DAY 8		24APR2003	8	ITT	-12	NO	23	-3	4	4	2	0	0	3	3	4	2	1
		DAY 8	*	28APR2003	12	ITT	-8	NO	24	-2	4	4	1	0	2	3	2	4	3	1
	E0009010	DAY 1		13MAR2003	1	PP			34		3	4	3	4	3	4	3	4	3	3
		DAY 8		20MAR2003	8	PP	-32	NO	23	-11	3	3	4	2	1	3	0	2	3	2
		DAY 15		26MAR2003	14	PP	-38	NO	21	-13	2	3	2	2	0	3	3	2	2	2
		DAY 22		02APR2003	21	PP	-38	NO	21	-13	3	4	4	2	0	1	1	2	2	2
	E0009011	DAY 1		06MAY2003	1	PP			31		4	5	0	2	3	3	5	4	3	2
		DAY 8		12MAY2003	7	PP	-36	NO	20	-11	2	2	1	2	0	1	3	3	3	3
		DAY 15		19MAY2003	14	PP	-32	NO	21	-10	2	2	2	0	3	2	3	4	2	1
		DAY 22		27MAY2003	22	PP	-58	NO	13	-18	1	1	2	0	2	1	1	1	3	1
		DAY 29		03JUN2003	29	PP	-90	YES	3	-28	0	0	1	0	2	0	0	0	0	0
		DAY 36		10JUN2003	36	PP	-100	YES	0	-31	0	0	0	0	0	0	0	0	0	0
		DAY 43		17JUN2003	43	PP	-32	NO	21	-10	2	3	0	0	4	1	3	4	2	2
		DAY 50		24JUN2003	50	PP	-100	YES	0	-31	0	0	0	0	0	0	0	0	0	0
		DAY 57		03JUL2003	59	PP	-77	YES	7	-24	2	0	0	0	0	0	0	2	2	1
	E0010005	DAY 1		18DEC2002	1	SAFETY			29		3	3	5	5	0	3	4	4	2	0
	E0011016	DAY 1		21APR2003	1	PP			28		3	4	3	4	0	4	3	3	2	2
		DAY 8		28APR2003	8	PP	-11	NO	25	-3	1	2	3	3	1	4	3	3	2	3
		DAY 15		05MAY2003	15	PP	25	NO	35	7	4	4	4	5	2	4	2	3	3	4
		DAY 22		12MAY2003	22	PP	7	NO	30	2	3	4	4	2	2	4	3	3	3	2
		DAY 29		19MAY2003	29	PP	0	NO	28	0	3	4	3	0	2	4	2	3	3	4
		DAY 36		27MAY2003	37	PP	0	NO	28	0	4	4	3	0	0	4	3	3	3	4

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	DAY 43		02JUN2003	43	PP	11	NO	31	3	3	4	4	2	2	4	2	3	3	4
		DAY 50		09JUN2003	50	PP	-18	NO	23	-5	3	3	3	1	2	2	2	2	3	2
		DAY 57		16JUN2003	57	PP	-7	NO	26	-2	2	3	3	2	2	4	2	3	3	2
	E0011020	DAY 1		08MAY2003	1	SAFETY			28		3	4	3	4	1	2	4	3	3	1
	E0018002	DAY 1		29NOV2002	1	PP			31		4	4	4	4	3	3	3	3	2	1
		DAY 8		04DEC2002	6	PP	-3	NO	30	-1	4	4	4	1	1	4	5	3	3	1
		DAY 15		11DEC2002	13	PP	-55	NO	14	-17	2	2	2	0	0	3	2	1	2	0
		DAY 22		18DEC2002	20	PP	-48	NO	16	-15	1	2	2	0	2	2	2	2	2	1
		DAY 22	*	24DEC2002	26	PP	-29	NO	22	-9	3	3	3	2	2	3	2	2	2	0
		DAY 29		30DEC2002	32	PP	-32	NO	21	-10	2	2	2	2	1	3	3	3	3	0
		DAY 43		08JAN2003	41	PP	-55	NO	14	-17	2	2	0	3	3	2	1	0	1	0
		DAY 50		15JAN2003	48	PP	-36	NO	20	-11	3	3	3	0	0	3	3	3	2	0
		DAY 57		22JAN2003	55	PP	-23	NO	24	-7	3	3	4	2	0	4	3	3	2	0
	E0018003	DAY 1		26NOV2002	1	PP			29		4	4	4	3	2	3	3	3	3	0
		DAY 8		03DEC2002	8	PP	3	NO	30	1	4	4	2	0	3	4	4	4	4	1
		DAY 15		10DEC2002	15	PP	-24	NO	22	-7	3	3	2	0	0	4	4	3	3	0
	E0018013	DAY 1		24JAN2003	1	ITT			33		4	4	4	4	0	4	4	4	4	1
		DAY 8		31JAN2003	8	ITT	-36	NO	21	-12	3	3	3	2	0	3	3	2	2	0
	E0019002	DAY 1		12NOV2002	1	ITT			27		3	3	4	1	0	4	4	4	3	1
		DAY 8		19NOV2002	8	ITT	-67	YES	9	-18	2	0	0	0	0	1	3	2	1	0
	E0019008	DAY 1		21NOV2002	1	PP			31		2	3	4	4	4	4	4	1	4	1
		DAY 8		27NOV2002	7	PP	-10	NO	28	-3	4	3	3	3	2	2	4	2	3	2
		DAY 15		05DEC2002	15	PP	-16	NO	26	-5	3	2	2	3	2	3	4	3	2	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0019008	DAY 22	12DEC2002	22	PP	-42	NO	18	-13	2	1	2	2	2	2	3	1	2	1
		DAY 29	19DEC2002	29	PP	-81	YES	6	-25	1	0	1	0	0	1	2	1	0	0
	E0019009	DAY 1	14NOV2002	1	PP			22		1	2	4	3	0	4	4	0	4	0
		DAY 8	21NOV2002	8	PP	-18	NO	18	-4	2	0	4	0	2	3	2	1	4	0
		DAY 15	27NOV2002	14	PP	18	NO	26	4	2	0	4	5	3	2	0	4	4	2
		DAY 22	05DEC2002	22	PP	-32	NO	15	-7	2	2	2	0	2	0	2	1	2	2
		DAY 29	10DEC2002	27	PP	14	NO	25	3	4	2	3	0	2	2	5	4	1	2
	E0019016	DAY 1	06JAN2003	1	PP			31		3	4	4	4	0	3	4	4	4	1
		DAY 8	13JAN2003	8	PP	-55	NO	14	-17	2	4	3	0	0	0	2	2	1	0
		DAY 15	20JAN2003	15	PP	-58	NO	13	-18	2	2	1	0	1	2	2	1	2	0
		DAY 22	27JAN2003	22	PP	-65	YES	11	-20	2	1	0	3	2	1	1	1	0	0
		DAY 29	03FEB2003	29	PP	-61	YES	12	-19	2	2	2	2	1	0	1	1	1	0
		DAY 36	10FEB2003	36	PP	-68	YES	10	-21	2	1	2	2	0	0	1	1	1	0
		DAY 43	17FEB2003	43	PP	-87	YES	4	-27	0	0	2	1	0	0	1	0	0	0
		DAY 50	27FEB2003	53	PP	-77	YES	7	-24	1	0	0	3	0	3	0	0	0	0
		DAY 57	03MAR2003	57	PP	-90	YES	3	-28	0	0	0	3	0	0	0	0	0	0
	E0019020	DAY 1	23JAN2003	1	PP (64)			31		3	2	4	4	2	3	4	4	4	1
		DAY 8	30JAN2003	8	PP (64)	-7	NO	29	-2	5	4	3	3	0	2	4	4	3	1
		DAY 15	06FEB2003	15	PP (64)	-71	YES	9	-22	1	1	2	1	0	0	1	1	2	0
		DAY 22	13FEB2003	22	PP (64)	-61	YES	12	-19	2	1	2	0	0	1	2	2	2	0
		DAY 29	20FEB2003	29	PP (64)	-71	YES	9	-22	2	1	1	0	0	0	2	2	1	0
		DAY 36	27FEB2003	36	PP (64)	-55	NO	14	-17	2	2	2	4	0	0	1	1	2	0
		DAY 43	06MAR2003	43	PP (64)	-58	NO	13	-18	2	2	2	0	0	0	3	1	3	0
		DAY 50	13MAR2003	50	PP (64)	-68	YES	10	-21	1	1	0	1	0	0	2	2	2	1
		DAY 57	27MAR2003	64	PP (64)	16	NO	36	5	3	4	4	6	0	4	4	4	4	3

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	DAY 1	30JAN2003	1	PP (33)			33		5	4	4	5	0	2	4	4	4	1
		DAY 8	06FEB2003	8	PP (33)	-46	NO	18	-15	2	2	3	3	0	1	2	2	2	1
		DAY 29	03MAR2003	33	PP (33)	-33	NO	22	-11	4	2	2	4	0	2	4	2	1	1
	E0019024	DAY 1	30JAN2003	1	PP			25		4	3	3	4	0	3	2	2	3	1
		DAY 8	06FEB2003	8	PP	-60	YES	10	-15	2	2	2	1	0	1	1	1	0	0
	E0019031	DAY 1	13MAR2003	1	ITT			35		4	4	3	2	4	5	4	4	4	1
		DAY 15	25MAR2003	13	ITT	-63	NO	13	-22	3	3	0	0	0	3	4	0	0	0
	E0019035	DAY 1	18MAR2003	1	PP			34		4	5	4	2	0	4	5	4	4	2
		DAY 8	27MAR2003	10	PP	-15	NO	29	-5	3	4	4	0	0	4	4	4	4	2
		DAY 15	03APR2003	17	PP	-27	NO	25	-9	2	2	4	1	0	4	4	4	3	1
		DAY 22	10APR2003	24	PP	6	NO	36	2	4	4	4	0	2	4	6	4	4	4
		DAY 29	17APR2003	31	PP	-47	NO	18	-16	2	3	3	0	0	3	2	2	2	1
	E0019040	DAY 1	20MAY2003	1	PP			30		3	4	4	5	2	3	0	4	4	1
		DAY 8	29MAY2003	10	PP	-10	NO	27	-3	3	4	4	0	2	3	2	4	4	1
		DAY 15	05JUN2003	17	PP	-20	NO	24	-6	3	4	4	2	0	2	0	4	4	1
		DAY 22	12JUN2003	24	PP	-27	NO	22	-8	3	3	3	0	2	2	2	2	4	1
		DAY 29	18JUN2003	30	PP	-27	NO	22	-8	3	3	3	0	1	2	2	3	4	1
		DAY 36	26JUN2003	38	PP	-77	YES	7	-23	0	0	0	0	0	2	2	2	0	1
		DAY 43	03JUL2003	45	PP	-63	YES	11	-19	1	2	0	2	0	0	2	0	4	0
		DAY 50	10JUL2003	52	PP	-30	NO	21	-9	4	2	3	2	0	2	4	2	2	0
		DAY 57	17JUL2003	59	PP	-60	YES	12	-18	2	1	2	1	0	0	1	3	2	0
	E0019042	DAY 1	04JUN2003	1	PP			31		3	4	3	5	0	4	4	3	4	1
		DAY 8	12JUN2003	9	PP	-45	NO	17	-14	4	3	3	0	0	4	0	2	0	1
		DAY 15	19JUN2003	16	PP	-48	NO	16	-15	1	0	2	0	0	4	4	3	2	0

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	DAY 1	26JUN2003	1	PP (12)			32		4	4	3	4	4	3	4	4	2	0
		DAY 8	03JUL2003	8	PP (12)	-22	NO	25	-7	4	4	1	0	0	4	5	4	1	2
	E0020024	DAY 1	23JUN2003	1	PP			18		2	2	3	2	0	3	4	2	0	0
		DAY 8	30JUN2003	8	PP	22	NO	22	4	4	4	3	2	0	3	4	0	2	0
		DAY 15	07JUL2003	15	PP	-22	NO	14	-4	3	0	2	3	0	3	2	0	0	1
		DAY 22	15JUL2003	23	PP	-33	YES	12	-6	2	0	0	0	0	4	4	0	2	0
		DAY 29	21JUL2003	29	PP	-61	YES	7	-11	1	0	0	0	0	3	2	1	0	0
		DAY 36	28JUL2003	36	PP	-89	YES	2	-16	0	0	0	0	0	2	0	0	0	0
		DAY 43	04AUG2003	43	PP	-72	YES	5	-13	0	0	0	0	0	3	0	0	2	0
		DAY 50	12AUG2003	51	PP	-61	YES	7	-11	0	0	0	4	0	0	2	0	1	0
		DAY 57	20AUG2003	59	PP	-67	YES	6	-12	0	0	0	0	0	3	3	0	0	0
	E0022044	DAY 1	18MAR2003	1	PP			32		4	4	2	4	2	4	4	4	2	2
		DAY 8	25MAR2003	8	PP	-19	NO	26	-6	3	3	3	2	0	4	3	4	2	2
		DAY 15	01APR2003	15	PP	-38	NO	20	-12	3	2	3	2	0	2	3	2	2	1
		DAY 22	08APR2003	22	PP	-25	NO	24	-8	2	2	3	4	0	2	3	4	2	2
		DAY 29	15APR2003	29	PP	-31	NO	22	-10	2	2	4	2	0	4	3	2	2	1
		DAY 36	22APR2003	36	PP	-3	NO	31	-1	3	3	4	4	2	4	4	4	2	1
		DAY 43	29APR2003	43	PP	-25	NO	24	-8	3	3	2	3	0	4	2	4	2	1
		DAY 50	06MAY2003	50	PP	-6	NO	30	-2	4	4	4	2	0	4	4	4	2	2
		DAY 57	12MAY2003	56	PP	-25	NO	24	-8	3	3	3	4	0	3	3	2	2	1
	E0023007	DAY 1	14JAN2003	1	PP			25		3	2	3	3	2	3	3	3	2	1
		DAY 8	21JAN2003	8	PP	-24	NO	19	-6	2	2	2	0	2	2	3	3	3	0
		DAY 15	28JAN2003	15	PP	-40	NO	15	-10	2	2	1	0	2	1	3	2	2	0
		DAY 22	07FEB2003	25	PP	-76	YES	6	-19	1	1	0	0	0	2	1	1	0	0
		DAY 29	11FEB2003	29	PP	-72	YES	7	-18	1	1	0	0	1	2	1	1	0	0
		DAY 36	18FEB2003	36	PP	-32	NO	17	-8	2	1	1	0	1	4	2	5	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	DAY 43		25FEB2003	43	PP	-60	YES	10	-15	0	0	0	0	1	4	2	3	0	0
		DAY 50		04MAR2003	50	PP	-60	YES	10	-15	0	0	0	0	1	4	2	3	0	0
		DAY 57		11MAR2003	57	PP	-84	YES	4	-21	0	0	0	0	0	3	1	0	0	0
	E0023011	DAY 1		04FEB2003	1	PP			34		4	4	4	4	2	3	3	4	3	3
		DAY 8		11FEB2003	8	PP	-18	NO	28	-6	3	3	4	3	2	3	2	4	2	2
		DAY 15		21FEB2003	18	PP	-21	NO	27	-7	3	3	4	3	0	3	3	4	3	1
		DAY 22		25FEB2003	22	PP	-29	NO	24	-10	3	2	4	3	0	2	3	3	3	1
		DAY 29		04MAR2003	29	PP	-44	NO	19	-15	2	2	3	3	0	1	2	3	2	1
		DAY 36		11MAR2003	36	PP	-47	NO	18	-16	2	2	3	3	0	2	2	2	1	1
		DAY 43		18MAR2003	43	PP	-18	NO	28	-6	4	3	4	2	0	4	2	3	3	3
		DAY 50		27MAR2003	52	PP	-56	NO	15	-19	2	2	3	4	0	1	1	0	1	1
		DAY 57		01APR2003	57	PP	-53	NO	16	-18	2	2	3	2	0	2	1	1	2	1
	E0023014	DAY 1		21FEB2003	1	PP			30		4	5	3	3	0	4	3	3	3	2
		DAY 8		02MAR2003	10	PP	20	NO	36	6	4	5	4	2	0	4	4	4	5	4
		DAY 15		06MAR2003	14	PP	-10	NO	27	-3	4	5	4	0	0	1	2	3	4	4
		DAY 22		18MAR2003	26	PP	-3	NO	29	-1	4	3	5	2	0	2	4	4	3	2
		DAY 29		25MAR2003	33	PP	0	NO	30	0	5	4	5	2	0	2	4	4	3	1
		DAY 36		01APR2003	40	PP	23	NO	37	7	6	6	5	3	2	4	3	4	2	2
		DAY 50		09APR2003	48	PP	20	NO	36	6	6	4	4	4	1	4	4	4	3	2
		DAY 50	*	15APR2003	54	PP	43	NO	43	13	6	5	4	4	4	4	4	4	4	4
		DAY 57		25APR2003	64	PP	-7	NO	28	-2	3	3	4	4	2	4	2	2	3	1
	E0023019	DAY 1		07APR2003	1	PP			23		3	4	3	2	2	2	2	3	2	0
		DAY 8		15APR2003	9	PP	-44	NO	13	-10	2	3	2	0	0	1	2	2	1	0
		DAY 15		22APR2003	16	PP	-39	NO	14	-9	3	3	2	0	0	1	2	2	1	0
		DAY 22		02MAY2003	26	PP	-30	NO	16	-7	1	1	2	0	3	3	2	2	2	0
		DAY 29		06MAY2003	30	PP	-61	YES	9	-14	0	0	2	0	3	0	2	1	1	0

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0023019	DAY 36	13MAY2003	37	PP	-44	NO	13	-10	1	2	2	0	2	0	2	1	2	1
		DAY 43	20MAY2003	44	PP	-57	YES	10	-13	2	3	0	0	0	0	1	1	2	1
		DAY 50	29MAY2003	53	PP	-44	NO	13	-10	2	3	2	0	0	1	1	1	3	0
		DAY 57	03JUN2003	58	PP	-74	YES	6	-17	0	0	2	0	2	1	0	0	1	0
	E0023022	DAY 1	18APR2003	1	PP			24		4	3	2	3	2	3	2	3	2	0
		DAY 8	25APR2003	8	PP	-17	NO	20	-4	4	3	2	0	2	3	1	3	2	0
		DAY 15	01MAY2003	14	PP	-4	NO	23	-1	4	3	3	1	3	2	2	3	2	0
		DAY 22	08MAY2003	21	PP	-29	NO	17	-7	3	2	2	0	3	1	2	2	2	0
		DAY 29	15MAY2003	28	PP	-71	YES	7	-17	1	0	0	0	2	1	1	0	2	0
		DAY 36	22MAY2003	35	PP	-96	YES	1	-23	0	0	0	0	0	0	0	0	1	0
		DAY 43	30MAY2003	43	PP	-96	YES	1	-23	0	0	0	0	0	0	0	0	1	0
		DAY 50	06JUN2003	50	PP	-83	YES	4	-20	0	0	2	1	0	0	0	0	1	0
		DAY 57	12JUN2003	56	PP	-92	YES	2	-22	0	0	0	0	0	1	0	0	1	0
	E0023023	DAY 1	25APR2003	1	ITT			26		4	4	3	3	2	3	1	3	2	1
		DAY 8	01MAY2003	7	ITT	12	NO	29	3	4	4	2	3	3	3	2	3	2	3
	E0023029	DAY 1	23MAY2003	1	SAFETY			25		3	4	1	3	2	2	3	4	2	1
	E0023031	DAY 1	24JUN2003	1	PP			37		5	5	5	4	1	3	4	4	4	2
		DAY 8	01JUL2003	8	PP	-41	NO	22	-15	1	3	3	2	2	2	4	2	2	1
		DAY 15	08JUL2003	15	PP	-41	NO	22	-15	2	2	3	2	2	3	3	2	2	1
		DAY 22	15JUL2003	22	PP	-30	NO	26	-11	4	4	4	2	2	3	3	1	2	1
		DAY 29	22JUL2003	29	PP	-70	YES	11	-26	1	1	2	0	0	2	1	2	1	1
		DAY 36	29JUL2003	36	PP	-70	YES	11	-26	1	1	2	0	0	2	1	2	1	1
		DAY 43	05AUG2003	43	PP	-70	YES	11	-26	1	1	2	0	0	2	1	2	1	1
		DAY 50	12AUG2003	50	PP	-65	NO	13	-24	1	1	2	1	0	2	2	2	1	1
		DAY 57	19AUG2003	57	PP	-19	NO	30	-7	3	4	3	4	1	4	4	4	2	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	DAY 1	09JUL2003	1	PP			27		4	4	2	3	2	2	3	4	1	2
		DAY 8	16JUL2003	8	PP	11	NO	30	3	4	4	2	3	3	2	4	4	3	1
		DAY 15	24JUL2003	16	PP	-19	NO	22	-5	2	3	2	2	2	2	3	3	2	1
		DAY 22	30JUL2003	22	PP	-26	NO	20	-7	2	3	2	1	2	2	2	3	1	2
		DAY 29	06AUG2003	29	PP	-19	NO	22	-5	3	3	2	1	2	2	3	3	1	2
		DAY 36	13AUG2003	36	PP	-48	NO	14	-13	2	2	0	0	3	1	2	2	1	1
		DAY 43	20AUG2003	43	PP	-33	NO	18	-9	3	3	0	0	3	1	3	3	1	1
		DAY 50	27AUG2003	50	PP	-41	NO	16	-11	3	3	0	0	0	1	4	3	1	1
		DAY 57	05SEP2003	59	PP	-41	NO	16	-11	3	3	0	0	0	1	4	3	1	1
	E0023043	DAY 1	14JUL2003	1	PP			36		5	5	4	2	4	4	4	4	2	2
		DAY 8	23JUL2003	10	PP	-58	NO	15	-21	2	2	2	0	1	2	1	2	2	1
		DAY 15	28JUL2003	15	PP	-81	YES	7	-29	1	1	2	0	1	0	0	1	0	1
		DAY 22	05AUG2003	23	PP	-19	NO	29	-7	4	4	3	0	4	3	4	4	2	1
		DAY 29	12AUG2003	30	PP	-53	NO	17	-19	1	1	4	0	4	2	2	0	2	1
		DAY 36	19AUG2003	37	PP	-83	YES	6	-30	0	0	3	0	3	0	0	0	0	0
		DAY 43	26AUG2003	44	PP	-97	YES	1	-35	0	0	0	0	1	0	0	0	0	0
		DAY 50	02SEP2003	51	PP	-94	YES	2	-34	0	0	0	0	1	1	0	0	0	0
		DAY 57	09SEP2003	58	PP	-100	YES	0	-36	0	0	0	0	0	0	0	0	0	0
	E0026003	DAY 1	04DEC2002	1	ITT			41		5	5	4	5	4	4	4	4	4	2
		DAY 8	12DEC2002	9	ITT	-54	NO	19	-22	1	2	4	0	0	2	4	1	3	2
		DAY 15	19DEC2002	16	ITT	-66	NO	14	-27	0	0	4	0	0	2	3	3	1	1
		DAY 22	26DEC2002	23	ITT	-88	YES	5	-36	0	0	1	2	0	0	2	0	0	0
		DAY 29	02JAN2003	30	ITT	-81	YES	8	-33	0	0	1	0	3	0	4	0	0	0
		DAY 36	09JAN2003	37	ITT	-100	YES	0	-41	0	0	0	0	0	0	0	0	0	0
		DAY 43	16JAN2003	44	ITT	-95	YES	2	-39	0	0	0	0	0	1	0	0	1	0
		DAY 50	23JAN2003	51	ITT	-100	YES	0	-41	0	0	0	0	0	0	0	0	0	0
		DAY 57	03FEB2003	62	ITT	-44	NO	23	-18	0	0	0	0	6	6	5	6	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0026005	DAY 1	30DEC2002	1	ITT			30		3	3	3	3	0	4	4	4	4	2
		DAY 8	06JAN2003	8	ITT	-13	NO	26	-4	3	3	4	2	2	4	5	1	1	1
	E0026009	DAY 1	15JAN2003	1	ITT			31		4	5	0	4	4	2	5	4	1	2
		DAY 8	21JAN2003	7	ITT	-39	NO	19	-12	0	0	0	0	4	4	5	4	1	1
	E0026015	DAY 1	27FEB2003	1	PP			27		4	5	3	0	2	3	4	4	1	1
		DAY 8	07MAR2003	9	PP	-44	NO	15	-12	2	3	2	6	0	0	0	1	0	1
		DAY 15	13MAR2003	15	PP	-7	NO	25	-2	3	4	4	0	0	4	4	3	2	1
		DAY 22	20MAR2003	22	PP	26	NO	34	7	4	4	4	5	0	4	4	4	4	1
		DAY 29	27MAR2003	29	PP	-4	NO	26	-1	2	2	2	5	0	2	4	4	4	1
		DAY 36	03APR2003	36	PP	-7	NO	25	-2	4	3	4	0	0	2	4	4	3	1
		DAY 43	10APR2003	43	PP	-78	YES	6	-21	0	1	2	2	0	0	1	0	0	0
		DAY 50	17APR2003	50	PP	-56	YES	12	-15	2	3	0	2	0	0	3	1	1	0
		DAY 57	25APR2003	58	PP	-78	YES	6	-21	1	1	0	0	0	0	3	0	1	0
	E0026023	DAY 1	30APR2003	1	PP			26		2	4	0	4	5	1	3	3	2	2
		DAY 8	07MAY2003	8	PP	-46	NO	14	-12	2	3	0	0	2	1	3	1	1	1
		DAY 15	14MAY2003	15	PP	-42	NO	15	-11	2	2	1	3	0	0	0	1	4	2
		DAY 22	21MAY2003	22	PP	-54	YES	12	-14	3	2	1	3	0	0	0	1	1	1
		DAY 29	28MAY2003	29	PP	-54	YES	12	-14	3	2	1	3	3	0	0	0	0	0
		DAY 36	04JUN2003	36	PP	-62	YES	10	-16	2	1	1	3	3	0	0	0	0	0
		DAY 43	11JUN2003	43	PP	-69	YES	8	-18	1	1	1	2	3	0	0	0	0	0
		DAY 50	18JUN2003	50	PP	-73	YES	7	-19	1	1	1	1	3	0	0	0	0	0
		DAY 57	27JUN2003	59	PP	-73	YES	7	-19	1	1	0	1	3	0	1	0	0	0
	E0027016	DAY 1	09APR2003	1	PP			33		3	4	3	2	3	4	4	4	4	2
		DAY 8	14APR2003	6	PP	-3	NO	32	-1	4	4	4	0	3	4	4	4	4	1
		DAY 15	22APR2003	14	PP	-46	NO	18	-15	2	1	3	0	0	2	3	2	4	1

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	DAY 22	29APR2003	21	PP	-52	NO	16	-17	1	1	2	0	0	4	3	2	2	1
		DAY 29	05MAY2003	27	PP	-76	YES	8	-25	0	0	0	0	0	2	1	2	2	1
		DAY 36	14MAY2003	36	PP	-55	NO	15	-18	2	1	2	0	0	3	1	2	2	2
		DAY 43	19MAY2003	41	PP	-67	YES	11	-22	1	0	1	0	0	2	3	2	1	1
		DAY 50	27MAY2003	49	PP	-55	NO	15	-18	1	1	2	2	0	2	1	2	2	2
		DAY 57	03JUN2003	56	PP	-67	YES	11	-22	1	0	1	0	0	1	2	2	2	2
	E0027018	DAY 1	25MAR2003	1	PP			34		4	3	3	3	4	4	4	4	3	2
		DAY 8	02APR2003	9	PP	-6	NO	32	-2	5	4	4	0	4	4	4	4	1	2
		DAY 15	08APR2003	15	PP	-85	YES	5	-29	1	0	2	0	0	0	0	0	1	1
		DAY 22	15APR2003	22	PP	-94	YES	2	-32	1	0	1	0	0	0	0	0	0	0
		DAY 29	22APR2003	29	PP	-97	YES	1	-33	1	0	0	0	0	0	0	0	0	0
		DAY 36	29APR2003	36	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	42	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	50	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	59	PP	-100	YES	0	-34	0	0	0	0	0	0	0	0	0	0
	E0028032	DAY 1	25MAR2003	1	PP			30		4	4	0	4	0	4	4	4	4	2
		DAY 8	01APR2003	8	PP	-20	NO	24	-6	3	3	1	0	2	3	4	3	2	3
		DAY 15	08APR2003	15	PP	-7	NO	28	-2	4	4	2	0	0	4	4	4	4	2
		DAY 22	15APR2003	22	PP	-53	NO	14	-16	2	2	0	0	0	2	2	2	0	4
		DAY 29	22APR2003	29	PP	0	NO	30	0	4	4	2	0	2	2	4	4	4	4
		DAY 36	30APR2003	37	PP	-27	NO	22	-8	4	4	0	0	2	2	2	2	4	2
		DAY 43	06MAY2003	43	PP	-7	NO	28	-2	4	4	2	0	0	4	4	4	4	2
		DAY 50	13MAY2003	50	PP	-13	NO	26	-4	4	4	2	1	0	3	2	2	4	4
	E0029003	DAY 1	04NOV2002	1	PP			30		3	4	5	4	0	3	2	4	4	1
		DAY 8	11NOV2002	8	PP	-33	NO	20	-10	3	3	4	0	2	2	3	2	1	0
		DAY 15	18NOV2002	15	PP	-83	YES	5	-25	0	2	3	0	0	0	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 22	25NOV2002	22	PP	-30	NO	21	-9	2	2	4	1	2	4	2	2	2	0
		DAY 29	02DEC2002	29	PP	-57	NO	13	-17	1	0	4	0	0	3	2	2	1	0
		DAY 36	09DEC2002	36	PP	-63	YES	11	-19	3	2	1	0	0	2	0	3	0	0
		DAY 43	16DEC2002	43	PP	-57	NO	13	-17	0	1	2	0	0	4	1	0	3	2
		DAY 50	23DEC2002	50	PP	3	NO	31	1	3	3	2	0	3	4	4	4	4	4
		DAY 57	30DEC2002	57	PP	-40	NO	18	-12	2	2	3	0	2	3	2	0	2	2
	E0029020	DAY 1	04MAR2003	-1	ITT			27		4	4	3	4	0	3	0	3	4	2
		DAY 8	11MAR2003	7	ITT	7	NO	29	2	3	4	3	2	1	4	4	2	4	2
	E0031005	DAY 1	20DEC2002	1	PP			29		4	4	0	4	0	4	5	4	4	0
		DAY 8	27DEC2002	8	PP	-52	NO	14	-15	2	1	3	2	0	3	1	2	0	0
		DAY 15	03JAN2003	15	PP	-59	YES	12	-17	2	2	0	2	0	2	2	2	0	0
		DAY 22	10JAN2003	22	PP	-28	NO	21	-8	2	2	3	2	0	4	4	4	0	0
		DAY 29	17JAN2003	29	PP	-72	YES	8	-21	2	1	0	1	0	2	0	2	0	0
		DAY 36	24JAN2003	36	PP	-59	YES	12	-17	1	2	0	2	0	3	2	2	0	0
		DAY 43	30JAN2003	42	PP	-24	NO	22	-7	2	3	2	3	0	4	2	3	3	0
		DAY 50	07FEB2003	50	PP	-83	YES	5	-24	1	0	0	2	0	2	0	0	0	0
		DAY 57	14FEB2003	57	PP	-59	YES	12	-17	2	2	0	2	0	3	1	2	0	0
	E0031006	DAY 1	18FEB2003	1	PP			22		2	2	3	6	0	4	0	2	2	1
		DAY 8	26FEB2003	9	PP	-36	NO	14	-8	2	2	2	2	0	2	1	1	2	0
		DAY 15	05MAR2003	16	PP	-36	NO	14	-8	1	2	2	2	0	3	0	2	2	0
		DAY 22	11MAR2003	22	PP	-50	YES	11	-11	1	1	2	3	0	2	1	1	0	0
		DAY 29	18MAR2003	29	PP	-64	YES	8	-14	0	2	0	2	0	2	1	1	0	0
		DAY 36	25MAR2003	36	PP	-46	YES	12	-10	0	2	2	2	0	3	1	1	0	1
		DAY 43	02APR2003	44	PP	-23	NO	17	-5	0	2	3	4	0	4	2	0	0	2
		DAY 50	07APR2003	49	PP	-64	YES	8	-14	0	0	2	3	0	3	0	0	0	0
		DAY 57	15APR2003	57	PP	-68	YES	7	-15	0	1	0	2	0	2	0	0	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0031010	DAY 1	19FEB2003	1	PP			27		2	4	3	4	2	3	4	2	3	0
		DAY 8	26FEB2003	8	PP	-37	NO	17	-10	2	4	2	0	0	2	2	2	2	1
		DAY 15	05MAR2003	15	PP	-19	NO	22	-5	4	4	2	0	2	0	4	2	3	1
	E0031011	DAY 1	27FEB2003	1	PP			22		1	2	2	2	3	3	4	3	2	0
		DAY 8	06MAR2003	8	PP	-64	YES	8	-14	1	0	2	0	0	0	2	1	2	0
		DAY 15	13MAR2003	15	PP	-73	YES	6	-16	0	0	1	1	0	0	0	2	2	0
		DAY 22	20MAR2003	22	PP	-18	NO	18	-4	3	3	4	2	2	2	0	2	0	0
		DAY 29	27MAR2003	29	PP	-100	YES	0	-22	0	0	0	0	0	0	0	0	0	0
		DAY 36	03APR2003	36	PP	-100	YES	0	-22	0	0	0	0	0	0	0	0	0	0
		DAY 43	11APR2003	44	PP	27	NO	28	6	4	3	2	3	2	4	4	2	3	1
		DAY 50	17APR2003	50	PP	-36	NO	14	-8	2	2	2	2	0	2	0	2	2	0
		DAY 57	24APR2003	57	PP	-100	YES	0	-22	0	0	0	0	0	0	0	0	0	0
	E0031015	DAY 1	26MAR2003	1	ITT			20		2	3	3	0	2	2	2	2	4	0
		DAY 8	01APR2003	7	ITT	0	NO	20	0	1	2	3	0	2	4	4	2	2	0
	E0031031	DAY 1	08JUL2003	1	PP			19		2	3	2	2	1	4	1	3	1	0
		DAY 8	15JUL2003	8	PP	-58	YES	8	-11	1	1	2	0	0	3	0	1	0	0
		DAY 15	22JUL2003	15	PP	-5	NO	18	-1	2	3	2	1	0	4	2	3	1	0
		DAY 22	29JUL2003	22	PP	-79	YES	4	-15	0	1	0	0	0	2	0	1	0	0
	E0033009	DAY 1	12FEB2003	1	SAFETY			35		4	4	4	4	0	4	4	4	3	4
	E0034009	DAY 1	19JUN2003	1	PP			37		4	4	3	5	4	5	3	4	3	2
		DAY 8	27JUN2003	9	PP	-24	NO	28	-9	4	4	3	0	2	3	4	4	2	2
		DAY 15	03JUL2003	15	PP	-51	NO	18	-19	2	2	2	0	0	3	4	3	2	0
		DAY 22	10JUL2003	22	PP	-73	YES	10	-27	1	1	0	0	0	2	4	2	0	0
		DAY 29	18JUL2003	30	PP	-78	YES	8	-29	1	1	0	0	0	2	4	0	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0034009	DAY 36	25JUL2003	37	PP	-78	YES	8	-29	1	1	0	0	0	2	4	0	0	0
		DAY 43	31JUL2003	43	PP	-76	YES	9	-28	2	1	0	0	0	2	4	0	0	0
		DAY 50	07AUG2003	50	PP	-78	YES	8	-29	1	1	0	0	0	2	4	0	0	0
		DAY 57	18AUG2003	61	PP	-95	YES	2	-35	0	0	0	0	0	1	1	0	0	0
	E0037007	DAY 1	11APR2003	1	PP			35		4	4	2	5	3	4	3	4	4	2
		DAY 8	17APR2003	7	PP	-20	NO	28	-7	2	3	2	3	3	4	3	4	4	0
	E0037012	DAY 1	16JUL2003	1	PP			28		3	3	2	3	3	3	4	3	2	2
		DAY 8	24JUL2003	9	PP	-57	YES	12	-16	1	1	2	2	0	4	2	0	0	0
		DAY 15	01AUG2003	17	PP	-57	YES	12	-16	1	2	2	0	0	3	2	0	2	0
		DAY 22	08AUG2003	24	PP	-86	YES	4	-24	0	0	2	0	0	1	1	0	0	0
		DAY 29	15AUG2003	31	PP	-86	YES	4	-24	0	0	2	0	0	1	1	0	0	0
		DAY 36	22AUG2003	38	PP	-93	YES	2	-26	0	0	1	0	0	0	1	0	0	0
		DAY 43	29AUG2003	45	PP	-89	YES	3	-25	0	0	1	2	0	0	0	0	0	0
		DAY 50	05SEP2003	52	PP	-96	YES	1	-27	0	0	1	0	0	0	0	0	0	0
		DAY 57	08SEP2003	55	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
	E0039019	DAY 1	06FEB2003	1	PP			30		4	4	3	4	0	3	4	4	2	2
		DAY 8	13FEB2003	8	PP	-33	NO	20	-10	2	3	2	1	0	2	2	4	2	2
		DAY 15	20FEB2003	15	PP	-43	NO	17	-13	2	2	3	0	0	2	2	3	2	1
		DAY 22	27FEB2003	22	PP	-60	YES	12	-18	2	2	2	0	0	1	1	2	1	1
		DAY 29	07MAR2003	30	PP	-77	YES	7	-23	2	1	2	0	0	0	1	1	0	0
		DAY 36	13MAR2003	36	PP	-30	NO	21	-9	3	2	2	0	0	4	3	3	2	2
		DAY 43	20MAR2003	43	PP	-73	YES	8	-22	2	2	0	0	0	0	2	0	2	0
		DAY 50	27MAR2003	50	PP	-60	YES	12	-18	2	2	4	0	0	0	2	2	0	0
		DAY 57	03APR2003	57	PP	-53	NO	14	-16	2	2	4	0	0	0	2	2	2	0
	E0039043	DAY 1	08MAY2003	1	PP (25)			29		4	4	3	3	3	3	3	3	2	1

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0039043	DAY 8	15MAY2003	8	PP (25)	-52	NO	14	-15	1	2	2	0	0	2	3	2	2	0
		DAY 15	23MAY2003	16	PP (25)	-83	YES	5	-24	1	1	1	0	0	1	0	1	0	0
		DAY 22	29MAY2003	22	PP (25)	-83	YES	5	-24	1	1	1	0	0	0	0	2	0	0
		DAY 29	05JUN2003	29	PP (25)	-93	YES	2	-27	0	0	1	0	0	0	0	0	1	0
		DAY 36	13JUN2003	37	PP (25)	-48	NO	15	-14	2	2	2	1	1	2	1	2	2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	PP			34		2	4	2	4	1	4	4	5	3	5
		DAY 8	06JAN2003	8	PP	-24	NO	26	-8	1	4	0	3	3	2	3	2	4	4
		DAY 15	14JAN2003	16	PP	-35	NO	22	-12	2	1	0	1	2	3	2	4	4	3
		DAY 22	21JAN2003	23	PP	-56	NO	15	-19	1	2	2	0	0	2	1	2	3	2
		DAY 29	29JAN2003	31	PP	-59	NO	14	-20	1	4	2	0	0	1	0	2	3	1
		DAY 36	05FEB2003	38	PP	-53	NO	16	-18	1	2	2	1	0	2	0	2	4	2
		DAY 43	12FEB2003	45	PP	-44	NO	19	-15	1	2	2	3	0	1	1	2	4	3
		DAY 50	19FEB2003	52	PP	-65	YES	12	-22	1	3	2	0	0	1	0	1	3	1
		DAY 57	26FEB2003	59	PP	-79	YES	7	-27	0	1	2	0	0	0	0	1	2	1
	E0002003	DAY 1	22JAN2003	1	PP			23		1	2	4	4	0	3	2	2	3	2
		DAY 8	29JAN2003	8	PP	30	NO	30	7	3	4	4	3	0	2	4	2	4	4
		DAY 15	05FEB2003	15	PP	-13	NO	20	-3	2	2	2	2	2	2	2	2	3	1
		DAY 22	12FEB2003	22	PP	22	NO	28	5	3	4	4	3	0	3	4	3	2	2
		DAY 29	19FEB2003	29	PP	-26	NO	17	-6	1	2	2	1	2	2	2	2	2	1
		DAY 36	26FEB2003	36	PP	-4	NO	22	-1	2	2	3	1	0	2	4	4	2	2
		DAY 43	05MAR2003	43	PP	-39	NO	14	-9	1	1	2	0	0	2	2	2	3	1
		DAY 50	11MAR2003	49	PP	-22	NO	18	-5	2	2	3	2	0	2	3	1	2	1
		DAY 57	18MAR2003	56	PP	-35	NO	15	-8	1	2	1	2	1	2	2	1	2	1
	E0002004	DAY 1	25JAN2003	1	SAFETY			24		1	2	4	3	0	3	2	4	3	2
	E0002008	DAY 1	25FEB2003	1	PP			21		1	3	2	3	0	2	2	3	3	2
		DAY 8	05MAR2003	9	PP	5	NO	22	1	1	3	3	3	0	2	2	2	4	2
		DAY 15	13MAR2003	17	PP	-24	NO	16	-5	2	1	2	1	0	2	2	2	2	2
		DAY 22	20MAR2003	24	PP	-19	NO	17	-4	2	1	3	1	0	2	3	1	2	2
		DAY 29	27MAR2003	31	PP	-10	NO	19	-2	2	2	2	2	0	2	3	2	2	2
		DAY 36	03APR2003	38	PP	10	NO	23	2	2	3	3	2	0	3	4	2	2	2
		DAY 43	11APR2003	46	PP	-14	NO	18	-3	1	1	3	1	0	2	3	2	3	2
		DAY 50	16APR2003	51	PP	5	NO	22	1	2	2	3	2	0	2	3	3	3	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0002008	DAY 57	23APR2003	58	PP	-10	NO	19	-2	2	2	3	1	0	2	2	2	3	2
	E0002016	DAY 1	24JUL2003	1	PP			26		3	3	3	2	2	2	3	3	3	2
		DAY 8	30JUL2003	7	PP	-39	NO	16	-10	2	2	2	0	2	1	2	2	2	1
		DAY 15	06AUG2003	14	PP	-39	NO	16	-10	2	2	2	1	3	1	1	1	2	1
		DAY 22	13AUG2003	21	PP	-31	NO	18	-8	2	2	2	2	2	2	2	1	2	1
		DAY 29	21AUG2003	29	PP	-50	NO	13	-13	2	2	2	0	2	1	1	1	1	1
		DAY 36	27AUG2003	35	PP	-46	NO	14	-12	2	1	2	0	2	3	1	1	1	1
		DAY 43	03SEP2003	42	PP	-58	YES	11	-15	2	1	2	0	2	1	0	1	1	1
		DAY 50	11SEP2003	50	PP	-54	YES	12	-14	2	1	2	0	2	1	1	1	1	1
		DAY 57	17SEP2003	56	PP	-58	YES	11	-15	2	2	1	0	2	0	1	1	1	1
	E0003008	DAY 1	28JAN2003	1	PP			31		4	3	3	3	0	4	4	4	4	2
		DAY 8	04FEB2003	8	PP	3	NO	32	1	4	3	4	4	0	4	3	4	4	2
		DAY 15	11FEB2003	15	PP	-7	NO	29	-2	3	3	4	2	0	4	4	4	4	1
		DAY 22	18FEB2003	22	PP	-13	NO	27	-4	3	3	3	3	0	4	4	4	3	0
	E0004003	DAY 1	10OCT2002	1	PP			30		3	4	3	0	2	4	4	4	4	2
		DAY 8	17OCT2002	8	PP	-17	NO	25	-5	3	2	2	2	2	3	3	4	2	2
	E0004006	DAY 1	04NOV2002	1	PP			32		4	4	3	2	3	4	4	4	2	2
		DAY 8	11NOV2002	8	PP	-34	NO	21	-11	2	3	3	2	0	2	3	3	2	1
		DAY 15	18NOV2002	15	PP	-47	NO	17	-15	2	2	3	2	1	1	2	2	1	1
		DAY 22	25NOV2002	22	PP	-44	NO	18	-14	2	2	1	2	2	3	3	2	0	1
		DAY 29	02DEC2002	29	PP	-53	NO	15	-17	2	2	0	2	2	2	3	2	0	0
		DAY 36	09DEC2002	36	PP	0	NO	32	0	4	4	2	4	3	3	4	4	3	1
		DAY 43	16DEC2002	43	PP	3	NO	33	1	4	4	2	4	4	3	4	4	3	1
		DAY 57	06JAN2003	64	PP	-6	NO	30	-2	4	4	3	4	2	3	4	4	1	1
	E0004016	DAY 1	19FEB2003	1	PP			33		4	4	4	4	3	4	3	3	2	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0004016	DAY 8	26FEB2003	8	PP	-15	NO	28	-5	3	4	4	1	2	4	4	3	2	1
		DAY 15	05MAR2003	15	PP	-33	NO	22	-11	2	3	3	1	0	4	4	2	3	0
		DAY 22	13MAR2003	23	PP	-58	NO	14	-19	1	1	3	1	0	4	1	1	2	0
		DAY 36	26MAR2003	36	PP	-64	YES	12	-21	2	1	1	1	0	4	2	1	0	0
		DAY 43	03APR2003	44	PP	-70	YES	10	-23	1	0	2	0	0	4	2	1	0	0
		DAY 50	10APR2003	51	PP	-88	YES	4	-29	1	0	1	0	0	1	1	0	0	0
		DAY 57	17APR2003	58	PP	-82	YES	6	-27	1	0	2	2	0	1	0	0	0	0
	E0004024	DAY 1	03JUL2003	1	PP			34		4	4	4	4	0	4	4	5	4	1
		DAY 8	10JUL2003	8	PP	-18	NO	28	-6	4	3	2	3	0	4	4	5	3	0
		DAY 15	17JUL2003	15	PP	-35	NO	22	-12	3	3	2	2	0	2	3	4	3	0
		DAY 22	24JUL2003	22	PP	-47	NO	18	-16	2	2	3	2	0	1	2	4	2	0
		DAY 29	31JUL2003	29	PP	-59	NO	14	-20	1	1	2	2	0	1	2	3	2	0
		DAY 36	07AUG2003	36	PP	-56	NO	15	-19	1	1	2	2	1	1	2	3	2	0
		DAY 43	14AUG2003	43	PP	-71	YES	10	-24	1	1	0	2	2	0	1	2	1	0
		DAY 50	21AUG2003	50	PP	-82	YES	6	-28	1	1	0	1	1	0	1	1	0	0
		DAY 57	28AUG2003	57	PP	-77	YES	8	-26	2	1	2	0	0	0	0	1	2	0
	E0005006	DAY 1	03OCT2002	1	PP			28		4	4	3	4	0	3	4	3	2	1
		DAY 8	14OCT2002	12	PP	-54	NO	13	-15	1	1	1	3	0	2	2	1	2	0
	E0005017	DAY 1	30DEC2002	1	PP			37		4	4	4	5	3	4	4	4	4	1
		DAY 8	06JAN2003	8	PP	0	NO	37	0	4	4	4	5	3	4	4	4	4	1
		DAY 15	14JAN2003	16	PP	-5	NO	35	-2	4	4	4	4	3	4	4	4	3	1
		DAY 22	22JAN2003	24	PP	-16	NO	31	-6	3	4	3	4	3	4	3	3	3	1
		DAY 29	30JAN2003	32	PP	-19	NO	30	-7	3	4	3	4	3	4	3	3	2	1
		DAY 36	04FEB2003	37	PP	-22	NO	29	-8	3	4	3	3	3	4	3	3	2	1
		DAY 43	13FEB2003	46	PP	-30	NO	26	-11	2	4	3	1	3	4	3	3	2	1
		DAY 50	20FEB2003	53	PP	-24	NO	28	-9	3	4	3	2	2	4	3	3	3	1
		DAY 57	04MAR2003	65	PP	-16	NO	31	-6	3	4	4	2	3	4	3	3	3	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0005019	DAY 1	15JAN2003	1	ITT			32		4	4	3	4	0	4	4	4	3	2
		DAY 8	23JAN2003	9	ITT	16	NO	37	5	5	5	2	3	2	4	4	4	3	5
	E0005026	DAY 1	06MAR2003	1	PP			32		4	4	3	4	0	3	4	4	4	2
		DAY 8	13MAR2003	8	PP	9	NO	35	3	4	4	4	4	2	4	4	4	3	2
		DAY 15	20MAR2003	15	PP	13	NO	36	4	5	5	4	5	4	4	0	3	4	2
		DAY 22	25MAR2003	20	PP	28	NO	41	9	4	5	4	5	4	4	2	5	4	4
	E0005039	DAY 1	22MAY2003	1	PP			32		4	4	3	5	0	4	4	4	3	1
		DAY 8	28MAY2003	7	PP	6	NO	34	2	4	5	4	5	0	4	4	4	3	1
		DAY 15	05JUN2003	15	PP	-25	NO	24	-8	3	3	3	2	0	4	3	3	2	1
		DAY 22	12JUN2003	22	PP	-9	NO	29	-3	4	4	3	2	0	4	4	4	3	1
		DAY 29	18JUN2003	28	PP	-19	NO	26	-6	4	3	3	2	0	4	4	3	2	1
		DAY 36	24JUN2003	34	PP	-13	NO	28	-4	4	4	3	2	0	4	4	3	3	1
		DAY 43	03JUL2003	43	PP	-22	NO	25	-7	3	4	2	2	0	4	4	3	2	1
		DAY 50	10JUL2003	50	PP	-9	NO	29	-3	4	4	4	2	0	4	4	3	3	1
		DAY 57	16JUL2003	56	PP	-6	NO	30	-2	4	4	4	4	0	4	4	3	3	0
	E0005043	DAY 1	09JUL2003	1	PP			25		4	3	3	0	0	2	4	4	4	1
		DAY 8	17JUL2003	9	PP	-8	NO	23	-2	4	4	2	0	0	2	4	4	2	1
		DAY 15	24JUL2003	16	PP	-4	NO	24	-1	3	3	3	0	0	2	4	4	4	1
		DAY 22	31JUL2003	23	PP	-4	NO	24	-1	3	4	3	0	0	2	4	4	3	1
		DAY 29	07AUG2003	30	PP	4	NO	26	1	3	4	3	0	0	4	4	4	3	1
		DAY 36	13AUG2003	36	PP	-8	NO	23	-2	3	4	3	0	0	2	4	4	2	1
		DAY 43	20AUG2003	43	PP	-8	NO	23	-2	4	4	3	0	0	2	4	4	2	0
		DAY 50	27AUG2003	50	PP	-16	NO	21	-4	4	4	3	0	0	0	4	4	2	0
		DAY 57	03SEP2003	57	PP	-32	NO	17	-8	2	3	3	0	0	3	2	2	2	0
	E0006020	DAY 1	13MAY2003	1	PP			31		4	4	4	3	1	4	3	3	3	2
		DAY 8	20MAY2003	8	PP	-13	NO	27	-4	3	3	4	3	1	4	3	2	3	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0006020	DAY 15		27MAY2003	15	PP	-16	NO	26	-5	3	3	4	3	1	4	2	2	3	1
		DAY 22		03JUN2003	22	PP	-26	NO	23	-8	3	3	3	2	1	3	2	2	3	1
		DAY 29		10JUN2003	29	PP	-32	NO	21	-10	3	3	3	2	0	2	2	2	3	1
		DAY 36		17JUN2003	36	PP	-39	NO	19	-12	3	3	3	1	0	2	2	2	2	1
		DAY 43		24JUN2003	43	PP	-48	NO	16	-15	2	2	2	1	0	2	2	2	2	1
		DAY 50		01JUL2003	50	PP	-48	NO	16	-15	2	2	2	1	0	2	2	2	2	1
		DAY 57		08JUL2003	57	PP	-48	NO	16	-15	2	2	2	1	0	2	2	2	2	1
	E0007001	DAY 1		31DEC2002	1	PP			32		4	5	3	4	1	2	3	4	4	2
		DAY 8		07JAN2003	8	PP	-3	NO	31	-1	4	5	2	5	0	2	3	4	4	2
		DAY 15		14JAN2003	15	PP	-19	NO	26	-6	4	4	2	3	0	2	3	4	3	1
		DAY 22		21JAN2003	22	PP	-28	NO	23	-9	3	3	2	3	0	2	3	3	3	1
		DAY 29		28JAN2003	29	PP	-34	NO	21	-11	3	3	2	2	0	1	2	4	3	1
		DAY 36		04FEB2003	36	PP	-31	NO	22	-10	3	3	2	3	0	2	2	3	3	1
		DAY 43		11FEB2003	43	PP	-28	NO	23	-9	3	3	2	3	0	2	2	4	3	1
		DAY 50		18FEB2003	50	PP	-44	NO	18	-14	2	2	1	3	0	1	2	3	3	1
		DAY 50	*	22FEB2003	54	PP	-66	YES	11	-21	1	2	1	2	0	1	0	2	2	0
	E0007003	DAY 1		30JAN2003	1	PP (40)			29		4	4	2	5	2	2	2	4	3	1
		DAY 8		06FEB2003	8	PP (40)	-7	NO	27	-2	4	4	2	5	0	2	2	4	3	1
		DAY 15		14FEB2003	16	PP (40)	-14	NO	25	-4	3	3	2	4	2	2	2	4	2	1
		DAY 22		22FEB2003	24	PP (40)	-21	NO	23	-6	4	4	2	5	0	0	2	3	2	1
		DAY 36		10MAR2003	40	PP (40)	-31	NO	20	-9	2	2	2	4	0	0	2	4	3	1
	E0007006	DAY 1		05MAR2003	1	PP			21		4	3	2	4	0	2	1	1	3	1
		DAY 8		12MAR2003	8	PP	5	NO	22	1	4	3	2	3	0	2	1	3	3	1
		DAY 15		19MAR2003	15	PP	-52	YES	10	-11	4	1	1	0	0	1	0	2	1	0
		DAY 22	*	25MAR2003	21	PP	-38	NO	13	-8	4	1	2	0	0	1	2	2	1	0
		DAY 22		26MAR2003	22	PP	-38	NO	13	-8	4	1	2	0	0	1	2	2	1	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0009004	DAY 1	26NOV2002	1	PP			47		6	6	5	5	4	4	5	5	4	3
		DAY 8	04DEC2002	9	PP	-66	NO	16	-31	0	0	3	5	3	0	3	2	0	0
		DAY 15	11DEC2002	16	PP	-38	NO	29	-18	3	3	4	5	0	3	4	4	3	0
		DAY 22	18DEC2002	23	PP	-21	NO	37	-10	4	5	4	5	0	4	5	4	4	2
	E0009012	DAY 1	25JUN2003	1	ITT			33		4	4	4	3	2	4	4	4	2	2
		DAY 8	03JUL2003	9	ITT	-12	NO	29	-4	3	3	3	3	2	3	3	4	3	2
	E0010008	DAY 1	18DEC2002	1	PP			33		3	5	4	3	3	4	3	4	2	2
		DAY 8	26DEC2002	9	PP	-3	NO	32	-1	3	4	5	4	2	4	4	3	3	0
		DAY 15	02JAN2003	16	PP	6	NO	35	2	4	4	4	4	2	4	4	4	3	2
		DAY 22	08JAN2003	22	PP	-18	NO	27	-6	2	4	4	3	3	3	2	3	3	0
		DAY 29	15JAN2003	29	PP	-36	NO	21	-12	3	2	2	4	3	2	1	2	2	0
	E0010018	DAY 1	19MAR2003	1	PP			31		2	5	4	4	3	1	2	4	3	3
		DAY 8	26MAR2003	8	PP	-61	YES	12	-19	1	1	2	1	3	0	3	1	0	0
		DAY 15	02APR2003	15	PP	-29	NO	22	-9	3	4	3	4	3	0	2	3	0	0
		DAY 22	09APR2003	22	PP	-74	YES	8	-23	0	0	2	3	2	0	1	0	0	0
		DAY 29	16APR2003	29	PP	-74	YES	8	-23	1	1	1	3	1	0	1	0	0	0
		DAY 36	23APR2003	36	PP	-77	YES	7	-24	0	0	2	3	0	0	2	0	0	0
		DAY 43	01MAY2003	44	PP	-74	YES	8	-23	1	1	1	3	0	0	2	0	0	0
	E0010028	DAY 1	16JUN2003	1	PP			26		3	3	2	5	2	0	4	4	3	0
		DAY 8	24JUN2003	9	PP	12	NO	29	3	3	3	4	5	0	3	4	4	3	0
		DAY 15	01JUL2003	16	PP	15	NO	30	4	4	4	4	4	0	3	3	3	3	2
		DAY 22	08JUL2003	23	PP	8	NO	28	2	3	2	4	5	0	2	3	4	3	2
		DAY 29	15JUL2003	30	PP	50	NO	39	13	4	5	5	6	0	4	4	5	4	2
	E0011008	DAY 1	30JAN2003	1	PP			23		4	4	3	3	3	0	1	2	2	1
		DAY 8	06FEB2003	8	PP	-52	YES	11	-12	2	2	2	2	0	0	1	1	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0011008	DAY 15		13FEB2003	15	PP	-52	YES	11	-12	2	0	2	1	2	2	0	0	2	0
	E0011009	DAY 1		26DEC2002	-1	PP			28		3	3	2	4	3	3	4	3	2	1
		DAY 8		02JAN2003	7	PP	-4	NO	27	-1	3	4	2	4	3	3	3	2	2	1
		DAY 15		09JAN2003	14	PP	-11	NO	25	-3	3	3	2	4	2	3	3	2	2	1
		DAY 22		16JAN2003	21	PP	-43	NO	16	-12	1	2	0	3	2	1	4	2	1	0
		DAY 29		23JAN2003	28	PP	-36	NO	18	-10	2	2	3	4	0	1	1	2	1	2
		DAY 36		30JAN2003	35	PP	-21	NO	22	-6	2	2	3	3	2	3	2	2	2	1
		DAY 43		06FEB2003	42	PP	-29	NO	20	-8	2	2	2	4	2	2	2	1	2	1
		DAY 50		13FEB2003	49	PP	-43	NO	16	-12	1	1	2	3	0	2	1	2	3	1
		DAY 57		20FEB2003	56	PP	-50	NO	14	-14	0	0	0	3	2	2	2	2	2	1
	E0011010	DAY 1		10FEB2003	1	PP			29		4	4	3	0	3	4	4	3	2	2
		DAY 8		17FEB2003	8	PP	-21	NO	23	-6	2	3	2	2	0	4	3	3	2	2
		DAY 15		24FEB2003	15	PP	-35	NO	19	-10	1	3	2	2	0	2	2	3	2	2
		DAY 22		03MAR2003	22	PP	-35	NO	19	-10	2	3	1	2	0	2	2	3	2	2
		DAY 29		10MAR2003	29	PP	-69	YES	9	-20	1	2	1	2	0	1	2	0	0	0
		DAY 36		17MAR2003	36	PP	-24	NO	22	-7	1	3	1	4	0	3	3	3	2	2
		DAY 36	*	19MAR2003	38	PP	-21	NO	23	-6	2	3	2	4	0	3	2	3	2	2
	E0013001	DAY 1		14NOV2002	1	PP			31		4	4	3	4	3	3	4	4	1	1
		DAY 8		21NOV2002	8	PP	-23	NO	24	-7	4	3	2	4	0	3	3	3	1	1
		DAY 15		27NOV2002	14	PP	-16	NO	26	-5	3	3	3	3	3	3	3	3	1	1
		DAY 22		06DEC2002	23	PP	-55	NO	14	-17	2	2	3	2	0	0	2	2	0	1
		DAY 29		11DEC2002	28	PP	-94	YES	2	-29	0	0	0	0	0	0	1	1	0	0
		DAY 36		18DEC2002	35	PP	-90	YES	3	-28	0	0	0	1	0	0	0	0	1	1
		DAY 43		27DEC2002	44	PP	-100	YES	0	-31	0	0	0	0	0	0	0	0	0	0
		DAY 50		02JAN2003	50	PP	-100	YES	0	-31	0	0	0	0	0	0	0	0	0	0
		DAY 57		10JAN2003	58	PP	-100	YES	0	-31	0	0	0	0	0	0	0	0	0	0

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PLACEBO (BIPOLAR I)	E0013003	DAY 1		12NOV2002	1	PP			31		4	4	3	4	0	4	4	4	3	1
		DAY 8		19NOV2002	8	PP	10	NO	34	3	4	4	4	4	0	4	4	4	4	2
		DAY 15		26NOV2002	15	PP	-7	NO	29	-2	3	4	3	4	0	3	4	4	3	1
		DAY 22		03DEC2002	22	PP	3	NO	32	1	3	3	3	5	0	4	4	4	4	2
		DAY 29		11DEC2002	30	PP	0	NO	31	0	4	4	3	5	0	2	4	4	3	2
		DAY 36		18DEC2002	37	PP	10	NO	34	3	4	5	4	5	0	2	4	5	3	2
		DAY 43		23DEC2002	42	PP	7	NO	33	2	4	5	3	5	0	2	4	5	3	2
		DAY 50		30DEC2002	49	PP	3	NO	32	1	4	4	3	5	0	2	4	5	4	1
		DAY 57		06JAN2003	56	PP	0	NO	31	0	3	4	1	5	0	4	4	5	4	1
	E0013005	DAY 1		18FEB2003	1	ITT			29		2	4	4	3	3	3	3	4	2	1
		DAY 8		25FEB2003	8	ITT	-7	NO	27	-2	3	3	4	3	0	3	3	3	3	2
		DAY 15		04MAR2003	15	ITT	-35	NO	19	-10	2	1	3	2	1	3	1	3	1	2
		DAY 22		11MAR2003	22	ITT	-41	NO	17	-12	2	2	3	1	0	2	2	2	1	2
		DAY 29		19MAR2003	30	ITT	-76	YES	7	-22	1	0	2	0	1	0	1	1	1	0
		DAY 36		25MAR2003	36	ITT	-52	NO	14	-15	2	1	2	2	2	2	1	1	0	1
		DAY 43		02APR2003	44	ITT	-31	NO	20	-9	2	2	3	3	2	2	2	2	1	1
		DAY 50		08APR2003	50	ITT	-45	NO	16	-13	1	1	2	1	2	3	1	3	1	1
		DAY 57		15APR2003	57	ITT	-14	NO	25	-4	2	2	4	3	2	4	2	3	1	2
	E0013013	DAY 1		06MAY2003	1	PP			31		4	4	4	2	2	5	4	3	2	1
		DAY 8		12MAY2003	7	PP	-97	YES	1	-30	0	0	0	0	1	0	0	0	0	0
		DAY 15		19MAY2003	14	PP	-16	NO	26	-5	2	4	3	4	3	3	2	3	1	1
		DAY 22		27MAY2003	22	PP	-16	NO	26	-5	1	3	4	1	2	5	4	3	2	1
		DAY 22	*	30MAY2003	25	PP	-16	NO	26	-5	1	1	3	5	0	5	3	3	3	2
	E0014002	DAY 1		26FEB2003	1	PP (44)			28		3	3	3	3	0	3	4	4	3	2
		DAY 8		04MAR2003	7	PP (44)	-36	NO	18	-10	2	3	2	1	0	2	2	3	2	1
		DAY 15		12MAR2003	15	PP (44)	-50	NO	14	-14	1	2	2	0	0	2	2	2	2	1
		DAY 22		20MAR2003	23	PP (44)	4	NO	29	1	4	4	4	5	0	4	3	3	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0014002	DAY 29		27MAR2003	30	PP (44)	-7	NO	26	-2	3	3	4	3	0	2	1	5	3	2
		DAY 43		10APR2003	44	PP (44)	-18	NO	23	-5	3	3	2	2	0	3	5	3	2	0
	E0014004	DAY 1		12MAR2003	1	PP (35)			40		5	5	5	5	1	5	5	5	3	1
		DAY 8		20MAR2003	9	PP (35)	-23	NO	31	-9	4	4	3	4	2	4	4	2	4	0
		DAY 15		25MAR2003	14	PP (35)	-63	NO	15	-25	1	1	3	2	0	2	2	2	2	0
		DAY 22		01APR2003	21	PP (35)	-45	NO	22	-18	3	2	3	3	0	3	3	4	1	0
		DAY 36		15APR2003	35	PP (35)	-35	NO	26	-14	1	3	4	5	0	3	4	3	3	0
	E0014009	DAY 1		23APR2003	1	ITT			33		4	5	3	4	0	3	3	4	4	3
		DAY 8		30APR2003	8	ITT	0	NO	33	0	4	4	4	5	2	3	2	2	4	3
	E0014015	DAY 1		18JUN2003	1	PP			26		2	4	5	1	0	4	5	3	1	1
		DAY 8		26JUN2003	9	PP	-65	YES	9	-17	1	2	1	0	0	0	2	1	2	0
	E0014017	DAY 1		27JUN2003	1	PP			32		3	3	4	3	3	4	4	3	3	2
		DAY 8		02JUL2003	6	PP	-19	NO	26	-6	2	3	3	3	3	3	2	2	2	3
		DAY 15		09JUL2003	13	PP	-84	YES	5	-27	0	1	0	1	0	1	0	1	0	1
		DAY 22		16JUL2003	20	PP	-84	YES	5	-27	0	1	0	2	0	0	1	1	0	0
		DAY 29		23JUL2003	27	PP	-91	YES	3	-29	0	0	1	1	0	1	0	0	0	0
		DAY 29	*	29JUL2003	33	PP	-84	YES	5	-27	0	0	1	0	0	2	1	1	0	0
		DAY 36		05AUG2003	40	PP	-81	YES	6	-26	1	0	2	0	0	2	1	0	0	0
		DAY 43		12AUG2003	47	PP	-88	YES	4	-28	1	1	0	0	0	1	0	0	1	0
		DAY 50		19AUG2003	54	PP	-97	YES	1	-31	0	0	1	0	0	0	0	0	0	0
	E0014018	DAY 1		01JUL2003	1	PP			29		3	3	1	2	3	5	5	3	3	1
		DAY 8		09JUL2003	9	PP	17	NO	34	5	3	4	4	3	4	3	5	4	2	2
		DAY 15		16JUL2003	16	PP	24	NO	36	7	3	4	4	2	3	5	5	5	3	2
		DAY 22		22JUL2003	22	PP	7	NO	31	2	3	3	3	3	3	4	4	3	3	2
		DAY 29		29JUL2003	29	PP	-31	NO	20	-9	2	2	2	2	0	2	3	3	3	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0014018	DAY 36		05AUG2003	36	PP	-21	NO	23	-6	3	3	1	5	1	3	3	3	1	0
		DAY 43		12AUG2003	43	PP	14	NO	33	4	3	4	3	5	3	3	4	4	3	1
		DAY 50		19AUG2003	50	PP	0	NO	29	0	4	3	3	4	2	3	4	3	2	1
		DAY 57		27AUG2003	58	PP	-10	NO	26	-3	3	3	2	2	3	3	4	3	2	1
	E0015005	DAY 1		02DEC2002	1	PP			30		3	4	4	4	0	4	4	4	2	1
		DAY 8		11DEC2002	10	PP	-3	NO	29	-1	3	4	4	4	0	4	3	4	2	1
		DAY 15		18DEC2002	17	PP	-10	NO	27	-3	4	4	3	4	0	3	3	3	2	1
	E0018009	DAY 1		06JAN2003	1	PP			34		4	4	4	5	3	4	4	3	3	0
		DAY 8		13JAN2003	8	PP	3	NO	35	1	4	4	4	4	3	4	4	4	3	1
		DAY 8	*	14JAN2003	9	PP	9	NO	37	3	4	4	4	4	4	4	4	4	4	1
	E0018010	DAY 1		16JAN2003	1	PP			32		4	4	4	4	3	3	3	3	3	1
		DAY 8		23JAN2003	8	PP	-13	NO	28	-4	4	4	4	4	3	3	2	2	2	0
		DAY 15		30JAN2003	15	PP	-19	NO	26	-6	3	3	4	2	2	3	2	3	3	1
		DAY 22		06FEB2003	22	PP	-25	NO	24	-8	3	3	3	2	2	3	3	3	2	0
		DAY 29		13FEB2003	29	PP	-50	NO	16	-16	2	3	2	3	2	1	1	1	1	0
		DAY 36		20FEB2003	36	PP	-25	NO	24	-8	1	2	2	3	2	4	4	4	2	0
		DAY 43		26FEB2003	42	PP	-41	NO	19	-13	2	2	1	1	2	2	3	3	2	1
		DAY 50		06MAR2003	50	PP	-72	YES	9	-23	1	1	2	0	0	1	2	1	1	0
		DAY 57		13MAR2003	57	PP	-47	NO	17	-15	1	1	3	2	2	2	2	2	2	0
	E0018015	DAY 1		28JAN2003	1	PP			31		4	4	4	4	3	2	4	4	2	0
		DAY 8		04FEB2003	8	PP	-13	NO	27	-4	4	4	4	2	0	3	3	3	3	1
		DAY 15		13FEB2003	17	PP	-16	NO	26	-5	4	4	3	0	3	2	3	3	3	1
		DAY 22		20FEB2003	24	PP	-13	NO	27	-4	4	4	3	0	3	3	3	4	3	0
		DAY 29		26FEB2003	30	PP	-55	NO	14	-17	3	3	2	0	0	2	1	1	2	0
		DAY 36		06MAR2003	38	PP	-77	YES	7	-24	1	1	1	0	0	0	1	1	2	0
		DAY 43		13MAR2003	45	PP	-58	NO	13	-18	2	2	2	2	0	0	1	2	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0018015	DAY 50		20MAR2003	52	PP	-84	YES	5	-26	0	0	1	1	0	0	1	0	2	0
		DAY 57		27MAR2003	59	PP	-58	NO	13	-18	1	2	2	2	0	0	2	2	2	0
	E0020015	DAY 1		27MAR2003	1	PP			41		4	5	4	5	4	5	4	4	4	2
		DAY 8		03APR2003	8	PP	0	NO	41	0	4	5	4	5	4	5	4	4	4	2
		DAY 15		10APR2003	15	PP	-15	NO	35	-6	4	4	4	5	4	4	4	4	0	2
		DAY 22		16APR2003	21	PP	-22	NO	32	-9	2	3	3	4	4	4	4	4	2	2
		DAY 29		23APR2003	28	PP	-22	NO	32	-9	2	3	3	4	3	4	4	4	3	2
		DAY 36		30APR2003	35	PP	-22	NO	32	-9	3	3	3	3	4	4	4	4	2	2
		DAY 43		08MAY2003	43	PP	-20	NO	33	-8	2	4	3	3	4	3	4	4	4	2
		DAY 50		15MAY2003	50	PP	-15	NO	35	-6	4	4	3	3	4	3	4	4	4	2
		DAY 57		23MAY2003	58	PP	-15	NO	35	-6	4	4	4	5	4	2	4	3	3	2
	E0020017	DAY 1		03APR2003	1	PP			20		2	2	4	1	0	3	4	4	0	0
		DAY 8		10APR2003	8	PP	-30	NO	14	-6	2	2	3	0	0	3	4	0	0	0
		DAY 15		17APR2003	15	PP	-25	NO	15	-5	1	4	4	1	0	2	1	0	2	0
		DAY 22		22APR2003	20	PP	-30	NO	14	-6	1	2	3	3	0	3	2	0	0	0
		DAY 29		29APR2003	27	PP	-70	YES	6	-14	1	0	3	0	0	2	0	0	0	0
		DAY 29	*	05MAY2003	33	PP	20	NO	24	4	2	3	3	4	0	3	3	4	2	0
		DAY 36		12MAY2003	40	PP	-50	YES	10	-10	2	0	3	1	0	3	1	0	0	0
		DAY 50		20MAY2003	48	PP	-70	YES	6	-14	0	0	3	0	0	2	1	0	0	0
	E0020020	DAY 1		12MAY2003	1	PP			38		4	5	4	4	2	4	4	5	4	2
		DAY 8		19MAY2003	8	PP	5	NO	40	2	4	5	4	4	3	4	4	5	4	3
		DAY 8	*	23MAY2003	12	PP	13	NO	43	5	5	5	5	4	0	6	5	3	5	5
	E0020022	DAY 1		16JUN2003	1	PP			26		2	2	2	2	1	5	4	4	4	0
		DAY 8		23JUN2003	8	PP	-89	YES	3	-23	0	0	0	2	0	0	0	1	0	0
		DAY 15		30JUN2003	15	PP	-58	YES	11	-15	1	0	0	2	0	0	4	0	4	0
		DAY 22		07JUL2003	22	PP	-54	YES	12	-14	0	0	0	4	0	4	4	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0020022	DAY 29	14JUL2003	29	PP	-46	NO	14	-12	2	4	3	0	2	0	3	0	0	0
		DAY 36	21JUL2003	36	PP	-100	YES	0	-26	0	0	0	0	0	0	0	0	0	0
		DAY 43	28JUL2003	43	PP	-100	YES	0	-26	0	0	0	0	0	0	0	0	0	0
		DAY 50	04AUG2003	50	PP	-100	YES	0	-26	0	0	0	0	0	0	0	0	0	0
		DAY 57	11AUG2003	57	PP	-96	YES	1	-25	0	0	0	0	0	0	1	0	0	0
	E0022001	DAY 1	28OCT2002	1	PP			38		4	4	4	3	4	4	4	4	4	3
		DAY 8	04NOV2002	8	PP	3	NO	39	1	4	4	3	5	3	4	4	4	4	4
		DAY 15	11NOV2002	15	PP	-16	NO	32	-6	4	4	2	3	3	3	4	4	4	1
		DAY 22	18NOV2002	22	PP	-13	NO	33	-5	4	4	4	4	2	3	4	4	3	1
		DAY 29	26NOV2002	30	PP	-50	NO	19	-19	2	3	2	4	0	2	2	2	2	0
		DAY 36	02DEC2002	36	PP	-29	NO	27	-11	3	3	3	4	2	3	3	3	2	1
		DAY 43	09DEC2002	43	PP	-66	NO	13	-25	1	1	2	2	1	2	2	1	1	0
		DAY 50	16DEC2002	50	PP	-79	YES	8	-30	0	1	1	2	0	2	1	0	1	0
		DAY 57	26DEC2002	60	PP	-16	NO	32	-6	4	4	3	4	2	4	4	2	4	1
	E0022004	DAY 1	28OCT2002	1	PP			39		4	4	3	5	3	5	4	4	4	3
		DAY 8	04NOV2002	8	PP	-26	NO	29	-10	3	3	3	4	2	3	3	3	3	2
		DAY 15	11NOV2002	15	PP	-10	NO	35	-4	4	4	3	4	3	4	4	4	3	2
		DAY 22	19NOV2002	23	PP	-8	NO	36	-3	4	4	3	6	3	3	3	4	3	3
		DAY 29	26NOV2002	30	PP	-36	NO	25	-14	3	3	3	4	3	3	2	2	2	0
		DAY 36	02DEC2002	36	PP	-5	NO	37	-2	4	4	3	6	2	4	4	4	3	3
		DAY 43	10DEC2002	44	PP	-18	NO	32	-7	4	2	4	4	2	4	3	4	4	1
		DAY 50	16DEC2002	50	PP	-21	NO	31	-8	4	4	3	5	0	4	4	3	2	2
		DAY 57	23DEC2002	57	PP	-15	NO	33	-6	3	3	3	5	2	4	4	4	3	2
	E0022005	DAY 1	08NOV2002	1	ITT			28		4	4	3	3	0	3	3	3	2	3
		DAY 8	15NOV2002	8	ITT	-11	NO	25	-3	3	3	3	3	0	3	3	3	2	2
		DAY 15	22NOV2002	15	ITT	7	NO	30	2	3	3	4	3	0	4	4	4	3	2
		DAY 22	29NOV2002	22	ITT	0	NO	28	0	4	4	3	0	0	4	4	4	3	2

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PLACEBO (BIPOLAR I)	E0022005	DAY 29	06DEC2002	29	ITT	14	NO	32	4	4	4	3	4	0	4	4	4	3	2
		DAY 36	13DEC2002	36	ITT	-25	NO	21	-7	3	3	2	4	0	2	3	2	2	0
		DAY 43	20DEC2002	43	ITT	7	NO	30	2	4	4	3	4	0	4	3	3	3	2
		DAY 50	27DEC2002	50	ITT	4	NO	29	1	4	4	3	3	0	3	4	3	3	2
		DAY 57	03JAN2003	57	ITT	11	NO	31	3	4	4	3	4	0	3	4	4	3	2
	E0022011	DAY 1	29NOV2002	1	SAFETY			32		4	4	3	2	2	4	4	4	4	1
	E0022015	DAY 1	10DEC2002	1	PP			30		4	4	4	5	0	4	3	3	2	1
		DAY 8	17DEC2002	8	PP	17	NO	35	5	4	4	4	4	3	2	3	3	4	4
		DAY 15	26DEC2002	17	PP	-47	NO	16	-14	2	1	2	4	2	2	1	1	1	0
		DAY 22	02JAN2003	24	PP	-77	YES	7	-23	1	0	1	3	0	2	0	0	0	0
		DAY 29	09JAN2003	31	PP	-10	NO	27	-3	3	3	4	3	0	3	3	4	2	2
		DAY 36	16JAN2003	38	PP	20	NO	36	6	4	4	4	4	3	4	3	3	4	3
		DAY 43	23JAN2003	45	PP	-3	NO	29	-1	3	4	4	5	0	2	2	4	4	1
		DAY 50	30JAN2003	52	PP	-30	NO	21	-9	2	3	3	4	0	4	0	1	4	0
		DAY 57	06FEB2003	59	PP	-17	NO	25	-5	3	4	3	5	0	2	2	2	4	0
	E0022016	DAY 1	17DEC2002	1	PP			31		4	4	2	4	2	4	4	4	2	1
		DAY 8	26DEC2002	10	PP	3	NO	32	1	4	4	3	4	2	4	4	4	2	1
		DAY 15	30DEC2002	14	PP	0	NO	31	0	4	4	2	4	0	4	4	4	3	2
		DAY 22	06JAN2003	21	PP	16	NO	36	5	5	5	3	5	0	4	4	4	4	2
		DAY 29	13JAN2003	28	PP	3	NO	32	1	5	4	2	5	0	4	4	4	2	2
		DAY 36	21JAN2003	36	PP	3	NO	32	1	4	4	3	5	0	4	4	4	2	2
		DAY 43	30JAN2003	45	PP	7	NO	33	2	5	5	2	5	0	4	5	4	2	1
		DAY 50	06FEB2003	52	PP	16	NO	36	5	4	4	3	5	3	4	4	4	3	2
		DAY 57	11FEB2003	57	PP	13	NO	35	4	5	5	2	5	0	4	5	4	3	2
	E0022020	DAY 1	12DEC2002	1	PP (43)			30		4	4	2	4	0	2	5	3	4	2
		DAY 8	19DEC2002	8	PP (43)	-13	NO	26	-4	4	4	2	2	0	2	4	4	2	2

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# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%@	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0022020	DAY 15	26DEC2002	15	PP (43)	-17	NO	25	-5	3	2	2	2	0	4	4	4	2	2
		DAY 22	02JAN2003	22	PP (43)	-57	NO	13	-17	2	2	2	2	0	2	0	2	0	1
		DAY 29	10JAN2003	30	PP (43)	-57	NO	13	-17	2	2	2	2	0	0	2	2	0	1
		DAY 36	16JAN2003	36	PP (43)	-80	YES	6	-24	1	0	0	0	0	0	2	2	0	1
		DAY 43	23JAN2003	43	PP (43)	-93	YES	2	-28	0	0	0	0	0	0	0	0	2	0
	E0022023	DAY 1	24DEC2002	-1	PP			44		6	6	4	5	4	5	5	5	2	2
		DAY 8	02JAN2003	9	PP	-16	NO	37	-7	6	4	2	4	2	2	5	4	4	4
		DAY 15	09JAN2003	16	PP	-59	NO	18	-26	2	2	2	2	0	2	2	2	2	2
		DAY 22	16JAN2003	23	PP	-57	NO	19	-25	2	2	2	4	0	2	2	2	1	2
		DAY 29	23JAN2003	30	PP	-59	NO	18	-26	1	2	2	4	0	2	2	2	2	1
		DAY 36	30JAN2003	37	PP	-50	NO	22	-22	2	2	2	4	0	4	2	2	2	2
		DAY 43	06FEB2003	44	PP	-39	NO	27	-17	4	4	2	5	0	4	4	2	1	1
		DAY 50	13FEB2003	51	PP	-64	NO	16	-28	2	2	0	4	0	2	2	2	1	1
		DAY 57	20FEB2003	58	PP	-66	NO	15	-29	2	2	2	2	0	2	2	2	0	1
	E0022029	DAY 1	19FEB2003	1	PP			23		2	4	2	5	0	2	3	3	2	0
		DAY 8	26FEB2003	8	PP	-22	NO	18	-5	2	2	3	2	0	2	2	2	3	0
		DAY 15	03MAR2003	13	PP	-4	NO	22	-1	2	4	2	3	0	2	3	3	3	0
		DAY 22	12MAR2003	22	PP	-35	NO	15	-8	1	1	2	3	0	3	2	0	3	0
		DAY 29	18MAR2003	28	PP	-39	NO	14	-9	1	1	2	4	0	3	1	0	2	0
		DAY 36	26MAR2003	36	PP	-57	YES	10	-13	0	1	1	3	0	2	1	0	2	0
		DAY 43	02APR2003	43	PP	-44	NO	13	-10	2	2	1	3	0	2	1	0	2	0
		DAY 50	07APR2003	48	PP	-22	NO	18	-5	2	3	2	3	0	3	2	1	2	0
		DAY 57	14APR2003	55	PP	-17	NO	19	-4	3	2	2	4	0	3	2	0	3	0
	E0022041	DAY 1	18MAR2003	1	PP			34		4	4	3	3	4	4	4	4	2	2
		DAY 8	25MAR2003	8	PP	-24	NO	26	-8	4	4	2	2	0	4	3	4	2	1
		DAY 15	01APR2003	15	PP	-27	NO	25	-9	4	4	2	4	0	2	3	3	2	1
		DAY 22	08APR2003	22	PP	-47	NO	18	-16	1	2	1	3	3	0	3	2	2	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0022041	DAY 29		15APR2003	29	PP	-27	NO	25	-9	3	3	2	3	0	2	3	3	3	3
		DAY 36		21APR2003	35	PP	-71	YES	10	-24	2	2	0	2	0	0	2	2	0	0
		DAY 43		29APR2003	43	PP	-68	YES	11	-23	2	2	2	2	0	0	0	2	1	0
		DAY 50		06MAY2003	50	PP	-71	YES	10	-24	1	1	2	3	0	0	0	2	1	0
		DAY 57		13MAY2003	57	PP	-74	YES	9	-25	0	0	2	2	0	1	2	1	1	0
	E0022042	DAY 1		12MAR2003	1	PP (62)			31		4	4	2	3	0	4	4	4	4	2
		DAY 8		19MAR2003	8	PP (62)	16	NO	36	5	4	5	3	5	0	4	4	4	4	3
		DAY 15		27MAR2003	16	PP (62)	3	NO	32	1	4	4	2	4	0	4	4	4	2	4
		DAY 22		02APR2003	22	PP (62)	-13	NO	27	-4	5	4	1	3	0	3	4	2	3	2
		DAY 29		10APR2003	30	PP (62)	-26	NO	23	-8	3	4	1	4	0	2	3	3	2	1
		DAY 36		17APR2003	37	PP (62)	-13	NO	27	-4	4	4	1	5	0	2	3	3	3	2
		DAY 43		24APR2003	44	PP (62)	0	NO	31	0	4	4	2	4	0	3	4	3	4	3
		DAY 50		01MAY2003	51	PP (62)	0	NO	31	0	4	4	2	4	0	3	4	3	4	3
		DAY 57		12MAY2003	62	PP (62)	0	NO	31	0	4	4	2	5	0	2	4	3	4	3
	E0022043	DAY 1		20MAR2003	1	PP			21		3	4	2	1	2	2	2	2	3	0
		DAY 8		26MAR2003	7	PP	-19	NO	17	-4	3	2	2	2	0	2	2	2	2	0
		DAY 15		03APR2003	15	PP	-38	NO	13	-8	1	2	2	2	0	2	1	1	2	0
		DAY 22		10APR2003	22	PP	-33	NO	14	-7	2	2	1	3	0	2	0	2	2	0
		DAY 29		17APR2003	29	PP	-48	YES	11	-10	2	2	2	0	0	2	1	0	2	0
		DAY 36		24APR2003	36	PP	-62	YES	8	-13	1	1	0	2	0	2	1	0	1	0
		DAY 43		01MAY2003	43	PP	-38	NO	13	-8	2	3	1	2	0	2	0	1	2	0
		DAY 50		08MAY2003	50	PP	-57	YES	9	-12	1	1	2	2	0	1	1	0	1	0
		DAY 50	*	12MAY2003	54	PP	-71	YES	6	-15	1	0	2	1	0	1	0	0	1	0
	E0022054	DAY 1		11APR2003	1	PP			36		4	4	4	4	3	4	4	4	3	2
		DAY 8		18APR2003	8	PP	-39	NO	22	-14	4	4	3	0	0	3	3	2	1	2
		DAY 15		28APR2003	18	PP	-56	NO	16	-20	2	2	2	2	0	3	2	2	1	0
		DAY 22		02MAY2003	22	PP	-75	YES	9	-27	1	1	2	0	0	2	1	1	1	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0022054	DAY 29		12MAY2003	32	PP	-64	NO	13	-23	2	2	2	2	0	0	2	2	1	0
		DAY 36		16MAY2003	36	PP	-75	YES	9	-27	0	0	2	0	0	2	1	2	1	1
	E0022059	DAY 1		06MAY2003	1	PP			32		4	4	4	5	0	4	3	2	2	4
		DAY 8		13MAY2003	8	PP	-13	NO	28	-4	3	3	3	3	0	4	3	3	2	4
		DAY 15		20MAY2003	15	PP	-34	NO	21	-11	4	3	2	0	0	4	2	2	2	2
		DAY 22		27MAY2003	22	PP	-22	NO	25	-7	3	3	3	0	0	3	3	4	2	4
		DAY 29		03JUN2003	29	PP	-25	NO	24	-8	3	3	3	2	0	4	2	1	3	3
		DAY 36		10JUN2003	36	PP	-34	NO	21	-11	3	2	2	0	0	4	2	2	2	4
		DAY 43		17JUN2003	43	PP	-38	NO	20	-12	3	3	2	0	0	4	2	2	2	2
		DAY 43	*	20JUN2003	46	PP	-22	NO	25	-7	4	3	2	1	0	4	2	2	3	4
		DAY 57		08JUL2003	64	PP	-16	NO	27	-5	3	3	2	2	0	5	2	2	4	4
	E0022065	DAY 1		07MAY2003	1	PP			28		3	4	4	3	0	4	2	4	3	1
		DAY 8		14MAY2003	8	PP	7	NO	30	2	3	4	4	5	0	4	3	4	3	0
		DAY 15		21MAY2003	15	PP	-29	NO	20	-8	3	3	3	1	0	3	2	2	3	0
		DAY 22		28MAY2003	22	PP	-43	NO	16	-12	2	2	4	2	0	1	1	1	3	0
		DAY 29		04JUN2003	29	PP	-43	NO	16	-12	2	3	3	0	0	2	2	2	2	0
		DAY 36		11JUN2003	36	PP	-75	YES	7	-21	1	0	2	0	0	1	0	0	3	0
		DAY 43		18JUN2003	43	PP	-71	YES	8	-20	1	0	2	0	0	0	1	2	2	0
		DAY 50		25JUN2003	50	PP	-39	NO	17	-11	2	3	1	3	0	2	1	1	3	1
		DAY 57		02JUL2003	57	PP	-71	YES	8	-20	2	1	1	0	0	1	0	1	2	0
	E0022070	DAY 1		12JUN2003	1	ITT			42		4	4	4	5	4	4	4	5	4	4
		DAY 8		18JUN2003	7	ITT	7	NO	45	3	4	5	4	5	4	5	4	5	4	5
	E0023001	DAY 1		15NOV2002	1	ITT			27		4	3	4	1	1	3	4	3	2	2
		DAY 8		22NOV2002	8	ITT	4	NO	28	1	3	3	4	3	0	3	4	3	3	2
		DAY 15		29NOV2002	15	ITT	-41	NO	16	-11	1	2	2	2	0	2	2	2	2	1
		DAY 22		06DEC2002	22	ITT	-22	NO	21	-6	3	3	3	1	2	2	1	2	2	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0023001	DAY 29		16DEC2002	32	ITT	-22	NO	21	-6	2	3	3	2	3	2	2	1	2	1
		DAY 36		23DEC2002	39	ITT	-33	NO	18	-9	2	2	3	2	3	1	2	1	1	1
		DAY 43		30DEC2002	46	ITT	-19	NO	22	-5	3	3	3	2	2	1	3	2	2	1
		DAY 50		07JAN2003	54	ITT	56	NO	42	15	4	4	4	4	6	4	4	4	4	4
		DAY 57		14JAN2003	61	ITT	30	NO	35	8	2	3	4	4	6	3	4	3	4	2
	E0023009	DAY 1		11FEB2003	1	ITT			23		3	3	3	0	0	3	4	3	2	2
		DAY 8		18FEB2003	8	ITT	4	NO	24	1	3	3	2	1	2	3	4	3	1	2
		DAY 15		27FEB2003	17	ITT	-22	NO	18	-5	2	2	2	2	0	3	2	3	1	1
		DAY 22		04MAR2003	22	ITT	-35	NO	15	-8	2	2	1	2	0	3	2	2	1	0
		DAY 29		11MAR2003	29	ITT	-74	YES	6	-17	0	0	1	0	0	2	2	0	1	0
		DAY 36		18MAR2003	36	ITT	-74	YES	6	-17	0	0	1	2	0	2	1	0	0	0
		DAY 43		25MAR2003	43	ITT	-70	YES	7	-16	0	0	1	2	0	2	1	0	1	0
		DAY 50		03APR2003	52	ITT	-74	YES	6	-17	0	0	2	0	0	2	1	0	1	0
		DAY 57		08APR2003	57	ITT	-78	YES	5	-18	0	0	2	0	0	2	0	0	1	0
	E0023028	DAY 1		29MAY2003	1	PP			28		4	4	3	3	3	2	3	3	2	1
		DAY 8		05JUN2003	8	PP	-86	YES	4	-24	0	0	0	2	2	0	0	0	0	0
		DAY 15		12JUN2003	15	PP	-89	YES	3	-25	0	0	2	0	0	1	0	0	0	0
		DAY 22		19JUN2003	22	PP	-86	YES	4	-24	0	0	0	3	0	1	0	0	0	0
		DAY 29		25JUN2003	28	PP	-82	YES	5	-23	0	0	2	0	0	1	1	1	0	0
		DAY 43		09JUL2003	42	PP	-89	YES	3	-25	0	0	0	0	0	2	1	0	0	0
		DAY 50		16JUL2003	49	PP	-89	YES	3	-25	0	0	0	0	0	1	2	0	0	0
		DAY 50	*	21JUL2003	54	PP	-82	YES	5	-23	0	0	1	1	0	1	2	0	0	0
	E0023033	DAY 1		05JUN2003	1	ITT			28		4	4	4	2	2	2	3	3	3	1
		DAY 8		12JUN2003	8	ITT	21	NO	34	6	4	4	4	4	2	3	4	4	3	2
	E0023047	DAY 1		18JUL2003	1	PP			31		4	4	3	3	2	3	4	4	3	1
		DAY 8		25JUL2003	8	PP	-10	NO	28	-3	3	3	3	3	2	3	4	3	3	1

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0023047	DAY 15	31JUL2003	14	PP	-7	NO	29	-2	4	3	3	3	3	3	4	2	3	1
		DAY 22	08AUG2003	22	PP	-10	NO	28	-3	2	3	3	4	3	3	4	2	3	1
		DAY 29	15AUG2003	29	PP	-16	NO	26	-5	2	3	3	4	3	2	4	2	2	1
		DAY 36	21AUG2003	35	PP	-36	NO	20	-11	2	2	3	3	3	1	4	1	1	0
		DAY 43	29AUG2003	43	PP	-26	NO	23	-8	2	2	3	4	3	2	3	3	1	0
		DAY 50	05SEP2003	50	PP	-39	NO	19	-12	0	0	4	3	3	1	4	3	1	0
		DAY 57	12SEP2003	57	PP	-36	NO	20	-11	0	0	4	4	3	1	4	3	1	0
	E0025001	DAY 1	01APR2003	1	PP			31		4	3	3	4	2	4	3	3	3	2
		DAY 8	10APR2003	10	PP	-3	NO	30	-1	4	3	3	5	3	3	3	2	2	2
		DAY 15	16APR2003	16	PP	0	NO	31	0	4	4	4	4	4	2	2	1	3	3
		DAY 22	23APR2003	23	PP	23	NO	38	7	4	4	3	5	3	4	4	4	3	4
	E0026012	DAY 1	20FEB2003	1	PP			33		3	4	3	5	3	4	4	3	3	1
		DAY 8	27FEB2003	8	PP	-24	NO	25	-8	3	3	2	4	2	3	0	4	3	1
		DAY 15	06MAR2003	15	PP	-27	NO	24	-9	1	1	2	4	2	4	4	2	4	0
		DAY 22	13MAR2003	22	PP	-82	YES	6	-27	0	0	0	0	2	2	2	0	0	0
		DAY 29	20MAR2003	29	PP	-97	YES	1	-32	0	0	0	0	0	0	1	0	0	0
		DAY 36	27MAR2003	36	PP	-76	YES	8	-25	0	0	0	0	0	4	0	0	4	0
		DAY 43	03APR2003	43	PP	-39	NO	20	-13	2	3	0	0	2	4	0	4	4	1
		DAY 50	10APR2003	50	PP	-36	NO	21	-12	2	2	2	0	2	4	2	2	4	1
		DAY 57	17APR2003	57	PP	-64	YES	12	-21	1	1	1	2	0	4	0	1	1	1
	E0026020	DAY 1	01APR2003	1	PP			23		2	3	2	3	0	2	4	2	4	1
		DAY 8	08APR2003	8	PP	13	NO	26	3	2	2	2	3	0	4	4	4	2	3
		DAY 15	15APR2003	15	PP	-22	NO	18	-5	2	2	2	2	0	2	4	2	1	1
		DAY 22	22APR2003	22	PP	22	NO	28	5	2	3	4	3	0	4	4	3	4	1
	E0026024	DAY 1	02MAY2003	1	PP			33		3	3	1	5	2	4	4	5	4	2
		DAY 8	09MAY2003	8	PP	-6	NO	31	-2	3	4	2	5	0	4	3	5	4	1

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# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0026024	DAY 15		16MAY2003	15	PP	-12	NO	29	-4	2	4	1	5	1	4	3	4	3	2
		DAY 22		23MAY2003	22	PP	-21	NO	26	-7	2	2	2	5	5	5	0	2	3	0
		DAY 29		30MAY2003	29	PP	-30	NO	23	-10	2	2	2	4	4	5	0	2	2	0
	E0026028	DAY 1		20JUN2003	1	SAFETY			46		5	6	4	5	3	5	5	5	4	4
		DAY 8		27JUN2003	8	SAFETY			38	-8	3	3	5	5	5	5	3	3	3	3
		DAY 15		02JUL2003	13	SAFETY			35	-11	3	2	4	5	4	4	5	3	2	3
		DAY 15	*	08JUL2003	19	SAFETY			30	-16	2	3	4	4	5	4	2	2	3	1
	E0028001	DAY 1		10OCT2002	1	PP			31		4	4	2	5	0	2	4	4	4	2
		DAY 8		16OCT2002	7	PP	-7	NO	29	-2	3	4	4	4	0	2	4	4	2	2
		DAY 15		23OCT2002	14	PP	7	NO	33	2	4	4	4	4	0	2	4	4	4	3
		DAY 22		29OCT2002	20	PP	-23	NO	24	-7	2	3	3	4	0	2	4	2	2	2
		DAY 29		05NOV2002	27	PP	-10	NO	28	-3	2	4	4	4	0	0	4	2	4	4
		DAY 36		12NOV2002	34	PP	10	NO	34	3	4	4	4	4	0	2	4	4	4	4
		DAY 43		19NOV2002	41	PP	-32	NO	21	-10	3	4	4	0	0	2	4	2	2	0
		DAY 50		26NOV2002	48	PP	3	NO	32	1	2	4	4	4	0	2	4	4	4	4
		DAY 57		03DEC2002	55	PP	-23	NO	24	-7	4	4	2	4	0	0	4	2	2	2
	E0028003	DAY 1		30SEP2002	1	PP			31		4	5	1	4	2	4	4	4	3	0
		DAY 8		07OCT2002	8	PP	10	NO	34	3	4	5	2	4	2	4	4	4	4	1
		DAY 15		16OCT2002	17	PP	-39	NO	19	-12	1	2	1	4	2	2	4	1	1	1
		DAY 22		22OCT2002	23	PP	3	NO	32	1	4	4	2	2	4	4	4	4	4	0
		DAY 29		29OCT2002	30	PP	13	NO	35	4	4	4	2	4	0	5	4	4	4	4
		DAY 36		07NOV2002	39	PP	10	NO	34	3	4	4	2	4	4	2	4	2	4	4
		DAY 43		12NOV2002	44	PP	-7	NO	29	-2	2	3	4	4	4	4	2	2	4	0
		DAY 50		19NOV2002	51	PP	-7	NO	29	-2	4	4	3	4	0	4	4	2	4	0
		DAY 57		26NOV2002	58	PP	-10	NO	28	-3	2	2	4	4	0	4	4	4	2	2
	E0028005	DAY 1		03OCT2002	1	PP (29)			41		5	5	4	4	2	4	5	5	4	3

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0028005	DAY 8	11OCT2002	9	PP (29)	-7	NO	38	-3	4	4	2	4	4	4	4	4	4	4
		DAY 29	31OCT2002	29	PP (29)	-42	NO	24	-17	3	2	0	2	4	3	4	2	4	0
	E0028010	DAY 1	05NOV2002	1	PP			24		2	3	4	4	0	2	3	2	4	0
		DAY 8	12NOV2002	8	PP	-21	NO	19	-5	2	4	2	4	0	0	2	3	2	0
		DAY 15	19NOV2002	15	PP	-25	NO	18	-6	4	4	2	4	0	0	2	2	0	0
		DAY 22	25NOV2002	21	PP	-67	YES	8	-16	0	0	2	4	0	0	0	0	2	0
		DAY 29	03DEC2002	29	PP	-54	YES	11	-13	1	0	2	4	0	0	0	2	2	0
		DAY 36	10DEC2002	36	PP	-42	NO	14	-10	4	4	2	4	0	0	0	0	0	0
		DAY 43	17DEC2002	43	PP	-67	YES	8	-16	0	2	0	4	0	0	2	0	0	0
		DAY 50	23DEC2002	49	PP	-75	YES	6	-18	0	0	0	4	0	0	2	0	0	0
		DAY 57	31DEC2002	57	PP	-79	YES	5	-19	0	0	0	3	0	0	2	0	0	0
	E0028011	DAY 1	05DEC2002	1	SAFETY			28		4	4	2	4	0	4	4	4	2	0
		DAY 8	12DEC2002	8	SAFETY			15	-13	2	4	2	4	0	0	0	1	2	0
		DAY 15	19DEC2002	15	SAFETY			8	-20	2	2	0	3	0	0	0	0	1	0
		DAY 22	26DEC2002	22	SAFETY			6	-22	0	0	0	4	0	2	0	0	0	0
		DAY 29	02JAN2003	29	SAFETY			14	-14	1	2	2	4	0	2	2	1	0	0
		DAY 36	09JAN2003	36	SAFETY			2	-26	0	0	2	0	0	0	0	0	0	0
		DAY 43	16JAN2003	43	SAFETY			3	-25	0	2	0	1	0	0	0	0	0	0
		DAY 50	23JAN2003	50	SAFETY			7	-21	2	2	0	1	0	0	0	0	2	0
		DAY 57	30JAN2003	57	SAFETY			4	-24	0	2	2	0	0	0	0	0	0	0
	E0028030	DAY 1	04MAR2003	1	PP			34		4	4	2	4	2	4	4	4	4	2
		DAY 8	11MAR2003	8	PP	6	NO	36	2	4	4	4	4	4	4	4	4	4	0
		DAY 15	18MAR2003	15	PP	-27	NO	25	-9	4	4	0	3	0	2	4	4	4	0
		DAY 22	25MAR2003	22	PP	-18	NO	28	-6	4	4	2	4	2	4	4	4	0	0
		DAY 29	01APR2003	29	PP	-35	NO	22	-12	4	2	2	4	2	2	4	2	0	0
		DAY 36	08APR2003	36	PP	-41	NO	20	-14	4	4	0	2	2	2	4	2	0	0
		DAY 43	17APR2003	45	PP	-41	NO	20	-14	4	4	0	0	2	2	4	4	0	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0028030	DAY 50	22APR2003	50	PP	-38	NO	21	-13	4	3	0	2	2	0	4	4	2	0
		DAY 57	30APR2003	58	PP	-24	NO	26	-8	4	4	4	4	2	4	2	2	0	0
	E0028031	DAY 1	11MAR2003	1	SAFETY			31		4	3	4	4	2	2	4	4	4	0
		DAY 8	18MAR2003	8	SAFETY			23	-8	3	2	4	2	2	2	2	4	2	0
		DAY 15	25MAR2003	15	SAFETY			22	-9	2	2	2	4	4	2	2	2	2	0
	E0028047	DAY 1	14JUL2003	1	PP			32		4	4	2	4	2	3	3	4	4	2
		DAY 8	21JUL2003	8	PP	-6	NO	30	-2	4	4	4	4	0	4	4	4	2	0
		DAY 15	29JUL2003	16	PP	-13	NO	28	-4	4	4	4	4	0	2	4	4	2	0
		DAY 22	05AUG2003	23	PP	-13	NO	28	-4	4	4	4	4	2	2	4	2	2	0
		DAY 29	12AUG2003	30	PP	6	NO	34	2	4	4	4	4	4	4	4	4	2	0
		DAY 36	19AUG2003	37	PP	-6	NO	30	-2	4	4	4	4	2	2	4	4	2	0
		DAY 43	26AUG2003	44	PP	-19	NO	26	-6	4	4	4	4	2	2	4	2	0	0
		DAY 50	02SEP2003	51	PP	0	NO	32	0	4	4	4	4	2	2	4	4	4	0
		DAY 57	09SEP2003	58	PP	-19	NO	26	-6	4	4	4	4	0	2	4	4	0	0
	E0029001	DAY 1	01OCT2002	1	PP			29		4	4	2	6	2	2	2	4	1	2
		DAY 8	09OCT2002	9	PP	-7	NO	27	-2	4	4	2	4	2	3	1	4	2	1
	E0029014	DAY 1	04FEB2003	1	PP			32		3	4	4	4	2	4	4	2	3	2
		DAY 8	11FEB2003	8	PP	-22	NO	25	-7	1	3	4	4	2	3	3	3	2	0
		DAY 15	18FEB2003	15	PP	-38	NO	20	-12	0	2	3	5	2	3	3	0	2	0
		DAY 22	25FEB2003	22	PP	-66	YES	11	-21	0	0	2	2	1	3	2	0	1	0
		DAY 29	06MAR2003	31	PP	-16	NO	27	-5	3	4	3	3	0	4	4	4	2	0
		DAY 36	11MAR2003	36	PP	0	NO	32	0	4	5	4	4	0	4	3	4	3	1
		DAY 43	20MAR2003	45	PP	-53	NO	15	-17	0	0	2	5	3	5	0	0	0	0
		DAY 50	27MAR2003	52	PP	6	NO	34	2	3	3	4	2	4	6	4	4	3	1
		DAY 57	01APR2003	57	PP	-13	NO	28	-4	2	2	2	3	4	4	4	3	3	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0029023	DAY 1		08APR2003	1	ITT			27		4	4	3	2	0	1	4	2	4	3
		DAY 8		15APR2003	8	ITT	15	NO	31	4	4	5	1	5	0	3	4	4	2	3
		DAY 15		22APR2003	15	ITT	26	NO	34	7	4	4	3	4	0	4	4	4	4	3
		DAY 22		01MAY2003	24	ITT	26	NO	34	7	4	4	3	4	2	3	4	3	4	3
		DAY 36		12MAY2003	35	ITT	37	NO	37	10	4	4	4	4	2	3	4	4	4	4
		DAY 43		20MAY2003	43	ITT	30	NO	35	8	4	4	3	4	0	3	4	4	5	4
		DAY 50		29MAY2003	52	ITT	15	NO	31	4	4	4	3	4	0	2	4	4	4	2
	E0029032	DAY 1		10JUN2003	1	PP (22)			43		5	5	4	5	4	4	4	4	4	4
		DAY 8		17JUN2003	8	PP (22)	-2	NO	42	-1	5	5	3	5	4	4	4	4	4	4
		DAY 22		01JUL2003	22	PP (22)	2	NO	44	1	5	5	4	5	4	4	4	5	4	4
	E0029033	DAY 1		02JUN2003	1	PP			46		4	5	5	5	6	5	4	4	4	4
		DAY 8		09JUN2003	8	PP	-15	NO	39	-7	5	6	5	5	4	4	2	2	4	2
		DAY 15		16JUN2003	15	PP	-35	NO	30	-16	3	4	3	4	2	4	3	2	3	2
		DAY 22		23JUN2003	22	PP	-24	NO	35	-11	4	4	4	5	4	3	4	3	2	2
		DAY 29		30JUN2003	29	PP	-22	NO	36	-10	4	5	5	5	4	3	1	3	3	3
	E0029039	DAY 1		15JUL2003	1	PP			41		5	5	2	5	4	4	5	4	4	3
		DAY 8		23JUL2003	9	PP	-15	NO	35	-6	4	4	3	5	2	4	4	4	3	2
		DAY 15		28JUL2003	14	PP	-32	NO	28	-13	3	3	3	4	3	2	1	4	3	2
	E0030003	DAY 1		16DEC2002	1	ITT			32		3	4	3	4	2	4	4	3	3	2
		DAY 8		23DEC2002	8	ITT	-6	NO	30	-2	3	3	3	4	3	4	3	3	3	1
		DAY 8	*	24DEC2002	9	ITT	-6	NO	30	-2	3	3	3	4	3	4	3	3	3	1
	E0030009	DAY 1		23JAN2003	1	PP			29		4	4	3	4	4	2	3	4	0	1
		DAY 8		29JAN2003	7	PP	7	NO	31	2	4	4	4	4	2	4	2	4	2	1
		DAY 15		07FEB2003	16	PP	14	NO	33	4	4	4	5	4	3	3	3	4	1	2
		DAY 36		27FEB2003	36	PP	24	NO	36	7	5	4	5	4	0	4	4	5	4	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0030009	DAY 43	06MAR2003	43	PP	17	NO	34	5	4	4	4	4	0	4	4	4	4	2
		DAY 50	12MAR2003	49	PP	24	NO	36	7	4	4	4	4	3	4	4	4	3	2
		DAY 57	19MAR2003	56	PP	0	NO	29	0	4	4	4	4	1	3	2	4	2	1
	E0030016	DAY 1	03MAR2003	1	PP (51)			37		4	5	3	4	4	3	4	4	3	3
		DAY 8	10MAR2003	8	PP (51)	-22	NO	29	-8	3	3	3	4	3	4	2	4	2	1
		DAY 15	17MAR2003	15	PP (51)	5	NO	39	2	4	4	4	5	4	3	4	4	4	3
		DAY 22	25MAR2003	23	PP (51)	0	NO	37	0	4	5	3	2	4	4	4	4	4	3
		DAY 29	02APR2003	31	PP (51)	3	NO	38	1	4	4	4	4	4	4	4	4	4	2
		DAY 36	09APR2003	38	PP (51)	-41	NO	22	-15	2	2	3	2	3	1	3	2	2	2
		DAY 50	22APR2003	51	PP (51)	-32	NO	25	-12	3	3	3	2	3	2	3	2	2	2
	E0030021	DAY 1	20MAY2003	1	PP			29		4	4	1	2	3	3	4	4	2	2
		DAY 8	27MAY2003	8	PP	-41	NO	17	-12	2	3	1	0	0	2	3	4	2	0
		DAY 15	03JUN2003	15	PP	-52	NO	14	-15	1	2	1	2	0	1	2	2	3	0
		DAY 22	10JUN2003	22	PP	-66	YES	10	-19	0	1	1	2	0	2	3	1	0	0
		DAY 29	17JUN2003	29	PP	-48	NO	15	-14	0	2	1	2	2	1	1	2	2	2
	E0031001	DAY 1	21NOV2002	1	ITT			38		5	5	6	6	2	3	4	3	3	1
		DAY 8	27NOV2002	7	ITT	-34	NO	25	-13	4	5	2	2	0	3	2	2	4	1
		DAY 15	05DEC2002	15	ITT	-29	NO	27	-11	4	4	3	6	0	2	4	0	3	1
		DAY 22	11DEC2002	21	ITT	-50	NO	19	-19	4	4	3	2	0	0	4	0	2	0
		DAY 29	20DEC2002	30	ITT	-26	NO	28	-10	4	4	4	3	0	3	4	2	4	0
	E0031017	DAY 1	01APR2003	1	PP			33		4	4	3	4	3	4	4	3	4	0
		DAY 8	07APR2003	7	PP	-24	NO	25	-8	3	4	2	3	0	2	4	3	3	1
		DAY 15	15APR2003	15	PP	-24	NO	25	-8	2	3	3	3	0	4	4	3	2	1
		DAY 22	22APR2003	22	PP	-12	NO	29	-4	4	4	2	3	3	4	4	3	2	0
		DAY 29	29APR2003	29	PP	-21	NO	26	-7	3	3	2	3	2	4	3	3	3	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0031018	DAY 1	10APR2003	1	PP			23		2	3	2	2	2	4	2	3	3	0
		DAY 8	17APR2003	8	PP	-39	NO	14	-9	2	2	2	0	2	2	2	2	0	0
		DAY 15	24APR2003	15	PP	-52	YES	11	-12	1	2	0	0	0	2	2	2	2	0
	E0031023	DAY 1	29APR2003	1	PP			23		3	4	3	2	0	4	1	3	3	0
		DAY 8	07MAY2003	9	PP	9	NO	25	2	3	4	3	2	0	3	4	3	3	0
		DAY 15	13MAY2003	15	PP	-22	NO	18	-5	3	3	3	2	0	0	1	3	3	0
		DAY 22	20MAY2003	22	PP	-22	NO	18	-5	3	4	2	2	2	0	0	2	3	0
		DAY 29	27MAY2003	29	PP	-35	NO	15	-8	1	2	3	2	0	0	2	2	3	0
		DAY 36	04JUN2003	37	PP	-22	NO	18	-5	3	3	3	1	0	0	1	4	3	0
		DAY 43	10JUN2003	43	PP	-35	NO	15	-8	2	3	2	1	0	0	0	4	3	0
		DAY 50	17JUN2003	50	PP	-4	NO	22	-1	4	4	2	2	1	1	1	4	3	0
		DAY 57	24JUN2003	57	PP	-35	NO	15	-8	2	3	2	2	0	0	0	3	3	0
	E0033001	DAY 1	09JAN2003	1	PP			42		4	4	4	5	5	4	5	5	4	2
		DAY 8	16JAN2003	8	PP	0	NO	42	0	4	5	4	4	5	4	4	5	4	3
		DAY 15	23JAN2003	15	PP	10	NO	46	4	5	5	4	6	5	4	4	5	4	4
		DAY 22	30JAN2003	22	PP	14	NO	48	6	5	5	4	6	5	5	5	5	5	3
	E0033004	DAY 1	17JAN2003	1	PP			31		3	4	4	4	0	4	3	4	3	2
		DAY 8	24JAN2003	8	PP	-19	NO	25	-6	3	3	3	2	0	3	4	3	2	2
		DAY 15	31JAN2003	15	PP	-42	NO	18	-13	2	3	2	0	0	3	2	2	2	2
		DAY 22	07FEB2003	22	PP	-68	YES	10	-21	1	1	0	0	2	2	1	2	0	1
		DAY 29	14FEB2003	29	PP	-74	YES	8	-23	2	1	2	0	0	2	0	1	0	0
		DAY 36	21FEB2003	36	PP	-84	YES	5	-26	0	0	0	3	2	0	0	0	0	0
		DAY 43	28FEB2003	43	PP	-81	YES	6	-25	0	0	4	0	0	2	0	0	0	0
		DAY 50	07MAR2003	50	PP	-10	NO	28	-3	3	4	2	5	3	3	3	4	0	1
		DAY 57	14MAR2003	57	PP	7	NO	33	2	4	4	4	0	3	4	4	4	3	3
	E0033010	DAY 1	04FEB2003	1	PP			35		4	4	4	3	3	4	4	4	3	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0033010	DAY 8	11FEB2003	8	PP	-3	NO	34	-1	5	4	4	0	4	4	4	4	3	2
		DAY 15	20FEB2003	17	PP	-3	NO	34	-1	4	4	4	3	2	4	4	4	3	2
		DAY 22	27FEB2003	24	PP	-29	NO	25	-10	4	4	2	2	0	3	3	2	3	2
		DAY 29	04MAR2003	29	PP	-17	NO	29	-6	4	3	3	2	3	3	4	3	2	2
		DAY 36	14MAR2003	39	PP	3	NO	36	1	4	4	4	1	4	4	4	4	3	4
	E0033014	DAY 1	19MAR2003	1	PP			22		3	3	1	4	1	2	2	2	2	2
		DAY 8	26MAR2003	8	PP	9	NO	24	2	3	2	4	3	1	3	1	2	2	3
		DAY 15	03APR2003	16	PP	-9	NO	20	-2	3	3	2	1	0	2	3	3	2	1
		DAY 22	11APR2003	24	PP	-36	NO	14	-8	2	2	1	0	0	1	3	1	2	2
		DAY 29	16APR2003	29	PP	18	NO	26	4	4	4	3	1	0	3	2	4	4	1
		DAY 36	21APR2003	34	PP	18	NO	26	4	3	4	4	0	0	1	2	4	4	4
	E0035002	DAY 1	21NOV2002	1	PP			35		3	4	2	4	6	1	4	4	4	3
		DAY 8	27NOV2002	7	PP	11	NO	39	4	4	4	2	5	6	3	4	4	4	3
		DAY 15	05DEC2002	15	PP	-11	NO	31	-4	4	3	2	4	4	3	3	3	3	2
		DAY 22	12DEC2002	22	PP	-23	NO	27	-8	3	3	2	2	3	3	3	3	3	2
	E0035007	DAY 1	19DEC2002	1	PP			26		3	3	2	4	3	3	1	3	2	2
		DAY 8	26DEC2002	8	PP	-50	NO	13	-13	2	2	2	1	0	2	0	1	2	1
		DAY 15	02JAN2003	15	PP	-62	YES	10	-16	1	1	1	0	0	2	1	2	2	0
		DAY 22	09JAN2003	22	PP	-81	YES	5	-21	1	1	1	0	0	2	0	0	0	0
		DAY 29	17JAN2003	30	PP	31	NO	34	8	4	4	4	4	0	3	4	4	4	3
		DAY 36	23JAN2003	36	PP	-58	YES	11	-15	2	2	1	0	0	2	1	1	2	0
		DAY 43	30JAN2003	43	PP	0	NO	26	0	3	3	3	4	0	2	1	2	4	4
		DAY 50	06FEB2003	50	PP	-89	YES	3	-23	1	1	0	0	0	1	0	0	0	0
		DAY 57	11FEB2003	55	PP	-69	YES	8	-18	2	2	0	0	0	2	0	2	0	0
	E0035011	DAY 1	04FEB2003	1	PP			32		3	3	3	4	0	3	4	4	4	4
		DAY 8	11FEB2003	8	PP	-34	NO	21	-11	3	3	3	1	0	3	2	2	4	0

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@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0035011	DAY 15	18FEB2003	15	PP	-38	NO	20	-12	2	2	3	1	0	3	2	3	4	0
		DAY 22	25FEB2003	22	PP	-19	NO	26	-6	3	3	2	3	2	2	2	3	4	2
		DAY 29	04MAR2003	29	PP	-3	NO	31	-1	3	3	3	3	0	3	4	4	4	4
		DAY 36	11MAR2003	36	PP	-22	NO	25	-7	3	4	3	2	0	3	4	3	2	1
		DAY 43	18MAR2003	43	PP	-44	NO	18	-14	3	4	3	0	0	3	2	3	0	0
		DAY 50	25MAR2003	50	PP	-41	NO	19	-13	3	3	3	3	0	2	2	3	0	0
		DAY 57	01APR2003	57	PP	-59	NO	13	-19	2	2	2	2	0	2	1	0	2	0
	E0035020	DAY 1	18APR2003	1	PP			24		3	4	3	3	2	2	1	4	2	0
		DAY 8	25APR2003	8	PP	-38	NO	15	-9	2	2	2	3	0	2	0	0	4	0
		DAY 15	01MAY2003	14	PP	-58	YES	10	-14	1	1	2	2	0	2	0	0	2	0
		DAY 22	09MAY2003	22	PP	-46	NO	13	-11	2	2	2	3	0	3	0	1	0	0
		DAY 29	15MAY2003	28	PP	-63	YES	9	-15	2	1	2	2	0	2	0	0	0	0
		DAY 36	23MAY2003	36	PP	-75	YES	6	-18	1	0	2	2	0	1	0	0	0	0
		DAY 43	30MAY2003	43	PP	-67	YES	8	-16	2	2	2	2	0	0	0	0	0	0
		DAY 50	06JUN2003	50	PP	-67	YES	8	-16	2	2	2	2	0	0	0	0	0	0
		DAY 57	13JUN2003	57	PP	-54	YES	11	-13	4	2	3	2	0	0	0	0	0	0
	E0037003	DAY 1	30JAN2003	1	PP			31		4	3	3	4	0	4	4	4	3	2
		DAY 8	06FEB2003	8	PP	23	NO	38	7	4	4	3	5	3	4	4	4	4	3
		DAY 15	13FEB2003	15	PP	23	NO	38	7	4	4	3	5	3	4	4	4	4	3
		DAY 22	20FEB2003	22	PP	3	NO	32	1	4	4	2	4	0	4	4	4	3	3
	E0037004	DAY 1	13FEB2003	1	PP			33		3	3	2	4	3	5	4	4	3	2
		DAY 8	21FEB2003	9	PP	-39	NO	20	-13	1	2	2	2	0	4	2	2	3	2
		DAY 15	27FEB2003	15	PP	-27	NO	24	-9	2	2	2	3	0	4	2	4	3	2
		DAY 22	06MAR2003	22	PP	-67	YES	11	-22	0	1	1	1	0	4	1	2	1	0
		DAY 29	13MAR2003	29	PP	-61	NO	13	-20	0	1	0	2	0	4	2	1	2	1
		DAY 36	20MAR2003	36	PP	-36	NO	21	-12	1	1	2	4	0	4	3	4	2	0
		DAY 43	28MAR2003	44	PP	-73	YES	9	-24	0	1	0	4	0	0	1	2	1	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0037004	DAY 50	04APR2003	51	PP	-58	NO	14	-19	1	2	2	2	0	0	2	3	2	0
		DAY 57	10APR2003	57	PP	-76	YES	8	-25	0	1	2	0	0	0	1	2	1	1
	E0039007	DAY 1	04DEC2002	1	PP			30		5	5	4	2	3	2	2	4	2	1
		DAY 8	11DEC2002	8	PP	13	NO	34	4	4	4	4	4	4	2	3	4	3	2
		DAY 15	18DEC2002	15	PP	-30	NO	21	-9	2	2	2	3	2	2	3	2	2	1
		DAY 22	23DEC2002	20	PP	-40	NO	18	-12	2	2	2	2	1	2	2	2	2	1
		DAY 29	30DEC2002	27	PP	-27	NO	22	-8	2	2	2	3	2	4	3	1	2	1
		DAY 36	08JAN2003	36	PP	-17	NO	25	-5	3	4	3	2	1	2	2	3	3	2
		DAY 43	15JAN2003	43	PP	-3	NO	29	-1	4	4	4	0	2	4	3	3	3	2
		DAY 50	22JAN2003	50	PP	-27	NO	22	-8	2	2	3	0	3	2	3	4	2	1
		DAY 57	29JAN2003	57	PP	-53	NO	14	-16	2	2	1	1	1	1	2	2	1	1
	E0039022	DAY 1	25FEB2003	1	PP			31		4	4	3	4	3	3	3	4	2	1
		DAY 8	06MAR2003	10	PP	-65	YES	11	-20	2	2	2	1	0	0	1	2	1	0
		DAY 15	11MAR2003	15	PP	-84	YES	5	-26	1	0	1	1	0	1	0	1	0	0
		DAY 22	18MAR2003	22	PP	-29	NO	22	-9	2	3	3	2	3	2	2	3	2	0
		DAY 29	25MAR2003	29	PP	-58	NO	13	-18	1	1	2	3	0	2	1	2	1	0
		DAY 36	01APR2003	36	PP	-77	YES	7	-24	1	0	1	2	0	1	0	1	1	0
		DAY 43	07APR2003	42	PP	-87	YES	4	-27	0	0	2	2	0	0	0	0	0	0
		DAY 50	15APR2003	50	PP	-81	YES	6	-25	0	1	3	0	0	1	0	1	0	0
		DAY 57	24APR2003	59	PP	-61	YES	12	-19	2	2	2	2	0	0	0	2	2	0
	E0039023	DAY 1	24FEB2003	1	PP			26		3	3	3	4	2	2	2	3	3	1
		DAY 8	03MAR2003	8	PP	15	NO	30	4	3	4	3	4	0	4	3	3	4	2
	E0039030	DAY 1	24MAR2003	1	PP			27		4	4	2	3	0	3	3	4	3	1
		DAY 8	31MAR2003	8	PP	0	NO	27	0	4	4	2	3	0	3	3	4	3	1
		DAY 15	07APR2003	15	PP	-93	YES	2	-25	0	0	1	0	0	0	0	1	0	0
		DAY 22	14APR2003	22	PP	-93	YES	2	-25	0	0	1	0	0	1	0	0	0	0

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0039030	DAY 29	21APR2003	29	PP	-93	YES	2	-25	0	0	1	0	0	0	1	0	0	0
		DAY 36	28APR2003	36	PP	-100	YES	0	-27	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	43	PP	-100	YES	0	-27	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	51	PP	-85	YES	4	-23	0	0	2	0	0	0	1	0	1	0
		DAY 57	19MAY2003	57	PP	-100	YES	0	-27	0	0	0	0	0	0	0	0	0	0
	E0039031	DAY 1	24MAR2003	1	PP			34		4	4	3	3	4	3	4	4	3	2
		DAY 8	31MAR2003	8	PP	-24	NO	26	-8	3	4	2	0	2	3	4	3	3	2
		DAY 15	07APR2003	15	PP	-79	YES	7	-27	0	0	3	3	0	1	0	0	0	0
		DAY 22	15APR2003	23	PP	-91	YES	3	-31	0	0	1	0	0	1	1	0	0	0
		DAY 29	21APR2003	29	PP	-94	YES	2	-32	0	0	2	0	0	0	0	0	0	0
		DAY 36	28APR2003	36	PP	-91	YES	3	-31	0	0	2	0	0	0	0	1	0	0
		DAY 43	05MAY2003	43	PP	-85	YES	5	-29	0	0	3	2	0	0	0	0	0	0
		DAY 50	13MAY2003	51	PP	-24	NO	26	-8	3	3	3	0	3	2	3	4	3	2
		DAY 57	20MAY2003	58	PP	-88	YES	4	-30	1	1	1	0	0	0	0	0	1	0
	E0039037	DAY 1	16APR2003	1	PP			35		4	4	4	5	0	4	4	4	4	2
		DAY 8	23APR2003	8	PP	0	NO	35	0	4	4	4	4	0	4	5	4	4	2
		DAY 15	01MAY2003	16	PP	-6	NO	33	-2	4	4	4	3	0	3	5	4	4	2
		DAY 22	07MAY2003	22	PP	-63	NO	13	-22	0	0	4	1	2	4	0	0	2	0
		DAY 29	15MAY2003	30	PP	-57	NO	15	-20	2	2	4	2	0	3	0	0	2	0
		DAY 36	21MAY2003	36	PP	-69	YES	11	-24	0	0	4	2	0	3	2	0	0	0
		DAY 43	28MAY2003	43	PP	-40	NO	21	-14	2	2	4	0	0	4	3	3	3	0
		DAY 50	05JUN2003	51	PP	-71	YES	10	-25	0	0	4	0	0	0	2	2	2	0
		DAY 57	12JUN2003	58	PP	-31	NO	24	-11	2	2	4	4	0	4	3	3	2	0
	E0039038	DAY 1	23APR2003	1	PP (18)			30		3	4	3	4	3	3	2	4	2	2
		DAY 8	30APR2003	8	PP (18)	3	NO	31	1	4	4	3	2	3	3	3	4	3	2
		DAY 22	15MAY2003	23	PP (18)	-3	NO	29	-1	4	4	4	3	0	2	3	4	3	2
		DAY 29	21MAY2003	29	PP (18)	-67	YES	10	-20	1	1	2	2	0	1	2	1	0	0

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0039038	DAY 36	29MAY2003	37	PP (18)	-37	NO	19	-11	2	3	2	1	2	2	2	2	2	1
	E0039047	DAY 1	19MAY2003	1	PP			34		4	4	3	4	3	3	4	4	3	2
		DAY 8	27MAY2003	9	PP	-32	NO	23	-11	2	3	4	3	2	2	2	2	2	1
		DAY 15	03JUN2003	16	PP	-62	NO	13	-21	1	1	2	2	0	2	2	2	1	0
		DAY 22	09JUN2003	22	PP	-35	NO	22	-12	2	2	2	4	2	2	3	2	2	1
		DAY 29	16JUN2003	29	PP	-32	NO	23	-11	3	2	3	3	1	2	2	2	3	2
		DAY 36	23JUN2003	36	PP	-82	YES	6	-28	0	0	2	2	1	0	0	1	0	0
		DAY 43	30JUN2003	43	PP	-68	YES	11	-23	2	2	2	2	0	0	1	1	1	0
		DAY 50	07JUL2003	50	PP	-94	YES	2	-32	0	0	0	2	0	0	0	0	0	0
		DAY 57	14JUL2003	57	PP	-79	YES	7	-27	1	0	2	2	0	0	0	1	1	0
	E0039059	DAY 1	11JUL2003	1	PP			33		4	4	2	4	2	4	4	3	4	2
		DAY 8	18JUL2003	8	PP	-46	NO	18	-15	2	2	3	0	0	3	3	2	2	1
		DAY 15	25JUL2003	15	PP	-64	YES	12	-21	1	2	1	0	0	3	2	3	0	0
		DAY 22	01AUG2003	22	PP	-79	YES	7	-26	1	1	1	0	0	1	1	1	1	0
		DAY 29	07AUG2003	28	PP	-85	YES	5	-28	0	1	1	0	0	1	0	1	1	0
		DAY 36	15AUG2003	36	PP	-88	YES	4	-29	0	0	1	0	0	1	0	1	1	0
		DAY 43	21AUG2003	42	PP	-97	YES	1	-32	0	0	0	0	0	0	0	1	0	0
		DAY 50	29AUG2003	50	PP	-100	YES	0	-33	0	0	0	0	0	0	0	0	0	0
		DAY 57	05SEP2003	57	PP	-100	YES	0	-33	0	0	0	0	0	0	0	0	0	0
	E0041007	DAY 1	13MAR2003	1	PP			24		3	3	2	3	3	2	2	3	3	0
		DAY 8	20MAR2003	8	PP	-4	NO	23	-1	3	3	3	2	2	2	3	2	3	0
		DAY 15	27MAR2003	15	PP	-21	NO	19	-5	2	2	2	2	2	2	2	2	3	0
		DAY 22	03APR2003	22	PP	-21	NO	19	-5	2	3	0	3	3	2	0	3	3	0
		DAY 29	10APR2003	29	PP	-13	NO	21	-3	2	3	1	3	3	2	1	2	3	1
		DAY 36	17APR2003	36	PP	-8	NO	22	-2	2	3	2	3	3	2	1	3	3	0
		DAY 43	25APR2003	44	PP	0	NO	24	0	3	3	2	3	3	2	3	2	3	0
		DAY 50	01MAY2003	50	PP	4	NO	25	1	3	4	0	3	4	2	4	2	3	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0041007	DAY 57	08MAY2003	57	PP	17	NO	28	4	4	4	3	2	3	2	4	3	3	0
	E0041010	DAY 1	30APR2003	1	PP			23		3	4	3	4	0	3	2	2	2	0
		DAY 8	08MAY2003	9	PP	17	NO	27	4	3	3	3	3	3	2	4	3	3	0
		DAY 15	14MAY2003	15	PP	0	NO	23	0	2	2	3	4	3	2	4	3	0	0
		DAY 22	21MAY2003	22	PP	-4	NO	22	-1	2	2	2	3	2	3	3	2	1	2
		DAY 29	28MAY2003	29	PP	9	NO	25	2	2	2	3	4	2	3	3	3	3	0
		DAY 36	04JUN2003	36	PP	26	NO	29	6	3	4	4	4	3	2	4	2	3	0
		DAY 43	11JUN2003	43	PP	-30	NO	16	-7	0	0	4	5	3	4	0	0	0	0
	E0041011	DAY 1	22MAY2003	1	PP			30		4	5	2	4	0	4	4	3	3	1
		DAY 8	02JUN2003	12	PP	-60	YES	12	-18	1	1	2	2	0	2	2	2	0	0
		DAY 15	06JUN2003	16	PP	-23	NO	23	-7	3	3	3	2	0	2	3	3	3	1
		DAY 22	16JUN2003	26	PP	-13	NO	26	-4	3	3	3	2	0	3	3	4	3	2
		DAY 29	20JUN2003	30	PP	7	NO	32	2	4	4	4	2	3	2	4	3	4	2
		DAY 36	26JUN2003	36	PP	-3	NO	29	-1	3	3	3	2	3	2	4	3	4	2
		DAY 43	03JUL2003	43	PP	-3	NO	29	-1	3	3	3	2	2	2	4	3	4	3
		DAY 50	10JUL2003	50	PP	0	NO	30	0	3	3	4	2	2	2	4	3	4	3
		DAY 57	17JUL2003	57	PP	-3	NO	29	-1	3	3	3	2	3	2	4	3	4	2
	E0041012	DAY 1	19JUN2003	1	PP			28		4	4	4	4	0	3	4	2	3	0
		DAY 8	26JUN2003	8	PP	0	NO	28	0	2	3	4	4	3	4	4	2	2	0
		DAY 15	03JUL2003	15	PP	-18	NO	23	-5	2	3	3	4	0	2	3	3	3	0
		DAY 22	10JUL2003	22	PP	-29	NO	20	-8	2	2	3	3	0	2	3	3	2	0
		DAY 29	17JUL2003	29	PP	-18	NO	23	-5	2	2	4	4	0	3	2	3	3	0
		DAY 36	24JUL2003	36	PP	-21	NO	22	-6	2	2	4	4	0	2	2	2	4	0
		DAY 43	31JUL2003	43	PP	-64	YES	10	-18	0	0	4	4	0	2	0	0	0	0
		DAY 50	07AUG2003	50	PP	-64	YES	10	-18	0	0	4	3	0	3	0	0	0	0
		DAY 57	14AUG2003	57	PP	-50	NO	14	-14	1	1	4	3	0	3	0	0	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0001004	DAY 1	01MAY2003	1	PP			24		3	3	3	2	3	2	3	2	3	0
		DAY 8	09MAY2003	9	PP	-58	YES	10	-14	0	2	4	2	1	0	1	0	0	0
		DAY 15	16MAY2003	16	PP	-75	YES	6	-18	0	2	2	1	0	0	1	0	0	0
		DAY 22	23MAY2003	23	PP	-92	YES	2	-22	0	0	1	0	0	0	1	0	0	0
		DAY 29	29MAY2003	29	PP	-92	YES	2	-22	0	0	0	1	0	0	1	0	0	0
		DAY 36	06JUN2003	37	PP	-58	YES	10	-14	1	2	1	2	2	0	1	0	1	0
		DAY 43	12JUN2003	43	PP	-92	YES	2	-22	0	1	0	0	0	0	0	0	1	0
		DAY 50	20JUN2003	51	PP	-46	NO	13	-11	2	3	2	1	1	0	2	1	1	0
		DAY 57	27JUN2003	58	PP	-83	YES	4	-20	0	0	1	2	0	0	1	0	0	0
	E0005023	DAY 1	05FEB2003	1	PP			31		3	4	3	6	3	3	4	4	0	1
		DAY 8	13FEB2003	9	PP	-77	YES	7	-24	0	0	0	1	0	4	2	0	0	0
		DAY 15	20FEB2003	16	PP	-87	YES	4	-27	0	0	0	0	0	4	0	0	0	0
		DAY 22	27FEB2003	23	PP	-94	YES	2	-29	0	0	0	0	0	2	0	0	0	0
		DAY 29	06MAR2003	30	PP	-87	YES	4	-27	2	0	0	0	0	0	2	0	0	0
		DAY 36	13MAR2003	37	PP	-94	YES	2	-29	0	0	0	0	0	2	0	0	0	0
		DAY 43	18MAR2003	42	PP	-94	YES	2	-29	0	0	0	0	0	2	0	0	0	0
		DAY 50	26MAR2003	50	PP	-94	YES	2	-29	0	0	0	0	0	2	0	0	0	0
		DAY 57	01APR2003	56	PP	-94	YES	2	-29	0	0	0	0	0	2	0	0	0	0
	E0005034	DAY 1	15APR2003	1	PP			24		3	3	3	2	0	4	3	3	2	1
		DAY 8	23APR2003	9	PP	4	NO	25	1	3	3	3	3	0	4	4	3	1	1
		DAY 15	01MAY2003	17	PP	-21	NO	19	-5	1	0	2	4	0	4	4	4	0	0
		DAY 22	06MAY2003	22	PP	4	NO	25	1	4	3	2	3	0	4	3	4	1	1
		DAY 29	13MAY2003	29	PP	17	NO	28	4	4	3	2	3	3	3	4	4	1	1
		DAY 36	22MAY2003	38	PP	8	NO	26	2	1	1	2	4	4	4	4	3	2	1
		DAY 43	28MAY2003	44	PP	0	NO	24	0	1	1	2	3	3	4	4	3	2	1
		DAY 50	05JUN2003	52	PP	25	NO	30	6	4	4	4	3	1	4	4	3	2	1
		DAY 57	09JUN2003	56	PP	21	NO	29	5	4	4	4	2	0	3	4	4	3	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0005041	DAY 1	24JUN2003	1	PP			23		4	3	3	2	2	2	2	2	2	1
		DAY 8	01JUL2003	8	PP	-52	YES	11	-12	1	1	2	0	0	2	1	2	2	0
		DAY 15	08JUL2003	15	PP	-70	YES	7	-16	0	0	2	0	0	2	1	2	0	0
		DAY 22	16JUL2003	23	PP	-65	YES	8	-15	0	0	3	1	0	2	0	2	0	0
		DAY 29	22JUL2003	29	PP	-65	YES	8	-15	0	0	2	1	0	1	2	2	0	0
		DAY 36	28JUL2003	35	PP	-44	NO	13	-10	1	2	2	2	2	0	2	2	0	0
		DAY 43	04AUG2003	42	PP	-87	YES	3	-20	0	0	0	0	0	0	1	2	0	0
		DAY 50	11AUG2003	49	PP	-83	YES	4	-19	0	0	2	0	0	0	0	2	0	0
		DAY 57	18AUG2003	56	PP	-87	YES	3	-20	0	0	2	1	0	0	0	0	0	0
	E0007004	DAY 1	30JAN2003	1	PP			30		4	4	3	5	2	2	2	4	3	1
		DAY 8	07FEB2003	9	PP	-3	NO	29	-1	5	4	3	4	0	2	2	4	4	1
		DAY 15	12FEB2003	14	PP	-7	NO	28	-2	4	4	2	4	2	2	2	4	3	1
	E0007010	DAY 1	18APR2003	1	PP			27		4	4	2	4	0	2	2	4	4	1
		DAY 8	25APR2003	8	PP	-4	NO	26	-1	4	3	2	5	2	2	2	3	2	1
		DAY 15	02MAY2003	15	PP	-63	YES	10	-17	1	1	1	4	0	0	1	1	1	0
		DAY 22	09MAY2003	22	PP	-48	NO	14	-13	1	1	1	4	0	2	1	1	1	2
		DAY 29	16MAY2003	29	PP	-89	YES	3	-24	0	1	0	1	0	0	1	0	0	0
		DAY 36	23MAY2003	36	PP	-70	YES	8	-19	1	1	2	2	0	0	1	1	0	0
		DAY 43	29MAY2003	42	PP	-19	NO	22	-5	4	4	2	3	0	1	2	3	2	1
		DAY 50	06JUN2003	50	PP	4	NO	28	1	4	4	2	3	2	2	2	4	4	1
		DAY 57	16JUN2003	60	PP	-22	NO	21	-6	3	3	1	4	0	2	2	3	2	1
	E0007012	DAY 1	16MAY2003	1	PP			27		4	3	2	3	2	3	2	4	3	1
		DAY 8	23MAY2003	8	PP	0	NO	27	0	4	3	2	3	2	3	2	4	3	1
		DAY 15	29MAY2003	14	PP	-11	NO	24	-3	3	3	2	2	1	3	2	4	3	1
		DAY 22	06JUN2003	22	PP	-11	NO	24	-3	4	3	2	3	1	2	2	4	2	1
		DAY 29	13JUN2003	29	PP	-48	NO	14	-13	1	2	2	0	0	2	2	2	2	1
		DAY 36	20JUN2003	36	PP	-44	NO	15	-12	2	2	2	0	0	2	2	2	2	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0007012	DAY 43		25JUN2003	41	PP	-4	NO	26	-1	4	4	2	3	0	2	2	4	4	1
		DAY 43	*	01JUL2003	47	PP	0	NO	27	0	4	4	2	3	0	2	3	4	4	1
	E0009007	DAY 1		03FEB2003	1	PP			33		3	4	3	5	3	4	2	4	3	2
		DAY 8		10FEB2003	8	PP	3	NO	34	1	3	3	3	6	5	4	0	4	4	2
		DAY 15		17FEB2003	15	PP	27	NO	42	9	3	4	5	6	4	5	4	4	4	3
		DAY 22		25FEB2003	23	PP	6	NO	35	2	4	4	4	4	4	3	3	4	3	2
		DAY 29		03MAR2003	29	PP	21	NO	40	7	4	5	4	5	4	3	5	4	3	3
	E0009008	DAY 1		12FEB2003	1	PP			27		3	3	5	3	0	2	4	3	2	2
		DAY 8		19FEB2003	8	PP	0	NO	27	0	3	4	3	0	0	3	3	4	4	3
		DAY 15		25FEB2003	14	PP	-30	NO	19	-8	2	4	3	2	0	0	0	3	3	2
		DAY 22		04MAR2003	21	PP	-85	YES	4	-23	1	1	0	1	0	0	0	0	1	0
		DAY 29		11MAR2003	28	PP	15	NO	31	4	3	4	3	2	3	3	3	4	4	2
		DAY 36		18MAR2003	35	PP	-7	NO	25	-2	4	3	3	1	0	2	3	4	3	2
		DAY 43		26MAR2003	43	PP	-59	YES	11	-16	2	1	1	0	0	2	1	1	2	1
		DAY 50		03APR2003	51	PP	-78	YES	6	-21	1	1	1	0	0	1	0	1	0	1
		DAY 57		08APR2003	56	PP	-89	YES	3	-24	0	1	0	0	0	0	0	1	1	0
	E0011001	DAY 1		01NOV2002	1	PP			35		4	4	4	3	4	5	3	4	2	2
		DAY 8		07NOV2002	7	PP	-31	NO	24	-11	3	2	3	0	2	2	3	4	3	2
		DAY 15		14NOV2002	14	PP	-40	NO	21	-14	2	4	2	0	3	3	2	2	2	1
		DAY 22		21NOV2002	21	PP	-31	NO	24	-11	3	3	3	3	3	3	1	2	2	1
		DAY 29		27NOV2002	27	PP	-46	NO	19	-16	2	1	3	0	3	3	2	2	2	1
		DAY 36		05DEC2002	35	PP	-37	NO	22	-13	2	2	3	2	2	4	2	2	2	1
		DAY 43		12DEC2002	42	PP	-40	NO	21	-14	3	2	2	1	2	3	2	2	3	1
		DAY 50		19DEC2002	49	PP	-51	NO	17	-18	2	2	1	2	2	2	1	2	2	1
		DAY 57		26DEC2002	56	PP	-54	NO	16	-19	2	1	3	2	0	2	3	0	2	1
	E0011011	DAY 1		20FEB2003	1	PP			25		2	3	2	3	2	3	3	3	2	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0011011	DAY 8	26FEB2003	7	PP	-16	NO	21	-4	2	2	2	2	2	3	2	2	3	1
		DAY 15	05MAR2003	14	PP	-24	NO	19	-6	1	2	2	3	0	3	2	2	3	1
		DAY 22	12MAR2003	21	PP	-4	NO	24	-1	2	3	3	3	2	2	2	3	3	1
		DAY 29	19MAR2003	28	PP	-20	NO	20	-5	1	1	2	3	4	2	2	2	2	1
		DAY 36	26MAR2003	35	PP	-52	YES	12	-13	1	1	0	0	0	3	2	2	2	1
		DAY 43	02APR2003	42	PP	-8	NO	23	-2	2	3	2	3	1	3	2	3	3	1
		DAY 50	09APR2003	49	PP	-8	NO	23	-2	3	2	2	4	1	3	2	2	3	1
		DAY 57	16APR2003	56	PP	-60	YES	10	-15	0	0	1	2	0	1	2	2	2	0
	E0011013	DAY 1	17APR2003	1	ITT			25		3	3	4	3	0	2	2	2	3	3
		DAY 8	24APR2003	8	ITT	12	NO	28	3	4	4	4	2	0	1	4	2	3	4
		DAY 15	01MAY2003	15	ITT	24	NO	31	6	4	4	4	3	0	3	3	3	3	4
		DAY 22	08MAY2003	22	ITT	28	NO	32	7	4	4	4	3	0	3	3	3	4	4
		DAY 29	15MAY2003	29	ITT	20	NO	30	5	4	4	4	3	0	3	2	3	3	4
		DAY 36	22MAY2003	36	ITT	16	NO	29	4	4	4	4	2	0	2	3	2	4	4
		DAY 43	29MAY2003	43	ITT	12	NO	28	3	4	4	4	2	0	0	3	3	4	4
		DAY 50	05JUN2003	50	ITT	28	NO	32	7	4	4	4	2	1	2	4	3	4	4
		DAY 57	12JUN2003	57	ITT	8	NO	27	2	4	4	4	0	0	0	4	3	4	4
	E0011014	DAY 1	07APR2003	1	PP			33		4	4	3	5	2	3	3	3	4	2
		DAY 8	14APR2003	8	PP	-55	NO	15	-18	2	2	1	0	0	2	2	3	2	1
	E0011021	DAY 1	22MAY2003	1	PP			33		4	3	4	4	3	4	4	3	3	1
		DAY 8	29MAY2003	8	PP	-12	NO	29	-4	3	3	4	2	3	4	3	3	3	1
		DAY 15	05JUN2003	15	PP	-15	NO	28	-5	3	3	3	2	3	4	3	3	3	1
		DAY 22	12JUN2003	22	PP	-24	NO	25	-8	2	2	3	3	3	2	4	3	2	1
		DAY 29	20JUN2003	30	PP	-36	NO	21	-12	1	2	3	2	2	2	3	3	2	1
		DAY 36	27JUN2003	37	PP	-76	YES	8	-25	0	0	2	1	0	2	2	0	1	0
		DAY 43	02JUL2003	42	PP	-85	YES	5	-28	0	0	2	0	0	2	1	0	0	0
		DAY 50	10JUL2003	50	PP	-61	NO	13	-20	0	1	3	3	0	1	2	0	3	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0011021	DAY 57	21JUL2003	61	PP	-91	YES	3	-30	0	0	0	1	0	0	0	0	1	1
	E0013008	DAY 1	26MAR2003	1	PP			33		4	4	4	4	4	3	3	4	1	2
		DAY 8	02APR2003	8	PP	6	NO	35	2	4	4	3	5	2	5	4	3	3	2
		DAY 15	09APR2003	15	PP	15	NO	38	5	4	4	3	5	2	5	5	3	4	3
		DAY 22	17APR2003	23	PP	-24	NO	25	-8	1	1	4	6	0	5	2	2	2	2
		DAY 29	23APR2003	29	PP	27	NO	42	9	5	5	4	5	4	5	4	4	4	2
		DAY 36	30APR2003	36	PP	6	NO	35	2	4	5	3	5	0	5	4	3	3	3
		DAY 43	07MAY2003	43	PP	12	NO	37	4	4	4	4	5	2	5	4	4	3	2
		DAY 50	12MAY2003	48	PP	-18	NO	27	-6	4	3	4	4	0	3	2	4	2	1
		DAY 57	19MAY2003	55	PP	-3	NO	32	-1	4	4	4	4	0	4	3	4	3	2
	E0014001	DAY 1	26FEB2003	1	PP			26		3	4	4	4	0	3	1	4	3	0
		DAY 8	05MAR2003	8	PP	-19	NO	21	-5	4	4	3	0	1	1	5	1	2	0
		DAY 15	12MAR2003	15	PP	-81	YES	5	-21	1	1	1	1	0	1	0	0	0	0
		DAY 22	19MAR2003	22	PP	-96	YES	1	-25	1	0	0	0	0	0	0	0	0	0
		DAY 29	25MAR2003	28	PP	-96	YES	1	-25	1	0	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	35	PP	-77	YES	6	-20	0	2	3	0	1	0	0	0	0	0
	E0014013	DAY 1	27MAY2003	1	PP			35		5	5	4	5	0	2	4	4	3	3
		DAY 8	04JUN2003	9	PP	-23	NO	27	-8	4	4	4	0	0	2	4	4	3	2
		DAY 15	13JUN2003	18	PP	-29	NO	25	-10	4	4	4	0	0	2	4	3	2	2
		DAY 22	18JUN2003	23	PP	-40	NO	21	-14	3	2	3	1	2	2	3	3	1	1
		DAY 29	25JUN2003	30	PP	-11	NO	31	-4	4	4	4	3	3	2	3	4	3	1
		DAY 36	02JUL2003	37	PP	-46	NO	19	-16	2	2	3	1	3	2	2	3	1	0
		DAY 43	10JUL2003	45	PP	-31	NO	24	-11	3	3	4	0	4	0	4	4	1	1
		DAY 50	16JUL2003	51	PP	-23	NO	27	-8	3	3	4	2	2	3	3	4	2	1
		DAY 57	23JUL2003	58	PP	-63	NO	13	-22	1	1	4	0	2	2	1	1	1	0
	E0014014	DAY 1	10JUN2003	1	PP			33		4	4	3	5	0	2	5	4	3	3

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0014014	DAY 8		18JUN2003	9	PP	-33	NO	22	-11	3	2	2	2	0	2	4	3	2	2
		DAY 15		24JUN2003	15	PP	-49	NO	17	-16	2	2	3	0	0	2	2	3	2	1
		DAY 22		03JUL2003	24	PP	-91	YES	3	-30	1	1	1	0	0	0	0	0	0	0
		DAY 29		10JUL2003	31	PP	-97	YES	1	-32	0	1	0	0	0	0	0	0	0	0
		DAY 36		18JUL2003	39	PP	-61	NO	13	-20	2	2	2	0	0	2	2	2	1	0
		DAY 50		30JUL2003	51	PP	-70	YES	10	-23	1	1	2	3	0	1	1	1	0	0
		DAY 57		06AUG2003	58	PP	-76	YES	8	-25	2	1	2	1	0	1	0	1	0	0
	E0015004	DAY 1		02DEC2002	1	PP			30		3	4	3	4	2	4	4	3	2	1
		DAY 8		11DEC2002	10	PP	-3	NO	29	-1	3	3	2	4	2	4	4	4	2	1
		DAY 15		18DEC2002	17	PP	3	NO	31	1	3	4	2	5	2	4	4	4	2	1
		DAY 22		27DEC2002	26	PP	7	NO	32	2	4	4	3	5	1	4	4	4	2	1
		DAY 36		06JAN2003	36	PP	-13	NO	26	-4	3	4	3	4	0	3	3	3	2	1
		DAY 36	*	09JAN2003	39	PP	-3	NO	29	-1	3	4	3	4	2	3	3	3	2	2
		DAY 43		17JAN2003	47	PP	7	NO	32	2	4	4	3	4	2	4	3	4	2	2
		DAY 57		29JAN2003	59	PP	-10	NO	27	-3	3	4	3	4	0	4	3	3	2	1
	E0018005	DAY 1		20DEC2002	1	PP			30		3	3	3	4	4	4	4	3	2	0
		DAY 8		27DEC2002	8	PP	-37	NO	19	-11	3	3	3	0	0	3	3	2	2	0
		DAY 8	*	31DEC2002	12	PP	-53	NO	14	-16	2	2	2	0	0	2	2	2	2	0
		DAY 22		10JAN2003	22	PP	-83	YES	5	-25	0	0	2	0	0	2	0	1	0	0
		DAY 29		17JAN2003	29	PP	-77	YES	7	-23	0	0	2	2	0	0	1	1	1	0
		DAY 36		24JAN2003	36	PP	-67	YES	10	-20	1	1	2	0	0	2	2	1	1	0
		DAY 43		31JAN2003	43	PP	-73	YES	8	-22	1	1	1	1	0	1	1	1	1	0
		DAY 50		07FEB2003	50	PP	-83	YES	5	-25	0	0	2	0	0	1	1	1	0	0
		DAY 57		14FEB2003	57	PP	-90	YES	3	-27	0	0	2	0	0	1	0	0	0	0
	E0018012	DAY 1		24JAN2003	1	PP			33		4	4	4	4	3	3	3	3	3	2
		DAY 8		30JAN2003	7	PP	-49	NO	17	-16	2	2	3	2	0	3	1	2	2	0
		DAY 15		07FEB2003	15	PP	-64	YES	12	-21	2	2	2	1	1	2	0	1	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0018012	DAY 22	14FEB2003	22	PP	-94	YES	2	-31	0	0	1	0	1	0	0	0	0	0
		DAY 29	21FEB2003	29	PP	-52	NO	16	-17	2	2	2	2	1	1	1	2	2	1
		DAY 36	26FEB2003	34	PP	-12	NO	29	-4	4	4	4	3	2	3	1	2	3	3
	E0019019	DAY 1	23JAN2003	1	PP			34		4	4	4	4	3	4	4	4	3	0
		DAY 8	30JAN2003	8	PP	-15	NO	29	-5	3	4	3	2	3	2	3	4	3	2
		DAY 15	06FEB2003	15	PP	-24	NO	26	-8	3	3	2	4	3	3	3	2	2	1
	E0019033	DAY 1	18MAR2003	1	PP			31		2	4	2	4	4	3	4	4	2	2
		DAY 8	27MAR2003	10	PP	-7	NO	29	-2	3	3	2	3	2	3	4	3	3	3
		DAY 15	03APR2003	17	PP	3	NO	32	1	4	4	3	3	1	2	4	4	4	3
		DAY 22	10APR2003	24	PP	10	NO	34	3	4	4	2	4	2	4	4	3	4	3
		DAY 29	14APR2003	28	PP	19	NO	37	6	4	4	3	3	4	3	4	4	4	4
		DAY 36	22APR2003	36	PP	16	NO	36	5	4	4	3	3	3	4	4	4	4	3
		DAY 43	01MAY2003	45	PP	26	NO	39	8	3	4	4	4	5	4	4	5	4	2
		DAY 50	08MAY2003	52	PP	19	NO	37	6	3	4	4	4	3	4	5	4	4	2
		DAY 57	15MAY2003	59	PP	7	NO	33	2	3	4	4	2	3	4	4	4	3	2
	E0019038	DAY 1	24APR2003	1	PP			40		4	4	5	4	4	4	5	4	4	2
		DAY 8	01MAY2003	8	PP	-65	NO	14	-26	3	1	2	2	0	2	2	1	1	0
		DAY 15	07MAY2003	14	PP	-18	NO	33	-7	4	4	3	3	2	4	4	4	3	2
		DAY 22	14MAY2003	21	PP	-20	NO	32	-8	4	4	4	2	3	3	4	4	2	2
		DAY 29	21MAY2003	28	PP	-40	NO	24	-16	4	2	2	2	2	3	4	2	3	0
		DAY 36	28MAY2003	35	PP	-68	NO	13	-27	2	1	1	1	2	2	1	1	2	0
		DAY 43	04JUN2003	42	PP	-40	NO	24	-16	3	4	0	4	0	4	2	2	4	1
		DAY 50	11JUN2003	49	PP	-33	NO	27	-13	2	3	3	4	0	3	4	3	4	1
		DAY 57	18JUN2003	56	PP	-63	NO	15	-25	2	2	2	1	0	2	3	1	2	0
	E0019046	DAY 1	26JUN2003	1	PP			37		4	4	3	4	4	4	5	4	3	2
		DAY 8	03JUL2003	8	PP	-30	NO	26	-11	3	2	0	3	3	4	4	4	3	0

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PLACEBO (BIPOLAR II)	E0019046	DAY 15	10JUL2003	15	PP	-46	NO	20	-17	2	2	0	2	2	4	4	4	0	0
		DAY 22	17JUL2003	22	PP	-73	YES	10	-27	0	0	2	0	2	2	2	2	0	0
		DAY 29	24JUL2003	29	PP	-84	YES	6	-31	2	0	0	2	0	0	2	0	0	0
		DAY 36	30JUL2003	35	PP	-89	YES	4	-33	1	0	2	1	0	0	0	0	0	0
		DAY 50	14AUG2003	50	PP	-89	YES	4	-33	2	0	2	0	0	0	0	0	0	0
		DAY 57	21AUG2003	57	PP	-95	YES	2	-35	1	0	0	0	0	0	1	0	0	0
	E0019047	DAY 1	08JUL2003	1	PP			24		2	3	2	4	2	4	4	2	1	0
		DAY 8	17JUL2003	10	PP	-71	YES	7	-17	2	0	0	0	0	3	2	0	0	0
		DAY 15	24JUL2003	17	PP	-83	YES	4	-20	2	0	1	0	0	0	1	0	0	0
		DAY 22	31JUL2003	24	PP	38	NO	33	9	4	4	2	4	4	4	4	4	3	0
		DAY 29	07AUG2003	31	PP	-38	NO	15	-9	2	1	2	2	2	2	2	0	2	0
		DAY 36	14AUG2003	38	PP	-83	YES	4	-20	1	0	1	2	0	0	0	0	0	0
		DAY 43	21AUG2003	45	PP	-79	YES	5	-19	2	0	1	2	0	0	0	0	0	0
		DAY 50	28AUG2003	52	PP	-71	YES	7	-17	2	1	2	1	0	0	0	0	1	0
		DAY 57	04SEP2003	59	PP	-71	YES	7	-17	2	1	2	2	0	0	0	0	0	0
	E0019048	DAY 1	10JUL2003	1	PP			27		3	4	4	4	0	4	4	3	1	0
		DAY 8	17JUL2003	8	PP	7	NO	29	2	2	4	2	4	4	4	4	2	3	0
		DAY 15	22JUL2003	13	PP	7	NO	29	2	3	4	3	4	2	4	4	3	2	0
		DAY 22	31JUL2003	22	PP	-4	NO	26	-1	2	3	2	4	3	4	4	2	2	0
		DAY 29	07AUG2003	29	PP	0	NO	27	0	2	2	4	4	3	4	4	4	0	0
		DAY 36	14AUG2003	36	PP	-7	NO	25	-2	2	2	2	4	3	4	4	4	0	0
		DAY 43	21AUG2003	43	PP	-26	NO	20	-7	2	2	2	4	0	2	4	4	0	0
		DAY 50	28AUG2003	50	PP	4	NO	28	1	2	4	3	4	2	4	3	4	2	0
		DAY 57	03SEP2003	56	PP	7	NO	29	2	4	4	4	4	2	2	4	3	2	0
	E0022006	DAY 1	12NOV2002	1	PP			29		4	4	3	3	0	2	4	4	3	2
		DAY 8	19NOV2002	8	PP	-7	NO	27	-2	4	3	3	4	0	2	4	3	3	1
		DAY 15	26NOV2002	15	PP	17	NO	34	5	4	4	3	6	0	4	4	4	4	1

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PLACEBO (BIPOLAR II)	E0022006	DAY 22		03DEC2002	22	PP	-31	NO	20	-9	2	2	2	3	2	3	2	2	2	0
		DAY 29		10DEC2002	29	PP	-55	NO	13	-16	1	2	2	2	0	1	2	1	2	0
		DAY 36		17DEC2002	36	PP	-62	YES	11	-18	0	1	2	2	0	2	2	0	2	0
		DAY 43		24DEC2002	43	PP	-72	YES	8	-21	0	0	2	2	0	2	1	0	1	0
		DAY 50		31DEC2002	50	PP	-72	YES	8	-21	1	0	1	1	0	2	1	1	1	0
		DAY 57		07JAN2003	57	PP	-86	YES	4	-25	0	0	2	0	0	2	0	0	0	0
	E0022047	DAY 1		28MAR2003	1	PP			36		4	4	3	4	2	4	4	4	4	3
		DAY 8		04APR2003	8	PP	-8	NO	33	-3	4	4	3	2	2	4	4	4	2	4
		DAY 15		11APR2003	15	PP	-36	NO	23	-13	3	3	2	2	0	3	3	3	2	2
		DAY 22		17APR2003	21	PP	-25	NO	27	-9	3	3	3	4	2	4	2	2	2	2
		DAY 29		25APR2003	29	PP	-33	NO	24	-12	3	3	2	2	0	3	4	3	2	2
		DAY 36		02MAY2003	36	PP	-39	NO	22	-14	2	2	2	2	0	3	3	4	2	2
		DAY 43		09MAY2003	43	PP	-28	NO	26	-10	3	4	2	2	0	4	3	2	2	4
		DAY 50		16MAY2003	50	PP	-6	NO	34	-2	4	4	2	4	3	4	4	3	2	4
		DAY 57		23MAY2003	57	PP	-17	NO	30	-6	4	4	2	4	0	2	3	3	4	4
	E0022075	DAY 8	*	09JUL2003	2	SAFETY			25		3	4	3	2	0	2	3	3	2	3
		DAY 8		15JUL2003	8	SAFETY			29		4	4	3	3	1	3	3	2	3	3
		DAY 15		22JUL2003	15	SAFETY			25		2	3	3	4	1	3	1	3	3	2
		DAY 22		29JUL2003	22	SAFETY			29		3	3	3	5	1	3	2	4	3	2
		DAY 29		05AUG2003	29	SAFETY			30		4	4	3	4	2	2	3	4	3	1
		DAY 36		12AUG2003	36	SAFETY			33		4	4	3	4	2	3	3	3	4	3
		DAY 43		19AUG2003	43	SAFETY			25		3	2	2	4	0	3	3	3	2	3
		DAY 50		26AUG2003	50	SAFETY			28		4	4	2	3	3	2	2	2	3	3
		DAY 57		03SEP2003	58	SAFETY			24		2	4	3	0	0	3	3	3	3	3
	E0023012	DAY 1		06FEB2003	1	PP			24		3	2	2	4	2	3	2	2	2	2
		DAY 8		17FEB2003	12	PP	-4	NO	23	-1	2	2	4	5	1	3	3	2	0	1
		DAY 15		20FEB2003	15	PP	13	NO	27	3	3	3	4	4	2	3	3	3	2	0

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0023012	DAY 22	28FEB2003	23	PP	-42	NO	14	-10	2	2	2	2	2	2	1	1	0	0
		DAY 29	07MAR2003	30	PP	-42	NO	14	-10	2	3	2	2	2	2	0	1	0	0
		DAY 36	14MAR2003	37	PP	-4	NO	23	-1	3	4	3	3	2	2	1	1	2	2
		DAY 43	21MAR2003	44	PP	-8	NO	22	-2	4	4	4	0	2	2	0	1	3	2
		DAY 50	28MAR2003	51	PP	8	NO	26	2	4	4	3	0	2	4	0	4	3	2
		DAY 57	04APR2003	58	PP	-46	NO	13	-11	1	0	3	0	0	4	0	3	1	1
	E0023016	DAY 1	22MAY2003	1	PP			27		4	4	3	3	2	3	2	3	2	1
		DAY 8	29MAY2003	8	PP	-7	NO	25	-2	4	4	3	1	2	3	2	3	2	1
		DAY 15	05JUN2003	15	PP	-19	NO	22	-5	3	4	3	0	2	3	2	3	1	1
		DAY 22	12JUN2003	22	PP	-11	NO	24	-3	3	4	3	0	3	3	3	3	1	1
		DAY 29	19JUN2003	29	PP	-22	NO	21	-6	3	4	2	0	2	2	3	3	1	1
		DAY 36	26JUN2003	36	PP	-33	NO	18	-9	3	3	2	0	0	2	3	3	1	1
		DAY 43	01JUL2003	41	PP	-22	NO	21	-6	3	3	3	0	2	2	3	3	1	1
		DAY 50	14JUL2003	54	PP	33	NO	36	9	5	4	3	3	4	4	4	4	3	2
		DAY 57	17JUL2003	57	PP	19	NO	32	5	4	4	3	3	4	3	3	4	2	2
	E0023018	DAY 1	27MAR2003	1	PP			30		3	4	3	4	0	3	4	4	3	2
		DAY 8	03APR2003	8	PP	-43	NO	17	-13	1	0	4	4	2	1	0	1	2	2
		DAY 15	10APR2003	15	PP	-53	NO	14	-16	1	1	3	4	2	0	0	0	2	1
		DAY 22	16APR2003	21	PP	-40	NO	18	-12	2	2	3	2	1	3	1	0	2	2
		DAY 29	24APR2003	29	PP	-47	NO	16	-14	2	2	2	2	0	2	2	1	2	1
		DAY 36	02MAY2003	37	PP	-90	YES	3	-27	0	0	2	0	0	0	0	0	1	0
		DAY 43	12MAY2003	47	PP	-57	NO	13	-17	2	2	3	2	0	1	0	0	1	2
		DAY 50	15MAY2003	50	PP	-67	YES	10	-20	0	0	2	4	0	0	1	1	1	1
		DAY 57	22MAY2003	57	PP	-80	YES	6	-24	0	0	0	3	0	3	0	0	0	0
	E0023036	DAY 1	20JUN2003	1	PP			31		3	4	3	4	2	3	4	4	2	2
		DAY 8	26JUN2003	7	PP	-7	NO	29	-2	3	3	3	4	2	3	3	4	2	2
		DAY 15	02JUL2003	13	PP	0	NO	31	0	3	3	3	4	2	4	4	4	2	2

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0023036	DAY 22		09JUL2003	20	PP	-39	NO	19	-12	2	1	2	2	2	3	2	2	2	1
		DAY 29		16JUL2003	27	PP	-45	NO	17	-14	2	1	2	1	2	2	2	2	2	1
		DAY 29	*	22JUL2003	33	PP	-19	NO	25	-6	3	3	3	4	2	3	2	2	2	1
		DAY 36		29JUL2003	40	PP	-23	NO	24	-7	2	2	3	3	3	3	2	3	2	1
		DAY 43		05AUG2003	47	PP	-48	NO	16	-15	2	2	3	2	0	2	1	2	1	1
		DAY 57		13AUG2003	55	PP	-48	NO	16	-15	1	1	3	2	0	3	2	2	1	1
	E0023046	DAY 1		23JUL2003	1	PP			33		4	4	3	4	4	3	3	4	2	2
		DAY 8		01AUG2003	10	PP	0	NO	33	0	4	4	3	4	4	3	3	4	2	2
		DAY 15		08AUG2003	17	PP	-15	NO	28	-5	3	3	3	4	4	2	2	4	1	2
		DAY 22		14AUG2003	23	PP	-21	NO	26	-7	3	3	3	4	4	2	2	4	0	1
		DAY 29		22AUG2003	31	PP	-21	NO	26	-7	3	3	3	4	4	2	2	4	0	1
		DAY 36		28AUG2003	37	PP	-21	NO	26	-7	3	3	3	4	4	3	2	4	0	0
		DAY 43		04SEP2003	44	PP	-33	NO	22	-11	2	2	1	4	4	3	2	4	0	0
		DAY 50		11SEP2003	51	PP	-30	NO	23	-10	2	2	2	4	4	3	2	4	0	0
		DAY 57		16SEP2003	56	PP	-30	NO	23	-10	2	2	2	4	4	3	2	4	0	0
	E0026006	DAY 1		08JAN2003	1	SAFETY			25		4	4	2	1	0	1	4	5	4	0
		DAY 8		15JAN2003	8	SAFETY			1	-24	0	0	1	0	0	0	0	0	0	0
		DAY 15		22JAN2003	15	SAFETY			26	1	4	4	3	2	0	4	3	2	3	1
		DAY 22		29JAN2003	22	SAFETY			10	-15	2	2	2	0	0	0	0	0	3	1
		DAY 29		05FEB2003	29	SAFETY			2	-23	1	1	0	0	0	0	0	0	0	0
		DAY 36		12FEB2003	36	SAFETY			4	-21	1	1	0	0	0	0	0	1	0	1
		DAY 43		19FEB2003	43	SAFETY			17	-8	1	2	2	0	3	3	0	1	4	1
	E0026021	DAY 1		23APR2003	1	ITT			34		4	4	4	3	5	2	2	4	4	2
		DAY 8		29APR2003	7	ITT	-15	NO	29	-5	2	3	3	4	5	3	2	4	2	1
	E0026027	DAY 1		19JUN2003	1	SAFETY			37		5	4	5	5	0	4	5	4	4	1

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POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

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Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0029002		*	12NOV2002		NODOSE			35		5	4	4	4	4	4	4	2	4	0
	E0029004	DAY 1		19NOV2002	1	PP			37		3	4	4	4	3	4	4	4	4	3
		DAY 8		26NOV2002	8	PP	3	NO	38	1	4	4	4	4	2	4	4	4	4	4
		DAY 15		04DEC2002	16	PP	-41	NO	22	-15	2	2	2	4	0	2	2	4	4	0
		DAY 22		12DEC2002	24	PP	-51	NO	18	-19	2	1	2	4	0	3	1	4	1	0
		DAY 36		26DEC2002	38	PP	-3	NO	36	-1	3	4	2	5	4	4	4	4	2	4
		DAY 43		02JAN2003	45	PP	-43	NO	21	-16	2	2	2	4	0	0	2	4	1	4
		DAY 50		09JAN2003	52	PP	-65	NO	13	-24	1	0	0	3	0	3	2	4	0	0
		DAY 57		16JAN2003	59	PP	0	NO	37	0	4	4	2	4	4	4	2	5	4	4
	E0029013	DAY 1		19FEB2003	1	PP			27		3	4	3	4	0	2	4	3	3	1
		DAY 8		25FEB2003	7	PP	-41	NO	16	-11	2	2	2	2	0	2	2	2	2	0
		DAY 15		04MAR2003	14	PP	-52	NO	13	-14	0	1	1	4	0	2	2	2	1	0
		DAY 22		13MAR2003	23	PP	-74	YES	7	-20	0	0	1	0	0	1	4	1	0	0
		DAY 29		20MAR2003	30	PP	-56	YES	12	-15	0	0	2	2	2	0	4	2	0	0
		DAY 36		25MAR2003	35	PP	-59	YES	11	-16	1	1	2	0	2	0	3	2	0	0
		DAY 43		31MAR2003	41	PP	-52	NO	13	-14	2	2	2	0	0	0	2	3	2	0
		DAY 50		10APR2003	51	PP	-41	NO	16	-11	1	0	2	2	4	2	2	2	0	1
	E0029019	DAY 1		03MAR2003	1	PP			24		1	3	4	2	2	3	3	3	2	1
		DAY 8		10MAR2003	8	PP	-58	YES	10	-14	1	1	2	0	0	0	1	2	3	0
		DAY 15		17MAR2003	15	PP	-13	NO	21	-3	2	3	3	0	2	0	4	4	2	1
	E0029024	DAY 1		17MAR2003	1	PP			24		4	2	1	0	0	4	4	4	2	3
		DAY 8		25MAR2003	9	PP	4	NO	25	1	4	4	2	0	0	4	3	2	3	3
		DAY 15		02APR2003	17	PP	-38	NO	15	-9	2	2	2	0	0	2	2	2	2	1
		DAY 22		09APR2003	24	PP	4	NO	25	1	4	2	2	0	0	4	2	4	4	3
		DAY 29		17APR2003	32	PP	17	NO	28	4	4	4	2	4	0	3	4	4	2	1
		DAY 36		24APR2003	39	PP	-4	NO	23	-1	3	3	3	0	0	3	4	4	2	1

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PLACEBO (BIPOLAR II)	E0029024	DAY 50		05MAY2003	50	PP	-29	NO	17	-7	2	2	0	1	0	3	3	2	2	2
		DAY 57	*	12MAY2003	57	PP	-50	YES	12	-12	1	1	2	0	0	2	2	2	1	1
		DAY 57		20MAY2003	65	PP	-58	YES	10	-14	1	1	2	0	0	2	1	0	2	1
	E0029038	DAY 1		07JUL2003	1	SAFETY			20		3	3	3	4	0	1	2	2	2	0
	E0031004	DAY 1		19DEC2002	1	PP			20		2	2	3	3	2	3	3	0	2	0
		DAY 8		27DEC2002	9	PP	-30	NO	14	-6	1	0	2	3	2	3	1	2	0	0
		DAY 15		03JAN2003	16	PP	-25	NO	15	-5	2	2	2	4	0	2	2	1	0	0
		DAY 22		09JAN2003	22	PP	-20	NO	16	-4	0	0	2	4	2	2	2	2	2	0
		DAY 29		16JAN2003	29	PP	-45	YES	11	-9	0	0	2	2	2	2	2	1	0	0
		DAY 36		23JAN2003	36	PP	-60	YES	8	-12	0	0	2	3	0	0	2	1	0	0
		DAY 43		30JAN2003	43	PP	-50	YES	10	-10	0	0	2	2	2	1	2	1	0	0
		DAY 50		06FEB2003	50	PP	-60	YES	8	-12	0	0	2	2	0	2	0	2	0	0
		DAY 57		13FEB2003	57	PP	-60	YES	8	-12	0	0	2	4	0	0	2	0	0	0
	E0031013	DAY 1		13MAR2003	1	PP			27		2	3	2	3	0	4	4	4	4	1
		DAY 8		20MAR2003	8	PP	-30	NO	19	-8	1	2	2	2	0	4	2	3	2	1
		DAY 15		27MAR2003	15	PP	-22	NO	21	-6	1	2	2	3	0	4	3	2	4	0
		DAY 22		04APR2003	23	PP	-56	YES	12	-15	0	1	3	2	0	2	2	0	2	0
		DAY 29		11APR2003	30	PP	-41	NO	16	-11	0	1	3	2	0	4	2	1	3	0
		DAY 36		17APR2003	36	PP	-44	NO	15	-12	0	1	3	1	0	4	3	1	2	0
		DAY 43		24APR2003	43	PP	-59	YES	11	-16	0	1	0	1	2	0	4	2	0	1
		DAY 50		01MAY2003	50	PP	-44	NO	15	-12	0	1	3	1	0	4	4	0	2	0
		DAY 57		08MAY2003	57	PP	-48	NO	14	-13	0	1	3	1	0	4	2	1	2	0
	E0031016	DAY 1		24MAR2003	1	PP			27		4	4	0	4	0	4	4	3	4	0
		DAY 8		31MAR2003	8	PP	-41	NO	16	-11	0	2	0	4	0	4	2	2	2	0
		DAY 15		07APR2003	15	PP	-30	NO	19	-8	2	2	0	4	0	4	4	3	0	0
		DAY 22		14APR2003	22	PP	-11	NO	24	-3	3	3	2	4	0	4	4	4	0	0

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PLACEBO (BIPOLAR II)	E0031019	DAY 1		11APR2003	1	PP			33		4	4	3	4	3	2	4	3	4	2
		DAY 8		18APR2003	8	PP	-24	NO	25	-8	3	3	2	5	0	2	2	3	3	2
		DAY 15		25APR2003	15	PP	-36	NO	21	-12	3	4	2	5	0	0	0	3	2	2
		DAY 22		02MAY2003	22	PP	-30	NO	23	-10	3	3	2	5	2	0	2	2	2	2
		DAY 29		09MAY2003	29	PP	-67	YES	11	-22	1	2	0	4	2	0	0	2	0	0
		DAY 29	*	12MAY2003	32	PP	-46	NO	18	-15	2	3	0	4	2	0	2	2	2	1
	E0031022	DAY 1		28APR2003	1	PP			22		2	4	2	4	0	4	0	2	4	0
		DAY 8		06MAY2003	9	PP	-23	NO	17	-5	2	3	2	1	0	2	1	2	3	1
		DAY 15		13MAY2003	16	PP	-41	NO	13	-9	0	0	3	4	0	2	0	1	2	1
		DAY 22		20MAY2003	23	PP	14	NO	25	3	3	3	3	4	0	2	4	2	3	1
		DAY 29		27MAY2003	30	PP	-14	NO	19	-3	2	2	3	2	0	2	2	2	3	1
	E0033007	DAY 1		28JAN2003	1	PP			38		5	5	2	4	3	3	4	4	4	4
		DAY 8		04FEB2003	8	PP	-5	NO	36	-2	4	4	3	4	4	2	4	4	4	3
		DAY 15		12FEB2003	16	PP	-21	NO	30	-8	3	3	2	4	4	1	4	2	4	3
		DAY 22		20FEB2003	24	PP	-40	NO	23	-15	3	3	0	4	3	2	4	1	2	1
		DAY 29		25FEB2003	29	PP	11	NO	42	4	5	5	3	4	4	4	5	4	4	4
		DAY 36		04MAR2003	36	PP	-11	NO	34	-4	4	4	2	4	3	2	4	4	4	3
		DAY 43		13MAR2003	45	PP	5	NO	40	2	4	4	3	4	5	3	5	5	4	3
		DAY 50		18MAR2003	50	PP	-8	NO	35	-3	4	4	2	4	3	4	4	3	4	3
		DAY 57		25MAR2003	57	PP	-16	NO	32	-6	2	3	3	4	4	3	4	4	3	2
	E0033013	DAY 1		19FEB2003	1	PP			28		4	4	3	2	2	1	4	4	2	2
		DAY 8		26FEB2003	8	PP	-14	NO	24	-4	3	3	3	4	2	2	1	3	2	1
		DAY 15		05MAR2003	15	PP	-7	NO	26	-2	3	2	3	4	3	1	4	4	2	0
		DAY 22		13MAR2003	23	PP	18	NO	33	5	4	4	2	4	4	3	4	5	2	1
		DAY 29		19MAR2003	29	PP	7	NO	30	2	4	3	3	4	3	2	4	4	2	1
		DAY 36		27MAR2003	37	PP	-4	NO	27	-1	4	4	3	3	4	0	3	3	2	1
		DAY 43		01APR2003	42	PP	-4	NO	27	-1	3	3	3	4	3	2	2	4	2	1

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0033013	DAY 50		10APR2003	51	PP	-32	NO	19	-9	3	3	1	0	3	1	1	4	2	1
		DAY 57		16APR2003	57	PP	4	NO	29	1	4	3	3	3	4	2	2	4	3	1
	E0033016	DAY 1		08MAY2003	1	PP			31		3	3	4	3	3	4	4	4	2	1
		DAY 8		13MAY2003	6	PP	-16	NO	26	-5	3	2	3	4	2	4	4	2	2	0
		DAY 15		20MAY2003	13	PP	-26	NO	23	-8	3	3	3	4	0	3	3	2	2	0
		DAY 22		28MAY2003	21	PP	-39	NO	19	-12	2	2	3	3	0	3	3	2	1	0
		DAY 29		09JUN2003	33	PP	-36	NO	20	-11	2	3	3	2	0	2	3	2	2	1
		DAY 43		17JUN2003	41	PP	-68	YES	10	-21	1	1	0	3	0	2	1	1	1	0
		DAY 43	*	23JUN2003	47	PP	-65	YES	11	-20	1	1	2	3	0	3	1	0	0	0
		DAY 50		27JUN2003	51	PP	-81	YES	6	-25	1	0	0	2	0	2	0	0	1	0
		DAY 57		02JUL2003	56	PP	-77	YES	7	-24	0	0	2	2	0	2	0	0	1	0
	E0033022	DAY 1		14JUL2003	1	PP			35		4	4	4	3	3	3	4	4	3	3
		DAY 8		23JUL2003	10	PP	-43	NO	20	-15	2	2	2	3	3	2	2	2	2	0
		DAY 15		30JUL2003	17	PP	-29	NO	25	-10	3	4	3	2	3	2	2	2	2	2
		DAY 22		06AUG2003	24	PP	-37	NO	22	-13	3	3	2	1	2	2	3	2	2	2
		DAY 29		11AUG2003	29	PP	-54	NO	16	-19	1	2	2	1	3	2	2	2	0	1
		DAY 36		18AUG2003	36	PP	-31	NO	24	-11	3	3	3	0	3	1	3	3	3	2
		DAY 43		26AUG2003	44	PP	-57	NO	15	-20	1	1	3	3	2	3	0	2	0	0
		DAY 50		04SEP2003	53	PP	-3	NO	34	-1	4	4	4	3	3	4	3	3	3	3
		DAY 57		11SEP2003	60	PP	-49	NO	18	-17	2	3	4	2	2	0	3	2	0	0
	E0034007	DAY 1		16MAY2003	1	PP			34		4	5	3	3	0	4	5	4	3	3
		DAY 8		24MAY2003	9	PP	9	NO	37	3	4	5	3	4	2	4	5	4	3	3
		DAY 15		02JUN2003	18	PP	9	NO	37	3	4	5	3	4	2	4	5	4	3	3
		DAY 22		09JUN2003	25	PP	12	NO	38	4	4	5	3	4	2	4	5	4	4	3
		DAY 29		16JUN2003	32	PP	21	NO	41	7	4	5	4	5	2	4	5	4	4	4
		DAY 36		20JUN2003	36	PP	18	NO	40	6	4	5	4	5	2	3	5	4	4	4
		DAY 43		30JUN2003	46	PP	27	NO	43	9	4	5	4	5	4	4	5	4	4	4

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0034007	DAY 50		07JUL2003	53	PP	27	NO	43	9	4	5	4	5	4	4	5	4	4	4
		DAY 57		14JUL2003	60	PP	27	NO	43	9	4	5	4	5	4	4	5	4	4	4
	E0035004	DAY 1		27NOV2002	1	ITT			33		3	3	3	4	6	2	3	4	3	2
		DAY 8		04DEC2002	8	ITT	-39	NO	20	-13	2	2	2	3	2	2	2	2	2	1
	E0035009	DAY 1		27DEC2002	1	PP			28		2	2	4	4	3	4	2	3	3	1
		DAY 8		31DEC2002	5	PP	-7	NO	26	-2	3	3	4	4	3	2	0	4	3	0
		DAY 15		08JAN2003	13	PP	-61	YES	11	-17	1	2	1	1	2	0	0	2	2	0
		DAY 22		15JAN2003	20	PP	-25	NO	21	-7	2	3	2	1	3	2	2	3	3	0
		DAY 29		22JAN2003	27	PP	-71	YES	8	-20	1	1	1	0	0	3	0	1	1	0
		DAY 36		29JAN2003	34	PP	-71	YES	8	-20	0	1	1	0	0	3	0	1	2	0
		DAY 43		05FEB2003	41	PP	-93	YES	2	-26	0	0	0	1	0	1	0	0	0	0
		DAY 43	*	11FEB2003	47	PP	-93	YES	2	-26	0	0	0	1	0	1	0	0	0	0
		DAY 57		19FEB2003	55	PP	-100	YES	0	-28	0	0	0	0	0	0	0	0	0	0
	E0035010	DAY 1		10JAN2003	1	PP			31		3	3	3	4	3	3	2	4	4	2
		DAY 8		17JAN2003	8	PP	-32	NO	21	-10	3	3	2	0	0	3	2	3	4	1
		DAY 15		24JAN2003	15	PP	-16	NO	26	-5	3	4	3	1	0	2	2	4	4	3
		DAY 22		31JAN2003	22	PP	-19	NO	25	-6	3	3	1	1	0	3	4	4	4	2
		DAY 29		07FEB2003	29	PP	-7	NO	29	-2	4	4	4	1	2	3	2	3	4	2
		DAY 36		14FEB2003	36	PP	-19	NO	25	-6	3	3	3	1	0	2	2	3	4	4
		DAY 43		24FEB2003	46	PP	-45	NO	17	-14	2	2	2	2	0	1	3	3	2	0
		DAY 50		28FEB2003	50	PP	-48	NO	16	-15	2	2	2	1	0	2	3	4	0	0
		DAY 57		06MAR2003	56	PP	-55	NO	14	-17	2	2	4	0	0	1	1	2	2	0
	E0035022	DAY 1		09MAY2003	1	PP			34		4	4	3	4	6	3	2	4	4	0
		DAY 8		15MAY2003	7	PP	9	NO	37	3	5	5	4	4	4	3	4	4	4	0
		DAY 15		23MAY2003	15	PP	-18	NO	28	-6	3	4	3	4	2	3	3	3	3	0
		DAY 22		30MAY2003	22	PP	-24	NO	26	-8	3	3	3	4	2	3	2	4	2	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0035022	DAY 29	06JUN2003	29	PP	-41	NO	20	-14	3	3	3	2	2	3	1	2	1	0
		DAY 36	13JUN2003	36	PP	-59	NO	14	-20	2	2	2	2	2	1	1	2	0	0
		DAY 43	20JUN2003	43	PP	-71	YES	10	-24	2	2	2	0	0	2	0	2	0	0
		DAY 50	27JUN2003	50	PP	-82	YES	6	-28	1	1	2	0	0	1	0	1	0	0
		DAY 57	07JUL2003	60	PP	-97	YES	1	-33	0	0	1	0	0	0	0	0	0	0
	E0039003	DAY 1	25NOV2002	1	PP			34		5	4	2	5	0	4	4	4	4	2
		DAY 8	02DEC2002	8	PP	-32	NO	23	-11	4	4	3	2	0	2	2	3	1	2
		DAY 15	09DEC2002	15	PP	-50	NO	17	-17	2	2	2	2	0	2	2	2	1	2
	E0040001	DAY 1	27JUN2003	1	PP			21		3	2	2	3	2	2	2	2	2	1
		DAY 8	03JUL2003	7	PP	10	NO	23	2	3	2	3	3	3	2	2	2	2	1
		DAY 15	11JUL2003	15	PP	0	NO	21	0	2	2	3	2	3	2	2	2	2	1
		DAY 22	18JUL2003	22	PP	0	NO	21	0	3	2	2	3	2	2	3	2	2	0
		DAY 29	25JUL2003	29	PP	5	NO	22	1	2	3	3	3	2	2	3	2	2	0
		DAY 36	01AUG2003	36	PP	-33	NO	14	-7	3	2	2	1	0	2	1	2	1	0
		DAY 43	08AUG2003	43	PP	-14	NO	18	-3	4	3	2	2	0	2	1	2	2	0
		DAY 50	15AUG2003	50	PP	-29	NO	15	-6	2	2	2	1	0	2	2	2	2	0
		DAY 57	22AUG2003	57	PP	-24	NO	16	-5	2	2	2	2	0	2	2	2	2	0
	E0040004	DAY 1	18JUL2003	1	SAFETY			20		3	2	2	2	2	2	2	2	2	1
	E0041002	DAY 1	21JAN2003	1	PP			33		4	4	4	4	4	3	3	3	4	0
		DAY 8	28JAN2003	8	PP	-12	NO	29	-4	3	3	4	3	3	3	3	3	4	0
		DAY 15	04FEB2003	15	PP	-15	NO	28	-5	3	3	4	3	3	2	3	3	4	0
		DAY 22	11FEB2003	22	PP	-58	NO	14	-19	0	0	4	3	3	2	2	0	0	0
		DAY 29	18FEB2003	29	PP	-52	NO	16	-17	1	2	3	2	3	2	2	1	0	0
		DAY 36	25FEB2003	36	PP	-49	NO	17	-16	1	1	3	4	2	2	2	2	0	0
	E0041005	DAY 1	05MAR2003	1	PP			25		3	3	3	3	1	3	3	3	3	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.1 Montgomery-Asberg Depression Rating Scale (MADRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	POP# (EXCLUDE AFTER DAY)	RESPONSE RATE%	REMISSION	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0041005	DAY 8	11MAR2003	7	PP	4	NO	26	1	2	3	4	4	0	3	4	3	3	0
		DAY 15	19MAR2003	15	PP	12	NO	28	3	3	4	3	4	2	2	4	3	3	0
		DAY 22	26MAR2003	22	PP	28	NO	32	7	4	4	4	4	3	2	4	3	3	1
		DAY 29	02APR2003	29	PP	-32	NO	17	-8	2	3	2	4	0	0	0	3	3	0
		DAY 36	09APR2003	36	PP	-40	NO	15	-10	2	2	2	3	0	0	2	2	2	0
		DAY 43	16APR2003	43	PP	-24	NO	19	-6	3	3	1	4	0	0	2	2	3	1
		DAY 50	23APR2003	50	PP	-44	NO	14	-11	0	0	4	4	0	3	1	2	0	0
		DAY 57	30APR2003	57	PP	-44	NO	14	-11	1	1	2	4	0	2	0	2	2	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
# POPULATIONS: DOSE=RANDOMIZED, NO DOSE SAFETY=SAFETY ITT=INTENT-TO-TREAT PP=PER-PROTOCOL
@ Response Rate is only calculated for Intent-to-treat and per-protocol populations.
Item Scores: 1=Apparent Sadness, 2=Reported Sadness, 3=Inner Tension, 4=Reduced Sleep, 5=Reduced Appetite, 6=Concentration difficulties, 7=Lassitude, 8=Inability to feel, 9=Pessimistic thoughts 10=Suicidal thoughts.
POSSIBLE SCORES RANGE FROM 0 (NONE, NORMAL, ABSENT) TO 6 (CONTINUOUS, EXTREME, INCAPACITATING).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MADRS100.SAS
GENERATED: 12JUL2005 17:44:18 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	SCREEN	14JAN2003	-21	23		2	2	0	2	1	2	3	0	1	3	2	1	2	2	0	0	0
		DAY 1	04FEB2003	1	28		3	2	0	2	1	2	2	0	1	4	3	2	2	2	0	2	0
		DAY 8	12FEB2003	9	17	-11	2	1	0	0	0	0	2	1	0	2	2	2	2	2	0	1	0
		DAY 15	19FEB2003	16	14	-14	3	0	0	0	1	0	2	1	0	0	1	1	2	1	0	2	0
		DAY 22	26FEB2003	23	9	-19	1	0	0	0	0	1	1	0	0	1	1	1	2	1	0	0	0
		DAY 29	05MAR2003	30	8	-20	1	0	0	0	0	0	1	0	0	1	1	1	2	1	0	0	0
		DAY 36	11MAR2003	36	7	-21	0	0	0	0	0	0	1	0	0	1	2	0	2	1	0	0	0
		DAY 43	18MAR2003	43	6	-22	1	0	0	0	0	0	0	0	0	1	1	0	2	1	0	0	0
		DAY 50	25MAR2003	50	6	-22	1	0	0	0	0	0	1	0	0	1	1	0	1	1	0	0	0
		DAY 57	02APR2003	58	5	-23	1	0	0	0	0	0	0	0	0	1	1	0	2	0	0	0	0
	E0002010	SCREEN	25MAR2003	-10	25		2	2	2	2	2	1	3	1	0	2	2	0	2	1	1	2	0
		DAY 1	04APR2003	1	21		2	1	2	1	1	2	2	1	0	2	2	1	2	1	1	0	0
		DAY 8	10APR2003	7	24	3	2	1	2	2	1	1	2	2	0	2	2	1	2	1	2	1	0
	E0002012	SCREEN	16APR2003	-5	22		2	2	1	2	2	2	3	0	0	2	2	1	2	1	0	0	0
		DAY 1	21APR2003	1	23		2	2	1	2	2	2	3	1	0	2	2	1	2	1	0	0	0
		DAY 8	29APR2003	9	16	-7	1	0	0	2	2	1	1	0	0	2	2	1	2	1	1	0	0
		DAY 15	06MAY2003	16	11	-12	1	1	0	2	0	0	1	0	0	2	0	0	2	1	1	0	0
		DAY 22	15MAY2003	25	10	-13	1	1	0	0	1	0	2	0	0	2	1	0	1	0	1	0	0
		DAY 29	21MAY2003	31	11	-12	1	1	0	0	0	1	1	0	0	2	1	1	2	0	1	0	0
		DAY 36	28MAY2003	38	6	-17	0	1	0	1	1	0	0	0	0	1	0	1	0	0	1	0	0
		DAY 43	04JUN2003	45	5	-18	1	1	0	0	0	0	0	0	0	2	0	0	0	0	1	0	0
		DAY 50	11JUN2003	52	2	-21	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0
		DAY 57	16JUN2003	57	2	-21	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0002015	SCREEN	22MAY2003	-13	22		2	2	1	2	1	2	3	1	0	2	2	0	2	1	1	0	0
		DAY 1	04JUN2003	1	21		2	2	1	2	2	1	3	0	1	2	0	0	2	1	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	SCREEN		16JUL2003	-8	23		2	2	1	1	2	2	3	0	3	2	2	0	2	0	1	0	0
		DAY 1		24JUL2003	1	20		2	2	0	1	2	1	3	0	3	2	1	0	2	0	1	0	0
		DAY 8	*	30JUL2003	7	11	-9	2	1	0	1	0	0	2	0	1	1	0	0	2	0	1	0	0
		DAY 8		01AUG2003	9	11	-9	2	1	0	1	1	1	2	0	1	0	0	0	1	0	1	0	0
	E0003004	SCREEN		03DEC2002	-14	27		3	3	2	2	2	1	3	1	2	2	1	1	2	0	2	0	0
		DAY 1		17DEC2002	1	20		2	2	1	2	1	0	3	1	1	2	2	0	2	0	0	0	1
	E0003005	SCREEN		16DEC2002	-7	20		2	3	2	2	0	0	2	0	1	2	1	0	2	2	1	0	0
		DAY 1		23DEC2002	1	20		2	3	0	1	1	0	2	1	1	3	2	1	2	0	0	0	1
		DAY 8		30DEC2002	8	17	-3	1	0	0	0	0	0	1	0	1	3	3	1	2	2	3	0	0
		DAY 15		06JAN2003	15	14	-6	1	1	0	0	1	0	1	1	1	2	1	1	2	1	1	0	0
		DAY 22		14JAN2003	23	8	-12	0	1	0	0	0	0	0	0	0	1	1	0	2	0	3	0	0
		DAY 29		21JAN2003	30	15	-5	3	1	1	1	0	0	1	0	1	3	1	0	2	0	1	0	0
		DAY 36		28JAN2003	37	15	-5	1	1	1	0	0	0	2	0	2	4	1	1	2	0	0	0	0
		DAY 43		04FEB2003	44	16	-4	2	1	1	0	0	0	2	0	0	4	2	1	2	0	0	1	0
		DAY 50		11FEB2003	51	12	-8	1	1	0	1	0	0	2	0	1	1	2	0	2	0	0	1	0
		DAY 57		18FEB2003	58	15	-5	1	1	1	2	0	0	2	0	1	2	2	0	2	1	0	0	0
	E0003007	SCREEN		19DEC2002	-14	20		2	1	0	2	1	2	3	0	2	2	1	1	2	0	0	1	0
		DAY 1		02JAN2003	1	22		2	2	0	2	1	2	2	0	2	2	2	2	1	0	0	2	0
		DAY 8		09JAN2003	8	11	-11	1	1	0	1	0	0	1	0	1	2	1	1	1	0	0	1	0
		DAY 15		16JAN2003	15	14	-8	2	0	0	0	0	0	1	1	2	2	3	2	1	0	0	0	0
		DAY 22		23JAN2003	22	9	-13	1	1	0	0	1	0	0	0	1	1	2	1	0	0	0	1	0
		DAY 29		30JAN2003	29	12	-10	1	1	0	0	0	0	3	0	0	4	1	1	1	0	0	0	0
		DAY 36		07FEB2003	37	5	-17	0	0	0	0	1	0	0	0	0	0	1	1	2	0	0	0	0
		DAY 43		13FEB2003	43	4	-18	0	0	0	0	0	0	0	1	0	1	1	0	1	0	0	0	0
		DAY 50		20FEB2003	50	6	-16	0	0	0	2	1	1	1	0	0	0	1	0	0	0	0	0	0
		DAY 57		27FEB2003	57	4	-18	0	0	0	0	0	0	0	0	0	1	1	0	2	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	SCREEN	28APR2003	-7	23		2	3	0	2	2	2	3	1	1	2	1	0	2	2	0	0	0
		DAY 1	05MAY2003	1	25		2	3	1	2	2	2	3	1	1	2	1	0	2	2	1	0	0
		DAY 8	13MAY2003	9	24	-1	3	2	2	1	1	1	3	1	1	3	1	0	2	2	1	0	0
		DAY 15	19MAY2003	15	19	-6	2	2	1	0	0	1	2	1	2	2	1	1	1	1	1	1	0
		DAY 22	27MAY2003	23	9	-16	1	1	0	0	0	0	1	0	1	1	1	0	1	1	1	0	0
		DAY 29	04JUN2003	31	9	-16	1	1	0	0	0	2	0	0	2	0	2	0	0	0	1	0	0
		DAY 36	10JUN2003	37	1	-24	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	17JUN2003	44	5	-20	1	0	0	0	0	0	1	0	0	2	0	0	0	1	0	0	0
		DAY 50	24JUN2003	51	8	-17	1	1	0	0	0	0	1	0	1	0	0	0	2	1	1	0	0
		DAY 57	02JUL2003	59	15	-10	0	2	0	0	2	1	0	0	1	2	3	1	2	0	1	0	0
	E0004002	SCREEN	24SEP2002	-7	24		3	3	0	0	0	0	3	1	2	3	3	0	2	2	2	0	0
		DAY 1	01OCT2002	1	24		3	3	0	0	0	0	3	1	2	3	3	0	2	2	2	0	0
		DAY 8	10OCT2002	10	19	-5	3	3	0	0	0	0	3	1	1	2	2	0	2	2	0	0	0
		DAY 15	17OCT2002	17	13	-11	1	3	0	0	0	0	2	0	1	2	1	0	0	2	1	0	0
		DAY 22	22OCT2002	22	9	-15	1	2	0	0	0	0	2	0	1	1	0	0	0	2	0	0	0
		DAY 29	29OCT2002	29	10	-14	2	2	0	0	0	0	0	1	1	1	1	0	0	2	0	0	0
		DAY 36	05NOV2002	36	8	-16	1	1	0	0	0	0	0	0	1	2	0	0	1	2	0	0	0
		DAY 43	12NOV2002	43	10	-14	2	0	0	0	0	0	2	1	0	1	0	0	2	2	0	0	0
		DAY 50	19NOV2002	50	7	-17	2	0	0	0	0	0	0	0	1	1	1	0	0	2	0	0	0
		DAY 57	26NOV2002	57	8	-16	1	1	0	1	0	0	0	0	0	1	2	0	0	2	0	0	0
	E0004013	SCREEN	08JAN2003	-6	30		3	3	0	2	2	2	3	1	1	3	3	1	2	1	2	1	0
		DAY 1	14JAN2003	1	32		3	3	1	2	2	2	3	1	1	3	3	2	2	1	2	1	0
		DAY 8	21JAN2003	8	22	-10	3	3	1	0	2	0	3	1	0	2	3	1	2	0	1	0	0
		DAY 15	30JAN2003	17	18	-14	2	1	0	2	2	2	3	0	0	2	2	0	1	0	1	0	0
		DAY 22	05FEB2003	23	23	-9	3	1	0	0	2	0	3	0	2	2	2	1	2	2	3	0	0
	E0004018	SCREEN	12MAR2003	-7	24		3	2	2	2	1	1	3	1	1	3	1	2	1	0	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	DAY 1		19MAR2003	1	21		3	2	1	2	0	1	3	1	1	3	1	1	1	0	1	0	0
		DAY 8		26MAR2003	8	15	-6	2	2	0	0	1	0	2	1	1	3	0	1	1	0	1	0	0
		DAY 15		02APR2003	15	20	-1	3	2	1	0	1	1	2	1	1	3	1	1	2	0	1	0	0
		DAY 22		09APR2003	22	17	-4	2	2	0	2	1	0	2	1	1	2	1	1	1	0	1	0	0
		DAY 29		16APR2003	29	9	-12	1	1	0	2	0	0	1	1	0	2	0	1	0	0	0	0	0
		DAY 36		23APR2003	36	8	-13	1	1	0	2	0	0	0	1	0	1	0	1	0	0	1	0	0
		DAY 43		30APR2003	43	5	-16	1	1	0	1	0	0	0	1	0	0	0	1	0	0	0	0	0
		DAY 50		06MAY2003	49	8	-13	1	0	0	0	0	0	1	1	0	1	0	1	2	0	1	0	0
		DAY 57		13MAY2003	56	9	-12	1	0	0	1	1	0	1	1	0	1	0	2	0	0	1	0	0
	E0004021	SCREEN		07MAY2003	-7	22		3	1	0	2	1	1	3	1	2	3	2	0	2	1	0	0	0
		DAY 1		14MAY2003	1	21		3	1	1	0	2	2	3	1	1	2	1	0	2	1	1	0	0
		DAY 8		21MAY2003	8	14	-7	1	1	0	0	1	0	2	1	1	2	1	0	2	2	0	0	0
		DAY 15		28MAY2003	15	11	-10	2	1	1	0	1	0	2	0	1	1	1	0	1	0	0	0	0
		DAY 22		04JUN2003	22	6	-15	1	1	0	0	1	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 29		11JUN2003	29	5	-16	1	0	0	0	1	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 36		18JUN2003	36	5	-16	1	0	0	0	1	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 43		25JUN2003	43	5	-16	0	0	0	0	1	0	1	1	0	1	0	0	1	0	0	0	0
		DAY 50		02JUL2003	50	6	-15	1	0	0	0	0	0	2	0	0	1	1	0	1	0	0	0	0
		DAY 57		09JUL2003	57	4	-17	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0
	E0005002	SCREEN		23SEP2002	-10	23		3	1	1	2	2	0	3	2	1	3	2	0	2	0	1	0	0
		DAY 1		03OCT2002	1	25		3	1	1	2	2	0	3	2	1	3	2	0	2	2	1	0	0
		DAY 8		08OCT2002	6	24	-1	3	2	1	2	2	0	3	2	1	1	2	0	2	2	1	0	0
		DAY 8	*	14OCT2002	12	11	-14	1	1	0	2	0	0	0	1	1	0	1	0	1	2	1	0	0
		DAY 15		21OCT2002	19	13	-12	1	1	0	2	2	0	1	1	1	1	2	0	1	0	0	0	0
		DAY 22		28OCT2002	26	8	-17	0	0	0	2	2	0	0	0	1	1	2	0	0	0	0	0	0
		DAY 29		04NOV2002	33	6	-19	0	1	0	0	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		13NOV2002	42	10	-15	1	1	0	0	2	1	1	0	0	1	2	1	0	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	DAY 43	* 18NOV2002	47	6	-19	0	0	0	1	2	0	0	0	0	0	2	1	0	0	0	0	0
		DAY 50	25NOV2002	54	6	-19	0	0	0	1	2	0	0	0	0	0	2	0	0	1	0	0	0
	E0005004	SCREEN	24SEP2002	-7	27		3	2	0	2	1	2	3	2	3	3	1	0	2	2	1	0	0
		DAY 1	01OCT2002	1	26		3	1	0	2	1	2	3	2	3	3	1	0	2	2	1	0	0
		DAY 8	10OCT2002	10	15	-11	1	2	0	0	0	0	3	2	1	2	0	0	1	2	1	0	0
		DAY 15	15OCT2002	15	9	-17	1	0	0	0	0	0	1	1	0	1	1	0	2	2	0	0	0
	E0005013	SCREEN	30OCT2002	-8	26		3	2	1	2	0	2	3	2	1	3	2	0	2	1	2	0	0
		DAY 1	07NOV2002	1	26		3	2	1	2	0	2	2	2	1	3	2	1	2	1	2	0	0
		DAY 43	19DEC2002	43	23	-3	2	2	1	2	0	2	3	2	1	3	2	0	2	1	0	0	0
	E0005024	SCREEN	05FEB2003	-5	21		3	2	0	1	1	0	3	2	1	3	1	1	2	0	1	0	0
		DAY 1	10FEB2003	1	24		3	2	0	1	1	1	3	2	1	3	2	2	2	0	1	0	0
		DAY 8	18FEB2003	9	13	-11	2	2	0	0	0	0	2	2	0	1	1	1	1	0	1	0	0
		DAY 15	26FEB2003	17	3	-21	1	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
		DAY 22	06MAR2003	25	2	-22	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
		DAY 29	13MAR2003	32	2	-22	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
		DAY 36	20MAR2003	39	2	-22	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
		DAY 43	25MAR2003	44	2	-22	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
		DAY 50	02APR2003	52	6	-18	0	0	0	0	0	0	1	1	0	1	2	0	1	0	0	0	0
		DAY 57	09APR2003	59	2	-22	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
	E0005027	SCREEN	03MAR2003	-8	23		3	2	2	0	1	0	3	2	2	3	2	0	2	0	1	0	0
		DAY 1	11MAR2003	1	23		3	2	2	0	1	0	3	2	2	3	2	0	2	0	1	0	0
		DAY 8	19MAR2003	9	24	1	3	2	2	0	0	0	3	2	2	3	2	0	2	2	1	0	0
		DAY 15	26MAR2003	16	21	-2	3	1	1	0	0	0	3	2	2	3	2	0	2	2	0	0	0
		DAY 22	03APR2003	24	22	-1	3	2	1	0	1	0	3	2	2	2	2	0	2	2	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	SCREEN	30APR2003	-7	24		3	1	1	2	2	2	3	2	1	1	2	0	2	2	0	0	0
		DAY 1	07MAY2003	1	26		3	1	1	2	2	2	3	2	1	2	2	1	2	2	0	0	0
		DAY 8	15MAY2003	9	18	-8	3	1	0	0	0	0	3	2	0	2	2	1	2	2	0	0	0
		DAY 15	22MAY2003	16	23	-3	3	1	0	1	2	1	3	2	0	2	2	1	2	2	1	0	0
		DAY 22	27MAY2003	21	25	-1	3	1	0	2	2	1	3	2	0	3	2	1	2	2	1	0	0
		DAY 29	05JUN2003	30	18	-8	2	1	0	2	1	0	2	1	0	2	2	1	2	2	0	0	0
		DAY 36	12JUN2003	37	18	-8	2	2	0	1	0	0	3	1	1	2	2	0	2	2	0	0	0
		DAY 57	02JUL2003	57	19	-7	2	1	0	1	1	0	3	2	0	2	2	1	2	2	0	0	0
	E0005042	SCREEN	19JUN2003	-5	23		3	2	1	0	1	0	3	2	2	2	1	0	2	2	2	0	0
		DAY 1	24JUN2003	1	24		3	2	1	0	1	0	3	2	2	3	1	0	2	2	2	0	0
		DAY 8	02JUL2003	9	15	-9	1	2	1	0	0	0	2	2	1	1	1	0	2	1	1	0	0
		DAY 15	09JUL2003	16	10	-14	1	2	0	0	0	0	1	1	1	1	0	0	2	1	0	0	0
		DAY 22	16JUL2003	23	11	-13	1	1	0	0	0	0	1	1	1	2	1	0	2	1	0	0	0
		DAY 29	23JUL2003	30	8	-16	1	2	0	0	0	0	1	1	0	1	0	0	1	1	0	0	0
		DAY 36	30JUL2003	37	8	-16	1	1	0	0	0	0	1	1	1	1	0	0	1	1	0	0	0
		DAY 43	06AUG2003	44	9	-15	0	1	0	0	0	0	1	1	1	1	1	0	1	1	1	0	0
		DAY 50	12AUG2003	50	6	-18	0	0	0	0	0	0	1	1	1	1	0	0	1	1	0	0	0
		DAY 57	18AUG2003	56	5	-19	0	0	0	0	0	0	1	1	1	0	0	0	1	1	0	0	0
	E0006005	SCREEN	25NOV2002	-10	25		3	3	2	1	1	2	4	1	1	3	1	0	2	0	1	0	0
		DAY 1	05DEC2002	1	27		3	3	2	1	1	2	4	1	2	3	1	1	2	0	1	0	0
		DAY 8	12DEC2002	8	20	-7	3	3	1	1	1	0	4	1	1	1	0	1	2	0	1	0	0
		DAY 15	20DEC2002	16	25	-2	3	3	1	2	1	0	4	1	1	3	1	1	2	0	2	0	0
		DAY 22	30DEC2002	26	18	-9	3	2	1	2	1	0	1	1	0	2	2	1	2	0	0	0	0
		DAY 29	03JAN2003	30	13	-14	2	1	2	2	1	0	0	0	1	1	1	0	0	0	1	1	0
		DAY 36	09JAN2003	36	22	-5	2	2	2	2	0	0	4	1	1	3	1	1	1	0	2	0	0
		DAY 43	16JAN2003	43	21	-6	2	2	1	2	1	0	3	1	1	3	1	1	2	0	1	0	0
		DAY 50	23JAN2003	50	20	-7	2	1	2	2	1	0	2	1	1	3	1	1	2	0	1	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 57	30JAN2003	57	19	-8	2	2	1	2	0	1	3	1	1	2	1	0	2	0	1	0	0
	E0006018	SCREEN	06MAR2003	-7	26		3	2	0	1	1	2	3	2	2	3	1	1	2	0	3	0	0
		DAY 1	13MAR2003	1	25		3	2	0	1	1	2	3	1	2	3	1	1	2	0	3	0	0
		DAY 8	24MAR2003	12	24	-1	3	2	0	1	1	2	3	1	2	3	1	1	2	0	2	0	0
	E0007013	SCREEN	06JUN2003	-7	22		4	1	0	2	2	2	4	0	0	3	2	0	2	0	0	0	0
		DAY 1	13JUN2003	1	23		3	2	0	2	2	2	4	0	0	3	2	0	2	1	0	0	0
		DAY 8	20JUN2003	8	24	1	3	2	0	2	2	2	4	0	0	3	2	0	2	1	1	0	0
		DAY 15	26JUN2003	14	17	-6	2	1	0	0	2	1	4	0	0	2	2	0	2	1	0	0	0
		DAY 22	03JUL2003	21	18	-5	2	1	0	0	2	2	4	0	0	2	2	0	2	1	0	0	0
		DAY 29	10JUL2003	28	13	-10	1	0	0	0	2	2	4	0	0	1	0	0	2	1	0	0	0
		DAY 36	17JUL2003	35	15	-8	1	0	0	0	2	1	4	0	0	1	2	0	2	1	1	0	0
		DAY 43	24JUL2003	42	15	-8	1	0	0	0	2	1	4	0	0	1	2	0	2	1	1	0	0
		DAY 50	01AUG2003	50	11	-12	0	0	0	0	2	1	4	0	0	1	1	0	1	1	0	0	0
		DAY 57	07AUG2003	56	12	-11	1	0	0	0	2	1	4	0	0	1	1	0	1	1	0	0	0
	E0010004	SCREEN	05DEC2002	-6	27		3	3	2	2	1	1	4	2	1	3	2	0	1	2	0	0	0
		DAY 1	11DEC2002	1	26		3	3	1	2	1	2	4	0	1	3	2	0	1	2	1	0	0
		DAY 8	18DEC2002	8	20	-6	2	2	1	0	0	0	4	2	1	2	0	0	1	2	2	1	0
		DAY 15	26DEC2002	16	15	-11	1	2	0	0	0	0	4	1	2	2	1	0	0	2	0	0	0
		DAY 22	02JAN2003	23	29	3	3	3	2	2	1	0	3	1	2	2	3	1	2	2	1	1	0
		DAY 36	13JAN2003	34	11	-15	1	2	0	0	0	0	3	0	0	0	2	1	0	2	0	0	0
		DAY 43	21JAN2003	42	10	-16	1	2	0	0	0	0	1	0	1	1	2	0	0	2	0	0	0
		DAY 50	31JAN2003	52	20	-6	2	3	0	0	0	0	3	2	1	2	2	2	1	2	0	0	0
		DAY 57	06FEB2003	58	11	-15	1	2	0	0	0	0	1	1	0	2	2	0	0	2	0	0	0
	E0010012	SCREEN	30DEC2002	-8	26		3	3	1	1	1	2	3	1	1	3	2	2	2	1	0	0	0
		DAY 1	07JAN2003	1	28		3	3	1	0	2	1	3	2	1	2	2	2	2	2	2	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	DAY 8	14JAN2003	8	20	-8	3	3	1	0	0	0	3	1	1	2	2	1	1	2	0	0	0
		DAY 15	21JAN2003	15	12	-16	1	2	0	0	0	0	1	1	1	1	1	1	1	2	0	0	0
		DAY 22	28JAN2003	22	9	-19	1	3	0	0	0	0	1	0	1	1	0	1	1	0	0	0	0
		DAY 29	04FEB2003	29	14	-14	2	2	0	0	0	0	1	0	0	2	2	1	2	0	1	1	0
		DAY 36	11FEB2003	36	9	-19	1	2	0	0	0	0	1	0	0	1	1	1	1	0	1	0	0
		DAY 43	18FEB2003	43	7	-21	1	2	0	0	0	0	1	0	0	1	0	1	1	0	0	0	0
		DAY 50	25FEB2003	50	2	-26	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
		DAY 57	05MAR2003	58	2	-26	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0
	E0010024	SCREEN	23APR2003	-12	25		3	2	2	2	1	1	3	2	0	3	0	0	2	2	0	2	0
		DAY 1	05MAY2003	1	21		3	1	2	2	2	1	1	1	1	1	0	0	2	1	1	2	0
		DAY 8	12MAY2003	8	15	-6	2	1	2	0	0	0	1	1	1	1	1	0	2	2	0	1	0
		DAY 15	19MAY2003	15	13	-8	2	2	2	0	1	0	0	1	2	1	1	0	0	0	1	0	0
		DAY 22	27MAY2003	23	11	-10	2	2	2	0	0	0	0	1	1	1	2	0	0	0	0	0	0
		DAY 29	04JUN2003	31	14	-7	2	2	2	0	1	0	1	1	2	1	0	0	2	0	0	0	0
		DAY 36	11JUN2003	38	14	-7	2	2	2	0	0	0	1	2	1	1	1	0	2	0	0	0	0
		DAY 43	18JUN2003	45	14	-7	2	2	2	0	0	0	1	1	2	1	2	0	1	0	0	0	0
		DAY 50	25JUN2003	52	13	-8	2	2	2	0	0	0	1	1	2	1	1	0	1	0	0	0	0
		DAY 57	02JUL2003	59	10	-11	1	2	2	0	0	0	1	1	1	1	0	0	1	0	0	0	0
	E0010032	SCREEN	03JUL2003	-7	20		3	3	2	0	0	0	3	1	0	2	1	0	2	2	1	0	0
		DAY 1	10JUL2003	1	27		3	3	1	2	2	2	3	1	0	2	2	1	1	2	1	1	0
		DAY 8	17JUL2003	8	26	-1	3	3	2	0	0	2	3	2	0	2	2	0	2	2	3	0	0
	E0011025	SCREEN	20JUN2003	-6	24		3	1	2	0	1	0	3	1	2	2	2	1	2	2	2	0	0
		DAY 1	26JUN2003	1	25		3	1	2	0	1	2	3	2	0	2	2	1	2	2	2	0	0
		DAY 8	02JUL2003	7	20	-5	3	1	2	0	1	0	3	2	0	2	0	1	2	2	1	0	0
		DAY 15	10JUL2003	15	18	-7	2	2	2	0	0	0	3	1	0	2	0	1	2	2	1	0	0
		DAY 22	17JUL2003	22	19	-6	2	2	2	0	0	0	3	1	1	2	0	1	2	2	1	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	DAY 29	22JUL2003	27	15	-10	2	1	1	0	0	0	3	0	0	2	0	1	2	2	1	0	0
		DAY 36	30JUL2003	35	14	-11	2	1	0	0	0	0	2	1	1	2	1	1	1	1	1	0	0
		DAY 43	07AUG2003	43	10	-15	2	0	0	0	0	0	1	0	1	2	1	0	1	1	1	0	0
		DAY 50	14AUG2003	50	7	-18	1	0	0	0	0	1	1	0	0	1	1	0	0	1	1	0	0
		DAY 57	22AUG2003	58	5	-20	1	0	0	0	0	1	1	0	0	0	0	0	0	1	1	0	0
	E0013007	SCREEN	13MAR2003	-7	21		3	2	2	2	2	0	3	1	0	2	1	1	2	0	0	0	0
		DAY 1	20MAR2003	1	22		3	2	2	2	2	2	3	0	0	2	1	1	2	0	0	0	0
		DAY 8	27MAR2003	8	11	-11	2	2	0	0	0	0	2	0	0	2	0	1	2	0	0	0	0
		DAY 15	07APR2003	19	21	-1	2	2	1	2	2	2	3	0	1	2	0	2	2	0	0	0	0
	E0013009	SCREEN	26MAR2003	-7	20		2	2	0	2	2	2	3	1	0	2	2	0	2	0	0	0	0
		DAY 1	02APR2003	1	22		2	2	0	2	2	2	3	1	2	2	2	0	2	0	0	0	0
		DAY 8	09APR2003	8	13	-9	2	2	0	0	0	0	3	0	0	2	2	0	2	0	0	0	0
		DAY 15	16APR2003	15	12	-10	1	2	0	0	1	0	3	0	0	2	1	0	2	0	0	0	0
		DAY 22	24APR2003	23	7	-15	1	1	0	0	0	0	3	0	0	1	1	0	0	0	0	0	0
		DAY 29	01MAY2003	30	11	-11	1	1	0	2	2	2	3	0	0	0	0	0	0	0	0	0	0
		DAY 36	07MAY2003	36	2	-20	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	16MAY2003	45	6	-16	1	1	0	0	0	0	3	0	0	0	0	0	1	0	0	0	0
		DAY 50	21MAY2003	50	4	-18	1	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0
		DAY 57	29MAY2003	58	5	-17	0	1	0	0	0	0	0	0	0	1	1	0	0	0	0	2	0
	E0014006	SCREEN	11MAR2003	-14	26		2	3	1	2	1	2	3	1	2	3	1	1	2	0	2	0	0
		DAY 1	25MAR2003	1	23		3	2	1	1	1	2	2	1	2	3	1	0	1	1	2	0	0
		DAY 8	02APR2003	9	21	-2	3	2	1	0	0	0	2	1	2	3	2	0	2	1	2	0	0
		DAY 15	09APR2003	16	14	-9	3	1	2	1	0	0	1	1	1	2	0	0	1	1	0	0	0
		DAY 22	16APR2003	23	5	-18	1	1	0	0	0	0	1	0	0	1	0	0	0	1	0	0	0
		DAY 29	23APR2003	30	6	-17	0	0	0	1	0	0	0	0	0	0	2	0	2	1	0	0	0
		DAY 36	30APR2003	37	3	-20	1	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	DAY 43	07MAY2003	44	3	-20	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0
		DAY 50	14MAY2003	51	4	-19	1	0	0	1	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 57	21MAY2003	58	2	-21	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0
	E0014010	SCREEN	15APR2003	-7	25		3	2	2	2	1	0	3	3	1	2	2	0	2	0	2	0	0
		DAY 1	22APR2003	1	24		3	2	2	2	1	0	3	2	1	2	2	0	2	0	2	0	0
		DAY 8	30APR2003	9	11	-13	2	0	0	0	0	0	2	1	0	1	1	1	2	0	1	0	0
		DAY 15	07MAY2003	16	9	-15	1	1	0	1	0	0	1	1	0	1	1	0	1	0	1	0	0
		DAY 22	14MAY2003	23	9	-15	1	1	0	0	1	0	1	1	0	1	1	0	1	0	1	0	0
		DAY 29	21MAY2003	30	7	-17	1	0	0	0	0	0	1	1	0	1	1	0	1	0	1	0	0
		DAY 36	28MAY2003	37	7	-17	1	0	0	0	0	0	1	0	1	1	1	0	1	0	1	0	0
		DAY 43	03JUN2003	43	14	-10	1	0	1	2	0	0	2	1	1	2	1	0	1	1	1	0	0
		DAY 50	11JUN2003	51	16	-8	2	2	2	1	1	0	1	1	1	2	1	0	1	0	1	0	0
		DAY 57	17JUN2003	57	12	-12	1	1	1	1	0	0	1	1	1	2	1	0	1	0	1	0	0
	E0016001	SCREEN	02JAN2003	-20	32		3	1	2	2	2	1	4	2	4	3	3	2	1	0	0	2	0
		DAY 1	22JAN2003	1	21		3	1	0	2	2	1	2	2	2	2	1	0	1	1	1	0	0
		DAY 8	29JAN2003	8	14	-7	2	1	0	2	2	1	2	1	1	2	0	0	0	0	0	0	0
		DAY 15	05FEB2003	15	5	-16	1	1	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 22	12FEB2003	22	4	-17	0	0	0	0	0	0	1	0	0	1	0	0	0	1	1	0	0
		DAY 29	19FEB2003	29	2	-19	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 36	26FEB2003	36	3	-18	0	0	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0
		DAY 43	05MAR2003	43	0	-21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	12MAR2003	50	0	-21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAR2003	57	3	-18	0	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
	E0016004	SCREEN	27JAN2003	-7	27		3	2	0	2	2	2	2	2	3	2	3	1	0	0	2	1	0
		DAY 1	03FEB2003	1	24		3	2	1	2	2	1	3	2	2	2	1	1	0	0	2	0	0
		DAY 8	10FEB2003	8	17	-7	2	2	0	1	1	1	2	1	2	1	1	1	0	0	2	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	SCREEN	22OCT2002	-7	22		2	1	0	0	0	0	3	2	3	2	2	2	2	2	1	0	0
		DAY 1	29OCT2002	1	21		3	2	1	0	1	0	2	2	2	2	2	1	1	2	0	0	0
		DAY 8	05NOV2002	8	17	-4	3	2	0	0	0	0	3	2	0	2	1	0	2	1	1	0	0
		DAY 15	13NOV2002	16	5	-16	1	0	0	0	0	0	1	0	1	1	1	0	0	0	0	0	0
		DAY 22	20NOV2002	23	3	-18	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0
		DAY 29	27NOV2002	30	2	-19	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 36	04DEC2002	37	2	-19	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 43	11DEC2002	44	1	-20	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	18DEC2002	51	7	-14	0	0	0	0	0	0	2	1	1	1	0	1	1	0	0	0	0
		DAY 57	24DEC2002	57	1	-20	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	E0018006	SCREEN	10DEC2002	-7	24		3	2	1	2	2	2	2	0	3	2	2	0	1	1	1	0	0
		DAY 1	17DEC2002	1	25		3	2	1	2	2	2	3	2	1	2	2	1	1	1	0	0	0
		DAY 8	23DEC2002	7	14	-11	2	1	0	0	0	0	1	0	2	2	2	1	1	1	1	0	0
		DAY 15	31DEC2002	15	11	-14	1	1	0	0	0	0	3	1	1	1	1	0	1	0	1	0	0
		DAY 22	07JAN2003	22	10	-15	1	1	0	0	0	0	2	2	0	1	1	1	1	0	0	0	0
		DAY 29	14JAN2003	29	6	-19	1	1	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0
		DAY 36	21JAN2003	36	9	-16	1	1	0	0	0	0	1	0	1	2	2	0	1	0	0	0	0
		DAY 43	28JAN2003	43	8	-17	1	1	0	0	0	0	1	0	1	1	1	1	1	0	0	0	0
		DAY 50	06FEB2003	52	6	-19	1	1	0	0	0	0	1	0	1	1	1	0	0	0	0	0	0
		DAY 57	13FEB2003	59	15	-10	2	1	0	0	0	0	3	0	1	2	1	0	2	2	1	0	0
	E0019004	SCREEN	30OCT2002	-8	23		2	2	0	2	2	1	3	0	2	2	2	0	1	1	3	0	0
		DAY 1	07NOV2002	1	22		2	2	1	2	2	2	3	0	2	1	2	0	1	1	1	0	0
		DAY 8	14NOV2002	8	9	-13	0	0	0	2	1	0	0	0	2	2	2	0	0	0	0	0	0
		DAY 15	21NOV2002	15	16	-6	1	0	0	1	2	0	3	0	1	1	3	0	1	1	2	0	0
		DAY 22	26NOV2002	20	9	-13	0	0	0	2	2	2	0	1	0	0	1	0	0	1	0	0	0
		DAY 29	05DEC2002	29	16	-6	1	1	0	0	2	0	3	1	0	3	2	0	1	2	0	0	0
		DAY 36	12DEC2002	36	11	-11	1	0	0	2	2	1	0	0	0	1	2	0	1	1	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	DAY 43	19DEC2002	43	17	-5	3	0	0	2	2	2	2	0	2	3	0	0	1	0	0	0	0
	E0019011	SCREEN	12NOV2002	-9	23		3	2	0	0	0	0	4	1	1	3	2	2	2	2	1	0	0
		DAY 1	21NOV2002	1	28		4	2	0	1	2	0	4	0	2	4	3	1	2	2	1	0	0
		DAY 8	27NOV2002	7	20	-8	3	3	0	0	1	0	3	1	1	2	1	1	1	2	0	0	1
		DAY 15	05DEC2002	15	15	-13	2	2	0	2	0	0	3	0	1	2	0	0	1	2	0	0	0
		DAY 22	12DEC2002	22	19	-9	3	2	0	2	0	0	3	3	0	2	1	0	1	0	2	0	0
		DAY 29	19DEC2002	29	12	-16	2	2	0	0	1	0	3	0	0	1	0	0	1	0	2	0	0
		DAY 43	02JAN2003	43	18	-10	3	2	0	2	0	0	2	1	1	1	1	0	2	2	1	0	0
		DAY 50	09JAN2003	50	18	-10	2	2	0	0	1	0	3	0	2	2	1	1	1	2	1	0	0
		DAY 57	16JAN2003	57	15	-13	2	2	0	0	0	0	3	0	1	2	0	1	1	2	1	0	0
	E0019025	SCREEN	30JAN2003	-7	26		3	2	1	0	1	0	3	2	2	3	2	1	2	1	2	1	0
		DAY 1	06FEB2003	1	23		3	1	0	1	1	1	3	2	1	2	2	1	2	1	2	0	0
		DAY 8	13FEB2003	8	17	-6	3	0	0	0	1	0	3	1	1	2	2	1	2	1	0	0	0
		DAY 15	20FEB2003	15	10	-13	1	0	0	0	1	0	1	1	0	0	2	2	1	0	0	1	0
		DAY 22	27FEB2003	22	12	-11	1	0	0	0	1	0	2	2	0	0	1	2	1	0	0	2	0
		DAY 29	06MAR2003	29	11	-12	1	0	0	0	0	1	2	2	0	0	2	1	1	0	0	1	0
		DAY 36	13MAR2003	36	9	-14	0	0	0	1	2	0	2	0	0	1	1	1	0	1	0	0	0
		DAY 43	20MAR2003	43	11	-12	1	0	0	1	0	0	1	1	1	1	1	1	1	1	0	1	0
		DAY 50	27MAR2003	50	6	-17	0	0	0	1	0	0	1	1	0	0	2	1	0	0	0	0	0
		DAY 57	03APR2003	57	8	-15	0	0	0	1	1	0	1	1	0	0	2	1	0	0	0	1	0
	E0019026	SCREEN	10FEB2003	-14	23		2	2	1	0	0	0	3	2	2	2	3	0	2	2	2	0	0
		DAY 1	24FEB2003	1	21		3	2	1	0	0	0	3	1	2	2	1	0	2	2	1	0	1
	E0019043	SCREEN	21MAY2003	-13	31		3	2	2	2	2	2	3	1	1	2	2	2	2	2	1	2	0
		DAY 1	03JUN2003	1	31		3	2	2	2	2	2	3	2	0	2	2	2	2	2	1	2	0
		DAY 8	10JUN2003	8	16	-15	3	2	0	0	2	0	3	0	0	0	1	1	2	2	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	DAY 15		17JUN2003	15	16	-15	2	2	0	0	1	0	2	2	1	1	2	0	1	1	1	0	0
		DAY 22		24JUN2003	22	21	-10	3	2	1	0	0	0	3	2	0	2	2	2	2	2	0	0	0
		DAY 29		01JUL2003	29	13	-18	2	1	0	0	0	0	2	2	1	0	2	1	1	1	0	0	0
		DAY 36		08JUL2003	36	19	-12	2	1	0	0	1	1	3	2	1	2	3	1	1	1	0	0	0
		DAY 43		15JUL2003	43	13	-18	2	1	0	1	1	0	2	1	1	1	1	1	1	0	0	0	0
		DAY 50		22JUL2003	50	15	-16	1	1	0	1	1	0	1	1	1	2	2	1	1	1	1	0	0
		DAY 57		29JUL2003	57	15	-16	2	1	0	0	1	0	2	2	1	1	2	1	1	1	0	0	0
	E0020001	SCREEN		15OCT2002	-14	22		3	3	2	1	1	2	3	1	0	0	3	0	2	0	1	0	0
		DAY 1		29OCT2002	1	23		3	2	2	1	2	1	3	0	0	3	2	1	2	0	0	0	1
		DAY 8		05NOV2002	8	13	-10	1	1	0	0	1	1	3	1	0	1	2	0	2	0	0	0	0
		DAY 15		12NOV2002	15	15	-8	3	2	0	1	0	0	3	0	0	3	2	0	0	0	0	0	1
		DAY 22		19NOV2002	22	11	-12	1	2	2	0	0	1	3	0	0	1	0	0	1	0	0	0	0
		DAY 29		26NOV2002	29	12	-11	1	2	0	1	1	0	2	0	0	1	2	0	1	0	0	0	1
		DAY 36		03DEC2002	36	16	-7	2	2	1	2	2	0	0	0	0	3	2	1	0	0	0	1	0
		DAY 43		10DEC2002	43	13	-10	3	1	0	1	0	1	0	0	0	3	2	0	2	0	0	0	0
		DAY 50		16DEC2002	49	11	-12	2	2	0	1	2	0	0	0	0	1	2	1	0	0	0	0	0
		DAY 50	*	20DEC2002	53	12	-11	2	1	2	1	0	0	0	0	0	2	2	0	2	0	0	0	0
	E0020006	SCREEN		26NOV2002	-20	29		3	3	1	2	2	2	2	1	1	2	2	1	2	2	2	0	1
		DAY 1		16DEC2002	1	23		3	2	1	2	2	0	3	0	0	1	2	1	2	1	2	1	0
		DAY 8		20DEC2002	5	30	7	2	3	2	2	1	1	3	1	1	2	2	1	2	2	3	1	1
	E0020007	SCREEN		19DEC2002	-27	31		3	3	2	2	2	2	3	1	1	2	2	1	2	2	2	1	0
		DAY 1		15JAN2003	1	29		3	3	1	2	2	2	3	1	1	2	3	1	2	2	1	0	0
		DAY 8		22JAN2003	8	13	-16	1	2	0	0	0	0	2	0	0	2	2	0	2	2	0	0	0
	E0020011	SCREEN		19FEB2003	-7	26		3	2	2	2	0	1	3	1	0	2	2	1	2	2	3	0	0
		DAY 1		26FEB2003	1	20		3	2	1	1	0	0	3	1	1	1	0	0	2	1	3	0	1

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	DAY 8	05MAR2003	8	6	-14	2	0	0	0	0	0	0	1	1	1	0	0	0	0	1	0	0
		DAY 15	12MAR2003	15	4	-16	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
		DAY 22	20MAR2003	23	11	-9	1	0	0	2	0	0	1	0	0	1	2	1	2	1	0	0	0
		DAY 29	26MAR2003	29	8	-12	0	1	0	0	0	2	3	0	0	0	2	0	0	0	0	0	0
		DAY 36	02APR2003	36	4	-16	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0
		DAY 43	09APR2003	43	4	-16	1	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
		DAY 50	16APR2003	50	8	-12	0	0	0	1	0	2	1	0	1	0	2	0	1	0	0	0	0
		DAY 57	23APR2003	57	2	-18	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
	E0020013	SCREEN	25FEB2003	-8	24		2	2	1	2	2	2	3	1	1	3	2	1	1	0	0	0	1
		DAY 1	05MAR2003	1	23		3	1	1	2	2	2	3	1	1	3	2	0	1	0	0	0	1
		DAY 8	12MAR2003	8	1	-22	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0022008	SCREEN	05NOV2002	-7	25		3	2	2	2	1	0	3	2	2	2	2	0	2	0	2	0	0
		DAY 1	12NOV2002	1	26		3	2	1	2	1	2	3	2	2	2	2	0	2	0	2	0	0
		DAY 8	19NOV2002	8	11	-15	2	1	1	0	0	0	1	1	2	1	2	0	0	0	0	0	0
		DAY 15	26NOV2002	15	6	-20	1	0	0	0	0	0	1	0	2	1	1	0	0	0	0	0	0
		DAY 22	03DEC2002	22	0	-26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	12DEC2002	31	0	-26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	17DEC2002	36	0	-26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	24DEC2002	43	0	-26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	31DEC2002	50	0	-26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	57	0	-26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022017	SCREEN	03DEC2002	-16	26		3	2	0	2	2	0	3	1	1	2	2	2	2	0	2	2	0
		DAY 1	19DEC2002	1	22		3	3	0	2	1	0	4	0	1	2	2	0	2	0	2	0	0
		DAY 8	26DEC2002	8	17	-5	3	2	1	1	1	0	2	0	1	2	1	0	2	0	1	0	0
		DAY 15	03JAN2003	16	19	-3	3	3	1	1	1	0	2	0	1	2	2	0	1	0	2	0	0
		DAY 22	09JAN2003	22	19	-3	3	3	1	0	0	0	3	0	1	2	2	0	1	0	2	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	DAY 29	17JAN2003	30	12	-10	2	2	0	0	0	0	0	0	0	2	2	1	1	0	2	0	0
		DAY 36	22JAN2003	35	6	-16	0	0	0	0	0	0	0	0	1	1	2	0	1	0	1	0	0
		DAY 43	31JAN2003	44	12	-10	0	2	0	1	1	0	2	0	0	2	1	0	1	0	2	0	0
		DAY 50	06FEB2003	50	10	-12	0	1	0	1	0	0	2	0	1	1	2	0	1	0	1	0	0
		DAY 57	13FEB2003	57	4	-18	0	0	0	1	0	0	0	0	1	0	1	0	1	0	0	0	0
	E0022018	SCREEN	04DEC2002	-8	24		3	2	1	2	1	0	3	0	1	2	3	0	2	2	2	0	0
		DAY 1	12DEC2002	1	29		3	3	2	1	2	1	3	1	1	3	3	1	2	1	2	0	0
		DAY 8	19DEC2002	8	26	-3	3	2	1	1	2	1	3	2	1	2	2	1	2	1	2	0	0
		DAY 15	26DEC2002	15	29	0	3	2	2	2	2	0	3	1	2	3	2	1	2	2	2	0	0
		DAY 22	02JAN2003	22	23	-6	1	2	2	1	2	0	3	1	2	3	1	1	2	1	1	0	0
		DAY 29	09JAN2003	29	22	-7	2	2	2	2	2	0	3	0	1	1	2	1	2	2	0	0	0
		DAY 36	16JAN2003	36	24	-5	3	2	2	1	1	0	3	1	1	1	2	2	2	2	1	0	0
		DAY 43	23JAN2003	43	18	-11	3	2	1	1	1	0	2	1	0	1	1	1	2	2	0	0	0
		DAY 50	30JAN2003	50	14	-15	2	1	0	0	1	0	1	1	1	1	2	1	2	1	0	0	0
		DAY 57	06FEB2003	57	15	-14	1	1	1	0	1	0	2	1	1	1	2	1	2	1	0	0	0
	E0022022	SCREEN	16DEC2002	-14	35		4	4	2	2	2	1	4	2	2	2	2	2	2	0	2	2	0
		DAY 1	30DEC2002	1	33		4	4	2	2	2	0	3	1	2	3	2	2	2	2	2	0	0
		DAY 8	06JAN2003	8	29	-4	4	4	2	0	0	0	4	2	1	3	2	0	2	2	3	0	0
		DAY 15	14JAN2003	16	25	-8	3	1	3	2	0	0	3	0	1	2	1	2	2	2	3	0	0
		DAY 22	21JAN2003	23	23	-10	3	2	0	2	2	0	3	0	1	3	1	0	2	1	3	0	0
		DAY 29	28JAN2003	30	26	-7	3	1	1	0	2	0	3	0	1	3	2	2	2	1	3	2	0
		DAY 36	04FEB2003	37	21	-12	2	1	2	2	2	0	2	0	0	2	2	2	2	0	2	0	0
		DAY 57	27FEB2003	60	27	-6	3	1	2	2	2	2	3	0	1	1	2	2	1	2	2	1	0
	E0022027	SCREEN	23JAN2003	-14	22		3	1	1	0	2	1	3	1	2	3	1	0	2	1	1	0	0
		DAY 1	06FEB2003	1	22		3	1	1	0	2	0	3	1	2	2	1	0	2	1	1	2	0
		DAY 8	13FEB2003	8	14	-8	2	0	0	0	1	0	2	1	2	1	1	0	2	1	1	0	0

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@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	DAY 15	20FEB2003	15	10	-12	2	1	0	0	0	0	2	1	1	1	0	0	1	1	0	0	0
		DAY 22	27FEB2003	22	10	-12	2	1	0	0	0	0	1	1	1	1	1	0	2	0	0	0	0
		DAY 29	06MAR2003	29	6	-16	0	0	0	0	0	0	1	1	0	1	1	0	1	1	0	0	0
		DAY 36	13MAR2003	36	2	-20	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
		DAY 43	20MAR2003	43	4	-18	0	1	0	0	0	0	0	1	1	0	0	0	1	0	0	0	0
		DAY 50	27MAR2003	50	4	-18	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	2	0
		DAY 57	03APR2003	57	1	-21	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0022030	SCREEN	07FEB2003	-7	29		3	3	2	2	2	2	4	2	1	3	3	0	2	0	0	0	0
		DAY 1	14FEB2003	1	32		3	2	2	2	2	2	4	2	2	3	2	0	2	2	0	2	0
		DAY 8	20FEB2003	7	16	-16	2	2	1	0	0	0	4	1	1	2	1	0	2	0	0	0	0
		DAY 15	28FEB2003	15	14	-18	2	1	1	0	0	0	3	1	0	2	0	0	2	1	1	0	0
		DAY 22	07MAR2003	22	6	-26	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	2	1
	E0022031	SCREEN	10FEB2003	-8	30		3	2	2	2	2	2	3	1	2	3	2	1	1	2	2	0	0
		DAY 1	18FEB2003	1	30		3	2	2	2	2	2	4	1	1	3	2	1	2	2	1	0	0
		DAY 8	25FEB2003	8	19	-11	2	1	1	2	0	0	4	0	1	2	1	0	2	2	1	0	0
		DAY 15	04MAR2003	15	26	-4	3	2	2	0	1	1	4	1	1	3	2	0	2	2	2	0	0
		DAY 22	11MAR2003	22	17	-13	2	1	2	0	0	1	3	0	2	2	0	0	2	2	0	0	0
		DAY 29	18MAR2003	29	16	-14	1	1	1	0	2	1	2	0	1	1	1	1	1	2	1	0	0
		DAY 36	25MAR2003	36	13	-17	1	1	0	0	2	1	1	0	1	2	2	0	0	2	0	0	0
		DAY 43	01APR2003	43	15	-15	1	1	1	0	2	1	2	1	0	1	1	0	2	2	0	0	0
		DAY 50	08APR2003	50	16	-14	1	2	1	0	2	1	2	0	1	2	0	1	1	2	0	0	0
		DAY 57	15APR2003	57	12	-18	1	0	0	0	2	1	1	1	1	1	1	0	1	2	0	0	0
	E0022032	SCREEN	11FEB2003	-7	20		3	2	1	2	0	0	3	2	0	1	0	1	2	2	1	0	0
		DAY 1	18FEB2003	1	25		3	2	1	2	2	1	3	2	0	2	2	1	2	2	0	0	0
		DAY 8	28FEB2003	11	15	-10	3	2	0	0	0	0	3	1	0	1	0	1	2	2	0	0	0
		DAY 15	04MAR2003	15	11	-14	1	1	0	0	0	0	3	1	1	0	0	0	2	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	DAY 22	11MAR2003	22	9	-16	1	0	0	0	0	0	2	1	0	1	0	1	2	1	0	0	0
		DAY 29	21MAR2003	32	9	-16	0	1	0	0	1	0	1	0	1	1	1	1	1	1	0	0	0
		DAY 36	27MAR2003	38	6	-19	1	0	0	0	0	0	2	0	0	0	0	1	1	1	0	0	0
		DAY 43	03APR2003	45	5	-20	0	0	0	0	0	0	1	1	0	0	0	1	1	1	0	0	0
		DAY 50	10APR2003	52	6	-19	1	1	0	0	0	0	1	1	0	0	0	0	1	1	0	0	0
		DAY 57	18APR2003	60	9	-16	1	0	0	0	0	0	1	1	0	1	0	1	2	2	0	0	0
	E0022035	SCREEN	11FEB2003	-8	21		3	1	1	2	1	1	2	0	2	2	1	0	2	2	1	0	0
		DAY 1	19FEB2003	1	20		3	2	0	2	1	1	3	0	2	1	1	0	2	1	1	0	0
		DAY 8	26FEB2003	8	22	2	3	2	0	1	1	1	3	0	2	3	2	0	2	1	1	0	0
	E0022036	SCREEN	13FEB2003	-12	29		3	2	2	2	0	2	4	2	1	2	2	1	2	0	2	2	0
		DAY 1	25FEB2003	1	24		3	1	2	1	1	1	2	2	1	2	2	1	2	1	2	0	0
		DAY 8	03MAR2003	7	24	0	3	2	2	0	1	0	3	2	1	3	2	0	2	1	2	0	0
		DAY 15	10MAR2003	14	16	-8	3	2	0	1	0	0	2	1	1	1	1	0	2	1	1	0	0
		DAY 22	18MAR2003	22	21	-3	3	1	1	2	1	0	3	1	1	3	1	1	2	1	0	0	0
		DAY 29	25MAR2003	29	16	-8	2	2	1	2	0	0	2	2	1	2	1	0	0	1	0	0	0
		DAY 36	01APR2003	36	18	-6	3	1	2	2	0	0	2	1	1	1	2	0	2	0	1	0	0
		DAY 43	08APR2003	43	18	-6	3	2	2	2	0	2	1	2	0	1	1	0	1	0	1	0	0
		DAY 50	15APR2003	50	18	-6	3	2	3	0	0	0	3	1	0	2	1	1	2	0	0	0	0
		DAY 57	22APR2003	57	23	-1	3	2	2	2	0	0	3	2	1	2	2	0	2	1	1	0	0
	E0022056	SCREEN	09APR2003	-8	24		3	2	2	2	2	2	3	1	2	2	2	0	1	0	0	0	0
		DAY 1	17APR2003	1	26		3	2	0	2	2	2	3	2	1	3	1	2	2	1	2	0	0
		DAY 8	24APR2003	8	20	-6	3	2	1	1	0	0	2	1	1	2	1	2	2	2	0	0	0
		DAY 15	01MAY2003	15	20	-6	3	1	1	2	0	0	3	1	1	3	1	2	1	0	1	0	0
		DAY 22	08MAY2003	22	21	-5	3	1	2	2	0	0	3	2	1	2	1	1	1	1	1	0	0
	E0022060	SCREEN	23APR2003	-7	23		3	2	2	2	0	0	3	1	1	4	2	1	2	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	DAY 1		30APR2003	1	25		3	2	2	1	1	1	3	1	1	2	2	1	2	0	1	2	0
		DAY 8		05MAY2003	6	19	-6	3	2	2	0	0	1	2	1	0	2	1	1	2	0	1	1	0
		DAY 15		12MAY2003	13	17	-8	3	2	2	0	0	0	1	1	0	2	1	1	2	0	2	0	0
		DAY 22		19MAY2003	20	16	-9	2	2	0	0	1	1	1	1	0	2	2	1	1	0	1	1	0
		DAY 29		28MAY2003	29	17	-8	3	2	0	0	0	0	2	2	1	4	0	1	2	0	0	0	0
		DAY 36		02JUN2003	34	15	-10	3	2	0	0	0	0	2	1	1	1	1	1	2	0	1	0	0
		DAY 43		10JUN2003	42	14	-11	2	2	0	0	0	0	1	1	0	3	2	1	2	0	0	0	0
		DAY 50		17JUN2003	49	14	-11	2	1	0	0	0	0	2	1	0	3	2	1	2	0	0	0	0
		DAY 57		24JUN2003	56	10	-15	0	1	0	0	0	0	1	1	1	2	2	1	1	0	0	0	0
	E0022063	SCREEN		28APR2003	-9	22		3	2	2	2	2	1	3	1	1	2	0	0	2	0	1	0	0
		DAY 1		07MAY2003	1	21		3	2	0	2	2	1	3	1	2	2	1	0	1	0	1	0	0
		DAY 8		12MAY2003	6	14	-7	3	2	0	1	0	0	2	0	2	2	0	0	1	0	1	0	0
		DAY 15		21MAY2003	15	13	-8	2	2	0	0	0	0	2	1	0	2	2	0	0	0	2	0	0
		DAY 22		28MAY2003	22	9	-12	0	1	0	1	0	0	1	1	1	1	2	0	0	0	1	0	0
		DAY 29		04JUN2003	29	9	-12	2	2	0	0	0	0	0	0	1	1	1	0	0	0	2	0	0
		DAY 36		11JUN2003	36	5	-16	0	2	0	0	1	0	0	0	2	0	0	0	0	0	0	0	0
	E0023008	SCREEN		23JAN2003	-7	25		3	3	0	0	2	2	3	1	1	2	2	2	2	0	1	1	0
		DAY 1		30JAN2003	1	28		3	3	1	2	2	2	3	0	2	3	2	2	2	0	1	0	0
		DAY 8		06FEB2003	8	22	-6	4	3	2	0	0	0	3	1	2	4	1	0	1	0	1	0	0
		DAY 15		13FEB2003	15	19	-9	4	3	1	0	0	0	3	0	2	3	1	0	1	0	1	0	0
		DAY 22		20FEB2003	22	24	-4	3	3	3	1	2	0	0	1	2	3	2	0	2	1	1	0	0
		DAY 29		25FEB2003	27	18	-10	3	2	1	0	0	0	1	0	3	4	2	0	1	1	0	0	0
		DAY 36		06MAR2003	36	18	-10	3	2	1	0	0	0	1	0	3	4	2	0	1	1	0	0	0
		DAY 43		11MAR2003	41	16	-12	3	2	1	1	0	0	1	0	1	3	2	0	1	1	0	0	0
		DAY 50		18MAR2003	48	16	-12	3	2	1	0	0	0	1	0	2	3	2	0	1	1	0	0	0
		DAY 50	*	24MAR2003	54	20	-8	3	2	1	0	0	0	2	0	2	3	2	2	2	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0023013	SCREEN	13FEB2003	-14	28		3	2	2	0	2	2	3	1	1	3	2	2	2	2	1	0	0
		DAY 1	27FEB2003	1	27		3	2	2	1	1	1	3	1	1	3	3	2	1	1	2	0	0
		DAY 8	06MAR2003	8	23	-4	3	2	0	0	1	1	3	1	1	3	3	1	1	1	2	0	0
	E0023015	SCREEN	04MAR2003	-7	20		3	3	1	0	0	0	4	0	2	2	0	0	2	2	1	0	0
		DAY 1	11MAR2003	1	23		4	2	0	0	1	0	1	3	3	4	1	0	2	2	0	0	0
		DAY 8	18MAR2003	8	13	-10	1	2	0	0	0	0	0	0	3	2	2	1	1	0	1	0	0
		DAY 15	25MAR2003	15	7	-16	1	0	0	0	0	0	0	0	2	2	1	1	0	0	0	0	0
		DAY 22	01APR2003	22	6	-17	2	0	0	0	0	0	0	0	1	2	1	0	0	0	0	0	0
		DAY 29	08APR2003	29	7	-16	2	1	0	0	0	0	0	0	1	2	1	0	0	0	0	0	0
		DAY 36	15APR2003	36	0	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	22APR2003	43	1	-22	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	29APR2003	50	2	-21	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	06MAY2003	57	4	-19	1	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0
	E0023034	SCREEN	03JUN2003	-6	20		3	2	1	2	1	2	3	1	1	1	1	0	2	0	0	0	0
		DAY 1	09JUN2003	1	20		3	1	0	2	1	0	3	2	1	2	2	0	2	0	1	0	0
		DAY 8	16JUN2003	8	16	-4	2	1	0	2	2	0	3	1	1	1	2	0	1	0	0	0	0
		DAY 15	23JUN2003	15	17	-3	2	1	0	2	2	0	3	2	1	1	2	0	1	0	0	0	0
		DAY 22	30JUN2003	22	11	-9	1	0	0	1	1	1	3	1	1	1	0	0	1	0	0	0	0
		DAY 29	07JUL2003	29	18	-2	3	2	1	1	2	0	3	1	1	1	1	0	2	0	0	0	0
		DAY 36	14JUL2003	36	7	-13	2	1	0	0	1	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 43	22JUL2003	44	6	-14	1	0	0	0	1	0	1	0	0	1	0	1	1	0	0	0	0
		DAY 57	05AUG2003	58	7	-13	1	0	0	0	1	0	1	0	0	1	0	1	1	0	1	0	0
	E0023037	SCREEN	11JUN2003	-7	21		3	2	0	2	1	0	3	2	1	2	1	1	2	0	1	0	0
		DAY 1	18JUN2003	1	21		3	2	1	2	2	0	3	1	1	3	1	0	2	0	0	0	0
		DAY 8	24JUN2003	7	13	-8	2	1	0	1	1	0	4	0	1	1	1	0	1	0	0	0	0
		DAY 15	01JUL2003	14	6	-15	1	1	0	0	0	0	3	0	1	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0023037	DAY 29 *	14JUL2003	27	5	-16	1	1	0	0	0	0	2	0	1	0	0	0	0	0	0	0	0
		DAY 29	18JUL2003	31	2	-19	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	25JUL2003	38	2	-19	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 43	01AUG2003	45	1	-20	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 50	08AUG2003	52	1	-20	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	15AUG2003	59	3	-18	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
	E0023038	SCREEN	20JUN2003	-10	23		3	1	0	0	1	0	4	2	1	3	2	1	1	1	3	0	0
		DAY 1	30JUN2003	1	26		3	2	1	0	1	0	4	2	1	3	2	0	1	2	3	1	0
		DAY 8	09JUL2003	10	23	-3	3	2	1	0	0	1	4	1	1	2	3	0	1	1	3	0	0
		DAY 15	15JUL2003	16	16	-10	1	2	0	0	0	1	4	0	1	1	2	0	1	1	2	0	0
		DAY 22	21JUL2003	22	15	-11	1	2	0	0	0	0	4	0	1	1	2	0	1	1	2	0	0
		DAY 29	28JUL2003	29	14	-12	1	2	0	0	0	0	4	0	1	2	1	0	1	1	1	0	0
		DAY 36	07AUG2003	39	12	-14	2	1	1	0	0	0	4	1	0	2	0	0	0	1	0	0	0
		DAY 43	13AUG2003	45	8	-18	2	1	0	0	0	0	4	0	0	0	0	0	0	1	0	0	0
		DAY 50	21AUG2003	53	7	-19	2	1	0	0	0	0	3	0	0	0	0	0	0	1	0	0	0
		DAY 57	27AUG2003	59	8	-18	2	1	0	0	0	0	3	0	0	0	0	1	1	0	0	0	0
	E0023044	SCREEN	08JUL2003	-8	23		3	2	2	1	2	1	3	0	2	3	1	0	1	1	1	0	0
		DAY 1	16JUL2003	1	29		3	2	2	2	2	2	3	1	2	3	2	1	2	1	1	0	0
		DAY 8	22JUL2003	7	28	-1	3	2	1	1	2	2	3	2	1	3	2	1	2	1	2	0	0
		DAY 15	29JUL2003	14	24	-5	3	2	1	0	2	0	3	1	1	3	2	1	2	1	2	0	0
		DAY 22	05AUG2003	21	25	-4	3	2	1	0	2	1	3	1	1	3	2	1	2	1	2	0	0
		DAY 29	12AUG2003	28	26	-3	3	2	1	0	2	1	3	1	1	3	2	1	2	1	3	0	0
	E0023045	SCREEN	10JUL2003	-7	25		3	2	2	2	2	2	3	0	2	2	2	0	2	0	1	0	0
		DAY 1	17JUL2003	1	30		4	2	2	2	2	2	4	1	2	4	2	0	2	0	1	0	0
		DAY 8	24JUL2003	8	20	-10	3	2	2	0	0	0	4	1	2	3	1	0	1	0	1	0	0
		DAY 15	31JUL2003	15	18	-12	3	2	2	0	0	0	4	0	1	3	1	0	1	0	1	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	DAY 22	07AUG2003	22	16	-14	2	2	1	0	0	0	3	0	1	2	1	1	2	0	1	0	0
		DAY 29	14AUG2003	29	16	-14	2	2	1	1	1	0	3	0	0	2	0	1	1	1	1	0	0
		DAY 36	21AUG2003	36	12	-18	1	2	0	1	0	0	1	1	1	1	1	0	1	1	1	0	0
		DAY 43	28AUG2003	43	10	-20	1	1	0	1	0	0	1	0	1	1	1	0	1	1	1	0	0
		DAY 50	04SEP2003	50	4	-26	1	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 57	11SEP2003	57	3	-27	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0025002	SCREEN	27MAR2003	-7	25		3	2	2	1	1	1	3	2	0	3	2	0	1	2	2	0	0
		DAY 1	03APR2003	1	23		3	2	1	0	1	1	3	2	0	3	2	0	2	2	1	0	0
		DAY 8	10APR2003	8	8	-15	1	1	0	0	0	0	1	1	0	1	1	0	0	1	1	0	0
		DAY 15	17APR2003	15	24	1	3	2	1	1	1	1	3	2	1	3	2	1	1	2	0	0	0
		DAY 22	24APR2003	22	7	-16	1	2	0	0	0	0	1	1	0	1	0	0	0	1	0	0	0
		DAY 29	01MAY2003	29	3	-20	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0	0	0
		DAY 36	08MAY2003	36	3	-20	0	1	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 43	15MAY2003	43	4	-19	0	1	0	0	0	0	1	0	1	0	0	0	0	0	1	0	0
		DAY 50	22MAY2003	50	6	-17	1	0	0	0	0	0	1	1	0	1	0	0	1	1	0	0	0
		DAY 57	29MAY2003	57	3	-20	0	1	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0
	E0026010	SCREEN	15JAN2003	-7	23		2	1	0	2	2	2	3	1	0	2	2	1	2	0	1	2	0
		DAY 1	22JAN2003	1	26		2	2	0	2	2	2	2	2	0	3	1	1	2	1	2	2	0
		DAY 8	30JAN2003	9	17	-9	0	0	0	2	2	2	0	0	2	1	3	0	0	2	3	0	0
	E0026017	SCREEN	26FEB2003	-8	28		3	2	2	1	2	1	3	2	0	3	2	1	2	2	2	0	0
		DAY 1	06MAR2003	1	23		3	1	2	0	2	0	4	2	0	3	2	0	2	1	1	0	0
		DAY 15	21MAR2003	16	5	-18	0	0	0	0	0	2	0	0	0	2	1	0	0	0	0	0	0
	E0026018	SCREEN	06MAR2003	-14	27		3	2	2	2	2	1	3	1	0	3	2	1	2	2	0	1	0
		DAY 1	20MAR2003	1	27		3	2	2	2	2	1	3	2	0	2	2	2	2	2	0	0	0
		DAY 8	27MAR2003	8	13	-14	1	2	0	2	0	1	0	0	2	2	2	0	0	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	DAY 15	03APR2003	15	15	-12	2	0	3	2	0	0	0	0	1	2	2	0	1	0	2	0	0
		DAY 22	10APR2003	22	2	-25	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 29	17APR2003	29	8	-19	1	0	0	1	0	0	1	0	0	2	1	0	1	0	1	0	0
		DAY 36	24APR2003	36	6	-21	1	0	0	0	0	0	0	1	0	0	1	0	1	1	1	0	0
		DAY 43	01MAY2003	43	5	-22	0	0	0	2	0	0	1	1	0	0	0	0	0	1	0	0	0
		DAY 50	08MAY2003	50	7	-20	0	0	0	2	0	0	1	1	0	1	1	0	0	1	0	0	0
		DAY 57	15MAY2003	57	6	-21	0	0	0	2	0	0	0	0	0	0	1	0	2	1	0	0	0
	E0026025	SCREEN	01MAY2003	-8	27		3	3	2	0	2	0	4	2	0	2	2	2	1	1	1	2	0
		DAY 1	09MAY2003	1	27		4	3	2	0	1	0	4	2	0	3	1	2	1	1	1	2	0
		DAY 8	15MAY2003	7	24	-3	3	3	1	1	0	1	4	2	0	3	1	1	1	1	2	0	0
		DAY 15	22MAY2003	14	21	-6	3	3	1	1	0	0	3	2	0	3	1	1	1	1	1	0	0
		DAY 22	29MAY2003	21	14	-13	2	2	1	1	0	0	1	2	0	1	1	0	0	1	2	0	0
		DAY 29	05JUN2003	28	11	-16	2	2	0	1	0	0	1	2	0	1	0	0	0	1	1	0	0
		DAY 36	13JUN2003	36	8	-19	2	0	0	1	0	0	1	2	0	1	0	0	0	0	1	0	0
		DAY 43	20JUN2003	43	5	-22	1	0	0	0	0	0	1	1	0	1	0	0	0	0	1	0	0
		DAY 50	27JUN2003	50	9	-18	0	0	0	1	2	2	1	1	0	0	0	0	0	0	2	0	0
		DAY 57	03JUL2003	56	8	-19	0	0	0	1	1	2	0	1	1	0	0	0	2	0	0	0	0
	E0026029	SCREEN	02JUL2003	-7	28		3	3	0	2	2	2	3	1	2	2	2	2	2	1	1	0	0
		DAY 1	09JUL2003	1	32		3	3	0	2	2	2	3	1	3	3	2	2	2	1	3	0	0
		DAY 8	16JUL2003	8	26	-6	2	3	0	2	2	2	2	1	2	2	1	1	2	1	3	0	0
	E0026030	SCREEN	02JUL2003	-7	27		3	3	2	2	2	2	3	1	2	3	0	1	1	1	0	1	0
		DAY 1	09JUL2003	1	24		2	3	2	1	2	2	3	1	1	3	0	1	1	1	0	1	0
		DAY 8	16JUL2003	8	17	-7	1	2	2	0	0	1	3	0	1	2	1	1	1	1	0	1	0
		DAY 15	23JUL2003	15	16	-8	2	2	2	0	0	0	2	1	1	2	0	1	1	1	1	0	0
		DAY 22	30JUL2003	22	11	-13	1	3	0	0	0	1	1	0	1	2	0	1	0	1	0	0	0
		DAY 29	04AUG2003	27	9	-15	1	0	1	0	0	0	1	1	1	2	0	1	0	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	DAY 36		12AUG2003	35	3	-21	1	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43		19AUG2003	42	3	-21	0	0	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 50		26AUG2003	49	2	-22	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 57		03SEP2003	57	1	-23	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	E0026031	SCREEN		10JUL2003	-11	28		2	3	1	2	2	2	3	0	3	2	1	2	1	0	3	1	0
		DAY 1		21JUL2003	1	26		2	3	2	2	2	2	2	0	3	2	2	0	1	0	3	0	0
		DAY 8		28JUL2003	8	14	-12	1	0	0	0	1	1	2	0	3	2	1	0	0	0	3	0	0
		DAY 15		04AUG2003	15	14	-12	2	0	1	0	1	0	2	0	3	1	1	0	0	0	3	0	0
		DAY 22		11AUG2003	22	12	-14	2	0	0	0	0	0	2	0	3	0	1	0	0	1	3	0	0
		DAY 29		18AUG2003	29	14	-12	2	0	0	0	1	0	2	1	2	0	1	1	0	1	3	0	0
		DAY 36		25AUG2003	36	22	-4	1	1	0	0	1	0	3	0	3	2	1	2	2	1	3	2	0
		DAY 43		02SEP2003	44	17	-9	2	0	0	0	0	1	3	0	0	1	1	2	2	1	2	2	0
		DAY 50		08SEP2003	50	13	-13	0	0	2	1	1	1	2	0	1	0	2	1	2	0	0	0	0
		DAY 57		15SEP2003	57	13	-13	2	1	0	1	0	0	4	0	1	1	1	0	1	0	0	1	0
	E0027003	SCREEN	*	08JAN2003	-20	34		4	3	2	2	2	2	3	0	3	3	2	2	2	2	0	2	0
		SCREEN		23JAN2003	-5	29		4	2	2	2	2	2	3	1	3	3	2	0	1	2	0	0	0
		DAY 1		23JAN2003	-5	29		4	2	2	2	2	2	3	1	3	3	2	0	1	2	0	0	0
		DAY 8		06FEB2003	10	22	-7	3	2	1	2	2	1	3	0	1	3	2	0	1	1	0	0	0
		DAY 15		13FEB2003	17	17	-12	1	2	0	1	2	2	2	0	1	2	1	0	1	2	0	0	0
		DAY 22		19FEB2003	23	16	-13	3	2	0	0	2	2	2	0	1	1	0	0	1	2	0	0	0
		DAY 29		27FEB2003	31	15	-14	2	2	1	0	1	1	2	0	1	2	1	0	1	1	0	0	0
		DAY 36		06MAR2003	38	16	-13	3	2	0	0	2	2	1	0	1	2	2	0	0	1	0	0	0
		DAY 43		13MAR2003	45	13	-16	1	1	0	2	1	0	2	0	0	2	2	0	1	1	0	0	0
		DAY 50		20MAR2003	52	12	-17	1	1	0	1	1	1	2	0	1	2	0	0	1	1	0	0	0
		DAY 57		25MAR2003	57	10	-19	1	1	0	0	2	1	1	0	0	2	1	0	0	1	0	0	0
	E0028004	SCREEN		27SEP2002	-3	29		4	2	0	2	2	2	3	2	1	2	1	2	1	2	1	2	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	DAY 1		30SEP2002	1	29		4	2	0	2	2	2	3	2	0	3	1	2	1	2	1	2	0
		DAY 8		07OCT2002	8	16	-13	3	0	0	0	0	0	3	1	1	1	2	2	2	1	0	0	0
		DAY 8	*	09OCT2002	10	21	-8	3	0	0	2	0	0	3	1	1	2	2	2	2	1	0	2	0
	E0028006	SCREEN		01OCT2002	-3	21		3	2	1	2	2	1	2	2	2	1	1	1	0	1	0	0	0
		DAY 1		04OCT2002	1	20		3	2	1	2	2	0	2	2	2	1	1	1	0	1	0	0	0
		DAY 8		11OCT2002	8	19	-1	3	1	2	2	0	0	2	0	1	3	1	1	1	2	0	0	0
		DAY 15		16OCT2002	13	11	-9	2	1	0	0	0	1	1	0	1	2	0	0	1	1	1	0	0
		DAY 22		23OCT2002	20	11	-9	2	1	0	2	0	0	2	0	0	1	1	0	1	1	0	0	0
		DAY 29		31OCT2002	28	15	-5	2	2	0	0	0	1	2	0	1	1	1	1	1	2	1	0	0
		DAY 36		07NOV2002	35	19	-1	2	2	0	1	0	0	2	1	0	2	2	2	1	2	2	0	0
		DAY 43		14NOV2002	42	14	-6	3	1	0	1	0	0	1	0	0	3	1	0	1	2	1	0	0
		DAY 50		21NOV2002	49	18	-2	3	2	2	0	0	1	2	0	1	3	0	0	1	2	1	0	0
		DAY 57		04DEC2002	62	8	-12	2	0	0	1	0	0	0	0	0	2	2	0	0	1	0	0	0
	E0028008	SCREEN		08OCT2002	-7	22		3	1	1	2	2	0	4	2	0	2	1	1	1	2	0	0	0
		DAY 1		15OCT2002	1	24		2	3	0	0	1	0	3	2	2	3	3	0	2	2	1	0	0
		DAY 8		22OCT2002	8	20	-4	2	2	0	2	2	0	2	2	0	1	3	0	2	2	0	0	0
		DAY 15		29OCT2002	15	17	-7	2	3	0	2	1	1	3	1	1	2	0	0	0	0	0	1	0
		DAY 22		07NOV2002	24	14	-10	2	2	0	1	1	2	1	0	0	2	0	0	1	0	0	1	1
		DAY 29		14NOV2002	31	15	-9	2	0	0	1	1	2	4	0	0	1	2	0	1	0	0	0	1
		DAY 36		21NOV2002	38	18	-6	2	3	0	0	0	0	3	1	1	2	2	0	1	0	3	0	0
		DAY 43		26NOV2002	43	22	-2	2	3	0	2	1	1	2	0	2	3	3	0	2	1	0	0	0
		DAY 50		03DEC2002	50	20	-4	3	3	0	0	0	0	3	0	0	3	1	1	2	2	2	0	0
		DAY 57		10DEC2002	57	23	-1	3	3	0	2	2	2	3	0	0	2	2	0	2	2	0	0	0
	E0028009	SCREEN		10OCT2002	-5	25		3	1	1	2	0	1	4	3	2	1	1	1	1	2	0	2	0
		DAY 1		15OCT2002	1	22		2	2	0	2	1	0	3	2	0	0	2	1	2	2	1	2	0
		DAY 8		23OCT2002	9	5	-17	1	2	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	DAY 15	31OCT2002	17	6	-16	1	0	0	0	0	0	0	0	0	0	2	1	1	1	0	0	0
		DAY 22	07NOV2002	24	1	-21	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 29	14NOV2002	31	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	19NOV2002	36	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	26NOV2002	43	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	03DEC2002	50	4	-18	1	0	0	0	0	0	1	0	0	0	2	0	0	0	0	0	0
		DAY 57	12DEC2002	59	2	-20	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
	E0028016	SCREEN	07NOV2002	-7	24		3	1	2	2	2	0	3	2	1	1	1	2	1	2	1	0	0
		DAY 1	14NOV2002	1	26		2	2	3	2	2	2	3	0	0	3	2	1	2	2	0	0	0
		DAY 8	21NOV2002	8	22	-4	4	2	3	0	1	1	3	0	0	1	2	1	1	2	1	0	0
		DAY 15	26NOV2002	13	18	-8	3	4	2	0	1	1	1	1	0	1	1	0	1	2	0	0	0
		DAY 22	05DEC2002	22	24	-2	4	2	3	0	2	1	3	0	0	4	2	0	1	2	0	0	0
		DAY 29	12DEC2002	29	12	-14	2	0	0	0	0	0	3	0	0	1	0	0	2	2	0	2	0
		DAY 36	19DEC2002	36	7	-19	1	0	0	0	1	0	1	0	0	0	1	0	1	2	0	0	0
		DAY 43	26DEC2002	43	13	-13	1	1	1	0	1	1	2	0	0	1	1	0	1	2	1	0	0
		DAY 50	02JAN2003	50	14	-12	1	1	1	0	1	1	2	1	0	1	1	0	1	2	1	0	0
		DAY 57	09JAN2003	57	13	-13	1	0	0	0	1	1	2	1	1	1	2	0	1	2	0	0	0
	E0028017	*	12NOV2002		24		3	1	0	2	2	2	4	2	1	2	1	1	1	2	0	0	0
		*	19NOV2002		21		2	3	0	2	1	0	3	0	0	3	2	0	2	0	3	0	0
	E0028027	SCREEN	14JAN2003	-7	24		3	3	1	2	1	2	3	2	0	2	1	0	2	2	0	0	0
		DAY 1	21JAN2003	1	27		4	3	2	1	2	0	3	1	1	2	2	0	2	2	2	0	0
		DAY 8	28JAN2003	8	16	-11	3	2	2	0	0	0	4	2	0	0	2	0	0	1	0	0	0
		DAY 15	04FEB2003	15	12	-15	3	2	1	0	0	0	2	0	0	0	2	0	1	1	0	0	0
		DAY 22	11FEB2003	22	13	-14	3	2	2	0	0	0	3	0	0	0	0	0	1	2	0	0	0
		DAY 29	20FEB2003	31	17	-10	2	2	2	0	0	0	3	2	0	2	0	0	2	1	1	0	0
		DAY 36	28FEB2003	39	21	-6	3	3	1	0	0	0	0	1	3	3	2	0	1	2	2	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	SCREEN	28JAN2003	-7	26		3	1	0	2	1	2	4	2	1	2	1	2	1	2	0	2	0
		DAY 1	04FEB2003	1	21		3	2	0	2	1	1	3	2	0	0	2	1	1	2	1	0	0
		DAY 8	11FEB2003	8	10	-11	2	0	0	1	0	0	2	0	0	0	2	0	0	2	1	0	0
		DAY 15	17FEB2003	14	12	-9	2	0	0	0	0	0	3	0	2	1	2	0	1	1	0	0	0
		DAY 22	27FEB2003	24	7	-14	2	0	0	0	0	0	2	0	0	1	0	0	1	1	0	0	0
		DAY 29	06MAR2003	31	14	-7	3	0	0	0	0	0	3	2	1	1	0	2	0	2	0	0	0
		DAY 36	13MAR2003	38	3	-18	1	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0
		DAY 43	20MAR2003	45	8	-13	0	0	0	2	0	0	2	1	2	0	0	0	0	1	0	0	0
		DAY 50	27MAR2003	52	3	-18	1	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 57	03APR2003	59	1	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	E0028034	SCREEN	20MAR2003	-12	23		3	2	0	2	2	0	3	3	1	2	1	1	1	2	0	0	0
		DAY 1	01APR2003	1	22		2	1	0	2	2	2	2	1	1	3	0	0	2	2	2	0	0
		DAY 8	08APR2003	8	23	1	3	0	2	2	1	1	3	1	2	3	2	0	1	0	2	0	0
		DAY 15	15APR2003	15	11	-11	1	0	0	2	0	0	2	1	1	0	1	0	1	1	1	0	0
		DAY 22	22APR2003	22	6	-16	0	0	0	1	0	0	1	0	0	0	3	0	1	0	0	0	0
		DAY 29	01MAY2003	31	7	-15	1	0	0	2	0	0	0	0	1	1	2	0	0	0	0	0	0
		DAY 36	06MAY2003	36	2	-20	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 43	13MAY2003	43	6	-16	0	0	0	2	0	0	1	0	0	0	2	0	0	0	1	0	0
		DAY 50	21MAY2003	51	2	-20	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUN2003	63	6	-16	1	0	0	2	0	0	0	0	1	0	2	0	0	0	0	0	0
	E0028038	SCREEN	18APR2003	-7	24		3	2	1	2	2	2	3	3	1	1	1	0	1	2	0	0	0
		DAY 1	25APR2003	1	23		3	2	1	2	2	2	3	2	1	1	1	0	1	2	0	0	0
		DAY 8	02MAY2003	8	12	-11	2	0	0	0	1	0	3	1	0	2	0	0	2	1	0	0	0
		DAY 15	08MAY2003	14	13	-10	2	1	1	0	1	0	1	0	1	1	1	0	2	1	1	0	0
		DAY 29	22MAY2003	28	14	-9	1	1	1	1	1	1	2	0	1	2	0	0	1	1	1	0	0
		DAY 36	30MAY2003	36	16	-7	1	1	1	1	2	0	2	0	2	1	1	0	1	2	1	0	0
		DAY 43	05JUN2003	42	15	-8	1	2	0	0	1	0	2	0	1	2	1	0	2	2	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	DAY 50	12JUN2003	49	14	-9	1	1	1	1	0	0	2	0	1	2	1	0	1	2	1	0	0
		DAY 57	18JUN2003	55	15	-8	2	1	1	1	1	0	2	0	1	1	1	0	1	2	1	0	0
	E0028043	SCREEN	29MAY2003	-7	20		4	2	0	2	1	2	3	2	2	2	0	0	0	0	0	0	0
		DAY 1	05JUN2003	1	21		3	2	0	2	1	0	2	2	1	2	2	0	2	1	1	0	0
		DAY 8	12JUN2003	8	17	-4	3	1	0	2	1	0	3	1	0	1	2	0	2	0	1	0	0
		DAY 15	19JUN2003	15	19	-2	2	2	0	2	1	0	2	1	1	3	2	0	2	0	1	0	0
		DAY 22	26JUN2003	22	14	-7	2	1	0	2	1	1	1	1	0	2	1	0	1	0	0	1	0
		DAY 29	01JUL2003	27	16	-5	2	2	0	2	0	0	2	1	0	1	2	0	1	0	1	2	0
		DAY 36	08JUL2003	34	9	-12	1	1	0	2	1	0	1	0	0	0	1	0	2	0	0	0	0
		DAY 43	15JUL2003	41	11	-10	2	1	0	2	1	0	2	1	0	0	2	0	0	0	0	0	0
		DAY 50	22JUL2003	48	12	-9	1	1	0	2	1	0	2	1	0	1	1	0	1	0	1	0	0
		DAY 57	29JUL2003	55	9	-12	1	1	0	2	0	0	1	1	0	1	1	0	1	0	0	0	0
	E0028045	SCREEN	09JUN2003	-9	29		3	2	2	2	2	1	3	3	1	2	1	2	1	2	0	2	0
		DAY 1	18JUN2003	1	30		3	0	2	2	2	2	3	1	1	3	2	2	2	2	1	2	0
		DAY 8	25JUN2003	8	26	-4	3	1	1	2	2	2	3	1	0	3	2	2	2	2	0	0	0
		DAY 15	30JUN2003	13	24	-6	3	3	1	0	2	0	3	1	0	3	2	2	1	2	1	0	0
	E0029005	SCREEN	14NOV2002	-13	22		2	2	0	2	2	2	3	1	0	2	0	1	2	1	1	0	1
		DAY 1	27NOV2002	1	23		2	2	0	2	2	0	3	2	1	2	1	1	2	1	1	1	0
		DAY 8	03DEC2002	7	22	-1	2	3	0	1	2	1	2	1	1	2	2	1	2	1	0	1	0
		DAY 15	09DEC2002	13	14	-9	2	0	0	0	0	1	3	1	1	2	1	1	0	1	0	1	0
		DAY 22	16DEC2002	20	13	-10	1	2	0	0	0	1	3	1	0	2	1	1	0	1	0	0	0
		DAY 29	23DEC2002	27	16	-7	1	2	0	0	0	1	1	1	0	2	2	1	1	1	3	0	0
		DAY 36	30DEC2002	34	16	-7	2	2	0	0	0	0	3	1	0	2	2	0	2	1	1	0	0
		DAY 43	07JAN2003	42	18	-5	1	2	0	0	0	1	3	1	1	2	1	1	2	1	2	0	0
		DAY 50	14JAN2003	49	17	-6	1	1	0	2	0	0	3	1	1	2	1	1	2	1	1	0	0
		DAY 57	21JAN2003	56	12	-11	1	1	0	0	0	0	2	1	0	2	1	1	1	1	1	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	SCREEN		12NOV2002	-7	22		3	2	2	0	2	0	3	1	1	3	2	0	1	0	2	0	0
		DAY 1		19NOV2002	1	22		3	1	2	0	2	0	2	1	2	3	2	0	2	0	2	0	0
		DAY 8		26NOV2002	8	17	-5	3	1	1	0	2	0	2	1	1	2	1	0	1	1	1	0	0
		DAY 15		03DEC2002	15	14	-8	2	1	0	0	2	0	2	1	2	2	1	0	0	0	1	0	0
		DAY 22		10DEC2002	22	15	-7	2	1	1	0	2	0	2	1	1	2	1	0	1	0	1	0	0
		DAY 29		17DEC2002	29	14	-8	2	1	1	0	2	0	1	0	1	2	2	0	1	0	1	0	0
		DAY 43		02JAN2003	45	8	-14	1	1	0	0	1	0	0	0	1	2	1	0	1	0	0	0	0
		DAY 50		09JAN2003	52	14	-8	2	1	1	0	1	0	2	1	1	2	2	0	1	0	0	0	0
		DAY 57		16JAN2003	59	15	-7	2	1	1	0	2	0	2	1	1	2	1	0	2	0	0	0	0
	E0030008	SCREEN		07JAN2003	-7	23		3	2	2	1	1	2	3	1	1	2	1	1	1	1	1	0	0
		DAY 1		14JAN2003	1	21		2	2	0	2	2	2	3	0	1	2	1	0	2	1	1	0	0
		DAY 8		23JAN2003	10	18	-3	3	2	0	1	0	0	3	0	3	1	0	1	2	2	0	0	0
		DAY 15		30JAN2003	17	18	-3	2	1	0	2	2	2	2	0	2	1	0	1	1	2	0	0	0
		DAY 22		07FEB2003	25	19	-2	3	0	0	2	2	1	3	0	3	1	1	0	1	2	0	0	0
		DAY 29		14FEB2003	32	22	1	3	3	0	2	1	1	3	0	0	2	1	1	2	2	0	1	0
		DAY 36		21FEB2003	39	16	-5	2	1	0	2	1	2	3	0	1	0	1	0	1	2	0	0	0
		DAY 50		03MAR2003	49	13	-8	2	1	1	0	0	0	2	0	2	1	0	1	0	2	0	1	0
		DAY 57	*	11MAR2003	57	14	-7	1	2	0	2	0	0	3	0	2	0	1	1	1	0	0	1	0
		DAY 57		18MAR2003	64	14	-7	3	2	0	2	0	2	2	0	1	1	1	0	0	0	0	0	0
	E0030011	SCREEN		16JAN2003	-11	30		3	2	1	2	2	2	3	1	1	2	2	2	2	2	1	2	0
		DAY 1		27JAN2003	1	25		3	1	1	2	2	2	3	2	0	2	0	2	2	2	0	1	0
		DAY 8		03FEB2003	8	11	-14	0	1	0	0	0	0	2	0	1	2	1	1	1	2	0	0	0
		DAY 15		10FEB2003	15	4	-21	1	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0
		DAY 22		18FEB2003	23	1	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 29		24FEB2003	29	1	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 36		03MAR2003	36	4	-21	1	0	0	0	0	0	0	0	2	0	0	0	0	1	0	0	0
		DAY 43		10MAR2003	43	0	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	DAY 50		17MAR2003	50	1	-24	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57		24MAR2003	57	1	-24	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0030015	SCREEN		13FEB2003	-8	21		3	1	1	1	1	0	3	2	3	2	1	0	2	1	0	0	0
		DAY 1		21FEB2003	1	21		3	1	2	0	2	0	3	1	2	3	0	0	2	2	0	0	0
		DAY 8		03MAR2003	11	17	-4	3	2	2	0	0	0	3	2	1	2	0	0	2	0	0	0	0
		DAY 15		11MAR2003	19	13	-8	2	2	2	2	1	0	1	0	1	2	0	0	0	0	0	0	0
		DAY 29		19MAR2003	27	9	-12	2	2	2	0	0	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 36		26MAR2003	34	6	-15	1	2	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0
		DAY 43		02APR2003	41	5	-16	1	1	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0
		DAY 50		09APR2003	48	3	-18	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0
		DAY 57	*	17APR2003	56	1	-20	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57		22APR2003	61	1	-20	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	E0030022	SCREEN		06JUN2003	-10	23		3	3	0	0	2	0	4	0	2	2	2	0	2	0	3	0	0
		DAY 1		16JUN2003	1	22		3	3	0	1	2	1	3	0	1	2	2	0	2	0	2	0	0
		DAY 8		20JUN2003	5	17	-5	3	3	0	0	0	0	3	0	1	1	0	1	2	1	2	0	0
		DAY 15		30JUN2003	15	10	-12	1	1	0	0	0	0	1	0	1	2	2	0	0	2	0	0	0
		DAY 22		07JUL2003	22	10	-12	1	1	0	0	0	0	2	0	1	2	1	0	1	0	1	0	0
		DAY 29		14JUL2003	29	7	-15	2	2	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 36		21JUL2003	36	9	-13	1	1	0	0	1	0	1	0	1	2	0	0	1	0	1	0	0
		DAY 43		29JUL2003	44	5	-17	1	1	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 50		05AUG2003	51	9	-13	2	1	0	0	1	0	1	0	1	1	0	0	1	0	1	0	0
		DAY 57		14AUG2003	60	4	-18	2	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0031002	SCREEN		20NOV2002	-7	23		3	2	0	2	2	2	3	0	1	4	2	0	2	0	0	0	0
		DAY 1		27NOV2002	1	25		3	0	0	2	1	2	3	1	1	3	3	1	2	0	1	2	0
		DAY 8		06DEC2002	10	12	-13	1	2	0	0	0	0	1	0	1	2	2	1	2	0	0	0	0
		DAY 15		12DEC2002	16	19	-6	3	2	0	1	1	1	1	0	1	4	1	1	2	0	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	DAY 22		19DEC2002	23	12	-13	1	2	0	0	0	0	0	1	1	2	1	1	2	0	1	0	0
		DAY 29		27DEC2002	31	12	-13	2	0	0	0	2	0	2	0	0	2	1	1	2	0	0	0	0
		DAY 36		02JAN2003	37	9	-16	0	0	0	0	1	1	0	0	1	1	1	1	2	0	1	0	0
		DAY 50	*	13JAN2003	48	6	-19	0	0	0	0	0	0	0	0	1	1	1	0	2	0	1	0	0
		DAY 50		17JAN2003	52	5	-20	0	0	0	0	0	0	0	0	0	1	1	0	2	0	1	0	0
		DAY 57		22JAN2003	57	11	-14	0	1	0	0	0	0	3	0	1	1	1	0	2	0	2	0	0
	E0031003	SCREEN		03DEC2002	-7	23		3	2	1	1	2	2	3	1	0	3	2	1	0	1	1	0	0
		DAY 1		10DEC2002	1	22		3	1	1	1	1	1	2	1	2	4	1	0	1	1	2	0	0
		DAY 8		17DEC2002	8	13	-9	3	1	0	1	2	1	1	1	0	2	1	0	0	0	0	0	0
		DAY 15		23DEC2002	14	10	-12	1	0	0	2	0	0	2	0	1	2	1	0	0	1	0	0	0
		DAY 22		31DEC2002	22	13	-9	2	2	0	1	0	0	2	1	0	2	1	1	0	1	0	0	0
		DAY 29		07JAN2003	29	21	-1	2	2	1	1	2	1	0	1	1	3	1	2	1	1	2	0	0
		DAY 36		15JAN2003	37	19	-3	2	1	1	2	2	1	3	0	1	3	1	0	1	1	0	0	0
		DAY 43		21JAN2003	43	12	-10	2	1	0	1	2	0	1	0	1	2	0	0	1	1	0	0	0
		DAY 50		30JAN2003	52	12	-10	2	2	0	1	0	0	2	1	1	2	0	0	0	0	1	0	0
		DAY 57		04FEB2003	57	15	-7	2	2	0	0	2	0	2	1	1	2	1	0	0	1	1	0	0
	E0033015	SCREEN		03APR2003	-7	22		3	1	1	1	1	1	3	1	2	3	2	1	1	1	0	0	0
		DAY 1		10APR2003	1	22		3	1	1	1	1	1	3	1	2	3	1	1	1	1	1	0	0
		DAY 8		17APR2003	8	20	-2	2	1	1	1	0	0	3	1	2	3	2	0	2	1	1	0	0
		DAY 15		22APR2003	13	16	-6	2	1	1	0	1	0	2	1	2	2	2	0	1	0	1	0	0
		DAY 15	*	28APR2003	19	14	-8	2	0	1	0	0	0	2	1	1	1	2	0	2	0	0	2	0
		DAY 29		06MAY2003	27	15	-7	2	0	1	0	0	0	2	1	2	2	2	1	2	0	0	0	0
		DAY 36		13MAY2003	34	11	-11	1	1	1	0	0	1	1	1	2	1	1	0	0	0	1	0	0
		DAY 43		20MAY2003	41	8	-14	1	1	0	0	0	0	1	0	1	1	2	0	1	0	0	0	0
		DAY 50		27MAY2003	48	5	-17	2	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0
		DAY 57		04JUN2003	56	8	-14	1	1	0	0	0	0	1	1	1	1	1	0	0	1	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0034002	SCREEN	14MAR2003	-11	27		3	2	0	2	2	0	3	2	2	3	2	1	2	2	1	0	0
		DAY 1	25MAR2003	1	28		3	2	0	2	2	1	3	2	2	3	2	1	2	2	1	0	0
		DAY 8	01APR2003	8	14	-14	2	0	0	0	0	0	3	2	1	1	1	0	2	2	0	0	0
		DAY 15	08APR2003	15	11	-17	1	0	0	0	0	0	2	1	2	1	0	0	2	2	0	0	0
		DAY 22	15APR2003	22	13	-15	1	0	0	0	0	0	2	2	2	2	0	0	2	2	0	0	0
	E0034003	SCREEN	11APR2003	-13	24		3	1	0	0	0	0	3	3	2	3	2	1	2	2	2	0	0
		DAY 1	24APR2003	1	26		3	1	0	0	2	2	3	3	2	2	2	1	2	2	1	0	0
		DAY 8	01MAY2003	8	13	-13	1	0	0	0	0	0	2	2	1	1	0	1	2	2	1	0	0
		DAY 15	08MAY2003	15	7	-19	1	0	0	0	0	0	1	1	0	1	0	0	1	2	0	0	0
		DAY 22	15MAY2003	22	6	-20	1	0	0	0	0	0	1	0	0	1	0	0	1	2	0	0	0
		DAY 29	22MAY2003	29	2	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 36	29MAY2003	36	2	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 43	05JUN2003	43	2	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 50	12JUN2003	50	2	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 57	19JUN2003	57	2	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
	E0034006	SCREEN	25APR2003	-21	28		3	2	1	2	2	2	3	2	2	2	2	0	2	2	1	0	0
		DAY 1	16MAY2003	1	33		3	2	2	2	2	2	3	2	2	2	2	2	2	2	1	2	0
		DAY 8	23MAY2003	8	24	-9	3	2	1	0	0	0	3	2	2	2	2	2	2	2	1	0	0
		DAY 15	02JUN2003	18	25	-8	3	2	1	0	2	0	3	2	2	2	1	2	2	2	1	0	0
		DAY 22	09JUN2003	25	25	-8	3	2	0	0	2	0	3	2	2	3	2	1	2	2	1	0	0
		DAY 29	13JUN2003	29	23	-10	3	2	0	0	2	0	3	2	2	2	2	0	2	2	1	0	0
		DAY 36	20JUN2003	36	23	-10	3	2	0	0	2	0	3	2	1	3	2	0	2	2	1	0	0
		DAY 43	27JUN2003	43	26	-7	3	2	0	2	2	0	3	2	1	3	2	0	2	2	1	1	0
		DAY 50	03JUL2003	49	27	-6	3	2	0	2	2	0	3	2	2	3	3	0	2	2	1	0	0
		DAY 57	10JUL2003	56	27	-6	3	2	0	2	2	0	3	2	2	3	3	0	2	2	1	0	0
	E0034008	SCREEN	15MAY2003	-9	27		3	2	0	2	2	0	3	3	2	3	2	2	2	0	0	1	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 1	23MAY2003	-1	25		3	2	0	1	2	0	3	3	2	3	2	2	2	0	0	0	0
		DAY 8	02JUN2003	10	20	-5	3	2	0	0	0	0	3	3	2	3	2	0	2	0	0	0	0
		DAY 15	06JUN2003	14	17	-8	3	2	0	0	0	0	2	2	2	3	0	0	2	0	0	1	0
		DAY 22	13JUN2003	21	22	-3	3	2	1	0	0	0	3	2	2	3	0	1	2	1	0	2	0
		DAY 29	20JUN2003	28	8	-17	1	0	0	0	0	0	2	1	1	1	0	0	1	1	0	0	0
		DAY 36	27JUN2003	35	3	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	2	0
		DAY 43	07JUL2003	45	1	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 50	14JUL2003	52	0	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	21JUL2003	59	0	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0035003	SCREEN	15NOV2002	-7	22		3	2	1	1	1	2	4	0	1	2	2	0	1	1	0	1	0
		DAY 1	22NOV2002	1	23		3	1	1	2	2	2	4	0	0	2	2	1	1	1	0	1	0
		DAY 8	27NOV2002	6	17	-6	3	1	1	0	0	0	4	0	0	2	2	1	1	1	0	1	0
		DAY 15	04DEC2002	13	14	-9	2	1	0	0	0	0	4	0	1	2	1	1	1	1	0	0	0
		DAY 22	13DEC2002	22	14	-9	2	1	0	1	0	0	4	0	1	2	1	0	1	1	0	0	0
		DAY 29	20DEC2002	29	7	-16	1	0	0	1	0	0	0	0	1	2	1	0	0	1	0	0	0
		DAY 36	27DEC2002	36	8	-15	1	0	0	1	1	0	0	0	1	2	1	0	0	1	0	0	0
		DAY 43	03JAN2003	43	7	-16	1	0	0	1	1	1	0	0	0	1	1	0	0	1	0	0	0
		DAY 50	10JAN2003	50	5	-18	1	0	0	0	0	1	0	0	0	1	1	0	0	1	0	0	0
	E0035005	SCREEN	26NOV2002	-7	23		3	1	1	1	2	2	4	0	0	2	1	2	1	2	0	1	0
		DAY 1	03DEC2002	1	25		3	1	1	2	2	2	4	0	0	2	1	1	1	2	2	1	0
		DAY 8	12DEC2002	10	9	-16	2	1	0	0	0	1	0	0	0	1	0	0	1	1	1	1	0
		DAY 15	17DEC2002	15	7	-18	2	0	0	0	1	1	0	0	0	1	0	0	0	1	1	0	0
		DAY 22	24DEC2002	22	6	-19	2	1	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0
		DAY 29	31DEC2002	29	6	-19	2	0	0	0	1	0	0	0	0	1	0	0	0	1	1	0	0
		DAY 36	07JAN2003	36	7	-18	2	1	0	0	0	0	0	0	0	2	0	0	0	1	1	0	0
		DAY 43	14JAN2003	43	7	-18	0	1	0	0	1	1	0	0	0	1	0	0	1	1	1	0	0
		DAY 50	21JAN2003	50	7	-18	1	1	0	0	0	1	0	0	0	1	1	0	0	1	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	SCREEN	28JAN2003	-6	21		2	2	0	1	2	1	4	0	0	2	1	1	1	2	1	1	0
		DAY 1	03FEB2003	1	22		3	2	0	1	0	0	4	0	1	3	1	1	1	2	2	1	0
		DAY 8	10FEB2003	8	20	-2	3	2	1	0	1	1	4	0	0	2	2	0	1	2	0	1	0
		DAY 15	17FEB2003	15	12	-10	3	0	0	0	0	0	4	0	0	2	0	0	1	2	0	0	0
		DAY 22	24FEB2003	22	19	-3	2	0	0	1	1	0	4	0	0	1	2	2	1	2	2	1	0
		DAY 29	03MAR2003	29	16	-6	2	1	0	0	0	0	4	0	0	2	1	1	1	2	1	1	0
		DAY 36	10MAR2003	36	17	-5	2	2	0	1	2	0	4	0	0	3	0	0	1	2	0	0	0
		DAY 43	17MAR2003	43	11	-11	1	0	0	0	0	2	4	0	0	2	0	0	0	2	0	0	0
		DAY 50	24MAR2003	50	10	-12	1	0	0	0	0	0	4	0	0	2	1	0	0	2	0	0	0
		DAY 57	31MAR2003	57	7	-15	1	0	0	0	0	0	0	0	0	2	1	0	0	2	0	1	0
	E0035024	SCREEN	15MAY2003	-8	23		3	2	1	2	2	2	4	0	0	3	1	0	1	2	0	0	0
		DAY 1	22MAY2003	-1	26		3	2	1	2	2	2	4	0	1	3	2	1	1	2	0	0	0
		DAY 8	29MAY2003	7	22	-4	3	2	1	1	2	2	4	0	0	3	0	0	2	2	0	0	0
		DAY 15	05JUN2003	14	20	-6	3	2	1	0	1	2	4	0	0	3	1	0	1	2	0	0	0
		DAY 22	13JUN2003	22	18	-8	3	2	1	0	1	1	4	0	0	2	1	0	1	2	0	0	0
		DAY 29	19JUN2003	28	17	-9	3	2	1	0	0	0	4	0	0	3	1	0	1	2	0	0	0
		DAY 36	27JUN2003	36	18	-8	3	2	1	1	1	1	4	0	1	3	1	0	0	0	0	0	0
		DAY 43	03JUL2003	42	23	-3	3	2	1	2	1	2	4	0	0	3	2	0	2	1	0	0	0
		DAY 50	10JUL2003	49	19	-7	3	1	0	2	1	2	4	0	0	3	1	0	1	1	0	0	0
		DAY 57	18JUL2003	57	21	-5	3	2	1	1	1	2	4	0	1	2	1	0	2	1	0	0	0
	E0036005	SCREEN	24JUN2003	-7	21		3	2	1	0	0	2	1	2	2	2	1	1	2	0	2	0	0
		DAY 1	01JUL2003	1	22		3	2	0	0	0	0	3	2	1	3	2	1	2	1	2	0	0
		DAY 8	08JUL2003	8	21	-1	2	1	0	0	0	1	3	2	2	2	2	1	2	1	2	0	0
		DAY 15	15JUL2003	15	9	-13	0	0	0	1	0	0	2	0	1	1	2	1	0	1	0	0	0
		DAY 22	23JUL2003	23	12	-10	2	0	0	0	0	0	2	2	0	1	1	1	2	1	0	0	0
		DAY 29	29JUL2003	29	9	-13	1	0	0	0	0	0	1	0	1	2	1	1	1	1	0	0	0
		DAY 36	05AUG2003	36	8	-14	1	0	0	0	0	0	1	2	0	1	1	1	0	0	1	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	DAY 43	12AUG2003	43	10	-12	2	0	1	0	0	0	2	1	0	1	0	1	1	1	0	0	0
		DAY 50	19AUG2003	50	20	-2	3	0	3	0	0	0	3	1	1	3	1	1	1	1	2	0	0
		DAY 57	27AUG2003	58	10	-12	1	0	0	0	0	0	0	1	0	1	1	2	0	1	2	1	0
	E0037002	SCREEN	18DEC2002	-8	26		3	3	2	2	2	0	3	2	1	2	1	0	2	2	1	0	0
		DAY 1	26DEC2002	1	23		2	3	2	2	1	1	3	1	1	1	1	1	2	2	0	0	0
		DAY 8	03JAN2003	9	16	-7	3	2	2	0	0	0	2	1	0	2	1	0	0	2	1	0	0
		DAY 15	09JAN2003	15	11	-12	1	0	2	0	0	0	1	1	1	1	1	0	1	2	0	0	0
		DAY 22	17JAN2003	23	8	-15	1	2	0	0	0	0	0	0	0	1	1	0	0	2	1	0	0
		DAY 29	24JAN2003	30	15	-8	2	2	2	1	0	0	1	1	0	1	1	1	2	0	1	0	0
		DAY 36	31JAN2003	37	15	-8	2	2	2	2	0	0	2	1	0	1	1	1	0	0	1	0	0
		DAY 43	07FEB2003	44	11	-12	0	2	0	0	0	0	1	1	0	2	1	0	2	0	2	0	0
		DAY 50	13FEB2003	50	9	-14	0	1	0	0	0	0	1	0	0	1	1	1	2	0	2	0	0
		DAY 57	20FEB2003	57	8	-15	0	0	0	0	0	0	1	0	0	2	1	1	2	0	1	0	0
	E0037005	SCREEN	26FEB2003	-8	29		3	2	1	2	2	1	3	2	2	2	2	1	2	2	2	0	0
		DAY 1	06MAR2003	1	26		3	2	1	2	2	1	3	1	1	2	2	0	2	2	2	0	0
		DAY 8	13MAR2003	8	11	-15	0	1	0	0	0	0	2	1	0	1	2	0	2	1	1	0	0
		DAY 15	20MAR2003	15	18	-8	2	2	1	0	0	0	2	1	0	2	2	0	2	2	2	0	0
		DAY 22	27MAR2003	22	12	-14	1	0	0	0	0	0	2	1	0	2	1	0	2	1	1	0	1
		DAY 29	03APR2003	29	16	-10	1	2	0	0	0	0	2	1	1	2	1	0	2	2	2	0	0
		DAY 36	10APR2003	36	12	-14	1	1	0	0	0	0	1	0	1	1	1	0	2	2	2	0	0
		DAY 43	17APR2003	43	12	-14	1	2	0	0	0	0	1	0	0	1	1	0	2	2	2	0	0
		DAY 50	24APR2003	50	13	-13	1	2	0	0	0	0	1	1	0	1	1	0	2	2	2	0	0
		DAY 57	01MAY2003	57	15	-11	1	2	0	0	0	0	2	1	0	1	2	0	2	2	2	0	0
	E0037006	SCREEN	06MAR2003	-8	24		3	2	1	2	2	0	3	2	0	2	2	0	2	2	1	0	0
		DAY 1	14MAR2003	1	25		3	2	1	2	0	2	3	2	1	2	1	0	2	2	2	0	0
		DAY 8	21MAR2003	8	14	-11	2	2	0	0	0	0	2	1	1	1	1	0	2	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	DAY 15	28MAR2003	15	10	-15	1	2	0	0	0	0	1	1	0	0	1	0	1	2	1	0	0
		DAY 22	04APR2003	22	10	-15	1	2	1	0	0	0	1	1	0	0	1	0	2	1	0	0	0
		DAY 29	11APR2003	29	9	-16	1	0	0	0	0	0	1	1	0	1	1	0	1	2	1	0	0
		DAY 36	18APR2003	36	13	-12	2	1	1	0	0	0	2	0	0	1	1	0	1	2	2	0	0
		DAY 43	25APR2003	43	9	-16	1	1	1	1	0	0	1	0	0	1	1	0	0	2	0	0	0
		DAY 50	01MAY2003	49	9	-16	1	1	1	1	0	0	1	0	0	1	1	0	0	2	0	0	0
		DAY 57	09MAY2003	57	6	-19	0	1	0	0	0	0	0	0	0	1	1	0	0	2	1	0	0
	E0039006	SCREEN	10DEC2002	-20	27		2	1	2	2	2	2	3	1	2	2	1	0	2	2	2	1	0
		DAY 1	30DEC2002	1	24		3	2	0	2	2	2	3	1	0	1	1	2	1	2	1	1	0
		DAY 8	06JAN2003	8	30	6	3	3	1	2	2	2	3	1	2	2	2	1	2	2	1	1	0
		DAY 15	13JAN2003	15	27	3	3	3	1	1	1	1	3	1	2	2	2	1	2	2	1	1	0
		DAY 22	20JAN2003	22	25	1	3	2	2	2	1	2	3	1	1	0	1	1	2	2	1	1	0
		DAY 29	28JAN2003	30	22	-2	3	2	2	0	1	2	3	2	0	0	1	1	1	2	2	0	0
		DAY 36	04FEB2003	37	22	-2	3	2	2	0	1	2	3	2	0	0	1	1	1	2	2	0	0
		DAY 43	10FEB2003	43	7	-17	1	1	0	0	0	0	1	1	0	1	0	0	0	2	0	0	0
		DAY 50	18FEB2003	51	6	-18	1	1	0	0	0	0	1	0	0	1	0	0	0	2	0	0	0
		DAY 57	24FEB2003	57	4	-20	1	0	0	0	0	0	1	0	0	0	0	0	0	2	0	0	0
	E0039015	SCREEN	02JAN2003	-21	24		3	3	1	2	1	1	4	1	1	2	0	1	1	2	1	0	0
		DAY 1	23JAN2003	1	27		2	2	1	2	2	2	4	0	2	2	1	2	1	2	1	1	0
		DAY 8	30JAN2003	8	7	-20	1	1	0	0	0	0	1	0	0	1	2	0	0	1	0	0	0
		DAY 15	06FEB2003	15	5	-22	1	1	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0
		DAY 22	14FEB2003	23	8	-19	1	1	0	1	0	0	1	1	0	1	1	0	0	1	0	0	0
		DAY 29	20FEB2003	29	3	-24	1	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 36	27FEB2003	36	2	-25	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 43	06MAR2003	43	5	-22	1	1	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0
		DAY 50	14MAR2003	51	2	-25	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 57	20MAR2003	57	5	-22	0	1	0	0	0	0	1	0	0	1	1	0	0	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	SCREEN	05FEB2003	-22	22		3	2	1	2	1	1	2	1	1	1	3	1	1	2	0	0	0
		DAY 1	27FEB2003	1	24		2	2	2	2	2	1	2	0	2	2	2	1	1	2	0	1	0
		DAY 8	05MAR2003	7	10	-14	1	1	0	2	0	0	1	0	1	1	1	0	1	1	0	0	0
		DAY 15	11MAR2003	13	6	-18	0	0	0	2	0	0	1	0	0	1	1	0	1	0	0	0	0
		DAY 22	20MAR2003	22	8	-16	1	0	0	1	1	1	1	0	0	1	1	1	0	0	0	0	0
		DAY 29	27MAR2003	29	11	-13	2	0	0	2	1	0	1	0	0	0	1	1	2	1	0	0	0
		DAY 36	03APR2003	36	10	-14	2	0	1	2	1	0	1	0	0	0	1	0	1	1	0	0	0
		DAY 43	10APR2003	43	14	-10	1	1	1	0	1	0	3	1	0	1	1	1	1	2	0	0	0
		DAY 50	17APR2003	50	2	-22	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 57	24APR2003	57	1	-23	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	E0039025	SCREEN	26FEB2003	-20	20		3	2	1	2	2	2	2	1	2	2	0	1	0	0	0	0	0
		DAY 1	18MAR2003	1	24		3	3	1	2	2	2	3	1	1	2	2	1	0	1	0	0	0
		DAY 8	25MAR2003	8	11	-13	2	1	0	0	0	0	2	0	2	1	1	0	1	1	0	0	0
		DAY 15	01APR2003	15	5	-19	1	0	0	0	0	0	0	1	0	2	1	0	0	0	0	0	0
		DAY 22	10APR2003	24	1	-23	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	15APR2003	29	0	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	22APR2003	36	1	-23	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 43	29APR2003	43	1	-23	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 50	06MAY2003	50	1	-23	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0039041	SCREEN	07APR2003	-8	22		3	2	1	2	2	2	3	1	1	2	0	1	0	1	1	0	0
		DAY 1	15APR2003	1	21		2	2	1	2	2	2	2	1	1	1	0	1	1	2	1	0	0
		DAY 8	22APR2003	8	21	0	2	2	1	2	2	2	2	1	0	2	1	1	1	1	1	0	0
		DAY 15	29APR2003	15	7	-14	1	1	0	0	0	0	1	1	0	1	0	0	1	1	0	0	0
		DAY 22	06MAY2003	22	3	-18	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 29	13MAY2003	29	13	-8	1	0	0	2	2	1	1	1	1	1	1	0	1	1	0	0	0
		DAY 36	20MAY2003	36	3	-18	0	0	0	0	0	0	1	0	0	0	0	0	1	1	0	0	0
		DAY 43	27MAY2003	43	11	-10	1	1	0	1	0	1	1	1	1	1	0	1	1	1	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 50		03JUN2003	50	6	-15	0	1	0	0	0	0	1	0	1	1	1	0	0	0	1	0	0
		DAY 57		11JUN2003	58	4	-17	0	0	0	0	1	1	0	0	1	1	0	0	0	0	0	0	0
	E0039044	SCREEN		05MAY2003	-17	21		3	2	0	2	1	1	3	2	1	2	0	1	1	0	1	1	0
		DAY 1		22MAY2003	1	20		3	2	1	2	1	1	2	1	2	2	0	1	1	0	1	0	0
		DAY 8		29MAY2003	8	4	-16	1	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 15		04JUN2003	14	1	-19	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 22		11JUN2003	21	2	-18	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		18JUN2003	28	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		26JUN2003	36	3	-17	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 43		02JUL2003	42	2	-18	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 50		09JUL2003	49	1	-19	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0039046		*	06MAY2003		33		3	3	2	2	2	2	3	1	2	2	1	2	2	2	2	2	0
			*	21MAY2003		29		3	3	2	2	1	2	3	1	1	1	2	1	1	2	2	2	0
	E0039051	SCREEN		22MAY2003	-25	29		3	3	2	2	2	2	4	1	1	2	2	0	2	1	2	0	0
		DAY 1		16JUN2003	1	21		2	2	1	2	1	2	2	1	0	2	1	0	2	2	1	0	0
		DAY 8		23JUN2003	8	15	-6	1	1	1	0	0	1	1	1	0	2	2	1	1	2	1	0	0
		DAY 15		30JUN2003	15	11	-10	1	1	0	0	0	0	1	1	0	2	2	0	1	2	0	0	0
		DAY 22		07JUL2003	22	11	-10	1	2	0	0	0	0	1	1	0	2	1	0	1	2	0	0	0
		DAY 29		14JUL2003	29	9	-12	1	1	0	0	0	1	0	0	0	1	2	0	1	2	0	0	0
		DAY 36		22JUL2003	37	11	-10	1	1	0	0	0	0	1	1	0	2	2	0	1	1	1	0	0
		DAY 43		28JUL2003	43	3	-18	0	0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0
		DAY 50		04AUG2003	50	9	-12	1	1	0	0	0	0	0	0	0	1	2	1	1	2	0	0	0
		DAY 57		12AUG2003	58	7	-14	0	0	0	0	0	0	1	1	0	1	1	1	1	1	0	0	0
	E0039053	SCREEN		16JUN2003	-25	21		3	3	1	2	2	2	2	1	0	2	0	1	1	0	1	0	0
		DAY 1		11JUL2003	1	24		3	2	1	2	2	2	3	1	1	2	2	1	0	0	2	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	DAY 8	18JUL2003	8	18	-6	2	1	1	1	1	1	2	1	1	2	2	1	1	0	1	0	0
		DAY 15	25JUL2003	15	23	-1	2	2	1	2	2	2	2	1	1	2	1	1	1	0	2	1	0
		DAY 22	01AUG2003	22	16	-8	1	1	1	1	2	2	2	1	0	1	1	1	1	0	1	0	0
		DAY 29	07AUG2003	28	8	-16	2	1	1	1	0	0	1	0	0	0	1	0	1	0	0	0	0
		DAY 36	14AUG2003	35	5	-19	2	1	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	21AUG2003	42	7	-17	1	1	0	0	0	0	1	1	0	1	1	1	0	0	0	0	0
		DAY 50	29AUG2003	50	2	-22	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 57	08SEP2003	60	11	-13	2	1	0	0	0	0	1	1	0	2	0	1	1	2	0	0	0
	E0039057	SCREEN	02JUL2003	-12	26		3	2	2	2	2	1	3	0	2	2	1	1	1	2	1	1	0
		DAY 1	14JUL2003	1	22		3	2	1	2	1	2	3	0	2	2	2	1	1	0	0	0	0
		DAY 8	22JUL2003	9	4	-18	1	1	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
		DAY 15	28JUL2003	15	1	-21	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	04AUG2003	22	6	-16	0	0	0	0	0	0	1	1	0	1	1	0	1	1	0	0	0
		DAY 29	12AUG2003	30	1	-21	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 36	18AUG2003	36	1	-21	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43	26AUG2003	44	3	-19	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 50	02SEP2003	51	7	-15	1	1	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0
		DAY 57	09SEP2003	58	6	-16	0	0	0	0	0	0	1	1	1	0	1	0	1	0	1	0	0
	E0041003	SCREEN	16JAN2003	-12	21		3	3	0	0	0	2	2	2	0	2	0	2	2	1	2	0	0
		DAY 1	28JAN2003	1	21		2	2	0	1	1	2	3	1	1	1	1	1	2	1	2	0	0
		DAY 8	04FEB2003	8	8	-13	1	2	0	1	0	0	2	0	0	0	1	0	0	0	1	0	0
		DAY 15	11FEB2003	15	5	-16	1	2	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 22	18FEB2003	22	5	-16	1	2	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	25FEB2003	29	5	-16	1	2	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 36	04MAR2003	36	4	-17	1	1	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 43	11MAR2003	43	5	-16	1	2	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	18MAR2003	50	7	-14	1	2	0	1	0	0	0	0	0	0	1	0	0	0	1	1	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 57	25MAR2003	57	7	-14	1	1	0	0	0	0	1	1	1	0	0	1	1	0	0	0	0
	E0041008	SCREEN	26MAR2003	-12	25		3	2	0	2	2	2	3	1	1	2	1	1	2	2	0	1	0
		DAY 1	07APR2003	1	25		2	1	0	2	2	2	3	1	1	2	2	2	2	2	1	0	0
		DAY 8	14APR2003	8	24	-1	2	2	0	2	2	2	3	1	1	2	2	1	1	2	1	0	0
		DAY 15	22APR2003	16	22	-3	2	1	0	2	2	2	2	1	1	2	2	1	1	2	1	0	0
		DAY 22	28APR2003	22	21	-4	2	0	0	2	2	0	3	1	1	2	2	2	2	2	0	0	0
		DAY 29	05MAY2003	29	17	-8	1	0	0	2	2	0	3	1	1	1	2	2	2	0	0	0	0
		DAY 36	12MAY2003	36	20	-5	1	0	0	2	2	0	3	1	2	2	0	2	2	2	1	0	0
		DAY 43	21MAY2003	45	19	-6	0	0	0	2	2	0	3	1	1	2	2	2	2	2	0	0	0
		DAY 50	27MAY2003	51	20	-5	1	0	0	2	2	1	3	1	1	1	2	2	2	2	0	0	0
		DAY 57	02JUN2003	57	18	-7	1	0	0	2	2	0	3	1	0	2	2	2	1	2	0	0	0
	E0042001	SCREEN	17JUN2003	-15	22		3	2	0	1	2	1	2	1	1	3	1	0	2	0	2	1	0
		DAY 1	02JUL2003	1	26		3	2	0	2	2	1	2	1	2	3	2	0	2	0	3	1	0
		DAY 8	09JUL2003	8	15	-11	2	2	0	1	1	1	1	1	0	2	1	0	2	0	1	0	0
		DAY 15	15JUL2003	14	7	-19	1	1	0	0	0	0	1	0	0	1	1	0	1	0	1	0	0
		DAY 22	22JUL2003	21	7	-19	1	1	0	0	0	1	0	0	0	1	1	0	1	0	1	0	0
		DAY 29	29JUL2003	28	5	-21	1	1	0	0	0	0	0	0	0	1	0	0	2	0	0	0	0
		DAY 36	05AUG2003	35	6	-20	1	0	0	0	0	0	1	0	0	1	1	0	1	0	1	0	0
		DAY 43	12AUG2003	42	5	-21	0	0	0	0	0	0	1	0	0	1	0	0	2	0	1	0	0
		DAY 50	19AUG2003	49	5	-21	1	1	0	1	0	0	0	0	0	1	0	0	1	0	0	0	0
		DAY 57	26AUG2003	56	8	-18	1	0	0	2	0	0	1	0	0	1	0	0	2	0	1	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	SCREEN	26FEB2003	-14	23		4	3	1	0	2	1	2	1	0	1	1	2	2	1	0	2	0
		DAY 1	12MAR2003	1	28		4	3	0	2	2	0	3	2	1	3	2	2	2	0	1	1	0
		DAY 8	19MAR2003	8	15	-13	4	2	0	0	1	0	3	1	0	0	0	2	2	0	0	0	0
		DAY 15	26MAR2003	15	12	-16	3	1	1	0	0	0	2	0	0	1	0	1	2	1	0	0	0
		DAY 22	02APR2003	22	10	-18	1	1	0	0	1	0	2	0	0	2	1	1	1	0	0	0	0
		DAY 29	09APR2003	29	10	-18	1	1	0	0	0	0	2	0	0	3	1	1	1	0	0	0	0
		DAY 36	16APR2003	36	3	-25	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0
		DAY 43	23APR2003	43	5	-23	0	1	0	0	1	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 50	30APR2003	50	4	-24	0	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0
		DAY 57	07MAY2003	57	2	-26	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
	E0003018	SCREEN	06MAY2003	-7	29		3	3	2	2	2	0	4	1	1	4	1	1	2	2	1	0	0
		DAY 1	13MAY2003	1	27		2	3	1	2	1	1	4	1	2	4	1	1	1	2	1	0	0
		DAY 8	20MAY2003	8	23	-4	2	3	2	0	0	1	2	1	2	3	1	1	2	2	1	0	0
		DAY 15	27MAY2003	15	21	-6	3	3	2	1	0	1	1	1	1	2	1	0	2	2	1	0	0
		DAY 22	03JUN2003	22	27	0	2	3	2	1	2	1	3	1	1	4	2	0	2	1	2	0	0
		DAY 29	10JUN2003	29	26	-1	3	3	2	1	1	0	3	1	1	3	1	0	2	2	3	0	0
		DAY 36	17JUN2003	36	21	-6	3	3	0	1	0	0	2	1	2	2	2	0	2	2	1	0	0
		DAY 43	24JUN2003	43	22	-5	2	3	0	1	0	0	1	1	2	3	2	0	2	2	3	0	0
		DAY 50	02JUL2003	51	21	-6	2	2	1	1	1	0	1	1	2	2	2	0	2	2	2	0	0
		DAY 57	08JUL2003	57	19	-8	2	2	0	1	1	0	1	1	2	2	2	0	2	2	1	0	0
	E0005011	SCREEN	16OCT2002	-8	21		3	1	1	2	2	0	3	2	1	1	0	2	2	0	1	0	0
		DAY 1	24OCT2002	1	24		3	1	1	2	2	1	3	2	2	1	0	2	2	1	1	0	0
		DAY 8	31OCT2002	8	14	-10	3	1	1	0	0	0	3	1	2	0	1	1	1	0	0	0	0
		DAY 15	07NOV2002	15	11	-13	2	1	0	0	0	0	3	1	2	0	0	0	1	1	0	0	0
		DAY 22	14NOV2002	22	12	-12	2	1	1	0	0	0	3	1	0	0	1	0	1	1	1	0	0
		DAY 29	21NOV2002	29	8	-16	2	0	0	0	0	0	1	1	1	0	1	0	1	0	1	0	0
		DAY 36	26NOV2002	34	6	-18	1	0	0	0	0	0	1	0	0	2	1	0	0	0	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0005011	DAY 43	03DEC2002	41	3	-21	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
		DAY 50	12DEC2002	50	5	-19	1	0	0	0	0	0	1	0	0	0	2	0	1	0	0	0	0
	E0005030	SCREEN	18MAR2003	-8	26		3	3	0	2	2	2	3	1	2	3	1	2	2	0	0	0	0
		DAY 1	26MAR2003	1	25		3	1	0	2	2	2	3	2	1	3	2	2	2	0	0	0	0
		DAY 8	02APR2003	8	19	-6	2	2	1	0	0	0	2	1	2	3	2	2	2	0	0	0	0
		DAY 15	09APR2003	15	6	-19	1	0	0	2	0	0	0	1	0	1	0	1	0	0	0	0	0
		DAY 22	16APR2003	22	24	-1	3	2	1	2	2	0	3	0	2	3	1	0	2	2	1	0	0
	E0005036	SCREEN	28APR2003	-8	22		3	2	1	0	0	2	3	1	2	3	2	0	2	0	1	0	0
		DAY 1	06MAY2003	1	22		3	2	0	0	0	2	3	2	2	3	2	0	2	0	1	0	0
		DAY 8	12MAY2003	7	16	-6	2	0	0	2	0	0	1	2	2	2	2	0	1	1	1	0	0
	E0006015	SCREEN	06FEB2003	-5	20		3	2	0	2	2	0	4	2	0	2	1	0	2	0	0	0	0
		DAY 1	11FEB2003	1	21		3	2	0	1	1	0	4	2	0	3	2	0	2	0	1	0	0
		DAY 8	18FEB2003	8	20	-1	2	1	2	1	2	1	3	0	2	2	2	0	1	0	1	0	0
		DAY 15	25FEB2003	15	25	4	3	0	0	2	1	2	3	1	1	2	3	1	2	1	3	0	0
		DAY 22	04MAR2003	22	23	2	3	0	0	1	1	2	3	1	1	3	2	1	2	1	2	0	0
		DAY 29	11MAR2003	29	24	3	3	0	0	2	1	1	3	1	2	3	2	1	2	1	2	0	0
		DAY 36	18MAR2003	36	23	2	3	0	0	2	1	0	3	1	2	2	2	1	2	2	2	0	0
		DAY 43	25MAR2003	43	21	0	3	0	0	2	1	0	2	1	2	3	1	1	2	2	1	0	0
		DAY 50	01APR2003	50	14	-7	2	1	0	1	0	1	2	1	0	2	1	0	1	1	1	0	0
		DAY 57	08APR2003	57	12	-9	2	0	0	0	0	1	2	1	1	1	1	0	1	1	1	0	0
	E0006016	SCREEN	07FEB2003	-10	23		3	3	2	0	2	1	3	1	1	2	0	1	2	2	0	0	0
		DAY 1	17FEB2003	1	21		3	3	1	1	2	1	2	1	1	2	0	1	2	1	0	0	0
		DAY 8	24FEB2003	8	20	-1	3	2	1	0	2	1	2	1	1	2	0	1	2	1	1	0	0
		DAY 15	03MAR2003	15	20	-1	3	2	1	0	1	1	2	1	1	2	2	1	1	1	1	0	0
		DAY 22	10MAR2003	22	20	-1	2	2	0	1	2	1	2	1	1	2	2	1	2	0	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	DAY 29	17MAR2003	29	20	-1	2	2	0	1	1	1	2	1	2	2	2	0	1	1	2	0	0
		DAY 36	27MAR2003	39	17	-4	2	1	0	0	1	1	1	1	2	2	2	0	1	1	2	0	0
		DAY 43	03APR2003	46	15	-6	1	1	0	1	1	0	3	1	0	2	0	1	2	2	0	0	0
		DAY 50	10APR2003	53	13	-8	1	1	0	0	0	1	1	1	1	2	1	1	1	0	2	0	0
		DAY 57	18APR2003	61	11	-10	1	1	0	0	0	0	1	1	1	2	1	0	1	0	2	0	0
	E0007008	SCREEN	07APR2003	-11	23		3	2	0	2	2	2	3	0	1	3	1	1	2	0	1	0	0
		DAY 1	18APR2003	1	22		3	2	0	2	2	2	3	0	1	3	1	1	2	0	0	0	0
		DAY 8	25APR2003	8	14	-8	3	1	0	0	0	0	3	0	0	3	1	1	2	0	0	0	0
	E0009002	SCREEN	29OCT2002	-21	22		3	2	1	1	0	0	3	2	1	1	1	2	2	2	1	0	0
		DAY 1	19NOV2002	1	28		3	2	1	2	2	1	3	2	2	3	1	2	2	2	0	0	0
		DAY 8	26NOV2002	8	9	-19	0	0	0	0	0	0	2	1	1	1	0	0	2	2	0	0	0
		DAY 15	03DEC2002	15	20	-8	3	2	0	1	1	1	3	2	2	1	0	0	2	2	0	0	0
		DAY 22	10DEC2002	22	19	-9	3	2	1	0	0	0	3	2	2	1	1	0	2	2	0	0	0
		DAY 29	18DEC2002	30	8	-20	2	0	0	0	0	0	1	0	0	1	1	0	1	2	0	0	0
		DAY 36	23DEC2002	35	9	-19	1	1	0	0	0	0	3	0	0	1	2	0	0	1	0	0	0
		DAY 43	30DEC2002	42	15	-13	2	1	0	0	2	1	2	1	0	1	1	0	2	2	0	0	0
		DAY 50	07JAN2003	50	9	-19	1	0	0	0	0	0	2	1	0	1	1	0	1	2	0	0	0
		DAY 57	15JAN2003	58	17	-11	3	2	0	0	0	0	4	1	1	2	0	0	2	2	0	0	0
	E0009006	SCREEN	22JAN2003	-6	29		3	2	0	2	2	2	3	1	2	2	3	1	2	1	2	1	0
		DAY 1	28JAN2003	1	29		3	2	2	2	2	2	3	1	1	2	2	1	2	1	1	2	0
		DAY 8	04FEB2003	8	16	-13	3	2	1	0	0	0	2	1	1	1	2	1	1	0	1	0	0
		DAY 15	11FEB2003	15	15	-14	3	2	0	0	1	0	3	1	1	2	2	0	0	0	0	0	0
		DAY 22	18FEB2003	22	19	-10	3	2	1	1	1	1	2	1	1	2	2	1	1	0	0	0	0
		DAY 29	25FEB2003	29	17	-12	3	2	1	0	1	0	1	1	1	2	2	1	0	0	2	0	0
		DAY 36	04MAR2003	36	16	-13	3	2	1	0	0	1	2	1	0	1	2	0	2	0	1	0	0
		DAY 43	11MAR2003	43	18	-11	3	2	1	1	1	1	1	1	1	1	2	0	1	0	2	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	DAY 50	18MAR2003	50	13	-16	2	0	0	1	1	1	2	1	1	1	2	0	1	0	0	0	0
		DAY 57	25MAR2003	57	12	-17	1	0	0	1	1	0	1	1	1	2	2	0	2	0	0	0	0
	E0009009	SCREEN	27FEB2003	-13	26		3	2	0	2	2	2	3	0	2	3	2	1	1	1	2	0	0
		DAY 1	12MAR2003	1	21		3	2	1	2	2	1	3	1	0	2	1	1	1	0	1	0	0
		DAY 8	19MAR2003	8	7	-14	2	1	0	0	0	0	1	0	0	2	1	0	0	0	0	0	0
		DAY 15	24MAR2003	13	9	-12	1	0	0	0	0	0	2	0	2	1	1	1	1	0	0	0	0
	E0010015	SCREEN	29JAN2003	-22	29		3	2	2	2	2	2	4	2	0	1	3	0	2	2	2	0	0
		DAY 1	20FEB2003	1	27		3	2	2	0	2	2	3	2	0	3	2	1	1	2	2	0	0
		DAY 8	27FEB2003	8	9	-18	1	0	0	1	0	1	0	1	1	0	1	0	1	2	0	0	0
		DAY 15	06MAR2003	15	25	-2	3	2	2	2	2	2	3	2	0	1	1	1	1	1	2	0	0
		DAY 22	13MAR2003	22	20	-7	3	0	1	2	2	2	1	2	0	1	2	0	1	2	1	0	0
		DAY 29	20MAR2003	29	15	-12	2	0	0	2	2	2	1	1	1	0	2	0	1	1	0	0	0
		DAY 36	26MAR2003	35	12	-15	0	0	0	2	2	2	1	1	0	1	2	0	1	0	0	0	0
		DAY 43	02APR2003	42	10	-17	0	0	0	2	2	2	0	1	1	0	1	0	1	0	0	0	0
		DAY 50	09APR2003	49	8	-19	0	0	0	2	2	2	0	0	0	0	0	0	1	0	0	1	0
		DAY 57	15APR2003	55	8	-19	0	0	0	2	2	2	0	1	0	0	1	0	0	0	0	0	0
	E0011004	SCREEN	17DEC2002	-7	23		3	2	2	1	2	1	2	2	0	1	2	1	1	2	0	0	1
		DAY 1	24DEC2002	1	23		3	1	1	2	1	1	2	1	2	2	2	1	2	2	0	0	0
		DAY 8	31DEC2002	8	15	-8	2	0	0	2	1	1	1	1	1	2	1	1	1	1	0	0	0
		DAY 15	07JAN2003	15	9	-14	2	0	0	0	1	0	1	1	1	1	1	0	1	0	0	0	0
		DAY 22	14JAN2003	22	11	-12	1	1	1	2	1	0	1	0	0	0	1	0	1	0	0	2	0
		DAY 29	21JAN2003	29	4	-19	1	0	0	0	1	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 36	28JAN2003	36	10	-13	1	0	0	1	1	0	1	1	0	1	0	0	1	1	0	2	0
		DAY 43	04FEB2003	43	11	-12	2	0	0	2	2	0	2	0	1	1	0	0	1	0	0	0	0
		DAY 50	11FEB2003	50	7	-16	1	0	0	0	0	0	1	0	3	0	1	0	1	0	0	0	0
		DAY 57	18FEB2003	57	1	-22	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	SCREEN		12DEC2002	-7	21		3	2	1	0	2	1	3	1	2	3	2	0	1	0	0	0	0
		DAY 1		19DEC2002	1	22		3	1	1	0	1	2	3	0	3	2	1	1	1	2	1	0	0
		DAY 8		26DEC2002	8	11	-11	1	0	0	1	1	1	1	0	2	1	1	0	1	0	1	0	0
		DAY 15		02JAN2003	15	16	-6	3	1	1	0	2	1	3	1	1	1	1	0	1	0	0	0	0
		DAY 22		09JAN2003	22	10	-12	1	1	0	0	1	0	1	0	3	0	1	0	1	0	0	1	0
		DAY 29		17JAN2003	30	13	-9	1	2	1	1	1	1	2	0	0	1	1	0	1	1	0	0	0
		DAY 36		23JAN2003	36	15	-7	2	1	0	1	2	1	1	0	0	2	1	0	1	1	1	1	0
		DAY 43		30JAN2003	43	10	-12	1	1	0	1	0	0	1	0	1	2	1	0	1	0	1	0	0
		DAY 50		06FEB2003	50	7	-15	1	0	0	1	1	0	1	0	0	0	1	0	0	1	1	0	0
		DAY 57		13FEB2003	57	4	-18	0	1	0	0	1	0	0	0	0	0	0	0	1	0	1	0	0
	E0011018	SCREEN		15MAY2003	-7	24		2	2	2	2	1	0	3	0	2	2	2	1	2	1	0	1	1
		DAY 1		22MAY2003	1	24		2	3	1	2	1	1	2	2	1	2	1	1	2	1	0	2	0
		DAY 8		30MAY2003	9	18	-6	2	3	1	0	1	0	2	1	1	2	1	0	2	1	0	1	0
		DAY 22	*	10JUN2003	20	16	-8	2	3	2	0	0	0	2	1	0	1	0	1	1	1	0	2	0
		DAY 22		13JUN2003	23	9	-15	1	1	0	0	0	0	2	1	0	1	0	0	1	2	0	0	0
		DAY 29		20JUN2003	30	7	-17	0	2	0	0	0	0	1	0	0	1	0	0	1	2	0	0	0
		DAY 36		28JUN2003	38	9	-15	1	0	0	0	0	0	1	1	0	1	0	0	1	2	0	2	0
		DAY 43		03JUL2003	43	8	-16	0	0	0	0	0	0	1	1	0	1	0	0	1	2	0	2	0
		DAY 50		10JUL2003	50	4	-20	0	0	0	0	0	0	1	0	0	1	0	0	1	1	0	0	0
		DAY 57		17JUL2003	57	6	-18	0	0	0	0	0	0	1	2	0	1	0	0	1	1	0	0	0
	E0011024	SCREEN		17JUN2003	-7	22		3	1	0	2	1	1	3	1	0	2	2	1	2	1	1	1	0
		DAY 1		24JUN2003	1	23		3	2	1	1	2	1	2	2	0	2	2	1	2	1	1	0	0
		DAY 8		01JUL2003	8	18	-5	2	1	0	0	0	0	3	2	1	1	2	1	1	2	2	0	0
		DAY 15		08JUL2003	15	16	-7	2	1	0	0	0	0	3	2	1	1	2	0	1	1	2	0	0
		DAY 22		15JUL2003	22	16	-7	2	1	0	0	0	0	3	2	1	1	2	0	1	1	2	0	0
		DAY 29		22JUL2003	29	11	-12	1	1	0	0	0	0	2	1	0	1	1	0	1	1	2	0	0
		DAY 36		30JUL2003	37	7	-16	1	1	0	0	0	0	1	0	1	1	1	0	0	1	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	DAY 43		05AUG2003	43	5	-18	1	0	0	0	0	0	1	0	0	1	1	0	0	1	0	0	0
		DAY 50		12AUG2003	50	5	-18	1	0	0	0	0	0	1	1	0	1	0	0	0	1	0	0	0
		DAY 57		21AUG2003	59	5	-18	1	0	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0
	E0015003	SCREEN		13NOV2002	-12	23		3	2	1	2	0	1	3	0	2	3	1	1	2	0	2	0	0
		DAY 1		25NOV2002	1	25		3	2	1	2	0	2	3	0	2	3	1	1	2	1	2	0	0
		DAY 8		02DEC2002	8	20	-5	3	2	1	0	0	0	3	1	0	3	1	1	2	1	2	0	0
	E0019003	SCREEN		29OCT2002	-23	23		3	2	0	2	2	0	3	1	1	3	2	0	2	2	0	0	0
		DAY 1		21NOV2002	1	26		3	2	2	2	2	1	3	0	2	2	3	0	1	2	1	0	0
		DAY 8		27NOV2002	7	10	-16	1	1	0	0	0	0	2	0	1	1	2	0	1	0	1	0	0
		DAY 15		09DEC2002	19	4	-22	0	0	0	0	0	0	1	0	1	0	1	0	1	0	0	0	0
		DAY 22		16DEC2002	26	7	-19	2	1	0	0	0	0	0	0	1	1	1	0	1	0	0	0	0
		DAY 36		24DEC2002	34	10	-16	2	1	0	0	1	0	1	0	0	1	2	0	1	1	0	0	0
		DAY 36	*	30DEC2002	40	8	-18	1	0	0	0	0	0	1	0	1	1	1	0	1	2	0	0	0
		DAY 43		06JAN2003	47	6	-20	0	0	0	0	0	0	1	0	1	1	1	1	0	1	0	0	0
		DAY 57	*	14JAN2003	55	3	-23	0	0	0	0	0	0	0	0	0	0	2	0	0	1	0	0	0
		DAY 57		16JAN2003	57	6	-20	0	0	0	0	0	0	1	1	0	1	1	0	1	0	1	0	0
	E0019007	SCREEN		06NOV2002	-7	26		3	2	2	2	2	2	3	0	0	2	3	1	1	2	0	1	0
		DAY 1		13NOV2002	1	26		3	2	1	2	2	2	3	0	1	2	2	2	1	2	0	1	0
		DAY 8		21NOV2002	9	15	-11	3	2	1	0	1	0	1	0	1	1	0	2	1	2	0	0	0
		DAY 15		27NOV2002	15	12	-14	2	1	1	0	1	0	2	0	1	1	0	0	1	2	0	0	0
		DAY 22		05DEC2002	23	10	-16	2	1	1	0	1	0	1	0	0	2	0	0	0	2	0	0	0
		DAY 29		12DEC2002	30	8	-18	1	1	1	0	0	0	1	0	1	1	0	0	0	1	1	0	0
		DAY 36		17DEC2002	35	14	-12	2	2	1	1	1	0	1	0	1	1	1	0	1	2	0	0	0
		DAY 43		24DEC2002	42	14	-12	2	2	1	1	1	0	2	0	1	2	0	0	0	2	0	0	0
		DAY 50		30DEC2002	48	19	-7	3	1	1	1	1	0	3	0	1	2	2	1	1	2	0	0	0
		DAY 57		07JAN2003	56	25	-1	3	2	2	2	2	2	3	0	1	2	2	1	1	2	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	SCREEN	17DEC2002	-23	22		3	2	1	2	2	1	3	0	1	2	1	1	1	1	0	0	1
		DAY 1	09JAN2003	1	20		3	2	1	2	1	1	3	0	1	2	1	1	1	0	1	0	0
		DAY 8	20JAN2003	12	15	-5	2	1	1	1	1	0	2	0	2	1	1	1	1	0	1	0	0
	E0019018	SCREEN	14JAN2003	-16	25		3	2	2	1	2	2	3	2	1	1	2	0	2	2	0	0	0
		DAY 1	30JAN2003	1	28		3	3	1	1	2	2	3	1	2	2	2	1	1	2	1	0	1
		DAY 8	06FEB2003	8	22	-6	3	3	1	0	0	0	3	1	2	2	1	1	1	2	1	0	1
		DAY 15	13FEB2003	15	13	-15	1	2	0	0	0	0	3	1	1	1	0	0	1	2	1	0	0
		DAY 22	20FEB2003	22	14	-14	3	1	1	0	0	0	2	2	0	1	1	0	1	2	0	0	0
		DAY 29	27FEB2003	29	15	-13	2	2	0	0	0	0	2	1	3	1	0	1	1	2	0	0	0
		DAY 36	06MAR2003	36	23	-5	3	2	1	1	0	0	3	2	3	2	2	1	1	2	0	0	0
		DAY 43	13MAR2003	43	20	-8	3	2	2	0	0	0	3	1	1	3	0	1	2	2	0	0	0
		DAY 50	20MAR2003	50	16	-12	3	2	0	0	0	0	3	0	1	2	1	0	2	2	0	0	0
		DAY 57	27MAR2003	57	17	-11	3	2	0	0	0	0	3	1	1	2	1	0	2	2	0	0	0
	E0019022	SCREEN	23JAN2003	-7	21		3	2	1	2	0	0	4	1	1	3	2	0	2	0	0	0	0
		DAY 1	30JAN2003	1	24		3	2	0	2	1	1	3	0	3	2	2	1	1	0	1	1	1
		DAY 8	06FEB2003	8	21	-3	3	2	0	1	1	1	3	0	2	2	1	1	1	0	1	1	1
		DAY 15	13FEB2003	15	15	-9	2	2	0	0	0	0	3	0	3	2	1	0	0	0	1	0	1
		DAY 22	20FEB2003	22	15	-9	1	2	0	1	0	0	2	0	3	2	1	1	0	0	1	0	1
		DAY 29	27FEB2003	29	16	-8	1	2	0	1	0	0	2	0	3	2	1	1	1	0	1	0	1
		DAY 36	06MAR2003	36	12	-12	1	1	0	0	0	0	1	1	3	1	1	1	1	0	1	0	0
		DAY 43	13MAR2003	43	10	-14	1	1	0	0	0	1	2	0	0	2	1	0	1	0	1	0	0
		DAY 50	20MAR2003	50	12	-12	1	1	0	2	0	0	2	1	1	2	1	1	0	0	0	0	0
		DAY 57	27MAR2003	57	11	-13	1	0	0	2	0	0	2	0	3	1	0	2	0	0	0	0	0
	E0019027	SCREEN	20FEB2003	-7	28		3	2	1	2	2	1	3	1	1	2	2	2	1	2	1	2	0
		DAY 1	27FEB2003	1	24		3	2	1	2	2	1	2	2	0	2	1	1	2	1	1	1	0
		DAY 8	06MAR2003	8	14	-10	1	1	0	1	1	1	1	1	0	1	2	0	1	2	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	SCREEN	06MAR2003	-26	26		3	2	1	2	2	1	3	2	1	2	2	1	1	2	1	0	0
		DAY 1	01APR2003	1	27		3	2	1	2	2	1	3	2	1	2	2	1	2	2	1	0	0
		DAY 8	08APR2003	8	19	-8	2	1	0	0	1	1	3	2	0	2	2	0	2	2	1	0	0
		DAY 15	15APR2003	15	16	-11	1	0	0	0	1	1	3	2	0	2	1	0	2	2	1	0	0
		DAY 22	21APR2003	21	16	-11	1	0	0	0	1	1	3	2	0	2	1	1	2	2	0	0	0
		DAY 29	29APR2003	29	15	-12	1	1	0	0	1	1	2	2	1	2	1	0	1	2	0	0	0
		DAY 36	07MAY2003	37	8	-19	0	0	0	0	0	0	1	1	1	2	0	0	1	2	0	0	0
		DAY 43	14MAY2003	44	14	-13	1	1	0	1	0	0	1	2	1	2	1	0	1	2	1	0	0
		DAY 50	21MAY2003	51	10	-17	0	0	0	1	0	0	1	2	1	1	1	0	1	2	0	0	0
		DAY 57	27MAY2003	57	12	-15	1	0	0	0	0	0	0	1	2	3	3	0	0	2	0	0	0
	E0019034	SCREEN	10MAR2003	-8	32		3	3	2	2	2	1	3	1	2	3	3	2	1	2	0	2	0
		DAY 1	18MAR2003	1	26		3	2	1	2	2	0	3	1	1	3	2	2	1	2	0	1	0
		DAY 8	25MAR2003	8	12	-14	2	3	2	0	0	0	2	0	0	0	0	0	2	1	0	0	0
		DAY 15	01APR2003	15	7	-19	0	2	0	0	0	0	0	1	0	1	1	0	0	2	0	0	0
	E0019036	SCREEN	18MAR2003	-7	27		3	2	0	2	2	2	3	1	3	2	2	0	2	1	2	0	0
		DAY 1	25MAR2003	1	28		3	3	1	2	2	1	3	0	1	3	3	0	2	2	2	0	0
		DAY 8	31MAR2003	7	11	-17	1	1	0	0	0	0	1	0	2	2	1	1	0	1	1	0	0
		DAY 15	10APR2003	17	10	-18	1	1	0	0	0	0	1	1	0	1	2	0	1	1	1	0	0
		DAY 22	15APR2003	22	9	-19	1	0	0	0	0	0	1	0	1	1	2	0	1	1	1	0	0
		DAY 29	22APR2003	29	9	-19	0	1	0	0	0	0	0	0	2	1	2	0	1	1	1	0	0
		DAY 36	29APR2003	36	8	-20	0	0	0	0	0	0	1	0	2	1	2	0	0	1	1	0	0
	E0019039	SCREEN	22APR2003	-9	29		3	2	2	2	2	2	3	1	1	2	3	1	2	2	1	0	0
		DAY 1	01MAY2003	1	27		3	2	1	2	2	1	3	1	2	3	2	1	2	2	0	0	0
	E0019041	SCREEN	14MAY2003	-7	25		3	2	1	0	2	1	3	2	1	3	2	2	1	0	2	0	0
		DAY 1	21MAY2003	1	23		2	1	0	1	2	1	3	2	2	2	2	1	1	1	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	DAY 8	28MAY2003	8	11	-12	1	1	0	0	0	0	3	1	0	2	2	0	0	1	0	0	0
		DAY 15	04JUN2003	15	12	-11	2	2	0	0	0	0	1	1	0	2	1	0	1	1	1	0	0
		DAY 22	12JUN2003	23	16	-7	2	2	0	1	0	1	2	1	1	2	1	0	1	1	1	0	0
		DAY 29	18JUN2003	29	13	-10	1	2	0	1	1	0	1	2	1	2	1	0	1	0	0	0	0
		DAY 36	25JUN2003	36	8	-15	1	2	0	1	0	0	1	1	0	1	0	0	1	0	0	0	0
		DAY 43	02JUL2003	43	7	-16	1	1	0	1	0	1	1	1	1	0	0	0	0	0	0	0	0
		DAY 50	09JUL2003	50	8	-15	1	1	0	1	1	1	1	1	0	0	1	0	0	0	0	0	0
		DAY 57	16JUL2003	57	9	-14	1	1	0	2	1	0	1	1	1	0	0	0	0	0	1	0	0
	E0019049	SCREEN	03JUL2003	-7	29		3	2	2	2	2	2	3	1	1	3	2	2	2	2	0	0	0
		DAY 1	10JUL2003	1	30		3	1	1	2	2	1	3	2	3	3	2	2	1	2	1	0	1
		DAY 8	17JUL2003	8	17	-13	2	1	0	0	0	0	2	1	1	2	1	2	1	2	1	0	1
		DAY 15	24JUL2003	15	20	-10	3	1	0	2	0	0	2	2	1	2	2	2	1	1	1	0	0
		DAY 22	31JUL2003	22	24	-6	3	2	0	2	2	1	3	1	1	2	2	2	1	2	0	0	0
		DAY 29	07AUG2003	29	21	-9	2	2	0	2	2	1	1	1	2	2	2	1	1	2	0	0	0
		DAY 36	14AUG2003	36	21	-9	3	2	1	2	2	0	2	1	2	2	1	0	1	2	0	0	0
		DAY 50	26AUG2003	48	19	-11	2	2	1	2	0	0	3	1	2	1	2	0	1	2	0	0	0
		DAY 57	08SEP2003	61	23	-7	3	1	0	2	2	2	1	1	3	2	2	0	1	2	1	0	0
	E0022052	SCREEN	01APR2003	-9	28		4	2	2	1	2	0	4	2	0	3	2	0	2	2	2	0	0
		DAY 1	10APR2003	1	30		3	2	2	0	2	2	4	2	1	3	2	1	2	2	2	0	0
		DAY 8	17APR2003	8	24	-6	3	2	2	0	0	0	4	1	1	3	2	0	2	2	2	0	0
		DAY 15	24APR2003	15	24	-6	2	2	1	0	1	1	4	1	0	3	2	1	2	2	2	0	0
		DAY 22	01MAY2003	22	29	-1	3	2	2	2	2	1	4	1	1	3	2	0	2	2	2	0	0
		DAY 29	08MAY2003	29	28	-2	3	2	2	2	1	0	4	2	0	3	3	0	2	2	2	0	0
		DAY 36	15MAY2003	36	28	-2	3	2	2	2	2	0	3	2	0	3	3	0	2	2	2	0	0
		DAY 43	22MAY2003	43	27	-3	2	2	2	0	2	1	4	1	0	3	3	1	2	2	2	0	0
		DAY 50	29MAY2003	50	24	-6	2	2	1	0	2	1	4	1	0	3	2	0	2	2	2	0	0
		DAY 57	05JUN2003	57	27	-3	3	2	2	0	2	1	4	1	0	3	2	0	2	2	3	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	SCREEN	29APR2003	-7	27		3	3	2	2	0	0	4	2	1	3	2	1	2	0	0	2	0
		DAY 1	06MAY2003	1	26		3	2	2	2	0	2	4	1	1	3	1	1	2	0	0	2	0
		DAY 8	12MAY2003	7	14	-12	3	2	0	0	0	0	2	1	0	1	1	1	2	0	0	1	0
		DAY 15	20MAY2003	15	8	-18	1	1	0	0	0	0	1	1	0	1	0	1	1	0	0	1	0
		DAY 22	27MAY2003	22	7	-19	0	1	0	1	0	0	0	1	0	1	2	0	0	0	1	0	0
		DAY 29	03JUN2003	29	1	-25	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	10JUN2003	36	3	-23	0	0	0	0	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 43	17JUN2003	43	2	-24	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
		DAY 50	24JUN2003	50	1	-25	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	01JUL2003	57	1	-25	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	E0022073	SCREEN	19JUN2003	-7	25		3	2	2	2	2	1	3	2	0	2	2	0	2	1	1	0	0
		DAY 1	26JUN2003	1	26		3	2	1	2	2	2	2	1	2	3	2	0	2	1	1	0	0
		DAY 8	03JUL2003	8	14	-12	2	1	0	0	0	0	2	1	0	3	1	0	2	1	1	0	0
		DAY 15	10JUL2003	15	9	-17	1	1	0	0	0	0	1	1	0	3	1	0	0	1	0	0	0
		DAY 22	17JUL2003	22	7	-19	1	0	0	0	0	0	1	1	0	3	0	0	0	1	0	0	0
		DAY 29	24JUL2003	29	11	-15	2	1	0	0	0	0	0	1	0	3	2	0	0	2	0	0	0
		DAY 36	31JUL2003	36	9	-17	1	0	0	1	0	0	1	1	0	1	2	0	1	1	0	0	0
		DAY 43	07AUG2003	43	10	-16	1	1	0	1	0	0	1	1	0	3	0	0	1	1	0	0	0
		DAY 50	14AUG2003	50	10	-16	2	1	0	1	0	0	0	1	0	3	1	0	0	1	0	0	0
		DAY 57	21AUG2003	57	10	-16	2	0	0	2	1	0	1	1	0	3	0	0	0	0	0	0	0
	E0023002	SCREEN	25OCT2002	-11	24		3	2	3	0	0	0	3	2	2	3	3	1	1	0	1	0	0
		DAY 1	05NOV2002	1	21		3	2	0	0	0	0	3	2	2	3	2	1	2	0	1	0	0
		DAY 8	12NOV2002	8	22	1	3	3	1	0	0	0	3	2	2	3	2	1	2	0	0	0	0
		DAY 15	19NOV2002	15	24	3	3	3	1	0	1	0	3	2	2	3	3	1	2	0	0	0	0
		DAY 22	25NOV2002	21	21	0	3	3	1	0	0	0	3	1	2	3	2	1	2	0	0	0	0
		DAY 29	03DEC2002	29	21	0	3	3	1	0	0	0	3	1	2	3	2	1	2	0	0	0	0
		DAY 36	10DEC2002	36	20	-1	3	2	1	0	0	0	3	1	2	3	3	0	2	0	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	SCREEN	14MAR2003	-11	20		3	0	0	0	0	1	3	1	2	3	0	2	2	1	0	2	0
		DAY 1	25MAR2003	1	22		3	0	0	0	0	0	3	2	2	3	2	2	1	1	1	2	0
		DAY 8	03APR2003	10	15	-7	3	0	0	0	0	0	3	1	2	3	1	0	1	0	1	0	0
		DAY 15	10APR2003	17	5	-17	1	0	0	0	0	0	0	0	2	1	1	0	0	0	0	0	0
		DAY 22	18APR2003	25	3	-19	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 29	24APR2003	31	4	-18	1	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0
		DAY 36	01MAY2003	38	2	-20	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 43	08MAY2003	45	2	-20	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
		DAY 50	15MAY2003	52	1	-21	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 57	22MAY2003	59	3	-19	0	0	0	0	0	0	0	0	2	0	0	0	0	1	0	0	0
	E0023021	SCREEN	10APR2003	-13	25		3	2	1	2	2	2	3	1	1	3	2	0	2	0	1	0	0
		DAY 1	23APR2003	1	25		3	2	1	1	2	2	3	1	1	3	2	1	2	0	1	0	0
		DAY 8	29APR2003	7	20	-5	3	2	1	0	1	0	2	2	0	3	2	1	2	0	1	0	0
		DAY 15	06MAY2003	14	14	-11	2	2	0	0	1	0	2	1	0	2	1	0	2	0	1	0	0
		DAY 22	13MAY2003	21	13	-12	2	2	0	0	1	0	2	0	0	2	1	0	2	0	1	0	0
		DAY 29	20MAY2003	28	12	-13	2	2	1	0	0	0	2	0	0	2	2	0	1	0	0	0	0
		DAY 36	29MAY2003	37	21	-4	3	2	2	0	2	0	3	1	0	3	2	2	1	0	0	0	0
		DAY 43	03JUN2003	42	17	-8	3	2	0	0	2	0	2	0	1	3	1	2	1	0	0	0	0
		DAY 50	10JUN2003	49	20	-5	3	2	1	1	2	0	2	2	0	3	2	1	1	0	0	0	0
		DAY 57	17JUN2003	56	19	-6	3	2	0	1	2	1	2	1	0	3	2	1	1	0	0	0	0
	E0023027	SCREEN	07MAY2003	-9	23		3	1	0	2	0	0	4	2	2	3	2	0	2	1	1	0	0
		DAY 1	16MAY2003	1	24		3	1	1	0	2	1	4	2	1	3	2	0	2	2	0	0	0
		DAY 8	21MAY2003	6	24	0	3	1	2	0	0	0	4	1	2	3	2	0	2	2	2	0	0
		DAY 15	30MAY2003	15	19	-5	2	1	0	0	0	0	4	2	0	3	2	0	2	2	1	0	0
		DAY 22	05JUN2003	21	19	-5	2	0	0	1	1	1	4	1	0	2	2	1	2	2	0	0	0
		DAY 29	11JUN2003	27	24	0	3	2	1	0	2	0	4	2	0	2	2	2	1	2	1	0	0
		DAY 36	18JUN2003	34	22	-2	3	1	0	0	2	0	3	2	0	3	2	1	1	2	2	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	DAY 43		27JUN2003	43	20	-4	2	1	0	1	2	1	3	2	1	2	1	1	1	0	2	0	0
		DAY 50		02JUL2003	48	17	-7	2	1	0	2	2	1	3	1	0	2	1	1	1	0	0	0	0
		DAY 57		09JUL2003	55	27	3	3	1	2	2	2	1	3	2	0	3	1	2	2	2	1	0	0
	E0023030	SCREEN		16MAY2003	-18	22		3	1	1	0	1	2	3	0	1	3	2	2	0	2	1	0	0
		DAY 1		03JUN2003	1	24		3	2	1	0	0	2	3	1	1	2	2	2	2	2	1	0	0
		DAY 8		10JUN2003	8	18	-6	3	2	0	0	0	0	3	1	1	2	1	1	2	2	0	0	0
		DAY 15		17JUN2003	15	14	-10	2	1	0	0	0	0	3	1	0	2	1	1	1	2	0	0	0
		DAY 22		24JUN2003	22	9	-15	1	1	0	0	0	0	2	0	1	1	0	1	0	2	0	0	0
		DAY 29		01JUL2003	29	7	-17	1	1	0	0	0	0	1	0	1	1	0	0	1	1	0	0	0
		DAY 36		08JUL2003	36	3	-21	1	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0
		DAY 43		15JUL2003	43	1	-23	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 50		21JUL2003	49	1	-23	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 57		30JUL2003	58	1	-23	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	E0023040	SCREEN		25JUN2003	-8	25		3	2	1	2	1	2	3	1	1	3	2	0	1	2	1	0	0
		DAY 1		03JUL2003	1	26		3	2	1	2	1	2	3	1	1	3	2	0	2	2	1	0	0
		DAY 8		12JUL2003	10	22	-4	3	1	1	0	1	1	3	1	1	3	2	1	1	2	1	0	0
		DAY 15		17JUL2003	15	18	-8	2	1	1	0	1	0	3	1	0	3	2	1	1	2	0	0	0
		DAY 22		25JUL2003	23	13	-13	1	1	0	0	0	1	2	0	0	2	2	1	1	2	0	0	0
		DAY 36	*	05AUG2003	34	15	-11	2	2	0	0	0	1	2	0	0	2	2	1	1	2	0	0	0
		DAY 36		08AUG2003	37	14	-12	2	2	0	0	0	1	2	0	0	1	1	1	2	2	0	0	0
		DAY 43		18AUG2003	47	11	-15	1	1	0	0	0	1	2	0	0	1	1	1	1	2	0	0	0
		DAY 57	*	28AUG2003	57	15	-11	1	1	0	2	2	0	2	0	0	2	2	0	1	2	0	0	0
		DAY 57		05SEP2003	65	14	-12	1	1	0	2	0	0	2	0	0	2	2	1	1	2	0	0	0
	E0026014	SCREEN		12FEB2003	-7	23		2	2	0	2	2	2	3	2	0	3	1	2	2	0	0	0	0
		DAY 1		19FEB2003	1	25		3	2	0	2	2	2	3	2	0	3	1	2	1	0	0	2	0
		DAY 8		26FEB2003	8	11	-14	1	2	0	0	0	0	1	1	1	0	1	1	1	0	0	2	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	DAY 15	05MAR2003	15	8	-17	0	0	0	0	0	0	0	0	1	1	1	2	1	0	2	0	0
		DAY 22	12MAR2003	22	16	-9	3	1	0	0	0	0	3	0	0	3	2	2	1	0	0	1	0
		DAY 29	19MAR2003	29	16	-9	3	2	0	0	0	0	3	0	1	3	2	2	0	0	0	0	0
	E0026019	SCREEN	10MAR2003	-7	20		2	2	1	2	2	2	3	1	0	2	2	0	1	0	0	0	0
		DAY 1	17MAR2003	1	24		3	2	1	2	2	1	3	0	0	2	2	0	2	2	2	0	0
		DAY 8	24MAR2003	8	16	-8	3	2	0	0	0	0	4	2	0	1	2	0	2	0	0	0	0
		DAY 15	31MAR2003	15	9	-15	1	2	0	0	0	0	0	0	1	2	1	0	1	0	1	0	0
		DAY 22	07APR2003	22	18	-6	3	2	0	0	2	0	3	0	1	3	1	0	0	0	2	1	0
		DAY 29	14APR2003	29	12	-12	1	2	0	0	2	0	0	2	0	2	2	0	0	0	0	1	0
		DAY 36	21APR2003	36	8	-16	1	1	0	0	2	0	0	0	1	1	1	0	1	0	0	0	0
		DAY 43	28APR2003	43	12	-12	2	1	0	0	2	0	3	0	0	2	1	0	1	0	0	0	0
		DAY 50	05MAY2003	50	14	-10	3	0	0	0	2	2	2	0	1	3	0	0	1	0	0	0	0
		DAY 57	12MAY2003	57	11	-13	1	1	0	0	2	2	2	0	0	2	1	0	0	0	0	0	0
	E0027005	SCREEN	19DEC2002	-7	33		4	1	1	2	2	2	4	1	4	3	2	2	2	1	0	2	0
		DAY 1	26DEC2002	1	27		4	2	1	0	2	2	3	1	3	2	2	2	1	2	0	0	0
		DAY 8	02JAN2003	8	19	-8	2	1	0	0	1	2	3	1	2	1	1	2	1	2	0	0	0
		DAY 15	09JAN2003	15	16	-11	3	2	0	0	1	1	4	1	0	2	0	0	0	2	0	0	0
		DAY 22	16JAN2003	22	7	-20	1	1	0	0	0	1	1	0	0	1	1	0	0	1	0	0	0
		DAY 29	23JAN2003	29	8	-19	2	0	0	0	1	1	0	1	0	2	1	0	0	0	0	0	0
		DAY 36	30JAN2003	36	18	-9	1	1	0	0	2	2	0	0	3	2	2	2	0	1	0	2	0
		DAY 43	06FEB2003	43	24	-3	3	2	1	0	2	2	3	1	1	3	2	1	1	2	0	0	0
		DAY 50	12FEB2003	49	19	-8	3	1	0	1	2	2	3	1	0	1	1	1	1	2	0	0	0
		DAY 57	20FEB2003	57	14	-13	1	2	0	0	2	1	3	0	0	2	1	0	0	2	0	0	0
	E0029009	SCREEN	13JAN2003	-7	22		2	2	2	1	2	1	3	0	2	1	1	1	0	2	1	1	0
		DAY 1	20JAN2003	1	23		2	2	2	1	2	1	3	0	2	1	1	1	0	2	2	1	0
		DAY 8	27JAN2003	8	18	-5	1	1	0	0	1	1	1	0	1	3	2	1	2	2	2	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	DAY 15	03FEB2003	15	11	-12	0	0	0	1	0	0	1	0	2	1	1	0	1	2	2	0	0
		DAY 22	11FEB2003	23	11	-12	1	1	0	0	0	0	1	0	1	3	1	0	0	2	1	0	0
		DAY 29	17FEB2003	29	14	-9	1	1	0	0	0	0	2	0	2	2	2	0	1	2	1	0	0
		DAY 36	24FEB2003	36	16	-7	2	2	1	0	0	0	2	0	2	3	1	0	0	2	1	0	0
		DAY 43	03MAR2003	43	8	-15	0	1	0	0	0	1	1	0	1	1	1	0	0	1	1	0	0
		DAY 50	11MAR2003	51	12	-11	0	0	0	0	0	1	1	0	0	3	2	0	2	1	2	0	0
		DAY 57	18MAR2003	58	8	-15	0	0	0	0	0	0	2	0	1	1	0	0	1	2	1	0	0
	E0029021	SCREEN	03MAR2003	-15	20		2	2	0	0	2	2	3	1	0	2	2	1	2	0	1	0	0
		DAY 1	18MAR2003	1	20		3	2	0	0	1	2	2	0	1	3	2	0	2	0	2	0	0
		DAY 8	25MAR2003	8	10	-10	3	1	0	0	0	0	2	0	0	1	1	0	2	0	0	0	0
		DAY 15	01APR2003	15	9	-11	3	1	1	0	0	0	2	0	1	1	0	0	0	0	0	0	0
		DAY 22	07APR2003	21	6	-14	2	1	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0
		DAY 29	15APR2003	29	5	-15	1	1	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 36	22APR2003	36	7	-13	1	1	0	0	0	0	2	0	0	1	0	0	2	0	0	0	0
		DAY 43	29APR2003	43	4	-16	1	0	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0
		DAY 50	06MAY2003	50	7	-13	0	1	0	0	0	0	1	0	1	2	0	0	1	0	1	0	0
		DAY 57	15MAY2003	59	7	-13	1	1	0	0	0	0	1	0	0	1	1	0	1	0	1	0	0
	E0029026	SCREEN	07APR2003	-7	23		2	2	0	0	2	2	3	2	0	2	1	1	2	2	1	1	0
		DAY 1	14APR2003	1	21		3	2	0	0	2	2	3	2	0	0	0	1	2	2	1	1	0
		DAY 8	21APR2003	8	14	-7	2	0	0	0	0	0	3	2	0	0	0	1	2	2	1	1	0
		DAY 15	28APR2003	15	6	-15	1	0	0	0	0	0	2	0	0	0	0	0	1	1	1	0	0
		DAY 22	05MAY2003	22	3	-18	0	0	0	0	1	0	0	1	0	0	0	0	0	1	0	0	0
		DAY 29	12MAY2003	29	4	-17	0	0	0	0	0	0	0	1	0	0	0	0	1	1	1	0	0
		DAY 36	19MAY2003	36	4	-17	0	0	0	0	0	0	0	1	0	0	0	0	1	1	1	0	0
		DAY 43	28MAY2003	45	4	-17	0	0	0	0	0	0	0	1	0	0	0	0	1	1	1	0	0
		DAY 50	02JUN2003	50	6	-15	0	0	0	1	1	1	0	0	0	0	0	0	1	1	1	0	0
		DAY 57	10JUN2003	58	2	-19	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	SCREEN	13MAY2003	-14	22		3	2	2	2	0	0	3	1	0	2	2	2	2	0	0	1	0
		DAY 1	27MAY2003	1	22		3	2	0	2	1	1	2	2	0	2	2	2	2	0	0	1	0
		DAY 8	03JUN2003	8	16	-6	2	1	1	0	0	0	2	2	0	2	2	1	2	1	0	0	0
		DAY 15	10JUN2003	15	9	-13	1	0	0	1	0	0	1	0	1	1	1	0	2	0	1	0	0
		DAY 22	17JUN2003	22	8	-14	1	1	0	0	0	0	2	1	0	1	0	0	1	0	1	0	0
		DAY 29	26JUN2003	31	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	02JUL2003	37	3	-19	0	0	0	0	0	0	1	0	0	0	0	0	1	0	1	0	0
		DAY 43	09JUL2003	44	5	-17	0	0	0	0	0	0	0	1	0	2	2	0	0	0	0	0	0
		DAY 50	16JUL2003	51	3	-19	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0
		DAY 57	23JUL2003	58	3	-19	0	1	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
	E0031008	SCREEN	05FEB2003	-23	23		3	2	0	0	2	1	4	0	0	4	2	0	2	2	0	1	0
		DAY 1	28FEB2003	1	30		3	2	2	2	2	2	3	0	1	3	2	2	2	2	1	1	0
		DAY 8	07MAR2003	8	23	-7	3	2	1	0	1	1	3	0	0	3	2	1	2	2	1	1	0
		DAY 15	13MAR2003	14	21	-9	3	2	2	1	1	0	3	0	0	3	2	0	2	2	0	0	0
		DAY 22	21MAR2003	22	21	-9	3	2	2	0	0	2	3	0	0	3	2	0	2	2	0	0	0
		DAY 29	28MAR2003	29	18	-12	2	2	2	0	1	0	1	0	0	3	2	1	2	2	0	0	0
		DAY 36	04APR2003	36	20	-10	2	1	2	2	2	1	2	0	0	3	2	0	1	2	0	0	0
		DAY 43	10APR2003	42	15	-15	3	2	2	0	0	0	1	0	0	2	2	0	1	2	0	0	0
		DAY 50	17APR2003	49	16	-14	1	1	1	2	2	1	1	0	0	1	2	0	1	2	1	0	0
		DAY 57	24APR2003	56	21	-9	3	2	2	0	0	0	3	0	0	3	2	2	2	2	0	0	0
	E0031020	SCREEN	14APR2003	-7	21		3	1	0	2	2	0	3	0	1	4	1	0	2	1	1	0	0
		DAY 1	21APR2003	1	23		3	1	2	2	2	0	2	0	1	3	2	0	2	0	2	1	0
		DAY 8	28APR2003	8	12	-11	1	0	2	0	0	0	1	0	1	1	2	0	1	1	1	1	0
		DAY 15	05MAY2003	15	16	-7	2	0	2	0	0	0	2	0	1	3	1	1	1	1	1	1	0
		DAY 22	13MAY2003	23	8	-15	1	0	0	0	0	0	2	0	1	1	1	0	1	0	1	0	0
	E0031021	SCREEN	18APR2003	-7	22		3	2	2	2	1	1	3	0	1	4	0	0	2	0	1	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 1		25APR2003	1	26		3	3	2	2	1	2	3	0	1	3	0	2	2	2	0	0	0
		DAY 8		02MAY2003	8	12	-14	1	2	0	0	0	0	2	0	1	2	1	0	1	2	0	0	0
		DAY 15		09MAY2003	15	4	-22	0	0	0	0	0	0	0	0	1	2	0	0	0	0	1	0	0
		DAY 22		16MAY2003	22	7	-19	1	1	0	0	0	0	1	0	0	2	0	0	2	0	0	0	0
		DAY 29		23MAY2003	29	7	-19	1	1	0	0	1	0	0	0	0	2	1	0	1	0	0	0	0
		DAY 36		29MAY2003	35	9	-17	1	1	0	0	0	0	1	0	1	3	0	0	2	0	0	0	0
		DAY 43		06JUN2003	43	21	-5	3	0	2	2	1	1	1	0	1	3	1	2	2	1	0	1	0
		DAY 43	*	10JUN2003	47	4	-22	0	1	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 57		19JUN2003	56	9	-17	1	0	0	1	1	0	1	0	0	2	1	0	1	0	0	1	0
	E0031029	SCREEN		05JUN2003	-13	25		2	2	0	2	2	1	3	0	1	3	2	1	2	2	1	1	0
		DAY 1		18JUN2003	1	28		3	2	1	2	2	2	3	0	0	3	2	2	2	2	1	1	0
		DAY 8		23JUN2003	6	13	-15	1	1	0	0	0	0	2	1	0	2	2	1	1	2	0	0	0
	E0033002	SCREEN		19DEC2002	-22	22		3	2	2	1	2	2	2	1	1	3	1	0	1	0	0	0	1
		DAY 1		10JAN2003	1	25		3	1	2	2	2	2	3	1	0	2	2	0	2	0	2	0	1
		DAY 8		16JAN2003	7	21	-4	3	1	2	1	0	0	3	1	1	2	2	1	1	0	2	0	1
		DAY 15		24JAN2003	15	23	-2	3	2	1	0	0	0	3	1	1	3	2	1	2	1	2	0	1
		DAY 22		30JAN2003	21	20	-5	2	1	1	2	1	1	0	0	1	3	2	0	1	1	2	1	1
		DAY 29		06FEB2003	28	18	-7	2	1	1	0	1	1	2	0	1	3	2	0	1	0	2	0	1
		DAY 36		13FEB2003	35	17	-8	2	1	1	1	0	0	2	0	1	3	2	1	1	0	1	0	1
		DAY 43		24FEB2003	46	10	-15	2	1	0	0	0	0	1	1	1	1	1	0	0	1	0	0	1
		DAY 50		28FEB2003	50	14	-11	2	1	1	0	0	0	2	1	1	2	1	0	0	1	1	0	1
		DAY 57		07MAR2003	57	6	-19	0	0	0	0	0	0	0	0	1	0	1	0	1	1	1	0	1
	E0033006	SCREEN		13JAN2003	-10	28		3	1	1	2	2	2	3	0	2	3	2	2	0	1	2	2	0
		DAY 1		23JAN2003	1	29		3	3	1	2	2	1	3	0	2	3	2	1	1	1	2	2	0
		DAY 8		30JAN2003	8	24	-5	2	2	0	2	1	0	1	0	2	4	3	2	1	2	0	2	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	SCREEN		18JUN2003	-14	23		3	2	1	2	2	0	3	0	2	2	3	0	2	0	1	0	0
		DAY 1		02JUL2003	1	23		2	2	1	2	2	0	3	0	2	2	3	0	2	1	1	0	0
		DAY 8		11JUL2003	10	20	-3	2	2	1	2	1	1	2	1	0	2	1	0	2	1	2	0	0
		DAY 22	*	21JUL2003	20	17	-6	3	2	1	1	1	0	2	0	1	2	1	0	2	1	0	0	0
		DAY 22		25JUL2003	24	13	-10	2	1	1	0	1	0	2	1	1	1	1	0	2	0	0	0	0
		DAY 29		01AUG2003	31	12	-11	2	1	0	0	1	0	1	0	1	2	2	0	1	1	0	0	0
		DAY 36		06AUG2003	36	12	-11	2	0	0	1	1	1	2	0	1	1	1	0	1	1	0	0	0
	E0035013	SCREEN		27JAN2003	-8	22		2	2	0	2	1	1	4	1	0	3	1	1	0	2	1	1	0
		DAY 1		04FEB2003	1	25		3	2	0	0	2	2	4	1	0	3	2	1	1	2	1	1	0
		DAY 8		10FEB2003	7	18	-7	2	2	0	0	0	2	4	0	0	3	1	0	1	2	0	1	0
	E0035015	SCREEN		03FEB2003	-8	22		3	2	0	0	2	2	4	0	0	2	2	0	1	2	0	0	2
		DAY 1		11FEB2003	1	22		3	2	0	0	2	2	4	0	0	2	1	0	1	2	1	0	2
		DAY 8		18FEB2003	8	14	-8	3	0	0	0	0	0	4	0	0	2	1	0	0	1	1	0	2
	E0035016	SCREEN		10MAR2003	-25	23		3	2	1	1	1	2	4	0	0	3	2	0	1	2	1	0	0
		DAY 1		04APR2003	1	25		3	2	0	1	1	1	4	0	2	3	2	0	2	2	2	0	0
	E0035023	SCREEN		06MAY2003	-7	23		3	2	2	1	2	1	4	0	0	3	1	1	2	0	0	1	0
		DAY 1		13MAY2003	1	24		3	2	1	2	2	2	4	0	0	3	1	1	2	0	0	1	0
		DAY 8		20MAY2003	8	15	-9	2	2	0	0	0	1	4	0	0	2	1	1	1	0	0	1	0
		DAY 15		29MAY2003	17	18	-6	2	2	1	0	1	1	4	0	0	2	1	1	2	0	0	1	0
		DAY 22		03JUN2003	22	17	-7	2	2	0	0	1	1	4	0	0	3	1	1	1	0	0	1	0
		DAY 29		10JUN2003	29	13	-11	2	1	0	0	0	1	4	0	0	2	1	0	1	0	0	1	0
	E0039052	SCREEN		29MAY2003	-22	24		3	3	0	2	2	2	3	1	2	2	1	1	1	1	0	0	0
		DAY 1		20JUN2003	1	23		3	3	1	2	2	0	2	1	2	2	1	0	2	1	1	0	0
		DAY 8		27JUN2003	8	7	-16	1	1	0	0	0	0	1	0	2	1	0	0	1	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 300 MG (BIPOLAR II)	E0039052	DAY 15	03JUL2003	14	6	-17	1	1	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0
	E0039056	SCREEN	01JUL2003	-14	23		3	2	1	2	2	1	3	1	1	1	0	2	1	2	0	1	0
		DAY 1	14JUL2003	-1	21		3	2	1	2	2	2	3	1	0	1	1	1	1	1	0	0	0
	E0040003	SCREEN	09JUL2003	-10	23		3	0	0	2	2	2	3	2	1	1	1	1	2	2	1	0	0
		DAY 1	18JUL2003	-1	23		3	0	1	2	2	2	2	1	2	2	1	1	2	2	0	0	0
		DAY 8	25JUL2003	7	21	-2	2	0	1	2	2	2	2	1	1	2	1	1	2	2	0	0	0
		DAY 15	01AUG2003	14	13	-10	2	0	0	0	1	1	1	2	0	0	1	0	2	2	1	0	0
		DAY 22	08AUG2003	21	14	-9	2	0	0	0	1	0	1	2	1	1	1	1	2	2	0	0	0
		DAY 29	15AUG2003	28	18	-5	2	0	0	2	2	2	1	2	1	1	1	0	2	2	0	0	0
		DAY 36	22AUG2003	35	11	-12	1	0	0	0	0	0	1	1	1	1	1	1	1	2	1	0	0
		DAY 43	29AUG2003	42	17	-6	1	0	0	2	2	2	1	1	2	2	1	0	1	2	0	0	0
		DAY 50	05SEP2003	49	15	-8	0	0	0	0	2	2	1	1	2	2	2	0	1	2	0	0	0
		DAY 57	12SEP2003	56	15	-8	1	0	0	2	2	0	1	2	1	1	1	1	1	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	SCREEN	04FEB2003	-27	28		3	2	3	2	1	2	3	0	0	3	1	1	2	2	1	2	0
		DAY 1	03MAR2003	1	25		3	2	2	2	0	2	2	0	2	2	1	2	1	0	2	2	0
		DAY 8	11MAR2003	9	16	-9	2	1	2	0	0	0	2	0	2	2	1	1	2	0	1	0	0
		DAY 15	18MAR2003	16	12	-13	2	1	1	0	0	0	2	0	0	1	2	0	2	0	0	1	0
		DAY 22	25MAR2003	23	9	-16	1	0	0	0	0	0	1	0	0	2	1	1	2	0	1	0	0
		DAY 29	01APR2003	30	14	-11	1	0	1	0	0	0	2	0	0	2	2	1	2	0	2	1	0
		DAY 36	08APR2003	37	10	-15	1	0	1	0	0	0	1	0	0	1	1	1	2	0	2	0	0
		DAY 43	15APR2003	44	7	-18	1	0	1	0	0	0	1	0	0	2	0	0	1	0	1	0	0
		DAY 50	24APR2003	53	11	-14	2	1	1	1	0	0	2	0	0	1	1	1	0	1	0	0	0
		DAY 57	02MAY2003	61	8	-17	1	0	1	0	0	0	1	0	0	2	1	0	1	0	1	0	0
	E0002011	SCREEN	16APR2003	-13	22		2	2	2	1	2	1	3	0	2	2	2	1	2	0	0	0	0
		DAY 1	29APR2003	1	20		2	2	1	1	1	1	3	0	2	2	2	0	2	0	1	0	0
		DAY 8	08MAY2003	10	11	-9	1	1	0	0	1	0	1	0	1	2	1	0	2	0	1	0	0
		DAY 15	15MAY2003	17	12	-8	2	1	0	0	1	0	1	0	1	2	1	0	2	0	1	0	0
		DAY 22	22MAY2003	24	12	-8	2	1	0	0	1	1	1	0	0	1	2	0	2	0	1	0	0
		DAY 29	29MAY2003	31	7	-13	0	0	0	0	1	0	1	0	0	1	2	0	1	0	1	0	0
		DAY 36	05JUN2003	38	12	-8	2	0	0	0	1	0	3	0	1	1	1	0	2	0	1	0	0
		DAY 43	12JUN2003	45	11	-9	2	1	2	0	1	0	1	0	0	1	1	0	1	0	1	0	0
		DAY 50	19JUN2003	52	6	-14	1	0	0	0	1	0	0	0	0	1	1	0	1	0	1	0	0
		DAY 57	25JUN2003	58	9	-11	1	1	0	1	1	1	0	0	1	2	0	0	0	0	1	0	0
	E0003010	SCREEN	27JAN2003	-7	29		3	1	2	2	1	2	4	1	1	2	2	2	2	2	0	2	0
		DAY 1	03FEB2003	1	24		2	2	1	2	1	2	3	0	1	4	2	0	2	2	0	0	0
		DAY 8	10FEB2003	8	9	-15	1	1	0	0	0	0	0	0	0	2	2	0	1	2	0	0	0
		DAY 15	19FEB2003	17	6	-18	1	0	0	0	0	0	1	0	0	0	2	0	1	1	0	0	0
		DAY 22	27FEB2003	25	20	-4	2	1	0	2	0	1	1	1	0	2	3	0	2	2	3	0	0
		DAY 29	03MAR2003	29	14	-10	2	0	0	0	0	0	2	0	1	2	3	0	2	2	0	0	0
		DAY 36	14MAR2003	40	3	-21	0	0	0	1	0	0	1	0	0	0	0	0	0	1	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	DAY 43		20MAR2003	46	17	-7	1	0	0	1	1	0	3	0	1	0	4	0	2	1	3	0	0
		DAY 50		25MAR2003	51	7	-17	0	0	0	0	1	0	1	0	0	0	2	0	2	1	0	0	0
		DAY 57		31MAR2003	57	5	-19	0	0	0	0	0	0	0	0	0	0	2	0	2	1	0	0	0
	E0003011	SCREEN		28JAN2003	-7	29		2	3	0	2	2	2	3	1	2	3	1	1	2	2	3	0	0
		DAY 1		04FEB2003	1	26		3	3	0	0	1	1	3	1	2	3	1	1	2	2	3	0	0
		DAY 8		11FEB2003	8	14	-12	1	2	0	0	2	1	2	0	1	1	0	1	1	2	0	0	0
		DAY 15		18FEB2003	15	16	-10	2	2	0	0	2	0	2	0	0	1	1	1	2	2	1	0	0
	E0003016	SCREEN		01MAY2003	-21	20		2	3	2	2	1	0	3	0	1	2	1	0	1	2	0	0	0
		DAY 1		22MAY2003	1	23		3	3	0	1	0	0	3	0	1	2	2	2	2	2	0	2	0
		DAY 8		29MAY2003	8	20	-3	2	3	1	1	1	0	3	0	2	3	0	1	1	2	0	0	0
		DAY 15		05JUN2003	15	18	-5	2	3	0	0	1	0	3	0	2	2	1	1	1	2	0	0	0
		DAY 22		12JUN2003	22	20	-3	1	2	0	2	2	0	3	0	3	4	2	0	0	1	0	0	0
	E0003019	SCREEN		19JUN2003	-8	20		2	2	0	2	2	1	1	1	1	2	0	0	2	2	2	0	0
		DAY 1		27JUN2003	1	22		2	2	1	1	2	2	3	0	2	2	0	0	2	2	1	0	0
		DAY 8		03JUL2003	7	13	-9	1	2	1	0	0	0	3	0	0	2	1	0	1	1	1	0	0
		DAY 15		10JUL2003	14	16	-6	2	2	0	1	1	1	3	0	0	2	0	0	1	2	1	0	0
		DAY 15	*	15JUL2003	19	10	-12	2	1	0	0	1	1	1	0	0	1	1	0	0	1	1	0	0
		DAY 29		29JUL2003	33	13	-9	3	2	2	0	0	0	2	0	1	1	0	0	1	1	0	0	0
		DAY 43		07AUG2003	42	19	-3	3	2	2	0	1	0	3	0	1	2	0	0	2	2	1	0	0
		DAY 50		14AUG2003	49	21	-1	3	2	2	0	1	0	3	0	1	3	1	0	2	2	1	0	0
		DAY 57		21AUG2003	56	17	-5	2	2	1	0	1	0	2	1	1	2	1	0	1	2	1	0	0
	E0003020	SCREEN		24JUN2003	-29	26		2	2	2	2	1	1	3	0	2	3	2	0	2	2	2	0	0
		DAY 1		23JUL2003	1	27		2	3	3	2	1	1	3	1	1	3	2	0	2	2	1	0	0
		DAY 8		29JUL2003	7	13	-14	1	3	2	0	0	0	1	0	1	2	0	0	1	2	0	0	0
		DAY 15		06AUG2003	15	11	-16	1	2	1	1	0	1	0	0	1	1	0	0	1	2	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	DAY 22	13AUG2003	22	13	-14	1	3	0	0	1	1	1	0	1	2	0	0	1	2	0	0	0
		DAY 29	20AUG2003	29	23	-4	3	3	0	1	1	1	2	1	1	3	1	0	2	2	2	0	0
		DAY 36	27AUG2003	36	21	-6	3	2	0	1	1	1	2	1	1	2	1	0	2	2	2	0	0
		DAY 43	03SEP2003	43	10	-17	2	1	0	1	0	0	1	0	1	1	1	0	0	2	0	0	0
		DAY 50	10SEP2003	50	8	-19	2	1	0	1	0	0	1	0	0	1	0	0	0	2	0	0	0
		DAY 57	17SEP2003	57	7	-20	2	1	0	0	0	0	1	0	0	1	0	0	0	2	0	0	0
	E0004001	SCREEN	23SEP2002	-7	34		4	2	2	1	2	2	3	2	1	3	3	1	2	2	2	2	0
		DAY 1	30SEP2002	1	31		3	2	2	1	2	2	3	2	0	3	3	1	2	2	2	0	1
		DAY 8	07OCT2002	8	20	-11	3	2	2	0	0	0	2	1	0	2	2	1	2	1	2	0	0
		DAY 22	21OCT2002	22	16	-15	3	2	0	0	0	0	2	1	1	2	1	0	1	1	2	0	0
		DAY 29	28OCT2002	29	11	-20	2	1	0	0	0	0	2	1	1	1	1	0	0	1	1	0	0
	E0004009	SCREEN	17DEC2002	-9	25		3	2	2	1	1	0	4	1	1	1	1	2	2	2	0	2	0
		DAY 1	26DEC2002	1	22		3	1	1	0	1	0	4	1	1	1	1	2	2	2	0	2	0
		DAY 8	02JAN2003	8	16	-6	2	1	0	2	0	0	3	0	1	2	1	0	2	2	0	0	0
		DAY 15	08JAN2003	14	8	-14	1	0	0	0	0	0	1	0	1	1	1	1	0	2	0	0	0
		DAY 22	15JAN2003	21	6	-16	0	0	0	0	1	0	1	0	1	0	1	1	0	1	0	0	0
		DAY 29	22JAN2003	28	8	-14	1	1	1	0	0	0	1	1	1	1	0	0	0	1	0	0	0
		DAY 36	29JAN2003	35	5	-17	1	0	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0
		DAY 43	05FEB2003	42	3	-19	0	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0
		DAY 50	12FEB2003	49	4	-18	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0
		DAY 57	19FEB2003	56	2	-20	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0
	E0004012	SCREEN	07JAN2003	-7	27		3	2	2	2	1	1	3	1	1	2	1	2	2	2	0	2	0
		DAY 1	14JAN2003	1	26		3	2	1	2	1	1	3	1	1	2	1	2	2	2	0	2	0
		DAY 8	21JAN2003	8	20	-6	3	1	0	1	0	1	3	2	1	1	1	2	2	2	0	0	0
		DAY 15	28JAN2003	15	11	-15	2	0	0	1	0	0	3	1	0	1	0	0	1	2	0	0	0
		DAY 22	04FEB2003	22	8	-18	2	0	0	0	0	0	2	0	1	1	0	0	1	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	DAY 29	11FEB2003	29	5	-21	2	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 36	18FEB2003	36	4	-22	1	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 43	25FEB2003	43	4	-22	1	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 50	04MAR2003	50	5	-21	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0
		DAY 57	11MAR2003	57	6	-20	2	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0
	E0004015	SCREEN	06FEB2003	-14	20		3	2	1	0	2	0	3	1	1	2	1	1	2	0	0	1	0
		DAY 1	20FEB2003	1	21		3	1	1	0	2	0	3	1	1	3	1	1	2	0	0	2	0
		DAY 8	25FEB2003	6	21	0	3	1	0	0	2	1	3	1	1	3	2	1	2	0	0	1	0
		DAY 15	04MAR2003	13	12	-9	2	1	0	0	1	1	2	0	1	2	1	0	1	0	0	0	0
		DAY 22	11MAR2003	20	4	-17	1	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 29	18MAR2003	27	2	-19	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 36	25MAR2003	34	2	-19	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 43	01APR2003	41	2	-19	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	08APR2003	48	2	-19	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	15APR2003	55	2	-19	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	E0005003	SCREEN	23SEP2002	-9	23		3	2	1	0	0	0	3	2	2	3	2	1	0	2	2	0	0
		DAY 1	02OCT2002	1	22		3	2	1	0	0	0	3	2	2	3	2	1	0	2	1	0	0
		DAY 8	09OCT2002	8	20	-2	3	2	0	2	2	0	3	2	1	2	1	0	2	0	0	0	0
		DAY 15	16OCT2002	15	11	-11	1	1	0	1	2	0	1	1	0	1	0	1	0	2	0	0	0
		DAY 22	23OCT2002	22	15	-7	3	2	0	0	0	0	3	2	1	0	0	0	2	2	0	0	0
		DAY 29	30OCT2002	29	10	-12	2	1	0	0	0	0	2	2	0	0	0	0	1	2	0	0	0
		DAY 36	06NOV2002	36	7	-15	2	1	0	0	0	0	1	1	0	0	0	0	0	2	0	0	0
		DAY 43	14NOV2002	44	6	-16	2	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0	0
		DAY 50	21NOV2002	51	8	-14	1	2	0	0	0	0	0	0	0	2	1	0	0	2	0	0	0
		DAY 57	26NOV2002	56	6	-16	1	0	0	0	0	0	1	1	0	1	0	0	0	2	0	0	0
	E0005005	SCREEN	24SEP2002	-6	26		3	2	1	2	1	2	3	2	2	3	2	1	2	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	DAY 1	30SEP2002	1	25		3	2	0	2	1	2	3	2	2	3	2	1	2	0	0	0	0
	E0005007	SCREEN	02OCT2002	-7	32		4	3	2	2	2	2	3	2	1	3	2	2	2	2	0	0	0
		DAY 1	09OCT2002	1	33		3	3	2	2	2	2	4	2	1	3	2	2	2	2	0	1	0
		DAY 8	16OCT2002	8	26	-7	3	2	1	1	1	1	3	2	1	3	2	2	2	2	0	0	0
		DAY 15	23OCT2002	15	28	-5	4	3	1	2	2	2	3	2	0	2	1	2	2	2	0	0	0
		DAY 22	30OCT2002	22	20	-13	2	1	0	2	2	2	3	1	0	1	1	1	2	2	0	0	0
		DAY 29	06NOV2002	29	20	-13	1	1	0	2	2	2	2	1	2	1	1	1	1	2	1	0	0
		DAY 36	14NOV2002	37	17	-16	1	1	0	2	2	2	2	0	1	1	1	1	1	2	0	0	0
		DAY 43	20NOV2002	43	23	-10	3	1	0	2	2	2	2	2	0	2	2	1	2	2	0	0	0
		DAY 50	26NOV2002	49	20	-13	2	1	0	2	2	2	1	1	0	1	2	1	2	2	1	0	0
		DAY 57	04DEC2002	57	16	-17	1	1	0	2	2	0	1	0	1	2	1	1	1	2	1	0	0
	E0005008	SCREEN	08OCT2002	-7	22		3	2	2	0	2	1	3	2	1	3	0	0	2	0	1	0	0
		DAY 1	15OCT2002	1	25		3	2	2	2	2	1	3	2	1	3	1	0	2	0	1	0	0
		DAY 8	22OCT2002	8	14	-11	2	0	0	0	0	0	2	2	1	1	1	1	2	1	1	0	0
		DAY 15	29OCT2002	15	18	-7	3	1	0	0	0	0	3	2	0	1	2	1	2	2	1	0	0
		DAY 22	06NOV2002	23	17	-8	3	1	1	0	0	0	3	2	0	1	0	1	2	2	1	0	0
		DAY 29	13NOV2002	30	7	-18	0	0	0	0	0	0	2	0	0	0	2	1	1	0	1	0	0
		DAY 36	18NOV2002	35	4	-21	0	0	0	0	0	0	1	0	0	0	0	1	1	0	1	0	0
		DAY 43	25NOV2002	42	7	-18	1	0	0	0	0	0	0	0	0	1	2	1	1	0	1	0	0
		DAY 50	02DEC2002	49	2	-23	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0
		DAY 57	11DEC2002	58	4	-21	0	0	0	0	0	0	0	0	0	0	1	1	1	0	1	0	0
	E0005009	SCREEN	09OCT2002	-20	22		3	2	1	1	1	0	3	2	1	3	2	0	2	0	1	0	0
		DAY 1	29OCT2002	1	22		3	1	1	1	1	1	3	2	1	3	2	0	2	0	1	0	0
	E0005010	SCREEN	14OCT2002	-7	20		3	2	0	2	1	0	3	0	1	2	2	0	2	2	0	0	0
		DAY 1	21OCT2002	1	25		3	2	0	2	2	1	3	1	2	3	0	2	2	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	DAY 8		28OCT2002	8	17	-8	2	1	0	0	0	1	2	1	2	1	2	2	1	2	0	0	0
		DAY 15		04NOV2002	15	14	-11	2	0	0	0	0	1	1	2	2	3	0	0	1	2	0	0	0
		DAY 22		13NOV2002	24	14	-11	1	0	0	0	2	1	1	1	1	2	1	2	0	2	0	0	0
		DAY 29		19NOV2002	30	7	-18	0	0	0	0	0	0	0	1	1	0	1	2	0	2	0	0	0
		DAY 36		26NOV2002	37	5	-20	0	0	0	0	0	0	0	1	0	0	0	2	0	2	0	0	0
		DAY 43		03DEC2002	44	4	-21	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0	0	0
		DAY 50		09DEC2002	50	4	-21	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0	0	0
		DAY 57		17DEC2002	58	2	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
	E0005012	SCREEN		23OCT2002	-22	28		3	2	1	1	2	1	3	2	2	2	2	2	2	2	1	0	0
		DAY 1		14NOV2002	1	30		3	2	1	2	2	2	3	2	4	3	2	2	2	0	0	0	0
		DAY 8		20NOV2002	7	26	-4	3	2	1	0	2	2	3	2	4	3	2	0	2	0	0	0	0
		DAY 15		26NOV2002	13	18	-12	1	2	0	1	1	0	2	2	2	3	2	0	1	1	0	0	0
		DAY 22		06DEC2002	23	10	-20	1	1	0	1	0	0	2	0	1	1	1	0	1	1	0	0	0
		DAY 29		10DEC2002	27	10	-20	0	1	0	1	0	0	2	0	1	1	2	1	0	1	0	0	0
		DAY 36		18DEC2002	35	15	-15	2	2	0	1	1	0	1	1	2	1	1	1	1	1	0	0	0
		DAY 36	*	23DEC2002	40	17	-13	2	0	0	1	1	0	1	1	2	1	2	1	2	2	1	0	0
		DAY 50		02JAN2003	50	14	-16	1	0	0	1	1	0	2	1	1	1	2	0	2	2	0	0	0
		DAY 57		07JAN2003	55	15	-15	1	0	0	1	1	1	2	1	0	2	2	1	1	2	0	0	0
	E0005014	SCREEN		05NOV2002	-8	29		3	2	0	2	1	2	3	2	3	3	2	2	2	0	0	2	0
		DAY 1		13NOV2002	1	28		3	2	0	2	1	2	3	2	3	3	2	2	2	0	1	0	0
		DAY 8		20NOV2002	8	20	-8	2	2	0	0	0	0	3	2	3	3	2	0	2	0	1	0	0
		DAY 15		27NOV2002	15	15	-13	1	2	0	0	0	0	2	2	3	2	1	0	2	0	0	0	0
		DAY 22		03DEC2002	21	14	-14	1	2	0	0	0	0	2	2	3	2	1	0	1	0	0	0	0
		DAY 29		11DEC2002	29	13	-15	1	2	0	0	0	0	2	1	3	2	1	0	1	0	0	0	0
		DAY 36		17DEC2002	35	13	-15	1	2	0	0	0	0	2	1	3	2	1	0	1	0	0	0	0
		DAY 43		23DEC2002	41	13	-15	1	2	0	0	0	0	1	2	2	3	1	0	1	0	0	0	0
		DAY 50		30DEC2002	48	16	-12	2	2	0	1	0	0	1	2	2	3	2	0	1	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 57	06JAN2003	55	14	-14	1	2	0	0	0	0	1	2	2	3	2	0	1	0	0	0	0
	E0005022	SCREEN	23JAN2003	-6	25		3	2	1	2	1	0	3	2	4	2	1	1	2	0	1	0	0
		DAY 1	29JAN2003	1	22		3	0	0	1	1	0	3	2	4	3	1	1	2	1	0	0	0
		DAY 8	04FEB2003	7	24	2	3	2	1	0	1	0	3	2	4	3	1	1	2	1	0	0	0
		DAY 15	11FEB2003	14	21	-1	3	0	0	1	1	0	3	2	4	1	2	1	2	1	0	0	0
		DAY 22	21FEB2003	24	19	-3	2	0	0	0	1	0	3	2	2	3	1	2	2	1	0	0	0
		DAY 29	26FEB2003	29	8	-14	0	0	0	0	1	0	0	1	2	1	0	1	2	0	0	0	0
		DAY 36	06MAR2003	37	8	-14	0	0	0	0	0	0	1	1	2	0	2	1	1	0	0	0	0
	E0005025	SCREEN	20FEB2003	-7	28		3	2	1	2	1	0	4	2	4	3	1	1	2	2	0	0	0
		DAY 1	27FEB2003	1	27		3	2	0	2	2	0	3	2	3	2	2	2	2	2	0	0	0
		DAY 8	06MAR2003	8	10	-17	1	0	0	2	0	0	2	1	1	0	0	0	0	2	1	0	0
		DAY 15	14MAR2003	16	5	-22	0	0	0	0	0	0	1	0	1	0	0	0	0	2	1	0	0
		DAY 22	20MAR2003	22	1	-26	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 29	27MAR2003	29	13	-14	3	0	0	1	0	0	3	1	2	0	0	0	1	2	0	0	0
		DAY 36	03APR2003	36	9	-18	0	0	0	2	0	0	2	1	1	0	0	0	2	1	0	0	0
	E0006019	SCREEN	26MAR2003	-12	23		3	3	1	2	2	1	3	1	1	2	0	1	2	0	1	0	0
		DAY 1	07APR2003	1	21		3	3	1	2	1	1	2	1	1	2	0	1	2	0	1	0	0
		DAY 8	14APR2003	8	23	2	3	3	1	2	1	1	2	1	2	2	1	1	2	0	1	0	0
		DAY 15	21APR2003	15	22	1	3	3	0	2	1	1	2	1	2	2	1	1	2	0	1	0	0
		DAY 22	28APR2003	22	19	-2	2	2	0	2	1	1	1	1	2	2	1	0	2	0	2	0	0
		DAY 29	05MAY2003	29	20	-1	2	2	0	2	1	1	1	1	2	3	1	0	2	0	2	0	0
		DAY 36	12MAY2003	36	21	0	2	2	0	2	1	1	2	1	2	3	1	0	2	0	2	0	0
		DAY 43	19MAY2003	43	19	-2	2	2	0	1	1	1	2	1	2	2	1	0	2	0	2	0	0
		DAY 50	27MAY2003	51	18	-3	2	2	0	1	1	1	2	1	1	2	1	0	2	0	2	0	0
		DAY 57	03JUN2003	58	18	-3	2	2	0	1	1	1	2	1	1	2	1	0	2	0	2	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	SCREEN	27JAN2003	-4	23		4	2	1	2	2	1	4	0	0	2	1	0	2	2	0	0	0
		DAY 1	31JAN2003	1	26		4	2	1	2	2	1	4	1	0	2	2	1	2	2	0	0	0
		DAY 8	07FEB2003	8	21	-5	3	2	1	2	0	1	4	0	0	2	1	1	2	2	0	0	0
		DAY 15	14FEB2003	15	16	-10	3	2	0	0	0	0	4	0	0	3	0	0	2	2	0	0	0
		DAY 22	22FEB2003	23	17	-9	3	1	0	1	0	0	4	0	0	3	0	0	2	2	1	0	0
		DAY 29	03MAR2003	32	10	-16	2	1	0	0	0	0	2	0	0	2	0	0	1	2	0	0	0
		DAY 36	10MAR2003	39	13	-13	2	0	0	0	0	0	3	1	0	3	0	0	1	2	1	0	0
		DAY 43	14MAR2003	43	12	-14	2	1	0	0	0	0	4	1	0	1	0	0	1	2	0	0	0
		DAY 50	21MAR2003	50	22	-4	3	1	1	2	2	0	4	0	0	3	1	1	2	2	0	0	0
		DAY 57	28MAR2003	57	19	-7	3	2	0	2	0	0	4	1	0	3	0	0	2	2	0	0	0
	E0007015	SCREEN	09JUL2003	-7	20		4	2	1	0	0	0	3	1	0	3	1	0	2	2	1	0	0
		DAY 1	16JUL2003	1	20		4	2	1	0	0	0	3	1	0	3	1	0	2	2	1	0	0
		DAY 8	23JUL2003	8	20	0	4	1	1	0	0	0	3	1	0	2	1	1	2	2	2	0	0
		DAY 15	01AUG2003	17	15	-5	3	0	0	0	0	1	3	0	0	1	1	0	2	2	2	0	0
		DAY 22	06AUG2003	22	16	-4	3	1	1	0	0	0	3	1	0	1	0	1	2	2	1	0	0
		DAY 29	13AUG2003	29	4	-16	1	0	0	0	0	0	1	0	0	1	0	0	0	1	0	0	0
		DAY 36	20AUG2003	36	15	-5	3	1	1	0	0	0	1	0	0	2	1	0	2	2	2	0	0
		DAY 43	27AUG2003	43	15	-5	3	0	0	0	0	0	3	1	0	2	1	0	2	2	1	0	0
		DAY 50	03SEP2003	50	10	-10	1	0	0	0	0	0	2	0	0	2	0	0	2	2	1	0	0
		DAY 57	10SEP2003	57	14	-6	3	2	0	0	0	0	3	1	0	1	1	0	2	1	0	0	0
	E0009001	SCREEN	29OCT2002	-14	27		3	3	0	2	2	2	4	1	1	1	2	2	1	0	1	2	0
		DAY 1	12NOV2002	1	30		2	3	2	2	2	2	3	1	2	3	2	2	2	0	2	0	0
		DAY 8	21NOV2002	10	25	-5	3	3	0	0	0	0	3	1	1	3	2	2	2	2	2	1	0
		DAY 15	26NOV2002	15	26	-4	3	3	2	2	0	0	3	1	1	3	3	2	2	0	1	0	0
		DAY 22	04DEC2002	23	20	-10	2	3	1	2	2	1	3	1	0	2	2	0	0	0	1	0	0
		DAY 29	10DEC2002	29	23	-7	2	3	0	2	2	1	3	1	1	2	2	0	1	0	2	1	0
		DAY 36	17DEC2002	36	23	-7	2	3	0	2	2	1	3	1	1	2	2	2	0	0	2	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	DAY 43	23DEC2002	42	17	-13	2	3	0	1	2	1	2	1	0	1	2	1	0	0	1	0	0
		DAY 50	30DEC2002	49	17	-13	1	1	0	1	2	1	2	1	1	2	2	1	0	0	2	0	0
	E0010002	SCREEN	14NOV2002	-11	22		2	1	2	1	2	1	1	1	2	2	2	1	1	0	1	2	0
		DAY 1	25NOV2002	1	25		2	2	1	2	1	1	1	1	2	2	3	2	1	1	1	2	0
		DAY 8	02DEC2002	8	23	-2	3	2	2	1	1	1	3	1	2	2	2	0	0	0	2	0	1
	E0010009	SCREEN	18DEC2002	-8	21		2	2	0	2	2	2	3	1	2	1	1	0	1	2	0	0	0
		DAY 1	26DEC2002	1	21		2	1	0	2	1	2	3	1	1	1	2	0	2	2	1	0	0
		DAY 8	02JAN2003	8	10	-11	0	1	0	0	0	0	3	1	0	0	1	0	2	2	0	0	0
		DAY 15	09JAN2003	15	10	-11	1	1	0	0	0	0	2	2	0	0	1	0	1	2	0	0	0
		DAY 22	17JAN2003	23	11	-10	2	0	0	0	0	0	2	0	0	1	2	0	2	2	0	0	0
		DAY 29	22JAN2003	28	7	-14	1	0	0	0	0	0	1	1	0	1	1	0	0	2	0	0	0
		DAY 36	30JAN2003	36	8	-13	1	0	0	0	0	0	1	1	0	1	2	0	0	2	0	0	0
		DAY 43	05FEB2003	42	10	-11	1	0	0	0	0	0	2	1	0	1	1	0	1	2	0	1	0
		DAY 50	13FEB2003	50	6	-15	1	0	0	0	0	0	2	0	0	0	0	0	1	2	0	0	0
		DAY 57	19FEB2003	56	8	-13	1	0	0	0	0	0	1	0	2	1	0	0	1	2	0	0	0
	E0010010	SCREEN	20DEC2002	-10	24		2	2	1	0	0	0	4	1	2	4	2	2	2	2	0	0	0
		DAY 1	30DEC2002	1	24		3	2	1	0	0	0	4	2	2	3	2	1	2	2	0	0	0
		DAY 8	06JAN2003	8	24	0	2	3	1	0	2	1	4	4	1	2	1	1	0	2	0	0	0
		DAY 15	13JAN2003	15	23	-1	2	2	1	2	1	0	4	0	2	3	1	2	0	2	1	0	0
	E0010014	SCREEN	14JAN2003	-14	32		3	3	2	2	1	2	4	2	4	4	1	0	1	2	1	0	0
		DAY 1	28JAN2003	1	29		3	3	1	2	2	1	3	2	2	3	2	0	1	2	2	0	0
		DAY 8	04FEB2003	8	6	-23	1	0	0	0	0	0	0	1	1	1	1	0	0	0	1	0	0
		DAY 15	11FEB2003	15	7	-22	0	2	0	0	0	0	0	0	2	1	1	0	1	0	0	0	0
		DAY 22	18FEB2003	22	0	-29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	25FEB2003	29	2	-27	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	DAY 36	04MAR2003	36	1	-28	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 43	11MAR2003	43	0	-29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	18MAR2003	50	0	-29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	25MAR2003	57	0	-29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0010017	SCREEN	05FEB2003	-20	23		3	1	0	2	2	2	3	2	0	3	2	0	1	2	0	0	0
		DAY 1	25FEB2003	1	33		3	3	0	2	2	2	2	2	2	3	2	2	2	2	2	2	0
		DAY 8	03MAR2003	7	18	-15	2	2	0	1	0	0	2	1	0	2	2	2	2	2	0	0	0
		DAY 15	10MAR2003	14	9	-24	1	2	0	0	0	0	0	1	1	1	0	0	1	2	0	0	0
		DAY 22	18MAR2003	22	8	-25	1	0	0	0	0	0	0	0	2	1	1	1	0	2	0	0	0
		DAY 29	25MAR2003	29	7	-26	0	0	0	0	0	0	0	0	2	0	0	0	2	2	0	1	0
		DAY 36	01APR2003	36	4	-29	1	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0
		DAY 43	08APR2003	43	8	-25	0	0	0	0	0	0	0	0	3	1	1	0	0	2	1	0	0
		DAY 50	15APR2003	50	6	-27	0	0	0	0	0	1	0	0	3	0	0	0	0	2	0	0	0
		DAY 57	22APR2003	57	2	-31	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
	E0010023	SCREEN	10APR2003	-7	25		3	3	2	2	1	1	3	2	2	2	2	0	2	0	0	0	0
		DAY 1	17APR2003	1	22		3	3	1	2	0	0	3	1	0	3	2	0	2	2	0	0	0
		DAY 8	24APR2003	8	10	-12	2	2	0	0	0	0	0	1	0	1	1	0	1	2	0	0	0
		DAY 15	01MAY2003	15	19	-3	2	3	1	1	1	1	2	1	2	1	1	0	1	2	0	0	0
	E0010027	SCREEN	05JUN2003	-11	32		3	3	0	2	2	0	3	2	4	3	2	2	2	2	0	2	0
		DAY 1	16JUN2003	1	27		2	3	0	2	2	2	3	2	2	1	0	2	2	1	1	2	0
		DAY 8	23JUN2003	8	17	-10	1	3	0	0	0	0	3	2	1	1	1	1	2	2	0	0	0
		DAY 15	01JUL2003	16	18	-9	0	3	0	2	1	0	3	0	2	1	2	1	1	2	0	0	0
	E0010029	SCREEN	10JUN2003	-9	25		3	3	2	2	2	2	2	2	0	3	3	0	0	0	1	0	0
		DAY 1	19JUN2003	1	28		2	3	2	2	2	1	3	1	2	3	2	0	2	2	1	0	0
		DAY 8	25JUN2003	7	25	-3	2	3	2	1	1	2	2	1	2	3	2	0	2	2	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	SCREEN	02JUN2003	-7	25		3	1	1	2	2	2	3	0	3	2	2	0	2	1	1	0	0
		DAY 1	09JUN2003	1	25		3	2	1	2	2	2	2	0	3	3	2	0	1	1	1	0	0
		DAY 8	16JUN2003	8	25	0	3	2	1	0	2	2	2	1	3	2	2	1	2	1	1	0	0
		DAY 15	24JUN2003	16	26	1	2	2	0	2	2	1	2	1	2	2	2	1	2	1	2	2	0
		DAY 22	01JUL2003	23	21	-4	2	2	0	0	2	2	3	1	1	1	2	0	2	1	2	0	0
		DAY 29	08JUL2003	30	19	-6	3	2	1	0	0	2	2	1	0	1	3	0	2	1	1	0	0
		DAY 36	15JUL2003	37	23	-2	3	2	1	2	2	0	2	1	1	1	3	0	2	1	2	0	0
		DAY 43	24JUL2003	46	23	-2	3	3	2	0	0	0	3	1	2	2	2	0	2	2	1	0	0
		DAY 50	31JUL2003	53	20	-5	4	3	2	0	1	0	3	1	1	1	0	0	2	2	0	0	0
		DAY 57	05AUG2003	58	23	-2	3	3	2	0	0	0	3	1	1	2	3	0	2	1	1	1	0
	E0013006	SCREEN	05MAR2003	-8	25		4	2	3	0	1	0	4	1	2	2	2	0	2	2	0	0	0
		DAY 1	13MAR2003	1	23		3	2	1	0	2	1	3	0	2	2	2	0	2	2	1	0	0
		DAY 8	24MAR2003	12	11	-12	2	0	0	0	1	2	0	0	1	1	2	0	1	0	1	0	0
	E0013012	SCREEN	29APR2003	-8	23		3	2	0	1	2	2	3	1	0	2	2	1	2	2	0	0	0
		DAY 1	07MAY2003	1	25		3	2	1	2	2	2	3	1	1	1	2	1	2	2	0	0	0
		DAY 8	16MAY2003	10	10	-15	1	0	0	0	2	1	3	1	0	0	0	0	2	0	0	0	0
		DAY 15	22MAY2003	16	11	-14	1	0	0	0	2	1	3	1	0	0	1	0	2	0	0	0	0
		DAY 22	30MAY2003	24	8	-17	1	0	0	0	0	0	1	1	0	1	1	0	2	1	0	0	0
		DAY 29	05JUN2003	30	5	-20	1	0	0	0	1	0	0	0	0	1	1	0	1	0	0	0	0
		DAY 36	12JUN2003	37	6	-19	1	0	0	0	1	0	1	0	0	0	1	0	1	0	0	1	0
		DAY 43	19JUN2003	44	3	-22	1	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
		DAY 50	25JUN2003	50	3	-22	0	0	0	0	1	0	1	0	0	0	0	0	1	0	0	0	0
		DAY 57	02JUL2003	57	3	-22	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
	E0013014	SCREEN	08MAY2003	-26	22		3	2	2	2	2	0	3	1	0	2	2	1	2	0	0	0	0
		DAY 1	03JUN2003	1	20		3	2	2	2	1	0	3	2	0	2	0	1	2	0	0	0	0
		DAY 8	10JUN2003	8	21	1	2	1	2	2	2	1	3	0	1	3	2	0	1	0	0	1	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0013014	DAY 15	19JUN2003	17	18	-2	2	2	1	2	2	2	2	1	0	2	0	1	1	0	0	0	0
		DAY 29	30JUN2003	28	10	-10	1	0	1	2	2	0	2	0	0	0	0	0	2	0	0	0	0
	E0014005	SCREEN	04MAR2003	-7	33		4	3	1	0	2	0	4	3	2	4	4	0	2	2	2	0	0
		DAY 1	11MAR2003	1	32		4	3	1	1	2	0	4	3	2	3	3	0	2	2	2	0	0
		DAY 8	18MAR2003	8	18	-14	2	2	1	0	0	0	2	2	0	2	2	0	2	2	1	0	0
		DAY 15	25MAR2003	15	8	-24	1	1	1	0	0	0	0	1	0	1	1	0	1	1	0	0	0
		DAY 22	01APR2003	22	3	-29	0	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	08APR2003	29	6	-26	0	1	0	0	0	0	0	2	0	1	1	0	1	0	0	0	0
		DAY 36	16APR2003	37	7	-25	0	1	0	0	0	0	1	0	0	1	0	0	1	1	2	0	0
		DAY 43	23APR2003	44	4	-28	1	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 50	29APR2003	50	1	-31	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	06MAY2003	57	5	-27	1	1	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0
	E0014007	SCREEN	25MAR2003	-7	27		3	3	1	2	2	0	4	3	0	2	2	1	2	2	0	0	0
		DAY 1	01APR2003	1	29		3	3	0	2	2	2	4	3	0	3	3	0	2	2	0	0	0
		DAY 8	08APR2003	8	15	-14	2	1	0	0	0	0	2	3	0	3	2	0	2	0	0	0	0
		DAY 15	15APR2003	15	21	-8	3	1	0	0	0	0	2	4	2	3	2	1	2	1	0	0	0
		DAY 22	22APR2003	22	23	-6	3	2	0	2	2	2	4	2	0	2	3	0	1	0	0	0	0
	E0014011	SCREEN	06MAY2003	-7	22		3	2	2	2	0	0	2	1	1	3	2	1	2	1	0	0	0
		DAY 1	13MAY2003	1	23		3	2	2	2	1	0	2	1	1	3	2	1	2	1	0	0	0
		DAY 8	20MAY2003	8	12	-11	2	1	1	0	0	0	3	1	0	2	1	0	1	0	0	0	0
		DAY 15	27MAY2003	15	10	-13	1	1	1	0	0	0	2	1	0	1	1	1	1	0	0	0	0
		DAY 22	04JUN2003	23	5	-18	1	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0
		DAY 29	10JUN2003	29	5	-18	1	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0
		DAY 36	17JUN2003	36	3	-20	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
		DAY 43	26JUN2003	45	6	-17	1	0	0	0	0	0	0	0	0	1	2	0	0	2	0	0	0
		DAY 50	02JUL2003	51	4	-19	0	0	0	0	0	0	0	0	0	1	2	0	0	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	DAY 57	08JUL2003	57	2	-21	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0
	E0014012	SCREEN	19MAY2003	-8	33		3	3	0	2	2	2	3	3	2	4	3	2	2	2	0	0	0
		DAY 1	27MAY2003	1	34		4	3	0	2	2	2	3	3	2	4	3	2	2	2	0	0	0
		DAY 8	03JUN2003	8	27	-7	3	3	0	0	0	0	3	3	2	4	3	2	2	2	0	0	0
		DAY 15	10JUN2003	15	23	-11	2	2	2	2	0	0	3	2	1	3	2	1	1	2	0	0	0
		DAY 22	17JUN2003	22	21	-13	2	2	1	2	0	0	2	2	1	3	2	0	1	2	1	0	0
		DAY 29	24JUN2003	29	21	-13	2	2	1	2	0	0	2	2	1	3	2	0	1	2	1	0	0
	E0015001	SCREEN	08NOV2002	-21	25		3	2	1	2	2	2	3	0	1	2	1	0	2	2	2	0	0
		DAY 1	29NOV2002	1	23		3	2	1	2	2	2	3	0	0	2	1	0	2	2	1	0	0
		DAY 8	06DEC2002	8	16	-7	3	1	1	0	0	0	3	0	0	2	1	0	2	2	1	0	0
		DAY 15	13DEC2002	15	16	-7	2	1	1	0	0	0	2	1	1	2	1	0	2	2	1	0	0
		DAY 22	19DEC2002	21	16	-7	2	1	1	0	0	0	2	1	1	2	1	0	2	2	1	0	0
		DAY 29	27DEC2002	29	15	-8	2	1	1	0	0	0	2	1	1	2	1	0	1	2	1	0	0
		DAY 36	03JAN2003	36	11	-12	1	1	1	0	0	0	2	0	0	2	1	0	1	2	0	0	0
		DAY 43	09JAN2003	42	12	-11	1	1	1	0	0	0	2	0	0	2	1	0	1	2	1	0	0
		DAY 50	20JAN2003	53	11	-12	1	1	0	0	0	0	1	0	1	1	1	1	1	2	1	0	0
	E0015008	SCREEN	13DEC2002	-6	22		3	2	0	1	2	1	3	0	2	2	1	1	2	1	1	0	0
		DAY 1	19DEC2002	1	24		3	2	0	1	2	2	3	1	2	2	1	1	2	1	1	0	0
		DAY 8	27DEC2002	9	18	-6	3	2	0	0	0	0	3	1	1	2	1	0	2	2	1	0	0
		DAY 15	03JAN2003	16	14	-10	2	2	0	0	0	0	2	0	1	2	1	1	2	1	0	0	0
		DAY 22	10JAN2003	23	11	-13	1	2	0	0	0	0	2	0	1	1	0	0	2	1	1	0	0
		DAY 29	16JAN2003	29	12	-12	1	1	0	0	0	0	2	0	1	1	1	1	2	1	1	0	0
		DAY 36	23JAN2003	36	8	-16	1	0	0	0	0	0	1	0	2	1	1	1	0	0	1	0	0
	E0016003	SCREEN	10JAN2003	-14	21		3	2	1	2	1	1	3	1	2	2	1	1	0	1	0	0	0
		DAY 1	24JAN2003	1	22		3	2	1	2	1	1	3	2	2	2	0	1	2	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0016003	DAY 8	31JAN2003	8	25	3	3	3	1	1	1	2	3	2	2	2	2	0	1	0	2	0	0
		DAY 15	07FEB2003	15	23	1	3	3	1	2	2	2	3	1	2	2	2	0	0	0	0	0	0
		DAY 22	14FEB2003	22	7	-15	2	1	0	1	0	0	0	0	2	1	0	0	0	0	0	0	0
		DAY 29	21FEB2003	29	11	-11	2	1	0	1	1	1	3	0	2	0	0	0	0	0	0	0	0
		DAY 36	27FEB2003	35	7	-15	1	2	0	0	0	0	2	1	1	0	0	0	0	0	0	0	0
		DAY 43	07MAR2003	43	12	-10	2	1	0	1	0	0	2	1	2	2	1	0	0	0	0	0	0
	E0016005	SCREEN	20FEB2003	-5	28		3	3	1	1	1	1	3	1	3	3	2	1	1	0	3	1	0
		DAY 1	25FEB2003	1	28		3	3	2	2	1	2	3	1	3	3	1	1	0	0	3	0	0
		DAY 8	04MAR2003	8	16	-12	2	2	1	0	0	0	2	1	3	2	1	0	0	0	2	0	0
		DAY 15	11MAR2003	15	9	-19	2	1	0	0	0	0	0	0	1	1	1	0	0	0	3	0	0
		DAY 22	18MAR2003	22	5	-23	1	1	0	0	0	0	0	0	1	0	0	0	0	0	2	0	0
		DAY 29	25MAR2003	29	0	-28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	36	1	-27	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 43	08APR2003	43	0	-28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	17APR2003	52	2	-26	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 57	22APR2003	57	5	-23	0	0	0	0	0	0	1	1	1	0	1	0	0	0	1	0	0
	E0018007	SCREEN	16DEC2002	-11	25		3	2	1	2	2	2	2	0	2	2	2	1	2	1	1	0	0
		DAY 1	27DEC2002	1	24		3	2	0	2	2	2	2	2	1	2	2	0	1	2	1	0	0
		DAY 8	31DEC2002	5	12	-12	1	1	0	0	0	0	2	1	0	2	1	0	2	1	1	0	0
		DAY 15	10JAN2003	15	23	-1	3	2	0	2	2	2	4	0	1	2	2	0	2	1	0	0	0
	E0019005	SCREEN	30OCT2002	-6	21		3	2	1	1	2	1	2	1	0	2	2	0	1	2	1	0	0
		DAY 1	05NOV2002	1	21		3	2	1	2	1	1	3	0	1	2	0	2	1	2	0	0	0
		DAY 8	12NOV2002	8	17	-4	2	1	0	2	0	0	2	0	1	2	2	1	1	2	1	0	0
		DAY 15	19NOV2002	15	9	-12	2	0	0	2	0	0	1	0	0	1	2	0	0	1	0	0	0
		DAY 22	26NOV2002	22	12	-9	1	0	0	2	0	0	2	0	0	1	2	0	2	2	0	0	0
		DAY 29	05DEC2002	31	7	-14	1	0	0	2	0	0	1	0	0	1	0	1	0	1	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	DAY 36		12DEC2002	38	3	-18	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
		DAY 43		19DEC2002	45	7	-14	2	1	0	2	0	0	1	0	0	1	0	0	0	0	0	0	0
		DAY 57	*	30DEC2002	56	11	-10	3	0	1	1	0	0	2	0	1	2	0	0	0	1	0	0	0
		DAY 57		02JAN2003	59	8	-13	2	0	0	1	0	0	2	0	1	0	0	0	1	1	0	0	0
	E0019015	SCREEN		19DEC2002	-14	27		3	2	0	2	2	1	2	1	2	2	2	1	2	2	1	2	0
		DAY 1		02JAN2003	1	21		3	2	0	2	1	2	3	0	2	2	2	0	1	1	0	0	0
		DAY 8		09JAN2003	8	8	-13	1	1	0	0	0	0	1	0	2	1	1	1	0	0	0	0	0
		DAY 15		16JAN2003	15	11	-10	1	0	0	0	1	0	2	0	2	0	1	1	1	2	0	0	0
		DAY 22		23JAN2003	22	4	-17	0	0	0	0	0	0	0	0	2	1	1	0	0	0	0	0	0
		DAY 29		30JAN2003	29	4	-17	0	0	0	0	0	0	0	1	2	1	0	0	0	0	0	0	0
		DAY 36		06FEB2003	36	3	-18	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	0
		DAY 43		13FEB2003	43	3	-18	0	0	0	0	0	0	0	1	0	1	0	0	0	0	1	0	0
		DAY 50		20FEB2003	50	3	-18	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 57		27FEB2003	57	2	-19	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
	E0020004	SCREEN		21NOV2002	-18	28		3	1	1	1	2	2	4	2	1	3	2	1	2	1	0	1	1
		DAY 1		09DEC2002	1	24		3	1	0	2	2	2	3	2	0	2	2	1	2	2	0	0	0
		DAY 8		16DEC2002	8	15	-9	3	1	0	1	0	0	2	2	0	2	1	0	2	1	0	0	0
		DAY 8	*	20DEC2002	12	12	-12	3	0	0	0	1	0	1	1	0	2	2	0	2	0	0	0	0
		DAY 22		31DEC2002	23	20	-4	3	2	0	2	2	1	3	0	0	3	1	1	0	0	1	1	0
		DAY 29		07JAN2003	30	20	-4	3	2	2	0	0	0	3	1	0	3	2	0	1	2	0	1	0
		DAY 36		14JAN2003	37	28	4	3	2	1	1	2	2	3	1	0	3	3	1	1	2	2	1	0
		DAY 43		22JAN2003	45	24	0	4	2	1	0	1	0	3	1	0	3	2	1	2	2	1	1	0
	E0020010	SCREEN		28JAN2003	-8	29		3	3	0	2	2	2	3	1	1	3	3	1	2	2	0	0	1
		DAY 1		05FEB2003	1	29		3	3	2	2	2	2	3	0	1	3	3	0	2	2	1	0	0
		DAY 8		12FEB2003	8	21	-8	3	3	0	2	1	1	2	0	1	2	3	0	1	2	0	0	0
		DAY 15		19FEB2003	15	7	-22	0	0	0	0	1	0	0	0	1	1	2	0	2	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0020010	DAY 22	26FEB2003	22	10	-19	0	0	0	1	2	0	0	0	1	1	2	0	2	0	1	0	0
		DAY 29	05MAR2003	29	27	-2	3	3	1	2	2	2	3	1	2	3	2	0	2	1	0	0	0
		DAY 36	10MAR2003	34	14	-15	2	0	0	0	2	1	3	1	1	1	1	0	2	0	0	0	0
		DAY 43	17MAR2003	41	10	-19	0	2	0	1	2	2	0	0	0	0	2	0	1	0	0	0	0
		DAY 50	25MAR2003	49	6	-23	0	0	0	0	0	2	0	0	1	1	0	0	2	0	0	0	0
		DAY 57	02APR2003	57	8	-21	0	0	0	1	2	2	0	0	1	0	1	0	0	0	1	0	0
	E0020014	SCREEN	11MAR2003	-7	26		3	3	1	2	2	2	3	2	2	2	1	1	1	0	0	0	1
		DAY 1	18MAR2003	1	24		2	3	0	0	0	1	3	2	2	2	2	1	2	2	0	1	1
		DAY 8	25MAR2003	8	21	-3	3	3	0	0	2	2	3	1	1	2	1	0	1	0	0	1	1
		DAY 15	01APR2003	15	18	-6	2	3	0	0	0	2	3	1	1	2	1	0	2	0	0	0	1
		DAY 22	08APR2003	22	13	-11	1	3	0	0	0	2	1	1	1	2	1	0	1	0	0	0	0
		DAY 29	15APR2003	29	17	-7	2	3	0	2	0	1	1	1	1	2	2	0	1	1	0	0	0
		DAY 36	22APR2003	36	17	-7	2	3	0	2	0	2	1	1	1	1	2	0	2	0	0	0	0
		DAY 43	29APR2003	43	9	-15	1	3	0	0	0	0	1	0	0	1	1	1	1	0	0	0	0
		DAY 50	06MAY2003	50	14	-10	1	3	0	0	0	2	1	1	1	1	2	0	1	1	0	0	0
		DAY 57	12MAY2003	56	7	-17	1	3	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0
	E0020021	SCREEN	09MAY2003	-10	26		3	3	2	2	0	2	3	1	2	2	1	0	2	1	1	0	1
		DAY 1	19MAY2003	1	21		3	3	2	2	1	0	2	1	0	2	2	0	1	1	0	0	1
		DAY 8	23MAY2003	5	15	-6	2	2	0	0	0	0	3	3	0	1	0	0	2	2	0	0	0
		DAY 15	02JUN2003	15	15	-6	2	3	1	1	1	0	2	1	0	0	1	0	1	2	0	0	0
		DAY 22	10JUN2003	23	16	-5	1	3	0	2	1	2	2	0	0	0	2	0	1	1	0	0	1
		DAY 29	16JUN2003	29	7	-14	1	0	2	0	0	0	1	0	0	0	0	0	1	1	0	0	1
		DAY 36	23JUN2003	36	15	-6	2	3	2	0	1	0	2	1	0	0	0	1	1	2	0	0	0
		DAY 43	30JUN2003	43	16	-5	2	0	2	2	1	1	2	0	0	2	0	0	1	2	0	0	1
		DAY 50	07JUL2003	50	9	-12	1	0	2	0	0	0	1	0	0	0	0	1	2	1	1	0	0
		DAY 57	14JUL2003	57	8	-13	1	0	1	0	1	0	2	0	0	0	0	0	1	1	0	0	1

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	SCREEN	09JUN2003	-8	22		3	0	1	2	2	2	3	2	2	1	0	1	1	2	0	0	0
		DAY 1	16JUN2003	-1	25		2	2	0	2	2	2	3	1	1	3	2	0	2	2	1	0	0
		DAY 8	24JUN2003	8	14	-11	2	2	1	0	0	0	3	0	1	3	1	0	1	0	0	0	0
		DAY 15	30JUN2003	14	19	-6	1	2	2	1	2	2	3	0	0	1	1	1	1	2	0	0	0
		DAY 22	07JUL2003	21	24	-1	3	2	2	1	1	2	3	0	0	2	2	1	1	2	2	0	0
		DAY 29	14JUL2003	28	21	-4	2	2	2	1	2	2	2	0	0	2	2	1	1	2	0	0	0
		DAY 36	21JUL2003	35	13	-12	1	0	1	1	2	2	3	0	0	1	0	0	0	2	0	0	0
		DAY 43	28JUL2003	42	18	-7	1	2	2	1	2	2	3	0	0	1	1	0	1	2	0	0	0
		DAY 50	04AUG2003	49	16	-9	1	1	1	1	2	2	3	0	0	1	0	1	1	2	0	0	0
		DAY 57	11AUG2003	56	11	-14	1	0	2	1	0	0	3	0	0	1	0	0	1	2	0	0	0
	E0022007	SCREEN	01NOV2002	-6	20		3	2	0	2	2	1	3	0	0	2	0	0	2	2	1	0	0
		DAY 1	07NOV2002	1	20		3	2	0	2	2	1	2	0	1	2	1	0	1	2	1	0	0
		DAY 8	14NOV2002	8	13	-7	2	1	0	0	0	1	2	0	1	2	1	0	1	1	1	0	0
		DAY 15	22NOV2002	16	13	-7	2	1	0	0	0	1	2	0	1	1	1	0	1	2	1	0	0
		DAY 22	02DEC2002	26	15	-5	2	2	0	0	0	0	2	0	1	2	1	0	2	2	1	0	0
		DAY 29	09DEC2002	33	11	-9	1	1	0	0	2	0	2	0	0	1	0	0	1	2	1	0	0
	E0022010	SCREEN	14NOV2002	-7	24		3	2	1	2	0	2	3	2	2	2	0	0	2	1	2	0	0
		DAY 1	21NOV2002	1	23		3	2	1	2	0	1	3	1	2	2	1	0	2	1	2	0	0
		DAY 8	29NOV2002	9	12	-11	2	1	0	0	0	0	2	1	0	3	0	0	1	1	1	0	0
		DAY 15	06DEC2002	16	4	-19	1	0	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 22	12DEC2002	22	6	-17	0	0	0	0	0	0	1	0	2	1	0	0	1	0	1	0	0
		DAY 36	26DEC2002	36	4	-19	0	0	0	1	0	0	0	0	1	0	1	0	0	0	1	0	0
		DAY 43	02JAN2003	43	3	-20	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0
		DAY 50	09JAN2003	50	2	-21	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 57	16JAN2003	57	4	-19	0	0	0	0	2	0	0	0	1	0	0	0	0	0	1	0	0
	E0022012	SCREEN	21NOV2002	-14	21		3	2	0	2	2	1	3	0	1	2	2	0	2	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0022012	DAY 1		05DEC2002	1	21		3	1	0	2	2	0	3	1	1	2	1	0	2	2	1	0	0
		DAY 8		12DEC2002	8	12	-9	2	0	0	1	0	0	2	0	0	1	2	0	2	1	1	0	0
		DAY 15		19DEC2002	15	6	-15	1	0	0	0	0	0	1	0	0	1	2	0	1	0	0	0	0
		DAY 15	*	23DEC2002	19	6	-15	1	0	0	0	0	0	1	0	1	1	1	0	0	1	0	0	0
		DAY 29		02JAN2003	29	3	-18	0	0	0	0	0	0	0	0	0	0	1	0	1	1	0	0	0
		DAY 36		09JAN2003	36	5	-16	0	0	0	0	0	0	1	0	0	1	0	0	1	1	1	0	0
		DAY 43		16JAN2003	43	3	-18	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0
		DAY 50		23JAN2003	50	3	-18	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0
		DAY 57		30JAN2003	57	3	-18	0	0	0	0	1	0	0	0	0	0	1	0	1	0	0	0	0
	E0022019	SCREEN		04DEC2002	-7	20		3	2	1	2	0	2	3	0	2	2	0	0	2	0	1	0	0
		DAY 1		11DEC2002	1	20		3	2	1	2	0	2	3	0	1	2	2	0	1	0	1	0	0
		DAY 8		19DEC2002	9	9	-11	1	1	1	0	1	0	2	0	0	1	2	0	0	0	0	0	0
		DAY 15		26DEC2002	16	4	-16	1	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 22		03JAN2003	24	4	-16	0	0	0	0	0	0	1	0	0	0	1	0	1	0	1	0	0
		DAY 29		09JAN2003	30	2	-18	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0
		DAY 36		17JAN2003	38	1	-19	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 43		24JAN2003	45	5	-15	0	0	0	1	2	1	0	0	0	0	0	0	1	0	0	0	0
		DAY 50		30JAN2003	51	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		06FEB2003	58	1	-19	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	E0022025	SCREEN		08JAN2003	-20	29		3	3	2	2	2	2	4	1	1	2	2	0	2	2	1	0	0
		DAY 1		28JAN2003	1	28		3	3	2	2	2	1	4	1	1	2	2	0	2	2	1	0	0
		DAY 8		04FEB2003	8	33	5	3	3	1	2	2	2	4	2	2	3	3	0	2	2	2	0	0
	E0022033	SCREEN		11FEB2003	-7	29		3	2	2	2	2	2	3	1	3	3	2	0	2	1	1	0	0
		DAY 1		18FEB2003	1	22		3	2	1	2	2	2	2	1	1	2	2	0	2	0	0	0	0
		DAY 8		25FEB2003	8	17	-5	3	1	2	0	1	0	3	0	1	3	1	0	1	1	0	0	0
		DAY 15		04MAR2003	15	13	-9	1	0	0	0	0	1	2	1	1	2	1	0	1	2	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	DAY 22	11MAR2003	22	3	-19	0	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0
		DAY 29	18MAR2003	29	2	-20	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 36	27MAR2003	38	4	-18	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0
		DAY 43	01APR2003	43	3	-19	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0	0	0
		DAY 50	08APR2003	50	7	-15	0	0	0	0	1	0	1	0	0	1	1	0	2	1	0	0	0
		DAY 57	15APR2003	57	3	-19	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0
	E0022034	SCREEN	11FEB2003	-7	20		3	1	0	2	1	1	3	2	1	3	0	0	2	1	0	0	0
		DAY 1	18FEB2003	1	20		3	1	0	2	1	1	3	1	1	2	1	0	2	1	1	0	0
		DAY 8	25FEB2003	8	14	-6	3	2	0	0	0	0	2	1	1	1	0	0	2	0	2	0	0
		DAY 15	04MAR2003	15	13	-7	2	2	0	0	0	0	3	0	2	1	0	0	2	0	1	0	0
		DAY 22	11MAR2003	22	20	0	3	2	1	0	0	0	4	1	2	2	1	0	2	0	2	0	0
		DAY 29	18MAR2003	29	14	-6	2	1	0	0	0	0	2	1	2	2	1	0	1	0	2	0	0
		DAY 36	25MAR2003	36	12	-8	1	2	0	0	0	0	1	1	1	2	0	0	1	1	2	0	0
		DAY 43	01APR2003	43	9	-11	1	0	0	0	0	0	1	0	2	1	1	0	0	1	2	0	0
		DAY 50	07APR2003	49	9	-11	1	0	0	0	0	0	1	1	1	2	1	0	0	1	1	0	0
		DAY 57	15APR2003	57	7	-13	1	0	0	0	0	0	1	1	2	0	1	0	0	0	1	0	0
	E0022038	SCREEN	20FEB2003	-8	21		3	2	2	0	1	1	3	0	1	3	0	0	2	0	3	0	0
		DAY 1	28FEB2003	1	23		3	2	2	0	2	2	3	0	2	2	1	1	2	0	1	0	0
		DAY 8	07MAR2003	8	17	-6	3	2	1	0	0	0	2	1	1	1	1	1	1	2	1	0	0
		DAY 15	14MAR2003	15	19	-4	2	2	2	0	0	0	2	0	1	3	1	1	2	1	2	0	0
		DAY 22	21MAR2003	22	19	-4	1	1	1	0	2	1	1	0	1	2	2	0	2	2	2	0	1
		DAY 29	28MAR2003	29	12	-11	1	1	0	1	0	0	1	0	2	1	1	1	1	1	1	0	0
		DAY 36	04APR2003	36	15	-8	1	1	0	0	1	1	1	1	1	2	1	1	2	1	1	0	0
		DAY 43	11APR2003	43	15	-8	1	1	1	0	0	0	3	0	2	1	1	1	1	2	1	0	0
	E0022039	SCREEN	27FEB2003	-7	21		3	2	2	1	0	0	3	0	1	2	1	1	2	2	1	0	0
		DAY 1	06MAR2003	1	28		3	1	1	2	2	2	3	1	1	3	2	0	1	2	2	2	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	DAY 8	13MAR2003	8	22	-6	2	1	1	2	2	1	3	1	2	2	1	0	2	2	0	0	0
		DAY 15	20MAR2003	15	14	-14	2	0	1	0	2	2	1	1	0	1	2	0	1	1	0	0	0
		DAY 22	27MAR2003	22	18	-10	2	0	1	0	2	2	3	1	1	1	1	0	2	1	1	0	0
		DAY 29	04APR2003	30	6	-22	2	1	0	0	0	0	0	0	0	2	0	0	1	0	0	0	0
		DAY 36	10APR2003	36	3	-25	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0
		DAY 43	18APR2003	44	5	-23	0	1	0	0	0	0	0	0	1	0	1	1	0	1	0	0	0
		DAY 50	24APR2003	50	7	-21	0	1	0	0	0	0	0	1	1	1	1	0	1	0	1	0	0
		DAY 57	01MAY2003	57	5	-23	0	1	0	0	0	0	1	0	1	1	0	0	0	1	0	0	0
	E0022046	SCREEN	13MAR2003	-7	33		4	1	2	2	2	2	3	2	0	3	2	2	2	2	2	2	0
		DAY 1	20MAR2003	1	30		3	2	2	2	2	2	3	2	0	1	2	2	2	2	1	2	0
		DAY 8	27MAR2003	8	20	-10	2	0	1	1	1	0	3	2	0	1	1	2	2	2	2	0	0
		DAY 15	04APR2003	16	16	-14	1	1	2	0	0	1	3	1	0	1	1	0	2	2	1	0	0
		DAY 22	11APR2003	23	12	-18	0	1	0	0	1	0	3	1	0	1	1	1	1	2	0	0	0
		DAY 29	18APR2003	30	17	-13	2	0	2	0	0	0	3	2	0	1	1	2	2	2	0	0	0
		DAY 36	24APR2003	36	14	-16	2	1	1	0	0	0	2	1	0	1	1	1	2	2	0	0	0
		DAY 43	02MAY2003	44	15	-15	1	1	1	0	0	0	3	1	0	2	1	1	2	2	0	0	0
		DAY 50	12MAY2003	54	13	-17	1	1	1	0	0	1	3	1	0	1	1	0	0	2	1	0	0
		DAY 57	16MAY2003	58	19	-11	2	1	1	0	0	0	3	2	0	2	2	1	2	2	1	0	0
	E0022048	SCREEN	25MAR2003	-7	31		3	2	2	2	1	2	4	2	1	3	2	1	2	2	0	2	0
		DAY 1	01APR2003	1	23		3	1	2	2	1	1	4	2	0	2	1	0	2	1	1	0	0
		DAY 8	08APR2003	8	11	-12	2	0	1	0	0	0	2	2	1	1	0	0	1	1	0	0	0
		DAY 15	15APR2003	15	12	-11	1	0	1	0	0	0	3	2	0	1	1	1	2	0	0	0	0
		DAY 22	24APR2003	24	6	-17	1	0	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0
		DAY 29	02MAY2003	32	3	-20	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 36	06MAY2003	36	3	-20	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 43	13MAY2003	43	3	-20	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	0	0
		DAY 50	23MAY2003	53	0	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	SCREEN		31MAR2003	-7	33		3	3	2	1	1	1	4	3	0	2	2	2	2	2	3	2	0
		DAY 1		07APR2003	1	30		3	3	2	1	1	1	4	3	0	2	1	2	2	2	3	0	0
		DAY 8		14APR2003	8	22	-8	3	2	1	0	1	2	4	2	0	1	0	0	1	2	3	0	0
		DAY 15		21APR2003	15	15	-15	3	0	0	0	0	0	4	2	0	0	1	0	2	2	1	0	0
		DAY 22		28APR2003	22	8	-22	1	0	0	0	0	0	4	1	0	0	0	0	0	2	0	0	0
		DAY 29		05MAY2003	29	7	-23	1	0	0	0	0	0	1	1	0	1	1	0	0	2	0	0	0
		DAY 36		12MAY2003	36	2	-28	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		19MAY2003	43	7	-23	0	0	0	0	0	0	0	1	1	1	0	0	2	0	2	0	0
		DAY 50		28MAY2003	52	2	-28	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
		DAY 57		02JUN2003	57	1	-29	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	E0022053	SCREEN		04APR2003	-7	25		3	2	2	2	2	1	4	2	1	1	2	0	2	0	1	0	0
		DAY 1		11APR2003	1	28		3	3	2	2	2	2	3	2	1	2	2	0	2	1	1	0	0
	E0022058	SCREEN		11APR2003	-10	24		3	3	2	0	1	1	3	1	1	2	2	0	2	1	0	2	0
		DAY 1		21APR2003	1	20		3	2	2	0	1	0	3	2	1	2	1	0	2	0	1	0	0
		DAY 8		28APR2003	8	12	-8	1	1	1	0	0	0	2	1	0	2	1	0	2	0	1	0	0
		DAY 15		05MAY2003	15	7	-13	1	1	0	0	0	0	1	0	1	1	1	0	0	1	0	0	0
		DAY 22		12MAY2003	22	3	-17	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0
		DAY 29		19MAY2003	29	3	-17	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	0	0
		DAY 29	*	22MAY2003	32	8	-12	0	1	0	0	0	0	2	0	0	1	2	0	0	2	0	0	0
	E0022061	SCREEN		24APR2003	-6	22		3	2	1	0	0	0	4	1	2	1	1	0	2	2	3	0	0
		DAY 1		30APR2003	1	25		3	2	0	1	1	0	4	1	3	2	2	0	2	1	3	0	0
		DAY 8		07MAY2003	8	14	-11	2	1	0	0	0	0	2	1	2	1	1	0	1	1	2	0	0
		DAY 15		14MAY2003	15	9	-16	1	0	0	0	0	0	2	1	2	1	0	0	0	0	2	0	0
		DAY 22		22MAY2003	23	4	-21	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0
		DAY 29		28MAY2003	29	2	-23	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 36		04JUN2003	36	2	-23	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 50		18JUN2003	50	2	-23	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 57		26JUN2003	58	2	-23	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
	E0022062	SCREEN		25APR2003	-10	20		3	2	0	2	1	0	3	1	2	2	1	0	2	0	0	0	1
		DAY 1		05MAY2003	1	25		3	2	0	2	1	2	3	1	2	3	2	1	2	0	1	0	0
		DAY 8		12MAY2003	8	23	-2	3	2	1	2	2	0	2	1	1	1	2	0	2	2	0	2	0
		DAY 15		19MAY2003	15	29	4	3	2	1	2	2	1	3	1	2	3	2	1	2	2	2	0	0
		DAY 15	*	23MAY2003	19	26	1	3	2	0	2	2	2	3	0	1	2	2	1	2	1	3	0	0
	E0022068	SCREEN		14MAY2003	-9	26		3	2	2	2	2	2	3	2	0	2	2	0	2	1	1	0	0
		DAY 1		22MAY2003	-1	21		2	1	0	2	2	2	3	2	1	2	2	0	1	1	0	0	0
		DAY 8		29MAY2003	7	21	0	3	1	1	1	0	0	3	2	1	2	2	0	2	2	1	0	0
		DAY 15		05JUN2003	14	18	-3	3	1	0	0	0	0	3	2	0	2	1	1	2	2	1	0	0
	E0022069	SCREEN		04JUN2003	-6	23		3	4	2	2	2	0	3	2	0	1	2	0	2	0	0	0	0
		DAY 1		10JUN2003	1	24		3	4	2	0	2	1	3	2	1	3	0	1	2	0	0	0	0
		DAY 8		17JUN2003	8	15	-9	2	2	1	0	0	0	2	2	1	3	0	0	2	0	0	0	0
		DAY 15		24JUN2003	15	16	-8	3	1	2	0	0	0	2	1	2	1	1	1	2	0	0	0	0
		DAY 22		01JUL2003	22	8	-16	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	0
		DAY 29		08JUL2003	29	7	-17	2	0	0	1	1	0	1	1	0	1	0	0	0	0	0	0	0
		DAY 36		15JUL2003	36	2	-22	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 43		22JUL2003	43	2	-22	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0
		DAY 50		29JUL2003	50	3	-21	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0
		DAY 57		05AUG2003	57	4	-20	1	0	0	0	0	0	0	1	0	1	0	0	1	0	0	0	0
	E0022071	SCREEN		16JUN2003	-14	28		4	2	2	0	0	2	4	3	2	3	0	2	1	2	1	0	0
		DAY 1		30JUN2003	1	30		4	2	2	2	1	2	4	2	1	3	1	2	2	1	1	0	0
		DAY 8		07JUL2003	8	28	-2	3	2	2	2	2	0	4	2	1	3	2	1	1	2	1	0	0
		DAY 15		14JUL2003	15	20	-10	3	2	2	0	0	0	4	2	1	2	1	1	2	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 22	21JUL2003	22	20	-10	3	2	2	0	0	0	4	2	1	3	1	1	0	1	0	0	0
		DAY 29	28JUL2003	29	19	-11	3	2	2	0	0	0	3	2	0	3	2	1	1	0	0	0	0
		DAY 36	04AUG2003	36	19	-11	3	2	1	0	0	0	3	3	1	2	1	1	0	0	0	2	0
		DAY 43	11AUG2003	43	24	-6	3	2	2	0	1	2	3	3	1	2	2	1	1	0	1	0	0
		DAY 50	18AUG2003	50	17	-13	3	2	1	0	0	0	3	2	1	2	0	1	1	0	0	1	0
		DAY 57	25AUG2003	57	17	-13	3	2	1	0	0	0	3	2	1	2	0	1	1	0	1	0	0
	E0023003	SCREEN	12DEC2002	-5	27		3	1	2	2	2	1	3	0	2	3	2	1	2	1	2	0	0
		DAY 1	17DEC2002	1	26		3	1	2	2	2	2	3	0	2	3	2	1	2	1	0	0	0
		DAY 8	23DEC2002	7	28	2	3	2	2	1	2	2	3	0	2	3	3	1	2	2	0	0	0
		DAY 15	30DEC2002	14	28	2	2	2	1	2	2	2	3	0	3	3	2	1	2	1	2	0	0
		DAY 22	07JAN2003	22	27	1	3	2	2	2	2	2	3	1	0	3	2	1	2	1	1	0	0
		DAY 29	16JAN2003	31	18	-8	1	2	2	1	1	0	2	0	1	3	2	1	1	1	0	0	0
		DAY 36	21JAN2003	36	16	-10	3	2	1	0	0	0	2	1	0	3	2	0	1	1	0	0	0
		DAY 43	28JAN2003	43	14	-12	3	1	0	0	1	1	1	0	1	2	1	1	1	1	0	0	0
		DAY 50	06FEB2003	52	17	-9	2	1	0	0	1	2	2	0	1	3	2	1	1	0	1	0	0
		DAY 57	11FEB2003	57	13	-13	3	1	0	0	0	0	2	0	1	3	2	0	1	0	0	0	0
	E0023006	SCREEN	10DEC2002	-7	22		3	2	1	0	1	0	4	2	1	3	1	0	2	2	0	0	0
		DAY 1	17DEC2002	1	23		3	2	1	1	1	0	4	2	1	3	1	0	2	2	0	0	0
		DAY 8	23DEC2002	7	32	9	3	2	1	1	2	2	4	2	3	3	3	1	2	2	1	0	0
		DAY 15	02JAN2003	17	14	-9	2	2	0	0	1	0	3	1	0	2	0	0	1	2	0	0	0
		DAY 22	07JAN2003	22	11	-12	2	2	0	0	0	0	2	1	0	0	0	1	1	2	0	0	0
		DAY 29	16JAN2003	31	7	-16	2	1	0	0	0	0	1	1	0	0	0	1	1	0	0	0	0
		DAY 36	21JAN2003	36	10	-13	2	1	0	0	1	0	2	1	0	0	0	1	2	0	0	0	0
		DAY 43	28JAN2003	43	9	-14	2	0	0	0	0	0	1	1	0	1	1	1	2	0	0	0	0
		DAY 50	04FEB2003	50	5	-18	1	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0
		DAY 57	11FEB2003	57	3	-20	1	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	SCREEN	28JAN2003	-7	23		3	2	2	0	1	1	4	1	1	2	2	0	2	1	1	0	0
		DAY 1	04FEB2003	1	28		3	2	2	1	1	2	4	1	2	3	3	0	2	1	1	0	0
		DAY 8	11FEB2003	8	19	-9	3	2	1	0	1	0	4	0	0	2	2	0	2	1	1	0	0
		DAY 15	18FEB2003	15	15	-13	3	1	0	0	0	0	4	0	0	2	2	0	2	1	0	0	0
		DAY 22	25FEB2003	22	15	-13	3	1	0	0	0	0	4	0	0	2	2	0	2	1	0	0	0
		DAY 29	04MAR2003	29	14	-14	3	1	0	0	0	0	4	0	0	1	2	0	2	1	0	0	0
		DAY 36	11MAR2003	36	11	-17	2	0	0	0	0	1	4	0	0	1	1	0	1	1	0	0	0
		DAY 43	18MAR2003	43	10	-18	2	0	0	0	0	0	4	0	0	1	1	0	1	1	0	0	0
		DAY 50	25MAR2003	50	13	-15	2	1	0	0	0	1	4	0	0	1	2	0	1	1	0	0	0
		DAY 57	31MAR2003	56	10	-18	1	0	0	0	0	1	4	0	0	1	1	0	1	1	0	0	0
	E0023025	SCREEN	01MAY2003	-14	22		3	3	2	1	1	0	3	1	1	3	2	0	1	0	1	0	0
		DAY 1	15MAY2003	1	21		3	2	1	2	1	0	3	1	1	2	1	0	2	0	0	2	0
		DAY 8	22MAY2003	8	16	-5	3	2	1	0	0	0	3	0	1	3	1	0	2	0	0	0	0
		DAY 15	29MAY2003	15	14	-7	3	2	0	0	0	0	3	0	0	3	1	0	2	0	0	0	0
		DAY 22	05JUN2003	22	11	-10	2	2	0	0	0	0	2	0	0	2	1	0	2	0	0	0	0
		DAY 29	12JUN2003	29	6	-15	1	2	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0
		DAY 36	19JUN2003	36	8	-13	1	1	0	0	1	1	1	0	0	1	0	0	1	0	1	0	0
		DAY 43	27JUN2003	44	10	-11	2	1	0	0	0	0	2	0	1	2	0	0	1	0	1	0	0
		DAY 50	03JUL2003	50	7	-14	2	1	0	0	0	0	2	1	0	1	0	0	0	0	0	0	0
		DAY 57	10JUL2003	57	11	-10	2	1	0	0	1	1	2	1	0	1	1	0	1	0	0	0	0
	E0023039	SCREEN	24JUN2003	-7	25		3	2	1	2	2	1	4	0	2	3	1	1	1	2	0	0	0
		DAY 1	01JUL2003	1	26		3	2	1	2	1	2	4	1	1	3	2	1	1	2	0	0	0
		DAY 8	08JUL2003	8	15	-11	1	2	0	0	0	1	2	0	1	3	2	0	1	2	0	0	0
		DAY 15	15JUL2003	15	12	-14	2	2	0	0	0	0	2	0	1	3	0	0	1	1	0	0	0
		DAY 22	22JUL2003	22	8	-18	1	1	0	0	0	0	1	1	0	2	0	0	1	1	0	0	0
		DAY 29	29JUL2003	29	9	-17	2	2	0	0	0	0	1	0	0	2	0	0	1	1	0	0	0
		DAY 36	05AUG2003	36	7	-19	1	1	0	0	0	0	1	0	0	2	0	0	1	1	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	DAY 43	12AUG2003	43	6	-20	0	1	0	0	0	0	1	0	0	1	0	0	2	1	0	0	0
		DAY 50	19AUG2003	50	5	-21	0	1	0	0	0	0	1	0	0	1	0	0	1	1	0	0	0
		DAY 57	26AUG2003	57	4	-22	0	0	0	0	0	0	1	0	0	1	0	0	1	1	0	0	0
	E0026002	SCREEN	05NOV2002	-7	21		3	1	2	0	1	2	4	1	2	1	1	2	1	0	0	0	0
		DAY 1	12NOV2002	1	20		2	2	0	1	1	2	4	1	1	1	0	2	2	0	0	0	1
		DAY 8	19NOV2002	8	19	-1	2	3	2	0	0	0	4	1	3	0	1	1	2	0	0	3	0
		DAY 15	26NOV2002	15	9	-11	3	0	0	0	0	0	2	1	2	0	0	0	1	0	0	0	0
		DAY 22	03DEC2002	22	6	-14	0	0	0	0	0	0	0	0	2	0	2	0	1	0	0	0	1
		DAY 29	11DEC2002	30	6	-14	0	0	0	0	0	0	0	0	1	0	2	0	0	0	0	1	2
		DAY 36	18DEC2002	37	8	-12	2	0	0	1	0	0	0	0	1	1	0	0	1	0	0	2	0
		DAY 43	26DEC2002	45	2	-18	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 50	02JAN2003	52	20	0	2	2	2	0	1	2	3	0	2	3	2	1	0	0	0	0	0
		DAY 57	09JAN2003	59	4	-16	0	0	0	0	0	0	2	0	1	0	0	1	0	0	0	0	0
	E0026007	SCREEN	06JAN2003	-10	20		2	2	2	1	1	0	4	1	0	1	2	1	0	1	0	0	2
		DAY 1	16JAN2003	1	25		2	2	2	2	2	2	2	1	0	3	2	1	2	1	0	1	0
		DAY 8	23JAN2003	8	13	-12	2	2	1	0	0	0	0	2	0	1	0	2	0	0	1	2	0
		DAY 15	30JAN2003	15	5	-20	0	0	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0
		DAY 22	06FEB2003	22	5	-20	0	0	0	0	0	0	0	1	0	0	1	2	1	0	0	0	0
		DAY 29	13FEB2003	29	2	-23	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
		DAY 36	19FEB2003	35	5	-20	0	0	0	0	0	0	0	0	0	1	1	0	2	0	1	0	0
		DAY 43	26FEB2003	42	2	-23	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 50	05MAR2003	49	3	-22	0	0	0	0	0	0	0	1	0	0	1	0	0	0	1	0	0
		DAY 57	12MAR2003	56	3	-22	0	0	0	0	0	0	0	0	0	2	0	0	1	0	0	0	0
	E0026013	SCREEN	05FEB2003	-8	20		3	2	2	2	0	0	3	2	0	2	0	1	1	1	1	0	0
		DAY 1	13FEB2003	1	24		3	2	2	2	2	1	3	2	0	3	0	2	1	1	0	0	0
		DAY 8	20FEB2003	8	22	-2	3	2	2	1	0	0	3	2	0	3	0	2	1	1	1	1	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	DAY 15	27FEB2003	15	22	-2	4	2	2	0	0	0	3	2	0	3	0	1	1	1	1	2	0
		DAY 22	06MAR2003	22	26	2	3	2	2	2	2	0	3	1	0	3	1	2	1	2	2	0	0
		DAY 29	13MAR2003	29	12	-12	1	2	1	0	0	0	3	0	0	2	0	1	1	1	0	0	0
		DAY 36	20MAR2003	36	21	-3	4	2	3	0	0	0	3	1	0	4	0	2	0	0	2	0	0
		DAY 43	27MAR2003	43	6	-18	3	1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 50	03APR2003	50	8	-16	1	1	1	0	0	0	3	0	0	2	0	0	0	0	0	0	0
	E0028007	SCREEN	01OCT2002	-3	20		3	1	1	2	2	0	3	2	1	1	1	1	1	1	0	0	0
		DAY 1	04OCT2002	1	21		3	1	1	2	2	0	3	2	1	1	2	1	1	1	0	0	0
		DAY 8	11OCT2002	8	11	-10	2	1	0	0	0	0	1	0	2	1	1	0	1	0	0	2	0
		DAY 15	16OCT2002	13	8	-13	1	1	0	0	0	0	0	0	1	1	2	0	1	0	0	1	0
		DAY 22	23OCT2002	20	7	-14	1	0	0	0	0	0	1	1	0	1	2	0	0	0	1	0	0
		DAY 29	31OCT2002	28	8	-13	1	0	0	0	0	0	1	0	1	1	1	0	1	2	0	0	0
		DAY 36	07NOV2002	35	4	-17	0	0	0	0	0	0	0	0	0	1	1	0	1	0	1	0	0
		DAY 43	14NOV2002	42	5	-16	2	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0
	E0028023	SCREEN	14JAN2003	-7	26		3	1	1	2	2	1	2	3	1	2	2	1	2	1	0	2	0
		DAY 1	21JAN2003	1	21		3	2	1	2	1	1	3	2	0	3	0	0	1	0	2	0	0
		DAY 8	30JAN2003	10	19	-2	3	2	1	0	0	0	3	1	0	3	2	0	1	0	3	0	0
		DAY 15	04FEB2003	15	17	-4	3	0	0	2	2	0	3	2	0	2	0	0	1	0	2	0	0
		DAY 22	11FEB2003	22	21	0	3	2	1	0	1	2	3	1	1	2	2	0	1	0	2	0	0
		DAY 29	17FEB2003	28	20	-1	2	0	3	2	2	2	0	3	0	2	0	0	1	1	2	0	0
		DAY 36	27FEB2003	38	3	-18	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	04MAR2003	43	0	-21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0028025	SCREEN	08JAN2003	-5	24		3	2	0	2	1	2	3	3	1	1	1	2	1	1	0	1	0
		DAY 1	13JAN2003	1	33		3	3	2	2	2	1	2	2	1	3	3	2	2	0	3	2	0
		DAY 8	17JAN2003	5	11	-22	2	0	1	0	0	0	2	1	0	0	2	0	1	2	0	0	0
		DAY 15	27JAN2003	15	20	-13	1	3	0	1	1	1	2	2	1	1	3	1	1	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	SCREEN		18MAR2003	-9	22		3	1	1	2	2	0	3	3	0	2	1	0	2	2	0	0	0
		DAY 1		27MAR2003	1	20		2	1	0	0	2	1	3	1	2	1	1	1	2	1	0	1	1
		DAY 8		03APR2003	8	16	-4	2	1	0	2	1	0	2	1	1	1	1	0	2	1	1	0	0
		DAY 15		10APR2003	15	15	-5	1	1	0	0	1	0	3	2	1	2	1	0	2	0	1	0	0
		DAY 22		17APR2003	22	8	-12	0	0	0	1	1	0	1	0	1	1	2	0	1	0	0	0	0
		DAY 29		24APR2003	29	6	-14	1	0	0	1	1	0	0	0	1	1	1	0	0	0	0	0	0
		DAY 36		01MAY2003	36	11	-9	2	0	0	2	1	0	2	1	0	1	0	0	2	0	0	0	0
		DAY 43		08MAY2003	43	17	-3	2	1	0	2	1	1	2	2	0	2	2	0	2	0	0	0	0
		DAY 50		15MAY2003	50	15	-5	2	2	0	2	1	0	2	2	0	1	2	0	0	0	1	0	0
		DAY 57		22MAY2003	57	5	-15	0	0	0	1	1	0	0	0	1	0	1	0	1	0	0	0	0
	E0028035	SCREEN		27MAR2003	-7	22		3	2	1	1	2	0	3	1	2	2	2	1	1	1	0	0	0
		DAY 1		03APR2003	1	23		3	2	2	2	2	0	2	0	1	3	3	0	1	0	2	0	0
		DAY 8		10APR2003	8	22	-1	3	2	1	0	1	0	3	0	3	3	2	0	2	0	2	0	0
		DAY 15		17APR2003	15	20	-3	3	2	1	0	0	0	3	1	1	3	2	0	1	2	1	0	0
		DAY 22		24APR2003	22	18	-5	3	2	1	0	0	0	3	0	1	2	2	0	1	2	1	0	0
		DAY 29		01MAY2003	29	12	-11	0	2	0	1	0	0	1	1	1	0	2	0	1	1	2	0	0
		DAY 36		08MAY2003	36	17	-6	2	2	0	0	0	0	3	2	0	2	2	0	1	1	2	0	0
		DAY 43		15MAY2003	43	13	-10	0	0	0	2	2	0	0	1	1	1	2	0	1	1	2	0	0
		DAY 50		22MAY2003	50	18	-5	2	2	1	0	0	0	2	0	2	3	1	0	2	1	2	0	0
		DAY 57		29MAY2003	57	17	-6	2	0	0	1	2	0	2	1	0	2	2	0	2	1	2	0	0
	E0028037	SCREEN		09JUN2003	-4	28		3	2	0	2	2	1	3	3	0	3	1	2	2	2	0	2	0
		DAY 1		12JUN2003	-1	22		2	1	1	0	2	2	3	2	0	3	2	0	2	1	1	0	0
		DAY 8		20JUN2003	8	11	-11	1	2	1	0	0	0	1	1	1	2	1	0	0	1	0	0	0
		DAY 15		25JUN2003	13	11	-11	2	2	0	0	0	0	0	2	0	3	1	0	0	1	0	0	0
		DAY 15	*	01JUL2003	19	6	-16	1	2	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0
		DAY 22		08JUL2003	26	4	-18	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	2
		DAY 36		16JUL2003	34	4	-18	1	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	DAY 43	23JUL2003	41	5	-17	0	0	0	0	0	2	0	1	0	2	0	0	0	0	0	0	0
		DAY 50	30JUL2003	48	3	-19	1	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	08AUG2003	57	2	-20	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	E0028039	SCREEN	02MAY2003	-7	29		3	2	2	2	2	2	2	1	1	3	1	2	2	2	0	2	0
		DAY 1	08MAY2003	-1	29		3	2	2	2	2	2	2	1	1	3	1	2	2	2	0	2	0
		DAY 8	16MAY2003	8	28	-1	2	4	3	0	2	0	2	1	1	2	3	2	1	2	1	2	0
		DAY 15	22MAY2003	14	20	-9	2	2	1	0	0	0	1	0	1	2	2	2	2	2	1	2	0
		DAY 22	29MAY2003	21	18	-11	2	0	1	0	1	0	2	1	0	2	2	2	1	1	1	2	0
		DAY 29	05JUN2003	28	15	-14	1	1	0	0	1	1	1	1	0	3	1	1	2	1	1	0	0
	E0028046	SCREEN	17JUN2003	-8	22		3	1	2	2	2	1	2	0	1	2	1	1	2	2	0	0	0
		DAY 1	25JUN2003	1	28		3	2	2	2	0	2	3	1	1	3	3	1	2	2	0	1	0
	E0028048	SCREEN	11JUL2003	-6	23		3	1	0	2	2	1	2	2	0	2	1	1	2	2	1	1	0
		DAY 1	17JUL2003	1	26		3	1	0	2	2	2	3	2	0	3	3	1	2	1	1	0	0
		DAY 8	24JUL2003	8	15	-11	3	0	0	0	0	0	3	2	0	1	3	0	2	0	1	0	0
		DAY 15	31JUL2003	15	5	-21	1	0	0	0	0	0	0	1	0	0	2	0	0	1	0	0	0
		DAY 22	06AUG2003	21	3	-23	0	0	0	0	0	0	0	0	0	0	2	0	1	0	0	0	0
		DAY 29	14AUG2003	29	4	-22	0	0	0	0	0	0	1	0	0	0	3	0	0	0	0	0	0
		DAY 36	21AUG2003	36	3	-23	0	0	0	0	0	0	0	0	0	0	2	0	1	0	0	0	0
		DAY 43	29AUG2003	44	5	-21	0	0	0	0	0	0	2	1	0	0	2	0	0	0	0	0	0
		DAY 57	09SEP2003	55	11	-15	0	0	0	0	0	0	2	2	0	1	2	0	2	1	1	0	0
	E0029008	SCREEN	09DEC2002	-7	27		3	0	0	2	2	1	3	1	1	3	3	1	2	2	2	1	0
		DAY 1	16DEC2002	1	26		2	1	0	2	2	1	3	1	1	3	2	1	2	2	2	1	0
		DAY 8	23DEC2002	8	28	2	3	2	0	2	0	0	3	2	3	3	2	1	2	2	3	0	0
	E0029011	SCREEN	14JAN2003	-8	24		2	2	2	2	2	2	3	1	1	2	1	0	2	0	1	1	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	DAY 1	21JAN2003	-1	24		3	2	1	2	0	0	3	2	0	3	2	1	2	0	3	0	0
		DAY 8	28JAN2003	7	17	-7	2	2	0	0	0	0	2	1	2	2	1	1	2	0	1	1	0
		DAY 15	04FEB2003	14	20	-4	3	3	0	1	0	0	1	2	2	3	1	1	2	0	1	0	0
		DAY 22	13FEB2003	23	16	-8	3	2	0	0	0	0	2	2	0	2	0	1	2	0	1	1	0
	E0029012	SCREEN	04FEB2003	-7	27		3	2	3	0	2	1	3	1	1	3	2	1	2	2	1	0	0
		DAY 1	11FEB2003	1	27		4	2	3	0	1	0	2	3	2	3	1	0	2	2	2	0	0
		DAY 8	19FEB2003	9	15	-12	3	0	2	0	0	0	2	1	0	2	1	0	1	2	1	0	0
		DAY 15	26FEB2003	16	17	-10	2	1	2	0	0	0	2	1	1	1	2	0	2	2	1	0	0
		DAY 22	03MAR2003	21	15	-12	2	1	1	0	0	0	2	0	2	3	1	0	1	1	1	0	0
		DAY 29	11MAR2003	29	20	-7	4	0	3	0	0	0	3	2	1	3	1	0	2	0	1	0	0
		DAY 36	18MAR2003	36	27	0	4	3	3	0	0	0	3	2	1	3	2	0	2	2	2	0	0
	E0029015	SCREEN	11FEB2003	-13	26		3	2	1	2	2	2	3	0	3	3	1	1	2	0	1	0	0
		DAY 1	24FEB2003	1	26		3	2	0	2	2	1	3	0	3	3	3	1	2	0	1	0	0
		DAY 8	03MAR2003	8	22	-4	2	2	0	2	1	1	1	0	4	3	2	0	2	0	2	0	0
		DAY 15	11MAR2003	16	22	-4	2	2	0	1	2	0	2	0	3	3	2	0	2	0	1	2	0
	E0029018	SCREEN	26FEB2003	-8	20		2	2	0	1	1	1	3	2	0	2	2	1	2	0	1	0	0
		DAY 1	06MAR2003	1	20		2	2	0	2	2	0	3	2	0	2	0	0	2	1	2	0	0
	E0030014	SCREEN	14FEB2003	-7	28		3	2	2	2	2	0	3	2	2	3	3	0	2	2	0	0	0
		DAY 1	21FEB2003	1	29		3	2	2	2	2	1	4	1	1	1	2	2	2	2	2	0	0
		DAY 8	28FEB2003	8	16	-13	1	2	1	0	0	0	3	2	0	0	1	2	2	2	0	0	0
		DAY 15	07MAR2003	15	16	-13	3	0	2	0	0	0	3	0	0	1	2	1	1	2	1	0	0
		DAY 22	14MAR2003	22	13	-16	1	2	2	0	0	0	2	0	0	1	1	0	1	2	1	0	0
		DAY 29	21MAR2003	29	13	-16	1	1	2	0	0	0	1	1	1	1	2	0	1	2	0	0	0
		DAY 36	27MAR2003	35	11	-18	1	0	1	1	0	0	2	0	1	1	1	0	0	2	1	0	0
		DAY 43	04APR2003	43	17	-12	2	1	2	2	0	0	1	0	1	2	2	1	1	1	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	DAY 50	11APR2003	50	12	-17	1	0	1	1	0	0	1	0	0	1	2	1	2	2	0	0	0
		DAY 57	22APR2003	61	7	-22	1	0	0	0	0	0	1	0	1	1	0	1	1	1	0	0	0
	E0030020	SCREEN	13MAY2003	-16	23		3	2	2	2	2	1	3	0	1	2	2	0	2	0	1	0	0
		DAY 1	29MAY2003	1	27		3	3	2	2	0	1	2	2	1	2	2	1	2	2	2	0	0
		DAY 8	05JUN2003	8	17	-10	2	2	0	0	0	0	3	1	1	2	2	0	2	2	0	0	0
		DAY 15	12JUN2003	15	8	-19	0	0	0	0	0	0	1	2	1	0	2	0	1	0	1	0	0
		DAY 22	17JUN2003	20	12	-15	1	1	0	0	0	0	0	1	2	2	0	0	2	2	1	0	0
		DAY 29	24JUN2003	27	6	-21	0	0	0	0	0	1	0	1	1	0	0	0	0	2	1	0	0
	E0030024	SCREEN	17JUN2003	-24	28		3	2	2	2	1	1	3	1	1	2	2	1	2	2	3	0	0
		DAY 1	11JUL2003	1	25		3	2	0	2	2	1	3	0	0	2	2	1	2	2	3	0	0
		DAY 8	18JUL2003	8	22	-3	2	2	2	1	1	1	3	0	1	1	2	1	2	1	2	0	0
	E0030025	SCREEN	24JUN2003	-17	27		4	3	0	2	2	2	3	2	0	2	1	0	2	2	2	0	0
		DAY 1	11JUL2003	1	29		3	3	2	2	2	2	3	1	0	2	3	1	2	2	1	0	0
		DAY 8	18JUL2003	8	25	-4	3	3	2	2	1	1	2	1	0	1	2	1	2	2	2	0	0
		DAY 15	25JUL2003	15	15	-14	1	2	0	0	1	1	1	1	0	1	2	1	1	2	1	0	0
		DAY 22	31JUL2003	21	13	-16	1	1	0	1	2	0	1	2	1	0	0	1	1	2	0	0	0
		DAY 29	11AUG2003	32	16	-13	2	1	1	0	0	0	2	2	0	1	1	2	1	2	1	0	0
		DAY 36	19AUG2003	40	25	-4	2	2	0	0	1	0	3	2	1	2	2	2	2	2	2	2	0
	E0031027	SCREEN	27MAY2003	-7	26		3	2	0	2	2	1	2	0	1	3	2	2	2	1	1	2	0
		DAY 1	03JUN2003	1	29		3	2	0	2	2	1	3	0	1	3	3	2	2	1	2	2	0
		DAY 8	11JUN2003	9	19	-10	3	0	0	1	1	1	1	0	2	3	2	2	1	1	1	0	0
		DAY 15	17JUN2003	15	20	-9	3	2	0	2	2	1	1	0	1	2	2	1	1	1	0	1	0
		DAY 22	24JUN2003	22	15	-14	1	0	0	1	2	2	1	0	2	2	0	2	1	0	0	1	0
		DAY 29	01JUL2003	29	17	-12	2	0	0	2	0	1	1	0	2	3	2	2	2	0	0	0	0
		DAY 36	09JUL2003	37	9	-20	2	0	0	1	0	0	1	0	1	2	0	1	0	0	0	1	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0031027	DAY 43	15JUL2003	43	6	-23	1	0	0	0	0	0	0	0	3	2	0	0	0	0	0	0	0
		DAY 50	22JUL2003	50	3	-26	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0
		DAY 57	29JUL2003	57	2	-27	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
	E0031030	SCREEN	17JUN2003	-7	23		3	1	2	2	2	2	3	0	1	2	2	1	2	0	0	0	0
		DAY 1	24JUN2003	1	22		3	2	2	2	2	2	2	0	0	3	1	1	2	0	0	0	0
		DAY 8	01JUL2003	8	10	-12	2	2	0	0	1	1	2	0	0	1	0	0	0	1	0	0	0
		DAY 15	08JUL2003	15	9	-13	0	0	0	0	2	2	1	1	0	1	1	0	1	0	0	0	0
		DAY 22	16JUL2003	23	12	-10	0	0	0	1	2	2	1	1	0	2	1	1	1	0	0	0	0
		DAY 29	23JUL2003	30	2	-20	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	31JUL2003	38	2	-20	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	08AUG2003	46	3	-19	0	0	0	1	0	2	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	14AUG2003	52	15	-7	1	1	0	0	2	2	1	0	0	2	2	1	2	0	0	1	0
		DAY 57	21AUG2003	59	8	-14	0	0	0	1	2	2	0	0	1	2	0	0	0	0	0	0	0
	E0033012	SCREEN	05FEB2003	-5	27		3	2	2	2	1	0	3	2	2	3	1	2	2	1	0	1	0
		DAY 1	10FEB2003	1	27		3	2	2	2	2	0	3	2	1	3	2	2	2	1	0	0	0
	E0034001	SCREEN	13MAR2003	-7	28		4	2	0	0	2	0	4	3	2	3	2	0	2	2	2	0	0
		DAY 1	20MAR2003	1	30		4	2	0	1	2	0	4	3	3	3	2	0	2	2	2	0	0
		DAY 8	27MAR2003	8	27	-3	4	2	0	0	1	0	4	3	2	3	2	0	2	2	2	0	0
		DAY 15	03APR2003	15	12	-18	2	1	0	0	0	0	1	2	1	1	0	0	2	2	0	0	0
		DAY 22	10APR2003	22	14	-16	2	2	0	0	0	0	1	2	1	2	0	0	2	2	0	0	0
		DAY 29	17APR2003	29	13	-17	2	2	0	0	0	0	1	2	0	2	0	0	2	2	0	0	0
		DAY 36	24APR2003	36	12	-18	2	2	0	0	0	0	1	1	0	2	0	0	2	2	0	0	0
		DAY 43	01MAY2003	43	12	-18	2	2	0	0	0	0	1	1	0	2	0	0	2	2	0	0	0
		DAY 50	08MAY2003	50	12	-18	2	2	0	0	0	0	1	1	0	2	0	0	1	2	0	1	0
		DAY 57	15MAY2003	57	9	-21	2	2	0	0	0	0	1	0	0	1	0	0	1	2	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	SCREEN		11APR2003	-10	28		3	2	2	0	2	2	3	2	2	2	2	0	2	2	2	0	0
		DAY 1		21APR2003	1	27		3	2	2	0	2	2	3	2	2	2	2	0	2	2	1	0	0
		DAY 8		30APR2003	10	19	-8	2	2	2	0	0	0	2	1	2	2	2	0	2	2	0	0	0
		DAY 15		05MAY2003	15	14	-13	2	0	0	0	2	0	1	0	1	2	2	0	2	2	0	0	0
		DAY 22		13MAY2003	23	4	-23	1	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	0
		DAY 29		19MAY2003	29	3	-24	0	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	0
		DAY 29	*	23MAY2003	33	3	-24	0	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	0
		DAY 43		02JUN2003	43	2	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 50		09JUN2003	50	2	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 57		16JUN2003	57	2	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
	E0035001	SCREEN		12NOV2002	-8	24		3	2	2	0	2	1	4	0	0	2	3	2	1	1	0	1	0
		DAY 1		20NOV2002	1	22		3	1	0	0	1	2	4	0	1	2	1	2	1	1	1	2	0
		DAY 8		27NOV2002	8	13	-9	2	1	0	0	0	1	4	0	0	1	0	1	1	1	0	1	0
		DAY 15		03DEC2002	14	14	-8	2	1	0	0	0	1	4	0	0	2	0	1	1	1	0	1	0
		DAY 22		12DEC2002	23	14	-8	2	1	0	0	0	1	4	0	0	2	0	1	1	1	0	1	0
		DAY 29		18DEC2002	29	12	-10	2	1	0	0	1	1	4	0	0	2	0	0	0	1	0	0	0
		DAY 36		23DEC2002	34	11	-11	2	0	0	0	1	1	4	0	0	2	0	0	0	1	0	0	0
		DAY 43		30DEC2002	41	10	-12	2	0	0	0	0	1	4	0	0	2	0	0	0	1	0	0	0
		DAY 50		07JAN2003	49	10	-12	2	0	0	0	0	1	4	0	0	2	0	0	0	1	0	0	0
		DAY 57		14JAN2003	56	2	-20	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0
	E0035006	SCREEN		03DEC2002	-9	25		3	2	2	1	2	2	4	0	0	2	0	2	1	2	2	0	0
		DAY 1		12DEC2002	1	26		3	2	2	1	2	2	4	0	1	2	1	2	1	2	1	0	0
		DAY 8		19DEC2002	8	23	-3	3	2	2	1	1	1	4	0	0	2	1	1	1	2	2	0	0
		DAY 15		26DEC2002	15	27	1	3	2	2	2	2	2	4	0	0	2	1	2	1	2	2	0	0
		DAY 22		02JAN2003	22	27	1	3	2	2	1	1	2	4	0	1	2	2	2	1	2	2	0	0
		DAY 29		09JAN2003	29	24	-2	3	1	1	2	1	2	4	0	0	2	1	2	1	2	2	0	0
		DAY 36		16JAN2003	36	26	0	3	1	2	2	2	2	4	0	0	2	1	2	1	2	2	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 43	24JAN2003	44	26	0	3	2	2	0	2	1	4	0	0	3	2	1	1	2	2	1	0
		DAY 50	30JAN2003	50	30	4	3	2	3	1	2	2	4	0	0	3	2	2	1	2	2	1	0
		DAY 57	06FEB2003	57	23	-3	3	0	0	1	2	1	4	0	1	2	1	2	1	2	2	1	0
	E0035021	SCREEN	18APR2003	-7	21		3	2	0	1	2	2	4	0	0	2	2	0	1	2	0	0	0
		DAY 1	25APR2003	1	23		2	2	0	2	2	2	4	0	0	2	2	0	1	2	0	2	0
		DAY 8	01MAY2003	7	12	-11	1	1	0	0	0	0	4	0	0	1	1	0	0	2	0	2	0
		DAY 15	09MAY2003	15	14	-9	1	0	0	0	0	0	4	0	0	2	1	1	1	2	0	2	0
		DAY 22	15MAY2003	21	12	-11	1	1	0	0	0	0	4	0	0	2	0	1	1	0	0	2	0
		DAY 29	23MAY2003	29	11	-12	1	1	0	0	0	0	4	0	0	2	0	1	0	0	0	2	0
		DAY 36	30MAY2003	36	18	-5	1	2	0	0	0	0	4	0	0	3	2	2	2	0	0	2	0
		DAY 43	09JUN2003	46	4	-19	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	2	0
		DAY 50	13JUN2003	50	4	-19	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	2	0
		DAY 57	20JUN2003	57	5	-18	1	1	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0
	E0036002	SCREEN	10JUN2003	-7	27		3	2	2	2	2	2	3	1	0	3	1	1	2	2	1	0	0
		DAY 1	17JUN2003	1	25		3	2	2	2	2	0	3	1	1	3	1	2	2	1	0	0	0
		DAY 8	24JUN2003	8	17	-8	2	1	2	0	0	0	2	1	0	3	1	2	2	1	0	0	0
		DAY 15	30JUN2003	14	11	-14	2	1	0	0	0	0	2	0	1	1	1	1	1	1	0	0	0
		DAY 22	08JUL2003	22	12	-13	0	1	0	0	0	0	2	0	3	2	2	0	1	0	1	0	0
		DAY 29	14JUL2003	28	5	-20	0	0	0	0	1	0	0	0	3	1	0	0	0	0	0	0	0
	E0036006	SCREEN	24JUN2003	-9	24		3	2	0	2	2	0	3	2	1	2	2	0	2	1	2	0	0
		DAY 1	03JUL2003	1	24		3	2	1	2	2	0	3	2	1	2	1	0	2	1	2	0	0
		DAY 8	10JUL2003	8	7	-17	0	0	0	0	0	0	2	0	1	2	0	0	2	0	0	0	0
		DAY 15	18JUL2003	16	3	-21	0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0
		DAY 22	25JUL2003	23	4	-20	0	0	0	0	1	0	1	0	1	0	0	0	1	0	0	0	0
		DAY 29	31JUL2003	29	1	-23	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 36	07AUG2003	36	2	-22	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	DAY 43	13AUG2003	42	3	-21	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0
		DAY 50	20AUG2003	49	1	-23	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	27AUG2003	56	1	-23	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	E0036007	SCREEN	26JUN2003	-7	23		3	2	1	2	2	0	3	2	0	2	2	0	2	2	0	0	0
		DAY 1	03JUL2003	1	24		3	2	1	2	2	0	3	2	0	2	2	1	2	2	0	0	0
		DAY 8	08JUL2003	6	20	-4	2	1	1	2	1	1	3	2	2	2	0	0	1	2	0	0	0
		DAY 15	18JUL2003	16	5	-19	0	0	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0
	E0037009	SCREEN	09MAY2003	-7	26		3	2	1	2	2	2	3	1	1	2	1	1	2	0	2	1	0
		DAY 1	16MAY2003	1	24		3	2	1	2	2	2	2	1	0	2	1	1	2	0	2	1	0
		DAY 8	23MAY2003	8	16	-8	2	2	1	1	2	0	2	0	0	2	1	0	1	0	2	0	0
		DAY 15	29MAY2003	14	13	-11	1	2	0	1	2	0	1	1	0	1	1	0	1	0	2	0	0
		DAY 22	05JUN2003	21	15	-9	2	2	1	2	2	0	2	0	0	1	1	0	1	1	0	0	0
		DAY 29	12JUN2003	28	15	-9	2	2	1	2	2	0	1	0	0	0	1	0	2	1	1	0	0
		DAY 36	19JUN2003	35	16	-8	2	2	1	1	2	0	2	0	1	1	1	0	2	0	1	0	0
		DAY 43	26JUN2003	42	12	-12	2	2	0	0	0	0	2	0	1	1	1	0	2	0	1	0	0
		DAY 50	03JUL2003	49	11	-13	2	1	2	1	0	0	2	0	0	1	1	0	0	0	1	0	0
		DAY 57	10JUL2003	56	11	-13	1	2	0	1	1	0	1	0	0	1	1	0	2	0	1	0	0
	E0039011	SCREEN	16DEC2002	-17	27		3	2	1	2	2	2	4	0	2	1	1	2	2	2	0	1	0
		DAY 1	02JAN2003	1	27		3	2	2	2	0	2	3	1	3	2	2	1	1	2	0	1	0
		DAY 8	09JAN2003	8	12	-15	1	0	1	0	0	0	2	1	1	1	1	1	1	2	0	0	0
		DAY 15	16JAN2003	15	17	-10	1	0	1	2	1	1	2	1	2	1	1	1	1	2	0	0	0
		DAY 22	23JAN2003	22	18	-9	2	1	1	2	1	2	2	1	3	1	2	0	0	0	0	0	0
		DAY 29	03FEB2003	33	1	-26	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	06FEB2003	36	0	-27	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	13FEB2003	43	4	-23	0	0	0	0	0	0	0	0	2	0	0	0	0	2	0	0	0
		DAY 50	19FEB2003	49	4	-23	0	0	0	0	0	0	0	0	2	0	0	0	0	2	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0039018	SCREEN	14JAN2003	-9	20		3	0	0	2	2	0	3	2	1	2	2	0	2	0	1	0	0
		DAY 1	23JAN2003	1	31		3	3	2	2	2	2	4	1	2	2	2	1	2	2	0	1	0
		DAY 8	30JAN2003	8	9	-22	2	2	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0
		DAY 15	06FEB2003	15	13	-18	2	1	1	1	0	0	2	1	1	2	1	0	1	0	0	0	0
		DAY 22	13FEB2003	22	5	-26	1	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0
		DAY 29	20FEB2003	29	6	-25	1	0	0	0	0	0	0	1	0	1	2	0	0	0	1	0	0
	E0039026	SCREEN	26FEB2003	-9	21		3	2	1	2	2	1	3	2	0	2	0	1	1	0	1	0	0
		DAY 1	07MAR2003	1	22		3	2	1	0	1	2	3	2	1	2	1	0	1	2	1	0	0
		DAY 8	14MAR2003	8	7	-15	1	1	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0
		DAY 15	19MAR2003	13	5	-17	0	0	0	0	0	0	0	0	1	1	1	0	0	1	1	0	0
		DAY 22	28MAR2003	22	6	-16	1	1	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0
		DAY 29	04APR2003	29	6	-16	1	1	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0
		DAY 36	11APR2003	36	9	-13	1	0	0	0	0	0	1	1	1	1	2	0	0	1	1	0	0
		DAY 43	18APR2003	43	4	-18	0	0	0	0	0	0	1	0	1	1	1	0	0	0	0	0	0
		DAY 50	25APR2003	50	5	-17	0	0	0	0	0	0	0	1	1	0	2	0	0	1	0	0	0
		DAY 57	01MAY2003	56	3	-19	0	0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0
	E0039028	SCREEN	03MAR2003	-21	27		3	2	2	2	2	2	3	1	2	2	1	0	1	2	2	0	0
		DAY 1	24MAR2003	1	28		3	2	2	2	2	2	3	1	2	2	1	1	1	2	2	0	0
		DAY 8	31MAR2003	8	12	-16	1	0	0	0	0	0	3	0	1	2	1	0	1	2	1	0	0
		DAY 15	07APR2003	15	9	-19	1	1	0	0	0	0	2	0	1	1	1	0	0	2	0	0	0
		DAY 22	14APR2003	22	8	-20	1	1	0	0	0	0	0	0	1	1	2	0	0	2	0	0	0
		DAY 29	21APR2003	29	19	-9	2	2	2	0	0	2	2	1	0	2	2	0	1	2	1	0	0
		DAY 36	28APR2003	36	14	-14	1	2	1	0	0	0	1	0	1	2	1	0	1	2	2	0	0
		DAY 43	05MAY2003	43	7	-21	0	0	0	0	0	0	0	0	0	1	2	0	0	2	2	0	0
	E0039032	SCREEN	07MAR2003	-7	25		3	3	1	2	2	2	4	1	0	2	1	1	1	0	1	1	0
		DAY 1	14MAR2003	1	26		3	3	2	2	2	2	4	1	0	2	1	1	1	0	1	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	DAY 8	19MAR2003	6	9	-17	0	1	0	0	0	0	2	0	1	2	1	1	0	0	1	0	0
	E0039034	SCREEN	12MAR2003	-7	24		3	2	1	2	2	0	3	1	1	2	2	1	1	2	1	0	0
		DAY 1	19MAR2003	1	21		3	2	1	1	2	0	3	2	1	2	1	0	1	1	1	0	0
		DAY 8	26MAR2003	8	6	-15	1	1	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0
		DAY 15	02APR2003	15	6	-15	1	1	0	0	0	0	0	0	0	1	1	0	2	0	0	0	0
		DAY 22	09APR2003	22	3	-18	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0
		DAY 29	16APR2003	29	4	-17	0	0	0	0	0	0	1	0	1	1	1	0	0	0	0	0	0
		DAY 36	24APR2003	37	1	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 43	30APR2003	43	2	-19	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 50	09MAY2003	52	2	-19	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 57	14MAY2003	57	0	-21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0039042	SCREEN	24APR2003	-13	23		3	2	2	2	1	2	3	0	2	2	1	0	2	0	1	0	0
		DAY 1	07MAY2003	1	21		3	2	0	2	2	1	3	1	1	1	0	1	2	2	0	0	0
		DAY 8	14MAY2003	8	12	-9	2	2	0	0	0	0	1	1	1	1	2	0	1	0	1	0	0
		DAY 15	21MAY2003	15	9	-12	1	1	0	1	0	0	1	0	2	1	1	0	1	0	0	0	0
		DAY 22	28MAY2003	22	5	-16	1	1	0	0	0	0	1	1	0	0	1	0	0	0	0	0	0
		DAY 29	05JUN2003	30	2	-19	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0
		DAY 36	11JUN2003	36	3	-18	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0
		DAY 43	18JUN2003	43	1	-20	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	25JUN2003	50	6	-15	1	1	0	0	0	0	1	0	1	0	1	0	0	1	0	0	0
		DAY 57	02JUL2003	57	3	-18	0	0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0
	E0041004	SCREEN	22JAN2003	-8	21		2	2	0	2	1	1	2	1	2	2	2	0	2	0	2	0	0
		DAY 1	30JAN2003	1	22		2	2	0	2	0	1	2	1	2	1	2	2	2	0	2	1	0
		DAY 8	10FEB2003	12	9	-13	1	0	0	0	0	0	1	0	2	0	2	0	2	0	1	0	0
		DAY 15	14FEB2003	16	6	-16	0	0	0	0	0	0	0	0	1	1	2	0	1	0	1	0	0
		DAY 22	20FEB2003	22	6	-16	0	0	0	0	0	0	0	0	1	0	1	1	1	1	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	DAY 29	27FEB2003	29	8	-14	1	0	0	2	1	0	0	0	0	1	1	1	0	0	1	0	0
		DAY 36	07MAR2003	37	6	-16	0	0	0	0	0	0	0	0	1	0	1	1	1	1	1	0	0
		DAY 43	14MAR2003	44	5	-17	0	0	0	0	0	0	0	0	1	1	2	0	0	0	1	0	0
		DAY 50	21MAR2003	51	4	-18	0	0	0	0	0	0	0	0	1	1	1	0	0	0	1	0	0
		DAY 57	31MAR2003	61	5	-17	0	1	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0
	E0041009	SCREEN	22APR2003	-9	23		2	2	0	2	2	2	2	1	2	2	1	0	2	1	2	0	0
		DAY 1	01MAY2003	1	28		2	3	0	2	2	2	3	1	1	2	2	1	2	2	2	1	0
		DAY 8	08MAY2003	8	16	-12	1	2	0	2	1	1	2	1	0	0	1	0	1	2	2	0	0
		DAY 15	15MAY2003	15	20	-8	2	2	0	2	2	1	1	1	1	2	1	0	1	2	2	0	0
		DAY 22	22MAY2003	22	7	-21	0	0	0	2	1	0	1	1	0	0	0	0	0	0	2	0	0
	E0042002	SCREEN	02JUL2003	-7	21		2	2	0	1	1	2	2	1	1	2	2	0	2	1	2	0	0
		DAY 1	09JUL2003	1	25		2	2	0	2	1	2	2	2	2	2	2	0	2	1	3	0	0
		DAY 8	15JUL2003	7	9	-16	1	0	0	1	0	0	1	1	0	1	1	0	2	0	1	0	0
		DAY 15	22JUL2003	14	4	-21	0	0	0	0	0	1	0	0	1	1	0	0	1	0	0	0	0
		DAY 22	29JUL2003	21	5	-20	1	0	0	0	0	0	1	1	0	0	0	0	1	0	1	0	0
		DAY 29	05AUG2003	28	4	-21	0	0	0	0	0	0	0	0	1	1	1	0	1	0	0	0	0
		DAY 36	12AUG2003	35	1	-24	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	19AUG2003	42	2	-23	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 50	26AUG2003	49	0	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	02SEP2003	56	1	-24	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	SCREEN	23JUN2003	-18	24		4	3	2	0	1	0	3	2	1	4	2	0	2	0	0	0	0
		DAY 1	11JUL2003	1	23		4	3	1	0	0	0	3	2	2	3	2	0	2	0	1	0	0
		DAY 8	18JUL2003	8	13	-10	3	2	0	0	0	0	3	1	1	3	0	0	0	0	0	0	0
	E0003002	SCREEN	22OCT2002	-7	34		3	3	2	2	2	1	3	1	2	3	3	1	2	2	3	1	0
		DAY 1	29OCT2002	1	31		3	3	2	2	2	0	2	2	2	3	2	2	0	2	3	1	0
		DAY 8	05NOV2002	8	13	-18	3	3	0	2	0	0	0	1	1	0	0	0	1	1	0	1	0
		DAY 15	14NOV2002	17	8	-23	1	1	0	0	0	0	2	0	0	2	1	0	1	0	0	0	0
		DAY 22	19NOV2002	22	12	-19	2	3	0	0	0	0	2	1	1	2	0	0	0	1	0	0	0
		DAY 29	26NOV2002	29	9	-22	0	0	0	0	0	0	0	1	1	3	0	0	2	1	0	0	1
		DAY 36	03DEC2002	36	5	-26	1	0	0	0	0	0	1	0	0	2	0	0	1	0	0	0	0
		DAY 43	10DEC2002	43	3	-28	0	2	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 50	17DEC2002	50	2	-29	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 57	23DEC2002	56	1	-30	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0005031	SCREEN	26MAR2003	-7	24		3	2	1	0	2	0	3	2	2	3	2	0	2	1	1	0	0
		DAY 1	02APR2003	1	20		3	2	0	1	1	0	3	1	2	3	1	1	1	0	1	0	0
		DAY 8	09APR2003	8	11	-9	1	1	0	1	0	0	0	1	3	1	1	1	1	0	0	0	0
		DAY 15	16APR2003	15	10	-10	0	1	0	0	0	0	1	1	3	1	1	1	1	0	0	0	0
		DAY 22	24APR2003	23	15	-5	2	1	1	0	0	0	2	1	2	2	2	0	2	0	0	0	0
		DAY 29	01MAY2003	30	16	-4	2	1	0	0	0	0	2	2	3	2	2	0	1	0	1	0	0
		DAY 36	07MAY2003	36	7	-13	1	0	0	0	0	0	1	1	1	1	1	0	1	0	0	0	0
		DAY 43	14MAY2003	43	8	-12	1	0	0	0	0	0	1	1	1	1	1	0	1	0	1	0	0
	E0005033	SCREEN	08APR2003	-8	29		3	3	2	2	2	2	3	2	1	2	2	0	2	2	1	0	0
		DAY 1	15APR2003	-1	29		3	3	2	2	2	2	3	1	1	2	2	1	2	2	1	0	0
		DAY 8	22APR2003	7	24	-5	3	3	1	0	1	0	3	2	1	2	2	1	2	2	1	0	0
		DAY 15	30APR2003	15	23	-6	3	3	1	0	0	0	3	2	1	3	2	0	2	2	1	0	0
		DAY 22	06MAY2003	21	24	-5	3	3	1	0	1	0	3	2	1	3	2	0	2	2	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0005038	SCREEN		05MAY2003	-9	31		3	2	2	2	2	2	3	2	1	3	2	1	2	2	2	0	0
		DAY 1		14MAY2003	1	27		3	2	1	2	2	2	3	2	1	3	0	1	2	1	2	0	0
		DAY 8		22MAY2003	9	24	-3	3	2	1	2	2	0	3	1	1	3	1	1	1	2	1	0	0
		DAY 15		28MAY2003	15	29	2	3	2	1	2	2	2	3	2	3	3	2	0	2	1	1	0	0
		DAY 22		05JUN2003	23	24	-3	3	2	1	1	2	1	3	1	1	3	1	1	1	2	1	0	0
	E0007009	SCREEN		09APR2003	-8	22		4	2	1	0	0	0	3	2	0	3	2	1	2	2	0	0	0
		DAY 1		17APR2003	1	21		4	2	1	0	0	0	3	1	0	3	2	1	2	2	0	0	0
		DAY 8		24APR2003	8	14	-7	3	2	0	0	0	0	3	0	0	2	1	0	2	1	0	0	0
		DAY 8	*	28APR2003	12	19	-2	3	2	0	0	0	0	3	1	0	3	2	1	2	2	0	0	0
	E0009010	SCREEN		27FEB2003	-14	29		3	2	2	2	2	2	3	1	2	2	2	1	1	2	0	2	0
		DAY 1		13MAR2003	1	27		3	2	2	2	2	1	3	1	2	2	2	1	2	0	1	1	0
		DAY 8		20MAR2003	8	19	-8	2	2	1	1	0	0	2	1	2	2	2	1	1	1	1	0	0
		DAY 15		26MAR2003	14	21	-6	1	2	2	2	1	0	1	1	2	1	3	0	2	1	2	0	0
		DAY 22		02APR2003	21	19	-8	2	2	2	0	1	1	1	0	2	2	3	0	1	1	1	0	0
	E0009011	SCREEN		28APR2003	-8	20		3	2	2	1	0	0	4	1	1	1	0	0	2	2	0	0	1
		DAY 1		06MAY2003	1	22		3	2	2	1	1	0	4	1	2	0	0	2	2	2	0	0	0
		DAY 8		12MAY2003	7	15	-7	2	2	2	0	1	1	3	1	1	1	0	0	1	0	0	0	0
		DAY 15		19MAY2003	14	11	-11	2	1	0	0	0	0	2	1	0	2	1	1	1	0	0	0	0
		DAY 22		27MAY2003	22	8	-14	1	1	0	0	0	0	1	0	1	0	1	1	1	0	0	1	0
		DAY 29		03JUN2003	29	4	-18	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	2	0
		DAY 36		10JUN2003	36	2	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
		DAY 43		17JUN2003	43	14	-8	2	1	2	0	0	0	2	0	0	0	0	2	2	2	0	0	1
		DAY 50		24JUN2003	50	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		03JUL2003	59	6	-16	3	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
	E0010005	SCREEN		10DEC2002	-8	21		3	2	0	2	1	0	3	1	1	3	1	0	1	0	2	0	1

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0010005	DAY 1		18DEC2002	1	22		3	2	0	2	2	2	3	1	1	3	1	0	1	0	0	0	1
	E0011016	SCREEN		14APR2003	-7	27		3	2	2	2	2	1	2	2	1	2	2	0	2	1	2	0	1
		DAY 1		21APR2003	1	23		3	2	2	2	2	2	2	0	1	3	2	0	1	0	1	0	0
		DAY 8		28APR2003	8	18	-5	2	1	1	2	1	0	2	0	2	1	2	0	1	2	1	0	0
		DAY 15		05MAY2003	15	26	3	3	2	2	2	2	2	2	0	1	3	2	1	1	2	0	1	0
		DAY 22		12MAY2003	22	20	-3	2	2	1	2	0	0	2	0	2	2	2	1	2	1	1	0	0
		DAY 29		19MAY2003	29	16	-7	2	1	2	0	0	0	2	0	1	1	2	1	1	2	1	0	0
		DAY 36		27MAY2003	37	18	-5	3	1	2	1	0	0	2	0	1	2	2	0	1	2	1	0	0
		DAY 43		02JUN2003	43	21	-2	2	1	2	2	0	0	2	0	2	3	2	1	1	2	1	0	0
		DAY 50		09JUN2003	50	18	-5	1	0	1	2	0	1	1	1	2	1	2	1	1	1	1	2	0
		DAY 57		16JUN2003	57	18	-5	1	1	0	2	0	1	2	1	2	1	2	1	1	2	1	0	0
	E0011020	SCREEN		01MAY2003	-7	25		3	2	0	2	1	2	3	1	2	2	2	0	2	2	0	0	1
		DAY 1		08MAY2003	1	23		3	2	0	1	1	2	3	1	1	3	1	1	2	1	1	0	0
	E0018002	SCREEN		13NOV2002	-16	22		3	2	1	1	1	1	2	2	1	2	2	1	2	1	0	0	0
		DAY 1		29NOV2002	1	23		3	2	0	2	2	1	2	0	2	2	2	1	2	1	1	0	0
		DAY 8		04DEC2002	6	17	-6	3	2	0	1	1	1	3	2	0	1	1	0	2	0	0	0	0
		DAY 15		11DEC2002	13	8	-15	1	1	0	0	0	0	1	0	1	1	1	0	1	1	0	0	0
		DAY 22		18DEC2002	20	10	-13	1	1	0	0	0	0	2	0	0	1	1	1	1	1	1	0	0
		DAY 22	*	24DEC2002	26	18	-5	1	2	0	2	1	0	2	0	2	2	2	1	1	1	1	0	0
		DAY 29		30DEC2002	32	14	-9	1	1	0	0	0	1	2	2	0	2	1	1	1	1	1	0	0
		DAY 43		08JAN2003	41	12	-11	1	1	0	1	1	0	1	1	1	1	2	0	2	0	0	0	0
		DAY 50		15JAN2003	48	10	-13	1	1	0	0	0	0	2	1	1	1	1	0	1	1	0	0	0
		DAY 57		22JAN2003	55	16	-7	2	1	0	2	0	0	2	1	2	2	2	0	1	1	0	0	0
	E0018003	SCREEN		19NOV2002	-7	24		3	2	0	2	2	1	2	2	2	2	2	0	2	1	1	0	0
		DAY 1		26NOV2002	1	20		3	1	0	2	0	2	2	1	1	2	2	0	2	1	1	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	DAY 8	03DEC2002	8	17	-3	2	2	0	0	0	0	3	2	0	2	0	1	2	2	1	0	0
		DAY 15	10DEC2002	15	18	-2	2	2	0	0	0	0	3	2	1	2	1	1	2	1	1	0	0
	E0018013	SCREEN	17JAN2003	-7	30		3	2	1	2	2	2	4	2	1	2	2	1	1	2	1	1	1
		DAY 1	24JAN2003	1	25		3	2	0	2	2	2	4	0	1	2	2	0	2	1	1	0	1
		DAY 8	31JAN2003	8	16	-9	2	1	0	0	1	1	2	0	2	2	2	0	1	1	1	0	0
	E0019002	SCREEN	29OCT2002	-14	23		4	2	0	0	1	0	3	1	2	3	3	0	2	2	0	0	0
		DAY 1	12NOV2002	1	22		2	2	0	0	2	1	3	1	2	3	3	0	1	1	1	0	0
		DAY 8	19NOV2002	8	6	-16	0	0	0	0	0	0	2	0	1	0	2	0	0	1	0	0	0
	E0019008	SCREEN	06NOV2002	-15	25		2	1	1	2	2	1	3	0	2	2	3	1	1	1	2	0	1
		DAY 1	21NOV2002	1	23		3	2	0	2	2	0	3	0	1	2	2	1	0	1	3	1	0
		DAY 8	27NOV2002	7	22	-1	3	2	1	1	1	0	3	1	1	2	2	1	1	2	1	0	0
		DAY 15	05DEC2002	15	18	-5	1	1	1	2	1	0	2	1	1	2	2	1	1	2	0	0	0
		DAY 22	12DEC2002	22	9	-14	1	1	0	1	0	0	1	1	0	1	1	0	1	0	1	0	0
		DAY 29	19DEC2002	29	4	-19	0	0	0	0	0	0	1	0	1	0	1	0	1	0	0	0	0
	E0019009	SCREEN	06NOV2002	-8	22		3	2	1	2	0	0	3	0	2	3	2	0	2	1	1	0	0
		DAY 1	14NOV2002	1	20		3	2	0	2	0	0	1	0	2	3	2	0	2	0	3	0	0
		DAY 8	21NOV2002	8	15	-5	1	2	0	0	0	0	2	0	1	3	2	1	2	1	0	0	0
		DAY 15	27NOV2002	14	18	-2	0	2	1	1	2	2	2	0	1	2	3	2	0	0	0	0	0
		DAY 22	05DEC2002	22	15	-5	1	1	2	0	0	0	1	1	1	3	1	1	1	0	0	1	1
		DAY 29	10DEC2002	27	16	-4	2	0	1	0	0	0	3	1	2	2	1	1	1	2	0	0	0
	E0019016	SCREEN	30DEC2002	-7	24		3	2	1	1	1	2	3	1	2	2	2	0	1	2	1	0	0
		DAY 1	06JAN2003	1	24		3	2	1	2	2	1	3	0	2	2	2	0	1	2	0	0	1
		DAY 8	13JAN2003	8	11	-13	3	1	0	0	0	0	1	0	1	1	2	0	0	2	0	0	0
		DAY 15	20JAN2003	15	11	-13	3	1	0	0	0	0	1	0	1	1	1	0	1	2	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	DAY 22	27JAN2003	22	12	-12	1	0	0	0	2	1	1	0	2	0	2	1	1	1	0	0	0
		DAY 29	03FEB2003	29	8	-16	1	0	0	2	0	0	1	0	2	0	2	0	0	0	0	0	0
		DAY 36	10FEB2003	36	9	-15	2	0	0	2	1	0	0	1	1	0	2	0	0	0	0	0	0
		DAY 43	17FEB2003	43	6	-18	1	0	0	1	0	0	0	0	1	1	1	0	0	1	0	0	0
		DAY 50	27FEB2003	53	7	-17	0	0	0	2	1	1	0	0	2	0	1	0	0	0	0	0	0
		DAY 57	03MAR2003	57	2	-22	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0019020	SCREEN	16JAN2003	-7	23		3	2	2	1	2	2	3	0	1	2	2	0	1	1	1	0	0
		DAY 1	23JAN2003	1	23		2	2	1	2	2	2	3	0	2	2	2	1	1	1	0	0	0
		DAY 8	30JAN2003	8	20	-3	3	1	1	0	2	2	2	0	2	2	2	0	1	1	1	0	0
		DAY 15	06FEB2003	15	10	-13	1	1	0	0	1	0	1	0	2	1	1	0	0	2	0	0	0
		DAY 22	13FEB2003	22	8	-15	1	1	0	0	1	0	1	0	1	1	0	0	1	1	0	0	0
		DAY 29	20FEB2003	29	9	-14	1	1	0	0	0	0	1	0	2	1	1	0	1	1	0	0	0
		DAY 36	27FEB2003	36	14	-9	2	2	0	0	2	1	1	0	3	1	2	0	0	0	0	0	0
		DAY 43	06MAR2003	43	11	-12	2	2	0	0	0	0	1	0	2	2	1	0	1	0	0	0	0
		DAY 50	13MAR2003	50	7	-16	1	1	0	0	1	0	0	0	0	1	1	0	1	0	0	1	0
		DAY 57	27MAR2003	64	25	2	3	3	3	2	2	2	3	0	1	2	2	0	2	0	0	0	0
	E0019021	SCREEN	16JAN2003	-14	20		3	2	1	1	1	0	3	2	2	3	1	0	1	0	0	0	0
		DAY 1	30JAN2003	1	22		3	2	1	2	1	1	3	1	2	2	1	0	1	1	1	0	0
		DAY 8	06FEB2003	8	14	-8	2	2	1	2	1	0	2	0	1	1	1	0	0	1	0	0	0
		DAY 29	03MAR2003	33	20	-2	2	1	1	2	2	1	3	1	1	1	2	0	1	1	1	0	0
	E0019024	SCREEN	23JAN2003	-7	26		3	2	1	2	1	1	4	1	1	2	3	1	2	0	1	1	0
		DAY 1	30JAN2003	1	22		3	2	0	2	1	1	3	1	1	3	2	0	1	1	1	0	0
		DAY 8	06FEB2003	8	11	-11	2	0	0	1	0	1	1	1	1	0	0	0	1	1	2	0	0
	E0019031	SCREEN	06MAR2003	-7	22		3	2	1	0	1	2	3	2	0	1	2	1	1	1	1	1	0
		DAY 1	13MAR2003	1	27		3	3	0	0	0	2	3	2	1	3	1	2	2	2	1	2	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	DAY 15	25MAR2003	13	12	-15	3	0	0	0	0	1	3	0	1	1	0	0	2	0	1	0	0
	E0019035	SCREEN	11MAR2003	-7	25		3	2	2	0	2	0	4	2	1	3	2	0	2	2	0	0	0
		DAY 1	18MAR2003	1	26		3	2	2	0	2	0	4	2	1	3	2	0	2	2	1	0	0
		DAY 8	27MAR2003	10	16	-10	3	2	1	0	0	0	3	0	1	2	2	0	1	0	1	0	0
		DAY 15	03APR2003	17	16	-10	2	2	1	0	0	0	3	0	2	2	2	0	1	0	1	0	0
		DAY 22	10APR2003	24	19	-7	3	4	2	0	0	0	3	1	0	1	2	1	2	0	0	0	0
		DAY 29	17APR2003	31	20	-6	3	2	1	0	0	0	3	0	3	2	2	0	1	1	2	0	0
	E0019040	SCREEN	08MAY2003	-12	22		2	3	0	2	1	2	4	0	2	2	2	0	2	0	0	0	0
		DAY 1	20MAY2003	1	26		3	3	1	2	1	2	4	0	2	2	2	1	1	2	0	0	0
		DAY 8	29MAY2003	10	15	-11	2	3	0	0	0	0	3	0	1	2	0	1	1	0	1	1	0
		DAY 15	05JUN2003	17	19	-7	3	2	1	1	0	0	3	1	1	2	2	0	2	0	1	0	0
		DAY 22	12JUN2003	24	13	-13	2	3	0	0	0	0	1	0	0	1	1	1	2	0	2	0	0
		DAY 29	18JUN2003	30	13	-13	2	3	0	0	0	0	1	0	0	1	1	1	2	0	2	0	0
		DAY 36	26JUN2003	38	2	-24	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
		DAY 43	03JUL2003	45	4	-22	1	0	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0
		DAY 50	10JUL2003	52	17	-9	2	1	0	1	1	0	3	1	2	2	2	0	1	0	1	0	0
		DAY 57	17JUL2003	59	8	-18	1	0	0	1	0	0	2	0	0	1	1	0	1	0	1	0	0
	E0019042	SCREEN	28MAY2003	-7	27		3	3	2	2	2	1	3	1	1	3	2	1	2	1	0	0	0
		DAY 1	04JUN2003	1	27		3	3	2	2	2	1	3	1	1	3	2	1	2	1	0	0	0
		DAY 8	12JUN2003	9	15	-12	3	2	0	0	0	0	3	0	1	1	3	0	2	0	0	0	0
		DAY 15	19JUN2003	16	11	-16	0	2	0	0	0	0	3	0	0	2	2	0	2	0	0	0	0
	E0019045	SCREEN	19JUN2003	-7	24		3	2	0	2	1	1	3	1	2	2	2	1	1	1	2	0	0
		DAY 1	26JUN2003	1	24		2	1	0	2	2	1	3	1	2	2	2	2	1	2	1	0	0
		DAY 8	03JUL2003	8	15	-9	3	0	1	0	0	0	3	1	2	1	0	0	1	2	1	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	SCREEN	11JUN2003	-12	25		3	2	2	2	2	2	3	2	1	2	0	0	1	0	1	1	1
		DAY 1	23JUN2003	1	20		2	3	0	2	1	1	3	1	1	1	2	0	2	0	0	0	1
		DAY 8	30JUN2003	8	17	-3	3	2	0	1	2	0	1	0	1	3	2	0	2	0	0	0	0
		DAY 15	07JUL2003	15	8	-12	0	0	0	1	0	0	1	0	0	2	2	0	2	0	0	0	0
		DAY 22	15JUL2003	23	2	-18	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0
		DAY 29	21JUL2003	29	3	-17	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0
		DAY 36	28JUL2003	36	2	-18	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	04AUG2003	43	3	-17	0	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0	0
		DAY 50	12AUG2003	51	3	-17	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0
		DAY 57	20AUG2003	59	3	-17	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0
	E0022044	SCREEN	11MAR2003	-7	29		3	1	2	2	2	2	2	2	2	2	1	1	2	2	1	2	0
		DAY 1	18MAR2003	1	23		3	2	1	2	2	2	3	1	0	2	1	1	1	1	1	0	0
		DAY 8	25MAR2003	8	17	-6	3	2	1	0	2	0	2	1	2	2	1	0	1	0	0	0	0
		DAY 15	01APR2003	15	16	-7	3	2	1	0	2	0	1	0	2	2	1	0	1	0	1	0	0
		DAY 22	08APR2003	22	21	-2	3	2	2	2	2	0	2	0	2	3	1	0	2	0	0	0	0
		DAY 29	15APR2003	29	21	-2	3	2	1	2	2	0	2	1	1	3	1	0	2	0	1	0	0
		DAY 36	22APR2003	36	23	0	3	2	1	0	2	1	3	0	3	3	1	1	1	1	1	0	0
		DAY 43	29APR2003	43	20	-3	3	1	1	0	2	1	2	1	2	3	1	0	2	0	1	0	0
		DAY 50	06MAY2003	50	19	-4	3	2	1	0	2	0	3	0	2	3	1	0	2	0	0	0	0
		DAY 57	12MAY2003	56	19	-4	2	2	1	2	2	1	3	0	2	1	1	0	2	0	0	0	0
	E0023007	SCREEN	07JAN2003	-7	25		3	3	2	2	2	2	3	0	0	2	1	2	2	0	1	0	0
		DAY 1	14JAN2003	1	23		2	2	1	2	2	2	3	1	0	2	2	1	2	0	1	0	0
		DAY 8	21JAN2003	8	14	-9	2	1	0	0	0	0	3	1	0	2	1	1	2	0	1	0	0
		DAY 15	28JAN2003	15	12	-11	2	1	0	0	0	0	3	1	0	1	0	1	2	0	1	0	0
		DAY 22	07FEB2003	25	4	-19	1	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0
		DAY 29	11FEB2003	29	5	-18	1	0	0	0	0	0	1	0	0	1	0	1	1	0	0	0	0
		DAY 36	18FEB2003	36	6	-17	1	0	0	0	0	0	4	0	0	0	0	1	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	DAY 43		25FEB2003	43	5	-18	0	0	0	0	0	0	3	0	0	0	0	1	1	0	0	0	0
		DAY 50		04MAR2003	50	4	-19	0	0	0	0	0	0	1	0	0	0	0	1	1	0	1	0	0
		DAY 57		11MAR2003	57	1	-22	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	E0023011	SCREEN		28JAN2003	-7	28		3	2	2	0	2	0	4	1	2	4	2	1	2	2	1	0	0
		DAY 1		04FEB2003	1	33		3	2	2	2	2	2	4	2	1	4	3	1	2	2	1	0	0
		DAY 8		11FEB2003	8	28	-5	3	1	1	1	2	2	4	1	2	3	3	1	1	2	1	0	0
		DAY 15		21FEB2003	18	24	-9	2	2	0	1	2	1	3	1	3	3	2	0	1	1	2	0	0
		DAY 22		25FEB2003	22	20	-13	2	2	1	1	1	0	2	0	2	3	2	0	1	1	2	0	0
		DAY 29		04MAR2003	29	13	-20	1	2	0	0	2	0	1	0	2	1	1	0	1	1	1	0	0
		DAY 36		11MAR2003	36	13	-20	1	1	0	1	2	0	1	0	1	1	2	0	2	0	1	0	0
		DAY 43		18MAR2003	43	22	-11	3	3	2	0	1	1	3	1	3	2	1	0	1	0	1	0	0
		DAY 50		27MAR2003	52	12	-21	1	1	0	2	1	0	0	1	0	1	1	0	2	0	2	0	0
		DAY 57		01APR2003	57	13	-20	1	0	0	2	1	0	1	1	0	2	1	0	1	1	2	0	0
	E0023014	SCREEN		14FEB2003	-7	29		4	2	2	1	2	1	3	1	1	3	2	2	2	1	2	0	0
		DAY 1		21FEB2003	1	26		4	2	2	1	2	2	3	1	0	3	2	0	1	1	2	0	0
		DAY 8		02MAR2003	10	26	0	3	3	2	0	1	1	4	2	1	4	3	0	1	1	0	0	0
		DAY 15		06MAR2003	14	25	-1	3	3	2	0	0	0	4	2	1	4	3	0	1	1	1	0	0
		DAY 22		18MAR2003	26	19	-7	2	2	0	0	1	1	2	1	2	2	2	1	1	1	1	0	0
		DAY 29		25MAR2003	33	23	-3	3	1	0	1	1	1	4	1	2	4	3	0	1	0	1	0	0
		DAY 36		01APR2003	40	25	-1	3	2	1	0	1	0	4	2	2	4	2	1	1	1	1	0	0
		DAY 50		09APR2003	48	26	0	3	2	1	0	2	1	4	1	2	3	2	1	1	1	2	0	0
		DAY 50	*	15APR2003	54	32	6	3	2	2	0	2	2	4	2	2	4	3	2	1	1	1	1	0
		DAY 57		25APR2003	64	24	-2	2	1	1	2	2	2	4	1	1	2	2	1	1	1	1	0	0
	E0023019	SCREEN		21MAR2003	-17	21		3	2	1	0	2	0	3	0	2	3	2	2	0	0	1	0	0
		DAY 1		07APR2003	1	21		3	2	0	0	2	0	3	1	2	3	2	2	0	0	1	0	0
		DAY 8		15APR2003	9	13	-8	2	2	0	0	0	0	1	1	1	2	2	0	1	1	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0023019	DAY 15	22APR2003	16	13	-8	2	2	0	0	0	0	1	1	1	2	1	0	2	1	0	0	0
		DAY 22	02MAY2003	26	10	-11	1	1	0	0	0	0	2	0	0	2	1	2	0	1	0	0	0
		DAY 29	06MAY2003	30	8	-13	0	1	0	0	0	0	1	0	0	2	1	2	0	1	0	0	0
		DAY 36	13MAY2003	37	11	-10	1	2	1	0	0	0	1	1	0	2	1	1	0	1	0	0	0
		DAY 43	20MAY2003	44	9	-12	2	2	1	0	0	0	1	0	0	2	0	0	0	1	0	0	0
		DAY 50	29MAY2003	53	10	-11	2	2	0	0	0	0	1	0	0	3	1	0	0	1	0	0	0
		DAY 57	03JUN2003	58	6	-15	0	2	0	0	0	0	0	1	0	1	0	0	1	1	0	0	0
	E0023022	SCREEN	10APR2003	-8	20		3	1	0	2	0	0	2	2	2	3	1	1	2	1	0	0	0
		DAY 1	18APR2003	1	20		3	1	0	2	0	0	2	2	2	3	1	1	2	1	0	0	0
		DAY 8	25APR2003	8	16	-4	3	1	0	0	0	0	2	2	0	3	1	1	2	1	0	0	0
		DAY 15	01MAY2003	14	19	-1	3	1	0	0	0	1	2	1	2	3	1	2	2	1	0	0	0
		DAY 22	08MAY2003	21	13	-7	2	1	0	0	0	0	2	0	0	2	1	2	1	1	1	0	0
		DAY 29	15MAY2003	28	3	-17	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0
		DAY 36	22MAY2003	35	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	30MAY2003	43	1	-19	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	06JUN2003	50	2	-18	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	12JUN2003	56	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0023023	SCREEN	17APR2003	-8	22		3	2	0	0	1	0	3	0	1	3	3	1	2	0	2	0	1
		DAY 1	25APR2003	1	25		3	2	0	2	0	2	2	0	1	3	3	1	2	2	2	0	0
		DAY 8	01MAY2003	7	25	0	3	2	0	2	0	2	2	0	2	3	3	2	0	2	2	0	0
	E0023029	SCREEN	16MAY2003	-7	24		3	2	1	0	2	1	3	0	2	3	2	1	1	2	1	0	0
		DAY 1	23MAY2003	1	23		3	2	1	0	2	1	3	0	2	3	2	1	1	1	1	0	0
	E0023031	SCREEN	22MAY2003	-33	29		3	2	1	2	2	2	3	0	2	3	2	2	2	2	1	0	0
		DAY 1	24JUN2003	1	33		4	2	2	2	2	2	4	2	1	4	3	1	1	2	1	0	0
		DAY 8	01JUL2003	8	20	-13	2	1	1	0	2	1	4	0	2	2	2	1	1	1	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	DAY 15	08JUL2003	15	20	-13	2	1	1	0	2	0	4	0	2	2	2	1	1	1	1	0	0
		DAY 22	15JUL2003	22	23	-10	2	1	1	0	2	0	4	0	2	3	3	1	2	0	2	0	0
		DAY 29	22JUL2003	29	13	-20	2	1	0	0	0	1	4	0	1	1	1	0	1	1	0	0	0
		DAY 36	29JUL2003	36	14	-19	2	1	0	0	0	1	4	0	1	1	2	0	0	1	1	0	0
		DAY 43	05AUG2003	43	14	-19	2	1	0	0	0	2	4	0	1	1	1	0	0	1	1	0	0
		DAY 50	12AUG2003	50	10	-23	1	1	0	0	0	1	4	0	1	1	0	0	0	1	0	0	0
		DAY 57	19AUG2003	57	19	-14	3	1	0	2	2	2	4	0	1	4	0	0	0	0	0	0	0
	E0023041	SCREEN	02JUL2003	-7	21		3	2	1	1	1	1	3	1	1	2	1	1	2	1	0	0	0
		DAY 1	09JUL2003	1	22		3	2	1	1	1	1	3	1	1	3	1	1	2	1	0	0	0
		DAY 8	16JUL2003	8	24	2	3	2	1	1	1	1	3	2	1	1	2	1	2	1	2	0	0
		DAY 15	24JUL2003	16	19	-3	3	1	1	0	1	1	2	1	1	1	1	1	2	1	2	0	0
		DAY 22	30JUL2003	22	13	-9	3	0	1	1	0	0	2	1	0	1	0	1	2	1	0	0	0
		DAY 29	06AUG2003	29	12	-10	3	0	1	0	0	0	2	1	0	1	0	1	2	1	0	0	0
		DAY 36	13AUG2003	36	10	-12	3	0	0	0	0	0	2	1	0	1	0	1	1	1	0	0	0
		DAY 43	20AUG2003	43	11	-11	3	0	0	0	0	0	2	2	0	1	0	1	1	1	0	0	0
		DAY 50	27AUG2003	50	12	-10	3	1	1	0	0	0	2	1	0	1	0	0	2	1	0	0	0
		DAY 57	05SEP2003	59	12	-10	3	1	1	0	0	0	2	1	0	1	0	0	2	1	0	0	0
	E0023043	SCREEN	07JUL2003	-7	32		3	2	2	1	2	2	3	2	1	4	3	2	1	1	1	2	0
		DAY 1	14JUL2003	1	31		3	2	2	0	2	2	3	2	1	4	3	2	1	1	1	2	0
		DAY 8	23JUL2003	10	18	-13	2	1	0	0	0	0	3	0	2	3	1	1	1	1	1	2	0
		DAY 15	28JUL2003	15	10	-21	2	1	0	0	0	0	0	0	1	1	0	1	1	1	0	2	0
		DAY 22	05AUG2003	23	19	-12	3	2	0	0	0	0	2	2	0	3	2	2	2	1	0	0	0
		DAY 29	12AUG2003	30	10	-21	1	1	0	0	0	0	2	0	1	1	1	1	0	0	0	2	0
		DAY 36	19AUG2003	37	6	-25	0	0	0	0	0	0	0	0	1	2	1	1	0	0	0	1	0
		DAY 43	26AUG2003	44	3	-28	0	0	0	0	0	0	0	0	1	0	2	0	0	0	0	0	0
		DAY 50	02SEP2003	51	2	-29	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	09SEP2003	58	1	-30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	SCREEN	25NOV2002	-9	28		4	3	2	0	2	2	4	2	0	1	2	2	1	0	3	0	0
		DAY 1	04DEC2002	1	31		3	2	2	2	2	2	4	1	0	3	2	2	2	0	2	2	0
		DAY 8	12DEC2002	9	24	-7	2	2	2	0	2	2	2	0	3	2	2	0	2	0	3	0	0
		DAY 15	19DEC2002	16	17	-14	0	0	0	0	1	0	4	1	0	3	3	0	2	0	3	0	0
		DAY 22	26DEC2002	23	5	-26	0	0	0	1	0	0	0	0	1	0	1	0	2	0	0	0	0
		DAY 29	02JAN2003	30	6	-25	0	0	0	0	0	0	0	0	0	1	2	2	1	0	0	0	0
		DAY 36	09JAN2003	37	3	-28	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0	0
		DAY 43	16JAN2003	44	6	-25	0	1	0	0	0	0	0	1	0	0	1	0	0	0	2	1	0
		DAY 50	23JAN2003	51	3	-28	0	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0
		DAY 57	03FEB2003	62	23	-8	0	0	1	2	2	2	2	0	0	0	3	2	2	2	3	2	0
	E0026005	SCREEN	23DEC2002	-7	32		3	3	3	2	2	2	3	0	3	2	3	0	2	2	2	0	0
		DAY 1	30DEC2002	1	24		3	2	2	2	1	2	3	0	1	2	3	0	1	0	2	0	0
		DAY 8	06JAN2003	8	23	-1	2	0	0	2	1	1	3	0	2	4	3	1	1	0	3	0	0
	E0026009	SCREEN	10JAN2003	-5	22		3	1	2	2	1	2	4	0	2	1	0	1	1	2	0	0	0
		DAY 1	15JAN2003	1	23		3	1	0	2	2	2	3	2	0	2	0	2	2	1	0	1	0
		DAY 8	21JAN2003	7	11	-12	0	0	0	0	0	0	3	0	0	0	1	2	2	0	3	0	0
	E0026015	SCREEN	20FEB2003	-7	20		3	1	0	2	1	0	3	1	0	3	3	0	2	1	0	0	0
		DAY 1	27FEB2003	1	20		3	1	0	1	1	0	3	0	3	3	2	1	2	0	0	0	0
		DAY 8	07MAR2003	9	21	1	3	0	1	2	2	2	0	0	3	3	2	0	1	1	1	0	0
		DAY 15	13MAR2003	15	20	0	3	1	1	0	0	0	3	2	0	3	2	0	2	1	2	0	0
		DAY 22	20MAR2003	22	23	3	3	0	1	2	0	2	3	0	1	3	2	0	2	2	2	0	0
		DAY 29	27MAR2003	29	12	-8	1	2	0	2	0	0	1	0	1	2	2	0	1	0	0	0	0
		DAY 36	03APR2003	36	18	-2	3	2	2	0	0	0	3	1	0	3	2	0	2	0	0	0	0
		DAY 43	10APR2003	43	12	-8	1	0	0	0	1	0	1	0	3	1	2	0	2	0	1	0	0
		DAY 50	17APR2003	50	8	-12	1	0	0	1	1	0	1	0	0	0	2	0	2	0	0	0	0
		DAY 57	25APR2003	58	7	-13	1	1	0	1	0	0	0	1	1	0	1	0	1	0	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0026023	SCREEN	23APR2003	-7	20		3	2	0	0	2	1	3	1	0	3	0	1	2	0	0	2	0
		DAY 1	30APR2003	1	22		3	1	1	1	2	2	3	2	0	0	2	2	2	0	0	1	0
		DAY 8	07MAY2003	8	15	-7	3	1	1	0	0	0	2	2	0	0	2	1	2	0	0	1	0
		DAY 15	14MAY2003	15	13	-9	3	2	2	2	0	0	0	2	2	0	0	0	0	0	0	0	0
		DAY 22	21MAY2003	22	10	-12	3	1	0	2	0	0	0	2	1	0	0	0	0	0	0	1	0
		DAY 29	28MAY2003	29	14	-8	3	1	0	2	1	0	2	1	1	0	0	1	1	0	0	1	0
		DAY 36	04JUN2003	36	13	-9	3	0	0	2	1	0	1	2	2	0	0	1	1	0	0	0	0
		DAY 43	11JUN2003	43	9	-13	1	0	0	1	0	0	1	1	2	0	1	1	1	0	0	0	0
		DAY 50	18JUN2003	50	5	-17	1	0	0	0	0	0	0	1	2	0	0	1	0	0	0	0	0
		DAY 57	27JUN2003	59	4	-18	1	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	0
	E0027016	SCREEN	19MAR2003	-21	21		3	2	2	1	1	1	3	0	2	2	1	1	1	1	0	0	0
		DAY 1	09APR2003	1	24		2	2	1	0	1	1	3	1	3	2	2	2	1	0	1	2	0
		DAY 8	14APR2003	6	20	-4	3	2	1	0	0	0	3	1	3	2	2	2	1	0	0	0	0
		DAY 15	22APR2003	14	11	-13	1	2	0	0	0	1	1	0	2	2	1	0	1	0	0	0	0
		DAY 22	29APR2003	21	9	-15	1	2	0	0	0	1	1	0	1	1	1	0	1	0	0	0	0
		DAY 29	05MAY2003	27	11	-13	1	1	1	1	1	0	3	0	0	1	1	0	1	0	0	0	0
		DAY 36	14MAY2003	36	10	-14	2	1	1	0	0	0	2	0	1	1	0	0	1	1	0	0	0
		DAY 43	19MAY2003	41	8	-16	1	2	0	0	0	0	1	0	2	1	0	0	1	0	0	0	0
		DAY 50	27MAY2003	49	11	-13	1	2	0	1	1	0	1	0	1	1	1	1	1	0	0	0	0
		DAY 57	03JUN2003	56	7	-17	1	2	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0
	E0027018	SCREEN	21MAR2003	-4	27		4	1	1	2	2	1	3	1	3	3	2	2	1	1	0	0	0
		DAY 1	25MAR2003	1	26		4	1	0	2	2	1	4	1	3	3	2	2	1	0	0	0	0
		DAY 8	02APR2003	9	20	-6	4	0	0	0	0	0	4	1	1	3	3	1	1	2	0	0	0
		DAY 15	08APR2003	15	6	-20	0	0	0	0	0	0	0	0	2	1	2	0	0	1	0	0	0
		DAY 22	15APR2003	22	8	-18	1	0	0	0	0	1	0	0	3	1	0	0	1	1	0	0	0
		DAY 29	22APR2003	29	2	-24	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 36	29APR2003	36	1	-25	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	DAY 43	05MAY2003	42	1	-25	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	50	0	-26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	59	1	-25	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	E0028032	SCREEN	13MAR2003	-12	24		3	2	1	2	2	0	3	2	1	3	1	1	1	2	0	0	0
		DAY 1	25MAR2003	1	21		3	2	2	2	2	0	3	1	0	0	2	0	2	2	0	0	0
		DAY 8	01APR2003	8	16	-5	3	0	2	0	0	0	3	2	1	0	0	1	2	2	0	0	0
		DAY 15	08APR2003	15	15	-6	3	0	1	0	0	0	3	2	0	2	2	0	0	2	0	0	0
		DAY 22	15APR2003	22	13	-8	2	1	2	0	0	0	2	1	0	0	2	0	1	2	0	0	0
		DAY 29	22APR2003	29	18	-3	3	2	2	0	0	0	2	2	2	0	2	1	1	1	0	0	0
		DAY 36	30APR2003	37	12	-9	3	0	1	0	0	0	2	1	0	0	2	1	1	1	0	0	0
		DAY 43	06MAY2003	43	16	-5	3	2	2	0	0	0	3	2	0	0	2	0	2	0	0	0	0
		DAY 50	13MAY2003	50	21	0	3	2	2	1	1	0	2	2	2	0	3	0	2	1	0	0	0
	E0029003	SCREEN	28OCT2002	-7	26		3	2	1	1	1	1	3	1	1	3	3	0	2	2	1	0	1
		DAY 1	04NOV2002	1	27		3	2	1	2	2	2	2	0	2	3	2	0	2	2	1	0	1
		DAY 8	11NOV2002	8	14	-13	2	0	0	0	0	0	2	0	1	2	2	1	1	2	1	0	0
		DAY 15	18NOV2002	15	11	-16	1	0	0	0	0	0	1	0	1	2	1	0	2	2	1	0	0
		DAY 22	25NOV2002	22	13	-14	1	0	0	1	1	0	1	1	0	2	2	1	1	2	0	0	0
		DAY 29	02DEC2002	29	13	-14	0	1	0	0	0	0	1	0	2	3	2	0	1	2	1	0	0
		DAY 36	09DEC2002	36	10	-17	3	0	0	0	0	0	0	0	1	2	2	0	0	2	0	0	0
		DAY 43	16DEC2002	43	10	-17	0	1	2	0	0	0	0	0	1	2	2	0	2	0	0	0	0
		DAY 50	23DEC2002	50	21	-6	3	2	2	0	0	0	2	1	2	2	1	1	2	2	1	0	0
		DAY 57	30DEC2002	57	16	-11	1	1	1	0	0	0	2	0	2	3	2	1	1	1	1	0	0
	E0029020	SCREEN	25FEB2003	-8	20		2	2	2	2	1	0	2	0	1	3	1	0	2	1	0	0	1
		DAY 1	04MAR2003	-1	20		3	2	1	2	2	1	2	1	0	1	1	0	2	1	1	0	0
		DAY 8	11MAR2003	7	19	-1	3	2	1	0	2	1	2	1	0	2	1	1	1	1	1	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	SCREEN	13DEC2002	-7	24		3	2	0	2	1	2	3	1	0	3	1	1	1	2	0	2	0
		DAY 1	20DEC2002	1	24		3	2	0	2	1	1	3	1	1	4	2	0	1	2	1	0	0
		DAY 8	27DEC2002	8	11	-13	2	0	0	0	1	0	0	1	1	1	1	0	0	2	2	0	0
		DAY 15	03JAN2003	15	15	-9	2	0	0	0	1	0	3	0	1	2	1	0	0	2	3	0	0
		DAY 22	10JAN2003	22	17	-7	2	0	0	1	1	1	3	0	1	1	0	0	2	2	3	0	0
		DAY 29	17JAN2003	29	9	-15	1	0	0	0	1	0	1	0	1	2	0	0	0	2	1	0	0
		DAY 36	24JAN2003	36	13	-11	2	0	0	1	1	0	0	0	1	2	0	0	2	2	2	0	0
		DAY 43	30JAN2003	42	20	-4	2	2	0	1	1	2	3	0	0	4	0	0	2	2	1	0	0
		DAY 50	07FEB2003	50	11	-13	0	0	0	1	1	1	1	0	2	0	0	0	2	2	1	0	0
		DAY 57	14FEB2003	57	12	-12	1	0	0	0	1	1	1	0	1	2	0	0	2	2	1	0	0
	E0031006	SCREEN	29JAN2003	-20	24		2	1	1	2	2	2	2	1	1	4	1	0	2	0	3	0	0
		DAY 1	18FEB2003	1	20		3	1	2	2	2	2	2	0	1	2	1	0	1	0	0	1	0
		DAY 8	26FEB2003	9	15	-5	2	1	0	2	2	1	1	0	1	1	1	0	2	0	1	0	0
		DAY 15	05MAR2003	16	11	-9	2	2	0	1	2	0	2	0	0	1	1	0	0	0	0	0	0
		DAY 22	11MAR2003	22	7	-13	1	0	0	2	1	1	0	0	0	1	1	0	0	0	0	0	0
		DAY 29	18MAR2003	29	9	-11	2	0	0	1	1	1	1	0	0	1	1	0	0	0	1	0	0
		DAY 36	25MAR2003	36	13	-7	2	0	1	1	2	1	1	0	0	2	1	0	1	0	1	0	0
		DAY 43	02APR2003	44	15	-5	1	0	2	2	2	1	0	0	1	2	1	0	1	0	2	0	0
		DAY 50	07APR2003	49	9	-11	0	0	0	1	2	0	0	0	1	2	1	0	1	0	1	0	0
		DAY 57	15APR2003	57	7	-13	1	1	0	0	1	0	0	0	0	2	1	0	0	0	1	0	0
	E0031010	SCREEN	12FEB2003	-7	23		2	2	0	2	2	1	3	0	1	3	2	1	2	1	1	0	0
		DAY 1	19FEB2003	1	21		3	1	0	2	2	1	3	0	2	2	1	1	2	0	1	0	0
		DAY 8	26FEB2003	8	20	-1	3	1	1	0	1	1	3	0	2	2	2	0	2	1	1	0	0
		DAY 15	05MAR2003	15	17	-4	3	2	1	0	0	0	3	0	1	1	3	1	2	0	0	0	0
	E0031011	SCREEN	18FEB2003	-9	27		2	2	2	1	2	1	3	0	2	3	2	2	2	1	1	1	0
		DAY 1	27FEB2003	1	25		2	2	0	1	2	1	3	0	2	3	2	1	2	2	0	2	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	DAY 8	06MAR2003	8	10	-15	0	1	0	0	0	0	1	0	1	2	2	0	2	1	0	0	0
		DAY 15	13MAR2003	15	10	-15	0	2	0	1	0	1	1	0	0	2	1	0	1	1	0	0	0
		DAY 22	20MAR2003	22	16	-9	2	0	0	2	1	0	1	0	2	1	2	1	2	2	0	0	0
		DAY 29	27MAR2003	29	0	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	03APR2003	36	2	-23	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 43	11APR2003	44	23	-2	3	2	2	1	1	1	2	0	1	3	2	2	2	0	0	1	0
		DAY 50	17APR2003	50	13	-12	1	1	0	1	0	0	1	0	1	2	2	0	2	2	0	0	0
		DAY 57	24APR2003	57	1	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	E0031015	SCREEN	13MAR2003	-13	20		3	2	0	0	0	0	3	0	2	3	1	0	2	2	2	0	0
		DAY 1	26MAR2003	1	23		3	2	0	0	0	1	3	0	2	3	1	1	2	2	2	1	0
		DAY 8	01APR2003	7	9	-14	2	1	0	0	0	0	0	0	1	2	0	1	1	0	1	0	0
	E0031031	SCREEN	01JUL2003	-7	20		3	1	0	2	1	1	2	0	1	2	2	0	2	2	1	0	0
		DAY 1	08JUL2003	1	20		3	0	0	2	2	1	2	1	1	2	0	1	2	2	1	0	0
		DAY 8	15JUL2003	8	9	-11	1	0	0	0	0	0	1	1	0	1	1	0	2	2	0	0	0
		DAY 15	22JUL2003	15	15	-5	2	0	0	0	2	0	2	1	1	1	1	0	2	2	1	0	0
		DAY 22	29JUL2003	22	7	-13	1	0	0	0	1	1	1	0	0	0	1	0	1	1	0	0	0
	E0033009	SCREEN	22JAN2003	-21	21		3	1	2	0	1	1	3	0	1	2	2	0	2	2	1	0	0
		DAY 1	12FEB2003	1	25		3	2	2	2	2	0	3	1	1	3	2	0	2	2	0	0	0
	E0034009	SCREEN	10JUN2003	-9	30		3	2	1	2	2	0	3	2	2	2	2	2	2	2	1	2	0
		DAY 1	19JUN2003	1	32		3	2	1	2	2	2	3	2	2	2	2	2	2	2	1	2	0
		DAY 8	27JUN2003	9	21	-11	3	2	0	0	0	0	3	2	1	2	2	1	2	2	1	0	0
		DAY 15	03JUL2003	15	14	-18	1	0	0	0	0	0	2	2	1	2	1	0	2	2	1	0	0
		DAY 22	10JUL2003	22	9	-23	1	0	0	0	0	0	1	2	1	1	2	0	1	0	0	0	0
		DAY 29	18JUL2003	30	7	-25	1	0	0	0	0	0	1	2	0	1	1	0	1	0	0	0	0
		DAY 36	25JUL2003	37	6	-26	1	0	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0034009	DAY 43	31JUL2003	43	6	-26	1	0	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0
		DAY 50	07AUG2003	50	4	-28	1	0	0	0	0	0	1	1	0	0	0	0	1	0	0	0	0
		DAY 57	18AUG2003	61	2	-30	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
	E0037007	SCREEN	04APR2003	-7	26		3	2	1	2	2	2	3	2	1	1	1	1	2	2	1	0	0
		DAY 1	11APR2003	1	25		3	2	1	2	2	2	3	1	1	2	1	1	2	2	0	0	0
		DAY 8	17APR2003	7	12	-13	2	0	0	1	0	0	2	1	0	2	1	1	0	2	0	0	0
	E0037012	SCREEN	11JUL2003	-5	20		3	2	2	1	1	0	2	1	1	2	1	1	2	0	1	0	0
		DAY 1	16JUL2003	1	23		3	2	2	1	2	1	3	1	1	2	1	1	2	0	1	0	0
		DAY 8	24JUL2003	9	11	-12	2	1	0	0	2	0	1	0	0	2	1	0	2	0	0	0	0
		DAY 15	01AUG2003	17	9	-14	2	2	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0
		DAY 22	08AUG2003	24	5	-18	1	0	0	0	0	0	0	0	0	2	1	0	1	0	0	0	0
		DAY 29	15AUG2003	31	6	-17	0	0	0	0	0	0	1	0	1	1	1	0	1	0	1	0	0
		DAY 36	22AUG2003	38	3	-20	0	0	0	0	0	0	0	0	0	0	1	0	2	0	0	0	0
		DAY 43	29AUG2003	45	4	-19	0	0	0	1	0	0	0	0	0	1	0	0	2	0	0	0	0
		DAY 50	05SEP2003	52	3	-20	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0
		DAY 57	08SEP2003	55	3	-20	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0
	E0039019	SCREEN	20JAN2003	-17	22		3	2	1	1	1	2	3	2	1	1	1	1	1	0	1	1	0
		DAY 1	06FEB2003	1	25		3	2	2	2	2	2	3	2	0	2	2	0	1	0	2	0	0
		DAY 8	13FEB2003	8	16	-9	2	1	2	0	0	0	3	2	0	1	1	0	0	2	2	0	0
		DAY 15	20FEB2003	15	14	-11	2	1	1	0	0	0	3	1	0	2	2	0	0	0	2	0	0
		DAY 22	27FEB2003	22	10	-15	1	1	1	0	0	0	1	1	0	2	1	0	0	1	1	0	0
		DAY 29	07MAR2003	30	9	-16	1	1	0	0	1	0	1	1	0	1	2	0	0	0	1	0	0
		DAY 36	13MAR2003	36	17	-8	2	2	1	0	0	1	3	1	0	1	2	0	0	2	2	0	0
		DAY 43	20MAR2003	43	2	-23	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	27MAR2003	50	6	-19	1	0	0	0	0	0	1	0	0	2	1	0	1	0	0	0	0
		DAY 57	03APR2003	57	4	-21	1	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
QUETIAPINE 600 MG (BIPOLAR II)	E0039043	SCREEN	25APR2003	-13	22		3	2	1	2	2	0	3	1	1	2	0	1	1	1	1	1	0
		DAY 1	08MAY2003	1	20		3	2	1	2	0	0	2	1	2	2	0	1	2	0	1	1	0
		DAY 8	15MAY2003	8	8	-12	1	1	0	0	0	0	2	1	0	1	0	0	1	0	1	0	0
		DAY 15	23MAY2003	16	5	-15	1	1	0	0	0	0	1	1	0	0	1	0	0	0	0	0	0
		DAY 22	29MAY2003	22	4	-16	0	1	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0
		DAY 29	05JUN2003	29	1	-19	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 36	13JUN2003	37	7	-13	1	0	0	0	0	0	1	0	0	1	1	0	1	0	1	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0002001	SCREEN	17DEC2002	-13	33		3	2	3	2	2	2	4	1	1	3	2	2	2	1	1	2	0
		DAY 1	30DEC2002	1	27		2	2	3	2	2	1	4	1	1	1	3	1	2	2	0	0	0
		DAY 8	06JAN2003	8	15	-12	2	2	2	0	0	1	2	0	0	3	0	1	1	1	0	0	0
		DAY 15	14JAN2003	16	17	-10	3	2	2	0	1	1	2	0	1	1	0	1	1	2	0	0	0
		DAY 22	21JAN2003	23	15	-12	3	2	2	0	0	0	2	0	0	1	1	1	1	2	0	0	0
		DAY 29	29JAN2003	31	13	-14	2	2	1	0	0	0	2	0	1	2	0	0	1	2	0	0	0
		DAY 36	05FEB2003	38	17	-10	1	2	2	1	1	1	1	0	1	3	1	0	2	1	0	0	0
		DAY 43	12FEB2003	45	17	-10	3	2	3	1	1	1	1	0	1	2	0	0	0	1	1	0	0
		DAY 50	19FEB2003	52	8	-19	1	2	2	0	0	0	1	0	0	1	0	0	0	1	0	0	0
		DAY 57	26FEB2003	59	6	-21	1	2	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0
	E0002003	SCREEN	03JAN2003	-19	21		2	2	0	1	1	1	3	0	2	2	1	0	1	0	3	1	1
		DAY 1	22JAN2003	1	22		2	2	1	2	2	2	2	0	0	2	3	0	2	1	1	0	0
		DAY 8	29JAN2003	8	23	1	3	1	3	1	0	1	3	1	2	3	1	0	2	2	0	0	0
		DAY 15	05FEB2003	15	22	0	3	2	1	1	1	0	2	0	1	3	1	1	2	2	1	1	0
		DAY 22	12FEB2003	22	25	3	3	2	2	2	1	1	3	0	1	2	2	1	2	2	1	0	0
		DAY 29	19FEB2003	29	14	-8	2	1	1	0	1	1	1	0	1	1	2	1	1	0	0	1	0
		DAY 36	26FEB2003	36	12	-10	1	1	1	1	1	0	2	0	0	2	2	0	1	0	0	0	0
		DAY 43	05MAR2003	43	17	-5	2	2	0	2	1	0	2	0	0	2	1	0	2	1	2	0	0
		DAY 50	11MAR2003	49	10	-12	1	1	0	0	1	1	2	0	0	1	1	0	2	0	0	0	0
		DAY 57	18MAR2003	56	13	-9	1	2	2	0	1	0	0	0	1	1	1	1	1	0	1	1	0
	E0002004	SCREEN	14JAN2003	-11	24		3	2	2	0	1	1	3	1	0	3	3	0	2	2	1	0	0
		DAY 1	25JAN2003	1	25		2	2	2	1	2	2	3	1	0	3	2	0	2	2	1	0	0
	E0002008	SCREEN	29JAN2003	-27	20		2	2	1	1	1	1	3	0	1	2	2	0	2	2	0	0	0
		DAY 1	25FEB2003	1	25		2	2	2	2	1	1	1	2	2	2	1	1	2	0	1	2	1
		DAY 8	05MAR2003	9	15	-10	2	1	1	0	1	1	3	1	1	2	1	0	1	0	0	0	0
		DAY 15	13MAR2003	17	14	-11	2	1	1	0	1	1	1	0	0	2	2	0	1	1	1	0	0
		DAY 22	20MAR2003	24	15	-10	2	1	1	1	1	1	2	0	0	2	1	0	2	0	1	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0002008	DAY 29	27MAR2003	31	11	-14	1	1	1	0	1	1	2	0	0	2	1	0	1	0	0	0	0
		DAY 36	03APR2003	38	15	-10	2	1	1	1	1	1	2	0	0	2	1	0	2	0	1	0	0
		DAY 43	11APR2003	46	12	-13	2	1	1	0	0	1	2	0	0	2	1	0	2	0	0	0	0
		DAY 50	16APR2003	51	15	-10	2	1	1	1	1	1	2	0	0	2	1	0	2	0	1	0	0
		DAY 57	23APR2003	58	15	-10	2	1	1	1	1	1	2	0	0	2	2	0	1	0	1	0	0
	E0002016	SCREEN	14JUL2003	-10	27		3	2	1	2	2	1	3	0	1	2	2	0	2	2	2	2	0
		DAY 1	24JUL2003	1	24		2	2	1	2	2	1	3	0	0	2	2	1	2	2	2	0	0
		DAY 8	30JUL2003	7	19	-5	2	1	1	1	1	1	2	0	1	2	2	1	2	1	1	0	0
		DAY 15	06AUG2003	14	17	-7	1	1	0	1	2	1	2	0	0	1	1	1	2	1	1	2	0
		DAY 22	13AUG2003	21	11	-13	2	0	1	1	0	0	1	0	0	1	1	1	1	2	0	0	0
		DAY 29	21AUG2003	29	11	-13	1	0	0	0	0	0	1	0	0	1	2	1	1	1	2	1	0
		DAY 36	27AUG2003	35	9	-15	1	0	1	0	0	0	1	0	0	1	1	1	1	1	1	0	0
		DAY 43	03SEP2003	42	9	-15	1	1	0	0	0	0	1	0	0	1	1	1	1	1	1	0	0
		DAY 50	11SEP2003	50	9	-15	1	0	0	0	1	0	1	0	0	1	1	1	1	1	1	0	0
		DAY 57	17SEP2003	56	11	-13	1	1	1	0	1	0	1	0	0	1	1	1	1	1	1	0	0
	E0003008	SCREEN	21JAN2003	-7	27		3	3	2	1	2	1	3	0	2	4	2	0	2	0	2	0	0
		DAY 1	28JAN2003	1	24		3	3	2	2	1	1	3	0	2	4	0	0	2	0	1	0	0
		DAY 8	04FEB2003	8	23	-1	3	3	1	2	2	0	3	0	2	4	0	0	2	0	1	0	0
		DAY 15	11FEB2003	15	22	-2	3	3	0	2	1	0	3	0	2	3	1	0	2	0	2	0	0
		DAY 22	18FEB2003	22	20	-4	2	2	0	2	2	1	3	0	1	3	0	0	2	0	2	0	0
	E0004003	SCREEN	02OCT2002	-8	25		3	2	2	0	0	0	4	0	4	4	2	0	2	2	0	0	0
		DAY 1	10OCT2002	1	21		3	2	2	0	0	0	4	0	2	2	1	1	2	2	0	0	0
		DAY 8	17OCT2002	8	18	-3	2	1	2	1	1	1	2	0	1	2	1	1	2	1	0	0	0
	E0004006	SCREEN	28OCT2002	-7	21		3	2	2	0	0	0	4	2	1	2	1	1	2	1	0	0	0
		DAY 1	04NOV2002	1	21		3	1	1	1	1	1	3	1	1	3	1	1	2	1	0	0	0
		DAY 8	11NOV2002	8	13	-8	2	1	0	0	1	1	2	0	0	1	1	0	2	2	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0004006	DAY 15	18NOV2002	15	12	-9	1	0	0	0	1	1	1	0	2	1	1	1	2	1	0	0	0
		DAY 22	25NOV2002	22	13	-8	2	0	0	0	1	1	2	1	1	1	0	1	2	1	0	0	0
		DAY 29	02DEC2002	29	13	-8	2	0	0	0	1	1	3	1	0	1	0	1	2	1	0	0	0
		DAY 36	09DEC2002	36	21	0	3	2	1	1	0	2	3	1	1	1	1	1	2	2	0	0	0
		DAY 43	16DEC2002	43	22	1	3	2	1	2	1	1	3	1	1	1	1	1	2	2	0	0	0
		DAY 57	06JAN2003	64	15	-6	3	1	0	2	0	1	2	1	0	1	0	1	1	2	0	0	0
	E0004016	SCREEN	12FEB2003	-7	28		3	2	2	2	1	1	2	1	0	3	2	2	2	2	1	2	0
		DAY 1	19FEB2003	1	26		3	2	1	2	2	1	2	1	0	2	2	2	1	2	1	2	0
		DAY 8	26FEB2003	8	17	-9	3	2	1	0	0	0	2	1	0	2	2	1	1	2	0	0	0
		DAY 15	05MAR2003	15	13	-13	2	1	0	0	0	1	2	1	0	2	2	0	0	2	0	0	0
		DAY 22	13MAR2003	23	11	-15	1	1	0	0	1	1	1	1	0	2	2	0	0	1	0	0	0
		DAY 36	26MAR2003	36	5	-21	0	0	0	0	0	1	1	1	0	1	1	0	0	0	0	0	0
		DAY 43	03APR2003	44	5	-21	0	0	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0
		DAY 50	10APR2003	51	2	-24	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0
		DAY 57	17APR2003	58	5	-21	0	0	0	2	0	0	0	1	0	1	1	0	0	0	0	0	0
	E0004024	SCREEN	25JUN2003	-8	24		3	2	2	1	1	2	3	1	0	4	1	0	2	1	1	0	0
		DAY 1	03JUL2003	1	24		3	2	1	2	2	1	3	1	0	3	2	0	2	1	1	0	0
		DAY 8	10JUL2003	8	21	-3	2	2	0	1	2	2	3	1	0	2	2	0	2	1	1	0	0
		DAY 15	17JUL2003	15	18	-6	2	2	0	1	1	2	2	1	0	2	2	0	1	1	1	0	0
		DAY 22	24JUL2003	22	14	-10	2	1	0	0	0	2	2	1	0	1	2	0	1	1	1	0	0
		DAY 29	31JUL2003	29	11	-13	1	0	0	0	1	1	2	1	0	1	1	0	1	1	1	0	0
		DAY 36	07AUG2003	36	12	-12	1	1	0	0	0	2	2	1	0	2	0	0	2	1	0	0	0
		DAY 43	14AUG2003	43	10	-14	1	1	0	0	1	1	1	1	0	1	1	1	1	0	0	0	0
		DAY 50	21AUG2003	50	5	-19	1	0	0	0	0	0	1	1	0	0	0	1	1	0	0	0	0
		DAY 57	28AUG2003	57	7	-17	1	1	0	0	0	0	1	1	0	2	0	0	0	0	1	0	0
	E0005006	SCREEN	24SEP2002	-9	20		3	2	0	1	2	1	3	1	3	3	0	0	1	0	0	0	0
		DAY 1	03OCT2002	1	23		3	2	0	1	2	1	3	2	3	3	2	0	1	0	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0005006	DAY 8	14OCT2002	12	12	-11	1	2	0	0	1	1	2	1	1	0	2	0	0	0	0	0	1
	E0005017	SCREEN	11DEC2002	-19	27		3	2	0	1	1	2	3	2	3	3	2	1	2	2	0	0	0
		DAY 1	30DEC2002	1	30		3	2	1	2	1	1	3	2	3	3	2	2	2	2	1	0	0
		DAY 8	06JAN2003	8	29	-1	3	2	1	1	1	1	3	2	3	3	2	2	2	2	1	0	0
		DAY 15	14JAN2003	16	27	-3	3	2	1	0	1	1	3	2	3	3	2	1	2	2	1	0	0
		DAY 22	22JAN2003	24	26	-4	3	2	0	0	1	1	3	2	3	3	2	1	2	2	1	0	0
		DAY 29	30JAN2003	32	27	-3	3	2	0	1	1	1	3	2	3	3	2	1	2	2	1	0	0
		DAY 36	04FEB2003	37	25	-5	3	2	0	1	0	0	3	2	3	3	2	1	2	2	1	0	0
		DAY 43	13FEB2003	46	22	-8	3	2	0	0	0	0	3	2	3	3	1	1	2	2	0	0	0
		DAY 50	20FEB2003	53	22	-8	3	1	0	1	0	2	3	1	2	2	2	1	2	1	1	0	0
		DAY 57	04MAR2003	65	24	-6	2	2	1	0	0	1	3	2	3	3	2	1	2	2	0	0	0
	E0005019	SCREEN	19DEC2002	-27	25		3	2	1	2	2	1	3	2	0	2	2	1	2	2	0	0	0
		DAY 1	15JAN2003	1	23		3	2	1	2	1	1	3	2	1	2	2	0	2	1	0	0	0
		DAY 8	23JAN2003	9	25	2	4	2	3	2	0	1	3	1	2	2	1	1	2	1	0	0	0
	E0005026	SCREEN	26FEB2003	-8	27		3	3	2	2	1	1	3	2	1	3	2	0	2	1	1	0	0
		DAY 1	06MAR2003	1	25		3	2	0	2	0	2	3	2	2	3	2	0	2	2	0	0	0
		DAY 8	13MAR2003	8	25	0	3	2	1	2	2	1	3	1	1	3	1	1	2	2	0	0	0
		DAY 15	20MAR2003	15	28	3	3	2	1	2	2	2	2	1	2	3	2	2	1	2	0	1	0
		DAY 22	25MAR2003	20	27	2	3	2	2	2	0	2	2	2	1	3	1	2	2	2	0	1	0
	E0005039	SCREEN	15MAY2003	-7	24		3	2	0	1	1	1	3	2	2	3	2	0	2	1	1	0	0
		DAY 1	22MAY2003	1	24		3	2	1	1	1	1	3	2	2	3	2	0	2	1	0	0	0
		DAY 8	28MAY2003	7	25	1	3	2	1	1	1	1	3	2	2	3	2	0	2	1	1	0	0
		DAY 15	05JUN2003	15	15	-9	2	2	0	0	0	1	2	0	2	3	1	0	2	0	0	0	0
		DAY 22	12JUN2003	22	19	-5	3	2	0	0	1	0	3	2	2	3	2	0	1	0	0	0	0
		DAY 29	18JUN2003	28	16	-8	2	1	0	0	1	0	3	2	1	2	1	0	2	1	0	0	0
		DAY 36	24JUN2003	34	20	-4	3	2	0	0	1	1	3	2	1	3	2	0	1	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0005039	DAY 43	03JUL2003	43	16	-8	3	1	0	0	1	0	3	2	1	1	2	0	1	1	0	0	0
		DAY 50	10JUL2003	50	20	-4	3	2	0	1	0	0	3	2	2	3	2	0	1	1	0	0	0
		DAY 57	16JUL2003	56	22	-2	3	2	0	2	1	0	3	1	2	2	2	0	2	1	1	0	0
	E0005043	SCREEN	01JUL2003	-8	20		3	2	1	0	0	0	3	1	1	3	1	0	2	1	1	0	1
		DAY 1	09JUL2003	1	21		3	2	1	0	0	0	3	1	1	3	1	0	2	2	1	0	1
		DAY 8	17JUL2003	9	17	-4	3	2	0	0	0	0	3	1	0	2	0	0	2	2	1	0	1
		DAY 15	24JUL2003	16	18	-3	3	2	0	0	0	0	3	1	1	3	0	0	2	1	1	0	1
		DAY 22	31JUL2003	23	15	-6	3	1	0	0	0	0	3	1	1	3	0	0	2	0	1	0	0
		DAY 29	07AUG2003	30	16	-5	3	2	0	0	0	0	3	1	1	3	0	0	2	0	1	0	0
		DAY 36	13AUG2003	36	16	-5	2	2	0	0	0	0	3	1	1	3	0	0	2	1	1	0	0
		DAY 43	20AUG2003	43	18	-3	3	2	0	0	0	0	3	1	1	3	0	0	2	2	1	0	0
		DAY 50	27AUG2003	50	17	-4	3	2	0	0	0	0	3	2	1	2	0	0	2	1	1	0	0
		DAY 57	03SEP2003	57	13	-8	2	2	0	0	0	0	2	1	0	1	0	0	2	2	1	0	0
	E0006020	SCREEN	02MAY2003	-11	26		3	3	1	1	2	1	3	1	2	2	1	1	2	1	1	1	0
		DAY 1	13MAY2003	1	28		3	3	1	1	2	1	3	1	2	3	1	1	2	1	2	1	0
		DAY 8	20MAY2003	8	26	-2	3	3	0	1	2	1	2	1	2	3	1	1	2	1	2	1	0
		DAY 15	27MAY2003	15	25	-3	3	3	0	1	2	1	2	1	2	2	1	1	2	1	2	1	0
		DAY 22	03JUN2003	22	19	-9	2	2	0	1	1	1	1	1	1	2	1	1	2	1	2	0	0
		DAY 29	10JUN2003	29	19	-9	2	2	0	1	1	1	1	1	1	2	1	1	2	1	2	0	0
		DAY 36	17JUN2003	36	17	-11	2	2	0	1	0	1	1	1	1	2	1	1	1	1	2	0	0
		DAY 43	24JUN2003	43	15	-13	1	2	0	1	0	1	1	1	1	2	1	1	0	1	2	0	0
		DAY 50	01JUL2003	50	14	-14	1	2	0	1	0	0	1	1	1	2	1	1	0	1	2	0	0
		DAY 57	08JUL2003	57	14	-14	1	2	0	1	0	0	1	1	1	2	1	1	0	1	2	0	0
	E0007001	SCREEN	10DEC2002	-21	23		3	2	1	2	2	1	3	1	0	3	1	0	2	1	1	0	0
		DAY 1	31DEC2002	1	21		3	2	1	2	2	1	3	1	0	3	0	0	2	1	0	0	0
		DAY 8	07JAN2003	8	21	0	3	2	1	2	2	1	3	1	0	2	0	0	2	1	1	0	0
		DAY 15	14JAN2003	15	21	0	3	2	1	2	2	1	3	1	0	2	0	0	2	1	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0007001	DAY 22		21JAN2003	22	18	-3	3	2	1	1	1	1	3	1	0	2	1	0	1	1	0	0	0
		DAY 29		28JAN2003	29	15	-6	3	2	1	1	1	0	3	1	0	2	0	0	1	0	0	0	0
		DAY 36		04FEB2003	36	16	-5	2	2	0	1	1	0	3	1	0	2	1	0	1	1	1	0	0
		DAY 43		11FEB2003	43	14	-7	2	2	0	2	0	0	3	1	0	2	0	0	1	1	0	0	0
		DAY 50		18FEB2003	50	14	-7	2	2	0	2	1	0	4	1	0	1	0	0	0	1	0	0	0
		DAY 50	*	22FEB2003	54	12	-9	1	2	0	2	1	1	4	0	0	0	0	0	0	1	0	0	0
	E0007003	SCREEN		03JAN2003	-27	30		4	2	1	2	2	2	3	0	1	3	1	1	2	2	2	2	0
		DAY 1		30JAN2003	1	25		3	2	1	2	2	2	3	0	1	3	1	1	2	2	0	0	0
		DAY 8		06FEB2003	8	24	-1	3	2	0	2	2	2	3	0	1	3	1	0	2	1	2	0	0
		DAY 15		14FEB2003	16	20	-5	2	2	0	2	1	2	3	0	0	3	0	1	2	1	1	0	0
		DAY 22		22FEB2003	24	23	-2	3	2	0	2	1	2	3	0	0	3	1	0	2	2	2	0	0
		DAY 36		10MAR2003	40	18	-7	3	2	0	0	2	0	4	0	0	3	1	0	1	1	1	0	0
	E0007006	SCREEN		21FEB2003	-12	20		3	2	0	1	2	2	4	0	0	3	1	0	2	0	0	0	0
		DAY 1		05MAR2003	1	20		3	1	0	1	2	2	4	0	1	3	1	0	1	0	1	0	0
		DAY 8		12MAR2003	8	16	-4	3	1	0	0	1	1	4	0	0	3	1	0	1	0	1	0	0
		DAY 15		19MAR2003	15	14	-6	3	0	0	0	0	0	4	1	0	3	0	0	1	0	2	0	0
		DAY 22	*	25MAR2003	21	14	-6	3	0	0	0	0	0	4	1	0	3	0	0	0	0	2	0	1
		DAY 22		26MAR2003	22	13	-7	3	0	0	0	0	0	4	0	0	3	0	0	0	0	2	0	1
	E0009004	SCREEN		19NOV2002	-7	27		3	2	0	2	2	2	4	1	3	1	2	1	1	1	2	0	0
		DAY 1		26NOV2002	1	29		4	2	2	2	2	1	3	2	1	3	1	2	2	1	1	0	0
		DAY 8		04DEC2002	9	15	-14	0	0	0	2	2	2	3	0	1	1	0	1	1	2	0	0	0
		DAY 15		11DEC2002	16	24	-5	3	1	0	2	2	2	3	0	2	3	2	0	1	1	2	0	0
		DAY 22		18DEC2002	23	27	-2	3	2	1	2	2	1	4	0	2	3	2	0	1	2	1	0	1
	E0009012	SCREEN		16JUN2003	-9	31		3	2	2	2	2	1	3	1	2	3	2	1	2	2	2	1	0
		DAY 1		25JUN2003	1	30		3	2	2	2	1	1	3	1	2	3	2	1	2	2	1	2	0
		DAY 8		03JUL2003	9	25	-5	3	2	2	1	1	1	3	0	2	2	3	1	2	2	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0010008	SCREEN	11DEC2002	-7	27		3	2	2	2	0	2	3	1	2	2	1	2	1	2	0	2	0
		DAY 1	18DEC2002	1	28		3	2	1	2	0	1	3	2	3	3	2	1	1	2	0	2	0
		DAY 8	26DEC2002	9	21	-7	3	2	0	2	0	0	3	1	2	2	2	1	1	2	0	0	0
		DAY 15	02JAN2003	16	27	-1	3	2	2	2	0	1	3	0	3	3	2	1	2	2	0	0	1
		DAY 22	08JAN2003	22	23	-5	2	2	0	2	0	1	3	1	2	3	2	1	2	2	0	0	0
		DAY 29	15JAN2003	29	18	-10	1	0	0	2	0	0	1	1	3	3	2	1	2	2	0	0	0
	E0010018	SCREEN	26FEB2003	-21	28		3	3	1	2	2	1	3	0	2	3	1	2	1	2	0	2	0
		DAY 1	19MAR2003	1	26		3	3	2	2	2	1	2	0	2	1	1	2	2	2	0	1	0
		DAY 8	26MAR2003	8	10	-16	2	0	0	0	0	1	1	0	0	1	1	1	1	2	0	0	0
		DAY 15	02APR2003	15	21	-5	3	0	0	2	2	2	2	0	1	2	2	1	2	2	0	0	0
		DAY 22	09APR2003	22	8	-18	0	0	0	2	0	1	0	0	0	1	1	1	0	2	0	0	0
		DAY 29	16APR2003	29	12	-14	1	1	0	2	1	2	0	0	0	1	1	0	1	2	0	0	0
		DAY 36	23APR2003	36	11	-15	0	0	0	2	0	2	0	0	0	1	2	0	1	2	1	0	0
		DAY 43	01MAY2003	44	7	-19	1	0	0	2	0	2	0	0	0	0	0	0	0	2	0	0	0
	E0010028	SCREEN	09JUN2003	-7	28		3	3	1	2	2	2	3	2	2	2	2	0	2	2	0	0	0
		DAY 1	16JUN2003	1	26		2	2	0	2	2	2	3	0	4	3	2	1	1	2	0	0	0
		DAY 8	24JUN2003	9	22	-4	2	3	0	2	2	2	3	1	0	2	1	0	2	2	0	0	0
		DAY 15	01JUL2003	16	26	0	3	3	1	2	1	0	3	1	2	3	2	0	2	2	0	0	1
		DAY 22	08JUL2003	23	22	-4	1	1	1	2	2	2	3	1	2	3	2	0	2	0	0	0	0
		DAY 29	15JUL2003	30	27	1	3	1	1	2	2	2	3	2	1	3	2	0	2	2	1	0	0
	E0011008	SCREEN	23JAN2003	-7	25		3	1	0	2	2	2	3	2	1	3	2	1	1	0	0	2	0
		DAY 1	30JAN2003	1	22		3	1	0	2	2	2	2	0	3	2	0	1	1	0	1	2	0
		DAY 8	06FEB2003	8	10	-12	2	2	0	1	0	1	1	0	1	1	0	0	1	0	0	0	0
		DAY 15	13FEB2003	15	10	-12	1	2	0	0	1	0	0	0	0	2	0	1	0	0	1	2	0
	E0011009	SCREEN	19DEC2002	-8	25		3	1	1	2	2	1	2	1	2	2	1	1	2	0	2	2	0
		DAY 1	26DEC2002	-1	23		3	1	1	2	2	1	2	1	1	2	2	1	2	0	2	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0011009	DAY 8		02JAN2003	7	20	-3	3	1	0	2	1	1	3	1	0	2	1	1	1	1	2	0	0
		DAY 15		09JAN2003	14	18	-5	2	0	0	2	2	1	3	1	0	1	1	1	2	1	0	1	0
		DAY 22		16JAN2003	21	12	-11	1	0	0	2	1	0	3	0	0	0	1	1	2	1	0	0	0
		DAY 29		23JAN2003	28	16	-7	1	0	0	2	2	2	3	0	1	1	2	0	0	0	1	1	0
		DAY 36		30JAN2003	35	17	-6	2	2	0	2	2	1	2	0	0	2	1	1	1	1	0	0	0
		DAY 43		06FEB2003	42	16	-7	1	1	0	2	1	1	2	0	0	2	1	1	1	0	1	2	0
		DAY 50		13FEB2003	49	13	-10	1	1	0	2	1	0	1	0	1	2	1	0	1	0	2	0	0
		DAY 57		20FEB2003	56	12	-11	0	1	0	2	1	1	1	0	0	0	2	1	1	0	1	1	0
	E0011010	SCREEN		03FEB2003	-7	20		3	1	2	0	1	0	3	1	1	2	2	0	2	2	0	0	0
		DAY 1		10FEB2003	1	22		3	2	2	0	0	0	3	1	1	2	1	1	2	2	2	0	0
		DAY 8		17FEB2003	8	17	-5	3	1	1	0	1	2	2	0	0	2	2	0	2	0	1	0	0
		DAY 15		24FEB2003	15	17	-5	2	2	1	1	1	0	2	0	1	2	2	0	1	1	1	0	0
		DAY 22		03MAR2003	22	13	-9	3	1	1	1	0	0	2	0	0	1	2	0	0	1	1	0	0
		DAY 29		10MAR2003	29	14	-8	2	1	0	0	2	0	1	0	1	1	1	0	2	1	1	1	0
		DAY 36		17MAR2003	36	17	-5	3	2	1	0	2	1	2	0	0	1	2	0	2	1	0	0	0
		DAY 36	*	19MAR2003	38	18	-4	3	1	1	0	2	2	2	0	0	1	2	0	2	1	1	0	0
	E0013001	SCREEN		31OCT2002	-14	22		3	2	1	2	2	0	3	1	0	2	2	1	2	0	1	0	0
		DAY 1		14NOV2002	1	23		3	2	1	1	2	2	3	1	0	2	2	1	2	0	1	0	0
		DAY 8		21NOV2002	8	20	-3	2	2	1	0	2	2	3	1	0	2	2	0	2	0	1	0	0
		DAY 15		27NOV2002	14	17	-6	3	1	0	1	2	1	3	0	0	2	1	1	1	0	1	0	0
		DAY 22		06DEC2002	23	13	-10	2	2	0	0	0	2	2	1	0	2	0	0	0	2	0	0	0
		DAY 29		11DEC2002	28	2	-21	0	0	0	0	0		0	0	0	0	0	0	0	2	0	0	0
		DAY 36		18DEC2002	35	0	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		27DEC2002	44	1	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 50		02JAN2003	50	0	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		10JAN2003	58	0	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0013003	SCREEN		06NOV2002	-6	23		3	2	1	2	2	0	3	2	0	2	2	0	2	2	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0013003	DAY 1	12NOV2002	1	22		2	2	1	2	2	1	3	1	0	2	2	0	2	2	0	0	0
		DAY 8	19NOV2002	8	22	0	3	2	0	1	2	1	3	1	0	3	2	0	2	2	0	0	0
		DAY 15	26NOV2002	15	18	-4	2	2	0	0	2	1	3	1	0	2	1	0	2	2	0	0	0
		DAY 22	03DEC2002	22	20	-2	3	2	0	1	2	1	3	1	0	2	1	0	2	2	0	0	0
		DAY 29	11DEC2002	30	23	1	3	2	1	2	2	1	3	1	1	2	1	0	2	2	0	0	0
		DAY 36	18DEC2002	37	26	4	3	2	1	2	2	2	3	1	1	3	2	0	2	2	0	0	0
		DAY 43	23DEC2002	42	23	1	3	2	1	2	2	1	3	1	1	1	2	0	2	2	0	0	0
		DAY 50	30DEC2002	49	21	-1	2	2	0	2	2	1	3	2	0	1	2	0	2	2	0	0	0
		DAY 57	06JAN2003	56	20	-2	3	2	0	1	2	1	2	1	0	2	2	0	2	2	0	0	0
	E0013005	SCREEN	11FEB2003	-7	25		4	2	1	2	2	1	3	0	0	2	2	1	2	2	0	1	0
		DAY 1	18FEB2003	1	27		4	2	1	2	2	1	3	0	1	2	2	1	2	2	1	1	0
		DAY 8	25FEB2003	8	17	-10	2	2	1	1	0	0	3	1	0	2	2	0	1	2	0	0	0
		DAY 15	04MAR2003	15	14	-13	1	2	1	1	0	0	2	0	0	1	2	0	1	2	0	1	0
		DAY 22	11MAR2003	22	11	-16	1	1	1	0	0	0	2	0	0	2	2	0	1	1	0	0	0
		DAY 29	19MAR2003	30	7	-20	1	0	0	0	1	0	1	0	0	1	1	0	1	1	0	0	0
		DAY 36	25MAR2003	36	12	-15	1	0	0	1	0	0	2	0	0	2	2	1	1	2	0	0	0
		DAY 43	02APR2003	44	19	-8	1	2	1	2	1	0	3	0	0	2	2	1	1	2	0	1	0
		DAY 50	08APR2003	50	10	-17	1	0	0	0	0	0	3	0	0	2	1	0	1	2	0	0	0
		DAY 57	15APR2003	57	20	-7	2	2	0	0	2	2	3	0	0	2	2	1	1	2	1	0	0
	E0013013	SCREEN	01MAY2003	-5	21		3	2	0	0	2	1	3	1	0	2	2	1	2	2	0	0	0
		DAY 1	06MAY2003	1	22		3	2	0	0	2	1	3	1	1	2	2	1	2	2	0	0	0
		DAY 8	12MAY2003	7	2	-20	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
		DAY 15	19MAY2003	14	20	-2	2	1	0	2	2	2	3	1	0	2	2	2	1	0	0	0	0
		DAY 22	27MAY2003	22	13	-9	2	1	0	1	0	0	1	0	1	2	2	0	1	2	0	0	0
		DAY 22 *	30MAY2003	25	19	-3	1	0	0	2	2	2	1	0	3	2	2	0	0	2	0	2	0
	E0014002	SCREEN	19FEB2003	-7	23		3	2	0	2	1	2	3	1	2	3	0	0	2	2	0	0	0
		DAY 1	26FEB2003	1	23		3	2	0	2	0	0	3	1	2	3	1	0	2	2	2	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0014002	DAY 8		04MAR2003	7	14	-9	1	1	0	0	1	1	3	0	1	3	0	0	1	2	0	0	0
		DAY 15		12MAR2003	15	9	-14	1	1	0	0	0	0	2	0	0	2	0	0	1	2	0	0	0
		DAY 22		20MAR2003	23	26	3	2	2	0	2	1	2	3	3	0	3	3	0	2	2	1	0	0
		DAY 29		27MAR2003	30	25	2	2	3	1	1	1	1	3	1	0	3	4	0	2	2	1	0	0
		DAY 43		10APR2003	44	22	-1	3	2	0	1	1	1	4	3	0	2	2	0	1	2	0	0	0
	E0014004	SCREEN		04MAR2003	-8	30		3	1	0	0	2	2	4	4	1	4	3	0	2	2	2	0	0
		DAY 1		12MAR2003	1	31		3	1	0	1	2	2	4	3	1	4	3	0	2	2	3	0	0
		DAY 8		20MAR2003	9	28	-3	3	2	0	1	2	2	3	2	0	3	3	1	2	2	2	0	0
		DAY 15		25MAR2003	14	12	-19	0	0	0	0	1	0	2	0	0	2	3	0	1	2	1	0	0
		DAY 22		01APR2003	21	17	-14	1	0	0	0	2	0	2	2	0	2	2	0	2	2	2	0	0
		DAY 36		15APR2003	35	23	-8	2	0	0	2	2	1	2	2	2	3	3	0	2	2	0	0	0
	E0014009	SCREEN		15APR2003	-8	32		3	3	2	2	2	2	3	3	2	4	2	0	2	2	0	0	0
		DAY 1		23APR2003	1	32		3	2	2	2	2	2	3	2	2	4	2	0	2	2	2	0	0
		DAY 8		30APR2003	8	31	-1	3	2	2	2	2	2	2	1	2	4	2	0	2	2	2	1	0
	E0014015	SCREEN		11JUN2003	-7	21		3	2	1	0	1	1	4	2	0	2	2	0	2	1	0	0	0
		DAY 1		18JUN2003	1	26		3	1	1	0	1	1	4	3	1	4	2	0	2	2	0	0	1
		DAY 8		26JUN2003	9	6	-20	2	0	0	0	0	0	0	1	2	0	0	0	1	0	0	0	0
	E0014017	SCREEN		17JUN2003	-10	26		2	2	2	2	2	1	3	1	1	2	2	2	2	2	0	0	0
		DAY 1		27JUN2003	1	24		2	1	2	2	2	1	2	1	1	2	2	2	2	2	0	0	0
		DAY 8		02JUL2003	6	22	-2	2	2	2	2	1	1	3	0	1	2	1	2	2	0	0	1	0
		DAY 15		09JUL2003	13	5	-19	1	1	0	1	0	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 22		16JUL2003	20	2	-22	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 29		23JUL2003	27	1	-23	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	*	29JUL2003	33	2	-22	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 36		05AUG2003	40	5	-19	0	0	0	0	0	0	0	0	0	1	2	0	2	0	0	0	0
		DAY 43		12AUG2003	47	2	-22	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0014017	DAY 50	19AUG2003	54	2	-22	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	E0014018	SCREEN	24JUN2003	-7	24		2	1	1	2	2	0	4	3	1	1	2	1	2	1	1	0	0
		DAY 1	01JUL2003	1	26		3	1	1	2	2	0	4	3	1	1	3	2	2	0	1	0	0
		DAY 8	09JUL2003	9	30	4	3	2	2	1	2	0	4	4	2	3	2	2	2	0	1	0	0
		DAY 15	16JUL2003	16	32	6	3	2	1	1	1	1	4	4	2	3	3	2	2	0	1	0	2
		DAY 22	22JUL2003	22	27	1	2	2	2	2	1	1	4	1	1	3	2	2	2	0	1	0	1
		DAY 29	29JUL2003	29	14	-12	1	1	0	2	0	0	3	0	1	1	2	0	2	0	1	0	0
		DAY 36	05AUG2003	36	23	-3	3	1	0	2	2	2	2	2	1	1	3	0	2	1	1	0	0
		DAY 43	12AUG2003	43	25	-1	2	2	1	2	2	2	2	2	0	2	2	2	2	1	1	0	0
		DAY 50	19AUG2003	50	26	0	2	2	1	2	1	2	3	2	0	3	3	2	2	1	0	0	0
		DAY 57	27AUG2003	58	21	-5	3	2	1	1	1	1	3	1	1	2	1	1	1	1	1	0	0
	E0015005	SCREEN	25NOV2002	-7	22		3	2	0	2	1	2	3	1	1	2	1	0	2	2	0	0	0
		DAY 1	02DEC2002	1	22		3	2	0	1	2	2	3	1	1	2	1	0	2	2	0	0	0
		DAY 8	11DEC2002	10	23	1	2	2	0	2	2	2	3	1	2	2	1	0	2	2	0	0	0
		DAY 15	18DEC2002	17	25	3	3	2	1	2	2	2	3	1	1	2	1	0	2	2	1	0	0
	E0017002	SCREEN	06MAY2003	-28	20		3	3	0	0	1	1	4	2	0	1	0	0	2	1	1	1	0
		DAY 1	03JUN2003	1	23		3	2	2	1	1	0	3	2	0	3	2	0	2	1	0	1	0
	E0018009	SCREEN	17DEC2002	-20	24		2	2	1	2	2	2	3	0	2	2	2	0	2	1	1	0	0
		DAY 1	06JAN2003	1	24		3	2	0	2	2	2	3	2	1	2	2	1	1	0	1	0	0
		DAY 8	13JAN2003	8	24	0	3	2	0	2	2	2	3	2	1	2	2	1	2	0	0	0	0
		DAY 8 *	14JAN2003	9	25	1	3	2	1	2	2	2	2	0	2	2	2	1	2	1	1	0	0
	E0018010	SCREEN	09JAN2003	-7	25		2	2	1	2	2	2	2	0	2	2	2	1	2	1	1	1	0
		DAY 1	16JAN2003	1	25		3	1	1	2	2	2	2	2	1	2	2	1	1	1	1	1	0
		DAY 8	23JAN2003	8	24	-1	2	1	0	2	2	2	3	2	1	2	2	1	2	1	1	0	0
		DAY 15	30JAN2003	15	18	-7	2	1	0	1	1	0	3	0	2	2	2	1	1	1	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0018010	DAY 22	06FEB2003	22	12	-13	2	0	0	0	1	1	2	0	1	1	1	0	1	1	1	0	0
		DAY 29	13FEB2003	29	13	-12	2	0	0	1	1	1	1	1	0	1	1	1	1	1	1	0	0
		DAY 36	20FEB2003	36	16	-9	1	0	0	1	2	1	3	2	0	1	1	1	1	1	1	0	0
		DAY 43	26FEB2003	42	11	-14	2	0	0	0	0	1	2	1	0	1	0	1	1	1	1	0	0
		DAY 50	06MAR2003	50	7	-18	1	1	0	0	0	0	1	1	0	1	0	0	1	1	0	0	0
		DAY 57	13MAR2003	57	10	-15	1	1	0	1	1	0	0	0	1	1	1	1	1	0	0	1	0
	E0018015	SCREEN	21JAN2003	-7	27		3	2	1	1	2	1	4	2	1	2	2	0	2	0	1	2	1
		DAY 1	28JAN2003	1	23		3	2	0	1	2	0	3	2	0	2	2	1	1	2	1	1	0
		DAY 8	04FEB2003	8	17	-6	3	2	1	0	1	0	2	2	0	2	2	0	1	0	1	0	0
		DAY 15	13FEB2003	17	15	-8	2	2	1	0	0	0	2	2	0	1	1	1	2	1	0	0	0
		DAY 22	20FEB2003	24	16	-7	3	2	0	0	0	0	3	2	0	2	0	1	1	1	1	0	0
		DAY 29	26FEB2003	30	8	-15	2	2	0	0	0	0	1	0	0	1	1	0	0	1	0	0	0
		DAY 36	06MAR2003	38	3	-20	0	1	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
		DAY 43	13MAR2003	45	5	-18	1	1	0	0	1	0	1	0	0	1	0	0	0	0	0	0	0
		DAY 50	20MAR2003	52	3	-20	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	27MAR2003	59	10	-13	1	1	0	0	1	1	1	1	0	2	1	0	1	0	0	0	0
	E0020015	SCREEN	18MAR2003	-9	29		3	3	1	2	2	2	4	1	0	3	2	2	2	2	0	0	0
		DAY 1	27MAR2003	1	27		3	3	2	2	1	0	4	1	0	3	2	2	2	2	0	0	0
		DAY 8	03APR2003	8	26	-1	3	3	1	2	1	0	4	1	0	3	2	2	2	2	0	0	0
		DAY 15	10APR2003	15	25	-2	3	3	2	2	1	0	4	1	0	3	2	2	0	2	0	0	0
		DAY 22	16APR2003	21	23	-4	2	3	2	2	1	0	4	0	1	1	2	2	1	2	0	0	0
		DAY 29	23APR2003	28	21	-6	2	1	2	2	1	0	4	0	0	2	2	1	1	2	1	0	0
		DAY 36	30APR2003	35	22	-5	2	3	2	2	1	0	3	0	0	1	2	2	2	2	0	0	0
		DAY 43	08MAY2003	43	21	-6	2	3	2	2	1	0	3	0	0	1	2	2	1	2	0	0	0
		DAY 50	15MAY2003	50	22	-5	2	3	2	2	1	0	3	0	0	1	2	2	2	2	0	0	0
		DAY 57	23MAY2003	58	29	2	3	2	2	2	1	2	4	1	0	2	2	2	2	2	2	0	0
	E0020017	SCREEN	27MAR2003	-7	23		2	2	0	1	2	1	3	1	2	3	2	0	2	1	0	0	1

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0020017	DAY 1		03APR2003	1	21		2	2	0	0	0	1	3	1	2	3	2	0	2	1	1	0	1
		DAY 8		10APR2003	8	13	-8	2	2	0	0	0	0	1	0	1	2	2	0	2	1	0	0	0
		DAY 15		17APR2003	15	23	2	3	2	0	0	0	1	3	0	2	4	3	0	2	0	3	0	0
		DAY 22		22APR2003	20	12	-9	1	2	0	0	1	0	1	0	1	2	2	0	2	0	0	0	0
		DAY 29		29APR2003	27	10	-11	1	2	0	0	0	0	0	0	1	2	2	0	2	0	0	0	0
		DAY 29	*	05MAY2003	33	15	-6	2	2	0	0	0	1	3	0	1	1	2	0	2	0	1	0	0
		DAY 36		12MAY2003	40	9	-12	0	0	0	0	1	0	1	0	1	1	2	0	2	0	1	0	0
		DAY 50		20MAY2003	48	7	-14	0	0	0	0	0	0	1	0	1	1	2	0	2	0	0	0	0
	E0020020	SCREEN		07MAY2003	-5	20		3	2	2	0	0	0	3	1	1	3	2	0	2	1	0	0	0
		DAY 1		12MAY2003	1	28		3	3	2	2	2	2	3	0	1	3	2	1	2	2	0	0	0
		DAY 8		19MAY2003	8	23	-5	3	1	2	2	2	0	3	0	1	2	2	1	2	2	0	0	0
		DAY 8	*	23MAY2003	12	33	5	4	4	3	2	2	2	3	0	4	4	3	0	0	2	0	0	0
	E0020022	SCREEN		09JUN2003	-7	28		3	2	0	2	2	0	3	1	1	3	2	1	2	2	3	0	1
		DAY 1		16JUN2003	1	21		2	0	0	2	2	0	3	1	1	1	2	1	1	2	2	0	1
		DAY 8		23JUN2003	8	10	-11	0	0	0	2	0	0	1	1	1	0	0	0	1	2	2	0	0
		DAY 15		30JUN2003	15	9	-12	0	0	0	2	0	0	1	1	0	0	0	0	1	2	2	0	0
		DAY 22		07JUL2003	22	10	-11	0	0	0	0	0	2	3	0	0	0	0	2	1	2	0	0	0
		DAY 29		14JUL2003	29	6	-15	1	0	0	0	0	0	1	0	0	1	0	1	0	2	0	0	0
		DAY 36		21JUL2003	36	2	-19	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 43		28JUL2003	43	2	-19	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 50		04AUG2003	50	2	-19	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 57		11AUG2003	57	2	-19	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
	E0022001	SCREEN		07OCT2002	-21	32		3	3	2	2	2	1	3	2	1	2	1	2	2	2	2	2	0
		DAY 1		28OCT2002	1	29		3	2	2	2	2	1	3	2	1	2	2	1	2	2	2	0	0
		DAY 8		04NOV2002	8	26	-3	3	2	2	2	2	1	3	1	0	2	2	1	2	2	1	0	0
		DAY 15		11NOV2002	15	18	-11	3	2	0	2	0	0	3	1	0	1	0	1	1	2	2	0	0
		DAY 22		18NOV2002	22	25	-4	3	2	0	2	0	2	3	2	0	3	1	1	2	2	2	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0022001	DAY 29	26NOV2002	30	18	-11	2	1	0	2	1	1	2	1	0	2	2	0	1	1	2	0	0
		DAY 36	02DEC2002	36	26	-3	3	2	0	2	2	2	3	2	0	3	1	1	2	1	2	0	0
		DAY 43	09DEC2002	43	14	-15	1	0	0	2	1	0	2	1	0	1	2	0	1	1	2	0	0
		DAY 50	16DEC2002	50	7	-22	1	0	0	2	0	0	0	0	1	0	0	0	1	0	2	0	0
		DAY 57	26DEC2002	60	25	-4	3	2	0	2	2	1	3	1	0	2	2	1	2	2	2	0	0
	E0022004	SCREEN	17OCT2002	-11	33		3	2	2	2	2	2	3	2	2	2	1	2	2	2	2	2	0
		DAY 1	28OCT2002	1	31		3	2	2	2	2	1	3	2	1	3	2	2	2	2	2	0	0
		DAY 8	04NOV2002	8	28	-3	3	2	1	2	2	2	3	2	1	2	2	1	2	1	2	0	0
		DAY 15	11NOV2002	15	28	-3	3	2	1	2	2	2	3	2	1	2	2	1	2	1	2	0	0
		DAY 22	19NOV2002	23	32	1	3	2	2	2	2	2	3	2	2	3	2	1	2	2	2	0	0
		DAY 29	26NOV2002	30	25	-6	2	2	0	2	2	2	3	2	2	2	0	1	2	2	1	0	0
		DAY 36	02DEC2002	36	32	1	3	2	2	2	2	2	3	2	2	3	2	1	2	2	2	0	0
		DAY 43	10DEC2002	44	26	-5	2	2	0	2	1	2	3	1	1	3	2	1	2	2	2	0	0
		DAY 50	16DEC2002	50	27	-4	3	2	1	2	2	2	3	2	2	2	0	0	2	2	2	0	0
		DAY 57	23DEC2002	57	29	-2	2	2	1	2	2	2	3	2	2	2	2	1	2	2	2	0	0
	E0022005	SCREEN	17OCT2002	-22	28		3	2	2	0	2	2	3	2	2	3	2	0	2	1	2	0	0
		DAY 1	08NOV2002	1	28		3	2	2	0	2	2	3	2	2	3	2	0	2	2	1	0	0
		DAY 8	15NOV2002	8	24	-4	3	2	1	0	1	1	3	2	2	2	2	0	2	1	2	0	0
		DAY 15	22NOV2002	15	24	-4	3	2	1	0	2	2	3	2	2	2	2	0	2	1	0	0	0
		DAY 22	29NOV2002	22	23	-5	3	2	1	0	0	0	3	2	2	3	2	0	2	1	2	0	0
		DAY 29	06DEC2002	29	24	-4	3	1	1	2	2	0	3	2	2	3	2	0	2	1	0	0	0
		DAY 36	13DEC2002	36	19	-9	2	2	0	0	2	2	2	1	2	2	2	0	1	1	0	0	0
		DAY 43	20DEC2002	43	26	-2	3	2	1	0	2	2	3	2	2	2	2	0	2	1	2	0	0
		DAY 50	27DEC2002	50	27	-1	3	2	1	2	0	1	3	2	2	3	2	0	2	2	2	0	0
		DAY 57	03JAN2003	57	25	-3	3	2	1	2	2	1	3	2	2	2	2	0	2	1	0	0	0
	E0022011	SCREEN	20NOV2002	-9	25		3	2	0	0	0	0	4	2	2	3	2	1	2	2	2	0	0
		DAY 1	29NOV2002	1	25		3	2	0	0	2	0	4	2	1	3	2	1	2	1	2	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0022015	SCREEN	29NOV2002	-11	26		3	2	0	2	2	1	3	1	1	3	2	0	2	2	2	0	0
		DAY 1	10DEC2002	1	24		3	2	2	2	1	2	2	0	1	3	2	0	2	2	0	0	0
		DAY 8	17DEC2002	8	24	0	3	2	2	2	1	1	2	1	0	2	1	1	2	2	0	0	0
		DAY 15	26DEC2002	17	13	-11	2	2	0	2	1	2	1	0	0	2	0	1	0	0	0	0	0
		DAY 22	02JAN2003	24	10	-14	0	1	0	2	1	2	1	0	0	0	1	0	0	1	1	0	0
		DAY 29	09JAN2003	31	19	-5	2	2	1	2	1	1	2	1	0	2	1	0	2	2	0	0	0
		DAY 36	16JAN2003	38	25	1	3	2	2	1	2	2	2	1	0	2	2	2	2	1	1	0	0
		DAY 43	23JAN2003	45	19	-5	2	2	0	2	2	1	1	0	0	3	2	0	1	1	2	0	0
		DAY 50	30JAN2003	52	18	-6	2	2	0	2	1	2	1	1	0	3	1	0	0	1	2	0	0
		DAY 57	06FEB2003	59	21	-3	3	2	0	2	2	2	2	0	1	2	2	0	1	1	1	0	0
	E0022016	SCREEN	03DEC2002	-14	25		3	2	2	0	2	0	3	2	1	2	2	0	2	2	2	0	0
		DAY 1	17DEC2002	1	23		3	2	1	1	1	1	3	2	1	1	2	0	2	2	1	0	0
		DAY 8	26DEC2002	10	25	2	3	3	1	1	1	1	3	2	1	2	2	0	2	2	1	0	0
		DAY 15	30DEC2002	14	27	4	3	2	2	2	0	2	3	2	1	1	2	0	2	2	1	2	0
		DAY 22	06JAN2003	21	24	1	3	2	1	2	1	1	3	2	1	1	2	0	2	2	1	0	0
		DAY 29	13JAN2003	28	26	3	3	2	1	2	2	2	3	2	1	1	2	0	2	2	1	0	0
		DAY 36	21JAN2003	36	25	2	3	2	1	2	1	2	3	2	1	2	2	0	2	2	0	0	0
		DAY 43	30JAN2003	45	24	1	3	2	1	2	2	1	3	2	1	1	2	0	2	2	0	0	0
		DAY 50	06FEB2003	52	29	6	3	2	1	2	2	1	3	2	1	2	2	1	2	2	1	2	0
		DAY 57	11FEB2003	57	25	2	3	2	1	2	2	1	3	2	1	2	0	0	2	2	2	0	0
	E0022020	SCREEN	05DEC2002	-7	35		3	2	1	2	2	2	4	2	2	3	2	1	2	2	3	2	0
		DAY 1	12DEC2002	1	22		3	1	1	2	1	0	4	1	2	3	1	0	2	1	0	0	0
		DAY 8	19DEC2002	8	27	5	3	2	1	1	2	2	3	2	2	3	2	0	2	1	1	0	0
		DAY 15	26DEC2002	15	22	0	3	1	1	2	1	0	3	1	2	3	1	0	2	2	0	0	0
		DAY 22	02JAN2003	22	14	-8	2	0	0	0	1	1	2	1	1	2	0	0	1	1	0	2	0
		DAY 29	10JAN2003	30	15	-7	2	0	0	2	1	0	1	1	1	2	1	0	1	1	0	2	0
		DAY 36	16JAN2003	36	8	-14	1	0	1	0	0	0	1	0	1	1	0	0	1	2	0	0	0
		DAY 43	23JAN2003	43	10	-12	1	0	0	2	1	0	1	0	1	1	1	0	2	0	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0022023	SCREEN	19DEC2002	-6	31		3	2	1	2	2	2	4	2	1	3	1	1	2	2	1	2	0
		DAY 1	24DEC2002	-1	35		4	1	1	2	2	2	4	3	2	3	2	1	2	2	2	2	0
		DAY 8	02JAN2003	9	31	-4	4	2	2	2	2	2	4	2	1	3	1	1	2	2	1	0	0
		DAY 15	09JAN2003	16	18	-17	2	1	1	2	1	0	1	1	0	3	2	0	2	1	1	0	0
		DAY 22	16JAN2003	23	23	-12	3	1	1	2	2	2	2	2	1	1	2	0	2	1	1	0	0
		DAY 29	23JAN2003	30	15	-20	1	1	1	2	2	1	1	1	1	1	1	0	1	0	1	0	0
		DAY 36	30JAN2003	37	14	-21	2	0	0	2	2	0	2	2	0	1	0	0	1	1	1	0	0
		DAY 43	06FEB2003	44	19	-16	3	0	0	2	2	1	3	2	0	1	1	0	2	1	1	0	0
		DAY 50	13FEB2003	51	14	-21	2	0	0	2	2	1	2	2	0	0	0	0	1	1	1	0	0
		DAY 57	20FEB2003	58	8	-27	1	0	0	0	1	0	2	1	0	1	0	0	1	0	1	0	0
	E0022029	SCREEN	05FEB2003	-14	21		3	3	2	2	2	0	3	1	0	2	0	0	2	0	1	0	0
		DAY 1	19FEB2003	1	20		3	2	0	2	2	1	3	1	1	2	0	0	2	0	1	0	0
		DAY 8	26FEB2003	8	13	-7	2	2	0	0	1	1	2	0	0	2	0	0	1	0	2	0	0
		DAY 15	03MAR2003	13	18	-2	2	2	0	1	2	1	3	0	0	2	2	0	2	0	1	0	0
		DAY 22	12MAR2003	22	11	-9	1	1	0	1	2	1	1	0	0	2	0	0	1	0	1	0	0
		DAY 29	18MAR2003	28	10	-10	1	2	0	0	2	1	1	0	0	2	0	0	0	0	1	0	0
		DAY 36	26MAR2003	36	11	-9	1	2	0	0	2	1	1	0	0	0	2	0	1	0	1	0	0
		DAY 43	02APR2003	43	12	-8	2	1	0	0	2	1	2	1	0	1	0	0	1	0	1	0	0
		DAY 50	07APR2003	48	16	-4	2	2	0	0	2	1	2	1	0	2	2	0	1	0	1	0	0
		DAY 57	14APR2003	55	15	-5	2	2	0	0	2	1	2	1	0	2	0	0	2	0	1	0	0
	E0022041	SCREEN	04MAR2003	-14	23		3	2	2	0	1	1	3	0	1	2	2	2	2	2	0	0	0
		DAY 1	18MAR2003	1	26		3	2	1	0	2	0	3	1	1	1	2	2	2	2	2	2	0
		DAY 8	25MAR2003	8	17	-9	3	2	1	0	1	0	3	1	1	1	2	0	0	2	0	0	0
		DAY 15	01APR2003	15	17	-9	3	1	1	2	2	2	3	0	1	1	0	0	1	0	0	0	0
		DAY 22	08APR2003	22	13	-13	1	1	0	0	1	1	3	0	0	0	0	1	2	2	1	0	0
		DAY 29	15APR2003	29	13	-13	2	1	0	0	2	1	2	0	1	1	1	0	1	1	0	0	0
		DAY 36	21APR2003	35	9	-17	2	0	0	0	0	1	1	0	1	0	1	0	1	2	0	0	0
		DAY 43	29APR2003	43	6	-20	1	1	0	0	0	1	0	0	0	1	1	0	0	1	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0022041	DAY 50	06MAY2003	50	10	-16	1	0	0	0	2	1	0	0	0	1	1	0	1	2	1	0	0
		DAY 57	13MAY2003	57	8	-18	0	0	0	0	0	1	1	0	1	1	2	0	0	1	0	1	0
	E0022042	SCREEN	05MAR2003	-7	22		3	2	2	1	1	1	3	2	1	1	0	0	2	2	1	0	0
		DAY 1	12MAR2003	1	25		3	2	2	1	2	1	3	2	2	1	1	0	2	2	1	0	0
		DAY 8	19MAR2003	8	28	3	3	2	2	2	2	2	3	2	1	1	2	0	2	2	2	0	0
		DAY 15	27MAR2003	16	24	-1	3	2	2	2	2	2	1	1	2	1	0	2	2	2	0	0	0
		DAY 22	02APR2003	22	20	-5	4	2	2	0	2	1	3	1	1	0	0	0	1	2	1	0	0
		DAY 29	10APR2003	30	23	-2	3	2	1	2	2	1	3	1	0	1	2	0	2	2	1	0	0
		DAY 36	17APR2003	37	20	-5	3	1	1	2	2	1	3	1	0	0	2	0	2	2	0	0	0
		DAY 43	24APR2003	44	25	0	3	2	2	2	2	1	3	1	1	1	2	0	2	2	1	0	0
		DAY 50	01MAY2003	51	24	-1	3	2	2	2	2	1	3	2	0	1	2	0	2	2	0	0	0
		DAY 57	12MAY2003	62	25	0	3	2	2	2	2	1	3	2	1	1	2	0	2	2	0	0	0
	E0022043	SCREEN	10MAR2003	-10	20		3	2	0	0	1	0	3	2	0	3	2	0	2	1	1	0	0
		DAY 1	20MAR2003	1	20		3	2	0	1	0	0	3	2	0	3	2	1	2	0	1	0	0
		DAY 8	26MAR2003	7	13	-7	3	1	0	1	1	0	1	1	0	3	2	0	0	0	0	0	0
		DAY 15	03APR2003	15	10	-10	2	0	0	1	1	0	0	0	0	3	2	0	1	0	0	0	0
		DAY 22	10APR2003	22	14	-6	2	1	0	2	1	0	0	1	0	3	2	0	1	0	1	0	0
		DAY 29	17APR2003	29	10	-10	2	0	0	0	0	0	1	0	1	0	2	0	2	0	2	0	0
		DAY 36	24APR2003	36	8	-12	1	0	0	2	1	0	0	1	0	0	2	0	1	0	0	0	0
		DAY 43	01MAY2003	43	12	-8	2	2	0	1	1	0	0	1	0	2	2	0	1	0	0	0	0
		DAY 50	08MAY2003	50	8	-12	1	1	0	2	0	0	0	0	0	1	2	0	1	0	0	0	0
		DAY 50 *	12MAY2003	54	5	-15	0	0	0	1	0	0	0	0	0	1	2	0	1	0	0	0	0
	E0022054	SCREEN	04APR2003	-7	26		3	2	1	2	2	0	4	1	1	2	2	1	2	2	1	0	0
		DAY 1	11APR2003	1	26		3	2	1	2	2	1	4	1	0	2	2	1	2	2	1	0	0
		DAY 8	18APR2003	8	14	-12	3	1	1	0	0	0	3	1	1	1	2	0	1	0	0	0	0
		DAY 15	28APR2003	18	8	-18	1	0	0	1	0	0	1	0	1	1	2	0	1	0	0	0	0
		DAY 22	02MAY2003	22	6	-20	0	0	0	0	0	0	1	0	1	1	2	0	0	0	0	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0022054	DAY 29		12MAY2003	32	8	-18	0	0	0	2	0	0	0	1	0	1	2	0	2	0	0	0	0
		DAY 36		16MAY2003	36	8	-18	0	1	0	0	0	0	2	1	1	2	1	0	0	0	0	0	0
	E0022059	SCREEN		22APR2003	-14	28		3	2	2	2	2	2	3	1	2	3	1	0	2	2	1	0	0
		DAY 1		06MAY2003	1	25		3	1	2	2	2	2	3	0	3	2	1	0	2	0	1	0	1
		DAY 8		13MAY2003	8	19	-6	3	2	2	2	1	0	2	0	2	2	1	0	2	0	0	0	0
		DAY 15		20MAY2003	15	19	-6	3	2	1	0	0	0	3	1	2	2	2	0	2	1	0	0	0
		DAY 22		27MAY2003	22	18	-7	3	1	2	0	0	0	3	0	2	3	1	0	2	1	0	0	0
		DAY 29		03JUN2003	29	17	-8	2	2	2	2	0	0	2	1	2	1	0	0	2	1	0	0	0
		DAY 36		10JUN2003	36	17	-8	2	2	2	0	0	0	2	0	3	2	1	0	1	1	1	0	0
		DAY 43		17JUN2003	43	15	-10	2	2	2	0	0	0	2	0	2	2	0	0	2	1	0	0	0
		DAY 43	*	20JUN2003	46	19	-6	2	2	2	0	1	0	3	0	2	2	0	0	2	1	2	0	0
		DAY 57		08JUL2003	64	19	-6	2	2	2	1	1	1	2	0	2	2	1	0	2	1	0	0	0
	E0022065	SCREEN		30APR2003	-7	28		3	2	2	2	2	1	3	1	2	3	2	0	2	2	1	0	0
		DAY 1		07MAY2003	1	24		3	2	1	1	1	2	3	1	1	2	2	0	2	2	1	0	0
		DAY 8		14MAY2003	8	23	-1	3	3	0	2	2	2	2	0	1	2	2	0	1	2	1	0	0
		DAY 15		21MAY2003	15	15	-9	2	2	0	0	1	0	2	1	0	2	1	0	1	2	1	0	0
		DAY 22		28MAY2003	22	14	-10	2	1	0	1	0	0	1	1	0	1	2	0	2	2	1	0	0
		DAY 29		04JUN2003	29	16	-8	2	1	0	0	0	0	2	0	2	2	2	0	2	2	1	0	0
		DAY 36		11JUN2003	36	9	-15	0	2	0	0	0	0	0	0	0	1	2	0	1	2	1	0	0
		DAY 43		18JUN2003	43	10	-14	0	1	0	0	0	0	1	0	0	2	2	0	1	2	1	0	0
		DAY 50		25JUN2003	50	15	-9	2	2	0	0	1	2	1	0	0	1	2	0	2	2	0	0	0
		DAY 57		02JUL2003	57	5	-19	1	1	0	0	0	0	0	0	0	1	0	0	0	1	1	0	0
	E0022070	SCREEN		05JUN2003	-7	26		3	3	2	2	0	2	3	2	1	2	2	0	2	2	0	0	0
		DAY 1		12JUN2003	1	31		3	3	2	2	2	2	3	2	0	2	2	2	2	2	0	2	0
		DAY 8		18JUN2003	7	32	1	3	3	3	2	2	2	3	2	0	2	2	2	2	2	0	2	0
	E0023001	SCREEN		24OCT2002	-22	24		3	2	1	0	2	1	4	1	2	3	2	0	1	1	1	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0023001	DAY 1	15NOV2002	1	23		3	2	1	0	2	1	4	1	2	3	2	0	1	1	0	0	0
		DAY 8	22NOV2002	8	23	0	3	2	1	2	1	1	3	0	1	4	2	0	1	1	1	0	0
		DAY 15	29NOV2002	15	16	-7	1	1	1	1	1	1	2	0	1	3	2	0	1	1	0	0	0
		DAY 22	06DEC2002	22	20	-3	3	1	1	0	0	1	3	0	2	4	2	1	1	0	1	0	0
		DAY 29	16DEC2002	32	16	-7	1	1	0	1	1	1	2	0	1	3	1	2	1	0	1	0	0
		DAY 36	23DEC2002	39	14	-9	1	0	0	1	1	1	2	0	1	3	1	2	1	0	0	0	0
		DAY 43	30DEC2002	46	18	-5	3	1	0	1	1	1	2	1	1	3	1	1	1	1	0	0	0
		DAY 50	07JAN2003	54	27	4	3	3	2	1	1	1	3	1	2	4	2	2	1	0	1	0	0
		DAY 57	14JAN2003	61	23	0	2	2	1	1	1	1	3	1	1	3	2	2	2	0	1	0	0
	E0023009	SCREEN	24JAN2003	-18	21		3	2	1	0	0	0	3	1	1	3	1	1	2	2	1	0	0
		DAY 1	11FEB2003	1	21		3	2	1	0	0	0	3	1	1	3	1	1	2	2	1	0	0
		DAY 8	18FEB2003	8	18	-3	3	0	1	1	0	0	3	1	0	2	1	1	2	2	1	0	0
		DAY 15	27FEB2003	17	9	-12	2	0	0	2	0	0	1	0	1	1	0	0	1	1	0	0	0
		DAY 22	04MAR2003	22	8	-13	2	0	0	2	0	0	1	0	0	1	0	0	1	1	0	0	0
		DAY 29	11MAR2003	29	2	-19	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0
		DAY 36	18MAR2003	36	5	-16	0	0	0	1	0	0	0	0	0	1	1	0	1	1	0	0	0
		DAY 43	25MAR2003	43	5	-16	0	0	0	1	0	0	0	0	0	1	1	0	1	1	0	0	0
		DAY 50	03APR2003	52	5	-16	0	0	0	0	0	0	0	0	0	2	2	0	0	1	0	0	0
		DAY 57	08APR2003	57	4	-17	0	0	0	0	0	0	0	0	0	2	1	0	0	1	0	0	0
	E0023028	SCREEN	16MAY2003	-13	23		3	2	1	0	1	0	3	1	1	3	2	2	2	2	0	0	0
		DAY 1	29MAY2003	1	24		3	2	0	2	2	0	3	1	0	3	2	2	2	2	0	0	0
		DAY 8	05JUN2003	8	8	-16	0	0	0	0	2	0	0	0	2	1	1	1	0	1	0	0	0
		DAY 15	12JUN2003	15	2	-22	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 22	19JUN2003	22	4	-20	0	0	0	2	0	1	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	25JUN2003	28	2	-22	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 43	09JUL2003	42	3	-21	0	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 50	16JUL2003	49	3	-21	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0
		DAY 50 *	21JUL2003	54	4	-20	0	0	0	0	0	0	0	1	0	1	2	0	0	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0023033	SCREEN	30MAY2003	-6	22		3	2	0	0	2	1	3	0	2	3	2	1	2	1	0	0	0
		DAY 1	05JUN2003	1	21		3	2	0	0	2	1	3	0	1	3	2	1	2	1	0	0	0
		DAY 8	12JUN2003	8	25	4	3	2	1	2	2	1	3	1	0	3	2	1	2	2	0	0	0
	E0023047	SCREEN	11JUL2003	-7	28		3	2	0	2	2	2	3	2	1	2	2	2	2	1	2	0	0
		DAY 1	18JUL2003	1	27		3	2	0	0	2	2	3	2	0	3	3	2	2	1	2	0	0
		DAY 8	25JUL2003	8	23	-4	2	2	0	2	0	2	3	1	0	3	2	2	1	1	2	0	0
		DAY 15	31JUL2003	14	23	-4	3	2	0	2	0	2	2	1	0	3	2	2	1	1	2	0	0
		DAY 22	08AUG2003	22	24	-3	2	1	0	2	2	2	2	1	0	3	2	2	2	1	2	0	0
		DAY 29	15AUG2003	29	21	-6	2	2	0	2	0	2	2	1	0	3	1	1	2	1	2	0	0
		DAY 36	21AUG2003	35	18	-9	1	2	0	2	0	2	2	0	0	3	1	1	1	1	2	0	0
		DAY 43	29AUG2003	43	18	-9	1	1	0	2	2	2	3	0	0	2	0	1	2	1	1	0	0
		DAY 50	05SEP2003	50	15	-12	0	1	0	2	1	2	3	0	0	2	0	1	2	1	0	0	0
		DAY 57	12SEP2003	57	15	-12	0	1	0	2	1	2	2	0	0	3	0	1	2	1	0	0	0
	E0025001	SCREEN	25MAR2003	-7	22		3	1	2	0	1	1	3	1	2	3	1	0	1	2	1	0	0
		DAY 1	01APR2003	1	23		3	2	1	2	1	2	3	0	2	2	1	1	1	1	1	0	0
		DAY 8	10APR2003	10	23	0	3	1	2	2	2	2	1	2	0	1	2	1	0	2	2	0	0
		DAY 15	16APR2003	16	25	2	3	1	2	2	2	2	2	1	0	3	2	1	1	2	1	0	0
		DAY 22	23APR2003	23	31	8	4	2	2	2	2	2	3	2	0	3	2	1	2	2	1	1	0
	E0026012	SCREEN	05FEB2003	-15	27		3	3	1	2	2	1	3	1	0	3	2	2	2	0	0	2	0
		DAY 1	20FEB2003	1	27		3	3	1	2	2	1	3	2	0	3	2	2	2	1	0	0	0
		DAY 8	27FEB2003	8	24	-3	3	3	0	2	2	1	3	1	0	3	2	1	2	0	0	1	0
		DAY 15	06MAR2003	15	21	-6	0	2	0	2	2	1	3	2	0	2	2	1	2	0	2	0	0
		DAY 22	13MAR2003	22	7	-20	0	0	0	0	0	0	0	1	0	1	1	1	2	1	0	0	0
		DAY 29	20MAR2003	29	7	-20	0	1	0	0	0	0	0	0	0	2	0	0	2	0	2	0	0
		DAY 36	27MAR2003	36	9	-18	0	3	0	0	0	0	0	2	0	0	1	0	2	0	1	0	0
		DAY 43	03APR2003	43	13	-14	1	2	0	0	0	0	3	1	0	2	0	1	1	0	1	1	0
		DAY 50	10APR2003	50	18	-9	1	2	0	0	0	1	3	3	0	2	0	1	2	0	2	1	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0026012	DAY 57		17APR2003	57	10	-17	1	0	0	0	1	0	1	1	0	2	0	0	1	0	2	1	0
	E0026020	SCREEN		28MAR2003	-4	25		3	2	0	2	2	2	3	2	0	2	2	1	1	2	0	1	0
		DAY 1		01APR2003	1	20		3	2	0	2	2	1	3	1	0	2	2	0	1	1	0	0	0
		DAY 8		08APR2003	8	24	4	2	1	2	2	2	2	3	1	0	3	1	0	1	2	1	1	0
		DAY 15		15APR2003	15	10	-10	2	1	0	0	1	0	1	0	0	2	0	0	1	0	2	0	0
		DAY 22		22APR2003	22	18	-2	3	2	2	2	2	0	3	0	1	3	0	0	0	0	0	0	0
	E0026024	SCREEN		25APR2003	-7	25		3	2	1	2	2	2	3	1	0	2	1	1	2	2	0	1	0
		DAY 1		02MAY2003	1	26		3	2	2	0	2	2	3	1	2	1	2	1	1	2	0	2	0
		DAY 8		09MAY2003	8	22	-4	3	2	1	1	2	2	3	1	1	1	1	0	1	2	0	1	0
		DAY 15		16MAY2003	15	22	-4	3	2	1	0	2	2	3	1	0	1	2	0	2	2	1	0	0
		DAY 22		23MAY2003	22	24	-2	2	2	0	2	2	2	3	1	0	2	1	2	2	2	1	0	0
		DAY 29		30MAY2003	29	21	-5	1	2	0	1	1	2	3	1	1	2	1	1	1	2	1	1	0
	E0026028	SCREEN		06JUN2003	-14	28		3	3	2	2	2	2	3	2	0	2	1	1	1	2	0	2	0
		DAY 1		20JUN2003	1	29		3	4	3	2	2	2	3	2	0	1	1	1	1	2	0	2	0
		DAY 8		27JUN2003	8	24	-5	1	3	2	2	2	2	2	1	0	1	1	2	1	2	0	2	0
		DAY 15		02JUL2003	13	24	-5	3	3	0	2	2	2	2	1	1	2	1	1	1	2	0	1	0
		DAY 15	*	08JUL2003	19	21	-8	1	3	1	2	2	2	1	1	0	2	1	2	1	0	1	1	0
	E0028001	SCREEN		20SEP2002	-20	25		3	1	1	2	2	2	3	2	1	2	1	1	1	2	0	1	0
		DAY 1		10OCT2002	1	24		3	2	2	2	2	2	3	1	0	3	0	0	1	2	1	0	0
		DAY 8		16OCT2002	7	19	-5	3	1	1	2	2	2	3	0	1	2	1	0	0	1	0	0	0
		DAY 15		23OCT2002	14	19	-5	3	2	2	0	2	2	2	1	1	3	0	0	0	1	0	0	0
		DAY 22		29OCT2002	20	18	-6	2	1	1	2	0	2	2	1	0	3	1	0	1	1	1	0	0
		DAY 29		05NOV2002	27	24	0	3	2	2	1	2	2	2	1	1	3	1	0	2	2	0	0	0
		DAY 36		12NOV2002	34	23	-1	3	2	2	1	0	2	3	1	0	3	2	0	1	2	1	0	0
		DAY 43		19NOV2002	41	18	-6	3	2	2	0	0	0	2	1	0	3	0	0	1	2	2	0	0
		DAY 50		26NOV2002	48	20	-4	4	2	2	1	0	2	3	1	0	3	0	0	0	2	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0028001	DAY 57	03DEC2002	55	16	-8	3	2	2	1	0	2	2	0	1	1	0	0	1	1	0	0	0
	E0028003	SCREEN	23SEP2002	-7	22		3	2	1	1	0	0	4	2	1	2	1	0	2	2	1	0	0
		DAY 1	30SEP2002	1	24		3	2	1	1	1	1	4	2	1	2	1	0	2	2	1	0	0
		DAY 8	07OCT2002	8	28	4	4	2	1	2	1	0	3	2	1	2	3	1	2	1	3	0	0
		DAY 15	16OCT2002	17	19	-5	2	2	2	0	1	1	1	0	2	1	1	1	2	2	1	0	0
		DAY 22	22OCT2002	23	23	-1	2	1	0	0	1	0	3	2	1	2	3	1	1	1	3	2	0
		DAY 29	29OCT2002	30	23	-1	3	2	2	1	1	2	3	1	0	1	2	0	1	1	3	0	0
		DAY 36	07NOV2002	39	26	2	3	2	2	0	1	2	3	1	1	2	2	1	2	1	3	0	0
		DAY 43	12NOV2002	44	22	-2	2	0	0	2	1	1	2	1	1	2	3	1	2	1	2	1	0
		DAY 50	19NOV2002	51	22	-2	3	0	0	2	2	1	3	1	0	2	3	0	1	1	3	0	0
		DAY 57	26NOV2002	58	21	-3	2	0	1	1	2	2	3	1	0	3	2	0	2	0	2	0	0
	E0028005	SCREEN	30SEP2002	-3	26		4	2	1	0	2	2	3	3	1	2	1	2	1	2	0	0	0
		DAY 1	03OCT2002	1	27		4	2	1	0	2	2	3	3	1	2	2	2	1	2	0	0	0
		DAY 8	11OCT2002	9	25	-2	4	2	2	0	0	2	3	1	0	3	1	2	1	2	2	0	0
		DAY 29	31OCT2002	29	14	-13	2	2	0	0	0	2	3	1	0	0	0	1	1	1	1	0	0
	E0028010	SCREEN	15OCT2002	-21	22		3	1	1	2	2	1	3	2	1	2	1	1	1	1	0	0	0
		DAY 1	05NOV2002	1	20		2	2	0	2	2	2	2	1	1	3	2	0	1	0	0	0	0
		DAY 8	12NOV2002	8	21	1	3	3	0	2	1	1	2	0	1	3	3	0	1	1	0	0	0
		DAY 15	19NOV2002	15	23	3	3	0	0	2	2	2	2	0	0	3	3	0	2	2	2	0	0
		DAY 22	25NOV2002	21	13	-7	0	1	0	2	1	2	0	0	0	1	3	0	2	1	0	0	0
		DAY 29	03DEC2002	29	13	-7	0	1	0	2	1	1	1	0	0	2	3	0	1	1	0	0	0
		DAY 36	10DEC2002	36	13	-7	3	0	0	2	0	1	1	0	0	1	3	0	1	1	0	0	0
		DAY 43	17DEC2002	43	8	-12	1	0	0	2	2	1	1	0	0	0	0	0	1	0	0	0	0
		DAY 50	23DEC2002	49	7	-13	0	0	0	2	1	1	1	0	0	0	1	0	1	0	0	0	0
		DAY 57	31DEC2002	57	6	-14	0	0	0	2	1	1	1	0	0	0	0	0	1	0	0	0	0
	E0028011	SCREEN	25NOV2002	-10	27		3	2	1	2	2	1	3	3	1	2	1	1	1	2	0	2	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0028011	DAY 1	05DEC2002	1	20		3	3	0	2	0	2	3	1	1	1	2	0	1	0	1	0	0
		DAY 8	12DEC2002	8	15	-5	3	3	0	0	1	2	1	0	1	3	1	0	0	0	0	0	0
		DAY 15	19DEC2002	15	8	-12	1	2	0	2	0	0	0	0	0	0	1	0	2	0	0	0	0
		DAY 22	26DEC2002	22	4	-16	1	1	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
		DAY 29	02JAN2003	29	7	-13	1	1	0	1	1	0	1	1	0	0	0	1	0	0	0	0	0
		DAY 36	09JAN2003	36	8	-12	0	1	0	0	0	0	0	0	2	1	2	0	1	0	1	0	0
		DAY 43	16JAN2003	43	6	-14	2	0	0	1	0	0	0	0	1	0	1	0	1	0	0	0	0
		DAY 50	23JAN2003	50	6	-14	1	1	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0
		DAY 57	30JAN2003	57	5	-15	1	0	0	0	0	0	0	0	1	0	2	0	1	0	0	0	0
	E0028030	SCREEN	26FEB2003	-6	23		3	2	1	0	2	2	3	2	1	2	1	1	1	2	0	0	0
		DAY 1	04MAR2003	1	25		3	2	2	2	1	2	3	3	1	1	1	1	2	0	0	1	0
		DAY 8	11MAR2003	8	17	-8	3	0	0	0	0	2	3	1	0	3	0	1	2	0	2	0	0
		DAY 15	18MAR2003	15	14	-11	3	0	0	2	1	0	3	2	0	0	1	0	1	0	1	0	0
		DAY 22	25MAR2003	22	16	-9	3	0	0	2	2	0	2	2	0	3	0	1	1	0	0	0	0
		DAY 29	01APR2003	29	15	-10	2	0	0	0	2	1	2	2	0	3	0	1	2	0	0	0	0
		DAY 36	08APR2003	36	9	-16	2	0	0	0	1	1	3	0	0	0	0	1	1	0	0	0	0
		DAY 43	17APR2003	45	16	-9	3	0	0	0	1	0	3	2	0	3	2	1	1	0	0	0	0
		DAY 50	22APR2003	50	12	-13	2	0	0	0	1	0	3	0	0	0	1	2	1	1	1	0	0
		DAY 57	30APR2003	58	18	-7	3	0	0	0	2	2	2	2	0	3	0	1	1	0	0	2	0
	E0028031	SCREEN	06MAR2003	-5	26		3	2	1	2	2	1	3	2	1	1	1	2	1	2	0	2	0
		DAY 1	11MAR2003	1	27		2	3	0	2	2	2	3	1	0	3	3	1	1	1	1	2	0
		DAY 8	18MAR2003	8	20	-7	2	3	0	0	2	2	2	1	0	3	1	1	1	1	1	0	0
		DAY 15	25MAR2003	15	18	-9	2	0	0	0	2	2	2	0	0	3	2	2	1	1	1	0	0
	E0028047	SCREEN	09JUL2003	-5	22		2	2	1	2	2	2	3	2	0	2	1	0	0	2	1	0	0
		DAY 1	14JUL2003	1	25		3	2	1	2	2	2	3	3	0	2	1	1	0	2	1	0	0
		DAY 8	21JUL2003	8	24	-1	3	2	0	2	2	2	3	1	1	3	0	0	1	2	2	0	0
		DAY 15	29JUL2003	16	27	2	3	2	0	2	2	2	3	2	0	3	2	0	2	2	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0028047	DAY 22	05AUG2003	23	28	3	3	2	0	2	2	2	3	1	1	3	2	1	1	2	2	1	0
		DAY 29	12AUG2003	30	30	5	3	2	0	2	2	2	3	2	1	3	2	2	2	2	2	0	0
		DAY 36	19AUG2003	37	23	-2	3	0	0	2	2	2	3	1	1	3	0	1	2	1	2	0	0
		DAY 43	26AUG2003	44	23	-2	3	0	0	2	2	2	3	2	1	3	0	1	2	2	0	0	0
		DAY 50	02SEP2003	51	27	2	3	2	0	2	2	2	3	2	1	3	0	1	2	2	2	0	0
		DAY 57	09SEP2003	58	28	3	3	0	0	2	2	2	3	2	1	3	3	0	2	2	3	0	0
	E0029001	SCREEN	24SEP2002	-7	29		3	1	2	2	1	2	4	3	2	3	1	1	0	1	0	2	1
		DAY 1	01OCT2002	1	27		3	1	1	0	2	2	3	2	3	2	1	1	2	1	0	2	1
		DAY 8	09OCT2002	9	27	0	3	0	2	1	1	2	3	2	3	3	1	1	2	1	0	1	1
	E0029014	SCREEN	28JAN2003	-7	21		2	2	0	2	1	1	3	0	2	2	1	0	2	2	0	0	1
		DAY 1	04FEB2003	1	21		2	2	0	1	2	2	2	0	2	2	0	1	2	1	1	0	1
		DAY 8	11FEB2003	8	20	-1	2	2	0	1	1	1	2	1	1	3	1	1	2	1	1	0	0
		DAY 15	18FEB2003	15	18	-3	1	0	0	2	2	1	2	0	1	2	1	1	2	2	1	0	0
		DAY 22	25FEB2003	22	10	-11	1	0	0	1	1	1	1	0	1	1	0	0	1	1	1	0	0
		DAY 29	06MAR2003	31	18	-3	3	0	0	1	2	1	2	1	0	2	2	0	1	2	1	0	0
		DAY 36	11MAR2003	36	22	1	2	2	0	0	2	1	2	1	1	3	2	0	2	2	1	0	1
		DAY 43	20MAR2003	45	14	-7	0	2	0	0	1	2	0	0	3	1	1	1	2	0	1	0	0
		DAY 50	27MAR2003	52	23	2	2	2	1	1	1	1	2	0	3	3	2	1	1	2	1	0	0
		DAY 57	01APR2003	57	19	-2	2	2	1	0	2	1	2	1	1	1	1	1	2	1	1	0	0
	E0029023	SCREEN	11MAR2003	-28	20		3	2	2	2	2	0	3	1	1	1	1	0	1	0	1	0	0
		DAY 1	08APR2003	1	23		3	3	2	2	2	2	2	0	1	2	1	0	2	0	1	0	0
		DAY 8	15APR2003	8	25	2	3	3	2	2	2	0	3	1	1	2	2	0	2	0	2	0	0
		DAY 15	22APR2003	15	25	2	3	3	2	2	2	2	3	0	1	2	2	0	2	0	1	0	0
		DAY 22	01MAY2003	24	25	2	3	3	2	2	2	2	2	1	1	2	1	1	2	0	1	0	0
		DAY 36	12MAY2003	35	26	3	3	3	2	2	2	2	3	1	1	2	1	1	2	0	1	0	0
		DAY 43	20MAY2003	43	24	1	3	3	2	2	2	0	3	1	1	2	1	0	2	0	2	0	0
		DAY 50	29MAY2003	52	25	2	2	2	2	2	1	1	3	0	2	3	2	0	2	2	1	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0029032	SCREEN		22MAY2003	-19	33		3	2	2	2	2	2	3	2	0	3	3	2	2	2	3	0	0
		DAY 1		10JUN2003	1	32		4	2	2	2	2	1	3	2	0	3	2	2	2	2	3	0	0
		DAY 8		17JUN2003	8	35	3	4	3	2	2	2	2	3	2	0	3	2	2	2	2	3	1	0
		DAY 22		01JUL2003	22	35	3	4	3	2	2	2	2	3	2	0	4	2	2	2	2	3	0	0
	E0029033	SCREEN		27MAY2003	-6	29		3	2	2	2	2	2	3	1	0	3	1	2	2	2	1	1	0
		DAY 1		02JUN2003	1	32		3	2	2	2	2	2	3	0	2	3	2	2	2	2	2	1	0
		DAY 8		09JUN2003	8	27	-5	2	0	2	2	2	2	3	0	2	3	2	2	2	2	1	0	0
		DAY 15		16JUN2003	15	22	-10	3	0	2	2	2	1	2	1	1	2	1	1	2	1	1	0	0
		DAY 22		23JUN2003	22	27	-5	2	2	2	2	2	2	3	0	2	3	2	1	2	1	1	0	0
		DAY 29		30JUN2003	29	27	-5	2	1	2	2	2	2	2	0	2	3	3	1	2	2	1	0	0
	E0029039	SCREEN		10JUL2003	-5	33		4	3	2	2	2	1	4	2	0	2	2	2	2	2	1	2	0
		DAY 1		15JUL2003	1	33		4	3	2	2	2	2	4	2	0	2	2	2	2	2	0	2	0
		DAY 8		23JUL2003	9	28	-5	3	2	2	2	2	2	3	1	1	1	2	1	2	2	2	0	0
		DAY 15		28JUL2003	14	28	-5	2	1	1	2	2	2	3	1	2	3	2	2	1	2	2	0	0
	E0030003	SCREEN		03DEC2002	-13	26		3	2	0	1	2	1	3	1	1	3	2	1	1	1	2	2	0
		DAY 1		16DEC2002	1	22		3	2	0	1	2	2	3	1	0	3	2	1	1	1	0		0
		DAY 8		23DEC2002	8	18	-4	3	1	0	1	2	2	3	1	0	2	0	1	1	1	0	0	0
		DAY 8	*	24DEC2002	9	18	-4	3	1	0	1	2	2	3	1	0	2	0	1	1	1	0	0	0
	E0030009	SCREEN		10JAN2003	-13	29		3	2	0	1	2	2	3	1	2	2	2	2	2	2	1	2	0
		DAY 1		23JAN2003	1	24		3	2	0	0	2	1	3	1	3	3	1	1	2	2	0	0	0
		DAY 8		29JAN2003	7	25	1	3	2	1	0	2	2	3	1	1	2	1	2	2	2	1	0	0
		DAY 15		07FEB2003	16	28	4	3	2	1	0	2	1	3	1	3	4	2	1	2	2	1	0	0
		DAY 36		27FEB2003	36	28	4	4	2	0	1	2	2	3	1	2	3	2	0	2	2	2	0	0
		DAY 43		06MAR2003	43	27	3	3	2	1	1	2	2	3	1	2	2	2	0	2	2	2	0	0
		DAY 50		12MAR2003	49	29	5	3	2	1	1	2	2	3	1	2	3	2	1	2	2	2	0	0
		DAY 57		19MAR2003	56	28	4	3	2	1	1	2	2	3	0	2	3	2	1	2	2	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0030016	SCREEN	21FEB2003	-10	25		3	2	2	2	0	2	3	1	0	1	2	2	2	1	2	0	0
		DAY 1	03MAR2003	1	30		3	3	2	2	0	2	3	1	1	2	2	2	2	2	2	1	0
		DAY 8	10MAR2003	8	25	-5	2	3	2	2	2	2	3	1	0	2	2	2	1	1	0	0	0
		DAY 15	17MAR2003	15	28	-2	3	3	2	1	1	2	3	0	1	3	2	1	2	2	2	0	0
		DAY 22	25MAR2003	23	26	-4	3	3	2	0	0	2	3	0	1	2	2	2	2	2	2	0	0
		DAY 29	02APR2003	31	26	-4	3	3	2	1	0	2	3	1	0	2	2	2	1	1	1	2	0
		DAY 36	09APR2003	38	17	-13	2	3	1	0	0	2	2	0	0	1	2	1	2	0	1	0	0
		DAY 50	22APR2003	51	19	-11	3	3	1	0	0	2	2	1	0	1	2	1	2	0	1	0	0
	E0030021	SCREEN	13MAY2003	-7	20		3	2	1	1	0	0	3	0	2	1	0	2	2	1	0	2	0
		DAY 1	20MAY2003	1	22		3	1	1	2	0	0	3	2	3	1	0	1	2	2	0	1	0
		DAY 8	27MAY2003	8	14	-8	2	1	0	0	0	0	3	1	1	1	1	0	2	2	0	0	0
		DAY 15	03JUN2003	15	11	-11	1	1	0	2	0	0	1	0	1	1	1	0	1	2	0	0	0
		DAY 22	10JUN2003	22	11	-11	1	1	0	0	2	0	1	1	1	1	1	0	0	2	0	0	0
		DAY 29	17JUN2003	29	13	-9	1	1	1	1	0	0	2	0	2	1	1	1	0	2	0	0	0
	E0031001	SCREEN	14NOV2002	-7	24		3	2	1	2	0	0	3	1	1	3	2	1	2	1	2	0	0
		DAY 1	21NOV2002	1	23		3	2	0	2	1	2	3	1	0	3	3	1	2	0	0	0	0
		DAY 8	27NOV2002	7	19	-4	3	3	0	1	0	0	3	1	0	3	1	0	2	0	0	2	0
		DAY 15	05DEC2002	15	24	1	3	2	1	1	2	1	3	1	1	3	3	0	2	1	0	0	0
		DAY 22	11DEC2002	21	20	-3	3	1	0	2	2	1	3	1	0	3	2	0	2	0	0	0	0
		DAY 29	20DEC2002	30	17	-6	3	2	0	1	0	0	3	1	1	3	2	0	1	0	0	0	0
	E0031017	SCREEN	25MAR2003	-7	23		3	2	1	0	2	2	3	0	0	3	2	1	2	1	0	1	0
		DAY 1	01APR2003	1	23		3	2	0	0	2	1	3	0	1	3	1	1	2	2	0	2	0
		DAY 8	07APR2003	7	21	-2	3	2	1	1	2	0	3	0	1	2	2	0	2	2	0	0	0
		DAY 15	15APR2003	15	17	-6	2	1	1	0	2	1	3	0	1	1	1	0	2	2	0	0	0
		DAY 22	22APR2003	22	19	-4	3	1	0	0	2	1	3	0	1	1	1	2	2	2	0	0	0
		DAY 29	29APR2003	29	17	-6	2	2	0	1	2	0	2	1	0	2	0	1	2	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0031018	SCREEN	01APR2003	-9	22		3	2	0	2	1	0	2	0	1	3	2	2	2	0	0	2	0
		DAY 1	10APR2003	1	20		3	2	0	1	1	0	2	0	2	3	2	1	1	0	1	1	0
		DAY 8	17APR2003	8	14	-6	2	0	0	0	0	0	2	0	1	2	2	1	2	0	1	1	0
		DAY 15	24APR2003	15	11	-9	2	1	0	1	0	0	2	0	1	0	2	0	2	0	0	0	0
	E0031023	SCREEN	21APR2003	-8	23		3	2	0	2	2	1	3	0	1	3	2	0	2	2	0	0	0
		DAY 1	29APR2003	1	20		3	2	0	2	1	0	3	1	1	3	2	0	2	0	0	0	0
		DAY 8	07MAY2003	9	19	-1	3	2	0	2	1	0	3	0	0	3	2	0	1	2	0	0	0
		DAY 15	13MAY2003	15	21	1	2	2	0	2	1	1	3	0	1	3	2	0	2	1	1	0	0
		DAY 22	20MAY2003	22	18	-2	3	2	0	2	2	0	3	0	1	3	0	1	1	0	0	0	0
		DAY 29	27MAY2003	29	17	-3	1	2	0	2	1	1	1	0	1	3	1	0	2	2	0	0	0
		DAY 36	04JUN2003	37	16	-4	3	2	0	2	0	0	2	0	1	3	1	0	1	0	1	0	0
		DAY 43	10JUN2003	43	16	-4	2	2	0	2	0	0	3	0	0	2	2	0	2	0	1	0	0
		DAY 50	17JUN2003	50	20	0	3	2	0	2	0	1	3	0	1	3	2	1	1	0	1	0	0
		DAY 57	24JUN2003	57	15	-5	2	2	0	2	0	1	2	0	1	2	1	0	1	0	1	0	0
	E0033001	SCREEN	19DEC2002	-21	34		3	3	2	2	2	2	3	2	0	3	3	2	2	2	1	2	0
		DAY 1	09JAN2003	1	30		3	2	1	2	1	2	3	2	1	3	3	2	2	2	1	0	0
		DAY 8	16JAN2003	8	31	1	3	2	2	2	2	2	3	2	1	3	2	2	2	2	0	1	0
		DAY 15	23JAN2003	15	32	2	3	3	2	2	2	2	3	2	1	3	2	2	1	2	1	1	0
		DAY 22	30JAN2003	22	32	2	4	3	2	2	2	2	3	2	1	3	2	2	2	2	0	0	0
	E0033004	SCREEN	08JAN2003	-9	25		3	2	1	2	1	2	3	1	1	1	3	0	2	2	1	0	0
		DAY 1	17JAN2003	1	26		3	2	1	2	1	2	3	1	1	2	2	0	2	2	1	0	1
		DAY 8	24JAN2003	8	19	-7	3	1	1	1	0	1	2	0	2	2	2	1	1	2	0	0	0
		DAY 15	31JAN2003	15	17	-9	3	2	1	0	0	0	2	0	2	1	2	0	2	2	0	0	0
		DAY 22	07FEB2003	22	11	-15	0	0	0	0	0	1	1	1	2	0	1	1	1	2	0	1	0
		DAY 29	14FEB2003	29	9	-17	1	0	0	0	0	0	0	0	2	1	1	0	1	2	0	1	0
		DAY 36	21FEB2003	36	8	-18	0	0	0	2	0	0	0	0	2	0	1	1	1	1	0	0	0
		DAY 43	28FEB2003	43	5	-21	0	0	0	0	0	0	0	0	2	1	1	0	0	1	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0033004	DAY 50	07MAR2003	50	20	-6	3	0	1	2	2	0	2	1	2	2	1	1	2	1	0	0	0
		DAY 57	14MAR2003	57	23	-3	3	1	2	0	0	0	3	2	2	3	2	1	2	2	0	0	0
	E0033010	SCREEN	22JAN2003	-13	23		3	2	2	2	0	0	3	1	1	3	2	0	2	2	0	0	0
		DAY 1	04FEB2003	1	22		3	2	1	2	0	0	3	2	0	2	2	1	2	1	1	0	0
		DAY 8	11FEB2003	8	22	0	3	2	1	0	0	0	3	2	1	3	1	1	2	1	0	2	0
		DAY 15	20FEB2003	17	22	0	3	1	1	1	1	2	3	1	0	2	2	1	2	1	0	1	0
		DAY 22	27FEB2003	24	19	-3	3	2	1	0	0	1	2	2	1	3	2	0	1	1	0	0	0
		DAY 29	04MAR2003	29	20	-2	3	1	1	1	1	0	3	1	2	2	1	1	2	1	0	0	0
		DAY 36	14MAR2003	39	21	-1	3	2	2	0	1	0	3	1	0	3	1	1	2	1	0	1	0
	E0033014	SCREEN	12MAR2003	-7	20		2	2	2	1	0	1	1	1	2	2	3	0	2	0	1	0	0
		DAY 1	19MAR2003	1	20		2	0	1	1	2	2	1	0	2	2	2	1	1	1	2	0	0
		DAY 8	26MAR2003	8	16	-4	2	2	2	0	2	1	1	0	1	1	2	1	1	0	0	0	0
		DAY 15	03APR2003	16	15	-5	2	2	1	0	0	0	2	0	2	1	2	0	2	0	1	0	0
		DAY 22	11APR2003	24	12	-8	1	2	1	0	0	0	1	0	1	1	2	0	2	0	1	0	0
		DAY 29	16APR2003	29	12	-8	1	2	1	0	0	0	1	0	1	1	1	0	2	0	2	0	0
		DAY 36	21APR2003	34	16	-4	2	2	3	0	1	1	2	0	1	1	2	0	1	0	0	0	0
	E0035002	SCREEN	14NOV2002	-7	26		3	2	1	2	1	2	4	0	0	1	2	2	1	2	2	1	0
		DAY 1	21NOV2002	1	27		3	2	1	2	1	2	4	0	0	2	1	2	1	2	2	2	0
		DAY 8	27NOV2002	7	29	2	3	2	1	2	2	2	4	0	1	2	2	2	1	2	2	1	0
		DAY 15	05DEC2002	15	26	-1	2	2	1	2	1	2	4	0	1	2	2	1	1	2	2	1	0
		DAY 22	12DEC2002	22	25	-2	2	2	1	2	1	2	4	0	0	2	2	1	1	2	2	1	0
	E0035007	SCREEN	13DEC2002	-6	21		2	2	2	0	2	2	4	0	0	2	0	1	1	2	0	1	0
		DAY 1	19DEC2002	1	22		2	2	2	1	2	2	4	0	0	2	0	1	1	2	0	1	0
		DAY 8	26DEC2002	8	15	-7	2	2	1	0	0	2	4	0	0	1	0	0	1	2	0	0	0
		DAY 15	02JAN2003	15	10	-12	2	2	0	0	0	0	4	0	0	1	0	0	0	1	0	0	0
		DAY 22	09JAN2003	22	9	-13	2	0	0	0	0	1	4	0	0	2	0	0	0	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0035007	DAY 29	17JAN2003	30	20	-2	3	2	3	1	1	1	4	0	0	3	1	0	1	0	0	0	0
		DAY 36	23JAN2003	36	11	-11	2	1	0	0	0	0	4	0	0	3	0	0	0	0	1	0	0
		DAY 43	30JAN2003	43	20	-2	2	2	3	1	2	2	4	0	0	3	0	0	0	1	0	0	0
		DAY 50	06FEB2003	50	5	-17	1	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	55	9	-13	2	0	0	0	0	1	4	0	0	2	0	0	0	0	0	0	0
	E0035011	SCREEN	09JAN2003	-26	21		3	1	1	2	1	1	4	0	0	1	1	1	1	2	2	0	0
		DAY 1	04FEB2003	1	26		3	2	2	2	2	2	4	0	1	3	2	0	1	2	0	0	0
		DAY 8	11FEB2003	8	19	-7	2	2	1	1	0	2	4	1	0	2	0	0	1	2	1	0	0
		DAY 15	18FEB2003	15	19	-7	2	2	0	0	0	2	4	0	1	2	1	0	1	2	2	0	0
		DAY 22	25FEB2003	22	20	-6	3	2	2	1	0	1	4	0	1	2	0	1	1	2	0	0	0
		DAY 29	04MAR2003	29	24	-2	3	2	2	1	2	1	4	1	1	3	1	0	1	2	0	0	0
		DAY 36	11MAR2003	36	17	-9	2	1	1	0	1	0	4	1	1	2	1	0	1	2	0	0	0
		DAY 43	18MAR2003	43	15	-11	2	0	0	0	1	1	4	1	0	2	1	0	1	2	0	0	0
		DAY 50	25MAR2003	50	21	-5	2	0	0	2	1	1	4	1	1	3	2	0	1	2	1	0	0
		DAY 57	01APR2003	57	17	-9	2	1	0	1	1	2	4	1	0	2	1	0	0	2	0	0	0
	E0035020	SCREEN	11APR2003	-7	20		3	2	0	0	2	1	4	1	0	2	2	0	1	2	0	0	0
		DAY 1	18APR2003	1	24		3	1	0	1	2	2	4	1	1	3	2	1	1	2	0	0	0
		DAY 8	25APR2003	8	18	-6	2	2	0	0	2	1	4	0	1	1	2	0	1	2	0	0	0
		DAY 15	01MAY2003	14	15	-9	2	1	0	0	2	1	4	0	1	1	1	0	0	2	0	0	0
		DAY 22	09MAY2003	22	16	-8	2	0	0	0	2	1	4	1	0	3	0	0	1	2	0	0	0
		DAY 29	15MAY2003	28	15	-9	1	0	0	0	0	1	4	1	1	3	1	0	1	2	0	0	0
		DAY 36	23MAY2003	36	12	-12	1	0	0	0	0	1	4	0	0	2	1	0	1	2	0	0	0
		DAY 43	30MAY2003	43	15	-9	2	0	0	0	1	1	4	0	0	3	1	0	1	2	0	0	0
		DAY 50	06JUN2003	50	12	-12	1	0	0	0	1	1	4	0	0	2	1	0	0	2	0	0	0
		DAY 57	13JUN2003	57	15	-9	1	0	0	0	1	1	4	0	1	3	0	0	1	2	0	1	0
	E0037003	SCREEN	22JAN2003	-8	26		3	2	2	2	2	2	3	1	1	1	2	0	2	2	1	0	0
		DAY 1	30JAN2003	1	27		3	2	2	2	2	2	3	1	1	1	2	0	2	2	2	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0037003	DAY 8	06FEB2003	8	28	1	3	2	2	2	2	0	3	2	1	2	2	1	2	2	2	0	0
		DAY 15	13FEB2003	15	23	-4	3	2	2	2	0	2	3	1	0	2	0	0	2	2	2	0	0
		DAY 22	20FEB2003	22	29	2	3	2	2	2	2	2	2	2	2	2	2	0	2	2	2	0	0
	E0037004	SCREEN	06FEB2003	-7	23		3	2	1	2	0	1	3	1	1	2	1	0	2	2	2	0	0
		DAY 1	13FEB2003	1	25		3	2	1	2	1	1	3	1	1	2	1	1	2	2	2	0	0
		DAY 8	21FEB2003	9	12	-13	2	2	1	1	0	0	1	0	0	1	1	0	0	1	2	0	0
		DAY 15	27FEB2003	15	14	-11	1	2	1	1	2	0	2	0	0	1	2	0	0	2	0	0	0
		DAY 22	06MAR2003	22	9	-16	1	1	0	0	1	0	1	0	0	0	1	0	1	2	1	0	0
		DAY 29	13MAR2003	29	11	-14	1	1	0	0	2	0	2	0	0	0	1	0	1	2	1	0	0
		DAY 36	20MAR2003	36	13	-12	1	0	0	0	0	2	2	0	1	1	1	0	2	2	1	0	0
		DAY 43	28MAR2003	44	11	-14	0	1	0	1	2	1	1	0	0	0	2	0	2	1	0	0	0
		DAY 50	04APR2003	51	12	-13	1	2	0	1	2	0	1	0	0	1	1	0	1	1	1	0	0
		DAY 57	10APR2003	57	9	-16	1	0	0	0	0	0	2	0	0	1	1	0	1	2	1	0	0
	E0039007	SCREEN	25NOV2002	-9	25		3	2	0	0	2	1	4	0	2	2	2	1	2	0	2	2	0
		DAY 1	04DEC2002	1	26		3	1	1	0	2	1	3	1	2	2	2	2	2	0	2	2	0
		DAY 8	11DEC2002	8	24	-2	3	2	1	2	2	1	3	1	2	2	1	2	1	1	0	0	0
		DAY 15	18DEC2002	15	15	-11	2	1	1	0	1	2	2	0	1	1	0	1	1	1	0	1	0
		DAY 22	23DEC2002	20	9	-17	1	1	0	0	1	0	1	0	1	1	1	0	1	1	0	0	0
		DAY 29	30DEC2002	27	10	-16	1	1	1	0	1	0	1	0	1	1	0	0	1	1	1	0	0
		DAY 36	08JAN2003	36	20	-6	2	2	1	1	0	0	3	0	2	2	2	1	1	1	1	1	0
		DAY 43	15JAN2003	43	19	-7	2	0	1	0	0	0	3	0	2	2	2	1	2	1	2	1	0
		DAY 50	22JAN2003	50	18	-8	1	1	1	0	0	0	3	1	1	1	1	1	2	2	2	1	0
		DAY 57	29JAN2003	57	9	-17	1	1	0	0	1	0	1	0	1	1	1	0	1	1	0	0	0
	E0039022	SCREEN	04FEB2003	-21	24		3	2	1	2	2	0	3	2	0	2	1	1	1	1	1	2	0
		DAY 1	25FEB2003	1	24		3	2	1	2	2	1	3	1	1	2	1	1	2	1	1	0	0
		DAY 8	06MAR2003	10	13	-11	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	0	0
		DAY 15	11MAR2003	15	7	-17	1	1	0	0	1	0	0	0	0	1	1	0	1	0	1	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0039022	DAY 22	18MAR2003	22	18	-6	2	2	0	1	1	0	2	2	0	1	1	1	2	2	1	0	0
		DAY 29	25MAR2003	29	9	-15	1	1	0	0	1	1	1	0	1	1	1	0	0	1	0	0	0
		DAY 36	01APR2003	36	8	-16	1	1	0	0	1	1	1	1	1	0	0	0	0	1	0	0	0
		DAY 43	07APR2003	42	4	-20	0	0	0	0	0	0	1	0	0	1	1	0	0	1	0	0	0
		DAY 50	15APR2003	50	6	-18	0	0	0	1	0	0	1	0	0	2	1	0	0	1	0	0	0
		DAY 57	24APR2003	59	12	-12	1	1	0	1	1	1	1	1	0	1	1	0	1	2	0	0	0
	E0039023	SCREEN	05FEB2003	-19	25		3	2	1	2	2	2	3	1	2	2	1	1	1	1	1	0	0
		DAY 1	24FEB2003	1	21		2	2	1	2	2	2	3	0	1	2	2	1	0	1	0	0	0
		DAY 8	03MAR2003	8	22	1	3	2	1	2	2	2	2	1	1	2	2	0	0	1	1	0	0
	E0039030	SCREEN	12MAR2003	-12	23		3	2	2	2	0	0	3	1	1	2	1	1	2	2	1	0	0
		DAY 1	24MAR2003	1	21		3	2	1	2	0	0	3	1	1	2	1	0	2	2	1	0	0
		DAY 8	31MAR2003	8	21	0	3	2	1	2	0	0	3	1	1	2	1	0	2	2	1	0	0
		DAY 15	07APR2003	15	4	-17	0	0	0	0	0	0	1	0	0	1	0	0	0	1	1	0	0
		DAY 22	14APR2003	22	3	-18	0	0	0	0	0	0	1	0	0	1	0	0	0	1	0	0	0
		DAY 29	21APR2003	29	4	-17	0	0	0	0	0	0	1	0	0	1	1	0	0	1	0	0	0
		DAY 36	28APR2003	36	0	-21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	43	0	-21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	51	2	-19	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 57	19MAY2003	57	1	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	E0039031	SCREEN	05MAR2003	-19	24		3	2	2	2	1	1	3	2	1	2	1	1	1	0	1	1	0
		DAY 1	24MAR2003	1	29		3	3	2	2	1	1	3	2	1	2	3	1	2	2	1	0	0
		DAY 8	31MAR2003	8	18	-11	2	2	1	0	0	0	3	1	1	1	2	1	1	2	1	0	0
		DAY 15	07APR2003	15	9	-20	0	0	0	1	1	0	0	0	2	1	1	0	0	2	1	0	0
		DAY 22	15APR2003	23	6	-23	0	1	0	0	0	0	2	0	0	0	1	0	0	2	0	0	0
		DAY 29	21APR2003	29	3	-26	0	0	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0
		DAY 36	28APR2003	36	0	-29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	43	5	-24	0	0	0	2	0	0	0	0	0	1	0	0	0	2	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0039031	DAY 50	13MAY2003	51	21	-8	3	2	1	1	0	0	2	0	2	2	1	2	2	2	1	0	0
		DAY 57	20MAY2003	58	2	-27	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0039037	SCREEN	26MAR2003	-21	27		3	2	1	2	2	2	3	1	0	2	2	0	2	2	1	2	0
		DAY 1	16APR2003	1	28		3	2	1	2	2	2	3	0	2	2	2	0	2	2	1	2	0
		DAY 8	23APR2003	8	25	-3	3	2	1	0	2	2	3	0	1	2	2	0	2	2	1	2	0
		DAY 15	01MAY2003	16	24	-4	3	2	1	0	2	2	3	0	1	2	2	0	2	2	1	1	0
		DAY 22	07MAY2003	22	7	-21	0	0	0	0	1	0	0	0	2	2	1	1	0	0	0	0	0
		DAY 29	15MAY2003	30	6	-22	1	1	0	0	1	0	0	0	0	2	1	0	0	0	0	0	0
		DAY 36	21MAY2003	36	9	-19	0	0	0	0	2	0	0	0	2	2	2	0	1	0	0	0	0
		DAY 43	28MAY2003	43	8	-20	1	0	0	0	0	0	2	1	0	2	1	0	1	0	0	0	0
		DAY 50	05JUN2003	51	4	-24	0	0	0	0	0	0	0	0	0	2	1	0	1	0	0	0	0
		DAY 57	12JUN2003	58	15	-13	1	0	0	0	2	2	2	0	2	2	0	0	2	1	1	0	0
	E0039038	SCREEN	26MAR2003	-28	28		3	2	1	2	2	2	3	0	3	2	1	2	1	2	1	1	0
		DAY 1	23APR2003	1	21		2	1	1	2	2	0	2	0	3	2	1	1	1	2	1	0	0
		DAY 8	30APR2003	8	25	4	3	2	1	1	1	2	3	2	0	2	1	2	2	2	1	0	0
		DAY 22	15MAY2003	23	26	5	3	3	1	2	1	2	3	0	3	2	2	0	0	2	2	0	0
		DAY 29	21MAY2003	29	8	-13	1	1	1	1	0	0	1	0	1	1	1	0	0	0	0	0	0
		DAY 36	29MAY2003	37	12	-9	2	1	1	0	0	1	1	1	1	1	1	0	1	1	0	0	0
	E0039047	SCREEN	12MAY2003	-7	27		3	3	1	2	2	1	3	1	2	2	2	1	2	0	1	1	0
		DAY 1	19MAY2003	1	29		3	3	1	2	2	1	3	2	1	3	2	2	2	0	1	1	0
		DAY 8	27MAY2003	9	17	-12	2	2	1	0	1	1	3	0	2	2	1	1	1	0	0	0	0
		DAY 15	03JUN2003	16	8	-21	1	1	0	0	1	0	1	0	1	1	1	0	0	0	1	0	0
		DAY 22	09JUN2003	22	18	-11	1	1	0	2	2	1	2	0	1	1	2	1	2	1	1	0	0
		DAY 29	16JUN2003	29	19	-10	2	1	1	1	2	1	1	0	2	2	2	0	2	1	1	0	0
		DAY 36	23JUN2003	36	5	-24	0	0	0	0	1	0	0	0	1	1	1	0	0	1	0	0	0
		DAY 43	30JUN2003	43	8	-21	1	1	0	0	1	0	1	1	0	1	1	0	0	0	1	0	0
		DAY 50	07JUL2003	50	4	-25	0	0	0	0	1	1	0	1	0	0	0	0	1	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0039047	DAY 57	14JUL2003	57	8	-21	0	0	0	0	2	1	1	0	0	1	1	0	1	0	1	0	0
	E0039059	SCREEN	03JUL2003	-8	25		3	2	2	2	2	0	3	1	1	2	2	0	2	2	1	0	0
		DAY 1	11JUL2003	1	24		3	2	2	2	0	2	3	2	0	1	0	1	2	2	1	1	0
		DAY 8	18JUL2003	8	16	-8	2	2	1	1	0	0	2	1	1	2	1	0	1	1	1	0	0
		DAY 15	25JUL2003	15	6	-18	1	0	0	0	0	0	1	0	0	0	1	0	1	2	0	0	0
		DAY 22	01AUG2003	22	7	-17	1	1	0	0	0	0	1	0	0	1	1	0	1	1	0	0	0
		DAY 29	07AUG2003	28	3	-21	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
		DAY 36	15AUG2003	36	3	-21	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
		DAY 43	21AUG2003	42	1	-23	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	29AUG2003	50	0	-24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	05SEP2003	57	1	-23	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	E0041007	SCREEN	05MAR2003	-8	23		2	3	1	2	2	2	2	1	2	2	0	1	0	0	1	1	1
		DAY 1	13MAR2003	1	20		2	2	1	2	1	2	1	1	1	1	0	2	2	0	1	1	0
		DAY 8	20MAR2003	8	15	-5	2	2	0	2	0	1	2	1	1	2	0	1	0	0	1	0	0
		DAY 15	27MAR2003	15	10	-10	1	2	0	2	0	0	1	1	0	1	0	1	0	0	1	0	0
		DAY 22	03APR2003	22	15	-5	2	2	0	2	1	1	1	1	2	0	0	2	0	0	0	1	0
		DAY 29	10APR2003	29	16	-4	2	3	0	2	0	1	1	1	2	1	0	2	0	0	0	1	0
		DAY 36	17APR2003	36	18	-2	2	3	0	2	0	1	2	1	1	2	0	2	0	0	0	2	0
		DAY 43	25APR2003	44	17	-3	2	3	0	2	0	1	2	1	1	0	0	2	1	0	0	2	0
		DAY 50	01MAY2003	50	17	-3	2	3	0	2	0	1	2	1	0	0	0	2	1	0	1	2	0
		DAY 57	08MAY2003	57	21	1	3	2	0	2	1	0	3	1	0	2	0	2	2	0	1	2	0
	E0041010	SCREEN	23APR2003	-7	20		2	2	0	2	2	2	3	2	1	1	2	0	1	0	0	0	0
		DAY 1	30APR2003	1	20		2	2	0	2	2	2	3	1	1	1	2	0	1	1	0	0	0
		DAY 8	08MAY2003	9	20	0	2	2	0	2	0	2	3	1	1	1	2	2	1	0	1	0	0
		DAY 15	14MAY2003	15	19	-1	1	0	0	2	1	2	3	1	1	1	2	2	1	1	0	1	0
		DAY 22	21MAY2003	22	16	-4	1	0	0	2	0	2	2	2	0	1	2	1	2	1	0	0	0
		DAY 29	28MAY2003	29	18	-2	1	2	0	2	1	2	2	1	0	2	2	1	1	1	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR I)	E0041010	DAY 36	04JUN2003	36	23	3	2	2	0	2	1	2	2	1	0	2	2	2	1	2	2	0	0
		DAY 43	11JUN2003	43	15	-5	0	0	0	2	2	2	0	1	1	3	2	2	0	0	0	0	0
	E0041011	SCREEN	15MAY2003	-7	22		3	0	0	2	0	0	2	2	2	2	2	1	2	2	2	0	0
		DAY 1	22MAY2003	1	25		3	2	1	2	2	2	3	1	1	1	1	0	2	2	2	0	0
		DAY 8	02JUN2003	12	10	-15	1	0	0	2	0	0	1	1	0	1	2	0	0	0	2	0	0
		DAY 15	06JUN2003	16	17	-8	2	2	1	2	0	0	2	1	0	2	0	0	1	2	2	0	0
		DAY 22	16JUN2003	26	24	-1	2	2	2	2	0	0	3	1	2	3	2	0	0	2	3	0	0
		DAY 29	20JUN2003	30	24	-1	3	3	1	2	0	0	3	2	0	2	0	2	2	2	1	1	0
		DAY 36	26JUN2003	36	20	-5	2	2	1	2	0	0	3	2	0	1	0	1	2	2	1	1	0
		DAY 43	03JUL2003	43	24	-1	2	2	2	2	1	0	3	1	2	1	2	1	2	2	1	0	0
		DAY 50	10JUL2003	50	24	-1	2	3	2	2	0	0	3	0	2	3	1	1	1	2	2	0	0
		DAY 57	17JUL2003	57	22	-3	2	3	1	2	0	0	3	1	1	2	0	2	1	2	2	0	0
	E0041012	SCREEN	05JUN2003	-14	24		3	2	0	2	1	1	3	1	1	2	2	1	2	0	2	1	0
		DAY 1	19JUN2003	1	22		2	2	0	2	2	1	2	2	1	2	2	0	2	0	2	0	0
		DAY 8	26JUN2003	8	24	2	1	2	0	2	2	2	2	2	2	2	2	1	2	0	2	0	0
		DAY 15	03JUL2003	15	22	0	1	2	0	2	2	2	2	1	2	2	2	0	2	0	2	0	0
		DAY 22	10JUL2003	22	20	-2	1	1	0	1	2	2	2	1	2	2	2	0	2	0	2	0	0
		DAY 29	17JUL2003	29	20	-2	1	2	0	2	1	2	1	1	2	2	2	0	2	0	2	0	0
		DAY 36	24JUL2003	36	20	-2	1	2	0	2	1	2	1	1	2	2	2	0	2	0	2	0	0
		DAY 43	31JUL2003	43	11	-11	0	0	0	2	0	1	0	1	2	1	2	0	1	0	1	0	0
		DAY 50	07AUG2003	50	13	-9	0	0	0	2	1	0	0	1	2	2	2	0	1	0	2	0	0
		DAY 57	14AUG2003	57	13	-9	1	1	0	2	1	0	0	1	2	2	2	0	1	0	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0001004	SCREEN	23APR2003	-8	24		4	2	2	1	2	0	3	1	0	3	2	2	2	0	0	0	0
		DAY 1	01MAY2003	1	20		3	2	0	0	1	1	3	1	0	3	1	1	2	1	1	0	0
		DAY 8	09MAY2003	9	10	-10	1	0	0	1	1	0	1	0	2	2	1	0	1	0	0	0	0
		DAY 15	16MAY2003	16	7	-13	1	0	0	1	0	0	1	0	1	2	0	0	1	0	0	0	0
		DAY 22	23MAY2003	23	3	-17	0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0
		DAY 29	29MAY2003	29	2	-18	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 36	06JUN2003	37	7	-13	1	0	0	0	1	0	0	1	0	1	0	1	1	0	1	0	0
		DAY 43	12JUN2003	43	2	-18	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	20JUN2003	51	12	-8	2	1	0	0	0	0	3	1	0	2	1	1	1	0	0	0	0
		DAY 57	27JUN2003	58	4	-16	0	0	0	1	0	0	0	0	0	2	0	0	1	0	0	0	0
	E0005023	SCREEN	28JAN2003	-8	22		3	0	0	2	2	1	3	2	1	2	1	2	2	0	1	0	0
		DAY 1	05FEB2003	1	25		3	0	0	2	2	1	3	1	2	2	2	2	2	2	1	0	0
		DAY 8	13FEB2003	9	10	-15	0	0	0	0	0	1	1	2	2	0	1	0	0	2	1	0	0
		DAY 15	20FEB2003	16	6	-19	0	0	0	0	0	1	0	1	2	0	0	0	0	1	1	0	0
		DAY 22	27FEB2003	23	5	-20	0	0	0	0	0	0	0	2	1	0	0	0	0	2	0	0	0
		DAY 29	06MAR2003	30	9	-16	0	0	0	0	0	0	2	2	1	1	2	0	1	0	0	0	0
		DAY 36	13MAR2003	37	5	-20	0	0	0	0	0	0	0	2	1	0	0	0	1	1	0	0	0
		DAY 43	18MAR2003	42	3	-22	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0	0
		DAY 50	26MAR2003	50	4	-21	0	0	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0
		DAY 57	01APR2003	56	4	-21	0	0	0	0	0	0	0	1	1	0	0	0	0	2	0	0	0
	E0005034	SCREEN	08APR2003	-7	21		3	2	0	0	1	0	3	2	1	3	2	0	2	2	0	0	0
		DAY 1	15APR2003	1	22		2	1	0	0	1	2	3	2	1	3	2	0	2	2	1	0	0
		DAY 8	23APR2003	9	21	-1	2	1	0	0	2	2	3	2	0	2	2	0	2	2	1	0	0
		DAY 15	01MAY2003	17	16	-6	1	0	0	0	1	2	3	2	0	1	1	0	2	2	1	0	0
		DAY 22	06MAY2003	22	20	-2	3	2	0	0	1	2	3	2	0	1	1	0	2	2	1	0	0
		DAY 29	13MAY2003	29	21	-1	3	1	0	0	1	2	3	2	0	1	1	2	2	2	1	0	0
		DAY 36	22MAY2003	38	19	-3	1	2	0	0	1	2	3	2	0	1	2	2	1	2	0	0	0
		DAY 43	28MAY2003	44	15	-7	1	2	0	0	1	0	3	2	0	1	0	1	2	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0005034	DAY 50	05JUN2003	52	22	0	3	2	0	0	1	1	3	2	1	3	2	0	2	2	0	0	0
		DAY 57	09JUN2003	56	19	-3	3	2	0	0	1	0	3	2	0	3	1	0	2	2	0	0	0
	E0005041	SCREEN	17JUN2003	-7	23		3	2	1	2	2	1	3	1	1	2	1	0	2	2	0	0	0
		DAY 1	24JUN2003	1	21		3	1	1	1	1	0	3	2	1	1	2	1	2	2	0	0	0
		DAY 8	01JUL2003	8	9	-12	1	1	0	0	0	0	1	1	1	1	0	0	1	2	0	0	0
		DAY 15	08JUL2003	15	8	-13	0	0	0	0	0	0	2	1	1	1	0	0	1	2	0	0	0
		DAY 22	16JUL2003	23	10	-11	0	0	0	0	1	0	2	1	1	1	1	0	1	2	0	0	0
		DAY 29	22JUL2003	29	6	-15	0	0	0	0	1	0	1	0	0	1	1	0	0	2	0	0	0
		DAY 36	28JUL2003	35	12	-9	1	0	0	1	1	0	1	1	1	1	1	1	1	2	0	0	0
		DAY 43	04AUG2003	42	6	-15	0	0	0	0	0	0	1	1	0	0	1	0	1	2	0	0	0
		DAY 50	11AUG2003	49	7	-14	0	1	0	0	1	0	0	0	1	1	0	0	1	2	0	0	0
		DAY 57	18AUG2003	56	6	-15	0	0	0	0	1	0	0	0	1	1	0	0	1	2	0	0	0
	E0007004	SCREEN	24JAN2003	-6	21		3	2	0	2	2	2	3	1	0	3	1	0	2	0	0	0	0
		DAY 1	30JAN2003	1	24		3	2	1	2	2	2	3	1	0	2	1	1	2	2	0	0	0
		DAY 8	07FEB2003	9	24	0	3	2	1	2	2	1	3	1	0	3	2	0	2	2	0	0	0
		DAY 15	12FEB2003	14	24	0	3	2	0	2	2	2	3	0	0	2	2	1	2	2	1	0	0
	E0007010	SCREEN	11APR2003	-7	22		3	2	1	2	2	2	3	0	1	2	0	0	2	2	0	0	0
		DAY 1	18APR2003	1	23		3	2	1	2	2	2	3	1	0	3	0	0	2	2	0	0	0
		DAY 8	25APR2003	8	22	-1	3	2	0	2	2	1	3	0	0	3	1	1	2	2	0	0	0
		DAY 15	02MAY2003	15	10	-13	1	0	0	2	2	1	0	0	0	0	1	0	1	2	0	0	0
		DAY 22	09MAY2003	22	15	-8	1	0	0	2	2	0	1	0	0	3	1	0	2	2	1	0	0
		DAY 29	16MAY2003	29	5	-18	0	0	0	1	1	0	1	0	0	0	0	0	1	1	0	0	0
		DAY 36	23MAY2003	36	7	-16	1	0	0	1	1	0	0	0	0	2	0	0	0	2	0	0	0
		DAY 43	29MAY2003	42	15	-8	3	0	0	0	2	0	2	0	0	3	0	0	2	2	1	0	0
		DAY 50	06JUN2003	50	23	0	3	2	1	0	2	0	3	0	0	3	2	1	2	2	2	0	0
		DAY 57	16JUN2003	60	16	-7	1	1	0	0	2	1	3	0	0	2	1	0	2	2	1	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0007012	SCREEN		02MAY2003	-14	22		3	2	0	0	0	2	3	0	1	3	2	1	2	1	2	0	0
		DAY 1		16MAY2003	1	24		3	2	0	1	1	2	3	0	1	3	2	1	2	1	2	0	0
		DAY 8		23MAY2003	8	24	0	3	2	0	1	1	2	3	0	1	3	2	1	2	1	2	0	0
		DAY 15		29MAY2003	14	18	-6	2	2	0	0	1	1	3	0	0	3	1	1	2	1	1	0	0
		DAY 22		06JUN2003	22	15	-9	2	1	0	0	1	0	3	0	0	3	1	1	2	1	0	0	0
		DAY 29		13JUN2003	29	9	-15	1	1	0	0	0	0	2	0	0	1	1	0	2	1	0	0	0
		DAY 36		20JUN2003	36	7	-17	1	1	0	0	0	0	2	0	0	1	1	0	0	1	0	0	0
		DAY 43		25JUN2003	41	21	-3	3	2	1	1	0	1	3	0	0	3	2	0	2	1	2	0	0
		DAY 43	*	01JUL2003	47	20	-4	3	2	0	2	1	0	3	0	0	3	2	0	2	1	1	0	0
	E0009007	SCREEN		27JAN2003	-7	27		3	2	2	2	2	0	3	0	2	2	3	1	2	0	3	0	0
		DAY 1		03FEB2003	1	29		3	2	2	2	2	2	3	1	2	2	2	1	2	1	2	0	0
		DAY 8		10FEB2003	8	25	-4	3	2	2	2	2	2	2	0	2	3	1	1	2	0	1	0	0
		DAY 15		17FEB2003	15	26	-3	3	2	2	2	2	2	3	1	1	3	2	1	1	0	1	0	0
		DAY 22		25FEB2003	23	28	-1	3	2	2	2	2	0	3	1	2	3	2	1	2	1	2	0	0
		DAY 29		03MAR2003	29	33	4	3	2	3	2	2	2	3	1	1	3	3	2	2	1	2	1	0
	E0009008	SCREEN		04FEB2003	-8	25		3	2	2	0	2	2	3	1	2	3	1	1	0	0	1	2	0
		DAY 1		12FEB2003	1	21		3	2	2	1	1	1	2	0	3	2	1	0	0	1	0	1	1
		DAY 8		19FEB2003	8	16	-5	3	2	3	0	1	1	3	1	1	1	0	0	0	0	0	0	0
		DAY 15		25FEB2003	14	16	-5	2	2	1	2	0	1	2	2	1	2	1	0	0	0	0	0	0
		DAY 22		04MAR2003	21	3	-18	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		11MAR2003	28	17	-4	2	2	2	1	0	1	2	0	1	2	2	1	1	0	0	0	0
		DAY 36		18MAR2003	35	16	-5	3	2	2	0	1	0	3	2	0	2	0	0	0	0	0	0	1
		DAY 43		26MAR2003	43	8	-13	1	1	1	1	0	0	1	1	1	0	0	0	0	0	0	1	0
		DAY 50		03APR2003	51	2	-19	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		08APR2003	56	2	-19	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0011001	SCREEN		25OCT2002	-7	24		3	2	1	2	1	1	3	2	1	2	1	1	2	0	2	0	0
		DAY 1		01NOV2002	1	24		3	3	1	0	1	2	3	2	1	2	1	1	2	0	2	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0011001	DAY 8	07NOV2002	7	20	-4	2	1	1	2	1	0	3	2	2	2	2	1	1	0	0	0	0
		DAY 15	14NOV2002	14	18	-6	2	1	1	1	1	0	3	1	2	2	1	1	1	0	0	1	0
		DAY 22	21NOV2002	21	17	-7	1	1	0	2	1	1	2	1	2	2	1	1	1	0	1	0	0
		DAY 29	27NOV2002	27	18	-6	1	1	1	2	1	0	3	1	2	1	2	1	1	0	1	0	0
		DAY 36	05DEC2002	35	17	-7	2	0	0	2	1	0	2	2	1	1	2	1	1	0	0	2	0
		DAY 43	12DEC2002	42	15	-9	2	1	0	0	1	0	2	1	1	2	1	1	2	0	1	0	0
		DAY 50	19DEC2002	49	13	-11	1	1	1	1	1	0	2	0	2	2	1	0	1	0	0	0	0
		DAY 57	26DEC2002	56	13	-11	2	1	0	1	1	0	2	0	1	1	1	0	2	0	1	0	0
	E0011011	SCREEN	12FEB2003	-8	27		3	1	1	2	2	2	3	1	2	2	2	0	2	1	2	0	1
		DAY 1	20FEB2003	1	26		3	2	1	2	2	1	2	0	3	2	2	0	2	1	1	1	1
		DAY 8	26FEB2003	7	17	-9	2	2	0	0	0	2	1	0	1	1	2	1	1	1	2	0	1
		DAY 15	05MAR2003	14	18	-8	2	2	0	1	2	0	2	0	1	1	2	0	1	0	2	1	1
		DAY 22	12MAR2003	21	21	-5	2	2	0	1	1	2	2	0	1	2	2	1	2	0	2	0	1
		DAY 29	19MAR2003	28	18	-8	1	1	0	2	2	0	2	0	0	1	2	2	1	0	1	2	1
		DAY 36	26MAR2003	35	9	-17	1	1	0	0	0	0	1	0	1	0	1	0	1	1	1	0	1
		DAY 43	02APR2003	42	21	-5	2	2	1	1	1	2	2	0	1	2	2	0	1	1	0	2	1
		DAY 50	09APR2003	49	18	-8	1	1	0	1	1	2	2	0	1	2	2	1	1	1	1	0	1
		DAY 57	16APR2003	56	12	-14	0	1	0	0	1	0	1	0	1	2	2	0	1	0	1	2	0
	E0011013	SCREEN	25MAR2003	-23	24		3	1	2	2	1	1	3	2	1	2	1	0	2	0	2	0	1
		DAY 1	17APR2003	1	22		3	3	2	1	2	2	2	0	1	2	1	0	1	1	0	1	0
		DAY 8	24APR2003	8	22	0	3	3	2	2	1	0	2	0	1	3	1	0	2	0	0	2	0
		DAY 15	01MAY2003	15	21	-1	3	3	2	2	2	0	2	0	1	2	1	0	1	1	1	0	0
		DAY 22	08MAY2003	22	26	4	3	3	2	2	2	2	2	0	1	3	1	0	2	1	0	2	0
		DAY 29	15MAY2003	29	20	-2	3	3	2	2	2	0	2	0	1	2	1	0	1	1	0	0	0
		DAY 36	22MAY2003	36	17	-5	3	2	2	1	0	0	1	1	1	2	2	0	2	0	0	0	0
		DAY 43	29MAY2003	43	16	-6	3	2	2	0	0	0	2	0	1	2	1	0	2	0	0	1	0
		DAY 50	05JUN2003	50	22	0	3	3	2	1	1	0	2	0	1	3	1	1	2	1	1	0	0
		DAY 57	12JUN2003	57	17	-5	3	2	2	0	0	0	2	1	1	2	1	0	2	1	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0011014	SCREEN	31MAR2003	-7	25		3	2	0	2	2	2	3	0	3	2	1	0	0	2	0	2	1
		DAY 1	07APR2003	1	25		3	3	1	2	2	2	2	0	1	3	2	1	1	1	0	0	1
		DAY 8	14APR2003	8	11	-14	2	2	0	0	0	0	2	0	1	2	1	0	1	0	0	0	0
	E0011021	SCREEN	15MAY2003	-7	22		3	2	0	1	2	1	3	0	2	2	1	0	2	2	1	0	0
		DAY 1	22MAY2003	1	27		3	2	1	2	2	1	3	1	3	2	1	1	2	2	1	0	0
		DAY 8	29MAY2003	8	20	-7	3	3	0	1	1	0	2	0	3	2	1	1	1	1	0	1	0
		DAY 15	05JUN2003	15	15	-12	2	2	0	1	0	1	2	0	1	1	0	1	1	2	0	1	0
		DAY 22	12JUN2003	22	18	-9	2	1	0	0	2	1	2	1	2	2	0	1	1	1	1	1	0
		DAY 29	20JUN2003	30	16	-11	1	1	0	0	1	1	2	1	2	2	0	1	1	2	1	0	0
		DAY 36	27JUN2003	37	9	-18	0	2	0	0	0	1	0	1	0	1	0	0	0	2	2	0	0
		DAY 43	02JUL2003	42	9	-18	0	0	0	0	0	0	1	1	2	1	1	0	0	2	1	0	0
		DAY 50	10JUL2003	50	14	-13	1	2	0	0	1	1	1	1	1	2	0	1	0	2	1	0	0
		DAY 57	21JUL2003	61	5	-22	0	0	0	0	1	0	0	0	0	1	0	0	0	2	1	0	0
	E0013008	SCREEN	19MAR2003	-7	24		3	2	2	2	2	2	3	1	0	2	2	1	2	0	0	0	0
		DAY 1	26MAR2003	1	25		3	2	2	2	2	2	3	1	0	2	2	1	2	0	0	1	0
		DAY 8	02APR2003	8	28	3	3	2	2	2	2	2	4	1	1	2	2	1	2	2	0	0	0
		DAY 15	09APR2003	15	28	3	3	2	2	2	2	2	4	1	1	2	2	1	2	2	0	0	0
		DAY 22	17APR2003	23	18	-7	1	1	1	2	0	2	1	0	1	1	2	0	2	2	0	2	0
		DAY 29	23APR2003	29	30	5	3	2	2	2	2	2	3	2	1	2	3	2	2	2	0	0	0
		DAY 36	30APR2003	36	25	0	3	2	2	2	2	1	3	2	0	2	2	0	2	2	0	0	0
		DAY 43	07MAY2003	43	28	3	3	3	2	2	2	2	3	1	1	2	2	1	2	2	0	0	0
		DAY 50	12MAY2003	48	23	-2	3	2	2	2	2	1	3	1	0	2	2	0	1	2	0	0	0
		DAY 57	19MAY2003	55	27	2	4	2	2	2	2	1	3	1	0	2	2	0	2	2	0	2	0
	E0014001	SCREEN	18FEB2003	-8	23		3	2	0	2	2	0	3	0	0	4	3	1	1	2	0	0	0
		DAY 1	26FEB2003	1	24		3	2	0	0	2	2	3	2	0	3	3	0	2	2	0	0	0
		DAY 8	05MAR2003	8	22	-2	3	0	0	0	0	0	4	4	0	2	3	1	2	2	1	0	0
		DAY 15	12MAR2003	15	6	-18	1	0	0	0	0	1	0	0	0	1	0	0	1	2	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0014001	DAY 22	19MAR2003	22	5	-19	0	0	0	0	0	0	0	1	0	1	1	0	1	1	0	0	0
		DAY 29	25MAR2003	28	3	-21	0	0	0	0	0	0	1	0	0	0	0	0	0	2	0	0	0
		DAY 36	01APR2003	35	8	-16	1	0	0	0	0	0	0	0	0	2	1	1	0	2	1	0	0
	E0014013	SCREEN	20MAY2003	-7	34		2	2	2	2	2	1	4	3	2	4	4	0	2	2	2	0	0
		DAY 1	27MAY2003	1	30		3	2	2	2	2	1	3	1	2	3	3	0	2	2	2	0	0
		DAY 8	04JUN2003	9	23	-7	3	2	1	0	0	0	3	1	1	3	3	0	2	2	2	0	0
		DAY 15	13JUN2003	18	23	-7	3	2	1	0	0	0	3	1	1	3	3	0	2	2	2	0	0
		DAY 22	18JUN2003	23	16	-14	2	1	0	0	0	0	2	1	2	2	2	1	1	1	1	0	0
		DAY 29	25JUN2003	30	23	-7	2	2	1	1	1	1	3	1	1	3	2	1	2	1	1	0	0
		DAY 36	02JUL2003	37	14	-16	1	0	0	0	0	0	2	1	1	2	2	1	2	1	1	0	0
		DAY 43	10JUL2003	45	28	-2	2	3	1	0	0	0	3	2	3	3	3	2	2	0	2	2	0
		DAY 50	16JUL2003	51	23	-7	2	2	1	1	0	0	3	2	2	3	3	1	2	0	1	0	0
		DAY 57	23JUL2003	58	10	-20	0	0	0	0	0	0	1	1	1	3	2	1	1	0	0	0	0
	E0014014	SCREEN	03JUN2003	-7	24		3	2	2	2	2	0	3	1	1	2	2	0	0	0	1	2	1
		DAY 1	10JUN2003	1	26		3	2	2	2	2	0	3	1	1	2	2	0	2	0	1	2	1
		DAY 8	18JUN2003	9	17	-9	2	1	1	1	1	0	2	1	1	1	1	0	2	0	1	2	0
		DAY 15	24JUN2003	15	12	-14	1	1	1	0	0	0	2	2	1	1	1	0	0	1	1	0	0
		DAY 22	03JUL2003	24	5	-21	0	0	0	0	0	0	0	1	0	1	0	0	1	2	0	0	0
		DAY 29	10JUL2003	31	3	-23	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0
		DAY 36	18JUL2003	39	8	-18	1	0	0	0	0	0	1	1	1	1	1	0	1	0	0	0	1
		DAY 50	30JUL2003	51	9	-17	1	0	0	0	2	0	1	0	0	1	1	0	1	1	0	0	1
		DAY 57	06AUG2003	58	5	-21	0	0	0	0	0	0	1	0	0	1	0	0	1	1	0	0	1
	E0015004	SCREEN	25NOV2002	-7	24		3	2	0	2	1	2	3	1	1	2	2	1	2	1	1	0	0
		DAY 1	02DEC2002	1	24		3	1	1	2	1	2	3	1	1	2	2	1	2	1	1	0	0
		DAY 8	11DEC2002	10	24	0	3	2	0	2	2	2	3	1	1	2	1	1	2	1	1	0	0
		DAY 15	18DEC2002	17	23	-1	3	2	0	2	2	2	2	1	1	3	1	0	2	1	1	0	0
		DAY 22	27DEC2002	26	25	1	3	2	1	2	2	2	3	1	1	2	1	0	2	2	1	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0015004	DAY 36		06JAN2003	36	22	-2	3	2	1	2	1	1	3	1	1	2	1	0	2	1	1	0	0
		DAY 36	*	09JAN2003	39	26	2	3	2	1	2	2	1	3	1	1	3	1	1	2	2	1	0	0
		DAY 43		17JAN2003	47	26	2	3	2	1	2	2	1	3	1	1	3	1	1	2	2	1	0	0
		DAY 57		29JAN2003	59	24	0	3	2	1	2	2	1	3	1	1	3	1	0	2	1	1	0	0
	E0018005	SCREEN		10DEC2002	-10	21		3	2	2	2	2	1	3	0	0	2	2	0	1	1	0	0	0
		DAY 1		20DEC2002	1	21		2	2	0	2	2	1	3	2	0	2	2	1	1	1	0	0	0
		DAY 8		27DEC2002	8	10	-11	2	1	0	0	0	0	1	2	0	1	1	0	1	1	0	0	0
		DAY 8	*	31DEC2002	12	8	-13	1	1	0	0	0	0	1	0	1	1	1	0	1	1	0	0	0
		DAY 22		10JAN2003	22	6	-15	0	1	0	0	0	0	0	0	1	1	1	0	1	1	0	0	0
		DAY 29		17JAN2003	29	7	-14	0	0	0	0	1	0	0	0	2	1	1	0	1	1	0	0	0
		DAY 36		24JAN2003	36	6	-15	0	1	0	0	0	0	0	0	1	1	1	0	1	1	0	0	0
		DAY 43		31JAN2003	43	7	-14	1	1	0	0	0	1	1	0	1	1	1	0	0	0	0	0	0
		DAY 50		07FEB2003	50	4	-17	0	0	0	0	0	0	0	0	1	1	1	0	0	1	0	0	0
		DAY 57		14FEB2003	57	3	-18	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0
	E0018012	SCREEN		17JAN2003	-7	25		2	2	1	2	2	2	2	0	2	2	2	1	2	0	2	0	1
		DAY 1		24JAN2003	1	24		2	2	1	2	2	2	3	0	2	2	2	1	1	0	1	0	1
		DAY 8		30JAN2003	7	14	-10	1	1	0	1	1	1	1	0	2	2	2	1	1	0	0	0	0
		DAY 15		07FEB2003	15	7	-17	1	0	0	0	1	0	0	0	1	1	1	0	0	0	1	1	0
		DAY 22		14FEB2003	22	1	-23	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 29		21FEB2003	29	10	-14	1	1	1	0	1	0	1	0	1	1	1	1	0	0	1	0	0
		DAY 36		26FEB2003	34	19	-5	3	2	3	1	1	1	2	0	1	1	1	1	1	1	0	0	0
	E0019019	SCREEN		14JAN2003	-9	24		3	2	1	1	1	2	3	0	1	2	2	1	1	2	1	1	0
		DAY 1		23JAN2003	1	28		3	2	0	2	1	2	3	1	2	3	2	2	1	2	1	1	0
		DAY 8		30JAN2003	8	23	-5	3	2	1	1	1	0	2	1	2	2	2	1	1	2	1	1	0
		DAY 15		06FEB2003	15	21	-7	2	3	1	0	2	2	1	1	1	1	1	2	1	0	1	2	0
	E0019033	SCREEN		10MAR2003	-8	23		3	1	2	2	1	1	3	1	1	1	1	2	1	2	0	1	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0019033	DAY 1	18MAR2003	1	25		3	1	1	2	1	2	3	1	1	2	2	2	1	2	0	1	0
		DAY 8	27MAR2003	10	20	-5	2	2	2	1	1	1	2	2	0	1	1	1	2	2	0	0	0
		DAY 15	03APR2003	17	23	-2	3	2	1	1	1	2	2	2	0	1	2	0	2	2	2	0	0
		DAY 22	10APR2003	24	26	1	3	3	2	2	1	1	3	2	0	1	3	1	2	2	0	0	0
		DAY 29	14APR2003	28	24	-1	3	3	2	1	2	2	2	2	0	1	1	1	2	2	0	0	0
		DAY 36	22APR2003	36	27	2	3	3	2	1	2	2	3	2	0	1	1	2	2	2	0	1	0
		DAY 43	01MAY2003	45	23	-2	3	3	1	1	1	1	3	1	0	2	1	2	2	2	0	0	0
		DAY 50	08MAY2003	52	26	1	3	2	2	1	0	2	3	2	0	2	1	1	2	2	1	2	0
		DAY 57	15MAY2003	59	23	-2	3	2	1	1	0	2	3	1	1	2	1	1	1	2	1	1	0
	E0019038	SCREEN	10APR2003	-14	26		2	2	1	2	1	1	3	2	1	2	2	1	1	2	1	1	1
		DAY 1	24APR2003	1	31		3	3	2	2	0	2	3	0	4	2	2	2	2	2	0	2	0
		DAY 8	01MAY2003	8	14	-17	2	1	1	1	1	0	2	1	1	1	1	0	1	1	0	0	0
		DAY 15	07MAY2003	14	24	-7	3	2	1	2	2	1	3	2	1	2	2	1	1	1	0	0	0
		DAY 22	14MAY2003	21	21	-10	3	2	1	1	1	0	2	2	1	2	2	1	1	2	0	0	0
		DAY 29	21MAY2003	28	17	-14	2	2	0	1	1	1	2	1	0	2	2	1	0	1	1	0	0
		DAY 36	28MAY2003	35	12	-19	1	2	0	1	0	1	1	1	1	1	1	1	1	0	0	0	0
		DAY 43	04JUN2003	42	17	-14	2	3	1	2	2	2	2	0	0	0	2	0	0	1	0	0	0
		DAY 50	11JUN2003	49	14	-17	1	3	1	2	0	1	1	0	0	2	2	0	0	0	1	0	0
		DAY 57	18JUN2003	56	16	-15	1	2	0	1	0	1	1	1	1	2	2	0	1	2	1	0	0
	E0019046	SCREEN	19JUN2003	-7	26		3	3	1	2	2	2	3	1	1	2	1	1	2	2	0	0	0
		DAY 1	26JUN2003	1	28		3	2	1	2	2	2	3	1	1	2	2	2	1	2	1	1	0
		DAY 8	03JUL2003	8	17	-11	1	1	0	1	2	2	3	0	0	1	0	2	2	2	0	0	0
		DAY 15	10JUL2003	15	13	-15	2	0	0	0	0	1	3	1	0	1	1	1	1	2	0	0	0
		DAY 22	17JUL2003	22	9	-19	0	0	0	0	0	0	2	0	1	1	1	1	1	2	0	0	0
		DAY 29	24JUL2003	29	7	-21	1	0	0	0	0	2	1	0	1	1	0	0	0	1	0	0	0
		DAY 36	30JUL2003	35	2	-26	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	14AUG2003	50	1	-27	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	21AUG2003	57	2	-26	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0019047	SCREEN	26JUN2003	-12	21		2	1	0	2	2	1	3	1	2	2	2	0	1	0	2	0	0
		DAY 1	08JUL2003	1	20		2	1	0	2	2	1	3	1	2	1	3	1	1	0	0	0	0
		DAY 8	17JUL2003	10	4	-16	1	0	0	1	0	0	1	0	0	0	1	0	0	0	0	0	0
		DAY 15	24JUL2003	17	4	-16	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0
		DAY 22	31JUL2003	24	21	1	3	2	0	2	2	1	3	1	1	0	2	2	1	1	0	0	0
		DAY 29	07AUG2003	31	10	-10	1	1	0	1	1	0	2	0	1	1	1	1	0	0	0	0	0
		DAY 36	14AUG2003	38	3	-17	0	0	0	0	1	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 43	21AUG2003	45	5	-15	1	0	0	1	1	0	0	0	1	0	0	0	1	0	0	0	0
		DAY 50	28AUG2003	52	6	-14	1	1	0	0	0	1	0	0	1	0	2	0	0	0	0	0	0
		DAY 57	04SEP2003	59	5	-15	1	0	0	1	0	0	0	0	1	1	1	0	0	0	0	0	0
	E0019048	SCREEN	03JUL2003	-7	24		3	2	0	2	2	1	3	1	2	2	3	1	1	0	1	0	0
		DAY 1	10JUL2003	1	21		3	1	0	2	2	1	3	1	2	2	2	0	1	0	1	0	0
		DAY 8	17JUL2003	8	22	1	3	2	0	2	2	2	3	0	1	2	2	1	1	0	1	0	0
		DAY 15	22JUL2003	13	20	-1	2	1	0	2	2	1	3	0	1	2	2	1	1	1	0	1	0
		DAY 22	31JUL2003	22	17	-4	2	1	0	2	2	1	3	0	1	2	1	1	1	0	0	0	0
		DAY 29	07AUG2003	29	17	-4	2	0	0	2	2	1	3	1	1	2	0	1	1	0	0	1	0
		DAY 36	14AUG2003	36	15	-6	2	0	0	2	1	0	3	0	1	2	0	1	1	1	0	1	0
		DAY 43	21AUG2003	43	15	-6	2	0	0	2	1	0	3	0	1	2	0	1	1	1	0	1	0
		DAY 50	28AUG2003	50	19	-2	3	1	0	2	2	1	2	0	2	2	2	1	1	0	0	0	0
		DAY 57	03SEP2003	56	19	-2	3	1	0	2	2	0	3	0	2	2	2	1	1	0	0	0	0
	E0022006	SCREEN	21OCT2002	-22	23		3	2	1	2	2	0	3	1	0	3	1	0	2	2	1	0	0
		DAY 1	12NOV2002	1	22		3	2	2	2	1	0	3	1	0	2	1	0	2	2	1	0	0
		DAY 8	19NOV2002	8	19	-3	3	1	0	2	1	0	3	1	0	3	2	0	2	0	1	0	0
		DAY 15	26NOV2002	15	20	-2	3	1	0	2	2	2	3	1	0	3	0	0	2	0	1	0	0
		DAY 22	03DEC2002	22	14	-8	2	1	0	2	0	0	2	0	1	1	2	1	1	0	1	0	0
		DAY 29	10DEC2002	29	11	-11	2	1	0	2	1	0	2	0	0	1	0	0	1	0	1	0	0
		DAY 36	17DEC2002	36	11	-11	1	0	0	2	0	0	1	0	1	2	1	0	2	0	1	0	0
		DAY 43	24DEC2002	43	8	-14	0	0	0	1	0	0	1	0	1	1	0	0	2	1	1	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0022006	DAY 50	31DEC2002	50	7	-15	0	1	0	1	0	0	1	0	0	2	0	0	1	0	1	0	0
		DAY 57	07JAN2003	57	5	-17	0	0	0	0	0	0	1	0	0	1	0	0	1	1	1	0	0
	E0022047	SCREEN	21MAR2003	-7	31		3	2	2	2	2	2	3	1	2	3	2	1	2	2	2	0	0
		DAY 1	28MAR2003	1	30		3	2	1	2	2	2	4	2	1	3	2	1	2	2	1	0	0
		DAY 8	04APR2003	8	27	-3	3	2	2	2	2	2	3	1	1	3	1	1	2	1	1	0	0
		DAY 15	11APR2003	15	23	-7	3	2	1	2	0	1	3	1	2	2	1	0	2	1	1	0	1
		DAY 22	17APR2003	21	23	-7	3	2	1	2	2	1	2	1	1	2	1	1	2	1	1	0	0
		DAY 29	25APR2003	29	20	-10	2	2	2	2	0	0	3	1	2	2	1	0	2	0	1	0	0
		DAY 36	02MAY2003	36	20	-10	2	2	1	1	0	1	3	1	1	2	2	0	2	1	1	0	0
		DAY 43	09MAY2003	43	23	-7	2	2	2	1	1	2	3	0	2	3	2	0	2	0	1	0	0
		DAY 50	16MAY2003	50	26	-4	3	2	2	2	2	0	3	2	1	2	2	2	1	1	1	0	0
		DAY 57	23MAY2003	57	23	-7	3	2	2	2	2	2	3	0	1	2	1	0	2	0	1	0	0
	E0022075	SCREEN	25JUN2003	-13	23		3	2	1	1	1	1	3	1	1	3	2	0	2	1	1	0	0
		DAY 1	08JUL2003	1	22		2	2	2	1	1	0	3	1	1	3	2	0	1	2	1	0	0
		DAY 8	15JUL2003	8	22	0	3	2	1	2	1	0	3	0	0	2	3	0	1	2	2	0	0
		DAY 15	22JUL2003	15	19	-3	2	1	1	2	1	1	2	0	1	2	1	0	1	2	2	0	0
		DAY 22	29JUL2003	22	22	0	3	1	1	2	2	2	2	1	1	1	2	0	0	2	2	0	0
		DAY 29	05AUG2003	29	22	0	3	2	1	2	1	1	3	2	0	1	0	1	2	2	1	0	0
		DAY 36	12AUG2003	36	29	7	3	2	2	1	2	1	3	2	1	3	2	1	2	2	1	1	0
		DAY 43	19AUG2003	43	25	3	2	2	2	1	2	2	2	1	2	3	2	0	2	1	1	0	0
		DAY 50	26AUG2003	50	24	2	3	2	2	1	1	1	2	1	2	1	1	1	2	2	1	1	0
		DAY 57	03SEP2003	58	21	-1	3	2	2	0	0	0	2	1	1	2	2	0	2	2	1	1	0
	E0023012	SCREEN	31JAN2003	-6	24		3	0	1	2	2	2	3	0	1	3	2	1	2	0	2	0	0
		DAY 1	06FEB2003	1	23		3	0	1	2	2	2	3	0	2	3	1	1	1	0	2	0	0
		DAY 8	17FEB2003	12	15	-8	1	0	0	2	2	2	2	0	0	3	2	0	1	0	0	0	0
		DAY 15	20FEB2003	15	18	-5	2	0	0	1	2	2	2	0	0	3	2	1	1	1	1	0	0
		DAY 22	28FEB2003	23	12	-11	1	0	0	2	1	1	1	0	0	2	1	1	1	1	0	0	0

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0023012	DAY 29	07MAR2003	30	11	-12	2	0	0	0	1	1	1	0	0	2	2	1	0	1	0	0	0
		DAY 36	14MAR2003	37	20	-3	3	0	1	2	2	2	1	0	1	3	2	1	0	2	0	0	0
		DAY 43	21MAR2003	44	15	-8	3	1	1	0	0	0	1	0	1	3	2	1	0	2	0	0	0
		DAY 50	28MAR2003	51	18	-5	3	0	1	0	1	0	0	2	2	3	2	1	0	1	2	0	0
		DAY 57	04APR2003	58	8	-15	1	0	0	0	0	0	0	0	2	2	2	0	0	0	1	0	0
	E0023016	SCREEN	15MAY2003	-7	24		3	2	0	2	2	0	3	1	1	3	2	1	2	0	1	1	0
		DAY 1	22MAY2003	1	23		3	2	0	2	2	0	3	1	0	3	2	1	2	1	1	0	0
		DAY 8	29MAY2003	8	17	-6	3	2	0	0	1	0	3	1	0	1	1	1	2	1	1	0	0
		DAY 15	05JUN2003	15	17	-6	3	2	0	0	0	0	3	1	0	1	1	1	2	2	1	0	0
		DAY 22	12JUN2003	22	14	-9	3	2	0	0	0	0	3	0	0	1	1	1	2	1	0	0	0
		DAY 29	19JUN2003	29	12	-11	3	1	0	0	0	0	3	0	0	1	1	1	2	0	0	0	0
		DAY 36	26JUN2003	36	14	-9	3	1	0	0	0	0	3	0	2	2	1	1	1	0	0	0	0
		DAY 43	01JUL2003	41	14	-9	3	1	0	0	0	0	3	0	1	2	2	1	1	0	0	0	0
		DAY 50	14JUL2003	54	23	0	3	2	1	0	2	1	2	1	0	2	2	2	2	2	1	0	0
		DAY 57	17JUL2003	57	24	1	3	2	1	1	2	1	3	0	0	2	2	2	2	2	1	0	0
	E0023018	SCREEN	18MAR2003	-9	22		3	2	1	2	2	0	2	0	2	2	2	0	2	1	1	0	0
		DAY 1	27MAR2003	1	20		3	2	1	2	2	0	3	0	2	2	2	0	0	0	1	0	0
		DAY 8	03APR2003	8	13	-7	0	0	0	0	0	0	2	0	2	2	2	1	1	1	1	1	0
		DAY 15	10APR2003	15	17	-3	1	0	0	2	1	2	0	0	2	1	2	2	1	1	1	1	0
		DAY 22	16APR2003	21	16	-4	1	2	2	0	1	1	3	0	1	1	1	0	1	1	1	0	0
		DAY 29	24APR2003	29	12	-8	1	1	0	2	0	0	2	0	1	1	1	0	1	1	1	0	0
		DAY 36	02MAY2003	37	5	-15	1	1	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0
		DAY 43	12MAY2003	47	16	-4	3	1	2	1	0	0	0	0	1	3	2	0	1	1	1	0	0
		DAY 50	15MAY2003	50	8	-12	1	0	0	2	0	0	1	0	1	1	0	0	0	1	1	0	0
		DAY 57	22MAY2003	57	9	-11	0	0	0	2	0	0	0	0	2	1	1	0	1	1	1	0	0
	E0023036	SCREEN	10JUN2003	-10	25		3	2	1	2	2	1	3	1	1	2	2	2	2	1	0	0	0
		DAY 1	20JUN2003	1	25		3	2	2	2	2	1	3	1	1	2	2	1	2	1	0	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0023036	DAY 8		26JUN2003	7	23	-2	2	2	1	2	2	1	3	1	1	2	1	1	2	1	1	0	0
		DAY 15		02JUL2003	13	26	1	3	2	1	2	2	2	3	0	1	3	2	1	2	1	1	0	0
		DAY 22		09JUL2003	20	13	-12	2	1	0	1	0	0	2	1	0	1	1	1	1	1	1	0	0
		DAY 29		16JUL2003	27	15	-10	2	1	0	1	0	0	2	0	2	2	1	1	1	1	1	0	0
		DAY 29	*	22JUL2003	33	15	-10	2	1	0	2	0	0	1	1	1	2	1	1	1	1	1	0	0
		DAY 36		29JUL2003	40	16	-9	2	1	0	2	1	0	2	1	1	1	1	1	1	1	1	0	0
		DAY 43		05AUG2003	47	10	-15	1	1	0	0	1	0	2	0	1	1	1	0	1	1	0	0	0
		DAY 57		13AUG2003	55	8	-17	1	0	0	0	1	0	1	0	1	1	1	0	1	1	0	0	0
	E0023046	SCREEN		11JUL2003	-12	26		3	2	1	2	2	2	3	0	1	2	2	2	2	1	1	0	0
		DAY 1		23JUL2003	1	27		3	2	1	2	2	2	3	0	1	2	1	2	2	2	2	0	0
		DAY 8		01AUG2003	10	26	-1	3	2	1	2	2	2	3	0	0	2	1	2	2	2	2	0	0
		DAY 15		08AUG2003	17	25	-2	2	2	1	2	2	2	3	0	0	2	1	2	2	2	2	0	0
		DAY 22		14AUG2003	23	21	-6	2	2	0	2	2	2	3	0	0	1	0	2	1	2	2	0	0
		DAY 29		22AUG2003	31	21	-6	2	2	0	2	2	2	3	0	0	1	0	2	1	2	2	0	0
		DAY 36		28AUG2003	37	20	-7	2	2	0	2	2	2	3	0	0	1	0	2	1	2	1	0	0
		DAY 43		04SEP2003	44	21	-6	2	2	0	2	2	2	3	0	0	1	1	2	1	2	1	0	0
		DAY 50		11SEP2003	51	21	-6	2	2	0	2	2	2	3	0	0	1	1	2	1	2	1	0	0
		DAY 57		16SEP2003	56	22	-5	2	2	0	2	2	2	3	0	0	1	1	2	2	2	1	0	0
	E0026006	SCREEN		31DEC2002	-8	25		3	2	0	2	1	2	3	1	1	3	2	2	2	0	0	1	0
		DAY 1		08JAN2003	1	20		2	2	0	1	0	2	3	1	1	3	1	0	1	1	2	0	0
		DAY 8		15JAN2003	8	3	-17	0	0	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 15		22JAN2003	15	18	-2	2	2	0	2	0	0	2	2	0	4	1	0	0	1	2	0	0
		DAY 22		29JAN2003	22	7	-13	2	2	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0
		DAY 29		05FEB2003	29	4	-16	1	0	0	0	0	0	0	0	0	1	0	0	1	0	1	0	0
		DAY 36		12FEB2003	36	4	-16	2	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 43		19FEB2003	43	8	-12	1	2	0	0	0	0	0	0	1	0	1	1	0	0	2	0	0
	E0026021	SCREEN		14APR2003	-9	26		3	2	1	2	2	2	3	1	0	3	1	2	1	2	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0026021	DAY 1	23APR2003	1	29		3	2	3	2	2	2	3	2	0	3	1	2	2	2	0	0	0
		DAY 8	29APR2003	7	23	-6	1	1	1	2	2	2	3	0	0	2	2	2	2	2	1	0	0
	E0026027	SCREEN	05JUN2003	-14	21		3	3	0	2	0	0	3	2	1	2	1	1	1	2	0	0	0
		DAY 1	19JUN2003	1	26		4	2	0	2	1	2	3	2	2	2	2	0	2	2	0	0	0
	E0029002	*	05NOV2002		28		3	2	0	1	2	2	3	2	0	3	2	2	2	0	2	2	0
		*	12NOV2002		24		4	2	0	2	2	2	3	2	0	3	0	1	2	0	1	0	0
	E0029004	SCREEN	13NOV2002	-6	25		3	2	1	0	2	1	3	0	2	3	2	1	2	2	1	0	0
		DAY 1	19NOV2002	1	27		2	2	2	0	2	2	3	1	2	3	2	1	2	2	1	0	0
		DAY 8	26NOV2002	8	29	2	2	2	2	2	2	2	3	2	0	3	0	1	2	2	3	1	0
		DAY 15	04DEC2002	16	16	-11	1	1	0	1	2	2	1	1	2	2	1	0	1	1	0	0	0
		DAY 22	12DEC2002	24	14	-13	1	0	0	1	1	0	1	2	0	2	2	0	2	2	0	0	0
		DAY 36	26DEC2002	38	34	7	3	3	2	2	2	2	3	2	3	2	2	1	2	2	3	0	0
		DAY 43	02JAN2003	45	14	-13	2	0	2	0	0	0	2	2	1	2	0	0	2	1	0	0	0
		DAY 50	09JAN2003	52	11	-16	0	0	0	0	2	1	0	1	1	2	0	0	2	2	0	0	0
		DAY 57	16JAN2003	59	22	-5	3	3	2	1	2	0	2	2	0	3	0	1	2	1	0	0	0
	E0029013	SCREEN	27JAN2003	-23	26		3	2	1	2	0	0	3	2	2	2	1	1	2	2	3	0	0
		DAY 1	19FEB2003	1	26		3	2	0	2	2	0	3	0	1	3	2	0	2	2	2	2	0
		DAY 8	25FEB2003	7	10	-16	1	0	0	0	0	2	1	0	0	1	1	0	1	2	1	0	0
		DAY 15	04MAR2003	14	16	-10	1	1	0	2	2	2	1	0	0	1	2	0	1	2	1	0	0
		DAY 22	13MAR2003	23	9	-17	0	0	0	0	0	0	3	0	0	1	1	0	2	1	1	0	0
		DAY 29	20MAR2003	30	11	-15	0	0	0	0	0	0	3	0	0	1	1	1	2	2	1	0	0
		DAY 36	25MAR2003	35	12	-14	0	0	0	0	0	2	2	0	1	1	1	1	1	2	1	0	0
		DAY 43	31MAR2003	41	14	-12	1	2	0	0	0	0	2	0	0	2	1	0	2	2	2	0	0
		DAY 50	10APR2003	51	12	-14	1	0	0	0	2	0	1	1	1	1	1	1	0	2	1	0	0
	E0029019	SCREEN	24FEB2003	-7	21		2	2	0	0	0	1	3	2	1	3	2	1	2	2	0	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0029019	DAY 1		03MAR2003	1	22		2	2	0	0	1	0	3	2	1	3	2	1	2	2	1	0	0
		DAY 8		10MAR2003	8	10	-12	1	2	0	0	0	0	1	1	0	2	1	0	1	1	0	0	0
		DAY 15		17MAR2003	15	13	-9	2	2	0	0	0	0	3	0	1	2	1	0	0	1	1	0	0
	E0029024	SCREEN		11MAR2003	-6	21		2	2	1	0	0	0	4	0	4	3	3	0	2	0	0	0	0
		DAY 1		17MAR2003	1	20		3	2	2	0	0	0	3	1	2	1	2	0	2	0	2	0	0
		DAY 8		25MAR2003	9	18	-2	2	2	2	0	0	0	2	2	1	0	2	0	2	1	2	0	0
		DAY 15		02APR2003	17	13	-7	2	2	0	0	0	0	1	1	3	2	0	0	0	0	2	0	0
		DAY 22		09APR2003	24	19	-1	2	3	2	0	0	0	3	1	2	2	0	0	1	1	2	0	0
		DAY 29		17APR2003	32	21	1	2	2	0	0	2	2	3	1	1	2	0	0	2	2	2	0	0
		DAY 36		24APR2003	39	13	-7	3	2	0	0	0	0	2	1	0	2	0	0	0	2	1	0	0
		DAY 50		05MAY2003	50	9	-11	1	0	2	0	0	0	2	0	1	2	0	0	0	0	1	0	0
		DAY 57	*	12MAY2003	57	10	-10	1	0	1	0	0	0	2	1	1	2	0	0	1	0	1	0	0
		DAY 57		20MAY2003	65	8	-12	1	0	0	0	1	0	0	1	1	2	0	0	1	0	1	0	0
	E0029038	SCREEN		30JUN2003	-7	21		2	2	0	1	1	2	3	2	1	1	0	1	0	2	2	1	0
		DAY 1		07JUL2003	1	23		3	2	0	2	1	1	3	2	1	1	1	1	1	2	2	0	0
	E0031004	SCREEN		12DEC2002	-7	23		3	2	0	1	0	1	3	0	0	4	1	0	2	2	3	1	0
		DAY 1		19DEC2002	1	22		2	0	0	1	2	0	0	0	4	4	2	1	2	1	2	1	0
		DAY 8		27DEC2002	9	15	-7	0	0	0	1	2	2	1	0	1	1	1	1	2	1	1	1	0
		DAY 15		03JAN2003	16	16	-6	2	0	0	1	2	1	2	0	1	2	1	0	2	0	2	0	0
		DAY 22		09JAN2003	22	13	-9	0	0	0	1	1	1	1	0	1	2	1	1	2	1	1	0	0
		DAY 29		16JAN2003	29	13	-9	0	0	0	1	2	1	1	0	1	2	1	1	2	0	0	1	0
		DAY 36		23JAN2003	36	9	-13	0	0	0	1	1	0	1	0	2	1	1	0	1	0	1	0	0
		DAY 43		30JAN2003	43	11	-11	0	0	0	1	2	0	2	0	1	2	1	1	1	0	0	0	0
		DAY 50		06FEB2003	50	12	-10	0	0	0	1	2	1	1	0	1	2	1	0	1	1	1	0	0
		DAY 57		13FEB2003	57	9	-13	0	0	0	1	2	0	1	0	2	2	1	0	0	0	0	0	0
	E0031013	SCREEN		06MAR2003	-7	25		3	2	2	2	1	1	3	0	1	1	2	0	2	2	3	0	0

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^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

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GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0031013	DAY 1		13MAR2003	1	22		3	2	1	0	2	1	3	0	1	3	2	0	2	0	2	0	0
		DAY 8		20MAR2003	8	22	0	2	1	1	1	2	1	2	0	2	3	2	0	2	0	3	0	0
		DAY 15		27MAR2003	15	18	-4	1	2	0	1	2	0	2	0	1	3	2	0	1	0	3	0	0
		DAY 22		04APR2003	23	15	-7	1	2	0	1	1	0	0	0	1	3	2	0	1	0	3	0	0
		DAY 29		11APR2003	30	14	-8	1	2	0	1	1	0	1	0	0	2	2	0	1	0	3	0	0
		DAY 36		17APR2003	36	13	-9	1	1	0	1	0	0	1	0	1	2	2	0	2	0	2	0	0
		DAY 43		24APR2003	43	16	-6	1	0	1	1	1	1	1	0	1	2	1	1	2	1	2	0	0
		DAY 50		01MAY2003	50	10	-12	1	1	0	1	0	0	0	0	1	2	2	0	1	0	1	0	0
		DAY 57		08MAY2003	57	13	-9	1	1	0	1	1	0	1	0	1	2	2	0	1	0	2	0	0
	E0031016	SCREEN		17MAR2003	-7	20		3	1	0	2	2	2	3	1	0	2	1	0	2	1	0	0	0
		DAY 1		24MAR2003	1	20		3	2	0	2	2	0	3	1	0	3	2	0	2	0	0	0	0
		DAY 8		31MAR2003	8	19	-1	2	2	0	2	1	1	2	0	1	3	1	0	1	1	1	1	0
		DAY 15		07APR2003	15	12	-8	2	0	0	1	2	1	2	0	0	2	0	0	2	0	0	0	0
		DAY 22		14APR2003	22	16	-4	3	0	0	2	1	1	3	0	0	2	1	0	2	0	1	0	0
	E0031019	SCREEN		03APR2003	-8	26		3	2	2	2	2	1	2	0	2	2	0	2	2	2	0	2	0
		DAY 1		11APR2003	1	25		3	2	2	2	2	2	3	0	1	2	0	1	2	2	0	1	0
		DAY 8		18APR2003	8	26	1	3	2	2	2	2	2	3	0	2	3	2	1	2	0	0	0	0
		DAY 15		25APR2003	15	21	-4	3	2	3	2	1	0	2	0	1	3	1	1	1	1	0	0	0
		DAY 22		02MAY2003	22	19	-6	3	1	2	2	2	1	2	0	1	2	0	1	1	0	0	1	0
		DAY 29		09MAY2003	29	17	-8	2	0	1	2	2	1	2	0	0	0	1	1	1	2	0	2	0
		DAY 29	*	12MAY2003	32	18	-7	1	1	1	2	0	2	2	0	1	2	1	2	1	1	0	1	0
	E0031022	SCREEN		21APR2003	-7	21		3	2	0	2	2	1	2	0	1	3	2	0	2	0	1	0	0
		DAY 1		28APR2003	1	20		3	2	0	2	2	0	2	0	1	3	2	0	2	0	1	0	0
		DAY 8		06MAY2003	9	16	-4	3	2	1	1	1	0	1	0	0	3	2	0	2	0	0	0	0
		DAY 15		13MAY2003	16	15	-5	0	1	1	1	2	2	1	0	1	2	2	0	2	0	0	0	0
		DAY 22		20MAY2003	23	21	1	3	2	1	2	2	1	1	0	0	3	2	0	2	1	1	0	0
		DAY 29		27MAY2003	30	19	-1	2	2	1	1	1	1	2	0	1	3	2	0	2	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0033007	SCREEN	13JAN2003	-15	29		3	2	2	2	2	1	4	1	2	3	2	1	1	2	0	1	0
		DAY 1	28JAN2003	1	28		3	1	2	2	1	1	3	2	2	3	1	2	1	2	1	1	0
		DAY 8	04FEB2003	8	26	-2	3	2	2	2	1	1	3	1	2	2	1	2	1	2	1	0	0
		DAY 15	12FEB2003	16	21	-7	2	2	2	2	1	1	3	1	2	1	1	1	1	1	0	0	0
		DAY 22	20FEB2003	24	19	-9	1	2	1	2	1	1	2	1	2	1	1	1	1	1	1	0	0
		DAY 29	25FEB2003	29	24	-4	4	2	2	2	1	1	3	1	2	1	1	1	1	1	1	0	0
		DAY 36	04MAR2003	36	26	-2	3	2	2	2	1	1	2	1	2	3	1	1	1	2	2	0	0
		DAY 43	13MAR2003	45	30	2	3	2	2	2	1	1	3	1	2	2	2	2	2	2	2	1	0
		DAY 50	18MAR2003	50	24	-4	2	2	2	2	1	1	2	1	2	2	1	1	1	1	2	1	0
		DAY 57	25MAR2003	57	25	-3	2	2	2	2	1	1	3	0	2	2	2	1	2	1	1	1	0
	E0033013	SCREEN	06FEB2003	-13	22		2	2	1	1	1	1	2	1	1	2	2	2	0	2	1	1	0
		DAY 1	19FEB2003	1	22		2	3	1	1	0	1	3	2	1	1	2	1	1	1	2	0	0
		DAY 8	26FEB2003	8	18	-4	2	0	1	2	1	1	1	1	1	2	2	1	1	1	1	0	0
		DAY 15	05MAR2003	15	15	-7	2	0	0	2	1	1	2	1	1	1	0	1	0	1	2	0	0
		DAY 22	13MAR2003	23	20	-2	2	2	0	2	0	1	2	1	2	2	2	2	1	1	0	0	0
		DAY 29	19MAR2003	29	16	-6	2	0	0	2	0	1	1	1	2	1	1	1	1	1	2	0	0
		DAY 36	27MAR2003	37	15	-7	2	1	0	0	2	2	0	1	0	1	2	1	2	1	0	0	0
		DAY 43	01APR2003	42	15	-7	2	0	0	1	0	2	2	1	1	1	2	1	1	1	0	0	0
		DAY 50	10APR2003	51	10	-12	1	0	0	0	0	0	3	1	1	1	0	1	1	1	0	0	0
		DAY 57	16APR2003	57	12	-10	1	1	0	1	0	1	1	1	1	2	1	1	0	1	0	0	0
	E0033016	SCREEN	14APR2003	-24	21		2	2	1	2	1	1	2	0	1	2	2	0	2	1	2	0	0
		DAY 1	08MAY2003	1	23		2	2	0	2	1	2	2	1	1	2	2	1	2	1	1	1	0
		DAY 8	13MAY2003	6	19	-4	1	2	0	2	1	2	2	0	1	2	2	1	1	1	1	0	0
		DAY 15	20MAY2003	13	18	-5	1	2	0	1	1	2	2	0	0	2	2	0	2	1	2	0	0
		DAY 22	28MAY2003	21	12	-11	1	0	0	0	0	1	2	0	1	2	2	0	1	1	1	0	0
		DAY 29	09JUN2003	33	13	-10	2	1	0	0	1	1	2	1	1	2	1	0	0	1	0	0	0
		DAY 43	17JUN2003	41	10	-13	0	2	0	0	0	1	1	0	1	2	2	0	0	1	0	0	0
		DAY 43	* 23JUN2003	47	12	-11	1	2	0	0	1	1	1	0	0	2	2	0	0	1	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.

^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass

@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0033016	DAY 50	27JUN2003	51	10	-13	0	2	0	1	1	1	1	0	1	0	2	0	0	0	1	0	0
		DAY 57	02JUL2003	56	7	-16	0	0	0	1	0	1	0	0	1	1	2	0	0	0	1	0	0
	E0033022	SCREEN	25JUN2003	-19	22		3	2	2	0	2	1	2	1	1	2	2	0	2	1	1	0	0
		DAY 1	14JUL2003	1	25		3	1	2	0	0	2	3	1	1	2	3	1	2	1	2	1	0
		DAY 8	23JUL2003	10	13	-12	2	1	0	2	0	0	1	1	1	1	1	1	1	0	0	1	0
		DAY 15	30JUL2003	17	17	-8	3	1	1	2	0	1	2	0	1	2	1	1	1	0	1	0	0
		DAY 22	06AUG2003	24	16	-9	3	1	1	0	0	0	2	1	1	2	1	1	1	1	1	0	0
		DAY 29	11AUG2003	29	12	-13	2	0	0	0	0	1	2	0	1	1	1	1	1	0	1	1	0
		DAY 36	18AUG2003	36	17	-8	3	1	1	0	0	0	2	0	1	2	2	1	1	1	2	0	0
		DAY 43	26AUG2003	44	10	-15	1	0	0	1	1	0	0	0	1	2	1	1	1	0	1	0	0
		DAY 50	04SEP2003	53	22	-3	3	2	2	0	1	1	2	0	1	2	2	1	2	1	1	1	0
		DAY 57	11SEP2003	60	13	-12	2	0	0	0	1	0	2	0	1	3	1	1	1	0	1	0	0
	E0034007	SCREEN	06MAY2003	-10	29		3	2	2	0	2	2	3	2	2	3	2	0	2	2	2	0	0
		DAY 1	16MAY2003	1	31		3	2	2	2	2	2	3	2	2	3	2	0	2	2	2	0	0
		DAY 8	24MAY2003	9	32	1	3	2	2	2	2	2	3	2	2	2	3	1	2	2	2	0	0
		DAY 15	02JUN2003	18	32	1	3	2	1	2	2	2	3	2	2	2	3	1	2	2	2	1	0
		DAY 22	09JUN2003	25	30	-1	3	2	1	2	2	2	3	2	2	2	2	1	2	2	2	0	0
		DAY 29	16JUN2003	32	31	0	3	2	2	2	2	2	3	2	2	2	2	1	2	2	2	0	0
		DAY 36	20JUN2003	36	31	0	3	2	2	2	2	2	3	2	2	2	2	1	2	2	2	0	0
		DAY 43	30JUN2003	46	33	2	3	2	2	2	2	2	3	2	2	3	2	2	2	2	2	0	0
		DAY 50	07JUL2003	53	33	2	3	2	2	2	2	2	3	2	2	3	2	2	2	2	2	0	0
		DAY 57	14JUL2003	60	31	0	3	2	2	2	2	2	3	2	2	2	2	2	2	2	1	0	0
	E0035004	SCREEN	22NOV2002	-5	26		3	2	1	2	2	2	4	0	1	2	1	2	1	2	0	1	0
		DAY 1	27NOV2002	1	26		3	2	1	2	2	2	4	0	1	2	1	2	1	2	0	1	0
		DAY 8	04DEC2002	8	20	-6	3	1	0	1	2	2	4	0	1	2	1	1	1	1	0	0	0
	E0035009	SCREEN	20DEC2002	-7	24		3	2	2	2	1	2	2	0	0	2	2	2	1	1	0	2	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0035009	DAY 1		27DEC2002	1	23		3	2	1	2	1	2	2	0	0	2	2	2	1	2	0	1	0
		DAY 8		31DEC2002	5	14	-9	3	2	0	2	0	2	0	0	0	2	0	1	1	1	0	0	0
		DAY 15		08JAN2003	13	7	-16	1	1	0	0	0	1	0	0	1	1	0	1	0	1	0	0	0
		DAY 22		15JAN2003	20	14	-9	2	2	0	0	0	1	1	1	0	2	1	1	1	2	0	0	0
		DAY 29		22JAN2003	27	6	-17	1	0	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0
		DAY 36		29JAN2003	34	5	-18	1	0	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0
		DAY 43		05FEB2003	41	2	-21	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 43	*	11FEB2003	47	2	-21	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 57		19FEB2003	55	1	-22	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0035010	SCREEN		06JAN2003	-4	23		3	2	0	1	2	2	4	0	0	2	1	1	1	2	2	0	0
		DAY 1		10JAN2003	1	26		3	2	1	2	2	2	4	0	0	3	1	1	1	2	2	0	0
		DAY 8		17JAN2003	8	17	-9	3	2	1	0	0	0	4	0	0	2	1	0	1	2	1	0	0
		DAY 15		24JAN2003	15	22	-4	3	2	3	0	1	1	4	0	0	3	1	0	1	2	1	0	0
		DAY 22		31JAN2003	22	23	-3	3	2	2	0	1	0	4	0	0	3	2	0	2	2	2	0	0
		DAY 29		07FEB2003	29	23	-3	3	2	1	0	1	0	4	1	1	3	1	1	1	2	2	0	0
		DAY 36		14FEB2003	36	21	-5	3	2	2	0	1	2	4	0	0	2	1	0	1	2	1	0	0
		DAY 43		24FEB2003	46	18	-8	2	1	0	0	1	2	4	0	0	2	1	0	1	2	2	0	0
		DAY 50		28FEB2003	50	15	-11	2	0	0	0	1	1	4	0	0	2	1	0	1	2	1	0	0
		DAY 57		06MAR2003	56	18	-8	1	1	0	0	0	2	4	0	1	3	1	0	1	2	2	0	0
	E0035022	SCREEN		01MAY2003	-8	29		4	2	0	0	2	2	4	2	2	3	3	1	1	2	1	0	0
		DAY 1		09MAY2003	1	28		3	2	0	1	2	2	4	2	1	3	3	2	1	2	0	0	0
		DAY 8		15MAY2003	7	30	2	4	2	0	2	2	2	4	1	2	3	2	2	2	2	0	0	0
		DAY 15		23MAY2003	15	25	-3	3	2	0	2	2	1	4	1	2	3	1	1	2	1	0	0	0
		DAY 22		30MAY2003	22	22	-6	2	1	0	2	2	2	4	1	1	3	1	1	1	1	0	0	0
		DAY 29		06JUN2003	29	20	-8	2	1	0	1	2	1	4	1	1	3	2	0	1	1	0	0	0
		DAY 36		13JUN2003	36	15	-13	2	0	0	0	1	0	4	0	1	2	1	1	1	1	0	1	0
		DAY 43		20JUN2003	43	12	-16	2	0	0	0	0	0	4	0	0	2	1	0	1	1	0	1	0
		DAY 50		27JUN2003	50	8	-20	1	0	0	0	0	0	4	0	0	1	0	0	1	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0035022	DAY 57	07JUL2003	60	6	-22	1	0	0	0	0	0	4	0	0	1	0	0	0	0	0	0	0
	E0039003	SCREEN	06NOV2002	-19	27		3	3	2	2	2	1	2	2	1	2	2	0	2	1	2	0	0
		DAY 1	25NOV2002	1	28		3	3	2	2	2	1	2	2	1	2	2	0	2	1	3	0	0
		DAY 8	02DEC2002	8	21	-7	3	3	2	1	1	0	1	1	1	2	2	0	1	1	2	0	0
		DAY 15	09DEC2002	15	17	-11	2	1	1	0	1	0	1	1	1	2	2	0	1	2	2	0	0
	E0040001	SCREEN	18JUN2003	-9	20		3	2	2	0	0	0	2	2	2	3	2	0	1	0	1	0	0
		DAY 1	27JUN2003	1	20		2	1	2	1	0	2	2	2	1	2	1	1	0	2	1	0	0
		DAY 8	03JUL2003	7	21	1	2	1	2	1	0	2	2	2	1	2	1	1	0	2	1	1	0
		DAY 15	11JUL2003	15	19	-1	2	1	1	1	0	2	2	2	1	2	1	1	0	2	0	1	0
		DAY 22	18JUL2003	22	19	-1	3	1	0	2	0	2	2	2	1	2	0	1	2	1	0	0	0
		DAY 29	25JUL2003	29	20	0	3	1	0	2	1	2	1	2	1	2	1	1	2	1	0	0	0
		DAY 36	01AUG2003	36	16	-4	3	1	0	1	1	0	2	2	1	2	1	0	1	1	0	0	0
		DAY 43	08AUG2003	43	17	-3	3	1	0	1	1	2	1	2	1	2	1	0	1	1	0	0	0
		DAY 50	15AUG2003	50	12	-8	2	1	0	0	1	1	1	1	1	2	1	0	0	1	0	0	0
		DAY 57	22AUG2003	57	14	-6	2	1	0	1	1	2	1	1	1	2	1	0	0	1	0	0	0
	E0040004	SCREEN	11JUL2003	-7	21		3	1	2	1	1	2	2	2	2	1	1	1	1	0	0	1	0
		DAY 1	18JUL2003	1	20		3	1	1	1	1	2	2	2	2	2	1	1	1	0	0	0	0
	E0041002	SCREEN	13JAN2003	-8	26		3	3	0	2	2	2	1	1	2	2	2	2	2	0	2	0	0
		DAY 1	21JAN2003	1	28		3	3	0	2	2	2	2	1	2	2	2	2	2	0	2	1	0
		DAY 8	28JAN2003	8	20	-8	2	3	0	2	0	2	2	1	1	2	2	1	1	0	1	0	0
		DAY 15	04FEB2003	15	20	-8	2	3	0	2	0	2	2	1	1	2	2	1	1	0	1	0	0
		DAY 22	11FEB2003	22	13	-15	0	0	0	2	2	0	1	1	1	2	0	1	2	0	1	0	0
		DAY 29	18FEB2003	29	15	-13	1	0	0	1	2	0	1	1	1	2	2	1	1	1	1	0	0
		DAY 36	25FEB2003	36	13	-15	1	0	0	2	2	0	1	1	1	2	0	1	2	0	0	0	0
	E0041005	SCREEN	24FEB2003	-9	21		2	2	0	2	2	2	2	1	1	2	2	1	1	1	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
PLACEBO (BIPOLAR II)	E0041005	DAY 1	05MAR2003	1	23		2	2	0	2	2	2	3	1	1	2	1	1	1	2	1	0	0
		DAY 8	11MAR2003	7	20	-3	2	2	0	2	2	2	2	1	1	2	2	0	1	0	1	0	0
		DAY 15	19MAR2003	15	23	0	2	2	0	2	2	2	2	1	0	2	2	1	2	2	1	0	0
		DAY 22	26MAR2003	22	28	5	3	2	1	2	2	2	3	1	1	2	1	2	2	2	2	0	0
		DAY 29	02APR2003	29	17	-6	2	2	0	2	2	2	0	0	1	1	2	0	0	2	1	0	0
		DAY 36	09APR2003	36	15	-8	1	1	0	2	1	1	1	0	1	1	2	0	1	2	1	0	0
		DAY 43	16APR2003	43	16	-7	2	2	1	2	2	2	1	0	1	1	0	0	0	1	1	0	0
		DAY 50	23APR2003	50	15	-8	0	0	0	2	2	2	1	1	1	2	2	0	0	1	1	0	0
		DAY 57	30APR2003	57	13	-10	1	1	0	2	2	2	0	1	0	1	0	0	0	2	1	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0001003	*	06MAR2003		23		3	2	0	2	2	0	3	0	3	3	1	1	2	1	0	0	0
		*	13MAR2003		6		1	0	0	2	2	0	0	0	1	0	0	0	0	0	0	0	0
	E0002005	*	14JAN2003		21		3	0	1	1	2	2	3	0	0	2	2	1	1	1	2	0	0
	E0002013	*	21MAY2003		20		3	2	1	0	1	1	3	0	1	2	2	0	1	0	2	1	0
	E0002014	*	04JUN2003		22		2	2	2	1	0	1	2	1	2	3	1	0	2	2	1	0	0
	E0002017	*	14JUL2003		20		2	2	2	0	0	0	3	1	2	2	2	0	2	1	1	0	0
	E0003001	*	21OCT2002		30		3	2	2	2	2	2	3	0	1	1	2	2	2	1	3	2	0
	E0003003	*	18NOV2002		21		3	2	2	2	2	2	2	0	1	1	0	1	1	2	0	0	0
	E0003006	*	17DEC2002		20		3	2	2	2	1	0	3	1	1	1	0	1	2	1	0	0	0
	E0003012	*	28JAN2003		33		3	3	2	2	2	2	3	0	2	4	3	1	2	2	1	1	0
	E0003014	*	18FEB2003		25		3	2	0	2	2	2	3	1	0	2	2	2	2	0	0	2	0
	E0003017	*	05MAY2003		34		3	4	2	2	2	2	3	2	1	4	2	1	2	1	2	1	0
	E0003021	*	27JUN2003		20		2	3	0	0	1	1	3	0	1	3	3	0	1	1	1	0	0
	E0004008	*	05DEC2002		24		3	2	0	1	2	0	3	1	1	3	1	2	2	0	1	2	0
	E0004010	*	19DEC2002		21		3	3	1	1	0	0	3	1	1	3	1	0	2	0	2	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0004011	*	02JAN2003		25		3	2	1	2	2	2	3	0	1	3	2	1	1	0	1	1	0
	E0004014	*	04FEB2003		30		3	2	2	2	1	2	4	1	0	2	3	2	2	2	0	2	0
	E0004017	*	13FEB2003		26		3	2	2	2	1	0	3	1	1	3	2	1	2	2	1	0	0
	E0004022	*	19MAY2003		21		3	2	2	0	1	1	3	0	1	2	2	1	2	0	1	0	0
	E0004023	*	20MAY2003		25		3	2	0	2	2	1	3	1	1	3	1	0	2	2	0	2	0
	E0005001	*	19SEP2002		25		3	2	1	2	2	0	3	2	0	3	1	1	2	1	2	0	0
	E0005015	*	25NOV2002		7		0	1	0	0	0	0	0	2	1	1	0	0	1	1	0	0	0
	E0005018	*	23DEC2002		32		3	2	2	1	2	2	3	2	2	3	2	2	2	2	1	1	0
	E0005021	*	16JAN2003		27		3	2	1	2	1	2	3	2	1	3	1	1	2	2	0	1	0
	E0005028	*	05MAR2003		28		3	2	2	2	0	2	3	1	2	3	1	2	2	2	1	0	0
	E0005032	*	31MAR2003		31		3	3	0	2	2	2	3	2	2	2	2	2	2	2	0	2	0
	E0007002	*	11DEC2002		20		3	2	0	2	1	1	3	0	1	3	2	0	2	0	0	0	0
	E0007014	*	11JUN2003		23		3	2	0	2	2	2	3	0	0	3	1	1	2	0	1	1	0
	E0010001	*	14NOV2002		30		3	2	0	2	2	1	3	2	2	2	2	2	1	2	2	2	0
	E0010003	*	02DEC2002		27		3	2	2	2	1	1	3	0	2	2	1	1	1	2	2	1	1

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0010007	*	10DEC2002		28		3	3	2	2	0	1	4	1	2	4	2	1	2	1	0	0	0
	E0010011	*	26DEC2002		27		3	2	0	2	2	1	4	2	2	3	2	1	1	0	1	1	0
	E0010022	*	09APR2003		35		4	3	2	2	1	1	4	2	1	3	2	2	2	1	3	2	0
	E0010025	*	20MAY2003		24		2	3	0	0	2	1	3	2	2	3	2	0	2	2	0	0	0
		*	03JUN2003		17		1	3	0	0	2	0	1	1	4	1	1	0	1	1	1	0	0
	E0010030	*	24JUN2003		23		2	2	0	2	2		3	0	2	0	2	2	2	2	0	1	0
	E0010031	*	03JUL2003		36			2	1	2	2	2	3	2	3	2	2	1	2	2	2	2	0
	E0010033	*	09JUL2003		21		3	2	0	0	2	2	4	1	0	2	1	1	2	1	0	0	0
	E0011003	*	26NOV2002		23		3	0	2	2	2	2	3	0	2	1	3	0	1	2	0	0	0
	E0011005	*	10DEC2002		21		3	1	0	2	0	1	3	0	2	2	2	1	2	2	0	0	0
	E0011017	*	21APR2003		25		3	1	0	2	2	2	3	0	1	2	2	0	2	2	2	1	0
	E0013004	*	21NOV2002		23		2	2	0	2	2	2	4	1	0	2	2	1	2	0	0	1	0
	E0014003	*	26FEB2003		25		2	1	0	2	2	2	3	1	2	3	2	0	2	1	2	0	0
		*	07MAR2003		20		2	1	0	1	2	1	2	1	2	3	2	0	1	0	2	0	0
	E0014008	*	26MAR2003		23		3	2	1	1	2	0	3	2	1	1	1	2	2	1	1	0	0
	E0015009	*	12FEB2003		27		3	2	0	2	2	2	4	1	1	2	2	1	2	1	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0015010	*	21FEB2003		25		3	2	1	2	1	1	3	0	1	2	2	1	2	2	2	0	0
	E0016002	*	02JAN2003		21		3	1	3	1	1	1	2	1	2	2	2	1	1	0	0	0	0
	E0018004	*	26NOV2002		29		3	2	1	2	2	2	3	0	2	2	2	0	2	1	3	1	1
	E0018008	*	17DEC2002		22		2	2	0	2	2	1	2	1	2	2	2	0	2	1	1	0	0
	E0018011	*	13JAN2003		26		3	2	1	2	2	2	3	0	2	2	2	1	2	1	1	0	0
	E0018016	*	21JAN2003		24		3	2	0	2	2	2	3	1	2	2	2	0	2	0	1	0	0
	E0018018	*	28JAN2003		26		3	2	1	2	2	2	3	1	2	2	2	0	2	2	0	0	0
	E0019001	*	24OCT2002		19		3	3	1	2	2	2	1	0	0	3	2	0	0	0	0	0	0
	E0019023	*	23JAN2003		26		3	3	2	2	2	2	3	0	1	1	2	0	1	2	1	0	1
	E0020003	*	17OCT2002		26		2	3	2	2	2	2	3	0	0	2	2	1	2	2	0	1	0
	E0020005	*	21NOV2002		27		3	4	0	2	2	2	2	0	3	2	0	1	2	2	2	0	0
	E0020008	*	06JAN2003		25		3	3	2	1	2	0	3	3	1	3	1	0	0	0	3	0	0
	E0020009	*	07JAN2003		23		2	2	1	2	2	2	3	0	0	1	2	0	1	2	2	1	0
	E0020012	*	19FEB2003		26		3	0	2	0	2	2	3	1	2	3	2	2	2	0	0	1	1
	E0020016	*	17MAR2003		25		3	2	0	2	2	1	3	1	1	2	2	1	2	1	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0020018	*	08APR2003		30		2	2	2	2	2	2	3	1	1	2	2	1	2	2	2	1	1
	E0022002	*	08OCT2002		21		3	2	2	2	0	0	3	0	1	2	3	0	2	0	1	0	0
	E0022009	*	12NOV2002		21		3	2	0	2	2	1	3	1	0	1	1	0	2	2	1	0	0
		*	26NOV2002		7		0	1	0	1	0	1	0	0	1	0	1	0	1	0	1	0	0
	E0022013	*	26NOV2002		23		3	1	0	2	2	2	3	1	0	3	2	0	2	2	0	0	0
	E0022014	*	03DEC2002		21		3	3	2	0	0	0	3	1	2	3	2	1	1	0	0	0	0
		*	10DEC2002		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022021	*	09DEC2002		30		3	2	2	2	2	2	3	0	3	3	2	1	2	2	0	1	0
	E0022026	*	15JAN2003		23		3	2	0	2	2	1	3	2	0	1	2	0	2	2	1	0	0
	E0022028	*	28JAN2003		24		3	2	2	2	1	0	3	3	0	2	2	0	2	2	0	0	0
	E0022037	*	18FEB2003		29		3	3	2	2	2	2	3	1	1	3	2	0	2	2	1	0	0
	E0022040	*	04MAR2003		26		3	2	2	2	1	2	3	0	3	3	1	0	1	2	1	0	0
	E0022049	*	25MAR2003		25		3	2	2	0	1	0	4	2	1	2	2	0	2	2	2	0	0
	E0022050	*	25MAR2003		25		3	3	2	0	1	1	4	2	0	3	1	0	2	2	1	0	0
	E0022055	*	08APR2003		26		3	2	2	2	2	1	3	3	0	2	2	0	2	0	2	0	0
	E0022057	*	10APR2003		29		3	3	2	2	2	0	3	2	1	3	1	0	2	2	1	2	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0022066	*	02MAY2003		37		4	2	2	2	2	2	4	2	1	3	2	2	2	2	3	2	0
	E0022067	*	12MAY2003		21		3	2	2	0	1	0	4	2	0	1	0	1	2	1	0	2	0
	E0022072	*	18JUN2003		32		3	3	2	0	1	1	4	2	0	3	3	2	2	2	3	1	0
	E0022074	*	24JUN2003		27		3	2	2	1	2	2	3	1	1	3	2	1	2	1	1	0	0
	E0023005	*	09DEC2002		23		3	2	2	0	2	0	3	2	1	3	1	0	2	2	0	0	0
	E0023024	*	28APR2003		29		3	2	1	2	1	1	4	2	1	3	2	2	1	1	2	1	0
	E0023026	*	05MAY2003		30		3	3	2	0	1	1	3	1	2	4	2	2	2	2	1	1	0
	E0025003	*	28APR2003		22		3	2	0	2	2	2	3	0	1	3	2	0	1	1	0	0	0
	E0026011	*	21JAN2003		29		4	3	2	2	2	2	3	2	2	2	1	1	1	2	0	0	0
	E0026026	*	23MAY2003		23		3	2	2	0	2	2	3	0	3	2	1	0	1	1	1	0	0
	E0027001	*	20NOV2002		20		3	1	2	2	2	2	0	0	2	3	2	0	1	0	0	0	0
		*	26NOV2002		10		2	0	0	2	1	1	0	0	0	2	1	0	1	0	0	0	0
	E0027002	*	17DEC2002		26		4	2	1	0	2	2	3	1	2	3	2	1	1	2	0	0	0
	E0027009	*	23JAN2003		20		3	0	2	2	2	0	3	1	0	2	2	0	1	2	0	0	0
	E0027010	*	31MAR2003		29		2	3	1	2	2	2	3	1	3	3	2	1	1	0	3	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0027012	*	21MAR2003		33		4	2	0	2	2	2	4	2	0	3	3	2	2	2	2	1	0
	E0027014	*	05MAR2003		26		3	2	1	2	1	2	3	0	3	2	1	2	1	1	0	2	0
	E0027015	*	10MAR2003		20		2	2	1	2	1	1	4	0	1	2	2	0	1	1	0	0	0
	E0028002	*	20SEP2002		28		3	2	1	1	2	1	4	2	1	3	2	1	1	1	1	2	0
	E0028013	*	29OCT2002		25		3	1	1	2	1	2	3	2	1	2	1	2	0	2	0	2	0
	E0028014	*	29OCT2002		24		3	2	0	2	1	2	3	2	0	2	1	2	2	2	0	0	0
	E0028018	*	14NOV2002		24		3	2	0	2	2	1	3	1	2	2	1	2	0	2	1	0	0
	E0028020	*	19NOV2002		26		3	1	1	2	1	1	3	3	1	2	1	2	1	2	0	2	0
	E0028021	*	25NOV2002		25		3	3	1	2	2	0	3	2	2	2	1	1	1	2	0	0	0
		*	05DEC2002		24		3	3	1	2	2	2	3	0	1	2	2	0	1	1	1	0	0
	E0028022	*	12DEC2002		21		3	1	1	1	0	0	4	3	1	2	1	0	2	2	0	0	0
	E0028024	*	08JAN2003		26		3	2	1	2	1	2	3	3	1	1	1	1	2	1	0	2	0
	E0028026	*	09JAN2003		24		3	1	0	2	2	2	2	2	2	3	1	2	1	1	0	0	0
	E0028036	*	15APR2003		27		3	2	1	2	2	1	3	2	1	2	2	1	1	2	2	0	0
	E0028040	*	02MAY2003		23		3	2	1	2	2	1	2	2	1	2	1	0	2	1	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0028042	*	13MAY2003		24		3	2	1	2	2	2	3	1	1	1	1	2	1	2	0	0	0
	E0029006	*	21NOV2002		22		2	2	0	2	2	0	3	2	0	3	2	0	2	1	0	0	1
	E0029007	*	03DEC2002		23		2	2	1	1	2	1	2	2	0	3	2	1	2	2	0	0	0
	E0029010	*	14JAN2003		20		3	1	1	1	1	1	3	2	1	1	1	0	2	1	1	0	0
	E0029022	*	11MAR2003		29		3	3	1	2	1	1	4	3	1	3	1	2	2	2	0	0	0
	E0029027	*	10APR2003		24		4	1	2	0	1	1	3	2	1	1	2	0	2	2	2	0	0
	E0029029	*	05MAY2003		22		2	3	2	0	1	0	3	2	2	3	0	0	2	0	1	0	1
	E0029034	*	16JUN2003		21		2	1	0	2	1	1	3	1	1	2	2	0	1	2	0	2	0
	E0030002	*	13NOV2002		31		3	2	2	2	2	0	3	1	1	2	2	2	2	2	3	2	0
	E0030004	*	03DEC2002		28		3	2	2	2	1	2	2	0	2	3	1	1	2	1	2	2	0
	E0030010	*	14JAN2003		21		2	2	1	1	0	2	4	0	1	1	1	0	2	2	2	0	0
	E0030012	*	27JAN2003		22		3	2	0	2	0	0	3	2	1	3	1	0	2	2	1	0	0
	E0030013	*	31JAN2003		20		3	1	1	0	2	0	4	1	2	2	1	0	2	0	0	0	1
	E0030018	*	05MAR2003		27		3	2	2	2	1	2	3	1	0	2	3	1	2	2	1	0	0
	E0030023	*	16JUN2003		27		3	3	2	2	2	0	3	0	2	2	3	0	1	2	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMD100.SAS
GENERATED: 12JUL2005 17:43:04 iceadmn3

Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0031007	*	04FEB2003		20		3	2	2	2	0	0	3	0	2	1	2	1	2	0	0	0	0
	E0031012	*	21FEB2003		20		3	2	0	2	2	2	2	0	2	3	0	0	2	0	0	0	0
		*	28FEB2003		13		1	1	0	2	1	0	2	0	2	2	0	0	2	0	0	0	0
	E0031014	*	07MAR2003		22		3	2	2	0	0	0	4	0	2	4	1	0	2	2	0	0	0
		*	13MAR2003		18		1	2	0	2	1	1	1	0	3	3	1	0	2	0	0	1	0
	E0031025	*	27MAY2003		25		2	2	0	2	2	1	3	0	3	2	2	1	2	2	0	1	0
	E0031026	*	27MAY2003		23		3	2	2	2	2	2	1	1	2	1	1	2	1	0	0	1	0
		*	06JUN2003		12		3	0	0	0	0	0	0	1	1	3	0	1	2	0	1	0	0
	E0033017	*	29APR2003		23		2	2	2	2	2	1	2	0	2	2	2	0	2	1	1	0	0
	E0033020	*	10JUN2003		26		3	2	2	0	1	1	3	0	2	3	3	1	2	2	1	0	0
	E0035008	*	16DEC2002		23		3	1	1	1	2	2	4	0	0	2	1	2	1	2	0	1	0
	E0035012	*	10JAN2003		21		2	2	1	1	2	2	4	0	0	2	1	1	1	2	0	0	0
	E0035017	*	28MAR2003		26		4	2	0	2	2	2	4	2	1	3	1	0	1	2	0	0	0
	E0035018	*	04APR2003		22		3	2	1	2	2	2	4	0	0	3	0	0	1	2	0	0	0
	E0035019	*	10APR2003		24		3	2	2	2	1	2	4	1	0	2	2	0	1	2	0	0	0
	E0035025	*	16JUN2003		25		3	2	1	2	2	2	4	0	1	3	1	0	1	2	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0036003	*	18JUN2003		23		3	2	2	0	2	1	3	2	0	3	2	0	2	0	1	0	0
		*	24JUN2003		14		3	1	0	0	2	0	3	1	0	1	1	0	2	0	0	0	0
	E0036004	*	19JUN2003		21		3	0	0	0	0	0	3	2	1	3	3	2	2	0	0	2	0
	E0037001	*	13NOV2002		24		3	2	0	2	2	0	3	2	1	1	2	1	2	2	1	0	0
	E0037008	*	11APR2003		23		3	2	0	1	1	2	3	0	1	2	2	1	2	2	1	0	0
	E0037010	*	06JUN2003		23		3	2	2	2	2	0	3	0	2	2	1	0	2	1	1	0	0
	E0039002	*	06NOV2002		25		3	3	2	2	0	2	3	1	1	3	0	0	2	2	1	0	0
	E0039005	*	08NOV2002		28		3	3	2	2	2	2	4	2	1	1	1	1	1	2	0	1	0
	E0039008	*	06DEC2002		29		3	3	2	2	2	2	3	2	1	2	1	0	2	2	2	0	0
	E0039009	*	10DEC2002		26		3	2	2	1	2	1	3	2	1	2	2	2	1	0	0	2	0
	E0039010	*	16DEC2002		26		3	2	1	1	2	2	4	1	2	2	2	0	0	2	2	0	0
	E0039013	*	17DEC2002		27		3	2	0	1	2	2	4	0	2	2	2	1	2	2	0	2	0
	E0039014	*	26DEC2002		24		3	3	2	1	2	2	3	0	2	2	0	0	1	2	1	0	0
	E0039016	*	10FEB2003		24		3	2	2	2	0	1	3	1	0	2	0	1	1	2	2	2	0
	E0039017	*	08JAN2003		28		3	3	2	2	2	2	3	1	1	2	2	1	2	1	1	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0039020	*	23JAN2003		26		3	2	2	2	2	2	3	1	2	2	1	0	0	2	1	1	0
	E0039021	*	30JAN2003		22		3	2	1	2	2	1	3	0	3	2	0	0	1	1	1	0	0
	E0039027	*	27FEB2003		22		3	2	1	0	2	2	3	2	0	2	1	0	1	2	1	0	0
	E0039029	*	03MAR2003		28		3	3	2	2	2	2	3	1	2	2	1	0	1	2	2	0	0
	E0039033	*	12MAR2003		27		3	3	2	1	2	2	3	2	1	2	2	1	1	2	0	0	0
	E0039035	*	18MAR2003		26		3	2	1	2	2	2	4	1	2	2	2	0	2	0	1	0	0
	E0039036	*	25MAR2003		29		3	2	2	2	2	2	3	1	2	2	2	0	2	2	2	0	0
	E0039039	*	31MAR2003		28		3	2	1	2	2	2	3	1	2	2	1	2	1	2	2	0	0
	E0039045	*	05MAY2003		24		3	2	1	2	2	0	3	1	2	2	1	1	2	0	2	0	0
	E0039048	*	13MAY2003		25		3	3	1	2	2	2	3	0	2	2	0	2	2	1	0	0	0
	E0039049	*	14MAY2003		31		3	3	2	2	2	0	3	2	2	2	2	2	2	0	2	2	0
	E0039054	*	24JUN2003		25		3	2	0	1	2	2	3	2	0	2	1	1	2	2	1	1	0
	E0039055	*	26JUN2003		29		3	3	2	2	2	2	3	0	2	2	2	0	2	2	2	0	0
	E0039058	*	02JUL2003		26		3	2	2	0	2	2	3	1	1	2	2	1	1	1	1	2	0
	E0039060	*	08JUL2003		26		3	3	2	2	2	1	3	1	1	2	2	1	1	0	2	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR I)	E0041006	*	25FEB2003		22		3	3	0	2	2	0	3	1	1	1	1	2	2	0	1	0	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR II)	E0001001	*	13JAN2003		17		3	2	0	0	2	2	3	1	0	3	0	0	1	0	0	0	0
	E0001005	*	04JUN2003		7		1	1	0	1	0	0	0	0	0	3	0	0	1	0	0	0	0
	E0005020	*	07JAN2003		22		3	2	0	2	2	1	3	2	0	1	2	0	2	1	1	0	0
	E0005029	*	18MAR2003		21		3	2	0	0	0	2	3	1	2	3	1	1	2	0	1	0	0
	E0006009	*	16DEC2002		27		3	2	2	0	2	2	3	1	0	3	3	1	2	1	1	1	0
	E0007007	*	04APR2003		20		3	2	0	2	1	0	3	0	0	3	1	0	2	1	2	0	0
	E0007011	*	23APR2003		23		3	2	1	1	2	2	3	0	0	3	2	1	2	1	0	0	0
	E0009003	*	31OCT2002		20		2	2	2	0	0	0	3	0	3	3	1	0	2	2	0	0	0
	E0009013	*	24JUN2003		21		3	2	2	0	0	0	4	1	2	3	0	0	2	0	1	0	1
	E0010006	*	05DEC2002		23		2	3	0	2	2	2	3	0	2	2	1	0	1	2	1	0	0
	E0010026	*	21MAY2003		29		3	3	2	2	2	1	3	2	3	3	2	0	2	0	1	0	0
	E0011012	*	24FEB2003		21		3	1	2	0	1	1	3	1	2	3	0	0	2	0	2	0	0
	E0011015	*	01APR2003		23		3	3	1	2	1	0	2	1	3	2	2	0	2	0	1	0	0
	E0011019	*	30APR2003		21		3	1	0	2	1	1	3	2	1	2	2	1	2	0	0	0	0
	E0011023	*	03JUN2003		7		2	1	1	1	0	0	1	0	0	1	0	0	0	0	0	0	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR II)	E0011026	*	27JUN2003		23		3	2	2	1	1	0	4	2	1	2	1	0	2	1	1	0	0
	E0013002	*	31OCT2002		26		4	2	1	2	2	2	3	1	0	2	2	0	2	2	0	1	0
	E0013011	*	26FEB2003		22		3	2	1	2	2	2	3	1	0	2	2	1	1	0	0	0	0
	E0013015	*	09JUL2003		25		3	2	0	2	2	2	3	2	1	2	2	2	1	0	0	1	0
	E0015006	*	11DEC2002		25		3	2	1	2	2	0	3	1	2	3	2	1	2	0	1	0	0
	E0015007	*	11DEC2002		26		3	2	1	2	2	2	3	1	2	2	1	1	2	1	1	0	0
	E0017001	*	06MAY2003		21		3	2	0	2	1	0	3	2	1	0	0	2	2	1	0	2	0
	E0019006	*	06NOV2002		26		3	3	1	2	2	2	3	1	1	3	1	1	2	1	0	0	0
	E0019013	*	09DEC2002		28		3	3	1	2	1	0	4	2	0	3	2	0	2	2	3	0	0
		*	19DEC2002		22		3	2	1	1	1	0	4	0	2	3	2	0	1	0	2	0	0
	E0019017	*	14JAN2003		25		3	2	1	2	2	1	3	0	2	2	2	0	1	1	3	0	0
	E0019029	*	25FEB2003		24		3	2	0	2	1	1	3	1	2	2	1	2	1	0	1	1	1
		*	04MAR2003		23		2	2	0	2	1	1	3	1	2	1	2	1	1	0	1	2	1
	E0019030	*	06MAR2003		26		3	2	1	2	2	2	3	1	1	1	2	0	2	2	2	0	0
	E0019044	*	12JUN2003		23		3	2	1	0	2	1	3	1	2	3	1	0	2	2	0	0	0
	E0019050	*	10JUL2003		24		3	2	1	2	2	2	3	0	1	2	2	1	1	0	1	1	0

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR II)	E0020002	*	16OCT2002		25		2	1	1	0	2	1	2	2	2	2	2	1	2	2	2	0	1
	E0020019	*	06MAY2003		25		3	3	1	1	1	1	3	1	1	3	2	1	2	2	0	0	0
	E0022003	*	11OCT2002		21		3	2	1	2	2	0	2	0	1	2	2	0	2	2	0	0	0
	E0022024	*	20DEC2002		23		3	2	0	2	2	1	3	1	1	3	1	0	2	2	0	0	0
	E0022045	*	13MAR2003		25		4	3	2	0	2	1	3	2	0	1	1	1	1	2	2	0	0
	E0023004	*	19NOV2002		24		3	3	1	2	1	2	3	1	1	3	2	0	1	0	1	0	0
	E0023032	*	22MAY2003		26		3	2	1	1	2	2	3	0	2	3	2	0	2	2	1	0	0
	E0023035	*	06JUN2003		24		3	1	1	2	1	1	3	1	1	2	2	1	2	1	1	1	0
	E0023042	*	07JUL2003		28		3	2	1	2	2	2	3	0	2	2	2	2	2	2	1	0	0
	E0023048	*	11JUL2003		29		3	2	1	2	2	2	3	2	0	3	3	2	2	1	1	0	0
	E0026008	*	06JAN2003		24		3	2	0	2	1	0	2	1	2	3	2	1	2	0	1	2	0
	E0026016	*	25FEB2003		23		3	3	1	2	2	2	3	2	0	1	0	0	1	2	0	0	1
	E0027007	*	02JAN2003		32		4	3	2	2	2	2	3	2	0	3	2	2	1	2	0	2	0
	E0027011	*	10FEB2003		26		3	2	2	0	1	0	3	0	2	4	2	2	2	2	0	0	1
	E0027013	*	13MAR2003		25		3	3	2	2	2	2	3	0	1	1	2	0	1	2	0	1	0

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Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR II)	E0027017	*	08MAY2003		16		1	1	0	1	1	0	2	0	1	3	1	1	1	0	1	2	0
	E0028012	*	22OCT2002		24		3	2	0	2	2	2	4	2	1	2	1	0	1	2	0	0	0
	E0028015	*	05NOV2002		23		3	2	1	0	1	2	3	2	1	1	1	1	1	2	0	2	0
	E0029017	*	18FEB2003		23		3	2	0	0	1	2	3	3	1	3	2	0	2	0	1	0	0
	E0029025	*	18MAR2003		30		3	3	1	2	2	2	4	0	2	3	2	1	2	2	0	1	0
	E0029031	*	19MAY2003		22		3	2	1	2	0	0	3	2	0	3	2	0	2	2	0	0	0
	E0029035	*	17JUN2003		22		3	1	0	2	2	1	3	2	0	1	2	0	2	2	1	0	0
	E0030005	*	05DEC2002		20		3	2	1	0	0	0	3	0	1	2	1	1	1	1	2	2	0
	E0030017	*	24FEB2003		30		3	3	2	2	2	1	3	0	1	3	3	0	2	2	3	0	0
	E0030019	*	16APR2003		21		3	2	1	0	0	1	3	1	1	3	3	0	1	0	2	0	0
	E0031009	*	12FEB2003		26		4	2	2	2	2	2	3	1	2	2	1	1	2	0	0	0	0
	E0031024	*	23MAY2003		24		3	2	0	1	0	2	3	0	1	3	2	2	1	1	1	2	0
	E0031028	*	28MAY2003		23		3	2	1	1	1	1	3	1	1	3	2	0	2	1	1	0	0
	E0033003	*	08JAN2003		22		3	2	1	1	0	0	3	0	2	3	2	1	2	1	1	0	0
	E0033005	*	09JAN2003		24		3	1	2	0	2	1	2	2	1	3	2	0	0	2	3	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE (BIPOLAR II)	E0033008	*	17JAN2003		26		3	2	2	2	2	2	3	0	2	3	2	0	1	2	0	0	0
	E0033011	*	03FEB2003		24		3	2	2	2	2	1	2	2	1	2	2	0	1	2	0	0	0
	E0033018	*	19MAY2003		22		3	1	0	1	2	1	3	0	2	3	2	1	1	0	0	2	0
	E0033019	*	22MAY2003		20		2	3	1	0	1	2	3	0	1	2	2	0	1	1	1	0	0
	E0034005	*	15APR2003		32		3	3	0	2	2	1	4	3	1	3	2	2	2	2	0	2	0
	E0034010	*	08JUL2003		25		3	2	0	0	0	2	3	3	2	2	1	2	2	2	1	0	0
	E0037011	*	12JUN2003		22		3	2	1	2	0	0	3	1	1	2	1	0	2	2	2	0	0
	E0039001	*	29OCT2002		20		3	2	1	2	1	1	2	1	1	2	0	1	2	0	1	0	0
	E0039004	*	06NOV2002		23		3	3	0	2	2	2	4	2	0	1	1	1	1	1	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE ( )	E0004004	*	17OCT2002		24		3	2	0	2	2	0	4	2	1	3	3	0	2	0	0	0	0
	E0004005	*	23OCT2002		26		4	4	0	2	2	2	3	1	0	2	2	0	2	2	0	0	0
	E0004007	*	26NOV2002		23		3	2	0	2	1	1	3	0	1	3	3	0	2	2	0	0	0
	E0004019	*	25MAR2003		21		3	2	2	2	1	1	3	1	0	1	1	0	2	1	1	0	0
	E0004020	*	20APR2003		22		3	2	2	0	2	1	3	1	2	2	2	0	2	0	0	0	0
	E0005016	*	26NOV2002		26		3	2	0	2	2	1	3	2	3	2	2	2	2	0	0	0	0
	E0005040	*	03JUN2003		17		1	0	0	2	2	2	1	2	2	1	2	0	1	0	1	0	0
	E0006010	*	08JAN2003		8		1	1	0	0	2	1	0	0	1	2	0	0	0	0	0	0	0
	E0010021	*	20MAR2003		25		3	3	1	2	2	1	2	2	2	2	2	0	1	2	0	0	0
	E0018014	*	20JAN2003		8		1	1	0	0	1	0	0	0	1	1	1	0	0	1	0	0	1
	E0018019	*	03FEB2003		9		1	1	0	2	0	1	1	0	0	1	1	0	0	1	0	0	0
	E0019010	*	12NOV2002		28		3	2	2	2	2	1	3	0	0	3	2	2	2	2	2	0	0
	E0026001	*	30OCT2002		25		3	2	2	2	2	2	3	2	0	2	0	2	1	0	2	0	0
	E0026004	*	04DEC2002		5		0	2	0	0	2	0	1	0	0	0	0	0	0	0	0	0	0
	E0026022	*	09APR2003		16		2	2	2	0	0	0	3	1	0	3	0	0	1	0	0	2	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.2 Hamilton Rating Scale for Depression (HAM-D)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.^	5.^	6.^	7.	8.	9.	10.	11.	12.^	13.^	14.^	15.	16.#	17.@
SCREEN FAILURE ( )	E0028044	*	30MAY2003		20		3	3	1	1	1	0	2	1	1	3	0	0	1	1	2	0	0
	E0029016	*	13FEB2003		21		3	1	2	2	1	1	2	0	2	2	2	0	2	0	1	0	0
	E0029028	*	05MAY2003		26		3	3	2	2	1	0	3	2	0	3	2	0	2	2	1	0	0
	E0030006	*	07JAN2003		14		2	2	0	1	0	2	1	0	1	1	1	0	1	2	0	0	0
	E0030007	*	02JAN2003		15		3	2	0	1	0	0	3	0	1	2	0	1	1	0	1	0	0
	E0036001	*	09JUN2003		19		3	2	1	1	2	0	2	2	1	0	0	1	2	0	0	2	0
	E0039040	*	04APR2003		24		3	2	0	1	2	2	3	1	2	3	0	1	1	0	2	1	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Depressed Mood, 2=Feeling of guilt, 3=Suicide, 4=Insomnia Early, 5=Insomnia middle, 6=Insomnia late, 7=Work/activities, 8=Retardation:psychomotor, 9=Agitation, 10=Anxiety-psychological, 11=Anxiety somatic, 12=Somatic-gastrointestinal, 13=Somatic-general, 14=Genital symptoms, 15=Hypochondriasis, 16=Loss of weight, 17=Insight.
^ difficulty/symptoms: 0(none) - 2 (increase) # Weight Loss: 0=none,1=probable,2=definite,3=not ass
@ Illness: 0=Acknowledges,1=acknowledges/blames other things,2=denies Other: 0 (not present) - 4 (increase).

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	SCREEN		14JAN2003	-21	5		
		DAY 1		04FEB2003	1	4		
		DAY 8		12FEB2003	9	4	0	3
		DAY 15		19FEB2003	16	4	0	3
		DAY 22		26FEB2003	23	3	-1	2
		DAY 29		05MAR2003	30	3	-1	2
		DAY 36		11MAR2003	36	3	-1	2
		DAY 43		18MAR2003	43	3	-1	2
		DAY 50		25MAR2003	50	2	-2	2
		DAY 57		02APR2003	58	2	-2	2
	E0002010	SCREEN		25MAR2003	-10	5		
		DAY 1		04APR2003	1	5		
		DAY 8		10APR2003	7	5	0	5
	E0002012	SCREEN		16APR2003	-5	5		
		DAY 1		21APR2003	1	4		
		DAY 8		29APR2003	9	4	0	3
		DAY 15		06MAY2003	16	4	0	3
		DAY 22		15MAY2003	25	4	0	3
		DAY 29		21MAY2003	31	4	0	4
		DAY 36		28MAY2003	38	4	0	2
		DAY 43		04JUN2003	45	4	0	3
		DAY 50		11JUN2003	52	3	-1	3
		DAY 57		16JUN2003	57	3	-1	2
	E0002015	SCREEN		21MAY2003	-14	4		
		DAY 1		04JUN2003	1	4		
	E0002018	SCREEN		09JUL2003	-15	5		
		DAY 1		24JUL2003	1	5		
		DAY 8	*	30JUL2003	7	5	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	DAY 8	01AUG2003	9	3	-2	2
	E0003004	SCREEN	03DEC2002	-14	5		
		DAY 1	17DEC2002	1	5		
	E0003005	SCREEN	16DEC2002	-7	4		
		DAY 1	23DEC2002	1	4		
		DAY 8	30DEC2002	8	4	0	4
		DAY 15	06JAN2003	15	4	0	3
		DAY 22	14JAN2003	23	2	-2	2
		DAY 29	21JAN2003	30	3	-1	3
		DAY 36	28JAN2003	37	3	-1	3
		DAY 43	04FEB2003	44	4	0	4
		DAY 50	11FEB2003	51	3	-1	3
		DAY 57	18FEB2003	58	3	-1	3
	E0003007	SCREEN	19DEC2002	-14	4		
		DAY 1	02JAN2003	1	4		
		DAY 8	09JAN2003	8	2	-2	3
		DAY 15	16JAN2003	15	3	-1	3
		DAY 22	23JAN2003	22	3	-1	4
		DAY 29	30JAN2003	29	3	-1	3
		DAY 36	10FEB2003	40	1	-3	1
		DAY 43	13FEB2003	43	1	-3	1
		DAY 50	20FEB2003	50	1	-3	1
		DAY 57	27FEB2003	57	1	-3	1
	E0003015	SCREEN	28APR2003	-7	4		
		DAY 1	05MAY2003	1	4		
		DAY 8	13MAY2003	9	4	0	5
		DAY 15	19MAY2003	15	3	-1	3
		DAY 22	27MAY2003	23	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	DAY 29	04JUN2003	31	2	-2	2
		DAY 36	10JUN2003	37	1	-3	1
		DAY 43	17JUN2003	44	1	-3	1
		DAY 50	24JUN2003	51	1	-3	1
		DAY 57	02JUL2003	59	3	-1	4
	E0004002	SCREEN	24SEP2002	-7	5		
		DAY 1	01OCT2002	1	5		
		DAY 8	10OCT2002	10	4	-1	3
		DAY 15	17OCT2002	17	2	-3	2
		DAY 22	22OCT2002	22	2	-3	2
		DAY 29	29OCT2002	29	2	-3	2
		DAY 36	05NOV2002	36	1	-4	1
		DAY 43	12NOV2002	43	2	-3	2
		DAY 50	19NOV2002	50	1	-4	1
		DAY 57	26NOV2002	57	1	-4	1
	E0004013	SCREEN	08JAN2003	-6	5		
		DAY 1	14JAN2003	1	5		
		DAY 8	21JAN2003	8	4	-1	3
		DAY 15	30JAN2003	17	3	-2	3
		DAY 22	05FEB2003	23	3	-2	3
	E0004018	SCREEN	12MAR2003	-7	4		
		DAY 1	19MAR2003	1	4		
		DAY 8	26MAR2003	8	4	0	3
		DAY 15	02APR2003	15	4	0	3
		DAY 22	09APR2003	22	4	0	3
		DAY 29	16APR2003	29	2	-2	1
		DAY 36	23APR2003	36	1	-3	1
		DAY 43	30APR2003	43	1	-3	1
		DAY 50	06MAY2003	49	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	DAY 57		13MAY2003	56	1	-3	1
	E0004021	SCREEN		07MAY2003	-7	4		
		DAY 1		14MAY2003	1	4		
		DAY 8		21MAY2003	8	4	0	2
		DAY 15		28MAY2003	15	3	-1	2
		DAY 22		04JUN2003	22	2	-2	1
		DAY 29		11JUN2003	29	2	-2	1
		DAY 36		18JUN2003	36	1	-3	1
		DAY 43		25JUN2003	43	1	-3	1
		DAY 50		02JUL2003	50	1	-3	1
		DAY 57		09JUL2003	57	1	-3	1
	E0005002	SCREEN		23SEP2002	-10	5		
		DAY 1		03OCT2002	1	5		
		DAY 8		08OCT2002	6	5	0	4
		DAY 8	*	14OCT2002	12	3	-2	2
		DAY 15		21OCT2002	19	3	-2	2
		DAY 22		28OCT2002	26	2	-3	2
		DAY 29		04NOV2002	33	2	-3	1
		DAY 43		13NOV2002	42	2	-3	2
		DAY 43	*	18NOV2002	47	2	-3	1
		DAY 50		25NOV2002	54	2	-3	1
	E0005004	SCREEN		24SEP2002	-7	5		
		DAY 1		01OCT2002	1	5		
		DAY 8		10OCT2002	10	3	-2	3
		DAY 15		15OCT2002	15	2	-3	2
	E0005013	SCREEN		30OCT2002	-8	5		
		DAY 1		07NOV2002	1	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	SCREEN	05FEB2003	-5	5		
		DAY 1	10FEB2003	1	5		
		DAY 8	18FEB2003	9	3	-2	2
		DAY 15	26FEB2003	17	2	-3	1
		DAY 22	06MAR2003	25	1	-4	1
		DAY 29	13MAR2003	32	1	-4	1
		DAY 36	20MAR2003	39	1	-4	1
		DAY 43	25MAR2003	44	1	-4	1
		DAY 50	02APR2003	52	2	-3	2
		DAY 57	09APR2003	59	1	-4	1
	E0005027	SCREEN	03MAR2003	-8	5		
		DAY 1	11MAR2003	1	5		
		DAY 8	19MAR2003	9	5	0	4
		DAY 15	26MAR2003	16	5	0	4
		DAY 22	03APR2003	24	5	0	4
	E0005037	SCREEN	30APR2003	-7	5		
		DAY 1	07MAY2003	1	5		
		DAY 8	15MAY2003	9	4	-1	3
		DAY 15	22MAY2003	16	5	0	4
		DAY 22	27MAY2003	21	5	0	4
		DAY 29	05JUN2003	30	4	-1	3
		DAY 36	12JUN2003	37	4	-1	3
		DAY 57	02JUL2003	57	4	-1	3
	E0005042	SCREEN	19JUN2003	-5	5		
		DAY 1	24JUN2003	1	5		
		DAY 8	02JUL2003	9	3	-2	2
		DAY 15	09JUL2003	16	2	-3	2
		DAY 22	16JUL2003	23	3	-2	2
		DAY 29	23JUL2003	30	2	-3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	DAY 36	30JUL2003	37	3	-2	2
		DAY 43	06AUG2003	44	2	-3	2
		DAY 50	12AUG2003	50	2	-3	1
		DAY 57	18AUG2003	56	2	-3	1
	E0006005	SCREEN	25NOV2002	-10	5		
		DAY 1	05DEC2002	1	5		
		DAY 8	12DEC2002	8	5	0	3
		DAY 15	20DEC2002	16	5	0	4
		DAY 22	30DEC2002	26	5	0	3
		DAY 29	03JAN2003	30	4	-1	3
		DAY 36	09JAN2003	36	4	-1	3
		DAY 43	16JAN2003	43	4	-1	3
		DAY 50	23JAN2003	50	4	-1	3
		DAY 57	30JAN2003	57	4	-1	3
	E0006018	SCREEN	06MAR2003	-7	5		
		DAY 1	13MAR2003	1	5		
		DAY 8	24MAR2003	12	5	0	4
	E0007013	SCREEN	06JUN2003	-7	5		
		DAY 1	13JUN2003	1	5		
		DAY 8	20JUN2003	8	5	0	4
		DAY 15	26JUN2003	14	4	-1	3
		DAY 22	03JUL2003	21	4	-1	3
		DAY 29	10JUL2003	28	3	-2	3
		DAY 36	17JUL2003	35	3	-2	3
		DAY 43	24JUL2003	42	3	-2	3
		DAY 50	01AUG2003	50	2	-3	2
		DAY 57	07AUG2003	56	3	-2	2
	E0010004	SCREEN	04DEC2002	-7	6		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	DAY 1	11DEC2002	1	5		
		DAY 8	18DEC2002	8	5	0	3
		DAY 15	26DEC2002	16	3	-2	2
		DAY 22	02JAN2003	23	5	0	3
		DAY 36	13JAN2003	34	4	-1	2
		DAY 43	21JAN2003	42	4	-1	2
		DAY 50	31JAN2003	52	3	-2	1
		DAY 57	06FEB2003	58	3	-2	2
	E0010012	SCREEN	30DEC2002	-8	5		
		DAY 1	07JAN2003	1	5		
		DAY 8	14JAN2003	8	5	0	3
		DAY 15	21JAN2003	15	4	-1	2
		DAY 22	28JAN2003	22	4	-1	2
		DAY 29	04FEB2003	29	4	-1	3
		DAY 36	11FEB2003	36	3	-2	1
		DAY 43	18FEB2003	43	3	-2	1
		DAY 50	25FEB2003	50	2	-3	1
		DAY 57	05MAR2003	58	2	-3	1
	E0010024	SCREEN	23APR2003	-12	5		
		DAY 1	05MAY2003	1	5		
		DAY 8	12MAY2003	8	4	-1	3
		DAY 15	19MAY2003	15	3	-2	2
		DAY 22	27MAY2003	23	3	-2	2
		DAY 29	04JUN2003	31	3	-2	2
		DAY 36	11JUN2003	38	3	-2	2
		DAY 43	18JUN2003	45	3	-2	2
		DAY 50	25JUN2003	52	3	-2	2
		DAY 57	02JUL2003	59	2	-3	1
	E0010032	SCREEN	03JUL2003	-7	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0010032	DAY 1	10JUL2003	1	5		
		DAY 8	17JUL2003	8	5	0	5
	E0011025	SCREEN	20JUN2003	-6	4		
		DAY 1	26JUN2003	1	4		
		DAY 8	02JUL2003	7	4	0	4
		DAY 15	10JUL2003	15	4	0	3
		DAY 22	17JUL2003	22	4	0	3
		DAY 29	22JUL2003	27	4	0	3
		DAY 36	30JUL2003	35	4	0	3
		DAY 43	07AUG2003	43	3	-1	2
		DAY 50	14AUG2003	50	3	-1	2
		DAY 57	22AUG2003	58	2	-2	1
	E0013007	SCREEN	13MAR2003	-7	4		
		DAY 1	20MAR2003	1	4		
		DAY 8	27MAR2003	8	4	0	4
		DAY 15	07APR2003	19	4	0	4
	E0013009	SCREEN	26MAR2003	-7	4		
		DAY 1	02APR2003	1	4		
		DAY 8	09APR2003	8	4	0	3
		DAY 15	16APR2003	15	4	0	3
		DAY 22	24APR2003	23	3	-1	2
		DAY 29	01MAY2003	30	3	-1	3
		DAY 36	07MAY2003	36	1	-3	1
		DAY 43	16MAY2003	45	1	-3	1
		DAY 50	21MAY2003	50	2	-2	1
		DAY 57	29MAY2003	58	2	-2	1
	E0014006	SCREEN	11MAR2003	-14	4		
		DAY 1	25MAR2003	1	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	DAY 8	02APR2003	9	4	0	4
		DAY 15	09APR2003	16	4	0	4
		DAY 22	16APR2003	23	3	-1	2
		DAY 29	23APR2003	30	3	-1	2
		DAY 36	30APR2003	37	1	-3	1
		DAY 43	07MAY2003	44	1	-3	1
		DAY 50	14MAY2003	51	2	-2	1
		DAY 57	21MAY2003	58	1	-3	1
	E0014010	SCREEN	15APR2003	-7	5		
		DAY 1	22APR2003	1	5		
		DAY 8	30APR2003	9	4	-1	2
		DAY 15	07MAY2003	16	3	-2	2
		DAY 22	14MAY2003	23	3	-2	2
		DAY 29	21MAY2003	30	3	-2	2
		DAY 36	28MAY2003	37	3	-2	2
		DAY 43	03JUN2003	43	4	-1	3
		DAY 50	11JUN2003	51	4	-1	3
		DAY 57	17JUN2003	57	3	-2	2
	E0016001	SCREEN	02JAN2003	-20	5		
		DAY 1	22JAN2003	1	4		
		DAY 8	29JAN2003	8	2	-2	2
		DAY 15	05FEB2003	15	2	-2	2
		DAY 22	12FEB2003	22	1	-3	1
		DAY 29	19FEB2003	29	2	-2	1
		DAY 36	26FEB2003	36	1	-3	1
		DAY 43	05MAR2003	43	1	-3	1
		DAY 50	12MAR2003	50	1	-3	1
		DAY 57	19MAR2003	57	1	-3	1
	E0016004	SCREEN	27JAN2003	-7	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0016004	DAY 1	03FEB2003	1	5		
		DAY 8	10FEB2003	8	3	-2	3
	E0018001	SCREEN	22OCT2002	-7	4		
		DAY 1	29OCT2002	1	4		
		DAY 8	05NOV2002	8	4	0	4
		DAY 15	13NOV2002	16	2	-2	2
		DAY 22	20NOV2002	23	1	-3	1
		DAY 29	27NOV2002	30	1	-3	1
		DAY 36	04DEC2002	37	1	-3	1
		DAY 43	11DEC2002	44	1	-3	1
		DAY 50	18DEC2002	51	3	-1	2
		DAY 57	24DEC2002	57	1	-3	1
	E0018006	SCREEN	10DEC2002	-7	4		
		DAY 1	17DEC2002	1	4		
		DAY 8	23DEC2002	7	4	0	4
		DAY 15	31DEC2002	15	3	-1	3
		DAY 22	07JAN2003	22	3	-1	3
		DAY 29	14JAN2003	29	2	-2	2
		DAY 36	21JAN2003	36	2	-2	2
		DAY 43	28JAN2003	43	2	-2	2
		DAY 50	06FEB2003	52	2	-2	1
		DAY 57	13FEB2003	59	3	-1	2
	E0019004	SCREEN	30OCT2002	-8	5		
		DAY 1	07NOV2002	1	4		
		DAY 8	14NOV2002	8	3	-1	2
		DAY 15	21NOV2002	15	3	-1	2
		DAY 22	26NOV2002	20	3	-1	2
		DAY 29	05DEC2002	29	4	0	3
		DAY 36	12DEC2002	36	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	DAY 43	19DEC2002	43	4	0	5
	E0019011	SCREEN	13NOV2002	-8	5		
		DAY 1	21NOV2002	1	5		
		DAY 8	27NOV2002	7	5	0	4
		DAY 15	05DEC2002	15	4	-1	3
		DAY 22	12DEC2002	22	5	0	4
		DAY 29	19DEC2002	29	4	-1	3
		DAY 43	02JAN2003	43	4	-1	3
		DAY 50	09JAN2003	50	4	-1	3
		DAY 57	16JAN2003	57	4	-1	3
	E0019025	SCREEN	30JAN2003	-7	5		
		DAY 1	06FEB2003	1	5		
		DAY 8	13FEB2003	8	4	-1	3
		DAY 15	20FEB2003	15	3	-2	2
		DAY 22	27FEB2003	22	3	-2	2
		DAY 29	06MAR2003	29	3	-2	3
		DAY 36	13MAR2003	36	2	-3	2
		DAY 43	20MAR2003	43	3	-2	2
		DAY 50	27MAR2003	50	2	-3	2
		DAY 57	03APR2003	57	2	-3	2
	E0019026	SCREEN	10FEB2003	-14	4		
		DAY 1	24FEB2003	1	4		
	E0019043	SCREEN	21MAY2003	-13	4		
		DAY 1	03JUN2003	1	4		
		DAY 8	10JUN2003	8	4	0	3
		DAY 15	17JUN2003	15	4	0	3
		DAY 22	24JUN2003	22	5	1	4
		DAY 29	01JUL2003	29	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	DAY 36		08JUL2003	36	4	0	3
		DAY 43		15JUL2003	43	4	0	3
		DAY 50		22JUL2003	50	4	0	3
		DAY 57		29JUL2003	57	4	0	3
	E0020001	SCREEN		15OCT2002	-14	4		
		DAY 1		29OCT2002	1	5		
		DAY 8		05NOV2002	8	3	-2	3
		DAY 15		12NOV2002	15	3	-2	3
		DAY 22		19NOV2002	22	3	-2	3
		DAY 29		26NOV2002	29	3	-2	2
		DAY 36		03DEC2002	36	3	-2	2
		DAY 43		10DEC2002	43	3	-2	2
		DAY 50		16DEC2002	49	3	-2	2
		DAY 50	*	20DEC2002	53	3	-2	2
	E0020006	SCREEN		26NOV2002	-20	4		
		DAY 1		16DEC2002	1	4		
		DAY 8		20DEC2002	5	4	0	3
	E0020007	SCREEN		19DEC2002	-27	5		
		DAY 1		15JAN2003	1	5		
		DAY 8		22JAN2003	8	3	-2	2
	E0020011	SCREEN		19FEB2003	-7	4		
		DAY 1		26FEB2003	1	4		
		DAY 8		05MAR2003	8	2	-2	1
		DAY 15		12MAR2003	15	1	-3	1
		DAY 22		20MAR2003	23	3	-1	2
		DAY 29		26MAR2003	29	1	-3	1
		DAY 36		02APR2003	36	1	-3	1
		DAY 43		09APR2003	43	2	-2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	DAY 50	16APR2003	50	1	-3	1
		DAY 57	23APR2003	57	1	-3	1
	E0020013	SCREEN	25FEB2003	-8	4		
		DAY 1	05MAR2003	1	4		
		DAY 8	12MAR2003	8	1	-3	1
	E0022008	SCREEN	05NOV2002	-7	4		
		DAY 1	12NOV2002	1	4		
		DAY 8	19NOV2002	8	3	-1	2
		DAY 15	26NOV2002	15	2	-2	2
		DAY 22	03DEC2002	22	1	-3	1
		DAY 29	12DEC2002	31	1	-3	1
		DAY 36	17DEC2002	36	1	-3	1
		DAY 43	24DEC2002	43	1	-3	1
		DAY 50	31DEC2002	50	1	-3	1
		DAY 57	07JAN2003	57	1	-3	1
	E0022017	SCREEN	03DEC2002	-16	4		
		DAY 1	19DEC2002	1	4		
		DAY 8	26DEC2002	8	4	0	4
		DAY 15	03JAN2003	16	4	0	4
		DAY 22	09JAN2003	22	4	0	3
		DAY 29	17JAN2003	30	3	-1	2
		DAY 36	22JAN2003	35	2	-2	2
		DAY 43	31JAN2003	44	2	-2	2
		DAY 50	06FEB2003	50	2	-2	1
		DAY 57	13FEB2003	57	1	-3	1
	E0022018	SCREEN	04DEC2002	-8	4		
		DAY 1	12DEC2002	1	4		
		DAY 8	19DEC2002	8	4	0	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	DAY 15	26DEC2002	15	4	0	3
		DAY 22	02JAN2003	22	4	0	3
		DAY 29	09JAN2003	29	4	0	3
		DAY 36	16JAN2003	36	4	0	3
		DAY 43	23JAN2003	43	4	0	3
		DAY 50	30JAN2003	50	3	-1	3
		DAY 57	06FEB2003	57	3	-1	3
	E0022022	SCREEN	16DEC2002	-14	4		
		DAY 1	30DEC2002	1	4		
		DAY 8	06JAN2003	8	4	0	4
		DAY 15	14JAN2003	16	4	0	4
		DAY 22	21JAN2003	23	4	0	4
		DAY 29	28JAN2003	30	4	0	4
		DAY 36	04FEB2003	37	4	0	4
		DAY 57	27FEB2003	60	4	0	4
	E0022027	SCREEN	23JAN2003	-14	4		
		DAY 1	06FEB2003	1	4		
		DAY 8	13FEB2003	8	3	-1	3
		DAY 15	20FEB2003	15	2	-2	2
		DAY 22	27FEB2003	22	2	-2	2
		DAY 29	06MAR2003	29	1	-3	1
		DAY 36	13MAR2003	36	1	-3	1
		DAY 43	20MAR2003	43	1	-3	1
		DAY 50	27MAR2003	50	1	-3	1
		DAY 57	03APR2003	57	1	-3	1
	E0022030	SCREEN	07FEB2003	-7	4		
		DAY 1	14FEB2003	1	4		
		DAY 8	20FEB2003	7	4	0	3
		DAY 15	28FEB2003	15	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022030	DAY 22	07MAR2003	22	3	-1	2
	E0022031	SCREEN	10FEB2003	-8	4		
		DAY 1	18FEB2003	1	4		
		DAY 8	25FEB2003	8	4	0	3
		DAY 15	04MAR2003	15	4	0	3
		DAY 22	11MAR2003	22	3	-1	3
		DAY 29	18MAR2003	29	2	-2	2
		DAY 36	25MAR2003	36	1	-3	1
		DAY 43	01APR2003	43	2	-2	2
		DAY 50	08APR2003	50	2	-2	2
		DAY 57	15APR2003	57	1	-3	1
	E0022032	SCREEN	11FEB2003	-7	4		
		DAY 1	18FEB2003	1	5		
		DAY 8	28FEB2003	11	3	-2	2
		DAY 15	04MAR2003	15	2	-3	2
		DAY 22	11MAR2003	22	2	-3	2
		DAY 29	21MAR2003	32	2	-3	2
		DAY 36	27MAR2003	38	1	-4	1
		DAY 43	03APR2003	45	1	-4	1
		DAY 50	10APR2003	52	1	-4	1
		DAY 57	18APR2003	60	2	-3	2
	E0022035	SCREEN	11FEB2003	-8	4		
		DAY 1	19FEB2003	1	4		
		DAY 8	26FEB2003	8	4	0	4
	E0022036	SCREEN	13FEB2003	-12	5		
		DAY 1	25FEB2003	1	5		
		DAY 8	03MAR2003	7	5	0	4
		DAY 15	10MAR2003	14	4	-1	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	DAY 22	18MAR2003	22	4	-1	4
		DAY 29	25MAR2003	29	3	-2	3
		DAY 36	01APR2003	36	3	-2	3
		DAY 43	08APR2003	43	3	-2	3
		DAY 50	15APR2003	50	3	-2	3
		DAY 57	22APR2003	57	4	-1	4
	E0022056	SCREEN	09APR2003	-8	4		
		DAY 1	17APR2003	1	4		
		DAY 8	24APR2003	8	4	0	4
		DAY 15	01MAY2003	15	4	0	4
		DAY 22	08MAY2003	22	4	0	4
	E0022060	SCREEN	23APR2003	-7	4		
		DAY 1	30APR2003	1	4		
		DAY 8	05MAY2003	6	4	0	4
		DAY 15	12MAY2003	13	4	0	3
		DAY 22	19MAY2003	20	3	-1	3
		DAY 29	28MAY2003	29	4	0	3
		DAY 36	02JUN2003	34	3	-1	3
		DAY 43	10JUN2003	42	3	-1	2
		DAY 50	17JUN2003	49	3	-1	3
		DAY 57	24JUN2003	56	2	-2	2
	E0022063	SCREEN	28APR2003	-9	4		
		DAY 1	07MAY2003	1	4		
		DAY 8	12MAY2003	6	3	-1	3
		DAY 15	21MAY2003	15	3	-1	3
		DAY 22	28MAY2003	22	2	-2	2
		DAY 29	04JUN2003	29	2	-2	2
		DAY 36	11JUN2003	36	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	SCREEN		23JAN2003	-7	5		
		DAY 1		30JAN2003	1	5		
		DAY 8		06FEB2003	8	5	0	5
		DAY 15		13FEB2003	15	5	0	3
		DAY 22		20FEB2003	22	5	0	6
		DAY 29		25FEB2003	27	5	0	3
		DAY 36		06MAR2003	36	5	0	4
		DAY 43		11MAR2003	41	5	0	3
		DAY 50		18MAR2003	48	5	0	4
		DAY 50	*	24MAR2003	54	5	0	4
	E0023013	SCREEN		13FEB2003	-14	5		
		DAY 1		27FEB2003	1	5		
		DAY 8		06MAR2003	8	5	0	3
	E0023015	SCREEN		04MAR2003	-7	5		
		DAY 1		11MAR2003	1	5		
		DAY 8		18MAR2003	8	5	0	2
		DAY 15		25MAR2003	15	4	-1	3
		DAY 22		01APR2003	22	4	-1	4
		DAY 29		08APR2003	29	4	-1	4
		DAY 36		15APR2003	36	1	-4	1
		DAY 43		22APR2003	43	1	-4	1
		DAY 50		29APR2003	50	1	-4	1
		DAY 57		06MAY2003	57	3	-2	2
	E0023034	SCREEN		03JUN2003	-6	5		
		DAY 1		09JUN2003	1	5		
		DAY 8		16JUN2003	8	5	0	4
		DAY 15		23JUN2003	15	5	0	4
		DAY 22		30JUN2003	22	4	-1	3
		DAY 29		07JUL2003	29	5	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	DAY 36		14JUL2003	36	4	-1	2
		DAY 43		22JUL2003	44	4	-1	2
		DAY 57		05AUG2003	58	4	-1	2
	E0023037	SCREEN		11JUN2003	-7	5		
		DAY 1		18JUN2003	1	5		
		DAY 8		24JUN2003	7	5	0	3
		DAY 15		01JUL2003	14	4	-1	2
		DAY 29	*	14JUL2003	27	3	-2	2
		DAY 29		18JUL2003	31	3	-2	2
		DAY 36		25JUL2003	38	2	-3	1
		DAY 43		01AUG2003	45	2	-3	1
		DAY 50		08AUG2003	52	2	-3	1
		DAY 57		15AUG2003	59	2	-3	1
	E0023038	SCREEN		20JUN2003	-10	5		
		DAY 1		30JUN2003	1	5		
		DAY 8		09JUL2003	10	5	0	3
		DAY 15		15JUL2003	16	4	-1	2
		DAY 22		21JUL2003	22	4	-1	2
		DAY 29		28JUL2003	29	4	-1	2
		DAY 36		07AUG2003	39	4	-1	2
		DAY 43		13AUG2003	45	4	-1	2
		DAY 50		21AUG2003	53	4	-1	2
		DAY 57		27AUG2003	59	4	-1	2
	E0023044	SCREEN		08JUL2003	-8	5		
		DAY 1		16JUL2003	1	5		
		DAY 8		22JUL2003	7	5	0	4
		DAY 15		29JUL2003	14	5	0	4
		DAY 22		05AUG2003	21	5	0	4
		DAY 29		12AUG2003	28	5	0	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	SCREEN	10JUL2003	-7	5		
		DAY 1	17JUL2003	1	5		
		DAY 8	24JUL2003	8	5	0	3
		DAY 15	31JUL2003	15	5	0	3
		DAY 22	07AUG2003	22	5	0	3
		DAY 29	14AUG2003	29	5	0	3
		DAY 36	21AUG2003	36	5	0	3
		DAY 43	28AUG2003	43	4	-1	2
		DAY 50	04SEP2003	50	4	-1	2
		DAY 57	11SEP2003	57	4	-1	2
	E0025002	SCREEN	27MAR2003	-7	5		
		DAY 1	03APR2003	1	5		
		DAY 8	10APR2003	8	5	0	4
		DAY 15	17APR2003	15	5	0	4
		DAY 22	24APR2003	22	4	-1	3
		DAY 29	01MAY2003	29	4	-1	3
		DAY 36	08MAY2003	36	3	-2	2
		DAY 43	15MAY2003	43	3	-2	2
		DAY 50	22MAY2003	50	3	-2	2
		DAY 57	29MAY2003	57	3	-2	2
	E0026010	SCREEN	15JAN2003	-7	4		
		DAY 1	22JAN2003	1	4		
		DAY 8	30JAN2003	9	3	-1	2
	E0026017	SCREEN	26FEB2003	-8	5		
		DAY 1	06MAR2003	1	5		
		DAY 15	21MAR2003	16	3	-2	2
	E0026018	SCREEN	06MAR2003	-14	4		
		DAY 1	20MAR2003	1	5		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	DAY 8	27MAR2003	8	3	-2	2
		DAY 15	03APR2003	15	3	-2	2
		DAY 22	10APR2003	22	2	-3	1
		DAY 29	17APR2003	29	2	-3	2
		DAY 36	24APR2003	36	2	-3	2
		DAY 43	01MAY2003	43	1	-4	1
		DAY 50	08MAY2003	50	1	-4	1
		DAY 57	15MAY2003	57	1	-4	1
	E0026025	SCREEN	01MAY2003	-8	5		
		DAY 1	09MAY2003	1	5		
		DAY 8	15MAY2003	7	4	-1	3
		DAY 15	22MAY2003	14	4	-1	3
		DAY 22	29MAY2003	21	4	-1	3
		DAY 29	05JUN2003	28	3	-2	2
		DAY 36	13JUN2003	36	3	-2	1
		DAY 43	20JUN2003	43	3	-2	1
		DAY 50	27JUN2003	50	3	-2	1
		DAY 57	03JUL2003	56	2	-3	1
	E0026029	SCREEN	02JUL2003	-7	4		
		DAY 1	09JUL2003	1	5		
		DAY 8	16JUL2003	8	4	-1	3
	E0026030	SCREEN	02JUL2003	-7	4		
		DAY 1	09JUL2003	1	4		
		DAY 8	16JUL2003	8	4	0	3
		DAY 15	23JUL2003	15	4	0	3
		DAY 22	30JUL2003	22	3	-1	3
		DAY 29	04AUG2003	27	3	-1	2
		DAY 36	12AUG2003	35	1	-3	1
		DAY 43	19AUG2003	42	2	-2	1

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	DAY 50		26AUG2003	49	1	-3	1
		DAY 57		03SEP2003	57	1	-3	1
	E0026031	SCREEN		10JUL2003	-11	4		
		DAY 1		21JUL2003	1	4		
		DAY 8		28JUL2003	8	3	-1	3
		DAY 15		04AUG2003	15	3	-1	3
		DAY 22		11AUG2003	22	3	-1	2
		DAY 29		18AUG2003	29	3	-1	2
		DAY 36		25AUG2003	36	4	0	3
		DAY 43		02SEP2003	44	3	-1	2
		DAY 50		08SEP2003	50	3	-1	3
		DAY 57		15SEP2003	57	3	-1	2
	E0027003	SCREEN	*	08JAN2003	-20	5		
		SCREEN		23JAN2003	-5	5		
		DAY 1		23JAN2003	-5	5		
		DAY 8		06FEB2003	10	5	0	4
		DAY 15		13FEB2003	17	4	-1	3
		DAY 22		19FEB2003	23	3	-2	2
		DAY 29		27FEB2003	31	3	-2	2
		DAY 36		06MAR2003	38	3	-2	2
		DAY 43		13MAR2003	45	3	-2	2
		DAY 50		20MAR2003	52	3	-2	2
		DAY 57		25MAR2003	57	3	-2	2
	E0028004	SCREEN		27SEP2002	-3	5		
		DAY 1		30SEP2002	1	5		
		DAY 8		07OCT2002	8	4	-1	4
	E0028006	SCREEN		01OCT2002	-3	4		
		DAY 1		04OCT2002	1	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	DAY 8	11OCT2002	8	4	0	4
		DAY 15	16OCT2002	13	4	0	3
		DAY 22	23OCT2002	20	4	0	4
		DAY 29	31OCT2002	28	4	0	3
		DAY 36	07NOV2002	35	4	0	3
		DAY 43	14NOV2002	42	4	0	3
		DAY 50	21NOV2002	49	4	0	3
		DAY 57	04DEC2002	62	4	0	4
	E0028008	SCREEN	08OCT2002	-7	4		
		DAY 1	15OCT2002	1	4		
		DAY 8	22OCT2002	8	4	0	4
		DAY 15	29OCT2002	15	4	0	4
		DAY 22	07NOV2002	24	4	0	4
		DAY 29	14NOV2002	31	4	0	4
		DAY 36	21NOV2002	38	4	0	3
		DAY 50	03DEC2002	50	4	0	4
		DAY 57	10DEC2002	57	4	0	3
	E0028009	SCREEN	10OCT2002	-5	4		
		DAY 1	15OCT2002	1	4		
		DAY 8	23OCT2002	9	4	0	3
		DAY 15	31OCT2002	17	4	0	3
		DAY 22	07NOV2002	24	3	-1	2
		DAY 29	14NOV2002	31	3	-1	2
		DAY 36	19NOV2002	36	2	-2	2
		DAY 43	26NOV2002	43	2	-2	1
		DAY 50	03DEC2002	50	3	-1	2
		DAY 57	12DEC2002	59	2	-2	1
	E0028016	SCREEN	07NOV2002	-7	4		
		DAY 1	14NOV2002	1	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	DAY 8		21NOV2002	8	4	0	3
		DAY 15		26NOV2002	13	4	0	3
		DAY 22		05DEC2002	22	4	0	4
		DAY 29		12DEC2002	29	3	-1	2
		DAY 36		19DEC2002	36	3	-1	2
		DAY 43		26DEC2002	43	3	-1	3
		DAY 50		02JAN2003	50	3	-1	3
		DAY 57		09JAN2003	57	3	-1	2
	E0028017		*	12NOV2002		4		
			*	19NOV2002		4		
	E0028027	SCREEN		14JAN2003	-7	4		
		DAY 1		21JAN2003	1	4		
		DAY 8		28JAN2003	8	4	0	4
		DAY 15		04FEB2003	15	4	0	3
		DAY 22		11FEB2003	22	4	0	3
		DAY 29		20FEB2003	31	4	0	4
		DAY 36		28FEB2003	39	3	-1	3
	E0028029	SCREEN		28JAN2003	-7	4		
		DAY 1		04FEB2003	1	4		
		DAY 8		11FEB2003	8	4	0	4
		DAY 15		17FEB2003	14	4	0	3
		DAY 22		27FEB2003	24	3	-1	2
		DAY 29		06MAR2003	31	4	0	4
		DAY 36		13MAR2003	38	2	-2	2
		DAY 43		20MAR2003	45	3	-1	2
		DAY 50		27MAR2003	52	3	-1	3
		DAY 57		03APR2003	59	2	-2	1
	E0028034	SCREEN		20MAR2003	-12	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	DAY 1	01APR2003	1	4		
		DAY 8	08APR2003	8	4	0	5
		DAY 15	15APR2003	15	4	0	3
		DAY 22	22APR2003	22	2	-2	2
		DAY 29	01MAY2003	31	3	-1	2
		DAY 36	06MAY2003	36	3	-1	2
		DAY 43	13MAY2003	43	2	-2	1
		DAY 50	21MAY2003	51	2	-2	1
		DAY 57	02JUN2003	63	4	0	2
	E0028038	SCREEN	18APR2003	-7	4		
		DAY 1	25APR2003	1	4		
		DAY 8	02MAY2003	8	4	0	4
		DAY 15	08MAY2003	14	4	0	4
		DAY 29	22MAY2003	28	4	0	4
		DAY 36	30MAY2003	36	4	0	4
		DAY 43	05JUN2003	42	4	0	4
		DAY 50	12JUN2003	49	4	0	4
		DAY 57	18JUN2003	55	4	0	4
	E0028043	SCREEN	29MAY2003	-7	4		
		DAY 1	05JUN2003	1	4		
		DAY 8	12JUN2003	8	4	0	4
		DAY 15	19JUN2003	15	4	0	3
		DAY 22	26JUN2003	22	4	0	3
		DAY 29	01JUL2003	27	4	0	3
		DAY 36	08JUL2003	34	3	-1	3
		DAY 43	15JUL2003	41	3	-1	3
		DAY 50	22JUL2003	48	3	-1	2
		DAY 57	29JUL2003	55	3	-1	2
	E0028045	SCREEN	09JUN2003	-9	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028045	DAY 1	18JUN2003	1	5		
		DAY 8	25JUN2003	8	4	-1	4
		DAY 15	30JUN2003	13	4	-1	3
	E0029005	SCREEN	14NOV2002	-13	5		
		DAY 1	27NOV2002	1	4		
		DAY 8	03DEC2002	7	4	0	3
		DAY 15	09DEC2002	13	4	0	3
		DAY 22	16DEC2002	20	3	-1	2
		DAY 29	23DEC2002	27	3	-1	2
		DAY 36	30DEC2002	34	3	-1	2
		DAY 43	07JAN2003	42	3	-1	2
		DAY 50	14JAN2003	49	3	-1	2
		DAY 57	21JAN2003	56	3	-1	2
	E0030001	SCREEN	12NOV2002	-7	5		
		DAY 1	19NOV2002	1	5		
		DAY 8	26NOV2002	8	5	0	4
		DAY 15	03DEC2002	15	5	0	4
		DAY 22	10DEC2002	22	2	-3	3
		DAY 29	17DEC2002	29	3	-2	3
		DAY 43	02JAN2003	45	2	-3	2
		DAY 50	09JAN2003	52	2	-3	2
		DAY 57	16JAN2003	59	2	-3	2
	E0030008	SCREEN	07JAN2003	-7	4		
		DAY 1	14JAN2003	1	4		
		DAY 8	23JAN2003	10	4	0	4
		DAY 15	30JAN2003	17	4	0	4
		DAY 22	07FEB2003	25	4	0	4
		DAY 29	14FEB2003	32	4	0	4
		DAY 36	21FEB2003	39	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	DAY 50		03MAR2003	49	3	-1	3
		DAY 57	*	11MAR2003	57	3	-1	2
		DAY 57		18MAR2003	64	3	-1	2
	E0030011	SCREEN		16JAN2003	-11	5		
		DAY 1		27JAN2003	1	5		
		DAY 8		03FEB2003	8	2	-3	2
		DAY 15		10FEB2003	15	2	-3	1
		DAY 22		18FEB2003	23	1	-4	1
		DAY 29		24FEB2003	29	1	-4	1
		DAY 36		03MAR2003	36	2	-3	1
		DAY 43		10MAR2003	43	1	-4	1
		DAY 50		17MAR2003	50	1	-4	1
		DAY 57		24MAR2003	57	1	-4	1
	E0030015	SCREEN		13FEB2003	-8	4		
		DAY 1		21FEB2003	1	4		
		DAY 8		03MAR2003	11	4	0	4
		DAY 15		11MAR2003	19	3	-1	3
		DAY 29		19MAR2003	27	2	-2	2
		DAY 36		26MAR2003	34	2	-2	1
		DAY 43		02APR2003	41	2	-2	1
		DAY 50		09APR2003	48	1	-3	1
		DAY 57	*	17APR2003	56	1	-3	1
		DAY 57		22APR2003	61	1	-3	1
	E0030022	SCREEN		06JUN2003	-10	4		
		DAY 1		16JUN2003	1	4		
		DAY 8		20JUN2003	5	4	0	3
		DAY 15		30JUN2003	15	2	-2	2
		DAY 22		07JUL2003	22	2	-2	1
		DAY 29		14JUL2003	29	2	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	DAY 36		21JUL2003	36	2	-2	2
		DAY 43		29JUL2003	44	2	-2	1
		DAY 50		05AUG2003	51	2	-2	2
		DAY 57		14AUG2003	60	2	-2	1
	E0031002	SCREEN		20NOV2002	-7	4		
		DAY 1		27NOV2002	1	4		
		DAY 8		06DEC2002	10	3	-1	3
		DAY 15		12DEC2002	16	3	-1	3
		DAY 22		19DEC2002	23	3	-1	2
		DAY 29		27DEC2002	31	3	-1	2
		DAY 36		02JAN2003	37	2	-2	1
		DAY 50	*	13JAN2003	48	2	-2	1
		DAY 50		17JAN2003	52	2	-2	1
		DAY 57		22JAN2003	57	2	-2	1
	E0031003	SCREEN		03DEC2002	-7	4		
		DAY 1		10DEC2002	1	4		
		DAY 8		17DEC2002	8	4	0	3
		DAY 15		23DEC2002	14	3	-1	2
		DAY 22		31DEC2002	22	3	-1	2
		DAY 29		07JAN2003	29	4	0	3
		DAY 36		15JAN2003	37	4	0	3
		DAY 43		21JAN2003	43	3	-1	2
		DAY 50		30JAN2003	52	3	-1	2
		DAY 57		04FEB2003	57	3	-1	2
	E0033015	SCREEN		03APR2003	-7	4		
		DAY 1		10APR2003	1	4		
		DAY 8		17APR2003	8	4	0	4
		DAY 15		22APR2003	13	3	-1	3
		DAY 15	*	28APR2003	19	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	DAY 29	06MAY2003	27	3	-1	2
		DAY 36	13MAY2003	34	2	-2	2
		DAY 43	20MAY2003	41	2	-2	2
		DAY 50	27MAY2003	48	2	-2	1
		DAY 57	04JUN2003	56	2	-2	1
	E0034002	SCREEN	14MAR2003	-11	5		
		DAY 1	25MAR2003	1	5		
		DAY 8	01APR2003	8	3	-2	2
		DAY 15	08APR2003	15	3	-2	2
		DAY 22	15APR2003	22	3	-2	2
	E0034003	SCREEN	11APR2003	-13	5		
		DAY 1	24APR2003	1	5		
		DAY 8	01MAY2003	8	3	-2	2
		DAY 15	08MAY2003	15	2	-3	1
		DAY 22	15MAY2003	22	2	-3	1
		DAY 29	22MAY2003	29	1	-4	1
		DAY 36	29MAY2003	36	1	-4	1
		DAY 43	05JUN2003	43	1	-4	1
		DAY 50	12JUN2003	50	1	-4	1
		DAY 57	19JUN2003	57	1	-4	1
	E0034006	SCREEN	25APR2003	-21	5		
		DAY 1	16MAY2003	1	5		
		DAY 8	23MAY2003	8	4	-1	3
		DAY 15	02JUN2003	18	4	-1	3
		DAY 22	09JUN2003	25	4	-1	3
		DAY 29	13JUN2003	29	4	-1	3
		DAY 36	20JUN2003	36	4	-1	3
		DAY 43	27JUN2003	43	5	0	4
		DAY 50	03JUL2003	49	5	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	DAY 57	10JUL2003	56	5	0	4
	E0034008	SCREEN	15MAY2003	-9	5		
		DAY 1	23MAY2003	-1	5		
		DAY 8	02JUN2003	10	4	-1	3
		DAY 15	06JUN2003	14	4	-1	3
		DAY 22	13JUN2003	21	5	0	4
		DAY 29	20JUN2003	28	3	-2	2
		DAY 36	27JUN2003	35	1	-4	1
		DAY 43	07JUL2003	45	1	-4	1
		DAY 50	14JUL2003	52	1	-4	1
		DAY 57	21JUL2003	59	1	-4	1
	E0035003	SCREEN	15NOV2002	-7	4		
		DAY 1	22NOV2002	1	4		
		DAY 8	27NOV2002	6	4	0	4
		DAY 15	04DEC2002	13	4	0	3
		DAY 22	13DEC2002	22	4	0	3
		DAY 29	20DEC2002	29	3	-1	2
		DAY 36	27DEC2002	36	3	-1	2
		DAY 43	03JAN2003	43	3	-1	2
		DAY 50	10JAN2003	50	3	-1	2
	E0035005	SCREEN	26NOV2002	-7	4		
		DAY 1	03DEC2002	1	4		
		DAY 8	12DEC2002	10	4	0	3
		DAY 15	17DEC2002	15	3	-1	2
		DAY 22	24DEC2002	22	3	-1	2
		DAY 29	31DEC2002	29	3	-1	2
		DAY 36	07JAN2003	36	3	-1	2
		DAY 43	14JAN2003	43	3	-1	2
		DAY 50	21JAN2003	50	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	SCREEN	28JAN2003	-6	3		
		DAY 1	03FEB2003	1	3		
		DAY 8	10FEB2003	8	3	0	4
		DAY 15	17FEB2003	15	3	0	2
		DAY 22	24FEB2003	22	3	0	2
		DAY 29	03MAR2003	29	3	0	2
		DAY 36	10MAR2003	36	3	0	2
		DAY 43	17MAR2003	43	2	-1	1
		DAY 50	24MAR2003	50	2	-1	1
		DAY 57	31MAR2003	57	2	-1	1
	E0035024	SCREEN	15MAY2003	-8	4		
		DAY 1	22MAY2003	-1	4		
		DAY 8	29MAY2003	7	4	0	4
		DAY 15	05JUN2003	14	4	0	4
		DAY 22	13JUN2003	22	4	0	4
		DAY 29	19JUN2003	28	4	0	4
		DAY 36	27JUN2003	36	4	0	4
		DAY 43	03JUL2003	42	4	0	3
		DAY 50	10JUL2003	49	4	0	3
		DAY 57	18JUL2003	57	4	0	3
	E0036005	SCREEN	24JUN2003	-7	4		
		DAY 1	01JUL2003	1	4		
		DAY 8	08JUL2003	8	4	0	3
		DAY 15	15JUL2003	15	3	-1	3
		DAY 22	23JUL2003	23	3	-1	3
		DAY 29	29JUL2003	29	3	-1	2
		DAY 36	05AUG2003	36	3	-1	2
		DAY 43	12AUG2003	43	3	-1	3
		DAY 50	19AUG2003	50	4	0	4
		DAY 57	27AUG2003	58	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	SCREEN	19DEC2002	-7	4		
		DAY 1	26DEC2002	1	4		
		DAY 8	03JAN2003	9	4	0	4
		DAY 15	09JAN2003	15	4	0	3
		DAY 22	17JAN2003	23	3	-1	3
		DAY 29	24JAN2003	30	4	0	3
		DAY 36	31JAN2003	37	4	0	3
		DAY 43	07FEB2003	44	3	-1	3
		DAY 50	13FEB2003	50	3	-1	2
		DAY 57	20FEB2003	57	3	-1	2
	E0037005	SCREEN	26FEB2003	-8	4		
		DAY 1	06MAR2003	1	4		
		DAY 8	13MAR2003	8	4	0	4
		DAY 15	20MAR2003	15	4	0	4
		DAY 22	27MAR2003	22	3	-1	2
		DAY 29	03APR2003	29	4	0	3
		DAY 36	10APR2003	36	3	-1	2
		DAY 43	17APR2003	43	3	-1	2
		DAY 50	24APR2003	50	3	-1	2
		DAY 57	01MAY2003	57	3	-1	3
	E0037006	SCREEN	06MAR2003	-8	4		
		DAY 1	14MAR2003	1	4		
		DAY 8	21MAR2003	8	3	-1	3
		DAY 15	28MAR2003	15	3	-1	2
		DAY 22	04APR2003	22	3	-1	2
		DAY 29	11APR2003	29	3	-1	2
		DAY 36	18APR2003	36	3	-1	3
		DAY 43	25APR2003	43	3	-1	3
		DAY 50	01MAY2003	49	3	-1	3
		DAY 57	09MAY2003	57	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	SCREEN	10DEC2002	-20	4		
		DAY 1	30DEC2002	1	4		
		DAY 8	06JAN2003	8	5	1	4
		DAY 15	13JAN2003	15	5	1	4
		DAY 22	20JAN2003	22	4	0	4
		DAY 29	28JAN2003	30	5	1	4
		DAY 36	04FEB2003	37	5	1	4
		DAY 43	10FEB2003	43	2	-2	2
		DAY 50	18FEB2003	51	2	-2	2
		DAY 57	24FEB2003	57	2	-2	1
	E0039015	SCREEN	02JAN2003	-21	4		
		DAY 1	23JAN2003	1	5		
		DAY 8	30JAN2003	8	2	-3	2
		DAY 15	06FEB2003	15	2	-3	2
		DAY 22	14FEB2003	23	2	-3	1
		DAY 29	20FEB2003	29	2	-3	1
		DAY 36	27FEB2003	36	2	-3	2
		DAY 43	06MAR2003	43	2	-3	1
		DAY 50	14MAR2003	51	1	-4	1
		DAY 57	20MAR2003	57	2	-3	1
	E0039024	SCREEN	05FEB2003	-22	4		
		DAY 1	27FEB2003	1	4		
		DAY 8	05MAR2003	7	3	-1	2
		DAY 15	11MAR2003	13	1	-3	1
		DAY 22	20MAR2003	22	2	-2	2
		DAY 29	27MAR2003	29	3	-1	2
		DAY 36	03APR2003	36	3	-1	2
		DAY 43	10APR2003	43	3	-1	2
		DAY 50	17APR2003	50	1	-3	1
		DAY 57	24APR2003	57	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0039025	SCREEN	26FEB2003	-20	4		
		DAY 1	18MAR2003	1	4		
		DAY 8	25MAR2003	8	3	-1	3
		DAY 15	01APR2003	15	2	-2	2
		DAY 22	10APR2003	24	1	-3	1
		DAY 29	15APR2003	29	1	-3	1
		DAY 36	22APR2003	36	1	-3	1
		DAY 43	29APR2003	43	1	-3	1
		DAY 50	06MAY2003	50	1	-3	1
	E0039041	SCREEN	07APR2003	-8	4		
		DAY 1	15APR2003	1	4		
		DAY 8	22APR2003	8	4	0	4
		DAY 15	29APR2003	15	3	-1	2
		DAY 22	06MAY2003	22	1	-3	1
		DAY 29	13MAY2003	29	3	-1	2
		DAY 36	20MAY2003	36	1	-3	1
		DAY 43	27MAY2003	43	3	-1	2
		DAY 50	03JUN2003	50	2	-2	1
		DAY 57	11JUN2003	58	1	-3	1
	E0039044	SCREEN	05MAY2003	-17	4		
		DAY 1	22MAY2003	1	4		
		DAY 8	29MAY2003	8	1	-3	1
		DAY 15	04JUN2003	14	1	-3	1
		DAY 22	11JUN2003	21	1	-3	1
		DAY 29	18JUN2003	28	1	-3	1
		DAY 36	26JUN2003	36	1	-3	1
		DAY 43	02JUL2003	42	1	-3	1
		DAY 50	09JUL2003	49	1	-3	1
	E0039046	*	06MAY2003		5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0039046		*	21MAY2003		5		
	E0039051	SCREEN		22MAY2003	-25	4		
		DAY 1		16JUN2003	1	4		
		DAY 8		23JUN2003	8	3	-1	3
		DAY 15		30JUN2003	15	3	-1	2
		DAY 22		07JUL2003	22	3	-1	2
		DAY 29		14JUL2003	29	3	-1	2
		DAY 36		22JUL2003	37	3	-1	2
		DAY 43		28JUL2003	43	1	-3	1
		DAY 50		04AUG2003	50	2	-2	2
		DAY 57		12AUG2003	58	2	-2	1
	E0039053	SCREEN		16JUN2003	-25	4		
		DAY 1		11JUL2003	1	4		
		DAY 8		18JUL2003	8	4	0	3
		DAY 15		25JUL2003	15	4	0	3
		DAY 22		01AUG2003	22	4	0	3
		DAY 29		07AUG2003	28	2	-2	2
		DAY 36		14AUG2003	35	2	-2	1
		DAY 43		21AUG2003	42	2	-2	2
		DAY 50		29AUG2003	50	1	-3	1
		DAY 57		08SEP2003	60	3	-1	2
	E0039057	SCREEN		02JUL2003	-12	4		
		DAY 1		14JUL2003	1	4		
		DAY 8		22JUL2003	9	2	-2	1
		DAY 15		28JUL2003	15	1	-3	1
		DAY 22		04AUG2003	22	2	-2	1
		DAY 29		12AUG2003	30	1	-3	1
		DAY 36		18AUG2003	36	1	-3	1
		DAY 43		26AUG2003	44	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0039057	DAY 50	02SEP2003	51	2	-2	1
		DAY 57	09SEP2003	58	1	-3	1
	E0041003	SCREEN	16JAN2003	-12	4		
		DAY 1	28JAN2003	1	4		
		DAY 8	04FEB2003	8	2	-2	2
		DAY 15	11FEB2003	15	2	-2	2
		DAY 22	18FEB2003	22	2	-2	1
		DAY 29	25FEB2003	29	2	-2	1
		DAY 36	04MAR2003	36	2	-2	1
		DAY 43	11MAR2003	43	2	-2	1
		DAY 50	18MAR2003	50	2	-2	1
		DAY 57	25MAR2003	57	2	-2	1
	E0041008	SCREEN	26MAR2003	-12	4		
		DAY 1	07APR2003	1	4		
		DAY 8	14APR2003	8	4	0	4
		DAY 15	22APR2003	16	4	0	4
		DAY 22	28APR2003	22	4	0	4
		DAY 29	05MAY2003	29	4	0	4
		DAY 36	12MAY2003	36	4	0	4
		DAY 43	21MAY2003	45	4	0	3
		DAY 50	27MAY2003	51	4	0	4
		DAY 57	02JUN2003	57	4	0	3
	E0042001	SCREEN	17JUN2003	-15	5		
		DAY 1	02JUL2003	1	5		
		DAY 8	09JUL2003	8	4	-1	3
		DAY 15	15JUL2003	14	3	-2	2
		DAY 22	22JUL2003	21	3	-2	2
		DAY 29	29JUL2003	28	2	-3	3
		DAY 36	05AUG2003	35	3	-2	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0042001	DAY 43	12AUG2003	42	3	-2	2
		DAY 50	19AUG2003	49	3	-2	2
		DAY 57	26AUG2003	56	2	-3	2

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GENERATED: 12JUL2005 17:39:44 iceadmn3

Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	SCREEN	26FEB2003	-14	4		
		DAY 1	12MAR2003	1	5		
		DAY 8	19MAR2003	8	4	-1	3
		DAY 15	26MAR2003	15	4	-1	1
		DAY 22	02APR2003	22	3	-2	2
		DAY 29	09APR2003	29	3	-2	1
		DAY 36	16APR2003	36	2	-3	1
		DAY 43	23APR2003	43	1	-4	1
		DAY 50	30APR2003	50	1	-4	1
		DAY 57	07MAY2003	57	1	-4	1
	E0003018	SCREEN	08MAY2003	-5	5		
		DAY 1	13MAY2003	1	4		
		DAY 8	20MAY2003	8	4	0	4
		DAY 15	27MAY2003	15	3	-1	3
		DAY 22	03JUN2003	22	4	0	4
		DAY 29	10JUN2003	29	5	1	5
		DAY 36	17JUN2003	36	4	0	4
		DAY 43	24JUN2003	43	4	0	4
		DAY 50	02JUL2003	51	3	-1	3
		DAY 57	08JUL2003	57	4	0	4
	E0005011	SCREEN	16OCT2002	-8	5		
		DAY 1	24OCT2002	1	5		
		DAY 8	31OCT2002	8	4	-1	3
		DAY 15	07NOV2002	15	3	-2	3
		DAY 22	14NOV2002	22	3	-2	2
		DAY 29	21NOV2002	29	2	-3	2
		DAY 36	26NOV2002	34	2	-3	2
		DAY 43	03DEC2002	41	2	-3	1
		DAY 50	12DEC2002	50	2	-3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0005030	SCREEN	18MAR2003	-8	5		
		DAY 1	26MAR2003	1	5		
		DAY 8	02APR2003	8	5	0	3
		DAY 15	09APR2003	15	2	-3	2
		DAY 22	16APR2003	22	5	0	4
	E0005036	SCREEN	28APR2003	-8	5		
		DAY 1	06MAY2003	1	5		
		DAY 8	12MAY2003	7	3	-2	3
	E0006015	SCREEN	06FEB2003	-5	5		
		DAY 1	11FEB2003	1	5		
		DAY 8	18FEB2003	8	4	-1	3
		DAY 15	25FEB2003	15	5	0	5
		DAY 22	04MAR2003	22	5	0	4
		DAY 29	11MAR2003	29	5	0	4
		DAY 36	18MAR2003	36	5	0	4
		DAY 43	25MAR2003	43	5	0	4
		DAY 50	01APR2003	50	4	-1	3
		DAY 57	08APR2003	57	3	-2	2
	E0006016	SCREEN	07FEB2003	-10	5		
		DAY 1	17FEB2003	1	5		
		DAY 8	24FEB2003	8	5	0	4
		DAY 15	03MAR2003	15	4	-1	3
		DAY 22	10MAR2003	22	4	-1	3
		DAY 29	17MAR2003	29	4	-1	3
		DAY 36	27MAR2003	39	3	-2	2
		DAY 43	03APR2003	46	3	-2	2
		DAY 50	10APR2003	53	3	-2	2
		DAY 57	18APR2003	61	3	-2	2

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	SCREEN	07APR2003	-11	4		
		DAY 1	18APR2003	1	4		
		DAY 8	25APR2003	8	4	0	4
	E0009002	SCREEN	29OCT2002	-21	4		
		DAY 1	19NOV2002	1	4		
		DAY 8	26NOV2002	8	2	-2	2
		DAY 15	03DEC2002	15	4	0	3
		DAY 22	10DEC2002	22	4	0	3
		DAY 29	18DEC2002	30	2	-2	2
		DAY 36	23DEC2002	35	3	-1	2
		DAY 43	30DEC2002	42	3	-1	3
		DAY 50	07JAN2003	50	2	-2	2
		DAY 57	15JAN2003	58	4	0	3
	E0009006	SCREEN	22JAN2003	-6	5		
		DAY 1	28JAN2003	1	5		
		DAY 8	04FEB2003	8	4	-1	3
		DAY 15	11FEB2003	15	4	-1	3
		DAY 22	18FEB2003	22	4	-1	3
		DAY 29	25FEB2003	29	4	-1	3
		DAY 36	04MAR2003	36	4	-1	3
		DAY 43	11MAR2003	43	4	-1	3
		DAY 50	18MAR2003	50	4	-1	3
		DAY 57	25MAR2003	57	4	-1	3
	E0009009	SCREEN	27FEB2003	-13	4		
		DAY 1	12MAR2003	1	4		
		DAY 8	19MAR2003	8	3	-1	2
		DAY 15	24MAR2003	13	3	-1	2
	E0010015	SCREEN	29JAN2003	-22	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	DAY 1	20FEB2003	1	5		
		DAY 8	27FEB2003	8	4	-1	2
		DAY 15	06MAR2003	15	5	0	4
		DAY 22	13MAR2003	22	5	0	3
		DAY 29	20MAR2003	29	5	0	3
		DAY 36	26MAR2003	35	4	-1	2
		DAY 43	02APR2003	42	4	-1	2
		DAY 50	09APR2003	49	3	-2	1
		DAY 57	15APR2003	55	3	-2	1
	E0011004	SCREEN	17DEC2002	-7	4		
		DAY 1	24DEC2002	1	4		
		DAY 8	31DEC2002	8	4	0	3
		DAY 15	07JAN2003	15	4	0	3
		DAY 22	14JAN2003	22	3	-1	2
		DAY 29	21JAN2003	29	3	-1	2
		DAY 36	28JAN2003	36	3	-1	2
		DAY 43	04FEB2003	43	3	-1	2
		DAY 50	11FEB2003	50	3	-1	2
		DAY 57	18FEB2003	57	2	-2	2
	E0011007	SCREEN	12DEC2002	-7	4		
		DAY 1	19DEC2002	1	4		
		DAY 8	26DEC2002	8	4	0	3
		DAY 15	02JAN2003	15	4	0	4
		DAY 22	09JAN2003	22	4	0	3
		DAY 29	17JAN2003	30	3	-1	3
		DAY 36	23JAN2003	36	3	-1	3
		DAY 43	30JAN2003	43	3	-1	3
		DAY 50	06FEB2003	50	3	-1	2
		DAY 57	13FEB2003	57	2	-2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	SCREEN		15MAY2003	-7	4		
		DAY 1		22MAY2003	1	4		
		DAY 8		30MAY2003	9	4	0	4
		DAY 22	*	10JUN2003	20	4	0	4
		DAY 22		13JUN2003	23	3	-1	2
		DAY 29		20JUN2003	30	3	-1	2
		DAY 36		28JUN2003	38	3	-1	2
		DAY 43		03JUL2003	43	3	-1	2
		DAY 50		10JUL2003	50	3	-1	2
		DAY 57		17JUL2003	57	3	-1	2
	E0011024	SCREEN		17JUN2003	-7	4		
		DAY 1		24JUN2003	1	4		
		DAY 8		01JUL2003	8	4	0	3
		DAY 15		08JUL2003	15	4	0	4
		DAY 22		15JUL2003	22	4	0	3
		DAY 29		22JUL2003	29	3	-1	3
		DAY 36		30JUL2003	37	3	-1	2
		DAY 43		05AUG2003	43	2	-2	2
		DAY 50		12AUG2003	50	2	-2	2
		DAY 57		21AUG2003	59	3	-1	2
	E0015003	SCREEN		13NOV2002	-12	5		
		DAY 1		25NOV2002	1	5		
		DAY 8		02DEC2002	8	5	0	4
	E0019003	SCREEN		29OCT2002	-23	4		
		DAY 1		21NOV2002	1	5		
		DAY 8		27NOV2002	7	3	-2	2
		DAY 15		09DEC2002	19	2	-3	1
		DAY 22		16DEC2002	26	2	-3	1
		DAY 36		24DEC2002	34	3	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	DAY 36	*	30DEC2002	40	2	-3	2
		DAY 43		06JAN2003	47	2	-3	2
		DAY 57	*	14JAN2003	55	2	-3	2
		DAY 57		16JAN2003	57	2	-3	2
	E0019007	SCREEN		06NOV2002	-7	5		
		DAY 1		13NOV2002	1	5		
		DAY 8		21NOV2002	9	4	-1	3
		DAY 15		27NOV2002	15	4	-1	3
		DAY 22		05DEC2002	23	3	-2	2
		DAY 29		12DEC2002	30	2	-3	2
		DAY 36		17DEC2002	35	3	-2	3
		DAY 43		24DEC2002	42	3	-2	3
		DAY 50		30DEC2002	48	4	-1	3
		DAY 57		07JAN2003	56	4	-1	3
	E0019014	SCREEN		17DEC2002	-23	4		
		DAY 1		09JAN2003	1	4		
		DAY 8		20JAN2003	12	3	-1	3
	E0019018	SCREEN		14JAN2003	-16	4		
		DAY 1		30JAN2003	1	4		
		DAY 8		06FEB2003	8	4	0	4
		DAY 15		13FEB2003	15	3	-1	3
		DAY 22		20FEB2003	22	4	0	3
		DAY 29		27FEB2003	29	4	0	3
		DAY 36		06MAR2003	36	5	1	4
		DAY 43		13MAR2003	43	5	1	4
		DAY 50		20MAR2003	50	5	1	4
		DAY 57		27MAR2003	57	5	1	4
	E0019022	SCREEN		23JAN2003	-7	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 1	30JAN2003	1	4		
		DAY 8	06FEB2003	8	4	0	4
		DAY 15	13FEB2003	15	3	-1	3
		DAY 22	20FEB2003	22	3	-1	3
		DAY 29	27FEB2003	29	3	-1	3
		DAY 36	06MAR2003	36	3	-1	3
		DAY 43	13MAR2003	43	2	-2	2
		DAY 50	20MAR2003	50	3	-1	3
		DAY 57	27MAR2003	57	3	-1	3
	E0019027	SCREEN	20FEB2003	-7	5		
		DAY 1	27FEB2003	1	5		
		DAY 8	06MAR2003	8	4	-1	3
	E0019032	SCREEN	06MAR2003	-26	5		
		DAY 1	01APR2003	1	4		
		DAY 8	08APR2003	8	4	0	3
		DAY 15	15APR2003	15	4	0	3
		DAY 22	21APR2003	21	4	0	3
		DAY 29	29APR2003	29	3	-1	2
		DAY 36	07MAY2003	37	3	-1	2
		DAY 43	14MAY2003	44	3	-1	2
		DAY 50	21MAY2003	51	3	-1	2
		DAY 57	27MAY2003	57	3	-1	2
	E0019034	SCREEN	10MAR2003	-8	5		
		DAY 1	18MAR2003	1	4		
		DAY 8	25MAR2003	8	3	-1	2
		DAY 15	01APR2003	15	3	-1	2
	E0019036	SCREEN	18MAR2003	-7	4		
		DAY 1	25MAR2003	1	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019036	DAY 8	31MAR2003	7	4	0	3
		DAY 15	10APR2003	17	4	0	3
		DAY 22	15APR2003	22	3	-1	2
		DAY 29	22APR2003	29	3	-1	2
		DAY 36	29APR2003	36	2	-2	2
	E0019039	SCREEN	22APR2003	-9	4		
		DAY 1	01MAY2003	1	4		
	E0019041	SCREEN	14MAY2003	-7	4		
		DAY 1	21MAY2003	1	4		
		DAY 8	28MAY2003	8	4	0	3
		DAY 15	04JUN2003	15	4	0	3
		DAY 22	12JUN2003	23	4	0	3
		DAY 29	18JUN2003	29	3	-1	2
		DAY 36	25JUN2003	36	3	-1	2
		DAY 43	02JUL2003	43	2	-2	2
		DAY 50	09JUL2003	50	2	-2	2
		DAY 57	16JUL2003	57	2	-2	2
	E0019049	SCREEN	03JUL2003	-7	5		
		DAY 1	10JUL2003	1	5		
		DAY 8	17JUL2003	8	4	-1	3
		DAY 15	24JUL2003	15	4	-1	4
		DAY 22	31JUL2003	22	4	-1	4
		DAY 29	07AUG2003	29	3	-2	3
		DAY 36	14AUG2003	36	4	-1	3
		DAY 50	26AUG2003	48	4	-1	3
		DAY 57	08SEP2003	61	4	-1	3
	E0022052	SCREEN	01APR2003	-9	5		
		DAY 1	10APR2003	1	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	DAY 8	17APR2003	8	4	-1	3
		DAY 15	24APR2003	15	4	-1	3
		DAY 22	01MAY2003	22	5	0	4
		DAY 29	08MAY2003	29	5	0	4
		DAY 36	15MAY2003	36	5	0	4
		DAY 43	22MAY2003	43	5	0	4
		DAY 50	29MAY2003	50	5	0	4
		DAY 57	05JUN2003	57	5	0	4
	E0022064	SCREEN	29APR2003	-7	5		
		DAY 1	06MAY2003	1	5		
		DAY 8	12MAY2003	7	3	-2	2
		DAY 15	20MAY2003	15	2	-3	1
		DAY 22	27MAY2003	22	2	-3	1
		DAY 29	03JUN2003	29	1	-4	1
		DAY 36	10JUN2003	36	1	-4	1
		DAY 43	17JUN2003	43	1	-4	1
		DAY 50	24JUN2003	50	1	-4	1
		DAY 57	01JUL2003	57	1	-4	1
	E0022073	SCREEN	19JUN2003	-7	4		
		DAY 1	26JUN2003	1	4		
		DAY 8	03JUL2003	8	3	-1	2
		DAY 15	10JUL2003	15	2	-2	2
		DAY 22	17JUL2003	22	2	-2	2
		DAY 29	24JUL2003	29	2	-2	2
		DAY 36	31JUL2003	36	2	-2	2
		DAY 43	07AUG2003	43	2	-2	2
		DAY 50	14AUG2003	50	2	-2	2
		DAY 57	21AUG2003	57	2	-2	2
	E0023002	SCREEN	25OCT2002	-11	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	DAY 1	05NOV2002	1	5		
		DAY 8	12NOV2002	8	5	0	5
		DAY 15	19NOV2002	15	5	0	5
		DAY 22	25NOV2002	21	5	0	3
		DAY 29	03DEC2002	29	5	0	5
		DAY 36	10DEC2002	36	5	0	5
	E0023017	SCREEN	14MAR2003	-11	5		
		DAY 1	25MAR2003	1	5		
		DAY 8	03APR2003	10	4	-1	3
		DAY 15	10APR2003	17	4	-1	2
		DAY 22	18APR2003	25	3	-2	2
		DAY 29	24APR2003	31	4	-1	3
		DAY 36	01MAY2003	38	3	-2	2
		DAY 43	08MAY2003	45	3	-2	2
		DAY 50	15MAY2003	52	2	-3	1
		DAY 57	22MAY2003	59	2	-3	2
	E0023021	SCREEN	10APR2003	-13	5		
		DAY 1	23APR2003	1	5		
		DAY 8	29APR2003	7	5	0	4
		DAY 15	06MAY2003	14	4	-1	3
		DAY 22	13MAY2003	21	4	-1	3
		DAY 29	20MAY2003	28	4	-1	3
		DAY 36	29MAY2003	37	5	0	5
		DAY 43	03JUN2003	42	4	-1	3
		DAY 50	10JUN2003	49	5	0	3
		DAY 57	17JUN2003	56	5	0	3
	E0023027	SCREEN	07MAY2003	-9	5		
		DAY 1	16MAY2003	1	5		
		DAY 8	21MAY2003	6	5	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	DAY 15		30MAY2003	15	5	0	4
		DAY 22		05JUN2003	21	5	0	4
		DAY 29		11JUN2003	27	5	0	4
		DAY 36		18JUN2003	34	5	0	3
		DAY 43		27JUN2003	43	5	0	3
		DAY 50		02JUL2003	48	5	0	4
		DAY 57		09JUL2003	55	5	0	5
	E0023030	SCREEN		16MAY2003	-18	5		
		DAY 1		03JUN2003	1	5		
		DAY 8		10JUN2003	8	5	0	3
		DAY 15		17JUN2003	15	4	-1	3
		DAY 22		24JUN2003	22	4	-1	3
		DAY 29		01JUL2003	29	4	-1	2
		DAY 36		08JUL2003	36	3	-2	1
		DAY 43		15JUL2003	43	2	-3	1
		DAY 50		21JUL2003	49	2	-3	1
		DAY 57		30JUL2003	58	2	-3	1
	E0023040	SCREEN		25JUN2003	-8	5		
		DAY 1		03JUL2003	1	5		
		DAY 8		12JUL2003	10	5	0	3
		DAY 15		17JUL2003	15	4	-1	3
		DAY 22		25JUL2003	23	4	-1	2
		DAY 36	*	05AUG2003	34	4	-1	3
		DAY 36		08AUG2003	37	4	-1	3
		DAY 43		18AUG2003	47	4	-1	2
		DAY 57	*	28AUG2003	57	4	-1	3
		DAY 57		05SEP2003	65	4	-1	3
	E0026014	SCREEN		12FEB2003	-7	4		
		DAY 1		19FEB2003	1	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	DAY 8	26FEB2003	8	3	-1	3
		DAY 15	05MAR2003	15	3	-1	2
		DAY 22	12MAR2003	22	3	-1	3
		DAY 29	19MAR2003	29	4	0	5
	E0026019	SCREEN	10MAR2003	-7	4		
		DAY 1	17MAR2003	1	4		
		DAY 8	24MAR2003	8	4	0	4
		DAY 15	31MAR2003	15	3	-1	3
		DAY 22	07APR2003	22	4	0	4
		DAY 29	14APR2003	29	4	0	3
		DAY 36	21APR2003	36	3	-1	2
		DAY 43	28APR2003	43	3	-1	3
		DAY 50	05MAY2003	50	4	0	3
		DAY 57	12MAY2003	57	3	-1	3
	E0027005	SCREEN	19DEC2002	-7	5		
		DAY 1	26DEC2002	1	6		
		DAY 8	02JAN2003	8	4	-2	3
		DAY 15	09JAN2003	15	4	-2	2
		DAY 22	16JAN2003	22	3	-3	2
		DAY 29	23JAN2003	29	4	-2	2
		DAY 36	30JAN2003	36	3	-3	2
		DAY 43	06FEB2003	43	5	-1	4
		DAY 50	12FEB2003	49	3	-3	2
		DAY 57	20FEB2003	57	3	-3	3
	E0029009	SCREEN	13JAN2003	-7	4		
		DAY 1	20JAN2003	1	5		
		DAY 8	27JAN2003	8	4	-1	3
		DAY 15	03FEB2003	15	3	-2	1
		DAY 22	11FEB2003	23	3	-2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	DAY 29	17FEB2003	29	3	-2	2
		DAY 36	24FEB2003	36	4	-1	4
		DAY 43	03MAR2003	43	3	-2	1
		DAY 50	11MAR2003	51	3	-2	1
		DAY 57	18MAR2003	58	2	-3	1
	E0029021	SCREEN	03MAR2003	-15	4		
		DAY 1	18MAR2003	1	4		
		DAY 8	25MAR2003	8	4	0	3
		DAY 15	01APR2003	15	4	0	3
		DAY 22	07APR2003	21	3	-1	2
		DAY 29	15APR2003	29	3	-1	2
		DAY 36	22APR2003	36	4	0	3
		DAY 43	29APR2003	43	2	-2	1
		DAY 50	06MAY2003	50	3	-1	2
		DAY 57	15MAY2003	59	3	-1	2
	E0029026	SCREEN	07APR2003	-7	4		
		DAY 1	14APR2003	1	4		
		DAY 8	21APR2003	8	4	0	4
		DAY 15	28APR2003	15	3	-1	2
		DAY 22	05MAY2003	22	2	-2	1
		DAY 29	12MAY2003	29	2	-2	1
		DAY 36	19MAY2003	36	1	-3	1
		DAY 43	28MAY2003	45	1	-3	1
		DAY 50	02JUN2003	50	1	-3	1
		DAY 57	10JUN2003	58	1	-3	1
	E0029030	SCREEN	13MAY2003	-14	4		
		DAY 1	27MAY2003	1	4		
		DAY 8	03JUN2003	8	4	0	3
		DAY 15	10JUN2003	15	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	DAY 22	17JUN2003	22	3	-1	2
		DAY 29	26JUN2003	31	1	-3	1
		DAY 36	02JUL2003	37	1	-3	1
		DAY 43	09JUL2003	44	1	-3	1
		DAY 50	16JUL2003	51	1	-3	1
		DAY 57	23JUL2003	58	1	-3	1
	E0031008	SCREEN	05FEB2003	-23	4		
		DAY 1	28FEB2003	1	4		
		DAY 8	07MAR2003	8	5	1	4
		DAY 15	13MAR2003	14	5	1	5
		DAY 22	21MAR2003	22	4	0	3
		DAY 29	28MAR2003	29	3	-1	2
		DAY 36	04APR2003	36	4	0	3
		DAY 43	10APR2003	42	3	-1	2
		DAY 50	17APR2003	49	3	-1	2
		DAY 57	24APR2003	56	4	0	3
	E0031020	SCREEN	14APR2003	-7	4		
		DAY 1	21APR2003	1	4		
		DAY 8	28APR2003	8	4	0	3
		DAY 15	05MAY2003	15	4	0	3
		DAY 22	13MAY2003	23	4	0	3
	E0031021	SCREEN	18APR2003	-7	5		
		DAY 1	25APR2003	1	5		
		DAY 8	02MAY2003	8	2	-3	1
		DAY 15	09MAY2003	15	2	-3	1
		DAY 22	16MAY2003	22	2	-3	1
		DAY 29	23MAY2003	29	2	-3	1
		DAY 36	29MAY2003	35	3	-2	2
		DAY 43	06JUN2003	43	4	-1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 43	*	10JUN2003	47	2	-3	1
		DAY 57		19JUN2003	56	2	-3	1
	E0031029	SCREEN		05JUN2003	-13	4		
		DAY 1		18JUN2003	1	4		
		DAY 8		23JUN2003	6	4	0	3
	E0033002	SCREEN		19DEC2002	-22	4		
		DAY 1		10JAN2003	1	4		
		DAY 8		16JAN2003	7	4	0	4
		DAY 15		24JAN2003	15	4	0	4
		DAY 22		30JAN2003	21	4	0	3
		DAY 29		06FEB2003	28	3	-1	3
		DAY 36		13FEB2003	35	3	-1	2
		DAY 43		24FEB2003	46	2	-2	2
		DAY 50		28FEB2003	50	3	-1	2
		DAY 57		07MAR2003	57	1	-3	1
	E0033006	SCREEN		15JAN2003	-8	5		
		DAY 1		23JAN2003	1	5		
		DAY 8		30JAN2003	8	5	0	4
	E0033021	SCREEN		18JUN2003	-14	4		
		DAY 1		02JUL2003	1	4		
		DAY 8		11JUL2003	10	4	0	4
		DAY 22	*	21JUL2003	20	4	0	3
		DAY 22		25JUL2003	24	3	-1	2
		DAY 29		01AUG2003	31	2	-2	2
		DAY 36		06AUG2003	36	2	-2	2
	E0035013	SCREEN		27JAN2003	-8	4		
		DAY 1		04FEB2003	1	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0035013	DAY 8	10FEB2003	7	4	0	5
	E0035015	SCREEN	03FEB2003	-8	4		
		DAY 1	11FEB2003	1	4		
		DAY 8	18FEB2003	8	4	0	4
	E0035016	SCREEN	10MAR2003	-25	4		
		DAY 1	04APR2003	1	4		
	E0035023	SCREEN	06MAY2003	-7	5		
		DAY 1	13MAY2003	1	5		
		DAY 8	20MAY2003	8	4	-1	3
		DAY 15	29MAY2003	17	4	-1	2
		DAY 22	03JUN2003	22	3	-2	2
		DAY 29	10JUN2003	29	3	-2	2
	E0039052	SCREEN	29MAY2003	-22	4		
		DAY 1	20JUN2003	1	4		
		DAY 8	27JUN2003	8	3	-1	2
		DAY 15	03JUL2003	14	2	-2	1
	E0039056	SCREEN	01JUL2003	-14	4		
		DAY 1	14JUL2003	-1	4		
	E0040003	SCREEN	09JUL2003	-10	4		
		DAY 1	18JUL2003	-1	4		
		DAY 8	25JUL2003	7	4	0	4
		DAY 15	01AUG2003	14	3	-1	3
		DAY 22	08AUG2003	21	3	-1	3
		DAY 29	15AUG2003	28	4	0	4
		DAY 36	22AUG2003	35	3	-1	3
		DAY 43	29AUG2003	42	3	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	DAY 50	05SEP2003	49	3	-1	2
		DAY 57	12SEP2003	56	3	-1	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	SCREEN	04FEB2003	-27	5		
		DAY 1	03MAR2003	1	4		
		DAY 8	11MAR2003	9	4	0	4
		DAY 15	18MAR2003	16	4	0	3
		DAY 22	25MAR2003	23	4	0	3
		DAY 29	01APR2003	30	4	0	3
		DAY 36	08APR2003	37	3	-1	2
		DAY 43	15APR2003	44	3	-1	2
		DAY 50	24APR2003	53	3	-1	2
		DAY 57	02MAY2003	61	2	-2	1
	E0002011	SCREEN	12APR2003	-17	5		
		DAY 1	29APR2003	1	4		
		DAY 8	08MAY2003	10	4	0	3
		DAY 15	15MAY2003	17	4	0	4
		DAY 22	22MAY2003	24	4	0	5
		DAY 29	29MAY2003	31	4	0	3
		DAY 36	05JUN2003	38	4	0	5
		DAY 43	12JUN2003	45	4	0	3
		DAY 50	19JUN2003	52	4	0	3
		DAY 57	25JUN2003	58	3	-1	2
	E0003010	SCREEN	27JAN2003	-7	5		
		DAY 1	03FEB2003	1	5		
		DAY 8	10FEB2003	8	2	-3	2
		DAY 22	27FEB2003	25	3	-2	5
		DAY 29	03MAR2003	29	2	-3	1
		DAY 43	20MAR2003	46	3	-2	5
		DAY 50	25MAR2003	51	1	-4	1
		DAY 57	31MAR2003	57	1	-4	1
	E0003011	SCREEN	28JAN2003	-7	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	DAY 1		04FEB2003	1	4		
		DAY 8		11FEB2003	8	3	-1	3
		DAY 15		18FEB2003	15	3	-1	3
	E0003016	SCREEN		01MAY2003	-21	5		
		DAY 1		22MAY2003	1	6		
		DAY 8		29MAY2003	8	5	-1	3
		DAY 15		05JUN2003	15	4	-2	2
		DAY 22		12JUN2003	22	4	-2	2
	E0003019	SCREEN		19JUN2003	-8	4		
		DAY 1		27JUN2003	1	4		
		DAY 8		03JUL2003	7	3	-1	3
		DAY 15		10JUL2003	14	3	-1	3
		DAY 15	*	15JUL2003	19	3	-1	3
		DAY 29		29JUL2003	33	4	0	4
		DAY 43		07AUG2003	42	4	0	4
		DAY 50		14AUG2003	49	4	0	4
		DAY 57		21AUG2003	56	4	0	4
	E0003020	SCREEN		24JUN2003	-29	5		
		DAY 1		23JUL2003	1	5		
		DAY 8		29JUL2003	7	4	-1	3
		DAY 15		06AUG2003	15	3	-2	2
		DAY 22		13AUG2003	22	4	-1	3
		DAY 29		20AUG2003	29	4	-1	3
		DAY 36		27AUG2003	36	4	-1	3
		DAY 43		03SEP2003	43	3	-2	2
		DAY 50		10SEP2003	50	3	-2	2
		DAY 57		17SEP2003	57	3	-2	2
	E0004001	SCREEN		23SEP2002	-7	5		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	DAY 1	30SEP2002	1	5		
		DAY 8	07OCT2002	8	4	-1	3
		DAY 22	21OCT2002	22	3	-2	2
		DAY 29	28OCT2002	29	2	-3	1
		DAY 36	05NOV2002	37	3	-2	2
	E0004009	SCREEN	17DEC2002	-9	4		
		DAY 1	26DEC2002	1	4		
		DAY 8	02JAN2003	8	3	-1	3
		DAY 15	08JAN2003	14	2	-2	2
		DAY 22	15JAN2003	21	1	-3	1
		DAY 29	22JAN2003	28	1	-3	1
		DAY 36	29JAN2003	35	1	-3	1
		DAY 43	05FEB2003	42	1	-3	1
		DAY 50	12FEB2003	49	1	-3	1
		DAY 57	19FEB2003	56	1	-3	1
	E0004012	SCREEN	07JAN2003	-7	5		
		DAY 1	14JAN2003	1	5		
		DAY 8	21JAN2003	8	5	0	4
		DAY 15	28JAN2003	15	2	-3	2
		DAY 22	04FEB2003	22	2	-3	1
		DAY 29	11FEB2003	29	2	-3	1
		DAY 36	18FEB2003	36	2	-3	1
		DAY 43	25FEB2003	43	2	-3	1
		DAY 50	04MAR2003	50	2	-3	1
		DAY 57	11MAR2003	57	2	-3	1
	E0004015	SCREEN	06FEB2003	-14	4		
		DAY 1	20FEB2003	1	4		
		DAY 8	25FEB2003	6	4	0	4
		DAY 15	04MAR2003	13	3	-1	2

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	DAY 22	11MAR2003	20	1	-3	1
		DAY 29	18MAR2003	27	1	-3	1
		DAY 36	25MAR2003	34	1	-3	1
		DAY 43	01APR2003	41	1	-3	1
		DAY 50	08APR2003	48	1	-3	1
		DAY 57	15APR2003	55	1	-3	1
	E0005003	SCREEN	23SEP2002	-9	5		
		DAY 1	02OCT2002	1	5		
		DAY 8	09OCT2002	8	5	0	4
		DAY 15	16OCT2002	15	3	-2	2
		DAY 22	23OCT2002	22	4	-1	3
		DAY 29	30OCT2002	29	3	-2	2
		DAY 36	06NOV2002	36	2	-3	2
		DAY 43	14NOV2002	44	2	-3	1
		DAY 50	21NOV2002	51	2	-3	2
		DAY 57	26NOV2002	56	2	-3	2
	E0005005	SCREEN	24SEP2002	-6	5		
		DAY 1	30SEP2002	1	5		
	E0005007	SCREEN	02OCT2002	-7	6		
		DAY 1	09OCT2002	1	6		
		DAY 8	16OCT2002	8	5	-1	3
		DAY 15	23OCT2002	15	6	0	4
		DAY 22	30OCT2002	22	4	-2	3
		DAY 29	06NOV2002	29	4	-2	2
		DAY 36	14NOV2002	37	3	-3	2
		DAY 43	20NOV2002	43	5	-1	3
		DAY 50	26NOV2002	49	4	-2	3
		DAY 57	04DEC2002	57	3	-3	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	SCREEN	08OCT2002	-7	5		
		DAY 1	15OCT2002	1	5		
		DAY 8	22OCT2002	8	3	-2	3
		DAY 15	29OCT2002	15	5	0	4
		DAY 22	06NOV2002	23	5	0	4
		DAY 29	13NOV2002	30	2	-3	1
		DAY 36	18NOV2002	35	2	-3	1
		DAY 43	25NOV2002	42	2	-3	1
		DAY 50	02DEC2002	49	2	-3	1
		DAY 57	11DEC2002	58	2	-3	1
	E0005009	SCREEN	09OCT2002	-20	5		
		DAY 1	29OCT2002	1	4		
	E0005010	SCREEN	14OCT2002	-7	5		
		DAY 1	21OCT2002	1	5		
		DAY 8	28OCT2002	8	5	0	2
		DAY 15	04NOV2002	15	3	-2	3
		DAY 22	13NOV2002	24	3	-2	2
		DAY 29	19NOV2002	30	2	-3	1
		DAY 36	26NOV2002	37	1	-4	1
		DAY 43	03DEC2002	44	2	-3	1
		DAY 50	09DEC2002	50	2	-3	1
		DAY 57	17DEC2002	58	1	-4	1
	E0005012	SCREEN	24OCT2002	-21	5		
		DAY 1	14NOV2002	1	5		
		DAY 8	20NOV2002	7	5	0	4
		DAY 15	26NOV2002	13	4	-1	3
		DAY 22	06DEC2002	23	2	-3	2
		DAY 29	10DEC2002	27	2	-3	2
		DAY 36	18DEC2002	35	3	-2	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0005012	DAY 36	*	23DEC2002	40	3	-2	3
		DAY 50		02JAN2003	50	3	-2	2
		DAY 57		07JAN2003	55	3	-2	2
	E0005014	SCREEN		05NOV2002	-8	4		
		DAY 1		13NOV2002	1	5		
		DAY 8		20NOV2002	8	5	0	3
		DAY 15		27NOV2002	15	3	-2	3
		DAY 22		03DEC2002	21	3	-2	2
		DAY 29		11DEC2002	29	3	-2	2
		DAY 36		17DEC2002	35	3	-2	2
		DAY 43		23DEC2002	41	3	-2	2
		DAY 50		30DEC2002	48	3	-2	3
		DAY 57		06JAN2003	55	3	-2	2
	E0005022	SCREEN		23JAN2003	-6	5		
		DAY 1		29JAN2003	1	5		
		DAY 8		04FEB2003	7	5	0	4
		DAY 15		11FEB2003	14	5	0	4
		DAY 22		21FEB2003	24	4	-1	3
		DAY 29		26FEB2003	29	2	-3	2
		DAY 36		06MAR2003	37	2	-3	1
	E0005025	SCREEN		20FEB2003	-7	5		
		DAY 1		27FEB2003	1	5		
		DAY 8		06MAR2003	8	3	-2	2
		DAY 15		14MAR2003	16	2	-3	1
		DAY 22		20MAR2003	22	1	-4	1
		DAY 29		27MAR2003	29	3	-2	3
		DAY 36		03APR2003	36	2	-3	2
	E0006019	SCREEN		26MAR2003	-12	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 1	07APR2003	1	5		
		DAY 8	14APR2003	8	5	0	4
		DAY 15	21APR2003	15	5	0	3
		DAY 22	28APR2003	22	4	-1	3
		DAY 29	05MAY2003	29	4	-1	4
		DAY 36	12MAY2003	36	4	-1	4
		DAY 43	19MAY2003	43	4	-1	4
		DAY 50	27MAY2003	51	4	-1	3
	E0007005	SCREEN	27JAN2003	-4	5		
		DAY 1	31JAN2003	1	5		
		DAY 8	07FEB2003	8	5	0	3
		DAY 15	14FEB2003	15	4	-1	3
		DAY 22	22FEB2003	23	4	-1	3
		DAY 29	03MAR2003	32	3	-2	2
		DAY 36	10MAR2003	39	4	-1	3
		DAY 43	14MAR2003	43	3	-2	2
		DAY 50	21MAR2003	50	5	0	4
		DAY 57	28MAR2003	57	4	-1	4
	E0007015	SCREEN	09JUL2003	-7	4		
		DAY 1	16JUL2003	1	4		
		DAY 8	23JUL2003	8	4	0	4
		DAY 15	01AUG2003	17	4	0	3
		DAY 22	06AUG2003	22	4	0	4
		DAY 29	13AUG2003	29	2	-2	1
		DAY 36	20AUG2003	36	4	0	3
		DAY 43	27AUG2003	43	4	0	4
		DAY 50	03SEP2003	50	4	0	3
		DAY 57	10SEP2003	57	4	0	4
	E0009001	SCREEN	29OCT2002	-14	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	DAY 1	12NOV2002	1	4		
		DAY 8	21NOV2002	10	4	0	4
		DAY 15	26NOV2002	15	4	0	4
		DAY 22	04DEC2002	23	4	0	3
		DAY 29	10DEC2002	29	4	0	3
		DAY 36	17DEC2002	36	4	0	3
		DAY 43	23DEC2002	42	4	0	3
		DAY 50	30DEC2002	49	4	0	3
	E0010002	SCREEN	14NOV2002	-11	5		
		DAY 1	25NOV2002	1	5		
		DAY 8	02DEC2002	8	5	0	4
	E0010009	SCREEN	18DEC2002	-8	4		
		DAY 1	26DEC2002	1	4		
		DAY 8	02JAN2003	8	3	-1	2
		DAY 15	09JAN2003	15	3	-1	1
		DAY 29	22JAN2003	28	3	-1	1
		DAY 36	30JAN2003	36	3	-1	1
		DAY 43	05FEB2003	42	3	-1	1
		DAY 50	13FEB2003	50	3	-1	1
		DAY 57	19FEB2003	56	3	-1	2
	E0010010	SCREEN	20DEC2002	-10	6		
		DAY 1	30DEC2002	1	5		
		DAY 8	06JAN2003	8	5	0	4
		DAY 15	13JAN2003	15	5	0	4
	E0010014	SCREEN	14JAN2003	-14	5		
		DAY 1	28JAN2003	1	5		
		DAY 8	04FEB2003	8	3	-2	2
		DAY 15	11FEB2003	15	2	-3	1

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	DAY 22	18FEB2003	22	1	-4	1
		DAY 29	25FEB2003	29	1	-4	1
		DAY 36	04MAR2003	36	1	-4	1
		DAY 43	11MAR2003	43	1	-4	1
		DAY 50	18MAR2003	50	2	-3	1
		DAY 57	25MAR2003	57	1	-4	1
	E0010017	SCREEN	05FEB2003	-20	5		
		DAY 1	25FEB2003	1	5		
		DAY 8	03MAR2003	7	5	0	4
		DAY 15	10MAR2003	14	4	-1	2
		DAY 22	18MAR2003	22	3	-2	2
		DAY 29	25MAR2003	29	2	-3	1
		DAY 36	01APR2003	36	2	-3	1
		DAY 43	08APR2003	43	2	-3	1
		DAY 50	15APR2003	50	2	-3	1
		DAY 57	22APR2003	57	1	-4	1
	E0010023	SCREEN	10APR2003	-7	5		
		DAY 1	17APR2003	1	5		
		DAY 8	24APR2003	8	4	-1	2
		DAY 15	01MAY2003	15	4	-1	3
	E0010027	SCREEN	05JUN2003	-11	4		
		DAY 1	16JUN2003	1	5		
		DAY 8	23JUN2003	8	4	-1	2
		DAY 15	01JUL2003	16	5	0	3
	E0010029	SCREEN	10JUN2003	-9	5		
		DAY 1	19JUN2003	1	5		
		DAY 8	25JUN2003	7	4	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	SCREEN	02JUN2003	-7	4		
		DAY 1	09JUN2003	1	4		
		DAY 8	16JUN2003	8	4	0	4
		DAY 15	24JUN2003	16	4	0	3
		DAY 22	01JUL2003	23	4	0	4
		DAY 29	08JUL2003	30	4	0	3
		DAY 36	15JUL2003	37	4	0	5
		DAY 43	24JUL2003	46	4	0	4
		DAY 50	31JUL2003	53	5	1	6
		DAY 57	05AUG2003	58	4	0	4
	E0013006	SCREEN	05MAR2003	-8	4		
		DAY 1	13MAR2003	1	4		
		DAY 8	24MAR2003	12	3	-1	4
	E0013012	SCREEN	29APR2003	-8	4		
		DAY 1	07MAY2003	1	4		
		DAY 8	16MAY2003	10	3	-1	3
		DAY 15	22MAY2003	16	2	-2	2
		DAY 22	30MAY2003	24	2	-2	2
		DAY 29	05JUN2003	30	2	-2	2
		DAY 36	12JUN2003	37	2	-2	1
		DAY 43	19JUN2003	44	2	-2	2
		DAY 50	25JUN2003	50	2	-2	1
		DAY 57	02JUL2003	57	1	-3	1
	E0013014	SCREEN	08MAY2003	-26	4		
		DAY 1	03JUN2003	1	4		
		DAY 8	10JUN2003	8	4	0	4
		DAY 15	19JUN2003	17	4	0	4
		DAY 29	30JUN2003	28	4	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	SCREEN	04MAR2003	-7	6		
		DAY 1	11MAR2003	1	6		
		DAY 8	18MAR2003	8	4	-2	3
		DAY 15	25MAR2003	15	3	-3	2
		DAY 22	01APR2003	22	2	-4	1
		DAY 29	08APR2003	29	2	-4	1
		DAY 36	16APR2003	37	2	-4	1
		DAY 43	23APR2003	44	3	-3	1
		DAY 50	29APR2003	50	2	-4	1
		DAY 57	06MAY2003	57	2	-4	1
	E0014007	SCREEN	25MAR2003	-7	5		
		DAY 1	01APR2003	1	5		
		DAY 8	08APR2003	8	4	-1	3
		DAY 15	15APR2003	15	5	0	4
		DAY 22	22APR2003	22	5	0	4
	E0014011	SCREEN	06MAY2003	-7	4		
		DAY 1	13MAY2003	1	4		
		DAY 8	20MAY2003	8	4	0	3
		DAY 15	27MAY2003	15	3	-1	1
		DAY 22	04JUN2003	23	3	-1	1
		DAY 29	10JUN2003	29	3	-1	1
		DAY 36	17JUN2003	36	2	-2	1
		DAY 43	26JUN2003	45	3	-1	2
		DAY 50	02JUL2003	51	1	-3	1
		DAY 57	08JUL2003	57	1	-3	1
	E0014012	SCREEN	19MAY2003	-8	6		
		DAY 1	27MAY2003	1	6		
		DAY 8	03JUN2003	8	6	0	4
		DAY 15	10JUN2003	15	6	0	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0014012	DAY 22	17JUN2003	22	5	-1	3
		DAY 29	24JUN2003	29	5	-1	3
	E0015001	SCREEN	08NOV2002	-21	6		
		DAY 1	29NOV2002	1	6		
		DAY 8	06DEC2002	8	5	-1	3
		DAY 15	13DEC2002	15	5	-1	3
		DAY 22	19DEC2002	21	5	-1	3
		DAY 29	27DEC2002	29	4	-2	2
		DAY 36	03JAN2003	36	3	-3	2
		DAY 43	09JAN2003	42	3	-3	2
		DAY 50	20JAN2003	53	2	-4	1
	E0015008	SCREEN	13DEC2002	-6	6		
		DAY 1	19DEC2002	1	6		
		DAY 8	27DEC2002	9	5	-1	3
		DAY 15	03JAN2003	16	4	-2	2
		DAY 22	10JAN2003	23	3	-3	2
		DAY 29	16JAN2003	29	3	-3	1
		DAY 36	23JAN2003	36	3	-3	1
	E0016003	SCREEN	10JAN2003	-14	3		
		DAY 1	24JAN2003	1	4		
		DAY 8	31JAN2003	8	5	1	4
		DAY 15	07FEB2003	15	5	1	5
		DAY 22	14FEB2003	22	3	-1	3
		DAY 29	21FEB2003	29	3	-1	2
		DAY 36	27FEB2003	35	3	-1	3
		DAY 43	07MAR2003	43	4	0	4
	E0016005	SCREEN	20FEB2003	-5	5		
		DAY 1	25FEB2003	1	5		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	DAY 8		04MAR2003	8	4	-1	3
		DAY 15		11MAR2003	15	4	-1	3
		DAY 22		18MAR2003	22	2	-3	2
		DAY 29		25MAR2003	29	1	-4	1
		DAY 36		01APR2003	36	1	-4	1
		DAY 43		08APR2003	43	1	-4	1
		DAY 50		17APR2003	52	1	-4	1
		DAY 57		22APR2003	57	1	-4	1
	E0018007	SCREEN		16DEC2002	-11	4		
		DAY 1		27DEC2002	1	4		
		DAY 8		31DEC2002	5	4	0	4
		DAY 15		10JAN2003	15	4	0	4
	E0019005	SCREEN		30OCT2002	-6	4		
		DAY 1		05NOV2002	1	4		
		DAY 8		12NOV2002	8	4	0	3
		DAY 15		19NOV2002	15	3	-1	2
		DAY 22		26NOV2002	22	3	-1	2
		DAY 29		05DEC2002	31	2	-2	2
		DAY 36		12DEC2002	38	1	-3	1
		DAY 43		19DEC2002	45	2	-2	2
		DAY 57	*	30DEC2002	56	3	-1	3
		DAY 57		02JAN2003	59	2	-2	2
	E0019015	SCREEN		19DEC2002	-14	5		
		DAY 1		02JAN2003	1	4		
		DAY 8		09JAN2003	8	2	-2	2
		DAY 15		16JAN2003	15	2	-2	2
		DAY 22		23JAN2003	22	2	-2	2
		DAY 29		30JAN2003	29	1	-3	1
		DAY 36		06FEB2003	36	3	-1	2

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	DAY 43		13FEB2003	43	1	-3	1
		DAY 50		20FEB2003	50	1	-3	1
		DAY 57		27FEB2003	57	1	-3	1
	E0020004	SCREEN		21NOV2002	-18	4		
		DAY 1		09DEC2002	1	4		
		DAY 8		16DEC2002	8	3	-1	3
		DAY 8	*	20DEC2002	12	3	-1	2
		DAY 22		31DEC2002	23	3	-1	3
		DAY 29		07JAN2003	30	4	0	4
		DAY 36		14JAN2003	37	4	0	5
		DAY 43		22JAN2003	45	4	0	5
	E0020010	SCREEN		28JAN2003	-8	4		
		DAY 1		05FEB2003	1	4		
		DAY 8		12FEB2003	8	4	0	3
		DAY 15		19FEB2003	15	2	-2	1
		DAY 22		26FEB2003	22	2	-2	1
		DAY 29		05MAR2003	29	4	0	4
		DAY 36		10MAR2003	34	2	-2	1
		DAY 43		17MAR2003	41	2	-2	1
		DAY 50		25MAR2003	49	1	-3	1
		DAY 57		02APR2003	57	1	-3	1
	E0020014	SCREEN		11MAR2003	-7	5		
		DAY 1		18MAR2003	1	5		
		DAY 8		25MAR2003	8	4	-1	3
		DAY 15		01APR2003	15	3	-2	2
		DAY 22		08APR2003	22	3	-2	2
		DAY 29		15APR2003	29	3	-2	2
		DAY 36		22APR2003	36	3	-2	2
		DAY 43		29APR2003	43	3	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	DAY 50	06MAY2003	50	2	-3	2
		DAY 57	12MAY2003	56	2	-3	1
	E0020021	SCREEN	09MAY2003	-10	4		
		DAY 1	19MAY2003	1	4		
		DAY 8	23MAY2003	5	3	-1	3
		DAY 15	02JUN2003	15	3	-1	3
		DAY 22	10JUN2003	23	3	-1	3
		DAY 29	16JUN2003	29	3	-1	2
		DAY 36	23JUN2003	36	4	0	3
		DAY 43	30JUN2003	43	4	0	3
		DAY 50	07JUL2003	50	4	0	3
		DAY 57	14JUL2003	57	3	-1	3
	E0020023	SCREEN	09JUN2003	-8	4		
		DAY 1	16JUN2003	-1	5		
		DAY 8	24JUN2003	8	5	0	3
		DAY 15	30JUN2003	14	5	0	3
		DAY 22	07JUL2003	21	5	0	3
		DAY 29	14JUL2003	28	4	-1	3
		DAY 36	21JUL2003	35	4	-1	1
		DAY 43	28JUL2003	42	4	-1	2
		DAY 50	04AUG2003	49	4	-1	2
		DAY 57	11AUG2003	56	3	-2	2
	E0022007	SCREEN	01NOV2002	-6	4		
		DAY 1	07NOV2002	1	4		
		DAY 8	14NOV2002	8	4	0	3
		DAY 15	22NOV2002	16	3	-1	3
		DAY 22	02DEC2002	26	3	-1	3
		DAY 29	09DEC2002	33	3	-1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	SCREEN		14NOV2002	-7	4		
		DAY 1		21NOV2002	1	4		
		DAY 8		29NOV2002	9	3	-1	3
		DAY 15		06DEC2002	16	1	-3	1
		DAY 22		12DEC2002	22	1	-3	1
		DAY 36		26DEC2002	36	1	-3	1
		DAY 43		02JAN2003	43	1	-3	1
		DAY 50		09JAN2003	50	1	-3	1
		DAY 57		16JAN2003	57	1	-3	1
	E0022012	SCREEN		21NOV2002	-14	4		
		DAY 1		05DEC2002	1	4		
		DAY 8		12DEC2002	8	2	-2	2
		DAY 15		19DEC2002	15	1	-3	1
		DAY 15	*	23DEC2002	19	1	-3	1
		DAY 29		02JAN2003	29	1	-3	1
		DAY 36		09JAN2003	36	1	-3	1
		DAY 43		16JAN2003	43	1	-3	1
		DAY 50		23JAN2003	50	1	-3	1
		DAY 57		30JAN2003	57	1	-3	1
	E0022019	SCREEN		04DEC2002	-7	4		
		DAY 1		11DEC2002	1	4		
		DAY 8		19DEC2002	9	3	-1	2
		DAY 15		26DEC2002	16	2	-2	2
		DAY 22		03JAN2003	24	1	-3	1
		DAY 29		09JAN2003	30	1	-3	1
		DAY 36		17JAN2003	38	1	-3	1
		DAY 43		24JAN2003	45	1	-3	1
		DAY 50		30JAN2003	51	1	-3	1
		DAY 57		06FEB2003	58	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	SCREEN	08JAN2003	-20	5		
		DAY 1	28JAN2003	1	5		
		DAY 8	04FEB2003	8	5	0	4
	E0022033	SCREEN	11FEB2003	-7	4		
		DAY 1	18FEB2003	1	4		
		DAY 8	25FEB2003	8	4	0	3
		DAY 15	04MAR2003	15	3	-1	2
		DAY 22	11MAR2003	22	1	-3	1
		DAY 29	18MAR2003	29	1	-3	1
		DAY 36	27MAR2003	38	1	-3	1
		DAY 43	01APR2003	43	1	-3	1
		DAY 50	08APR2003	50	1	-3	1
		DAY 57	15APR2003	57	1	-3	1
	E0022034	SCREEN	11FEB2003	-7	4		
		DAY 1	18FEB2003	1	4		
		DAY 8	25FEB2003	8	3	-1	3
		DAY 15	04MAR2003	15	3	-1	2
		DAY 22	11MAR2003	22	4	0	4
		DAY 29	18MAR2003	29	3	-1	3
		DAY 36	25MAR2003	36	2	-2	2
		DAY 43	01APR2003	43	2	-2	1
		DAY 50	07APR2003	49	2	-2	1
		DAY 57	15APR2003	57	2	-2	1
	E0022038	SCREEN	20FEB2003	-8	4		
		DAY 1	28FEB2003	1	4		
		DAY 8	07MAR2003	8	4	0	3
		DAY 15	14MAR2003	15	4	0	3
		DAY 22	21MAR2003	22	4	0	3
		DAY 29	28MAR2003	29	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	DAY 36	04APR2003	36	3	-1	3
		DAY 43	11APR2003	43	3	-1	3
	E0022039	SCREEN	27FEB2003	-7	4		
		DAY 1	06MAR2003	1	4		
		DAY 8	13MAR2003	8	4	0	4
		DAY 15	20MAR2003	15	3	-1	3
		DAY 22	27MAR2003	22	3	-1	2
		DAY 29	04APR2003	30	1	-3	1
		DAY 36	10APR2003	36	1	-3	1
		DAY 43	18APR2003	44	1	-3	1
		DAY 50	24APR2003	50	1	-3	1
		DAY 57	01MAY2003	57	1	-3	1
	E0022046	SCREEN	13MAR2003	-7	5		
		DAY 1	20MAR2003	1	5		
		DAY 8	27MAR2003	8	4	-1	3
		DAY 15	04APR2003	16	3	-2	2
		DAY 22	11APR2003	23	2	-3	2
		DAY 29	18APR2003	30	3	-2	3
		DAY 36	24APR2003	36	3	-2	3
		DAY 43	02MAY2003	44	3	-2	3
		DAY 50	12MAY2003	54	3	-2	3
		DAY 57	16MAY2003	58	3	-2	3
	E0022048	SCREEN	25MAR2003	-7	4		
		DAY 1	01APR2003	1	4		
		DAY 8	08APR2003	8	2	-2	2
		DAY 15	15APR2003	15	2	-2	2
		DAY 22	24APR2003	24	1	-3	1
		DAY 29	02MAY2003	32	1	-3	1
		DAY 36	06MAY2003	36	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022048	DAY 43		13MAY2003	43	1	-3	1
		DAY 50		23MAY2003	53	1	-3	1
	E0022051	SCREEN		31MAR2003	-7	5		
		DAY 1		07APR2003	1	5		
		DAY 8		14APR2003	8	4	-1	3
		DAY 15		21APR2003	15	3	-2	3
		DAY 22		28APR2003	22	2	-3	2
		DAY 29		05MAY2003	29	1	-4	1
		DAY 36		12MAY2003	36	4	-1	3
		DAY 43		19MAY2003	43	3	-2	2
		DAY 50		28MAY2003	52	1	-4	1
		DAY 57		02JUN2003	57	1	-4	1
	E0022053	SCREEN		04APR2003	-7	4		
		DAY 1		11APR2003	1	4		
	E0022058	SCREEN		11APR2003	-10	4		
		DAY 1		21APR2003	1	4		
		DAY 8		28APR2003	8	3	-1	2
		DAY 15		05MAY2003	15	2	-2	1
		DAY 22		12MAY2003	22	1	-3	1
		DAY 29		19MAY2003	29	1	-3	1
		DAY 29	*	22MAY2003	32	2	-2	2
	E0022061	SCREEN		24APR2003	-6	4		
		DAY 1		30APR2003	1	4		
		DAY 8		07MAY2003	8	3	-1	2
		DAY 15		14MAY2003	15	2	-2	1
		DAY 22		22MAY2003	23	1	-3	1
		DAY 29		28MAY2003	29	1	-3	1
		DAY 36		04JUN2003	36	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 50		18JUN2003	50	1	-3	1
		DAY 57		26JUN2003	58	1	-3	1
	E0022062	SCREEN		25APR2003	-10	4		
		DAY 1		05MAY2003	1	4		
		DAY 8		12MAY2003	8	4	0	4
		DAY 15		19MAY2003	15	4	0	4
		DAY 15	*	23MAY2003	19	4	0	4
	E0022068	SCREEN		14MAY2003	-9	4		
		DAY 1		22MAY2003	-1	4		
		DAY 8		29MAY2003	7	4	0	4
		DAY 15		05JUN2003	14	4	0	4
	E0022069	SCREEN		03JUN2003	-7	5		
		DAY 1		10JUN2003	1	5		
		DAY 8		17JUN2003	8	3	-2	3
		DAY 15		24JUN2003	15	3	-2	3
		DAY 22		01JUL2003	22	2	-3	1
		DAY 29		08JUL2003	29	2	-3	1
		DAY 36		15JUL2003	36	1	-4	1
		DAY 43		22JUL2003	43	1	-4	1
		DAY 50		29JUL2003	50	1	-4	1
		DAY 57		05AUG2003	57	1	-4	1
	E0022071	SCREEN		16JUN2003	-14	5		
		DAY 1		30JUN2003	1	5		
		DAY 8		07JUL2003	8	5	0	4
		DAY 15		14JUL2003	15	5	0	4
		DAY 22		21JUL2003	22	5	0	4
		DAY 29		28JUL2003	29	5	0	4
		DAY 36		04AUG2003	36	5	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 43	11AUG2003	43	5	0	4
		DAY 50	18AUG2003	50	4	-1	3
		DAY 57	25AUG2003	57	5	0	4
	E0023003	SCREEN	12DEC2002	-5	5		
		DAY 1	17DEC2002	1	5		
		DAY 8	23DEC2002	7	5	0	5
		DAY 15	30DEC2002	14	5	0	3
		DAY 22	07JAN2003	22	5	0	5
		DAY 29	16JAN2003	31	4	-1	3
		DAY 36	21JAN2003	36	3	-2	3
		DAY 43	28JAN2003	43	3	-2	3
		DAY 50	06FEB2003	52	3	-2	3
		DAY 57	11FEB2003	57	3	-2	3
	E0023006	SCREEN	10DEC2002	-7	5		
		DAY 1	17DEC2002	1	5		
		DAY 8	23DEC2002	7	6	1	6
		DAY 15	02JAN2003	17	4	-1	2
		DAY 22	07JAN2003	22	3	-2	2
		DAY 29	16JAN2003	31	2	-3	2
		DAY 36	21JAN2003	36	2	-3	5
		DAY 43	28JAN2003	43	2	-3	5
		DAY 50	04FEB2003	50	2	-3	3
		DAY 57	11FEB2003	57	2	-3	3
	E0023010	SCREEN	28JAN2003	-7	5		
		DAY 1	04FEB2003	1	6		
		DAY 8	11FEB2003	8	5	-1	2
		DAY 15	18FEB2003	15	5	-1	3
		DAY 22	25FEB2003	22	5	-1	4
		DAY 29	04MAR2003	29	5	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	DAY 36	11MAR2003	36	4	-2	3
		DAY 43	18MAR2003	43	4	-2	3
		DAY 50	25MAR2003	50	4	-2	3
		DAY 57	31MAR2003	56	3	-3	3
	E0023025	SCREEN	01MAY2003	-14	5		
		DAY 1	15MAY2003	1	5		
		DAY 8	22MAY2003	8	5	0	4
		DAY 15	29MAY2003	15	5	0	4
		DAY 22	05JUN2003	22	4	-1	4
		DAY 29	12JUN2003	29	4	-1	2
		DAY 36	19JUN2003	36	4	-1	2
		DAY 43	27JUN2003	44	4	-1	2
		DAY 50	03JUL2003	50	4	-1	2
		DAY 57	10JUL2003	57	4	-1	2
	E0023039	SCREEN	24JUN2003	-7	5		
		DAY 1	01JUL2003	1	5		
		DAY 8	08JUL2003	8	5	0	2
		DAY 15	15JUL2003	15	4	-1	2
		DAY 22	22JUL2003	22	3	-2	2
		DAY 29	29JUL2003	29	3	-2	2
		DAY 36	05AUG2003	36	3	-2	2
		DAY 43	12AUG2003	43	3	-2	1
		DAY 50	19AUG2003	50	3	-2	1
		DAY 57	26AUG2003	57	3	-2	1
	E0026002	SCREEN	05NOV2002	-7	5		
		DAY 1	12NOV2002	1	5		
		DAY 8	19NOV2002	8	5	0	4
		DAY 15	26NOV2002	15	3	-2	2
		DAY 22	03DEC2002	22	3	-2	2

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 29	11DEC2002	30	3	-2	2
		DAY 36	18DEC2002	37	3	-2	2
		DAY 43	26DEC2002	45	2	-3	1
		DAY 50	02JAN2003	52	5	0	4
		DAY 57	09JAN2003	59	3	-2	2
	E0026007	SCREEN	06JAN2003	-10	4		
		DAY 1	16JAN2003	1	5		
		DAY 8	23JAN2003	8	3	-2	3
		DAY 15	30JAN2003	15	3	-2	2
		DAY 22	06FEB2003	22	2	-3	1
		DAY 29	13FEB2003	29	2	-3	1
		DAY 36	19FEB2003	35	2	-3	1
		DAY 43	26FEB2003	42	1	-4	1
		DAY 50	05MAR2003	49	1	-4	1
		DAY 57	12MAR2003	56	1	-4	1
	E0026013	SCREEN	05FEB2003	-8	5		
		DAY 1	13FEB2003	1	5		
		DAY 8	20FEB2003	8	5	0	3
		DAY 15	27FEB2003	15	5	0	3
		DAY 22	06MAR2003	22	5	0	4
		DAY 29	13MAR2003	29	4	-1	3
		DAY 36	20MAR2003	36	5	0	4
		DAY 43	27MAR2003	43	3	-2	2
		DAY 50	03APR2003	50	2	-3	3
	E0028007	SCREEN	01OCT2002	-3	4		
		DAY 1	04OCT2002	1	4		
		DAY 8	11OCT2002	8	4	0	3
		DAY 15	16OCT2002	13	4	0	3
		DAY 22	23OCT2002	20	3	-1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	DAY 29	31OCT2002	28	3	-1	2
		DAY 36	07NOV2002	35	3	-1	2
		DAY 43	14NOV2002	42	4	0	4
	E0028023	SCREEN	14JAN2003	-7	4		
		DAY 1	21JAN2003	1	4		
		DAY 8	30JAN2003	10	4	0	4
		DAY 15	04FEB2003	15	4	0	4
		DAY 22	11FEB2003	22	4	0	3
		DAY 29	17FEB2003	28	4	0	4
		DAY 36	27FEB2003	38	3	-1	3
		DAY 43	04MAR2003	43	2	-2	2
	E0028025	SCREEN	08JAN2003	-5	4		
		DAY 1	13JAN2003	1	4		
		DAY 8	17JAN2003	5	4	0	4
		DAY 15	27JAN2003	15	4	0	4
	E0028033	SCREEN	18MAR2003	-9	4		
		DAY 1	27MAR2003	1	4		
		DAY 8	03APR2003	8	4	0	4
		DAY 15	10APR2003	15	4	0	4
		DAY 22	17APR2003	22	2	-2	1
		DAY 29	24APR2003	29	3	-1	1
		DAY 36	01MAY2003	36	3	-1	2
		DAY 43	08MAY2003	43	3	-1	3
		DAY 50	15MAY2003	50	2	-2	2
		DAY 57	22MAY2003	57	3	-1	2
	E0028035	SCREEN	27MAR2003	-7	4		
		DAY 1	03APR2003	1	4		
		DAY 8	10APR2003	8	4	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	DAY 15		17APR2003	15	4	0	4
		DAY 22		24APR2003	22	4	0	4
		DAY 29		01MAY2003	29	4	0	3
		DAY 36		08MAY2003	36	3	-1	3
		DAY 43		15MAY2003	43	3	-1	3
		DAY 50		22MAY2003	50	3	-1	3
		DAY 57		29MAY2003	57	3	-1	3
	E0028037	SCREEN		09JUN2003	-4	4		
		DAY 1		12JUN2003	-1	4		
		DAY 8		20JUN2003	8	3	-1	2
		DAY 15		25JUN2003	13	3	-1	2
		DAY 15	*	01JUL2003	19	2	-2	1
		DAY 22		08JUL2003	26	2	-2	1
		DAY 36		16JUL2003	34	2	-2	1
		DAY 43		23JUL2003	41	2	-2	1
		DAY 50		30JUL2003	48	2	-2	1
		DAY 57		08AUG2003	57	2	-2	1
	E0028039	SCREEN		02MAY2003	-7	4		
		DAY 1		08MAY2003	-1	4		
		DAY 8		16MAY2003	8	4	0	4
		DAY 15		22MAY2003	14	4	0	4
		DAY 22		29MAY2003	21	4	0	2
		DAY 29		05JUN2003	28	4	0	2
	E0028046	SCREEN		17JUN2003	-8	4		
		DAY 1		25JUN2003	1	4		
	E0028048	SCREEN		11JUL2003	-6	4		
		DAY 1		17JUL2003	1	4		
		DAY 8		24JUL2003	8	4	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	DAY 15	31JUL2003	15	4	0	4
		DAY 22	06AUG2003	21	4	0	3
		DAY 29	14AUG2003	29	4	0	3
		DAY 36	21AUG2003	36	4	0	4
		DAY 43	29AUG2003	44	3	-1	3
		DAY 57	09SEP2003	55	4	0	4
	E0029008	SCREEN	09DEC2002	-7	4		
		DAY 1	16DEC2002	1	4		
		DAY 8	23DEC2002	8	4	0	4
	E0029011	SCREEN	14JAN2003	-8	4		
		DAY 1	21JAN2003	-1	4		
		DAY 8	28JAN2003	7	4	0	3
		DAY 15	04FEB2003	14	4	0	3
		DAY 22	13FEB2003	23	4	0	3
	E0029012	SCREEN	04FEB2003	-7	5		
		DAY 1	11FEB2003	1	6		
		DAY 8	19FEB2003	9	5	-1	3
		DAY 15	26FEB2003	16	5	-1	3
		DAY 22	03MAR2003	21	5	-1	3
		DAY 29	11MAR2003	29	6	0	4
		DAY 36	18MAR2003	36	6	0	5
	E0029015	SCREEN	11FEB2003	-13	5		
		DAY 1	24FEB2003	1	5		
		DAY 8	03MAR2003	8	4	-1	3
		DAY 15	11MAR2003	16	5	0	4
	E0029018	SCREEN	26FEB2003	-8	4		
		DAY 1	06MAR2003	1	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	SCREEN	14FEB2003	-7	5		
		DAY 1	21FEB2003	1	5		
		DAY 8	28FEB2003	8	3	-2	3
		DAY 15	07MAR2003	15	3	-2	3
		DAY 22	14MAR2003	22	3	-2	3
		DAY 29	21MAR2003	29	3	-2	2
		DAY 36	27MAR2003	35	2	-3	2
		DAY 43	04APR2003	43	2	-3	2
		DAY 50	11APR2003	50	2	-3	1
		DAY 57	22APR2003	61	2	-3	1
	E0030020	SCREEN	13MAY2003	-16	5		
		DAY 1	29MAY2003	1	5		
		DAY 8	05JUN2003	8	4	-1	3
		DAY 15	12JUN2003	15	2	-3	1
		DAY 22	17JUN2003	20	2	-3	1
		DAY 29	24JUN2003	27	2	-3	1
	E0030024	SCREEN	17JUN2003	-24	5		
		DAY 1	11JUL2003	1	5		
		DAY 8	18JUL2003	8	4	-1	3
	E0030025	SCREEN	24JUN2003	-17	5		
		DAY 1	11JUL2003	1	5		
		DAY 8	18JUL2003	8	5	0	4
		DAY 15	25JUL2003	15	3	-2	2
		DAY 22	31JUL2003	21	3	-2	2
		DAY 29	11AUG2003	32	3	-2	2
		DAY 36	19AUG2003	40	5	0	3
	E0031027	SCREEN	27MAY2003	-7	4		
		DAY 1	03JUN2003	1	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0031027	DAY 8	11JUN2003	9	4	0	3
		DAY 15	17JUN2003	15	4	0	3
		DAY 22	24JUN2003	22	3	-1	3
		DAY 29	01JUL2003	29	3	-1	3
		DAY 36	09JUL2003	37	3	-1	2
		DAY 43	15JUL2003	43	2	-2	1
		DAY 50	22JUL2003	50	2	-2	1
		DAY 57	29JUL2003	57	1	-3	1
	E0031030	SCREEN	17JUN2003	-7	4		
		DAY 1	24JUN2003	1	4		
		DAY 8	01JUL2003	8	3	-1	2
		DAY 15	08JUL2003	15	3	-1	2
		DAY 22	16JUL2003	23	3	-1	2
		DAY 29	23JUL2003	30	2	-2	1
		DAY 36	31JUL2003	38	2	-2	1
		DAY 43	08AUG2003	46	2	-2	1
		DAY 50	14AUG2003	52	3	-1	3
		DAY 57	21AUG2003	59	4	0	4
	E0033012	SCREEN	05FEB2003	-5	5		
		DAY 1	10FEB2003	1	5		
	E0034001	SCREEN	13MAR2003	-7	5		
		DAY 1	20MAR2003	1	5		
		DAY 8	27MAR2003	8	5	0	4
		DAY 15	03APR2003	15	3	-2	2
		DAY 22	10APR2003	22	3	-2	2
		DAY 29	17APR2003	29	3	-2	2
		DAY 36	24APR2003	36	3	-2	2
		DAY 43	01MAY2003	43	3	-2	2
		DAY 50	08MAY2003	50	3	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	DAY 57		15MAY2003	57	2	-3	1
	E0034004	SCREEN		11APR2003	-10	5		
		DAY 1		21APR2003	1	5		
		DAY 8		30APR2003	10	4	-1	3
		DAY 15		05MAY2003	15	3	-2	2
		DAY 22		13MAY2003	23	2	-3	1
		DAY 29		19MAY2003	29	1	-4	1
		DAY 29	*	23MAY2003	33	1	-4	1
		DAY 43		02JUN2003	43	1	-4	1
		DAY 50		09JUN2003	50	1	-4	1
		DAY 57		16JUN2003	57	1	-4	1
	E0035001	SCREEN		12NOV2002	-8	3		
		DAY 1		20NOV2002	1	4		
		DAY 8		27NOV2002	8	4	0	3
		DAY 15		03DEC2002	14	3	-1	3
		DAY 22		12DEC2002	23	3	-1	2
		DAY 29		18DEC2002	29	3	-1	2
		DAY 36		23DEC2002	34	3	-1	2
		DAY 43		30DEC2002	41	3	-1	2
		DAY 50		07JAN2003	49	2	-2	1
		DAY 57		14JAN2003	56	2	-2	1
	E0035006	SCREEN		03DEC2002	-9	3		
		DAY 1		12DEC2002	1	4		
		DAY 8		19DEC2002	8	4	0	4
		DAY 15		26DEC2002	15	4	0	4
		DAY 22		02JAN2003	22	4	0	4
		DAY 29		09JAN2003	29	4	0	3
		DAY 36		16JAN2003	36	4	0	5
		DAY 43		24JAN2003	44	4	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 50	30JAN2003	50	4	0	4
		DAY 57	06FEB2003	57	4	0	4
	E0035021	SCREEN	18APR2003	-7	4		
		DAY 1	25APR2003	1	4		
		DAY 8	01MAY2003	7	3	-1	2
		DAY 15	09MAY2003	15	3	-1	2
		DAY 22	15MAY2003	21	3	-1	2
		DAY 29	23MAY2003	29	2	-2	1
		DAY 36	30MAY2003	36	2	-2	1
		DAY 43	09JUN2003	46	2	-2	1
		DAY 50	13JUN2003	50	2	-2	1
		DAY 57	20JUN2003	57	1	-3	1
	E0036002	SCREEN	10JUN2003	-7	5		
		DAY 1	17JUN2003	1	5		
		DAY 8	24JUN2003	8	4	-1	3
		DAY 15	30JUN2003	14	4	-1	2
		DAY 22	08JUL2003	22	4	-1	3
		DAY 29	14JUL2003	28	4	-1	6
	E0036006	SCREEN	24JUN2003	-9	5		
		DAY 1	03JUL2003	1	5		
		DAY 8	10JUL2003	8	3	-2	2
		DAY 15	18JUL2003	16	2	-3	2
		DAY 22	25JUL2003	23	2	-3	1
		DAY 29	31JUL2003	29	1	-4	1
		DAY 36	07AUG2003	36	1	-4	1
		DAY 43	13AUG2003	42	1	-4	1
		DAY 50	20AUG2003	49	1	-4	1
		DAY 57	27AUG2003	56	1	-4	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	SCREEN	26JUN2003	-7	5		
		DAY 1	03JUL2003	1	5		
		DAY 8	08JUL2003	6	5	0	3
		DAY 15	18JUL2003	16	2	-3	1
	E0037009	SCREEN	09MAY2003	-7	4		
		DAY 1	16MAY2003	1	4		
		DAY 8	23MAY2003	8	4	0	4
		DAY 15	29MAY2003	14	4	0	3
		DAY 22	05JUN2003	21	4	0	3
		DAY 29	12JUN2003	28	4	0	3
		DAY 36	19JUN2003	35	4	0	3
		DAY 43	26JUN2003	42	4	0	3
		DAY 50	03JUL2003	49	4	0	3
		DAY 57	10JUL2003	56	4	0	3
	E0039011	SCREEN	16DEC2002	-17	4		
		DAY 1	02JAN2003	1	5		
		DAY 8	09JAN2003	8	3	-2	3
		DAY 15	16JAN2003	15	4	-1	3
		DAY 22	23JAN2003	22	3	-2	3
		DAY 29	03FEB2003	33	1	-4	1
		DAY 36	06FEB2003	36	1	-4	1
		DAY 43	13FEB2003	43	2	-3	1
		DAY 50	19FEB2003	49	2	-3	1
	E0039018	SCREEN	14JAN2003	-9	4		
		DAY 1	23JAN2003	1	5		
		DAY 8	30JAN2003	8	3	-2	3
		DAY 15	06FEB2003	15	4	-1	3
		DAY 22	13FEB2003	22	2	-3	2
		DAY 29	20FEB2003	29	2	-3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	SCREEN	26FEB2003	-9	4		
		DAY 1	07MAR2003	1	4		
		DAY 8	14MAR2003	8	2	-2	2
		DAY 15	19MAR2003	13	2	-2	2
		DAY 22	28MAR2003	22	1	-3	1
		DAY 29	04APR2003	29	1	-3	1
		DAY 36	11APR2003	36	2	-2	1
		DAY 43	18APR2003	43	2	-2	1
		DAY 50	25APR2003	50	1	-3	1
		DAY 57	01MAY2003	56	1	-3	1
	E0039028	SCREEN	03MAR2003	-21	4		
		DAY 1	24MAR2003	1	4		
		DAY 8	31MAR2003	8	3	-1	2
		DAY 15	07APR2003	15	3	-1	2
		DAY 22	14APR2003	22	2	-2	1
		DAY 29	21APR2003	29	4	0	3
		DAY 36	28APR2003	36	3	-1	2
		DAY 43	05MAY2003	43	2	-2	1
	E0039032	SCREEN	07MAR2003	-7	4		
		DAY 1	14MAR2003	1	5		
		DAY 8	19MAR2003	6	3	-2	2
	E0039034	SCREEN	12MAR2003	-7	4		
		DAY 1	19MAR2003	1	4		
		DAY 8	26MAR2003	8	2	-2	1
		DAY 15	02APR2003	15	2	-2	1
		DAY 22	09APR2003	22	1	-3	1
		DAY 29	16APR2003	29	1	-3	1
		DAY 36	24APR2003	37	1	-3	1
		DAY 43	30APR2003	43	1	-3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	DAY 50	09MAY2003	52	1	-3	1
		DAY 57	14MAY2003	57	1	-3	1
	E0039042	SCREEN	24APR2003	-13	4		
		DAY 1	07MAY2003	1	4		
		DAY 8	14MAY2003	8	3	-1	2
		DAY 15	21MAY2003	15	2	-2	2
		DAY 22	28MAY2003	22	1	-3	1
		DAY 29	05JUN2003	30	1	-3	1
		DAY 36	11JUN2003	36	1	-3	1
		DAY 43	18JUN2003	43	2	-2	1
		DAY 50	25JUN2003	50	2	-2	1
		DAY 57	02JUL2003	57	1	-3	1
	E0041004	SCREEN	22JAN2003	-8	4		
		DAY 1	30JAN2003	1	4		
		DAY 8	10FEB2003	12	3	-1	2
		DAY 15	14FEB2003	16	1	-3	1
		DAY 22	20FEB2003	22	1	-3	1
		DAY 29	27FEB2003	29	3	-1	2
		DAY 36	07MAR2003	37	1	-3	1
		DAY 43	14MAR2003	44	1	-3	1
		DAY 50	21MAR2003	51	1	-3	1
		DAY 57	31MAR2003	61	1	-3	1
	E0041009	SCREEN	22APR2003	-9	4		
		DAY 1	01MAY2003	1	4		
		DAY 8	08MAY2003	8	4	0	3
		DAY 15	15MAY2003	15	4	0	3
		DAY 22	22MAY2003	22	2	-2	1
		DAY 36	03JUN2003	34	4	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	SCREEN	02JUL2003	-7	4		
		DAY 1	09JUL2003	1	4		
		DAY 8	15JUL2003	7	3	-1	2
		DAY 15	22JUL2003	14	2	-2	1
		DAY 22	29JUL2003	21	2	-2	2
		DAY 29	05AUG2003	28	2	-2	2
		DAY 36	12AUG2003	35	2	-2	2
		DAY 43	19AUG2003	42	2	-2	2
		DAY 50	26AUG2003	49	2	-2	2
		DAY 57	02SEP2003	56	2	-2	1

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	SCREEN	23JUN2003	-18	5		
		DAY 1	11JUL2003	1	5		
		DAY 8	18JUL2003	8	5	0	4
	E0003002	SCREEN	22OCT2002	-7	6		
		DAY 1	29OCT2002	1	5		
		DAY 8	05NOV2002	8	3	-2	2
		DAY 15	14NOV2002	17	3	-2	2
		DAY 22	19NOV2002	22	3	-2	2
		DAY 29	26NOV2002	29	2	-3	1
		DAY 36	03DEC2002	36	1	-4	1
		DAY 43	10DEC2002	43	1	-4	1
		DAY 50	17DEC2002	50	1	-4	1
		DAY 57	23DEC2002	56	1	-4	1
	E0005031	SCREEN	26MAR2003	-7	5		
		DAY 1	02APR2003	1	4		
		DAY 8	09APR2003	8	3	-1	3
		DAY 15	16APR2003	15	2	-2	2
		DAY 29	01MAY2003	30	3	-1	3
		DAY 36	07MAY2003	36	2	-2	2
		DAY 43	14MAY2003	43	2	-2	2
	E0005033	SCREEN	08APR2003	-8	5		
		DAY 1	15APR2003	-1	5		
		DAY 8	22APR2003	7	5	0	4
		DAY 15	30APR2003	15	5	0	4
		DAY 22	06MAY2003	21	5	0	4
	E0005038	SCREEN	05MAY2003	-9	5		
		DAY 1	14MAY2003	1	5		
		DAY 8	22MAY2003	9	5	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0005038	DAY 15		28MAY2003	15	5	0	4
		DAY 22		05JUN2003	23	5	0	4
	E0007009	SCREEN		09APR2003	-8	4		
		DAY 1		17APR2003	1	4		
		DAY 8		24APR2003	8	4	0	4
		DAY 8	*	28APR2003	12	4	0	4
	E0009010	SCREEN		27FEB2003	-14	5		
		DAY 1		13MAR2003	1	5		
		DAY 8		20MAR2003	8	4	-1	3
		DAY 15		26MAR2003	14	4	-1	3
		DAY 22		02APR2003	21	4	-1	3
	E0009011	SCREEN		28APR2003	-8	4		
		DAY 1		06MAY2003	1	4		
		DAY 8		12MAY2003	7	3	-1	3
		DAY 15		19MAY2003	14	3	-1	3
		DAY 22		27MAY2003	22	3	-1	2
		DAY 29		03JUN2003	29	2	-2	1
		DAY 36		10JUN2003	36	1	-3	1
		DAY 43		17JUN2003	43	3	-1	3
		DAY 50		24JUN2003	50	1	-3	1
		DAY 57		03JUL2003	59	2	-2	2
	E0010005	SCREEN		10DEC2002	-8	4		
		DAY 1		18DEC2002	1	5		
	E0011016	SCREEN		14APR2003	-7	4		
		DAY 1		21APR2003	1	4		
		DAY 8		28APR2003	8	4	0	4
		DAY 15		05MAY2003	15	4	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	DAY 22		12MAY2003	22	4	0	3
		DAY 29		19MAY2003	29	4	0	3
		DAY 36		27MAY2003	37	4	0	4
		DAY 43		02JUN2003	43	4	0	3
		DAY 50		09JUN2003	50	4	0	3
		DAY 57		16JUN2003	57	3	-1	2
	E0011020	SCREEN		01MAY2003	-7	4		
		DAY 1		08MAY2003	1	4		
		DAY 8		15MAY2003	8	4	0	4
	E0018002	SCREEN		13NOV2002	-16	4		
		DAY 1		29NOV2002	1	4		
		DAY 8		04DEC2002	6	4	0	4
		DAY 15		11DEC2002	13	3	-1	2
		DAY 22		18DEC2002	20	3	-1	2
		DAY 22	*	24DEC2002	26	4	0	3
		DAY 29		30DEC2002	32	3	-1	3
		DAY 43		08JAN2003	41	3	-1	3
		DAY 50		15JAN2003	48	3	-1	3
		DAY 57		22JAN2003	55	3	-1	3
	E0018003	SCREEN		19NOV2002	-7	4		
		DAY 1		26NOV2002	1	4		
		DAY 8		03DEC2002	8	4	0	4
		DAY 15		10DEC2002	15	4	0	4
	E0018013	SCREEN		17JAN2003	-7	4		
		DAY 1		24JAN2003	1	4		
		DAY 8		31JAN2003	8	3	-1	3
	E0019002	SCREEN		29OCT2002	-14	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019002	DAY 1	12NOV2002	1	4		
		DAY 8	19NOV2002	8	3	-1	2
	E0019008	SCREEN	06NOV2002	-15	4		
		DAY 1	21NOV2002	1	4		
		DAY 8	27NOV2002	7	4	0	3
		DAY 15	05DEC2002	15	3	-1	3
		DAY 22	12DEC2002	22	2	-2	2
		DAY 29	19DEC2002	29	2	-2	1
	E0019009	SCREEN	06NOV2002	-8	4		
		DAY 1	14NOV2002	1	4		
		DAY 8	21NOV2002	8	3	-1	3
		DAY 15	27NOV2002	14	4	0	4
		DAY 22	05DEC2002	22	4	0	3
		DAY 29	10DEC2002	27	4	0	3
	E0019016	SCREEN	30DEC2002	-7	4		
		DAY 1	06JAN2003	1	4		
		DAY 8	13JAN2003	8	4	0	3
		DAY 15	20JAN2003	15	3	-1	3
		DAY 22	27JAN2003	22	3	-1	2
		DAY 29	03FEB2003	29	2	-2	2
		DAY 36	10FEB2003	36	2	-2	2
		DAY 43	17FEB2003	43	2	-2	2
		DAY 50	27FEB2003	53	2	-2	2
		DAY 57	03MAR2003	57	1	-3	1
	E0019020	SCREEN	16JAN2003	-7	4		
		DAY 1	23JAN2003	1	4		
		DAY 8	30JAN2003	8	4	0	4
		DAY 15	06FEB2003	15	3	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	DAY 22	13FEB2003	22	3	-1	2
		DAY 29	20FEB2003	29	3	-1	2
		DAY 36	27FEB2003	36	3	-1	3
		DAY 43	06MAR2003	43	3	-1	2
		DAY 50	13MAR2003	50	2	-2	2
		DAY 57	27MAR2003	64	5	1	5
	E0019021	SCREEN	16JAN2003	-14	4		
		DAY 1	30JAN2003	1	4		
		DAY 8	06FEB2003	8	3	-1	3
		DAY 29	03MAR2003	33	4	0	4
	E0019024	SCREEN	23JAN2003	-7	4		
		DAY 1	30JAN2003	1	4		
		DAY 8	06FEB2003	8	3	-1	3
	E0019031	SCREEN	06MAR2003	-7	5		
		DAY 1	13MAR2003	1	5		
		DAY 15	25MAR2003	13	3	-2	3
	E0019035	SCREEN	11MAR2003	-7	4		
		DAY 1	18MAR2003	1	4		
		DAY 8	27MAR2003	10	4	0	3
		DAY 15	03APR2003	17	4	0	3
		DAY 22	10APR2003	24	4	0	3
		DAY 29	17APR2003	31	5	1	5
	E0019040	SCREEN	08MAY2003	-12	4		
		DAY 1	20MAY2003	1	4		
		DAY 8	29MAY2003	10	4	0	3
		DAY 15	05JUN2003	17	4	0	3
		DAY 22	12JUN2003	24	3	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	DAY 29	18JUN2003	30	3	-1	3
		DAY 36	26JUN2003	38	2	-2	2
		DAY 43	03JUL2003	45	2	-2	2
		DAY 50	10JUL2003	52	3	-1	3
		DAY 57	17JUL2003	59	2	-2	2
	E0019042	SCREEN	28MAY2003	-7	4		
		DAY 1	04JUN2003	1	5		
		DAY 8	12JUN2003	9	4	-1	3
		DAY 15	19JUN2003	16	3	-2	3
	E0019045	SCREEN	19JUN2003	-7	5		
		DAY 1	26JUN2003	1	5		
		DAY 8	03JUL2003	8	5	0	4
		DAY 22	16JUL2003	21	5	0	4
	E0020024	SCREEN	11JUN2003	-12	5		
		DAY 1	23JUN2003	1	4		
		DAY 8	30JUN2003	8	4	0	4
		DAY 15	07JUL2003	15	2	-2	2
		DAY 22	15JUL2003	23	2	-2	2
		DAY 29	21JUL2003	29	1	-3	1
		DAY 36	28JUL2003	36	1	-3	1
		DAY 43	04AUG2003	43	1	-3	1
		DAY 50	12AUG2003	51	1	-3	1
		DAY 57	20AUG2003	59	1	-3	1
	E0022044	SCREEN	11MAR2003	-7	4		
		DAY 1	18MAR2003	1	4		
		DAY 8	25MAR2003	8	4	0	3
		DAY 15	01APR2003	15	3	-1	3
		DAY 22	08APR2003	22	4	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0022044	DAY 29	15APR2003	29	4	0	4
		DAY 36	22APR2003	36	4	0	4
		DAY 43	29APR2003	43	4	0	3
		DAY 50	06MAY2003	50	4	0	3
		DAY 57	12MAY2003	56	4	0	3
	E0023007	SCREEN	07JAN2003	-7	5		
		DAY 1	14JAN2003	1	5		
		DAY 8	21JAN2003	8	4	-1	2
		DAY 15	28JAN2003	15	3	-2	2
		DAY 22	07FEB2003	25	2	-3	2
		DAY 29	11FEB2003	29	2	-3	4
		DAY 36	18FEB2003	36	3	-2	5
		DAY 43	25FEB2003	43	2	-3	2
		DAY 50	04MAR2003	50	2	-3	2
		DAY 57	11MAR2003	57	1	-4	2
	E0023011	SCREEN	28JAN2003	-7	5		
		DAY 1	04FEB2003	1	6		
		DAY 8	11FEB2003	8	5	-1	3
		DAY 15	21FEB2003	18	5	-1	3
		DAY 22	25FEB2003	22	5	-1	3
		DAY 29	04MAR2003	29	5	-1	3
		DAY 36	11MAR2003	36	3	-3	4
		DAY 43	18MAR2003	43	5	-1	5
		DAY 50	27MAR2003	52	4	-2	2
		DAY 57	01APR2003	57	4	-2	2
	E0023014	SCREEN	14FEB2003	-7	6		
		DAY 1	21FEB2003	1	6		
		DAY 8	02MAR2003	10	6	0	5
		DAY 15	06MAR2003	14	6	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023014	DAY 22		18MAR2003	26	5	-1	4
		DAY 29		25MAR2003	33	5	-1	4
		DAY 36		01APR2003	40	5	-1	5
		DAY 50		09APR2003	48	5	-1	5
		DAY 50	*	15APR2003	54	5	-1	5
		DAY 57		25APR2003	64	5	-1	4
	E0023019	SCREEN		21MAR2003	-17	5		
		DAY 1		07APR2003	1	5		
		DAY 8		15APR2003	9	4	-1	2
		DAY 15		22APR2003	16	4	-1	2
		DAY 22		02MAY2003	26	4	-1	2
		DAY 29		06MAY2003	30	3	-2	2
		DAY 36		13MAY2003	37	3	-2	3
		DAY 43		20MAY2003	44	3	-2	2
		DAY 50		29MAY2003	53	3	-2	2
		DAY 57		03JUN2003	58	3	-2	2
	E0023022	SCREEN		10APR2003	-8	5		
		DAY 1		18APR2003	1	5		
		DAY 8		25APR2003	8	5	0	3
		DAY 15		01MAY2003	14	5	0	4
		DAY 22		08MAY2003	21	4	-1	2
		DAY 29		15MAY2003	28	3	-2	2
		DAY 36		22MAY2003	35	1	-4	1
		DAY 43		30MAY2003	43	1	-4	1
		DAY 50		06JUN2003	50	1	-4	1
		DAY 57		12JUN2003	56	1	-4	1
	E0023023	SCREEN		17APR2003	-8	5		
		DAY 1		25APR2003	1	5		
		DAY 8		01MAY2003	7	5	0	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023029	SCREEN	16MAY2003	-7	5		
		DAY 1	23MAY2003	1	5		
	E0023031	SCREEN	22MAY2003	-33	6		
		DAY 1	24JUN2003	1	6		
		DAY 8	01JUL2003	8	5	-1	3
		DAY 15	08JUL2003	15	5	-1	3
		DAY 22	15JUL2003	22	5	-1	3
		DAY 29	22JUL2003	29	5	-1	2
		DAY 36	29JUL2003	36	4	-2	2
		DAY 43	05AUG2003	43	4	-2	2
		DAY 50	12AUG2003	50	4	-2	2
		DAY 57	19AUG2003	57	4	-2	3
	E0023041	SCREEN	02JUL2003	-7	5		
		DAY 1	09JUL2003	1	5		
		DAY 8	16JUL2003	8	5	0	4
		DAY 15	24JUL2003	16	5	0	3
		DAY 22	30JUL2003	22	5	0	3
		DAY 29	06AUG2003	29	5	0	3
		DAY 36	13AUG2003	36	5	0	3
		DAY 43	20AUG2003	43	5	0	3
		DAY 50	27AUG2003	50	5	0	3
		DAY 57	05SEP2003	59	5	0	3
	E0023043	SCREEN	07JUL2003	-7	5		
		DAY 1	14JUL2003	1	5		
		DAY 8	23JUL2003	10	5	0	2
		DAY 15	28JUL2003	15	3	-2	2
		DAY 22	05AUG2003	23	5	0	3
		DAY 29	12AUG2003	30	3	-2	2
		DAY 36	19AUG2003	37	3	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	DAY 43	26AUG2003	44	2	-3	1
		DAY 50	02SEP2003	51	3	-2	1
		DAY 57	09SEP2003	58	2	-3	1
	E0026003	SCREEN	25NOV2002	-9	4		
		DAY 1	04DEC2002	1	5		
		DAY 8	12DEC2002	9	4	-1	3
		DAY 15	19DEC2002	16	3	-2	2
		DAY 22	26DEC2002	23	2	-3	1
		DAY 29	02JAN2003	30	2	-3	1
		DAY 36	09JAN2003	37	1	-4	1
		DAY 43	16JAN2003	44	2	-3	1
		DAY 50	23JAN2003	51	1	-4	1
		DAY 57	03FEB2003	62	1	-4	1
	E0026005	SCREEN	23DEC2002	-7	4		
		DAY 1	30DEC2002	1	4		
		DAY 8	06JAN2003	8	4	0	4
	E0026009	SCREEN	10JAN2003	-5	4		
		DAY 1	15JAN2003	1	4		
		DAY 8	21JAN2003	7	3	-1	3
	E0026015	SCREEN	20FEB2003	-7	4		
		DAY 1	27FEB2003	1	4		
		DAY 8	07MAR2003	9	4	0	4
		DAY 15	13MAR2003	15	5	1	5
		DAY 22	20MAR2003	22	5	1	5
		DAY 29	27MAR2003	29	4	0	4
		DAY 36	03APR2003	36	4	0	4
		DAY 43	10APR2003	43	3	-1	2
		DAY 50	17APR2003	50	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	DAY 57	25APR2003	58	2	-2	2
	E0026023	SCREEN	23APR2003	-7	4		
		DAY 1	30APR2003	1	4		
		DAY 8	07MAY2003	8	3	-1	2
		DAY 15	14MAY2003	15	3	-1	2
		DAY 22	21MAY2003	22	3	-1	2
		DAY 29	28MAY2003	29	3	-1	2
		DAY 36	04JUN2003	36	3	-1	2
		DAY 43	11JUN2003	43	3	-1	2
		DAY 50	18JUN2003	50	3	-1	2
		DAY 57	27JUN2003	59	3	-1	2
	E0027016	SCREEN	19MAR2003	-21	4		
		DAY 1	09APR2003	1	4		
		DAY 8	14APR2003	6	4	0	4
		DAY 15	22APR2003	14	4	0	3
		DAY 22	29APR2003	21	4	0	2
		DAY 29	05MAY2003	27	4	0	2
		DAY 36	14MAY2003	36	4	0	2
		DAY 43	19MAY2003	41	4	0	2
		DAY 50	27MAY2003	49	4	0	3
		DAY 57	03JUN2003	56	3	-1	2
	E0027018	SCREEN	21MAR2003	-4	4		
		DAY 1	25MAR2003	1	4		
		DAY 8	02APR2003	9	5	1	4
		DAY 15	08APR2003	15	3	-1	2
		DAY 22	15APR2003	22	3	-1	2
		DAY 29	22APR2003	29	3	-1	2
		DAY 36	29APR2003	36	2	-2	1
		DAY 43	05MAY2003	42	2	-2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	DAY 50	13MAY2003	50	2	-2	1
		DAY 57	22MAY2003	59	2	-2	1
	E0028032	SCREEN	13MAR2003	-12	3		
		DAY 1	25MAR2003	1	4		
		DAY 8	01APR2003	8	4	0	4
		DAY 15	08APR2003	15	4	0	4
		DAY 22	15APR2003	22	4	0	3
		DAY 29	22APR2003	29	4	0	4
		DAY 36	30APR2003	37	4	0	3
		DAY 43	06MAY2003	43	4	0	4
		DAY 50	13MAY2003	50	4	0	4
	E0029003	SCREEN	28OCT2002	-7	4		
		DAY 1	04NOV2002	1	4		
		DAY 8	11NOV2002	8	4	0	3
		DAY 15	18NOV2002	15	3	-1	2
		DAY 22	25NOV2002	22	4	0	3
		DAY 29	02DEC2002	29	3	-1	2
		DAY 36	09DEC2002	36	3	-1	2
		DAY 43	16DEC2002	43	3	-1	2
		DAY 50	23DEC2002	50	5	1	5
		DAY 57	30DEC2002	57	4	0	3
	E0029020	SCREEN	25FEB2003	-8	4		
		DAY 1	04MAR2003	-1	4		
		DAY 8	11MAR2003	7	4	0	4
	E0031005	SCREEN	13DEC2002	-7	4		
		DAY 1	20DEC2002	1	4		
		DAY 8	27DEC2002	8	3	-1	2
		DAY 15	03JAN2003	15	3	-1	2

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	DAY 22	10JAN2003	22	4	0	3
		DAY 29	17JAN2003	29	3	-1	2
		DAY 36	24JAN2003	36	3	-1	2
		DAY 43	30JAN2003	42	4	0	3
		DAY 50	07FEB2003	50	3	-1	1
		DAY 57	14FEB2003	57	3	-1	1
	E0031006	SCREEN	31JAN2003	-18	5		
		DAY 1	18FEB2003	1	4		
		DAY 8	26FEB2003	9	3	-1	2
		DAY 15	05MAR2003	16	3	-1	2
		DAY 22	11MAR2003	22	2	-2	1
		DAY 29	18MAR2003	29	2	-2	1
		DAY 36	25MAR2003	36	2	-2	1
		DAY 43	02APR2003	44	3	-1	2
		DAY 50	07APR2003	49	3	-1	2
		DAY 57	15APR2003	57	1	-3	1
	E0031010	SCREEN	12FEB2003	-7	4		
		DAY 1	19FEB2003	1	4		
		DAY 8	26FEB2003	8	4	0	4
		DAY 15	05MAR2003	15	4	0	5
	E0031011	SCREEN	18FEB2003	-9	4		
		DAY 1	27FEB2003	1	4		
		DAY 8	06MAR2003	8	2	-2	2
		DAY 15	13MAR2003	15	2	-2	2
		DAY 22	20MAR2003	22	3	-1	3
		DAY 29	27MAR2003	29	1	-3	1
		DAY 36	03APR2003	36	1	-3	1
		DAY 43	11APR2003	44	5	1	6
		DAY 50	17APR2003	50	4	0	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	DAY 57	24APR2003	57	1	-3	1
	E0031015	SCREEN	13MAR2003	-13	4		
		DAY 1	26MAR2003	1	4		
		DAY 8	01APR2003	7	3	-1	3
	E0031031	SCREEN	01JUL2003	-7	4		
		DAY 1	08JUL2003	1	4		
		DAY 8	15JUL2003	8	3	-1	3
		DAY 15	22JUL2003	15	3	-1	3
		DAY 22	29JUL2003	22	2	-2	2
	E0033009	SCREEN	22JAN2003	-21	4		
		DAY 1	12FEB2003	1	5		
	E0034009	SCREEN	10JUN2003	-9	5		
		DAY 1	19JUN2003	1	5		
		DAY 8	27JUN2003	9	4	-1	3
		DAY 15	03JUL2003	15	3	-2	2
		DAY 22	10JUL2003	22	2	-3	2
		DAY 29	18JUL2003	30	2	-3	2
		DAY 36	25JUL2003	37	2	-3	2
		DAY 43	31JUL2003	43	2	-3	2
		DAY 50	07AUG2003	50	2	-3	2
		DAY 57	18AUG2003	61	0	-5	1
	E0037007	SCREEN	04APR2003	-7	4		
		DAY 1	11APR2003	1	4		
		DAY 8	17APR2003	7	4	0	4
	E0037012	SCREEN	11JUL2003	-5	4		
		DAY 1	16JUL2003	1	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 8	24JUL2003	9	3	-1	2
		DAY 15	01AUG2003	17	3	-1	2
		DAY 22	08AUG2003	24	3	-1	2
		DAY 29	15AUG2003	31	2	-2	1
		DAY 36	22AUG2003	38	1	-3	1
		DAY 43	29AUG2003	45	1	-3	1
		DAY 50	05SEP2003	52	1	-3	1
		DAY 57	08SEP2003	55	1	-3	1
	E0039019	SCREEN	20JAN2003	-17	4		
		DAY 1	06FEB2003	1	4		
		DAY 8	13FEB2003	8	4	0	3
		DAY 15	20FEB2003	15	3	-1	3
		DAY 22	27FEB2003	22	3	-1	2
		DAY 29	07MAR2003	30	2	-2	2
		DAY 36	13MAR2003	36	4	0	4
		DAY 43	20MAR2003	43	1	-3	1
		DAY 50	27MAR2003	50	2	-2	2
		DAY 57	03APR2003	57	2	-2	2
	E0039043	SCREEN	25APR2003	-13	4		
		DAY 1	08MAY2003	1	4		
		DAY 8	15MAY2003	8	3	-1	2
		DAY 15	23MAY2003	16	1	-3	1
		DAY 22	29MAY2003	22	1	-3	1
		DAY 29	05JUN2003	29	2	-2	1
		DAY 36	13JUN2003	37	3	-1	2

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0002001	SCREEN	17DEC2002	-13	5		
		DAY 1	30DEC2002	1	5		
		DAY 8	06JAN2003	8	5	0	3
		DAY 15	14JAN2003	16	4	-1	3
		DAY 22	21JAN2003	23	4	-1	3
		DAY 29	29JAN2003	31	4	-1	3
		DAY 36	05FEB2003	38	4	-1	5
		DAY 43	12FEB2003	45	4	-1	5
		DAY 50	19FEB2003	52	3	-2	2
		DAY 57	26FEB2003	59	2	-3	2
	E0002003	SCREEN	03JAN2003	-19	4		
		DAY 1	22JAN2003	1	4		
		DAY 8	29JAN2003	8	5	1	6
		DAY 15	05FEB2003	15	3	-1	3
		DAY 22	12FEB2003	22	4	0	5
		DAY 29	19FEB2003	29	4	0	4
		DAY 36	26FEB2003	36	3	-1	3
		DAY 43	05MAR2003	43	3	-1	3
		DAY 50	11MAR2003	49	3	-1	3
		DAY 57	18MAR2003	56	3	-1	3
	E0002004	SCREEN	14JAN2003	-11	5		
		DAY 1	25JAN2003	1	4		
	E0002008	SCREEN	29JAN2003	-27	4		
		DAY 1	25FEB2003	1	4		
		DAY 8	05MAR2003	9	4	0	4
		DAY 15	13MAR2003	17	4	0	4
		DAY 22	20MAR2003	24	4	0	5
		DAY 29	27MAR2003	31	4	0	4
		DAY 36	03APR2003	38	4	0	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0002008	DAY 43	11APR2003	46	4	0	5
		DAY 50	16APR2003	51	4	0	5
		DAY 57	23APR2003	58	4	0	3
	E0002016	SCREEN	09JUL2003	-15	6		
		DAY 1	24JUL2003	1	5		
		DAY 8	30JUL2003	7	5	0	3
		DAY 15	06AUG2003	14	4	-1	2
		DAY 22	13AUG2003	21	4	-1	3
		DAY 29	21AUG2003	29	4	-1	5
		DAY 36	27AUG2003	35	4	-1	3
		DAY 43	03SEP2003	42	4	-1	3
		DAY 50	11SEP2003	50	4	-1	3
		DAY 57	17SEP2003	56	4	-1	3
	E0003008	SCREEN	21JAN2003	-7	5		
		DAY 1	28JAN2003	1	5		
		DAY 8	04FEB2003	8	4	-1	3
		DAY 15	11FEB2003	15	4	-1	3
		DAY 22	18FEB2003	22	4	-1	3
	E0004003	SCREEN	02OCT2002	-8	4		
		DAY 1	10OCT2002	1	4		
		DAY 8	17OCT2002	8	4	0	3
	E0004006	SCREEN	28OCT2002	-7	5		
		DAY 1	04NOV2002	1	4		
		DAY 8	11NOV2002	8	3	-1	3
		DAY 15	18NOV2002	15	2	-2	2
		DAY 22	25NOV2002	22	2	-2	2
		DAY 29	02DEC2002	29	2	-2	2
		DAY 36	09DEC2002	36	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0004006	DAY 43	16DEC2002	43	4	0	4
		DAY 57	06JAN2003	64	4	0	3
	E0004016	SCREEN	12FEB2003	-7	5		
		DAY 1	19FEB2003	1	5		
		DAY 8	26FEB2003	8	5	0	4
		DAY 15	05MAR2003	15	3	-2	2
		DAY 22	13MAR2003	23	2	-3	2
		DAY 36	26MAR2003	36	2	-3	1
		DAY 43	03APR2003	44	2	-3	1
		DAY 50	10APR2003	51	1	-4	1
		DAY 57	17APR2003	58	1	-4	1
	E0004024	SCREEN	25JUN2003	-8	4		
		DAY 1	03JUL2003	1	4		
		DAY 8	10JUL2003	8	4	0	3
		DAY 15	17JUL2003	15	4	0	3
		DAY 22	24JUL2003	22	3	-1	2
		DAY 29	31JUL2003	29	3	-1	2
		DAY 36	07AUG2003	36	3	-1	2
		DAY 43	14AUG2003	43	2	-2	1
		DAY 50	21AUG2003	50	1	-3	1
		DAY 57	28AUG2003	57	1	-3	1
	E0005006	SCREEN	24SEP2002	-9	4		
		DAY 1	03OCT2002	1	5		
		DAY 8	14OCT2002	12	3	-2	2
	E0005017	SCREEN	11DEC2002	-19	5		
		DAY 1	30DEC2002	1	5		
		DAY 8	06JAN2003	8	5	0	4
		DAY 15	14JAN2003	16	5	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0005017	DAY 22	22JAN2003	24	5	0	4
		DAY 29	30JAN2003	32	5	0	4
		DAY 36	04FEB2003	37	5	0	4
		DAY 43	13FEB2003	46	5	0	4
		DAY 50	20FEB2003	53	5	0	4
		DAY 57	04MAR2003	65	5	0	4
	E0005019	SCREEN	19DEC2002	-27	5		
		DAY 1	15JAN2003	1	5		
		DAY 8	23JAN2003	9	6	1	5
	E0005026	SCREEN	26FEB2003	-8	5		
		DAY 1	06MAR2003	1	5		
		DAY 8	13MAR2003	8	5	0	4
		DAY 15	20MAR2003	15	5	0	5
		DAY 22	25MAR2003	20	6	1	5
	E0005039	SCREEN	15MAY2003	-7	5		
		DAY 1	22MAY2003	1	5		
		DAY 8	28MAY2003	7	5	0	4
		DAY 15	05JUN2003	15	4	-1	3
		DAY 22	12JUN2003	22	4	-1	3
		DAY 29	18JUN2003	28	4	-1	3
		DAY 36	24JUN2003	34	4	-1	3
		DAY 43	03JUL2003	43	4	-1	3
		DAY 50	10JUL2003	50	4	-1	3
		DAY 57	16JUL2003	56	5	0	4
	E0005043	SCREEN	01JUL2003	-8	4		
		DAY 1	09JUL2003	1	4		
		DAY 8	17JUL2003	9	4	0	4
		DAY 15	24JUL2003	16	4	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0005043	DAY 22		31JUL2003	23	4	0	3
		DAY 29		07AUG2003	30	4	0	4
		DAY 36		13AUG2003	36	4	0	4
		DAY 43		20AUG2003	43	4	0	4
		DAY 50		27AUG2003	50	4	0	4
		DAY 57		03SEP2003	57	3	-1	3
	E0006020	SCREEN		02MAY2003	-11	5		
		DAY 1		13MAY2003	1	5		
		DAY 8		20MAY2003	8	5	0	4
		DAY 15		27MAY2003	15	5	0	4
		DAY 29		10JUN2003	29	4	-1	2
		DAY 36		17JUN2003	36	4	-1	2
		DAY 43		24JUN2003	43	3	-2	2
		DAY 50		01JUL2003	50	3	-2	2
		DAY 57		08JUL2003	57	3	-2	2
	E0007001	SCREEN		10DEC2002	-21	5		
		DAY 1		31DEC2002	1	5		
		DAY 8		07JAN2003	8	5	0	4
		DAY 15		14JAN2003	15	5	0	4
		DAY 22		21JAN2003	22	4	-1	3
		DAY 29		28JAN2003	29	4	-1	3
		DAY 36		04FEB2003	36	4	-1	3
		DAY 43		11FEB2003	43	3	-2	3
		DAY 50		18FEB2003	50	3	-2	3
		DAY 50	*	22FEB2003	54	3	-2	2
	E0007003	SCREEN		03JAN2003	-27	5		
		DAY 1		30JAN2003	1	5		
		DAY 8		06FEB2003	8	5	0	4
		DAY 15		14FEB2003	16	4	-1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0007003	DAY 22		22FEB2003	24	4	-1	3
		DAY 36		10MAR2003	40	4	-1	3
	E0007006	SCREEN		21FEB2003	-12	5		
		DAY 1		05MAR2003	1	4		
		DAY 8		12MAR2003	8	4	0	3
		DAY 15		19MAR2003	15	3	-1	2
		DAY 22	*	25MAR2003	21	3	-1	2
		DAY 22		26MAR2003	22	3	-1	2
	E0009004	SCREEN		19NOV2002	-7	4		
		DAY 1		26NOV2002	1	5		
		DAY 8		04DEC2002	9	3	-2	2
		DAY 15		11DEC2002	16	5	0	4
		DAY 22		18DEC2002	23	5	0	4
	E0009012	SCREEN		16JUN2003	-9	4		
		DAY 1		25JUN2003	1	4		
		DAY 8		03JUL2003	9	4	0	4
	E0010008	SCREEN		11DEC2002	-7	5		
		DAY 1		18DEC2002	1	5		
		DAY 8		26DEC2002	9	5	0	5
		DAY 15		02JAN2003	16	5	0	4
		DAY 22		08JAN2003	22	5	0	3
		DAY 29		15JAN2003	29	4	-1	2
	E0010018	SCREEN		26FEB2003	-21	5		
		DAY 1		19MAR2003	1	6		
		DAY 8		26MAR2003	8	5	-1	3
		DAY 15		02APR2003	15	5	-1	4
		DAY 22		09APR2003	22	4	-2	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0010018	DAY 29	16APR2003	29	4	-2	3
		DAY 36	23APR2003	36	3	-3	2
		DAY 43	01MAY2003	44	2	-4	1
		DAY 57	14MAY2003	57	2	-4	1
	E0010028	SCREEN	09JUN2003	-7	5		
		DAY 1	16JUN2003	1	5		
		DAY 8	24JUN2003	9	5	0	4
		DAY 15	01JUL2003	16	5	0	5
		DAY 22	08JUL2003	23	5	0	3
		DAY 29	15JUL2003	30	6	1	6
	E0011008	SCREEN	23JAN2003	-7	4		
		DAY 1	30JAN2003	1	4		
		DAY 8	06FEB2003	8	3	-1	2
		DAY 15	13FEB2003	15	4	0	5
	E0011009	SCREEN	19DEC2002	-8	4		
		DAY 1	26DEC2002	-1	4		
		DAY 8	02JAN2003	7	4	0	4
		DAY 15	09JAN2003	14	4	0	4
		DAY 22	16JAN2003	21	4	0	3
		DAY 29	23JAN2003	28	4	0	3
		DAY 36	30JAN2003	35	4	0	3
		DAY 43	06FEB2003	42	3	-1	2
		DAY 50	13FEB2003	49	3	-1	1
		DAY 57	20FEB2003	56	2	-2	1
	E0011010	SCREEN	03FEB2003	-7	4		
		DAY 1	10FEB2003	1	4		
		DAY 8	17FEB2003	8	4	0	3
		DAY 15	24FEB2003	15	4	0	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0011010	DAY 22		03MAR2003	22	3	-1	2
		DAY 29		10MAR2003	29	3	-1	2
		DAY 36		17MAR2003	36	4	0	5
		DAY 36	*	19MAR2003	38	4	0	5
	E0013001	SCREEN		31OCT2002	-14	4		
		DAY 1		14NOV2002	1	5		
		DAY 8		21NOV2002	8	5	0	4
		DAY 15		27NOV2002	14	4	-1	3
		DAY 22		06DEC2002	23	3	-2	3
		DAY 29		11DEC2002	28	2	-3	2
		DAY 36		18DEC2002	35	1	-4	2
		DAY 43		27DEC2002	44	1	-4	1
		DAY 50		02JAN2003	50	1	-4	1
		DAY 57		10JAN2003	58	1	-4	1
	E0013003	SCREEN		06NOV2002	-6	5		
		DAY 1		12NOV2002	1	5		
		DAY 8		19NOV2002	8	5	0	4
		DAY 15		26NOV2002	15	5	0	4
		DAY 22		03DEC2002	22	5	0	4
		DAY 29		11DEC2002	30	5	0	4
		DAY 36		18DEC2002	37	5	0	5
		DAY 43		23DEC2002	42	5	0	4
		DAY 50		30DEC2002	49	5	0	4
		DAY 57		06JAN2003	56	5	0	4
	E0013005	SCREEN		11FEB2003	-7	4		
		DAY 1		18FEB2003	1	4		
		DAY 8		25FEB2003	8	4	0	3
		DAY 15		04MAR2003	15	3	-1	3
		DAY 22		11MAR2003	22	3	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0013005	DAY 29		19MAR2003	30	3	-1	2
		DAY 36		25MAR2003	36	2	-2	2
		DAY 43		02APR2003	44	4	0	4
		DAY 50		08APR2003	50	4	0	3
		DAY 57		15APR2003	57	4	0	4
	E0013013	SCREEN		01MAY2003	-5	4		
		DAY 1		06MAY2003	1	4		
		DAY 8		12MAY2003	7	3	-1	2
		DAY 15		19MAY2003	14	4	0	4
		DAY 22		27MAY2003	22	4	0	4
		DAY 22	*	30MAY2003	25	4	0	5
	E0014002	SCREEN		19FEB2003	-7	4		
		DAY 1		26FEB2003	1	4		
		DAY 8		04MAR2003	7	4	0	4
		DAY 15		12MAR2003	15	4	0	4
		DAY 22		20MAR2003	23	5	1	4
		DAY 29		27MAR2003	30	4	0	4
		DAY 43		10APR2003	44	4	0	4
	E0014004	SCREEN		04MAR2003	-8	6		
		DAY 1		12MAR2003	1	6		
		DAY 8		20MAR2003	9	5	-1	4
		DAY 15		25MAR2003	14	4	-2	3
		DAY 22		01APR2003	21	5	-1	3
		DAY 36		15APR2003	35	4	-2	4
	E0014009	SCREEN		15APR2003	-8	5		
		DAY 1		23APR2003	1	5		
		DAY 8		30APR2003	8	5	0	6

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0014015	SCREEN		11JUN2003	-7	4		
		DAY 1		18JUN2003	1	4		
		DAY 8		26JUN2003	9	3	-1	2
	E0014017	SCREEN		17JUN2003	-10	4		
		DAY 1		27JUN2003	1	4		
		DAY 8		02JUL2003	6	4	0	4
		DAY 15		09JUL2003	13	3	-1	2
		DAY 22		16JUL2003	20	2	-2	2
		DAY 29		23JUL2003	27	1	-3	2
		DAY 29	*	29JUL2003	33	1	-3	1
		DAY 36		05AUG2003	40	2	-2	1
		DAY 43		12AUG2003	47	1	-3	1
		DAY 50		19AUG2003	54	1	-3	1
	E0014018	SCREEN		24JUN2003	-7	4		
		DAY 1		01JUL2003	1	4		
		DAY 8		09JUL2003	9	5	1	4
		DAY 15		16JUL2003	16	4	0	4
		DAY 22		22JUL2003	22	4	0	4
		DAY 29		29JUL2003	29	3	-1	3
		DAY 36		05AUG2003	36	4	0	4
		DAY 43		12AUG2003	43	4	0	4
		DAY 50		19AUG2003	50	4	0	4
		DAY 57		27AUG2003	58	5	1	4
	E0015005	SCREEN		25NOV2002	-7	6		
		DAY 1		02DEC2002	1	6		
		DAY 8		11DEC2002	10	6	0	4
		DAY 15		18DEC2002	17	6	0	5
	E0017002	SCREEN		06MAY2003	-28	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0017002	DAY 1		06MAY2003	-28	4		
	E0018009	SCREEN		17DEC2002	-20	4		
		DAY 1		06JAN2003	1	4		
		DAY 8		13JAN2003	8	4	0	4
		DAY 8	*	14JAN2003	9	4	0	4
	E0018010	SCREEN		09JAN2003	-7	4		
		DAY 1		16JAN2003	1	4		
		DAY 8		23JAN2003	8	4	0	4
		DAY 15		30JAN2003	15	4	0	3
		DAY 22		06FEB2003	22	3	-1	3
		DAY 29		13FEB2003	29	3	-1	2
		DAY 36		20FEB2003	36	3	-1	3
		DAY 43		26FEB2003	42	3	-1	3
		DAY 50		06MAR2003	50	2	-2	2
		DAY 57		13MAR2003	57	2	-2	2
	E0018015	SCREEN		21JAN2003	-7	4		
		DAY 1		28JAN2003	1	4		
		DAY 8		04FEB2003	8	4	0	4
		DAY 15		13FEB2003	17	4	0	3
		DAY 22		20FEB2003	24	3	-1	3
		DAY 29		26FEB2003	30	3	-1	3
		DAY 36		06MAR2003	38	2	-2	2
		DAY 43		13MAR2003	45	2	-2	2
		DAY 50		20MAR2003	52	1	-3	1
		DAY 57		27MAR2003	59	2	-2	2
	E0020015	SCREEN		18MAR2003	-9	4		
		DAY 1		27MAR2003	1	4		
		DAY 8		03APR2003	8	4	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0020015	DAY 15		10APR2003	15	4	0	4
		DAY 22		16APR2003	21	4	0	4
		DAY 29		23APR2003	28	4	0	3
		DAY 36		30APR2003	35	4	0	3
		DAY 43		08MAY2003	43	4	0	3
		DAY 50		15MAY2003	50	4	0	3
		DAY 57		23MAY2003	58	4	0	3
	E0020017	SCREEN		27MAR2003	-7	4		
		DAY 1		03APR2003	1	4		
		DAY 8		10APR2003	8	3	-1	2
		DAY 15		17APR2003	15	3	-1	3
		DAY 22		22APR2003	20	2	-2	1
		DAY 29		29APR2003	27	3	-1	2
		DAY 29	*	05MAY2003	33	3	-1	1
		DAY 36		12MAY2003	40	2	-2	1
		DAY 50		20MAY2003	48	1	-3	1
	E0020020	SCREEN		07MAY2003	-5	4		
		DAY 1		12MAY2003	1	5		
		DAY 8		19MAY2003	8	4	-1	4
		DAY 8	*	23MAY2003	12	7	2	7
	E0020022	SCREEN		09JUN2003	-7	5		
		DAY 1		16JUN2003	1	5		
		DAY 8		23JUN2003	8	3	-2	1
		DAY 15		30JUN2003	15	2	-3	2
		DAY 22		07JUL2003	22	2	-3	2
		DAY 29		14JUL2003	29	2	-3	1
		DAY 36		21JUL2003	36	1	-4	1
		DAY 43		28JUL2003	43	1	-4	1
		DAY 50		04AUG2003	50	1	-4	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0020022	DAY 57	11AUG2003	57	1	-4	1
	E0022001	SCREEN	07OCT2002	-21	5		
		DAY 1	28OCT2002	1	5		
		DAY 8	04NOV2002	8	5	0	4
		DAY 15	11NOV2002	15	4	-1	3
		DAY 22	18NOV2002	22	5	0	4
		DAY 29	26NOV2002	30	4	-1	3
		DAY 36	02DEC2002	36	4	-1	3
		DAY 43	09DEC2002	43	3	-2	3
		DAY 50	16DEC2002	50	2	-3	2
		DAY 57	26DEC2002	60	4	-1	3
	E0022004	SCREEN	17OCT2002	-11	4		
		DAY 1	28OCT2002	1	4		
		DAY 8	04NOV2002	8	4	0	4
		DAY 15	11NOV2002	15	4	0	4
		DAY 22	19NOV2002	23	4	0	4
		DAY 29	26NOV2002	30	4	0	3
		DAY 36	02DEC2002	36	4	0	4
		DAY 43	10DEC2002	44	4	0	3
		DAY 50	16DEC2002	50	4	0	3
		DAY 57	23DEC2002	57	4	0	4
	E0022005	SCREEN	17OCT2002	-22	4		
		DAY 1	08NOV2002	1	4		
		DAY 8	15NOV2002	8	4	0	4
		DAY 15	22NOV2002	15	4	0	4
		DAY 22	29NOV2002	22	4	0	4
		DAY 29	06DEC2002	29	4	0	4
		DAY 36	13DEC2002	36	4	0	3
		DAY 43	20DEC2002	43	4	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0022005	DAY 50	27DEC2002	50	4	0	4
		DAY 57	03JAN2003	57	4	0	4
	E0022011	SCREEN	20NOV2002	-9	4		
		DAY 1	29NOV2002	1	4		
	E0022015	SCREEN	29NOV2002	-11	4		
		DAY 1	10DEC2002	1	4		
		DAY 8	17DEC2002	8	4	0	4
		DAY 15	26DEC2002	17	3	-1	2
		DAY 22	02JAN2003	24	2	-2	2
		DAY 29	09JAN2003	31	3	-1	3
		DAY 36	16JAN2003	38	4	0	4
		DAY 43	23JAN2003	45	4	0	3
		DAY 50	30JAN2003	52	4	0	3
		DAY 57	06FEB2003	59	4	0	3
	E0022016	SCREEN	03DEC2002	-14	4		
		DAY 1	17DEC2002	1	4		
		DAY 8	26DEC2002	10	4	0	4
		DAY 15	30DEC2002	14	4	0	4
		DAY 22	06JAN2003	21	4	0	4
		DAY 29	13JAN2003	28	4	0	4
		DAY 36	21JAN2003	36	4	0	4
		DAY 43	30JAN2003	45	4	0	4
		DAY 50	06FEB2003	52	4	0	4
		DAY 57	11FEB2003	57	4	0	4
	E0022020	SCREEN	05DEC2002	-7	4		
		DAY 1	12DEC2002	1	4		
		DAY 8	19DEC2002	8	4	0	4
		DAY 15	26DEC2002	15	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0022020	DAY 22	02JAN2003	22	3	-1	2
		DAY 29	10JAN2003	30	3	-1	2
		DAY 36	16JAN2003	36	2	-2	1
		DAY 43	23JAN2003	43	2	-2	1
	E0022023	SCREEN	19DEC2002	-6	4		
		DAY 1	24DEC2002	-1	4		
		DAY 8	02JAN2003	9	4	0	4
		DAY 15	09JAN2003	16	3	-1	3
		DAY 22	16JAN2003	23	3	-1	3
		DAY 29	23JAN2003	30	3	-1	2
		DAY 36	30JAN2003	37	3	-1	2
		DAY 43	06FEB2003	44	4	0	3
		DAY 50	13FEB2003	51	3	-1	2
		DAY 57	20FEB2003	58	2	-2	2
	E0022029	SCREEN	05FEB2003	-14	4		
		DAY 1	19FEB2003	1	4		
		DAY 8	26FEB2003	8	3	-1	3
		DAY 15	03MAR2003	13	4	0	3
		DAY 22	12MAR2003	22	2	-2	2
		DAY 29	18MAR2003	28	2	-2	1
		DAY 36	26MAR2003	36	2	-2	2
		DAY 43	02APR2003	43	2	-2	2
		DAY 50	07APR2003	48	3	-1	3
		DAY 57	14APR2003	55	3	-1	3
	E0022041	SCREEN	04MAR2003	-14	4		
		DAY 1	18MAR2003	1	4		
		DAY 8	25MAR2003	8	4	0	3
		DAY 15	01APR2003	15	3	-1	3
		DAY 22	08APR2003	22	2	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0022041	DAY 29		15APR2003	29	3	-1	2
		DAY 36		21APR2003	35	2	-2	2
		DAY 43		29APR2003	43	1	-3	1
		DAY 50		06MAY2003	50	1	-3	1
		DAY 57		13MAY2003	57	1	-3	1
	E0022042	SCREEN		05MAR2003	-7	4		
		DAY 1		12MAR2003	1	4		
		DAY 8		19MAR2003	8	4	0	4
		DAY 15		27MAR2003	16	4	0	4
		DAY 22		02APR2003	22	4	0	4
		DAY 29		10APR2003	30	4	0	4
		DAY 36		17APR2003	37	4	0	4
		DAY 43		24APR2003	44	4	0	4
		DAY 50		01MAY2003	51	4	0	4
		DAY 57		12MAY2003	62	4	0	4
	E0022043	SCREEN		10MAR2003	-10	4		
		DAY 1		20MAR2003	1	4		
		DAY 8		26MAR2003	7	3	-1	3
		DAY 15		03APR2003	15	2	-2	2
		DAY 22		10APR2003	22	3	-1	3
		DAY 29		17APR2003	29	2	-2	2
		DAY 36		24APR2003	36	2	-2	1
		DAY 43		01MAY2003	43	2	-2	2
		DAY 50		08MAY2003	50	2	-2	1
		DAY 50	*	12MAY2003	54	1	-3	1
	E0022054	SCREEN		04APR2003	-7	5		
		DAY 1		11APR2003	1	5		
		DAY 8		18APR2003	8	5	0	4
		DAY 15		28APR2003	18	2	-3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0022054	DAY 22		02MAY2003	22	1	-4	1
		DAY 29		12MAY2003	32	2	-3	1
		DAY 36		16MAY2003	36	2	-3	2
	E0022059	SCREEN		22APR2003	-14	4		
		DAY 1		06MAY2003	1	4		
		DAY 8		13MAY2003	8	4	0	4
		DAY 15		20MAY2003	15	4	0	3
		DAY 22		27MAY2003	22	4	0	3
		DAY 29		03JUN2003	29	3	-1	3
		DAY 36		10JUN2003	36	3	-1	3
		DAY 43		17JUN2003	43	3	-1	3
		DAY 43	*	20JUN2003	46	3	-1	3
		DAY 57		08JUL2003	64	3	-1	3
	E0022065	SCREEN		30APR2003	-7	4		
		DAY 1		07MAY2003	1	4		
		DAY 8		14MAY2003	8	4	0	4
		DAY 15		21MAY2003	15	3	-1	3
		DAY 22		28MAY2003	22	3	-1	2
		DAY 29		04JUN2003	29	1	-3	1
		DAY 36		11JUN2003	36	1	-3	1
		DAY 43		18JUN2003	43	1	-3	1
		DAY 50		25JUN2003	50	2	-2	1
		DAY 57		02JUL2003	57	2	-2	1
	E0022070	SCREEN		05JUN2003	-7	4		
		DAY 1		12JUN2003	1	5		
		DAY 8		18JUN2003	7	5	0	4
	E0023001	SCREEN		24OCT2002	-22	5		
		DAY 1		15NOV2002	1	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0023001	DAY 8		22NOV2002	8	5	0	5
		DAY 15		29NOV2002	15	3	-2	2
		DAY 22		06DEC2002	22	3	-2	5
		DAY 29		16DEC2002	32	3	-2	4
		DAY 36		23DEC2002	39	3	-2	3
		DAY 43		30DEC2002	46	4	-1	5
		DAY 50		07JAN2003	54	5	0	6
		DAY 57		14JAN2003	61	5	0	3
	E0023009	SCREEN		24JAN2003	-18	5		
		DAY 1		11FEB2003	1	5		
		DAY 8		18FEB2003	8	5	0	4
		DAY 15		27FEB2003	17	4	-1	2
		DAY 22		04MAR2003	22	3	-2	3
		DAY 29		11MAR2003	29	2	-3	1
		DAY 36		18MAR2003	36	2	-3	5
		DAY 43		25MAR2003	43	2	-3	5
		DAY 50		03APR2003	52	2	-3	5
		DAY 57		08APR2003	57	2	-3	4
	E0023028	SCREEN		16MAY2003	-13	5		
		DAY 1		29MAY2003	1	5		
		DAY 8		05JUN2003	8	5	0	5
		DAY 15		12JUN2003	15	5	0	5
		DAY 22		19JUN2003	22	5	0	5
		DAY 29		25JUN2003	28	5	0	3
		DAY 43		09JUL2003	42	5	0	3
		DAY 50		16JUL2003	49	4	-1	3
		DAY 50	*	21JUL2003	54	4	-1	3
	E0023033	SCREEN		30MAY2003	-6	5		
		DAY 1		05JUN2003	1	5		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0023033	DAY 8	12JUN2003	8	5	0	5
	E0023047	SCREEN	11JUL2003	-7	5		
		DAY 1	18JUL2003	1	5		
		DAY 8	25JUL2003	8	5	0	3
		DAY 15	31JUL2003	14	5	0	3
		DAY 22	08AUG2003	22	5	0	3
		DAY 29	15AUG2003	29	5	0	3
		DAY 36	21AUG2003	35	4	-1	3
		DAY 43	29AUG2003	43	4	-1	3
		DAY 50	05SEP2003	50	4	-1	3
		DAY 57	12SEP2003	57	4	-1	3
	E0025001	SCREEN	25MAR2003	-7	5		
		DAY 1	01APR2003	1	5		
		DAY 8	10APR2003	10	5	0	4
		DAY 15	16APR2003	16	5	0	4
		DAY 22	23APR2003	23	5	0	4
	E0026012	SCREEN	05FEB2003	-15	5		
		DAY 1	20FEB2003	1	5		
		DAY 8	27FEB2003	8	5	0	4
		DAY 15	06MAR2003	15	5	0	3
		DAY 22	13MAR2003	22	4	-1	3
		DAY 29	20MAR2003	29	3	-2	2
		DAY 36	27MAR2003	36	3	-2	2
		DAY 43	03APR2003	43	3	-2	2
		DAY 50	10APR2003	50	3	-2	2
		DAY 57	17APR2003	57	3	-2	2
	E0026020	SCREEN	28MAR2003	-4	4		
		DAY 1	01APR2003	1	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0026020	DAY 8		08APR2003	8	4	0	4
		DAY 15		15APR2003	15	4	0	3
		DAY 22		22APR2003	22	4	0	4
	E0026024	SCREEN		25APR2003	-7	4		
		DAY 1		02MAY2003	1	4		
		DAY 8		09MAY2003	8	4	0	4
		DAY 15		16MAY2003	15	4	0	4
		DAY 22		23MAY2003	22	4	0	3
		DAY 29		30MAY2003	29	4	0	3
	E0026028	SCREEN		06JUN2003	-14	5		
		DAY 1		20JUN2003	1	5		
		DAY 15		02JUL2003	13	4	-1	3
		DAY 15	*	08JUL2003	19	4	-1	2
	E0028001	SCREEN		20SEP2002	-20	4		
		DAY 1		10OCT2002	1	4		
		DAY 8		16OCT2002	7	4	0	4
		DAY 15		23OCT2002	14	4	0	4
		DAY 22		29OCT2002	20	4	0	3
		DAY 29		05NOV2002	27	4	0	4
		DAY 36		12NOV2002	34	4	0	4
		DAY 43		19NOV2002	41	4	0	4
		DAY 50		26NOV2002	48	4	0	4
		DAY 57		03DEC2002	55	4	0	4
	E0028003	SCREEN		23SEP2002	-7	4		
		DAY 1		30SEP2002	1	4		
		DAY 8		07OCT2002	8	4	0	5
		DAY 15		16OCT2002	17	4	0	3
		DAY 22		22OCT2002	23	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0028003	DAY 29	29OCT2002	30	4	0	3
		DAY 36	07NOV2002	39	4	0	4
		DAY 43	12NOV2002	44	4	0	4
		DAY 50	19NOV2002	51	3	-1	2
		DAY 57	26NOV2002	58	4	0	4
	E0028005	SCREEN	30SEP2002	-3	5		
		DAY 1	03OCT2002	1	5		
		DAY 8	11OCT2002	9	5	0	4
		DAY 29	31OCT2002	29	5	0	4
	E0028010	SCREEN	15OCT2002	-21	4		
		DAY 1	05NOV2002	1	4		
		DAY 8	12NOV2002	8	4	0	4
		DAY 15	19NOV2002	15	4	0	4
		DAY 22	25NOV2002	21	4	0	3
		DAY 29	03DEC2002	29	3	-1	2
		DAY 36	10DEC2002	36	4	0	3
		DAY 43	17DEC2002	43	3	-1	2
		DAY 50	23DEC2002	49	2	-2	1
		DAY 57	31DEC2002	57	3	-1	2
	E0028011	SCREEN	25NOV2002	-10	4		
		DAY 1	05DEC2002	1	4		
		DAY 8	12DEC2002	8	4	0	4
		DAY 15	19DEC2002	15	4	0	3
		DAY 22	26DEC2002	22	3	-1	1
		DAY 29	02JAN2003	29	3	-1	2
		DAY 36	09JAN2003	36	3	-1	2
		DAY 43	16JAN2003	43	3	-1	2
		DAY 50	23JAN2003	50	3	-1	2
		DAY 57	30JAN2003	57	2	-2	2

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0028030	SCREEN	26FEB2003	-6	4		
		DAY 1	04MAR2003	1	4		
		DAY 8	11MAR2003	8	4	0	4
		DAY 15	18MAR2003	15	4	0	4
		DAY 22	25MAR2003	22	4	0	4
		DAY 29	01APR2003	29	4	0	4
		DAY 36	08APR2003	36	4	0	4
		DAY 43	17APR2003	45	4	0	4
		DAY 50	22APR2003	50	4	0	4
		DAY 57	30APR2003	58	4	0	4
	E0028031	SCREEN	06MAR2003	-5	4		
		DAY 1	11MAR2003	1	4		
		DAY 8	18MAR2003	8	4	0	4
		DAY 15	25MAR2003	15	3	-1	2
	E0028047	SCREEN	08JUL2003	-6	4		
		DAY 1	14JUL2003	1	4		
		DAY 8	21JUL2003	8	4	0	4
		DAY 15	29JUL2003	16	4	0	4
		DAY 22	05AUG2003	23	4	0	4
		DAY 29	12AUG2003	30	4	0	4
		DAY 36	19AUG2003	37	4	0	4
		DAY 43	26AUG2003	44	4	0	4
		DAY 50	02SEP2003	51	4	0	4
		DAY 57	09SEP2003	58	4	0	4
	E0029001	SCREEN	24SEP2002	-7	5		
		DAY 1	01OCT2002	1	5		
		DAY 8	09OCT2002	9	5	0	4
	E0029014	SCREEN	28JAN2003	-7	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0029014	DAY 1	04FEB2003	1	5		
		DAY 8	11FEB2003	8	4	-1	3
		DAY 15	18FEB2003	15	3	-2	2
		DAY 22	25FEB2003	22	3	-2	2
		DAY 29	06MAR2003	31	4	-1	3
		DAY 36	11MAR2003	36	5	0	4
		DAY 43	20MAR2003	45	4	-1	1
		DAY 50	27MAR2003	52	5	0	4
		DAY 57	01APR2003	57	4	-1	3
	E0029023	SCREEN	11MAR2003	-28	5		
		DAY 1	08APR2003	1	5		
		DAY 8	15APR2003	8	5	0	4
		DAY 15	22APR2003	15	5	0	4
		DAY 22	01MAY2003	24	5	0	4
		DAY 36	12MAY2003	35	5	0	4
		DAY 43	20MAY2003	43	5	0	5
		DAY 50	29MAY2003	52	5	0	4
		DAY 57	10JUN2003	64	5	0	4
	E0029032	SCREEN	22MAY2003	-19	6		
		DAY 1	10JUN2003	1	6		
		DAY 8	17JUN2003	8	6	0	4
		DAY 22	01JUL2003	22	6	0	5
	E0029033	SCREEN	27MAY2003	-6	5		
		DAY 1	02JUN2003	1	5		
		DAY 8	09JUN2003	8	5	0	4
		DAY 15	16JUN2003	15	4	-1	3
		DAY 22	23JUN2003	22	5	0	4
		DAY 29	30JUN2003	29	5	0	4

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0029039	SCREEN		10JUL2003	-5	6		
		DAY 1		15JUL2003	1	6		
		DAY 8		23JUL2003	9	5	-1	3
		DAY 15		28JUL2003	14	5	-1	3
	E0030003	SCREEN		03DEC2002	-13	5		
		DAY 1		16DEC2002	1	5		
		DAY 8		23DEC2002	8	5	0	4
		DAY 8	*	24DEC2002	9	5	0	4
	E0030009	SCREEN		10JAN2003	-13	5		
		DAY 1		23JAN2003	1	5		
		DAY 8		29JAN2003	7	5	0	4
		DAY 15		07FEB2003	16	5	0	4
		DAY 36		27FEB2003	36	5	0	4
		DAY 43		06MAR2003	43	5	0	4
		DAY 50		12MAR2003	49	5	0	4
		DAY 57		19MAR2003	56	5	0	4
	E0030016	SCREEN		21FEB2003	-10	5		
		DAY 1		03MAR2003	1	5		
		DAY 8		10MAR2003	8	5	0	3
		DAY 15		17MAR2003	15	5	0	4
		DAY 22		25MAR2003	23	5	0	4
		DAY 29		02APR2003	31	5	0	4
		DAY 36		09APR2003	38	4	-1	3
		DAY 50		22APR2003	51	4	-1	3
	E0030021	SCREEN		13MAY2003	-7	4		
		DAY 1		20MAY2003	1	4		
		DAY 8		27MAY2003	8	3	-1	3
		DAY 15		03JUN2003	15	2	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0030021	DAY 22	10JUN2003	22	2	-2	1
		DAY 29	17JUN2003	29	3	-1	2
	E0031001	SCREEN	14NOV2002	-7	4		
		DAY 1	21NOV2002	1	4		
		DAY 8	27NOV2002	7	4	0	3
		DAY 15	05DEC2002	15	4	0	3
		DAY 22	11DEC2002	21	4	0	3
		DAY 29	20DEC2002	30	4	0	3
	E0031017	SCREEN	25MAR2003	-7	4		
		DAY 1	01APR2003	1	4		
		DAY 8	07APR2003	7	4	0	3
		DAY 15	15APR2003	15	4	0	3
		DAY 22	22APR2003	22	4	0	3
		DAY 29	29APR2003	29	4	0	4
	E0031018	SCREEN	01APR2003	-9	4		
		DAY 1	10APR2003	1	4		
		DAY 8	17APR2003	8	4	0	3
		DAY 15	24APR2003	15	3	-1	3
	E0031023	SCREEN	21APR2003	-8	4		
		DAY 1	29APR2003	1	4		
		DAY 8	07MAY2003	9	4	0	4
		DAY 15	13MAY2003	15	4	0	4
		DAY 22	20MAY2003	22	4	0	3
		DAY 29	27MAY2003	29	4	0	3
		DAY 36	04JUN2003	37	4	0	3
		DAY 43	10JUN2003	43	4	0	3
		DAY 50	17JUN2003	50	4	0	3
		DAY 57	24JUN2003	57	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0033001	SCREEN	19DEC2002	-21	6		
		DAY 1	09JAN2003	1	6		
		DAY 8	16JAN2003	8	6	0	4
		DAY 15	23JAN2003	15	6	0	5
		DAY 22	03FEB2003	26	6	0	5
	E0033004	SCREEN	08JAN2003	-9	5		
		DAY 1	17JAN2003	1	5		
		DAY 8	24JAN2003	8	4	-1	3
		DAY 15	31JAN2003	15	3	-2	3
		DAY 22	07FEB2003	22	2	-3	2
		DAY 29	14FEB2003	29	2	-3	2
		DAY 36	21FEB2003	36	2	-3	2
		DAY 43	28FEB2003	43	2	-3	2
		DAY 50	07MAR2003	50	4	-1	3
		DAY 57	14MAR2003	57	4	-1	4
	E0033010	SCREEN	22JAN2003	-13	4		
		DAY 1	04FEB2003	1	4		
		DAY 8	11FEB2003	8	4	0	4
		DAY 15	20FEB2003	17	4	0	4
		DAY 22	27FEB2003	24	4	0	3
		DAY 29	04MAR2003	29	4	0	4
		DAY 36	14MAR2003	39	4	0	4
	E0033014	SCREEN	12MAR2003	-7	4		
		DAY 1	19MAR2003	1	4		
		DAY 8	26MAR2003	8	4	0	4
		DAY 15	03APR2003	16	4	0	4
		DAY 22	11APR2003	24	4	0	4
		DAY 29	16APR2003	29	5	1	4
		DAY 36	21APR2003	34	5	1	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0035002	SCREEN	14NOV2002	-7	4		
		DAY 1	21NOV2002	1	4		
		DAY 8	27NOV2002	7	4	0	4
		DAY 15	05DEC2002	15	4	0	3
		DAY 22	12DEC2002	22	4	0	3
	E0035007	SCREEN	13DEC2002	-6	3		
		DAY 1	19DEC2002	1	3		
		DAY 8	26DEC2002	8	3	0	2
		DAY 15	02JAN2003	15	3	0	2
		DAY 22	09JAN2003	22	3	0	2
		DAY 29	17JAN2003	30	4	1	5
		DAY 36	23JAN2003	36	4	1	3
		DAY 43	30JAN2003	43	4	1	3
		DAY 50	06FEB2003	50	4	1	3
		DAY 57	11FEB2003	55	4	1	3
	E0035011	SCREEN	09JAN2003	-26	4		
		DAY 1	04FEB2003	1	4		
		DAY 8	11FEB2003	8	4	0	4
		DAY 15	18FEB2003	15	4	0	3
		DAY 22	25FEB2003	22	4	0	3
		DAY 29	04MAR2003	29	4	0	3
		DAY 36	11MAR2003	36	3	-1	2
		DAY 43	18MAR2003	43	3	-1	3
		DAY 50	25MAR2003	50	3	-1	3
		DAY 57	01APR2003	57	3	-1	3
	E0035020	SCREEN	11APR2003	-7	4		
		DAY 1	18APR2003	1	4		
		DAY 8	25APR2003	8	4	0	3
		DAY 15	01MAY2003	14	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0035020	DAY 22	09MAY2003	22	4	0	3
		DAY 29	15MAY2003	28	4	0	3
		DAY 36	23MAY2003	36	4	0	3
		DAY 43	30MAY2003	43	4	0	3
		DAY 50	06JUN2003	50	4	0	3
		DAY 57	13JUN2003	57	4	0	3
	E0037003	SCREEN	23JAN2003	-7	4		
		DAY 1	30JAN2003	1	4		
		DAY 8	06FEB2003	8	4	0	4
		DAY 15	13FEB2003	15	4	0	4
		DAY 22	20FEB2003	22	4	0	4
	E0037004	SCREEN	06FEB2003	-7	4		
		DAY 1	13FEB2003	1	4		
		DAY 8	21FEB2003	9	4	0	3
		DAY 15	27FEB2003	15	4	0	4
		DAY 22	06MAR2003	22	3	-1	3
		DAY 29	13MAR2003	29	3	-1	2
		DAY 36	20MAR2003	36	3	-1	3
		DAY 43	28MAR2003	44	3	-1	2
		DAY 50	04APR2003	51	3	-1	2
		DAY 57	10APR2003	57	3	-1	2
	E0039007	SCREEN	25NOV2002	-9	4		
		DAY 1	04DEC2002	1	4		
		DAY 8	11DEC2002	8	5	1	4
		DAY 15	18DEC2002	15	4	0	3
		DAY 22	23DEC2002	20	3	-1	3
		DAY 29	30DEC2002	27	3	-1	3
		DAY 36	08JAN2003	36	4	0	3
		DAY 43	15JAN2003	43	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0039007	DAY 50	22JAN2003	50	4	0	3
		DAY 57	29JAN2003	57	3	-1	3
	E0039022	SCREEN	04FEB2003	-21	4		
		DAY 1	25FEB2003	1	4		
		DAY 8	06MAR2003	10	3	-1	3
		DAY 15	11MAR2003	15	2	-2	2
		DAY 22	18MAR2003	22	4	0	4
		DAY 29	25MAR2003	29	3	-1	3
		DAY 36	01APR2003	36	2	-2	2
		DAY 43	07APR2003	42	1	-3	1
		DAY 50	15APR2003	50	2	-2	1
		DAY 57	24APR2003	59	3	-1	2
	E0039023	SCREEN	05FEB2003	-19	4		
		DAY 1	24FEB2003	1	4		
		DAY 8	03MAR2003	8	4	0	4
	E0039030	SCREEN	12MAR2003	-12	4		
		DAY 1	24MAR2003	1	4		
		DAY 8	31MAR2003	8	4	0	4
		DAY 15	07APR2003	15	1	-3	1
		DAY 22	14APR2003	22	1	-3	1
		DAY 29	21APR2003	29	1	-3	1
		DAY 36	28APR2003	36	1	-3	1
		DAY 43	05MAY2003	43	1	-3	1
		DAY 50	13MAY2003	51	1	-3	1
		DAY 57	19MAY2003	57	1	-3	1
	E0039031	SCREEN	05MAR2003	-19	4		
		DAY 1	24MAR2003	1	5		
		DAY 8	31MAR2003	8	4	-1	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0039031	DAY 15	07APR2003	15	3	-2	3
		DAY 22	15APR2003	23	1	-4	1
		DAY 29	21APR2003	29	1	-4	1
		DAY 36	28APR2003	36	1	-4	1
		DAY 43	05MAY2003	43	2	-3	2
		DAY 50	13MAY2003	51	4	-1	5
		DAY 57	20MAY2003	58	1	-4	1
	E0039037	SCREEN	26MAR2003	-21	5		
		DAY 1	16APR2003	1	5		
		DAY 8	23APR2003	8	5	0	4
		DAY 15	01MAY2003	16	5	0	4
		DAY 22	07MAY2003	22	2	-3	2
		DAY 29	15MAY2003	30	2	-3	2
		DAY 36	21MAY2003	36	3	-2	2
		DAY 43	28MAY2003	43	3	-2	3
		DAY 50	05JUN2003	51	2	-3	2
		DAY 57	12JUN2003	58	3	-2	3
	E0039038	SCREEN	26MAR2003	-28	4		
		DAY 1	23APR2003	1	4		
		DAY 8	30APR2003	8	4	0	4
		DAY 22	15MAY2003	23	4	0	4
		DAY 29	21MAY2003	29	3	-1	2
		DAY 36	29MAY2003	37	3	-1	2
	E0039047	SCREEN	12MAY2003	-7	4		
		DAY 1	19MAY2003	1	4		
		DAY 8	27MAY2003	9	3	-1	3
		DAY 15	03JUN2003	16	3	-1	2
		DAY 22	09JUN2003	22	4	0	3
		DAY 29	16JUN2003	29	4	0	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0039047	DAY 36	23JUN2003	36	1	-3	1
		DAY 43	30JUN2003	43	3	-1	2
		DAY 50	07JUL2003	50	1	-3	1
		DAY 57	14JUL2003	57	2	-2	1
	E0039059	SCREEN	03JUL2003	-8	4		
		DAY 1	11JUL2003	1	4		
		DAY 8	18JUL2003	8	3	-1	2
		DAY 15	25JUL2003	15	2	-2	1
		DAY 22	01AUG2003	22	2	-2	1
		DAY 29	07AUG2003	28	1	-3	1
		DAY 36	15AUG2003	36	1	-3	1
		DAY 43	21AUG2003	42	1	-3	1
		DAY 50	29AUG2003	50	1	-3	1
		DAY 57	05SEP2003	57	1	-3	1
	E0041007	SCREEN	05MAR2003	-8	3		
		DAY 1	13MAR2003	1	3		
		DAY 8	20MAR2003	8	4	1	4
		DAY 15	27MAR2003	15	4	1	3
		DAY 22	03APR2003	22	3	0	4
		DAY 29	10APR2003	29	4	1	4
		DAY 36	17APR2003	36	4	1	4
		DAY 43	25APR2003	44	4	1	4
		DAY 50	01MAY2003	50	4	1	4
		DAY 57	08MAY2003	57	4	1	4
	E0041010	SCREEN	23APR2003	-7	3		
		DAY 1	30APR2003	1	4		
		DAY 8	08MAY2003	9	4	0	4
		DAY 15	14MAY2003	15	4	0	4
		DAY 22	21MAY2003	22	4	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR I)	E0041010	DAY 29	28MAY2003	29	4	0	4
		DAY 36	04JUN2003	36	4	0	4
		DAY 43	11JUN2003	43	5	1	6
	E0041011	SCREEN	15MAY2003	-7	4		
		DAY 1	22MAY2003	1	4		
		DAY 8	02JUN2003	12	3	-1	2
		DAY 15	06JUN2003	16	4	0	3
		DAY 22	16JUN2003	26	4	0	3
		DAY 29	20JUN2003	30	4	0	4
		DAY 36	26JUN2003	36	4	0	4
		DAY 43	03JUL2003	43	4	0	4
		DAY 50	10JUL2003	50	4	0	4
		DAY 57	17JUL2003	57	4	0	4
	E0041012	SCREEN	05JUN2003	-14	4		
		DAY 1	19JUN2003	1	4		
		DAY 8	26JUN2003	8	4	0	3
		DAY 15	03JUL2003	15	4	0	3
		DAY 22	10JUL2003	22	3	-1	4
		DAY 29	17JUL2003	29	4	0	3
		DAY 36	24JUL2003	36	4	0	3
		DAY 43	31JUL2003	43	4	0	4
		DAY 50	07AUG2003	50	4	0	4
		DAY 57	14AUG2003	57	4	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0001004	SCREEN		24APR2003	-7	4		
		DAY 1		01MAY2003	1	4		
		DAY 8		09MAY2003	9	2	-2	1
		DAY 15		16MAY2003	16	1	-3	1
		DAY 22		23MAY2003	23	1	-3	1
		DAY 29		29MAY2003	29	1	-3	1
		DAY 36		06JUN2003	37	2	-2	1
		DAY 50	*	17JUN2003	48	1	-3	1
		DAY 50		20JUN2003	51	3	-1	2
		DAY 57		27JUN2003	58	1	-3	1
	E0005023	SCREEN		28JAN2003	-8	5		
		DAY 1		05FEB2003	1	5		
		DAY 8		13FEB2003	9	2	-3	2
		DAY 15		20FEB2003	16	2	-3	2
		DAY 22		27FEB2003	23	2	-3	1
		DAY 29		06MAR2003	30	2	-3	2
		DAY 36		13MAR2003	37	2	-3	1
		DAY 43		18MAR2003	42	2	-3	1
		DAY 50		26MAR2003	50	1	-4	1
		DAY 57		01APR2003	56	2	-3	1
	E0005034	SCREEN		08APR2003	-7	4		
		DAY 1		15APR2003	1	4		
		DAY 8		23APR2003	9	4	0	4
		DAY 15		01MAY2003	17	4	0	3
		DAY 22		06MAY2003	22	4	0	4
		DAY 29		13MAY2003	29	4	0	4
		DAY 36		22MAY2003	38	4	0	3
		DAY 43		28MAY2003	44	4	0	3
		DAY 50		05JUN2003	52	5	1	4
		DAY 57		09JUN2003	56	5	1	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0005041	SCREEN	17JUN2003	-7	5		
		DAY 1	24JUN2003	1	4		
		DAY 8	01JUL2003	8	2	-2	2
		DAY 15	08JUL2003	15	2	-2	2
		DAY 22	16JUL2003	23	2	-2	2
		DAY 29	22JUL2003	29	2	-2	2
		DAY 36	28JUL2003	35	3	-1	2
		DAY 43	04AUG2003	42	2	-2	1
		DAY 50	11AUG2003	49	2	-2	1
		DAY 57	18AUG2003	56	2	-2	1
	E0007004	SCREEN	24JAN2003	-6	4		
		DAY 1	30JAN2003	1	5		
		DAY 8	07FEB2003	9	5	0	4
		DAY 15	12FEB2003	14	4	-1	4
	E0007010	SCREEN	11APR2003	-7	4		
		DAY 1	18APR2003	1	4		
		DAY 8	25APR2003	8	4	0	4
		DAY 15	02MAY2003	15	2	-2	1
		DAY 22	09MAY2003	22	3	-1	2
		DAY 29	16MAY2003	29	1	-3	1
		DAY 36	23MAY2003	36	2	-2	1
		DAY 43	29MAY2003	42	3	-1	3
		DAY 50	06JUN2003	50	4	0	4
		DAY 57	16JUN2003	60	3	-1	3
	E0007012	SCREEN	02MAY2003	-14	4		
		DAY 1	16MAY2003	1	4		
		DAY 8	23MAY2003	8	4	0	4
		DAY 15	29MAY2003	14	4	0	3
		DAY 22	06JUN2003	22	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0007012	DAY 29		13JUN2003	29	3	-1	2
		DAY 36		20JUN2003	36	3	-1	2
		DAY 43		25JUN2003	41	4	0	4
		DAY 43	*	01JUL2003	47	4	0	4
	E0009007	SCREEN		27JAN2003	-7	4		
		DAY 1		03FEB2003	1	5		
		DAY 8		10FEB2003	8	5	0	5
		DAY 15		17FEB2003	15	5	0	5
		DAY 22		25FEB2003	23	5	0	4
		DAY 29		03MAR2003	29	5	0	5
	E0009008	SCREEN		04FEB2003	-8	4		
		DAY 1		12FEB2003	1	4		
		DAY 8		19FEB2003	8	4	0	4
		DAY 15		25FEB2003	14	4	0	3
		DAY 22		04MAR2003	21	2	-2	1
		DAY 29		11MAR2003	28	4	0	4
		DAY 36		18MAR2003	35	4	0	3
		DAY 43		26MAR2003	43	3	-1	2
		DAY 50		03APR2003	51	1	-3	1
		DAY 57		08APR2003	56	1	-3	1
	E0011001	SCREEN		25OCT2002	-7	4		
		DAY 1		01NOV2002	1	4		
		DAY 8		07NOV2002	7	4	0	4
		DAY 15		14NOV2002	14	4	0	3
		DAY 22		21NOV2002	21	4	0	3
		DAY 29		27NOV2002	27	4	0	3
		DAY 36		05DEC2002	35	4	0	3
		DAY 43		12DEC2002	42	4	0	3
		DAY 50		19DEC2002	49	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0011001	DAY 57	26DEC2002	56	3	-1	2
	E0011011	SCREEN	12FEB2003	-8	4		
		DAY 1	20FEB2003	1	4		
		DAY 8	26FEB2003	7	4	0	3
		DAY 15	05MAR2003	14	4	0	3
		DAY 22	12MAR2003	21	4	0	3
		DAY 29	19MAR2003	28	4	0	3
		DAY 36	26MAR2003	35	3	-1	2
		DAY 43	02APR2003	42	4	0	5
		DAY 50	09APR2003	49	4	0	4
		DAY 57	16APR2003	56	3	-1	3
	E0011013	SCREEN	25MAR2003	-23	4		
		DAY 1	17APR2003	1	4		
		DAY 8	24APR2003	8	4	0	4
		DAY 15	01MAY2003	15	4	0	4
		DAY 22	08MAY2003	22	4	0	4
		DAY 29	15MAY2003	29	4	0	4
		DAY 36	22MAY2003	36	4	0	4
		DAY 43	29MAY2003	43	4	0	3
		DAY 50	05JUN2003	50	4	0	4
		DAY 57	12JUN2003	57	4	0	3
	E0011014	SCREEN	31MAR2003	-7	4		
		DAY 1	07APR2003	1	4		
		DAY 8	14APR2003	8	4	0	3
		DAY 29	08MAY2003	32	4	0	3
	E0011021	SCREEN	15MAY2003	-7	4		
		DAY 1	22MAY2003	1	4		
		DAY 8	29MAY2003	8	4	0	4

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0011021	DAY 15	05JUN2003	15	4	0	3
		DAY 22	12JUN2003	22	4	0	3
		DAY 29	20JUN2003	30	4	0	3
		DAY 36	27JUN2003	37	3	-1	2
		DAY 43	02JUL2003	42	3	-1	2
		DAY 50	10JUL2003	50	3	-1	5
		DAY 57	21JUL2003	61	2	-2	1
	E0013008	SCREEN	19MAR2003	-7	4		
		DAY 1	26MAR2003	1	5		
		DAY 8	02APR2003	8	5	0	4
		DAY 15	09APR2003	15	5	0	4
		DAY 22	17APR2003	23	4	-1	4
		DAY 29	23APR2003	29	5	0	4
		DAY 36	30APR2003	36	5	0	4
		DAY 43	07MAY2003	43	5	0	4
		DAY 50	12MAY2003	48	4	-1	4
		DAY 57	19MAY2003	55	4	-1	4
	E0014001	SCREEN	18FEB2003	-8	4		
		DAY 1	26FEB2003	1	5		
		DAY 8	05MAR2003	8	4	-1	3
		DAY 15	12MAR2003	15	2	-3	1
		DAY 22	19MAR2003	22	1	-4	1
		DAY 29	25MAR2003	28	2	-3	1
		DAY 36	01APR2003	35	2	-3	1
	E0014013	SCREEN	20MAY2003	-7	5		
		DAY 1	27MAY2003	1	5		
		DAY 8	04JUN2003	9	5	0	4
		DAY 15	13JUN2003	18	5	0	4
		DAY 22	18JUN2003	23	4	-1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0014013	DAY 29		25JUN2003	30	5	0	4
		DAY 36		02JUL2003	37	4	-1	2
		DAY 43		10JUL2003	45	4	-1	4
		DAY 50		16JUL2003	51	5	0	4
		DAY 57		23JUL2003	58	3	-2	2
	E0014014	SCREEN		03JUN2003	-7	4		
		DAY 1		10JUN2003	1	4		
		DAY 8		18JUN2003	9	4	0	3
		DAY 15		24JUN2003	15	4	0	3
		DAY 22		03JUL2003	24	3	-1	1
		DAY 29		10JUL2003	31	2	-2	1
		DAY 36		18JUL2003	39	3	-1	2
		DAY 50		30JUL2003	51	3	-1	2
		DAY 57		06AUG2003	58	2	-2	1
	E0015004	SCREEN		25NOV2002	-7	5		
		DAY 1		02DEC2002	1	5		
		DAY 8		11DEC2002	10	5	0	4
		DAY 15		18DEC2002	17	5	0	4
		DAY 22		27DEC2002	26	5	0	4
		DAY 36		06JAN2003	36	5	0	4
		DAY 36	*	09JAN2003	39	5	0	4
		DAY 43		17JAN2003	47	5	0	4
		DAY 57		29JAN2003	59	5	0	3
	E0018005	SCREEN		10DEC2002	-10	4		
		DAY 1		20DEC2002	1	4		
		DAY 8		27DEC2002	8	4	0	3
		DAY 8	*	31DEC2002	12	3	-1	3
		DAY 22		10JAN2003	22	2	-2	2
		DAY 29		17JAN2003	29	2	-2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0018005	DAY 36	24JAN2003	36	2	-2	1
		DAY 43	31JAN2003	43	1	-3	1
		DAY 50	07FEB2003	50	1	-3	1
		DAY 57	14FEB2003	57	2	-2	1
	E0018012	SCREEN	17JAN2003	-7	4		
		DAY 1	24JAN2003	1	4		
		DAY 8	30JAN2003	7	3	-1	3
		DAY 15	07FEB2003	15	2	-2	2
		DAY 22	14FEB2003	22	2	-2	1
		DAY 29	21FEB2003	29	3	-1	3
		DAY 36	26FEB2003	34	4	0	4
	E0019019	SCREEN	14JAN2003	-9	4		
		DAY 1	23JAN2003	1	4		
		DAY 8	30JAN2003	8	4	0	3
		DAY 15	06FEB2003	15	4	0	4
	E0019033	SCREEN	10MAR2003	-8	4		
		DAY 1	18MAR2003	1	4		
		DAY 8	27MAR2003	10	4	0	4
		DAY 15	03APR2003	17	4	0	4
		DAY 22	10APR2003	24	5	1	5
		DAY 29	14APR2003	28	5	1	5
		DAY 36	22APR2003	36	5	1	5
		DAY 43	01MAY2003	45	5	1	4
		DAY 50	08MAY2003	52	5	1	4
		DAY 57	15MAY2003	59	5	1	4
	E0019038	SCREEN	10APR2003	-14	4		
		DAY 1	24APR2003	1	4		
		DAY 8	01MAY2003	8	3	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0019038	DAY 15	07MAY2003	14	4	0	4
		DAY 22	14MAY2003	21	4	0	4
		DAY 29	21MAY2003	28	4	0	3
		DAY 36	28MAY2003	35	3	-1	2
		DAY 43	04JUN2003	42	3	-1	2
		DAY 50	11JUN2003	49	4	0	3
		DAY 57	18JUN2003	56	4	0	3
	E0019046	SCREEN	19JUN2003	-7	5		
		DAY 1	26JUN2003	1	5		
		DAY 8	03JUL2003	8	4	-1	3
		DAY 15	10JUL2003	15	2	-3	2
		DAY 22	17JUL2003	22	2	-3	2
		DAY 29	24JUL2003	29	2	-3	1
		DAY 36	30JUL2003	35	2	-3	1
		DAY 50	14AUG2003	50	2	-3	2
		DAY 57	21AUG2003	57	2	-3	1
	E0019047	SCREEN	26JUN2003	-12	4		
		DAY 1	08JUL2003	1	4		
		DAY 8	17JUL2003	10	3	-1	2
		DAY 15	24JUL2003	17	2	-2	2
		DAY 22	31JUL2003	24	4	0	4
		DAY 29	07AUG2003	31	2	-2	2
		DAY 36	14AUG2003	38	1	-3	1
		DAY 43	21AUG2003	45	1	-3	1
		DAY 50	28AUG2003	52	1	-3	1
		DAY 57	04SEP2003	59	1	-3	1
	E0019048	SCREEN	03JUL2003	-7	4		
		DAY 1	10JUL2003	1	4		
		DAY 8	17JUL2003	8	4	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0019048	DAY 15	22JUL2003	13	4	0	4
		DAY 22	31JUL2003	22	4	0	4
		DAY 29	07AUG2003	29	4	0	4
		DAY 36	14AUG2003	36	4	0	3
		DAY 43	21AUG2003	43	4	0	3
		DAY 50	28AUG2003	50	4	0	4
		DAY 57	03SEP2003	56	4	0	4
	E0022006	SCREEN	21OCT2002	-22	4		
		DAY 1	12NOV2002	1	4		
		DAY 8	19NOV2002	8	4	0	3
		DAY 15	26NOV2002	15	4	0	3
		DAY 22	03DEC2002	22	3	-1	2
		DAY 29	10DEC2002	29	2	-2	2
		DAY 36	17DEC2002	36	2	-2	2
		DAY 43	24DEC2002	43	1	-3	1
		DAY 50	31DEC2002	50	1	-3	1
		DAY 57	07JAN2003	57	1	-3	1
	E0022047	SCREEN	21MAR2003	-7	5		
		DAY 1	28MAR2003	1	5		
		DAY 8	04APR2003	8	5	0	3
		DAY 15	11APR2003	15	5	0	3
		DAY 22	17APR2003	21	4	-1	3
		DAY 29	25APR2003	29	4	-1	3
		DAY 36	02MAY2003	36	4	-1	3
		DAY 43	09MAY2003	43	4	-1	3
		DAY 50	16MAY2003	50	4	-1	3
		DAY 57	23MAY2003	57	4	-1	3
	E0022075	SCREEN	25JUN2003	-13	4		
		DAY 1	08JUL2003	1	4		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0022075	DAY 8	15JUL2003	8	4	0	4
		DAY 15	22JUL2003	15	4	0	3
		DAY 22	29JUL2003	22	4	0	3
		DAY 29	05AUG2003	29	4	0	3
		DAY 36	12AUG2003	36	4	0	4
		DAY 43	19AUG2003	43	4	0	4
		DAY 50	26AUG2003	50	4	0	4
		DAY 57	03SEP2003	58	4	0	4
	E0023012	SCREEN	31JAN2003	-6	5		
		DAY 1	06FEB2003	1	5		
		DAY 8	17FEB2003	12	5	0	3
		DAY 15	20FEB2003	15	5	0	5
		DAY 22	28FEB2003	23	4	-1	2
		DAY 29	07MAR2003	30	4	-1	4
		DAY 36	14MAR2003	37	5	0	5
		DAY 43	21MAR2003	44	5	0	4
		DAY 50	28MAR2003	51	5	0	5
		DAY 57	04APR2003	58	4	-1	3
	E0023016	SCREEN	15MAY2003	-7	5		
		DAY 1	22MAY2003	1	5		
		DAY 8	29MAY2003	8	5	0	3
		DAY 15	05JUN2003	15	5	0	3
		DAY 22	12JUN2003	22	5	0	3
		DAY 29	19JUN2003	29	5	0	3
		DAY 36	26JUN2003	36	5	0	3
		DAY 43	01JUL2003	41	5	0	3
		DAY 50	14JUL2003	54	6	1	5
		DAY 57	17JUL2003	57	5	0	5
	E0023018	SCREEN	18MAR2003	-9	5		

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0023018	DAY 1		27MAR2003	1	5		
		DAY 8		03APR2003	8	5	0	4
		DAY 15		10APR2003	15	5	0	3
		DAY 22		16APR2003	21	5	0	3
		DAY 29		24APR2003	29	4	-1	2
		DAY 36		02MAY2003	37	3	-2	2
		DAY 43		12MAY2003	47	4	-1	3
		DAY 50		15MAY2003	50	4	-1	3
		DAY 57		22MAY2003	57	2	-3	2
	E0023036	SCREEN		10JUN2003	-10	5		
		DAY 1		20JUN2003	1	5		
		DAY 8		26JUN2003	7	5	0	4
		DAY 15		02JUL2003	13	5	0	4
		DAY 22		09JUL2003	20	5	0	2
		DAY 29		16JUL2003	27	5	0	2
		DAY 29	*	22JUL2003	33	5	0	3
		DAY 36		29JUL2003	40	5	0	3
		DAY 43		05AUG2003	47	4	-1	3
		DAY 57		13AUG2003	55	4	-1	3
	E0023046	SCREEN		11JUL2003	-12	5		
		DAY 1		23JUL2003	1	5		
		DAY 8		01AUG2003	10	5	0	4
		DAY 15		08AUG2003	17	5	0	3
		DAY 22		14AUG2003	23	5	0	3
		DAY 29		22AUG2003	31	5	0	3
		DAY 36		28AUG2003	37	5	0	3
		DAY 43		04SEP2003	44	5	0	3
		DAY 50		11SEP2003	51	5	0	3
		DAY 57		16SEP2003	56	5	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0026006	SCREEN		31DEC2002	-8	5		
		DAY 1		08JAN2003	1	5		
		DAY 8		15JAN2003	8	2	-3	1
		DAY 15		22JAN2003	15	5	0	4
		DAY 22		29JAN2003	22	4	-1	3
		DAY 29		05FEB2003	29	2	-3	1
		DAY 36		12FEB2003	36	2	-3	1
		DAY 43		19FEB2003	43	3	-2	2
	E0026021	SCREEN		14APR2003	-9	5		
		DAY 1		23APR2003	1	5		
		DAY 8		29APR2003	7	4	-1	3
	E0026027	SCREEN		05JUN2003	-14	4		
		DAY 1		19JUN2003	1	5		
	E0029002		*	05NOV2002		5		
			*	12NOV2002		5		
	E0029004	SCREEN		13NOV2002	-6	5		
		DAY 1		19NOV2002	1	5		
		DAY 8		26NOV2002	8	5	0	4
		DAY 15		04DEC2002	16	4	-1	2
		DAY 22		12DEC2002	24	4	-1	2
		DAY 36		26DEC2002	38	4	-1	2
		DAY 43		02JAN2003	45	4	-1	2
		DAY 50		09JAN2003	52	3	-2	1
		DAY 57		16JAN2003	59	4	-1	3
	E0029013	SCREEN		27JAN2003	-23	4		
		DAY 1		19FEB2003	1	5		
		DAY 8		25FEB2003	7	4	-1	3

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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0029013	DAY 15		04MAR2003	14	3	-2	2
		DAY 22		13MAR2003	23	2	-3	1
		DAY 29		20MAR2003	30	2	-3	1
		DAY 36		25MAR2003	35	2	-3	1
		DAY 43		31MAR2003	41	2	-3	1
		DAY 50		10APR2003	51	2	-3	1
	E0029019	SCREEN		24FEB2003	-7	4		
		DAY 1		03MAR2003	1	4		
		DAY 8		10MAR2003	8	3	-1	2
		DAY 15		17MAR2003	15	4	0	4
	E0029024	SCREEN		11MAR2003	-6	4		
		DAY 1		17MAR2003	1	4		
		DAY 8		25MAR2003	9	4	0	4
		DAY 15		02APR2003	17	4	0	3
		DAY 22		09APR2003	24	4	0	4
		DAY 29		17APR2003	32	4	0	3
		DAY 36		24APR2003	39	4	0	3
		DAY 50		05MAY2003	50	4	0	3
		DAY 57	*	12MAY2003	57	3	-1	3
		DAY 57		20MAY2003	65	2	-2	1
	E0029038	SCREEN		30JUN2003	-7	4		
		DAY 1		07JUL2003	1	4		
	E0031004	SCREEN		12DEC2002	-7	4		
		DAY 1		19DEC2002	1	4		
		DAY 8		27DEC2002	9	4	0	3
		DAY 15		03JAN2003	16	4	0	3
		DAY 22		09JAN2003	22	4	0	3
		DAY 29		16JAN2003	29	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0031004	DAY 36		23JAN2003	36	3	-1	2
		DAY 43		30JAN2003	43	3	-1	2
		DAY 50		06FEB2003	50	3	-1	2
		DAY 57		13FEB2003	57	2	-2	1
	E0031013	SCREEN		06MAR2003	-7	5		
		DAY 1		13MAR2003	1	4		
		DAY 8		20MAR2003	8	4	0	4
		DAY 15		27MAR2003	15	4	0	3
		DAY 22		04APR2003	23	3	-1	3
		DAY 29		11APR2003	30	3	-1	2
		DAY 36		17APR2003	36	3	-1	2
		DAY 43		24APR2003	43	3	-1	2
		DAY 50		01MAY2003	50	4	0	3
		DAY 57		08MAY2003	57	3	-1	2
	E0031016	SCREEN		17MAR2003	-7	4		
		DAY 1		24MAR2003	1	4		
		DAY 8		31MAR2003	8	4	0	3
		DAY 15		07APR2003	15	4	0	3
		DAY 22		14APR2003	22	4	0	4
	E0031019	SCREEN		03APR2003	-8	4		
		DAY 1		11APR2003	1	5		
		DAY 8		18APR2003	8	5	0	4
		DAY 15		25APR2003	15	4	-1	4
		DAY 22		02MAY2003	22	4	-1	4
		DAY 29		09MAY2003	29	4	-1	3
		DAY 29	*	12MAY2003	32	3	-2	3
	E0031022	SCREEN		21APR2003	-7	4		
		DAY 1		28APR2003	1	4		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0031022	DAY 8	06MAY2003	9	4	0	3
		DAY 22	20MAY2003	23	4	0	3
		DAY 29	27MAY2003	30	4	0	3
	E0033007	SCREEN	15JAN2003	-13	5		
		DAY 1	28JAN2003	1	5		
		DAY 8	04FEB2003	8	5	0	4
		DAY 15	12FEB2003	16	5	0	4
		DAY 22	20FEB2003	24	5	0	3
		DAY 29	25FEB2003	29	5	0	4
		DAY 36	04MAR2003	36	5	0	4
		DAY 43	13MAR2003	45	5	0	4
		DAY 50	18MAR2003	50	5	0	4
		DAY 57	25MAR2003	57	5	0	4
	E0033013	SCREEN	06FEB2003	-13	4		
		DAY 1	19FEB2003	1	5		
		DAY 8	26FEB2003	8	5	0	4
		DAY 15	05MAR2003	15	4	-1	3
		DAY 22	13MAR2003	23	5	0	4
		DAY 29	19MAR2003	29	5	0	4
		DAY 36	27MAR2003	37	5	0	4
		DAY 43	01APR2003	42	5	0	4
		DAY 50	10APR2003	51	5	0	4
		DAY 57	16APR2003	57	5	0	4
	E0033016	SCREEN	14APR2003	-24	4		
		DAY 1	08MAY2003	1	4		
		DAY 8	13MAY2003	6	4	0	4
		DAY 15	20MAY2003	13	4	0	4
		DAY 22	28MAY2003	21	4	0	4
		DAY 29	09JUN2003	33	3	-1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SEVERITY: 0=NOT ASSESSED, 1=NORMAL, NOT ILL AT ALL, 2=BORDERLINE, MENTALLY ILL, 3=MILDLY ILL, 4=MODERATELY ILL, 5=MARKEDLY ILL, 6=SEVERELY ILL, 7=AMONG THE MOST EXTREMELY ILL SUBJECTS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0033016	DAY 43		17JUN2003	41	3	-1	2
		DAY 43	*	23JUN2003	47	3	-1	2
		DAY 50		27JUN2003	51	2	-2	2
		DAY 57		02JUL2003	56	1	-3	1
	E0033022	SCREEN		25JUN2003	-19	4		
		DAY 1		14JUL2003	1	4		
		DAY 8		23JUL2003	10	3	-1	2
		DAY 15		30JUL2003	17	3	-1	3
		DAY 22		06AUG2003	24	3	-1	3
		DAY 29		11AUG2003	29	2	-2	2
		DAY 36		18AUG2003	36	3	-1	3
		DAY 43		26AUG2003	44	3	-1	3
		DAY 50		04SEP2003	53	4	0	4
		DAY 57		11SEP2003	60	3	-1	3
	E0034007	SCREEN		06MAY2003	-10	5		
		DAY 1		16MAY2003	1	5		
		DAY 8		24MAY2003	9	5	0	4
		DAY 15		02JUN2003	18	5	0	4
		DAY 22		09JUN2003	25	5	0	4
		DAY 29		16JUN2003	32	5	0	4
		DAY 36		20JUN2003	36	5	0	4
		DAY 43		30JUN2003	46	5	0	4
		DAY 50		07JUL2003	53	5	0	4
		DAY 57		14JUL2003	60	5	0	4
	E0035004	SCREEN		22NOV2002	-5	4		
		DAY 1		27NOV2002	1	4		
		DAY 8		04DEC2002	8	4	0	3
	E0035009	SCREEN		20DEC2002	-7	3		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
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Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0035009	DAY 1		27DEC2002	1	3		
		DAY 8		31DEC2002	5	3	0	4
		DAY 15		08JAN2003	13	3	0	3
		DAY 22		15JAN2003	20	3	0	4
		DAY 29		22JAN2003	27	3	0	3
		DAY 36		29JAN2003	34	3	0	2
		DAY 43		05FEB2003	41	3	0	2
		DAY 43	*	11FEB2003	47	3	0	2
		DAY 57		19FEB2003	55	1	-2	1
	E0035010	SCREEN		06JAN2003	-4	3		
		DAY 1		10JAN2003	1	3		
		DAY 8		17JAN2003	8	3	0	4
		DAY 15		24JAN2003	15	3	0	4
		DAY 22		31JAN2003	22	3	0	3
		DAY 29		07FEB2003	29	3	0	4
		DAY 36		14FEB2003	36	3	0	3
		DAY 43		24FEB2003	46	3	0	2
		DAY 50		28FEB2003	50	3	0	2
		DAY 57		06MAR2003	56	3	0	2
	E0035022	SCREEN		01MAY2003	-8	4		
		DAY 1		09MAY2003	1	5		
		DAY 8		15MAY2003	7	5	0	4
		DAY 15		23MAY2003	15	4	-1	2
		DAY 22		30MAY2003	22	4	-1	2
		DAY 29		06JUN2003	29	3	-2	2
		DAY 36		13JUN2003	36	3	-2	2
		DAY 43		20JUN2003	43	2	-3	1
		DAY 50		27JUN2003	50	1	-4	1
		DAY 57		07JUL2003	60	1	-4	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
GENERATED: 12JUL2005 17:39:44 iceadmn3

Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0039003	SCREEN	06NOV2002	-19	4		
		DAY 1	25NOV2002	1	4		
		DAY 8	02DEC2002	8	3	-1	2
		DAY 15	09DEC2002	15	3	-1	1
	E0040001	SCREEN	18JUN2003	-9	4		
		DAY 1	27JUN2003	1	4		
		DAY 8	03JUL2003	7	4	0	4
		DAY 15	11JUL2003	15	4	0	4
		DAY 22	18JUL2003	22	4	0	3
		DAY 29	25JUL2003	29	4	0	3
		DAY 36	01AUG2003	36	4	0	3
		DAY 43	08AUG2003	43	4	0	3
		DAY 50	15AUG2003	50	3	-1	3
		DAY 57	22AUG2003	57	3	-1	3
	E0040004	SCREEN	11JUL2003	-7	4		
		DAY 1	18JUL2003	1	4		
	E0041002	SCREEN	13JAN2003	-8	4		
		DAY 1	21JAN2003	1	4		
		DAY 8	28JAN2003	8	4	0	3
		DAY 15	04FEB2003	15	4	0	3
		DAY 22	11FEB2003	22	3	-1	2
		DAY 29	18FEB2003	29	3	-1	2
		DAY 36	25FEB2003	36	3	-1	2
	E0041005	SCREEN	24FEB2003	-9	4		
		DAY 1	05MAR2003	1	4		
		DAY 8	11MAR2003	7	4	0	4
		DAY 15	19MAR2003	15	4	0	4
		DAY 22	26MAR2003	22	4	0	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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IMPROVEMENT: 0=NOT ASSESSED, 1=VERY MUCH IMPROVED, 2=MUCH IMPROVED, 3=MINIMALLY IMPROVED, 4=NO CHANGE, 5=MINIMALLY WORSE, 6=MUCH WORSE, 7=VERY MUCH WORSE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
GENERATED: 12JUL2005 17:39:44 iceadmn3

Listing 12.2.6.3 Clinical Global Impression (CGI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SEVERITY OF ILLNESS	CHANGE FROM BASELINE IN SEVERITY OF ILLNESS	IMPROVEMENT
PLACEBO (BIPOLAR II)	E0041005	DAY 29	02APR2003	29	4	0	4
		DAY 36	09APR2003	36	3	-1	2
		DAY 43	16APR2003	43	3	-1	2
		DAY 50	23APR2003	50	4	0	3
		DAY 57	30APR2003	57	3	-1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CGI100.SAS
GENERATED: 12JUL2005 17:39:44 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	SCREEN	14JAN2003	-21	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	04FEB2003	1	4		0	0	0	1	2	0	0	0	0	1	0
		DAY 8	12FEB2003	9	5	1	1	1	0	0	2	0	0	0	0	1	0
		DAY 15	19FEB2003	16	1	-3	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	26FEB2003	23	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	05MAR2003	30	3	-1	1	0	0	0	2	0	0	0	0	0	0
		DAY 36	11MAR2003	36	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	18MAR2003	43	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	25MAR2003	50	3	-1	0	1	0	0	2	0	0	0	0	0	0
		DAY 57	02APR2003	58	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0002010	SCREEN	25MAR2003	-10	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 1	04APR2003	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8	10APR2003	7	3	0	0	0	0	0	2	0	0	0	0	1	0
	E0002012	SCREEN	16APR2003	-5	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	21APR2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	29APR2003	9	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	06MAY2003	16	3	0	1	0	0	0	2	0	0	0	0	0	0
		DAY 22	15MAY2003	25	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	21MAY2003	31	3	0	1	0	0	0	2	0	0	0	0	0	0
		DAY 36	28MAY2003	38	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	04JUN2003	45	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	11JUN2003	52	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	16JUN2003	57	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0002015	SCREEN	22MAY2003	-13	3		1	0	0	0	2	0	0	0	0	0	0
		DAY 1	04JUN2003	1	5		1	1	0	0	2	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
OTHER: 0=ABSENT/NORMAL, 1=MILD, 2=MODERTE, 3=SEVERE, 4=EXTREME.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	SCREEN		16JUL2003	-8	5		1	1	0	0	0	2	1	0	0	0	0
		DAY 1		24JUL2003	1	3		1	0	0	0	0	2	0	0	0	0	0
		DAY 8	*	30JUL2003	7	3	0	0	1	0	0	2	0	0	0	0	0	0
		DAY 8		01AUG2003	9	4	1	1	0	0	0	0	1	1	1	0	0	0
	E0003004	SCREEN		03DEC2002	-14	9		0	2	0	2	3	0	0	0	2	0	0
		DAY 1		17DEC2002	1	9		0	0	0	2	2	0	2	0	2	0	1
	E0003005	SCREEN		16DEC2002	-7	7		0	1	0	0	0	0	2	0	4	0	0
		DAY 1		23DEC2002	1	5		0	0	0	0	3	0	1	1	0	0	0
		DAY 8		30DEC2002	8	7	2	1	0	0	0	1	0	1	2	2	0	0
		DAY 15		06JAN2003	15	8	3	1	0	0	0	3	0	2	0	2	0	0
		DAY 22		14JAN2003	23	9	4	2	0	1	0	1	0	2	0	3	0	0
		DAY 29		21JAN2003	30	12	7	2	1	1	0	3	0	1	0	4	0	0
		DAY 36		28JAN2003	37	14	9	0	0	0	0	6	0	1	0	7	0	0
		DAY 43		04FEB2003	44	7	2	0	0	2	0	1	0	0	1	3	0	0
		DAY 50		11FEB2003	51	12	7	2	0	0	0	4	1	1	0	4	0	0
		DAY 57		18FEB2003	58	17	12	1	1	0	1	6	0	2	1	4	1	0
	E0003007	SCREEN		19DEC2002	-14	7		1	1	0	0	0	1	2	0	2	0	0
		DAY 1		02JAN2003	1	10		0	1	0	2	2	0	1	0	4	0	0
		DAY 8		09JAN2003	8	7	-3	1	1	0	0	3	0	0	2	0	0	0
		DAY 15		16JAN2003	15	6	-4	2	1	0	0	3	0	0	0	0	0	0
		DAY 22		23JAN2003	22	7	-3	1	2	0	0	4	0	0	0	0	0	0
		DAY 29		30JAN2003	29	4	-6	0	0	0	0	3	0	1	0	0	0	0
		DAY 43		13FEB2003	43	7	-3	2	1	0	1	0	2	1	0	0	0	0
		DAY 50		20FEB2003	50	6	-4	2	0	0	1	0	2	0	0	1	0	0
		DAY 57		27FEB2003	57	3	-7	1	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	SCREEN	28APR2003	-7	3		0	0	0	0	3	0	0	0	0	0	0
		DAY 1	05MAY2003	1	7		2	2	0	0	2	1	0	0	0	0	0
		DAY 8	13MAY2003	9	3	-4	0	0	0	1	2	0	0	0	0	0	0
		DAY 15	19MAY2003	15	3	-4	0	0	0	0	2	0	1	0	0	0	0
		DAY 22	27MAY2003	23	3	-4	1	0	0	0	1	0	0	0	1	0	0
		DAY 29	04JUN2003	31	9	2	2	1	1	2	0	2	1	0	0	0	0
		DAY 36	10JUN2003	37	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	17JUN2003	44	1	-6	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	24JUN2003	51	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	59	27	20	2	3	0	3	3	5	2	8	1	0	0
	E0004002	DAY 1	01OCT2002	1	12		0	0	0	0	5	0	1	0	5	1	0
		DAY 8	10OCT2002	10	8	-4	0	0	0	0	4	0	0	0	3	1	0
		DAY 15	17OCT2002	17	7	-5	0	0	0	0	4	0	0	1	2	0	0
		DAY 22	22OCT2002	22	6	-6	0	0	0	0	4	0	0	0	2	0	0
		DAY 29	29OCT2002	29	7	-5	0	0	0	0	4	0	0	0	2	1	0
		DAY 36	05NOV2002	36	5	-7	0	0	0	0	2	0	2	0	1	0	0
		DAY 43	12NOV2002	43	6	-6	0	0	0	0	3	0	1	0	2	0	0
		DAY 50	19NOV2002	50	4	-8	0	0	0	0	2	0	0	0	1	1	0
		DAY 57	26NOV2002	57	4	-8	0	0	0	1	2	0	0	0	1	0	0
	E0004013	SCREEN	08JAN2003	-6	6		0	0	0	3	2	0	0	0	0	1	0
		DAY 1	14JAN2003	1	10		1	1	0	0	4	0	1	0	3	0	0
		DAY 8	21JAN2003	8	8	-2	0	0	0	1	4	0	1	0	2	0	0
		DAY 15	30JAN2003	17	7	-3	0	0	0	2	3	0	0	0	2	0	0
		DAY 22	05FEB2003	23	11	1	0	1	0	0	5	2	0	0	3	0	0
	E0004018	SCREEN	12MAR2003	-7	7		0	0	0	1	3	0	1	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	DAY 1		19MAR2003	1	6		1	1	0	1	2	0	1	0	0	0	0
		DAY 8		26MAR2003	8	1	-5	0	0	0	1	0	0	0	0	0	0	0
		DAY 15		02APR2003	15	6	0	0	0	0	1	3	0	0	0	2	0	0
		DAY 22		09APR2003	22	7	1	1	0	0	2	2	0	1	0	1	0	0
		DAY 29		16APR2003	29	6	0	0	0	0	2	2	0	1	0	1	0	0
		DAY 36		23APR2003	36	7	1	0	1	0	2	2	0	1	0	1	0	0
		DAY 43		30APR2003	43	2	-4	0	1	0	1	0	0	0	0	0	0	0
		DAY 50		06MAY2003	49	1	-5	0	0	0	0	1	0	0	0	0	0	0
		DAY 57		13MAY2003	56	4	-2	0	0	0	2	2	0	0	0	0	0	0
	E0004021	SCREEN		07MAY2003	-7	6		0	0	0	2	2	0	1	0	0	1	0
		DAY 1		14MAY2003	1	10		0	0	0	1	4	2	0	0	3	0	0
		DAY 8		21MAY2003	8	12	2	1	0	0	1	4	1	1	1	3	0	0
		DAY 15		28MAY2003	15	7	-3	2	0	0	0	3	0	0	0	2	0	0
		DAY 22		04JUN2003	22	9	-1	1	0	0	1	3	0	0	2	2	0	0
		DAY 29		11JUN2003	29	9	-1	2	1	0	1	2	1	0	1	1	0	0
		DAY 36		18JUN2003	36	4	-6	2	1	0	1	0	0	0	0	0	0	0
		DAY 43		25JUN2003	43	6	-4	2	1	0	1	1	0	0	1	0	0	0
		DAY 50		02JUL2003	50	8	-2	2	0	0	0	3	0	0	2	1	0	0
		DAY 57		09JUL2003	57	8	-2	2	1	0	1	2	0	0	1	1	0	0
	E0005002	DAY 1		03OCT2002	1	5		1	0	0	2	2	0	0	0	0	0	0
		DAY 8		08OCT2002	6	6	1	1	1	0	2	2	0	0	0	0	0	0
		DAY 8	*	14OCT2002	12	5	0	1	0	0	0	0	2	0	0	2	0	0
		DAY 15		21OCT2002	19	8	3	0	0	0	2	2	0	2	0	2	0	0
		DAY 22		28OCT2002	26	3	-2	0	0	0	2	1	0	0	0	0	0	0
		DAY 29		04NOV2002	33	2	-3	0	0	0	2	0	0	0	0	0	0	0
		DAY 43		13NOV2002	42	4	-1	0	0	0	2	1	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	DAY 43	*	18NOV2002	47	2	-3	0	0	0	2	0	0	0	0	0	0	0
		DAY 50		25NOV2002	54	2	-3	0	0	0	2	0	0	0	0	0	0	0
	E0005004	DAY 1		01OCT2002	1	6		0	1	0	2	2	0	1	0	0	0	0
		DAY 8		10OCT2002	10	5	-1	2	0	0	0	2	0	1	0	0	0	0
		DAY 15		15OCT2002	15	7	1	0	0	0	0	4	0	1	0	2	0	0
	E0005013	SCREEN		30OCT2002	-8	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		07NOV2002	1	7		0	0	0	2	2	0	1	0	2	0	0
	E0005024	SCREEN		05FEB2003	-5	4		0	0	0	1	2	0	1	0	0	0	0
		DAY 1		10FEB2003	1	4		0	0	0	2	1	0	1	0	0	0	0
		DAY 8		18FEB2003	9	2	-2	0	0	0	0	1	0	1	0	0	0	0
		DAY 15		26FEB2003	17	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		06MAR2003	25	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		13MAR2003	32	1	-3	0	0	0	0	0	0	1	0	0	0	0
		DAY 36		20MAR2003	39	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		25MAR2003	44	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		02APR2003	52	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		09APR2003	59	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0005027	SCREEN		03MAR2003	-8	4		0	0	1	0	2	0	1	0	0	0	0
		DAY 1		11MAR2003	1	6		0	0	0	0	3	0	1	0	2	0	0
		DAY 8		19MAR2003	9	3	-3	0	0	0	0	2	0	1	0	0	0	0
		DAY 15		26MAR2003	16	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		03APR2003	24	1	-5	0	0	0	1	0	0	0	0	0	0	0
	E0005037	SCREEN		30APR2003	-7	4		0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	DAY 1	07MAY2003	1	7		0	0	0	3	2	0	2	0	0	0	0
		DAY 8	15MAY2003	9	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	22MAY2003	16	7	0	0	0	0	4	2	0	1	0	0	0	0
		DAY 22	27MAY2003	21	2	-5	0	0	0	2	0	0	0	0	0	0	0
		DAY 29	05JUN2003	30	5	-2	0	0	0	2	2	0	1	0	0	0	0
		DAY 36	12JUN2003	37	3	-4	0	0	0	1	1	0	1	0	0	0	0
		DAY 57	02JUL2003	57	4	-3	0	0	0	1	2	0	1	0	0	0	0
	E0005042	SCREEN	19JUN2003	-5	2		1	0	0	0	0	0	1	0	0	0	0
		DAY 1	24JUN2003	1	4		0	0	0	1	2	0	1	0	0	0	0
		DAY 8	02JUL2003	9	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	09JUL2003	16	2	-2	0	0	0	0	1	0	1	0	0	0	0
		DAY 22	16JUL2003	23	7	3	1	1	0	0	2	0	1	2	0	0	0
		DAY 29	23JUL2003	30	8	4	2	0	0	0	2	2	1	1	0	0	0
		DAY 36	30JUL2003	37	2	-2	0	0	0	0	1	0	1	0	0	0	0
		DAY 43	06AUG2003	44	1	-3	0	0	0	0	0	0	1	0	0	0	0
		DAY 50	12AUG2003	50	2	-2	0	0	0	0	1	0	1	0	0	0	0
		DAY 57	18AUG2003	56	1	-3	0	0	0	0	0	0	1	0	0	0	0
	E0006005	SCREEN	25NOV2002	-10	7		1	0	0	0	2	0	3	0	0	1	0
		DAY 1	05DEC2002	1	6		0	0	0	0	3	0	1	1	1	0	0
		DAY 8	12DEC2002	8	7	1	0	0	0	0	3	0	2	0	1	1	0
		DAY 15	20DEC2002	16	5	-1	0	0	0	0	2	0	2	0	0	1	0
		DAY 22	30DEC2002	26	5	-1	0	0	0	0	2	0	2	0	0	1	0
		DAY 29	03JAN2003	30	9	3	0	1	0	0	2	2	2	0	0	2	0
		DAY 36	09JAN2003	36	7	1	0	0	0	0	2	1	2	0	1	1	0
		DAY 43	16JAN2003	43	6	0	0	0	0	0	2	0	2	0	1	1	0
		DAY 50	23JAN2003	50	6	0	1	0	0	0	1	1	2	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 57	30JAN2003	57	5	-1	0	0	0	0	1	1	2	0	0	1	0
	E0006018	SCREEN	06MAR2003	-7	2		0	0	0	0	0	0	0	0	2	0	0
		DAY 1	13MAR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	24MAR2003	12	2	0	0	0	0	0	2	0	0	0	0	0	0
	E0007013	SCREEN	06JUN2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	13JUN2003	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8	20JUN2003	8	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	26JUN2003	14	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	03JUL2003	21	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	10JUL2003	28	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 36	17JUL2003	35	3	1	0	0	0	1	2	0	0	0	0	0	0
		DAY 43	24JUL2003	42	3	1	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	01AUG2003	50	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	07AUG2003	56	3	1	0	0	0	1	2	0	0	0	0	0	0
	E0010004	SCREEN	05DEC2002	-6	6		0	0	0	1	3	0	2	0	0	0	0
		DAY 1	11DEC2002	1	8		0	1	0	2	2	1	2	0	0	0	0
		DAY 8	18DEC2002	8	3	-5	0	0	0	0	2	0	1	0	0	0	0
		DAY 15	26DEC2002	16	10	2	0	3	0	0	0	4	2	0	0	1	0
		DAY 22	02JAN2003	23	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	13JAN2003	34	5	-3	2	0	0	1	0	1	0	0	0	1	0
		DAY 43	21JAN2003	42	7	-1	1	1	0	0	2	0	1	1	0	1	0
		DAY 50	31JAN2003	52	4	-4	0	1	0	0	2	0	0	0	0	1	0
		DAY 57	06FEB2003	58	3	-5	0	0	0	0	2	0	1	0	0	0	0
	E0010012	SCREEN	30DEC2002	-8	5		0	0	0	2	2	0	1	0	0	0	0

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QUETIAPINE 300 MG (BIPOLAR I)	E0010012	DAY 1	07JAN2003	1	11		1	3	0	2	2	1	2	0	0	0	0
		DAY 8	14JAN2003	8	8	-3	0	0	0	0	4	0	1	0	3	0	0
		DAY 15	21JAN2003	15	5	-6	1	0	0	0	2	2	0	0	0	0	0
		DAY 22	28JAN2003	22	1	-10	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	04FEB2003	29	2	-9	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	11FEB2003	36	3	-8	0	0	1	0	2	0	0	0	0	0	0
		DAY 43	18FEB2003	43	2	-9	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	25FEB2003	50	2	-9	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	05MAR2003	58	3	-8	0	0	0	0	2	0	0	0	1	0	0
	E0010024	SCREEN	23APR2003	-12	8		1	1	0	2	2	0	2	0	0	0	0
		DAY 1	05MAY2003	1	9		0	0	0	2	0	3	2	2	0	0	0
		DAY 8	12MAY2003	8	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	19MAY2003	15	11	2	2	2	0	0	2	3	2	0	0	0	0
		DAY 22	27MAY2003	23	12	3	2	3	0	0	1	3	2	0	0	1	0
		DAY 29	04JUN2003	31	16	7	2	3	0	1	2	3	2	0	2	1	0
		DAY 36	11JUN2003	38	19	10	2	3	2	0	4	0	2	2	3	1	0
		DAY 43	18JUN2003	45	12	3	2	3	0	0	3	2	2	0	0	0	0
		DAY 50	25JUN2003	52	8	-1	2	2	0	0	2	0	2	0	0	0	0
		DAY 57	02JUL2003	59	3	-6	1	0	0	0	2	0	0	0	0	0	0
	E0010032	SCREEN	03JUL2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	10JUL2003	1	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 8	17JUL2003	8	3	-2	0	0	0	0	2	0	0	0	0	1	0
	E0011025	SCREEN	20JUN2003	-6	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	26JUN2003	1	2		0	0	0	0	1	0	1	0	0	0	0
		DAY 8	02JUL2003	7	2	0	0	0	0	0	1	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	DAY 15	10JUL2003	15	3	1	0	1	0	0	1	0	1	0	0	0	0
		DAY 22	17JUL2003	22	3	1	0	1	0	0	1	0	1	0	0	0	0
		DAY 29	22JUL2003	27	5	3	2	2	0	0	0	0	1	0	0	0	0
		DAY 36	30JUL2003	35	2	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 43	07AUG2003	43	2	0	0	2	0	0	0	0	0	0	0	0	0
		DAY 50	14AUG2003	50	3	1	0	2	0	1	0	0	0	0	0	0	0
		DAY 57	22AUG2003	58	2	0	1	1	0	0	0	0	0	0	0	0	0
	E0013007	SCREEN	13MAR2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	20MAR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	27MAR2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	07APR2003	19	1	1	0	0	0	0	1	0	0	0	0	0	0
	E0013009	SCREEN	26MAR2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	02APR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	09APR2003	8	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	16APR2003	15	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	24APR2003	23	1	1	1	0	0	0	0	0	0	0	0	0	0
		DAY 29	01MAY2003	30	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	07MAY2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	16MAY2003	45	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	21MAY2003	50	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	29MAY2003	58	2	2	0	0	0	0	1	1	0	0	0	0	0
	E0014006	SCREEN	11MAR2003	-14	7		0	0	0	2	2	0	0	2	0	1	0
		DAY 1	25MAR2003	1	5		0	1	0	2	2	0	0	0	0	0	0
		DAY 8	02APR2003	9	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	09APR2003	16	2	-3	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	DAY 22	16APR2003	23	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	23APR2003	30	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	30APR2003	37	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	07MAY2003	44	1	-4	0	0	0	0	0	0	0	0	0	1	0
		DAY 50	14MAY2003	51	1	-4	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	21MAY2003	58	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0014010	SCREEN	15APR2003	-7	5		0	0	0	0	4	0	0	0	0	1	0
		DAY 1	22APR2003	1	4		0	0	0	1	2	0	0	0	0	1	0
		DAY 8	30APR2003	9	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	07MAY2003	16	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 22	14MAY2003	23	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	21MAY2003	30	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	28MAY2003	37	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	03JUN2003	43	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	11JUN2003	51	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	17JUN2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0016001	SCREEN	02JAN2003	-20	5		1	0	0	2	0	0	0	0	0	2	0
		DAY 1	22JAN2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	29JAN2003	8	3	-2	0	1	0	0	2	0	0	0	0	0	0
		DAY 15	05FEB2003	15	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	12FEB2003	22	2	-3	1	1	0	0	0	0	0	0	0	0	0
		DAY 29	19FEB2003	29	2	-3	0	1	0	1	0	0	0	0	0	0	0
		DAY 36	26FEB2003	36	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAR2003	43	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	12MAR2003	50	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAR2003	57	2	-3	0	0	0	0	0	2	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0016004	SCREEN	27JAN2003	-7	2		0	1	0	0	0	0	1	0	0	0	0
		DAY 1	03FEB2003	1	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 8	10FEB2003	8	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0018001	SCREEN	22OCT2002	-7	7		0	0	0	0	4	2	0	0	0	1	0
		DAY 1	29OCT2002	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8	05NOV2002	8	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	13NOV2002	16	2	-1	0	0	0	0	0	2	0	0	0	0	0
		DAY 22	20NOV2002	23	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	27NOV2002	30	1	-2	0	1	0	0	0	0	0	0	0	0	0
		DAY 36	04DEC2002	37	3	0	0	1	0	0	0	2	0	0	0	0	0
		DAY 43	11DEC2002	44	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	18DEC2002	51	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	24DEC2002	57	3	0	1	0	0	0	0	2	0	0	0	0	0
	E0018006	SCREEN	10DEC2002	-7	9		0	2	0	2	2	2	1	0	0	0	0
		DAY 1	17DEC2002	1	6		0	0	0	2	2	0	1	0	0	1	0
		DAY 8	23DEC2002	7	5	-1	0	1	0	0	2	0	1	0	0	1	0
		DAY 15	31DEC2002	15	5	-1	0	0	0	0	2	0	1	2	0	0	0
		DAY 22	07JAN2003	22	6	0	0	0	0	0	2	0	1	2	0	1	0
		DAY 29	14JAN2003	29	2	-4	0	0	0	0	0	0	1	0	0	1	0
		DAY 36	21JAN2003	36	5	-1	0	0	0	0	2	2	1	0	0	0	0
		DAY 43	28JAN2003	43	3	-3	0	0	0	0	2	0	1	0	0	0	0
		DAY 50	06FEB2003	52	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	13FEB2003	59	1	-5	0	0	0	0	0	0	1	0	0	0	0
	E0019004	SCREEN	30OCT2002	-8	8		1	0	0	2	2	0	1	2	0	0	0
		DAY 1	07NOV2002	1	5		1	1	1	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	DAY 8	14NOV2002	8	16	11	3	4	2	3	2	2	0	0	0	0	0
		DAY 15	21NOV2002	15	4	-1	0	0	1	0	2	0	0	0	0	1	0
		DAY 22	26NOV2002	20	10	5	2	3	0	3	0	1	0	0	0	1	0
		DAY 29	05DEC2002	29	4	-1	0	0	0	0	3	0	0	0	0	1	0
		DAY 36	12DEC2002	36	8	3	1	1	0	2	2	0	2	0	0	0	0
		DAY 43	19DEC2002	43	10	5	0	0	0	2	6	1	0	0	0	1	0
	E0019011	SCREEN	12NOV2002	-9	5		0	0	0	0	2	2	1	0	0	0	0
		DAY 1	21NOV2002	1	6		0	0	0	2	2	2	0	0	0	0	0
		DAY 8	27NOV2002	7	3	-3	0	0	0	0	2	0	0	0	0	1	0
		DAY 15	05DEC2002	15	4	-2	1	0	0	1	1	0	0	0	0	1	0
		DAY 22	12DEC2002	22	12	6	0	2	0	1	4	2	1	0	2	0	0
		DAY 29	19DEC2002	29	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	02JAN2003	43	2	-4	0	0	0	0	1	0	0	0	0	1	0
		DAY 50	09JAN2003	50	10	4	0	2	0	0	2	3	1	1	1	0	0
		DAY 57	16JAN2003	57	2	-4	0	0	0	0	2	0	0	0	0	0	0
	E0019025	SCREEN	30JAN2003	-7	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 1	06FEB2003	1	2		0	0	0	1	1	0	0	0	0	0	0
		DAY 8	13FEB2003	8	1	-1	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	20FEB2003	15	2	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 22	27FEB2003	22	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	06MAR2003	29	1	-1	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	13MAR2003	36	6	4	0	0	0	1	2	2	1	0	0	0	0
		DAY 43	20MAR2003	43	2	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 50	27MAR2003	50	2	0	0	1	0	1	0	0	0	0	0	0	0
		DAY 57	03APR2003	57	0	-2	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0019026	SCREEN		10FEB2003	-14	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		24FEB2003	1	2		0	0	0	0	2	0	0	0	0	0	0
	E0019043	SCREEN		21MAY2003	-13	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		03JUN2003	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8		10JUN2003	8	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 15		17JUN2003	15	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 22		24JUN2003	22	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		01JUL2003	29	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		08JUL2003	36	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 43		15JUL2003	43	2	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 50		22JUL2003	50	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 57		29JUL2003	57	1	-1	0	0	0	1	0	0	0	0	0	0	0
	E0020001	SCREEN		15OCT2002	-14	5		0	0	0	0	2	2	1	0	0	0	0
		DAY 1		29OCT2002	1	5		0	0	0	0	3	0	0	0	2	0	0
		DAY 8		05NOV2002	8	5	0	1	0	0	0	4	0	0	0	0	0	0
		DAY 15		12NOV2002	15	9	4	1	1	0	1	4	0	1	0	1	0	0
		DAY 22		19NOV2002	22	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		26NOV2002	29	10	5	0	1	0	1	2	3	1	0	2	0	0
		DAY 36		03DEC2002	36	10	5	1	0	0	1	3	3	1	1	0	0	0
		DAY 43		10DEC2002	43	19	14	1	1	0	2	5	4	1	1	3	1	0
		DAY 50		16DEC2002	49	13	8	2	1	0	2	2	2	2	0	2	0	0
		DAY 50	*	20DEC2002	53	8	3	2	0	0	1	2	2	1	0	0	0	0
	E0020006	SCREEN		26NOV2002	-20	9		1	0	0	2	2	0	1	0	3	0	0
		DAY 1		16DEC2002	1	6		0	0	0	1	2	2	1	0	0	0	0
		DAY 8		20DEC2002	5	7	1	1	0	0	0	2	3	1	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0020007	SCREEN	19DEC2002	-27	5		1	1	0	2	1	0	0	0	0	0	0
		DAY 1	15JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	22JAN2003	8	2	-2	0	0	0	0	1	0	0	0	0	0	1
	E0020011	SCREEN	19FEB2003	-7	6		0	0	0	0	2	0	2	0	2	0	0
		DAY 1	26FEB2003	1	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 8	05MAR2003	8	8	4	2	0	0	0	2	3	1	0	0	0	0
		DAY 15	12MAR2003	15	2	-2	0	1	0	0	0	0	0	0	0	0	1
		DAY 22	20MAR2003	23	3	-1	0	0	0	0	2	0	0	0	0	1	0
		DAY 29	26MAR2003	29	13	9	2	1	2	2	0	3	0	0	2	1	0
		DAY 36	02APR2003	36	12	8	2	1	0	0	2	3	0	0	2	2	0
		DAY 43	09APR2003	43	8	4	0	0	0	0	3	0	0	0	2	3	0
		DAY 50	16APR2003	50	14	10	2	2	1	0	0	3	1	0	2	3	0
		DAY 57	23APR2003	57	11	7	1	1	2	0	0	3	0	0	1	3	0
	E0020013	SCREEN	25FEB2003	-8	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 1	05MAR2003	1	9		1	0	1	0	2	2	2	0	1	0	0
		DAY 8	12MAR2003	8	2	-7	0	0	0	0	2	0	0	0	0	0	0
	E0022008	SCREEN	05NOV2002	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	19NOV2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	26NOV2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	03DEC2002	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	12DEC2002	31	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	17DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	24DEC2002	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	31DEC2002	50	0	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 57	07JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022017	SCREEN	03DEC2002	-16	6		0	0	1	0	0	0	1	2	2	0	0
		DAY 1	19DEC2002	1	5		0	0	0	0	4	0	1	0	0	0	0
		DAY 8	26DEC2002	8	7	2	0	0	0	0	4	2	1	0	0	0	0
		DAY 15	03JAN2003	16	3	-2	0	0	0	0	2	0	1	0	0	0	0
		DAY 22	09JAN2003	22	8	3	2	0	0	0	2	4	0	0	0	0	0
		DAY 29	17JAN2003	30	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	22JAN2003	35	4	-1	0	0	0	0	0	2	0	0	2	0	0
		DAY 43	31JAN2003	44	2	-3	0	0	0	0	0	0	0	0	2	0	0
		DAY 50	06FEB2003	50	1	-4	0	1	0	0	0	0	0	0	0	0	0
		DAY 57	13FEB2003	57	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0022018	SCREEN	04DEC2002	-8	10		0	0	0	1	4	2	1	0	2	0	0
		DAY 1	12DEC2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	19DEC2002	8	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	26DEC2002	15	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	02JAN2003	22	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	09JAN2003	29	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	16JAN2003	36	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	23JAN2003	43	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	30JAN2003	50	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	06FEB2003	57	2	2	0	0	0	0	2	0	0	0	0	0	0
	E0022022	SCREEN	16DEC2002	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	30DEC2002	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	06JAN2003	8	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	14JAN2003	16	10	8	0	0	0	0	4	0	0	0	4	2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	DAY 22	21JAN2003	23	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	28JAN2003	30	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	04FEB2003	37	19	17	2	0	3	0	4	0	2	2	4	2	0
		DAY 57	27FEB2003	60	7	5	0	0	0	0	4	0	0	0	2	1	0
	E0022027	SCREEN	23JAN2003	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	06FEB2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	13FEB2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	20FEB2003	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	27FEB2003	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	06MAR2003	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	13MAR2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	20MAR2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	27MAR2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	03APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022030	SCREEN	07FEB2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	14FEB2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	20FEB2003	7	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	28FEB2003	15	6	6	1	1	0	0	0	0	0	2	0	2	0
		DAY 22	07MAR2003	22	4	4	0	0	0	0	0	0	0	2	0	2	0
	E0022031	SCREEN	10FEB2003	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	25FEB2003	8	5	5	0	0	0	0	2	2	1	0	0	0	0
		DAY 15	04MAR2003	15	4	4	1	1	0	0	2	0	0	0	0	0	0
		DAY 22	11MAR2003	22	6	6	0	0	0	0	2	4	0	0	0	0	0
		DAY 29	18MAR2003	29	2	2	0	0	0	0	0	2	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0022031	DAY 36	25MAR2003	36	2	2	0	0	0	0	0	2	0	0	0	0	0
		DAY 43	01APR2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	08APR2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022032	SCREEN	11FEB2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	28FEB2003	11	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	04MAR2003	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	11MAR2003	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	21MAR2003	32	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	27MAR2003	38	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	03APR2003	45	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	10APR2003	52	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	18APR2003	60	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022035	SCREEN	11FEB2003	-8	5		0	0	0	1	4	0	0	0	0	0	0
		DAY 1	19FEB2003	1	6		0	0	0	1	2	2	1	0	0	0	0
		DAY 8	26FEB2003	8	8	2	0	1	0	2	2	2	1	0	0	0	0
	E0022036	SCREEN	13FEB2003	-12	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	25FEB2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	03MAR2003	7	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	10MAR2003	14	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	18MAR2003	22	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	25MAR2003	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	36	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	08APR2003	43	2	2	0	0	0	0	0	0	0	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	DAY 50	15APR2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	57	1	1	0	1	0	0	0	0	0	0	0	0	0
	E0022056	SCREEN	09APR2003	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	17APR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	24APR2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	01MAY2003	15	5	5	1	0	0	0	2	0	0	2	0	0	0
		DAY 22	08MAY2003	22	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022060	SCREEN	23APR2003	-7	4		0	0	0	1	2	0	1	0	0	0	0
		DAY 1	30APR2003	1	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 8	05MAY2003	6	1	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 15	12MAY2003	13	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	19MAY2003	20	4	3	0	0	0	1	2	0	1	0	0	0	0
		DAY 29	28MAY2003	29	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	02JUN2003	34	4	3	0	0	0	0	4	0	0	0	0	0	0
		DAY 43	10JUN2003	42	4	3	1	1	0	0	0	2	0	0	0	0	0
		DAY 50	17JUN2003	49	3	2	0	0	0	0	2	0	0	0	0	1	0
		DAY 57	24JUN2003	56	0	-1	0	0	0	0	0	0	0	0	0	0	0
	E0022063	SCREEN	28APR2003	-9	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	07MAY2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8	12MAY2003	6	4	-2	0	0	0	0	2	0	0	0	2	0	0
		DAY 15	21MAY2003	15	4	-2	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	28MAY2003	22	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	04JUN2003	29	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	11JUN2003	36	2	-4	0	0	0	0	0	0	0	2	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	SCREEN		23JAN2003	-7	1		1	0	0	0	0	0	0	0	0	0	0
		DAY 1		30JAN2003	1	4		0	0	0	0	2	2	0	0	0	0	0
		DAY 8		06FEB2003	8	6	2	0	0	0	0	4	0	0	0	2	0	0
		DAY 15		13FEB2003	15	8	4	0	0	0	0	4	2	0	0	2	0	0
		DAY 22		20FEB2003	22	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 29		25FEB2003	27	8	4	0	0	0	0	4	2	0	0	2	0	0
		DAY 36		06MAR2003	36	7	3	0	0	0	0	4	1	0	0	2	0	0
		DAY 43		11MAR2003	41	7	3	0	0	0	0	4	2	1	0	0	0	0
		DAY 50		18MAR2003	48	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	*	24MAR2003	54	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0023013	SCREEN		13FEB2003	-14	6		1	0	0	0	2	2	1	0	0	0	0
		DAY 1		27FEB2003	1	5		0	0	0	1	2	0	0	0	1	1	0
		DAY 8		06MAR2003	8	7	2	1	0	0	0	2	0	1	1	2	0	0
	E0023015	SCREEN		04MAR2003	-7	4		0	0	0	0	4	0	0	0	0	0	0
		DAY 1		11MAR2003	1	5		0	1	0	0	4	0	0	0	0	0	0
		DAY 8		18MAR2003	8	13	8	2	2	1	0	3	2	0	2	1	0	0
		DAY 15		25MAR2003	15	14	9	2	2	0	0	3	3	1	2	1	0	0
		DAY 22		01APR2003	22	11	6	2	1	0	0	3	2	1	1	1	0	0
		DAY 29		08APR2003	29	10	5	2	2	0	0	3	1	1	0	1	0	0
		DAY 36		15APR2003	36	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		22APR2003	43	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 50		29APR2003	50	5	0	1	1	0	0	2	1	0	0	0	0	0
		DAY 57		06MAY2003	57	2	-3	0	0	0	0	2	0	0	0	0	0	0
	E0023034	SCREEN		03JUN2003	-6	4		1	1	0	0	2	0	0	0	0	0	0
		DAY 1		09JUN2003	1	6		1	0	0	0	4	0	0	0	1	0	0

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QUETIAPINE 300 MG (BIPOLAR I)	E0023034	DAY 8		16JUN2003	8	5	-1	0	0	0	2	3	0	0	0	0	0	0
		DAY 15		23JUN2003	15	9	3	0	0	0	2	4	0	0	0	3	0	0
		DAY 22		30JUN2003	22	9	3	2	1	0	0	4	0	0	0	2	0	0
		DAY 29		07JUL2003	29	8	2	2	2	0	0	4	0	0	0	0	0	0
		DAY 36		14JUL2003	36	4	-2	1	1	0	0	2	0	0	0	0	0	0
		DAY 43		22JUL2003	44	5	-1	2	1	0	0	2	0	0	0	0	0	0
		DAY 57		05AUG2003	58	2	-4	0	1	0	0	1	0	0	0	0	0	0
	E0023037	SCREEN		11JUN2003	-7	4		1	1	0	0	2	0	0	0	0	0	0
		DAY 1		18JUN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		24JUN2003	7	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 15		01JUL2003	14	3	-1	1	1	0	0	1	0	0	0	0	0	0
		DAY 29	*	14JUL2003	27	8	4	2	2	0	0	0	2	2	0	0	0	0
		DAY 29		18JUL2003	31	8	4	2	2	0	0	0	2	1	1	0	0	0
		DAY 36		25JUL2003	38	3	-1	0	0	0	0	0	2	1	0	0	0	0
		DAY 43		01AUG2003	45	3	-1	0	0	0	0	0	2	1	0	0	0	0
		DAY 50		08AUG2003	52	3	-1	0	0	0	0	0	2	1	0	0	0	0
		DAY 57		15AUG2003	59	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0023038	SCREEN		20JUN2003	-10	4		0	0	0	1	3	0	0	0	0	0	0
		DAY 1		30JUN2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8		09JUL2003	10	3	-2	0	0	1	0	2	0	0	0	0	0	0
		DAY 15		15JUL2003	16	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		21JUL2003	22	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		28JUL2003	29	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		07AUG2003	39	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		13AUG2003	45	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 50		21AUG2003	53	2	-3	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0023038	DAY 57	27AUG2003	59	2	-3	0	0	0	0	2	0	0	0	0	0	0
	E0023044	SCREEN	08JUL2003	-8	8		1	1	0	1	3	2	0	0	0	0	0
		DAY 1	16JUL2003	1	7		0	0	0	2	3	0	0	0	2	0	0
		DAY 8	22JUL2003	7	5	-2	0	0	0	2	3	0	0	0	0	0	0
		DAY 15	29JUL2003	14	5	-2	0	0	0	2	3	0	0	0	0	0	0
		DAY 22	05AUG2003	21	5	-2	0	0	0	2	3	0	0	0	0	0	0
		DAY 29	12AUG2003	28	6	-1	0	0	0	2	4	0	0	0	0	0	0
	E0023045	SCREEN	10JUL2003	-7	6		1	1	1	0	2	0	0	0	1	0	0
		DAY 1	17JUL2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8	24JUL2003	8	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 15	31JUL2003	15	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 22	07AUG2003	22	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 29	14AUG2003	29	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	21AUG2003	36	3	-3	0	0	0	1	2	0	0	0	0	0	0
		DAY 43	28AUG2003	43	1	-5	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	04SEP2003	50	1	-5	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	11SEP2003	57	1	-5	0	0	0	0	1	0	0	0	0	0	0
	E0025002	SCREEN	27MAR2003	-7	8		0	0	0	2	4	0	0	0	2	0	0
		DAY 1	03APR2003	1	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 8	10APR2003	8	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	17APR2003	15	3	-4	0	0	0	0	2	0	0	0	0	1	0
		DAY 22	24APR2003	22	5	-2	1	0	0	0	2	2	0	0	0	0	0
		DAY 29	01MAY2003	29	4	-3	2	0	0	0	0	2	0	0	0	0	0
		DAY 36	08MAY2003	36	3	-4	1	0	0	0	0	2	0	0	0	0	0
		DAY 43	15MAY2003	43	5	-2	1	2	0	0	0	2	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	DAY 50	22MAY2003	50	3	-4	1	0	0	0	0	2	0	0	0	0	0
		DAY 57	29MAY2003	57	3	-4	1	0	0	0	0	2	0	0	0	0	0
	E0026010	SCREEN	15JAN2003	-7	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1	22JAN2003	1	7		0	0	0	2	4	1	0	0	0	0	0
		DAY 8	30JAN2003	9	21	14	2	2	3	3	2	3	2	4	0	0	0
	E0026017	SCREEN	26FEB2003	-8	7		0	0	0	1	2	1	0	0	0	2	1
		DAY 1	06MAR2003	1	3		0	0	0	0	0	0	0	2	0	1	0
		DAY 15	21MAR2003	16	6	3	0	0	2	2	0	0	0	2	0	0	0
	E0026018	SCREEN	06MAR2003	-14	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 1	20MAR2003	1	7		0	0	0	2	2	0	0	2	0	1	0
		DAY 8	27MAR2003	8	12	5	2	2	1	0	2	2	1	2	0	0	0
		DAY 15	03APR2003	15	7	0	1	0	0	0	2	1	0	2	0	1	0
		DAY 22	10APR2003	22	8	1	1	0	1	0	2	2	0	2	0	0	0
		DAY 29	17APR2003	29	6	-1	0	0	2	0	2	1	0	0	0	1	0
		DAY 36	24APR2003	36	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	01MAY2003	43	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	08MAY2003	50	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	15MAY2003	57	2	-5	0	0	0	1	0	0	0	1	0	0	0
	E0026025	SCREEN	01MAY2003	-8	5		0	0	0	0	3	0	1	0	0	1	0
		DAY 1	09MAY2003	1	11		0	0	0	1	4	0	1	0	3	2	0
		DAY 8	15MAY2003	7	14	3	0	0	0	1	4	0	1	2	4	2	0
		DAY 15	22MAY2003	14	7	-4	0	0	0	0	4	0	1	0	1	1	0
		DAY 22	29MAY2003	21	4	-7	0	0	0	0	2	0	1	0	0	1	0
		DAY 29	05JUN2003	28	4	-7	0	0	1	0	1	0	1	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	DAY 36	13JUN2003	36	4	-7	0	0	0	0	2	0	1	0	0	1	0
		DAY 43	20JUN2003	43	3	-8	0	0	0	0	1	0	1	0	0	1	0
		DAY 50	27JUN2003	50	7	-4	1	0	0	2	0	2	1	0	0	1	0
		DAY 57	03JUL2003	56	5	-6	0	0	0	2	1	0	1	0	0	1	0
	E0026029	SCREEN	02JUL2003	-7	7		0	0	0	2	2	0	1	1	0	1	0
		DAY 1	09JUL2003	1	6		0	0	0	2	2	0	1	0	0	1	0
		DAY 8	16JUL2003	8	10	4	1	1	0	2	2	3	1	0	0	0	0
	E0026030	SCREEN	02JUL2003	-7	9		0	0	0	2	2	3	0	1	0	1	0
		DAY 1	09JUL2003	1	6		0	0	0	2	2	1	0	0	0	1	0
		DAY 8	16JUL2003	8	8	2	0	0	0	1	4	0	0	1	0	2	0
		DAY 15	23JUL2003	15	5	-1	0	0	0	0	3	0	0	1	0	1	0
		DAY 22	30JUL2003	22	7	1	1	0	0	1	2	1	0	0	1	1	0
		DAY 29	04AUG2003	27	6	0	1	1	0	0	1	2	0	0	0	1	0
		DAY 36	12AUG2003	35	3	-3	1	0	1	0	1	0	0	0	0	0	0
		DAY 43	19AUG2003	42	3	-3	0	0	0	0	2	0	0	0	0	1	0
		DAY 50	26AUG2003	49	4	-2	1	1	0	0	0	1	0	0	0	1	0
		DAY 57	03SEP2003	57	2	-4	0	0	0	1	0	0	0	0	0	1	0
	E0026031	SCREEN	10JUL2003	-11	9		1	2	0	2	1	2	1	0	0	0	0
		DAY 1	21JUL2003	1	8		1	2	0	2	1	0	1	1	0	0	0
		DAY 8	28JUL2003	8	11	3	2	2	0	0	0	3	2	1	1	0	0
		DAY 15	04AUG2003	15	8	0	2	1	0	0	1	2	1	0	1	0	0
		DAY 22	11AUG2003	22	5	-3	0	2	0	0	0	2	1	0	0	0	0
		DAY 29	18AUG2003	29	3	-5	0	2	0	0	0	0	1	0	0	0	0
		DAY 36	25AUG2003	36	7	-1	0	2	0	1	0	1	1	0	0	2	0
		DAY 43	02SEP2003	44	3	-5	0	0	0	1	0	1	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0026031	DAY 50		08SEP2003	50	3	-5	0	0	0	1	0	0	1	0	0	1	0
		DAY 57		15SEP2003	57	3	-5	0	0	0	0	2	0	0	0	0	1	0
	E0027003	SCREEN	*	08JAN2003	-20	9		0	0	0	2	2	2	2	0	0	1	0
		SCREEN		23JAN2003	-5	6		0	0	0	2	2	0	0	0	0	2	0
		DAY 1		23JAN2003	-5	6		0	0	0	2	2	0	0	0	0	2	0
		DAY 8		06FEB2003	10	3	-3	0	0	0	2	0	0	1	0	0	0	0
		DAY 15		13FEB2003	17	5	-1	0	0	0	2	1	0	1	0	0	1	0
		DAY 22		19FEB2003	23	3	-3	0	0	0	1	1	0	1	0	0	0	0
		DAY 29		27FEB2003	31	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		06MAR2003	38	2	-4	0	0	0	0	1	0	1	0	0	0	0
		DAY 43		13MAR2003	45	1	-5	0	0	0	0	1	0	0	0	0	0	0
		DAY 50		20MAR2003	52	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		25MAR2003	57	1	-5	0	0	0	0	1	0	0	0	0	0	0
	E0028004	DAY 1		30SEP2002	1	3		0	0	0	2	0	0	0	0	0	1	0
		DAY 8		07OCT2002	8	7	4	0	0	0	0	2	0	1	0	2	2	0
		DAY 8	*	09OCT2002	10	8	5	0	0	0	2	0	0	0	0	3	3	0
	E0028006	DAY 1		04OCT2002	1	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 8		11OCT2002	8	9	8	0	0	0	0	4	0	2	0	2	1	0
		DAY 15		16OCT2002	13	11	10	0	0	0	0	2	4	2	0	2	1	0
		DAY 22		23OCT2002	20	5	4	0	0	0	1	2	0	2	0	0	0	0
		DAY 29		31OCT2002	28	3	2	0	0	0	0	2	0	1	0	0	0	0
		DAY 36		07NOV2002	35	8	7	0	0	0	2	4	0	0	0	2	0	0
		DAY 43		14NOV2002	42	6	5	0	0	0	0	4	0	0	0	2	0	0
		DAY 50		21NOV2002	49	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 57		04DEC2002	62	1	0	0	0	0	0	0	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	SCREEN	08OCT2002	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	15OCT2002	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8	22OCT2002	8	6	3	0	0	1	3	2	0	0	0	0	0	0
		DAY 15	29OCT2002	15	10	7	0	0	0	3	4	0	1	2	0	0	0
		DAY 22	07NOV2002	24	10	7	0	0	0	2	4	0	1	2	0	1	0
		DAY 29	14NOV2002	31	7	4	0	0	0	0	2	0	0	0	4	1	0
		DAY 36	21NOV2002	38	5	2	0	0	0	0	2	0	1	0	2	0	0
		DAY 43	26NOV2002	43	6	3	0	0	0	0	2	0	2	0	0	2	0
		DAY 50	03DEC2002	50	5	2	1	0	0	0	0	2	1	0	0	1	0
		DAY 57	10DEC2002	57	12	9	4	0	0	0	2	2	2	0	0	2	0
	E0028009	SCREEN	10OCT2002	-5	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	15OCT2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	23OCT2002	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	31OCT2002	17	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	07NOV2002	24	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	14NOV2002	31	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	19NOV2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	26NOV2002	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	03DEC2002	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	12DEC2002	59	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0028016	SCREEN	07NOV2002	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	14NOV2002	1	9		0	1	1	0	4	2	1	0	0	0	0
		DAY 8	21NOV2002	8	2	-7	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	26NOV2002	13	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	05DEC2002	22	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	12DEC2002	29	2	-7	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	DAY 36		19DEC2002	36	5	-4	0	0	1	0	0	0	0	4	0	0	0
		DAY 43		26DEC2002	43	3	-6	1	0	0	0	0	0	1	1	0	0	0
		DAY 50		02JAN2003	50	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		09JAN2003	57	3	-6	0	1	0	0	2	0	0	0	0	0	0
	E0028017		*	12NOV2002		2		0	0	0	2	0	0	0	0	0	0	0
			*	19NOV2002		13		1	0	0	0	4	4	1	0	2	1	0
	E0028027	SCREEN		14JAN2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		21JAN2003	1	8		0	0	0	2	2	2	2	0	0	0	0
		DAY 8		28JAN2003	8	7	-1	0	0	0	0	2	0	3	2	0	0	0
		DAY 15		04FEB2003	15	6	-2	0	0	0	2	0	0	2	2	0	0	0
		DAY 22		11FEB2003	22	2	-6	0	0	0	0	0	0	2	0	0	0	0
		DAY 29		20FEB2003	31	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		28FEB2003	39	20	12	3	0	0	0	2	4	3	4	4	0	0
	E0028029	SCREEN		28JAN2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		04FEB2003	1	3		0	0	0	0	0	0	3	0	0	0	0
		DAY 8		11FEB2003	8	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 15		17FEB2003	14	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		27FEB2003	24	1	-2	0	0	0	0	0	0	0	0	0	1	0
		DAY 29		06MAR2003	31	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		13MAR2003	38	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		20MAR2003	45	12	9	3	3	0	0	0	4	2	0	0	0	0
		DAY 50		27MAR2003	52	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		03APR2003	59	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0028034	SCREEN		20MAR2003	-12	2		0	0	0	2	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	DAY 1	01APR2003	1	9		0	0	0	2	4	0	1	0	2	0	0
		DAY 8	08APR2003	8	4	-5	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	15APR2003	15	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	22APR2003	22	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	01MAY2003	31	1	-8	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	06MAY2003	36	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	13MAY2003	43	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	21MAY2003	51	1	-8	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUN2003	63	4	-5	1	1	0	0	0	2	0	0	0	0	0
	E0028038	SCREEN	18APR2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	25APR2003	1	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 8	02MAY2003	8	3	-3	0	0	0	0	0	0	0	0	2	1	0
		DAY 15	08MAY2003	14	6	0	0	0	0	1	2	0	0	0	2	1	0
		DAY 29	22MAY2003	28	1	-5	0	0	0	0	0	0	0	0	0	1	0
		DAY 36	30MAY2003	36	3	-3	0	0	0	0	0	0	0	0	2	1	0
		DAY 43	05JUN2003	42	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	12JUN2003	49	7	1	1	1	0	0	2	2	0	0	0	1	0
		DAY 57	18JUN2003	55	4	-2	0	0	0	1	2	0	0	0	0	1	0
	E0028043	SCREEN	29MAY2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	05JUN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	12JUN2003	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	19JUN2003	15	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	26JUN2003	22	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	01JUL2003	27	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 36	08JUL2003	34	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 43	15JUL2003	41	2	-2	0	0	0	2	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	DAY 50	22JUL2003	48	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 57	29JUL2003	55	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0028045	SCREEN	09JUN2003	-9	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	18JUN2003	1	6		2	0	0	0	2	2	0	0	0	0	0
		DAY 8	25JUN2003	8	5	-1	0	0	0	2	2	0	1	0	0	0	0
		DAY 15	30JUN2003	13	8	2	2	0	0	0	2	4	0	0	0	0	0
	E0029005	SCREEN	14NOV2002	-13	5		0	0	0	2	0	2	0	0	0	0	1
		DAY 1	27NOV2002	1	4		0	0	0	2	0	0	1	0	0	1	0
		DAY 8	03DEC2002	7	11	7	0	0	0	2	3	2	2	0	2	0	0
		DAY 15	09DEC2002	13	12	8	0	0	0	1	2	2	1	2	4	0	0
		DAY 22	16DEC2002	20	4	0	0	0	0	1	2	0	0	1	0	0	0
		DAY 29	23DEC2002	27	3	-1	0	0	0	0	2	0	0	0	0	1	0
		DAY 36	30DEC2002	34	3	-1	0	0	0	0	2	0	0	0	0	1	0
		DAY 43	07JAN2003	42	8	4	0	0	0	1	1	3	0	2	0	1	0
		DAY 50	14JAN2003	49	5	1	0	0	0	1	0	2	1	0	0	1	0
		DAY 57	21JAN2003	56	6	2	0	0	0	1	2	1	0	1	0	1	0
	E0030001	SCREEN	12NOV2002	-7	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	19NOV2002	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	26NOV2002	8	4	1	0	0	0	1	2	0	1	0	0	0	0
		DAY 15	03DEC2002	15	6	3	1	0	0	1	2	0	2	0	0	0	0
		DAY 22	10DEC2002	22	3	0	0	0	0	0	2	0	1	0	0	0	0
		DAY 29	17DEC2002	29	5	2	1	0	0	0	2	1	1	0	0	0	0
		DAY 43	02JAN2003	45	5	2	2	0	0	0	2	0	1	0	0	0	0
		DAY 50	09JAN2003	52	3	0	0	0	0	0	2	0	1	0	0	0	0
		DAY 57	16JAN2003	59	3	0	0	0	0	0	2	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	SCREEN		07JAN2003	-7	9		1	0	0	2	2	2	2	0	0	0	0
		DAY 1		14JAN2003	1	6		0	0	0	2	2	0	2	0	0	0	0
		DAY 8		23JAN2003	10	2	-4	0	0	0	0	0	1	0	0	0	1	0
		DAY 15		30JAN2003	17	11	5	0	2	0	3	3	3	0	0	0	0	0
		DAY 22		07FEB2003	25	6	0	1	1	0	2	1	1	0	0	0	0	0
		DAY 29		14FEB2003	32	4	-2	0	0	0	2	2	0	0	0	0	0	0
		DAY 36		21FEB2003	39	4	-2	0	2	0	0	0	0	0	0	0	2	0
		DAY 50		03MAR2003	49	8	2	1	2	0	0	0	4	0	0	0	1	0
		DAY 57	*	11MAR2003	57	2	-4	0	0	0	2	0	0	0	0	0	0	0
		DAY 57		18MAR2003	64	1	-5	0	1	0	0	0	0	0	0	0	0	0
	E0030011	SCREEN		16JAN2003	-11	10		2	1	0	2	2	2	1	0	0	0	0
		DAY 1		27JAN2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8		03FEB2003	8	6	0	1	0	0	0	1	3	0	0	0	1	0
		DAY 15		10FEB2003	15	1	-5	0	0	0	0	1	0	0	0	0	0	0
		DAY 22		18FEB2003	23	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		24FEB2003	29	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		03MAR2003	36	4	-2	1	2	0	0	1	0	0	0	0	0	0
		DAY 43		10MAR2003	43	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		17MAR2003	50	4	-2	2	1	0	0	0	1	0	0	0	0	0
		DAY 57		24MAR2003	57	2	-4	1	1	0	0	0	0	0	0	0	0	0
	E0030015	SCREEN		13FEB2003	-8	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		21FEB2003	1	5		1	0	0	0	2	1	0	0	0	1	0
		DAY 8		03MAR2003	11	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 15		11MAR2003	19	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 29		19MAR2003	27	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		26MAR2003	34	2	-3	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	DAY 43		02APR2003	41	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 50		09APR2003	48	1	-4	0	0	0	0	0	1	0	0	0	0	0
		DAY 57	*	17APR2003	56	1	-4	0	1	0	0	0	0	0	0	0	0	0
		DAY 57		22APR2003	61	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0030022	SCREEN		06JUN2003	-10	5		0	0	2	0	3	0	0	0	0	0	0
		DAY 1		16JUN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		20JUN2003	5	3	-1	0	1	0	0	2	0	0	0	0	0	0
		DAY 15		30JUN2003	15	3	-1	0	0	0	0	2	0	0	0	1	0	0
		DAY 22		07JUL2003	22	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 29		14JUL2003	29	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 36		21JUL2003	36	4	0	0	0	0	0	2	1	0	0	1	0	0
		DAY 43		29JUL2003	44	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 50		05AUG2003	51	7	3	1	0	0	0	3	1	0	0	2	0	0
		DAY 57		14AUG2003	60	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0031002	SCREEN		20NOV2002	-7	12		0	0	0	2	4	2	2	0	2	0	0
		DAY 1		27NOV2002	1	4		0	0	0	1	2	0	1	0	0	0	0
		DAY 8		06DEC2002	10	5	1	0	0	0	0	2	0	1	0	2	0	0
		DAY 15		12DEC2002	16	11	7	0	0	0	1	4	2	1	0	2	0	1
		DAY 22		19DEC2002	23	11	7	1	1	0	0	2	4	1	0	2	0	0
		DAY 29		27DEC2002	31	6	2	0	0	0	0	2	0	2	0	2	0	0
		DAY 36		02JAN2003	37	6	2	0	0	0	1	2	0	1	0	2	0	0
		DAY 50	*	13JAN2003	48	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 50		17JAN2003	52	6	2	0	0	0	0	0	2	2	0	2	0	0
		DAY 57		22JAN2003	57	7	3	0	0	0	0	4	0	1	0	2	0	0
	E0031003	SCREEN		03DEC2002	-7	7		0	0	0	2	2	0	1	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	DAY 1		10DEC2002	1	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 8		17DEC2002	8	2	-4	0	1	0	0	0	0	1	0	0	0	0
		DAY 15		23DEC2002	14	3	-3	0	0	0	0	0	2	1	0	0	0	0
		DAY 22		31DEC2002	22	2	-4	0	0	0	2	0	0	0	0	0	0	0
		DAY 29		07JAN2003	29	2	-4	0	0	0	2	0	0	0	0	0	0	0
		DAY 36		15JAN2003	37	2	-4	0	0	0	2	0	0	0	0	0	0	0
		DAY 43		21JAN2003	43	9	3	0	0	0	2	4	0	1	0	2	0	0
		DAY 50		30JAN2003	52	2	-4	0	0	0	0	0	0	0	0	2	0	0
		DAY 57		04FEB2003	57	3	-3	0	0	0	0	0	0	1	0	2	0	0
	E0033015	SCREEN		03APR2003	-7	10		1	1	0	1	2	2	1	0	2	0	0
		DAY 1		10APR2003	1	3		1	1	0	1	0	0	0	0	0	0	0
		DAY 8		17APR2003	8	5	2	1	1	0	0	2	0	1	0	0	0	0
		DAY 15		22APR2003	13	8	5	0	0	1	0	2	2	1	0	2	0	0
		DAY 15	*	28APR2003	19	3	0	1	1	0	0	0	0	1	0	0	0	0
		DAY 29		06MAY2003	27	3	0	0	0	1	0	2	0	0	0	0	0	0
		DAY 36		13MAY2003	34	5	2	1	1	0	0	0	2	1	0	0	0	0
		DAY 43		20MAY2003	41	4	1	1	1	1	0	0	0	1	0	0	0	0
		DAY 50		27MAY2003	48	2	-1	0	1	0	0	0	0	1	0	0	0	0
		DAY 57		04JUN2003	56	5	2	1	1	0	0	2	0	1	0	0	0	0
	E0034002	SCREEN		14MAR2003	-11	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		25MAR2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8		01APR2003	8	4	-1	0	0	0	0	4	0	0	0	0	0	0
		DAY 15		08APR2003	15	3	-2	0	0	0	0	3	0	0	0	0	0	0
		DAY 22		15APR2003	22	3	-2	0	0	0	0	3	0	0	0	0	0	0
	E0034003	SCREEN		11APR2003	-13	3		0	0	0	0	3	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	DAY 1	24APR2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	01MAY2003	8	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	08MAY2003	15	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	15MAY2003	22	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	22MAY2003	29	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	29MAY2003	36	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05JUN2003	43	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	12JUN2003	50	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19JUN2003	57	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0034006	SCREEN	25APR2003	-21	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 1	16MAY2003	1	8		0	0	0	2	6	0	0	0	0	0	0
		DAY 8	23MAY2003	8	6	-2	0	0	0	0	6	0	0	0	0	0	0
		DAY 15	02JUN2003	18	6	-2	0	0	0	0	6	0	0	0	0	0	0
		DAY 22	09JUN2003	25	6	-2	0	0	0	0	6	0	0	0	0	0	0
		DAY 29	13JUN2003	29	6	-2	0	0	0	0	6	0	0	0	0	0	0
		DAY 36	20JUN2003	36	6	-2	0	0	0	0	6	0	0	0	0	0	0
		DAY 43	27JUN2003	43	7	-1	0	0	0	0	6	0	0	0	0	1	0
		DAY 50	03JUL2003	49	4	-4	0	0	0	0	3	0	0	0	0	1	0
		DAY 57	10JUL2003	56	4	-4	0	0	0	0	4	0	0	0	0	0	0
	E0034008	SCREEN	15MAY2003	-9	3		0	0	0	0	3	0	0	0	0	0	0
		DAY 1	23MAY2003	-1	6		0	0	0	0	6	0	0	0	0	0	0
		DAY 8	02JUN2003	10	6	0	0	0	0	0	6	0	0	0	0	0	0
		DAY 15	06JUN2003	14	6	0	0	0	0	0	6	0	0	0	0	0	0
		DAY 22	13JUN2003	21	6	0	0	0	0	0	6	0	0	0	0	0	0
		DAY 29	20JUN2003	28	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 36	27JUN2003	35	0	-6	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 43	07JUL2003	45	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	14JUL2003	52	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	21JUL2003	59	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0035003	SCREEN	15NOV2002	-7	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 1	22NOV2002	1	4		0	0	0	2	0	0	0	0	2	0	0
		DAY 8	27NOV2002	6	2	-2	0	0	0	0	0	0	0	0	2	0	0
		DAY 15	04DEC2002	13	2	-2	0	0	0	0	0	0	0	0	2	0	0
		DAY 22	13DEC2002	22	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	20DEC2002	29	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 36	27DEC2002	36	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 43	03JAN2003	43	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	10JAN2003	50	3	-1	0	0	0	1	2	0	0	0	0	0	0
	E0035005	SCREEN	26NOV2002	-7	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 1	03DEC2002	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8	12DEC2002	10	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	17DEC2002	15	3	1	1	0	0	0	2	0	0	0	0	0	0
		DAY 22	24DEC2002	22	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	31DEC2002	29	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	07JAN2003	36	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	14JAN2003	43	3	1	0	0	0	0	2	0	0	0	0	1	0
		DAY 50	21JAN2003	50	2	0	0	0	0	0	2	0	0	0	0	0	0
	E0035014	SCREEN	28JAN2003	-6	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	03FEB2003	1	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 8	10FEB2003	8	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 15	17FEB2003	15	2	-2	1	1	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	DAY 22	24FEB2003	22	5	1	0	0	0	1	2	0	0	0	2	0	0
		DAY 29	03MAR2003	29	3	-1	1	0	0	0	2	0	0	0	0	0	0
		DAY 36	10MAR2003	36	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 43	17MAR2003	43	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 50	24MAR2003	50	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	31MAR2003	57	4	0	1	1	0	0	0	0	0	0	2	0	0
	E0035024	SCREEN	15MAY2003	-8	8		0	0	0	2	2	2	0	0	2	0	0
		DAY 1	22MAY2003	-1	8		0	0	0	2	2	0	1	0	2	1	0
		DAY 8	29MAY2003	7	7	-1	0	0	0	2	2	0	1	0	2	0	0
		DAY 15	05JUN2003	14	4	-4	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	13JUN2003	22	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	19JUN2003	28	4	-4	0	0	0	0	2	0	0	0	2	0	0
		DAY 36	27JUN2003	36	7	-1	0	0	0	0	4	0	1	0	2	0	0
		DAY 43	03JUL2003	42	8	0	0	0	0	2	4	0	0	0	2	0	0
		DAY 50	10JUL2003	49	9	1	0	0	1	2	4	0	0	0	2	0	0
		DAY 57	18JUL2003	57	6	-2	0	0	0	2	2	0	0	0	2	0	0
	E0036005	SCREEN	24JUN2003	-7	6		0	0	0	2	2	0	0	1	0	1	0
		DAY 1	01JUL2003	1	10		0	0	0	0	2	3	0	1	3	1	0
		DAY 8	08JUL2003	8	3	-7	1	0	0	0	2	0	0	0	0	0	0
		DAY 15	15JUL2003	15	19	9	3	3	0	1	3	5	2	1	1	0	0
		DAY 22	23JUL2003	23	5	-5	0	1	0	0	2	1	1	0	0	0	0
		DAY 29	29JUL2003	29	7	-3	1	0	0	0	2	2	0	0	2	0	0
		DAY 36	05AUG2003	36	8	-2	0	1	0	0	3	1	0	0	2	1	0
		DAY 43	12AUG2003	43	2	-8	0	0	0	0	0	0	1	0	0	1	0
		DAY 50	19AUG2003	50	3	-7	0	0	0	0	2	0	0	0	0	1	0
		DAY 57	27AUG2003	58	6	-4	0	0	0	0	1	3	0	0	1	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	SCREEN	18DEC2002	-8	6		0	0	0	2	2	0	1	0	1	0	0
		DAY 1	26DEC2002	1	6		1	1	0	2	2	0	0	0	0	0	0
		DAY 8	03JAN2003	9	7	1	1	2	0	0	2	0	1	1	0	0	0
		DAY 15	09JAN2003	15	7	1	0	1	0	0	2	1	1	0	2	0	0
		DAY 22	17JAN2003	23	9	3	1	0	0	0	4	1	1	1	1	0	0
		DAY 29	24JAN2003	30	3	-3	0	0	0	1	2	0	0	0	0	0	0
		DAY 36	31JAN2003	37	3	-3	0	0	0	2	1	0	0	0	0	0	0
		DAY 43	07FEB2003	44	7	1	1	1	0	0	2	2	0	0	1	0	0
		DAY 50	13FEB2003	50	5	-1	1	1	0	0	2	0	1	0	0	0	0
		DAY 57	20FEB2003	57	9	3	1	2	0	0	2	2	1	0	1	0	0
	E0037005	SCREEN	26FEB2003	-8	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 1	06MAR2003	1	8		0	0	0	2	2	0	1	0	2	1	0
		DAY 8	13MAR2003	8	5	-3	0	0	0	0	2	2	1	0	0	0	0
		DAY 15	20MAR2003	15	4	-4	0	0	0	0	2	0	2	0	0	0	0
		DAY 22	27MAR2003	22	7	-1	0	0	0	0	2	1	2	0	2	0	0
		DAY 29	03APR2003	29	8	0	1	1	0	0	3	0	2	0	1	0	0
		DAY 36	10APR2003	36	4	-4	0	0	0	0	4	0	0	0	0	0	0
		DAY 43	17APR2003	43	3	-5	0	0	0	0	3	0	0	0	0	0	0
		DAY 50	24APR2003	50	4	-4	0	0	0	0	4	0	0	0	0	0	0
		DAY 57	01MAY2003	57	4	-4	0	0	0	0	3	0	1	0	0	0	0
	E0037006	SCREEN	06MAR2003	-8	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	14MAR2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	21MAR2003	8	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	28MAR2003	15	5	0	1	0	0	0	0	2	1	0	0	1	0
		DAY 22	04APR2003	22	1	-4	0	0	0	0	0	0	0	0	0	1	0
		DAY 29	11APR2003	29	2	-3	0	0	0	0	1	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	DAY 36	18APR2003	36	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	25APR2003	43	1	-4	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	01MAY2003	49	3	-2	1	0	0	1	0	1	0	0	0	0	0
		DAY 57	09MAY2003	57	2	-3	0	0	0	0	2	0	0	0	0	0	0
	E0039006	SCREEN	10DEC2002	-20	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	30DEC2002	1	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 8	06JAN2003	8	2	-1	0	0	0	2	0	0	0	0	0	0	0
		DAY 15	13JAN2003	15	2	-1	0	0	0	2	0	0	0	0	0	0	0
		DAY 22	20JAN2003	22	2	-1	0	0	0	2	0	0	0	0	0	0	0
		DAY 29	28JAN2003	30	2	-1	0	0	0	2	0	0	0	0	0	0	0
		DAY 36	04FEB2003	37	2	-1	0	0	0	2	0	0	0	0	0	0	0
		DAY 43	10FEB2003	43	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	18FEB2003	51	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	24FEB2003	57	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0039015	SCREEN	02JAN2003	-21	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	23JAN2003	1	7		0	1	0	2	1	3	0	0	0	0	0
		DAY 8	30JAN2003	8	2	-5	1	1	0	0	0	0	0	0	0	0	0
		DAY 15	06FEB2003	15	5	-2	1	1	0	0	2	1	0	0	0	0	0
		DAY 22	14FEB2003	23	1	-6	0	0	0	1	0	0	0	0	0	0	0
		DAY 29	20FEB2003	29	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	27FEB2003	36	5	-2	1	1	1	0	0	2	0	0	0	0	0
		DAY 43	06MAR2003	43	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	14MAR2003	51	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	20MAR2003	57	0	-7	0	0	0	0	0	0	0	0	0	0	0
	E0039024	SCREEN	05FEB2003	-22	2		0	0	0	2	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	DAY 1	27FEB2003	1	5		1	0	0	2	2	0	0	0	0	0	0
		DAY 8	05MAR2003	7	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	11MAR2003	13	2	-3	0	0	0	1	1	0	0	0	0	0	0
		DAY 22	20MAR2003	22	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	27MAR2003	29	5	0	0	0	0	2	3	0	0	0	0	0	0
		DAY 36	03APR2003	36	5	0	0	0	0	2	3	0	0	0	0	0	0
		DAY 43	10APR2003	43	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	17APR2003	50	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	24APR2003	57	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0039025	SCREEN	26FEB2003	-20	6		1	1	0	2	2	0	0	0	0	0	0
		DAY 1	18MAR2003	1	5		0	1	0	2	1	0	0	1	0	0	0
		DAY 8	25MAR2003	8	5	0	0	1	0	0	2	0	0	0	2	0	0
		DAY 15	01APR2003	15	5	0	0	0	0	0	3	0	0	0	2	0	0
		DAY 22	10APR2003	24	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	15APR2003	29	6	1	2	2	1	1	0	0	0	0	0	0	0
		DAY 36	22APR2003	36	8	3	1	1	1	1	2	2	0	0	0	0	0
		DAY 43	29APR2003	43	3	-2	0	0	0	1	0	2	0	0	0	0	0
		DAY 50	06MAY2003	50	4	-1	0	1	0	1	0	1	0	1	0	0	0
	E0039041	SCREEN	07APR2003	-8	7		1	1	0	3	2	0	0	0	0	0	0
		DAY 1	15APR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	22APR2003	8	5	1	0	0	0	2	3	0	0	0	0	0	0
		DAY 15	29APR2003	15	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	06MAY2003	22	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	13MAY2003	29	8	4	0	1	0	2	2	2	1	0	0	0	0
		DAY 36	20MAY2003	36	3	-1	0	0	0	0	2	0	0	1	0	0	0
		DAY 43	27MAY2003	43	6	2	0	0	0	2	2	1	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 50		03JUN2003	50	3	-1	0	0	0	1	1	0	0	1	0	0	0
		DAY 57		11JUN2003	58	5	1	1	1	1	1	0	0	0	1	0	0	0
	E0039044	SCREEN		05MAY2003	-17	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1		22MAY2003	1	5		0	1	0	2	2	0	0	0	0	0	0
		DAY 8		29MAY2003	8	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		04JUN2003	14	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		11JUN2003	21	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		18JUN2003	28	2	-3	0	0	0	0	0	2	0	0	0	0	0
		DAY 36		26JUN2003	36	4	-1	0	0	0	0	1	2	1	0	0	0	0
		DAY 43		02JUL2003	42	4	-1	0	1	0	0	0	2	1	0	0	0	0
		DAY 50		09JUL2003	49	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0039046		*	06MAY2003		3		0	0	0	2	0	0	1	0	0	0	0
			*	21MAY2003		3		0	0	0	2	1	0	0	0	0	0	0
	E0039051	SCREEN		22MAY2003	-25	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 1		16JUN2003	1	7		0	0	0	2	3	0	2	0	0	0	0
		DAY 8		23JUN2003	8	4	-3	0	0	0	1	2	0	1	0	0	0	0
		DAY 15		30JUN2003	15	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		07JUL2003	22	5	-2	0	0	0	0	3	2	0	0	0	0	0
		DAY 29		14JUL2003	29	2	-5	0	0	0	1	1	0	0	0	0	0	0
		DAY 36		22JUL2003	37	4	-3	0	0	0	0	2	2	0	0	0	0	0
		DAY 43		28JUL2003	43	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 50		04AUG2003	50	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 57		12AUG2003	58	2	-5	0	0	0	0	2	0	0	0	0	0	0
	E0039053	SCREEN		16JUN2003	-25	6		0	0	0	2	3	1	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	DAY 1	11JUL2003	1	10		0	0	0	2	3	0	2	0	3	0	0
		DAY 8	18JUL2003	8	11	1	0	1	0	1	3	2	2	0	2	0	0
		DAY 15	25JUL2003	15	11	1	0	0	0	2	3	2	2	0	2	0	0
		DAY 22	01AUG2003	22	3	-7	0	0	0	2	1	0	0	0	0	0	0
		DAY 29	07AUG2003	28	2	-8	0	0	0	1	0	0	1	0	0	0	0
		DAY 36	14AUG2003	35	3	-7	0	1	0	1	0	0	1	0	0	0	0
		DAY 43	21AUG2003	42	0	-10	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	29AUG2003	50	0	-10	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	08SEP2003	60	2	-8	0	0	0	0	2	0	0	0	0	0	0
	E0039057	SCREEN	02JUL2003	-12	9		0	1	0	2	3	2	1	0	0	0	0
		DAY 1	14JUL2003	1	8		0	1	0	2	2	2	1	0	0	0	0
		DAY 8	22JUL2003	9	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	28JUL2003	15	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	04AUG2003	22	1	-7	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	12AUG2003	30	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	18AUG2003	36	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	26AUG2003	44	4	-4	0	0	0	0	1	2	1	0	0	0	0
		DAY 50	02SEP2003	51	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	09SEP2003	58	2	-6	0	0	0	0	2	0	0	0	0	0	0
	E0041003	SCREEN	16JAN2003	-12	8		0	0	0	1	2	0	1	2	2	0	0
		DAY 1	28JAN2003	1	8		1	0	0	0	2	0	1	2	2	0	0
		DAY 8	04FEB2003	8	2	-6	0	0	0	0	0	0	0	0	2	0	0
		DAY 15	11FEB2003	15	1	-7	1	0	0	0	0	0	0	0	0	0	0
		DAY 22	18FEB2003	22	2	-6	1	0	0	1	0	0	0	0	0	0	0
		DAY 29	25FEB2003	29	1	-7	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	04MAR2003	36	1	-7	1	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 43	11MAR2003	43	1	-7	1	0	0	0	0	0	0	0	0	0	0
		DAY 50	18MAR2003	50	1	-7	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	25MAR2003	57	2	-6	1	1	0	0	0	0	0	0	0	0	0
	E0041008	SCREEN	26MAR2003	-12	10		0	0	0	2	4	0	0	2	2	0	0
		DAY 1	07APR2003	1	11		1	0	0	2	2	0	2	2	2	0	0
		DAY 8	14APR2003	8	10	-1	1	0	0	2	2	0	2	1	2	0	0
		DAY 15	22APR2003	16	10	-1	1	0	0	2	2	0	2	1	2	0	0
		DAY 22	28APR2003	22	12	1	0	1	0	2	4	0	2	1	2	0	0
		DAY 29	05MAY2003	29	8	-3	0	1	0	2	2	0	1	0	2	0	0
		DAY 36	12MAY2003	36	14	3	1	2	0	2	4	0	1	0	4	0	0
		DAY 43	21MAY2003	45	9	-2	1	1	0	2	2	0	1	0	2	0	0
		DAY 50	27MAY2003	51	9	-2	1	1	0	2	2	0	1	0	2	0	0
		DAY 57	02JUN2003	57	12	1	1	1	0	2	4	0	0	0	4	0	0
	E0042001	SCREEN	17JUN2003	-15	5		0	0	0	1	0	2	0	0	0	2	0
		DAY 1	02JUL2003	1	5		0	0	0	1	0	2	0	0	0	2	0
		DAY 8	09JUL2003	8	2	-3	0	0	0	0	0	0	0	0	0	2	0
		DAY 15	15JUL2003	14	2	-3	0	0	0	0	0	0	0	0	0	2	0
		DAY 22	22JUL2003	21	4	-1	1	0	0	0	2	0	0	0	0	1	0
		DAY 29	29JUL2003	28	6	1	1	1	0	0	2	0	0	0	0	2	0
		DAY 36	05AUG2003	35	6	1	0	1	0	0	0	2	1	0	0	2	0
		DAY 43	12AUG2003	42	5	0	1	0	0	0	2	0	0	0	0	2	0
		DAY 50	19AUG2003	49	2	-3	0	0	0	1	0	0	0	0	0	1	0
		DAY 57	26AUG2003	56	4	-1	0	0	0	0	0	2	1	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	SCREEN	26FEB2003	-14	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	12MAR2003	1	7		0	0	0	2	3	0	2	0	0	0	0
		DAY 8	19MAR2003	8	3	-4	0	0	0	0	2	0	1	0	0	0	0
		DAY 15	26MAR2003	15	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	02APR2003	22	6	-1	0	0	0	0	2	1	1	1	1	0	0
		DAY 29	09APR2003	29	4	-3	0	1	0	0	0	1	2	0	0	0	0
		DAY 36	16APR2003	36	1	-6	1	0	0	0	0	0	0	0	0	0	0
		DAY 43	23APR2003	43	3	-4	0	0	0	0	2	0	0	0	1	0	0
		DAY 50	30APR2003	50	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	07MAY2003	57	2	-5	0	0	0	0	0	2	0	0	0	0	0
	E0003018	SCREEN	06MAY2003	-7	9		2	1	0	2	3	0	1	0	0	0	0
		DAY 1	13MAY2003	1	5		0	0	0	1	2	0	0	0	2	0	0
		DAY 8	20MAY2003	8	10	5	2	2	0	0	2	2	1	0	1	0	0
		DAY 15	27MAY2003	15	6	1	1	1	0	1	3	0	0	0	0	0	0
		DAY 22	03JUN2003	22	8	3	0	1	0	1	4	0	0	0	2	0	0
		DAY 29	10JUN2003	29	15	10	1	1	0	1	2	3	1	2	4	0	0
		DAY 36	17JUN2003	36	5	0	1	0	0	1	1	0	1	0	1	0	0
		DAY 43	24JUN2003	43	7	2	0	1	0	1	2	0	1	0	2	0	0
		DAY 50	02JUL2003	51	8	3	0	1	0	1	2	0	1	1	2	0	0
		DAY 57	08JUL2003	57	9	4	1	0	0	2	2	0	1	2	1	0	0
	E0005011	SCREEN	16OCT2002	-8	6		0	0	0	3	2	0	1	0	0	0	0
		DAY 1	24OCT2002	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	31OCT2002	8	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	07NOV2002	15	1	-4	0	0	0	0	0	0	1	0	0	0	0
		DAY 22	14NOV2002	22	1	-4	0	0	0	0	0	0	1	0	0	0	0
		DAY 29	21NOV2002	29	1	-4	0	0	0	0	0	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0005011	DAY 36	26NOV2002	34	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	03DEC2002	41	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	12DEC2002	50	1	-4	0	0	0	0	0	0	1	0	0	0	0
	E0005030	SCREEN	18MAR2003	-8	12		0	1	0	2	4	2	1	0	2	0	0
		DAY 1	26MAR2003	1	9		0	0	2	2	2	0	1	0	2	0	0
		DAY 8	02APR2003	8	9	0	0	0	1	0	4	0	2	0	2	0	0
		DAY 15	09APR2003	15	7	-2	0	1	0	0	2	2	0	2	0	0	0
		DAY 22	16APR2003	22	12	3	0	0	0	2	4	2	2	0	2	0	0
	E0005036	SCREEN	28APR2003	-8	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	06MAY2003	1	6		0	0	0	2	3	0	1	0	0	0	0
		DAY 8	12MAY2003	7	7	1	0	0	0	2	2	2	1	0	0	0	0
	E0006015	SCREEN	06FEB2003	-5	2		0	0	0	0	1	0	0	0	1	0	0
		DAY 1	11FEB2003	1	4		0	0	0	0	2	0	0	1	1	0	0
		DAY 8	18FEB2003	8	2	-2	0	1	1	0	0	0	0	0	0	0	0
		DAY 15	25FEB2003	15	3	-1	0	0	0	0	2	0	1	0	0	0	0
		DAY 22	04MAR2003	22	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 29	11MAR2003	29	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	18MAR2003	36	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 43	25MAR2003	43	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	01APR2003	50	6	2	1	0	0	2	2	0	0	0	1	0	0
		DAY 57	08APR2003	57	4	0	1	0	1	0	2	0	0	0	0	0	0
	E0006016	SCREEN	07FEB2003	-10	3		0	0	0	0	3	0	0	0	0	0	0
		DAY 1	17FEB2003	1	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 8	24FEB2003	8	4	0	0	0	0	0	2	0	0	0	2	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	DAY 15	03MAR2003	15	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	10MAR2003	22	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	17MAR2003	29	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	27MAR2003	39	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	03APR2003	46	3	-1	0	0	0	0	3	0	0	0	0	0	0
		DAY 50	10APR2003	53	4	0	1	0	1	0	2	0	0	0	0	0	0
		DAY 57	18APR2003	61	4	0	1	0	1	0	2	0	0	0	0	0	0
	E0007008	SCREEN	07APR2003	-11	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	18APR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	25APR2003	8	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0009002	SCREEN	29OCT2002	-21	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	19NOV2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	26NOV2002	8	4	0	0	0	0	0	4	0	0	0	0	0	0
		DAY 15	03DEC2002	15	2	-2	0	0	0	1	1	0	0	0	0	0	0
		DAY 22	10DEC2002	22	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	18DEC2002	30	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	23DEC2002	35	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 43	30DEC2002	42	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	07JAN2003	50	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	15JAN2003	58	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0009006	SCREEN	22JAN2003	-6	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1	28JAN2003	1	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 8	04FEB2003	8	5	-2	0	0	0	0	2	0	1	0	2	0	0
		DAY 15	11FEB2003	15	6	-1	0	0	0	0	2	0	2	0	2	0	0
		DAY 22	18FEB2003	22	8	1	0	1	0	2	2	0	1	2	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	DAY 29	25FEB2003	29	7	0	1	1	1	1	2	0	1	0	0	0	0
		DAY 36	04MAR2003	36	4	-3	0	0	0	0	2	0	1	0	0	1	0
		DAY 43	11MAR2003	43	8	1	1	1	1	1	2	0	2	0	0	0	0
		DAY 50	18MAR2003	50	10	3	0	0	0	0	4	0	2	2	2	0	0
		DAY 57	25MAR2003	57	8	1	0	0	0	0	2	0	2	2	2	0	0
	E0009009	SCREEN	27FEB2003	-13	8		0	1	0	2	2	2	1	0	0	0	0
		DAY 1	12MAR2003	1	7		0	0	0	0	2	0	1	2	2	0	0
		DAY 8	19MAR2003	8	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	24MAR2003	13	4	-3	1	0	0	0	2	0	1	0	0	0	0
	E0010015	SCREEN	29JAN2003	-22	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	20FEB2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	27FEB2003	8	4	0	2	0	0	2	0	0	0	0	0	0	0
		DAY 15	06MAR2003	15	5	1	0	0	0	2	3	0	0	0	0	0	0
		DAY 22	13MAR2003	22	6	2	0	0	0	2	2	0	1	1	0	0	0
		DAY 29	20MAR2003	29	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 36	26MAR2003	35	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 43	02APR2003	42	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 50	09APR2003	49	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 57	15APR2003	55	2	-2	0	0	0	2	0	0	0	0	0	0	0
	E0011004	SCREEN	17DEC2002	-7	6		1	1	0	0	0	2	0	0	0	1	1
		DAY 1	24DEC2002	1	6		0	0	0	2	3	0	0	0	0	1	0
		DAY 8	31DEC2002	8	3	-3	0	0	0	2	0	0	0	0	0	1	0
		DAY 15	07JAN2003	15	5	-1	0	0	0	2	2	0	0	0	0	1	0
		DAY 22	14JAN2003	22	3	-3	0	0	0	1	0	0	0	0	2	0	0
		DAY 29	21JAN2003	29	2	-4	0	0	0	1	0	0	0	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	DAY 36		28JAN2003	36	5	-1	0	0	0	2	2	0	0	0	1	0	0
		DAY 43		04FEB2003	43	3	-3	0	0	0	2	1	0	0	0	0	0	0
		DAY 50		11FEB2003	50	2	-4	0	1	0	0	0	0	1	0	0	0	0
		DAY 57		18FEB2003	57	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0011007	SCREEN		12DEC2002	-7	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1		19DEC2002	1	3		0	1	0	0	0	1	0	0	1	0	0
		DAY 8		26DEC2002	8	5	2	0	0	1	0	2	0	0	0	1	1	0
		DAY 15		02JAN2003	15	4	1	0	0	0	2	2	0	0	0	0	0	0
		DAY 22		09JAN2003	22	2	-1	0	1	0	0	0	1	0	0	0	0	0
		DAY 29		17JAN2003	30	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 36		23JAN2003	36	2	-1	0	0	0	0	1	0	1	0	0	0	0
		DAY 43		30JAN2003	43	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 50		06FEB2003	50	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		13FEB2003	57	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0011018	SCREEN		15MAY2003	-7	5		0	1	0	2	1	0	0	0	0	0	1
		DAY 1		22MAY2003	1	5		0	0	0	2	1	0	1	0	0	1	0
		DAY 8		30MAY2003	9	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	*	10JUN2003	20	4	-1	0	0	0	1	1	0	0	2	0	0	0
		DAY 22		13JUN2003	23	2	-3	0	0	0	0	1	0	0	1	0	0	0
		DAY 29		20JUN2003	30	3	-2	1	0	0	0	1	0	0	1	0	0	0
		DAY 36		28JUN2003	38	2	-3	0	1	0	0	0	0	1	0	0	0	0
		DAY 43		03JUL2003	43	4	-1	1	1	0	0	1	0	1	0	0	0	0
		DAY 50		10JUL2003	50	8	3	1	0	0	0	2	2	1	2	0	0	0
		DAY 57		17JUL2003	57	1	-4	0	0	0	0	1	0	0	0	0	0	0
	E0011024	SCREEN		17JUN2003	-7	2		0	0	0	2	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	DAY 1		24JUN2003	1	4		0	0	0	2	1	0	1	0	0	0	0
		DAY 8		01JUL2003	8	5	1	0	1	0	0	2	1	0	0	1	0	0
		DAY 15		08JUL2003	15	4	0	0	1	0	0	2	1	0	0	0	0	0
		DAY 22		15JUL2003	22	5	1	0	1	0	0	3	1	0	0	0	0	0
		DAY 29		22JUL2003	29	3	-1	1	2	0	0	0	0	0	0	0	0	0
		DAY 36		30JUL2003	37	5	1	1	2	0	0	0	0	0	0	2	0	0
		DAY 43		05AUG2003	43	4	0	1	2	0	0	0	0	0	0	1	0	0
		DAY 50		12AUG2003	50	4	0	1	2	0	0	0	0	0	0	1	0	0
		DAY 57		21AUG2003	59	3	-1	1	2	0	0	0	0	0	0	0	0	0
	E0015003	SCREEN		13NOV2002	-12	7		0	0	0	2	2	0	1	2	0	0	0
		DAY 1		25NOV2002	1	8		0	0	0	2	2	1	1	2	0	0	0
		DAY 8		02DEC2002	8	3	-5	0	0	0	1	2	0	0	0	0	0	0
	E0019003	SCREEN		29OCT2002	-23	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		21NOV2002	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8		27NOV2002	7	5	2	0	0	2	0	2	0	0	0	0	1	0
		DAY 15		09DEC2002	19	4	1	1	0	2	0	0	0	0	0	0	1	0
		DAY 22		16DEC2002	26	4	1	0	0	1	0	2	0	0	0	0	1	0
		DAY 36		24DEC2002	34	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	*	30DEC2002	40	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 43		06JAN2003	47	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	*	14JAN2003	55	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		16JAN2003	57	2	-1	0	0	0	0	2	0	0	0	0	0	0
	E0019007	SCREEN		06NOV2002	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		13NOV2002	1	5		1	1	0	0	2	1	0	0	0	0	0
		DAY 8		21NOV2002	9	1	-4	0	0	0	0	1	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0019007	DAY 15	27NOV2002	15	2	-3	0	1	0	0	1	0	0	0	0	0	0
		DAY 22	05DEC2002	23	4	-1	1	1	0	0	2	0	0	0	0	0	0
		DAY 29	12DEC2002	30	7	2	1	0	0	0	2	2	2	0	0	0	0
		DAY 36	17DEC2002	35	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	24DEC2002	42	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	30DEC2002	48	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	07JAN2003	56	7	2	0	0	0	0	3	3	0	1	0	0	0
	E0019014	SCREEN	17DEC2002	-23	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	09JAN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	20JAN2003	12	2	0	0	0	0	0	2	0	0	0	0	0	0
	E0019018	SCREEN	14JAN2003	-16	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 1	30JAN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	06FEB2003	8	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	13FEB2003	15	2	0	1	0	0	0	1	0	0	0	0	0	0
		DAY 22	20FEB2003	22	3	1	0	0	0	0	2	0	0	0	0	1	0
		DAY 29	27FEB2003	29	5	3	1	0	0	0	4	0	0	0	0	0	0
		DAY 36	06MAR2003	36	7	5	0	0	0	1	3	0	2	0	0	1	0
		DAY 43	13MAR2003	43	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	20MAR2003	50	3	1	0	0	0	0	2	0	1	0	0	0	0
		DAY 57	27MAR2003	57	3	1	0	0	0	0	2	0	1	0	0	0	0
	E0019022	SCREEN	23JAN2003	-7	6		0	0	0	2	2	0	0	2	0	0	0
		DAY 1	30JAN2003	1	3		0	0	1	0	2	0	0	0	0	0	0
		DAY 8	06FEB2003	8	4	1	0	1	0	1	2	0	0	0	0	0	0
		DAY 15	13FEB2003	15	6	3	1	2	0	0	2	1	0	0	0	0	0
		DAY 22	20FEB2003	22	5	2	2	2	0	0	1	0	0	0	0	0	0

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QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 29	27FEB2003	29	3	0	0	0	1	0	2	0	0	0	0	0	0
		DAY 36	06MAR2003	36	9	6	2	2	1	0	2	1	0	0	1	0	0
		DAY 43	13MAR2003	43	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	20MAR2003	50	6	3	0	1	2	1	1	0	0	0	1	0	0
		DAY 57	27MAR2003	57	5	2	1	1	0	1	2	0	0	0	0	0	0
	E0019027	SCREEN	20FEB2003	-7	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1	27FEB2003	1	2		0	0	0	1	1	0	0	0	0	0	0
		DAY 8	06MAR2003	8	2	0	0	0	0	1	1	0	0	0	0	0	0
	E0019032	SCREEN	06MAR2003	-26	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	01APR2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	08APR2003	8	5	0	0	0	0	1	2	0	2	0	0	0	0
		DAY 15	15APR2003	15	3	-2	0	0	0	0	2	0	1	0	0	0	0
		DAY 22	21APR2003	21	6	1	0	0	0	1	4	0	1	0	0	0	0
		DAY 29	29APR2003	29	2	-3	0	0	0	1	1	0	0	0	0	0	0
		DAY 36	07MAY2003	37	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	14MAY2003	44	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	21MAY2003	51	4	-1	0	0	0	1	3	0	0	0	0	0	0
		DAY 57	27MAY2003	57	2	-3	0	0	0	0	2	0	0	0	0	0	0
	E0019034	SCREEN	10MAR2003	-8	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	18MAR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	25MAR2003	8	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	01APR2003	15	3	-1	1	0	0	0	2	0	0	0	0	0	0
	E0019036	SCREEN	18MAR2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	25MAR2003	1	11		0	0	0	2	2	4	1	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0019036	DAY 8	31MAR2003	7	12	1	1	2	0	0	2	2	2	2	1	0	0
		DAY 15	10APR2003	17	2	-9	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	15APR2003	22	2	-9	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	22APR2003	29	5	-6	1	1	0	0	2	1	0	0	0	0	0
		DAY 36	29APR2003	36	1	-10	0	0	0	0	1	0	0	0	0	0	0
	E0019039	SCREEN	22APR2003	-9	8		0	1	0	2	2	0	2	1	0	0	0
		DAY 1	01MAY2003	1	5		0	0	0	2	3	0	0	0	0	0	0
	E0019041	SCREEN	14MAY2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	21MAY2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	28MAY2003	8	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	04JUN2003	15	3	-2	0	0	0	0	2	0	1	0	0	0	0
		DAY 22	12JUN2003	23	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	18JUN2003	29	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 36	25JUN2003	36	4	-1	0	0	0	1	1	0	0	2	0	0	0
		DAY 43	02JUL2003	43	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	09JUL2003	50	2	-3	0	0	0	1	1	0	0	0	0	0	0
		DAY 57	16JUL2003	57	2	-3	0	0	0	2	0	0	0	0	0	0	0
	E0019049	SCREEN	03JUL2003	-7	9		0	0	0	2	2	4	1	0	0	0	0
		DAY 1	10JUL2003	1	8		0	0	0	2	4	1	0	1	0	0	0
		DAY 8	17JUL2003	8	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	24JUL2003	15	5	-3	0	0	0	1	4	0	0	0	0	0	0
		DAY 22	31JUL2003	22	4	-4	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	07AUG2003	29	8	0	0	0	0	2	4	1	0	0	1	0	0
		DAY 36	14AUG2003	36	4	-4	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	26AUG2003	48	3	-5	0	0	0	1	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	DAY 57	08SEP2003	61	5	-3	0	0	0	2	3	0	0	0	0	0	0
	E0022052	SCREEN	01APR2003	-9	9		0	0	0	2	4	0	1	0	2	0	0
		DAY 1	10APR2003	1	7		0	0	0	2	4	0	1	0	0	0	0
		DAY 8	17APR2003	8	5	-2	0	0	0	0	4	0	1	0	0	0	0
		DAY 15	24APR2003	15	3	-4	0	0	0	1	2	0	0	0	0	0	0
		DAY 22	01MAY2003	22	8	1	0	0	0	2	4	0	0	0	2	0	0
		DAY 29	08MAY2003	29	4	-3	0	0	0	2	2	0	0	0	0	0	0
		DAY 36	15MAY2003	36	2	-5	0	0	0	2	0	0	0	0	0	0	0
		DAY 43	22MAY2003	43	4	-3	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	29MAY2003	50	4	-3	0	0	0	0	2	0	0	0	2	0	0
		DAY 57	05JUN2003	57	2	-5	0	0	0	2	0	0	0	0	0	0	0
	E0022064	SCREEN	29APR2003	-7	4		0	0	0	0	4	0	0	0	0	0	0
		DAY 1	06MAY2003	1	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 8	12MAY2003	7	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	20MAY2003	15	1	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 22	27MAY2003	22	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	03JUN2003	29	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	10JUN2003	36	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	17JUN2003	43	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	24JUN2003	50	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	01JUL2003	57	3	2	0	0	0	0	0	0	1	2	0	0	0
	E0022073	SCREEN	19JUN2003	-7	8		0	0	0	2	4	0	0	0	0	2	0
		DAY 1	26JUN2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8	03JUL2003	8	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	10JUL2003	15	0	-6	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0022073	DAY 22	17JUL2003	22	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	24JUL2003	29	1	-5	0	0	0	0	0	0	0	0	0	1	0
		DAY 36	31JUL2003	36	1	-5	0	0	0	0	0	0	0	0	0	1	0
		DAY 43	07AUG2003	43	3	-3	0	0	0	0	2	0	0	0	0	1	0
		DAY 50	14AUG2003	50	5	-1	0	0	0	1	2	0	0	0	0	2	0
		DAY 57	21AUG2003	57	1	-5	0	0	0	0	0	0	0	0	0	1	0
	E0023002	SCREEN	25OCT2002	-11	7		0	0	0	0	4	2	1	0	0	0	0
		DAY 1	05NOV2002	1	6		1	0	0	0	2	2	1	0	0	0	0
		DAY 8	12NOV2002	8	3	-3	0	0	0	0	2	0	1	0	0	0	0
		DAY 15	19NOV2002	15	1	-5	0	0	0	0	0	0	1	0	0	0	0
		DAY 22	25NOV2002	21	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	03DEC2002	29	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	10DEC2002	36	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0023017	SCREEN	14MAR2003	-11	3		1	1	1	0	0	0	0	0	0	0	0
		DAY 1	25MAR2003	1	4		0	1	0	1	2	0	0	0	0	0	0
		DAY 8	03APR2003	10	6	2	2	1	0	1	2	0	0	0	0	0	0
		DAY 15	10APR2003	17	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	18APR2003	25	3	-1	1	1	0	0	1	0	0	0	0	0	0
		DAY 29	24APR2003	31	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 36	01MAY2003	38	1	-3	1	0	0	0	0	0	0	0	0	0	0
		DAY 43	08MAY2003	45	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	15MAY2003	52	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	59	1	-3	0	1	0	0	0	0	0	0	0	0	0
	E0023021	SCREEN	10APR2003	-13	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 1	23APR2003	1	0		0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	DAY 8	29APR2003	7	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	06MAY2003	14	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	13MAY2003	21	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	20MAY2003	28	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	29MAY2003	37	4	4	0	0	0	0	2	0	0	0	2	0	0
		DAY 43	03JUN2003	42	2	2	0	0	0	0	1	0	0	0	1	0	0
		DAY 50	10JUN2003	49	4	4	0	0	0	0	3	0	0	0	1	0	0
		DAY 57	17JUN2003	56	3	3	0	0	0	0	2	0	0	0	1	0	0
	E0023027	SCREEN	07MAY2003	-9	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	16MAY2003	1	4		1	1	0	0	2	0	0	0	0	0	0
		DAY 8	21MAY2003	6	4	0	0	0	0	0	4	0	0	0	0	0	0
		DAY 15	30MAY2003	15	4	0	0	0	0	0	3	0	0	0	1	0	0
		DAY 22	05JUN2003	21	8	4	1	1	0	0	4	0	0	0	2	0	0
		DAY 29	11JUN2003	27	6	2	0	0	0	0	4	0	0	0	2	0	0
		DAY 36	18JUN2003	34	4	0	0	0	0	0	4	0	0	0	0	0	0
		DAY 43	27JUN2003	43	6	2	0	0	1	2	3	0	0	0	0	0	0
		DAY 50	02JUL2003	48	3	-1	0	0	0	0	3	0	0	0	0	0	0
		DAY 57	09JUL2003	55	4	0	0	0	0	0	4	0	0	0	0	0	0
	E0023030	SCREEN	16MAY2003	-18	4		1	1	0	0	2	0	0	0	0	0	0
		DAY 1	03JUN2003	1	3		0	1	0	0	2	0	0	0	0	0	0
		DAY 8	10JUN2003	8	2	-1	1	1	0	0	0	0	0	0	0	0	0
		DAY 15	17JUN2003	15	2	-1	1	1	0	0	0	0	0	0	0	0	0
		DAY 22	24JUN2003	22	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	01JUL2003	29	3	0	1	1	0	0	1	0	0	0	0	0	0
		DAY 36	08JUL2003	36	4	1	1	1	0	0	1	1	0	0	0	0	0
		DAY 43	15JUL2003	43	0	-3	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	DAY 50		21JUL2003	49	2	-1	1	1	0	0	0	0	0	0	0	0	0
		DAY 57		30JUL2003	58	2	-1	1	1	0	0	0	0	0	0	0	0	0
	E0023040	SCREEN		25JUN2003	-8	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 1		03JUL2003	1	4		1	0	0	0	3	0	0	0	0	0	0
		DAY 8		12JUL2003	10	5	1	1	1	0	0	3	0	0	0	0	0	0
		DAY 15		17JUL2003	15	5	1	1	1	0	0	3	0	0	0	0	0	0
		DAY 22		25JUL2003	23	5	1	1	1	0	0	3	0	0	0	0	0	0
		DAY 36	*	05AUG2003	34	3	-1	0	0	0	0	3	0	0	0	0	0	0
		DAY 36		08AUG2003	37	4	0	1	0	0	0	3	0	0	0	0	0	0
		DAY 43		18AUG2003	47	9	5	2	2	0	0	2	2	1	0	0	0	0
		DAY 57	*	28AUG2003	57	7	3	2	2	0	0	3	0	0	0	0	0	0
		DAY 57		05SEP2003	65	4	0	1	1	0	0	2	0	0	0	0	0	0
	E0026014	SCREEN		12FEB2003	-7	4		0	0	0	2	0	1	0	1	0	0	0
		DAY 1		19FEB2003	1	4		0	0	1	2	0	1	0	0	0	0	0
		DAY 8		26FEB2003	8	2	-2	0	0	0	0	0	1	0	1	0	0	0
		DAY 15		05MAR2003	15	6	2	1	1	0	0	2	1	0	0	0	1	0
		DAY 22		12MAR2003	22	1	-3	0	0	0	0	0	0	0	0	0	1	0
		DAY 29		19MAR2003	29	4	0	0	0	0	0	2	1	0	0	0	1	0
	E0026019	SCREEN		10MAR2003	-7	10		0	0	1	1	3	1	0	2	0	1	1
		DAY 1		17MAR2003	1	12		0	1	0	3	4	0	1	0	2	1	0
		DAY 8		24MAR2003	8	8	-4	0	0	2	0	4	0	0	0	1	1	0
		DAY 15		31MAR2003	15	14	2	1	1	2	0	2	3	2	2	1	0	0
		DAY 22		07APR2003	22	15	3	0	2	2	1	3	2	1	2	2	0	0
		DAY 29		14APR2003	29	9	-3	0	0	2	0	4	0	0	0	2	1	0
		DAY 36		21APR2003	36	11	-1	1	1	2	0	2	1	0	2	0	2	0

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QUETIAPINE 300 MG (BIPOLAR II)	E0026019	DAY 43	28APR2003	43	13	1	0	0	1	2	6	1	1	0	2	0	0
		DAY 50	05MAY2003	50	15	3	0	0	0	2	6	0	1	2	3	1	0
		DAY 57	12MAY2003	57	8	-4	0	0	0	2	4	0	0	0	2	0	0
	E0027005	SCREEN	19DEC2002	-7	8		1	1	0	2	2	0	1	0	0	1	0
		DAY 1	26DEC2002	1	8		0	0	0	2	2	0	2	0	0	2	0
		DAY 8	02JAN2003	8	2	-6	0	0	0	0	0	0	1	0	0	1	0
		DAY 15	09JAN2003	15	3	-5	1	1	0	0	1	0	0	0	0	0	0
		DAY 22	16JAN2003	22	3	-5	1	1	0	0	1	0	0	0	0	0	0
		DAY 29	23JAN2003	29	3	-5	0	1	0	0	1	1	0	0	0	0	0
		DAY 36	30JAN2003	36	23	15	2	3	1	2	4	5	2	1	2	1	0
		DAY 43	06FEB2003	43	4	-4	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	12FEB2003	49	4	-4	0	0	0	2	2	0	0	0	0	0	0
		DAY 57	20FEB2003	57	1	-7	0	0	0	0	1	0	0	0	0	0	0
	E0029009	SCREEN	13JAN2003	-7	6		0	1	0	2	0	2	1	0	0	0	0
		DAY 1	20JAN2003	1	8		0	0	0	2	2	2	0	2	0	0	0
		DAY 8	27JAN2003	8	3	-5	1	0	0	0	0	0	0	2	0	0	0
		DAY 15	03FEB2003	15	3	-5	1	0	0	0	0	0	0	2	0	0	0
		DAY 22	11FEB2003	23	6	-2	0	1	0	0	2	2	1	0	0	0	0
		DAY 29	17FEB2003	29	4	-4	0	0	0	0	4	0	0	0	0	0	0
		DAY 36	24FEB2003	36	6	-2	0	0	0	0	3	0	1	0	2	0	0
		DAY 43	03MAR2003	43	1	-7	0	0	0	0	0	0	1	0	0	0	0
		DAY 50	11MAR2003	51	7	-1	0	0	0	1	1	2	1	2	0	0	0
		DAY 57	18MAR2003	58	4	-4	1	0	0	0	2	0	1	0	0	0	0
	E0029021	SCREEN	03MAR2003	-15	3		0	0	0	0	2	0	1	0	0	0	0
		DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	DAY 8	25MAR2003	8	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	01APR2003	15	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	07APR2003	21	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	15APR2003	29	2	2	1	1	0	0	0	0	0	0	0	0	0
		DAY 36	22APR2003	36	3	3	1	1	0	0	1	0	0	0	0	0	0
		DAY 43	29APR2003	43	11	11	1	1	0	0	2	2	1	2	2	0	0
		DAY 50	06MAY2003	50	4	4	1	1	0	0	2	0	0	0	0	0	0
		DAY 57	15MAY2003	59	6	6	0	0	0	0	2	0	1	1	2	0	0
	E0029026	SCREEN	07APR2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	14APR2003	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8	21APR2003	8	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	28APR2003	15	1	-1	1	0	0	0	0	0	0	0	0	0	0
		DAY 22	05MAY2003	22	1	-1	0	1	0	0	0	0	0	0	0	0	0
		DAY 29	12MAY2003	29	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	19MAY2003	36	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	28MAY2003	45	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	02JUN2003	50	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	10JUN2003	58	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0029030	SCREEN	13MAY2003	-14	6		0	0	1	2	2	0	1	0	0	0	0
		DAY 1	27MAY2003	1	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 8	03JUN2003	8	5	0	0	0	0	0	3	0	1	0	0	1	0
		DAY 15	10JUN2003	15	4	-1	0	0	0	0	2	1	1	0	0	0	0
		DAY 22	17JUN2003	22	4	-1	0	0	0	0	2	0	0	0	2	0	0
		DAY 29	26JUN2003	31	1	-4	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	02JUL2003	37	1	-4	0	0	0	0	0	0	0	0	0	1	0
		DAY 43	09JUL2003	44	3	-2	0	0	0	0	2	1	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	DAY 50	16JUL2003	51	3	-2	0	0	0	0	2	1	0	0	0	0	0
		DAY 57	23JUL2003	58	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0031008	SCREEN	05FEB2003	-23	5		0	0	0	0	2	0	1	0	2	0	0
		DAY 1	28FEB2003	1	9		0	0	0	2	4	0	1	0	2	0	0
		DAY 8	07MAR2003	8	7	-2	0	0	0	0	4	0	1	0	2	0	0
		DAY 15	13MAR2003	14	8	-1	0	0	0	1	2	2	1	0	2	0	0
		DAY 22	21MAR2003	22	8	-1	0	0	0	2	2	0	2	0	2	0	0
		DAY 29	28MAR2003	29	8	-1	0	1	0	2	2	0	1	0	2	0	0
		DAY 36	04APR2003	36	18	9	2	3	0	3	2	4	2	0	2	0	0
		DAY 43	10APR2003	42	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	17APR2003	49	11	2	2	3	0	2	2	0	2	0	0	0	0
		DAY 57	24APR2003	56	0	-9	0	0	0	0	0	0	0	0	0	0	0
	E0031020	SCREEN	14APR2003	-7	12		0	2	0	2	0	4	2	0	2	0	0
		DAY 1	21APR2003	1	11		0	0	0	2	2	4	1	0	2	0	0
		DAY 8	28APR2003	8	17	6	2	3	0	0	2	4	2	2	2	0	0
		DAY 15	05MAY2003	15	15	4	0	0	0	0	2	4	1	0	8	0	0
		DAY 22	13MAY2003	23	11	0	0	0	0	0	2	4	1	2	2	0	0
	E0031021	SCREEN	18APR2003	-7	11		0	0	1	2	4	2	1	0	0	1	0
		DAY 1	25APR2003	1	6		0	0	0	3	2	0	1	0	0	0	0
		DAY 8	02MAY2003	8	9	3	0	1	0	0	4	2	0	0	2	0	0
		DAY 15	09MAY2003	15	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 22	16MAY2003	22	4	-2	0	0	0	0	2	0	0	0	2	0	0
		DAY 29	23MAY2003	29	5	-1	0	0	0	0	2	2	1	0	0	0	0
		DAY 36	29MAY2003	35	6	0	0	0	0	0	2	2	0	0	2	0	0
		DAY 43	06JUN2003	43	4	-2	0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 43	*	10JUN2003	47	4	-2	1	0	0	0	1	0	0	0	2	0	0
		DAY 57		19JUN2003	56	7	1	0	0	0	2	2	0	1	0	2	0	0
	E0031029	SCREEN		05JUN2003	-13	11		1	1	0	2	2	2	1	0	2	0	0
		DAY 1		18JUN2003	1	11		1	1	0	2	2	0	1	2	2	0	0
		DAY 8		23JUN2003	6	13	2	1	3	0	0	2	4	1	0	2	0	0
	E0033002	SCREEN		19DEC2002	-22	8		0	0	0	3	4	0	1	0	0	0	0
		DAY 1		10JAN2003	1	11		1	1	0	3	4	0	1	0	0	0	1
		DAY 8		16JAN2003	7	8	-3	1	0	0	0	4	0	2	0	0	0	1
		DAY 15		24JAN2003	15	6	-5	0	0	0	0	4	0	1	0	0	0	1
		DAY 22		30JAN2003	21	6	-5	0	1	0	2	2	0	0	0	0	0	1
		DAY 29		06FEB2003	28	8	-3	1	1	0	0	2	0	1	2	0	0	1
		DAY 36		13FEB2003	35	3	-8	0	0	0	1	0	0	1	0	0	0	1
		DAY 43		24FEB2003	46	4	-7	0	0	0	0	2	0	1	0	0	0	1
		DAY 50		28FEB2003	50	4	-7	0	0	0	0	0	0	1	2	0	0	1
		DAY 57		07MAR2003	57	2	-9	1	0	0	0	0	0	0	0	0	0	1
	E0033006	SCREEN		13JAN2003	-10	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1		23JAN2003	1	7		0	0	0	2	2	0	2	0	1	0	0
		DAY 8		30JAN2003	8	6	-1	0	0	0	1	3	0	0	0	2	0	0
	E0033021	SCREEN		18JUN2003	-14	10		1	1	1	1	0	2	2	2	0	0	0
		DAY 1		02JUL2003	1	8		1	1	0	2	2	0	2	0	0	0	0
		DAY 8		11JUL2003	10	8	0	2	1	0	2	2	0	1	0	0	0	0
		DAY 22	*	21JUL2003	20	7	-1	2	1	0	1	2	0	1	0	0	0	0
		DAY 22		25JUL2003	24	6	-2	1	1	1	0	0	2	1	0	0	0	0
		DAY 29		01AUG2003	31	4	-4	0	1	0	0	2	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	DAY 36	06AUG2003	36	6	-2	0	1	0	0	2	2	1	0	0	0	0
	E0035013	SCREEN	27JAN2003	-8	7		0	0	0	1	2	0	2	0	2	0	0
		DAY 1	04FEB2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	10FEB2003	7	6	1	0	0	0	0	2	0	2	0	2	0	0
	E0035015	SCREEN	03FEB2003	-8	8		0	0	0	2	2	0	0	0	2	0	2
		DAY 1	11FEB2003	1	8		0	0	0	1	2	0	0	0	2	0	3
		DAY 8	18FEB2003	8	5	-3	0	0	0	0	2	0	0	0	0	0	3
	E0035016	SCREEN	10MAR2003	-25	7		1	0	0	1	2	0	0	0	2	1	0
		DAY 1	04APR2003	1	9		1	0	0	1	4	0	0	0	2	1	0
	E0035023	SCREEN	06MAY2003	-7	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 1	13MAY2003	1	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 8	20MAY2003	8	5	-1	1	0	0	0	2	0	0	0	2	0	0
		DAY 15	29MAY2003	17	9	3	1	0	1	1	2	0	2	0	2	0	0
		DAY 22	03JUN2003	22	7	1	1	0	0	1	2	0	1	0	2	0	0
		DAY 29	10JUN2003	29	7	1	1	0	0	0	2	0	2	0	2	0	0
	E0039052	SCREEN	29MAY2003	-22	7		0	0	0	2	4	0	0	0	1	0	0
		DAY 1	20JUN2003	1	10		0	0	0	3	4	0	1	1	1	0	0
		DAY 8	27JUN2003	8	4	-6	0	1	1	0	2	0	0	0	0	0	0
		DAY 15	03JUL2003	14	2	-8	0	0	1	0	1	0	0	0	0	0	0
	E0039056	SCREEN	01JUL2003	-14	4		0	0	0	2	1	0	1	0	0	0	0
		DAY 1	14JUL2003	-1	2		0	0	0	2	0	0	0	0	0	0	0

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QUETIAPINE 300 MG (BIPOLAR II)	E0040003	SCREEN	09JUL2003	-10	5		0	1	0	2	2	0	0	0	0	0	0
		DAY 1	18JUL2003	-1	5		0	1	0	2	2	0	0	0	0	0	0
		DAY 8	25JUL2003	7	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	01AUG2003	14	3	-2	0	1	0	2	0	0	0	0	0	0	0
		DAY 22	08AUG2003	21	3	-2	0	1	0	0	2	0	0	0	0	0	0
		DAY 29	15AUG2003	28	5	0	0	1	0	2	2	0	0	0	0	0	0
		DAY 36	22AUG2003	35	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	29AUG2003	42	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	05SEP2003	49	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 57	12SEP2003	56	4	-1	0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	SCREEN	04FEB2003	-27	3		1	0	0	0	2	0	0	0	0	0	0
		DAY 1	03MAR2003	1	4		1	0	1	0	2	0	0	0	0	0	0
		DAY 8	11MAR2003	9	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	18MAR2003	16	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	25MAR2003	23	3	-1	0	1	0	0	2	0	0	0	0	0	0
		DAY 29	01APR2003	30	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	08APR2003	37	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	15APR2003	44	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	24APR2003	53	4	0	1	1	0	0	2	0	0	0	0	0	0
		DAY 57	02MAY2003	61	2	-2	1	1	0	0	0	0	0	0	0	0	0
	E0002011	SCREEN	16APR2003	-13	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	29APR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	08MAY2003	10	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	15MAY2003	17	4	2	1	1	0	0	2	0	0	0	0	0	0
		DAY 22	22MAY2003	24	3	1	1	0	0	0	2	0	0	0	0	0	0
		DAY 29	29MAY2003	31	2	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 36	05JUN2003	38	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	12JUN2003	45	4	2	1	1	0	0	2	0	0	0	0	0	0
		DAY 50	19JUN2003	52	4	2	1	1	0	0	2	0	0	0	0	0	0
		DAY 57	25JUN2003	58	6	4	1	2	0	1	2	0	0	0	0	0	0
	E0003010	SCREEN	27JAN2003	-7	4		0	0	0	2	1	0	1	0	0	0	0
		DAY 1	03FEB2003	1	6		0	0	0	2	2	1	1	0	0	0	0
		DAY 8	10FEB2003	8	6	0	2	1	0	0	1	1	0	0	1	0	0
		DAY 15	19FEB2003	17	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	27FEB2003	25	1	-5	0	1	0	0	0	0	0	0	0	0	0
		DAY 29	03MAR2003	29	4	-2	1	1	0	0	0	1	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	DAY 36		14MAR2003	40	4	-2	1	1	0	1	0	1	0	0	0	0	0
		DAY 43		20MAR2003	46	3	-3	0	0	0	2	0	1	0	0	0	0	0
		DAY 50		25MAR2003	51	5	-1	2	1	0	0	0	2	0	0	0	0	0
		DAY 57		31MAR2003	57	4	-2	2	1	0	0	0	1	0	0	0	0	0
	E0003011	SCREEN		28JAN2003	-7	7		1	1	0	1	2	0	0	0	2	0	0
		DAY 1		04FEB2003	1	7		0	0	0	1	4	0	0	0	2	0	0
		DAY 8		11FEB2003	8	8	1	0	0	0	0	5	2	0	0	1	0	0
		DAY 15		18FEB2003	15	5	-2	0	0	0	0	3	0	0	0	2	0	0
	E0003016	SCREEN		01MAY2003	-21	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 1		22MAY2003	1	8		0	0	0	0	4	0	2	0	2	0	0
		DAY 8		29MAY2003	8	7	-1	0	0	0	0	3	0	0	0	4	0	0
		DAY 15		05JUN2003	15	7	-1	1	1	0	2	3	0	0	0	0	0	0
		DAY 22		12JUN2003	22	15	7	0	1	0	2	5	0	2	0	5	0	0
	E0003019	SCREEN		19JUN2003	-8	3		0	0	0	1	0	0	0	0	2	0	0
		DAY 1		27JUN2003	1	3		1	0	0	0	1	0	0	0	1	0	0
		DAY 8		03JUL2003	7	9	6	0	0	0	0	3	2	1	0	3	0	0
		DAY 15		10JUL2003	14	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	*	15JUL2003	19	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		29JUL2003	33	2	-1	0	0	0	0	1	0	0	0	1	0	0
		DAY 43		07AUG2003	42	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 50		14AUG2003	49	1	-2	0	0	0	1	0	0	0	0	0	0	0
		DAY 57		21AUG2003	56	2	-1	0	0	0	1	1	0	0	0	0	0	0
	E0003020	SCREEN		24JUN2003	-29	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		23JUL2003	1	2		0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	DAY 8	29JUL2003	7	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	06AUG2003	15	2	0	0	0	0	0	1	1	0	0	0	0	0
		DAY 22	13AUG2003	22	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	20AUG2003	29	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 36	27AUG2003	36	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 43	03SEP2003	43	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	10SEP2003	50	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	17SEP2003	57	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0004001	DAY 1	30SEP2002	1	13		0	0	0	2	4	2	1	0	2	1	1
		DAY 8	07OCT2002	8	8	-5	1	0	1	0	2	2	1	0	0	0	1
		DAY 22	21OCT2002	22	3	-10	0	0	0	0	2	0	1	0	0	0	0
		DAY 29	28OCT2002	29	2	-11	0	0	0	0	1	0	1	0	0	0	0
	E0004009	SCREEN	17DEC2002	-9	7		0	0	0	1	4	0	0	0	2	0	0
		DAY 1	26DEC2002	1	7		0	0	0	1	3	0	0	0	2	1	0
		DAY 8	02JAN2003	8	7	0	0	1	0	0	2	2	1	1	0	0	0
		DAY 15	08JAN2003	14	6	-1	0	1	0	0	3	0	0	0	1	1	0
		DAY 22	15JAN2003	21	1	-6	0	0	0	1	0	0	0	0	0	0	0
		DAY 29	22JAN2003	28	4	-3	0	0	0	0	2	0	0	0	2	0	0
		DAY 36	29JAN2003	35	4	-3	0	0	0	0	3	0	0	0	1	0	0
		DAY 43	05FEB2003	42	7	0	0	1	0	0	3	0	0	1	2	0	0
		DAY 50	12FEB2003	49	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	19FEB2003	56	0	-7	0	0	0	0	0	0	0	0	0	0	0
	E0004012	SCREEN	07JAN2003	-7	9		0	0	0	2	4	0	1	0	2	0	0
		DAY 1	14JAN2003	1	8		0	0	0	2	4	0	0	0	2	0	0
		DAY 8	21JAN2003	8	9	1	0	0	0	1	4	0	1	0	2	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	DAY 15	28JAN2003	15	6	-2	0	0	0	1	3	0	0	0	1	1	0
		DAY 22	04FEB2003	22	6	-2	0	0	0	0	4	0	0	0	2	0	0
		DAY 29	11FEB2003	29	6	-2	0	0	0	0	4	0	0	0	2	0	0
		DAY 36	18FEB2003	36	4	-4	0	0	0	0	3	0	0	0	1	0	0
		DAY 43	25FEB2003	43	6	-2	0	0	0	0	4	0	0	0	2	0	0
		DAY 50	04MAR2003	50	8	0	0	0	0	0	5	0	0	0	3	0	0
		DAY 57	11MAR2003	57	4	-4	0	0	0	0	3	0	0	0	1	0	0
	E0004015	SCREEN	06FEB2003	-14	9		1	0	1	2	2	0	1	0	2	0	0
		DAY 1	20FEB2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	25FEB2003	6	5	0	0	0	0	2	3	0	0	0	0	0	0
		DAY 15	04MAR2003	13	6	1	0	0	0	1	3	0	0	0	2	0	0
		DAY 22	11MAR2003	20	3	-2	2	1	0	0	0	0	0	0	0	0	0
		DAY 29	18MAR2003	27	4	-1	1	1	0	0	1	1	0	0	0	0	0
		DAY 36	25MAR2003	34	3	-2	1	1	0	0	1	0	0	0	0	0	0
		DAY 43	01APR2003	41	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	08APR2003	48	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	15APR2003	55	2	-3	1	1	0	0	0	0	0	0	0	0	0
	E0005003	SCREEN	23SEP2002	-9	10		0	0	0	0	4	0	2	2	2	0	0
		DAY 1	02OCT2002	1	8		0	0	0	0	4	0	0	2	2	0	0
		DAY 8	09OCT2002	8	8	0	0	0	0	2	3	0	1	0	2	0	0
		DAY 15	16OCT2002	15	5	-3	0	0	0	1	2	0	0	0	2	0	0
		DAY 22	23OCT2002	22	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	30OCT2002	29	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	06NOV2002	36	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	14NOV2002	44	6	-2	0	0	0	0	2	0	0	2	2	0	0
		DAY 50	21NOV2002	51	4	-4	0	0	0	0	2	0	0	2	0	0	0

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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	DAY 57	26NOV2002	56	2	-6	0	0	0	0	2	0	0	0	0	0	0
	E0005005	DAY 1	30SEP2002	1	7		0	0	0	2	4	0	1	0	0	0	0
	E0005007	SCREEN	02OCT2002	-7	12		0	0	0	2	6	0	2	0	2	0	0
		DAY 1	09OCT2002	1	11		0	0	0	2	4	0	2	0	2	1	0
		DAY 8	16OCT2002	8	10	-1	0	0	0	2	4	0	2	0	2	0	0
		DAY 15	23OCT2002	15	10	-1	0	0	0	2	4	0	2	0	2	0	0
		DAY 22	30OCT2002	22	6	-5	0	0	0	2	2	0	2	0	0	0	0
		DAY 29	06NOV2002	29	8	-3	0	2	0	2	2	0	2	0	0	0	0
		DAY 36	14NOV2002	37	3	-8	0	0	0	2	0	0	1	0	0	0	0
		DAY 43	20NOV2002	43	9	-2	0	0	0	2	4	0	2	0	0	1	0
		DAY 50	26NOV2002	49	7	-4	0	0	0	2	2	0	1	0	2	0	0
		DAY 57	04DEC2002	57	7	-4	0	0	0	1	2	0	2	0	2	0	0
	E0005008	SCREEN	08OCT2002	-7	4		0	0	0	0	4	0	0	0	0	0	0
		DAY 1	15OCT2002	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8	22OCT2002	8	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	29OCT2002	15	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	06NOV2002	23	3	-3	0	0	0	0	2	0	0	0	0	1	0
		DAY 29	13NOV2002	30	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	18NOV2002	35	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	25NOV2002	42	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	02DEC2002	49	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	11DEC2002	58	1	-5	0	0	0	0	1	0	0	0	0	0	0
	E0005009	SCREEN	09OCT2002	-20	6		0	0	0	0	4	0	2	0	0	0	0
		DAY 1	29OCT2002	1	3		0	0	0	0	2	0	1	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	SCREEN		14OCT2002	-7	9		0	0	0	2	4	0	1	0	2	0	0
		DAY 1		21OCT2002	1	9		2	0	0	2	2	0	1	0	2	0	0
		DAY 8		28OCT2002	8	7	-2	1	0	0	0	1	3	2	0	0	0	0
		DAY 15		04NOV2002	15	5	-4	1	1	0	0	1	0	2	0	0	0	0
		DAY 22		13NOV2002	24	7	-2	0	0	0	3	2	0	2	0	0	0	0
		DAY 29		19NOV2002	30	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		26NOV2002	37	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		03DEC2002	44	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		09DEC2002	50	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		17DEC2002	58	0	-9	0	0	0	0	0	0	0	0	0	0	0
	E0005012	SCREEN		23OCT2002	-22	11		0	0	0	2	4	0	2	0	2	1	0
		DAY 1		14NOV2002	1	10		1	3	0	2	2	2	0	0	0	0	0
		DAY 8		20NOV2002	7	8	-2	0	3	0	2	2	0	1	0	0	0	0
		DAY 15		26NOV2002	13	6	-4	0	0	0	2	2	0	1	0	1	0	0
		DAY 22		06DEC2002	23	5	-5	0	0	0	1	2	2	0	0	0	0	0
		DAY 29		10DEC2002	27	0	-10	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		18DEC2002	35	6	-4	0	0	0	2	2	0	0	0	2	0	0
		DAY 36	*	23DEC2002	40	4	-6	0	0	0	2	2	0	0	0	0	0	0
		DAY 50		02JAN2003	50	3	-7	0	0	0	2	1	0	0	0	0	0	0
		DAY 57		07JAN2003	55	4	-6	0	0	0	2	2	0	0	0	0	0	0
	E0005014	SCREEN		05NOV2002	-8	5		0	0	0	3	2	0	0	0	0	0	0
		DAY 1		13NOV2002	1	8		0	3	0	2	2	0	1	0	0	0	0
		DAY 8		20NOV2002	8	6	-2	0	3	0	0	2	0	1	0	0	0	0
		DAY 15		27NOV2002	15	3	-5	0	0	0	0	2	0	1	0	0	0	0
		DAY 22		03DEC2002	21	3	-5	0	0	0	0	2	0	1	0	0	0	0
		DAY 29		11DEC2002	29	2	-6	0	0	0	0	1	0	1	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 36	17DEC2002	35	3	-5	0	0	0	0	2	0	1	0	0	0	0
		DAY 43	23DEC2002	41	3	-5	0	0	0	0	2	0	1	0	0	0	0
		DAY 50	30DEC2002	48	4	-4	0	0	0	0	2	0	1	1	0	0	0
		DAY 57	06JAN2003	55	3	-5	0	0	0	0	2	0	1	0	0	0	0
	E0005022	SCREEN	23JAN2003	-6	9		1	0	0	2	2	2	2	0	0	0	0
		DAY 1	29JAN2003	1	8		0	0	0	1	2	0	1	2	2	0	0
		DAY 8	04FEB2003	7	5	-3	0	0	0	0	2	0	1	0	2	0	0
		DAY 15	11FEB2003	14	2	-6	0	0	0	0	1	0	1	0	0	0	0
		DAY 22	21FEB2003	24	5	-3	1	0	0	0	2	0	1	1	0	0	0
		DAY 29	26FEB2003	29	1	-7	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	06MAR2003	37	0	-8	0	0	0	0	0	0	0	0	0	0	0
	E0005025	SCREEN	20FEB2003	-7	6		0	0	0	1	4	0	1	0	0	0	0
		DAY 1	27FEB2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	06MAR2003	8	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	14MAR2003	16	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	20MAR2003	22	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	27MAR2003	29	4	-1	0	0	0	0	4	0	0	0	0	0	0
		DAY 36	03APR2003	36	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0006019	SCREEN	26MAR2003	-12	4		0	0	1	1	2	0	0	0	0	0	0
		DAY 1	07APR2003	1	5		0	0	1	2	2	0	0	0	0	0	0
		DAY 8	14APR2003	8	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 15	21APR2003	15	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	28APR2003	22	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	05MAY2003	29	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 36	12MAY2003	36	3	-2	0	0	0	1	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 43	19MAY2003	43	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	27MAY2003	51	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	03JUN2003	58	4	-1	0	0	0	1	2	0	0	0	0	1	0
	E0007005	SCREEN	27JAN2003	-4	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	31JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	07FEB2003	8	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 15	14FEB2003	15	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	22FEB2003	23	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	03MAR2003	32	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	10MAR2003	39	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	14MAR2003	43	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	21MAR2003	50	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 57	28MAR2003	57	2	-2	0	0	0	1	1	0	0	0	0	0	0
	E0007015	SCREEN	09JUL2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	16JUL2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	23JUL2003	8	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	01AUG2003	17	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	06AUG2003	22	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	13AUG2003	29	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	20AUG2003	36	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	27AUG2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	03SEP2003	50	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	10SEP2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0009001	SCREEN	29OCT2002	-14	8		1	1	2	0	2	0	0	2	0	0	0
		DAY 1	12NOV2002	1	8		1	1	2	0	2	0	0	2	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	DAY 8	21NOV2002	10	5	-3	0	0	0	0	2	0	1	2	0	0	0
		DAY 15	26NOV2002	15	8	0	0	0	2	0	2	2	0	2	0	0	0
		DAY 22	04DEC2002	23	6	-2	0	0	2	0	0	2	0	2	0	0	0
		DAY 29	10DEC2002	29	6	-2	0	0	2	0	0	2	0	2	0	0	0
		DAY 36	17DEC2002	36	6	-2	0	0	2	0	0	2	0	2	0	0	0
		DAY 43	23DEC2002	42	11	3	1	1	1	2	2	0	1	0	2	1	0
		DAY 50	30DEC2002	49	14	6	2	1	1	1	2	2	1	2	2	0	0
	E0010002	SCREEN	14NOV2002	-11	7		0	0	0	1	3	1	1	0	1	0	0
		DAY 1	25NOV2002	1	7		0	1	0	2	4	0	0	0	0	0	0
		DAY 8	02DEC2002	8	14	7	0	1	0	2	4	2	1	1	2	0	1
	E0010009	SCREEN	18DEC2002	-8	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1	26DEC2002	1	4		0	0	0	2	1	0	1	0	0	0	0
		DAY 8	02JAN2003	8	6	2	0	0	0	0	2	0	2	2	0	0	0
		DAY 15	09JAN2003	15	6	2	2	0	0	0	0	1	1	1	1	0	0
		DAY 22	17JAN2003	23	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	22JAN2003	28	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	30JAN2003	36	2	-2	1	0	0	0	1	0	0	0	0	0	0
		DAY 43	05FEB2003	42	2	-2	1	0	0	0	1	0	0	0	0	0	0
		DAY 50	13FEB2003	50	1	-3	0	0	0	0	0	0	1	0	0	0	0
		DAY 57	19FEB2003	56	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0010010	SCREEN	20DEC2002	-10	4		0	0	0	0	2	0	0	0	0	2	0
		DAY 1	30DEC2002	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8	06JAN2003	8	6	3	0	0	0	2	2	0	0	1	0	1	0
		DAY 15	13JAN2003	15	9	6	0	0	0	2	2	0	0	2	1	2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	SCREEN	14JAN2003	-14	11		0	2	0	2	4	0	1	0	2	0	0
		DAY 1	28JAN2003	1	9		0	0	0	2	3	0	2	0	2	0	0
		DAY 8	04FEB2003	8	2	-7	1	0	0	0	1	0	0	0	0	0	0
		DAY 15	11FEB2003	15	10	1	3	2	0	0	2	2	1	0	0	0	0
		DAY 22	18FEB2003	22	1	-8	1	0	0	0	0	0	0	0	0	0	0
		DAY 29	25FEB2003	29	2	-7	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	04MAR2003	36	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	11MAR2003	43	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	18MAR2003	50	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	25MAR2003	57	3	-6	2	0	0	0	0	0	0	0	1	0	0
	E0010017	SCREEN	05FEB2003	-20	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1	25FEB2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	03MAR2003	7	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	10MAR2003	14	4	0	0	0	0	0	2	0	2	0	0	0	0
		DAY 22	18MAR2003	22	7	3	1	3	0	0	2	0	1	0	0	0	0
		DAY 29	25MAR2003	29	2	-2	1	1	0	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	36	3	-1	1	0	0	0	0	0	2	0	0	0	0
		DAY 43	08APR2003	43	11	7	0	3	0	0	2	4	2	0	0	0	0
		DAY 50	15APR2003	50	6	2	2	2	0	0	0	0	2	0	0	0	0
		DAY 57	22APR2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0010023	SCREEN	10APR2003	-7	10		0	0	0	2	3	0	2	0	2	1	0
		DAY 1	17APR2003	1	10		0	0	0	1	4	0	2	1	2	0	0
		DAY 8	24APR2003	8	5	-5	0	1	0	0	1	1	1	0	1	0	0
		DAY 15	01MAY2003	15	14	4	0	0	0	1	4	0	1	6	2	0	0
	E0010027	SCREEN	05JUN2003	-11	9		0	3	0	2	0	1	2	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0010027	DAY 1	16JUN2003	1	11		2	3	0	2	0	0	2	2	0	0	0
		DAY 8	23JUN2003	8	4	-7	0	0	0	0	2	0	0	2	0	0	0
		DAY 15	01JUL2003	16	6	-5	0	0	0	2	3	0	0	0	0	1	0
	E0010029	SCREEN	10JUN2003	-9	12		0	0	3	2	4	0	1	0	1	1	0
		DAY 1	19JUN2003	1	6		0	0	0	2	0	0	2	0	2	0	0
		DAY 8	25JUN2003	7	14	8	2	0	0	1	5	0	2	0	4	0	0
	E0011022	SCREEN	02JUN2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	09JUN2003	1	5		0	1	0	2	1	0	0	0	0	1	0
		DAY 8	16JUN2003	8	5	0	0	0	0	0	2	0	1	0	2	0	0
		DAY 15	24JUN2003	16	2	-3	1	0	0	0	1	0	0	0	0	0	0
		DAY 22	01JUL2003	23	6	1	0	0	0	2	2	0	0	0	2	0	0
		DAY 29	08JUL2003	30	10	5	0	0	0	0	4	0	1	1	4	0	0
		DAY 36	15JUL2003	37	4	-1	0	0	0	0	3	0	1	0	0	0	0
		DAY 43	24JUL2003	46	3	-2	0	0	0	0	2	0	0	0	0	1	0
		DAY 50	31JUL2003	53	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	05AUG2003	58	7	2	0	0	0	0	3	0	0	0	4	0	0
	E0013006	SCREEN	05MAR2003	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	13MAR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	24MAR2003	12	7	3	1	1	2	2	1	0	0	0	0	0	0
	E0013012	SCREEN	29APR2003	-8	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 1	07MAY2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	16MAY2003	10	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	22MAY2003	16	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	30MAY2003	24	0	-4	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	DAY 29	05JUN2003	30	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	12JUN2003	37	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	19JUN2003	44	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	25JUN2003	50	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0013014	SCREEN	08MAY2003	-26	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	03JUN2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	10JUN2003	8	4	4	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	19JUN2003	17	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	30JUN2003	28	2	2	0	0	0	0	2	0	0	0	0	0	0
	E0014005	SCREEN	04MAR2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	11MAR2003	1	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 8	18MAR2003	8	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	25MAR2003	15	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	01APR2003	22	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	08APR2003	29	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	16APR2003	37	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	23APR2003	44	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	29APR2003	50	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	06MAY2003	57	0	-1	0	0	0	0	0	0	0	0	0	0	0
	E0014007	SCREEN	25MAR2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	08APR2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	15APR2003	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	22APR2003	22	0	0	0	0	0	0	0	0	0	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	SCREEN	06MAY2003	-7	4		0	1	0	0	2	0	1	0	0	0	0
		DAY 1	13MAY2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	20MAY2003	8	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	27MAY2003	15	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	04JUN2003	23	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	10JUN2003	29	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	17JUN2003	36	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	26JUN2003	45	13	10	1	0	0	0	6	0	0	0	6	0	0
		DAY 50	02JUL2003	51	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	08JUL2003	57	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0014012	SCREEN	19MAY2003	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	27MAY2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	03JUN2003	8	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	10JUN2003	15	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	17JUN2003	22	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	24JUN2003	29	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0015001	SCREEN	08NOV2002	-21	8		0	0	0	3	2	2	1	0	0	0	0
		DAY 1	29NOV2002	1	8		0	0	0	3	2	0	1	2	0	0	0
		DAY 8	06DEC2002	8	6	-2	0	0	0	0	2	2	0	2	0	0	0
		DAY 15	13DEC2002	15	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	19DEC2002	21	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	27DEC2002	29	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	03JAN2003	36	4	-4	0	0	0	0	2	0	0	2	0	0	0
		DAY 43	09JAN2003	42	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	20JAN2003	53	2	-6	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0015008	SCREEN	13DEC2002	-6	6		0	0	1	1	2	2	0	0	0	0	0
		DAY 1	19DEC2002	1	6		0	0	1	1	2	2	0	0	0	0	0
		DAY 8	27DEC2002	9	2	-4	0	0	0	0	0	2	0	0	0	0	0
		DAY 15	03JAN2003	16	4	-2	0	0	0	0	2	2	0	0	0	0	0
		DAY 22	10JAN2003	23	4	-2	0	0	0	0	2	2	0	0	0	0	0
		DAY 29	16JAN2003	29	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	23JAN2003	36	5	-1	1	0	0	0	2	0	0	0	2	0	0
	E0016003	SCREEN	10JAN2003	-14	5		0	0	0	0	2	0	0	2	0	1	0
		DAY 1	24JAN2003	1	4		0	0	1	1	0	0	0	0	2	0	0
		DAY 8	31JAN2003	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	07FEB2003	15	6	2	0	0	0	0	2	0	0	0	4	0	0
		DAY 22	14FEB2003	22	15	11	1	1	1	2	2	2	2	0	2	2	0
		DAY 29	21FEB2003	29	5	1	1	0	0	0	2	0	0	0	2	0	0
		DAY 36	27FEB2003	35	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	07MAR2003	43	15	11	0	0	0	0	4	4	1	2	2	2	0
	E0016005	SCREEN	20FEB2003	-5	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	25FEB2003	1	6		2	0	0	2	2	0	0	0	0	0	0
		DAY 8	04MAR2003	8	7	1	1	1	0	0	0	2	1	2	0	0	0
		DAY 15	11MAR2003	15	9	3	1	1	0	0	4	2	1	0	0	0	0
		DAY 22	18MAR2003	22	3	-3	0	1	0	0	0	2	0	0	0	0	0
		DAY 29	25MAR2003	29	4	-2	0	2	0	0	0	2	0	0	0	0	0
		DAY 36	01APR2003	36	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	08APR2003	43	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	17APR2003	52	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	57	2	-4	0	1	0	0	0	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0018007	SCREEN		16DEC2002	-11	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		27DEC2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		31DEC2002	5	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15		10JAN2003	15	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0019005	SCREEN		30OCT2002	-6	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1		05NOV2002	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8		12NOV2002	8	4	1	1	1	0	0	2	0	0	0	0	0	0
		DAY 15		19NOV2002	15	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		26NOV2002	22	6	3	1	1	0	1	2	0	1	0	0	0	0
		DAY 29		05DEC2002	31	6	3	2	1	1	0	2	0	0	0	0	0	0
		DAY 36		12DEC2002	38	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 43		19DEC2002	45	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	*	30DEC2002	56	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		02JAN2003	59	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0019015	SCREEN		19DEC2002	-14	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1		02JAN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8		09JAN2003	8	3	1	1	1	1	0	0	0	0	0	0	0	0
		DAY 15		16JAN2003	15	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		23JAN2003	22	7	5	1	1	0	1	1	1	2	0	0	0	0
		DAY 29		30JAN2003	29	2	0	0	0	0	0	1	0	1	0	0	0	0
		DAY 36		06FEB2003	36	17	15	2	2	0	3	1	4	0	2	2	0	1
		DAY 43		13FEB2003	43	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		20FEB2003	50	3	1	2	1	0	0	0	0	0	0	0	0	0
		DAY 57		27FEB2003	57	3	1	1	0	1	0	1	0	0	0	0	0	0
	E0020004	SCREEN		21NOV2002	-18	5		0	0	0	2	2	0	0	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	DAY 1		09DEC2002	1	9		0	0	0	2	2	0	0	2	2	1	0
		DAY 8		16DEC2002	8	3	-6	0	0	0	0	2	0	0	0	0	1	0
		DAY 8	*	20DEC2002	12	4	-5	0	1	0	0	2	0	0	0	0	1	0
		DAY 22		31DEC2002	23	4	-5	0	0	0	1	2	0	0	0	0	1	0
		DAY 29		07JAN2003	30	5	-4	0	0	0	1	2	0	1	0	0	1	0
		DAY 36		14JAN2003	37	4	-5	0	0	0	0	2	0	1	0	0	1	0
		DAY 43		22JAN2003	45	0	-9	0	0	0	0	0	0	0	0	0	0	0
	E0020010	SCREEN		28JAN2003	-8	5		0	0	0	0	2	0	2	0	1	0	0
		DAY 1		05FEB2003	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8		12FEB2003	8	4	2	0	1	0	0	2	0	1	0	0	0	0
		DAY 15		19FEB2003	15	6	4	1	1	2	0	1	0	0	0	1	0	0
		DAY 22		26FEB2003	22	7	5	2	0	1	0	2	1	0	0	1	0	0
		DAY 29		05MAR2003	29	8	6	0	0	0	1	3	1	1	0	2	0	0
		DAY 36		10MAR2003	34	5	3	2	1	0	0	2	0	0	0	0	0	0
		DAY 43		17MAR2003	41	1	-1	0	1	0	0	0	0	0	0	0	0	0
		DAY 50		25MAR2003	49	4	2	1	1	0	0	2	0	0	0	0	0	0
		DAY 57		02APR2003	57	4	2	2	1	0	0	0	0	0	0	0	1	0
	E0020014	SCREEN		11MAR2003	-7	1		0	0	0	0	0	0	0	0	0	1	0
		DAY 1		18MAR2003	1	7		1	1	0	0	2	1	1	0	1	0	0
		DAY 8		25MAR2003	8	7	0	1	0	0	2	2	2	0	0	0	0	0
		DAY 15		01APR2003	15	10	3	1	1	1	2	2	2	0	0	0	1	0
		DAY 22		08APR2003	22	10	3	1	1	1	2	2	2	0	0	0	1	0
		DAY 29		15APR2003	29	5	-2	0	0	0	1	2	1	1	0	0	0	0
		DAY 36		22APR2003	36	6	-1	1	1	0	0	2	2	0	0	0	0	0
		DAY 43		29APR2003	43	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		06MAY2003	50	8	1	1	1	0	0	2	2	1	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	DAY 57	12MAY2003	56	4	-3	1	1	0	0	0	2	0	0	0	0	0
	E0020021	SCREEN	09MAY2003	-10	7		0	0	0	2	2	0	0	0	2	1	0
		DAY 1	19MAY2003	1	5		1	0	0	2	2	0	0	0	0	0	0
		DAY 8	23MAY2003	5	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	02JUN2003	15	2	-3	0	0	0	2	0	0	0	0	0	0	0
		DAY 22	10JUN2003	23	3	-2	0	0	0	2	0	0	0	0	0	1	0
		DAY 29	16JUN2003	29	6	1	2	1	0	0	0	2	0	0	0	1	0
		DAY 36	23JUN2003	36	2	-3	0	0	0	2	0	0	0	0	0	0	0
		DAY 43	30JUN2003	43	7	2	0	0	0	2	2	2	1	0	0	0	0
		DAY 50	07JUL2003	50	1	-4	0	0	0	0	0	1	0	0	0	0	0
		DAY 57	14JUL2003	57	3	-2	0	0	0	2	0	0	0	0	0	1	0
	E0020023	SCREEN	09JUN2003	-8	8		0	0	0	2	2	0	2	0	2	0	0
		DAY 1	16JUN2003	-1	4		0	0	0	0	2	0	0	0	2	0	0
		DAY 8	24JUN2003	8	5	1	0	1	0	0	4	0	0	0	0	0	0
		DAY 15	30JUN2003	14	9	5	0	0	0	1	2	3	1	0	2	0	0
		DAY 22	07JUL2003	21	4	0	0	0	0	1	2	0	0	0	0	1	0
		DAY 29	14JUL2003	28	6	2	0	0	0	2	2	0	2	0	0	0	0
		DAY 36	21JUL2003	35	9	5	2	1	0	0	2	4	0	0	0	0	0
		DAY 43	28JUL2003	42	8	4	0	1	0	0	2	0	2	0	2	1	0
		DAY 50	04AUG2003	49	3	-1	0	1	0	0	0	2	0	0	0	0	0
		DAY 57	11AUG2003	56	4	0	1	1	0	0	2	0	0	0	0	0	0
	E0022007	SCREEN	01NOV2002	-6	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	07NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	14NOV2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	22NOV2002	16	0	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0022007	DAY 22		02DEC2002	26	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		09DEC2002	33	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022010	SCREEN		14NOV2002	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		21NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8		29NOV2002	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		06DEC2002	16	8	8	0	0	1	0	2	2	1	0	2	0	0
		DAY 22		12DEC2002	22	2	2	0	0	0	0	0	2	0	0	0	0	0
		DAY 36		26DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		02JAN2003	43	3	3	0	1	0	0	0	2	0	0	0	0	0
		DAY 50		09JAN2003	50	6	6	2	1	0	0	0	2	1	0	0	0	0
		DAY 57		16JAN2003	57	6	6	1	1	0	1	0	2	1	0	0	0	0
	E0022012	SCREEN		21NOV2002	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		05DEC2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8		12DEC2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		19DEC2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	*	23DEC2002	19	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		02JAN2003	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		09JAN2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		16JAN2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		23JAN2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		30JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022019	SCREEN		04DEC2002	-7	9		0	1	0	0	2	0	2	2	2	0	0
		DAY 1		11DEC2002	1	7		0	1	1	3	2	0	0	0	0	0	0
		DAY 8		19DEC2002	9	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		26DEC2002	16	8	1	0	0	0	0	4	0	0	0	4	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0022019	DAY 22	03JAN2003	24	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	09JAN2003	30	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	17JAN2003	38	3	-4	0	0	1	0	0	0	0	0	2	0	0
		DAY 43	24JAN2003	45	6	-1	2	0	1	1	0	0	0	2	0	0	0
		DAY 50	30JAN2003	51	5	-2	1	0	0	0	0	0	0	2	2	0	0
		DAY 57	06FEB2003	58	3	-4	0	0	1	0	0	0	0	0	2	0	0
	E0022025	SCREEN	08JAN2003	-20	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	28JAN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	04FEB2003	8	2	0	0	0	0	2	0	0	0	0	0	0	0
	E0022033	SCREEN	11FEB2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	25FEB2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	04MAR2003	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	11MAR2003	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	18MAR2003	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	27MAR2003	38	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	01APR2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	08APR2003	50	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022034	SCREEN	11FEB2003	-7	4		0	0	0	1	2	0	0	0	0	1	0
		DAY 1	18FEB2003	1	7		0	0	0	2	2	0	1	0	0	2	0
		DAY 8	25FEB2003	8	5	-2	0	0	0	0	2	0	1	0	0	2	0
		DAY 15	04MAR2003	15	4	-3	0	0	0	0	2	0	1	0	0	1	0
		DAY 22	11MAR2003	22	5	-2	0	0	0	0	2	0	1	0	0	2	0
		DAY 29	18MAR2003	29	2	-5	0	0	0	0	0	0	1	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	DAY 36	25MAR2003	36	2	-5	0	0	0	0	0	0	1	0	0	1	0
		DAY 43	01APR2003	43	4	-3	0	0	0	0	0	2	1	0	0	1	0
		DAY 50	07APR2003	49	2	-5	0	0	0	0	0	0	1	0	0	1	0
		DAY 57	15APR2003	57	5	-2	0	1	0	0	0	2	1	0	0	1	0
	E0022038	SCREEN	20FEB2003	-8	9		0	1	0	1	2	4	1	0	0	0	0
		DAY 1	28FEB2003	1	5		0	0	0	0	2	2	1	0	0	0	0
		DAY 8	07MAR2003	8	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	14MAR2003	15	4	-1	0	0	0	0	0	4	0	0	0	0	0
		DAY 22	21MAR2003	22	8	3	0	1	0	0	2	4	1	0	0	0	0
		DAY 29	28MAR2003	29	6	1	0	2	0	0	0	4	0	0	0	0	0
		DAY 36	04APR2003	36	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	11APR2003	43	6	1	0	2	0	0	2	2	0	0	0	0	0
	E0022039	SCREEN	27FEB2003	-7	5		0	0	0	0	0	0	1	2	2	0	0
		DAY 1	06MAR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	13MAR2003	8	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	20MAR2003	15	5	3	1	0	0	0	0	2	0	0	2	0	0
		DAY 22	27MAR2003	22	2	0	0	0	0	0	0	2	0	0	0	0	0
		DAY 29	04APR2003	30	2	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 36	10APR2003	36	6	4	1	1	0	0	2	2	0	0	0	0	0
		DAY 43	18APR2003	44	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	24APR2003	50	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	01MAY2003	57	1	-1	1	0	0	0	0	0	0	0	0	0	0
	E0022046	SCREEN	13MAR2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	20MAR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	27MAR2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	DAY 15	04APR2003	16	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	11APR2003	23	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	18APR2003	30	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	24APR2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	02MAY2003	44	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	12MAY2003	54	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	16MAY2003	58	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022048	SCREEN	25MAR2003	-7	1		0	0	0	0	0	0	0	0	0	1	0
		DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	08APR2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	15APR2003	15	1	1	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	24APR2003	24	1	1	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	02MAY2003	32	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	06MAY2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	13MAY2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	23MAY2003	53	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022051	SCREEN	31MAR2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	07APR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	14APR2003	8	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	21APR2003	15	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	28APR2003	22	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	05MAY2003	29	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	12MAY2003	36	22	18	2	2	1	2	5	4	1	3	2	0	0
		DAY 43	19MAY2003	43	16	12	2	1	0	0	4	3	1	2	3	0	0
		DAY 50	28MAY2003	52	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUN2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0022053	SCREEN		04APR2003	-7	5		0	0	0	0	0	2	1	0	2	0	0
		DAY 1		11APR2003	1	7		0	0	0	0	4	0	1	0	2	0	0
	E0022058	SCREEN		11APR2003	-10	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		21APR2003	1	6		0	0	1	0	2	0	1	2	0	0	0
		DAY 8		28APR2003	8	3	-3	0	0	1	0	2	0	0	0	0	0	0
		DAY 15		05MAY2003	15	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		12MAY2003	22	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		19MAY2003	29	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	*	22MAY2003	32	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0022061	SCREEN		24APR2003	-6	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		30APR2003	1	4		0	0	0	1	2	0	1	0	0	0	0
		DAY 8		07MAY2003	8	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 15		14MAY2003	15	5	1	0	0	0	0	2	0	1	0	2	0	0
		DAY 22		22MAY2003	23	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		28MAY2003	29	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 36		04JUN2003	36	5	1	0	1	0	0	2	0	0	0	2	0	0
		DAY 50		18JUN2003	50	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57		26JUN2003	58	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0022062	SCREEN		25APR2003	-10	3		0	0	0	0	2	0	1	0	0	0	0
		DAY 1		05MAY2003	1	5		0	0	0	0	2	0	1	0	2	0	0
		DAY 8		12MAY2003	8	8	3	0	1	0	0	2	2	1	0	2	0	0
		DAY 15		19MAY2003	15	7	2	0	0	0	0	4	2	1	0	0	0	0
		DAY 15	*	23MAY2003	19	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0022068	SCREEN		14MAY2003	-9	7		0	0	0	2	2	0	0	0	3	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0022068	DAY 1	22MAY2003	-1	11		1	0	0	2	2	2	2	2	0	0	0
		DAY 8	29MAY2003	7	6	-5	0	0	0	2	2	0	2	0	0	0	0
		DAY 15	05JUN2003	14	4	-7	0	0	0	0	2	0	2	0	0	0	0
	E0022069	SCREEN	03JUN2003	-7	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 1	10JUN2003	1	11		0	0	0	2	6	0	1	0	2	0	0
		DAY 8	17JUN2003	8	7	-4	0	0	0	0	4	0	1	0	2	0	0
		DAY 15	24JUN2003	15	4	-7	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	01JUL2003	22	4	-7	0	0	0	0	2	0	0	0	2	0	0
		DAY 29	08JUL2003	29	6	-5	0	0	0	0	4	0	0	0	2	0	0
		DAY 36	15JUL2003	36	0	-11	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	22JUL2003	43	0	-11	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	29JUL2003	50	0	-11	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	05AUG2003	57	5	-6	0	0	0	0	2	0	0	0	2	1	0
	E0022071	SCREEN	16JUN2003	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	30JUN2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	07JUL2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	14JUL2003	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	21JUL2003	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	28JUL2003	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	04AUG2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	11AUG2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	18AUG2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	25AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0023003	SCREEN	12DEC2002	-5	6		0	0	0	2	2	0	1	0	0	1	0
		DAY 1	17DEC2002	1	5		0	0	0	0	2	2	1	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	DAY 8	23DEC2002	7	9	4	0	0	0	0	4	4	1	0	0	0	0
		DAY 15	30DEC2002	14	22	17	2	3	1	2	3	5	2	2	2	0	0
		DAY 22	07JAN2003	22	11	6	1	1	0	0	4	2	1	0	2	0	0
		DAY 29	16JAN2003	31	9	4	1	1	0	0	4	2	1	0	0	0	0
		DAY 36	21JAN2003	36	4	-1	1	1	0	0	2	0	0	0	0	0	0
		DAY 43	28JAN2003	43	6	1	0	0	0	0	4	1	1	0	0	0	0
		DAY 50	06FEB2003	52	4	-1	0	0	0	0	2	2	0	0	0	0	0
		DAY 57	11FEB2003	57	6	1	1	1	0	0	2	2	0	0	0	0	0
	E0023006	SCREEN	10DEC2002	-7	3		0	0	0	0	0	2	1	0	0	0	0
		DAY 1	17DEC2002	1	1		0	0	0	0	0	0	1	0	0	0	0
		DAY 8	23DEC2002	7	5	4	1	0	0	0	2	0	2	0	0	0	0
		DAY 15	02JAN2003	17	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	07JAN2003	22	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	16JAN2003	31	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	21JAN2003	36	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	28JAN2003	43	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	04FEB2003	50	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	57	0	-1	0	0	0	0	0	0	0	0	0	0	0
	E0023010	SCREEN	28JAN2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	04FEB2003	1	3		0	0	0	0	2	0	1	0	0	0	0
		DAY 8	11FEB2003	8	4	1	1	0	0	1	1	0	1	0	0	0	0
		DAY 15	18FEB2003	15	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	25FEB2003	22	2	-1	1	1	0	0	0	0	0	0	0	0	0
		DAY 29	04MAR2003	29	1	-2	0	1	0	0	0	0	0	0	0	0	0
		DAY 36	11MAR2003	36	2	-1	1	1	0	0	0	0	0	0	0	0	0
		DAY 43	18MAR2003	43	0	-3	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	DAY 50	25MAR2003	50	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	31MAR2003	56	2	-1	1	1	0	0	0	0	0	0	0	0	0
	E0023025	SCREEN	01MAY2003	-14	8		0	0	3	0	4	0	0	0	1	0	0
		DAY 1	15MAY2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8	22MAY2003	8	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 15	29MAY2003	15	4	-2	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	05JUN2003	22	7	1	1	1	1	0	2	0	0	0	2	0	0
		DAY 29	12JUN2003	29	4	-2	0	0	0	0	2	0	0	0	2	0	0
		DAY 36	19JUN2003	36	5	-1	0	0	0	1	2	0	0	0	2	0	0
		DAY 43	27JUN2003	44	5	-1	0	0	0	1	2	0	0	0	2	0	0
		DAY 50	03JUL2003	50	5	-1	1	0	0	0	3	0	0	0	1	0	0
		DAY 57	10JUL2003	57	3	-3	0	0	0	1	2	0	0	0	0	0	0
	E0023039	SCREEN	24JUN2003	-7	8		0	1	0	2	3	2	0	0	0	0	0
		DAY 1	01JUL2003	1	4		1	1	0	0	1	1	0	0	0	0	0
		DAY 8	08JUL2003	8	8	4	2	1	0	0	2	2	1	0	0	0	0
		DAY 15	15JUL2003	15	6	2	1	1	0	0	2	1	1	0	0	0	0
		DAY 22	22JUL2003	22	7	3	1	1	0	0	3	1	1	0	0	0	0
		DAY 29	29JUL2003	29	3	-1	0	0	0	0	2	1	0	0	0	0	0
		DAY 36	05AUG2003	36	5	1	1	0	0	0	2	2	0	0	0	0	0
		DAY 43	12AUG2003	43	3	-1	0	0	0	0	1	2	0	0	0	0	0
		DAY 50	19AUG2003	50	5	1	1	1	0	0	1	2	0	0	0	0	0
		DAY 57	26AUG2003	57	4	0	1	0	0	0	1	2	0	0	0	0	0
	E0026002	SCREEN	05NOV2002	-7	7		0	0	0	1	2	0	0	0	2	1	1
		DAY 1	12NOV2002	1	2		0	0	0	0	0	0	0	0	0	2	0
		DAY 8	19NOV2002	8	3	1	1	0	0	0	0	0	0	0	0	2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 15	26NOV2002	15	2	0	0	0	0	0	0	0	0	0	0	2	0
		DAY 22	03DEC2002	22	10	8	1	1	0	2	0	2	1	0	0	1	2
		DAY 29	11DEC2002	30	7	5	1	1	1	1	0	0	0	0	0	0	3
		DAY 36	18DEC2002	37	9	7	1	1	0	0	0	2	0	0	0	1	4
		DAY 43	26DEC2002	45	6	4	1	1	0	0	0	2	0	2	0	0	0
		DAY 50	02JAN2003	52	5	3	1	1	0	1	1	0	0	0	0	1	0
		DAY 57	09JAN2003	59	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0026007	SCREEN	06JAN2003	-10	5		0	0	0	1	2	0	0	2	0	0	0
		DAY 1	16JAN2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	23JAN2003	8	5	0	0	0	0	0	3	0	0	0	2	0	0
		DAY 15	30JAN2003	15	12	7	2	1	0	0	3	1	0	2	2	0	1
		DAY 22	06FEB2003	22	6	1	2	0	0	2	0	1	0	1	0	0	0
		DAY 29	13FEB2003	29	8	3	1	1	0	1	0	2	0	3	0	0	0
		DAY 36	19FEB2003	35	10	5	1	1	0	0	2	2	0	2	2	0	0
		DAY 43	26FEB2003	42	7	2	1	1	0	0	2	1	0	1	1	0	0
		DAY 50	05MAR2003	49	3	-2	1	0	0	0	0	0	0	2	0	0	0
		DAY 57	12MAR2003	56	6	1	1	0	0	0	2	1	0	2	0	0	0
	E0026013	SCREEN	05FEB2003	-8	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 1	13FEB2003	1	5		0	0	0	1	2	2	0	0	0	0	0
		DAY 8	20FEB2003	8	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 15	27FEB2003	15	3	-2	0	0	0	0	3	0	0	0	0	0	0
		DAY 22	06MAR2003	22	5	0	0	0	0	2	2	0	0	0	0	1	0
		DAY 29	13MAR2003	29	5	0	0	0	0	0	2	0	0	0	3	0	0
		DAY 36	20MAR2003	36	7	2	0	0	0	0	3	2	0	0	1	1	0
		DAY 43	27MAR2003	43	8	3	1	1	0	0	2	2	0	2	0	0	0
		DAY 50	03APR2003	50	8	3	1	1	0	0	2	2	1	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	DAY 1	04OCT2002	1	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 8	11OCT2002	8	8	7	1	2	0	0	1	2	0	0	2	0	0
		DAY 15	16OCT2002	13	10	9	2	2	0	0	0	0	0	2	2	2	0
		DAY 22	23OCT2002	20	7	6	2	2	0	0	0	2	1	0	0	0	0
		DAY 29	31OCT2002	28	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	07NOV2002	35	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	14NOV2002	42	4	3	0	0	0	0	2	0	0	0	2	0	0
	E0028023	SCREEN	14JAN2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	21JAN2003	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8	30JAN2003	10	10	8	2	1	2	2	0	2	0	0	0	1	0
		DAY 15	04FEB2003	15	4	2	0	0	0	2	0	0	0	0	2	0	0
		DAY 22	11FEB2003	22	7	5	1	1	0	2	0	2	0	0	0	1	0
		DAY 29	17FEB2003	28	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	27FEB2003	38	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	04MAR2003	43	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0028025	SCREEN	08JAN2003	-5	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	13JAN2003	1	10		0	0	3	2	2	0	1	0	2	0	0
		DAY 8	17JAN2003	5	5	-5	2	2	0	1	0	0	0	0	0	0	0
		DAY 15	27JAN2003	15	12	2	2	2	2	2	0	2	0	0	2	0	0
	E0028033	SCREEN	18MAR2003	-9	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	27MAR2003	1	4		0	1	0	1	0	0	0	0	0	1	1
		DAY 8	03APR2003	8	1	-3	0	0	0	0	0	0	0	0	0	1	0
		DAY 15	10APR2003	15	1	-3	0	0	0	0	0	0	0	0	0	1	0
		DAY 22	17APR2003	22	1	-3	0	0	0	0	0	0	0	0	0	1	0
		DAY 29	24APR2003	29	2	-2	0	0	0	1	0	0	0	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	DAY 36		01MAY2003	36	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 43		08MAY2003	43	5	1	0	0	0	2	2	0	0	0	0	1	0
		DAY 50		15MAY2003	50	9	5	2	2	0	0	0	4	1	0	0	0	0
		DAY 57		22MAY2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0028035	SCREEN		27MAR2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		03APR2003	1	6		0	0	0	2	0	4	0	0	0	0	0
		DAY 8		10APR2003	8	8	2	0	0	0	0	2	0	1	2	2	1	0
		DAY 15		17APR2003	15	3	-3	0	0	0	0	2	0	0	0	0	1	0
		DAY 22		24APR2003	22	3	-3	0	0	0	0	2	0	0	0	0	1	0
		DAY 29		01MAY2003	29	4	-2	0	1	0	0	0	0	1	2	0	0	0
		DAY 36		08MAY2003	36	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		15MAY2003	43	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		22MAY2003	50	8	2	2	0	0	0	2	2	0	0	2	0	0
		DAY 57		29MAY2003	57	2	-4	2	0	0	0	0	0	0	0	0	0	0
	E0028037	SCREEN		09JUN2003	-4	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		12JUN2003	-1	8		0	0	0	2	2	2	0	0	2	0	0
		DAY 8		20JUN2003	8	1	-7	0	0	0	0	0	0	1	0	0	0	0
		DAY 15		25JUN2003	13	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	*	01JUL2003	19	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		08JUL2003	26	4	-4	0	1	0	0	2	0	0	0	0	1	0
		DAY 36		16JUL2003	34	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		23JUL2003	41	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		30JUL2003	48	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		08AUG2003	57	2	-6	0	0	0	0	0	2	0	0	0	0	0
	E0028039	SCREEN		02MAY2003	-7	6		0	0	0	1	2	0	0	0	2	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 1	08MAY2003	-1	4		0	0	0	1	2	0	0	0	0	1	0
		DAY 8	16MAY2003	8	5	1	0	0	0	0	4	0	1	0	0	0	0
		DAY 15	22MAY2003	14	3	-1	0	0	0	0	2	0	0	0	0	1	0
		DAY 22	29MAY2003	21	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	05JUN2003	28	1	-3	0	0	0	0	0	0	0	0	0	1	0
	E0028046	SCREEN	17JUN2003	-8	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 1	25JUN2003	1	6		0	0	0	2	4	0	0	0	0	0	0
	E0028048	SCREEN	11JUL2003	-6	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	17JUL2003	1	6		0	0	0	2	2	0	2	0	0	0	0
		DAY 8	24JUL2003	8	3	-3	0	0	1	0	2	0	0	0	0	0	0
		DAY 15	31JUL2003	15	1	-5	0	1	0	0	0	0	0	0	0	0	0
		DAY 22	06AUG2003	21	4	-2	0	0	2	0	2	0	0	0	0	0	0
		DAY 29	14AUG2003	29	2	-4	0	1	1	0	0	0	0	0	0	0	0
		DAY 36	21AUG2003	36	1	-5	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	29AUG2003	44	4	-2	2	2	0	0	0	0	0	0	0	0	0
		DAY 57	09SEP2003	55	3	-3	0	1	0	0	2	0	0	0	0	0	0
	E0029008	SCREEN	09DEC2002	-7	6		0	0	0	0	3	0	0	0	2	1	0
		DAY 1	16DEC2002	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	23DEC2002	8	12	10	0	1	0	2	4	0	2	0	2	1	0
	E0029011	SCREEN	14JAN2003	-8	5		0	0	0	0	3	0	0	0	2	0	0
		DAY 1	21JAN2003	-1	6		0	0	0	0	3	0	1	0	2	0	0
		DAY 8	28JAN2003	7	18	12	0	0	0	2	4	4	2	4	2	0	0
		DAY 15	04FEB2003	14	10	4	0	0	0	2	4	0	2	0	2	0	0
		DAY 22	13FEB2003	23	8	2	0	0	0	0	2	2	1	0	3	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	SCREEN	04FEB2003	-7	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	11FEB2003	1	8		0	0	0	0	6	0	0	0	2	0	0
		DAY 8	19FEB2003	9	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	26FEB2003	16	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	03MAR2003	21	2	-6	0	0	0	0	1	0	1	0	0	0	0
		DAY 29	11MAR2003	29	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	18MAR2003	36	4	-4	0	0	0	0	4	0	0	0	0	0	0
	E0029015	SCREEN	11FEB2003	-13	9		0	0	0	2	3	1	0	0	2	1	0
		DAY 1	24FEB2003	1	8		1	3	0	0	2	2	0	0	0	0	0
		DAY 8	03MAR2003	8	9	1	0	2	0	2	0	3	0	2	0	0	0
		DAY 15	11MAR2003	16	6	-2	1	1	2	0	2	0	0	0	0	0	0
	E0029018	SCREEN	26FEB2003	-8	8		0	0	0	0	4	0	1	0	2	1	0
		DAY 1	06MAR2003	1	7		0	0	0	1	4	0	0	2	0	0	0
	E0030014	SCREEN	14FEB2003	-7	9		0	0	0	2	6	0	0	0	1	0	0
		DAY 1	21FEB2003	1	3		0	0	0	0	3	0	0	0	0	0	0
		DAY 8	28FEB2003	8	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	07MAR2003	15	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	14MAR2003	22	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	21MAR2003	29	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	27MAR2003	35	2	-1	0	0	0	0	1	1	0	0	0	0	0
		DAY 43	04APR2003	43	4	1	0	2	0	0	2	0	0	0	0	0	0
		DAY 50	11APR2003	50	3	0	1	0	0	0	1	1	0	0	0	0	0
		DAY 57	22APR2003	61	1	-2	0	0	0	0	1	0	0	0	0	0	0
	E0030020	SCREEN	13MAY2003	-16	2		0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	DAY 1	29MAY2003	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8	05JUN2003	8	3	0	0	1	0	0	2	0	0	0	0	0	0
		DAY 15	12JUN2003	15	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	17JUN2003	20	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	24JUN2003	27	1	-2	0	0	0	0	1	0	0	0	0	0	0
	E0030024	SCREEN	17JUN2003	-24	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	11JUL2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8	18JUL2003	8	6	0	0	0	0	2	4	0	0	0	0	0	0
	E0030025	SCREEN	24JUN2003	-17	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 1	11JUL2003	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8	18JUL2003	8	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	25JUL2003	15	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	31JUL2003	21	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	11AUG2003	32	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	19AUG2003	40	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0031027	SCREEN	27MAY2003	-7	12		0	0	0	2	4	1	2	0	2	1	0
		DAY 1	03JUN2003	1	12		1	0	1	2	2	1	2	0	2	1	0
		DAY 8	11JUN2003	9	10	-2	1	0	0	2	4	0	0	0	2	1	0
		DAY 15	17JUN2003	15	17	5	0	0	0	2	4	2	1	0	8	0	0
		DAY 22	24JUN2003	22	11	-1	0	1	3	2	2	2	0	0	0	1	0
		DAY 29	01JUL2003	29	13	1	0	0	0	2	4	2	1	0	3	1	0
		DAY 36	09JUL2003	37	6	-6	1	0	0	1	2	0	0	0	2	0	0
		DAY 43	15JUL2003	43	5	-7	0	1	1	0	0	0	0	0	2	1	0
		DAY 50	22JUL2003	50	15	3	1	3	3	2	1	0	0	2	2	1	0
		DAY 57	29JUL2003	57	2	-10	0	0	0	0	0	0	1	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	SCREEN	17JUN2003	-7	12		1	1	0	2	4	2	2	0	0	0	0
		DAY 1	24JUN2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	01JUL2003	8	5	0	0	0	0	2	2	0	1	0	0	0	0
		DAY 15	08JUL2003	15	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	16JUL2003	23	4	-1	0	0	1	2	1	0	0	0	0	0	0
		DAY 29	23JUL2003	30	2	-3	0	0	1	1	0	0	0	0	0	0	0
		DAY 36	31JUL2003	38	3	-2	0	0	1	2	0	0	0	0	0	0	0
		DAY 43	08AUG2003	46	3	-2	0	0	1	2	0	0	0	0	0	0	0
		DAY 50	14AUG2003	52	11	6	0	0	1	2	2	2	2	2	0	0	0
		DAY 57	21AUG2003	59	12	7	0	3	1	2	2	0	2	0	2	0	0
	E0033012	SCREEN	05FEB2003	-5	4		0	0	0	0	2	0	2	0	0	0	0
		DAY 1	10FEB2003	1	9		0	0	0	2	2	0	1	2	2	0	0
	E0034001	SCREEN	13MAR2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	20MAR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	27MAR2003	8	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	03APR2003	15	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	10APR2003	22	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	17APR2003	29	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	24APR2003	36	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	01MAY2003	43	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	08MAY2003	50	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	15MAY2003	57	1	-1	0	0	0	0	1	0	0	0	0	0	0
	E0034004	SCREEN	11APR2003	-10	7		0	0	0	2	5	0	0	0	0	0	0
		DAY 1	21APR2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	30APR2003	10	2	-3	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	DAY 15		05MAY2003	15	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 22		13MAY2003	23	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 29		19MAY2003	29	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	*	23MAY2003	33	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		02JUN2003	43	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		09JUN2003	50	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		16JUN2003	57	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0035001	SCREEN		12NOV2002	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		20NOV2002	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8		27NOV2002	8	3	1	1	0	0	0	2	0	0	0	0	0	0
		DAY 15		03DEC2002	14	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		12DEC2002	23	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		18DEC2002	29	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		23DEC2002	34	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		30DEC2002	41	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 50		07JAN2003	49	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		14JAN2003	56	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0035006	SCREEN		03DEC2002	-9	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1		12DEC2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		19DEC2002	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15		26DEC2002	15	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 22		02JAN2003	22	6	2	0	0	0	1	2	0	3	0	0	0	0
		DAY 29		09JAN2003	29	6	2	0	0	0	2	2	0	2	0	0	0	0
		DAY 36		16JAN2003	36	7	3	0	0	0	2	2	0	3	0	0	0	0
		DAY 43		24JAN2003	44	6	2	0	0	0	1	2	0	3	0	0	0	0
		DAY 50		30JAN2003	50	6	2	0	0	0	2	2	0	2	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 57	06FEB2003	57	7	3	0	0	0	2	2	0	1	0	2	0	0
	E0035021	SCREEN	18APR2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	25APR2003	1	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 8	01MAY2003	7	10	3	1	0	0	0	2	2	1	0	4	0	0
		DAY 15	09MAY2003	15	4	-3	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	15MAY2003	21	5	-2	1	0	0	0	2	0	0	0	2	0	0
		DAY 29	23MAY2003	29	3	-4	1	0	0	0	2	0	0	0	0	0	0
		DAY 36	30MAY2003	36	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	09JUN2003	46	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	13JUN2003	50	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	20JUN2003	57	0	-7	0	0	0	0	0	0	0	0	0	0	0
	E0036002	SCREEN	10JUN2003	-7	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1	17JUN2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	24JUN2003	8	12	7	0	0	0	0	4	1	2	0	5	0	0
		DAY 15	30JUN2003	14	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	08JUL2003	22	22	17	1	3	2	0	5	3	2	1	5	0	0
		DAY 29	14JUL2003	28	31	26	2	4	2	1	5	6	2	4	5	0	0
	E0036006	SCREEN	24JUN2003	-9	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	03JUL2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	10JUL2003	8	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	18JUL2003	16	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	25JUL2003	23	4	0	1	1	0	0	0	2	0	0	0	0	0
		DAY 29	31JUL2003	29	2	-2	0	0	0	0	0	2	0	0	0	0	0
		DAY 36	07AUG2003	36	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 43	13AUG2003	42	0	-4	0	0	0	0	0	0	0	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR I)	E0036006	DAY 50	20AUG2003	49	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	27AUG2003	56	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0036007	SCREEN	26JUN2003	-7	9		0	0	0	2	3	0	2	0	2	0	0
		DAY 1	03JUL2003	1	11		0	0	0	2	5	0	0	0	3	1	0
		DAY 8	08JUL2003	6	9	-2	0	0	0	2	3	0	1	0	2	1	0
		DAY 15	18JUL2003	16	5	-6	0	0	0	0	2	2	1	0	0	0	0
	E0037009	SCREEN	09MAY2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	16MAY2003	1	7		0	0	0	2	4	0	1	0	0	0	0
		DAY 8	23MAY2003	8	9	2	1	0	0	1	4	2	1	0	0	0	0
		DAY 15	29MAY2003	14	11	4	1	0	2	0	4	2	1	1	0	0	0
		DAY 22	05JUN2003	21	11	4	0	0	0	2	2	4	2	0	0	1	0
		DAY 29	12JUN2003	28	4	-3	0	0	0	2	0	2	0	0	0	0	0
		DAY 36	19JUN2003	35	6	-1	0	0	0	1	2	2	1	0	0	0	0
		DAY 43	26JUN2003	42	5	-2	0	0	0	0	2	2	1	0	0	0	0
		DAY 50	03JUL2003	49	8	1	0	0	0	1	2	2	1	0	2	0	0
		DAY 57	10JUL2003	56	11	4	1	0	0	1	2	4	1	2	0	0	0
	E0039011	SCREEN	16DEC2002	-17	7		0	0	0	2	2	1	2	0	0	0	0
		DAY 1	02JAN2003	1	5		0	0	0	2	2	0	0	0	1	0	0
		DAY 8	09JAN2003	8	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	16JAN2003	15	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	23JAN2003	22	9	4	1	1	2	2	1	1	0	0	1	0	0
		DAY 29	03FEB2003	33	2	-3	0	1	0	0	0	1	0	0	0	0	0
		DAY 36	06FEB2003	36	2	-3	1	0	0	0	1	0	0	0	0	0	0
		DAY 43	13FEB2003	43	2	-3	0	0	0	0	0	2	0	0	0	0	0
		DAY 50	19FEB2003	49	2	-3	0	0	0	0	0	2	0	0	0	0	0

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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0039018	SCREEN	14JAN2003	-9	12		0	0	0	2	2	0	3	2	3	0	0
		DAY 1	23JAN2003	1	9		0	0	0	2	4	0	0	0	3	0	0
		DAY 8	30JAN2003	8	2	-7	0	0	0	1	1	0	0	0	0	0	0
		DAY 15	06FEB2003	15	4	-5	0	0	0	1	3	0	0	0	0	0	0
		DAY 22	13FEB2003	22	1	-8	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	20FEB2003	29	3	-6	0	0	0	0	2	1	0	0	0	0	0
	E0039026	SCREEN	26FEB2003	-9	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1	07MAR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	14MAR2003	8	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	19MAR2003	13	10	6	2	2	0	0	3	0	0	3	0	0	0
		DAY 22	28MAR2003	22	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	04APR2003	29	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	11APR2003	36	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	18APR2003	43	8	4	0	2	1	0	1	2	2	0	0	0	0
		DAY 50	25APR2003	50	2	-2	0	0	0	0	0	0	2	0	0	0	0
		DAY 57	01MAY2003	56	1	-3	0	0	0	0	1	0	0	0	0	0	0
	E0039028	SCREEN	03MAR2003	-21	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1	24MAR2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	31MAR2003	8	7	2	0	0	0	0	3	2	2	0	0	0	0
		DAY 15	07APR2003	15	10	5	0	0	0	0	3	3	2	0	2	0	0
		DAY 22	14APR2003	22	7	2	0	1	0	0	3	2	1	0	0	0	0
		DAY 29	21APR2003	29	10	5	0	0	0	2	3	0	2	0	3	0	0
		DAY 36	28APR2003	36	10	5	0	1	0	0	3	2	2	0	2	0	0
		DAY 43	05MAY2003	43	2	-3	0	0	0	0	2	0	0	0	0	0	0
	E0039032	SCREEN	07MAR2003	-7	5		0	0	2	2	1	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	DAY 1	14MAR2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	19MAR2003	6	5	0	2	1	0	0	1	0	0	1	0	0	0
	E0039034	SCREEN	12MAR2003	-7	4		0	0	0	1	3	0	0	0	0	0	0
		DAY 1	19MAR2003	1	5		0	0	0	1	2	0	0	0	2	0	0
		DAY 8	26MAR2003	8	5	0	0	1	0	0	3	1	0	0	0	0	0
		DAY 15	02APR2003	15	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	09APR2003	22	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	16APR2003	29	3	-2	0	0	0	0	2	0	0	0	1	0	0
		DAY 36	24APR2003	37	3	-2	0	0	0	0	3	0	0	0	0	0	0
		DAY 43	30APR2003	43	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	09MAY2003	52	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	14MAY2003	57	1	-4	0	0	0	0	1	0	0	0	0	0	0
	E0039042	SCREEN	24APR2003	-13	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	07MAY2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	14MAY2003	8	6	1	0	1	1	0	3	1	0	0	0	0	0
		DAY 15	21MAY2003	15	7	2	0	2	1	0	2	0	0	1	1	0	0
		DAY 22	28MAY2003	22	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	05JUN2003	30	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	11JUN2003	36	6	1	1	1	1	0	0	0	0	3	0	0	0
		DAY 43	18JUN2003	43	10	5	2	1	0	3	0	3	1	0	0	0	0
		DAY 50	25JUN2003	50	1	-4	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	02JUL2003	57	1	-4	0	0	0	0	1	0	0	0	0	0	0
	E0041004	SCREEN	22JAN2003	-8	5		0	1	0	0	2	0	0	2	0	0	0
		DAY 1	30JAN2003	1	11		0	2	0	0	4	0	1	2	2	0	0
		DAY 8	10FEB2003	12	12	1	1	0	1	0	2	2	2	2	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	DAY 15	14FEB2003	16	14	3	1	1	0	0	2	2	2	4	2	0	0
		DAY 22	20FEB2003	22	4	-7	0	0	0	0	0	2	0	2	0	0	0
		DAY 29	27FEB2003	29	8	-3	1	1	0	0	2	2	0	2	0	0	0
		DAY 36	07MAR2003	37	9	-2	1	1	0	0	2	4	1	0	0	0	0
		DAY 43	14MAR2003	44	8	-3	1	2	1	0	0	2	0	2	0	0	0
		DAY 50	21MAR2003	51	15	4	2	0	0	0	2	4	1	4	2	0	0
		DAY 57	31MAR2003	61	11	0	2	0	0	0	2	2	1	2	2	0	0
	E0041009	SCREEN	22APR2003	-9	9		1	0	0	2	0	2	2	2	0	0	0
		DAY 1	01MAY2003	1	11		0	1	0	2	2	0	2	2	2	0	0
		DAY 8	08MAY2003	8	5	-6	0	0	0	2	0	0	1	2	0	0	0
		DAY 15	15MAY2003	15	6	-5	0	0	0	2	0	2	2	0	0	0	0
		DAY 22	22MAY2003	22	4	-7	1	0	0	1	0	0	0	2	0	0	0
	E0042002	SCREEN	02JUL2003	-7	3		1	0	0	0	2	0	0	0	0	0	0
		DAY 1	09JUL2003	1	5		1	0	0	0	2	0	0	0	2	0	0
		DAY 8	15JUL2003	7	3	-2	1	0	0	0	2	0	0	0	0	0	0
		DAY 15	22JUL2003	14	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	29JUL2003	21	5	0	1	1	1	0	2	0	0	0	0	0	0
		DAY 29	05AUG2003	28	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	12AUG2003	35	7	2	0	1	0	0	2	2	0	0	2	0	0
		DAY 43	19AUG2003	42	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	26AUG2003	49	3	-2	1	1	0	0	0	0	1	0	0	0	0
		DAY 57	02SEP2003	56	0	-5	0	0	0	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	SCREEN	23JUN2003	-18	6		0	0	0	1	2	0	2	1	0	0	0
		DAY 1	11JUL2003	1	10		0	1	0	0	4	0	2	1	2	0	0
		DAY 8	18JUL2003	8	16	6	2	0	0	0	4	6	2	2	0	0	0
	E0003002	SCREEN	22OCT2002	-7	4		0	1	0	0	2	0	0	0	0	1	0
		DAY 1	29OCT2002	1	4		0	1	0	2	0	0	0	0	0	1	0
		DAY 8	05NOV2002	8	7	3	0	1	1	0	2	2	1	0	0	0	0
		DAY 15	14NOV2002	17	3	-1	0	1	0	0	1	1	0	0	0	0	0
		DAY 22	19NOV2002	22	3	-1	0	0	0	0	2	0	1	0	0	0	0
		DAY 29	26NOV2002	29	3	-1	2	1	0	0	0	0	0	0	0	0	0
		DAY 36	03DEC2002	36	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	10DEC2002	43	3	-1	1	1	0	0	0	0	0	1	0	0	0
		DAY 50	17DEC2002	50	1	-3	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	23DEC2002	56	8	4	1	1	2	0	0	2	1	1	0	0	0
	E0005031	SCREEN	26MAR2003	-7	7		0	0	0	1	3	0	1	0	2	0	0
		DAY 1	02APR2003	1	8		1	1	0	0	2	0	2	2	0	0	0
		DAY 8	09APR2003	8	16	8	2	2	0	0	2	2	2	4	2	0	0
		DAY 15	16APR2003	15	9	1	1	1	0	0	2	2	1	2	0	0	0
		DAY 22	24APR2003	23	5	-3	0	0	0	0	2	0	1	0	2	0	0
		DAY 29	01MAY2003	30	5	-3	0	0	0	0	2	0	1	0	2	0	0
		DAY 36	07MAY2003	36	6	-2	0	0	2	0	2	0	2	0	0	0	0
		DAY 43	14MAY2003	43	3	-5	0	0	0	0	2	0	1	0	0	0	0
	E0005033	SCREEN	08APR2003	-8	8		0	0	0	2	4	0	2	0	0	0	0
		DAY 1	15APR2003	-1	10		0	0	0	2	4	0	2	0	2	0	0
		DAY 8	22APR2003	7	8	-2	0	0	0	0	4	0	2	0	2	0	0
		DAY 15	30APR2003	15	11	1	2	0	1	0	4	2	2	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0005033	DAY 22		06MAY2003	21	9	-1	0	0	0	1	4	0	2	0	2	0	0
	E0005038	SCREEN		05MAY2003	-9	10		0	0	0	2	4	0	2	0	2	0	0
		DAY 1		14MAY2003	1	11		0	0	0	2	4	2	1	0	2	0	0
		DAY 8		22MAY2003	9	8	-3	0	0	0	1	4	0	1	0	2	0	0
		DAY 15		28MAY2003	15	9	-2	0	0	0	2	4	0	1	0	2	0	0
		DAY 22		05JUN2003	23	12	1	0	3	0	2	4	2	1	0	0	0	0
	E0007009	SCREEN		09APR2003	-8	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		17APR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8		24APR2003	8	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 8	*	28APR2003	12	2	0	0	0	0	0	2	0	0	0	0	0	0
	E0009010	SCREEN		27FEB2003	-14	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 1		13MAR2003	1	8		1	0	2	2	2	0	1	0	0	0	0
		DAY 8		20MAR2003	8	8	0	2	1	0	0	2	2	1	0	0	0	0
		DAY 15		26MAR2003	14	5	-3	0	0	0	0	2	0	1	0	2	0	0
		DAY 22		02APR2003	21	6	-2	1	1	0	0	2	0	2	0	0	0	0
	E0009011	SCREEN		28APR2003	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		06MAY2003	1	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 8		12MAY2003	7	4	3	0	0	0	0	0	0	2	0	2	0	0
		DAY 15		19MAY2003	14	8	7	1	0	0	0	2	0	1	2	2	0	0
		DAY 22		27MAY2003	22	3	2	1	1	0	0	0	0	1	0	0	0	0
		DAY 29		03JUN2003	29	1	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 36		10JUN2003	36	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		17JUN2003	43	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		24JUN2003	50	0	-1	0	0	0	0	0	0	0	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR II)	E0009011	DAY 57		03JUL2003	59	0	-1	0	0	0	0	0	0	0	0	0	0	0
	E0010005	SCREEN		10DEC2002	-8	8		0	1	1	0	2	0	0	1	2	0	1
		DAY 1		18DEC2002	1	11		0	0	0	2	4	0	0	0	4	0	1
	E0011016	SCREEN		14APR2003	-7	6		0	0	0	2	2	0	1	0	0	0	1
		DAY 1		21APR2003	1	4		0	0	0	2	1	0	1	0	0	0	0
		DAY 8		28APR2003	8	4	0	0	0	0	0	1	2	1	0	0	0	0
		DAY 15		05MAY2003	15	7	3	0	0	0	2	3	0	1	0	1	0	0
		DAY 22		12MAY2003	22	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		19MAY2003	29	1	-3	0	1	0	0	0	0	0	0	0	0	0
		DAY 36		27MAY2003	37	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		02JUN2003	43	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 50		09JUN2003	50	2	-2	0	0	0	0	1	0	0	0	1	0	0
		DAY 57		16JUN2003	57	2	-2	0	0	0	1	1	0	0	0	0	0	0
	E0011020	SCREEN		01MAY2003	-7	6		0	0	0	2	2	0	0	0	1	0	1
		DAY 1		08MAY2003	1	7		0	0	0	2	3	0	1	0	1	0	0
	E0018002	SCREEN		13NOV2002	-16	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		29NOV2002	1	5		0	1	0	2	2	0	0	0	0	0	0
		DAY 8		04DEC2002	6	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 15		11DEC2002	13	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		18DEC2002	20	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	*	24DEC2002	26	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 29		30DEC2002	32	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		08JAN2003	41	4	-1	0	1	0	1	2	0	0	0	0	0	0
		DAY 50		15JAN2003	48	2	-3	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	DAY 57	22JAN2003	55	4	-1	0	1	0	1	2	0	0	0	0	0	0
	E0018003	SCREEN	19NOV2002	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	26NOV2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	03DEC2002	8	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	10DEC2002	15	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0018013	SCREEN	17JAN2003	-7	6		0	0	0	2	2	0	1	0	0	1	0
		DAY 1	24JAN2003	1	9		0	1	0	2	2	2	1	0	0	0	1
		DAY 8	31JAN2003	8	3	-6	0	1	0	0	2	0	0	0	0	0	0
	E0019002	SCREEN	29OCT2002	-14	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 1	12NOV2002	1	4		1	0	1	0	2	0	0	0	0	0	0
		DAY 8	19NOV2002	8	3	-1	1	1	1	0	0	0	0	0	0	0	0
	E0019008	SCREEN	06NOV2002	-15	7		1	1	0	0	1	3	0	0	0	1	0
		DAY 1	21NOV2002	1	5		1	1	0	0	1	2	0	0	0	0	0
		DAY 8	27NOV2002	7	3	-2	0	0	0	0	2	0	0	0	0	1	0
		DAY 15	05DEC2002	15	2	-3	1	0	0	0	1	0	0	0	0	0	0
		DAY 22	12DEC2002	22	3	-2	0	0	0	1	1	0	0	0	0	1	0
		DAY 29	19DEC2002	29	3	-2	0	0	0	0	1	0	0	0	0	2	0
	E0019009	SCREEN	06NOV2002	-8	5		0	0	2	0	2	0	0	0	0	1	0
		DAY 1	14NOV2002	1	2		0	0	1	0	1	0	0	0	0	0	0
		DAY 8	21NOV2002	8	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	27NOV2002	14	7	5	1	1	1	2	2	0	0	0	0	0	0
		DAY 22	05DEC2002	22	6	4	0	0	0	0	2	0	1	0	0	1	2
		DAY 29	10DEC2002	27	4	2	0	0	0	0	3	0	0	0	0	1	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	SCREEN	30DEC2002	-7	4		0	1	0	1	1	0	0	0	0	1	0
		DAY 1	06JAN2003	1	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 8	13JAN2003	8	4	3	0	1	0	0	3	0	0	0	0	0	0
		DAY 15	20JAN2003	15	2	1	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	27JAN2003	22	3	2	1	1	1	0	0	0	0	0	0	0	0
		DAY 29	03FEB2003	29	2	1	0	0	0	1	1	0	0	0	0	0	0
		DAY 36	10FEB2003	36	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 43	17FEB2003	43	2	1	0	0	0	0	1	0	0	0	0	1	0
		DAY 50	27FEB2003	53	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	03MAR2003	57	1	0	0	0	0	1	0	0	0	0	0	0	0
	E0019020	SCREEN	16JAN2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	23JAN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	30JAN2003	8	6	4	0	0	1	0	3	2	0	0	0	0	0
		DAY 15	06FEB2003	15	5	3	2	1	0	0	1	1	0	0	0	0	0
		DAY 22	13FEB2003	22	5	3	1	1	1	0	1	1	0	0	0	0	0
		DAY 29	20FEB2003	29	3	1	1	1	0	0	1	0	0	0	0	0	0
		DAY 36	27FEB2003	36	9	7	1	2	1	2	2	1	0	0	0	0	0
		DAY 43	06MAR2003	43	1	-1	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	13MAR2003	50	3	1	0	0	0	0	2	0	1	0	0	0	0
		DAY 57	27MAR2003	64	6	4	0	0	0	2	2	0	2	0	0	0	0
	E0019021	SCREEN	16JAN2003	-14	4		0	0	0	0	2	0	1	0	0	1	0
		DAY 1	30JAN2003	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8	06FEB2003	8	4	1	1	1	0	1	1	0	0	0	0	0	0
		DAY 29	03MAR2003	33	5	2	0	0	0	2	3	0	0	0	0	0	0
	E0019024	SCREEN	23JAN2003	-7	4		0	0	0	0	2	0	1	0	0	1	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0019024	DAY 1	30JAN2003	1	6		0	0	1	2	1	0	0	0	0	1	1
		DAY 8	06FEB2003	8	4	-2	0	0	1	2	0	0	0	0	0	1	0
	E0019031	SCREEN	06MAR2003	-7	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	13MAR2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 15	25MAR2003	13	5	2	1	0	0	0	2	0	2	0	0	0	0
	E0019035	SCREEN	11MAR2003	-7	5		0	0	0	0	2	0	1	0	2	0	0
		DAY 1	18MAR2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	27MAR2003	10	5	2	0	0	3	0	2	0	0	0	0	0	0
		DAY 15	03APR2003	17	5	2	1	1	3	0	0	0	0	0	0	0	0
		DAY 22	10APR2003	24	6	3	0	0	2	0	2	0	0	0	2	0	0
		DAY 29	17APR2003	31	26	23	2	3	2	0	6	4	2	2	4	1	0
	E0019040	SCREEN	08MAY2003	-12	7		0	0	2	2	3	0	0	0	0	0	0
		DAY 1	20MAY2003	1	6		0	1	0	2	2	0	0	1	0	0	0
		DAY 8	29MAY2003	10	3	-3	0	0	0	0	1	2	0	0	0	0	0
		DAY 15	05JUN2003	17	6	0	0	0	2	1	2	0	1	0	0	0	0
		DAY 22	12JUN2003	24	5	-1	0	0	0	0	2	0	1	2	0	0	0
		DAY 29	18JUN2003	30	6	0	0	0	0	0	2	2	0	2	0	0	0
		DAY 36	26JUN2003	38	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	03JUL2003	45	3	-3	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	10JUL2003	52	5	-1	0	0	2	1	2	0	0	0	0	0	0
		DAY 57	17JUL2003	59	4	-2	0	0	0	1	2	1	0	0	0	0	0
	E0019042	SCREEN	28MAY2003	-7	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1	04JUN2003	1	6		0	0	0	2	2	0	2	0	0	0	0
		DAY 8	12JUN2003	9	3	-3	0	0	0	0	2	0	1	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	DAY 15	19JUN2003	16	2	-4	0	0	0	0	2	0	0	0	0	0	0
	E0019045	SCREEN	19JUN2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	26JUN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	03JUL2003	8	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0020024	SCREEN	11JUN2003	-12	10		0	0	0	0	4	0	2	0	3	1	0
		DAY 1	23JUN2003	1	12		2	0	0	0	2	2	2	2	2	0	0
		DAY 8	30JUN2003	8	10	-2	1	0	0	0	3	0	1	1	3	1	0
		DAY 15	07JUL2003	15	8	-4	2	0	0	1	2	0	1	0	2	0	0
		DAY 22	15JUL2003	23	10	-2	1	1	0	0	0	3	2	0	2	1	0
		DAY 29	21JUL2003	29	3	-9	0	1	1	0	0	0	1	0	0	0	0
		DAY 36	28JUL2003	36	0	-12	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	04AUG2003	43	0	-12	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	12AUG2003	51	3	-9	0	0	0	2	0	0	1	0	0	0	0
		DAY 57	20AUG2003	59	4	-8	1	0	0	0	0	1	1	0	1	0	0
	E0022044	SCREEN	11MAR2003	-7	7		0	1	0	0	2	2	0	0	2	0	0
		DAY 1	18MAR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	25MAR2003	8	3	1	0	0	0	0	2	0	1	0	0	0	0
		DAY 15	01APR2003	15	7	5	0	2	1	0	2	2	0	0	0	0	0
		DAY 22	08APR2003	22	7	5	1	0	0	0	4	0	0	0	2	0	0
		DAY 29	15APR2003	29	6	4	1	1	2	0	0	2	0	0	0	0	0
		DAY 36	22APR2003	36	4	2	0	0	0	0	2	2	0	0	0	0	0
		DAY 43	29APR2003	43	6	4	0	1	1	0	2	0	1	0	1	0	0
		DAY 50	06MAY2003	50	9	7	1	1	0	0	2	2	1	0	2	0	0
		DAY 57	12MAY2003	56	5	3	0	0	0	0	2	2	1	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	SCREEN	07JAN2003	-7	5		1	0	1	1	2	0	0	0	0	0	0
		DAY 1	14JAN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	21JAN2003	8	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	28JAN2003	15	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	07FEB2003	25	4	2	1	1	0	0	2	0	0	0	0	0	0
		DAY 29	11FEB2003	29	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	18FEB2003	36	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	25FEB2003	43	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	04MAR2003	50	3	1	2	1	0	0	0	0	0	0	0	0	0
		DAY 57	11MAR2003	57	2	0	1	1	0	0	0	0	0	0	0	0	0
	E0023011	SCREEN	28JAN2003	-7	1		0	0	0	0	0	0	1	0	0	0	0
		DAY 1	04FEB2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	11FEB2003	8	7	5	1	1	0	0	2	1	0	1	1	0	0
		DAY 15	21FEB2003	18	5	3	0	0	0	2	2	0	0	0	0	1	0
		DAY 22	25FEB2003	22	10	8	0	1	0	0	2	2	1	2	2	0	0
		DAY 29	04MAR2003	29	5	3	0	0	0	1	2	1	0	0	1	0	0
		DAY 36	11MAR2003	36	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	18MAR2003	43	4	2	0	0	0	0	4	0	0	0	0	0	0
		DAY 50	27MAR2003	52	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 57	01APR2003	57	2	0	0	0	0	1	1	0	0	0	0	0	0
	E0023014	SCREEN	14FEB2003	-7	5		1	1	0	0	0	2	1	0	0	0	0
		DAY 1	21FEB2003	1	3		1	1	0	0	0	0	1	0	0	0	0
		DAY 8	02MAR2003	10	3	0	0	0	0	0	2	0	0	0	0	1	0
		DAY 15	06MAR2003	14	9	6	2	2	0	0	2	2	1	0	0	0	0
		DAY 22	18MAR2003	26	5	2	0	0	0	1	4	0	0	0	0	0	0
		DAY 29	25MAR2003	33	3	0	0	0	0	1	2	0	0	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR II)	E0023014	DAY 36		01APR2003	40	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 50		09APR2003	48	4	1	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	*	15APR2003	54	5	2	0	0	0	2	3	0	0	0	0	0	0
		DAY 57		25APR2003	64	4	1	0	0	0	2	2	0	0	0	0	0	0
	E0023019	SCREEN		21MAR2003	-17	2		0	0	0	0	0	2	0	0	0	0	0
		DAY 1		07APR2003	1	7		1	1	0	0	2	2	1	0	0	0	0
		DAY 8		15APR2003	9	3	-4	1	0	0	0	1	1	0	0	0	0	0
		DAY 15		22APR2003	16	2	-5	1	1	0	0	0	0	0	0	0	0	0
		DAY 22		02MAY2003	26	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 29		06MAY2003	30	5	-2	2	1	0	0	0	2	0	0	0	0	0
		DAY 36		13MAY2003	37	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 43		20MAY2003	44	2	-5	1	1	0	0	0	0	0	0	0	0	0
		DAY 50		29MAY2003	53	2	-5	1	1	0	0	0	0	0	0	0	0	0
		DAY 57		03JUN2003	58	3	-4	2	1	0	0	0	0	0	0	0	0	0
	E0023022	SCREEN		10APR2003	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		18APR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8		25APR2003	8	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		01MAY2003	14	3	1	1	0	0	0	2	0	0	0	0	0	0
		DAY 22		08MAY2003	21	3	1	2	1	0	0	0	0	0	0	0	0	0
		DAY 29		15MAY2003	28	2	0	1	0	0	0	0	1	0	0	0	0	0
		DAY 36		22MAY2003	35	2	0	0	0	0	0	0	1	0	1	0	0	0
		DAY 43		30MAY2003	43	5	3	2	2	0	0	0	0	1	0	0	0	0
		DAY 50		06JUN2003	50	2	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 57		12JUN2003	56	2	0	1	1	0	0	0	0	0	0	0	0	0
	E0023023	SCREEN		17APR2003	-8	4		0	0	0	0	2	1	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	DAY 1	25APR2003	1	5		1	1	0	0	2	1	0	0	0	0	0
		DAY 8	01MAY2003	7	8	3	1	2	0	0	2	2	0	0	1	0	0
	E0023029	SCREEN	16MAY2003	-7	7		0	0	0	2	4	1	0	0	0	0	0
		DAY 1	23MAY2003	1	4		1	1	0	0	2	0	0	0	0	0	0
	E0023031	SCREEN	22MAY2003	-33	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	24JUN2003	1	7		0	0	0	2	5	0	0	0	0	0	0
		DAY 8	01JUL2003	8	11	4	2	2	1	0	3	3	0	0	0	0	0
		DAY 15	08JUL2003	15	8	1	0	2	0	1	3	2	0	0	0	0	0
		DAY 22	15JUL2003	22	5	-2	0	0	0	1	3	1	0	0	0	0	0
		DAY 29	22JUL2003	29	6	-1	1	1	0	0	2	2	0	0	0	0	0
		DAY 36	29JUL2003	36	6	-1	1	1	0	0	2	2	0	0	0	0	0
		DAY 43	05AUG2003	43	7	0	0	1	0	2	2	2	0	0	0	0	0
		DAY 50	12AUG2003	50	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19AUG2003	57	5	-2	0	0	0	2	3	0	0	0	0	0	0
	E0023041	SCREEN	02JUL2003	-7	5		0	0	0	1	4	0	0	0	0	0	0
		DAY 1	09JUL2003	1	4		0	0	0	0	4	0	0	0	0	0	0
		DAY 8	16JUL2003	8	3	-1	0	0	0	0	3	0	0	0	0	0	0
		DAY 15	24JUL2003	16	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	30JUL2003	22	3	-1	1	0	0	0	2	0	0	0	0	0	0
		DAY 29	06AUG2003	29	3	-1	0	0	0	0	3	0	0	0	0	0	0
		DAY 36	13AUG2003	36	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 43	20AUG2003	43	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	27AUG2003	50	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	05SEP2003	59	1	-3	0	0	0	0	1	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	SCREEN	07JUL2003	-7	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 1	14JUL2003	1	4		0	0	0	1	3	0	0	0	0	0	0
		DAY 8	23JUL2003	10	5	1	1	1	0	0	2	1	0	0	0	0	0
		DAY 15	28JUL2003	15	2	-2	0	1	0	0	1	0	0	0	0	0	0
		DAY 22	05AUG2003	23	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	12AUG2003	30	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	19AUG2003	37	1	-3	0	1	0	0	0	0	0	0	0	0	0
		DAY 43	26AUG2003	44	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	02SEP2003	51	3	-1	0	1	0	0	0	2	0	0	0	0	0
		DAY 57	09SEP2003	58	1	-3	0	1	0	0	0	0	0	0	0	0	0
	E0026003	SCREEN	25NOV2002	-9	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	04DEC2002	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	12DEC2002	9	9	4	1	1	0	0	2	2	0	3	0	0	0
		DAY 15	19DEC2002	16	7	2	1	1	1	0	2	2	0	0	0	0	0
		DAY 22	26DEC2002	23	5	0	1	0	0	0	0	2	0	2	0	0	0
		DAY 29	02JAN2003	30	8	3	2	1	1	0	0	2	0	2	0	0	0
		DAY 36	09JAN2003	37	8	3	1	1	2	0	0	2	0	2	0	0	0
		DAY 43	16JAN2003	44	6	1	1	1	1	0	0	1	1	1	0	0	0
		DAY 50	23JAN2003	51	9	4	1	1	2	0	0	2	1	2	0	0	0
		DAY 57	03FEB2003	62	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0026005	SCREEN	23DEC2002	-7	11		1	1	0	0	4	4	0	0	0	1	0
		DAY 1	30DEC2002	1	5		0	0	0	0	2	1	0	0	0	1	1
		DAY 8	06JAN2003	8	23	18	1	2	2	0	6	6	2	2	0	1	1
	E0026009	SCREEN	10JAN2003	-5	10		1	1	0	2	2	2	0	0	1	1	0
		DAY 1	15JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0026009	DAY 8	21JAN2003	7	7	3	1	2	0	0	0	2	1	0	0	1	0
	E0026015	SCREEN	20FEB2003	-7	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 1	27FEB2003	1	10		0	2	0	0	2	3	1	0	1	1	0
		DAY 8	07MAR2003	9	21	11	0	3	0	3	2	4	2	4	2	1	0
		DAY 15	13MAR2003	15	5	-5	0	0	0	0	2	0	0	2	0	1	0
		DAY 22	20MAR2003	22	16	6	0	1	0	2	4	4	2	2	0	1	0
		DAY 29	27MAR2003	29	11	1	1	0	2	2	2	2	0	2	0	0	0
		DAY 36	03APR2003	36	6	-4	0	0	0	0	2	1	0	2	0	1	0
		DAY 43	10APR2003	43	14	4	2	2	0	0	0	3	1	4	1	1	0
		DAY 50	17APR2003	50	5	-5	0	0	0	1	0	0	0	4	0	0	0
		DAY 57	25APR2003	58	4	-6	0	0	0	0	0	0	0	3	0	1	0
	E0026023	SCREEN	23APR2003	-7	8		0	0	2	2	2	1	0	0	0	1	0
		DAY 1	30APR2003	1	9		0	0	0	2	1	0	1	0	2	3	0
		DAY 8	07MAY2003	8	3	-6	0	0	0	0	0	0	1	0	0	2	0
		DAY 15	14MAY2003	15	7	-2	0	0	0	1	0	0	0	3	0	3	0
		DAY 22	21MAY2003	22	11	2	0	0	0	1	4	0	0	4	0	2	0
		DAY 29	28MAY2003	29	14	5	0	0	0	2	4	0	0	4	0	4	0
		DAY 36	04JUN2003	36	10	1	0	0	1	1	2	0	0	3	0	3	0
		DAY 43	11JUN2003	43	9	0	0	0	1	1	3	0	0	2	0	2	0
		DAY 50	18JUN2003	50	7	-2	0	0	0	0	2	0	1	2	0	2	0
	E0027016	SCREEN	19MAR2003	-21	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	09APR2003	1	8		0	0	1	0	4	0	1	0	2	0	0
		DAY 8	14APR2003	6	8	0	0	0	1	0	4	0	1	0	2	0	0
		DAY 15	22APR2003	14	2	-6	0	0	0	0	1	0	0	0	1	0	0
		DAY 22	29APR2003	21	2	-6	0	0	1	0	1	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	DAY 29	05MAY2003	27	2	-6	0	0	0	0	1	0	0	0	1	0	0
		DAY 36	14MAY2003	36	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	19MAY2003	41	1	-7	0	0	0	0	1	0	0	0	0	0	0
		DAY 50	27MAY2003	49	3	-5	1	0	0	1	1	0	0	0	0	0	0
		DAY 57	03JUN2003	56	3	-5	0	0	1	0	1	1	0	0	0	0	0
	E0027018	SCREEN	21MAR2003	-4	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	25MAR2003	1	6		0	0	1	0	2	0	0	0	3	0	0
		DAY 8	02APR2003	9	2	-4	0	0	0	0	1	0	0	0	1	0	0
		DAY 15	08APR2003	15	4	-2	0	1	0	0	1	1	0	0	1	0	0
		DAY 22	15APR2003	22	2	-4	0	1	0	0	1	0	0	0	0	0	0
		DAY 29	22APR2003	29	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	29APR2003	36	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	42	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	50	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	59	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0028032	SCREEN	13MAR2003	-12	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	25MAR2003	1	4		0	1	0	2	0	0	1	0	0	0	0
		DAY 8	01APR2003	8	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	08APR2003	15	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	15APR2003	22	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	22APR2003	29	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	30APR2003	37	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	06MAY2003	43	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	50	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0029003	SCREEN	28OCT2002	-7	5		0	1	0	0	3	0	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 1	04NOV2002	1	8		0	0	0	2	4	0	0	0	2	0	0
		DAY 8	11NOV2002	8	8	0	0	0	0	0	2	2	0	2	2	0	0
		DAY 15	18NOV2002	15	2	-6	1	1	0	0	0	0	0	0	0	0	0
		DAY 22	25NOV2002	22	10	2	0	0	0	1	4	0	1	0	3	1	0
		DAY 29	02DEC2002	29	9	1	1	1	0	0	3	2	0	0	2	0	0
		DAY 36	09DEC2002	36	12	4	0	1	0	0	4	0	0	2	5	0	0
		DAY 43	16DEC2002	43	14	6	2	1	1	0	4	2	0	0	4	0	0
		DAY 50	23DEC2002	50	8	0	1	0	0	0	3	0	2	0	2	0	0
		DAY 57	30DEC2002	57	15	7	1	0	0	0	5	2	1	1	4	1	0
	E0029020	SCREEN	25FEB2003	-8	3		0	0	0	0	2	0	1	0	0	0	0
		DAY 1	04MAR2003	-1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	11MAR2003	7	5	2	0	0	0	0	3	0	0	0	2	0	0
	E0031005	SCREEN	13DEC2002	-7	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1	20DEC2002	1	7		1	0	0	2	4	0	0	0	0	0	0
		DAY 8	27DEC2002	8	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	03JAN2003	15	3	-4	0	0	0	0	2	0	1	0	0	0	0
		DAY 22	10JAN2003	22	5	-2	0	0	0	1	2	0	0	0	2	0	0
		DAY 29	17JAN2003	29	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	24JAN2003	36	4	-3	0	0	0	0	4	0	0	0	0	0	0
		DAY 43	30JAN2003	42	5	-2	0	0	0	2	2	0	1	0	0	0	0
		DAY 50	07FEB2003	50	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	14FEB2003	57	5	-2	0	0	0	1	4	0	0	0	0	0	0
	E0031006	SCREEN	29JAN2003	-20	12		0	0	0	2	4	0	2	0	4	0	0
		DAY 1	18FEB2003	1	11		1	1	0	2	2	0	1	0	4	0	0
		DAY 8	26FEB2003	9	3	-8	0	0	0	0	2	0	1	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0031006	DAY 15	05MAR2003	16	6	-5	0	0	0	1	2	0	1	0	2	0	0
		DAY 22	11MAR2003	22	9	-2	0	1	1	2	0	2	1	0	2	0	0
		DAY 29	18MAR2003	29	4	-7	0	0	1	2	0	0	1	0	0	0	0
		DAY 36	25MAR2003	36	12	1	1	0	1	2	2	2	2	0	2	0	0
		DAY 43	02APR2003	44	12	1	0	0	1	3	4	0	2	0	2	0	0
		DAY 50	07APR2003	49	8	-3	1	1	1	2	0	0	1	0	2	0	0
		DAY 57	15APR2003	57	4	-7	0	0	0	2	0	0	0	0	2	0	0
	E0031010	SCREEN	12FEB2003	-7	9		0	0	0	2	4	0	1	0	2	0	0
		DAY 1	19FEB2003	1	8		0	0	0	2	4	0	0	0	2	0	0
		DAY 8	26FEB2003	8	4	-4	0	0	0	0	2	0	0	0	2	0	0
		DAY 15	05MAR2003	15	4	-4	0	0	0	0	2	0	0	0	2	0	0
	E0031011	SCREEN	18FEB2003	-9	12		1	2	0	2	4	0	1	0	2	0	0
		DAY 1	27FEB2003	1	8		2	3	0	0	2	0	1	0	0	0	0
		DAY 8	06MAR2003	8	11	3	2	2	0	0	2	2	1	0	2	0	0
		DAY 15	13MAR2003	15	2	-6	0	0	0	1	0	0	1	0	0	0	0
		DAY 22	20MAR2003	22	8	0	0	0	0	1	4	0	1	0	2	0	0
		DAY 29	27MAR2003	29	3	-5	0	0	1	0	0	2	0	0	0	0	0
		DAY 36	03APR2003	36	9	1	2	2	1	0	0	2	0	0	2	0	0
		DAY 43	11APR2003	44	4	-4	0	0	1	2	0	0	1	0	0	0	0
		DAY 50	17APR2003	50	6	-2	0	0	0	1	2	0	1	0	2	0	0
		DAY 57	24APR2003	57	2	-6	0	0	0	0	0	0	0	0	2	0	0
	E0031015	SCREEN	13MAR2003	-13	9		0	0	0	0	4	2	1	0	2	0	0
		DAY 1	26MAR2003	1	9		1	1	0	0	2	2	1	0	2	0	0
		DAY 8	01APR2003	7	6	-3	0	0	0	0	2	2	0	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0031031	SCREEN	01JUL2003	-7	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 1	08JUL2003	1	7		0	0	0	1	4	0	0	0	2	0	0
		DAY 8	15JUL2003	8	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	22JUL2003	15	9	2	0	0	0	1	4	0	2	0	2	0	0
		DAY 22	29JUL2003	22	4	-3	2	1	0	0	0	0	1	0	0	0	0
	E0033009	SCREEN	22JAN2003	-21	7		1	1	0	0	2	2	1	0	0	0	0
		DAY 1	12FEB2003	1	8		0	0	0	2	4	0	2	0	0	0	0
	E0034009	SCREEN	10JUN2003	-9	5		0	0	0	0	4	0	0	0	0	1	0
		DAY 1	19JUN2003	1	4		0	0	0	0	4	0	0	0	0	0	0
		DAY 8	27JUN2003	9	6	2	0	0	0	0	6	0	0	0	0	0	0
		DAY 15	03JUL2003	15	7	3	0	0	0	0	6	0	0	0	0	1	0
		DAY 22	10JUL2003	22	4	0	0	0	0	0	4	0	0	0	0	0	0
		DAY 29	18JUL2003	30	4	0	0	0	0	0	4	0	0	0	0	0	0
		DAY 36	25JUL2003	37	4	0	0	0	0	0	4	0	0	0	0	0	0
		DAY 43	31JUL2003	43	4	0	0	0	0	0	4	0	0	0	0	0	0
		DAY 50	07AUG2003	50	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	18AUG2003	61	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0037007	SCREEN	04APR2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	11APR2003	1	5		0	1	0	2	1	0	1	0	0	0	0
		DAY 8	17APR2003	7	1	-4	0	0	0	1	0	0	0	0	0	0	0
	E0037012	SCREEN	11JUL2003	-5	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	16JUL2003	1	6		1	0	0	2	2	0	1	0	0	0	0
		DAY 8	24JUL2003	9	4	-2	0	0	0	1	2	0	1	0	0	0	0
		DAY 15	01AUG2003	17	3	-3	0	0	0	0	2	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 22	08AUG2003	24	1	-5	0	0	0	0	0	0	1	0	0	0	0
		DAY 29	15AUG2003	31	3	-3	0	0	0	0	2	0	1	0	0	0	0
		DAY 36	22AUG2003	38	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	29AUG2003	45	5	-1	0	0	0	1	2	0	1	0	1	0	0
		DAY 50	05SEP2003	52	2	-4	0	0	0	0	1	0	1	0	0	0	0
		DAY 57	08SEP2003	55	1	-5	0	0	0	0	1	0	0	0	0	0	0
	E0039019	SCREEN	20JAN2003	-17	5		0	0	1	2	2	0	0	0	0	0	0
		DAY 1	06FEB2003	1	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 8	13FEB2003	8	2	-1	1	0	0	0	1	0	0	0	0	0	0
		DAY 15	20FEB2003	15	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	27FEB2003	22	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	07MAR2003	30	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	13MAR2003	36	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 43	20MAR2003	43	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	27MAR2003	50	2	-1	1	0	0	0	1	0	0	0	0	0	0
		DAY 57	03APR2003	57	2	-1	0	0	0	0	2	0	0	0	0	0	0
	E0039043	SCREEN	25APR2003	-13	6		0	0	0	2	2	0	2	0	0	0	0
		DAY 1	08MAY2003	1	8		0	0	0	2	2	1	2	1	0	0	0
		DAY 8	15MAY2003	8	2	-6	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	23MAY2003	16	4	-4	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	29MAY2003	22	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	05JUN2003	29	5	-3	0	0	0	0	3	0	2	0	0	0	0
		DAY 36	13JUN2003	37	7	-1	0	1	0	1	2	0	2	1	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0002001	SCREEN	17DEC2002	-13	7		1	0	0	1	0	4	1	0	0	0	0
		DAY 1	30DEC2002	1	10		0	2	0	2	2	2	1	0	0	1	0
		DAY 8	06JAN2003	8	5	-5	1	1	0	0	2	0	1	0	0	0	0
		DAY 15	14JAN2003	16	3	-7	0	1	0	0	2	0	0	0	0	0	0
		DAY 22	21JAN2003	23	1	-9	0	1	0	0	0	0	0	0	0	0	0
		DAY 29	29JAN2003	31	2	-8	1	1	0	0	0	0	0	0	0	0	0
		DAY 36	05FEB2003	38	7	-3	1	1	1	0	2	2	0	0	0	0	0
		DAY 43	12FEB2003	45	5	-5	1	0	1	1	0	2	0	0	0	0	0
		DAY 50	19FEB2003	52	0	-10	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	26FEB2003	59	2	-8	1	1	0	0	0	0	0	0	0	0	0
	E0002003	SCREEN	03JAN2003	-19	11		1	1	2	1	0	2	1	2	0	0	1
		DAY 1	22JAN2003	1	5		0	0	0	1	2	2	0	0	0	0	0
		DAY 8	29JAN2003	8	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	05FEB2003	15	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	12FEB2003	22	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	19FEB2003	29	3	-2	1	0	2	0	0	0	0	0	0	0	0
		DAY 36	26FEB2003	36	2	-3	0	0	2	0	0	0	0	0	0	0	0
		DAY 43	05MAR2003	43	1	-4	1	0	0	0	0	0	0	0	0	0	0
		DAY 50	11MAR2003	49	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 57	18MAR2003	56	1	-4	0	1	0	0	0	0	0	0	0	0	0
	E0002004	SCREEN	14JAN2003	-11	4		1	0	0	0	2	0	1	0	0	0	0
		DAY 1	25JAN2003	1	3		1	0	0	0	2	0	0	0	0	0	0
	E0002008	SCREEN	29JAN2003	-27	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	25FEB2003	1	3		0	0	1	0	2	0	0	0	0	0	0
		DAY 8	05MAR2003	9	6	3	1	1	0	1	2	0	0	0	0	1	0
		DAY 15	13MAR2003	17	4	1	0	0	0	1	2	0	0	0	0	1	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0002008	DAY 22	20MAR2003	24	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	27MAR2003	31	4	1	1	0	0	0	2	0	0	0	0	1	0
		DAY 36	03APR2003	38	4	1	0	0	0	1	2	0	0	0	0	1	0
		DAY 43	11APR2003	46	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	16APR2003	51	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	23APR2003	58	2	-1	0	0	0	0	2	0	0	0	0	0	0
	E0002016	SCREEN	14JUL2003	-10	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	24JUL2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	30JUL2003	7	4	1	1	0	1	0	2	0	0	0	0	0	0
		DAY 15	06AUG2003	14	5	2	1	1	1	0	2	0	0	0	0	0	0
		DAY 22	13AUG2003	21	3	0	0	1	0	0	2	0	0	0	0	0	0
		DAY 29	21AUG2003	29	1	-2	0	0	1	0	0	0	0	0	0	0	0
		DAY 36	27AUG2003	35	3	0	0	0	1	0	2	0	0	0	0	0	0
		DAY 43	03SEP2003	42	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	11SEP2003	50	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	17SEP2003	56	2	-1	0	0	0	0	2	0	0	0	0	0	0
	E0003008	SCREEN	21JAN2003	-7	11		2	1	0	2	2	0	2	0	2	0	0
		DAY 1	28JAN2003	1	8		1	1	0	1	2	0	1	0	2	0	0
		DAY 8	04FEB2003	8	7	-1	0	0	0	2	2	0	1	0	2	0	0
		DAY 15	11FEB2003	15	10	2	2	1	0	0	2	2	1	0	2	0	0
		DAY 22	18FEB2003	22	5	-3	0	0	0	0	2	0	1	0	2	0	0
	E0004003	DAY 1	10OCT2002	1	10		0	0	0	0	2	2	2	0	4	0	0
		DAY 8	17OCT2002	8	7	-3	1	1	1	0	0	0	2	0	2	0	0
	E0004006	SCREEN	28OCT2002	-7	5		0	0	0	0	3	0	0	0	2	0	0
		DAY 1	04NOV2002	1	7		0	0	0	0	3	0	1	0	3	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0004006	DAY 8	11NOV2002	8	10	3	1	3	0	2	2	0	0	0	2	0	0
		DAY 15	18NOV2002	15	7	0	1	1	0	1	3	0	0	0	1	0	0
		DAY 22	25NOV2002	22	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	02DEC2002	29	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 36	09DEC2002	36	8	1	0	0	0	2	4	0	0	0	2	0	0
		DAY 43	16DEC2002	43	9	2	0	0	0	2	4	0	0	0	2	1	0
		DAY 57	06JAN2003	64	6	-1	0	0	0	2	2	0	1	0	1	0	0
	E0004016	SCREEN	12FEB2003	-7	7		0	0	0	2	3	0	0	0	2	0	0
		DAY 1	19FEB2003	1	6		0	0	0	2	3	0	1	0	0	0	0
		DAY 8	26FEB2003	8	4	-2	0	0	0	1	3	0	0	0	0	0	0
		DAY 15	05MAR2003	15	2	-4	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	13MAR2003	23	8	2	2	2	0	1	0	1	1	1	0	0	0
		DAY 36	26MAR2003	36	4	-2	0	0	0	1	1	0	2	0	0	0	0
		DAY 43	03APR2003	44	7	1	2	0	0	0	3	0	0	0	2	0	0
		DAY 50	10APR2003	51	3	-3	2	1	0	0	0	0	0	0	0	0	0
		DAY 57	17APR2003	58	3	-3	1	1	0	1	0	0	0	0	0	0	0
	E0004024	SCREEN	25JUN2003	-8	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	03JUL2003	1	9		1	0	0	2	3	0	1	0	2	0	0
		DAY 8	10JUL2003	8	8	-1	1	0	0	1	3	0	1	0	2	0	0
		DAY 15	17JUL2003	15	6	-3	1	0	0	2	2	0	0	0	1	0	0
		DAY 22	24JUL2003	22	4	-5	1	0	0	1	2	0	0	0	0	0	0
		DAY 29	31JUL2003	29	6	-3	1	1	0	0	1	2	0	1	0	0	0
		DAY 36	07AUG2003	36	7	-2	1	1	0	0	1	2	1	1	0	0	0
		DAY 43	14AUG2003	43	4	-5	1	0	0	1	0	1	1	0	0	0	0
		DAY 50	21AUG2003	50	3	-6	1	1	0	1	0	0	0	0	0	0	0
		DAY 57	28AUG2003	57	5	-4	1	0	0	0	1	2	1	0	0	0	0

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PLACEBO (BIPOLAR I)	E0005006	DAY 1	03OCT2002	1	5		0	0	1	2	2	0	0	0	0	0	0
		DAY 8	14OCT2002	12	6	1	0	0	0	2	2	0	1	0	0	0	1
	E0005017	SCREEN	11DEC2002	-19	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 1	30DEC2002	1	8		0	0	0	2	2	0	2	0	2	0	0
		DAY 8	06JAN2003	8	8	0	0	0	0	2	2	0	2	2	0	0	0
		DAY 15	14JAN2003	16	4	-4	0	0	0	2	1	0	1	0	0	0	0
		DAY 22	22JAN2003	24	4	-4	0	0	0	2	1	0	1	0	0	0	0
		DAY 29	30JAN2003	32	4	-4	0	0	0	2	1	0	1	0	0	0	0
		DAY 36	04FEB2003	37	3	-5	0	0	0	1	1	0	1	0	0	0	0
		DAY 43	13FEB2003	46	3	-5	0	0	0	1	1	0	1	0	0	0	0
		DAY 50	20FEB2003	53	3	-5	0	0	0	2	0	0	1	0	0	0	0
		DAY 57	04MAR2003	65	3	-5	0	0	0	1	1	0	1	0	0	0	0
	E0005019	SCREEN	19DEC2002	-27	10		0	0	0	2	4	0	2	0	2	0	0
		DAY 1	15JAN2003	1	10		0	0	0	2	4	0	1	0	2	1	0
		DAY 8	23JAN2003	9	9	-1	0	0	0	2	4	0	1	0	2	0	0
	E0005026	SCREEN	26FEB2003	-8	10		0	0	0	2	4	0	2	0	2	0	0
		DAY 1	06MAR2003	1	6		0	0	0	2	2	0	2	0	0	0	0
		DAY 8	13MAR2003	8	8	2	0	0	0	2	4	0	2	0	0	0	0
		DAY 15	20MAR2003	15	23	17	0	3	2	3	4	4	2	2	2	1	0
		DAY 22	25MAR2003	20	19	13	0	3	1	3	4	0	2	4	2	0	0
	E0005039	SCREEN	15MAY2003	-7	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 1	22MAY2003	1	7		0	0	0	2	2	0	1	2	0	0	0
		DAY 8	28MAY2003	7	5	-2	0	0	0	2	2	0	1	0	0	0	0
		DAY 15	05JUN2003	15	4	-3	0	0	0	1	2	0	1	0	0	0	0
		DAY 22	12JUN2003	22	4	-3	0	0	0	1	2	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0005039	DAY 29	18JUN2003	28	3	-4	0	0	0	0	2	0	1	0	0	0	0
		DAY 36	24JUN2003	34	2	-5	0	0	0	1	0	0	1	0	0	0	0
		DAY 43	03JUL2003	43	1	-6	0	0	0	0	0	0	1	0	0	0	0
		DAY 50	10JUL2003	50	6	-1	0	1	0	1	2	0	2	0	0	0	0
		DAY 57	16JUL2003	56	11	4	0	1	0	2	2	2	2	2	0	0	0
	E0005043	SCREEN	01JUL2003	-8	5		0	0	0	0	3	0	0	0	2	0	0
		DAY 1	09JUL2003	1	6		0	0	0	0	3	0	1	0	2	0	0
		DAY 8	17JUL2003	9	4	-2	0	0	0	0	2	0	0	0	2	0	0
		DAY 15	24JUL2003	16	6	0	0	0	0	0	3	0	1	0	2	0	0
		DAY 22	31JUL2003	23	5	-1	0	0	0	0	2	0	1	0	2	0	0
		DAY 29	07AUG2003	30	5	-1	0	0	0	0	2	0	1	0	2	0	0
		DAY 36	13AUG2003	36	5	-1	0	0	0	0	2	0	1	0	2	0	0
		DAY 43	20AUG2003	43	4	-2	0	0	0	0	2	0	0	0	2	0	0
		DAY 50	27AUG2003	50	6	0	0	0	0	0	4	0	0	0	2	0	0
		DAY 57	03SEP2003	57	6	0	0	0	0	0	2	2	0	0	2	0	0
	E0006020	SCREEN	02MAY2003	-11	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	13MAY2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	20MAY2003	8	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 15	27MAY2003	15	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 22	03JUN2003	22	4	1	1	0	0	1	2	0	0	0	0	0	0
		DAY 29	10JUN2003	29	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 36	17JUN2003	36	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	24JUN2003	43	5	2	1	0	0	0	2	2	0	0	0	0	0
		DAY 50	01JUL2003	50	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	08JUL2003	57	2	-1	0	0	0	0	2	0	0	0	0	0	0
	E0007001	SCREEN	10DEC2002	-21	0		0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0007001	DAY 1		31DEC2002	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8		07JAN2003	8	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 15		14JAN2003	15	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 22		21JAN2003	22	3	1	0	0	0	1	2	0	0	0	0	0	0
		DAY 29		28JAN2003	29	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		04FEB2003	36	3	1	0	0	0	1	2	0	0	0	0	0	0
		DAY 43		11FEB2003	43	3	1	0	0	0	1	2	0	0	0	0	0	0
		DAY 50		18FEB2003	50	3	1	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	*	22FEB2003	54	3	1	0	0	0	1	2	0	0	0	0	0	0
	E0007003	SCREEN		03JAN2003	-27	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		30JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		06FEB2003	8	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 15		14FEB2003	16	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 22		22FEB2003	24	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 36		10MAR2003	40	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0007006	SCREEN		21FEB2003	-12	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		05MAR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		12MAR2003	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15		19MAR2003	15	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	*	25MAR2003	21	1	-3	0	0	1	0	0	0	0	0	0	0	0
		DAY 22		26MAR2003	22	2	-2	1	0	1	0	0	0	0	0	0	0	0
	E0009004	SCREEN		19NOV2002	-7	7		0	2	0	2	2	0	0	0	0	1	0
		DAY 1		26NOV2002	1	7		0	1	0	2	4	0	0	0	0	0	0
		DAY 8		04DEC2002	9	9	2	2	2	0	3	2	0	0	0	0	0	0
		DAY 15		11DEC2002	16	8	1	0	2	1	2	2	0	1	0	0	0	0
		DAY 22		18DEC2002	23	6	-1	0	3	0	2	1	0	0	0	0	0	0

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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0009012	SCREEN	16JUN2003	-9	6		1	1	0	2	2	0	0	0	0	0	0
		DAY 1	25JUN2003	1	7		1	1	0	2	2	0	1	0	0	0	0
		DAY 8	03JUL2003	9	7	0	1	1	0	1	2	0	1	0	0	1	0
	E0010008	SCREEN	11DEC2002	-7	9		0	1	0	2	3	0	2	0	1	0	0
		DAY 1	18DEC2002	1	5		0	1	0	2	0	1	0	0	0	1	0
		DAY 8	26DEC2002	9	9	4	0	1	0	1	4	0	0	0	3	0	0
		DAY 15	02JAN2003	16	9	4	0	2	0	2	2	2	0	0	0	0	1
		DAY 22	08JAN2003	22	17	12	1	3	0	2	2	3	2	0	4	0	0
		DAY 29	15JAN2003	29	12	7	0	2	0	2	3	0	2	1	2	0	0
	E0010018	SCREEN	26FEB2003	-21	6		0	0	0	2	2	0	2	0	0	0	0
		DAY 1	19MAR2003	1	8		0	0	0	2	3	0	2	0	1	0	0
		DAY 8	26MAR2003	8	5	-3	2	0	0	0	2	0	0	1	0	0	0
		DAY 15	02APR2003	15	7	-1	0	0	0	2	2	0	2	0	1	0	0
		DAY 22	09APR2003	22	5	-3	1	0	0	1	2	0	0	1	0	0	0
		DAY 29	16APR2003	29	3	-5	0	0	0	1	2	0	0	0	0	0	0
		DAY 36	23APR2003	36	2	-6	0	0	0	2	0	0	0	0	0	0	0
		DAY 43	01MAY2003	44	4	-4	0	0	0	2	2	0	0	0	0	0	0
	E0010028	SCREEN	09JUN2003	-7	12		2	1	0	2	1	2	2	0	2	0	0
		DAY 1	16JUN2003	1	12		1	2	0	2	2	1	2	0	2	0	0
		DAY 8	24JUN2003	9	13	1	0	0	0	2	4	2	2	0	3	0	0
		DAY 15	01JUL2003	16	12	0	0	2	0	2	3	1	2	0	2	0	0
		DAY 22	08JUL2003	23	17	5	0	3	1	2	4	2	2	0	2	1	0
		DAY 29	15JUL2003	30	23	11	0	0	0	2	7	4	3	2	4	1	0
	E0011008	SCREEN	23JAN2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	30JAN2003	1	6		0	0	1	2	1	0	1	1	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0011008	DAY 8		06FEB2003	8	5	-1	0	1	1	0	0	0	0	2	1	0	0
		DAY 15		13FEB2003	15	14	8	0	1	2	1	2	2	1	2	2	0	1
	E0011009	SCREEN		19DEC2002	-8	3		0	1	0	2	0	0	0	0	0	0	0
		DAY 1		26DEC2002	-1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8		02JAN2003	7	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 15		09JAN2003	14	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 22		16JAN2003	21	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 29		23JAN2003	28	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 36		30JAN2003	35	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 43		06FEB2003	42	3	1	0	0	0	2	1	0	0	0	0	0	0
		DAY 50		13FEB2003	49	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 57		20FEB2003	56	2	0	0	0	0	2	0	0	0	0	0	0	0
	E0011010	SCREEN		03FEB2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1		10FEB2003	1	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 8		17FEB2003	8	6	5	0	1	0	1	0	1	1	1	1	0	0
		DAY 15		24FEB2003	15	1	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 22		03MAR2003	22	4	3	0	0	0	1	1	1	0	1	0	0	0
		DAY 29		10MAR2003	29	3	2	0	1	0	1	1	0	0	0	0	0	0
		DAY 36		17MAR2003	36	4	3	0	0	0	2	2	0	0	0	0	0	0
		DAY 36	*	19MAR2003	38	4	3	0	0	0	2	2	0	0	0	0	0	0
	E0013001	SCREEN		31OCT2002	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		14NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8		21NOV2002	8	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15		27NOV2002	14	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		06DEC2002	23	2	2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		11DEC2002	28	1	1	0	0	0	0	1	0	0	0	0	0	0

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PLACEBO (BIPOLAR I)	E0013001	DAY 36	18DEC2002	35	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	27DEC2002	44	1	1	0	0	0	0	0	0	0	0	1	0	0
		DAY 50	02JAN2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	10JAN2003	58	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0013003	SCREEN	06NOV2002	-6	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 1	12NOV2002	1	3		0	0	0	0	2	0	0	0	0	1	0
		DAY 8	19NOV2002	8	3	0	0	0	0	0	2	0	0	0	0	1	0
		DAY 15	26NOV2002	15	4	1	0	1	0	0	2	0	0	0	0	1	0
		DAY 22	03DEC2002	22	3	0	0	0	0	0	2	0	0	0	0	1	0
		DAY 29	11DEC2002	30	5	2	0	1	0	0	2	1	0	0	0	1	0
		DAY 36	18DEC2002	37	3	0	0	0	0	0	2	0	0	0	0	1	0
		DAY 43	23DEC2002	42	1	-2	0	0	0	0	0	0	0	0	0	1	0
		DAY 50	30DEC2002	49	3	0	0	0	0	0	2	0	0	0	0	1	0
		DAY 57	06JAN2003	56	4	1	0	1	0	0	2	0	0	0	0	1	0
	E0013005	SCREEN	11FEB2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	25FEB2003	8	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 15	04MAR2003	15	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	11MAR2003	22	2	2	1	0	0	0	1	0	0	0	0	0	0
		DAY 29	19MAR2003	30	3	3	1	0	0	1	0	1	0	0	0	0	0
		DAY 36	25MAR2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	02APR2003	44	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	08APR2003	50	1	1	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0013013	SCREEN	01MAY2003	-5	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 1	06MAY2003	1	2		0	0	0	0	2	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0013013	DAY 8		12MAY2003	7	1	-1	1	0	0	0	0	0	0	0	0	0	0
		DAY 15		19MAY2003	14	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		27MAY2003	22	12	10	2	2	0	0	2	2	2	0	2	0	0
		DAY 22	*	30MAY2003	25	21	19	3	3	0	4	4	4	2	1	0	0	0
	E0014002	SCREEN		19FEB2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		26FEB2003	1	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 8		04MAR2003	7	2	1	0	0	0	0	0	0	0	2	0	0	0
		DAY 15		12MAR2003	15	1	0	0	0	0	0	0	0	1	0	0	0	0
		DAY 22		20MAR2003	23	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		27MAR2003	30	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		10APR2003	44	0	-1	0	0	0	0	0	0	0	0	0	0	0
	E0014004	SCREEN		04MAR2003	-8	6		0	0	0	0	6	0	0	0	0	0	0
		DAY 1		12MAR2003	1	11		0	1	0	2	4	0	2	0	2	0	0
		DAY 8		20MAR2003	9	0	-11	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		25MAR2003	14	0	-11	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		01APR2003	21	0	-11	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		15APR2003	35	0	-11	0	0	0	0	0	0	0	0	0	0	0
	E0014009	SCREEN		15APR2003	-8	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		23APR2003	1	5		0	1	0	2	2	0	0	0	0	0	0
		DAY 8		30APR2003	8	14	9	0	2	0	3	4	0	2	0	2	1	0
	E0014015	SCREEN		11JUN2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		18JUN2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8		26JUN2003	9	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0014017	SCREEN		17JUN2003	-10	4		0	0	0	0	2	2	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0014017	DAY 1		27JUN2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8		02JUL2003	6	6	3	0	0	2	2	2	0	0	0	0	0	0
		DAY 15		09JUL2003	13	4	1	0	0	0	2	2	0	0	0	0	0	0
		DAY 22		16JUL2003	20	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 29		23JUL2003	27	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	*	29JUL2003	33	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		05AUG2003	40	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		12AUG2003	47	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		19AUG2003	54	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0014018	SCREEN		24JUN2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		01JUL2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8		09JUL2003	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		16JUL2003	16	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		22JUL2003	22	3	3	0	0	0	1	2	0	0	0	0	0	0
		DAY 29		29JUL2003	29	1	1	0	1	0	0	0	0	0	0	0	0	0
		DAY 36		05AUG2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		12AUG2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		19AUG2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		27AUG2003	58	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0015005	SCREEN		25NOV2002	-7	7		0	0	0	1	2	0	2	2	0	0	0
		DAY 1		02DEC2002	1	7		0	0	0	1	2	0	2	2	0	0	0
		DAY 8		11DEC2002	10	8	1	0	0	0	1	2	0	1	2	2	0	0
		DAY 15		18DEC2002	17	11	4	0	0	0	2	4	2	1	2	0	0	0
	E0017002	SCREEN		06MAY2003	-28	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		03JUN2003	1	5		0	0	0	0	2	0	2	0	0	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0018009	SCREEN		17DEC2002	-20	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		06JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		13JAN2003	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 8	*	14JAN2003	9	9	5	0	0	0	2	4	2	1	0	0	0	0
	E0018010	SCREEN		09JAN2003	-7	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1		16JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		23JAN2003	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15		30JAN2003	15	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 22		06FEB2003	22	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 29		13FEB2003	29	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 36		20FEB2003	36	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 43		26FEB2003	42	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		06MAR2003	50	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		13MAR2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0018015	SCREEN		21JAN2003	-7	4		0	0	1	1	2	0	0	0	0	0	0
		DAY 1		28JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		04FEB2003	8	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 15		13FEB2003	17	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		20FEB2003	24	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		26FEB2003	30	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		06MAR2003	38	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		13MAR2003	45	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		20MAR2003	52	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		27MAR2003	59	1	-3	0	0	0	1	0	0	0	0	0	0	0
	E0020015	SCREEN		18MAR2003	-9	11		0	0	0	2	4	0	0	0	2	3	0
		DAY 1		27MAR2003	1	9		0	0	0	2	4	0	0	0	2	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0020015	DAY 8		03APR2003	8	7	-2	0	0	0	0	2	0	1	0	2	2	0
		DAY 15		10APR2003	15	5	-4	0	1	0	1	2	0	1	0	0	0	0
		DAY 22		16APR2003	21	12	3	1	1	0	2	2	3	1	1	1	0	0
		DAY 29		23APR2003	28	8	-1	1	1	0	2	2	0	1	0	1	0	0
		DAY 36		30APR2003	35	5	-4	1	1	0	0	2	0	0	0	0	1	0
		DAY 43		08MAY2003	43	6	-3	1	1	0	0	2	0	1	0	0	1	0
		DAY 50		15MAY2003	50	4	-5	0	0	0	0	2	0	1	0	0	1	0
		DAY 57		23MAY2003	58	0	-9	0	0	0	0	0	0	0	0	0	0	0
	E0020017	SCREEN		27MAR2003	-7	9		0	0	0	0	2	3	1	0	3	0	0
		DAY 1		03APR2003	1	4		1	1	0	0	2	0	0	0	0	0	0
		DAY 8		10APR2003	8	7	3	1	1	0	0	2	2	1	0	0	0	0
		DAY 15		17APR2003	15	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 22		22APR2003	20	9	5	1	1	1	1	2	0	1	0	2	0	0
		DAY 29		29APR2003	27	7	3	0	0	0	1	4	0	0	0	2	0	0
		DAY 29	*	05MAY2003	33	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 36		12MAY2003	40	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 50		20MAY2003	48	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0020020	SCREEN		07MAY2003	-5	6		1	0	0	0	2	0	0	0	2	1	0
		DAY 1		12MAY2003	1	12		0	0	0	2	3	2	2	0	2	1	0
		DAY 8		19MAY2003	8	9	-3	0	0	0	2	2	0	2	0	2	1	0
		DAY 8	*	23MAY2003	12	5	-7	0	0	0	3	2	0	0	0	0	0	0
	E0020022	SCREEN		09JUN2003	-7	9		0	0	0	3	2	0	2	0	2	0	0
		DAY 1		16JUN2003	1	5		1	0	0	0	2	2	0	0	0	0	0
		DAY 8		23JUN2003	8	4	-1	0	1	0	0	0	2	0	0	1	0	0
		DAY 15		30JUN2003	15	2	-3	0	0	0	2	0	0	0	0	0	0	0
		DAY 22		07JUL2003	22	2	-3	0	0	0	2	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0020022	DAY 29	14JUL2003	29	2	-3	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	21JUL2003	36	2	-3	2	0	0	0	0	0	0	0	0	0	0
		DAY 43	28JUL2003	43	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	04AUG2003	50	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	11AUG2003	57	0	-5	0	0	0	0	0	0	0	0	0	0	0
	E0022001	SCREEN	07OCT2002	-21	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	28OCT2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	04NOV2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	11NOV2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	18NOV2002	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	26NOV2002	30	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	02DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	09DEC2002	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	16DEC2002	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	26DEC2002	60	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022004	SCREEN	17OCT2002	-11	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	28OCT2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	04NOV2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	11NOV2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	19NOV2002	23	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	26NOV2002	30	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	02DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	10DEC2002	44	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	16DEC2002	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	23DEC2002	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022005	SCREEN	17OCT2002	-22	0		0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0022005	DAY 1	08NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	15NOV2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	22NOV2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	29NOV2002	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	06DEC2002	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	13DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	20DEC2002	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	27DEC2002	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	03JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022011	SCREEN	20NOV2002	-9	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	29NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0
	E0022015	SCREEN	29NOV2002	-11	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	10DEC2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	17DEC2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	26DEC2002	17	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	02JAN2003	24	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	09JAN2003	31	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	16JAN2003	38	6	6	0	0	0	2	4	0	0	0	0	0	0
		DAY 43	23JAN2003	45	2	2	0	0	0	2	0	0	0	0	0	0	0
		DAY 50	30JAN2003	52	2	2	0	0	0	2	0	0	0	0	0	0	0
		DAY 57	06FEB2003	59	2	2	0	0	0	2	0	0	0	0	0	0	0
	E0022016	SCREEN	03DEC2002	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	17DEC2002	1	3		0	0	0	0	0	2	1	0	0	0	0
		DAY 8	26DEC2002	10	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	30DEC2002	14	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	06JAN2003	21	2	-1	0	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0022016	DAY 29	13JAN2003	28	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	21JAN2003	36	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	30JAN2003	45	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	06FEB2003	52	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	57	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0022020	SCREEN	05DEC2002	-7	4		0	0	0	0	0	2	0	2	0	0	0
		DAY 1	12DEC2002	1	5		1	0	0	0	0	2	0	0	2	0	0
		DAY 8	19DEC2002	8	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	26DEC2002	15	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	02JAN2003	22	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	10JAN2003	30	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	16JAN2003	36	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	23JAN2003	43	4	-1	0	0	0	0	2	2	0	0	0	0	0
	E0022023	SCREEN	19DEC2002	-6	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	24DEC2002	-1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	02JAN2003	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	09JAN2003	16	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	16JAN2003	23	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	23JAN2003	30	2	2	0	0	0	0	0	0	2	0	0	0	0
		DAY 36	30JAN2003	37	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	06FEB2003	44	5	5	0	0	0	2	2	0	0	0	0	1	0
		DAY 50	13FEB2003	51	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	20FEB2003	58	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022029	SCREEN	05FEB2003	-14	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	19FEB2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	26FEB2003	8	3	-2	0	0	0	1	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0022029	DAY 15	03MAR2003	13	5	0	0	0	0	2	2	0	1	0	0	0	0
		DAY 22	12MAR2003	22	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	18MAR2003	28	2	-3	0	0	0	1	0	0	1	0	0	0	0
		DAY 36	26MAR2003	36	2	-3	0	0	0	1	0	0	1	0	0	0	0
		DAY 43	02APR2003	43	1	-4	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	07APR2003	48	2	-3	0	0	0	1	0	0	1	0	0	0	0
		DAY 57	14APR2003	55	3	-2	0	0	0	2	0	0	1	0	0	0	0
	E0022041	SCREEN	04MAR2003	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	25MAR2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	01APR2003	15	10	10	0	2	1	0	2	4	1	0	0	0	0
		DAY 22	08APR2003	22	5	5	1	0	0	0	0	4	0	0	0	0	0
		DAY 29	15APR2003	29	4	4	0	0	0	0	0	4	0	0	0	0	0
		DAY 36	21APR2003	35	4	4	0	0	0	0	0	4	0	0	0	0	0
		DAY 43	29APR2003	43	2	2	0	0	0	0	0	2	0	0	0	0	0
		DAY 50	06MAY2003	50	5	5	0	0	0	1	2	2	0	0	0	0	0
		DAY 57	13MAY2003	57	3	3	1	0	0	0	0	2	0	0	0	0	0
	E0022042	SCREEN	05MAR2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	12MAR2003	1	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 8	19MAR2003	8	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 15	27MAR2003	16	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	02APR2003	22	1	-1	0	0	0	1	0	0	0	0	0	0	0
		DAY 29	10APR2003	30	4	2	0	1	0	2	0	0	1	0	0	0	0
		DAY 36	17APR2003	37	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 43	24APR2003	44	4	2	0	0	0	2	0	0	1	0	0	1	0
		DAY 50	01MAY2003	51	3	1	0	0	0	2	0	0	0	0	0	1	0
		DAY 57	12MAY2003	62	2	0	0	0	0	2	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0022043	SCREEN		10MAR2003	-10	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		20MAR2003	1	3		0	0	0	0	0	2	1	0	0	0	0
		DAY 8		26MAR2003	7	6	3	0	0	0	1	0	4	1	0	0	0	0
		DAY 15		03APR2003	15	5	2	0	0	0	1	0	2	2	0	0	0	0
		DAY 22		10APR2003	22	2	-1	0	0	0	1	0	0	1	0	0	0	0
		DAY 29		17APR2003	29	6	3	1	0	0	0	0	2	1	0	2	0	0
		DAY 36		24APR2003	36	4	1	0	0	0	1	0	2	1	0	0	0	0
		DAY 43		01MAY2003	43	3	0	0	0	0	2	0	0	1	0	0	0	0
		DAY 50		08MAY2003	50	5	2	0	0	0	1	2	2	0	0	0	0	0
		DAY 50	*	12MAY2003	54	2	-1	0	0	0	0	0	2	0	0	0	0	0
	E0022054	SCREEN		04APR2003	-7	2		0	0	0	0	0	2	0	0	0	0	0
		DAY 1		11APR2003	1	5		0	0	0	0	4	0	1	0	0	0	0
		DAY 8		18APR2003	8	4	-1	0	0	0	0	2	0	2	0	0	0	0
		DAY 15		28APR2003	18	8	3	1	1	1	0	2	2	1	0	0	0	0
		DAY 22		02MAY2003	22	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		12MAY2003	32	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		16MAY2003	36	5	0	1	0	2	0	0	2	0	0	0	0	0
	E0022059	SCREEN		22APR2003	-14	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1		06MAY2003	1	7		1	1	1	0	0	2	1	0	1	0	0
		DAY 8		13MAY2003	8	8	1	1	1	1	0	0	4	1	0	0	0	0
		DAY 15		20MAY2003	15	4	-3	1	1	0	0	0	2	0	0	0	0	0
		DAY 22		27MAY2003	22	9	2	1	1	0	0	2	4	1	0	0	0	0
		DAY 29		03JUN2003	29	6	-1	0	0	0	1	2	2	1	0	0	0	0
		DAY 36		10JUN2003	36	8	1	0	1	0	0	2	4	1	0	0	0	0
		DAY 43		17JUN2003	43	11	4	1	2	0	0	2	4	2	0	0	0	0
		DAY 43	*	20JUN2003	46	8	1	0	0	0	0	2	2	2	0	2	0	0
		DAY 57		08JUL2003	64	6	-1	0	1	0	0	2	2	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0022065	SCREEN	30APR2003	-7	11		0	0	0	2	4	2	0	0	2	1	0
		DAY 1	07MAY2003	1	10		0	0	0	1	4	2	1	0	2	0	0
		DAY 8	14MAY2003	8	9	-1	2	1	0	1	2	0	1	0	2	0	0
		DAY 15	21MAY2003	15	4	-6	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	28MAY2003	22	4	-6	0	0	0	0	2	0	0	0	2	0	0
		DAY 29	04JUN2003	29	6	-4	0	0	0	0	2	2	0	0	2	0	0
		DAY 36	11JUN2003	36	2	-8	0	0	0	0	0	0	0	0	2	0	0
		DAY 43	18JUN2003	43	7	-3	0	0	0	0	2	2	0	0	2	1	0
		DAY 50	25JUN2003	50	4	-6	0	0	0	1	0	0	0	0	2	1	0
		DAY 57	02JUL2003	57	2	-8	0	0	0	0	0	0	0	0	2	0	0
	E0022070	SCREEN	05JUN2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	12JUN2003	1	5		0	0	0	2	0	0	2	0	0	1	0
		DAY 8	18JUN2003	7	4	-1	0	0	0	2	0	0	2	0	0	0	0
	E0023001	SCREEN	24OCT2002	-22	6		0	1	0	0	2	0	1	0	2	0	0
		DAY 1	15NOV2002	1	7		1	1	0	0	2	2	1	0	0	0	0
		DAY 8	22NOV2002	8	28	21	3	3	3	3	4	4	2	2	2	2	0
		DAY 15	29NOV2002	15	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	06DEC2002	22	3	-4	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	16DEC2002	32	4	-3	0	0	0	1	2	0	0	0	0	1	0
		DAY 36	23DEC2002	39	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	30DEC2002	46	2	-5	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	07JAN2003	54	6	-1	0	0	0	2	3	0	1	0	0	0	0
		DAY 57	14JAN2003	61	2	-5	0	0	0	0	2	0	0	0	0	0	0
	E0023009	SCREEN	24JAN2003	-18	1		0	1	0	0	0	0	0	0	0	0	0
		DAY 1	11FEB2003	1	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 8	18FEB2003	8	2	1	0	0	0	0	1	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0023009	DAY 15		27FEB2003	17	1	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 22		04MAR2003	22	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		11MAR2003	29	3	2	1	1	0	0	0	0	1	0	0	0	0
		DAY 36		18MAR2003	36	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		25MAR2003	43	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		03APR2003	52	3	2	1	1	0	0	0	0	1	0	0	0	0
		DAY 57		08APR2003	57	1	0	1	0	0	0	0	0	0	0	0	0	0
	E0023028	SCREEN		16MAY2003	-13	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 1		29MAY2003	1	2		1	1	0	0	0	0	0	0	0	0	0
		DAY 8		05JUN2003	8	18	16	3	3	0	0	2	4	2	3	0	1	0
		DAY 15		12JUN2003	15	19	17	3	3	1	0	2	5	2	3	0	0	0
		DAY 22		19JUN2003	22	16	14	3	2	2	2	1	4	2	0	0	0	0
		DAY 29		25JUN2003	28	10	8	2	3	2	0	0	3	0	0	0	0	0
		DAY 43		09JUL2003	42	15	13	2	3	2	0	0	4	2	1	0	1	0
		DAY 50		16JUL2003	49	9	7	2	2	1	0	0	2	1	1	0	0	0
		DAY 50	*	21JUL2003	54	9	7	2	2	1	0	0	2	1	1	0	0	0
	E0023033	SCREEN		30MAY2003	-6	5		1	1	0	0	0	2	1	0	0	0	0
		DAY 1		05JUN2003	1	4		0	0	0	0	2	2	0	0	0	0	0
		DAY 8		12JUN2003	8	1	-3	0	0	0	0	1	0	0	0	0	0	0
	E0023047	SCREEN		11JUL2003	-7	4		1	1	0	0	2	0	0	0	0	0	0
		DAY 1		18JUL2003	1	1		0	1	0	0	0	0	0	0	0	0	0
		DAY 8		25JUL2003	8	4	3	1	1	0	0	2	0	0	0	0	0	0
		DAY 15		31JUL2003	14	3	2	1	1	0	0	1	0	0	0	0	0	0
		DAY 22		08AUG2003	22	3	2	0	0	0	0	2	0	0	0	1	0	0
		DAY 29		15AUG2003	29	2	1	1	1	0	0	0	0	0	0	0	0	0
		DAY 36		21AUG2003	35	3	2	2	1	0	0	0	0	0	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0023047	DAY 43	29AUG2003	43	6	5	2	2	0	0	2	0	0	0	0	0	0
		DAY 50	05SEP2003	50	13	12	2	1	0	0	2	2	2	3	1	0	0
		DAY 57	12SEP2003	57	11	10	2	1	0	0	2	2	2	2	0	0	0
	E0025001	SCREEN	25MAR2003	-7	9		2	1	0	0	2	2	0	0	2	0	0
		DAY 1	01APR2003	1	8		2	2	0	2	0	2	0	0	0	0	0
		DAY 8	10APR2003	10	7	-1	1	0	0	2	2	0	0	0	2	0	0
		DAY 15	16APR2003	16	6	-2	0	0	0	2	4	0	0	0	0	0	0
		DAY 22	23APR2003	23	8	0	0	0	0	2	4	0	2	0	0	0	0
	E0026012	SCREEN	05FEB2003	-15	5		0	0	0	2	2	1	0	0	0	0	0
		DAY 1	20FEB2003	1	8		0	0	0	2	4	0	0	0	2	0	0
		DAY 8	27FEB2003	8	8	0	0	0	0	2	3	1	1	0	1	0	0
		DAY 15	06MAR2003	15	8	0	0	0	1	2	2	0	0	2	0	1	0
		DAY 22	13MAR2003	22	4	-4	0	0	0	0	2	0	0	2	0	0	0
		DAY 29	20MAR2003	29	7	-1	1	1	1	0	1	1	0	2	0	0	0
		DAY 36	27MAR2003	36	8	0	1	1	2	0	0	2	0	2	0	0	0
		DAY 43	03APR2003	43	6	-2	0	0	0	0	2	1	0	2	0	1	0
		DAY 50	10APR2003	50	3	-5	0	0	0	0	0	0	0	2	0	1	0
		DAY 57	17APR2003	57	4	-4	1	0	2	0	0	1	0	0	0	0	0
	E0026020	SCREEN	28MAR2003	-4	6		0	0	0	2	2	1	0	0	0	1	0
		DAY 1	01APR2003	1	5		0	0	0	2	2	0	0	0	0	1	0
		DAY 8	08APR2003	8	8	3	0	0	0	2	2	2	1	0	0	1	0
		DAY 15	15APR2003	15	10	5	1	0	1	0	2	2	1	2	0	1	0
		DAY 22	22APR2003	22	12	7	0	1	2	0	3	3	2	0	0	1	0
	E0026024	SCREEN	25APR2003	-7	6		0	0	0	2	1	1	1	1	0	0	0
		DAY 1	02MAY2003	1	5		0	0	0	2	1	0	1	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0026024	DAY 8		09MAY2003	8	5	0	0	0	0	2	1	0	1	0	1	0	0
		DAY 15		16MAY2003	15	8	3	0	0	0	2	3	0	1	0	2	0	0
		DAY 22		23MAY2003	22	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 29		30MAY2003	29	4	-1	0	0	0	2	2	0	0	0	0	0	0
	E0026028	SCREEN		06JUN2003	-14	8		0	0	0	2	1	4	1	0	0	0	0
		DAY 1		20JUN2003	1	9		0	0	0	2	1	4	1	0	0	1	0
		DAY 8		27JUN2003	8	12	3	0	0	0	2	3	4	2	1	0	0	0
		DAY 15		02JUL2003	13	10	1	0	1	0	2	3	3	1	0	0	0	0
		DAY 15	*	08JUL2003	19	11	2	0	0	1	2	3	4	1	0	0	0	0
	E0028001	DAY 1		10OCT2002	1	4		0	0	0	0	2	2	0	0	0	0	0
		DAY 8		16OCT2002	7	7	3	0	0	0	0	4	2	0	0	0	1	0
		DAY 15		23OCT2002	14	7	3	0	0	0	2	4	0	0	0	1	0	0
		DAY 22		29OCT2002	20	5	1	0	0	0	2	2	0	1	0	0	0	0
		DAY 29		05NOV2002	27	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		12NOV2002	34	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 43		19NOV2002	41	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 50		26NOV2002	48	6	2	0	0	0	2	4	0	0	0	0	0	0
		DAY 57		03DEC2002	55	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0028003	DAY 1		30SEP2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		07OCT2002	8	8	4	0	0	0	2	2	2	2	0	0	0	0
		DAY 15		16OCT2002	17	3	-1	0	0	0	2	0	0	1	0	0	0	0
		DAY 22		22OCT2002	23	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		29OCT2002	30	7	3	0	0	0	3	4	0	0	0	0	0	0
		DAY 36		07NOV2002	39	7	3	0	0	0	3	4	0	0	0	0	0	0
		DAY 43		12NOV2002	44	7	3	0	0	0	3	4	0	0	0	0	0	0
		DAY 50		19NOV2002	51	8	4	0	0	0	2	4	0	2	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0028003	DAY 57	26NOV2002	58	5	1	0	0	0	2	2	0	1	0	0	0	0
	E0028005	DAY 1	03OCT2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	11OCT2002	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	31OCT2002	29	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0028010	SCREEN	15OCT2002	-21	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 1	05NOV2002	1	5		0	0	0	0	2	0	1	2	0	0	0
		DAY 8	12NOV2002	8	9	4	0	0	0	2	4	0	1	2	0	0	0
		DAY 15	19NOV2002	15	3	-2	0	0	0	0	2	0	1	0	0	0	0
		DAY 22	25NOV2002	21	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	03DEC2002	29	5	0	0	0	0	2	2	0	1	0	0	0	0
		DAY 36	10DEC2002	36	5	0	0	0	0	2	2	0	1	0	0	0	0
		DAY 43	17DEC2002	43	2	-3	0	0	0	2	0	0	0	0	0	0	0
		DAY 50	23DEC2002	49	2	-3	0	0	0	2	0	0	0	0	0	0	0
		DAY 57	31DEC2002	57	2	-3	0	0	0	2	0	0	0	0	0	0	0
	E0028011	SCREEN	25NOV2002	-10	1		0	0	0	1	0	0	0	0	0	0	0
		DAY 1	05DEC2002	1	7		1	0	0	2	0	2	2	0	0	0	0
		DAY 8	12DEC2002	8	6	-1	1	0	0	3	0	0	2	0	0	0	0
		DAY 15	19DEC2002	15	4	-3	0	0	2	1	0	0	1	0	0	0	0
		DAY 22	26DEC2002	22	3	-4	0	0	0	2	0	0	1	0	0	0	0
		DAY 29	02JAN2003	29	2	-5	0	0	0	2	0	0	0	0	0	0	0
		DAY 36	09JAN2003	36	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	16JAN2003	43	1	-6	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	23JAN2003	50	11	4	2	2	2	3	2	0	0	0	0	0	0
		DAY 57	30JAN2003	57	0	-7	0	0	0	0	0	0	0	0	0	0	0
	E0028030	SCREEN	26FEB2003	-6	2		0	0	0	2	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0028030	DAY 1	04MAR2003	1	3		0	0	0	2	0	0	1	0	0	0	0
		DAY 8	11MAR2003	8	6	3	0	0	0	2	2	0	2	0	0	0	0
		DAY 15	18MAR2003	15	1	-2	0	0	0	0	0	0	1	0	0	0	0
		DAY 22	25MAR2003	22	3	0	0	0	0	2	0	0	1	0	0	0	0
		DAY 29	01APR2003	29	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	08APR2003	36	3	0	0	0	0	2	0	0	1	0	0	0	0
		DAY 43	17APR2003	45	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	22APR2003	50	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	30APR2003	58	3	0	1	0	0	0	0	2	0	0	0	0	0
	E0028031	SCREEN	06MAR2003	-5	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	11MAR2003	1	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 8	18MAR2003	8	12	7	2	2	0	0	0	4	2	2	0	0	0
		DAY 15	25MAR2003	15	10	5	0	0	0	2	4	2	2	0	0	0	0
	E0028047	SCREEN	09JUL2003	-5	7		0	0	0	2	2	0	0	0	2	1	0
		DAY 1	14JUL2003	1	3		0	0	0	2	0	0	0	0	0	1	0
		DAY 8	21JUL2003	8	4	1	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	29JUL2003	16	8	5	0	0	0	2	4	0	0	0	2	0	0
		DAY 22	05AUG2003	23	8	5	0	2	0	2	4	0	0	0	0	0	0
		DAY 29	12AUG2003	30	8	5	0	0	0	2	4	0	0	0	2	0	0
		DAY 36	19AUG2003	37	4	1	1	1	0	0	0	2	0	0	0	0	0
		DAY 43	26AUG2003	44	4	1	1	1	0	0	2	0	0	0	0	0	0
		DAY 50	02SEP2003	51	6	3	1	1	0	0	4	0	0	0	0	0	0
		DAY 57	09SEP2003	58	6	3	1	1	0	0	4	0	0	0	0	0	0
	E0029001	DAY 1	01OCT2002	1	7		0	2	0	3	0	0	0	0	0	1	1
		DAY 8	09OCT2002	9	7	0	0	0	0	3	2	0	0	0	0	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0029014	SCREEN	28JAN2003	-7	10		0	1	0	1	2	2	1	0	3	0	0
		DAY 1	04FEB2003	1	4		0	0	1	1	2	0	0	0	0	0	0
		DAY 8	11FEB2003	8	12	8	0	1	0	2	3	3	1	0	2	0	0
		DAY 15	18FEB2003	15	11	7	1	0	0	2	3	2	1	0	2	0	0
		DAY 22	25FEB2003	22	4	0	0	0	0	1	2	0	0	0	1	0	0
		DAY 29	06MAR2003	31	6	2	0	0	0	2	3	0	0	0	0	1	0
		DAY 36	11MAR2003	36	16	12	0	1	0	3	5	0	2	2	2	1	0
		DAY 43	20MAR2003	45	28	24	3	3	2	3	2	4	3	4	3	1	0
		DAY 50	27MAR2003	52	21	17	0	2	0	2	6	4	2	2	2	1	0
		DAY 57	01APR2003	57	15	11	2	1	1	2	3	2	2	2	0	0	0
	E0029023	SCREEN	11MAR2003	-28	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	08APR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	15APR2003	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	22APR2003	15	7	7	1	0	1	0	2	2	1	0	0	0	0
		DAY 22	01MAY2003	24	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	12MAY2003	35	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	20MAY2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	29MAY2003	52	7	7	0	1	0	2	0	2	0	0	0	2	0
	E0029032	SCREEN	22MAY2003	-19	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	10JUN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	17JUN2003	8	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 22	01JUL2003	22	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0029033	SCREEN	27MAY2003	-6	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 1	02JUN2003	1	10		0	1	0	3	4	0	0	0	2	0	0
		DAY 8	09JUN2003	8	16	6	0	3	0	2	4	0	2	0	5	0	0
		DAY 15	16JUN2003	15	8	-2	0	0	0	2	2	0	0	2	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0029033	DAY 22		23JUN2003	22	9	-1	0	0	0	2	4	0	1	0	2	0	0
		DAY 29		30JUN2003	29	16	6	0	0	0	3	5	0	1	2	5	0	0
	E0029039	SCREEN		10JUL2003	-5	8		0	0	0	2	4	0	0	0	2	0	0
		DAY 1		15JUL2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8		23JUL2003	9	4	4	0	0	0	2	2	0	0	0	0	0	0
		DAY 15		28JUL2003	14	4	4	0	0	0	2	2	0	0	0	0	0	0
	E0030003	SCREEN		03DEC2002	-13	6		0	0	0	2	2	0	2	0	0	0	0
		DAY 1		16DEC2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		23DEC2002	8	5	1	0	0	0	2	2	0	1	0	0	0	0
		DAY 8	*	24DEC2002	9	5	1	0	0	0	2	2	0	1	0	0	0	0
	E0030009	SCREEN		10JAN2003	-13	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1		23JAN2003	1	5		0	2	0	0	3	0	0	0	0	0	0
		DAY 8		29JAN2003	7	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 15		07FEB2003	16	5	0	0	1	0	2	2	0	0	0	0	0	0
		DAY 36		27FEB2003	36	4	-1	0	0	0	0	3	0	0	0	0	1	0
		DAY 43		06MAR2003	43	6	1	0	0	0	2	4	0	0	0	0	0	0
		DAY 50		12MAR2003	49	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 57		19MAR2003	56	4	-1	0	0	0	2	2	0	0	0	0	0	0
	E0030016	SCREEN		21FEB2003	-10	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		03MAR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8		10MAR2003	8	4	2	0	0	0	2	0	0	0	2	0	0	0
		DAY 15		17MAR2003	15	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		25MAR2003	23	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		02APR2003	31	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 36		09APR2003	38	1	-1	0	0	0	0	0	1	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0030016	DAY 50	22APR2003	51	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0030021	SCREEN	13MAY2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	20MAY2003	1	5		1	0	0	0	1	0	0	0	1	2	0
		DAY 8	27MAY2003	8	4	-1	0	0	0	0	2	0	0	0	1	1	0
		DAY 15	03JUN2003	15	8	3	1	2	0	0	1	2	2	0	0	0	0
		DAY 22	10JUN2003	22	2	-3	0	0	0	0	0	0	0	0	1	1	0
		DAY 29	17JUN2003	29	6	1	1	1	0	0	2	1	0	0	0	1	0
	E0031001	SCREEN	14NOV2002	-7	12		1	0	1	2	4	0	0	0	4	0	0
		DAY 1	21NOV2002	1	10		0	0	2	2	4	0	0	0	2	0	0
		DAY 8	27NOV2002	7	3	-7	0	0	0	0	2	0	1	0	0	0	0
		DAY 15	05DEC2002	15	4	-6	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	11DEC2002	21	3	-7	0	0	1	0	2	0	0	0	0	0	0
		DAY 29	20DEC2002	30	9	-1	0	0	0	2	4	0	1	0	2	0	0
	E0031017	SCREEN	25MAR2003	-7	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 1	01APR2003	1	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 8	07APR2003	7	8	1	0	0	0	2	2	0	1	0	2	1	0
		DAY 15	15APR2003	15	10	3	0	0	0	2	4	0	1	0	2	1	0
		DAY 22	22APR2003	22	5	-2	0	0	0	2	2	0	1	0	0	0	0
		DAY 29	29APR2003	29	9	2	0	0	0	2	4	0	2	0	0	1	0
	E0031018	SCREEN	01APR2003	-9	8		0	0	0	2	2	4	0	0	0	0	0
		DAY 1	10APR2003	1	7		1	0	1	2	2	0	1	0	0	0	0
		DAY 8	17APR2003	8	8	1	2	0	0	0	0	2	2	0	2	0	0
		DAY 15	24APR2003	15	8	1	1	0	0	0	0	4	1	0	2	0	0
	E0031023	SCREEN	21APR2003	-8	3		0	0	0	2	0	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0031023	DAY 1	29APR2003	1	8		0	0	0	2	4	0	2	0	0	0	0
		DAY 8	07MAY2003	9	9	1	0	0	0	2	4	0	1	0	2	0	0
		DAY 15	13MAY2003	15	7	-1	0	0	0	0	4	0	1	0	2	0	0
		DAY 22	20MAY2003	22	5	-3	0	0	0	0	2	0	1	0	2	0	0
		DAY 29	27MAY2003	29	5	-3	0	0	0	1	2	0	0	0	2	0	0
		DAY 36	04JUN2003	37	6	-2	0	0	0	0	4	0	0	0	2	0	0
		DAY 43	10JUN2003	43	5	-3	0	0	0	0	2	0	1	0	2	0	0
		DAY 50	17JUN2003	50	5	-3	0	0	0	2	2	0	1	0	0	0	0
		DAY 57	24JUN2003	57	5	-3	0	0	0	2	2	0	1	0	0	0	0
	E0033001	SCREEN	19DEC2002	-21	10		1	1	0	3	2	0	2	0	0	1	0
		DAY 1	09JAN2003	1	8		0	0	0	3	2	0	2	0	0	1	0
		DAY 8	16JAN2003	8	7	-1	0	0	0	3	2	0	2	0	0	0	0
		DAY 15	23JAN2003	15	23	15	1	1	1	3	2	4	2	6	2	1	0
		DAY 22	30JAN2003	22	13	5	0	0	0	3	2	0	2	6	0	0	0
	E0033004	SCREEN	08JAN2003	-9	10		1	0	0	3	2	0	2	0	0	1	1
		DAY 1	17JAN2003	1	9		1	0	0	3	2	0	2	0	0	1	0
		DAY 8	24JAN2003	8	9	0	0	1	0	0	4	2	1	0	0	1	0
		DAY 15	31JAN2003	15	14	5	2	2	0	0	4	2	1	0	2	1	0
		DAY 22	07FEB2003	22	5	-4	0	1	0	0	0	0	1	2	0	1	0
		DAY 29	14FEB2003	29	12	3	2	2	0	0	2	2	0	2	2	0	0
		DAY 36	21FEB2003	36	7	-2	1	1	0	2	0	0	1	2	0	0	0
		DAY 43	28FEB2003	43	9	0	2	2	0	0	2	2	1	0	0	0	0
		DAY 50	07MAR2003	50	12	3	0	1	0	3	2	2	1	0	2	1	0
		DAY 57	14MAR2003	57	8	-1	0	0	0	0	4	0	1	0	2	1	0
	E0033010	SCREEN	22JAN2003	-13	6		0	0	0	0	4	0	2	0	0	0	0
		DAY 1	04FEB2003	1	7		0	0	0	1	4	0	2	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0033010	DAY 8	11FEB2003	8	1	-6	0	0	0	0	0	0	1	0	0	0	0
		DAY 15	20FEB2003	17	5	-2	0	0	0	2	2	0	1	0	0	0	0
		DAY 22	27FEB2003	24	4	-3	0	0	0	1	2	0	1	0	0	0	0
		DAY 29	04MAR2003	29	4	-3	0	0	0	1	2	0	1	0	0	0	0
		DAY 36	14MAR2003	39	5	-2	0	0	0	0	2	0	1	0	2	0	0
	E0033014	SCREEN	12MAR2003	-7	8		0	0	0	2	1	1	1	2	1	0	0
		DAY 1	19MAR2003	1	4		0	0	0	2	1	0	0	1	0	0	0
		DAY 8	26MAR2003	8	5	1	1	0	0	1	2	0	0	0	1	0	0
		DAY 15	03APR2003	16	4	0	0	0	0	0	3	0	0	0	1	0	0
		DAY 22	11APR2003	24	8	4	2	1	0	0	1	3	0	1	0	0	0
		DAY 29	16APR2003	29	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	21APR2003	34	5	1	0	0	0	0	3	0	0	1	1	0	0
	E0035002	SCREEN	14NOV2002	-7	8		0	0	0	2	2	0	2	0	2	0	0
		DAY 1	21NOV2002	1	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 8	27NOV2002	7	6	0	0	0	0	2	2	0	0	0	2	0	0
		DAY 15	05DEC2002	15	2	-4	0	0	0	2	0	0	0	0	0	0	0
		DAY 22	12DEC2002	22	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0035007	SCREEN	13DEC2002	-6	5		1	0	0	1	2	0	0	0	0	1	0
		DAY 1	19DEC2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	26DEC2002	8	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	02JAN2003	15	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 22	09JAN2003	22	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29	17JAN2003	30	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 36	23JAN2003	36	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	30JAN2003	43	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	06FEB2003	50	1	-3	0	0	1	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0035007	DAY 57	11FEB2003	55	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0035011	SCREEN	09JAN2003	-26	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	04FEB2003	1	8		0	0	0	2	4	0	0	0	2	0	0
		DAY 8	11FEB2003	8	6	-2	0	0	0	0	2	0	2	0	2	0	0
		DAY 15	18FEB2003	15	4	-4	0	0	0	0	2	0	0	0	2	0	0
		DAY 22	25FEB2003	22	7	-1	0	0	0	1	2	0	2	0	2	0	0
		DAY 29	04MAR2003	29	8	0	1	0	0	1	2	0	2	0	2	0	0
		DAY 36	11MAR2003	36	4	-4	1	0	0	0	2	0	1	0	0	0	0
		DAY 43	18MAR2003	43	7	-1	1	0	0	0	2	0	2	0	2	0	0
		DAY 50	25MAR2003	50	7	-1	0	0	0	1	2	0	2	0	2	0	0
		DAY 57	01APR2003	57	8	0	1	1	0	2	2	0	0	0	2	0	0
	E0035020	SCREEN	11APR2003	-7	7		1	0	0	0	2	0	2	0	2	0	0
		DAY 1	18APR2003	1	7		1	1	0	1	2	0	0	0	2	0	0
		DAY 8	25APR2003	8	6	-1	1	0	0	1	2	0	0	0	2	0	0
		DAY 15	01MAY2003	14	9	2	2	0	0	1	2	0	0	2	2	0	0
		DAY 22	09MAY2003	22	5	-2	0	0	0	1	2	0	0	0	2	0	0
		DAY 29	15MAY2003	28	3	-4	0	0	0	1	2	0	0	0	0	0	0
		DAY 36	23MAY2003	36	5	-2	1	0	0	1	2	0	1	0	0	0	0
		DAY 43	30MAY2003	43	4	-3	1	0	0	1	2	0	0	0	0	0	0
		DAY 50	06JUN2003	50	7	0	1	0	0	1	2	0	1	2	0	0	0
		DAY 57	13JUN2003	57	7	0	2	0	0	1	2	0	0	0	2	0	0
	E0037003	SCREEN	22JAN2003	-8	6		0	0	0	2	2	0	0	0	1	1	0
		DAY 1	30JAN2003	1	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 8	06FEB2003	8	6	0	0	0	0	2	3	0	1	0	0	0	0
		DAY 15	13FEB2003	15	4	-2	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	20FEB2003	22	7	1	0	0	0	2	2	0	1	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0037004	SCREEN	06FEB2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	13FEB2003	1	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 8	21FEB2003	9	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 15	27FEB2003	15	8	5	0	0	0	2	2	1	1	0	2	0	0
		DAY 22	06MAR2003	22	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	13MAR2003	29	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	20MAR2003	36	5	2	0	0	0	2	2	0	0	0	0	1	0
		DAY 43	28MAR2003	44	4	1	0	0	0	2	0	1	1	0	0	0	0
		DAY 50	04APR2003	51	1	-2	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	10APR2003	57	3	0	0	0	0	0	2	0	0	0	0	1	0
	E0039007	SCREEN	25NOV2002	-9	7		0	0	0	2	4	0	0	1	0	0	0
		DAY 1	04DEC2002	1	9		0	0	1	0	4	4	0	0	0	0	0
		DAY 8	11DEC2002	8	5	-4	0	1	0	2	2	0	0	0	0	0	0
		DAY 15	18DEC2002	15	4	-5	0	0	0	2	1	1	0	0	0	0	0
		DAY 22	23DEC2002	20	2	-7	0	0	0	1	1	0	0	0	0	0	0
		DAY 29	30DEC2002	27	6	-3	0	1	0	2	1	1	1	0	0	0	0
		DAY 36	08JAN2003	36	6	-3	0	1	0	1	2	1	1	0	0	0	0
		DAY 43	15JAN2003	43	5	-4	0	1	0	0	2	1	1	0	0	0	0
		DAY 50	22JAN2003	50	0	-9	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	29JAN2003	57	3	-6	0	0	0	1	2	0	0	0	0	0	0
	E0039022	SCREEN	04FEB2003	-21	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	25FEB2003	1	1		0	0	0	0	1	0	0	0	0	0	0
		DAY 8	06MAR2003	10	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	11MAR2003	15	2	1	0	1	0	1	0	0	0	0	0	0	0
		DAY 22	18MAR2003	22	4	3	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	25MAR2003	29	2	1	0	0	0	1	1	0	0	0	0	0	0
		DAY 36	01APR2003	36	3	2	0	0	0	1	2	0	0	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0039022	DAY 43	07APR2003	42	2	1	0	0	0	1	1	0	0	0	0	0	0
		DAY 50	15APR2003	50	1	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	24APR2003	59	7	6	0	0	0	1	4	0	0	0	2	0	0
	E0039023	SCREEN	05FEB2003	-19	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	24FEB2003	1	3		0	0	0	2	1	0	0	0	0	0	0
		DAY 8	03MAR2003	8	4	1	0	0	0	2	2	0	0	0	0	0	0
	E0039030	SCREEN	12MAR2003	-12	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	24MAR2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8	31MAR2003	8	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 15	07APR2003	15	4	1	0	0	0	0	0	2	0	2	0	0	0
		DAY 22	14APR2003	22	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	21APR2003	29	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	28APR2003	36	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	43	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 50	13MAY2003	51	0	-3	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAY2003	57	0	-3	0	0	0	0	0	0	0	0	0	0	0
	E0039031	SCREEN	05MAR2003	-19	5		0	0	1	2	2	0	0	0	0	0	0
		DAY 1	24MAR2003	1	6		0	0	0	1	2	0	0	0	3	0	0
		DAY 8	31MAR2003	8	3	-3	0	0	0	0	3	0	0	0	0	0	0
		DAY 15	07APR2003	15	17	11	2	2	0	2	4	3	2	0	2	0	0
		DAY 22	15APR2003	23	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	21APR2003	29	3	-3	0	0	0	0	2	0	1	0	0	0	0
		DAY 36	28APR2003	36	3	-3	0	0	0	0	3	0	0	0	0	0	0
		DAY 43	05MAY2003	43	12	6	0	1	0	2	3	0	2	2	2	0	0
		DAY 50	13MAY2003	51	5	-1	0	0	0	2	3	0	0	0	0	0	0
		DAY 57	20MAY2003	58	0	-6	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0039037	SCREEN	26MAR2003	-21	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 1	16APR2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8	23APR2003	8	5	-1	0	0	0	2	3	0	0	0	0	0	0
		DAY 15	01MAY2003	16	7	1	0	2	0	1	4	0	0	0	0	0	0
		DAY 22	07MAY2003	22	6	0	0	2	2	0	2	0	0	0	0	0	0
		DAY 29	15MAY2003	30	6	0	0	2	2	0	2	0	0	0	0	0	0
		DAY 36	21MAY2003	36	14	8	2	2	2	1	4	0	1	2	0	0	0
		DAY 43	28MAY2003	43	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 50	05JUN2003	51	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 57	12JUN2003	58	9	3	1	2	0	2	4	0	0	0	0	0	0
	E0039038	SCREEN	26MAR2003	-28	11		0	2	0	2	3	4	0	0	0	0	0
		DAY 1	23APR2003	1	12		1	2	0	1	4	1	1	0	1	1	0
		DAY 8	30APR2003	8	7	-5	0	0	0	2	2	2	1	0	0	0	0
		DAY 22	15MAY2003	23	13	1	0	2	0	2	3	2	2	0	2	0	0
		DAY 29	21MAY2003	29	11	-1	2	1	0	1	2	2	2	0	0	1	0
		DAY 36	29MAY2003	37	3	-9	0	1	0	0	1	0	0	0	0	1	0
	E0039047	SCREEN	12MAY2003	-7	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1	19MAY2003	1	8		0	0	1	2	3	0	2	0	0	0	0
		DAY 8	27MAY2003	9	4	-4	0	0	0	1	3	0	0	0	0	0	0
		DAY 15	03JUN2003	16	8	0	0	1	1	1	2	1	2	0	0	0	0
		DAY 22	09JUN2003	22	12	4	0	0	0	2	3	1	2	0	4	0	0
		DAY 29	16JUN2003	29	10	2	0	0	0	2	4	2	2	0	0	0	0
		DAY 36	23JUN2003	36	3	-5	0	0	0	1	2	0	0	0	0	0	0
		DAY 43	30JUN2003	43	3	-5	0	0	0	1	2	0	0	0	0	0	0
		DAY 50	07JUL2003	50	0	-8	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	14JUL2003	57	4	-4	0	0	0	2	2	0	0	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0039059	SCREEN	03JUL2003	-8	5		0	0	0	1	2	1	1	0	0	0	0
		DAY 1	11JUL2003	1	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 8	18JUL2003	8	8	1	0	1	0	0	3	1	1	0	2	0	0
		DAY 15	25JUL2003	15	5	-2	0	0	0	0	0	2	1	2	0	0	0
		DAY 22	01AUG2003	22	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	07AUG2003	28	1	-6	0	0	0	0	0	0	1	0	0	0	0
		DAY 36	15AUG2003	36	1	-6	0	0	0	0	0	0	1	0	0	0	0
		DAY 43	21AUG2003	42	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	29AUG2003	50	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	05SEP2003	57	3	-4	0	1	0	0	1	1	0	0	0	0	0
	E0041007	SCREEN	05MAR2003	-8	8		0	0	1	2	0	0	2	2	0	0	1
		DAY 1	13MAR2003	1	7		1	1	1	2	0	0	2	0	0	0	0
		DAY 8	20MAR2003	8	10	3	1	1	2	1	2	0	1	0	2	0	0
		DAY 15	27MAR2003	15	11	4	1	1	2	2	0	2	1	2	0	0	0
		DAY 22	03APR2003	22	12	5	0	1	2	2	2	0	1	2	2	0	0
		DAY 29	10APR2003	29	13	6	0	1	2	2	3	0	1	1	2	1	0
		DAY 36	17APR2003	36	12	5	0	1	2	2	3	0	1	0	2	1	0
		DAY 43	25APR2003	44	10	3	1	1	2	2	0	0	2	2	0	0	0
		DAY 50	01MAY2003	50	8	1	0	0	2	2	0	0	2	0	2	0	0
		DAY 57	08MAY2003	57	7	0	0	0	0	2	2	0	1	0	2	0	0
	E0041010	SCREEN	23APR2003	-7	8		0	0	0	2	2	0	2	0	2	0	0
		DAY 1	30APR2003	1	12		1	2	0	2	1	0	2	2	2	0	0
		DAY 8	08MAY2003	9	8	-4	0	1	0	2	2	0	1	0	2	0	0
		DAY 15	14MAY2003	15	11	-1	0	1	0	2	4	0	2	0	2	0	0
		DAY 22	21MAY2003	22	12	0	0	0	0	2	4	0	2	0	4	0	0
		DAY 29	28MAY2003	29	13	1	0	1	0	2	4	0	2	0	4	0	0
		DAY 36	04JUN2003	36	12	0	0	1	0	2	4	0	1	0	4	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR I)	E0041010	DAY 43	11JUN2003	43	30	18	3	3	3	3	6	2	2	2	6	0	0
	E0041011	SCREEN	15MAY2003	-7	10		0	0	0	2	4	0	0	0	2	2	0
		DAY 1	22MAY2003	1	12		0	0	0	2	4	0	2	0	4	0	0
		DAY 8	02JUN2003	12	11	-1	2	1	1	0	2	2	1	0	2	0	0
		DAY 15	06JUN2003	16	6	-6	1	0	0	0	2	0	1	0	2	0	0
		DAY 22	16JUN2003	26	9	-3	0	1	0	0	3	0	2	0	3	0	0
		DAY 29	20JUN2003	30	7	-5	1	0	0	0	2	0	2	0	2	0	0
		DAY 36	26JUN2003	36	9	-3	1	1	0	1	2	0	2	0	2	0	0
		DAY 43	03JUL2003	43	9	-3	1	1	0	0	2	1	2	0	2	0	0
		DAY 50	10JUL2003	50	10	-2	0	0	0	0	3	2	2	0	3	0	0
		DAY 57	17JUL2003	57	13	1	1	1	0	1	4	0	2	0	4	0	0
	E0041012	SCREEN	05JUN2003	-14	11		0	1	0	2	4	0	0	2	2	0	0
		DAY 1	19JUN2003	1	12		0	1	0	2	4	1	0	2	2	0	0
		DAY 8	26JUN2003	8	17	5	1	2	0	2	4	2	2	2	2	0	0
		DAY 15	03JUL2003	15	17	5	0	0	1	1	4	2	2	2	4	1	0
		DAY 22	10JUL2003	22	16	4	0	0	1	1	4	2	2	1	4	1	0
		DAY 29	17JUL2003	29	17	5	1	1	1	2	4	2	2	0	4	0	0
		DAY 36	24JUL2003	36	19	7	1	2	1	2	4	2	1	2	4	0	0
		DAY 43	31JUL2003	43	24	12	2	2	1	2	5	2	2	4	4	0	0
		DAY 50	07AUG2003	50	24	12	2	2	2	2	4	2	2	3	4	0	1
		DAY 57	14AUG2003	57	20	8	1	2	0	2	4	2	2	2	4	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0001004	SCREEN	23APR2003	-8	6		0	0	0	1	4	0	0	0	1	0	0
		DAY 1	01MAY2003	1	7		0	1	0	1	2	0	0	0	2	1	0
		DAY 8	09MAY2003	9	4	-3	1	1	0	1	1	0	0	0	0	0	0
		DAY 15	16MAY2003	16	3	-4	0	1	0	0	1	0	1	0	0	0	0
		DAY 22	23MAY2003	23	3	-4	1	1	0	0	1	0	0	0	0	0	0
		DAY 29	29MAY2003	29	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	06JUN2003	37	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	12JUN2003	43	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	20JUN2003	51	4	-3	0	0	0	0	3	0	0	0	1	0	0
		DAY 57	27JUN2003	58	4	-3	0	0	0	1	1	0	1	0	1	0	0
	E0005023	SCREEN	28JAN2003	-8	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	05FEB2003	1	4		0	0	0	2	1	0	1	0	0	0	0
		DAY 8	13FEB2003	9	1	-3	0	0	0	0	0	0	1	0	0	0	0
		DAY 15	20FEB2003	16	1	-3	0	0	0	0	0	0	1	0	0	0	0
		DAY 22	27FEB2003	23	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	06MAR2003	30	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	13MAR2003	37	1	-3	0	0	0	0	0	0	1	0	0	0	0
		DAY 43	18MAR2003	42	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	26MAR2003	50	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	01APR2003	56	1	-3	0	0	0	0	0	0	1	0	0	0	0
	E0005034	SCREEN	08APR2003	-7	6		0	0	0	0	3	0	1	0	2	0	0
		DAY 1	15APR2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	23APR2003	9	5	3	0	0	0	2	2	0	1	0	0	0	0
		DAY 15	01MAY2003	17	3	1	0	0	0	2	0	0	1	0	0	0	0
		DAY 22	06MAY2003	22	1	-1	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	13MAY2003	29	2	0	0	0	0	2	0	0	0	0	0	0	0
		DAY 36	22MAY2003	38	3	1	0	0	0	2	0	0	1	0	0	0	0

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PLACEBO (BIPOLAR II)	E0005034	DAY 43	28MAY2003	44	2	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 50	05JUN2003	52	3	1	0	0	0	1	2	0	0	0	0	0	0
		DAY 57	09JUN2003	56	4	2	0	0	0	1	2	0	1	0	0	0	0
	E0005041	SCREEN	17JUN2003	-7	2		0	0	0	2	0	0	0	0	0	0	0
		DAY 1	24JUN2003	1	4		0	0	0	1	2	0	1	0	0	0	0
		DAY 8	01JUL2003	8	3	-1	0	0	0	0	2	0	1	0	0	0	0
		DAY 15	08JUL2003	15	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	16JUL2003	23	3	-1	0	0	0	0	2	0	1	0	0	0	0
		DAY 29	22JUL2003	29	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 36	28JUL2003	35	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	04AUG2003	42	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	11AUG2003	49	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	18AUG2003	56	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0007004	SCREEN	24JAN2003	-6	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1	30JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	07FEB2003	9	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	12FEB2003	14	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0007010	SCREEN	11APR2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	18APR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	25APR2003	8	5	1	0	0	0	2	2	0	0	1	0	0	0
		DAY 15	02MAY2003	15	4	0	1	0	0	1	2	0	0	0	0	0	0
		DAY 22	09MAY2003	22	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 29	16MAY2003	29	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 36	23MAY2003	36	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 43	29MAY2003	42	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	06JUN2003	50	1	-3	0	0	0	1	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0007010	DAY 57		16JUN2003	60	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0007012	SCREEN		02MAY2003	-14	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 1		16MAY2003	1	3		0	0	0	1	2	0	0	0	0	0	0
		DAY 8		23MAY2003	8	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 15		29MAY2003	14	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 22		06JUN2003	22	3	0	0	0	0	1	2	0	0	0	0	0	0
		DAY 29		13JUN2003	29	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		20JUN2003	36	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		25JUN2003	41	2	-1	0	0	0	2	0	0	0	0	0	0	0
		DAY 43	*	01JUL2003	47	4	1	0	0	0	2	2	0	0	0	0	0	0
	E0009007	SCREEN		27JAN2003	-7	6		0	0	1	0	2	0	1	0	2	0	0
		DAY 1		03FEB2003	1	10		0	1	0	2	2	0	1	2	2	0	0
		DAY 8		10FEB2003	8	18	8	2	2	1	3	2	2	2	2	2	0	0
		DAY 15		17FEB2003	15	7	-3	0	0	0	2	2	0	1	0	2	0	0
		DAY 22		25FEB2003	23	10	0	0	0	0	2	2	2	2	0	2	0	0
		DAY 29		03MAR2003	29	8	-2	0	0	0	2	2	0	2	0	2	0	0
	E0009008	SCREEN		04FEB2003	-8	4		0	0	0	0	2	2	0	0	0	0	0
		DAY 1		12FEB2003	1	7		0	0	0	2	1	4	0	0	0	0	0
		DAY 8		19FEB2003	8	9	2	1	0	0	0	4	0	1	0	2	1	0
		DAY 15		25FEB2003	14	6	-1	1	0	0	0	2	2	1	0	0	0	0
		DAY 22		04MAR2003	21	0	-7	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		11MAR2003	28	11	4	0	1	0	2	2	0	2	2	2	0	0
		DAY 36		18MAR2003	35	1	-6	0	0	0	0	0	0	0	0	0	0	1
		DAY 43		26MAR2003	43	3	-4	0	0	0	0	2	0	1	0	0	0	0
		DAY 50		03APR2003	51	1	-6	0	0	0	0	0	0	1	0	0	0	0
		DAY 57		08APR2003	56	2	-5	1	0	0	0	0	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0011001	SCREEN	25OCT2002	-7	9		0	0	0	0	2	3	2	0	2	0	0
		DAY 1	01NOV2002	1	7		0	0	0	0	2	0	2	1	2	0	0
		DAY 8	07NOV2002	7	6	-1	0	0	0	0	2	2	1	0	1	0	0
		DAY 15	14NOV2002	14	3	-4	0	0	0	0	2	0	0	0	1	0	0
		DAY 22	21NOV2002	21	5	-2	0	0	0	1	2	0	1	0	0	1	0
		DAY 29	27NOV2002	27	4	-3	0	0	0	0	1	0	1	0	1	1	0
		DAY 36	05DEC2002	35	4	-3	0	0	0	1	1	0	1	0	0	1	0
		DAY 43	12DEC2002	42	1	-6	0	0	0	0	0	0	0	0	1	0	0
		DAY 50	19DEC2002	49	1	-6	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	26DEC2002	56	4	-3	0	0	0	2	2	0	0	0	0	0	0
	E0011011	SCREEN	12FEB2003	-8	5		0	0	0	2	2	0	0	0	0	0	1
		DAY 1	20FEB2003	1	3		0	0	0	2	0	0	0	0	0	0	1
		DAY 8	26FEB2003	7	4	1	1	0	0	0	0	0	0	1	1	0	1
		DAY 15	05MAR2003	14	7	4	0	0	0	1	1	2	1	1	0	0	1
		DAY 22	12MAR2003	21	7	4	0	0	0	2	2	0	0	1	1	0	1
		DAY 29	19MAR2003	28	4	1	0	0	0	2	1	0	0	0	0	0	1
		DAY 36	26MAR2003	35	2	-1	0	0	0	0	0	1	0	0	0	0	1
		DAY 43	02APR2003	42	9	6	0	0	0	1	2	3	1	1	0	0	1
		DAY 50	09APR2003	49	6	3	0	0	0	2	1	0	1	0	1	0	1
		DAY 57	16APR2003	56	5	2	0	0	0	0	0	3	1	1	0	0	0
	E0011013	SCREEN	25MAR2003	-23	5		0	0	0	2	2	0	0	0	0	0	1
		DAY 1	17APR2003	1	4		0	1	0	1	1	0	0	0	1	0	0
		DAY 8	24APR2003	8	4	0	0	0	0	0	2	0	0	0	2	0	0
		DAY 15	01MAY2003	15	4	0	0	0	0	1	1	1	0	0	1	0	0
		DAY 22	08MAY2003	22	3	-1	0	0	0	1	1	0	0	0	1	0	0
		DAY 29	15MAY2003	29	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 36	22MAY2003	36	3	-1	0	0	0	0	1	0	0	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0011013	DAY 43	29MAY2003	43	3	-1	0	0	0	1	1	0	0	0	1	0	0
		DAY 50	05JUN2003	50	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	12JUN2003	57	2	-2	0	0	0	0	1	0	0	0	1	0	0
	E0011014	SCREEN	31MAR2003	-7	5		0	0	0	2	2	0	0	0	0	0	1
		DAY 1	07APR2003	1	7		0	1	0	2	2	0	0	0	1	0	1
		DAY 8	14APR2003	8	1	-6	0	0	0	0	0	0	0	1	0	0	0
	E0011021	SCREEN	15MAY2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	22MAY2003	1	5		0	0	0	2	1	0	1	0	1	0	0
		DAY 8	29MAY2003	8	4	-1	0	1	0	1	1	0	1	0	0	0	0
		DAY 15	05JUN2003	15	5	0	0	1	0	1	1	0	1	0	1	0	0
		DAY 22	12JUN2003	22	3	-2	0	0	0	1	1	0	1	0	0	0	0
		DAY 29	20JUN2003	30	10	5	1	1	0	1	1	2	2	0	2	0	0
		DAY 36	27JUN2003	37	5	0	2	1	0	0	1	0	1	0	0	0	0
		DAY 43	02JUL2003	42	10	5	2	1	0	0	2	2	1	0	2	0	0
		DAY 50	10JUL2003	50	11	6	1	0	0	0	4	2	0	0	4	0	0
		DAY 57	21JUL2003	61	7	2	0	0	0	0	2	2	0	1	2	0	0
	E0013008	SCREEN	19MAR2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	26MAR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	02APR2003	8	4	4	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	09APR2003	15	6	6	0	0	0	2	4	0	0	0	0	0	0
		DAY 22	17APR2003	23	15	15	2	1	0	3	3	3	2	1	0	0	0
		DAY 29	23APR2003	29	6	6	0	0	0	2	4	0	0	0	0	0	0
		DAY 36	30APR2003	36	5	5	0	0	0	2	3	0	0	0	0	0	0
		DAY 43	07MAY2003	43	4	4	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	12MAY2003	48	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAY2003	55	4	4	0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0014001	SCREEN	18FEB2003	-8	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	26FEB2003	1	6		0	0	0	0	6	0	0	0	0	0	0
		DAY 8	05MAR2003	8	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	12MAR2003	15	3	-3	2	1	0	0	0	0	0	0	0	0	0
		DAY 22	19MAR2003	22	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	25MAR2003	28	0	-6	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	35	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0014013	SCREEN	20MAY2003	-7	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	27MAY2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	04JUN2003	9	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	13JUN2003	18	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	18JUN2003	23	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	25JUN2003	30	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	02JUL2003	37	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	10JUL2003	45	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	16JUL2003	51	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	23JUL2003	58	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0014014	SCREEN	03JUN2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	10JUN2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	18JUN2003	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	24JUN2003	15	4	4	0	0	0	0	4	0	0	0	0	0	0
		DAY 22	03JUL2003	24	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	10JUL2003	31	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	18JUL2003	39	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	30JUL2003	51	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	06AUG2003	58	0	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0015004	SCREEN		25NOV2002	-7	7		0	0	0	1	2	2	1	0	0	1	0
		DAY 1		02DEC2002	1	8		0	0	0	2	2	2	1	0	0	1	0
		DAY 8		11DEC2002	10	12	4	1	1	0	2	2	2	1	2	0	1	0
		DAY 15		18DEC2002	17	13	5	1	1	0	3	2	2	1	2	0	1	0
		DAY 22		27DEC2002	26	6	-2	0	0	1	2	2	0	0	0	0	1	0
		DAY 36		06JAN2003	36	11	3	1	0	0	2	2	2	1	2	0	1	0
		DAY 36	*	09JAN2003	39	10	2	1	0	0	2	2	2	1	2	0	0	0
		DAY 43		17JAN2003	47	11	3	1	0	0	2	2	2	1	2	0	1	0
		DAY 57		29JAN2003	59	12	4	1	0	0	2	2	2	1	2	2	0	0
	E0018005	SCREEN		10DEC2002	-10	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		20DEC2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		27DEC2002	8	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 8	*	31DEC2002	12	4	0	0	0	0	0	2	2	0	0	0	0	0
		DAY 22		10JAN2003	22	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		17JAN2003	29	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 36		24JAN2003	36	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		31JAN2003	43	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 50		07FEB2003	50	0	-4	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		14FEB2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0
	E0018012	SCREEN		17JAN2003	-7	8		1	1	1	2	2	0	1	0	0	0	0
		DAY 1		24JAN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		30JAN2003	7	7	3	0	1	2	0	2	2	0	0	0	0	0
		DAY 15		07FEB2003	15	6	2	0	1	0	1	2	2	0	0	0	0	0
		DAY 22		14FEB2003	22	4	0	1	1	0	0	0	2	0	0	0	0	0
		DAY 29		21FEB2003	29	3	-1	0	0	0	1	2	0	0	0	0	0	0
		DAY 36		26FEB2003	34	6	2	0	0	0	1	4	0	1	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0019019	SCREEN	14JAN2003	-9	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	23JAN2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	30JAN2003	8	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 15	06FEB2003	15	6	4	0	0	0	2	2	2	0	0	0	0	0
	E0019033	SCREEN	10MAR2003	-8	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	18MAR2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	27MAR2003	10	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 15	03APR2003	17	5	1	0	0	0	2	2	0	1	0	0	0	0
		DAY 22	10APR2003	24	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 29	14APR2003	28	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 36	22APR2003	36	4	0	0	0	0	1	1	0	2	0	0	0	0
		DAY 43	01MAY2003	45	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 50	08MAY2003	52	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 57	15MAY2003	59	6	2	0	0	0	1	1	3	1	0	0	0	0
	E0019038	SCREEN	10APR2003	-14	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	24APR2003	1	6		0	3	0	2	1	0	0	0	0	0	0
		DAY 8	01MAY2003	8	4	-2	1	0	1	1	1	0	0	0	0	0	0
		DAY 15	07MAY2003	14	4	-2	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	14MAY2003	21	3	-3	0	0	0	1	2	0	0	0	0	0	0
		DAY 29	21MAY2003	28	5	-1	1	1	0	1	2	0	0	0	0	0	0
		DAY 36	28MAY2003	35	3	-3	0	0	0	1	2	0	0	0	0	0	0
		DAY 43	04JUN2003	42	7	1	1	1	0	2	0	2	0	1	0	0	0
		DAY 50	11JUN2003	49	7	1	0	0	0	2	2	0	0	0	3	0	0
		DAY 57	18JUN2003	56	0	-6	0	0	0	0	0	0	0	0	0	0	0
	E0019046	SCREEN	19JUN2003	-7	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	26JUN2003	1	4		0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0019046	DAY 8	03JUL2003	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	10JUL2003	15	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 22	17JUL2003	22	4	0	2	0	0	0	2	0	0	0	0	0	0
		DAY 29	24JUL2003	29	3	-1	0	0	1	1	1	0	0	0	0	0	0
		DAY 36	30JUL2003	35	4	0	1	1	1	0	1	0	0	0	0	0	0
		DAY 50	14AUG2003	50	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	21AUG2003	57	2	-2	0	0	0	0	2	0	0	0	0	0	0
	E0019047	SCREEN	26JUN2003	-12	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	08JUL2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	17JUL2003	10	1	-3	1	0	0	0	0	0	0	0	0	0	0
		DAY 15	24JUL2003	17	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 22	31JUL2003	24	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 29	07AUG2003	31	4	0	2	1	0	1	0	0	0	0	0	0	0
		DAY 36	14AUG2003	38	2	-2	0	1	0	0	0	1	0	0	0	0	0
		DAY 43	21AUG2003	45	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	28AUG2003	52	1	-3	0	0	0	0	1	0	0	0	0	0	0
		DAY 57	04SEP2003	59	2	-2	0	0	0	1	1	0	0	0	0	0	0
	E0019048	SCREEN	03JUL2003	-7	6		0	0	1	2	3	0	0	0	0	0	0
		DAY 1	10JUL2003	1	5		0	0	1	2	2	0	0	0	0	0	0
		DAY 8	17JUL2003	8	5	0	0	0	1	2	2	0	0	0	0	0	0
		DAY 15	22JUL2003	13	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	31JUL2003	22	5	0	0	0	1	2	2	0	0	0	0	0	0
		DAY 29	07AUG2003	29	5	0	0	0	1	2	2	0	0	0	0	0	0
		DAY 36	14AUG2003	36	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 43	21AUG2003	43	7	2	0	1	1	2	2	1	0	0	0	0	0
		DAY 50	28AUG2003	50	4	-1	0	0	0	2	2	0	0	0	0	0	0
		DAY 57	03SEP2003	56	4	-1	0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0022006	SCREEN	21OCT2002	-22	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8	19NOV2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	26NOV2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	03DEC2002	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	10DEC2002	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	17DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	24DEC2002	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	31DEC2002	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022047	SCREEN	21MAR2003	-7	4		0	0	0	0	0	4	0	0	0	0	0
		DAY 1	28MAR2003	1	2		0	0	0	0	0	2	0	0	0	0	0
		DAY 8	04APR2003	8	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	11APR2003	15	7	5	0	0	0	0	2	2	1	2	0	0	0
		DAY 22	17APR2003	21	5	3	1	1	0	0	0	0	1	2	0	0	0
		DAY 29	25APR2003	29	10	8	1	1	0	0	0	2	2	2	2	0	0
		DAY 36	02MAY2003	36	9	7	0	1	0	0	2	2	2	2	0	0	0
		DAY 43	09MAY2003	43	10	8	1	1	1	0	2	2	1	2	0	0	0
		DAY 50	16MAY2003	50	3	1	0	0	0	0	2	0	1	0	0	0	0
		DAY 57	23MAY2003	57	6	4	0	0	0	0	0	4	2	0	0	0	0
	E0022075	SCREEN	25JUN2003	-13	5		0	0	0	1	2	0	0	0	2	0	0
		DAY 1	08JUL2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	15JUL2003	8	6	4	0	0	0	0	2	2	1	0	0	1	0
		DAY 15	22JUL2003	15	4	2	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	29JUL2003	22	15	13	0	1	0	3	4	2	2	0	2	1	0
		DAY 29	05AUG2003	29	7	5	0	0	0	2	2	0	1	0	2	0	0
		DAY 36	12AUG2003	36	10	8	0	0	0	2	4	2	0	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0022075	DAY 43	19AUG2003	43	12	10	0	0	0	3	4	0	1	0	2	2	0
		DAY 50	26AUG2003	50	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	03SEP2003	58	8	6	0	0	0	0	4	0	0	0	2	2	0
	E0023012	SCREEN	31JAN2003	-6	4		1	1	0	0	2	0	0	0	0	0	0
		DAY 1	06FEB2003	1	3		1	1	0	0	0	0	1	0	0	0	0
		DAY 8	17FEB2003	12	6	3	0	0	0	2	2	0	0	0	2	0	0
		DAY 15	20FEB2003	15	7	4	0	1	0	0	4	0	0	0	2	0	0
		DAY 22	28FEB2003	23	1	-2	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	07MAR2003	30	7	4	1	1	0	1	2	2	0	0	0	0	0
		DAY 36	14MAR2003	37	2	-1	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	21MAR2003	44	7	4	0	0	0	0	4	2	1	0	0	0	0
		DAY 50	28MAR2003	51	5	2	0	0	0	0	5	0	0	0	0	0	0
		DAY 57	04APR2003	58	3	0	0	0	0	0	3	0	0	0	0	0	0
	E0023016	SCREEN	15MAY2003	-7	3		1	1	0	0	1	0	0	0	0	0	0
		DAY 1	22MAY2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8	29MAY2003	8	3	1	0	0	0	0	2	1	0	0	0	0	0
		DAY 15	05JUN2003	15	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	12JUN2003	22	0	-2	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	19JUN2003	29	1	-1	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	26JUN2003	36	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 43	01JUL2003	41	4	2	0	0	0	0	3	1	0	0	0	0	0
		DAY 50	14JUL2003	54	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	17JUL2003	57	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0023018	SCREEN	18MAR2003	-9	5		0	0	0	0	2	2	1	0	0	0	0
		DAY 1	27MAR2003	1	5		0	0	0	2	3	0	0	0	0	0	0
		DAY 8	03APR2003	8	16	11	2	2	0	3	3	4	0	2	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0023018	DAY 15		10APR2003	15	9	4	1	2	0	2	2	2	0	0	0	0	0
		DAY 22		16APR2003	21	6	1	0	0	0	2	2	0	0	2	0	0	0
		DAY 29		24APR2003	29	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		02MAY2003	37	2	-3	1	1	0	0	0	0	0	0	0	0	0
		DAY 43		12MAY2003	47	3	-2	0	0	0	1	2	0	0	0	0	0	0
		DAY 50		15MAY2003	50	4	-1	1	0	0	2	1	0	0	0	0	0	0
		DAY 57		22MAY2003	57	8	3	2	0	0	2	2	2	0	0	0	0	0
	E0023036	SCREEN		10JUN2003	-10	3		0	0	0	0	2	0	1	0	0	0	0
		DAY 1		20JUN2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8		26JUN2003	7	7	1	0	0	0	2	5	0	0	0	0	0	0
		DAY 15		02JUL2003	13	9	3	0	0	0	2	5	2	0	0	0	0	0
		DAY 22		09JUL2003	20	3	-3	0	0	0	1	1	1	0	0	0	0	0
		DAY 29		16JUL2003	27	3	-3	0	0	0	1	1	1	0	0	0	0	0
		DAY 29	*	22JUL2003	33	5	-1	0	0	0	2	3	0	0	0	0	0	0
		DAY 36		29JUL2003	40	5	-1	0	0	0	2	3	0	0	0	0	0	0
		DAY 43		05AUG2003	47	6	0	1	1	0	0	2	2	0	0	0	0	0
		DAY 57		13AUG2003	55	7	1	1	1	0	0	2	3	0	0	0	0	0
	E0023046	SCREEN		11JUL2003	-12	4		1	1	0	0	0	2	0	0	0	0	0
		DAY 1		23JUL2003	1	5		0	0	0	0	2	2	1	0	0	0	0
		DAY 8		01AUG2003	10	6	1	0	0	0	2	3	1	0	0	0	0	0
		DAY 15		08AUG2003	17	3	-2	1	1	0	0	0	1	0	0	0	0	0
		DAY 22		14AUG2003	23	2	-3	1	1	0	0	0	0	0	0	0	0	0
		DAY 29		22AUG2003	31	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		28AUG2003	37	0	-5	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		04SEP2003	44	1	-4	1	0	0	0	0	0	0	0	0	0	0
		DAY 50		11SEP2003	51	1	-4	1	0	0	0	0	0	0	0	0	0	0
		DAY 57		16SEP2003	56	3	-2	1	0	0	0	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0026006	SCREEN		31DEC2002	-8	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1		08JAN2003	1	3		0	0	0	0	2	1	0	0	0	0	0
		DAY 8		15JAN2003	8	14	11	3	1	3	0	0	4	1	2	0	0	0
		DAY 15		22JAN2003	15	7	4	0	0	0	1	1	1	0	2	0	2	0
		DAY 22		29JAN2003	22	11	8	1	1	0	0	3	3	1	2	0	0	0
		DAY 29		05FEB2003	29	4	1	1	0	0	0	1	1	0	1	0	0	0
		DAY 36		12FEB2003	36	4	1	1	1	1	0	0	1	0	0	0	0	0
		DAY 43		19FEB2003	43	5	2	1	1	0	0	1	1	0	1	0	0	0
	E0026021	SCREEN		14APR2003	-9	6		0	0	0	0	2	1	1	2	0	0	0
		DAY 1		23APR2003	1	5		0	0	0	0	4	1	0	0	0	0	0
		DAY 8		29APR2003	7	4	-1	0	0	0	2	2	0	0	0	0	0	0
	E0026027	SCREEN		05JUN2003	-14	5		0	0	0	2	2	0	1	0	0	0	0
		DAY 1		19JUN2003	1	9		0	1	0	2	1	3	1	0	0	1	0
	E0029002		*	12NOV2002		25		2	2	2	2	4	2	2	4	4	1	0
	E0029004	SCREEN		13NOV2002	-6	6		0	0	0	0	2	2	0	0	2	0	0
		DAY 1		19NOV2002	1	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 8		26NOV2002	8	11	4	0	1	0	2	3	0	2	0	2	1	0
		DAY 15		04DEC2002	16	11	4	0	0	0	2	2	2	1	0	4	0	0
		DAY 22		12DEC2002	24	5	-2	0	0	0	2	1	0	2	0	0	0	0
		DAY 36		26DEC2002	38	14	7	0	0	0	2	2	2	2	2	4	0	0
		DAY 43		02JAN2003	45	12	5	0	0	0	2	2	2	2	0	4	0	0
		DAY 50		09JAN2003	52	12	5	0	1	0	2	0	2	1	2	4	0	0
		DAY 57		16JAN2003	59	7	0	0	0	0	2	2	0	1	0	2	0	0
	E0029013	SCREEN		27JAN2003	-23	4		0	0	0	0	2	0	2	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0029013	DAY 1		19FEB2003	1	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 8		25FEB2003	7	1	-1	1	0	0	0	0	0	0	0	0	0	0
		DAY 15		04MAR2003	14	9	7	2	0	0	2	2	2	1	0	0	0	0
		DAY 22		13MAR2003	23	3	1	1	0	0	0	2	0	0	0	0	0	0
		DAY 29		20MAR2003	30	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 36		25MAR2003	35	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 43		31MAR2003	41	2	0	0	0	0	0	2	0	0	0	0	0	0
		DAY 50		10APR2003	51	0	-2	0	0	0	0	0	0	0	0	0	0	0
	E0029019	SCREEN		24FEB2003	-7	5		0	0	0	0	2	2	1	0	0	0	0
		DAY 1		03MAR2003	1	1		0	1	0	0	0	0	0	0	0	0	0
		DAY 8		10MAR2003	8	0	-1	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		17MAR2003	15	0	-1	0	0	0	0	0	0	0	0	0	0	0
	E0029024	SCREEN		11MAR2003	-6	4		0	3	0	0	0	0	1	0	0	0	0
		DAY 1		17MAR2003	1	0		0	0	0	0	0	0	0	0	0	0	0
		DAY 8		25MAR2003	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		02APR2003	17	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		09APR2003	24	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		17APR2003	32	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		24APR2003	39	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		05MAY2003	50	1	1	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	*	12MAY2003	57	1	1	1	0	0	0	0	0	0	0	0	0	0
		DAY 57		20MAY2003	65	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0029038	SCREEN		30JUN2003	-7	4		1	0	0	0	0	0	1	2	0	0	0
		DAY 1		07JUL2003	1	8		1	2	0	0	0	2	1	2	0	0	0
	E0031004	SCREEN		12DEC2002	-7	6		0	0	0	1	2	2	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0031004	DAY 1	19DEC2002	1	10		2	1	0	2	2	0	1	0	2	0	0
		DAY 8	27DEC2002	9	5	-5	0	0	0	0	2	0	1	0	2	0	0
		DAY 15	03JAN2003	16	11	1	1	1	0	2	4	0	1	0	2	0	0
		DAY 22	09JAN2003	22	5	-5	0	0	0	2	2	0	1	0	0	0	0
		DAY 29	16JAN2003	29	10	0	0	1	0	2	2	2	1	0	2	0	0
		DAY 36	23JAN2003	36	9	-1	0	0	0	1	4	0	2	0	2	0	0
		DAY 43	30JAN2003	43	8	-2	1	1	0	1	2	0	1	0	2	0	0
		DAY 50	06FEB2003	50	6	-4	0	0	0	1	2	0	1	0	2	0	0
		DAY 57	13FEB2003	57	7	-3	0	0	0	2	2	0	1	0	2	0	0
	E0031013	SCREEN	06MAR2003	-7	10		0	2	0	1	2	2	1	0	2	0	0
		DAY 1	13MAR2003	1	9		0	0	1	2	2	2	2	0	0	0	0
		DAY 8	20MAR2003	8	10	1	0	0	0	2	4	0	2	0	2	0	0
		DAY 15	27MAR2003	15	17	8	0	1	0	2	4	4	2	0	4	0	0
		DAY 22	04APR2003	23	15	6	0	2	2	1	4	2	2	0	2	0	0
		DAY 29	11APR2003	30	15	6	0	0	0	1	4	4	2	0	4	0	0
		DAY 36	17APR2003	36	13	4	1	0	0	0	4	4	2	0	2	0	0
		DAY 43	24APR2003	43	5	-4	0	0	0	1	2	0	0	0	2	0	0
		DAY 50	01MAY2003	50	15	6	0	0	0	1	4	4	2	0	4	0	0
		DAY 57	08MAY2003	57	12	3	0	1	0	1	4	2	2	0	2	0	0
	E0031016	SCREEN	17MAR2003	-7	4		0	0	0	2	0	0	0	0	2	0	0
		DAY 1	24MAR2003	1	7		0	0	0	2	2	0	1	0	2	0	0
		DAY 8	31MAR2003	8	21	14	3	3	0	3	2	2	2	4	2	0	0
		DAY 15	07APR2003	15	3	-4	0	0	0	2	0	0	1	0	0	0	0
		DAY 22	14APR2003	22	4	-3	0	0	0	2	2	0	0	0	0	0	0
	E0031019	SCREEN	03APR2003	-8	6		1	0	0	2	0	2	1	0	0	0	0
		DAY 1	11APR2003	1	3		0	0	0	2	0	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0031019	DAY 8		18APR2003	8	9	6	0	0	0	2	4	0	0	0	2	1	0
		DAY 15		25APR2003	15	10	7	0	0	0	2	4	2	0	0	2	0	0
		DAY 22		02MAY2003	22	6	3	0	0	0	2	2	2	0	0	0	0	0
		DAY 29		09MAY2003	29	4	1	0	0	0	2	0	0	0	0	2	0	0
		DAY 29	*	12MAY2003	32	2	-1	0	0	0	2	0	0	0	0	0	0	0
	E0031022	SCREEN		21APR2003	-7	9		0	0	0	2	2	0	2	0	2	1	0
		DAY 1		28APR2003	1	10		0	0	0	2	2	2	2	0	2	0	0
		DAY 8		06MAY2003	9	10	0	0	0	0	1	4	2	1	0	2	0	0
		DAY 15		13MAY2003	16	9	-1	0	0	0	2	2	2	1	0	2	0	0
		DAY 22		20MAY2003	23	11	1	0	0	0	2	4	2	1	0	2	0	0
		DAY 29		27MAY2003	30	12	2	0	0	0	2	4	2	2	0	2	0	0
	E0033007	SCREEN		13JAN2003	-15	5		1	0	0	2	1	0	0	0	0	1	0
		DAY 1		28JAN2003	1	6		0	0	0	2	1	0	0	0	1	2	0
		DAY 8		04FEB2003	8	2	-4	0	0	0	0	1	0	0	0	0	1	0
		DAY 15		12FEB2003	16	6	0	1	0	0	2	0	1	0	1	0	1	0
		DAY 22		20FEB2003	24	11	5	2	2	2	0	0	3	0	0	0	2	0
		DAY 29		25FEB2003	29	6	0	0	0	0	1	1	0	0	1	1	2	0
		DAY 36		04MAR2003	36	6	0	0	0	0	2	2	0	1	0	0	1	0
		DAY 43		13MAR2003	45	9	3	1	1	0	2	2	1	0	0	1	1	0
		DAY 50		18MAR2003	50	9	3	1	1	0	2	2	1	1	0	0	1	0
		DAY 57		25MAR2003	57	8	2	0	0	0	2	2	1	1	0	1	1	0
	E0033013	SCREEN		06FEB2003	-13	11		2	0	0	1	4	2	0	0	1	1	0
		DAY 1		19FEB2003	1	11		1	1	0	1	3	1	1	0	2	1	0
		DAY 8		26FEB2003	8	7	-4	0	1	0	2	2	0	2	0	0	0	0
		DAY 15		05MAR2003	15	9	-2	1	0	0	2	3	2	1	0	0	0	0
		DAY 22		13MAR2003	23	11	0	0	0	0	2	2	1	2	1	2	1	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0033013	DAY 29		19MAR2003	29	6	-5	1	0	0	2	1	0	1	0	0	1	0
		DAY 36		27MAR2003	37	8	-3	1	0	0	2	2	0	1	1	0	1	0
		DAY 43		01APR2003	42	10	-1	2	0	0	2	4	0	1	0	0	1	0
		DAY 50		10APR2003	51	2	-9	0	0	0	0	0	0	1	0	0	1	0
		DAY 57		16APR2003	57	6	-5	0	0	0	1	1	1	0	1	1	1	0
	E0033016	SCREEN		14APR2003	-24	10		1	2	0	0	2	2	1	0	2	0	0
		DAY 1		08MAY2003	1	9		1	0	0	2	2	0	2	0	2	0	0
		DAY 8		13MAY2003	6	11	2	0	1	0	2	2	2	2	0	2	0	0
		DAY 15		20MAY2003	13	7	-2	1	0	0	2	2	0	0	0	2	0	0
		DAY 22		28MAY2003	21	6	-3	0	0	0	1	2	2	1	0	0	0	0
		DAY 29		09JUN2003	33	6	-3	0	1	0	0	2	2	1	0	0	0	0
		DAY 43		17JUN2003	41	7	-2	2	1	0	2	1	0	0	1	0	0	0
		DAY 43	*	23JUN2003	47	5	-4	2	0	0	1	1	0	1	0	0	0	0
		DAY 50		27JUN2003	51	2	-7	0	0	0	1	0	0	1	0	0	0	0
		DAY 57		02JUL2003	56	4	-5	0	0	0	1	2	0	1	0	0	0	0
	E0033022	SCREEN		25JUN2003	-19	3		0	0	0	0	2	0	1	0	0	0	0
		DAY 1		14JUL2003	1	8		1	1	0	0	4	0	2	0	0	0	0
		DAY 8		23JUL2003	10	10	2	1	1	1	2	2	2	1	0	0	0	0
		DAY 15		30JUL2003	17	8	0	1	1	1	0	2	2	1	0	0	0	0
		DAY 22		06AUG2003	24	8	0	1	1	0	0	2	2	1	0	0	1	0
		DAY 29		11AUG2003	29	6	-2	0	0	0	0	2	2	1	0	0	1	0
		DAY 36		18AUG2003	36	5	-3	0	0	0	0	4	0	1	0	0	0	0
		DAY 43		26AUG2003	44	12	4	2	2	1	1	2	2	2	0	0	0	0
		DAY 50		04SEP2003	53	12	4	2	1	0	2	4	2	1	0	0	0	0
		DAY 57		11SEP2003	60	7	-1	2	1	0	0	2	2	0	0	0	0	0
	E0034007	SCREEN		06MAY2003	-10	4		0	0	0	0	4	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0034007	DAY 1		16MAY2003	1	6		0	0	0	2	4	0	0	0	0	0	0
		DAY 8		24MAY2003	9	6	0	0	0	0	2	4	0	0	0	0	0	0
		DAY 15		02JUN2003	18	6	0	0	0	0	2	4	0	0	0	0	0	0
		DAY 22		09JUN2003	25	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 29		16JUN2003	32	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 36		20JUN2003	36	4	-2	0	0	0	0	4	0	0	0	0	0	0
		DAY 43		30JUN2003	46	6	0	0	0	0	0	6	0	0	0	0	0	0
		DAY 50		07JUL2003	53	7	1	0	0	0	0	6	0	0	0	0	1	0
		DAY 57		14JUL2003	60	6	0	0	0	0	0	6	0	0	0	0	0	0
	E0035004	SCREEN		22NOV2002	-5	3		0	0	0	2	0	0	1	0	0	0	0
		DAY 1		27NOV2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		04DEC2002	8	1	-3	0	0	0	1	0	0	0	0	0	0	0
	E0035009	SCREEN		20DEC2002	-7	5		0	0	0	1	2	0	0	0	2	0	0
		DAY 1		27DEC2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8		31DEC2002	5	5	1	0	1	0	2	2	0	0	0	0	0	0
		DAY 15		08JAN2003	13	1	-3	0	0	0	1	0	0	0	0	0	0	0
		DAY 22		15JAN2003	20	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 29		22JAN2003	27	2	-2	1	1	0	0	0	0	0	0	0	0	0
		DAY 36		29JAN2003	34	3	-1	1	1	0	0	1	0	0	0	0	0	0
		DAY 43		05FEB2003	41	2	-2	1	1	0	0	0	0	0	0	0	0	0
		DAY 43	*	11FEB2003	47	2	-2	1	1	0	0	0	0	0	0	0	0	0
		DAY 57		19FEB2003	55	4	0	0	1	1	0	2	0	0	0	0	0	0
	E0035010	SCREEN		06JAN2003	-4	10		3	3	0	2	0	2	0	0	0	0	0
		DAY 1		10JAN2003	1	6		0	0	0	2	2	0	0	0	2	0	0
		DAY 8		17JAN2003	8	5	-1	1	0	0	0	2	0	0	0	2	0	0
		DAY 15		24JAN2003	15	8	2	2	1	0	1	2	0	0	0	2	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0035010	DAY 22	31JAN2003	22	9	3	2	0	0	1	2	2	0	0	2	0	0
		DAY 29	07FEB2003	29	8	2	1	0	0	0	4	0	1	0	2	0	0
		DAY 36	14FEB2003	36	8	2	2	0	0	0	2	0	2	0	2	0	0
		DAY 43	24FEB2003	46	9	3	2	0	0	1	2	2	0	0	2	0	0
		DAY 50	28FEB2003	50	5	-1	0	0	0	1	2	0	0	0	2	0	0
		DAY 57	06MAR2003	56	6	0	1	0	0	0	2	0	1	0	2	0	0
	E0035022	SCREEN	01MAY2003	-8	7		0	0	0	0	2	0	1	0	2	2	0
		DAY 1	09MAY2003	1	8		1	0	0	2	2	0	1	0	2	0	0
		DAY 8	15MAY2003	7	8	0	0	0	0	2	2	0	2	0	2	0	0
		DAY 15	23MAY2003	15	10	2	1	1	1	2	2	0	1	0	2	0	0
		DAY 22	30MAY2003	22	7	-1	1	0	0	2	2	0	0	0	2	0	0
		DAY 29	06JUN2003	29	12	4	1	1	1	2	2	0	1	2	2	0	0
		DAY 36	13JUN2003	36	4	-4	1	0	0	1	2	0	0	0	0	0	0
		DAY 43	20JUN2003	43	7	-1	2	1	0	0	2	0	0	0	2	0	0
		DAY 50	27JUN2003	50	9	1	2	1	0	0	2	2	0	0	2	0	0
		DAY 57	07JUL2003	60	11	3	2	1	2	0	2	2	0	0	2	0	0
	E0039003	SCREEN	06NOV2002	-19	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 1	25NOV2002	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	02DEC2002	8	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	09DEC2002	15	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0040001	SCREEN	18JUN2003	-9	5		0	1	0	0	2	2	0	0	0	0	0
		DAY 1	27JUN2003	1	4		0	0	0	2	2	0	0	0	0	0	0
		DAY 8	03JUL2003	7	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 15	11JUL2003	15	4	0	0	0	0	2	2	0	0	0	0	0	0
		DAY 22	18JUL2003	22	2	-2	0	0	0	2	0	0	0	0	0	0	0
		DAY 29	25JUL2003	29	4	0	0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
PLACEBO (BIPOLAR II)	E0040001	DAY 36	01AUG2003	36	6	2	0	0	0	2	4	0	0	0	0	0	0
		DAY 43	08AUG2003	43	7	3	0	1	0	2	4	0	0	0	0	0	0
		DAY 50	15AUG2003	50	2	-2	0	0	0	0	2	0	0	0	0	0	0
		DAY 57	22AUG2003	57	4	0	0	0	0	2	2	0	0	0	0	0	0
	E0040004	SCREEN	11JUL2003	-7	2		0	0	0	0	2	0	0	0	0	0	0
		DAY 1	18JUL2003	1	4		0	0	0	2	2	0	0	0	0	0	0
	E0041002	SCREEN	13JAN2003	-8	12		0	2	0	0	2	2	2	2	2	0	0
		DAY 1	21JAN2003	1	9		0	2	0	0	2	2	1	0	2	0	0
		DAY 8	28JAN2003	8	6	-3	0	1	0	0	2	0	1	0	2	0	0
		DAY 15	04FEB2003	15	9	0	1	1	0	0	2	2	1	2	0	0	0
		DAY 22	11FEB2003	22	15	6	1	2	2	1	2	2	1	2	2	0	0
		DAY 29	18FEB2003	29	13	4	1	2	0	1	2	2	1	2	2	0	0
		DAY 36	25FEB2003	36	12	3	1	1	0	0	2	2	0	2	4	0	0
	E0041005	SCREEN	24FEB2003	-9	9		0	1	0	1	2	0	1	2	2	0	0
		DAY 1	05MAR2003	1	10		0	1	0	2	4	0	1	0	2	0	0
		DAY 8	11MAR2003	7	18	8	2	2	0	2	2	4	2	2	2	0	0
		DAY 15	19MAR2003	15	8	-2	0	0	0	1	2	2	2	0	0	1	0
		DAY 22	26MAR2003	22	12	2	0	1	0	2	4	0	1	2	2	0	0
		DAY 29	02APR2003	29	15	5	2	1	0	2	2	2	0	4	2	0	0
		DAY 36	09APR2003	36	13	3	2	1	0	2	2	1	1	2	2	0	0
		DAY 43	16APR2003	43	28	18	3	3	2	3	4	3	2	4	4	0	0
		DAY 50	23APR2003	50	17	7	1	2	0	3	4	0	1	2	4	0	0
		DAY 57	30APR2003	57	14	4	1	2	0	2	4	0	1	2	2	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0001003	*	06MAR2003		9		1	1	0	0	4	0	1	0	2	0	0
		*	13MAR2003		20		3	4	0	3	3	3	2	0	2	0	0
	E0002005	*	14JAN2003		2		0	0	0	0	2	0	0	0	0	0	0
	E0002013	*	21MAY2003		3		1	0	0	0	2	0	0	0	0	0	0
	E0002014	*	04JUN2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0002017	*	14JUL2003		2		0	0	0	0	2	0	0	0	0	0	0
	E0003001	*	21OCT2002		6		0	0	0	2	2	0	2	0	0	0	0
	E0003003	*	18NOV2002		7		0	0	0	2	3	0	1	0	1	0	0
	E0003006	*	17DEC2002		6		0	0	0	2	2	0	0	0	2	0	0
	E0003012	*	28JAN2003		9		0	0	0	1	3	0	0	1	4	0	0
	E0003014	*	18FEB2003		7		0	0	0	2	3	0	1	0	1	0	0
	E0003017	*	05MAY2003		4		0	0	0	1	2	0	1	0	0	0	0
	E0003021	*	27JUN2003		8		0	0	0	0	4	0	2	0	2	0	0
	E0004008	*	05DEC2002		4		0	0	0	0	2	0	2	0	0	0	0
	E0004010	*	19DEC2002		6		0	0	0	2	2	0	2	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0004011	*	02JAN2003		11		1	1	2	3	2	0	2	0	0	0	0
	E0004014	*	04FEB2003		7		0	0	0	2	3	0	1	1	0	0	0
	E0004017	*	13FEB2003		4		0	0	0	0	2	0	2	0	0	0	0
	E0004022	*	19MAY2003		8		0	0	2	1	3	1	0	0	1	0	0
	E0004023	*	20MAY2003		6		0	1	0	2	2	0	1	0	0	0	0
	E0005015	*	25NOV2002		15		3	0	0	0	4	2	2	2	2	0	0
	E0005018	*	23DEC2002		21		2	3	0	4	2	4	2	2	2	0	0
	E0005021	*	16JAN2003		3		0	0	0	2	1	0	0	0	0	0	0
	E0005028	*	05MAR2003		7		0	0	0	2	2	0	2	0	0	1	0
	E0005032	*	31MAR2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0007002	*	11DEC2002		4		0	0	0	2	2	0	0	0	0	0	0
	E0007014	*	11JUN2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0010001	*	14NOV2002		5		0	0	0	2	2	0	1	0	0	0	0
	E0010003	*	02DEC2002		10		0	1	0	2	2	3	1	0	0	0	1

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0010007	*	10DEC2002		7		0	0	0	2	2	1	2	0	0	0	0
	E0010011	*	26DEC2002		3		0	0	0	2	0	0	0	0	1	0	0
	E0010022	*	09APR2003		6		0	0	0	2	2	0	2	0	0	0	0
	E0010025	*	20MAY2003		8		0	0	0	0	3	0	2	0	2	1	0
	E0010030	*	24JUN2003		6		0	0	0	2	0	2	2	0	0	0	0
	E0010031	*	03JUL2003		12		0	3	0	2	2	1	1	2	1	0	0
	E0010033	*	09JUL2003		5		0	0	0	2	2	0	0	0	0	1	0
	E0011003	*	26NOV2002		4		0	1	0	2	0	0	0	0	0	0	1
	E0011005	*	10DEC2002		2		0	1	0	1	0	0	0	0	0	0	0
	E0011017	*	21APR2003		6		0	0	0	2	3	0	1	0	0	0	0
	E0013004	*	21NOV2002		0		0	0	0	0	0	0	0	0	0	0	0
	E0014003	*	26FEB2003		4		0	0	0	2	2	0	0	0	0	0	0
		*	07MAR2003		5		0	0	0	1	4	0	0	0	0	0	0
	E0014008	*	26MAR2003		5		0	0	0	0	4	0	0	0	0	1	0
	E0015009	*	12FEB2003		6		1	0	1	0	2	2	0	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0015010	*	21FEB2003		5		0	0	0	1	0	2	0	0	2	0	0
	E0016002	*	02JAN2003		10		1	0	0	0	2	2	1	2	2	0	0
	E0018004	*	26NOV2002		7		0	2	0	2	2	0	1	0	0	0	0
	E0018008	*	17DEC2002		4		0	0	0	2	2	0	0	0	0	0	0
	E0018011	*	13JAN2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0018016	*	21JAN2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0018018	*	28JAN2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0019001	*	24OCT2002		9		0	0	3	3	1	0	0	2	0	0	0
	E0019023	*	23JAN2003		2		0	0	0	0	2	0	0	0	0	0	0
	E0020003	*	17OCT2002		11		2	2	0	2	2	2	0	1	0	0	0
	E0020005	*	21NOV2002		5		0	0	0	2	2	0	0	0	0	1	0
	E0020008	*	06JAN2003		11		0	0	0	1	4	0	2	0	4	0	0
	E0020009	*	07JAN2003		12		0	1	0	2	2	3	2	0	2	0	0
	E0020012	*	19FEB2003		7		0	0	1	0	3	0	0	0	2	1	0

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SCREEN FAILURE (BIPOLAR I)	E0020016		* 17MAR2003		7		0	0	0	0	3	0	2	0	2	0	0
	E0020018		* 08APR2003		5		0	0	0	2	2	0	1	0	0	0	0
	E0022002		* 08OCT2002		2		0	0	0	0	2	0	0	0	0	0	0
	E0022009		* 12NOV2002		0		0	0	0	0	0	0	0	0	0	0	0
			* 26NOV2002		13		1	1	2	2	2	2	1	2	0	0	0
	E0022013		* 26NOV2002		0		0	0	0	0	0	0	0	0	0	0	0
	E0022014		* 03DEC2002		0		0	0	0	0	0	0	0	0	0	0	0
	E0022021		* 09DEC2002		3		0	0	0	0	0	0	1	0	2	0	0
	E0022026		* 15JAN2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0022028		* 28JAN2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0022037		* 18FEB2003		9		0	0	0	2	4	0	1	0	2	0	0
	E0022040		* 04MAR2003		6		0	3	0	0	0	2	1	0	0	0	0
	E0022049		* 25MAR2003		3		0	0	0	1	2	0	0	0	0	0	0
	E0022050		* 25MAR2003		3		0	0	0	0	2	0	1	0	0	0	0
	E0022055		* 08APR2003		0		0	0	0	0	0	0	0	0	0	0	0

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SCREEN FAILURE (BIPOLAR I)	E0022057		* 10APR2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0022066		* 02MAY2003		4		0	0	0	0	0	0	2	2	0	0	0
	E0022067		* 12MAY2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0022072		* 18JUN2003		8		0	0	0	0	2	4	0	0	2	0	0
	E0022074		* 24JUN2003		4		0	0	0	0	0	2	2	0	0	0	0
	E0023005		* 09DEC2002		1		0	0	0	0	0	0	1	0	0	0	0
	E0023024		* 28APR2003		7		0	0	0	2	4	0	0	0	0	1	0
	E0023026		* 05MAY2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0025003		* 28APR2003		12		0	2	0	2	2	4	2	0	0	0	0
	E0026011		* 21JAN2003		3		0	0	0	2	0	0	0	0	0	1	0
	E0026026		* 23MAY2003		9		2	1	0	1	3	1	0	1	0	0	0
	E0027001		* 20NOV2002		11		0	1	0	2	4	0	2	0	2	0	0
			* 26NOV2002		5		2	1	0	0	2	0	0	0	0	0	0
	E0027002		* 17DEC2002		11		0	0	0	1	4	1	2	0	2	1	0
	E0027009		* 23JAN2003		5		0	0	0	0	2	0	1	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SCREEN FAILURE (BIPOLAR I)	E0027010	*	31JAN2003		8		0	0	0	2	2	2	1	0	0	1	0
	E0027012	*	19MAR2003		3		0	0	0	2	0	0	0	0	0	1	0
	E0027014	*	05MAR2003		6		0	1	0	3	2	0	0	0	0	0	0
	E0027015	*	10MAR2003		5		0	0	0	1	4	0	0	0	0	0	0
	E0028013	*	29OCT2002		2		0	0	0	2	0	0	0	0	0	0	0
	E0028014	*	29OCT2002		3		0	0	0	2	0	0	0	0	0	1	0
	E0028018	*	14NOV2002		2		0	0	0	2	0	0	0	0	0	0	0
	E0028020	*	19NOV2002		3		0	0	0	2	0	0	0	0	0	1	0
	E0028021	*	25NOV2002		1		0	0	0	1	0	0	0	0	0	0	0
		*	05DEC2002		9		0	0	0	2	4	2	1	0	0	0	0
	E0028022	*	12DEC2002		0		0	0	0	0	0	0	0	0	0	0	0
	E0028024	*	08JAN2003		2		0	0	0	2	0	0	0	0	0	0	0
	E0028026	*	09JAN2003		2		0	0	0	2	0	0	0	0	0	0	0
	E0028036	*	15APR2003		2		0	0	0	2	0	0	0	0	0	0	0
	E0028040	*	02MAY2003		1		0	0	0	1	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0028042	*	13MAY2003		2		0	0	0	2	0	0	0	0	0	0	0
	E0029006	*	21NOV2002		2		0	0	0	2	0	0	0	0	0	0	0
	E0029007	*	03DEC2002		6		0	0	0	2	3	0	0	0	0	1	0
	E0029010	*	14JAN2003		3		0	0	0	0	2	0	0	0	0	1	0
	E0029022	*	11MAR2003		8		0	0	0	0	0	0	2	2	2	2	0
	E0029027	*	10APR2003		6		0	0	0	0	6	0	0	0	0	0	0
	E0029029	*	05MAY2003		4		1	0	0	0	2	0	0	0	0	0	1
	E0029034	*	16JUN2003		3		0	0	0	1	2	0	0	0	0	0	0
	E0030002	*	13NOV2002		4		0	0	0	0	4	0	0	0	0	0	0
	E0030004	*	03DEC2002		6		0	2	0	0	2	0	2	0	0	0	0
		*	30DEC2002		24		2	1	3	3	4	4	2	2	2	1	0
	E0030010	*	14JAN2003		11		2	2	0	0	0	4	2	0	0	1	0
	E0030012	*	27JAN2003		3		0	0	0	0	2	0	0	0	0	1	0
	E0030013	*	04FEB2003		4		1	0	0	0	0	2	0	0	0	0	1
	E0030018	*	05MAR2003		4		0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
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OTHER: 0=ABSENT/NORMAL, 1=MILD, 2=MODERTE, 3=SEVERE, 4=EXTREME.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0030023	*	16JUN2003		3		0	1	0	0	2	0	0	0	0	0	0
	E0031007	*	04FEB2003		6		0	1	0	0	2	0	2	0	0	1	0
	E0031012	*	21FEB2003		8		1	1	0	2	2	2	0	0	0	0	0
		*	28FEB2003		18		1	3	0	2	4	0	2	0	6	0	0
	E0031014	*	07MAR2003		8		0	0	0	0	4	0	2	0	2	0	0
		*	13MAR2003		9		0	0	0	2	2	2	1	0	2	0	0
	E0031025	*	27MAY2003		7		0	0	0	1	4	0	0	0	2	0	0
	E0031026	*	27MAY2003		11		0	0	1	2	4	0	2	0	2	0	0
		*	06JUN2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0033017	*	29APR2003		10		1	2	0	2	2	2	1	0	0	0	0
	E0033020	*	10JUN2003		8		1	1	0	0	2	0	2	0	2	0	0
	E0035008	*	16DEC2002		5		0	0	0	1	2	0	0	0	2	0	0
	E0035012	*	10JAN2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0035017	*	28MAR2003		7		0	0	0	2	2	0	0	0	2	1	0
	E0035018	*	04APR2003		7		1	0	0	2	2	0	0	0	2	0	0
	E0035019	*	10APR2003		7		0	0	0	2	2	0	1	0	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0035025	*	16JUN2003		7		0	0	0	2	2	0	1	0	2	0	0
	E0036003	*	18JUN2003		6		0	0	0	1	3	0	0	0	1	1	0
	E0036004	*	19JUN2003		6		0	0	0	0	4	0	1	0	1	0	0
	E0037001	*	13NOV2002		5		0	0	0	2	2	0	0	0	0	1	0
	E0037008	*	11APR2003		10		0	0	0	2	2	2	1	0	2	1	0
	E0037010	*	06JUN2003		6		0	0	0	2	2	2	0	0	0	0	0
	E0039002	*	06NOV2002		3		0	0	0	1	2	0	0	0	0	0	0
	E0039005	*	08NOV2002		4		0	0	0	2	2	0	0	0	0	0	0
	E0039008	*	06DEC2002		4		0	0	0	2	2	0	0	0	0	0	0
	E0039009	*	10DEC2002		3		0	0	1	2	0	0	0	0	0	0	0
	E0039010	*	16DEC2002		4		0	0	0	2	2	0	0	0	0	0	0
	E0039013	*	17DEC2002		5		0	0	0	2	1	1	1	0	0	0	0
	E0039014	*	26DEC2002		3		0	0	0	2	0	1	0	0	0	0	0
	E0039016	*	10FEB2003		4		0	0	0	2	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0039017	*	08JAN2003		2		0	0	0	2	0	0	0	0	0	0	0
	E0039020	*	23JAN2003		6		0	0	0	2	2	2	0	0	0	0	0
	E0039021	*	30JAN2003		6		0	0	1	2	3	0	0	0	0	0	0
	E0039027	*	27FEB2003		6		0	0	0	2	4	0	0	0	0	0	0
	E0039029	*	03MAR2003		5		0	0	0	2	3	0	0	0	0	0	0
	E0039033	*	12MAR2003		5		0	0	0	2	3	0	0	0	0	0	0
	E0039035	*	18MAR2003		8		0	1	1	2	2	2	0	0	0	0	0
	E0039036	*	25MAR2003		7		0	0	0	2	2	2	1	0	0	0	0
	E0039039	*	31MAR2003		5		0	1	0	2	2	0	0	0	0	0	0
	E0039045	*	05MAY2003		11		1	0	1	2	3	0	1	0	3	0	0
	E0039048	*	13MAY2003		7		0	0	0	2	3	2	0	0	0	0	0
	E0039049	*	14MAY2003		6		0	0	0	2	3	0	0	0	1	0	0
	E0039054	*	24JUN2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0039055	*	26JUN2003		7		0	0	0	2	2	2	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR I)	E0039058	*	02JUL2003		5		0	0	0	2	2	0	1	0	0	0	0
	E0039060	*	08JUL2003		4		0	0	1	2	1	0	0	0	0	0	0
	E0041006	*	25FEB2003		8		0	0	0	0	2	0	2	0	4	0	0

999

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR II)	E0001001	*	13JAN2003		2		0	0	0	2	0	0	0	0	0	0	0
	E0001005	*	04JUN2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0005020	*	07JAN2003		5		0	0	0	2	2	0	1	0	0	0	0
	E0005029	*	18MAR2003		3		0	0	0	1	1	0	1	0	0	0	0
	E0006009	*	16DEC2002		16		0	1	0	2	3	3	2	2	2	1	0
	E0007007	*	04APR2003		3		0	0	0	2	1	0	0	0	0	0	0
	E0007011	*	23APR2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0009003	*	31OCT2002		8		0	2	0	0	2	3	0	0	1	0	0
	E0009013	*	24JUN2003		4		0	2	0	0	0	0	0	0	0	1	1
	E0010006	*	05DEC2002		12		0	2	0	1	4	3	2	0	0	0	0
	E0010026	*	21MAY2003		12		0	2	0	2	2	3	2	0	1	0	0
	E0011012	*	24FEB2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0011015	*	01APR2003		6		0	0	0	2	3	0	1	0	0	0	0
	E0011019	*	30APR2003		5		0	0	0	2	2	0	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR II)	E0011023	*	03JUN2003		3		1	1	0	0	0	0	0	1	0	0	0
	E0011026	*	27JUN2003		3		0	0	0	1	2	0	0	0	0	0	0
	E0013002	*	31OCT2002		2		0	0	0	0	2	0	0	0	0	0	0
	E0013011	*	26FEB2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0013015	*	09JUL2003		1		0	0	0	0	1	0	0	0	0	0	0
	E0015006	*	11DEC2002		8		0	0	0	2	2	2	1	0	0	1	0
	E0015007	*	11DEC2002		9		0	0	0	2	2	2	1	2	0	0	0
	E0017001	*	06MAY2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0019006	*	06NOV2002		1		0	0	0	0	1	0	0	0	0	0	0
	E0019013	*	09DEC2002		2		0	0	0	0	2	0	0	0	0	0	0
		*	19DEC2002		2		0	0	0	0	2	0	0	0	0	0	0
	E0019017	*	14JAN2003		3		0	0	0	0	2	0	0	0	0	1	0
	E0019029	*	25FEB2003		5		0	0	2	2	1	0	0	0	0	0	0
		*	04MAR2003		5		0	0	1	2	2	0	0	0	0	0	0
	E0019030	*	06MAR2003		4		0	0	0	2	2	0	0	0	0	0	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR II)	E0019044	*	12JUN2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0019050	*	10JUL2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0020002	*	16OCT2002		11		0	1	0	1	2	0	1	1	4	1	0
	E0020019	*	06MAY2003		8		1	1	0	2	2	1	0	0	1	0	0
	E0022003	*	11OCT2002		0		0	0	0	0	0	0	0	0	0	0	0
	E0022024	*	20DEC2002		0		0	0	0	0	0	0	0	0	0	0	0
	E0022045	*	13MAR2003		7		0	0	0	2	4	0	0	0	0	1	0
	E0023004	*	19NOV2002		2		1	1	0	0	0	0	0	0	0	0	0
	E0023032	*	22MAY2003		3		0	0	0	0	1	2	0	0	0	0	0
	E0023035	*	06JUN2003		3		0	0	0	0	2	0	1	0	0	0	0
	E0023042	*	07JUL2003		6		1	1	0	0	4	0	0	0	0	0	0
	E0023048	*	11JUL2003		2		0	0	0	0	2	0	0	0	0	0	0
	E0026008	*	06JAN2003		6		1	1	0	0	0	2	1	0	0	0	1
	E0026016	*	25FEB2003		7		0	0	0	2	4	0	0	0	0	1	0

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Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR II)	E0027007	*	02JAN2003		6		0	0	0	1	2	0	1	0	0	2	0
	E0027011	*	10FEB2003		2		0	0	0	0	2	0	0	0	0	0	0
	E0027013	*	13MAR2003		1		0	0	0	0	1	0	0	0	0	0	0
	E0028012	*	22OCT2002		3		0	0	0	2	0	0	0	0	0	1	0
	E0028015	*	05NOV2002		2		0	0	0	2	0	0	0	0	0	0	0
	E0029017	*	18FEB2003		6		0	0	1	2	2	0	1	0	0	0	0
	E0029025	*	18MAR2003		4		0	0	0	0	4	0	0	0	0	0	0
	E0029031	*	19MAY2003		6		0	0	0	1	3	0	0	0	2	0	0
	E0029035	*	17JUN2003		4		0	0	0	1	2	0	0	0	1	0	0
	E0030005	*	05DEC2002		2		0	0	0	0	0	0	2	0	0	0	0
	E0030017	*	24FEB2003		4		0	0	0	2	2	0	0	0	0	0	0
	E0030019	*	16APR2003		2		0	0	0	0	2	0	0	0	0	0	0
	E0031009	*	12FEB2003		9		0	0	0	2	4	0	1	0	2	0	0
	E0031024	*	23MAY2003		8		0	0	0	2	2	2	2	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
OTHER: 0=ABSENT/NORMAL, 1=MILD, 2=MODERTE, 3=SEVERE, 4=EXTREME.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE (BIPOLAR II)	E0031028	*	28MAY2003		9		0	0	0	2	4	0	1	0	2	0	0
	E0033003	*	08JAN2003		10		1	2	0	0	2	2	1	0	2	0	0
	E0033005	*	09JAN2003		10		0	0	0	0	0	2	2	3	2	1	0
	E0033008	*	17JAN2003		12		0	2	0	2	2	3	2	0	0	1	0
	E0033011	*	03FEB2003		4		0	0	0	1	1	0	0	2	0	0	0
	E0033018	*	19MAY2003		11		0	1	1	2	2	4	1	0	0	0	0
	E0033019	*	22MAY2003		12		1	1	0	2	2	3	1	0	1	1	0
	E0034005	*	15APR2003		3		0	0	0	2	0	0	0	0	0	1	0
	E0034010	*	08JUL2003		6		0	0	0	0	4	0	0	0	0	2	0
	E0037011	*	12JUN2003		6		0	0	0	2	2	1	0	0	0	1	0
	E0039001	*	29OCT2002		5		0	0	0	3	2	0	0	0	0	0	0
	E0039004	*	06NOV2002		3		0	0	0	1	2	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE ( )	E0004004	*	17OCT2002		12		0	0	2	0	2	0	2	6	0	0	0
	E0004005	*	23OCT2002		12		0	0	0	0	2	0	2	8	0	0	0
	E0004007	*	26NOV2002		10		1	1	0	0	2	2	2	0	2	0	0
	E0004019	*	25MAR2003		10		0	0	0	2	4	1	0	0	3	0	0
	E0004020	*	15APR2003		8		0	2	0	0	2	2	1	0	1	0	0
	E0005016	*	26NOV2002		19		0	3	0	4	4	2	2	2	2	0	0
	E0005040	*	03JUN2003		19		2	3	1	3	2	2	2	2	2	0	0
	E0006013	*	21JAN2003		18		0	3	0	2	4	3	3	0	2	1	0
	E0018014	*	20JAN2003		3		0	1	0	0	2	0	0	0	0	0	0
	E0019010	*	12NOV2002		2		0	0	0	0	2	0	0	0	0	0	0
	E0026022	*	09APR2003		5		0	0	0	0	2	2	1	0	0	0	0
	E0029016	*	13FEB2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0029028	*	05MAY2003		0		0	0	0	0	0	0	0	0	0	0	0
	E0030007	*	02JAN2003		5		1	0	0	0	2	0	2	0	0	0	0
	E0036001	*	09JUN2003		2		0	0	0	2	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.4 Young Mania Rating Scale (YMRS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.**	6.**	7.	8.**	9.**	10.	11.
SCREEN FAILURE ( )	E0039040	*	04APR2003		6		1	0	0	2	0	0	0	0	0	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
IF BASELINE IS MISSING, SCREENING VISIT CLOSEST TO DAY 1 IS USED AS BASELINE.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Elevated Mood, 2=Inc. Motor Activity-Energy, 3=Sexual Interest, 4=Sleep, 5=Irritability, 6=Speech-rate/amount, 7=Language/thought disorder, 8=Content, 9=Disruptive behavior, 10=Appearance, 11=Insight.
** 0=ABSENT/NORMAL, 2=MILD, 4=MODERATE, 6=SEVERE, 8=EXTREME.
OTHER: 0=ABSENT/NORMAL, 1=MILD, 2=MODERTE, 3=SEVERE, 4=EXTREME.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/YMRS100.SAS
GENERATED: 12JUL2005 17:47:24 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1		04FEB2003	1	21		2	2	1	2	1	2	2	1	1	0	1	3	2	1
		DAY 8		12FEB2003	9	12	-9	2	1	0	0	0	2	1	1	1	0	1	1	2	0
		DAY 15		19FEB2003	16	8	-13	0	0	0	0	0	2	1	2	0	0	1	1	1	0
		DAY 22		26FEB2003	23	7	-14	0	1	0	0	0	1	1	1	0	0	1	1	1	0
		DAY 29		05MAR2003	30	8	-13	1	0	0	1	0	1	2	1	0	0	1	1	0	0
		DAY 36		11MAR2003	36	6	-15	1	2	0	0	0	0	1	0	0	0	1	0	1	0
		DAY 43		18MAR2003	43	6	-15	1	1	0	0	0	1	1	0	0	0	1	0	1	0
		DAY 50		25MAR2003	50	8	-13	1	1	0	0	0	1	1	1	0	0	1	1	1	0
		DAY 57		02APR2003	58	7	-14	1	1	0	0	0	1	1	1	0	0	1	0	1	0
	E0002010	DAY 1		04APR2003	1	16		2	2	0	2	2	2	1	1	1	0	1	1	1	0
		DAY 8		10APR2003	7	17	1	2	2	0	2	2	2	1	1	1	0	1	1	2	0
	E0002012	DAY 1		21APR2003	1	11		2	2	0	2	2	2	0	0	0	0	0	0	1	0
		DAY 8		29APR2003	9	14	3	2	2	0	2	1	2	2	1	0	0	1	0	1	0
		DAY 15		06MAY2003	16	12	1	2	2	0	2	1	1	1	1	1	0	0	0	1	0
		DAY 22		15MAY2003	25	7	-4	1	1	0	1	1	1	0	1	0	0	0	0	1	0
		DAY 29		21MAY2003	31	8	-3	2	1	0	0	1	1	1	1	0	0	0	0	1	0
		DAY 36		28MAY2003	38	4	-7	1	1	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 43		04JUN2003	45	2	-9	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		11JUN2003	52	4	-7	1	1	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 57		16JUN2003	57	3	-8	1	1	0	0	0	0	0	0	0	0	0	0	1	0
	E0002015	DAY 1		04JUN2003	1	11		2	1	0	1	2	1	1	1	0	0	1	0	0	1
	E0002018	DAY 1		24JUL2003	1	10		1	1	1	1	1	1	2	1	0	0	0	0	0	1
		DAY 8	*	30JUL2003	7	8	-2	1	1	0	1	1	1	1	1	0	0	0	0	0	1
		DAY 8		01AUG2003	9	8	-2	1	1	0	1	1	1	1	1	0	0	0	0	0	1
	E0003004	DAY 1		17DEC2002	1	25		3	2	0	3	4	3	3	0	0	1	1	1	3	1

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Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	DAY 1	23DEC2002	1	15		2	4	0	1	1	2	3	0	0	0	0	0	1	1
		DAY 8	30DEC2002	8	15	0	2	1	0	0	1	3	4	1	0	1	1	0	0	1
		DAY 15	06JAN2003	15	17	2	1	3	0	0	3	4	4	0	0	0	1	0	1	0
		DAY 22	14JAN2003	23	13	-2	1	1	0	1	2	1	4	0	1	1	0	0	0	1
		DAY 29	21JAN2003	30	12	-3	1	2	0	0	1	2	4	1	0	0	1	0	0	0
		DAY 36	28JAN2003	37	21	6	4	2	0	0	2	2	4	1	0	1	2	0	2	1
		DAY 43	04FEB2003	44	17	2	4	1	0	1	2	4	3	0	0	0	1	0	1	0
		DAY 50	11FEB2003	51	16	1	3	2	0	1	2	0	3	0	1	0	1	0	2	1
		DAY 57	18FEB2003	58	20	5	2	3	0	4	2	1	4	0	0	1	1	0	1	1
	E0003007	DAY 1	02JAN2003	1	15		2	2	0	2	2	3	0	0	0	0	2	0	1	1
		DAY 8	09JAN2003	8	13	-2	1	2	0	3	0	1	2	0	1	0	1	0	2	0
		DAY 15	16JAN2003	15	15	0	1	2	1	0	1	2	2	0	2	0	1	0	2	1
		DAY 22	23JAN2003	22	22	7	3	3	0	1	0	1	3	1	2	0	3	0	4	1
		DAY 29	30JAN2003	29	14	-1	3	2	0	0	2	2	2	0	0	0	0	0	2	1
		DAY 36	07FEB2003	37	9	-6	1	0	0	1	0	1	2	0	0	0	2	0	2	0
		DAY 43	13FEB2003	43	3	-12	1	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 50	20FEB2003	50	6	-9	0	0	0	3	0	0	1	0	0	0	1	0	1	0
		DAY 57	27FEB2003	57	7	-8	1	1	0	0	0	1	1	0	1	0	1	1	0	0
	E0003015	DAY 1	05MAY2003	1	11		1	1	0	2	0	2	1	0	1	1	1	1	0	0
		DAY 8	13MAY2003	9	9	-2	2	1	0	1	1	2	2	0	0	0	0	0	0	0
		DAY 15	19MAY2003	15	9	-2	2	1	0	0	1	1	2	0	0	0	1	0	0	1
		DAY 22	27MAY2003	23	3	-8	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	04JUN2003	31	16	5	1	2	1	1	1	1	3	2	0	0	2	0	1	1
		DAY 36	10JUN2003	37	0	-11	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	17JUN2003	44	6	-5	2	2	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 50	24JUN2003	51	7	-4	1	1	1	0	0	1	0	0	1	1	1	0	0	0
		DAY 57	02JUL2003	59	26	15	3	3	1	1	3	0	3	2	2	2	2	0	2	2

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	DAY 1	01OCT2002	1	30		3	2	3	0	3	3	3	3	2	1	1	3	2	1
		DAY 8	10OCT2002	10	20	-10	3	1	1	0	2	2	2	0	2	1	1	3	1	1
		DAY 15	17OCT2002	17	12	-18	2	1	1	0	1	1	0	0	1	1	0	3	1	0
		DAY 22	22OCT2002	22	8	-22	1	1	1	0	1	1	0	0	0	0	0	3	0	0
		DAY 29	29OCT2002	29	9	-21	1	1	1	0	1	1	0	0	0	0	0	3	1	0
		DAY 36	05NOV2002	36	12	-18	1	2	0	0	1	1	1	0	1	0	0	3	1	1
		DAY 43	12NOV2002	43	17	-13	1	2	2	0	1	1	2	2	0	2	1	3	0	0
		DAY 50	19NOV2002	50	6	-24	1	1	1	0	1	1	0	0	0	0	0	0	1	0
		DAY 57	26NOV2002	57	9	-21	2	2	0	1	0	1	0	0	2	1	0	0	0	0
	E0004013	DAY 1	14JAN2003	1	26		3	2	2	3	2	3	0	1	3	2	1	2	1	1
		DAY 8	21JAN2003	8	16	-10	3	2	2	1	1	2	0	0	2	0	1	1	1	0
		DAY 15	30JAN2003	17	13	-13	2	2	2	2	2	2	0	0	0	0	0	0	0	1
		DAY 22	05FEB2003	23	20	-6	2	2	2	0	1	2	0	2	2	2	0	2	2	1
	E0004018	DAY 1	19MAR2003	1	15		2	2	0	2	2	2	2	0	1	0	1	0	0	1
		DAY 8	26MAR2003	8	9	-6	2	1	0	1	2	2	0	0	0	0	0	0	0	1
		DAY 15	02APR2003	15	11	-4	2	2	0	1	2	2	0	0	0	0	1	0	0	1
		DAY 22	09APR2003	22	10	-5	2	1	0	2	2	2	0	0	0	0	0	0	1	0
		DAY 29	16APR2003	29	6	-9	2	1	0	2	0	1	0	0	0	0	0	0	0	0
		DAY 36	23APR2003	36	5	-10	1	1	0	2	0	1	0	0	0	0	0	0	0	0
		DAY 43	30APR2003	43	2	-13	0	0	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 50	06MAY2003	49	2	-13	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	13MAY2003	56	4	-11	1	0	0	2	0	1	0	0	0	0	0	0	0	0
	E0004021	DAY 1	14MAY2003	1	16		2	2	0	1	2	3	1	0	0	1	0	1	2	1
		DAY 8	21MAY2003	8	10	-6	2	2	0	1	1	1	1	0	0	0	0	0	2	0
		DAY 15	28MAY2003	15	10	-6	2	1	0	0	1	2	0	0	0	0	1	1	1	1
		DAY 22	04JUN2003	22	5	-11	1	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 29	11JUN2003	29	5	-11	1	1	0	1	1	1	0	0	0	0	0	0	0	0

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Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	DAY 36		18JUN2003	36	4	-12	0	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 43		25JUN2003	43	4	-12	1	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 50		02JUL2003	50	4	-12	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 57		09JUL2003	57	2	-14	1	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0005002	DAY 1		03OCT2002	1	26		3	2	0	3	3	3	0	2	0	0	2	3	2	3
		DAY 8		08OCT2002	6	23	-3	2	2	0	3	3	3	0	2	0	0	2	3	1	2
		DAY 8	*	14OCT2002	12	11	-15	0	1	0	1	0	1	0	0	1	1	2	2	2	0
		DAY 15		21OCT2002	19	12	-14	2	1	0	2	2	1	0	0	0	0	2	0	1	1
		DAY 22		28OCT2002	26	7	-19	1	1	0	3	0	0	0	0	0	0	2	0	0	0
		DAY 29		04NOV2002	33	7	-19	1	0	0	2	0	1	0	0	0	0	2	0	1	0
		DAY 43		13NOV2002	42	10	-16	1	1	0	2	1	1	0	1	0	0	2	0	0	1
		DAY 43	*	18NOV2002	47	3	-23	0	0	0	1	0	0	0	0	0	0	2	0	0	0
		DAY 50		25NOV2002	54	5	-21	0	0	0	2	0	0	0	0	0	0	2	1	0	0
	E0005004	DAY 1		01OCT2002	1	27		3	3	0	4	3	3	2	0	1	1	0	3	1	3
		DAY 8		10OCT2002	10	13	-14	2	2	0	0	2	2	0	0	0	0	0	3	1	1
		DAY 15		15OCT2002	15	12	-15	1	2	0	1	1	1	0	2	1	0	0	2	1	0
	E0005013	DAY 1		07NOV2002	1	25		3	3	0	3	2	3	2	0	0	1	2	1	2	3
	E0005024	DAY 1		10FEB2003	1	23		2	2	1	3	3	3	1	0	1	1	2	0	2	2
		DAY 8		18FEB2003	9	6	-17	1	1	0	0	1	1	0	0	0	0	1	0	1	0
		DAY 15		26FEB2003	17	2	-21	0	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 22		06MAR2003	25	1	-22	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 29		13MAR2003	32	1	-22	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 36		20MAR2003	39	1	-22	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43		25MAR2003	44	1	-22	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50		02APR2003	52	8	-15	2	1	0	0	1	0	1	0	0	0	2	0	0	1
		DAY 57		09APR2003	59	1	-22	0	0	0	0	1	0	0	0	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	DAY 1	11MAR2003	1	25		3	3	0	2	3	3	2	0	2	2	2	0	1	2
		DAY 8	19MAR2003	9	25	0	3	3	0	0	3	3	2	1	0	2	2	2	2	2
		DAY 15	26MAR2003	16	24	-1	3	3	0	0	3	3	2	1	0	2	2	2	1	2
		DAY 22	03APR2003	24	20	-5	2	2	0	1	2	3	1	1	0	1	2	2	1	2
	E0005037	DAY 1	07MAY2003	1	25		2	3	1	3	3	3	2	0	0	0	1	3	2	2
		DAY 8	15MAY2003	9	22	-3	2	3	1	0	3	3	1	0	1	0	2	3	1	2
		DAY 15	22MAY2003	16	21	-4	2	2	0	2	2	3	0	1	0	0	2	3	2	2
		DAY 22	27MAY2003	21	23	-2	2	2	1	3	3	3	0	0	0	0	2	3	2	2
		DAY 29	05JUN2003	30	19	-6	2	2	1	2	2	2	0	0	0	0	2	3	1	2
		DAY 36	12JUN2003	37	18	-7	2	1	0	1	2	2	2	0	0	0	2	3	1	2
		DAY 57	02JUL2003	57	20	-5	2	2	1	2	2	3	0	0	0	0	2	3	1	2
	E0005042	DAY 1	24JUN2003	1	24		2	2	1	2	3	3	2	1	1	1	0	3	1	2
		DAY 8	02JUL2003	9	13	-11	1	1	1	0	2	1	1	0	1	1	0	1	2	1
		DAY 15	09JUL2003	16	9	-15	1	2	1	0	1	1	0	0	0	1	0	1	1	0
		DAY 22	16JUL2003	23	9	-15	1	1	1	0	1	1	0	1	1	0	0	1	1	0
		DAY 29	23JUL2003	30	6	-18	1	1	0	0	1	1	0	0	0	0	0	2	0	0
		DAY 36	30JUL2003	37	7	-17	1	1	0	0	2	1	0	0	0	0	0	1	1	0
		DAY 43	06AUG2003	44	6	-18	2	1	0	0	1	0	0	0	0	0	0	1	0	1
		DAY 50	12AUG2003	50	4	-20	1	1	0	0	1	0	0	0	0	0	0	1	0	0
		DAY 57	18AUG2003	56	3	-21	0	1	0	0	1	0	0	0	0	0	0	1	0	0
	E0006005	DAY 1	05DEC2002	1	21		3	2	0	4	1	3	0	1	1	1	1	0	2	2
		DAY 8	12DEC2002	8	14	-7	1	2	1	1	2	2	1	0	1	1	0	0	1	1
		DAY 15	20DEC2002	16	18	-3	2	3	0	3	1	3	1	1	1	1	1	0	0	1
		DAY 22	30DEC2002	26	21	0	3	2	2	2	1	2	1	1	1	1	1	1	2	1
		DAY 29	03JAN2003	30	17	-4	3	2	2	0	1	3	0	1	1	1	1	0	1	1
		DAY 36	09JAN2003	36	15	-6	3	2	0	2	1	2	1	0	0	1	1	0	0	2
		DAY 43	16JAN2003	43	16	-5	2	2	0	2	2	2	0	0	0	1	1	0	2	2

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 50	23JAN2003	50	16	-5	3	2	0	2	2	2	0	0	0	1	2	0	1	1
		DAY 57	30JAN2003	57	16	-5	2	2	0	3	1	2	1	0	0	1	1	0	2	1
	E0006018	DAY 1	13MAR2003	1	13		1	2	0	1	3	3	0	1	0	0	0	1	0	1
		DAY 8	24MAR2003	12	12	-1	1	1	0	1	1	2	1	1	1	0	0	0	1	2
	E0007013	DAY 1	13JUN2003	1	13		1	2	0	2	2	2	0	0	0	0	1	1	1	1
		DAY 8	20JUN2003	8	13	0	1	2	0	2	1	2	0	0	0	0	1	1	2	1
		DAY 15	26JUN2003	14	12	-1	1	1	0	2	1	2	0	0	0	0	2	1	2	0
		DAY 22	03JUL2003	21	11	-2	2	2	0	2	1	2	0	0	0	0	1	1	0	0
		DAY 29	10JUL2003	28	9	-4	1	1	0	2	1	1	0	0	0	0	2	1	0	0
		DAY 36	17JUL2003	35	13	0	1	1	0	1	1	1	1	0	0	0	2	2	2	1
		DAY 43	24JUL2003	42	11	-2	1	1	0	1	1	1	0	1	0	0	2	1	2	0
		DAY 50	01AUG2003	50	7	-6	0	1	0	2	0	1	0	0	0	0	2	1	0	0
		DAY 57	07AUG2003	56	9	-4	1	1	0	1	1	1	0	0	0	0	2	1	1	0
	E0010004	DAY 1	11DEC2002	1	26		2	3	1	3	2	3	1	2	1	0	2	3	2	1
		DAY 8	18DEC2002	8	21	-5	2	2	1	1	3	2	1	1	1	1	1	2	2	1
		DAY 15	26DEC2002	16	21	-5	2	3	1	1	3	2	1	1	1	0	1	2	2	1
		DAY 22	02JAN2003	23	19	-7	2	3	1	1	3	2	1	1	1	0	0	2	2	0
		DAY 36	13JAN2003	34	17	-9	2	2	1	1	1	1	0	1	1	0	1	3	2	1
		DAY 43	21JAN2003	42	15	-11	2	2	1	1	1	1	0	0	0	0	0	3	3	1
		DAY 50	31JAN2003	52	22	-4	2	2	1	0	2	2	1	1	1	1	2	3	3	1
		DAY 57	06FEB2003	58	14	-12	1	1	1	0	1	1	1	1	0	0	0	3	3	1
	E0010012	DAY 1	07JAN2003	1	24		3	3	0	3	3	3	1	0	1	2	0	3	1	1
		DAY 8	14JAN2003	8	20	-4	3	3	0	2	2	2	0	1	1	1	0	3	1	1
		DAY 15	21JAN2003	15	13	-11	2	2	0	0	1	1	0	1	1	0	0	3	2	0
		DAY 22	28JAN2003	22	8	-16	1	2	0	0	1	1	0	1	1	0	0	0	1	0
		DAY 29	04FEB2003	29	9	-15	2	1	0	0	0	2	1	0	0	1	1	0	1	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	DAY 36	11FEB2003	36	7	-17	2	2	0	0	0	1	0	0	0	0	0	0	1	1
		DAY 43	18FEB2003	43	3	-21	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 50	25FEB2003	50	2	-22	1	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	05MAR2003	58	4	-20	1	1	0	0	0	0	1	0	0	0	0	0	1	0
	E0010024	DAY 1	05MAY2003	1	14		2	2	0	3	2	3	0	0	0	0	0	1	0	1
		DAY 8	12MAY2003	8	9	-5	2	2	0	0	1	2	0	0	0	0	0	2	0	0
		DAY 15	19MAY2003	15	17	3	2	2	0	1	2	2	1	2	0	0	0	1	2	2
		DAY 22	27MAY2003	23	13	-1	2	1	0	2	1	2	0	0	0	0	2	1	1	1
		DAY 29	04JUN2003	31	12	-2	2	2	0	2	2	2	1	0	0	0	0	0	0	1
		DAY 36	11JUN2003	38	15	1	2	2	0	1	2	2	2	1	0	0	0	0	2	1
		DAY 43	18JUN2003	45	15	1	2	2	0	1	2	2	1	1	0	0	1	0	2	1
		DAY 50	25JUN2003	52	15	1	3	3	0	1	2	2	0	1	0	0	0	1	1	1
		DAY 57	02JUL2003	59	8	-6	2	2	0	0	1	1	0	0	0	0	0	0	1	1
	E0010032	DAY 1	10JUL2003	1	23		2	2	0	3	3	3	2	1	1	0	1	3	1	1
		DAY 8	17JUL2003	8	24	1	2	2	0	0	3	3	3	2	3	0	1	3	1	1
	E0011025	DAY 1	26JUN2003	1	21		3	3	0	2	3	3	0	0	0	0	3	2	2	0
		DAY 8	02JUL2003	7	18	-3	3	2	0	2	3	3	1	0	0	0	0	3	1	0
		DAY 15	10JUL2003	15	17	-4	2	2	0	2	3	3	1	0	0	0	0	3	1	0
		DAY 22	17JUL2003	22	17	-4	2	2	0	2	3	3	1	0	0	0	0	3	1	0
		DAY 29	22JUL2003	27	12	-9	2	2	0	0	2	2	1	0	0	0	0	2	1	0
		DAY 36	30JUL2003	35	11	-10	2	2	0	0	1	1	0	1	1	0	0	1	2	0
		DAY 43	07AUG2003	43	8	-13	2	1	0	0	1	0	0	1	1	0	0	0	2	0
		DAY 50	14AUG2003	50	8	-13	1	1	0	1	1	1	1	0	0	1	0	0	1	0
		DAY 57	22AUG2003	58	3	-18	0	0	0	0	0	1	0	0	0	1	0	0	1	0
	E0013007	DAY 1	20MAR2003	1	17		3	3	0	3	3	3	1	0	0	0	0	1	0	0
		DAY 8	27MAR2003	8	17	0	3	3	0	3	3	3	1	0	0	0	0	0	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0013007	DAY 15	07APR2003	19	14	-3	3	3	0	3	2	3	0	0	0	0	0	0	0	0
	E0013009	DAY 1	02APR2003	1	20		3	3	0	3	3	3	2	1	0	0	1	0	1	0
		DAY 8	09APR2003	8	8	-12	2	1	0	0	2	1	2	0	0	0	0	0	0	0
		DAY 15	16APR2003	15	6	-14	2	1	0	0	2	1	0	0	0	0	0	0	0	0
		DAY 22	24APR2003	23	3	-17	0	0	0	0	1	0	0	0	0	0	1	0	1	0
		DAY 29	01MAY2003	30	5	-15	2	0	0	0	2	0	0	1	0	0	0	0	0	0
		DAY 36	07MAY2003	36	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43	16MAY2003	45	2	-18	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	21MAY2003	50	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 57	29MAY2003	58	3	-17	1	0	0	0	1	0	0	0	0	0	1	0	0	0
	E0014006	DAY 1	25MAR2003	1	19		2	2	1	2	2	3	1	1	0	1	1	1	1	1
		DAY 8	02APR2003	9	15	-4	1	2	0	0	2	3	0	1	1	2	0	1	1	1
		DAY 15	09APR2003	16	14	-5	1	2	0	1	2	3	0	0	1	1	0	2	0	1
		DAY 22	16APR2003	23	5	-14	0	1	0	0	1	1	0	0	0	1	0	1	0	0
		DAY 29	23APR2003	30	3	-16	0	0	0	1	0	0	0	0	1	0	0	1	0	0
		DAY 36	30APR2003	37	4	-15	0	0	0	0	0	1	0	0	1	0	0	1	1	0
		DAY 43	07MAY2003	44	1	-18	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 50	14MAY2003	51	3	-16	0	0	0	1	0	1	0	0	0	0	0	1	0	0
		DAY 57	21MAY2003	58	3	-16	0	0	0	0	0	0	0	0	1	0	1	1	0	0
	E0014010	DAY 1	22APR2003	1	24		2	2	0	2	2	3	3	1	2	1	2	1	1	2
		DAY 8	30APR2003	9	16	-8	1	2	0	0	1	2	2	1	1	0	2	1	1	2
		DAY 15	07MAY2003	16	12	-12	1	1	0	1	1	1	1	1	1	0	1	1	1	1
		DAY 22	14MAY2003	23	10	-14	1	1	0	1	1	1	1	1	0	0	1	0	1	1
		DAY 29	21MAY2003	30	9	-15	1	1	0	0	1	1	1	0	0	0	1	1	1	1
		DAY 36	28MAY2003	37	8	-16	1	1	0	0	0	1	0	1	0	0	1	1	1	1
		DAY 43	03JUN2003	43	16	-8	2	2	0	2	1	1	1	0	1	1	1	1	1	2
		DAY 50	11JUN2003	51	16	-8	2	2	1	1	1	1	1	1	1	1	1	0	1	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	DAY 57	17JUN2003	57	14	-10	2	2	1	1	1	1	1	0	1	1	1	0	1	1
	E0016001	DAY 1	22JAN2003	1	32		2	2	4	3	3	3	2	1	2	2	2	1	3	2
		DAY 8	29JAN2003	8	10	-22	0	2	2	2	1	2	0	0	0	0	0	0	0	1
		DAY 15	05FEB2003	15	5	-27	0	1	1	1	0	1	0	0	0	0	0	0	0	1
		DAY 22	12FEB2003	22	2	-30	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	19FEB2003	29	3	-29	1	0	1	0	1	0	0	0	0	0	0	0	0	0
		DAY 36	26FEB2003	36	1	-31	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAR2003	43	2	-30	1	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 50	12MAR2003	50	1	-31	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAR2003	57	0	-32	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0016004	DAY 1	03FEB2003	1	19		3	4	2	1	3	3	1	0	0	0	0	0	0	2
		DAY 8	10FEB2003	8	10	-9	3	2	0	1	0	2	0	0	0	0	0	0	0	2
	E0018001	DAY 1	29OCT2002	1	21		2	2	2	1	2	2	2	1	0	1	1	2	2	1
		DAY 8	05NOV2002	8	14	-7	2	1	1	0	2	2	1	1	0	0	0	1	2	1
		DAY 15	13NOV2002	16	7	-14	1	1	1	0	1	1	1	0	0	0	0	0	0	1
		DAY 22	20NOV2002	23	6	-15	1	1	1	0	1	0	0	0	0	0	0	0	1	1
		DAY 29	27NOV2002	30	6	-15	1	1	0	0	1	0	1	0	0	0	0	0	1	1
		DAY 36	04DEC2002	37	5	-16	1	1	0	0	0	0	1	0	0	0	0	0	1	1
		DAY 43	11DEC2002	44	6	-15	1	1	1	0	1	0	1	0	0	0	0	0	0	1
		DAY 50	18DEC2002	51	10	-11	0	1	0	0	2	1	2	1	0	0	1	0	1	1
		DAY 57	24DEC2002	57	1	-20	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	E0018006	DAY 1	17DEC2002	1	23		2	2	2	3	2	3	1	1	0	1	1	2	2	1
		DAY 8	23DEC2002	7	18	-5	2	2	2	0	2	2	1	0	1	1	1	1	1	2
		DAY 15	31DEC2002	15	12	-11	1	2	1	0	2	2	0	1	0	0	0	0	1	2
		DAY 22	07JAN2003	22	10	-13	1	1	1	0	2	2	1	0	0	0	0	0	1	1
		DAY 29	14JAN2003	29	9	-14	1	1	1	0	2	1	1	0	0	0	0	0	1	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	DAY 36	21JAN2003	36	11	-12	1	1	1	0	2	1	1	1	0	0	0	1	1	1
		DAY 43	28JAN2003	43	8	-15	1	1	0	0	2	1	1	0	0	0	0	0	1	1
		DAY 50	06FEB2003	52	9	-14	1	1	1	0	2	1	1	0	0	0	0	0	1	1
		DAY 57	13FEB2003	59	12	-11	1	2	1	0	2	1	0	0	0	0	1	2	1	1
	E0019004	DAY 1	07NOV2002	1	25		3	2	3	3	2	3	2	1	2	0	1	0	1	2
		DAY 8	14NOV2002	8	16	-9	2	3	2	2	0	0	3	0	1	0	1	0	1	1
		DAY 15	21NOV2002	15	22	-3	3	2	3	1	1	2	1	0	2	2	2	1	1	1
		DAY 22	26NOV2002	20	19	-6	0	4	3	4	0	0	2	1	2	2	0	1	0	0
		DAY 29	05DEC2002	29	20	-5	3	2	2	2	2	3	1	0	0	0	2	2	0	1
		DAY 36	12DEC2002	36	18	-7	1	2	1	3	2	0	2	1	1	1	1	2	1	0
		DAY 43	19DEC2002	43	18	-7	4	2	1	4	1	2	0	0	0	0	0	2	0	2
	E0019011	DAY 1	21NOV2002	1	18		3	3	0	2	3	3	0	0	0	0	0	3	0	1
		DAY 8	27NOV2002	7	22	4	3	3	1	1	2	3	2	1	0	0	1	2	1	2
		DAY 15	05DEC2002	15	16	-2	2	2	0	2	2	3	2	0	0	0	0	1	0	2
		DAY 22	12DEC2002	22	16	-2	2	2	1	3	2	2	1	0	0	0	0	1	1	1
		DAY 29	19DEC2002	29	15	-3	2	2	1	1	2	3	1	1	0	0	0	1	1	0
		DAY 43	02JAN2003	43	12	-6	2	1	0	2	2	2	1	0	0	0	0	1	0	1
		DAY 50	09JAN2003	50	16	-2	2	3	0	2	1	3	1	0	0	0	0	1	1	2
		DAY 57	16JAN2003	57	9	-9	2	1	0	0	1	2	0	0	0	0	0	2	0	1
	E0019025	DAY 1	06FEB2003	1	14		1	0	0	1	2	3	1	0	1	0	1	1	2	1
		DAY 8	13FEB2003	8	10	-4	1	1	0	1	1	3	0	0	0	0	0	1	1	1
		DAY 15	20FEB2003	15	8	-6	1	1	0	1	1	2	0	0	0	0	0	1	1	0
		DAY 22	27FEB2003	22	3	-11	0	0	0	1	0	2	0	0	0	0	0	0	0	0
		DAY 29	06MAR2003	29	2	-12	0	0	0	0	0	1	0	0	0	0	0	0	1	0
		DAY 36	13MAR2003	36	12	-2	1	1	0	1	2	2	1	0	2	0	1	1	0	0
		DAY 43	20MAR2003	43	6	-8	1	0	0	1	0	1	0	0	0	0	1	1	0	1
		DAY 50	27MAR2003	50	6	-8	0	0	0	1	0	1	1	0	0	0	1	0	2	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	DAY 57		03APR2003	57	5	-9	1	0	0	1	0	1	0	0	0	0	1	0	1	0
	E0019026	DAY 1		24FEB2003	1	15		2	1	1	0	2	3	1	0	0	0	0	2	1	2
	E0019043	DAY 1		03JUN2003	1	26		0	2	1	3	3	3	2	2	2	0	2	2	2	2
		DAY 8		10JUN2003	8	12	-14	0	0	0	1	2	3	0	1	1	0	0	2	1	1
		DAY 15		17JUN2003	15	15	-11	2	2	0	1	1	2	0	1	1	1	2	1	0	1
		DAY 22		24JUN2003	22	20	-6	2	2	0	0	3	3	0	2	2	0	2	2	1	1
		DAY 29		01JUL2003	29	14	-12	3	2	0	0	2	2	0	0	0	0	2	1	1	1
		DAY 36		08JUL2003	36	19	-7	2	3	0	2	2	2	0	0	1	1	3	1	1	1
		DAY 43		15JUL2003	43	9	-17	2	1	0	1	1	2	0	0	0	0	1	0	0	1
		DAY 50		22JUL2003	50	11	-15	1	2	0	1	0	1	0	0	1	0	2	1	1	1
		DAY 57		29JUL2003	57	11	-15	1	1	0	1	1	2	0	0	0	0	2	1	1	1
	E0020001	DAY 1		29OCT2002	1	18		2	3	0	1	2	2	0	2	0	0	2	0	2	2
		DAY 8		05NOV2002	8	15	-3	2	2	0	2	1	2	1	2	0	0	1	0	2	0
		DAY 15		12NOV2002	15	17	-1	2	2	0	1	2	2	0	2	0	0	2	0	2	2
		DAY 22		19NOV2002	22	11	-7	2	2	0	2	2	1	0	0	1	0	0	0	0	1
		DAY 29		26NOV2002	29	14	-4	2	2	0	2	2	2	0	0	0	0	2	0	2	0
		DAY 36		03DEC2002	36	16	-2	2	2	1	2	2	2	0	2	0	0	1	0	2	0
		DAY 43		10DEC2002	43	17	-1	2	2	0	2	1	3	0	1	0	0	2	0	2	2
		DAY 50		16DEC2002	49	13	-5	1	1	0	2	2	1	0	2	0	0	2	0	2	0
		DAY 50	*	20DEC2002	53	14	-4	1	2	0	1	2	2	2	1	0	0	1	0	2	0
	E0020006	DAY 1		16DEC2002	1	28		3	3	2	2	2	3	3	2	1	1	2	1	1	2
		DAY 8		20DEC2002	5	26	-2	2	2	2	2	2	3	2	2	1	0	2	3	2	1
	E0020007	DAY 1		15JAN2003	1	23		2	2	0	3	2	3	3	0	0	0	0	3	3	2
		DAY 8		22JAN2003	8	18	-5	2	2	0	0	1	2	3	1	1	0	0	3	2	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	DAY 1	26FEB2003	1	16		2	2	0	2	2	3	2	0	0	0	0	1	0	2
		DAY 8	05MAR2003	8	12	-4	1	1	2	0	2	1	2	0	0	0	0	0	2	1
		DAY 15	12MAR2003	15	10	-6	1	0	2	0	2	0	2	0	0	0	0	0	2	1
		DAY 22	20MAR2003	23	12	-4	1	1	2	1	1	1	2	0	0	0	0	1	1	1
		DAY 29	26MAR2003	29	6	-10	0	0	0	0	2	0	0	0	1	0	0	0	2	1
		DAY 36	02APR2003	36	7	-9	0	2	0	0	2	0	0	0	0	0	0	0	2	1
		DAY 43	09APR2003	43	8	-8	0	3	0	0	0	1	0	0	0	0	0	0	2	2
		DAY 50	16APR2003	50	12	-4	1	2	0	1	2	1	2	0	0	0	0	0	2	1
		DAY 57	23APR2003	57	2	-14	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	E0020013	DAY 1	05MAR2003	1	12		1	2	0	3	2	3	0	0	0	0	0	0	0	1
		DAY 8	12MAR2003	8	1	-11	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	E0022008	DAY 1	12NOV2002	1	15		2	1	0	2	2	3	0	0	0	1	1	0	1	2
		DAY 8	19NOV2002	8	4	-11	1	0	0	0	0	2	0	0	0	0	0	0	0	1
		DAY 15	26NOV2002	15	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	03DEC2002	22	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	12DEC2002	31	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	17DEC2002	36	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	24DEC2002	43	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	31DEC2002	50	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	57	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022017	DAY 1	19DEC2002	1	18		2	2	0	2	2	3	1	1	2	0	2	0	0	1
		DAY 8	26DEC2002	8	13	-5	3	2	1	0	0	2	1	0	1	1	0	0	1	1
		DAY 15	03JAN2003	16	14	-4	2	2	0	1	2	2	2	0	0	1	1	0	1	0
		DAY 22	09JAN2003	22	13	-5	2	2	0	0	2	2	1	1	0	1	0	0	2	0
		DAY 29	17JAN2003	30	7	-11	1	0	0	0	0	1	1	0	1	1	1	0	1	0
		DAY 36	22JAN2003	35	4	-14	0	1	0	0	1	0	0	1	0	0	1	0	0	0
		DAY 43	31JAN2003	44	9	-9	1	1	0	0	1	1	1	1	1	0	1	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	DAY 50	06FEB2003	50	3	-15	0	1	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 57	13FEB2003	57	2	-16	0	0	0	0	0	0	1	0	0	1	0	0	0	0
	E0022018	DAY 1	12DEC2002	1	4		1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 8	19DEC2002	8	4	0	1	1	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 15	26DEC2002	15	8	4	1	0	1	0	0	2	1	0	0	0	2	0	0	1
		DAY 22	02JAN2003	22	10	6	2	2	1	1	1	1	1	0	0	0	1	0	0	0
		DAY 29	09JAN2003	29	8	4	1	1	0	1	1	1	0	0	0	0	1	1	0	1
		DAY 36	16JAN2003	36	4	0	1	0	0	0	0	2	0	0	0	1	0	0	0	0
		DAY 43	23JAN2003	43	5	1	1	0	0	0	0	2	0	0	1	0	1	0	0	0
		DAY 50	30JAN2003	50	6	2	1	0	0	0	1	1	1	0	0	0	1	0	0	1
		DAY 57	06FEB2003	57	6	2	2	0	0	0	1	0	1	0	0	0	2	0	0	0
	E0022022	DAY 1	30DEC2002	1	7		1	2	0	1	0	1	1	0	0	0	0	0	0	1
		DAY 8	06JAN2003	8	9	2	1	2	1	0	0	1	0	0	1	1	1	1	0	0
		DAY 15	14JAN2003	16	12	5	2	1	1	0	1	1	1	1	1	0	1	0	1	1
		DAY 22	21JAN2003	23	7	0	1	1	0	1	0	1	0	0	1	0	2	0	0	0
		DAY 29	28JAN2003	30	6	-1	1	1	0	1	0	1	0	0	0	0	2	0	0	0
		DAY 36	04FEB2003	37	6	-1	1	1	0	0	1	2	0	0	1	0	0	0	0	0
		DAY 57	27FEB2003	60	9	2	1	1	0	1	1	1	0	1	1	0	1	0	1	0
	E0022027	DAY 1	06FEB2003	1	15		2	2	2	0	0	3	0	0	1	2	1	0	0	2
		DAY 8	13FEB2003	8	7	-8	1	1	0	0	0	2	1	0	1	0	1	0	0	0
		DAY 15	20FEB2003	15	3	-12	1	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 22	27FEB2003	22	4	-11	1	0	0	0	0	2	0	0	0	0	0	1	0	0
		DAY 29	06MAR2003	29	4	-11	1	1	0	0	0	1	0	0	1	0	0	0	0	0
		DAY 36	13MAR2003	36	4	-11	1	1	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 43	20MAR2003	43	4	-11	1	1	0	0	0	0	0	0	0	0	1	0	0	1
		DAY 50	27MAR2003	50	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	03APR2003	57	1	-14	0	0	0	0	0	0	0	0	0	0	0	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0022030	DAY 1	14FEB2003	1	3		0	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 8	20FEB2003	7	2	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 15	28FEB2003	15	2	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 22	07MAR2003	22	2	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	0
	E0022031	DAY 1	18FEB2003	1	3		0	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 8	25FEB2003	8	4	1	1	0	0	0	0	2	0	0	0	0	0	0	0	1
		DAY 15	04MAR2003	15	2	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 22	11MAR2003	22	4	1	1	0	0	0	0	2	1	0	0	0	0	0	0	0
		DAY 29	18MAR2003	29	2	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 36	25MAR2003	36	1	-2	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	01APR2003	43	5	2	1	1	0	0	0	2	0	0	0	0	0	0	0	1
		DAY 50	08APR2003	50	2	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	1	-2	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	E0022032	DAY 1	18FEB2003	1	7		2	0	0	1	0	3	0	0	0	0	0	0	0	1
		DAY 8	28FEB2003	11	5	-2	0	0	1	0	0	2	2	0	0	0	0	0	0	0
		DAY 15	04MAR2003	15	1	-6	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	11MAR2003	22	4	-3	1	1	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 29	21MAR2003	32	8	1	1	0	0	0	1	1	0	0	0	0	1	1	3	0
		DAY 36	27MAR2003	38	2	-5	0	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	03APR2003	45	4	-3	0	0	1	0	1	1	1	0	0	0	0	0	0	0
		DAY 50	10APR2003	52	2	-5	0	0	1	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	18APR2003	60	3	-4	0	0	0	0	0	1	1	0	0	1	0	0	0	0
	E0022035	DAY 1	19FEB2003	1	4		0	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 8	26FEB2003	8	5	1	0	0	0	1	1	2	0	0	1	0	0	0	0	0
	E0022036	DAY 1	25FEB2003	1	5		1	0	0	0	0	2	0	0	0	0	1	0	1	0
		DAY 8	03MAR2003	7	0	-5	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	DAY 15	10MAR2003	14	3	-2	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	18MAR2003	22	2	-3	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 29	25MAR2003	29	2	-3	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	36	4	-1	0	1	0	0	0	2	1	0	0	0	0	0	0	0
		DAY 43	08APR2003	43	2	-3	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 50	15APR2003	50	4	-1	1	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	57	4	-1	1	0	0	0	0	3	0	0	0	0	0	0	0	0
	E0022056	DAY 1	17APR2003	1	6		1	0	0	0	0	3	0	1	0	0	0	0	0	1
		DAY 8	24APR2003	8	7	1	1	0	1	0	0	3	0	1	0	0	0	0	0	1
		DAY 15	01MAY2003	15	5	-1	1	1	0	0	0	2	0	0	0	0	0	0	0	1
		DAY 22	08MAY2003	22	5	-1	1	1	0	0	0	3	0	0	0	0	0	0	0	0
	E0022060	DAY 1	30APR2003	1	6		2	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 8	05MAY2003	6	10	4	2	2	0	1	1	2	1	0	0	0	0	0	0	1
		DAY 15	12MAY2003	13	8	2	2	1	0	0	1	2	1	0	0	0	0	0	0	1
		DAY 22	19MAY2003	20	12	6	2	2	0	1	2	2	1	0	1	0	0	0	0	1
		DAY 29	28MAY2003	29	11	5	2	2	0	0	1	2	1	0	0	0	0	0	1	2
		DAY 36	02JUN2003	34	10	4	2	2	0	0	1	2	1	0	0	0	0	0	1	1
		DAY 43	10JUN2003	42	11	5	2	2	0	0	1	2	1	1	0	0	1	0	0	1
		DAY 50	17JUN2003	49	9	3	2	1	0	0	1	2	1	0	0	0	0	0	1	1
		DAY 57	24JUN2003	56	1	-5	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0022063	DAY 1	07MAY2003	1	8		2	2	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 8	12MAY2003	6	7	-1	2	1	0	0	1	2	0	0	0	0	0	0	0	1
		DAY 15	21MAY2003	15	4	-4	1	0	0	0	1	1	0	0	0	0	1	0	0	0
		DAY 22	28MAY2003	22	7	-1	1	0	0	0	1	0	0	1	1	0	1	0	1	1
		DAY 29	04JUN2003	29	2	-6	0	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36	11JUN2003	36	1	-7	0	0	0	0	1	0	0	0	0	0	0	0	0	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	DAY 1		30JAN2003	1	25		3	3	1	3	3	3	1	0	2	1	2	0	1	2
		DAY 8		06FEB2003	8	20	-5	3	3	0	0	3	3	1	1	1	2	0	0	1	2
		DAY 15		13FEB2003	15	18	-7	3	3	0	0	3	3	1	0	1	2	0	0	0	2
		DAY 22		20FEB2003	22	35	10	3	4	1	2	2	4	3	3	3	3	1	1	2	3
		DAY 29		25FEB2003	27	29	4	4	4	1	2	3	4	2	1	2	2	0	1	0	3
		DAY 36		06MAR2003	36	29	4	4	4	1	2	3	4	1	1	2	2	0	1	0	4
		DAY 43		11MAR2003	41	27	2	4	4	1	2	2	4	1	1	1	2	1	1	0	3
		DAY 50		18MAR2003	48	27	2	4	4	1	2	2	4	1	1	1	2	1	1	0	3
		DAY 50	*	24MAR2003	54	28	3	4	4	1	2	2	4	1	1	1	2	1	1	1	3
	E0023013	DAY 1		27FEB2003	1	23		3	3	1	2	3	2	1	1	1	1	3	1	0	1
		DAY 8		06MAR2003	8	21	-2	3	3	1	1	2	2	1	1	1	1	3	1	0	1
	E0023015	DAY 1		11MAR2003	1	21		3	3	0	0	3	3	1	0	0	0	0	3	2	3
		DAY 8		18MAR2003	8	27	6	3	2	2	0	3	2	2	2	2	1	2	1	2	3
		DAY 15		25MAR2003	15	16	-5	2	2	0	0	3	1	1	1	1	1	0	1	2	1
		DAY 22		01APR2003	22	12	-9	2	1	0	0	2	1	1	0	1	0	0	1	2	1
		DAY 29		08APR2003	29	12	-9	2	1	0	0	2	1	1	0	1	0	0	1	2	1
		DAY 36		15APR2003	36	1	-20	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43		22APR2003	43	1	-20	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50		29APR2003	50	2	-19	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		06MAY2003	57	3	-18	1	0	0	0	0	1	0	0	0	0	0	0	0	1
	E0023034	DAY 1		09JUN2003	1	19		2	3	1	3	3	3	2	0	0	0	0	0	0	2
		DAY 8		16JUN2003	8	19	0	3	3	0	2	2	2	2	1	0	0	2	1	0	1
		DAY 15		23JUN2003	15	17	-2	3	3	0	3	2	2	0	0	0	0	2	0	0	2
		DAY 22		30JUN2003	22	10	-9	1	2	0	2	2	2	0	0	0	0	1	0	0	0
		DAY 29		07JUL2003	29	13	-6	1	2	1	2	3	3	0	0	0	0	1	0	0	0
		DAY 36		14JUL2003	36	7	-12	1	1	1	1	1	2	0	0	0	0	0	0	0	0
		DAY 43		22JUL2003	44	6	-13	1	1	0	1	1	1	0	0	0	0	1	0	0	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	DAY 57		05AUG2003	58	8	-11	1	1	0	1	1	1	0	0	0	0	3	0	0	0
	E0023037	DAY 1		18JUN2003	1	20		3	3	0	3	3	3	0	0	0	0	2	0	0	3
		DAY 8		24JUN2003	7	8	-12	2	1	0	1	2	2	0	0	0	0	0	0	0	0
		DAY 15		01JUL2003	14	6	-14	1	1	0	0	1	1	0	0	0	0	0	0	1	1
		DAY 29	*	14JUL2003	27	3	-17	0	0	0	0	0	1	0	0	0	0	0	0	1	1
		DAY 29		18JUL2003	31	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 36		25JUL2003	38	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		01AUG2003	45	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		08AUG2003	52	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		15AUG2003	59	2	-18	1	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0023038	DAY 1		30JUN2003	1	40		4	4	1	2	3	3	3	3	3	3	4	1	2	4
		DAY 8		09JUL2003	10	27	-13	2	2	0	1	3	3	3	3	2	2	3	0	1	2
		DAY 15		15JUL2003	16	17	-23	1	1	0	1	2	2	2	2	1	1	2	0	1	1
		DAY 22		21JUL2003	22	17	-23	2	2	0	0	2	2	2	2	1	1	1	0	1	1
		DAY 29		28JUL2003	29	14	-26	2	1	0	0	2	2	2	1	1	0	1	0	1	1
		DAY 36		07AUG2003	39	9	-31	2	1	0	0	2	2	0	0	0	0	0	0	0	2
		DAY 43		13AUG2003	45	5	-35	1	1	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 50		21AUG2003	53	11	-29	2	1	0	0	2	2	0	0	0	0	1	1	0	2
		DAY 57		27AUG2003	59	7	-33	2	1	0	0	2	2	0	0	0	0	0	0	0	0
	E0023044	DAY 1		16JUL2003	1	38		4	4	1	2	3	3	3	3	3	3	3	1	3	2
		DAY 8		22JUL2003	7	38	0	4	4	0	3	3	3	3	3	3	3	3	1	3	2
		DAY 15		29JUL2003	14	37	-1	4	3	0	3	3	3	3	3	3	3	3	1	3	2
		DAY 22		05AUG2003	21	37	-1	4	3	0	3	3	3	3	3	3	3	3	1	3	2
		DAY 29		12AUG2003	28	40	2	4	4	0	3	3	4	4	3	3	3	3	1	3	2
	E0023045	DAY 1		17JUL2003	1	26		4	4	0	2	3	4	1	1	1	1	1	0	1	3
		DAY 8		24JUL2003	8	21	-5	3	3	0	0	3	3	3	1	0	0	1	0	1	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	DAY 15	31JUL2003	15	18	-8	3	3	0	0	3	3	2	1	0	0	0	0	0	3
		DAY 22	07AUG2003	22	14	-12	3	2	0	0	3	2	2	0	0	0	0	0	0	2
		DAY 29	14AUG2003	29	15	-11	3	2	0	1	3	2	2	0	0	0	0	0	0	2
		DAY 36	21AUG2003	36	10	-16	2	2	0	1	2	2	0	0	0	0	0	0	0	1
		DAY 43	28AUG2003	43	6	-20	1	1	0	1	1	1	0	0	0	0	0	0	0	1
		DAY 50	04SEP2003	50	3	-23	1	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 57	11SEP2003	57	3	-23	1	0	0	0	1	1	0	0	0	0	0	0	0	0
	E0025002	DAY 1	03APR2003	1	27		3	3	0	3	2	3	2	0	2	3	0	3	0	3
		DAY 8	10APR2003	8	13	-14	2	1	0	0	2	2	0	0	0	1	0	2	1	2
		DAY 15	17APR2003	15	27	0	3	3	2	2	2	3	0	0	0	2	3	2	2	3
		DAY 22	24APR2003	22	10	-17	2	2	0	0	0	2	0	0	0	1	0	1	0	2
		DAY 29	01MAY2003	29	5	-22	1	1	0	0	0	1	0	0	0	0	0	0	1	1
		DAY 36	08MAY2003	36	3	-24	1	1	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43	15MAY2003	43	2	-25	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	22MAY2003	50	9	-18	2	2	0	0	0	2	0	0	0	2	0	0	0	1
		DAY 57	29MAY2003	57	3	-24	0	1	0	0	0	0	0	0	1	1	0	0	0	0
	E0026010	DAY 1	22JAN2003	1	20		2	1	0	3	2	3	2	1	1	1	2	0	2	0
		DAY 8	30JAN2003	9	19	-1	1	3	0	4	0	0	1	1	1	0	3	0	3	2
	E0026017	DAY 1	06MAR2003	1	21		2	2	0	2	2	3	1	2	1	1	2	0	2	1
		DAY 15	21MAR2003	16	5	-16	1	0	0	0	0	0	0	0	1	0	1	0	2	0
	E0026018	DAY 1	20MAR2003	1	30		4	2	1	2	2	3	2	2	2	1	2	3	2	2
		DAY 8	27MAR2003	8	26	-4	2	3	1	3	2	1	3	0	2	1	3	0	2	3
		DAY 15	03APR2003	15	22	-8	2	2	1	2	2	0	2	1	2	2	3	0	2	1
		DAY 22	10APR2003	22	9	-21	1	1	0	0	2	0	1	1	0	0	1	0	2	0
		DAY 29	17APR2003	29	12	-18	1	1	0	1	1	1	1	1	1	1	1	0	2	0
		DAY 36	24APR2003	36	9	-21	0	0	1	0	0	0	2	1	0	0	2	1	2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	DAY 43	01MAY2003	43	4	-26	0	0	0	1	0	0	0	0	0	0	1	1	1	0
		DAY 50	08MAY2003	50	4	-26	0	0	0	1	0	0	0	0	0	0	1	1	1	0
		DAY 57	15MAY2003	57	8	-22	0	0	1	2	0	0	2	0	0	0	2	1	0	0
	E0026025	DAY 1	09MAY2003	1	15		2	1	1	1	2	4	0	0	0	0	2	1	0	1
		DAY 8	15MAY2003	7	11	-4	2	2	1	0	1	2	0	0	0	0	0	1	0	2
		DAY 15	22MAY2003	14	15	0	2	2	1	0	2	3	1	0	0	0	0	1	0	3
		DAY 22	29MAY2003	21	12	-3	2	1	1	0	2	2	1	0	0	0	0	1	0	2
		DAY 29	05JUN2003	28	9	-6	2	1	1	0	1	1	1	0	0	0	0	1	0	1
		DAY 36	13JUN2003	36	9	-6	2	1	1	0	1	1	1	0	0	0	1	0	0	1
		DAY 43	20JUN2003	43	9	-6	2	1	1	0	0	1	2	0	0	0	1	0	0	1
		DAY 50	27JUN2003	50	9	-6	1	0	0	2	2	0	1	0	1	0	0	0	1	1
		DAY 57	03JUL2003	56	9	-6	1	0	0	2	3	0	1	0	0	0	0	0	1	1
	E0026029	DAY 1	09JUL2003	1	26		2	3	0	3	3	3	2	1	1	0	3	1	1	3
		DAY 8	16JUL2003	8	25	-1	2	3	0	3	2	2	2	2	1	1	2	1	1	3
	E0026030	DAY 1	09JUL2003	1	16		2	2	0	3	2	3	0	0	0	1	0	1	0	2
		DAY 8	16JUL2003	8	15	-1	2	2	0	1	2	2	1	0	1	0	1	2	0	1
		DAY 15	23JUL2003	15	12	-4	2	3	1	1	0	1	1	0	0	0	0	1	1	1
		DAY 22	30JUL2003	22	10	-6	2	2	1	1	1	1	0	0	0	0	0	1	0	1
		DAY 29	04AUG2003	27	11	-5	2	2	1	1	1	0	0	0	0	0	0	1	2	1
		DAY 36	12AUG2003	35	4	-12	1	0	0	0	0	0	0	0	0	0	0	0	2	1
		DAY 43	19AUG2003	42	5	-11	1	0	0	0	0	1	0	0	0	0	0	0	2	1
		DAY 50	26AUG2003	49	2	-14	0	0	0	0	0	0	0	0	0	0	0	0	1	1
		DAY 57	03SEP2003	57	3	-13	0	0	0	1	0	0	0	0	0	0	0	0	2	0
	E0026031	DAY 1	21JUL2003	1	20		3	2	1	2	1	2	1	1	0	1	3	0	1	2
		DAY 8	28JUL2003	8	16	-4	1	2	1	1	2	2	1	0	0	0	2	0	1	3
		DAY 15	04AUG2003	15	14	-6	1	2	1	0	2	2	1	0	0	0	1	0	1	3

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Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0026031	DAY 22		11AUG2003	22	15	-5	1	1	1	0	2	2	1	0	0	2	1	1	2	1
		DAY 29		18AUG2003	29	12	-8	1	1	1	1	1	2	1	0	0	0	0	1	2	1
		DAY 36		25AUG2003	36	24	4	3	2	3	2	0	3	2	2	0	0	0	3	2	2
		DAY 43		02SEP2003	44	13	-7	2	1	0	1	0	2	2	0	0	0	1	2	2	0
		DAY 50		08SEP2003	50	8	-12	0	0	1	1	0	2	1	1	0	0	1	0	0	1
		DAY 57		15SEP2003	57	11	-9	2	1	0	0	0	2	2	0	0	0	1	0	2	1
	E0027003	DAY 1		23JAN2003	-5	29		3	3	3	3	3	3	2	1	1	1	1	2	1	2
		DAY 8		06FEB2003	10	21	-8	2	3	2	3	2	3	2	0	0	0	1	2	0	1
		DAY 15		13FEB2003	17	13	-16	2	1	3	1	2	2	0	0	0	0	0	2	0	0
		DAY 22		19FEB2003	23	12	-17	1	1	1	1	2	1	0	0	0	0	0	2	2	1
		DAY 29		27FEB2003	31	10	-19	1	1	1	0	1	1	1	0	1	0	0	1	2	0
		DAY 36		06MAR2003	38	19	-10	3	2	2	1	1	2	2	1	2	0	0	1	2	0
		DAY 43		13MAR2003	45	13	-16	2	2	2	2	1	1	0	0	1	0	0	1	1	0
		DAY 50		20MAR2003	52	15	-14	2	2	2	1	2	1	0	0	1	0	0	1	2	1
		DAY 57		25MAR2003	57	12	-17	1	2	2	1	1	1	0	0	1	0	0	1	2	0
	E0028004	DAY 1		30SEP2002	1	12		2	1	0	3	3	3	0	0	0	0	0	0	0	0
		DAY 8		07OCT2002	8	10	-2	1	1	0	0	1	3	1	0	0	0	0	1	2	0
		DAY 8	*	09OCT2002	10	10	-2	1	1	0	2	1	3	0	1	0	0	0	0	1	0
	E0028006	DAY 1		04OCT2002	1	13		2	3	0	2	2	2	0	0	0	0	1	1	0	0
		DAY 8		11OCT2002	8	22	9	3	3	1	3	1	3	1	1	1	1	1	1	1	1
		DAY 15		16OCT2002	13	16	3	2	3	0	1	2	2	1	1	1	0	0	2	1	0
		DAY 22		23OCT2002	20	19	6	3	3	0	2	1	3	0	2	2	0	1	2	0	0
		DAY 29		31OCT2002	28	16	3	3	3	0	1	1	2	1	0	1	0	0	2	0	2
		DAY 36		07NOV2002	35	23	10	3	3	0	2	2	4	2	2	2	0	0	2	1	0
		DAY 43		14NOV2002	42	18	5	3	3	0	1	2	4	0	0	0	1	0	2	0	2
		DAY 50		21NOV2002	49	17	4	3	3	1	1	2	3	0	0	0	0	0	2	0	2
		DAY 57		04DEC2002	62	12	-1	3	1	0	1	3	3	0	0	0	0	0	1	0	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	DAY 1	15OCT2002	1	29		3	2	2	2	2	3	2	3	2	0	3	1	1	3
		DAY 8	22OCT2002	8	30	1	2	2	2	3	3	3	3	2	2	2	3	2	0	1
		DAY 15	29OCT2002	15	17	-12	3	0	0	2	3	3	3	0	0	0	0	2	0	1
		DAY 22	07NOV2002	24	17	-12	2	1	2	0	3	2	4	0	0	0	0	0	0	3
		DAY 29	14NOV2002	31	30	1	3	3	3	3	4	2	4	1	2	2	3	0	0	0
		DAY 36	21NOV2002	38	23	-6	3	3	0	1	4	2	4	0	2	0	0	0	2	2
		DAY 43	26NOV2002	43	29	0	3	0	0	3	2	3	3	2	3	0	3	2	2	3
		DAY 50	03DEC2002	50	21	-8	3	0	1	2	3	4	4	2	0	0	2	0	0	0
		DAY 57	10DEC2002	57	26	-3	3	3	2	3	3	3	1	1	3	2	2	0	0	0
	E0028009	DAY 1	15OCT2002	1	16		2	2	0	3	1	2	2	0	0	0	2	1	1	0
		DAY 8	23OCT2002	9	5	-11	0	0	0	0	0	2	2	0	0	0	1	0	0	0
		DAY 15	31OCT2002	17	6	-10	0	1	0	0	0	2	0	0	0	0	2	1	0	0
		DAY 22	07NOV2002	24	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	14NOV2002	31	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	19NOV2002	36	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	26NOV2002	43	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	03DEC2002	50	5	-11	0	1	0	0	0	2	0	0	0	0	0	0	2	0
		DAY 57	12DEC2002	59	3	-13	0	0	0	0	0	1	0	0	0	0	1	0	1	0
	E0028016	DAY 1	14NOV2002	1	27		4	2	3	4	3	3	2	2	0	0	0	4	0	0
		DAY 8	21NOV2002	8	16	-11	2	0	0	0	2	4	0	0	0	0	0	4	4	0
		DAY 15	26NOV2002	13	17	-10	0	0	2	0	2	4	0	1	0	0	0	4	4	0
		DAY 22	05DEC2002	22	26	-1	4	3	3	4	1	4	0	0	0	0	0	4	3	0
		DAY 29	12DEC2002	29	4	-23	2	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 36	19DEC2002	36	5	-22	0	0	0	1	1	1	1	0	0	0	0	0	1	0
		DAY 43	26DEC2002	43	13	-14	0	1	2	2	2	2	1	0	0	0	0	1	2	0
		DAY 50	02JAN2003	50	13	-14	0	1	2	2	2	2	1	0	0	0	0	1	2	0
		DAY 57	09JAN2003	57	16	-11	2	2	1	2	1	2	0	0	1	0	0	2	1	2

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0028017	*	19NOV2002		31		2	3	4	3	0	3	4	0	2	2	4	0	4	0
	E0028027	DAY 1	21JAN2003	1	29		3	3	0	3	3	4	3	1	2	0	2	3	0	2
		DAY 8	28JAN2003	8	15	-14	3	0	0	0	3	3	0	0	0	0	1	2	2	1
		DAY 15	04FEB2003	15	10	-19	0	0	0	0	0	3	1	0	0	0	1	2	2	1
		DAY 22	11FEB2003	22	10	-19	2	3	0	0	0	3	0	0	0	0	0	2	0	0
		DAY 29	20FEB2003	31	15	-14	2	2	0	1	2	3	0	0	0	0	0	2	1	2
		DAY 36	28FEB2003	39	20	-9	3	3	0	0	3	3	0	0	2	0	2	2	0	2
	E0028029	DAY 1	04FEB2003	1	15		0	0	1	3	3	3	0	0	0	0	0	2	2	1
		DAY 8	11FEB2003	8	12	-3	0	2	1	0	0	3	0	1	0	0	0	2	2	1
		DAY 15	17FEB2003	14	10	-5	0	3	0	0	0	2	0	1	0	0	0	2	0	2
		DAY 22	27FEB2003	24	7	-8	0	1	0	0	0	2	0	1	0	0	0	2	0	1
		DAY 29	06MAR2003	31	13	-2	1	1	0	0	3	3	1	0	0	0	0	3	0	1
		DAY 36	13MAR2003	38	1	-14	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	20MAR2003	45	5	-10	0	0	0	3	0	0	1	0	0	0	0	1	0	0
		DAY 50	27MAR2003	52	4	-11	0	0	0	0	0	1	1	0	0	0	0	2	0	0
		DAY 57	03APR2003	59	1	-14	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	E0028034	DAY 1	01APR2003	1	23		3	2	0	3	2	3	2	1	1	0	0	2	2	2
		DAY 8	08APR2003	8	19	-4	2	2	0	2	2	3	0	0	1	0	2	1	2	2
		DAY 15	15APR2003	15	7	-16	1	0	0	1	1	1	0	0	0	0	0	1	1	1
		DAY 22	22APR2003	22	9	-14	0	0	0	1	0	1	0	0	3	0	2	0	2	0
		DAY 29	01MAY2003	31	5	-18	1	0	0	1	0	1	0	0	0	0	0	0	2	0
		DAY 36	06MAY2003	36	2	-21	0	0	0	1	0	0	0	0	0	0	0	0	1	0
		DAY 43	13MAY2003	43	6	-17	0	0	0	1	0	0	1	0	1	1	1	0	1	0
		DAY 50	21MAY2003	51	2	-21	0	0	0	1	0	0	1	0	0	0	0	0	0	0
		DAY 57	02JUN2003	63	7	-16	1	1	0	1	0	1	0	1	0	0	1	0	1	0
	E0028038	DAY 1	25APR2003	1	14		2	1	0	2	2	3	0	0	0	0	0	2	0	2

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	DAY 8	02MAY2003	8	13	-1	2	2	0	2	2	2	0	0	0	0	0	2	1	0
		DAY 15	08MAY2003	14	13	-1	2	2	0	1	2	2	1	0	0	0	0	1	1	1
		DAY 29	22MAY2003	28	12	-2	2	0	0	1	2	2	1	0	0	0	0	2	1	1
		DAY 36	30MAY2003	36	11	-3	1	1	1	1	1	1	1	0	0	0	0	2	1	1
		DAY 43	05JUN2003	42	14	0	2	1	0	1	2	2	0	0	0	0	1	2	1	2
		DAY 50	12JUN2003	49	11	-3	2	0	0	1	2	1	1	1	0	0	1	0	1	1
		DAY 57	18JUN2003	55	14	0	2	1	0	1	2	2	1	1	0	0	0	2	1	1
	E0028043	DAY 1	05JUN2003	1	20		3	3	0	2	2	3	2	0	0	0	2	2	0	1
		DAY 8	12JUN2003	8	19	-1	3	2	1	3	2	3	1	0	0	0	0	0	2	2
		DAY 15	19JUN2003	15	20	0	3	2	0	3	2	3	0	1	0	0	2	0	1	3
		DAY 22	26JUN2003	22	10	-10	2	1	0	2	1	2	0	0	0	0	0	0	1	1
		DAY 29	01JUL2003	27	13	-7	2	1	0	2	1	2	1	0	0	0	2	0	0	2
		DAY 36	08JUL2003	34	7	-13	1	1	0	1	1	1	1	0	0	0	0	0	1	0
		DAY 43	15JUL2003	41	16	-4	3	3	0	2	1	2	0	0	0	0	1	0	2	2
		DAY 50	22JUL2003	48	10	-10	2	2	0	2	1	1	0	0	0	0	0	0	1	1
		DAY 57	29JUL2003	55	11	-9	2	1	0	2	1	2	2	0	0	0	0	0	0	1
	E0028045	DAY 1	18JUN2003	1	25		3	1	0	3	3	3	0	2	0	0	2	3	3	2
		DAY 8	25JUN2003	8	26	1	3	3	0	3	3	3	3	0	0	0	0	3	3	2
		DAY 15	30JUN2003	13	24	-1	3	2	1	1	3	3	2	1	0	0	0	3	2	3
	E0029005	DAY 1	27NOV2002	1	14		2	2	0	2	2	2	1	0	0	1	1	1	0	0
		DAY 8	03DEC2002	7	15	1	2	1	0	1	2	2	2	1	0	0	1	1	1	1
		DAY 15	09DEC2002	13	12	-2	2	2	1	1	2	2	0	0	0	0	0	1	1	0
		DAY 22	16DEC2002	20	11	-3	2	2	0	1	2	2	0	0	0	1	0	1	0	0
		DAY 29	23DEC2002	27	15	1	2	1	0	1	2	1	2	0	0	2	2	1	1	0
		DAY 36	30DEC2002	34	12	-2	2	2	1	0	1	2	0	0	0	1	1	1	1	0
		DAY 43	07JAN2003	42	11	-3	2	2	1	1	1	1	0	0	0	1	0	1	1	0
		DAY 50	14JAN2003	49	12	-2	1	1	1	1	2	1	0	1	0	1	1	1	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	DAY 57		21JAN2003	56	9	-5	1	1	0	1	1	1	0	1	0	1	0	1	1	0
	E0030001	DAY 1		19NOV2002	1	23		3	3	1	2	2	3	2	0	1	1	1	0	2	2
		DAY 8		26NOV2002	8	19	-4	3	2	1	1	3	3	1	0	0	0	1	1	1	2
		DAY 15		03DEC2002	15	22	-1	3	2	1	2	3	3	2	1	1	0	1	0	1	2
		DAY 22		10DEC2002	22	17	-6	3	2	1	1	1	3	2	0	0	0	1	0	1	2
		DAY 29		17DEC2002	29	21	-2	3	2	1	1	2	2	2	1	1	1	2	0	1	2
		DAY 43		02JAN2003	45	12	-11	1	2	1	1	0	2	1	0	0	0	2	0	1	1
		DAY 50		09JAN2003	52	12	-11	1	1	0	1	1	2	1	0	0	0	2	0	2	1
		DAY 57		16JAN2003	59	16	-7	2	1	0	2	1	2	2	1	1	1	1	0	1	1
	E0030008	DAY 1		14JAN2003	1	15		2	2	1	2	3	3	0	0	0	0	0	1	0	1
		DAY 8		23JAN2003	10	15	0	1	2	0	1	2	3	2	1	0	0	0	0	0	3
		DAY 15		30JAN2003	17	13	-2	1	3	0	3	1	2	1	0	0	0	0	0	0	2
		DAY 22		07FEB2003	25	15	0	1	2	0	3	2	3	1	0	0	0	0	0	1	2
		DAY 29		14FEB2003	32	18	3	2	1	2	1	2	3	0	1	1	1	1	2	1	0
		DAY 36		21FEB2003	39	16	1	1	1	0	2	3	2	1	0	0	1	1	0	1	3
		DAY 50		03MAR2003	49	8	-7	1	1	0	0	2	2	0	0	0	0	0	0	0	2
		DAY 57	*	11MAR2003	57	10	-5	0	1	0	2	1	1	1	0	0	0	1	0	1	2
		DAY 57		18MAR2003	64	16	1	1	1	0	3	2	3	1	0	1	0	0	0	2	2
	E0030011	DAY 1		27JAN2003	1	15		3	2	0	4	3	3	0	0	0	0	0	0	0	0
		DAY 8		03FEB2003	8	6	-9	1	2	0	0	2	0	0	0	0	0	0	0	0	1
		DAY 15		10FEB2003	15	2	-13	0	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 22		18FEB2003	23	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		24FEB2003	29	3	-12	0	0	0	0	0	0	0	0	0	0	0	1	2	0
		DAY 36		03MAR2003	36	6	-9	0	0	0	0	0	1	0	0	0	0	1	1	2	1
		DAY 43		10MAR2003	43	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		17MAR2003	50	1	-14	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 57		24MAR2003	57	1	-14	0	0	0	0	0	0	0	0	0	0	0	0	0	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	DAY 1		21FEB2003	1	14		2	2	0	2	2	3	0	0	0	0	0	0	0	3
		DAY 8		03MAR2003	11	11	-3	2	2	0	0	2	3	0	0	0	0	0	0	0	2
		DAY 15		11MAR2003	19	6	-8	2	0	0	2	0	2	0	0	0	0	0	0	0	0
		DAY 29		19MAR2003	27	5	-9	1	1	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 36		26MAR2003	34	2	-12	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43		02APR2003	41	3	-11	1	0	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 50		09APR2003	48	1	-13	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 57	*	17APR2003	56	2	-12	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 57		22APR2003	61	0	-14	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0030022	DAY 1		16JUN2003	1	19		2	2	1	2	1	3	1	1	1	1	2	0	1	1
		DAY 8		20JUN2003	5	12	-7	2	3	0	0	3	3	0	0	0	0	0	0	0	1
		DAY 15		30JUN2003	15	9	-10	1	2	0	0	0	1	2	0	0	0	0	0	2	1
		DAY 22		07JUL2003	22	7	-12	2	0	0	0	1	1	0	0	1	1	0	0	0	1
		DAY 29		14JUL2003	29	6	-13	1	2	0	0	0	2	0	0	0	0	0	0	1	0
		DAY 36		21JUL2003	36	6	-13	2	0	0	1	1	1	0	0	0	0	0	0	0	1
		DAY 43		29JUL2003	44	2	-17	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 50		05AUG2003	51	7	-12	2	1	0	1	0	2	0	0	0	0	0	0	0	1
		DAY 57		14AUG2003	60	4	-15	0	1	0	0	0	2	0	0	0	0	0	0	0	1
	E0031002	DAY 1		27NOV2002	1	27		3	2	1	2	2	3	2	2	2	1	3	1	2	1
		DAY 8		06DEC2002	10	16	-11	2	2	0	0	1	1	1	2	2	0	2	0	2	1
		DAY 15		12DEC2002	16	17	-10	2	2	0	1	1	2	2	2	1	1	1	0	1	1
		DAY 22		19DEC2002	23	15	-12	1	2	0	0	1	1	2	2	1	1	2	0	1	1
		DAY 29		27DEC2002	31	14	-13	2	2	0	1	2	2	2	1	0	0	1	0	1	0
		DAY 36		02JAN2003	37	10	-17	1	1	0	1	1	1	1	1	0	0	1	0	1	1
		DAY 50	*	13JAN2003	48	4	-23	1	1	0	0	0	0	1	0	0	0	0	0	1	0
		DAY 50		17JAN2003	52	6	-21	0	1	0	0	1	0	1	1	0	0	1	0	1	0
		DAY 57		22JAN2003	57	10	-17	1	2	0	0	1	0	2	1	0	0	1	0	1	1

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Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	DAY 1		10DEC2002	1	21		2	2	1	2	1	3	2	1	1	1	1	2	1	1
		DAY 8		17DEC2002	8	12	-9	2	2	1	1	1	2	0	0	1	1	0	0	1	0
		DAY 15		23DEC2002	14	12	-9	2	1	0	2	1	1	1	0	0	0	1	1	1	1
		DAY 22		31DEC2002	22	10	-11	2	1	0	1	1	1	1	0	0	0	1	1	1	0
		DAY 29		07JAN2003	29	14	-7	2	1	0	2	2	2	1	0	0	0	1	1	1	1
		DAY 36		15JAN2003	37	15	-6	2	2	1	2	1	2	0	0	0	0	2	1	1	1
		DAY 43		21JAN2003	43	11	-10	2	1	0	1	1	2	0	0	1	1	0	1	0	1
		DAY 50		30JAN2003	52	8	-13	2	0	0	1	2	1	0	0	0	0	1	0	0	1
		DAY 57		04FEB2003	57	8	-13	1	1	0	1	1	1	0	0	0	0	0	1	1	1
	E0033015	DAY 1		10APR2003	1	17		2	2	0	2	2	2	2	0	0	0	1	2	0	2
		DAY 8		17APR2003	8	24	7	2	2	1	1	2	2	2	2	2	1	1	2	2	2
		DAY 15		22APR2003	13	19	2	2	2	0	2	2	2	1	1	0	1	0	2	2	2
		DAY 15	*	28APR2003	19	21	4	1	3	0	3	2	2	1	1	1	1	1	1	2	2
		DAY 29		06MAY2003	27	16	-1	2	3	0	2	2	2	1	1	0	0	0	1	0	2
		DAY 36		13MAY2003	34	12	-5	1	2	0	1	2	1	0	1	0	0	0	2	0	2
		DAY 43		20MAY2003	41	17	0	1	2	1	2	2	1	1	1	1	0	0	2	2	1
		DAY 50		27MAY2003	48	8	-9	0	0	0	1	2	1	0	1	0	0	0	2	0	1
		DAY 57		04JUN2003	56	13	-4	1	1	0	1	1	1	0	1	0	1	2	2	1	1
	E0034002	DAY 1		25MAR2003	1	18		3	2	1	3	2	3	2	0	0	0	0	0	0	2
		DAY 8		01APR2003	8	5	-13	2	0	0	0	0	1	0	0	0	0	0	0	1	1
		DAY 15		08APR2003	15	6	-12	2	0	0	0	1	0	1	0	0	0	0	0	1	1
		DAY 22		15APR2003	22	8	-10	2	2	0	0	1	0	1	0	0	0	0	0	1	1
	E0034003	DAY 1		24APR2003	1	14		2	2	0	2	2	3	0	0	0	0	1	2	0	0
		DAY 8		01MAY2003	8	6	-8	1	1	0	0	1	1	0	0	0	0	0	2	0	0
		DAY 15		08MAY2003	15	3	-11	0	0	0	0	0	1	0	0	0	0	0	2	0	0
		DAY 22		15MAY2003	22	3	-11	0	0	0	0	0	1	0	0	0	0	0	2	0	0
		DAY 29		22MAY2003	29	0	-14	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	DAY 36	29MAY2003	36	1	-13	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 43	05JUN2003	43	1	-13	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 50	12JUN2003	50	1	-13	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 57	19JUN2003	57	0	-14	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0034006	DAY 1	16MAY2003	1	21		2	3	0	2	3	3	2	0	1	0	1	2	1	1
		DAY 8	23MAY2003	8	19	-2	2	3	0	0	3	3	2	0	1	0	1	2	1	1
		DAY 15	02JUN2003	18	22	1	3	3	0	2	3	3	2	0	1	0	1	2	1	1
		DAY 22	09JUN2003	25	23	2	3	3	0	2	3	3	2	0	1	0	2	2	1	1
		DAY 29	13JUN2003	29	22	1	3	3	0	2	3	3	2	0	1	0	2	2	0	1
		DAY 36	20JUN2003	36	24	3	3	3	0	2	3	3	3	0	1	0	2	2	1	1
		DAY 43	27JUN2003	43	25	4	3	3	0	2	3	3	3	0	1	0	2	2	2	1
		DAY 50	03JUL2003	49	23	2	3	3	0	2	3	3	3	0	1	0	0	2	2	1
		DAY 57	10JUL2003	56	24	3	3	3	0	2	3	3	3	0	1	0	0	2	2	2
	E0034008	DAY 1	23MAY2003	-1	11		2	2	0	1	2	3	0	0	0	0	0	0	0	1
		DAY 8	02JUN2003	10	11	0	2	3	0	0	2	3	0	0	0	0	0	0	0	1
		DAY 15	06JUN2003	14	10	-1	2	2	0	0	2	3	0	0	0	0	0	0	0	1
		DAY 22	13JUN2003	21	13	2	3	3	0	0	2	3	0	0	0	0	0	0	0	2
		DAY 29	20JUN2003	28	4	-7	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36	27JUN2003	35	0	-11	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	07JUL2003	45	0	-11	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	14JUL2003	52	0	-11	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	21JUL2003	59	0	-11	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0035003	DAY 1	22NOV2002	1	21		2	2	2	3	1	3	2	0	0	0	2	1	2	1
		DAY 8	27NOV2002	6	18	-3	2	2	2	0	1	3	2	0	0	0	2	1	2	1
		DAY 15	04DEC2002	13	17	-4	2	2	1	0	1	2	2	0	0	0	2	1	2	2
		DAY 22	13DEC2002	22	18	-3	2	2	1	1	1	2	2	0	0	0	2	1	2	2
		DAY 29	20DEC2002	29	13	-8	2	2	1	1	1	2	0	0	0	0	1	1	1	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	DAY 36	27DEC2002	36	14	-7	2	2	1	1	1	2	0	0	0	1	1	1	1	1
		DAY 43	03JAN2003	43	9	-12	1	2	0	1	1	1	0	0	0	0	1	1	1	0
		DAY 50	10JAN2003	50	10	-11	1	2	1	1	1	1	0	0	0	0	1	1	1	0
	E0035005	DAY 1	03DEC2002	1	21		3	1	2	3	2	2	1	1	1	1	1	1	2	0
		DAY 8	12DEC2002	10	17	-4	3	1	2	1	1	1	1	1	1	1	1	1	2	0
		DAY 15	17DEC2002	15	11	-10	2	1	1	1	1	1	1	1	0	0	0	1	1	0
		DAY 22	24DEC2002	22	7	-14	1	1	1	1	0	1	0	0	0	1	0	1	0	0
		DAY 29	31DEC2002	29	10	-11	2	1	1	1	1	1	0	0	0	0	1	1	1	0
		DAY 36	07JAN2003	36	6	-15	1	1	0	0	1	1	0	0	0	0	0	1	1	0
		DAY 43	14JAN2003	43	5	-16	1	0	1	0	0	1	1	0	0	0	0	1	0	0
		DAY 50	21JAN2003	50	9	-12	1	2	1	1	0	1	1	0	0	0	1	1	0	0
	E0035014	DAY 1	03FEB2003	1	17		3	2	2	1	1	3	0	0	0	0	1	3	0	1
		DAY 8	10FEB2003	8	15	-2	2	2	0	0	1	3	1	1	1	0	0	2	2	0
		DAY 15	17FEB2003	15	11	-6	1	1	0	0	1	2	1	1	0	0	0	2	2	0
		DAY 22	24FEB2003	22	16	-1	1	2	0	1	1	2	1	1	1	0	2	2	2	0
		DAY 29	03MAR2003	29	12	-5	2	2	0	0	0	2	0	0	1	0	1	2	2	0
		DAY 36	10MAR2003	36	12	-5	2	2	0	1	1	2	0	0	1	0	0	2	1	0
		DAY 43	17MAR2003	43	6	-11	1	1	0	0	0	1	0	0	0	0	0	2	1	0
		DAY 50	24MAR2003	50	6	-11	1	1	0	0	0	1	0	0	0	0	0	2	1	0
		DAY 57	31MAR2003	57	8	-9	1	1	0	0	1	1	0	0	0	0	1	3	0	0
	E0035024	DAY 1	22MAY2003	-1	24		3	2	3	4	1	3	1	1	0	0	1	3	1	1
		DAY 8	29MAY2003	7	25	1	3	3	3	3	2	3	1	1	0	0	0	3	2	1
		DAY 15	05JUN2003	14	18	-6	3	2	1	1	2	3	1	0	0	0	0	3	2	0
		DAY 22	13JUN2003	22	18	-6	3	2	1	1	2	3	1	0	0	0	0	3	2	0
		DAY 29	19JUN2003	28	16	-8	3	2	1	0	2	3	1	0	0	0	0	3	1	0
		DAY 36	27JUN2003	36	16	-8	3	2	1	1	2	3	0	0	0	0	0	2	1	1
		DAY 43	03JUL2003	42	18	-6	3	2	1	1	2	3	0	0	0	0	2	2	1	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	DAY 50	10JUL2003	49	19	-5	3	2	2	1	2	3	0	0	0	0	2	2	1	1
		DAY 57	18JUL2003	57	18	-6	3	2	1	1	2	3	0	0	0	0	2	2	1	1
	E0036005	DAY 1	01JUL2003	1	21		2	3	3	0	1	2	1	2	1	2	1	1	1	1
		DAY 8	08JUL2003	8	14	-7	2	1	0	1	2	2	1	0	2	0	0	0	2	1
		DAY 15	15JUL2003	15	10	-11	1	1	0	1	2	0	0	0	1	2	0	1	0	1
		DAY 22	23JUL2003	23	10	-11	1	1	0	0	2	2	0	1	0	0	1	1	1	0
		DAY 29	29JUL2003	29	6	-15	1	1	0	0	0	0	0	1	0	0	0	0	2	1
		DAY 36	05AUG2003	36	6	-15	2	0	1	0	0	1	0	1	1	0	0	0	0	0
		DAY 43	12AUG2003	43	9	-12	1	1	0	0	1	2	0	1	0	0	0	1	1	1
		DAY 50	19AUG2003	50	11	-10	2	1	0	0	2	2	0	0	2	0	0	1	0	1
		DAY 57	27AUG2003	58	6	-15	1	0	0	0	0	1	0	0	0	2	0	1	1	0
	E0037002	DAY 1	26DEC2002	1	17		2	2	0	2	2	3	0	0	1	1	1	1	2	0
		DAY 8	03JAN2003	9	12	-5	2	2	0	0	2	2	0	0	1	0	0	2	1	0
		DAY 15	09JAN2003	15	9	-8	1	1	0	0	1	1	1	0	1	0	0	2	1	0
		DAY 22	17JAN2003	23	8	-9	1	1	0	0	0	1	1	0	1	0	0	2	1	0
		DAY 29	24JAN2003	30	11	-6	1	2	0	1	2	2	0	0	0	0	1	1	1	0
		DAY 36	31JAN2003	37	9	-8	1	1	0	2	2	2	0	0	0	1	0	0	0	0
		DAY 43	07FEB2003	44	6	-11	1	1	0	0	1	1	1	0	0	0	0	0	1	0
		DAY 50	13FEB2003	50	10	-7	2	2	0	0	1	0	0	0	1	1	1	1	1	0
		DAY 57	20FEB2003	57	7	-10	2	0	0	0	2	0	0	0	0	0	1	0	2	0
	E0037005	DAY 1	06MAR2003	1	19		2	2	0	2	2	2	2	1	1	0	1	2	2	0
		DAY 8	13MAR2003	8	10	-9	1	1	0	0	1	1	1	0	1	0	1	1	2	0
		DAY 15	20MAR2003	15	15	-4	2	2	0	0	2	2	1	1	1	0	1	2	1	0
		DAY 22	27MAR2003	22	16	-3	2	2	0	0	2	2	2	1	1	1	1	1	1	0
		DAY 29	03APR2003	29	15	-4	2	2	0	0	1	2	2	0	1	1	0	2	2	0
		DAY 36	10APR2003	36	15	-4	1	2	0	0	2	2	2	0	1	1	1	2	1	0
		DAY 43	17APR2003	43	12	-7	1	2	0	0	2	1	1	0	0	1	1	2	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	DAY 50	24APR2003	50	12	-7	1	2	0	0	2	1	1	0	0	1	1	2	1	0
		DAY 57	01MAY2003	57	16	-3	2	2	0	0	2	1	2	1	1	1	1	2	1	0
	E0037006	DAY 1	14MAR2003	1	16		2	2	0	2	2	2	2	0	0	0	0	2	2	0
		DAY 8	21MAR2003	8	9	-7	1	2	0	0	1	1	1	0	0	0	0	2	1	0
		DAY 15	28MAR2003	15	8	-8	1	0	0	0	1	2	1	0	0	0	0	2	1	0
		DAY 22	04APR2003	22	6	-10	1	1	0	0	0	1	1	0	0	0	0	1	1	0
		DAY 29	11APR2003	29	8	-8	1	1	0	0	1	1	1	0	0	0	0	2	1	0
		DAY 36	18APR2003	36	11	-5	2	2	0	0	1	2	1	0	0	0	0	2	1	0
		DAY 43	25APR2003	43	9	-7	1	1	0	1	1	1	0	0	0	0	1	2	1	0
		DAY 50	01MAY2003	49	9	-7	1	1	0	1	1	1	0	0	0	0	1	2	1	0
		DAY 57	09MAY2003	57	5	-11	1	1	0	0	0	0	0	0	0	0	0	2	1	0
	E0039006	DAY 1	30DEC2002	1	8		1	1	0	2	1	2	0	0	0	0	0	0	1	0
		DAY 8	06JAN2003	8	15	7	3	3	0	2	2	2	1	0	0	0	0	1	0	1
		DAY 15	13JAN2003	15	15	7	3	3	0	2	2	2	1	0	0	0	0	1	0	1
		DAY 22	20JAN2003	22	8	0	0	1	0	2	1	3	1	0	0	0	0	0	0	0
		DAY 29	28JAN2003	30	7	-1	0	1	0	2	2	2	0	0	0	0	0	0	0	0
		DAY 36	04FEB2003	37	7	-1	0	1	0	2	2	2	0	0	0	0	0	0	0	0
		DAY 43	10FEB2003	43	4	-4	0	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 50	18FEB2003	51	6	-2	0	1	0	1	1	1	0	0	0	0	0	2	0	0
		DAY 57	24FEB2003	57	2	-6	1	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0039015	DAY 1	23JAN2003	1	14		2	1	0	3	1	2	1	0	1	1	1	0	0	1
		DAY 8	30JAN2003	8	5	-9	1	1	0	0	1	1	0	0	0	0	0	0	1	0
		DAY 15	06FEB2003	15	4	-10	1	1	0	0	0	1	0	0	0	0	0	0	1	0
		DAY 22	14FEB2003	23	4	-10	0	1	0	0	1	1	0	0	0	0	0	0	1	0
		DAY 29	20FEB2003	29	1	-13	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	27FEB2003	36	3	-11	0	1	0	0	0	0	1	0	0	0	0	0	0	1
		DAY 43	06MAR2003	43	4	-10	1	1	0	0	0	1	0	0	0	0	0	0	1	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0039015	DAY 50	14MAR2003	51	2	-12	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	20MAR2003	57	2	-12	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	E0039024	DAY 1	27FEB2003	1	10		2	2	1	2	1	2	0	0	0	0	0	0	0	0
		DAY 8	05MAR2003	7	6	-4	2	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 15	11MAR2003	13	3	-7	0	1	0	1	0	0	0	0	0	0	0	1	0	0
		DAY 22	20MAR2003	22	5	-5	1	1	0	1	0	1	0	0	0	1	0	0	0	0
		DAY 29	27MAR2003	29	10	0	0	0	0	2	2	2	1	0	0	0	1	1	1	0
		DAY 36	03APR2003	36	10	0	0	0	0	2	2	2	1	0	0	0	1	1	1	0
		DAY 43	10APR2003	43	5	-5	1	0	0	1	1	1	0	0	0	1	0	0	0	0
		DAY 50	17APR2003	50	3	-7	1	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	24APR2003	57	1	-9	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0039025	DAY 1	18MAR2003	1	7		1	1	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 8	25MAR2003	8	4	-3	1	1	0	0	0	1	0	0	0	0	0	0	0	1
		DAY 15	01APR2003	15	5	-2	2	1	0	0	1	0	0	0	0	0	0	0	0	1
		DAY 22	10APR2003	24	1	-6	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	15APR2003	29	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	22APR2003	36	5	-2	1	1	0	0	0	0	0	2	0	0	0	0	0	1
		DAY 43	29APR2003	43	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	06MAY2003	50	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0039041	DAY 1	15APR2003	1	7		1	1	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 8	22APR2003	8	8	1	2	1	0	2	0	2	0	0	0	0	0	0	0	1
		DAY 15	29APR2003	15	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	06MAY2003	22	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	13MAY2003	29	9	2	2	2	0	2	1	1	0	0	0	0	0	0	0	1
		DAY 36	20MAY2003	36	2	-5	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	27MAY2003	43	4	-3	1	1	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 50	03JUN2003	50	1	-6	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 57	11JUN2003	58	1	-6	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	E0039044	DAY 1	22MAY2003	1	6		1	1	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 8	29MAY2003	8	2	-4	0	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 15	04JUN2003	14	2	-4	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	11JUN2003	21	3	-3	1	1	0	0	0	0	0	0	1	0	0	0	0	0
		DAY 29	18JUN2003	28	0	-6	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	26JUN2003	36	2	-4	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	02JUL2003	42	5	-1	1	2	0	0	0	0	0	0	1	0	0	0	0	1
		DAY 50	09JUL2003	49	4	-2	2	1	0	0	1	0	0	0	0	0	0	0	0	0
	E0039046	*	21MAY2003		8		1	1	0	1	1	2	0	0	0	0	1	0	1	0
	E0039051	DAY 1	16JUN2003	1	7		1	1	0	1	1	1	1	0	0	0	0	0	1	0
		DAY 8	23JUN2003	8	7	0	1	1	0	1	1	1	0	0	0	1	0	1	0	0
		DAY 15	30JUN2003	15	5	-2	1	1	0	0	0	1	0	1	1	0	0	0	0	0
		DAY 22	07JUL2003	22	8	1	2	1	0	0	1	1	0	1	1	0	0	0	1	0
		DAY 29	14JUL2003	29	5	-2	1	0	0	1	0	1	0	0	1	0	0	0	1	0
		DAY 36	22JUL2003	37	8	1	1	1	0	0	1	1	1	1	1	1	0	0	0	0
		DAY 43	28JUL2003	43	3	-4	1	1	0	0	0	0	0	0	0	0	0	0	1	0
		DAY 50	04AUG2003	50	6	-1	1	1	0	0	0	1	0	0	1	0	1	0	1	0
		DAY 57	12AUG2003	58	4	-3	1	1	0	0	0	1	0	0	1	0	0	0	0	0
	E0039053	DAY 1	11JUL2003	1	10		2	0	0	2	1	2	0	0	1	1	0	0	1	0
		DAY 8	18JUL2003	8	8	-2	1	1	0	1	1	1	1	0	1	0	1	0	0	0
		DAY 15	25JUL2003	15	8	-2	2	1	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 22	01AUG2003	22	5	-5	1	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 29	07AUG2003	28	2	-8	1	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	14AUG2003	35	2	-8	1	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 43	21AUG2003	42	2	-8	1	0	0	0	0	0	0	0	0	0	1	0	0	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	DAY 50	29AUG2003	50	0	-10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	08SEP2003	60	8	-2	2	2	0	0	1	1	0	0	1	0	0	0	0	1
	E0039057	DAY 1	14JUL2003	1	8		1	1	0	2	1	2	0	0	1	0	0	0	0	0
		DAY 8	22JUL2003	9	2	-6	0	0	0	0	0	1	0	0	0	0	1	0	0	0
		DAY 15	28JUL2003	15	1	-7	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 22	04AUG2003	22	4	-4	1	0	0	0	1	0	0	0	0	0	1	1	0	0
		DAY 29	12AUG2003	30	1	-7	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	18AUG2003	36	0	-8	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	26AUG2003	44	3	-5	1	1	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 50	02SEP2003	51	4	-4	1	1	0	0	0	1	0	0	0	0	0	0	1	0
		DAY 57	09SEP2003	58	3	-5	0	1	0	0	1	0	0	0	0	0	0	0	0	1
	E0041003	DAY 1	28JAN2003	1	10		1	1	1	2	1	2	0	0	0	0	1	0	0	1
		DAY 8	04FEB2003	8	4	-6	0	0	0	1	0	1	0	0	0	0	0	0	2	0
		DAY 15	11FEB2003	15	2	-8	0	0	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 22	18FEB2003	22	3	-7	0	0	0	1	0	0	1	0	0	0	0	0	1	0
		DAY 29	25FEB2003	29	1	-9	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 36	04MAR2003	36	2	-8	0	0	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 43	11MAR2003	43	3	-7	0	0	0	1	0	1	0	0	0	0	0	0	1	0
		DAY 50	18MAR2003	50	3	-7	0	0	0	1	0	1	0	0	0	0	0	0	1	0
		DAY 57	25MAR2003	57	1	-9	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0041008	DAY 1	07APR2003	1	20		1	2	1	2	1	2	2	1	0	1	2	2	2	1
		DAY 8	14APR2003	8	20	0	2	2	1	2	1	2	2	1	0	1	1	2	2	1
		DAY 15	22APR2003	16	14	-6	2	2	0	2	1	1	0	0	0	0	1	2	2	1
		DAY 22	28APR2003	22	16	-4	2	1	1	2	1	2	0	1	0	0	1	2	2	1
		DAY 29	05MAY2003	29	13	-7	1	1	1	2	1	1	0	2	0	0	1	0	2	1
		DAY 36	12MAY2003	36	11	-9	2	1	0	2	1	1	0	1	0	0	0	2	0	1
		DAY 43	21MAY2003	45	13	-7	1	1	1	2	1	0	0	2	0	1	0	2	1	1

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	DAY 50	27MAY2003	51	14	-6	1	1	1	2	1	1	1	1	0	0	0	2	2	1
		DAY 57	02JUN2003	57	15	-5	2	2	1	2	1	1	0	0	0	0	2	2	2	0
	E0042001	DAY 1	02JUL2003	1	9		2	2	0	2	1	1	0	0	0	0	1	0	0	0
		DAY 8	09JUL2003	8	16	7	2	2	0	2	2	2	2	1	0	0	0	1	1	1
		DAY 15	15JUL2003	14	4	-5	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 22	22JUL2003	21	4	-5	1	1	0	0	1	0	0	0	0	0	1	0	0	0
		DAY 29	29JUL2003	28	6	-3	2	1	0	0	1	0	0	0	0	0	0	0	1	1
		DAY 36	05AUG2003	35	3	-6	1	0	0	0	1	0	0	0	0	0	1	0	0	0
		DAY 43	12AUG2003	42	3	-6	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 50	19AUG2003	49	4	-5	1	1	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 57	26AUG2003	56	3	-6	1	0	0	1	0	0	0	0	0	0	0	0	1	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	20		2	3	2	3	2	3	1	1	1	1	1	0	0	0
		DAY 8	19MAR2003	8	8	-12	1	0	0	1	2	3	0	0	0	0	0	0	1	0
		DAY 15	26MAR2003	15	5	-15	1	1	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 22	02APR2003	22	5	-15	1	1	0	0	1	1	0	0	1	0	0	0	0	0
		DAY 29	09APR2003	29	7	-13	2	1	0	1	1	1	0	0	1	0	0	0	0	0
		DAY 36	16APR2003	36	6	-14	1	0	0	0	1	1	0	1	1	0	0	0	1	0
		DAY 43	23APR2003	43	2	-18	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	30APR2003	50	1	-19	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	07MAY2003	57	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0003018	DAY 1	13MAY2003	1	8		2	1	0	1	1	2	0	0	0	0	1	0	0	0
		DAY 8	20MAY2003	8	5	-3	1	1	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 15	27MAY2003	15	12	4	2	2	0	1	2	2	1	0	0	1	0	0	0	1
		DAY 22	03JUN2003	22	16	8	2	2	2	1	1	2	1	0	1	1	1	1	0	1
		DAY 29	10JUN2003	29	22	14	3	2	1	2	2	3	2	0	1	1	1	1	2	1
		DAY 36	17JUN2003	36	14	6	2	2	0	1	1	2	1	0	1	1	1	1	0	1
		DAY 43	24JUN2003	43	10	2	2	1	1	1	1	1	1	0	0	1	0	0	0	1
		DAY 50	02JUL2003	51	19	11	2	2	2	2	1	1	1	2	2	2	0	0	1	1
		DAY 57	08JUL2003	57	22	14	2	2	2	2	1	1	2	2	2	2	1	1	1	1
	E0005011	DAY 1	24OCT2002	1	12		1	0	0	3	2	3	0	0	0	1	0	1	0	1
		DAY 8	31OCT2002	8	10	-2	0	0	0	0	2	3	0	0	2	1	1	1	0	0
		DAY 15	07NOV2002	15	8	-4	0	0	0	0	2	2	0	0	0	0	0	2	1	1
		DAY 22	14NOV2002	22	9	-3	0	1	0	0	0	2	0	1	1	1	0	1	1	1
		DAY 29	21NOV2002	29	6	-6	0	1	0	0	0	2	0	0	0	1	1	0	1	0
		DAY 36	26NOV2002	34	4	-8	1	1	0	0	0	1	0	0	0	0	1	0	0	0
		DAY 43	03DEC2002	41	4	-8	0	0	0	0	0	1	1	0	0	0	1	0	1	0
		DAY 50	12DEC2002	50	5	-7	0	0	0	0	0	1	1	1	0	0	2	0	0	0
	E0005030	DAY 1	26MAR2003	1	19		3	2	0	2	2	2	2	1	2	0	0	0	1	2

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0005030	DAY 8	02APR2003	8	18	-1	3	3	0	0	2	2	1	0	1	2	1	0	1	2
		DAY 15	09APR2003	15	8	-11	1	1	0	1	1	1	1	1	0	0	0	0	1	0
		DAY 22	16APR2003	22	20	1	3	2	0	2	1	2	1	1	0	1	1	2	1	3
	E0005036	DAY 1	06MAY2003	1	18		2	2	0	2	2	3	2	1	0	0	0	0	2	2
		DAY 8	12MAY2003	7	17	-1	2	2	0	1	2	2	2	1	1	0	0	1	2	1
	E0006015	DAY 1	11FEB2003	1	21		3	2	1	2	3	3	0	2	0	0	1	1	1	2
		DAY 8	18FEB2003	8	19	-2	2	2	1	2	3	2	0	1	1	1	1	1	1	1
		DAY 15	25FEB2003	15	31	10	2	2	2	3	4	4	2	3	3	1	1	1	2	1
		DAY 22	04MAR2003	22	25	4	2	2	2	2	3	3	1	2	2	1	1	1	2	1
		DAY 29	11MAR2003	29	22	1	2	2	2	1	3	3	2	2	1	1	1	1	0	1
		DAY 36	18MAR2003	36	19	-2	2	1	2	2	3	3	1	1	1	0	1	1	0	1
		DAY 43	25MAR2003	43	18	-3	2	2	1	2	3	3	1	1	1	0	0	1	0	1
		DAY 50	01APR2003	50	14	-7	1	2	0	2	2	2	1	1	0	1	1	0	1	0
		DAY 57	08APR2003	57	12	-9	1	2	0	2	2	2	1	1	0	0	0	0	1	0
	E0006016	DAY 1	17FEB2003	1	15		2	3	0	3	1	3	0	1	0	0	0	1	0	1
		DAY 8	24FEB2003	8	14	-1	1	1	0	0	2	3	0	0	0	0	2	2	2	1
		DAY 15	03MAR2003	15	13	-2	2	1	0	1	1	2	0	2	0	0	1	1	1	1
		DAY 22	10MAR2003	22	12	-3	2	1	0	1	1	2	0	2	0	0	1	0	1	1
		DAY 29	17MAR2003	29	12	-3	2	1	0	1	1	2	0	1	0	0	1	1	1	1
		DAY 36	27MAR2003	39	10	-5	1	1	0	1	1	2	0	1	0	0	0	1	1	1
		DAY 43	03APR2003	46	11	-4	1	2	0	2	2	1	0	1	0	0	0	0	1	1
		DAY 50	10APR2003	53	9	-6	1	1	0	0	2	1	1	1	0	0	0	0	1	1
		DAY 57	18APR2003	61	9	-6	1	1	0	0	2	1	1	1	0	0	0	0	1	1
	E0007008	DAY 1	18APR2003	1	10		2	2	0	2	1	2	0	0	0	0	0	0	0	1
		DAY 8	25APR2003	8	10	0	2	2	0	2	2	2	0	0	0	0	0	0	0	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0009002	DAY 1	19NOV2002	1	25		3	3	1	4	4	3	0	1	0	0	0	3	0	3
		DAY 8	26NOV2002	8	11	-14	1	2	0	0	2	1	0	1	0	0	0	2	0	2
		DAY 15	03DEC2002	15	13	-12	2	2	2	2	0	3	0	0	0	0	0	0	0	2
		DAY 22	10DEC2002	22	16	-9	2	2	3	1	2	2	0	0	0	0	0	1	1	2
		DAY 29	18DEC2002	30	12	-13	1	2	0	0	2	1	2	0	0	0	0	2	1	1
		DAY 36	23DEC2002	35	18	-7	2	1	2	0	3	2	2	1	0	1	1	2	0	1
		DAY 43	30DEC2002	42	18	-7	3	1	1	2	1	2	1	0	1	1	0	2	1	2
		DAY 50	07JAN2003	50	9	-16	1	1	1	0	1	1	0	0	1	0	0	2	1	0
		DAY 57	15JAN2003	58	14	-11	2	2	1	1	2	2	0	0	0	0	0	2	1	1
	E0009006	DAY 1	28JAN2003	1	20		3	1	1	3	2	3	2	1	1	0	0	0	2	1
		DAY 8	04FEB2003	8	13	-7	2	1	0	0	1	1	2	1	1	1	0	0	1	2
		DAY 15	11FEB2003	15	16	-4	2	1	1	0	1	2	1	1	2	1	1	0	2	1
		DAY 22	18FEB2003	22	16	-4	2	2	0	1	1	2	2	2	0	0	0	0	2	2
		DAY 29	25FEB2003	29	13	-7	1	1	1	1	1	2	0	1	1	1	0	0	2	1
		DAY 36	04MAR2003	36	12	-8	1	1	0	1	1	2	2	1	1	1	0	0	1	0
		DAY 43	11MAR2003	43	14	-6	1	2	1	1	1	2	1	1	1	0	0	0	2	1
		DAY 50	18MAR2003	50	18	-2	2	2	1	1	2	2	1	2	2	0	0	0	2	1
		DAY 57	25MAR2003	57	17	-3	2	1	1	2	1	2	1	1	2	0	0	0	2	2
	E0009009	DAY 1	12MAR2003	1	11		2	2	0	2	1	2	1	0	1	0	0	0	0	0
		DAY 8	19MAR2003	8	12	1	2	1	0	0	1	2	1	1	1	1	0	0	1	1
		DAY 15	24MAR2003	13	7	-4	1	1	1	0	1	1	1	0	0	0	1	0	0	0
	E0010015	DAY 1	20FEB2003	1	28		2	3	0	4	2	3	1	1	2	1	2	3	2	2
		DAY 8	27FEB2003	8	14	-14	1	0	0	2	1	1	1	2	1	0	0	3	1	1
		DAY 15	06MAR2003	15	23	-5	2	3	0	4	3	3	1	2	1	0	0	1	2	1
		DAY 22	13MAR2003	22	20	-8	2	2	0	3	2	3	1	1	0	0	0	3	2	1
		DAY 29	20MAR2003	29	14	-14	0	1	0	3	1	2	1	1	0	0	2	1	1	1
		DAY 36	26MAR2003	35	14	-14	2	1	0	4	1	0	1	1	0	0	1	0	2	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	DAY 43		02APR2003	42	12	-16	0	1	0	4	1	0	1	1	0	0	2	0	1	1
		DAY 50		09APR2003	49	10	-18	0	1	0	3	0	0	1	1	0	0	1	0	2	1
		DAY 57		15APR2003	55	9	-19	0	0	0	3	1	0	0	1	0	0	2	0	1	1
	E0011004	DAY 1		24DEC2002	1	20		2	2	0	3	1	3	2	1	0	0	1	3	0	2
		DAY 8		31DEC2002	8	13	-7	2	2	0	2	1	2	0	0	0	0	1	1	0	2
		DAY 15		07JAN2003	15	15	-5	2	2	0	2	1	1	2	1	1	1	0	0	1	1
		DAY 22		14JAN2003	22	13	-7	1	1	0	2	2	1	1	0	0	1	3	0	1	0
		DAY 29		21JAN2003	29	5	-15	0	0	0	1	1	1	0	0	0	0	0	0	1	1
		DAY 36		28JAN2003	36	15	-5	2	2	0	2	1	2	0	1	1	0	0	1	2	1
		DAY 43		04FEB2003	43	15	-5	2	2	0	3	2	2	0	0	0	1	2	0	0	1
		DAY 50		11FEB2003	50	10	-10	2	2	0	0	0	2	0	0	1	0	1	0	0	2
		DAY 57		18FEB2003	57	3	-17	0	0	0	1	0	1	1	0	0	0	0	0	0	0
	E0011007	DAY 1		19DEC2002	1	14		2	2	0	1	2	2	0	0	1	1	0	2	1	0
		DAY 8		26DEC2002	8	14	0	1	1	0	2	1	1	2	1	1	0	1	0	2	1
		DAY 15		02JAN2003	15	18	4	2	2	0	2	1	2	2	0	0	0	2	2	2	1
		DAY 22		09JAN2003	22	14	0	1	2	0	1	1	1	1	1	1	1	1	0	1	2
		DAY 29		17JAN2003	30	13	-1	1	1	0	2	1	1	0	0	1	1	2	1	1	1
		DAY 36		23JAN2003	36	20	6	3	2	0	2	1	1	0	0	2	2	3	1	2	1
		DAY 43		30JAN2003	43	14	0	2	1	0	1	1	1	0	1	2	0	1	0	3	1
		DAY 50		06FEB2003	50	8	-6	0	0	0	2	0	1	0	0	1	0	0	1	2	1
		DAY 57		13FEB2003	57	7	-7	0	1	0	1	1	0	1	0	0	0	0	0	2	1
	E0011018	DAY 1		22MAY2003	1	19		3	3	0	3	2	2	1	1	0	0	0	2	1	1
		DAY 8		30MAY2003	9	15	-4	2	2	0	1	2	2	1	0	0	0	1	2	1	1
		DAY 22	*	10JUN2003	20	12	-7	1	1	0	2	1	2	1	0	0	0	1	1	1	1
		DAY 22		13JUN2003	23	8	-11	1	1	0	1	1	0	0	0	0	0	0	3	1	0
		DAY 29		20JUN2003	30	8	-11	1	1	0	1	1	1	0	0	0	0	0	3	0	0
		DAY 36		28JUN2003	38	7	-12	1	2	0	0	2	1	1	0	0	0	0	0	0	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	DAY 43		03JUL2003	43	8	-11	1	1	0	0	2	0	1	0	0	0	0	3	0	0
		DAY 50		10JUL2003	50	4	-15	1	1	0	0	0	1	0	0	0	0	0	1	0	0
		DAY 57		17JUL2003	57	4	-15	1	1	0	0	1	0	0	0	0	0	0	1	0	0
	E0011024	DAY 1		24JUN2003	1	17		2	2	0	3	2	3	0	0	1	1	2	0	0	1
		DAY 8		01JUL2003	8	16	-1	2	3	0	1	1	3	0	0	0	0	3	2	0	1
		DAY 15		08JUL2003	15	17	0	2	3	0	1	1	3	0	1	0	0	3	2	0	1
		DAY 22		15JUL2003	22	18	1	2	3	0	1	1	3	0	1	1	0	3	2	0	1
		DAY 29		22JUL2003	29	16	-1	1	2	0	1	1	2	1	1	1	0	2	2	1	1
		DAY 36		30JUL2003	37	11	-6	1	1	0	0	1	1	1	1	0	0	1	2	1	1
		DAY 43		05AUG2003	43	9	-8	1	1	0	0	1	1	1	1	0	0	0	1	1	1
		DAY 50		12AUG2003	50	2	-15	0	0	0	0	1	0	0	0	0	0	0	0	0	1
		DAY 57		21AUG2003	59	7	-10	1	1	0	0	1	0	0	1	0	1	0	1	0	1
	E0015003	DAY 1		25NOV2002	1	15		2	2	0	2	0	3	0	1	1	1	1	0	1	1
		DAY 8		02DEC2002	8	16	1	2	3	0	0	3	3	0	0	1	1	1	0	1	1
	E0019003	DAY 1		21NOV2002	1	29		3	3	2	3	3	3	1	2	1	0	2	2	3	1
		DAY 8		27NOV2002	7	13	-16	2	1	2	1	2	2	0	0	0	0	2	1	0	0
		DAY 15		09DEC2002	19	6	-23	0	0	0	0	2	1	0	0	0	0	1	1	0	1
		DAY 22		16DEC2002	26	6	-23	2	1	0	0	0	1	1	0	0	0	1	0	0	0
		DAY 36		24DEC2002	34	11	-18	2	2	0	1	0	2	1	0	0	0	2	1	0	0
		DAY 36	*	30DEC2002	40	5	-24	0	0	0	0	0	1	1	0	0	0	1	1	0	1
		DAY 43		06JAN2003	47	7	-22	1	0	0	1	1	1	0	0	0	0	1	1	0	1
		DAY 57	*	14JAN2003	55	4	-25	0	0	0	0	1	0	0	0	0	0	2	1	0	0
		DAY 57		16JAN2003	57	6	-23	2	1	0	0	0	0	0	1	0	0	1	0	1	0
	E0019007	DAY 1		13NOV2002	1	21		3	3	2	3	1	3	1	1	1	1	1	0	1	0
		DAY 8		21NOV2002	9	18	-3	3	2	2	0	2	2	0	1	1	0	0	3	1	1
		DAY 15		27NOV2002	15	10	-11	2	1	1	1	1	2	0	0	0	0	0	2	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0019007	DAY 22	05DEC2002	23	7	-14	2	1	0	1	0	1	0	0	0	0	0	2	0	0
		DAY 29	12DEC2002	30	4	-17	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36	17DEC2002	35	11	-10	1	1	0	2	1	2	0	0	1	0	0	2	0	1
		DAY 43	24DEC2002	42	10	-11	2	1	0	2	1	1	0	0	0	0	0	2	0	1
		DAY 50	30DEC2002	48	17	-4	2	2	0	1	2	2	1	0	1	1	1	2	1	1
		DAY 57	07JAN2003	56	21	0	2	2	0	2	2	3	1	0	1	0	2	2	2	2
	E0019014	DAY 1	09JAN2003	1	13		3	2	0	3	1	2	0	0	0	0	0	0	1	1
		DAY 8	20JAN2003	12	11	-2	2	1	0	2	1	2	1	0	0	0	0	0	1	1
	E0019018	DAY 1	30JAN2003	1	24		3	3	1	2	2	3	1	0	1	1	1	2	2	2
		DAY 8	06FEB2003	8	17	-7	2	1	1	0	3	3	0	0	1	1	1	2	0	2
		DAY 15	13FEB2003	15	8	-16	1	1	0	0	1	1	0	0	0	0	0	2	0	2
		DAY 22	20FEB2003	22	12	-12	2	1	1	0	2	2	1	0	0	0	0	2	0	1
		DAY 29	27FEB2003	29	11	-13	2	2	0	0	1	2	0	0	0	0	0	2	0	2
		DAY 36	06MAR2003	36	19	-5	3	2	1	1	2	3	1	0	1	0	1	2	0	2
		DAY 43	13MAR2003	43	15	-9	2	2	1	0	3	3	0	0	0	0	0	2	0	2
		DAY 50	20MAR2003	50	17	-7	2	2	1	0	3	2	0	0	1	0	0	3	2	1
		DAY 57	27MAR2003	57	15	-9	2	2	1	0	3	2	0	0	1	0	0	3	0	1
	E0019022	DAY 1	30JAN2003	1	18		3	2	1	2	1	3	0	0	0	0	2	0	2	2
		DAY 8	06FEB2003	8	16	-2	2	2	1	1	2	3	1	0	0	0	1	0	1	2
		DAY 15	13FEB2003	15	12	-6	2	2	0	0	2	2	1	0	0	0	1	0	0	2
		DAY 22	20FEB2003	22	11	-7	2	1	0	1	2	2	0	0	0	0	1	0	0	2
		DAY 29	27FEB2003	29	9	-9	1	0	0	1	2	2	0	0	0	0	1	0	0	2
		DAY 36	06MAR2003	36	7	-11	0	2	0	0	1	1	0	0	0	0	0	0	1	2
		DAY 43	13MAR2003	43	8	-10	2	1	1	0	1	0	0	0	1	0	2	0	0	0
		DAY 50	20MAR2003	50	8	-10	1	2	0	1	0	1	0	0	0	0	2	0	0	1
		DAY 57	27MAR2003	57	9	-9	2	1	0	1	1	1	1	0	0	0	0	0	0	2

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	DAY 1	27FEB2003	1	23		3	3	2	3	3	3	1	1	0	0	0	3	1	0
		DAY 8	06MAR2003	8	24	1	2	2	2	2	1	2	2	1	3	1	2	2	1	1
	E0019032	DAY 1	01APR2003	1	26		3	2	2	3	2	3	1	1	1	0	2	3	2	1
		DAY 8	08APR2003	8	21	-5	2	2	1	1	2	2	1	0	1	1	2	3	3	0
		DAY 15	15APR2003	15	23	-3	2	3	1	1	3	2	1	1	1	0	2	3	3	0
		DAY 22	21APR2003	21	25	-1	2	3	1	1	3	2	1	1	1	0	2	3	3	2
		DAY 29	29APR2003	29	10	-16	1	0	1	1	1	2	0	0	0	0	1	2	0	1
		DAY 36	07MAY2003	37	9	-17	2	1	0	0	2	1	0	0	0	0	0	2	0	1
		DAY 43	14MAY2003	44	10	-16	2	1	0	1	1	1	0	0	0	0	0	2	1	1
		DAY 50	21MAY2003	51	15	-11	3	2	0	1	2	2	0	0	0	0	1	2	1	1
		DAY 57	27MAY2003	57	22	-4	2	3	1	0	2	1	1	0	2	2	3	2	1	2
	E0019034	DAY 1	18MAR2003	1	22		2	2	1	3	2	3	1	0	1	1	2	2	1	1
		DAY 8	25MAR2003	8	7	-15	0	0	0	0	2	2	0	0	0	0	0	1	2	0
		DAY 15	01APR2003	15	8	-14	1	1	3	0	0	0	0	0	0	0	0	3	0	0
	E0019036	DAY 1	25MAR2003	1	36		3	3	2	2	2	3	2	2	3	2	3	3	3	3
		DAY 8	31MAR2003	7	19	-17	2	2	2	0	2	2	0	0	2	1	1	1	2	2
		DAY 15	10APR2003	17	11	-25	2	2	0	0	1	2	0	0	0	0	2	1	1	0
		DAY 22	15APR2003	22	15	-21	2	2	1	0	1	1	1	0	1	1	1	1	1	2
		DAY 29	22APR2003	29	12	-24	2	1	1	0	1	0	0	0	1	1	1	1	1	2
		DAY 36	29APR2003	36	9	-27	1	1	1	0	0	0	0	0	1	0	2	1	1	1
	E0019039	DAY 1	01MAY2003	1	23		3	2	1	2	2	3	1	0	1	0	2	2	2	2
	E0019041	DAY 1	21MAY2003	1	20		2	3	0	2	3	2	0	0	1	2	1	1	1	2
		DAY 8	28MAY2003	8	13	-7	2	1	0	0	2	2	0	0	1	0	2	1	1	1
		DAY 15	04JUN2003	15	16	-4	2	2	0	0	2	2	1	1	1	0	2	1	2	0
		DAY 22	12JUN2003	23	12	-8	2	2	0	1	1	2	0	0	1	0	1	1	0	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	DAY 29	18JUN2003	29	9	-11	2	1	0	2	1	1	0	0	0	0	0	0	1	1
		DAY 36	25JUN2003	36	4	-16	1	1	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 43	02JUL2003	43	3	-17	0	0	0	1	0	1	0	0	0	0	0	0	0	1
		DAY 50	09JUL2003	50	4	-16	0	0	0	1	0	1	0	0	0	0	1	0	1	0
		DAY 57	16JUL2003	57	5	-15	1	0	0	2	0	1	0	0	0	0	0	0	0	1
	E0019049	DAY 1	10JUL2003	1	28		3	3	1	3	2	3	1	0	2	1	2	2	2	3
		DAY 8	17JUL2003	8	13	-15	2	2	0	0	1	2	0	0	1	1	1	2	0	1
		DAY 15	24JUL2003	15	19	-9	3	1	0	2	1	2	0	0	1	2	2	2	1	2
		DAY 22	31JUL2003	22	17	-11	2	1	0	2	1	2	2	0	1	1	2	2	0	1
		DAY 29	07AUG2003	29	20	-8	3	3	0	3	0	2	0	0	1	1	2	2	1	2
		DAY 36	14AUG2003	36	14	-14	2	2	0	2	0	3	0	0	0	0	1	2	0	2
		DAY 50	26AUG2003	48	17	-11	2	2	0	1	1	3	1	0	0	1	1	2	1	2
		DAY 57	08SEP2003	61	22	-6	3	3	0	3	2	3	1	0	0	0	0	2	2	3
	E0022052	DAY 1	10APR2003	1	13		2	1	0	2	2	3	0	0	1	0	0	1	0	1
		DAY 8	17APR2003	8	8	-5	1	1	0	0	1	2	1	0	1	0	0	1	0	0
		DAY 15	24APR2003	15	13	0	2	2	0	1	1	2	1	0	1	1	1	1	0	0
		DAY 22	01MAY2003	22	16	3	2	2	0	2	2	2	0	0	1	1	0	2	1	1
		DAY 29	08MAY2003	29	18	5	2	2	1	2	2	2	1	1	1	1	1	1	1	0
		DAY 36	15MAY2003	36	21	8	3	3	1	2	2	2	1	1	1	1	1	1	1	1
		DAY 43	22MAY2003	43	20	7	2	2	1	2	1	3	1	1	1	1	2	1	1	1
		DAY 50	29MAY2003	50	17	4	2	2	1	2	1	2	1	0	1	1	1	1	1	1
		DAY 57	05JUN2003	57	14	1	2	2	0	2	2	2	1	0	1	0	0	1	1	0
	E0022064	DAY 1	06MAY2003	1	11		2	2	0	1	2	2	1	0	0	0	1	0	0	0
		DAY 8	12MAY2003	7	5	-6	1	0	0	0	1	2	0	0	1	0	0	0	0	0
		DAY 15	20MAY2003	15	1	-10	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 22	27MAY2003	22	2	-9	0	0	0	0	1	0	0	0	0	0	1	0	0	0
		DAY 29	03JUN2003	29	2	-9	0	0	0	0	1	1	0	0	0	0	0	0	0	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	DAY 36	10JUN2003	36	1	-10	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43	17JUN2003	43	1	-10	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	24JUN2003	50	1	-10	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 57	01JUL2003	57	2	-9	0	0	0	0	1	0	0	0	0	0	1	0	0	0
	E0022073	DAY 1	26JUN2003	1	8		1	0	0	2	1	2	1	0	0	0	0	0	0	1
		DAY 8	03JUL2003	8	6	-2	1	1	0	0	1	1	1	0	0	0	0	1	0	0
		DAY 15	10JUL2003	15	1	-7	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 22	17JUL2003	22	2	-6	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 29	24JUL2003	29	2	-6	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 36	31JUL2003	36	3	-5	0	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 43	07AUG2003	43	5	-3	1	0	0	0	1	1	0	0	0	0	0	1	0	1
		DAY 50	14AUG2003	50	7	-1	1	0	0	1	1	1	1	0	0	0	1	0	1	0
		DAY 57	21AUG2003	57	4	-4	0	0	0	1	1	1	1	0	0	0	0	0	0	0
	E0023002	DAY 1	05NOV2002	1	23		3	2	0	1	3	3	3	0	1	0	3	0	2	2
		DAY 8	12NOV2002	8	22	-1	3	3	0	0	3	3	3	0	0	0	3	0	2	2
		DAY 15	19NOV2002	15	23	0	3	3	0	1	3	3	3	0	0	0	3	0	2	2
		DAY 22	25NOV2002	21	22	-1	3	3	0	0	3	3	3	0	0	0	3	0	2	2
		DAY 29	03DEC2002	29	21	-2	3	3	0	0	3	3	3	0	0	0	3	0	2	1
		DAY 36	10DEC2002	36	22	-1	3	3	0	0	3	3	3	0	1	0	3	0	2	1
	E0023017	DAY 1	25MAR2003	1	18		2	2	0	3	3	3	1	0	0	0	0	1	0	3
		DAY 8	03APR2003	10	15	-3	2	2	0	0	4	3	0	0	0	1	0	1	0	2
		DAY 15	10APR2003	17	4	-14	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 22	18APR2003	25	4	-14	1	0	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 29	24APR2003	31	8	-10	1	1	0	1	3	1	0	0	0	0	0	0	0	1
		DAY 36	01MAY2003	38	0	-18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	08MAY2003	45	2	-16	0	0	0	0	2	0	0	0	0	0	0	0	0	0
		DAY 50	15MAY2003	52	1	-17	0	0	0	0	1	0	0	0	0	0	0	0	0	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	DAY 57	22MAY2003	59	3	-15	0	0	0	1	2	0	0	0	0	0	0	0	0	0
	E0023021	DAY 1	23APR2003	1	25		3	2	2	3	2	3	2	0	2	2	2	0	1	1
		DAY 8	29APR2003	7	25	0	3	2	2	1	2	3	2	1	2	2	2	0	2	1
		DAY 15	06MAY2003	14	14	-11	2	2	2	1	2	2	0	1	1	0	1	0	0	0
		DAY 22	13MAY2003	21	13	-12	2	2	0	1	2	2	1	1	1	0	1	0	0	0
		DAY 29	20MAY2003	28	11	-14	2	2	0	0	1	2	1	1	1	0	1	0	0	0
		DAY 36	29MAY2003	37	21	-4	3	3	0	2	1	3	2	1	1	1	2	0	1	1
		DAY 43	03JUN2003	42	13	-12	3	1	0	2	1	2	2	1	0	0	0	0	1	0
		DAY 50	10JUN2003	49	21	-4	3	2	1	2	2	3	2	2	2	1	0	0	1	0
		DAY 57	17JUN2003	56	23	-2	3	2	1	3	2	3	2	2	2	2	0	0	1	0
	E0023027	DAY 1	16MAY2003	1	25		3	3	2	2	2	3	2	0	3	0	2	2	0	1
		DAY 8	21MAY2003	6	30	5	3	3	0	0	2	3	2	2	1	2	3	3	3	3
		DAY 15	30MAY2003	15	28	3	3	2	0	0	2	3	2	2	2	2	3	3	3	1
		DAY 22	05JUN2003	21	22	-3	2	2	0	2	2	2	0	1	1	2	3	1	3	1
		DAY 29	11JUN2003	27	30	5	3	3	0	2	2	3	2	2	1	2	2	3	3	2
		DAY 36	18JUN2003	34	23	-2	3	3	0	1	2	2	2	2	0	0	2	2	2	2
		DAY 43	27JUN2003	43	20	-5	2	2	0	1	2	3	1	1	0	0	2	2	2	2
		DAY 50	02JUL2003	48	20	-5	2	2	0	3	2	3	2	1	0	0	2	1	1	1
		DAY 57	09JUL2003	55	22	-3	3	3	0	3	3	3	2	0	0	0	2	1	1	1
	E0023030	DAY 1	03JUN2003	1	20		3	3	2	2	3	3	0	0	0	0	0	3	0	1
		DAY 8	10JUN2003	8	18	-2	3	3	1	0	2	3	1	1	0	0	1	1	2	0
		DAY 15	17JUN2003	15	14	-6	2	2	1	0	1	2	1	1	0	0	1	1	2	0
		DAY 22	24JUN2003	22	7	-13	1	1	0	0	2	2	0	0	0	0	0	0	0	1
		DAY 29	01JUL2003	29	6	-14	1	1	0	0	2	2	0	0	0	0	0	0	0	0
		DAY 36	08JUL2003	36	3	-17	1	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 43	15JUL2003	43	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	21JUL2003	49	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	DAY 57		30JUL2003	58	1	-19	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0023040	DAY 1		03JUL2003	1	22		3	3	2	3	2	3	1	0	2	0	1	1	0	1
		DAY 8		12JUL2003	10	20	-2	3	2	1	1	2	3	2	0	1	1	1	1	1	1
		DAY 15		17JUL2003	15	15	-7	3	2	0	1	1	2	2	1	0	1	0	1	1	0
		DAY 22		25JUL2003	23	15	-7	2	2	0	1	1	2	0	1	1	1	2	1	1	0
		DAY 36	*	05AUG2003	34	19	-3	3	3	0	1	1	2	1	1	1	1	2	1	2	0
		DAY 36		08AUG2003	37	16	-6	3	3	0	1	2	2	0	1	1	1	1	0	1	0
		DAY 43		18AUG2003	47	10	-12	1	1	0	1	2	1	0	1	1	0	1	0	1	0
		DAY 57	*	28AUG2003	57	15	-7	2	2	0	2	2	1	1	1	1	0	2	0	1	0
		DAY 57		05SEP2003	65	15	-7	2	3	0	1	3	1	1	1	1	0	2	0	0	0
	E0026014	DAY 1		19FEB2003	1	19		1	2	2	4	3	2	1	0	1	0	2	0	1	0
		DAY 8		26FEB2003	8	9	-10	1	0	1	0	0	0	0	0	1	1	2	0	2	1
		DAY 15		05MAR2003	15	5	-14	1	1	1	0	0	0	0	1	0	0	0	0	1	0
		DAY 22		12MAR2003	22	12	-7	1	1	1	0	0	3	0	0	1	1	1	0	2	1
		DAY 29		19MAR2003	29	17	-2	1	3	1	0	1	4	1	1	1	1	0	0	2	1
	E0026019	DAY 1		17MAR2003	1	41		4	3	2	4	4	4	3	3	2	3	2	3	3	1
		DAY 8		24MAR2003	8	23	-18	3	3	1	0	3	3	1	1	2	1	2	0	1	2
		DAY 15		31MAR2003	15	23	-18	2	3	1	0	2	0	2	1	3	2	2	0	2	3
		DAY 22		07APR2003	22	20	-21	3	3	0	2	2	1	1	2	1	1	1	0	1	2
		DAY 29		14APR2003	29	14	-27	2	3	0	1	2	0	1	0	2	1	1	0	1	0
		DAY 36		21APR2003	36	14	-27	2	2	0	1	2	0	1	1	1	1	1	0	1	1
		DAY 43		28APR2003	43	12	-29	2	2	1	1	2	2	1	0	0	0	0	0	0	1
		DAY 50		05MAY2003	50	18	-23	3	3	1	3	3	3	0	0	0	0	0	0	0	2
		DAY 57		12MAY2003	57	15	-26	3	2	1	3	2	3	0	0	0	0	0	0	0	1
	E0027005	DAY 1		26DEC2002	1	27		2	3	3	3	3	3	1	0	1	1	2	1	2	2
		DAY 8		02JAN2003	8	19	-8	2	1	3	2	2	2	2	0	0	0	0	2	2	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0027005	DAY 15	09JAN2003	15	13	-14	2	2	0	1	2	2	1	0	0	0	1	0	1	1
		DAY 22	16JAN2003	22	14	-13	2	2	2	1	2	1	1	0	0	0	1	1	1	0
		DAY 29	23JAN2003	29	14	-13	2	1	2	1	2	2	0	0	0	0	0	2	2	0
		DAY 36	30JAN2003	36	17	-10	2	2	2	2	2	1	1	0	1	0	1	2	0	1
		DAY 43	06FEB2003	43	18	-9	2	2	2	2	2	2	1	0	1	1	0	2	0	1
		DAY 50	12FEB2003	49	17	-10	2	1	2	2	1	2	0	0	1	0	2	2	1	1
		DAY 57	20FEB2003	57	16	-11	2	1	2	2	1	2	0	0	1	0	2	2	1	0
	E0029009	DAY 1	20JAN2003	1	22		2	2	0	2	2	2	2	2	0	0	2	2	2	2
		DAY 8	27JAN2003	8	17	-5	1	2	0	1	2	1	2	0	1	1	2	2	1	1
		DAY 15	03FEB2003	15	7	-15	1	1	0	1	2	0	0	0	0	0	0	2	0	0
		DAY 22	11FEB2003	23	12	-10	2	2	0	0	2	0	1	0	0	0	0	2	1	2
		DAY 29	17FEB2003	29	11	-11	2	2	0	0	1	1	0	0	0	0	1	2	1	1
		DAY 36	24FEB2003	36	14	-8	2	2	0	0	2	2	2	0	0	0	0	2	0	2
		DAY 43	03MAR2003	43	6	-16	1	1	0	1	1	1	0	0	0	0	0	1	0	0
		DAY 50	11MAR2003	51	13	-9	2	2	0	1	1	0	2	0	0	0	1	2	1	1
		DAY 57	18MAR2003	58	6	-16	1	1	0	0	1	0	1	0	0	0	0	2	0	0
	E0029021	DAY 1	18MAR2003	1	22		3	3	0	2	2	3	2	1	2	1	0	0	2	1
		DAY 8	25MAR2003	8	13	-9	1	2	0	0	2	2	1	1	1	1	0	0	1	1
		DAY 15	01APR2003	15	10	-12	2	2	0	0	3	2	0	0	0	0	0	0	1	0
		DAY 22	07APR2003	21	4	-18	1	1	0	0	0	1	0	0	0	0	0	0	1	0
		DAY 29	15APR2003	29	5	-17	1	1	0	0	2	0	0	0	0	0	0	0	0	1
		DAY 36	22APR2003	36	6	-16	1	1	0	1	1	1	0	0	0	0	0	1	0	0
		DAY 43	29APR2003	43	2	-20	0	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 50	06MAY2003	50	6	-16	1	2	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 57	15MAY2003	59	6	-16	0	2	0	0	1	1	0	0	0	1	1	0	0	0
	E0029026	DAY 1	14APR2003	1	11		0	0	0	3	2	3	1	0	0	0	1	1	0	0
		DAY 8	21APR2003	8	8	-3	0	0	0	0	0	2	1	1	1	0	1	2	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	DAY 15	28APR2003	15	3	-8	0	0	0	0	0	1	1	0	0	0	0	1	0	0
		DAY 22	05MAY2003	22	0	-11	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	12MAY2003	29	3	-8	0	0	0	0	0	0	1	0	0	0	1	1	0	0
		DAY 36	19MAY2003	36	3	-8	0	0	0	0	0	0	1	0	0	0	1	1	0	0
		DAY 43	28MAY2003	45	6	-5	0	0	0	0	0	0	2	0	0	0	2	2	0	0
		DAY 50	02JUN2003	50	4	-7	0	0	0	1	0	0	1	0	0	0	1	1	0	0
		DAY 57	10JUN2003	58	2	-9	0	0	0	0	0	0	1	0	0	0	1	0	0	0
	E0029030	DAY 1	27MAY2003	1	17		2	2	2	2	2	3	1	0	0	0	1	0	1	1
		DAY 8	03JUN2003	8	14	-3	2	2	0	0	2	2	1	0	0	0	2	2	1	0
		DAY 15	10JUN2003	15	6	-11	1	1	0	1	1	1	1	0	0	0	0	0	0	0
		DAY 22	17JUN2003	22	4	-13	1	1	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 29	26JUN2003	31	0	-17	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	02JUL2003	37	2	-15	0	0	0	0	1	0	1	0	0	0	0	0	0	0
		DAY 43	09JUL2003	44	5	-12	1	2	0	0	0	0	1	1	0	0	0	0	0	0
		DAY 50	16JUL2003	51	3	-14	0	1	0	0	0	0	0	0	0	0	1	0	1	0
		DAY 57	23JUL2003	58	2	-15	0	1	0	0	0	0	0	0	0	1	0	0	0	0
	E0031008	DAY 1	28FEB2003	1	22		3	2	0	3	1	2	2	1	1	1	1	2	2	1
		DAY 8	07MAR2003	8	19	-3	2	2	0	1	2	2	2	1	1	1	1	2	2	0
		DAY 15	13MAR2003	14	19	-3	2	2	0	1	1	2	2	1	1	1	1	2	2	1
		DAY 22	21MAR2003	22	17	-5	2	1	0	1	1	2	2	0	1	1	1	2	2	1
		DAY 29	28MAR2003	29	17	-5	2	2	0	1	0	2	2	0	1	1	1	2	2	1
		DAY 36	04APR2003	36	18	-4	2	2	0	2	1	2	2	0	1	1	1	2	2	0
		DAY 43	10APR2003	42	13	-9	2	1	0	0	1	2	2	0	0	0	1	2	2	0
		DAY 50	17APR2003	49	15	-7	1	1	0	2	1	1	2	1	1	0	1	2	2	0
		DAY 57	24APR2003	56	15	-7	3	2	0	0	1	2	2	0	0	0	1	2	2	0
	E0031020	DAY 1	21APR2003	1	20		3	3	0	2	2	2	0	1	1	1	2	1	1	1
		DAY 8	28APR2003	8	13	-7	1	1	0	0	2	1	1	1	1	1	1	1	1	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	DAY 15		05MAY2003	15	18	-2	3	2	0	0	2	2	2	1	1	1	1	1	1	1
		DAY 22		13MAY2003	23	12	-8	1	2	0	0	2	1	1	1	1	0	1	0	1	1
	E0031021	DAY 1		25APR2003	1	15		3	2	0	2	0	3	2	0	0	0	0	2	0	1
		DAY 8		02MAY2003	8	12	-3	2	1	1	0	0	2	1	0	1	0	0	2	1	1
		DAY 15		09MAY2003	15	4	-11	2	0	0	0	0	0	0	0	0	0	0	0	1	1
		DAY 22		16MAY2003	22	5	-10	1	1	0	0	0	1	1	0	0	0	0	0	1	0
		DAY 29		23MAY2003	29	10	-5	2	1	0	1	1	1	1	1	0	0	0	1	1	0
		DAY 36		29MAY2003	35	8	-7	2	2	0	0	0	1	1	0	0	0	0	0	1	1
		DAY 43		06JUN2003	43	15	0	3	1	1	3	0	2	0	1	0	1	1	1	1	0
		DAY 43	*	10JUN2003	47	4	-11	1	1	0	0	0	1	0	0	0	0	0	0	0	1
		DAY 57		19JUN2003	56	7	-8	2	1	0	1	0	1	0	0	0	0	1	0	1	0
	E0031029	DAY 1		18JUN2003	1	27		3	2	1	3	2	3	2	1	2	2	1	2	2	1
		DAY 8		23JUN2003	6	18	-9	2	2	0	0	2	2	2	2	1	1	1	2	1	0
	E0033002	DAY 1		10JAN2003	1	29		3	3	1	4	2	3	3	2	0	1	0	2	3	2
		DAY 8		16JAN2003	7	24	-5	3	2	2	1	2	3	1	1	1	2	1	1	2	2
		DAY 15		24JAN2003	15	21	-8	3	3	1	0	2	3	2	1	0	1	0	2	1	2
		DAY 22		30JAN2003	21	18	-11	2	2	0	3	2	2	1	1	0	0	0	1	2	2
		DAY 29		06FEB2003	28	19	-10	3	2	1	2	2	2	1	2	0	0	0	0	2	2
		DAY 36		13FEB2003	35	19	-10	3	2	1	1	2	2	2	1	0	1	0	1	1	2
		DAY 43		24FEB2003	46	15	-14	1	1	1	0	2	1	1	2	0	1	1	1	2	1
		DAY 50		28FEB2003	50	14	-15	2	3	0	0	1	1	1	1	0	1	0	1	1	2
		DAY 57		07MAR2003	57	12	-17	1	2	1	0	1	0	1	1	0	1	0	1	2	1
	E0033006	DAY 1		23JAN2003	1	26		2	2	0	3	3	3	2	2	2	2	0	2	0	3
		DAY 8		30JAN2003	8	24	-2	2	3	0	1	3	3	0	0	3	0	2	3	1	3
	E0033021	DAY 1		02JUL2003	1	28		3	3	2	2	3	2	1	1	2	1	1	2	3	2

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QUETIAPINE 300 MG (BIPOLAR II)	E0033021	DAY 8		11JUL2003	10	16	-12	2	2	0	2	2	2	1	0	1	1	1	1	1	0
		DAY 22	*	21JUL2003	20	17	-11	3	2	1	2	1	2	1	0	1	0	0	2	1	1
		DAY 22		25JUL2003	24	16	-12	1	2	0	2	1	2	2	1	0	0	1	1	2	1
		DAY 29		01AUG2003	31	16	-12	2	1	0	1	1	1	1	2	0	0	2	1	2	2
		DAY 36		06AUG2003	36	16	-12	2	2	0	1	1	2	1	1	1	1	1	1	1	1
	E0035013	DAY 1		04FEB2003	1	21		2	2	1	3	1	3	0	0	1	0	2	3	3	0
		DAY 8		10FEB2003	7	15	-6	3	2	2	0	1	3	0	0	0	0	0	3	1	0
	E0035015	DAY 1		11FEB2003	1	16		2	2	1	1	1	3	0	1	0	1	1	2	1	0
		DAY 8		18FEB2003	8	15	-1	2	2	1	0	1	3	0	1	0	1	1	2	1	0
	E0035016	DAY 1		04APR2003	1	21		2	3	1	2	2	3	1	0	0	0	1	3	2	1
	E0035023	DAY 1		13MAY2003	1	21		3	3	1	4	2	4	2	0	1	1	0	0	0	0
		DAY 8		20MAY2003	8	17	-4	3	2	1	1	1	2	2	1	1	0	1	0	2	0
		DAY 15		29MAY2003	17	15	-6	3	2	1	2	1	2	1	1	0	0	0	0	2	0
		DAY 22		03JUN2003	22	14	-7	3	2	1	2	1	2	1	1	0	0	0	0	1	0
		DAY 29		10JUN2003	29	12	-9	2	2	1	2	1	2	0	1	0	0	0	0	1	0
	E0039052	DAY 1		20JUN2003	1	10		1	1	0	2	1	2	1	1	0	0	0	0	0	1
		DAY 8		27JUN2003	8	6	-4	1	1	0	0	1	1	0	1	0	0	0	0	0	1
		DAY 15		03JUL2003	14	3	-7	1	0	0	0	0	1	0	1	0	0	0	0	0	0
	E0039056	DAY 1		14JUL2003	-1	6		1	0	0	2	1	2	0	0	0	0	0	0	0	0
	E0040003	DAY 1		18JUL2003	-1	12		1	2	0	2	1	2	0	0	0	0	0	2	1	1
		DAY 8		25JUL2003	7	13	1	2	2	0	2	1	2	0	0	1	0	0	2	0	1
		DAY 15		01AUG2003	14	9	-3	0	1	0	1	1	2	0	0	0	0	0	2	1	1
		DAY 22		08AUG2003	21	8	-4	1	1	0	0	1	1	0	0	0	0	0	1	2	1

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QUETIAPINE 300 MG (BIPOLAR II)	E0040003	DAY 29	15AUG2003	28	10	-2	0	2	0	2	1	1	0	0	0	0	0	2	1	1
		DAY 36	22AUG2003	35	8	-4	1	1	0	0	0	1	1	0	0	1	0	2	0	1
		DAY 43	29AUG2003	42	12	0	2	1	0	2	1	2	0	0	0	0	0	2	1	1
		DAY 50	05SEP2003	49	12	0	1	2	0	2	1	0	1	0	0	0	0	2	1	2
		DAY 57	12SEP2003	56	10	-2	2	1	0	2	1	0	1	0	0	0	0	2	0	1

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QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	12		2	1	0	2	2	3	1	0	0	0	1	0	0	0
		DAY 8	11MAR2003	9	12	0	2	0	0	0	2	2	2	0	0	0	1	1	1	1
		DAY 15	18MAR2003	16	6	-6	1	0	0	0	1	1	0	1	0	0	1	0	1	0
		DAY 22	25MAR2003	23	10	-2	2	1	0	0	2	1	1	2	0	0	0	0	1	0
		DAY 29	01APR2003	30	10	-2	0	0	0	0	1	2	1	2	0	0	2	0	2	0
		DAY 36	08APR2003	37	9	-3	1	1	0	0	1	1	1	2	0	0	1	0	1	0
		DAY 43	15APR2003	44	6	-6	1	1	0	0	1	1	0	2	0	0	0	0	0	0
		DAY 50	24APR2003	53	11	-1	2	2	0	0	1	1	0	1	1	1	0	1	1	0
		DAY 57	02MAY2003	61	6	-6	1	0	0	0	1	1	0	1	0	0	1	0	1	0
	E0002011	DAY 1	29APR2003	1	12		2	2	0	1	1	1	1	1	0	0	1	0	1	1
		DAY 8	08MAY2003	10	13	1	1	2	0	0	1	1	2	1	0	0	3	0	1	1
		DAY 15	15MAY2003	17	13	1	2	2	0	1	1	1	1	1	0	0	2	0	1	1
		DAY 22	22MAY2003	24	9	-3	2	2	0	0	1	1	0	1	0	0	1	0	1	0
		DAY 29	29MAY2003	31	5	-7	0	0	0	0	0	0	1	1	0	0	2	0	1	0
		DAY 36	05JUN2003	38	11	-1	2	1	0	0	1	2	1	1	0	0	2	0	0	1
		DAY 43	12JUN2003	45	7	-5	2	1	0	0	0	1	0	0	0	0	2	0	1	0
		DAY 50	19JUN2003	52	6	-6	1	1	0	1	0	0	0	0	0	0	2	0	1	0
		DAY 57	25JUN2003	58	7	-5	2	1	0	0	1	0	1	0	0	0	1	0	1	0
	E0003010	DAY 1	03FEB2003	1	31		3	3	0	4	2	3	2	2	2	3	2	3	1	1
		DAY 8	10FEB2003	8	6	-25	1	1	0	0	0	0	1	0	1	0	1	1	0	0
		DAY 15	19FEB2003	17	4	-27	1	0	0	0	0	0	1	0	0	0	1	1	0	0
		DAY 22	27FEB2003	25	25	-6	2	3	0	4	1	2	2	3	2	2	3	0	1	0
		DAY 29	03MAR2003	29	12	-19	1	2	0	0	1	1	2	2	1	0	2	0	0	0
		DAY 36	14MAR2003	40	5	-26	0	1	0	1	0	1	0	0	0	0	1	1	0	0
		DAY 43	20MAR2003	46	16	-15	0	2	0	3	1	1	0	2	1	0	4	0	1	1
		DAY 50	25MAR2003	51	10	-21	0	1	0	1	1	0	1	3	0	0	3	0	0	0
		DAY 57	31MAR2003	57	9	-22	0	0	0	0	0	0	1	4	0	0	3	1	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	DAY 1		04FEB2003	1	7		1	1	0	1	1	1	1	0	0	0	1	0	0	0
		DAY 8		11FEB2003	8	11	4	2	1	0	0	2	3	0	0	0	0	1	1	0	1
		DAY 15		18FEB2003	15	4	-3	2	1	0	0	0	0	0	0	0	1	0	0	0	0
	E0003016	DAY 1		22MAY2003	1	31		3	3	0	3	2	4	2	0	0	3	0	4	3	4
		DAY 8		29MAY2003	8	26	-5	3	3	0	2	3	3	0	2	0	0	2	3	3	2
		DAY 15		05JUN2003	15	26	-5	3	3	0	2	2	2	1	2	2	0	1	3	3	2
		DAY 22		12JUN2003	22	27	-4	4	4	0	4	4	2	0	0	0	0	0	3	2	4
	E0003019	DAY 1		27JUN2003	1	21		2	2	0	4	2	3	0	3	0	0	0	4	0	1
		DAY 8		03JUL2003	7	7	-14	2	1	0	0	1	1	0	1	0	0	1	0	0	0
		DAY 15		10JUL2003	14	19	-2	3	1	0	2	4	3	0	1	0	0	0	4	1	0
		DAY 15	*	15JUL2003	19	11	-10	2	2	0	1	2	2	0	0	1	0	0	1	0	0
		DAY 29		29JUL2003	33	16	-5	3	2	0	0	3	3	0	0	0	0	1	3	0	1
		DAY 43		07AUG2003	42	10	-11	2	2	0	0	2	2	0	0	0	0	0	1	0	1
		DAY 50		14AUG2003	49	13	-8	2	2	0	1	2	2	0	2	1	0	0	1	0	0
		DAY 57		21AUG2003	56	12	-9	2	2	0	2	2	2	0	0	1	0	0	0	0	1
	E0003020	DAY 1		23JUL2003	1	11		2	2	0	2	0	2	0	0	1	0	0	1	0	1
		DAY 8		29JUL2003	7	8	-3	1	1	0	0	1	2	1	0	0	0	0	0	1	1
		DAY 15		06AUG2003	15	14	3	1	2	1	0	1	3	1	1	0	0	1	2	0	1
		DAY 22		13AUG2003	22	18	7	4	3	1	2	1	2	1	0	0	0	1	1	1	1
		DAY 29		20AUG2003	29	23	12	3	2	0	4	1	3	3	1	0	0	0	3	2	1
		DAY 36		27AUG2003	36	22	11	3	3	1	2	3	2	1	0	0	0	0	3	2	2
		DAY 43		03SEP2003	43	16	5	2	2	0	1	3	1	1	0	0	0	0	3	2	1
		DAY 50		10SEP2003	50	15	4	1	1	1	1	3	1	1	0	0	0	0	3	2	1
		DAY 57		17SEP2003	57	12	1	1	1	1	1	2	1	1	0	0	0	0	2	1	1
	E0004001	DAY 1		30SEP2002	1	33		3	3	2	3	2	3	2	2	2	2	3	3	2	1
		DAY 8		07OCT2002	8	27	-6	2	3	2	0	2	2	2	2	3	2	2	2	2	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	DAY 22	21OCT2002	22	16	-17	2	2	0	0	1	2	2	0	1	0	3	2	0	1
		DAY 29	28OCT2002	29	11	-22	1	1	0	0	1	2	1	0	1	0	0	2	1	1
	E0004009	DAY 1	26DEC2002	1	16		2	2	1	1	2	3	2	0	0	0	0	2	0	1
		DAY 8	02JAN2003	8	15	-1	1	1	0	2	2	2	2	0	0	0	1	3	1	0
		DAY 15	08JAN2003	14	11	-5	1	0	1	1	2	1	1	0	1	1	0	2	0	0
		DAY 22	15JAN2003	21	6	-10	0	0	1	1	1	1	1	0	0	0	0	1	0	0
		DAY 29	22JAN2003	28	6	-10	1	1	1	0	0	1	1	0	0	0	0	1	0	0
		DAY 36	29JAN2003	35	4	-12	1	1	1	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	05FEB2003	42	2	-14	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	12FEB2003	49	2	-14	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 57	19FEB2003	56	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0004012	DAY 1	14JAN2003	1	20		2	2	0	1	2	3	3	0	2	1	1	2	0	1
		DAY 8	21JAN2003	8	15	-5	2	1	0	1	2	3	1	0	1	1	1	2	0	0
		DAY 15	28JAN2003	15	9	-11	1	0	0	1	2	2	1	0	0	0	0	2	0	0
		DAY 22	04FEB2003	22	8	-12	2	1	0	0	2	1	1	0	0	0	0	1	0	0
		DAY 29	11FEB2003	29	4	-16	2	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36	18FEB2003	36	3	-17	1	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 43	25FEB2003	43	3	-17	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 50	04MAR2003	50	5	-15	2	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 57	11MAR2003	57	3	-17	1	0	0	0	1	1	0	0	0	0	0	0	0	0
	E0004015	DAY 1	20FEB2003	1	16		2	1	0	2	2	2	2	1	1	0	1	0	1	1
		DAY 8	25FEB2003	6	14	-2	2	1	0	2	2	2	0	0	0	0	2	0	2	1
		DAY 15	04MAR2003	13	7	-9	1	1	0	1	1	1	0	0	0	0	2	0	0	0
		DAY 22	11MAR2003	20	1	-15	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	18MAR2003	27	1	-15	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	25MAR2003	34	3	-13	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	01APR2003	41	1	-15	0	0	0	0	0	1	0	0	0	0	0	0	0	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	DAY 50	08APR2003	48	1	-15	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	55	3	-13	0	0	0	0	0	0	0	0	0	0	1	1	1	0
	E0005003	DAY 1	02OCT2002	1	18		3	4	0	0	0	3	0	0	0	0	0	3	2	3
		DAY 8	09OCT2002	8	16	-2	2	1	0	2	0	2	2	1	0	0	1	2	2	1
		DAY 15	16OCT2002	15	8	-10	1	0	0	2	0	1	1	0	0	0	0	2	1	0
		DAY 22	23OCT2002	22	5	-13	0	0	0	0	0	0	0	0	0	0	0	3	2	0
		DAY 29	30OCT2002	29	6	-12	1	0	0	0	0	2	0	0	0	0	0	2	1	0
		DAY 36	06NOV2002	36	6	-12	0	1	0	0	0	2	0	0	0	0	0	2	1	0
		DAY 43	14NOV2002	44	5	-13	1	0	0	0	0	2	0	0	0	0	0	2	0	0
		DAY 50	21NOV2002	51	6	-12	1	1	0	0	0	1	0	0	1	0	0	2	0	0
		DAY 57	26NOV2002	56	3	-15	1	0	0	0	0	0	0	0	0	0	0	2	0	0
	E0005005	DAY 1	30SEP2002	1	18		2	2	0	2	2	3	0	0	2	2	0	0	2	1
	E0005007	DAY 1	09OCT2002	1	21		3	3	0	3	3	3	0	1	0	0	0	2	1	2
		DAY 8	16OCT2002	8	22	1	3	2	0	2	3	3	0	1	2	0	1	2	2	1
		DAY 15	23OCT2002	15	24	3	3	3	0	3	3	3	0	1	0	0	2	2	2	2
		DAY 22	30OCT2002	22	18	-3	2	2	0	2	2	2	1	1	0	0	2	2	1	1
		DAY 29	06NOV2002	29	18	-3	2	1	0	3	2	2	1	1	0	0	2	2	1	1
		DAY 36	14NOV2002	37	15	-6	2	1	0	2	1	1	2	1	1	0	0	2	1	1
		DAY 43	20NOV2002	43	16	-5	2	2	0	2	2	2	2	1	0	0	1	2	0	0
		DAY 50	26NOV2002	49	16	-5	1	1	0	2	2	2	2	1	1	0	2	2	0	0
		DAY 57	04DEC2002	57	16	-5	2	2	0	1	2	1	2	1	0	0	2	2	0	1
	E0005008	DAY 1	15OCT2002	1	17		3	1	0	3	3	3	0	1	0	0	1	0	0	2
		DAY 8	22OCT2002	8	11	-6	1	1	0	0	2	2	0	0	0	1	2	1	0	1
		DAY 15	29OCT2002	15	16	-1	2	0	0	0	3	3	2	0	0	0	2	2	1	1
		DAY 22	06NOV2002	23	12	-5	2	0	0	0	2	3	0	1	0	0	0	2	1	1
		DAY 29	13NOV2002	30	5	-12	0	0	0	0	0	2	0	0	0	1	2	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	DAY 36	18NOV2002	35	3	-14	0	0	0	0	0	2	0	0	0	1	0	0	0	0
		DAY 43	25NOV2002	42	4	-13	1	0	0	0	0	1	0	0	0	0	0	0	2	0
		DAY 50	02DEC2002	49	1	-16	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	11DEC2002	58	3	-14	0	0	0	0	1	1	0	0	0	0	0	0	1	0
	E0005009	DAY 1	29OCT2002	1	25		3	1	0	2	3	3	1	2	2	2	2	0	2	2
	E0005010	DAY 1	21OCT2002	1	21		3	3	1	3	2	2	0	1	0	0	0	3	0	3
		DAY 8	28OCT2002	8	17	-4	2	1	1	0	1	2	0	0	1	1	2	3	1	2
		DAY 15	04NOV2002	15	15	-6	3	2	1	0	2	2	0	0	0	0	0	3	0	2
		DAY 22	13NOV2002	24	15	-6	2	2	0	3	1	1	0	0	0	0	2	3	0	1
		DAY 29	19NOV2002	30	6	-15	0	0	0	0	1	0	0	0	0	0	0	3	1	1
		DAY 36	26NOV2002	37	4	-17	0	0	0	0	1	0	0	0	0	0	0	3	0	0
		DAY 43	03DEC2002	44	3	-18	0	0	0	0	0	0	0	0	0	0	0	3	0	0
		DAY 50	09DEC2002	50	3	-18	0	0	0	0	0	0	0	0	0	0	0	3	0	0
		DAY 57	17DEC2002	58	2	-19	0	0	0	0	0	0	0	0	0	0	0	2	0	0
	E0005012	DAY 1	14NOV2002	1	23		3	3	0	3	3	3	2	0	1	0	0	0	2	3
		DAY 8	20NOV2002	7	22	-1	3	3	0	2	3	3	2	0	1	0	2	0	1	2
		DAY 15	26NOV2002	13	20	-3	2	2	0	2	2	2	2	1	1	0	2	1	1	2
		DAY 22	06DEC2002	23	11	-12	1	1	0	1	0	1	2	1	0	0	2	1	1	0
		DAY 29	10DEC2002	27	12	-11	1	1	0	1	0	1	2	1	0	0	2	2	1	0
		DAY 36	18DEC2002	35	14	-9	2	1	0	2	1	2	2	1	0	0	0	1	1	1
		DAY 36 *	23DEC2002	40	16	-7	1	1	0	2	0	2	2	1	0	0	2	2	2	1
		DAY 50	02JAN2003	50	13	-10	1	1	0	2	1	1	0	1	0	0	2	2	1	1
		DAY 57	07JAN2003	55	12	-11	1	1	0	2	1	1	0	1	0	0	2	2	1	0
	E0005014	DAY 1	13NOV2002	1	30		3	3	2	3	3	3	2	2	1	1	2	0	2	3
		DAY 8	20NOV2002	8	26	-4	3	3	2	0	3	3	2	2	1	1	2	0	2	2
		DAY 15	27NOV2002	15	16	-14	2	2	1	0	3	1	1	1	1	1	1	0	1	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 22	03DEC2002	21	16	-14	2	2	0	0	3	1	1	1	1	1	2	0	1	1
		DAY 29	11DEC2002	29	13	-17	2	2	0	0	2	1	1	1	0	1	1	0	1	1
		DAY 36	17DEC2002	35	11	-19	2	2	0	0	2	1	1	0	0	0	1	0	1	1
		DAY 43	23DEC2002	41	15	-15	3	2	0	0	2	1	1	0	1	1	2	0	1	1
		DAY 50	30DEC2002	48	17	-13	3	2	0	1	2	2	1	0	1	1	1	0	1	2
		DAY 57	06JAN2003	55	14	-16	2	2	0	0	2	1	1	1	1	1	1	0	1	1
	E0005022	DAY 1	29JAN2003	1	21		2	3	0	2	2	3	1	1	0	0	2	2	1	2
		DAY 8	04FEB2003	7	19	-2	2	2	0	2	2	3	1	1	0	0	2	1	1	2
		DAY 15	11FEB2003	14	17	-4	1	1	0	2	2	3	1	1	0	0	2	1	1	2
		DAY 22	21FEB2003	24	17	-4	2	2	0	2	2	3	1	1	0	1	0	1	0	2
		DAY 29	26FEB2003	29	6	-15	1	0	0	2	1	0	1	1	0	0	0	0	0	0
		DAY 36	06MAR2003	37	5	-16	0	0	0	0	1	0	0	1	0	0	2	0	0	1
	E0005025	DAY 1	27FEB2003	1	17		2	2	0	2	0	3	1	0	0	1	0	2	2	2
		DAY 8	06MAR2003	8	7	-10	0	1	0	0	1	1	0	0	0	0	0	2	1	1
		DAY 15	14MAR2003	16	6	-11	0	0	0	0	0	0	0	0	1	1	0	2	2	0
		DAY 22	20MAR2003	22	2	-15	0	0	0	0	0	0	1	0	0	0	0	0	1	0
		DAY 29	27MAR2003	29	10	-7	2	2	0	0	0	2	0	0	0	0	0	2	1	1
		DAY 36	03APR2003	36	6	-11	0	0	0	1	1	1	0	0	0	0	0	1	1	1
	E0006019	DAY 1	07APR2003	1	14		1	2	0	3	2	3	0	0	0	0	0	1	1	1
		DAY 8	14APR2003	8	15	1	1	2	0	3	2	3	1	0	0	0	0	1	1	1
		DAY 15	21APR2003	15	14	0	1	2	0	2	2	3	1	0	0	0	0	1	1	1
		DAY 22	28APR2003	22	10	-4	1	1	0	2	1	2	1	0	0	0	0	0	1	1
		DAY 29	05MAY2003	29	10	-4	1	1	0	1	1	2	1	0	0	0	1	0	1	1
		DAY 36	12MAY2003	36	10	-4	1	1	0	1	1	2	1	1	0	0	0	0	1	1
		DAY 43	19MAY2003	43	11	-3	1	1	0	1	2	2	1	1	0	0	0	0	1	1
		DAY 50	27MAY2003	51	10	-4	1	1	0	1	2	2	1	0	0	0	0	0	1	1
		DAY 57	03JUN2003	58	9	-5	1	1	0	1	2	2	1	0	0	0	0	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	DAY 1	31JAN2003	1	18		2	2	0	3	2	2	0	0	1	0	0	4	2	0
		DAY 8	07FEB2003	8	11	-7	2	2	0	2	2	3	0	0	0	0	0	0	0	0
		DAY 15	14FEB2003	15	10	-8	2	1	0	0	0	2	0	0	0	0	0	4	1	0
		DAY 22	22FEB2003	23	10	-8	2	1	0	1	1	2	0	0	0	0	0	2	0	1
		DAY 29	03MAR2003	32	4	-14	1	0	0	0	1	1	0	0	0	0	0	0	1	0
		DAY 36	10MAR2003	39	10	-8	2	1	0	0	1	2	0	0	0	0	0	2	1	1
		DAY 43	14MAR2003	43	6	-12	1	1	0	0	1	1	0	0	0	0	2	0	0	0
		DAY 50	21MAR2003	50	14	-4	2	2	0	2	1	2	0	0	0	0	0	3	1	1
		DAY 57	28MAR2003	57	9	-9	1	1	0	1	1	2	0	0	0	0	0	2	0	1
	E0007015	DAY 1	16JUL2003	1	10		1	2	0	0	0	2	0	0	0	0	1	3	0	1
		DAY 8	23JUL2003	8	10	0	1	1	0	0	1	2	0	0	1	0	1	2	1	0
		DAY 15	01AUG2003	17	11	1	1	1	0	1	1	2	0	0	0	1	1	2	1	0
		DAY 22	06AUG2003	22	10	0	1	1	0	0	1	2	0	1	0	1	0	2	1	0
		DAY 29	13AUG2003	29	2	-8	1	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 36	20AUG2003	36	10	0	1	1	0	0	1	2	0	0	0	0	2	2	1	0
		DAY 43	27AUG2003	43	7	-3	1	0	0	0	0	2	0	0	0	0	1	3	0	0
		DAY 50	03SEP2003	50	6	-4	1	0	0	0	0	1	0	0	0	0	0	3	1	0
		DAY 57	10SEP2003	57	5	-5	1	0	0	0	1	2	0	0	0	0	0	1	0	0
	E0009001	DAY 1	12NOV2002	1	22		3	2	0	3	3	2	2	2	1	0	1	1	1	1
		DAY 8	21NOV2002	10	21	-1	2	2	0	0	2	2	1	2	2	1	2	2	2	1
		DAY 15	26NOV2002	15	22	0	2	2	1	1	2	2	2	1	2	1	2	1	2	1
		DAY 22	04DEC2002	23	19	-3	2	2	1	2	1	2	2	1	0	1	2	1	1	1
		DAY 29	10DEC2002	29	23	1	2	2	1	3	2	2	1	2	1	0	1	2	2	2
		DAY 36	17DEC2002	36	22	0	2	2	1	3	2	2	2	2	1	1	1	1	1	1
		DAY 43	23DEC2002	42	16	-6	1	1	0	2	1	1	2	1	1	1	2	2	1	0
		DAY 50	30DEC2002	49	16	-6	0	2	0	1	1	1	2	2	1	1	2	1	1	1
	E0010002	DAY 1	25NOV2002	1	24		3	2	1	3	1	2	1	1	2	1	2	2	2	1

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0010002	DAY 8	02DEC2002	8	24	0	3	2	1	2	2	3	1	1	2	1	2	1	1	2
	E0010009	DAY 1	26DEC2002	1	17		2	1	0	0	3	2	1	1	1	1	0	3	1	1
		DAY 8	02JAN2003	8	12	-5	1	1	0	0	3	2	0	0	1	1	0	3	0	0
		DAY 15	09JAN2003	15	8	-9	0	0	0	0	2	1	0	0	0	0	0	3	2	0
		DAY 22	17JAN2003	23	14	-3	1	1	0	1	1	2	0	1	0	0	1	3	2	1
		DAY 29	22JAN2003	28	9	-8	1	0	0	0	1	1	0	1	0	0	0	3	2	0
		DAY 36	30JAN2003	36	14	-3	1	1	0	0	1	1	0	1	0	1	3	3	2	0
		DAY 43	05FEB2003	42	10	-7	1	1	0	0	1	1	1	0	0	0	0	3	1	1
		DAY 50	13FEB2003	50	6	-11	0	0	0	0	1	1	1	0	0	0	0	3	0	0
		DAY 57	19FEB2003	56	8	-9	1	1	0	0	0	1	0	0	0	0	1	3	0	1
	E0010010	DAY 1	30DEC2002	1	18		3	2	0	0	1	3	2	0	0	0	0	3	2	2
		DAY 8	06JAN2003	8	19	1	2	3	0	2	3	2	1	1	1	0	0	3	0	1
		DAY 15	13JAN2003	15	19	1	2	2	0	3	1	2	0	0	1	0	1	3	2	2
	E0010014	DAY 1	28JAN2003	1	29		3	3	2	3	3	3	1	1	0	1	2	3	2	2
		DAY 8	04FEB2003	8	6	-23	1	1	1	0	0	1	0	0	1	0	0	0	1	0
		DAY 15	11FEB2003	15	9	-20	2	3	1	0	0	0	1	0	1	0	0	0	0	1
		DAY 22	18FEB2003	22	1	-28	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 29	25FEB2003	29	4	-25	2	0	0	0	0	0	0	0	1	0	0	0	0	1
		DAY 36	04MAR2003	36	2	-27	1	0	0	0	0	0	0	0	1	0	0	0	0	0
		DAY 43	11MAR2003	43	1	-28	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 50	18MAR2003	50	1	-28	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 57	25MAR2003	57	2	-27	0	0	0	0	0	0	0	0	0	0	1	0	0	1
	E0010017	DAY 1	25FEB2003	1	26		3	3	1	3	3	3	1	1	1	0	1	3	1	2
		DAY 8	03MAR2003	7	18	-8	2	3	0	1	2	2	1	1	0	0	0	3	2	1
		DAY 15	10MAR2003	14	13	-13	2	2	0	1	1	1	1	0	0	0	0	3	2	0
		DAY 22	18MAR2003	22	10	-16	1	1	0	1	0	0	0	1	0	0	0	2	3	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	DAY 29	25MAR2003	29	9	-17	0	1	0	1	0	0	1	0	0	0	1	3	2	0
		DAY 36	01APR2003	36	7	-19	0	0	0	1	0	1	1	0	0	0	0	3	1	0
		DAY 43	08APR2003	43	12	-14	1	3	0	0	1	0	0	0	0	0	0	3	1	3
		DAY 50	15APR2003	50	7	-19	0	2	0	0	0	0	0	0	0	0	0	3	1	1
		DAY 57	22APR2003	57	2	-24	0	0	0	1	0	0	0	0	0	0	0	0	1	0
	E0010023	DAY 1	17APR2003	1	28		3	3	2	3	2	3	2	2	1	0	1	3	1	2
		DAY 8	24APR2003	8	16	-12	2	2	0	2	2	2	0	1	0	0	1	3	1	0
		DAY 15	01MAY2003	15	24	-4	3	3	2	3	0	2	2	0	1	0	2	3	2	1
	E0010027	DAY 1	16JUN2003	1	19		1	3	0	3	2	2	1	0	0	1	2	1	1	2
		DAY 8	23JUN2003	8	16	-3	2	2	0	1	2	1	1	1	0	0	1	2	2	1
		DAY 15	01JUL2003	16	23	4	2	3	0	3	0	3	2	2	1	0	1	2	2	2
	E0010029	DAY 1	19JUN2003	1	29		3	3	1	3	3	2	2	2	2	0	2	3	1	2
		DAY 8	25JUN2003	7	27	-2	4	3	0	2	3	2	1	1	2	0	2	3	2	2
	E0011022	DAY 1	09JUN2003	1	22		3	3	1	3	3	2	0	1	1	0	1	1	1	2
		DAY 8	16JUN2003	8	23	1	3	3	0	2	3	3	0	1	0	1	2	1	2	2
		DAY 15	24JUN2003	16	23	1	3	3	0	3	1	3	0	1	0	1	2	2	2	2
		DAY 22	01JUL2003	23	25	3	3	2	0	3	1	3	1	2	3	1	1	2	1	2
		DAY 29	08JUL2003	30	17	-5	3	3	0	0	0	2	0	1	3	1	0	1	3	0
		DAY 36	15JUL2003	37	32	10	2	3	1	3	1	3	2	3	3	2	3	2	3	1
		DAY 43	24JUL2003	46	21	-1	3	3	0	2	1	3	0	2	0	0	1	3	1	2
		DAY 50	31JUL2003	53	15	-7	2	3	0	2	1	3	0	0	0	0	0	3	0	1
		DAY 57	05AUG2003	58	17	-5	3	2	0	1	1	3	2	1	0	0	0	1	2	1
	E0013006	DAY 1	13MAR2003	1	30		2	2	2	2	3	3	2	1	3	2	2	2	2	2
		DAY 8	24MAR2003	12	16	-14	1	2	0	2	0	2	1	1	2	1	1	0	2	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	DAY 1	07MAY2003	1	23		2	2	0	3	3	3	2	1	1	1	1	2	1	1
		DAY 8	16MAY2003	10	15	-8	1	3	0	0	1	2	2	2	0	0	0	3	1	0
		DAY 15	22MAY2003	16	10	-13	1	1	0	1	1	1	1	1	1	0	0	1	1	0
		DAY 22	30MAY2003	24	9	-14	1	1	0	0	1	1	1	1	1	0	1	0	1	0
		DAY 29	05JUN2003	30	7	-16	1	0	0	1	1	1	0	1	1	0	0	0	1	0
		DAY 36	12JUN2003	37	5	-18	0	0	0	1	1	0	0	1	0	0	0	1	1	0
		DAY 43	19JUN2003	44	5	-18	0	0	0	0	1	1	0	0	1	0	1	1	0	0
		DAY 50	25JUN2003	50	0	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	57	2	-21	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	E0013014	DAY 1	03JUN2003	1	19		2	3	0	3	3	3	0	1	1	0	0	3	0	0
		DAY 8	10JUN2003	8	19	0	2	2	0	2	2	2	1	1	2	1	1	1	1	1
		DAY 15	19JUN2003	17	26	7	2	3	0	3	3	3	2	3	2	0	1	2	2	0
		DAY 29	30JUN2003	28	14	-5	2	2	0	3	0	2	2	2	0	0	1	0	0	0
	E0014005	DAY 1	11MAR2003	1	31		4	3	1	2	3	4	3	2	2	2	0	2	2	1
		DAY 8	18MAR2003	8	17	-14	2	3	1	0	1	2	2	1	2	1	0	2	0	0
		DAY 15	25MAR2003	15	7	-24	1	1	2	0	1	1	1	0	0	0	0	0	0	0
		DAY 22	01APR2003	22	0	-31	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	08APR2003	29	7	-24	1	1	0	0	2	0	1	1	0	0	0	0	1	0
		DAY 36	16APR2003	37	9	-22	1	2	0	0	2	0	2	0	1	0	0	0	1	0
		DAY 43	23APR2003	44	4	-27	0	1	0	0	2	1	0	0	0	0	0	0	0	0
		DAY 50	29APR2003	50	0	-31	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	06MAY2003	57	3	-28	1	0	0	0	0	1	1	0	0	0	0	0	0	0
	E0014007	DAY 1	01APR2003	1	22		3	3	0	3	2	3	1	0	1	2	2	0	2	0
		DAY 8	08APR2003	8	12	-10	1	1	0	0	3	2	0	1	2	1	0	0	0	1
		DAY 15	15APR2003	15	18	-4	2	2	3	1	4	3	0	1	0	2	0	0	0	0
		DAY 22	22APR2003	22	20	-2	1	1	3	4	3	3	2	2	0	0	0	0	0	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	DAY 1	13MAY2003	1	20		3	2	0	2	1	2	2	1	0	1	2	1	1	2
		DAY 8	20MAY2003	8	12	-8	1	2	0	0	2	2	1	1	0	0	2	0	1	0
		DAY 15	27MAY2003	15	5	-15	1	1	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 22	04JUN2003	23	5	-15	1	1	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 29	10JUN2003	29	5	-15	1	1	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 36	17JUN2003	36	4	-16	1	1	0	0	0	1	0	0	0	0	0	0	0	1
		DAY 43	26JUN2003	45	3	-17	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 50	02JUL2003	51	9	-11	1	1	0	0	0	0	2	1	0	0	1	1	1	1
		DAY 57	08JUL2003	57	1	-19	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	E0014012	DAY 1	27MAY2003	1	38		4	3	1	3	3	4	2	2	3	2	4	2	2	3
		DAY 8	03JUN2003	8	35	-3	4	3	1	0	3	4	2	2	3	2	4	2	2	3
		DAY 15	10JUN2003	15	23	-15	3	2	1	1	2	3	2	1	1	1	2	1	1	2
		DAY 22	17JUN2003	22	22	-16	3	3	1	1	2	2	2	1	1	1	1	1	1	2
		DAY 29	24JUN2003	29	22	-16	3	3	1	1	2	2	2	1	1	1	0	1	1	3
	E0015001	DAY 1	29NOV2002	1	23		3	3	1	3	2	3	1	0	1	0	0	3	2	1
		DAY 8	06DEC2002	8	19	-4	3	3	1	0	2	3	1	0	1	0	0	3	2	0
		DAY 15	13DEC2002	15	15	-8	2	1	0	0	2	2	0	0	1	1	1	3	1	1
		DAY 22	19DEC2002	21	15	-8	2	1	0	0	2	2	0	0	1	1	1	3	1	1
		DAY 29	27DEC2002	29	15	-8	2	1	0	0	2	2	0	0	1	2	1	3	0	1
		DAY 36	03JAN2003	36	13	-10	2	2	0	0	2	1	0	0	0	1	1	3	0	1
		DAY 43	09JAN2003	42	15	-8	2	2	0	0	2	1	0	0	0	2	1	3	1	1
		DAY 50	20JAN2003	53	9	-14	1	1	0	0	1	1	0	0	0	0	1	3	0	1
	E0015008	DAY 1	19DEC2002	1	19		2	2	1	2	2	3	1	0	1	1	0	3	0	1
		DAY 8	27DEC2002	9	14	-5	2	0	0	0	2	3	1	0	1	1	0	3	0	1
		DAY 15	03JAN2003	16	11	-8	2	2	0	0	1	2	0	1	0	1	0	1	0	1
		DAY 22	10JAN2003	23	12	-7	2	1	0	0	2	1	1	0	1	1	1	1	0	1
		DAY 29	16JAN2003	29	8	-11	1	1	0	0	0	1	0	0	1	1	1	1	0	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0015008	DAY 36	23JAN2003	36	8	-11	2	1	0	0	1	1	1	0	0	0	1	0	0	1
	E0016003	DAY 1	24JAN2003	1	29		3	3	2	2	3	3	2	2	2	1	2	1	1	2
		DAY 8	31JAN2003	8	19	-10	3	3	2	1	3	3	2	0	1	1	0	0	0	0
		DAY 15	07FEB2003	15	22	-7	3	3	1	3	1	3	1	1	1	1	1	0	0	3
		DAY 22	14FEB2003	22	11	-18	2	2	0	2	1	2	0	0	0	0	0	0	0	2
		DAY 29	21FEB2003	29	8	-21	2	0	0	2	1	2	0	0	0	0	0	0	0	1
		DAY 36	27FEB2003	35	11	-18	2	2	1	0	2	2	0	0	0	0	0	0	0	2
		DAY 43	07MAR2003	43	12	-17	3	2	0	1	2	2	0	0	0	0	0	0	0	2
	E0016005	DAY 1	25FEB2003	1	22		3	3	2	1	3	4	1	1	1	0	0	0	0	3
		DAY 8	04MAR2003	8	19	-3	2	1	2	1	2	2	1	2	1	1	0	1	1	2
		DAY 15	11MAR2003	15	10	-12	0	2	1	0	3	1	1	1	0	0	0	0	1	0
		DAY 22	18MAR2003	22	2	-20	1	0	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 29	25MAR2003	29	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	36	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	08APR2003	43	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	17APR2003	52	0	-22	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	57	5	-17	0	1	0	0	1	0	1	0	0	0	1	0	1	0
	E0018007	DAY 1	27DEC2002	1	27		2	2	2	3	3	3	2	1	1	2	1	1	2	2
		DAY 8	31DEC2002	5	16	-11	2	2	1	0	2	2	2	0	0	0	0	1	2	2
		DAY 15	10JAN2003	15	30	3	2	2	2	3	3	3	3	1	1	1	1	2	3	3
	E0019005	DAY 1	05NOV2002	1	13		2	1	2	2	2	3	0	0	0	0	0	0	0	1
		DAY 8	12NOV2002	8	13	0	2	1	0	1	2	2	0	0	0	0	1	2	1	1
		DAY 15	19NOV2002	15	11	-2	2	1	0	2	2	2	0	0	0	0	0	1	1	0
		DAY 22	26NOV2002	22	13	0	2	2	0	1	1	1	0	1	0	0	0	3	2	0
		DAY 29	05DEC2002	31	4	-9	0	1	0	2	0	1	0	0	0	0	0	0	0	0
		DAY 36	12DEC2002	38	3	-10	1	0	0	0	2	0	0	0	0	0	0	0	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	DAY 43		19DEC2002	45	7	-6	1	0	0	2	2	2	0	0	0	0	0	0	0	0
		DAY 57	*	30DEC2002	56	5	-8	0	0	0	1	0	2	0	0	0	0	0	1	0	1
		DAY 57		02JAN2003	59	4	-9	0	0	0	1	0	1	0	0	0	0	0	1	0	1
	E0019015	DAY 1		02JAN2003	1	19		3	2	1	3	1	3	0	0	0	0	1	2	1	2
		DAY 8		09JAN2003	8	11	-8	1	1	0	0	1	1	1	0	0	0	2	0	2	2
		DAY 15		16JAN2003	15	8	-11	0	1	0	1	0	2	1	0	0	0	0	2	0	1
		DAY 22		23JAN2003	22	6	-13	1	1	0	0	1	0	1	0	0	0	0	0	1	1
		DAY 29		30JAN2003	29	6	-13	1	1	0	0	1	1	0	0	0	0	0	0	0	2
		DAY 36		06FEB2003	36	6	-13	2	1	0	0	1	0	0	0	0	0	0	1	0	1
		DAY 43		13FEB2003	43	3	-16	0	1	0	0	0	1	0	0	0	1	0	0	0	0
		DAY 50		20FEB2003	50	2	-17	0	0	0	0	0	1	0	0	0	0	0	0	0	1
		DAY 57		27FEB2003	57	2	-17	1	0	0	0	0	0	0	0	0	0	0	0	0	1
	E0020004	DAY 1		09DEC2002	1	18		2	2	0	3	2	3	0	1	0	0	1	3	1	0
		DAY 8		16DEC2002	8	20	2	2	2	1	1	2	2	2	2	1	0	0	1	2	2
		DAY 8	*	20DEC2002	12	21	3	2	2	1	2	2	2	2	2	1	0	0	2	2	1
		DAY 22		31DEC2002	23	14	-4	2	2	0	3	2	2	0	0	0	0	0	0	1	2
		DAY 29		07JAN2003	30	20	2	2	1	0	3	2	2	1	0	0	0	2	3	2	2
		DAY 36		14JAN2003	37	21	3	3	3	0	2	0	3	0	2	0	0	2	3	0	3
		DAY 43		22JAN2003	45	22	4	3	3	0	1	1	3	1	2	0	1	0	3	1	3
	E0020010	DAY 1		05FEB2003	1	23		3	3	0	4	1	3	1	0	2	1	0	3	1	1
		DAY 8		12FEB2003	8	22	-1	2	2	0	3	2	2	2	0	2	0	0	3	3	1
		DAY 15		19FEB2003	15	14	-9	1	1	1	1	2	1	1	0	1	1	1	0	2	1
		DAY 22		26FEB2003	22	10	-13	1	1	0	1	1	1	2	0	0	0	0	0	2	1
		DAY 29		05MAR2003	29	21	-2	3	3	0	3	3	3	0	2	0	0	0	1	1	2
		DAY 36		10MAR2003	34	12	-11	1	1	0	2	2	2	0	0	0	1	0	0	2	1
		DAY 43		17MAR2003	41	11	-12	1	0	0	2	2	1	0	0	2	0	0	0	2	1
		DAY 50		25MAR2003	49	9	-14	1	1	0	1	2	0	1	0	0	0	0	0	2	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0020010	DAY 57	02APR2003	57	9	-14	0	0	0	2	1	0	0	0	2	1	0	0	2	1
	E0020014	DAY 1	18MAR2003	1	18		2	1	1	1	2	3	1	1	0	0	0	3	1	2
		DAY 8	25MAR2003	8	19	1	2	2	1	2	2	3	1	2	0	0	0	0	2	2
		DAY 15	01APR2003	15	13	-5	2	1	0	2	2	2	0	2	0	0	1	0	0	1
		DAY 22	08APR2003	22	13	-5	1	1	1	2	1	2	0	0	0	1	1	0	1	2
		DAY 29	15APR2003	29	19	1	2	1	1	2	1	2	0	1	2	0	2	1	2	2
		DAY 36	22APR2003	36	15	-3	1	1	1	2	1	2	0	1	1	0	2	0	2	1
		DAY 43	29APR2003	43	3	-15	0	0	0	0	0	0	0	1	0	0	1	0	0	1
		DAY 50	06MAY2003	50	12	-6	1	1	0	2	1	2	0	0	0	0	1	1	1	2
		DAY 57	12MAY2003	56	3	-15	0	0	0	0	1	1	0	0	0	0	0	0	0	1
	E0020021	DAY 1	19MAY2003	1	14		2	2	0	2	2	3	0	0	0	0	0	1	0	2
		DAY 8	23MAY2003	5	15	1	2	1	0	0	2	2	0	1	1	0	2	2	2	0
		DAY 15	02JUN2003	15	12	-2	0	0	0	2	1	2	0	0	0	0	0	3	2	2
		DAY 22	10JUN2003	23	10	-4	0	0	0	2	1	2	1	0	0	0	0	1	2	1
		DAY 29	16JUN2003	29	6	-8	0	0	0	0	1	1	1	0	0	0	0	1	1	1
		DAY 36	23JUN2003	36	8	-6	0	0	0	2	0	2	0	0	0	0	0	3	0	1
		DAY 43	30JUN2003	43	12	-2	2	2	0	2	0	2	0	0	0	0	0	3	0	1
		DAY 50	07JUL2003	50	9	-5	0	0	0	0	1	1	2	0	0	0	0	1	2	2
		DAY 57	14JUL2003	57	10	-4	0	0	0	1	2	2	0	0	0	0	0	1	2	2
	E0020023	DAY 1	16JUN2003	-1	15		0	2	0	3	2	3	0	0	0	0	0	3	0	2
		DAY 8	24JUN2003	8	16	1	2	2	0	0	2	2	2	1	1	0	0	1	1	2
		DAY 15	30JUN2003	14	23	8	2	2	2	2	2	2	0	0	2	1	1	3	2	2
		DAY 22	07JUL2003	21	28	13	2	2	2	2	2	3	2	0	2	2	2	3	2	2
		DAY 29	14JUL2003	28	27	12	2	2	2	2	2	3	1	2	0	2	2	3	2	2
		DAY 36	21JUL2003	35	13	-2	2	2	0	1	1	2	0	0	0	1	0	3	0	1
		DAY 43	28JUL2003	42	16	1	1	1	0	1	2	2	1	0	0	1	0	3	2	2
		DAY 50	04AUG2003	49	16	1	0	2	0	2	1	2	0	0	1	1	1	3	2	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	DAY 57		11AUG2003	56	13	-2	0	1	0	1	1	1	0	0	1	1	1	3	2	1
	E0022007	DAY 1		07NOV2002	1	7		0	0	0	2	1	3	0	0	0	0	0	1	0	0
		DAY 8		14NOV2002	8	5	-2	2	0	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 15		22NOV2002	16	4	-3	1	0	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 22		02DEC2002	26	4	-3	1	0	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 29		09DEC2002	33	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022010	DAY 1		21NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 8		29NOV2002	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		06DEC2002	16	5	5	1	1	1	0	0	1	0	0	0	0	0	0	0	1
		DAY 22		12DEC2002	22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		26DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		02JAN2003	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		09JAN2003	50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		16JAN2003	57	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0022012	DAY 1		05DEC2002	1	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 8		12DEC2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15		19DEC2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	*	23DEC2002	19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		02JAN2003	29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		09JAN2003	36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		16JAN2003	43	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		23JAN2003	50	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 57		30JAN2003	57	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0022019	DAY 1		11DEC2002	1	12		3	1	0	1	2	2	1	0	0	0	0	0	2	0
		DAY 8		19DEC2002	9	5	-7	0	1	0	0	0	0	0	0	2	0	1	0	1	0
		DAY 15		26DEC2002	16	3	-9	0	0	0	0	0	1	0	0	1	0	1	0	0	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0022019	DAY 22	03JAN2003	24	2	-10	0	1	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 29	09JAN2003	30	3	-9	0	1	0	0	0	0	1	0	0	0	0	0	0	1
		DAY 36	17JAN2003	38	0	-12	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	24JAN2003	45	2	-10	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 50	30JAN2003	51	0	-12	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	06FEB2003	58	1	-11	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	E0022025	DAY 1	28JAN2003	1	10		1	1	0	1	1	2	1	0	0	0	1	1	0	1
		DAY 8	04FEB2003	8	19	9	3	2	0	3	3	3	1	0	1	1	0	1	0	1
	E0022033	DAY 1	18FEB2003	1	5		0	0	0	0	0	3	1	0	1	0	0	0	0	0
		DAY 8	25FEB2003	8	4	-1	1	0	0	0	0	2	0	0	0	0	0	0	0	1
		DAY 15	04MAR2003	15	1	-4	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	11MAR2003	22	0	-5	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	18MAR2003	29	0	-5	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	27MAR2003	38	0	-5	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	01APR2003	43	0	-5	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	08APR2003	50	1	-4	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	1	-4	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022034	DAY 1	18FEB2003	1	7		1	0	0	2	1	2	0	0	1	0	0	0	0	0
		DAY 8	25FEB2003	8	4	-3	0	0	0	0	1	2	1	0	0	0	0	0	0	0
		DAY 15	04MAR2003	15	5	-2	1	0	0	0	1	2	1	0	0	0	0	0	0	0
		DAY 22	11MAR2003	22	5	-2	1	0	0	0	1	2	0	0	0	0	0	0	0	1
		DAY 29	18MAR2003	29	6	-1	1	0	0	0	1	2	0	0	1	0	0	0	0	1
		DAY 36	25MAR2003	36	4	-3	1	0	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 43	01APR2003	43	2	-5	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	07APR2003	49	4	-3	0	0	0	0	1	1	0	0	1	0	0	0	0	1
		DAY 57	15APR2003	57	5	-2	0	1	0	0	1	1	0	0	1	0	0	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	DAY 1	28FEB2003	1	3		1	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 8	07MAR2003	8	4	1	1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 15	14MAR2003	15	4	1	1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 22	21MAR2003	22	4	1	1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 29	28MAR2003	29	3	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0
		DAY 36	04APR2003	36	3	0	1	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 43	11APR2003	43	6	3	1	1	0	0	0	2	1	0	0	0	0	0	0	1
	E0022039	DAY 1	06MAR2003	1	4		1	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 8	13MAR2003	8	5	1	1	1	1	0	0	2	0	0	0	0	0	0	0	0
		DAY 15	20MAR2003	15	4	0	1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 22	27MAR2003	22	2	-2	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 29	04APR2003	30	2	-2	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 36	10APR2003	36	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	18APR2003	44	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	24APR2003	50	1	-3	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	01MAY2003	57	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022046	DAY 1	20MAR2003	1	20		3	2	0	1	2	3	1	1	1	0	2	1	1	2
		DAY 8	27MAR2003	8	12	-8	2	2	1	0	0	3	2	0	0	0	0	0	1	1
		DAY 15	04APR2003	16	7	-13	1	1	0	0	1	1	1	0	0	0	1	1	0	0
		DAY 22	11APR2003	23	8	-12	1	1	1	0	0	1	1	1	0	0	1	0	0	1
		DAY 29	18APR2003	30	7	-13	0	0	0	0	0	2	0	0	0	0	2	1	1	1
		DAY 36	24APR2003	36	7	-13	1	1	0	0	0	2	1	0	0	0	1	0	1	0
		DAY 43	02MAY2003	44	10	-10	2	1	0	0	0	2	2	1	0	0	1	0	0	1
		DAY 50	12MAY2003	54	5	-15	1	1	0	0	0	2	1	0	0	0	0	0	0	0
		DAY 57	16MAY2003	58	9	-11	2	2	0	0	0	2	1	0	0	0	1	0	0	1
	E0022048	DAY 1	01APR2003	1	3		0	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 8	08APR2003	8	2	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0022048	DAY 15		15APR2003	15	4	1	1	0	0	0	0	2	0	0	1	0	0	0	0	0
		DAY 22		24APR2003	24	0	-3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		02MAY2003	32	0	-3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		06MAY2003	36	0	-3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		13MAY2003	43	0	-3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		23MAY2003	53	0	-3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022051	DAY 1		07APR2003	1	21		2	2	2	3	2	3	1	2	0	1	0	3	0	0
		DAY 8		14APR2003	8	17	-4	1	1	2	2	1	3	0	2	0	1	1	3	0	0
		DAY 15		21APR2003	15	7	-14	0	0	2	0	1	3	0	0	0	0	1	0	0	0
		DAY 22		28APR2003	22	4	-17	0	0	0	0	1	1	0	0	0	0	0	2	0	0
		DAY 29		05MAY2003	29	7	-14	1	0	0	0	1	1	0	1	0	0	0	3	0	0
		DAY 36		12MAY2003	36	12	-9	2	2	0	2	2	0	2	0	1	0	0	0	1	0
		DAY 43		19MAY2003	43	10	-11	2	1	0	0	1	1	2	1	0	0	2	0	0	0
		DAY 50		28MAY2003	52	2	-19	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 57		02JUN2003	57	1	-20	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	E0022053	DAY 1		11APR2003	1	15		2	1	0	2	0	3	2	1	0	1	2	0	0	1
	E0022058	DAY 1		21APR2003	1	2		0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 8		28APR2003	8	3	1	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 15		05MAY2003	15	2	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0
		DAY 22		12MAY2003	22	0	-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		19MAY2003	29	0	-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	*	22MAY2003	32	3	1	1	1	0	0	0	0	0	1	0	0	0	0	0	0
	E0022061	DAY 1		30APR2003	1	17		2	2	0	1	2	3	1	1	0	0	1	2	0	2
		DAY 8		07MAY2003	8	7	-10	1	1	0	0	1	2	1	0	0	0	0	1	0	0
		DAY 15		14MAY2003	15	9	-8	2	2	0	0	1	1	0	0	0	1	0	1	0	1
		DAY 22		22MAY2003	23	2	-15	0	0	0	0	0	0	0	0	0	0	1	0	1	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 29		28MAY2003	29	1	-16	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		04JUN2003	36	2	-15	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		18JUN2003	50	1	-16	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		26JUN2003	58	1	-16	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022062	DAY 1		05MAY2003	1	5		0	0	0	0	0	2	1	1	0	0	0	0	0	1
		DAY 8		12MAY2003	8	5	0	1	0	0	0	0	3	0	0	0	0	0	0	0	1
		DAY 15		19MAY2003	15	7	2	1	1	0	0	0	3	1	0	0	0	0	0	0	1
		DAY 15	*	23MAY2003	19	5	0	1	1	0	0	0	3	0	0	0	0	0	0	0	0
	E0022068	DAY 1		22MAY2003	-1	13		2	2	0	2	1	2	1	0	0	0	0	1	2	0
		DAY 8		29MAY2003	7	16	3	2	0	0	2	2	3	2	0	0	0	0	3	2	0
		DAY 15		05JUN2003	14	14	1	2	0	0	0	2	3	2	0	0	0	0	3	2	0
	E0022069	DAY 1		10JUN2003	1	8		2	0	0	2	2	2	0	0	0	0	0	0	0	0
		DAY 8		17JUN2003	8	7	-1	1	1	0	0	2	2	0	0	0	0	0	0	1	0
		DAY 15		24JUN2003	15	4	-4	1	0	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 22		01JUL2003	22	4	-4	1	0	0	0	1	1	1	0	0	0	0	0	0	0
		DAY 29		08JUL2003	29	2	-6	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 36		15JUL2003	36	0	-8	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		22JUL2003	43	0	-8	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		29JUL2003	50	2	-6	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 57		05AUG2003	57	2	-6	1	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0022071	DAY 1		30JUN2003	1	22		3	3	0	3	2	4	2	1	0	0	1	1	0	2
		DAY 8		07JUL2003	8	18	-4	3	3	0	2	1	3	2	2	0	0	0	0	0	2
		DAY 15		14JUL2003	15	17	-5	3	3	0	0	2	3	2	1	0	0	1	0	0	2
		DAY 22		21JUL2003	22	17	-5	3	3	0	0	1	3	2	1	0	0	1	0	1	2
		DAY 29		28JUL2003	29	17	-5	3	3	0	0	0	3	0	2	1	0	2	0	1	2
		DAY 36		04AUG2003	36	19	-3	3	3	0	1	2	3	1	1	0	1	2	0	0	2

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 43	11AUG2003	43	12	-10	2	2	0	1	0	3	0	0	0	1	2	0	0	1
		DAY 50	18AUG2003	50	9	-13	2	2	0	0	0	3	0	1	0	0	0	0	0	1
		DAY 57	25AUG2003	57	14	-8	2	2	0	0	0	3	1	1	1	1	0	0	1	2
	E0023003	DAY 1	17DEC2002	1	25		3	2	1	3	3	3	2	1	2	0	2	1	0	2
		DAY 8	23DEC2002	7	29	4	3	2	1	3	3	3	2	2	2	1	1	2	1	3
		DAY 15	30DEC2002	14	26	1	3	3	1	3	3	3	3	0	1	1	1	0	1	3
		DAY 22	07JAN2003	22	25	0	3	3	1	3	3	3	3	0	2	1	1	0	1	1
		DAY 29	16JAN2003	31	22	-3	3	3	1	2	2	2	3	0	2	1	1	0	1	1
		DAY 36	21JAN2003	36	19	-6	3	2	1	0	2	3	3	0	1	1	2	1	0	0
		DAY 43	28JAN2003	43	17	-8	2	2	1	1	2	2	2	1	1	0	0	1	1	1
		DAY 50	06FEB2003	52	11	-14	1	2	0	1	2	1	1	0	0	0	2	0	0	1
		DAY 57	11FEB2003	57	17	-8	3	2	0	0	2	3	2	0	1	2	1	0	0	1
	E0023006	DAY 1	17DEC2002	1	18		3	2	1	1	3	3	1	0	0	0	1	2	0	1
		DAY 8	23DEC2002	7	37	19	3	3	1	3	3	3	3	3	3	2	2	2	3	3
		DAY 15	02JAN2003	17	8	-10	2	2	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 22	07JAN2003	22	0	-18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	16JAN2003	31	0	-18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	21JAN2003	36	0	-18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	28JAN2003	43	2	-16	1	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 50	04FEB2003	50	4	-14	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	57	4	-14	1	1	0	0	1	1	0	0	0	0	0	0	0	0
	E0023010	DAY 1	04FEB2003	1	27		3	3	1	3	3	3	1	2	2	2	1	0	1	2
		DAY 8	11FEB2003	8	20	-7	3	2	1	1	2	3	1	1	2	2	0	0	1	1
		DAY 15	18FEB2003	15	19	-8	3	2	1	0	2	3	2	2	2	2	0	0	0	0
		DAY 22	25FEB2003	22	20	-7	3	2	0	0	3	3	2	2	2	2	1	0	0	0
		DAY 29	04MAR2003	29	16	-11	2	2	0	0	2	3	2	1	2	2	0	0	0	0
		DAY 36	11MAR2003	36	11	-16	1	1	0	1	2	2	2	0	0	1	0	0	1	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	DAY 43	18MAR2003	43	12	-15	1	1	0	0	2	2	2	1	1	1	1	0	0	0
		DAY 50	25MAR2003	50	11	-16	1	1	0	1	0	2	2	1	1	0	0	0	1	1
		DAY 57	31MAR2003	56	6	-21	1	0	0	1	1	1	0	0	1	0	0	0	1	0
	E0023025	DAY 1	15MAY2003	1	15		2	2	0	2	3	2	1	0	1	0	0	1	0	1
		DAY 8	22MAY2003	8	13	-2	2	2	0	0	3	3	0	0	0	0	0	0	2	1
		DAY 15	29MAY2003	15	15	0	2	3	1	0	3	3	0	0	0	0	0	0	2	1
		DAY 22	05JUN2003	22	8	-7	1	3	0	0	0	2	0	0	0	0	0	0	2	0
		DAY 29	12JUN2003	29	7	-8	2	1	0	0	2	1	1	0	0	0	0	0	0	0
		DAY 36	19JUN2003	36	7	-8	2	1	0	0	2	1	1	0	0	0	0	0	0	0
		DAY 43	27JUN2003	44	7	-8	2	1	0	0	2	1	1	0	0	0	0	0	0	0
		DAY 50	03JUL2003	50	5	-10	2	0	0	0	2	1	0	0	0	0	0	0	0	0
		DAY 57	10JUL2003	57	10	-5	2	1	0	1	2	1	0	0	1	0	1	0	0	1
	E0023039	DAY 1	01JUL2003	1	25		3	3	1	3	2	3	2	1	2	2	0	2	0	1
		DAY 8	08JUL2003	8	18	-7	3	1	1	1	1	1	1	1	1	1	2	1	2	1
		DAY 15	15JUL2003	15	9	-16	3	1	1	0	1	2	0	0	0	0	0	0	1	0
		DAY 22	22JUL2003	22	6	-19	1	1	1	0	1	1	0	0	0	0	0	0	1	0
		DAY 29	29JUL2003	29	8	-17	2	1	1	0	1	2	0	0	0	0	0	0	1	0
		DAY 36	05AUG2003	36	7	-18	2	1	1	0	1	1	0	0	0	0	0	0	1	0
		DAY 43	12AUG2003	43	5	-20	2	1	0	0	1	0	0	0	0	0	0	0	1	0
		DAY 50	19AUG2003	50	5	-20	1	1	0	0	1	0	1	0	0	0	0	0	1	0
		DAY 57	26AUG2003	57	3	-22	1	1	0	0	1	0	0	0	0	0	0	0	0	0
	E0026002	DAY 1	12NOV2002	1	14		0	2	3	2	2	2	1	1	0	0	0	0	0	1
		DAY 8	19NOV2002	8	21	7	1	2	3	1	2	2	1	3	0	0	1	1	2	2
		DAY 15	26NOV2002	15	12	-2	0	1	0	0	2	3	0	3	0	0	1	0	1	1
		DAY 22	03DEC2002	22	8	-6	0	1	1	0	3	2	0	1	0	0	0	0	0	0
		DAY 29	11DEC2002	30	13	-1	0	1	0	0	3	0	0	1	2	2	2	0	0	2
		DAY 36	18DEC2002	37	12	-2	0	1	0	2	3	1	1	1	1	1	0	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 43	26DEC2002	45	6	-8	1	0	1	0	1	0	0	0	1	0	0	1	0	1
		DAY 50	02JAN2003	52	12	-2	1	0	0	1	2	3	0	1	1	0	1	0	0	2
		DAY 57	09JAN2003	59	13	-1	0	0	0	0	3	4	1	0	3	0	1	0	0	1
	E0026007	DAY 1	16JAN2003	1	22		2	2	2	3	1	2	1	3	1	1	1	1	1	1
		DAY 8	23JAN2003	8	15	-7	3	3	2	0	3	1	0	0	0	0	2	0	1	0
		DAY 15	30JAN2003	15	14	-8	1	2	2	0	0	0	0	0	1	1	3	0	3	1
		DAY 22	06FEB2003	22	8	-14	0	0	1	0	0	0	2	0	1	1	1	0	2	0
		DAY 29	13FEB2003	29	6	-16	0	0	2	0	0	0	1	0	0	1	2	0	0	0
		DAY 36	19FEB2003	35	8	-14	1	0	2	0	0	0	1	0	0	1	2	0	1	0
		DAY 43	26FEB2003	42	5	-17	1	0	1	0	0	0	0	0	0	0	1	0	1	1
		DAY 50	05MAR2003	49	6	-16	0	0	2	0	0	0	0	1	0	0	2	0	1	0
		DAY 57	12MAR2003	56	4	-18	2	1	1	0	0	0	0	0	0	0	0	0	0	0
	E0026013	DAY 1	13FEB2003	1	20		3	3	2	2	3	3	2	0	1	0	0	1	0	0
		DAY 8	20FEB2003	8	13	-7	2	1	1	1	2	2	1	0	0	0	0	2	0	1
		DAY 15	27FEB2003	15	19	-1	4	2	2	0	2	3	2	0	0	0	1	1	2	0
		DAY 22	06MAR2003	22	26	6	4	4	2	3	3	3	1	0	0	0	0	3	2	1
		DAY 29	13MAR2003	29	11	-9	2	2	1	0	2	3	0	0	0	0	0	1	0	0
		DAY 36	20MAR2003	36	24	4	4	3	2	0	3	4	1	0	0	0	2	3	0	2
		DAY 43	27MAR2003	43	8	-12	4	2	1	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	03APR2003	50	8	-12	2	1	0	0	2	3	0	0	0	0	0	0	0	0
	E0028007	DAY 1	04OCT2002	1	10		2	1	0	2	2	2	0	0	0	0	1	0	0	0
		DAY 8	11OCT2002	8	10	0	2	1	0	0	1	2	0	1	1	0	1	0	1	0
		DAY 15	16OCT2002	13	11	1	1	1	2	0	2	0	0	1	1	0	1	0	0	2
		DAY 22	23OCT2002	20	7	-3	1	0	0	0	1	2	0	0	0	0	1	1	0	1
		DAY 29	31OCT2002	28	5	-5	0	0	1	0	0	1	0	0	0	0	1	1	1	0
		DAY 36	07NOV2002	35	5	-5	1	0	0	0	0	0	0	0	0	2	2	0	0	0
		DAY 43	14NOV2002	42	6	-4	0	2	0	0	1	0	0	0	0	0	0	1	0	2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	DAY 1	21JAN2003	1	14		3	3	0	2	1	3	0	0	0	0	0	0	0	2
		DAY 8	30JAN2003	10	15	1	2	2	1	0	1	3	0	2	0	0	0	2	0	2
		DAY 15	04FEB2003	15	12	-2	0	0	0	3	3	3	1	0	0	0	0	0	0	2
		DAY 22	11FEB2003	22	19	5	2	3	0	3	2	3	2	2	0	0	0	0	2	0
		DAY 29	17FEB2003	28	9	-5	3	0	0	3	0	2	0	0	0	0	0	1	0	0
		DAY 36	27FEB2003	38	3	-11	0	0	0	2	0	1	0	0	0	0	0	0	0	0
		DAY 43	04MAR2003	43	0	-14	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0028025	DAY 1	13JAN2003	1	33		3	3	1	3	2	3	3	2	3	2	3	0	3	2
		DAY 8	17JAN2003	5	14	-19	1	0	0	1	1	2	0	2	2	0	0	3	2	0
		DAY 15	27JAN2003	15	22	-11	0	2	0	3	2	2	2	0	0	1	2	3	3	2
	E0028033	DAY 1	27MAR2003	1	17		2	1	0	2	3	2	1	1	0	0	0	2	1	2
		DAY 8	03APR2003	8	15	-2	1	1	0	2	3	2	0	1	1	1	0	1	1	1
		DAY 15	10APR2003	15	12	-5	2	1	0	1	2	2	0	1	1	0	0	0	1	1
		DAY 22	17APR2003	22	12	-5	1	1	0	2	2	0	0	1	0	0	2	0	2	1
		DAY 29	24APR2003	29	7	-10	1	1	0	1	1	1	0	0	0	0	0	0	1	1
		DAY 36	01MAY2003	36	15	-2	2	2	0	2	2	2	2	1	0	0	0	0	1	1
		DAY 43	08MAY2003	43	17	0	2	2	0	2	2	2	2	1	0	0	1	0	1	2
		DAY 50	15MAY2003	50	17	0	2	1	0	3	2	3	0	2	0	0	0	2	2	0
		DAY 57	22MAY2003	57	10	-7	0	1	0	1	1	1	1	1	0	0	1	1	1	1
	E0028035	DAY 1	03APR2003	1	21		2	2	0	3	2	3	0	0	1	0	3	2	2	1
		DAY 8	10APR2003	8	21	0	2	3	0	2	2	3	0	2	0	0	0	2	3	2
		DAY 15	17APR2003	15	11	-10	1	0	0	0	2	3	0	0	0	0	0	2	2	1
		DAY 22	24APR2003	22	12	-9	1	0	0	0	2	3	0	0	0	0	0	2	2	2
		DAY 29	01MAY2003	29	8	-13	0	0	0	1	0	0	0	2	1	1	0	1	2	0
		DAY 36	08MAY2003	36	17	-4	3	2	0	0	3	2	0	0	0	0	2	2	2	1
		DAY 43	15MAY2003	43	19	-2	2	2	2	2	2	1	0	0	2	0	2	2	2	0
		DAY 50	22MAY2003	50	20	-1	2	0	0	2	3	3	0	0	2	0	2	2	2	2

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	DAY 57		29MAY2003	57	12	-9	2	0	0	1	2	3	0	0	0	0	2	2	0	0
	E0028037	DAY 1		12JUN2003	-1	20		3	3	0	2	3	3	0	0	0	0	0	2	2	2
		DAY 8		20JUN2003	8	12	-8	3	2	0	1	0	1	0	0	1	0	0	3	0	1
		DAY 15		25JUN2003	13	12	-8	2	2	0	0	1	2	0	0	0	0	0	2	1	2
		DAY 15	*	01JUL2003	19	8	-12	2	3	0	0	0	1	0	1	0	0	0	0	0	1
		DAY 22		08JUL2003	26	4	-16	1	1	0	0	1	0	0	0	0	0	0	0	1	0
		DAY 36		16JUL2003	34	9	-11	1	2	0	0	0	1	0	0	2	0	0	0	2	1
		DAY 43		23JUL2003	41	6	-14	2	1	0	1	0	0	0	0	0	0	0	0	1	1
		DAY 50		30JUL2003	48	4	-16	1	1	0	0	0	1	0	0	0	0	0	0	1	0
		DAY 57		08AUG2003	57	3	-17	2	0	0	0	0	0	0	0	0	0	0	0	1	0
	E0028039	DAY 1		08MAY2003	-1	17		3	2	0	3	2	3	0	0	0	0	0	2	1	1
		DAY 8		16MAY2003	8	31	14	4	4	4	2	2	3	1	1	0	2	2	2	2	2
		DAY 15		22MAY2003	14	15	-2	2	2	1	0	3	1	0	0	0	1	2	2	0	1
		DAY 22		29MAY2003	21	17	0	3	2	1	1	2	2	0	0	0	0	2	2	1	1
		DAY 29		05JUN2003	28	14	-3	3	1	0	1	2	2	0	0	0	0	1	2	1	1
	E0028046	DAY 1		25JUN2003	1	28		3	1	3	3	2	3	2	1	2	0	2	3	1	2
	E0028048	DAY 1		17JUL2003	1	31		3	3	1	3	2	3	3	2	2	0	2	2	2	3
		DAY 8		24JUL2003	8	22	-9	0	2	3	0	3	3	0	2	3	0	3	0	3	0
		DAY 15		31JUL2003	15	13	-18	2	1	1	0	1	1	0	1	1	1	1	1	1	1
		DAY 22		06AUG2003	21	6	-25	0	0	0	0	0	0	0	0	0	2	2	0	2	0
		DAY 29		14AUG2003	29	8	-23	0	0	0	2	0	1	0	0	0	1	2	0	2	0
		DAY 36		21AUG2003	36	2	-29	0	0	0	0	0	0	0	0	1	0	0	0	1	0
		DAY 43		29AUG2003	44	12	-19	0	0	0	0	0	2	0	0	2	2	2	0	2	2
		DAY 57		09SEP2003	55	17	-14	1	0	0	2	2	2	0	2	2	0	0	2	2	2
	E0029008	DAY 1		16DEC2002	1	29		2	2	2	2	2	3	1	2	2	2	3	2	2	2

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0029008	DAY 8	23DEC2002	8	21	-8	2	2	0	2	2	2	1	0	3	2	2	2	1	0
	E0029011	DAY 1	21JAN2003	-1	20		3	3	1	1	2	3	1	1	1	1	1	1	1	0
		DAY 8	28JAN2003	7	16	-4	2	2	1	2	1	2	2	1	0	0	0	1	1	1
		DAY 15	04FEB2003	14	19	-1	2	2	1	1	2	2	2	1	1	1	0	1	3	0
		DAY 22	13FEB2003	23	19	-1	2	2	1	0	3	3	1	2	1	0	0	0	2	2
	E0029012	DAY 1	11FEB2003	1	26		3	3	0	3	2	4	2	1	0	0	1	2	2	3
		DAY 8	19FEB2003	9	18	-8	3	3	0	1	2	3	1	0	0	0	1	2	1	1
		DAY 15	26FEB2003	16	22	-4	3	3	0	3	3	3	1	0	0	0	3	1	0	2
		DAY 22	03MAR2003	21	14	-12	3	3	0	0	1	2	0	0	0	0	1	1	1	2
		DAY 29	11MAR2003	29	19	-7	3	2	0	2	3	3	2	1	0	0	2	0	0	1
		DAY 36	18MAR2003	36	27	1	3	3	0	3	3	4	2	0	0	0	2	2	2	3
	E0029015	DAY 1	24FEB2003	1	25		3	3	2	2	2	2	3	2	0	0	2	1	0	3
		DAY 8	03MAR2003	8	26	1	2	3	1	2	2	1	3	2	1	0	1	2	3	3
		DAY 15	11MAR2003	16	20	-5	3	3	0	2	2	2	2	1	0	0	2	0	1	2
	E0029018	DAY 1	06MAR2003	1	20		1	2	2	3	3	2	2	0	1	0	0	2	1	1
	E0030014	DAY 1	21FEB2003	1	20		2	2	0	3	2	3	2	1	1	0	1	0	2	1
		DAY 8	28FEB2003	8	13	-7	0	0	2	0	2	1	0	1	1	1	2	2	1	0
		DAY 15	07MAR2003	15	16	-4	1	2	2	0	1	2	2	1	1	1	1	1	1	0
		DAY 22	14MAR2003	22	14	-6	2	2	2	0	1	1	0	1	0	1	1	2	1	0
		DAY 29	21MAR2003	29	14	-6	1	1	2	0	1	1	1	1	0	0	2	2	1	1
		DAY 36	27MAR2003	35	15	-5	2	1	3	1	0	1	2	0	0	0	2	1	1	1
		DAY 43	04APR2003	43	18	-2	2	2	2	1	1	2	0	0	0	1	2	2	2	1
		DAY 50	11APR2003	50	11	-9	2	1	0	1	1	1	1	0	0	0	2	0	2	0
		DAY 57	22APR2003	61	6	-14	1	1	0	0	0	1	0	0	0	0	0	1	1	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	DAY 1	29MAY2003	1	21		3	1	2	2	1	3	2	2	0	2	0	0	2	1
		DAY 8	05JUN2003	8	14	-7	3	1	2	0	1	2	0	0	0	0	1	1	2	1
		DAY 15	12JUN2003	15	8	-13	1	0	0	0	0	0	1	0	0	0	2	1	2	1
		DAY 22	17JUN2003	20	7	-14	1	1	0	0	0	1	2	0	0	0	0	0	0	2
		DAY 29	24JUN2003	27	2	-19	0	1	0	0	0	0	0	0	0	0	0	0	0	1
	E0030024	DAY 1	11JUL2003	1	22		2	2	2	2	0	3	2	1	1	1	2	2	2	0
		DAY 8	18JUL2003	8	19	-3	2	2	0	2	2	2	2	1	1	0	2	1	2	0
	E0030025	DAY 1	11JUL2003	1	26		3	2	2	3	2	3	2	2	1	1	1	2	2	0
		DAY 8	18JUL2003	8	21	-5	1	2	2	3	2	3	2	0	1	0	2	2	1	0
		DAY 15	25JUL2003	15	14	-12	1	2	2	1	0	1	1	1	1	0	2	1	1	0
		DAY 22	31JUL2003	21	12	-14	1	1	1	2	2	1	1	0	0	0	1	1	0	1
		DAY 29	11AUG2003	32	9	-17	1	1	0	0	1	2	2	1	0	0	0	1	0	0
		DAY 36	19AUG2003	40	19	-7	2	2	1	2	2	3	2	0	1	1	0	0	2	1
	E0031027	DAY 1	03JUN2003	1	26		3	3	1	2	1	3	1	2	2	2	2	1	2	1
		DAY 8	11JUN2003	9	19	-7	3	3	0	2	0	2	1	1	1	1	1	1	1	2
		DAY 15	17JUN2003	15	17	-9	2	3	0	2	0	2	1	1	1	1	1	1	1	1
		DAY 22	24JUN2003	22	13	-13	1	2	0	2	0	1	0	1	1	1	1	0	1	2
		DAY 29	01JUL2003	29	16	-10	2	2	0	2	1	2	0	1	1	1	0	0	2	2
		DAY 36	09JUL2003	37	7	-19	1	1	0	1	1	1	0	0	0	0	1	0	0	1
		DAY 43	15JUL2003	43	7	-19	2	2	0	0	0	1	0	0	0	0	0	0	0	2
		DAY 50	22JUL2003	50	9	-17	1	2	0	1	0	0	0	0	1	1	1	0	0	2
		DAY 57	29JUL2003	57	4	-22	0	1	0	0	0	0	0	1	0	0	1	0	0	1
	E0031030	DAY 1	24JUN2003	1	15		2	2	0	3	1	2	1	0	1	1	0	0	1	1
		DAY 8	01JUL2003	8	10	-5	1	1	0	1	1	2	0	0	1	1	0	1	1	0
		DAY 15	08JUL2003	15	13	-2	2	2	0	2	2	1	0	1	1	1	0	0	1	0
		DAY 22	16JUL2003	23	10	-5	1	1	0	2	1	1	0	1	1	1	0	0	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	DAY 29		23JUL2003	30	7	-8	0	1	0	0	1	1	0	1	1	1	0	0	1	0
		DAY 36		31JUL2003	38	5	-10	0	1	0	0	0	1	0	0	1	1	0	0	1	0
		DAY 43		08AUG2003	46	4	-11	0	0	0	1	0	1	0	0	1	0	0	0	1	0
		DAY 50		14AUG2003	52	16	1	2	2	0	1	1	2	1	1	1	1	2	0	1	1
		DAY 57		21AUG2003	59	13	-2	2	3	0	2	0	1	1	0	1	1	0	0	1	1
	E0033012	DAY 1		10FEB2003	1	25		3	3	0	3	3	3	1	1	2	0	1	2	1	2
	E0034001	DAY 1		20MAR2003	1	17		2	2	0	2	2	3	1	0	0	0	1	3	0	1
		DAY 8		27MAR2003	8	15	-2	2	2	0	0	2	3	1	0	0	0	1	3	0	1
		DAY 15		03APR2003	15	5	-12	1	1	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 22		10APR2003	22	6	-11	1	2	0	0	0	2	0	0	0	0	0	1	0	0
		DAY 29		17APR2003	29	7	-10	2	2	0	0	0	2	0	0	0	0	0	1	0	0
		DAY 36		24APR2003	36	7	-10	2	2	0	0	0	2	0	0	0	0	0	1	0	0
		DAY 43		01MAY2003	43	7	-10	2	2	0	0	0	2	0	0	0	0	0	1	0	0
		DAY 50		08MAY2003	50	7	-10	2	2	0	0	0	2	0	0	0	0	0	1	0	0
		DAY 57		15MAY2003	57	3	-14	1	0	0	0	0	1	0	0	0	0	0	1	0	0
	E0034004	DAY 1		21APR2003	1	15		2	2	0	2	2	3	0	0	0	0	1	2	0	1
		DAY 8		30APR2003	10	11	-4	2	2	0	0	1	2	0	0	0	0	1	2	0	1
		DAY 15		05MAY2003	15	9	-6	2	1	0	2	0	1	0	0	0	0	1	1	0	1
		DAY 22		13MAY2003	23	1	-14	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 29		19MAY2003	29	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	*	23MAY2003	33	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		02JUN2003	43	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50		09JUN2003	50	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		16JUN2003	57	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0035001	DAY 1		20NOV2002	1	15		2	1	2	2	1	3	1	0	0	0	0	1	1	1
		DAY 8		27NOV2002	8	6	-9	1	1	0	0	1	2	0	0	0	0	0	1	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0035001	DAY 15	03DEC2002	14	6	-9	1	1	0	0	1	2	0	0	0	0	0	1	0	0
		DAY 22	12DEC2002	23	6	-9	1	1	0	0	1	2	0	0	0	0	0	1	0	0
		DAY 29	18DEC2002	29	5	-10	1	1	0	0	1	1	0	0	0	0	0	1	0	0
		DAY 36	23DEC2002	34	5	-10	1	1	0	0	1	1	0	0	0	0	0	1	0	0
		DAY 43	30DEC2002	41	5	-10	1	1	0	0	1	1	0	0	0	0	0	1	0	0
		DAY 50	07JAN2003	49	5	-10	1	1	0	0	1	1	0	0	0	0	0	1	0	0
		DAY 57	14JAN2003	56	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0035006	DAY 1	12DEC2002	1	23		2	1	1	2	2	3	2	2	1	2	1	2	1	1
		DAY 8	19DEC2002	8	22	-1	2	1	2	2	2	3	2	2	0	2	1	2	1	0
		DAY 15	26DEC2002	15	23	0	2	2	1	3	2	3	2	2	0	2	1	2	1	0
		DAY 22	02JAN2003	22	24	1	2	2	1	2	2	3	2	2	0	2	2	2	1	1
		DAY 29	09JAN2003	29	25	2	2	2	1	3	2	3	2	2	0	2	2	2	2	0
		DAY 36	16JAN2003	36	26	3	3	2	1	3	2	3	2	2	0	2	2	2	2	0
		DAY 43	24JAN2003	44	24	1	3	2	1	1	2	3	2	2	0	2	2	2	2	0
		DAY 50	30JAN2003	50	25	2	3	2	1	3	2	3	2	1	0	2	2	2	2	0
		DAY 57	06FEB2003	57	21	-2	3	2	1	3	2	3	0	0	0	0	2	2	2	1
	E0035021	DAY 1	25APR2003	1	23		2	2	1	3	2	3	1	1	2	0	1	3	2	0
		DAY 8	01MAY2003	7	14	-9	2	1	0	0	1	1	2	1	2	0	1	1	2	0
		DAY 15	09MAY2003	15	7	-16	1	1	0	0	0	1	0	0	0	0	2	2	0	0
		DAY 22	15MAY2003	21	7	-16	1	1	0	0	0	2	1	0	0	0	0	2	0	0
		DAY 29	23MAY2003	29	4	-19	1	1	0	0	0	1	0	0	0	0	0	1	0	0
		DAY 36	30MAY2003	36	4	-19	1	0	0	0	1	1	0	0	0	0	0	1	0	0
		DAY 43	09JUN2003	46	2	-21	1	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	13JUN2003	50	1	-22	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	20JUN2003	57	2	-21	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	E0036002	DAY 1	17JUN2003	1	20		2	3	2	2	2	4	0	0	0	0	1	2	1	1
		DAY 8	24JUN2003	8	17	-3	3	3	2	0	3	2	0	0	0	0	1	2	0	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	DAY 15	30JUN2003	14	13	-7	1	2	2	0	2	2	0	0	1	0	0	2	0	1
		DAY 22	08JUL2003	22	13	-7	2	2	2	0	2	2	0	0	0	0	1	0	0	2
		DAY 29	14JUL2003	28	13	-7	1	3	2	2	3	0	0	0	0	0	0	0	0	2
	E0036006	DAY 1	03JUL2003	1	20		2	3	2	3	3	3	1	0	0	0	1	1	0	1
		DAY 8	10JUL2003	8	9	-11	2	2	0	0	2	1	0	0	0	1	0	0	0	1
		DAY 15	18JUL2003	16	3	-17	1	0	0	0	1	0	0	0	0	0	0	0	0	1
		DAY 22	25JUL2003	23	2	-18	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		DAY 29	31JUL2003	29	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	07AUG2003	36	3	-17	1	0	0	0	0	0	0	0	1	0	0	0	1	0
		DAY 43	13AUG2003	42	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	20AUG2003	49	1	-19	0	0	0	0	0	0	0	0	0	0	0	0	1	0
		DAY 57	27AUG2003	56	1	-19	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	E0036007	DAY 1	03JUL2003	1	28		4	2	1	3	3	3	1	3	2	2	0	1	2	1
		DAY 8	08JUL2003	6	20	-8	3	1	1	2	3	2	1	1	1	1	0	2	1	1
		DAY 15	18JUL2003	16	4	-24	1	1	0	0	1	0	0	0	0	0	0	1	0	0
	E0037009	DAY 1	16MAY2003	1	10		1	1	0	2	0	3	0	0	0	0	1	1	1	0
		DAY 8	23MAY2003	8	16	6	2	2	0	1	1	3	1	1	1	1	1	1	1	0
		DAY 15	29MAY2003	14	15	5	2	2	0	1	1	3	1	0	1	1	1	1	1	0
		DAY 22	05JUN2003	21	10	0	2	1	0	2	0	2	0	0	1	0	0	1	1	0
		DAY 29	12JUN2003	28	12	2	1	2	0	2	1	2	0	0	1	1	0	1	1	0
		DAY 36	19JUN2003	35	11	1	2	2	0	1	1	2	1	1	0	0	0	0	1	0
		DAY 43	26JUN2003	42	10	0	2	2	0	0	1	2	1	1	0	0	0	0	1	0
		DAY 50	03JUL2003	49	8	-2	1	1	0	1	1	2	0	0	1	0	0	0	1	0
		DAY 57	10JUL2003	56	10	0	1	1	0	1	1	1	1	1	1	0	0	1	1	0
	E0039011	DAY 1	02JAN2003	1	12		1	1	0	3	2	3	0	0	0	0	1	0	0	1
		DAY 8	09JAN2003	8	7	-5	1	1	1	0	1	1	0	0	0	0	1	0	0	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0039011	DAY 15	16JAN2003	15	7	-5	1	1	1	0	1	1	0	0	0	0	1	0	0	1
		DAY 22	23JAN2003	22	10	-2	2	1	0	2	1	2	1	0	0	0	0	0	0	1
		DAY 29	03FEB2003	33	3	-9	0	0	0	0	1	0	0	0	0	0	0	1	0	1
		DAY 36	06FEB2003	36	0	-12	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	13FEB2003	43	3	-9	0	1	0	0	0	0	0	0	0	0	0	0	0	2
		DAY 50	19FEB2003	49	3	-9	0	1	0	0	0	0	0	0	0	0	0	0	0	2
	E0039018	DAY 1	23JAN2003	1	21		2	2	1	3	1	3	1	1	2	1	2	0	1	1
		DAY 8	30JAN2003	8	7	-14	1	1	0	1	1	2	0	0	0	0	0	0	1	0
		DAY 15	06FEB2003	15	15	-6	2	2	0	1	1	2	0	1	1	1	1	1	1	1
		DAY 22	13FEB2003	22	4	-17	1	1	0	0	0	1	0	0	0	0	1	0	0	0
		DAY 29	20FEB2003	29	3	-18	1	0	0	0	1	1	0	0	0	0	0	0	0	0
	E0039026	DAY 1	07MAR2003	1	9		2	2	0	1	2	2	0	0	0	0	0	0	0	0
		DAY 8	14MAR2003	8	4	-5	2	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 15	19MAR2003	13	6	-3	2	1	0	0	0	0	0	1	0	0	1	0	1	0
		DAY 22	28MAR2003	22	4	-5	1	0	0	1	1	0	0	1	0	0	0	0	0	0
		DAY 29	04APR2003	29	4	-5	1	0	0	0	1	1	0	0	1	0	0	0	0	0
		DAY 36	11APR2003	36	6	-3	1	0	0	0	1	1	0	0	1	1	1	0	0	0
		DAY 43	18APR2003	43	4	-5	2	1	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	25APR2003	50	4	-5	0	1	0	0	0	0	0	0	1	1	1	0	0	0
		DAY 57	01MAY2003	56	1	-8	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0039028	DAY 1	24MAR2003	1	9		1	2	0	2	2	2	0	0	0	0	0	0	0	0
		DAY 8	31MAR2003	8	4	-5	1	1	0	0	1	0	0	0	0	0	0	0	1	0
		DAY 15	07APR2003	15	4	-5	1	2	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	14APR2003	22	5	-4	1	1	0	0	0	1	0	0	0	0	1	0	1	0
		DAY 29	21APR2003	29	6	-3	2	2	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 36	28APR2003	36	5	-4	1	2	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	43	6	-3	0	1	0	0	0	0	0	0	2	2	0	0	0	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	DAY 1	14MAR2003	1	10		2	2	0	2	2	2	0	0	0	0	0	0	0	0
		DAY 8	19MAR2003	6	2	-8	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	E0039034	DAY 1	19MAR2003	1	10		2	2	0	2	1	2	0	0	0	0	0	0	1	0
		DAY 8	26MAR2003	8	5	-5	2	1	0	0	0	0	0	0	0	0	1	0	0	1
		DAY 15	02APR2003	15	2	-8	0	0	0	0	0	1	0	0	1	0	0	0	0	0
		DAY 22	09APR2003	22	2	-8	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	16APR2003	29	1	-9	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	24APR2003	37	2	-8	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 43	30APR2003	43	1	-9	0	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	09MAY2003	52	3	-7	1	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 57	14MAY2003	57	1	-9	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	E0039042	DAY 1	07MAY2003	1	7		1	1	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 8	14MAY2003	8	5	-2	1	1	0	0	0	1	0	0	0	0	2	0	0	0
		DAY 15	21MAY2003	15	4	-3	1	1	0	0	0	1	0	0	0	0	1	0	0	0
		DAY 22	28MAY2003	22	2	-5	0	0	0	0	0	1	0	0	0	0	1	0	0	0
		DAY 29	05JUN2003	30	1	-6	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	11JUN2003	36	1	-6	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 43	18JUN2003	43	2	-5	0	1	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 50	25JUN2003	50	5	-2	1	1	0	0	0	1	0	0	0	1	0	0	1	0
		DAY 57	02JUL2003	57	2	-5	0	1	0	0	0	0	0	0	0	0	1	0	0	0
	E0041004	DAY 1	30JAN2003	1	17		1	2	1	2	1	2	1	1	1	1	0	0	2	2
		DAY 8	10FEB2003	12	8	-9	1	1	0	0	0	1	0	1	0	0	1	0	2	1
		DAY 15	14FEB2003	16	8	-9	1	1	0	0	0	0	1	1	0	1	0	0	2	1
		DAY 22	20FEB2003	22	7	-10	0	1	0	0	0	0	1	0	1	0	0	1	2	1
		DAY 29	27FEB2003	29	8	-9	1	1	1	1	0	1	1	1	0	0	0	0	0	1
		DAY 36	07MAR2003	37	7	-10	1	1	0	0	1	0	0	0	1	0	1	1	0	1
		DAY 43	14MAR2003	44	7	-10	1	1	0	0	0	0	1	1	0	0	0	0	2	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	DAY 50	21MAR2003	51	4	-13	1	1	0	0	0	0	0	0	0	0	0	0	1	1
		DAY 57	31MAR2003	61	5	-12	1	1	0	0	0	0	0	0	0	1	0	0	1	1
	E0041009	DAY 1	01MAY2003	1	20		2	1	1	2	1	2	2	1	1	0	2	2	2	1
		DAY 8	08MAY2003	8	12	-8	0	0	1	2	1	1	1	1	1	0	1	2	1	0
		DAY 15	15MAY2003	15	10	-10	2	1	0	2	1	2	1	0	0	0	0	0	0	1
		DAY 22	22MAY2003	22	4	-16	0	0	0	1	1	0	1	0	0	0	0	0	1	0
	E0042002	DAY 1	09JUL2003	1	7		1	1	1	1	1	1	1	0	0	0	0	0	0	0
		DAY 8	15JUL2003	7	4	-3	0	0	0	0	1	0	1	1	0	0	1	0	0	0
		DAY 15	22JUL2003	14	1	-6	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 22	29JUL2003	21	1	-6	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		DAY 29	05AUG2003	28	1	-6	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 36	12AUG2003	35	2	-5	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	19AUG2003	42	3	-4	1	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 50	26AUG2003	49	3	-4	0	0	0	0	1	0	0	1	0	0	1	0	0	0
		DAY 57	02SEP2003	56	2	-5	1	0	0	0	0	0	0	0	0	0	1	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	15		3	2	0	0	3	2	2	0	1	0	0	0	1	1
		DAY 8	18JUL2003	8	10	-5	2	2	0	0	3	3	0	0	0	0	0	0	0	0
	E0003002	DAY 1	29OCT2002	1	25		3	2	2	3	3	3	0	1	1	1	2	2	1	1
		DAY 8	05NOV2002	8	16	-9	2	1	1	0	2	3	2	0	1	0	1	1	1	1
		DAY 15	14NOV2002	17	9	-16	2	1	0	0	0	3	2	0	0	0	1	0	0	0
		DAY 22	19NOV2002	22	7	-18	2	1	0	0	1	1	0	0	0	0	0	1	0	1
		DAY 29	26NOV2002	29	8	-17	1	2	0	1	0	1	1	0	0	0	0	1	1	0
		DAY 36	03DEC2002	36	2	-23	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43	10DEC2002	43	0	-25	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	17DEC2002	50	2	-23	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	23DEC2002	56	2	-23	1	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0005031	DAY 1	02APR2003	1	21		3	2	1	2	2	2	3	1	0	1	0	0	1	3
		DAY 8	09APR2003	8	11	-10	1	1	0	1	2	1	1	0	1	0	0	0	1	2
		DAY 15	16APR2003	15	12	-9	1	1	1	0	2	1	1	1	0	0	2	0	1	1
		DAY 22	24APR2003	23	16	-5	2	2	0	0	2	2	1	1	1	0	2	0	1	2
		DAY 29	01MAY2003	30	17	-4	2	2	0	0	3	1	0	0	1	2	2	1	1	2
		DAY 36	07MAY2003	36	12	-9	1	1	1	0	1	1	1	1	0	1	2	0	1	1
		DAY 43	14MAY2003	43	10	-11	1	1	0	0	2	1	1	1	0	0	1	0	1	1
	E0005033	DAY 1	15APR2003	-1	22		3	2	1	3	2	3	1	0	0	0	2	2	1	2
		DAY 8	22APR2003	7	22	0	3	3	0	1	2	3	1	1	2	0	1	2	1	2
		DAY 15	30APR2003	15	20	-2	3	3	1	0	2	3	0	1	2	0	1	2	0	2
		DAY 22	06MAY2003	21	22	0	3	3	1	1	2	3	0	1	1	1	1	2	1	2
	E0005038	DAY 1	14MAY2003	1	16		3	2	1	2	2	3	0	1	0	0	0	1	0	1
		DAY 8	22MAY2003	9	19	3	3	2	1	1	1	3	0	0	1	1	1	2	1	2
		DAY 15	28MAY2003	15	20	4	3	2	1	2	1	3	0	0	2	2	0	1	1	2
		DAY 22	05JUN2003	23	30	14	3	3	0	3	2	3	2	1	2	2	2	2	2	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0007009	DAY 1		17APR2003	1	16		2	2	0	0	1	2	2	0	1	1	1	2	0	2
		DAY 8		24APR2003	8	10	-6	2	2	0	0	2	2	0	0	0	0	0	1	1	0
		DAY 8	*	28APR2003	12	11	-5	2	1	0	0	1	2	0	0	1	0	1	2	0	1
	E0009010	DAY 1		13MAR2003	1	14		2	2	0	2	1	2	1	1	1	0	0	0	1	1
		DAY 8		20MAR2003	8	21	7	2	2	1	0	1	2	1	2	2	2	2	2	1	1
		DAY 15		26MAR2003	14	19	5	2	1	0	2	1	2	1	1	2	1	2	1	1	2
		DAY 22		02APR2003	21	22	8	2	2	1	0	1	2	1	2	2	1	3	2	1	2
	E0009011	DAY 1		06MAY2003	1	9		0	0	0	1	2	3	0	0	0	0	0	2	0	1
		DAY 8		12MAY2003	7	8	-1	1	1	0	1	1	2	0	0	0	0	0	0	1	1
		DAY 15		19MAY2003	14	7	-2	1	1	0	0	1	0	1	0	0	0	0	1	1	1
		DAY 22		27MAY2003	22	5	-4	0	1	0	0	0	1	0	0	1	0	0	0	1	1
		DAY 29		03JUN2003	29	3	-6	0	1	0	0	0	0	0	0	0	0	1	0	0	1
		DAY 36		10JUN2003	36	1	-8	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 43		17JUN2003	43	6	-3	0	1	0	0	1	2	0	0	0	0	0	1	1	0
		DAY 50		24JUN2003	50	0	-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57		03JUL2003	59	3	-6	0	0	0	0	0	1	0	0	0	0	0	1	0	1
	E0010005	DAY 1		18DEC2002	1	18		3	2	0	3	3	2	0	1	1	0	0	0	1	2
	E0011016	DAY 1		21APR2003	1	21		3	3	1	2	3	2	1	1	0	0	1	0	2	2
		DAY 8		28APR2003	8	25	4	2	2	1	2	3	2	3	2	1	0	0	2	3	2
		DAY 15		05MAY2003	15	23	2	3	3	1	3	3	2	0	1	0	1	0	1	2	3
		DAY 22		12MAY2003	22	23	2	3	2	1	2	3	2	0	1	0	2	1	1	3	2
		DAY 29		19MAY2003	29	18	-3	2	2	1	1	3	2	1	0	0	1	0	2	2	1
		DAY 36		27MAY2003	37	18	-3	3	2	0	1	3	3	0	0	2	1	0	2	1	0
		DAY 43		02JUN2003	43	21	0	3	3	0	1	3	2	1	0	1	1	0	2	2	2
		DAY 50		09JUN2003	50	16	-5	1	1	1	2	1	2	1	1	1	1	0	1	2	1
		DAY 57		16JUN2003	57	19	-2	2	2	1	1	3	2	0	1	1	1	0	2	2	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0011020	DAY 1		08MAY2003	1	22		2	2	0	3	2	3	1	2	2	0	1	0	2	2
	E0018002	DAY 1		29NOV2002	1	26		2	2	2	2	2	2	2	1	1	2	2	2	2	2
		DAY 8		04DEC2002	6	21	-5	2	2	2	2	2	2	1	1	1	1	1	1	2	1
		DAY 15		11DEC2002	13	12	-14	1	1	1	2	2	1	1	0	0	0	1	0	1	1
		DAY 22		18DEC2002	20	14	-12	1	1	1	0	2	2	1	0	1	1	1	1	1	1
		DAY 22	*	24DEC2002	26	23	-3	2	2	2	2	2	2	2	1	1	1	1	1	2	2
		DAY 29		30DEC2002	32	20	-6	2	2	2	1	3	2	1	1	0	0	1	2	2	1
		DAY 43		08JAN2003	41	14	-12	2	1	1	1	2	2	1	0	0	0	0	0	2	2
		DAY 50		15JAN2003	48	11	-15	1	1	0	0	2	2	1	1	0	0	0	1	1	1
		DAY 57		22JAN2003	55	20	-6	2	2	2	2	3	2	1	1	0	0	0	1	2	2
	E0018003	DAY 1		26NOV2002	1	27		2	2	2	2	2	2	2	1	2	2	2	2	2	2
		DAY 8		03DEC2002	8	16	-11	2	2	1	0	3	2	1	2	0	0	1	1	1	0
		DAY 15		10DEC2002	15	16	-11	2	2	2	0	3	2	1	0	0	0	0	1	2	1
	E0018013	DAY 1		24JAN2003	1	22		2	2	2	3	3	3	1	1	0	0	0	1	2	2
		DAY 8		31JAN2003	8	17	-5	2	2	2	1	2	2	2	1	0	0	0	1	1	1
	E0019002	DAY 1		12NOV2002	1	22		2	2	0	3	3	2	2	1	1	0	2	1	2	1
		DAY 8		19NOV2002	8	10	-12	0	1	0	0	1	2	2	0	0	0	2	1	0	1
	E0019008	DAY 1		21NOV2002	1	29		3	3	2	3	3	3	3	2	1	0	2	2	1	1
		DAY 8		27NOV2002	7	26	-3	2	3	2	2	2	3	2	1	2	1	2	2	2	0
		DAY 15		05DEC2002	15	15	-14	2	2	0	2	1	2	0	0	1	0	2	1	1	1
		DAY 22		12DEC2002	22	9	-20	1	1	2	1	1	1	0	0	0	1	1	0	0	0
		DAY 29		19DEC2002	29	4	-25	0	1	0	0	1	0	0	0	0	0	1	0	0	1
	E0019009	DAY 1		14NOV2002	1	21		3	3	1	2	3	2	1	1	1	0	2	0	1	1
		DAY 8		21NOV2002	8	18	-3	3	3	1	0	3	2	0	1	1	0	1	1	1	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0019009	DAY 15	27NOV2002	14	19	-2	3	2	1	3	1	0	2	0	2	1	1	0	2	1
		DAY 22	05DEC2002	22	15	-6	2	1	0	0	1	2	1	1	1	1	1	1	2	1
		DAY 29	10DEC2002	27	15	-6	3	1	0	0	2	3	1	0	0	0	1	2	0	2
	E0019016	DAY 1	06JAN2003	1	21		3	2	0	2	2	3	1	1	1	1	1	2	1	1
		DAY 8	13JAN2003	8	15	-6	2	1	2	0	0	2	0	0	2	1	1	1	1	2
		DAY 15	20JAN2003	15	11	-10	2	1	0	0	1	1	0	1	0	0	1	2	1	1
		DAY 22	27JAN2003	22	8	-13	0	0	1	2	1	1	0	0	0	0	1	1	0	1
		DAY 29	03FEB2003	29	8	-13	1	0	1	2	0	1	0	0	0	0	2	0	0	1
		DAY 36	10FEB2003	36	13	-8	1	1	1	2	2	0	0	1	0	0	2	0	1	2
		DAY 43	17FEB2003	43	11	-10	1	1	2	1	0	0	1	1	0	0	0	2	1	1
		DAY 50	27FEB2003	53	9	-12	1	1	0	2	1	0	0	0	0	0	1	0	1	2
		DAY 57	03MAR2003	57	4	-17	0	2	0	2	0	0	0	0	0	0	0	0	0	0
	E0019020	DAY 1	23JAN2003	1	22		3	3	0	3	2	2	2	1	0	0	1	1	2	2
		DAY 8	30JAN2003	8	18	-4	3	2	1	2	1	3	1	0	0	0	0	1	2	2
		DAY 15	06FEB2003	15	10	-12	1	1	0	0	0	1	0	0	0	1	1	2	1	2
		DAY 22	13FEB2003	22	6	-16	1	1	0	0	1	1	0	0	0	0	0	1	0	1
		DAY 29	20FEB2003	29	7	-15	1	1	0	1	0	1	0	0	0	0	0	1	0	2
		DAY 36	27FEB2003	36	10	-12	2	2	0	2	0	1	0	0	0	0	1	0	0	2
		DAY 43	06MAR2003	43	6	-16	1	0	0	0	0	2	0	0	0	0	0	0	1	2
		DAY 50	13MAR2003	50	8	-14	1	1	0	0	0	1	1	1	0	0	1	0	1	1
		DAY 57	27MAR2003	64	23	1	2	2	0	3	2	2	2	2	1	0	2	2	2	1
	E0019021	DAY 1	30JAN2003	1	19		3	2	0	3	1	3	1	0	0	0	1	2	1	2
		DAY 8	06FEB2003	8	11	-8	2	1	0	2	1	1	0	0	1	0	1	1	0	1
		DAY 29	03MAR2003	33	13	-6	1	2	0	3	1	2	0	0	0	0	2	1	0	1
	E0019024	DAY 1	30JAN2003	1	17		2	2	0	2	2	3	1	0	0	0	1	2	1	1
		DAY 8	06FEB2003	8	16	-1	1	1	0	2	1	0	1	1	2	1	1	2	2	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	DAY 1	13MAR2003	1	17		2	2	0	1	3	3	0	0	0	0	1	3	0	2
		DAY 15	25MAR2003	13	10	-7	3	3	0	0	1	2	0	0	0	0	0	0	0	1
	E0019035	DAY 1	18MAR2003	1	19		3	3	0	1	3	3	0	0	1	0	0	2	1	2
		DAY 8	27MAR2003	10	19	0	2	2	1	0	2	2	1	0	1	2	2	0	2	2
		DAY 15	03APR2003	17	18	-1	2	2	1	1	2	2	1	0	1	1	2	0	1	2
		DAY 22	10APR2003	24	31	12	3	3	3	0	3	3	2	2	1	3	3	2	3	0
		DAY 29	17APR2003	31	23	4	3	2	2	0	3	2	2	0	1	2	1	1	2	2
	E0019040	DAY 1	20MAY2003	1	22		2	2	3	3	2	2	1	0	0	0	1	2	2	2
		DAY 8	29MAY2003	10	12	-10	2	1	0	0	2	2	1	0	1	0	0	2	0	1
		DAY 15	05JUN2003	17	15	-7	2	2	0	1	1	2	2	0	0	0	2	0	2	1
		DAY 22	12JUN2003	24	13	-9	2	2	0	0	2	2	2	0	0	0	1	0	1	1
		DAY 29	18JUN2003	30	14	-8	3	2	0	0	2	2	2	0	0	0	1	0	1	1
		DAY 36	26JUN2003	38	1	-21	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43	03JUL2003	45	7	-15	1	1	0	1	0	2	1	0	0	0	0	0	0	1
		DAY 50	10JUL2003	52	18	-4	2	2	2	1	2	2	1	1	0	0	2	0	1	2
		DAY 57	17JUL2003	59	8	-14	1	1	0	1	0	1	2	0	0	0	1	1	0	0
	E0019042	DAY 1	04JUN2003	1	19		3	3	0	3	2	3	0	1	1	0	1	0	0	2
		DAY 8	12JUN2003	9	12	-7	2	0	0	0	3	3	0	0	2	0	1	0	0	1
		DAY 15	19JUN2003	16	9	-10	1	1	0	0	2	0	0	1	1	0	0	0	2	1
	E0019045	DAY 1	26JUN2003	1	22		3	2	1	2	2	3	1	0	1	0	2	2	1	2
		DAY 8	03JUL2003	8	13	-9	3	0	0	0	3	3	0	0	0	0	0	2	0	2
	E0020024	DAY 1	23JUN2003	1	16		2	2	0	2	2	2	2	0	0	0	0	0	2	2
		DAY 8	30JUN2003	8	14	-2	2	2	0	2	2	2	0	0	0	0	0	0	2	2
		DAY 15	07JUL2003	15	11	-5	2	1	0	1	2	1	0	1	0	0	0	0	1	2
		DAY 22	15JUL2003	23	6	-10	0	0	0	2	2	0	0	0	0	0	0	0	0	2

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 29	21JUL2003	29	4	-12	0	0	0	0	2	0	0	0	0	0	1	0	0	1
		DAY 36	28JUL2003	36	2	-14	0	0	0	0	1	0	0	0	0	0	0	0	0	1
		DAY 43	04AUG2003	43	5	-11	0	0	0	0	2	0	0	0	0	0	0	0	2	1
		DAY 50	12AUG2003	51	1	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 57	20AUG2003	59	3	-13	0	0	0	0	2	0	0	0	0	0	0	0	0	1
	E0022044	DAY 1	18MAR2003	1	4		1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 8	25MAR2003	8	4	0	1	0	0	0	0	2	0	0	0	0	0	0	0	1
		DAY 15	01APR2003	15	3	-1	1	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 22	08APR2003	22	6	2	0	1	0	0	0	3	0	0	0	0	0	0	0	2
		DAY 29	15APR2003	29	6	2	2	2	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 36	22APR2003	36	8	4	1	1	0	0	0	3	0	1	0	0	0	0	0	2
		DAY 43	29APR2003	43	4	0	1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 50	06MAY2003	50	8	4	1	1	0	0	0	3	0	1	0	0	0	0	0	2
		DAY 57	12MAY2003	56	3	-1	0	0	0	0	0	2	0	0	0	0	0	0	0	1
	E0023007	DAY 1	14JAN2003	1	16		2	3	0	3	3	2	0	0	0	0	3	0	0	0
		DAY 8	21JAN2003	8	11	-5	2	2	0	0	3	2	0	0	0	0	2	0	0	0
		DAY 15	28JAN2003	15	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	07FEB2003	25	5	-11	1	1	0	0	1	1	0	0	0	0	1	0	0	0
		DAY 29	11FEB2003	29	4	-12	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36	18FEB2003	36	6	-10	1	0	0	0	3	1	0	0	0	0	0	0	0	1
		DAY 43	25FEB2003	43	3	-13	0	0	0	0	3	0	0	0	0	0	0	0	0	0
		DAY 50	04MAR2003	50	3	-13	0	0	0	0	3	0	0	0	0	0	0	0	0	0
		DAY 57	11MAR2003	57	1	-15	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0023011	DAY 1	04FEB2003	1	34		3	3	2	3	3	3	3	1	2	2	3	2	1	3
		DAY 8	11FEB2003	8	28	-6	3	3	2	1	2	3	3	2	1	2	2	1	1	2
		DAY 15	21FEB2003	18	28	-6	4	2	0	2	2	3	2	2	2	2	3	1	0	3
		DAY 22	25FEB2003	22	25	-9	3	2	1	2	2	2	2	1	2	2	3	1	0	2

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	DAY 29		04MAR2003	29	19	-15	2	2	1	2	1	2	1	1	1	2	2	1	0	1
		DAY 36		11MAR2003	36	19	-15	2	2	1	2	1	2	2	0	1	2	2	1	0	1
		DAY 43		18MAR2003	43	28	-6	3	3	1	2	3	4	2	2	2	1	1	1	1	2
		DAY 50		27MAR2003	52	27	-7	2	2	0	2	2	2	3	1	0	2	3	2	4	2
		DAY 57		01APR2003	57	19	-15	2	1	0	1	1	2	2	2	2	2	1	1	2	0
	E0023014	DAY 1		21FEB2003	1	24		3	3	1	3	3	3	2	2	1	1	0	0	1	1
		DAY 8		02MAR2003	10	30	6	4	4	2	2	4	4	2	1	1	1	1	1	0	3
		DAY 15		06MAR2003	14	26	2	4	4	2	0	1	4	2	1	1	1	2	1	0	3
		DAY 22		18MAR2003	26	24	0	3	3	1	2	2	3	1	1	1	1	1	1	1	3
		DAY 29		25MAR2003	33	25	1	4	4	0	1	2	3	2	0	0	0	2	1	3	3
		DAY 36		01APR2003	40	18	-6	3	3	0	1	3	4	2	0	0	1	0	1	0	0
		DAY 50		09APR2003	48	25	1	3	3	1	2	3	4	3	1	1	0	0	1	1	2
		DAY 50	*	15APR2003	54	22	-2	4	4	0	2	3	4	1	0	0	0	0	2	0	2
		DAY 57		25APR2003	64	21	-3	3	3	0	3	3	3	1	0	1	1	0	1	0	2
	E0023019	DAY 1		07APR2003	1	18		3	2	2	1	1	3	2	0	0	2	0	0	0	2
		DAY 8		15APR2003	9	7	-11	2	1	1	0	0	2	0	0	0	1	0	0	0	0
		DAY 15		22APR2003	16	8	-10	2	1	1	0	0	2	0	0	0	1	0	0	1	0
		DAY 22		02MAY2003	26	16	-2	2	2	0	1	3	2	0	3	0	0	0	1	2	0
		DAY 29		06MAY2003	30	7	-11	1	1	1	0	0	0	0	0	0	0	2	1	1	0
		DAY 36		13MAY2003	37	5	-13	1	1	1	0	0	1	0	0	0	0	0	0	1	0
		DAY 43		20MAY2003	44	5	-13	1	0	1	0	0	2	0	0	0	0	0	0	1	0
		DAY 50		29MAY2003	53	8	-10	1	1	1	0	1	2	0	0	0	1	0	0	0	1
		DAY 57		03JUN2003	58	4	-14	1	1	1	0	1	0	0	0	0	0	0	0	0	0
	E0023022	DAY 1		18APR2003	1	16		3	2	0	3	2	3	0	0	0	0	1	1	0	1
		DAY 8		25APR2003	8	15	-1	3	2	0	0	2	3	0	0	0	0	1	1	2	1
		DAY 15		01MAY2003	14	15	-1	3	2	0	1	2	3	0	0	0	0	0	1	2	1
		DAY 22		08MAY2003	21	11	-5	2	2	0	0	1	2	0	0	0	0	3	0	1	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0023022	DAY 29	15MAY2003	28	4	-12	1	1	0	0	1	0	0	0	0	0	0	0	1	0
		DAY 36	22MAY2003	35	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	30MAY2003	43	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	06JUN2003	50	3	-13	1	1	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	12JUN2003	56	2	-14	1	0	0	0	1	0	0	0	0	0	0	0	0	0
	E0023023	DAY 1	25APR2003	1	28		3	3	2	3	3	3	2	2	1	0	3	1	1	1
		DAY 8	01MAY2003	7	28	0	3	2	2	3	3	3	2	2	1	0	3	1	1	2
	E0023029	DAY 1	23MAY2003	1	21		3	1	1	2	2	3	2	1	1	0	2	0	1	2
	E0023031	DAY 1	24JUN2003	1	30		4	4	1	3	3	4	2	2	1	1	0	3	0	2
		DAY 8	01JUL2003	8	19	-11	3	2	0	0	2	2	2	2	0	0	2	1	2	1
		DAY 15	08JUL2003	15	21	-9	2	2	0	1	3	2	2	2	0	0	2	1	2	2
		DAY 22	15JUL2003	22	22	-8	2	3	0	1	3	2	2	2	0	0	2	1	2	2
		DAY 29	22JUL2003	29	16	-14	2	2	0	0	2	1	1	0	2	2	2	1	0	1
		DAY 36	29JUL2003	36	10	-20	2	2	0	0	2	1	0	0	0	0	0	1	0	2
		DAY 43	05AUG2003	43	10	-20	2	2	0	0	2	1	0	0	0	0	0	1	0	2
		DAY 50	12AUG2003	50	5	-25	1	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 57	19AUG2003	57	21	-9	4	3	0	3	4	3	0	0	0	0	1	0	0	3
	E0023041	DAY 1	09JUL2003	1	15		3	2	0	2	2	3	0	0	1	1	0	1	0	0
		DAY 8	16JUL2003	8	22	7	2	1	0	1	2	3	3	2	0	0	3	1	2	2
		DAY 15	24JUL2003	16	21	6	2	2	0	2	2	2	2	2	1	0	2	1	1	2
		DAY 22	30JUL2003	22	11	-4	2	2	0	2	2	2	0	0	0	0	0	0	1	0
		DAY 29	06AUG2003	29	11	-4	2	1	0	1	2	3	0	0	0	0	1	0	1	0
		DAY 36	13AUG2003	36	7	-8	1	1	0	0	1	2	0	0	0	0	0	1	1	0
		DAY 43	20AUG2003	43	6	-9	1	1	0	0	1	2	0	0	0	0	0	1	0	0
		DAY 50	27AUG2003	50	6	-9	1	1	0	0	1	2	0	0	0	0	0	1	0	0
		DAY 57	05SEP2003	59	6	-9	1	1	0	0	1	2	0	0	0	0	0	1	0	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	DAY 1	14JUL2003	1	27		3	3	0	1	3	3	2	0	0	1	4	1	3	3
		DAY 8	23JUL2003	10	15	-12	2	2	0	0	1	2	1	0	0	0	2	1	2	2
		DAY 15	28JUL2003	15	4	-23	1	2	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	05AUG2003	23	23	-4	3	3	2	0	3	3	2	1	0	0	2	0	2	2
		DAY 29	12AUG2003	30	6	-21	2	2	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36	19AUG2003	37	5	-22	2	1	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 43	26AUG2003	44	2	-25	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	02SEP2003	51	1	-26	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 57	09SEP2003	58	0	-27	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0026003	DAY 1	04DEC2002	1	32		3	3	2	3	2	3	3	3	2	1	2	0	3	2
		DAY 8	12DEC2002	9	28	-4	2	2	1	2	1	1	3	2	3	2	3	0	3	3
		DAY 15	19DEC2002	16	19	-13	3	1	2	1	1	1	2	3	2	1	1	0	1	0
		DAY 22	26DEC2002	23	7	-25	0	0	0	1	0	0	2	2	0	0	1	0	1	0
		DAY 29	02JAN2003	30	5	-27	0	0	1	0	0	0	1	0	0	0	1	0	2	0
		DAY 36	09JAN2003	37	6	-26	0	0	1	0	0	0	1	1	0	0	1	0	2	0
		DAY 43	16JAN2003	44	7	-25	0	0	0	0	0	0	2	3	0	0	1	0	1	0
		DAY 50	23JAN2003	51	8	-24	0	0	2	0	0	0	2	1	0	0	2	0	1	0
		DAY 57	03FEB2003	62	31	-1	1	1	2	0	3	3	3	3	2	2	4	3	3	1
	E0026005	DAY 1	30DEC2002	1	29		3	3	1	2	2	2	3	2	3	1	3	0	2	2
		DAY 8	06JAN2003	8	33	4	3	3	1	1	3	1	2	3	3	3	3	0	4	3
	E0026009	DAY 1	15JAN2003	1	15		1	2	0	3	2	3	1	0	1	1	1	0	0	0
		DAY 8	21JAN2003	7	14	-1	0	2	1	0	3	2	1	1	1	0	1	0	1	1
	E0026015	DAY 1	27FEB2003	1	26		3	3	0	0	2	3	2	1	2	1	4	0	2	3
		DAY 8	07MAR2003	9	25	-1	4	4	0	4	0	0	1	1	2	1	2	1	2	3
		DAY 15	13MAR2003	15	29	3	3	3	1	0	3	3	3	2	2	2	1	4	2	0
		DAY 22	20MAR2003	22	38	12	4	4	0	3	2	3	2	2	3	3	4	3	3	2

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	DAY 29	27MAR2003	29	25	-1	2	3	0	3	2	1	3	2	2	2	2	0	2	1
		DAY 36	03APR2003	36	22	-4	3	3	0	0	2	3	2	1	2	1	3	0	2	0
		DAY 43	10APR2003	43	11	-15	1	2	0	0	0	0	1	1	0	0	0	0	3	3
		DAY 50	17APR2003	50	9	-17	0	0	0	1	0	2	0	1	0	0	2	1	2	0
		DAY 57	25APR2003	58	5	-21	0	0	0	1	0	0	0	2	0	0	0	0	0	2
	E0026023	DAY 1	30APR2003	1	15		1	0	0	3	1	3	2	1	1	0	3	0	0	0
		DAY 8	07MAY2003	8	8	-7	1	0	0	0	1	1	1	1	1	0	2	0	0	0
		DAY 15	14MAY2003	15	11	-4	0	1	0	2	0	2	2	0	0	0	0	0	2	2
		DAY 22	21MAY2003	22	7	-8	0	1	0	2	0	1	0	0	1	1	0	0	0	1
		DAY 29	28MAY2003	29	10	-5	1	1	0	3	0	1	0	0	1	1	0	0	1	1
		DAY 36	04JUN2003	36	7	-8	0	1	0	2	0	1	0	0	0	1	0	0	1	1
		DAY 43	11JUN2003	43	5	-10	0	1	0	1	0	1	0	0	0	0	0	0	0	2
		DAY 50	18JUN2003	50	4	-11	0	1	0	0	0	0	1	0	0	0	0	0	0	2
	E0027016	DAY 1	09APR2003	1	19		2	2	1	2	2	2	1	2	0	0	2	0	2	1
		DAY 8	14APR2003	6	19	0	2	1	1	2	3	2	2	1	1	0	0	0	2	2
		DAY 15	22APR2003	14	13	-6	2	2	0	2	1	1	2	0	0	0	0	0	2	1
		DAY 22	29APR2003	21	10	-9	1	2	0	1	2	1	1	0	0	0	0	0	2	0
		DAY 29	05MAY2003	27	15	-4	1	1	0	1	2	2	1	0	0	2	1	1	2	1
		DAY 36	14MAY2003	36	11	-8	2	2	0	0	1	2	1	1	0	0	0	0	1	1
		DAY 43	19MAY2003	41	10	-9	1	1	0	2	1	1	1	0	0	0	1	0	1	1
		DAY 50	27MAY2003	49	13	-6	1	2	0	2	2	2	1	1	0	0	0	0	1	1
		DAY 57	03JUN2003	56	10	-9	1	2	0	1	2	1	1	0	0	0	0	0	1	1
	E0027018	DAY 1	25MAR2003	1	18		3	3	1	3	2	3	1	0	0	0	0	0	0	2
		DAY 8	02APR2003	9	22	4	3	3	3	2	2	2	0	0	1	2	0	2	1	1
		DAY 15	08APR2003	15	6	-12	1	1	0	0	0	0	0	0	1	1	0	1	0	1
		DAY 22	15APR2003	22	4	-14	1	1	0	0	0	0	0	0	0	0	0	1	0	1
		DAY 29	22APR2003	29	1	-17	0	1	0	0	0	0	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	DAY 36	29APR2003	36	2	-16	0	0	0	1	0	0	0	0	0	0	0	1	0	0
		DAY 43	05MAY2003	42	0	-18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	50	0	-18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	59	0	-18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0028032	DAY 1	25MAR2003	1	26		2	3	0	3	3	3	3	0	0	0	2	2	3	2
		DAY 8	01APR2003	8	12	-14	1	0	0	0	3	3	1	0	0	0	0	3	0	1
		DAY 15	08APR2003	15	19	-7	2	0	0	0	3	3	3	0	0	0	2	2	2	2
		DAY 22	15APR2003	22	16	-10	0	0	0	0	2	3	3	0	0	0	2	2	2	2
		DAY 29	22APR2003	29	13	-13	0	0	0	0	2	3	2	0	0	0	1	1	2	2
		DAY 36	30APR2003	37	10	-16	0	0	0	0	2	2	0	0	0	0	2	2	2	0
		DAY 43	06MAY2003	43	15	-11	0	2	0	0	3	3	3	0	0	0	0	2	2	0
		DAY 50	13MAY2003	50	21	-5	3	1	0	1	3	3	3	0	0	0	2	2	2	1
	E0029003	DAY 1	04NOV2002	1	23		3	3	0	2	2	2	3	0	0	0	1	3	2	2
		DAY 8	11NOV2002	8	19	-4	2	2	2	0	2	2	2	0	0	0	1	2	2	2
		DAY 15	18NOV2002	15	13	-10	1	1	0	0	0	1	1	1	0	0	2	2	2	2
		DAY 22	25NOV2002	22	18	-5	2	2	0	0	2	1	2	1	0	1	1	2	2	2
		DAY 29	02DEC2002	29	16	-7	2	2	1	0	2	0	2	0	0	0	1	2	2	2
		DAY 36	09DEC2002	36	16	-7	3	2	0	0	1	1	1	1	0	0	1	2	2	2
		DAY 43	16DEC2002	43	17	-6	2	3	0	0	3	0	2	0	0	2	0	1	2	2
		DAY 50	23DEC2002	50	18	-5	2	2	1	0	2	2	2	1	0	0	1	2	2	1
		DAY 57	30DEC2002	57	15	-8	2	2	0	0	3	2	2	0	0	0	1	1	1	1
	E0029020	DAY 1	04MAR2003	-1	14		2	1	0	2	2	2	1	0	1	0	0	2	0	1
		DAY 8	11MAR2003	7	17	3	2	2	0	1	2	2	0	0	1	2	1	2	1	1
	E0031005	DAY 1	20DEC2002	1	20		2	2	0	3	2	2	1	0	1	1	2	2	0	2
		DAY 8	27DEC2002	8	16	-4	2	2	0	1	2	1	2	0	1	1	0	2	1	1
		DAY 15	03JAN2003	15	15	-5	1	1	0	1	1	2	2	1	1	1	0	2	1	1

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	DAY 22	10JAN2003	22	18	-2	2	2	0	1	2	2	2	1	1	1	0	2	1	1
		DAY 29	17JAN2003	29	10	-10	0	1	0	1	1	1	0	0	1	1	0	2	1	1
		DAY 36	24JAN2003	36	12	-8	1	1	0	1	1	1	2	0	0	1	0	2	1	1
		DAY 43	30JAN2003	42	17	-3	2	2	0	2	2	2	2	0	0	1	0	2	1	1
		DAY 50	07FEB2003	50	11	-9	0	1	0	1	1	1	1	0	1	1	0	2	1	1
		DAY 57	14FEB2003	57	14	-6	1	1	0	1	2	1	2	1	0	1	0	2	1	1
	E0031006	DAY 1	18FEB2003	1	18		2	1	2	2	2	2	1	1	1	1	1	0	1	1
		DAY 8	26FEB2003	9	14	-4	1	1	1	1	2	1	1	1	1	1	1	0	1	1
		DAY 15	05MAR2003	16	11	-7	1	1	1	1	2	1	1	1	0	0	1	0	1	0
		DAY 22	11MAR2003	22	10	-8	0	1	1	1	1	1	0	1	0	1	1	0	1	1
		DAY 29	18MAR2003	29	7	-11	0	0	0	1	1	1	1	0	0	1	1	0	1	0
		DAY 36	25MAR2003	36	15	-3	2	2	1	1	2	1	1	1	1	1	1	0	1	0
		DAY 43	02APR2003	44	18	0	2	2	2	2	2	1	1	1	1	1	1	0	1	1
		DAY 50	07APR2003	49	13	-5	2	2	0	1	2	0	0	1	1	1	1	0	1	1
		DAY 57	15APR2003	57	10	-8	1	1	1	1	1	1	1	1	0	0	1	0	1	0
	E0031010	DAY 1	19FEB2003	1	14		2	1	0	2	2	2	1	1	1	0	1	0	0	1
		DAY 8	26FEB2003	8	14	0	2	2	0	0	1	2	0	1	1	0	2	1	1	1
		DAY 15	05MAR2003	15	19	5	2	1	1	0	0	3	2	1	1	1	3	2	1	1
	E0031011	DAY 1	27FEB2003	1	20		2	2	0	1	2	2	2	1	1	1	1	2	2	1
		DAY 8	06MAR2003	8	11	-9	1	1	0	0	0	1	1	1	1	1	0	1	2	1
		DAY 15	13MAR2003	15	10	-10	2	1	0	1	0	1	0	0	1	1	0	1	1	1
		DAY 22	20MAR2003	22	16	-4	2	2	0	1	1	2	0	1	1	1	1	2	1	1
		DAY 29	27MAR2003	29	0	-20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	03APR2003	36	3	-17	0	0	0	0	0	0	0	0	1	0	0	0	1	1
		DAY 43	11APR2003	44	19	-1	2	3	0	2	2	2	2	0	1	1	1	0	2	1
		DAY 50	17APR2003	50	12	-8	1	1	0	1	1	1	0	0	1	1	0	2	2	1
		DAY 57	24APR2003	57	2	-18	1	0	0	0	0	0	0	0	0	0	0	1	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	DAY 1	26MAR2003	1	18		2	2	0	1	1	2	2	1	1	1	1	2	1	1
		DAY 8	01APR2003	7	12	-6	1	1	0	0	2	2	1	1	1	1	1	0	1	0
	E0031031	DAY 1	08JUL2003	1	16		1	2	0	2	3	2	2	1	0	0	0	2	0	1
		DAY 8	15JUL2003	8	13	-3	2	2	0	0	2	1	1	1	0	0	0	2	1	1
		DAY 15	22JUL2003	15	19	3	2	3	0	2	3	2	0	1	0	0	1	2	2	1
		DAY 22	29JUL2003	22	8	-8	0	2	0	1	1	1	0	0	0	0	1	1	1	0
	E0033009	DAY 1	12FEB2003	1	30		3	3	0	3	3	3	2	2	1	1	2	3	2	2
	E0034009	DAY 1	19JUN2003	1	16		2	2	0	3	2	3	1	0	0	0	2	0	0	1
		DAY 8	27JUN2003	9	12	-4	2	2	0	0	2	3	1	0	0	0	2	0	0	0
		DAY 15	03JUL2003	15	11	-5	2	2	0	0	1	1	2	0	0	0	1	1	0	1
		DAY 22	10JUL2003	22	8	-8	2	0	0	0	1	1	2	0	0	0	1	1	0	0
		DAY 29	18JUL2003	30	4	-12	1	0	0	0	0	1	2	0	0	0	0	0	0	0
		DAY 36	25JUL2003	37	5	-11	1	0	0	0	0	1	2	0	0	0	1	0	0	0
		DAY 43	31JUL2003	43	3	-13	1	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 50	07AUG2003	50	2	-14	0	0	0	0	0	1	1	0	0	0	0	0	0	0
		DAY 57	18AUG2003	61	0	-16	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0037007	DAY 1	11APR2003	1	17		2	2	0	3	2	3	1	0	0	0	1	2	1	0
		DAY 8	17APR2003	7	11	-6	0	1	0	1	2	2	1	0	1	0	1	2	0	0
	E0037012	DAY 1	16JUL2003	1	10		1	1	0	2	1	2	1	1	0	0	1	0	0	0
		DAY 8	24JUL2003	9	10	0	1	1	0	1	2	1	1	0	1	0	1	0	1	0
		DAY 15	01AUG2003	17	10	0	1	1	0	0	2	2	1	0	1	0	1	0	1	0
		DAY 22	08AUG2003	24	5	-5	1	0	0	0	1	0	1	1	0	0	0	0	1	0
		DAY 29	15AUG2003	31	6	-4	1	1	0	0	0	0	1	0	1	1	0	0	1	0
		DAY 36	22AUG2003	38	2	-8	1	0	0	0	0	0	0	0	0	0	0	0	1	0
		DAY 43	29AUG2003	45	4	-6	1	0	0	1	0	0	0	1	0	0	0	0	1	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 50	05SEP2003	52	3	-7	1	0	0	0	0	0	0	1	0	0	0	0	1	0
		DAY 57	08SEP2003	55	4	-6	1	0	0	0	0	0	1	1	0	0	0	0	1	0
	E0039019	DAY 1	06FEB2003	1	9		1	2	0	2	1	2	0	0	0	0	0	0	1	0
		DAY 8	13FEB2003	8	6	-3	1	1	0	0	1	2	0	1	0	0	0	0	0	0
		DAY 15	20FEB2003	15	5	-4	1	1	0	0	1	1	0	0	0	0	0	0	1	0
		DAY 22	27FEB2003	22	6	-3	2	1	0	0	1	1	0	1	0	0	0	0	0	0
		DAY 29	07MAR2003	30	5	-4	1	1	0	0	0	1	0	0	0	0	2	0	0	0
		DAY 36	13MAR2003	36	14	5	2	2	0	0	2	2	1	1	2	0	1	0	1	0
		DAY 43	20MAR2003	43	3	-6	0	0	0	0	0	1	0	1	0	0	0	0	1	0
		DAY 50	27MAR2003	50	7	-2	2	1	0	0	1	1	0	1	1	0	0	0	0	0
		DAY 57	03APR2003	57	4	-5	2	1	0	0	0	1	0	0	0	0	0	0	0	0
	E0039043	DAY 1	08MAY2003	1	9		2	1	0	2	1	2	1	0	0	0	0	0	0	0
		DAY 8	15MAY2003	8	5	-4	1	1	0	0	1	1	0	1	0	0	0	0	0	0
		DAY 15	23MAY2003	16	1	-8	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	29MAY2003	22	2	-7	0	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	05JUN2003	29	3	-6	1	1	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 36	13JUN2003	37	7	-2	1	1	0	1	1	1	0	0	0	0	1	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	33		4	3	2	3	3	3	3	2	1	1	0	4	3	1
		DAY 8	06JAN2003	8	18	-15	2	3	1	2	2	3	1	0	0	0	0	2	1	1
		DAY 15	14JAN2003	16	13	-20	2	2	2	0	1	2	0	0	0	0	0	3	0	1
		DAY 22	21JAN2003	23	13	-20	1	1	2	0	1	2	1	1	0	0	0	3	1	0
		DAY 29	29JAN2003	31	10	-23	2	2	1	0	1	2	0	0	0	0	0	2	0	0
		DAY 36	05FEB2003	38	12	-21	2	1	1	1	1	2	1	1	0	0	1	1	0	0
		DAY 43	12FEB2003	45	12	-21	3	3	1	1	0	2	0	0	0	0	0	2	0	0
		DAY 50	19FEB2003	52	10	-23	1	1	2	0	0	2	1	1	0	0	0	2	0	0
		DAY 57	26FEB2003	59	5	-28	2	0	1	0	0	1	0	1	0	0	0	0	0	0
	E0002003	DAY 1	22JAN2003	1	25		3	3	2	3	2	2	1	1	1	1	2	2	1	1
		DAY 8	29JAN2003	8	25	0	3	3	2	1	2	3	2	1	0	2	1	2	1	2
		DAY 15	05FEB2003	15	20	-5	2	2	1	1	2	2	1	1	1	0	1	3	2	1
		DAY 22	12FEB2003	22	23	-2	2	3	0	2	2	3	2	1	1	0	1	2	2	2
		DAY 29	19FEB2003	29	12	-13	2	1	0	1	1	2	1	1	0	1	1	0	1	0
		DAY 36	26FEB2003	36	12	-13	2	2	1	1	1	1	1	1	0	0	1	0	1	0
		DAY 43	05MAR2003	43	11	-14	1	1	0	1	2	1	1	1	0	0	1	1	1	0
		DAY 50	11MAR2003	49	10	-15	1	1	0	1	1	1	1	1	1	0	1	0	1	0
		DAY 57	18MAR2003	56	9	-16	1	1	0	0	1	1	1	1	1	0	1	0	1	0
	E0002004	DAY 1	25JAN2003	1	27		3	3	1	2	2	2	2	1	1	2	2	2	3	1
	E0002008	DAY 1	25FEB2003	1	14		2	2	1	2	1	1	1	1	1	0	1	0	1	0
		DAY 8	05MAR2003	9	13	-1	2	2	0	1	1	1	0	1	1	0	1	1	1	1
		DAY 15	13MAR2003	17	9	-5	2	2	0	1	1	1	0	1	0	0	0	0	1	0
		DAY 22	20MAR2003	24	9	-5	2	1	0	1	1	1	0	1	0	0	1	0	1	0
		DAY 29	27MAR2003	31	9	-5	2	1	1	1	1	2	0	0	0	0	0	0	1	0
		DAY 36	03APR2003	38	11	-3	2	2	0	1	2	2	0	0	0	0	1	0	1	0
		DAY 43	11APR2003	46	11	-3	2	2	0	1	1	1	1	1	0	0	1	0	1	0
		DAY 50	16APR2003	51	11	-3	2	2	0	2	1	1	0	1	0	0	1	0	1	0
		DAY 57	23APR2003	58	11	-3	2	2	0	2	1	1	1	1	0	0	0	0	1	0

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0002016	DAY 1	24JUL2003	1	16		2	2	1	2	2	2	1	1	0	0	1	0	2	0
		DAY 8	30JUL2003	7	11	-5	2	2	0	1	1	1	1	1	0	0	1	0	1	0
		DAY 15	06AUG2003	14	8	-8	1	1	0	1	1	1	1	1	0	0	1	0	0	0
		DAY 22	13AUG2003	21	9	-7	2	1	0	1	1	1	1	0	0	0	1	0	1	0
		DAY 29	21AUG2003	29	9	-7	1	1	0	0	1	1	0	2	1	0	1	0	1	0
		DAY 36	27AUG2003	35	5	-11	1	1	0	0	1	1	0	1	0	0	0	0	0	0
		DAY 43	03SEP2003	42	5	-11	1	1	0	0	1	1	0	1	0	0	0	0	0	0
		DAY 50	11SEP2003	50	6	-10	1	1	0	0	1	1	0	1	0	0	0	0	1	0
		DAY 57	17SEP2003	56	4	-12	2	1	0	0	0	0	0	0	0	0	0	0	1	0
	E0003008	DAY 1	28JAN2003	1	8		1	1	0	1	1	2	0	0	0	0	0	0	1	1
		DAY 8	04FEB2003	8	6	-2	2	0	0	2	1	1	0	0	0	0	0	0	0	0
		DAY 15	11FEB2003	15	10	2	3	2	0	1	1	1	0	0	1	0	0	0	0	1
		DAY 22	18FEB2003	22	9	1	1	1	0	1	1	1	2	0	0	0	0	0	1	1
	E0004003	DAY 1	10OCT2002	1	30		3	3	2	3	3	3	1	3	2	0	0	3	2	2
		DAY 8	17OCT2002	8	16	-14	1	0	0	2	3	2	0	1	0	0	2	1	1	3
	E0004006	DAY 1	04NOV2002	1	26		2	3	3	3	3	3	0	2	1	0	2	2	1	1
		DAY 8	11NOV2002	8	20	-6	2	3	3	2	2	2	0	0	2	0	0	1	2	1
		DAY 15	18NOV2002	15	14	-12	2	2	3	1	1	1	0	0	1	0	0	1	1	1
		DAY 22	25NOV2002	22	14	-12	1	2	3	1	2	2	0	0	1	0	0	1	1	0
		DAY 29	02DEC2002	29	11	-15	1	1	2	1	1	2	0	0	1	1	0	1	0	0
		DAY 36	09DEC2002	36	18	-8	2	2	1	2	2	3	0	1	1	1	1	2	0	0
		DAY 43	16DEC2002	43	12	-14	1	1	1	2	1	2	0	0	0	0	1	2	0	1
		DAY 57	06JAN2003	64	22	-4	2	3	3	3	2	3	0	0	2	1	0	3	0	0
	E0004016	DAY 1	19FEB2003	1	23		2	2	1	2	2	2	2	1	1	2	2	2	1	1
		DAY 8	26FEB2003	8	21	-2	2	2	0	1	2	2	2	1	2	2	1	2	1	1
		DAY 15	05MAR2003	15	18	-5	2	2	0	0	2	2	1	1	2	2	0	2	1	1
		DAY 22	13MAR2003	23	16	-7	2	2	0	1	2	1	1	1	1	1	1	1	1	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0004016	DAY 36	26MAR2003	36	4	-19	1	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 43	03APR2003	44	6	-17	1	1	0	0	2	0	0	0	1	0	0	1	0	0
		DAY 50	10APR2003	51	0	-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	17APR2003	58	5	-18	1	1	0	1	1	0	0	0	0	0	0	0	1	0
	E0004024	DAY 1	03JUL2003	1	25		3	3	0	3	2	2	3	1	2	0	2	1	2	1
		DAY 8	10JUL2003	8	20	-5	3	2	0	2	2	2	2	1	2	0	2	1	1	0
		DAY 15	17JUL2003	15	13	-12	2	1	0	1	1	2	0	0	0	0	2	2	1	1
		DAY 22	24JUL2003	22	9	-16	1	1	0	1	1	1	2	0	0	0	1	0	1	0
		DAY 29	31JUL2003	29	10	-15	2	2	0	1	1	1	1	0	0	0	1	0	1	0
		DAY 36	07AUG2003	36	8	-17	2	1	0	1	1	1	0	0	0	0	1	0	1	0
		DAY 43	14AUG2003	43	5	-20	1	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 50	21AUG2003	50	3	-22	0	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 57	28AUG2003	57	3	-22	1	1	0	0	0	1	0	0	0	0	0	0	0	0
	E0005006	DAY 1	03OCT2002	1	18		2	2	1	2	2	3	0	1	0	0	2	0	1	2
		DAY 8	14OCT2002	12	8	-10	0	0	0	2	1	1	0	0	1	0	0	0	2	1
	E0005017	DAY 1	30DEC2002	1	27		3	3	0	3	3	3	2	1	1	0	1	3	2	2
		DAY 8	06JAN2003	8	26	-1	3	3	0	3	3	3	1	1	1	0	1	3	2	2
		DAY 15	14JAN2003	16	23	-4	3	2	0	3	2	3	1	1	0	1	0	3	2	2
		DAY 22	22JAN2003	24	20	-7	2	2	0	2	2	2	1	1	0	1	0	3	2	2
		DAY 29	30JAN2003	32	20	-7	2	2	0	2	2	2	1	1	0	1	0	3	2	2
		DAY 36	04FEB2003	37	20	-7	2	2	0	1	2	2	1	1	1	1	0	3	2	2
		DAY 43	13FEB2003	46	20	-7	2	2	0	1	3	2	1	2	0	1	0	3	1	2
		DAY 50	20FEB2003	53	17	-10	2	2	0	1	3	2	1	1	1	0	0	1	2	1
		DAY 57	04MAR2003	65	23	-4	3	3	0	1	3	3	1	1	0	1	0	3	2	2
	E0005019	DAY 1	15JAN2003	1	19		2	3	0	2	2	3	0	1	0	2	2	0	1	1
		DAY 8	23JAN2003	9	18	-1	2	2	1	2	2	3	0	0	0	2	1	1	0	2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0005026	DAY 1	06MAR2003	1	21		3	2	0	2	2	2	1	0	2	1	2	2	0	2
		DAY 8	13MAR2003	8	20	-1	3	2	2	2	1	3	0	0	0	1	0	2	2	2
		DAY 15	20MAR2003	15	24	3	3	3	2	3	2	3	1	0	1	1	2	0	0	3
		DAY 22	25MAR2003	20	23	2	3	3	2	2	2	3	1	0	0	1	1	2	1	2
	E0005039	DAY 1	22MAY2003	1	22		2	2	1	3	3	3	0	1	0	1	1	1	2	2
		DAY 8	28MAY2003	7	24	2	2	3	1	3	3	3	2	0	0	0	2	1	2	2
		DAY 15	05JUN2003	15	14	-8	2	2	0	0	3	2	1	0	0	0	0	0	2	2
		DAY 22	12JUN2003	22	19	-3	3	3	0	2	3	3	1	0	0	0	0	0	2	2
		DAY 29	18JUN2003	28	15	-7	2	2	0	1	3	2	1	0	0	0	0	1	1	2
		DAY 36	24JUN2003	34	17	-5	2	3	0	1	3	3	0	0	0	0	0	1	2	2
		DAY 43	03JUL2003	43	17	-5	1	2	0	2	3	2	2	0	0	0	0	1	2	2
		DAY 50	10JUL2003	50	17	-5	2	3	0	1	3	3	0	0	0	0	0	1	2	2
		DAY 57	16JUL2003	56	16	-6	2	2	0	1	3	3	0	0	0	0	0	1	2	2
	E0005043	DAY 1	09JUL2003	1	14		3	2	1	0	2	3	0	0	0	1	0	1	0	1
		DAY 8	17JUL2003	9	8	-6	2	1	0	0	1	3	0	0	0	0	0	0	0	1
		DAY 15	24JUL2003	16	12	-2	3	2	0	0	2	3	0	0	0	0	0	1	0	1
		DAY 22	31JUL2003	23	10	-4	2	2	0	0	2	3	0	0	0	0	0	0	0	1
		DAY 29	07AUG2003	30	9	-5	2	1	0	0	2	3	0	0	0	0	0	0	0	1
		DAY 36	13AUG2003	36	9	-5	2	1	0	0	2	3	0	0	0	0	0	0	0	1
		DAY 43	20AUG2003	43	8	-6	2	1	0	0	1	3	0	0	0	0	0	0	0	1
		DAY 50	27AUG2003	50	6	-8	2	1	0	0	0	2	0	0	0	0	0	1	0	0
		DAY 57	03SEP2003	57	5	-9	1	1	0	0	0	1	0	0	0	0	0	1	0	1
	E0006020	DAY 1	13MAY2003	1	12		1	1	0	2	2	2	1	0	0	0	1	1	0	1
		DAY 8	20MAY2003	8	11	-1	0	1	0	2	2	2	1	0	0	0	1	1	0	1
		DAY 15	27MAY2003	15	12	0	0	2	0	2	2	2	1	0	0	0	1	1	0	1
		DAY 22	03JUN2003	22	10	-2	0	1	0	1	2	2	1	0	0	0	1	1	0	1
		DAY 29	10JUN2003	29	11	-1	1	1	0	1	2	2	1	0	0	0	1	1	0	1
		DAY 36	17JUN2003	36	11	-1	1	1	0	1	2	2	1	0	0	0	1	1	0	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0006020	DAY 43		24JUN2003	43	9	-3	1	1	0	1	1	1	1	0	0	0	1	1	0	1
		DAY 50		01JUL2003	50	9	-3	1	1	0	1	1	1	1	0	0	0	1	1	0	1
		DAY 57		08JUL2003	57	9	-3	1	1	0	1	1	1	1	0	0	0	1	1	0	1
	E0007001	DAY 1		31DEC2002	1	10		2	1	0	2	1	2	0	0	0	0	0	2	0	0
		DAY 8		07JAN2003	8	12	2	2	2	0	2	1	2	0	0	1	0	0	2	0	0
		DAY 15		14JAN2003	15	9	-1	2	2	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 22		21JAN2003	22	8	-2	2	2	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 29		28JAN2003	29	7	-3	2	1	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 36		04FEB2003	36	7	-3	1	1	0	1	1	2	0	0	0	0	1	0	0	0
		DAY 43		11FEB2003	43	9	-1	2	1	0	2	1	2	0	0	0	0	0	1	0	0
		DAY 50		18FEB2003	50	5	-5	1	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 50	*	22FEB2003	54	6	-4	1	1	0	1	1	1	0	0	0	0	0	1	0	0
	E0007003	DAY 1		30JAN2003	1	14		2	2	0	3	1	2	1	0	0	0	0	2	0	1
		DAY 8		06FEB2003	8	11	-3	2	2	0	3	1	2	1	0	0	0	0	0	0	0
		DAY 15		14FEB2003	16	10	-4	1	1	0	3	1	2	0	0	0	0	0	2	0	0
		DAY 22		22FEB2003	24	15	1	2	2	0	3	0	2	2	0	0	1	0	2	0	1
		DAY 36		10MAR2003	40	9	-5	2	2	0	2	0	2	0	0	0	0	0	0	0	1
	E0007006	DAY 1		05MAR2003	1	9		2	1	0	2	1	2	0	0	0	0	0	0	0	1
		DAY 8		12MAR2003	8	12	3	2	2	0	2	2	2	1	0	0	0	0	0	0	1
		DAY 15		19MAR2003	15	2	-7	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 22	*	25MAR2003	21	5	-4	1	1	0	0	1	1	0	0	0	0	0	0	0	1
		DAY 22		26MAR2003	22	5	-4	1	1	0	0	1	1	0	0	0	0	0	0	0	1
	E0009004	DAY 1		26NOV2002	1	33		4	4	0	4	4	4	3	0	1	2	3	2	0	2
		DAY 8		04DEC2002	9	12	-21	3	3	0	4	0	0	0	0	0	0	0	0	0	2
		DAY 15		11DEC2002	16	24	-9	2	3	0	3	2	3	2	1	2	1	1	1	0	3
		DAY 22		18DEC2002	23	20	-13	1	2	0	3	3	3	1	0	0	0	1	3	1	2

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0009012	DAY 1	25JUN2003	1	28		3	3	2	2	2	3	1	2	2	1	2	1	2	2
		DAY 8	03JUL2003	9	18	-10	2	1	1	2	2	2	1	1	2	0	1	1	1	1
	E0010008	DAY 1	18DEC2002	1	23		2	3	1	2	3	3	2	0	1	0	0	3	1	2
		DAY 8	26DEC2002	9	22	-1	3	3	0	3	3	3	1	1	0	0	0	3	0	2
		DAY 15	02JAN2003	16	27	4	3	3	1	2	3	3	2	0	1	0	0	4	2	3
		DAY 22	08JAN2003	22	22	-1	3	3	0	2	2	2	1	0	2	0	1	3	2	1
		DAY 29	15JAN2003	29	16	-7	2	3	0	2	1	1	0	0	0	0	0	3	2	2
	E0010018	DAY 1	19MAR2003	1	23		2	3	1	3	0	3	1	1	2	0	2	3	1	1
		DAY 8	26MAR2003	8	12	-11	2	2	0	1	0	1	0	0	0	0	1	3	2	0
		DAY 15	02APR2003	15	23	0	3	2	0	4	0	3	1	0	1	0	3	3	2	1
		DAY 22	09APR2003	22	8	-15	1	0	0	2	0	0	1	0	0	0	0	3	1	0
		DAY 29	16APR2003	29	8	-15	1	0	0	2	0	1	0	0	0	0	0	3	1	0
		DAY 36	23APR2003	36	10	-13	1	2	0	2	0	0	0	0	0	0	1	3	1	0
		DAY 43	01MAY2003	44	9	-14	1	1	0	2	0	1	0	0	0	0	1	3	0	0
	E0010028	DAY 1	16JUN2003	1	26		3	3	0	4	0	3	0	2	2	0	2	3	2	2
		DAY 8	24JUN2003	9	24	-2	3	3	0	4	2	2	1	1	1	0	2	3	1	1
		DAY 15	01JUL2003	16	32	6	3	4	0	4	2	3	1	2	2	0	3	3	2	3
		DAY 22	08JUL2003	23	20	-6	3	3	0	4	1	2	0	0	1	0	2	1	1	2
		DAY 29	15JUL2003	30	31	5	4	4	0	4	3	4	1	1	1	1	1	3	1	3
	E0011008	DAY 1	30JAN2003	1	13		2	2	1	2	1	2	1	0	0	0	0	0	1	1
		DAY 8	06FEB2003	8	7	-6	1	1	0	1	0	1	1	0	0	0	0	0	1	1
		DAY 15	13FEB2003	15	10	-3	2	1	0	0	2	1	1	0	0	0	1	1	0	1
	E0011009	DAY 1	26DEC2002	-1	19		2	1	0	3	3	3	2	0	0	0	2	2	0	1
		DAY 8	02JAN2003	7	14	-5	2	1	0	2	2	2	0	0	0	0	1	2	1	1
		DAY 15	09JAN2003	14	15	-4	2	1	1	3	1	1	0	0	1	1	1	1	1	1
		DAY 22	16JAN2003	21	11	-8	0	1	0	2	1	2	1	0	0	1	0	1	2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0011009	DAY 29	23JAN2003	28	20	1	1	3	2	3	1	1	1	0	2	0	3	0	2	1
		DAY 36	30JAN2003	35	19	0	3	2	1	3	2	2	1	0	2	0	0	1	2	0
		DAY 43	06FEB2003	42	10	-9	2	1	1	3	1	1	1	0	0	0	0	0	0	0
		DAY 50	13FEB2003	49	10	-9	2	0	0	2	1	1	1	0	1	0	1	0	0	1
		DAY 57	20FEB2003	56	11	-8	2	1	1	2	1	1	1	0	0	0	2	0	0	0
	E0011010	DAY 1	10FEB2003	1	25		2	3	1	0	3	3	3	3	1	0	0	2	2	2
		DAY 8	17FEB2003	8	24	-1	2	3	0	2	3	3	2	2	0	2	1	1	2	1
		DAY 15	24FEB2003	15	20	-5	3	2	0	1	2	2	1	1	1	2	1	1	1	2
		DAY 22	03MAR2003	22	14	-11	2	2	0	2	2	2	0	0	0	0	1	1	1	1
		DAY 29	10MAR2003	29	10	-15	1	1	0	2	1	1	0	0	0	0	1	1	1	1
		DAY 36	17MAR2003	36	20	-5	1	3	0	3	3	3	2	2	0	0	0	1	1	1
		DAY 36 *	19MAR2003	38	21	-4	2	2	0	3	3	3	1	1	1	0	0	2	2	1
	E0013001	DAY 1	14NOV2002	1	15		2	3	0	3	3	3	1	0	0	0	0	0	0	0
		DAY 8	21NOV2002	8	25	10	3	3	0	3	2	3	2	0	2	3	2	0	2	0
		DAY 15	27NOV2002	14	6	-9	0	1	0	1	1	2	1	0	0	0	0	0	0	0
		DAY 22	06DEC2002	23	4	-11	2	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	11DEC2002	28	2	-13	1	0	0	0	0	0	0	0	0	0	0	1	0	0
		DAY 36	18DEC2002	35	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	27DEC2002	44	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	02JAN2003	50	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	10JAN2003	58	0	-15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0013003	DAY 1	12NOV2002	1	21		2	1	0	3	3	3	1	2	1	1	0	2	2	0
		DAY 8	19NOV2002	8	24	3	3	2	0	2	3	3	1	2	1	1	1	2	2	1
		DAY 15	26NOV2002	15	18	-3	2	2	0	2	2	2	1	1	1	0	0	2	2	1
		DAY 22	03DEC2002	22	19	-2	2	1	0	3	2	3	1	1	1	1	0	2	1	1
		DAY 29	11DEC2002	30	18	-3	2	2	0	3	1	3	0	1	1	1	0	2	1	1
		DAY 36	18DEC2002	37	24	3	3	2	0	3	2	3	1	2	1	1	0	2	2	2
		DAY 43	23DEC2002	42	20	-1	1	1	0	3	1	3	1	2	1	0	2	2	2	1

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PLACEBO (BIPOLAR I)	E0013003	DAY 50		30DEC2002	49	17	-4	3	0	0	3	2	3	0	2	0	0	0	2	2	0
		DAY 57		06JAN2003	56	21	0	2	2	0	3	2	3	2	2	0	0	0	2	2	1
	E0013005	DAY 1		18FEB2003	1	19		3	3	0	3	2	3	3	1	0	0	0	0	1	0
		DAY 8		25FEB2003	8	14	-5	2	2	0	2	3	3	2	0	0	0	0	0	0	0
		DAY 15		04MAR2003	15	13	-6	2	2	0	1	2	3	2	1	0	0	0	0	0	0
		DAY 22		11MAR2003	22	11	-8	2	1	0	0	2	2	2	2	0	0	0	0	0	0
		DAY 29		19MAR2003	30	6	-13	0	2	0	0	0	0	1	1	0	0	1	0	1	0
		DAY 36		25MAR2003	36	7	-12	1	2	0	0	0	1	2	1	0	0	0	0	0	0
		DAY 43		02APR2003	44	10	-9	2	2	0	1	1	1	2	1	0	0	0	0	0	0
		DAY 50		08APR2003	50	8	-11	1	1	0	0	2	1	2	1	0	0	0	0	0	0
		DAY 57		15APR2003	57	10	-9	1	2	0	1	2	2	1	1	0	0	0	0	0	0
	E0013013	DAY 1		06MAY2003	1	23		3	2	0	2	3	3	2	0	1	0	2	2	2	1
		DAY 8		12MAY2003	7	6	-17	1	0	0	0	0	0	0	2	2	0	0	0	1	0
		DAY 15		19MAY2003	14	16	-7	3	3	0	3	3	3	0	0	0	0	0	1	0	0
		DAY 22		27MAY2003	22	23	0	3	3	0	1	3	2	2	1	0	0	2	2	2	2
		DAY 22	*	30MAY2003	25	23	0	3	3	0	3	3	1	2	0	0	0	2	2	2	2
	E0014002	DAY 1		26FEB2003	1	13		0	2	0	2	1	1	0	0	1	1	1	2	1	1
		DAY 8		04MAR2003	7	9	-4	2	2	0	1	1	2	0	0	0	0	0	0	0	1
		DAY 15		12MAR2003	15	7	-6	0	0	0	1	1	1	0	0	0	1	0	2	0	1
		DAY 22		20MAR2003	23	23	10	3	3	2	3	3	3	2	0	0	0	0	1	2	1
		DAY 29		27MAR2003	30	18	5	3	3	0	2	1	2	3	0	0	1	0	0	2	1
		DAY 43		10APR2003	44	17	4	2	1	0	2	2	3	3	0	0	0	0	2	1	1
	E0014004	DAY 1		12MAR2003	1	37		4	3	2	2	3	3	4	2	2	2	3	2	2	3
		DAY 8		20MAR2003	9	33	-4	3	3	2	3	3	3	3	2	2	0	3	1	3	2
		DAY 15		25MAR2003	14	22	-15	2	2	1	1	1	1	2	1	1	2	2	3	2	1
		DAY 22		01APR2003	21	24	-13	3	3	1	2	2	2	3	2	0	0	0	2	2	2
		DAY 36		15APR2003	35	23	-14	3	3	0	3	3	3	2	2	0	0	2	0	1	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0014009	DAY 1		23APR2003	1	26		3	3	2	3	3	3	1	0	1	1	0	3	1	2
		DAY 8		30APR2003	8	24	-2	3	3	0	3	2	3	2	2	0	0	0	3	1	2
	E0014015	DAY 1		18JUN2003	1	18		3	3	0	1	4	3	0	0	0	0	1	1	1	1
		DAY 8		26JUN2003	9	6	-12	0	2	0	0	2	1	0	0	0	0	0	0	0	1
	E0014017	DAY 1		27JUN2003	1	20		2	3	0	3	2	3	2	0	0	1	0	1	2	1
		DAY 8		02JUL2003	6	15	-5	1	2	0	2	2	2	2	1	0	1	0	0	1	1
		DAY 15		09JUL2003	13	5	-15	0	1	0	1	1	1	0	0	0	0	0	0	1	0
		DAY 22		16JUL2003	20	8	-12	1	1	0	1	1	1	1	0	0	0	0	0	2	0
		DAY 29		23JUL2003	27	4	-16	1	0	0	1	0	0	0	1	0	0	0	0	1	0
		DAY 29	*	29JUL2003	33	4	-16	0	0	0	0	1	0	1	0	0	0	0	1	1	0
		DAY 36		05AUG2003	40	11	-9	0	2	0	0	2	0	2	0	0	0	0	2	2	1
		DAY 43		12AUG2003	47	7	-13	0	1	0	0	1	0	1	1	0	0	1	1	1	0
		DAY 50		19AUG2003	54	4	-16	0	1	0	0	0	0	1	1	0	0	0	0	1	0
	E0014018	DAY 1		01JUL2003	1	14		1	1	0	2	4	3	0	1	0	0	0	0	2	0
		DAY 8		09JUL2003	9	17	3	2	3	0	2	2	3	1	1	0	0	0	0	3	0
		DAY 15		16JUL2003	16	22	8	3	2	0	1	3	3	2	2	0	0	2	0	3	1
		DAY 22		22JUL2003	22	14	0	1	1	0	2	3	2	0	1	1	0	1	0	1	1
		DAY 29		29JUL2003	29	8	-6	1	1	0	1	1	1	0	0	0	0	1	0	1	1
		DAY 36		05AUG2003	36	18	4	2	1	0	4	2	2	0	0	0	0	2	1	3	1
		DAY 43		12AUG2003	43	18	4	2	2	1	4	2	3	1	0	0	0	3	0	0	0
		DAY 50		19AUG2003	50	20	6	3	2	0	3	3	3	0	0	0	1	2	1	2	0
		DAY 57		27AUG2003	58	16	2	2	2	2	2	3	3	1	0	0	0	1	0	0	0
	E0015005	DAY 1		02DEC2002	1	27		3	3	0	2	3	3	2	0	1	2	2	3	1	2
		DAY 8		11DEC2002	10	25	-2	2	2	0	2	3	3	2	0	1	2	2	3	1	2
		DAY 15		18DEC2002	17	19	-8	2	2	0	3	2	3	1	0	1	2	1	1	0	1
	E0018009	DAY 1		06JAN2003	1	23		2	2	2	3	2	3	1	0	1	1	2	0	2	2

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0018009	DAY 8		13JAN2003	8	21	-2	2	2	2	3	3	3	1	0	0	0	1	1	2	1
		DAY 8	*	14JAN2003	9	21	-2	2	2	2	3	3	3	1	0	0	0	0	0	3	2
	E0018010	DAY 1		16JAN2003	1	24		2	2	1	3	3	3	2	0	1	0	2	1	2	2
		DAY 8		23JAN2003	8	16	-8	2	2	0	2	2	2	2	1	0	0	1	0	1	1
		DAY 15		30JAN2003	15	16	-8	2	2	2	1	2	2	0	0	0	0	1	1	1	2
		DAY 22		06FEB2003	22	10	-14	1	1	0	1	2	1	0	0	0	0	1	1	1	1
		DAY 29		13FEB2003	29	9	-15	0	1	0	2	0	1	1	0	0	0	1	1	1	1
		DAY 36		20FEB2003	36	10	-14	1	1	0	2	2	1	0	0	0	0	1	1	1	0
		DAY 43		26FEB2003	42	7	-17	1	1	0	1	1	1	0	0	0	0	0	1	1	0
		DAY 50		06MAR2003	50	5	-19	1	1	1	0	1	1	0	0	0	0	0	0	0	0
		DAY 57		13MAR2003	57	13	-11	2	2	1	1	2	1	1	0	0	0	1	0	1	1
	E0018015	DAY 1		28JAN2003	1	22		2	2	2	2	2	3	2	0	1	1	0	2	2	1
		DAY 8		04FEB2003	8	14	-8	1	2	1	1	1	2	2	0	0	0	1	0	2	1
		DAY 15		13FEB2003	17	11	-11	1	1	1	0	0	2	1	0	0	0	2	1	1	1
		DAY 22		20FEB2003	24	11	-11	2	1	0	0	2	2	1	0	0	0	1	1	1	0
		DAY 29		26FEB2003	30	9	-13	1	1	1	0	1	2	1	0	0	0	0	1	1	0
		DAY 36		06MAR2003	38	3	-19	1	1	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 43		13MAR2003	45	6	-16	1	1	1	1	0	1	0	0	0	0	0	0	0	1
		DAY 50		20MAR2003	52	1	-21	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 57		27MAR2003	59	8	-14	2	1	1	1	0	1	1	0	0	0	0	0	1	0
	E0020015	DAY 1		27MAR2003	1	32		3	3	2	3	3	3	2	0	2	2	2	3	2	2
		DAY 8		03APR2003	8	32	0	3	3	2	3	3	3	2	0	2	2	2	3	2	2
		DAY 15		10APR2003	15	30	-2	3	3	2	3	3	3	0	2	0	2	2	3	2	2
		DAY 22		16APR2003	21	27	-5	0	2	2	3	3	3	1	2	2	2	2	3	0	2
		DAY 29		23APR2003	28	29	-3	2	2	2	3	3	3	2	0	2	2	1	3	2	2
		DAY 36		30APR2003	35	28	-4	2	2	2	3	2	3	2	2	1	2	0	3	2	2
		DAY 43		08MAY2003	43	22	-10	2	2	2	3	2	3	1	0	0	2	0	3	0	2
		DAY 50		15MAY2003	50	27	-5	1	2	2	3	2	3	2	1	2	2	0	3	2	2

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0020015	DAY 57		23MAY2003	58	32	0	3	3	3	3	2	3	2	0	3	3	2	2	1	2
	E0020017	DAY 1		03APR2003	1	26		2	3	1	1	2	3	2	2	1	2	2	1	2	2
		DAY 8		10APR2003	8	24	-2	2	2	0	2	2	2	2	2	1	2	2	1	2	2
		DAY 15		17APR2003	15	30	4	3	3	0	3	2	2	3	2	3	3	1	1	3	1
		DAY 22		22APR2003	20	19	-7	1	2	0	1	2	2	2	1	2	2	1	0	2	1
		DAY 29		29APR2003	27	20	-6	2	2	0	1	2	1	3	1	0	1	2	1	2	2
		DAY 29	*	05MAY2003	33	18	-8	2	2	0	1	2	2	2	1	0	0	2	0	2	2
		DAY 36		12MAY2003	40	16	-10	2	2	0	1	2	0	2	1	0	0	2	0	2	2
		DAY 50		20MAY2003	48	12	-14	1	2	0	0	1	0	2	1	0	0	1	0	2	2
	E0020020	DAY 1		12MAY2003	1	24		3	3	0	3	3	3	0	0	0	0	2	3	2	2
		DAY 8		19MAY2003	8	21	-3	2	3	0	3	3	3	0	0	0	0	2	3	0	2
		DAY 8	*	23MAY2003	12	33	9	4	4	0	3	3	4	0	0	1	2	3	4	2	3
	E0020022	DAY 1		16JUN2003	1	21		2	2	0	2	3	3	0	2	0	0	0	3	2	2
		DAY 8		23JUN2003	8	6	-15	0	0	0	2	0	0	0	0	0	0	0	3	0	1
		DAY 15		30JUN2003	15	6	-15	0	0	0	2	0	0	0	0	0	0	0	3	0	1
		DAY 22		07JUL2003	22	8	-13	0	0	0	2	2	1	0	0	0	0	0	3	0	0
		DAY 29		14JUL2003	29	8	-13	0	2	0	0	0	2	0	0	0	0	0	3	0	1
		DAY 36		21JUL2003	36	3	-18	0	0	0	0	0	0	0	0	0	0	0	3	0	0
		DAY 43		28JUL2003	43	3	-18	0	0	0	0	0	0	0	0	0	0	0	3	0	0
		DAY 50		04AUG2003	50	3	-18	0	0	0	0	0	0	0	0	0	0	0	3	0	0
		DAY 57		11AUG2003	57	3	-18	0	0	0	0	0	0	0	0	0	0	0	3	0	0
	E0022001	DAY 1		28OCT2002	1	4		0	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 8		04NOV2002	8	12	8	1	0	0	3	2	3	1	0	0	0	1	1	0	0
		DAY 15		11NOV2002	15	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22		18NOV2002	22	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29		26NOV2002	30	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36		02DEC2002	36	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0022001	DAY 43	09DEC2002	43	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	16DEC2002	50	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	26DEC2002	60	0	-4	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022004	DAY 1	28OCT2002	1	14		1	1	0	3	2	3	1	0	0	0	2	1	0	0
		DAY 8	04NOV2002	8	17	3	2	1	0	3	2	3	1	1	0	0	2	0	0	2
		DAY 15	11NOV2002	15	17	3	2	1	0	3	2	3	1	1	0	0	2	0	0	2
		DAY 22	19NOV2002	23	16	2	3	2	0	2	2	3	1	0	0	1	0	0	0	2
		DAY 29	26NOV2002	30	14	0	2	2	2	2	2	2	0	0	0	0	0	0	0	2
		DAY 36	02DEC2002	36	18	4	2	2	0	4	2	3	1	0	0	0	1	1	0	2
		DAY 43	10DEC2002	44	19	5	2	2	0	3	2	3	1	0	0	1	1	1	1	2
		DAY 50	16DEC2002	50	19	5	2	2	0	3	3	3	1	0	0	1	0	2	0	2
		DAY 57	23DEC2002	57	22	8	2	2	0	3	2	3	2	0	1	1	0	2	2	2
	E0022005	DAY 1	08NOV2002	1	16		2	2	0	1	2	3	1	0	0	0	1	1	1	2
		DAY 8	15NOV2002	8	14	-2	2	2	1	1	2	2	0	0	0	0	0	1	1	2
		DAY 15	22NOV2002	15	20	4	2	2	2	2	2	3	0	0	0	1	2	1	1	2
		DAY 22	29NOV2002	22	13	-3	3	2	0	0	2	3	0	0	0	0	0	0	1	2
		DAY 29	06DEC2002	29	20	4	2	2	0	2	2	3	2	1	0	0	2	1	1	2
		DAY 36	13DEC2002	36	16	0	2	1	0	2	2	2	1	0	0	1	1	1	1	2
		DAY 43	20DEC2002	43	25	9	2	2	2	2	2	3	1	2	1	1	1	2	2	2
		DAY 50	27DEC2002	50	22	6	2	2	2	2	2	3	2	0	1	2	0	2	0	2
		DAY 57	03JAN2003	57	25	9	2	2	2	2	2	3	2	2	2	1	2	1	0	2
	E0022011	DAY 1	29NOV2002	1	3		1	0	0	0	0	2	0	0	0	0	0	0	0	0
	E0022015	DAY 1	10DEC2002	1	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 8	17DEC2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	26DEC2002	17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	02JAN2003	24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	09JAN2003	31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0022015	DAY 36	16JAN2003	38	7	7	1	0	0	2	1	2	0	0	1	0	0	0	0	0
		DAY 43	23JAN2003	45	7	7	1	1	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 50	30JAN2003	52	5	5	1	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 57	06FEB2003	59	8	8	1	0	0	2	2	2	0	0	0	0	0	1	0	0
	E0022016	DAY 1	17DEC2002	1	10		1	1	0	0	0	2	2	1	0	0	2	0	0	1
		DAY 8	26DEC2002	10	7	-3	2	1	0	0	0	1	0	0	0	0	2	0	0	1
		DAY 15	30DEC2002	14	7	-3	1	1	0	0	0	2	1	0	0	0	2	0	0	0
		DAY 22	06JAN2003	21	16	6	2	2	0	0	0	3	2	2	0	0	2	0	2	1
		DAY 29	13JAN2003	28	13	3	1	1	0	0	0	3	2	1	0	0	2	0	2	1
		DAY 36	21JAN2003	36	14	4	2	2	0	2	0	3	1	1	0	0	2	0	0	1
		DAY 43	30JAN2003	45	9	-1	1	1	0	0	0	3	0	0	0	0	2	1	0	1
		DAY 50	06FEB2003	52	11	1	2	1	0	0	0	3	1	0	0	0	1	0	2	1
		DAY 57	11FEB2003	57	5	-5	1	1	0	0	0	3	0	0	0	0	0	0	0	0
	E0022020	DAY 1	12DEC2002	1	6		1	1	0	0	0	3	0	0	0	0	0	0	0	1
		DAY 8	19DEC2002	8	3	-3	1	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 15	26DEC2002	15	4	-2	0	0	0	0	0	3	0	0	0	0	0	0	0	1
		DAY 22	02JAN2003	22	1	-5	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	10JAN2003	30	1	-5	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	16JAN2003	36	0	-6	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	23JAN2003	43	0	-6	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022023	DAY 1	24DEC2002	-1	5		0	1	0	0	0	3	0	0	0	0	1	0	0	0
		DAY 8	02JAN2003	9	3	-2	0	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 15	09JAN2003	16	3	-2	1	0	0	0	0	1	0	0	0	0	0	0	0	1
		DAY 22	16JAN2003	23	4	-1	1	0	0	0	0	2	1	0	0	0	0	0	0	0
		DAY 29	23JAN2003	30	2	-3	0	0	0	0	0	1	0	0	0	0	0	0	0	1
		DAY 36	30JAN2003	37	2	-3	0	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 43	06FEB2003	44	8	3	1	1	0	2	1	2	0	0	0	0	0	1	0	0
		DAY 50	13FEB2003	51	2	-3	0	0	0	0	0	2	0	0	0	0	0	0	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0022023	DAY 57	20FEB2003	58	1	-4	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0022029	DAY 1	19FEB2003	1	5		0	0	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 8	26FEB2003	8	5	0	1	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 15	03MAR2003	13	5	0	1	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 22	12MAR2003	22	4	-1	1	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 29	18MAR2003	28	3	-2	0	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 36	26MAR2003	36	4	-1	1	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 43	02APR2003	43	4	-1	0	0	0	2	1	1	0	0	0	0	0	0	0	0
		DAY 50	07APR2003	48	6	1	1	0	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 57	14APR2003	55	6	1	1	0	0	2	1	2	0	0	0	0	0	0	0	0
	E0022041	DAY 1	18MAR2003	1	16		1	1	1	1	0	3	2	0	1	0	2	1	2	1
		DAY 8	25MAR2003	8	13	-3	1	1	0	0	2	3	2	1	0	0	2	0	0	1
		DAY 15	01APR2003	15	3	-13	1	0	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 22	08APR2003	22	3	-13	1	0	1	0	0	1	0	0	0	0	0	0	0	0
		DAY 29	15APR2003	29	7	-9	1	1	0	0	0	2	2	0	0	0	0	0	0	1
		DAY 36	21APR2003	35	3	-13	0	0	0	0	0	1	1	0	0	0	1	0	0	0
		DAY 43	29APR2003	43	5	-11	1	1	0	0	0	1	1	0	0	0	1	0	0	0
		DAY 50	06MAY2003	50	6	-10	1	0	0	1	0	1	1	0	1	0	0	1	0	0
		DAY 57	13MAY2003	57	4	-12	1	1	0	0	0	0	1	0	0	0	1	0	0	0
	E0022042	DAY 1	12MAR2003	1	4		0	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 8	19MAR2003	8	8	4	0	0	0	2	1	2	0	0	0	0	0	2	0	1
		DAY 15	27MAR2003	16	4	0	0	0	0	0	0	3	0	1	0	0	0	0	0	0
		DAY 22	02APR2003	22	5	1	0	0	0	1	1	2	0	0	0	0	0	1	0	0
		DAY 29	10APR2003	30	6	2	0	0	0	1	1	2	0	0	0	0	1	1	0	0
		DAY 36	17APR2003	37	6	2	0	0	0	2	1	2	0	0	0	0	0	1	0	0
		DAY 43	24APR2003	44	5	1	0	0	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 50	01MAY2003	51	6	2	0	0	0	2	1	2	0	0	0	0	0	1	0	0
		DAY 57	12MAY2003	62	5	1	0	0	0	2	1	2	0	0	0	0	0	0	0	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0022043	DAY 1		20MAR2003	1	4		1	0	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 8		26MAR2003	7	5	1	1	0	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 15		03APR2003	15	4	0	1	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 22		10APR2003	22	4	0	1	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 29		17APR2003	29	2	-2	0	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36		24APR2003	36	3	-1	0	0	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 43		01MAY2003	43	6	2	1	1	0	1	1	1	0	0	0	0	1	0	0	0
		DAY 50		08MAY2003	50	3	-1	1	0	0	1	0	0	0	0	0	0	1	0	0	0
		DAY 50	*	12MAY2003	54	2	-2	1	0	0	0	0	0	0	0	0	0	1	0	0	0
	E0022054	DAY 1		11APR2003	1	13		2	1	0	1	0	3	2	0	0	1	0	0	2	1
		DAY 8		18APR2003	8	8	-5	1	1	0	0	0	3	1	1	0	0	0	0	0	1
		DAY 15		28APR2003	18	8	-5	1	1	0	0	0	1	1	1	0	0	0	1	1	1
		DAY 22		02MAY2003	22	3	-10	1	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 29		12MAY2003	32	9	-4	1	1	0	0	0	1	2	1	0	0	0	0	2	1
		DAY 36		16MAY2003	36	2	-11	1	0	0	0	0	0	0	1	0	0	0	0	0	0
	E0022059	DAY 1		06MAY2003	1	6		1	1	0	0	0	3	0	0	0	0	0	0	0	1
		DAY 8		13MAY2003	8	4	-2	0	0	0	0	0	3	1	0	0	0	0	0	0	0
		DAY 15		20MAY2003	15	3	-3	0	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 22		27MAY2003	22	6	0	1	1	0	0	0	3	0	0	0	0	0	0	0	1
		DAY 29		03JUN2003	29	7	1	1	1	0	1	2	2	0	0	0	0	0	0	0	0
		DAY 36		10JUN2003	36	4	-2	1	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 43		17JUN2003	43	4	-2	1	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 43	*	20JUN2003	46	3	-3	0	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 57		08JUL2003	64	4	-2	1	1	0	0	0	2	0	0	0	0	0	0	0	0
	E0022065	DAY 1		07MAY2003	1	14		2	2	0	1	2	2	1	0	0	0	1	1	1	1
		DAY 8		14MAY2003	8	13	-1	2	2	0	0	1	2	1	1	1	0	2	0	1	0
		DAY 15		21MAY2003	15	11	-3	2	1	0	0	1	2	1	0	0	0	0	2	1	1
		DAY 22		28MAY2003	22	8	-6	1	1	0	0	0	1	1	1	0	0	1	1	1	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0022065	DAY 29	04JUN2003	29	7	-7	1	1	0	0	1	1	0	0	0	0	1	1	0	1
		DAY 36	11JUN2003	36	3	-11	1	1	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 43	18JUN2003	43	6	-8	1	1	0	0	0	1	1	0	0	0	1	1	0	0
		DAY 50	25JUN2003	50	7	-7	0	0	0	1	1	1	1	0	0	0	1	1	1	0
		DAY 57	02JUL2003	57	4	-10	0	1	0	0	1	0	0	0	0	0	1	1	0	0
	E0022070	DAY 1	12JUN2003	1	22		2	0	0	3	3	3	2	2	2	0	2	3	0	0
		DAY 8	18JUN2003	7	25	3	3	2	0	3	3	3	2	2	2	0	2	3	0	0
	E0023001	DAY 1	15NOV2002	1	21		3	3	0	0	2	3	2	1	0	2	0	1	2	2
		DAY 8	22NOV2002	8	23	2	3	4	2	2	2	3	2	1	0	2	0	1	0	1
		DAY 15	29NOV2002	15	20	-1	3	2	0	2	1	2	2	1	2	2	1	1	0	1
		DAY 22	06DEC2002	22	16	-5	2	2	0	1	2	2	1	1	2	1	1	0	0	1
		DAY 29	16DEC2002	32	12	-9	2	1	0	2	1	1	0	0	1	1	2	0	0	1
		DAY 36	23DEC2002	39	13	-8	2	1	0	2	1	1	1	0	1	1	2	0	0	1
		DAY 43	30DEC2002	46	19	-2	3	2	0	2	1	2	2	0	1	1	2	1	0	2
		DAY 50	07JAN2003	54	28	7	4	4	0	2	3	4	1	0	1	2	1	3	0	3
		DAY 57	14JAN2003	61	22	1	3	4	0	2	2	3	1	0	1	2	1	2	0	1
	E0023009	DAY 1	11FEB2003	1	14		3	3	0	0	3	3	0	0	0	0	1	0	0	1
		DAY 8	18FEB2003	8	13	-1	2	2	0	1	3	3	0	0	0	0	2	0	0	0
		DAY 15	27FEB2003	17	15	1	3	2	1	1	2	2	1	0	0	0	1	1	0	1
		DAY 22	04MAR2003	22	10	-4	2	2	1	1	2	2	0	0	0	0	0	0	0	0
		DAY 29	11MAR2003	29	3	-11	0	1	0	0	2	0	0	0	0	0	0	0	0	0
		DAY 36	18MAR2003	36	7	-7	1	1	0	1	2	0	2	0	0	0	0	0	0	0
		DAY 43	25MAR2003	43	9	-5	1	1	0	1	2	0	3	0	0	0	1	0	0	0
		DAY 50	03APR2003	52	11	-3	2	2	0	0	1	0	3	0	1	1	1	0	0	0
		DAY 57	08APR2003	57	10	-4	2	1	0	0	1	0	3	1	1	0	1	0	0	0
	E0023028	DAY 1	29MAY2003	1	19		3	2	1	2	1	3	1	0	1	1	0	0	3	1
		DAY 8	05JUN2003	8	10	-9	1	0	1	2	0	0	0	1	1	1	1	0	0	2

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0023028	DAY 15		12JUN2003	15	3	-16	1	1	0	0	0	0	0	0	0	0	0	0	0	1
		DAY 22		19JUN2003	22	6	-13	1	0	0	2	2	0	0	0	0	0	0	0	0	1
		DAY 29		25JUN2003	28	5	-14	1	2	0	0	1	0	0	0	0	0	0	0	0	1
		DAY 43		09JUL2003	42	3	-16	1	0	1	0	1	0	0	0	0	0	0	0	0	0
		DAY 50		16JUL2003	49	3	-16	1	0	0	0	1	0	1	0	0	0	0	0	0	0
		DAY 50	*	21JUL2003	54	6	-13	1	1	0	0	1	0	1	0	0	0	0	0	2	0
	E0023033	DAY 1		05JUN2003	1	17		3	4	1	1	1	3	1	0	0	1	1	0	0	1
		DAY 8		12JUN2003	8	20	3	3	4	1	3	3	3	1	1	0	0	0	0	0	1
	E0023047	DAY 1		18JUL2003	1	21		3	3	1	2	3	3	0	0	2	2	0	0	2	0
		DAY 8		25JUL2003	8	19	-2	3	3	1	2	3	2	2	0	1	2	0	0	0	0
		DAY 15		31JUL2003	14	18	-3	3	3	0	2	3	3	0	0	2	0	2	0	0	0
		DAY 22		08AUG2003	22	20	-1	3	3	0	3	3	3	0	1	1	0	2	0	1	0
		DAY 29		15AUG2003	29	17	-4	3	3	0	3	2	3	0	0	1	0	2	0	0	0
		DAY 36		21AUG2003	35	14	-7	3	3	0	3	1	1	0	0	0	1	2	0	0	0
		DAY 43		29AUG2003	43	11	-10	2	3	0	3	2	1	0	0	0	0	0	0	0	0
		DAY 50		05SEP2003	50	11	-10	3	3	0	2	3	0	0	0	0	0	0	0	0	0
		DAY 57		12SEP2003	57	12	-9	3	3	0	3	3	0	0	0	0	0	0	0	0	0
	E0025001	DAY 1		01APR2003	1	23		3	2	2	3	3	3	1	0	0	0	2	0	2	2
		DAY 8		10APR2003	10	18	-5	1	2	0	3	3	3	0	0	0	0	2	2	0	2
		DAY 15		16APR2003	16	21	-2	3	3	0	3	1	4	0	0	0	0	3	2	0	2
		DAY 22		23APR2003	23	32	9	3	3	0	4	3	4	2	0	1	2	2	3	2	3
	E0026012	DAY 1		20FEB2003	1	19		2	2	0	3	2	2	1	2	2	1	0	1	1	0
		DAY 8		27FEB2003	8	31	12	2	2	3	3	3	3	2	2	2	2	3	0	2	2
		DAY 15		06MAR2003	15	34	15	3	3	3	3	3	3	1	3	3	3	3	0	3	0
		DAY 22		13MAR2003	22	14	-5	1	0	3	0	2	0	2	1	0	1	1	1	2	0
		DAY 29		20MAR2003	29	10	-9	2	0	1	0	1	0	2	1	1	0	1	0	1	0
		DAY 36		27MAR2003	36	21	2	1	2	1	0	3	0	2	3	1	1	4	0	2	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0026012	DAY 43		03APR2003	43	14	-5	2	1	1	0	2	3	0	1	0	0	2	0	1	1
		DAY 50		10APR2003	50	20	1	1	2	3	0	3	3	2	2	1	1	1	0	1	0
		DAY 57		17APR2003	57	20	1	1	0	3	1	3	1	2	2	2	2	2	0	1	0
	E0026020	DAY 1		01APR2003	1	30		3	3	2	3	3	3	2	4	2	1	1	2	1	0
		DAY 8		08APR2003	8	26	-4	3	3	2	3	3	3	0	1	2	3	0	3	0	0
		DAY 15		15APR2003	15	13	-17	2	3	0	2	2	0	0	1	1	1	0	0	0	1
		DAY 22		22APR2003	22	24	-6	3	3	2	2	4	3	0	1	1	1	1	0	1	2
	E0026024	DAY 1		02MAY2003	1	22		2	2	1	3	3	3	0	1	0	0	2	3	0	2
		DAY 8		09MAY2003	8	21	-1	2	1	1	3	3	3	0	1	0	0	2	3	0	2
		DAY 15		16MAY2003	15	22	0	2	2	0	3	3	3	3	0	0	0	2	3	0	1
		DAY 22		23MAY2003	22	19	-3	1	1	0	3	3	2	3	0	0	0	2	3	0	1
		DAY 29		30MAY2003	29	15	-7	2	1	0	2	2	1	2	0	0	0	1	3	0	1
	E0026028	DAY 1		20JUN2003	1	18		3	2	0	2	2	3	1	2	0	0	0	1	0	2
		DAY 8		27JUN2003	8	22	4	3	2	2	3	2	2	1	1	1	0	1	1	1	2
		DAY 15		02JUL2003	13	19	1	2	3	2	3	2	2	0	1	0	0	1	1	0	2
		DAY 15	*	08JUL2003	19	19	1	3	2	2	3	1	1	0	1	1	1	2	1	0	1
	E0028001	DAY 1		10OCT2002	1	18		3	2	0	4	1	4	0	1	0	0	0	1	1	1
		DAY 8		16OCT2002	7	20	2	3	2	3	3	2	3	0	0	0	0	0	1	1	2
		DAY 15		23OCT2002	14	17	-1	3	2	2	3	1	3	0	0	0	0	0	1	0	2
		DAY 22		29OCT2002	20	19	1	3	3	2	3	1	2	0	0	1	0	1	1	0	2
		DAY 29		05NOV2002	27	18	0	3	1	2	3	0	3	0	1	0	2	0	1	0	2
		DAY 36		12NOV2002	34	22	4	3	3	2	3	2	4	0	0	3	0	0	2	0	0
		DAY 43		19NOV2002	41	14	-4	3	3	2	0	1	3	0	0	0	0	0	1	0	1
		DAY 50		26NOV2002	48	19	1	3	0	2	3	1	4	0	0	0	0	0	2	1	3
		DAY 57		03DEC2002	55	17	-1	3	2	2	3	0	3	0	0	0	0	0	2	0	2
	E0028003	DAY 1		30SEP2002	1	11		2	2	0	2	1	3	0	0	0	0	1	0	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0028003	DAY 8	07OCT2002	8	25	14	2	1	0	3	3	4	2	2	0	2	2	1	2	1
		DAY 15	16OCT2002	17	24	13	1	1	0	3	2	4	2	2	0	1	3	2	2	1
		DAY 22	22OCT2002	23	28	17	2	3	0	1	3	4	1	2	1	2	3	2	3	1
		DAY 29	29OCT2002	30	26	15	2	2	0	2	3	4	1	1	2	2	3	1	1	2
		DAY 36	07NOV2002	39	33	22	2	3	0	3	2	4	2	3	3	2	3	2	2	2
		DAY 43	12NOV2002	44	26	15	3	2	0	3	3	3	2	2	0	2	2	2	0	2
		DAY 50	19NOV2002	51	29	18	3	3	0	3	2	3	1	3	2	1	3	1	2	2
		DAY 57	26NOV2002	58	31	20	4	3	1	3	2	3	3	3	0	2	3	1	2	1
	E0028005	DAY 1	03OCT2002	1	19		2	3	0	3	2	4	2	1	0	0	1	0	0	1
		DAY 8	11OCT2002	9	19	0	2	2	0	4	3	4	0	0	0	0	2	2	0	0
		DAY 29	31OCT2002	29	6	-13	0	0	0	1	1	3	0	0	0	0	0	1	0	0
	E0028010	DAY 1	05NOV2002	1	19		2	2	0	4	1	3	1	0	0	0	2	0	2	2
		DAY 8	12NOV2002	8	23	4	3	3	1	3	0	4	0	0	0	0	3	2	2	2
		DAY 15	19NOV2002	15	22	3	3	0	1	3	0	4	0	0	0	0	3	3	3	2
		DAY 22	25NOV2002	21	14	-5	1	0	0	3	0	0	0	0	1	0	3	2	3	1
		DAY 29	03DEC2002	29	13	-6	2	0	0	3	0	1	0	0	1	0	2	1	3	0
		DAY 36	10DEC2002	36	16	-3	2	0	0	3	0	3	0	0	0	0	2	2	2	2
		DAY 43	17DEC2002	43	9	-10	0	0	0	3	0	3	0	0	0	0	0	0	2	1
		DAY 50	23DEC2002	49	7	-12	0	0	0	3	0	2	0	0	0	0	2	0	0	0
		DAY 57	31DEC2002	57	7	-12	0	0	0	3	0	2	0	0	0	0	2	0	0	0
	E0028011	DAY 1	05DEC2002	1	26		2	2	0	3	4	4	2	1	0	2	3	0	0	3
		DAY 8	12DEC2002	8	14	-12	2	2	0	3	0	3	0	0	0	0	1	0	1	2
		DAY 15	19DEC2002	15	3	-23	0	0	0	1	0	1	0	0	0	0	0	0	1	0
		DAY 22	26DEC2002	22	8	-18	1	0	0	2	1	0	0	0	0	0	1	0	2	1
		DAY 29	02JAN2003	29	8	-18	1	1	0	2	1	1	0	0	0	0	0	0	1	1
		DAY 36	09JAN2003	36	11	-15	0	2	0	0	0	0	2	0	0	2	3	0	0	2
		DAY 43	16JAN2003	43	6	-20	0	0	0	1	0	1	0	0	0	1	1	0	1	1
		DAY 50	23JAN2003	50	9	-17	2	0	0	1	0	2	1	0	0	1	0	0	1	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0028011	DAY 57	30JAN2003	57	5	-21	1	1	0	0	0	1	0	0	0	0	1	0	1	0
	E0028030	DAY 1	04MAR2003	1	20		1	1	3	3	3	3	2	0	0	0	0	0	2	2
		DAY 8	11MAR2003	8	20	0	3	2	1	3	2	3	1	0	0	0	2	0	0	3
		DAY 15	18MAR2003	15	14	-6	3	0	0	3	0	3	0	0	0	0	2	1	0	2
		DAY 22	25MAR2003	22	17	-3	2	2	2	3	3	3	0	0	0	0	0	0	0	2
		DAY 29	01APR2003	29	13	-7	3	0	1	2	1	3	0	0	0	0	0	0	0	3
		DAY 36	08APR2003	36	14	-6	1	1	1	2	2	3	0	0	0	0	0	1	2	1
		DAY 43	17APR2003	45	11	-9	1	0	1	0	2	3	0	0	0	0	2	0	0	2
		DAY 50	22APR2003	50	6	-14	0	0	1	1	0	3	0	0	0	0	0	1	0	0
		DAY 57	30APR2003	58	17	-3	3	0	1	3	2	3	0	0	0	0	0	1	2	2
	E0028031	DAY 1	11MAR2003	1	23		3	3	1	3	1	3	1	0	0	0	3	2	0	3
		DAY 8	18MAR2003	8	15	-8	3	3	1	2	2	3	0	0	0	0	0	1	0	0
		DAY 15	25MAR2003	15	24	1	2	3	2	3	2	2	0	2	2	0	3	1	0	2
	E0028047	DAY 1	14JUL2003	1	21		2	2	1	3	3	3	1	1	0	0	1	2	1	1
		DAY 8	21JUL2003	8	26	5	3	3	1	3	3	3	3	2	0	0	0	3	0	2
		DAY 15	29JUL2003	16	26	5	3	3	0	3	2	3	1	1	0	2	2	2	2	2
		DAY 22	05AUG2003	23	21	0	3	2	0	3	2	3	2	0	0	0	0	2	2	2
		DAY 29	12AUG2003	30	25	4	3	3	0	3	3	3	2	0	0	1	2	2	0	3
		DAY 36	19AUG2003	37	23	2	3	3	2	3	2	3	3	0	0	0	0	2	0	2
		DAY 43	26AUG2003	44	19	-2	3	2	2	3	2	3	0	0	0	0	0	2	0	2
		DAY 50	02SEP2003	51	20	-1	3	3	2	3	2	3	0	0	0	0	0	2	0	2
		DAY 57	09SEP2003	58	29	8	3	3	2	3	2	3	0	3	3	2	0	2	0	3
	E0029001	DAY 1	01OCT2002	1	20		2	2	0	3	2	3	0	1	0	0	2	1	2	2
	E0029014	DAY 1	04FEB2003	1	24		2	2	2	2	3	2	2	2	1	0	1	1	2	2
		DAY 8	11FEB2003	8	19	-5	1	2	3	2	2	2	2	1	1	1	0	0	1	1
		DAY 15	18FEB2003	15	17	-7	1	1	0	2	2	1	2	0	0	2	1	2	2	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0029014	DAY 22	25FEB2003	22	8	-16	1	1	0	1	1	0	1	0	0	0	0	1	1	1
		DAY 29	06MAR2003	31	18	-6	2	2	0	2	2	2	2	0	1	0	0	2	2	1
		DAY 36	11MAR2003	36	27	3	2	3	2	2	2	2	2	2	1	1	1	3	2	2
		DAY 43	20MAR2003	45	14	-10	1	1	0	2	3	0	2	2	0	0	1	0	2	0
		DAY 50	27MAR2003	52	29	5	3	3	3	1	3	2	2	1	1	1	2	2	3	2
		DAY 57	01APR2003	57	16	-8	1	1	2	2	3	2	1	0	0	0	1	1	1	1
	E0029023	DAY 1	08APR2003	1	17		2	1	0	2	1	3	2	1	1	0	2	0	1	1
		DAY 8	15APR2003	8	16	-1	2	2	2	3	1	2	0	0	1	0	1	1	0	1
		DAY 15	22APR2003	15	18	1	2	2	2	2	2	3	0	0	1	0	2	0	0	2
		DAY 22	01MAY2003	24	20	3	3	3	2	2	2	3	1	0	1	0	1	0	1	1
		DAY 36	12MAY2003	35	16	-1	2	2	1	3	0	3	1	0	0	0	2	0	1	1
		DAY 43	20MAY2003	43	18	1	2	2	2	2	2	3	2	1	0	0	1	0	0	1
		DAY 50	29MAY2003	52	21	4	2	2	2	3	0	2	2	1	1	0	0	2	2	2
	E0029032	DAY 1	10JUN2003	1	31		3	2	3	3	3	3	3	1	1	1	0	3	2	3
		DAY 8	17JUN2003	8	33	2	3	3	0	3	3	4	3	2	1	2	2	3	2	2
		DAY 22	01JUL2003	22	38	7	4	3	2	3	3	4	3	2	2	2	2	3	2	3
	E0029033	DAY 1	02JUN2003	1	31		3	3	0	3	3	3	3	2	0	2	2	2	2	3
		DAY 8	09JUN2003	8	31	0	3	3	0	3	3	3	1	1	2	1	3	3	2	3
		DAY 15	16JUN2003	15	21	-10	2	2	0	2	3	2	2	1	0	1	1	2	1	2
		DAY 22	23JUN2003	22	23	-8	3	3	0	3	2	2	3	0	0	0	2	2	1	2
		DAY 29	30JUN2003	29	32	1	3	3	0	3	2	3	2	2	2	2	2	2	3	3
	E0029039	DAY 1	15JUL2003	1	29		3	3	2	3	3	4	3	0	0	0	1	3	2	2
		DAY 8	23JUL2003	9	24	-5	2	2	0	3	3	4	2	0	2	1	0	3	0	2
		DAY 15	28JUL2003	14	25	-4	2	2	3	3	1	3	1	0	2	1	0	3	2	2
	E0030003	DAY 1	16DEC2002	1	18		2	2	0	3	3	3	0	0	1	0	0	2	1	1
		DAY 8	23DEC2002	8	14	-4	2	2	0	2	2	3	0	0	1	0	0	1	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0030003	DAY 8	*	24DEC2002	9	14	-4	2	2	0	2	2	3	0	0	1	0	0	1	0	1
	E0030009	DAY 1		23JAN2003	1	20		3	3	0	3	2	3	3	0	0	0	0	0	1	2
		DAY 8		29JAN2003	7	20	0	2	3	0	3	2	3	2	0	1	1	0	2	0	1
		DAY 15		07FEB2003	16	26	6	3	4	2	3	2	3	2	1	1	1	0	1	0	3
		DAY 36		27FEB2003	36	25	5	3	3	3	3	3	3	3	0	1	0	0	0	0	3
		DAY 43		06MAR2003	43	28	8	3	3	0	3	3	3	3	1	1	1	1	2	2	2
		DAY 50		12MAR2003	49	21	1	3	3	0	3	0	3	2	1	1	1	0	2	0	2
		DAY 57		19MAR2003	56	21	1	3	2	0	3	2	3	2	1	0	1	0	2	0	2
	E0030016	DAY 1		03MAR2003	1	24		3	2	2	3	3	3	1	1	1	0	2	1	1	1
		DAY 8		10MAR2003	8	20	-4	2	2	1	3	2	2	1	1	1	0	2	2	1	0
		DAY 15		17MAR2003	15	25	1	3	3	3	3	2	3	0	0	1	0	2	2	2	1
		DAY 22		25MAR2003	23	25	1	2	3	3	1	3	3	0	1	1	1	2	2	2	1
		DAY 29		02APR2003	31	20	-4	2	2	0	2	2	3	2	1	1	1	2	1	1	0
		DAY 36		09APR2003	38	23	-1	3	2	0	2	1	2	2	2	1	1	2	2	2	1
		DAY 50		22APR2003	51	23	-1	3	2	0	2	1	2	2	2	1	1	2	2	2	1
	E0030021	DAY 1		20MAY2003	1	14		1	2	2	1	2	3	1	0	0	0	0	0	0	2
		DAY 8		27MAY2003	8	9	-5	2	1	0	0	1	2	1	0	0	0	0	1	1	0
		DAY 15		03JUN2003	15	7	-7	0	2	0	1	1	1	0	0	0	0	0	0	1	1
		DAY 22		10JUN2003	22	8	-6	1	1	0	1	1	1	0	0	0	0	1	0	1	1
		DAY 29		17JUN2003	29	8	-6	1	1	0	1	1	1	0	0	0	0	0	0	1	2
	E0031001	DAY 1		21NOV2002	1	20		3	3	0	2	2	2	2	0	2	2	2	0	0	0
		DAY 8		27NOV2002	7	20	0	3	2	2	1	2	3	1	1	1	1	1	0	1	1
		DAY 15		05DEC2002	15	21	1	3	3	0	2	1	2	2	1	2	1	1	1	1	1
		DAY 22		11DEC2002	21	18	-2	2	2	0	2	0	2	2	2	1	2	1	0	2	0
		DAY 29		20DEC2002	30	20	0	2	3	0	1	1	3	0	2	2	2	0	0	2	2
	E0031017	DAY 1		01APR2003	1	19		2	1	0	2	2	2	1	2	1	0	2	2	1	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0031017	DAY 8	07APR2003	7	18	-1	2	2	0	2	2	2	1	1	0	0	1	2	2	1
		DAY 15	15APR2003	15	17	-2	2	2	0	2	2	2	1	1	0	0	1	2	1	1
		DAY 22	22APR2003	22	16	-3	1	1	0	2	2	2	1	1	0	0	1	2	2	1
		DAY 29	29APR2003	29	13	-6	2	1	0	2	2	2	1	1	0	0	0	2	0	0
	E0031018	DAY 1	10APR2003	1	21		3	2	2	1	2	2	1	1	1	1	1	0	2	2
		DAY 8	17APR2003	8	14	-7	1	1	0	0	2	2	1	1	1	1	1	0	2	1
		DAY 15	24APR2003	15	14	-7	1	2	0	1	1	2	1	1	1	1	0	0	2	1
	E0031023	DAY 1	29APR2003	1	17		3	2	2	2	2	2	0	1	0	0	2	0	0	1
		DAY 8	07MAY2003	9	18	1	2	2	1	2	0	2	1	1	1	0	2	2	2	0
		DAY 15	13MAY2003	15	17	0	2	2	2	2	0	2	1	1	1	0	0	1	2	1
		DAY 22	20MAY2003	22	10	-7	2	1	1	1	0	2	0	1	0	0	1	0	0	1
		DAY 29	27MAY2003	29	17	0	2	2	2	2	0	2	1	1	1	0	1	2	0	1
		DAY 36	04JUN2003	37	14	-3	3	2	1	1	0	2	0	1	0	1	1	0	1	1
		DAY 43	10JUN2003	43	13	-4	2	2	1	1	0	2	1	1	1	1	0	0	0	1
		DAY 50	17JUN2003	50	13	-4	2	2	1	2	1	2	1	0	0	0	1	0	0	1
		DAY 57	24JUN2003	57	15	-2	2	1	2	2	0	2	1	1	1	1	1	0	0	1
	E0033001	DAY 1	09JAN2003	1	35		3	3	3	4	3	4	2	2	1	2	0	4	2	2
		DAY 8	16JAN2003	8	33	-2	3	3	3	3	3	4	3	2	1	1	2	1	2	2
		DAY 15	23JAN2003	15	34	-1	3	3	2	4	3	3	2	2	2	2	1	3	2	2
		DAY 22	30JAN2003	22	35	0	3	3	2	4	3	4	2	2	2	2	1	4	1	2
	E0033004	DAY 1	17JAN2003	1	30		3	3	0	3	3	3	2	1	1	2	2	3	2	2
		DAY 8	24JAN2003	8	24	-6	3	3	0	2	2	2	2	1	0	2	1	3	1	2
		DAY 15	31JAN2003	15	23	-7	2	3	1	1	2	2	2	1	1	0	1	3	2	2
		DAY 22	07FEB2003	22	16	-14	1	1	0	0	2	1	2	1	0	1	1	3	1	2
		DAY 29	14FEB2003	29	16	-14	2	1	0	0	2	1	1	1	1	1	1	2	1	2
		DAY 36	21FEB2003	36	8	-22	0	1	0	2	0	0	1	0	0	0	0	2	0	2
		DAY 43	28FEB2003	43	14	-16	2	3	0	0	2	0	1	0	1	0	0	1	2	2

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0033004	DAY 50	07MAR2003	50	25	-5	3	2	0	3	2	3	2	0	2	1	2	2	1	2
		DAY 57	14MAR2003	57	24	-6	3	3	0	1	3	3	2	0	1	2	0	3	1	2
	E0033010	DAY 1	04FEB2003	1	23		3	3	0	1	3	3	3	1	0	1	1	1	2	1
		DAY 8	11FEB2003	8	19	-4	3	3	0	1	3	3	0	2	0	0	0	2	1	1
		DAY 15	20FEB2003	17	23	0	3	3	1	2	3	3	2	1	0	0	1	1	2	1
		DAY 22	27FEB2003	24	18	-5	2	2	0	1	2	2	2	0	0	1	0	2	2	2
		DAY 29	04MAR2003	29	17	-6	2	3	0	2	2	3	0	0	0	1	1	1	1	1
		DAY 36	14MAR2003	39	20	-3	3	3	0	1	3	3	1	2	0	1	1	1	0	1
	E0033014	DAY 1	19MAR2003	1	13		1	2	0	2	1	1	1	1	3	0	1	0	0	0
		DAY 8	26MAR2003	8	7	-6	2	1	0	1	1	1	0	0	0	0	0	0	0	1
		DAY 15	03APR2003	16	6	-7	1	1	0	0	1	2	1	0	0	0	0	0	0	0
		DAY 22	11APR2003	24	6	-7	1	0	0	0	1	1	1	0	0	0	0	0	2	0
		DAY 29	16APR2003	29	9	-4	1	1	0	0	1	2	1	1	0	0	0	1	1	0
		DAY 36	21APR2003	34	7	-6	2	1	0	0	1	2	0	0	1	0	0	0	0	0
	E0035002	DAY 1	21NOV2002	1	22		2	3	2	3	1	3	1	2	0	0	1	2	1	1
		DAY 8	27NOV2002	7	23	1	2	3	2	3	1	3	1	2	0	0	2	2	1	1
		DAY 15	05DEC2002	15	24	2	2	3	2	3	1	3	1	2	1	0	2	2	1	1
		DAY 22	12DEC2002	22	22	0	2	3	2	2	1	3	1	2	1	0	2	2	1	0
	E0035007	DAY 1	19DEC2002	1	8		1	1	1	1	1	1	0	0	0	1	0	1	0	0
		DAY 8	26DEC2002	8	5	-3	1	0	1	0	1	1	0	0	0	0	0	1	0	0
		DAY 15	02JAN2003	15	5	-3	1	1	0	0	1	1	0	0	0	0	0	1	0	0
		DAY 22	09JAN2003	22	4	-4	1	1	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 29	17JAN2003	30	15	7	3	3	0	3	2	3	0	0	0	0	1	0	0	0
		DAY 36	23JAN2003	36	6	-2	2	1	0	0	2	1	0	0	0	0	0	0	0	0
		DAY 43	30JAN2003	43	15	7	2	3	1	3	2	3	0	0	0	0	0	1	0	0
		DAY 50	06FEB2003	50	2	-6	1	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	55	8	0	2	1	0	1	1	2	0	0	0	0	1	0	0	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0035011	DAY 1	04FEB2003	1	25		3	2	1	3	2	3	1	0	2	0	2	3	2	1
		DAY 8	11FEB2003	8	19	-6	2	2	1	0	2	3	1	0	2	0	0	3	2	1
		DAY 15	18FEB2003	15	18	-7	1	2	1	0	2	2	0	1	1	0	2	3	2	1
		DAY 22	25FEB2003	22	19	-6	2	2	1	1	2	2	2	1	0	0	0	3	2	1
		DAY 29	04MAR2003	29	21	-4	3	2	1	2	2	3	2	0	0	0	1	2	2	1
		DAY 36	11MAR2003	36	17	-8	2	2	2	1	2	2	1	0	0	0	0	2	2	1
		DAY 43	18MAR2003	43	13	-12	2	2	1	0	2	2	1	1	0	0	0	2	0	0
		DAY 50	25MAR2003	50	24	-1	3	2	1	2	2	3	3	1	0	0	2	3	1	1
		DAY 57	01APR2003	57	20	-5	2	2	0	2	2	2	2	2	0	0	1	3	1	1
	E0035020	DAY 1	18APR2003	1	21		2	2	0	2	2	3	3	0	0	0	1	3	2	1
		DAY 8	25APR2003	8	21	0	2	2	1	2	2	2	3	0	0	0	2	2	2	1
		DAY 15	01MAY2003	14	11	-10	1	1	0	2	2	1	1	0	0	0	0	2	0	1
		DAY 22	09MAY2003	22	11	-10	1	2	0	1	2	1	0	0	0	0	1	2	0	1
		DAY 29	15MAY2003	28	9	-12	1	2	0	1	1	1	0	0	0	0	1	2	0	0
		DAY 36	23MAY2003	36	8	-13	1	1	0	1	1	1	1	0	0	0	0	2	0	0
		DAY 43	30MAY2003	43	7	-14	1	1	0	1	1	1	0	0	0	0	0	2	0	0
		DAY 50	06JUN2003	50	8	-13	1	1	0	1	1	1	0	1	0	0	0	2	0	0
		DAY 57	13JUN2003	57	10	-11	1	2	0	1	1	1	0	0	0	0	0	3	0	1
	E0037003	DAY 1	30JAN2003	1	19		1	2	0	2	2	3	1	0	1	2	0	2	2	1
		DAY 8	06FEB2003	8	23	4	2	2	0	2	2	3	2	2	0	2	1	2	2	1
		DAY 15	13FEB2003	15	16	-3	1	1	0	2	2	3	1	0	0	1	1	2	2	0
		DAY 22	20FEB2003	22	18	-1	2	2	0	2	2	3	2	0	0	0	1	2	2	0
	E0037004	DAY 1	13FEB2003	1	14		1	1	0	3	2	3	0	0	0	0	1	2	1	0
		DAY 8	21FEB2003	9	11	-3	1	0	0	1	2	2	0	0	1	0	1	1	2	0
		DAY 15	27FEB2003	15	15	1	2	2	0	2	2	2	0	0	0	0	2	2	1	0
		DAY 22	06MAR2003	22	13	-1	2	2	0	2	2	2	0	0	0	0	1	1	1	0
		DAY 29	13MAR2003	29	8	-6	1	0	0	1	2	1	0	0	0	0	1	1	1	0
		DAY 36	20MAR2003	36	12	-2	1	1	0	2	2	1	0	0	1	0	1	2	1	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0037004	DAY 43	28MAR2003	44	9	-5	1	1	0	2	0	1	0	0	0	0	2	1	1	0
		DAY 50	04APR2003	51	8	-6	1	2	0	1	0	1	0	0	0	0	1	1	1	0
		DAY 57	10APR2003	57	7	-7	1	1	0	0	0	1	0	0	1	0	0	2	1	0
	E0039007	DAY 1	04DEC2002	1	14		2	2	0	1	2	2	0	1	1	0	2	0	0	1
		DAY 8	11DEC2002	8	10	-4	2	2	0	1	1	2	0	0	1	0	0	0	1	0
		DAY 15	18DEC2002	15	11	-3	1	2	0	2	1	2	0	0	0	0	0	2	0	1
		DAY 22	23DEC2002	20	9	-5	1	2	0	1	2	1	0	0	0	0	0	1	0	1
		DAY 29	30DEC2002	27	10	-4	1	1	0	2	2	1	1	0	0	0	1	0	0	1
		DAY 36	08JAN2003	36	12	-2	2	2	0	1	1	2	0	0	0	0	1	1	1	1
		DAY 43	15JAN2003	43	14	0	2	2	0	0	2	2	0	0	0	0	2	0	3	1
		DAY 50	22JAN2003	50	11	-3	1	2	0	0	1	1	1	0	0	0	1	1	2	1
		DAY 57	29JAN2003	57	7	-7	1	1	0	1	1	1	0	0	0	1	0	1	0	0
	E0039022	DAY 1	25FEB2003	1	9		2	1	0	2	1	2	1	0	0	0	0	0	0	0
		DAY 8	06MAR2003	10	5	-4	1	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 15	11MAR2003	15	4	-5	1	1	0	1	0	0	0	0	0	0	0	0	1	0
		DAY 22	18MAR2003	22	9	0	1	1	0	2	1	2	0	0	1	0	1	0	0	0
		DAY 29	25MAR2003	29	4	-5	0	1	0	1	0	1	0	0	1	0	0	0	0	0
		DAY 36	01APR2003	36	4	-5	1	1	0	1	1	0	0	0	0	0	0	0	0	0
		DAY 43	07APR2003	42	3	-6	1	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 50	15APR2003	50	3	-6	2	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	24APR2003	59	4	-5	1	1	0	1	0	1	0	0	0	0	0	0	0	0
	E0039023	DAY 1	24FEB2003	1	11		2	2	1	2	2	2	0	0	0	0	0	0	0	0
		DAY 8	03MAR2003	8	11	0	2	2	0	2	1	2	0	0	0	0	1	0	0	1
	E0039030	DAY 1	24MAR2003	1	7		1	2	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 8	31MAR2003	8	7	0	1	2	0	1	1	2	0	0	0	0	0	0	0	0
		DAY 15	07APR2003	15	1	-6	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	14APR2003	22	1	-6	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0039030	DAY 29	21APR2003	29	2	-5	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	28APR2003	36	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	43	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	13MAY2003	51	2	-5	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAY2003	57	0	-7	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0039031	DAY 1	24MAR2003	1	12		2	2	0	1	2	2	1	0	0	0	2	0	0	0
		DAY 8	31MAR2003	8	9	-3	1	1	0	0	2	2	1	1	0	0	1	0	0	0
		DAY 15	07APR2003	15	4	-8	1	1	0	1	0	0	0	0	0	0	0	0	0	1
		DAY 22	15APR2003	23	2	-10	1	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 29	21APR2003	29	5	-7	1	2	0	0	0	0	0	0	1	1	0	0	0	0
		DAY 36	28APR2003	36	1	-11	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	05MAY2003	43	6	-6	2	1	0	1	0	0	0	0	0	1	0	0	0	1
		DAY 50	13MAY2003	51	5	-7	1	0	0	0	2	2	0	0	0	0	0	0	0	0
		DAY 57	20MAY2003	58	2	-10	1	0	0	0	0	1	0	0	0	0	0	0	0	0
	E0039037	DAY 1	16APR2003	1	20		2	2	1	3	2	3	1	1	1	0	1	0	1	2
		DAY 8	23APR2003	8	14	-6	2	1	0	2	2	3	1	1	1	0	0	0	0	1
		DAY 15	01MAY2003	16	16	-4	2	2	0	2	2	3	1	0	1	0	0	1	1	1
		DAY 22	07MAY2003	22	10	-10	2	2	0	1	2	0	0	0	0	0	0	0	1	2
		DAY 29	15MAY2003	30	9	-11	2	2	0	1	2	1	1	0	0	0	0	0	0	0
		DAY 36	21MAY2003	36	11	-9	2	2	0	1	2	0	1	0	0	0	0	0	1	2
		DAY 43	28MAY2003	43	11	-9	2	2	0	0	2	1	1	1	1	0	0	0	1	0
		DAY 50	05JUN2003	51	6	-14	2	2	0	0	0	0	1	0	0	0	0	0	1	0
		DAY 57	12JUN2003	58	14	-6	2	2	0	2	2	1	1	0	0	0	0	1	1	2
	E0039038	DAY 1	23APR2003	1	10		2	2	0	1	1	2	0	0	0	0	0	0	1	1
		DAY 8	30APR2003	8	7	-3	2	2	0	0	1	2	0	0	0	0	0	0	0	0
		DAY 22	15MAY2003	23	9	-1	2	2	0	2	1	2	0	0	0	0	0	0	0	0
		DAY 29	21MAY2003	29	4	-6	1	0	0	1	0	1	0	0	0	0	1	0	0	0
		DAY 36	29MAY2003	37	8	-2	2	2	0	0	1	1	0	0	0	0	1	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0039047	DAY 1	19MAY2003	1	13		2	2	0	2	2	2	1	0	1	0	0	0	0	1
		DAY 8	27MAY2003	9	7	-6	2	1	0	1	1	1	0	0	0	0	0	0	0	1
		DAY 15	03JUN2003	16	12	-1	2	2	0	1	1	1	2	0	0	1	1	0	1	0
		DAY 22	09JUN2003	22	11	-2	2	1	0	2	1	1	1	0	0	2	0	0	0	1
		DAY 29	16JUN2003	29	15	2	2	2	0	2	1	2	1	0	1	1	1	0	1	1
		DAY 36	23JUN2003	36	2	-11	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	30JUN2003	43	9	-4	2	2	0	1	0	1	1	0	0	1	0	1	0	0
		DAY 50	07JUL2003	50	1	-12	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 57	14JUL2003	57	3	-10	1	1	0	1	0	0	0	0	0	0	0	0	0	0
	E0039059	DAY 1	11JUL2003	1	8		1	1	0	1	2	2	0	1	0	0	0	0	0	0
		DAY 8	18JUL2003	8	8	0	2	2	0	0	1	1	1	0	0	0	0	0	1	0
		DAY 15	25JUL2003	15	4	-4	0	1	0	0	1	1	0	0	0	0	0	0	1	0
		DAY 22	01AUG2003	22	5	-3	1	1	0	0	1	1	0	0	0	0	0	0	1	0
		DAY 29	07AUG2003	28	1	-7	0	0	0	0	0	0	0	0	0	0	0	0	1	0
		DAY 36	15AUG2003	36	1	-7	0	0	0	0	0	0	0	0	0	0	0	0	1	0
		DAY 43	21AUG2003	42	2	-6	1	0	0	0	0	0	0	0	0	0	1	0	0	0
		DAY 50	29AUG2003	50	0	-8	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	05SEP2003	57	1	-7	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	E0041007	DAY 1	13MAR2003	1	10		1	1	0	2	1	2	1	0	0	1	0	0	0	1
		DAY 8	20MAR2003	8	8	-2	1	1	0	2	1	2	0	0	0	0	0	0	0	1
		DAY 15	27MAR2003	15	4	-6	0	1	0	1	1	1	0	0	0	0	0	0	0	0
		DAY 22	03APR2003	22	7	-3	0	0	0	2	2	2	0	0	0	0	0	0	0	1
		DAY 29	10APR2003	29	10	0	1	1	0	2	2	2	1	0	0	0	0	0	0	1
		DAY 36	17APR2003	36	10	0	1	1	0	2	2	2	0	0	0	0	1	0	0	1
		DAY 43	25APR2003	44	6	-4	0	1	0	1	1	2	0	0	0	0	0	0	0	1
		DAY 50	01MAY2003	50	7	-3	0	0	0	2	1	2	0	0	0	0	2	0	0	0
		DAY 57	08MAY2003	57	8	-2	2	1	0	2	1	2	0	0	0	0	0	0	0	0
	E0041010	DAY 1	30APR2003	1	11		1	1	0	2	1	2	0	0	0	0	0	1	2	1

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR I)	E0041010	DAY 8	08MAY2003	9	13	2	2	1	0	2	1	2	0	1	0	0	1	0	2	1
		DAY 15	14MAY2003	15	12	1	2	1	1	2	1	1	0	0	0	0	0	1	2	1
		DAY 22	21MAY2003	22	13	2	2	1	1	2	2	1	1	0	0	0	1	1	1	0
		DAY 29	28MAY2003	29	11	0	2	1	0	2	1	1	0	0	0	0	1	1	2	0
		DAY 36	04JUN2003	36	16	5	2	1	0	2	1	2	1	0	0	1	2	2	2	0
		DAY 43	11JUN2003	43	14	3	3	3	0	3	2	0	0	0	0	0	0	0	2	1
	E0041011	DAY 1	22MAY2003	1	15		2	1	0	2	1	3	1	0	1	1	0	2	0	1
		DAY 8	02JUN2003	12	13	-2	2	1	1	1	1	1	2	0	1	1	0	0	2	0
		DAY 15	06JUN2003	16	13	-2	1	1	2	1	1	2	1	0	1	1	0	2	0	0
		DAY 22	16JUN2003	26	19	4	2	2	2	1	2	2	1	1	2	1	0	2	0	1
		DAY 29	20JUN2003	30	13	-2	2	2	0	1	1	2	2	0	1	0	0	2	0	0
		DAY 36	26JUN2003	36	10	-5	1	1	1	1	1	2	0	0	1	0	0	2	0	0
		DAY 43	03JUL2003	43	15	0	2	2	1	1	1	2	1	0	1	0	0	2	1	1
		DAY 50	10JUL2003	50	15	0	3	2	1	1	2	2	0	0	1	0	0	2	0	1
		DAY 57	17JUL2003	57	14	-1	2	2	1	1	1	2	1	0	1	1	0	2	0	0
	E0041012	DAY 1	19JUN2003	1	18		2	2	1	2	2	3	2	0	1	0	1	0	1	1
		DAY 8	26JUN2003	8	16	-2	2	2	0	2	2	1	2	0	0	0	2	0	1	2
		DAY 15	03JUL2003	15	17	-1	2	2	0	2	2	1	2	1	1	1	1	0	1	1
		DAY 22	10JUL2003	22	17	-1	2	2	0	2	2	1	2	1	1	1	1	0	1	1
		DAY 29	17JUL2003	29	18	0	2	2	0	2	1	1	2	1	1	1	2	0	2	1
		DAY 36	24JUL2003	36	19	1	2	2	0	2	1	1	2	1	1	1	2	0	2	2
		DAY 43	31JUL2003	43	18	0	2	2	0	2	1	0	2	1	1	1	2	0	2	2
		DAY 50	07AUG2003	50	16	-2	2	2	0	1	1	0	2	1	1	1	2	0	2	1
		DAY 57	14AUG2003	57	18	0	2	2	0	2	1	1	2	1	1	1	2	0	2	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0001004	DAY 1	01MAY2003	1	9		2	1	0	1	1	2	0	0	0	1	0	0	0	1
		DAY 8	09MAY2003	9	9	0	2	2	0	0	0	0	0	0	0	2	2	0	0	1
		DAY 15	16MAY2003	16	4	-5	1	1	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 22	23MAY2003	23	2	-7	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	29MAY2003	29	0	-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	06JUN2003	37	3	-6	1	0	0	0	0	1	0	0	0	1	0	0	0	0
		DAY 43	12JUN2003	43	1	-8	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		DAY 50	20JUN2003	51	3	-6	1	0	0	0	0	1	0	0	0	0	0	0	1	0
		DAY 57	27JUN2003	58	1	-8	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0005023	DAY 1	05FEB2003	1	22		2	2	0	3	2	3	1	0	0	1	1	3	2	2
		DAY 8	13FEB2003	9	9	-13	0	0	0	0	2	1	0	0	0	1	1	3	1	0
		DAY 15	20FEB2003	16	6	-16	1	0	0	0	2	0	0	0	1	0	0	1	0	1
		DAY 22	27FEB2003	23	3	-19	0	0	0	0	1	0	0	0	0	0	0	2	0	0
		DAY 29	06MAR2003	30	5	-17	1	0	0	1	0	0	0	0	0	0	0	0	2	1
		DAY 36	13MAR2003	37	4	-18	0	0	0	0	2	0	0	0	0	0	0	1	0	1
		DAY 43	18MAR2003	42	4	-18	0	0	0	0	1	0	0	0	0	0	0	2	0	1
		DAY 50	26MAR2003	50	4	-18	0	0	0	0	1	0	0	0	0	0	0	2	0	1
		DAY 57	01APR2003	56	4	-18	0	0	0	0	1	0	0	0	0	0	0	2	0	1
	E0005034	DAY 1	15APR2003	1	18		2	2	0	2	3	2	1	0	0	0	0	3	2	1
		DAY 8	23APR2003	9	20	2	2	2	0	2	3	2	0	1	0	0	1	3	2	2
		DAY 15	01MAY2003	17	19	1	1	2	0	2	3	2	1	1	0	1	0	3	2	1
		DAY 22	06MAY2003	22	19	1	1	2	0	2	2	2	1	1	0	1	0	3	2	2
		DAY 29	13MAY2003	29	18	0	0	2	0	2	2	2	1	1	0	1	0	3	2	2
		DAY 36	22MAY2003	38	17	-1	1	2	0	2	3	1	1	1	0	1	0	2	2	1
		DAY 43	28MAY2003	44	14	-4	1	2	0	2	3	1	1	0	0	0	0	2	1	1
		DAY 50	05JUN2003	52	25	7	3	3	0	1	3	3	1	1	1	1	1	3	2	2
		DAY 57	09JUN2003	56	24	6	3	3	0	1	2	3	1	1	1	1	1	3	2	2
	E0005041	DAY 1	24JUN2003	1	15		1	1	0	1	1	2	1	1	0	2	1	2	1	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0005041	DAY 8		01JUL2003	8	7	-8	1	1	0	0	1	1	0	0	0	0	1	1	1	0
		DAY 15		08JUL2003	15	7	-8	1	0	0	0	1	0	0	1	0	0	0	3	1	0
		DAY 22		16JUL2003	23	9	-6	2	0	0	0	2	1	0	0	0	1	0	2	1	0
		DAY 29		22JUL2003	29	9	-6	1	0	0	1	1	1	0	1	1	0	0	2	1	0
		DAY 36		28JUL2003	35	8	-7	0	1	0	1	0	1	1	0	0	0	1	2	1	0
		DAY 43		04AUG2003	42	6	-9	0	1	0	0	0	1	1	1	0	0	1	1	0	0
		DAY 50		11AUG2003	49	4	-11	1	0	0	0	0	1	0	1	0	0	0	1	0	0
		DAY 57		18AUG2003	56	5	-10	1	1	0	1	0	0	0	1	0	0	0	1	0	0
	E0007004	DAY 1		30JAN2003	1	19		2	2	0	3	1	2	1	1	1	1	1	2	1	1
		DAY 8		07FEB2003	9	17	-2	2	2	0	2	2	2	0	1	1	0	0	3	1	1
		DAY 15		12FEB2003	14	17	-2	2	2	0	2	1	2	1	1	1	1	1	2	1	0
	E0007010	DAY 1		18APR2003	1	13		2	2	0	2	1	2	1	0	0	0	0	3	0	0
		DAY 8		25APR2003	8	15	2	2	2	0	2	1	2	1	0	0	0	1	3	1	0
		DAY 15		02MAY2003	15	9	-4	1	1	0	2	0	0	1	0	0	0	0	3	1	0
		DAY 22		09MAY2003	22	11	-2	1	1	0	2	1	1	0	0	2	0	0	2	0	1
		DAY 29		16MAY2003	29	1	-12	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 36		23MAY2003	36	6	-7	1	1	0	1	0	0	0	0	0	0	0	2	1	0
		DAY 43		29MAY2003	42	14	1	2	1	0	2	1	2	2	0	0	0	0	3	0	1
		DAY 50		06JUN2003	50	16	3	2	2	0	2	2	2	2	0	0	0	0	3	0	1
		DAY 57		16JUN2003	60	9	-4	1	1	0	2	1	1	0	0	0	0	0	2	1	0
	E0007012	DAY 1		16MAY2003	1	17		2	2	0	2	2	2	1	0	1	1	1	1	1	1
		DAY 8		23MAY2003	8	15	-2	2	2	0	2	2	2	0	0	1	1	1	1	0	1
		DAY 15		29MAY2003	14	9	-8	2	1	0	1	2	2	0	0	0	0	0	1	0	0
		DAY 22		06JUN2003	22	9	-8	1	1	0	1	1	2	0	0	0	0	0	1	1	1
		DAY 29		13JUN2003	29	10	-7	1	1	0	0	1	1	1	0	1	0	0	1	2	1
		DAY 36		20JUN2003	36	7	-10	1	1	0	0	1	1	1	0	0	0	0	1	1	0
		DAY 43		25JUN2003	41	17	0	2	2	0	2	2	2	1	0	1	1	1	1	1	1
		DAY 43	*	01JUL2003	47	17	0	2	2	0	2	2	2	1	0	1	1	1	1	1	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0009007	DAY 1	03FEB2003	1	24		2	2	1	3	3	2	1	2	2	2	1	1	1	1
		DAY 8	10FEB2003	8	21	-3	2	2	1	4	2	2	1	1	1	1	1	0	1	2
		DAY 15	17FEB2003	15	19	-5	3	2	1	3	2	3	1	1	1	0	0	0	1	1
		DAY 22	25FEB2003	23	13	-11	2	2	1	2	1	2	0	1	0	0	0	0	0	2
		DAY 29	03MAR2003	29	27	3	3	2	0	3	2	2	3	2	2	2	3	1	1	1
	E0009008	DAY 1	12FEB2003	1	15		2	3	0	2	1	2	0	0	0	0	1	1	0	3
		DAY 8	19FEB2003	8	8	-7	2	0	0	0	2	2	1	0	0	0	0	0	0	1
		DAY 15	25FEB2003	14	7	-8	1	0	0	1	1	2	1	1	0	0	0	0	0	0
		DAY 22	04MAR2003	21	2	-13	0	0	0	1	0	1	0	0	0	0	0	0	0	0
		DAY 29	11MAR2003	28	17	2	2	2	0	1	2	2	1	0	2	1	2	0	1	1
		DAY 36	18MAR2003	35	9	-6	2	0	0	1	2	3	0	0	0	0	0	0	0	1
		DAY 43	26MAR2003	43	4	-11	0	0	0	0	1	1	0	0	0	0	1	0	0	1
		DAY 50	03APR2003	51	5	-10	1	0	0	1	1	1	0	0	0	0	1	0	0	0
		DAY 57	08APR2003	56	2	-13	0	0	0	1	0	1	0	0	0	0	0	0	0	0
	E0011001	DAY 1	01NOV2002	1	23		3	3	1	2	2	2	2	1	1	1	1	1	1	2
		DAY 8	07NOV2002	7	20	-3	2	2	0	2	2	2	2	2	1	1	1	0	1	2
		DAY 15	14NOV2002	14	14	-9	2	1	0	3	3	2	0	0	1	0	0	0	1	1
		DAY 22	21NOV2002	21	14	-9	3	1	0	1	1	2	1	0	1	0	0	1	1	2
		DAY 29	27NOV2002	27	14	-9	2	2	0	0	2	1	2	0	0	1	1	0	1	2
		DAY 36	05DEC2002	35	18	-5	2	2	0	2	3	2	2	1	1	0	1	0	1	1
		DAY 43	12DEC2002	42	15	-8	2	1	0	1	3	2	1	1	1	0	1	0	1	1
		DAY 50	19DEC2002	49	11	-12	1	1	0	1	2	2	0	0	0	1	1	0	1	1
		DAY 57	26DEC2002	56	12	-11	1	2	0	1	1	1	2	0	0	0	1	0	2	1
	E0011011	DAY 1	20FEB2003	1	17		3	2	0	2	2	2	1	0	0	1	1	2	0	1
		DAY 8	26FEB2003	7	19	2	1	2	1	2	2	2	0	0	1	1	2	2	2	1
		DAY 15	05MAR2003	14	17	0	3	2	1	2	2	2	0	0	1	1	0	0	2	1
		DAY 22	12MAR2003	21	21	4	3	2	0	3	2	2	2	1	1	1	1	1	1	1
		DAY 29	19MAR2003	28	19	2	2	2	3	3	1	2	1	1	0	1	0	1	2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0011011	DAY 36	26MAR2003	35	18	1	2	1	2	1	2	1	0	1	1	1	3	1	2	0
		DAY 43	02APR2003	42	25	8	3	2	3	2	2	2	0	2	2	1	1	1	2	2
		DAY 50	09APR2003	49	21	4	2	2	2	3	2	2	0	1	1	1	0	2	2	1
		DAY 57	16APR2003	56	12	-5	2	0	1	2	1	1	0	1	1	1	0	1	1	0
	E0011013	DAY 1	17APR2003	1	20		3	3	1	2	2	2	1	0	0	2	0	1	1	2
		DAY 8	24APR2003	8	14	-6	3	3	0	2	1	2	0	0	0	0	1	0	0	2
		DAY 15	01MAY2003	15	18	-2	3	3	0	3	2	2	0	0	0	0	1	1	1	2
		DAY 22	08MAY2003	22	18	-2	3	3	0	3	1	2	1	1	0	0	0	1	1	2
		DAY 29	15MAY2003	29	16	-4	3	3	0	3	2	2	0	0	0	0	0	1	0	2
		DAY 36	22MAY2003	36	17	-3	3	3	0	1	1	2	0	1	2	1	1	0	0	2
		DAY 43	29MAY2003	43	14	-6	3	3	0	1	0	3	0	0	0	1	0	0	1	2
		DAY 50	05JUN2003	50	23	3	3	3	0	2	1	3	1	1	2	2	1	1	1	2
		DAY 57	12JUN2003	57	18	-2	3	3	0	0	0	3	0	0	1	2	1	1	2	2
	E0011014	DAY 1	07APR2003	1	24		3	3	3	3	3	3	0	0	0	0	0	2	2	2
		DAY 8	14APR2003	8	13	-11	2	1	2	1	2	2	1	0	0	0	1	0	0	1
	E0011021	DAY 1	22MAY2003	1	21		3	3	0	3	3	3	0	1	0	0	1	2	0	2
		DAY 8	29MAY2003	8	18	-3	3	3	0	2	3	3	0	0	0	0	1	2	0	1
		DAY 15	05JUN2003	15	12	-9	2	1	0	1	3	2	0	0	0	0	1	2	0	0
		DAY 22	12JUN2003	22	12	-9	2	2	0	1	1	2	0	0	0	0	1	2	0	1
		DAY 29	20JUN2003	30	13	-8	2	2	0	1	1	2	0	0	0	0	0	3	0	2
		DAY 36	27JUN2003	37	9	-12	1	2	0	0	2	1	0	0	0	0	0	3	0	0
		DAY 43	02JUL2003	42	11	-10	1	2	0	0	2	0	1	0	0	0	0	3	0	2
		DAY 50	10JUL2003	50	13	-8	3	2	0	3	1	1	0	0	0	0	0	3	0	0
		DAY 57	21JUL2003	61	5	-16	1	0	0	1	0	0	0	0	0	0	0	3	0	0
	E0013008	DAY 1	26MAR2003	1	20		3	3	1	3	3	3	2	1	1	0	0	0	0	0
		DAY 8	02APR2003	8	22	2	2	2	1	3	3	3	2	1	0	0	1	2	2	0
		DAY 15	09APR2003	15	27	7	3	2	1	3	3	3	3	1	1	1	1	2	2	1

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Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0013008	DAY 22	17APR2003	23	27	7	3	3	2	4	3	1	2	2	0	1	0	2	2	2
		DAY 29	23APR2003	29	28	8	3	2	1	3	3	3	1	1	2	2	2	2	3	0
		DAY 36	30APR2003	36	27	7	3	3	2	3	3	3	2	1	1	1	1	2	2	0
		DAY 43	07MAY2003	43	29	9	3	3	2	3	3	3	2	1	1	1	2	2	2	1
		DAY 50	12MAY2003	48	29	9	3	3	3	3	3	3	3	2	1	0	0	3	2	0
		DAY 57	19MAY2003	55	27	7	3	3	2	3	2	3	2	1	1	1	2	2	2	0
	E0014001	DAY 1	26FEB2003	1	25		2	4	1	3	2	4	3	0	0	0	1	2	2	1
		DAY 8	05MAR2003	8	16	-9	2	3	0	0	0	3	2	0	0	0	2	1	2	1
		DAY 15	12MAR2003	15	3	-22	0	0	0	1	1	0	1	0	0	0	0	0	0	0
		DAY 22	19MAR2003	22	2	-23	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		DAY 29	25MAR2003	28	1	-24	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	01APR2003	35	6	-19	2	2	0	0	0	1	1	0	0	0	0	0	0	0
	E0014013	DAY 1	27MAY2003	1	35		3	3	2	3	1	3	3	2	3	2	2	2	3	3
		DAY 8	04JUN2003	9	31	-4	3	3	1	0	1	3	3	2	3	2	2	2	3	3
		DAY 15	13JUN2003	18	29	-6	3	3	1	0	1	3	3	2	2	2	2	2	2	3
		DAY 22	18JUN2003	23	21	-14	2	2	0	0	1	2	2	2	1	1	2	2	2	2
		DAY 29	25JUN2003	30	28	-7	3	3	1	1	1	3	2	2	1	2	2	2	2	3
		DAY 36	02JUL2003	37	15	-20	2	2	0	0	1	1	2	2	0	1	1	1	1	1
		DAY 43	10JUL2003	45	17	-18	3	3	0	0	1	2	2	0	0	2	0	0	2	2
		DAY 50	16JUL2003	51	22	-13	3	3	0	1	1	2	3	2	0	2	0	0	2	3
		DAY 57	23JUL2003	58	18	-17	3	3	0	0	1	0	2	1	1	2	0	1	1	3
	E0014014	DAY 1	10JUN2003	1	18		2	2	0	2	1	3	2	0	1	1	1	1	0	2
		DAY 8	18JUN2003	9	10	-8	1	1	0	1	1	2	1	0	0	0	0	0	1	2
		DAY 15	24JUN2003	15	10	-8	1	2	0	0	1	1	1	0	0	0	0	1	1	2
		DAY 22	03JUL2003	24	3	-15	1	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 29	10JUL2003	31	1	-17	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		DAY 36	18JUL2003	39	8	-10	1	1	0	0	1	1	1	0	0	1	0	0	1	1
		DAY 50	30JUL2003	51	8	-10	1	1	0	1	0	1	0	1	0	0	0	1	0	2

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0014014	DAY 57		06AUG2003	58	6	-12	1	1	0	0	1	0	0	1	0	0	0	1	0	1
	E0015004	DAY 1		02DEC2002	1	23		2	2	0	3	3	3	2	0	0	2	2	3	0	1
		DAY 8		11DEC2002	10	21	-2	3	2	0	3	2	3	1	1	0	1	1	1	1	2
		DAY 15		18DEC2002	17	20	-3	3	2	0	3	2	2	1	1	2	2	1	0	0	1
		DAY 22		27DEC2002	26	19	-4	2	2	0	3	2	3	1	0	0	2	0	2	1	1
		DAY 36		06JAN2003	36	17	-6	2	2	0	3	2	3	1	0	0	2	0	1	0	1
		DAY 36	*	09JAN2003	39	23	0	3	2	0	3	2	3	1	1	1	1	1	3	1	1
		DAY 43		17JAN2003	47	23	0	3	2	0	3	2	3	1	1	1	1	1	3	1	1
		DAY 57		29JAN2003	59	20	-3	3	3	0	3	2	3	1	0	0	1	1	1	1	1
	E0018005	DAY 1		20DEC2002	1	20		2	2	2	3	3	2	2	0	0	0	0	0	2	2
		DAY 8		27DEC2002	8	14	-6	1	1	1	0	2	2	1	2	0	0	0	1	2	1
		DAY 8	*	31DEC2002	12	10	-10	1	1	1	0	2	1	1	0	0	0	0	1	1	1
		DAY 22		10JAN2003	22	7	-13	1	1	1	0	1	0	1	0	0	0	0	0	1	1
		DAY 29		17JAN2003	29	7	-13	1	1	0	1	1	0	0	0	0	0	0	1	1	1
		DAY 36		24JAN2003	36	8	-12	1	1	1	0	1	0	1	0	0	0	0	1	1	1
		DAY 43		31JAN2003	43	9	-11	1	1	1	1	1	1	1	0	0	0	0	0	1	1
		DAY 50		07FEB2003	50	7	-13	1	1	1	0	0	0	1	0	0	0	0	1	1	1
		DAY 57		14FEB2003	57	5	-15	1	1	0	0	0	0	1	0	0	0	0	1	1	0
	E0018012	DAY 1		24JAN2003	1	21		2	2	2	3	2	3	1	0	0	0	1	1	2	2
		DAY 8		30JAN2003	7	17	-4	2	2	2	1	3	2	1	0	0	0	0	0	2	2
		DAY 15		07FEB2003	15	10	-11	1	1	1	1	1	1	0	0	0	0	1	1	1	1
		DAY 22		14FEB2003	22	3	-18	1	0	0	0	0	0	0	0	0	0	0	0	1	1
		DAY 29		21FEB2003	29	11	-10	1	1	1	1	1	1	1	0	0	0	1	1	1	1
		DAY 36		26FEB2003	34	16	-5	2	2	2	1	1	2	1	0	0	0	1	1	2	1
	E0019019	DAY 1		23JAN2003	1	25		3	3	2	3	2	3	2	0	0	0	1	2	1	3
		DAY 8		30JAN2003	8	19	-6	3	2	2	1	1	3	0	0	1	0	2	2	1	1
		DAY 15		06FEB2003	15	12	-13	1	1	0	2	1	2	2	1	0	0	0	0	1	1

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0019033	DAY 1	18MAR2003	1	17		2	1	1	2	1	3	0	0	1	1	2	2	0	1
		DAY 8	27MAR2003	10	19	2	2	3	0	2	1	3	1	0	2	2	0	3	0	0
		DAY 15	03APR2003	17	23	6	2	2	1	2	1	3	1	1	0	3	2	3	2	0
		DAY 22	10APR2003	24	23	6	2	3	0	2	3	3	2	0	2	3	0	3	0	0
		DAY 29	14APR2003	28	18	1	1	2	0	2	1	3	1	1	1	2	1	3	0	0
		DAY 36	22APR2003	36	18	1	2	2	0	2	2	2	1	0	1	0	2	3	0	1
		DAY 43	01MAY2003	45	17	0	3	2	0	2	2	3	0	0	1	0	1	2	0	1
		DAY 50	08MAY2003	52	22	5	2	2	0	2	2	3	1	1	1	2	1	3	0	2
		DAY 57	15MAY2003	59	12	-5	1	2	0	1	1	2	0	0	1	0	1	2	0	1
	E0019038	DAY 1	24APR2003	1	19		1	2	0	2	2	3	0	0	1	1	1	3	1	2
		DAY 8	01MAY2003	8	9	-10	1	1	0	1	1	1	0	0	1	0	1	1	1	0
		DAY 15	07MAY2003	14	17	-2	2	2	1	2	2	2	0	0	1	0	2	1	1	1
		DAY 22	14MAY2003	21	16	-3	2	2	0	1	2	2	0	0	1	0	2	2	1	1
		DAY 29	21MAY2003	28	13	-6	2	1	0	1	3	2	0	0	0	0	1	1	2	0
		DAY 36	28MAY2003	35	10	-9	2	1	0	1	2	1	0	0	0	0	1	0	1	1
		DAY 43	04JUN2003	42	22	3	0	2	0	3	2	2	2	1	2	1	2	1	2	2
		DAY 50	11JUN2003	49	24	5	3	2	0	3	1	1	2	1	1	2	2	2	2	2
		DAY 57	18JUN2003	56	11	-8	1	1	0	0	1	1	0	0	1	0	2	2	1	1
	E0019046	DAY 1	26JUN2003	1	25		3	2	1	3	3	3	1	0	1	0	2	2	2	2
		DAY 8	03JUL2003	8	11	-14	0	1	0	2	2	1	0	0	0	0	1	3	0	1
		DAY 15	10JUL2003	15	10	-15	0	1	0	1	3	2	0	0	0	0	0	2	1	0
		DAY 22	17JUL2003	22	9	-16	2	1	0	0	1	1	0	0	1	0	0	2	0	1
		DAY 29	24JUL2003	29	5	-20	2	0	0	1	0	0	0	0	0	0	0	1	0	1
		DAY 36	30JUL2003	35	3	-22	1	1	0	1	0	0	0	0	0	0	0	0	0	0
		DAY 50	14AUG2003	50	3	-22	2	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	21AUG2003	57	2	-23	1	0	0	0	0	0	0	0	0	0	0	1	0	0
	E0019047	DAY 1	08JUL2003	1	16		2	2	0	3	2	2	0	0	0	0	3	0	0	2
		DAY 8	17JUL2003	10	6	-10	0	1	0	0	2	1	0	0	0	0	1	0	0	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0019047	DAY 15	24JUL2003	17	4	-12	1	1	0	0	0	1	0	0	0	0	0	0	0	1
		DAY 22	31JUL2003	24	17	1	1	1	0	3	2	3	0	0	1	0	2	2	1	1
		DAY 29	07AUG2003	31	8	-8	1	1	0	1	0	1	0	1	0	0	1	0	1	1
		DAY 36	14AUG2003	38	3	-13	0	0	0	1	0	1	0	0	0	0	0	0	0	1
		DAY 43	21AUG2003	45	3	-13	0	1	0	2	0	0	0	0	0	0	0	0	0	0
		DAY 50	28AUG2003	52	8	-8	1	1	0	1	0	1	0	0	0	0	2	0	1	1
		DAY 57	04SEP2003	59	5	-11	1	1	0	1	0	1	0	0	0	0	0	0	0	1
	E0019048	DAY 1	10JUL2003	1	23		3	3	1	3	2	3	0	1	0	1	2	0	2	2
		DAY 8	17JUL2003	8	18	-5	2	2	0	3	2	3	1	0	1	0	0	2	1	1
		DAY 15	22JUL2003	13	18	-5	2	2	0	3	2	3	0	1	0	0	2	1	1	1
		DAY 22	31JUL2003	22	16	-7	3	1	0	3	3	3	0	0	0	0	1	0	1	1
		DAY 29	07AUG2003	29	14	-9	2	3	0	3	3	2	0	0	0	0	0	0	0	1
		DAY 36	14AUG2003	36	13	-10	2	2	0	3	2	2	0	0	0	0	0	1	0	1
		DAY 43	21AUG2003	43	14	-9	3	2	0	3	2	2	0	0	0	0	0	1	0	1
		DAY 50	28AUG2003	50	16	-7	3	2	0	2	3	3	0	0	0	0	0	0	2	1
		DAY 57	03SEP2003	56	17	-6	3	3	0	3	2	3	0	0	0	0	0	0	1	2
	E0022006	DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 8	19NOV2002	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 15	26NOV2002	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 22	03DEC2002	22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 29	10DEC2002	29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 36	17DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43	24DEC2002	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 50	31DEC2002	50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	E0022047	DAY 1	28MAR2003	1	8		1	1	0	0	0	3	1	0	1	0	0	0	0	1
		DAY 8	04APR2003	8	8	0	1	1	0	0	0	3	1	0	0	0	1	0	0	1
		DAY 15	11APR2003	15	5	-3	1	1	0	0	0	2	1	0	0	0	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0022047	DAY 22	17APR2003	21	6	-2	1	1	0	0	0	2	0	0	1	0	0	0	0	1
		DAY 29	25APR2003	29	4	-4	1	1	0	0	0	2	0	0	0	0	0	0	0	0
		DAY 36	02MAY2003	36	3	-5	0	0	0	0	0	2	0	0	0	0	0	0	0	1
		DAY 43	09MAY2003	43	4	-4	1	0	0	0	0	3	0	0	0	0	0	0	0	0
		DAY 50	16MAY2003	50	6	-2	1	1	0	0	0	3	0	0	0	0	0	0	0	1
		DAY 57	23MAY2003	57	3	-5	0	0	0	0	0	3	0	0	0	0	0	0	0	0
	E0022075	DAY 1	08JUL2003	1	9		1	1	0	1	1	2	1	0	0	1	0	1	0	0
		DAY 8	15JUL2003	8	10	1	2	1	1	1	1	2	0	0	0	0	1	1	0	0
		DAY 15	22JUL2003	15	9	0	1	1	1	2	1	1	0	0	0	0	1	1	0	0
		DAY 22	29JUL2003	22	12	3	1	0	1	3	1	2	0	0	0	0	0	2	1	1
		DAY 29	05AUG2003	29	10	1	1	1	1	1	1	2	1	0	0	1	0	1	0	0
		DAY 36	12AUG2003	36	10	1	1	1	1	1	1	2	1	0	0	0	0	1	0	1
		DAY 43	19AUG2003	43	9	0	1	1	1	2	1	2	1	0	0	0	0	0	0	0
		DAY 50	26AUG2003	50	10	1	1	0	0	1	1	2	1	1	1	0	1	1	0	0
		DAY 57	03SEP2003	58	10	1	2	1	1	0	1	2	1	0	0	0	0	1	1	0
	E0023012	DAY 1	06FEB2003	1	31		3	3	0	3	3	3	2	3	2	2	2	1	2	2
		DAY 8	17FEB2003	12	22	-9	3	2	0	3	3	2	1	2	2	1	3	0	0	0
		DAY 15	20FEB2003	15	22	-9	3	3	0	3	3	2	1	1	2	1	3	0	0	0
		DAY 22	28FEB2003	23	9	-22	1	1	0	1	1	1	1	0	1	1	1	0	0	0
		DAY 29	07MAR2003	30	12	-19	1	1	0	1	2	2	1	1	1	1	1	0	0	0
		DAY 36	14MAR2003	37	17	-14	3	2	0	3	2	3	1	1	0	1	1	0	0	0
		DAY 43	21MAR2003	44	19	-12	3	3	0	3	2	3	2	1	0	1	1	0	0	0
		DAY 50	28MAR2003	51	26	-5	4	3	0	0	3	3	3	0	2	2	1	1	0	4
		DAY 57	04APR2003	58	14	-17	3	3	0	0	4	1	1	0	0	1	1	0	0	0
	E0023016	DAY 1	22MAY2003	1	20		3	3	1	2	2	3	3	1	2	0	0	0	0	0
		DAY 8	29MAY2003	8	16	-4	2	3	1	1	2	3	2	1	1	0	0	0	0	0
		DAY 15	05JUN2003	15	14	-6	2	3	0	0	2	3	1	3	0	0	0	0	0	0
		DAY 22	12JUN2003	22	14	-6	2	3	0	0	2	3	2	1	0	1	0	0	0	0

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Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0023016	DAY 29		19JUN2003	29	14	-6	2	2	1	0	1	3	2	1	0	1	1	0	0	0
		DAY 36		26JUN2003	36	14	-6	2	2	0	0	2	3	2	1	0	1	1	0	0	0
		DAY 43		01JUL2003	41	20	0	3	3	1	0	2	3	2	1	1	2	2	0	0	0
		DAY 50		14JUL2003	54	29	9	3	3	2	3	3	3	3	1	2	1	2	2	1	0
		DAY 57		17JUL2003	57	27	7	3	3	2	3	3	3	3	1	1	1	2	2	0	0
	E0023018	DAY 1		27MAR2003	1	29		4	2	2	4	3	3	2	2	0	2	2	1	0	2
		DAY 8		03APR2003	8	32	3	3	3	3	3	2	1	2	2	2	2	2	2	2	3
		DAY 15		10APR2003	15	15	-14	2	2	1	3	0	1	1	0	1	0	2	1	0	1
		DAY 22		16APR2003	21	22	-7	2	2	1	1	2	3	2	1	2	2	1	1	1	1
		DAY 29		24APR2003	29	17	-12	2	2	1	2	1	2	2	2	0	0	1	1	0	1
		DAY 36		02MAY2003	37	2	-27	1	1	0	0	0	0	0	0	0	0	0	0	0	0
		DAY 43		12MAY2003	47	12	-17	2	3	0	1	1	2	0	0	0	0	1	0	1	1
		DAY 50		15MAY2003	50	9	-20	1	0	0	3	0	1	1	0	1	0	0	1	0	1
		DAY 57		22MAY2003	57	8	-21	1	0	0	1	2	0	0	0	0	0	0	2	1	1
	E0023036	DAY 1		20JUN2003	1	27		3	2	0	3	3	3	2	0	2	2	2	1	2	2
		DAY 8		26JUN2003	7	27	0	4	2	0	3	3	3	2	0	2	1	2	1	2	2
		DAY 15		02JUL2003	13	30	3	4	3	0	4	4	3	2	0	2	1	2	1	2	2
		DAY 22		09JUL2003	20	14	-13	2	1	0	1	2	1	1	0	1	1	1	1	1	1
		DAY 29		16JUL2003	27	14	-13	2	1	0	1	2	2	1	0	1	1	1	1	0	1
		DAY 29	*	22JUL2003	33	16	-11	3	2	0	1	2	2	1	0	1	1	1	1	0	1
		DAY 36		29JUL2003	40	17	-10	2	3	0	2	2	2	1	0	1	1	1	1	0	1
		DAY 43		05AUG2003	47	9	-18	2	2	0	1	2	2	0	0	0	0	0	0	0	0
		DAY 57		13AUG2003	55	10	-17	2	2	0	1	3	2	0	0	0	0	0	0	0	0
	E0023046	DAY 1		23JUL2003	1	21		3	2	2	3	3	3	2	1	0	0	1	0	1	0
		DAY 8		01AUG2003	10	20	-1	3	2	2	3	3	3	2	0	0	0	1	0	1	0
		DAY 15		08AUG2003	17	18	-3	3	2	2	3	2	3	2	0	0	0	1	0	0	0
		DAY 22		14AUG2003	23	14	-7	2	2	2	3	2	2	1	0	0	0	0	0	0	0
		DAY 29		22AUG2003	31	16	-5	2	2	2	3	2	2	1	0	0	0	2	0	0	0

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0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0023046	DAY 36	28AUG2003	37	14	-7	2	2	2	3	3	2	0	0	0	0	0	0	0	0
		DAY 43	04SEP2003	44	15	-6	2	1	2	3	3	2	1	0	0	0	0	0	1	0
		DAY 50	11SEP2003	51	15	-6	2	1	2	3	3	2	1	0	0	0	0	0	1	0
		DAY 57	16SEP2003	56	15	-6	2	1	2	3	3	2	1	0	0	0	0	0	1	0
	E0026006	DAY 1	08JAN2003	1	20		3	1	0	0	1	3	1	1	1	2	3	1	1	2
		DAY 8	15JAN2003	8	9	-11	0	0	0	1	0	0	1	0	1	1	2	0	2	1
		DAY 15	22JAN2003	15	22	2	2	2	0	3	3	3	1	0	1	1	2	2	0	2
		DAY 22	29JAN2003	22	8	-12	1	1	0	0	1	1	0	0	0	0	2	0	0	2
		DAY 29	05FEB2003	29	3	-17	1	1	0	0	0	0	1	0	0	0	0	0	0	0
		DAY 36	12FEB2003	36	2	-18	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		DAY 43	19FEB2003	43	6	-14	1	0	0	0	2	0	0	0	0	0	1	0	0	2
	E0026021	DAY 1	23APR2003	1	37		4	3	4	4	2	3	2	3	2	2	2	3	2	1
		DAY 8	29APR2003	7	28	-9	4	3	4	3	2	2	1	2	0	0	2	3	2	0
	E0026027	DAY 1	19JUN2003	1	31		3	4	2	2	2	2	1	2	3	3	1	1	2	3
	E0029002	*	12NOV2002		19		3	3	2	2	2	3	0	1	0	0	0	1	1	1
	E0029004	DAY 1	19NOV2002	1	25		2	2	2	2	2	3	2	1	1	0	2	2	2	2
		DAY 8	26NOV2002	8	18	-7	2	2	0	3	2	2	2	0	0	0	1	3	1	0
		DAY 15	04DEC2002	16	16	-9	1	1	1	2	1	1	2	0	0	2	2	1	1	1
		DAY 22	12DEC2002	24	13	-12	1	0	0	2	2	1	2	1	0	0	2	2	0	0
		DAY 36	26DEC2002	38	21	-4	2	2	2	3	1	3	2	1	0	0	1	2	1	1
		DAY 43	02JAN2003	45	9	-16	2	2	1	1	0	1	0	1	0	0	0	1	0	0
		DAY 50	09JAN2003	52	9	-16	1	0	0	2	2	0	1	1	0	0	0	2	0	0
		DAY 57	16JAN2003	59	11	-14	2	0	0	2	2	2	0	0	0	0	2	0	1	0
	E0029013	DAY 1	19FEB2003	1	17		3	3	0	3	1	2	0	1	1	0	0	1	1	1
		DAY 8	25FEB2003	7	11	-6	1	1	0	1	1	2	1	1	0	0	1	1	1	0

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0029013	DAY 15		04MAR2003	14	13	-4	1	1	0	3	1	1	0	0	0	0	2	2	1	1
		DAY 22		13MAR2003	23	5	-12	1	0	0	0	1	0	0	1	0	0	1	1	0	0
		DAY 29		20MAR2003	30	13	-4	2	2	0	3	0	1	0	1	0	0	1	2	1	0
		DAY 36		25MAR2003	35	11	-6	1	2	0	2	1	2	1	0	0	0	1	0	0	1
		DAY 43		31MAR2003	41	8	-9	2	0	0	1	0	1	0	1	0	0	1	2	0	0
		DAY 50		10APR2003	51	7	-10	2	1	0	2	0	0	0	0	0	0	1	0	0	1
	E0029019	DAY 1		03MAR2003	1	14		2	1	0	1	2	2	0	0	1	1	1	1	1	1
		DAY 8		10MAR2003	8	7	-7	1	1	0	0	1	1	0	0	0	0	0	1	1	1
		DAY 15		17MAR2003	15	15	1	3	3	0	0	0	3	0	1	0	0	1	2	1	1
	E0029024	DAY 1		17MAR2003	1	20		2	2	0	0	3	2	2	1	1	1	2	0	2	2
		DAY 8		25MAR2003	9	18	-2	2	1	0	0	3	2	2	0	0	1	2	0	2	3
		DAY 15		02APR2003	17	11	-9	2	2	2	0	2	1	0	0	0	0	0	0	1	1
		DAY 22		09APR2003	24	18	-2	2	2	2	0	3	3	1	0	0	0	0	2	1	2
		DAY 29		17APR2003	32	11	-9	2	1	0	2	1	2	1	0	0	0	0	1	0	1
		DAY 36		24APR2003	39	5	-15	3	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 50		05MAY2003	50	6	-14	0	0	0	0	3	2	0	0	0	0	0	0	0	1
		DAY 57	*	12MAY2003	57	7	-13	1	1	0	0	2	1	1	0	0	0	0	0	0	1
		DAY 57		20MAY2003	65	7	-13	2	1	0	1	1	1	0	0	0	0	0	0	0	1
	E0029038	DAY 1		07JUL2003	1	13		1	1	0	2	2	2	1	0	0	0	0	2	0	2
	E0031004	DAY 1		19DEC2002	1	22		2	2	1	2	2	2	2	0	2	1	1	1	1	3
		DAY 8		27DEC2002	9	15	-7	2	1	0	2	2	1	2	0	1	1	1	1	0	1
		DAY 15		03JAN2003	16	12	-10	1	2	0	2	1	1	2	0	1	0	1	0	0	1
		DAY 22		09JAN2003	22	14	-8	1	2	0	2	1	1	2	0	1	1	1	1	0	1
		DAY 29		16JAN2003	29	13	-9	2	1	0	1	1	1	1	0	1	1	1	1	1	1
		DAY 36		23JAN2003	36	11	-11	1	2	0	1	0	1	1	1	0	0	1	1	1	1
		DAY 43		30JAN2003	43	11	-11	1	1	0	1	1	1	0	1	1	1	1	0	1	1
		DAY 50		06FEB2003	50	12	-10	2	1	0	1	1	1	0	1	1	1	1	1	0	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0031004	DAY 57		13FEB2003	57	7	-15	1	1	0	1	0	0	0	1	0	1	0	1	0	1
	E0031013	DAY 1		13MAR2003	1	19		2	1	1	2	2	2	1	1	1	1	2	1	1	1
		DAY 8		20MAR2003	8	21	2	2	2	1	1	2	2	1	2	1	1	1	1	2	2
		DAY 15		27MAR2003	15	17	-2	2	2	0	1	2	1	2	1	1	1	1	1	1	1
		DAY 22		04APR2003	23	21	2	3	2	2	1	1	1	2	1	2	1	1	1	2	1
		DAY 29		11APR2003	30	18	-1	3	2	1	1	2	1	2	1	1	1	1	1	1	0
		DAY 36		17APR2003	36	18	-1	3	1	1	0	2	1	2	1	1	1	1	1	2	1
		DAY 43		24APR2003	43	11	-8	1	1	0	1	0	1	2	0	0	0	1	1	2	1
		DAY 50		01MAY2003	50	15	-4	2	2	0	1	2	1	1	1	0	0	1	1	2	1
		DAY 57		08MAY2003	57	17	-2	2	2	0	1	2	1	1	1	1	0	2	1	2	1
	E0031016	DAY 1		24MAR2003	1	16		2	2	0	2	2	2	0	2	0	0	0	1	2	1
		DAY 8		31MAR2003	8	12	-4	2	1	0	2	2	2	0	0	1	0	1	1	0	0
		DAY 15		07APR2003	15	16	0	2	2	2	2	2	2	1	2	0	0	0	0	0	1
		DAY 22		14APR2003	22	13	-3	1	2	0	2	2	2	0	1	0	0	1	0	1	1
	E0031019	DAY 1		11APR2003	1	14		2	2	0	3	1	2	0	0	0	0	1	2	0	1
		DAY 8		18APR2003	8	17	3	3	2	0	3	1	2	1	1	0	0	1	0	2	1
		DAY 15		25APR2003	15	12	-2	2	2	0	2	0	2	1	0	0	0	0	1	1	1
		DAY 22		02MAY2003	22	9	-5	2	1	0	2	0	2	0	0	0	0	1	0	0	1
		DAY 29		09MAY2003	29	9	-5	1	1	0	2	0	1	1	0	0	0	1	2	0	0
		DAY 29	*	12MAY2003	32	8	-6	1	0	0	2	0	2	0	0	0	0	1	1	0	1
	E0031022	DAY 1		28APR2003	1	23		3	2	1	2	2	2	2	2	0	1	1	2	2	1
		DAY 8		06MAY2003	9	19	-4	2	2	0	1	2	2	2	1	1	1	1	1	2	1
		DAY 15		13MAY2003	16	19	-4	2	2	1	2	1	1	2	1	1	1	1	1	2	1
		DAY 22		20MAY2003	23	20	-3	3	2	1	2	1	2	2	1	1	1	0	1	2	1
		DAY 29		27MAY2003	30	17	-6	2	2	0	2	1	2	1	0	1	1	1	1	2	1
	E0033007	DAY 1		28JAN2003	1	21		3	2	0	3	2	3	2	1	1	0	0	3	0	1

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0033007	DAY 8	04FEB2003	8	18	-3	2	3	0	2	2	3	1	0	2	0	1	2	0	0
		DAY 15	12FEB2003	16	15	-6	1	1	0	2	2	3	0	1	2	0	0	2	0	1
		DAY 22	20FEB2003	24	15	-6	2	1	0	2	2	2	1	0	2	0	1	1	1	0
		DAY 29	25FEB2003	29	18	-3	2	3	0	3	2	3	1	1	2	0	0	1	0	0
		DAY 36	04MAR2003	36	18	-3	2	2	0	3	1	2	0	1	2	1	0	2	1	1
		DAY 43	13MAR2003	45	17	-4	2	2	0	2	1	3	1	0	2	0	2	1	0	1
		DAY 50	18MAR2003	50	17	-4	1	2	0	2	2	2	2	1	1	1	1	1	0	1
		DAY 57	25MAR2003	57	16	-5	2	1	0	2	1	2	1	0	2	2	1	1	0	1
	E0033013	DAY 1	19FEB2003	1	11		1	2	0	1	0	2	0	0	0	1	0	2	2	0
		DAY 8	26FEB2003	8	21	10	1	1	2	2	1	2	2	1	2	2	1	1	2	1
		DAY 15	05MAR2003	15	12	1	2	1	1	3	0	2	1	0	0	0	0	1	1	0
		DAY 22	13MAR2003	23	12	1	2	2	0	2	1	2	0	1	0	0	0	1	1	0
		DAY 29	19MAR2003	29	14	3	1	1	2	2	1	2	1	0	0	0	0	1	1	2
		DAY 36	27MAR2003	37	9	-2	2	1	0	1	0	2	0	0	0	0	0	0	2	1
		DAY 43	01APR2003	42	12	1	3	3	0	1	0	2	0	0	0	0	0	1	1	1
		DAY 50	10APR2003	51	6	-5	2	0	1	0	0	2	0	0	0	0	0	1	0	0
		DAY 57	16APR2003	57	10	-1	1	2	0	1	0	2	0	0	0	0	0	2	1	1
	E0033016	DAY 1	08MAY2003	1	19		2	2	0	2	2	2	1	2	1	0	2	1	1	1
		DAY 8	13MAY2003	6	14	-5	2	1	0	2	2	2	0	1	0	0	1	1	0	2
		DAY 15	20MAY2003	13	14	-5	1	2	0	2	2	2	0	1	0	0	2	1	0	1
		DAY 22	28MAY2003	21	10	-9	1	2	0	0	1	1	0	1	0	0	2	1	0	1
		DAY 29	09JUN2003	33	19	0	2	2	1	1	2	2	1	1	1	1	1	2	1	1
		DAY 43	17JUN2003	41	5	-14	1	0	0	0	2	1	0	0	0	0	0	0	1	0
		DAY 43 *	23JUN2003	47	14	-5	1	1	0	1	2	2	0	2	0	0	2	1	2	0
		DAY 50	27JUN2003	51	3	-16	0	0	0	1	1	0	0	0	0	0	0	1	0	0
		DAY 57	02JUL2003	56	6	-13	1	1	0	1	1	1	0	0	0	0	0	1	0	0
	E0033022	DAY 1	14JUL2003	1	25		3	3	2	2	2	3	2	1	0	1	0	2	3	1
		DAY 8	23JUL2003	10	12	-13	1	2	0	2	1	2	1	0	0	0	1	0	1	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0033022	DAY 15		30JUL2003	17	17	-8	2	3	0	1	1	2	2	1	1	1	0	0	1	2
		DAY 22		06AUG2003	24	14	-11	2	2	0	1	1	2	2	1	0	0	0	1	1	1
		DAY 29		11AUG2003	29	12	-13	2	2	0	1	1	1	1	1	0	0	1	0	1	1
		DAY 36		18AUG2003	36	19	-6	3	2	0	1	1	3	2	2	0	1	0	1	2	1
		DAY 43		26AUG2003	44	16	-9	3	2	0	2	2	1	2	1	0	0	1	0	1	1
		DAY 50		04SEP2003	53	25	0	3	3	0	2	3	3	2	1	1	1	2	2	1	1
		DAY 57		11SEP2003	60	15	-10	3	1	0	1	0	2	2	1	0	1	1	1	1	1
	E0034007	DAY 1		16MAY2003	1	18		3	2	0	2	3	3	2	0	0	0	0	1	1	1
		DAY 8		24MAY2003	9	19	1	3	2	0	2	3	3	2	0	0	1	0	1	1	1
		DAY 15		02JUN2003	18	20	2	3	2	0	3	3	3	2	0	0	1	0	1	1	1
		DAY 22		09JUN2003	25	20	2	3	2	0	3	3	3	2	0	0	1	0	1	1	1
		DAY 29		16JUN2003	32	22	4	3	2	0	3	3	3	2	0	0	1	1	1	1	2
		DAY 36		20JUN2003	36	23	5	3	2	0	3	3	3	3	0	0	1	1	1	1	2
		DAY 43		30JUN2003	46	23	5	3	3	0	3	3	3	3	0	0	1	1	0	1	2
		DAY 50		07JUL2003	53	22	4	3	3	0	3	3	3	3	0	0	0	1	0	1	2
		DAY 57		14JUL2003	60	20	2	2	2	0	3	3	3	3	0	0	0	1	0	1	2
	E0035004	DAY 1		27NOV2002	1	20		2	1	1	3	2	3	1	1	0	2	1	1	1	1
		DAY 8		04DEC2002	8	17	-3	2	1	1	2	2	2	1	1	0	1	1	1	1	1
	E0035009	DAY 1		27DEC2002	1	16		2	2	0	3	1	2	0	0	0	0	1	2	3	0
		DAY 8		31DEC2002	5	16	0	2	2	1	3	2	2	0	0	0	0	0	2	2	0
		DAY 15		08JAN2003	13	6	-10	1	1	1	1	0	1	0	0	0	0	0	1	0	0
		DAY 22		15JAN2003	20	12	-4	2	1	2	1	1	3	0	1	0	0	0	1	0	0
		DAY 29		22JAN2003	27	3	-13	1	0	0	0	1	1	0	0	0	0	0	0	0	0
		DAY 36		29JAN2003	34	6	-10	1	1	1	0	1	1	1	0	0	0	0	0	0	0
		DAY 43		05FEB2003	41	2	-14	0	0	1	0	0	0	1	0	0	0	0	0	0	0
		DAY 43	*	11FEB2003	47	2	-14	0	0	1	0	0	0	1	0	0	0	0	0	0	0
		DAY 57		19FEB2003	55	1	-15	0	0	1	0	0	0	0	0	0	0	0	0	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HAMA100.SAS
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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0035010	DAY 1	10JAN2003	1	26		3	3	0	3	2	3	2	2	0	0	2	4	2	0
		DAY 8	17JAN2003	8	23	-3	3	3	0	0	2	3	2	2	0	0	2	4	2	0
		DAY 15	24JAN2003	15	26	0	3	2	1	1	2	3	3	2	0	2	2	3	2	0
		DAY 22	31JAN2003	22	26	0	3	2	1	1	2	3	3	2	0	2	2	3	2	0
		DAY 29	07FEB2003	29	27	1	3	3	1	1	2	3	3	2	0	1	2	3	2	1
		DAY 36	14FEB2003	36	22	-4	3	2	1	0	2	3	2	2	0	0	2	3	2	0
		DAY 43	24FEB2003	46	19	-7	2	2	1	1	1	1	2	2	0	0	2	3	2	0
		DAY 50	28FEB2003	50	18	-8	2	2	1	1	1	1	2	2	0	0	1	3	2	0
		DAY 57	06MAR2003	56	19	-7	3	2	1	0	2	2	2	2	0	0	0	3	1	1
	E0035022	DAY 1	09MAY2003	1	35		3	3	2	3	3	3	2	2	0	2	3	3	4	2
		DAY 8	15MAY2003	7	36	1	3	3	2	4	3	3	2	2	0	2	3	3	4	2
		DAY 15	23MAY2003	15	28	-7	2	3	2	4	2	2	2	2	0	1	2	2	3	1
		DAY 22	30MAY2003	22	28	-7	2	3	2	3	2	3	2	2	0	1	2	2	3	1
		DAY 29	06JUN2003	29	22	-13	2	3	2	2	1	2	2	2	0	1	1	1	2	1
		DAY 36	13JUN2003	36	17	-18	2	2	1	2	1	2	2	1	0	1	1	1	1	0
		DAY 43	20JUN2003	43	6	-29	1	0	0	0	1	1	0	0	0	0	1	1	1	0
		DAY 50	27JUN2003	50	3	-32	1	0	0	0	0	1	0	0	0	0	0	1	0	0
		DAY 57	07JUL2003	60	3	-32	1	1	0	0	0	1	0	0	0	0	0	0	0	0
	E0039003	DAY 1	25NOV2002	1	11		1	2	0	3	2	3	0	0	0	0	0	0	0	0
		DAY 8	02DEC2002	8	10	-1	2	2	0	1	1	2	1	0	0	0	0	1	0	0
		DAY 15	09DEC2002	15	9	-2	2	2	0	1	1	1	1	0	0	0	0	1	0	0
	E0040001	DAY 1	27JUN2003	1	14		2	1	0	2	1	3	0	0	0	0	0	3	0	2
		DAY 8	03JUL2003	7	14	0	2	1	0	2	1	3	0	0	0	0	0	3	0	2
		DAY 15	11JUL2003	15	14	0	2	1	0	2	1	3	0	0	0	0	0	3	1	1
		DAY 22	18JUL2003	22	11	-3	2	1	0	2	1	2	0	0	0	0	0	2	0	1
		DAY 29	25JUL2003	29	11	-3	2	2	0	1	1	2	0	0	0	0	0	2	0	1
		DAY 36	01AUG2003	36	8	-6	2	1	0	1	1	2	0	0	0	0	0	1	0	0
		DAY 43	08AUG2003	43	10	-4	2	1	0	1	1	2	1	0	0	0	0	1	0	1

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

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Listing 12.2.6.5 Hamilton Rating Scale for Anxiety (HAM-A)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
PLACEBO (BIPOLAR II)	E0040001	DAY 50	15AUG2003	50	8	-6	2	1	0	0	1	1	0	0	0	0	0	2	1	0
		DAY 57	22AUG2003	57	12	-2	2	1	0	1	1	2	0	0	1	0	0	2	1	1
	E0040004	DAY 1	18JUL2003	1	8		1	2	0	1	1	2	0	0	0	0	0	0	0	1
	E0041002	DAY 1	21JAN2003	1	19		2	2	1	2	2	3	1	0	0	0	1	1	2	2
		DAY 8	28JAN2003	8	14	-5	2	2	0	2	2	2	0	0	0	0	1	0	2	1
		DAY 15	04FEB2003	15	15	-4	2	2	0	2	1	2	0	1	0	0	0	2	2	1
		DAY 22	11FEB2003	22	10	-9	2	2	0	2	1	0	0	0	0	0	0	2	0	1
		DAY 29	18FEB2003	29	12	-7	2	2	0	1	1	1	0	1	0	0	1	2	0	1
		DAY 36	25FEB2003	36	11	-8	2	2	0	2	1	1	1	1	0	0	0	0	0	1
	E0041005	DAY 1	05MAR2003	1	13		2	2	1	2	1	2	0	0	0	0	0	2	0	1
		DAY 8	11MAR2003	7	16	3	2	2	1	2	2	2	1	1	0	0	0	0	2	1
		DAY 15	19MAR2003	15	18	5	2	2	0	2	1	2	2	1	0	1	0	2	2	1
		DAY 22	26MAR2003	22	17	4	2	1	0	2	1	3	2	1	0	1	0	2	1	1
		DAY 29	02APR2003	29	15	2	1	0	0	2	0	2	2	1	0	1	1	2	2	1
		DAY 36	09APR2003	36	11	-2	1	1	0	2	0	1	2	1	0	0	0	0	2	1
		DAY 43	16APR2003	43	12	-1	1	1	0	3	0	2	1	0	0	1	1	1	0	1
		DAY 50	23APR2003	50	12	-1	2	2	0	2	1	0	1	0	0	0	2	1	0	1
		DAY 57	30APR2003	57	9	-4	1	1	0	2	1	1	1	0	0	0	0	2	0	0

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Anxious Mood, 2=Tension, 3=Fears, 4=Insomnia, 5=Intellectual, 6=Depressed Mood, 7=Somatic-Muscular, 8=Somatic-Sensory, 9=Cardiovascular symptoms, 10=Respiratory Symptoms, 11=Gastrointestinal Symptoms, 12=Genitourinary Symptoms, 13=Autonomic symptoms, 14=Behavior at Interview.
0=NOT PRESENT, 1=MILD, 2=MODERATE, 3=SEVERE, 4=VERY SEVERE.

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GENERATED: 12JUL2005 17:42:40 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1	04FEB2003	1	8		1	1	1	0	1	3	1
		DAY 29	05MAR2003	30	5	-3	0	0	0	0	1	3	1
		DAY 57	02APR2003	58	5	-3	1	0	1	0	1	0	2
		FINAL	02APR2003	58	5	-3	1	0	1	0	1	0	2
	E0002010	DAY 1	04APR2003	1	14		3	2	0	0	3	3	3
	E0002012	DAY 1	21APR2003	1	10		2	3	1	1	1	0	2
		DAY 29	21MAY2003	31	8	-2	1	1	2	1	1	0	2
		DAY 57	16JUN2003	57	6	-4	1	2	1	0	1	0	1
		FINAL	16JUN2003	57	6	-4	1	2	1	0	1	0	1
	E0002015	DAY 1	04JUN2003	1	6		2	2	0	0	2	0	0
	E0002018	DAY 1	24JUL2003	1	7		1	2	1	0	2	0	1
		DAY 29	01AUG2003	9	4	-3	1	1	0	0	1	0	1
		FINAL	01AUG2003	9	4	-3	1	1	0	0	1	0	1
	E0003004	DAY 1	17DEC2002	1	12		2	3	1	3	1	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1	04FEB2003	1	0:00	20	7:00	6	1	2	1	0	0	0	2	0	1	
		DAY 29	05MAR2003	30	23:00	5	8:00	8	0	1	1	0	0	0	1	0	0	
		DAY 57	02APR2003	58	0:00	15	7:00	7	0	2	1	0	0	0	2	0	0	
		FINAL	02APR2003	58	0:00	15	7:00	7	0	2	1	0	0	0	2	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	DAY 1	04APR2003	1	22:00	30	7:00	8	3	3	3	3	3	3	3	3	3	
QUETIAPINE 300 MG (BIPOLAR I)	E0002012	DAY 1	21APR2003	1	23:30	60	7:00	6	3	2	2	0	1	0	2	0	0	
		DAY 29	21MAY2003	31	1:00	20	7:30	5	1	2	0	2	2	0	0	0	0	
		DAY 57	16JUN2003	57	0:00	20	7:00	6	2	1	0	2	1	0	0	0	1	
		FINAL	16JUN2003	57	0:00	20	7:00	6	2	1	0	2	1	0	0	0	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0002015	DAY 1	04JUN2003	1	0:00	30	11:00	10	3	2	3	0	0	1	3	2	2	
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	DAY 1	24JUL2003	1	22:00	30	6:00	7	2	2	3	0	3	0	0	0	3	
		DAY 29	01AUG2003	9	22:00	20	6:00	8	0	1	3	0	3	0	0	0	1	
		FINAL	01AUG2003	9	22:00	20	6:00	8	0	1	3	0	3	0	0	0	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0003004	DAY 1	17DEC2002	1	23:30	60	10:00	6	3	3	1	0	0	0	1	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1	04FEB2003	1	0	2	0						
		DAY 29	05MAR2003	30	1	1	0						
		DAY 57	02APR2003	58	2	1	0						
		FINAL	02APR2003	58	2	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	DAY 1	04APR2003	1	3	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0002012	DAY 1	21APR2003	1	1	2	1	1	0	1	0		
		DAY 29	21MAY2003	31	1	2	0						
		DAY 57	16JUN2003	57	1	0	3	2	0	2	0		
		FINAL	16JUN2003	57	1	0	3	2	0	2	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0002015	DAY 1	04JUN2003	1	0	0	0	1	0	2	3	3	UNCOMFORTABLE SLEEP
QUETIAPINE 300 MG (BIPOLAR I)	E0002018	DAY 1	24JUL2003	1	0	2	0						
		DAY 29	01AUG2003	9	0	1	0						
		FINAL	01AUG2003	9	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0003004	DAY 1	17DEC2002	1	0	1	1						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	DAY 1	23DEC2002	1	7		1	2	1	1	1	0	1
		DAY 29	21JAN2003	30	7	0	1	2	0	0	1	2	1
		DAY 57	18FEB2003	58	9	2	2	3	0	0	1	2	1
		FINAL	18FEB2003	58	9	2	2	3	0	0	1	2	1
	E0003007	DAY 1	02JAN2003	1	7		1	3	1	0	1	0	1
		DAY 29	30JAN2003	29	6	-1	1	1	1	1	1	0	1
		DAY 57	27FEB2003	57	6	-1	1	2	1	1	1	0	0
		FINAL	27FEB2003	57	6	-1	1	2	1	1	1	0	0
	E0003015	DAY 1	05MAY2003	1	14		2	3	2	2	1	1	3
		DAY 29	04JUN2003	31	7	-7	1	1	2	1	1	0	1
		DAY 57	02JUL2003	59	4	-10	1	0	1	0	1	0	1
		FINAL	02JUL2003	59	4	-10	1	0	1	0	1	0	1
	E0004002	DAY 1	24SEP2002	-7	9		1	2	2	0	1	0	3
		DAY 1 *	24SEP2002	-7	9		1	2	2	0	1	0	3
		DAY 29	29OCT2002	29	1	-8	0	0	0	0	1	0	0
		DAY 57	26NOV2002	57	5	-4	1	1	1	0	1	0	1
		FINAL	26NOV2002	57	5	-4	1	1	1	0	1	0	1
	E0004013	DAY 1	14JAN2003	1	17		2	3	3	3	2	2	2
		DAY 29	05FEB2003	23	6	-11	0	2	0	0	1	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	DAY 1		23DEC2002	1	20:45	30	5:30	7	2	1	1	0	0	0	0	1	0		
		DAY 29		21JAN2003	30	21:45	30	6:30	8	2	0	0	0	0	0	0	1	0		
		DAY 57		18FEB2003	58	22:00	45	7:00	8	3	0	0	0	0	1	0	0	0		
		FINAL		18FEB2003	58	22:00	45	7:00	8	3	0	0	0	0	1	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	DAY 1		02JAN2003	1	0:30	60	7:00	6	3	2	1	0	0	0	2	1	0		
		DAY 29		30JAN2003	29	23:30	20	7:15	6	1	2	0	0	0	0	0	0	0		
		DAY 57		27FEB2003	57	22:45	20	7:15	7	2	1	1	0	0	0	0	0	0		
		FINAL		27FEB2003	57	22:45	20	7:15	7	2	1	1	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	DAY 1		05MAY2003	1	0:00	50	7:00	5	3	3	0	0	0	0	0	3	2		
		DAY 29		04JUN2003	31	0:00	15	6:00	5	1	3	1	0	0	2	0	1	0		
		DAY 57		02JUL2003	59	0:30	15	7:15	7	0	3	0	0	0	1	1	0	0		
		FINAL		02JUL2003	59	0:30	15	7:15	7	0	3	0	0	0	1	1	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	DAY 1		24SEP2002	-7	3:00	30	8:00	5	2	0	0	0	0	0	3	3	0	3	PET (CAT) WAKING UP
		DAY 1	*	24SEP2002	-7	3:00	30	8:00	5	2	0	0	0	0	0	3	3	0	3	CAT IN BED WAKING UP
		DAY 29		29OCT2002	29	23:00	10	7:30	8	0	0	0	0	3	0	0	0	0		
		DAY 57		26NOV2002	57	23:00	10	6:00	7	2	0	0	2	3	1	0	0	0		
		FINAL		26NOV2002	57	23:00	10	6:00	7	2	0	0	2	3	1	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	DAY 1		14JAN2003	1	21:00	150	5:00	4	3	3	3	0	0	0	3	3	0		
		DAY 29		05FEB2003	23	23:00	30	13:00	13	2	3	3	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	DAY 1		23DEC2002	1	0	2	1						
		DAY 29		21JAN2003	30	0	1	1						
		DAY 57		18FEB2003	58	0	2	1						
		FINAL		18FEB2003	58	0	2	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	DAY 1		02JAN2003	1	0	2	1						
		DAY 29		30JAN2003	29	0	1	1						
		DAY 57		27FEB2003	57	0	0	0						
		FINAL		27FEB2003	57	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	DAY 1		05MAY2003	1	3	2	0						
		DAY 29		04JUN2003	31	0	1	0						
		DAY 57		02JUL2003	59	0	1	3	0	0	0	0		
		FINAL		02JUL2003	59	0	1	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	DAY 1		24SEP2002	-7	3	2	3	0	0	3	0		
		DAY 1	*	24SEP2002	-7	3	2	3	0	0	3	0		
		DAY 29		29OCT2002	29	0	0	3						
		DAY 57		26NOV2002	57	1	1	3						
		FINAL		26NOV2002	57	1	1	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	DAY 1		14JAN2003	1	0	3	3						
		DAY 29		05FEB2003	23	3	3	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	FINAL	05FEB2003	23	6	-11	0	2	0	0	1	0	3
	E0004018	DAY 1	19MAR2003	1	9		2	3	1	1	1	0	1
		DAY 29	16APR2003	29	7	-2	2	3	1	1	0	0	0
		DAY 57	13MAY2003	56	4	-5	1	1	0	0	1	0	1
		FINAL	13MAY2003	56	4	-5	1	1	0	0	1	0	1
	E0004021	DAY 1	14MAY2003	1	11		2	2	1	1	2	0	3
		DAY 29	11JUN2003	29	5	-6	1	1	1	0	1	0	1
		DAY 57	09JUL2003	57	4	-7	0	0	2	0	1	0	1
		FINAL	09JUL2003	57	4	-7	0	0	2	0	1	0	1
	E0005002	DAY 29	28OCT2002	26	9		2	3	2	0	1	0	1
		DAY 57	25NOV2002	54	10		1	3	2	2	1	0	1
		FINAL	25NOV2002	54	10		1	3	2	2	1	0	1
	E0005004	DAY 1	24SEP2002	-7	7		2	2	0	0	1	0	2
	E0005013	DAY 1	07NOV2002	1	13		3	0	2	1	3	3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	FINAL	05FEB2003	23	23:00	30	13:00	13	2	3	3	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	DAY 1	19MAR2003	1	23:00	60	6:30	6	3	3	0	0	0	0	0	0	0	
		DAY 29	16APR2003	29	1:00	45	8:30	6	3	0	0	0	0	0	0	0	0	
		DAY 57	13MAY2003	56	22:30	30	8:00	9	0	1	0	0	0	0	0	0	0	
		FINAL	13MAY2003	56	22:30	30	8:00	9	0	1	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	DAY 1	14MAY2003	1	23:00	30	7:00	6	2	3	3	0	0	0	2	2	0	
		DAY 29	11JUN2003	29	23:00	30	7:00	7	0	3	3	0	0	0	0	2	0	
		DAY 57	09JUL2003	57	2:00	10	7:00	5	0	0	1	0	0	0	0	0	0	
		FINAL	09JUL2003	57	2:00	10	7:00	5	0	0	1	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	DAY 29	28OCT2002	26	0:00	60	5:30	5	3	3	3	0	0	0	0	0	3	
		DAY 57	25NOV2002	54	23:00	60	6:00	5	3	3	3	3	0	0	0	0	0	
		FINAL	25NOV2002	54	23:00	60	6:00	5	3	3	3	3	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0005004	DAY 1	24SEP2002	-7	23:30	60	9:15	10	2	3	3	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0005013	DAY 1	07NOV2002	1	22:30	15	5:00	5	0	3	2	1	3	3	1	3	3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	FINAL	05FEB2003	23	3	3	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	DAY 1	19MAR2003	1	0	2	0						
		DAY 29	16APR2003	29	0	0	0						
		DAY 57	13MAY2003	56	0	2	0						
		FINAL	13MAY2003	56	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	DAY 1	14MAY2003	1	2	3	3						
		DAY 29	11JUN2003	29	0	1	3						
		DAY 57	09JUL2003	57	2	0	3						
		FINAL	09JUL2003	57	2	0	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	DAY 29	28OCT2002	26	0	1	0						
		DAY 57	25NOV2002	54	0	1	0						
		FINAL	25NOV2002	54	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0005004	DAY 1	24SEP2002	-7	0	3	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0005013	DAY 1	07NOV2002	1	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	DAY 1	10FEB2003	1	10		2	2	2	1	1	0	2
		DAY 29	13MAR2003	32	6	-4	1	1	1	1	1	0	1
		DAY 57	09APR2003	59	3	-7	1	1	1	0	0	0	0
		FINAL	09APR2003	59	3	-7	1	1	1	0	0	0	0
	E0005027	DAY 1	11MAR2003	1	6		2	0	0	0	2	0	2
		DAY 29	03APR2003	24	5	-1	2	0	0	0	2	0	1
		FINAL	03APR2003	24	5	-1	2	0	0	0	2	0	1
	E0005037	DAY 1	07MAY2003	1	12		2	3	2	3	2	0	0
		DAY 29	05JUN2003	30	6	-6	1	1	1	0	2	0	1
		DAY 57	02JUL2003	57	12	0	1	3	3	2	2	0	1
		FINAL	02JUL2003	57	12	0	1	3	3	2	2	0	1
	E0005042	DAY 1	24JUN2003	1	11		1	2	1	3	1	1	2
		DAY 29	23JUL2003	30	5	-6	0	1	1	1	1	0	1
		DAY 57	18AUG2003	56	4	-7	0	1	0	1	1	0	1
		FINAL	18AUG2003	56	4	-7	0	1	0	1	1	0	1
	E0006005	DAY 1	05DEC2002	1	15		2	3	1	2	2	3	2
		DAY 29	03JAN2003	30	7	-8	1	3	0	0	1	0	2
		DAY 57	30JAN2003	57	7	-8	1	3	0	0	1	0	2
		FINAL	30JAN2003	57	7	-8	1	3	0	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	DAY 1	10FEB2003	1	0:00	30	6:00	5	3	3	1	0	0	1	1	0	3	
		DAY 29	13MAR2003	32	0:00	20	8:00	6	0	0	0	0	0	0	0	0	1	
		DAY 57	09APR2003	59	0:00	20	8:00	7	0	0	0	0	0	0	0	0	0	
		FINAL	09APR2003	59	0:00	20	8:00	7	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	DAY 1	11MAR2003	1	23:00	10	7:00	8	0	0	2	2	3	0	0	2	1	
		DAY 29	03APR2003	24	22:30	10	7:00	8	0	2	3	2	3	0	0	1	0	
		FINAL	03APR2003	24	22:30	10	7:00	8	0	2	3	2	3	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	DAY 1	07MAY2003	1	13:00	90	5:45	5	3	3	2	0	0	0	1	0	2	3 NOT SLEEPY
		DAY 29	05JUN2003	30	23:00	30	5:30	7	0	3	3	0	0	0	2	0	3	
		DAY 57	02JUL2003	57	0:00	45	6:00	4	3	3	3	0	1	0	1	1	3	
		FINAL	02JUL2003	57	0:00	45	6:00	4	3	3	3	0	1	0	1	1	3	
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	DAY 1	24JUN2003	1	13:30	20	8:30	7	2	2	1	0	0	1	1	2	0	
		DAY 29	23JUL2003	30	22:00	30	7:00	7	1	1	1	0	0	0	0	1	0	
		DAY 57	18AUG2003	56	22:30	15	8:30	8	1	0	1	0	1	1	1	2	0	
		FINAL	18AUG2003	56	22:30	15	8:30	8	1	0	1	0	1	1	1	2	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 1	05DEC2002	1	0:30	60	9:00	6	3	3	1	0	0	1	1	2	1	3 MIND RACING
		DAY 29	03JAN2003	30	0:00	75	10:30	9	3	1	1	0	1	2	1	2	0	
		DAY 57	30JAN2003	57	2:00	90	9:30	8	3	1	1	0	0	2	0	1	2	
		FINAL	30JAN2003	57	2:00	90	9:30	8	3	1	1	0	0	2	0	1	2	

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU- SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	DAY 1	10FEB2003	1	1	3	0						
		DAY 29	13MAR2003	32	0	1	0						
		DAY 57	09APR2003	59	0	0	0						
		FINAL	09APR2003	59	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	DAY 1	11MAR2003	1	1	2	3						
		DAY 29	03APR2003	24	0	2	3						
		FINAL	03APR2003	24	0	2	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	DAY 1	07MAY2003	1	0	0	0						
		DAY 29	05JUN2003	30	0	2	0						
		DAY 57	02JUL2003	57	0	2	0						
		FINAL	02JUL2003	57	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	DAY 1	24JUN2003	1	0	3	3						
		DAY 29	23JUL2003	30	1	1	3						
		DAY 57	18AUG2003	56	0	1	3						
		FINAL	18AUG2003	56	0	1	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0006005	DAY 1	05DEC2002	1	0	3	0						
		DAY 29	03JAN2003	30	1	3	0						
		DAY 57	30JAN2003	57	0	3	0						
		FINAL	30JAN2003	57	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0006018	DAY 1	13MAR2003	1	5		0	2	0	0	1	0	2
		DAY 29	24MAR2003	12	7	2	1	2	1	1	1	0	1
		FINAL	24MAR2003	12	7	2	1	2	1	1	1	0	1
	E0007013	DAY 1	13JUN2003	1	11		3	3	1	1	1	0	2
		DAY 29	10JUL2003	28	13	2	3	3	2	3	1	0	1
		DAY 57	07AUG2003	56	6	-5	1	1	1	1	1	0	1
		FINAL	07AUG2003	56	6	-5	1	1	1	1	1	0	1
	E0010004	DAY 1	11DEC2002	1	16		2	3	2	3	2	2	2
		DAY 57	06FEB2003	58	7	-9	1	0	1	3	1	0	1
		FINAL	06FEB2003	58	7	-9	1	0	1	3	1	0	1
	E0010012	DAY 1	07JAN2003	1	17		3	1	3	3	2	3	2
		DAY 29	04FEB2003	29	4	-13	0	0	1	0	2	0	1
		DAY 57	05MAR2003	58	2	-15	0	0	1	0	0	0	1
		FINAL	05MAR2003	58	2	-15	0	0	1	0	0	0	1
	E0010024	DAY 1	05MAY2003	1	15		2	2	1	3	2	3	2
		DAY 29	04JUN2003	31	13	-2	1	1	1	2	2	3	3
		DAY 57	02JUL2003	59	3	-12	0	0	0	0	1	0	2
		FINAL	02JUL2003	59	3	-12	0	0	0	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0006018	DAY 1	13MAR2003	1	22:00	30	6:30	8	2	2	3	2	0	0	1	0	1	
		DAY 29	24MAR2003	12	22:00	30	6:30	7	2	1	3	0	0	0	0	0	0	
		FINAL	24MAR2003	12	22:00	30	6:30	7	2	1	3	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0007013	DAY 1	13JUN2003	1	21:00	60	6:00	7	3	3	3	0	0	0	0	0	0	
		DAY 29	10JUL2003	28	22:00	45	6:00	5	3	3	3	0	0	0	0	3	0	
		DAY 57	07AUG2003	56	22:00	30	7:00	7	0	3	3	0	0	0	0	1	0	
		FINAL	07AUG2003	56	22:00	30	7:00	7	0	3	3	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	DAY 1	11DEC2002	1	2:00	45	10:00	5	3	3	3	3	0	0	3	0	0	
		DAY 57	06FEB2003	58	22:00	10	9:00	7	0	3	3	1	0	0	0	1	0	
		FINAL	06FEB2003	58	22:00	10	9:00	7	0	3	3	1	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	DAY 1	07JAN2003	1	22:00	15	3:45	3	2	3	0	2	0	0	0	3	3	
		DAY 29	04FEB2003	29	21:00	5	3:30	6	0	2	1	0	0	3	0	3	2	3 HEADACHE
		DAY 57	05MAR2003	58	21:00	10	3:30	6	0	0	0	0	0	0	0	0	0	
		FINAL	05MAR2003	58	21:00	10	3:30	6	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	DAY 1	05MAY2003	1	21:00	30	8:00	7	3	3	3	0	0	1	2	0	2	
		DAY 29	04JUN2003	31	19:00	10	4:30	7	1	3	2	1	1	1	1	0	1	
		DAY 57	02JUL2003	59	20:00	10	4:45	8	0	2	2	0	3	0	0	0	2	
		FINAL	02JUL2003	59	20:00	10	4:45	8	0	2	2	0	3	0	0	0	2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0006018	DAY 1	13MAR2003	1	1	3	3	0	0	0	0		
		DAY 29	24MAR2003	12	1	1	2	0	0	0	0		
		FINAL	24MAR2003	12	1	1	2	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0007013	DAY 1	13JUN2003	1	0	3	3	0	0	0	0		
		DAY 29	10JUL2003	28	0	2	3	0	0	0	0		
		DAY 57	07AUG2003	56	0	1	3	0	0	0	0		
		FINAL	07AUG2003	56	0	1	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	DAY 1	11DEC2002	1	0	3	3	0	0	0	0		
		DAY 57	06FEB2003	58	1	1	1	1	0	2	0		
		FINAL	06FEB2003	58	1	1	1	1	0	2	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	DAY 1	07JAN2003	1	0	3	1						
		DAY 29	04FEB2003	29	0	2	0						
		DAY 57	05MAR2003	58	0	1	0						
		FINAL	05MAR2003	58	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	DAY 1	05MAY2003	1	1	2	1						
		DAY 29	04JUN2003	31	3	2	2						
		DAY 57	02JUL2003	59	2	1	0						
		FINAL	02JUL2003	59	2	1	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0010032	DAY 1	10JUL2003	1	10		2	3	1	1	2	0	1
		DAY 29	17JUL2003	8	8	-2	1	2	1	1	1	0	2
		FINAL	17JUL2003	8	8	-2	1	2	1	1	1	0	2
	E0011025	DAY 1	26JUN2003	1	4		1	0	1	0	1	0	1
		DAY 29	22JUL2003	27	3	-1	0	0	0	0	1	0	2
		DAY 57	22AUG2003	58	2	-2	0	0	0	0	1	0	1
		FINAL	22AUG2003	58	2	-2	0	0	0	0	1	0	1
	E0013007	DAY 1	20MAR2003	1	13		2	3	1	3	2	0	2
		DAY 29	07APR2003	19	10	-3	2	3	1	1	1	0	2
		FINAL	07APR2003	19	10	-3	2	3	1	1	1	0	2
	E0013009	DAY 1	02APR2003	1	14		2	3	2	1	2	1	3
		DAY 29	01MAY2003	30	2	-12	0	0	1	0	0	0	1
		DAY 57	29MAY2003	58	5	-9	1	1	1	0	1	0	1
		FINAL	29MAY2003	58	5	-9	1	1	1	0	1	0	1
	E0014006	DAY 1	25MAR2003	1	12		2	3	3	0	2	0	2
		DAY 29	23APR2003	30	10	-2	1	1	3	3	1	0	1
		DAY 57	21MAY2003	58	6	-6	1	2	1	1	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0010032	DAY 1	10JUL2003	1	23:30	40	7:00	6	3	3	3	1	1	0	3	0	1	3	ANXIETY STRESS
		DAY 29	17JUL2003	8	23:00	30	7:30	7	2	2	3	0	0	0	3	1	0		
		FINAL	17JUL2003	8	23:00	30	7:30	7	2	2	3	0	0	0	3	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	DAY 1	26JUN2003	1	0:00	3	6:00	6	0	0	2	0	0	1	1	0	0		
		DAY 29	22JUL2003	27	2:00	2	10:00	8	0	1	0	0	0	1	0	0	0		
		DAY 57	22AUG2003	58	2:30	5	10:00	8	0	1	1	1	0	0	0	0	0		
		FINAL	22AUG2003	58	2:30	5	10:00	8	0	1	1	1	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0013007	DAY 1	20MAR2003	1	23:30	60	10:30	7	3	3	3	0	0	0	0	1	0	3	WAKE UP & WORRY
		DAY 29	07APR2003	19	0:30	45	9:30	7	3	3	1	0	0	0	0	0	0	3	WAKE UP AND WORRY
		FINAL	07APR2003	19	0:30	45	9:30	7	3	3	1	0	0	0	0	0	0	3	WAKE UP AND WORRY
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	DAY 1	02APR2003	1	22:00	60	4:30	5	3	3	3	0	3	1	3	0	0		
		DAY 29	01MAY2003	30	22:00	5	4:30	6	0	0	0	0	0	0	0	0	0		
		DAY 57	29MAY2003	58	21:30	30	4:30	7	1	1	2	1	0	0	1	1	0		
		FINAL	29MAY2003	58	21:30	30	4:30	7	1	1	2	1	0	0	1	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	DAY 1	25MAR2003	1	2:50	120	6:00	4	3	2	1	2	2	2	2	0	2	3	HAVE ANXIETY/PANIC ATTACK
		DAY 29	23APR2003	30	22:30	30	6:30	4	1	0	0	0	0	1	1	0	3		
		DAY 57	21MAY2003	58	21:30	40	6:30	7	1	0	0	1	0	0	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0010032	DAY 1	10JUL2003	1	0	2	3	0	0	0	0	3	TOSSING & TURNING
		DAY 29	17JUL2003	8	1	2	3	0	0	0	1	2	RESTLESS LEG SYNDROME
		FINAL	17JUL2003	8	1	2	3	0	0	0	1	2	RESTLESS LEG SYNDROME
QUETIAPINE 300 MG (BIPOLAR I)	E0011025	DAY 1	26JUN2003	1	0	2	0						
		DAY 29	22JUL2003	27	1	2	0						
		DAY 57	22AUG2003	58	0	1	0						
		FINAL	22AUG2003	58	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0013007	DAY 1	20MAR2003	1	0	3	0						
		DAY 29	07APR2003	19	0	3	0						
		FINAL	07APR2003	19	0	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	DAY 1	02APR2003	1	2	3	3	3	0	0	0		
		DAY 29	01MAY2003	30	0	1	3						
		DAY 57	29MAY2003	58	1	1	3	2	0	0	0		
		FINAL	29MAY2003	58	1	1	3	2	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	DAY 1	25MAR2003	1	1	3	2	1	0	0	0	2	TOSS & TURN AND THROW OFF BLANKETS
		DAY 29	23APR2003	30	0	1	2	1	0	0	0	1	TOSSING/TURNING, MOANING
		DAY 57	21MAY2003	58	0	0	2	0	0	0	0		

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	FINAL	21MAY2003	58	6	-6	1	2	1	1	1	0	0
	E0014010	DAY 1	22APR2003	1	10		1	3	1	0	2	2	1
		DAY 29	21MAY2003	30	3	-7	0	1	0	0	1	0	1
		DAY 57	17JUN2003	57	5	-5	1	2	0	0	1	0	1
		FINAL	17JUN2003	57	5	-5	1	2	0	0	1	0	1
	E0016001	DAY 1	22JAN2003	1	20		3	3	3	3	3	3	2
		DAY 29	19FEB2003	29	3	-17	0	1	0	0	2	0	0
		DAY 57	19MAR2003	57	2	-18	0	1	0	0	1	0	0
		FINAL	19MAR2003	57	2	-18	0	1	0	0	1	0	0
	E0016004	DAY 1	03FEB2003	1	16		3	3	3	3	2	0	2
	E0018001	DAY 1	29OCT2002	1			1	0	0		1	0	1
		DAY 29	27NOV2002	30	2		0	1	0	0	1	0	0
		DAY 57	24DEC2002	57	3		1	1	0	0	1	0	0
		FINAL	24DEC2002	57	3		1	1	0	0	1	0	0
	E0018006	DAY 1	17DEC2002	1	11		3	2	1	0	2	0	3
		DAY 29	14JAN2003	29	5	-6	0	0	0	3	1	0	1
		DAY 57	13FEB2003	59	3	-8	0	0	0	0	1	0	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	FINAL	21MAY2003	58	21:30	40	6:30	7	1	0	0	1	0	0	1	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	DAY 1	22APR2003	1	1:00	120	8:30	7	3	2	1	0	2	0	1	3	2		
		DAY 29	21MAY2003	30	23:30	10	8:30	9	1	0	0	1	0	0	0	0	0		
		DAY 57	17JUN2003	57	0:00	90	9:30	10	0	0	0	0	1	0	2	1	1		
		FINAL	17JUN2003	57	0:00	90	9:30	10	0	0	0	0	1	0	2	1	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	DAY 1	22JAN2003	1	22:00	90	8:00	4	3	3	3	2	3	2	2	3	3		
		DAY 29	19FEB2003	29	21:00	30	5:00	8	1	2	0	0	3	2	0	3	2		
		DAY 57	19MAR2003	57	21:30	10	6:30	9	1	1	2	1	0	0	0	2	0		
		FINAL	19MAR2003	57	21:30	10	6:30	9	1	1	2	1	0	0	0	2	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0016004	DAY 1	03FEB2003	1	22:00	90	6:00	4	3	3	3	1	1	2	2	1	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	DAY 1	29OCT2002	1	22:15	15		13	0	0	3	0	0	1	1	1	1	2	BED PARTNER DISTURBANCE
		DAY 29	27NOV2002	30	22:30	20	8:30	10	1	0	0	0	0	0	0	1	0		
		DAY 57	24DEC2002	57	22:30	30	9:00	10	0	1	1	0	3	1	0	1	1		
		FINAL	24DEC2002	57	22:30	30	9:00	10	0	1	1	0	3	1	0	1	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	DAY 1	17DEC2002	1	20:30	0	3:00	6	3	3	2	0	3	0	0	3	0		
		DAY 29	14JAN2003	29	18:00	15	11:00	11	0	0	1	0	0	0	0	3	0		
		DAY 57	13FEB2003	59	22:30	15	11:00	12	0	0	1	0	0	0	0	2	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0014006	FINAL	21MAY2003	58	0	0	2	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	DAY 1	22APR2003	1	0	2	3	2	1	0	0	2	BAD DREAMS
		DAY 29	21MAY2003	30	0	1	3	1	0	0	0		
		DAY 57	17JUN2003	57	1	1	3	1	0	1	0		
		FINAL	17JUN2003	57	1	1	3	1	0	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	DAY 1	22JAN2003	1	0	3	3	0	3	3	1	3	TOSSING AND TURNING
		DAY 29	19FEB2003	29	0	0	3	1	1	1	1		
		DAY 57	19MAR2003	57	0	0	3	2	2	1	0		
		FINAL	19MAR2003	57	0	0	3	2	2	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0016004	DAY 1	03FEB2003	1	0	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	DAY 1	29OCT2002	1	0	2	3	1	0	1	0		
		DAY 29	27NOV2002	30	0	0	3	3	0	3	0		
		DAY 57	24DEC2002	57	0	0	3	2	0	2	1		
		FINAL	24DEC2002	57	0	0	3	2	0	2	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	DAY 1	17DEC2002	1	3	3	0						
		DAY 29	14JAN2003	29	0	2	0						
		DAY 57	13FEB2003	59	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	FINAL		13FEB2003	59	3	-8	0	0	0	0	1	0	2
	E0019004	DAY 1		07NOV2002	1	17		2	3	3	2	2	3	2
		DAY 29		05DEC2002	29	12	-5	1	3	3	1	2	0	2
		DAY 29	*	19DEC2002	43	13	-4	3	3	3	0	2	0	2
		FINAL		19DEC2002	43	13	-4	3	3	3	0	2	0	2
	E0019011	DAY 1		21NOV2002	1	7		0	3	0	0	2	0	2
		DAY 29		19DEC2002	29	10	3	1	3	0	0	1	3	2
		DAY 57		16JAN2003	57	6	-1	0	1	0	0	2	0	3
		FINAL		16JAN2003	57	6	-1	0	1	0	0	2	0	3
	E0019025	DAY 1		06FEB2003	1	8		3	1	0	0	2	0	2
		DAY 29		06MAR2003	29	2	-6	0	1	0	0	1	0	0
		DAY 57		03APR2003	57	3	-5	1	1	0	0	1	0	0
		FINAL		03APR2003	57	3	-5	1	1	0	0	1	0	0
	E0019026	DAY 1		24FEB2003	1	3		0	0	0	0	0	0	3
	E0019043	DAY 1		03JUN2003	1	14		2	2	1	1	3	3	2
		DAY 29		01JUL2003	29	5	-9	1	0	0	1	2	0	1
		DAY 57		29JUL2003	57	3	-11	1	0	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	FINAL		13FEB2003	59	22:30	15	11:00	12	0	0	1	0	0	0	0	2	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	DAY 1		07NOV2002	1	4:00	120	10:00	4	3	3	3	2	0	0	3	3	1	3	WORRIED & CAN'T SHUT MIND DOWN
		DAY 29		05DEC2002	29	5:00	45	10:00	4	3	3	2	2	1	1	3	3	1		
		DAY 29	*	19DEC2002	43	6:00	60	9:00	3	3	3	3	3	1	0	3	3	1		
		FINAL		19DEC2002	43	6:00	60	9:00	3	3	3	3	3	1	0	3	3	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0019011	DAY 1		21NOV2002	1	2:00	60	11:00	9	3	3	3	0	3	1	0	0	0		
		DAY 29		19DEC2002	29	2:00	45	11:00	10	3	3	3	0	1	0	0	0	1		
		DAY 57		16JAN2003	57	2:00	30	11:00	10	1	1	3	0	3	3	0	1	3		
		FINAL		16JAN2003	57	2:00	30	11:00	10	1	1	3	0	3	3	0	1	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	DAY 1		06FEB2003	1	2:00	10	11:00	9	1	3	3	0	2	1	1	0	1		
		DAY 29		06MAR2003	29	1:00	30	11:00	10	0	2	2	0	0	0	0	3	0		
		DAY 57		03APR2003	57	12:00	30	13:00	12	1	0	3	0	0	0	0	2	0		
		FINAL		03APR2003	57	12:00	30	13:00	12	1	0	3	0	0	0	0	2	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0019026	DAY 1		24FEB2003	1	20:00	2	14:00	16	0	0	0	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	DAY 1		03JUN2003	1	22:30	30	6:00	6	2	3	3	2	2	2	2	3	2		
		DAY 29		01JUL2003	29	23:00	15	9:30	8	0	1	3	2	0	1	1	2	1		
		DAY 57		29JUL2003	57	23:00	10	7:00	8	0	2	3	1	0	0	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	FINAL	13FEB2003	59	0	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	DAY 1	07NOV2002	1	1	2	3	3	1	2	0		
		DAY 29	05DEC2002	29	1	3	3	0	1	1	0		
		DAY 29 *	19DEC2002	43	2	2	3	1	3	3	3		
		FINAL	19DEC2002	43	2	2	3	1	3	3	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0019011	DAY 1	21NOV2002	1	0	3	3	3	0	1	3		
		DAY 29	19DEC2002	29	1	3	2	3	3	3	3		
		DAY 57	16JAN2003	57	2	3	3	3	3	3	2		
		FINAL	16JAN2003	57	2	3	3	3	3	3	2		
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	DAY 1	06FEB2003	1	0	3	3						
		DAY 29	06MAR2003	29	0	0	0						
		DAY 57	03APR2003	57	0	0	0						
		FINAL	03APR2003	57	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0019026	DAY 1	24FEB2003	1	2	3	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	DAY 1	03JUN2003	1	1	3	0						
		DAY 29	01JUL2003	29	0	2	0						
		DAY 57	29JUL2003	57	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	FINAL	29JUL2003	57	3	-11	1	0	0	0	1	0	1
	E0020001	DAY 1	29OCT2002	1			2	2	2	1		0	3
		DAY 29	26NOV2002	29	7		1	1	1	0	2	0	2
		DAY 57	20DEC2002	53			1	3	1	0		0	1
		FINAL	20DEC2002	53			1	3	1	0		0	1
	E0020006	DAY 1	16DEC2002	1			3	3	0	2		3	1
	E0020007	DAY 1	15JAN2003	1	10		2	3	1	0	1	2	1
	E0020011	DAY 1	26FEB2003	1	5		1	2	0	0	0	0	2
		DAY 29	26MAR2003	29	3	-2	0	1	0	0	0	0	2
		DAY 57	23APR2003	57	5	0	0	1	0	1	1	0	2
		FINAL	23APR2003	57	5	0	0	1	0	1	1	0	2
	E0020013	DAY 1	05MAR2003	1	8		2	3	2	0	1	0	0
	E0022008	DAY 1	12NOV2002	1	8		1	2	1	2	1	0	1
		DAY 29	12DEC2002	31	5	-3	1	0	1	1	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	FINAL	29JUL2003	57	23:00	10	7:00	8	0	2	3	1	0	0	1	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	DAY 1	29OCT2002	1	0:00	30	6:00	5	3	3	2	1		3	3	2	3	3	CAN'T STOP THOUGHTS CAN'T STOP CRYING
		DAY 29	26NOV2002	29	0:00	15	7:00	6	2	2	2	0	1	3	2	0	1	2	THINK TOO MUCH
		DAY 57	20DEC2002	53	0:00	45	6:30	6	3	2	2	0		3	2	1	1		
		FINAL	20DEC2002	53	0:00	45	6:30	6	3	2	2	0		3	2	1	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0020006	DAY 1	16DEC2002	1	22:00	240	10:00	8	3	3	2	3		3	3	3	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0020007	DAY 1	15JAN2003	1	1:00	60	6:30	6	3	2	2	0	1	1	0	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	DAY 1	26FEB2003	1	0:00	20	14:00	14	2	0	0	0	0	0	0	0	0		
		DAY 29	26MAR2003	29	0:00	6	14:00	14	1	0	0	0	0	0	0	0	0		
		DAY 57	23APR2003	57	1:00	20	13:00	10	0	0	0	0	0	1	1	0	0		
		FINAL	23APR2003	57	1:00	20	13:00	10	0	0	0	0	0	1	1	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0020013	DAY 1	05MAR2003	1	1:30	45	6:15	5	3	3	1	0	3	0	0	2	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 1	12NOV2002	1	22:00	30	6:30	6	2	0	3	0	0	0	0	0	0		
		DAY 29	12DEC2002	31	22:00	15	7:00	7	0	0	1	0	0	1	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0019043	FINAL	29JUL2003	57	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	DAY 1	29OCT2002	1	2	3	0						
		DAY 29	26NOV2002	29	1	2	0						
		DAY 57	20DEC2002	53	0	2	0						
		FINAL	20DEC2002	53	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0020006	DAY 1	16DEC2002	1	0	2	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0020007	DAY 1	15JAN2003	1	0	2	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	DAY 1	26FEB2003	1	2	2	0						
		DAY 29	26MAR2003	29	3	1	0						
		DAY 57	23APR2003	57	2	1	0						
		FINAL	23APR2003	57	2	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0020013	DAY 1	05MAR2003	1	0	0	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 1	12NOV2002	1	0	1	3	2	2	0	1		
		DAY 29	12DEC2002	31	0	1	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 57	07JAN2003	57			1	1	1		2	0	1
		FINAL	07JAN2003	57			1	1	1		2	0	1
	E0022017	DAY 1	19DEC2002	1	15		2	3	1	2	2	3	2
		DAY 29	17JAN2003	30	5	-10	1	1	0	0	1	1	1
		DAY 57	13FEB2003	57	3	-12	0	1	1	0	1	0	0
		FINAL	13FEB2003	57	3	-12	0	1	1	0	1	0	0
	E0022018	DAY 1	12DEC2002	1	9		1	2	1	0	2	0	3
		DAY 29	09JAN2003	29	10	1	2	2	1	0	2	0	3
		DAY 57	06FEB2003	57	7	-2	1	1	1	0	2	0	2
		FINAL	06FEB2003	57	7	-2	1	1	1	0	2	0	2
	E0022022	DAY 1	30DEC2002	1	18		3	3	3	3	3	0	3
		DAY 29	28JAN2003	30	15	-3	3	1	3	0	3	2	3
		DAY 57	27FEB2003	60	13	-5	3	3	1	0	3	0	3
		FINAL	27FEB2003	60	13	-5	3	3	1	0	3	0	3
	E0022027	DAY 1	06FEB2003	1	10		2	1	1	3	1	0	2
		DAY 29	06MAR2003	29	2	-8	0	0	0	0	1	0	1
		DAY 57	03APR2003	57	1	-9	0	0	0	0	1	0	0
		FINAL	03APR2003	57	1	-9	0	0	0	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 57	07JAN2003	57	10:30	20		7	1	1	1	2	1	2	1	0	2		
		FINAL	07JAN2003	57	10:30	20		7	1	1	1	2	1	2	1	0	2		
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	DAY 1	19DEC2002	1	23:00	120	8:00	6	2	0	1	2	2	3	2	1	2		
		DAY 29	17JAN2003	30	22:00	20	6:00	8	1	0	0	1	1	2	0	0	2		
		DAY 57	13FEB2003	57	23:00	15	6:00	7	1	0	0	0	0	2	0	0	0		
		FINAL	13FEB2003	57	23:00	15	6:00	7	1	0	0	0	0	2	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	DAY 1	12DEC2002	1	0:00	30	7:00	6	2	2	3	1	3	0	1	2	0		
		DAY 29	09JAN2003	29	23:59	30	7:00	6	3	2	3	3	3	0	0	2	0		
		DAY 57	06FEB2003	57	23:59	15	7:00	7	1	2	3	2	3	0	0	0	0		
		FINAL	06FEB2003	57	23:59	15	7:00	7	1	2	3	2	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	DAY 1	30DEC2002	1	22:00	120	7:00	2	3	3	0	2	0	3	3	3	3	3	WEIRD DREAMS
		DAY 29	28JAN2003	30	0:00	20	1:00	1	1	3	3	3	3	0	3	3	3	3	THE MEDS
		DAY 57	27FEB2003	60	0:00	90	6:30	6	3	3	3	3	1	3	3	3	3	3	CANNOT MOVE
		FINAL	27FEB2003	60	0:00	90	6:30	6	3	3	3	3	1	3	3	3	3	3	CANNOT MOVE
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	DAY 1	06FEB2003	1	20:30	20	6:00	6	0	3	3	0	3	0	0	0	0		
		DAY 29	06MAR2003	29	20:30	15	5:35	8	0	0	2	0	2	0	0	0	0		
		DAY 57	03APR2003	57	21:00	15	6:00	8	0	0	1	0	0	0	0	0	0		
		FINAL	03APR2003	57	21:00	15	6:00	8	0	0	1	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 57	07JAN2003	57	0	1	3						
		FINAL	07JAN2003	57	0	1	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	DAY 1	19DEC2002	1	1	3	3	2	2	3	1		
		DAY 29	17JAN2003	30	1	1	3	0	0	1	0		
		DAY 57	13FEB2003	57	0	0	3	0	0	0	0		
		FINAL	13FEB2003	57	0	0	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	DAY 1	12DEC2002	1	3	3	3	2	3	2	0		
		DAY 29	09JAN2003	29	3	3	3	2	3	1	0		
		DAY 57	06FEB2003	57	1	2	3	2	3	0	0		
		FINAL	06FEB2003	57	1	2	3	2	3	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	DAY 1	30DEC2002	1	3	3	3	0	3	3	3	3	SHAKING, RESTLESS
		DAY 29	28JAN2003	30	3	3	3	0	2	3	3	3	TOSSING AND TURNING, CONSTANT MOVING
		DAY 57	27FEB2003	60	3	3	3	1		0	3		
		FINAL	27FEB2003	60	3	3	3	1		0	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	DAY 1	06FEB2003	1	0	3	3						
		DAY 29	06MAR2003	29	0	1	3						
		DAY 57	03APR2003	57	0	0	3						
		FINAL	03APR2003	57	0	0	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0022030	DAY 1	14FEB2003	1	15		3	3	1	0	2	3	3
	E0022031	DAY 1	18FEB2003	1	12		2	3	1	2	2	0	2
		DAY 29	18MAR2003	29	9	-3	1	3	0	1	2	0	2
		DAY 57	15APR2003	57	6	-6	1	2	0	0	1	0	2
		FINAL	15APR2003	57	6	-6	1	2	0	0	1	0	2
	E0022032	DAY 1	18FEB2003	1	14		3	3	1	2	2	0	3
		DAY 29	21MAR2003	32	8	-6	1	1	1	2	1	0	2
		DAY 57	18APR2003	60	5	-9	1	1	0	0	1	0	2
		FINAL	18APR2003	60	5	-9	1	1	0	0	1	0	2
	E0022035	DAY 1	19FEB2003	1	7		1	2	1	0	2	0	1
		DAY 29	26FEB2003	8	5	-2	1	1	0	0	2	0	1
		FINAL	26FEB2003	8	5	-2	1	1	0	0	2	0	1
	E0022036	DAY 1	25FEB2003	1	12		1	2	1	3	2	0	3
		DAY 29	25MAR2003	29	5	-7	1	1	0	1	1	0	1
		DAY 57	22APR2003	57	7	-5	1	1	1	2	1	0	1
		FINAL	22APR2003	57	7	-5	1	1	1	2	1	0	1
	E0022056	DAY 1	17APR2003	1	16		3	3	3	3	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0022030	DAY 1	14FEB2003	1	23:30	45	5:00	7	3	3	3	1	3	2	2	1	1	2	LARGE SOUND
QUETIAPINE 300 MG (BIPOLAR I)	E0022031	DAY 1	18FEB2003	1	23:00	120	8:00	6	3	2	2	1	1	1	1	2	2		
		DAY 29	18MAR2003	29	23:30	90	9:00	8	3	2	1	3	0	2	1	1	3		
		DAY 57	15APR2003	57	1:00	30	10:00	8	2	3	1	1	0	1	0	1	1		
		FINAL	15APR2003	57	1:00	30	10:00	8	2	3	1	1	0	1	0	1	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	DAY 1	18FEB2003	1	23:59	60	9:00	6	3	3	2	0	3	2	2	2	2		
		DAY 29	21MAR2003	32	23:00	30	8:45	7	1	1	1	0	0	2	0	0	1		
		DAY 57	18APR2003	60	0:00	30	8:30	8	1	0	1	0	0	1	0	1	1		
		FINAL	18APR2003	60	0:00	30	8:30	8	1	0	1	0	0	1	0	1	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0022035	DAY 1	19FEB2003	1	0:30	30	7:45	7	2	2	1	2	2	2	2	3	1		
		DAY 29	26FEB2003	8	23:00	15	7:30	8	2	1	1	2	1	2	2	3	2		
		FINAL	26FEB2003	8	23:00	15	7:30	8	2	1	1	2	1	2	2	3	2		
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	DAY 1	25FEB2003	1	11:00	45	8:00	7	2	2	1	3	3	3	3	0	3		
		DAY 29	25MAR2003	29	20:30	30	6:00	8	1	1	0	0	0	0	1	0	1		
		DAY 57	22APR2003	57	23:59	30	10:00	7	1	0	0	0	0	1	1	0	1		
		FINAL	22APR2003	57	23:59	30	10:00	7	1	0	0	0	0	1	1	0	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0022056	DAY 1	17APR2003	1	22:00	120	10:00	4	3	3	2	1	2	0	3	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0022030	DAY 1	14FEB2003	1	3	2	3	3	1	3	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0022031	DAY 1	18FEB2003	1	0	3	0						
		DAY 29	18MAR2003	29	1	3	0						
		DAY 57	15APR2003	57	1	2	0						
		FINAL	15APR2003	57	1	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	DAY 1	18FEB2003	1	2	3	3						
		DAY 29	21MAR2003	32	2	2	3						
		DAY 57	18APR2003	60	1	3	3						
		FINAL	18APR2003	60	1	3	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0022035	DAY 1	19FEB2003	1	0	2	0						
		DAY 29	26FEB2003	8	0	2	0						
		FINAL	26FEB2003	8	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	DAY 1	25FEB2003	1	3	2	1						
		DAY 29	25MAR2003	29	1	1	0						
		DAY 57	22APR2003	57	1	1	0						
		FINAL	22APR2003	57	1	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0022056	DAY 1	17APR2003	1	0	3	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	DAY 1	30APR2003	1	12		2	3	1	2	2	0	2
		DAY 29	28MAY2003	29	4	-8	0	1	0	0	1	0	2
		DAY 57	24JUN2003	56	4	-8	0	1	0	0	1	0	2
		FINAL	24JUN2003	56	4	-8	0	1	0	0	1	0	2
	E0022063	DAY 1	07MAY2003	1	9		1	3	2	0	2	0	1
		DAY 29	04JUN2003	29	4	-5	0	1	1	0	1	0	1
		FINAL	04JUN2003	29	4	-5	0	1	1	0	1	0	1
	E0023008	DAY 1	30JAN2003	1	16		3	3	3	3	2	0	2
		DAY 29	25FEB2003	27	3	-13	0	1	0	0	1	0	1
		DAY 57	24MAR2003	54	4	-12	1	1	0	0	0	0	2
		FINAL	24MAR2003	54	4	-12	1	1	0	0	0	0	2
	E0023013	DAY 1	27FEB2003	1	16		2	2	3	3	2	1	3
		DAY 29	06MAR2003	8	16	0	2	2	3	3	2	1	3
		FINAL	06MAR2003	8	16	0	2	2	3	3	2	1	3
	E0023015	DAY 1	11MAR2003	1	2		0	0	0	0	1	0	1
		DAY 29	08APR2003	29	2	0	0	0	0	0	0	0	2
		DAY 57	06MAY2003	57	2	0	0	0	1	0	1	0	0
		FINAL	06MAY2003	57	2	0	0	0	1	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	DAY 1	30APR2003	1	0:00	60	10:00	7	3	1	1	3	0	1	2	1	1	
		DAY 29	28MAY2003	29	0:00	30	10:00	9	0	2	1	1	0	1	1	0	1	
		DAY 57	24JUN2003	56	22:00	30	6:30	9	1	0	0	1	0	1	1	0	0	
		FINAL	24JUN2003	56	22:00	30	6:30	9	1	0	0	1	0	1	1	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	DAY 1	07MAY2003	1	1:00	60	6:00	5	3	3	3	0	0	0	0	3	2	
		DAY 29	04JUN2003	29	23:00	30	6:00	7	0	0	1	0	0	0	0	2	0	
		FINAL	04JUN2003	29	23:00	30	6:00	7	0	0	1	0	0	0	0	2	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	DAY 1	30JAN2003	1	22:00	70	6:00	3	3	3	3	2	0	2	0	3	2	
		DAY 29	25FEB2003	27	22:00	30	6:00	8	0	0	0	0	0	0	0	1	0	
		DAY 57	24MAR2003	54	21:00	25	6:00	9	1	0	0	0	0	0	0	0	0	
		FINAL	24MAR2003	54	21:00	25	6:00	9	1	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0023013	DAY 1	27FEB2003	1	22:00	20	7:30	4	2	3	3	0	3	3	0	3	3	
		DAY 29	06MAR2003	8	22:00	20	7:30	4	2	3	3	0	3	3	0	3	3	
		FINAL	06MAR2003	8	22:00	20	7:30	4	2	3	3	0	3	3	0	3	3	
QUETIAPINE 300 MG (BIPOLAR I)	E0023015	DAY 1	11MAR2003	1	23:00	10	6:30	8	0	0	0	0	0	0	0	2	0	
		DAY 29	08APR2003	29	23:00	5	7:30	8	0	0	0	0	0	0	0	0	0	
		DAY 57	06MAY2003	57	0:00	5	6:45	6	0	0	0	0	1	1	1	3	0	
		FINAL	06MAY2003	57	0:00	5	6:45	6	0	0	0	0	1	1	1	3	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	DAY 1	30APR2003	1	1	2	1						
		DAY 29	28MAY2003	29	2	2	1						
		DAY 57	24JUN2003	56	2	1	1						
		FINAL	24JUN2003	56	2	1	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	DAY 1	07MAY2003	1	0	2	1						
		DAY 29	04JUN2003	29	0	1	1						
		FINAL	04JUN2003	29	0	1	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	DAY 1	30JAN2003	1	0	3	0						
		DAY 29	25FEB2003	27	0	2	0						
		DAY 57	24MAR2003	54	0	3	0						
		FINAL	24MAR2003	54	0	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0023013	DAY 1	27FEB2003	1	2	3	1	2	0	1	0		
		DAY 29	06MAR2003	8	2	3	1	2	0	1	0		
		FINAL	06MAR2003	8	2	3	1	2	0	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0023015	DAY 1	11MAR2003	1	0	1	3	0	0	0	0		
		DAY 29	08APR2003	29	2	1	3	0	0	0	0		
		DAY 57	06MAY2003	57	0	0	3	1	0	0	0		
		FINAL	06MAY2003	57	0	0	3	1	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	DAY 1	09JUN2003	1	12		2	3	1	2	1	0	3
		DAY 29	07JUL2003	29	15	3	3	3	3	3	1	0	2
		DAY 57	05AUG2003	58	6	-6	1	1	1	0	1	0	2
		FINAL	05AUG2003	58	6	-6	1	1	1	0	1	0	2
	E0023037	DAY 1	18JUN2003	1	14		3	3	2	3	1	0	2
		DAY 29	18JUL2003	31	1	-13	0	0	0	0	1	0	0
		DAY 57	15AUG2003	59	1	-13	0	1	0	0	0	0	0
		FINAL	15AUG2003	59	1	-13	0	1	0	0	0	0	0
	E0023038	DAY 1	30JUN2003	1	6		1	0	1	0	2	0	2
		DAY 29	28JUL2003	29	5	-1	0	0	0	3	1	0	1
		DAY 57	27AUG2003	59	2	-4	0	0	0	0	1	0	1
		FINAL	27AUG2003	59	2	-4	0	0	0	0	1	0	1
	E0023044	DAY 1	16JUL2003	1	14		2	3	1	3	3	0	2
		DAY 29	12AUG2003	28	10	-4	3	0	1	3	1	0	2
		FINAL	12AUG2003	28	10	-4	3	0	1	3	1	0	2
	E0023045	DAY 1	17JUL2003	1	12		2	3	1	2	2	0	2
		DAY 29	14AUG2003	29	10	-2	2	3	0	1	2	0	2
		DAY 57	11SEP2003	57	9	-3	1	3	1	0	2	1	1
		FINAL	11SEP2003	57	9	-3	1	3	1	0	2	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	DAY 1	09JUN2003	1	1:00	90	9:30	6	3	1	0	0	0	0	1	2	0	
		DAY 29	07JUL2003	29	23:30	45	6:00	4	3	3	3	0	0	0	0	0	1	
		DAY 57	05AUG2003	58	23:00	30	6:00	7	1	2	2	0	0	0	0	0	1	
		FINAL	05AUG2003	58	23:00	30	6:00	7	1	2	2	0	0	0	0	0	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0023037	DAY 1	18JUN2003	1	23:00	180	10:30	5	3	1	3	0	1	0	0	0	0	
		DAY 29	18JUL2003	31	23:00	15	7:15	8	0	1	1	0	0	0	0	0	0	
		DAY 57	15AUG2003	59	23:00	25	8:00	8	0	0	0	0	0	0	0	0	0	
		FINAL	15AUG2003	59	23:00	25	8:00	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0023038	DAY 1	30JUN2003	1	2:00	10	8:00	6	0	0	0	3	3	0	0	2	2	
		DAY 29	28JUL2003	29	10:30	5	9:30	11	0	0	0	0	3	0	0	0	0	
		DAY 57	27AUG2003	59	23:00	3	10:00	11	0	0	0	0	0	0	0	1	0	
		FINAL	27AUG2003	59	23:00	3	10:00	11	0	0	0	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0023044	DAY 1	16JUL2003	1	10:00	120	6:50	7	3	3	3	2	3	0	3	3	3	
		DAY 29	12AUG2003	28	9:00	15	7:00	7	0	3	0	0	0	3	0	0	3	
		FINAL	12AUG2003	28	9:00	15	7:00	7	0	3	0	0	0	3	0	0	3	
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	DAY 1	17JUL2003	1	23:00	120	9:00	7	3	3	3	0	0	0	3	2	3	
		DAY 29	14AUG2003	29	23:00	60	9:30	8	3	3	2	2	0	0	3	2	3	
		DAY 57	11SEP2003	57	0:00	60	8:00	7	3	2	2	2	0	0	1	1	2	
		FINAL	11SEP2003	57	0:00	60	8:00	7	3	2	2	2	0	0	1	1	2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0023034	DAY 1	09JUN2003	1	3	2	0						
		DAY 29	07JUL2003	29	1	2	0						
		DAY 57	05AUG2003	58	1	2	0						
		FINAL	05AUG2003	58	1	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0023037	DAY 1	18JUN2003	1	0	3	0						
		DAY 29	18JUL2003	31	0	0	0						
		DAY 57	15AUG2003	59	0	0	0						
		FINAL	15AUG2003	59	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0023038	DAY 1	30JUN2003	1	0	3	0						
		DAY 29	28JUL2003	29	0	2	0						
		DAY 57	27AUG2003	59	0	2	0						
		FINAL	27AUG2003	59	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0023044	DAY 1	16JUL2003	1	0	3	0						
		DAY 29	12AUG2003	28	0	3	0						
		FINAL	12AUG2003	28	0	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	DAY 1	17JUL2003	1	0	3	1	0	0	0	0		
		DAY 29	14AUG2003	29	0	3	1	0	0	0	0		
		DAY 57	11SEP2003	57	0	1	1	0	0	0	0		
		FINAL	11SEP2003	57	0	1	1	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	DAY 1	03APR2003	1	9		2	1	2	1	1	0	2
		DAY 29	01MAY2003	29	3	-6	0	0	1	0	1	0	1
		DAY 57	29MAY2003	57	2	-7	0	0	1	0	0	0	1
		FINAL	29MAY2003	57	2	-7	0	0	1	0	0	0	1
	E0026010	DAY 1	22JAN2003	1	15		3	2	3	3	1	1	2
		DAY 29	30JAN2003	9	13	-2	3	2	3	3	1	0	1
		FINAL	30JAN2003	9	13	-2	3	2	3	3	1	0	1
	E0026017	DAY 1	06MAR2003	1	6		2	1	0	0	1	0	2
		DAY 29	21MAR2003	16	4	-2	1	1	0	0	1	0	1
		FINAL	21MAR2003	16	4	-2	1	1	0	0	1	0	1
	E0026018	DAY 1	20MAR2003	1	11		2	3	2	2	1	0	1
		DAY 29	17APR2003	29	8	-3	1	3	0	3	1	0	0
		DAY 57	15MAY2003	57	6	-5	1	3	0	1	1	0	0
		FINAL	15MAY2003	57	6	-5	1	3	0	1	1	0	0
	E0026025	DAY 1	09MAY2003	1	5		1	0	0	0	1	0	3
		DAY 29	05JUN2003	28	4	-1	1	1	0	0	1	0	1
		DAY 57	03JUL2003	56	6	1	1	1	1	1	1	0	1
		FINAL	03JUL2003	56	6	1	1	1	1	1	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	DAY 1	03APR2003	1	23:00	15	5:30	5	1	2	1	0	0	1	0	0	3	
		DAY 29	01MAY2003	29	23:00	5	5:30	6	0	1	0	0	0	0	0	0	0	
		DAY 57	29MAY2003	57	23:00	5	5:30	6	0	0	0	0	0	0	0	0	0	
		FINAL	29MAY2003	57	23:00	5	5:30	6	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0026010	DAY 1	22JAN2003	1	3:00	20	12:00	3	2	2	2	0	0	2	0	3	0	
		DAY 29	30JAN2003	9	1:00	20	9:00	4	2	3	2	0	0	2	0	2	0	
		FINAL	30JAN2003	9	1:00	20	9:00	4	2	3	2	0	0	2	0	2	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0026017	DAY 1	06MAR2003	1	21:15	25	6:30	8	0	3	2	0	0	3	0	0	0	
		DAY 29	21MAR2003	16	22:00	5	6:30	8	1	2	2	0	0	0	0	0	1	
		FINAL	21MAR2003	16	22:00	5	6:30	8	1	2	2	0	0	0	0	0	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	DAY 1	20MAR2003	1	22:00	60	5:30	5	3	3	1	0	0	2	2	1	0	
		DAY 29	17APR2003	29	22:00	60	11:00	8	3	0	1	0	0	0	2	2	1	
		DAY 57	15MAY2003	57	0:00	60	10:30	8	3	0	1	0	1	0	0	1	1	
		FINAL	15MAY2003	57	0:00	60	10:30	8	3	0	1	0	1	0	0	1	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	DAY 1	09MAY2003	1	20:00	10	8:30	12	0	0	1	0	0	0	0	0	0	
		DAY 29	05JUN2003	28	22:00	15	5:00	10	1	2	2	0	0	0	0	1	0	
		DAY 57	03JUL2003	56	21:00	15	5:00	6	1	1	1	0	0	0	0	0	0	
		FINAL	03JUL2003	56	21:00	15	5:00	6	1	1	1	0	0	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	DAY 1	03APR2003	1	1	3	3	1	0	3	0		
		DAY 29	01MAY2003	29	1	1	3	0	0	0	0		
		DAY 57	29MAY2003	57	0	1	3	0	0	0	0		
		FINAL	29MAY2003	57	0	1	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0026010	DAY 1	22JAN2003	1	1	2	1	1	0	0	0	2	CONSTANT TOSSING & TURNING
		DAY 29	30JAN2003	9	0	1	1	1	0	0	1		
		FINAL	30JAN2003	9	0	1	1	1	0	0	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0026017	DAY 1	06MAR2003	1	0	3	2	0	0	0	1	2	WAKING UP 4 TIMES A NIGHT.
		DAY 29	21MAR2003	16	0	1	0						
		FINAL	21MAR2003	16	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	DAY 1	20MAR2003	1	0	2	3	3	0	3	0	3	MOVE A LOT, WAKE UP A LOT
		DAY 29	17APR2003	29	0	0	3	0	0	2	0		
		DAY 57	15MAY2003	57	0	0	3	0	0	0	1		
		FINAL	15MAY2003	57	0	0	3	0	0	0	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	DAY 1	09MAY2003	1	3	3	0	0	0	0	2		
		DAY 29	05JUN2003	28	0	1	0						
		DAY 57	03JUL2003	56	1	1	0						
		FINAL	03JUL2003	56	1	1	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0026029	DAY 1	09JUL2003	1	16		3	3	3	3	2	0	2
	E0026030	DAY 1	09JUL2003	1	6		1	1	1	0	1	0	2
		DAY 29	04AUG2003	27	3	-3	0	0	0	0	1	0	2
		DAY 57	03SEP2003	57	8	2	1	1	1	0	1	3	1
		FINAL	03SEP2003	57	8	2	1	1	1	0	1	3	1
	E0026031	DAY 1	21JUL2003	1	6		1	1	1	1	1	0	1
		DAY 29	18AUG2003	29	10	4	1	2	1	1	1	3	1
		DAY 57	15SEP2003	57	7	1	1	1	0	0	1	3	1
		FINAL	15SEP2003	57	7	1	1	1	0	0	1	3	1
	E0027003	DAY 1	23JAN2003	-5	14		2	2	2	1	2	3	2
		DAY 29	27FEB2003	31	10	-4	1	2	1	0	2	3	1
		DAY 57	25MAR2003	57	9	-5	1	2	0	0	2	3	1
		FINAL	25MAR2003	57	9	-5	1	2	0	0	2	3	1
	E0028004	DAY 1	27SEP2002	-3	7		1	2	0	0	1	0	3
		DAY 29	09OCT2002	10	10	3	3	3	0	0	1	1	2
		FINAL	09OCT2002	10	10	3	3	3	0	0	1	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0026029	DAY 1	09JUL2003	1	2:00	120	10:30	3	3	3	2	2	1	3	1	2	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	DAY 1	09JUL2003	1	22:00	15	5:00	6	2	2	2	0	0	3	0	2	0		
		DAY 29	04AUG2003	27	22:00	10	7:00	8	0	1	3	0	0	1	0	0	0		
		DAY 57	03SEP2003	57	23:00	20	6:30	7	0	2	1	0	0	0	0	0	0		
		FINAL	03SEP2003	57	23:00	20	6:30	7	0	2	1	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0026031	DAY 1	21JUL2003	1	23:00	30	7:30	7	1	3	1	0	0	0	0	0	3		
		DAY 29	18AUG2003	29	23:00	30	7:30	7	2	3	2	0	0	0	0	0	3		
		DAY 57	15SEP2003	57	23:00	20	7:30	8	0	2	2	0	0	0	0	1	3		
		FINAL	15SEP2003	57	23:00	20	7:30	8	0	2	2	0	0	0	0	1	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0027003	DAY 1	23JAN2003	-5	23:00	30	5:00	5	3	3	2	0	3	2	3	3	2		
		DAY 29	27FEB2003	31	20:00	20	4:00	7	2	2	3	0	2	0	0	1	1	2	ITCHING OR CAN'T GET FEET COMFORTABLE
		DAY 57	25MAR2003	57	20:00	30	5:00	8	2	3	3	0	0	0	0	2	2		
		FINAL	25MAR2003	57	20:00	30	5:00	8	2	3	3	0	0	0	0	2	2		
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	DAY 1	27SEP2002	-3	21:00	30	6:30	9	3	0	1	0	0	0	0	0	0		
		DAY 29	09OCT2002	10	21:00	60	7:00	9	3	0	0	0	0	0	2	0	0		
		FINAL	09OCT2002	10	21:00	60	7:00	9	3	0	0	0	0	0	2	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0026029	DAY 1	09JUL2003	1	1	3	2	0	1	3	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	DAY 1	09JUL2003	1	2	2	0						
		DAY 29	04AUG2003	27	2	1	0						
		DAY 57	03SEP2003	57	1	1	3	1	2	0	0		
		FINAL	03SEP2003	57	1	1	3	1	2	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0026031	DAY 1	21JUL2003	1	0	1	1	0	0	0	0	2	HIP PAIN MAKES ME MOVE AROUND - SOMETIMES EVEN WAKES ME UP.
		DAY 29	18AUG2003	29	0	1	0						
		DAY 57	15SEP2003	57	0	2	0						
		FINAL	15SEP2003	57	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0027003	DAY 1	23JAN2003	-5	0	3	0						
		DAY 29	27FEB2003	31	0	2	0						
		DAY 57	25MAR2003	57	0	2	0						
		FINAL	25MAR2003	57	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	DAY 1	27SEP2002	-3	2	3	3	0	0	0	0		
		DAY 29	09OCT2002	10	1	3	3	0	0	0	0		
		FINAL	09OCT2002	10	1	3	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	DAY 1		01OCT2002	-3			2		1	1	2	3	2
		DAY 1	*	01OCT2002	-3			2		1	1	2	3	2
		DAY 29		31OCT2002	28	7		1	1	0	0	2	1	2
		DAY 57		04DEC2002	62	7		1	2	0	1	1	0	2
		FINAL		04DEC2002	62	7		1	2	0	1	1	0	2
	E0028008	DAY 1		08OCT2002	-7	11		1	3	1	1	2	0	3
		DAY 1	*	08OCT2002	-7	11		1	3	1	1	2	0	3
		DAY 29		14NOV2002	31	13	2	1	2	0	2	2	3	3
		DAY 57		10DEC2002	57	18	7	3	3	3	3	3	0	3
		FINAL		10DEC2002	57	18	7	3	3	3	3	3	0	3
	E0028009	DAY 1		10OCT2002	-5	6		2	2	0	0	1	0	1
		DAY 29		14NOV2002	31	4	-2	1	1	0	0	1	0	1
		DAY 57		12DEC2002	59	3	-3	1	1	0	0	1	0	0
		FINAL		12DEC2002	59	3	-3	1	1	0	0	1	0	0
	E0028016	DAY 1		14NOV2002	1	12		2	2	1	0	2	3	2
		DAY 29		12DEC2002	29	6	-6	1	1	0	0	2	0	2
		DAY 57		09JAN2003	57	5	-7	1	1	0	0	1	0	2
		FINAL		09JAN2003	57	5	-7	1	1	0	0	1	0	2
	E0028017			19NOV2002		18		3	2	2	3	2	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	DAY 1		01OCT2002	-3	23:00		6:45	6	3	2	3	0	0	0	2	1	2		
		DAY 1	*	01OCT2002	-3	23:00		6:45	6	3	2	3	0	0	0	2	1	2		
		DAY 29		31OCT2002	28	22:30	30	7:30	8	1	2	1	0	2	2	0	2	2		
		DAY 57		04DEC2002	62	20:00	30	6:30	8	2	1	1	0	0	2	1	1	0		
		FINAL		04DEC2002	62	20:00	30	6:30	8	2	1	1	0	0	2	1	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	DAY 1		08OCT2002	-7	22:00	120	5:30	6	3	2	3	3	2	2	2	0	2		
		DAY 1	*	08OCT2002	-7	22:00	120	5:30	6	3	2	3	3	2	2	2	0	2		
		DAY 29		14NOV2002	31	19:00	0	6:30	8	3	0	2	3	2	0	2	0	1		
		DAY 57		10DEC2002	57	21:00	180	6:00	4	3	3	3	3	2	2	2	2	3	3	OUTDOOR NOISE
		FINAL		10DEC2002	57	21:00	180	6:00	4	3	3	3	3	2	2	2	2	3	3	OUTDOOR NOISE
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	DAY 1		10OCT2002	-5	2:00	3	11:00	8	3	0	0	1	3	0	0	0	2		
		DAY 29		14NOV2002	31	0:00	30	9:00	9	1	0	1	0	0	0	0	0	0		
		DAY 57		12DEC2002	59	23:00	15	8:00	9	1	0	1	0	0	0	0	0	0		
		FINAL		12DEC2002	59	23:00	15	8:00	9	1	0	1	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	DAY 1		14NOV2002	1	0:00	100	7:30	7	0	3	3	0	3	1	3	3	0		
		DAY 29		12DEC2002	29	22:00	20	7:20	9	1	2	3	0	2	1	1	2	0		
		DAY 57		09JAN2003	57	23:00	15	7:30	8	1	1	3	0	0	0	1	2	0	2	SKIN CRAWLING
		FINAL		09JAN2003	57	23:00	15	7:30	8	1	1	3	0	0	0	1	2	0	2	SKIN CRAWLING
QUETIAPINE 300 MG (BIPOLAR I)	E0028017			19NOV2002		21:00	30	6:00	5	3	2	3	0	2	2	2	3	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	DAY 1		01OCT2002	-3	0	3	3	0	0	0	0	3	TOSSING
		DAY 1	*	01OCT2002	-3	0	3	3	0	0	0	0	3	TOSSING
		DAY 29		31OCT2002	28	1	2	3	2	0	1	0		
		DAY 57		04DEC2002	62	0	3	3	1	0	0	0		
		FINAL		04DEC2002	62	0	3	3	1	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	DAY 1		08OCT2002	-7	3	3	0						
		DAY 1	*	08OCT2002	-7	3	3	0						
		DAY 29		14NOV2002	31	3	2	0						
		DAY 57		10DEC2002	57	3	2	0						
		FINAL		10DEC2002	57	3	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0028009	DAY 1		10OCT2002	-5	0	2	1						
		DAY 29		14NOV2002	31	1	0	1						
		DAY 57		12DEC2002	59	0	0	1						
		FINAL		12DEC2002	59	0	0	1						
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	DAY 1		14NOV2002	1	1	3	3	3	0	3	3	2	TALKING
		DAY 29		12DEC2002	29	2	2	3	3	2	3	2		
		DAY 57		09JAN2003	57	1	2	3	0	0	2	3	2	FORMACATION
		FINAL		09JAN2003	57	1	2	3	0	0	2	3	2	FORMACATION
QUETIAPINE 300 MG (BIPOLAR I)	E0028017			19NOV2002		2	3	3	1	1	2	3	3	SHAKING IN SLEEP

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	DAY 1	21JAN2003	1	19		3	2	3	3	3	3	2
		DAY 29	20FEB2003	31	5	-14	1	1	0	0	1	0	2
		FINAL	20FEB2003	31	5	-14	1	1	0	0	1	0	2
	E0028029	DAY 1	04FEB2003	1	10		2	3	1	1	1	0	2
		DAY 29	06MAR2003	31	6	-4	1	1	0	1	1	0	2
		DAY 57	03APR2003	59	3	-7	0	2	0	0	1	0	0
		FINAL	03APR2003	59	3	-7	0	2	0	0	1	0	0
	E0028034	DAY 1	01APR2003	1			2	2	1	3		0	2
		DAY 29	01MAY2003	31	8		1	3	0	0	2	0	2
		DAY 57	02JUN2003	63			1	3	0	0		0	1
		FINAL	02JUN2003	63			1	3	0	0		0	1
	E0028038	DAY 1	25APR2003	1	15		2	3	1	2	2	3	2
		DAY 29	22MAY2003	28	7	-8	1	2	0	0	2	0	2
		DAY 57	18JUN2003	55	9	-6	1	3	0	1	1	0	3
		FINAL	18JUN2003	55	9	-6	1	3	0	1	1	0	3
	E0028043	DAY 1	05JUN2003	1	10		1	3	1	1	2	0	2
		DAY 29	01JUL2003	27	9	-1	1	3	1	2	1	0	1
		DAY 57	29JUL2003	55	8	-2	1	3	1	1	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	DAY 1	21JAN2003	1	22:00	30	6:00	4	3	3	3	3	3	3	3	3	1		
		DAY 29	20FEB2003	31	22:00	20	7:00	8	0	0	3	0	0	0	0	0	0		
		FINAL	20FEB2003	31	22:00	20	7:00	8	0	0	3	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	DAY 1	04FEB2003	1	23:00	45	7:00	6	3	3	0	0	3	1	1	1	0		
		DAY 29	06MAR2003	31	20:00	20	8:00	10	0	1	0	2	0	0	0	0	0		
		DAY 57	03APR2003	59	20:00	20	8:00	12	2	1	0	0	0	0	0	0	0		
		FINAL	03APR2003	59	20:00	20	8:00	12	2	1	0	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	DAY 1	01APR2003	1	19:45	55	5:00	6	2	3	3	2		0	3	3	2	3	JUST STRESSED ABOUT LIFE, WORK AND SOCIETY
		DAY 29	01MAY2003	31	22:30	45	8:00	9	3	2	3	0	1	2	2	1	0	2	DRY MOUTH MEDICINE: ANXIETY FEELING
		DAY 57	02JUN2003	63	23:00	40	9:00	10	3	2	1	0		1	2	1	1	1	OUTSIDE NOISES
		FINAL	02JUN2003	63	23:00	40	9:00	10	3	2	1	0		1	2	1	1	1	OUTSIDE NOISES
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	DAY 1	25APR2003	1	22:00	90	8:00	7	3	3	3	1	0	1	0	2	2		
		DAY 29	22MAY2003	28	21:30	30	9:00	10	2	2	3	3	3	0	0	1	3		
		DAY 57	18JUN2003	55	19:00	60	8:00	10	3	3	3	0	0	0	0	1	0		
		FINAL	18JUN2003	55	19:00	60	8:00	10	3	3	3	0	0	0	0	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	DAY 1	05JUN2003	1	23:00	120	7:00	6	3	2	1	0	3	0	2	1	3		
		DAY 29	01JUL2003	27	23:00	180	7:30	6	3	1	0	0	0	0	0	0	0		
		DAY 57	29JUL2003	55	23:00	120	7:00	6	3	1	0	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	DAY 1	21JAN2003	1	1	3	0						
		DAY 29	20FEB2003	31	1	3	0						
		FINAL	20FEB2003	31	1	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	DAY 1	04FEB2003	1	1	3	0						
		DAY 29	06MAR2003	31	1	2	0						
		DAY 57	03APR2003	59	0	0	0						
		FINAL	03APR2003	59	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	DAY 1	01APR2003	1	1	2	0						
		DAY 29	01MAY2003	31	2	1	0						
		DAY 57	02JUN2003	63	1	1	0						
		FINAL	02JUN2003	63	1	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	DAY 1	25APR2003	1	1	3	0						
		DAY 29	22MAY2003	28	1	3	0						
		DAY 57	18JUN2003	55	2	3	0						
		FINAL	18JUN2003	55	2	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	DAY 1	05JUN2003	1	0	3	0						
		DAY 29	01JUL2003	27	0	1	1	3	2	1	1		
		DAY 57	29JUL2003	55	1	1	1	1	1	2	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	FINAL	29JUL2003	55	8	-2	1	3	1	1	1	0	1
	E0028045	DAY 1	18JUN2003	1	18		3	2	3	2	2	3	3
	E0029005	DAY 1	27NOV2002	1	11		2	2	1	3	2	0	1
		DAY 29	23DEC2002	27	10	-1	1	3	0	1	2	2	1
		DAY 57	21JAN2003	56	8	-3	1	1	1	3	2	0	0
		FINAL	21JAN2003	56	8	-3	1	1	1	3	2	0	0
	E0030001	DAY 1	19NOV2002	1	10		2	1	1	1	3	1	1
		DAY 29	17DEC2002	29	3	-7	0	0	0	0	2	0	1
		DAY 57	16JAN2003	59	5	-5	1	1	0	0	2	0	1
		FINAL	16JAN2003	59	5	-5	1	1	0	0	2	0	1
	E0030008	DAY 1	14JAN2003	1	10		1	3	2	1	2	0	1
		DAY 29	14FEB2003	32	8	-2	1	3	1	1	1	0	1
		DAY 57	18MAR2003	64	10	0	1	3	1	2	2	0	1
		FINAL	18MAR2003	64	10	0	1	3	1	2	2	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	FINAL	29JUL2003	55	23:00	120	7:00	6	3	1	0	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0028045	DAY 1	18JUN2003	1	23:00	10	5:00	4	3	3	3	2	0	0	1	0	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	DAY 1	27NOV2002	1	1:00	75	11:00	6	0	3	1	2	1	2	2	0	2		
		DAY 29	23DEC2002	27	0:00	60	10:00	8	3	2	2	3	2	1	2	1	2	2	COLD
		DAY 57	21JAN2003	56	1:15	30	11:00	6	0	2	2	3	2	1	1	0	0		
		FINAL	21JAN2003	56	1:15	30	11:00	6	0	2	2	3	2	1	1	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	DAY 1	19NOV2002	1	22:00	20	7:00	7	0	3	2	0	3	3	3	3	3		
		DAY 29	17DEC2002	29	22:00	5	8:00	10	0	3	2	0	0	2	1	2	1	2	NUMBNESS AT END OF FINGERS
		DAY 57	16JAN2003	59	22:00	20	11:00	13	0	3	3	0	3	0	0	2	3		
		FINAL	16JAN2003	59	22:00	20	11:00	13	0	3	3	0	3	0	0	2	3		
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	DAY 1	14JAN2003	1	23:00	90	5:30	5	3	3	3	0	0	2	0	0	3		
		DAY 29	14FEB2003	32	23:30	90	7:00	6	3	2	3	0	0	1	0	0	0		
		DAY 57	18MAR2003	64	23:00	90	7:45	6	3	3	3	0	0	2	0	0	1	3	CRAMPS OR TWICHING IN LOWER LEGS
		FINAL	18MAR2003	64	23:00	90	7:45	6	3	3	3	0	0	2	0	0	1	3	CRAMPS OR TWICHING IN LOWER LEGS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	FINAL	29JUL2003	55	1	1	1	1	1	2	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0028045	DAY 1	18JUN2003	1	3	3	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	DAY 1	27NOV2002	1	0	1	3	2	1	0	0		
		DAY 29	23DEC2002	27	0	2	3	2	3	0	1	2	COMMON COLD
		DAY 57	21JAN2003	56	0	0	3	2	3	1	2		
		FINAL	21JAN2003	56	0	0	3	2	3	1	2		
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	DAY 1	19NOV2002	1	0	1	0						
		DAY 29	17DEC2002	29	0	2	0						
		DAY 57	16JAN2003	59	0	1	0						
		FINAL	16JAN2003	59	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	DAY 1	14JAN2003	1	0	2	0	0	0	2	0		
		DAY 29	14FEB2003	32	0	2	0	0	0	0	0		
		DAY 57	18MAR2003	64	0	2	0	0	0	2	0	2	TOSS AND TURN TO GET COMFORTABLE
		FINAL	18MAR2003	64	0	2	0	0	0	2	0	2	TOSS AND TURN TO GET COMFORTABLE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	DAY 1	27JAN2003	1	13		3	3	3	0	2	0	2
		DAY 29	24FEB2003	29	1	-12	0	0	0	0	1	0	0
		DAY 57	24MAR2003	57	1	-12	0	0	0	0	1	0	0
		FINAL	24MAR2003	57	1	-12	0	0	0	0	1	0	0
	E0030015	DAY 1	21FEB2003	1	9		2	2	1	1	1	0	2
		DAY 29	26MAR2003	34	5	-4	2	1	0	0	1	0	1
		DAY 57	22APR2003	61	2	-7	0	0	0	0	1	0	1
		FINAL	22APR2003	61	2	-7	0	0	0	0	1	0	1
	E0030022	DAY 1	16JUN2003	1	9		2	1	1	2	1	0	2
		DAY 29	14JUL2003	29	4	-5	1	1	0	0	1	0	1
		DAY 57	14AUG2003	60	4	-5	1	1	0	0	1	0	1
		FINAL	14AUG2003	60	4	-5	1	1	0	0	1	0	1
	E0031002	DAY 1	27NOV2002	1	13		2	3	3	0	1	1	3
		DAY 29	27DEC2002	31	6	-7	1	1	0	0	2	0	2
		DAY 57	22JAN2003	57	6	-7	1	1	1	0	1	1	1
		FINAL	22JAN2003	57	6	-7	1	1	1	0	1	1	1
	E0031003	DAY 1	10DEC2002	1	14		2	2	2	3	1	3	1
		DAY 29	07JAN2003	29	5	-9	1	1	1	0	1	0	1
		DAY 57	04FEB2003	57	5	-9	1	1	1	0	1	0	1
		FINAL	04FEB2003	57	5	-9	1	1	1	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	DAY 1	27JAN2003	1	2:00	120	5:00	4	3	3	2	0	3	0	0	2	0	
		DAY 29	24FEB2003	29	22:00	10	11:00	12	0	1	0	0	0	0	0	1	0	
		DAY 57	24MAR2003	57	23:00	10	10:00	11	0	0	0	0	0	0	0	1	0	
		FINAL	24MAR2003	57	23:00	10	10:00	11	0	0	0	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	DAY 1	21FEB2003	1	2:30	20	11:00	7	2	2	0	0	0	0	0	0	0	
		DAY 29	26MAR2003	34	2:00	15	14:00	11	1	2	0	0	0	0	0	1	0	
		DAY 57	22APR2003	61	2:00	12	12:30	9	0	0	0	0	0	0	0	2	0	
		FINAL	22APR2003	61	2:00	12	12:30	9	0	0	0	0	0	0	0	2	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	DAY 1	16JUN2003	1	23:00	20	7:30	6	1	3	2	0	2	0	0	2	0	
		DAY 29	14JUL2003	29	23:00	20	7:00	9	1	1	1	0	3	0	0	2	0	
		DAY 57	14AUG2003	60	22:00	20	7:15	11	0	1	1	0	1	0	0	1	0	
		FINAL	14AUG2003	60	22:00	20	7:15	11	0	1	1	0	1	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	DAY 1	27NOV2002	1	3:30	45	8:00	4	3	2	2	1	0	1	1	2	0	
		DAY 29	27DEC2002	31	0:00	15	8:00	8	1	2	1	0	0	3	3	1	1	
		DAY 57	22JAN2003	57	2:00	15	8:30	6	1	2	0	0	0	2	2	2	0	
		FINAL	22JAN2003	57	2:00	15	8:30	6	1	2	0	0	0	2	2	2	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	DAY 1	10DEC2002	1	1:00	35	12:00	5	1	2	2	1	0	1	0	1	0	
		DAY 29	07JAN2003	29	3:00	30	10:00	6	1	1	0	2	0	2	0	1	0	
		DAY 57	04FEB2003	57	23:00	15	6:00	7	1	2	1	0	0	1	1	1	0	
		FINAL	04FEB2003	57	23:00	15	6:00	7	1	2	1	0	0	1	1	1	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	DAY 1	27JAN2003	1	0	3	0						
		DAY 29	24FEB2003	29	0	0	0						
		DAY 57	24MAR2003	57	0	0	0						
		FINAL	24MAR2003	57	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	DAY 1	21FEB2003	1	2	2	2	0	0	0	0		
		DAY 29	26MAR2003	34	0	1	2	0	0	0	0		
		DAY 57	22APR2003	61	1	1	0						
		FINAL	22APR2003	61	1	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	DAY 1	16JUN2003	1	0	3	0						
		DAY 29	14JUL2003	29	0	1	1	3	0	2	0		
		DAY 57	14AUG2003	60	0	2	0						
		FINAL	14AUG2003	60	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	DAY 1	27NOV2002	1	3	3	2	0	0	3	0		
		DAY 29	27DEC2002	31	2	2	3						
		DAY 57	22JAN2003	57	0	2	0						
		FINAL	22JAN2003	57	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	DAY 1	10DEC2002	1	0	2	2						
		DAY 29	07JAN2003	29	0	1	2						
		DAY 57	04FEB2003	57	0	1	2	0	0	0	1		
		FINAL	04FEB2003	57	0	1	2	0	0	0	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	DAY 1	10APR2003	1	7		1	2	1	0	1	0	2
		DAY 29	06MAY2003	27	6	-1	2	1	0	0	1	0	2
		DAY 57	04JUN2003	56	5	-2	1	1	0	0	1	0	2
		FINAL	04JUN2003	56	5	-2	1	1	0	0	1	0	2
	E0034002	DAY 1	25MAR2003	1	17		3	3	1	2	3	3	2
		DAY 29	16APR2003	23	9	-8	1	1	0	1	2	1	3
		FINAL	16APR2003	23	9	-8	1	1	0	1	2	1	3
	E0034003	DAY 1	24APR2003	1	12		2	3	2	0	2	0	3
		DAY 29	22MAY2003	29	3	-9	0	0	0	0	1	0	2
		DAY 57	19JUN2003	57	3	-9	1	0	0	0	1	0	1
		FINAL	19JUN2003	57	3	-9	1	0	0	0	1	0	1
	E0034006	DAY 1	16MAY2003	1	13		2	3	2	2	2	0	2
		DAY 29	13JUN2003	29	15	2	2	2	2	3	3	0	3
		DAY 57	10JUL2003	56	17	4	3	3	3	3	2	0	3
		FINAL	10JUL2003	56	17	4	3	3	3	3	2	0	3
	E0034008	DAY 1	23MAY2003	-1	13		3	3	3	1	2	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	DAY 1	10APR2003	1	0:30	30	8:00	7	3	1	2	0	1	0	0	3	0	2 RESTLESSNESS
		DAY 29	06MAY2003	27	22:00	10	8:30	11	1	1	1	0	0	0	0	2	0	
		DAY 57	04JUN2003	56	23:30	10	8:45	9	1	1	0	0	0	0	0	1	0	
		FINAL	04JUN2003	56	23:30	10	8:45	9	1	1	0	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0034002	DAY 1	25MAR2003	1	23:00	75	8:00	6	3	3	3	1	2	3	0	3	3	3 TOO COLD
		DAY 29	16APR2003	23	21:00	15	7:00	8	1	3	3	3	3	0	0	0	3	
		FINAL	16APR2003	23	21:00	15	7:00	8	1	3	3	3	3	0	0	0	3	
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	DAY 1	24APR2003	1	0:00	35	5:00	5	3	3	3	1	2	0	0	2	2	
		DAY 29	22MAY2003	29	23:30	10	7:00	8	0	0	2	0	0	0	0	0	0	
		DAY 57	19JUN2003	57	23:30	10	7:30	8	0	0	2	2	0	0	0	0	0	
		FINAL	19JUN2003	57	23:30	10	7:30	8	0	0	2	2	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	DAY 1	16MAY2003	1	0:00	45	7:30	5	3	3	3	2	3	0	0	1	2	
		DAY 29	13JUN2003	29	23:30	30	21:00	5	3	3	3	3	3	1	3	2	2	
		DAY 57	10JUL2003	56	0:30	45	8:30	4	3	3	3	2	3	1	2	2	1	
		FINAL	10JUL2003	56	0:30	45	8:30	4	3	3	3	2	3	1	2	2	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 1	23MAY2003	-1	1:00	60	6:00	4	3	3	2	0	0	0	3	2	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	DAY 1	10APR2003	1	1	3	0						
		DAY 29	06MAY2003	27	2	2	0						
		DAY 57	04JUN2003	56	1	2	0						
		FINAL	04JUN2003	56	1	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0034002	DAY 1	25MAR2003	1	2	2	3	3	3	3	1		
		DAY 29	16APR2003	23	3	2	3	0	3	1	0	3	NEEDED TO GO TO THE BATHROOM OFTEN
		FINAL	16APR2003	23	3	2	3	0	3	1	0	3	NEEDED TO GO TO THE BATHROOM OFTEN
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	DAY 1	24APR2003	1	3	2	0						
		DAY 29	22MAY2003	29	2	1	0						
		DAY 57	19JUN2003	57	2	0	0						
		FINAL	19JUN2003	57	2	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	DAY 1	16MAY2003	1	1	3	0						
		DAY 29	13JUN2003	29	2	3	2	3	3	2	1		
		DAY 57	10JUL2003	56	2	3	1	2	3	1	0		
		FINAL	10JUL2003	56	2	3	1	2	3	1	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 1	23MAY2003	-1	0	2	1	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 29	20JUN2003	28	1	-12	0	0	0	0	0	0	1
		DAY 57	21JUL2003	59	1	-12	0	0	0	0	0	0	1
		FINAL	21JUL2003	59	1	-12	0	0	0	0	0	0	1
	E0035003	DAY 1	22NOV2002	1	16		2	3	2	1	2	3	3
		DAY 29	20DEC2002	29	10	-6	1	3	1	3	1	0	1
		FINAL	20DEC2002	29	10	-6	1	3	1	3	1	0	1
	E0035005	DAY 1	03DEC2002	1	15		2	3	2	2	1	2	3
		DAY 29	31DEC2002	29	5	-10	1	1	1	0	1	0	1
		FINAL	31DEC2002	29	5	-10	1	1	1	0	1	0	1
	E0035014	DAY 1	03FEB2003	1	8		1	2	2	1	1	0	1
		DAY 29	03MAR2003	29	8	0	1	2	1	1	1	0	2
		DAY 57	31MAR2003	57	6	-2	1	2	1	2	0	0	0
		FINAL	31MAR2003	57	6	-2	1	2	1	2	0	0	0
	E0035024	DAY 1	22MAY2003	-1	15		3	3	2	3	2	0	2
		DAY 29	19JUN2003	28	9	-6	1	3	1	1	1	0	2
		DAY 57	18JUL2003	57	10	-5	2	3	1	1	1	0	2
		FINAL	18JUL2003	57	10	-5	2	3	1	1	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 29	20JUN2003	28	0:00	5	10:00	9	0	0	0	0	0	0	0	0	0	
		DAY 57	21JUL2003	59	0:00	10	6:00	8	0	0	0	0	0	0	0	0	0	
		FINAL	21JUL2003	59	0:00	10	6:00	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	DAY 1	22NOV2002	1	22:30	60	5:00	5	3	2	3	3	0	0	0	3	3	
		DAY 29	20DEC2002	29	9:00	45	7:00	7	3	0	0	3	0	0	0	0	0	
		FINAL	20DEC2002	29	9:00	45	7:00	7	3	0	0	3	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0035005	DAY 1	03DEC2002	1	21:00	45	4:00	5	3	3	2	0	0	0	0	2	0	
		DAY 29	31DEC2002	29	21:30	20	5:00	7	1	1	1	0	0	0	0	0	0	
		FINAL	31DEC2002	29	21:30	20	5:00	7	1	1	1	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	DAY 1	03FEB2003	1	1:00	30	7:30	5	2	1	0	0	0	1	2	1	0	
		DAY 29	03MAR2003	29	23:00	25	7:00	6	2	2	0	0	0	1	1	1	0	
		DAY 57	31MAR2003	57	22:00	25	7:00	6	3	0	0	0	0	0	0	0	0	
		FINAL	31MAR2003	57	22:00	25	7:00	6	3	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	DAY 1	22MAY2003	-1	1:00	120	9:00	5	3	3	3	0	1	0	1	1	3	
		DAY 29	19JUN2003	28	22:00	60	6:00	6	3	2	1	0	0	0	0	1	0	
		DAY 57	18JUL2003	57	23:00	65	7:00	6	3	1	1	0	0	0	0	0	0	
		FINAL	18JUL2003	57	23:00	65	7:00	6	3	1	1	0	0	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 29	20JUN2003	28	0	1	1	0	0	0	0		
		DAY 57	21JUL2003	59	0	1	1	0	0	0	0		
		FINAL	21JUL2003	59	0	1	1	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	DAY 1	22NOV2002	1	3	2	0						
		DAY 29	20DEC2002	29	0	1	0						
		FINAL	20DEC2002	29	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0035005	DAY 1	03DEC2002	1	3	2	0						
		DAY 29	31DEC2002	29	1	1	0						
		FINAL	31DEC2002	29	1	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	DAY 1	03FEB2003	1	0	2	0						
		DAY 29	03MAR2003	29	0	3	0						
		DAY 57	31MAR2003	57	0	0	0						
		FINAL	31MAR2003	57	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	DAY 1	22MAY2003	-1	1	3	0						
		DAY 29	19JUN2003	28	0	3	0						
		DAY 57	18JUL2003	57	0	3	0						
		FINAL	18JUL2003	57	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	DAY 1	01JUL2003	1	5		1	0	1	0	1	1	1
		DAY 29	29JUL2003	29	3	-2	1	0	0	0	1	0	1
		DAY 57	27AUG2003	58	5	0	1	0	1	3	0	0	0
		FINAL	27AUG2003	58	5	0	1	0	1	3	0	0	0
	E0037002	DAY 1	26DEC2002	1	11		2	2	1	1	2	1	2
		DAY 29	24JAN2003	30	13	2	1	2	0	3	2	3	2
		DAY 57	20FEB2003	57	9	-2	1	1	0	0	2	3	2
		FINAL	20FEB2003	57	9	-2	1	1	0	0	2	3	2
	E0037005	DAY 1	06MAR2003	1	11		2	2	1	0	2	2	2
		DAY 29	03APR2003	29	4	-7	1	0	1	0	1	0	1
		DAY 57	01MAY2003	57	7	-4	1	0	1	1	1	1	2
		FINAL	01MAY2003	57	7	-4	1	0	1	1	1	1	2
	E0037006	DAY 1	14MAR2003	1	13		2	2	1	0	2	3	3
		DAY 29	11APR2003	29	3	-10	0	0	1	0	1	0	1
		DAY 57	09MAY2003	57	4	-9	1	1	0	0	1	0	1
		FINAL	09MAY2003	57	4	-9	1	1	0	0	1	0	1
	E0039006	DAY 1	30DEC2002	1	8		1	2	1	0	1	3	0
		DAY 29	28JAN2003	30			2	3	3	1		1	1
		DAY 57	24FEB2003	57	11	3	1	3	2	2	2	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	DAY 1	01JUL2003	1	0:30	5	7:30	7	0	1	0	2	2	1	1	0	2	
		DAY 29	29JUL2003	29	0:30	5	9:00	8	0	1	0	0	0	3	0	0	2	
		DAY 57	27AUG2003	58	23:00	5	10:00	6	0	0	0	0	0	0	0	0	0	
		FINAL	27AUG2003	58	23:00	5	10:00	6	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	DAY 1	26DEC2002	1	2:00	30	10:00	6	3	3	3	2	2	1	3	1	0	
		DAY 29	24JAN2003	30	12:00	30	10:30	9	2	1	2	1	3	1	2	1	1	
		DAY 57	20FEB2003	57	22:30	30	10:00	12	1	2	1	1	2	1	3	1	0	
		FINAL	20FEB2003	57	22:30	30	10:00	12	1	2	1	1	2	1	3	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	DAY 1	06MAR2003	1	0:30	30	6:00	7	2	3	3	1	0	2	2	3	2	
		DAY 29	03APR2003	29	23:30	10	7:30	7	0	2	1	0	1	1	1	1	1	
		DAY 57	01MAY2003	57	22:30	10	7:30	7	0	0	1	0	0	1	2	1	1	
		FINAL	01MAY2003	57	22:30	10	7:30	7	0	0	1	0	0	1	2	1	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	DAY 1	14MAR2003	1	21:30	30	3:30	6	3	3	3	3	0	0	3	0	3	
		DAY 29	11APR2003	29	22:00	5	5:15	7	0	1	2	0	0	0	2	0	0	
		DAY 57	09MAY2003	57	20:30	30	5:00	8	0	1	2	0	0	0	0	0	0	
		FINAL	09MAY2003	57	20:30	30	5:00	8	0	1	2	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	DAY 1	30DEC2002	1	0:00	30	7:00	7	2	3	3	0	0	0	0	3	0	
		DAY 29	28JAN2003	30	2:00	60	7:00	4	3	3	3	3	0	3	0		0	
		DAY 57	24FEB2003	57	0:00	40	7:00	5	3	3	3	0	0	3	0	3	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	DAY 1	01JUL2003	1	1	1	0						
		DAY 29	29JUL2003	29	0	1	1	0	0	1	0		
		DAY 57	27AUG2003	58	0	0	1	0	0	0	1		
		FINAL	27AUG2003	58	0	0	1	0	0	0	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	DAY 1	26DEC2002	1	0	3	3	0	0	3	0		
		DAY 29	24JAN2003	30	1	3	3	3	1	3	0		
		DAY 57	20FEB2003	57	1	2	3	2	0	2	0		
		FINAL	20FEB2003	57	1	2	3	2	0	2	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	DAY 1	06MAR2003	1	2	2	3	0	0	2	0	2	WAKING UP, SWEATING, UNCOMFORTABLE, NIGHTMARES
		DAY 29	03APR2003	29	0	2	3	0	0	2	2		
		DAY 57	01MAY2003	57	1	2	3	0	0	1	1		
		FINAL	01MAY2003	57	1	2	3	0	0	1	1		
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	DAY 1	14MAR2003	1	2	3	0						
		DAY 29	11APR2003	29	1	1	0						
		DAY 57	09MAY2003	57	0	1	0						
		FINAL	09MAY2003	57	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	DAY 1	30DEC2002	1	0	0	0						
		DAY 29	28JAN2003	30	0	2	0						
		DAY 57	24FEB2003	57	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	FINAL	24FEB2003	57	11	3	1	3	2	2	2	0	1
	E0039015	DAY 1	23JAN2003	1	16		3	3	3	3	2	0	2
		DAY 29	20FEB2003	29	4	-12	1	0	0	1	1	0	1
		DAY 57	20MAR2003	57	4	-12	0	1	0	1	1	0	1
		FINAL	20MAR2003	57	4	-12	0	1	0	1	1	0	1
	E0039024	DAY 1	27FEB2003	1	11		1	3	3	2	1	0	1
		DAY 29	27MAR2003	29	10	-1	1	3	2	1	1	0	2
		DAY 57	24APR2003	57	9	-2	1	2	2	2	1	0	1
		FINAL	24APR2003	57	9	-2	1	2	2	2	1	0	1
	E0039025	DAY 1	18MAR2003	1	10		1	3	3	2	1	0	0
		DAY 29	15APR2003	29	4	-6	0	2	1	0	1	0	0
		FINAL	15APR2003	29	4	-6	0	2	1	0	1	0	0
	E0039041	DAY 1	15APR2003	1	8		2	2	2	1	1	0	0
		DAY 29	13MAY2003	29	12	4	2	3	3	2	1	0	1
		DAY 57	11JUN2003	58	7	-1	2	2	1	0	1	0	1
		FINAL	11JUN2003	58	7	-1	2	2	1	0	1	0	1
	E0039044	DAY 1	22MAY2003	1	4		1	1	1	0	0	0	1

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	FINAL	24FEB2003	57	0:00	40	7:00	5	3	3	3	0	0	3	0	3	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039015	DAY 1	23JAN2003	1	2:30	360	12:00	4	3	3	3	2	0	3	3	1	0	
		DAY 29	20FEB2003	29	20:00	10	8:00	10	0	0	1	0	0	0	0	0	0	
		DAY 57	20MAR2003	57	20:00	30	10:00	11	0	0	1	0	0	0	0	1	0	
		FINAL	20MAR2003	57	20:00	30	10:00	11	0	0	1	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	DAY 1	27FEB2003	1	21:00	60	3:00	4	3	3	2	0	0	0	3	0	0	
		DAY 29	27MAR2003	29	21:00	60	3:00	5	3	2	2	1	0	0	2	0	0	
		DAY 57	24APR2003	57	20:00	30	3:00	5	2	1	1	0	0	0	2	0	0	
		FINAL	24APR2003	57	20:00	30	3:00	5	2	1	1	0	0	0	2	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039025	DAY 1	18MAR2003	1	23:00	240	5:00	4	3	0	0	0	1	1	1	2	1	
		DAY 29	15APR2003	29	23:00	30	6:00	7	2	0	1	0	0	0	0	2	0	
		FINAL	15APR2003	29	23:00	30	6:00	7	2	0	1	0	0	0	0	2	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 1	15APR2003	1	0:30	30	6:30	5	2	3	1	0	0	0	0	0	0	
		DAY 29	13MAY2003	29	0:30	60	6:00	4	3	3	3	0	0	0	0	1	0	
		DAY 57	11JUN2003	58	0:00	45	6:30	7	2	3	2	0	0	0	0	1	0	
		FINAL	11JUN2003	58	0:00	45	6:30	7	2	3	2	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	DAY 1	22MAY2003	1	23:00	30	7:00	7	0	0	0	0	0	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	FINAL	24FEB2003	57	0	2	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0039015	DAY 1	23JAN2003	1	0	3	3						
		DAY 29	20FEB2003	29	0	2	3						
		DAY 57	20MAR2003	57	0	1	3						
		FINAL	20MAR2003	57	0	1	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	DAY 1	27FEB2003	1	0	1	3						
		DAY 29	27MAR2003	29	2	2	3						
		DAY 57	24APR2003	57	1	1	3						
		FINAL	24APR2003	57	1	1	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0039025	DAY 1	18MAR2003	1	0	0	3						
		DAY 29	15APR2003	29	0	0	0						
		FINAL	15APR2003	29	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 1	15APR2003	1	0	0	0						
		DAY 29	13MAY2003	29	0	1	0						
		DAY 57	11JUN2003	58	1	1	0						
		FINAL	11JUN2003	58	1	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	DAY 1	22MAY2003	1	0	1	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	DAY 29	18JUN2003	28	4	0	1	1	1	0	0	0	1
		DAY 57	09JUL2003	49	3	-1	0	1	1	0	0	0	1
		FINAL	09JUL2003	49	3	-1	0	1	1	0	0	0	1
	E0039046		21MAY2003		9		1	2	1	1	2	1	1
	E0039051	DAY 1	16JUN2003	1	10		2	3	1	1	2	0	1
		DAY 29	14JUL2003	29	4	-6	1	0	1	0	2	0	0
		DAY 57	12AUG2003	58	1	-9	0	0	0	0	1	0	0
		FINAL	12AUG2003	58	1	-9	0	0	0	0	1	0	0
	E0039053	DAY 1	11JUL2003	1	10		1	1	2	3	2	0	1
		DAY 29	07AUG2003	28	11	1	1	3	1	3	2	0	1
		DAY 57	08SEP2003	60	5	-5	1	2	0	0	1	0	1
		FINAL	08SEP2003	60	5	-5	1	2	0	0	1	0	1
	E0039057	DAY 1	14JUL2003	1	12		2	3	3	0	2	0	2
		DAY 29	12AUG2003	30	7	-5	1	1	1	3	1	0	0
		DAY 57	09SEP2003	58	2	-10	1	0	0	0	1	0	0
		FINAL	09SEP2003	58	2	-10	1	0	0	0	1	0	0
	E0041003	DAY 1	28JAN2003	1	6		0	1	0	2	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	DAY 29	18JUN2003	28	23:00	30	6:00	7	0	0	0	0	0	0	0	0	0	
		DAY 57	09JUL2003	49	23:00	30	6:00	7	0	0	0	0	0	0	0	0	0	
		FINAL	09JUL2003	49	23:00	30	6:00	7	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039046		21MAY2003		23:00	30	7:00	6	2	2	0	0	2	3	3	1	1	
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	DAY 1	16JUN2003	1	22:00	60	6:00	6	3	3	3	0	1	3	2	1	3	
		DAY 29	14JUL2003	29	23:00	15	6:00	7	0	2	3	0	0	3	2	1	1	
		DAY 57	12AUG2003	58	22:00	15	6:30	8	0	0	3	0	0	2	2	0	0	
		FINAL	12AUG2003	58	22:00	15	6:30	8	0	0	3	0	0	2	2	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	DAY 1	11JUL2003	1	21:30	30	6:00	5	1	3	2	2	2	0	1	0	0	
		DAY 29	07AUG2003	28	21:00	45	7:30	6	3	3	2	2	0	0	0	1	2	
		DAY 57	08SEP2003	60	20:30	20	7:30	10	3	1	2	0	0	0	0	0	0	
		FINAL	08SEP2003	60	20:30	20	7:30	10	3	1	2	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0039057	DAY 1	14JUL2003	1	2:00	40	6:30	4	3	3	3	0	0	2	3	2	1	
		DAY 29	12AUG2003	30	0:00	20	11:00	7	0	0	3	0	0	0	3	0	0	
		DAY 57	09SEP2003	58	23:00	15	8:30	9	0	1	1	0	0	0	0	1	0	
		FINAL	09SEP2003	58	23:00	15	8:30	9	0	1	1	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 1	28JAN2003	1	23:00	20	11:00	8	0	1	2	2	0	0	2	0	2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU- SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	DAY 29	18JUN2003	28	0	1	0						
		DAY 57	09JUL2003	49	0	1	0						
		FINAL	09JUL2003	49	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0039046		21MAY2003		0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	DAY 1	16JUN2003	1	0	1	3						
		DAY 29	14JUL2003	29	0	0	3						
		DAY 57	12AUG2003	58	0	0	3						
		FINAL	12AUG2003	58	0	0	3						
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	DAY 1	11JUL2003	1	0	2	3						
		DAY 29	07AUG2003	28	0	2	3						
		DAY 57	08SEP2003	60	0	1	0						
		FINAL	08SEP2003	60	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0039057	DAY 1	14JUL2003	1	1	3	0						
		DAY 29	12AUG2003	30	0	0	0						
		DAY 57	09SEP2003	58	0	0	0						
		FINAL	09SEP2003	58	0	0	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 1	28JAN2003	1	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 29	25FEB2003	29	3	-3	0	1	0	0	1	0	1
		DAY 57	25MAR2003	57	3	-3	0	0	0	1	1	0	1
		FINAL	25MAR2003	57	3	-3	0	0	0	1	1	0	1
	E0041008	DAY 1	07APR2003	1	18		3	2	2	3	2	3	3
		DAY 29	05MAY2003	29	14	-4	2	3	1	2	2	2	2
		DAY 57	02JUN2003	57	14	-4	2	2	1	3	2	2	2
		FINAL	02JUN2003	57	14	-4	2	2	1	3	2	2	2
	E0042001	DAY 1	02JUL2003	1	12		2	2	2	1	3	0	2
		DAY 29	29JUL2003	28	5	-7	0	2	0	0	1	0	2
		DAY 57	26AUG2003	56	10	-2	1	3	0	1	2	0	3
		FINAL	26AUG2003	56	10	-2	1	3	0	1	2	0	3
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	10		2	3	1	0	2	0	2
		DAY 29	09APR2003	29	5	-5	1	1	0	0	1	0	2
		DAY 57	07MAY2003	57	4	-6	1	1	1	0	1	0	0
		FINAL	07MAY2003	57	4	-6	1	1	1	0	1	0	0
	E0003018	DAY 1	13MAY2003	1	14		2	2	2	3	1	3	1
		DAY 29	10JUN2003	29	10	-4	1	2	1	2	1	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 29	25FEB2003	29	23:30	20	12:00	11	0	1	1	0	0	0	1	0	0		
		DAY 57	25MAR2003	57	23:30	15	11:30	10	0	0	2	1	0	0	0	0	0		
		FINAL	25MAR2003	57	23:30	15	11:30	10	0	0	2	1	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	DAY 1	07APR2003	1	19:00	30	5:00	5	3	3	3	1	1	2	2	2	1	3	CAN'T SLEEP WORRY A LOT
		DAY 29	05MAY2003	29	19:00	60	5:00	7	3	3	3	1	1	3	3	1	0	3	REAL THIRSTY WAKE UP DURING NIGHT
		DAY 57	02JUN2003	57	20:00	30	9:00	6	2	3	2	0	0	2	2	1	0	2	REAL THRISTY WAKE UP IN NIGHT
		FINAL	02JUN2003	57	20:00	30	9:00	6	2	3	2	0	0	2	2	1	0	2	REAL THRISTY WAKE UP IN NIGHT
QUETIAPINE 300 MG (BIPOLAR I)	E0042001	DAY 1	02JUL2003	1	22:00	30	4:00	5	2	3	3	3	3	2	3	3	3		
		DAY 29	29JUL2003	28	21:00	30	10:00	12	2	3	3	0	0	0	0	0	0		
		DAY 57	26AUG2003	56	20:00	45	6:00	8	3	3	3	0	3	0	3	0	3		
		FINAL	26AUG2003	56	20:00	45	6:00	8	3	3	3	0	3	0	3	0	3		
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	22:30	90	5:30	7	2	3	3	1	2	0	2	0	1		
		DAY 29	09APR2003	29	21:30	30	5:40	8	0	2	3	0	1	1	1	0	0		
		DAY 57	07MAY2003	57	22:00	45	5:45	7	0	2	2	0	1	0	0	0	0		
		FINAL	07MAY2003	57	22:00	45	5:45	7	0	2	2	0	1	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	DAY 1	13MAY2003	1	3:00	30	12:00	5	3	3	0	0	0	0	0	2	0		
		DAY 29	10JUN2003	29	1:30	40	12:00	7	2	2	0	2	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 29	25FEB2003	29	0	1	0						
		DAY 57	25MAR2003	57	0	1	0						
		FINAL	25MAR2003	57	0	1	0						
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	DAY 1	07APR2003	1	3	3	0						
		DAY 29	05MAY2003	29	2	2	3	1	1	0	0	3	CAN'T STAY ASLEEP
		DAY 57	02JUN2003	57	2	2	3	1	1	0	0		
		FINAL	02JUN2003	57	2	2	3	1	1	0	0		
QUETIAPINE 300 MG (BIPOLAR I)	E0042001	DAY 1	02JUL2003	1	0	3	3	3	0	2	2		
		DAY 29	29JUL2003	28	0	3	3	3	0	0	0		
		DAY 57	26AUG2003	56	3	3	2	3	0	3	0		
		FINAL	26AUG2003	56	3	3	2	3	0	3	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	1	3	0						
		DAY 29	09APR2003	29	1	2	0						
		DAY 57	07MAY2003	57	0	0	0						
		FINAL	07MAY2003	57	0	0	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	DAY 1	13MAY2003	1	0	1	1	0	0	0	0		
		DAY 29	10JUN2003	29	3	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	DAY 57	08JUL2003	57	11	-3	1	2	1	1	2	3	1
		FINAL	08JUL2003	57	11	-3	1	2	1	1	2	3	1
	E0005011	DAY 1	24OCT2002	1	11		2	3	1	0	2	0	3
		DAY 29	21NOV2002	29	6	-5	1	2	0	0	1	0	2
		FINAL	21NOV2002	29	6	-5	1	2	0	0	1	0	2
	E0005030	DAY 1	26MAR2003	1	12		2	3	1	3	2	0	1
	E0005036	DAY 1	06MAY2003	1	12		2	0	2	3	1	1	3
	E0006015	DAY 1	11FEB2003	1	12		1	3	1	1	2	1	3
		DAY 29	11MAR2003	29	9	-3	2	3	0	0	1	1	2
		DAY 57	08APR2003	57	7	-5	2	3	0	0	1	0	1
		FINAL	08APR2003	57	7	-5	2	3	0	0	1	0	1
	E0006016	DAY 1	17FEB2003	1	9		2	0	1	2	1	0	3
		DAY 29	17MAR2003	29	5	-4	1	1	1	1	1	0	0
		DAY 57	18APR2003	61	2	-7	0	0	1	0	0	0	1
		FINAL	18APR2003	61	2	-7	0	0	1	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	DAY 57	08JUL2003	57	1:00	30	10:00	7	2	3	0	3	0	3	3	1	2	2	NECK & SHOULDER PAIN
		FINAL	08JUL2003	57	1:00	30	10:00	7	2	3	0	3	0	3	3	1	2	2	NECK & SHOULDER PAIN
QUETIAPINE 300 MG (BIPOLAR II)	E0005011	DAY 1	24OCT2002	1	2:30	60	8:45	6	3	3	1	2	0	2	3	0	0	3	GOOD T. V. SHOW
		DAY 29	21NOV2002	29	23:30	40	8:30	8	2	2	0	2	1	1	2	1	0		
		FINAL	21NOV2002	29	23:30	40	8:30	8	2	2	0	2	1	1	2	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0005030	DAY 1	26MAR2003	1	23:00	120	11:00	6	3	3	3	2	0	2	2	1	2		
QUETIAPINE 300 MG (BIPOLAR II)	E0005036	DAY 1	06MAY2003	1	22:00	5	7:00	5	0	3	3	0	0	0	1	0	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	DAY 1	11FEB2003	1	23:30	90	7:00	6	3	3	0	0	0	3	0	0	3	3	MEDICATION (LITHOBID)
		DAY 29	11MAR2003	29	1:00	45	7:00	11	3	3	0	0	0	3	1	0	1		
		DAY 57	08APR2003	57	0:00	60	7:00	11	3	1	0	0	0	2	2	0	1		
		FINAL	08APR2003	57	0:00	60	7:00	11	3	1	0	0	0	2	2	0	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	DAY 1	17FEB2003	1	21:00	15	6:30	7	0	3	1	0	0	0	1	0	0		
		DAY 29	17MAR2003	29	22:00	30	6:30	7	1	1	3	0	0	0	0	0	0		
		DAY 57	18APR2003	61	23:00	10	6:00	6	0	0	0	0	0	0	0	0	0		
		FINAL	18APR2003	61	23:00	10	6:00	6	0	0	0	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	DAY 57	08JUL2003	57	0	2	0						
		FINAL	08JUL2003	57	0	2	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0005011	DAY 1	24OCT2002	1	3	3	1	0	0	1	2		
		DAY 29	21NOV2002	29	1	2	1	1	0	1	2		
		FINAL	21NOV2002	29	1	2	1	1	0	1	2		
QUETIAPINE 300 MG (BIPOLAR II)	E0005030	DAY 1	26MAR2003	1	0	2	3						
QUETIAPINE 300 MG (BIPOLAR II)	E0005036	DAY 1	06MAY2003	1	3	3	3						
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	DAY 1	11FEB2003	1	2	3	3	3	0	0	0		
		DAY 29	11MAR2003	29	0	3	3	0	0	0	0		
		DAY 57	08APR2003	57	0	2	3	0	0	0	0		
		FINAL	08APR2003	57	0	2	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	DAY 1	17FEB2003	1	2	3	3	2	0	0	0		
		DAY 29	17MAR2003	29	0	0	3	0	0	0	0		
		DAY 57	18APR2003	61	0	1	3	0	0	0	0		
		FINAL	18APR2003	61	0	1	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	DAY 1	18APR2003	1	9		2	3	1	0	1	0	2
		DAY 29	25APR2003	8	3	-6	0	0	0	0	0	0	3
		FINAL	25APR2003	8	3	-6	0	0	0	0	0	0	3
	E0009002	DAY 1	19NOV2002	1	14		2	2	1	1	3	2	3
		DAY 29	18DEC2002	30	6	-8	0	1	1	0	1	0	3
		DAY 57	15JAN2003	58	6	-8	1	1	0	0	1	0	3
		FINAL	15JAN2003	58	6	-8	1	1	0	0	1	0	3
	E0009006	DAY 1	28JAN2003	1	13		2	3	2	1	2	2	1
		DAY 29	25FEB2003	29	8	-5	1	3	1	0	2	0	1
		DAY 57	25MAR2003	57	8	-5	1	2	1	2	2	0	0
		FINAL	25MAR2003	57	8	-5	1	2	1	2	2	0	0
	E0009009	DAY 1	12MAR2003	1	14		2	3	2	3	2	0	2
		DAY 29	24MAR2003	13	10	-4	1	2	2	3	1	0	1
		FINAL	24MAR2003	13	10	-4	1	2	2	3	1	0	1
	E0010015	DAY 1	20FEB2003	1	19		3	3	3	3	1	3	3
		DAY 29	20MAR2003	29			3	3	0		1	1	2
		DAY 57	15APR2003	55	15	-4	3	3	2	2	1	3	1
		FINAL	15APR2003	55	15	-4	3	3	2	2	1	3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	DAY 1	18APR2003	1	1:00	45	7:30	6	3	3	3	0	0	0	0	0	0		
		DAY 29	25APR2003	8	22:00	5	12:00	14	0	0	0	0	0	0	0	0	0		
		FINAL	25APR2003	8	22:00	5	12:00	14	0	0	0	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0009002	DAY 1	19NOV2002	1	23:00	25	6:30	6	3	3	3	3	3	0	3	2	2		
		DAY 29	18DEC2002	30	23:00	10	6:00	7	1	1	1	2	3	0	1	1	0		
		DAY 57	15JAN2003	58	23:00	5	6:30	8	1	2	2	1	3	0	1	0	0		
		FINAL	15JAN2003	58	23:00	5	6:30	8	1	2	2	1	3	0	1	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	DAY 1	28JAN2003	1	3:30	90	10:00	5	2	2	1	1	1	0	3	2	1	3	HEADACHE
		DAY 29	25FEB2003	29	2:00	45	9:00	6	3	2	2	1	0	0	3	2	1	3	HEADACHE
		DAY 57	25MAR2003	57	0:30	30	9:00	6	2	1	2	1	0	1	3	2	1		
		FINAL	25MAR2003	57	0:30	30	9:00	6	2	1	2	1	0	1	3	2	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0009009	DAY 1	12MAR2003	1	23:00	45	7:00	5	3	3	1	0	0	1	1	1	1	3	DON'T FALL INTO A DEEP SLEEP
		DAY 29	24MAR2003	13	22:00	30	7:00	5	2	3	1	0	0	0	1	0	0		
		FINAL	24MAR2003	13	22:00	30	7:00	5	2	3	1	0	0	0	1	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	DAY 1	20FEB2003	1	16:00	120	1:00	3	3	3	2	0	0	0	0	0	0		
		DAY 29	20MAR2003	29	5:00	180		90	3	1	0	0	0	0	0	0	0		
		DAY 57	15APR2003	55	4:00	240	11:00	5	3	3	3	0	0	0	0	0	0		
		FINAL	15APR2003	55	4:00	240	11:00	5	3	3	3	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	DAY 1	18APR2003	1	0	3	3	0	0	0	0	3	TOSS & TURN
		DAY 29	25APR2003	8	3	3	3	0	0	0	0		
		FINAL	25APR2003	8	3	3	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0009002	DAY 1	19NOV2002	1	3	3	3	3	0	0	0		
		DAY 29	18DEC2002	30	3	2	3						
		DAY 57	15JAN2003	58	2	3	3	3	2	1	1		
		FINAL	15JAN2003	58	2	3	3	3	2	1	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	DAY 1	28JAN2003	1	0	1	0						
		DAY 29	25FEB2003	29	0	1	0						
		DAY 57	25MAR2003	57	0	0	0						
		FINAL	25MAR2003	57	0	0	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0009009	DAY 1	12MAR2003	1	1	2	1	1	0	0	1	3	VERY RESTLESS KICKING, TALKING, ETC
		DAY 29	24MAR2003	13	0	1	1	0	0	0	1	1	CAN'T GET COMFORTABLE
		FINAL	24MAR2003	13	0	1	1	0	0	0	1	1	CAN'T GET COMFORTABLE
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	DAY 1	20FEB2003	1	3	3	2	1	1	3	3		
		DAY 29	20MAR2003	29	2	2	2	0	0	0	0		
		DAY 57	15APR2003	55	0	2	1	0	0	3	0		
		FINAL	15APR2003	55	0	2	1	0	0	3	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	DAY 1	24DEC2002	1	15		2	2	3	1	2	3	2
		DAY 29	21JAN2003	29	9	-6	1	2	2	0	2	0	2
		DAY 57	18FEB2003	57	5	-10	1	0	1	1	2	0	0
		FINAL	18FEB2003	57	5	-10	1	0	1	1	2	0	0
	E0011007	DAY 1	19DEC2002	1	9		2	1	1	0	2	0	3
		DAY 29	17JAN2003	30	4	-5	1	1	0	0	1	0	1
		DAY 57	13FEB2003	57	6	-3	1	1	0	1	2	0	1
		FINAL	13FEB2003	57	6	-3	1	1	0	1	2	0	1
	E0011018	DAY 1	22MAY2003	1	10		2	3	1	0	2	1	1
		DAY 29	20JUN2003	30	2	-8	0	0	0	0	1	0	1
		DAY 57	17JUL2003	57	5	-5	1	1	0	1	1	0	1
		FINAL	17JUL2003	57	5	-5	1	1	0	1	1	0	1
	E0011024	DAY 1	24JUN2003	1	12		2	2	2	2	2	0	2
		DAY 29	22JUL2003	29	6	-6	1	1	1	0	1	0	2
		DAY 57	21AUG2003	59	5	-7	0	1	0	0	2	0	2
		FINAL	21AUG2003	59	5	-7	0	1	0	0	2	0	2
	E0015003	DAY 1	25NOV2002	1	9		1	2	2	0	2	0	2
		DAY 29	02DEC2002	8	9	0	3	0	0	0	0	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	DAY 1	24DEC2002	1	2:00	90	7:00	4	1	3	3	2	2	2	2	1	2		
		DAY 29	21JAN2003	29	2:30	35	7:30	5	1	2	2	2	2	0	0	0	3		
		DAY 57	18FEB2003	57	0:00	15	7:30	6	0	2	2	1	1	1	1	1	1		
		FINAL	18FEB2003	57	0:00	15	7:30	6	0	2	2	1	1	1	1	1	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	DAY 1	19DEC2002	1	22:00	15	6:00	7	2	3	2	0	2	1	2	0	2	2	ANXIETY
		DAY 29	17JAN2003	30	22:00	10	7:30	9	1	2	1	0	2	2	0	0	2		
		DAY 57	13FEB2003	57	22:00	15	9:00	9	1	2	0	0	3	2	0	1	1	3	DIZZINESS
		FINAL	13FEB2003	57	22:00	15	9:00	9	1	2	0	0	3	2	0	1	1	3	DIZZINESS
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	DAY 1	22MAY2003	1	2:30	180	9:00	7	3	2	2	1	0	1	2	1	0	2	SLEEPWALK
		DAY 29	20JUN2003	30	22:00	10	7:00	8	0	0	1	0	0	0	1	1	1	2	SLEEP WALKS
		DAY 57	17JUL2003	57	22:30	30	8:30	8	0	1	1	0	2	1	1	1	0		
		FINAL	17JUL2003	57	22:30	30	8:30	8	0	1	1	0	2	1	1	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	DAY 1	24JUN2003	1	22:00	30	5:15	5	2	3	3	2	3	2	2	1	1		
		DAY 29	22JUL2003	29	23:00	20	5:15	6	1	1	2	1	0	0	1	1	1		
		DAY 57	21AUG2003	59	21:00	30	5:15	8	0	0	3	0	3	2	2	0	0		
		FINAL	21AUG2003	59	21:00	30	5:15	8	0	0	3	0	3	2	2	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0015003	DAY 1	25NOV2002	1	2:00	55	7:30	5	2	3	2	0	0	0	2	3	0	3	RUMINATION
		DAY 29	02DEC2002	8	2:00	5	13:00	11	0	0	0	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	DAY 1	24DEC2002	1	1	3	3	2	2	0	0	3	COUGHING, GOING TO POTTY
		DAY 29	21JAN2003	29	2	1	3	0	0	3	0		
		DAY 57	18FEB2003	57	0	0	3	1	0	1	0		
		FINAL	18FEB2003	57	0	0	3	1	0	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	DAY 1	19DEC2002	1	2	3	3	1	1	2	0	2	ROLLING AROUND
		DAY 29	17JAN2003	30	0	2	3	2	1	1	0	2	TOSSING & TURNING
		DAY 57	13FEB2003	57	0	1	3	2	1	2	0	1	CANNOT FALL ASLEEP
		FINAL	13FEB2003	57	0	1	3	2	1	2	0	1	CANNOT FALL ASLEEP
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	DAY 1	22MAY2003	1	0	2	3	1	1	2	2	2	
		DAY 29	20JUN2003	30	2	0	3	1	1	2	2	2	
		DAY 57	17JUL2003	57	0	1	3						
		FINAL	17JUL2003	57	0	1	3						
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	DAY 1	24JUN2003	1	1	2	3	3	2	3	2	3	SHE SLEPT A LOT DURING THE DAY
		DAY 29	22JUL2003	29	1	2	3	3	0	2	2		
		DAY 57	21AUG2003	59	2	1	3						
		FINAL	21AUG2003	59	2	1	3						
QUETIAPINE 300 MG (BIPOLAR II)	E0015003	DAY 1	25NOV2002	1	0	3	0						
		DAY 29	02DEC2002	8	3	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0015003	FINAL	02DEC2002	8	9	0	3	0	0	0	0	3	3
	E0019003	DAY 1	21NOV2002	1	18		3	3	3	3	3	0	3
		DAY 29	24DEC2002	34	6	-12	0	0	1	1	2	0	2
		DAY 57	16JAN2003	57	4	-14	0	0	1	0	1	0	2
		FINAL	16JAN2003	57	4	-14	0	0	1	0	1	0	2
	E0019007	DAY 1	13NOV2002	1	18		3	3	3	3	1	3	2
		DAY 29	12DEC2002	30	6	-12	1	2	1	0	1	0	1
		DAY 57	07JAN2003	56	10	-8	1	3	2	1	1	0	2
		FINAL	07JAN2003	56	10	-8	1	3	2	1	1	0	2
	E0019014	DAY 1	09JAN2003	1	16		3	2	3	3	2	0	3
		DAY 29	20JAN2003	12	12	-4	3	3	2	0	2	0	2
		FINAL	20JAN2003	12	12	-4	3	3	2	0	2	0	2
	E0019018	DAY 1	30JAN2003	1	11		1	1	1	3	1	1	3
		DAY 29	27FEB2003	29	6	-5	1	1	1	0	1	0	2
		DAY 57	27MAR2003	57	8	-3	1	2	1	0	1	0	3
		FINAL	27MAR2003	57	8	-3	1	2	1	0	1	0	3
	E0019022	DAY 1	30JAN2003	1	9		3	3	0	0	1	0	2

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0015003	FINAL	02DEC2002	8	2:00	5	13:00	11	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	DAY 1	21NOV2002	1	23:00	90	6:00	4	3	3	2	3	3	3	1	2	3	
		DAY 29	24DEC2002	34	22:00	15	6:00	6	0	3	2	0	0	2	0	2	1	
		DAY 57	16JAN2003	57	22:00	5	6:00	7	0	1	1	0	1	2	1	3	0	
		FINAL	16JAN2003	57	22:00	5	6:00	7	0	1	1	0	1	2	1	3	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0019007	DAY 1	13NOV2002	1	0:00	120	6:00	3	3	3	2	0	0	0	0	0	0	
		DAY 29	12DEC2002	30	23:00	30	6:00	7	2	2	2	0	0	0	0	0	0	
		DAY 57	07JAN2003	56	0:00	70	6:00	5	3	3	2	0	0	0	0	1	0	
		FINAL	07JAN2003	56	0:00	70	6:00	5	3	3	2	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	DAY 1	09JAN2003	1	0:00	45	7:00	4	1	3	2	0	3	1	2	3	0	
		DAY 29	20JAN2003	12	2:00	45	7:30	5	3	3	3	0	0	0	2	2	0	
		FINAL	20JAN2003	12	2:00	45	7:30	5	3	3	3	0	0	0	2	2	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0019018	DAY 1	30JAN2003	1	10:00	30	4:30	6	0	3	2	0	0	2	0	2	0	
		DAY 29	27FEB2003	29	21:30	30	5:00	7	0	1	2	0	0	0	0	1	0	
		DAY 57	27MAR2003	57	21:30	40	5:30	7	1	2	0	0	0	0	0	0	0	
		FINAL	27MAR2003	57	21:30	40	5:30	7	1	2	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 1	30JAN2003	1	3:00	60	14:00	10	3	0	1	0	3	0	3	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0015003	FINAL	02DEC2002	8	3	3	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	DAY 1	21NOV2002	1	3	3	3	3	0	3	3	3	TALKING AND WALKING IN SLEEP
		DAY 29	24DEC2002	34	2	1	3	0	0	0	2		
		DAY 57	16JAN2003	57	3	1	3	2	0	1	1	1	"TALKING"
		FINAL	16JAN2003	57	3	1	3	2	0	1	1	1	"TALKING"
QUETIAPINE 300 MG (BIPOLAR II)	E0019007	DAY 1	13NOV2002	1	0	3	3	0	0	0	0		
		DAY 29	12DEC2002	30	0	2	3	0	0	0	0		
		DAY 57	07JAN2003	56	1	3	3	0	0	3	0		
		FINAL	07JAN2003	56	1	3	3	0	0	3	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0019014	DAY 1	09JAN2003	1	3	3	0						
		DAY 29	20JAN2003	12	1	2	0						
		FINAL	20JAN2003	12	1	2	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0019018	DAY 1	30JAN2003	1	2	3	0	0	0	3	2	2	TALKING, CURSING, AGGRESSIVE
		DAY 29	27FEB2003	29	1	2	0						
		DAY 57	27MAR2003	57	2	3	0						
		FINAL	27MAR2003	57	2	3	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 1	30JAN2003	1	1	2	3	3	0	2	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 29	27FEB2003	29	5	-4	0	1	0	1	2	0	1
		DAY 57	27MAR2003	57	5	-4	1	2	0	0	1	0	1
		FINAL	27MAR2003	57	5	-4	1	2	0	0	1	0	1
	E0019027	DAY 1	27FEB2003	1	15		3	3	1	1	2	3	2
		DAY 29	06MAR2003	8	12	-3	2	3	1	1	2	2	1
		FINAL	06MAR2003	8	12	-3	2	3	1	1	2	2	1
	E0019032	DAY 1	01APR2003	1	15		2	3	3	3	2	0	2
		DAY 29	29APR2003	29	5	-10	1	0	0	1	1	0	2
		DAY 57	27MAY2003	57	3	-12	1	0	0	0	1	0	1
		FINAL	27MAY2003	57	3	-12	1	0	0	0	1	0	1
	E0019034	DAY 1	18MAR2003	1	16		3	3	3	3	2	0	2
	E0019036	DAY 1	25MAR2003	1	16		3	3	2	2	3	0	3
		DAY 29	22APR2003	29	4	-12	1	1	0	0	1	0	1
		FINAL	22APR2003	29	4	-12	1	1	0	0	1	0	1
	E0019039	DAY 1	01MAY2003	1	15		2	3	1	1	2	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 29	27FEB2003	29	22:00	30	11:00	10	0	0	1	1	3	0	3	0	3		
		DAY 57	27MAR2003	57	23:00	35	9:00	9	2	1	0	0	0	0	0	0	2		
		FINAL	27MAR2003	57	23:00	35	9:00	9	2	1	0	0	0	0	0	0	2		
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	DAY 1	27FEB2003	1	0:00	50	9:00	7	3	3	3	1	1	2	0	3	1	3	SUDDEN WAKENFULNESS
		DAY 29	06MAR2003	8	0:00	40	9:00	7	3	3	3	1	1	1	1	3	2		
		FINAL	06MAR2003	8	0:00	40	9:00	7	3	3	3	1	1	1	1	3	2		
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	DAY 1	01APR2003	1	2:00	90	10:00	4	3	3	3	0	0	2	1	2	1	2	CAT
		DAY 29	29APR2003	29	0:00	15	12:00	10	0	3	3	0	0	0	0	2	0		
		DAY 57	27MAY2003	57	1:30	15	12:00	10	0	0	3	0	0	0	0	0	0		
		FINAL	27MAY2003	57	1:30	15	12:00	10	0	0	3	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0019034	DAY 1	18MAR2003	1	2:00	120	6:30	2	3	3	0	2	0	3	0	3	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0019036	DAY 1	25MAR2003	1	23:00	50	6:30	5	3	3	3	2	3	1	3	3	2	3	RESTLESS
		DAY 29	22APR2003	29	23:00	20	6:45	8	1	1	1	1	1	0	1	1	1		
		FINAL	22APR2003	29	23:00	20	6:45	8	1	1	1	1	1	0	1	1	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0019039	DAY 1	01MAY2003	1	23:00	60	6:30	6	3	3	3	2	2	1	2	0	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	DAY 29	27FEB2003	29	0	2	3	3	0	2	0		
		DAY 57	27MAR2003	57	0	2	3	3	0	1	0		
		FINAL	27MAR2003	57	0	2	3	3	0	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	DAY 1	27FEB2003	1	1	3	2	1	0	1	1	2	NIGHTMARE
		DAY 29	06MAR2003	8	0	2	3	1	0	1	1	2	NIGHTMARES
		FINAL	06MAR2003	8	0	2	3	1	0	1	1	2	NIGHTMARES
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	DAY 1	01APR2003	1	0	3	1						
		DAY 29	29APR2003	29	0	3	0						
		DAY 57	27MAY2003	57	0	2	1						
		FINAL	27MAY2003	57	0	2	1						
QUETIAPINE 300 MG (BIPOLAR II)	E0019034	DAY 1	18MAR2003	1	0	3	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0019036	DAY 1	25MAR2003	1	2	3	1	3	3	3	3	3	MOVEMENT ALL THE TIME
		DAY 29	22APR2003	29	1	1	1	1	1	1	1		
		FINAL	22APR2003	29	1	1	1	1	1	1	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0019039	DAY 1	01MAY2003	1	2	3	3	0	0	3	0	3	WAKING UP FROM A DEAD SLEEP, SITTING UP TO CALM DOWN, HEART RACING.

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	DAY 1	21MAY2003	1	7		2	0	1	0	2	0	2
		DAY 29	18JUN2003	29	3	-4	0	0	0	1	1	0	1
		DAY 57	16JUL2003	57	4	-3	1	1	0	0	1	0	1
		FINAL	16JUL2003	57	4	-3	1	1	0	0	1	0	1
	E0019049	DAY 1	10JUL2003	1	16		3	3	3	2	3	0	2
		DAY 29	07AUG2003	29	11	-5	1	3	2	1	2	0	2
		DAY 57	08SEP2003	61	9	-7	1	2	0	0	2	3	1
		FINAL	08SEP2003	61	9	-7	1	2	0	0	2	3	1
	E0022052	DAY 1	10APR2003	1	17		3	1	3	3	3	1	3
		DAY 29	08MAY2003	29	15	-2	2	1	3	3	2	2	2
		DAY 57	05JUN2003	57	16	-1	2	1	2	3	3	3	2
		FINAL	05JUN2003	57	16	-1	2	1	2	3	3	3	2
	E0022064	DAY 1	06MAY2003	1	6		1	2	0	0	1	0	2
		DAY 29	03JUN2003	29	2	-4	0	0	0	0	1	0	1
		DAY 57	01JUL2003	57	4	-2	1	1	0	0	1	0	1
		FINAL	01JUL2003	57	4	-2	1	1	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	DAY 1	21MAY2003	1	1:00	10	7:30	6	0	3	2	2	0	1	1	3	1	3	MIND RACING
		DAY 29	18JUN2003	29	23:00	10	11:00	10	0	0	1	0	0	0	0	1	1		
		DAY 57	16JUL2003	57	3:00	10	12:00	9	2	2	2	0	0	0	0	2	0		
		FINAL	16JUL2003	57	3:00	10	12:00	9	2	2	2	0	0	0	0	2	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	DAY 1	10JUL2003	1	4:00	45	9:30	4	3	3	2	3	3	0	0	3	2	3	EVERY NIGHT, REGARDLESS HOW TIRED I AM MY MIND RUNS 98 HOT - CONSTANT THOUGHTS OF IMPENDING DOOM
		DAY 29	07AUG2003	29	3:00	150	9:30	5	3	2	1	2	3	2	2	3	2		
		DAY 57	08SEP2003	61	2:00	45	9:00	10	1	2	2	3	3	0	0	3	0		
		FINAL	08SEP2003	61	2:00	45	9:00	10	1	2	2	3	3	0	0	3	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	DAY 1	10APR2003	1	19:00	20	6:00	3	0	3	2	3	2	2	3	3	3		
		DAY 29	08MAY2003	29	23:00	30	7:00	4	1	3	1	2	2	3	0	3	2		
		DAY 57	05JUN2003	57	23:00	30	7:00	5	0	3	3	2	2	2	3	3	3		
		FINAL	05JUN2003	57	23:00	30	7:00	5	0	3	3	2	2	2	3	3	3		
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	DAY 1	06MAY2003	1	0:30	30	9:30	9	3	1	0	0	0	1	1	0	0		
		DAY 29	03JUN2003	29	23:30	5	9:30	10	0	1	0	0	0	0	0	0	0		
		DAY 57	01JUL2003	57	23:30	5	9:30	10	1	0	0	0	0	0	1	0	0		
		FINAL	01JUL2003	57	23:30	5	9:30	10	1	0	0	0	0	0	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU- SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	DAY 1	21MAY2003	1	1	3	1	0	1	0	2		
		DAY 29	18JUN2003	29	0	2	1	0	0	0	3		
		DAY 57	16JUL2003	57	0	1	3	0	0	0	2		
		FINAL	16JUL2003	57	0	1	3	0	0	0	2		
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	DAY 1	10JUL2003	1	0	3	3	2	3	3	3	3	VIOLENT DREAMS
		DAY 29	07AUG2003	29	0	3	3	2		3	3		
		DAY 57	08SEP2003	61	0	2	3	3	0	3	3		
		FINAL	08SEP2003	61	0	2	3	3	0	3	3		
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	DAY 1	10APR2003	1	2	3	1						
		DAY 29	08MAY2003	29	2	2	1						
		DAY 57	05JUN2003	57	0	3	1						
		FINAL	05JUN2003	57	0	3	1						
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	DAY 1	06MAY2003	1	0	3	0						
		DAY 29	03JUN2003	29	1	0	0						
		DAY 57	01JUL2003	57	1	0	0						
		FINAL	01JUL2003	57	1	0	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0022073	DAY 1	26JUN2003	1	15		2	3	3	3	1	0	3
		DAY 29	24JUL2003	29	4	-11	0	1	0	1	1	0	1
		DAY 57	21AUG2003	57	3	-12	0	1	0	0	1	0	1
		FINAL	21AUG2003	57	3	-12	0	1	0	0	1	0	1
	E0023002	DAY 1	05NOV2002	1			1		0	0		0	1
		DAY 29	03DEC2002	29	3		2	0	0	0	0	0	1
		FINAL	03DEC2002	29	3		2	0	0	0	0	0	1
	E0023017	DAY 1	25MAR2003	1	7		2	0	1	3	0	0	1
		DAY 29	24APR2003	31	3	-4	1	0	1	0	0	0	1
		DAY 57	22MAY2003	59	1	-6	1	0	0	0	0	0	0
		FINAL	22MAY2003	59	1	-6	1	0	0	0	0	0	0
	E0023021	DAY 1	23APR2003	1	16		3	3	3	3	2	0	2
		DAY 29	20MAY2003	28	5	-11	1	0	1	0	1	0	2
		DAY 57	17JUN2003	56	13	-3	2	2	2	3	2	0	2
		FINAL	17JUN2003	56	13	-3	2	2	2	3	2	0	2
	E0023027	DAY 1	16MAY2003	1	10		2	3	0	1	1	0	3
		DAY 29	11JUN2003	27	7	-3	1	0	0	1	2	0	3
		DAY 57	09JUL2003	55	13	3	3	3	1	2	1	0	3
		FINAL	09JUL2003	55	13	3	3	3	1	2	1	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0022073	DAY 1	26JUN2003	1	1:00	120	9:00	4	3	2	2	1	0	1	1	0	1	
		DAY 29	24JUL2003	29	23:30	30	9:00	8	1	0	0	1	0	0	2	0	1	
		DAY 57	21AUG2003	57	23:00	30	8:00	8	1	1	0	1	1	0	2	0	0	
		FINAL	21AUG2003	57	23:00	30	8:00	8	1	1	0	1	1	0	2	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	DAY 1	05NOV2002	1	23:00	5	8:15	9										
		DAY 29	03DEC2002	29	23:00	5	8:15	9	0	0	0	0	0	0	0	0	0	
		FINAL	03DEC2002	29	23:00	5	8:15	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	DAY 1	25MAR2003	1	11:00	15	5:45	6	0	0	0	0	0	0	0	0	0	
		DAY 29	24APR2003	31	23:30	15	5:45	6	0	0	0	0	0	0	0	0	0	
		DAY 57	22MAY2003	59	23:00	10	7:45	8	0	0	0	0	0	0	0	0	0	
		FINAL	22MAY2003	59	23:00	10	7:45	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	DAY 1	23APR2003	1	22:30	40	6:00	2	3	3	0	2	3	1	1	2	0	
		DAY 29	20MAY2003	28	22:00	15	6:00	7	0	1	0	3	1	1	1	0	2	
		DAY 57	17JUN2003	56	21:30	30	8:00	5	3	3	0	2	2	0	0	0	3	
		FINAL	17JUN2003	56	21:30	30	8:00	5	3	3	0	2	2	0	0	0	3	
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	DAY 1	16MAY2003	1	1:00	45	10:30	8	3	2	0	1	0	0	2	2	2	
		DAY 29	11JUN2003	27	21:30	10	10:00	10	0	3	2	3	2	0	3	0	3	
		DAY 57	09JUL2003	55	23:30	60	10:00	7	3	2	0	0	0	0	2	0	0	
		FINAL	09JUL2003	55	23:30	60	10:00	7	3	2	0	0	0	0	2	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0022073	DAY 1	26JUN2003	1	2	3	0						
		DAY 29	24JUL2003	29	0	1	0						
		DAY 57	21AUG2003	57	0	1	0						
		FINAL	21AUG2003	57	0	1	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	DAY 1	05NOV2002	1	1	1	0						
		DAY 29	03DEC2002	29	1	1	0						
		FINAL	03DEC2002	29	1	1	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	DAY 1	25MAR2003	1	0	2	0						
		DAY 29	24APR2003	31	1	0	1	0	0	0	0		
		DAY 57	22MAY2003	59	0	0	1	0	0	0	0		
		FINAL	22MAY2003	59	0	0	1	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	DAY 1	23APR2003	1	0	3	1	3	0	0	0		
		DAY 29	20MAY2003	28	2	2	2	2	0	2	1		
		DAY 57	17JUN2003	56	1	3	2	2	0	0	1		
		FINAL	17JUN2003	56	1	3	2	2	0	0	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	DAY 1	16MAY2003	1	3	3	3	2	0	0	0		
		DAY 29	11JUN2003	27	3	3	3	2	2	0	0		
		DAY 57	09JUL2003	55	3	3	3	0	0	0	0		
		FINAL	09JUL2003	55	3	3	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	DAY 1	03JUN2003	1	6		1	0	1	0	1	0	3
		DAY 29	01JUL2003	29	7	1	0	0	0	3	1	0	3
		DAY 57	30JUL2003	58	0	-6	0	0	0	0	0	0	0
		FINAL	30JUL2003	58	0	-6	0	0	0	0	0	0	0
	E0023040	DAY 1	03JUL2003	1	14		3	3	3	1	2	0	2
		DAY 29	05AUG2003	34	7	-7	1	0	1	3	1	0	1
		DAY 57	05SEP2003	65	7	-7	1	3	1	0	1	0	1
		FINAL	05SEP2003	65	7	-7	1	3	1	0	1	0	1
	E0026014	DAY 1	19FEB2003	1	8		1	2	0	0	1	3	1
		DAY 29	19MAR2003	29	11	3	1	1	1	0	2	3	3
		FINAL	19MAR2003	29	11	3	1	1	1	0	2	3	3
	E0026019	DAY 1	17MAR2003	1	8		1	2	1	0	1	0	3
		DAY 29	14APR2003	29	4	-4	1	1	0	0	2	0	0
		DAY 57	12MAY2003	57	6	-2	1	1	2	0	1	0	1
		FINAL	12MAY2003	57	6	-2	1	1	2	0	1	0	1
	E0027005	DAY 1	26DEC2002	1	12		3	0	2	1	1	3	2
		DAY 29	23JAN2003	29	6	-6	0	1	0	0	1	3	1
		DAY 57	20FEB2003	57	8	-4	1	0	0	0	2	2	3
		FINAL	20FEB2003	57	8	-4	1	0	0	0	2	2	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	DAY 1	03JUN2003	1	22:30	10	5:00	6	0	2	0	0	3	0	0	0	1	
		DAY 29	01JUL2003	29	10:15	1	6:00	8	0	1	0	1	0	0	0	0	0	
		DAY 57	30JUL2003	58	22:00	1	6:30	8	0	0	0	0	0	0	0	0	0	
		FINAL	30JUL2003	58	22:00	1	6:30	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0023040	DAY 1	03JUL2003	1	0:30	45	5:30	4	3	3	0	0	0	0	2	3	2	
		DAY 29	05AUG2003	34	12:00	10	7:30	7	0	0	0	1	0	0	1	1	0	
		DAY 57	05SEP2003	65	23:30	35	6:30	6	3	1	0	0	0	0	0	1	0	
		FINAL	05SEP2003	65	23:30	35	6:30	6	3	1	0	0	0	0	0	1	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	DAY 1	19FEB2003	1	20:00	15	4:00	8	3	2	1	0	2	3	1	0	0	
		DAY 29	19MAR2003	29	21:00	20	5:00	7	0	2	1	2	3	3	0	2	0	
		FINAL	19MAR2003	29	21:00	20	5:00	7	0	2	1	2	3	3	0	2	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0026019	DAY 1	17MAR2003	1	20:45	60	3:00	7	2	3	1	0	0	1	0	0	0	
		DAY 29	14APR2003	29	21:00	30	6:00	10	0	3	3	1	3	1	1	0	0	
		DAY 57	12MAY2003	57	0:00	15	5:30	5	1	3	0	0	0	1	1	0	0	
		FINAL	12MAY2003	57	0:00	15	5:30	5	1	3	0	0	0	1	1	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0027005	DAY 1	26DEC2002	1	20:30	5	2:30	5	0	3	0	0	0	0	0	0	0	
		DAY 29	23JAN2003	29	22:00	20	6:30	8	0	3	3	0	0	3	0	0	0	
		DAY 57	20FEB2003	57	20:00	15	5:00	10	0	3	3	0	0	2	0	1	0	3 ACID REFLUX
		FINAL	20FEB2003	57	20:00	15	5:00	10	0	3	3	0	0	2	0	1	0	3 ACID REFLUX

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0023030	DAY 1	03JUN2003	1	3	2	3	3	0	0	2		
		DAY 29	01JUL2003	29	3	2	3	0	0	0	0		
		DAY 57	30JUL2003	58	0	0	3	2	0	0	0		
		FINAL	30JUL2003	58	0	0	3	2	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0023040	DAY 1	03JUL2003	1	0	3	0						
		DAY 29	05AUG2003	34	0	2	0						
		DAY 57	05SEP2003	65	0	2	0						
		FINAL	05SEP2003	65	0	2	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	DAY 1	19FEB2003	1	0	2	0						
		DAY 29	19MAR2003	29	2	3	0						
		FINAL	19MAR2003	29	2	3	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0026019	DAY 1	17MAR2003	1	3	2	0						
		DAY 29	14APR2003	29	0	0	1	0	0	0	0		
		DAY 57	12MAY2003	57	0	1	2	0	0	0	0		
		FINAL	12MAY2003	57	0	1	2	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0027005	DAY 1	26DEC2002	1	0	3	1	0	0	0	0	3	CONSTANTLY TOSS AND TURN WHICH CAUSES DOG TO MOVE AROUND
		DAY 29	23JAN2003	29	0	1	0						
		DAY 57	20FEB2003	57	3	3	1						
		FINAL	20FEB2003	57	3	3	1						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	DAY 1	20JAN2003	1	8		2	2	1	0	1	0	2
		DAY 29	17FEB2003	29	1	-7	0	0	0	0	0	0	1
		DAY 57	18MAR2003	58	2	-6	1	0	0	0	0	0	1
		FINAL	18MAR2003	58	2	-6	1	0	0	0	0	0	1
	E0029021	DAY 1	18MAR2003	1	6		2	0	1	0	1	0	2
		DAY 29	15APR2003	29	3	-3	0	0	1	0	1	0	1
		DAY 57	15MAY2003	59	3	-3	1	0	1	0	0	0	1
		FINAL	15MAY2003	59	3	-3	1	0	1	0	0	0	1
	E0029026	DAY 1	14APR2003	1	9		1	0	2	2	1	2	1
		DAY 29	12MAY2003	29	0	-9	0	0	0	0	0	0	0
		DAY 57	10JUN2003	58	0	-9	0	0	0	0	0	0	0
		FINAL	10JUN2003	58	0	-9	0	0	0	0	0	0	0
	E0029030	DAY 1	27MAY2003	1	8		2	2	1	0	1	0	2
		DAY 29	26JUN2003	31	3	-5	0	0	1	0	0	0	2
		DAY 57	23JUL2003	58	2	-6	1	1	0	0	0	0	0
		FINAL	23JUL2003	58	2	-6	1	1	0	0	0	0	0
	E0031008	DAY 1	28FEB2003	1	16		2	3	1	3	2	3	2
		DAY 29	28MAR2003	29	10	-6	1	1	1	3	2	0	2
		DAY 57	24APR2003	56	8	-8	1	1	1	3	1	0	1
		FINAL	24APR2003	56	8	-8	1	1	1	3	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	DAY 1	20JAN2003	1	1:00	30	8:00	6	2	3	1	0	0	1	0	1	0	
		DAY 29	17FEB2003	29	22:30	5	8:30	10	0	0	0	0	0	0	0	0	0	
		DAY 57	18MAR2003	58	22:30	10	7:00	8	0	0	0	0	0	0	0	0	0	
		FINAL	18MAR2003	58	22:30	10	7:00	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	DAY 1	18MAR2003	1	22:00	10	5:00	6	0	2	0	1	3	0	0	1	0	
		DAY 29	15APR2003	29	22:00	10	5:00	7	0	0	0	0	1	0	0	0	0	
		DAY 57	15MAY2003	59	22:15	10	5:30	7	0	0	0	0	0	0	0	0	0	
		FINAL	15MAY2003	59	22:15	10	5:30	7	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	DAY 1	14APR2003	1	22:00	15	5:30	5	0	3	1	0	0	0	0	0	0	
		DAY 29	12MAY2003	29	22:30	10	8:00	9	0	0	0	0	0	0	0	0	0	
		DAY 57	10JUN2003	58	22:00	10	7:00	9	0	0	0	0	0	0	0	0	0	
		FINAL	10JUN2003	58	22:00	10	7:00	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	DAY 1	27MAY2003	1	1:00	45	7:00	6	2	1	1	0	0	1	3	1	2	
		DAY 29	26JUN2003	31	0:00	10	7:30	7	0	0	0	0	0	0	0	0	0	
		DAY 57	23JUL2003	58	23:00	30	8:00	8	0	0	0	0	0	0	0	0	0	
		FINAL	23JUL2003	58	23:00	30	8:00	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 300 MG (BIPOLAR II)	E0031008	DAY 1	28FEB2003	1	23:00	60	9:00	6	3	3	3	0	0	0	0	2	2	
		DAY 29	28MAR2003	29	23:00	30	10:00	6	1	3	2	0	0	0	0	3	2	
		DAY 57	24APR2003	56	23:00	30	11:00	7	1	1	2	0	0	0	0	2	0	
		FINAL	24APR2003	56	23:00	30	11:00	7	1	1	2	0	0	0	0	2	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	DAY 1	20JAN2003	1	0	3	0						
		DAY 29	17FEB2003	29	0	1	0						
		DAY 57	18MAR2003	58	0	1	0						
		FINAL	18MAR2003	58	0	1	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0029021	DAY 1	18MAR2003	1	0	3	3	3	0	2	0		
		DAY 29	15APR2003	29	0	2	3	3	0	1	0		
		DAY 57	15MAY2003	59	0	1	3	3	0	0	0		
		FINAL	15MAY2003	59	0	1	3	3	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	DAY 1	14APR2003	1	0	2	3	0	0	0	0		
		DAY 29	12MAY2003	29	0	0	3	0	0	0	0		
		DAY 57	10JUN2003	58	0	0	3	0	0	0	0		
		FINAL	10JUN2003	58	0	0	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	DAY 1	27MAY2003	1	2	2	0						
		DAY 29	26JUN2003	31	3	0	0						
		DAY 57	23JUL2003	58	0	0	0						
		FINAL	23JUL2003	58	0	0	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0031008	DAY 1	28FEB2003	1	0	3	0						
		DAY 29	28MAR2003	29	0	3	0						
		DAY 57	24APR2003	56	0	2	0						
		FINAL	24APR2003	56	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	DAY 1	21APR2003	1	13		2	2	2	3	2	0	2
		DAY 29	13MAY2003	23	7	-6	0	0	0	0	1	3	3
		FINAL	13MAY2003	23	7	-6	0	0	0	0	1	3	3
	E0031021	DAY 1	25APR2003	1	12		1	3	3	3	1	0	1
		DAY 29	23MAY2003	29	4	-8	1	1	0	0	1	0	1
		DAY 57	19JUN2003	56	11	-1	2	2	3	3	1	0	0
		FINAL	19JUN2003	56	11	-1	2	2	3	3	1	0	0
	E0031029	DAY 1	18JUN2003	1	16		2	3	2	3	2	1	3
	E0033002	DAY 1	10JAN2003	1	18		3	3	3	3	2	3	1
		DAY 29	06FEB2003	28	7	-11	0	1	0	0	2	3	1
		DAY 57	07MAR2003	57	5	-13	1	1	0	0	2	0	1
		FINAL	07MAR2003	57	5	-13	1	1	0	0	2	0	1
	E0033006	DAY 1	23JAN2003	1	10		2	3	1	0	2	0	2
	E0033021	DAY 1	02JUL2003	1	19		3	3	3	3	2	3	2
		DAY 29	01AUG2003	31	9	-10	1	1	1	0	2	1	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	DAY 1	21APR2003	1	21:30	45	8:00	5	2	3	3	1	0	0	0	2	0	2	ACID REFLUX
		DAY 29	13MAY2003	23	21:00	10	8:00	11	0	1	2	0	0	0	0	2	0		
		FINAL	13MAY2003	23	21:00	10	8:00	11	0	1	2	0	0	0	0	2	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 1	25APR2003	1	21:00	100	10:00	4	3	3	3	0	0	0	0	0	1		
		DAY 29	23MAY2003	29	0:00	35	13:00	12	0	2	3	0	0	0	0	0	0		
		DAY 57	19JUN2003	56	0:00	60	13:00	4	2	2	1	0	0	0	0	0	0		
		FINAL	19JUN2003	56	0:00	60	13:00	4	2	2	1	0	0	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0031029	DAY 1	18JUN2003	1	22:00	240	7:00	5	3	3	3	3	0	0	0	0	2	3	BRAIN WON'T SHUT OFF
QUETIAPINE 300 MG (BIPOLAR II)	E0033002	DAY 1	10JAN2003	1	23:30	240	6:00	4	3	3	3	1	3	0	3	1	1		
		DAY 29	06FEB2003	28	22:00	30	8:00	9	1	2	2	3	3	0	2	0	3		
		DAY 57	07MAR2003	57	22:00	10	9:00	10	1	1	0	1	3	1	2	2	0		
		FINAL	07MAR2003	57	22:00	10	9:00	10	1	1	0	1	3	1	2	2	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0033006	DAY 1	23JAN2003	1	0:00	90	7:00	6	3	3	3	2	3	0	0	1	2	3	RACING THOUGHTS, NOT SLEEPY
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	DAY 1	02JUL2003	1	4:00	120	12:00	4	3	3	0	2	0	3	3	0	2	3	SHAKING OR HEADACHE
		DAY 29	01AUG2003	31	0:00	30	6:00	6	0	0	2	1	0	2	2	2	3	3	LEG CRAMPS IN CALFS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	DAY 1	21APR2003	1	0	3	3	0	0	0	0		
		DAY 29	13MAY2003	23	2	3	3	0	0	0	0		
		FINAL	13MAY2003	23	2	3	3	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 1	25APR2003	1	0	2	0						
		DAY 29	23MAY2003	29	0	1	0						
		DAY 57	19JUN2003	56	0	0	0						
		FINAL	19JUN2003	56	0	0	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0031029	DAY 1	18JUN2003	1	2	3	3	1	0	1	1	2	LAY AWAKE AT NIGHT WHILE WIFE SLEEPS
QUETIAPINE 300 MG (BIPOLAR II)	E0033002	DAY 1	10JAN2003	1	0	2	0						
		DAY 29	06FEB2003	28	0	1	0						
		DAY 57	07MAR2003	57	0	1	0						
		FINAL	07MAR2003	57	0	1	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0033006	DAY 1	23JAN2003	1	1	2	3	3	2	3	3	3	TOSSING AND TURNING
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	DAY 1	02JUL2003	1	0	3	0						
		DAY 29	01AUG2003	31	3	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	FINAL	01AUG2003	31	9	-10	1	1	1	0	2	1	3
	E0035013	DAY 1	04FEB2003	1	12		1	3	1	3	1	3	0
		DAY 29	10FEB2003	7	10	-2	1	1	1	3	1	3	0
		FINAL	10FEB2003	7	10	-2	1	1	1	3	1	3	0
	E0035015	DAY 1	11FEB2003	1	6		1	0	1	1	2	0	1
		DAY 29	18FEB2003	8	9	3	1	0	1	2	2	0	3
		FINAL	18FEB2003	8	9	3	1	0	1	2	2	0	3
	E0035016	DAY 1	04APR2003	1	10		2	2	0	2	1	0	3
	E0035023	DAY 1	13MAY2003	1	15		2	2	1	3	1	3	3
		DAY 29	10JUN2003	29	4	-11	1	0	0	0	2	0	1
		FINAL	10JUN2003	29	4	-11	1	0	0	0	2	0	1
	E0039052	DAY 1	20JUN2003	1	13		3	3	2	2	2	0	1
		DAY 29	03JUL2003	14	12	-1	0	2	2	3	1	1	3
		FINAL	03JUL2003	14	12	-1	0	2	2	3	1	1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	FINAL	01AUG2003	31	0:00	30	6:00	6	0	0	2	1	0	2	2	2	3	3	LEG CRAMPS IN CALFS
QUETIAPINE 300 MG (BIPOLAR II)	E0035013	DAY 1	04FEB2003	1	22:00	35	8:00	6	3	3	2	0	0	0	0	0	0		
		DAY 29	10FEB2003	7	20:00	30	6:00	6	1	2	2	0	1	0	0	0	0		
		FINAL	10FEB2003	7	20:00	30	6:00	6	1	2	2	0	1	0	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0035015	DAY 1	11FEB2003	1	22:00	10	6:00	6	0	0	1	2	2	2	2	1	0		
		DAY 29	18FEB2003	8	22:00	10	7:30	7	0	0	1	2	2	2	2	1	0		
		FINAL	18FEB2003	8	22:00	10	7:30	7	0	0	1	2	2	2	2	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0035016	DAY 1	04APR2003	1	23:00	30	10:00	8	3	2	0	0	0	0	0	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0035023	DAY 1	13MAY2003	1	21:00	30	7:00	6	3	3	2	0	0	0	0	2	2		
		DAY 29	10JUN2003	29	21:00	5	7:30	10	0	2	3	0	0	1	1	3	1		
		FINAL	10JUN2003	29	21:00	5	7:30	10	0	2	3	0	0	1	1	3	1		
QUETIAPINE 300 MG (BIPOLAR II)	E0039052	DAY 1	20JUN2003	1	23:00	90	6:00	5	3	3	3	0	2	0	2	3	0		
		DAY 29	03JUL2003	14	21:00	30	6:30	5	3	2	2	0	0	1	1	1	0		
		FINAL	03JUL2003	14	21:00	30	6:30	5	3	2	2	0	0	1	1	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0033021	FINAL	01AUG2003	31	3	2	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0035013	DAY 1	04FEB2003	1	0	0	0						
		DAY 29	10FEB2003	7	0	0	0						
		FINAL	10FEB2003	7	0	0	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0035015	DAY 1	11FEB2003	1	0	2	0						
		DAY 29	18FEB2003	8	3	2	0						
		FINAL	18FEB2003	8	3	2	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0035016	DAY 1	04APR2003	1	2	3	3	1	0	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0035023	DAY 1	13MAY2003	1	2	3	0						
		DAY 29	10JUN2003	29	0	2	3	1	1	1	0		
		FINAL	10JUN2003	29	0	2	3	1	1	1	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0039052	DAY 1	20JUN2003	1	0	2	3						
		DAY 29	03JUL2003	14	3	2	3						
		FINAL	03JUL2003	14	3	2	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 300 MG (BIPOLAR II)	E0039056	DAY 1	14JUL2003	-1	9		2	3	3	0	1	0	0
	E0040003	DAY 1	18JUL2003	-1	15		2	3	2	3	1	2	2
		DAY 29	15AUG2003	28	11	-4	2	2	0	3	1	2	1
		DAY 57	12SEP2003	56	16	1	3	3	1	3	1	3	2
		FINAL	12SEP2003	56	16	1	3	3	1	3	1	3	2
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	15		3	3	1	2	2	2	2
		DAY 29	01APR2003	30	4	-11	0	2	0	0	1	0	1
		DAY 57	02MAY2003	61	5	-10	0	2	1	0	1	0	1
		FINAL	02MAY2003	61	5	-10	0	2	1	0	1	0	1
	E0002011	DAY 1	29APR2003	1	6		2	1	0	0	2	0	1
		DAY 29	29MAY2003	31	5	-1	2	0	0	0	1	0	2
		DAY 57	25JUN2003	58	4	-2	1	1	0	0	1	0	1
		FINAL	25JUN2003	58	4	-2	1	1	0	0	1	0	1
	E0003010	DAY 1	03FEB2003	1	18		3	3	3	3	1	3	2
		DAY 29	03MAR2003	29	6	-12	0	2	0	1	1	0	2
		DAY 57	31MAR2003	57	3	-15	0	1	0	0	1	0	1
		FINAL	31MAR2003	57	3	-15	0	1	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0039056	DAY 1	14JUL2003	-1	3:30	60	8:00	4	3	2	0	0	0	1	0	0	0		
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	DAY 1	18JUL2003	-1	23:00	50	8:30	5	3	2	1	0	0	1	1	2	0		
		DAY 29	15AUG2003	28	23:30	15	12:00	8	3	3	3	0	0	0	0	0	0		
		DAY 57	12SEP2003	56	23:00	60	12:00	6	3	3	3	0	0	0	0	0	0		
		FINAL	12SEP2003	56	23:00	60	12:00	6	3	3	3	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	23:30	120	9:00	7	3	3	1	0	3	0	3	2	0	3	RESTLESNES, MIND IS SPINNING WITH THOUGHTS
		DAY 29	01APR2003	30	23:00	60	8:00	8	1	0	0	0	2	0	0	1	0		
		DAY 57	02MAY2003	61	23:00	60	7:00	7	1	0	0	0	3	0	1	2	0		
		FINAL	02MAY2003	61	23:00	60	7:00	7	1	0	0	0	3	0	1	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0002011	DAY 1	29APR2003	1	23:00	10	7:30	9	1	1	3	1	3	1	2	3	1		
		DAY 29	29MAY2003	31	23:00	10	7:30	9	0	1	2	0	0	1	0	3	0		
		DAY 57	25JUN2003	58	23:00	20	7:30	8	1	1	2	0	0	0	1	0	0		
		FINAL	25JUN2003	58	23:00	20	7:30	8	1	1	2	0	0	0	1	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	DAY 1	03FEB2003	1	22:00	90	6:30	3	3	3	1	0	0	0	2	3	0		
		DAY 29	03MAR2003	29	22:00	35	9:15	9	1	0	3	2	0	0	2	0	2		
		DAY 57	31MAR2003	57	21:00	20	7:30	10	1	1	3	0	0	0	1	0	0		
		FINAL	31MAR2003	57	21:00	20	7:30	10	1	1	3	0	0	0	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 300 MG (BIPOLAR II)	E0039056	DAY 1	14JUL2003	-1	0	0	0						
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	DAY 1	18JUL2003	-1	2	2	0						
		DAY 29	15AUG2003	28	0	2	0						
		DAY 57	12SEP2003	56	0	3	0						
		FINAL	12SEP2003	56	0	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	0	3	3	2	0	0	0	3	RACING THOUGHTS WORRISOME; HYPERACTIVITY
		DAY 29	01APR2003	30	0	1	3	2	0	0	0		
		DAY 57	02MAY2003	61	0	1	3	3	0	0	0		
		FINAL	02MAY2003	61	0	1	3	3	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0002011	DAY 1	29APR2003	1	0	2	3	3	0	3	0	3	CRYING, SCREAMING, TALKING
		DAY 29	29MAY2003	31	1	2	3	3	0	3	2	3	WHOLE BODY JERKING MOVEMENT
		DAY 57	25JUN2003	58	0	1	3	2	0	0	3		
		FINAL	25JUN2003	58	0	1	3	2	0	0	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	DAY 1	03FEB2003	1	0	3	3	0	0	0	0		
		DAY 29	03MAR2003	29	2	2	3	0	0	0	0		
		DAY 57	31MAR2003	57	1	0	3	0	0	0	0		
		FINAL	31MAR2003	57	1	0	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	DAY 1	04FEB2003	1	12		2	3	2	1	2	0	2
	E0003016	DAY 1	22MAY2003	1	9		2	2	1	1	1	0	2
		DAY 29	13JUN2003	23	15	6	3	2	3	3	2	0	2
		FINAL	13JUN2003	23	15	6	3	2	3	3	2	0	2
	E0003019	DAY 1	27JUN2003	1	14		2	3	1	0	3	3	2
		DAY 57	21AUG2003	56	6	-8	0	0	0	3	1	0	2
		FINAL	21AUG2003	56	6	-8	0	0	0	3	1	0	2
	E0003020	DAY 1	23JUL2003	1	9		2	3	2	0	1	0	1
		DAY 29	20AUG2003	29	5	-4	1	1	1	0	1	0	1
		DAY 57	17SEP2003	57	3	-6	1	0	0	0	1	0	1
		FINAL	17SEP2003	57	3	-6	1	0	0	0	1	0	1
	E0004001	DAY 1	23SEP2002	-7	13		2	3	2	1	2	0	3
		DAY 29	28OCT2002	29	6	-7	1	1	0	1	1	0	2
		FINAL	28OCT2002	29	6	-7	1	1	0	1	1	0	2
	E0004009	DAY 1	26DEC2002	1	6		1	1	1	0	1	0	2
		DAY 29	22JAN2003	28	2	-4	0	1	0	0	1	0	0

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	DAY 1	04FEB2003	1	0:00	40	6:30	5	3	3	3	1	0	0	2	2	2	
QUETIAPINE 600 MG (BIPOLAR I)	E0003016	DAY 1	22MAY2003	1	22:00	30	6:45	7	3	1	0	0	0	1	2	2	0	
		DAY 29	13JUN2003	23	22:00	45	6:45	4	1	3	1	1	2	0	2	3	0	
		FINAL	13JUN2003	23	22:00	45	6:45	4	1	3	1	1	2	0	2	3	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	DAY 1	27JUN2003	1	0:30	60	6:30	6	3	3	3	3	3	3	2	3	0	
		DAY 57	21AUG2003	56	10:00	15	8:00	10	0	2	0	1	0	0	0	0	0	
		FINAL	21AUG2003	56	10:00	15	8:00	10	0	2	0	1	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	DAY 1	23JUL2003	1	0:30	60	5:45	5	3	3	0	0	0	0	0	3	2	
		DAY 29	20AUG2003	29	0:00	25	5:00	6	0	2	1	0	0	0	0	2	0	
		DAY 57	17SEP2003	57	23:00	15	7:00	8	0	0	1	0	0	0	0	0	1	
		FINAL	17SEP2003	57	23:00	15	7:00	8	0	0	1	0	0	0	0	0	1	
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	DAY 1	23SEP2002	-7	23:00	60	5:15	5	3	2	3	2	2	3	2	1	2	
		DAY 29	28OCT2002	29	20:00	30	7:00	9	0	0	0	0	0	0	0	0	2	
		FINAL	28OCT2002	29	20:00	30	7:00	9	0	0	0	0	0	0	0	0	2	
QUETIAPINE 600 MG (BIPOLAR I)	E0004009	DAY 1	26DEC2002	1	23:00	15	7:00	7	1	2	0	0	0	0	0	0	2	
		DAY 29	22JAN2003	28	23:00	25	8:30	9	1	0	0	0	0	0	0	3	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	DAY 1	04FEB2003	1	0	3	3	0	0	2	1	1	SOMETIMES PARTNER REPORTS PT. CUSSES/TALKS IN HER SLEEP
QUETIAPINE 600 MG (BIPOLAR I)	E0003016	DAY 1	22MAY2003	1	0	3	0						
		DAY 29	13JUN2003	23	0	3	0						
		FINAL	13JUN2003	23	0	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	DAY 1	27JUN2003	1	0	3	0						
		DAY 57	21AUG2003	56	0	3	0						
		FINAL	21AUG2003	56	0	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	DAY 1	23JUL2003	1	0	1	0						
		DAY 29	20AUG2003	29	0	2	0						
		DAY 57	17SEP2003	57	0	1	0						
		FINAL	17SEP2003	57	0	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	DAY 1	23SEP2002	-7	3	3	3	0	0	2	0		
		DAY 29	28OCT2002	29	2	2	3						
		FINAL	28OCT2002	29	2	2	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0004009	DAY 1	26DEC2002	1	0	3	3						
		DAY 29	22JAN2003	28	0	0	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0004009	DAY 57		19FEB2003	56	1	-5	0	0	0	0	1	0	0
		FINAL		19FEB2003	56	1	-5	0	0	0	0	1	0	0
	E0004012	DAY 1		14JAN2003	1	12		2	3	2	2	2	0	1
		DAY 29		11FEB2003	29	4	-8	1	1	1	0	1	0	0
		DAY 57		11MAR2003	57	3	-9	0	1	1	0	0	0	1
		FINAL		11MAR2003	57	3	-9	0	1	1	0	0	0	1
	E0004015	DAY 1		20FEB2003	1	11		2	0	2	3	2	0	2
		DAY 29		18MAR2003	27	1	-10	0	0	0	0	0	0	1
		DAY 57		15APR2003	55	0	-11	0	0	0	0	0	0	0
		FINAL		15APR2003	55	0	-11	0	0	0	0	0	0	0
	E0005003	DAY 1		23SEP2002	-9	2		0	0	0	0	1	0	1
		DAY 29		30OCT2002	29	8	6	1	1	0	1	1	1	3
		DAY 57		26NOV2002	56	6	4	1	2	0	0	2	0	1
		FINAL		26NOV2002	56	6	4	1	2	0	0	2	0	1
	E0005005	DAY 1		24SEP2002	-6	14		2	3	2	3	1	1	2
	E0005007	DAY 1	*	02OCT2002	-7	19		3	3	3	1	3	3	3
		DAY 1		09OCT2002	1	20		3	3	3	3	2	3	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0004009	DAY 57	19FEB2003	56	23:00	15	9:30	9	0	0	0	0	0	0	0	2	0		
		FINAL	19FEB2003	56	23:00	15	9:30	9	0	0	0	0	0	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	DAY 1	14JAN2003	1	23:30	60	6:45	5	3	3	0	0	0	3	3	1	0	3	GRINDING TEETH
		DAY 29	11FEB2003	29	23:30	20	6:30	7	0	0	0	0	0	0	0	0	0	2	DRY MOUTH
		DAY 57	11MAR2003	57	23:00	20	6:30	7	0	0	0	0	0	0	0	0	0		
		FINAL	11MAR2003	57	23:00	20	6:30	7	0	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	DAY 1	20FEB2003	1	22:30	10	6:15	5	0	3	1	1	3	1	1	1	1		
		DAY 29	18MAR2003	27	22:30	15	6:15	8	0	0	0	0	0	0	0	0	0		
		DAY 57	15APR2003	55	23:00	0	6:30	8	0	0	0	0	0	0	0	0	0		
		FINAL	15APR2003	55	23:00	0	6:30	8	0	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	DAY 1	23SEP2002	-9	23:30	1	7:00	8	0	0	3	0	0	0	0	0	0		
		DAY 29	30OCT2002	29	22:00	5	8:00	8	1	1	3	3	0	0	0	0	1		
		DAY 57	26NOV2002	56	23:00	200	8:00	8	1	2	3	1	2	0	0	2	0		
		FINAL	26NOV2002	56	23:00	200	8:00	8	1	2	3	1	2	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	DAY 1	24SEP2002	-6	12:00	120	5:00	5	3	3	0	0	0	2	0	1	0	2	STRESSED OUT
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 1 *	02OCT2002	-7	0:00	60	2:30	2	3	3	3	1	3	1	1	3	2	3	CAN'T SJUT MY BRAIN OFF.
		DAY 1	09OCT2002	1	22:00	120	5:00	3	3	3	0	0	3	0	3	3	3		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0004009	DAY 57		19FEB2003	56	0	0	3						
		FINAL		19FEB2003	56	0	0	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	DAY 1		14JAN2003	1	0	2	3						
		DAY 29		11FEB2003	29	0	0	3						
		DAY 57		11MAR2003	57	0	1	3						
		FINAL		11MAR2003	57	0	1	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	DAY 1		20FEB2003	1	2	2	3						
		DAY 29		18MAR2003	27	0	1	3						
		DAY 57		15APR2003	55	0	0	3						
		FINAL		15APR2003	55	0	0	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	DAY 1		23SEP2002	-9	0	1							
		DAY 29		30OCT2002	29	2	3	3						
		DAY 57		26NOV2002	56	1	1	3						
		FINAL		26NOV2002	56	1	1	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	DAY 1		24SEP2002	-6	1	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 1	*	02OCT2002	-7	3	3	3						
		DAY 1		09OCT2002	1	3	3	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 29	06NOV2002	29	17	-3	3	3	3	3	2	2	1
		DAY 57	04DEC2002	57	16	-4	2	3	2	2	1	3	3
		FINAL	04DEC2002	57	16	-4	2	3	2	2	1	3	3
	E0005008	DAY 1	15OCT2002	1	10		1	3	1	0	2	0	3
		DAY 29	13NOV2002	30			0	3	0	0		0	3
		DAY 57	11DEC2002	58	6	-4	1	2	0	0	2	0	1
		FINAL	11DEC2002	58	6	-4	1	2	0	0	2	0	1
	E0005009	DAY 1	29OCT2002	1	5		1	1	0	0	2	0	1
	E0005010	DAY 1	21OCT2002	1	9		2	2	1	2	1	0	1
		DAY 29	19NOV2002	30	4	-5	1	1	0	0	1	0	1
		DAY 57	17DEC2002	58	1	-8	0	1	0	0	0	0	0
		FINAL	17DEC2002	58	1	-8	0	1	0	0	0	0	0
	E0005012	DAY 1	14NOV2002	1	14		3	3	1	2	1	2	2
		DAY 29	10DEC2002	27	7	-7	1	1	1	0	1	1	2
		DAY 57	07JAN2003	55	10	-4	2	2	1	1	1	2	1
		FINAL	07JAN2003	55	10	-4	2	2	1	1	1	2	1
	E0005014	DAY 1	13NOV2002	1	15		3	3	3	2	1	0	3

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 29	06NOV2002	29	22:00	90	7:00	4	3	3	2	0	3	0	2	0	3	
		DAY 57	04DEC2002	57	22:30	90	5:30	5	3	3	1	0	0	0	0	0	3	
		FINAL	04DEC2002	57	22:30	90	5:30	5	3	3	1	0	0	0	0	0	3	
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	DAY 1	15OCT2002	1	22:40	130	4:30	7	2	3	3	0	0	2	2	1	3	
		DAY 29	13NOV2002	30	20:00	90	4:45	8	2	3	3	2		1	1	0	3	
		DAY 57	11DEC2002	58	20:00	60	4:30	9	2	2	3	0	3	1	1	0	2	
		FINAL	11DEC2002	58	20:00	60	4:30	9	2	2	3	0	3	1	1	0	2	
QUETIAPINE 600 MG (BIPOLAR I)	E0005009	DAY 1	29OCT2002	1	1:00	30	9:30	8	1	2	1	3	3	0	3	3	1	
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	DAY 1	21OCT2002	1	0:00	150	9:30	7	0	3	1	0	0	1	1	0	0	
		DAY 29	19NOV2002	30	0:00	30	9:30	9	1	1	0	0	0	0	0	0	0	
		DAY 57	17DEC2002	58	0:00	30	9:45	9	0	0	0	0	0	0	0	0	0	
		FINAL	17DEC2002	58	0:00	30	9:45	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0005012	DAY 1	14NOV2002	1	22:00	60	7:00	6	3	3	2	0	0	0	0	0	3	
		DAY 29	10DEC2002	27	23:00	25	6:30	7	1	1	2	0	0	0	0	0	3	
		DAY 57	07JAN2003	55	23:00	30	7:00	6	2	2	1	1	1	0	0	0	3	
		FINAL	07JAN2003	55	23:00	30	7:00	6	2	2	1	1	1	0	0	0	3	
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 1	13NOV2002	1	2:30	60	7:00	3	3	3	0	1	0	0	2	0	0	3 HEART RACING

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 29	06NOV2002	29	0	2	0						
		DAY 57	04DEC2002	57	3	3	3						
		FINAL	04DEC2002	57	3	3	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	DAY 1	15OCT2002	1	2	3	0						
		DAY 29	13NOV2002	30	3	2	0						
		DAY 57	11DEC2002	58	0	1	0						
		FINAL	11DEC2002	58	0	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0005009	DAY 1	29OCT2002	1	1	1	3	1	0	0	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	DAY 1	21OCT2002	1	0	2	0						
		DAY 29	19NOV2002	30	0	1	0						
		DAY 57	17DEC2002	58	0	0	0						
		FINAL	17DEC2002	58	0	0	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0005012	DAY 1	14NOV2002	1	1	3	3	0	0	0	0	3	TIGHTNESS IN SHOULDERS
		DAY 29	10DEC2002	27	1	2	3	2	0	0	1	1	PAINFUL MUSCLES
		DAY 57	07JAN2003	55	0	2	3	1	0	0	1	2	TOSSING, TURNING
		FINAL	07JAN2003	55	0	2	3	1	0	0	1	2	TOSSING, TURNING
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 1	13NOV2002	1	2	3	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 29	11DEC2002	29	7	-8	1	1	2	0	1	0	2
		DAY 57	06JAN2003	55	6	-9	1	1	1	0	1	0	2
		FINAL	06JAN2003	55	6	-9	1	1	1	0	1	0	2
	E0005022	DAY 1	29JAN2003	1	9		2	3	0	1	1	0	2
		DAY 29	26FEB2003	29	3	-6	2	0	0	0	0	0	1
		DAY 29 *	06MAR2003	37	5	-4	2	1	0	0	1	0	1
		FINAL	06MAR2003	37	5	-4	2	1	0	0	1	0	1
	E0005025	DAY 1	27FEB2003	1	12		2	3	1	1	1	2	2
		DAY 29	03APR2003	36	7	-5	1	3	0	0	1	0	2
		FINAL	03APR2003	36	7	-5	1	3	0	0	1	0	2
	E0006019	DAY 1	07APR2003	1	8		2	1	1	1	1	0	2
		DAY 29	05MAY2003	29	6	-2	1	2	0	0	1	0	2
		DAY 57	03JUN2003	58	6	-2	1	2	0	1	1	0	1
		FINAL	03JUN2003	58	6	-2	1	2	0	1	1	0	1
	E0007005	DAY 1	31JAN2003	1	12		3	3	2	1	1	0	2
		DAY 29	03MAR2003	32	4	-8	1	1	0	0	1	0	1
		DAY 57	28MAR2003	57	6	-6	1	3	0	0	0	0	2
		FINAL	28MAR2003	57	6	-6	1	3	0	0	0	0	2

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 29		11DEC2002	29	2:30	15	7:00	5	2	2	2	0	0	0	2	0	0	
		DAY 57		06JAN2003	55	1:30	15	7:00	6	2	2	1	0	0	0	2	0	0	
		FINAL		06JAN2003	55	1:30	15	7:00	6	2	2	1	0	0	0	2	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0005022	DAY 1		29JAN2003	1	0:00	90	10:00	8	3	1	1	0	0	0	1	0	0	
		DAY 29		26FEB2003	29	1:00	5	10:00	9	0	0	0	0	0	0	0	0	0	
		DAY 29	*	06MAR2003	37	1:00	10	10:00	9	1	0	1	0	0	0	1	0	0	
		FINAL		06MAR2003	37	1:00	10	10:00	9	1	0	1	0	0	0	1	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0005025	DAY 1		27FEB2003	1	0:00	120	7:30	6	3	3	1	1	1	0	0	1	0	
		DAY 29		03APR2003	36	23:00	90	7:30	8	3	0	0	2	0	0	0	0	0	
		FINAL		03APR2003	36	23:00	90	7:30	8	3	0	0	2	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 1		07APR2003	1	23:59	10	8:30	7	2	2	0	0	0	1	0	0	0	
		DAY 29		05MAY2003	29	23:59	25	9:00	8	2	0	0	0	0	0	0	0	1	
		DAY 57		03JUN2003	58	23:30	20	9:00	8	2	0	0	0	0	0	0	0	1	
		FINAL		03JUN2003	58	23:30	20	9:00	8	2	0	0	0	0	0	0	0	1	
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	DAY 1		31JAN2003	1	2:30	60	9:00	5	3	3	3	0	0	0	0	1	1	
		DAY 29		03MAR2003	32	1:30	20	9:00	8	1	1	0	0	0	0	0	0	0	
		DAY 57		28MAR2003	57	2:00	45	12:00	10	3	0	0	0	0	0	0	0	0	
		FINAL		28MAR2003	57	2:00	45	12:00	10	3	0	0	0	0	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 29		11DEC2002	29	1	3	3						
		DAY 57		06JAN2003	55	1	2	3						
		FINAL		06JAN2003	55	1	2	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0005022	DAY 1		29JAN2003	1	1	2	3						
		DAY 29		26FEB2003	29	0	2	3						
		DAY 29	*	06MAR2003	37	0	2	3						
		FINAL		06MAR2003	37	0	2	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0005025	DAY 1		27FEB2003	1	0	3	3						
		DAY 29		03APR2003	36	0	3	3						
		FINAL		03APR2003	36	0	3	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 1		07APR2003	1	1	3	3	0	0	0	0		
		DAY 29		05MAY2003	29	1	2	3	0	0	0	0		
		DAY 57		03JUN2003	58	0	1	3	0	0	0	0		
		FINAL		03JUN2003	58	0	1	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	DAY 1		31JAN2003	1	1	3	0						
		DAY 29		03MAR2003	32	0	2	0						
		DAY 57		28MAR2003	57	0	3	0						
		FINAL		28MAR2003	57	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	DAY 1	16JUL2003	1	4		0	0	1	0	1	0	2
		DAY 29	13AUG2003	29	2	-2	0	1	0	0	0	0	1
		DAY 57	10SEP2003	57	2	-2	0	1	0	0	0	0	1
		FINAL	10SEP2003	57	2	-2	0	1	0	0	0	0	1
	E0009001	DAY 1	12NOV2002	1	14		3	3	3	1	2	1	1
		DAY 29	10DEC2002	29	11	-3	2	3	3	0	2	0	1
		FINAL	10DEC2002	29	11	-3	2	3	3	0	2	0	1
	E0010002	DAY 1	25NOV2002	1	13		1	3	1	1	2	3	2
		DAY 29	02DEC2002	8	12	-1	1	3	1	1	2	3	1
		FINAL	02DEC2002	8	12	-1	1	3	1	1	2	3	1
	E0010009	DAY 1	26DEC2002	1			1	1	1	2		0	1
		DAY 29	22JAN2003	28			0	2	0	0		0	1
		DAY 57	19FEB2003	56	3		0	1	0	0	1	0	1
		FINAL	19FEB2003	56	3		0	1	0	0	1	0	1
	E0010010	DAY 1	30DEC2002	1	5		1	0	0	0	1	0	3
		DAY 29	13JAN2003	15	13	8	2	3	1	2	2	0	3
		FINAL	13JAN2003	15	13	8	2	3	1	2	2	0	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	DAY 1	16JUL2003	1	23:00	10	6:30	7	0	0	1	0	3	0	0	0	0	
		DAY 29	13AUG2003	29	22:00	25	6:00	8	0	0	0	0	0	0	0	0	0	
		DAY 57	10SEP2003	57	22:00	20	6:30	8	0	0	0	0	0	0	0	0	0	
		FINAL	10SEP2003	57	22:00	20	6:30	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	DAY 1	12NOV2002	1	3:30	60	7:30	3	3	3	3	0	1	0	2	0	1	
		DAY 29	10DEC2002	29	1:30	60	3:30	2	3	3	3	1	0	0	2	3	2	1 MIGRAINE
		FINAL	10DEC2002	29	1:30	60	3:30	2	3	3	3	1	0	0	2	3	2	1 MIGRAINE
QUETIAPINE 600 MG (BIPOLAR I)	E0010002	DAY 1	25NOV2002	1	0:00	60	8:00	6	3	3	3	3	3	3	3	0	0	
		DAY 29	02DEC2002	8	0:00	60	8:00	6	3	3	3	3	3	0	0	0	0	
		FINAL	02DEC2002	8	0:00	60	8:00	6	3	3	3	3	3	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	DAY 1	26DEC2002	1	21:00	30	6:30	7	1	3	3	2	1			0	1	
		DAY 29	22JAN2003	28	20:30	30	6:00	9	2		0	0	0	0	2	0	0	
		DAY 57	19FEB2003	56	21:00	25	6:00	9	0	0	1	0	0	0	0	0	0	
		FINAL	19FEB2003	56	21:00	25	6:00	9	0	0	1	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0010010	DAY 1	30DEC2002	1	22:00	5	6:30	8	0	1	1	0	0	2	0	1	0	
		DAY 29	13JAN2003	15	22:00	60	6:30	6	3	2	2	0	0	3	0	2	2	
		FINAL	13JAN2003	15	22:00	60	6:30	6	3	2	2	0	0	3	0	2	2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	DAY 1	16JUL2003	1	1	3	0						
		DAY 29	13AUG2003	29	0	2	0						
		DAY 57	10SEP2003	57	0	2	0						
		FINAL	10SEP2003	57	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	DAY 1	12NOV2002	1	0	2	0						
		DAY 29	10DEC2002	29	0	2	0						
		FINAL	10DEC2002	29	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0010002	DAY 1	25NOV2002	1	0	3	1	3	3	2	0		
		DAY 29	02DEC2002	8	0	2	1	3	3	0	3		
		FINAL	02DEC2002	8	0	2	1	3	3	0	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	DAY 1	26DEC2002	1	0	2	0						
		DAY 29	22JAN2003	28	0	2	0						
		DAY 57	19FEB2003	56	0	1	0						
		FINAL	19FEB2003	56	0	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0010010	DAY 1	30DEC2002	1	2	3	0						
		DAY 29	13JAN2003	15	2	3	0						
		FINAL	13JAN2003	15	2	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	DAY 1	28JAN2003	1	16		2	3	3	1	2	3	2
		DAY 29	25FEB2003	29	1	-15	0	0	1	0	0	0	0
		DAY 57	25MAR2003	57	0	-16	0	0	0	0	0	0	0
		FINAL	25MAR2003	57	0	-16	0	0	0	0	0	0	0
	E0010017	DAY 1	25FEB2003	1	15		2	3	3	3	2	0	2
		DAY 29	25MAR2003	29	4	-11	0	1	1	0	1	0	1
		DAY 57	22APR2003	57			1	1	0	0		0	1
		FINAL	22APR2003	57			1	1	0	0		0	1
	E0010023	DAY 1	17APR2003	1	10		1	3	1	0	2	0	3
		DAY 29	01MAY2003	15	7	-3	1	2	0	0	2	0	2
		FINAL	01MAY2003	15	7	-3	1	2	0	0	2	0	2
	E0010027	DAY 1	16JUN2003	1			2	2	1	0		3	3
		DAY 29	01JUL2003	16	10		2	3	1	0	1	2	1
		FINAL	01JUL2003	16	10		2	3	1	0	1	2	1
	E0010029	DAY 1	19JUN2003	1	16		3	2	1	2	2	3	3
	E0011022	DAY 1	09JUN2003	1	21		3	3	3	3	3	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	DAY 1	28JAN2003	1	0:00	50	4:55	4	3	3	3	0	1	3	0	3	0		
		DAY 29	25FEB2003	29	22:30	15	6:00	7	0	0	0	0	0	0	0	0	0		
		DAY 57	25MAR2003	57	22:00	15	5:30	8	0	0	0	0	0	0	0	0	0		
		FINAL	25MAR2003	57	22:00	15	5:30	8	0	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	DAY 1	25FEB2003	1	22:00	90	6:00	4	3	3	3	0	0	2	1	3	0		
		DAY 29	25MAR2003	29	22:00	15	6:00	7	1	2	2	0	0	0	0	2	0		
		DAY 57	22APR2003	57	2:20	20	6:00	8	1		2	0	0	0	0	2	0		
		FINAL	22APR2003	57	2:20	20	6:00	8	1		2	0	0	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0010023	DAY 1	17APR2003	1	23:00	45	7:00	7	3	2	3	0	1	2	2	3	0	3	PARANOID OF SOMEONE COMING IN THE HOUSE
		DAY 29	01MAY2003	15	23:00	20	7:00	8	2	2	3	1	1	2	2	3	0		
		FINAL	01MAY2003	15	23:00	20	7:00	8	2	2	3	1	1	2	2	3	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0010027	DAY 1	16JUN2003	1	2:30	30	9:30	6	3	3	2	2	3		3	2	0	3	DIFFICULTY RELAXING
		DAY 29	01JUL2003	16	2:00	45	9:30	7	3	2	2	1	1	0	0	2	0		
		FINAL	01JUL2003	16	2:00	45	9:30	7	3	2	2	1	1	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0010029	DAY 1	19JUN2003	1	20:30	20	5:00	6	2	3	3	0	3	0	0	0	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	DAY 1	09JUN2003	1	21:00	120	5:00	4	3	3	3	3	3	1	3	2	1	2	NO REASON - JUST GET UP WITH HUSBAND

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0010014	DAY 1	28JAN2003	1	1	3	3	0	0	0	2		
		DAY 29	25FEB2003	29	0	0	3	0	0	0	0		
		DAY 57	25MAR2003	57	0	0	3	0	0	0	0		
		FINAL	25MAR2003	57	0	0	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	DAY 1	25FEB2003	1	2	2	2	0	0	0	0		
		DAY 29	25MAR2003	29	1	1	2	0	0	0	0		
		DAY 57	22APR2003	57	1	0	2	0	0	0	0		
		FINAL	22APR2003	57	1	0	2	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0010023	DAY 1	17APR2003	1	2	3	1	2	0	0	0		
		DAY 29	01MAY2003	15	1	3	0	0	0	0	0		
		FINAL	01MAY2003	15	1	3	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0010027	DAY 1	16JUN2003	1	3	3	0						
		DAY 29	01JUL2003	16	0	2	0						
		FINAL	01JUL2003	16	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0010029	DAY 1	19JUN2003	1	2	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	DAY 1	09JUN2003	1	3	2	3	3	1	3	3	3	TALK, SWING ARMS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	DAY 29	08JUL2003	30	12	-9	2	1	1	3	3	0	2
		DAY 57	05AUG2003	58	10	-11	1	1	0	3	2	0	3
		FINAL	05AUG2003	58	10	-11	1	1	0	3	2	0	3
	E0013006	DAY 1	13MAR2003	1	10		2	1	1	1	3	0	2
		DAY 29	24MAR2003	12	7	-3	2	0	1	1	1	0	2
		FINAL	24MAR2003	12	7	-3	2	0	1	1	1	0	2
	E0013012	DAY 1	07MAY2003	1	12		2	3	2	0	2	0	3
		DAY 29	05JUN2003	30	4	-8	1	0	0	0	1	0	2
		DAY 57	02JUL2003	57	4	-8	0	1	1	0	1	0	1
		FINAL	02JUL2003	57	4	-8	0	1	1	0	1	0	1
	E0013014	DAY 1	03JUN2003	1	15		3	3	1	2	2	3	1
		DAY 29	30JUN2003	28	17	2	3	3	1	3	2	3	2
		FINAL	30JUN2003	28	17	2	3	3	1	3	2	3	2
	E0014005	DAY 1	11MAR2003	1	13		3	2	0	0	2	3	3
		DAY 29	08APR2003	29	3	-10	0	1	0	0	1	0	1
		DAY 57	06MAY2003	57	3	-10	1	0	0	0	1	0	1
		FINAL	06MAY2003	57	3	-10	1	0	0	0	1	0	1

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	DAY 29	08JUL2003	30	10:00	30	7:00	7	1	3	3	3	3	1	3	1	1	3	HUNGRY
		DAY 57	05AUG2003	58	10:00	20	9:00	9	1	1	2	2	3	1	3	0	0		
		FINAL	05AUG2003	58	10:00	20	9:00	9	1	1	2	2	3	1	3	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	DAY 1	13MAR2003	1	22:00	15	6:00	6	1	3	3	3	0	2	2	3	3		
		DAY 29	24MAR2003	12	22:00	15	6:00	6	0	3	2	0	0	0	0	2	1		
		FINAL	24MAR2003	12	22:00	15	6:00	6	0	3	2	0	0	0	0	2	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	DAY 1	07MAY2003	1	23:00	45	4:30	5	3	3	3	3	0	0	3	0	1		
		DAY 29	05JUN2003	30	22:15	15	6:30	8	0	1	3	0	0	0	0	0	0		
		DAY 57	02JUL2003	57	22:00	20	6:00	7	0	0	0	0	0	0	3	0	0		
		FINAL	02JUL2003	57	22:00	20	6:00	7	0	0	0	0	0	0	3	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0013014	DAY 1	03JUN2003	1	0:00	45	9:00	6	3	3	3	0	0	0	2	3	0		
		DAY 29	30JUN2003	28	23:00	60	8:30	6	3	3	3	0	0	1	1	2	1	3	RESTLESSNESS
		FINAL	30JUN2003	28	23:00	60	8:30	6	3	3	3	0	0	1	1	2	1	3	RESTLESSNESS
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	DAY 1	11MAR2003	1	23:00	20	9:00	10	2	0	1	2	0	3	3	2	3		
		DAY 29	08APR2003	29	22:30	10	7:00	9	1	0	0	0	0	2	0	1	2		
		DAY 57	06MAY2003	57	22:30	10	7:45	9	0	0	0	0	1	1	0	0	2		
		FINAL	06MAY2003	57	22:30	10	7:45	9	0	0	0	0	1	1	0	0	2		

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU- SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT					
								10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	DAY 29	08JUL2003	30	2	2	3	3	3	3	2	3	WAKING UP TOSSING, TURNING
		DAY 57	05AUG2003	58	2	3	3	2	2	3	3	3	TOSS TURN, FLAP ARMS, KICK FEET
		FINAL	05AUG2003	58	2	3	3	2	2	3	3	3	TOSS TURN, FLAP ARMS, KICK FEET
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	DAY 1	13MAR2003	1	0	3	1						
		DAY 29	24MAR2003	12	2	2	1	0	0	0	0		
		FINAL	24MAR2003	12	2	2	1	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	DAY 1	07MAY2003	1	2	3	0						
		DAY 29	05JUN2003	30	1	2	0						
		DAY 57	02JUL2003	57	0	1	0						
		FINAL	02JUL2003	57	0	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0013014	DAY 1	03JUN2003	1	0	1	0						
		DAY 29	30JUN2003	28	2	2	0						
		FINAL	30JUN2003	28	2	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	DAY 1	11MAR2003	1	2	3	0						
		DAY 29	08APR2003	29	0	1	0						
		DAY 57	06MAY2003	57	0	1	0						
		FINAL	06MAY2003	57	0	1	0						

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	DAY 1	01APR2003	1	11		2	2	1	3	1	0	2
		DAY 29	22APR2003	22	11	0	1	3	0	2	2	1	2
		FINAL	22APR2003	22	11	0	1	3	0	2	2	1	2
	E0014011	DAY 1	13MAY2003	1	16		2	3	3	3	2	0	3
		DAY 29	10JUN2003	29	4	-12	0	2	0	0	1	0	1
		DAY 57	08JUL2003	57	3	-13	0	1	0	1	1	0	0
		FINAL	08JUL2003	57	3	-13	0	1	0	1	1	0	0
	E0014012	DAY 1	27MAY2003	1	19		3	3	3	3	2	3	2
		DAY 29	24JUN2003	29	15	-4	2	3	1	3	1	3	2
		FINAL	24JUN2003	29	15	-4	2	3	1	3	1	3	2
	E0015001	DAY 1	29NOV2002	1	13		3	3	1	0	1	3	2
		DAY 29	27DEC2002	29	5	-8	0	1	0	0	1	0	3
		DAY 57	20JAN2003	53	4	-9	0	0	0	0	1	0	3
		FINAL	20JAN2003	53	4	-9	0	0	0	0	1	0	3
	E0015008	DAY 1	19DEC2002	1	11		2	3	0	2	1	1	2
		DAY 29	16JAN2003	29	4	-7	0	1	0	0	1	0	2
		FINAL	16JAN2003	29	4	-7	0	1	0	0	1	0	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	DAY 1	01APR2003	1	23:00	24	10:00	7	3	3	3	0	0	1	0	2	0		
		DAY 29	22APR2003	22	23:00	240	11:00	8	3	3	3	2	0	2	0	1	0		
		FINAL	22APR2003	22	23:00	240	11:00	8	3	3	3	2	0	2	0	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	DAY 1	13MAY2003	1	1:00	60	10:00	2	3	3	3	3	2	0	2	0	0		
		DAY 29	10JUN2003	29	23:00	45	10:00	12	1	1	1	2	0	0	0	0	0		
		DAY 57	08JUL2003	57	22:00	60	10:00	10	0	0	0	1	0	0	0	0	0		
		FINAL	08JUL2003	57	22:00	60	10:00	10	0	0	0	1	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0014012	DAY 1	27MAY2003	1	22:00	180	10:00	3	3	3	3	1	0	1	3	2	1	3	FITFULL - TOSSING & TURNING
		DAY 29	24JUN2003	29	23:00	120	10:00	6	3	2	1	0	0	0	1	0	0	3	RESTLESS LEG
		FINAL	24JUN2003	29	23:00	120	10:00	6	3	2	1	0	0	0	1	0	0	3	RESTLESS LEG
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	DAY 1	29NOV2002	1	23:30	60	4:30	6	3	3	1	1	0	1	1	1	0		
		DAY 29	27DEC2002	29	23:50	30	8:15	8	0	2	2	0	0	0	0	1	0		
		DAY 57	20JAN2003	53	22:30	15	8:00	9	0	2	2	0	0	0	0	0	0		
		FINAL	20JAN2003	53	22:30	15	8:00	9	0	2	2	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0015008	DAY 1	19DEC2002	1	0:00	60	12:00	8	3	3	2	0	0	0	0	1	0		
		DAY 29	16JAN2003	29	21:00	30	11:00	14	1	0	2	0	0	0	0	0	0		
		FINAL	16JAN2003	29	21:00	30	11:00	14	1	0	2	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	DAY 1	01APR2003	1	0	3	0						
		DAY 29	22APR2003	22	0	3	0						
		FINAL	22APR2003	22	0	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	DAY 1	13MAY2003	1	2	3	0						
		DAY 29	10JUN2003	29	0	1	3	0	0	0	0		
		DAY 57	08JUL2003	57	0	0	3						
		FINAL	08JUL2003	57	0	0	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0014012	DAY 1	27MAY2003	1	0	3	1						
		DAY 29	24JUN2003	29	0	3	1						
		FINAL	24JUN2003	29	0	3	1						
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	DAY 1	29NOV2002	1	1	3	1	0	0	0	0		
		DAY 29	27DEC2002	29	2	3	1	0	0	0	0		
		DAY 57	20JAN2003	53	3	3	1	0	0	0	0		
		FINAL	20JAN2003	53	3	3	1	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0015008	DAY 1	19DEC2002	1	1	3	0						
		DAY 29	16JAN2003	29	3	1	0						
		FINAL	16JAN2003	29	3	1	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0016003	DAY 1	24JAN2003	1	9		2	3	0	1	2	0	1
		DAY 29	21FEB2003	29	10	1	2	2	1	3	2	0	0
		FINAL	21FEB2003	29	10	1	2	2	1	3	2	0	0
	E0016005	DAY 1	25FEB2003	1	18		3	3	3	3	3	0	3
		DAY 29	25MAR2003	29	2	-16	0	1	0	0	1	0	0
		DAY 57	22APR2003	57	9	-9	0	2	3	3	1	0	0
		FINAL	22APR2003	57	9	-9	0	2	3	3	1	0	0
	E0018007	DAY 1	27DEC2002	1	15		3	3	2	2	3	0	2
		DAY 29	10JAN2003	15	12	-3	2	2	1	1	3	1	2
		FINAL	10JAN2003	15	12	-3	2	2	1	1	3	1	2
	E0019005	DAY 1	05NOV2002	1	10		2	2	3	0	1	0	2
		DAY 29	05DEC2002	31	8	-2	1	3	1	0	1	0	2
		DAY 57	02JAN2003	59	6	-4	1	3	1	0	0	0	1
		FINAL	02JAN2003	59	6	-4	1	3	1	0	0	0	1
	E0019015	DAY 1	02JAN2003	1	8		1	2	1	0	1	1	2
		DAY 29	30JAN2003	29	1	-7	0	0	0	0	0	0	1
		DAY 57	27FEB2003	57	4	-4	0	1	0	0	1	0	2
		FINAL	27FEB2003	57	4	-4	0	1	0	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0016003	DAY 1	24JAN2003	1	21:30	90	9:30	10	3	2	1	0	2	3	2	0	0	
		DAY 29	21FEB2003	29	22:00	30	10:00	6	3	3	2	3	3	1	1	2	0	
		FINAL	21FEB2003	29	22:00	30	10:00	6	3	3	2	3	3	1	1	2	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	DAY 1	25FEB2003	1	22:00	70	8:00	4	3	3	3	2	1	2	3	3	3	
		DAY 29	25MAR2003	29	21:30	10	8:00	9	1	1	1	0	0	1	1	0	0	
		DAY 57	22APR2003	57	21:00	45	7:30	1	1	1	3	0	2	2	0	0	1	
		FINAL	22APR2003	57	21:00	45	7:30	1	1	1	3	0	2	2	0	0	1	
QUETIAPINE 600 MG (BIPOLAR I)	E0018007	DAY 1	27DEC2002	1	23:00	45	6:00	5	3	3	3	3	3	0	2	3	3	
		DAY 29	10JAN2003	15	23:00	30	7:00	6	3	3	3	2	3	1	1	3	3	
		FINAL	10JAN2003	15	23:00	30	7:00	6	3	3	3	2	3	1	1	3	3	
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	DAY 1	05NOV2002	1	22:30	30	2:30	4	3	3	0	0	0	0	0	0	0	
		DAY 29	05DEC2002	31	23:00	90	5:00	6	3	1	0	0	0	0	0	0	0	
		DAY 57	02JAN2003	59	22:30	60	4:30	6	3	0	0	0	0	0	0	0	0	
		FINAL	02JAN2003	59	22:30	60	4:30	6	3	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	DAY 1	02JAN2003	1	1:00	30	8:30	7	2	3	0	0	0	0	0	1	1	
		DAY 29	30JAN2003	29	22:30	10	7:00	8	0	0	0	0	0	0	0	0	0	
		DAY 57	27FEB2003	57	22:00	10	7:00	9	1	1	0	0	0	0	0	0	0	
		FINAL	27FEB2003	57	22:00	10	7:00	9	1	1	0	0	0	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0016003	DAY 1	24JAN2003	1	0	1	3						
		DAY 29	21FEB2003	29	0	0	3						
		FINAL	21FEB2003	29	0	0	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	DAY 1	25FEB2003	1	3	3	0						
		DAY 29	25MAR2003	29	0	0	0						
		DAY 57	22APR2003	57	0	0	0						
		FINAL	22APR2003	57	0	0	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0018007	DAY 1	27DEC2002	1	2	2	1	3	3				
		DAY 29	10JAN2003	15	1	2	1	3	1	2	2		
		FINAL	10JAN2003	15	1	2	1	3	1	2	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	DAY 1	05NOV2002	1	0	3	0						
		DAY 29	05DEC2002	31	2	1	0						
		DAY 57	02JAN2003	59	0	1	0						
		FINAL	02JAN2003	59	0	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	DAY 1	02JAN2003	1	1	2	3	0	1	1	0	3	HAVING TO GET UP FOR JOB
		DAY 29	30JAN2003	29	2	0	3	0	0	0	0		
		DAY 57	27FEB2003	57	2	1	3	0	0	0	0		
		FINAL	27FEB2003	57	2	1	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	DAY 1	09DEC2002	1	16		2	3	1	2	2	3	3
		DAY 29	07JAN2003	30	8	-8	1	2	0	0	2	1	2
		DAY 57	22JAN2003	45	8	-8	1	2	0	0	2	1	2
		FINAL	22JAN2003	45	8	-8	1	2	0	0	2	1	2
	E0020010	DAY 1	05FEB2003	1	19		3	3	3	3	3	2	2
		DAY 29	05MAR2003	29	6	-13	1	1	0	1	2	0	1
		DAY 57	02APR2003	57	5	-14	0	2	1	0	1	0	1
		FINAL	02APR2003	57	5	-14	0	2	1	0	1	0	1
	E0020014	DAY 1	18MAR2003	1	10		2	2	1	0	3	0	2
		DAY 29	15APR2003	29	7	-3	1	1	1	0	2	1	1
		DAY 57	12MAY2003	56	6	-4	1	1	1	0	1	1	1
		FINAL	12MAY2003	56	6	-4	1	1	1	0	1	1	1
	E0020021	DAY 1	19MAY2003	1	15		3	2	2	2	3	0	3
		DAY 29	16JUN2003	29	10	-5	2	1	1	1	2	0	3
		DAY 57	14JUL2003	57	13	-2	3	0	2	3	2	0	3
		FINAL	14JUL2003	57	13	-2	3	0	2	3	2	0	3
	E0020023	DAY 1	16JUN2003	-1	18		3	3	3	3	1	3	2
		DAY 29	14JUL2003	28	12	-6	1	3	1	3	2	0	2
		DAY 57	11AUG2003	56	10	-8	1	3	1	3	1	0	1
		FINAL	11AUG2003	56	10	-8	1	3	1	3	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	DAY 1	09DEC2002	1	1:00	360	10:00	6	3	2	2	2	2	1	1	2	1		
		DAY 29	07JAN2003	30	22:00	20	11:00	13	2	2	2	1	1	2	1	2	3		
		DAY 57	22JAN2003	45	23:00	20	9:00	10	2	2	3	2	1	3	2	1	1		
		FINAL	22JAN2003	45	23:00	20	9:00	10	2	2	3	2	1	3	2	1	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0020010	DAY 1	05FEB2003	1	16:00	120	7:00	3	3	3	3	2	3	3	3	2	2	3	CAN NOT STOP RACING THOUGHTS, BAD THOUGHTS
		DAY 29	05MAR2003	29	22:00	10	7:30	8	2	2	3	1	1	1	1	1	1		
		DAY 57	02APR2003	57	0:00	20	7:00	7	2	2	2	0	0	0	0	0	0		
		FINAL	02APR2003	57	0:00	20	7:00	7	2	2	2	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	DAY 1	18MAR2003	1	0:00	5	6:30	6	3	3	3	3	3	3	3	1	2		
		DAY 29	15APR2003	29	1:00	30	7:00	6	1	1	3	1	1	2	1	1	1		
		DAY 57	12MAY2003	56	23:30	30	6:30	7	1	1	2	1	1	1	1	1	1		
		FINAL	12MAY2003	56	23:30	30	6:30	7	1	1	2	1	1	1	1	1	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	DAY 1	19MAY2003	1	23:00	11	6:00	5	3	3	3	3	3	1	1	1	1	3	SLEEPING ON AIR MATTRESS
		DAY 29	16JUN2003	29	23:00	30	7:00	6	1	0	2	3	3	1	2	1	0	1	NUMBNESS IN HAND
		DAY 57	14JUL2003	57	23:00	10	7:30	5	0	2	2	3	3	0	1	0	2		
		FINAL	14JUL2003	57	23:00	10	7:30	5	0	2	2	3	3	0	1	0	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	DAY 1	16JUN2003	-1	11:00	120	23:00	4	3	3	2	0	0	0	1	0	0		
		DAY 29	14JUL2003	28	10:30	120	22:00	6	3	3	3	2	0	1	1	0	1		
		DAY 57	11AUG2003	56	10:30	120	20:30	6	2	1	1	2	0	0	0	1	1		
		FINAL	11AUG2003	56	10:30	120	20:30	6	2	1	1	2	0	0	0	1	1		

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU- SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	DAY 1	09DEC2002	1	2	3	0						
		DAY 29	07JAN2003	30	1	2	0						
		DAY 57	22JAN2003	45	1	3	0						
		FINAL	22JAN2003	45	1	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0020010	DAY 1	05FEB2003	1	0	3	3						
		DAY 29	05MAR2003	29	0	2	3						
		DAY 57	02APR2003	57	0	1	3						
		FINAL	02APR2003	57	0	1	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	DAY 1	18MAR2003	1	1	3	0						
		DAY 29	15APR2003	29	1	1	0						
		DAY 57	12MAY2003	56	1	1	0						
		FINAL	12MAY2003	56	1	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	DAY 1	19MAY2003	1	3	2	1						
		DAY 29	16JUN2003	29	3	2	1						
		DAY 57	14JUL2003	57	3	3	1						
		FINAL	14JUL2003	57	3	3	1						
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	DAY 1	16JUN2003	-1	0	3	0						
		DAY 29	14JUL2003	28	1	2	0						
		DAY 57	11AUG2003	56	0	2	0						
		FINAL	11AUG2003	56	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0022007	DAY 1	07NOV2002	1	14		2	3	3	3	2	0	1
		DAY 29	09DEC2002	33	2	-12	0	0	0	0	1	0	1
		FINAL	09DEC2002	33	2	-12	0	0	0	0	1	0	1
	E0022010	DAY 1	21NOV2002	1	10		1	2	2	1	1	1	2
		DAY 57	16JAN2003	57	7	-3	1	1	1	0	0	3	1
		FINAL	16JAN2003	57	7	-3	1	1	1	0	0	3	1
	E0022012	DAY 1	05DEC2002	1	14		2	2	3	3	1	1	2
		DAY 29	02JAN2003	29	3	-11	0	1	0	0	1	0	1
		DAY 57	30JAN2003	57	3	-11	0	1	0	0	1	0	1
		FINAL	30JAN2003	57	3	-11	0	1	0	0	1	0	1
	E0022019	DAY 1	11DEC2002	1	7		1	1	1	1	2	0	1
		DAY 29	09JAN2003	30	1	-6	0	0	0	0	0	0	1
		DAY 57	06FEB2003	58	1	-6	0	0	0	0	0	0	1
		FINAL	06FEB2003	58	1	-6	0	0	0	0	0	0	1
	E0022025	DAY 1	28JAN2003	1	13		2	3	2	3	2	0	1
		DAY 29	04FEB2003	8	12	-1	2	2	2	3	2	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022007	DAY 1	07NOV2002	1	12:30	90	7:00	4	3	3	0	0	1	2	0	2	0	2	STRESS
		DAY 29	09DEC2002	33	22:00	15	6:00	8	0	1	0	0	0	1	0	1	0		
		FINAL	09DEC2002	33	22:00	15	6:00	8	0	1	0	0	0	1	0	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	DAY 1	21NOV2002	1	22:00	30	4:00	5	2	1	0	0	0	0	0	0	2		
		DAY 57	16JAN2003	57	21:00	20	4:20	7	1	0	0	0	0	0	0	0	0		
		FINAL	16JAN2003	57	21:00	20	4:20	7	1	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022012	DAY 1	05DEC2002	1	2:00	25	9:00	4	2	1	0	0	3	2	2	0	0		
		DAY 29	02JAN2003	29	0:00	30	9:00	8	0	1	1	0	0	0	0	0	0		
		DAY 57	30JAN2003	57	23:00	20	10:00	10	0	0	0	0	3	0	0	2	0		
		FINAL	30JAN2003	57	23:00	20	10:00	10	0	0	0	0	3	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022019	DAY 1	11DEC2002	1	22:30	15	6:00	6	1	2	2	0	1	0	3	1	1		
		DAY 29	09JAN2003	30	23:00	10	8:00	9	0	0	0	0	0	0	0	0	0		
		DAY 57	06FEB2003	58	22:00	10	8:00	9	0	0	0	0	0	0	0	0	0		
		FINAL	06FEB2003	58	22:00	10	8:00	9	0	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	DAY 1	28JAN2003	1	22:00	180	7:30	5	3	3	3	1	0	3	3	1	3		
		DAY 29	04FEB2003	8	22:00	180	6:00	5	0	3	3	1	0	3	3	1	2	0	WAS ON NEW MEDICATION FOR 1 WEEK.

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022007	DAY 1	07NOV2002	1	0	2	0						
		DAY 29	09DEC2002	33	0	2	0						
		FINAL	09DEC2002	33	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	DAY 1	21NOV2002	1	2	2	0						
		DAY 57	16JAN2003	57	1	1	0						
		FINAL	16JAN2003	57	1	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0022012	DAY 1	05DEC2002	1	1	2	3						
		DAY 29	02JAN2003	29	1	1	1						
		DAY 57	30JAN2003	57	0	1	1						
		FINAL	30JAN2003	57	0	1	1						
QUETIAPINE 600 MG (BIPOLAR I)	E0022019	DAY 1	11DEC2002	1	0	1	3	2	0	3	0	2	WAKING UP PERIODICALLY
		DAY 29	09JAN2003	30	0	1	3	1	0	1	0		
		DAY 57	06FEB2003	58	0	1	3	1	0	1	0		
		FINAL	06FEB2003	58	0	1	3	1	0	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	DAY 1	28JAN2003	1	0	2	0						
		DAY 29	04FEB2003	8	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	FINAL		04FEB2003	8	12	-1	2	2	2	3	2	0	1
	E0022033	DAY 1		18FEB2003	1	9		1	2	1	0	1	3	1
		DAY 29		18MAR2003	29	3	-6	1	0	0	0	1	0	1
		DAY 57		15APR2003	57	3	-6	0	0	0	0	2	0	1
		FINAL		15APR2003	57	3	-6	0	0	0	0	2	0	1
	E0022034	DAY 1		18FEB2003	1	11		3	2	1	2	2	0	1
		DAY 29		18MAR2003	29	3	-8	0	1	0	0	1	0	1
		DAY 57		15APR2003	57	3	-8	0	1	0	0	1	0	1
		FINAL		15APR2003	57	3	-8	0	1	0	0	1	0	1
	E0022038	DAY 1		28FEB2003	1	10		2	0	2	2	1	0	3
		DAY 29		28MAR2003	29	5	-5	0	1	1	0	1	0	2
		DAY 29	*	11APR2003	43	6	-4	0	1	1	0	1	0	3
		FINAL		11APR2003	43	6	-4	0	1	1	0	1	0	3
	E0022039	DAY 1		06MAR2003	1	10		2	3	0	0	3	0	2
		DAY 29		04APR2003	30	6	-4	1	1	0	1	2	0	1
		DAY 57		01MAY2003	57	4	-6	0	1	0	0	1	1	1
		FINAL		01MAY2003	57	4	-6	0	1	0	0	1	1	1

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	FINAL	04FEB2003	8	22:00	180	6:00	5	0	3	3	1	0	3	3	1	2	0	WAS ON NEW MEDICATION FOR 1 WEEK.
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	DAY 1	18FEB2003	1	22:00	30	6:00	7	2	3	3	0	0	0	0	0	3		
		DAY 29	18MAR2003	29	21:00	10	6:00	8	0	1	1	1	1	0	1	0	3		
		DAY 57	15APR2003	57	21:00	10	8:00	10	0	1	2	1	3	0	0	0	3		
		FINAL	15APR2003	57	21:00	10	8:00	10	0	1	2	1	3	0	0	0	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	DAY 1	18FEB2003	1	0:00	30	10:00	7	3	3	2	0	0	2	0	1	2	3	WORRIES FINANCIAL
		DAY 29	18MAR2003	29	0:00	10	10:00	10	2	0	0	0	0	0	0	0	1		
		DAY 57	15APR2003	57	0:00	10	9:00	9	1	0	0	0	0	0	0	0	1		
		FINAL	15APR2003	57	0:00	10	9:00	9	1	0	0	0	0	0	0	0	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	DAY 1	28FEB2003	1	19:30	10	2:35	5	0	3	2	3	0	0	0	0	0		
		DAY 29	28MAR2003	29	19:00	10	2:30	7	1	2	2	1	0	0	0	0	0		
		DAY 29 *	11APR2003	43	19:00	5	2:30	7	1	2	2	1	0	0	0	0	0		
		FINAL	11APR2003	43	19:00	5	2:30	7	1	2	2	1	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	DAY 1	06MAR2003	1	1:00	120	12:00	12	3	3	3	2	3	3	1	1	2	3	WEIRD DREAMS
		DAY 29	04APR2003	30	23:30	30	14:00	12	1	2	2	3	3	2	1	2	3		
		DAY 57	01MAY2003	57	23:30	30	8:30	9	1	1	1	0	0	1	1	0	0		
		FINAL	01MAY2003	57	23:30	30	8:30	9	1	1	1	0	0	1	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	FINAL	04FEB2003	8	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	DAY 1	18FEB2003	1	0	2	3	1	0	0	0	1	TALKING IN SLEEP
		DAY 29	18MAR2003	29	0	2	3	1	0	0	1		
		DAY 57	15APR2003	57	0	1	3	3	0	2	2		
		FINAL	15APR2003	57	0	1	3	3	0	2	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	DAY 1	18FEB2003	1	0	2	0						
		DAY 29	18MAR2003	29	0	1	0						
		DAY 57	15APR2003	57	0	1	0						
		FINAL	15APR2003	57	0	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	DAY 1	28FEB2003	1	3	3	3	0	0	0	0	2	RESTLESSNESS
		DAY 29	28MAR2003	29	3	1	3	0	0	0	2	3	TOSSING, TURNING, & STRETCHING
		DAY 29 *	11APR2003	43	3	2	3	0	0	0	0		
		FINAL	11APR2003	43	3	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	DAY 1	06MAR2003	1	0	3	3	3	1	0	0		
		DAY 29	04APR2003	30	0	1	3	3	0	0	0		
		DAY 57	01MAY2003	57	0	2	0						
		FINAL	01MAY2003	57	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	DAY 1	20MAR2003	1	20		3	3	3	3	3	3	2
		DAY 29	18APR2003	30	10	-10	1	2	0	1	1	3	2
		DAY 57	16MAY2003	58	5	-15	1	1	0	0	1	0	2
		FINAL	16MAY2003	58	5	-15	1	1	0	0	1	0	2
	E0022048	DAY 1	01APR2003	1	11		3	3	1	1	1	0	2
		DAY 29	02MAY2003	32	0	-11	0	0	0	0	0	0	0
		FINAL	02MAY2003	32	0	-11	0	0	0	0	0	0	0
	E0022051	DAY 1	07APR2003	1	9		3	1	1	0	2	0	2
		DAY 29	05MAY2003	29	3	-6	1	1	0	0	1	0	0
		DAY 57	02JUN2003	57	0	-9	0	0	0	0	0	0	0
		FINAL	02JUN2003	57	0	-9	0	0	0	0	0	0	0
	E0022053	DAY 1	11APR2003	1	16		3	3	3	3	3	0	1
	E0022058	DAY 1	21APR2003	1	5		1	1	0	0	1	0	2
		DAY 29	19MAY2003	29	3	-2	0	0	0	0	1	0	2
		DAY 29 *	22MAY2003	32	4	-1	0	0	0	0	1	0	3
		FINAL	22MAY2003	32	4	-1	0	0	0	0	1	0	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	DAY 1	20MAR2003	1	22:30	120	5:30	4	3	3	3	2	2	3	2	2	2	
		DAY 29	18APR2003	30	21:00	40	9:00	10	1	1	1	0	1	0	0	0	0	
		DAY 57	16MAY2003	58	22:00	30	8:00	12	0	1	1	0	1	0	0	0	0	
		FINAL	16MAY2003	58	22:00	30	8:00	12	0	1	1	0	1	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0022048	DAY 1	01APR2003	1	23:59	45	7:30	6	3	1	1	0	0	0	2	2	0	
		DAY 29	02MAY2003	32	22:00	10	7:00	9	0	0	0	0	0	0	0	0	0	
		FINAL	02MAY2003	32	22:00	10	7:00	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	DAY 1	07APR2003	1	23:00	30	7:00	7	1	2	2	0	0	3	3	0	0	
		DAY 29	05MAY2003	29	23:30	20	8:30	9	0	1	1	0	1	0	1	0	0	
		DAY 57	02JUN2003	57	23:00	15	8:30	9	0	0	0	0	0	0	0	0	0	
		FINAL	02JUN2003	57	23:00	15	8:30	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0022053	DAY 1	11APR2003	1	22:00	90	11:00	4	3	3	3	3	3	3	3	3	3	
QUETIAPINE 600 MG (BIPOLAR I)	E0022058	DAY 1	21APR2003	1	21:00	5	6:30	9	1	1	1	1	1	2	2	0	1	
		DAY 29	19MAY2003	29	22:00	10	7:00	9	0	0	0	0	2	2	1	0	0	
		DAY 29 *	22MAY2003	32	22:00	10	7:00	9	0	0	2	0	0	1	0	0	0	
		FINAL	22MAY2003	32	22:00	10	7:00	9	0	0	2	0	0	1	0	0	0	

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	DAY 1	20MAR2003	1	0	3	0						
		DAY 29	18APR2003	30	1	3	0						
		DAY 57	16MAY2003	58	0	3	0						
		FINAL	16MAY2003	58	0	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0022048	DAY 1	01APR2003	1	1	2	0						
		DAY 29	02MAY2003	32	0	0	0						
		FINAL	02MAY2003	32	0	0	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	DAY 1	07APR2003	1	0	3	3	1	0	0	0		
		DAY 29	05MAY2003	29	0	0	3	3	0	0	0	2	MAKING NOISE LIKE TALKING SOUNDS
		DAY 57	02JUN2003	57	0	0	3						
		FINAL	02JUN2003	57	0	0	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0022053	DAY 1	11APR2003	1	0	2	3	3	0	3	0	3	SHE GOES THROUGH HOT AND COLD, MOVES A LOT WHILE SLEEPING, A LOT OF JERKING
QUETIAPINE 600 MG (BIPOLAR I)	E0022058	DAY 1	21APR2003	1	1	2	3	0	0	0	0		
		DAY 29	19MAY2003	29	1	2	3	2	0	0	0		
		DAY 29 *	22MAY2003	32	3	3	3	2	1	2	1		
		FINAL	22MAY2003	32	3	3	3	2	1	2	1		

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 1	30APR2003	1	10		2	2	0	2	2	0	2
		DAY 29	28MAY2003	29	2	-8	1	0	0	0	1	0	0
		DAY 57	26JUN2003	58	2	-8	0	0	0	0	1	0	1
		FINAL	26JUN2003	58	2	-8	0	0	0	0	1	0	1
	E0022062	DAY 1	05MAY2003	1	19		3	2	2	3	3	3	3
		DAY 29	23MAY2003	19	15	-4	3	2	3	3	3	0	1
		FINAL	23MAY2003	19	15	-4	3	2	3	3	3	0	1
	E0022068	DAY 1	22MAY2003	-1			2	3	1	0		0	2
	E0022069	DAY 1	10JUN2003	1	10		2	2	1	0	1	2	2
		DAY 29	08JUL2003	29	7	-3	2	2	0	0	1	1	1
		DAY 57	05AUG2003	57	7	-3	1	1	1	0	2	1	1
		FINAL	05AUG2003	57	7	-3	1	1	1	0	2	1	1
	E0022071	DAY 1	30JUN2003	1	14		2	3	1	2	1	3	2
		DAY 29	28JUL2003	29	5	-9	1	0	0	0	1	1	2
		DAY 57	25AUG2003	57	7	-7	1	1	0	1	1	1	2
		FINAL	25AUG2003	57	7	-7	1	1	0	1	1	1	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 1	30APR2003	1	20:30	30	10:30	10	3	2	3	1	0	0	3	3	0		
		DAY 29	28MAY2003	29	22:30	15	8:30	9	0	1	1	0	0	0	0	0	0		
		DAY 57	26JUN2003	58	22:30	0	9:30	10	0	0	1	0	0	0	0	0	0		
		FINAL	26JUN2003	58	22:30	0	9:30	10	0	0	1	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	DAY 1	05MAY2003	1	21:00	30	6:00	5	3	3	3	3	3	3	2	3	1	3	RACING THOUGHTS
		DAY 29	23MAY2003	19	21:00	30	7:00	4	3	3	3	3	3	3	0	2	2	3	SUFFOCATING/SHIFFED NOSE
		FINAL	23MAY2003	19	21:00	30	7:00	4	3	3	3	3	3	3	0	2	2	3	SUFFOCATING/SHIFFED NOSE
QUETIAPINE 600 MG (BIPOLAR I)	E0022068	DAY 1	22MAY2003	-1	1:00	45	7:00	6	3	3	3	0		2	2	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	DAY 1	10JUN2003	1	22:00	30	4:00	6	2	3	2	0	0	0	0	1	0		
		DAY 29	08JUL2003	29	21:00	20	6:00	9	2	1	1	1	0	1	0	1	1		
		DAY 57	05AUG2003	57	0:00	5	6:30	6	1	2	3	0	0	1	3	0	1		
		FINAL	05AUG2003	57	0:00	5	6:30	6	1	2	3	0	0	1	3	0	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 1	30JUN2003	1	21:00	45	6:00	6	3	3	0	0	0	0	0	3	0		
		DAY 29	28JUL2003	29	23:00	15	9:00	9	0	1	0	2	1	0	0	0	0		
		DAY 57	25AUG2003	57	23:00	30	9:00	8	1	1	0	1	0	0	0	1	0		
		FINAL	25AUG2003	57	23:00	30	9:00	8	1	1	0	1	0	0	0	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 1	30APR2003	1	1	3	3	0	0	3	1	1	WILL SAY OR YELL RANDOM THINGS IN SLEEP
		DAY 29	28MAY2003	29	0	0	3	0	0	1	0		
		DAY 57	26JUN2003	58	0	1	3						
		FINAL	26JUN2003	58	0	1	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	DAY 1	05MAY2003	1	3	3	3	3	0	3	0		
		DAY 29	23MAY2003	19	2	0	1	3	3	3	3		
		FINAL	23MAY2003	19	2	0	1	3	3	3	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0022068	DAY 1	22MAY2003	-1	2	2	3	0	0	2	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	DAY 1	10JUN2003	1	2	2	3						
		DAY 29	08JUL2003	29	1	1	1						
		DAY 57	05AUG2003	57	1	1	1						
		FINAL	05AUG2003	57	1	1	1						
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 1	30JUN2003	1	0	3	3	0	0	3	0	3	TOSS AND TURN
		DAY 29	28JUL2003	29	0	3	3	0	0	2	0	3	RESTLESS LEG AFTER TAKING MEDICATION
		DAY 57	25AUG2003	57	0	3	3	0	0	2	0		
		FINAL	25AUG2003	57	0	3	3	0	0	2	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	DAY 1	17DEC2002	1	15		3	3	2	3	2	0	2
		DAY 29	16JAN2003	31	13	-2	2	3	2	2	2	0	2
		DAY 57	11FEB2003	57	7	-8	1	2	1	0	1	0	2
		FINAL	11FEB2003	57	7	-8	1	2	1	0	1	0	2
	E0023006	DAY 1	17DEC2002	1	4		1	1	0	0	0	0	2
		DAY 29	16JAN2003	31	4	0	1	1	0	0	1	0	1
		DAY 57	11FEB2003	57	4	0	0	1	0	0	1	0	2
		FINAL	11FEB2003	57	4	0	0	1	0	0	1	0	2
	E0023010	DAY 1	04FEB2003	1	14		2	2	2	3	2	1	2
		DAY 29	04MAR2003	29	5	-9	0	1	0	0	2	0	2
		DAY 57	31MAR2003	56	3	-11	0	1	0	0	1	0	1
		FINAL	31MAR2003	56	3	-11	0	1	0	0	1	0	1
	E0023025	DAY 1	15MAY2003	1	6		0	3	0	0	2	0	1
		DAY 29	12JUN2003	29	4	-2	0	1	0	0	2	0	1
		DAY 57	10JUL2003	57	6	0	1	1	0	1	1	0	2
		FINAL	10JUL2003	57	6	0	1	1	0	1	1	0	2
	E0023039	DAY 1	01JUL2003	1	14		2	3	2	3	1	0	3
		DAY 29	29JUL2003	29	3	-11	0	0	0	0	1	0	2
		DAY 57	26AUG2003	57	1	-13	0	0	0	0	0	0	1
		FINAL	26AUG2003	57	1	-13	0	0	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	DAY 1	17DEC2002	1	0:30	240	9:30	5	3	3	3	2	1	2	2	3	0	
		DAY 29	16JAN2003	31	21:00	75	3:45	5	3	3	2	3	1	2	2	3	1	
		DAY 57	11FEB2003	57	20:45	25	3:45	7	2	1	2	1	0	0	2	0	0	
		FINAL	11FEB2003	57	20:45	25	3:45	7	2	1	2	1	0	0	2	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	DAY 1	17DEC2002	1	0:00	35	12:00	12	0	0	0	0	0	0	0	0	0	
		DAY 29	16JAN2003	31	1:00	20	12:00	12	0	1	0	3	0	0	0	0	0	
		DAY 57	11FEB2003	57	0:15	25	10:30	9	0	0	0	1	0	0	0	1	1	
		FINAL	11FEB2003	57	0:15	25	10:30	9	0	0	0	1	0	0	0	1	1	
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	DAY 1	04FEB2003	1	22:00	45	6:00	5	2	2	3	2	3	1	1	3	0	
		DAY 29	04MAR2003	29	21:00	15	6:00	8	1	1	3	2	2	1	1	1	1	
		DAY 57	31MAR2003	56	21:30	10	6:30	9	1	1	1	1	1	1	1	1	2	
		FINAL	31MAR2003	56	21:30	10	6:30	9	1	1	1	1	1	1	1	1	2	
QUETIAPINE 600 MG (BIPOLAR I)	E0023025	DAY 1	15MAY2003	1	1:00	60	14:00	12	3	3	2	0	0	0	3	3	0	
		DAY 29	12JUN2003	29	0:00	30	12:00	11	1	0	0	0	0	3	3	2	2	
		DAY 57	10JUL2003	57	0:00	20	12:00	10	0	3	0	0	0	2	2	1	0	
		FINAL	10JUL2003	57	0:00	20	12:00	10	0	3	0	0	0	2	2	1	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	DAY 1	01JUL2003	1	23:30	60	7:30	5	3	2	0	0	0	0	0	0	2	
		DAY 29	29JUL2003	29	23:30	15	8:00	8	0	0	1	0	0	0	0	0	0	
		DAY 57	26AUG2003	57	0:00	10	8:15	8	0	0	0	0	0	0	0	0	0	
		FINAL	26AUG2003	57	0:00	10	8:15	8	0	0	0	0	0	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	DAY 1	17DEC2002	1	0	3	3	3	1	3	3		
		DAY 29	16JAN2003	31	2	2	3	0	3	3	1		
		DAY 57	11FEB2003	57	2	2	3	0	1	3	1		
		FINAL	11FEB2003	57	2	2	3	0	1	3	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	DAY 1	17DEC2002	1	0	3	0						
		DAY 29	16JAN2003	31	0	2	0						
		DAY 57	11FEB2003	57	1	2	0						
		FINAL	11FEB2003	57	1	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	DAY 1	04FEB2003	1	0	3	0						
		DAY 29	04MAR2003	29	0	3	0						
		DAY 57	31MAR2003	56	0	2	0						
		FINAL	31MAR2003	56	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0023025	DAY 1	15MAY2003	1	0	2	1	0	0	0	0		
		DAY 29	12JUN2003	29	0	1	1	0	0	0	0		
		DAY 57	10JUL2003	57	2	2	1	0	0	0	0		
		FINAL	10JUL2003	57	2	2	1	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	DAY 1	01JUL2003	1	2	3	3	0	0	0	0		
		DAY 29	29JUL2003	29	1	2	0						
		DAY 57	26AUG2003	57	0	2	3	1	0	0	0		
		FINAL	26AUG2003	57	0	2	3	1	0	0	0		

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 1	12NOV2002	1	5		1	1	1	0	1	0	1
		DAY 29	11DEC2002	30	7	2	1	1	1	1	2	0	1
		DAY 57	09JAN2003	59	4	-1	1	0	1	0	1	0	1
		FINAL	09JAN2003	59	4	-1	1	0	1	0	1	0	1
	E0026007	DAY 1	16JAN2003	1	16		3	3	1	3	3	0	3
		DAY 29	13FEB2003	29	2	-14	0	0	0	1	1	0	0
		DAY 57	12MAR2003	56	2	-14	0	0	0	0	2	0	0
		FINAL	12MAR2003	56	2	-14	0	0	0	0	2	0	0
	E0026013	DAY 1	13FEB2003	1	11		3	3	1	0	1	0	3
		DAY 29	13MAR2003	29	5	-6	1	1	0	0	1	0	2
		FINAL	13MAR2003	29	5	-6	1	1	0	0	1	0	2
	E0028007	DAY 1	01OCT2002	-3	11		2	3	3	0	2	0	1
		DAY 29	31OCT2002	28	5	-6	1	2	0	0	1	0	1
		DAY 29 *	14NOV2002	42	6	-5	1	2	1	0	1	0	1
		FINAL	14NOV2002	42	6	-5	1	2	1	0	1	0	1
	E0028023	DAY 1	21JAN2003	1	12		2	3	1	1	2	0	3
		DAY 29	17FEB2003	28	20	8	3	3	3	3	2	3	3
		FINAL	17FEB2003	28	20	8	3	3	3	3	2	3	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 1	12NOV2002	1	21:30	30	4:00	6	1	1	1	0	0	1	0	0	0		
		DAY 29	11DEC2002	30	21:00	18	6:00	7	1	1	2	2	3	3	1	1	1		
		DAY 57	09JAN2003	59	21:30	15	4:30	6	0	0	0	0	0	1	0	0	0		
		FINAL	09JAN2003	59	21:30	15	4:30	6	0	0	0	0	0	1	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0026007	DAY 1	16JAN2003	1	22:00	75	10:00	6	3	3	3	1	1	1	3	2	3	3	THINKING
		DAY 29	13FEB2003	29	20:00	10	11:00	12	0	0	3	0	0	0	1	1	3		
		DAY 57	12MAR2003	56	22:00	5	10:00	12	0	1	2	0	0	1	1	0	3	3	BACK PAIN
		FINAL	12MAR2003	56	22:00	5	10:00	12	0	1	2	0	0	1	1	0	3	3	BACK PAIN
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	DAY 1	13FEB2003	1	22:00	120	4:00	6	3	3	0	0	0	0	0	0	0		
		DAY 29	13MAR2003	29	22:00	30	7:00	9	1	0	0	0	0	0	0	1	0		
		FINAL	13MAR2003	29	22:00	30	7:00	9	1	0	0	0	0	0	0	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	DAY 1	01OCT2002	-3	3:00	60	6:30	3	3	3	1	0	0	3	3	3	1		
		DAY 29	31OCT2002	28	22:00	30	8:30	9	2	2	1	0	0	0	2	3	0		
		DAY 29 *	14NOV2002	42	1:00	30	9:00	7	2	1	0	0	1	0	0	2	0		
		FINAL	14NOV2002	42	1:00	30	9:00	7	2	1	0	0	1	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	DAY 1	21JAN2003	1	19:30	60	3:30	6	3	3	0	3	0	3	2	3	0		
		DAY 29	17FEB2003	28	17:00	80	3:15	4	2	2	2	3	1	1	1	0	0		
		FINAL	17FEB2003	28	17:00	80	3:15	4	2	2	2	3	1	1	1	0	0		

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0026002	DAY 1	12NOV2002	1	0	2	3	0	0	3	2		
		DAY 29	11DEC2002	30	0	1	3	0	0	3	2		
		DAY 57	09JAN2003	59	0	2	3	1	0	3	1		
		FINAL	09JAN2003	59	0	2	3	1	0	3	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0026007	DAY 1	16JAN2003	1	2	3	1						
		DAY 29	13FEB2003	29	0	0	2	0	0	0	0		
		DAY 57	12MAR2003	56	0	0	2	0	0	0	0		
		FINAL	12MAR2003	56	0	0	2	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	DAY 1	13FEB2003	1	2	3	1						
		DAY 29	13MAR2003	29	1	2	0					1	NIGHTMARE YELLING
		FINAL	13MAR2003	29	1	2	0					1	NIGHTMARE YELLING
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	DAY 1	01OCT2002	-3	0	2	3	0	0	2	1		
		DAY 29	31OCT2002	28	0	1	0						
		DAY 29 *	14NOV2002	42	0	1	3	1	0	2	0		
		FINAL	14NOV2002	42	0	1	3	1	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	DAY 1	21JAN2003	1	3	2	0						
		DAY 29	17FEB2003	28	3	3	0						
		FINAL	17FEB2003	28	3	3	0						

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	DAY 1	13JAN2003	1	20		3	3	3	3	3	3	2
		DAY 29	27JAN2003	15	3	-17	1	0	0	0	1	0	1
		FINAL	27JAN2003	15	3	-17	1	0	0	0	1	0	1
	E0028033	DAY 1	27MAR2003	1	13		2	3	2	2	2	0	2
		DAY 29	24APR2003	29	10	-3	1	2	1	2	2	0	2
		DAY 57	22MAY2003	57	12	-1	1	1	1	2	2	3	2
		FINAL	22MAY2003	57	12	-1	1	1	1	2	2	3	2
	E0028035	DAY 1	03APR2003	1	5		1	1	1	0	1	0	1
		DAY 29	01MAY2003	29	4	-1	0	1	0	0	2	0	1
		DAY 57	29MAY2003	57	6	1	0	2	0	0	1	1	2
		FINAL	29MAY2003	57	6	1	0	2	0	0	1	1	2
	E0028037	DAY 1	12JUN2003	-1	3		1	0	0	0	1	0	1
		DAY 29	08JUL2003	26	2	-1	0	0	0	0	1	0	1
		DAY 57	08AUG2003	57	3	0	1	0	0	0	1	0	1
		FINAL	08AUG2003	57	3	0	1	0	0	0	1	0	1
	E0028039	DAY 1	08MAY2003	-1	11		2	3	1	1	2	0	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	DAY 1	13JAN2003	1	22:00	120	6:30	4	3	3	3	3	1	1	3	1	3	3	SEXUAL ARROUSAL
		DAY 29	27JAN2003	15	21:00	10	6:00	8	0	0	0	1	0	0	0	1	1	0	SEXUAL ARROUSAL
		FINAL	27JAN2003	15	21:00	10	6:00	8	0	0	0	1	0	0	0	1	1	0	SEXUAL ARROUSAL
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	DAY 1	27MAR2003	1	23:20	45	6:45	5	3	3	3	1	1	1	2	0	2		
		DAY 29	24APR2003	29	22:30	30	6:45	6	2	2	3	1	0	0	2	0	2		
		DAY 57	22MAY2003	57	22:00	15	6:45	6	2	1	3	1	1	0	2	2	1		
		FINAL	22MAY2003	57	22:00	15	6:45	6	2	1	3	1	1	0	2	2	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	DAY 1	03APR2003	1	1:00	15	7:00	6	2	2	1	0	0	0	0	1	0	2	HEARTBURN
		DAY 29	01MAY2003	29	0:30	15	9:15	9	2	3	3	1	0	0	0	1	1	3	HEARTBURN
		DAY 57	29MAY2003	57	0:00	20	9:30	10	2	3	3	1	0	0	0	2	0		
		FINAL	29MAY2003	57	0:00	20	9:30	10	2	3	3	1	0	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	DAY 1	12JUN2003	-1	20:30	5	4:30	8	0	2	2	0	0	0	0	1	0		
		DAY 29	08JUL2003	26	21:00	5	5:00	8	0	0	3	0	0	0	1	1	0		
		DAY 57	08AUG2003	57	22:00	15	6:00	8	0	1	3	0	0	0	0	0	0		
		FINAL	08AUG2003	57	22:00	15	6:00	8	0	1	3	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 1	08MAY2003	-1	23:00	60	6:30	6	3	3	1	2	2	1	1	3	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	DAY 1	13JAN2003	1	3	1	3	2	1	3	3	3	GETS UP AT NIGHT FOR ABOUT 3 HOURS
		DAY 29	27JAN2003	15	1	1	3	0	0	2	0	0	AWAKENING FOR LONG PERIODS AT NIGHT.
		FINAL	27JAN2003	15	1	1	3	0	0	2	0	0	AWAKENING FOR LONG PERIODS AT NIGHT.
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	DAY 1	27MAR2003	1	2	2	0						
		DAY 29	24APR2003	29	1	2	0						
		DAY 57	22MAY2003	57	1	2	0						
		FINAL	22MAY2003	57	1	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	DAY 1	03APR2003	1	0	2	0						
		DAY 29	01MAY2003	29	0	2	0						
		DAY 57	29MAY2003	57	1	2	0						
		FINAL	29MAY2003	57	1	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	DAY 1	12JUN2003	-1	0	2	1						
		DAY 29	08JUL2003	26	0	1	1						
		DAY 57	08AUG2003	57	0	1	1						
		FINAL	08AUG2003	57	0	1	1						
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 1	08MAY2003	-1	1	2	3	1	0	2	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 29		05JUN2003	28	5	-6	1	1	0	0	2	0	1
		FINAL		05JUN2003	28	5	-6	1	1	0	0	2	0	1
	E0028046	DAY 1		25JUN2003	1	16		3	2	3	3	2	0	3
	E0028048	DAY 1		17JUL2003	1	16		2	3	3	3	3	0	2
		DAY 29		14AUG2003	29	4	-12	1	1	0	0	2	0	0
		FINAL		14AUG2003	29	4	-12	1	1	0	0	2	0	0
	E0029008	DAY 1		16DEC2002	1	17		2	3	3	2	3	1	3
		DAY 29		23DEC2002	8	13	-4	3	3	1	0	2	1	3
		FINAL		23DEC2002	8	13	-4	3	3	1	0	2	1	3
	E0029011	DAY 1		21JAN2003	-1	9		2	3	0	0	2	0	2
	E0029012	DAY 1		11FEB2003	1	8		3	0	0	0	2	0	3
		DAY 29		11MAR2003	29	5	-3	1	0	0	0	1	0	3
		DAY 29	*	18MAR2003	36	5	-3	1	0	0	0	1	0	3
		FINAL		18MAR2003	36	5	-3	1	0	0	0	1	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 29		05JUN2003	28	1:00	30	12:30	12	0	2	2	2	2	2	2	2	1		
		FINAL		05JUN2003	28	1:00	30	12:30	12	0	2	2	2	2	2	2	2	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0028046	DAY 1		25JUN2003	1	9:00	60	5:30	4	2	3	3	3	0	1	1	3	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	DAY 1		17JUL2003	1	0:00	150	10:00	4	3	3	3	3	3	3	3	3	3		
		DAY 29		14AUG2003	29	21:00	20	8:00	11	0	0	0	2	2	1	1	2	2	1	CHEST PAINS
		FINAL		14AUG2003	29	21:00	20	8:00	11	0	0	0	2	2	1	1	2	2	1	CHEST PAINS
QUETIAPINE 600 MG (BIPOLAR I)	E0029008	DAY 1		16DEC2002	1	1:30	60	7:15	4	3	3	3	1	1	3	3	3	1	3	TOSS AND TURN
		DAY 29		23DEC2002	8	2:00	60	9:00	6	3	3	3	2	0	2	2	2	2		
		FINAL		23DEC2002	8	2:00	60	9:00	6	3	3	3	2	0	2	2	2	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	DAY 1		21JAN2003	-1	6:45	45	14:30	8	3	1	0	0	2	0	2	3	3	3	MIND RACING
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	DAY 1		11FEB2003	1	21:00	15	6:45	10	0	2	3	0	3	0	1	3	0		
		DAY 29		11MAR2003	29	22:00	5	6:30	9	0	0	0	0	3	1	1	1	2		
		DAY 29	*	18MAR2003	36	22:00	5	6:30	9	0	0	0	0	3	1	1	1	2		
		FINAL		18MAR2003	36	22:00	5	6:30	9	0	0	0	0	3	1	1	1	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 29	05JUN2003	28	0	2	3	0	0	1	0		
		FINAL	05JUN2003	28	0	2	3	0	0	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0028046	DAY 1	25JUN2003	1	3	3	3	0	0	2	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	DAY 1	17JUL2003	1	1	2	2	3	2	3	2	2	TALKING IN SLEEP
		DAY 29	14AUG2003	29	0	0	2	1	1	1	1	1	TOSSING AND TURNING
		FINAL	14AUG2003	29	0	0	2	1	1	1	1	1	TOSSING AND TURNING
QUETIAPINE 600 MG (BIPOLAR I)	E0029008	DAY 1	16DEC2002	1	3	3	0						
		DAY 29	23DEC2002	8	3	3	0						
		FINAL	23DEC2002	8	3	3	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	DAY 1	21JAN2003	-1	1	2	3	2	0	0	2	2	MIND RACING DREAM TO DREAM
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	DAY 1	11FEB2003	1	3	3	3	3	3	3	3	3	BAD DREAMS
		DAY 29	11MAR2003	29	3	2	3	3	3	0	0		
		DAY 29 *	18MAR2003	36	3	2	3	3	3	0	0		
		FINAL	18MAR2003	36	3	2	3	3	3	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0029015	DAY 1	24FEB2003	1	14		2	3	1	1	2	3	2
		DAY 29	11MAR2003	16	14	0	2	3	1	1	2	3	2
		FINAL	11MAR2003	16	14	0	2	3	1	1	2	3	2
	E0029018	DAY 1	06MAR2003	1	10		2	2	2	0	2	1	1
	E0030014	DAY 1	21FEB2003	1	15		2	3	2	3	2	1	2
		DAY 29	21MAR2003	29	7	-8	1	2	0	0	1	0	3
		DAY 57	22APR2003	61	6	-9	0	1	1	0	1	0	3
		FINAL	22APR2003	61	6	-9	0	1	1	0	1	0	3
	E0030020	DAY 1	29MAY2003	1	16		3	3	2	3	2	1	2
		DAY 29	24JUN2003	27	3	-13	0	0	0	1	1	0	1
		FINAL	24JUN2003	27	3	-13	0	0	0	1	1	0	1
	E0030024	DAY 1	11JUL2003	1	13		2	3	1	2	2	1	2
		DAY 29	18JUL2003	8	15	2	2	3	1	3	2	2	2
		FINAL	18JUL2003	8	15	2	2	3	1	3	2	2	2

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0029015	DAY 1	24FEB2003	1	22:00	60	6:00	6	3	3	3	0	3	2	2	0	0		
		DAY 29	11MAR2003	16	22:00	60	5:45	6	3	3	3	0	3	0	0	3	3		
		FINAL	11MAR2003	16	22:00	60	5:45	6	3	3	3	0	3	0	0	3	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0029018	DAY 1	06MAR2003	1	2:00	90	7:00	5	1	3	0	1	3	1	3	1	3		
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	DAY 1	21FEB2003	1	23:00	120	8:00	5	3	3	3	0	0	0	2	1	0	3	WORRY OR STRESS
		DAY 29	21MAR2003	29	22:30	30	7:00	8	2	1	3	1	0	0	1	1	0		
		DAY 57	22APR2003	61	23:00	20	7:00	7	1	1	2	0	0	0	2	1	0		
		FINAL	22APR2003	61	23:00	20	7:00	7	1	1	2	0	0	0	2	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	DAY 1	29MAY2003	1	0:00	180	8:00	5	3	2	1	0	0	3	3	1	0		
		DAY 29	24JUN2003	27	22:00	5	8:00	8	0	0	1	0	0	0	0	0	0	2	DRY MOUTH & SINUS CONGESTION
		FINAL	24JUN2003	27	22:00	5	8:00	8	0	0	1	0	0	0	0	0	0	2	DRY MOUTH & SINUS CONGESTION
QUETIAPINE 600 MG (BIPOLAR I)	E0030024	DAY 1	11JUL2003	1	2:00	60	10:30	6	3	3	3	3	0	0	3	3	2		
		DAY 29	18JUL2003	8	22:30	45	10:00	6	3	3	3	1	0	0	3	0	1		
		FINAL	18JUL2003	8	22:30	45	10:00	6	3	3	3	1	0	0	3	0	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0029015	DAY 1	24FEB2003	1	1	3	3	3	0	0	0		
		DAY 29	11MAR2003	16	0	3	3	3	0	3	0		
		FINAL	11MAR2003	16	0	3	3	3	0	3	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0029018	DAY 1	06MAR2003	1	0	2	2	2	1	3	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	DAY 1	21FEB2003	1	0	3	0						
		DAY 29	21MAR2003	29	3	2	0						
		DAY 57	22APR2003	61	3	2	0						
		FINAL	22APR2003	61	3	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	DAY 1	29MAY2003	1	1	3	2	1	0	0	0		
		DAY 29	24JUN2003	27	1	0	2	0	0	1	0		
		FINAL	24JUN2003	27	1	0	2	0	0	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0030024	DAY 1	11JUL2003	1	0	3	3	0	0	0	1	3	TOSSING & TURNING
		DAY 29	18JUL2003	8	0	3	3	0	0	1	0	3	TOSSING AND TURNING
		FINAL	18JUL2003	8	0	3	3	0	0	1	0	3	TOSSING AND TURNING

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0030025	DAY 1	11JUL2003	1	17		3	3	3	3	2	0	3
		DAY 29	11AUG2003	32	13	-4	1	1	2	3	2	3	1
		DAY 29 *	19AUG2003	40			1	1	2		2	3	3
		FINAL	19AUG2003	40			1	1	2		2	3	3
	E0031027	DAY 1	03JUN2003	1	9		1	3	0	1	2	0	2
		DAY 29	01JUL2003	29	16	7	2	3	1	3	2	3	2
		DAY 57	29JUL2003	57	4	-5	1	2	0	0	1	0	0
		FINAL	29JUL2003	57	4	-5	1	2	0	0	1	0	0
	E0031030	DAY 1	24JUN2003	1	8		2	2	1	0	1	0	2
		DAY 29	23JUL2003	30	10	2	1	3	1	0	2	3	0
		DAY 57	21AUG2003	59	9	1	1	3	1	0	1	3	0
		FINAL	21AUG2003	59	9	1	1	3	1	0	1	3	0
	E0033012	DAY 1	10FEB2003	1	10		3	3	0	0	1	1	2
	E0034001	DAY 1	20MAR2003	1	5		1	1	0	0	1	0	2
		DAY 29	17APR2003	29	3	-2	1	0	0	0	1	0	1
		DAY 57	15MAY2003	57	2	-3	0	0	0	0	1	0	1
		FINAL	15MAY2003	57	2	-3	0	0	0	0	1	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0030025	DAY 1		11JUL2003	1	22:00	120	6:00	3	3	3	1	3	1	1	3	1	3	
		DAY 29		11AUG2003	32	22:00	30	6:30	5	1	2	1	1	1	1	3	1	3	
		DAY 29	*	19AUG2003	40	22:00	30		5	0	3	1	0	0	0	3	0	3	
		FINAL		19AUG2003	40	22:00	30		5	0	3	1	0	0	0	3	0	3	
QUETIAPINE 600 MG (BIPOLAR I)	E0031027	DAY 1		03JUN2003	1	23:00	60	9:00	8	3	3	3	3	3	2	1	2	1	
		DAY 29		01JUL2003	29	1:00	120	11:30	6	3	3	0	0	1	1	2	3	0	
		DAY 57		29JUL2003	57	23:00	60	10:30	10	2	2	1	0	0	0	0	1	0	
		FINAL		29JUL2003	57	23:00	60	10:30	10	2	2	1	0	0	0	0	1	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	DAY 1		24JUN2003	1	0:00	120	4:00	6	0	3	3	0	0	0	0	1	0	
		DAY 29		23JUL2003	30	22:00	45	5:00	7	3	3	3	0	0	2	2	2	0	
		DAY 57		21AUG2003	59	22:00	45	4:30	6	3	3	3	0	0	1	0	2	0	
		FINAL		21AUG2003	59	22:00	45	4:30	6	3	3	3	0	0	1	0	2	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0033012	DAY 1		10FEB2003	1	4:00	60	12:00	11	3	2	1	0	0	1	1	2	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	DAY 1		20MAR2003	1	20:30	15	6:30	9	1	1	2	0	0	0	0	0	0	
		DAY 29		17APR2003	29	20:30	15	6:00	10	0	0	2	0	0	0	0	0	0	
		DAY 57		15MAY2003	57	20:30	15	7:00	10	0	1	2	0	0	0	0	1	1	
		FINAL		15MAY2003	57	20:30	15	7:00	10	0	1	2	0	0	0	0	1	1	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0030025	DAY 1		11JUL2003	1	2	3	1	0	0	0	3	3	BODY TWITCHING
		DAY 29		11AUG2003	32	0	1	1	0	0	0	0		
		DAY 29	*	19AUG2003	40	2	3	1	0	0	0	0		
		FINAL		19AUG2003	40	2	3	1	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0031027	DAY 1		03JUN2003	1	2	2	3	1	3	1	1		
		DAY 29		01JUL2003	29	1	2	3	0	0	0	0		
		DAY 57		29JUL2003	57	0	0	3	0	1	0	0		
		FINAL		29JUL2003	57	0	0	3	0	1	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	DAY 1		24JUN2003	1	2	2	0						
		DAY 29		23JUL2003	30	0	0	0						
		DAY 57		21AUG2003	59	0	0	0						
		FINAL		21AUG2003	59	0	0	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0033012	DAY 1		10FEB2003	1	1	3	1						
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	DAY 1		20MAR2003	1	0	3	0						
		DAY 29		17APR2003	29	0	2	0						
		DAY 57		15MAY2003	57	0	2	0						
		FINAL		15MAY2003	57	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	DAY 1	21APR2003	1	7		2	0	2	1	1	0	1
		DAY 29	19MAY2003	29	1	-6	0	0	1	0	0	0	0
		DAY 57	16JUN2003	57	3	-4	0	0	0	0	0	3	0
		FINAL	16JUN2003	57	3	-4	0	0	0	0	0	3	0
	E0035001	DAY 1	20NOV2002	1	11		1	1	1	3	1	3	1
		DAY 29	18DEC2002	29	7	-4	0	2	0	3	1	0	1
		DAY 57	14JAN2003	56	1	-10	0	0	0	0	1	0	0
		FINAL	14JAN2003	56	1	-10	0	0	0	0	1	0	0
	E0035006	DAY 1	12DEC2002	1	18		3	2	2	3	3	2	3
		DAY 29	09JAN2003	29	15	-3	3	3	2	3	2	0	2
		DAY 57	06FEB2003	57	13	-5	1	3	1	3	2	0	3
		FINAL	06FEB2003	57	13	-5	1	3	1	3	2	0	3
	E0035021	DAY 1	25APR2003	1	9		2	3	1	1	1	0	1
		DAY 29	23MAY2003	29	1	-8	0	1	0	0	0	0	0
		DAY 57	20JUN2003	57	3	-6	1	2	0	0	0	0	0
		FINAL	20JUN2003	57	3	-6	1	2	0	0	0	0	0
	E0036002	DAY 1	17JUN2003	1	11		1	3	2	2	1	0	2
		DAY 29	14JUL2003	28	5	-6	1	1	0	0	1	0	2
		FINAL	14JUL2003	28	5	-6	1	1	0	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	DAY 1	21APR2003	1	22:00	10	4:30	5	0	3	0	0	1	0	0	2	0	
		DAY 29	19MAY2003	29	22:00	5	5:00	7	0	0	0	0	0	0	0	0	0	
		DAY 57	16JUN2003	57	22:00	10	5:30	8	0	0	0	0	0	0	0	0	0	
		FINAL	16JUN2003	57	22:00	10	5:30	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0035001	DAY 1	20NOV2002	1	21:00	10	7:00	6	1	1	0	0	0	0	0	0	0	
		DAY 29	18DEC2002	29	9:00	30	7:00	8	3	2	0	0	0	0	0	0	0	
		DAY 57	14JAN2003	56	21:30	10	6:30	8	0	1	0	0	0	0	0	0	0	
		FINAL	14JAN2003	56	21:30	10	6:30	8	0	1	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 1	12DEC2002	1	22:00	30	7:30	5	3	3	3	3	1	3	3	3	3	
		DAY 29	09JAN2003	29	23:00	60	7:00	5	3	3	1	1	0	2	2	3	2	
		DAY 57	06FEB2003	57	19:30	75	6:00	6	3	3	1	2	0	3	3	1	1	
		FINAL	06FEB2003	57	19:30	75	6:00	6	3	3	1	2	0	3	3	1	1	
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	DAY 1	25APR2003	1	22:30	90	6:30	6	3	3	0	0	0	0	0	0	0	
		DAY 29	23MAY2003	29	21:00	40	7:15	9	0	0	0	0	0	0	0	0	0	
		DAY 57	20JUN2003	57	21:00	25	7:00	12	2	0	0	0	0	0	0	0	0	
		FINAL	20JUN2003	57	21:00	25	7:00	12	2	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	DAY 1	17JUN2003	1	23:00	105	6:30	5	3	3	2	0	0	0	2	2	0	
		DAY 29	14JUL2003	28	22:00	30	8:00	9	1	1	2	0	2	0	1	2	1	
		FINAL	14JUL2003	28	22:00	30	8:00	9	1	1	2	0	2	0	1	2	1	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	DAY 1	21APR2003	1	0	2	0						
		DAY 29	19MAY2003	29	0	0	0						
		DAY 57	16JUN2003	57	0	0	0						
		FINAL	16JUN2003	57	0	0	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0035001	DAY 1	20NOV2002	1	0	2	0						
		DAY 29	18DEC2002	29	0	1	0						
		DAY 57	14JAN2003	56	0	0	0						
		FINAL	14JAN2003	56	0	0	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 1	12DEC2002	1	3	3	0						
		DAY 29	09JAN2003	29	1	2	0						
		DAY 57	06FEB2003	57	3	2	0						
		FINAL	06FEB2003	57	3	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	DAY 1	25APR2003	1	0	1	0						
		DAY 29	23MAY2003	29	0	0	2	0	0	0	0		
		DAY 57	20JUN2003	57	0	0	0						
		FINAL	20JUN2003	57	0	0	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	DAY 1	17JUN2003	1	1	3	3	0	0	0	0		
		DAY 29	14JUL2003	28	1	2	3	2	0	3	2		
		FINAL	14JUL2003	28	1	2	3	2	0	3	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	DAY 1	03JUL2003	1	15		3	3	1	1	2	3	2
		DAY 29	31JUL2003	29	2	-13	0	1	0	0	0	0	1
		DAY 57	27AUG2003	56	1	-14	0	0	0	0	0	0	1
		FINAL	27AUG2003	56	1	-14	0	0	0	0	0	0	1
	E0036007	DAY 1	03JUL2003	1	15		3	2	1	3	3	0	3
		DAY 29	18JUL2003	16	7	-8	1	2	0	0	2	0	2
		FINAL	18JUL2003	16	7	-8	1	2	0	0	2	0	2
	E0037009	DAY 1	16MAY2003	1	9		1	2	0	1	1	3	1
		DAY 29	12JUN2003	28	8	-1	1	2	0	1	2	1	1
		DAY 57	10JUL2003	56	7	-2	1	2	0	1	1	1	1
		FINAL	10JUL2003	56	7	-2	1	2	0	1	1	1	1
	E0039011	DAY 1	02JAN2003	1	11		3	3	3	0	1	0	1
		DAY 29	03FEB2003	33	5	-6	1	1	1	0	1	0	1
		FINAL	03FEB2003	33	5	-6	1	1	1	0	1	0	1
	E0039018	DAY 1	23JAN2003	1	12		2	3	3	0	2	0	2
		DAY 29	20FEB2003	29	2	-10	0	0	0	1	1	0	0
		FINAL	20FEB2003	29	2	-10	0	0	0	1	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	DAY 1	03JUL2003	1	1:00	45	8:30	6	3	3	2	2	1	0	0	2	0	
		DAY 29	31JUL2003	29	23:00	30	8:30	9	0	0	0	0	0	0	0	0	0	
		DAY 57	27AUG2003	56	23:00	15	8:30	9	0	0	0	0	0	0	0	0	0	
		FINAL	27AUG2003	56	23:00	15	8:30	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	DAY 1	03JUL2003	1	21:00	30	7:00	6	3	3	2	3	3	3	3	3	0	
		DAY 29	18JUL2003	16	21:00	10	7:30	11	3	2	1	2	2	2	2	1	3	
		FINAL	18JUL2003	16	21:00	10	7:30	11	3	2	1	2	2	2	2	1	3	
QUETIAPINE 600 MG (BIPOLAR I)	E0037009	DAY 1	16MAY2003	1	22:30	30	9:00	8	3	2	1	2	0	0	0	2	0	
		DAY 29	12JUN2003	28	23:15	30	9:30	8	3	3	3	3	1	0	1	0	0	3 "I WAKE WANTING TO EAT"
		DAY 57	10JUL2003	56	23:00	3	9:30	8	3	3	3	1	1	0	1	0	0	
		FINAL	10JUL2003	56	23:00	3	9:30	8	3	3	3	1	1	0	1	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0039011	DAY 1	02JAN2003	1	4:00	240	7:00	3	3	3	1	1	0	1	1	0	0	
		DAY 29	03FEB2003	33	23:30	30	7:00	7	0	0	0	2	0	0	0	0	0	
		FINAL	03FEB2003	33	23:30	30	7:00	7	0	0	0	2	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR I)	E0039018	DAY 1	23JAN2003	1	6:00	240	8:00	4	3	3	2	0	1	3	3	3	3	
		DAY 29	20FEB2003	29	22:00	5	7:30	8	0	0	3	0	0	2	3	0	0	
		FINAL	20FEB2003	29	22:00	5	7:30	8	0	0	3	0	0	2	3	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	DAY 1	03JUL2003	1	0	3	1						
		DAY 29	31JUL2003	29	0	1	0						
		DAY 57	27AUG2003	56	0	1	0						
		FINAL	27AUG2003	56	0	1	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	DAY 1	03JUL2003	1	3	3	3	0	3	3	3	3	"CAN' T STOP TURNING FROM ONE SIDE TO THE OTHER."
		DAY 29	18JUL2003	16	3	1	3	0	2	3	2		
		FINAL	18JUL2003	16	3	1	3	0	2	3	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0037009	DAY 1	16MAY2003	1	0	2	0						
		DAY 29	12JUN2003	28	0	1	1	1	3	0	0		
		DAY 57	10JUL2003	56	0	1	1	1	1	0	0		
		FINAL	10JUL2003	56	0	1	1	1	1	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0039011	DAY 1	02JAN2003	1	0	2	0						
		DAY 29	03FEB2003	33	0	2	0						
		FINAL	03FEB2003	33	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0039018	DAY 1	23JAN2003	1	2	1	0						
		DAY 29	20FEB2003	29	0	0	0						
		FINAL	20FEB2003	29	0	0	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	DAY 1	07MAR2003	1	11		2	3	2	1	1	0	2
		DAY 29	04APR2003	29	3	-8	0	1	0	0	1	0	1
		DAY 57	01MAY2003	56	6	-5	0	3	0	0	2	0	1
		FINAL	01MAY2003	56	6	-5	0	3	0	0	2	0	1
	E0039028	DAY 1	24MAR2003	1	9		3	2	1	1	1	0	1
		DAY 29	21APR2003	29	7	-2	2	0	1	0	2	0	2
		FINAL	21APR2003	29	7	-2	2	0	1	0	2	0	2
	E0039032	DAY 1	14MAR2003	1	7		2	0	2	0	2	0	1
	E0039034	DAY 1	19MAR2003	1	11		1	2	2	2	2	0	2
		DAY 29	16APR2003	29	2	-9	0	0	0	0	1	0	1
		DAY 57	14MAY2003	57	1	-10	0	0	0	0	1	0	0
		FINAL	14MAY2003	57	1	-10	0	0	0	0	1	0	0
	E0039042	DAY 1	07MAY2003	1	16		2	3	3	3	2	0	3
		DAY 29	05JUN2003	30	8	-8	1	1	1	3	1	0	1
		DAY 57	02JUL2003	57	5	-11	1	1	0	1	2	0	0
		FINAL	02JUL2003	57	5	-11	1	1	0	1	2	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	DAY 1	07MAR2003	1	1:00	60	7:00	5	3	3	2	0	0	0	0	0	1	3	STRESS
		DAY 29	04APR2003	29	21:50	60	7:30	10	0	0	1	3	1	0	0	1	0		
		DAY 57	01MAY2003	56	23:55	60	7:30	11	3	0	0	3	3	0	3	0	0	3	AFRAID SOMETIMES WON'T BE ABLE TO BREATHE
		FINAL	01MAY2003	56	23:55	60	7:30	11	3	0	0	3	3	0	3	0	0	3	AFRAID SOMETIMES WON'T BE ABLE TO BREATHE
QUETIAPINE 600 MG (BIPOLAR I)	E0039028	DAY 1	24MAR2003	1	21:00	30	5:00	6	3	3	3	0	3	0	0	0	0		
		DAY 29	21APR2003	29	22:00	15	4:30	7	0	2	3	0	3	0	2	1	0		
		FINAL	21APR2003	29	22:00	15	4:30	7	0	2	3	0	3	0	2	1	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	DAY 1	14MAR2003	1	23:00	15	4:00	5	0	3	2	0	3	1	1	0	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	DAY 1	19MAR2003	1	23:30	30	7:00	5	2	3	3	0	0	2	2	2	2		
		DAY 29	16APR2003	29	22:00	10	7:00	10	0	0	0	0	0	0	0	0	2		
		DAY 57	14MAY2003	57	22:00	15	7:00	9	0	0	0	0	0	0	0	0	2		
		FINAL	14MAY2003	57	22:00	15	7:00	9	0	0	0	0	0	0	0	0	2		
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	DAY 1	07MAY2003	1	1:00	60	11:00	4	3	2	3	2	0	1	2	3	1	3	UNCOMFORTABLE
		DAY 29	05JUN2003	30	22:00	30	9:00	7	1	1	2	2	1	0	1	0	1		
		DAY 57	02JUL2003	57	23:00	30	10:00	9	1	1	2	3	0	0	2	1	2		
		FINAL	02JUL2003	57	23:00	30	10:00	9	1	1	2	3	0	0	2	1	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	DAY 1	07MAR2003	1	1	3	3						
		DAY 29	04APR2003	29	0	1	3						
		DAY 57	01MAY2003	56	0	1	3						
		FINAL	01MAY2003	56	0	1	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0039028	DAY 1	24MAR2003	1	0	2	0						
		DAY 29	21APR2003	29	1	2	0						
		FINAL	21APR2003	29	1	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	DAY 1	14MAR2003	1	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	DAY 1	19MAR2003	1	1	3	3						
		DAY 29	16APR2003	29	0	1	3						
		DAY 57	14MAY2003	57	0	0	3						
		FINAL	14MAY2003	57	0	0	3						
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	DAY 1	07MAY2003	1	2	3	3						
		DAY 29	05JUN2003	30	1	1	3						
		DAY 57	02JUL2003	57	0	0	3						
		FINAL	02JUL2003	57	0	0	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	DAY 1	30JAN2003	1	6		1	2	0	0	1	0	2
		DAY 57	31MAR2003	61	6	0	1	2	0	0	1	0	2
		FINAL	31MAR2003	61	6	0	1	2	0	0	1	0	2
	E0041009	DAY 1	01MAY2003	1	18		3	3	3	3	2	2	2
		DAY 57	16JUN2003	47			1	1	2	3		0	1
		FINAL	16JUN2003	47			1	1	2	3		0	1
	E0042002	DAY 1	09JUL2003	1	10		2	2	0	1	2	2	1
		DAY 29	05AUG2003	28	4	-6	0	2	0	0	1	0	1
		DAY 57	02SEP2003	56	9	-1	1	1	0	2	1	3	1
		FINAL	02SEP2003	56	9	-1	1	1	0	2	1	3	1
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	7		1	1	1	0	1	0	3
		DAY 29	18JUL2003	8	7	0	1	1	1	0	1	0	3
		FINAL	18JUL2003	8	7	0	1	1	1	0	1	0	3
	E0003002	DAY 1	29OCT2002	1	11		2	3	1	3	1	0	1
		DAY 29	26NOV2002	29	4	-7	1	2	0	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	DAY 1	30JAN2003	1	0:00	30	9:00	8	2	1	0	1	2	1	1	0	0		
		DAY 57	31MAR2003	61	22:00	30	9:30	10	2	1	0	0	2	1	1	2	0		
		FINAL	31MAR2003	61	22:00	30	9:30	10	2	1	0	0	2	1	1	2	0		
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	DAY 1	01MAY2003	1	22:00	120	5:00	4	3	3	2	1	0	2	2	1	2	3	ANXIETY WORRY ABOUT HOW I WILL TAKE CARE OF MYSELF
		DAY 57	16JUN2003	47	23:00	60	7:00	5	0	3	2	1		0	3	1	1	1	HAVE VERY VIVID DREAMS DURING PAST MONTH
		FINAL	16JUN2003	47	23:00	60	7:00	5	0	3	2	1		0	3	1	1	1	HAVE VERY VIVID DREAMS DURING PAST MONTH
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	DAY 1	09JUL2003	1	22:30	30	8:00	8	2	3	3	3	0	0	1	0	2		
		DAY 29	05AUG2003	28	22:30	20	7:30	8	2	2	0	1	0	0	0	0	2		
		DAY 57	02SEP2003	56	21:00	20	8:00	8	0	0	3	0	1	0	2	0	2		
		FINAL	02SEP2003	56	21:00	20	8:00	8	0	0	3	0	1	0	2	0	2		
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	23:00	30	5:30	6	1	1	1	0	1	0	0	0	0		
		DAY 29	18JUL2003	8	23:00	30	5:00	6	0	0	1	0	0	0	0	0	0		
		FINAL	18JUL2003	8	23:00	30	5:00	6	0	0	1	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 1	29OCT2002	1	23:00	180	11:30	6	3	2	1	0	0	0	2	0	0	3	WORRY
		DAY 29	26NOV2002	29	23:00	30	9:30	10	3	1	2	1	2	0	2	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	DAY 1	30JAN2003	1	1	2	3	2	1	0	2		
		DAY 57	31MAR2003	61	2	1	1	2	1	0	1		
		FINAL	31MAR2003	61	2	1	1	2	1	0	1		
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	DAY 1	01MAY2003	1	0	3	0						
		DAY 57	16JUN2003	47	0	2	0						
		FINAL	16JUN2003	47	0	2	0						
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	DAY 1	09JUL2003	1	0	2	0						
		DAY 29	05AUG2003	28	0	1	0						
		DAY 57	02SEP2003	56	1	1	0						
		FINAL	02SEP2003	56	1	1	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	3	3	3	0	0	0	0		
		DAY 29	18JUL2003	8	3	3	3	0	0	0	0		
		FINAL	18JUL2003	8	3	3	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 1	29OCT2002	1	0	2	3	3	2	3	1	2	TALKS IN SLEEP
		DAY 29	26NOV2002	29	0	0	3	2	0	0	0	2	MUMBLING, TALKING

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 57	23DEC2002	56	3	-8	0	1	1	0	1	0	0
		FINAL	23DEC2002	56	3	-8	0	1	1	0	1	0	0
	E0005031	DAY 1	02APR2003	1	5		1	1	0	0	2	0	1
		DAY 29	01MAY2003	30	3	-2	0	0	0	1	1	0	1
		FINAL	01MAY2003	30	3	-2	0	0	0	1	1	0	1
	E0005033	DAY 1	15APR2003	-1	14		3	2	2	0	2	3	2
		DAY 29	06MAY2003	21	7	-7	1	1	0	0	2	0	3
		FINAL	06MAY2003	21	7	-7	1	1	0	0	2	0	3
	E0005038	DAY 1	14MAY2003	1	17		2	3	2	1	3	3	3
		DAY 29	05JUN2003	23	13	-4	2	1	2	3	2	0	3
		FINAL	05JUN2003	23	13	-4	2	1	2	3	2	0	3
	E0007009	DAY 1	17APR2003	1	4		1	0	0	0	0	0	3
		DAY 29	28APR2003	12	4	0	0	0	1	0	0	0	3
		FINAL	28APR2003	12	4	0	0	0	1	0	0	0	3
	E0009010	DAY 1	13MAR2003	1	12		2	3	2	3	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING									
									5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 57	23DEC2002	56	3:00	30	10:30	7	0	0	1	0	0	0	2	2	0	
		FINAL	23DEC2002	56	3:00	30	10:30	7	0	0	1	0	0	0	2	2	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0005031	DAY 1	02APR2003	1	0:30	15	8:30	8	2	2	3	0	0	0	3	1	1	
		DAY 29	01MAY2003	30	23:00	15	8:45	8	0	0	2	0	3	0	3	1	0	
		FINAL	01MAY2003	30	23:00	15	8:45	8	0	0	2	0	3	0	3	1	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0005033	DAY 1	15APR2003	-1	0:30	40	6:00	5	2	3	3	0	0	1	2	3	1	
		DAY 29	06MAY2003	21	22:00	5	6:00	8	1	2	3	3	3	1	1	3	1	
		FINAL	06MAY2003	21	22:00	5	6:00	8	1	2	3	3	3	1	1	3	1	
QUETIAPINE 600 MG (BIPOLAR II)	E0005038	DAY 1	14MAY2003	1	0:00	60	6:00	5	3	3	3	3	3	3	3	3	1	
		DAY 29	05JUN2003	23	9:00	30	18:00	5	1	3	3	3	3	1	1	2	1	
		FINAL	05JUN2003	23	9:00	30	18:00	5	1	3	3	3	3	1	1	2	1	
QUETIAPINE 600 MG (BIPOLAR II)	E0007009	DAY 1	17APR2003	1	21:00	5	6:30	9	0	0	0	0	0	0	0	0	0	
		DAY 29	28APR2003	12	23:45	5	6:00	6	0	0	0	0	0	0	0	0	0	
		FINAL	28APR2003	12	23:45	5	6:00	6	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0009010	DAY 1	13MAR2003	1	23:00	90	10:00	5	3	3	3	0	0	0	0	3	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 57	23DEC2002	56	0	0	3	2	0	1	0		
		FINAL	23DEC2002	56	0	0	3	2	0	1	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0005031	DAY 1	02APR2003	1	0	2	3						
		DAY 29	01MAY2003	30	0	1	3						
		FINAL	01MAY2003	30	0	1	3						
QUETIAPINE 600 MG (BIPOLAR II)	E0005033	DAY 1	15APR2003	-1	0	3	3						
		DAY 29	06MAY2003	21	3	3	3						
		FINAL	06MAY2003	21	3	3	3						
QUETIAPINE 600 MG (BIPOLAR II)	E0005038	DAY 1	14MAY2003	1	2	3	3	1	2	0	0	3	CONSTANTLY CHANGING SLEEP POSITION
		DAY 29	05JUN2003	23	2	3	3	1	3	3	1		
		FINAL	05JUN2003	23	2	3	3	1	3	3	1		
QUETIAPINE 600 MG (BIPOLAR II)	E0007009	DAY 1	17APR2003	1	3	3	0						
		DAY 29	28APR2003	12	3	3	0						
		FINAL	28APR2003	12	3	3	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0009010	DAY 1	13MAR2003	1	0	2	1						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0009011	DAY 1	06MAY2003	1	5		1	1	0	0	1	0	2
		DAY 29	03JUN2003	29	2	-3	0	0	0	0	1	0	1
		DAY 57	03JUL2003	59	1	-4	0	0	0	0	0	0	1
		FINAL	03JUL2003	59	1	-4	0	0	0	0	0	0	1
	E0010005	DAY 1	18DEC2002	1	13		2	1	1	3	2	3	1
	E0011016	DAY 1	21APR2003	1	12		2	3	1	1	3	0	2
		DAY 29	19MAY2003	29	7	-5	1	1	0	0	2	0	3
		DAY 57	16JUN2003	57	4	-8	0	2	0	0	1	0	1
		FINAL	16JUN2003	57	4	-8	0	2	0	0	1	0	1
	E0011020	DAY 1	08MAY2003	1	9		1	3	1	1	2	0	1
	E0018002	DAY 1	29NOV2002	1	14		3	2	0	0	3	3	3
		DAY 29	24DEC2002	26	9	-5	1	2	1	0	3	0	2
		DAY 57	22JAN2003	55	9	-5	1	2	0	0	3	0	3
		FINAL	22JAN2003	55	9	-5	1	2	0	0	3	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0009011	DAY 1	06MAY2003	1	23:00	15	7:00	8	2	1	3	0	0	0	0	0	0		
		DAY 29	03JUN2003	29	23:00	5	8:00	9	0	0	2	0	0	0	0	0	0		
		DAY 57	03JUL2003	59	23:00	10	8:00	9	0	0	0	0	0	0	0	0	0		
		FINAL	03JUL2003	59	23:00	10	8:00	9	0	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0010005	DAY 1	18DEC2002	1	23:00	15	12:00	7	2	3	1	0	1	0	3	2	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	DAY 1	21APR2003	1	23:00	60	7:00	6	3	3	3	0	3	0	3	3	3	3	ANXIETY, THINKING
		DAY 29	19MAY2003	29	1:00	30	11:00	10	1	1	2	3	0	0	3	2	3	3	SORE BACK, KNEES
		DAY 57	16JUN2003	57	1:00	60	10:00	10	1	1	1	0	0	0	2	1	1		
		FINAL	16JUN2003	57	1:00	60	10:00	10	1	1	1	0	0	0	2	1	1		
QUETIAPINE 600 MG (BIPOLAR II)	E0011020	DAY 1	08MAY2003	1	22:00	90	5:30	6	3	3	3	0	0	0	2	2	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	DAY 1	29NOV2002	1	20:30	10	4:15	8	3	3	3	3	3	3	3	3	3	3	STRESS
		DAY 29	24DEC2002	26	20:30	20	4:10	7	2	3	3	3	3	3	2	2	3		
		DAY 57	22JAN2003	55	20:00	20	4:30	8	2	3	3	3	3	3	3	1	3		
		FINAL	22JAN2003	55	20:00	20	4:30	8	2	3	3	3	3	3	3	1	3		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0009011	DAY 1	06MAY2003	1	0	3	0						
		DAY 29	03JUN2003	29	0	1	0						
		DAY 57	03JUL2003	59	0	1	0						
		FINAL	03JUL2003	59	0	1	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0010005	DAY 1	18DEC2002	1	0	2	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	DAY 1	21APR2003	1	1	3	0						
		DAY 29	19MAY2003	29	2	3	0						
		DAY 57	16JUN2003	57	1	1	0						
		FINAL	16JUN2003	57	1	1	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0011020	DAY 1	08MAY2003	1	0	2	3						
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	DAY 1	29NOV2002	1	3	3	3	3	0	3	0	3	NIGHT SWEATS
		DAY 29	24DEC2002	26	1	3	3	3	0	3	1		
		DAY 57	22JAN2003	55	3	3	3	3	1	2	0	3	PAIN OR STIFFNESS DUE TO ARTHRITIS
		FINAL	22JAN2003	55	3	3	3	3	1	2	0	3	PAIN OR STIFFNESS DUE TO ARTHRITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	DAY 1	26NOV2002	1	9		1	2	1	2	1	0	2
		DAY 29	10DEC2002	15	6	-3	1	1	0	1	1	0	2
		FINAL	10DEC2002	15	6	-3	1	1	0	1	1	0	2
	E0018013	DAY 1	24JAN2003	1	11		2	0	3	2	1	1	2
		DAY 29	31JAN2003	8	17	6	2	3	3	3	2	3	1
		FINAL	31JAN2003	8	17	6	2	3	3	3	2	3	1
	E0019002	DAY 1	12NOV2002	1	5		1	1	0	0	1	0	2
	E0019008	DAY 1	21NOV2002	1	14		2	3	2	2	3	0	2
		DAY 29	19DEC2002	29	12	-2	2	2	1	3	2	0	2
		FINAL	19DEC2002	29	12	-2	2	2	1	3	2	0	2
	E0019009	DAY 1	14NOV2002	1	13		2	3	1	3	2	0	2
		DAY 29	10DEC2002	27	9	-4	1	2	0	3	1	0	2
		FINAL	10DEC2002	27	9	-4	1	2	0	3	1	0	2
	E0019016	DAY 1	06JAN2003	1	15		2	2	3	2	3	0	3
		DAY 29	03FEB2003	29	5	-10	1	1	1	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	DAY 1	26NOV2002	1	0:30	30	10:00	7	2	1	0	0	0	0	0	0	1		
		DAY 29	10DEC2002	15	0:00	15	12:00	10	1	0	1	0	0	0	0	1	0		
		FINAL	10DEC2002	15	0:00	15	12:00	10	1	0	1	0	0	0	0	1	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	DAY 1	24JAN2003	1	23:00	10	5:00	4	0	3	3	1	1	0	0	0	0		
		DAY 29	31JAN2003	8	21:00	60	11:00	4	3	3	3	3	2	0	0	2	0	3	TENSE MUSCLES
		FINAL	31JAN2003	8	21:00	60	11:00	4	3	3	3	3	2	0	0	2	0	3	TENSE MUSCLES
QUETIAPINE 600 MG (BIPOLAR II)	E0019002	DAY 1	12NOV2002	1	8:00	10	20:00	12	1	2	3	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0019008	DAY 1	21NOV2002	1	0:30	60	7:30	5	3	1	3	1	1	3	3	1	3	3	PAIN
		DAY 29	19DEC2002	29	11:00	120	7:00	6	1	0	2	2	2	1	1	1	2		
		FINAL	19DEC2002	29	11:00	120	7:00	6	1	0	2	2	2	1	1	1	2		
QUETIAPINE 600 MG (BIPOLAR II)	E0019009	DAY 1	14NOV2002	1	10:30	60	8:00	6	3	1	1	0	2	2	3	3	0		
		DAY 29	10DEC2002	27	12:30	60	10:00	8	2	0	0	0	1	1	0	3	1		
		FINAL	10DEC2002	27	12:30	60	10:00	8	2	0	0	0	1	1	0	3	1		
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	DAY 1	06JAN2003	1	22:30	45	4:30	4	2	3	3	2	3	2	2	1	3		
		DAY 29	03FEB2003	29	21:30	20	4:30	7	1	1	0	0	3	0	1	0	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	DAY 1	26NOV2002	1	1	2	3	3	0	3	0		
		DAY 29	10DEC2002	15	2	2	3	3	0	2	0		
		FINAL	10DEC2002	15	2	2	3	3	0	2	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	DAY 1	24JAN2003	1	0	3	3	1	1	2	0	2	INSOMNIA
		DAY 29	31JAN2003	8	0	1	3	0	0	3	3	3	TALKING AND RESTLESS
		FINAL	31JAN2003	8	0	1	3	0	0	3	3	3	TALKING AND RESTLESS
QUETIAPINE 600 MG (BIPOLAR II)	E0019002	DAY 1	12NOV2002	1	0	3	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0019008	DAY 1	21NOV2002	1	0	3	3	0	0	0	3		
		DAY 29	19DEC2002	29	1	2	3	0	0	0	1		
		FINAL	19DEC2002	29	1	2	3	0	0	0	1		
QUETIAPINE 600 MG (BIPOLAR II)	E0019009	DAY 1	14NOV2002	1	2	2	1	0	0	0	0		
		DAY 29	10DEC2002	27	1	2	1	0	0	1	1		
		FINAL	10DEC2002	27	1	2	1	0	0	1	1		
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	DAY 1	06JAN2003	1	3	3	1	3	1	2	0		
		DAY 29	03FEB2003	29	0	1	1	3	0	0	0	3	TOSSING & TURNING

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	DAY 57	03MAR2003	57	7	-8	1	2	1	1	1	0	1
		FINAL	03MAR2003	57	7	-8	1	2	1	1	1	0	1
	E0019020	DAY 1	23JAN2003	1	17		3	3	3	3	2	1	2
		DAY 29	20FEB2003	29	7	-10	1	1	1	1	1	0	2
		DAY 57	27MAR2003	64	7	-10	1	1	1	1	1	0	2
		FINAL	27MAR2003	64	7	-10	1	1	1	1	1	0	2
	E0019021	DAY 1	30JAN2003	1	10		1	3	0	0	2	2	2
		DAY 29	03MAR2003	33	9	-1	2	3	0	0	1	1	2
		FINAL	03MAR2003	33	9	-1	2	3	0	0	1	1	2
	E0019024	DAY 1	30JAN2003	1	8		2	3	0	0	2	0	1
		DAY 29	06FEB2003	8	8	0	2	3	0	0	2	0	1
		FINAL	06FEB2003	8	8	0	2	3	0	0	2	0	1
	E0019031	DAY 1	13MAR2003	1	7		1	2	1	0	1	0	2
		DAY 29	25MAR2003	13	7	0	1	2	1	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	DAY 57	03MAR2003	57	21:00	35	4:30	6	2	1	1	0	3	0	0	1	0		
		FINAL	03MAR2003	57	21:00	35	4:30	6	2	1	1	0	3	0	0	1	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	DAY 1	23JAN2003	1	22:00	60	7:00	4	3	3	3	0	0	1	3	2	1	2	SWEATING
		DAY 29	20FEB2003	29	22:00	5	7:00	7	1	1	1	0	0	0	0	2	0		
		DAY 57	27MAR2003	64	23:00	20	6:30	6	1	2	1	0	0	1	1	0	0		
		FINAL	27MAR2003	64	23:00	20	6:30	6	1	2	1	0	0	1	1	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	DAY 1	30JAN2003	1	3:00	90	12:00	10	3	2	3	0	2	2	2	2	0		
		DAY 29	03MAR2003	33	1:00	90	11:00	10	2	2	3	0	0	0	0	2	0		
		FINAL	03MAR2003	33	1:00	90	11:00	10	2	2	3	0	0	0	0	2	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0019024	DAY 1	30JAN2003	1	4:00	60	15:00	10	3	2	2	2	3	2	2	2	1		
		DAY 29	06FEB2003	8	4:00	60	15:00	12	3	2	2	1	3	2	2	1	0	3	THINKING CONSTANTLY. TOO MUCH ON MY MIND.
		FINAL	06FEB2003	8	4:00	60	15:00	12	3	2	2	1	3	2	2	1	0	3	THINKING CONSTANTLY. TOO MUCH ON MY MIND.
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	DAY 1	13MAR2003	1	23:00	30	6:00	6	2	0	0	1	3	0	0	1	0		
		DAY 29	25MAR2003	13	23:00	30	6:00	6	2	1	0	1	3	0	0	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	DAY 57	03MAR2003	57	0	1	1	3	0	0	0	2	TOSSING AND TURNING
		FINAL	03MAR2003	57	0	1	1	3	0	0	0	2	TOSSING AND TURNING
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	DAY 1	23JAN2003	1	0	3	3	0	0	2	0		
		DAY 29	20FEB2003	29	1	2	3	0	0	2	0		
		DAY 57	27MAR2003	64	2	2	3	2	0	0	0		
		FINAL	27MAR2003	64	2	2	3	2	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	DAY 1	30JAN2003	1	0	3	0						
		DAY 29	03MAR2003	33	0	3	0						
		FINAL	03MAR2003	33	0	3	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0019024	DAY 1	30JAN2003	1	0	2	3	3	2	3	0	3	COUGHING TOO MUCH. TROUBLE GETTING COMFORTABLE
		DAY 29	06FEB2003	8	0	2	0						
		FINAL	06FEB2003	8	0	2	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	DAY 1	13MAR2003	1	2	2	0						
		DAY 29	25MAR2003	13	2	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	FINAL	25MAR2003	13	7	0	1	2	1	0	1	0	2
	E0019035	DAY 1	18MAR2003	1	7		1	1	0	0	2	0	3
		DAY 29	17APR2003	31			0	0			2	1	2
		FINAL	17APR2003	31			0	0			2	1	2
	E0019040	DAY 1	20MAY2003	1	15		3	2	0	3	2	3	2
		DAY 29	18JUN2003	30	6	-9	1	2	0	0	2	0	1
		DAY 57	17JUL2003	59	5	-10	0	2	0	0	2	0	1
		FINAL	17JUL2003	59	5	-10	0	2	0	0	2	0	1
	E0019042	DAY 1	04JUN2003	1	16		3	3	2	3	2	2	1
		DAY 29	19JUN2003	16	4	-12	0	0	0	1	1	0	2
		FINAL	19JUN2003	16	4	-12	0	0	0	1	1	0	2
	E0019045	DAY 1	26JUN2003	1	14		2	3	3	3	2	0	1
		DAY 29	16JUL2003	21	10	-4	1	2	2	3	1	0	1
		FINAL	16JUL2003	21	10	-4	1	2	2	3	1	0	1
	E0020024	DAY 1	23JUN2003	1	14		2	3	1	1	2	3	2
		DAY 29	21JUL2003	29	4	-10	1	1	1	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	FINAL	25MAR2003	13	23:00	30	6:00	6	2	1	0	1	3	0	0	1	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0019035	DAY 1	18MAR2003	1	1:00	35	11:00	9	0	3	3	3	3	0	3	0	0	
		DAY 29	17APR2003	31	23:00	0	14:00		0	1	0	3	3	0	1	2	0	
		FINAL	17APR2003	31	23:00	0	14:00		0	1	0	3	3	0	1	2	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	DAY 1	20MAY2003	1	19:00	120	11:00	8	0	3	2	1	3	3	3	0	0	
		DAY 29	18JUN2003	30	21:00	60	9:30	11	2	1	2	1	3	0	1	0	2	
		DAY 57	17JUL2003	59	21:00	60	7:30	9	2	1	1	3	3	0	0	2	1	
		FINAL	17JUL2003	59	21:00	60	7:30	9	2	1	1	3	3	0	0	2	1	
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	DAY 1	04JUN2003	1	22:30	60	7:00	5	3	3	3	0	1	2	2	0	0	
		DAY 29	19JUN2003	16	22:00	10	7:30	8	0	0	2	0	0	0	0	0	0	
		FINAL	19JUN2003	16	22:00	10	7:30	8	0	0	2	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	DAY 1	26JUN2003	1	0:00	120	9:00	4	3	3	3	1	0	1	3	2	2	
		DAY 29	16JUL2003	21	23:00	30	9:00	5	2	2	3	0	0	0	2	0	0	
		FINAL	16JUL2003	21	23:00	30	9:00	5	2	2	3	0	0	0	2	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 1	23JUN2003	1	23:00	60	6:30	6	3	0	0	1	0	3	3	0	3	
		DAY 29	21JUL2003	29	0:00	20	6:00	6	1	0	0	2	0	0	2	0	1	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	FINAL	25MAR2003	13	2	2	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0019035	DAY 1	18MAR2003	1	3	3	3	3	0	0	0		
		DAY 29	17APR2003	31	3	0	3	3	1	3	3		
		FINAL	17APR2003	31	3	0	3	3	1	3	3		
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	DAY 1	20MAY2003	1	1	3	3	3	0	3	0		
		DAY 29	18JUN2003	30	0	2	3	2	1	1	0	1	C - PAP
		DAY 57	17JUL2003	59	0	1	3	2	2	2	0		
		FINAL	17JUL2003	59	0	1	3	2	2	2	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	DAY 1	04JUN2003	1	0	2	1	1	0	1	0	3	TOSSING/TURNING
		DAY 29	19JUN2003	16	2	2	3	0	0	0	0		
		FINAL	19JUN2003	16	2	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	DAY 1	26JUN2003	1	0	1	3	0	0	0	0	3	GETTING UP & DOWN OUT OF BED. - TOSSING & TURNING
		DAY 29	16JUL2003	21	0	2	3	0	0	0	0		
		FINAL	16JUL2003	21	0	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 1	23JUN2003	1	2	2	0						
		DAY 29	21JUL2003	29	0	0	0						

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 57	20AUG2003	59	4	-10	0	1	1	0	1	0	1
		FINAL	20AUG2003	59	4	-10	0	1	1	0	1	0	1
	E0022044	DAY 1	18MAR2003	1	12		2	3	1	1	3	0	2
		DAY 29	15APR2003	29	8	-4	1	2	1	0	2	1	1
		DAY 57	12MAY2003	56	7	-5	1	0	1	1	2	0	2
		FINAL	12MAY2003	56	7	-5	1	0	1	1	2	0	2
	E0023007	DAY 1	14JAN2003	1	13		2	3	1	3	2	0	2
		DAY 29	11FEB2003	29	2	-11	0	1	0	0	0	0	1
		DAY 57	11MAR2003	57	7	-6	1	1	1	1	0	0	3
		FINAL	11MAR2003	57	7	-6	1	1	1	1	0	0	3
	E0023011	DAY 1	04FEB2003	1			3	2	0		1	2	2
		DAY 29	04MAR2003	29			1	1	0		1	1	1
		DAY 57	01APR2003	57	5		1	2	0	0	1	0	1
		FINAL	01APR2003	57	5		1	2	0	0	1	0	1
	E0023014	DAY 1	21FEB2003	1	13		2	3	1	1	2	2	2
		DAY 29	25MAR2003	33	9	-4	1	1	1	3	2	0	1
		DAY 57	25APR2003	64	11	-2	2	3	0	2	2	0	2
		FINAL	25APR2003	64	11	-2	2	3	0	2	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 57	20AUG2003	59	1:00	30	6:00	6	1	0	0	2	0	1	2	0	0	
		FINAL	20AUG2003	59	1:00	30	6:00	6	1	0	0	2	0	1	2	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0022044	DAY 1	18MAR2003	1	22:00	60	5:30	6	3	3	2	2	3	3	3	3	0	3 2 1/2 YR OLD DAUGHTER
		DAY 29	15APR2003	29	22:00	60	2:00	7	2	3	2	0	3	2	3	3	2	
		DAY 57	12MAY2003	56	22:00	15	6:00	6	0	2	2	2	3	2	0	3	0	
		FINAL	12MAY2003	56	22:00	15	6:00	6	0	2	2	2	3	2	0	3	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	DAY 1	14JAN2003	1	0:00	45	11:30	7	3	3	2	0	0	2	2	2	0	
		DAY 29	11FEB2003	29	2:00	30	12:00	10	0	0	0	0	0	0	0	0	0	
		DAY 57	11MAR2003	57	23:00	30	7:00	6	0	0	0	0	0	0	0	0	0	
		FINAL	11MAR2003	57	23:00	30	7:00	6	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	DAY 1	04FEB2003	1	10:30	30	10:30	8	3	3	3	0	1	0	0	1	1	
		DAY 29	04MAR2003	29	10:30	20	10:30	8	1	3	3	0	1	0	0	1	1	
		DAY 57	01APR2003	57	23:00	60	9:00	9	2	2	3	0	0	0	0	1	0	
		FINAL	01APR2003	57	23:00	60	9:00	9	2	2	3	0	0	0	0	1	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023014	DAY 1	21FEB2003	1	22:00	60	7:00	7	3	3	3	0	1	0	2	2	0	
		DAY 29	25MAR2003	33	10:00	15	5:00	6	2	1	3	0	3	0	3	3	0	
		DAY 57	25APR2003	64	20:00	120	8:00	8	3	3	3	0	3	0	0	3	3	
		FINAL	25APR2003	64	20:00	120	8:00	8	3	3	3	0	3	0	0	3	3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 57	20AUG2003	59	1	0	0						
		FINAL	20AUG2003	59	1	0	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0022044	DAY 1	18MAR2003	1	2	2	3	3	3	2	1	3	COUGHING
		DAY 29	15APR2003	29	0	2	3	3	0	0	2		
		DAY 57	12MAY2003	56	1	3	3	3	2	0	2		
		FINAL	12MAY2003	56	1	3	3	3	2	0	2		
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	DAY 1	14JAN2003	1	1	3	3	0	0	3	2		
		DAY 29	11FEB2003	29	0	2	0						
		DAY 57	11MAR2003	57	3	2	0						
		FINAL	11MAR2003	57	3	2	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	DAY 1	04FEB2003	1	0	3	3	0	0	0	0		
		DAY 29	04MAR2003	29	0	2	3	0	0	0	0		
		DAY 57	01APR2003	57	0	2	3	0	0	0	0		
		FINAL	01APR2003	57	0	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0023014	DAY 1	21FEB2003	1	0	3	0						
		DAY 29	25MAR2003	33	0	2	0						
		DAY 57	25APR2003	64	0	3	0						
		FINAL	25APR2003	64	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0023019	DAY 1	07APR2003	1	3		1	0	0	0	1	0	1
		DAY 29	06MAY2003	30	2	-1	0	0	0	0	1	0	1
		DAY 57	03JUN2003	58	1	-2	0	0	0	0	0	0	1
		FINAL	03JUN2003	58	1	-2	0	0	0	0	0	0	1
	E0023022	DAY 1	18APR2003	1	10		2	3	1	2	1	0	1
		DAY 29	15MAY2003	28	3	-7	0	1	0	0	1	0	1
		DAY 57	12JUN2003	56	2	-8	0	0	0	0	1	0	1
		FINAL	12JUN2003	56	2	-8	0	0	0	0	1	0	1
	E0023023	DAY 1	25APR2003	1	9		1	3	1	1	1	1	1
		DAY 29	01MAY2003	7	8	-1	1	3	1	0	1	1	1
		FINAL	01MAY2003	7	8	-1	1	3	1	0	1	1	1
	E0023029	DAY 1	23MAY2003	1	11		2	2	2	3	1	0	1
	E0023031	DAY 1	24JUN2003	1	16		3	2	3	3	3	0	2
		DAY 29	22JUL2003	29	5	-11	0	3	0	0	1	0	1
		DAY 57	19AUG2003	57	8	-8	2	3	1	0	1	0	1
		FINAL	19AUG2003	57	8	-8	2	3	1	0	1	0	1
	E0023041	DAY 1	09JUL2003	1	9		1	2	1	1	1	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0023019	DAY 1	07APR2003	1	22:30	15	6:30	8	0	2	0	0	0	1	1	0	0	
		DAY 29	06MAY2003	30	22:00	5	7:15	9	0	1	0	0	0	1	0	0	0	
		DAY 57	03JUN2003	58	22:30	15	7:30	9	0	0	0	0	0	0	0	0	0	
		FINAL	03JUN2003	58	22:30	15	7:30	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023022	DAY 1	18APR2003	1	0:00	60	8:15	6	3	0	0	0	0	1	1	0	0	
		DAY 29	15MAY2003	28	22:00	20	9:30	10	1	0	0	0	0	1	1	0	0	
		DAY 57	12JUN2003	56	23:00	15	9:30	10	0	1	0	0	0	0	0	0	0	
		FINAL	12JUN2003	56	23:00	15	9:30	10	0	1	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	DAY 1	25APR2003	1	23:30	75	7:00	6	3	2	0	0	0	0	0	1	1	
		DAY 29	01MAY2003	7	23:30	75	6:00	6	3	2	0	0	0	0	0	1	1	
		FINAL	01MAY2003	7	23:30	75	6:00	6	3	2	0	0	0	0	0	1	1	
QUETIAPINE 600 MG (BIPOLAR II)	E0023029	DAY 1	23MAY2003	1	23:30	20	7:30	5	2	3	0	0	0	0	0	3	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	DAY 1	24JUN2003	1	0:00	120	7:00	4	0	3	3	3	3	3	3	2	2	
		DAY 29	22JUL2003	29	19:00	60	7:00	11	3	3	3	0	2	0	0	0	0	
		DAY 57	19AUG2003	57	21:00	60	4:00	6	3	3	3	0	0	0	0	3	0	
		FINAL	19AUG2003	57	21:00	60	4:00	6	3	3	3	0	0	0	0	3	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	DAY 1	09JUL2003	1	22:00	20	7:00	7	2	1	2	0	0	1	2	1	1	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0023019	DAY 1	07APR2003	1	0	2	0						
		DAY 29	06MAY2003	30	0	2	0						
		DAY 57	03JUN2003	58	0	2	0						
		FINAL	03JUN2003	58	0	2	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0023022	DAY 1	18APR2003	1	0	2	0						
		DAY 29	15MAY2003	28	0	1	0						
		DAY 57	12JUN2003	56	1	1	0						
		FINAL	12JUN2003	56	1	1	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	DAY 1	25APR2003	1	0	2	3	0	0	0	0		
		DAY 29	01MAY2003	7	0	2	3	0	0	0	0		
		FINAL	01MAY2003	7	0	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0023029	DAY 1	23MAY2003	1	0	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	DAY 1	24JUN2003	1	0	3	3	3	0	2	0		
		DAY 29	22JUL2003	29	0	2	3	2	0	2	0		
		DAY 57	19AUG2003	57	0	2	3	0	0	0	0		
		FINAL	19AUG2003	57	0	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	DAY 1	09JUL2003	1	2	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	DAY 29	06AUG2003	29	5	-4	1	0	0	1	1	0	2
		DAY 57	05SEP2003	59	4	-5	1	0	0	0	2	0	1
		FINAL	05SEP2003	59	4	-5	1	0	0	0	2	0	1
	E0023043	DAY 1	14JUL2003	1	4		1	1	0	0	1	0	1
		DAY 29	12AUG2003	30	2	-2	0	0	0	0	1	0	1
		DAY 57	09SEP2003	58	0	-4	0	0	0	0	0	0	0
		FINAL	09SEP2003	58	0	-4	0	0	0	0	0	0	0
	E0026003	DAY 1	04DEC2002	1	11		2	3	1	2	1	0	2
		DAY 29	02JAN2003	30	4	-7	0	2	0	0	1	0	1
		DAY 57	03FEB2003	62	7	-4	1	1	0	0	1	3	1
		FINAL	03FEB2003	62	7	-4	1	1	0	0	1	3	1
	E0026005	DAY 1	30DEC2002	1	15		2	3	1	1	3	2	3
		DAY 29	06JAN2003	8	15	0	2	3	0	1	3	3	3
		FINAL	06JAN2003	8	15	0	2	3	0	1	3	3	3
	E0026009	DAY 1	15JAN2003	1	13		2	3	2	3	1	0	2
		DAY 29	21JAN2003	7	5	-8	1	2	0	0	1	0	1
		FINAL	21JAN2003	7	5	-8	1	2	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	DAY 29	06AUG2003	29	22:00	15	8:30	8	0	1	0	0	1	1	1	2	0	
		DAY 57	05SEP2003	59	23:00	15	7:00	8	0	3	2	0	0	2	2	2	0	
		FINAL	05SEP2003	59	23:00	15	7:00	8	0	3	2	0	0	2	2	2	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	DAY 1	14JUL2003	1	23:00	10	7:00	8	1	3	3	0	0	0	2	0	0	
		DAY 29	12AUG2003	30	23:00	15	8:00	8	0	0	0	0	0	0	2	0	0	
		DAY 57	09SEP2003	58	23:00	15	7:30	8	0	0	0	0	0	0	0	0	0	
		FINAL	09SEP2003	58	23:00	15	7:30	8	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	DAY 1	04DEC2002	1	22:00	60	8:30	7	3	3	3	0	0	0	0	0	3	
		DAY 29	02JAN2003	30	22:00	30	9:00	10	2	0	0	0	0	0	0	1	0	
		DAY 57	03FEB2003	62	23:00	30	9:00	10	0	2	3	0	0	0	0	2	2	
		FINAL	03FEB2003	62	23:00	30	9:00	10	0	2	3	0	0	0	0	2	2	
QUETIAPINE 600 MG (BIPOLAR II)	E0026005	DAY 1	30DEC2002	1	23:00	45	6:30	6	3	3	3	2	2	3	3	3	3	
		DAY 29	06JAN2003	8	20:00	75	7:00	9	3	3	2	3	3	3	3	3	3	
		FINAL	06JAN2003	8	20:00	75	7:00	9	3	3	2	3	3	3	3	3	3	
QUETIAPINE 600 MG (BIPOLAR II)	E0026009	DAY 1	15JAN2003	1	20:00	90	5:00	5	3	3	2	0	0	0	0	0	0	
		DAY 29	21JAN2003	7	20:00	60	5:00	14	1	1	0	0	0	0	0	1	0	
		FINAL	21JAN2003	7	20:00	60	5:00	14	1	1	0	0	0	0	0	1	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	DAY 29	06AUG2003	29	1	3	0						
		DAY 57	05SEP2003	59	0	2	0						
		FINAL	05SEP2003	59	0	2	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	DAY 1	14JUL2003	1	0	2	0						
		DAY 29	12AUG2003	30	0	1	0						
		DAY 57	09SEP2003	58	0	0	0						
		FINAL	09SEP2003	58	0	0	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	DAY 1	04DEC2002	1	1	2	1	0	0	1	0		
		DAY 29	02JAN2003	30	0	2	1						
		DAY 57	03FEB2003	62	0	1	1	0	0	0	0		
		FINAL	03FEB2003	62	0	1	1	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0026005	DAY 1	30DEC2002	1	2	3	1	3	3	3	2	3	WOULD AWAKE TO GO TO RESTROOM
		DAY 29	06JAN2003	8	3	3	1	3	3	3	3		
		FINAL	06JAN2003	8	3	3	1	3	3	3	3		
QUETIAPINE 600 MG (BIPOLAR II)	E0026009	DAY 1	15JAN2003	1	0	3	0						
		DAY 29	21JAN2003	7	0	1	0						
		FINAL	21JAN2003	7	0	1	0						

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	DAY 1	27FEB2003	1	6		1	1	0	0	2	0	2
		DAY 29	27MAR2003	29	11	5	2	2	3	1	2	0	1
		DAY 57	25APR2003	58	9	3	1	1	3	2	1	0	1
		FINAL	25APR2003	58	9	3	1	1	3	2	1	0	1
	E0026023	DAY 1	30APR2003	1	15		3	3	3	3	2	0	1
		DAY 29	28MAY2003	29	8	-7	2	1	0	2	2	0	1
		FINAL	28MAY2003	29	8	-7	2	1	0	2	2	0	1
	E0027016	DAY 1	09APR2003	1	6		1	1	0	1	1	0	2
		DAY 29	05MAY2003	27	5	-1	0	1	0	1	1	0	2
		DAY 57	03JUN2003	56	5	-1	1	1	0	1	1	0	1
		FINAL	03JUN2003	56	5	-1	1	1	0	1	1	0	1
	E0027018	DAY 1	25MAR2003	1	8		3	2	0	0	1	0	2
		DAY 29	22APR2003	29	1	-7	0	0	0	0	1	0	0
		DAY 57	22MAY2003	59	0	-8	0	0	0	0	0	0	0
		FINAL	22MAY2003	59	0	-8	0	0	0	0	0	0	0
	E0028032	DAY 1	25MAR2003	1	16		2	3	2	3	2	2	2
		DAY 29	22APR2003	29	5	-11	1	1	0	0	1	0	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	DAY 1	27FEB2003	1	2:00	20	12:00	12	1	2	1	0	1	3	0	2	3	2	"BRAIN RACING UNSOLVABLE IMAGINARY PROBLEMS SO NEEDLESS WORRY SO TO SPEAK"
		DAY 29	27MAR2003	29	2:00	30	6:00	3	2	1	0	2	0	1	2	0	2	2	MIND - BUSY
		DAY 57	25APR2003	58	4:00	30	8:30	3	1	0	0	0	0	2	3	1	3		
		FINAL	25APR2003	58	4:00	30	8:30	3	1	0	0	0	0	2	3	1	3		
QUETIAPINE 600 MG (BIPOLAR II)	E0026023	DAY 1	30APR2003	1	23:30	50	6:50	4	3	3	0	2	3	1	2	3	3		
		DAY 29	28MAY2003	29	20:30	30	7:45	8	1	2	2	0	2	0	1	0	3		
		FINAL	28MAY2003	29	20:30	30	7:45	8	1	2	2	0	2	0	1	0	3		
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	DAY 1	09APR2003	1	23:00	15	9:30	8	1	2	0	0	0	2	2	0	0	1	SEXUAL DREAMS
		DAY 29	05MAY2003	27	23:00	15	11:00	10	1	1	0	1	1	1	1	0	0		
		DAY 57	03JUN2003	56	23:30	20	11:00	9	1	0	0	0	1	1	1	0	0		
		FINAL	03JUN2003	56	23:30	20	11:00	9	1	0	0	0	1	1	1	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	DAY 1	25MAR2003	1	22:00	35	6:00	8	2	3	0	0	0	0	0	0	0		
		DAY 29	22APR2003	29	22:00	5	7:00	9	0	0	2	0	0	0	0	0	0		
		DAY 57	22MAY2003	59	22:00	5	7:00	9	0	0	0	0	0	0	0	0	0		
		FINAL	22MAY2003	59	22:00	5	7:00	9	0	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	DAY 1	25MAR2003	1	1:00	45	9:00	5	3	3	3	2	0	0	2	3	1		
		DAY 29	22APR2003	29	1:00	15	9:00	8	1	1	0	2	0	0	1	2	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0026015	DAY 1	27FEB2003	1	1	3	3	1	0	2	1	2	BAD DREAMS
		DAY 29	27MAR2003	29	0	1	0						
		DAY 57	25APR2003	58	0	1	0						
		FINAL	25APR2003	58	0	1	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0026023	DAY 1	30APR2003	1	0	2	0						
		DAY 29	28MAY2003	29	0	1	0						
		FINAL	28MAY2003	29	0	1	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	DAY 1	09APR2003	1	0	3	3	0	0	0	0	1	TALK IN SLEEP
		DAY 29	05MAY2003	27	1	2	3	0	0	0	0		
		DAY 57	03JUN2003	56	0	2	3	0	0	0	0		
		FINAL	03JUN2003	56	0	2	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	DAY 1	25MAR2003	1	0	3	3	1	0	3	0		
		DAY 29	22APR2003	29	0	0	3	0	0	0	0		
		DAY 57	22MAY2003	59	0	0	3	2	0	0	0		
		FINAL	22MAY2003	59	0	0	3	2	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	DAY 1	25MAR2003	1	1	3	0						
		DAY 29	22APR2003	29	2	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	FINAL	22APR2003	29	5	-11	1	1	0	0	1	0	2
	E0029003	DAY 1	04NOV2002	1	17		2	3	2	2	3	3	2
		DAY 29	02DEC2002	29	6	-11	0	0	0	3	1	0	2
		DAY 57	30DEC2002	57	2	-15	0	0	0	0	0	0	2
		FINAL	30DEC2002	57	2	-15	0	0	0	0	0	0	2
	E0029020	DAY 1	04MAR2003	-1	13		2	3	2	3	1	0	2
	E0031005	DAY 1	20DEC2002	1	16		2	3	2	3	1	3	2
		DAY 29	17JAN2003	29	3	-13	1	0	0	0	1	0	1
		DAY 57	14FEB2003	57			1	1	0		1	0	1
		FINAL	14FEB2003	57			1	1	0		1	0	1
	E0031006	DAY 1	18FEB2003	1	18		3	2	3	3	3	2	2
		DAY 29	18MAR2003	29	6	-12	0	3	1	0	1	0	1
		DAY 57	15APR2003	57	9	-9	0	3	1	2	2	0	1
		FINAL	15APR2003	57	9	-9	0	3	1	2	2	0	1
	E0031010	DAY 1	19FEB2003	1	13		2	3	1	3	2	0	2
		DAY 29	05MAR2003	15	9	-4	2	1	0	2	2	0	2
		FINAL	05MAR2003	15	9	-4	2	1	0	2	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	FINAL	22APR2003	29	1:00	15	9:00	8	1	1	0	2	0	0	1	2	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 1	04NOV2002	1	23:00	45	6:30	5	3	3	2	2	2	3	3	3	2	
		DAY 29	02DEC2002	29	10:30	5	6:45	8	0	0	0	0	2	1	2	0	0	
		DAY 57	30DEC2002	57	23:00	5	7:30	9	0	0	0	0	0	0	0	0	0	
		FINAL	30DEC2002	57	23:00	5	7:30	9	0	0	0	0	0	0	0	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0029020	DAY 1	04MAR2003	-1	2:00	45	10:30	5	3	2	2	0	0	0	1	3	1	
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	DAY 1	20DEC2002	1	2:00	60	10:00	5	3	3	2	0	0	0	0	0	3	
		DAY 29	17JAN2003	29	23:30	10	11:00	11	0	1	2	0	0	0	0	0	0	3 PAIN IN ARM
		DAY 57	14FEB2003	57	23:00	10		9	1	2	2	0	0	0	0	0	2	
		FINAL	14FEB2003	57	23:00	10		9	1	2	2	0	0	0	0	0	2	
QUETIAPINE 600 MG (BIPOLAR II)	E0031006	DAY 1	18FEB2003	1	20:00	120	5:30	3	1	3	3	1	1	1	3	2	2	3 RACING THOUGHTS
		DAY 29	18MAR2003	29	21:00	45	5:00	7	3	3	3	0	0	0	1	0	1	
		DAY 57	15APR2003	57	20:00	45	5:45	7	3	3	3	2	1	0	1	0	0	
		FINAL	15APR2003	57	20:00	45	5:45	7	3	3	3	2	1	0	1	0	0	
QUETIAPINE 600 MG (BIPOLAR II)	E0031010	DAY 1	19FEB2003	1	22:30	120	10:00	7	3	3	1	0	0	3	1	1	2	
		DAY 29	05MAR2003	15	20:30	30	13:00	12	0	3	3	1	0	2	0	2	2	
		FINAL	05MAR2003	15	20:30	30	13:00	12	0	3	3	1	0	2	0	2	2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	FINAL	22APR2003	29	2	2	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 1	04NOV2002	1	1	2	1	0	0	3	1		
		DAY 29	02DEC2002	29	3	1	3	1	0	3	0		
		DAY 57	30DEC2002	57	3	1	3	0	0	0	0		
		FINAL	30DEC2002	57	3	1	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0029020	DAY 1	04MAR2003	-1	1	3	3	0	0	0	2		
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	DAY 1	20DEC2002	1	0	3	3	3	2	2	1		
		DAY 29	17JAN2003	29	0	1	3	2	0	0	0		
		DAY 57	14FEB2003	57	0	1	3	2	0	0	0		
		FINAL	14FEB2003	57	0	1	3	2	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0031006	DAY 1	18FEB2003	1	1	3	2	2	3	3	1		
		DAY 29	18MAR2003	29	0	1	0						
		DAY 57	15APR2003	57	0	1	0						
		FINAL	15APR2003	57	0	1	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0031010	DAY 1	19FEB2003	1	1	3	0						
		DAY 29	05MAR2003	15	1	3	0						
		FINAL	05MAR2003	15	1	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	DAY 1	27FEB2003	1	6		1	2	1	0	1	0	1
		DAY 29	27MAR2003	29	2	-4	0	0	1	0	1	0	0
		DAY 57	24APR2003	57	2	-4	0	0	1	0	1	0	0
		FINAL	24APR2003	57	2	-4	0	0	1	0	1	0	0
	E0031015	DAY 1	26MAR2003	1	6		1	1	0	0	2	0	2
		DAY 29	01APR2003	7	2	-4	0	0	0	0	0	0	2
		FINAL	01APR2003	7	2	-4	0	0	0	0	0	0	2
	E0031031	DAY 1	08JUL2003	1	9		2	3	1	1	1	0	1
	E0033009	DAY 1	12FEB2003	1	20		3	3	3	3	3	2	3
	E0034009	DAY 1	19JUN2003	1	16		2	3	3	3	3	0	2
		DAY 29	18JUL2003	30	4	-12	0	0	1	0	1	0	2
		DAY 57	18AUG2003	61	4	-12	0	1	0	0	1	0	2
		FINAL	18AUG2003	61	4	-12	0	1	0	0	1	0	2
	E0037007	DAY 1	11APR2003	1	16		3	3	3	3	1	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	DAY 1	27FEB2003	1	23:30	30	6:30	7	2	3	2	0	0	0	0	2	0		
		DAY 29	27MAR2003	29	23:00	10	6:30	7	0	1	2	0	0	0	0	0	0		
		DAY 57	24APR2003	57	23:00	10	6:30	7	0	0	1	0	0	0	0	0	0		
		FINAL	24APR2003	57	23:00	10	6:30	7	0	0	1	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	DAY 1	26MAR2003	1	22:30	25	6:45	8	1	2	1	1	1	1	1	1	2		
		DAY 29	01APR2003	7	22:30	10	10:00	10	0	0	0	0	0	0	0	0	0		
		FINAL	01APR2003	7	22:30	10	10:00	10	0	0	0	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0031031	DAY 1	08JUL2003	1	23:00	45	6:30	6	3	2	1	0	0	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0033009	DAY 1	12FEB2003	1	20:00	60	8:00	4	3	3	3	3	3	3	3	3	3		
QUETIAPINE 600 MG (BIPOLAR II)	E0034009	DAY 1	19JUN2003	1	23:00	60	5:30	4	3	3	3	2	1	2	2	2	2	2	STRESS
		DAY 29	18JUL2003	30	23:00	15	6:00	7	0	0	0	0	0	0	0	1	0		
		DAY 57	18AUG2003	61	22:00	15	6:00	8	1	2	1	0	0	0	0	1	1		
		FINAL	18AUG2003	61	22:00	15	6:00	8	1	2	1	0	0	0	0	1	1		
QUETIAPINE 600 MG (BIPOLAR II)	E0037007	DAY 1	11APR2003	1	22:00	60	7:00	4	3	3	1	0	0	1	1	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	DAY 1	27FEB2003	1	0	2	0						
		DAY 29	27MAR2003	29	0	0	0						
		DAY 57	24APR2003	57	0	0	0						
		FINAL	24APR2003	57	0	0	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	DAY 1	26MAR2003	1	0	3	1						
		DAY 29	01APR2003	7	3	1	1						
		FINAL	01APR2003	7	3	1	1						
QUETIAPINE 600 MG (BIPOLAR II)	E0031031	DAY 1	08JUL2003	1	0	2	1						
QUETIAPINE 600 MG (BIPOLAR II)	E0033009	DAY 1	12FEB2003	1	2	3	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0034009	DAY 1	19JUN2003	1	1	3	2	0	0	1	1	2	CONSTANTLY WAKING UP DURING THE NIGHT
		DAY 29	18JUL2003	30	3	1	3	0	0	0	0		
		DAY 57	18AUG2003	61	3	1	2	0	0	0	0		
		FINAL	18AUG2003	61	3	1	2	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0037007	DAY 1	11APR2003	1	0	3	1	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 1	16JUL2003	1	8		1	1	0	0	2	2	2
		DAY 29	15AUG2003	31	5	-3	0	0	0	0	1	3	1
		DAY 57	08SEP2003	55	2	-6	0	0	1	0	1	0	0
		FINAL	08SEP2003	55	2	-6	0	0	1	0	1	0	0
	E0039019	DAY 1	06FEB2003	1	11		2	3	1	1	2	1	1
		DAY 29	07MAR2003	30	5	-6	1	2	0	0	1	0	1
		DAY 57	03APR2003	57	5	-6	0	3	0	1	1	0	0
		FINAL	03APR2003	57	5	-6	0	3	0	1	1	0	0
	E0039043	DAY 1	08MAY2003	1	16		3	3	1	2	2	3	2
		DAY 29	05JUN2003	29	1	-15	0	1	0	0	0	0	0
		FINAL	05JUN2003	29	1	-15	0	1	0	0	0	0	0
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	19		3	3	3	3	2	3	2
		DAY 29	29JAN2003	31	7	-12	1	1	1	2	1	0	1
		DAY 57	26FEB2003	59	5	-14	0	1	1	1	1	0	1
		FINAL	26FEB2003	59	5	-14	0	1	1	1	1	0	1
	E0002003	DAY 1	22JAN2003	1	14		2	3	1	3	2	0	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 1	16JUL2003	1	1:00	15	13:00	12	1	2	1	1	0	1	3	2	1		
		DAY 29	15AUG2003	31	0:00	5	8:00	8	0	0	0	1	0	0	2	1	1		
		DAY 57	08SEP2003	55	0:00	5	7:00	7	0	0	0	0	0	0	2	1	0		
		FINAL	08SEP2003	55	0:00	5	7:00	7	0	0	0	0	0	0	2	1	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	DAY 1	06FEB2003	1	21:00	180	6:00	7	3	3	1	3	3	3	0	0	0		
		DAY 29	07MAR2003	30	23:00	90	7:00	10	1	2	1	0	0	0	0	0	0		
		DAY 57	03APR2003	57	23:00	90	9:00	8	2	2	1	1	0	0	1	0	0		
		FINAL	03APR2003	57	23:00	90	9:00	8	2	2	1	1	0	0	1	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0039043	DAY 1	08MAY2003	1	0:00	60	10:00	7	3	1	1	3	1	1	1	1	3		
		DAY 29	05JUN2003	29	0:00	30	14:00	14	0	0	0	0	0	0	0	0	0		
		FINAL	05JUN2003	29	0:00	30	14:00	14	0	0	0	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	21:30	90	5:00	4	3	3	3	0	1	0	2	0	3	3	ANXIOUS, FEARFUL
		DAY 29	29JAN2003	31	21:30	20	6:00	6	0	2	0	0	0	0	0	0	0		
		DAY 57	26FEB2003	59	21:00	20	6:00	7	0	2	1	0	0	0	0	0	0		
		FINAL	26FEB2003	59	21:00	20	6:00	7	0	2	1	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0002003	DAY 1	22JAN2003	1	23:00	180	10:00	6	3	2	1	2	2	2	1	2	3	3	JUVENILE RHEUMATOID ARTHRITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 1	16JUL2003	1	1	2	3	1	0	3	1		
		DAY 29	15AUG2003	31	1	0	3	0	0	0	0		
		DAY 57	08SEP2003	55	0	0	3	0	0	0	0		
		FINAL	08SEP2003	55	0	0	3	0	0	0	0		
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	DAY 1	06FEB2003	1	0	1	0						
		DAY 29	07MAR2003	30	0	1	0						
		DAY 57	03APR2003	57	0	0	0						
		FINAL	03APR2003	57	0	0	0						
QUETIAPINE 600 MG (BIPOLAR II)	E0039043	DAY 1	08MAY2003	1	1	2	0						
		DAY 29	05JUN2003	29	0	0	0						
		FINAL	05JUN2003	29	0	0	0						
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	0	3	0						
		DAY 29	29JAN2003	31	0	1	0						
		DAY 57	26FEB2003	59	0	1	0						
		FINAL	26FEB2003	59	0	1	0						
PLACEBO (BIPOLAR I)	E0002003	DAY 1	22JAN2003	1	2	3	3	2	0	3	3		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0002003	DAY 29	19FEB2003	29	9	-5	2	2	0	0	2	0	3
		DAY 57	18MAR2003	56	7	-7	1	1	1	0	2	0	2
		FINAL	18MAR2003	56	7	-7	1	1	1	0	2	0	2
	E0002004	DAY 1	25JAN2003	1	12		1	2	1	0	3	3	2
	E0002008	DAY 1	25FEB2003	1	11		2	2	1	0	2	1	3
		DAY 29	27MAR2003	31	12	1	2	2	2	2	2	0	2
		DAY 57	23APR2003	58	14	3	2	2	3	3	2	0	2
		FINAL	23APR2003	58	14	3	2	2	3	3	2	0	2
	E0002016	DAY 1	24JUL2003	1	12		2	3	2	1	2	0	2
		DAY 29	21AUG2003	29	9	-3	1	2	1	2	1	0	2
		DAY 57	17SEP2003	56	5	-7	1	1	1	0	1	0	1
		FINAL	17SEP2003	56	5	-7	1	1	1	0	1	0	1
	E0003008	DAY 1	28JAN2003	1	11		1	3	1	2	2	0	2
	E0004003	DAY 1	02OCT2002	-8	4		0	1	0	0	1	0	2
	E0004006	DAY 1	04NOV2002	1	5		2	1	0	0	0	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0002003	DAY 29	19FEB2003	29	3:00	45	11:00	9	2	2	1	1	1	3	2	1	3	3	I HAVE SEVERE RHEUMOTOID ARTHRITIS THROUGHAT MY BODY. (I ALSO HAVE AN 8 MONTH OLD WHO WAKES UP DURING THE NIGHT)
		DAY 57	18MAR2003	56	4:00	30	11:00	6	1	3	1	0	0	3	3	2	3		
		FINAL	18MAR2003	56	4:00	30	11:00	6	1	3	1	0	0	3	3	2	3		
PLACEBO (BIPOLAR I)	E0002004	DAY 1	25JAN2003	1	21:00	60	2:00	7	2	2	3	2	3	3	2	1	3		
PLACEBO (BIPOLAR I)	E0002008	DAY 1	25FEB2003	1	6:00	30	13:00	7	2	3	3	0	0	2	1	3	1	3	SLEEP ON ARMS
		DAY 29	27MAR2003	31	7:00	40	14:00	5	2	3	3	1	0	1	0	3	1		
		DAY 57	23APR2003	58	6:30	30	14:00	4	3	3	2	0	0	2	1	2	0		
		FINAL	23APR2003	58	6:30	30	14:00	4	3	3	2	0	0	2	1	2	0		
PLACEBO (BIPOLAR I)	E0002016	DAY 1	24JUL2003	1	23:30	45	5:30	5	3	3	3	0	2	2	3	3	0		
		DAY 29	21AUG2003	29	23:00	30	7:30	6	2	2	3	0	1	0	0	1	0		
		DAY 57	17SEP2003	56	22:30	15	6:30	7	1	2	2	0	0	0	0	0	0		
		FINAL	17SEP2003	56	22:30	15	6:30	7	1	2	2	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0003008	DAY 1	28JAN2003	1	22:30	40	7:00	6	3	3	1	2	0	2	0	2	0	1	HUSBAND'S SNORING
PLACEBO (BIPOLAR I)	E0004003	DAY 1	02OCT2002	-8	23:00	20	10:00	10	0	1	0	0	0	0	3	0	0		
PLACEBO (BIPOLAR I)	E0004006	DAY 1	04NOV2002	1	23:00	20	10:00	11	0	0	0	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0002003	DAY 29	19FEB2003	29	3	3	3	1	0	2	3	3	IN PAIN SEVERE RHEUMATOID ARTHRITIS
		DAY 57	18MAR2003	56	1	3	3	0	0	2	1		
		FINAL	18MAR2003	56	1	3	3	0	0	2	1		
PLACEBO (BIPOLAR I)	E0002004	DAY 1	25JAN2003	1	1	3	0						
PLACEBO (BIPOLAR I)	E0002008	DAY 1	25FEB2003	1	2	3	0						
		DAY 29	27MAR2003	31	0	3	0						
		DAY 57	23APR2003	58	0	3	0						
		FINAL	23APR2003	58	0	3	0						
PLACEBO (BIPOLAR I)	E0002016	DAY 1	24JUL2003	1	1	3	1	3	1	3	3		
		DAY 29	21AUG2003	29	1	2	1	1	0	1	2		
		DAY 57	17SEP2003	56	1	1	1	0	0	0	0		
		FINAL	17SEP2003	56	1	1	1	0	0	0	0		
PLACEBO (BIPOLAR I)	E0003008	DAY 1	28JAN2003	1	0	3	3	0	2	2	0	2	MOANING, ROCKING
PLACEBO (BIPOLAR I)	E0004003	DAY 1	02OCT2002	-8	0	3	3						
PLACEBO (BIPOLAR I)	E0004006	DAY 1	04NOV2002	1	1	3	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0004006	DAY 29	02DEC2002	29	5	0	1	1	1	0	1	0	1
		DAY 57	06JAN2003	64	9	4	2	3	1	0	1	0	2
		FINAL	06JAN2003	64	9	4	2	3	1	0	1	0	2
	E0004016	DAY 1	19FEB2003	1	16		3	3	3	2	1	1	3
		DAY 57	17APR2003	58	4	-12	1	3	0	0	0	0	0
		FINAL	17APR2003	58	4	-12	1	3	0	0	0	0	0
	E0004024	DAY 1	03JUL2003	1	12		2	3	2	1	1	0	3
		DAY 29	31JUL2003	29	7	-5	1	2	1	0	1	0	2
		DAY 57	28AUG2003	57	5	-7	0	1	1	0	1	0	2
		FINAL	28AUG2003	57	5	-7	0	1	1	0	1	0	2
	E0005006	DAY 1	24SEP2002	-9	7		2	2	1	0	1	0	1
	E0005017	DAY 1	30DEC2002	1	17		2	2	3	3	2	2	3
		DAY 29	30JAN2003	32	11	-6	1	1	2	3	2	1	1
		DAY 57	04MAR2003	65	12	-5	1	1	1	2	2	3	2
		FINAL	04MAR2003	65	12	-5	1	1	1	2	2	3	2
	E0005019	DAY 1	15JAN2003	1	11		2	2	1	0	2	2	2
		DAY 29	23JAN2003	9	12	1	2	3	1	2	2	0	2
		FINAL	23JAN2003	9	12	1	2	3	1	2	2	0	2
	E0005026	DAY 1	06MAR2003	1	11		2	1	2	3	1	0	2
		DAY 29	25MAR2003	20	17	6	3	3	3	2	1	3	2
		FINAL	25MAR2003	20	17	6	3	3	3	2	1	3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0004006	DAY 29	02DEC2002	29	0:00	20	7:15	7	0	3	0	0	0	0	0	0	0		
		DAY 57	06JAN2003	64	0:00	40	7:00	6	3	3	0	0	0	1	0	0	0		
		FINAL	06JAN2003	64	0:00	40	7:00	6	3	3	0	0	0	1	0	0	0		
PLACEBO (BIPOLAR I)	E0004016	DAY 1	19FEB2003	1	1:30	150	7:30	4	3	3	1	1	0	0	0	1	0		
		DAY 57	17APR2003	58	1:30	45	9:00	8	3	0	0	0	0	0	0	0	0		
		FINAL	17APR2003	58	1:30	45	9:00	8	3	0	0	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0004024	DAY 1	03JUL2003	1	23:00	90	5:00	5	3	3	3	1	0	0	1	0	0		
		DAY 29	31JUL2003	29	23:00	30	5:30	6	2	3	2	0	0	0	3	0	0		
		DAY 57	28AUG2003	57	23:00	20	5:30	6	0	0	3	0	0	0	0	0	0		
		FINAL	28AUG2003	57	23:00	20	5:30	6	0	0	3	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0005006	DAY 1	24SEP2002	-9	23:00	20	6:00	7	2	3	0	0	0	0	0	0	0	3	"JUST WAKE UP"
PLACEBO (BIPOLAR I)	E0005017	DAY 1	30DEC2002	1	23:00	30	5:30	4	2	3	3	0	0	1	2	2	2		
		DAY 29	30JAN2003	32	22:00	15	6:00	5	2	3	2	0	0	1	3	1	2		
		DAY 57	04MAR2003	65	22:00	15	6:30	6	1	2	2	0	0	1	2	1	2		
		FINAL	04MAR2003	65	22:00	15	6:30	6	1	2	2	0	0	1	2	1	2		
PLACEBO (BIPOLAR I)	E0005019	DAY 1	15JAN2003	1	2:00	30	9:30	7	3	2	1	3	1	2	1	2	3		
		DAY 29	23JAN2003	9	0:00	90	9:00	6	3	2	1	1	1	1	1	2	2		
		FINAL	23JAN2003	9	0:00	90	9:00	6	3	2	1	1	1	1	1	2	2		
PLACEBO (BIPOLAR I)	E0005026	DAY 1	06MAR2003	1	11:30	30	6:00	5	1	2	2	0	0	2	2	1	0		
		DAY 29	25MAR2003	20	2:30	60	8:00	4	3	2	1	0	0	2	0	2	1		
		FINAL	25MAR2003	20	2:30	60	8:00	4	3	2	1	0	0	2	0	2	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0004006	DAY 29	02DEC2002	29	0	2	3						
		DAY 57	06JAN2003	64	1	3	3	2	1	3	1		
		FINAL	06JAN2003	64	1	3	3	2	1	3	1		
PLACEBO (BIPOLAR I)	E0004016	DAY 1	19FEB2003	1	3	2	0						
		DAY 57	17APR2003	58	0	0	0						
		FINAL	17APR2003	58	0	0	0						
PLACEBO (BIPOLAR I)	E0004024	DAY 1	03JUL2003	1	2	3	3						
		DAY 29	31JUL2003	29	0	3	3						
		DAY 57	28AUG2003	57	2	2	3						
		FINAL	28AUG2003	57	2	2	3						
PLACEBO (BIPOLAR I)	E0005006	DAY 1	24SEP2002	-9	0	1	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0005017	DAY 1	30DEC2002	1	2	3	3						
		DAY 29	30JAN2003	32	0	2	3						
		DAY 57	04MAR2003	65	1	2	3						
		FINAL	04MAR2003	65	1	2	3						
PLACEBO (BIPOLAR I)	E0005019	DAY 1	15JAN2003	1	1	3	0						
		DAY 29	23JAN2003	9	1	3	0						
		FINAL	23JAN2003	9	1	3	0						
PLACEBO (BIPOLAR I)	E0005026	DAY 1	06MAR2003	1	0	3	3						
		DAY 29	25MAR2003	20	0	3	3						
		FINAL	25MAR2003	20	0	3	3						

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0005039	DAY 1	22MAY2003	1	14		2	2	3	3	2	0	2
		DAY 29	18JUN2003	28	8	-6	1	1	2	1	1	0	2
		DAY 57	16JUL2003	56	11	-3	2	2	2	2	1	0	2
		FINAL	16JUL2003	56	11	-3	2	2	2	2	1	0	2
	E0005043	DAY 1	09JUL2003	1	3		0	0	1	0	0	0	2
		DAY 29	07AUG2003	30	2	-1	0	0	0	0	1	0	1
		DAY 57	03SEP2003	57	2	-1	0	0	1	0	0	0	1
		FINAL	03SEP2003	57	2	-1	0	0	1	0	0	0	1
	E0006020	DAY 1	13MAY2003	1	6		1	1	1	0	1	0	2
		DAY 29	10JUN2003	29	4	-2	0	1	1	0	1	0	1
		DAY 57	08JUL2003	57	3	-3	0	0	1	0	1	0	1
		FINAL	08JUL2003	57	3	-3	0	0	1	0	1	0	1
	E0007001	DAY 1	31DEC2002	1	11		2	3	1	1	2	0	2
		DAY 29	28JAN2003	29	7	-4	1	2	1	0	1	0	2
		DAY 57	22FEB2003	54	7	-4	1	3	1	0	1	0	1
		FINAL	22FEB2003	54	7	-4	1	3	1	0	1	0	1
	E0007003	DAY 1	30JAN2003	1	15		3	1	3	2	1	3	2
		DAY 29	10MAR2003	40	10	-5	2	3	2	0	1	0	2
		FINAL	10MAR2003	40	10	-5	2	3	2	0	1	0	2
	E0007006	DAY 1	05MAR2003	1	7		1	2	1	0	1	0	2
		DAY 29	26MAR2003	22	4	-3	1	1	0	0	1	0	1
		FINAL	26MAR2003	22	4	-3	1	1	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
PLACEBO (BIPOLAR I)	E0005039	DAY 1	22MAY2003	1	22:30	30	5:00	4	3	3	2	0	2	0	2	2	1	3 RESTLESS
		DAY 29	18JUN2003	28	23:00	15	5:00	5	1	2	2	0	1	0	1	2	0	
		DAY 57	16JUL2003	56	22:00	30	5:00	5	2	1	1	1	1	0	1	2	2	
		FINAL	16JUL2003	56	22:00	30	5:00	5	2	1	1	1	1	0	1	2	2	
PLACEBO (BIPOLAR I)	E0005043	DAY 1	09JUL2003	1	0:00	10	7:00	7	0	0	0	0	0	0	0	0	0	
		DAY 29	07AUG2003	30	0:00	10	7:00	8	0	0	3	0	2	0	0	0	0	
		DAY 57	03SEP2003	57	0:00	10	7:30	7	0	0	0	0	0	0	0	0	0	
		FINAL	03SEP2003	57	0:00	10	7:30	7	0	0	0	0	0	0	0	0	0	
PLACEBO (BIPOLAR I)	E0006020	DAY 1	13MAY2003	1	0:00	20	7:00	7	1	2	0	0	0	1	1	0	0	
		DAY 29	10JUN2003	29	23:30	20	6:30	6	0	1	0	0	0	0	0	0	0	
		DAY 57	08JUL2003	57	23:30	10	6:30	7	0	1	0	0	0	0	0	0	0	
		FINAL	08JUL2003	57	23:30	10	6:30	7	0	1	0	0	0	0	0	0	0	
PLACEBO (BIPOLAR I)	E0007001	DAY 1	31DEC2002	1	23:00	45	7:00	6	3	3	3	2	1	1	2	1	2	
		DAY 29	28JAN2003	29	23:00	30	7:00	7	2	2	2	1	0	0	0	0	0	
		DAY 57	22FEB2003	54	23:00	60	7:00	7	3	2	3	0	0	0	0	0	0	
		FINAL	22FEB2003	54	23:00	60	7:00	7	3	2	3	0	0	0	0	0	0	
PLACEBO (BIPOLAR I)	E0007003	DAY 1	30JAN2003	1	0:00	60	6:00	4	0	3	3	0	0	0	0	2	0	
		DAY 29	10MAR2003	40	0:00	60	5:30	5	3	3	3	0	0	0	0	0	2	
		FINAL	10MAR2003	40	0:00	60	5:30	5	3	3	3	0	0	0	0	0	2	
PLACEBO (BIPOLAR I)	E0007006	DAY 1	05MAR2003	1	22:00	30	4:30	7	2	3	3	0	3	0	0	0	0	
		DAY 29	26MAR2003	22	22:30	10	5:00	8	1	1	0	0	3	0	0	0	0	
		FINAL	26MAR2003	22	22:30	10	5:00	8	1	1	0	0	3	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0005039	DAY 1	22MAY2003	1	2	2	3	2	0	3	2	3	AGITATED, MOVING AROUND ALOT, TALKATIVE
		DAY 29	18JUN2003	28	2	2	3	1	0	1	0		
		DAY 57	16JUL2003	56	2	2	3						
		FINAL	16JUL2003	56	2	2	3						
PLACEBO (BIPOLAR I)	E0005043	DAY 1	09JUL2003	1	0	3	3						
		DAY 29	07AUG2003	30	0	2	3						
		DAY 57	03SEP2003	57	0	2	3						
		FINAL	03SEP2003	57	0	2	3						
PLACEBO (BIPOLAR I)	E0006020	DAY 1	13MAY2003	1	1	2	3	0	0	0	0		
		DAY 29	10JUN2003	29	0	2	3	0	0	0	0		
		DAY 57	08JUL2003	57	0	1	3	1	0	0	0		
		FINAL	08JUL2003	57	0	1	3	1	0	0	0		
PLACEBO (BIPOLAR I)	E0007001	DAY 1	31DEC2002	1	0	3	0						
		DAY 29	28JAN2003	29	0	3	0						
		DAY 57	22FEB2003	54	0	2	0						
		FINAL	22FEB2003	54	0	2	0						
PLACEBO (BIPOLAR I)	E0007003	DAY 1	30JAN2003	1	1	3	0						
		DAY 29	10MAR2003	40	2	2	0						
		FINAL	10MAR2003	40	2	2	0						
PLACEBO (BIPOLAR I)	E0007006	DAY 1	05MAR2003	1	1	2	1	0	0	0	0		
		DAY 29	26MAR2003	22	0	2	0						
		FINAL	26MAR2003	22	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0009004	DAY 1	26NOV2002	1	18		3	3	2	3	3	3	1
		DAY 29	18DEC2002	23	18	0	3	3	3	3	1	3	2
		FINAL	18DEC2002	23	18	0	3	3	3	3	1	3	2
	E0009012	DAY 1	25JUN2003	1	12		2	2	2	2	1	0	3
		DAY 29	03JUL2003	9	10	-2	2	2	2	1	1	0	2
		FINAL	03JUL2003	9	10	-2	2	2	2	1	1	0	2
	E0010008	DAY 1	18DEC2002	1	16		1	3	3	3	1	3	2
		DAY 29	15JAN2003	29	13	-3	1	3	1	3	1	3	1
		FINAL	15JAN2003	29	13	-3	1	3	1	3	1	3	1
	E0010018	DAY 1	19MAR2003	1	17		2	3	2	2	2	3	3
		DAY 29	16APR2003	29	12	-5	2	3	2	3	1	0	1
		FINAL	16APR2003	29	12	-5	2	3	2	3	1	0	1
	E0010028	DAY 1	16JUN2003	1	15		2	3	1	2	2	3	2
		DAY 29	15JUL2003	30	17	2	3	3	3	3	1	2	2
		FINAL	15JUL2003	30	17	2	3	3	3	3	1	2	2
	E0011008	DAY 1	30JAN2003	1	6		1	3	1	0	1	0	0
		DAY 29	13FEB2003	15	2	-4	1	1	0	0	0	0	0
		FINAL	13FEB2003	15	2	-4	1	1	0	0	0	0	0
	E0011009	DAY 1	26DEC2002	-1	18		3	3	3	3	2	3	1
		DAY 29	23JAN2003	28	15	-3	3	3	3	3	2	0	1
		DAY 57	20FEB2003	56	13	-5	2	3	2	3	1	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
PLACEBO (BIPOLAR I)	E0009004	DAY 1	26NOV2002	1	23:00	90	7:00	5	3	3	2	0	2	1	3	2	3	3 HANDS PAIN
		DAY 29	18DEC2002	23	23:00	120	9:00	4	3	3	1	0	0	1	1	0	1	
		FINAL	18DEC2002	23	23:00	120	9:00	4	3	3	1	0	0	1	1	0	1	
PLACEBO (BIPOLAR I)	E0009012	DAY 1	25JUN2003	1	1:00	30	8:00	5	3	2	0	1	0	0	2	2	0	
		DAY 29	03JUL2003	9	2:00	30	8:30	5	3	2	2	0	0	0	2	1	2	
		FINAL	03JUL2003	9	2:00	30	8:30	5	3	2	2	0	0	0	2	1	2	
PLACEBO (BIPOLAR I)	E0010008	DAY 1	18DEC2002	1	22:00	180	7:30	4	3	2	0	0	0	1	1	0	0	
		DAY 29	15JAN2003	29	22:00	90	7:45	6	3	2	0	0	0	1	1	0	0	
		FINAL	15JAN2003	29	22:00	90	7:45	6	3	2	0	0	0	1	1	0	0	
PLACEBO (BIPOLAR I)	E0010018	DAY 1	19MAR2003	1	22:00	60	5:00	5	3	3	2	2	3	0	3	3	0	
		DAY 29	16APR2003	29	22:30	60	6:30	5	3	3	1	0	0	0	0	0	0	
		FINAL	16APR2003	29	22:30	60	6:30	5	3	3	1	0	0	0	0	0	0	
PLACEBO (BIPOLAR I)	E0010028	DAY 1	16JUN2003	1	0:30	90	11:00	7	3	3	3	1	1	0	0	2	2	
		DAY 29	15JUL2003	30	23:30	210	8:00	3	3	3	3	0	0	0	0	0	3	
		FINAL	15JUL2003	30	23:30	210	8:00	3	3	3	3	0	0	0	0	0	3	
PLACEBO (BIPOLAR I)	E0011008	DAY 1	30JAN2003	1	2:30	45	9:00	7	3	2	0	0	0	0	0	0	0	
		DAY 29	13FEB2003	15	1:00	10	9:30	9	1	0	0	0	0	0	0	0	0	
		FINAL	13FEB2003	15	1:00	10	9:30	9	1	0	0	0	0	0	0	0	0	
PLACEBO (BIPOLAR I)	E0011009	DAY 1	26DEC2002	-1	9:00	180	16:00	3	3	3	3	3	3	0	0	0	0	
		DAY 29	23JAN2003	28	8:00	180	16:00	4	3	3	2	3	3	3	1	1	2	
		DAY 57	20FEB2003	56	9:00	90	17:00	5	3	3	1	1	1	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0009004	DAY 1	26NOV2002	1	0	2	3	2	0	3	0	3	HAND PAIN
		DAY 29	18DEC2002	23	1	2	3	1	0	3	0		
		FINAL	18DEC2002	23	1	2	3	1	0	3	0		
PLACEBO (BIPOLAR I)	E0009012	DAY 1	25JUN2003	1	2	3	3	0	0	2			
		DAY 29	03JUL2003	9	1	3	3	0	0	2	0		
		FINAL	03JUL2003	9	1	3	3	0	0	2	0		
PLACEBO (BIPOLAR I)	E0010008	DAY 1	18DEC2002	1	1	3	3	1	0	0	1		
		DAY 29	15JAN2003	29	0	2	3	0	0	0	0		
		FINAL	15JAN2003	29	0	2	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0010018	DAY 1	19MAR2003	1	2	3	0						
		DAY 29	16APR2003	29	0	2							
		FINAL	16APR2003	29	0	2							
PLACEBO (BIPOLAR I)	E0010028	DAY 1	16JUN2003	1	0	3	3	1	0	3	1	3	TOSSING TURNING, JUMPING
		DAY 29	15JUL2003	30	1	3	3	0	0	0	0	3	TOSSING, TURNING
		FINAL	15JUL2003	30	1	3	3	0	0	0	0	3	TOSSING, TURNING
PLACEBO (BIPOLAR I)	E0011008	DAY 1	30JAN2003	1	0	0	0						
		DAY 29	13FEB2003	15	0	0	3						
		FINAL	13FEB2003	15	0	0	3						
PLACEBO (BIPOLAR I)	E0011009	DAY 1	26DEC2002	-1	0	2	1	3	3	3	1		
		DAY 29	23JAN2003	28	0	2	1	3	3	3	2		
		DAY 57	20FEB2003	56	0	2	3	3	3	3	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0011009	FINAL		20FEB2003	56	13	-5	2	3	2	3	1	1	1
	E0011010	DAY 1		10FEB2003	1	7		0	0	1	1	2	0	3
		DAY 29		10MAR2003	29	6	-1	1	1	0	0	2	0	2
		DAY 29	*	19MAR2003	38	8	1	2	0	1	1	2	0	2
		FINAL		19MAR2003	38	8	1	2	0	1	1	2	0	2
	E0013001	DAY 1	*	31OCT2002	-14	12		2	3	2	1	2	0	2
		DAY 1		14NOV2002	1	12		2	3	2	2	1	0	2
		DAY 29		11DEC2002	28	8	-4	1	2	2	1	1	0	1
		DAY 57		10JAN2003	58	4	-8	1	0	1	1	1	0	0
		FINAL		10JAN2003	58	4	-8	1	0	1	1	1	0	0
	E0013003	DAY 1		12NOV2002	1	16		3	3	3	3	2	0	2
		DAY 29		11DEC2002	30	14	-2	3	1	3	3	2	0	2
		DAY 57		06JAN2003	56	14	-2	3	1	3	3	2	0	2
		FINAL		06JAN2003	56	14	-2	3	1	3	3	2	0	2
	E0013005	DAY 1		18FEB2003	1	16		2	3	1	3	2	2	3
		DAY 29		19MAR2003	30	7	-9	1	1	0	1	1	1	2
		DAY 57		15APR2003	57	7	-9	2	2	0	1	1	0	1
		FINAL		15APR2003	57	7	-9	2	2	0	1	1	0	1
	E0013013	DAY 1		06MAY2003	1	5		1	0	0	0	1	0	3
		DAY 29		30MAY2003	25	12	7	2	2	1	3	1	1	2
		FINAL		30MAY2003	25	12	7	2	2	1	3	1	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0011009	FINAL		20FEB2003	56	9:00	90	17:00	5	3	3	1	1	1	0	0	0	0		
PLACEBO (BIPOLAR I)	E0011010	DAY 1		10FEB2003	1	22:30	10	7:00	7	0	2	3	0	0	3	3	2	1		
		DAY 29		10MAR2003	29	22:00	10	7:00	8	1	3	3	0	0	3	3	0	0	3	WAKE UP AND EAT CEREAL AT MIDNIGHT.
		DAY 29	*	19MAR2003	38	22:00	5	7:00	7	0	3	3	0	0	2	3	0	3	3	HEADACHE
		FINAL		19MAR2003	38	22:00	5	7:00	7	0	3	3	0	0	2	3	0	3	3	HEADACHE
PLACEBO (BIPOLAR I)	E0013001	DAY 1	*	31OCT2002	-14	0:00	60	6:00	5	3	3	1	2	2	1	1	0	0	1	NOISE
		DAY 1		14NOV2002	1	23:00	60	6:00	5	3	3	2	0	2	1	1	0	0		
		DAY 29		11DEC2002	28	23:00	30	5:30	5	2	1	1	2	2	0	0	0	0		
		DAY 57		10JAN2003	58	23:00	10	6:30	6	0	0	0	0	3	0	0	0	0		
		FINAL		10JAN2003	58	23:00	10	6:30	6	0	0	0	0	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0013003	DAY 1		12NOV2002	1	1:00	60	6:30	3	3	3	3	0	3	0	3	1	0		
		DAY 29		11DEC2002	30	0:00	20	6:30	3	0	3	3	0	0	1	3	1	0		
		DAY 57		06JAN2003	56	0:00	15	6:00	2	1	3	3	1	0	3	3	0	0		
		FINAL		06JAN2003	56	0:00	15	6:00	2	1	3	3	1	0	3	3	0	0		
PLACEBO (BIPOLAR I)	E0013005	DAY 1		18FEB2003	1	23:30	90	9:30	6	3	3	3	1	1	1	1	2	0		
		DAY 29		19MAR2003	30	23:30	30	9:30	8	0	3	2	0	0	0	0	0	0		
		DAY 57		15APR2003	57	23:30	30	10:00	8	2	3	1	0	0	1	0	1	0		
		FINAL		15APR2003	57	23:30	30	10:00	8	2	3	1	0	0	1	0	1	0		
PLACEBO (BIPOLAR I)	E0013013	DAY 1		06MAY2003	1	9:00	5	17:00	9	0	2	2	0	0	0	2	3	0		
		DAY 29		30MAY2003	25	21:30	30	8:00	6	2	3	2	0	0	0	0	2	0		
		FINAL		30MAY2003	25	21:30	30	8:00	6	2	3	2	0	0	0	0	2	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0011009	FINAL		20FEB2003	56	0	2	3	3	3	3	2		
PLACEBO (BIPOLAR I)	E0011010	DAY 1		10FEB2003	1	3	3	1	0	0	0	0	3	TOSSING & TURNING
		DAY 29		10MAR2003	29	2	2	1	0	0	0	0	2	TOSSING & TURNING, SLEEP LIGHTLY.
		DAY 29	*	19MAR2003	38	1	2	1	0	0	0	0	3	RESTLESSNESS
		FINAL		19MAR2003	38	1	2	1	0	0	0	0	3	RESTLESSNESS
PLACEBO (BIPOLAR I)	E0013001	DAY 1	*	31OCT2002	-14	1	3	1	2	3	1	0		
		DAY 1		14NOV2002	1	1	2	1						
		DAY 29		11DEC2002	28	1	1	1						
		DAY 57		10JAN2003	58	0	0	3	3	1	0	0		
		FINAL		10JAN2003	58	0	0	3	3	1	0	0		
PLACEBO (BIPOLAR I)	E0013003	DAY 1		12NOV2002	1	0	3	0						
		DAY 29		11DEC2002	30	0	3	0						
		DAY 57		06JAN2003	56	0	3	0						
		FINAL		06JAN2003	56	0	3	0						
PLACEBO (BIPOLAR I)	E0013005	DAY 1		18FEB2003	1	2	3	0						
		DAY 29		19MAR2003	30	1	2	0						
		DAY 57		15APR2003	57	0	2	0						
		FINAL		15APR2003	57	0	2	0						
PLACEBO (BIPOLAR I)	E0013013	DAY 1		06MAY2003	1	2	3	3	0	0	0	0		
		DAY 29		30MAY2003	25	0	3	3	0	0	0	0		
		FINAL		30MAY2003	25	0	3	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0014002	DAY 1	26FEB2003	1	10		2	2	1	0	2	1	2
		DAY 29	27MAR2003	30	15	5	2	3	3	2	2	1	2
		DAY 57	10APR2003	44	8	-2	1	2	1	0	2	1	1
		FINAL	10APR2003	44	8	-2	1	2	1	0	2	1	1
	E0014004	DAY 1	12MAR2003	1	8		2	2	0	0	2	0	2
		DAY 29	15APR2003	35	14	6	2	1	3	3	2	0	3
		FINAL	15APR2003	35	14	6	2	1	3	3	2	0	3
	E0014009	DAY 1	23APR2003	1	19		3	3	3	3	2	3	2
		DAY 29	16MAY2003	24	13	-6	1	2	2	2	2	3	1
		FINAL	16MAY2003	24	13	-6	1	2	2	2	2	3	1
	E0014015	DAY 1	18JUN2003	1	5		0	1	0	1	1	0	2
	E0014017	DAY 1	27JUN2003	1	10		2	3	1	0	2	0	2
		DAY 29	23JUL2003	27	6	-4	1	1	1	0	2	0	1
		DAY 57	19AUG2003	54	6	-4	1	1	1	0	2	0	1
		FINAL	19AUG2003	54	6	-4	1	1	1	0	2	0	1
	E0014018	DAY 1	01JUL2003	1	11		2	3	1	1	1	0	3
		DAY 29	29JUL2003	29	6	-5	2	2	0	0	1	0	1
		DAY 57	27AUG2003	58	8	-3	2	3	1	0	1	0	1
		FINAL	27AUG2003	58	8	-3	2	3	1	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0014002	DAY 1	26FEB2003	1	23:00	40	6:00	6	2	1	3	0	0	3	0	1	3	3	WAKE UP FROM HUSBAND SNORING OR KIDS
		DAY 29	27MAR2003	30	23:30	45	5:30	4	3	3	3	2	0	3	2	1	3		
		DAY 57	10APR2003	44	23:00	30	6:00	7	2	2	3	2	0	3	0	1	3		
		FINAL	10APR2003	44	23:00	30	6:00	7	2	2	3	2	0	3	0	1	3		
PLACEBO (BIPOLAR I)	E0014004	DAY 1	12MAR2003	1	23:00	40	10:00	14	2	3	3	2	1	0	3	0	1	3	NEED TO SMOKE
		DAY 29	15APR2003	35	23:00	30	6:30	3	1	3	3	1	0	0	3	1	2		
		FINAL	15APR2003	35	23:00	30	6:30	3	1	3	3	1	0	0	3	1	2		
PLACEBO (BIPOLAR I)	E0014009	DAY 1	23APR2003	1	22:30	120	6:30	3	3	3	3	2	0	0	2	3	2	3	CAN'T SLOW MY THOUGHTS DOWN
		DAY 29	16MAY2003	24	0:00	30	7:00	5	2	2	2	1	1	1	2	2	1		
		FINAL	16MAY2003	24	0:00	30	7:00	5	2	2	2	1	1	1	2	2	1		
PLACEBO (BIPOLAR I)	E0014015	DAY 1	18JUN2003	1	23:00	40	17:00	14	0	3	3	0	0	0	2	1	0		
PLACEBO (BIPOLAR I)	E0014017	DAY 1	27JUN2003	1	2:30	60	10:00	7	3	2	1	3	2	2	2	1	1		
		DAY 29	23JUL2003	27	2:00	30	8:00	7	1	2	2	0	1	1	1	1	2		
		DAY 57	19AUG2003	54	1:00	30	9:00	7	0	1	2	0	2	2	1	2	1		
		FINAL	19AUG2003	54	1:00	30	9:00	7	0	1	2	0	2	2	1	2	1		
PLACEBO (BIPOLAR I)	E0014018	DAY 1	01JUL2003	1	3:30	60	12:00	7	3	1	0	0	0	1	1	1	2		
		DAY 29	29JUL2003	29	2:00	45	11:00	8	2	2	0	0	0	0	0	0	2		
		DAY 57	27AUG2003	58	3:00	60	10:00	6	3	2	0	0	0	0	2	1	2		
		FINAL	27AUG2003	58	3:00	60	10:00	6	3	2	0	0	0	0	2	1	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0014002	DAY 1	26FEB2003	1	0	3	3						
		DAY 29	27MAR2003	30	1	3	3	0	0	0	0		
		DAY 57	10APR2003	44	0	2	3	0	0	2	0		
		FINAL	10APR2003	44	0	2	3	0	0	2	0		
PLACEBO (BIPOLAR I)	E0014004	DAY 1	12MAR2003	1	1	3	3	2	3	1	0	3	WAKING OFTEN UP TO 10X NIGHTLY
		DAY 29	15APR2003	35	2	3	3	0	2	2	0	3	" WAKING SEVERAL TIMES NIGHTLY"
		FINAL	15APR2003	35	2	3	3	0	2	2	0	3	" WAKING SEVERAL TIMES NIGHTLY"
PLACEBO (BIPOLAR I)	E0014009	DAY 1	23APR2003	1	1	3	3	0	0	0	1	3	CAN'T GET COMFORTABLE/STAY COMFORTABLE
		DAY 29	16MAY2003	24	0	2	3	0	0	0	0		
		FINAL	16MAY2003	24	0	2	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0014015	DAY 1	18JUN2003	1	1	2	3	0	0	3	3		
PLACEBO (BIPOLAR I)	E0014017	DAY 1	27JUN2003	1	2	2	0						
		DAY 29	23JUL2003	27	1	0	0						
		DAY 57	19AUG2003	54	2	0	0						
		FINAL	19AUG2003	54	2	0	0						
PLACEBO (BIPOLAR I)	E0014018	DAY 1	01JUL2003	1	2	3	1						
		DAY 29	29JUL2003	29	0	2	0						
		DAY 57	27AUG2003	58	0	2	0						
		FINAL	27AUG2003	58	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0015005	DAY 1	02DEC2002	1	16		2	3	2	3	3	1	2
		DAY 29	18DEC2002	17	17	1	2	3	3	3	2	2	2
		FINAL	18DEC2002	17	17	1	2	3	3	3	2	2	2
	E0018009	DAY 1	06JAN2003	1	15		3	3	3	2	2	0	2
		DAY 29	14JAN2003	9	12	-3	2	3	2	1	2	0	2
		FINAL	14JAN2003	9	12	-3	2	3	2	1	2	0	2
	E0018010	DAY 1	16JAN2003	1	15		2	3	1	1	3	2	3
		DAY 29	13FEB2003	29	11	-4	3	2	0	0	3	0	3
		DAY 57	13MAR2003	57	12	-3	2	3	0	1	3	0	3
		FINAL	13MAR2003	57	12	-3	2	3	0	1	3	0	3
	E0018015	DAY 1	28JAN2003	1	5		1	1	0	0	1	0	2
		DAY 29	26FEB2003	30	8	3	1	1	0	0	2	3	1
		DAY 57	27MAR2003	59	4	-1	1	1	0	0	1	0	1
		FINAL	27MAR2003	59	4	-1	1	1	0	0	1	0	1
	E0020015	DAY 1	27MAR2003	1			3		3	0		0	3
		DAY 29	23APR2003	28	11		2	1	3	0	2	0	3
		DAY 57	23MAY2003	58	13		3	2	1	3	2	0	2
		FINAL	23MAY2003	58	13		3	2	1	3	2	0	2
	E0020017	DAY 1	03APR2003	1	3		1	0	1	0	0	0	1
		DAY 29	29APR2003	27	5	2	1	0	1	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0015005	DAY 1	02DEC2002	1	21:00	120	7:00	5	3	3	2	2	2	3	3	2	2		
		DAY 29	18DEC2002	17	21:00	120	5:30	4	3	3	1	2	2	2	2	2	2		
		FINAL	18DEC2002	17	21:00	120	5:30	4	3	3	1	2	2	2	2	2	2		
PLACEBO (BIPOLAR I)	E0018009	DAY 1	06JAN2003	1	3:00	120	9:00	4	3	3	1	1	1	1	1	2	0	2	RACING THOUGHTS
		DAY 29	14JAN2003	9	0:00	90	6:00	5	3	2	2	2	2	0	0	3	1		
		FINAL	14JAN2003	9	0:00	90	6:00	5	3	2	2	2	2	0	0	3	1		
PLACEBO (BIPOLAR I)	E0018010	DAY 1	16JAN2003	1	22:00	60	6:00	6	3	3	3	3	3	3	3	3	2		
		DAY 29	13FEB2003	29	21:00	30	4:00	8	3	3	2	3	3	1	3	2	2		
		DAY 57	13MAR2003	57	20:00	60	6:00	8	3	3	2	3	3	3	3	3	1		
		FINAL	13MAR2003	57	20:00	60	6:00	8	3	3	2	3	3	3	3	3	1		
PLACEBO (BIPOLAR I)	E0018015	DAY 1	28JAN2003	1	0:00	20	10:00	9	0	3	0	1	0	1	1	0	3		
		DAY 29	26FEB2003	30	1:00	20	10:00	9	0	3	0	0	0	2	2	0	3		
		DAY 57	27MAR2003	59	0:00	20	10:00	9	1	3	0	0	0	0	2	0	3		
		FINAL	27MAR2003	59	0:00	20	10:00	9	1	3	0	0	0	0	2	0	3		
PLACEBO (BIPOLAR I)	E0020015	DAY 1	27MAR2003	1	5:00		8:00	3	3	3	1	2		3	3	2	3		
		DAY 29	23APR2003	28	5:00	10	8:00	3	2	2	0	1	0	3	3	2	3		
		DAY 57	23MAY2003	58	8:00	30	21:00	6	3	3	2	0	0	3	3	2	3		
		FINAL	23MAY2003	58	8:00	30	21:00	6	3	3	2	0	0	3	3	2	3		
PLACEBO (BIPOLAR I)	E0020017	DAY 1	03APR2003	1	23:00	15	5:30	6	0	0	0	0	0	0	0	0	0		
		DAY 29	29APR2003	27	0:00	10	5:30	6	0	0	0	0	0	0	0	0	3	3	WAKE UP WIT TERRIBLE HEAD AND NECK ACHE.

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0015005	DAY 1	02DEC2002	1	1	3	3	2	0	2	2	3	WAKING UP 3 - 4 TIMES A NIGHT
		DAY 29	18DEC2002	17	1	2	3	2	1	1	1		
		FINAL	18DEC2002	17	1	2	3	2	1	1	1		
PLACEBO (BIPOLAR I)	E0018009	DAY 1	06JAN2003	1	0	3	1	0	0	0	0	3	TALKING AND YELLING DURING SLEEP
		DAY 29	14JAN2003	9	1	3	2	3	3	3	1		
		FINAL	14JAN2003	9	1	3	2	3	3	3	1		
PLACEBO (BIPOLAR I)	E0018010	DAY 1	16JAN2003	1	3	2	3	3	1	1	1	2	TALKING IN SLEEP
		DAY 29	13FEB2003	29	3	3	3	3	1	2	0	3	WAKE UP EARLY
		DAY 57	13MAR2003	57	3	3	3	3	2	1	1		
		FINAL	13MAR2003	57	3	3	3	3	2	1	1		
PLACEBO (BIPOLAR I)	E0018015	DAY 1	28JAN2003	1	0	3	1						
		DAY 29	26FEB2003	30	0	2	1						
		DAY 57	27MAR2003	59	0	2	1						
		FINAL	27MAR2003	59	0	2	1						
PLACEBO (BIPOLAR I)	E0020015	DAY 1	27MAR2003	1	3	3	0						
		DAY 29	23APR2003	28	2	3	0						
		DAY 57	23MAY2003	58	0	3	0						
		FINAL	23MAY2003	58	0	3	0						
PLACEBO (BIPOLAR I)	E0020017	DAY 1	03APR2003	1	0	2	0						
		DAY 29	29APR2003	27	1	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0020017	FINAL	29APR2003	27	5	2	1	0	1	0	1	0	2
	E0020020	DAY 1	12MAY2003	1	5		1	0	1	0	1	0	2
		DAY 29	23MAY2003	12	17	12	3	3	3	3	1	2	2
		FINAL	23MAY2003	12	17	12	3	3	3	3	1	2	2
	E0020022	DAY 1	16JUN2003	1	15		3	3	3	3	1	0	2
		DAY 29	14JUL2003	29	3	-12	0	1	1	0	0	0	1
		DAY 57	11AUG2003	57	4	-11	0	1	1	0	1	0	1
		FINAL	11AUG2003	57	4	-11	0	1	1	0	1	0	1
	E0022001	DAY 1	28OCT2002	1	9		2	3	0	0	1	0	3
		DAY 29	26NOV2002	30	11	2	2	3	0	2	1	0	3
		DAY 57	26DEC2002	60	10	1	3	3	0	0	2	0	2
		FINAL	26DEC2002	60	10	1	3	3	0	0	2	0	2
	E0022004	DAY 1	28OCT2002	1	11		2	3	1	1	2	0	2
		DAY 29	26NOV2002	30	11	0	2	3	1	2	1	0	2
		DAY 57	23DEC2002	57	8	-3	2	2	1	0	1	0	2
		FINAL	23DEC2002	57	8	-3	2	2	1	0	1	0	2
	E0022005	DAY 1	08NOV2002	1	8		1	0	1	0	3	0	3
		DAY 29	06DEC2002	29	6	-2	1	0	0	0	3	0	2
		DAY 57	03JAN2003	57	8	0	1	1	1	1	2	0	2
		FINAL	03JAN2003	57	8	0	1	1	1	1	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0020017	FINAL	29APR2003	27	0:00	10	5:30	6	0	0	0	0	0	0	0	0	3	3	WAKE UP WIT TERRIBLE HEAD AND NECK ACHE.
PLACEBO (BIPOLAR I)	E0020020	DAY 1	12MAY2003	1	21:00	10	5:00	7	0	1	3	0	0	0	0	0	0		
		DAY 29	23MAY2003	12	21:00	90	5:00	4	3	2	3	1	0	0	0	1	0		
		FINAL	23MAY2003	12	21:00	90	5:00	4	3	2	3	1	0	0	0	1	0		
PLACEBO (BIPOLAR I)	E0020022	DAY 1	16JUN2003	1	23:00	180	9:00	3	3	3	3	0	0	0	0	0	0		
		DAY 29	14JUL2003	29	23:00	30	6:30	7	0	0	0	0	0	0	0	0	0		
		DAY 57	11AUG2003	57	23:00	30	6:00	7	0	0	1	0	0	0	0	0	0		
		FINAL	11AUG2003	57	23:00	30	6:00	7	0	0	1	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0022001	DAY 1	28OCT2002	1	2:00	120	11:00	9	3	3	2	0	0	0	0	2	0		
		DAY 29	26NOV2002	30	0:00	120	12:00	8	3	3	1	2	0	0	0	3	0		
		DAY 57	26DEC2002	60	2:00	120	13:00	10	3	2	1	0	0	2	0	3	3		
		FINAL	26DEC2002	60	2:00	120	13:00	10	3	2	1	0	0	2	0	3	3		
PLACEBO (BIPOLAR I)	E0022004	DAY 1	28OCT2002	1	23:00	60	7:00	6	3	3	1	1	0	3	3	1	1		
		DAY 29	26NOV2002	30	22:30	45	7:00	6	3	3	2	0	0	1	1	0	1		
		DAY 57	23DEC2002	57	1:00	30	8:00	6	2	3	1	0	0	0	0	0	0		
		FINAL	23DEC2002	57	1:00	30	8:00	6	2	3	1	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0022005	DAY 1	08NOV2002	1	23:00	15	6:45	7	0	3	3	2	1	2	3	3	0	3	RESTLESS LEGS
		DAY 29	06DEC2002	29	23:00	15	7:45	9	0	3	3	2	2	2	3	1	0	3	RESTLESS LEGS
		DAY 57	03JAN2003	57	0:00	30	8:00	6	1	2	1	2	2	3	3	1	1	3	RESTLESS LEGS
		FINAL	03JAN2003	57	0:00	30	8:00	6	1	2	1	2	2	3	3	1	1	3	RESTLESS LEGS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0020017	FINAL	29APR2003	27	1	2	0						
PLACEBO (BIPOLAR I)	E0020020	DAY 1	12MAY2003	1	0	3	0						
		DAY 29	23MAY2003	12	0	3	0						
		FINAL	23MAY2003	12	0	3	0						
PLACEBO (BIPOLAR I)	E0020022	DAY 1	16JUN2003	1	0	3	1						
		DAY 29	14JUL2003	29	0	2	1						
		DAY 57	11AUG2003	57	0	1	1						
		FINAL	11AUG2003	57	0	1	1						
PLACEBO (BIPOLAR I)	E0022001	DAY 1	28OCT2002	1	2	3	0						
		DAY 29	26NOV2002	30	3	3	0						
		DAY 57	26DEC2002	60	1	3	0						
		FINAL	26DEC2002	60	1	3	0						
PLACEBO (BIPOLAR I)	E0022004	DAY 1	28OCT2002	1	2	2	1	0	0	0	0		
		DAY 29	26NOV2002	30	2	2	1	0	0	0	0		
		DAY 57	23DEC2002	57	1	3	1	0	0	0	0		
		FINAL	23DEC2002	57	1	3	1	0	0	0	0		
PLACEBO (BIPOLAR I)	E0022005	DAY 1	08NOV2002	1	2	3	1	2	0	3	1		
		DAY 29	06DEC2002	29	1	3	1						
		DAY 57	03JAN2003	57	0	3	1						
		FINAL	03JAN2003	57	0	3	1						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0022011	DAY 1	29NOV2002	1	8		2	0	1	2	1	0	2
	E0022015	DAY 1	10DEC2002	1	13		3	3	3	0	2	0	2
		DAY 29	09JAN2003	31	8	-5	1	3	0	0	2	1	1
		DAY 57	06FEB2003	59	10	-3	2	3	2	0	2	0	1
		FINAL	06FEB2003	59	10	-3	2	3	2	0	2	0	1
	E0022016	DAY 1	17DEC2002	1	11		2	2	2	0	2	1	2
		DAY 29	13JAN2003	28	14	3	2	3	2	0	2	3	2
		DAY 57	11FEB2003	57	13	2	2	3	2	1	2	1	2
		FINAL	11FEB2003	57	13	2	2	3	2	1	2	1	2
	E0022020	DAY 1	12DEC2002	1	14		2	3	1	3	2	0	3
		DAY 29	10JAN2003	30	13	-1	1	3	2	3	2	0	2
		DAY 29 *	23JAN2003	43	8	-6	1	2	1	1	1	0	2
		FINAL	23JAN2003	43	8	-6	1	2	1	1	1	0	2
	E0022023	DAY 1	24DEC2002	-1	17		3	2	1	3	2	3	3
		DAY 29	23JAN2003	30	19	2	3	3	3	3	2	2	3
		DAY 57	20FEB2003	58	17	0	3	2	3	3	3	0	3
		FINAL	20FEB2003	58	17	0	3	2	3	3	3	0	3
	E0022029	DAY 1	19FEB2003	1	10		2	0	3	2	1	0	2
		DAY 29	18MAR2003	28	9	-1	2	1	3	1	1	0	1
		DAY 57	14APR2003	55	7	-3	2	0	2	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0022011	DAY 1	29NOV2002	1	22:30	10	7:30	6	0	2	1	2	0	0	3	0	0		
PLACEBO (BIPOLAR I)	E0022015	DAY 1	10DEC2002	1	1:00	90	5:00	4	3	3	2	1	1	3	0	3	2	3	TOO MANY THOUGHTS AND WORRIES.
		DAY 29	09JAN2003	31	1:20	120	9:00	8	3	2	2	0	0	2	0	3	2		
		DAY 57	06FEB2003	59	1:00	90	6:30	5	3	3	1	1	1	2	1	3	0		
		FINAL	06FEB2003	59	1:00	90	6:30	5	3	3	1	1	1	2	1	3	0		
PLACEBO (BIPOLAR I)	E0022016	DAY 1	17DEC2002	1	4:30	35	9:30	5	2	2	1	0	0	2	2	1	3		
		DAY 29	13JAN2003	28	4:00	60	8:00	5	3	3	2	0	0	2	2	1	3		
		DAY 57	11FEB2003	57	1:00	120	7:30	5	3	3	2	0	0	1	2	1	1		
		FINAL	11FEB2003	57	1:00	120	7:30	5	3	3	2	0	0	1	2	1	1		
PLACEBO (BIPOLAR I)	E0022020	DAY 1	12DEC2002	1	2:00	60	16:00	6	3	2	3	3	0	2	1	2	2		
		DAY 29	10JAN2003	30	1:30	90	10:00	5	3	2	2	1	0	2	1	2	0		
		DAY 29 *	23JAN2003	43	1:30	60	10:00	7	2	2	2	0	0	2	2	0	1		
		FINAL	23JAN2003	43	1:30	60	10:00	7	2	2	2	0	0	2	2	0	1		
PLACEBO (BIPOLAR I)	E0022023	DAY 1	24DEC2002	-1	23:00	30	11:00	6	2	3	3	1	0	1	2	1	0	3	NOT TAKING TRAZODONE MAKES IT WORSE
		DAY 29	23JAN2003	30	23:00	200	9:00	4	3	3	3	0	0	0	2	3	3	3	"RACING THOUGHTS"
		DAY 57	20FEB2003	58	23:00	30	9:40	4	2	2	3	2	3	0	2	3	3	3	"LOTS OF DREAMING"
		FINAL	20FEB2003	58	23:00	30	9:40	4	2	2	3	2	3	0	2	3	3	3	"LOTS OF DREAMING"
PLACEBO (BIPOLAR I)	E0022029	DAY 1	19FEB2003	1	23:30	15	5:00	4	0	3	3	0	2	0	0	0	0		
		DAY 29	18MAR2003	28	23:30	15	4:30	4	1	3	3	0	0	0	0	0	0		
		DAY 57	14APR2003	55	23:30	10	5:00	5	0	3	3	0	0	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0022011	DAY 1		29NOV2002	1	2	2	3						
PLACEBO (BIPOLAR I)	E0022015	DAY 1		10DEC2002	1	1	2	0						
		DAY 29		09JAN2003	31	1	1	0						
		DAY 57		06FEB2003	59	1	1	0						
		FINAL		06FEB2003	59	1	1	0						
PLACEBO (BIPOLAR I)	E0022016	DAY 1		17DEC2002	1	0	3	3						
		DAY 29		13JAN2003	28	0	3	3						
		DAY 57		11FEB2003	57	0	3	3						
		FINAL		11FEB2003	57	0	3	3						
PLACEBO (BIPOLAR I)	E0022020	DAY 1		12DEC2002	1	2	3	3	0	0	0	0		
		DAY 29		10JAN2003	30	2	2	3	0	1	3	0	3	CRYING/MOANING
		DAY 29	*	23JAN2003	43	2	1	3	0	0	2	0		
		FINAL		23JAN2003	43	2	1	3	0	0	2	0		
PLACEBO (BIPOLAR I)	E0022023	DAY 1		24DEC2002	-1	3	3	0						
		DAY 29		23JAN2003	30	3	3	0						
		DAY 57		20FEB2003	58	2	3	3	3	3	0	0	3	STRONG DREAMING RESTLESS
		FINAL		20FEB2003	58	2	3	3	3	3	0	0	3	STRONG DREAMING RESTLESS
PLACEBO (BIPOLAR I)	E0022029	DAY 1		19FEB2003	1	1	2	1						
		DAY 29		18MAR2003	28	0	1	1						
		DAY 57		14APR2003	55	1	2	1						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0022029	FINAL	14APR2003	55	7	-3	2	0	2	0	1	0	2
	E0022041	DAY 1	18MAR2003	1	12		2	1	0	0	3	3	3
		DAY 29	15APR2003	29	7	-5	1	1	1	1	1	0	2
		DAY 57	13MAY2003	57	7	-5	1	1	1	2	1	0	1
		FINAL	13MAY2003	57	7	-5	1	1	1	2	1	0	1
	E0022042	DAY 1	12MAR2003	1	6		1	1	0	0	2	0	2
		DAY 29	10APR2003	30	11	5	2	3	1	1	2	0	2
		DAY 57	12MAY2003	62	11	5	2	3	0	1	2	1	2
		FINAL	12MAY2003	62	11	5	2	3	0	1	2	1	2
	E0022043	DAY 1	20MAR2003	1	7		1	2	1	0	2	0	1
		DAY 29	17APR2003	29	6	-1	1	1	1	0	2	0	1
		DAY 57	12MAY2003	54	7	0	1	1	2	1	2	0	0
		FINAL	12MAY2003	54	7	0	1	1	2	1	2	0	0
	E0022054	DAY 1	11APR2003	1	16		3	3	2	3	3	0	2
		DAY 29	12MAY2003	32	6	-10	1	1	1	1	1	0	1
		FINAL	12MAY2003	32	6	-10	1	1	1	1	1	0	1
	E0022059	DAY 1	06MAY2003	1	14		2	3	2	0	3	2	2
		DAY 29	03JUN2003	29	7	-7	1	2	1	0	1	0	2
		DAY 57	08JUL2003	64	11	-3	1	2	1	0	2	3	2
		FINAL	08JUL2003	64	11	-3	1	2	1	0	2	3	2
	E0022065	DAY 1	07MAY2003	1	9		2	2	1	0	3	0	1

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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0022029	FINAL	14APR2003	55	23:30	10	5:00	5	0	3	3	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0022041	DAY 1	18MAR2003	1	21:00	10	9:30	11	1	3	3	3	3	2	3	3	3	3	HUNGER
		DAY 29	15APR2003	29	22:00	10	6:00	6	2	2	2	0	1	0	0	1	1		
		DAY 57	13MAY2003	57	20:00	10	6:00	7	1	2	2	0	0	1	1	0	0		
		FINAL	13MAY2003	57	20:00	10	6:00	7	1	2	2	0	0	1	1	0	0		
PLACEBO (BIPOLAR I)	E0022042	DAY 1	12MAR2003	1	23:00	15	9:30	9	1	3	2	0	3	1	1	2	0		
		DAY 29	10APR2003	30	23:00	60	8:00	7	3	3	2	0	3	1	1	1	1		
		DAY 57	12MAY2003	62	23:00	60	9:00	8	3	3	2	0	1	1	1	1	1		
		FINAL	12MAY2003	62	23:00	60	9:00	8	3	3	2	0	1	1	1	1	1		
PLACEBO (BIPOLAR I)	E0022043	DAY 1	20MAR2003	1	23:30	60	4:15	6	1	2	3	1	1	3	1	2	1		
		DAY 29	17APR2003	29	22:00	30	4:15	6	1	1	3	0	2	3	1	1	3		
		DAY 57	12MAY2003	54	23:30	30	5:30	5	0	1	2	0	1	3	2	1	1		
		FINAL	12MAY2003	54	23:30	30	5:30	5	0	1	2	0	1	3	2	1	1		
PLACEBO (BIPOLAR I)	E0022054	DAY 1	11APR2003	1	0:00	60	10:00	5	3	3	3	0	1	3	3	2	3	3	THINKING ABOUT LIFE
		DAY 29	12MAY2003	32	22:00	15	6:00	6	2	0	3	0	0	0	3	1	0		
		FINAL	12MAY2003	32	22:00	15	6:00	6	2	0	3	0	0	0	3	1	0		
PLACEBO (BIPOLAR I)	E0022059	DAY 1	06MAY2003	1	23:00	60	1:00	5	3	3	3	3	3	3	3	3	3		
		DAY 29	03JUN2003	29	23:00	60	5:30	6	2	1	3	0	1	0	0	1	1		
		DAY 57	08JUL2003	64	22:30	45	5:00	7	2	1	3	0	1	1	1	0	3		
		FINAL	08JUL2003	64	22:30	45	5:00	7	2	1	3	0	1	1	1	0	3		
PLACEBO (BIPOLAR I)	E0022065	DAY 1	07MAY2003	1	10:00	30	16:30	6	2	3	3	1	0	2	2	3	3	3	NOISE/LIGHT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0022029	FINAL	14APR2003	55	1	2	1						
PLACEBO (BIPOLAR I)	E0022041	DAY 1	18MAR2003	1	3	3	2						
		DAY 29	15APR2003	29	0	3	2	2	0	2	0		
		DAY 57	13MAY2003	57	0	2	2	0	0	0	0		
		FINAL	13MAY2003	57	0	2	2	0	0	0	0		
PLACEBO (BIPOLAR I)	E0022042	DAY 1	12MAR2003	1	0	3	0						
		DAY 29	10APR2003	30	0	3	0						
		DAY 57	12MAY2003	62	0	3	0						
		FINAL	12MAY2003	62	0	3	0						
PLACEBO (BIPOLAR I)	E0022043	DAY 1	20MAR2003	1	0	1	3						
		DAY 29	17APR2003	29	1	0	3						
		DAY 57	12MAY2003	54	0	0	3						
		FINAL	12MAY2003	54	0	0	3						
PLACEBO (BIPOLAR I)	E0022054	DAY 1	11APR2003	1	0	3	1						
		DAY 29	12MAY2003	32	0	1	1	0	0	0	0		
		FINAL	12MAY2003	32	0	1	1	0	0	0	0		
PLACEBO (BIPOLAR I)	E0022059	DAY 1	06MAY2003	1	3	1	0						
		DAY 29	03JUN2003	29	3	0	0						
		DAY 57	08JUL2003	64	2	1	0						
		FINAL	08JUL2003	64	2	1	0						
PLACEBO (BIPOLAR I)	E0022065	DAY 1	07MAY2003	1	0	2	3						

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0022065	DAY 29	04JUN2003	29	6	-3	1	1	1	0	2	0	1
		DAY 57	02JUL2003	57	7	-2	1	1	1	1	2	0	1
		FINAL	02JUL2003	57	7	-2	1	1	1	1	2	0	1
	E0022070	DAY 1	12JUN2003	1	16		3	3	3	3	2	0	2
		DAY 29	18JUN2003	7	17	1	3	3	3	3	3	0	2
		FINAL	18JUN2003	7	17	1	3	3	3	3	3	0	2
	E0023001	DAY 1	15NOV2002	1	6		2	2	0	0	1	0	1
		DAY 29	16DEC2002	32	11	5	2	3	1	2	2	0	1
		DAY 57	14JAN2003	61	10	4	2	3	1	2	1	0	1
		FINAL	14JAN2003	61	10	4	2	3	1	2	1	0	1
	E0023009	DAY 1	11FEB2003	1	7		0	1	0	3	1	0	2
		DAY 29	11MAR2003	29	4	-3	0	2	0	0	1	0	1
		DAY 57	08APR2003	57	2	-5	0	1	0	0	1	0	0
		FINAL	08APR2003	57	2	-5	0	1	0	0	1	0	0
	E0023028	DAY 1	29MAY2003	1	9		2	2	0	2	1	0	2
		DAY 29	25JUN2003	28	1	-8	0	0	0	0	1	0	0
		DAY 57	21JUL2003	54	0	-9	0	0	0	0	0	0	0
		FINAL	21JUL2003	54	0	-9	0	0	0	0	0	0	0
	E0023033	DAY 1	05JUN2003	1	6		2	0	1	0	1	0	2
		DAY 29	12JUN2003	8	7	1	2	1	1	0	1	0	2
		FINAL	12JUN2003	8	7	1	2	1	1	0	1	0	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0022065	DAY 29	04JUN2003	29	9:30	30	16:30	6	1	3	3	0	0	0	3	1	0	2	NOISE
		DAY 57	02JUL2003	57	9:00	15	16:30	6	1	3	3	0	1	2	3	1	1	2	NOISE OUTSIDE
		FINAL	02JUL2003	57	9:00	15	16:30	6	1	3	3	0	1	2	3	1	1	2	NOISE OUTSIDE
PLACEBO (BIPOLAR I)	E0022070	DAY 1	12JUN2003	1	13:00	120	8:00	3	3	3	3	1	2	2	2	0	3		
		DAY 29	18JUN2003	7	2:00	120	11:00	4	3	3	3	3	3	2	2	0	3		
		FINAL	18JUN2003	7	2:00	120	11:00	4	3	3	3	3	3	2	2	0	3		
PLACEBO (BIPOLAR I)	E0023001	DAY 1	15NOV2002	1	1:00	25	9:30	8	2	3	2	0	1	0	0	2	0		
		DAY 29	16DEC2002	32	0:00	60	9:00	6	3	3	3	0	0	0	0	3	1		
		DAY 57	14JAN2003	61	0:00	60	9:00	6	3	3	3	1	0	0	0	1	0		
		FINAL	14JAN2003	61	0:00	60	9:00	6	3	3	3	1	0	0	0	1	0		
PLACEBO (BIPOLAR I)	E0023009	DAY 1	11FEB2003	1	11:15	25	8:00	8	0	1	1	0	0	0	2	0	0		
		DAY 29	11MAR2003	29	23:30	25	8:00	8	2	1	1	0	0	1	1	0	0		
		DAY 57	08APR2003	57	23:30	20	8:00	8	1	2	1	0	0	2	2	0	0		
		FINAL	08APR2003	57	23:30	20	8:00	8	1	2	1	0	0	2	2	0	0		
PLACEBO (BIPOLAR I)	E0023028	DAY 1	29MAY2003	1	23:00	45	10:00	8	2	2	2	0	0	0	0	0	0		
		DAY 29	25JUN2003	28	23:00	10	9:00	10	0	0	0	0	3	0	0	2	0		
		DAY 57	21JUL2003	54	22:00	15	8:00	10	0	0	0	0	0	0	0	0	0		
		FINAL	21JUL2003	54	22:00	15	8:00	10	0	0	0	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0023033	DAY 1	05JUN2003	1	1:00	10	7:30	6	0	3	0	0	0	0	1	1	0		
		DAY 29	12JUN2003	8	1:00	30	7:30	6	1	3	0	0	0	0	1	1	0		
		FINAL	12JUN2003	8	1:00	30	7:30	6	1	3	0	0	0	0	1	1	0		

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0022065	DAY 29	04JUN2003	29	0	1	3						
		DAY 57	02JUL2003	57	0	1	3						
		FINAL	02JUL2003	57	0	1	3						
PLACEBO (BIPOLAR I)	E0022070	DAY 1	12JUN2003	1	0	3	0						
		DAY 29	18JUN2003	7	1	3	0						
		FINAL	18JUN2003	7	1	3	0						
PLACEBO (BIPOLAR I)	E0023001	DAY 1	15NOV2002	1	0	2	1	0	0	0	0		
		DAY 29	16DEC2002	32	0	2	1	0	0	1	0	3	HARD TIME BEING STILL IN BED.
		DAY 57	14JAN2003	61	0	2	3	0	0	2	1		
		FINAL	14JAN2003	61	0	2	3	0	0	2	1		
PLACEBO (BIPOLAR I)	E0023009	DAY 1	11FEB2003	1	0	3	0						
		DAY 29	11MAR2003	29	0	2	0						
		DAY 57	08APR2003	57	0	0	0						
		FINAL	08APR2003	57	0	0	0						
PLACEBO (BIPOLAR I)	E0023028	DAY 1	29MAY2003	1	0	3	1	0	0	0	0		
		DAY 29	25JUN2003	28	0	0	1	3	0	0	0		
		DAY 57	21JUL2003	54	0	0	0						
		FINAL	21JUL2003	54	0	0	0						
PLACEBO (BIPOLAR I)	E0023033	DAY 1	05JUN2003	1	1	3	0						
		DAY 29	12JUN2003	8	1	3	0						
		FINAL	12JUN2003	8	1	3	0						

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0023047	DAY 1		18JUL2003	1	6		1	2	0	0	1	0	2
		DAY 29		15AUG2003	29	8	2	1	3	1	1	1	0	1
		DAY 57		12SEP2003	57	8	2	1	2	1	2	1	0	1
		FINAL		12SEP2003	57	8	2	1	2	1	2	1	0	1
	E0025001	DAY 1		01APR2003	1	14		2	3	1	1	1	3	3
		DAY 29		23APR2003	23			3	3	3	3		3	2
		FINAL		23APR2003	23			3	3	3	3		3	2
	E0026012	DAY 1		20FEB2003	1	18		2	3	3	3	3	2	2
		DAY 29		20MAR2003	29	12	-6	1	3	2	1	1	2	2
		DAY 57		17APR2003	57	8	-10	1	1	1	2	2	0	1
		FINAL		17APR2003	57	8	-10	1	1	1	2	2	0	1
	E0026020	DAY 1		01APR2003	1	15		2	3	3	3	1	0	3
		DAY 29		22APR2003	22	12	-3	1	3	1	3	2	0	2
		FINAL		22APR2003	22	12	-3	1	3	1	3	2	0	2
	E0026024	DAY 1		02MAY2003	1	15		3	3	2	0	2	3	2
		DAY 29		30MAY2003	29	8	-7	1	2	1	0	2	2	0
		FINAL		30MAY2003	29	8	-7	1	2	1	0	2	2	0
	E0026028	DAY 1		20JUN2003	1	11		2	3	2	0	3	0	1
	E0028001	DAY 1	*	20SEP2002	-20	12		3	3	3	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0023047	DAY 1	18JUL2003	1	22:00	30	8:00	9	3	3	0	0	0	3	0	2	0		
		DAY 29	15AUG2003	29	23:00	60	8:00	7	3	3	0	0	0	1	0	0	0		
		DAY 57	12SEP2003	57	23:00	6	8:30	7	3	3	0	0	0	2	0	0	0		
		FINAL	12SEP2003	57	23:00	6	8:30	7	3	3	0	0	0	2	0	0	0		
PLACEBO (BIPOLAR I)	E0025001	DAY 1	01APR2003	1	2:00	60	10:00	6	3	1	1	0	0	0	0	0	2		
		DAY 29	23APR2003	23	1:00	60	9:30	4	3		2	0	0	0	3	2	0		
		FINAL	23APR2003	23	1:00	60	9:30	4	3		2	0	0	0	3	2	0		
PLACEBO (BIPOLAR I)	E0026012	DAY 1	20FEB2003	1	22:30	45	6:00	4	3	3	3	2	0	3	2	3	3		
		DAY 29	20MAR2003	29	22:00	45	4:00	5	3	3	3	0	0	0	1	2	0		
		DAY 57	17APR2003	57	22:00	25	6:30	6	1	2	2	1	1	1	1	2	3	2	RIGHT SHOULDER PAIN
		FINAL	17APR2003	57	22:00	25	6:30	6	1	2	2	1	1	1	1	2	3	2	RIGHT SHOULDER PAIN
PLACEBO (BIPOLAR I)	E0026020	DAY 1	01APR2003	1	21:00	120	4:00	4	3	3	3	0	0	0	0	3	0		
		DAY 29	22APR2003	22	21:00	45	8:00	7	3	3	3	1	3	0	0	3	0		
		FINAL	22APR2003	22	21:00	45	8:00	7	3	3	3	1	3	0	0	3	0		
PLACEBO (BIPOLAR I)	E0026024	DAY 1	02MAY2003	1	23:30	60	4:30	5	3	3	3	0	0	2	2	3	0		
		DAY 29	30MAY2003	29	23:00	30	5:00	6	3	2	2	0	3	1	1	0	2		
		FINAL	30MAY2003	29	23:00	30	5:00	6	3	2	2	0	3	1	1	0	2		
PLACEBO (BIPOLAR I)	E0026028	DAY 1	20JUN2003	1	2:00	100	6:30	5	3	3	3	2	3	1	3	3	1		
PLACEBO (BIPOLAR I)	E0028001	DAY 1 *	20SEP2002	-20	3:00	60	7:00	4	3	3	2	0	0	0	1	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0023047	DAY 1	18JUL2003	1	0	3	3	0	0	0	3		
		DAY 29	15AUG2003	29	0	2	3	0	0	0	2		
		DAY 57	12SEP2003	57	0	1	3	0	0	0	1		
		FINAL	12SEP2003	57	0	1	3	0	0	0	1		
PLACEBO (BIPOLAR I)	E0025001	DAY 1	01APR2003	1	2	3	0						
		DAY 29	23APR2003	23	1	3	0						
		FINAL	23APR2003	23	1	3	0						
PLACEBO (BIPOLAR I)	E0026012	DAY 1	20FEB2003	1	2	2	3	0	0	0	2		
		DAY 29	20MAR2003	29	2	1	1	0	0	1	2		
		DAY 57	17APR2003	57	1	1	3	0	0	2	0		
		FINAL	17APR2003	57	1	1	3	0	0	2	0		
PLACEBO (BIPOLAR I)	E0026020	DAY 1	01APR2003	1	3	3	1	0	0	2	0		
		DAY 29	22APR2003	22	0	3	1	3	0	0	0		
		FINAL	22APR2003	22	0	3	1	3	0	0	0		
PLACEBO (BIPOLAR I)	E0026024	DAY 1	02MAY2003	1	0	3	0						
		DAY 29	30MAY2003	29	0	0	0						
		FINAL	30MAY2003	29	0	0	0						
PLACEBO (BIPOLAR I)	E0026028	DAY 1	20JUN2003	1	0	2	1	2	2	0	2		
PLACEBO (BIPOLAR I)	E0028001	DAY 1 *	20SEP2002	-20	1	3	1						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0028001	DAY 1	10OCT2002	1	11		2	2	3	1	1	0	2
		DAY 29	05NOV2002	27	9	-2	2	2	3	0	1	0	1
		DAY 57	03DEC2002	55	10	-1	2	2	3	0	1	0	2
		FINAL	03DEC2002	55	10	-1	2	2	3	0	1	0	2
	E0028003	DAY 1	23SEP2002	-7	5		1	1	0	0	2	0	1
		DAY 29	29OCT2002	30	7	2	1	1	1	0	2	0	2
		DAY 57	26NOV2002	58	9	4	2	2	1	0	2	0	2
		FINAL	26NOV2002	58	9	4	2	2	1	0	2	0	2
	E0028005	DAY 1	30SEP2002	-3	5		2	0	0	0	1	0	2
		DAY 29	31OCT2002	29	6	1	2	0	0	1	1	0	2
		FINAL	31OCT2002	29	6	1	2	0	0	1	1	0	2
	E0028010	DAY 1 *	15OCT2002	-21	15		3	3	3	3	2	0	1
		DAY 1	05NOV2002	1	14		2	3	2	2	2	2	1
		DAY 29	03DEC2002	29	13	-1	2	3	2	2	1	2	1
		DAY 57	31DEC2002	57	9	-5	2	3	1	0	1	1	1
		FINAL	31DEC2002	57	9	-5	2	3	1	0	1	1	1
	E0028011	DAY 1	05DEC2002	1	11		2	2	2	3	1	0	1
		DAY 29	02JAN2003	29	6	-5	1	2	1	0	1	0	1
		DAY 57	30JAN2003	57	5	-6	1	2	1	0	1	0	0
		FINAL	30JAN2003	57	5	-6	1	2	1	0	1	0	0
	E0028030	DAY 1	04MAR2003	1	15		2	3	3	3	1	0	3
		DAY 29	01APR2003	29	9	-6	2	1	0	1	1	1	3
		DAY 57	30APR2003	58	11	-4	2	2	1	3	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0028001	DAY 1		10OCT2002	1	3:00	30	7:00	3	3	3	2	0	0	0	0	2	0		
		DAY 29		05NOV2002	27	0:00	30	4:30	4	2	3	2	0	0	0	1	1	1		
		DAY 57		03DEC2002	55	0:00	30	4:30	4	2	3	2	0	0	0	0	0	2		
		FINAL		03DEC2002	55	0:00	30	4:30	4	2	3	2	0	0	0	0	0	2		
PLACEBO (BIPOLAR I)	E0028003	DAY 1		23SEP2002	-7	0:00	10	9:30	10	1	1	1	0	3	1	3	1	1		
		DAY 29		29OCT2002	30	0:00	15	8:00	7	1	3	2	3	3	2	2	0	0		
		DAY 57		26NOV2002	58	0:00	30	7:00	6	2	3	3	3	0	2	2	1	0		
		FINAL		26NOV2002	58	0:00	30	7:00	6	2	3	3	3	0	2	2	1	0		
PLACEBO (BIPOLAR I)	E0028005	DAY 1		30SEP2002	-3	23:00	10	8:30	9	0	3	0	0	0	0	0	3	1		
		DAY 29		31OCT2002	29	23:00	10	9:00	8	0	3	1	0	0	0	0	3	0		
		FINAL		31OCT2002	29	23:00	10	9:00	8	0	3	1	0	0	0	0	3	0		
PLACEBO (BIPOLAR I)	E0028010	DAY 1	*	15OCT2002	-21	2:00	180	11:00	4	3	3	3	0	0	3	3	3	0	3	THOUGHTS RUNNING THROUGH MY HEAD
		DAY 1		05NOV2002	1	1:00	105	8:30	5	3	3	3	0	0	1	1	3	0		
		DAY 29		03DEC2002	29	1:00	90	8:30	5	3	3	3	0	0	0	0	3	0		
		DAY 57		31DEC2002	57	2:00	105	9:00	6	3	3	3	0	0	0	0	3	0		
		FINAL		31DEC2002	57	2:00	105	9:00	6	3	3	3	0	0	0	0	3	0		
PLACEBO (BIPOLAR I)	E0028011	DAY 1		05DEC2002	1	20:00	45	5:00	5	2	2	1	0	0	1	0	0	1		
		DAY 29		02JAN2003	29	22:00	60	5:00	6	2	2	2	0	0	1	0	1	1		
		DAY 57		30JAN2003	57	22:00	20	6:00	7	2	1	2	0	0	0	0	0	0		
		FINAL		30JAN2003	57	22:00	20	6:00	7	2	1	2	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0028030	DAY 1		04MAR2003	1	5:30	45	13:30	4	3	3	0	0	0	0	0	0	0		
		DAY 29		01APR2003	29	3:00	20	13:00	8	0	3	0	0	0	1	1	1	1		
		DAY 57		30APR2003	58	2:00	45	1:00	6	2	3	0	0	0	0	2	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0028001	DAY 1		10OCT2002	1	0	3	1						
		DAY 29		05NOV2002	27	0	2	1						
		DAY 57		03DEC2002	55	0	3	1						
		FINAL		03DEC2002	55	0	3	1						
PLACEBO (BIPOLAR I)	E0028003	DAY 1		23SEP2002	-7	0	2	0						
		DAY 29		29OCT2002	30	0	3	0						
		DAY 57		26NOV2002	58	0	3	0						
		FINAL		26NOV2002	58	0	3	0						
PLACEBO (BIPOLAR I)	E0028005	DAY 1		30SEP2002	-3	0	3	2	2	0	0	0		
		DAY 29		31OCT2002	29	0	3	3	0	0	0	0		
		FINAL		31OCT2002	29	0	3	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0028010	DAY 1	*	15OCT2002	-21	0	2	0						
		DAY 1		05NOV2002	1	0	1	3	1	3	0	0		
		DAY 29		03DEC2002	29	0	1	0						
		DAY 57		31DEC2002	57	0	1	0						
		FINAL		31DEC2002	57	0	1	0						
PLACEBO (BIPOLAR I)	E0028011	DAY 1		05DEC2002	1	1	1	0						
		DAY 29		02JAN2003	29	0	1	0						
		DAY 57		30JAN2003	57	0	0	0						
		FINAL		30JAN2003	57	0	0	0						
PLACEBO (BIPOLAR I)	E0028030	DAY 1		04MAR2003	1	2	3	1						
		DAY 29		01APR2003	29	2	3	0						
		DAY 57		30APR2003	58	1	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0028030	FINAL	30APR2003	58	11	-4	2	2	1	3	1	0	2
	E0028031	DAY 1	11MAR2003	1	13		2	3	2	1	2	0	3
	E0028047	DAY 1	14JUL2003	1			2				2	0	3
		DAY 29	12AUG2003	30	13		2	3	2	3	2	0	1
		DAY 57	09SEP2003	58	14		2	2	3	2	1	3	1
		FINAL	09SEP2003	58	14		2	2	3	2	1	3	1
	E0029001	DAY 1	24SEP2002	-7	8		3	0	3	0	1	1	0
	E0029014	DAY 1	04FEB2003	1	11		2	2	1	2	1	1	2
		DAY 29	06MAR2003	31	5	-6	1	0	1	1	1	0	1
		DAY 57	01APR2003	57	9	-2	2	2	1	2	1	0	1
		FINAL	01APR2003	57	9	-2	2	2	1	2	1	0	1
	E0029023	DAY 1	08APR2003	1	13		2	3	0	2	2	2	2
		DAY 29	12MAY2003	35	9	-4	2	2	0	0	1	2	2
		FINAL	12MAY2003	35	9	-4	2	2	0	0	1	2	2
	E0029032	DAY 1	10JUN2003	1	13		3	3	2	0	3	0	2
		DAY 29	01JUL2003	22	15	2	3	3	3	0	3	0	3
		FINAL	01JUL2003	22	15	2	3	3	3	0	3	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
PLACEBO (BIPOLAR I)	E0028030	FINAL	30APR2003	58	2:00	45	1:00	6	2	3	0	0	0	0	2	1	0	
PLACEBO (BIPOLAR I)	E0028031	DAY 1	11MAR2003	1	23:00	60	5:30	5	3	3	3	2	3	0	2	3	0	
PLACEBO (BIPOLAR I)	E0028047	DAY 1	14JUL2003	1					3	3	3	0	0	3	3	2	0	
		DAY 29	12AUG2003	30	22:00	150	6:00	5	3	3	3	1	0	1	3	1	3	
		DAY 57	09SEP2003	58	23:00	180	5:00	4	0	3	3	1	0	0	2	0	0	
		FINAL	09SEP2003	58	23:00	180	5:00	4	0	3	3	1	0	0	2	0	0	
PLACEBO (BIPOLAR I)	E0029001	DAY 1	24SEP2002	-7	2:00	10	5:30	3	0	3	0	0	0	0	0	0	0	
PLACEBO (BIPOLAR I)	E0029014	DAY 1	04FEB2003	1	23:00	30	8:00	6	2	3	0	0	0	0	0	0	1	
		DAY 29	06MAR2003	31	22:30	15	7:15	7	0	2	1	0	0	0	0	0	0	
		DAY 57	01APR2003	57	22:30	25	7:30	6	2	3	3	0	0	0	0	0	0	
		FINAL	01APR2003	57	22:30	25	7:30	6	2	3	3	0	0	0	0	0	0	
PLACEBO (BIPOLAR I)	E0029023	DAY 1	08APR2003	1	2:00	60	16:00	10	3	3	3	0	0	1	1	2	0	
		DAY 29	12MAY2003	35	3:00	30	12:00	9	3	0	3	0	0	1	1	0	0	
		FINAL	12MAY2003	35	3:00	30	12:00	9	3	0	3	0	0	1	1	0	0	
PLACEBO (BIPOLAR I)	E0029032	DAY 1	10JUN2003	1	3:00	60	6:00	5	3	3	2	2	3	2	1	3	3	
		DAY 29	01JUL2003	22	3:00	60	6:30	3	3	3	2	3	2	3	3	3	3	
		FINAL	01JUL2003	22	3:00	60	6:30	3	3	3	2	3	2	3	3	3	3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0028030	FINAL	30APR2003	58	1	3	0						
PLACEBO (BIPOLAR I)	E0028031	DAY 1	11MAR2003	1	3	2	1	3	3	0	0		
PLACEBO (BIPOLAR I)	E0028047	DAY 1	14JUL2003	1	2	3	0						
		DAY 29	12AUG2003	30	0	2	0						
		DAY 57	09SEP2003	58	0	2	0						
		FINAL	09SEP2003	58	0	2	0						
PLACEBO (BIPOLAR I)	E0029001	DAY 1	24SEP2002	-7	0	0	0						
PLACEBO (BIPOLAR I)	E0029014	DAY 1	04FEB2003	1	1	3	3	0	0	0	0		
		DAY 29	06MAR2003	31	0	1	3	0	0	0	0		
		DAY 57	01APR2003	57	0	2	3	0	0	0	0	3	FINGERS FIDGET IN BED - EVEN WHILE ASLEEP
		FINAL	01APR2003	57	0	2	3	0	0	0	0	3	FINGERS FIDGET IN BED - EVEN WHILE ASLEEP
PLACEBO (BIPOLAR I)	E0029023	DAY 1	08APR2003	1	0	3	0						
		DAY 29	12MAY2003	35	0	3	0						
		FINAL	12MAY2003	35	0	3	0						
PLACEBO (BIPOLAR I)	E0029032	DAY 1	10JUN2003	1	1	3	3	1	2	3	3		
		DAY 29	01JUL2003	22	3	3	3	2	3	3	3		
		FINAL	01JUL2003	22	3	3	3	2	3	3	3		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0029033	DAY 1	02JUN2003	1	18		3	3	3	3	1	3	2
		DAY 29	30JUN2003	29	16	-2	3	3	3	3	1	1	2
		FINAL	30JUN2003	29	16	-2	3	3	3	3	1	1	2
	E0029039	DAY 1	15JUL2003	1	15		3	3	2	3	2	0	2
		DAY 29	28JUL2003	14	16	1	3	3	3	3	2	0	2
		FINAL	28JUL2003	14	16	1	3	3	3	3	2	0	2
	E0030003	DAY 1	16DEC2002	1	12		2	3	3	1	2	0	1
		DAY 29	24DEC2002	9	11	-1	2	3	2	1	2	0	1
		FINAL	24DEC2002	9	11	-1	2	3	2	1	2	0	1
	E0030009	DAY 1	23JAN2003	1	14		2	1	3	3	2	0	3
		DAY 57	19MAR2003	56	13	-1	3	3	2	1	2	0	2
		FINAL	19MAR2003	56	13	-1	3	3	2	1	2	0	2
	E0030016	DAY 1	03MAR2003	1	13		2	3	2	1	2	0	3
		DAY 29	02APR2003	31	12	-1	2	2	2	1	2	0	3
		DAY 57	22APR2003	51	9	-4	2	1	1	0	2	0	3
		FINAL	22APR2003	51	9	-4	2	1	1	0	2	0	3
	E0030021	DAY 1	20MAY2003	1	9		3	0	0	0	2	2	2
		DAY 29	17JUN2003	29	5	-4	1	1	0	0	1	0	2
		FINAL	17JUN2003	29	5	-4	1	1	0	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0029033	DAY 1	02JUN2003	1	22:00	120	4:30	3	3	3	0	0	0	0	0	0	3		
		DAY 29	30JUN2003	29	22:30	180	4:30	2	3	3	0	0	0	0	0	0	3		
		FINAL	30JUN2003	29	22:30	180	4:30	2	3	3	0	0	0	0	0	0	3		
PLACEBO (BIPOLAR I)	E0029039	DAY 1	15JUL2003	1	21:00	60	8:00	5	3	3	2	0	0	0	0	3	3		
		DAY 29	28JUL2003	14	22:00	120	5:30	4	3	3	3	2	0	0	0	3	2		
		FINAL	28JUL2003	14	22:00	120	5:30	4	3	3	3	2	0	0	0	3	2		
PLACEBO (BIPOLAR I)	E0030003	DAY 1	16DEC2002	1	22:00	60	3:00	4	3	3	3	1	1	1	2	2	1		
		DAY 29	24DEC2002	9	22:00	90	4:00	5	3	3	2	1	1	1	1	1	1		
		FINAL	24DEC2002	9	22:00	90	4:00	5	3	3	2	1	1	1	1	1	1		
PLACEBO (BIPOLAR I)	E0030009	DAY 1	23JAN2003	1	0:00	15	7:00	4	2	3	3	0	0	2	0	2	2	3	WAKE UP (2:30 OR 3:00 AM) VERY DIFFICULT TO RETURN TO SLEEP - LAY AWAKE
		DAY 57	19MAR2003	56	23:30	45	5:30	5	3	3	3	1	0	0	0	2	3		
		FINAL	19MAR2003	56	23:30	45	5:30	5	3	3	3	1	0	0	0	2	3		
PLACEBO (BIPOLAR I)	E0030016	DAY 1	03MAR2003	1	23:00	60	5:00	5	3	3	3	1	3	3	0	1	0		
		DAY 29	02APR2003	31	23:00	30	5:00	5	3	2	2	0	3	2	1	1	0	2	ANXIETY
		DAY 57	22APR2003	51	22:00	15	5:30	7	2	3	3	0	3	3	1	1	0		
		FINAL	22APR2003	51	22:00	15	5:30	7	2	3	3	0	3	3	1	1	0		
PLACEBO (BIPOLAR I)	E0030021	DAY 1	20MAY2003	1	22:00	0	6:00	8	0	1	0	2	1	1	2	1	1	2	RESTLESS SOMETIMES WEAK
		DAY 29	17JUN2003	29	22:00	30	7:00	8	0	1	1	0	0	0	0	1	0		
		FINAL	17JUN2003	29	22:00	30	7:00	8	0	1	1	0	0	0	0	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0029033	DAY 1	02JUN2003	1	0	3	3	0	0	0	0		
		DAY 29	30JUN2003	29	0	3	3	0	0	0	0		
		FINAL	30JUN2003	29	0	3	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0029039	DAY 1	15JUL2003	1	0	3	3	0	0	2	1		
		DAY 29	28JUL2003	14	0	3	3	0	2	3	3		
		FINAL	28JUL2003	14	0	3	3	0	2	3	3		
PLACEBO (BIPOLAR I)	E0030003	DAY 1	16DEC2002	1	0	2	3	0	0	1	0		
		DAY 29	24DEC2002	9	0	2	3	0	0	0	0		
		FINAL	24DEC2002	9	0	2	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0030009	DAY 1	23JAN2003	1	3	3	0						
		DAY 57	19MAR2003	56	1	3	0						
		FINAL	19MAR2003	56	1	3	0						
PLACEBO (BIPOLAR I)	E0030016	DAY 1	03MAR2003	1	2	3	0						
		DAY 29	02APR2003	31	2	3	0						
		DAY 57	22APR2003	51	2	3	0						
		FINAL	22APR2003	51	2	3	0						
PLACEBO (BIPOLAR I)	E0030021	DAY 1	20MAY2003	1	1	2	1	0	0	1	2		
		DAY 29	17JUN2003	29	1	2	0						
		FINAL	17JUN2003	29	1	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0031001	DAY 1	21NOV2002	1	13		3	3	3	0	2	0	2
		DAY 29	20DEC2002	30	9	-4	1	2	1	2	1	0	2
		FINAL	20DEC2002	30	9	-4	1	2	1	2	1	0	2
	E0031017	DAY 1	01APR2003	1	13		2	1	2	3	2	0	3
		DAY 29	29APR2003	29	9	-4	2	1	1	1	2	0	2
		FINAL	29APR2003	29	9	-4	2	1	1	1	2	0	2
	E0031018	DAY 1	10APR2003	1	3		0	2	0	0	1	0	0
	E0031023	DAY 1	29APR2003	1	11		2	3	0	2	2	0	2
		DAY 29	27MAY2003	29	6	-5	2	1	0	0	2	0	1
		DAY 57	24JUN2003	57	9	-2	2	3	1	1	1	0	1
		FINAL	24JUN2003	57	9	-2	2	3	1	1	1	0	1
	E0033001	DAY 1	09JAN2003	1	14		2	3	3	0	3	0	3
		DAY 29	30JAN2003	22	15	1	3	3	3	0	3	0	3
		FINAL	30JAN2003	22	15	1	3	3	3	0	3	0	3
	E0033004	DAY 1	17JAN2003	1	14		3	1	2	3	3	0	2
		DAY 29	14FEB2003	29	3	-11	0	0	1	0	1	0	1
		DAY 57	14MAR2003	57	3	-11	0	1	0	0	1	0	1
		FINAL	14MAR2003	57	3	-11	0	1	0	0	1	0	1
	E0033010	DAY 1	04FEB2003	1	9		2	3	0	0	2	0	2
		DAY 29	04MAR2003	29	7	-2	1	3	0	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0031001	DAY 1	21NOV2002	1	23:30	60	3:00	4	3	3	0	0	0	0	0	2	3	3	CHRONIC PAIN
		DAY 29	20DEC2002	30	1:00	45	9:30	6	2	1	1	0	0	0	0	1	2		
		FINAL	20DEC2002	30	1:00	45	9:30	6	2	1	1	0	0	0	0	1	2		
PLACEBO (BIPOLAR I)	E0031017	DAY 1	01APR2003	1	23:50	20	8:50	5	1	3	3	0	0	0	1	0	0	3	THINKING
		DAY 29	29APR2003	29	23:00	15	8:00	7	1	3	3	0	3	1	3	0	0		
		FINAL	29APR2003	29	23:00	15	8:00	7	1	3	3	0	3	1	3	0	0		
PLACEBO (BIPOLAR I)	E0031018	DAY 1	10APR2003	1	21:00	30	5:30	8	2	1	2	0	0	0	0	1	0		
PLACEBO (BIPOLAR I)	E0031023	DAY 1	29APR2003	1	23:00	240	11:00	8	3	2	2	2	2	3	3	3	1		
		DAY 29	27MAY2003	29	2:00	60	11:00	10	0	2	3	0	0	1	1	2	2		
		DAY 57	24JUN2003	57	2:00	120	10:30	7	3	0	2	0	0	0	0	3	0		
		FINAL	24JUN2003	57	2:00	120	10:30	7	3	0	2	0	0	0	0	3	0		
PLACEBO (BIPOLAR I)	E0033001	DAY 1	09JAN2003	1	0:00	120	3:00	3	3	3	3	3	2	3	3	3	3	3	ALLERGY; HAY FEVER
		DAY 29	30JAN2003	22	2:00	60	4:00	2	3	3	3	3	3	3	3	2	3	3	ALLERGIES
		FINAL	30JAN2003	22	2:00	60	4:00	2	3	3	3	3	3	3	3	2	3	3	ALLERGIES
PLACEBO (BIPOLAR I)	E0033004	DAY 1	17JAN2003	1	2:00	15	10:00	5	2	3	2	2	3	1	3	2	3		
		DAY 29	14FEB2003	29	0:00	10	7:30	7	0	0	0	0	0	0	0	1	0		
		DAY 57	14MAR2003	57	1:00	15	9:30	8	1	0	0	0	0	0	0	1	0		
		FINAL	14MAR2003	57	1:00	15	9:30	8	1	0	0	0	0	0	0	1	0		
PLACEBO (BIPOLAR I)	E0033010	DAY 1	04FEB2003	1	1:00	45	10:00	8	3	2	2	0	3	1	1	1	0		
		DAY 29	04MAR2003	29	0:00	45	9:00	8	3	2	2	0	0	1	1	2	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0031001	DAY 1	21NOV2002	1	0	3	3	0	0	0	0	3	LEG INJURY
		DAY 29	20DEC2002	30	0	3	1	0	0	0	0		
		FINAL	20DEC2002	30	0	3	1	0	0	0	0		
PLACEBO (BIPOLAR I)	E0031017	DAY 1	01APR2003	1	2	3	0						
		DAY 29	29APR2003	29	1	3	0						
		FINAL	29APR2003	29	1	3	0						
PLACEBO (BIPOLAR I)	E0031018	DAY 1	10APR2003	1	0	0	3	0	0	1	0		
PLACEBO (BIPOLAR I)	E0031023	DAY 1	29APR2003	1	0	3	3	1	0	0	0	3	TOSSING AND TURNING, NIGHTMARES
		DAY 29	27MAY2003	29	0	2	3	0	0	0	0		
		DAY 57	24JUN2003	57	0	1	3	0	0	0	0		
		FINAL	24JUN2003	57	0	1	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0033001	DAY 1	09JAN2003	1	3	3	0						
		DAY 29	30JAN2003	22	2	3	0						
		FINAL	30JAN2003	22	2	3	0						
PLACEBO (BIPOLAR I)	E0033004	DAY 1	17JAN2003	1	0	3	3	3	3	3	3		
		DAY 29	14FEB2003	29	0	1	3	1	0	0	0		
		DAY 57	14MAR2003	57	0	2	3	1	0	0	0		
		FINAL	14MAR2003	57	0	2	3	1	0	0	0		
PLACEBO (BIPOLAR I)	E0033010	DAY 1	04FEB2003	1	1	3	0						
		DAY 29	04MAR2003	29	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0033010	FINAL	04MAR2003	29	7	-2	1	3	0	0	1	0	2
	E0033014	DAY 1	19MAR2003	1	11		2	2	1	2	2	0	2
		DAY 29	16APR2003	29	6	-5	1	1	0	0	2	0	2
		FINAL	16APR2003	29	6	-5	1	1	0	0	2	0	2
	E0035002	DAY 1	21NOV2002	1	12		2	3	1	0	2	1	3
	E0035007	DAY 1	19DEC2002	1	11		2	2	2	3	1	0	1
		DAY 29	17JAN2003	30	7	-4	1	1	1	2	1	0	1
		DAY 57	11FEB2003	55	4	-7	2	1	0	0	1	0	0
		FINAL	11FEB2003	55	4	-7	2	1	0	0	1	0	0
	E0035011	DAY 1	04FEB2003	1	13		2	3	2	3	1	0	2
		DAY 29	04MAR2003	29	9	-4	1	2	1	3	1	0	1
		DAY 57	01APR2003	57	10	-3	1	2	2	3	1	0	1
		FINAL	01APR2003	57	10	-3	1	2	2	3	1	0	1
	E0035020	DAY 1	18APR2003	1	8		1	1	0	2	1	3	0
		DAY 29	15MAY2003	28	6	-2	1	2	1	1	1	0	0
		DAY 57	13JUN2003	57	7	-1	1	3	1	1	1	0	0
		FINAL	13JUN2003	57	7	-1	1	3	1	1	1	0	0
	E0037003	DAY 1	30JAN2003	1	15		2	3	3	0	2	3	2
		DAY 29	20FEB2003	22	17	2	2	3	2	1	3	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0033010	FINAL	04MAR2003	29	0:00	45	9:00	8	3	2	2	0	0	1	1	2	1		
PLACEBO (BIPOLAR I)	E0033014	DAY 1	19MAR2003	1	22:30	30	7:00	6	3	3	3	3	3	1	1	0	1		
		DAY 29	16APR2003	29	22:00	20	8:00	9	0	2	3	2	3	0	0	1	2		
		FINAL	16APR2003	29	22:00	20	8:00	9	0	2	3	2	3	0	0	1	2		
PLACEBO (BIPOLAR I)	E0035002	DAY 1	21NOV2002	1	22:00	45	4:00	6	3	3	2	1	0	2	2	3	1		
PLACEBO (BIPOLAR I)	E0035007	DAY 1	19DEC2002	1	22:00	30	7:30	5	2	3	2	0	0	0	0	2	2		
		DAY 29	17JAN2003	30	22:00	15	7:00	6	1	2	2	0	0	0	0	3	0		
		DAY 57	11FEB2003	55	22:00	20	7:00	9	0	3	1	0	0	0	0	0	0		
		FINAL	11FEB2003	55	22:00	20	7:00	9	0	3	1	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0035011	DAY 1	04FEB2003	1	23:00	60	10:30	5	3	3	0	0	0	3	3	0	0		
		DAY 29	04MAR2003	29	21:00	20	10:00	7	2	3	0	0	0	0	2	0	0		
		DAY 57	01APR2003	57	21:00	30	6:30	5	2	3	0	0	0	1	1	0	0		
		FINAL	01APR2003	57	21:00	30	6:30	5	2	3	0	0	0	1	1	0	0		
PLACEBO (BIPOLAR I)	E0035020	DAY 1	18APR2003	1	20:00	30	7:30	8	0	2	2	0	0	0	2	0	3		
		DAY 29	15MAY2003	28	23:00	30	6:30	6	3	1	2	0	0	0	2	0	2		
		DAY 57	13JUN2003	57	23:00	40	7:00	6	3	3	3	0	0	0	0	0	1		
		FINAL	13JUN2003	57	23:00	40	7:00	6	3	3	3	0	0	0	0	0	1		
PLACEBO (BIPOLAR I)	E0037003	DAY 1	30JAN2003	1	22:00	120	2:00	4	3	3	3	2	0	2	2	3	3		
		DAY 29	20FEB2003	22	22:00	60	4:30	5	3	3	3	2	0	0	3	3	3	3	RHEUMATOID ARTHRITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0033010	FINAL	04MAR2003	29	0	3	0						
PLACEBO (BIPOLAR I)	E0033014	DAY 1	19MAR2003	1	1	2	0						
		DAY 29	16APR2003	29	2	1	0						
		FINAL	16APR2003	29	2	1	0						
PLACEBO (BIPOLAR I)	E0035002	DAY 1	21NOV2002	1	2	3	3	0	0	0	1		
PLACEBO (BIPOLAR I)	E0035007	DAY 1	19DEC2002	1	0	2	3	0	0	2	0		
		DAY 29	17JAN2003	30	0	2	3	0	0	2	0		
		DAY 57	11FEB2003	55	0	0	3	0	0	2	0		
		FINAL	11FEB2003	55	0	0	3	0	0	2	0		
PLACEBO (BIPOLAR I)	E0035011	DAY 1	04FEB2003	1	2	2	0						
		DAY 29	04MAR2003	29	0	2	0						
		DAY 57	01APR2003	57	1	0	0						
		FINAL	01APR2003	57	1	0	0						
PLACEBO (BIPOLAR I)	E0035020	DAY 1	18APR2003	1	0	0	0						
		DAY 29	15MAY2003	28	0	0	0						
		DAY 57	13JUN2003	57	0	0	0						
		FINAL	13JUN2003	57	0	0	0						
PLACEBO (BIPOLAR I)	E0037003	DAY 1	30JAN2003	1	2	2	3	0	0	0	0	3	CANNOT SLEEP
		DAY 29	20FEB2003	22	2	3	3	0	0	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0037003	FINAL	20FEB2003	22	17	2	2	3	2	1	3	3	3
	E0037004	DAY 1	13FEB2003	1	8		2	3	0	0	1	0	2
		DAY 29	13MAR2003	29	5	-3	1	1	0	0	1	0	2
		DAY 57	10APR2003	57	4	-4	1	1	0	0	1	0	1
		FINAL	10APR2003	57	4	-4	1	1	0	0	1	0	1
	E0039007	DAY 1	04DEC2002	1	9		2	1	0	1	2	0	3
		DAY 29	30DEC2002	27	5	-4	2	0	0	0	1	0	2
		DAY 57	29JAN2003	57	4	-5	1	0	0	0	1	0	2
		FINAL	29JAN2003	57	4	-5	1	0	0	0	1	0	2
	E0039022	DAY 1	25FEB2003	1	12		2	1	2	2	3	0	2
		DAY 29	25MAR2003	29	7	-5	1	0	1	1	2	0	2
		DAY 57	24APR2003	59	11	-1	2	1	2	3	2	0	1
		FINAL	24APR2003	59	11	-1	2	1	2	3	2	0	1
	E0039023	DAY 1	24FEB2003	1	15		3	3	3	3	2	0	1
	E0039030	DAY 1	24MAR2003	1	9		3	3	0	0	1	0	2
		DAY 29	21APR2003	29	5	-4	0	1	1	1	1	0	1
		DAY 57	19MAY2003	57	4	-5	1	2	0	0	1	0	0
		FINAL	19MAY2003	57	4	-5	1	2	0	0	1	0	0
	E0039031	DAY 1	24MAR2003	1	12		1	2	2	3	1	2	1
		DAY 29	21APR2003	29	7	-5	1	1	1	1	1	0	2
		DAY 57	20MAY2003	58	6	-6	1	1	1	1	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0037003	FINAL	20FEB2003	22	22:00	60	4:30	5	3	3	3	2	0	0	3	3	3	3	RHEUMATOID ARTHRITIS
PLACEBO (BIPOLAR I)	E0037004	DAY 1	13FEB2003	1	0:30	90	9:30	8	3	1	0	0	0	0	1	2	0	2	ANXIETY
		DAY 29	13MAR2003	29	0:00	10	7:30	8	2	1	1	0	0	0	1	1	0		
		DAY 57	10APR2003	57	0:00	10	7:30	8	2	1	1	0	0	0	1	0	0		
		FINAL	10APR2003	57	0:00	10	7:30	8	2	1	1	0	0	0	1	0	0		
PLACEBO (BIPOLAR I)	E0039007	DAY 1	04DEC2002	1	21:00	15	7:00	8	2	3	0	0	0	2	2	3	0	3	STRESSING
		DAY 29	30DEC2002	27	22:30	10	7:00	8	0	3	0	0	0	0	0	2	1		
		DAY 57	29JAN2003	57	23:00	10	11:00	12	0	0	0	0	0	0	0	2	0		
		FINAL	29JAN2003	57	23:00	10	11:00	12	0	0	0	0	0	0	0	2	0		
PLACEBO (BIPOLAR I)	E0039022	DAY 1	25FEB2003	1	0:00	15	7:00	5	1	3	3	2	3	3	2	2	3		
		DAY 29	25MAR2003	29	23:00	5	7:00	6	0	3	3	0	1	2	3	2	2	2	CAT WHINING
		DAY 57	24APR2003	59	21:00	15	6:30	5	2	3	3	2	2	2	3	0	0		
		FINAL	24APR2003	59	21:00	15	6:30	5	2	3	3	2	2	2	3	0	0		
PLACEBO (BIPOLAR I)	E0039023	DAY 1	24FEB2003	1	3:00	60	11:00	3	3	3	1	0	3	0	0	1	3		
PLACEBO (BIPOLAR I)	E0039030	DAY 1	24MAR2003	1	0:00	120	13:00	12	3	0	0	1	0	2	0	3	3		
		DAY 29	21APR2003	29	23:00	60	8:00	7	0	0	1	0	0	0	0	1	0		
		DAY 57	19MAY2003	57	23:00	60	7:00	8	1	0	0	0	0	1	0	0	1		
		FINAL	19MAY2003	57	23:00	60	7:00	8	1	0	0	0	0	1	0	0	1		
PLACEBO (BIPOLAR I)	E0039031	DAY 1	24MAR2003	1	23:00	30	7:50	5	3	2	2	0	0	1	2	2	0		
		DAY 29	21APR2003	29	23:00	15	7:50	7	2	1	1	0	1	0	2	0	0		
		DAY 57	20MAY2003	58	23:00	15	7:50	7	1	2	2	1	1	0	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0037003	FINAL	20FEB2003	22	2	3	3	0	0	0	0		
PLACEBO (BIPOLAR I)	E0037004	DAY 1	13FEB2003	1	0	3	0						
		DAY 29	13MAR2003	29	1	2	0						
		DAY 57	10APR2003	57	0	1	0						
		FINAL	10APR2003	57	0	1	0						
PLACEBO (BIPOLAR I)	E0039007	DAY 1	04DEC2002	1	3	3	0						
		DAY 29	30DEC2002	27	0	3	0						
		DAY 57	29JAN2003	57	0	3	0						
		FINAL	29JAN2003	57	0	3	0						
PLACEBO (BIPOLAR I)	E0039022	DAY 1	25FEB2003	1	1	3	3						
		DAY 29	25MAR2003	29	1	2	3						
		DAY 57	24APR2003	59	0	2	3						
		FINAL	24APR2003	59	0	2	3						
PLACEBO (BIPOLAR I)	E0039023	DAY 1	24FEB2003	1	0	2	0						
PLACEBO (BIPOLAR I)	E0039030	DAY 1	24MAR2003	1	0	3	0						
		DAY 29	21APR2003	29	0	1	0						
		DAY 57	19MAY2003	57	0	0	0						
		FINAL	19MAY2003	57	0	0	0						
PLACEBO (BIPOLAR I)	E0039031	DAY 1	24MAR2003	1	0	2	3						
		DAY 29	21APR2003	29	1	2	3						
		DAY 57	20MAY2003	58	0	2	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0039031	FINAL	20MAY2003	58	6	-6	1	1	1	1	1	0	1
	E0039037	DAY 1	16APR2003	1	19		3	3	3	3	2	3	2
		DAY 29	15MAY2003	30	4	-15	0	0	1	0	2	0	1
		DAY 57	12JUN2003	58	7	-12	0	2	1	0	2	0	2
		FINAL	12JUN2003	58	7	-12	0	2	1	0	2	0	2
	E0039038	DAY 1	23APR2003	1	11		3	3	0	1	2	0	2
		DAY 29	21MAY2003	29	13	2	3	3	1	1	3	0	2
		FINAL	21MAY2003	29	13	2	3	3	1	1	3	0	2
	E0039047	DAY 1	19MAY2003	1	10		1	3	1	1	2	0	2
		DAY 29	16JUN2003	29	16	6	2	3	0	3	3	3	2
		DAY 57	14JUL2003	57	7	-3	1	3	0	0	2	0	1
		FINAL	14JUL2003	57	7	-3	1	3	0	0	2	0	1
	E0039059	DAY 1	11JUL2003	1	10		0	3	1	3	1	0	2
		DAY 29	07AUG2003	28	4	-6	0	1	1	0	1	0	1
		DAY 57	05SEP2003	57	3	-7	0	0	0	0	1	0	2
		FINAL	05SEP2003	57	3	-7	0	0	0	0	1	0	2
	E0041007	DAY 1	13MAR2003	1	15		3	3	3	3	1	0	2
		DAY 29	10APR2003	29	11	-4	0	3	2	2	1	0	3
		DAY 57	08MAY2003	57	12	-3	2	3	2	1	1	0	3
		FINAL	08MAY2003	57	12	-3	2	3	2	1	1	0	3
	E0041010	DAY 1	30APR2003	1	14		2	3	3	3	1	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
PLACEBO (BIPOLAR I)	E0039031	FINAL	20MAY2003	58	23:00	15	7:50	7	1	2	2	1	1	0	1	0	0	
PLACEBO (BIPOLAR I)	E0039037	DAY 1	16APR2003	1	23:00	60	7:00	4	3	3	2	0	2	1	2	3	3	
		DAY 29	15MAY2003	30	23:00	15	7:00	7	0	1	2	0	3	1	1	2	1	
		DAY 57	12JUN2003	58	0:00	20	7:00	6	2	2	3	0	3	0	0	2	2	
		FINAL	12JUN2003	58	0:00	20	7:00	6	2	2	3	0	3	0	0	2	2	
PLACEBO (BIPOLAR I)	E0039038	DAY 1	23APR2003	1	5:00	300	15:00	8	3	3	3	0	3	0	0	3	3	
		DAY 29	21MAY2003	29	6:00	60	14:00	6	3	3	3	3	3	3	0	3	1	
		FINAL	21MAY2003	29	6:00	60	14:00	6	3	3	3	3	3	3	0	3	1	
PLACEBO (BIPOLAR I)	E0039047	DAY 1	19MAY2003	1	23:30	90	8:30	7	3	3	3	1	0	3	3	3	1	
		DAY 29	16JUN2003	29	23:00	120	13:00	8	3	3	3	3	3	3	3	3	3	
		DAY 57	14JUL2003	57	23:00	90	6:30	8	3	3	3	1	0	3	2	3	1	
		FINAL	14JUL2003	57	23:00	90	6:30	8	3	3	3	1	0	3	2	3	1	
PLACEBO (BIPOLAR I)	E0039059	DAY 1	11JUL2003	1	22:00	120	10:00	6	3	3	2	0	0	1	2	0	0	
		DAY 29	07AUG2003	28	1:00	10	8:30	7	1	1	1	0	0	0	0	0	0	
		DAY 57	05SEP2003	57	23:30	15	8:30	8	0	1	0	0	0	0	1	0	0	
		FINAL	05SEP2003	57	23:30	15	8:30	8	0	1	0	0	0	0	1	0	0	
PLACEBO (BIPOLAR I)	E0041007	DAY 1	13MAR2003	1	2:00	50	8:00	3	3	3	1	0	0	0	2	3	0	
		DAY 29	10APR2003	29	1:00	45	8:00	5	3	0	1	0	1	3	0	2	0	
		DAY 57	08MAY2003	57	2:00	45	8:00	5	3	3	0	0	0	0	0	1	0	
		FINAL	08MAY2003	57	2:00	45	8:00	5	3	3	0	0	0	0	0	1	0	
PLACEBO (BIPOLAR I)	E0041010	DAY 1	30APR2003	1	23:00	60	6:30	4	3	3	0	0	0	0	0	0	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0039031	FINAL	20MAY2003	58	0	2	3						
PLACEBO (BIPOLAR I)	E0039037	DAY 1	16APR2003	1	1	3	0						
		DAY 29	15MAY2003	30	1	1	0						
		DAY 57	12JUN2003	58	1	2	0						
		FINAL	12JUN2003	58	1	2	0						
PLACEBO (BIPOLAR I)	E0039038	DAY 1	23APR2003	1	0	3	0						
		DAY 29	21MAY2003	29	0	3	0						
		FINAL	21MAY2003	29	0	3	0						
PLACEBO (BIPOLAR I)	E0039047	DAY 1	19MAY2003	1	1	2	3						
		DAY 29	16JUN2003	29	1	3	3						
		DAY 57	14JUL2003	57	0	2	3						
		FINAL	14JUL2003	57	0	2	3						
PLACEBO (BIPOLAR I)	E0039059	DAY 1	11JUL2003	1	0	3	0						
		DAY 29	07AUG2003	28	0	1	0						
		DAY 57	05SEP2003	57	2	1	0						
		FINAL	05SEP2003	57	2	1	0						
PLACEBO (BIPOLAR I)	E0041007	DAY 1	13MAR2003	1	2	1	0						
		DAY 29	10APR2003	29	3	2	0						
		DAY 57	08MAY2003	57	2	3	0						
		FINAL	08MAY2003	57	2	3	0						
PLACEBO (BIPOLAR I)	E0041010	DAY 1	30APR2003	1	0	2	3	0	0	0	0	1	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR I)	E0041010	DAY 29		28MAY2003	29	12	-2	1	3	3	3	1	0	1
		DAY 29	*	11JUN2003	43	14	0	2	3	3	3	1	0	2
		FINAL		11JUN2003	43	14	0	2	3	3	3	1	0	2
	E0041011	DAY 1		22MAY2003	1	18		2	3	2	3	2	3	3
		DAY 29		20JUN2003	30	6	-12	1	2	0	0	1	0	2
		DAY 57		17JUL2003	57	8	-10	1	2	0	2	1	0	2
		FINAL		17JUL2003	57	8	-10	1	2	0	2	1	0	2
	E0041012	DAY 1		19JUN2003	1	12		1	2	2	1	2	2	2
		DAY 29		17JUL2003	29	13	1	2	3	2	3	2	0	1
		DAY 57		14AUG2003	57	13	1	2	3	2	1	2	0	3
		FINAL		14AUG2003	57	13	1	2	3	2	1	2	0	3
PLACEBO (BIPOLAR II)	E0001004	DAY 1		01MAY2003	1	4		1	0	0	0	1	0	2
		DAY 29		29MAY2003	29	1	-3	0	0	0	0	1	0	0
		DAY 57		27JUN2003	58	4	0	1	1	0	0	1	0	1
		FINAL		27JUN2003	58	4	0	1	1	0	0	1	0	1
	E0005023	DAY 1		05FEB2003	1	10		3	3	0	0	0	3	1
		DAY 29		06MAR2003	30	2	-8	0	0	0	0	1	0	1
		DAY 57		01APR2003	56	3	-7	0	0	1	1	1	0	0
		FINAL		01APR2003	56	3	-7	0	0	1	1	1	0	0
	E0005034	DAY 1		15APR2003	1	5		1	0	1	0	1	0	2
		DAY 29		13MAY2003	29	4	-1	1	0	1	0	1	0	1
		DAY 57		09JUN2003	56	5	0	1	0	1	1	1	0	1
		FINAL		09JUN2003	56	5	0	1	0	1	1	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR I)	E0041010	DAY 29		28MAY2003	29	22:00	180	6:00	4	3	2	1	1	0	0	0	0	0		
		DAY 29	*	11JUN2003	43	23:00	180	6:00	4	3	1	1	0	0	0	0	0	0		
		FINAL		11JUN2003	43	23:00	180	6:00	4	3	1	1	0	0	0	0	0	0		
PLACEBO (BIPOLAR I)	E0041011	DAY 1		22MAY2003	1	23:00	120	12:00	5	3	3	1	0	0	0	0	2	1	3	MIND RACING CAN'T RELAX RESTLESSNESS
		DAY 29		20JUN2003	30	22:00	60	9:00	11	2	2	1	2	0	0	0	1	2		
		DAY 57		17JUL2003	57	21:00	60	9:30	9	1	1	1	2	1	0	1	1	2		
		FINAL		17JUL2003	57	21:00	60	9:30	9	1	1	1	2	1	0	1	1	2		
PLACEBO (BIPOLAR I)	E0041012	DAY 1		19JUN2003	1	22:00	60	4:00	5	2	3	3	2	3	0	3	1	3		
		DAY 29		17JUL2003	29	21:00	60	5:00	5	3	3	3	1	1	0	3	0	1		
		DAY 57		14AUG2003	57	23:00	60	5:00	5	3	3	3	1	3	0	3	1	3		
		FINAL		14AUG2003	57	23:00	60	5:00	5	3	3	3	1	3	0	3	1	3		
PLACEBO (BIPOLAR II)	E0001004	DAY 1		01MAY2003	1	23:50	15	10:30	10	0	1	1	0	0	1	2	1	1		
		DAY 29		29MAY2003	29	23:30	10	10:00	10	0	1	1	0	0	0	1	0	0		
		DAY 57		27JUN2003	58	23:30	15	10:00	11	1	0	1	0	0	0	1	0	0		
		FINAL		27JUN2003	58	23:30	15	10:00	11	1	0	1	0	0	0	1	0	0		
PLACEBO (BIPOLAR II)	E0005023	DAY 1		05FEB2003	1	3:00	120	5:30	9	3	0	0	0	0	0	0	0	0		
		DAY 29		06MAR2003	30	20:00	15	6:15	9	0	1	0	0	0	0	0	0	0		
		DAY 57		01APR2003	56	21:00	15	6:15	7	0	0	1	0	0	0	0	0	0		
		FINAL		01APR2003	56	21:00	15	6:15	7	0	0	1	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0005034	DAY 1		15APR2003	1	22:30	5	5:00	6	0	3	2	0	0	2	1	0	0		
		DAY 29		13MAY2003	29	22:30	5	5:30	6	0	3	1	0	0	0	2	0	0		
		DAY 57		09JUN2003	56	22:30	5	6:00	6	0	3	1	0	0	2	2	0	0		
		FINAL		09JUN2003	56	22:30	5	6:00	6	0	3	1	0	0	2	2	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR I)	E0041010	DAY 29		28MAY2003	29	0	2	3	2	0	1	1		
		DAY 29	*	11JUN2003	43	1	2	3	1	0	0	0		
		FINAL		11JUN2003	43	1	2	3	1	0	0	0		
PLACEBO (BIPOLAR I)	E0041011	DAY 1		22MAY2003	1	3	3	0						
		DAY 29		20JUN2003	30	1	2	0						
		DAY 57		17JUL2003	57	1	2	0						
		FINAL		17JUL2003	57	1	2	0						
PLACEBO (BIPOLAR I)	E0041012	DAY 1		19JUN2003	1	2	2	0						
		DAY 29		17JUL2003	29	0	1	0						
		DAY 57		14AUG2003	57	3	2	0						
		FINAL		14AUG2003	57	3	2	0						
PLACEBO (BIPOLAR II)	E0001004	DAY 1		01MAY2003	1	0	3	3	0	0	0	0	3	TOSSING & TURNING
		DAY 29		29MAY2003	29	0	0	3	0	0	0	0		
		DAY 57		27JUN2003	58	0	1	3	0	0	0	0		
		FINAL		27JUN2003	58	0	1	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0005023	DAY 1		05FEB2003	1	0	2	0						
		DAY 29		06MAR2003	30	0	1	0						
		DAY 57		01APR2003	56	0	0	0						
		FINAL		01APR2003	56	0	0	0						
PLACEBO (BIPOLAR II)	E0005034	DAY 1		15APR2003	1	2	2	3						
		DAY 29		13MAY2003	29	0	2	3						
		DAY 57		09JUN2003	56	0	2	3						
		FINAL		09JUN2003	56	0	2	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0005041	DAY 1	24JUN2003	1	13		1	2	1	2	2	2	3
		DAY 29	22JUL2003	29	4	-9	3	0	0	0	0	0	1
		DAY 57	18AUG2003	56	2	-11	0	0	0	0	1	0	1
		FINAL	18AUG2003	56	2	-11	0	0	0	0	1	0	1
	E0007004	DAY 1	30JAN2003	1	15		3	3	2	3	2	0	2
		DAY 29	12FEB2003	14	13	-2	3	3	1	2	1	1	2
		FINAL	12FEB2003	14	13	-2	3	3	1	2	1	1	2
	E0007010	DAY 1	18APR2003	1	12		3	3	2	1	1	0	2
		DAY 29	16MAY2003	29	7	-5	2	3	1	0	1	0	0
		DAY 57	16JUN2003	60	9	-3	2	1	2	2	1	0	1
		FINAL	16JUN2003	60	9	-3	2	1	2	2	1	0	1
	E0007012	DAY 1	16MAY2003	1	11		2	3	2	0	1	0	3
		DAY 29	13JUN2003	29	5	-6	1	1	1	0	1	0	1
		DAY 57	01JUL2003	47	9	-2	2	3	1	0	1	0	2
		FINAL	01JUL2003	47	9	-2	2	3	1	0	1	0	2
	E0009007	DAY 1	03FEB2003	1	14		2	3	3	3	2	0	1
		DAY 29	03MAR2003	29			3		3		2	0	2
		FINAL	03MAR2003	29			3		3		2	0	2
	E0009008	DAY 1	12FEB2003	1	10		1	3	1	1	2	1	1
		DAY 29	11MAR2003	28	4	-6	1	1	0	0	1	0	1
		DAY 57	08APR2003	56	3	-7	0	1	0	0	1	0	1
		FINAL	08APR2003	56	3	-7	0	1	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
PLACEBO (BIPOLAR II)	E0005041	DAY 1	24JUN2003	1	22:00	30	7:00	6	2	3	2	0	2	0	3	0	3	
		DAY 29	22JUL2003	29	23:00	15	6:30	8	0	0	0	0	0	0	0	0	0	
		DAY 57	18AUG2003	56	23:00	15	6:30	8	0	2	2	0	0	0	0	2	2	
		FINAL	18AUG2003	56	23:00	15	6:30	8	0	2	2	0	0	0	0	2	2	
PLACEBO (BIPOLAR II)	E0007004	DAY 1	30JAN2003	1	21:00	45	5:00	5	3	3	3	0	2	0	0	2	0	
		DAY 29	12FEB2003	14	21:00	60	6:00	6	3	3	3	0	0	0	1	2	0	
		FINAL	12FEB2003	14	21:00	60	6:00	6	3	3	3	0	0	0	1	2	0	
PLACEBO (BIPOLAR II)	E0007010	DAY 1	18APR2003	1	0:00	45	6:00	5	3	3	3	0	3	0	0	0	0	
		DAY 29	16MAY2003	29	23:30	40	6:00	6	3	3	1	0	3	0	0	0	0	
		DAY 57	16JUN2003	60	22:30	20	5:45	5	1	3	3	0	2	0	0	0	0	
		FINAL	16JUN2003	60	22:30	20	5:45	5	1	3	3	0	2	0	0	0	0	
PLACEBO (BIPOLAR II)	E0007012	DAY 1	16MAY2003	1	1:30	40	7:00	5	3	2	1	0	0	0	0	0	0	
		DAY 29	13JUN2003	29	0:00	10	7:30	7	2	2	1	0	0	0	0	1	0	
		DAY 57	01JUL2003	47	1:00	45	8:00	7	3	2	0	0	0	0	0	0	0	
		FINAL	01JUL2003	47	1:00	45	8:00	7	3	2	0	0	0	0	0	0	0	
PLACEBO (BIPOLAR II)	E0009007	DAY 1	03FEB2003	1	2:00	60	10:00	4	3	3	3	0	1	3	0	1	1	
		DAY 29	03MAR2003	29	22:00			1	3	3	2	0	0	3	0	3	0	
		FINAL	03MAR2003	29	22:00			1	3	3	2	0	0	3	0	3	0	
PLACEBO (BIPOLAR II)	E0009008	DAY 1	12FEB2003	1	21:30	60	6:50	7	3	3	1	0	3	1	0	2	0	
		DAY 29	11MAR2003	28	21:30	30	6:00	8	1	3	0	0	3	0	0	1	0	
		DAY 57	08APR2003	56	21:00	30	6:00	8	0	1	0	0	0	0	0	2	0	
		FINAL	08APR2003	56	21:00	30	6:00	8	0	1	0	0	0	0	0	2	0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0005041	DAY 1	24JUN2003	1	2	3	3						
		DAY 29	22JUL2003	29	0	1	3						
		DAY 57	18AUG2003	56	0	1	3						
		FINAL	18AUG2003	56	0	1	3						
PLACEBO (BIPOLAR II)	E0007004	DAY 1	30JAN2003	1	0	3	0						
		DAY 29	12FEB2003	14	0	3	0						
		FINAL	12FEB2003	14	0	3	0						
PLACEBO (BIPOLAR II)	E0007010	DAY 1	18APR2003	1	0	3	0						
		DAY 29	16MAY2003	29	0	0	0						
		DAY 57	16JUN2003	60	0	2	0						
		FINAL	16JUN2003	60	0	2	0						
PLACEBO (BIPOLAR II)	E0007012	DAY 1	16MAY2003	1	3	3	3	0	0	0	0		
		DAY 29	13JUN2003	29	0	2	3	2	0	0	0		
		DAY 57	01JUL2003	47	0	3	0						
		FINAL	01JUL2003	47	0	3	0						
PLACEBO (BIPOLAR II)	E0009007	DAY 1	03FEB2003	1	0	2	3	0	0	1	0		
		DAY 29	03MAR2003	29	1	3	3	0	0	2	0		
		FINAL	03MAR2003	29	1	3	3	0	0	2	0		
PLACEBO (BIPOLAR II)	E0009008	DAY 1	12FEB2003	1	0	2	0						
		DAY 29	11MAR2003	28	0	2	0						
		DAY 57	08APR2003	56	0	1	0						
		FINAL	08APR2003	56	0	1	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0011001	DAY 1	01NOV2002	1	10		2	1	1	0	2	2	2
		DAY 29	27NOV2002	27	10	0	2	2	1	0	2	1	2
		DAY 57	26DEC2002	56	6	-4	1	1	1	0	1	0	2
		FINAL	26DEC2002	56	6	-4	1	1	1	0	1	0	2
	E0011011	DAY 1	20FEB2003	1	14		3	3	2	2	2	0	2
		DAY 29	19MAR2003	28	16	2	2	3	2	3	3	0	3
		DAY 57	16APR2003	56	9	-5	1	2	1	1	2	0	2
		FINAL	16APR2003	56	9	-5	1	2	1	1	2	0	2
	E0011013	DAY 1	17APR2003	1	6		1	1	1	0	2	0	1
		DAY 29	15MAY2003	29	11	5	2	2	2	1	2	0	2
		DAY 57	12JUN2003	57	6	0	1	1	1	0	1	0	2
		FINAL	12JUN2003	57	6	0	1	1	1	0	1	0	2
	E0011014	DAY 1	07APR2003	1	11		3	3	3	0	1	0	1
	E0011021	DAY 1	22MAY2003	1	13		2	1	3	2	2	0	3
		DAY 29	20JUN2003	30	7	-6	1	0	1	3	1	0	1
		DAY 57	21JUL2003	61	7	-6	1	0	1	3	1	0	1
		FINAL	21JUL2003	61	7	-6	1	0	1	3	1	0	1
	E0013008	DAY 1	26MAR2003	1	13		3	3	3	0	2	0	2
		DAY 29	23APR2003	29	17	4	3	3	3	3	3	0	2
		DAY 57	19MAY2003	55	18	5	3	3	3	3	3	1	2
		FINAL	19MAY2003	55	18	5	3	3	3	3	3	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0011001	DAY 1	01NOV2002	1	0:30	10	6:30	7	2	2	1	2	1	2	0	1	3		
		DAY 29	27NOV2002	27	23:00	40	6:30	7	1	2	1	2	1	2	2	1	1		
		DAY 57	26DEC2002	56	0:30	15	6:30	7	2	2	1	0	0	2	0	1	2		
		FINAL	26DEC2002	56	0:30	15	6:30	7	2	2	1	0	0	2	0	1	2		
PLACEBO (BIPOLAR II)	E0011011	DAY 1	20FEB2003	1	0:00	120	7:00	5	3	3	3	3	0	2	2	3	2		
		DAY 29	19MAR2003	28	22:00	60	6:00	5	3	3	3	3	1	2	3	3	1		
		DAY 57	16APR2003	56	23:00	60	6:30	6	2	2	3	2	0	0	1	3	1		
		FINAL	16APR2003	56	23:00	60	6:30	6	2	2	3	2	0	0	1	3	1		
PLACEBO (BIPOLAR II)	E0011013	DAY 1	17APR2003	1	0:00	20	6:00	6	1	1	3	1	3	2	0	0	2	3	GRANDSON
		DAY 29	15MAY2003	29	0:00	30	6:00	5	3	3	3	0	3	2	1	1	3		
		DAY 57	12JUN2003	57	0:00	15	6:00	6	1	1	1	3	3	0	0	0	1		
		FINAL	12JUN2003	57	0:00	15	6:00	6	1	1	1	3	3	0	0	0	1		
PLACEBO (BIPOLAR II)	E0011014	DAY 1	07APR2003	1	3:00	90	6:30	3	3	3	3	0	0	1	0	0	0		
PLACEBO (BIPOLAR II)	E0011021	DAY 1	22MAY2003	1	0:30	15	6:00	4	2	3	3	1	1	1	2	0	0	2	WORRYING ABOUT THINGS
		DAY 29	20JUN2003	30	11:00	15	5:15	6	0	1	0	0	0	0	0	0	0		
		DAY 57	21JUL2003	61	11:30	15	5:30	6	0	1	0	0	0	0	0	0	0		
		FINAL	21JUL2003	61	11:30	15	5:30	6	0	1	0	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0013008	DAY 1	26MAR2003	1	3:00	60	6:00	3	3	3	1	0	1	3	3	3	3		
		DAY 29	23APR2003	29	3:00	60	7:00	2	3	3	2	3	2	2	3	3	3		
		DAY 57	19MAY2003	55	2:00	60	6:30	2	3	3	3	2	2	1	3	3	3		
		FINAL	19MAY2003	55	2:00	60	6:30	2	3	3	3	2	2	1	3	3	3		

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0011001	DAY 1	01NOV2002	1	2	2	0						
		DAY 29	27NOV2002	27	1	2	0						
		DAY 57	26DEC2002	56	2	2	0						
		FINAL	26DEC2002	56	2	2	0						
PLACEBO (BIPOLAR II)	E0011011	DAY 1	20FEB2003	1	2	2	0						
		DAY 29	19MAR2003	28	2	3	0						
		DAY 57	16APR2003	56	2	1	1						
		FINAL	16APR2003	56	2	1	1						
PLACEBO (BIPOLAR II)	E0011013	DAY 1	17APR2003	1	0	1	1	3	0	0	2		
		DAY 29	15MAY2003	29	0	3	1	3	3	3	2		
		DAY 57	12JUN2003	57	1	3	1						
		FINAL	12JUN2003	57	1	3	1						
PLACEBO (BIPOLAR II)	E0011014	DAY 1	07APR2003	1	0	2	0						
PLACEBO (BIPOLAR II)	E0011021	DAY 1	22MAY2003	1	2	3	3	0	0	2	0		
		DAY 29	20JUN2003	30	0	2	3	0	0	2	0		
		DAY 57	21JUL2003	61	0	1	3	0	0	2	0		
		FINAL	21JUL2003	61	0	1	3	0	0	2	0		
PLACEBO (BIPOLAR II)	E0013008	DAY 1	26MAR2003	1	0	3	3	1	0	3	0	3	TOSS AND TURN
		DAY 29	23APR2003	29	0	3	3	2	0	3	0	3	TOSSING AND TURNING
		DAY 57	19MAY2003	55	0	3	3	2	1	3	1		
		FINAL	19MAY2003	55	0	3	3	2	1	3	1		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0014001	DAY 1		26FEB2003	1	11		2	0	2	2	2	2	1
		DAY 29		25MAR2003	28	9	-2	1	0	1	2	2	2	1
		DAY 29	*	01APR2003	35	6	-5	1	1	1	1	1	0	1
		FINAL		01APR2003	35	6	-5	1	1	1	1	1	0	1
	E0014013	DAY 1		27MAY2003	1	13		2	3	1	3	2	0	2
		DAY 29		25JUN2003	30	11	-2	1	3	1	3	2	0	1
		DAY 57		23JUL2003	58	7	-6	1	1	0	1	2	0	2
		FINAL		23JUL2003	58	7	-6	1	1	0	1	2	0	2
	E0014014	DAY 1		10JUN2003	1	12		3	3	1	0	2	1	2
		DAY 29		10JUL2003	31	6	-6	1	2	1	0	1	0	1
		DAY 57		06AUG2003	58	4	-8	0	1	1	1	1	0	0
		FINAL		06AUG2003	58	4	-8	0	1	1	1	1	0	0
	E0015004	DAY 1		02DEC2002	1	15		3	3	2	1	3	0	3
		DAY 29		06JAN2003	36	10	-5	2	3	2	0	1	0	2
		DAY 57		29JAN2003	59	15	0	2	3	2	2	3	0	3
		FINAL		29JAN2003	59	15	0	2	3	2	2	3	0	3
	E0018005	DAY 1		20DEC2002	1	11		1	2	2	3	1	0	2
		DAY 29		17JAN2003	29	3	-8	1	0	0	0	1	0	1
		DAY 57		14FEB2003	57	7	-4	1	1	1	2	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0014001	DAY 1		26FEB2003	1	22:20	15	6:00	5	0	3	3	0	0	2	2	0	0	3	JUST CANNOT SLEEP
		DAY 29		25MAR2003	28	22:00	15	6:30	6	0	3	3	0	2	2	3	1	1		
		DAY 29	*	01APR2003	35	22:00	20	6:30	7	0	2	3	0	0	2	2	0	0		
		FINAL		01APR2003	35	22:00	20	6:30	7	0	2	3	0	0	2	2	0	0		
PLACEBO (BIPOLAR II)	E0014013	DAY 1		27MAY2003	1	21:30	60	9:00	6	3	3	3	1	0	0	3	1	2		
		DAY 29		25JUN2003	30	22:30	45	8:00	6	3	2	3	3	0	2	3	0	0	3	RESTLESS
		DAY 57		23JUL2003	58	23:00	30	9:00	8	0	0	3	3	0	0	3	0	1		
		FINAL		23JUL2003	58	23:00	30	9:00	8	0	0	3	3	0	0	3	0	1		
PLACEBO (BIPOLAR II)	E0014014	DAY 1		10JUN2003	1	2:00	90	8:00	6	3	3	3	2	0	0	3	1	0		
		DAY 29		10JUL2003	31	0:00	30	7:00	7	2	1	2	0	0	0	2	0	0		
		DAY 57		06AUG2003	58	23:30	30	7:00	6	0	2	3	0	0	0	0	0	0		
		FINAL		06AUG2003	58	23:30	30	7:00	6	0	2	3	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0015004	DAY 1		02DEC2002	1	0:00	60	6:00	5	3	3	3	2	3	3	3	1	2		
		DAY 29		06JAN2003	36	23:45	60	5:30	5	3	2	2	0	0	1	1	1	0		
		DAY 57		29JAN2003	59	0:00	90	7:00	5	3	3	3	2	2	3	3	1	3		
		FINAL		29JAN2003	59	0:00	90	7:00	5	3	3	3	2	2	3	3	1	3		
PLACEBO (BIPOLAR II)	E0018005	DAY 1		20DEC2002	1	23:30	30	7:30	5	2	3	1	0	0	1	0	2	0	1	NOT TIRED ANYMORE
		DAY 29		17JAN2003	29	23:00	10	7:30	8	0	2	1	0	0	0	1	1	0		
		DAY 57		14FEB2003	57	22:00	20	7:30	7	1	1	1	0	0	0	1	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0014001	DAY 1	26FEB2003	1	0	1	3	0	0	2	2	2	TOSS & TURN - TALK IN SLEEP
		DAY 29	25MAR2003	28	0	1	3	0	0	2	1	2	TOSSING/TURNING TALKING IN SLEEP RESTLESSNESS
		DAY 29 *	01APR2003	35	0	1	3	0	0	2	2	2	TOSS & TURN TALK IN SLEEP
		FINAL	01APR2003	35	0	1	3	0	0	2	2	2	TOSS & TURN TALK IN SLEEP
PLACEBO (BIPOLAR II)	E0014013	DAY 1	27MAY2003	1	1	3	0						
		DAY 29	25JUN2003	30	0	2	0						
		DAY 57	23JUL2003	58	1	2	0						
		FINAL	23JUL2003	58	1	2	0						
PLACEBO (BIPOLAR II)	E0014014	DAY 1	10JUN2003	1	0	3	3	0	1	0	0		
		DAY 29	10JUL2003	31	0	1	3	0	0	0	0		
		DAY 57	06AUG2003	58	0	0	3	0	0	0	0		
		FINAL	06AUG2003	58	0	0	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0015004	DAY 1	02DEC2002	1	3	3	3	3	2	3	1		
		DAY 29	06JAN2003	36	1	3	0						
		DAY 57	29JAN2003	59	3	3	3	0	1	1	2	3	TOSSING AND TURNING
		FINAL	29JAN2003	59	3	3	3	0	1	1	2	3	TOSSING AND TURNING
PLACEBO (BIPOLAR II)	E0018005	DAY 1	20DEC2002	1	1	3	3	0	0	0	0		
		DAY 29	17JAN2003	29	1	1	0						
		DAY 57	14FEB2003	57	0	1	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0018005	FINAL		14FEB2003	57	7	-4	1	1	1	2	1	0	1
	E0018012	DAY 1		24JAN2003	1	14		2	2	2	3	3	0	2
		DAY 29		21FEB2003	29	10	-4	1	1	2	3	2	0	1
		DAY 29	*	26FEB2003	34	9	-5	2	1	1	2	2	0	1
		FINAL		26FEB2003	34	9	-5	2	1	1	2	2	0	1
	E0019019	DAY 1		23JAN2003	1	11		2	3	1	1	2	0	2
	E0019033	DAY 1		18MAR2003	1	14		2	3	3	2	2	0	2
		DAY 29		14APR2003	28	10	-4	2	2	2	0	2	0	2
		DAY 57		15MAY2003	59	10	-4	2	2	2	1	1	0	2
		FINAL		15MAY2003	59	10	-4	2	2	2	1	1	0	2
	E0019038	DAY 1		24APR2003	1			2				1	0	3
		DAY 29		21MAY2003	28	7		1	1	1	0	2	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0018005	FINAL		14FEB2003	57	22:00	20	7:30	7	1	1	1	0	0	0	1	1	0		
PLACEBO (BIPOLAR II)	E0018012	DAY 1		24JAN2003	1	23:00	30	7:30	5	2	3	3	2	3	3	3	2	2	2	CHILDREN UP
		DAY 29		21FEB2003	29	23:00	10	7:30	5	1	3	3	2	3	1	1	2	1		
		DAY 29	*	26FEB2003	34	23:00	20	7:30	6	1	3	3	1	3	2	1	2	0		
		FINAL		26FEB2003	34	23:00	20	7:30	6	1	3	3	1	3	2	1	2	0		
PLACEBO (BIPOLAR II)	E0019019	DAY 1		23JAN2003	1	8:30	60	16:30	6	3	2	3	0	3	1	1	2	0		
PLACEBO (BIPOLAR II)	E0019033	DAY 1		18MAR2003	1	23:30	60	5:30	4	3	3	3	3	2	0	3	2	0		
		DAY 29		14APR2003	28	23:30	30	5:00	5	2	3	1	2	1	3	1	1	0	3	FEEL JITTERY & HAVE RACING THOUGHTS BEFORE EVEN WAKING UP.
		DAY 57		15MAY2003	59	23:30	30	5:30	5	3	3	1	0	1	0	0	2	0	2	TOSS & TURN, LOTS OF UNINTELLIGIBLE THOUGHTS
		FINAL		15MAY2003	59	23:30	30	5:30	5	3	3	1	0	1	0	0	2	0	2	TOSS & TURN, LOTS OF UNINTELLIGIBLE THOUGHTS
PLACEBO (BIPOLAR II)	E0019038	DAY 1		24APR2003	1					3	3	0	1	0	3	0	0	0		
		DAY 29		21MAY2003	28	0:00	15	6:35	6	2	2	0	2	0	3	2	0	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0018005	FINAL		14FEB2003	57	0	1	0						
PLACEBO (BIPOLAR II)	E0018012	DAY 1		24JAN2003	1	1	3	3	3	3	3	2	3	TOSSING AND TURNING
		DAY 29		21FEB2003	29	0	1	3	3	3	3	3	3	TOSSING AND TURNING
		DAY 29	*	26FEB2003	34	1	1	3	3	3	3	3	3	TOSSING & TURNING
		FINAL		26FEB2003	34	1	1	3	3	3	3	3	3	TOSSING & TURNING
PLACEBO (BIPOLAR II)	E0019019	DAY 1		23JAN2003	1	0	3	3	3	2	2	0		
PLACEBO (BIPOLAR II)	E0019033	DAY 1		18MAR2003	1	1	3	3	2	3	1	0	3	INCREASED DREAMING. TOSSING AND TURNING. INSOMNIA INTERRUPTED SLEEP.
		DAY 29		14APR2003	28	1	3	3	2	2	2	0	3	LOTS OF TURNING & MOVING AROUND IN THE BED.
		DAY 57		15MAY2003	59	1	3	3	0	2	0	0	2	SOME MOANING/GROANING. RESTLESS
		FINAL		15MAY2003	59	1	3	3	0	2	0	0	2	SOME MOANING/GROANING. RESTLESS
PLACEBO (BIPOLAR II)	E0019038	DAY 1		24APR2003	1	3	3	3	0	0	0	0		
		DAY 29		21MAY2003	28	0	2	3	0	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0019038	DAY 57	18JUN2003	56	9		1	2	1	0	2	1	2
		FINAL	18JUN2003	56	9		1	2	1	0	2	1	2
	E0019046	DAY 1	26JUN2003	1	14		2	3	3	2	2	0	2
		DAY 29	24JUL2003	29	6	-8	0	1	1	2	1	0	1
		DAY 57	21AUG2003	57	3	-11	0	1	0	0	1	0	1
		FINAL	21AUG2003	57	3	-11	0	1	0	0	1	0	1
	E0019047	DAY 1	08JUL2003	1	12		2	3	1	2	2	0	2
		DAY 29	07AUG2003	31	9	-3	1	2	1	3	1	0	1
		DAY 57	04SEP2003	59	4	-8	1	1	0	0	1	0	1
		FINAL	04SEP2003	59	4	-8	1	1	0	0	1	0	1
	E0019048	DAY 1	10JUL2003	1	19		3	3	2	3	3	3	2
		DAY 29	07AUG2003	29	17	-2	3	3	2	2	2	3	2
		DAY 57	03SEP2003	56	19	0	3	3	3	3	2	3	2
		FINAL	03SEP2003	56	19	0	3	3	3	3	2	3	2
	E0022006	DAY 1	12NOV2002	1	8		1	3	0	0	1	2	1
		DAY 29	10DEC2002	29	8	0	1	3	0	1	1	1	1
		DAY 57	07JAN2003	57	4	-4	1	1	0	0	1	0	1
		FINAL	07JAN2003	57	4	-4	1	1	0	0	1	0	1
	E0022047	DAY 1	28MAR2003	1	13		2	2	1	3	3	0	2
		DAY 29	25APR2003	29	8	-5	1	2	1	1	1	0	2
		DAY 57	23MAY2003	57	8	-5	1	3	0	1	1	0	2
		FINAL	23MAY2003	57	8	-5	1	3	0	1	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0019038	DAY 57	18JUN2003	56	0:00	30	6:45	6	3	2	0	3	0	1	3	1	2		
		FINAL	18JUN2003	56	0:00	30	6:45	6	3	2	0	3	0	1	3	1	2		
PLACEBO (BIPOLAR II)	E0019046	DAY 1	26JUN2003	1	22:00	60	4:00	4	3	3	3	0	0	0	3	3	0	3	MIND RACING
		DAY 29	24JUL2003	29	21:00	20	6:30	7	0	2	2	0	0	0	0	0	0		
		DAY 57	21AUG2003	57	21:30	30	6:30	8	0	0	2	0	0	0	0	1	0		
		FINAL	21AUG2003	57	21:30	30	6:30	8	0	0	2	0	0	0	0	1	0		
PLACEBO (BIPOLAR II)	E0019047	DAY 1	08JUL2003	1	23:30	60	8:00	6	3	3	1	1	0	0	3	2	1		
		DAY 29	07AUG2003	31	23:00	30	8:45	6	2	2	1	0	0	0	3	1	0		
		DAY 57	04SEP2003	59	22:00	15	8:00	12	1	2	1	0	0	0	2	1	0		
		FINAL	04SEP2003	59	22:00	15	8:00	12	1	2	1	0	0	0	2	1	0		
PLACEBO (BIPOLAR II)	E0019048	DAY 1	10JUL2003	1	23:00	60	7:00	5	3	3	3	2	1	0	3	3	3	3	HAVE TROUBLE "RELAXING". NIGHT THINKING
		DAY 29	07AUG2003	29	0:00	60	7:30	5	3	3	3	2	1	0	3	2	2		
		DAY 57	03SEP2003	56	23:00	60	7:00	4	3	3	3	1	1	0	3	2	1		
		FINAL	03SEP2003	56	23:00	60	7:00	4	3	3	3	1	1	0	3	2	1		
PLACEBO (BIPOLAR II)	E0022006	DAY 1	12NOV2002	1	2:00	60	13:00	12	3	1	2	2	0	0	1	0	0		
		DAY 29	10DEC2002	29	3:00	60	12:30	8	3	1	1	0	1	1	1	0	2		
		DAY 57	07JAN2003	57	23:59	20	9:00	8	1	0	0	1	0	2	1	0	2		
		FINAL	07JAN2003	57	23:59	20	9:00	8	1	0	0	1	0	2	1	0	2		
PLACEBO (BIPOLAR II)	E0022047	DAY 1	28MAR2003	1	0:45	30	10:00	6	3	3	3	2	2	2	1	2	3	3	WORRY / JOB SEARCH
		DAY 29	25APR2003	29	23:00	40	7:45	7	2	1	1	1	1	1	1	1	0		
		DAY 57	23MAY2003	57	22:30	120	8:40	8	3	2	2	0	0	0	0	1	0		
		FINAL	23MAY2003	57	22:30	120	8:40	8	3	2	2	0	0	0	0	1	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0019038	DAY 57	18JUN2003	56	1	2	3	0	0	0	1		
		FINAL	18JUN2003	56	1	2	3	0	0	0	1		
PLACEBO (BIPOLAR II)	E0019046	DAY 1	26JUN2003	1	0	3	3	2	2	3	0		
		DAY 29	24JUL2003	29	0	1	3	0	0	0	0		
		DAY 57	21AUG2003	57	0	1	3	0	0	0	0		
		FINAL	21AUG2003	57	0	1	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0019047	DAY 1	08JUL2003	1	1	2	3	0	0	0	0	1	TOSSING & TURNING
		DAY 29	07AUG2003	31	0	1	1	0	0	1	0		
		DAY 57	04SEP2003	59	0	1	1	0	0	0	0		
		FINAL	04SEP2003	59	0	1	1	0	0	0	0		
PLACEBO (BIPOLAR II)	E0019048	DAY 1	10JUL2003	1	0	3	0						
		DAY 29	07AUG2003	29	0	3	0						
		DAY 57	03SEP2003	56	1	3	0						
		FINAL	03SEP2003	56	1	3	0						
PLACEBO (BIPOLAR II)	E0022006	DAY 1	12NOV2002	1	0	2	0						
		DAY 29	10DEC2002	29	0	2	0						
		DAY 57	07JAN2003	57	0	2	0						
		FINAL	07JAN2003	57	0	2	0						
PLACEBO (BIPOLAR II)	E0022047	DAY 1	28MAR2003	1	1	3	0						
		DAY 29	25APR2003	29	1	2	0						
		DAY 57	23MAY2003	57	1	2	0						
		FINAL	23MAY2003	57	1	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0022075	DAY 1	08JUL2003	1	15		1	1	2	3	3	3	2
		DAY 29	05AUG2003	29	17	2	3	3	3	3	2	0	3
		DAY 57	03SEP2003	58	15	0	2	2	2	2	2	3	2
		FINAL	03SEP2003	58	15	0	2	2	2	2	2	3	2
	E0023012	DAY 1	06FEB2003	1	13		0	3	3	3	2	0	2
		DAY 29	07MAR2003	30	14	1	2	3	2	3	2	0	2
		DAY 57	04APR2003	58	2	-11	0	1	0	0	1	0	0
		FINAL	04APR2003	58	2	-11	0	1	0	0	1	0	0
	E0023016	DAY 1	22MAY2003	1	16		3	3	3	3	2	0	2
		DAY 29	19JUN2003	29	5	-11	0	1	1	0	1	0	2
		DAY 57	17JUL2003	57	9	-7	2	2	1	1	1	0	2
		FINAL	17JUL2003	57	9	-7	2	2	1	1	1	0	2
	E0023018	DAY 1	27MAR2003	1	12		2	3	2	3	1	0	1
		DAY 29	24APR2003	29	6	-6	1	3	1	0	1	0	0
		DAY 57	22MAY2003	57	7	-5	1	3	1	1	1	0	0
		FINAL	22MAY2003	57	7	-5	1	3	1	1	1	0	0
	E0023036	DAY 1	20JUN2003	1	15		2	3	3	3	2	0	2
		DAY 29	16JUL2003	27	8	-7	2	0	2	1	2	0	1
		DAY 57	13AUG2003	55	12	-3	2	3	2	3	1	0	1
		FINAL	13AUG2003	55	12	-3	2	3	2	3	1	0	1
	E0023046	DAY 1	23JUL2003	1	14		3	3	3	3	1	0	1
		DAY 29	22AUG2003	31	13	-1	2	3	3	2	2	0	1
		DAY 57	16SEP2003	56	10	-4	1	3	2	1	2	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
PLACEBO (BIPOLAR II)	E0022075	DAY 1	08JUL2003	1	22:00	30	7:00	5	0	2	3	0	3	3	3	3	3	
		DAY 29	05AUG2003	29	0:00	60	7:00	4	3	3	3	1	3	2	1	3	1	
		DAY 57	03SEP2003	58	22:00	30	5:00	5	2	2	2	0	3	3	2	2	2	
		FINAL	03SEP2003	58	22:00	30	5:00	5	2	2	2	0	3	3	2	2	2	
PLACEBO (BIPOLAR II)	E0023012	DAY 1	06FEB2003	1	21:30	75	6:45	4	3	3	3	1	3	3	1	3	1	
		DAY 29	07MAR2003	30	21:00	35	6:30	5	3	3	3	2	2	3	2	0	1	
		DAY 57	04APR2003	58	22:00	30	6:30	8	1	1	3	0	0	0	3	0	0	
		FINAL	04APR2003	58	22:00	30	6:30	8	1	1	3	0	0	0	3	0	0	
PLACEBO (BIPOLAR II)	E0023016	DAY 1	22MAY2003	1	22:00	60	7:00	3	3	3	0	0	0	0	3	2	3	
		DAY 29	19JUN2003	29	0:30	20	7:00	6	0	0	1	0	0	0	1	1	1	
		DAY 57	17JUL2003	57	0:30	30	8:00	6	2	2	1	0	0	0	0	0	0	
		FINAL	17JUL2003	57	0:30	30	8:00	6	2	2	1	0	0	0	0	0	0	
PLACEBO (BIPOLAR II)	E0023018	DAY 1	27MAR2003	1	23:00	60	7:00	5	3	3	0	0	0	0	3	3	0	
		DAY 29	24APR2003	29	1:30	75	9:30	7	3	0	0	0	0	0	0	2	0	
		DAY 57	22MAY2003	57	23:30	90	8:30	7	3	1	1	0	0	0	2	0	0	
		FINAL	22MAY2003	57	23:30	90	8:30	7	3	1	1	0	0	0	2	0	0	
PLACEBO (BIPOLAR II)	E0023036	DAY 1	20JUN2003	1	10:30	180	9:00	4	3	3	2	0	1	3	3	0	0	
		DAY 29	16JUL2003	27	2:00	15	8:00	5	0	3	2	0	0	3	2	0	0	
		DAY 57	13AUG2003	55	11:00	45	6:30	5	3	2	0	0	0	3	3	0	0	
		FINAL	13AUG2003	55	11:00	45	6:30	5	3	2	0	0	0	3	3	0	0	
PLACEBO (BIPOLAR II)	E0023046	DAY 1	23JUL2003	1	22:00	60	6:00	4	3	3	1	0	0	1	2	1	1	
		DAY 29	22AUG2003	31	23:00	90	5:00	4	3	3	2	0	0	2	2	1	3	
		DAY 57	16SEP2003	56	22:00	75	4:30	5	3	3	2	0	0	1	2	1	1	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0022075	DAY 1	08JUL2003	1	0	3	2						
		DAY 29	05AUG2003	29	2	3	1						
		DAY 57	03SEP2003	58	1	3	1						
		FINAL	03SEP2003	58	1	3	1						
PLACEBO (BIPOLAR II)	E0023012	DAY 1	06FEB2003	1	1	3	3	3	0	2	0		
		DAY 29	07MAR2003	30	1	2	3	2	0	0	0		
		DAY 57	04APR2003	58	0	0	3	0	0	0	0		
		FINAL	04APR2003	58	0	0	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0023016	DAY 1	22MAY2003	1	0	3	3	0	0	0	0		
		DAY 29	19JUN2003	29	1	3	3	2	0	0	1		
		DAY 57	17JUL2003	57	1	2	0						
		FINAL	17JUL2003	57	1	2	0						
PLACEBO (BIPOLAR II)	E0023018	DAY 1	27MAR2003	1	0	2	0						
		DAY 29	24APR2003	29	0	0	0						
		DAY 57	22MAY2003	57	0	0	1	0	0	0	0		
		FINAL	22MAY2003	57	0	0	1	0	0	0	0		
PLACEBO (BIPOLAR II)	E0023036	DAY 1	20JUN2003	1	0	3	1	0	0	0	0		
		DAY 29	16JUL2003	27	0	2	1	0	0	0	0		
		DAY 57	13AUG2003	55	0	2	0						
		FINAL	13AUG2003	55	0	2	0						
PLACEBO (BIPOLAR II)	E0023046	DAY 1	23JUL2003	1	0	2	0						
		DAY 29	22AUG2003	31	0	2	0						
		DAY 57	16SEP2003	56	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0023046	FINAL	16SEP2003	56	10	-4	1	3	2	1	2	0	1
	E0026006	DAY 1	08JAN2003	1	10		2	3	2	1	1	0	1
		DAY 29	05FEB2003	29	5	-5	1	1	1	0	1	0	1
		FINAL	05FEB2003	29	5	-5	1	1	1	0	1	0	1
	E0026021	DAY 1	23APR2003	1	14		3	3	2	3	1	0	2
	E0026027	DAY 1	19JUN2003	1	16		2	3	2	1	2	3	3
	E0029002		12NOV2002		11		2	2	1	0	2	2	2
	E0029004	DAY 1	19NOV2002	1	11		3	0	2	3	1	0	2
		DAY 57	16JAN2003	59	13	2	2	3	2	1	2	1	2
		FINAL	16JAN2003	59	13	2	2	3	2	1	2	1	2
	E0029013	DAY 1	19FEB2003	1	9		1	3	1	0	2	0	2
		DAY 29	20MAR2003	30	4	-5	1	0	0	0	0	0	3
		FINAL	20MAR2003	30	4	-5	1	0	0	0	0	0	3
	E0029019	DAY 1	03MAR2003	1	4		0	1	0	0	1	0	2
		DAY 29	17MAR2003	15	4	0	1	0	0	0	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0023046	FINAL	16SEP2003	56	22:00	75	4:30	5	3	3	2	0	0	1	2	1	1		
PLACEBO (BIPOLAR II)	E0026006	DAY 1	08JAN2003	1	22:00	45	4:00	5	3	2	3	0	0	2	1	1	0		
		DAY 29	05FEB2003	29	22:00	15	5:00	7	1	1	2	0	0	0	0	0	0		
		FINAL	05FEB2003	29	22:00	15	5:00	7	1	1	2	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0026021	DAY 1	23APR2003	1	22:00	60	6:00	5	3	3	1	0	0	0	0	2	0		
PLACEBO (BIPOLAR II)	E0026027	DAY 1	19JUN2003	1	3:00	120	9:00	5	3	3	2	3	3	3	1	2	0		
PLACEBO (BIPOLAR II)	E0029002		12NOV2002		22:30	20	4:30	6	2	3	3	0	3	3	3	0	0		
PLACEBO (BIPOLAR II)	E0029004	DAY 1	19NOV2002	1	20:00	0	6:00	5	0	3	2	0	0	0	0	0	0		
		DAY 57	16JAN2003	59	23:00	60	5:30	5	3	3	2	0	0	2	0	2	0	2	JUST THINKING ABOUT EVERYTHING THAT IS NOT RIGHT
		FINAL	16JAN2003	59	23:00	60	5:30	5	3	3	2	0	0	2	0	2	0	2	JUST THINKING ABOUT EVERYTHING THAT IS NOT RIGHT
PLACEBO (BIPOLAR II)	E0029013	DAY 1	19FEB2003	1	22:00	60	4:00	6	3	3	3	0	3	0	2	0	0		
		DAY 29	20MAR2003	30	22:00	5	5:30	9	0	0	0	0	0	0	0	0	0		
		FINAL	20MAR2003	30	22:00	5	5:30	9	0	0	0	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0029019	DAY 1	03MAR2003	1	21:30	5	7:45	9	2	1	1	0	0	0	0	0	0		
		DAY 29	17MAR2003	15	22:00	5	8:00	9	0	0	1	0	3	1	1	0	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0023046	FINAL	16SEP2003	56	0	2	0						
PLACEBO (BIPOLAR II)	E0026006	DAY 1	08JAN2003	1	0	2	3	0	0	0	0		
		DAY 29	05FEB2003	29	0	2	0						
		FINAL	05FEB2003	29	0	2	0						
PLACEBO (BIPOLAR II)	E0026021	DAY 1	23APR2003	1	0	3	1	0	0	0	0	3	TURNING A LOT
PLACEBO (BIPOLAR II)	E0026027	DAY 1	19JUN2003	1	2	3	0						
PLACEBO (BIPOLAR II)	E0029002		12NOV2002		0	3	0						
PLACEBO (BIPOLAR II)	E0029004	DAY 1	19NOV2002	1	0	3	3	1	0	0	0	3	GRITTING TEETH
		DAY 57	16JAN2003	59	1	3	3	0	0	1	0		
		FINAL	16JAN2003	59	1	3	3	0	0	1	0		
PLACEBO (BIPOLAR II)	E0029013	DAY 1	19FEB2003	1	0	3	3	3	0	0	0		
		DAY 29	20MAR2003	30	3	3	3	3	0	0	0		
		FINAL	20MAR2003	30	3	3	3	3	0	0	0		
PLACEBO (BIPOLAR II)	E0029019	DAY 1	03MAR2003	1	0	3	3	1	0	0	0		
		DAY 29	17MAR2003	15	0	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0029019	FINAL	17MAR2003	15	4	0	1	0	0	0	1	0	2
	E0029024	DAY 1	17MAR2003	1	3		0	0	1	0	0	0	2
		DAY 29	17APR2003	32	9	6	1	0	2	3	1	0	2
		DAY 57	20MAY2003	65	3	0	0	0	1	0	1	0	1
		FINAL	20MAY2003	65	3	0	0	0	1	0	1	0	1
	E0029038	DAY 1	07JUL2003	1	11		1	2	2	2	1	2	1
	E0031004	DAY 1	19DEC2002	1			1	2	2	3		2	1
		DAY 29	16JAN2003	29	9		1	2	2	0	2	0	2
		DAY 57	13FEB2003	57	7		1	2	1	0	2	0	1
		FINAL	13FEB2003	57	7		1	2	1	0	2	0	1
	E0031013	DAY 1	13MAR2003	1	11		2	2	1	1	2	0	3
		DAY 29	11APR2003	30	11	0	1	2	1	3	2	0	2
		DAY 57	08MAY2003	57	10	-1	1	2	1	2	2	0	2
		FINAL	08MAY2003	57	10	-1	1	2	1	2	2	0	2
	E0031016	DAY 1	24MAR2003	1	14		2	3	1	1	2	3	2
		DAY 29	14APR2003	22	12	-2	2	3	1	2	2	0	2
		FINAL	14APR2003	22	12	-2	2	3	1	2	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0029019	FINAL	17MAR2003	15	22:00	5	8:00	9	0	0	1	0	3	1	1	0	0		
PLACEBO (BIPOLAR II)	E0029024	DAY 1	17MAR2003	1	23:00	5	6:00	7	0	0	0	0	0	0	0	0	0		
		DAY 29	17APR2003	32	22:30	5	7:00	5	0	3	0	0	0	0	0	3	3		
		DAY 57	20MAY2003	65	23:30	1	7:00	7	0	0	0	0	0	0	0	1	0		
		FINAL	20MAY2003	65	23:30	1	7:00	7	0	0	0	0	0	0	0	1	0		
PLACEBO (BIPOLAR II)	E0029038	DAY 1	07JUL2003	1	0:30	30	7:30	5	3	2	1	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0031004	DAY 1	19DEC2002	1	4:00	30	12:00	5	2	2	3	0	1	0	0		1	3	RESTLESS LEG SYNDROME SOME INSOMNIA
		DAY 29	16JAN2003	29	3:30	25	9:00	5	3	2	3	0	3	1	0	0	2	3	RESTLESS LEG SYNDROME
		DAY 57	13FEB2003	57	4:00	30	10:00	6	3	2	3	0	3	0	0	0	0	3	RESTLESS LEG SYNDROME
		FINAL	13FEB2003	57	4:00	30	10:00	6	3	2	3	0	3	0	0	0	0	3	RESTLESS LEG SYNDROME
PLACEBO (BIPOLAR II)	E0031013	DAY 1	13MAR2003	1	21:30	30	6:30	7	3	3	3	2	3	0	2	3	2		
		DAY 29	11APR2003	30	22:30	30	10:00	7	2	3	3	0	3	0	0	2	1		
		DAY 57	08MAY2003	57	20:00	30	6:30	7	2	2	3	0	3	0	2	1	1		
		FINAL	08MAY2003	57	20:00	30	6:30	7	2	2	3	0	3	0	2	1	1		
PLACEBO (BIPOLAR II)	E0031016	DAY 1	24MAR2003	1	0:00	60	8:30	7	3	3	3	0	0	2	2	2	1		
		DAY 29	14APR2003	22	0:00	60	8:30	6	3	3	3	1	0	1	1	2	2		
		FINAL	14APR2003	22	0:00	60	8:30	6	3	3	3	1	0	1	1	2	2		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0029019	FINAL	17MAR2003	15	0	3	0						
PLACEBO (BIPOLAR II)	E0029024	DAY 1	17MAR2003	1	0	3	0						
		DAY 29	17APR2003	32	0	3	0						
		DAY 57	20MAY2003	65	0	2	0						
		FINAL	20MAY2003	65	0	2	0						
PLACEBO (BIPOLAR II)	E0029038	DAY 1	07JUL2003	1	0	2	3	3	1	3	0		
PLACEBO (BIPOLAR II)	E0031004	DAY 1	19DEC2002	1	0	2	0						
		DAY 29	16JAN2003	29	1	2	0						
		DAY 57	13FEB2003	57	0	1	0						
		FINAL	13FEB2003	57	0	1	0						
PLACEBO (BIPOLAR II)	E0031013	DAY 1	13MAR2003	1	2	3	3	3	2	2	2	3	TALK IN SLEEP
		DAY 29	11APR2003	30	2	2	3	3	2	0	0		
		DAY 57	08MAY2003	57	2	2	3	3	2	0	1		
		FINAL	08MAY2003	57	2	2	3	3	2	0	1		
PLACEBO (BIPOLAR II)	E0031016	DAY 1	24MAR2003	1	0	3	1						
		DAY 29	14APR2003	22	1	3	0						
		FINAL	14APR2003	22	1	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
GENERATED: 12JUL2005 17:45:58 iceadmn3

Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0031019	DAY 1		11APR2003	1	14		3	3	1	3	1	2	1
		DAY 29		09MAY2003	29	12	-2	2	3	2	3	1	0	1
		DAY 29	*	12MAY2003	32	11	-3	2	3	2	2	1	0	1
		FINAL		12MAY2003	32	11	-3	2	3	2	2	1	0	1
	E0031022	DAY 1		28APR2003	1	11		2	3	0	1	3	0	2
		DAY 29		27MAY2003	30	11	0	2	3	1	1	2	0	2
		FINAL		27MAY2003	30	11	0	2	3	1	1	2	0	2
	E0033007	DAY 1		28JAN2003	1	19		3	3	2	3	3	3	2
		DAY 29		25FEB2003	29	15	-4	3	3	2	3	2	0	2
		DAY 57		25MAR2003	57	15	-4	3	3	2	3	2	0	2
		FINAL		25MAR2003	57	15	-4	3	3	2	3	2	0	2
	E0033013	DAY 1		19FEB2003	1	9		1	3	1	2	1	0	1
		DAY 29		19MAR2003	29	11	2	3	3	1	2	1	0	1
		DAY 57		16APR2003	57	6	-3	2	2	0	0	1	0	1
		FINAL		16APR2003	57	6	-3	2	2	0	0	1	0	1
	E0033016	DAY 1		08MAY2003	1	11		2	3	1	1	2	1	1
		DAY 29		09JUN2003	33	7	-4	1	1	1	2	1	0	1
		DAY 57		02JUL2003	56	10	-1	1	2	2	3	1	0	1
		FINAL		02JUL2003	56	10	-1	1	2	2	3	1	0	1
	E0033022	DAY 1		14JUL2003	1	9		1	1	0	3	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0031019	DAY 1		11APR2003	1	23:00	90	9:30	6	3	3	2	0	0	0	0	0	0		
		DAY 29		09MAY2003	29	22:30	150	6:30	5	3	3	0	0	0	0	0	0	0		
		DAY 29	*	12MAY2003	32	22:30	150	6:00	5	3	3	0	0	0	0	0	0	0		
		FINAL		12MAY2003	32	22:30	150	6:00	5	3	3	0	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0031022	DAY 1		28APR2003	1	20:30	60	7:00	8	3	3	3	1	1	3	3	1	3	3	RACING THOUGHTS
		DAY 29		27MAY2003	30	22:00	60	6:00	6	3	3	3	2	1	1	1	1	3	1	FEAR OF DARK
		FINAL		27MAY2003	30	22:00	60	6:00	6	3	3	3	2	1	1	1	1	3	1	FEAR OF DARK
PLACEBO (BIPOLAR II)	E0033007	DAY 1		28JAN2003	1	4:00	100	14:00	5	3	3	3	0	1	3	3	2	3	3	CAN'T GET BRAIN TO "SHUT DOWN" - SELDOM GOES INTO DEEP SLEEP
		DAY 29		25FEB2003	29	5:00	220	16:30	5	3	3	3	1	0	3	3	2	3		
		DAY 57		25MAR2003	57	4:30	90	14:30	5	3	3	3	1	0	2	3	2	3		
		FINAL		25MAR2003	57	4:30	90	14:30	5	3	3	3	1	0	2	3	2	3		
PLACEBO (BIPOLAR II)	E0033013	DAY 1		19FEB2003	1	23:00	60	9:00	7	3	0	0	0	0	0	0	1	0		
		DAY 29		19MAR2003	29	23:00	60	8:00	6	3	2	0	0	0	0	0	0	0		
		DAY 57		16APR2003	57	23:00	60	8:00	8	2	0	0	0	0	0	0	1	0		
		FINAL		16APR2003	57	23:00	60	8:00	8	2	0	0	0	0	0	0	1	0		
PLACEBO (BIPOLAR II)	E0033016	DAY 1		08MAY2003	1	0:00	60	8:00	6	3	2	1	0	0	1	3	3	2		
		DAY 29		09JUN2003	33	23:00	30	9:00	7	1	2	2	0	0	0	0	0	2		
		DAY 57		02JUL2003	56	22:00	60	6:00	5	2	3	3	0	0	0	0	0	0		
		FINAL		02JUL2003	56	22:00	60	6:00	5	2	3	3	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0033022	DAY 1		14JUL2003	1	11:00	30	7:30	8	0	2	0	1	3	0	2	1	0	2	ILLNESSES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0031019	DAY 1		11APR2003	1	0	2	0						
		DAY 29		09MAY2003	29	0	1	0						
		DAY 29	*	12MAY2003	32	0	1	0						
		FINAL		12MAY2003	32	0	1	0						
PLACEBO (BIPOLAR II)	E0031022	DAY 1		28APR2003	1	0	3	0						
		DAY 29		27MAY2003	30	0	3	0						
		FINAL		27MAY2003	30	0	3	0						
PLACEBO (BIPOLAR II)	E0033007	DAY 1		28JAN2003	1	0	3	0						
		DAY 29		25FEB2003	29	0	3	0						
		DAY 57		25MAR2003	57	0	3	0						
		FINAL		25MAR2003	57	0	3	0						
PLACEBO (BIPOLAR II)	E0033013	DAY 1		19FEB2003	1	0	2	3	0	0	2	0	2	HEADACHES
		DAY 29		19MAR2003	29	0	1	3	0	0	1	0		
		DAY 57		16APR2003	57	0	1	3	0	0	0	0		
		FINAL		16APR2003	57	0	1	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0033016	DAY 1		08MAY2003	1	0	2	3	0	0	0	0	2	AGITATED AND RESTLESS
		DAY 29		09JUN2003	33	0	1	3	0	0	0	0	1	FEELING UNCOMFORTABLE
		DAY 57		02JUL2003	56	0	1	3	0	0	0	0		
		FINAL		02JUL2003	56	0	1	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0033022	DAY 1		14JUL2003	1	1	3	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0033022	DAY 29	11AUG2003	29	6	-3	1	1	1	0	1	0	2
		DAY 57	11SEP2003	60	6	-3	1	0	1	0	2	0	2
		FINAL	11SEP2003	60	6	-3	1	0	1	0	2	0	2
	E0034007	DAY 1	16MAY2003	1	11		1	3	0	0	2	3	2
		DAY 29	16JUN2003	32	9	-2	2	3	0	0	2	0	2
		DAY 57	14JUL2003	60	9	-2	2	2	0	0	2	1	2
		FINAL	14JUL2003	60	9	-2	2	2	0	0	2	1	2
	E0035004	DAY 1	27NOV2002	1	10		2	3	2	0	1	1	1
	E0035009	DAY 1	27DEC2002	1	8		2	2	0	0	1	1	2
		DAY 29	22JAN2003	27	5	-3	1	1	0	1	1	0	1
		DAY 57	19FEB2003	55	3	-5	0	1	0	0	1	0	1
		FINAL	19FEB2003	55	3	-5	0	1	0	0	1	0	1
	E0035010	DAY 1	10JAN2003	1	14		2	3	2	3	2	0	2
		DAY 29	07FEB2003	29	10	-4	1	1	1	3	2	0	2
		DAY 57	06MAR2003	56	6	-8	1	0	1	1	2	0	1
		FINAL	06MAR2003	56	6	-8	1	0	1	1	2	0	1
	E0035022	DAY 1	09MAY2003	1	16		3	3	2	3	2	0	3
		DAY 29	06JUN2003	29	11	-5	1	2	1	1	3	0	3
		DAY 57	07JUL2003	60	0	-16	0	0	0	0	0	0	0
		FINAL	07JUL2003	60	0	-16	0	0	0	0	0	0	0
	E0039003	DAY 1	25NOV2002	1	13		1	2	3	3	3	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j	OTHER REASON
PLACEBO (BIPOLAR II)	E0033022	DAY 29	11AUG2003	29	1:00	20	7:00	6	1	1	0	0	1	0	0	0	0		
		DAY 57	11SEP2003	60	23:00	15	7:00	7	0	3	1	0	1	2	2	1	0		
		FINAL	11SEP2003	60	23:00	15	7:00	7	0	3	1	0	1	2	2	1	0		
PLACEBO (BIPOLAR II)	E0034007	DAY 1	16MAY2003	1	0:00	45	11:00	10	3	3	3	0	0	0	2	3	0	2	CAN'T STOP THINKING
		DAY 29	16JUN2003	32	1:00	60	11:30	10	3	3	3	2	1	0	2	2	1	3	CAN'T RELAX
		DAY 57	14JUL2003	60	0:00	30	10:30	10	2	3	3	0	0	1	2	2	0	2	CAN'T RELAX
		FINAL	14JUL2003	60	0:00	30	10:30	10	2	3	3	0	0	1	2	2	0	2	CAN'T RELAX
PLACEBO (BIPOLAR II)	E0035004	DAY 1	27NOV2002	1	0:00	60	5:30	5	3	3	2	1	0	0	0	1	0		
PLACEBO (BIPOLAR II)	E0035009	DAY 1	27DEC2002	1	0:00	60	8:00	8	2	2	3	0	0	3	0	0	0		
		DAY 29	22JAN2003	27	21:30	15	9:30	10	2	2	0	0	0	2	0	0	0		
		DAY 57	19FEB2003	55	21:30	20	6:30	8	1	2	0	0	0	1	0	0	0		
		FINAL	19FEB2003	55	21:30	20	6:30	8	1	2	0	0	0	1	0	0	0		
PLACEBO (BIPOLAR II)	E0035010	DAY 1	10JAN2003	1	21:00	35	5:00	5	3	3	3	0	3	3	3	0	3		
		DAY 29	07FEB2003	29	20:00	15	7:30	6	1	3	3	0	3	2	2	0	2		
		DAY 57	06MAR2003	56	20:00	10	5:10	7	0	2	3	0	3	2	2	1	2		
		FINAL	06MAR2003	56	20:00	10	5:10	7	0	2	3	0	3	2	2	1	2		
PLACEBO (BIPOLAR II)	E0035022	DAY 1	09MAY2003	1	19:30	75	6:00	5	3	3	2	1	0	1	2	2	1		
		DAY 29	06JUN2003	29	22:00	30	6:00	6	3	3	3	3	0	3	3	3	3		
		DAY 57	07JUL2003	60	21:00	5	6:00	10	0	0	0	0	0	0	0	0	0		
		FINAL	07JUL2003	60	21:00	5	6:00	10	0	0	0	0	0	0	0	0	0		
PLACEBO (BIPOLAR II)	E0039003	DAY 1	25NOV2002	1	22:00	30	8:00	3	3	3	3	3	3	3	2	2	0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0033022	DAY 29	11AUG2003	29	2	1	3	1	0	0	0		
		DAY 57	11SEP2003	60	1	2	3	0	0	2	0		
		FINAL	11SEP2003	60	1	2	3	0	0	2	0		
PLACEBO (BIPOLAR II)	E0034007	DAY 1	16MAY2003	1	0	3	3	0	0	0	2		
		DAY 29	16JUN2003	32	0	3	3	0	0	0	1	3	CAN'T RELAX
		DAY 57	14JUL2003	60	0	3	3	0	0	0	1	3	CAN'T RELAX
		FINAL	14JUL2003	60	0	3	3	0	0	0	1	3	CAN'T RELAX
PLACEBO (BIPOLAR II)	E0035004	DAY 1	27NOV2002	1	0	2	0						
PLACEBO (BIPOLAR II)	E0035009	DAY 1	27DEC2002	1	0	3	0						
		DAY 29	22JAN2003	27	0	1	3	0	0	3	0		
		DAY 57	19FEB2003	55	0	1	3	0	0	2	0		
		FINAL	19FEB2003	55	0	1	3	0	0	2	0		
PLACEBO (BIPOLAR II)	E0035010	DAY 1	10JAN2003	1	2	1	0						
		DAY 29	07FEB2003	29	2	2	0						
		DAY 57	06MAR2003	56	0	1	0						
		FINAL	06MAR2003	56	0	1	0						
PLACEBO (BIPOLAR II)	E0035022	DAY 1	09MAY2003	1	2	3	0						
		DAY 29	06JUN2003	29	3	2	1	0	0	2	1		
		DAY 57	07JUL2003	60	0	0	0						
		FINAL	07JUL2003	60	0	0	0						
PLACEBO (BIPOLAR II)	E0039003	DAY 1	25NOV2002	1	0	1	3						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	SLEEP COMPONENTS 1	2	3	4	5	6	7
PLACEBO (BIPOLAR II)	E0040001	DAY 1	27JUN2003	1	8		2	3	1	0	1	0	1
		DAY 29	25JUL2003	29	9	1	1	2	1	0	1	2	2
		DAY 57	22AUG2003	57	6	-2	1	1	1	0	1	0	2
		FINAL	22AUG2003	57	6	-2	1	1	1	0	1	0	2
	E0040004	DAY 1	18JUL2003	1	12		2	3	2	3	1	0	1
	E0041002	DAY 1	21JAN2003	1	11		2	3	1	1	1	1	2
		DAY 29	18FEB2003	29	7	-4	1	2	1	1	1	0	1
		FINAL	18FEB2003	29	7	-4	1	2	1	1	1	0	1
	E0041005	DAY 1	05MAR2003	1	15		2	3	3	1	1	3	2
		DAY 29	02APR2003	29	15	0	3	3	3	3	1	0	2
		DAY 57	30APR2003	57	14	-1	2	3	3	3	1	1	1
		FINAL	30APR2003	57	14	-1	2	3	3	3	1	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	USUAL BED TIME	MINS TO FALL ASLEEP	USUAL GET UP TIME	HRS SLEEP PER NIGHT	TROUBLE SLEEPING 5a	5b	5c	5d	5e	5f	5g	5h	5i	5j OTHER REASON
PLACEBO (BIPOLAR II)	E0040001	DAY 1	27JUN2003	1	23:00	35	5:30	6	3	0	1	0	0	0	0	0	0	
		DAY 29	25JUL2003	29	23:00	20	6:00	7	2	0	1	0	0	0	0	0	0	
		DAY 57	22AUG2003	57	23:00	30	5:00	6	0	3	0	0	0	0	0	0	0	
		FINAL	22AUG2003	57	23:00	30	5:00	6	0	3	0	0	0	0	0	0	0	
PLACEBO (BIPOLAR II)	E0040004	DAY 1	18JUL2003	1	23:00	50	7:00	5	3	3	0	0	0	0	0	0	0	
PLACEBO (BIPOLAR II)	E0041002	DAY 1	21JAN2003	1	22:00	90	5:30	6	2	2	2	0	0	0	2	1	1	
		DAY 29	18FEB2003	29	0:00	60	9:00	7	1	2	2	0	1	0	1	0	0	
		FINAL	18FEB2003	29	0:00	60	9:00	7	1	2	2	0	1	0	1	0	0	
PLACEBO (BIPOLAR II)	E0041005	DAY 1	05MAR2003	1	23:30	45	3:30	3	3	3	3	0	0	0	0	1	2	
		DAY 29	02APR2003	29	23:30	45	6:00	3	3	3	3	0	0	0	0	0	3	
		DAY 57	30APR2003	57	23:30	45	6:00	4	3	3	3	0	0	0	0	0	1	
		FINAL	30APR2003	57	23:30	45	6:00	4	3	3	3	0	0	0	0	0	1	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TROUBLE STAYING AWAKE	ENTHU-SIASM	BED PARTNER/ ROOMMATE	PARTNER'S COMMENT 10a	10b	10c	10d	10e	OTHER REASON
PLACEBO (BIPOLAR II)	E0040001	DAY 1	27JUN2003	1	0	2	3	0	0	0	0		
		DAY 29	25JUL2003	29	1	2	0						
		DAY 57	22AUG2003	57	0	3	3	0	0	0	0		
		FINAL	22AUG2003	57	0	3	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0040004	DAY 1	18JUL2003	1	0	2	3	0	0	0	0		
PLACEBO (BIPOLAR II)	E0041002	DAY 1	21JAN2003	1	1	2	3	2	0	2	0	2	GETTING UP IN THE MIDDLE OF THE NIGHT
		DAY 29	18FEB2003	29	0	1	3	2	0	1	0		
		FINAL	18FEB2003	29	0	1	3	2	0	1	0		
PLACEBO (BIPOLAR II)	E0041005	DAY 1	05MAR2003	1	0	3	0						
		DAY 29	02APR2003	29	2	2	0						
		DAY 57	30APR2003	57	0	2	0						
		FINAL	30APR2003	57	0	2	0						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Refer to the last page to see decodes for the scores.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/PSQI100.SAS
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Listing 12.2.6.6 Pittsburgh Sleep Quality Index (PSQI)

SLEEP COMPONENTS
1. Overall Patient Sleep Quality -- 0 = Very good, 1 = Fairly good, 2 = Fairly bad, 3 = Very bad
2. Sleep Latency -- sum of question 2 (# of min takes to fall asleep each night)& question 5a (cannot get to sleep within 30 min)
   question 2 score -- 0 = <= 15 min, 1 = 16-30 min, 2 = 31-60 min, 3 = >60 min
   question 5 score -- 0 = Not during past month, 1 = Less than once per wk, 2 = Once or twice a wk, 3 = Three or more times a wk
   0 = total 0, 1 = total 1-2 2 = total 3-4, 3 = total 5-6
3. Sleep Duration -- using question 4 (number of hours of actual sleep)
   0 = >7, 1 = 6-7, 2 = 5-<6, 3 = <5
4. Habitual Sleep Efficiency -- uses questions 1 (usual bed time), 3 (usual getting up time), & question 4 (hr of sleep per night)
   Calculate number of hours in bed -- question 3 -question 1
   Calculate habitual sleep efficiency -- question 4 response/hours spent in bed)*100
   final score definition -- 0 = >=85%, 1 = 75-84%, 2 = 65-74%, 3 = <65%
5. Sleep Disturbances -- the sum of questions 5b through 5j
   0 = Not during the past month, 1 = Less than once a week, 2 = Once or twice a week, 3 = Three or more times a week
6. Sleep Medication -- question 7 (how often take medication during the past month to help you sleep)
   0 = Not during the past month, 1 = Less than once a week, 2 = Once or twice a week, 3 = Three or more times a week
7. Daytime Dysfunction -- sum of question 8 (trouble staying awake) & question 9 (problem to keep up enthusiasm to get things done)
   0 = No problems during the past month, 1 = Less than once a week and only a very slight problem
   2 = Once or twice a week and somewhat of a problem, 3 = Three or more times a week and a very big problem

TROUBLE SLEEPING
0 = Not during the past month, 1 = Less than once a week, 2 = Once or twice a week, 3 = Three or more times a week
5a. Cannot get to sleep within 30 minutes
5b. Wake up in the middle of the night or early morning
5c. Have to get up to use the bathroom
5d. Cannot breathe comfortabley
5e. Cough or snore loudly
5f. Feel too cold
5g. Feel too hot
5h. Had bad dreams
5i. Have pain
5j. Other reasons

Trouble Staying Awake - 0 = Not during the past month, 1 = Less than once a wk, 2 = Once or twice a wk, 3 = Three or more times a wk
Enthusiasm -- 0 = No problem at all, 1 = Only a very slight problem, 2 = Somewhat of a problem, 3 = A very big problem
Bed Partner/roomate
   0 = No bed partner or roommate, 1 = Partner/roommate in other room
   2 = Partner in same room, but not same bed, 3 = Partner in same bed

PARTNER'S COMMENTS
0 = Not during the past month, 1 = Less than once a week, 2 = Once or twice a week, 3 = Three or more times a week
10a. Loud Snoring
10b. Long pauses between breaths while sleeping
10c. Legs twitching or jerking while you sleep
10d. Episodes of disorientation or confusion during sleep
10e. Other restlessness while you sleep

Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1	04FEB2003	1	40		46		3	4		4	3	3	2	3	1	1	2	4	4	3	0	2
		DAY 29	05MAR2003	30	48	8	61	15	4	4		4	4	3	4	3	3	2	3	3	4	4	0	4
		DAY 57	02APR2003	58	48	8	61	15	4	3		4	4	4	4	4	2	1	3	4	4	4	0	4
	E0002010	DAY 1	04APR2003	1	21		13		1	1	1	3	1	1	1	1	1	1	4	3	1	1	0	1
	E0002012	DAY 1	21APR2003	1	42		50		3	3	2	3	3	3	3	3	2	2	2	5	5	3	0	3
		DAY 29	21MAY2003	31	48	6	61	11	4	4	5	3	3	4	3	4	3	2	1	3	5	4	0	4
		DAY 57	16JUN2003	57	56	14	75	25	4	5	4	3	4	5	4	5	4	3	2	4	4	5	0	4
	E0002015	DAY 1	04JUN2003	1	33		34		3	1		3	1	4	2	2	1	1	3	4	4	2	0	1
	E0002018	DAY 1	24JUL2003	1	40		46		3	3		3	1	3	3	2	4	1	4	4	3	3	0	3
		DAY 29	01AUG2003	9	38	-2	43	-3	2	3		4	1	2	4	4	4	1	4	1	2	3	0	4
	E0003004	DAY 1	17DEC2002	1	32		32		2	2		2	3	1	2	1	3	1	1	5	5	2	0	2
	E0003005	DAY 1	23DEC2002	1	29		27		1	2	1	2	2	2	1	2	1	1	2	5	5	2	0	2
		DAY 29	21JAN2003	30	35	6	38	11	1	2	2	1	1	3	5	4	1	1	2	5	5	2	3	2
		DAY 57	18FEB2003	58	36	7	39	12	2	2	2	2	2	3	3	3	1	1	3	5	5	2	2	2
	E0003007	DAY 1	02JAN2003	1	46		57		3	3	3	3	4	2	4	4	4	1	2	5	5	3	2	3
		DAY 29	30JAN2003	29	49	3	63	6	4	2	3	4	4	4	4	3	4	4	1	5	4	3	4	3
		DAY 57	27FEB2003	57	56	10	75	18	4	4	4	4	4	3	4	4	4	3	4	5	5	4	4	4
	E0003015	DAY 1	05MAY2003	1	35		38		3	2	2	1	2	3	3	3	2	2	3	4	2	3	0	3
		DAY 29	04JUN2003	31	52	17	68	30	4	4	5	3	4	2	4	4	5	2	2	5	4	4	4	4
		DAY 57	02JUL2003	59	46	11	57	19	3	3	3	4	4	2	4	3	4	3	3	4	2	4	4	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	DAY 1	*	24SEP2002	-7	37		41		4	1	3	3	1	2	2	3	1	2	3	5	5	2	0	2
		DAY 1		01OCT2002	1	33		34		4	1	2	2	2	3	1	2	1	1	4	4	5	1	5	1
		DAY 29	*	10OCT2002	10	45	12	55	21	4	3	4	3	3	2	3	4	1	2	3	5	5	3	3	3
		DAY 29		29OCT2002	29	51	18	66	32	4	3	4	5	3	4	4	4	1	2	4	5	5	3	4	4
		DAY 57		26NOV2002	57	46	13	57	23	4	2	4	2	3	3	4	4	1	2	4	5	5	3	4	2
	E0004013	DAY 1		14JAN2003	1	39		45		3	1	3	1	4	4	3	3	2	2	4	3	4	2	0	2
		DAY 29		05FEB2003	23	25	-14	20	-25	1	1	2	1	2	1	2	1	2	2	4	2	2	2	2	1
	E0004018	DAY 1		19MAR2003	1	40		46		2	3	4	2	2	1	3	3	3	2	4	5	4	2	0	3
		DAY 29		16APR2003	29	52	12	68	22	3	4	4	3	4	2	4	4	4	3	4	4	5	4	4	4
		DAY 57		13MAY2003	56	49	9	63	17	2	4	4	3	4	2	3	4	4	3	4	4	4	4	4	4
	E0004021	DAY 1		14MAY2003	1	38		43		3	3	2	2	2	3	3	3	3	2	3	4	3	2	0	3
		DAY 29		11JUN2003	29	48	10	61	18	3	4	4	3	4	4	4	3	3	1	3	4	4	4	4	4
		DAY 57		09JUL2003	57	53	15	70	27	3	4	4	3	4	4	4	3	4	5	4	4	3	4	4	4
	E0005002	DAY 1		03OCT2002	1	44		54		4	3	3	3	3	4	3	3	2	4		3	3	3	4	3
		DAY 29		28OCT2002	26	54	10	71	17	4	4	4	4	3	4	3	4	4	5	5	3	3	4	4	4
		DAY 57		25NOV2002	54	55	11	73	19	4	4	3	4	4	4	4	4	4	4	4	4	4	4	4	4
	E0005004	DAY 1		24SEP2002	-7	43		52		4	3	5	3	4	2	2	2	1	1	4	5	5	2	0	2
	E0005013	DAY 1		07NOV2002	1	39		45		2	3	4	2	2	3	3	3	3	2	3	4	3	2	2	3
	E0005024	DAY 1		10FEB2003	1	25		20		1	1	1	2	1	2	2	1	3	1	1	4	4	1	0	1
		DAY 29		13MAR2003	32	54	29	71	51	4	4	3	4	4	4	5	4	4	3	4	4	3	4	4	4
		DAY 57		09APR2003	59	57	32	77	57	4	4	4	4	4	4	5	4	4	4	4	4	4	4	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0005027	DAY 1	11MAR2003	1	39		45		4	2	1	3	3	4	2	3	4	2	2	4	3	2	0	2
		DAY 29	03APR2003	24	47	8	59	14	4	3	3	4	4	4	2	3	3	3	3	4	4	3	1	3
	E0005037	DAY 1	07MAY2003	1	30		29		3	2	2	1	2	2	2	2	4	2	2	3	1	2	0	2
		DAY 29	05JUN2003	30	31	1	30	1	3	3	2	2	2	2	2	3	1	2	2	2	2	3	3	3
		DAY 57	02JUL2003	57	35	5	38	9	2	3	2	2	3	3	2	3	1	3	3	2	3	3	3	3
	E0005042	DAY 1	24JUN2003	1	32		32		2	1	1	1	3	3	2	2	1	3	5	4	2	2	0	2
		DAY 29	23JUL2003	30	54	22	71	39	4	4	3	3	4	3	4	4	3	4	5	5	4	4	5	4
		DAY 57	18AUG2003	56	55	23	73	41	4	4	3	4	4	4	4	4	3	3	4	5	4	5	4	4
	E0006005	DAY 1	05DEC2002	1	42		50		2	1	2	3	3	3	4	1	5	3	4	5	3	3	0	1
		DAY 29	03JAN2003	30	38	-4	43	-7	4	3	1	1	3	3	3	3	5	1	3	3	3	2	3	3
		DAY 57	30JAN2003	57	39	-3	45	-5	4	1	1	1	3	3	3	3	5	1	3	4	4	3	3	3
	E0006018	DAY 1	13MAR2003	1	44		54		2	2	3	4	4	4	3	3	3	3	4	4	3	2	0	2
		DAY 29	24MAR2003	12	55	11	73	19	4	4	4	4	4	4	4	4	4	4	4	4	4	4	0	4
	E0007013	DAY 1	13JUN2003	1	40		46		5	1	1	2	3	2	3	2	2	3	4	5	5	2	0	2
		DAY 29	10JUL2003	28	43	3	52	6	5	3	1	3	3	1	3	2	2	3	4	5	5	3	3	3
		DAY 57	07AUG2003	56	47	7	59	13	5	3	1	2	3	2	3	3	3	4	4	5	5	4	4	3
	E0010004	DAY 1	11DEC2002	1	23		16		2	1	1	1	1	1	1	1	1	1	4	5	1	2	4	2
		DAY 57	06FEB2003	58	37	14	41	25	4	2	1	3	3	3	3	2	1	3	3	3	3	3	3	3
	E0010012	DAY 1	07JAN2003	1	34		36		2	3	1	2	2	3	1	3	2	1	4	4	4	2	0	2
		DAY 29	04FEB2003	29	42	8	50	14	2	3	2	2	3	4	2	3	3	3	4	4	4	3	3	3
		DAY 57	05MAR2003	58	45	11	55	19	3	2	2	3	3	4	3	4	3	3	4	4	4	3	4	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	DAY 1	05MAY2003	1	44		54		4	2	4	3	4	2	3	3	3	1	1	5	5	4	0	2
		DAY 29	04JUN2003	31	51	7	66	12	4	4	5	3	3	2	3	4	3	3	2	5	5	5	5	4
		DAY 57	02JUL2003	59	49	5	63	9	3	4	5	1	4	2	4	4	4	4	1	5	4	4	5	4
	E0010032	DAY 1	10JUL2003	1	33		34		3	2	3	3	2	2	1	2	1	1	2	4	5	2	0	2
		DAY 29	17JUL2003	8	33	0	34	0	2	3	3	2	3	4	2	2	1	1	3	1	4	2	1	1
	E0011025	DAY 1	26JUN2003	1	38		43		3	2	2	3	3	3	2	3	2	3	3	4	2	3	0	3
		DAY 29	22JUL2003	27	46	8	57	14	4	3	4	3	2	4	3	3	2	4	4	3	4	3	4	4
		DAY 57	22AUG2003	58	55	17	73	30	4	4	4	4	4	5	3	4	3	4	4	4	4	4	0	4
	E0013007	DAY 1	20MAR2003	1	41		48		3	2	2	2	3	3	2	2	3	2	5	5	5	2	3	2
		DAY 29	07APR2003	19	45	4	55	7	3	2	4	3	3	4	2	2	4	3	5	4	4	2	3	2
	E0013009	DAY 1	02APR2003	1	33		34		3	2	1	2	3	2	1	2	2	1	3	5	4	2	0	2
		DAY 29	01MAY2003	30	48	15	61	27	3	3	3	4	4	4	4	3	3	3	4	4	3	3	3	4
		DAY 57	29MAY2003	58	50	17	64	30	3	3	3	4	4	4	4	3	4	3	4	5	3	3	4	4
	E0014006	DAY 1	25MAR2003	1	27		23		3	2	2	2	2	2	1	1	3	2	1	3	2	1	0	2
		DAY 29	23APR2003	30	40	13	46	23	3	3	3	2	3	1	3	3	3	2	2	5	3	4	4	4
		DAY 57	21MAY2003	58	44	17	54	31	4	3	3	3	3	3	3	3	3	2	2	4	4	4	3	4
	E0014010	DAY 1	22APR2003	1	33		34		2	3	2	2	1	3	3	2	4	1	1	4	2	3	0	2
		DAY 29	21MAY2003	30	42	9	50	16	2	3	4	5	3	3	3	3	4	2	1	3	3	3	3	3
		DAY 57	17JUN2003	57	37	4	41	7	3	2	4	3	3	4	3	3	1	1	1	4	3	2	3	2
	E0016001	DAY 1	22JAN2003	1	36		39		3	2	2	2	2	4	3	1	3	2	3	4	3	2	0	3
		DAY 29	19FEB2003	29	55	19	73	34	3	5	4	4	4	4	4	5	2	3	4	4	5	4	4	4
		DAY 57	19MAR2003	57	60	24	82	43	5	5	4	4	4	4	4	5	3	4	4	4	5	5	5	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0016004	DAY 1		03FEB2003	1	23		16		3	2	2	2	2	2	1	1	1	1	1	3	1	1	0	1
	E0018001	DAY 1		29OCT2002	1	40		46		4	2	4	3	3	4	1	2	1	3	4	5	2	2	0	3
		DAY 29		27NOV2002	30	59	19	80	34	4	3	4	5	4	4	4	5	5	4	4	5	3	5	4	5
		DAY 57		24DEC2002	57	65	25	91	45	5	5	5	4	5	5	4	5	5	4	4	5	4	5	5	5
	E0018006	DAY 1		17DEC2002	1	24		18		3	1	5	1	3	1	1	1	3	1	1	1	1	1	0	1
		DAY 29		14JAN2003	29	43	19	52	34	3	3		3	3	3	3	3	3	3	3	4	3	3	5	3
		DAY 57		13FEB2003	59					3	3		3	3	3	2	3		2	3	2	3	3	5	3
	E0019004	DAY 1		07NOV2002	1	36		39		4	1	2	3	1		3	3	2	3	3	3	2	3	0	3
		DAY 29		05DEC2002	29	30	-6	29	-10	3	1	2	2	1		2	2	1	2	4	4	2	2	3	2
		DAY 29	*	19DEC2002	43	34	-2	36	-3	3	1	3	3	1	3	2	2	1	3	4	2	3	3	1	3
	E0019011	DAY 1		21NOV2002	1	26		21		5	1	1	1	1	1	1	1	1	1	1	5	5	1	0	1
		DAY 29		19DEC2002	29	32	6	32	11	4	3	2	2	2	3	2	2	1	2	1	3	2	3	2	3
		DAY 57		16JAN2003	57	18	-8	7	-14	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	E0019025	DAY 1		06FEB2003	1	45		55		4	2	3	3	2	3	2	3	4	4	4	4	5	2	0	3
		DAY 29		06MAR2003	29	58	13	79	24	5	4	5	4	3	3	3	5	3	5	5	5	4	4	4	4
		DAY 57		03APR2003	57	61	16	84	29	3	4	5	4	5	4	4	5	4	5	5	4	4	5	5	5
	E0019026	DAY 1		24FEB2003	1	36		39		3	2	2	3	4	1	3	3	2	4	1	4	2	2	0	3
	E0019043	DAY 1		03JUN2003	1	27		23		4	1	1	2	2	3	1	2	2	2	1	2	2	2	3	1
		DAY 29		01JUL2003	29	43	16	52	29	4	3	3	4	3	3	2	3	3	3	3	3	3	3	3	3
		DAY 57		29JUL2003	57	40	13	46	23	4	2	3	3	3	3	2	2	2	3	3	4	3	3	3	3
	E0020001	DAY 1		29OCT2002	1	36		39		3	1	3	2	2	3	3	3	4	3	2	4	2	1	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	DAY 29	26NOV2002	29	47	11	59	20	5	3	4	3	3	4	4	3	4	3	2	5	1	3	4	3
		DAY 57	20DEC2002	53	45	9	55	16	4	2	3	3	3	3	4	4	4	3	2	4	3	3	3	3
	E0020006	DAY 1	16DEC2002	1	25		20		2	1	1	1	2	3	2	1	2	2	2	3	1	2	0	1
	E0020007	DAY 1	15JAN2003	1	35		38		4	3	3	2	2	2	1	3	1	1	2	4	4	3	0	3
	E0020011	DAY 1	26FEB2003	1	34		36		2	2	2	1	4	2	3	2	3	2	3	3	2	3	0	2
		DAY 29	26MAR2003	29	47	13	59	23	4	3	3	3	4	3	4	3	5	2	3	3	3	4	4	4
		DAY 57	23APR2003	57	54	20	71	35	4	5	4	3	5	1	5	4	5	4	2	3	5	4	4	4
	E0020013	DAY 1	05MAR2003	1	64		89		4	3	5	4	5	5	5	5	5	4	4	5	5	5	0	5
	E0022008	DAY 1	12NOV2002	1	51		66		4	3	3	3	3	4	3	3	4	3	4	5	5	4	0	3
		DAY 29	12DEC2002	31	51	0	66	0	4	3	3	3	3	4	4	4	3	4	4	4	4	4	4	4
		DAY 57	07JAN2003	57	49	-2	63	-3	4	4	3	3	3	3	4	4	3	3	3	4	4	4	4	4
	E0022017	DAY 1	19DEC2002	1	26		21		2	2	1	2	2	2	2	2	2	1	2	3	1	2	0	2
		DAY 29	17JAN2003	30	56	30	75	54	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
		DAY 57	13FEB2003	57	69	43	98	77	5	5	5	5	5	5	4	5	5	5	5	5	5	5	5	5
	E0022018	DAY 1	12DEC2002	1	45		55		3	3	4	4	4	3	3	3	1	3	3	4	4	3	0	2
		DAY 29	09JAN2003	29	30	-15	29	-26	3	2	1	3	2	3	1	1	2	1	1	4	4	2	2	2
		DAY 57	06FEB2003	57	36	-9	39	-16	4	3	2	3	3	3	1	2	2	2	2	3	4	2	0	2
	E0022022	DAY 1	30DEC2002	1	18		7		1	1	1	1	1	1	1	1	5	1	1	1	1	1	1	1
		DAY 29	28JAN2003	30	18	0	7	0	1	1	2	1	1	1	1	1	2	1	2	1	1	2	1	2
		DAY 57	27FEB2003	60	17	-1	5	-2	1	1	1	1	2	2	1	1	1	1	1	1	2	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	DAY 1	06FEB2003	1	35		38		3	2	2	2	1	2	1	3	2	3	3	4	4	3	0	2
		DAY 29	06MAR2003	29	52	17	68	30	4	4	4	4	3	3	3	4	4	3	4	4	4	4	4	4
		DAY 57	03APR2003	57	57	22	77	39	4	4	4	4	4	4	4	5	5	3	4	4	4	4	4	5
	E0022030	DAY 1	14FEB2003	1	22		14		3	2	1	1	2	1	1	2	1	1	1	2	2	2	0	2
	E0022031	DAY 1	18FEB2003	1	27		23		4	2	1	2	2	2	2	1	1	1	2	3	3	1	0	2
		DAY 29	18MAR2003	29	30	3	29	6	3	2	1	2	2	3	2	2	1	1	2	4	3	2	3	3
		DAY 57	15APR2003	57	40	13	46	23	4	3	2	2	3	3	3	3	2	2	2	4	4	3	3	4
	E0022032	DAY 1	18FEB2003	1	24		18		1	1	2	1	2	1	1	1	1	1	2	4	4	2	0	2
		DAY 29	21MAR2003	32	43	19	52	34	3	3	3	3	3	4	3	3	2	3	4	3	3	3	3	3
		DAY 57	18APR2003	60	36	12	39	21	3	3	2	1	3	3	1	2	1	3	3	4	4	3	3	3
	E0022035	DAY 1	19FEB2003	1	43		52		2	3	4	1	3	4	4	3	3	3	2	3	4	4	0	3
		DAY 29	26FEB2003	8	32	-11	32	-20	1	2	3	1	3	3	2	2	3	3	2	2	2	3	1	2
	E0022036	DAY 1	25FEB2003	1	38		43		1	3	4	3	3	3	2	3	4	1	3	2	3	3	0	1
		DAY 29	25MAR2003	29	43	5	52	9	4	3	4	3	2	2	2	3	4	1	3	4	4	4	3	3
		DAY 57	22APR2003	57	44	6	54	11	4	3	4	4	4	1	4	3	4	1	1	3	4	4	3	3
	E0022056	DAY 1	17APR2003	1	39		45		3	2	4	3	2	3	4	2	2	1	2	4	4	3	0	3
	E0022060	DAY 1	30APR2003	1	47		59		4	3	4	2	3	3	3	3	5	4	3	4	3	3	0	3
		DAY 29	28MAY2003	29	42	-5	50	-9	3	2	2	2	3	4	3	3	4	4	2	5	2	3	2	2
		DAY 57	24JUN2003	56	56	9	75	16	5	4	3	4	4	4	4	4	5	4	3	4	4	4	4	4
	E0022063	DAY 1	07MAY2003	1	43		52		4	2	3	3	4	4	3	2	3	2	2	4	4	3	0	3
		DAY 29	04JUN2003	29	63	20	88	36	4	5	4	4	5	5	5	5	4	4	4	5	5	4	5	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	DAY 1	30JAN2003	1	35		38		4	2	2	2	1	1	1	2	5	2	2	3	4	4	0	1
		DAY 29	25FEB2003	27	33	-2	34	-4	3	1	4	3	1	1	1	2	1	3	4	4	3	2	2	1
		DAY 57	24MAR2003	54	41	6	48	10	4	2	4	4	1	5	5	1	3	1	2	5	1	3	4	1
	E0023013	DAY 1	27FEB2003	1	34		36		2	3	4	4	1	1	1	3	2	4	3	1	3	2	3	2
		DAY 29	06MAR2003	8	34	0	36	0	2	3	4	4	1	1	1	3	2	4	3	1	3	2	3	2
	E0023015	DAY 1	11MAR2003	1	36		39		4	1	3	3	3	1	2	3	1	3	3	5	2	2	2	2
		DAY 29	08APR2003	29	44	8	54	15	4	2	3	4	2	2	4	3	3	4	2	4	4	3	3	3
		DAY 57	06MAY2003	57	58	22	79	40	5	4	4	4	3	3	3	5	3	4	5	5	5	5	5	4
	E0023034	DAY 1	09JUN2003	1	39		45		4	2	4	2	2	3	2	2	3	2	3	5	3	2	0	2
		DAY 29	07JUL2003	29	38	-1	43	-2	3	2	3	1	3	2	2	2	4	4	3	4	3	2	4	2
		DAY 57	05AUG2003	58	44	5	54	9	3	3	3	3	3	2	3	3	4	4	3	4	3	3	4	3
	E0023037	DAY 1	18JUN2003	1	26		21		3	1	1	1	2	3	1	1	5	1	1	4	1	1	0	1
		DAY 29	18JUL2003	31	62	36	86	65	5	5	5	4	5	5	4	5	5	2	2	5	5	5	5	4
		DAY 57	15AUG2003	59	57	31	77	56	5	4	4	4	4	4	4	5	5	1	2	5	5	5	5	4
	E0023038	DAY 1	30JUN2003	1	30		29		2	2	1	2	1	2	2	4	2	2	3	4	1	2	0	2
		DAY 29	28JUL2003	29	42	12	50	21	4	3	2	5	3	2	3	2	4	1	4	4	2	3	4	3
		DAY 57	27AUG2003	59	44	14	54	25	3	4	2	4	3	2	4	2	4	1	3	5	4	3	4	3
	E0023044	DAY 1	16JUL2003	1	28		25		1	1	2	1	1	3	2	1	3	4	2	2	3	2	0	2
		DAY 29	12AUG2003	28	29	1	27	2	2	1	2	2	2	3	2	2	2	4	3	2	1	1	1	1
	E0023045	DAY 1	17JUL2003	1	22		14		1	1	1	3	1	1	2	1	5	1	1	1	2	1	0	1
		DAY 29	14AUG2003	29	32	10	32	18	2	2	2	2	3	1	3	2	3	3	1	4	2	2	3	2
		DAY 57	11SEP2003	57	48	26	61	47	2	4	5	3	2	1	2	5	4	4	4	5	4	3	5	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	DAY 1	03APR2003	1	30		29		4	1	2	1	1	2	3	2	1	1	3	5	3	1	0	1
		DAY 29	01MAY2003	29	51	21	66	37	4	4	3	3	4	4	3	4	3	2	4	5	4	4	4	3
		DAY 57	29MAY2003	57	55	25	73	44	4	4	4	4	4	4	4	4	4	2	4	5	4	4	4	4
	E0026010	DAY 1	22JAN2003	1	35		38		3	2	2	2	3	1	3	3	3	1	3	4	3	2	0	3
		DAY 29	30JAN2003	9	52	17	68	30	3	4	5	4	4	2	4	4	5	2	4	4	4	3	3	3
	E0026017	DAY 1	06MAR2003	1	24		18		4	2	1	1	1	1	2	1	1	1	1	3	4	1	0	2
		DAY 29	21MAR2003	16	50	26	64	46	4	3	1	4	4	3	4	4	4	2	4	5	4	4	5	4
	E0026018	DAY 1	20MAR2003	1	29		27		3	2	2	2	2	3	2	2	1	1	2	2	3	2	0	2
		DAY 29	17APR2003	29	55	26	73	46	3	4	4	5	4	5	4	5	3	4	2	3	5	4	4	4
		DAY 57	15MAY2003	57	53	24	70	43	3	4	4	4	4	4	4	4	2	4	4	4	4	4	4	4
	E0026025	DAY 1	09MAY2003	1	19		9		2	1	1	1	1	2	1	1	1	1	1	4	1	1	0	1
		DAY 29	05JUN2003	28	52	33	68	59	4	3	3	3	4	5	4	4	4	2	3	5	4	4	4	4
		DAY 57	03JUL2003	56	50	31	64	55	3	3	3	4	4	5	4	4	4	2	2	4	4	4	4	4
	E0026029	DAY 1	09JUL2003	1	25		20		1	1	1	2	3	4	2	1	2	1	1	2	3	1	0	1
	E0026030	DAY 1	09JUL2003	1	42		50		5	2	3	3	3	3	2	3	3	2	1	5	4	3	0	3
		DAY 29	04AUG2003	27	55	13	73	23	5	4	4	3	4	4	4	5	3	3	3	5	4	4	4	4
		DAY 57	03SEP2003	57	51	9	66	16	4	4	3	3	4	4	4	4	3	3	3	4	4	4	4	3
	E0026031	DAY 1	21JUL2003	1	53		70		4	4	3	4	4	5	3	3	5	4	4	3	4	3	0	3
		DAY 29	18AUG2003	29	53	0	70	0	2	3	5	4	5	5	3	4	4	4	5	1	4	4	4	3
		DAY 57	15SEP2003	57	52	-1	68	-2	2	3	3	4	5	5	4	4	3	3	5	4	4	3	5	3
	E0027003	DAY 1	23JAN2003	-5	36		39		2	2	2	3	1	4	3	3	2	1	3	4	4	2	3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0027003	DAY 29		27FEB2003	31	42	6	50	11	3	3	3	3	3	4	2	4	1	1	4	4	4	3	4	3
		DAY 57		25MAR2003	57	42	6	50	11	3	3	3	4	3	4	3	3	2	2	3	4	2	3	4	3
	E0028004	DAY 1	*	27SEP2002	-3	18		7		4	1	1	1	1	1	1	1	2	1	1	1	1	1	0	2
		DAY 1		30SEP2002	1	31		30		5	2	3	1	3	3	1	1	2	1	1	3	3	2	0	1
		DAY 29	*	07OCT2002	8	39	8	45	15	3	3	1	2	3	3	3	3	3	3	3	3	3	3	2	3
		DAY 29		09OCT2002	10	18	-13	7	-23	4	1	1	1	1	2	1	1	1	1	1	1	1	1	3	1
	E0028006	DAY 1	*	01OCT2002	-3	35		38		3	1	1	2	2	5	3	3	2	2	2	3	4	2	4	2
		DAY 1		04OCT2002	1	27		23		3	1	1	3	2	4	2	1	1	2	1	3	2	1	0	1
		DAY 29	*	11OCT2002	8	28	1	25	2	1	1	3	2	2	4	2	2	1	1	1	3	4	1	3	1
		DAY 29		31OCT2002	28	42	15	50	27	2	3	4	4	3	4	3	3	2	2	2	4	4	2	4	3
		DAY 57		04DEC2002	62	46	19	57	34	4	2	3	3	4	5	5	4	2	3	1	4	4	2	4	4
	E0028008	DAY 1	*	08OCT2002	-7	25		20		3	1	3	3	1	1	1	2	1	3	1	2	1	2	3	2
		DAY 1		15OCT2002	1	43		52		4	3	4	3	3	3	3	3	1	3	3	3	4	3	5	4
		DAY 29		14NOV2002	31	42	-1	50	-2	4	4	3	3	4	1	3	3	1	3	2	4	3	4	5	4
		DAY 57		10DEC2002	57	41	-2	48	-4	4	3	2	4	4	2	3	3	3	2	1	3	3	4	3	3
	E0028009	DAY 1	*	10OCT2002	-5	40		46		3	3	1	2	2	4	2	3	3	2	3	4	5	3	0	3
		DAY 1		15OCT2002	1	43		52		2	3	3	2	4	4	2	3	4	2	3	5	3	3	0	3
		DAY 29		14NOV2002	31	53	10	70	18	3	4	3	3	4	5	4	4	5	2	4	5	3	4	3	4
		DAY 57		12DEC2002	59	44	1	54	2	1	4	3	2	5	5	3	2	3	3	4	4	3	2	4	4
	E0028016	DAY 1		14NOV2002	1	17		5		1	1	1	1	1	1	1	1	1	1	1	4	1	1	0	1
		DAY 29		12DEC2002	29	37	20	41	36	4	3	4	3	3	3	1	3	1	1	1	4	3	3	2	3
		DAY 57		09JAN2003	57	52	35	68	63	3	4	4	4	4	4	3	4	2	3	4	5	4	4	4	4
	E0028017			19NOV2002		39		45		3	1	1	3	4	4	2	3	4	3	1	3	4	3	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT MAX	CHG FROM BSLN MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	DAY 1	21JAN2003	1	23		16		3	1	1	1	2	2	1	1	2	1	1	3	3	1	0	1
		DAY 29	20FEB2003	31	29	6	27	11	4	1	2	2	2	2	3	2	2	1	1	3	2	2	0	2
	E0028029	DAY 1	04FEB2003	1	32		32		2	1	2	1	3	3	2	3	2	1	2	5	4	1	0	2
		DAY 29	06MAR2003	31	42	10	50	18	3	1	1	3	4	4	4	3	1	2	3	5	5	3	3	2
		DAY 57	03APR2003	59	61	29	84	52	4	5	4	4	5	5	5	5	2	3	4	5	5	5	3	4
	E0028034	DAY 1	01APR2003	1	28		25		3	2	1	2	3	2	2	2	1	2	1	3	2	2	0	2
		DAY 29	01MAY2003	31	51	23	66	41	3	4	4	3	3	3	4	4	4	4	3	4	4	4	4	4
		DAY 57	02JUN2003	63	57	29	77	52	4	4	4	4	5	4	5	4	4	3	3	5	4	4	3	4
	E0028038	DAY 1	25APR2003	1	31		30		2	2	2	1	3	2	1	2	2	3	3	4	2	2	3	2
		DAY 29	22MAY2003	28	39	8	45	15	3	3		3	2	1	1	2	3	3	4	4	3	4	3	3
		DAY 57	18JUN2003	55	35	4	38	8	3	2	3	2	2	2	2	3	2	1	3	3	4	3	3	2
	E0028043	DAY 1	05JUN2003	1	37		41		3	2	4	2	3	3	3	3	2	1	1	4	3	3	4	2
		DAY 29	01JUL2003	27	41	4	48	7	3	3	4	3	3	3	3	3	3	1	1	4	4	3	3	3
		DAY 57	29JUL2003	55	41	4	48	7	3	3	3	3	3	3	3	3	3	2	2	4	3	3	3	3
	E0028045	DAY 1	18JUN2003	1	36		39		3	3	2	3	2	4	3	3	2	1	1	4	3	2	0	1
	E0029005	DAY 1	27NOV2002	1	38		43		3	2	3	3	3	3	2	2	3	2	3	3	3	3	3	3
		DAY 29	23DEC2002	27	42	4	50	7	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	3
		DAY 57	21JAN2003	56	52	14	68	25	3	4	3	4	4	3	4	4	3	3	4	4	4	5	4	4
	E0030001	DAY 1	19NOV2002	1	41		48		3	2	4	3	2	2	2	3	5	2	2	5	4	2	0	2
		DAY 29	17DEC2002	29	39	-2	45	-3	4	3	3	4	2	2	2	2	4	1	2	4	4	2	3	3
		DAY 57	16JAN2003	59	42	1	50	2	4	3	3	3	3	3	3	3	4	2	2	3	4	2	2	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATISFACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	DAY 1	14JAN2003	1	42		50		3	3	2	2	3	4	3	4	2	3	4	4	2	3	0	3
		DAY 29	14FEB2003	32	40	-2	46	-4	3	3	2	2	3	3	2	3	2	3	4	4	3	3	4	3
		DAY 57	18MAR2003	64	51	9	66	16	4	4	3	3	4	3	3	4	3	3	4	5	4	4	4	4
	E0030011	DAY 1	27JAN2003	1	30		29		4	1	1	1	2	2	1	2	2	3	3	5	2	1	0	2
		DAY 29	24FEB2003	29	66	36	93	64	5	5	5	5	5	4	5	5	4	4	4	5	5	5	5	5
		DAY 57	24MAR2003	57	70	40	100	71	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	E0030015	DAY 1	21FEB2003	1	52		68		4	3	3	4	3	5	4	3	3	2	5	5	5	3	0	4
		DAY 29	26MAR2003	34	58	6	79	11	5	4	4	4	4	5	4	3	4	2	5	5	5	4	4	4
		DAY 57	22APR2003	61	65	13	91	23	5	5	5	4	5	5	5	4	5	3	5	5	5	4	5	5
	E0030022	DAY 1	16JUN2003	1	40		46		3	3	1	4	4	4	3	3	3	1	3	4	2	2	0	3
		DAY 29	14JUL2003	29	46	6	57	11	3	3	2	4	4	4	4	3	4	1	3	4	4	3	4	4
		DAY 57	14AUG2003	60	48	8	61	15	4	3	3	4	4	4	3	3	4	2	3	4	4	3	3	3
	E0031002	DAY 1	27NOV2002	1	38		43		3	2	1	4	3	2	3	3	3	2	1	4	4	3	0	2
		DAY 29	27DEC2002	31	51	13	66	23	4	3	3	3	4	3	3	4	4	3	4	4	5	4	4	4
		DAY 57	22JAN2003	57	47	9	59	16	3	3	4	4	4	3	3	3	3	2	4	3	4	4	4	4
	E0031003	DAY 1	10DEC2002	1	34		36		2	2	1	3	3	2	3	2	2	2	1	4	4	3	0	2
		DAY 29	07JAN2003	29	42	8	50	14	4	3	2	3	3	3	3	3	3	2	2	4	4	3	4	3
		DAY 57	04FEB2003	57	38	4	43	7	3	3	3	2	2	3	2	2	3	2	2	4	4	3	3	3
	E0033015	DAY 1	10APR2003	1	31		30		3	3	4	2	1	1	2	3	1	2	1	4	3	1	0	2
		DAY 29	06MAY2003	27	41	10	48	18	4	4	4	4	3	2	3	3	2	3	1	2	3	3	3	3
		DAY 57	04JUN2003	56	51	20	66	36	5	4	4	3	4	3	4	4	3	3	2	4	4	4	5	4
	E0034002	DAY 1	25MAR2003	1	39		45		3	2	3	4	3	4	2	2	2	2	4	2	3	3	1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0034002	DAY 29	16APR2003	23	44	5	54	9	2	1	3	3	4	5	3	2	3	5	5	2	4	2	1	3
	E0034003	DAY 1	24APR2003	1	43		52		4	3	3	3	2	3	4	3	2	2	3	4	4	3	0	3
		DAY 29	22MAY2003	29	64	21	89	37	5	5	5	5	3	5	5	5	3	3	5	5	5	5	4	4
		DAY 57	19JUN2003	57	55	12	73	21	5	4	4	4	4	4	4	4	3	3	4	4	4	4	4	4
	E0034006	DAY 1	16MAY2003	1	38		43		3	2	3	3	2	3	2	3	1	2	4	3	4	3	0	2
		DAY 29	13JUN2003	29	36	-2	39	-4	3	2	2	3	2	2	2	3	2	2	2	4	4	3	4	2
		DAY 57	10JUL2003	56	34	-4	36	-7	3	2	3	2	2	3	2	2	2	2	3	3	2	3	2	3
	E0034008	DAY 1	23MAY2003	-1	51		66		5	2	2	4	3	5	3	3	3	3	5	5	5	3	0	3
		DAY 29	20JUN2003	28	57	6	77	11	5	4	5	4	4	5	2	4	3	4	3	5	5	4	4	4
		DAY 57	21JUL2003	59	69	18	98	32	5	5	5	5	5	5	5	5	5	5	4	5	5	5	5	4
	E0035003	DAY 1	22NOV2002	1	29		27		2	2	1	3	3	3	2	2	2	1	1	3	2	2	0	2
		DAY 29	20DEC2002	29	48	19	61	34	4	3	4	3	4	4	2	4	3	3	3	4	4	3	4	3
	E0035005	DAY 1	03DEC2002	1	29		27		2	2	2	2	2	3	2	2	2	2	2	2	2	2	0	2
		DAY 29	31DEC2002	29	39	10	45	18	3	4	3	2	2	3	3	3	2	2	2	3	4	3	5	3
	E0035014	DAY 1	03FEB2003	1	38		43		3	2	2	3	2	3	2	3	2	3	4	4	2	3	0	2
		DAY 29	03MAR2003	29	43	5	52	9	3	2	2	4	4	2	5	3	2	2	2	5	4	3	3	3
		DAY 57	31MAR2003	57	50	12	64	21	3	3	4	4	4	4	4	4	1	4	3	4	4	4	3	4
	E0035024	DAY 1	22MAY2003	-1	25		20		4	1	1	1	1	1	1	1	1	1	4	5	1	2	1	1
		DAY 29	19JUN2003	28	32	7	32	12	2	3	2	3	2	3	2	2	2	2	2	5	1	1	5	3
		DAY 57	18JUL2003	57	36	11	39	19	4	3	2	2	2	2	2	3	2	2	4	3	2	3	3	3
	E0036005	DAY 1	01JUL2003	1	35		38		3	2	2	2	3	3	3	3	2	2	2	3	3	2	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATISFACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	DAY 29	29JUL2003	29	48	13	61	23	4	4	3	3	4	4	4	4	2	2	3	4	4	3	4	4
		DAY 57	27AUG2003	58	43	8	52	14	4	4	3	4	4	1	3	3	3	1	2	4	4	3	4	4
	E0037002	DAY 1	26DEC2002	1	24		18		3	1	1	1	1	2	1	1	2	1	1	3	4	2	0	1
		DAY 29	24JAN2003	30	38	14	43	25	5	2		3	2	3	1	2	3	2	3	3	4	2	3	2
		DAY 57	20FEB2003	57	42	18	50	32	4	3	3	3	3	4	3	4	3	2	1	3	3	3	5	3
	E0037005	DAY 1	06MAR2003	1	29		27		1	1	3	2	3	3	2	3	1	1	1	3	4	1	0	2
		DAY 29	03APR2003	29	38	9	43	16	2	1	4	3	3	3	3	3	1	1	4	4	3	3	3	3
		DAY 57	01MAY2003	57	34	5	36	9	2	1	4	2	2	2	2	3	1	2	3	4	4	2	3	3
	E0037006	DAY 1	14MAR2003	1	26		21		2	2	3	1	2	3	1	2	1	1	2	3	1	2	0	2
		DAY 29	11APR2003	29	39	13	45	24	4	3	4	1	3	3	2	3	1	2	3	4	4	2	4	3
		DAY 57	09MAY2003	57	43	17	52	31	3	3	2	3	3	4	3	3	2	2	4	4	4	3	4	3
	E0039006	DAY 1	30DEC2002	1	35		38		3	3	2	2	3	3	3	3	1	2	2	3	2	3	0	3
		DAY 29	28JAN2003	30	39	4	45	7	3	3	3	3	3	3	3	3	1	2	2	4	3	3	4	3
		DAY 57	24FEB2003	57	43	8	52	14	4	4	3	3	3	4	3	3	2	2	3	4	2	3	3	3
	E0039015	DAY 1	23JAN2003	1	32		32		5	3	1	2	1	2	2	2	1	1	2	4	4	2	0	2
		DAY 29	20FEB2003	29	37	5	41	9	3	3	2	2	2	3	2	3	2	2	2	3	5	3	5	3
		DAY 57	20MAR2003	57	43	11	52	20	5	3	1	3	2	3	3	4	2	2	1	5	5	4	5	4
	E0039024	DAY 1	27FEB2003	1	54		71		4	4	5	3	4	3	4	4	2	3	4	5	5	4	5	4
		DAY 29	27MAR2003	29	49	-5	63	-8	4	3	4	4	4	3	3	3	3	2	3	5	5	3	4	3
		DAY 57	24APR2003	57	61	7	84	13	5	4	4	4	5	4	5	4	5	3	4	5	5	4	4	4
	E0039025	DAY 1	18MAR2003	1	54		71		4	3	3	5	4	4	4	4	5	3	3	4	5	3	0	3
		DAY 29	15APR2003	29	69	15	98	27	5	5	5	5	5	4	5	5	5	5	5	5	5	5	5	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	DAY 1	15APR2003	1	50		64		5	3	3	3	3	3	4	3	3	2	5	5	5	3	3	3
		DAY 29	13MAY2003	29	48	-2	61	-3	5	3	3	3	3	3	3	3	3	2	4	5	5	3	4	3
		DAY 57	11JUN2003	58	47	-3	59	-5	4	3	3	3	3	3	3	4	4	3	3	4	4	3	3	4
	E0039044	DAY 1	22MAY2003	1	54		71		4	4	3	3	4	4	3	4	4	3	4	5	5	4	0	3
		DAY 29	18JUN2003	28	65	11	91	20	5	5	5	5	4	4	5	5	4	4	5	5	5	4	4	4
		DAY 57	09JUL2003	49	57	3	77	6	5	4	4	5	4	4	4	4	4	4	4	4	4	3	3	4
	E0039046		21MAY2003		44		54		4	3	2	4	5	2	4	3	2	1	1	5	4	4	0	4
	E0039051	DAY 1	16JUN2003	1	42		50		3	3	3	4	4	3	3	3	2	3	2	3	3	3	0	3
		DAY 29	14JUL2003	29	46	4	57	7	4	3	3	3	4	4	3	4	1	3	3	4	3	4	3	3
		DAY 57	12AUG2003	58	43	1	52	2	3	3	3	3	4	4	3	4	2	2	2	4	3	3	4	3
	E0039053	DAY 1	11JUL2003	1	47		59		5	3	1	4	3	4	3	3	4	2	4	3	4	4	0	3
		DAY 29	07AUG2003	28	53	6	70	11	4	3	3	3	4	5	3	4	4	4	5	3	4	4	3	4
		DAY 57	08SEP2003	60	43	-4	52	-7	3	3	3	2	3	4	3	3	3	3	2	4	4	3	2	3
	E0039057	DAY 1	14JUL2003	1	36		39		3	2	1	2	3	2	3	3	3	2	1	4	4	3	0	2
		DAY 29	12AUG2003	30	46	10	57	18	4	4	4	3	3	2	2	4	2	2	2	5	5	4	4	2
		DAY 57	09SEP2003	58	44	8	54	15	3	3	4	3	3	2	2	4	4	3	2	4	4	3	4	3
	E0041003	DAY 1	28JAN2003	1	40		46		3	3	1	2	3	4	2	2	3	2	4	4	4	3	0	3
		DAY 29	25FEB2003	29	54	14	71	25	4	4	3	4	4	4	4	4	4	3	4	4	4		4	4
		DAY 57	25MAR2003	57	51	11	66	20	4	4	2	4	4	4	4	4	4	2	3	4	4		4	4
	E0041008	DAY 1	07APR2003	1	44		54		4	2	4	3	3	3	3	2	1	3	5	3	4	4	0	3
		DAY 29	05MAY2003	29	44	0	54	0	3	3	3	3	4	4	3	3	2	2	4	4	3	3	3	3
		DAY 57	02JUN2003	57	43	-1	52	-2	3	3	4	3	3	3	3	3	1	3	3	4	4	3	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR I)	E0042001	DAY 1	02JUL2003	1	32		32		2	3	3	2	3	2	2	2	3	1	2	3	2	2	1	2
		DAY 29	29JUL2003	28	31	-1	30	-2	2	2	3	2	3	1	2	2	3	1	1	3	4	2	3	2
		DAY 57	26AUG2003	56	31	-1	30	-2	3	2	2	2	2	2	3	2	1	2	2	2	3	3	3	3
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	36		39		3	2	3	3	2	3	2	1	3	3	3	3	3	2	0	2
		DAY 29	09APR2003	29	47	11	59	20	3	3	4	4	3	4	3	3		3	4	3	4	3	4	4
		DAY 57	07MAY2003	57	56	20	75	36	4	4	4	4	4	5	3	4	4	4	4	4	4	4	5	4
	E0003018	DAY 1	13MAY2003	1	41		48		3	2	3	3	3	3	4	3	2	2	3	4	3	3	0	3
		DAY 29	10JUN2003	29	36	-5	39	-9	3	2	2	2	2	3	2	3	1	2	4	4	4	2	4	2
		DAY 57	08JUL2003	57	43	2	52	4	3	3	3	3	2	4	3	3	2	2	4	4	4	3	3	3
	E0005011	DAY 1	24OCT2002	1	43		52		5	2	1	1	3	2	4	3	5	2	3	5	5	2	0	2
		DAY 29	21NOV2002	29	39	-4	45	-7	2	1	1	3	3	2	5	2	4	2	4	5	2	3	3	2
	E0005030	DAY 1	26MAR2003	1	38		43		4	2	2	2	3	2	2	2	5	3	1	3	4	3	0	3
	E0005036	DAY 1	06MAY2003	1	52		68		5	2	3	3	4	3	3	3	4	5	5	5	5	2	0	3
	E0006015	DAY 1	11FEB2003	1	46		57		4	3	2	2	3	3	2	2	3	5	4	5	5	3	0	3
		DAY 29	11MAR2003	29	36	-10	39	-18	2	3	1	2	2	3	2	2	2	5	5	2	3	2	0	3
		DAY 57	08APR2003	57	55	9	73	16	4	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	E0006016	DAY 1	17FEB2003	1	34		36		3	2	4	1	1	3	2	2	2	2	2	4	4	2	0	2
		DAY 29	17MAR2003	29	51	17	66	30	4	3	5	3	3	4	3	4	5	2	3	4	4	4	0	3
		DAY 57	18APR2003	61	52	18	68	32	4	4	4	3	3	4	4	4	3	4	4	4	3	4	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR II)	E0007008	DAY 1	18APR2003	1	42		50		4	2	2	3	2	2	2	2	4	4	4	5	4	2	2	3
		DAY 29	25APR2003	8	37	-5	41	-9	4	2		2	2	2	2	2	3	4	4	1	4	2	1	2
	E0009002	DAY 1	19NOV2002	1	31		30		3	2	1	1	2	3	2	1	1	1	4	5	4	1	0	2
		DAY 29	18DEC2002	30	43	12	52	22	4	3	3	3	4	4	3	3	1	2	4	3	3	3	3	3
		DAY 57	15JAN2003	58	35	4	38	8	4	2	2	2	3	3	2	2	1	1	3	4	3	3	2	2
	E0009006	DAY 1	28JAN2003	1	53		70		5	3	4	3	4	4	3	3	5	3	4	5	5	2	0	3
		DAY 29	25FEB2003	29	57	4	77	7	4	4	3	3	5	5	4	4	4	3	5	5	5	3	4	4
		DAY 57	25MAR2003	57	56	3	75	5	4	4	3	4	4	4	4	4	5	3	5	4	5	3	4	4
	E0009009	DAY 1	12MAR2003	1	30		29		3	1	2	1	3	2	1	2	3	2	1	4	3	2	0	1
		DAY 29	24MAR2003	13	44	14	54	25	4	4	2	3	3	4	3	4	3	2	2	3	4	3	2	4
	E0010015	DAY 1	20FEB2003	1	25		20		2	2		1	2	2	2	1	1	1	1	4	3	1	0	2
		DAY 29	20MAR2003	29	45	20	55	35	3	3	3	3	3	3	4	3	3	3	3	4	4	3	4	4
		DAY 57	15APR2003	55	52	27	68	48	4	4	4	3	4	4	4	3	4	3	4	4	4	3	4	3
	E0011004	DAY 1	24DEC2002	1	24		18		3	1	2	1	2	1	1	2	2	1	2	3	2	1	0	2
		DAY 29	21JAN2003	29	45	21	55	37	3	3	3	3	3	4	3	3	4	3	3	3	3	4	4	4
		DAY 57	18FEB2003	57	56	32	75	57	4	4	5	4	4	4	4	4	5	3	3	4	4	4	5	4
	E0011007	DAY 1	19DEC2002	1	32		32		3	1	3	3	2	2	2	2	1	3	2	5	2	1	0	3
		DAY 29	17JAN2003	30	42	10	50	18	4	3	3	2	4	3	3	3	2	3	2	4	3	3	4	3
		DAY 57	13FEB2003	57	50	18	64	32	4	4	3	3	4	4	4	4	3	4	3	2	4	4	5	4
	E0011018	DAY 1	22MAY2003	1	38		43		3	3	2	2	3	3	2	3	3	2	2	5	2	3	4	3
		DAY 29	20JUN2003	30	47	9	59	16	3	4	4	4	3	3	3	4	2	2	2	5	4	4	0	4
		DAY 57	17JUL2003	57	48	10	61	18	4	4	3	3	4	3	3	4	3	3	3	4	3	4	0	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATISFACTION
QUETIAPINE 300 MG (BIPOLAR II)	E0011024	DAY 1	24JUN2003	1	44		54		3	3	3	3	3	3	3	3	3	3	3	5	3	3	0	3
		DAY 29	22JUL2003	29	43	-1	52	-2	3	3	3	4	3	3	2	4	2	3	3	3	4	3	0	4
		DAY 57	21AUG2003	59	53	9	70	16	4	3	3	4	4	5	3	4	4	3	4	4	4	4	4	3
	E0015003	DAY 1	25NOV2002	1	34		36		4	2	1	2	2	1	2	2	3	2	4	5	2	2	0	1
		DAY 29	02DEC2002	8	28	-6	25	-11	1	1	1	1	3	1	1	1	3	3	4	4	1	3	1	1
	E0019003	DAY 1	21NOV2002	1	25		20		1	2	4	2	2	2	1	1	1	1	1	3	2	2	0	1
		DAY 29	24DEC2002	34	51	26	66	46	2	5	5	3	3	4	3	5	4	2	1	5	5	4	4	4
		DAY 57	16JAN2003	57	51	26	66	46	2	4	5	3	5	5	3	4	4	1	2	5	4	4	4	4
	E0019007	DAY 1	13NOV2002	1	41		48		4	2		3	3	2	2	2	1	3	4	5	5	2	0	2
		DAY 29	12DEC2002	30	41	0	48	0	4	3	3	3	3	2	3	3	1	3	2	4	4	3	4	3
		DAY 57	07JAN2003	56	40	-1	46	-2	3	2	3	3	3	2	3	2	1	3	3	5	5	2	2	2
	E0019014	DAY 1	09JAN2003	1	39		45		3	2	2	2	3	3	2	2	4	3	4	3	4	2	0	2
		DAY 29	20JAN2003	12	39	0	45	0	3	3	3	2	2	3	2	2	4	2	4	3	3	3	0	2
	E0019018	DAY 1	30JAN2003	1	35		38		3	2	3	2	2	2	1	3	2	3	3	3	3	3	0	3
		DAY 29	27FEB2003	29	32	-3	32	-6	2	3	3	1	3	3	1	3	1	1	1	3	4	3	0	3
		DAY 57	27MAR2003	57	37	2	41	3	3	2	3	1	3	3	2	3	2	3	3	4	2	3	0	3
	E0019022	DAY 1	30JAN2003	1	39		45		1	1	3	2	3	5	3	2	4	1	3	5	4	2	0	3
		DAY 29	27FEB2003	29	43	4	52	7	1	3	1	4	4	5	2	3	5	1	3	5	3	3	0	4
		DAY 57	27MAR2003	57	46	7	57	12	3	4	2	4	4	4	3	3	5	1	3	4	3	3	4	4
	E0019027	DAY 1	27FEB2003	1	31		30		3	1	3	1	1	2	1	3	1	4	4	2	3	2	4	1
		DAY 29	06MAR2003	8	37	6	41	11	2	3	4	1	3	2	2	3	1	5	5	2	2	2	1	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	DAY 1	01APR2003	1	33		34		1	2	2	2	3	3	2	2	1	2	3	4	4	2	0	2
		DAY 29	29APR2003	29	38	5	43	9	2	3	2	2	4	4	2	3	1	2	4	4	2	3	4	3
		DAY 57	27MAY2003	57	44	11	54	20	1	3	4	3	4	4	4	3	1	2	4	4	4	3	3	3
	E0019034	DAY 1	18MAR2003	1	28		25		5	1	3	1	2	1	1	1	1	2	3	4	2	1	0	1
	E0019036	DAY 1	25MAR2003	1	26		21		3	2	2	2	2	3	2	2	1	1	2	1	1	2	0	2
		DAY 29	22APR2003	29	45	19	55	34	4	3	4	3	3	4	3	3	2	3	3	4	3	3	4	4
	E0019039	DAY 1	01MAY2003	1	37		41		4	2	2	3	3	3	2	2	1	1	3	5	4	2	0	2
	E0019041	DAY 1	21MAY2003	1	46		57		4	3	4	3	3	3	3	2	3	3	4	4	4	3	3	3
		DAY 29	18JUN2003	29	57	11	77	20	5	4	4	4	3	3	3	5	4	4	4	5	5	4		5
		DAY 57	16JUL2003	57	57	11	77	20	4	4	4	4	4	3	4	4	4	4	4	5	5	4	4	4
	E0019049	DAY 1	10JUL2003	1	34		36		3	1	5	1	3	5	1	1	1	3	1	2	5	2	0	2
		DAY 29	07AUG2003	29	40	6	46	10	4	2	5	2	3	4	2	2	1	3	1	4	3	4		3
		DAY 57	08SEP2003	61	43	9	52	16	5	2	5	2	3	5	2	2	1	4	1	4	4	3	4	3
	E0022052	DAY 1	10APR2003	1	23		16		1	1	1	2	2	2	2	2	1	2	3	1	2	1	0	2
		DAY 29	08MAY2003	29	24	1	18	2	2	2	1	2	1	3	1	1	1	2	3	2	2	1	3	2
		DAY 57	05JUN2003	57	24	1	18	2	2	3	2	1	2	2	1	2	1	1	2	2	1	2	3	2
	E0022064	DAY 1	06MAY2003	1	35		38		4	3	2	2	2	2	1	2	3	1	2	4	4	3	0	3
		DAY 29	03JUN2003	29	57	22	77	39	4	4	5	4	5	3	4	5	3	4	3	4	4	5	5	4
		DAY 57	01JUL2003	57	56	21	75	37	4	5	4	4	5	3	4	4	3	3	3	5	4	5	5	5
	E0022073	DAY 1	26JUN2003	1	36		39		3	3	3	1	2	3	2	2	3	2	4	4	2	2	0	3
		DAY 29	24JUL2003	29	54	18	71	32	3	4	4	4	4	3	4	5	3	3	5	4	4	4	5	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR II)	E0022073	DAY 57	21AUG2003	57	63	27	88	49	4	5	5	4	4	4	4	5	4	4	5	5	5	5	5	5
	E0023002	DAY 1	05NOV2002	1	42		50		2	3	4	2	3	2	3	3	3	4	2	4	4	3	0	3
		DAY 29	03DEC2002	29	39	-3	45	-5	2	2	3	2	3	2	3	3	3	4	3	4	3	2	2	2
	E0023017	DAY 1	25MAR2003	1	40		46		4	3	3	3	1	3	2	2	2	2	3	5	3	4	0	3
		DAY 29	24APR2003	31	54	14	71	25	5	4	4	5	5	3	5	3	3	1	4	4	4	4	4	4
		DAY 57	22MAY2003	59	54	14	71	25	4	4	4	4	4	4	4	4	4	1	4	5	4	4	3	4
	E0023021	DAY 1	23APR2003	1	38		43		4	1	3	4	4	1	4	2	4	1	1	3	4	2	0	1
		DAY 29	20MAY2003	28	42	4	50	7	3	4	3	3	4	3	3	2	4	1	2	3	4	3	4	2
		DAY 57	17JUN2003	56	37	-1	41	-2	2	3	3	2	3	2	4	2	5	1	2	2	4	2	5	3
	E0023027	DAY 1	16MAY2003	1	35		38		3	1	2	1	3	4	3	2	2	2	4	3	2	3	3	2
		DAY 29	11JUN2003	27	35	0	38	0	2	2	2	1	3	4	2	3	3	1	4	3	2	3	3	1
		DAY 57	09JUL2003	55	33	-2	34	-4	3	1	2	2	2	2	2	2	2	2	2	4	4	3	3	1
	E0023030	DAY 1	03JUN2003	1	32		32		2	1	3	2	1	4	2	4	1	1	1	5	3	2	0	1
		DAY 29	01JUL2003	29	51	19	66	34	4	4	3	4	4	4	4	4	2	2	3	5	4	4	4	3
		DAY 57	30JUL2003	58	59	27	80	48	4	4	4	4	4	5	4	4	4	4	4	5	4	5	5	5
	E0023040	DAY 1	03JUL2003	1	36		39		3	1	3	3	1	3	1	3	3	3	4	4	2	2	0	5
		DAY 29	05AUG2003	34	51	15	66	27	5	3	3	5	3	3	3	5	3	3	4	4	3	4	3	3
		DAY 57	05SEP2003	65	49	13	63	24	4	4	4	4	3	4	3	4	3	3	3	4	3	3	4	4
	E0026014	DAY 1	19FEB2003	1	48		61		4	3	4	3	3	2	3	4	5	2	4	4	4	3	4	4
		DAY 29	19MAR2003	29	44	-4	54	-7	4	3	3	2	4	1	2	2	4	3	4	4	4	4	3	3
	E0026019	DAY 1	17MAR2003	1	41		48		3	3	3	3	3	4	2	3	3	2	3	3	3	3	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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GENERATED: 12JUL2005 17:46:10 iceadmn3

Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR II)	E0026019	DAY 29	14APR2003	29	42	1	50	2	4	3	2	4	3	3	2	3	5	2	3	3	2	3	3	2
		DAY 57	12MAY2003	57	40	-1	46	-2	3	2	2	3	3	2	3	3	4	3	3	4	3	2	3	3
	E0027005	DAY 1	26DEC2002	1	26		21		1	1	1	1	2	3	1	1	1	2	3	4	4	1	2	1
		DAY 29	23JAN2003	29	45	19	55	34	4	4	1	5	3	2	1	3	1	3	4	5	5	4	5	3
		DAY 57	20FEB2003	57	38	12	43	22	3	3	5	3	1	1	3	2	1	2	3	5	3	3	4	3
	E0029009	DAY 1	20JAN2003	1	39		45		4	3	3	2	2	3	2	3	3	2	2	4	3	3	0	2
		DAY 29	17FEB2003	29	45	6	55	10	4	3	3	4	3	3	3	4	2	2	2	4	4	4	4	3
		DAY 57	18MAR2003	58	48	9	61	16	4	4	3	4	4	3	3	4	2	2	3	4	4	4	4	4
	E0029021	DAY 1	18MAR2003	1	44		54		3	2	2	2	3	3	3	3	3	3	4	5	5	3	0	3
		DAY 29	15APR2003	29	51	7	66	12	4	3	3	3	4	4	3	3	4	3	3	5	5	4	4	4
		DAY 57	15MAY2003	59	50	6	64	10	3	3	3	3	4	3	4	4	4	3	3	5	4	4	4	4
	E0029026	DAY 1	14APR2003	1	52		68		5	3	3	3	3	4	3	3	3	4	4	5	5	4	4	3
		DAY 29	12MAY2003	29	58	6	79	11	5	4	5	5	4	4	4	4	3	4	4	4	4	4	3	4
		DAY 57	10JUN2003	58	58	6	79	11	4	4	4	4	4	5	5	4	4	4	4	4	4	4	4	4
	E0029030	DAY 1	27MAY2003	1	40		46		3	2	3	1	3	4	3	3	2	2	3	4	4	3	0	3
		DAY 29	26JUN2003	31	59	19	80	34	4	5	4	5	4	4	4	5	5	3	4	4	4	4	4	4
		DAY 57	23JUL2003	58	53	13	70	24	4	4	3	4	4	4	4	4	4	3	3	4	4	4	4	4
	E0031008	DAY 1	28FEB2003	1	41		48		3	2	2	2	4	4	3	3	1	3	1	5	5	3	0	2
		DAY 29	28MAR2003	29	50	9	64	16	4	4	4	4	4	4	4	4	1	2	2	4	5	4	3	4
		DAY 57	24APR2003	56	36	-5	39	-9	4	1	1	2	3	3	2	2	1	3	4	5	3	2	3	2
	E0031020	DAY 1	21APR2003	1	40		46		3	2	2	2	3	3	3	2	5	3	3	4	3	2	0	3
		DAY 29	13MAY2003	23	51	11	66	20	4	4	3	3	4	4	3	3	4	4	4	4	4	3	3	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 1	25APR2003	1	37		41		3	1	2	2	2	2	2	3	4	1	4	5	3	3	0	3
		DAY 29	23MAY2003	29	61	24	84	43	5	5	2	4	5	4	5	5	4	2	5	5	5	5	5	5
		DAY 57	19JUN2003	56	63	26	88	47	3	5	3	4	5	5	4	5	5	4	5	5	5	5	5	5
	E0031029	DAY 1	18JUN2003	1	32		32		2	2	3	3	2	1	2	3	1	1	3	3	4	2	0	3
	E0033002	DAY 1	10JAN2003	1	30		29		1	2	2	2	1	1	2	2	4	4	2	3	2	2	0	2
		DAY 29	06FEB2003	28	45	15	55	26	4	4	3	4	3	2	3	3	3	4	3	4	2	3	3	3
		DAY 57	07MAR2003	57	58	28	79	50	5	4	5	5	4	3	5	4	3	3	4	5	4	4	5	4
	E0033006	DAY 1	23JAN2003	1	40		46		3	2	3	2	3	3	3	3	3	2	3	4	4	2	0	2
	E0033021	DAY 1	02JUL2003	1	30		29		3	2	2	1	3	3	3	2	3	1	2	1	2	2	0	3
		DAY 29	01AUG2003	31	42	12	50	21	3	3	4	3	3	4	4	3	3	1	1	4	3	3	4	5
	E0035013	DAY 1	04FEB2003	1	42		50		3	2	2	3	3	4	3	4	1	2	3	4	4	4	4	2
		DAY 29	10FEB2003	7	37	-5	41	-9	3	2	2	2	2	4	3	3	1	2	3	4	3	3	2	1
	E0035015	DAY 1	11FEB2003	1	37		41		2	2	2	3	3	3	2	3	2	3	3	3	3	3	4	3
		DAY 29	18FEB2003	8	33	-4	34	-7	2	2	2	2	2	3	2	2	3	2	4	2	2	3	3	3
	E0035016	DAY 1	04APR2003	1	29		27		2	2	2	2	3	2	2	2	1	2	1	4	2	2	0	2
	E0035023	DAY 1	13MAY2003	1	31		30		2	2	2	2	3	3	2	2	3	2	1	2	3	2	0	2
		DAY 29	10JUN2003	29	43	12	52	22	3	3	2	3	3	3	3	3	4	2	4	4	3	3	3	3
	E0039052	DAY 1	20JUN2003	1	39		45		3	3	4	3	2	3	2	3	2	2	1	4	4	3	0	2
		DAY 29	03JUL2003	14	45	6	55	10	3	4	2	3	3	4	3	4	4	4	2	2	3	4	2	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 300 MG (BIPOLAR II)	E0039056	DAY 1	14JUL2003	-1	45			55	3	3	2	3	3	4	3	3	3	3	2	5	4	4	0	3
	E0040003	DAY 1	18JUL2003	-1	30			29	2	1	2	2	1	1	1	2	1	4	4	3	3	3	1	2
		DAY 29	15AUG2003	28	37	7	41	12	3	2	1	2	3	4	1	3	1	4	4	3	3	3	3	3
		DAY 57	12SEP2003	56	40	10	46	17	2	2	1	3	3	2	4	2	1	5	5	3	4	3	3	3
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	40			46	3	1	3	3	4	1	3	4	4	1	2	5	4	2	3	1
		DAY 29	01APR2003	30	52	12	68	22	4	4	3	3	4	4	3	4	5	3	2	5	3	5	4	4
		DAY 57	02MAY2003	61	56	16	75	29	3	4	4	4	5	5	4	5	5	3	2	5	3	4	5	5
	E0002011	DAY 1	29APR2003	1	51			66	4	3	3	3	3	4	4	4	4	2	4	5	5	3	0	3
		DAY 29	29MAY2003	31	60	9	82	16	2	5	4	5	4	5	5	5	5	2	5	5	5	3	0	5
		DAY 57	25JUN2003	58	59	8	80	14	3	4	5	5	4	4	4	5	4	1	5	5	5	5	0	5
	E0003010	DAY 1	03FEB2003	1	30			29	2	1	3	2	1	2	2	2	1	2	2	5	3	2	0	1
		DAY 29	03MAR2003	29	45	15	55	26	4	3	4	3	3	4	3	4	1	3	4	5	1	3	4	3
		DAY 57	31MAR2003	57	59	29	80	51	5	5	4	5	5	5	4	5	3	4	4	4	2	4	4	5
	E0003011	DAY 1	04FEB2003	1	38			43	2	2	1	2	3	3	3	2	1	2	4	5	5	3	0	2
	E0003016	DAY 1	22MAY2003	1	26			21	4	1	1	1	1	1	1	1	1	2	3	4	4	1	0	1
		DAY 29	13JUN2003	23	31	5	30	9	4	1	2	1	1	3	1	1	1	3	4	4	4	1	1	1
	E0003019	DAY 1	27JUN2003	1	37			41	4	2	2	2	3	4	2	3	1	1	3	5	3	2	0	2
		DAY 57	21AUG2003	56	39	2	45	4	4	2	2	2	3	4	2	2	2	2	4	5	3	2	4	3
	E0003020	DAY 1	23JUL2003	1	34			36	2	2	1	3	3	3	2	3	1	1	1	5	5	2	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATISFACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	DAY 29		20AUG2003	29	43	9	52	16	3	3	1	3	3	5	3	4	1	2	3	4	5	3	0	3
		DAY 57		17SEP2003	57	48	14	61	25	4	4	4	3	3	3	3	4	2	3	3	4	4	4	4	5
	E0004001	DAY 1	*	23SEP2002	-7	27		23		2	1	2	1	3	3	3	1	2	1	2	2	3	1	0	2
		DAY 1		30SEP2002	1	22		14		1	1	3	1	2	2	2	1	1	1	1	2	3	1	3	1
		DAY 29	*	07OCT2002	8	29	7	27	13	1	3	3	1	3	3	2	2	2	1	2	1	3	2	2	2
		DAY 29		28OCT2002	29	41	19	48	34	3	3	4	2	3	3	3	3	3	3	3	3	2	3	3	3
	E0004009	DAY 1		26DEC2002	1	30		29		3	2	1	3	3	2	2	2	1	1	1	3	3	3	4	3
		DAY 29		22JAN2003	28	52	22	68	39	4	3	3	4	3	4	4	4	3	4	4	4	4	4	4	4
		DAY 57		19FEB2003	56	62	32	86	57	4	5	5	4	4	4	5	4	5	4	4	5	4	5	5	5
	E0004012	DAY 1		14JAN2003	1	35		38		4	2	3	3	2	2	2	2	1	2	3	4	3	2	0	2
		DAY 29		11FEB2003	29	54	19	71	33	4	3	4	4	4	3	3	4	4	4	4	5	4	4	4	4
		DAY 57		11MAR2003	57	55	20	73	35	4	3	3	4	4	4	4	4	4	3	4	5	5	4	4	4
	E0004015	DAY 1		20FEB2003	1	35		38		4	2	1	2	3	3	2	2	3	2	3	5	1	2	0	2
		DAY 29		18MAR2003	27	59	24	80	42	5	4	4	4	4	4	5	5	4	3	3	5	5	4	5	4
		DAY 57		15APR2003	55	60	25	82	44	5	5	4	4	5	4	4	5	4	3	3	5	5	4	5	4
	E0005003	DAY 1	*	23SEP2002	-9	39		45		5	1	3	3	1	1	3	3	1	2	2	5	5	4	5	1
		DAY 1		02OCT2002	1	38		43		5	1	2	3	3	2	3	2	1	2	2	5	4	3	0	1
		DAY 29		30OCT2002	29	38	0	43	0	4	1	3	2	2	2	3	3	1	3	3	5	3	3	4	3
		DAY 57		26NOV2002	56	48	10	61	18	4	3	4	4	3	3	3	4	1	3	3	5	4	4	4	4
	E0005005	DAY 1	*	24SEP2002	-6	41		48		3	2	3	3	3	3	3	3	3	2	3	4	4	2	0	2
		DAY 1		30SEP2002	1	40		46		3	3	3	3	2	3	3	3	3	1	3	4	4	2	0	2
	E0005007	DAY 1	*	02OCT2002	-7	19		9		1	1	1	1	1	1	1	2	1	1	1	3	3	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 1		09OCT2002	1	15		2		1	1	1	1	1	1	1	1	1	1	2	1		1	0	1
		DAY 29		06NOV2002	29	31	16	30	28	2	3	3	3	1	2	1	2	1	1	2	4	4	2	4	3
		DAY 57		04DEC2002	57	30	15	29	27	2	2	2	2	2	1	1	2	1	2	1	5	5	2	5	2
	E0005008	DAY 1		15OCT2002	1	37		41		2	2	4	2	2	2	2	3	3	3	4	4	1	3	0	2
		DAY 29		13NOV2002	30	47	10	59	18	3	3	4	3	3	4	3	4	3	3	4	3	3	4	4	3
		DAY 57		11DEC2002	58	55	18	73	32	4	4	4	4	4	4	4	4	4	3	4	4	4	4	4	4
	E0005009	DAY 1		29OCT2002	1	44		54		4	2	3	4	3	3	3	3	4	3	3	3	3	3	4	3
	E0005010	DAY 1		21OCT2002	1	38		43		4	2	3	2	2	2	2	3	1	2	3	5	4	3	0	4
		DAY 29		19NOV2002	30	53	15	70	27	5	4	4	4	3	4	4	4	1	3	4	5	4	4	4	4
		DAY 57		17DEC2002	58	53	15	70	27	4	4	4	4	4	4	4	4	1	4	4	4	4	4	5	4
	E0005012	DAY 1		14NOV2002	1	30		29		3	3	2	2	1	1	2	3	3	1	2	4	2	1	0	2
		DAY 29		10DEC2002	27	49	19	63	34	3	4	4	3	3	3	4	4	2	2	3	5	5	4	4	4
		DAY 57		07JAN2003	55	36	6	39	10	2	2	3	3	3	3	2	2	1	1	4	5	3	2	2	2
	E0005014	DAY 1		13NOV2002	1	32		32		2	2	3	2	2	3	1	2	3	1	3	3	3	2	0	2
		DAY 29		11DEC2002	29	46	14	57	25	4	4	4	2	3	3	3	4	4	1	3	4	4	3	4	3
		DAY 57		06JAN2003	55	42	10	50	18	4	3	3	1	3	3	3	4	4	1	3	3	4	3	4	3
	E0005022	DAY 1		29JAN2003	1	45		55		4	3	3	3	3	4	2	3	4	2	3	5	3	3	0	3
		DAY 29		26FEB2003	29	57	12	77	22	4	4	4	4	4	4	4	4	4	4	4	5	4	4	3	4
		DAY 29	*	06MAR2003	37	62	17	86	31	5	5	4	4	5	4	4	5	5	3	4	5	4	5	2	5
	E0005025	DAY 1		27FEB2003	1	22		14		2	1	1	1	1	2	1	1	1	1	4	4	1	1	0	1
		DAY 29		03APR2003	36	35	13	38	24	4	3	2	2	3	4	2	2	2	1	4	1	3	2	2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATISFACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 1	07APR2003	1	40		46		4	3	4	2	2	3	2	3	4	2	2	3	4	2	0	2
		DAY 29	05MAY2003	29	42	2	50	4	3	3	1	3	3	3	4	3	2	2	4	4	4	3	3	3
		DAY 57	03JUN2003	58	34	-6	36	-10	2	2	1	1	2	2	3	4	3	2	2	4	4	2	2	2
	E0007005	DAY 1	31JAN2003	1	29		27		4	1	1	1	1	3	1	2	1	2	3	5	3	1	0	1
		DAY 29	03MAR2003	32	45	16	55	28	5	4	1	3	1	4	4	3	1	1	4	5	5	4	4	4
		DAY 57	28MAR2003	57	37	8	41	14	5	2	1	3	1	3	2	3	1	2	2	5	5	2	3	2
	E0007015	DAY 1	16JUL2003	1	32		32		4	1	2	1	1	2	1	2	1	2	3	5	5	2	0	2
		DAY 29	13AUG2003	29	54	22	71	39	5	4	3	4	2	4	4	4	3	3	4	5	5	4	4	4
		DAY 57	10SEP2003	57	39	7	45	13	5	2	2	2	2	2	1	3	3	3	3	5	4	2	1	2
	E0009001	DAY 1	12NOV2002	1	41		48		2	2	2	3	3	4	2	3	5	2	4	4	3	2	0	3
		DAY 29	10DEC2002	29	47	6	59	11	4	3	3	4	3	4	3	3	5	2	3	3	3	4	3	3
	E0010002	DAY 1	25NOV2002	1	41		48		3	3	2	4	3	3	3	3	3	3	2	3	3	3	3	3
		DAY 29	02DEC2002	8	37	-4	41	-7	3	3	2	3	2	2	2	2	3	3	3	3	3	3	3	3
	E0010009	DAY 1	26DEC2002	1	51		66		4	3	5	3	3	3	4	4	1	4	5	5	4	3	0	3
		DAY 29	22JAN2003	28	59	8	80	14	5	5	5	3	4	2	4	5	1	5	5	5	5	5	4	4
		DAY 57	19FEB2003	56	51	0	66	0	4	3	4	3	4	3	4	4	1	4	4	5	4	4	4	4
	E0010010	DAY 1	30DEC2002	1	30		29		4	2	1	2	1	4	1	1	1	1	1	5	5	1	0	1
		DAY 29	13JAN2003	15					3	1	1	3	3	4	1	1								
	E0010014	DAY 1	28JAN2003	1	34		36		5	1	3	2	1		2	2	3	1	3	4	3	2	0	2
		DAY 29	25FEB2003	29	61	27	84	48	4	4	4	5	5	4	4	4	4	3	5	5	5	5	5	5
		DAY 57	25MAR2003	57	66	32	93	57	5	4	5	5	5	5	4	5	4	4	5	5	5	5	5	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	DAY 1	25FEB2003	1	31		30		3	2	3	1	1	3	1	3	1	1	1	4	4	3	0	2
		DAY 29	25MAR2003	29	58	27	79	49	5	4	5	5	4	5	4	5	1	3	3	5	5	4	4	4
		DAY 57	22APR2003	57	55	24	73	43	4	4	5	4	4	5	3	5	1	3	3	5	5	4	5	4
	E0010023	DAY 1	17APR2003	1	23		16		2	1	2	2	1	1	1	2	1	1	3	4	1	1	0	1
		DAY 29	01MAY2003	15	27	4	23	7	3	1	1	2	2	2	1	1	2	2	2	4	1	3	1	1
	E0010027	DAY 1	16JUN2003	1	32		32		3	2	2	1	1	3	1	2	2	1	3	4	4	3	0	3
		DAY 29	01JUL2003	16	40	8	46	14	4	3	3	3	2	3	2	4	2	2	2	3	4	3	2	3
	E0010029	DAY 1	19JUN2003	1	36		39		2	3	4	1	1	4	1	3	2	4	4	2	2	3	0	2
	E0011022	DAY 1	09JUN2003	1	27		23		2	2	2	2	2	3	3	2	1	1	3	1	1	2	2	2
		DAY 29	08JUL2003	30	32	5	32	9	3	2	1	3	2	2	2	2	1	1	4	4	2	3	4	3
		DAY 57	05AUG2003	58	30	3	29	6	2	2	1	2	2	2	2	2	1	2	3	3	4	2	3	2
	E0013006	DAY 1	13MAR2003	1	35		38		3	2	3	3	2	4	2	2	2	1	1	3	4	3	0	2
		DAY 29	24MAR2003	12	50	15	64	26	4	3	4	4	3	3	3	4	5	3	2	3	5	4	1	4
	E0013012	DAY 1	07MAY2003	1	30		29		2	1	3	2	3	3	1	2	2	2	2	2	2	3	3	1
		DAY 29	05JUN2003	30	47	17	59	30	3	3	2	3	4	4	3	3	5	2	5	3	4	3	3	3
		DAY 57	02JUL2003	57	53	23	70	41	5	4	4	3	3	5	4	3	4	1	4	5	5	3	5	4
	E0013014	DAY 1	03JUN2003	1	47		59		2	3	3	3	4	4	3	2	4	4	4	5	3	3	2	2
		DAY 29	30JUN2003	28	51	4	66	7	4	3	4	4	4	4	4	3	4	3	3	4	4	3	2	3
	E0014005	DAY 1	11MAR2003	1	23		16		1	1	1	1	1	4	2	2	1	3	3	1	1	1	0	1
		DAY 29	08APR2003	29	46	23	57	41	4	4		4	3	4	4	2	2	2	4	3	4	3	3	4
		DAY 57	06MAY2003	57	47	24	59	43	4	4	4	4	3	4	4	3	3	2	3	3	3	3	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	DAY 1	01APR2003	1	33		34		3	2	1	2	4	4	2	2	2	1	2	4	3	1	0	3
		DAY 29	22APR2003	22	40	7	46	12	4	3	1	3	3	3	4	2	4	3	1	4	3	2	2	3
	E0014011	DAY 1	13MAY2003	1	35		38		3	2	2	2	3	4	2	2	3	2	1	4	3	2	0	2
		DAY 29	10JUN2003	29	55	20	73	35	5	4	4	3	4	4	3	3	4	4	4	4	4	5	4	4
		DAY 57	08JUL2003	57	56	21	75	37	4	4	4	4	4	4	4	4	3	4	4	5	4	4	4	4
	E0014012	DAY 1	27MAY2003	1	22		14		3	1	1	1	1	1	1	1	1	2	2	3	3	1	0	1
		DAY 29	24JUN2003	29	29	7	27	13	4	1	1	1	1	2	2	2	1	2	3	4	3	2	2	2
	E0015001	DAY 1	29NOV2002	1	22		14		1	1	1	1	1	3	1	2	1	1	2	2	4	1	0	1
		DAY 29	27DEC2002	29	28	6	25	11	2	1	1	2	1	3	1	2	1	1	1	5	5	2	3	2
		DAY 57	20JAN2003	53	43	21	52	38	4	4	3	2	1	4	3	3	2	3	2	4	5	3	3	4
	E0015008	DAY 1	19DEC2002	1	24		18		1	2	1	1	1	2	2	2	1	1	2	5	1	2	0	2
		DAY 29	16JAN2003	29	35	11	38	20	4	3	1	3	3	3	2	3	1	1	2	3	3	3	4	4
	E0016003	DAY 1	24JAN2003	1	36		39		3	1	1	1	4	4	5	2	4	1	1	4	3	2	0	2
		DAY 29	21FEB2003	29	32	-4	32	-7	3	4	2	2	3	3	2	2	2	1	1	3	2	2	4	3
	E0016005	DAY 1	25FEB2003	1	23		16		2	1	1	1	4	3	1	2	2	1	1	2	1	1	0	1
		DAY 29	25MAR2003	29	60	37	82	66	5	5	5	5	3	3	5	5	3	3	3	5	5	5	5	5
		DAY 57	22APR2003	57	53	30	70	54	4	4		5	4	5	3	5	1	3	4	4	3	4	4	4
	E0018007	DAY 1	27DEC2002	1	44		54		4	3	2	4	4	4	3	3	2	1	3	4	4	3	0	3
		DAY 29	10JAN2003	15	27	-17	23	-31	1	2	1	1	3	5	1	1	1	1	5	1	3	1	1	2
	E0019005	DAY 1	05NOV2002	1	27		23		4	1	2	1	1	2	1	2	1	2	2	5	2	1	3	1
		DAY 29	05DEC2002	31	51	24	66	43	5	5	4	4	3	3	4	5	3	2	2	4	3	4	5	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	DAY 57	02JAN2003	59	49	22	63	40	4	4	4	3	3	3	3	4	4	3	3	4	3	4	4	3
	E0019015	DAY 1	02JAN2003	1					4	3	5	3		2	2	3	4		5	5	5	3	0	4
		DAY 29	30JAN2003	29	58		79		4	4	5	5	4	3	4	4	4	4	4	4	4	5	0	4
		DAY 57	27FEB2003	57	63		88		4	4	4	4	5	5	5	5	4	5	4	5	4	5	5	5
	E0020004	DAY 1	09DEC2002	1	31		30		2	2	3	1	3	1	2	2	3	1	3	3	3	2	0	2
		DAY 29	07JAN2003	30	29	-2	27	-3	2	1	2	1	2	2	3	3	2	1	1	4	3	2	3	1
		DAY 57	22JAN2003	45	18	-13	7	-23	1	1	1	1	2	1	1	1	1	1	2	2	2	1	2	1
	E0020010	DAY 1	05FEB2003	1	32		32		4	1	3	3	2		2	3	1	3	1	4	2	1	3	1
		DAY 29	05MAR2003	29	42	10	50	18	3	1	3	3	3	3	3	3	3	4	4	3	3	3	4	3
		DAY 57	02APR2003	57	67	35	95	63	5	5	5	4	5	4	4	5	5	5	5	5	5	5	5	5
	E0020014	DAY 1	18MAR2003	1	37		41		3	3	2	3	2	2	3	3	3	2	3	3	3	2	0	3
		DAY 29	15APR2003	29	47	10	59	18	3	3	4	3	4	3	3	3	4	2	4	4	4	3	4	3
		DAY 57	12MAY2003	56	54	17	71	30	4	4	4	4	4	4	4	4	4	2	4	4	4	4	4	4
	E0020021	DAY 1	19MAY2003	1	33		34		2	3	2	2	3	3	2	3	2	1	2	3	3	2	0	2
		DAY 29	16JUN2003	29	38	5	43	9	2	3	3	3	3	4	2	3	3	2	2	2	3	3	3	3
		DAY 57	14JUL2003	57	37	4	41	7	2	3	2	3	2	3	2	3	3	2	3	3	3	3	3	2
	E0020023	DAY 1	16JUN2003	-1	28		25		3	2	3	1	2	3	1	1	2	1	2	3	2	2	0	2
		DAY 29	14JUL2003	28	33	5	34	9	3	2	3	3	2	3	1	2	2	2	3	3	2	2	3	2
		DAY 57	11AUG2003	56	39	11	45	20	4	3	3	3	2	2	3	3	2	2	3	3	3	3	4	3
	E0022007	DAY 1	07NOV2002	1	47		59		4	3	2	4	3	4	4	4	2	3	2	5	4	3	0	3
		DAY 29	09DEC2002	33	48	1	61	2	4	3	4	3	3	3	3	4	2	4	3	4	4	4	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	DAY 1		21NOV2002	1	51		66		4	3	3	3	3	4	3	3	4	4	4	5	5	3	0	3
		DAY 57		16JAN2003	57	61	10	84	18	5	4	4	4	4	4	4	5	5	4	4	5	5	4	4	4
	E0022012	DAY 1		05DEC2002	1	36		39		2	3	2	2	3	2	2	3	1	1	3	5	3	4	0	3
		DAY 29		02JAN2003	29	53	17	70	31	4	4	4	3	4	4	4	4	3	3	4	4	4	4	4	5
		DAY 57		30JAN2003	57	58	22	79	40	4	4	4	5	5	5	4	4	4	3	4	4	4	4	5	5
	E0022019	DAY 1		11DEC2002	1	34		36		3	3	2	2	1	1	2	2	4	2	2	3	4	3	0	2
		DAY 29		09JAN2003	30	54	20	71	35	4	4	4	4	3	4	4	4	3	3	4	5	4	4	4	4
		DAY 57		06FEB2003	58	55	21	73	37	4	4	5	4	4	3	3	4	4	4	4	4	4	4	4	4
	E0022025	DAY 1		28JAN2003	1	36		39		3	2		2	2	3	3	2	2	3	3	3	2	3	0	3
		DAY 29		04FEB2003	8	31	-5	30	-9	1	3		3	1	3	2	3	1	3	2	3	2	2	2	2
	E0022033	DAY 1		18FEB2003	1	55		73		4	4	4	4	4	4	4	4	3	4	4	5	3	4	0	4
		DAY 29		18MAR2003	29	47	-8	59	-14	2	4	4	3	4	3	3	4	2	4	3	4	3	4	4	4
		DAY 57		15APR2003	57	59	4	80	7	4	3	5	4	5	4	4	5	3	4	5	5	4	4	5	4
	E0022034	DAY 1		18FEB2003	1	33		34		3	2	1	3	3	3	3	3	3	1	1	2	3	2	3	2
		DAY 29		18MAR2003	29	42	9	50	16	3	3	1	4	4	3	3	3	4	2	2	5	2	3	4	3
		DAY 57		15APR2003	57	54	21	71	37	4	4	4	4	4	4	4	4	4	3	3	4	4	4	5	4
	E0022038	DAY 1		28FEB2003	1	40		46		3	2	3	2	3	2	2	3	2	3	3	5	5	2	0	3
		DAY 29		28MAR2003	29	57	17	77	31	4	4	4	4	5	4	4	4	4	4	4	4	4	4	4	4
		DAY 29	*	11APR2003	43	33	-7	34	-12	2	2	1	2	2	3	2	1	1	3	3	4	4	3	1	3
	E0022039	DAY 1		06MAR2003	1	33		34		1	3	2	1	2	3	2	3	2	2	4	4	2	2	0	3
		DAY 29		04APR2003	30	52	19	68	34	3	5	4	4	4	1	4	4	3	4	4	5	4	3	5	5
		DAY 57		01MAY2003	57	57	24	77	43	4	5	4	1	4	3	5	5	3	5	5	5	3	5	5	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	DAY 1		20MAR2003	1	29		27		3	1	2	2	2	2	2	2	2	2	2	3	3	1	0	2
		DAY 29		18APR2003	30	39	10	45	18	3	3	1	2	3	3	2	3	1	2	4	4	5	3	3	3
		DAY 57		16MAY2003	58	39	10	45	18	3	3	2	2	3	3	3	2	3	2	3	4	3	3	3	3
	E0022048	DAY 1		01APR2003	1	36		39		3	2	2	2	3	3	2	2	3	2	3	4	2	3	0	2
		DAY 29		02MAY2003	32	50	14	64	25	3	4	3	3	4	3	4	4	4	3	3	4	4	4	4	5
	E0022051	DAY 1		07APR2003	1	20		11		1	1	1	1	1	1	1	1	1	5	3	1	1	1	1	1
		DAY 29		05MAY2003	29	46	26	57	46	3	2	4	4	4	1	4	4	2	3	4	4	4	3	1	2
		DAY 57		02JUN2003	57	55	35	73	62	5	4	4	4	4	4	4	4	3	3	4	4	4	4	5	5
	E0022053	DAY 1		11APR2003	1	27		23		3	1	1	1	2	3	3	2	2	1	1	2	3	2	0	2
	E0022058	DAY 1		21APR2003	1	35		38		2	2	2	2	2	3	3	3	4	2	2	3	3	2	0	2
		DAY 29		19MAY2003	29	46	11	57	19	4	4	3	3	3	3	3	3	4	2	3	4	3	4	4	4
		DAY 29	*	22MAY2003	32	37	2	41	3	3	4	2	2	3	2	2	2	3	3	3	2	3	3	3	3
	E0022061	DAY 1		30APR2003	1	24		18		2	2	1	1	1	3	2	1	1	1	3	3	1	2	0	1
		DAY 29		28MAY2003	29	59	35	80	62	4	5	5	4	4	5	4	4	4	3	4	5	4	4	5	4
		DAY 57		26JUN2003	58	63	39	88	70	4	5	5	4	4	5	4	5	4	4	4	5	5	5		4
	E0022062	DAY 1		05MAY2003	1	46		57		4	3	4	3	3	4	3	3	2	3	4	4	3	3	2	4
		DAY 29		23MAY2003	19	50	4	64	7	2	4	4	4	5	5	2	4	2	4	5	3	2	4	1	4
	E0022068	DAY 1		22MAY2003	-1	36		39		4	2	1	3	3	3	3	2	2	2	2	4	2	3	0	2
	E0022069	DAY 1		10JUN2003	1	43		52		2	4	1	1	5	3	3	3	3	3	4	5	3	3	4	3
		DAY 29		08JUL2003	29	42	-1	50	-2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		DAY 57		05AUG2003	57	52	9	68	16	4	3	4	4	4	4	3	4	4	4	3	4	4	3	4	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 1	30JUN2003	1	23		16		3	1	1	1	2	2	1	1	2	2	2	3	1	1	0	1
		DAY 29	28JUL2003	29	35	12	38	22	4	2	2	2	2	3	2	2	2	2	2	4	4	2	3	2
		DAY 57	25AUG2003	57	37	14	41	25	4	2	2	3	2	3	2	2	3	2	2	4	4	2	2	2
	E0023003	DAY 1	17DEC2002	1	30		29		3	1	1	2	3	2	1	2	3	1	1	5	2	3	1	3
		DAY 29	16JAN2003	31	42	12	50	21	3	2	5	2	3	3	3	2	3	2	2	5	4	3	0	3
		DAY 57	11FEB2003	57	43	13	52	23	4	3	3	3	3	3	2	3	3	2	1	5	5	3	3	2
	E0023006	DAY 1	17DEC2002	1	28		25		4	3	1	1	2	3	1	2	3	1	1	2	1	3	1	3
		DAY 29	16JAN2003	31	48	20	61	36	3	4	4	2	5	5	1	4	4	4	2	4	2	4	0	4
		DAY 57	11FEB2003	57	59	31	80	55	5	5	5	4	5	4	5	4	3	1	3	5	5	5	5	5
	E0023010	DAY 1	04FEB2003	1	27		23		3	2	2	1	2	3	2	1	1	1	2	3	2	2	3	1
		DAY 29	04MAR2003	29	38	11	43	20	3	3	2	2	2	3	2	3	2	4	4	4	2	2	3	2
		DAY 57	31MAR2003	56	55	28	73	50	5	4	3	3	3	4	4	4	3	5	5	4	4	4	4	5
	E0023025	DAY 1	15MAY2003	1	38		43		4	3	2	2	2	3	2	2	4	2	3	5	2	2	0	2
		DAY 29	12JUN2003	29	47	9	59	16	3	3	3	3	4	3	4	3	5	2	3	5	3	3	3	4
		DAY 57	10JUL2003	57	41	3	48	5	4	3	2	2	2	2	3	3	4	2	3	5	3	3	3	3
	E0023039	DAY 1	01JUL2003	1	26		21		2	2	1	2	1	2	2	2	2	1	2	3	2	2	0	2
		DAY 29	29JUL2003	29	45	19	55	34	3	3	4	3	2	4	4	4	2	2	3	4	4	3	4	3
		DAY 57	26AUG2003	57	43	17	52	31	4	4	3	4	2	2	2	4	2	1	3	4	4	4	4	4
	E0026002	DAY 1	12NOV2002	1	33		34		4	2	1	2	3	2	2	2	2	2	3	3	2	3	0	2
		DAY 29	11DEC2002	30	40	7	46	12	3	3	3	3	3	3	2	3	3	3	3	3	2	3	3	3
		DAY 57	09JAN2003	59	42	9	50	16	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	E0026007	DAY 1	16JAN2003	1	30		29		3	2	2	1	1	1	2	3	1	2	2	4	3	3	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0026007	DAY 29		13FEB2003	29	61	31	84	55	4	5	5	5	5	4	5	5	1	4	4	5	5	4	5	5
		DAY 57		12MAR2003	56	60	30	82	53	5	4	4	4	4	5	5	5	1	4	4	5	5	5	5	5
	E0026013	DAY 1		13FEB2003	1	24		18		3	1	1	1	1	1	1	1	1	1	1	5	5	1	0	1
		DAY 29		13MAR2003	29	27	3	23	5	4	2	1	1	1	3	1	1	1	1	3	5	2	1	3	2
	E0028007	DAY 1	*	01OCT2002	-3	44		54		4	2	1	3	4	3	3	3	4	1	4	5	4	3	0	3
		DAY 1		04OCT2002	1	42		50		4	2	1	3	4	4	4	3	3	1	2	5	3	3	0	3
		DAY 29	*	11OCT2002	8	55	13	73	23	4	4	2	4	5	5	5	4	4	4	4	3	4	3	0	3
		DAY 29		31OCT2002	28	57	15	77	27	4	4	4	3	5	5	4	4	3	4	4	5	4	4	4	4
		DAY 29	*	14NOV2002	42	58	16	79	29	4	3	4	4	5	4	4	4	4	4	5	5	4	4	4	3
	E0028023	DAY 1		21JAN2003	1	34		36		4	1	2	3	2	2	2	1	2	3	3	4	3	2	1	2
		DAY 29		17FEB2003	28	35	1	38	2	3	2	3	2	2	3	2	3	1	3	3	4	2	2	3	4
	E0028025	DAY 1		13JAN2003	1	46		57		4	3	3	3	3	3	4	3	4	3	3	4	4	2	0	3
		DAY 29		27JAN2003	15	39	-7	45	-12	4	3	3	2	1	1	2	3	1	4	4	4	4	3	1	2
	E0028033	DAY 1		27MAR2003	1	33		34		1	2	3	3	4	3	2	1	3	4	2	2	2	1	0	2
		DAY 29		24APR2003	29	48	15	61	27	3	4	3	3	3	5	4	4	4	4	3	3	2	3	4	4
		DAY 57		22MAY2003	57	56	23	75	41	4	4	5	4	3	4	4	4	4	4	4	5	3	4	4	4
	E0028035	DAY 1		03APR2003	1	24		18		1	1	2	2	2	2	2	2	1	1	2	3	2	1	0	1
		DAY 29		01MAY2003	29	42	18	50	32	1	4	3	4	3	3	3	3	3	3	3	3	3	3	1	3
		DAY 57		29MAY2003	57	36	12	39	21	2	3	4	2	2	3	2	3	2	1	2	4	4	2	2	3
	E0028037	DAY 1		12JUN2003	-1	44		54		4	3	3	3	3	3	3	3	3	2	3	4	4	3	0	3
		DAY 29		08JUL2003	26	48	4	61	7	4	4	3	3	3	3	4	4	3	3	3	4	3	4	4	4
		DAY 57		08AUG2003	57	60	16	82	28	5	5	4	5	4	4	4	4	4	3	3	5	5	5	5	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	DAY 1		08MAY2003	-1	35		38		3	2	2	3	3	3	2	3	2	2	2	3	2	3	0	2
		DAY 29		05JUN2003	28					4	4	2	4	4	3		3	3		3	4	4	4	4	3
	E0028046	DAY 1		25JUN2003	1	27		23		4	1	1	1	3	1	1	1	2	1	2	3	3	3	0	2
	E0028048	DAY 1		17JUL2003	1	30		29		4	2	3	2	1	2	2	2	1	2	2	3	2	2	0	2
		DAY 29		14AUG2003	29	41	11	48	19	3	3	3	3	3	2	3	3	4	3	3	2	3	3	3	3
	E0029008	DAY 1		16DEC2002	1	42		50		4	2	1	3	3	4	2	3	3	3	3	4	4	3	4	3
		DAY 29		23DEC2002	8	26	-16	21	-29	3	1	1	2	2	3	1	1	2	3	3	1	1	2	3	1
	E0029011	DAY 1		21JAN2003	-1	37		41		3	2	3	4	2	2	1	2	4	1	4	4	2	3	0	2
	E0029012	DAY 1		11FEB2003	1	24		18		3	1	1	1	1	1	1	1	1	2	2	4	4	1	1	1
		DAY 29		11MAR2003	29	33	9	34	16	1	1	3	3	1	3	1	2	3	2	3	4	4	2	3	1
		DAY 29	*	18MAR2003	36	35	11	38	20	1	2	3	3	2	3	2	2	2	2	3	5	4	1	2	1
	E0029015	DAY 1		24FEB2003	1	43		52		3	3	3	3	3	2	3	4	3	3	2	4	4	3	3	3
		DAY 29		11MAR2003	16	39	-4	45	-7	2	3	3	3	2	3	3	1	4	4	4	1	3	3	1	3
	E0029018	DAY 1		06MAR2003	1	43		52		3	2	4	3	2	1	4	3	3	2	4	5	4	3	3	3
	E0030014	DAY 1		21FEB2003	1	23		16		2	1	2	3	1	3	1	1	1	1	1	3	2	1	0	1
		DAY 29		21MAR2003	29	37	14	41	25	2	3	3	3	2	4	2	3	2	2	2	3	3	3	4	3
		DAY 57		22APR2003	61	48	25	61	45	4	3	3	4	3	4	4	3	3	3	3	3	4	4	4	3
	E0030020	DAY 1		29MAY2003	1	30		29		3	2	1	3	2	2	1	2	3	1	2	4	3	1	0	2
		DAY 29		24JUN2003	27	53	23	70	41	4	3	5	3	4	4	4	4	2	3	4	4	4	5	4	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0030024	DAY 1		11JUL2003	1	27		23		1	2		3	3	1	2	2	1	1	2	3	2	2	0	2
		DAY 29		18JUL2003	8	44	17	54	31	1	3	3	3	4	4	4	3	3	2	2	4	5	3	1	3
	E0030025	DAY 1		11JUL2003	1	25		20		2	1	2	1	2	1	3	1	1	1	2	3	3	2	0	1
		DAY 29		11AUG2003	32	44	19	54	34	3	3	4	4	3	4	3	3	1	2	4	3	4	3	4	3
		DAY 29	*	19AUG2003	40	29	4	27	7	1	3	3	2	2	3	2	2	2	1	2	2	2	2	3	3
	E0031027	DAY 1		03JUN2003	1	45		55		2	2	1	2	4	5	5	3	5	1	5	4	2	4	0	3
		DAY 29		01JUL2003	29	44	-1	54	-1	4	2	2	4	4	4	2	4	2	1	3	4	4	4	4	4
		DAY 57		29JUL2003	57	67	22	95	40	5	5	4	5	5	5	5	5	5	3	5	5	5	5	5	5
	E0031030	DAY 1		24JUN2003	1	37		41		3	2	3	3	2	3	2	2	3	3	3	3	3	2	0	2
		DAY 29		23JUL2003	30	56	19	75	34	4	4	4	4	4	4	4	4	4	4	4	4	4	4	5	5
		DAY 57		21AUG2003	59	62	25	86	45	4	4	4	4	5	4	5	5	5	4	4	5	4	5	5	4
	E0033012	DAY 1		10FEB2003	1	31		30		3	2	1	2	1	1	3	2	2	1	4	3	4	2	0	2
	E0034001	DAY 1		20MAR2003	1	25		20		3	3	1	2	1	1	1	1	1	1	1	4	3	2	0	2
		DAY 29		17APR2003	29	33	8	34	14	3	3	2	2	2	2	3	3	1	2	1	3	3	3	3	3
		DAY 57		15MAY2003	57	44	19	54	34	4	4	3	2	3	3	4	3	1	4	1	4	4	4	4	4
	E0034004	DAY 1		21APR2003	1	48		61		4	3	3	4	4	4	3	3	1	3	4	5	4	3	0	3
		DAY 29		19MAY2003	29	66	18	93	32	5	5	5	5	5	5	4	5	3	4	5	5	5	5	5	5
		DAY 57		16JUN2003	57	65	17	91	30	5	5	5	5	5	5	5	5	2	4	4	5	5	5	5	5
	E0035001	DAY 1		20NOV2002	1	43		52		4	3	3	4	2	2	2	3	2	3	4	4	4	3	5	3
		DAY 29		18DEC2002	29	59	16	80	28	5	4	3	5	3	3	5	5	3	4	5	5	5	4	5	3
		DAY 57		14JAN2003	56	64	21	89	37	5	4	5	5	5	5	4	5	3	3	5	5	5	5	5	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 1	12DEC2002	1	30		29		2	2	2	3	2	2	3	2	2	2	2	2	2	2	0	2
		DAY 29	09JAN2003	29	35	5	38	9	2	2	3	3	3	4	3	3	2	3	2	2	1	2	3	3
		DAY 57	06FEB2003	57	35	5	38	9	2	2	2	3	3	3	2	3	2	3	3	2	2	3	3	3
	E0035021	DAY 1	25APR2003	1	40		46		3	2	2	3	4	2	4	3	2	2	3	3	4	3	0	2
		DAY 29	23MAY2003	29	50	10	64	18	4	3	4	4	4	2	3	4	3	2	4	5	4	4	4	4
		DAY 57	20JUN2003	57	48	8	61	15	3	3	4	4	4	3	3	4	3	3	3	4	4	3	4	4
	E0036002	DAY 1	17JUN2003	1	33		34		4	2	1	2	2	2	2	3	1	3	2	4	3	2	0	2
		DAY 29	14JUL2003	28	50	17	64	30	4	2	4	4	2	1	4	4	4	4	5	5	5	2	2	2
	E0036006	DAY 1	03JUL2003	1	22		14		4	1	1	1	1	1	1	1	1	1	3	4	1	1	0	1
		DAY 29	31JUL2003	29	66	44	93	79	5	5	5	5	4	5	5	5	3	4	5	5	5	5	5	5
		DAY 57	27AUG2003	56	67	45	95	81	5	5	5	5	5	5	4	5	4	4	5	5	5	5	5	5
	E0036007	DAY 1	03JUL2003	1	23		16		2	1	1	1	1	1	1	1	1	3	3	4	2	1	0	1
		DAY 29	18JUL2003	16	54	31	71	55	4	3	5	4	4	4	4	4	3	3	4	4	4	4	4	4
	E0037009	DAY 1	16MAY2003	1	40		46		4	2	3	3	3	3	3	3	3	1	2	4	3	3	3	3
		DAY 29	12JUN2003	28	45	5	55	9	2	3	3	5	4	4	4	3	3	1	3	2	4	4	3	4
		DAY 57	10JUL2003	56	47	7	59	13	3	3	2	5	4	4	4	3	4	1	4	2	4	4	3	4
	E0039011	DAY 1	02JAN2003	1	33		34		4	1	1	1	1	1	3	3	1	2	2	5	5	3	0	1
		DAY 29	03FEB2003	33	56	23	75	41	5	5	3	4	5	3	4	5	3	3	3	5	4	4	5	5
	E0039018	DAY 1	23JAN2003	1	38		43		5	1	1	2	2	1	5	3	3	2	2	4	4	3	0	3
		DAY 29	20FEB2003	29	51	13	66	23	4	3	4	5	4	3	5	3	3	2	3	4	4	4	5	3
	E0039026	DAY 1	07MAR2003	1	42		50		4	1	2	2	2	2	3	3	4	4	4	5	4	2	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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GENERATED: 12JUL2005 17:46:10 iceadmn3

Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	DAY 29	04APR2003	29	44	2	54	4	3	4	4	4	2	2	2	4	2	4	4	3	4	2	4	4
		DAY 57	01MAY2003	56	55	13	73	23	3	4	4	4	4	4	4	4	3	4	5	5	3	4	4	3
	E0039028	DAY 1	24MAR2003	1	42		50		4	3	3	4	3	3	4	3	1	1	3	4	3	3	4	3
		DAY 29	21APR2003	29	30	-12	29	-21	3	2	2	2	1	2	2	2	1	2	2	4	3	2	3	2
	E0039032	DAY 1	14MAR2003	1	36		39		3	2	2	3	2	2	2	2	2	2	1	5	5	3	0	1
	E0039034	DAY 1	19MAR2003	1	46		57		4	3	3	3	3	2	3	3	3	2	4	5	5	3	4	3
		DAY 29	16APR2003	29	54	8	71	14	4	4	4	4	4	3	4	4	4	3	4	4	4	4	5	4
		DAY 57	14MAY2003	57	64	18	89	32	5	4	5	4	4	5	4	5	4	4	5	5	5	5	5	5
	E0039042	DAY 1	07MAY2003	1	31		30		3	2	2	2	1	1	3	3	1	3	1	5	2	2	0	1
		DAY 29	05JUN2003	30	55	24	73	43	4	4	4	4	4	4	4	4	4	3	4	4	4	4	4	4
		DAY 57	02JUL2003	57	54	23	71	41	4	4	4	4	4	4	4	4	2	4	4	4	4	4	4	4
	E0041004	DAY 1	30JAN2003	1	44		54		2	3	3	4	3	4	2	3	3	3	3	4	4	3	0	3
		DAY 57	31MAR2003	61	55	11	73	19	3	4	4	5	4	4	4	4	4	4	3	4	4		4	4
	E0041009	DAY 1	01MAY2003	1	19		9		2	2	1	1	1	1	1	1	1	1	1	3	2		0	1
		DAY 57	16JUN2003	47	32	13	32	23	2	3	1	2	3	3	3	2	3	1	2	3	2	2	3	2
	E0042002	DAY 1	09JUL2003	1	40		46		3	2	4	3	2	2	3	3	1	3	4	4	3	3	2	3
		DAY 29	05AUG2003	28	56	16	75	29	4	3	4	4	4	4	5	4	4	3	4	5	4	4	5	4
		DAY 57	02SEP2003	56	54	14	71	25	4	4	3	4	4	4	4	4	4	3	4	4	4	4	4	4
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	36		39		3	1	2	3	3	3	2	1	5	2	3	4	2	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATISFACTION
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 29	18JUL2003	8	34	-2	36	-3	4	1	2	2	2	2	2	2	4	2	3	4	2	2	1	2
	E0003002	DAY 1	29OCT2002	1	27		23		1	2	1	1	2	2	2	2	2	1	1	4	4	2	0	1
		DAY 29	26NOV2002	29	47	20	59	36	4	3	4	4	4	4	2	4	4	2	2	4	4	2	4	4
		DAY 57	23DEC2002	56	63	36	88	65	5	3	5	4	5	5	5	5	5	3	4	5	4	5	5	5
	E0005031	DAY 1	02APR2003	1	33		34		2	2	2	2	2	2	2	3	3	2	3	3	2	3	0	4
		DAY 29	01MAY2003	30	42	9	50	16	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	E0005033	DAY 1	15APR2003	-1	33		34		5	1	4	4	1	1	2	1	1	1	1	5	5	1	0	1
		DAY 29	06MAY2003	21	31	-2	30	-4	4	1	2	2	1	1	2	2	1	2	2	5	4	2	1	1
	E0005038	DAY 1	14MAY2003	1	24		18		2	1	2	1	2	1	2	2	2	1	2	3	2	1	0	1
		DAY 29	05JUN2003	23	20	-4	11	-7	1	1	2	1	1	1	1	2	1	2	2	3	1	1	1	1
	E0007009	DAY 1	17APR2003	1	34		36		4	1	2	2	2	2	2	2	2	2	2	5	4	2	2	2
		DAY 29	28APR2003	12	38	4	43	7	4	2	3	2	3	3	3	3	2	2	2	3	4	2	1	2
	E0009010	DAY 1	13MAR2003	1	34		36		4	1	3	2	1	1	3	2	5	1	1	5	3	2	0	2
	E0009011	DAY 1	06MAY2003	1	39		45		4	1		4	2	1	2	2	2	3	4	5	4	2	0	1
		DAY 29	03JUN2003	29	55	16	73	28	4	4		4	4	4	4	4	4	4	4	4	4	3		4
		DAY 57	03JUL2003	59	50	11	64	19	3	4		4	3	1	3	4	4	4	4	5	4	3	4	3
	E0010005	DAY 1	18DEC2002	1	41		48		3	2	3	3	2	2	2	3	3	3	3	5	4	3	0	3
	E0011016	DAY 1	21APR2003	1	27		23		2	1	1	3	2	3	2	1	3	2	2	2	1	2	1	2
		DAY 29	19MAY2003	29	30	3	29	6	2	3	1	2	2	3	1	2	2	3	3	2	2	2	3	3
		DAY 57	16JUN2003	57	44	17	54	31	3	3	4	4	3	3	3	3	2	3	3	4	3	3	5	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR II)	E0011020	DAY 1	08MAY2003	1	33			34	3	1	3	2	2	2	2	2	4	2	2	4	2	2	4	2
	E0018002	DAY 1	29NOV2002	1	31			30	2	1	3	2	2	2	2	2	1	3	3	4	3	1	4	1
		DAY 29	24DEC2002	26	28	-3	-5	25	2	2	3	1	1	2	2	1	1	2	3	4	3	1	3	1
		DAY 57	22JAN2003	55	33	2	4	34	3	1	3	2	2	3	1	2	2	3	3	4	2	2	1	2
	E0018003	DAY 1	26NOV2002	1	38			43	2	3	3	3	3	3	2	3	2	2	3	4	2	3	3	3
		DAY 29	10DEC2002	15	33	-5	-9	34	2	3	3	2	3	2	2	1	2	1	3	4	3	2	1	2
	E0018013	DAY 1	24JAN2003	1	38			43	3	3	2	3	3	3	3	3	2	2	2	3	3	3	0	3
		DAY 29	31JAN2003	8	49	11	20	63	4	3	3	3	4	4	3	3	4	3	3	4	4	4	0	3
	E0019002	DAY 1	12NOV2002	1	41			48	4	3	4	1	1	3	1	4	1	3	2	5	5	4	0	4
	E0019008	DAY 1	21NOV2002	1	33			34	3	3	2	1	3	3	2	2	1	1	3	3	3	3	4	3
		DAY 29	19DEC2002	29	48	15	27	61	4	3	3	3	4	3	3	4	2	3	4	4	4	4	3	4
	E0019009	DAY 1	14NOV2002	1	45			55	4	3	1	1	2	4	3	3	5	3	4	5	4	3	0	4
		DAY 29	10DEC2002	27	42	-3	-5	50	3	2	2	3	4	4	2	2	3	2	4	4	4	3	3	2
	E0019016	DAY 1	06JAN2003	1	26			21	3	2	2	1	1	1	2	2	1	1	2	4	2	2	0	2
		DAY 29	03FEB2003	29	53	27	49	70	4	4	4	4	3	3	4	4	4	3	4	4	4	4	4	4
		DAY 57	03MAR2003	57	56	30	54	75	3	4	4	4	3	4	5	5	4	3	4	5	4	4	4	4
	E0019020	DAY 1	23JAN2003	1	26			21	3	2	3	1	1	1	1	2	2	1	3	2	2		0	2
		DAY 29	20FEB2003	29	47	21	38	59	4	3	3	4	3	3	3	4	3	3	4	4	3		2	3
		DAY 57	27MAR2003	64	36	10	18	39	3	2	2	3	2	2	2	3	3	3	3	3	3	2	0	2
	E0019021	DAY 1	30JAN2003	1	27			23	3	1	1	1	1	1	1	3	4	1	1	5	3	1	3	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	DAY 29	03MAR2003	33	43	16	52	29	3	2	2	2	3	3	3	4	3	3	3	5	5	2	2	2
	E0019024	DAY 1	30JAN2003	1	46		57		4	3	4	2	3	2	3	4	5	1	2	5	5	3	0	3
		DAY 29	06FEB2003	8	61	15	84	27	4	5	5	5	4	5	4	5	5	4	5	3	3	4	3	5
	E0019031	DAY 1	13MAR2003	1	35		38		3	1	3	2	1	2	2	2	2	3	3	4	4	3	0	2
		DAY 29	25MAR2003	13	41	6	48	10	3	3	4	3	3	3	3	2	2	3	3	3	3	3	3	3
	E0019035	DAY 1	18MAR2003	1	29		27		4	1	1	1	1	1	1	1	5	1	5	1	4		2	
		DAY 29	17APR2003	31	14	-15	0	-27	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	E0019040	DAY 1	20MAY2003	1	25		20		2	1	1	3	3	1	2	1	3	1	1	4	1	1	3	2
		DAY 29	18JUN2003	30	37	12	41	21	3	3	3	2	3	2	3	3	4	1	3	2	2	3	2	2
		DAY 57	17JUL2003	59	38	13	43	23	3	3	1	3	3	4	2	3	4	1	3	3	2	3	2	3
	E0019042	DAY 1	04JUN2003	1	39		45		4	1	2	3	2	4	3	3	4	3	1	4	3	2	0	2
		DAY 29	19JUN2003	16	44	5	54	9	4	3	3	3	3	4	4	2	3	3	2	3	4	3	1	4
	E0019045	DAY 1	26JUN2003	1	42		50		4	2	3	2	4	3	2	3	2	2	4	5	3	3	3	3
		DAY 29	16JUL2003	21	42	0	50	0	4	3	3	3	3	2	2	2	3	3	4	4	3	3	0	3
	E0020024	DAY 1	23JUN2003	1	49		63		4	3	5	3	4	3	2	4	5	3	1	4	4	4	0	3
		DAY 29	21JUL2003	29	54	5	71	8	5	5	5	4	4	4	2	3	4	4	3	4	3	4	3	5
		DAY 57	20AUG2003	59	62	13	86	23	5	5	5	4	5	5	3	5	5	3	2	5	5	5	5	5
	E0022044	DAY 1	18MAR2003	1	38		43		3	3	3	3	3	2	3	3	2	3	3	1	3	3	0	1
		DAY 29	15APR2003	29	49	11	63	20	4	3	3	4	3	4	4	3	4	4	4	3	3	3	4	3
		DAY 57	12MAY2003	56	50	12	64	21	4	4	3	3	4	3	3	4	4	3	3	4	4	4	4	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	DAY 1	14JAN2003	1	39		45		1	2	2	2	4	4	3	4	4	1	2	3	4	3	3	3
		DAY 29	11FEB2003	29	50	11	64	19	4	3	2	4	4	4	4	3	4	3	4	5	2	4	2	4
		DAY 57	11MAR2003	57	62	23	86	41	4	4	5	3	5	5	5	4	5	2	5	5	5	5	3	5
	E0023011	DAY 1	04FEB2003	1	20		11		2	1	1	1	2	2	1	1	1	2	2	2	1	1	2	1
		DAY 29	04MAR2003	29	38	18	43	32	3	3	2	3	3	2	2	3	2	3	3	3	3	3	3	3
		DAY 57	01APR2003	57	49	29	63	52	3	4	4	4	3	4	3	4	3	3	4	4	2	4	4	4
	E0023014	DAY 1	21FEB2003	1	20		11		1	1	1	3	1	1	1	2	2	1	1	2	2	1	2	1
		DAY 29	25MAR2003	33	34	14	36	25	2	3	1	3	2	1	3	3	3	1	3	5	1	3	3	3
		DAY 57	25APR2003	64	41	21	48	37	3	3	2	5	3	2	2	3	2	2	3	5	3	3	1	3
	E0023019	DAY 1	07APR2003	1	42		50		4	2	3	2	3	3	4	3	3	3	4	4	3	1	4	3
		DAY 29	06MAY2003	30	49	7	63	13	4	3	4	3	3	3	3	3	3	4	4	4	4	4	4	4
		DAY 57	03JUN2003	58	54	12	71	21	4	4	4	4	4	3	4	4	4	3	4	4	4	4	5	4
	E0023022	DAY 1	18APR2003	1	40		46		3	2	3	3	3	4	3	3	3	2	3	4	2	2	0	2
		DAY 29	15MAY2003	28	59	19	80	34	4	5	4	3	5	5	5	4	4	3	4	5	4	4	4	4
		DAY 57	12JUN2003	56	61	21	84	38	5	4	4	5	5	5	4	4	4	4	4	5	4	4	5	5
	E0023023	DAY 1	25APR2003	1	42		50		3	3	3	3	2	4	2	4	3	2	2	5	3	3	3	2
		DAY 29	01MAY2003	7	41	-1	48	-2	4	4	2	2	4	4	2	3	3	3	2	3	3	2	1	1
	E0023029	DAY 1	23MAY2003	1	43		52		3	2	4	2	4	4	2	3	3	4	3	5	2	2	0	3
	E0023031	DAY 1	24JUN2003	1	16		4		2	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1
		DAY 29	22JUL2003	29	45	29	55	51	4	4	2	4	2	4	4	4	2	2	3	3	3	4	4	4
		DAY 57	19AUG2003	57	36	20	39	35	4	2	2	2	2	4	2	2	3	2	3	4	2	2	3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	DAY 1	09JUL2003	1	39		45	4	2	4	1	3	3	3	2	3	3	3	5	1	2	0	2
		DAY 29	06AUG2003	29	40	1	46 1	4	2	3	2	3	3	2	3	3	3	3	4	2	3	2	2
		DAY 57	05SEP2003	59	37	-2	41 -4	4	1	3	1	3	3	3	2	2	3	4	3	3	2	2	1
	E0023043	DAY 1	14JUL2003	1	48		61	5	3	4	3	3	4	3	3	4	2	4	3	4	3	3	3
		DAY 29	12AUG2003	30	49	1	63 2	4	4	3	4	3	4	4	4	4	1	4	4	3	3	4	3
		DAY 57	09SEP2003	58	56	8	75 14	4	4	3	4	4	4	3	5	5	2	5	5	4	4	5	4
	E0026003	DAY 1	04DEC2002	1	31		30	3	1	1	2	1	1	1	2	1	4	4	4	4	2	0	2
		DAY 29	02JAN2003	30	66	35	93 63	4	5	4	4	4	5	5	5	5	5	5	5	5	5	0	5
		DAY 57	03FEB2003	62	34	3	36 6	1	4	1	1	4	5	2	2	1	5	5	1	1	1	0	1
	E0026005	DAY 1	30DEC2002	1	31		30	2	2	1	2	3	3	2	2	1	2	3	3	3	2	0	2
		DAY 29	06JAN2003	8	17	-14	5 -25	1	1	1	1	1	1	1	1	1	2	3	1	1	1	1	1
	E0026009	DAY 1	15JAN2003	1	27		23	2	1	1	1	1	3	2	1	1	3	3	3	3	2	0	1
		DAY 29	21JAN2003	7	28	1	25 2	2	2	2	2	2	3	2	2	2	3	2	1	1	2	1	1
	E0026015	DAY 1	27FEB2003	1	35		38	4	2	1	2	1	3	2	2	5	3	2	4	2	2	0	2
		DAY 29	27MAR2003	29	42	7	50 12	4	2	2	4	3	3	3	4	3	2	1	4	4	3	3	2
		DAY 57	25APR2003	58	43	8	52 14	4	3	3	4	3	2	3	3	3	2	2	4	4	3	3	3
	E0026023	DAY 1	30APR2003	1	27		23	2	1	1	1	1	1	1	5	5	1	1	3	1	3	0	2
		DAY 29	28MAY2003	29	48	21	61 38	3	1	4	5	5	3	1	5	5	3	1	5	3	4	5	3
	E0027016	DAY 1	09APR2003	1	33		34	2	2	5	2	2	2	2	2	4	1	1	2	4	2	0	2
		DAY 29	05MAY2003	27	44	11	54 20	3	4	5	3	2	2	3	3	4	1	1	5	5	3	4	3
		DAY 57	03JUN2003	56	46	13	57 23	3	4	5	2	3	2	3	4	4	2	1	5	5	3	4	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	DAY 1	25MAR2003	1	31			30	2	1	2	2	2	2	2	1	1	2	3	3	3	5	5	2
		DAY 29	22APR2003	29	64	33	89	59	3	5	4	4	5	5	5	5	4	4	5	5	5	5	5	4
		DAY 57	22MAY2003	59	63	32	88	58	5	4	5	5	4	4	5	4	4	4	5	5	4	5	5	4
	E0028032	DAY 1	25MAR2003	1	40			46	4	3	1	3	2	4	3	3	2	2	4	3	4	2	3	2
		DAY 29	22APR2003	29	41	1	48	2	4	3	2	3	2	3	2	3	3	1	5	4	4	2	3	2
	E0029003	DAY 1	04NOV2002	1	35			38	4	2	3	2	1	1	2	3	2	3	1	4	4	3	0	3
		DAY 29	02DEC2002	29	44	9	54	16	4	2	3	4	3	1	2	3	2	3	5	5	3	4	4	3
		DAY 57	30DEC2002	57	39	4	45	7	3	2	2	3	2	2	2	3	1	3	4	5	3	4	3	3
	E0029020	DAY 1	04MAR2003	-1	39			45	2	2	3	2	3	3	2	1	4	1	4	5	5	2	0	2
	E0031005	DAY 1	20DEC2002	1	52			68	4	3	4	4	4	4	4	4	1	4	4	4	4	4	0	4
		DAY 29	17JAN2003	29	56	4	75	7	4	4	4	4	4	4	4	4	2	4	4	5	5	4	4	4
		DAY 57	14FEB2003	57	54	2	71	3	4	4	4	4	4	4	4	4	2	4	4	4	4	4	4	4
	E0031006	DAY 1	18FEB2003	1	31			30	4	2	1	3	1	2	3	2	3	1	1	3	2	3	0	2
		DAY 29	18MAR2003	29	48	17	61	31	4	4	3	4	5	2	4	4	3	2	3	4	2	4	5	4
		DAY 57	15APR2003	57	42	11	50	20	4	4	2	3	2	2	4	4	4	2	1	4	2	4	5	4
	E0031010	DAY 1	19FEB2003	1	29			27	3	2	1	1	1	1	3	2	3	1	1	4	5	1	0	1
		DAY 29	05MAR2003	15	34	5	36	9	1	1	2	3	2	3	2	2	3	3	2	4	4	2	1	2
	E0031011	DAY 1	27FEB2003	1	44			54	4	3	3	3	3	2	3	4	2	3	4	4	2	4	0	3
		DAY 29	27MAR2003	29	64	20	89	35	5	5	4	4	4	5	5	5	4	4	4	5	5	5	5	5
		DAY 57	24APR2003	57	62	18	86	32	5	4	4	5	4	4	5	5	3	4	4	5	5	5	5	5
	E0031015	DAY 1	26MAR2003	1	33			34	2	2	2	1	3	4	1	3	2	3	3	3	2	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	DAY 29	01APR2003	7	38	5	43	9	2	2	2	3	3	4	4	1	4	3	4	1	2	3	2	3
	E0031031	DAY 1	08JUL2003	1	40		46		3	2	2	3	4	3	3	3	2	2	3	5	3	2	0	3
	E0033009	DAY 1	12FEB2003	1	21		13		1	1	1	1	1	3	1	1	1	1	3	3	2	1	0	1
	E0034009	DAY 1	19JUN2003	1	30		29		4	2	2	2	2	2	2	2	2	1	1	4	2	2	0	2
		DAY 29	18JUL2003	30	43	13	52	23	4	3	3	3	3	3	3	3	4	3	2	2	4	3	3	3
		DAY 57	18AUG2003	61	54	24	71	42	4	3	4	4	4	3	4	4	4	4	4	4	4	4	3	4
	E0037007	DAY 1	11APR2003	1	40		46		3	2	3	3	3	3	3	2	1	2	3	5	4	3	0	1
	E0037012	DAY 1	16JUL2003	1	46		57		4	3	5	1	3	2	4	3	5	2	1	5	5	3	0	3
		DAY 29	15AUG2003	31	62	16	86	29	5	4	5	5	5	4	5	5	5	3	4	3	5	4	5	5
		DAY 57	08SEP2003	55	66	20	93	36	5	5	5	5	5	3	5	5	5	3	5	5	5	5	5	5
	E0039019	DAY 1	06FEB2003	1	41		48		4	3	1	2	4	2	2	4	4	1	3	4	4	3	0	3
		DAY 29	07MAR2003	30	57	16	77	29	4	4	4	4	4	4	5	4	5	4	4	3	4	4	4	4
		DAY 57	03APR2003	57	51	10	66	18	4	4	4	3	3	4	4	4	4	3	3	4	4	3	4	3
	E0039043	DAY 1	08MAY2003	1	45		55		3	2	1	4	3	4	3	2	4	3	4	4	4	4	0	3
		DAY 29	05JUN2003	29	54	9	71	16	5	5	1	4	5	3	3	5	4	1	3	5	5	5	5	3
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	34		36		3	2		2	1	2	2	2	1	3	3	4	4	3	0	2
		DAY 29	29JAN2003	31	47	13	59	23	4	2		5	1	3	4	4	1	4	4	5	4	3	4	2
		DAY 57	26FEB2003	59	42	8	50	14	3	3		3	3	2	3	4	1	3	3	4	4	3	4	4
	E0002003	DAY 1	22JAN2003	1	27		23		4	2	1	1	2	1	3	1	1	1	1	2	4	3	4	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0002003	DAY 29		19FEB2003	29	40	13	46	23	3	4	1	1	5	4	4	3	5	1	1	2	3	3	3	4
		DAY 57		18MAR2003	56	40	13	46	23	3	4		2	3	1	2	3	5	2	1	4	4	3	3	4
	E0002004	DAY 1		25JAN2003	1	40		46		2	3		3	2	2	4	3	2	4	4	2	4	2	4	2
	E0002008	DAY 1		25FEB2003	1	37		41		4	2	2	3	2	3	3	2	4	2	1	4	3	2	0	2
		DAY 29		27MAR2003	31	31	-6	30	-11	3	2	2	1	2	3	2	1	3	2	1	4	3	2	0	2
		DAY 57		23APR2003	58	35	-2	38	-3	3	2	2	2	1	3	3	3	4	2	1	4	3	2	0	2
	E0002016	DAY 1		24JUL2003	1	29		27		3	2	2	1	2	1	1	2	1	1	4	3	4	2	4	2
		DAY 29		21AUG2003	29	39	10	45	18	1	3	3	2	3	4	4	3	2	1	4	2	4	3	4	3
		DAY 57		17SEP2003	56	48	19	61	34	4	3		3	4	3	4	4	3	2	4	3	4	4	4	3
	E0003008	DAY 1		28JAN2003	1	44		54		4	3	3	2	3	3	3	3	4	2	3	5	4	2	0	2
	E0004003	DAY 1		10OCT2002	1	36		39		4	2	1	2	3	3	2	2	2	1	4	4	4	2	0	1
		DAY 57		02OCT2003	358	39	3	45	6	4	1	1	2	4	4	2	2	2	2	4	5	4	2	0	1
	E0004006	DAY 1		04NOV2002	1	44		54		4	3	2	2	3	3	3	3	3	2	4	4	4	4	0	3
		DAY 29		02DEC2002	29	41	-3	48	-6	4	3	2	1	3	4	3	2	3	2	3	4	4	3	3	3
		DAY 57		06JAN2003	64	39	-5	45	-9	4	2	2	2	2	3	3	2	1	3	4	4	4	3	2	2
	E0004016	DAY 1		19FEB2003	1	41		48		4	2	2	2	4	4	4	3	1	3	4	2	3	3	0	2
		DAY 57		17APR2003	58	57	16	77	29	5	5	4	3	4	4	5	4	2	3	5	5	3	5	5	5
	E0004024	DAY 1		03JUL2003	1	35		38		2	3	2	2	3	3	2	2	2	2	3	4	2	3	0	3
		DAY 29		31JUL2003	29	42	7	50	12	3	3	3	3	4	4	2	3	3	2	3	4	2	3	3	3
		DAY 57		28AUG2003	57	50	15	64	26	4	4	4	3	3	4	3	4	3	3	4	5	3	3	4	4
	E0005006	DAY 1	*	24SEP2002	-9	52		68		4	3	2	4	5	5	4	3	4	3	4	5	3	3	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0005006	DAY 1	03OCT2002	1	63		88		5	4	4	5	5	4	4	4	5	5	5	5	4	4	4	4
	E0005017	DAY 1	30DEC2002	1	36		39		3	2	3	2	2	3	2	2	2	3	3	4	3	2	3	3
		DAY 29	30JAN2003	32	38	2	43	4	2	3	3	3	3	3	2	3	1	3	3	4	2	3	2	3
		DAY 57	04MAR2003	65	37	1	41	2	3	3	3	2	2	2	2	3	1	3	3	4	3	3	3	3
	E0005019	DAY 1	15JAN2003	1	27		23		2	1	2	2	2	2	2	2	2	1	1	4	2	2	0	2
		DAY 29	23JAN2003	9	25	-2	20	-3	3	1	1	2	2	2	2	1	2	2	1	4	1	1	1	1
	E0005026	DAY 1	06MAR2003	1	33		34		3	1	2	2	1	3	1	3	1	1	3	5	4	3	0	3
		DAY 29	25MAR2003	20	22	-11	14	-20	1	1	3	2	2	1	1	1	1	1	2	4	1	1	1	1
	E0005039	DAY 1	22MAY2003	1	35		38		3	2	2	2	3	3	2	2	3	2	3	3	2	3	0	3
		DAY 29	18JUN2003	28	44	9	54	16	4	3	3	3	3	3	3	3	3	3	3	4	3	3	0	3
		DAY 57	16JUL2003	56	39	4	45	7	3	2	2	2	3	3	3	3	2	3	3	4	3	3	3	3
	E0005043	DAY 1	09JUL2003	1	30		29		3	1	1	1	1	1	1	2	2	2	2	5	5	3	0	2
		DAY 29	07AUG2003	30	37	7	41	12	3	3	2	2	2	2	2	2	3	2	3	5	3	3	1	3
		DAY 57	03SEP2003	57	57	27	77	48	4	4	4	5	4	4	4	4	3	3	4	5	5	4	2	4
	E0006020	DAY 1	13MAY2003	1	25		20		2	2	1	2	1	2	1	2	2	1	2	3	2	2	0	1
		DAY 29	10JUN2003	29	45	20	55	35	3	3	2	4	3	3	3	4	4	3	3	4	3	3	4	4
		DAY 57	08JUL2003	57	49	24	63	43	3	4	4	3	4	3	3	4	3	4	3	3	4	4	3	4
	E0007001	DAY 1	31DEC2002	1	33		34		3	2	1	3	2	2	2	2	3	2	3	4	2	2	0	2
		DAY 29	28JAN2003	29	35	2	38	4	5	2	1	2	2	2	2	3	2	2	3	5	2	2	0	3
		DAY 57	22FEB2003	54	49	16	63	29	4	3	1	3	4	4	4	4	3	3	4	4	4	4	4	3
	E0007003	DAY 1	30JAN2003	1	34		36		3	1	1	2	2	3	1	3	2	3	4	5	2	2	0	2
		DAY 29	10MAR2003	40	37	3	41	5	2	2	1	3	2	3	1	3	3	3	4	4	4	2	3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:46:10 iceadmn3

Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0007006	DAY 1		05MAR2003	1	46		57		5	2	2	3	3	2	3	3	4	4	4	4	4	3	0	2
		DAY 29		26MAR2003	22	45	-1	55	-2	4	4	1	3	2	2	3	3	3	4	4	5	4	3	3	3
	E0009004	DAY 1		26NOV2002	1	40		46		3	2	2	3	3	4	3	2	2	2	4	4	4	2	0	2
		DAY 29		18DEC2002	23	34	-6	36	-10	3	1	2	2	3	3	2	2	3	1	2	4	4	2	2	2
	E0009012	DAY 1		25JUN2003	1	39		45		4	5	3	2	2	2	2	2	3	3	3	4	2	2	0	2
		DAY 29		03JUL2003	9	37	-2	41	-4	2	2	2	2	2	2	2	2	3	3	4	5	4	2	2	2
	E0010008	DAY 1		18DEC2002	1	35		38		4	3	2	2	2	3	2	1	1	3	1	5	5	1	3	2
		DAY 29		15JAN2003	29	43	8	52	14	4	3	2	4	2	2	3	4	1	3	3	5	4	3	3	3
	E0010018	DAY 1		19MAR2003	1	26		21		3	1	1	1	1	1	1	3	1	3	4	4	1	1	0	1
		DAY 29		16APR2003	29	42	16	50	29	4	2	5	1	2	1	3	2	2	3	4	5	5	3	3	3
	E0010028	DAY 1		16JUN2003	1	35		38		3	2	2	2	3	3	2	2	1	2	4	4	2	3	0	3
		DAY 29		15JUL2003	30	22	-13	14	-24	1	1	1	1	1	1	1	1	1	4	4	3	1	1	1	1
	E0011008	DAY 1		30JAN2003	1	43		52		3	3	2	2	4	4	2	3	5	2	3	4	3	3	0	1
		DAY 29		13FEB2003	15	47	4	59	7	3	3	3	4	3	4	4	4	2	3	3	4	3	4	0	3
	E0011009	DAY 1		26DEC2002	-1	39		45		3	3	4	3	2	2	1	3	3	2	2	3	4	4	0	3
		DAY 29		23JAN2003	28	44	5	54	9	3	3	4	3	2	4	2	4	3	2	3	4	4	3	3	3
		DAY 57		20FEB2003	56	44	5	54	9	3	3	4	3	2	3	3	4	4	2	3	4	3	3	3	3
	E0011010	DAY 1		10FEB2003	1	24		18		1	1	1	1	1	3	1	1	1	3	4	4	1	1	1	1
		DAY 29		10MAR2003	29	53	29	70	52	4	4	4	4	4	4	4	4	2	3	4	4	4	4	3	4
		DAY 29	*	19MAR2003	38	39	15	45	27	2	2	2	3	3	3	3	2	1	2	4	5	5	2	1	2
	E0013001	DAY 1	*	31OCT2002	-14	45		55		3	3	3	4	2	3	3	3	3	2	4	5	4	3	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0013001	DAY 1		14NOV2002	1	45		55		3	3	2	3	4	3	3	3	2	3	3	5	5	3	0	3
		DAY 29		11DEC2002	28	52	7	68	13	3	4	4	4	4	3	4	4	2	4	4	4	4	4	3	4
		DAY 57	*	02JAN2003	50																				
		DAY 57		10JAN2003	58	56	11	75	20	4	4	4	4	4	4	4	4	3	4	4	4	5	4	3	4
	E0013003	DAY 1		12NOV2002	1	31		30		2	2	2	2	2	3	2	3	1	1	3	3	3	2	0	2
		DAY 29		11DEC2002	30	23	-8	16	-14	1	1	1	1	1	1	1	2	2	1	2	4	3	2	1	2
		DAY 57		06JAN2003	56	25	-6	20	-10	2	2	1	2	1	2	2	2	1	2	2	2	3	1	2	2
	E0013005	DAY 1		18FEB2003	1	29		27		3	1	1	2	1	3	1	2	1	1	1	4	4	4	0	2
		DAY 29		19MAR2003	30	39	10	45	18	2	3	2	2	3	2	4	3	1	3	2	4	5	3	3	3
		DAY 57		15APR2003	57	43	14	52	25	3	3	4	2	3	3	3	3	2	3	3	4	4	3	3	3
	E0013013	DAY 1		06MAY2003	1	25		20		1	1	1	1	1	1	1	1	1	1	5	4	5	1	0	1
		DAY 29		30MAY2003	25	28	3	25	5	3	1	1	3	1	1	1	1	1	2	1	5	5	2	1	2
	E0014002	DAY 1		26FEB2003	1	33		34		1	1	1	1	3	4	3	2	1	1	4	5	4	2	0	2
		DAY 29		27MAR2003	30	40	7	46	12	4	3	3	1	3	4	1	3	2	2	3	5	3	3	2	3
		DAY 57		10APR2003	44	28	-5	25	-9	2	2	1	1	2	3	2	1	1	2	2	5	2	2	2	2
	E0014004	DAY 1		12MAR2003	1	37		41		3	3	2	2	3	3	1	3	1	2	3	3	4	4	0	3
		DAY 29		15APR2003	35	32	-5	32	-9	3	2	2	2	2	2	2	2	2	1	2	3	4	3	0	2
	E0014009	DAY 1		23APR2003	1	33		34		2	1	3	2	2	2	3	3	1	1	2	5	4	2	3	2
		DAY 29		16MAY2003	24	42	9	50	16	4	1	3	5	1	2	3	3	1	1	5	5	5	3	3	4
	E0014015	DAY 1		18JUN2003	1	46		57		3	1	1	3	5	5	5	3	2	3	5	3	4	3	3	3
	E0014017	DAY 1		27JUN2003	1	40		46		3	3	3	2	3	2	3	3	3	2	2	4	4	3	1	3
		DAY 29		23JUL2003	27	60	20	82	36	4	5	4	5	4	4	4	4	4	4	4	4	5	5	5	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0014017	DAY 57	19AUG2003	54	60	20	82	36	4	4	4	4	5	4	5	4	4	5	4	4	4	5	4	5
	E0014018	DAY 1	01JUL2003	1	34		36		2	3	1	2	3	3	4	1	3	1	3	1	5	2	0	3
		DAY 29	29JUL2003	29	45	11	55	19	3	4	2	3	4	4	4	2	4	2	4	2	4	3	1	3
		DAY 57	27AUG2003	58	47	13	59	23	3	4	3	3	4	4	4	2	4	3	4	3	3	3	3	3
	E0015005	DAY 1	02DEC2002	1	31		30		2	1	2	2	1	2	2	3	1	1	4	4	3	3	0	2
		DAY 29	18DEC2002	17	34	3	36	6	2	2	3	3	2	1	2	2	1	2	4	5	3	2	1	2
	E0018009	DAY 1	06JAN2003	1	31		30		4	1	1	1	5	1	3	1	5	1	1	4	1	2	0	2
		DAY 29	14JAN2003	9	30	-1	29	-1	3	1	2	3	4	2	2	1	4	1	1	3	2	1	1	1
	E0018010	DAY 1	16JAN2003	1	34		36		2	2	2	2	3	3	3	2	2	3	3	3	2	2	0	2
		DAY 29	13FEB2003	29	30	-4	29	-7	1	2	2	2	2	3	2	1	2	3	3	4	2	1	2	2
		DAY 57	13MAR2003	57	31	-3	30	-6	2	2	2	2	2	2	2	2	2	3	2	4	2	2	3	2
	E0018015	DAY 1	28JAN2003	1	30		29		3	2		2	1	2	2	2	2	2	2	4	2	2	0	2
		DAY 29	26FEB2003	30	34	4	36	7	3	3	1	3	1	2	3	3	3	2	2	4	2	2	2	1
		DAY 57	27MAR2003	59	37	7	41	12	3	3	2	3	2	2	2	3	3	2	2	4	3	3	0	1
	E0020015	DAY 1	27MAR2003	1	20		11		1	1	1	1	1	3	1	1	1	2	2	3	1	1	0	1
		DAY 29	23APR2003	28	24	4	18	7	1	1	1	2	1	4	2	1	1	1	2	4	2	1	2	1
		DAY 57	23MAY2003	58	20	0	11	0	2	2	1	1	1	1	1	1	1	1	1	3	3	1	3	1
	E0020017	DAY 1	03APR2003	1	40		46		4	3	3	4	1	3	4	2	3	1	3	3	3	3	0	3
		DAY 29	29APR2003	27	40	0	46	0	3	2	3	3	2	3	2	3	3	2	4	3	3	4	2	4
	E0020020	DAY 1	12MAY2003	1	28		25		3	1	1	2	2	3	1	1	1	2	2	4	4	1	0	1
		DAY 29	23MAY2003	12	19	-9	9	-16	2	1	1	1	2	2	1	1	1	2	1	2	1	1	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0020022	DAY 1		16JUN2003	1	40			46	4	3	2	2	2	3	3	3	1	2	4	4	4	3	0	3
		DAY 29		14JUL2003	29	52	12	68	22	4	4	4	4	4	4	4	4	1	3	4	4	4	4	4	4
		DAY 57		11AUG2003	57	53	13	70	24	4	4	4	4	4	4	4	4	1	4	4	4	4	4	4	4
	E0022001	DAY 1		28OCT2002	1	25			20	2	1	1	2	1	1	2	1	1	1	3	4	3	2	0	2
		DAY 29		26NOV2002	30	42	17	50	30	4	3	3	3	2		3	3	3	2	4	3	3	3	3	3
		DAY 57		26DEC2002	60	27	2	23	3	2	1	2	1	2		2	1	2	2	3	3	3	1	3	1
	E0022004	DAY 1		28OCT2002	1	40			46	4	2	4	3	3	3	2	3	1	1	4	4	3	3	0	2
		DAY 29		26NOV2002	30	45	5	55	9	4	4	3	3	3	4	3	3	2	1	3	4	4	4	4	4
		DAY 57		23DEC2002	57	45	5	55	9	4	4	3	3	3	3	3	3	2	2	4	4	4	3	4	4
	E0022005	DAY 1		08NOV2002	1	35			38	4	1	2	2	4	3	3	2	1	3	3	3	2	2	1	2
		DAY 29		06DEC2002	29	36	1	39	1	4	2	2	2	3	3	2	2	2	3	3	3	2	3	3	3
		DAY 57		03JAN2003	57	35	0	38	0	3	3	2	2	3	2	2	2	2	4	2	3	3	2	2	2
	E0022011	DAY 1		29NOV2002	1	38			43	4	3	2	2	2	1	1	3	4	2	4	5	3	2	0	3
	E0022015	DAY 1		10DEC2002	1	36			39	3	2	2	3	2	3	2	3	2	1	3	4	4	2	0	2
		DAY 29		09JAN2003	31	36	0	39	0	3	2	1	3	1	4	3	3	3	1	3	4	3	2	3	2
		DAY 57		06FEB2003	59	38	2	43	4	2	3	3	3	3	2	2	3	3	2	3	3	3	3	0	3
	E0022016	DAY 1		17DEC2002	1	24			18	1	1	1	1	3	2	2	2	1	2	1	3	3	1	0	2
		DAY 29		13JAN2003	28	17	-7	5	-13	1	1	1	1	1	1	1	1	1	1	2	2	2	1	1	1
		DAY 57		11FEB2003	57	21	-3	13	-5	2	1	1	1	1	1	1	1	1	2	2	3	3	1	1	2
	E0022020	DAY 1		12DEC2002	1	45			55	3	3	4	1	4	3	3	2	4	2	5	4	4	3	0	3
		DAY 29		10JAN2003	30	46	1	57	2	4	4	5	5	4	3	3	3	1	2	1	3	4	4	5	4
		DAY 29	*	23JAN2003	43	54	9	71	16	4	4	4	4	4	4	4	4	3	3	4	4	4	4	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0022023	DAY 1	24DEC2002	-1	26		21		3	2	1	1	2	1	2	1	1	2	2	4	2	2	2	1
		DAY 29	23JAN2003	30	39	13	45	24	4	3	2	3	3	2	3	2	3	1	4	5	2	2	2	3
		DAY 57	20FEB2003	58	31	5	30	9	3	2	1	2	2	1	2	2	3	1	2	5	3	2	2	2
	E0022029	DAY 1	19FEB2003	1	42		50		2	3	1	3	3	5	3	3	4	2	4	5	2	2	0	3
		DAY 29	18MAR2003	28	44	2	54	4	3	3	4	3	3	3	3	3	3	2	3	5	3	3	3	3
		DAY 57	14APR2003	55	41	-1	48	-2	2	3	3	3	4	3	3	3	3	2	3	4	3	2	3	3
	E0022041	DAY 1	18MAR2003	1	17		5		1	2	2	1	1	1	1	1	1	1	1	2	1	1	0	1
		DAY 29	15APR2003	29	26	9	21	16	1	1	2	1	1	1	1	1	1	2	3	4	4	3	4	3
		DAY 57	13MAY2003	57	48	31	61	56	4	4	4	4	3	3	4	3	1	3	3	4	4	4	4	4
	E0022042	DAY 1	12MAR2003	1	31		30		3	2	2	3	2	2	2	2	2	1	2	3	3	2	0	2
		DAY 29	10APR2003	30	35	4	38	8	3	3	3	2	2	3	2	2	2	2	3	3	2	3	3	3
		DAY 57	12MAY2003	62	27	-4	23	-7	3	2	1	1	2	2	2	1	2	1	2	3	4	1	3	2
	E0022043	DAY 1	20MAR2003	1	45		55		3	2	4	3	3	3	2	3	4	3	4	4	4	3	0	3
		DAY 29	17APR2003	29	53	8	70	15	3	3	4	4	4	4	3	3	4	4	5	4	4	4	4	3
		DAY 57	12MAY2003	54	56	11	75	20	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	E0022054	DAY 1	11APR2003	1	35		38		2	2	2	1	2	2	2	1	1	3	5	5	4	3	0	2
		DAY 29	12MAY2003	32	48	13	61	23	3	3	3	3	4	4	3	3	4	1	4	5	4	4	2	4
	E0022059	DAY 1	06MAY2003	1	48		61		3	3	5	5	2	3	4	4	5	2	2	2	5	3	0	3
		DAY 29	03JUN2003	29	52	4	68	7	4	4	4	5	4	4	2	4	3	3	3	5	3	4	5	4
		DAY 57	08JUL2003	64	54	6	71	10	4	3	5	5	3	4	4	3	4	2	3	5	5	4	4	3
	E0022065	DAY 1	07MAY2003	1	35		38		2	1	3	2	2	3	1	4	1	2	2	5	5	2	0	2
		DAY 29	04JUN2003	29	56	21	75	37	3	5	5	3	4	5	3	5	1	3	4	5	5	5	5	4
		DAY 57	02JUL2003	57	50	15	64	26	4	4	4	3	4	3	4	5	1	3	2	5	5	3	5	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0022070	DAY 1	12JUN2003	1	14		0		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		DAY 29	18JUN2003	7	16	2	4	4	1	1	1	1	1	1	1	1	1	1	1	3	1	1	1	1
	E0023001	DAY 1	15NOV2002	1	37		41		3	2		2	3	2	3	2	3	2	4	3	3	2	0	3
		DAY 29	16DEC2002	32	41	4	48	7	2	3	1	3	4	2	3	3	5	1	5	4	2	3	4	3
		DAY 57	14JAN2003	61	39	2	45	4	2	3	2	3	3	3	3	3	3	2	4	3	2	3	0	2
	E0023009	DAY 1	11FEB2003	1	36		39		5	1	4	1	3	4	1	2	1	3	3	4	2	2	0	1
		DAY 29	11MAR2003	29	56	20	75	36	4	4	5	3	4	5	3	4	2	4	4	5	5	4	5	5
		DAY 57	08APR2003	57	57	21	77	38	4	5	3	4	4	5	5	4	3	4	4	4	4	4	4	4
	E0023028	DAY 1	29MAY2003	1	31		30		2	2	2	2	2	2	3	2	2	2	2	4	2	2	0	2
		DAY 29	25JUN2003	28	57	26	77	47	5	5	3	4	4	4	4	4	4	3	4	5	4	4	4	4
		DAY 57	21JUL2003	54	63	32	88	58	4	5	5	5	5	5	5	5	4	4	4	5	3	4	4	5
	E0023033	DAY 1	05JUN2003	1	35		38		3	2	3	3	2	2	2	2	3	1	3	4	3	2	0	2
		DAY 29	12JUN2003	8	31	-4	30	-8	3	2	2	3	2	2	2	2	2	1	2	4	2	2	1	1
	E0023047	DAY 1	18JUL2003	1	43		52		3	3	3	2	4	4	3	3	3	3	2	5	3	2	2	3
		DAY 29	15AUG2003	29	53	10	70	18	3	4	3	2	4	4	4	4	4	4	3	4	5	5	5	5
		DAY 57	12SEP2003	57	56	13	75	23	5	4	4	4	5	4	3	4	3	4	3	5	4	4	5	4
	E0025001	DAY 1	01APR2003	1	26		21		2	1	1	2	3	2	3	2	3	1	1	2	2	1	0	2
		DAY 29	23APR2003	23	25	-1	20	-1	2	1	2	2	2	2	3	1		1	1	3	2	1	2	2
	E0026012	DAY 1	20FEB2003	1	38		43		4	3	3	2	3	3	2	3	2	3	3	2	2	3	0	3
		DAY 29	20MAR2003	29	53	15	70	27	4	4	4	4	4	3	3	4	4	3	3	4	5	4	4	3
		DAY 57	17APR2003	57	53	15	70	27	4	3	4	4	4	3	3	4	4	4	5	4	3	4	4	5
	E0026020	DAY 1	01APR2003	1	27		23		2	1	1	2	2	1	1	3	1	1	3	4	3	2	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT MAX	CHG FROM BSLN MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0026020	DAY 29		22APR2003	22	27	0	23	0	5	1	1	1	1	1	2	1	5	1	1	4	1	2	2	1
	E0026024	DAY 1		02MAY2003	1	25		20		1	1		4	2	1	3	2	1	1	1	3	2	1	0	1
		DAY 29		30MAY2003	29	50	25	64	44	4	4	4	4	4	4	3	4	2	3	3	4	3	4	4	4
	E0026028	DAY 1		20JUN2003	1	30		29		3	2	2	2	2	1	3	2	2	2	2	3	2	2	0	2
	E0028001	DAY 1	*	20SEP2002	-20	32		32		4	2	1	2	2	1	2	2	2	1	3	4	4	2	2	2
		DAY 1		10OCT2002	1	37		41		4	3	1	3	2	2	2	2	2	2	3	4	4	3	3	2
		DAY 29		05NOV2002	27	36	-1	39	-2	3	2	2	3	3	2	3	2	2	1	3	4	4	2	3	2
		DAY 57		03DEC2002	55	38	1	43	2	4	2	1	3	3	2	3	3	2	1	3	4	4	3	2	3
	E0028003	DAY 1	*	23SEP2002	-7	36		39		3	3	2	2	3	3	3	4	2	2	3	2	2	2	4	3
		DAY 1	*	23SEP2002	-7	34		36		2	3		2	3	3	3	3	2	2	3	2	2	2	4	4
		DAY 1		30SEP2002	1	24		18		2	2	1	1	2	1	1	2	3	1	3	2	1	2	0	2
		DAY 29		29OCT2002	30	26	2	21	3	3	2	2	1	2	1	2	2	2	1	2	3	2	1	2	2
		DAY 57		26NOV2002	58	28	4	25	7	3	2	2	2	2	2	2	1	2	1	2	4	2	1	2	2
	E0028005	DAY 1	*	30SEP2002	-3	32		32		3	2	1	2	1	3	3	3	2	1	1	5	3	2	0	2
		DAY 1		03OCT2002	1	30		29		2	2	1	2	3	3	3	2	2	1	1	4	2	2	0	2
		DAY 29	*	11OCT2002	9	28	-2	25	-4	3	2	1	1	3	3	2	1	2	1	1	4	2	2	4	2
		DAY 29		31OCT2002	29	43	13	52	23	2	2	2	3	4	4	4	3	3	2	2	5	4	3	3	3
	E0028010	DAY 1	*	15OCT2002	-21	44		54		3	1	3	3	4	4	3	3	3	2	4	4	4	3	4	3
		DAY 1		05NOV2002	1	56		75		4	4	4	4	4	4	4	4	4	3	4	5	4	4	0	4
		DAY 29		03DEC2002	29	51	-5	66	-9	4	3	3	3	3	4	4	4	3	3	4	5	4	4	3	4
		DAY 57		31DEC2002	57	55	-1	73	-2	4	4	4	4	4	4	4	4	3	3	4	5	4	4	3	4
	E0028011	DAY 1		05DEC2002	1	49		63		4	3	3	3	4	3	4	3	4	3	2	5	4	4	0	3
		DAY 29		02JAN2003	29	50	1	64	1	4	4	4	3	4	2	3	4	4	3	3	4	4	4	3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0028011	DAY 57		30JAN2003	57	54	5	71	8	4	4	3	4	4	4	4	4	4	3	3	5	4	4	4	4
	E0028030	DAY 1		04MAR2003	1	34		36		3	2	2	2	3	3	2	2	1	1	2	4	5	2	0	2
		DAY 29		01APR2003	29	40	6	46	10	3	3	2	2	3	3	3	2	3	2	3	3	5	3	3	3
		DAY 57		30APR2003	58	41	7	48	12	3	3	2	2	3	3	3	3	3	1	2	5	5	3	2	3
	E0028031	DAY 1		11MAR2003	1	34		36		3	2	2	2	2	1	2	2	2	3	3	4	3	3	0	2
	E0028047	DAY 1		14JUL2003	1	33		34		2	2	2	3	1	4	2	2	1	2	2	3	4	3	0	3
		DAY 29		12AUG2003	30	41	8	48	14	3	3	3	3	3	4	3	3	1	3	2	4	3	3	3	3
		DAY 57		09SEP2003	58	31	-2	30	-4	2	2	2	2	2	3	2	2	1	2	2	4	3	2	2	2
	E0029001	DAY 1	*	24SEP2002	-7	33		34		4	2	1	2	1	2	2	2	2	2	2	5	3	3	0	1
		DAY 1		01OCT2002	1	27		23		4	2	1	1	1	2	2	2	1	2	1	5	1	2	0	2
		DAY 29		09OCT2002	9	25	-2	20	-3	1	2	1	2	1	2	2	2	1	2	2	5	1	1	2	2
	E0029014	DAY 1		04FEB2003	1	32		32		1	2	3	1	3	2	2	2	2	2	3	4	3	2	0	2
		DAY 29		06MAR2003	31	38	6	43	11	2	4	3	3	2	1	1	3	2	2	3	4	4	4	3	2
		DAY 57		01APR2003	57	48	16	61	29	3	3	4	3	3	4	2	3	5	3	3	5	4	3	2	3
	E0029023	DAY 1		08APR2003	1	40		46		3	2	2	2	3	3	2	2	3	3	3	5	5	2	0	2
		DAY 29		12MAY2003	35	22	-18	14	-32	1	2	1	1	2	3	1	1	1	1	1	1	5	1	1	1
	E0029032	DAY 1		10JUN2003	1	22		14		1	1	1	1	1	1	1	2	1	1	4	4	2	1	0	2
		DAY 29		01JUL2003	22	23	1	16	2	1	2	1	2	1	2	1	2	1	1	3	3	2	1	2	1
	E0029033	DAY 1		02JUN2003	1	25		20		1	1	1	1	1	2	2	1	2	1	3	3	5	1	1	2
		DAY 29		30JUN2003	29	30	5	29	9	2	2	2	2	2	2	2	2	2	2	2	3	3	2	2	2
	E0029039	DAY 1		15JUL2003	1	33		34		2	2	1	2	2	2	3	1	3	2	4	4	3	2	3	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0029039	DAY 29	28JUL2003	14	40	7	46	12	3	3		3	2	2	3	3	2	3	4	3	3	3	4	3
	E0030003	DAY 1	16DEC2002	1	38		43		4	3	3	3	2	2	2	3	2	2	3	3	3	3	0	3
		DAY 29	24DEC2002	9	43	5	52	9	4	3	3	3	3	3	3	3	3	3	3	3	3	3		3
	E0030009	DAY 1	23JAN2003	1	32		32		3	2	1	3	1	2	2	2	1	2	4	4	2	3	0	2
		DAY 57	19MAR2003	56	31	-1	30	-2	2	2	1	3	2	3	2	3	1	1	3	3	2	3	3	2
	E0030016	DAY 1	03MAR2003	1	34		36		3	3	3	3	2	4	2	2	2	2	2	3	1	2	0	2
		DAY 29	02APR2003	31	36	2	39	3	3	3	3	3	3	4	2	2	2	2	2	3	2	2	2	2
		DAY 57	22APR2003	51	31	-3	30	-6	3	2	2	2	3	4	2	2	2	2	1	2	2	2	2	2
	E0030021	DAY 1	20MAY2003	1	40		46		3	2	2	3	4	2	3	2	2	4	4	3	4	2	0	3
		DAY 29	17JUN2003	29	42	2	50	4	4	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3
	E0031001	DAY 1	21NOV2002	1	34		36		4	1	1	1	1	3	2	2	2	5	1	5	5	1	0	1
		DAY 29	20DEC2002	30	42	8	50	14	5	2	2	2	2	4	2	2	4	1	4	5	5	2	4	2
	E0031017	DAY 1	01APR2003	1	34		36		3	2	1	2	2	2	2	3	2	2	3	4	4	2	0	2
		DAY 29	29APR2003	29	38	4	43	7	3	2	4	2	1	3	2	3	2	2	3	4	4	3	1	2
	E0031018	DAY 1	10APR2003	1	48		61		4	2	4	5	5	5	2	4	5	1	1	2	5	3	0	3
	E0031023	DAY 1	29APR2003	1	31		30		2	2	2	3	1	1	3	3	1	2	3	4	2	2	0	2
		DAY 29	27MAY2003	29	40	9	46	16	3	3	3	3	2	1	2	5	2	2	4	4	3	3	3	3
		DAY 57	24JUN2003	57	41	10	48	18	3	3	3	4	2	2	2	3	2	2	4	4	3	4	1	4
	E0033001	DAY 1	09JAN2003	1	23		16		2	1	1	3	1	1	1	3	1	1	1	2	3	2	0	1
		DAY 29	30JAN2003	22	24	1	18	2	2	1	1	3	1	1	1	2	1	1	2	3	3	2	2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0033004	DAY 1	17JAN2003	1	33		34		3	1	2	3	2	3	2	1	1	2	4	3	3	3	0	3
		DAY 29	14FEB2003	29	46	13	57	23	4	5	4	3	3	2	3	4	1	3	3	4	3	4	5	4
		DAY 57	14MAR2003	57	33	0	34	0	4	2	2	1	1	2	1	2	1	2	4	5	4	2	2	2
	E0033010	DAY 1	04FEB2003	1	31		30		1	1	1	2	2	3	2	2	3	1	2	4	5	2	0	2
		DAY 29	04MAR2003	29	41	10	48	18	4	2	1	3	3	4	3	2	3	2	2	5	5	2	2	3
	E0033014	DAY 1	19MAR2003	1	34		36		1	1	1	1	3	4	3	3	4	3	4	1	3	2	0	3
		DAY 29	16APR2003	29	41	7	48	12	3	2	3	3	3	4	3	2	4	3	4	3	2	2	2	2
	E0035002	DAY 1	21NOV2002	1	25		20		2	2	2	2	1	1	2	2	1	2	1	3	2	2	0	2
	E0035007	DAY 1	19DEC2002	1	36		39		3	2	2	3	4	1	3	3	2	2	3	4	2	2	0	2
		DAY 29	17JAN2003	30	43	7	52	13	4	2	1	4	3	2	3	3	3	3	5	5	2	3	5	2
		DAY 57	11FEB2003	55	44	8	54	15	4	2	2	4	3	1	4	3	4	3	4	4	3	3	3	4
	E0035011	DAY 1	04FEB2003	1	30		29		2	2	2	1	3	2	2	2	1	3	4	3	1	2	1	2
		DAY 29	04MAR2003	29	40	10	46	17	3	3	2	4	3	3	2	4	2	2	2	3	3	4	4	3
		DAY 57	01APR2003	57	43	13	52	23	3	3	2	3	3	3	4	3	2	3	3	3	4	4	2	2
	E0035020	DAY 1	18APR2003	1	43		52		3	3	3	4	3	1	4	4	1	4	1	4	4	4	0	3
		DAY 29	15MAY2003	28	44	1	54	2	3	3	2	3	3	1	4	4	2	4	3	4	4	4	0	4
		DAY 57	13JUN2003	57	37	-6	41	-11	4	4	2	3	3	1	3	3	1	3	1	3	3	3	3	3
	E0037003	DAY 1	30JAN2003	1	31		30		2	1		3	1	1	1	3	2	3	3	4	4	1	0	2
		DAY 29	20FEB2003	22	29	-2	27	-3	2	2	2	2	1	2	2	2	1	2	4	3	2	2	2	2
	E0037004	DAY 1	13FEB2003	1	31		30		1	3	3	1	1	3	1	2	1	3	4	5	1	2	0	1
		DAY 29	13MAR2003	29	44	13	54	24	3	4	3	2	2	3	4	3	1	4	5	5	2	3	5	4
		DAY 57	10APR2003	57	53	22	70	40	4	5	3	3	3	4	4	4	2	4	5	5	3	4	5	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0039007	DAY 1	04DEC2002	1	24		18	3	1	1	1	1	1	1	1	1	1	1	5	5	1	0	1
		DAY 29	30DEC2002	27	32	8	32 14	3	3	2	1	3	2	2	3	1	1	1	4	5	1	1	3
		DAY 57	29JAN2003	57	24	0	18 0	3	1	1	1	1	1	1	1	2	1	1	4	5	1	1	1
	E0039022	DAY 1	25FEB2003	1	43		52	3	3	3	3	3	3	2	3	3	2	3	4	5	3	0	2
		DAY 29	25MAR2003	29	56	13	75 23	4	3	4	5	4	4	4	4	3	3	4	5	5	4	3	3
		DAY 57	24APR2003	59	43	0	52 0	3	2	3	3	3	3	3	3	3	3	1	4	5	4	3	2
	E0039023	DAY 1	24FEB2003	1	37		41	3	1	4	4	3	2	2	2	2	2	2	4	4	2	0	2
	E0039030	DAY 1	24MAR2003	1	39		45	4	2	2	2	1	3	4	2	1	4	4	4	4	2	0	1
		DAY 29	21APR2003	29	48	9	61 16	2	4	4	4	3	2	3	4	4	3	3	4	4	4	4	3
		DAY 57	19MAY2003	57	45	6	55 10	1	3	3	3	3	3	4	4	4	4	3	2	4	4	3	5
	E0039031	DAY 1	24MAR2003	1	27		23	1	1	1	2	2	2	1	2	1	3	4	2	4	1	4	1
		DAY 29	21APR2003	29	58	31	79 56	5	4	4	4	4	4	4	4	4	3	4	5	5	4	5	4
		DAY 57	20MAY2003	58	55	28	73 50	4	3	4	4	4	4	4	4	4	3	4	5	5	3	4	4
	E0039037	DAY 1	16APR2003	1	38		43	3	2	1	3	3	4	3	1	4	2	1	5	4	2	0	1
		DAY 29	15MAY2003	30	49	11	63 20	4	3	3	4	4	2	4	4	4	2	4	4	4	3	2	2
		DAY 57	12JUN2003	58	39	1	45 2	3	3	2	3	3	2	3	3	3	1	3	4	3	3	3	2
	E0039038	DAY 1	23APR2003	1	32		32	3	1	3	3	2	2	3	1	1	1	1	5	4	2	0	1
		DAY 29	21MAY2003	29	34	2	36 4	3	2	2	2	2	2	2	2	2	2	2	4	4	3	4	2
	E0039047	DAY 1	19MAY2003	1	46		57	4	3	3	3	3	3	2	3	5	3	3	3	4	4	0	3
		DAY 29	16JUN2003	29	46	0	57 0	1	3	5	3	3	5	5	2	1	5	5	3	4	1	3	3
		DAY 57	14JUL2003	57	58	12	79 22	5	4	4	4	4	5	4	4	4	4	4	4	4	4	4	4
	E0039059	DAY 1	11JUL2003	1	40		46	4	5	1	1	2	3	3	3	1	2	1	5	5	4	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR I)	E0039059	DAY 29		07AUG2003	28	59	19	80	34	4	5	4	4	4	4	4	4	4	3	5	5	5	4	4	4
		DAY 57		05SEP2003	57	59	19	80	34	5	5	4	5	4	3	4	5	3	3	4	5	4	5	5	4
	E0041007	DAY 1		13MAR2003	1	40		46		5	1	3	3	2	2	1	3	5	1	1	5	5		0	3
		DAY 29		10APR2003	29	43	3	52	6	5	2	4	4	1	2	2	2	5	2	1	5	5		1	2
		DAY 57		08MAY2003	57	38	-2	43	-3	3	1	3	3	1	1	1	3	5	1	4	4	5	3	2	1
	E0041010	DAY 1		30APR2003	1	39		45		3	2	2	2	2	2	2	3	3	2	4	4	4	4	0	3
		DAY 29		28MAY2003	29	38	-1	43	-2	3	2	2	2	3	3	2	3	3	1	3	4	4	3	1	3
		DAY 29	*	11JUN2003	43	37	-2	41	-4	3	2	2	3	3	3	2	3	3	2	2	3	3	3	2	2
	E0041011	DAY 1		22MAY2003	1	15		2		1	1	1	1	1	1	1	1	1	1	1	2	1	1	0	1
		DAY 29		20JUN2003	30	35	20	38	36	3	3	3	3	2	3	3	2	1	1	3	3	3	2	3	3
		DAY 57		17JUL2003	57	27	12	23	21	3	3	2	2	1	2	1	1	1	1	2	3	3	2	3	2
	E0041012	DAY 1		19JUN2003	1	41		48		3	4	3	3	3	4	3	4	3	2	1	4	1	3	0	3
		DAY 29		17JUL2003	29	46	5	57	9	3	4	4	4	4	4	3	4	4	1	1	2	4	4	4	3
		DAY 57		14AUG2003	57	36	-5	39	-9	3	3	3	2	3	4	4	3	4	1	1	1	2	2	3	3
PLACEBO (BIPOLAR II)	E0001004	DAY 1		01MAY2003	1	48		61		4	3	1	3	5	4	4	3	4	2	3	5	3	4	0	4
		DAY 29		29MAY2003	29	66	18	93	32	5	5	5	4	5	5	5	5	4	4	4	5	5	5	5	5
		DAY 57		27JUN2003	58	59	11	80	19	4	4	4	4	4	4	4	4	4	4	4	5	5	5	5	5
	E0005023	DAY 1		05FEB2003	1	54		71		4	3	4	4	4	4	4	4	3	4	4	4	4	4	4	4
		DAY 29		06MAR2003	30	64	10	89	18	3	4	5	5	5	5	5	5	3	5	5	5	5	4	5	3
		DAY 57		01APR2003	56	67	13	95	24	5	5	5	5	5	5	5	5	2	5	5	5	5	5	5	5
	E0005034	DAY 1		15APR2003	1	52		68		4	4	4	3	4	4	3	4	2	4	4	4	4	4	4	4
		DAY 29		13MAY2003	29	47	-5	59	-9	4	4	4	3	3	2	3	4	1	4	3	4	4	4	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0005034	DAY 57	09JUN2003	56	46	-6	57	-11	4	4	3	3	4	2	3	4	2	3	2	4	4	4	3	3
	E0005041	DAY 1	24JUN2003	1	45		55		4	3	4	3	4	4	3	3	1	3	2	4	4	3	0	3
		DAY 29	22JUL2003	29	51	6	66	11	4	3	4	4	4	4	4	4	1	4	3	4	4	4	4	4
		DAY 57	18AUG2003	56	52	7	68	13	4	4	4	4	4	4	4	4	1	4	3	4	4	4	4	4
	E0007004	DAY 1	30JAN2003	1	37		41		4	1	2	2	2	3	2	2	2	3	4	5	3	2	0	2
		DAY 29	12FEB2003	14	36	-1	39	-2	3	1	2	2	3	4	1	2	2	2	4	5	3	2	2	2
	E0007010	DAY 1	18APR2003	1	33		34		4	1	3	3	2	2	1	2	1	2	1	5	4	2	0	2
		DAY 29	16MAY2003	29	58	25	79	45	4	4	4	4	5	5	4	4	2	3	4	5	5	5	5	5
		DAY 57	16JUN2003	60	41	8	48	14	3	3	3	3	3	2	2	3	1	2	4	4	5	3	3	3
	E0007012	DAY 1	16MAY2003	1	37		41		3	2	2	2	2	2	2	2	3	1	4	5	5	2	0	2
		DAY 29	13JUN2003	29	47	10	59	18	4	4	3	4	2	3	3	3	3	2	3	5	5	3	4	3
		DAY 57	01JUL2003	47	37	0	41	0	3	2	2	2	2	3	2	2	2	2	3	5	5	2	2	2
	E0009007	DAY 1	03FEB2003	1	31		30		3	2	2	2	2	2	2	2	3	2	2	3	2	2	0	2
		DAY 29	03MAR2003	29	24	-7	18	-12	2	1	1	1	1	1	1	2	3	2	1	3	2	3	3	1
	E0009008	DAY 1	12FEB2003	1	33		34		4	2	2	3	2	2	2	2	3	2	3	1	3	2	0	2
		DAY 29	11MAR2003	28	36	3	39	5	3	2	2	3	3	2	3	2	3	2	2	4	3	2	3	2
		DAY 57	08APR2003	56	53	20	70	36	5	4	4	4	4	4	3	3	4	3	4	4	4	3		4
	E0011001	DAY 1	01NOV2002	1	20		11		2	2	1	1	2	2	2	1	1	2	1	1	1	1	3	1
		DAY 29	27NOV2002	27	20	0	11	0	2	2	1	1	1	2	1	1	1	1	2	2	2	1	2	1
		DAY 57	26DEC2002	56	27	7	23	12	2	2	2	3	3	2	2	2	1	2	2	2	1	1	3	2
	E0011011	DAY 1	20FEB2003	1	25		20		2	1	2	3	2	2	1	1	2	1	3	1	2	2	0	2
		DAY 29	19MAR2003	28	44	19	54	34	3	3	3	3	3	3	4	4	3	2	4	3	3	3	3	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0011011	DAY 57		16APR2003	56	48	23	61	41	4	4	4	3	3	4	3	3	3	3	4	4	3	3	3	4
	E0011013	DAY 1		17APR2003	1	31		30		3	2	3	3	1	2	2	3	1	1	2	3	3	2	3	2
		DAY 29		15MAY2003	29	28	-3	25	-5	2	1	2	2	2	2	2	2	1	1	3	4	2	2	2	2
		DAY 57		12JUN2003	57	27	-4	23	-7	3	1	1	2	2	2	2	1	1	1	4	3	2	2	2	2
	E0011014	DAY 1		07APR2003	1	41		48		3	2	2	2	2	2	2	3	4	3	3	5	5	3	0	2
	E0011021	DAY 1		22MAY2003	1	30		29		4	1	5	1	2	2	2	1	1	1	3	3	2	2	4	2
		DAY 29		20JUN2003	30	52	22	68	39	5	4		3	3	4	4	4	2	3	4	5	3	4	4	4
		DAY 57		21JUL2003	61	53	23	70	41	5	4	4	4	4	3	4	4	1	3	4	5	4	4	4	4
	E0013008	DAY 1		26MAR2003	1	33		34		3	1	2	2	3	1	3	1	1	3	4	4	4	1	0	2
		DAY 29		23APR2003	29	33	0	34	0	3	1	2	2	2	3	1	1	1	3	4	4	4	2	1	1
		DAY 57		19MAY2003	55	23	-10	16	-18	2	1	1	1	2	1	1	1	1	1	3	4	3	1	1	1
	E0014001	DAY 1		26FEB2003	1	45		55		4	2	3	4	2	3	3	4	1	3	4	5	4	3	4	2
		DAY 29		25MAR2003	28	60	15	82	27	4	5	4	4	5	5	4	4	3	4	4	5	5	4	4	4
		DAY 29	*	01APR2003	35	52	7	68	13	3	4	4	4	4	4	3	4	2	4	4	4	4	4	4	4
	E0014013	DAY 1		27MAY2003	1	26		21		3	2	1	2	2	1	2	2	3	1	1	2	3	1	0	1
		DAY 29		25JUN2003	30	38	12	43	22	4	3	3	4	2	3	2	3	3	1	1	3	3	3	4	2
		DAY 57		23JUL2003	58	39	13	45	24	4	3	3	3	2	3	2	3	4	1	1	3	4	3	4	4
	E0014014	DAY 1		10JUN2003	1	39		45		4	2	3	3	2	2	3	2	3	3	3	4	2	3	0	3
		DAY 29		10JUL2003	31	43	4	52	7	3	3	3	3	3	4	4	4	2	2	3	3	3	3	3	3
		DAY 57		06AUG2003	58	55	16	73	28	4	4	3	4	4	3	5	5	2	3	3	5	5	5	4	4
	E0015004	DAY 1		02DEC2002	1	25		20		3	1	1	2	2	3	2	1	1	1	2	4	1	1	0	3
		DAY 29		06JAN2003	36	29	4	27	7	3	1	1	2	2	3	2	2	2	1	3	5	1	1	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT MAX	CHG FROM BSLN MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0015004	DAY 57		29JAN2003	59	35	10	38	18	2	1	1	2	2	3	3	2	2	1	4	5	4	3	1	2
	E0018005	DAY 1		20DEC2002	1	41		48		3	4	2	2	2	3	2	2	4	2	2	5	5	3	0	3
		DAY 29		17JAN2003	29	54	13	71	23	4	4	4	4	3	4	4	4	3	3	3	5	5	4	5	4
		DAY 57		14FEB2003	57	52	11	68	20	4	4	4	4	3	4	4	4	3	2	3	5	4	4	4	4
	E0018012	DAY 1		24JAN2003	1	36		39		4	1	2	2	4	3	1	2	3	2	4	4	2	2	0	2
		DAY 29		21FEB2003	29	49	13	63	24	4	3	4	4	4	2	3	4	2	4	2	5	4	4	4	4
		DAY 29	*	26FEB2003	34	44	8	54	15	3	1		3	3	3	3	3	5	3	3	5	3	3	0	3
	E0019019	DAY 1		23JAN2003	1	41		48		3	2	3	2	2	2	3	3	1	3	4	5	5	3	0	3
	E0019033	DAY 1		18MAR2003	1	36		39		3	2	2	3	3	3	2	2	2	2	1	5	5	1	0	1
		DAY 29		14APR2003	28	33	-3	34	-5	2	2	1	3	3	3	1	4	1	2	2	4	4	1	1	2
		DAY 57		15MAY2003	59	28	-8	25	-14	3	1	1	1	2	3	1	2	2	1	2	4	4	1	2	1
	E0019038	DAY 1		24APR2003	1	28		25		3	2	1	1	2	3	2	1	1	1	1	4	4	2		1
		DAY 29		21MAY2003	28	35	7	38	13	3	3	2	1	4	2	2	2	4	1	1	4	4	2	4	1
		DAY 57		18JUN2003	56	39	11	45	20	2	3	2	2	4	4	4	3	2	1	1	4	4	3		2
	E0019046	DAY 1		26JUN2003	1	31		30		3	1	3	2	2	2	1	1	1	2	3	4	4	2	0	2
		DAY 29		24JUL2003	29	54	23	71	41	4	4	4	4	3	4	4	4	3	4	4	4	4	4	4	4
		DAY 57		21AUG2003	57	56	25	75	45	4	4	4	4	4	4	4	4	3	4	4	5	4	4	4	4
	E0019047	DAY 1		08JUL2003	1	36		39		3	3	2	2	2	4	2	3	4	1	2	4	2	2	0	2
		DAY 29		07AUG2003	31	42	6	50	11	4	3	3	2	1	4	2	3	3	2	2	5	5	3	5	2
		DAY 57		04SEP2003	59	56	20	75	36	4	4	4	3	3	4	4	5	5	3	3	5	5	4		4
	E0019048	DAY 1		10JUL2003	1	46		57		4	2	3	3	3	3	4	3	3	3	4	5	3	3	4	3
		DAY 29		07AUG2003	29	35	-11	38	-19	4	1	3	1	1	3	1	3	3	3	3	5	1	3	4	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0019048	DAY 57	03SEP2003	56	40	-6	-11	46	4	1	3	2	2	3	1	3	3	3	5	5	2	3	1	3
	E0022006	DAY 1	12NOV2002	1	32			32	3	2	3	2	2	2	2	2	1	1	2	4	4	2	4	2
		DAY 29	10DEC2002	29	42	10	18	50	3	3	3	2	4	3	3	2	3	1	3	5	4	3	4	3
		DAY 57	07JAN2003	57	55	23	41	73	4	4	4	4	4	3	3	4	4	4	3	5	5	4	4	4
	E0022047	DAY 1	28MAR2003	1	28			25	3	2	2	1	2	2	3	1	2	1	1	3	3	2	0	1
		DAY 29	25APR2003	29	37	9	41	16	3	4	2	2	3	3	3	2	3	2	2	3	2	3	3	3
		DAY 57	23MAY2003	57	41	13	48	23	3	2	3	2	3	4	3	3	4	2	2	4	3	3	3	2
	E0022075	DAY 1	08JUL2003	1	35			38	3	3	3	3	3	3	3	3	1	1	3	1	3	2	2	1
		DAY 29	05AUG2003	29	22	-13	-24	14	3	1	1	1	1	1	1	3	1	1	1	3	3	1	1	1
		DAY 57	03SEP2003	58	32	-3	-6	32	1	2	2	3	2	1	3	3	3	1	2	4	4	1	1	2
	E0023012	DAY 1	06FEB2003	1	36			39	3	3	3	2	2	3	2	2	2	2	4	4	2	2	0	3
		DAY 29	07MAR2003	30	49	13	63	24	5	2	2	3	4	3	4	4	3	3	4	4	4	4	3	4
		DAY 57	04APR2003	58	52	16	68	29	5	4	3	4	3	4	4	5	2	2	3	5	4	4	3	4
	E0023016	DAY 1	22MAY2003	1	36			39	2	2	3	4	2	3	2	3	2	3	4	2	2	2	0	2
		DAY 29	19JUN2003	29	41	5	48	9	4	3	4	4	2	2	2	3	4	1	3	3	3	3	3	3
		DAY 57	17JUL2003	57	36	0	39	0	2	1	3	2	3	4	2	3	2	3	3	4	2	2	3	3
	E0023018	DAY 1	27MAR2003	1	41			48	3	2	3	3	2	3	5	2	3	3	2	5	3	2	0	3
		DAY 29	24APR2003	29	42	1	2	50	1	3	3	4	2	4	2	4	2	2	3	5	4	3	3	4
		DAY 57	22MAY2003	57	52	11	20	68	4	4	3	4	3	3	4	5	1	5	3	5	4	4	4	5
	E0023036	DAY 1	20JUN2003	1	35			38	3	2	2	2	2	3	2	3	1	2	3	5	2	3	0	1
		DAY 29	16JUL2003	27	46	11	19	57	5	2	4	1	2	3	4	4	4	3	3	5	3	3	3	3
		DAY 57	13AUG2003	55	46	11	19	57	4	3	3	3	4	3	3	3	3	3	3	4	3	4	2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0023046	DAY 1	23JUL2003	1	38		43		3	1	4	4	2	2	2	3	3	3	3	4	2	2	0	2
		DAY 29	22AUG2003	31	49	11	63	20	4	4	5	4	2	2	2	4	4	4	4	4	3	3	3	4
		DAY 57	16SEP2003	56	52	14	68	25	4	3	5	4	2	4	3	4	3	4	4	5	3	4	3	4
	E0026006	DAY 1	08JAN2003	1	32		32		3	2	2	2	2	1	2	3	3	2	2	3	3	2	3	2
		DAY 29	05FEB2003	29	57	25	77	45	4	4	4	4	4	3	4	5	4	4	4	5	4	4	4	4
	E0026021	DAY 1	23APR2003	1	35		38		4	1	2	1	1	3	2	2	1	5	5	4	2	2	0	2
	E0026027	DAY 1	19JUN2003	1	21		13		2	2	1	1	2	2	1	1	2	1	2	2	1	1	0	1
	E0029002		12NOV2002		37		41		3	2	2	1	2	4	3	3	5	1	2	4	3	2	3	2
	E0029004	DAY 1	19NOV2002	1	23		16		1	1	3	1	1	1	1	1	1	2	2	3	4	1	5	1
		DAY 57	16JAN2003	59	35	12	38	22	3	1	3	1	3	2	3	1	2	3	3	5	4	1	4	2
	E0029013	DAY 1	19FEB2003	1	39		45		3	2	4	2	3	3	3	2	1	2	2	5	5	2	0	2
		DAY 29	20MAR2003	30	28	-11	25	-20	1	2	1	1	1	1	1	1	1	4	3	5	5	1	1	3
	E0029019	DAY 1	03MAR2003	1	42		50		5	2	1	4	4	3	4	1	3	1	3	4	4	3	0	2
		DAY 29	17MAR2003	15	40	-2	46	-4	4	2	1	4	2	3	2	3	2	2	3	5	5	2	1	2
	E0029024	DAY 1	17MAR2003	1	40		46		4	2	1	2	3	4	1	2	3	3	4	5	4	2	0	3
		DAY 29	17APR2003	32	37	-3	41	-5	3	3	2	2	2	3	2	1	1	2	3	5	5	3	3	3
		DAY 57	20MAY2003	65	52	12	68	22	5	4	3	4	4	4	3	4	3	2	3	5	5	3	4	4
	E0029038	DAY 1	07JUL2003	1	40		46		4	3	3	3	2	2	2	3	1	1	3	5	5	3	0	3
	E0031004	DAY 1	19DEC2002	1	43		52		4	3	3	2	3	3	2	3	1	3	4	5	4	3	0	3
		DAY 29	16JAN2003	29	44	1	54	2	3	3	4	2	4	4	2	3	2	3	3	5	3	3	3	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0031004	DAY 57		13FEB2003	57	53	10	70	18	4	4	3	4	3	4	4	3	3	3	4	5	5	4	4	4
	E0031013	DAY 1		13MAR2003	1	30		29		2	2	2	2	2	1	2	2	2	2	2	3	4	2	0	2
		DAY 29		11APR2003	30	41	11	48	19	2	1	3	3	2	2	3	3	3	3	4	4	5	3	4	3
		DAY 57		08MAY2003	57	50	20	64	35	3	2	3	3	4	4	4	2	4	4	4	5	4	4	4	4
	E0031016	DAY 1		24MAR2003	1	37		41		3	2	2	3	2	3	3	2	3	2	2	4	4	2	0	2
		DAY 29		14APR2003	22	38	1	43	2	3	2	3	3	2	3	2	2	3	3	4	4	2	2	1	2
	E0031019	DAY 1		11APR2003	1	38		43		4	2	1	4	2	4	2	3	2	2	4	4	2	2	0	1
		DAY 29		09MAY2003	29	38	0	43	0	4	3	1	1	3	3	1	3	3	2	2	4	5	3	2	3
		DAY 29	*	12MAY2003	32	42	4	50	7	5	3	2	2	3	3	3	3	3	2	2	4	4	3	2	3
	E0031022	DAY 1		28APR2003	1	33		34		2	3	1	2	3	1	3	3	3	1	2	4	3	2	0	2
		DAY 29		27MAY2003	30	44	11	54	20	2	3	4	4	4	2	3	3	3	2	3	4	4	3	3	3
	E0033007	DAY 1		28JAN2003	1	22		14		2	1	1	1	1	1	1	1	1	1	1	4	5	1	3	1
		DAY 29		25FEB2003	29	23	1	16	2	1	1	1	1	1	1	1	1	2	1	1	5	5	1	4	1
		DAY 57		25MAR2003	57	28	6	25	11	2	2	1	1	2	1	2	1	2	1	1	5	5	2	3	1
	E0033013	DAY 1		19FEB2003	1	50		64		5	2	4	5	4	1	4	3	2	4	4	5	4	3	0	3
		DAY 29		19MAR2003	29	38	-12	43	-21	3	2	3	3	3	2	2	3	2	3	3	3	3	3	3	3
		DAY 57		16APR2003	57	42	-8	50	-14	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	E0033016	DAY 1		08MAY2003	1	30		29		3	1	2	2	2	3	1	2	2	1	2	3	3	3	0	2
		DAY 29		09JUN2003	33	43	13	52	23	3	3	3	2	3	3	4	4	2	2	3	3	4	4	3	4
		DAY 57		02JUL2003	56	53	23	70	41	4	4	3	3	4	4	5	4	4	2	4	4	4	4	4	4
	E0033022	DAY 1		14JUL2003	1	18		7		3	1	2	1	1	1	1	1	1	1	1	1	2	1	0	1
		DAY 29		11AUG2003	29	53	35	70	63	4	4	4	4	5	3	5	4	5	2	2	4	3	4	4	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	TOTAL PCT CHG FROM BSLN	TOTAL MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0033022	DAY 57	11SEP2003	60	39	21	45	38	4	2	3	2	2	1	3	2	4	1	4	5	4	2	1	3
	E0034007	DAY 1	16MAY2003	1	36		39		4	1	2	2	3	3	2	2	2	1	3	5	4	2	0	2
		DAY 29	16JUN2003	32	27	-9	23	-16	2	1	2	2	2	2	1	2	2	1	2	4	2	2	1	1
		DAY 57	14JUL2003	60	35	-1	38	-1	3	1	2	2	3	2	2	3	2	2	3	5	3	2	1	1
	E0035004	DAY 1	27NOV2002	1	31		30		3	2	2	1	1	2	1	3	4	2	3	3	2	2	0	2
	E0035009	DAY 1	27DEC2002	1	34		36		3	2	2	2	2	2	2	2	2	2	3	5	3	2	0	3
		DAY 29	22JAN2003	27	50	16	64	28	4	3	4	4	3	3	2	4	4	3	3	5	5	3	4	4
		DAY 57	19FEB2003	55	60	26	82	46	5	5	4	4	5	4	3	5	5	3	3	5	5	4	4	4
	E0035010	DAY 1	10JAN2003	1	36		39		3	2	2	4	2	2	3	3	1	2	3	3	3	3	3	3
		DAY 29	07FEB2003	29	33	-3	34	-5	3	2	2	3	2	2	3	3	1	2	2	3	2	3	3	2
		DAY 57	06MAR2003	56	43	7	52	13	4	3	2	3	3	3	3	3	2	2	3	4	4	4	4	4
	E0035022	DAY 1	09MAY2003	1	24		18		2	1	1	1	1	2	1	3	1	3	4	2	1	1	0	1
		DAY 29	06JUN2003	29	51	27	66	48	5	4	4	5	4	4	3	3	3	4	3	3	3	3	4	4
		DAY 57	07JUL2003	60	61	37	84	66	5	5	2	5	5	5	5	5	4	4	2	4	5	5	5	5
	E0039003	DAY 1	25NOV2002	1	40		46		3	3	3	3	2	3	3	3	2	3	3	3	3	3	3	3
	E0040001	DAY 1	27JUN2003	1	36		39		4	2	2	2	3	3	3	1	2	1	2	4	5	2	0	1
		DAY 29	25JUL2003	29	37	1	41	2	4	2	2	2	3	3	3	2	3	3	3	1	4	2	3	2
		DAY 57	22AUG2003	57	40	4	46	7	4	2	2	2	3	3	2	3	2	2	2	5	5	3	2	2
	E0040004	DAY 1	18JUL2003	1	48		61		5	3	1	3	3	4	3	4	4	3	3	4	4	4	0	3
	E0041002	DAY 1	21JAN2003	1	39		45		4	3	2	3	3	3	3	3	2	2	2	3	3	3	0	3
		DAY 29	18FEB2003	29	43	4	52	7	4	3	3	3	3	3	3	4	2	3	2	5	2	3	3	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications. 0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

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Listing 12.2.6.7 Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESSF)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	PCT CHG FROM BSLN MAX	MAX	LEVEL OF SATISFACTION 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	PAST WEEK LIFE SATIS-FACTION
PLACEBO (BIPOLAR II)	E0041005	DAY 1	05MAR2003	1	30		29		3	2	1	2	2	3	2	2	1	1	2	5	2		0	2
		DAY 29	02APR2003	29	40	10	46	17	3	3	3	2	2	4	3	3	1	2	3	4	4		3	3
		DAY 57	30APR2003	57	43	13	52	23	4	3	3	3	3	3	3	3	3	3	3	3	3		3	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Level of Satisfaction: 1=physical health, 2=mood, 3=work, 4=household, 5=social, 6=family, 7=leisure, 8=daily life, 9=sexual interest, 10=economic, 11=living, 12=get around, 13=work ability, 14=well being, 15=medications.
0=no medications, 1=very poor, 2=poor, 3=fair, 4=good, 5=very good.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/QLESQ100.SAS
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AstraZeneca

Clinical Study Report: Appendix 12.2.7

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.7
Adverse events listing, by subject

Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	57 YRS CAUCASIAN FEMALE	04FEB2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			05FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			16FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			20FEB2003-05MAR2003	ON	HEADACHE (Nervous system disorders) [RIGHT SIDE HEADACHE]	14	17	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0002010	32 YRS CAUCASIAN MALE	04APR2003-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG100.SAS
GENERATED: 12JUL2005 17:38:43 iceadmn3

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0002012	31 YRS CAUCASIAN MALE	26APR2003-03MAY2003	ON	MUSCLE SPASMS (Musculoskeletal and connective tissue disorders) [BACK SPASMS NOT DUE TO EPS]	8	6	MOD	NO	N	N	N	N	N	N	NO NO	None
			28APR2003-15MAY2003	ON	NASOPHARYNGITIS (Infections and infestations) [COMMON COLD]	18	8	MIL	NO	N	N	N	N	N	N	NO NO	None
			05MAY2003-26MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	22	15	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0002018	48 YRS CAUCASIAN MALE	24JUL2003-27JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	4	1	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0003004	20 YRS CAUCASIAN MALE	07JAN2003-CONTINUE	ON	ERYTHEMA (Skin and subcutaneous tissue disorders) [REDDENED LEFT EAR]	UNK	22	MIL	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG100.SAS
GENERATED: 12JUL2005 17:38:43 iceadmn3

Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	37 YRS CAUCASIAN FEMALE	26DEC2002-26DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	4	SEV	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			19JAN2003-19JAN2003	ON	EAR DISCOMFORT (Ear and labyrinth disorders) [BURNING EARS]	1	28	MIL	NO	N	N	N	N	N	N	NO NO	None
			21JAN2003-21JAN2003	ON	EAR DISCOMFORT (Ear and labyrinth disorders) [BURNING EARS]	1	30	MIL	NO	N	N	N	N	N	N	NO NO	None
			22JAN2003-22JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	31	MIL	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG100.SAS
GENERATED: 12JUL2005 17:38:43 iceadmn3

Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	37 YRS CAUCASIAN FEMALE	22JAN2003-22JAN2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [LEG CRAMP (NOT DUE TO EPS)]	1	31	MIL	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	31	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0003007	25 YRS CAUCASIAN FEMALE	02JAN2003-09JAN2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			03JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JAN2003-08JAN2003	ON	DYSMENORRHOEA (Reproductive system and breast disorders) [MENSTRUAL CRAMPS]	1	7	MOD	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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GENERATED: 12JUL2005 17:38:43 iceadmn3

Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	25 YRS CAUCASIAN FEMALE	10JAN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DIFFICULTY WAKING]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			30JAN2003-31JAN2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	2	29	MOD	NO	N	N	N	N	N	N	NO NO	None
			03FEB2003-04FEB2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	2	33	MOD	NO	N	N	N	N	N	N	NO NO	None
			17FEB2003-20FEB2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	4	47	MIL	NO	N	N	N	N	N	N	NO NO	None
			20FEB2003-20FEB2003	ON	FUNGAL INFECTION NOS (Infections and infestations) [YEAST INFECTION]	1	50	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0003015	20 YRS CAUCASIAN FEMALE	06MAY2003-08MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG100.SAS
GENERATED: 12JUL2005 17:38:43 iceadmn3

Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	20 YRS CAUCASIAN FEMALE	24MAY2003-24MAY2003	ON	ALCOHOL INTOLERANCE (Metabolism and nutrition disorders) [INCREASED SENSITIVITY TO ALCOHOL]	1	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			20JUN2003-24JUN2003	ON	FLATULENCE (Gastrointestinal disorders) [ABDOMINAL GAS]	5	47	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JUL2003-02JUL2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	59	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004002	24 YRS CAUCASIAN FEMALE	02OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [INTERMITTENT DROWSINESS PM]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	24 YRS CAUCASIAN FEMALE	04OCT2002-05OCT2002	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	2	4	MIL	NO	N	N	N	N	N	N	NO NO	None
			05OCT2002-22OCT2002	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	18	5	MIL	NO	N	N	N	N	N	N	NO NO	None
			06NOV2002-13NOV2002	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	8	37	MOD	NO	N	N	N	N	N	N	NO NO	None
					SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	8	37	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0004013	24 YRS CAUCASIAN FEMALE	15JAN2003-CONTINUE	ON	BREAST CYST (Reproductive system and breast disorders) [BENIGN CYST LEFT BREAST]	UNK	2	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0004013	24 YRS CAUCASIAN FEMALE	15JAN2003-CONTINUE	ON	NIPPLE EXUDATE BLOODY (Reproductive system and breast disorders) [BLOODY DISCHARGE FROM LEFT NIPPLE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			15JAN2003-07FEB2003	ON	SEDATION (Nervous system disorders) [AM SEDATION]	24	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			16JAN2003-07FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	23	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			22JAN2003-02FEB2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	12	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004018	24 YRS CAUCASIAN MALE	20MAR2003-CONTINUE	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0004018	24 YRS CAUCASIAN MALE	01APR2003-17APR2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	17	14	MIL	NO	N	N	N	N	N	N	NO NO	None
			10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	23	MIL	NO	N	N	N	N	N	N	NO YES	None
			03MAY2003-03MAY2003	ON	GAIT ABNORMAL (General disorders and administration site conditions) [UNSTEADY GAIT]	1	46	MOD	NO	N	N	N	N	N	N	NO YES	None
					VISION BLURRED (Eye disorders) [BLURRED VISION]	1	46	MOD	NO	N	N	N	N	N	N	NO YES	None
			04MAY2003-05MAY2003	ON	PYREXIA (General disorders and administration site conditions) [FEVER]	2	47	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0004018	24 YRS CAUCASIAN MALE	04MAY2003-10MAY2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	7	47	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0004021	53 YRS CAUCASIAN MALE	15MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS IN MORNING]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-28MAY2003	ON	IRRITABILITY (Psychiatric disorders) [INCREASED IRRITABILITY]	14	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			16MAY2003-23JUL2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	69	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-25JUL2003	ON	IRRITABILITY (Psychiatric disorders) [INCREASED IRRITABILITY]	15	59	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0005002	48 YRS CAUCASIAN MALE	03OCT2002-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			04OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			05OCT2002-27OCT2002	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [URI]	23	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			08OCT2002-CONTINUE	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA NOT RELATED TO ORTHOSTATIC HYPOTENSION]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0005004	36 YRS CAUCASIAN FEMALE	02OCT2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
			03OCT2002-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT RELATED TO ORTHOSTATIC HYPOTENSION)]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			03OCT2002-04OCT2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005013	43 YRS CAUCASIAN FEMALE	07NOV2002-11NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT RELATED TO ORTHOSTATIC HYPOTENSION)]	5	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR I)	E0005013	43 YRS CAUCASIAN FEMALE	07NOV2002-13NOV2002	ON	DYSKINESIA (Nervous system disorders) [MOTOR INCOORDINATION (DYSKINESIA)]	7	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	7	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			11NOV2002-21NOV2002	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [URI - UPPER RESPIRATORY INFECTION]	11	5	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0005024	19 YRS CAUCASIAN FEMALE	10FEB2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			11FEB2003-21FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0005024	19 YRS CAUCASIAN FEMALE	23FEB2003-24FEB2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU - LIKE SYMPTOMS]	2	14	MOD	NO	N	N	N	N	N	N	NO NO	None
			24MAR2003-24MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	1	43	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005027	41 YRS CAUCASIAN MALE	12MAR2003-31MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	20	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			17MAR2003-31MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	15	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005037	56 YRS CAUCASIAN FEMALE	07MAY2003-11MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0005037	56 YRS CAUCASIAN FEMALE	07MAY2003-30MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [WORSENING OF HEARTBURN]	24	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			16MAY2003-18MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	3	10	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005042	50 YRS CAUCASIAN MALE	24JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JUN2003-02JUL2003	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADY]	9	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0006005	37 YRS CAUCASIAN FEMALE	09DEC2002-03JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION IN AM]	26	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			10DEC2002-14DEC2002	ON	HERPES SIMPLEX (Infections and infestations) [COLD SORE]	5	6	MIL	NO	N	N	N	N	N	N	NO NO	None
			10DEC2002-12JAN2003	ON	THIRST (General disorders and administration site conditions) [INCREASED THIRST]	34	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-18JAN2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	17	29	MIL	NO	N	N	N	N	N	N	NO NO	None
			04JAN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [INTERMITTENT AM SEDATION]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0006005	37 YRS CAUCASIAN FEMALE	13JAN2003-CONTINUE	ON	THIRST (General disorders and administration site conditions) [INTERMITTENT THIRST]	UNK	40	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0006018	57 YRS CAUCASIAN MALE	13MAR2003-17MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [EXTREME SLEEPINESS]	5	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14MAR2003-17MAR2003	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	4	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			15MAR2003-17MAR2003	ON	COORDINATION ABNORMAL NOS (Nervous system disorders) [LOSS OF COORDINATION (NOT DUE TO EPS)]	3	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0007013	60 YRS CAUCASIAN FEMALE	14JUN2003-14JUN2003	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARE]	1	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			25JUN2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	13	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010004	57 YRS HISPANIC FEMALE	11DEC2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			12DEC2002-CONTINUE	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [LIGHTHEADED DUE TO POSTURAL HYPOTENSION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010012	51 YRS CAUCASIAN FEMALE	07JAN2003-09JAN2003	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			07JAN2003-31JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	1	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0010012	51 YRS CAUCASIAN FEMALE	15JAN2003-27JAN2003	ON	MUSCLE SPASMS (Musculoskeletal and connective tissue disorders) [MUSCLE SPASMS (NOT DUE TO EPS)]	13	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			24JAN2003-01FEB2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	9	18	MIL	NO	N	N	N	N	N	N	NO NO	None
					PULMONARY CONGESTION (Respiratory, thoracic and mediastinal disorders) [CHEST CONGESTION]	9	18	MIL	NO	N	N	N	N	N	N	NO NO	None
			30JAN2003-10FEB2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	12	24	MOD	NO	N	N	N	N	N	N	NO YES	None
			11FEB2003-05MAR2003	ON	EAR INFECTION NOS (Infections and infestations) [RIGHT EAR INFECTION]	23	36	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0010024	39 YRS CAUCASIAN MALE	05MAY2003-05MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	1	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06MAY2003-08MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAY2003-07MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [ORTHOSTATIC DIZZINESS]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			16MAY2003-16MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [ORTHOSTATIC DIZZINESS]	1	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-22MAY2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	18	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUN2003-13JUN2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	13	28	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0010024	39 YRS CAUCASIAN MALE	21JUN2003-CONTINUE	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	UNK	48	MIL	NO	N	N	N	N	N	N	NO NO	None
			21JUN2003-01JUL2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	11	48	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0010032	38 YRS CAUCASIAN FEMALE	11JUL2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATIVISM]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14JUL2003-CONTINUE	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	UNK	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					ORTHOSTATIC HYPOTENSION (Vascular disorders) [FAINTING FEELING (DUE TO POSTURAL HYPOTENSION)]	UNK	5	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR I)	E0011025	47 YRS CAUCASIAN FEMALE	29JUL2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	34	MIL	NO	N	N	N	N	N	N	NO YES	None
			13AUG2003-13AUG2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	49	MIL	NO	N	N	N	N	N	N	NO YES	None
			14AUG2003-14AUG2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	50	MIL	NO	N	N	N	N	N	N	NO YES	None
			20AUG2003-20AUG2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	56	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0013007	49 YRS CAUCASIAN MALE	20MAR2003-30MAR2003	ON	AKATHISIA (Nervous system disorders) [RESTLESSNESS (DUE TO EPS) AKATHISIA]	11	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0013007	49 YRS CAUCASIAN MALE	20MAR2003-30MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	1	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0013009	44 YRS CAUCASIAN FEMALE	02APR2003-02JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	62	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014006	18 YRS CAUCASIAN FEMALE	25MAR2003-27MAR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAR2003-10APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	17	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06APR2003-06APR2003	ON	MOOD SWINGS (Psychiatric disorders) [MOODINESS]	1	13	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0014006	18 YRS CAUCASIAN FEMALE	18MAY2003-24MAY2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACKACHE]	7	55	MOD	NO	N	N	N	N	N	N	NO NO	None
					DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	7	55	MOD	NO	N	N	N	N	N	N	NO NO	None
					LYMPHADENOPATHY (Blood and lymphatic system disorders) [INCREASED MANDIBULAR GLANDS (LYMPH NODE SWELLING)]	7	55	MOD	NO	N	N	N	N	N	N	NO NO	None
					PHARYNGEAL ERYTHEMA (Respiratory, thoracic and mediastinal disorders) [RED THROAT]	7	55	MOD	NO	N	N	N	N	N	N	NO NO	None
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	7	55	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0014006	18 YRS CAUCASIAN FEMALE	21MAY2003-24MAY2003	ON	TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	4	58	MOD	NO	N	N	N	N	N	N	NO NO	None
			25MAY2003-CONTINUE	ON	TENSION HEADACHE (Nervous system disorders) [TENSION HEADACHE]	UNK	62	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0014010	40 YRS CAUCASIAN FEMALE	23APR2003-25APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-03MAY2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	10	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-06MAY2003	ON	MICTURITION URGENCY (Renal and urinary disorders) [URINARY URGENCY]	13	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-18MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0014010	40 YRS CAUCASIAN FEMALE	30APR2003-02MAY2003	ON	DYSTONIA (Nervous system disorders) [JAW HYPERTONUS (DUE TO EPS) DYSTONIA]	3	9	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			30APR2003-18MAY2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	19	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-CONTINUE	ON	BLUNTED AFFECT (Psychiatric disorders) [EMOTIONAL BLUNTING]	UNK	24	MOD	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-31MAY2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	17	24	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [HYPERSOMNOLENCE]	UNK	31	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0016001	32 YRS CAUCASIAN MALE	06FEB2003-28FEB2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [CRAMPS - LEG (NOT DUE TO EPS)]	23	16	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0016001	32 YRS CAUCASIAN MALE	07FEB2003-18FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	12	17	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0016004	36 YRS CAUCASIAN MALE	03FEB2003-CONTINUE	ON	RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			05FEB2003-11FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	7	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			07FEB2003-11FEB2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	5	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			10FEB2003-CONTINUE	ON	TREMOR (Nervous system disorders) [PHYSICAL TREMORS (NOT DUE TO EPS.)]	UNK	8	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0018001	24 YRS CAUCASIAN FEMALE	30OCT2002-17NOV2002	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					TONGUE DISORDER NOS (Gastrointestinal disorders) [THICKENED TONGUE (NOT DUE TO EPS.)]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			30OCT2002-25NOV2002	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	27	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			02NOV2002-17NOV2002	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	16	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			02NOV2002-26NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			21NOV2002-23NOV2002	ON	MEMORY IMPAIRMENT (Nervous system disorders) [FORGETFULNESS]	3	24	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0018001	24 YRS CAUCASIAN FEMALE	07DEC2002-23DEC2002	ON	DYSKINESIA (Nervous system disorders) [NOCTURNAL MYOCLONUS (NOT DUE TO EPS)]	17	40	MIL	NO	N	N	N	N	N	N	NO YES	None
			07DEC2002-27DEC2002	ON	THOUGHT BLOCKING (Psychiatric disorders) [THOUGHT BLOCKING]	21	40	MOD	NO	N	N	N	N	N	N	NO YES	None
			23DEC2002-23DEC2002	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	1	56	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0018006	42 YRS CAUCASIAN MALE	19DEC2002-07JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	20	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			27DEC2002-CONTINUE	ON	MEMORY IMPAIRMENT (Nervous system disorders) [FORGETFULNESS]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0018006	42 YRS CAUCASIAN MALE	28DEC2002-07JAN2003	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH IN MORNINGS]	11	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			10JAN2003-06FEB2003	ON	ENURESIS (Renal and urinary disorders) [ENURESIS]	28	25	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019004	32 YRS CAUCASIAN FEMALE	08NOV2002-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					BALANCE IMPAIRED NOS (Nervous system disorders) [PROBLEM WITH EQUILIBRIUM (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			08NOV2002-26NOV2002	ON	MUSCLE TIGHTNESS (Musculoskeletal and connective tissue disorders) [MUSCLE TENSION (NOT DUE TO EPS)]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019004	32 YRS CAUCASIAN FEMALE	10NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			19NOV2002-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			24NOV2002-CONTINUE	ON	MANIA (Psychiatric disorders) [DECREASED NEED TO SLEEP (INCREASED ENERGY) (MANIA)]	UNK	18	SEV	NO	N	N	N	N	N	N	NO NO	None
			03DEC2002-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	UNK	27	MOD	NO	N	N	N	N	N	N	NO NO	None
			05DEC2002-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	29	SEV	NO	N	N	N	N	N	N	NO NO	None
					IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	UNK	29	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR I)	E0019004	32 YRS CAUCASIAN FEMALE	12DEC2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	36	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019011	50 YRS HISPANIC FEMALE	24NOV2002-05DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	12	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			25NOV2002-05DEC2002	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	11	5	SEV	NO	N	N	N	N	N	N	NO YES	None
			26NOV2002-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [GROGINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	UNK	6	SEV	NO	N	N	N	N	N	N	NO YES	None
			26NOV2002-06DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	11	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019011	50 YRS HISPANIC FEMALE	27NOV2002-CONTINUE	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS DUE TO EPS (AKATHISIA)]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			11DEC2002-19DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	9	21	MIL	NO	N	N	N	N	N	N	NO YES	None
			12DEC2002-02JAN2003	ON	ABDOMINAL PAIN LOWER (Gastrointestinal disorders) [LOWER LEFT ABDOMINAL PAIN]	22	22	MIL	NO	N	N	N	N	N	N	NO NO	None
			14DEC2002-02JAN2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	20	24	MIL	NO	N	N	N	N	N	N	NO YES	None
			31DEC2002-09JAN2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [VAGINAL CRAMPS (NOT RELATED TO MENSTRUAL CYCLE)]	10	41	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019011	50 YRS HISPANIC FEMALE	08JAN2003-09JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	49	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019025	30 YRS CAUCASIAN FEMALE	08FEB2003-13MAR2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS (UNSETTLING)]	34	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			08FEB2003-17MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	38	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	8	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0019043	54 YRS CAUCASIAN MALE	04JUN2003-CONTINUE	ON	ENURESIS (Renal and urinary disorders) [ENURISIS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019043	54 YRS CAUCASIAN MALE	04JUN2003-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			04JUN2003-08JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	35	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					MEMORY IMPAIRMENT (Nervous system disorders) [FORGETFULNESS]	35	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14JUN2003-08JUL2003	ON	TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	25	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			09JUL2003-23JUL2003	ON	INFLUENZA (Infections and infestations) [FLU]	15	37	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020001	48 YRS CAUCASIAN FEMALE	30OCT2002-10NOV2002	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	12	2	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020001	48 YRS CAUCASIAN FEMALE	06NOV2002-11NOV2002	ON	FLUSHING (Vascular disorders) [INTERMITTENT FLUSHING FEELING]	6	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			14NOV2002-19NOV2002	ON	EPISTAXIS (Respiratory, thoracic and mediastinal disorders) [EPISTAXIS]	6	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			14NOV2002-24NOV2002	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS "NOT DUE TO POSTURAL HYPOTENSION"]	11	17	MOD	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-28NOV2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASE APPETITE]	9	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			26NOV2002-03DEC2002	ON	WEIGHT INCREASED (Investigations) [INCREASE WEIGHT]	8	29	MIL	NO	N	N	N	N	N	N	NO YES	None
			05DEC2002-05DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	1	38	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020001	48 YRS CAUCASIAN FEMALE	08DEC2002-09DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	41	MOD	NO	N	N	N	N	N	N	NO YES	None
			14DEC2002-14DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	1	47	MOD	NO	N	N	N	N	N	N	NO YES	None
			18DEC2002-19DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	51	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020007	26 YRS CAUCASIAN FEMALE	19JAN2003-20JAN2003	ON	POLYMENORRHOEA (Reproductive system and breast disorders) [SHORTENED MENSES]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			16FEB2003-CONTINUE	ON	MENSTRUATION IRREGULAR (Reproductive system and breast disorders) [IRREGULAR MENSES]	UNK	33	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0020011	21 YRS CAUCASIAN FEMALE	28FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020011	21 YRS CAUCASIAN FEMALE	06MAR2003-13MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS AFTER EVENING DOSE (NOT DUE TO ORTHOSTATIC HYPOTENSION.)]	8	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-24MAR2003	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	8	20	MIL	NO	N	N	N	N	N	N	NO NO	None
			22MAR2003-22MAR2003	ON	CHEST DISCOMFORT (General disorders and administration site conditions) [CHEST DISCOMFORT]	1	25	MIL	NO	N	N	N	N	N	N	NO NO	None
			23MAR2003-25MAR2003	ON	SEASONAL ALLERGY (Immune system disorders) [SEASONAL ALLERGIES]	3	26	MOD	NO	N	N	N	N	N	N	NO NO	None
			26MAR2003-26MAR2003	ON	INJURY (Injury, poisoning and procedural complications) [TRIPPED AND FELL]	1	29	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020011	21 YRS CAUCASIAN FEMALE	26MAR2003-09APR2003	ON	ECCHYMOSIS (Skin and subcutaneous tissue disorders) [ECCHYMOSIS RIGHT FOREARM (2 1/2)]	15	29	MIL	NO	N	N	N	N	N	N	NO NO	None
			27MAR2003-27MAR2003	ON	SEASONAL ALLERGY (Immune system disorders) [SEASONAL ALLERGIES]	1	30	MOD	NO	N	N	N	N	N	N	NO NO	None
			31MAR2003-07APR2003	ON	CHEILITIS (Gastrointestinal disorders) [REDDENED RIGHT BOTTOM LIP AREA (ACCIDENTLY BIT LIP)]	8	34	MIL	NO	N	N	N	N	N	N	NO NO	None
			02APR2003-07APR2003	ON	SCRATCH (Injury, poisoning and procedural complications) [SUPERFICIAL SCRATCHES LEFT ANTERIOR CHEST AREA (PLAYING WITH PET RAT TODAY)]	6	36	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020013	23 YRS CAUCASIAN MALE	12MAR2003-12MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH EARLY MORNING]	1	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-17MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	13	SEV	YES	N	Y	N	N	N	N	YES NO	Permanently Stopped
	E0022017	41 YRS CAUCASIAN MALE	20DEC2002-22JAN2003	ON	TREMOR (Nervous system disorders) [TREMOR NOT DUE TO EPS]	34	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27DEC2002-31DEC2002	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	5	9	MIL	NO	N	N	N	N	N	N	NO NO	None
			19JAN2003-20JAN2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	2	32	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022018	41 YRS CAUCASIAN MALE	14DEC2002-30DEC2002	ON	BLEPHARITIS (Eye disorders) [BLEPHARITIS]	17	3	MIL	NO	N	N	N	N	N	N	NO NO	None
			14DEC2002-23JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS "NOT DUE TO POSTURAL HYPOTENSION"]	41	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			19DEC2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			27JAN2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPITORY INFECTION]	UNK	47	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022022	23 YRS CAUCASIAN FEMALE	31DEC2002-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			31DEC2002-18JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					MYOCLONUS (Nervous system disorders) [MYO - CLONIC JERKS]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			30JAN2003-18MAR2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	48	32	MIL	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	48	32	MOD	NO	N	N	N	N	N	N	NO NO	None
			09FEB2003-18MAR2003	ON	CONVERSION DISORDER (Psychiatric disorders) [CONVERSION DISORDER]	38	42	MOD	YES	N	N	Y	N	N	N	YES NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022027	45 YRS CAUCASIAN MALE	07FEB2003-07MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	29	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01MAR2003-14MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	14	24	MIL	NO	N	N	N	N	N	N	NO NO	None
			26MAR2003-01APR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	7	49	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022031	36 YRS CAUCASIAN MALE	19FEB2003-12MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	22	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			20FEB2003-12MAR2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL STUFFINESS]	21	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022031	36 YRS CAUCASIAN MALE	20FEB2003-12MAR2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS]	21	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-CONTINUE	ON	AKATHISIA (Nervous system disorders) [MOTOR RESTLESSNESS (DUE TO EPS AKATHISIA)]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			12APR2003-12APR2003	ON	DRUG ABUSER NOS (Social circumstances) [DRUG USE (COCAINE USE)]	1	54	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022032	21 YRS CAUCASIAN FEMALE	19FEB2003-07MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	17	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-01APR2003	ON	VIRAL INFECTION NOS (Infections and infestations) [VIRAL SYNDROME]	9	35	MIL	NO	N	N	N	N	N	N	NO NO	None
			14APR2003-CONTINUE	ON	HAEMORRHOIDS (Gastrointestinal disorders) [HEMORRHOIDS]	UNK	56	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022035	20 YRS CAUCASIAN FEMALE	20FEB2003-24FEB2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	5	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			24FEB2003-28FEB2003	ON	SINUSITIS NOS (Infections and infestations) [SINUSITIS]	5	6	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022036	22 YRS CAUCASIAN MALE	06APR2003-CONTINUE	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	UNK	41	MIL	NO	N	N	N	N	N	N	NO NO	None
			12MAY2003-14MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	3	77	MOD	YES	N	N	Y	N	N	N	NO NO	None
			13MAY2003-CONTINUE	ON	TINEA VERSICOLOUR (Infections and infestations) [TINEA VERSICOLOR]	UNK	78	MIL	NO	N	N	N	N	N	N	NO NO	None
			13MAY2003-30MAY2003	ON	CERUMEN IMPACTION (Ear and labyrinth disorders) [IMPACTED CERUMEN]	18	78	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022036	22 YRS CAUCASIAN MALE	14MAY2003-30MAY2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	17	79	MIL	NO	N	N	N	N	N	N	NO NO	None
			15MAY2003-30MAY2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	16	80	MIL	NO	N	N	N	N	N	N	NO NO	None
			17MAY2003-CONTINUE	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [EPIGASTRIC PAIN]	UNK	82	MIL	NO	N	N	N	N	N	N	NO NO	None
			30MAY2003-CONTINUE	POST	OTITIS EXTERNA NOS (Infections and infestations) [OTITIS EXTERNA]	UNK	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022060	24 YRS CAUCASIAN MALE	06MAY2003-17JUN2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	43	7	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR I)	E0023008	35 YRS CAUCASIAN FEMALE	30JAN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			08MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	38	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023013	40 YRS CAUCASIAN FEMALE	28FEB2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01MAR2003-01MAR2003	ON	DYSGEUSIA (Nervous system disorders) [METALLIC TASTE]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023015	43 YRS CAUCASIAN FEMALE	12MAR2003-08APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY - NOT RELATED TO ORTHOSTATIC HYPOTENSION]	28	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR I)	E0023015	43 YRS CAUCASIAN FEMALE	12MAR2003-08APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	28	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023034	18 YRS CAUCASIAN FEMALE	25JUN2003-27JUN2003	ON	DYSMENORRHOEA (Reproductive system and breast disorders) [MENSTRUAL CRAMPS]	3	17	MOD	NO	N	N	N	N	N	N	NO NO	None
			02JUL2003-06JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	5	24	MOD	NO	N	N	N	N	N	N	NO NO	None
			10JUL2003-31JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	22	32	MOD	NO	N	N	N	N	N	N	NO NO	None
			31JUL2003-01AUG2003	ON	ADNEXA UTERI PAIN (Reproductive system and breast disorders) [OVARIAN CYST PAIN]	2	53	SEV	YES	N	N	Y	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0023037	39 YRS CAUCASIAN MALE	11JUL2003-15JUL2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	5	24	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023044	44 YRS CAUCASIAN FEMALE	20JUL2003-CONTINUE	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS (NOT DUE TO EPS)]	UNK	5	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0025002	46 YRS CAUCASIAN FEMALE	05APR2003-17APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	13	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			08APR2003-17APR2003	ON	SLUGGISHNESS (General disorders and administration site conditions) [SLUGGISH IN THE MORNING]	10	6	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	22	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	46 YRS CAUCASIAN FEMALE	24APR2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [TIRED DURING DAY]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-CONTINUE	ON	VISUAL ACUITY REDUCED (Eye disorders) [WORSENING VISION (VISUAL ACUITY)]	UNK	50	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026010	31 YRS CAUCASIAN MALE	23JAN2003-28JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					VOMITING NOS (Gastrointestinal disorders) [EMESIS]	6	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			24JAN2003-28JAN2003	ON	INSOMNIA (Psychiatric disorders) [EXACERBATION OF INSOMNIA]	5	3	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026018	39 YRS CAUCASIAN FEMALE	20MAR2003-25MAR2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS]	6	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0026018	39 YRS CAUCASIAN FEMALE	20MAR2003-04APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	16	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-31MAY2003	ON	JOINT STIFFNESS (Musculoskeletal and connective tissue disorders) [JOINT STIFFNESS (NOT DUE TO EPS)]	73	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			03APR2003-16JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [HYPOTENSION ORTHOSTATIC]	75	15	MIL	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-07MAY2003	ON	SCABIES INFESTATION (Infections and infestations) [SCABIES]	23	27	MIL	NO	N	N	N	N	N	N	NO NO	None
			16MAY2003-CONTINUE	ON	UTERINE FIBROIDS (Neoplasms benign, malignant and unspecified (incl cysts and polyps)) [VAGINAL BLEEDING SECONDARY TO UTERINE FIBROIDS]	UNK	58	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0026025	41 YRS CAUCASIAN MALE	09MAY2003-11MAY2003	ON	PYREXIA (General disorders and administration site conditions) [FEVER]	3	1	MOD	NO	N	N	N	N	N	N	NO NO	None
			12MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [GROGGY]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			13MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			29MAY2003-CONTINUE	ON	HYPERTENSION NOS (Vascular disorders) [HYPERTENSION]	UNK	21	MOD	NO	N	N	N	N	N	N	NO YES	None
			13JUN2003-14JUN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	36	MIL	NO	N	N	N	N	N	N	NO NO	None
					VOMITING NOS (Gastrointestinal disorders) [EMESIS]	2	36	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0026029	22 YRS CAUCASIAN FEMALE	19JUL2003-19JUL2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [STUDY DRUG OVERDOSAGE (UNINTENTIONAL)]	1	11	MIL	NO	N	N	N	N	N	N	NO NO	None
			19JUL2003-20JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	2	11	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026030	29 YRS BLACK MALE	09JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			15AUG2003-CONTINUE	ON	LIMB INJURY NOS (Injury, poisoning and procedural complications) [LEFT FOOT INJURY]	UNK	38	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0026031	41 YRS BLACK MALE	21JUL2003-CONTINUE	ON	MUCOUS MEMBRANE DISORDER NOS (General disorders and administration site conditions) [FILM IN MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JUL2003-20AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	28	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			11AUG2003-01SEP2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	22	22	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0027003	50 YRS CAUCASIAN FEMALE	27FEB2003-06MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	8	31	MIL	NO	N	N	N	N	N	N	NO NO	None
					MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE ACHES]	8	31	MIL	NO	N	N	N	N	N	N	NO NO	None
					THIRST (General disorders and administration site conditions) [INCREASED THIRST]	8	31	MIL	NO	N	N	N	N	N	N	NO NO	None
			25MAR2003-08APR2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	15	57	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028004	30 YRS CAUCASIAN MALE	01OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028004	30 YRS CAUCASIAN MALE	01OCT2002-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			05OCT2002-06OCT2002	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [LOSS OF BALANCE (NOT DUE TO EPS)]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028006	40 YRS CAUCASIAN FEMALE	04OCT2002-04DEC2002	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	62	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			06OCT2002-12OCT2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			13OCT2002-23OCT2002	ON	PARAESTHESIA (Nervous system disorders) [PARASTHESIA]	11	10	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			21OCT2002-07NOV2002	ON	SINUSITIS NOS (Infections and infestations) [SINUS INFECTION]	18	18	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028008	36 YRS CAUCASIAN MALE	05NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	22	MOD	NO	N	N	N	N	N	N	NO NO	None
			30NOV2002-08DEC2002	ON	GINGIVAL INFECTION (Infections and infestations) [GUM INFECTION]	9	47	MIL	NO	N	N	N	N	N	N	NO NO	None
					TOOTH INFECTION (Infections and infestations) [TOOTH INFECTION]	9	47	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028009	21 YRS CAUCASIAN FEMALE	16OCT2002-17OCT2002	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	2	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			16OCT2002-02NOV2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	18	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20OCT2002-20OCT2002	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	6	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028009	21 YRS CAUCASIAN FEMALE	25OCT2002-25OCT2002	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	11	MIL	NO	N	N	N	N	N	N	NO NO	None
			09DEC2002-CONTINUE	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	UNK	56	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0028016	28 YRS CAUCASIAN MALE	15NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-CONTINUE	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	UNK	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			19DEC2002-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	36	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028016	28 YRS CAUCASIAN MALE	03JAN2003-CONTINUE	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	UNK	51	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028027	58 YRS HISPANIC MALE	21JAN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			22JAN2003-22JAN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	1	2	SEV	NO	N	N	N	N	N	N	NO NO	None
			22JAN2003-08FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	2	SEV	NO	N	N	N	N	N	N	NO YES	None
					DYSGEUSIA (Nervous system disorders) [BAD TASTE IN MOUTH]	18	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			27JAN2003-27JAN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	1	7	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028029	39 YRS HISPANIC MALE	04FEB2003-04FEB2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	1	MIL	NO	N	N	N	N	N	N	NO NO	None
			05FEB2003-18FEB2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	14	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			07FEB2003-18FEB2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	12	4	MOD	NO	N	N	N	N	N	N	NO NO	None
			12FEB2003-18FEB2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	7	9	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			28FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	UNK	25	SEV	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-CONTINUE	ON	AGITATION (Psychiatric disorders) [AGITATION]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	39 YRS CAUCASIAN MALE	01APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			04APR2003-08APR2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	5	4	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					CONFUSIONAL STATE (Psychiatric disorders) [CONFUSION]	5	4	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			04APR2003-01MAY2003	ON	CHEST PAIN (General disorders and administration site conditions) [RACING HEART (FEELING)]	28	4	SEV	NO	N	N	N	N	N	N	NO YES	None
			04APR2003-19MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	46	4	SEV	NO	N	N	N	N	N	N	NO YES	None
			05MAY2003-05MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	35	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028034	39 YRS CAUCASIAN MALE	07MAY2003-19MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	13	37	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAY2003-CONTINUE	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	UNK	49	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028038	50 YRS CAUCASIAN MALE	25APR2003-23JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	60	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	60	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			08MAY2003-23JUN2003	ON	HYPOAESTHESIA (Nervous system disorders) [NUMBNESS - RT. ARM]	47	14	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028038	50 YRS CAUCASIAN MALE	08MAY2003-23JUN2003	ON	NECK PAIN (Musculoskeletal and connective tissue disorders) [NECK PAIN (NOT DUE TO EPS)]	47	14	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028043	51 YRS CAUCASIAN MALE	06JUN2003-31JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	56	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			10JUN2003-31JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	52	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			11JUN2003-11JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-31JUL2003	ON	INSOMNIA (Psychiatric disorders) [WORSENED INSOMNIA]	44	14	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028045	46 YRS CAUCASIAN MALE	22JUN2003-22JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	5	SEV	NO	N	N	N	N	N	N	NO NO	None
			23JUN2003-24JUN2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEG SYNDROME (NOT DUE TO EPS)]	2	6	SEV	NO	N	N	N	N	N	N	NO YES	None
			15JUL2003-CONTINUE	ON	DYSKINESIA (Nervous system disorders) [DYSKINESIA]	UNK	28	MOD	NO	N	N	N	N	N	N	NO NO	None
					HEADACHE (Nervous system disorders) [HEADACHES]	UNK	28	MOD	NO	N	N	N	N	N	N	NO NO	None
					INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	28	MOD	NO	N	N	N	N	N	N	NO NO	None
			15JUL2003-29JUL2003	ON	MANIA (Psychiatric disorders) [MANIC EPISODE]	15	28	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028045	46 YRS CAUCASIAN MALE	24JUL2003-CONTINUE	ON	THERMAL BURN (Injury, poisoning and procedural complications) [LEFT FOOT BURN]	UNK	37	MOD	NO	N	N	N	N	N	N	NO NO	None
			26JUL2003-29JUL2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH ACUTE PSYCHOSIS]	4	39	SEV	YES	N	N	Y	N	N	N	YES NO	None
			01AUG2003-12AUG2003	ON	DRUG ABUSER NOS (Social circumstances) [METHAMPHETAMINE ABUSE]	12	45	MOD	NO	N	N	N	N	N	N	NO NO	None
			11AUG2003-11AUG2003	POST	INJURY (Injury, poisoning and procedural complications) [FALLING EPISODE SECONDARY TO METHAMPHETAMINE ABUSE]	1	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
			11AUG2003-27AUG2003	POST	BIPOLAR I DISORDER (Psychiatric disorders) [BIPOLAR AFFECTIVE DISORDER MIXED STATE WITH MOOD CONGRUENT PSYCHOSIS]	17	UNK	SEV	YES	N	N	Y	N	N	N	YES NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0029005	30 YRS BLACK FEMALE	27NOV2002-23JAN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS ONE HOUR AFTER DOSE]	58	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			28NOV2002-02DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	5	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01DEC2002-05DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			01DEC2002-07DEC2002	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [LOWER BACK PAIN]	7	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			03DEC2002-23JAN2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH 30 MINUTES AFTER DOSE]	52	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0029005	30 YRS BLACK FEMALE	21DEC2002-22DEC2002	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	2	25	MOD	NO	N	N	N	N	N	N	NO NO	None
			21DEC2002-23DEC2002	ON	NASOPHARYNGITIS (Infections and infestations) [COMMON COLD]	3	25	MOD	NO	N	N	N	N	N	N	NO NO	None
			07JAN2003-07JAN2003	ON	SINUS HEADACHE (Nervous system disorders) [SINUS HEADACHE]	1	42	MIL	NO	N	N	N	N	N	N	NO NO	None
			13JAN2003-13JAN2003	ON	SINUS HEADACHE (Nervous system disorders) [SINUS HEADACHE]	1	48	MOD	NO	N	N	N	N	N	N	NO NO	None
			14JAN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [DAYTIME TIREDNESS]	UNK	49	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0030001	41 YRS CAUCASIAN FEMALE	01DEC2002-01DEC2002	ON	VERTIGO (Ear and labyrinth disorders) [VERTIGO]	1	13	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0030001	41 YRS CAUCASIAN FEMALE	03DEC2002-CONTINUE	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
			03DEC2002-19DEC2002	ON	HYPOAESTHESIA (Nervous system disorders) [NUMBNESS (IN FINGERS)]	17	15	MOD	NO	N	N	N	N	N	N	NO NO	None
			07DEC2002-07DEC2002	ON	VERTIGO (Ear and labyrinth disorders) [VERTIGO]	1	19	MIL	NO	N	N	N	N	N	N	NO YES	None
			10DEC2002-10DEC2002	ON	VERTIGO (Ear and labyrinth disorders) [VERTIGO]	1	22	MIL	NO	N	N	N	N	N	N	NO YES	None
			15DEC2002-15DEC2002	ON	EAR CONGESTION (Ear and labyrinth disorders) [INNER EAR CONGESTION]	1	27	MIL	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	27	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0030001	41 YRS CAUCASIAN FEMALE	15DEC2002-15DEC2002	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	27	MIL	NO	N	N	N	N	N	N	NO NO	None
			19DEC2002-10JAN2003	ON	ABDOMINAL DISTENSION (Gastrointestinal disorders) [BLOATED]	23	31	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0030008	40 YRS CAUCASIAN MALE	27FEB2003-02MAR2003	ON	JOINT SWELLING (Musculoskeletal and connective tissue disorders) [SWOLLEN JAW]	4	45	MOD	NO	N	N	N	N	N	N	NO NO	None
			14MAR2003-17MAR2003	ON	TOOTH INFECTION (Infections and infestations) [TOOTH INFECTION]	4	60	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0030011	21 YRS CAUCASIAN MALE	27JAN2003-01FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	6	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0030011	21 YRS CAUCASIAN MALE	02FEB2003-02FEB2003	ON	SKIN LACERATION (Injury, poisoning and procedural complications) [EYEBROW LACERATION]	1	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			20FEB2003-08MAR2003	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	17	25	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0030015	21 YRS CAUCASIAN MALE	21FEB2003-05MAY2003	ON	SEDATION (Nervous system disorders) [EARLY AM SEDATION]	74	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0030022	39 YRS CAUCASIAN MALE	17JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR I)	E0030022	39 YRS CAUCASIAN MALE	17JUN2003-21JUN2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGY]	5	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25JUN2003-29JUN2003	ON	INFLUENZA (Infections and infestations) [FLU]	5	10	MIL	NO	N	N	N	N	N	N	NO NO	None
			25JUL2003-28JUL2003	ON	HYPERSENSITIVITY NOS (Immune system disorders) [ALLERGY ATTACK (WORSENING)]	4	40	MOD	NO	N	N	N	N	N	N	NO NO	None
			29JUL2003-03AUG2003	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	6	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031002	18 YRS CAUCASIAN FEMALE	28NOV2002-27DEC2002	ON	SLUGGISHNESS (General disorders and administration site conditions) [SLUGGISHNESS]	30	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	18 YRS CAUCASIAN FEMALE	01JAN2003-20JAN2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS (NOT DUE TO POSTURAL HYPOTENSION)]	20	36	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-23JAN2003	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	9	50	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031003	33 YRS CAUCASIAN MALE	12DEC2002-26JAN2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	46	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			12JAN2003-20JAN2003	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	9	34	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0033015	34 YRS CAUCASIAN FEMALE	10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH (NOT DUE TO EPS)]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0033015	34 YRS CAUCASIAN FEMALE	10APR2003-19APR2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	10	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-22MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	43	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			11APR2003-12APR2003	ON	NECK PAIN (Musculoskeletal and connective tissue disorders) [NECK PAIN]	2	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			14APR2003-16APR2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FLASHES]	3	5	MIL	NO	N	N	N	N	N	N	NO NO	None
					FLUSHING (Vascular disorders) [HOT FLASHES]	3	5	MIL	NO	N	N	N	N	N	N	NO NO	None
			15APR2003-15APR2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [AUDITORY HALLUCINATIONS]	1	6	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0033015	34 YRS CAUCASIAN FEMALE	15APR2003-16APR2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			16APR2003-16APR2003	ON	TREMOR (Nervous system disorders) [HAND TREMORS (NOT DUE TO EPS)]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			29APR2003-10MAY2003	ON	MEMORY IMPAIRMENT (Nervous system disorders) [MEMORY LOSS]	12	20	MOD	NO	N	N	N	N	N	N	NO YES	None
			01MAY2003-CONTINUE	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			20MAY2003-20MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	41	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0034002	55 YRS CAUCASIAN MALE	26MAR2003-29MAR2003	ON	PRURITUS (Skin and subcutaneous tissue disorders) [PRURITUS OF FACE]	4	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0034002	55 YRS CAUCASIAN MALE	26MAR2003-18APR2003	ON	SOMNOLENCE (Nervous system disorders) [DAYTIME DROWSINESS]	24	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			28MAR2003-18APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			29MAR2003-29MAR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	5	MIL	NO	N	N	N	N	N	N	NO NO	None
			02APR2003-18APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	17	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			05APR2003-09APR2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU LIKE SYMPTOMS]	5	12	MIL	NO	N	N	N	N	N	N	NO NO	None
			10APR2003-20APR2003	ON	BRONCHITIS NOS (Respiratory, thoracic and mediastinal disorders) [BRONCHITIS]	11	17	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0034003	49 YRS CAUCASIAN MALE	27APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			27APR2003-01JUN2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	36	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			27APR2003-02JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DAYTIME DROWSINESS]	37	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			20MAY2003-21MAY2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	2	27	MIL	NO	N	N	N	N	N	N	NO NO	None
			03JUN2003-03JUN2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	1	41	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0034006	35 YRS CAUCASIAN FEMALE	17MAY2003-17JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DAYTIME DROWSINESS]	62	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0034008	34 YRS BLACK MALE	24MAY2003-03JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-27MAY2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGINESS IN MORNING]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-18JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	26	MIL	NO	N	N	N	N	N	N	NO NO	None
			15JUL2003-15JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	53	MIL	NO	N	N	N	N	N	N	NO NO	None
			18JUL2003-18JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	56	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0035003	28 YRS CAUCASIAN MALE	27NOV2002-27DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	31	6	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0035005	48 YRS CAUCASIAN FEMALE	16DEC2002-16DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	14	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0035014	35 YRS BLACK FEMALE	03FEB2003-27MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	53	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			04FEB2003-26MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	51	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0035024	41 YRS BLACK FEMALE	24MAY2003-25MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	2	2	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0035024	41 YRS BLACK FEMALE	24MAY2003-13JUN2003	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	21	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			26MAY2003-05JUN2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	11	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			13JUN2003-15JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	33	22	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0036005	19 YRS CAUCASIAN FEMALE	02JUL2003-07JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	6	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-04JUL2003	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JUL2003-05AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	8	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0036005	19 YRS CAUCASIAN FEMALE	09JUL2003-09JUL2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			11JUL2003-11JUL2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	11	MIL	NO	N	N	N	N	N	N	NO NO	None
			11JUL2003-23JUL2003	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	13	11	MOD	NO	N	N	N	N	N	N	NO NO	None
			12JUL2003-12JUL2003	ON	CHEST WALL PAIN (Musculoskeletal and connective tissue disorders) [CHEST WALL PAIN "NOT CARDIAC RELATED"]	1	12	SEV	NO	N	N	N	N	N	N	NO NO	None
					VISION BLURRED (Eye disorders) [BLURRED VISION]	1	12	MOD	NO	N	N	N	N	N	N	NO NO	None
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	12	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0036005	19 YRS CAUCASIAN FEMALE	05AUG2003-19AUG2003	ON	MIGRAINE NOS (Nervous system disorders) [INCREASED MIGRAINE HEADACHES]	15	36	SEV	NO	N	N	N	N	N	N	NO NO	None
			18AUG2003-24AUG2003	ON	CHEST WALL PAIN (Musculoskeletal and connective tissue disorders) [INTERMITTENT CHEST WALL PAIN "NOT CARDIAC RELATED"]	7	49	MOD	NO	N	N	N	N	N	N	NO NO	None
			19AUG2003-19AUG2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION, WITH NO PLAN OR INTENT]	1	50	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0037002	28 YRS CAUCASIAN FEMALE	26DEC2002-07FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	44	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			20FEB2003-21FEB2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS (NOT DUE TO POSTURAL HYPOTENSION)]	2	57	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0037005	27 YRS CAUCASIAN FEMALE	20MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-17APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	29	15	MIL	NO	N	N	N	N	N	N	NO YES	None
					DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	29	15	MIL	NO	N	N	N	N	N	N	NO YES	None
			27MAR2003-CONTINUE	ON	TINNITUS (Ear and labyrinth disorders) [LEFT EAR RINGING]	UNK	22	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0037006	50 YRS CAUCASIAN FEMALE	14MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	50 YRS CAUCASIAN FEMALE	21MAR2003-04APR2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS - NOT DUE TO POSTURAL HYPOTENSION]	15	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			01MAY2003-07MAY2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESSNESS OF BILATERAL LOWER EXTREMITIES (NOT DUE TO EPS)]	7	49	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039015	41 YRS BLACK MALE	23JAN2003-23JAN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	1	MIL	NO	N	N	N	N	N	N	NO NO	None
					SWEATING INCREASED (Skin and subcutaneous tissue disorders) [DIAPHORESIS NOT DUE TO POSTURAL HYPOTENSION]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039015	41 YRS BLACK MALE	24JAN2003-24JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27JAN2003-27JAN2003	ON	DIZZINESS (Nervous system disorders) [LIGHT - HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	1	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			30JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			02FEB2003-02FEB2003	ON	NECK PAIN (Musculoskeletal and connective tissue disorders) [NECK PAIN]	1	11	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039015	41 YRS BLACK MALE	03FEB2003-03FEB2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	1	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-13FEB2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [HIP PAIN]	1	22	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0039024	35 YRS CAUCASIAN FEMALE	28FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSY POST DOSE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			28FEB2003-07MAY2003	ON	CHEST TIGHTNESS (General disorders and administration site conditions) [CHEST TIGHTNESS POST DOSE]	69	2	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039024	35 YRS CAUCASIAN FEMALE	28FEB2003-07MAY2003	ON	NASAL OEDEMA (Respiratory, thoracic and mediastinal disorders) [NASAL SWELLING POST DOSE]	69	2	MOD	NO	N	N	N	N	N	N	NO NO	None
					RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS POST DOSE (NOT DUE TO EPS)]	69	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-22MAR2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [NON - PRODUCTIVE COUGH]	5	20	MIL	NO	N	N	N	N	N	N	NO NO	None
					NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	5	20	MOD	NO	N	N	N	N	N	N	NO NO	None
			19MAR2003-19MAR2003	ON	EAR PRURITUS (Ear and labyrinth disorders) [ITCHING EARS]	1	21	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039024	35 YRS CAUCASIAN FEMALE	11APR2003-11APR2003	ON	INJURY (Injury, poisoning and procedural complications) [FALL]	1	44	MOD	NO	N	N	N	N	N	N	NO NO	None
			11APR2003-06MAY2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [RIGHT ANKLE PAIN]	26	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039041	35 YRS BLACK MALE	25APR2003-03MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	9	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			28APR2003-28APR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	14	MOD	NO	N	N	N	N	N	N	NO NO	None
			28MAY2003-31MAY2003	ON	PRODUCTIVE COUGH (Respiratory, thoracic and mediastinal disorders) [PRODUCTIVE COUGH]	4	44	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039041	35 YRS BLACK MALE	28MAY2003-05JUN2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	9	44	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039044	44 YRS CAUCASIAN MALE	24MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS (POST - DOSE)]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			07JUN2003-11JUN2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS POST - DOSE (NOT CARDIAC - RELATED)]	5	17	MIL	NO	N	N	N	N	N	N	NO NO	None
			09JUN2003-15JUN2003	ON	SCRATCH (Injury, poisoning and procedural complications) [OPEN AREAS ON NOSE (SCRATCHES)]	7	19	MIL	NO	N	N	N	N	N	N	NO NO	None
			22JUN2003-28JUN2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS POST - DOSE (NOT CARDIAC - RELATED)]	7	32	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039051	40 YRS BLACK FEMALE	16JUN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS POST-DOSE]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			17JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			13JUL2003-18JUL2003	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	6	28	MOD	NO	N	N	N	N	N	N	NO NO	None
			18JUL2003-18JUL2003	ON	TOOTH LOSS (Gastrointestinal disorders) [ONE TOOTH LOSS]	1	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			09AUG2003-CONTINUE	ON	GLOSSODYNIA (Gastrointestinal disorders) [TONGUE PAIN]	UNK	55	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039053	40 YRS BLACK MALE	05AUG2003-05AUG2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED WHEN STOOD UP (NOT DUE TO POSTURAL HYPOTENSION)]	1	26	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039057	38 YRS BLACK MALE	16JUL2003-18JUL2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	3	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			16JUL2003-06AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			22JUL2003-14AUG2003	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED SEX DRIVE]	24	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JUL2003-06AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	14	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			05AUG2003-CONTINUE	ON	ONYCHOPHAGIA (Psychiatric disorders) [FINGER NAIL BITING]	UNK	23	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039057	38 YRS BLACK MALE	23AUG2003-31AUG2003	ON	HERPES SIMPLEX (Infections and infestations) [COLD SORE]	9	41	MIL	NO	N	N	N	N	N	N	NO NO	None
			02SEP2003-02SEP2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	51	MIL	NO	N	N	N	N	N	N	NO NO	None
			05SEP2003-CONTINUE	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [LEFT LEG PAIN DUE TO BASKETBALL INJURY]	UNK	54	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0041003	36 YRS BLACK FEMALE	02FEB2003-12FEB2003	ON	DRY EYE NOS (Eye disorders) [DRY EYES]	11	6	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0041008	32 YRS CAUCASIAN FEMALE	23APR2003-10JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [INTERMITTENT DRY MOUTH]	49	17	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0041008	32 YRS CAUCASIAN FEMALE	23APR2003-10JUN2003	ON	SEDATION (Nervous system disorders) [INTERMITTENT SEDATION]	49	17	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0042001	59 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			14JUL2003-19AUG2003	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS (NOT POSTURAL HYPOTENSION)]	37	13	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0001002	47 YRS BLACK FEMALE	12MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			13MAR2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADED - (NOT DUE TO POSTURAL HYPOTENSION)]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					FEELING ABNORMAL (General disorders and administration site conditions) [MENTALLY FOGGY]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			16MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			16MAR2003-09APR2003	ON	SENSORY DISTURBANCE NOS (Nervous system disorders) [TWITCHY SENSATION IN LEGS AT BEDTIME NOT DUE TO EPS (SENSORY DISTURBANCE)]	25	5	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0001002	47 YRS BLACK FEMALE	24MAR2003-24MAR2003	ON	MICTURITION URGENCY (Renal and urinary disorders) [PRESSURE IN BLADDER TO URINATE (URINARY URGENCY)]	1	13	MIL	NO	N	N	N	N	N	N	NO NO	None
			02APR2003-CONTINUE	ON	HYPERTENSION NOS (Vascular disorders) [EXACERBATION OF HYPERTENSION]	UNK	22	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0003018	33 YRS BLACK FEMALE	16MAY2003-10JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	26	4	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005011	26 YRS CAUCASIAN MALE	24OCT2002-25OCT2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			24OCT2002-24NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	32	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0005011	26 YRS CAUCASIAN MALE	31OCT2002-15NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	16	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			09NOV2002-13NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	17	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005030	19 YRS CAUCASIAN FEMALE	27MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					DYSTONIA (Nervous system disorders) [DYSTONIA]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0005030	19 YRS CAUCASIAN FEMALE	31MAR2003-31MAR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-01APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	1	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-16APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	21	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	2	21	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
	E0005036	40 YRS CAUCASIAN FEMALE	06MAY2003-13MAY2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS DUE TO EPS (AKATHISIA)]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0005036	40 YRS CAUCASIAN FEMALE	06MAY2003-13MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					DYSKINESIA (Nervous system disorders) [DECREASED COORDINATION SECONDARY TO EPS (DYSKINESIA)]	8	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	8	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0006015	36 YRS CAUCASIAN FEMALE	11FEB2003-11FEB2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEAT]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0006015	36 YRS CAUCASIAN FEMALE	12FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [INCREASE SLEEPINESS]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			15FEB2003-15FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			16FEB2003-04MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	17	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			20FEB2003-20FEB2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZY (DUE TO POSTURAL HYPOTENSION)]	1	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			22FEB2003-23FEB2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-25FEB2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [FAINT (DUE TO POSTURAL HYPOTENSION)]	1	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0006015	36 YRS CAUCASIAN FEMALE	01MAR2003-CONTINUE	ON	ANXIETY (Psychiatric disorders) [INNER FEELING OF SHAKING OR BOUNCING (ANXIETY NOT DUE TO EPS)]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0006016	43 YRS CAUCASIAN MALE	19FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	30	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0007008	42 YRS CAUCASIAN FEMALE	18APR2003-25APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR II)	E0009002	47 YRS CAUCASIAN MALE	20NOV2002-27NOV2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					DEREALISATION (Psychiatric disorders) [DEREALIZATION]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH (NOT DUE TO EPS)]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [FATIGUE ON WALKING]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					NASAL DRYNESS (Respiratory, thoracic and mediastinal disorders) [DRY SINUSES]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					TONGUE DISORDER NOS (Gastrointestinal disorders) [THICK TONGUE]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0009002	47 YRS CAUCASIAN MALE	20NOV2002-27NOV2002	ON	TREMOR (Nervous system disorders) [TREMORS - (NOT DUE TO EPS)]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-17DEC2002	ON	SEDATION (Nervous system disorders) [SEDATION]	28	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			28NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH - (NOT DUE TO EPS)]	UNK	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			15DEC2002-CONTINUE	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [TWITCHING OF FINGERS - (NOT DUE TO EPS)]	UNK	27	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0009006	20 YRS CAUCASIAN MALE	14FEB2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [POST - STUDY MEDICATION DOSE HEADACHE]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0009009	23 YRS CAUCASIAN FEMALE	12MAR2003-22MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010015	42 YRS HISPANIC MALE	13MAR2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0011004	32 YRS CAUCASIAN MALE	31DEC2002-31DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO POSTURAL HYPOTENSION]	1	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			31DEC2002-06JAN2003	ON	GASTROENTERITIS VIRAL NOS (Infections and infestations) [VIRAL GASTROENTERITIS]	7	8	MOD	NO	N	N	N	N	N	N	NO NO	None
			16JAN2003-25JAN2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	10	24	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0011004	32 YRS CAUCASIAN MALE	24JAN2003-24JAN2003	ON	CHEST PAIN (General disorders and administration site conditions) [CHEST PAIN (NON - CARDIAC)]	1	32	MIL	NO	N	N	N	N	N	N	NO NO	None
					INJURY (Injury, poisoning and procedural complications) [FALL, WITHOUT LOSS OF CONSCIOUSNESS]	1	32	MOD	NO	N	N	N	N	N	N	NO NO	None
			24JAN2003-27JAN2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	4	32	SEV	NO	N	N	N	N	N	N	NO NO	None
			04FEB2003-04FEB2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	1	43	MIL	NO	N	N	N	N	N	N	NO NO	None
			08FEB2003-10FEB2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	3	47	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0011004	32 YRS CAUCASIAN MALE	09FEB2003-09FEB2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH, SECONDARY TO SMOKE INHALATION]	1	48	MIL	NO	N	N	N	N	N	N	NO NO	None
			10FEB2003-10FEB2003	ON	FOOD POISONING NOS (Gastrointestinal disorders) [VOMITING POSSIBLY SECONDARY TO FOOD POISONING]	1	49	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0011007	47 YRS CAUCASIAN FEMALE	23DEC2002-24DEC2002	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [LIGHTHEADEDNESS DUE TO POSTURAL HYPOTENSION]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			28DEC2002-29JAN2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	33	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			30DEC2002-30DEC2002	ON	URINARY INCONTINENCE (Renal and urinary disorders) [URINARY INCONTINENCE]	1	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0011007	47 YRS CAUCASIAN FEMALE	20JAN2003-20JAN2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			22JAN2003-22JAN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	1	35	MIL	NO	N	N	N	N	N	N	NO NO	None
			23JAN2003-CONTINUE	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO POSTURAL HYPOTENSION]	UNK	36	MOD	NO	N	N	N	N	N	N	NO YES	None
			23JAN2003-23JAN2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	36	MIL	NO	N	N	N	N	N	N	NO NO	None
			23JAN2003-29JAN2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	7	36	MIL	NO	N	N	N	N	N	N	NO YES	None
			05FEB2003-07FEB2003	ON	VIRAL INFECTION NOS (Infections and infestations) [VIRAL SYNDROME]	3	49	MIL	NO	N	N	N	N	N	N	NO NO	None

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Listing 12.2.7.1 Adverse Events

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QUETIAPINE 300 MG (BIPOLAR II)	E0011018	23 YRS OTHER MALE	30MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0011024	36 YRS BLACK FEMALE	24JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0015003	54 YRS CAUCASIAN FEMALE	25NOV2002-04DEC2002	ON	SEDATION (Nervous system disorders) [EXCESSIVE SEDATION]	10	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019003	27 YRS CAUCASIAN FEMALE	24NOV2002-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGIC (INCREASED)]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019003	27 YRS CAUCASIAN FEMALE	25NOV2002-09DEC2002	ON	MICTURITION URGENCY (Renal and urinary disorders) [URINATION URGENCY]	15	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			16DEC2002-19DEC2002	ON	MENSES DELAYED (Reproductive system and breast disorders) [DELAYED MENSTRUAL CYCLE (6 DAYS)]	4	26	MOD	NO	N	N	N	N	N	N	NO YES	None
			16DEC2002-23DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	8	26	MIL	NO	N	N	N	N	N	N	NO YES	None
			19DEC2002-21DEC2002	ON	POLYMENORRHOEA (Reproductive system and breast disorders) [SHORTENED MENSTRAL CYCLE]	3	29	MOD	NO	N	N	N	N	N	N	NO YES	None
			16JAN2003-CONTINUE	ON	FLUSHING (Vascular disorders) [FLUSHING]	UNK	57	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019007	39 YRS CAUCASIAN FEMALE	13NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019007	39 YRS CAUCASIAN FEMALE	13NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [TRANSIENT LETHARGY]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS (NOT DUE TO EPS)]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JAN2003-CONTINUE	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	UNK	50	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0019014	24 YRS CAUCASIAN MALE	10JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019014	24 YRS CAUCASIAN MALE	10JAN2003- CONTINUE	ON	FLAT AFFECT (Psychiatric disorders) [FLAT AFFECT]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARY]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JAN2003- CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [EQUILIBRIUM PROBLEMS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019018	34 YRS CAUCASIAN MALE	02FEB2003- 20FEB2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	19	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003- 14MAR2003	ON	GINGIVAL PAIN (Gastrointestinal disorders) [GUM PAIN]	1	44	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019018	34 YRS CAUCASIAN MALE	14MAR2003-14MAR2003	ON	TOOTH EXTRACTION NOS (Surgical and medical procedures) [TOOTH EXTRACTION]	1	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0019022	24 YRS CAUCASIAN FEMALE	03FEB2003-CONTINUE	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [EXACERBATION OF LOWER BACK PAIN]	UNK	5	SEV	NO	N	N	N	N	N	N	NO NO	None
			10FEB2003-11FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHIA]	2	12	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019027	26 YRS HISPANIC FEMALE	28FEB2003-03MAR2003	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [PROBLEMS WITH EQUILITRIUM]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR II)	E0019027	26 YRS HISPANIC FEMALE	28FEB2003-03MAR2003	ON	SEDATION (Nervous system disorders) [EXCESSIVE SEDATION]	4	2	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			28FEB2003-06MAR2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019032	28 YRS CAUCASIAN FEMALE	01APR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-22APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	22	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			02APR2003-01MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	30	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			02APR2003-28MAY2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	57	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019032	28 YRS CAUCASIAN FEMALE	03APR2003-01MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	29	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			18APR2003-24APR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	7	18	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0019034	33 YRS CAUCASIAN FEMALE	19MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0019036	27 YRS CAUCASIAN MALE	25MAR2003-09APR2003	ON	ARTHROPOD BITE (Injury, poisoning and procedural complications) [SPIDER BITE]	16	1	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019036	27 YRS CAUCASIAN MALE	31MAR2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	17	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEXUAL DYSFUNCTION NOS (Reproductive system and breast disorders) [SEXUAL DYSFUNCTION]	UNK	17	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019039	35 YRS CAUCASIAN MALE	01MAY2003-04MAY2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	4	1	MOD	NO	N	N	N	N	N	N	YES YES	None
			03MAY2003-04MAY2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	2	3	MOD	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019039	35 YRS CAUCASIAN MALE	03MAY2003-04MAY2003	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [DECREASED EQUILITRIUM (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					DISORIENTATION (Psychiatric disorders) [DISORIENTATION]	2	3	MIL	NO	N	N	N	N	N	N	YES NO	None
					DISTURBANCE IN ATTENTION (Nervous system disorders) [DECREASED CONCENTRATION]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					PANIC DISORDER NOS (Psychiatric disorders) [PANIC DISORDER SYMPTOMS]	2	3	MOD	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019039	35 YRS CAUCASIAN MALE	03MAY2003-04MAY2003	ON	PARANOIA (Psychiatric disorders) [PARANOIA]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					SUSPICIOUSNESS (Psychiatric disorders) [SUSPICIOUSNESS]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
			03MAY2003-05JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA (NOT DUE TO EPS)]	34	3	MOD	NO	N	N	N	N	N	N	YES YES	None
			24MAY2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	UNK	24	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0019041	22 YRS CAUCASIAN FEMALE	22MAY2003-19JUN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	22 YRS CAUCASIAN FEMALE	22MAY2003-19JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019049	33 YRS CAUCASIAN FEMALE	11JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None
					CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None
					NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019049	33 YRS CAUCASIAN FEMALE	18JUL2003-30JUL2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [LABORED BREATHING]	13	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			29JUL2003-01AUG2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [MUSCLE TWITCHING (NOT DUE TO EPS)]	4	20	MOD	NO	N	N	N	N	N	N	NO YES	None
			05AUG2003-06AUG2003	ON	SLEEP WALKING (Psychiatric disorders) [SLEEPWALKING]	2	27	MOD	NO	N	N	N	N	N	N	NO YES	None
			15AUG2003-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	37	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0022052	46 YRS BLACK FEMALE	11APR2003-29APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	19	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0022052	46 YRS BLACK FEMALE	11APR2003-20MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	40	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022064	19 YRS CAUCASIAN MALE	07MAY2003-15MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	9	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAY2003-17MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022073	25 YRS CAUCASIAN FEMALE	21JUL2003-23JUL2003	ON	URINARY TRACT INFECTION NOS (Infections and infestations) [URINARY TRACT INFECTION]	3	26	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0023002	19 YRS CAUCASIAN FEMALE	05NOV2002-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0023002	19 YRS CAUCASIAN FEMALE	10NOV2002-23NOV2002	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	14	6	MOD	NO	N	N	N	N	N	N	NO NO	None
			16NOV2002-23NOV2002	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	8	12	MOD	NO	N	N	N	N	N	N	NO NO	None
			27NOV2002-07DEC2002	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	11	23	MOD	NO	N	N	N	N	N	N	NO NO	None
			29NOV2002-29NOV2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	25	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0023017	18 YRS CAUCASIAN MALE	25MAR2003-07APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	14	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0023017	18 YRS CAUCASIAN MALE	25APR2003-02MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	8	32	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023021	49 YRS CAUCASIAN MALE	24APR2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-09MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	16	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-11JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	49	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			30APR2003-09MAY2003	ON	PHOTOPSIA (Eye disorders) [FLASHES OF WHITE LIGHT IN EYES]	10	8	MIL	NO	N	N	N	N	N	N	NO NO	None
			11MAY2003-11MAY2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	19	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0023021	49 YRS CAUCASIAN MALE	15MAY2003-18MAY2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU SYMPTOMS]	4	23	MOD	NO	N	N	N	N	N	N	NO NO	None
			22MAY2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	30	MOD	NO	N	N	N	N	N	N	NO NO	None
			31MAY2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [HIP PAIN]	UNK	39	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023027	25 YRS CAUCASIAN FEMALE	17MAY2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			21MAY2003-CONTINUE	ON	HYPERTENSION NOS (Vascular disorders) [WORSENING HYPERTENSION]	UNK	6	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0023027	25 YRS CAUCASIAN FEMALE	22MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	7	SEV	NO	N	N	N	N	N	N	NO YES	None
			28MAY2003-13JUN2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU SYMPTOMS]	17	13	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0023030	40 YRS CAUCASIAN FEMALE	04JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JUN2003-02JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	27	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023040	32 YRS BLACK FEMALE	04JUL2003-15JUL2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [PAIN IN RIGHT LEG]	12	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0023040	32 YRS BLACK FEMALE	04JUL2003-30AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	58	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			26JUL2003-30AUG2003	ON	FLUSHING (Vascular disorders) [HOT FLASHES]	36	24	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026014	57 YRS CAUCASIAN MALE	19FEB2003-05MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	15	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			19FEB2003-08MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			01MAR2003-01MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	11	MIL	NO	N	N	N	N	N	N	NO NO	None
			01MAR2003-04MAR2003	ON	PYREXIA (General disorders and administration site conditions) [FEVER]	4	11	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0026019	39 YRS BLACK FEMALE	18MAR2003-19MAR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	2	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-20MAR2003	ON	PALPITATIONS (Cardiac disorders) [HEART POUNDING]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-07APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	21	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-01MAY2003	ON	FLATULENCE (Gastrointestinal disorders) [GAS]	45	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-13MAY2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASE OF APPETITE]	57	2	SEV	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	57	2	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0026019	39 YRS BLACK FEMALE	18MAR2003-13MAY2003	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	57	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	57	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			23MAR2003-23MAR2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [STUDY DRUG OVERDOSE (ACCIDENTAL)]	1	7	MIL	NO	N	N	N	N	N	N	NO NO	None
			13APR2003-13APR2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [STUDY DRUG OVERDOSE (ACCIDENTAL)]	1	28	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0027005	58 YRS CAUCASIAN FEMALE	02JAN2003-09JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	8	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0027005	58 YRS CAUCASIAN FEMALE	06FEB2003-12FEB2003	ON	INFLUENZA (Infections and infestations) [FLU]	7	43	MIL	NO	N	N	N	N	N	N	NO NO	None
			18FEB2003-20FEB2003	ON	GASTROENTERITIS VIRAL NOS (Infections and infestations) [STOMACH FLU]	3	55	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0029009	44 YRS CAUCASIAN MALE	21JAN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			21JAN2003-22JAN2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [RIGHT HIP PAIN]	2	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			03FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None
					LIBIDO DECREASED (Psychiatric disorders) [DECREASED LIBIDO]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	44 YRS CAUCASIAN MALE	04MAR2003-18MAR2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	15	44	MOD	NO	N	N	N	N	N	N	NO NO	None
					NECK PAIN (Musculoskeletal and connective tissue disorders) [WORSENING OF NECK PAIN]	15	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0029021	38 YRS CAUCASIAN FEMALE	19MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029026	65 YRS CAUCASIAN MALE	16APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			16APR2003-22APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0029026	65 YRS CAUCASIAN MALE	16APR2003-22APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					TONGUE DISORDER NOS (Gastrointestinal disorders) [FEELING OF TONGUE THICKNESS]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			23APR2003-CONTINUE	ON	MUSCLE TIGHTNESS (Musculoskeletal and connective tissue disorders) [MUSCLE TIGHTNESS IN MORNING (NOT DUE TO EPS)]	UNK	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			25APR2003-02JUN2003	ON	URINARY HESITATION (Renal and urinary disorders) [URINARY HESITANCY]	39	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			06MAY2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	23	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0029026	65 YRS CAUCASIAN MALE	06MAY2003-19MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	14	23	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029030	31 YRS CAUCASIAN MALE	29MAY2003-16JUN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	19	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-21JUL2003	ON	SEDATION (Nervous system disorders) [MORNING SEDATION]	34	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			19JUL2003-CONTINUE	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	UNK	54	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031008	31 YRS CAUCASIAN FEMALE	01MAR2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0031008	31 YRS CAUCASIAN FEMALE	01MAR2003-07APR2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [INTERMITTENT DIZZINESS DUE TO POSTURAL HYPOTENSION]	38	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			02MAR2003-15MAR2003	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	14	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			13APR2003-19APR2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	7	45	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031020	44 YRS CAUCASIAN MALE	22APR2003-01MAY2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [ARM CRAMPS (NOT DUE TO EPS)]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [LEG CRAMPS (NOT DUE TO EPS)]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0031020	44 YRS CAUCASIAN MALE	22APR2003-16MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	25	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			29APR2003-12MAY2003	ON	DERMATITIS CONTACT (Skin and subcutaneous tissue disorders) [POISON IVY RASH]	14	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			07MAY2003-CONTINUE	ON	CHRONIC LYMPHOCYTIC LEUKAEMIA NOS (Neoplasms benign, malignant and unspecified (incl cysts and polyps)) [CHRONIC LYMPHOCYTIC LEUKEMIA]	UNK	17	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0031021	27 YRS BLACK MALE	26APR2003-06MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0031021	27 YRS BLACK MALE	26APR2003-10JUN2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	46	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			30MAY2003-10JUN2003	ON	DEPRESSION (Psychiatric disorders) [WORSENING OF DEPRESSIVE SYMPTOMS DUE TO STAB WOUNDS]	12	36	MIL	NO	N	N	N	N	N	N	NO NO	None
			30MAY2003-19JUN2003	ON	INJURY (Injury, poisoning and procedural complications) [STAB WOUNDS]	21	36	SEV	YES	N	N	Y	N	N	N	NO NO	None
			19JUN2003-CONTINUE	ON	ATRIOVENTRICULAR BLOCK FIRST DEGREE (Cardiac disorders) [FIRST DEGREE BLOCK]	UNK	56	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031029	24 YRS CAUCASIAN MALE	19JUN2003-03JUL2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			19JUN2003-04JUL2003	ON	AKATHISIA (Nervous system disorders) [AKATHESIA]	16	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0031029	24 YRS CAUCASIAN MALE	20JUN2003-07JUL2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	18	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			21JUN2003-07JUL2003	ON	COORDINATION ABNORMAL NOS (Nervous system disorders) [LOSS OF COORDINATION (NOT DUE TO EPS)]	17	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	17	4	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
	E0033002	59 YRS CAUCASIAN MALE	11JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			17JAN2003-26JAN2003	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	10	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			27JAN2003-07FEB2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	12	18	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033002	59 YRS CAUCASIAN MALE	04FEB2003-CONTINUE	ON	TINNITUS (Ear and labyrinth disorders) [TINNITUS]	UNK	26	MOD	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-27FEB2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [OVERDOSE (ACCIDENTAL) STUDY MEDICATION]	3	47	MOD	NO	N	N	N	N	N	N	NO NO	None
					SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	3	47	MOD	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-28FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	50	MIL	NO	N	N	N	N	N	N	NO YES	None
					SUSPICIOUSNESS (Psychiatric disorders) [SUSCPISIOUS]	1	50	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033006	38 YRS CAUCASIAN MALE	24JAN2003-CONTINUE	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					SPEECH DISORDER (Nervous system disorders) [ANXIOUS, PRESSED SPEECH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			25JAN2003-CONTINUE	ON	LOSS OF LIBIDO (Psychiatric disorders) [LOSS OF LIBIDO,]	UNK	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0033021	27 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS - (NOT DUE TO POSTURAL HYPOTENSION)]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033021	27 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [LEG CRAMPS (NOT DUE TO EPS)]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			03JUL2003-25JUL2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGY]	23	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-25JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	22	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			09JUL2003-CONTINUE	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033021	27 YRS CAUCASIAN FEMALE	14JUL2003-CONTINUE	ON	TREMOR (Nervous system disorders) [TREMORS - (NOT DUE TO EPS)]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			16JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-25JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	8	17	MOD	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-25JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	24	MOD	NO	N	N	N	N	N	N	NO NO	None
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	24	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033021	27 YRS CAUCASIAN FEMALE	17AUG2003-19AUG2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	3	47	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0035013	28 YRS CAUCASIAN FEMALE	08FEB2003-12FEB2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	5	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS NOT DUE TO EPS]	5	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0035015	33 YRS HISPANIC FEMALE	11FEB2003-16FEB2003	ON	SEDATION (Nervous system disorders) [EXTREME SEDATION]	6	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0035023	41 YRS CAUCASIAN MALE	15MAY2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR II)	E0035023	41 YRS CAUCASIAN MALE	15MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					FLUSHING (Vascular disorders) [HOT FLASHES]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0039052	37 YRS BLACK FEMALE	23JUN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	4	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			26JUN2003-26JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0039052	37 YRS BLACK FEMALE	01JUL2003-01JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	12	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039056	46 YRS BLACK MALE	21JUL2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	7	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0040003	50 YRS CAUCASIAN FEMALE	22JUL2003-29JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	8	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			23JUL2003-04AUG2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	13	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			19AUG2003-29AUG2003	ON	BRONCHITIS NOS (Respiratory, thoracic and mediastinal disorders) [BRONCHITIS]	11	32	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0002009	42 YRS CAUCASIAN FEMALE	05MAR2003-11APR2003	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	38	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-10MAR2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [TWITCHING IN LOWER LEGS UNKNOWN IF DUE TO EPS]	4	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			09MAR2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			11MAR2003-11APR2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	32	9	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0002009	42 YRS CAUCASIAN FEMALE	18MAR2003-CONTINUE	ON	ASTHENIA (General disorders and administration site conditions) [WEAKNESS IN LOWER LIMBS]	UNK	16	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			03APR2003-CONTINUE	ON	PARAESTHESIA (Nervous system disorders) [TINGLINESS IN LOWER LIMBS]	UNK	32	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0002011	35 YRS CAUCASIAN FEMALE	29APR2003-CONTINUE	ON	ABDOMINAL DISTENSION (Gastrointestinal disorders) [BLOATING]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0002011	35 YRS CAUCASIAN FEMALE	29APR2003-11JUN2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	44	1	MIL	NO	N	N	N	N	N	N	NO NO	None
			30APR2003-10MAY2003	ON	DYSTONIA (Nervous system disorders) [JOINT STIFFNESS DUE TO EPS DYSTONIA]	11	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			30APR2003-16MAY2003	ON	DYSKINESIA (Nervous system disorders) [MUSCLE TWITCHINGS IN LOWER EXTREMITIES DUE TO EPS - DYSKINESIA]	17	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			08MAY2003-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	UNK	10	MIL	NO	N	N	N	N	N	N	NO NO	None
			23MAY2003-06JUN2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACKACHE]	15	25	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0002011	35 YRS CAUCASIAN FEMALE	15JUN2003-CONTINUE	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE ACHE]	UNK	48	MIL	NO	N	N	N	N	N	N	NO NO	None
					PAIN NOS (General disorders and administration site conditions) [BODY ACHES]	UNK	48	MIL	NO	N	N	N	N	N	N	NO NO	None
			19JUN2003-19JUN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	1	52	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0003010	54 YRS CAUCASIAN FEMALE	04FEB2003-12FEB2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	9	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-15FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	3	11	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003010	54 YRS CAUCASIAN FEMALE	25FEB2003-25FEB2003	ON	MIGRAINE NOS (Nervous system disorders) [MIGRAINE]	1	23	SEV	NO	N	N	N	N	N	N	NO NO	None
			28FEB2003-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	UNK	26	MOD	NO	N	N	N	N	N	N	NO YES	None
			02MAR2003-02MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	28	MIL	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-08MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	3	32	MOD	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	UNK	40	SEV	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003-14MAR2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	1	40	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003011	26 YRS CAUCASIAN FEMALE	07FEB2003-07FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS - NOT DUE TO POSTURAL HYPOTENSION]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			08FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			08FEB2003-09FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0003016	33 YRS CAUCASIAN FEMALE	24MAY2003-24MAY2003	ON	DYSMENORRHOEA (Reproductive system and breast disorders) [MENSTRUAL CRAMPS]	1	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			24MAY2003-03JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	41	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003016	33 YRS CAUCASIAN FEMALE	24MAY2003-03JUL2003	ON	FEELING JITTERY (General disorders and administration site conditions) [JITTERY FEELING - INTERNAL]	41	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			31MAY2003-08JUN2003	ON	HOARSENESS (Respiratory, thoracic and mediastinal disorders) [HOARSENESS]	9	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			03JUN2003-12JUN2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	10	13	SEV	NO	N	N	N	N	N	N	NO YES	None
			09JUN2003-12JUN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	4	19	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0003019	51 YRS CAUCASIAN MALE	28JUN2003-15JUL2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	18	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01JUL2003-15JUL2003	ON	DERMATITIS CONTACT (Skin and subcutaneous tissue disorders) [POISON IVY RASH]	15	5	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003019	51 YRS CAUCASIAN MALE	24JUL2003-07AUG2003	ON	TINNITUS (Ear and labyrinth disorders) [TINNITUS]	15	28	MOD	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-21AUG2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	28	29	MIL	NO	N	N	N	N	N	N	NO YES	None
			29JUL2003-07AUG2003	ON	BLADDER DISORDER NOS (Renal and urinary disorders) [SLOW EMPTYING BLADDER]	10	33	MIL	NO	N	N	N	N	N	N	NO YES	None
			05AUG2003-21AUG2003	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	17	40	MOD	NO	N	N	N	N	N	N	NO NO	None
			14AUG2003-21AUG2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	8	49	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0003020	34 YRS CAUCASIAN MALE	27JUL2003-31JUL2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC HYPOTENSION]	5	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	34 YRS CAUCASIAN MALE	27JUL2003-06AUG2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			27JUL2003-20AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			06AUG2003-06AUG2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC HYPOTENSION]	1	15	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0004001	33 YRS HISPANIC FEMALE	30SEP2002-12OCT2002	ON	DIZZINESS (Nervous system disorders) [AM DIZZYNESS (NOT DUE TO POSTURAL HYPOTENSION)]	13	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0004001	33 YRS HISPANIC FEMALE	30SEP2002-12OCT2002	ON	SEDATION (Nervous system disorders) [SEDATION]	13	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			02OCT2002-07OCT2002	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [RIGHT SHOULDER PAIN]	6	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					INJURY (Injury, poisoning and procedural complications) [FALL]	6	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			02OCT2002-23OCT2002	ON	NECK PAIN (Musculoskeletal and connective tissue disorders) [RIGHT NECK PAIN]	22	3	MIL	NO	N	N	N	N	N	N	NO NO	None
			04OCT2002-12OCT2002	ON	ABDOMINAL DISTENSION (Gastrointestinal disorders) [FEELING BLOATED]	9	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004001	33 YRS HISPANIC FEMALE	06OCT2002-12OCT2002	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	7	7	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			12OCT2002-21OCT2002	ON	DIZZINESS (Nervous system disorders) [AM DIZZYNESS (NOT DUE TO POSTURAL HYPOTENSION)]	10	13	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	10	13	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			21OCT2002-01NOV2002	ON	DIZZINESS (Nervous system disorders) [AM DIZZYNESS (NOT DUE TO POSTURAL HYPOTENSION)]	12	22	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH IN P.M.]	12	22	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0004001	33 YRS HISPANIC FEMALE	21OCT2002-01NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	12	22	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			30OCT2002-CONTINUE	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	UNK	31	MIL	NO	N	N	N	N	N	N	NO NO	None
					KIDNEY INFECTION NOS (Infections and infestations) [KIDNEY INFECTION]	UNK	31	MOD	NO	N	N	N	N	N	N	NO NO	None
			30OCT2002-15NOV2002	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	17	31	MOD	NO	N	N	N	N	N	N	NO NO	None
					BLOOD URINE (Investigations) [BLOOD IN URINE]	17	31	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004001	33 YRS HISPANIC FEMALE	05NOV2002-05NOV2002	ON	FLANK PAIN (Musculoskeletal and connective tissue disorders) [PAIN ON PERCUSSION OF BOTH FLANKS DURING PHYSICAL]	1	37	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0004009	22 YRS CAUCASIAN FEMALE	27DEC2002-27DEC2002	ON	DYSPEPSIA (Gastrointestinal disorders) [STOMACH BUTTERFLIES (UPSET STOMACH)]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27DEC2002-31DEC2002	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [INCREASED LEG CRAMPS (NOT DUE TO EPS)]	5	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			27DEC2002-10JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004009	22 YRS CAUCASIAN FEMALE	18FEB2003-19MAR2003	ON	ABDOMINAL PAIN LOWER (Gastrointestinal disorders) [PAIN LOWER RIGHT ABDOMEN]	30	55	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0004012	20 YRS OTHER FEMALE	14JAN2003-14JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-30JAN2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	16	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-18FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	35	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			22JAN2003-30JAN2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	9	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004012	20 YRS OTHER FEMALE	05FEB2003-18FEB2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	14	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			17FEB2003-18FEB2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPING]	2	35	MOD	NO	N	N	N	N	N	N	NO NO	None
			26FEB2003-05MAR2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	8	44	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004015	47 YRS CAUCASIAN MALE	21FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [INTERMITTENT CONSTIPATION]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None
					POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004015	47 YRS CAUCASIAN MALE	28FEB2003-30MAR2003	ON	LETHARGY (General disorders and administration site conditions) [AM LETHARGY]	31	9	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0005003	48 YRS CAUCASIAN MALE	02OCT2002-13OCT2002	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	12	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	12	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			02OCT2002-16OCT2002	ON	INSOMNIA (Psychiatric disorders) [SLEEPLESSNESS]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			02OCT2002-07NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	37	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			04OCT2002-13OCT2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	10	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005003	48 YRS CAUCASIAN MALE	18OCT2002-31OCT2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	14	17	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	14	17	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	14	17	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			23OCT2002-07NOV2002	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	16	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005007	44 YRS CAUCASIAN FEMALE	10OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005007	44 YRS CAUCASIAN FEMALE	11OCT2002-20OCT2002	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	10	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			13OCT2002-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INTERMITTENT HEARTBURN]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			17OCT2002-31OCT2002	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	15	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			29OCT2002-03NOV2002	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	6	21	MOD	NO	N	N	N	N	N	N	NO NO	None
			30OCT2002-CONTINUE	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005007	44 YRS CAUCASIAN FEMALE	30OCT2002-CONTINUE	ON	DYSTONIA (Nervous system disorders) [MUSCLE TENSION SECONDARY TO EPS (DYSTONIA)]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			04DEC2002-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [RIGHT KNEE PATELLA TENDERNESS]	UNK	57	MIL	NO	N	N	N	N	N	N	NO NO	None
			15DEC2002-CONTINUE	ON	ARTHRITIS NOS (Musculoskeletal and connective tissue disorders) [WORSENING OF ARTHRITIS]	UNK	68	MOD	NO	N	N	N	N	N	N	NO NO	None
			31DEC2002-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	84	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005008	43 YRS CAUCASIAN MALE	15OCT2002-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADY]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			18NOV2002-CONTINUE	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	UNK	35	MIL	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	40	MIL	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0005009	24 YRS CAUCASIAN MALE	29OCT2002-03NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	6	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			30OCT2002-01NOV2002	ON	AKATHISIA (Nervous system disorders) [PARESTHESIA RELATED TO EPS (AKATHISIA)]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005010	20 YRS CAUCASIAN FEMALE	21OCT2002-20NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	31	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			21OCT2002-18DEC2002	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADY NOT DUE TO ORTHOSTATIC HYPOTENSION]	59	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	59	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005012	54 YRS CAUCASIAN MALE	14NOV2002-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			19NOV2002-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [WORSENING OF JOINT PAIN]	UNK	6	MOD	NO	N	N	N	N	N	N	NO NO	None
			20NOV2002-CONTINUE	ON	DUPUYTREN'S CONTRACTURE (Musculoskeletal and connective tissue disorders) [WORSENING OF DUPUYTREN'S CONTRACTURE]	UNK	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			20NOV2002-12JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	54	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			27NOV2002-12JAN2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FEELINGS]	47	14	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005012	54 YRS CAUCASIAN MALE	27DEC2002-12JAN2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	17	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0005014	30 YRS CAUCASIAN MALE	13NOV2002-05DEC2002	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	23	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			13NOV2002-17DEC2002	ON	LETHARGY (General disorders and administration site conditions) [LETHARGIC]	35	1	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			18NOV2002-05DEC2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	18	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			21NOV2002-05DEC2002	ON	ATAXIA (Nervous system disorders) [ATAXIA NOT DUE TO EPS]	15	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005014	30 YRS CAUCASIAN MALE	25NOV2002-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			29NOV2002-05DEC2002	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	7	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			03JAN2003-03JAN2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	1	52	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005022	25 YRS CAUCASIAN MALE	31JAN2003-01FEB2003	ON	SEDATION (Nervous system disorders) [SEDATION]	2	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			02FEB2003-14FEB2003	ON	APTYALISM (Gastrointestinal disorders) [XEROSTOMIA (DRY MOUTH)]	13	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005022	25 YRS CAUCASIAN MALE	04FEB2003-07FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	4	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			04FEB2003-04MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	29	7	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			10FEB2003-13FEB2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU - LIKE SYMPTOMS]	4	13	MOD	NO	N	N	N	N	N	N	NO NO	None
			24FEB2003-24FEB2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU - LIKE SYMPTOMS]	1	27	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0005025	40 YRS CAUCASIAN FEMALE	27FEB2003-20MAR2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	22	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005025	40 YRS CAUCASIAN FEMALE	28FEB2003-14MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	15	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
			28FEB2003-21MAR2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	22	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			04MAR2003-11MAR2003	ON	DYSTONIA (Nervous system disorders) [MUSCLE TENSION (DUE TO EPS - DYSTONIA)]	8	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAR2003-CONTINUE	ON	DYSTONIA (Nervous system disorders) [MUSCLE TIGHTNESS (DUE TO EPS - DYSTONIA)]	UNK	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAR2003-05APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	22	17	MIL	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0006019	42 YRS CAUCASIAN MALE	12APR2003-20APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	9	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-27MAY2003	ON	SPEECH DISORDER (Nervous system disorders) [SLOWED SPEECH]	43	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-02JUN2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING SLEEPINESS]	49	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0007005	34 YRS CAUCASIAN FEMALE	01FEB2003-24FEB2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS (AKATHISIA)]	24	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01FEB2003-28FEB2003	ON	SEDATION (Nervous system disorders) [SEDATION]	28	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0007005	34 YRS CAUCASIAN FEMALE	18FEB2003-23FEB2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [URI (UPPER RESPIRATORY INFECTION)]	6	19	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0007015	58 YRS CAUCASIAN FEMALE	20JUL2003-22JUL2003	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA HANDS]	3	5	MIL	NO	N	N	N	N	N	N	NO NO	None
			20JUL2003-23JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	4	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			20JUL2003-30JUL2003	ON	DYSPEPSIA (Gastrointestinal disorders) [DYSPEPSIA]	11	5	MIL	NO	N	N	N	N	N	N	NO NO	None
			20JUL2003-08AUG2003	ON	SEDATION (Nervous system disorders) [SEDATION]	20	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0007015	58 YRS CAUCASIAN FEMALE	15AUG2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATED]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			18AUG2003-20AUG2003	ON	DYSPEPSIA (Gastrointestinal disorders) [DYSPEPSIA]	3	34	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0009001	36 YRS BLACK FEMALE	13NOV2002-22NOV2002	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED - (NOT DUE TO POSTURAL HYPOTENSION)]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [FATIGUE]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0009001	36 YRS BLACK FEMALE	23NOV2002-CONTINUE	ON	ANXIETY (Psychiatric disorders) [ANXIETY BRIEFLY POST DOSE]	UNK	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-28NOV2002	ON	SOMNOLENCE (Nervous system disorders) [DROWSY]	6	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-29NOV2002	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	7	12	MIL	NO	N	N	N	N	N	N	NO YES	None
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	7	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-20DEC2002	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	28	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0009001	36 YRS BLACK FEMALE	25NOV2002-26NOV2002	ON	FEELING JITTERY (General disorders and administration site conditions) [JITTERY - (NOT DUE TO EPS)]	2	14	MIL	NO	N	N	N	N	N	N	NO YES	None
			26NOV2002-26NOV2002	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE OF STUDY MEDICATION]	1	15	MOD	NO	N	N	N	N	N	N	NO NO	None
			29DEC2002-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	48	MIL	NO	N	N	N	N	N	N	NO YES	None
			30DEC2002-CONTINUE	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU - LIKE SYMPTOMS]	UNK	49	SEV	YES	N	N	Y	N	N	N	NO NO	None
					NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	UNK	49	MIL	NO	N	N	N	N	N	N	NO NO	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0010002	46 YRS CAUCASIAN MALE	25NOV2002-25NOV2002	ON	DIZZINESS (Nervous system disorders) [FAINTING FEELING (NOT DUE TO POSTURAL HYPOTENSION)]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					FEELING COLD (General disorders and administration site conditions) [COLD FLASH]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					ORTHOSTATIC HYPOTENSION (Vascular disorders) [LIGHTHEADED DUE TO ORTHOSTATIC HYPOTENSION]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010009	58 YRS CAUCASIAN FEMALE	26DEC2002-05JAN2003	ON	HYPERSOMNIA (Nervous system disorders) [OVER SLEEPING]	11	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			26DEC2002-07FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	44	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0010009	58 YRS CAUCASIAN FEMALE	29JAN2003-29JAN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	35	MOD	NO	N	N	N	N	N	N	NO NO	None
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	35	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0010010	35 YRS CAUCASIAN FEMALE	01JAN2003-11JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	11	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-11JAN2003	ON	FLATULENCE (Gastrointestinal disorders) [GAS]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					MIDDLE INSOMNIA (Psychiatric disorders) [DIFFICULTY STAYING ASLEEP]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0010010	35 YRS CAUCASIAN FEMALE	05JAN2003-05JAN2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE OF STUDY MEDICATION]	1	7	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0010014	38 YRS CAUCASIAN FEMALE	28JAN2003-17FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	21	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	30	MIL	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-31MAR2003	ON	HERNIA NOS (General disorders and administration site conditions) [RECURRENT BOWEL HERNIA]	34	30	SEV	YES	N	N	Y	N	N	N	NO NO	None
			31MAR2003-31MAR2003	ON	INTESTINAL OBSTRUCTION NOS (Gastrointestinal disorders) [STRANGULATED BOWEL]	1	63	SEV	YES	N	N	Y	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0010017	32 YRS CAUCASIAN MALE	26FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-02MAR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	5	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-13APR2003	ON	SLUGGISHNESS (General disorders and administration site conditions) [SLUGGISH IN AM]	47	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-06APR2003	ON	MUSCLE STRAIN (Injury, poisoning and procedural complications) [PULLED BACK MUSCLE]	14	28	MOD	NO	N	N	N	N	N	N	NO NO	None
			05APR2003-14APR2003	ON	FEELING JITTERY (General disorders and administration site conditions) [JITTERNESS (NOT DUE TO EPS)]	10	40	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0010023	28 YRS CAUCASIAN FEMALE	18APR2003-28APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20APR2003-28APR2003	ON	PARANOIA (Psychiatric disorders) [PARANOID THINKING]	9	4	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			25APR2003-28APR2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [ORTHOSTATIC DIZZINESS]	4	9	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010027	32 YRS CAUCASIAN MALE	17JUN2003-28JUN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	12	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-28JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	11	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0010027	32 YRS CAUCASIAN MALE	18JUN2003-05JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			28JUN2003-03JUL2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	6	13	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010029	44 YRS CAUCASIAN MALE	20JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			24JUN2003-CONTINUE	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	UNK	6	MIL	NO	N	N	N	N	N	N	NO NO	None
			01JUL2003-CONTINUE	ON	EAR INFECTION NOS (Infections and infestations) [EAR INFECTION]	UNK	13	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0011022	35 YRS CAUCASIAN FEMALE	09JUN2003-CONTINUE	ON	ASTIGMATISM (Eye disorders) [ASTIGMATISM]	UNK	1	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0011022	35 YRS CAUCASIAN FEMALE	11JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			12JUN2003-13JUN2003	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	2	4	MIL	NO	N	N	N	N	N	N	NO NO	None
			24JUN2003-28JUL2003	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	35	16	MIL	NO	N	N	N	N	N	N	NO NO	None
			08JUL2003-15JUL2003	ON	DIZZINESS (Nervous system disorders) [NOT DUE TO POSTURAL HYPOTENSION DIZZINESS]	8	30	MIL	NO	N	N	N	N	N	N	NO YES	None
					DIZZINESS (Nervous system disorders) [NOT DUE TO POSTURAL HYPOTENSION FAINT FEELINGS]	8	30	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0011022	35 YRS CAUCASIAN FEMALE	20JUL2003-26JUL2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [STUFFY NOSE]	7	42	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0013006	28 YRS CAUCASIAN FEMALE	15MAR2003-22MAR2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-21MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	5	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-20MAR2003	ON	DYSTONIA (Nervous system disorders) [DYSTONIA]	1	8	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0013006	28 YRS CAUCASIAN FEMALE	20MAR2003-20MAR2003	ON	SENSATION OF BLOOD FLOW (General disorders and administration site conditions) [THROBBING VESSELS (SENSATION OF BLOOD RUSHING IN THE VEINS)]	1	8	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0013012	58 YRS BLACK FEMALE	09MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			10MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0013014	48 YRS CAUCASIAN MALE	04JUN2003-CONTINUE	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JUN2003-22JUN2003	ON	AKATHISIA (Nervous system disorders) [(RESTLESSNESS) AKATHISIA]	17	4	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0013014	48 YRS CAUCASIAN MALE	06JUN2003-22JUN2003	ON	PRURITUS (Skin and subcutaneous tissue disorders) [ITCHINESS]	17	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JUN2003-24JUN2003	ON	AKATHISIA (Nervous system disorders) [(RESTLESSNESS) AKATHISIA]	1	22	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					PRURITUS (Skin and subcutaneous tissue disorders) [ITCHINESS]	1	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014005	44 YRS CAUCASIAN FEMALE	12MAR2003-29APR2003	ON	COORDINATION ABNORMAL NOS (Nervous system disorders) [POOR COORDINATION (NOT DUE TO EPS)]	49	2	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					MUSCLE WEAKNESS NOS (Musculoskeletal and connective tissue disorders) [MUSCLE WEAKNESS (NOT DUE TO EPS)]	49	2	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0014005	44 YRS CAUCASIAN FEMALE	12MAR2003-29APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	49	2	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			29MAR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			01APR2003-29APR2003	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [SWOLLEN HANDS]	29	22	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			02APR2003-29APR2003	ON	BRADYPHRENIA (Psychiatric disorders) [SLOWED THINKING]	28	23	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			16APR2003-CONTINUE	ON	MUSCULOSKELETAL STIFFNESS (Musculoskeletal and connective tissue disorders) [EXACERBATED STIFF NECK (NOT DUE TO EPS)]	UNK	37	MOD	NO	N	N	N	N	N	N	NO NO	Temporarily Stopped
			16APR2003-29APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	14	37	MOD	NO	N	N	N	N	N	N	NO NO	Temporarily Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0014005	44 YRS CAUCASIAN FEMALE	16APR2003-29APR2003	ON	PYREXIA (General disorders and administration site conditions) [LOW GRADE FEVER]	14	37	MIL	NO	N	N	N	N	N	N	NO NO	Temporarily Stopped
			23APR2003-24APR2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	2	44	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			01MAY2003-27MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	27	52	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0014007	22 YRS CAUCASIAN FEMALE	03APR2003-19APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	17	3	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	17	3	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0014007	22 YRS CAUCASIAN FEMALE	03APR2003-19APR2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS (DUE TO ORTHOSTATIC HYPOTENSION)]	17	3	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					SEDATION (Nervous system disorders) [SEDATION]	17	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			04APR2003-19APR2003	ON	TREMOR (Nervous system disorders) [TREMOR (NOT DUE TO EPS)]	16	4	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			07APR2003-19APR2003	ON	THROAT TIGHTNESS (Respiratory, thoracic and mediastinal disorders) [TIGHT THROAT]	13	7	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			15APR2003-19APR2003	ON	TENSION (Psychiatric disorders) [TENSION]	5	15	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0014011	39 YRS CAUCASIAN MALE	14MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			01JUN2003-01JUL2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	31	20	MOD	NO	N	N	N	N	N	N	NO YES	None
			03JUN2003-15JUL2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	43	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			27JUN2003-18JUL2003	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED SEX DRIVE]	22	46	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014012	55 YRS CAUCASIAN FEMALE	29MAY2003-25JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	28	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			31MAY2003-26JUN2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	27	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0014012	55 YRS CAUCASIAN FEMALE	04JUN2003-25JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0015001	54 YRS CAUCASIAN MALE	03DEC2002-13DEC2002	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0015008	41 YRS CAUCASIAN MALE	16JAN2003-23JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	29	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0016003	22 YRS CAUCASIAN FEMALE	01FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0016003	22 YRS CAUCASIAN FEMALE	02FEB2003-20FEB2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	19	10	MIL	NO	N	N	N	N	N	N	NO NO	None
			03FEB2003-14FEB2003	ON	AGITATION (Psychiatric disorders) [AGITATION]	12	11	MIL	NO	N	N	N	N	N	N	NO NO	None
			04FEB2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	12	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0018007	42 YRS CAUCASIAN FEMALE	29DEC2002-07FEB2003	ON	SEDATION (Nervous system disorders) [SEDATION]	41	3	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGINESS]	41	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			30DEC2002-07FEB2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [WORSENING OF LEFT LEG PAIN]	40	4	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0018007	42 YRS CAUCASIAN FEMALE	31DEC2002-20MAR2003	ON	DEEP VEIN THROMBOSIS (Vascular disorders) [RECURRENT DEEP VEIN THROMBOSIS WITHOUT PULMONARY EMBOLISM]	80	5	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
			01JAN2003-01JAN2003	ON	MIGRAINE NOS (Nervous system disorders) [MIGRAINE HEADACHE]	1	6	SEV	YES	N	N	Y	N	N	N	NO NO	None
			02JAN2003-02JAN2003	ON	CHEST PAIN (General disorders and administration site conditions) [CHEST PAIN]	1	7	MOD	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			16JAN2003-CONTINUE	ON	FACTOR II DEFICIENCY (Congenital, familial and genetic disorders) [PROTHROMBIN GENE MUTATION]	UNK	21	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0018007	42 YRS CAUCASIAN FEMALE	17JAN2003-CONTINUE	ON	NEPHROLITHIASIS (Renal and urinary disorders) [KIDNEY STONE]	UNK	22	MIL	NO	N	N	N	N	N	N	NO NO	None
			17JAN2003-21JAN2003	ON	URINARY TRACT INFECTION NOS (Infections and infestations) [URINARY TRACT INFECTION]	5	22	MIL	NO	N	N	N	N	N	N	NO NO	None
			18JAN2003-18JAN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	23	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0019005	50 YRS CAUCASIAN FEMALE	05NOV2002-19NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0019005	50 YRS CAUCASIAN FEMALE	11NOV2002-11NOV2002	ON	HEADACHE (Nervous system disorders) [HEADACHES]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			14NOV2002-14NOV2002	ON	HALLUCINATION, VISUAL (Psychiatric disorders) [VISUAL HALLUCINATION]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0019015	24 YRS CAUCASIAN FEMALE	02JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-16JAN2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-23JAN2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	22	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			04JAN2003-19JAN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0019015	24 YRS CAUCASIAN FEMALE	12JAN2003-19JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	8	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			12JAN2003-27JAN2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	16	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			01FEB2003-09FEB2003	ON	INSOMNIA (Psychiatric disorders) [DECREASED SLEEP]	9	31	MOD	NO	N	N	N	N	N	N	NO YES	None
			01FEB2003-11FEB2003	ON	LOGORRHOEA (Psychiatric disorders) [INCREASED SPEECH (MORE TALKATIVE)]	11	31	MOD	NO	N	N	N	N	N	N	NO YES	None
					PSYCHOMOTOR HYPERACTIVITY (Nervous system disorders) [HYPERACTIVITY]	11	31	MOD	NO	N	N	N	N	N	N	NO YES	None
			12FEB2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	42	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0020004	61 YRS CAUCASIAN MALE	09DEC2002-24DEC2002	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	16	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			11DEC2002-11DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			24DEC2002-06JAN2003	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL PAIN]	14	16	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020010	31 YRS CAUCASIAN FEMALE	07FEB2003-08FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			15FEB2003-24FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INTERMITTENT HEARTBURN]	10	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			20FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	16	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0020010	31 YRS CAUCASIAN FEMALE	22FEB2003-23FEB2003	ON	PAIN NOS (General disorders and administration site conditions) [ACHES - ENTIRE BODY INTERMITTENT]	2	18	MOD	NO	N	N	N	N	N	N	NO NO	None
			05MAR2003-17MAR2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	13	29	MIL	NO	N	N	N	N	N	N	NO YES	None
			05MAR2003-19MAR2003	ON	AKATHISIA (Nervous system disorders) [BILATERAL HAND TREMORS (DUE TO EPS - AKATHISIA)]	15	29	MIL	NO	N	N	N	N	N	N	NO YES	None
			29MAR2003-30MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	2	53	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0020014	43 YRS BLACK FEMALE	22MAR2003-04APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	14	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

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QUETIAPINE 600 MG (BIPOLAR I)	E0020014	43 YRS BLACK FEMALE	02APR2003-04APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	3	16	MIL	NO	N	N	N	N	N	N	NO NO	None
			21APR2003-22APR2003	ON	TENSION HEADACHE (Nervous system disorders) [TENSION HEADACHE]	2	35	MIL	NO	N	N	N	N	N	N	NO NO	None
			29APR2003-09MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION UPON AWAKENING APPROXIMATELY 6:00 AM - NOON]	11	43	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0020021	47 YRS BLACK MALE	19MAY2003-04JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH IN THE MORNING]	17	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			03JUN2003-11AUG2003	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [BILATERAL HAND EDEMA]	70	16	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0020021	47 YRS BLACK MALE	03JUN2003-11AUG2003	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [BILATERAL PEDAL EDEMA]	70	16	MIL	NO	N	N	N	N	N	N	NO NO	None
			05JUL2003-07JUL2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [INTERMITTENT LEG ACHES]	3	48	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020023	46 YRS CAUCASIAN MALE	19JUN2003-26JUN2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [LEFT LEG TWITCH (NOT DUE TO EPS)]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUL2003-15JUL2003	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [BRADYKINESIA (DUE TO EPS)]	15	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0020023	46 YRS CAUCASIAN MALE	01JUL2003-15JUL2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	15	15	MIL	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0022007	31 YRS CAUCASIAN FEMALE	10NOV2002-28NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	19	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			10NOV2002-06DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	27	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			09DEC2002-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	33	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0022010	21 YRS CAUCASIAN MALE	24NOV2002-02DEC2002	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	9	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			28NOV2002-28NOV2002	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE OF STUDY MEDICATION]	1	8	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022012	27 YRS CAUCASIAN FEMALE	07DEC2002-13DEC2002	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022019	30 YRS CAUCASIAN MALE	20DEC2002-04JAN2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	16	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			22DEC2002-19JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0022025	46 YRS CAUCASIAN FEMALE	29JAN2003-05FEB2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEG SYNDROME (WORSENING) "NOT DUE TO EPS"]	8	2	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0022033	45 YRS CAUCASIAN FEMALE	24FEB2003-05MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	10	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAR2003-23MAR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	9	26	MIL	NO	N	N	N	N	N	N	NO NO	None
			17MAR2003-CONTINUE	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	UNK	28	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022038	39 YRS CAUCASIAN MALE	04MAR2003-21MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	18	5	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0022038	39 YRS CAUCASIAN MALE	01APR2003-08APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	8	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			05APR2003-10APR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	6	37	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0022039	31 YRS BLACK FEMALE	06MAR2003-22MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	17	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-22MAR2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	16	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			07MAR2003-28MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	22	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			16MAR2003-01APR2003	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	17	11	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0022048	26 YRS ORIENTAL FEMALE	02APR2003-24APR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			14APR2003-16APR2003	ON	MUSCULOSKELETAL PAIN (Musculoskeletal and connective tissue disorders) [MUSCULOSKELETAL PAIN]	3	14	MIL	NO	N	N	N	N	N	N	NO NO	None
			20APR2003-25APR2003	ON	VIRAL INFECTION NOS (Infections and infestations) [VIRAL SYNDROME WITH MYALGIA]	6	20	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022058	43 YRS CAUCASIAN MALE	22APR2003-24MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	33	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	33	2	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0022058	43 YRS CAUCASIAN MALE	25APR2003-12MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	18	5	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022061	22 YRS CAUCASIAN FEMALE	12MAY2003-12MAY2003	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	1	13	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022062	63 YRS CAUCASIAN MALE	05MAY2003-21MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	17	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			13MAY2003-19MAY2003	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [GASTRIC REFLUX]	7	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022068	44 YRS CAUCASIAN FEMALE	24MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0022068	44 YRS CAUCASIAN FEMALE	27MAY2003-01JUN2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	6	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022071	57 YRS CAUCASIAN MALE	30JUN2003-25AUG2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS (NOT DUE TO EPS)]	57	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			01JUL2003-25AUG2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	56	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023003	19 YRS CAUCASIAN MALE	19DEC2002-03JAN2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	16	3	MOD	NO	N	N	N	N	N	N	NO NO	None
					NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [CONGESTION (NASAL)]	16	3	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0023003	19 YRS CAUCASIAN MALE	25JAN2003-03FEB2003	ON	FLUSHING (Vascular disorders) [HOT FLASHES]	10	40	MOD	NO	N	N	N	N	N	N	NO NO	None
			07FEB2003-09FEB2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	3	53	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023006	39 YRS CAUCASIAN MALE	17DEC2002-17JAN2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	32	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			18DEC2002-20DEC2002	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [PRICKLING SENSATION IN LEGS (PAIN)]	3	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			18DEC2002-24DEC2002	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [MUSCLE TWITCHING (NOT DUE TO EPS)]	7	2	SEV	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	39 YRS CAUCASIAN MALE	20DEC2002-20DEC2002	ON	VERTIGO (Ear and labyrinth disorders) [VERTIGO (NOT DUE TO POSTURAL HYPOTENSION)]	1	4	MOD	NO	N	N	N	N	N	N	NO NO	None
			21DEC2002-24DEC2002	ON	CHEST TIGHTNESS (General disorders and administration site conditions) [CHEST CONSTRICTION]	4	5	SEV	NO	N	N	N	N	N	N	NO NO	None
					PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	4	5	SEV	NO	N	N	N	N	N	N	NO NO	None
			27DEC2002-29DEC2002	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	3	11	SEV	NO	N	N	N	N	N	N	NO NO	None
			16JAN2003-20JAN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	5	31	MOD	NO	N	N	N	N	N	N	NO NO	None
			18JAN2003-24JAN2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	7	33	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0023006	39 YRS CAUCASIAN MALE	25JAN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	40	MOD	NO	N	N	N	N	N	N	NO NO	None
			07FEB2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	53	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023010	46 YRS CAUCASIAN MALE	04FEB2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			12FEB2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0023010	46 YRS CAUCASIAN MALE	19FEB2003-27MAR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	37	16	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023039	48 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0026002	62 YRS CAUCASIAN MALE	15NOV2002-11JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	58	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			14DEC2002-11JAN2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS]	29	33	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0026007	59 YRS CAUCASIAN FEMALE	18JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0026013	28 YRS CAUCASIAN FEMALE	03MAR2003-10MAR2003	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [LOSS OF APPETITE (DECREASE)]	8	19	MOD	NO	N	N	N	N	N	N	NO NO	None
			18MAR2003-11APR2003	ON	RASH NOS (Skin and subcutaneous tissue disorders) [LEFT ARM RASH]	25	34	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028007	22 YRS CAUCASIAN FEMALE	05OCT2002-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			05OCT2002-05OCT2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07OCT2002-17OCT2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	11	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028007	22 YRS CAUCASIAN FEMALE	20OCT2002-21OCT2002	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	2	17	SEV	NO	N	N	N	N	N	N	NO NO	None
			30OCT2002-30OCT2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	27	MOD	NO	N	N	N	N	N	N	NO NO	None
			04NOV2002-11NOV2002	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	8	32	MIL	NO	N	N	N	N	N	N	NO NO	None
			05NOV2002-06NOV2002	ON	DYSMENORRHOEA (Reproductive system and breast disorders) [MENSTRAUL CRAMPS]	2	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			10NOV2002-10NOV2002	ON	DRUG ABUSER NOS (Social circumstances) [DRUG ABUSE (METHAMPHETAMINE)]	1	38	SEV	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
			11NOV2002-11NOV2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	39	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028007	22 YRS CAUCASIAN FEMALE	11NOV2002-11NOV2002	ON	NON-ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [OVERDOSE OF STUDY MEDICATION (INTENTIONAL)]	1	39	MOD	YES	N	N	N	N	N	Y	NO NO	None
					PANIC ATTACK (Psychiatric disorders) [PANIC ATTACK]	1	39	SEV	NO	N	N	N	N	N	N	NO NO	Dose Changed
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	39	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0028023	54 YRS BLACK MALE	25JAN2003-26JAN2003	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			25JAN2003-08FEB2003	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	15	5	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028023	54 YRS BLACK MALE	04FEB2003-04MAR2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	29	15	MOD	NO	N	N	N	N	N	N	NO NO	None
			17FEB2003-21FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSY]	5	28	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			09MAR2003-09MAR2003	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT]	1	48	SEV	YES	N	N	Y	N	N	N	YES NO	None
			11MAR2003-11MAR2003	ON	CONVULSIONS NOS (Nervous system disorders) [SEIZURE]	1	50	SEV	NO	N	N	N	N	N	N	NO NO	None
			12MAR2003-CONTINUE	ON	ATAXIA (Nervous system disorders) [GAIT ATAXIA]	UNK	51	MOD	NO	N	N	N	N	N	N	NO NO	None
			15MAR2003-02APR2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDE IDEATION]	19	54	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028025	27 YRS CAUCASIAN MALE	13JAN2003-13JAN2003	ON	HYPNAGOGIC HALLUCINATION (Psychiatric disorders) [HYPNOGOGIC PHENOMENA]	1	1	MOD	NO	N	N	N	N	N	N	NO NO	None
			13JAN2003-18JAN2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	6	1	SEV	NO	N	N	N	N	N	N	NO NO	None
			13JAN2003-25JAN2003	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED LIBIDO]	13	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			15JAN2003-18JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	4	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-25JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	3	SEV	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [FATIGUE]	11	3	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028025	27 YRS CAUCASIAN MALE	15JAN2003-25JAN2003	ON	FLAT AFFECT (Psychiatric disorders) [FLAT AFFECT]	11	3	SEV	NO	N	N	N	N	N	N	YES NO	None
			16JAN2003-16JAN2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [AUDITORY HALLUCINATIONS]	1	4	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028033	44 YRS CAUCASIAN FEMALE	27MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			20APR2003-25APR2003	ON	SINUS PAIN (Respiratory, thoracic and mediastinal disorders) [SINUS PAIN]	6	25	MIL	NO	N	N	N	N	N	N	NO NO	None
			23APR2003-CONTINUE	ON	VISUAL ACUITY REDUCED (Eye disorders) [WORSENED VISION (DECREASE IN VISUAL ACUITY)]	UNK	28	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028033	44 YRS CAUCASIAN FEMALE	09MAY2003-09MAY2003	ON	FLUSHING (Vascular disorders) [HOT FLASHES]	1	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028035	57 YRS CAUCASIAN MALE	05APR2003-05JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	62	3	SEV	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	62	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-22APR2003	ON	FAECES HARD (Gastrointestinal disorders) [HARD STOOL]	8	13	SEV	NO	N	N	N	N	N	N	NO NO	None
			08MAY2003-05JUN2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	29	36	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028037	61 YRS CAUCASIAN MALE	16JUN2003-16JUN2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS PER SUBJECT REPORT]	1	4	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028037	61 YRS CAUCASIAN MALE	16JUN2003-16JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	1	4	SEV	NO	N	N	N	N	N	N	NO YES	None
			26JUN2003-26JUN2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	1	14	MIL	NO	N	N	N	N	N	N	NO NO	None
			12JUL2003-12JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	1	30	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028039	28 YRS CAUCASIAN MALE	09MAY2003-11MAY2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	3	1	MOD	NO	N	N	N	N	N	N	NO NO	None
			09MAY2003-04JUN2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY SECONDARY TO ATTACK]	27	1	MOD	NO	N	N	N	N	N	N	NO NO	None
					NIGHTMARE (Psychiatric disorders) [NIGHTMARES SECONDARY TO ATTACK]	27	1	SEV	NO	N	N	N	N	N	N	NO NO	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	28 YRS CAUCASIAN MALE	10MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			12MAY2003-23MAY2003	ON	CHEST TIGHTNESS (General disorders and administration site conditions) [TIGHTNESS IN CHEST]	12	4	MOD	NO	N	N	N	N	N	N	NO NO	None
					GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	12	4	MOD	NO	N	N	N	N	N	N	NO NO	None
			13MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			13MAY2003-04JUN2003	ON	PARAESTHESIA (Nervous system disorders) [TORSO PARESTHESIA]	23	5	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028039	28 YRS CAUCASIAN MALE	17MAY2003-23MAY2003	ON	THROAT TIGHTNESS (Respiratory, thoracic and mediastinal disorders) [THROAT CONSTRICTION NOT DUE TO EPS]	7	9	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0028048	18 YRS HISPANIC FEMALE	18JUL2003-CONTINUE	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	UNK	2	MOD	NO	N	N	N	N	N	N	NO NO	None
					DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028048	18 YRS HISPANIC FEMALE	18JUL2003-27JUL2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	10	2	SEV	NO	N	N	N	N	N	N	NO YES	None
					TINNITUS (Ear and labyrinth disorders) [TINNITUS]	10	2	MIL	NO	N	N	N	N	N	N	NO NO	None
					VISION BLURRED (Eye disorders) [BLURRED VISION]	10	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			23JUL2003-23JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	1	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			27JUL2003-25AUG2003	ON	ALOPECIA (Skin and subcutaneous tissue disorders) [INCREASED HAIR LOSS]	30	11	MIL	NO	N	N	N	N	N	N	NO NO	None
			28AUG2003-28AUG2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	43	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0029008	22 YRS CAUCASIAN FEMALE	18DEC2002-21DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	4	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			19DEC2002-19DEC2002	ON	SYNCOPE (Nervous system disorders) [FAINTING (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	1	4	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
			19DEC2002-20DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	2	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			19DEC2002-21DEC2002	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	3	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029011	26 YRS CAUCASIAN MALE	22JAN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS AFTER DOSE]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0029011	26 YRS CAUCASIAN MALE	22JAN2003-24JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JAN2003-31JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			27JAN2003-CONTINUE	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE ACHES]	UNK	6	MOD	NO	N	N	N	N	N	N	NO NO	None
			30JAN2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	UNK	9	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			01FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	11	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0029011	26 YRS CAUCASIAN MALE	10FEB2003-CONTINUE	ON	CHAPPED LIPS (Gastrointestinal disorders) [SPLIT LIP]	UNK	20	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029012	39 YRS CAUCASIAN FEMALE	12FEB2003-20MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	37	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14FEB2003-20MAR2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGY IN AM.]	35	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			16FEB2003-CONTINUE	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	UNK	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			16FEB2003-01MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	14	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0029012	39 YRS CAUCASIAN FEMALE	16FEB2003-01MAR2003	ON	VISION BLURRED (Eye disorders) [CLOUDY EYES/VISION]	14	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			17FEB2003-CONTINUE	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [RIGHT FOOT PAIN]	UNK	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			26FEB2003-01MAR2003	ON	EYELIDS PRURITUS (Eye disorders) [ITCHY EYELIDS]	4	16	MIL	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-CONTINUE	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	UNK	38	MOD	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	UNK	38	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0029015	45 YRS CAUCASIAN FEMALE	24FEB2003-10MAR2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0029015	45 YRS CAUCASIAN FEMALE	24FEB2003-10MAR2003	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE PAIN]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-25FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-10MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	14	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			01MAR2003-10MAR2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	10	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0030014	32 YRS CAUCASIAN FEMALE	22FEB2003-25FEB2003	ON	DYSTONIA (Nervous system disorders) [OPTIC MUSCLE STIFFNESS DUE TO EPS (DYSTONIA)]	4	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0030014	32 YRS CAUCASIAN FEMALE	22FEB2003-23APR2003	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	61	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			23FEB2003-23FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24FEB2003-25FEB2003	ON	CHEST PAIN (General disorders and administration site conditions) [HEART FLUTTER (FEELING)]	2	4	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24FEB2003-23APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	59	4	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	59	4	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0030014	32 YRS CAUCASIAN FEMALE	24FEB2003-23APR2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	59	4	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25FEB2003-25FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	5	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25FEB2003-01MAR2003	ON	HYPOTENSION NOS (Vascular disorders) [LOW BLOOD PRESSURE HYPOTENSIVE EPISODE]	5	5	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			01MAR2003-01MAR2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS (DUE TO ORTHOSTATIC HYPOTENSION)]	1	9	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0030020	20 YRS CAUCASIAN MALE	29MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0030020	20 YRS CAUCASIAN MALE	29MAY2003-CONTINUE	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [MORE FREQUENT SINUS CONGESTION - DAILY]	UNK	1	MIL	NO	N	N	N	N	N	N	NO NO	None
			30MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [EARLY AM SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			30MAY2003-09JUN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [MORE FREQUENT HEARTBURN - DAILY]	11	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			14JUN2003-15JUN2003	ON	MUSCLE STIFFNESS (Musculoskeletal and connective tissue disorders) [MUSCLE STIFFNESS, SHOULDERS NOT DUE TO EPS]	2	17	MOD	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	20 YRS CAUCASIAN MALE	14JUN2003-15JUN2003	ON	MUSCULOSKELETAL STIFFNESS (Musculoskeletal and connective tissue disorders) [MUSCLE STIFFNESS NECK NOT DUE TO EPS]	2	17	MOD	NO	N	N	N	N	N	N	NO NO	None
			24JUN2003-CONTINUE	ON	AMNESIA (Nervous system disorders) [MEMORY PROBLEMS (SHORT TERM MEMORY LOSS)]	UNK	27	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0030024	30 YRS CAUCASIAN FEMALE	13JUL2003-16JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	4	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0030025	63 YRS BLACK FEMALE	18JUL2003-08AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	22	8	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0030025	63 YRS BLACK FEMALE	29JUL2003-CONTINUE	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [LEG PAIN]	UNK	19	MOD	NO	N	N	N	N	N	N	NO NO	None
			08AUG2003-11AUG2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	4	29	MOD	NO	N	N	N	N	N	N	NO NO	None
			15AUG2003-CONTINUE	ON	DELUSION NOS (Psychiatric disorders) [DELUSIONAL THINKING]	UNK	36	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
			18AUG2003-18AUG2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [TROUBLE BREATHING]	1	39	MIL	NO	N	N	N	N	N	N	NO NO	None
					PAIN NOS (General disorders and administration site conditions) [BODY ACHE]	1	39	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0031027	38 YRS CAUCASIAN MALE	10JUN2003-10JUN2003	ON	NON-ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [INTENTIONAL OVERDOSE " STUDY MEDICATION"]	1	8	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0031030	35 YRS CAUCASIAN FEMALE	24JUN2003-10AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	48	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			21AUG2003-CONTINUE	ON	HYPERREFLEXIA (Nervous system disorders) [HYPERREFLEXIC]	UNK	59	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0033012	39 YRS CAUCASIAN MALE	13FEB2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	4	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0034001	55 YRS CAUCASIAN FEMALE	23MAR2003-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [INCREASED DREAMING]	UNK	4	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0034004	46 YRS CAUCASIAN MALE	22APR2003-23APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY NOT DUE TO ORTHOSTATIC HYPOTENSION]	2	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27APR2003-03JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	38	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			30MAY2003-15JUN2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU - LIKE SYMPTOMS]	17	40	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0035021	29 YRS HISPANIC FEMALE	06MAY2003-14MAY2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	9	12	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	9	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0036002	32 YRS CAUCASIAN FEMALE	17JUN2003-24JUN2003	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS, (NOT DUE TO POSTURAL HYPOTENSION)]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			17JUN2003-14JUL2003	ON	SOMNOLENCE (Nervous system disorders) [INTERMITTENT SLEEPINESS]	28	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-14JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	27	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			19JUN2003-02JUL2003	ON	PARAESTHESIA (Nervous system disorders) [INTERMITTENT PARATHESIA IN LEFT ARM]	14	3	MIL	NO	N	N	N	N	N	N	NO NO	None
			20JUN2003-25JUN2003	ON	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	6	4	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0036002	32 YRS CAUCASIAN FEMALE	21JUN2003-21JUN2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	5	MOD	NO	N	N	N	N	N	N	NO NO	None
			27JUN2003-27JUN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	11	MOD	NO	N	N	N	N	N	N	NO NO	None
			28JUN2003-28JUN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	12	MIL	NO	N	N	N	N	N	N	NO NO	None
			29JUN2003-29JUN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	13	MOD	NO	N	N	N	N	N	N	NO NO	None
			08JUL2003-11JUL2003	ON	MANIA (Psychiatric disorders) [MANIA]	4	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			12JUL2003-17JUL2003	ON	MANIA (Psychiatric disorders) [MANIA]	6	26	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0036006	38 YRS CAUCASIAN MALE	03JUL2003-13JUL2003	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	11	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-14JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			14JUL2003-27AUG2003	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	45	12	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0036007	35 YRS CAUCASIAN FEMALE	03JUL2003-06JUL2003	ON	HYPOAESTHESIA (Nervous system disorders) [INTERMITTENT NUMBNESS IN BOTH LEGS]	4	1	MOD	NO	N	N	N	N	N	N	NO NO	None
			06JUL2003-06JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	4	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0036007	35 YRS CAUCASIAN FEMALE	06JUL2003-06JUL2003	ON	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	1	4	MOD	NO	N	N	N	N	N	N	NO NO	None
					VISION BLURRED (Eye disorders) [BLURRED VISION]	1	4	MOD	NO	N	N	N	N	N	N	NO NO	None
			07JUL2003-10JUL2003	ON	SOMNOLENCE (Nervous system disorders) [INTERMITTENT SLEEPINESS]	4	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			10JUL2003-12JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	8	SEV	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-14JUL2003	ON	URINARY INCONTINENCE (Renal and urinary disorders) [INTERMITTENT URINARY INCONTINENCE SECONDARY TO SEDATION]	4	9	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14JUL2003-15JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	2	12	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0036007	35 YRS CAUCASIAN FEMALE	14JUL2003-16JUL2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	3	12	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0037009	34 YRS HISPANIC FEMALE	20MAY2003-21MAY2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT SECONDARY TO POSTURAL HYPOTENSION]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			28MAY2003-04JUN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT SECONDARY TO POSTURAL HYPOTENSION]	8	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			12JUN2003-11JUL2003	ON	ASTHENIA (General disorders and administration site conditions) [WEAKNESS]	30	28	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	30	28	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0039011	34 YRS BLACK FEMALE	03JAN2003-03JAN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [MORNING LETHARGY]	1	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			05JAN2003-05JAN2003	ON	FLATULENCE (Gastrointestinal disorders) [FLATULENCE]	1	4	MIL	NO	N	N	N	N	N	N	NO NO	None
			08JAN2003-08JAN2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [BAD DREAMS]	1	7	MOD	NO	N	N	N	N	N	N	NO NO	None
					TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			16JAN2003-16JAN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	15	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039011	34 YRS BLACK FEMALE	20JAN2003-20JAN2003	ON	BUTTOCK PAIN (Musculoskeletal and connective tissue disorders) [SORE BUTTOCKS]	1	19	MOD	NO	N	N	N	N	N	N	NO NO	None
					INJURY (Injury, poisoning and procedural complications) [FALL]	1	19	MOD	NO	N	N	N	N	N	N	NO NO	None
			30JAN2003-05FEB2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	7	29	MOD	NO	N	N	N	N	N	N	NO NO	None
					PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	7	29	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039018	34 YRS BLACK FEMALE	23JAN2003-24JAN2003	ON	CHEST PAIN (General disorders and administration site conditions) [INTERMITTENT CHEST PAIN NOT CARDIAC RELATED]	2	1	MIL	NO	N	N	N	N	N	N	NO NO	None
			25JAN2003-27JAN2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [OVERDOSE (ACCIDENTAL STUDY MEDICATION)]	3	3	MIL	NO	N	N	N	N	N	N	NO NO	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	3	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			29JAN2003-29JAN2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [OVERDOSE (ACCIDENTAL STUDY MEDICATION)]	1	7	MIL	NO	N	N	N	N	N	N	NO NO	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	1	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039018	34 YRS BLACK FEMALE	05FEB2003-CONTINUE	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [INCREASED NIGHT SWEATS]	UNK	14	MOD	NO	N	N	N	N	N	N	NO YES	None
			11FEB2003-CONTINUE	ON	FLATULENCE (Gastrointestinal disorders) [FLATULENCE]	UNK	20	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039026	45 YRS BLACK FEMALE	07MAR2003-CONTINUE	ON	SUBCUTANEOUS NODULE (Skin and subcutaneous tissue disorders) [CYSTIC NODULE TOP LEFT SHOULDER (SUBCUTANEOUS)]	UNK	1	MIL	NO	N	N	N	N	N	N	NO NO	None
			10MAR2003-10MAR2003	ON	TREMOR (Nervous system disorders) [TREMORS RIGHT HAND (NOT DUE TO EPS)]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-11MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	2	4	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039026	45 YRS BLACK FEMALE	10MAR2003-18MAR2003	ON	ASTHENIA (General disorders and administration site conditions) [DECREASED ENERGY]	9	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			12MAR2003-18MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [INCREASED CONSTIPATION]	7	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			26MAR2003-27MAR2003	ON	ASTHENIA (General disorders and administration site conditions) [WEAK AFTER DOSE (NOT DUE TO POSTURAL HYPOTENSION)]	2	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-11APR2003	ON	RIGORS (General disorders and administration site conditions) [CHILLS]	2	35	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039026	45 YRS BLACK FEMALE	10APR2003-15APR2003	ON	PAIN NOS (General disorders and administration site conditions) [GENERALIZED BODY ACHES]	6	35	MOD	NO	N	N	N	N	N	N	NO NO	None
			10APR2003-16APR2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	7	35	MIL	NO	N	N	N	N	N	N	NO NO	None
					PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	7	35	MIL	NO	N	N	N	N	N	N	NO NO	None
			25APR2003-CONTINUE	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [PERIPHERAL EDEMA]	UNK	50	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039028	39 YRS BLACK MALE	24MAR2003-22MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS NOT DUE TO POSTURAL HYPOTENSION]	60	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039028	39 YRS BLACK MALE	08APR2003-08APR2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [PAIN LEFT FOREARM]	1	16	MIL	NO	N	N	N	N	N	N	NO NO	None
			10APR2003-10APR2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [PAIN LEFT FOREARM]	1	18	MIL	NO	N	N	N	N	N	N	NO NO	None
			12APR2003-28APR2003	ON	WEIGHT DECREASED (Investigations) [WEIGHT LOSS]	17	20	MIL	NO	N	N	N	N	N	N	NO NO	None
			14APR2003-21APR2003	ON	HYPERTENSION NOS (Vascular disorders) [WORSENING OF HYPERTENSION]	8	22	MIL	NO	N	N	N	N	N	N	NO NO	None
			01MAY2003-18MAY2003	ON	GROIN PAIN (Musculoskeletal and connective tissue disorders) [BILATERAL GROIN PAIN]	18	39	MOD	NO	N	N	N	N	N	N	NO NO	None
			05MAY2003-28MAY2003	ON	HYPERTENSION NOS (Vascular disorders) [WORSENING OF HYPERTENSION]	24	43	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039028	39 YRS BLACK MALE	08MAY2003-08MAY2003	ON	CHEST PAIN (General disorders and administration site conditions) [CHEST PAIN (NOT CARDIAC RELATED)]	1	46	MOD	YES	N	N	Y	N	N	N	NO NO	None
					DRUG ABUSER NOS (Social circumstances) [COCAINE ABUSE]	1	46	MIL	NO	N	N	N	N	N	N	NO NO	None
			09MAY2003-16MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	8	47	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
			15MAY2003-CONTINUE	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [INCREASED AUDITORY HALLUCINATIONS]	UNK	53	SEV	NO	N	N	N	N	N	N	NO NO	None
			20MAY2003-03JUN2003	ON	DEPRESSION (Psychiatric disorders) [WORSENING OF DEPRESSION]	15	58	SEV	YES	N	N	Y	N	N	N	NO NO	None
	E0039032	26 YRS BLACK FEMALE	14MAR2003-14MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039032	26 YRS BLACK FEMALE	14MAR2003-15MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-CONTINUE	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	UNK	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			28MAR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039034	29 YRS CAUCASIAN FEMALE	19MAR2003-25APR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	38	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			07APR2003-07MAY2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [RECURRENT RIGHT ARM PAIN]	31	20	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039034	29 YRS CAUCASIAN FEMALE	09APR2003-09APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	22	MOD	NO	N	N	N	N	N	N	NO NO	None
			21APR2003-25APR2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	5	34	MIL	NO	N	N	N	N	N	N	NO NO	None
			22APR2003-23APR2003	ON	PAIN NOS (General disorders and administration site conditions) [GENERALIZED BODY ACHES]	2	35	MOD	NO	N	N	N	N	N	N	NO NO	None
			22APR2003-28APR2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	7	35	MIL	NO	N	N	N	N	N	N	NO NO	None
			22APR2003-29APR2003	ON	PHARYNGITIS STREPTOCOCCAL (Infections and infestations) [STREP THROAT]	8	35	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039042	35 YRS BLACK FEMALE	08MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			08MAY2003-09JUN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	33	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			12MAY2003-12MAY2003	ON	INJURY (Injury, poisoning and procedural complications) [FALL "NOT DUE TO POSTURAL HYPOTENSION"]	1	6	MIL	NO	N	N	N	N	N	N	NO NO	None
			12MAY2003-18MAY2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [RIGHT FOREARM PAIN DUE TO FALL]	7	6	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039042	35 YRS BLACK FEMALE	17MAY2003-17MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [DIZZY WHEN STANDING "NOT DUE TO POSTURAL HYPOTENSION"]	1	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAY2003-20MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [DIZZY WHEN STANDING "NOT DUE TO POSTURAL HYPOTENSION"]	1	14	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-03JUN2003	ON	CONSTIPATION (Gastrointestinal disorders) [INCREASED CONSTIPATION]	13	16	MOD	NO	N	N	N	N	N	N	NO YES	None
			17JUN2003-CONTINUE	ON	EAR PAIN (Ear and labyrinth disorders) [LEFT EAR PAIN (DUE TO EAR PIERCING)]	UNK	42	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039042	35 YRS BLACK FEMALE	17JUN2003-CONTINUE	ON	FACIAL PAIN (Musculoskeletal and connective tissue disorders) [NOSE PAIN (DUE TO NOSE PIERCING)]	UNK	42	MOD	NO	N	N	N	N	N	N	NO NO	None
			30JUN2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [INCREASED CONSTIPATION]	UNK	55	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0041004	35 YRS CAUCASIAN MALE	30JAN2003-21FEB2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	23	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			30JAN2003-02APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	63	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			10FEB2003-23FEB2003	ON	TREMOR (Nervous system disorders) [TREMOR (NOT DUE TO EPS)]	14	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0041004	35 YRS CAUCASIAN MALE	17FEB2003-21FEB2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	5	19	MIL	NO	N	N	N	N	N	N	NO YES	None
			17FEB2003-23FEB2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	7	19	MOD	NO	N	N	N	N	N	N	NO NO	None
			23FEB2003-01MAR2003	ON	TINNITUS (Ear and labyrinth disorders) [INTERMITTENT TINNITUS]	7	25	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-17MAR2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FLASHES]	8	40	MIL	NO	N	N	N	N	N	N	NO YES	None
					FLUSHING (Vascular disorders) [HOT FLASHES]	8	40	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-25MAR2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	16	40	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

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QUETIAPINE 600 MG (BIPOLAR I)	E0042002	26 YRS CAUCASIAN MALE	09JUL2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-29AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [INTERMITTENT CONSTIPATION]	50	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0001006	29 YRS CAUCASIAN MALE	11JUL2003-17JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	7	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JUL2003-CONTINUE	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [LIPS TWITCHING NOT DUE TO EPS]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JUL2003-17JUL2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [MUSCLE CRAMPS NOT DUE TO EPS]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [MUSCLE TWITCHING NOT DUE TO EPS]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0003002	37 YRS CAUCASIAN MALE	12NOV2002-12NOV2002	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	15	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005031	29 YRS CAUCASIAN FEMALE	02APR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06APR2003-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			06APR2003-30APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			17APR2003-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	16	MIL	NO	N	N	N	N	N	N	NO YES	None
			23APR2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [WORSENING OF CONSTIPATION]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0005031	29 YRS CAUCASIAN FEMALE	02MAY2003-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE STIFFNESS OF BACK (SECONDARY TO EPS)]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005033	33 YRS CAUCASIAN FEMALE	16APR2003-14MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	29	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			18APR2003-14MAY2003	ON	FLUSHING (Vascular disorders) [INTERMITTENT HOT FLASHES]	27	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			20APR2003-14MAY2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	25	5	MOD	NO	N	N	N	N	N	N	NO YES	None
					NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	25	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0005033	33 YRS CAUCASIAN FEMALE	26APR2003-14MAY2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	19	11	MOD	NO	N	N	N	N	N	N	NO YES	None
					FLUID RETENTION (Metabolism and nutrition disorders) [WATER RETENTION]	19	11	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005038	31 YRS CAUCASIAN FEMALE	14MAY2003-CONTINUE	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14MAY2003-01JUN2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	19	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			23MAY2003-CONTINUE	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	UNK	10	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0007009	29 YRS CAUCASIAN FEMALE	19APR2003-CONTINUE	ON	SKIN LESION NOS (Skin and subcutaneous tissue disorders) [CIRCUMSCRIBED ERYTHEMATOUS LESION LEFT SIDE OF NECK 1 1/2CM]	UNK	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			19APR2003-24APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	6	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0009010	31 YRS CAUCASIAN MALE	14MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [OVERSEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-CONTINUE	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAR2003-CONTINUE	ON	LOSS OF LIBIDO (Psychiatric disorders) [LOSS OF LIBIDO]	UNK	10	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0009011	62 YRS CAUCASIAN MALE	13MAY2003-01JUN2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [DIZZINESS (UPON STANDING NOT DUE TO POSTURAL HYPOTENSION)]	20	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-30JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	47	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-01JUN2003	ON	TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	8	20	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0011016	40 YRS CAUCASIAN MALE	22APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			22APR2003-26APR2003	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE ACHES]	5	2	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0011016	40 YRS CAUCASIAN MALE	22APR2003-11MAY2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	20	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			23APR2003-29MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	37	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			23APR2003-03JUN2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	42	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			03JUN2003-15JUN2003	ON	DERMATITIS CONTACT (Skin and subcutaneous tissue disorders) [POISON IVY]	13	44	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0011020	33 YRS CAUCASIAN MALE	09MAY2003-10MAY2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS, SECONDARY TO POSTURAL HYPOTENSION]	2	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0011020	33 YRS CAUCASIAN MALE	09MAY2003-11MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			10MAY2003-11MAY2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	2	3	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0018002	53 YRS CAUCASIAN MALE	01DEC2002-CONTINUE	ON	DISTURBANCE IN ATTENTION (Nervous system disorders) [DECREASED CONCENTRATION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			03DEC2002-09DEC2002	ON	SEDATION (Nervous system disorders) [SEDATION]	7	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			04DEC2002-CONTINUE	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018002	53 YRS CAUCASIAN MALE	06DEC2002-06DEC2002	ON	HALLUCINATION, VISUAL (Psychiatric disorders) [VISUAL HALLUCINATIONS]	1	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002-12DEC2002	ON	DYSKINESIA (Nervous system disorders) [NOCTURNAL MYOCLONES (NOT DUE TO EPS)]	7	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002-15DEC2002	ON	ALCOHOL INTOLERANCE (Metabolism and nutrition disorders) [INTERMITTENT INCREASED EFFECTS OF ALCOHOL]	10	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			07DEC2002-CONTINUE	ON	THOUGHT BLOCKING (Psychiatric disorders) [THOUGHT BLOCKING]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			12DEC2002-14DEC2002	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	3	14	MOD	NO	N	N	N	N	N	N	NO YES	None
			20DEC2002-18JAN2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [PARTIAL IMPOTENCE]	30	22	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018002	53 YRS CAUCASIAN MALE	22DEC2002-22DEC2002	ON	SOMNOLENCE (Nervous system disorders) [GROGGINESS]	1	24	MIL	NO	N	N	N	N	N	N	NO YES	None
			25DEC2002-CONTINUE	ON	MUSCLE CONTRACTIONS INVOLUNTARY (Nervous system disorders) [MUSCLE FASCICULATION (NOT DUE TO EPS)]	UNK	27	MIL	NO	N	N	N	N	N	N	NO YES	None
			28DEC2002-20JAN2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	24	30	MIL	NO	N	N	N	N	N	N	NO YES	None
			01JAN2003-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	UNK	34	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0018003	27 YRS CAUCASIAN FEMALE	27NOV2002-27NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (UNKNOWN IF DUE TO POSTURAL HYPOTENSION)]	1	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018003	27 YRS CAUCASIAN FEMALE	29NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGIC]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATED]	UNK	4	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			02DEC2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
					NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			07DEC2002-09DEC2002	ON	GASTROENTERITIS VIRAL NOS (Infections and infestations) [VIRAL GASTRO ENTERITIS]	3	12	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018013	44 YRS CAUCASIAN MALE	25JAN2003-29JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	5	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [OVER SEDATION]	5	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			29JAN2003-30JAN2003	ON	HEADACHE (Nervous system disorders) [INCREASED INTENSITY HEADACHE]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019002	22 YRS CAUCASIAN FEMALE	13NOV2002-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18NOV2002-CONTINUE	ON	TENSION HEADACHE (Nervous system disorders) [TENSION HEADACHE]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019008	35 YRS CAUCASIAN FEMALE	22NOV2002-CONTINUE	ON	ALTERED VISUAL DEPTH PERCEPTION (Eye disorders) [PROBLEM WITH DEPTH PERCEPTION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGY]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27NOV2002-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			10DEC2002-12DEC2002	ON	GASTROENTERITIS VIRAL NOS (Infections and infestations) [(STOMACH VIRUS)]	3	20	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019008	35 YRS CAUCASIAN FEMALE	10DEC2002-16DEC2002	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	7	20	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0019009	22 YRS CAUCASIAN FEMALE	15NOV2002-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-20NOV2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019016	26 YRS CAUCASIAN FEMALE	06JAN2003-09FEB2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	35	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JAN2003-26FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	52	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JAN2003-20JAN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	13	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			10JAN2003-01FEB2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	23	5	MOD	NO	N	N	N	N	N	N	NO NO	None
			11JAN2003-17JAN2003	ON	NERVOUSNESS (Psychiatric disorders) [EXAGERATED STARTLE RESPONSE (JUMPY)]	7	6	MIL	NO	N	N	N	N	N	N	NO NO	None
			24JAN2003-CONTINUE	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS (NOT DUE TO EPS)]	UNK	19	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019020	35 YRS CAUCASIAN FEMALE	24JAN2003-07FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			06FEB2003-12FEB2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DYSPHAGIA (DIFFICULTY SWALLOWING)]	7	15	MIL	NO	N	N	N	N	N	N	NO YES	None
			17FEB2003-18FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	26	MIL	NO	N	N	N	N	N	N	NO YES	None
			08MAR2003-20MAR2003	ON	CONTUSION (Skin and subcutaneous tissue disorders) [GENERALIZED BRUISING]	13	45	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019020	35 YRS CAUCASIAN FEMALE	08MAR2003-20MAR2003	ON	PERIORBITAL HAEMATOMA (Injury, poisoning and procedural complications) [BLACK EYE RIGHT]	13	45	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0019021	41 YRS CAUCASIAN MALE	01FEB2003-17FEB2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEG DUE TO EPS (AKATHISIA)]	17	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGIC]	17	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			17FEB2003-CONTINUE	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	UNK	19	MIL	NO	N	N	N	N	N	N	NO NO	None
			20FEB2003-CONTINUE	ON	AGITATION (Psychiatric disorders) [AGITATION]	UNK	22	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	31JAN2003-06FEB2003	ON	CONFUSIONAL STATE (Psychiatric disorders) [CONFUSION]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DIZZINESS (Nervous system disorders) [LIGHTHEADED (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [DIFFICULTY BREATHING]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SOMNOLENCE (Nervous system disorders) [DROWSY]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	31JAN2003-06FEB2003	ON	TOOTH DISORDER NOS (Gastrointestinal disorders) [WEIRD FEELING IN TEETH]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			01FEB2003-06FEB2003	ON	LIMB DISCOMFORT NOS (Musculoskeletal and connective tissue disorders) [UNCOMFORTABLE FEELING IN LEGS AND ARMS]	6	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			02FEB2003-02FEB2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			04FEB2003-06FEB2003	ON	BRUXISM (Psychiatric disorders) [BRUXISM]	3	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	3	6	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	04FEB2003-06FEB2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	3	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			05FEB2003-05FEB2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [WORSENING OF COUGH]	1	7	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0019031	47 YRS CAUCASIAN MALE	13MAR2003-17MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	5	1	SEV	NO	N	N	N	N	N	N	YES YES	None
			14MAR2003-16MAR2003	ON	JOINT STIFFNESS (Musculoskeletal and connective tissue disorders) [TIGHTNESS IN JOINTS (NOT DUE TO EPS)]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None
					PARAESTHESIA (Nervous system disorders) [TINGLING IN ARMS]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019031	47 YRS CAUCASIAN MALE	14MAR2003-16MAR2003	ON	PARAESTHESIA (Nervous system disorders) [TINGLING IN LEGS]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None
	E0019035	34 YRS CAUCASIAN FEMALE	20MAR2003-24APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	36	3	SEV	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	36	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			23MAR2003-24APR2003	ON	LIBIDO INCREASED (Psychiatric disorders) [LIBIDO INCREASE]	33	6	MOD	NO	N	N	N	N	N	N	NO NO	None
			25MAR2003-CONTINUE	ON	ANGER (Psychiatric disorders) [INCREASED ANGER]	UNK	8	SEV	NO	N	N	N	N	N	N	NO YES	None
			31MAR2003-09APR2003	ON	INFLUENZA (Infections and infestations) [FLU]	10	14	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019035	34 YRS CAUCASIAN FEMALE	03APR2003-24APR2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS AT NIGHT NOT DUE TO EPS]	22	17	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			10APR2003-24APR2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	15	24	MOD	NO	N	N	N	N	N	N	NO NO	None
			11APR2003-24APR2003	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	14	25	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019040	49 YRS BLACK MALE	21MAY2003-24MAY2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	4	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			21MAY2003-01JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	42	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019040	49 YRS BLACK MALE	21MAY2003-01JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	42	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			29MAY2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JUN2003-19JUN2003	ON	DYSGEUSIA (Nervous system disorders) [ABNORMAL TASTE IN MOUTH]	12	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			09JUN2003-CONTINUE	ON	BRUXISM (Psychiatric disorders) [GRINDING TEETH]	UNK	21	MOD	NO	N	N	N	N	N	N	NO YES	None
			21JUN2003-CONTINUE	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [WORSENING OF BACKACHES]	UNK	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			04JUL2003-CONTINUE	ON	HYPOAESTHESIA (Nervous system disorders) [NUMBNESS IN FINGER TIPS]	UNK	46	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019042	27 YRS CAUCASIAN FEMALE	05JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION.]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14JUN2003-18JUN2003	ON	TREMOR (Nervous system disorders) [HAND TREMORS (NOT DUE TO EPS)]	5	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			15JUN2003-18JUN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	4	12	MIL	NO	N	N	N	N	N	N	YES YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	4	12	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019045	32 YRS CAUCASIAN FEMALE	27JUN2003-09JUL2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	13	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019045	32 YRS CAUCASIAN FEMALE	07JUL2003-09JUL2003	ON	DRUG ABUSER NOS (Social circumstances) [DRUG ABUSE - CRACK COCAINE]	3	12	SEV	NO	N	N	N	N	N	N	NO NO	Permanently Stopped
	E0020024	18 YRS CAUCASIAN MALE	30JUN2003-15JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE INTERMITTENT]	16	8	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			03AUG2003-03AUG2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	1	42	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0022044	34 YRS CAUCASIAN FEMALE	10APR2003-13APR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	4	24	MIL	NO	N	N	N	N	N	N	NO NO	None
			06MAY2003-08MAY2003	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	3	50	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023007	23 YRS CAUCASIAN FEMALE	15JAN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			15JAN2003-07FEB2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	24	2	MIL	NO	N	N	N	N	N	N	NO NO	None
					SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	24	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			22JAN2003-07FEB2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	17	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			26JAN2003-07FEB2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	13	13	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023007	23 YRS CAUCASIAN FEMALE	09FEB2003-17FEB2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	9	27	MOD	NO	N	N	N	N	N	N	NO NO	None
			21FEB2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	39	MIL	NO	N	N	N	N	N	N	NO NO	None
			23FEB2003-06MAR2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	12	41	MIL	NO	N	N	N	N	N	N	NO NO	None
					DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	12	41	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0023011	50 YRS CAUCASIAN FEMALE	07FEB2003-22MAR2003	ON	HYPOAESTHESIA (Nervous system disorders) [FACIAL NUMBNESS]	44	4	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023011	50 YRS CAUCASIAN FEMALE	08MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	33	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023014	40 YRS CAUCASIAN MALE	21FEB2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			21FEB2003-20MAR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	28	1	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			04MAR2003-18MAR2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [LEG PRICKLING SENSATION (PAIN)]	15	12	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0023019	32 YRS CAUCASIAN MALE	08APR2003-10APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023019	32 YRS CAUCASIAN MALE	09APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			26APR2003-15MAY2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED NOT DUE POSTURAL HYPOTENSION]	20	20	MOD	NO	N	N	N	N	N	N	NO NO	None
			20MAY2003-21MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	2	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023022	21 YRS CAUCASIAN MALE	19APR2003-26APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			19APR2003-17MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023022	21 YRS CAUCASIAN MALE	03MAY2003-06MAY2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU SYMPTOMS]	4	16	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0023023	35 YRS CAUCASIAN FEMALE	26APR2003-29APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY NOT DUE TO POSTURAL HYPOTENSION]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	None
					SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0023029	46 YRS HISPANIC FEMALE	24MAY2003-28MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0023029	46 YRS HISPANIC FEMALE	24MAY2003-28MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0023031	49 YRS CAUCASIAN FEMALE	24JUN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			26JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-10JUL2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	7	11	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023041	40 YRS CAUCASIAN FEMALE	09JUL2003-21JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	13	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	13	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			12JUL2003-12JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			13JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-10AUG2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	17	17	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE- STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA- TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	40 YRS CAUCASIAN FEMALE	07AUG2003- CONTINUE	ON	FATIGUE (General disorders and administration site con ditions) [FATIGUE]	UNK	30	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0026003	46 YRS CAUCASIAN MALE	06DEC2002- 13DEC2002	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	8	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002- 19DEC2002	ON	APPETITE INCREASED NOS (Metabolism and nutriti on disorders) [INCREASED APPETITE]	14	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002- 12JAN2003	ON	SEDATION (Nervous system disorde rs) [SEDATION]	38	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002- 12FEB2003	ON	DRY MOUTH (Gastrointestinal disor ders) [DRY MOUTH]	69	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			08DEC2002- 15DEC2002	ON	FOOD CRAVING (Metabolism and nutriti on disorders) [CRAVING FOR SODIUM]	8	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0026003	46 YRS CAUCASIAN MALE	29JAN2003- 03FEB2003	ON	PROSTATITIS (Reproductive system and breast disorders) [ACUTE PROSTATITIS]	6	57	SEV	YES	N	N	Y	N	N	N	NO NO	None
	E0026005	57 YRS CAUCASIAN FEMALE	30DEC2002- 11JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	13	1	SEV	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	13	1	SEV	NO	N	N	N	N	N	N	NO YES	None
					DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [LABORED BREATHING]	13	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					IRRITABILITY (Psychiatric disorders) [IRRITABLE]	13	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	13	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0026009	43 YRS CAUCASIAN FEMALE	17JAN2003-19JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	3	3	SEV	NO	N	N	N	N	N	N	YES YES	None
					HEADACHE (Nervous system disorders) [HEADACHE]	3	3	SEV	NO	N	N	N	N	N	N	NO YES	None
					VISION BLURRED (Eye disorders) [BLURRED VISION, BOTH EYES]	3	3	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0026015	47 YRS CAUCASIAN FEMALE	01MAR2003-25MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [WORSENING OF HEART BURN]	25	3	MIL	NO	N	N	N	N	N	N	NO NO	None
					FLATULENCE (Gastrointestinal disorders) [GAS]	25	3	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0026015	47 YRS CAUCASIAN FEMALE	05MAR2003-06MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-15APR2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FLASHES]	37	12	MOD	NO	N	N	N	N	N	N	NO NO	None
					FLUSHING (Vascular disorders) [HOT FLASHES]	37	12	MOD	NO	N	N	N	N	N	N	NO NO	None
			10MAR2003-20APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	42	12	MIL	NO	N	N	N	N	N	N	NO NO	None
			17MAR2003-15APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	30	19	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0026015	47 YRS CAUCASIAN FEMALE	19MAR2003-23MAR2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED NOT DUE TO POSTURAL HYPOTENSION]	5	21	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026023	20 YRS CAUCASIAN MALE	30APR2003-30MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	31	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			27JUN2003-28JUN2003	ON	HYPOTENSION NOS (Vascular disorders) [ACUTE HYPOTENSION]	2	59	SEV	NO	N	N	N	N	N	N	NO NO	None
					MENTAL STATUS CHANGES (Psychiatric disorders) [ALTERED MENTAL STATUS]	2	59	SEV	YES	N	N	Y	N	N	N	NO NO	None
	E0027016	24 YRS CAUCASIAN FEMALE	09APR2003-12APR2003	ON	DRUG WITHDRAWAL SYNDROME (General disorders and administration site conditions) [SEROTONIN WITHDRAWAL]	4	1	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0027016	24 YRS CAUCASIAN FEMALE	10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-22APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	13	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION IN AM]	UNK	16	MOD	NO	N	N	N	N	N	N	NO YES	None
			02MAY2003-08MAY2003	ON	BRONCHITIS NOS (Respiratory, thoracic and mediastinal disorders) [BRONCHITIS]	7	24	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0027018	23 YRS CAUCASIAN FEMALE	20MAY2003-CONTINUE	ON	NASOPHARYNGITIS (Infections and infestations) [COLD (COMMON COLD)]	UNK	57	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0028032	36 YRS CAUCASIAN MALE	25MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			27MAR2003-22MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	57	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-14MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	44	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAY2003-10MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	47	SEV	NO	N	N	N	N	N	N	NO YES	None
			18MAY2003-28MAY2003	ON	BIPOLAR I DISORDER (Psychiatric disorders) [MIXED EPISODE WITH PSYCHOSIS]	11	55	SEV	YES	N	N	Y	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0028032	36 YRS CAUCASIAN MALE	18MAY2003-28MAY2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	11	55	SEV	YES	N	N	Y	N	N	N	NO NO	None
	E0029003	20 YRS CAUCASIAN MALE	05NOV2002-14NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	10	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			05NOV2002-18NOV2002	ON	NASOPHARYNGITIS (Infections and infestations) [HEAD COLD]	14	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			14NOV2002-25NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	12	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			16NOV2002-25NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	10	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-25NOV2002	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	6	17	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0029003	20 YRS CAUCASIAN MALE	20NOV2002-25NOV2002	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	6	17	MOD	NO	N	N	N	N	N	N	NO NO	None
			26NOV2002-17DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	23	MIL	NO	N	N	N	N	N	N	NO YES	None
			27NOV2002-28NOV2002	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	2	24	MOD	NO	N	N	N	N	N	N	NO NO	None
			14DEC2002-CONTINUE	ON	BACK INJURY NOS (Injury, poisoning and procedural complications) [LOWER BACK STRAIN]	UNK	41	MOD	NO	N	N	N	N	N	N	NO NO	None
			20DEC2002-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRY VISION]	UNK	47	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0029020	33 YRS CAUCASIAN MALE	05MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			09MAR2003-CONTINUE	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-10MAR2003	ON	DYSURIA (Renal and urinary disorders) [DIFFICULTY URINATING]	1	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031005	44 YRS CAUCASIAN FEMALE	15JAN2003-CONTINUE	ON	PERIARTHRITIS (Musculoskeletal and connective tissue disorders) [ADHESIVE CAPSULITIS]	UNK	27	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031006	41 YRS CAUCASIAN MALE	20FEB2003-29MAR2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	38	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031006	41 YRS CAUCASIAN MALE	22MAR2003-24MAR2003	ON	ASTHMA NOS (Respiratory, thoracic and mediastinal disorders) [CHEST COLD INDUCED ASTHMA]	3	33	MOD	NO	N	N	N	N	N	N	NO NO	None
			12APR2003-21APR2003	ON	EXCORIATION (Injury, poisoning and procedural complications) [ABRASIONS]	10	54	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0031010	37 YRS OTHER FEMALE	19FEB2003-CONTINUE	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			20FEB2003-27FEB2003	ON	DYSGEUSIA (Nervous system disorders) [METALLIC TASTE IN MOUTH]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031010	37 YRS OTHER FEMALE	26FEB2003-01MAR2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	4	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-05MAR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	8	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			02MAR2003-03MAR2003	ON	DYSMENORRHOEA (Reproductive system and breast disorders) [PREMENSTRUAL CRAMPS]	2	12	MIL	NO	N	N	N	N	N	N	NO NO	None
			02MAR2003-05MAR2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [LOWER BACK PAINS]	4	12	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031011	46 YRS CAUCASIAN MALE	28FEB2003-21MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DIFFICULTY WAKING UP]	22	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-22MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031011	46 YRS CAUCASIAN MALE	17MAR2003-21MAR2003	ON	NERVOUSNESS (Psychiatric disorders) [INCREASED NERVOUS ENERGY (NERVOUSNESS)]	5	19	MOD	NO	N	N	N	N	N	N	NO YES	None
					SWOLLEN TONGUE (Gastrointestinal disorders) [SWOLLEN TONGUE]	5	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0031015	27 YRS CAUCASIAN FEMALE	27MAR2003-04APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	9	2	MIL	NO	N	N	N	N	N	N	YES YES	None
			29MAR2003-04APR2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	None
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					VISION BLURRED (Eye disorders) [BLURRED VISION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031031	33 YRS CAUCASIAN FEMALE	08JUL2003-20JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	13	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			09JUL2003-02AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-25JUL2003	ON	SINUSITIS NOS (Infections and infestations) [SINUSITIS]	15	4	MOD	NO	N	N	N	N	N	N	NO NO	None
			20JUL2003-06AUG2003	ON	SEDATION (Nervous system disorders) [AM SEDATION]	18	13	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0033009	46 YRS CAUCASIAN FEMALE	13FEB2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [MORE SEVERE HEADACHES]	UNK	2	SEV	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0034009	44 YRS BLACK MALE	20JUN2003-21AUG2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGY FEELING]	63	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			21JUN2003-01JUL2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	11	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			21JUN2003-21AUG2003	ON	SLUGGISHNESS (General disorders and administration site conditions) [DAYTIME SLUGGISHNESS]	62	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			27JUN2003-22JUL2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	26	9	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0037007	23 YRS CAUCASIAN FEMALE	12APR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0037007	23 YRS CAUCASIAN FEMALE	15APR2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
	E0037012	21 YRS CAUCASIAN MALE	17JUL2003-08AUG2003	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24JUL2003-24JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			07AUG2003-29AUG2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	23	23	MIL	NO	N	N	N	N	N	N	NO YES	None
			22AUG2003-08SEP2003	ON	TREMOR (Nervous system disorders) [BILATERAL HAND TREMOR (NOT DUE TO EPS)]	18	38	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0039019	35 YRS BLACK FEMALE	11FEB2003-12FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-16MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS (POST DOSE)]	32	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-23MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	39	8	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	39	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-16MAR2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	17	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			02MAR2003-29MAR2003	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL CRAMPING]	28	25	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0039019	35 YRS BLACK FEMALE	08MAR2003-30MAR2003	ON	ACNE NOS (Skin and subcutaneous tissue disorders) [ACNE]	23	31	MIL	NO	N	N	N	N	N	N	NO NO	None
			17MAR2003-23MAR2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	7	40	MIL	NO	N	N	N	N	N	N	NO YES	None
			26MAR2003-26MAR2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	1	49	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039043	20 YRS CAUCASIAN MALE	08MAY2003-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [HAVING DREAMS]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUN2003-CONTINUE	ON	DRUG ABUSER NOS (Social circumstances) [DRUG ABUSE WITH COCAINE]	UNK	25	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0039043	20 YRS CAUCASIAN MALE	01JUN2003- 10JUN2003	ON	SKIN LESION NOS (Skin and subcutaneous tissue disorders) [OPEN LESION RIGHT HAND]	10	25	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0002001	49 YRS BLACK FEMALE	06JAN2003-CONTINUE	ON	SKIN LACERATION (Injury, poisoning and procedural complications) [CUT ON LOWER LIP]	UNK	8	MIL	NO	N	N	N	N	N	N	NO NO	None
			06JAN2003-15JAN2003	ON	CHEST PAIN (General disorders and administration site conditions) [CHEST SORE FROM STEERING WHEEL IMPACT]	10	8	MIL	NO	N	N	N	N	N	N	NO NO	None
			06JAN2003-29JAN2003	ON	HAEMATOMA NOS (Vascular disorders) [LEFT LOWER LEG HEMATOMA]	24	8	MIL	NO	N	N	N	N	N	N	NO NO	None
			06JAN2003-09FEB2003	ON	JOINT SPRAIN (Injury, poisoning and procedural complications) [SPRAINED LEFT FOOT]	35	8	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0002003	22 YRS CAUCASIAN FEMALE	22JAN2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0002003	22 YRS CAUCASIAN FEMALE	09FEB2003-16FEB2003	ON	MUSCLE STRAIN (Injury, poisoning and procedural complications) [LEFT HAND, RING FINGER STRAIN]	8	19	MIL	NO	N	N	N	N	N	N	NO NO	None
			05MAR2003-05MAR2003	ON	BLOOD IN STOOL (Investigations) [BLOOD IN STOOLS]	1	43	MIL	NO	N	N	N	N	N	N	NO NO	None
			15MAR2003-CONTINUE	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	UNK	53	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0002008	41 YRS CAUCASIAN MALE	25FEB2003-25FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	1	1	MIL	NO	N	N	N	N	N	N	NO NO	None
			27FEB2003-02APR2003	ON	HERPES SIMPLEX (Infections and infestations) [COLD SORE]	35	3	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0002008	41 YRS CAUCASIAN MALE	20MAR2003-CONTINUE	ON	PRURITUS GENERALISED (Skin and subcutaneous tissue disorders) [GENERAL ITCHINESS]	UNK	24	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0002016	56 YRS CAUCASIAN FEMALE	26JUL2003-20AUG2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [INTERMITTENT STOMACH CRAMPS]	26	3	MIL	NO	N	N	N	N	N	N	NO NO	None
			26JUL2003-03SEP2003	ON	SOMNOLENCE (Nervous system disorders) [INTERMITTENT DROWSINESS]	40	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			14AUG2003-20AUG2003	ON	HEMIPARESIS (Nervous system disorders) [RIGHT SIDED WEAKNESS]	7	22	MOD	YES	N	N	Y	N	N	N	NO NO	None
			15AUG2003-15AUG2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	1	23	SEV	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0003008	35 YRS CAUCASIAN FEMALE	29JAN2003-29JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			29JAN2003-31JAN2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [INTENSE DREAMING (VIVID DREAMS)]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			08FEB2003-10FEB2003	ON	INFLUENZA (Infections and infestations) [FLU]	3	12	MOD	NO	N	N	N	N	N	N	NO NO	None
			13FEB2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	17	MOD	NO	N	N	N	N	N	N	NO NO	None
			15FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0004003	22 YRS CAUCASIAN MALE	10OCT2002-13OCT2002	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	4	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004006	37 YRS CAUCASIAN FEMALE	08NOV2002-20NOV2002	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	13	5	MIL	NO	N	N	N	N	N	N	NO YES	None
					POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	13	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			08NOV2002-03DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHES]	26	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			16JAN2003-23JAN2003	ON	DRUG HYPERSENSITIVITY (Immune system disorders) [HYPERSENSITIVITY REACTION TO LAMICTAL]	8	74	SEV	YES	N	N	Y	N	N	N	NO NO	None
	E0004016	20 YRS HISPANIC FEMALE	03MAR2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	13	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0004016	20 YRS HISPANIC FEMALE	10MAR2003-10MAR2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	1	20	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004024	39 YRS CAUCASIAN FEMALE	12JUL2003-08AUG2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	28	10	MIL	NO	N	N	N	N	N	N	NO NO	None
			18JUL2003-26JUL2003	ON	MUSCLE TIGHTNESS (Musculoskeletal and connective tissue disorders) [MUSCLE TIGHTNESS LEFT NECK AREA (NOT DUE TO EPS)]	9	16	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005006	35 YRS CAUCASIAN MALE	04OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			05OCT2002-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0005017	41 YRS CAUCASIAN FEMALE	26FEB2003- 01MAR2003	ON	GASTROENTERITIS VIRAL NOS (Infections and infestations) [GASTROINTESTINAL FLU]	4	59	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0005019	22 YRS CAUCASIAN FEMALE	16JAN2003- 16JAN2003	ON	NON-ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [INTENTIONAL OVERDOSE (OVER THE COUNTER SLEEPING PILL)]	1	2	MOD	YES	N	N	N	N	N	Y	YES NO	Permanently Stopped
			20JAN2003- 20JAN2003	ON	SKIN LACERATION (Injury, poisoning and procedural complications) [LACERATION RIGHT HAND]	1	6	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0005026	29 YRS CAUCASIAN FEMALE	07MAR2003- 17MAR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	11	2	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0005039	39 YRS CAUCASIAN FEMALE	24MAY2003-20JUN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	28	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-25MAY2003	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0006020	38 YRS CAUCASIAN MALE	21MAY2003-10JUN2003	ON	SENSATION OF HEAVINESS (Musculoskeletal and connective tissue disorders) [HEAVINESS IN ARMS AND LEGS]	21	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			21MAY2003-17JUN2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING SLEEPINESS]	28	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0007001	46 YRS CAUCASIAN MALE	30JAN2003-30JAN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [DYSPEPSIA]	1	31	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0007001	46 YRS CAUCASIAN MALE	03FEB2003-20FEB2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	18	35	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0007003	53 YRS CAUCASIAN MALE	02FEB2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [PAIN RIGHT HIP]	UNK	4	MOD	NO	N	N	N	N	N	N	NO NO	None
					BACK PAIN (Musculoskeletal and connective tissue disorders) [PAIN BACK]	UNK	4	MOD	NO	N	N	N	N	N	N	NO NO	None
					CONTUSION (Skin and subcutaneous tissue disorders) [BRUISED PELVIS]	UNK	4	MOD	NO	N	N	N	N	N	N	NO NO	None
			02FEB2003-02FEB2003	ON	INJURY (Injury, poisoning and procedural complications) [FALL]	1	4	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0007003	53 YRS CAUCASIAN MALE	21FEB2003-25FEB2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	5	23	MOD	NO	N	N	N	N	N	N	NO NO	None
			21FEB2003-27FEB2003	ON	DUODENAL ULCER HAEMORRHAGE (Gastrointestinal disorders) [BLEEDING ULCER (DUODENAL)]	7	23	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
			21FEB2003-10MAR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	18	23	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0007006	39 YRS BLACK MALE	22MAR2003-31MAR2003	ON	RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	10	18	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0009004	36 YRS CAUCASIAN MALE	27NOV2002-20DEC2002	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	24	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0009004	36 YRS CAUCASIAN MALE	06DEC2002-09DEC2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	4	11	MOD	NO	N	N	N	N	N	N	NO NO	None
					VOMITING NOS (Gastrointestinal disorders) [VOMITTING]	4	11	MOD	NO	N	N	N	N	N	N	NO NO	None
			13DEC2002-15DEC2002	ON	ECCHYMOSIS (Skin and subcutaneous tissue disorders) [ECCHYMOSIS LEFT CHECK BONE]	3	18	MIL	NO	N	N	N	N	N	N	NO NO	None
					ECCHYMOSIS (Skin and subcutaneous tissue disorders) [ECCHYMOSIS LEFT SHOULDER]	3	18	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0009012	28 YRS CAUCASIAN MALE	25JUN2003-26JUN2003	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [EPS (INVOLUNTARY MOVEMENT OF MOUTH) - DYSTONIA]	2	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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PLACEBO (BIPOLAR I)	E0010008	30 YRS CAUCASIAN FEMALE	20DEC2002-25DEC2002	ON	RHINORRHOEA (Respiratory, thoracic and mediastinal disorders) [RHINORRHEA]	6	3	MIL	NO	N	N	N	N	N	N	NO NO	None
			20DEC2002-01JAN2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	13	3	MIL	NO	N	N	N	N	N	N	NO NO	None
			03JAN2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [WORSENING OF HEADACHES]	UNK	17	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010018	37 YRS ORIENTAL FEMALE	19MAR2003-CONTINUE	ON	GASTROINTESTINAL PAIN NOS (Gastrointestinal disorders) [GASTRO - INTESTINAL CRAMPING]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAR2003-28APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	41	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0010018	37 YRS ORIENTAL FEMALE	27MAR2003-08APR2003	ON	INSOMNIA (Psychiatric disorders) [WORSENING OF INSOMNIA]	13	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			27MAR2003-09APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	14	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-28APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	28	14	SEV	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-09MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [ORTHOSTATIC DIZZINESS]	39	14	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0010028	32 YRS HISPANIC FEMALE	19JUN2003-17JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	29	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			28JUN2003-17JUL2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	20	13	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0010028	32 YRS HISPANIC FEMALE	02JUL2003-24JUL2003	ON	INSOMNIA (Psychiatric disorders) [WORSENING OF INSOMNIA]	23	17	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			10JUL2003-19JUL2003	ON	SKIN ULCER (Skin and subcutaneous tissue disorders) [ULCERATION LEFT CHEEK]	10	25	MIL	NO	N	N	N	N	N	N	NO NO	None
			05AUG2003-08AUG2003	ON	POST PROCEDURAL COMPLICATION (Injury, poisoning and procedural complications) [NAUSEA SECONDARY TO COLONOSCOPY]	4	51	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0011008	23 YRS CAUCASIAN MALE	08FEB2003-11FEB2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	4	10	MIL	NO	N	N	N	N	N	N	NO NO	None
			13FEB2003-CONTINUE	ON	MANIA (Psychiatric disorders) [ONSET OF MANIC SYMPTOMS]	UNK	15	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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PLACEBO (BIPOLAR I)	E0011009	57 YRS CAUCASIAN MALE	06JAN2003-06JAN2003	ON	NASOPHARYNGITIS (Infections and infestations) [COLD SYMPTOMS/COUGH]	1	11	MOD	NO	N	N	N	N	N	N	NO NO	None
			07JAN2003-12JAN2003	ON	VIRAL INFECTION NOS (Infections and infestations) [VIRAL SYNDROME]	6	12	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0011010	49 YRS CAUCASIAN FEMALE	14FEB2003-21FEB2003	ON	VIRAL INFECTION NOS (Infections and infestations) [VIRAL SYNDROME]	8	5	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0013001	34 YRS CAUCASIAN MALE	16NOV2002-16NOV2002	ON	PALPITATIONS (Cardiac disorders) [PALPITATION]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			17NOV2002-17NOV2002	ON	PALPITATIONS (Cardiac disorders) [PALPITATION]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			19NOV2002-19NOV2002	ON	PALPITATIONS (Cardiac disorders) [PALPITATION]	1	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0013001	34 YRS CAUCASIAN MALE	21NOV2002-CONTINUE	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	UNK	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			30NOV2002-01DEC2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	2	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			02DEC2002-10DEC2002	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [EDEMA OF THE HANDS]	9	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0013003	55 YRS CAUCASIAN FEMALE	12NOV2002-14NOV2002	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL CRAMPS]	3	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0013003	55 YRS CAUCASIAN FEMALE	12NOV2002-27NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	16	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			22NOV2002-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	11	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0013005	40 YRS CAUCASIAN MALE	13MAR2003-23MAR2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	11	24	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0013013	22 YRS CAUCASIAN FEMALE	06MAY2003-10MAY2003	ON	FLUSHING (Vascular disorders) [HOT FLASHES]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					PALPITATIONS (Cardiac disorders) [PALPITATION]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0013013	22 YRS CAUCASIAN FEMALE	06MAY2003-13MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014002	43 YRS CAUCASIAN FEMALE	26FEB2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [INCREASED WEIGHT]	UNK	1	MOD	NO	N	N	N	N	N	N	NO NO	None
			09MAR2003-20MAR2003	ON	APHTHOUS STOMATITIS (Gastrointestinal disorders) [CANKER SORES (MOUTH)]	12	12	MIL	NO	N	N	N	N	N	N	NO NO	None
			12APR2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE IN AFTERNOON]	UNK	46	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0014004	29 YRS CAUCASIAN FEMALE	13MAR2003-03APR2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN - LEFT SIDE]	22	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			16MAR2003-03APR2003	ON	URINARY HESITATION (Renal and urinary disorders) [URINARY HESITENCY]	19	5	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
	E0014015	23 YRS CAUCASIAN MALE	18JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014017	23 YRS CAUCASIAN FEMALE	27JUN2003-24AUG2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	59	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			28JUN2003-02JUL2003	ON	LIBIDO INCREASED (Psychiatric disorders) [AROUSED SEXUALLY]	5	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			02JUL2003-03JUL2003	ON	TINNITUS (Ear and labyrinth disorders) [TINNITIS]	2	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0014017	23 YRS CAUCASIAN FEMALE	04JUL2003-20JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	17	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-23JUL2003	ON	ACNE NOS (Skin and subcutaneous tissue disorders) [ACNE]	20	8	MIL	NO	N	N	N	N	N	N	NO NO	None
			09JUL2003-23JUL2003	ON	THIRST (General disorders and administration site conditions) [THIRSTY]	15	13	MIL	NO	N	N	N	N	N	N	NO NO	None
			10JUL2003-14JUL2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [RIGHT FOREARM PAIN]	5	14	MOD	NO	N	N	N	N	N	N	NO NO	None
			16JUL2003-20JUL2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTASIS (ORTHOSTATIC FAINTNESS)]	5	20	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0014017	23 YRS CAUCASIAN FEMALE	04AUG2003-05AUG2003	ON	DYSMENORRHOEA (Reproductive system and breast disorders) [PAINFUL MENSES]	2	39	MOD	NO	N	N	N	N	N	N	NO NO	None
			18AUG2003-23AUG2003	ON	SUNBURN (Injury, poisoning and procedural complications) [SUNBURN]	6	53	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0014018	24 YRS CAUCASIAN MALE	10JUL2003-20JUL2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	11	10	MIL	NO	N	N	N	N	N	N	NO NO	None
			26JUL2003-25AUG2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	31	26	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0018009	27 YRS CAUCASIAN MALE	13JAN2003-14JAN2003	ON	AGITATION (Psychiatric disorders) [AGITATION]	2	8	SEV	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0018010	47 YRS CAUCASIAN MALE	18JAN2003-27JAN2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	10	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			27JAN2003-06FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			08FEB2003-09FEB2003	ON	GASTROENTERITIS VIRAL NOS (Infections and infestations) [VIRAL GASTROENTERITIS]	2	24	MOD	NO	N	N	N	N	N	N	NO NO	None
			09FEB2003-16FEB2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	8	25	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0018015	50 YRS CAUCASIAN MALE	09FEB2003-10FEB2003	ON	ABDOMINAL DISCOMFORT (Gastrointestinal disorders) [ABDOMINAL DISCOMFORT]	2	13	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0018015	50 YRS CAUCASIAN MALE	13MAR2003-CONTINUE	ON	PRURITUS (Skin and subcutaneous tissue disorders) [ITCHING]	UNK	45	MIL	NO	N	N	N	N	N	N	NO NO	None
			30MAR2003-CONTINUE	ON	SEXUAL DYSFUNCTION NOS (Reproductive system and breast disorders) [SEXUAL DYSFUNCTION]	UNK	62	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020015	35 YRS CAUCASIAN MALE	11APR2003-29APR2003	ON	RASH NOS (Skin and subcutaneous tissue disorders) [BILATERAL PALM RASH]	19	16	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0020017	41 YRS CAUCASIAN FEMALE	04APR2003-14APR2003	ON	DYSTONIA (Nervous system disorders) [BILATERAL CALF PAIN (DUE TO EPS - DYSTONIA)]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					DYSTONIA (Nervous system disorders) [LEFT ELBOW RIGIDITY (DUE TO EPS - DYSTONIA)]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0020017	41 YRS CAUCASIAN FEMALE	04APR2003-30MAY2003	ON	DYSTONIA (Nervous system disorders) [RIGHT CERVICAL AREA ACHE "EXACERBATED" (DUE TO EPS - DYSTONIA) (NECK)]	57	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020020	36 YRS CAUCASIAN FEMALE	12MAY2003-17MAY2003	ON	MUSCLE RIGIDITY (Musculoskeletal and connective tissue disorders) [LEFT SHOULDER RIGIDITY (NOT DUE TO EPS)]	6	1	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0020022	49 YRS CAUCASIAN FEMALE	01JUL2003-13JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	13	16	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JUL2003-19JUL2003	ON	OTITIS MEDIA NOS (Infections and infestations) [OTITIS MEDIA]	18	17	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0020022	49 YRS CAUCASIAN FEMALE	05AUG2003-11AUG2003	ON	SIALOADENITIS NOS (Infections and infestations) [INFECTED SALIVARY GLAND]	7	51	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0022001	52 YRS CAUCASIAN MALE	29NOV2002-CONTINUE	ON	SCIATICA (Nervous system disorders) [SCIATICA]	UNK	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			29NOV2002-01DEC2002	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [OVERDOSE ON STUDY MEDICATION (ACCIDENTAL)]	3	33	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022004	30 YRS CAUCASIAN FEMALE	31OCT2002-08NOV2002	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	9	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			05NOV2002-26NOV2002	ON	AGITATION (Psychiatric disorders) [AGITATION]	22	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0022004	30 YRS CAUCASIAN FEMALE	20DEC2002-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [VIRAL SYMPTOMS (UPPER RESPIRATORY INFECTION)]	UNK	54	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022011	28 YRS CAUCASIAN MALE	30NOV2002-06MAR2003	ON	HIP FRACTURE (Injury, poisoning and procedural complications) [HIP FRACTURE]	97	2	MIL	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
					SPINAL FRACTURE NOS (Injury, poisoning and procedural complications) [MULTIPLE VERTEBRAL FRACTURES T11 - L4]	97	2	MIL	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
			04DEC2002-20MAY2003	ON	DEEP VEIN THROMBOSIS (Vascular disorders) [DEEP VEIN THROMBOSIS LEFT LEG]	168	6	MIL	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0022015	19 YRS CAUCASIAN FEMALE	16DEC2002-23DEC2002	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL PAIN]	8	7	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0022015	19 YRS CAUCASIAN FEMALE	06JAN2003-16JAN2003	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTH ACHE]	11	28	MIL	NO	N	N	N	N	N	N	NO NO	None
			01FEB2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPITORY INFECTION]	UNK	54	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022016	32 YRS CAUCASIAN FEMALE	31JAN2003-09FEB2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	10	46	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022020	18 YRS CAUCASIAN FEMALE	06JAN2003-17JAN2003	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL CRAMPS]	12	26	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0022023	50 YRS CAUCASIAN MALE	08FEB2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	46	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022029	25 YRS CAUCASIAN MALE	08APR2003-14APR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	7	49	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022041	51 YRS CAUCASIAN FEMALE	09APR2003-13APR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	5	23	MIL	NO	N	N	N	N	N	N	NO NO	None
			09APR2003-15APR2003	ON	DERMATITIS ALLERGIC (Skin and subcutaneous tissue disorders) [RASH - TORSO (ALLERGIC RESPONSE TO KEFLEX)]	7	23	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0022042	46 YRS CAUCASIAN MALE	25MAR2003-07APR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	14	14	MIL	NO	N	N	N	N	N	N	NO NO	None
			28MAR2003-13APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	17	17	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022043	43 YRS CAUCASIAN FEMALE	11APR2003-01MAY2003	ON	IRRITABLE BOWEL SYNDROME (Gastrointestinal disorders) [WORSENING OF IRRITABLE BOWEL SYNDROME]	21	23	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0022054	25 YRS CAUCASIAN MALE	27APR2003-01MAY2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	5	17	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0022054	25 YRS CAUCASIAN MALE	04MAY2003-13MAY2003	ON	EYE PAIN (Eye disorders) [EYE PAIN]	10	24	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			04MAY2003-14MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	11	24	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0022059	40 YRS BLACK FEMALE	07JUN2003-05JUL2003	ON	SINUSITIS NOS (Infections and infestations) [SINUSITIS]	29	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			04JUL2003-06JUL2003	ON	VAGINOSIS FUNGAL NOS (Infections and infestations) [CANDIDAL VAGINITIS]	3	60	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022065	32 YRS CAUCASIAN FEMALE	11JUN2003-19JUN2003	ON	ORAL PAIN (Gastrointestinal disorders) [GENERAL MOUTH PAIN]	9	36	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0022070	59 YRS CAUCASIAN MALE	16JUN2003-18JUN2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [ACTIVE SUICIDAL IDEATION]	3	5	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023001	31 YRS CAUCASIAN FEMALE	16NOV2002-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			07JAN2003-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	UNK	54	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0023009	62 YRS CAUCASIAN FEMALE	13FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-28FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0023009	62 YRS CAUCASIAN FEMALE	15FEB2003-CONTINUE	ON	ABDOMINAL DISTENSION (Gastrointestinal disorders) [BLOATED]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	32	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	43	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023028	53 YRS CAUCASIAN FEMALE	12JUL2003-14JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	3	45	MOD	NO	N	N	N	N	N	N	NO NO	None
			18JUL2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	51	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0023047	26 YRS CAUCASIAN MALE	24JUL2003-27JUL2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [SHOULDER PAIN]	4	7	MOD	NO	N	N	N	N	N	N	NO NO	None
			05AUG2003-22AUG2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	18	19	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026012	44 YRS BLACK MALE	21FEB2003-05MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	13	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-15MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	19	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			03MAR2003-07MAR2003	ON	HEADACHE (Nervous system disorders) [INCREASE OF INTENSITY HEADACHE]	5	12	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0026012	44 YRS BLACK MALE	03MAR2003-17APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	46	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			04MAR2003-07MAR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	4	13	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0026024	44 YRS ORIENTAL FEMALE	09MAY2003-CONTINUE	ON	NECK PAIN (Musculoskeletal and connective tissue disorders) [LEFT LOWER NECK PAIN]	UNK	8	MOD	NO	N	N	N	N	N	N	NO NO	None
			16MAY2003-CONTINUE	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASE IN APPETITE]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0026028	35 YRS CAUCASIAN MALE	23JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0026028	35 YRS CAUCASIAN MALE	11JUL2003-CONTINUE	ON	MAJOR DEPRESSIVE DISORDER NOS (Psychiatric disorders) [PSYCHOTIC: DEPRESSION]	UNK	22	SEV	YES	N	N	Y	N	N	N	YES NO	None
			15JUL2003-18JUL2003	ON	ACUTE PSYCHOSIS (Psychiatric disorders) [ACUTE PSYCHOSIS]	4	26	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0028001	53 YRS CAUCASIAN MALE	14OCT2002-14OCT2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			01NOV2002-04NOV2002	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	4	23	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028003	53 YRS CAUCASIAN FEMALE	02OCT2002-13OCT2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	12	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			03OCT2002-CONTINUE	ON	FLATULENCE (Gastrointestinal disorders) [GAS]	UNK	4	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0028003	53 YRS CAUCASIAN FEMALE	03OCT2002-04NOV2002	ON	CHOLECYSTITIS NOS (Hepatobiliary disorders) [CHOLECYSTITIS EXACERBATION]	33	4	SEV	YES	N	N	Y	N	N	N	NO NO	None
			04OCT2002-09OCT2002	ON	FATIGUE (General disorders and administration site conditions) [INCREASED FATIGUE]	6	5	SEV	NO	N	N	N	N	N	N	NO YES	None
			04OCT2002-10OCT2002	ON	COGNITIVE DISORDER (Nervous system disorders) [COGNITIVE SLOWING]	7	5	SEV	NO	N	N	N	N	N	N	NO NO	None
			04OCT2002-13OCT2002	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	10	5	SEV	NO	N	N	N	N	N	N	NO NO	None
			19OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			29OCT2002-CONTINUE	ON	MICTURITION URGENCY (Renal and urinary disorders) [URINARY URGENCY]	UNK	30	MOD	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

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PLACEBO (BIPOLAR I)	E0028003	53 YRS CAUCASIAN FEMALE	04NOV2002-10NOV2002	ON	POST PROCEDURAL PAIN (Injury, poisoning and procedural complications) [SURGERY PAIN]	7	36	MOD	NO	N	N	N	N	N	N	NO NO	None
			22NOV2002-CONTINUE	ON	BACK INJURY NOS (Injury, poisoning and procedural complications) [SPRAINED C6]	UNK	54	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0028010	28 YRS CAUCASIAN FEMALE	06NOV2002-27NOV2002	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	22	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			10NOV2002-10DEC2002	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED LIBIDO]	31	6	SEV	NO	N	N	N	N	N	N	NO NO	None
			12NOV2002-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	8	SEV	NO	N	N	N	N	N	N	NO NO	Dose Changed

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PLACEBO (BIPOLAR I)	E0028010	28 YRS CAUCASIAN FEMALE	13NOV2002-03DEC2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	21	9	MOD	NO	N	N	N	N	N	N	NO NO	Dose Changed
					DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS (NOT DUE TO POSTURAL HYPOTENSION)]	21	9	SEV	NO	N	N	N	N	N	N	NO NO	Dose Changed
					DRY MOUTH (Gastrointestinal disorders) [WORSENING OF DRY MOUTH]	21	9	MOD	NO	N	N	N	N	N	N	NO NO	Dose Changed
					THIRST (General disorders and administration site conditions) [INCREASED THIRST]	21	9	MOD	NO	N	N	N	N	N	N	NO NO	Dose Changed
			13NOV2002-10DEC2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	28	9	SEV	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0028010	28 YRS CAUCASIAN FEMALE	30DEC2002-CONTINUE	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU SYMPTOMS]	UNK	56	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028011	36 YRS CAUCASIAN MALE	09DEC2002-22DEC2002	ON	PHOTOPHOBIA (Eye disorders) [PHOTOPHOBIA]	14	5	MIL	NO	N	N	N	N	N	N	NO NO	None
			09DEC2002-02JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			31DEC2002-14JAN2003	ON	SKIN IRRITATION (Skin and subcutaneous tissue disorders) [SKIN IRRITATION ON BOTH THIGHS]	15	27	MIL	NO	N	N	N	N	N	N	NO NO	None
			09JAN2003-09JAN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [WORSENED DIARRHEA]	1	36	SEV	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	36	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0028011	36 YRS CAUCASIAN MALE	13JAN2003-23JAN2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	11	40	MIL	NO	N	N	N	N	N	N	NO NO	None
			20JAN2003-29JAN2003	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	10	47	MIL	NO	N	N	N	N	N	N	NO NO	None
			27JAN2003-29JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	3	54	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028031	35 YRS CAUCASIAN MALE	13MAR2003-28MAR2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGINESS]	16	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0028031	35 YRS CAUCASIAN MALE	27MAR2003-31MAR2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [SELF MUTILATING AUDITORY HALLUCINATIONS]	5	17	SEV	YES	N	N	Y	N	N	N	YES NO	None
	E0028047	50 YRS BLACK FEMALE	11AUG2003-11AUG2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	29	MOD	NO	N	N	N	N	N	N	NO NO	None
			19AUG2003-22AUG2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGINESS]	4	37	MOD	NO	N	N	N	N	N	N	NO NO	None
			05SEP2003-07SEP2003	ON	CHEST PAIN (General disorders and administration site conditions) [CHEST PAIN]	3	54	MIL	NO	N	N	N	N	N	N	NO NO	None
					DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	3	54	SEV	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0028047	50 YRS BLACK FEMALE	05SEP2003-07SEP2003	ON	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [INCREASED SWEATING]	3	54	SEV	NO	N	N	N	N	N	N	NO NO	None
					VISION BLURRED (Eye disorders) [BLURRED VISION]	3	54	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0029014	34 YRS CAUCASIAN FEMALE	14FEB2003-19FEB2003	ON	BRUXISM (Psychiatric disorders) [GRINDING TEETH]	6	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			21FEB2003-28FEB2003	ON	NASOPHARYNGITIS (Infections and infestations) [HEAD COLD]	8	18	MOD	NO	N	N	N	N	N	N	NO NO	None
			11MAR2003-26MAR2003	ON	TENSION HEADACHE (Nervous system disorders) [TENSION HEADACHE]	16	36	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029023	41 YRS CAUCASIAN FEMALE	08APR2003-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0029023	41 YRS CAUCASIAN FEMALE	08APR2003-22APR2003	ON	NON-ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [INTENTIONAL OVERDOSE (1 - 2 TABS OVER 2WKS. - STUDY MEDICATION)]	15	1	SEV	NO	N	N	N	N	N	N	NO NO	None
			17APR2003-23APR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN (INCREASED FROM MEDICAL LISTING)]	7	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			18APR2003-23APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	6	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			05MAY2003-09MAY2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU SYMPTOMS]	5	28	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0029032	52 YRS CAUCASIAN MALE	10JUN2003-22JUN2003	ON	NASOPHARYNGITIS (Infections and infestations) [COMMON COLD]	13	1	SEV	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0029032	52 YRS CAUCASIAN MALE	25JUN2003-CONTINUE	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	UNK	16	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0029033	36 YRS CAUCASIAN MALE	16JUN2003-24JUN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	9	15	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0029039	30 YRS HISPANIC FEMALE	19JUL2003-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [WORSENING OF INSOMNIA]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			23JUL2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [GROGGY IN THE MORNING]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			26JUL2003-26JUL2003	ON	DISSOCIATIVE DISORDER NOS (Psychiatric disorders) [DISSOCIATIVE EPISODE]	1	12	MOD	NO	N	N	N	N	N	N	YES NO	None
	E0030003	39 YRS BLACK FEMALE	19DEC2002-CONTINUE	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [URI]	UNK	4	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0030009	55 YRS CAUCASIAN MALE	07MAR2003-CONTINUE	ON	PROSTATE INFECTION (Infections and infestations) [PROSTATE INFECTION]	UNK	44	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0030016	49 YRS CAUCASIAN MALE	04MAR2003-01MAY2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS]	59	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-19APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	27	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0030021	25 YRS CAUCASIAN MALE	21MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [EARLY AM SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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PLACEBO (BIPOLAR I)	E0030021	25 YRS CAUCASIAN MALE	21MAY2003-CONTINUE	ON	SENSATION OF BLOOD FLOW (General disorders and administration site conditions) [NOT DUE TO POSTURAL HYPOTENSION BLOOD RUSH TO HEAD]	UNK	2	MIL	NO	N	N	N	N	N	N	NO NO	Dose Changed
			04JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	16	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0031001	44 YRS CAUCASIAN FEMALE	01DEC2002-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	11	MOD	NO	N	N	N	N	N	N	NO NO	None
			02DEC2002-09DEC2002	ON	INFLUENZA (Infections and infestations) [INFLUENZA]	8	12	MOD	NO	N	N	N	N	N	N	NO NO	None
			02DEC2002-14DEC2002	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	13	12	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0031001	44 YRS CAUCASIAN FEMALE	04DEC2002-06DEC2002	ON	PYREXIA (General disorders and administration site conditions) [FEVER]	3	14	MOD	NO	N	N	N	N	N	N	NO NO	None
			14DEC2002-CONTINUE	ON	MENTAL IMPAIRMENT NOS (Nervous system disorders) [FEELINGS OF DULLNESS (DECREASED MENTAL COMPREHENSION)]	UNK	24	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031017	42 YRS CAUCASIAN MALE	09APR2003-10APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	2	9	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031018	24 YRS CAUCASIAN FEMALE	16APR2003-16APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031023	25 YRS CAUCASIAN FEMALE	04MAY2003-16MAY2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	13	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0031023	25 YRS CAUCASIAN FEMALE	06MAY2003-14MAY2003	ON	HEADACHE (Nervous system disorders) [INTERMITTENT HEADACHES]	9	8	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0033001	42 YRS OTHER MALE	13JAN2003-27JAN2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	15	5	MIL	NO	N	N	N	N	N	N	NO NO	None
			17JAN2003-CONTINUE	ON	AGITATION (Psychiatric disorders) [AGITATION]	UNK	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			17JAN2003-25JAN2003	ON	POLLAKIURIA (Renal and urinary disorders) [INCREASED URINARY FREQUENCY]	9	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			24JAN2003-24JAN2003	ON	HYPOAESTHESIA (Nervous system disorders) [RIGHT ARM NUMBNESS]	1	16	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0033001	42 YRS OTHER MALE	24JAN2003-24JAN2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [RIGHT ARM PAIN]	1	16	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0033004	37 YRS CAUCASIAN FEMALE	22JAN2003-22JAN2003	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	1	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JAN2003-31JAN2003	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	8	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			26JAN2003-26JAN2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [AUDITORY HALLUCINATION]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
					ILLUSION (Psychiatric disorders) [VISUAL ILLUSION]	1	10	MOD	NO	N	N	N	N	N	N	NO YES	None
					PANIC ATTACK (Psychiatric disorders) [FEELING OF PANIC]	1	10	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0033004	37 YRS CAUCASIAN FEMALE	29JAN2003-29JAN2003	ON	PANIC ATTACK (Psychiatric disorders) [FEELING OF PANIC]	1	13	MOD	NO	N	N	N	N	N	N	NO YES	None
			12FEB2003-12FEB2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [RIGHT HAND TWITCHING (NOT DUE TO EPS)]	1	27	MIL	NO	N	N	N	N	N	N	NO NO	None
			25FEB2003-CONTINUE	ON	JOINT SPRAIN (Injury, poisoning and procedural complications) [LEFT SPRAINED ANKLE]	UNK	40	MOD	NO	N	N	N	N	N	N	NO NO	None
			25FEB2003-25FEB2003	ON	SYNCOPE (Nervous system disorders) [SYNCOPE (NOT DUE TO POSTURAL HYPOTENSION)]	1	40	MIL	NO	N	N	N	N	N	N	NO NO	None
			01MAR2003-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	44	MOD	NO	N	N	N	N	N	N	NO NO	None
					TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	UNK	44	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0033010	26 YRS BLACK FEMALE	08FEB2003-20FEB2003	ON	INFLUENZA (Infections and infestations) [INFLUENZA]	13	5	MOD	NO	N	N	N	N	N	N	NO NO	None
			19MAR2003-19MAR2003	ON	ECTOPIC PREGNANCY (Pregnancy, puerperium and perinatal conditions) [ECTOPIC PREGNANCY]	1	44	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0033014	53 YRS CAUCASIAN MALE	20MAR2003-01APR2003	ON	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	13	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			21MAR2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			23MAR2003-31MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	9	5	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0033014	53 YRS CAUCASIAN MALE	23MAR2003-31MAR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	9	5	MOD	NO	N	N	N	N	N	N	NO NO	None
			05APR2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	18	MIL	NO	N	N	N	N	N	N	NO NO	None
			18APR2003-CONTINUE	ON	INTERVERTEBRAL DISC HERNIATION (Musculoskeletal and connective tissue disorders) [HERNIATED SPINAL DISC PAIN]	UNK	31	MOD	YES	N	N	Y	N	N	N	NO NO	None
	E0035002	46 YRS CAUCASIAN MALE	05DEC2002-12DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	8	15	MIL	NO	N	N	N	N	N	N	NO YES	None
			14DEC2002-CONTINUE	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	UNK	24	MOD	YES	N	N	Y	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0035020	47 YRS BLACK FEMALE	19APR2003- 19APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	2	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0037003	38 YRS HISPANIC FEMALE	03FEB2003- CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039007	39 YRS HISPANIC MALE	05DEC2002- 05DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			05DEC2002- 12DEC2002	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002- 06DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0039007	39 YRS HISPANIC MALE	12DEC2002-CONTINUE	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [IMPOTENCE]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			14DEC2002-CONTINUE	ON	OBSESSIVE-COMPULSIVE DISORDER (Psychiatric disorders) [(COMPULSIVE) BEHAVIOR]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			24DEC2002-24DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	21	MIL	NO	N	N	N	N	N	N	NO NO	None
			24DEC2002-27DEC2002	ON	FEELING HOT (General disorders and administration site conditions) [WARM FEELING IN NECK]	4	21	MIL	NO	N	N	N	N	N	N	NO NO	None
			26DEC2002-04JAN2003	ON	ERYTHEMA (Skin and subcutaneous tissue disorders) [REDNESS ON BILATERAL CHEEKS]	10	23	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0039007	39 YRS HISPANIC MALE	02JAN2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	30	MOD	NO	N	N	N	N	N	N	NO YES	None
					PRURITUS (Skin and subcutaneous tissue disorders) [PRURITIC GROIN]	UNK	30	MOD	NO	N	N	N	N	N	N	NO NO	None
			02JAN2003-10JAN2003	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	9	30	MIL	NO	N	N	N	N	N	N	NO NO	None
			02JAN2003-11JAN2003	ON	DIZZINESS (Nervous system disorders) [LIGHT - HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	10	30	MIL	NO	N	N	N	N	N	N	NO NO	None
			04JAN2003-09JAN2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FLASHES]	6	32	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039007	39 YRS HISPANIC MALE	13JAN2003-19JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	7	41	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039022	33 YRS BLACK FEMALE	06MAR2003-06MAR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-07MAR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003-16MAR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	3	18	MIL	NO	N	N	N	N	N	N	NO NO	None
			15MAR2003-19MAR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	5	19	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039022	33 YRS BLACK FEMALE	26MAR2003-27MAR2003	ON	TINNITUS (Ear and labyrinth disorders) [RINGING IN EARS]	2	30	MIL	NO	N	N	N	N	N	N	NO NO	None
			28MAR2003-18APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	22	32	MIL	NO	N	N	N	N	N	N	NO YES	None
			31MAR2003-31MAR2003	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	1	35	MIL	NO	N	N	N	N	N	N	NO NO	None
			08APR2003-09APR2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [TWITCHING RIGHT EYE (NOT DUE TO EPS)]	2	43	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039030	52 YRS CAUCASIAN FEMALE	07APR2003-07APR2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [BILATERAL KNEE PAIN]	1	15	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039030	52 YRS CAUCASIAN FEMALE	07APR2003-07APR2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [BILATERAL ARM PAIN]	1	15	MOD	NO	N	N	N	N	N	N	NO NO	None
			05MAY2003-CONTINUE	ON	PAIN NOS (General disorders and administration site conditions) [GENERALIZED BODY ACHES]	UNK	43	MIL	NO	N	N	N	N	N	N	NO NO	None
			05MAY2003-08MAY2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	4	43	MIL	NO	N	N	N	N	N	N	NO NO	None
			16MAY2003-16MAY2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE (STUDY MEDICATION)]	1	54	MIL	NO	N	N	N	N	N	N	NO NO	None
			06JUN2003-08JUN2003	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	3	75	SEV	YES	N	N	Y	N	N	N	NO NO	None

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Listing 12.2.7.1 Adverse Events

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PLACEBO (BIPOLAR I)	E0039031	34 YRS CAUCASIAN FEMALE	26MAR2003-31MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	6	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			29MAR2003-03APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	6	6	MIL	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	6	MIL	NO	N	N	N	N	N	N	NO NO	None
			04APR2003-07APR2003	ON	RIGORS (General disorders and administration site conditions) [CHILLS]	4	12	MIL	NO	N	N	N	N	N	N	NO NO	None
			04APR2003-09MAY2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [NON PRODUCTIVE COUGH]	36	12	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039031	34 YRS CAUCASIAN FEMALE	11APR2003-12APR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	2	19	MOD	NO	N	N	N	N	N	N	NO NO	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	19	MOD	NO	N	N	N	N	N	N	NO NO	None
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	2	19	MOD	NO	N	N	N	N	N	N	NO NO	None
			01MAY2003-01MAY2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE (THYROTAB)]	1	39	MIL	NO	N	N	N	N	N	N	NO NO	None
			08MAY2003-08MAY2003	ON	PYREXIA (General disorders and administration site conditions) [FEVER]	1	46	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039031	34 YRS CAUCASIAN FEMALE	08MAY2003-10MAY2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	3	46	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039037	33 YRS CAUCASIAN FEMALE	18APR2003-04MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	17	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-10MAY2003	ON	HEADACHE (Nervous system disorders) [WORSENED HEADACHES (FRONT OF HEAD)]	17	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			28APR2003-09MAY2003	ON	DIZZINESS (Nervous system disorders) [LIGHT - HEADED WHEN STANDING FROM SITTING UNKNOWN WHETHER DUE TO ORTHOSTATIC HYPOTENSION]	12	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	30	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0039037	33 YRS CAUCASIAN FEMALE	18MAY2003-CONTINUE	ON	MUSCLE SPASMS (Musculoskeletal and connective tissue disorders) [MUSCLE SPASMS NOT DUE TO EPS]	UNK	33	MOD	NO	N	N	N	N	N	N	NO NO	None
			18MAY2003-07JUN2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [SORE JOINTS]	21	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			30MAY2003-CONTINUE	ON	PRODUCTIVE COUGH (Respiratory, thoracic and mediastinal disorders) [PRODUCTIVE COUGH]	UNK	45	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039038	40 YRS BLACK FEMALE	05MAY2003-05MAY2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE OF STUDY MEDICATION]	1	13	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039038	40 YRS BLACK FEMALE	05MAY2003-09MAY2003	ON	ASTHMA NOS (Respiratory, thoracic and mediastinal disorders) [ASTHMA ATTACK]	5	13	SEV	YES	N	N	Y	N	N	N	NO NO	Temporarily Stopped
			18JUN2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	57	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039047	32 YRS BLACK FEMALE	20MAY2003-24JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	36	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07JUN2003-10JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZY WHEN STANDING (DUE TO POSTURAL HYPOTENSION)]	4	20	MOD	NO	N	N	N	N	N	N	NO YES	None
			07JUN2003-01JUL2003	ON	PRODUCTIVE COUGH (Respiratory, thoracic and mediastinal disorders) [PRODUCTIVE COUGH]	25	20	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039047	32 YRS BLACK FEMALE	08JUN2003-09JUN2003	ON	PYREXIA (General disorders and administration site conditions) [FEVER]	2	21	MIL	NO	N	N	N	N	N	N	NO NO	None
			09JUN2003-20JUN2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [BILATERAL LEG PAIN]	12	22	MOD	NO	N	N	N	N	N	N	NO NO	None
			09JUN2003-21JUN2003	ON	MUSCLE SPASMS (Musculoskeletal and connective tissue disorders) [MUSCLE SPASMS BILATERAL LEGS (NOT DUE TO EPS)]	13	22	MOD	NO	N	N	N	N	N	N	NO NO	None
			17JUN2003-17JUN2003	ON	POST PROCEDURAL PAIN (Injury, poisoning and procedural complications) [ABDOMINAL PAIN (SECONDARY TO HYSTEROSALPINGOGRAM)]	1	30	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039047	32 YRS BLACK FEMALE	17JUN2003-03JUL2003	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL CRAMPING]	17	30	MOD	NO	N	N	N	N	N	N	NO NO	None
			07JUL2003-10JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FEELING TIRED]	4	50	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039059	55 YRS BLACK FEMALE	11JUL2003-17JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS POST - DOSE]	7	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			12JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			16JUL2003-22JUL2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	7	6	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039059	55 YRS BLACK FEMALE	17JUL2003-17JUL2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN]	1	7	MIL	NO	N	N	N	N	N	N	NO NO	None
			22JUL2003-23JUL2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [LEFT LEG CRAMPS (NOT DUE TO EPS)]	2	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			26JUL2003-CONTINUE	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [BILATERAL PEDAL EDEMA]	UNK	16	MIL	NO	N	N	N	N	N	N	NO YES	None
			11AUG2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	32	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0041010	32 YRS CAUCASIAN MALE	02MAY2003-12JUN2003	ON	HEADACHE (Nervous system disorders) [INCREASE OF FREQUENCY INTERMITTENT HEADACHE]	42	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0041010	32 YRS CAUCASIAN MALE	01JUN2003-05JUN2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [INTERMITTENT STOMACH CRAMPS]	5	33	MIL	NO	N	N	N	N	N	N	NO NO	None
			07JUN2003-13JUN2003	ON	MANIA (Psychiatric disorders) [MANIC EPISODE]	7	39	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0041012	47 YRS BLACK FEMALE	07JUL2003-18JUL2003	ON	BRONCHITIS NOS (Respiratory, thoracic and mediastinal disorders) [BRONCHITIS]	12	19	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0001004	25 YRS CAUCASIAN FEMALE	27MAY2003-10JUN2003	ON	BRONCHITIS NOS (Respiratory, thoracic and mediastinal disorders) [BRONCHITIS]	15	27	MOD	NO	N	N	N	N	N	N	NO NO	None
					NASOPHARYNGITIS (Infections and infestations) [COMMON COLD]	15	27	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0005023	29 YRS BLACK FEMALE	16FEB2003-23FEB2003	ON	INCREASED TENDENCY TO BRUISE (Skin and subcutaneous tissue disorders) [BRUISING EASILY]	8	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			04MAR2003-07MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	4	28	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0005034	25 YRS CAUCASIAN FEMALE	04JUN2003-11JUN2003	ON	EAR INFECTION VIRAL NOS (Infections and infestations) [VIRAL INNER EAR INFECTION]	8	51	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0005041	52 YRS CAUCASIAN FEMALE	10JUL2003-12JUL2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS SECONDARY TO EPS (AKATHISIA)]	3	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-24JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	7	25	MOD	NO	N	N	N	N	N	N	NO YES	None
			21JUL2003-22JUL2003	ON	AKATHISIA (Nervous system disorders) [JITTERINESS SECONDARY TO EPS (AKATHISIA)]	2	28	MIL	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-25JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	32	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0007010	59 YRS CAUCASIAN FEMALE	25APR2003-16JUN2003	ON	VENTRICULAR EXTRASYSTOLES (Cardiac disorders) [VENTRICULOR PREMATURE CONTRACTIONS]	53	8	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0007010	59 YRS CAUCASIAN FEMALE	26APR2003-01MAY2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	6	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			21MAY2003-10JUN2003	ON	JOINT SPRAIN (Injury, poisoning and procedural complications) [SPRAINED RIGHT FOOT]	21	34	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0009007	31 YRS CAUCASIAN MALE	05FEB2003-13FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS AFTER DOSING (NOT DUE TO POSTURAL HYPOTENSION)]	9	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			15FEB2003-17FEB2003	ON	PARAESTHESIA (Nervous system disorders) [TINGLING ON BOTH LEGS WHEN SITTING OR LAYING]	3	13	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0011011	28 YRS BLACK FEMALE	23FEB2003-26FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	4	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			21MAR2003-09APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	20	30	MOD	NO	N	N	N	N	N	N	NO YES	None
			14APR2003-15APR2003	ON	FOOD POISONING NOS (Gastrointestinal disorders) [VOMITING, SECONDARY TO FOOD]	2	54	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0011013	54 YRS CAUCASIAN FEMALE	17APR2003-19APR2003	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTHACHE]	3	1	MIL	NO	N	N	N	N	N	N	NO NO	None
			22MAY2003-03JUN2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	13	36	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0011013	54 YRS CAUCASIAN FEMALE	02JUN2003-04JUN2003	ON	PHOTOPSIA (Eye disorders) [VISUAL FLASHES OF LIGHT]	3	47	MIL	NO	N	N	N	N	N	N	NO NO	None
			04JUN2003-CONTINUE	ON	ASTHMA NOS (Respiratory, thoracic and mediastinal disorders) [ASTHMA]	UNK	49	MOD	NO	N	N	N	N	N	N	NO NO	None
			04JUN2003-04JUN2003	ON	ASTHMA NOS (Respiratory, thoracic and mediastinal disorders) [ASTHMA, ACUTE ATTACK]	1	49	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0011014	34 YRS BLACK FEMALE	13APR2003-20APR2003	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL PAIN]	8	7	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	8	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0011021	38 YRS CAUCASIAN FEMALE	08JUN2003-14JUN2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY TRACT INFECTION]	7	18	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0013008	33 YRS CAUCASIAN FEMALE	01MAY2003-01MAY2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	37	MOD	NO	N	N	N	N	N	N	NO NO	None
			01MAY2003-07MAY2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	7	37	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0014001	25 YRS CAUCASIAN FEMALE	28FEB2003-25MAR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	26	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-01APR2003	ON	FREQUENT BOWEL MOVEMENTS (Gastrointestinal disorders) [FREQUENT BOWEL MOVEMENTS]	26	10	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0014001	25 YRS CAUCASIAN FEMALE	13MAR2003-25MAR2003	ON	SINUSITIS NOS (Infections and infestations) [SINUSITIS]	13	16	MOD	NO	N	N	N	N	N	N	NO NO	None
			22MAR2003-29MAR2003	ON	PANCREATITIS NOS (Gastrointestinal disorders) [PANCREATITIS]	8	25	SEV	YES	N	N	Y	N	N	N	NO NO	Temporarily Stopped
			03APR2003-CONTINUE	ON	SLUGGISHNESS (General disorders and administration site conditions) [AM - SLUGGISHNESS]	UNK	37	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0014013	31 YRS CAUCASIAN FEMALE	06JUN2003-CONTINUE	ON	BLEPHAROSPASM (Eye disorders) [BLEPHAROSPASM]	UNK	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JUN2003-07JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	32	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			14JUN2003-CONTINUE	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC DIZZINESS (DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0014014	38 YRS CAUCASIAN MALE	10JUN2003-11JUN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					HEADACHE (Nervous system disorders) [HEADACHE]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			19JUN2003-08AUG2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	51	10	MOD	NO	N	N	N	N	N	N	NO YES	None
					LIBIDO DECREASED (Psychiatric disorders) [DECREASED SEX DRIVE]	51	10	SEV	NO	N	N	N	N	N	N	NO YES	None
			28JUL2003-03AUG2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	7	49	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0018005	24 YRS CAUCASIAN MALE	21DEC2002-23DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHES]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			21DEC2002-30DEC2002	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	10	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14JAN2003-26JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHESIA]	13	26	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0018012	33 YRS CAUCASIAN FEMALE	12FEB2003-12FEB2003	ON	BRONCHOSPASM NOS (Respiratory, thoracic and mediastinal disorders) [WORSENING OF REACTIVE AIRWAY DISEASE]	1	20	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0019019	22 YRS CAUCASIAN FEMALE	25JAN2003-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [PROBLEMS WITH EQUILIBRIUM NOT DUE TO ORTHOSTATIC HYPOTENSION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			26JAN2003-04FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	10	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			03FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			06FEB2003-CONTINUE	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [SORE CHEST MUSCLES]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0019033	58 YRS CAUCASIAN MALE	05APR2003-12APR2003	ON	HERPES SIMPLEX (Infections and infestations) [COLD SORE]	8	19	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0019038	19 YRS CAUCASIAN MALE	25APR2003-06MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	12	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAY2003-07MAY2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [POSSIBLE UNINTENTIONAL OVERDOSE OF STUDY DRUG]	1	14	MIL	NO	N	N	N	N	N	N	NO NO	None
			29MAY2003-17JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	20	36	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUN2003-04JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC HYPOTENSION]	1	42	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0019038	19 YRS CAUCASIAN MALE	04JUN2003-17JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	14	42	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019046	35 YRS CAUCASIAN FEMALE	30JUN2003-11JUL2003	ON	PARAESTHESIA (Nervous system disorders) [PARASTHESIA]	12	5	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	12	5	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			30JUN2003-18JUL2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	19	5	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			04JUL2003-04JUL2003	ON	HYPOREFLEXIA (Nervous system disorders) [DELAYED REACTION TO HEAT (DECREASE IN REFLEXIVE ACTION)]	1	9	SEV	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0019046	35 YRS CAUCASIAN FEMALE	04JUL2003-21AUG2003	ON	THERMAL BURN (Injury, poisoning and procedural complications) [RIGHT ARM BURN]	49	9	MIL	NO	N	N	N	N	N	N	NO NO	None
			01AUG2003-02AUG2003	ON	AGITATION (Psychiatric disorders) [AGITATION]	2	37	MOD	NO	N	N	N	N	N	N	NO NO	None
					RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS (NOT DUE TO EPS)]	2	37	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0019047	23 YRS CAUCASIAN MALE	09JUL2003-01AUG2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	24	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			09AUG2003-22AUG2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	14	33	MOD	NO	N	N	N	N	N	N	NO YES	None
			20AUG2003-20AUG2003	ON	PULMONARY CONGESTION (Respiratory, thoracic and mediastinal disorders) [CHEST CONGESTION]	1	44	MIL	NO	N	N	N	N	N	N	NO NO	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0019048	34 YRS CAUCASIAN FEMALE	11JUL2003-16JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					TREMOR (Nervous system disorders) [TREMOR (HANDS) "NOT DUE TO EPS"]	6	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-18JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZYNESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-CONTINUE	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0022006	20 YRS CAUCASIAN FEMALE	13NOV2002-20NOV2002	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [VIRAL ILLNESS (UPPER RESPIRATORY INFECTION)]	8	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			29NOV2002-29NOV2002	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	18	MIL	NO	N	N	N	N	N	N	NO NO	None
			28DEC2002-06JAN2003	ON	LARYNGITIS NOS (Respiratory, thoracic and mediastinal disorders) [LARYNGITIS]	10	47	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022047	51 YRS CAUCASIAN MALE	20MAY2003-23MAY2003	ON	ARTHROPOD BITE (Injury, poisoning and procedural complications) [INSECT BITES]	4	54	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022075	51 YRS CAUCASIAN FEMALE	10JUL2003-14JUL2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	5	3	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0023012	42 YRS CAUCASIAN FEMALE	15MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	38	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023016	42 YRS CAUCASIAN FEMALE	30MAY2003-04JUN2003	ON	DYSMENORRHOEA (Reproductive system and breast disorders) [MENSTRUAL CRAMPS]	6	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			31MAY2003-21JUN2003	ON	STAPHYLOCOCCAL INFECTION (Infections and infestations) [STAPH INFECTION IN HANDS]	22	10	MOD	NO	N	N	N	N	N	N	NO NO	None
			12JUL2003-CONTINUE	ON	STAPHYLOCOCCAL INFECTION (Infections and infestations) [STAPH INFECTION IN HANDS]	UNK	52	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023018	18 YRS CAUCASIAN MALE	05APR2003-10APR2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	6	10	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0023046	62 YRS BLACK FEMALE	16AUG2003-24AUG2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	9	25	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026006	37 YRS CAUCASIAN MALE	09JAN2003-11JAN2003	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	3	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			09JAN2003-17JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	9	2	MOD	NO	N	N	N	N	N	N	NO NO	None
			09JAN2003-19JAN2003	ON	HEADACHE (Nervous system disorders) [WORSENING OF HEADACHE]	11	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			20JAN2003-29JAN2003	ON	PHOTOPHOBIA (Eye disorders) [PHOTOPHOBIA]	10	13	MIL	NO	N	N	N	N	N	N	NO NO	None
			26JAN2003-30JAN2003	ON	DYSPEPSIA (Gastrointestinal disorders) [DYSPEPSIA]	5	19	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0026006	37 YRS CAUCASIAN MALE	19FEB2003-CONTINUE	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	UNK	43	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0026021	35 YRS CAUCASIAN FEMALE	28APR2003-12MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	15	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			28APR2003-13MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	16	6	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGY]	16	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			03MAY2003-12MAY2003	ON	INFLUENZA (Infections and infestations) [INFLUENZA]	10	11	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0026021	35 YRS CAUCASIAN FEMALE	08MAY2003-08MAY2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [STUDY DRUG OVERDOSE (ACCIDENTAL)]	1	16	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0026027	40 YRS CAUCASIAN FEMALE	19JUN2003-19JUN2003	ON	CONVULSIONS NOS (Nervous system disorders) [SEIZURE]	1	1	SEV	YES	N	N	N	N	N	Y	YES NO	Permanently Stopped
	E0029004	34 YRS BLACK FEMALE	23NOV2002-26NOV2002	ON	HICCUPS (Respiratory, thoracic and mediastinal disorders) [HICCUPS]	4	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-27NOV2002	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	5	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			29NOV2002-22DEC2002	ON	BRONCHITIS NOS (Respiratory, thoracic and mediastinal disorders) [BRONCHITIS]	24	11	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0029004	34 YRS BLACK FEMALE	01DEC2002-31DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	31	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			21DEC2002-25DEC2002	ON	PAIN NOS (General disorders and administration site conditions) [BODY ACHES]	5	33	MOD	NO	N	N	N	N	N	N	NO NO	None
					RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS (NOT DUE TO EPS)]	5	33	MOD	NO	N	N	N	N	N	N	NO NO	None
			31DEC2002-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRY VISION]	UNK	43	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-16JAN2003	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [LEFT ABDOMINAL PAIN]	2	58	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0029013	39 YRS CAUCASIAN FEMALE	19FEB2003-21FEB2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0029013	39 YRS CAUCASIAN FEMALE	20FEB2003-CONTINUE	ON	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [INCREASED SWEATING]	UNK	2	MIL	NO	N	N	N	N	N	N	NO NO	None
			23FEB2003-17MAR2003	ON	FLATULENCE (Gastrointestinal disorders) [GAS]	23	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			24FEB2003-24FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	6	MOD	NO	N	N	N	N	N	N	NO NO	None
			26FEB2003-17MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	20	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-28MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	19	20	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25MAR2003-31MAR2003	ON	DERMATITIS EXFOLIATIVE NOS (Skin and subcutaneous tissue disorders) [SKIN PEELING ON FINGERS]	7	35	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0029013	39 YRS CAUCASIAN FEMALE	08APR2003-15APR2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	8	49	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0029024	48 YRS CAUCASIAN FEMALE	18MAR2003-26MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	9	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAR2003-26MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	8	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAR2003-03APR2003	ON	HEADACHE (Nervous system disorders) [WORSENING OF HEADACHE]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			30MAR2003-06APR2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [LOWER BACK PAIN]	8	14	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0029024	48 YRS CAUCASIAN FEMALE	30MAR2003-06APR2003	ON	NECK PAIN (Musculoskeletal and connective tissue disorders) [NECK PAIN]	8	14	MOD	NO	N	N	N	N	N	N	NO NO	None
			10APR2003-14APR2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU SYMPTOMS]	5	25	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0029038	61 YRS CAUCASIAN MALE	08JUL2003-14JUL2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	7	2	MOD	NO	N	N	N	N	N	N	YES YES	None
	E0031004	37 YRS CAUCASIAN FEMALE	21DEC2002-21DEC2002	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [LOWER BACK PAIN]	1	3	MOD	NO	N	N	N	N	N	N	NO NO	None
			25DEC2002-15JAN2003	ON	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	22	7	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0031004	37 YRS CAUCASIAN FEMALE	27DEC2002-CONTINUE	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [CONGESTION (SINUS)]	UNK	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			27DEC2002-29JAN2003	ON	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	34	9	MOD	NO	N	N	N	N	N	N	NO NO	None
			29DEC2002-CONTINUE	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [LOWER BACK PAIN]	UNK	11	MOD	NO	N	N	N	N	N	N	NO NO	None
			01JAN2003-CONTINUE	ON	SINUSITIS NOS (Infections and infestations) [SINUSITIS]	UNK	14	MOD	NO	N	N	N	N	N	N	NO NO	None
			27JAN2003-27JAN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	40	MOD	NO	N	N	N	N	N	N	NO NO	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0031013	33 YRS CAUCASIAN FEMALE	16MAR2003-15MAY2003	ON	HEADACHE (Nervous system disorders) [INTERMITTENT HEADACHES]	61	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-05APR2003	ON	CHEST TIGHTNESS (General disorders and administration site conditions) [TIGHTNESS IN CHEST]	13	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-01MAY2003	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE ACHES]	39	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			26MAR2003-10MAY2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	46	14	MIL	NO	N	N	N	N	N	N	NO YES	None
			31MAR2003-05APR2003	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	6	19	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.1 Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0031013	33 YRS CAUCASIAN FEMALE	19APR2003-01MAY2003	ON	INFLUENZA (Infections and infestations) [INFLUENZA]	13	38	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031019	47 YRS CAUCASIAN MALE	12APR2003-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-18APR2003	ON	HEADACHE (Nervous system disorders) [INTERMITTENT HEADACHES]	4	5	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0033007	58 YRS CAUCASIAN FEMALE	11MAR2003-15MAR2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [MILD DYSPNEA]	5	43	MIL	NO	N	N	N	N	N	N	NO NO	None
			12MAR2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	44	MIL	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0033007	58 YRS CAUCASIAN FEMALE	22MAR2003-23MAR2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [MILD DYSPNEA]	2	54	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0033013	29 YRS CAUCASIAN FEMALE	20FEB2003-02MAR2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [MILD DYSPNEA]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20FEB2003-15MAR2003	ON	INSOMNIA (Psychiatric disorders) [SLEEPLESSNESS]	24	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0033016	34 YRS HISPANIC FEMALE	10MAY2003-19MAY2003	ON	CARPAL TUNNEL SYNDROME (Nervous system disorders) [WRIST PAIN (CARPEL TUNNEL)]	10	3	MIL	NO	N	N	N	N	N	N	NO NO	None
			12MAY2003-13MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	2	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0033016	34 YRS HISPANIC FEMALE	16MAY2003-19MAY2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	4	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAY2003-19MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	3	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAY2003-20MAY2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	2	12	MIL	NO	N	N	N	N	N	N	NO YES	None
					ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS (DUE TO POSTURAL HYPOTENSION)]	2	12	MIL	NO	N	N	N	N	N	N	NO NO	None
			19MAY2003-09JUN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	22	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-13JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	23	15	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0033016	34 YRS HISPANIC FEMALE	25MAY2003-CONTINUE	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [RIGHT EYE TWITCH (NOT DUE TO EPS)]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-12JUN2003	ON	FACIAL PAIN (Musculoskeletal and connective tissue disorders) [THROBBING PAIN ON RIGHT SIDE OF FACE]	19	18	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUN2003-03JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	3	25	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JUN2003-08JUN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	3	30	MIL	NO	N	N	N	N	N	N	NO NO	None
			13JUN2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	37	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0033016	34 YRS HISPANIC FEMALE	19JUN2003-CONTINUE	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	UNK	43	MOD	NO	N	N	N	N	N	N	NO YES	None
			19JUN2003-23JUN2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FLASHES]	5	43	MIL	NO	N	N	N	N	N	N	NO NO	None
					FLUSHING (Vascular disorders) [HOT FLASHES]	5	43	MIL	NO	N	N	N	N	N	N	NO NO	None
			22JUN2003-22JUN2003	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE ON STUDY MEDICATION]	1	46	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0034007	43 YRS CAUCASIAN FEMALE	19MAY2003-30MAY2003	ON	INFLUENZA LIKE ILLNESS (General disorders and administration site conditions) [FLU LIKE SYMPTOMS]	12	4	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0034007	43 YRS CAUCASIAN FEMALE	20JUN2003-23JUN2003	ON	JOINT SPRAIN (Injury, poisoning and procedural complications) [SPRAINED NECK MUSCLE]	4	36	MIL	NO	N	N	N	N	N	N	NO NO	None
			07JUL2003-07JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	1	53	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0035010	57 YRS BLACK FEMALE	12JAN2003-04MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	52	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24JAN2003-10FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	18	15	MIL	NO	N	N	N	N	N	N	NO NO	Dose Changed
			24JAN2003-20FEB2003	ON	RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	28	15	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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PLACEBO (BIPOLAR II)	E0035010	57 YRS BLACK FEMALE	05FEB2003-15FEB2003	ON	GASTROENTERITIS VIRAL NOS (Infections and infestations) [STOMACH FLU]	11	27	MIL	NO	N	N	N	N	N	N	NO NO	Dose Changed
	E0035022	48 YRS BLACK FEMALE	14MAY2003-19MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	6	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039003	34 YRS BLACK FEMALE	02DEC2002-03DEC2002	ON	TOOTHACHE (Gastrointestinal disorders) [TOOTH ACHE]	2	8	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0041002	47 YRS BLACK MALE	22JAN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			07FEB2003-CONTINUE	ON	SEXUAL DYSFUNCTION NOS (Reproductive system and breast disorders) [SEXUAL DYSFUNCTION]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0041005	49 YRS CAUCASIAN MALE	21MAR2003-27MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	7	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			07APR2003-10APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	4	34	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	57 YRS CAUCASIAN FEMALE	04FEB2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			05FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			16FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0002018	48 YRS CAUCASIAN MALE	24JUL2003-27JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	4	1	SEV	NO	N	N	N	N	N	N	YES YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	37 YRS CAUCASIAN FEMALE	26DEC2002-26DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	4	SEV	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0003007	25 YRS CAUCASIAN FEMALE	02JAN2003-09JAN2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			03JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			10JAN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DIFFICULTY WAKING]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	20 YRS CAUCASIAN FEMALE	06MAY2003-08MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			24MAY2003-24MAY2003	ON	ALCOHOL INTOLERANCE (Metabolism and nutrition disorders) [INCREASED SENSITIVITY TO ALCOHOL]	1	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			20JUN2003-24JUN2003	ON	FLATULENCE (Gastrointestinal disorders) [ABDOMINAL GAS]	5	47	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JUL2003-02JUL2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	59	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004002	24 YRS CAUCASIAN FEMALE	02OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0004002	24 YRS CAUCASIAN FEMALE	02OCT2002-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [INTERMITTENT DROWSINESS PM]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0004013	24 YRS CAUCASIAN FEMALE	15JAN2003-07FEB2003	ON	SEDATION (Nervous system disorders) [AM SEDATION]	24	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			16JAN2003-07FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	23	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			22JAN2003-02FEB2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	12	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004018	24 YRS CAUCASIAN MALE	20MAR2003-CONTINUE	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0004018	24 YRS CAUCASIAN MALE	20MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	23	MIL	NO	N	N	N	N	N	N	NO YES	None
			03MAY2003-03MAY2003	ON	GAIT ABNORMAL (General disorders and administration site conditions) [UNSTEADY GAIT]	1	46	MOD	NO	N	N	N	N	N	N	NO YES	None
					VISION BLURRED (Eye disorders) [BLURRED VISION]	1	46	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0004021	53 YRS CAUCASIAN MALE	15MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS IN MORNING]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0004021	53 YRS CAUCASIAN MALE	15MAY2003-28MAY2003	ON	IRRITABILITY (Psychiatric disorders) [INCREASED IRRITABILITY]	14	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			16MAY2003-23JUL2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	69	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005002	48 YRS CAUCASIAN MALE	03OCT2002-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			04OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	48 YRS CAUCASIAN MALE	08OCT2002-CONTINUE	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA NOT RELATED TO ORTHOSTATIC HYPOTENSION]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005004	36 YRS CAUCASIAN FEMALE	02OCT2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
			03OCT2002-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT RELATED TO ORTHOSTATIC HYPOTENSION)]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0005004	36 YRS CAUCASIAN FEMALE	03OCT2002-04OCT2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005013	43 YRS CAUCASIAN FEMALE	07NOV2002-11NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT RELATED TO ORTHOSTATIC HYPOTENSION)]	5	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			07NOV2002-13NOV2002	ON	DYSKINESIA (Nervous system disorders) [MOTOR INCOORDINATION (DYSKINESIA)]	7	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	7	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR I)	E0005024	19 YRS CAUCASIAN FEMALE	10FEB2003-CONTINUE	ON	SEDATION (Nervous system di sorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			11FEB2003-21FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-24MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	1	43	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005027	41 YRS CAUCASIAN MALE	12MAR2003-31MAR2003	ON	SEDATION (Nervous system di sorders) [SEDATION]	20	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			17MAR2003-31MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	15	7	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0005037	56 YRS CAUCASIAN FEMALE	07MAY2003-11MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			07MAY2003-30MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [WORSENING OF HEARTBURN]	24	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			16MAY2003-18MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	3	10	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005042	50 YRS CAUCASIAN MALE	24JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0005042	50 YRS CAUCASIAN MALE	24JUN2003-02JUL2003	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADY]	9	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0006005	37 YRS CAUCASIAN FEMALE	09DEC2002-03JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION IN AM]	26	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			10DEC2002-12JAN2003	ON	THIRST (General disorders and administration site conditions) [INCREASED THIRST]	34	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JAN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [INTERMITTENT AM SEDATION]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	None
			13JAN2003-CONTINUE	ON	THIRST (General disorders and administration site conditions) [INTERMITTENT THIRST]	UNK	40	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0006018	57 YRS CAUCASIAN MALE	13MAR2003-17MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [EXTREME SLEEPINESS]	5	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14MAR2003-17MAR2003	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	4	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			15MAR2003-17MAR2003	ON	COORDINATION ABNORMAL NOS (Nervous system disorders) [LOSS OF COORDINATION (NOT DUE TO EPS)]	3	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0007013	60 YRS CAUCASIAN FEMALE	25JUN2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	13	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0010004	57 YRS HISPANIC FEMALE	11DEC2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			12DEC2002-CONTINUE	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [LIGHTHEADED DUE TO POSTURAL HYPOTENSION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010012	51 YRS CAUCASIAN FEMALE	07JAN2003-09JAN2003	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			07JAN2003-31JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-27JAN2003	ON	MUSCLE SPASMS (Musculoskeletal and connective tissue disorders) [MUSCLE SPASMS (NOT DUE TO EPS)]	13	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0010012	51 YRS CAUCASIAN FEMALE	30JAN2003-10FEB2003	ON	HEADACHE (Nervous system di sorders) [HEADACHE]	12	24	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010024	39 YRS CAUCASIAN MALE	05MAY2003-05MAY2003	ON	SEDATION (Nervous system di sorders) [SEDATION]	1	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06MAY2003-08MAY2003	ON	HEADACHE (Nervous system di sorders) [HEADACHE]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAY2003-07MAY2003	ON	DIZZINESS POSTURAL (Nervous system di sorders) [ORTHOSTATIC DIZZINESS]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			16MAY2003-16MAY2003	ON	DIZZINESS POSTURAL (Nervous system di sorders) [ORTHOSTATIC DIZZINESS]	1	12	MOD	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	39 YRS CAUCASIAN MALE	22MAY2003-22MAY2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	18	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUN2003-13JUN2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	13	28	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0010032	38 YRS CAUCASIAN FEMALE	11JUL2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATIVISM]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14JUL2003-CONTINUE	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	UNK	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					ORTHOSTATIC HYPOTENSION (Vascular disorders) [FAINTING FEELING (DUE TO POSTURAL HYPOTENSION)]	UNK	5	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR I)	E0011025	47 YRS CAUCASIAN FEMALE	29JUL2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	34	MIL	NO	N	N	N	N	N	N	NO YES	None
			13AUG2003-13AUG2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	49	MIL	NO	N	N	N	N	N	N	NO YES	None
			14AUG2003-14AUG2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	50	MIL	NO	N	N	N	N	N	N	NO YES	None
			20AUG2003-20AUG2003	ON	CHOKING SENSATION (Respiratory, thoracic and mediastinal disorders) [CHOKING SENSATION]	1	56	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0013007	49 YRS CAUCASIAN MALE	20MAR2003-30MAR2003	ON	AKATHISIA (Nervous system disorders) [RESTLESSNESS (DUE TO EPS) AKATHISIA]	11	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	1	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0013009	44 YRS CAUCASIAN FEMALE	02APR2003-02JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	62	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014006	18 YRS CAUCASIAN FEMALE	25MAR2003-27MAR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0014006	18 YRS CAUCASIAN FEMALE	25MAR2003-10APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	17	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014010	40 YRS CAUCASIAN FEMALE	23APR2003-25APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-03MAY2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	10	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-06MAY2003	ON	MICTURITION URGENCY (Renal and urinary disorders) [URINARY URGENCY]	13	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-18MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0014010	40 YRS CAUCASIAN FEMALE	30APR2003-02MAY2003	ON	DYSTONIA (Nervous system disorders) [JAW HYPERTONUS (DUE TO EPS) DYSTONIA]	3	9	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			30APR2003-18MAY2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	19	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-CONTINUE	ON	BLUNTED AFFECT (Psychiatric disorders) [EMOTIONAL BLUNTING]	UNK	24	MOD	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-31MAY2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	17	24	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [HYPERSOMNOLENCE]	UNK	31	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0016001	32 YRS CAUCASIAN MALE	06FEB2003-28FEB2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [CRAMPS - LEG (NOT DUE TO EPS)]	23	16	MIL	NO	N	N	N	N	N	N	NO YES	None
			07FEB2003-18FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	12	17	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0016004	36 YRS CAUCASIAN MALE	03FEB2003-CONTINUE	ON	RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			05FEB2003-11FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	7	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			07FEB2003-11FEB2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	5	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0018001	24 YRS CAUCASIAN FEMALE	30OCT2002-17NOV2002	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					TONGUE DISORDER NOS (Gastrointestinal disorders) [THICKENED TONGUE (NOT DUE TO EPS.)]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			30OCT2002-25NOV2002	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	27	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			02NOV2002-17NOV2002	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	16	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			02NOV2002-26NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0018001	24 YRS CAUCASIAN FEMALE	21NOV2002-23NOV2002	ON	MEMORY IMPAIRMENT (Nervous system disorders) [FORGETFULNESS]	3	24	MIL	NO	N	N	N	N	N	N	NO YES	None
			07DEC2002-23DEC2002	ON	DYSKINESIA (Nervous system disorders) [NOCTURNAL MYOCLONUS (NOT DUE TO EPS)]	17	40	MIL	NO	N	N	N	N	N	N	NO YES	None
			07DEC2002-27DEC2002	ON	THOUGHT BLOCKING (Psychiatric disorders) [THOUGHT BLOCKING]	21	40	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0018006	42 YRS CAUCASIAN MALE	19DEC2002-07JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	20	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			27DEC2002-CONTINUE	ON	MEMORY IMPAIRMENT (Nervous system disorders) [FORGETFULNESS]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0018006	42 YRS CAUCASIAN MALE	28DEC2002-07JAN2003	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH IN MORNINGS]	11	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			10JAN2003-06FEB2003	ON	ENURESIS (Renal and urinary disorders) [ENURESIS]	28	25	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019004	32 YRS CAUCASIAN FEMALE	08NOV2002-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					BALANCE IMPAIRED NOS (Nervous system disorders) [PROBLEM WITH EQUILIBRIUM (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019004	32 YRS CAUCASIAN FEMALE	08NOV2002-26NOV2002	ON	MUSCLE TIGHTNESS (Musculoskeletal and connective tissue disorders) [MUSCLE TENSION (NOT DUE TO EPS)]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			10NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			19NOV2002-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			05DEC2002-CONTINUE	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	UNK	29	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12DEC2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	36	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019011	50 YRS HISPANIC FEMALE	24NOV2002-05DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	12	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			25NOV2002-05DEC2002	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	11	5	SEV	NO	N	N	N	N	N	N	NO YES	None
			26NOV2002-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [GROGINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	UNK	6	SEV	NO	N	N	N	N	N	N	NO YES	None
			26NOV2002-06DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	11	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0019011	50 YRS HISPANIC FEMALE	27NOV2002-CONTINUE	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS DUE TO EPS (AKATHISIA)]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			11DEC2002-19DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	9	21	MIL	NO	N	N	N	N	N	N	NO YES	None
			14DEC2002-02JAN2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	20	24	MIL	NO	N	N	N	N	N	N	NO YES	None
			08JAN2003-09JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	49	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019025	30 YRS CAUCASIAN FEMALE	08FEB2003-13MAR2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS (UNSETTLING)]	34	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019025	30 YRS CAUCASIAN FEMALE	08FEB2003-17MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	38	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	8	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0019043	54 YRS CAUCASIAN MALE	04JUN2003-CONTINUE	ON	ENURESIS (Renal and urinary disorders) [ENURISIS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			04JUN2003-08JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	35	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0019043	54 YRS CAUCASIAN MALE	04JUN2003-08JUL2003	ON	MEMORY IMPAIRMENT (Nervous system disorders) [FORGETFULNESS]	35	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14JUN2003-08JUL2003	ON	TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	25	12	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020001	48 YRS CAUCASIAN FEMALE	06NOV2002-11NOV2002	ON	FLUSHING (Vascular disorders) [INTERMITTENT FLUSHING FEELING]	6	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			14NOV2002-19NOV2002	ON	EPISTAXIS (Respiratory, thoracic and mediastinal disorders) [EPISTAXIS]	6	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			14NOV2002-24NOV2002	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS "NOT DUE TO POSTURAL HYPOTENSION"]	11	17	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020001	48 YRS CAUCASIAN FEMALE	20NOV2002-28NOV2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASE APPETITE]	9	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			26NOV2002-03DEC2002	ON	WEIGHT INCREASED (Investigations) [INCREASE WEIGHT]	8	29	MIL	NO	N	N	N	N	N	N	NO YES	None
			05DEC2002-05DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	1	38	MOD	NO	N	N	N	N	N	N	NO YES	None
			08DEC2002-09DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	41	MOD	NO	N	N	N	N	N	N	NO YES	None
			14DEC2002-14DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	1	47	MOD	NO	N	N	N	N	N	N	NO YES	None
			18DEC2002-19DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	51	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020007	26 YRS CAUCASIAN FEMALE	19JAN2003-20JAN2003	ON	POLYMENORRHOEA (Reproductive system and breast disorders) [SHORTENED MENSES]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0020011	21 YRS CAUCASIAN FEMALE	28FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-13MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS AFTER EVENING DOSE (NOT DUE TO ORTHOSTATIC HYPOTENSION.)]	8	9	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020013	23 YRS CAUCASIAN MALE	12MAR2003-12MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH EARLY MORNING]	1	8	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022017	41 YRS CAUCASIAN MALE	20DEC2002-22JAN2003	ON	TREMOR (Nervous system disorders) [TREMOR NOT DUE TO EPS]	34	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022018	41 YRS CAUCASIAN MALE	14DEC2002-23JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS "NOT DUE TO POSTURAL HYPOTENSION"]	41	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			19DEC2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022022	23 YRS CAUCASIAN FEMALE	31DEC2002-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022022	23 YRS CAUCASIAN FEMALE	31DEC2002-18JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					MYOCLONUS (Nervous system disorders) [MYO - CLONIC JERKS]	19	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0022027	45 YRS CAUCASIAN MALE	07FEB2003-07MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	29	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022031	36 YRS CAUCASIAN MALE	19FEB2003-12MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	22	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			20FEB2003-12MAR2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL STUFFINESS]	21	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0022031	36 YRS CAUCASIAN MALE	20FEB2003-12MAR2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS]	21	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-CONTINUE	ON	AKATHISIA (Nervous system disorders) [MOTOR RESTLESSNESS (DUE TO EPS AKATHISIA)]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0022032	21 YRS CAUCASIAN FEMALE	19FEB2003-07MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	17	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0022035	20 YRS CAUCASIAN FEMALE	20FEB2003-24FEB2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	5	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0022060	24 YRS CAUCASIAN MALE	06MAY2003-17JUN2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	43	7	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR I)	E0023008	35 YRS CAUCASIAN FEMALE	30JAN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			08MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	38	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023013	40 YRS CAUCASIAN FEMALE	28FEB2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01MAR2003-01MAR2003	ON	DYSGEUSIA (Nervous system disorders) [METALLIC TASTE]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0023015	43 YRS CAUCASIAN FEMALE	12MAR2003-08APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY - NOT RELATED TO ORTHOSTATIC HYPOTENSION]	28	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	28	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023044	44 YRS CAUCASIAN FEMALE	20JUL2003-CONTINUE	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS (NOT DUE TO EPS)]	UNK	5	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0025002	46 YRS CAUCASIAN FEMALE	05APR2003-17APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	13	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0025002	46 YRS CAUCASIAN FEMALE	08APR2003-17APR2003	ON	SLUGGISHNESS (General disorders and administration site conditions) [SLUGGISH IN THE MORNING]	10	6	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	22	MIL	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [TIRED DURING DAY]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-CONTINUE	ON	VISUAL ACUITY REDUCED (Eye disorders) [WORSENING VISION (VISUAL ACUITY)]	UNK	50	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026010	31 YRS CAUCASIAN MALE	23JAN2003-28JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0026010	31 YRS CAUCASIAN MALE	23JAN2003-28JAN2003	ON	VOMITING NOS (Gastrointestinal disorders) [EMESIS]	6	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0026018	39 YRS CAUCASIAN FEMALE	20MAR2003-25MAR2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS]	6	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-04APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	16	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-31MAY2003	ON	JOINT STIFFNESS (Musculoskeletal and connective tissue disorders) [JOINT STIFFNESS (NOT DUE TO EPS)]	73	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			03APR2003-16JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [HYPOTENSION ORTHOSTATIC]	75	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	41 YRS CAUCASIAN MALE	12MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [GROGGY]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			13MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			29MAY2003-CONTINUE	ON	HYPERTENSION NOS (Vascular disorders) [HYPERTENSION]	UNK	21	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0026030	29 YRS BLACK MALE	09JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0026031	41 YRS BLACK MALE	21JUL2003-CONTINUE	ON	MUCOUS MEMBRANE DISORDER NOS (General disorders and administration site conditions) [FILM IN MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JUL2003-20AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	28	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			11AUG2003-01SEP2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	22	22	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	30 YRS CAUCASIAN MALE	01OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					HEADACHE (Nervous system disorders) [HEADACHE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			05OCT2002-06OCT2002	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [LOSS OF BALANCE (NOT DUE TO EPS)]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028006	40 YRS CAUCASIAN FEMALE	04OCT2002-04DEC2002	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	62	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			06OCT2002-12OCT2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028006	40 YRS CAUCASIAN FEMALE	13OCT2002-23OCT2002	ON	PARAESTHESIA (Nervous system disorders) [PARASTHESIA]	11	10	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0028009	21 YRS CAUCASIAN FEMALE	16OCT2002-17OCT2002	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	2	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			16OCT2002-02NOV2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	18	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028016	28 YRS CAUCASIAN MALE	15NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028016	28 YRS CAUCASIAN MALE	19DEC2002-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	36	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028027	58 YRS HISPANIC MALE	21JAN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			22JAN2003-08FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	2	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0028029	39 YRS HISPANIC MALE	05FEB2003-18FEB2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	14	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			12FEB2003-18FEB2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	7	9	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR I)	E0028029	39 YRS HISPANIC MALE	28FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	UNK	25	SEV	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-CONTINUE	ON	AGITATION (Psychiatric disorders) [AGITATION]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028034	39 YRS CAUCASIAN MALE	01APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			04APR2003-08APR2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	5	4	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					CONFUSIONAL STATE (Psychiatric disorders) [CONFUSION]	5	4	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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QUETIAPINE 300 MG (BIPOLAR I)	E0028034	39 YRS CAUCASIAN MALE	04APR2003-01MAY2003	ON	CHEST PAIN (General disorders and administration site conditions) [RACING HEART (FEELING)]	28	4	SEV	NO	N	N	N	N	N	N	NO YES	None
			04APR2003-19MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	46	4	SEV	NO	N	N	N	N	N	N	NO YES	None
			07MAY2003-19MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	13	37	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAY2003-CONTINUE	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	UNK	49	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028038	50 YRS CAUCASIAN MALE	25APR2003-23JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	60	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028038	50 YRS CAUCASIAN MALE	25APR2003-23JUN2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	60	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028043	51 YRS CAUCASIAN MALE	06JUN2003-31JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	56	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			10JUN2003-31JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	52	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			11JUN2003-11JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028045	46 YRS CAUCASIAN MALE	23JUN2003-24JUN2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEG SYNDROME (NOT DUE TO EPS)]	2	6	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0029005	30 YRS BLACK FEMALE	27NOV2002-23JAN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS ONE HOUR AFTER DOSE]	58	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			28NOV2002-02DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	5	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01DEC2002-05DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			01DEC2002-07DEC2002	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [LOWER BACK PAIN]	7	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			03DEC2002-23JAN2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH 30 MINUTES AFTER DOSE]	52	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0030001	41 YRS CAUCASIAN FEMALE	01DEC2002-01DEC2002	ON	VERTIGO (Ear and labyrinth disorders) [VERTIGO]	1	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			03DEC2002-CONTINUE	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
			07DEC2002-07DEC2002	ON	VERTIGO (Ear and labyrinth disorders) [VERTIGO]	1	19	MIL	NO	N	N	N	N	N	N	NO YES	None
			10DEC2002-10DEC2002	ON	VERTIGO (Ear and labyrinth disorders) [VERTIGO]	1	22	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0030011	21 YRS CAUCASIAN MALE	27JAN2003-01FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	6	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0030011	21 YRS CAUCASIAN MALE	20FEB2003-08MAR2003	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	17	25	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0030015	21 YRS CAUCASIAN MALE	21FEB2003-05MAY2003	ON	SEDATION (Nervous system disorders) [EARLY AM SEDATION]	74	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0030022	39 YRS CAUCASIAN MALE	17JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			17JUN2003-21JUN2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGY]	5	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	18 YRS CAUCASIAN FEMALE	28NOV2002-27DEC2002	ON	SLUGGISHNESS (General disorders and administration site conditions) [SLUGGISHNESS]	30	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JAN2003-20JAN2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS (NOT DUE TO POSTURAL HYPOTENSION)]	20	36	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0033015	34 YRS CAUCASIAN FEMALE	10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH (NOT DUE TO EPS)]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-19APR2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	10	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0033015	34 YRS CAUCASIAN FEMALE	10APR2003-22MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	43	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-15APR2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [AUDITORY HALLUCINATIONS]	1	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-16APR2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			16APR2003-16APR2003	ON	TREMOR (Nervous system disorders) [HAND TREMORS (NOT DUE TO EPS)]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			29APR2003-10MAY2003	ON	MEMORY IMPAIRMENT (Nervous system disorders) [MEMORY LOSS]	12	20	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0033015	34 YRS CAUCASIAN FEMALE	01MAY2003-CONTINUE	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0034002	55 YRS CAUCASIAN MALE	26MAR2003-29MAR2003	ON	PRURITUS (Skin and subcutaneous tissue disorders) [PRURITUS OF FACE]	4	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			26MAR2003-18APR2003	ON	SOMNOLENCE (Nervous system disorders) [DAYTIME DROWSINESS]	24	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			28MAR2003-18APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			02APR2003-18APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	17	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0034003	49 YRS CAUCASIAN MALE	27APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			27APR2003-01JUN2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	36	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			27APR2003-02JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DAYTIME DROWSINESS]	37	4	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0034006	35 YRS CAUCASIAN FEMALE	17MAY2003-17JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DAYTIME DROWSINESS]	62	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0034008	34 YRS BLACK MALE	24MAY2003-03JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0034008	34 YRS BLACK MALE	25MAY2003-27MAY2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGINESS IN MORNING]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0035003	28 YRS CAUCASIAN MALE	27NOV2002-27DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	31	6	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0035014	35 YRS BLACK FEMALE	03FEB2003-27MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	53	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			04FEB2003-26MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	51	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0035024	41 YRS BLACK FEMALE	26MAY2003-05JUN2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	11	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0035024	41 YRS BLACK FEMALE	13JUN2003-15JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	33	22	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0036005	19 YRS CAUCASIAN FEMALE	02JUL2003-07JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	6	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-04JUL2003	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JUL2003-05AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	8	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0037002	28 YRS CAUCASIAN FEMALE	26DEC2002-07FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	44	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR I)	E0037002	28 YRS CAUCASIAN FEMALE	20FEB2003-21FEB2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS (NOT DUE TO POSTURAL HYPOTENSION)]	2	57	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0037005	27 YRS CAUCASIAN FEMALE	20MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-17APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	29	15	MIL	NO	N	N	N	N	N	N	NO YES	None
					DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	29	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0037005	27 YRS CAUCASIAN FEMALE	27MAR2003-CONTINUE	ON	TINNITUS (Ear and labyrinth disorders) [LEFT EAR RINGING]	UNK	22	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0037006	50 YRS CAUCASIAN FEMALE	14MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			21MAR2003-04APR2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS - NOT DUE TO POSTURAL HYPOTENSION]	15	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			01MAY2003-07MAY2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESSNESS OF BILATERAL LOWER EXTREMITIES (NOT DUE TO EPS)]	7	49	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039015	41 YRS BLACK MALE	23JAN2003-23JAN2003	ON	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [DIAPHORESIS NOT DUE TO POSTURAL HYPOTENSION]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			24JAN2003-24JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27JAN2003-27JAN2003	ON	DIZZINESS (Nervous system disorders) [LIGHT - HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	1	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039015	41 YRS BLACK MALE	30JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			03FEB2003-03FEB2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	1	12	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039024	35 YRS CAUCASIAN FEMALE	28FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSY POST DOSE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			28FEB2003-07MAY2003	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS POST DOSE (NOT DUE TO EPS)]	69	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039041	35 YRS BLACK MALE	25APR2003-03MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	9	11	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039044	44 YRS CAUCASIAN MALE	24MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS (POST - DOSE)]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039051	40 YRS BLACK FEMALE	16JUN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS POST - DOSE]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			17JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	40 YRS BLACK MALE	05AUG2003-05AUG2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED WHEN STOOD UP (NOT DUE TO POSTURAL HYPOTENSION)]	1	26	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039057	38 YRS BLACK MALE	16JUL2003-18JUL2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	3	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			16JUL2003-06AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			22JUL2003-14AUG2003	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED SEX DRIVE]	24	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JUL2003-06AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	14	11	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0041008	32 YRS CAUCASIAN FEMALE	23APR2003-10JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [INTERMITTENT DRY MOUTH]	49	17	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [INTERMITTENT SEDATION]	49	17	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0042001	59 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			14JUL2003-19AUG2003	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS (NOT POSTURAL HYPOTENSION)]	37	13	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0001002	47 YRS BLACK FEMALE	12MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			13MAR2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADED - (NOT DUE TO POSTURAL HYPOTENSION)]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					FEELING ABNORMAL (General disorders and administration site conditions) [MENTALLY FOGGY]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			16MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0003018	33 YRS BLACK FEMALE	16MAY2003-10JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	26	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0005011	26 YRS CAUCASIAN MALE	24OCT2002-25OCT2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			24OCT2002-24NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	32	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			31OCT2002-15NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	16	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			09NOV2002-13NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	17	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0005030	19 YRS CAUCASIAN FEMALE	27MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					DYSTONIA (Nervous system disorders) [DYSTONIA]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			31MAR2003-31MAR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-01APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	1	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0005030	19 YRS CAUCASIAN FEMALE	15APR2003-16APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	21	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	2	21	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
	E0005036	40 YRS CAUCASIAN FEMALE	06MAY2003-13MAY2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS DUE TO EPS (AKATHISIA)]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					DYSKINESIA (Nervous system disorders) [DECREASED COORDINATION SECONDARY TO EPS (DYSKINESIA)]	8	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0005036	40 YRS CAUCASIAN FEMALE	06MAY2003-13MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0006015	36 YRS CAUCASIAN FEMALE	11FEB2003-11FEB2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEAT]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			12FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [INCREASE SLEEPINESS]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			15FEB2003-15FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0006015	36 YRS CAUCASIAN FEMALE	16FEB2003-04MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	17	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			20FEB2003-20FEB2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZY (DUE TO POSTURAL HYPOTENSION)]	1	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			22FEB2003-23FEB2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-25FEB2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [FAINT (DUE TO POSTURAL HYPOTENSION)]	1	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0006015	36 YRS CAUCASIAN FEMALE	01MAR2003-CONTINUE	ON	ANXIETY (Psychiatric disorders) [INNER FEELING OF SHAKING OR BOUNCING (ANXIETY NOT DUE TO EPS)]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0006016	43 YRS CAUCASIAN MALE	19FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	30	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0007008	42 YRS CAUCASIAN FEMALE	18APR2003-25APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR II)	E0009002	47 YRS CAUCASIAN MALE	20NOV2002-27NOV2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					DEREALISATION (Psychiatric disorders) [DEREALIZATION]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH (NOT DUE TO EPS)]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [FATIGUE ON WALKING]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					NASAL DRYNESS (Respiratory, thoracic and mediastinal disorders) [DRY SINUSES]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0009002	47 YRS CAUCASIAN MALE	20NOV2002-27NOV2002	ON	TONGUE DISORDER NOS (Gastrointestinal disorders) [THICK TONGUE]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					TREMOR (Nervous system disorders) [TREMORS - (NOT DUE TO EPS)]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-17DEC2002	ON	SEDATION (Nervous system disorders) [SEDATION]	28	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			28NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH - (NOT DUE TO EPS)]	UNK	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			15DEC2002-CONTINUE	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [TWITCHING OF FINGERS - (NOT DUE TO EPS)]	UNK	27	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0009006	20 YRS CAUCASIAN MALE	14FEB2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [POST - STUDY MEDICATION DOSE HEADACHE]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0009009	23 YRS CAUCASIAN FEMALE	12MAR2003-22MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010015	42 YRS HISPANIC MALE	13MAR2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0011004	32 YRS CAUCASIAN MALE	31DEC2002-31DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO POSTURAL HYPOTENSION]	1	8	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	47 YRS CAUCASIAN FEMALE	23DEC2002-24DEC2002	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [LIGHTHEADEDNESS DUE TO POSTURAL HYPOTENSION]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			28DEC2002-29JAN2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	33	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			30DEC2002-30DEC2002	ON	URINARY INCONTINENCE (Renal and urinary disorders) [URINARY INCONTINENCE]	1	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			23JAN2003-CONTINUE	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO POSTURAL HYPOTENSION]	UNK	36	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0011007	47 YRS CAUCASIAN FEMALE	23JAN2003-29JAN2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	7	36	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0011018	23 YRS OTHER MALE	30MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0011024	36 YRS BLACK FEMALE	24JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0015003	54 YRS CAUCASIAN FEMALE	25NOV2002-04DEC2002	ON	SEDATION (Nervous system disorders) [EXCESSIVE SEDATION]	10	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019003	27 YRS CAUCASIAN FEMALE	24NOV2002-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019003	27 YRS CAUCASIAN FEMALE	24NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGIC (INCREASED)]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			25NOV2002-09DEC2002	ON	MICTURITION URGENCY (Renal and urinary disorders) [URINATION URGENCY]	15	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			16DEC2002-19DEC2002	ON	MENSES DELAYED (Reproductive system and breast disorders) [DELAYED MENSTRUAL CYCLE (6 DAYS)]	4	26	MOD	NO	N	N	N	N	N	N	NO YES	None
			16DEC2002-23DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	8	26	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019003	27 YRS CAUCASIAN FEMALE	19DEC2002-21DEC2002	ON	POLYMENORRHOEA (Reproductive system and breast disorders) [SHORTENED MENSTRAL CYCLE]	3	29	MOD	NO	N	N	N	N	N	N	NO YES	None
			16JAN2003-CONTINUE	ON	FLUSHING (Vascular disorders) [FLUSHING]	UNK	57	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019007	39 YRS CAUCASIAN FEMALE	13NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [TRANSIENT LETHARGY]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019007	39 YRS CAUCASIAN FEMALE	13NOV2002-CONTINUE	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS (NOT DUE TO EPS)]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019014	24 YRS CAUCASIAN MALE	10JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					FLAT AFFECT (Psychiatric disorders) [FLAT AFFECT]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019014	24 YRS CAUCASIAN MALE	10JAN2003-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARY]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JAN2003-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [EQUILIBRIUM PROBLEMS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019018	34 YRS CAUCASIAN MALE	02FEB2003-20FEB2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	19	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019022	24 YRS CAUCASIAN FEMALE	10FEB2003-11FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHIA]	2	12	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019027	26 YRS HISPANIC FEMALE	28FEB2003-03MAR2003	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [PROBLEMS WITH EQUILITRIUM]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [EXCESSIVE SEDATION]	4	2	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			28FEB2003-06MAR2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019032	28 YRS CAUCASIAN FEMALE	01APR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019032	28 YRS CAUCASIAN FEMALE	01APR2003-22APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	22	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			02APR2003-01MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	30	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			02APR2003-28MAY2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	57	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			03APR2003-01MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	29	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0019034	33 YRS CAUCASIAN FEMALE	19MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019034	33 YRS CAUCASIAN FEMALE	19MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0019036	27 YRS CAUCASIAN MALE	31MAR2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	17	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEXUAL DYSFUNCTION NOS (Reproductive system and breast disorders) [SEXUAL DYSFUNCTION]	UNK	17	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019039	35 YRS CAUCASIAN MALE	01MAY2003-04MAY2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	4	1	MOD	NO	N	N	N	N	N	N	YES YES	None
			03MAY2003-04MAY2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	2	3	MOD	NO	N	N	N	N	N	N	YES YES	None
					BALANCE IMPAIRED NOS (Nervous system disorders) [DECREASED EQUILITRIUM (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					DISTURBANCE IN ATTENTION (Nervous system disorders) [DECREASED CONCENTRATION]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019039	35 YRS CAUCASIAN MALE	03MAY2003-04MAY2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					PANIC DISORDER NOS (Psychiatric disorders) [PANIC DISORDER SYMPTOMS]	2	3	MOD	NO	N	N	N	N	N	N	YES YES	None
					PARANOIA (Psychiatric disorders) [PARANOIA]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
					SUSPICIOUSNESS (Psychiatric disorders) [SUSPICIOUSNESS]	2	3	MIL	NO	N	N	N	N	N	N	YES YES	None
			03MAY2003-05JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA (NOT DUE TO EPS)]	34	3	MOD	NO	N	N	N	N	N	N	YES YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	22 YRS CAUCASIAN FEMALE	22MAY2003-19JUN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019049	33 YRS CAUCASIAN FEMALE	11JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	33 YRS CAUCASIAN FEMALE	18JUL2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None
					NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-30JUL2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [LABORED BREATHING]	13	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			29JUL2003-01AUG2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [MUSCLE TWITCHING (NOT DUE TO EPS)]	4	20	MOD	NO	N	N	N	N	N	N	NO YES	None
			05AUG2003-06AUG2003	ON	SLEEP WALKING (Psychiatric disorders) [SLEEPWALKING]	2	27	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0019049	33 YRS CAUCASIAN FEMALE	15AUG2003-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	37	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0022052	46 YRS BLACK FEMALE	11APR2003-29APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	19	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			11APR2003-20MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	40	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022064	19 YRS CAUCASIAN MALE	07MAY2003-15MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	9	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAY2003-17MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0023002	19 YRS CAUCASIAN FEMALE	05NOV2002-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023017	18 YRS CAUCASIAN MALE	25MAR2003-07APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	14	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			25APR2003-02MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	8	32	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023021	49 YRS CAUCASIAN MALE	24APR2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-09MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	16	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	49 YRS CAUCASIAN MALE	24APR2003-11JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	49	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0023027	25 YRS CAUCASIAN FEMALE	17MAY2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			22MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	7	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0023030	40 YRS CAUCASIAN FEMALE	04JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JUN2003-02JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	27	4	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0023040	32 YRS BLACK FEMALE	04JUL2003-15JUL2003	ON	PAIN IN EXTREMITY (Musculoskeletal and connective tissue disorders) [PAIN IN RIGHT LEG]	12	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-30AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	58	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026014	57 YRS CAUCASIAN MALE	19FEB2003-05MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	15	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			19FEB2003-08MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026019	39 YRS BLACK FEMALE	18MAR2003-19MAR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	2	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0026019	39 YRS BLACK FEMALE	18MAR2003-20MAR2003	ON	PALPITATIONS (Cardiac disorders) [HEART POUNDING]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-07APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	21	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-01MAY2003	ON	FLATULENCE (Gastrointestinal disorders) [GAS]	45	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18MAR2003-13MAY2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASE OF APPETITE]	57	2	SEV	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	57	2	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0026019	39 YRS BLACK FEMALE	18MAR2003-13MAY2003	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	57	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	57	2	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0027005	58 YRS CAUCASIAN FEMALE	02JAN2003-09JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	8	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029009	44 YRS CAUCASIAN MALE	21JAN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			03FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0029009	44 YRS CAUCASIAN MALE	03FEB2003-CONTINUE	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED LIBIDO]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029021	38 YRS CAUCASIAN FEMALE	19MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029026	65 YRS CAUCASIAN MALE	16APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			16APR2003-22APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR II)	E0029026	65 YRS CAUCASIAN MALE	16APR2003-22APR2003	ON	TONGUE DISORDER NOS (Gastrointestinal disorders) [FEELING OF TONGUE THICKNESS]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			23APR2003-CONTINUE	ON	MUSCLE TIGHTNESS (Musculoskeletal and connective tissue disorders) [MUSCLE TIGHTNESS IN MORNING (NOT DUE TO EPS)]	UNK	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			25APR2003-02JUN2003	ON	URINARY HESITATION (Renal and urinary disorders) [URINARY HESITANCY]	39	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			06MAY2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			06MAY2003-19MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	14	23	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0029030	31 YRS CAUCASIAN MALE	29MAY2003-16JUN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	19	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-21JUL2003	ON	SEDATION (Nervous system disorders) [MORNING SEDATION]	34	23	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031008	31 YRS CAUCASIAN FEMALE	01MAR2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01MAR2003-07APR2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [INTERMITTENT DIZZINESS DUE TO POSTURAL HYPOTENSION]	38	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0031008	31 YRS CAUCASIAN FEMALE	02MAR2003-15MAR2003	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	14	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			13APR2003-19APR2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	7	45	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031020	44 YRS CAUCASIAN MALE	22APR2003-01MAY2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [ARM CRAMPS (NOT DUE TO EPS)]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [LEG CRAMPS (NOT DUE TO EPS)]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			22APR2003-16MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	44 YRS CAUCASIAN MALE	22APR2003-16MAY2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	25	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0031021	27 YRS BLACK MALE	26APR2003-06MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			26APR2003-10JUN2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	46	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			19JUN2003-CONTINUE	ON	ATRIOVENTRICULAR BLOCK FIRST DEGREE (Cardiac disorders) [FIRST DEGREE BLOCK]	UNK	56	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031029	24 YRS CAUCASIAN MALE	19JUN2003-03JUL2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0031029	24 YRS CAUCASIAN MALE	19JUN2003-04JUL2003	ON	AKATHISIA (Nervous system disorders) [AKATHESIA]	16	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20JUN2003-07JUL2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	18	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			21JUN2003-07JUL2003	ON	COORDINATION ABNORMAL NOS (Nervous system disorders) [LOSS OF COORDINATION (NOT DUE TO EPS)]	17	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	17	4	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
	E0033002	59 YRS CAUCASIAN MALE	11JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033002	59 YRS CAUCASIAN MALE	17JAN2003-26JAN2003	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	10	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			04FEB2003-CONTINUE	ON	TINNITUS (Ear and labyrinth disorders) [TINNITUS]	UNK	26	MOD	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-27FEB2003	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	3	47	MOD	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-28FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	50	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0033006	38 YRS CAUCASIAN MALE	24JAN2003-CONTINUE	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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QUETIAPINE 300 MG (BIPOLAR II)	E0033006	38 YRS CAUCASIAN MALE	24JAN2003-CONTINUE	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					SPEECH DISORDER (Nervous system disorders) [ANXIOUS, PRESSED SPEECH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			25JAN2003-CONTINUE	ON	LOSS OF LIBIDO (Psychiatric disorders) [LOSS OF LIBIDO,]	UNK	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0033021	27 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS - (NOT DUE TO POSTURAL HYPOTENSION)]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033021	27 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [LEG CRAMPS (NOT DUE TO EPS)]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			03JUL2003-25JUL2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGY]	23	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-25JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	22	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			09JUL2003-CONTINUE	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0033021	27 YRS CAUCASIAN FEMALE	14JUL2003-CONTINUE	ON	TREMOR (Nervous system disorders) [TREMORS - (NOT DUE TO EPS)]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			16JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-25JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	8	17	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0035013	28 YRS CAUCASIAN FEMALE	08FEB2003-12FEB2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	5	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS NOT DUE TO EPS]	5	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 300 MG (BIPOLAR II)	E0035015	33 YRS HISPANIC FEMALE	11FEB2003-16FEB2003	ON	SEDATION (Nervous system disorders) [EXTREME SEDATION]	6	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0035023	41 YRS CAUCASIAN MALE	15MAY2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					FLUSHING (Vascular disorders) [HOT FLASHES]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 300 MG (BIPOLAR II)	E0035023	41 YRS CAUCASIAN MALE	15MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0039052	37 YRS BLACK FEMALE	23JUN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	4	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			26JUN2003-26JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUL2003-01JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	12	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039056	46 YRS BLACK MALE	21JUL2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0040003	50 YRS CAUCASIAN FEMALE	22JUL2003-29JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	8	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			23JUL2003-04AUG2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	13	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0002009	42 YRS CAUCASIAN FEMALE	05MAR2003-11APR2003	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	38	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-10MAR2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [TWITCHING IN LOWER LEGS UNKNOWN IF DUE TO EPS]	4	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			09MAR2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0002009	42 YRS CAUCASIAN FEMALE	18MAR2003-CONTINUE	ON	ASTHENIA (General disorders and administration site conditions) [WEAKNESS IN LOWER LIMBS]	UNK	16	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			03APR2003-CONTINUE	ON	PARAESTHESIA (Nervous system disorders) [TINGLINESS IN LOWER LIMBS]	UNK	32	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0002011	35 YRS CAUCASIAN FEMALE	29APR2003-CONTINUE	ON	ABDOMINAL DISTENSION (Gastrointestinal disorders) [BLOATING]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0002011	35 YRS CAUCASIAN FEMALE	30APR2003-16MAY2003	ON	DYSKINESIA (Nervous system disorders) [MUSCLE TWITCHINGS IN LOWER EXTREMITIES DUE TO EPS - DYSKINESIA]	17	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0003010	54 YRS CAUCASIAN FEMALE	04FEB2003-12FEB2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	9	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-15FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	3	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	UNK	26	MOD	NO	N	N	N	N	N	N	NO YES	None
			02MAR2003-02MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	28	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003010	54 YRS CAUCASIAN FEMALE	06MAR2003-08MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	3	32	MOD	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	UNK	40	SEV	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003-14MAR2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	1	40	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0003011	26 YRS CAUCASIAN FEMALE	07FEB2003-07FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS - NOT DUE TO POSTURAL HYPOTENSION]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			08FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003011	26 YRS CAUCASIAN FEMALE	08FEB2003-09FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0003016	33 YRS CAUCASIAN FEMALE	24MAY2003-03JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	41	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					FEELING JITTERY (General disorders and administration site conditions) [JITTERY FEELING - INTERNAL]	41	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			31MAY2003-08JUN2003	ON	HOARSENESS (Respiratory, thoracic and mediastinal disorders) [HOARSENESS]	9	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			03JUN2003-12JUN2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	10	13	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003016	33 YRS CAUCASIAN FEMALE	09JUN2003-12JUN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	4	19	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0003019	51 YRS CAUCASIAN MALE	28JUN2003-15JUL2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	18	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			24JUL2003-07AUG2003	ON	TINNITUS (Ear and labyrinth disorders) [TINNITUS]	15	28	MOD	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-21AUG2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	28	29	MIL	NO	N	N	N	N	N	N	NO YES	None
			29JUL2003-07AUG2003	ON	BLADDER DISORDER NOS (Renal and urinary disorders) [SLOW EMPTYING BLADDER]	10	33	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003019	51 YRS CAUCASIAN MALE	14AUG2003-21AUG2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	8	49	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0003020	34 YRS CAUCASIAN MALE	27JUL2003-31JUL2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC HYPOTENSION]	5	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			27JUL2003-06AUG2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			27JUL2003-20AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0003020	34 YRS CAUCASIAN MALE	06AUG2003-06AUG2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC HYPOTENSION]	1	15	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0004001	33 YRS HISPANIC FEMALE	30SEP2002-12OCT2002	ON	DIZZINESS (Nervous system disorders) [AM DIZZYNESS (NOT DUE TO POSTURAL HYPOTENSION)]	13	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	13	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			02OCT2002-07OCT2002	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [RIGHT SHOULDER PAIN]	6	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004001	33 YRS HISPANIC FEMALE	02OCT2002-07OCT2002	ON	INJURY (Injury, poisoning and procedural complications) [FALL]	6	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			04OCT2002-12OCT2002	ON	ABDOMINAL DISTENSION (Gastrointestinal disorders) [FEELING BLOATED]	9	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			06OCT2002-12OCT2002	ON	DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	7	7	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			12OCT2002-21OCT2002	ON	DIZZINESS (Nervous system disorders) [AM DIZZYNESS (NOT DUE TO POSTURAL HYPOTENSION)]	10	13	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	10	13	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0004001	33 YRS HISPANIC FEMALE	21OCT2002-01NOV2002	ON	DIZZINESS (Nervous system disorders) [AM DIZZYNESS (NOT DUE TO POSTURAL HYPOTENSION)]	12	22	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH IN P.M.]	12	22	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	12	22	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0004009	22 YRS CAUCASIAN FEMALE	27DEC2002-27DEC2002	ON	DYSPEPSIA (Gastrointestinal disorders) [STOMACH BUTTERFLIES (UPSET STOMACH)]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004009	22 YRS CAUCASIAN FEMALE	27DEC2002-31DEC2002	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [INCREASED LEG CRAMPS (NOT DUE TO EPS)]	5	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			27DEC2002-10JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004012	20 YRS OTHER FEMALE	14JAN2003-14JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-30JAN2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	16	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-18FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	35	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004012	20 YRS OTHER FEMALE	22JAN2003-30JAN2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	9	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			05FEB2003-18FEB2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	14	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-05MAR2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	8	44	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004015	47 YRS CAUCASIAN MALE	21FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [INTERMITTENT CONSTIPATION]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0004015	47 YRS CAUCASIAN MALE	25FEB2003-CONTINUE	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-30MAR2003	ON	LETHARGY (General disorders and administration site conditions) [AM LETHARGY]	31	9	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0005003	48 YRS CAUCASIAN MALE	02OCT2002-13OCT2002	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	12	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	12	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			02OCT2002-16OCT2002	ON	INSOMNIA (Psychiatric disorders) [SLEEPLESSNESS]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	48 YRS CAUCASIAN MALE	02OCT2002-07NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	37	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			04OCT2002-13OCT2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	10	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			18OCT2002-31OCT2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	14	17	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	14	17	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	14	17	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	48 YRS CAUCASIAN MALE	23OCT2002-07NOV2002	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	16	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005007	44 YRS CAUCASIAN FEMALE	10OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			11OCT2002-20OCT2002	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	10	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			13OCT2002-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INTERMITTENT HEARTBURN]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			17OCT2002-31OCT2002	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	15	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	44 YRS CAUCASIAN FEMALE	30OCT2002-CONTINUE	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
					DYSTONIA (Nervous system disorders) [MUSCLE TENSION SECONDARY TO EPS (DYSTONIA)]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005008	43 YRS CAUCASIAN MALE	15OCT2002-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADY]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	43 YRS CAUCASIAN MALE	18NOV2002-CONTINUE	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	UNK	35	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005009	24 YRS CAUCASIAN MALE	29OCT2002-03NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	6	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			30OCT2002-01NOV2002	ON	AKATHISIA (Nervous system disorders) [PARESTHESIA RELATED TO EPS (AKATHISIA)]	3	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005010	20 YRS CAUCASIAN FEMALE	21OCT2002-20NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	31	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0005010	20 YRS CAUCASIAN FEMALE	21OCT2002-18DEC2002	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [UNSTEADY NOT DUE TO ORTHOSTATIC HYPOTENSION]	59	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	59	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005012	54 YRS CAUCASIAN MALE	14NOV2002-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-12JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	54	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			27NOV2002-12JAN2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FEELINGS]	47	14	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005014	30 YRS CAUCASIAN MALE	13NOV2002-05DEC2002	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	23	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			13NOV2002-17DEC2002	ON	LETHARGY (General disorders and administration site conditions) [LETHARGIC]	35	1	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			18NOV2002-05DEC2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	18	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			21NOV2002-05DEC2002	ON	ATAXIA (Nervous system disorders) [ATAXIA NOT DUE TO EPS]	15	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			25NOV2002-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005014	30 YRS CAUCASIAN MALE	29NOV2002-05DEC2002	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	7	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			03JAN2003-03JAN2003	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	1	52	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005022	25 YRS CAUCASIAN MALE	31JAN2003-01FEB2003	ON	SEDATION (Nervous system disorders) [SEDATION]	2	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			02FEB2003-14FEB2003	ON	APTYALISM (Gastrointestinal disorders) [XEROSTOMIA (DRY MOUTH)]	13	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			04FEB2003-07FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	4	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005022	25 YRS CAUCASIAN MALE	04FEB2003-04MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	29	7	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0005025	40 YRS CAUCASIAN FEMALE	27FEB2003-20MAR2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	22	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-14MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	15	2	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
			28FEB2003-21MAR2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	22	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0005025	40 YRS CAUCASIAN FEMALE	04MAR2003-11MAR2003	ON	DYSTONIA (Nervous system disorders) [MUSCLE TENSION (DUE TO EPS - DYSTONIA)]	8	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAR2003-CONTINUE	ON	DYSTONIA (Nervous system disorders) [MUSCLE TIGHTNESS (DUE TO EPS - DYSTONIA)]	UNK	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAR2003-05APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	22	17	MIL	NO	N	N	N	N	N	N	YES YES	None
	E0006019	42 YRS CAUCASIAN MALE	12APR2003-20APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	9	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-27MAY2003	ON	SPEECH DISORDER (Nervous system disorders) [SLOWED SPEECH]	43	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0006019	42 YRS CAUCASIAN MALE	15APR2003-02JUN2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING SLEEPINESS]	49	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0007005	34 YRS CAUCASIAN FEMALE	01FEB2003-24FEB2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS (AKATHISIA)]	24	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			01FEB2003-28FEB2003	ON	SEDATION (Nervous system disorders) [SEDATION]	28	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0007015	58 YRS CAUCASIAN FEMALE	20JUL2003-23JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	4	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			20JUL2003-08AUG2003	ON	SEDATION (Nervous system disorders) [SEDATION]	20	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0007015	58 YRS CAUCASIAN FEMALE	15AUG2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATED]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0009001	36 YRS BLACK FEMALE	13NOV2002-22NOV2002	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED - (NOT DUE TO POSTURAL HYPOTENSION)]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					FATIGUE (General disorders and administration site conditions) [FATIGUE]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	10	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-CONTINUE	ON	ANXIETY (Psychiatric disorders) [ANXIETY BRIEFLY POST DOSE]	UNK	12	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0009001	36 YRS BLACK FEMALE	23NOV2002-28NOV2002	ON	SOMNOLENCE (Nervous system disorders) [DROWSY]	6	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-29NOV2002	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	7	12	MIL	NO	N	N	N	N	N	N	NO YES	None
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	7	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			23NOV2002-20DEC2002	ON	DIZZINESS (Nervous system disorders) [LIGHT HEADED (NOT DUE TO POSTURAL HYPOTENSION)]	28	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			25NOV2002-26NOV2002	ON	FEELING JITTERY (General disorders and administration site conditions) [JITTERY - (NOT DUE TO EPS)]	2	14	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	36 YRS BLACK FEMALE	29DEC2002-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	48	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0010002	46 YRS CAUCASIAN MALE	25NOV2002-25NOV2002	ON	DIZZINESS (Nervous system disorders) [FAINTING FEELING (NOT DUE TO POSTURAL HYPOTENSION)]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					FEELING COLD (General disorders and administration site conditions) [COLD FLASH]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					ORTHOSTATIC HYPOTENSION (Vascular disorders) [LIGHTHEADED DUE TO ORTHOSTATIC HYPOTENSION]	1	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	58 YRS CAUCASIAN FEMALE	26DEC2002-05JAN2003	ON	HYPERSOMNIA (Nervous system disorders) [OVER SLEEPING]	11	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			26DEC2002-07FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	44	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010010	35 YRS CAUCASIAN FEMALE	01JAN2003-11JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	11	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-11JAN2003	ON	FLATULENCE (Gastrointestinal disorders) [GAS]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					MIDDLE INSOMNIA (Psychiatric disorders) [DIFFICULTY STAYING ASLEEP]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0010010	35 YRS CAUCASIAN FEMALE	02JAN2003-11JAN2003	ON	SEDATION (Nervous system di sorders) [SEDATION]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0010014	38 YRS CAUCASIAN FEMALE	28JAN2003-17FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	21	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	30	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0010017	32 YRS CAUCASIAN MALE	26FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-02MAR2003	ON	HEADACHE (Nervous system di sorders) [HEADACHE]	5	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0010017	32 YRS CAUCASIAN MALE	26FEB2003-13APR2003	ON	SLUGGISHNESS (General disorders and administration site conditions) [SLUGGISH IN AM]	47	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			05APR2003-14APR2003	ON	FEELING JITTERY (General disorders and administration site conditions) [JITTERNESS (NOT DUE TO EPS)]	10	40	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0010023	28 YRS CAUCASIAN FEMALE	18APR2003-28APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20APR2003-28APR2003	ON	PARANOIA (Psychiatric disorders) [PARANOID THINKING]	9	4	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0010023	28 YRS CAUCASIAN FEMALE	25APR2003-28APR2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [ORTHOSTATIC DIZZINESS]	4	9	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010027	32 YRS CAUCASIAN MALE	17JUN2003-28JUN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	12	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-28JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	11	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-05JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			28JUN2003-03JUL2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	6	13	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0010029	44 YRS CAUCASIAN MALE	20JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0011022	35 YRS CAUCASIAN FEMALE	11JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			08JUL2003-15JUL2003	ON	DIZZINESS (Nervous system disorders) [NOT DUE TO POSTURAL HYPOTENSION DIZZINESS]	8	30	MIL	NO	N	N	N	N	N	N	NO YES	None
					DIZZINESS (Nervous system disorders) [NOT DUE TO POSTURAL HYPOTENSION FAINT FEELINGS]	8	30	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0013006	28 YRS CAUCASIAN FEMALE	15MAR2003-22MAR2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-21MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	5	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-20MAR2003	ON	DYSTONIA (Nervous system disorders) [DYSTONIA]	1	8	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0013006	28 YRS CAUCASIAN FEMALE	20MAR2003-20MAR2003	ON	SENSATION OF BLOOD FLOW (General disorders and administration site conditions) [THROBBING VESSELS (SENSATION OF BLOOD RUSHING IN THE VEINS)]	1	8	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0013012	58 YRS BLACK FEMALE	09MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			10MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0013014	48 YRS CAUCASIAN MALE	04JUN2003-CONTINUE	ON	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0013014	48 YRS CAUCASIAN MALE	06JUN2003-22JUN2003	ON	AKATHISIA (Nervous system disorders) [(RESTLESSNESS) AKATHISIA]	17	4	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					PRURITUS (Skin and subcutaneous tissue disorders) [ITCHINESS]	17	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JUN2003-24JUN2003	ON	AKATHISIA (Nervous system disorders) [(RESTLESSNESS) AKATHISIA]	1	22	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					PRURITUS (Skin and subcutaneous tissue disorders) [ITCHINESS]	1	22	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0014005	44 YRS CAUCASIAN FEMALE	12MAR2003-29APR2003	ON	COORDINATION ABNORMAL NOS (Nervous system disorders) [POOR COORDINATION (NOT DUE TO EPS)]	49	2	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					MUSCLE WEAKNESS NOS (Musculoskeletal and connective tissue disorders) [MUSCLE WEAKNESS (NOT DUE TO EPS)]	49	2	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					SEDATION (Nervous system disorders) [SEDATION]	49	2	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			29MAR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			01APR2003-29APR2003	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [SWOLLEN HANDS]	29	22	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0014005	44 YRS CAUCASIAN FEMALE	02APR2003-29APR2003	ON	BRADYPHRENIA (Psychiatric disorders) [SLOWED THINKING]	28	23	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			23APR2003-24APR2003	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	2	44	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			01MAY2003-27MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	27	52	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0014007	22 YRS CAUCASIAN FEMALE	03APR2003-19APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	17	3	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	17	3	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0014007	22 YRS CAUCASIAN FEMALE	03APR2003-19APR2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS (DUE TO ORTHOSTATIC HYPOTENSION)]	17	3	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
					SEDATION (Nervous system disorders) [SEDATION]	17	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			04APR2003-19APR2003	ON	TREMOR (Nervous system disorders) [TREMOR (NOT DUE TO EPS)]	16	4	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			07APR2003-19APR2003	ON	THROAT TIGHTNESS (Respiratory, thoracic and mediastinal disorders) [TIGHT THROAT]	13	7	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
			15APR2003-19APR2003	ON	TENSION (Psychiatric disorders) [TENSION]	5	15	SEV	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	39 YRS CAUCASIAN MALE	14MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			01JUN2003-01JUL2003	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	31	20	MOD	NO	N	N	N	N	N	N	NO YES	None
			03JUN2003-15JUL2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	43	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			27JUN2003-18JUL2003	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED SEX DRIVE]	22	46	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014012	55 YRS CAUCASIAN FEMALE	29MAY2003-25JUN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	28	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0014012	55 YRS CAUCASIAN FEMALE	31MAY2003-26JUN2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	27	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			04JUN2003-25JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0015001	54 YRS CAUCASIAN MALE	03DEC2002-13DEC2002	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	11	5	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0015008	41 YRS CAUCASIAN MALE	16JAN2003-23JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	29	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0016003	22 YRS CAUCASIAN FEMALE	01FEB2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0018007	42 YRS CAUCASIAN FEMALE	29DEC2002-07FEB2003	ON	SEDATION (Nervous system disorders) [SEDATION]	41	3	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGINESS]	41	3	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019005	50 YRS CAUCASIAN FEMALE	05NOV2002-19NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0019005	50 YRS CAUCASIAN FEMALE	11NOV2002-11NOV2002	ON	HEADACHE (Nervous system disorders) [HEADACHES]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
			14NOV2002-14NOV2002	ON	HALLUCINATION, VISUAL (Psychiatric disorders) [VISUAL HALLUCINATION]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0019015	24 YRS CAUCASIAN FEMALE	02JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-16JAN2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-23JAN2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	22	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0019015	24 YRS CAUCASIAN FEMALE	04JAN2003-19JAN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			12JAN2003-19JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	8	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			12JAN2003-27JAN2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	16	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			01FEB2003-09FEB2003	ON	INSOMNIA (Psychiatric disorders) [DECREASED SLEEP]	9	31	MOD	NO	N	N	N	N	N	N	NO YES	None
			01FEB2003-11FEB2003	ON	LOGORRHOEA (Psychiatric disorders) [INCREASED SPEECH (MORE TALKATIVE)]	11	31	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0019015	24 YRS CAUCASIAN FEMALE	01FEB2003-11FEB2003	ON	PSYCHOMOTOR HYPERACTIVITY (Nervous system disorders) [HYPERACTIVITY]	11	31	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020004	61 YRS CAUCASIAN MALE	09DEC2002-24DEC2002	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	16	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020010	31 YRS CAUCASIAN FEMALE	07FEB2003-08FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			15FEB2003-24FEB2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INTERMITTENT HEARTBURN]	10	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			20FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	16	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0020010	31 YRS CAUCASIAN FEMALE	05MAR2003-17MAR2003	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	13	29	MIL	NO	N	N	N	N	N	N	NO YES	None
			05MAR2003-19MAR2003	ON	AKATHISIA (Nervous system disorders) [BILATERAL HAND TREMORS (DUE TO EPS - AKATHISIA)]	15	29	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0020014	43 YRS BLACK FEMALE	22MAR2003-04APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	14	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			29APR2003-09MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION UPON AWAKENING APPROXIMATELY 6:00 AM - NOON]	11	43	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0020021	47 YRS BLACK MALE	19MAY2003-04JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH IN THE MORNING]	17	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020023	46 YRS CAUCASIAN MALE	19JUN2003-26JUN2003	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [LEFT LEG TWITCH (NOT DUE TO EPS)]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUL2003-15JUL2003	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [BRADYKINESIA (DUE TO EPS)]	15	15	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	15	15	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0020023	46 YRS CAUCASIAN MALE	04JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0022007	31 YRS CAUCASIAN FEMALE	10NOV2002-28NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	19	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			10NOV2002-06DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	27	4	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022010	21 YRS CAUCASIAN MALE	24NOV2002-02DEC2002	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	9	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0022010	21 YRS CAUCASIAN MALE	28NOV2002-28NOV2002	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [ACCIDENTAL OVERDOSE OF STUDY MEDICATION]	1	8	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022012	27 YRS CAUCASIAN FEMALE	07DEC2002-13DEC2002	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	7	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022019	30 YRS CAUCASIAN MALE	20DEC2002-04JAN2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	16	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			22DEC2002-19JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0022033	45 YRS CAUCASIAN FEMALE	24FEB2003-05MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	10	7	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022038	39 YRS CAUCASIAN MALE	04MAR2003-21MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	18	5	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			05APR2003-10APR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	6	37	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0022039	31 YRS BLACK FEMALE	06MAR2003-22MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	17	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-22MAR2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	16	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	31 YRS BLACK FEMALE	07MAR2003-28MAR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	22	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0022048	26 YRS ORIENTAL FEMALE	02APR2003-24APR2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0022058	43 YRS CAUCASIAN MALE	22APR2003-24MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	33	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	33	2	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0022062	63 YRS CAUCASIAN MALE	05MAY2003-21MAY2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	17	1	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	63 YRS CAUCASIAN MALE	13MAY2003-19MAY2003	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [GASTRIC REFLUX]	7	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022068	44 YRS CAUCASIAN FEMALE	24MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			27MAY2003-01JUN2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	6	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022071	57 YRS CAUCASIAN MALE	30JUN2003-25AUG2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS (NOT DUE TO EPS)]	57	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	57 YRS CAUCASIAN MALE	01JUL2003-25AUG2003	ON	SOMNOLENCE (Nervous system disorders) [SOMNOLENCE]	56	2	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023006	39 YRS CAUCASIAN MALE	17DEC2002-17JAN2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	32	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JAN2003-24JAN2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	7	33	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023010	46 YRS CAUCASIAN MALE	04FEB2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	46 YRS CAUCASIAN MALE	12FEB2003-CONTINUE	ON	HEADACHE (Nervous system di sorders) [HEADACHE]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023039	48 YRS CAUCASIAN FEMALE	03JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0026002	62 YRS CAUCASIAN MALE	15NOV2002-11JAN2003	ON	SEDATION (Nervous system di sorders) [SEDATION]	58	4	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026007	59 YRS CAUCASIAN FEMALE	18JAN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028007	22 YRS CAUCASIAN FEMALE	05OCT2002-CONTINUE	ON	SOMNOLENCE (Nervous system di sorders) [SLEEPINESS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028007	22 YRS CAUCASIAN FEMALE	05OCT2002-05OCT2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07OCT2002-17OCT2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	11	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			11NOV2002-11NOV2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	39	SEV	NO	N	N	N	N	N	N	NO YES	None
					VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	39	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0028023	54 YRS BLACK MALE	25JAN2003-26JAN2003	ON	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028023	54 YRS BLACK MALE	17FEB2003-21FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSY]	5	28	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0028025	27 YRS CAUCASIAN MALE	13JAN2003-25JAN2003	ON	LIBIDO DECREASED (Psychiatric disorders) [DECREASED LIBIDO]	13	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			15JAN2003-18JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	4	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			15JAN2003-25JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	3	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0028033	44 YRS CAUCASIAN FEMALE	27MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028033	44 YRS CAUCASIAN FEMALE	27MAR2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028035	57 YRS CAUCASIAN MALE	05APR2003-05JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	62	3	SEV	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	62	3	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0028037	61 YRS CAUCASIAN MALE	16JUN2003-16JUN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	1	4	SEV	NO	N	N	N	N	N	N	NO YES	None
			12JUL2003-12JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	1	30	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028039	28 YRS CAUCASIAN MALE	10MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			13MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAY2003-23MAY2003	ON	THROAT TIGHTNESS (Respiratory, thoracic and mediastinal disorders) [THROAT CONSTRICTION NOT DUE TO EPS]	7	9	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0028048	18 YRS HISPANIC FEMALE	18JUL2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0028048	18 YRS HISPANIC FEMALE	18JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-27JUL2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	10	2	SEV	NO	N	N	N	N	N	N	NO YES	None
					VISION BLURRED (Eye disorders) [BLURRED VISION]	10	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029008	22 YRS CAUCASIAN FEMALE	18DEC2002-21DEC2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	4	3	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0029008	22 YRS CAUCASIAN FEMALE	19DEC2002-19DEC2002	ON	SYNCOPE (Nervous system disorders) [FAINTING (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	1	4	MOD	NO	N	N	N	N	N	N	YES YES	Dose Changed
			19DEC2002-20DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	2	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			19DEC2002-21DEC2002	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	3	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029011	26 YRS CAUCASIAN MALE	22JAN2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS AFTER DOSE]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0029011	26 YRS CAUCASIAN MALE	22JAN2003-24JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JAN2003-31JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	8	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			30JAN2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	UNK	9	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			01FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	11	SEV	NO	N	N	N	N	N	N	NO YES	None
			10FEB2003-CONTINUE	ON	CHAPPED LIPS (Gastrointestinal disorders) [SPLIT LIP]	UNK	20	MOD	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	39 YRS CAUCASIAN FEMALE	12FEB2003-20MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	37	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14FEB2003-20MAR2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGY IN AM.]	35	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			16FEB2003-CONTINUE	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	UNK	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			16FEB2003-01MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT RELATED TO ORTHOSTATIC HYPOTENSION]	14	6	MIL	NO	N	N	N	N	N	N	NO YES	None
					VISION BLURRED (Eye disorders) [CLOUDY EYES/VISION]	14	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0029012	39 YRS CAUCASIAN FEMALE	26FEB2003-01MAR2003	ON	EYELIDS PRURITUS (Eye disorders) [ITCHY EYELIDS]	4	16	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029015	45 YRS CAUCASIAN FEMALE	24FEB2003-10MAR2003	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE PAIN]	15	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-25FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-10MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	14	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0029015	45 YRS CAUCASIAN FEMALE	01MAR2003-10MAR2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	10	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0030014	32 YRS CAUCASIAN FEMALE	22FEB2003-25FEB2003	ON	DYSTONIA (Nervous system disorders) [OPTIC MUSCLE STIFFNESS DUE TO EPS (DYSTONIA)]	4	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			22FEB2003-23APR2003	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	61	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			23FEB2003-23FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24FEB2003-25FEB2003	ON	CHEST PAIN (General disorders and administration site conditions) [HEART FLUTTER (FEELING)]	2	4	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0030014	32 YRS CAUCASIAN FEMALE	24FEB2003-23APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	59	4	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					DYSARTHRIA (Nervous system disorders) [SLURRED SPEECH]	59	4	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	59	4	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25FEB2003-25FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	5	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25FEB2003-01MAR2003	ON	HYPOTENSION NOS (Vascular disorders) [LOW BLOOD PRESSURE HYPOTENSIVE EPISODE]	5	5	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0030014	32 YRS CAUCASIAN FEMALE	01MAR2003-01MAR2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS (DUE TO ORTHOSTATIC HYPOTENSION)]	1	9	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0030020	20 YRS CAUCASIAN MALE	29MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			30MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [EARLY AM SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0030024	30 YRS CAUCASIAN FEMALE	13JUL2003-16JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	4	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0030025	63 YRS BLACK FEMALE	18JUL2003-08AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	22	8	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031030	35 YRS CAUCASIAN FEMALE	24JUN2003-10AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	48	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0033012	39 YRS CAUCASIAN MALE	13FEB2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	4	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0034004	46 YRS CAUCASIAN MALE	22APR2003-23APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY NOT DUE TO ORTHOSTATIC HYPOTENSION]	2	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27APR2003-03JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	38	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0035021	29 YRS HISPANIC FEMALE	06MAY2003-14MAY2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	9	12	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	9	12	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0036002	32 YRS CAUCASIAN FEMALE	17JUN2003-24JUN2003	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS, (NOT DUE TO POSTURAL HYPOTENSION)]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			17JUN2003-14JUL2003	ON	SOMNOLENCE (Nervous system disorders) [INTERMITTENT SLEEPINESS]	28	1	SEV	NO	N	N	N	N	N	N	NO YES	None
			18JUN2003-14JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	27	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0036002	32 YRS CAUCASIAN FEMALE	20JUN2003-25JUN2003	ON	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	6	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JUL2003-11JUL2003	ON	MANIA (Psychiatric disorders) [MANIA]	4	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			12JUL2003-17JUL2003	ON	MANIA (Psychiatric disorders) [MANIA]	6	26	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0036006	38 YRS CAUCASIAN MALE	03JUL2003-13JUL2003	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	11	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-14JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0036006	38 YRS CAUCASIAN MALE	14JUL2003-27AUG2003	ON	SOMNOLENCE (Nervous system disorders) [SLEEPINESS]	45	12	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0036007	35 YRS CAUCASIAN FEMALE	07JUL2003-10JUL2003	ON	SOMNOLENCE (Nervous system disorders) [INTERMITTENT SLEEPINESS]	4	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			10JUL2003-12JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	8	SEV	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-14JUL2003	ON	URINARY INCONTINENCE (Renal and urinary disorders) [INTERMITTENT URINARY INCONTINENCE SECONDARY TO SEDATION]	4	9	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0036007	35 YRS CAUCASIAN FEMALE	14JUL2003-15JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	2	12	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0037009	34 YRS HISPANIC FEMALE	20MAY2003-21MAY2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT SECONDARY TO POSTURAL HYPOTENSION]	2	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			28MAY2003-04JUN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT SECONDARY TO POSTURAL HYPOTENSION]	8	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			12JUN2003-11JUL2003	ON	ASTHENIA (General disorders and administration site conditions) [WEAKNESS]	30	28	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR I)	E0037009	34 YRS HISPANIC FEMALE	12JUN2003-11JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	30	28	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0039011	34 YRS BLACK FEMALE	03JAN2003-03JAN2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	1	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039018	34 YRS BLACK FEMALE	25JAN2003-27JAN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	3	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			29JAN2003-29JAN2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	1	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			05FEB2003-CONTINUE	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [INCREASED NIGHT SWEATS]	UNK	14	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	45 YRS BLACK FEMALE	10MAR2003-10MAR2003	ON	TREMOR (Nervous system disorders) [TREMORS RIGHT HAND (NOT DUE TO EPS)]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-11MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	2	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-18MAR2003	ON	ASTHENIA (General disorders and administration site conditions) [DECREASED ENERGY]	9	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			12MAR2003-18MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [INCREASED CONSTIPATION]	7	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	45 YRS BLACK FEMALE	26MAR2003-27MAR2003	ON	ASTHENIA (General disorders and administration site conditions) [WEAK AFTER DOSE (NOT DUE TO POSTURAL HYPOTENSION)]	2	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			25APR2003-CONTINUE	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [PERIPHERAL EDEMA]	UNK	50	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039028	39 YRS BLACK MALE	24MAR2003-22MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS NOT DUE TO POSTURAL HYPOTENSION]	60	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039032	26 YRS BLACK FEMALE	14MAR2003-14MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	26 YRS BLACK FEMALE	14MAR2003-15MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			28MAR2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039034	29 YRS CAUCASIAN FEMALE	19MAR2003-25APR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	38	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039042	35 YRS BLACK FEMALE	08MAY2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	35 YRS BLACK FEMALE	17MAY2003-17MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [DIZZY WHEN STANDING "NOT DUE TO POSTURAL HYPOTENSION"]	1	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			20MAY2003-20MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [DIZZY WHEN STANDING "NOT DUE TO POSTURAL HYPOTENSION"]	1	14	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAY2003-03JUN2003	ON	CONSTIPATION (Gastrointestinal disorders) [INCREASED CONSTIPATION]	13	16	MOD	NO	N	N	N	N	N	N	NO YES	None
			30JUN2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [INCREASED CONSTIPATION]	UNK	55	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	35 YRS CAUCASIAN MALE	30JAN2003-21FEB2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	23	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			30JAN2003-02APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	63	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			10FEB2003-23FEB2003	ON	TREMOR (Nervous system disorders) [TREMOR (NOT DUE TO EPS)]	14	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			17FEB2003-21FEB2003	ON	PALPITATIONS (Cardiac disorders) [HEART PALPITATIONS]	5	19	MIL	NO	N	N	N	N	N	N	NO YES	None
			23FEB2003-01MAR2003	ON	TINNITUS (Ear and labyrinth disorders) [INTERMITTENT TINNITUS]	7	25	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0041004	35 YRS CAUCASIAN MALE	10MAR2003-17MAR2003	ON	FEELING COLD (General disorders and administration site conditions) [COLD FLASHES]	8	40	MIL	NO	N	N	N	N	N	N	NO YES	None
					FLUSHING (Vascular disorders) [HOT FLASHES]	8	40	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-25MAR2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	16	40	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0042002	26 YRS CAUCASIAN MALE	09JUL2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-29AUG2003	ON	CONSTIPATION (Gastrointestinal disorders) [INTERMITTENT CONSTIPATION]	50	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0001006	29 YRS CAUCASIAN MALE	11JUL2003-17JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	7	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JUL2003-CONTINUE	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [LIPS TWITCHING NOT DUE TO EPS]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			12JUL2003-17JUL2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [MUSCLE CRAMPS NOT DUE TO EPS]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [MUSCLE TWITCHING NOT DUE TO EPS]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0003002	37 YRS CAUCASIAN MALE	12NOV2002-12NOV2002	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	1	15	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0005031	29 YRS CAUCASIAN FEMALE	02APR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06APR2003-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			06APR2003-30APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			17APR2003-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	16	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0005031	29 YRS CAUCASIAN FEMALE	23APR2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [WORSENING OF CONSTIPATION]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			02MAY2003-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE STIFFNESS OF BACK (SECONDARY TO EPS)]	UNK	31	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005033	33 YRS CAUCASIAN FEMALE	16APR2003-14MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	29	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			18APR2003-14MAY2003	ON	FLUSHING (Vascular disorders) [INTERMITTENT HOT FLASHES]	27	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0005033	33 YRS CAUCASIAN FEMALE	20APR2003-14MAY2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	25	5	MOD	NO	N	N	N	N	N	N	NO YES	None
					NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	25	5	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			26APR2003-14MAY2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	19	11	MOD	NO	N	N	N	N	N	N	NO YES	None
					FLUID RETENTION (Metabolism and nutrition disorders) [WATER RETENTION]	19	11	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005038	31 YRS CAUCASIAN FEMALE	14MAY2003-CONTINUE	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0005038	31 YRS CAUCASIAN FEMALE	14MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			14MAY2003-01JUN2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	19	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			23MAY2003-CONTINUE	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	UNK	10	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0007009	29 YRS CAUCASIAN FEMALE	19APR2003-24APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	6	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0009010	31 YRS CAUCASIAN MALE	14MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [OVERSEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0009010	31 YRS CAUCASIAN MALE	17MAR2003-CONTINUE	ON	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			22MAR2003-CONTINUE	ON	LOSS OF LIBIDO (Psychiatric disorders) [LOSS OF LIBIDO]	UNK	10	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0009011	62 YRS CAUCASIAN MALE	13MAY2003-01JUN2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [DIZZINESS (UPON STANDING NOT DUE TO POSTURAL HYPOTENSION)]	20	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			15MAY2003-30JUN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	47	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-01JUN2003	ON	TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	8	20	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	40 YRS CAUCASIAN MALE	22APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			22APR2003-11MAY2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	20	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			23APR2003-29MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	37	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			23APR2003-03JUN2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	42	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0011020	33 YRS CAUCASIAN MALE	09MAY2003-10MAY2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS, SECONDARY TO POSTURAL HYPOTENSION]	2	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			09MAY2003-11MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0018002	53 YRS CAUCASIAN MALE	01DEC2002-CONTINUE	ON	DISTURBANCE IN ATTENTION (Nervous system disorders) [DECREASED CONCENTRATION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			03DEC2002-09DEC2002	ON	SEDATION (Nervous system disorders) [SEDATION]	7	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018002	53 YRS CAUCASIAN MALE	04DEC2002-CONTINUE	ON	SINUS CONGESTION (Respiratory, thoracic and mediastinal disorders) [SINUS CONGESTION]	UNK	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002-06DEC2002	ON	HALLUCINATION, VISUAL (Psychiatric disorders) [VISUAL HALLUCINATIONS]	1	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002-12DEC2002	ON	DYSKINESIA (Nervous system disorders) [NOCTURNAL MYOCLONES (NOT DUE TO EPS)]	7	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002-15DEC2002	ON	ALCOHOL INTOLERANCE (Metabolism and nutrition disorders) [INTERMITTENT INCREASED EFFECTS OF ALCOHOL]	10	8	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018002	53 YRS CAUCASIAN MALE	07DEC2002-CONTINUE	ON	THOUGHT BLOCKING (Psychiatric disorders) [THOUGHT BLOCKING]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			12DEC2002-14DEC2002	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	3	14	MOD	NO	N	N	N	N	N	N	NO YES	None
			20DEC2002-18JAN2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [PARTIAL IMPOTENCE]	30	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			22DEC2002-22DEC2002	ON	SOMNOLENCE (Nervous system disorders) [GROGGINESS]	1	24	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018002	53 YRS CAUCASIAN MALE	25DEC2002-CONTINUE	ON	MUSCLE CONTRACTIONS INVOLUNTARY (Nervous system disorders) [MUSCLE FASCICULATION (NOT DUE TO EPS)]	UNK	27	MIL	NO	N	N	N	N	N	N	NO YES	None
			28DEC2002-20JAN2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	24	30	MIL	NO	N	N	N	N	N	N	NO YES	None
			01JAN2003-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	UNK	34	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0018003	27 YRS CAUCASIAN FEMALE	27NOV2002-27NOV2002	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (UNKNOWN IF DUE TO POSTURAL HYPOTENSION)]	1	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0018003	27 YRS CAUCASIAN FEMALE	29NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGIC]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATED]	UNK	4	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			02DEC2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
					NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0018013	44 YRS CAUCASIAN MALE	25JAN2003-29JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	5	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0018013	44 YRS CAUCASIAN MALE	25JAN2003-29JAN2003	ON	SEDATION (Nervous system disorders) [OVER SEDATION]	5	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			29JAN2003-30JAN2003	ON	HEADACHE (Nervous system disorders) [INCREASED INTENSITY HEADACHE]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019002	22 YRS CAUCASIAN FEMALE	13NOV2002-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			18NOV2002-CONTINUE	ON	TENSION HEADACHE (Nervous system disorders) [TENSION HEADACHE]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019008	35 YRS CAUCASIAN FEMALE	22NOV2002-CONTINUE	ON	ALTERED VISUAL DEPTH PERCEPTION (Eye disorders) [PROBLEM WITH DEPTH PERCEPTION]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019008	35 YRS CAUCASIAN FEMALE	22NOV2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGY]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					TACHYCARDIA NOS (Cardiac disorders) [TACHYCARDIA]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			27NOV2002-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	UNK	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019009	22 YRS CAUCASIAN FEMALE	15NOV2002-CONTINUE	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019009	22 YRS CAUCASIAN FEMALE	15NOV2002-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			20NOV2002-20NOV2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019016	26 YRS CAUCASIAN FEMALE	06JAN2003-09FEB2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	35	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JAN2003-26FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	52	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JAN2003-20JAN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	13	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019016	26 YRS CAUCASIAN FEMALE	24JAN2003-CONTINUE	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS (NOT DUE TO EPS)]	UNK	19	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019020	35 YRS CAUCASIAN FEMALE	24JAN2003-07FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	15	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			06FEB2003-12FEB2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DYSPHAGIA (DIFFICULTY SWALLOWING)]	7	15	MIL	NO	N	N	N	N	N	N	NO YES	None
			17FEB2003-18FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	26	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019021	41 YRS CAUCASIAN MALE	01FEB2003-17FEB2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEG DUE TO EPS (AKATHISIA)]	17	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGIC]	17	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0019024	26 YRS CAUCASIAN MALE	31JAN2003-06FEB2003	ON	CONFUSIONAL STATE (Psychiatric disorders) [CONFUSION]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DIZZINESS (Nervous system disorders) [LIGHTHEADED (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	31JAN2003-06FEB2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [DIFFICULTY BREATHING]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [SHORTNESS OF BREATH]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SOMNOLENCE (Nervous system disorders) [DROWSY]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					TOOTH DISORDER NOS (Gastrointestinal disorders) [WEIRD FEELING IN TEETH]	7	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	01FEB2003-06FEB2003	ON	LIMB DISCOMFORT NOS (Musculoskeletal and connective tissue disorders) [UNCOMFORTABLE FEELING IN LEGS AND ARMS]	6	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			02FEB2003-02FEB2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			04FEB2003-06FEB2003	ON	BRUXISM (Psychiatric disorders) [BRUXISM]	3	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	3	6	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26 YRS CAUCASIAN MALE	04FEB2003-06FEB2003	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	3	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			05FEB2003-05FEB2003	ON	COUGH (Respiratory, thoracic and mediastinal disorders) [WORSENING OF COUGH]	1	7	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0019031	47 YRS CAUCASIAN MALE	13MAR2003-17MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	5	1	SEV	NO	N	N	N	N	N	N	YES YES	None
			14MAR2003-16MAR2003	ON	JOINT STIFFNESS (Musculoskeletal and connective tissue disorders) [TIGHTNESS IN JOINTS (NOT DUE TO EPS)]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019031	47 YRS CAUCASIAN MALE	14MAR2003-16MAR2003	ON	PARAESTHESIA (Nervous system disorders) [TINGLING IN ARMS]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None
					PARAESTHESIA (Nervous system disorders) [TINGLING IN LEGS]	3	2	MOD	NO	N	N	N	N	N	N	YES YES	None
	E0019035	34 YRS CAUCASIAN FEMALE	20MAR2003-24APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	36	3	SEV	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	36	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			25MAR2003-CONTINUE	ON	ANGER (Psychiatric disorders) [INCREASED ANGER]	UNK	8	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019035	34 YRS CAUCASIAN FEMALE	03APR2003-24APR2003	ON	RESTLESS LEGS SYNDROME (Nervous system disorders) [RESTLESS LEGS AT NIGHT NOT DUE TO EPS]	22	17	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			11APR2003-24APR2003	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	14	25	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0019040	49 YRS BLACK MALE	21MAY2003-24MAY2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	4	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			21MAY2003-01JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	42	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019040	49 YRS BLACK MALE	21MAY2003-01JUL2003	ON	SEDATION (Nervous system disorders) [SEDATION]	42	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			29MAY2003-CONTINUE	ON	WEIGHT INCREASED (Investigations) [WEIGHT GAIN]	UNK	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			08JUN2003-19JUN2003	ON	DYSGEUSIA (Nervous system disorders) [ABNORMAL TASTE IN MOUTH]	12	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			09JUN2003-CONTINUE	ON	BRUXISM (Psychiatric disorders) [GRINDING TEETH]	UNK	21	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-CONTINUE	ON	HYPOAESTHESIA (Nervous system disorders) [NUMBNESS IN FINGER TIPS]	UNK	46	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019042	27 YRS CAUCASIAN FEMALE	05JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION.]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14JUN2003-18JUN2003	ON	TREMOR (Nervous system disorders) [HAND TREMORS (NOT DUE TO EPS)]	5	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			15JUN2003-18JUN2003	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	4	12	MIL	NO	N	N	N	N	N	N	YES YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	4	12	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019045	32 YRS CAUCASIAN FEMALE	27JUN2003-09JUL2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	13	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0020024	18 YRS CAUCASIAN MALE	30JUN2003-15JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE INTERMITTENT]	16	8	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023007	23 YRS CAUCASIAN FEMALE	15JAN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023011	50 YRS CAUCASIAN FEMALE	08MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	33	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023014	40 YRS CAUCASIAN MALE	21FEB2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023014	40 YRS CAUCASIAN MALE	21FEB2003-20MAR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	28	1	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023019	32 YRS CAUCASIAN MALE	08APR2003-10APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			09APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023022	21 YRS CAUCASIAN MALE	19APR2003-26APR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			19APR2003-17MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	29	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023023	35 YRS CAUCASIAN FEMALE	26APR2003-29APR2003	ON	DIZZINESS (Nervous system disorders) [DIZZY NOT DUE TO POSTURAL HYPOTENSION]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	None
					SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0023029	46 YRS HISPANIC FEMALE	24MAY2003-28MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0023029	46 YRS HISPANIC FEMALE	24MAY2003-28MAY2003	ON	SEDATION (Nervous system disorders) [SEDATION]	5	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0023031	49 YRS CAUCASIAN FEMALE	24JUN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			26JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			04JUL2003-10JUL2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	7	11	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0023041	40 YRS CAUCASIAN FEMALE	09JUL2003-21JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	13	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023041	40 YRS CAUCASIAN FEMALE	09JUL2003-21JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	13	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			12JUL2003-12JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			13JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-10AUG2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	17	17	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026003	46 YRS CAUCASIAN MALE	06DEC2002-13DEC2002	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	8	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	46 YRS CAUCASIAN MALE	06DEC2002-19DEC2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	14	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002-12JAN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	38	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			06DEC2002-12FEB2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	69	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			08DEC2002-15DEC2002	ON	FOOD CRAVING (Metabolism and nutrition disorders) [CRAVING FOR SODIUM]	8	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026005	57 YRS CAUCASIAN FEMALE	30DEC2002-11JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	13	1	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0026005	57 YRS CAUCASIAN FEMALE	30DEC2002-11JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	13	1	SEV	NO	N	N	N	N	N	N	NO YES	None
					DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [LABORED BREATHING]	13	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					IRRITABILITY (Psychiatric disorders) [IRRITABLE]	13	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	13	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0026009	43 YRS CAUCASIAN FEMALE	17JAN2003-19JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	3	3	SEV	NO	N	N	N	N	N	N	YES YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0026009	43 YRS CAUCASIAN FEMALE	17JAN2003-19JAN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	3	3	SEV	NO	N	N	N	N	N	N	NO YES	None
					VISION BLURRED (Eye disorders) [BLURRED VISION, BOTH EYES]	3	3	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0026015	47 YRS CAUCASIAN FEMALE	05MAR2003-06MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	2	7	MIL	NO	N	N	N	N	N	N	NO YES	None
			06MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026023	20 YRS CAUCASIAN MALE	30APR2003-30MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	31	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	24 YRS CAUCASIAN FEMALE	10APR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			10APR2003-22APR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	13	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION IN AM]	UNK	16	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028032	36 YRS CAUCASIAN MALE	25MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			27MAR2003-22MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	57	3	SEV	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0028032	36 YRS CAUCASIAN MALE	01APR2003-CONTINUE	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	UNK	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-14MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	44	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAY2003-10MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	47	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0029003	20 YRS CAUCASIAN MALE	05NOV2002-14NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	10	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			14NOV2002-25NOV2002	ON	SEDATION (Nervous system disorders) [SEDATION]	12	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			16NOV2002-25NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	10	13	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0029003	20 YRS CAUCASIAN MALE	26NOV2002-17DEC2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	22	23	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029020	33 YRS CAUCASIAN MALE	05MAR2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			09MAR2003-CONTINUE	ON	DYSPHAGIA (Gastrointestinal disorders) [DIFFICULTY SWALLOWING]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-10MAR2003	ON	DYSURIA (Renal and urinary disorders) [DIFFICULTY URINATING]	1	6	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031006	41 YRS CAUCASIAN MALE	20FEB2003-29MAR2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	38	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			12APR2003-21APR2003	ON	EXCORIATION (Injury, poisoning and procedural complications) [ABRASIONS]	10	54	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0031010	37 YRS OTHER FEMALE	19FEB2003-CONTINUE	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			20FEB2003-27FEB2003	ON	DYSGEUSIA (Nervous system disorders) [METALLIC TASTE IN MOUTH]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031010	37 YRS OTHER FEMALE	26FEB2003-01MAR2003	ON	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	4	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			26FEB2003-05MAR2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	8	8	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031011	46 YRS CAUCASIAN MALE	28FEB2003-21MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DIFFICULTY WAKING UP]	22	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-22MAR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-21MAR2003	ON	NERVOUSNESS (Psychiatric disorders) [INCREASED NERVOUS ENERGY (NERVOUSNESS)]	5	19	MOD	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031011	46 YRS CAUCASIAN MALE	17MAR2003-21MAR2003	ON	SWOLLEN TONGUE (Gastrointestinal disorders) [SWOLLEN TONGUE]	5	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0031015	27 YRS CAUCASIAN FEMALE	27MAR2003-04APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	9	2	MIL	NO	N	N	N	N	N	N	YES YES	None
			29MAR2003-04APR2003	ON	DIZZINESS (Nervous system disorders) [LIGHTHEADEDNESS NOT DUE TO POSTURAL HYPOTENSION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	None
					SEDATION (Nervous system disorders) [DAYTIME SEDATION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					VISION BLURRED (Eye disorders) [BLURRED VISION]	7	4	MOD	NO	N	N	N	N	N	N	YES YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0031031	33 YRS CAUCASIAN FEMALE	08JUL2003-20JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	13	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			09JUL2003-02AUG2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			20JUL2003-06AUG2003	ON	SEDATION (Nervous system disorders) [AM SEDATION]	18	13	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0033009	46 YRS CAUCASIAN FEMALE	13FEB2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [MORE SEVERE HEADACHES]	UNK	2	SEV	NO	N	N	N	N	N	N	YES YES	None
	E0034009	44 YRS BLACK MALE	20JUN2003-21AUG2003	ON	SOMNOLENCE (Nervous system disorders) [GROGGY FEELING]	63	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed

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QUETIAPINE 600 MG (BIPOLAR II)	E0034009	44 YRS BLACK MALE	21JUN2003-01JUL2003	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	11	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			21JUN2003-21AUG2003	ON	SLUGGISHNESS (General disorders and administration site conditions) [DAYTIME SLUGGISHNESS]	62	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0037007	23 YRS CAUCASIAN FEMALE	12APR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	21 YRS CAUCASIAN MALE	17JUL2003-08AUG2003	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	23	2	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24JUL2003-24JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			07AUG2003-29AUG2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	23	23	MIL	NO	N	N	N	N	N	N	NO YES	None
			22AUG2003-08SEP2003	ON	TREMOR (Nervous system disorders) [BILATERAL HAND TREMOR (NOT DUE TO EPS)]	18	38	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039019	35 YRS BLACK FEMALE	11FEB2003-12FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	2	6	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	35 YRS BLACK FEMALE	13FEB2003-16MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS (POST DOSE)]	32	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-23MAR2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	39	8	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [DROWSINESS]	39	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			28FEB2003-16MAR2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	17	23	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAR2003-23MAR2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	7	40	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0039019	35 YRS BLACK FEMALE	26MAR2003-26MAR2003	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	1	49	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039043	20 YRS CAUCASIAN MALE	08MAY2003-CONTINUE	ON	ABNORMAL DREAMS (Psychiatric disorders) [HAVING DREAMS]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0002003	22 YRS CAUCASIAN FEMALE	22JAN2003-CONTINUE	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0002016	56 YRS CAUCASIAN FEMALE	26JUL2003-03SEP2003	ON	SOMNOLENCE (Nervous system disorders) [INTERMITTENT DROWSINESS]	40	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			15AUG2003-15AUG2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	1	23	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0003008	35 YRS CAUCASIAN FEMALE	29JAN2003-29JAN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO POSTURAL HYPOTENSION)]	1	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0003008	35 YRS CAUCASIAN FEMALE	29JAN2003-31JAN2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [INTENSE DREAMING (VIVID DREAMS)]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			15FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004003	22 YRS CAUCASIAN MALE	10OCT2002-13OCT2002	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	4	1	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004006	37 YRS CAUCASIAN FEMALE	08NOV2002-20NOV2002	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	13	5	MIL	NO	N	N	N	N	N	N	NO YES	None
					POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	13	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0004006	37 YRS CAUCASIAN FEMALE	08NOV2002-03DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHES]	26	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004016	20 YRS HISPANIC FEMALE	03MAR2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	13	MOD	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-10MAR2003	ON	NIGHT SWEATS (Skin and subcutaneous tissue disorders) [NIGHT SWEATS]	1	20	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0004024	39 YRS CAUCASIAN FEMALE	18JUL2003-26JUL2003	ON	MUSCLE TIGHTNESS (Musculoskeletal and connective tissue disorders) [MUSCLE TIGHTNESS LEFT NECK AREA (NOT DUE TO EPS)]	9	16	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0005006	35 YRS CAUCASIAN MALE	04OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			05OCT2002-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	3	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0005039	39 YRS CAUCASIAN FEMALE	24MAY2003-20JUN2003	ON	SEDATION (Nervous system disorders) [SEDATION]	28	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-25MAY2003	ON	GASTROOESOPHAGEAL REFLUX DISEASE (Gastrointestinal disorders) [ACID REFLUX]	1	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0006020	38 YRS CAUCASIAN MALE	21MAY2003-10JUN2003	ON	SENSATION OF HEAVINESS (Musculoskeletal and connective tissue disorders) [HEAVINESS IN ARMS AND LEGS]	21	9	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0006020	38 YRS CAUCASIAN MALE	21MAY2003-17JUN2003	ON	SOMNOLENCE (Nervous system disorders) [MORNING SLEEPINESS]	28	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0007006	39 YRS BLACK MALE	22MAR2003-31MAR2003	ON	RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	10	18	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0009004	36 YRS CAUCASIAN MALE	27NOV2002-20DEC2002	ON	IRRITABILITY (Psychiatric disorders) [IRRITABILITY]	24	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0009012	28 YRS CAUCASIAN MALE	25JUN2003-26JUN2003	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [EPS (INVOLUNTARY MOVEMENT OF MOUTH) - DYSTONIA]	2	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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PLACEBO (BIPOLAR I)	E0010008	30 YRS CAUCASIAN FEMALE	03JAN2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [WORSENING OF HEADACHES]	UNK	17	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0010018	37 YRS ORIENTAL FEMALE	19MAR2003-CONTINUE	ON	GASTROINTESTINAL PAIN NOS (Gastrointestinal disorders) [GASTRO - INTESTINAL CRAMPING]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAR2003-28APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	41	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			27MAR2003-08APR2003	ON	INSOMNIA (Psychiatric disorders) [WORSENING OF INSOMNIA]	13	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			27MAR2003-09APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	14	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0010018	37 YRS ORIENTAL FEMALE	01APR2003-28APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	28	14	SEV	NO	N	N	N	N	N	N	NO YES	None
			01APR2003-09MAY2003	ON	DIZZINESS POSTURAL (Nervous system disorders) [ORTHOSTATIC DIZZINESS]	39	14	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0010028	32 YRS HISPANIC FEMALE	19JUN2003-17JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	29	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			28JUN2003-17JUL2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	20	13	MOD	NO	N	N	N	N	N	N	NO YES	None
			02JUL2003-24JUL2003	ON	INSOMNIA (Psychiatric disorders) [WORSENING OF INSOMNIA]	23	17	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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PLACEBO (BIPOLAR I)	E0011008	23 YRS CAUCASIAN MALE	13FEB2003-CONTINUE	ON	MANIA (Psychiatric disorders) [ONSET OF MANIC SYMPTOMS]	UNK	15	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0013001	34 YRS CAUCASIAN MALE	16NOV2002-16NOV2002	ON	PALPITATIONS (Cardiac disorders) [PALPITATION]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			17NOV2002-17NOV2002	ON	PALPITATIONS (Cardiac disorders) [PALPITATION]	1	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			19NOV2002-19NOV2002	ON	PALPITATIONS (Cardiac disorders) [PALPITATION]	1	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			21NOV2002-CONTINUE	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	UNK	8	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0013001	34 YRS CAUCASIAN MALE	30NOV2002-01DEC2002	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	2	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			02DEC2002-10DEC2002	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [EDEMA OF THE HANDS]	9	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0013003	55 YRS CAUCASIAN FEMALE	12NOV2002-14NOV2002	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL CRAMPS]	3	1	MIL	NO	N	N	N	N	N	N	NO YES	None
					DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			12NOV2002-27NOV2002	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	16	1	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0013003	55 YRS CAUCASIAN FEMALE	22NOV2002-CONTINUE	ON	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	UNK	11	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0013013	22 YRS CAUCASIAN FEMALE	06MAY2003-10MAY2003	ON	FLUSHING (Vascular disorders) [HOT FLASHES]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					PALPITATIONS (Cardiac disorders) [PALPITATION]	5	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			06MAY2003-13MAY2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	8	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0014004	29 YRS CAUCASIAN FEMALE	13MAR2003-03APR2003	ON	BACK PAIN (Musculoskeletal and connective tissue disorders) [BACK PAIN - LEFT SIDE]	22	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			16MAR2003-03APR2003	ON	URINARY HESITATION (Renal and urinary disorders) [URINARY HESITENCY]	19	5	MOD	NO	N	N	N	N	N	N	NO YES	Temporarily Stopped
	E0014015	23 YRS CAUCASIAN MALE	18JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0014017	23 YRS CAUCASIAN FEMALE	27JUN2003-24AUG2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	59	1	MIL	NO	N	N	N	N	N	N	NO YES	None
			02JUL2003-03JUL2003	ON	TINNITUS (Ear and labyrinth disorders) [TINNITIS]	2	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0014017	23 YRS CAUCASIAN FEMALE	04JUL2003-20JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	17	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			16JUL2003-20JUL2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTASIS (ORTHOSTATIC FAINTNESS)]	5	20	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0018009	27 YRS CAUCASIAN MALE	13JAN2003-14JAN2003	ON	AGITATION (Psychiatric disorders) [AGITATION]	2	8	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0018010	47 YRS CAUCASIAN MALE	27JAN2003-06FEB2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	11	12	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0020017	41 YRS CAUCASIAN FEMALE	04APR2003-14APR2003	ON	DYSTONIA (Nervous system disorders) [BILATERAL CALF PAIN (DUE TO EPS - DYSTONIA)]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None
					DYSTONIA (Nervous system disorders) [LEFT ELBOW RIGIDITY (DUE TO EPS - DYSTONIA)]	11	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			04APR2003-30MAY2003	ON	DYSTONIA (Nervous system disorders) [RIGHT CERVICAL AREA ACHE "EXACERBATED" (DUE TO EPS - DYSTONIA) (NECK)]	57	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0020022	49 YRS CAUCASIAN FEMALE	01JUL2003-13JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	13	16	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0022004	30 YRS CAUCASIAN FEMALE	31OCT2002-08NOV2002	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	9	4	MIL	NO	N	N	N	N	N	N	NO YES	None
			05NOV2002-26NOV2002	ON	AGITATION (Psychiatric disorders) [AGITATION]	22	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0022054	25 YRS CAUCASIAN MALE	04MAY2003-13MAY2003	ON	EYE PAIN (Eye disorders) [EYE PAIN]	10	24	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			04MAY2003-14MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	11	24	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0023009	62 YRS CAUCASIAN FEMALE	13FEB2003-CONTINUE	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			13FEB2003-28FEB2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0023009	62 YRS CAUCASIAN FEMALE	15FEB2003-CONTINUE	ON	ABDOMINAL DISTENSION (Gastrointestinal disorders) [BLOATED]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			14MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	32	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			25MAR2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	43	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0026012	44 YRS BLACK MALE	21FEB2003-05MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	13	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			25FEB2003-15MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	19	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0026012	44 YRS BLACK MALE	03MAR2003-17APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	46	12	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0026024	44 YRS ORIENTAL FEMALE	16MAY2003-CONTINUE	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASE IN APPETITE]	UNK	15	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0026028	35 YRS CAUCASIAN MALE	23JUN2003-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	4	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028001	53 YRS CAUCASIAN MALE	14OCT2002-14OCT2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	5	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0028003	53 YRS CAUCASIAN FEMALE	04OCT2002-09OCT2002	ON	FATIGUE (General disorders and administration site conditions) [INCREASED FATIGUE]	6	5	SEV	NO	N	N	N	N	N	N	NO YES	None
			19OCT2002-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	20	MIL	NO	N	N	N	N	N	N	NO YES	None
			29OCT2002-CONTINUE	ON	MICTURITION URGENCY (Renal and urinary disorders) [URINARY URGENCY]	UNK	30	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0028010	28 YRS CAUCASIAN FEMALE	06NOV2002-27NOV2002	ON	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	22	2	SEV	NO	N	N	N	N	N	N	NO YES	None
			13NOV2002-10DEC2002	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	28	9	SEV	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0028011	36 YRS CAUCASIAN MALE	09DEC2002-02JAN2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	25	5	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0028031	35 YRS CAUCASIAN MALE	13MAR2003-28MAR2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGINESS]	16	3	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0029014	34 YRS CAUCASIAN FEMALE	14FEB2003-19FEB2003	ON	BRUXISM (Psychiatric disorders) [GRINDING TEETH]	6	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			11MAR2003-26MAR2003	ON	TENSION HEADACHE (Nervous system disorders) [TENSION HEADACHE]	16	36	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0029023	41 YRS CAUCASIAN FEMALE	17APR2003-23APR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN (INCREASED FROM MEDICAL LISTING)]	7	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			18APR2003-23APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	6	11	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029039	30 YRS HISPANIC FEMALE	19JUL2003-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [WORSENING OF INSOMNIA]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			23JUL2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [GROGGY IN THE MORNING]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0030016	49 YRS CAUCASIAN MALE	04MAR2003-01MAY2003	ON	PALPITATIONS (Cardiac disorders) [PALPITATIONS]	59	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0030016	49 YRS CAUCASIAN MALE	24MAR2003-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	22	MOD	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-19APR2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	27	22	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0030021	25 YRS CAUCASIAN MALE	21MAY2003-CONTINUE	ON	SEDATION (Nervous system disorders) [EARLY AM SEDATION]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
			04JUN2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	16	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0031001	44 YRS CAUCASIAN FEMALE	14DEC2002-CONTINUE	ON	MENTAL IMPAIRMENT NOS (Nervous system disorders) [FEELINGS OF DULLNESS (DECREASED MENTAL COMPREHENSION)]	UNK	24	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031017	42 YRS CAUCASIAN MALE	09APR2003-10APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	2	9	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031018	24 YRS CAUCASIAN FEMALE	16APR2003-16APR2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	7	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0031023	25 YRS CAUCASIAN FEMALE	04MAY2003-16MAY2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	13	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0031023	25 YRS CAUCASIAN FEMALE	06MAY2003-14MAY2003	ON	HEADACHE (Nervous system disorders) [INTERMITTENT HEADACHES]	9	8	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0033004	37 YRS CAUCASIAN FEMALE	22JAN2003-22JAN2003	ON	PARAESTHESIA (Nervous system disorders) [PARESTHESIA]	1	6	MOD	NO	N	N	N	N	N	N	NO YES	None
			24JAN2003-31JAN2003	ON	HYPERSOMNIA (Nervous system disorders) [HYPERSOMNIA]	8	8	MOD	NO	N	N	N	N	N	N	NO YES	None
			26JAN2003-26JAN2003	ON	HALLUCINATION, AUDITORY (Psychiatric disorders) [AUDITORY HALLUCINATION]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
					ILLUSION (Psychiatric disorders) [VISUAL ILLUSION]	1	10	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0033004	37 YRS CAUCASIAN FEMALE	26JAN2003-26JAN2003	ON	PANIC ATTACK (Psychiatric disorders) [FEELING OF PANIC]	1	10	MOD	NO	N	N	N	N	N	N	NO YES	None
			29JAN2003-29JAN2003	ON	PANIC ATTACK (Psychiatric disorders) [FEELING OF PANIC]	1	13	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0035002	46 YRS CAUCASIAN MALE	05DEC2002-12DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	8	15	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0037003	38 YRS HISPANIC FEMALE	03FEB2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	5	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039007	39 YRS HISPANIC MALE	05DEC2002-12DEC2002	ON	SOMNOLENCE (Nervous system disorders) [MORNING DROWSINESS]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0039007	39 YRS HISPANIC MALE	06DEC2002-06DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			12DEC2002-CONTINUE	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [IMPOTENCE]	UNK	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			14DEC2002-CONTINUE	ON	OBSESSIVE-COMPULSIVE DISORDER (Psychiatric disorders) [(COMPULSIVE) BEHAVIOR]	UNK	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			26DEC2002-04JAN2003	ON	ERYTHEMA (Skin and subcutaneous tissue disorders) [REDNESS ON BILATERAL CHEEKS]	10	23	MIL	NO	N	N	N	N	N	N	NO YES	None
			02JAN2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	30	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0039007	39 YRS HISPANIC MALE	13JAN2003-19JAN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	7	41	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039022	33 YRS BLACK FEMALE	06MAR2003-06MAR2003	ON	HEADACHE (Nervous system di sorders) [HEADACHE]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	1	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-07MAR2003	ON	HEADACHE (Nervous system di sorders) [HEADACHE]	1	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			28MAR2003-18APR2003	ON	HEADACHE (Nervous system di sorders) [HEADACHES]	22	32	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0039031	34 YRS CAUCASIAN FEMALE	26MAR2003-31MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	6	3	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0039037	33 YRS CAUCASIAN FEMALE	18APR2003-04MAY2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	17	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			24APR2003-10MAY2003	ON	HEADACHE (Nervous system disorders) [WORSENED HEADACHES (FRONT OF HEAD)]	17	9	MIL	NO	N	N	N	N	N	N	NO YES	None
			28APR2003-09MAY2003	ON	DIZZINESS (Nervous system disorders) [LIGHT - HEADED WHEN STANDING FROM SITTING UNKNOWN WHETHER DUE TO ORTHOSTATIC HYPOTENSION]	12	13	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0039037	33 YRS CAUCASIAN FEMALE	15MAY2003-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	30	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0039047	32 YRS BLACK FEMALE	20MAY2003-24JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHES]	36	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			07JUN2003-10JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZY WHEN STANDING (DUE TO POSTURAL HYPOTENSION)]	4	20	MOD	NO	N	N	N	N	N	N	NO YES	None
			07JUL2003-10JUL2003	ON	FATIGUE (General disorders and administration site conditions) [FEELING TIRED]	4	50	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0039059	55 YRS BLACK FEMALE	11JUL2003-17JUL2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS POST - DOSE]	7	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			12JUL2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			22JUL2003-23JUL2003	ON	MUSCLE CRAMP (Musculoskeletal and connective tissue disorders) [LEFT LEG CRAMPS (NOT DUE TO EPS)]	2	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			26JUL2003-CONTINUE	ON	OEDEMA PERIPHERAL (General disorders and administration site conditions) [BILATERAL PEDAL EDEMA]	UNK	16	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR I)	E0041010	32 YRS CAUCASIAN MALE	02MAY2003-12JUN2003	ON	HEADACHE (Nervous system disorders) [INCREASE OF FREQUENCY INTERMITTENT HEADACHE]	42	3	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0005023	29 YRS BLACK FEMALE	16FEB2003-23FEB2003	ON	INCREASED TENDENCY TO BRUISE (Skin and subcutaneous tissue disorders) [BRUISING EASILY]	8	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			04MAR2003-07MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	4	28	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0005041	52 YRS CAUCASIAN FEMALE	10JUL2003-12JUL2003	ON	AKATHISIA (Nervous system disorders) [RESTLESS LEGS SECONDARY TO EPS (AKATHISIA)]	3	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-24JUL2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	7	25	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0005041	52 YRS CAUCASIAN FEMALE	21JUL2003-22JUL2003	ON	AKATHISIA (Nervous system disorders) [JITTERINESS SECONDARY TO EPS (AKATHISIA)]	2	28	MIL	NO	N	N	N	N	N	N	NO YES	None
			25JUL2003-25JUL2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	1	32	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0009007	31 YRS CAUCASIAN MALE	05FEB2003-13FEB2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS AFTER DOSING (NOT DUE TO POSTURAL HYPOTENSION)]	9	3	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0011011	28 YRS BLACK FEMALE	23FEB2003-26FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	4	4	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0011011	28 YRS BLACK FEMALE	21MAR2003-09APR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	20	30	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0011014	34 YRS BLACK FEMALE	13APR2003-20APR2003	ON	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL PAIN]	8	7	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	8	7	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0014001	25 YRS CAUCASIAN FEMALE	28FEB2003-25MAR2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	26	3	SEV	NO	N	N	N	N	N	N	NO YES	None
			07MAR2003-01APR2003	ON	FREQUENT BOWEL MOVEMENTS (Gastrointestinal disorders) [FREQUENT BOWEL MOVEMENTS]	26	10	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0014013	31 YRS CAUCASIAN FEMALE	06JUN2003-CONTINUE	ON	BLEPHAROSPASM (Eye disorders) [BLEPHAROSPASM]	UNK	11	MOD	NO	N	N	N	N	N	N	NO YES	None
			06JUN2003-07JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	32	11	MIL	NO	N	N	N	N	N	N	NO YES	None
			14JUN2003-CONTINUE	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC DIZZINESS (DUE TO ORTHOSTATIC HYPOTENSION)]	UNK	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0014014	38 YRS CAUCASIAN MALE	10JUN2003-11JUN2003	ON	DIZZINESS (Nervous system disorders) [DIZZINESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0014014	38 YRS CAUCASIAN MALE	10JUN2003-11JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	2	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			19JUN2003-08AUG2003	ON	ERECTILE DYSFUNCTION NOS (Reproductive system and breast disorders) [ERECTILE DYSFUNCTION]	51	10	MOD	NO	N	N	N	N	N	N	NO YES	None
					LIBIDO DECREASED (Psychiatric disorders) [DECREASED SEX DRIVE]	51	10	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0018005	24 YRS CAUCASIAN MALE	21DEC2002-23DEC2002	ON	HEADACHE (Nervous system disorders) [HEADACHES]	3	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			21DEC2002-30DEC2002	ON	FATIGUE (General disorders and administration site conditions) [TIREDNESS]	10	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0018005	24 YRS CAUCASIAN MALE	14JAN2003-26JAN2003	ON	AKATHISIA (Nervous system disorders) [AKATHESIA]	13	26	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0019019	22 YRS CAUCASIAN FEMALE	25JAN2003-CONTINUE	ON	BALANCE IMPAIRED NOS (Nervous system disorders) [PROBLEMS WITH EQUILIBRIUM NOT DUE TO ORTHOSTATIC HYPOTENSION]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
			26JAN2003-04FEB2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	10	4	MIL	NO	N	N	N	N	N	N	NO YES	None
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	10	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			03FEB2003-CONTINUE	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	UNK	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0019019	22 YRS CAUCASIAN FEMALE	06FEB2003-CONTINUE	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [SORE CHEST MUSCLES]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0019038	19 YRS CAUCASIAN MALE	25APR2003-06MAY2003	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	12	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			29MAY2003-17JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	20	36	MOD	NO	N	N	N	N	N	N	NO YES	None
			04JUN2003-04JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [ORTHOSTATIC HYPOTENSION]	1	42	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0019038	19 YRS CAUCASIAN MALE	04JUN2003-17JUN2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	14	42	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019046	35 YRS CAUCASIAN FEMALE	30JUN2003-11JUL2003	ON	PARAESTHESIA (Nervous system disorders) [PARASTHESIA]	12	5	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
					SEDATION (Nervous system disorders) [SEDATION]	12	5	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
			30JUN2003-18JUL2003	ON	ORTHOSTATIC HYPOTENSION (Vascular disorders) [DIZZINESS DUE TO ORTHOSTATIC HYPOTENSION]	19	5	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed

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PLACEBO (BIPOLAR II)	E0019046	35 YRS CAUCASIAN FEMALE	04JUL2003-04JUL2003	ON	HYPOREFLEXIA (Nervous system disorders) [DELAYED REACTION TO HEAT (DECREASE IN REFLEXIVE ACTION)]	1	9	SEV	NO	N	N	N	N	N	N	NO YES	None
	E0019047	23 YRS CAUCASIAN MALE	09JUL2003-01AUG2003	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	24	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			09AUG2003-22AUG2003	ON	ABNORMAL DREAMS (Psychiatric disorders) [VIVID DREAMS]	14	33	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0019048	34 YRS CAUCASIAN FEMALE	11JUL2003-16JUL2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0019048	34 YRS CAUCASIAN FEMALE	11JUL2003-16JUL2003	ON	TREMOR (Nervous system disorders) [TREMOR (HANDS) "NOT DUE TO EPS"]	6	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			11JUL2003-18JUL2003	ON	DIZZINESS (Nervous system disorders) [DIZZYNESS (NOT DUE TO ORTHOSTATIC HYPOTENSION)]	8	2	MIL	NO	N	N	N	N	N	N	NO YES	None
					LETHARGY (General disorders and administration site conditions) [LETHARGY]	8	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			18JUL2003-CONTINUE	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0023012	42 YRS CAUCASIAN FEMALE	15MAR2003-CONTINUE	ON	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [JOINT PAIN]	UNK	38	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0026021	35 YRS CAUCASIAN FEMALE	28APR2003-12MAY2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	15	6	MIL	NO	N	N	N	N	N	N	NO YES	None
			28APR2003-13MAY2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	16	6	MIL	NO	N	N	N	N	N	N	NO YES	None
					SOMNOLENCE (Nervous system disorders) [GROGGY]	16	6	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029004	34 YRS BLACK FEMALE	23NOV2002-26NOV2002	ON	HICCUPS (Respiratory, thoracic and mediastinal disorders) [HICCUPS]	4	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0029004	34 YRS BLACK FEMALE	23NOV2002-27NOV2002	ON	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	5	5	MIL	NO	N	N	N	N	N	N	NO YES	None
			01DEC2002-31DEC2002	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	31	13	MIL	NO	N	N	N	N	N	N	NO YES	None
			31DEC2002-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRY VISION]	UNK	43	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0029013	39 YRS CAUCASIAN FEMALE	19FEB2003-21FEB2003	ON	ANXIETY (Psychiatric disorders) [INCREASED ANXIETY]	3	1	MOD	NO	N	N	N	N	N	N	NO YES	None
			23FEB2003-17MAR2003	ON	FLATULENCE (Gastrointestinal disorders) [GAS]	23	5	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0029013	39 YRS CAUCASIAN FEMALE	26FEB2003-17MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [HEARTBURN]	20	8	MIL	NO	N	N	N	N	N	N	NO YES	None
			10MAR2003-28MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	19	20	SEV	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0029024	48 YRS CAUCASIAN FEMALE	18MAR2003-26MAR2003	ON	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	9	2	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAR2003-26MAR2003	ON	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	8	3	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAR2003-03APR2003	ON	HEADACHE (Nervous system disorders) [WORSENING OF HEADACHE]	16	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0029038	61 YRS CAUCASIAN MALE	08JUL2003-14JUL2003	ON	ANXIETY (Psychiatric disorders) [ANXIETY]	7	2	MOD	NO	N	N	N	N	N	N	YES YES	None
	E0031013	33 YRS CAUCASIAN FEMALE	16MAR2003-15MAY2003	ON	HEADACHE (Nervous system disorders) [INTERMITTENT HEADACHES]	61	4	MOD	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-05APR2003	ON	CHEST TIGHTNESS (General disorders and administration site conditions) [TIGHTNESS IN CHEST]	13	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			24MAR2003-01MAY2003	ON	MYALGIA (Musculoskeletal and connective tissue disorders) [MUSCLE ACHES]	39	12	MIL	NO	N	N	N	N	N	N	NO YES	None
			26MAR2003-10MAY2003	ON	SEDATION (Nervous system disorders) [DAYTIME SEDATION]	46	14	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0031013	33 YRS CAUCASIAN FEMALE	31MAR2003-05APR2003	ON	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	6	19	MIL	NO	N	N	N	N	N	N	NO YES	None
	E0031019	47 YRS CAUCASIAN MALE	12APR2003-CONTINUE	ON	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
			15APR2003-18APR2003	ON	HEADACHE (Nervous system disorders) [INTERMITTENT HEADACHES]	4	5	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0033013	29 YRS CAUCASIAN FEMALE	20FEB2003-02MAR2003	ON	DYSPNOEA (Respiratory, thoracic and mediastinal disorders) [MILD DYSPNEA]	11	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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Listing 12.2.7.2 Treatment-Related Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0033013	29 YRS CAUCASIAN FEMALE	20FEB2003-15MAR2003	ON	INSOMNIA (Psychiatric disorders) [SLEEPLESSNESS]	24	2	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0033016	34 YRS HISPANIC FEMALE	12MAY2003-13MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	2	5	MOD	NO	N	N	N	N	N	N	NO YES	None
			16MAY2003-19MAY2003	ON	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	4	9	MOD	NO	N	N	N	N	N	N	NO YES	None
			17MAY2003-19MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	3	10	MIL	NO	N	N	N	N	N	N	NO YES	None
			19MAY2003-20MAY2003	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	2	12	MIL	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0033016	34 YRS HISPANIC FEMALE	19MAY2003-09JUN2003	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	22	12	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-CONTINUE	ON	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [RIGHT EYE TWITCH (NOT DUE TO EPS)]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None
			25MAY2003-12JUN2003	ON	FACIAL PAIN (Musculoskeletal and connective tissue disorders) [THROBBING PAIN ON RIGHT SIDE OF FACE]	19	18	MOD	NO	N	N	N	N	N	N	NO YES	None
			01JUN2003-03JUN2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	3	25	MOD	NO	N	N	N	N	N	N	NO YES	None
			13JUN2003-CONTINUE	ON	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	37	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0033016	34 YRS HISPANIC FEMALE	19JUN2003-CONTINUE	ON	ABDOMINAL PAIN UPPER (Gastrointestinal disorders) [STOMACH CRAMPS]	UNK	43	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0035010	57 YRS BLACK FEMALE	12JAN2003-04MAR2003	ON	SEDATION (Nervous system disorders) [SEDATION]	52	3	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
			24JAN2003-20FEB2003	ON	RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	28	15	MIL	NO	N	N	N	N	N	N	NO YES	Dose Changed
	E0035022	48 YRS BLACK FEMALE	14MAY2003-19MAY2003	ON	HEADACHE (Nervous system disorders) [HEADACHE]	6	6	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0041002	47 YRS BLACK MALE	22JAN2003-CONTINUE	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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PLACEBO (BIPOLAR II)	E0041002	47 YRS BLACK MALE	07FEB2003-CONTINUE	ON	SEXUAL DYSFUNCTION NOS (Reproductive system and breast disorders) [SEXUAL DYSFUNCTION]	UNK	18	MOD	NO	N	N	N	N	N	N	NO YES	None
	E0041005	49 YRS CAUCASIAN MALE	21MAR2003-27MAR2003	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	7	17	MIL	NO	N	N	N	N	N	N	NO YES	None
			07APR2003-10APR2003	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	4	34	MIL	NO	N	N	N	N	N	N	NO YES	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0004018	24 YRS CAUCASIAN MALE	15MAR2003-22MAR2003	EYE IRRITATION (Eye disorders) [EYE IRRITATION]	8	-4	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0016001	32 YRS CAUCASIAN MALE	18JAN2003-29JAN2003	HEADACHE (Nervous system disorders) [HEADACHE]	12	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020006	52 YRS CAUCASIAN FEMALE	03DEC2002-12DEC2002	NIGHTMARE (Psychiatric disorders) [NIGHTMARES]	10	-13	MOD	NO	N	N	N	N	N	N	NO NO	None
			03DEC2002-19DEC2002	CLAUSTROPHOBIA (Psychiatric disorders) [CLAUSTROPHOBIA]	17	-13	MOD	NO	N	N	N	N	N	N	NO NO	None
			03DEC2002-21DEC2002	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	19	-13	MOD	NO	N	N	N	N	N	N	NO NO	None
			03DEC2002-27DEC2002	FEELING COLD (General disorders and administration site conditions) [COLD FLASHES]	25	-13	MOD	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 300 MG (BIPOLAR I)	E0020006	52 YRS CAUCASIAN FEMALE	03DEC2002-27DEC2002	FLUSHING (Vascular disorders) [HOT FLASHES]	25	-13	MOD	NO	N	N	N	N	N	N	NO NO	None
			03DEC2002-04JAN2003	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL PAIN]	33	-13	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020007	26 YRS CAUCASIAN FEMALE	05JAN2003-08JAN2003	NASOPHARYNGITIS (Infections and infestations) [COMMON COLD]	4	-10	MOD	NO	N	N	N	N	N	N	NO NO	None
			09JAN2003-30JAN2003	PNEUMONIA NOS (Infections and infestations) [PNEUMONIA]	22	-6	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020011	21 YRS CAUCASIAN FEMALE	23FEB2003-01MAR2003	BACK PAIN (Musculoskeletal and connective tissue disorders) [LOWER AND MID BACK PAIN INTERMITTENT]	7	-3	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0020013	23 YRS CAUCASIAN MALE	27FEB2003-15MAR2003	COUGH (Respiratory, thoracic and mediastinal disorders) [INTERMITTENT COUGH]	17	-6	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022036	22 YRS CAUCASIAN MALE	22FEB2003-24FEB2003	GASTROENTERITIS NOS (Infections and infestations) [GASTROENTERITIS]	3	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0026025	41 YRS CAUCASIAN MALE	06MAY2003-11MAY2003	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	6	-3	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028008	36 YRS CAUCASIAN MALE	09OCT2002-CONTINUE	WEIGHT DECREASED (Investigations) [WEIGHT LOSS]	UNK	-6	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028009	21 YRS CAUCASIAN FEMALE	12OCT2002-14OCT2002	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	3	-3	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0028029	39 YRS HISPANIC MALE	01FEB2003-01FEB2003	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	1	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
			01FEB2003-18FEB2003	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028034	39 YRS CAUCASIAN MALE	31MAR2003-17APR2003	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	18	-1	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0031003	33 YRS CAUCASIAN MALE	03DEC2002-10DEC2002	INSOMNIA (Psychiatric disorders) [INSOMNIA]	8	-7	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0034002	55 YRS CAUCASIAN MALE	19MAR2003-21MAR2003	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	3	-6	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0034002	55 YRS CAUCASIAN MALE	19MAR2003-23MAR2003	HEADACHE (Nervous system disorders) [HEADACHE]	5	-6	MIL	NO	N	N	N	N	N	N	NO NO	None
			19MAR2003-25MAR2003	INSOMNIA (Psychiatric disorders) [INSOMNIA]	7	-6	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039046	36 YRS BLACK FEMALE	20MAY2003-CONTINUE	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	UNK	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
			21MAY2003-23MAY2003	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	3	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
			21MAY2003-24MAY2003	PYREXIA (General disorders and administration site conditions) [FEVER]	4	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR I)	E0039046	36 YRS BLACK FEMALE	21MAY2003-27MAY2003	SNEEZING (Respiratory, thoracic and mediastinal disorders) [SNEEZING]	7	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039051	40 YRS BLACK FEMALE	14JUN2003-17JUN2003	EAR PAIN (Ear and labyrinth disorders) [EAR ACHE]	4	-2	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0041003	36 YRS BLACK FEMALE	21JAN2003-31MAR2003	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	70	-7	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 300 MG (BIPOLAR II)	E0011004	32 YRS CAUCASIAN MALE	07DEC2002-13DEC2002	TOOTH ABSCESS (Infections and infestations) [TOOTH ABSCESS]	7	-17	MOD	NO	N	N	N	N	N	N	NO NO	None
			13DEC2002-13DEC2002	FOOD POISONING NOS (Gastrointestinal disorders) [ABDOMINAL PAIN DUE TO FOOD POISONING]	1	-11	MIL	NO	N	N	N	N	N	N	NO NO	None
				FOOD POISONING NOS (Gastrointestinal disorders) [VOMITING DUE TO FOOD POISONING]	1	-11	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0011018	23 YRS OTHER MALE	07MAY2003-12MAY2003	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	6	-15	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0019014	24 YRS CAUCASIAN MALE	06JAN2003-CONTINUE	HEADACHE (Nervous system disorders) [HEADACHE]	UNK	-3	SEV	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	26 YRS HISPANIC FEMALE	26FEB2003-27FEB2003	SINUS HEADACHE (Nervous system disorders) [SINUS HEADACHE]	2	-1	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0023027	25 YRS CAUCASIAN FEMALE	10MAY2003-22MAY2003	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	13	-6	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039052	37 YRS BLACK FEMALE	19JUN2003-19JUN2003	POLLAKIURIA (Renal and urinary disorders) [URINARY FREQUENCY]	1	-1	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0040003	50 YRS CAUCASIAN FEMALE	18JUL2003-CONTINUE	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	-1	MOD	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 600 MG (BIPOLAR I)	E0002011	35 YRS CAUCASIAN FEMALE	15APR2003-30APR2003	HEADACHE (Nervous system disorders) [HEADACHE]	16	-14	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0003010	54 YRS CAUCASIAN FEMALE	29JAN2003-29JAN2003	INSOMNIA (Psychiatric disorders) [INSOMNIA]	1	-5	MOD	NO	N	N	N	N	N	N	NO NO	None
			02FEB2003-02FEB2003	INSOMNIA (Psychiatric disorders) [INSOMNIA]	1	-1	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0003011	26 YRS CAUCASIAN FEMALE	29JAN2003-11FEB2003	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [RIGHT KNEE PAIN]	14	-6	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0005014	30 YRS CAUCASIAN MALE	12NOV2002-25NOV2002	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [COLD (UPPER RESPIRATORY INFECTION)]	14	-1	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0011022	35 YRS CAUCASIAN FEMALE	05JUN2003-14JUN2003	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL PAIN]	10	-4	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0020010	31 YRS CAUCASIAN FEMALE	02FEB2003-03FEB2003	HEADACHE (Nervous system disorders) [HEADACHE]	2	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
			02FEB2003-07FEB2003	EYE OEDEMA (Eye disorders) [EDEMA LEFT EYE]	6	-3	MOD	NO	N	N	N	N	N	N	NO NO	None
			02FEB2003-16FEB2003	THERMAL BURN (Injury, poisoning and procedural complications) [CERVICAL AREA BURN (NECK)]	15	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
			02FEB2003-25FEB2003	ECCHYMOSIS (Skin and subcutaneous tissue disorders) [ECCHYMOSIS LEFT EYE]	24	-3	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023003	19 YRS CAUCASIAN MALE	14DEC2002-CONTINUE	HEADACHE (Nervous system disorders) [INTERMITTENT HEADACHES]	UNK	-3	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0023003	19 YRS CAUCASIAN MALE	15DEC2002-03JAN2003	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	20	-2	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023006	39 YRS CAUCASIAN MALE	11DEC2002-11DEC2002	DYSPEPSIA (Gastrointestinal disorders) [UPSET STOMACH]	1	-6	SEV	NO	N	N	N	N	N	N	NO NO	None
				SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	1	-6	SEV	NO	N	N	N	N	N	N	NO NO	None
			12DEC2002-12DEC2002	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHO - STATIC HYPOTENSION]	1	-5	MOD	NO	N	N	N	N	N	N	NO NO	None
			15DEC2002-CONTINUE	ASTHMA NOS (Respiratory, thoracic and mediastinal disorders) [WORSENING OF BILATERAL WHEEZE DUE TO ASTHMA]	UNK	-2	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0026007	59 YRS CAUCASIAN FEMALE	14JAN2003-CONTINUE	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	UNK	-2	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0026013	28 YRS CAUCASIAN FEMALE	06FEB2003-11MAR2003	CONSTIPATION (Gastrointestinal disorders) [CONSTIPATION]	34	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
			06FEB2003-25MAR2003	SEDATION (Nervous system disorders) [SEDATION]	48	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
			06FEB2003-30MAR2003	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	53	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0028039	28 YRS CAUCASIAN MALE	02MAY2003-07MAY2003	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	6	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
			08MAY2003-08MAY2003	VICTIM OF CRIME NOS (Social circumstances) [VICTIM OF ATTACK]	1	-1	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0028039	28 YRS CAUCASIAN MALE	08MAY2003-08MAY2003	VISION BLURRED (Eye disorders) [BLURRED VISION SECONDARY TO ATTACK]	1	-1	SEV	NO	N	N	N	N	N	N	NO NO	None
			08MAY2003-09MAY2003	HEAD INJURY (Injury, poisoning and procedural complications) [HEAD INJURY SECONDARY TO ATTACK]	2	-1	SEV	YES	N	N	Y	N	N	N	NO NO	None
			08MAY2003-22MAY2003	HEADACHE (Nervous system disorders) [HEADACHES SECONDARY TO ATTACK]	15	-1	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0029012	39 YRS CAUCASIAN FEMALE	06FEB2003-08FEB2003	BREAST PAIN (Reproductive system and breast disorders) [RIGHT BREAST PAIN]	3	-5	MOD	NO	N	N	N	N	N	N	NO NO	None
			06FEB2003-10FEB2003	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [LEFT SHOULDER PAIN]	5	-5	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0029015	45 YRS CAUCASIAN FEMALE	23FEB2003-23FEB2003	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	1	-1	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0030024	30 YRS CAUCASIAN FEMALE	07JUL2003-CONTINUE	GINGIVAL INFECTION (Infections and infestations) [GUM INFECTION]	UNK	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0030025	63 YRS BLACK FEMALE	03JUL2003-CONTINUE	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [BODY TWITCHING (NOT DUE TO EPS)]	UNK	-8	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039011	34 YRS BLACK FEMALE	01JAN2003-03JAN2003	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [RIGHT HIP PAIN]	3	-1	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039028	39 YRS BLACK MALE	09MAR2003-CONTINUE	LIMB INJURY NOS (Injury, poisoning and procedural complications) [RIGHT FOOT INJURY]	UNK	-15	SEV	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR I)	E0039028	39 YRS BLACK MALE	12MAR2003-26MAR2003	MUSCLE TWITCHING (Musculoskeletal and connective tissue disorders) [TWITCHING RIGHT EYE NOT DUE TO EPS]	15	-12	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039034	29 YRS CAUCASIAN FEMALE	14MAR2003-15MAR2003	ORAL INFECTION (Infections and infestations) [ORAL INFECTION]	2	-5	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039042	35 YRS BLACK FEMALE	03MAY2003-27MAY2003	THERMAL BURN (Injury, poisoning and procedural complications) [BURN ON BACK OF NECK]	25	-4	MIL	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0011016	40 YRS CAUCASIAN MALE	20APR2003-23APR2003	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	4	-1	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0018002	53 YRS CAUCASIAN MALE	14NOV2002-CONTINUE	DRUG WITHDRAWAL SYNDROME (General disorders and administration site conditions) [SEROTONIN WITHDRAWAL SYNDROME]	UNK	-15	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0019002	22 YRS CAUCASIAN FEMALE	30OCT2002-CONTINUE	MIGRAINE NOS (Nervous system disorders) [INCREASE MIGRAINE]	UNK	-13	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0019008	35 YRS CAUCASIAN FEMALE	13NOV2002-CONTINUE	PULMONARY CONGESTION (Respiratory, thoracic and mediastinal disorders) [CHEST CONGESTION]	UNK	-8	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0019008	35 YRS CAUCASIAN FEMALE	13NOV2002-15NOV2002	SNEEZING (Respiratory, thoracic and mediastinal disorders) [SNEEZING]	3	-8	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0019040	49 YRS BLACK MALE	18MAY2003-10JUN2003	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	24	-2	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020024	18 YRS CAUCASIAN MALE	19JUN2003-20JUN2003	HEADACHE (Nervous system disorders) [HEADACHES]	2	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023007	23 YRS CAUCASIAN FEMALE	10JAN2003-07FEB2003	DYSPEPSIA (Gastrointestinal disorders) [HEART BURN]	29	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0023011	50 YRS CAUCASIAN FEMALE	01FEB2003-03FEB2003	HEADACHE (Nervous system disorders) [HEADACHES]	3	-3	MOD	NO	N	N	N	N	N	N	NO NO	None

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QUETIAPINE 600 MG (BIPOLAR II)	E0023011	50 YRS CAUCASIAN FEMALE	03FEB2003-12FEB2003	NAUSEA (Gastrointestinal disorders) [NAUSEA]	10	-1	MOD	NO	N	N	N	N	N	N	NO NO	None
			03FEB2003-13FEB2003	TREMOR (Nervous system disorders) [TREMOR IN HAND (NOT DUE TO EPS)]	11	-1	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0023014	40 YRS CAUCASIAN MALE	20FEB2003-21FEB2003	HEADACHE (Nervous system disorders) [HEADACHE]	2	-1	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026023	20 YRS CAUCASIAN MALE	27APR2003-04MAY2003	BRONCHITIS ACUTE NOS (Infections and infestations) [ACUTE BRONCHITIS]	8	-3	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031015	27 YRS CAUCASIAN FEMALE	19MAR2003-26MAR2003	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	8	-7	MOD	NO	N	N	N	N	N	N	NO NO	None

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0033009	46 YRS CAUCASIAN FEMALE	05FEB2003-CONTINUE	INSOMNIA (Psychiatric disorders) [INSOMNIA]	UNK	-7	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0034009	44 YRS BLACK MALE	17JUN2003-17JUN2003	JOINT DISLOCATION (Injury, poisoning and procedural complications) [DISLOCATED SHOULDER]	1	-2	MOD	NO	N	N	N	N	N	N	NO NO	None
			17JUN2003-28AUG2003	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [CURRENT SHOULDER PAIN]	73	-2	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039019	35 YRS BLACK FEMALE	24JAN2003-09FEB2003	APPETITE INCREASED NOS (Metabolism and nutrition disorders) [INCREASED APPETITE]	17	-13	MOD	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0002004	33 YRS CAUCASIAN FEMALE	17JAN2003-CONTINUE	DEPRESSION (Psychiatric disorders) [ANXIETY RELATED TO DEPRESSION]	UNK	-8	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
			17JAN2003-22JAN2003	BRONCHITIS NOS (Respiratory, thoracic and mediastinal disorders) [BRONCHITIS]	6	-8	MIL	NO	N	N	N	N	N	N	NO NO	None
				SINUSITIS NOS (Infections and infestations) [SINUS INFECTION]	6	-8	MIL	NO	N	N	N	N	N	N	NO NO	None
			18JAN2003-CONTINUE	PRURITUS (Skin and subcutaneous tissue disorders) [PRURITUS]	UNK	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
				RASH NOS (Skin and subcutaneous tissue disorders) [RASH]	UNK	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
			22JAN2003-CONTINUE	TENSION HEADACHE (Nervous system disorders) [TENSION HEADACHE]	UNK	-3	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0002016	56 YRS CAUCASIAN FEMALE	21JUL2003-03SEP2003	HEADACHE (Nervous system disorders) [INTER MITTENT HEADACHES]	45	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0004003	22 YRS CAUCASIAN MALE	06OCT2002-12OCT2002	HEADACHE (Nervous system disorders) [HEADACHE]	7	-4	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0004024	39 YRS CAUCASIAN FEMALE	25JUN2003-CONTINUE	HYPERTENSION NOS (Vascular disorders) [BORDERLINE HYPERTENSION]	UNK	-8	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0007006	39 YRS BLACK MALE	21FEB2003-CONTINUE	JOINT SWELLING (Musculoskeletal and connective tissue disorders) [LEFT KNEE SWELLING]	UNK	-12	MIL	NO	N	N	N	N	N	N	NO NO	None
				LIMB INJURY NOS (Injury, poisoning and procedural complications) [KNEE TRAUMA]	UNK	-12	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0014002	43 YRS CAUCASIAN FEMALE	23FEB2003-28FEB2003	EAR PAIN (Ear and labyrinth disorders) [EARACHE]	6	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0018009	27 YRS CAUCASIAN MALE	27DEC2002-02JAN2003	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	7	-10	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020015	35 YRS CAUCASIAN MALE	24MAR2003-28MAR2003	NAUSEA (Gastrointestinal disorders) [INTERMITTENT NAUSEA]	5	-3	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0020017	41 YRS CAUCASIAN FEMALE	31MAR2003-21APR2003	DIZZINESS (Nervous system disorders) [INTERMITTENT DIZZINESS (ATTRIBUTES TO ALLERGIES)]	22	-3	MIL	NO	N	N	N	N	N	N	NO NO	None
			01APR2003-03APR2003	DYSMENORRHOEA (Reproductive system and breast disorders) [MENSTRUAL CRAMPS]	3	-2	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0022041	51 YRS CAUCASIAN FEMALE	12MAR2003-19MAR2003	UPPER RESPIRATORY TRACT INFECTION NOS (Infections and infestations) [UPPER RESPIRATORY INFECTION]	8	-6	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0023028	53 YRS CAUCASIAN FEMALE	16MAY2003-13JUN2003	HEADACHE (Nervous system disorders) [HEADACHES]	29	-13	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0026012	44 YRS BLACK MALE	18FEB2003-20FEB2003	NAUSEA (Gastrointestinal disorders) [NAUSEA]	3	-2	MOD	NO	N	N	N	N	N	N	NO NO	None
				VOMITING NOS (Gastrointestinal disorders) [VOMITING]	3	-2	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0028003	53 YRS CAUCASIAN FEMALE	28SEP2002-22OCT2002	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	25	-2	SEV	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0029032	52 YRS CAUCASIAN MALE	23MAY2003-07JUN2003	INFLUENZA (Infections and infestations) [FLU]	16	-18	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0030016	49 YRS CAUCASIAN MALE	21FEB2003-20APR2003	DYSPEPSIA (Gastrointestinal disorders) [INDIGESTION]	59	-10	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0033010	26 YRS BLACK FEMALE	30JAN2003-CONTINUE	HEADACHE (Nervous system disorders) [HEADACHES]	UNK	-5	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039007	39 YRS HISPANIC MALE	25NOV2002-25NOV2002	DIZZINESS (Nervous system disorders) [LIGHTHEADED (SECONDARY TO VENIPUNCTURE)]	1	-9	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039022	33 YRS BLACK FEMALE	23FEB2003-26FEB2003	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	4	-2	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039023	44 YRS BLACK MALE	11FEB2003-12FEB2003	PHARYNGOLARYNGEAL PAIN (Respiratory, thoracic and mediastinal disorders) [SORE THROAT]	2	-13	MOD	NO	N	N	N	N	N	N	NO NO	None
			12FEB2003-13FEB2003	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	2	-12	MOD	NO	N	N	N	N	N	N	NO NO	None
				NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	-12	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039031	34 YRS CAUCASIAN FEMALE	16MAR2003-17APR2003	HEADACHE (Nervous system disorders) [WORSENING OF HEADACHES]	33	-8	MIL	NO	N	N	N	N	N	N	NO NO	None
			19MAR2003-28MAR2003	DIZZINESS (Nervous system disorders) [DIZZY (NOT DUE TO POSTURAL HYPOTENSION)]	10	-5	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039031	34 YRS CAUCASIAN FEMALE	19MAR2003-28MAR2003	NAUSEA (Gastrointestinal disorders) [NAUSEA]	10	-5	MOD	NO	N	N	N	N	N	N	NO NO	None
			20MAR2003-21MAR2003	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL CRAMPS]	2	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
				DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	2	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039037	33 YRS CAUCASIAN FEMALE	01APR2003-04APR2003	HEADACHE (Nervous system disorders) [WORSENED HEADACHES]	4	-15	MOD	NO	N	N	N	N	N	N	NO NO	None
			04APR2003-05APR2003	VOMITING NOS (Gastrointestinal disorders) [VOMITING]	2	-12	MOD	NO	N	N	N	N	N	N	NO NO	None
			06APR2003-07APR2003	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	2	-10	MOD	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR I)	E0039038	40 YRS BLACK FEMALE	04APR2003-25APR2003	GENITAL PRURITUS FEMALE (Reproductive system and breast disorders) [VAGINAL ITCHING]	22	-19	MIL	NO	N	N	N	N	N	N	NO NO	None
				VAGINAL DISCHARGE (Reproductive system and breast disorders) [VAGINAL DISCHARGE]	22	-19	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0001004	25 YRS CAUCASIAN FEMALE	27APR2003-30APR2003	DYSMENORRHOEA (Reproductive system and breast disorders) [MENSTRUAL CRAMPS]	4	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0022006	20 YRS CAUCASIAN FEMALE	31OCT2002-04NOV2002	DRUG WITHDRAWAL SYNDROME (General disorders and administration site conditions) [SEROTONIN WITHDRAWAL SYNDROME]	5	-12	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0022075	51 YRS CAUCASIAN FEMALE	01JUL2003-25JUL2003	ORAL PAIN (Gastrointestinal disorders) [DENTAL PAIN (GENERAL MOUTH PAIN)]	25	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0023012	42 YRS CAUCASIAN FEMALE	02FEB2003-07FEB2003	SWEATING INCREASED (Skin and subcutaneous tissue disorders) [SWEATING]	6	-4	MOD	NO	N	N	N	N	N	N	NO NO	None
			02FEB2003-21FEB2003	FLUSHING (Vascular disorders) [HOT FLASHES]	20	-4	MIL	NO	N	N	N	N	N	N	NO NO	None

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PLACEBO (BIPOLAR II)	E0026027	40 YRS CAUCASIAN FEMALE	12JUN2003-15JUN2003	NASOPHARYNGITIS (Respiratory, thoracic and mediastinal disorders) [COLD SYMPTOMS]	4	-7	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0029002	54 YRS CAUCASIAN FEMALE	05NOV2002-15NOV2002	EAR INFECTION NOS (Infections and infestations) [EAR INFECTION]	11	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0029004	34 YRS BLACK FEMALE	17NOV2002-07DEC2002	NASAL CONGESTION (Respiratory, thoracic and mediastinal disorders) [NASAL CONGESTION]	21	-2	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0031004	37 YRS CAUCASIAN FEMALE	16DEC2002-16DEC2002	DYSMENORRHOEA (Reproductive system and breast disorders) [PRE - MENSTRUAL CRAMPS]	1	-3	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0031016	24 YRS CAUCASIAN MALE	18MAR2003-23MAR2003	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	6	-6	MIL	NO	N	N	N	N	N	N	NO NO	None

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Listing 12.2.7.3 Adverse Events Reported Prior to Study Treatment

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
PLACEBO (BIPOLAR II)	E0031016	24 YRS CAUCASIAN MALE	18MAR2003-23MAR2003	NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	-6	MIL	NO	N	N	N	N	N	N	NO NO	None
				SEDATION (Nervous system disorders) [DAYTIME SEDATION]	6	-6	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0033022	20 YRS CAUCASIAN FEMALE	09JUL2003-CONTINUE	APPETITE DECREASED NOS (Metabolism and nutrition disorders) [DECREASED APPETITE]	UNK	-5	MIL	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 6.0.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/AELOG105.SAS
GENERATED: 12JUL2005 17:38:55 iceadmn3

Listing 12.2.7.3 Adverse Events Reported Prior to Study Treatment

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
SCREEN FAILURE (BIPOLAR I)	E0002014	40 YRS CAUCASIAN MALE	03JUN2003-CONTINUE	SOFT TISSUE INJURY NOS (Injury, poisoning and procedural complications) [GROIN SOFT TISSUE INJURY]	UNK	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0014003	45 YRS CAUCASIAN MALE	26FEB2003-05MAR2003	HEADACHE (Nervous system disorders) [HEADACHES]	8	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
				NECK PAIN (Musculoskeletal and connective tissue disorders) [NECK PAIN]	8	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0016002	50 YRS CAUCASIAN FEMALE	10JAN2003-16JAN2003	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH A PLAN]	7	UNK	SEV	YES	N	N	Y	N	N	N	YES NO	None
	E0027002	38 YRS CAUCASIAN FEMALE	14DEC2002-14DEC2002	COUGH (Respiratory, thoracic and mediastinal disorders) [COUGH]	1	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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Listing 12.2.7.3 Adverse Events Reported Prior to Study Treatment

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
SCREEN FAILURE (BIPOLAR I)	E0027010	52 YRS CAUCASIAN MALE	01FEB2003-10FEB2003	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	10	UNK	SEV	YES	N	N	Y	N	N	N	YES NO	None
	E0030004	35 YRS CAUCASIAN MALE	19DEC2002-CONTINUE	GONORRHOEA NOS (Infections and infestations) [GONORRHEA]	UNK	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
	E0039010	48 YRS BLACK MALE	13JAN2003-CONTINUE	HYPERTENSION NOS (Vascular disorders) [WORSENING OF HYPERTENSION]	UNK	UNK	MOD	NO	N	N	N	N	N	N	YES NO	None
	E0039033	39 YRS BLACK FEMALE	26MAR2003-CONTINUE	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO POSTURAL HYPOTENSION]	UNK	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
				PAIN NOS (General disorders and administration site conditions) [BODY ACHES]	UNK	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
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Listing 12.2.7.3 Adverse Events Reported Prior to Study Treatment

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
SCREEN FAILURE (BIPOLAR I)	E0039033	39 YRS BLACK FEMALE	26MAR2003-CONTINUE	RIGORS (General disorders and administration site conditions) [CHILLS]	UNK	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
				SWEATING INCREASED (Skin and subcutaneous tissue disorders) [DIAPHORESIS]	UNK	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039035	58 YRS CAUCASIAN FEMALE	29MAR2003-CONTINUE	HALLUCINATION, GUSTATORY (Psychiatric disorders) [GUSTATORY HALLUCINATION]	UNK	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
				HALLUCINATION, OLFACTORY (Psychiatric disorders) [OLFACTORY HALLUCINATION]	UNK	UNK	MIL	NO	N	N	N	N	N	N	NO NO	None
	E0039036	56 YRS BLACK FEMALE	06APR2003-06APR2003	ARTHRALGIA (Musculoskeletal and connective tissue disorders) [ARTHRITIC PAIN]	1	UNK	SEV	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.7.3 Adverse Events Reported Prior to Study Treatment

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
SCREEN FAILURE (BIPOLAR II)	E0010026	32 YRS CAUCASIAN FEMALE	25MAY2003-26MAY2003	ANGIONEUROTIC OEDEMA (Skin and subcutaneous tissue disorders) [ANGIOEDEMA]	2	UNK	SEV	NO	N	N	N	N	N	N	NO NO	None
			26MAY2003-CONTINUE	ABDOMINAL PAIN NOS (Gastrointestinal disorders) [ABDOMINAL PAIN]	UNK	UNK	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0022045	40 YRS CAUCASIAN FEMALE	14MAR2003-24MAR2003	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	11	UNK	MIL	YES	N	N	Y	N	N	N	YES NO	None
	E0027017	40 YRS CAUCASIAN FEMALE	18APR2003-24APR2003	POST PROCEDURAL PAIN (Injury, poisoning and procedural complications) [SURGERY PAIN SECONDARY TO CHOLECYSTECTOMY]	7	UNK	SEV	NO	N	N	N	N	N	N	NO NO	None
	E0030005	27 YRS HISPANIC FEMALE	12DEC2002-CONTINUE	INFLUENZA (Infections and infestations) [FLU]	UNK	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION,
DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY,
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Listing 12.2.7.3 Adverse Events Reported Prior to Study Treatment

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
SCREEN FAILURE (BIPOLAR II)	E0039001	36 YRS BLACK FEMALE	02NOV2002-CONTINUE	FUNGAL INFECTION NOS (Infections and infestations) [YEAST INFECTION]	UNK	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
			02NOV2002-05NOV2002	DIARRHOEA NOS (Gastrointestinal disorders) [DIARRHEA]	4	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
				VOMITING NOS (Gastrointestinal disorders) [VOMITING]	4	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None
			14NOV2002-15NOV2002	POSTOPERATIVE HYPERTENSION (Vascular disorders) [HYPERTENSION SECONDARY TO UMBILICAL HERNIA REPAIR]	2	UNK	SEV	YES	N	N	Y	N	N	N	NO NO	None
			14NOV2002-18NOV2002	POST PROCEDURAL PAIN (Injury, poisoning and procedural complications) [PAIN SECONDARY TO HERNIA REPAIR]	5	UNK	MOD	NO	N	N	N	N	N	N	NO NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
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Listing 12.2.7.3 Adverse Events Reported Prior to Study Treatment

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATE	ACTION TAKEN
SCREEN FAILURE (BIPOLAR II)	E0039001	36 YRS BLACK FEMALE	09DEC2002-CONTINUE	HYPERTENSION NOS (Vascular disorders) [UNCONTROLLED HYPERTENSION]	UNK	UNK	MOD	NO	N	N	N	N	N	N	YES NO	None
	E0041001	41 YRS BLACK FEMALE	08JAN2003-14JAN2003	CHEST PAIN (General disorders and administration site conditions) [CHEST PAIN]	7	UNK	SEV	YES	N	N	Y	N	N	N	YES NO	None

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
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AstraZeneca

Clinical Study Report: Appendix 12.2.8

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.8

Listing of individual laboratory measurements, by subject

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		28JAN2003	11:00	-7	0.445	15.1	4.8	303
		FINAL		02APR2003	10:10	58	0.422	14.2	4.5	240
	E0002010	BSLN		28MAR2003	10:00	-7	0.439	14.8	5.3	290
	E0002012	BSLN		16APR2003	10:10	-5	0.429	15.0	4.7	254
		FINAL		16JUN2003	11:30	57	0.427	14.8	4.7	229
	E0002015	BSLN		22MAY2003	10:15	-13	0.479	16.1	5.6	235
	E0002018	BSLN		16JUL2003	13:25	-8	0.494	16.5	5.7	169
		FINAL		04AUG2003	9:40	12	0.462	16.1	5.5	172
	E0003004	BSLN	*	03DEC2002	11:48	-14	0.481	16.6	5.1	221
		BSLN		17DEC2002	9:20	1	0.464	16.2	4.9	210
		FINAL		07JAN2003	15:40	22	0.484	16.7	5.0	233
	E0003005	BSLN		16DEC2002	15:00	-7	0.375	12.7	4.2	248
		FINAL		18FEB2003	8:55	58	0.399	13.4	4.4	240
	E0003007	BSLN		19DEC2002	10:15	-14	0.424	14.7	4.5	281
		FINAL		27FEB2003	8:50	57	0.426	14.4	4.5	220
	E0003015	BSLN		29APR2003	11:30	-6	0.410	13.9	4.7	352
		FINAL		02JUL2003	14:45	59	0.408	14.0	4.8	347
	E0004002	BSLN		24SEP2002	10:40	-7	0.418	14.2	4.6	266
		FINAL		26NOV2002	11:00	57	0.395	13.3	4.3	280
	E0004013	BSLN		08JAN2003	10:00	-6	0.437	14.8	4.6	221
		FINAL		19FEB2003	8:20	37	0.432	14.5	4.7	218
	E0004018	BSLN		12MAR2003	10:50	-7	0.480	16.4	5.0	312
		FINAL		13MAY2003	13:45	56	0.449	15.8	4.8	343

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	BSLN		07MAY2003	15:55	-7	0.406		13.3		5.3		327
		FINAL		09JUL2003	14:10	57	0.415		14.1		5.0		291
	E0005002	BSLN		30SEP2002	8:30	-3	0.495		16.7		5.1		228
		FINAL		25NOV2002	8:30	54	0.450		15.8		4.8		191
	E0005004	BSLN	*	24SEP2002	12:00	-7	0.323	L	10.5	L#	4.5		265
		BSLN		01OCT2002	15:46	1	0.274	L#	8.6	L#	3.7	L	292
	E0005013	BSLN		30OCT2002	8:00	-8	0.377		12.9		3.9		215
	E0005024	BSLN		05FEB2003	15:00	-5	0.376		12.7		4.7		261
		FINAL		10APR2003	11:30	60	0.392		13.2		4.8		241
	E0005027	BSLN		04MAR2003	7:45	-7	0.446		15.4		4.9		236
		FINAL		03APR2003	8:15	24	0.443		15.0		4.8		253
	E0005037	BSLN		30APR2003	12:00	-7	0.446		14.9		4.9		298
		FINAL		02JUL2003	12:15	57	0.408		13.7		4.5		276
	E0005042	BSLN		19JUN2003	11:30	-5	0.453		15.5		5.0		299
		FINAL		18AUG2003	16:25	56	0.436		15.1		4.9		203
	E0006005	BSLN		25NOV2002	12:15	-10	0.403		13.7		4.4		193
		FINAL		30JAN2003	16:10	57	0.382		12.6		4.2		219
	E0006018	BSLN		07MAR2003	12:40	-6	0.484		16.0		5.3		231
		FINAL		24MAR2003	10:45	12	0.476		16.0		5.3		225
	E0007013	BSLN		10JUN2003	9:25	-3	0.373		12.5		3.7	L	239
		FINAL		07AUG2003	9:20	56	0.384		13.0		3.8		261
	E0010004	BSLN		05DEC2002	11:10	-6	0.395		13.3		4.3		225
		FINAL		06FEB2003	12:40	58	0.397		13.1		4.3		256

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	BSLN	30DEC2002	9:48	-8	0.332	L	11.1	L	4.1	208
		FINAL	05MAR2003	13:59	58	0.332	L	11.0	L	4.1	215
	E0010024	BSLN	23APR2003	8:45	-12	0.443		14.9		5.0	198
		FINAL	02JUL2003	10:30	59	0.424		14.6		4.8	226
	E0010032	BSLN	03JUL2003	11:30	-7	0.413		13.9		4.6	254
		FINAL	17JUL2003	11:38	8	0.404		13.5		4.5	262
	E0011025	BSLN	20JUN2003	14:30	-6	0.428		14.5		4.6	205
		FINAL	22AUG2003	10:00	58	0.432		14.3		4.6	158
	E0013007	BSLN	14MAR2003	8:48	-6	0.457		15.4		4.8	317
		FINAL	07APR2003	17:15	19	0.448		15.3		4.8	339
	E0013009	BSLN	26MAR2003	9:09	-7	0.463		15.5		4.7	255
		FINAL	29MAY2003	17:50	58	0.407		14.1		4.2	268
	E0014006	BSLN	14MAR2003	11:30	-11	0.408		13.4		5.4	303
		FINAL	23APR2003	15:20	30	0.389		13.5		5.1	275
	E0014010	BSLN	15APR2003	17:20	-7	0.453		15.7		4.8	308
		FINAL	17JUN2003	18:10	57	0.469		16.1		5.0	324
	E0016001	BSLN	02JAN2003	8:50	-20	0.481		16.6		5.0	254
		FINAL	19MAR2003	12:00	57	0.470		15.9		5.0	220
	E0016004	BSLN	27JAN2003	9:30	-7	0.488		16.7		5.2	260
	E0018001	BSLN	22OCT2002	16:15	-7	0.418		13.9		4.7	413
		FINAL	24DEC2002	9:55	57	0.392		13.7		4.6	353
	E0018006	BSLN	10DEC2002	17:15	-7	0.477		16.2		5.0	378
		FINAL	27FEB2003	12:10	73	0.451		15.6		4.9	313

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	BSLN		30OCT2002	8:40	-8	0.349	L	11.9		3.7	L	307	
		FINAL		23DEC2002	15:35	47	0.357		12.3		3.9		235	
	E0019011	BSLN		12NOV2002	12:05	-9	0.405		13.1		5.1		324	
		FINAL		16JAN2003	14:20	57	0.383		12.4		4.8		319	
	E0019025	BSLN		30JAN2003	14:40	-7	0.416		14.2		4.4		198	
		FINAL		03APR2003	13:30	57	0.444		15.1		4.6		206	
	E0019026	BSLN		11FEB2003	11:10	-13	0.399		13.4		4.6		392	
	E0019043	BSLN		21MAY2003	11:04	-13	0.450		15.6		4.6		242	
		FINAL		29JUL2003	11:38	57	0.451		15.5		4.6		254	
	E0020001	BSLN		15OCT2002	20:00	-14	0.408		13.5		4.1		282	
		FINAL	*	19NOV2002	19:10	22	0.386		13.2		4.0		305	
		FINAL		20DEC2002	12:30	53	0.369		12.9		3.9		278	
	E0020006	BSLN		26NOV2002	18:00	-20	0.380		12.6		4.5		218	
		FINAL		08JAN2003	10:00	24	0.431		14.1		5.1		302	
	E0020007	BSLN		10JAN2003	12:00	-5	0.427		14.7		4.8		316	
		FINAL		25MAR2003	18:50	70	0.431		14.3		4.9		320	
	E0020011	BSLN		19FEB2003	13:45	-7	0.434		14.2		5.1		456	H
		FINAL		23APR2003	14:30	57	0.399		13.7		4.7		458	H
		FINAL	*	07MAY2003	12:00	71	0.401		13.4		4.7		418	
	E0020013	BSLN		26FEB2003	14:15	-7	0.468		16.0		5.2		220	
		FINAL		25MAR2003	12:00	21	0.461		15.8		5.0		282	
	E0022008	BSLN		05NOV2002	10:00	-7	0.418		14.4		4.5		239	
		FINAL		07JAN2003	9:45	57	0.394	L	13.3		4.2		275	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	BSLN		05DEC2002	12:35	-14	0.488		16.6		5.3	267
		FINAL		07MAR2003	9:47	79	0.468		15.9		5.2	263
	E0022018	BSLN		04DEC2002	10:15	-8	0.416		14.4		4.6	252
		FINAL		11FEB2003	8:40	62	0.402		13.9		4.3	250
	E0022022	BSLN		16DEC2002	13:15	-14	0.396		13.7		4.2	284
		FINAL		27FEB2003	11:35	60	0.411		13.9		4.4	322
	E0022027	BSLN		24JAN2003	7:40	-13	0.456		15.2		5.1	188
		FINAL		03APR2003	9:00	57	0.441		14.7		4.9	203
	E0022030	BSLN		10FEB2003	7:40	-4	0.462		15.4		5.5	298
	E0022031	BSLN		11FEB2003	10:25	-7	0.492		16.9		5.5	241
		FINAL		15APR2003	9:30	57	0.475		16.4		5.3	240
	E0022032	BSLN		13FEB2003	17:30	-5	0.380		13.0		4.0	284
		FINAL		18APR2003	10:30	60	0.414		14.5		4.5	273
	E0022035	BSLN		13FEB2003	13:50	-6	0.432		14.4		4.9	237
		FINAL		13MAR2003	17:55	23	0.441		14.4		5.0	246
	E0022036	BSLN		14FEB2003	8:55	-11	0.487		16.5		5.3	279
		FINAL		22APR2003	7:36	57	0.446		15.1		4.9	267
	E0022056	BSLN	*	11APR2003	8:07	-6			10.6	L	4.1	343
		BSLN		17APR2003	14:45	1	0.346	L	11.0	L	4.3	335
	E0022060	BSLN		24APR2003	12:05	-6	0.483		16.5		5.5	213
		FINAL		24JUN2003	9:25	56	0.470		15.8		5.3	229
	E0022063	BSLN		29APR2003	10:10	-8	0.364		12.5		3.9	370

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	BSLN		23JAN2003	10:00	-7	0.335	L	11.1	L	4.4		283	
		FINAL		24MAR2003	15:40	54	0.342	L	10.9	L	4.6			
	E0023013	BSLN		13FEB2003	11:00	-14	0.438		15.3		5.0		244	
		FINAL		06MAR2003	11:00	8	0.420		14.1		4.8		194	
	E0023015	BSLN		04MAR2003	11:00	-7	0.354		11.8		3.7	L	167	
		FINAL		06MAY2003	10:00	57	0.400		13.6		4.2		462	H
	E0023034	BSLN		03JUN2003	14:00	-6	0.399		13.4		4.4		266	
		FINAL		05AUG2003	16:00	58	0.350		11.7		3.9		355	
	E0023037	BSLN		11JUN2003	16:30	-7	0.437		15.0		4.7		395	
		FINAL	*	24JUN2003	16:30	7	0.436		14.6		4.7		308	
		FINAL		15AUG2003	9:30	59	0.435		14.6		4.6		345	
	E0023038	BSLN		20JUN2003	12:45	-10	0.319	L#	10.3	L#	4.1		359	
		FINAL		16SEP2003	18:30	79	0.442		14.4		5.0		247	
	E0023044	BSLN		08JUL2003	14:00	-8	0.423		13.6		5.1		302	
		FINAL		12AUG2003	12:00	28	0.398		12.9		4.8		319	
	E0023045	BSLN		10JUL2003	11:40	-7	0.415		14.4		4.3		199	
		FINAL		15SEP2003	11:00	61	0.402		13.7		4.1		188	
	E0025002	BSLN		27MAR2003	11:05	-7	0.425		14.5		5.1		187	
		FINAL		29MAY2003	11:40	57	0.401		13.7		4.8		144	
	E0026010	BSLN		15JAN2003	14:00	-7	0.443		15.5		4.8		124	L
		FINAL		14FEB2003	13:45	24	0.431		14.7		4.6		143	
	E0026017	BSLN		26FEB2003	11:50	-8	0.420		13.7		4.8		392	
		FINAL		21MAR2003	11:10	16	0.438		14.4		5.1		322	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	BSLN		06MAR2003	16:30	-14	0.413		13.2		5.1		305
		FINAL		15MAY2003	14:15	57	0.398		13.3		4.9		281
	E0026025	BSLN		01MAY2003	11:40	-8	0.416		13.9		4.5		245
		FINAL		03JUL2003	9:30	56	0.452		14.6		4.7		220
	E0026029	BSLN		02JUL2003	11:10	-7	0.409		13.8		4.0		258
		FINAL		28JUL2003	13:30	20	0.366		12.5		3.6	L	262
	E0026030	BSLN		02JUL2003	11:50	-7	0.428		14.4		4.4		219
		FINAL		03SEP2003	17:10	57	0.430		14.1		4.3		212
	E0026031	BSLN	*	10JUL2003	14:00	-11	0.488		16.9		5.4		
		BSLN		14JUL2003	10:20	-7	0.468		15.6		5.2		222
		FINAL		29SEP2003	13:15	71	0.387	L	13.0		4.3		244
	E0027003	BSLN		08JAN2003	14:40	-20	0.431		14.5		4.9		250
		FINAL		25MAR2003	11:55	57	0.450		14.9		4.7		253
	E0028004	BSLN		27SEP2002	9:45	-3	0.431		14.7		4.7		179
		FINAL		09OCT2002	14:30	10	0.438		14.7		4.6		209
	E0028006	BSLN		01OCT2002	10:00	-3	0.383		13.1		4.2		234
		FINAL		04DEC2002	10:15	62	0.392		13.4		4.4		219
	E0028008	BSLN		08OCT2002	12:45	-7	0.391	L	13.4		4.6		265
		FINAL		10DEC2002	12:30	57	0.398	L	13.9		4.6		311
	E0028009	BSLN		10OCT2002	10:45	-5	0.401		13.5		5.0		279
		FINAL		12DEC2002	13:50	59	0.410		14.1		4.9		323
	E0028016	BSLN		07NOV2002	10:15	-7	0.399	L	13.8		4.6		187
		FINAL		09JAN2003	11:50	57	0.408		14.1		4.7		241

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0028017		*	12NOV2002	9:45		0.404	13.5	4.3	148
	E0028027	BSLN		14JAN2003	10:15	-7	0.447	15.6	4.9	187
	E0028029	BSLN		28JAN2003	10:00	-7	0.443	14.9	4.8	239
		FINAL		04APR2003	10:55	60	0.425	14.7	4.7	209
	E0028034	BSLN		20MAR2003	9:40	-12	0.478	15.9	5.8	272
		FINAL		02JUN2003	12:54	63	0.441	15.1	5.4	221
	E0028038	BSLN		18APR2003	10:20	-7	0.422	14.5	4.6	207
		FINAL		18JUN2003	13:45	55	0.448	15.0	4.9	205
	E0028043	BSLN		29MAY2003	11:55	-7	0.448	15.7	5.1	190
		FINAL		29JUL2003	8:25	55	0.447	15.5	5.1	195
	E0028045	BSLN		09JUN2003	13:00	-9	0.466	15.7	5.1	160
		FINAL		11SEP2003	12:50	86	0.462	15.1	4.9	141
	E0029005	BSLN	*	14NOV2002	13:00	-13	0.390	12.6	4.7	199
		BSLN		21NOV2002	10:30	-6	0.382	12.2	4.6	184
		FINAL		21JAN2003	12:50	56	0.365	11.8	4.5	187
	E0030001	BSLN		12NOV2002	15:15	-7	0.407	13.7	4.0	225
		FINAL		16JAN2003	12:07	59	0.364	12.6	3.8	187
	E0030008	BSLN		07JAN2003	14:33	-7	0.441	14.6	4.8	223
		FINAL		18MAR2003	10:42	64	0.446	15.1	5.1	271
	E0030011	BSLN		21JAN2003	9:58	-6	0.450	15.6	4.7	297
		FINAL		24MAR2003	14:35	57	0.476	16.2	5.1	300
	E0030015	BSLN		13FEB2003	12:05	-8	0.481	16.4	5.4	270
		FINAL		22APR2003	12:10	61	0.493	16.5	5.5	248

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	BSLN	10JUN2003	11:15	-6	0.507	16.4	5.3	400
		FINAL	14AUG2003	15:30	60	0.471	15.6	4.9	465 H
	E0031002	BSLN	20NOV2002	17:05	-7	0.380	12.7	4.1	310
		FINAL	23JAN2003	12:55	58	0.411	13.9	4.5	358
	E0031003	BSLN	03DEC2002	16:07	-7	0.494	16.8	5.4	188
		FINAL	04FEB2003	16:20	57	0.468	15.9	5.1	170
	E0033015	BSLN	03APR2003	17:05	-7	0.374	12.2	4.1	276
		FINAL	04JUN2003	11:00	56	0.362	12.4	4.0	264
	E0034002	BSLN	18MAR2003	9:25	-7	0.450	15.4	5.0	329
		FINAL	16APR2003	14:40	23	0.419	14.5	4.6	407
	E0034003	BSLN	11APR2003	10:10	-13	0.440	15.4	4.9	240
		FINAL	19JUN2003	15:50	57	0.440	14.9	4.8	265
	E0034006	BSLN	25APR2003	11:33	-21	0.405	13.7	4.6	261
		FINAL	10JUL2003	9:54	56	0.406	13.4	4.8	260
	E0034008	BSLN	16MAY2003	13:26	-8	0.433	15.0	5.1	172
		FINAL	21JUL2003	10:07	59	0.441	14.9	5.1	137 L
	E0035003	BSLN	15NOV2002	10:30	-7	0.470	16.0	5.0	187
	E0035005	BSLN	26NOV2002	10:00	-7	0.358	11.8	4.0	292
	E0035014	BSLN	28JAN2003	11:10	-6	0.348 L	11.6	3.9	241
		FINAL	31MAR2003	9:20	57	0.341 L	11.0 L	3.8	229
	E0035024	BSLN	15MAY2003	11:30	-8	0.441	15.1	5.0	212
		FINAL	18JUL2003	9:00	57	0.405	13.9	4.6	170

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	BSLN		24JUN2003	10:45	-7	0.410		13.6		4.7		298	
		FINAL		27AUG2003	12:45	58	0.411		13.8		4.8		274	
	E0037002	BSLN		18DEC2002	12:10	-8	0.363		12.6		4.2		203	
		FINAL		20FEB2003	13:25	57	0.366		12.2		4.2		194	
	E0037005	BSLN		27FEB2003	15:00	-7	0.378		12.8		4.5		333	
		FINAL		01MAY2003	14:15	57	0.398		13.6		4.7		279	
	E0037006	BSLN		07MAR2003	12:00	-7	0.387		12.9		4.3		103	L
		FINAL		09MAY2003	12:18	57	0.382		13.2		4.3		87	L#
	E0039006	BSLN	*	11NOV2002	10:05	-49	0.391		12.8		4.5		516	H
		BSLN		10DEC2002	11:35	-20	0.327	L	10.9	L	3.9		571	H
		FINAL		24FEB2003	10:58	57	0.325	L	10.7	L	3.9		462	H
	E0039015	BSLN		02JAN2003	10:20	-21	0.440		14.3		5.2		274	
		FINAL		20MAR2003	9:30	57	0.440		14.2		5.3		260	
	E0039024	BSLN		14FEB2003	8:50	-13	0.427		14.7		4.5		412	
		FINAL		25APR2003	16:05	58	0.411		14.4		4.3		400	
	E0039025	BSLN		26FEB2003	11:00	-20	0.443		14.8		5.0		272	
		FINAL		27MAY2003	10:00	71	0.432		15.0		4.8		258	
	E0039041	BSLN		08APR2003	9:40	-7	0.436		14.2		4.6		250	
		FINAL		11JUN2003	11:25	58	0.426		14.2		4.5		282	
	E0039044	BSLN		06MAY2003	10:30	-16	0.463		16.2		5.2		268	
		FINAL		23JUL2003	18:20	63	0.465		15.5		5.0		243	
	E0039046		*	06MAY2003	11:46		0.480	H	16.0		5.6	H	214	
			*	03JUN2003	10:25		0.479	H	15.6		5.5		214	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	BSLN		23MAY2003	9:30	-24	0.447		15.6		4.5	183
		FINAL		12AUG2003	14:45	58	0.475	H	15.1		4.7	211
	E0039053	BSLN	*	16JUN2003	13:25	-25	0.332	L#	10.9	L#	4.3	251
		BSLN		07JUL2003	12:40	-4	0.360	L#	11.5	L#	4.6	277
		FINAL		08SEP2003	12:45	60	0.356	L#	11.2	L#	4.6	252
	E0039057	BSLN	*	02JUL2003	19:50	-12			13.5		5.0	317
		BSLN		11JUL2003	16:25	-3	0.402		13.3		4.9	266
		FINAL		09SEP2003	9:25	58	0.347	L#	11.4	L#	4.2	310
	E0041003	BSLN		16JAN2003	17:30	-12	0.390		13.6		4.2	264
		FINAL		25MAR2003	9:55	57	0.397		13.3		4.1	242
	E0041008	BSLN		26MAR2003	15:35	-12	0.413		13.6		4.6	313
		FINAL		02JUN2003	15:30	57	0.391		13.1		4.3	348
	E0042001	BSLN		17JUN2003	9:45	-15	0.443		14.9		4.9	368
		FINAL		26AUG2003	10:50	56	0.422		14.3		4.5	325

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN	26FEB2003	14:25	-14	0.388		12.8	4.2	321
		FINAL	07MAY2003	13:45	57	0.385		12.8	4.2	376
	E0003018	BSLN	06MAY2003	16:22	-7	0.398		13.4	4.3	381
		FINAL	08JUL2003	14:18	57	0.380		12.8	4.1	287
	E0005011	BSLN	17OCT2002	15:00	-7	0.476		16.8	5.2	226
	E0005030	BSLN	18MAR2003	14:00	-8	0.363		12.1	4.2	247
	E0005036	BSLN	28APR2003	13:30	-8	0.383		13.1	4.4	259
		FINAL	27MAY2003	10:00	22	0.387		13.3	4.5	217
	E0006015	BSLN	07FEB2003	9:30	-4	0.431		14.6	4.7	341
		FINAL	08APR2003	12:00	57	0.376		13.1	4.2	322
	E0006016	BSLN	07FEB2003	12:55	-10	0.453		15.3	5.0	260
		FINAL	18APR2003	12:15	61	0.447		15.2	4.9	245
	E0007008	BSLN	08APR2003	9:55	-10	0.405		13.5	4.4	246
		FINAL	02JUL2003	14:00	76	0.397		13.4	4.3	262
	E0009002	BSLN	30OCT2002	11:45	-20	0.493		16.7	5.1	204
		FINAL	15JAN2003	13:47	58	0.490		17.1	5.3	184
	E0009006	BSLN	23JAN2003	17:50	-5	0.384	L	13.0	4.2	297
		FINAL	25MAR2003	16:20	57	0.410		13.7	4.5	254
	E0009009	BSLN	27FEB2003	15:00	-13	0.438		15.4	4.9	233
		FINAL	24MAR2003	13:40	13	0.438		14.8	4.7	243
	E0010015	BSLN	30JAN2003	10:35	-21	0.457		14.6	5.3	264
		FINAL	15APR2003	13:29	55	0.417		13.8	5.1	228

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	BSLN		20DEC2002	17:55	-4	0.425	14.9	4.8	298	
		FINAL		18FEB2003	9:00	57	0.440	15.3	5.0	230	
	E0011007	BSLN		12DEC2002	10:43	-7	0.420	14.3	4.6	298	
		FINAL		13FEB2003	8:00	57	0.411	13.7	4.6	327	
	E0011018	BSLN		15MAY2003	12:30	-7	0.496	17.5	5.3	305	
		FINAL		17JUL2003	17:30	57	0.478	16.4	5.0	266	
	E0011024	BSLN		17JUN2003	12:10	-7	0.390	13.2	4.7	205	
		FINAL		21AUG2003	13:00	59	0.430	14.2	5.1	270	
	E0015003	BSLN		13NOV2002	12:20	-12	0.419	14.2	4.8	312	
		FINAL		02DEC2002	10:55	8	0.397	13.6	4.5	226	
	E0019003	BSLN		30OCT2002	9:10	-22	0.406	14.2	4.7	307	
		FINAL		16JAN2003	11:25	57	0.373	12.6	4.5	252	
	E0019007	BSLN		06NOV2002	10:32	-7	0.401	13.9	4.3	208	
		FINAL		07JAN2003	8:30	56	0.390	13.8	4.2	221	
		FINAL	*	16JAN2003	11:50	65	0.414	14.3	4.3	212	
	E0019014	BSLN	*	17DEC2002	11:02	-23	0.470	16.0	5.1	115	L
		BSLN		07JAN2003	11:30	-2	0.463	16.1	5.0	130	L
		FINAL		22JAN2003	9:00	14	0.465	15.8	5.0	161	
	E0019018	BSLN		14JAN2003	10:45	-16	0.479	16.4	5.1	351	
		FINAL		27MAR2003	9:30	57	0.460	15.5	4.9	288	
	E0019022	BSLN		23JAN2003	12:00	-7	0.466	15.3	4.9	242	
		FINAL		27MAR2003	15:10	57	0.442	15.0	4.8	252	
	E0019027	BSLN		20FEB2003	10:50	-7	0.412	13.7	4.6	315	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	BSLN	10MAR2003	13:15	-22	0.395	13.1	4.2	248
		FINAL	28MAY2003	11:00	58	0.412	14.3	4.4	242
	E0019034	BSLN	10MAR2003	16:55	-8	0.402	13.6	4.5	290
	E0019036	BSLN	18MAR2003	9:15	-7	0.466	15.8	5.0	249
	E0019039	BSLN	22APR2003	11:00	-9	0.481	16.4	5.1	303
		FINAL	08MAY2003	15:30	8	0.428	14.7	4.5	268
	E0019041	BSLN	14MAY2003	10:50	-7	0.378	12.7	3.8	314
		FINAL	16JUL2003	11:10	57	0.375	12.5	3.8	344
	E0019049	BSLN	03JUL2003	13:40	-7	0.392	13.7	4.3	285
		FINAL	08SEP2003	12:10	61	0.410	14.0	4.5	292
	E0022052	BSLN	01APR2003	10:50	-9	0.441	14.5	5.0	295
		FINAL	05JUN2003	9:32	57	0.409	13.7	4.6	290
	E0022064	BSLN	01MAY2003	10:40	-5	0.505	17.0	5.5	183
		FINAL	01JUL2003	12:30	57	0.484	16.3	5.3	189
	E0022073	BSLN	20JUN2003	14:10	-6	0.425	14.2	4.2	376
		FINAL	21AUG2003	9:45	57	0.402	13.6	4.0	298
	E0023002	BSLN	25OCT2002	16:00	-11	0.446	15.7	5.3	225
	E0023017	BSLN	14MAR2003	13:00	-11	0.428	14.8	5.1	218
		FINAL	22MAY2003	12:30	59	0.441	15.2	5.1	204
	E0023021	BSLN	10APR2003	10:20	-13	0.424	14.4	4.7	265
		FINAL	17JUN2003	16:00	56	0.435	14.7	4.8	200
	E0023027	BSLN	07MAY2003	13:30	-9	0.392	13.5	4.6	245

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	FINAL		09JUL2003	13:00	55	0.385	12.8	4.6	269
	E0023030	BSLN		21MAY2003	10:00	-13	0.381	12.8	4.4	183
		FINAL		30JUL2003	15:30	58	0.373	12.5	4.3	219
	E0023040	BSLN		25JUN2003	15:00	-8	0.413	13.9	4.1	199
		FINAL		05SEP2003	10:00	65	0.408	13.7	4.0	220
	E0026014	BSLN		12FEB2003	11:40	-7	0.492	16.7	5.3	179
	E0026019	BSLN		10MAR2003	11:45	-7	0.409	13.8	4.7	208
		FINAL		12MAY2003	9:10	57	0.425	14.3	4.7	231
	E0027005	BSLN		19DEC2002	14:50	-7	0.434	14.8	4.6	232
		FINAL		20FEB2003	11:28	57	0.450	15.0	4.9	202
	E0029009	BSLN		13JAN2003	12:50	-7	0.441	15.3	4.7	157
		FINAL		18MAR2003	9:05	58	0.440	15.0	4.7	147
	E0029021	BSLN		03MAR2003	10:40	-15	0.433	14.4	4.7	212
		FINAL		15MAY2003	12:30	59	0.422	14.8	4.6	198
		FINAL	*	27MAY2003	8:40	71	0.440	14.8	4.7	212
	E0029026	BSLN		07APR2003	9:10	-7	0.447	15.3	4.9	216
		FINAL		10JUN2003	15:00	58	0.425	14.5	4.6	218
	E0029030	BSLN		13MAY2003	11:20	-14	0.417	14.3	4.3	148
		FINAL		23JUL2003	17:25	58	0.417	14.1	4.2	140
	E0031008	BSLN		05FEB2003	11:40	-23	0.407	13.7	4.3	235
		FINAL		24APR2003	13:17	56	0.398	13.6	4.2	207
	E0031020	BSLN		14APR2003	10:35	-7	0.491	16.4	5.0	248
		FINAL	*	29APR2003	9:30	9	0.462	15.4	4.7	214

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	FINAL	13MAY2003	10:50	23	0.450	15.0	4.6	212
	E0031021	BSLN	18APR2003	10:40	-7	0.440	14.7	5.4	206
		FINAL	19JUN2003	10:40	56	0.423	14.1	5.2	217
	E0031029	BSLN	05JUN2003	10:45	-13	0.452	15.3	4.9	134 L
	E0033002	BSLN	23DEC2002	12:15	-18	0.428	14.6	4.7	158
		FINAL	07MAR2003	11:25	57	0.434	14.6	4.9	174
	E0033006	BSLN	21JAN2003	11:15	-2	0.503	17.6 H	5.4	210
		FINAL	12FEB2003	12:30	21	0.453	15.4	4.9	195
	E0033021	BSLN	25JUN2003	14:40	-7	0.405	13.6	4.3	215
		FINAL	18AUG2003	16:20	48	0.380	13.2	4.1	234
	E0035013	BSLN	27JAN2003	10:30	-8	0.442	14.8	4.8	292
		FINAL	10FEB2003	11:05	7	0.434	14.4	4.7	266
	E0035015	BSLN	03FEB2003	10:30	-8	0.421	13.9	4.8	329
		FINAL	18FEB2003	11:20	8	0.423	13.9	4.9	333
	E0035016	BSLN	10MAR2003	11:00	-25	0.427	14.1	4.7	240
	E0035023	BSLN	06MAY2003	10:30	-7	0.456	15.1	4.8	212
	E0039052	BSLN	29MAY2003	10:25	-22	0.384	12.9	4.1	207
	E0039056	BSLN	01JUL2003	12:50	-14	0.431	14.4	4.7	182
	E0040003	BSLN	09JUL2003	14:00	-10	0.385	12.9	4.1	296
		FINAL	12SEP2003	11:00	56	0.372	12.7	3.9	298
		FINAL *	25SEP2003	11:30	69	0.367	12.9	3.9	334

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	0.410		13.9	4.6	203
		FINAL	02MAY2003	10:30	61	0.371		12.4	4.2	204
	E0002011	BSLN	16APR2003	11:30	-13	0.350		11.9	3.8	209
		FINAL	25JUN2003	11:20	58	0.375		12.6	4.1	235
	E0003010	BSLN	28JAN2003	9:10	-6	0.422		14.2	4.8	210
		FINAL	31MAR2003	16:20	57	0.394		13.0	4.5	231
	E0003011	BSLN	28JAN2003	11:47	-7	0.415		13.8	4.7	294
	E0003016	BSLN	01MAY2003	11:40	-21	0.408		13.6	4.5	182
		FINAL	13JUN2003	8:45	23	0.405		13.9	4.5	192
	E0003019	BSLN	19JUN2003	11:30	-8	0.438		14.9	4.9	196
		FINAL	21AUG2003	8:50	56	0.466		15.8	5.1	207
	E0003020	BSLN	27JUN2003	8:55	-26	0.420		14.3	4.6	169
		FINAL	17SEP2003	15:00	57	0.419		14.5	4.5	204
	E0004001	BSLN	23SEP2002	11:00	-7	0.417		13.8	4.8	195
		FINAL	05NOV2002	13:30	37	0.388		13.1	4.5	207
	E0004009	BSLN	17DEC2002	10:10	-9	0.385		13.4	4.2	172
		FINAL	19FEB2003	16:00	56	0.370		12.9	4.1	169
	E0004012	BSLN	07JAN2003	12:45	-7	0.391		13.5	4.3	280
		FINAL	11MAR2003	11:35	57	0.422		14.4	4.6	254
	E0004015	BSLN	06FEB2003	10:05	-14	0.459		15.7	5.2	255
		FINAL	15APR2003	9:10	55	0.418		14.4	4.6	218
	E0005003	BSLN	23SEP2002	15:00	-9	0.400		13.6	4.7	176
		FINAL	26NOV2002	13:25	56	0.390	L	13.4	4.5	160

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	BSLN		24SEP2002	15:20	-6	0.457	15.7	5.0	177
	E0005007	BSLN		07OCT2002	15:15	-2	0.403	13.9	4.4	227
		FINAL		04DEC2002	14:20	57		13.6	4.3	197
		FINAL	*	23DEC2002	10:00	76		14.6	4.6	196
		FINAL		23DEC2002	10:00	76	0.427			
	E0005008	BSLN		08OCT2002	18:00	-7	0.455	14.8	5.1	337
		FINAL		11DEC2002	16:00	58	0.438	14.8	5.0	323
	E0005009	BSLN		09OCT2002	10:00	-20	0.446	15.6	5.0	230
	E0005010	BSLN		14OCT2002	13:00	-7	0.387	13.3	4.7	301
		FINAL		17DEC2002	14:25	58	0.378	12.8	4.5	287
	E0005012	BSLN		24OCT2002	7:00	-21	0.437	15.1	4.8	199
		FINAL		07JAN2003	11:00	55	0.408	14.3	4.7	219
	E0005014	BSLN		05NOV2002	16:30	-8	0.492	17.0	5.6	188
		FINAL		15JAN2003	9:00	64	0.450	15.4	5.0	168
	E0005022	BSLN		27JAN2003	10:30	-2	0.494	17.0	5.1	183
		FINAL		11MAR2003	10:10	42	0.471	16.4	4.9	189
	E0005025	BSLN		20FEB2003	13:20	-7	0.426	14.6	4.5	328
		FINAL		03APR2003	11:30	36	0.434	14.6	4.6	268
	E0006019	BSLN		26MAR2003	11:35	-12	0.457	15.9	5.0	257
		FINAL		03JUN2003	12:00	58	0.443	15.1	4.8	188
	E0007005	BSLN		27JAN2003	14:30	-4	0.426	14.8	4.5	323
		FINAL		28MAR2003	13:30	57	0.434	14.6	4.5	268
	E0007015	BSLN		10JUL2003	7:35	-6	0.401	13.9	4.1	332

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	FINAL	10SEP2003	7:40	57	0.370		12.5		3.8	307
	E0009001	BSLN	29OCT2002	15:30	-14	0.373		12.6		4.1	289
	E0010002	BSLN	14NOV2002	10:36	-11	0.443		14.9		5.0	298
	E0010009	BSLN	18DEC2002	9:42	-8	0.406		13.6		4.3	232
		FINAL	19FEB2003	13:59	56	0.380		12.9		4.2	220
	E0010010	BSLN	20DEC2002	8:45	-10	0.354		12.1		4.1	232
		FINAL	13JAN2003	10:28	15	0.374		12.8		4.3	239
	E0010014	BSLN	14JAN2003	9:05	-14	0.377		12.4		4.4	297
		FINAL	25MAR2003	11:05	57	0.352		11.5	L	4.1	264
	E0010017	BSLN	05FEB2003	8:51	-20	0.485		16.3		5.0	246
		FINAL	22APR2003	10:20	57	0.452		15.4		4.8	195
	E0010023	BSLN	10APR2003	9:22	-7	0.402		13.4		4.3	260
		FINAL	01MAY2003	10:19	15	0.398		13.4		4.2	283
	E0010027	BSLN	05JUN2003	9:10	-11	0.490		16.8		4.9	180
		FINAL	01JUL2003	13:00	16	0.503		17.1		4.9	
	E0010029	BSLN	10JUN2003	9:25	-9	0.462		15.2		5.1	267
	E0011022	BSLN	02JUN2003	11:00	-7	0.438		14.6		4.9	318
		FINAL	05AUG2003	10:30	58	0.482	H	15.9		5.3	351
	E0013006	BSLN	06MAR2003	10:15	-7	0.392		13.2		4.4	289
		FINAL	24MAR2003	12:42	12	0.385		13.1		4.4	269
	E0013012	BSLN	29APR2003	9:48	-8	0.411		13.5		4.8	245
		FINAL	02JUL2003	10:05	57	0.395		12.9		4.7	214

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0013014	BSLN	08MAY2003	11:15	-26	0.418	14.4	4.7	233
		FINAL	30JUN2003	12:21	28	0.439	15.0	4.9	247
	E0014005	BSLN	04MAR2003	17:20	-7	0.441	14.9	4.6	255
		FINAL	06MAY2003	12:20	57	0.424	14.1	4.4	
	E0014007	BSLN	25MAR2003	17:50	-7	0.413	13.8	4.6	311
		FINAL	22APR2003	13:50	22	0.401	13.9	4.5	289
	E0014011	BSLN	06MAY2003	16:45	-7	0.459	16.1	5.3	239
		FINAL	08JUL2003	15:50	57	0.444	15.0	5.0	247
	E0014012	BSLN	19MAY2003	10:05	-8	0.399	13.9	4.6	333
		FINAL	24JUN2003	18:40	29	0.420	14.2	4.7	350
	E0015001	BSLN	14NOV2002	11:15	-15	0.434	14.5	4.9	281
		FINAL	20JAN2003	7:30	53	0.439	14.9	5.1	271
	E0015008	BSLN	16DEC2002	7:45	-3	0.476	16.2	5.4	314
	E0016003	BSLN	10JAN2003	9:30	-14	0.438	15.1	4.6	224
	E0016005	BSLN	21FEB2003	8:45	-4	0.407	13.6	4.2	343
		FINAL	02MAY2003	8:00	67	0.393	13.6	4.2	268
	E0018007	BSLN	16DEC2002	10:15	-11	0.383	13.2	4.4	352
	E0019005	BSLN	30OCT2002	11:50	-6	0.407	14.1	4.3	196
	E0019015	BSLN	19DEC2002	10:49	-14	0.378	12.4	4.5	269
		FINAL	27FEB2003	11:23	57	0.387	13.0	4.7	280
	E0020004	BSLN	26NOV2002	18:50	-13	0.435	14.6	4.9	280
		FINAL	22JAN2003	16:15	45	0.438	14.9	5.2	161

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	FINAL *	24FEB2003	11:50	78	0.461	15.9	5.3	181
	E0020010	BSLN	31JAN2003	9:15	-5	0.393	13.3	4.0	354
		FINAL	02APR2003	10:30	57	0.400	13.3	4.1	272
	E0020014	BSLN	11MAR2003	10:00	-7	0.395	13.0	4.6	294
		FINAL	12MAY2003	11:15	56	0.329 L	11.3 L	3.8	278
	E0020021	BSLN	13MAY2003	9:45	-6	0.481	15.7	5.4	214
		FINAL	14JUL2003	13:25	57	0.435	13.9	4.8	223
	E0020023	BSLN	09JUN2003	19:05	-8	0.396 L	13.7	4.4	266
		FINAL	11AUG2003	11:40	56	0.410	13.3	4.4	256
	E0022007	BSLN	01NOV2002	10:23	-6	0.411	14.3	4.4	254
	E0022010	BSLN	15NOV2002	10:40	-6		16.3	5.1	316
		FINAL	16JAN2003	18:00	57	0.435	14.6	4.6	266
	E0022012	BSLN	29NOV2002	15:40	-6	0.433	14.8	4.9	255
		FINAL	30JAN2003	12:00	57	0.434	14.4	4.8	199
	E0022019	BSLN	06DEC2002	10:10	-5	0.455	16.1	5.0	220
		FINAL	06FEB2003	11:20	58	0.462	16.1	5.2	202
	E0022025	BSLN	08JAN2003	10:10	-20	0.388	13.4	4.2	195
		FINAL	04FEB2003	11:30	8	0.391	13.1	4.2	265
	E0022033	BSLN	12FEB2003	10:05	-6	0.405	13.9	4.5	331
		FINAL	15APR2003	12:10	57	0.385	13.0	4.3	276
	E0022034	BSLN	12FEB2003	12:40	-6	0.499	16.6	5.6	283
		FINAL	15APR2003	14:00	57	0.499	17.3	5.6	238

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0022038	BSLN	21FEB2003	11:05	-7	0.414	13.9	4.5	278
		FINAL	14APR2003	9:40	46	0.416	14.3	4.5	266
	E0022039	BSLN	27FEB2003	11:15	-7	0.395	13.0	4.4	223
		FINAL	01MAY2003	12:50	57	0.394	13.4	4.5	223
	E0022046	BSLN	14MAR2003	8:00	-6	0.467	15.9	5.0	293
		FINAL	16MAY2003	8:05	58	0.414	14.2	4.4	314
	E0022048	BSLN	26MAR2003	9:58	-6	0.404	13.4	4.5	157
	E0022051	BSLN	01APR2003	10:15	-6	0.416	13.8	4.5	306
		FINAL	02JUN2003	10:45	57	0.362	12.3	3.9	288
	E0022053	BSLN	04APR2003	12:50	-7	0.434	14.4	4.8	267
	E0022058	BSLN	14APR2003	10:25	-7	0.455	15.5	4.8	268
		FINAL	22MAY2003	14:00	32	0.406	14.2	4.3	282
	E0022061	BSLN	25APR2003	9:37	-5	0.403	13.7	4.2	182
		FINAL	26JUN2003	12:30	58	0.401	13.4	4.2	197
	E0022062	BSLN	28APR2003	7:43	-7	0.469	16.1	4.8	199
		FINAL	23MAY2003	7:40	19	0.483	16.9	5.0	207
	E0022068	BSLN	14MAY2003	10:23	-9	0.414	13.5	4.5	259
	E0022069	BSLN	04JUN2003	7:40	-6	0.430	14.6	4.7	196
		FINAL	05AUG2003	9:45	57	0.450	15.1	4.9	182
	E0022071	BSLN	16JUN2003	11:40	-14	0.529 H	18.3 H	5.3	183
		FINAL	26AUG2003	9:33	58	0.517	17.9 H	5.1	174
	E0023003	BSLN *	08NOV2002	16:00	-39	0.487	16.7	5.5	335

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	BSLN	12DEC2002	10:00	-5	0.447	15.3	5.1	285
		FINAL	11FEB2003	14:00	57	0.485	16.4	5.4	293
	E0023006	BSLN	10DEC2002	10:30	-7	0.440	15.4	4.7	214
		FINAL	11FEB2003	11:50	57	0.430	15.1	4.7	
	E0023010	BSLN	28JAN2003	9:30	-7	0.472	15.7	4.8	217
		FINAL	31MAR2003	10:00	56	0.473	16.3	4.9	306
	E0023025	BSLN	01MAY2003	15:00	-14	0.452	15.3	5.1	244
		FINAL	10JUL2003	13:30	57	0.462	15.6	5.2	277
	E0023039	BSLN	24JUN2003	13:30	-7	0.410	13.6	4.2	433
		FINAL	26AUG2003	13:30	57	0.447	14.8	5.0	263
	E0026002	BSLN	05NOV2002	10:15	-7	0.440	14.7	5.2	297
		FINAL	09JAN2003	9:25	59	0.450	14.9	5.2	300
	E0026007	BSLN	13JAN2003	9:30	-3	0.405	13.9	4.5	360
		FINAL	12MAR2003	14:25	56	0.407	13.6	4.6	316
	E0026013	BSLN	05FEB2003	12:20	-8	0.393	13.1	4.4	234
		FINAL	14APR2003	10:00	61	0.398	13.5	4.3	231
	E0028007	BSLN	01OCT2002	10:30	-3	0.408	13.9	4.6	227
		FINAL	14NOV2002	12:45	42	0.372	12.7	4.2	213
	E0028023	BSLN	15JAN2003	10:00	-6	0.319 L#	10.8 L#	3.4 L	151
	E0028025	BSLN	08JAN2003	12:07	-5	0.436	15.1	4.9	121 L
		FINAL	27JAN2003	9:25	15	0.448	15.4	5.1	193
	E0028033	BSLN	18MAR2003	10:50	-9	0.391	12.9	4.1	253
		FINAL	22MAY2003	10:50	57	0.399	13.4	4.3	244

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	BSLN		27MAR2003	12:00	-7	0.508		16.4		5.9		193
		FINAL		29MAY2003	15:40	57	0.450		15.6		5.3		194
	E0028037	BSLN	*	18APR2003	8:30	-56	0.467		16.4		5.0		218
		BSLN	*	24APR2003	7:50	-50	0.465		16.1		5.1		238
		BSLN		04JUN2003	8:33	-9	0.441		15.3		4.8		306
		FINAL		08AUG2003	15:30	57	0.373	L	13.0		3.9	L	373
	E0028039	BSLN		05MAY2003	7:10	-4	0.471		16.6		5.2		279
		FINAL		05JUN2003	12:30	28	0.413		14.2		4.6		238
	E0028046	BSLN		17JUN2003	13:45	-8	0.351		12.1		3.9		379
	E0028048	BSLN		11JUL2003	14:00	-6	0.356		12.4		4.0		316
	E0029008	BSLN		09DEC2002	11:40	-7	0.398		13.6		4.1		263
	E0029011	BSLN		14JAN2003	11:20	-8	0.421		14.5		4.5		197
	E0029012	BSLN		04FEB2003	10:05	-7	0.387		12.8		4.5		296
		FINAL		27MAR2003	8:45	45	0.373		12.4		4.4		297
	E0029015	BSLN		11FEB2003	10:05	-13	0.397		13.3		4.1		265
		FINAL		14MAR2003	10:30	19	0.408		13.6		4.2		274
	E0029018	BSLN	*	26FEB2003	16:25	-8	0.498		16.5		5.3		255
		BSLN		06MAR2003	16:05	1	0.488		16.1		5.1		251
	E0030014	BSLN		14FEB2003	10:35	-7	0.420		14.3		4.4		230
		FINAL		22APR2003	12:50	61	0.397		13.6		4.2		229
	E0030020	BSLN		13MAY2003	15:30	-16	0.477		16.2		5.6		196
	E0030024	BSLN		17JUN2003	15:35	-24	0.414		14.2		4.9		296

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0030024	FINAL	18JUL2003	15:35	8		13.7	4.8	280
	E0030025	BSLN	01JUL2003	11:50	-10	0.337 L	11.1 L	4.0	212
	E0031027	BSLN	28MAY2003	9:10	-6	0.474	16.4	4.8	117 L
		FINAL	29JUL2003	14:40	57	0.469	16.0	4.8	168
	E0031030	BSLN	17JUN2003	10:46	-7	0.377	12.8	4.0	231
		FINAL	21AUG2003	11:10	59	0.383	13.1	4.1	208
	E0033012	BSLN	05FEB2003	15:26	-5	0.443	15.1	5.1	176
	E0034001	BSLN	17MAR2003	10:03	-3	0.406	13.3	4.6	317
		FINAL	15MAY2003	9:55	57	0.415	14.1	4.7	298
	E0034004	BSLN	11APR2003	11:15	-10	0.452	15.9	5.0	307
		FINAL	16JUN2003	12:03	57	0.431	14.8	4.9	277
	E0035001	BSLN	12NOV2002	11:40	-8	0.354	12.0	3.9	269
		FINAL	14JAN2003	9:05	56	0.342 L	11.2 L	3.6 L	374
	E0035006	BSLN	03DEC2002	10:45	-9	0.387	13.2	4.4	239
		FINAL	06FEB2003	9:30	57	0.376	12.4	4.3	215
	E0035021	BSLN	18APR2003	10:45	-7	0.413	14.0	4.7	339
		FINAL	20JUN2003	8:15	57	0.422	14.3	4.7	327
	E0036002	BSLN	10JUN2003	13:45	-7	0.429	14.6	4.7	255
		FINAL	15JUL2003	10:05	29	0.409	13.9	4.6	248
	E0036006	BSLN	24JUN2003	16:45	-9	0.459	15.5	5.5	345
		FINAL	28AUG2003	9:50	57	0.430	14.8	5.2	294
	E0036007	BSLN	27JUN2003	10:00	-6	0.427	14.1	4.8	439

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	FINAL	18JUL2003	9:15	16	0.432	14.3		4.8	429
	E0037009	BSLN	12MAY2003	9:15	-4	0.388	13.1		4.5	330
		FINAL	10JUL2003	16:05	56	0.385	12.8		4.4	322
	E0039011	BSLN	16DEC2002	17:40	-17	0.379	12.7		3.9	283
	E0039018	BSLN	15JAN2003	9:10	-8	0.382	13.1		4.2	332
	E0039026	BSLN	03MAR2003	9:05	-4	0.412	13.6		4.3	271
		FINAL	02MAY2003	9:20	57	0.399	13.6		4.1	330
	E0039028	BSLN	03MAR2003	14:15	-21	0.460	15.4		5.8	156
		FINAL	16MAY2003	12:25	54	0.474	15.5		5.9	146
	E0039032	BSLN	07MAR2003	13:45	-7	0.367	12.0		4.2	321
		FINAL	04APR2003	11:45	22	0.375	12.4		4.3	311
	E0039034	BSLN	12MAR2003	20:05	-7	0.398	13.2		4.5	321
		FINAL	14MAY2003	15:00	57	0.373	12.8		4.3	304
	E0039042	BSLN	25APR2003	10:15	-12	0.421	14.6		4.4	346
		FINAL	02JUL2003	12:50	57	0.411	14.0		4.3	372
	E0041004	BSLN	27JAN2003	10:15	-3	0.517	17.9	H	5.3	275
		FINAL	31MAR2003	12:00	61	0.508	16.9		5.1	251
	E0041009	BSLN	22APR2003	15:15	-9	0.412	14.1		4.6	255
		FINAL	16JUN2003	13:00	47	0.390	13.1		4.3	256
	E0042002	BSLN	02JUL2003	12:10	-7	0.457	15.5		5.5	268
		FINAL	02SEP2003	10:25	56	0.436	14.8		5.1	315

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN	23JUN2003	10:00	-18	0.412	14.6	4.6	219
		FINAL	25JUL2003	9:00	15	0.444	15.0	4.8	247
	E0003002	BSLN	22OCT2002	11:05	-7	0.472	16.4	4.9	314
		FINAL	14JAN2003	12:15	78	0.481	16.2	4.8	284
	E0005031	BSLN	26MAR2003	12:30	-7	0.422	14.1	4.7	201
	E0005033	BSLN	08APR2003	14:00	-8	0.445	14.6	4.7	239
		FINAL	06MAY2003	11:20	21	0.402	13.9	4.3	238
	E0005038	BSLN	05MAY2003	11:40	-9	0.438	14.8	4.5	222
		FINAL	05JUN2003	13:00	23	0.422	14.6	4.5	231
	E0007009	BSLN	14APR2003	7:48	-3	0.408	14.3	4.2	203
	E0009010	BSLN	27FEB2003	16:55	-14	0.542 H	18.3 H	6.2 H#	357
	E0009011	BSLN	28APR2003	14:17	-8	0.390 L	13.1	4.7	328
		FINAL	03JUL2003	15:40	59	0.387 L	12.5 L	4.4	272
	E0010005	BSLN	11DEC2002	10:15	-7	0.456	15.3	5.6	238
	E0011016	BSLN	14APR2003	10:00	-7	0.513	16.3	5.7	257
		FINAL	16JUN2003	9:45	57	0.469	15.5	5.5	266
	E0011020	BSLN	01MAY2003	9:20	-7	0.502	16.8	5.6	242
		FINAL	15MAY2003	17:00	8	0.483	16.2	5.4	259
	E0018002	BSLN	15NOV2002	15:35	-14	0.440	15.4	4.6	191
		FINAL	22JAN2003	16:20	55	0.447	14.9	4.6	205
	E0018003	BSLN	19NOV2002	13:05	-7	0.382	13.1	4.4	246
		FINAL	10DEC2002	11:00	15	0.383	12.9	4.4	228

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	BSLN		17JAN2003	14:15	-7	0.446	15.5	4.8	175
		FINAL		06FEB2003	16:10	14	0.428	14.8	4.6	
	E0019002	BSLN		29OCT2002	10:45	-14	0.380	12.8	4.2	280
	E0019008	BSLN	*	06NOV2002	12:35	-15	0.426	14.5	4.5	235
		BSLN		13NOV2002	10:30	-8	0.417	14.3	4.4	207
	E0019009	BSLN		06NOV2002	13:35	-8	0.431	14.8	4.7	278
	E0019016	BSLN		30DEC2002	16:55	-7	0.413	13.8	4.5	254
		FINAL		03MAR2003	16:00	57	0.399	13.4	4.5	298
	E0019020	BSLN		16JAN2003	10:10	-7	0.384	12.8	4.2	354
		FINAL		27MAR2003	10:50	64	0.378	12.5	4.1	314
	E0019021	BSLN		16JAN2003	11:45	-14	0.441	15.1	4.7	242
		FINAL		03MAR2003	13:18	33	0.451	15.0	4.9	311
	E0019024	BSLN		24JAN2003	16:00	-6	0.470	16.4	5.2	171
		FINAL		06FEB2003	12:33	8	0.453	15.7	5.0	234
	E0019031	BSLN		06MAR2003	11:35	-7	0.439	14.8	5.1	186
		FINAL		25MAR2003	10:08	13	0.447	15.2	5.1	180
	E0019035	BSLN		11MAR2003	9:28	-7	0.421	14.3	4.7	315
		FINAL		17APR2003	14:30	31	0.410	14.0	4.5	311
	E0019040	BSLN		08MAY2003	15:25	-12	0.452	14.9	5.1	248
		FINAL		17JUL2003	9:50	59	0.405	13.3	4.7	228
	E0019042	BSLN		29MAY2003	8:50	-6	0.422	14.1	4.6	185
		FINAL		20JUN2003	8:20	17	0.454	15.2	4.9	191

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	BSLN		19JUN2003	14:54	-7	0.397		13.3	4.1	328
		FINAL		16JUL2003	10:15	21	0.375		12.5	3.9	342
	E0020024	BSLN		12JUN2003	15:40	-11	0.458		15.7	5.1	301
		FINAL		25AUG2003	14:20	64	0.449		15.4	5.0	304
	E0022044	BSLN		12MAR2003	9:50	-6	0.434		14.6	4.7	276
		FINAL		12MAY2003	9:55	56	0.387		13.0	4.2	326
	E0023007	BSLN		07JAN2003	14:30	-7	0.435		14.7	4.8	272
		FINAL		13MAR2003	15:00	59	0.409		13.4	4.6	287
	E0023011	BSLN		28JAN2003	11:45	-7	0.345	L	11.9	3.9	242
		FINAL		01APR2003	12:00	57	0.390		13.2	4.5	242
	E0023014	BSLN	*	14FEB2003	15:00	-7	0.473		16.1	5.2	
		BSLN		19FEB2003	11:30	-2	0.478		16.1	5.3	176
		FINAL		25APR2003	14:00	64	0.446		15.7	4.9	225
	E0023019	BSLN		21MAR2003	14:00	-17	0.408		13.8	4.3	397
		FINAL		03JUN2003	13:30	58	0.489		17.1	5.9	203
	E0023022	BSLN		10APR2003	16:00	-8	0.440		15.3	5.0	283
		FINAL		12JUN2003	15:40	56	0.457		15.6	5.1	219
	E0023023	BSLN		17APR2003	10:00	-8	0.385		12.9	4.1	268
		FINAL		01MAY2003	14:00	7	0.361		12.4	3.9	265
	E0023029	BSLN		16MAY2003	14:00	-7	0.375		13.1	4.1	231
	E0023031	BSLN	*	22MAY2003	12:00	-33	0.465		15.9	4.9	252
		BSLN		24JUN2003	12:00	1	0.463		15.6	4.9	228
		FINAL		19AUG2003	11:00	57	0.478	H	15.6	5.0	280

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	BSLN		03JUL2003	11:00	-6	0.414	13.7	4.5	381
		FINAL		05SEP2003	13:00	59	0.406	13.4	4.4	386
	E0023043	BSLN		11JUL2003	9:00	-3	0.427	14.7	4.5	257
		FINAL		09SEP2003	10:30	58	0.414	14.4	4.3	232
	E0026003	BSLN	*	25NOV2002	12:20	-9	0.493	16.8	5.2	257
		BSLN		02DEC2002	9:25	-2	0.489	17.1	5.3	173
		FINAL		03FEB2003	10:50	62	0.432	15.1	4.6	159
	E0026005	BSLN		23DEC2002	12:40	-7	0.373	12.7	4.1	248
		FINAL		06JAN2003	15:25	8	0.387	12.6	4.1	230
	E0026009	BSLN		10JAN2003	10:20	-5	0.372	12.3	4.1	279
	E0026015	BSLN		20FEB2003	11:30	-7	0.431	14.4	4.5	214
		FINAL		25APR2003	9:50	58	0.426	14.7	4.4	182
	E0026023	BSLN		23APR2003	10:50	-7	0.460	15.2	5.2	157
		FINAL		27JUN2003	12:25	59	0.402	13.5	4.6	160
	E0027016	BSLN	*	19MAR2003	11:55	-21	0.374	12.4	4.5	333
		BSLN		04APR2003	9:50	-5	0.387	12.9	4.6	308
		FINAL		03JUN2003	10:18	56	0.363	12.2	4.4	268
	E0027018	BSLN		21MAR2003	11:30	-4	0.377	12.5	4.2	315
		FINAL		22MAY2003	10:05	59	0.377	12.8	4.2	373
	E0028032	BSLN		13MAR2003	13:58	-12	0.452	15.1	4.8	213
		FINAL		06JUN2003	11:38	74	0.413	14.5	4.5	232
	E0029003	BSLN		28OCT2002	12:30	-7	0.466	15.6	5.3	212
		FINAL		30DEC2002	9:45	57		15.3	5.1	188

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0029020	BSLN	25FEB2003	10:12	-8	0.444	14.7	5.0	181
	E0031005	BSLN	13DEC2002	16:00	-7	0.405	14.0	4.5	203
		FINAL	14FEB2003	12:10	57	0.379	13.1	4.3	220
	E0031006	BSLN	31JAN2003	11:25	-18	0.396 L	12.6 L	4.8	497 H
		FINAL	15APR2003	9:25	57	0.388 L	12.8 L	4.2	397
	E0031010	BSLN	12FEB2003	14:50	-7	0.381	12.8	4.6	220
		FINAL	06MAR2003	12:50	16	0.360	12.0	4.4	258
	E0031011	BSLN	18FEB2003	11:50	-9	0.473	15.9	4.7	214
		FINAL	24APR2003	9:25	57	0.463	15.5	4.7	207
	E0031015	BSLN	14MAR2003	8:40	-12	0.396	13.1	4.1	305
		FINAL	01APR2003	11:55	7	0.419	14.3	4.4	315
	E0031031	BSLN	01JUL2003	10:30	-7	0.459	15.8	4.8	266
		FINAL	28AUG2003	10:35	52	0.409	13.8	4.3	245
	E0033009	BSLN	22JAN2003	13:40	-21	0.415	14.0	4.8	273
	E0034009	BSLN	10JUN2003	13:00	-9	0.432	14.2	4.5	241
		FINAL	18AUG2003	17:25	61	0.398 L	13.5	4.2	178
	E0037007	BSLN	04APR2003	11:30	-7	0.430	14.7	4.6	237
	E0037012	BSLN	11JUL2003	13:00	-5	0.485	16.5	5.0	211
		FINAL	08SEP2003	13:20	55	0.448	15.5	4.7	193
	E0039019	BSLN	20JAN2003	14:50	-17	0.428	14.7	4.8	302
		FINAL	03APR2003	11:05	57	0.409	14.2	4.6	280
	E0039043	BSLN	28APR2003	10:15	-10	0.474	15.9	5.2	178

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0002001	BSLN		21DEC2002	9:45	-9	0.392	13.0	4.5		309
		FINAL		26FEB2003	8:45	59	0.410	13.6	4.6		241
	E0002003	BSLN	*	03JAN2003	11:50	-19		13.4	4.4		188
		BSLN		10JAN2003	12:30	-12	0.367	12.6	4.1		224
		FINAL		19MAR2003	13:45	57	0.411	13.9	4.7		247
	E0002004	BSLN		14JAN2003	8:15	-11	0.428	14.4	4.4		210
	E0002008	BSLN		14FEB2003	16:00	-11	0.427	14.9	5.0		246
		FINAL		23APR2003	14:25	58	0.427	14.4	4.9		251
	E0002016	BSLN		14JUL2003	11:00	-10	0.351	11.9	3.7	L	281
		FINAL		17SEP2003	11:15	56	0.360	12.0	3.9		270
	E0003008	BSLN		21JAN2003	12:45	-7	0.385	13.1	4.5		254
	E0004003	BSLN		02OCT2002	11:00	-8	0.473	16.4	5.4		265
	E0004006	BSLN		28OCT2002	9:55	-7	0.393	13.1	4.6		274
		FINAL		06JAN2003	10:55	64	0.364	12.3	4.2		241
	E0004016	BSLN		12FEB2003	15:10	-7	0.382	13.3	4.2		314
		FINAL		17APR2003	17:10	58	0.388	13.0	4.2		355
	E0004024	BSLN		25JUN2003	16:00	-8	0.410	13.9	4.5		304
		FINAL		28AUG2003	9:50	57	0.402	13.4	4.4		328
	E0005006	BSLN		24SEP2002	15:30	-9	0.428	14.9	5.0		
	E0005017	BSLN	*	11DEC2002	10:30	-19	0.417	14.1	4.5		315
		BSLN		23DEC2002	12:30	-7	0.374	12.7	4.0		303
		FINAL		04MAR2003	13:00	65	0.357	12.1	3.8		324

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0005019	BSLN	19DEC2002	14:00	-27	0.425	14.9	4.7	215
		FINAL	23JAN2003	15:45	9	0.441	15.1	4.7	234
	E0005026	BSLN	28FEB2003	10:15	-6	0.406	14.0	4.4	216
		FINAL	02APR2003	9:40	28	0.377	13.4	4.0	218
	E0005039	BSLN	15MAY2003	9:00	-7	0.415	14.3	4.8	252
		FINAL	16JUL2003	8:40	56	0.392	13.3	4.5	254
	E0005043	BSLN	02JUL2003	8:30	-7	0.405	13.8	4.3	204
		FINAL	03SEP2003	9:45	57	0.410	14.0	4.3	216
	E0006020	BSLN	02MAY2003	13:30	-11	0.466	16.2	5.1	195
		FINAL	08JUL2003	14:45	57	0.183 L#	6.4 L#	2.0 L#	24 L#
		FINAL *	10JUL2003	16:30	59	0.463	15.9	5.1	207
	E0007001	BSLN	16DEC2002	9:25	-15	0.426	14.7	4.6	258
		FINAL	24FEB2003	8:43	56	0.455	15.4	4.9	245
	E0007003	BSLN	13JAN2003	10:30	-17	0.378 L	12.9 L	3.7 L	387
		FINAL	01APR2003	13:30	62	0.352 L#	11.9 L	3.7 L	252
	E0007006	BSLN	24FEB2003	11:00	-9	0.426	13.8	5.2	282
		FINAL	27MAR2003	10:50	23	0.446	14.3	5.3	277
	E0009004	BSLN	19NOV2002	12:30	-7	0.492	16.3	5.1	194
		FINAL	18DEC2002	14:50	23	0.519	17.6 H	5.6	190
	E0009012	BSLN	16JUN2003	14:45	-9	0.461	15.7	5.2	195
		FINAL	03JUL2003	17:45	9	0.467	15.9	5.3	201
	E0010008	BSLN	11DEC2002	9:15	-7	0.368	12.6	3.9	250
	E0010018	BSLN	26FEB2003	8:51	-21	0.390	13.2	3.9	196

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
PLACEBO (BIPOLAR I)	E0010018	FINAL		14MAY2003	10:45	57	0.373		12.8		3.7	L	188	
	E0010028	BSLN		09JUN2003	8:46	-7	0.395		13.6		4.2		261	
		FINAL		15JUL2003	13:50	30	0.365		12.4		3.8		243	
	E0011008	BSLN	*	17DEC2002	12:30	-44	0.459		15.8		5.0		212	
		BSLN		23JAN2003	9:20	-7	0.455		15.0		4.7		236	
		FINAL		13FEB2003	12:30	15	0.446		15.4		4.7		242	
	E0011009	BSLN		23DEC2002	14:30	-4	0.550	H#	18.9	H#	5.6		207	
		FINAL		20FEB2003	9:00	56	0.515		17.4		5.2		214	
	E0011010	BSLN		03FEB2003	10:00	-7	0.425		14.4		4.6		228	
		FINAL		19MAR2003	8:45	38	0.422		13.9		4.6		192	
	E0013001	BSLN		07NOV2002	9:10	-7	0.457		15.4		5.3			
		FINAL		10JAN2003	10:45	58	0.456		15.7		5.4			
	E0013003	BSLN		07NOV2002	9:25	-5	0.442		14.4		5.4		221	
		FINAL		06JAN2003	13:17	56	0.432		13.9		5.2		212	
	E0013005	BSLN		13FEB2003	11:42	-5	0.399	L	14.1		4.5		93	L#
		FINAL		15APR2003	12:16	57	0.425		14.2		4.8		129	L
	E0013013	BSLN		01MAY2003	10:14	-5	0.430		14.4		4.5		215	
		FINAL		30MAY2003	9:55	25	0.403		14.0		4.4		240	
	E0014002	BSLN		19FEB2003	16:35	-7	0.424		14.6		4.7		314	
		FINAL		10APR2003	13:05	44	0.403		13.6		4.4		259	
	E0014004	BSLN		04MAR2003	11:40	-8	0.478	H	15.9		5.2		204	
		FINAL		15APR2003	11:40	35	0.463		16.0		5.0		186	
	E0014009	BSLN	*	15APR2003	14:45	-8	0.416		14.1		4.9		326	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0014009	BSLN	17APR2003	12:30	-6	0.404	13.7	4.7	333
	E0014015	BSLN	11JUN2003	10:15	-7	0.456	15.4	5.2	280
	E0014017	BSLN	17JUN2003	17:00	-10	0.412	13.7	4.5	350
		FINAL	19AUG2003	17:05	54	0.432	14.6	4.9	305
	E0014018	BSLN	24JUN2003	16:35	-7	0.470	15.8	4.9	272
		FINAL	27AUG2003	16:00	58	0.458	15.5	4.8	263
	E0015005	BSLN	25NOV2002	13:15	-7	0.471	15.8	5.0	280
		FINAL	18DEC2002	9:30	17	0.480	16.1	5.1	278
	E0017002	BSLN	08MAY2003	17:00	-26	0.397	13.4	4.5	164
		FINAL	13JUN2003	16:00	11	0.396	13.4	4.6	182
	E0018009	BSLN	17DEC2002	10:45	-20	0.476	16.4	5.3	285
		FINAL	14JAN2003	13:15	9	0.452	15.7	5.0	297
	E0018010	BSLN	09JAN2003	9:30	-7	0.442	15.3	5.2	153
		FINAL	13MAR2003	9:20	57	0.449	15.0	5.3	151
	E0018015	BSLN	24JAN2003	10:40	-4	0.439	14.9	4.7	187
		FINAL	27MAR2003	10:50	59	0.412	14.1	4.4	189
	E0020015	BSLN	18MAR2003	13:30	-9	0.435	14.6	4.8	263
		FINAL	23MAY2003	13:40	58	0.470	16.1	5.2	236
	E0020017	BSLN	27MAR2003	12:00	-7	0.412	13.9	4.3	218
		FINAL	03JUN2003	17:40	62	0.369	12.7	4.0	190
	E0020020	BSLN	07MAY2003	15:00	-5	0.392	13.3	3.9	197
		FINAL	23MAY2003	14:00	12	0.372	12.9	3.7 L	177

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0020022	BSLN		09JUN2003	13:05	-7	0.417		14.2	4.7	300
		FINAL		11AUG2003	9:30	57	0.435		14.4	4.9	310
	E0022001	BSLN		09OCT2002	14:20	-19	0.451		15.8	4.7	163
		FINAL		26DEC2002	17:55	60	0.458		15.6	4.6	168
	E0022004	BSLN	*	17OCT2002	8:48	-11	0.458		15.5	5.2	317
		BSLN		28OCT2002	9:47	1	0.433		14.8	5.0	312
		FINAL		23DEC2002	10:15	57	0.427		14.7	4.9	307
	E0022005	BSLN		18OCT2002	7:40	-21	0.399		13.5	4.8	342
		FINAL		03JAN2003	9:20	57	0.414		14.1	5.0	346
	E0022011	BSLN		21NOV2002	9:25	-8	0.449		15.2	5.0	260
	E0022015	BSLN	*	29NOV2002	13:50	-11	0.422		14.7	4.7	255
		BSLN	*	03DEC2002	10:10	-7	0.425		14.6	4.8	278
		BSLN		10DEC2002	16:10	1	0.406		13.9	4.4	322
		FINAL		06FEB2003	9:50	59	0.408		14.1	4.5	235
	E0022016	BSLN		03DEC2002	12:10	-14	0.408		14.0	4.1	348
		FINAL		11FEB2003	11:05	57	0.415		14.5	4.3	433
	E0022020	BSLN		05DEC2002	12:21	-7	0.376		12.7	4.3	305
		FINAL		23JAN2003	16:20	43	0.359		12.2	4.0	220
		FINAL	*	28JAN2003	10:35	48	0.347	L	12.0	3.9	215
	E0022023	BSLN		20DEC2002	14:28	-5	0.426		14.6	5.0	263
		FINAL		20FEB2003	10:05	58	0.427		14.6	5.1	315
	E0022029	BSLN		10FEB2003	12:30	-9	0.471		16.0	5.5	315
		FINAL		14APR2003	9:45	55	0.462		15.5	5.3	324
	E0022041	BSLN		11MAR2003	9:53	-7	0.439		15.1	5.0	327

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0022041	FINAL	13MAY2003	9:18	57	0.441		14.7	4.9	288
	E0022042	BSLN	05MAR2003	9:50	-7	0.478		16.5	5.0	236
		FINAL	12MAY2003	9:35	62	0.491		16.6	5.1	267
	E0022043	BSLN	11MAR2003	13:50	-9	0.381		12.9	4.2	298
		FINAL	12MAY2003	8:05	54	0.393		13.1	4.3	289
	E0022054	BSLN	07APR2003	11:25	-4	0.475		15.8	5.3	202
	E0022059	BSLN	23APR2003	15:30	-13	0.390		13.4	4.2	229
		FINAL	08JUL2003	16:30	64	0.418		14.1	4.3	242
	E0022065	BSLN	01MAY2003	9:30	-6	0.428		14.6	4.6	
		FINAL	02JUL2003	8:50	57	0.404		14.0	4.4	270
	E0022070	BSLN	05JUN2003	11:40	-7	0.389	L	13.3	4.2	155
		FINAL	18JUN2003	15:15	7	0.438		14.6	4.8	152
	E0023001	BSLN	13NOV2002	13:30	-2	0.402		13.9	4.7	266
	E0023009	BSLN	24JAN2003	11:30	-18	0.410		13.6	4.5	302
		FINAL	08APR2003	11:15	57	0.416		14.1	4.6	365
	E0023028	BSLN	16MAY2003	12:15	-13	0.420		14.5	4.4	251
		FINAL	21JUL2003	11:00	54	0.413		13.8	4.3	405
	E0023033	BSLN	30MAY2003	12:10	-6	0.451		15.8	5.1	261
		FINAL	12JUN2003	13:15	8	0.445		15.4	5.0	240
	E0023047	BSLN	11JUL2003	15:00	-7	0.451		15.8	5.0	256
		FINAL	16SEP2003	13:00	61	0.444		15.1	5.1	182
	E0025001	BSLN	25MAR2003	16:00	-7	0.416		13.3	4.8	332

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0025001	FINAL		23APR2003	10:30	23	0.409		13.8		4.8		323
	E0026012	BSLN		05FEB2003	11:00	-15	0.472		15.9		5.6		231
		FINAL		17APR2003	9:10	57	0.436		14.7		5.1		258
	E0026020	BSLN		28MAR2003	10:50	-4	0.424		13.9		4.9		250
		FINAL		22APR2003	14:05	22	0.437		14.5		5.0		241
	E0026024	BSLN		25APR2003	12:30	-7	0.416		14.0		4.4		301
	E0026028	BSLN		06JUN2003	10:20	-14	0.466		15.4		5.3		257
		FINAL		23JUL2003	10:00	34	0.490		16.3		5.5		312
	E0028001	BSLN		07OCT2002	14:00	-3	0.441		15.3		4.7		378
		FINAL		03DEC2002	9:50	55	0.434		15.3		4.8		368
	E0028003	BSLN		23SEP2002	9:10	-7	0.392		13.2		4.3		185
		FINAL		26NOV2002	9:20	58	0.395		13.3		4.4		201
	E0028005	BSLN		30SEP2002	11:00	-3	0.344	L	11.6		4.0		311
		FINAL		31OCT2002	12:15	29	0.365		12.4		4.2		286
	E0028010	BSLN	*	15OCT2002	11:00	-21			12.0		3.8		270
		BSLN		25OCT2002	9:00	-11	0.347	L	11.5	L	3.7	L	262
		FINAL	*	19NOV2002	12:40	15	0.353		11.8		3.8		296
		FINAL		31DEC2002	9:20	57	0.337	L	11.4	L	3.7	L	227
	E0028011	BSLN	*	16OCT2002	15:10	-50	0.370	L#	12.0	L	4.1		219
		BSLN		03DEC2002	9:30	-2	0.364	L#	12.2	L	4.0	L	204
		FINAL		30JAN2003	12:35	57	0.378	L	12.4	L	4.0	L	163
	E0028030	BSLN		26FEB2003	11:30	-6	0.471		15.7		5.0		252
		FINAL		30APR2003	12:35	58	0.474		15.9		5.0		276

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0028031	BSLN	06MAR2003	9:00	-5	0.484		16.1		5.5	257
		FINAL	17APR2003	13:30	38	0.449		15.2		5.2	268
	E0028047	BSLN	09JUL2003	10:40	-5	0.451		14.8		5.2	254
		FINAL	09SEP2003	10:24	58	0.425		14.0		4.8	211
	E0029001	BSLN	25SEP2002	8:45	-6	0.476		16.3		5.1	
	E0029014	BSLN	28JAN2003	9:35	-7	0.448		15.4		4.4	274
		FINAL	01APR2003	11:20	57	0.450		14.9		4.5	258
	E0029023	BSLN	01APR2003	8:47	-7	0.466		16.3	H	4.9	302
		FINAL	10JUN2003	11:10	64	0.448		15.4		4.6	362
	E0029032	BSLN	22MAY2003	12:45	-19	0.471		16.3		5.1	182
		FINAL	01JUL2003	12:00	22	0.456		15.8		5.0	180
	E0029033	BSLN	27MAY2003	12:50	-6	0.473		15.9		4.9	306
	E0029039	BSLN	10JUL2003	13:02	-5	0.362		11.8		4.6	313
		FINAL	28JUL2003	15:30	14	0.333	L	10.9	L	4.1	216
	E0030003	BSLN	10DEC2002	9:00	-6	0.338	L	10.9	L	3.9	233
		FINAL	21MAR2003	9:50	96	0.332	L	10.2	L#	3.9	251
	E0030009	BSLN	14JAN2003	9:55	-9	0.446		15.2		4.6	231
		FINAL	19MAR2003	10:35	56	0.428		14.7		4.4	228
	E0030016	BSLN	21FEB2003	11:50	-10	0.509		17.0		5.1	212
		FINAL	22APR2003	18:55	51	0.492		16.6		4.9	193
	E0030021	BSLN	13MAY2003	17:25	-7	0.469		16.0		5.0	209
	E0031001	BSLN	14NOV2002	11:48	-7	0.399		13.4		4.5	271

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
PLACEBO (BIPOLAR I)	E0031017	BSLN	25MAR2003	16:15	-7	0.473		15.6		5.0		288	
		FINAL	29APR2003	10:30	29	0.456		15.4		4.8		248	
	E0031018	BSLN	01APR2003	14:45	-9	0.400		12.8		5.0		420	
	E0031023	BSLN	22APR2003	14:03	-7	0.446		15.5		4.9		273	
		FINAL	24JUN2003	11:48	57	0.456		15.8		5.0		289	
	E0033001	BSLN	23DEC2002	12:50	-17	0.405		14.1		4.6		251	
		FINAL	30JAN2003	13:25	22	0.399	L	13.6		4.4		240	
	E0033004	BSLN	09JAN2003	13:10	-8	0.404		13.9		4.6		311	
		FINAL	14MAR2003	11:40	57	0.406		13.7		4.6		306	
	E0033010	BSLN	22JAN2003	16:20	-13	0.396		13.9		4.2		238	
		FINAL	26MAR2003	16:00	51	0.350		11.9		3.6	L	385	
	E0033014	BSLN	12MAR2003	17:25	-7	0.456		15.5		5.0		287	
	E0035002	BSLN	14NOV2002	10:50	-7	0.474		16.4		4.8		260	
	E0035007	BSLN	13DEC2002	12:40	-6	0.395		13.9		4.0		291	
		FINAL	11FEB2003	10:10	55	0.395		14.0		4.0		293	
	E0035011	BSLN	13JAN2003	8:35	-22	0.402		13.6		4.6		250	
		FINAL	01APR2003	9:00	57	0.390		12.8		4.4		220	
	E0035020	BSLN	15APR2003	8:15	-3	0.396		13.3		3.9		336	
	E0037003	BSLN	28JAN2003	11:40	-2	0.397		13.4		4.4		277	
		FINAL	20FEB2003	15:32	22	0.373		12.4		4.2		351	
	E0037004	BSLN	06FEB2003	12:35	-7	0.412		13.8		4.2		247	
		FINAL	10APR2003	13:00	57	0.421		13.9		4.2		266	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:29 iceadmn3

Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)	
PLACEBO (BIPOLAR I)	E0039007	BSLN		25NOV2002	13:20	-9	0.465		15.7		5.1	229	
		FINAL		29JAN2003	14:15	57	0.468		15.9		5.3	216	
	E0039022	BSLN		06FEB2003	9:50	-19	0.345	L	11.1	L	4.3	263	
		FINAL		24APR2003	12:10	59	0.338	L	11.2	L	4.2	207	
	E0039023	BSLN	*	05FEB2003	10:37	-19	0.412		13.4		4.9		
		BSLN		14FEB2003	9:30	-10	0.395	L	13.1		4.7	129	L
	E0039030	BSLN		12MAR2003	8:55	-12	0.408		13.6		4.5	107	L
		FINAL		19MAY2003	9:15	57	0.433		14.7		4.7	100	L#
	E0039031	BSLN		05MAR2003	19:15	-19	0.425		14.1		4.5	251	
		FINAL		20MAY2003	12:50	58	0.409		14.1		4.3	276	
	E0039037	BSLN		26MAR2003	18:30	-21	0.364		12.0		4.0	227	
		FINAL		12JUN2003	11:30	58	0.365		12.4		3.9	267	
	E0039038	BSLN		27MAR2003	10:10	-27	0.426		14.4		4.6	416	
		FINAL		20JUN2003	11:15	59	0.428		14.4		4.5	330	
	E0039047	BSLN		13MAY2003	9:20	-6	0.411		13.4		5.1	270	
	E0039059	BSLN		07JUL2003	11:10	-4	0.405		13.2		5.0	214	
		FINAL		05SEP2003	11:10	57	0.416		13.3		5.1	232	
	E0041007	BSLN		05MAR2003	13:45	-8	0.425		14.2		4.2	233	
		FINAL		08MAY2003	13:45	57	0.454		15.6		4.4	328	
	E0041010	BSLN		23APR2003	14:45	-7	0.483		16.5		5.1	292	
		FINAL		11JUN2003	15:30	43	0.491		16.5		5.2	314	
	E0041011	BSLN		15MAY2003	16:00	-7	0.402		14.0		4.4	276	
		FINAL		17JUL2003	14:30	57	0.414		14.4		4.5	321	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0041012	BSLN	05JUN2003	12:28	-14	0.358	11.6	4.4	392
		FINAL	14AUG2003	11:45	57	0.337 L	11.0 L	4.1	268

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR II)	E0001004	BSLN	23APR2003	11:00	-8	0.424	14.6	4.3	276
		FINAL	27JUN2003	12:45	58	0.409	14.0	4.2	247
	E0005023	BSLN	29JAN2003	7:30	-7	0.399	13.5	4.2	268
		FINAL	01APR2003	16:30	56	0.413	14.4	4.3	294
	E0005034	BSLN	09APR2003	9:30	-6	0.385	13.5	4.2	238
		FINAL	09JUN2003	13:00	56	0.387	13.3	4.1	191
	E0005041	BSLN	17JUN2003	11:55	-7	0.405	13.8	4.8	211
		FINAL	18AUG2003	10:10	56	0.404	13.9	4.8	216
	E0007004	BSLN	28JAN2003	8:05	-2	0.474 H	15.7	5.4	365
		FINAL	13FEB2003	8:30	15	0.454	15.3	5.1	359
	E0007010	BSLN	14APR2003	8:10	-4	0.403	14.0	4.3	277
		FINAL	13JUN2003	7:40	57	0.416	14.1	4.4	312
		FINAL	* 16JUN2003	7:50	60	0.397	13.8	4.4	271
	E0007012	BSLN	12MAY2003	8:50	-4	0.442	15.1	5.0	222
		FINAL	02JUL2003	11:35	48	0.436	15.0	5.1	210
	E0009007	BSLN	27JAN2003	15:25	-7	0.458	15.9	5.0	213
		FINAL	03MAR2003	15:40	29	0.455	15.9	5.1	216
	E0009008	BSLN	04FEB2003	13:37	-8	0.448	15.4	4.5	184
		FINAL	15APR2003	12:30	63	0.440	15.1	4.4	209
	E0011001	BSLN	25OCT2002	16:00	-7	0.428	14.4	4.6	261
		FINAL	26DEC2002	8:30	56	0.426	14.7	4.6	249
	E0011011	BSLN	12FEB2003	12:00	-8	0.332 L	11.2 L	3.5 L	221
		FINAL	16APR2003	8:30	56	0.319 L#	10.7 L	3.4 L	253

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA100.SAS
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR II)	E0011013	BSLN		25MAR2003	9:45	-23	0.420		13.8		4.8		317
		FINAL		12JUN2003	8:45	57	0.393		13.2		4.5		316
	E0011014	BSLN		02APR2003	8:20	-5	0.359		11.3	L	5.1		312
		FINAL		08MAY2003	15:30	32	0.364		12.2		5.0		313
	E0011021	BSLN		15MAY2003	10:00	-7	0.413		13.9		4.4		150
		FINAL		21JUL2003	10:00	61	0.365		12.4		3.9		148
	E0013008	BSLN		19MAR2003	16:20	-7	0.426		14.2		4.9		284
		FINAL		19MAY2003	11:25	55	0.405		13.7		4.7		284
	E0014001	BSLN	*	18FEB2003	15:45	-8			13.2		4.6		293
		BSLN	*	25FEB2003	9:58	-1	0.406		13.6		4.8		302
		BSLN		25FEB2003	10:15	-1	0.390		13.1		4.5		269
		FINAL		08APR2003	11:10	42	0.290	L#	9.6	L#	3.1	L	442
		FINAL	*	16APR2003	10:40	50	0.307	L#	10.4	L#	3.3	L	261
	E0014013	BSLN		20MAY2003	14:50	-7	0.381		12.8		4.0		266
		FINAL		23JUL2003	15:00	58	0.419		13.9		4.3		254
	E0014014	BSLN		03JUN2003	16:35	-7	0.433		14.8		4.7		203
		FINAL		06AUG2003	10:50	58	0.457		15.8		5.0		227
	E0015004	BSLN		25NOV2002	8:50	-7	0.416		13.9		4.5		243
		FINAL		29JAN2003	8:45	59	0.402		13.8		4.5		259
	E0018005	BSLN		10DEC2002	16:00	-10	0.454		15.4		5.1		214
		FINAL		17FEB2003	11:05	60	0.477		16.4		5.5		210
	E0018012	BSLN		17JAN2003	10:30	-7	0.390		13.4		4.4		225
		FINAL		26FEB2003	19:20	34	0.388		13.3		4.3		253
	E0019019	BSLN		14JAN2003	10:30	-9	0.370		12.3		4.9		254

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
PLACEBO (BIPOLAR II)	E0019033	BSLN		10MAR2003	16:05	-8	0.438		14.9		4.8		291	
	E0019038	BSLN	*	10APR2003	12:30	-14	0.518		17.8	H	5.6		295	
		BSLN		17APR2003	11:05	-7	0.479		16.7		5.1		235	
		FINAL		19JUN2003	9:40	57	0.475		16.7		5.1		187	
	E0019046	BSLN		19JUN2003	15:00	-7	0.435		14.6		4.9		217	
		FINAL		21AUG2003	9:12	57	0.432		14.6		4.8		240	
	E0019047	BSLN		26JUN2003	12:30	-12	0.440		14.3		5.5		317	
		FINAL		04SEP2003	8:40	59	0.443		14.4		5.5		314	
	E0019048	BSLN		03JUL2003	11:05	-7	0.370		12.4		4.0		441	
		FINAL		03SEP2003	16:12	56	0.327	L	11.2	L	3.6	L	376	
	E0022006	BSLN		22OCT2002	10:10	-21	0.434		14.5		4.8		302	
		FINAL		07JAN2003	7:40	57	0.410		13.3		4.6		337	
	E0022047	BSLN		21MAR2003	8:10	-7	0.479		16.6		5.6		216	
		FINAL		23MAY2003	9:45	57	0.465		16.2		5.4		199	
	E0022075	BSLN		27JUN2003	7:45	-11	0.401		13.5		4.2		222	
		FINAL		03SEP2003	9:15	58	0.413		13.8		4.4		205	
	E0023012	BSLN		31JAN2003	15:30	-6	0.383		13.3		4.4		229	
		FINAL		04APR2003	12:15	58	0.370		12.9		4.4		263	
	E0023016	BSLN		15MAY2003	13:30	-7	0.384		13.0		4.2		298	
		FINAL		17JUL2003	11:10	57	0.400		13.9		4.3			
	E0023018	BSLN		18MAR2003	13:30	-9	0.424		14.3		4.5		406	
		FINAL		22MAY2003	10:15	57	0.469		16.1		5.3		209	
	E0023036	BSLN		10JUN2003	12:00	-10	0.375		12.7		4.2		139	L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
PLACEBO (BIPOLAR II)	E0023036	FINAL		13AUG2003	17:00	55	0.380		12.7		4.2		116	L
	E0023046	BSLN		11JUL2003	10:00	-12	0.395		13.4		4.9		349	
		FINAL		16SEP2003	14:00	56	0.378		12.1		4.7		385	
	E0026006	BSLN		06JAN2003	9:00	-2	0.375	L	12.8	L	4.0	L	198	
	E0026021	BSLN		14APR2003	15:45	-9	0.365		12.5		3.8		191	
	E0026027	BSLN		05JUN2003	13:10	-14	0.406		13.4		4.0		280	
	E0029002		*	05NOV2002	9:30		0.454		15.7		4.8		289	
	E0029004	BSLN		13NOV2002	14:50	-6	0.419		14.6		4.3		255	
		FINAL		17JAN2003	8:25	60	0.406		13.9		4.2		229	
	E0029013	BSLN		10FEB2003	8:55	-9	0.420		14.1		4.4		365	
	E0029019	BSLN		24FEB2003	9:30	-7	0.490		16.3		5.1		268	
		FINAL		17MAR2003	9:50	15	0.488		16.1		5.0		250	
	E0029024	BSLN		11MAR2003	12:10	-6	0.445		14.7		4.6		291	
		FINAL		20MAY2003	14:45	65	0.410		14.3		4.2		231	
	E0029038	BSLN		30JUN2003	9:25	-7	0.470		15.5		5.1		444	
	E0031004	BSLN		12DEC2002	13:59	-7	0.413		14.0		4.5		498	H
		FINAL		14FEB2003	10:50	58	0.400		13.3		4.4		438	
	E0031013	BSLN		06MAR2003	10:35	-7	0.422		13.9		5.2		372	
		FINAL		08MAY2003	11:05	57	0.406		13.2		4.9		347	
	E0031016	BSLN		17MAR2003	10:45	-7	0.448		15.0		4.9		165	
		FINAL		15APR2003	10:03	23	0.459		15.1		4.9		176	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR II)	E0031019	BSLN	03APR2003	11:25	-8	0.463	15.8	5.1	246
		FINAL	12MAY2003	16:40	32	0.457	15.5	5.1	220
	E0031022	BSLN	21APR2003	12:40	-7	0.360	11.8	4.5	295
	E0033007	BSLN	22JAN2003	16:00	-6	0.366	12.6	4.1	232
		FINAL	27MAR2003	15:35	59	0.379	12.6	4.2	223
	E0033013	BSLN	06FEB2003	11:45	-13	0.381	12.6	4.8	202
		FINAL	16APR2003	11:45	57	0.374	12.4	4.7	199
	E0033016	BSLN	17APR2003	12:00	-21	0.339 L	11.4 L	3.7 L	182
		FINAL	02JUL2003	13:00	56	0.350	11.6	3.8	202
	E0033022	BSLN	09JUL2003	11:00	-5	0.375	12.8	4.6	347
		FINAL	11SEP2003	12:00	60	0.385	12.9	4.7	299
	E0034007	BSLN	07MAY2003	14:05	-9	0.436	15.1	4.4	251
		FINAL	14JUL2003	11:15	60	0.445	15.4	4.4	200
	E0035004	BSLN	22NOV2002	11:45	-5	0.498	17.0	5.5	368
	E0035009	BSLN	23DEC2002	14:50	-4	0.443	15.4	4.9	205
		FINAL	19FEB2003	8:55	55	0.458	15.3	5.0	220
	E0035010	BSLN	07JAN2003	7:45	-3	0.360	12.1	4.3	183
		FINAL	06MAR2003	9:00	56	0.401	12.9	4.8	216
	E0035022	BSLN	01MAY2003	9:45	-8	0.382	12.5	4.1	258
		FINAL	07JUL2003	8:55	60	0.329 L	11.1 L	3.6 L	236
	E0039003	BSLN	12NOV2002	11:19	-13	0.390	13.0	4.5	354
		FINAL	02JAN2003	14:06	39	0.377	12.5	4.2	395

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.1 Hematology Data - Red Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)	HEMOGLOBIN (G/DL)	TOTAL RBC COUNT (X10**12/L)	PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR II)	E0040001	BSLN	18JUN2003	14:30	-9	0.399	13.1	4.4	225
		FINAL	22AUG2003	9:00	57	0.397	13.3	4.4	182
	E0040004	BSLN	11JUL2003	13:00	-7	0.470	15.8	5.3	262
	E0041002	BSLN	13JAN2003	14:35	-8	0.423	13.7	5.3	180
		FINAL	11MAR2003	10:35	50	0.460	14.4	5.7	205
	E0041005	BSLN	28FEB2003	12:31	-5	0.510	17.3	5.6	271
		FINAL	30APR2003	14:08	57	0.449	15.4	4.8	222

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		28JAN2003	11:00	-7	8.5	66.2	5.63	0.8	0.07	1.2	26.9	4.9
		FINAL		02APR2003	10:10	58	7.4	63.7	4.71	2.2	0.16	0.3	27.6	6.2
	E0002010	BSLN		28MAR2003	10:00	-7	8.5	72.1	6.13	2.0	0.17	0.0	19.8	6.1
	E0002012	BSLN		16APR2003	10:10	-5	4.8	71.9	3.45	0.8	0.04	0.5	23.0	3.8L
		FINAL		16JUN2003	11:30	57	3.9L	62.1	2.42	1.8	0.07	0.4	31.0	4.7
	E0002015	BSLN		22MAY2003	10:15	-13	5.7	58.2	3.32	3.6	0.21	0.5	31.6	6.1
	E0002018	BSLN		16JUL2003	13:25	-8	5.6	50.2	2.81	2.5	0.14	0.8	44.8	1.7L
		FINAL		04AUG2003	9:40	12	4.6	63.8	2.93	2.7	0.12	0.3	28.6	4.6
	E0003004	BSLN	*	03DEC2002	11:48	-14	8.9	54.5	4.85	4.3	0.38	0.0	40.0	1.2L
		BSLN		17DEC2002	9:20	1	7.6	46.1	3.50	7.1H	0.54H	0.4	39.3	7.1
		FINAL		07JAN2003	15:40	22	8.0	51.0	4.08	5.1	0.41	0.3	38.1	5.5
	E0003005	BSLN		16DEC2002	15:00	-7	7.3	67.9	4.96	1.0	0.07	0.2	27.5	3.4L
		FINAL		18FEB2003	8:55	58	6.9	66.6	4.60	2.9	0.20	0.3	24.3	5.9
	E0003007	BSLN		19DEC2002	10:15	-14	9.3	73.9	6.87	2.1	0.20	0.1	18.2	5.7
		FINAL		27FEB2003	8:50	57	6.7	63.2	4.23	4.2	0.28	0.1	26.9	5.6
	E0003015	BSLN		29APR2003	11:30	-6	6.9	68.1	4.70	1.2	0.08	0.2	25.3	5.2
		FINAL		02JUL2003	14:45	59	7.3	66.0	4.82	0.9	0.07	0.4	27.0	5.7
	E0004002	BSLN		24SEP2002	10:40	-7	7.9	65.4	5.17	1.4	0.11	0.2	27.1	5.9
		FINAL		26NOV2002	11:00	57	5.6	59.2	3.32	2.3	0.13	0.3	32.1	6.1
	E0004013	BSLN		08JAN2003	10:00	-6	10.6	67.1	7.11	1.4	0.15	0.3	25.5	5.7
		FINAL		19FEB2003	8:20	37	11.9	69.7	8.29	0.9	0.11	0.1	24.0	5.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	BSLN		12MAR2003	10:50	-7	6.3	63.6	4.01	5.5	0.35	0.8	21.0	9.1
		FINAL		13MAY2003	13:45	56	6.7	59.9	4.01	2.0	0.13	0.8	27.1	10.2H
	E0004021	BSLN		07MAY2003	15:55	-7	8.4	54.8	4.60	1.9	0.16	0.4	34.6	8.3
		FINAL		09JUL2003	14:10	57	6.2	51.5	3.19	2.7	0.17	0.4	34.9	10.5H
	E0005002	BSLN		30SEP2002	8:30	-3	8.1	61.7	5.00	2.0	0.16	0.3	28.3	7.7
		FINAL		25NOV2002	8:30	54	6.2	53.9	3.34	3.4	0.21	0.3	32.0	10.4H
	E0005004	BSLN	*	24SEP2002	12:00	-7	4.8	61.1	2.93	0.7	0.03	0.2	31.9	6.1
		BSLN		01OCT2002	15:46	1	5.4	54.1	2.92	0.7	0.04	0.6	35.5	9.1
	E0005013	BSLN		30OCT2002	8:00	-8	4.1	56.0	2.30	3.2	0.13	0.5	32.5	7.8
	E0005024	BSLN		05FEB2003	15:00	-5	7.3	60.9	4.45	4.2	0.31	0.6	30.4	3.9L
		FINAL		10APR2003	11:30	60	4.2	55.4	2.33	3.5	0.15	0.3	37.1	3.7L
	E0005027	BSLN		04MAR2003	7:45	-7	5.4	59.3	3.20	2.0	0.11	0.4	30.4	7.9
		FINAL		03APR2003	8:15	24	5.4	57.1	3.08	2.8	0.15	0.4	31.6	8.1
	E0005037	BSLN		30APR2003	12:00	-7	6.7	54.7	3.66	4.8	0.32	0.4	30.2	9.9H
		FINAL		02JUL2003	12:15	57	7.3	64.1	4.68	3.7	0.27	0.7	25.3	6.2
	E0005042	BSLN		19JUN2003	11:30	-5	7.9	57.9	4.57	8.0H	0.63H	0.5	27.0	6.6
		FINAL		18AUG2003	16:25	56	8.6	63.2	5.44	7.2H	0.62H	0.4	23.5	5.7
	E0006005	BSLN		25NOV2002	12:15	-10	7.4	56.2	4.16	2.5	0.19	0.5	34.7	6.1
		FINAL		30JAN2003	16:10	57	6.8	51.2	3.48	3.3	0.22	0.4	38.7	6.4
	E0006018	BSLN		07MAR2003	12:40	-6	9.1	68.5	6.23	1.3	0.12	0.4	23.5	6.3
		FINAL		24MAR2003	10:45	12	8.4	67.8	5.70	1.9	0.16	0.7	22.1	7.5

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0007013	BSLN	10JUN2003	9:25	-3	9.5	59.3	5.63	4.2	0.40	0.4	31.8	4.3
		FINAL	07AUG2003	9:20	56	8.8	56.0	4.93	4.8	0.42	0.8	33.6	4.8
	E0010004	BSLN	05DEC2002	11:10	-6	7.4	58.9	4.36	1.1	0.08	0.2	35.5	4.3
		FINAL	06FEB2003	12:40	58	5.6	55.0	3.08	1.2	0.07	0.5	37.1	6.2
	E0010012	BSLN	30DEC2002	9:48	-8	5.0	53.0	2.65	3.0	0.15	0.2	41.8	2.0L
		FINAL	05MAR2003	13:59	58	6.0	62.3	3.74	1.8	0.11	0.4	32.3	3.2L
	E0010024	BSLN	23APR2003	8:45	-12	6.4	53.9	3.45	2.5	0.16	0.3	37.2	6.1
		FINAL	02JUL2003	10:30	59	7.0	55.4	3.88	2.4	0.17	0.3	38.2	3.7L
	E0010032	BSLN	03JUL2003	11:30	-7	7.0	68.5	4.80	2.6	0.18	0.2	24.3	4.4
		FINAL	17JUL2003	11:38	8	6.2	64.6	4.01	4.0	0.25	0.2	25.7	5.5
	E0011025	BSLN	20JUN2003	14:30	-6	7.8	66.4	5.18	1.6	0.12	0.2	25.5	6.3
		FINAL	22AUG2003	10:00	58	5.6	54.2	3.04	2.2	0.12	0.2	35.9	7.5
	E0013007	BSLN	14MAR2003	8:48	-6	9.8	45.6	4.47	5.6	0.55	0.4	42.9	5.5
		FINAL	07APR2003	17:15	19	13.6H	54.9	7.47	4.9	0.67	0.4	33.8	6.0
	E0013009	BSLN	26MAR2003	9:09	-7	5.5	61.0	3.36	2.4	0.13	0.6	27.3	8.7
		FINAL	29MAY2003	17:50	58	6.4	57.1	3.65	3.7	0.24	0.5	31.6	7.1
	E0014006	BSLN	14MAR2003	11:30	-11	8.1	67.3	5.45	0.6	0.05	0.3	29.5	2.3L
		FINAL	23APR2003	15:20	30	8.8	66.4	5.84	1.3	0.11	0.2	26.8	5.3
	E0014010	BSLN	15APR2003	17:20	-7	13.4H	72.4	9.70	1.4	0.19	0.4	22.0	3.8L
		FINAL	17JUN2003	18:10	57	10.8	65.3	7.05	0.9	0.10	0.2	30.8	2.8L
	E0016001	BSLN	02JAN2003	8:50	-20	9.8	80.0H	7.84H	1.8	0.18	0.0	13.7L	4.5
		FINAL	19MAR2003	12:00	57	11.5	85.7H	9.86H	0.8	0.09	0.1	10.8L	2.6L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA101.SAS
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0016004	BSLN		27JAN2003	9:30	-7	6.1	69.5	4.24	1.0	0.06	0.2	20.8	8.5
	E0018001	BSLN		22OCT2002	16:15	-7	8.2	68.5	5.62	0.7	0.06	0.3	24.5	6.0
		FINAL		24DEC2002	9:55	57	8.0	69.9	5.59	1.6	0.13	0.4	22.9	5.2
	E0018006	BSLN		10DEC2002	17:15	-7	9.7	57.9	5.62	2.7	0.26	0.2	31.1	8.1
		FINAL		27FEB2003	12:10	73	9.1	62.8	5.71	1.9	0.17	0.3	25.9	9.1
	E0019004	BSLN		30OCT2002	8:40	-8	6.9	46.6	3.22	5.3	0.37	0.4	39.2	8.5
		FINAL		23DEC2002	15:35	47	13.5H	82.8H	11.18H#	0.4	0.05	0.1	13.7L	3.0L
	E0019011	BSLN		12NOV2002	12:05	-9	6.9	61.0	4.21	6.0	0.41	0.5	29.0	3.5L
		FINAL		16JAN2003	14:20	57	7.1	70.7	5.02	6.0	0.43	0.6	19.6	3.1L
	E0019025	BSLN		30JAN2003	14:40	-7	6.2	58.8	3.65	3.8	0.24	0.1	33.0	4.3
		FINAL		03APR2003	13:30	57	7.2	65.5	4.72	2.5	0.18	0.3	27.3	4.4
	E0019026	BSLN		11FEB2003	11:10	-13	7.4	57.9	4.28	2.9	0.21	0.2	33.8	5.2
	E0019043	BSLN		21MAY2003	11:04	-13	5.7	64.9	3.70	3.6	0.21	0.4	23.3	7.8
		FINAL		29JUL2003	11:38	57	6.2	59.8	3.71	5.1	0.32	0.4	28.0	6.7
	E0020001	BSLN		15OCT2002	20:00	-14	8.1	54.4	4.41	1.1	0.09	0.1	40.7	3.7L
		FINAL	*	19NOV2002	19:10	22	7.0	73.2	5.12	0.5	0.04	0.2	22.4	3.7L
		FINAL		20DEC2002	12:30	53	7.4	73.6	5.45	0.6	0.04	0.1	21.0	4.7
	E0020006	BSLN		26NOV2002	18:00	-20	7.2	52.3	3.77	2.9	0.21	0.3	37.3	7.2
		FINAL		08JAN2003	10:00	24	5.3	54.3	2.88	2.2	0.12	0.3	38.7	4.5
	E0020007	BSLN		10JAN2003	12:00	-5	13.8H	73.3	10.12 #	1.8	0.25	0.0	19.7	5.2
		FINAL		25MAR2003	18:50	70	14.9H	70.0	10.43 #	2.4	0.36	0.2	23.6	3.8L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	BSLN	19FEB2003	13:45	-7	11.7	70.3	8.23	2.4	0.28	0.2	27.0	0.1L
		FINAL	23APR2003	14:30	57	11.5	66.4	7.64	2.5	0.29	0.3	25.6	5.2
		FINAL *	07MAY2003	12:00	71	9.5	61.7	5.86	3.0	0.29	0.1	30.7	4.5
	E0020013	BSLN	26FEB2003	14:15	-7	7.4	63.9	4.73	1.5	0.11	0.3	27.2	7.1
		FINAL	25MAR2003	12:00	21	6.5	61.0	3.97	2.5	0.16	0.7	29.7	6.1
	E0022008	BSLN	05NOV2002	10:00	-7	8.9	66.9	5.95	3.3	0.29	0.2	21.6	8.0
		FINAL	07JAN2003	9:45	57	6.8	60.8	4.13	6.0	0.41	0.4	25.2	7.6
	E0022017	BSLN	05DEC2002	12:35	-14	13.9H	76.0	10.56 #	0.9	0.13	0.2	18.0	4.9
		FINAL	07MAR2003	9:47	79	13.8H	78.6H	10.85H#	1.7	0.23	0.2	14.9L	4.6
	E0022018	BSLN	04DEC2002	10:15	-8	5.5	67.6	3.72	2.9	0.16	0.2	22.7	6.6
		FINAL	11FEB2003	8:40	62	5.1	52.5	2.68	1.7	0.09	0.4	39.9	5.5
	E0022022	BSLN	16DEC2002	13:15	-14	12.2	66.0	8.05	3.3	0.40	0.2	28.4	2.1L
		FINAL	27FEB2003	11:35	60	9.6	53.1	5.10	3.5	0.34	0.5	37.5	5.4
	E0022027	BSLN	24JAN2003	7:40	-13	4.4	60.1	2.64	3.8	0.17	0.3	29.3	6.5
		FINAL	03APR2003	9:00	57	4.8	58.4	2.80	4.8	0.23	0.5	31.8	4.5
	E0022030	BSLN	10FEB2003	7:40	-4	9.4	63.5	5.97	3.4	0.32	0.4	25.2	7.5
	E0022031	BSLN	11FEB2003	10:25	-7	5.1	58.7	2.99	4.6	0.23	0.3	30.4	6.0
		FINAL	15APR2003	9:30	57	4.7	55.4	2.60	6.3H	0.30H	0.5	28.9	8.9
	E0022032	BSLN	13FEB2003	17:30	-5	9.1	78.4H	7.13H	1.0	0.09	0.2	16.7	3.7L
		FINAL	18APR2003	10:30	60	6.6	69.5	4.59	1.0	0.07	0.4	22.2	6.9
	E0022035	BSLN	13FEB2003	13:50	-6	8.6	62.0	5.33	4.0	0.34	0.4	23.6	10.0H
		FINAL	13MAR2003	17:55	23	10.0	65.4	6.54	5.3	0.53	0.4	23.0	5.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	BSLN		14FEB2003	8:55	-11	7.7	69.8	5.37	3.1	0.24	0.2	21.4	5.5
		FINAL		22APR2003	7:36	57	7.7	53.8	4.14	3.5	0.27	0.6	37.4	4.7
	E0022056	BSLN	*	11APR2003	8:07	-6	7.1	58.1	4.13	3.6	0.26	0.3	32.3	5.7
		BSLN		17APR2003	14:45	1	11.0	70.9	7.80	0.5	0.06	0.3	20.8	7.5
	E0022060	BSLN		24APR2003	12:05	-6	6.2	62.5	3.88	0.5	0.03	0.3	29.3	7.4
		FINAL		24JUN2003	9:25	56	5.7	50.9	2.90	2.4	0.14	0.5	38.3	7.9
	E0022063	BSLN		29APR2003	10:10	-8	7.5	67.5	5.06	0.9	0.07	0.3	27.1	4.2
	E0023008	BSLN		23JAN2003	10:00	-7	4.3	58.4	2.51	1.0	0.04	0.2	34.5	5.9
		FINAL		24MAR2003	15:40	54	5.1	62.1	3.17	0.4	0.02	0.3	31.5	5.7
	E0023013	BSLN		13FEB2003	11:00	-14	9.7	72.0	6.98	0.4	0.04	0.3	21.4	5.9
		FINAL		06MAR2003	11:00	8	6.8	60.9	4.14	0.9	0.06	0.2	29.6	8.4
	E0023015	BSLN		04MAR2003	11:00	-7	7.0	58.6	4.10	1.3	0.09	0.3	34.6	5.2
		FINAL		06MAY2003	10:00	57	9.4	57.1	5.37	2.4	0.23	0.5	32.9	7.1
	E0023034	BSLN		03JUN2003	14:00	-6	6.6	53.6	3.54	2.9	0.19	0.4	36.0	7.1
		FINAL		05AUG2003	16:00	58	6.5	63.7	4.14	3.3	0.21	0.3	25.9	6.8
	E0023037	BSLN		11JUN2003	16:30	-7	10.7	68.0	7.28	1.0	0.11	2.0	15.0L	5.0
		FINAL	*	24JUN2003	16:30	7	5.4	65.0	3.51	1.8	0.10	1.0	24.9	7.3
		FINAL		15AUG2003	9:30	59	6.0	55.4	3.32	3.9	0.23	0.7	31.3	8.7
	E0023038	BSLN		20JUN2003	12:45	-10	4.3	54.0	2.32	2.6	0.11	0.4	35.1	7.9
		FINAL		16SEP2003	18:30	79	5.6	60.2	3.37	2.8	0.16	0.5	29.1	7.4
	E0023044	BSLN		08JUL2003	14:00	-8	11.6	73.0	8.47	0.9	0.10	0.0	21.2	4.9
		FINAL		12AUG2003	12:00	28	9.5	68.0	6.46	2.2	0.21	0.2	24.4	5.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	BSLN		10JUL2003	11:40	-7	5.3	59.1	3.13	4.3	0.23	0.5	26.8	9.3
		FINAL		15SEP2003	11:00	61	4.1	19.0L	0.78L	16.0H	0.66H	0.0	52.0H	13.0H
	E0025002	BSLN		27MAR2003	11:05	-7	5.7	55.7	3.17	2.4	0.14	0.5	36.1	5.3
		FINAL		29MAY2003	11:40	57	5.3	55.4	2.94	2.6	0.14	0.4	35.7	5.9
	E0026010	BSLN		15JAN2003	14:00	-7	6.5	55.2	3.59	1.6	0.10	0.4	34.5	8.3
		FINAL		14FEB2003	13:45	24	6.4	75.2	4.81	1.2	0.08	0.2	17.5	5.9
	E0026017	BSLN		26FEB2003	11:50	-8	6.7	61.4	4.11	3.8	0.25	0.3	24.3	10.2H
		FINAL		21MAR2003	11:10	16	7.7	68.2	5.25	2.9	0.22	0.3	21.4	7.2
	E0026018	BSLN		06MAR2003	16:30	-14	11.0	69.3	7.62	0.9	0.10	0.3	25.1	4.4
		FINAL		15MAY2003	14:15	57	7.3	65.8	4.80	1.2	0.09	0.2	28.7	4.1
	E0026025	BSLN		01MAY2003	11:40	-8	8.4	78.1H	6.56H	0.9	0.08	0.2	18.3	2.5L
		FINAL		03JUL2003	9:30	56	7.0	79.1H	5.54H	0.7	0.05	0.0	14.7L	5.5
	E0026029	BSLN		02JUL2003	11:10	-7	4.6	39.4L	1.81L	0.0	0.00	0.6	49.9H	10.1H
		FINAL		28JUL2003	13:30	20	3.7L	40.8L	1.51	0.1	0.00	0.3	51.7H	7.1
	E0026030	BSLN		02JUL2003	11:50	-7	5.7	42.2	2.41	6.9H	0.39H	0.7	44.4	5.8
		FINAL		03SEP2003	17:10	57	4.6	53.8	2.47	1.4	0.06	0.5	40.2	4.1
	E0026031	BSLN	*	10JUL2003	14:00	-11	8.4	65.8	5.53	0.7	0.06	0.5	29.7	3.3L
		BSLN		14JUL2003	10:20	-7	6.3	69.8	4.40	1.1	0.07	0.3	25.4	3.4L
		FINAL		29SEP2003	13:15	71	7.4	81.1H	6.00H	0.5	0.04	0.0	15.3L	3.1L
	E0027003	BSLN		08JAN2003	14:40	-20	12.0	61.5	7.38	7.5H	0.90H	0.5	25.5	5.0
		FINAL		25MAR2003	11:55	57	9.3	63.4	5.90	4.8	0.45	0.3	26.4	5.1
	E0028004	BSLN		27SEP2002	9:45	-3	6.4	53.1	3.40	4.2	0.27	0.6	36.3	5.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	FINAL	09OCT2002	14:30	10	6.5	54.1	3.52	3.7	0.24	0.3	38.0	3.9L
	E0028006	BSLN	01OCT2002	10:00	-3	5.0	67.2	3.36	0.6	0.03	0.2	27.5	4.5
		FINAL	04DEC2002	10:15	62	6.4	68.0	4.35	0.7	0.04	0.3	26.5	4.5
	E0028008	BSLN	08OCT2002	12:45	-7	7.8	74.8	5.83	3.4	0.27	0.4	15.4L	6.0
		FINAL	10DEC2002	12:30	57	7.7	79.7H	6.14H	1.2	0.09	0.4	13.6L	5.1
	E0028009	BSLN	10OCT2002	10:45	-5	6.6	53.6	3.54	2.1	0.14	0.2	37.6	6.5
		FINAL	12DEC2002	13:50	59	7.2	56.9	4.10	1.6	0.12	0.2	33.6	7.7
	E0028016	BSLN	07NOV2002	10:15	-7	4.6	63.7	2.93	2.8	0.13	0.3	27.4	5.8
		FINAL	09JAN2003	11:50	57	5.6	59.2	3.32	2.7	0.15	0.8	29.3	8.0
	E0028017	*	12NOV2002	9:45		9.3	73.4	6.83	2.9	0.27	0.1	20.1	3.5L
	E0028027	BSLN	14JAN2003	10:15	-7	4.9	74.2	3.64	3.9	0.19	0.2	17.8	3.9L
	E0028029	BSLN	28JAN2003	10:00	-7	5.4	61.8	3.34	5.0	0.27	0.4	26.6	6.2
		FINAL	04APR2003	10:55	60	5.6	57.6	3.23	3.1	0.17	0.5	31.5	7.3
	E0028034	BSLN	20MAR2003	9:40	-12	5.4	60.8	3.28	0.9	0.05	0.5	30.2	7.6
		FINAL	02JUN2003	12:54	63	4.4	54.2	2.38	2.4	0.11	0.3	35.1	8.0
	E0028038	BSLN	18APR2003	10:20	-7	5.4	58.5	3.16	2.0	0.11	0.2	32.0	7.3
		FINAL	18JUN2003	13:45	55	5.8	57.6	3.34	2.1	0.12	0.2	32.3	7.8
	E0028043	BSLN	29MAY2003	11:55	-7	6.2	59.8	3.71	3.8	0.24	1.4	27.4	7.6
		FINAL	29JUL2003	8:25	55	5.8	67.0	3.89	4.6	0.27	0.3	21.7	6.4
	E0028045	BSLN	09JUN2003	13:00	-9	5.9	66.4	3.92	2.4	0.14	0.2	23.9	7.1
		FINAL	11SEP2003	12:50	86	5.9	61.8	3.65	2.9	0.17	0.3	29.7	5.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA101.SAS
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	BSLN	*	14NOV2002	13:00	-13	5.1	53.0	2.70	6.3H	0.32H	0.4	31.2	9.1
		BSLN		21NOV2002	10:30	-6	4.6	47.1	2.17	7.0H	0.32H	0.1	41.2	4.6
		FINAL		21JAN2003	12:50	56	6.1	61.0	3.72	7.6H	0.46H	0.3	25.2	5.9
	E0030001	BSLN		12NOV2002	15:15	-7	5.8	53.8	3.12	0.3	0.02	0.1	38.6	7.2
		FINAL		16JAN2003	12:07	59	4.9	55.1	2.70	1.4	0.07	0.2	38.8	4.5
	E0030008	BSLN		07JAN2003	14:33	-7	5.8	56.9	3.30	1.9	0.11	0.2	36.2	4.8
		FINAL		18MAR2003	10:42	64	5.5	62.7	3.45	2.3	0.13	0.2	26.3	8.5
	E0030011	BSLN		21JAN2003	9:58	-6	8.1	55.7	4.51	3.0	0.24	0.1	32.4	8.8
		FINAL		24MAR2003	14:35	57	7.3	63.0	4.60	2.1	0.15	0.3	24.7	9.9H
	E0030015	BSLN		13FEB2003	12:05	-8	7.4	60.7	4.49	1.2	0.09	0.1	30.0	8.0
		FINAL		22APR2003	12:10	61	6.8	65.7	4.47	1.2	0.08	0.3	25.4	7.4
	E0030022	BSLN		10JUN2003	11:15	-6	8.1	60.9	4.93	2.8	0.23	0.3	35.8	0.2L
		FINAL		14AUG2003	15:30	60	9.7	73.0	7.08	1.2	0.12	0.1	25.6	0.1L
	E0031002	BSLN		20NOV2002	17:05	-7	6.9	58.0	4.00	2.7	0.19	0.3	33.1	5.9
		FINAL		23JAN2003	12:55	58	11.0	76.4	8.40	2.2	0.24	0.2	16.5	4.7
	E0031003	BSLN		03DEC2002	16:07	-7	6.3	45.8	2.89	4.2	0.26	0.6	45.1	4.3
		FINAL		04FEB2003	16:20	57	4.3	53.6	2.30	5.6	0.24	0.6	31.4	8.8
	E0033015	BSLN		03APR2003	17:05	-7	9.1	65.8	5.99	1.3	0.12	0.4	28.9	3.6L
		FINAL		04JUN2003	11:00	56	8.9	69.0	6.14	0.9	0.08	0.1	24.4	5.6
	E0034002	BSLN		18MAR2003	9:25	-7	5.6	56.7	3.18	3.9	0.22	0.3	32.5	6.6
		FINAL		16APR2003	14:40	23	9.1	56.3	5.12	3.2	0.29	0.5	32.4	7.6
	E0034003	BSLN		11APR2003	10:10	-13	4.1	67.8	2.78	0.0	0.00	0.3	22.7	9.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	FINAL	19JUN2003	15:50	57	5.4	67.8	3.66	1.4	0.08	0.2	25.8	4.8
	E0034006	BSLN	25APR2003	11:33	-21	10.1	63.5	6.41	3.5	0.35	0.1	29.2	3.7L
		FINAL	10JUL2003	9:54	56	7.9	53.9	4.26	2.2	0.17	0.2	36.8	6.9
	E0034008	BSLN	16MAY2003	13:26	-8	5.7	66.4	3.78	1.1	0.06	0.4	26.0	6.1
		FINAL	21JUL2003	10:07	59	4.0L	49.5	1.98	1.6	0.06	0.4	42.1	6.4
	E0035003	BSLN	15NOV2002	10:30	-7	5.8	53.4	3.10	2.3	0.13	0.2	37.3	6.8
	E0035005	BSLN	26NOV2002	10:00	-7	6.2	61.1	3.79	1.2	0.07	0.4	31.0	6.3
	E0035014	BSLN	28JAN2003	11:10	-6	4.9	42.0	2.06	1.5	0.07	0.3	50.8H	5.4
		FINAL	31MAR2003	9:20	57	4.7	53.2	2.50	1.7	0.08	0.3	40.1	4.7
	E0035024	BSLN	15MAY2003	11:30	-8	6.3	56.5	3.56	0.6	0.04	0.4	38.2	4.3
		FINAL	18JUL2003	9:00	57	7.9	51.1	4.04	5.1	0.40	0.0	43.7	0.1L
	E0036005	BSLN	24JUN2003	10:45	-7	7.6	69.1	5.25	1.1	0.08	0.3	25.9	3.6L
		FINAL	27AUG2003	12:45	58	7.7	72.3	5.57	1.1	0.08	0.4	22.6	3.6L
	E0037002	BSLN	18DEC2002	12:10	-8	4.5	58.1	2.61	1.8	0.08	0.1	34.1	5.9
		FINAL	20FEB2003	13:25	57	3.9L	61.9	2.41	1.3	0.05	1.6	27.6	7.6
	E0037005	BSLN	27FEB2003	15:00	-7	7.8	69.1	5.39	1.0	0.08	0.3	26.2	3.4L
		FINAL	01MAY2003	14:15	57	4.9	57.2	2.80	0.4	0.02	0.3	37.1	5.0
	E0037006	BSLN	07MAR2003	12:00	-7	4.3	52.9	2.27	2.6	0.11	0.3	37.2	7.0
		FINAL	09MAY2003	12:18	57	4.6	58.0	2.67	2.5	0.12	0.4	33.3	5.8
	E0039006	BSLN *	11NOV2002	10:05	-49	7.2	51.7	3.72	2.3	0.17	0.5	37.2	8.3
		BSLN	10DEC2002	11:35	-20	5.6	56.4	3.16	1.7	0.10	0.2	37.4	4.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	FINAL		24FEB2003	10:58	57	6.2	65.8	4.08	0.9	0.06	0.1	27.3	5.9
	E0039015	BSLN		02JAN2003	10:20	-21	5.7	51.1	2.91	2.3	0.13	0.3	36.0	10.3H
		FINAL		20MAR2003	9:30	57	4.7	57.9	2.72	1.6	0.08	0.5	32.8	7.2
	E0039024	BSLN		14FEB2003	8:50	-13	9.6	68.3	6.56	2.1	0.20	0.9	22.4	6.3
		FINAL		25APR2003	16:05	58	10.1	67.9	6.86	1.5	0.15	0.3	24.1	6.2
	E0039025	BSLN		26FEB2003	11:00	-20	6.3	55.5	3.50	7.0H	0.44H	0.3	32.7	4.5
		FINAL		27MAY2003	10:00	71	6.3	75.2	4.74	2.5	0.16	0.0	17.1	5.2
	E0039041	BSLN		08APR2003	9:40	-7	3.6L	67.1	2.42	1.2	0.04	0.4	20.7	10.6H
		FINAL		11JUN2003	11:25	58	3.5L	52.1	1.82	2.3	0.08	0.7	35.7	9.2
	E0039044	BSLN		06MAY2003	10:30	-16	6.0	68.3	4.10	0.9	0.05	1.8	22.8	6.2
		FINAL		23JUL2003	18:20	63	6.3	66.5	4.19	2.7	0.17	0.3	25.0	5.5
	E0039046		*	06MAY2003	11:46		8.5	71.5	6.08	0.3	0.03	0.4	19.4	8.4
			*	03JUN2003	10:25		11.1	74.6	8.28	0.8	0.09	0.2	17.6	6.8
	E0039051	BSLN		23MAY2003	9:30	-24	7.9	69.5	5.49	2.1	0.17	0.2	20.1	8.1
		FINAL		12AUG2003	14:45	58	7.5	63.3	4.75	1.7	0.13	0.6	30.1	4.3
	E0039053	BSLN	*	16JUN2003	13:25	-25	4.4	53.3	2.35	7.9H	0.35H	0.5	31.6	6.7
		BSLN		07JUL2003	12:40	-4	4.8	56.6	2.72	4.8	0.23	0.4	33.3	4.9
		FINAL		08SEP2003	12:45	60	4.3	58.9	2.53	5.7	0.25	0.6	28.1	6.7
	E0039057	BSLN	*	02JUL2003	19:50	-12	8.0	58.5	4.68	2.6	0.21	0.5	33.6	4.8
		BSLN		11JUL2003	16:25	-3	6.0	57.4	3.44	1.6	0.10	0.3	32.5	8.2
		FINAL		09SEP2003	9:25	58	5.9	57.2	3.37	2.2	0.13	0.4	34.7	5.5
	E0041003	BSLN		16JAN2003	17:30	-12	5.6	59.1	3.31	1.0	0.06	1.2	34.9	3.8L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:32 iceadmn3

Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	FINAL	25MAR2003	9:55	57	5.8	48.0	2.78	2.3	0.13	0.3	45.7	3.7L
	E0041008	BSLN	26MAR2003	15:35	-12	7.3	49.3	3.60	2.3	0.17	0.3	41.5	6.6
		FINAL	02JUN2003	15:30	57	9.5	56.2	5.34	1.5	0.14	0.3	36.4	5.6
	E0042001	BSLN	17JUN2003	9:45	-15	9.4	69.7	6.55	1.3	0.12	0.3	20.6	8.1
		FINAL	26AUG2003	10:50	56	10.5	78.0H	8.19H	1.7	0.18	0.0	14.1L	6.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN	26FEB2003	14:25	-14	8.8	70.9	6.24	0.9	0.08	0.3	24.9	3.0L
		FINAL	07MAY2003	13:45	57	8.2	63.8	5.23	2.0	0.16	0.2	29.1	4.9
	E0003018	BSLN	06MAY2003	16:22	-7	4.8	59.9	2.88	0.1	0.00	0.4	34.3	5.3
		FINAL	08JUL2003	14:18	57	5.2	62.4	3.24	0.6	0.03	0.5	30.5	6.0
	E0005011	BSLN	17OCT2002	15:00	-7	7.7	67.2	5.17	3.5	0.27	0.2	21.3	7.8
	E0005030	BSLN	18MAR2003	14:00	-8	7.2	66.6	4.80	1.2	0.09	0.2	28.3	3.7L
	E0005036	BSLN	28APR2003	13:30	-8	7.2	53.0	3.82	1.0	0.07	0.0	37.0	9.0
		FINAL	27MAY2003	10:00	22	5.2	51.2	2.66	1.1	0.06	0.8	39.4	7.5
	E0006015	BSLN	07FEB2003	9:30	-4	4.9	57.9	2.84	2.6	0.13	0.4	35.3	3.8L
		FINAL	08APR2003	12:00	57	5.3	61.5	3.26	2.4	0.13	0.4	31.0	4.7
	E0006016	BSLN	07FEB2003	12:55	-10	12.0	77.7H	9.32H	1.7	0.20	0.3	17.2	3.1L
		FINAL	18APR2003	12:15	61	14.2H	80.4H	11.42H#	0.9	0.13	0.3	14.6L	3.8L
	E0007008	BSLN	08APR2003	9:55	-10	8.1	72.0	5.83	1.6	0.13	0.3	20.6	5.5
		FINAL	02JUL2003	14:00	76	7.9	66.8	5.28	1.2	0.09	0.2	26.7	5.1
	E0009002	BSLN	30OCT2002	11:45	-20	4.9	52.3	2.56	1.3	0.06	0.2	40.2	6.0
		FINAL	15JAN2003	13:47	58	6.0	62.4	3.74	3.4	0.20	0.3	28.1	5.8
	E0009006	BSLN	23JAN2003	17:50	-5	7.7	46.2	3.56	2.7	0.21	0.3	40.9	9.9H
		FINAL	25MAR2003	16:20	57	6.2	47.5	2.95	3.8	0.24	0.3	37.6	10.8H
	E0009009	BSLN	27FEB2003	15:00	-13	7.9	60.9	4.81	1.2	0.09	0.2	31.1	6.6
		FINAL	24MAR2003	13:40	13	10.3	70.5	7.26	1.1	0.11	0.3	22.8	5.3
	E0010015	BSLN	30JAN2003	10:35	-21	8.9	68.8	6.12	3.6	0.32	0.3	22.5	4.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	FINAL		15APR2003	13:29	55	6.6	51.9	3.43	4.1	0.27	0.5	36.1	7.4
	E0011004	BSLN		20DEC2002	17:55	-4	8.9	57.4	5.11	2.9	0.26	0.4	32.4	6.9
		FINAL		18FEB2003	9:00	57	5.5	53.9	2.96	3.8	0.21	1.3	33.2	7.8
	E0011007	BSLN		12DEC2002	10:43	-7	10.0	66.0	6.60	1.5	0.15	0.7	29.2	2.6L
		FINAL		13FEB2003	8:00	57	9.1	64.7	5.89	1.7	0.15	0.4	27.7	5.5
	E0011018	BSLN		15MAY2003	12:30	-7	9.3	67.4	6.27	2.6	0.24	0.4	22.8	6.8
		FINAL		17JUL2003	17:30	57	6.6	49.0	3.23	4.6	0.30	0.4	38.2	7.8
	E0011024	BSLN		17JUN2003	12:10	-7	4.9	65.4	3.20	1.8	0.09	0.1	24.1	8.6
		FINAL		21AUG2003	13:00	59	8.0	60.6	4.85	0.3	0.02	0.3	35.0	3.8L
	E0015003	BSLN		13NOV2002	12:20	-12	7.9	51.2	4.04	1.5	0.12	0.3	43.1	3.9L
		FINAL		02DEC2002	10:55	8	7.4	58.4	4.32	3.7	0.27	0.3	34.5	3.1L
	E0019003	BSLN		30OCT2002	9:10	-22	4.9	63.1	3.09	4.0	0.20	0.4	26.7	5.8
		FINAL		16JAN2003	11:25	57	3.3L	57.0	1.88	4.6	0.15	0.3	31.5	6.6
	E0019007	BSLN		06NOV2002	10:32	-7	4.8	64.5	3.10	1.0	0.05	0.3	31.7	2.5L
		FINAL		07JAN2003	8:30	56	3.7L	49.5	1.83	1.7	0.06	0.1	43.7	5.0
		FINAL	*	16JAN2003	11:50	65	3.7L	56.5	2.09	1.2	0.04	0.4	37.5	4.4
	E0019014	BSLN	*	17DEC2002	11:02	-23	6.2	68.5	4.25	5.1	0.32	0.2	20.0	6.2
		BSLN		07JAN2003	11:30	-2	7.2	66.4	4.78	6.3H	0.45H	0.2	21.3	5.8
		FINAL		22JAN2003	9:00	14	4.9	55.7	2.73	5.1	0.25	0.2	32.6	6.4
	E0019018	BSLN		14JAN2003	10:45	-16	8.9	72.3	6.43	2.8	0.25	0.2	19.5	5.2
		FINAL		27MAR2003	9:30	57	6.4	66.5	4.26	3.8	0.24	0.4	23.4	5.9
	E0019022	BSLN		23JAN2003	12:00	-7	10.1	56.3	5.69	2.8	0.28	0.2	34.0	6.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA101.SAS
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	FINAL	27MAR2003	15:10	57	8.8	50.7	4.46	2.5	0.22	0.4	36.9	9.5H
	E0019027	BSLN	20FEB2003	10:50	-7	9.8	64.2	6.29	0.4	0.04	0.3	31.8	3.3L
	E0019032	BSLN	10MAR2003	13:15	-22	6.5	60.4	3.93	2.9	0.19	0.3	31.7	4.7
		FINAL	28MAY2003	11:00	58	6.3	56.0	3.53	2.8	0.18	0.5	34.6	6.1
	E0019034	BSLN	10MAR2003	16:55	-8	8.6	64.3	5.53	1.5	0.13	0.2	32.6	1.4L
	E0019036	BSLN	18MAR2003	9:15	-7	7.2	70.5	5.08	2.4	0.17	0.1	19.5	7.5
	E0019039	BSLN	22APR2003	11:00	-9	7.5	71.5	5.36	1.7	0.13	0.2	20.7	5.9
		FINAL	08MAY2003	15:30	8	7.1	55.5	3.94	2.8	0.20	0.7	31.4	9.6H
	E0019041	BSLN	14MAY2003	10:50	-7	7.5	60.7	4.55	1.2	0.09	0.3	32.0	5.8
		FINAL	16JUL2003	11:10	57	8.1	65.0	5.27	1.5	0.12	0.3	26.9	6.3
	E0019049	BSLN	03JUL2003	13:40	-7	6.7	58.4	3.91	2.6	0.17	0.1	31.5	7.4
		FINAL	08SEP2003	12:10	61	7.4	59.8	4.43	1.9	0.14	0.6	30.8	6.9
	E0022052	BSLN	01APR2003	10:50	-9	6.8	66.0	4.49	1.8	0.12	0.1	28.6	3.5L
		FINAL	05JUN2003	9:32	57	6.7	65.0	4.36	2.1	0.14	0.2	27.9	4.8
	E0022064	BSLN	01MAY2003	10:40	-5	5.4	49.5	2.67	2.2	0.12	0.5	41.3	6.5
		FINAL	01JUL2003	12:30	57	5.0	48.6	2.43	1.9	0.10	0.5	41.0	8.0
	E0022073	BSLN	20JUN2003	14:10	-6	7.7	51.6	3.97	3.4	0.26	0.4	39.1	5.5
		FINAL	21AUG2003	9:45	57	6.8	55.3	3.76	4.2	0.29	0.4	34.3	5.8
	E0023002	BSLN	25OCT2002	16:00	-11	8.4	62.8	5.28	2.4	0.20	0.3	30.2	4.3
	E0023017	BSLN	14MAR2003	13:00	-11	6.1	53.0	3.23	1.3	0.08	0.4	38.3	7.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	FINAL	22MAY2003	12:30	59	5.3	49.6	2.63	1.5	0.08	0.4	42.0	6.5
	E0023021	BSLN	10APR2003	10:20	-13	8.0	63.7	5.10	2.0	0.16	0.2	28.2	5.9
		FINAL	17JUN2003	16:00	56	5.9	53.9	3.18	3.8	0.22	0.5	36.8	5.0
	E0023027	BSLN	07MAY2003	13:30	-9	4.9	40.3L	1.97L	3.0	0.15	0.4	51.6H	4.7
		FINAL	09JUL2003	13:00	55	6.3	54.3	3.42	1.5	0.09	0.3	39.1	4.8
	E0023030	BSLN	21MAY2003	10:00	-13	5.6	70.8	3.96	1.5	0.08	0.2	27.3	0.2L
		FINAL	30JUL2003	15:30	58	5.4	58.2	3.14	1.7	0.09	0.4	34.5	5.2
	E0023040	BSLN	25JUN2003	15:00	-8	5.2	54.9	2.85	5.0	0.26	0.4	28.4	11.3H
		FINAL	05SEP2003	10:00	65	5.1	57.6	2.94	4.4	0.22	0.5	27.0	10.5H
	E0026014	BSLN	12FEB2003	11:40	-7	8.9	58.8	5.23	1.8	0.16	0.2	30.3	8.9
	E0026019	BSLN	10MAR2003	11:45	-7	6.8	66.7	4.54	1.6	0.11	0.3	27.4	4.0
		FINAL	12MAY2003	9:10	57	5.8	61.4	3.56	2.1	0.12	0.0	30.8	5.7
	E0027005	BSLN	19DEC2002	14:50	-7	7.1	57.7	4.10	1.2	0.09	0.3	34.9	5.9
		FINAL	20FEB2003	11:28	57	8.1	69.5	5.63	1.2	0.10	0.2	24.1	5.0
	E0029009	BSLN	13JAN2003	12:50	-7	7.0	67.9	4.75	0.3	0.02	0.4	26.5	4.9
		FINAL	18MAR2003	9:05	58	5.9	68.8	4.06	1.4	0.08	0.2	25.8	3.8L
	E0029021	BSLN	03MAR2003	10:40	-15	4.7	58.2	2.74	1.8	0.08	0.3	31.5	8.2
		FINAL	15MAY2003	12:30	59	5.2	51.4	2.67	2.8	0.15	0.4	34.4	11.0H
		FINAL *	27MAY2003	8:40	71	4.3	60.8	2.61	2.1	0.09	0.3	31.0	5.8
	E0029026	BSLN	07APR2003	9:10	-7	9.0	69.4	6.25	0.7	0.06	0.4	21.2	8.3
		FINAL	10JUN2003	15:00	58	9.4	72.6	6.82	0.6	0.06	0.4	19.7	6.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	BSLN		13MAY2003	11:20	-14	10.2	61.7	6.29	4.7	0.48	0.2	29.9	3.5L
		FINAL		23JUL2003	17:25	58	10.4	64.4	6.70	4.3	0.45	0.3	27.6	3.4L
	E0031008	BSLN		05FEB2003	11:40	-23	7.0	65.0	4.55	4.8	0.34	0.3	26.7	3.2L
		FINAL		24APR2003	13:17	56	5.9	59.9	3.53	5.4	0.32	0.3	31.2	3.2L
	E0031020	BSLN		14APR2003	10:35	-7	23.4H#	19.0L	4.45L	0.0	0.00	0.0	79.0H	2.0L
		FINAL	*	29APR2003	9:30	9	19.4H#	15.4L	2.99L	0.6	0.12	0.2	81.3H	2.5L
		FINAL		13MAY2003	10:50	23	18.2H#	19.6L	3.57L	0.2	0.04	0.1	77.9H	2.2L
	E0031021	BSLN		18APR2003	10:40	-7	4.9	53.7	2.63	2.0	0.10	0.6	38.9	4.8
		FINAL		19JUN2003	10:40	56	4.7	53.3	2.51	1.9	0.09	0.3	40.9	3.6L
	E0031029	BSLN		05JUN2003	10:45	-13	5.9	51.7	3.05	1.8	0.11	0.3	38.9	7.3
	E0033002	BSLN		23DEC2002	12:15	-18	5.1	54.5	2.78	2.0	0.10	0.4	35.7	7.4
		FINAL		07MAR2003	11:25	57	5.1	61.7	3.15	2.2	0.11	0.7	29.0	6.4
	E0033006	BSLN		21JAN2003	11:15	-2	8.2	62.5	5.13	2.7	0.22	0.2	29.7	4.9
		FINAL		12FEB2003	12:30	21	8.3	63.5	5.27	3.6	0.30	0.3	25.9	6.7
	E0033021	BSLN		25JUN2003	14:40	-7	4.9	56.5	2.77	0.5	0.02	0.3	37.9	4.8
		FINAL		18AUG2003	16:20	48	4.0L	44.2	1.77	3.7	0.15	0.7	44.3	7.1
	E0035013	BSLN		27JAN2003	10:30	-8	6.5	63.8	4.15	2.5	0.16	0.3	28.3	5.1
		FINAL		10FEB2003	11:05	7	7.8	73.7	5.75	1.1	0.09	0.4	20.6	4.2
	E0035015	BSLN		03FEB2003	10:30	-8	7.3	58.2	4.25	8.1H	0.59H	0.2	25.8	7.7
		FINAL		18FEB2003	11:20	8	7.5	71.4	5.36	1.8	0.14	0.2	20.3	6.3
	E0035016	BSLN		10MAR2003	11:00	-25	7.4	67.4	4.99	0.9	0.07	0.1	28.8	2.8L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0035023	BSLN		06MAY2003	10:30	-7	9.3	66.2	6.16	2.8	0.26	0.3	26.7	4.0
	E0039052	BSLN		29MAY2003	10:25	-22	4.5	59.2	2.66	2.9	0.13	0.2	33.9	3.8L
	E0039056	BSLN		01JUL2003	12:50	-14	7.4	56.7	4.20	2.4	0.18	0.0	36.1	4.8
	E0040003	BSLN		09JUL2003	14:00	-10	5.8	54.5	3.16	3.3	0.19	0.4	38.2	3.6L
		FINAL		12SEP2003	11:00	56	5.7	50.9	2.90	14.9H	0.85H	0.1	26.9	7.2
		FINAL	*	25SEP2003	11:30	69	5.7	66.2	3.77	3.1	0.18	0.2	23.4	7.1

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	7.6	66.7	5.07	2.7	0.21	0.2	23.2	7.2
		FINAL	02MAY2003	10:30	61	4.6	55.2	2.54	2.8	0.13	0.5	34.3	7.2
	E0002011	BSLN	16APR2003	11:30	-13	3.5L	51.7	1.81	4.7	0.16	1.1	31.8	10.7H
		FINAL	25JUN2003	11:20	58	4.5	67.3	3.03	3.7	0.17	0.2	21.9	6.9
	E0003010	BSLN	28JAN2003	9:10	-6	4.5	64.4	2.90	0.8	0.04	0.3	28.8	5.7
		FINAL	31MAR2003	16:20	57	6.2	68.5	4.25	1.3	0.08	0.3	23.4	6.5
	E0003011	BSLN	28JAN2003	11:47	-7	8.2	66.9	5.49	1.7	0.14	0.3	26.1	5.0
	E0003016	BSLN	01MAY2003	11:40	-21	8.6	68.9	5.93	1.4	0.12	0.3	25.5	3.9L
		FINAL	13JUN2003	8:45	23	6.8	66.1	4.49	1.6	0.11	0.2	24.8	7.3
	E0003019	BSLN	19JUN2003	11:30	-8	6.7	59.1	3.96	1.4	0.09	0.3	30.7	8.5
		FINAL	21AUG2003	8:50	56	6.5	57.5	3.74	3.6	0.23	0.4	30.4	8.1
	E0003020	BSLN	27JUN2003	8:55	-26	4.7	57.9	2.72	2.4	0.11	0.4	33.5	5.8
		FINAL	17SEP2003	15:00	57	5.7	54.9	3.13	4.0	0.23	0.4	33.5	7.2
	E0004001	BSLN	23SEP2002	11:00	-7	8.9	70.8	6.30	3.3	0.29	0.4	22.9	2.6L
		FINAL	05NOV2002	13:30	37	8.3	70.1	5.82	0.7	0.06	0.0	22.4	6.8
	E0004009	BSLN	17DEC2002	10:10	-9	7.0	68.8	4.82	1.5	0.11	0.3	25.9	3.5L
		FINAL	19FEB2003	16:00	56	5.6	65.4	3.66	0.6	0.03	0.4	27.6	6.0
	E0004012	BSLN	07JAN2003	12:45	-7	5.8	69.3	4.02	2.5	0.15	0.6	22.4	5.2
		FINAL	11MAR2003	11:35	57	4.0L	61.8	2.47	3.0	0.12	0.1	29.8	5.3
	E0004015	BSLN	06FEB2003	10:05	-14	6.5	60.8	3.95	2.1	0.14	0.3	33.1	3.7L
		FINAL	15APR2003	9:10	55	5.4	61.5	3.32	1.8	0.10	0.3	32.6	3.8L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	BSLN		23SEP2002	15:00	-9	4.4	58.4	2.57	2.7	0.12	0.1	34.6	4.2
		FINAL		26NOV2002	13:25	56	3.4L	45.7	1.55	3.7	0.13	0.2	40.8	9.6H
	E0005005	BSLN		24SEP2002	15:20	-6	7.0	57.3	4.01	2.5	0.18	0.4	33.5	6.3
	E0005007	BSLN		07OCT2002	15:15	-2	6.7	58.2	3.90	2.2	0.15	0.2	35.0	4.4
		FINAL		04DEC2002	14:20	57	6.1	58.7	3.58	6.4H	0.39H	0.6	33.5	0.8L
		FINAL	*	23DEC2002	10:00	76	6.2	53.1	3.29	4.4	0.27	0.4	34.4	7.7
	E0005008	BSLN		08OCT2002	18:00	-7	12.5H	72.3	9.04	1.5	0.19	0.2	21.4	4.6
		FINAL		11DEC2002	16:00	58	12.7H	72.3	9.18	2.3	0.29	0.2	20.7	4.5
	E0005009	BSLN		09OCT2002	10:00	-20	8.8	78.7H	6.93H	0.5	0.04	0.4	16.2	4.2
	E0005010	BSLN		14OCT2002	13:00	-7	13.2H	67.5	8.91	2.3	0.30	1.7	25.0	3.5L
		FINAL		17DEC2002	14:25	58	10.6	70.4	7.46	0.0	0.00	0.2	24.9	4.5
	E0005012	BSLN		24OCT2002	7:00	-21	8.4	65.7	5.52	2.1	0.18	0.5	26.4	5.3
		FINAL		07JAN2003	11:00	55	6.7	64.4	4.31	0.9	0.06	0.1	28.5	6.1
	E0005014	BSLN		05NOV2002	16:30	-8	9.1	73.6	6.70	0.6	0.05	0.3	21.4	4.1
		FINAL		15JAN2003	9:00	64	7.2	69.5	5.00	1.9	0.14	0.3	21.8	6.5
	E0005022	BSLN		27JAN2003	10:30	-2	5.4	27.3L	1.47L	3.3	0.18	0.5	59.1H	9.8H
		FINAL		11MAR2003	10:10	42	6.7	57.0	3.82	1.8	0.12	0.3	34.4	6.5
	E0005025	BSLN		20FEB2003	13:20	-7	11.6	71.8	8.33	1.8	0.21	0.4	23.5	2.5L
		FINAL		03APR2003	11:30	36	10.4	72.6	7.55	1.9	0.20	0.3	22.0	3.2L
	E0006019	BSLN		26MAR2003	11:35	-12	5.8	67.0	3.89	3.2	0.19	0.7	26.4	2.7L
		FINAL		03JUN2003	12:00	58	4.5	55.4	2.49	3.8	0.17	0.5	33.2	7.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	BSLN	27JAN2003	14:30	-4	10.9	53.7	5.85	2.2	0.24	0.4	39.4	4.3
		FINAL	28MAR2003	13:30	57	8.9	52.2	4.65	3.9	0.35	0.2	37.9	5.8
	E0007015	BSLN	10JUL2003	7:35	-6	5.1	37.4L	1.91L	2.7	0.14	0.3	52.2H	7.4
		FINAL	10SEP2003	7:40	57	4.6	25.0L	1.15L	7.0H	0.32H	0.0	64.0H	4.0
	E0009001	BSLN	29OCT2002	15:30	-14	11.6	61.0	7.08	1.0	0.12	0.5	31.8	5.7
	E0010002	BSLN	14NOV2002	10:36	-11	6.7	53.7	3.60	13.0H	0.87H	0.2	28.8	4.3
	E0010009	BSLN	18DEC2002	9:42	-8	7.3	71.8	5.24	1.5	0.11	0.2	20.5	6.0
		FINAL	19FEB2003	13:59	56	6.0	70.4	4.22	0.2	0.01	0.3	24.3	4.8
	E0010010	BSLN	20DEC2002	8:45	-10	4.9	68.4	3.35	3.4	0.17	0.1	23.9	4.2
		FINAL	13JAN2003	10:28	15	4.8	66.8	3.21	4.4	0.21	0.6	19.6	8.6
	E0010014	BSLN	14JAN2003	9:05	-14	6.7	62.4	4.18	2.6	0.17	0.2	30.0	4.8
		FINAL	25MAR2003	11:05	57	6.0	60.2	3.61	3.2	0.19	0.1	31.4	5.1
	E0010017	BSLN	05FEB2003	8:51	-20	7.4	65.6	4.85	2.0	0.15	0.4	24.9	7.1
		FINAL	22APR2003	10:20	57	9.0	73.7	6.63	1.9	0.17	0.3	16.1	8.0
	E0010023	BSLN	10APR2003	9:22	-7	7.2	56.0	4.03	3.3	0.24	0.8	32.8	7.1
		FINAL	01MAY2003	10:19	15	6.8	62.4	4.24	2.6	0.18	0.3	28.1	6.6
	E0010027	BSLN	05JUN2003	9:10	-11	7.9	60.2	4.76	2.3	0.18	0.1	27.0	10.4H
		FINAL	01JUL2003	13:00	16	12.4H	67.0	8.31	1.0	0.12	0.0	24.0	7.0
	E0010029	BSLN	10JUN2003	9:25	-9	8.8	61.4	5.40	4.6	0.40	0.3	29.1	4.6
	E0011022	BSLN	02JUN2003	11:00	-7	8.7	56.1	4.88	3.9	0.34	0.3	34.2	5.5
		FINAL	05AUG2003	10:30	58	11.5	71.0	8.17	3.5	0.40	0.3	22.1	3.1L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	BSLN	06MAR2003	10:15	-7	8.1	60.0	4.86	2.4	0.19	0.3	31.6	5.7
		FINAL	24MAR2003	12:42	12	8.6	60.6	5.21	2.0	0.17	0.4	32.7	4.3
	E0013012	BSLN	29APR2003	9:48	-8	4.5	48.4	2.18	5.4	0.24	0.5	37.5	8.2
		FINAL	02JUL2003	10:05	57	4.9	49.7	2.44	5.4	0.26	0.5	36.2	8.2
	E0013014	BSLN	08MAY2003	11:15	-26	5.0	64.5	3.23	3.2	0.16	0.4	26.3	5.6
		FINAL	30JUN2003	12:21	28	4.5	59.8	2.69	5.7	0.26	0.4	27.2	6.9
	E0014005	BSLN	04MAR2003	17:20	-7	8.1	72.8	5.90	1.7	0.14	0.2	25.1	0.2L
		FINAL	06MAY2003	12:20	57	6.9	69.1	4.77	1.5	0.10	0.2	24.2	5.0
	E0014007	BSLN	25MAR2003	17:50	-7	8.5	71.6	6.09	1.3	0.11	0.1	24.2	2.8L
		FINAL	22APR2003	13:50	22	8.2	65.5	5.37	1.2	0.10	0.4	26.1	6.8
	E0014011	BSLN	06MAY2003	16:45	-7	5.5	62.7	3.45	0.3	0.02	0.0	30.5	6.5
		FINAL	08JUL2003	15:50	57	5.6	61.3	3.43	0.7	0.04	0.5	31.5	6.0
	E0014012	BSLN	19MAY2003	10:05	-8	5.1	58.4	2.98	4.6	0.23	0.4	31.6	5.0
		FINAL	24JUN2003	18:40	29	6.0	52.1	3.13	3.2	0.19	0.1	38.2	6.4
	E0015001	BSLN	14NOV2002	11:15	-15	7.2	71.7	5.16	2.8	0.20	0.2	20.0	5.3
		FINAL	20JAN2003	7:30	53	7.0	66.5	4.66	3.1	0.22	0.2	23.1	7.1
	E0015008	BSLN	16DEC2002	7:45	-3	8.4	44.3	3.72	14.7H	1.23H#	0.2	34.8	6.0
	E0016003	BSLN	10JAN2003	9:30	-14	6.5	57.9	3.76	2.9	0.19	0.3	32.4	6.5
	E0016005	BSLN	21FEB2003	8:45	-4	7.9	63.7	5.03	1.1	0.09	0.2	30.7	4.3
		FINAL	02MAY2003	8:00	67	6.6	57.2	3.78	1.1	0.07	0.4	36.5	4.8
	E0018007	BSLN	16DEC2002	10:15	-11	7.6	60.5	4.60	2.0	0.15	0.5	31.4	5.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	BSLN		30OCT2002	11:50	-6	5.2	62.6	3.26	2.2	0.11	0.3	29.4	5.5
	E0019015	BSLN		19DEC2002	10:49	-14	5.7	58.1	3.31	0.8	0.05	0.3	33.9	6.9
		FINAL		27FEB2003	11:23	57	6.1	60.9	3.71	1.6	0.10	0.2	29.0	8.3
	E0020004	BSLN		26NOV2002	18:50	-13	8.4	61.7	5.18	1.5	0.13	0.4	29.2	7.2
		FINAL		22JAN2003	16:15	45	7.6	64.9	4.93	0.5	0.04	0.2	29.9	4.5
		FINAL	*	24FEB2003	11:50	78	10.9	73.8	8.04	0.6	0.07	0.3	20.4	4.9
	E0020010	BSLN		31JAN2003	9:15	-5	7.0	59.2	4.14	4.3	0.30	0.6	29.8	6.1
		FINAL		02APR2003	10:30	57	7.3	61.1	4.46	0.7	0.05	0.4	30.2	7.6
	E0020014	BSLN		11MAR2003	10:00	-7	6.6	71.2	4.70	3.8	0.25	0.2	17.7	7.1
		FINAL		12MAY2003	11:15	56	7.8	76.7	5.98	2.1	0.16	0.4	14.1L	6.7
	E0020021	BSLN		13MAY2003	9:45	-6	4.3	46.8	2.01	2.0	0.09	0.7	42.9	7.6
		FINAL		14JUL2003	13:25	57	4.6	48.3	2.22	3.7	0.17	0.4	39.1	8.5
	E0020023	BSLN		09JUN2003	19:05	-8	7.4	64.7	4.79	0.9	0.07	0.3	28.5	5.6
		FINAL		11AUG2003	11:40	56	6.8	72.0	4.90	0.9	0.06	0.2	24.2	2.7L
	E0022007	BSLN		01NOV2002	10:23	-6	7.6	58.3	4.43	3.0	0.23	0.1	36.0	2.6L
	E0022010	BSLN		15NOV2002	10:40	-6	6.5	56.6	3.68	1.7	0.11	0.1	38.5	3.1L
		FINAL		16JAN2003	18:00	57	5.6	53.8	3.01	3.1	0.17	0.3	39.1	3.7L
	E0022012	BSLN		29NOV2002	15:40	-6	8.2	59.4	4.87	2.7	0.22	0.2	30.4	7.3
		FINAL		30JAN2003	12:00	57	6.0	58.8	3.53	3.3	0.20	0.5	30.3	7.1
	E0022019	BSLN		06DEC2002	10:10	-5	5.1	64.1	3.27	2.6	0.13	0.5	28.1	4.7
		FINAL		06FEB2003	11:20	58	4.7	65.4	3.07	3.4	0.16	1.5	25.0	4.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	BSLN	08JAN2003	10:10	-20	9.4	60.2	5.66	2.6	0.24	0.3	30.6	6.3
		FINAL	04FEB2003	11:30	8	7.9	56.3	4.45	2.4	0.19	0.4	36.1	4.8
	E0022033	BSLN	12FEB2003	10:05	-6	5.0	60.3	3.02	1.5	0.08	0.5	32.9	4.8
		FINAL	15APR2003	12:10	57	5.1	52.7	2.69	1.4	0.07	0.5	42.1	3.3L
	E0022034	BSLN	12FEB2003	12:40	-6	10.1	64.6	6.52	3.2	0.32	0.5	25.7	6.0
		FINAL	15APR2003	14:00	57	7.2	51.0	3.67	4.7	0.34	0.4	35.9	8.0
	E0022038	BSLN	21FEB2003	11:05	-7	3.8L	51.8	1.97	1.6	0.06	0.3	37.8	8.5
		FINAL	14APR2003	9:40	46	6.5	67.1	4.36	0.4	0.03	0.2	26.2	6.1
	E0022039	BSLN	27FEB2003	11:15	-7	7.4	58.4	4.32	6.6H	0.49H	0.6	28.2	6.2
		FINAL	01MAY2003	12:50	57	7.7	52.6	4.05	4.0	0.31	0.5	37.0	5.9
	E0022046	BSLN	14MAR2003	8:00	-6	8.7	65.9	5.73	1.8	0.16	0.2	28.2	3.9L
		FINAL	16MAY2003	8:05	58	6.6	67.3	4.44	0.8	0.05	0.3	27.3	4.3
	E0022048	BSLN	26MAR2003	9:58	-6	5.0	63.3	3.17	5.2	0.26	0.3	26.4	4.8
	E0022051	BSLN	01APR2003	10:15	-6	6.6	69.5	4.59	0.3	0.02	0.2	25.7	4.3
		FINAL	02JUN2003	10:45	57	6.2	60.0	3.72	2.7	0.17	0.4	32.7	4.2
	E0022053	BSLN	04APR2003	12:50	-7	6.2	62.8	3.89	1.9	0.12	0.4	29.2	5.7
	E0022058	BSLN	14APR2003	10:25	-7	6.7	56.2	3.77	0.8	0.05	0.3	34.6	8.1
		FINAL	22MAY2003	14:00	32	7.3	63.0	4.60	0.4	0.03	0.1	28.8	7.7
	E0022061	BSLN	25APR2003	9:37	-5	9.5	56.0	5.32	4.0	0.38	0.1	35.0	4.9
		FINAL	26JUN2003	12:30	58	7.1	50.9	3.61	3.4	0.24	0.3	38.7	6.7
	E0022062	BSLN	28APR2003	7:43	-7	7.1	63.6	4.52	3.4	0.24	0.1	28.6	4.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	FINAL		23MAY2003	7:40	19	7.8	66.5	5.19	1.2	0.09	0.1	27.5	4.7
	E0022068	BSLN		14MAY2003	10:23	-9	6.4	68.9	4.41	2.4	0.15	0.3	25.0	3.4L
	E0022069	BSLN		04JUN2003	7:40	-6	5.1	53.8	2.74	1.1	0.06	0.3	39.2	5.6
		FINAL		05AUG2003	9:45	57	5.5	49.1	2.70	0.4	0.02	0.9	43.4	6.2
	E0022071	BSLN		16JUN2003	11:40	-14	6.5	74.7	4.86	0.4	0.03	0.3	16.6	8.0
		FINAL		26AUG2003	9:33	58	4.1	60.2	2.47	1.1	0.05	0.5	28.9	9.3
	E0023003	BSLN	*	08NOV2002	16:00	-39	9.0	50.8	4.57	1.5	0.14	0.3	38.9	8.5
		BSLN		12DEC2002	10:00	-5	6.7	53.0	3.55	2.6	0.17	0.6	33.3	10.5H
		FINAL		11FEB2003	14:00	57	9.5	54.3	5.16	1.6	0.15	0.4	35.2	8.5
	E0023006	BSLN		10DEC2002	10:30	-7	5.6	48.1	2.69	10.6H	0.59H	0.6	28.5	12.2H
		FINAL		11FEB2003	11:50	57	5.1	52.6	2.68	12.9H	0.66H	0.2	21.7	12.6H
	E0023010	BSLN		28JAN2003	9:30	-7	9.0	56.7	5.10	1.5	0.14	0.4	35.5	5.9
		FINAL		31MAR2003	10:00	56	14.0H	71.1	9.95	2.4	0.34	0.2	20.4	5.9
	E0023025	BSLN		01MAY2003	15:00	-14	3.8L	64.1	2.44	4.5	0.17	0.4	22.8	8.2
		FINAL		10JUL2003	13:30	57	4.2	61.5	2.58	6.6H	0.28H	0.2	23.8	7.9
	E0023039	BSLN		24JUN2003	13:30	-7	9.2	63.6	5.85	1.4	0.13	0.1	28.2	6.7
		FINAL		26AUG2003	13:30	57	6.9	63.0	4.35	0.0	0.00	2.0	23.0	8.0
	E0026002	BSLN		05NOV2002	10:15	-7	8.1	69.1	5.60	1.7	0.14	0.4	23.8	5.0
		FINAL		09JAN2003	9:25	59	6.3	67.8	4.27	2.5	0.16	0.5	21.2	8.0
	E0026007	BSLN		13JAN2003	9:30	-3	7.4	54.4	4.03	3.7	0.27	0.2	35.4	6.3
		FINAL		12MAR2003	14:25	56	5.7	56.2	3.20	2.4	0.14	0.2	34.8	6.4

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	BSLN		05FEB2003	12:20	-8	7.0	57.5	4.03	0.9	0.06	0.1	32.4	9.1
		FINAL		14APR2003	10:00	61	11.0	77.9H	8.57H	1.1	0.12	0.3	15.3L	5.4
	E0028007	BSLN		01OCT2002	10:30	-3	6.9	70.1	4.84	1.9	0.13	0.3	21.4	6.3
		FINAL		14NOV2002	12:45	42	4.3	53.7	2.31	3.6	0.15	0.4	33.9	8.4
	E0028023	BSLN		15JAN2003	10:00	-6	6.0	52.4	3.14	2.2	0.13	0.5	35.2	9.7H
	E0028025	BSLN		08JAN2003	12:07	-5	4.6	41.4	1.90	2.9	0.13	0.2	51.0H	4.5
		FINAL		27JAN2003	9:25	15	4.2	47.7	2.00	1.5	0.06	0.2	47.0H	3.6L
	E0028033	BSLN		18MAR2003	10:50	-9	7.5	55.4	4.16	1.3	0.10	0.2	35.8	7.3
		FINAL		22MAY2003	10:50	57	5.2	51.0	2.65	2.4	0.12	0.3	36.5	9.8H
	E0028035	BSLN		27MAR2003	12:00	-7	5.4	57.4	3.10	2.3	0.12	0.5	32.1	7.7
		FINAL		29MAY2003	15:40	57	6.3	55.9	3.52	1.7	0.11	0.4	30.2	11.8H
	E0028037	BSLN	*	18APR2003	8:30	-56	3.7L	45.9	1.70	3.8	0.14	0.3	41.0	9.0
		BSLN	*	24APR2003	7:50	-50	4.5	51.6	2.32	2.8	0.13	0.3	35.8	9.5H
		BSLN		04JUN2003	8:33	-9	4.8	56.5	2.71	1.0	0.05	0.5	36.1	5.9
		FINAL		08AUG2003	15:30	57	9.9	60.4	5.98	1.5	0.15	0.3	31.0	6.8
	E0028039	BSLN		05MAY2003	7:10	-4	11.1	78.4H	8.70H	1.3	0.14	0.3	14.6L	5.4
		FINAL		05JUN2003	12:30	28	3.9L	61.3	2.39	1.4	0.05	0.7	20.9	15.7H
	E0028046	BSLN		17JUN2003	13:45	-8	6.5	68.8	4.47	4.0	0.26	0.2	23.4	3.6L
	E0028048	BSLN		11JUL2003	14:00	-6	6.3	56.8	3.58	1.8	0.11	0.4	33.3	7.7
	E0029008	BSLN		09DEC2002	11:40	-7	8.9	69.2	6.16	1.2	0.11	0.2	27.4	2.0L
	E0029011	BSLN		14JAN2003	11:20	-8	9.2	61.5	5.66	3.9	0.36	0.3	28.3	6.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	BSLN		04FEB2003	10:05	-7	8.3	66.7	5.54	0.4	0.03	0.2	28.2	4.5
		FINAL		27MAR2003	8:45	45	7.9	69.5	5.49	0.0	0.00	0.3	27.4	2.8L
	E0029015	BSLN		11FEB2003	10:05	-13	12.1	80.3H	9.72H	0.2	0.02	0.2	12.1L	7.2
		FINAL		14MAR2003	10:30	19	5.9	59.2	3.49	3.2	0.19	0.2	26.9	10.5H
	E0029018	BSLN	*	26FEB2003	16:25	-8	9.9	45.9	4.54	1.5	0.15	0.2	45.5	6.9
		BSLN		06MAR2003	16:05	1	8.8	63.4	5.58	1.9	0.17	0.1	29.4	5.2
	E0030014	BSLN		14FEB2003	10:35	-7	5.4	65.3	3.53	1.2	0.06	0.6	24.5	8.4
		FINAL		22APR2003	12:50	61	4.1	60.6	2.48	1.6	0.07	0.2	30.2	7.4
	E0030020	BSLN		13MAY2003	15:30	-16	6.9	60.7	4.19	5.9	0.41	0.5	27.5	5.4
	E0030024	BSLN		17JUN2003	15:35	-24	12.3	77.2H	9.50H	0.6	0.07	0.3	19.7	2.2L
		FINAL		18JUL2003	15:35	8	8.6	51.3	4.41	1.3	0.11	0.1	45.6	1.7L
	E0030025	BSLN		01JUL2003	11:50	-10	5.3	52.7	2.79	1.6	0.08	0.6	40.0	5.1
	E0031027	BSLN		28MAY2003	9:10	-6	5.3	55.3	2.93	0.9	0.05	0.2	35.7	7.9
		FINAL		29JUL2003	14:40	57	5.3	58.5	3.10	0.4	0.02	0.3	35.1	5.7
	E0031030	BSLN		17JUN2003	10:46	-7	4.8	62.7	3.01	3.1	0.15	0.4	27.5	6.3
		FINAL		21AUG2003	11:10	59	4.3	50.1	2.15	3.6	0.15	0.5	37.8	8.0
	E0033012	BSLN		05FEB2003	15:26	-5	11.5	60.8	6.99	2.3	0.26	0.7	29.0	7.2
	E0034001	BSLN		17MAR2003	10:03	-3	4.6	51.4	2.36	2.0	0.09	0.3	40.6	5.7
		FINAL		15MAY2003	9:55	57	5.0	55.4	2.77	1.6	0.08	0.5	35.7	6.8
	E0034004	BSLN		11APR2003	11:15	-10	6.1	51.7	3.15	3.7	0.23	0.2	36.4	8.0
		FINAL		16JUN2003	12:03	57	5.5	49.0	2.70	9.3H	0.51H	0.8	33.8	7.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0035001	BSLN	12NOV2002	11:40	-8	5.6	58.4	3.27	3.3	0.18	0.3	32.4	5.6
		FINAL	14JAN2003	9:05	56	6.4	63.4	4.06	2.0	0.13	0.5	28.1	6.0
	E0035006	BSLN	03DEC2002	10:45	-9	6.4	67.2	4.30	2.3	0.15	0.7	25.1	4.7
		FINAL	06FEB2003	9:30	57	5.8	67.1	3.89	3.5	0.20	0.2	23.4	5.8
	E0035021	BSLN	18APR2003	10:45	-7	9.0	76.4	6.88	3.4	0.31	0.2	15.9	4.1
		FINAL	20JUN2003	8:15	57	7.2	67.1	4.83	4.4	0.32	0.3	22.6	5.6
	E0036002	BSLN	10JUN2003	13:45	-7	6.9	56.7	3.91	0.8	0.06	0.4	37.8	4.3
		FINAL	15JUL2003	10:05	29	7.1	71.3	5.06	0.3	0.02	0.3	24.9	3.2L
	E0036006	BSLN	24JUN2003	16:45	-9	11.0	80.7H	8.88H	0.7	0.08	0.7	12.4L	5.5
		FINAL	28AUG2003	9:50	57	5.3	65.8	3.49	3.4	0.18	0.6	24.2	6.0
	E0036007	BSLN	27JUN2003	10:00	-6	13.7H	73.4	10.06 #	2.1	0.29	0.5	18.8	5.2
		FINAL	18JUL2003	9:15	16	15.4H	80.5H	12.40H#	1.0	0.15	0.4	14.6L	3.5L
	E0037009	BSLN	12MAY2003	9:15	-4	9.9	64.4	6.38	7.2H	0.71H	0.3	23.6	4.5
		FINAL	10JUL2003	16:05	56	8.9	48.7	4.33	12.6H	1.12H#	0.3	34.2	4.2
	E0039011	BSLN	16DEC2002	17:40	-17	5.6	63.0	3.53	0.8	0.04	0.1	34.9	1.2L
	E0039018	BSLN	15JAN2003	9:10	-8	4.9	58.2	2.85	1.8	0.09	0.6	31.1	8.3
	E0039026	BSLN	03MAR2003	9:05	-4	3.1L	43.5	1.35	4.8	0.15	0.6	43.2	7.9
		FINAL	02MAY2003	9:20	57	4.7	50.6	2.38	4.9	0.23	0.5	38.0	6.0
	E0039028	BSLN	03MAR2003	14:15	-21	7.9	60.4	4.77	1.7	0.13	0.5	31.0	6.4
		FINAL	16MAY2003	12:25	54	6.7	59.8	4.01	2.3	0.15	0.5	32.6	4.8
	E0039032	BSLN	07MAR2003	13:45	-7	8.2	64.0	5.25	0.7	0.06	0.9	29.3	5.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	FINAL	04APR2003	11:45	22	10.0	69.5	6.95	1.2	0.12	0.3	23.4	5.6
	E0039034	BSLN	12MAR2003	20:05	-7	9.5	56.0	5.32	2.0	0.19	0.4	37.5	4.1
		FINAL	14MAY2003	15:00	57	7.9	47.8	3.78	2.4	0.19	0.5	45.3	4.0
	E0039042	BSLN	25APR2003	10:15	-12	6.4	57.8	3.70	5.0	0.32	0.6	34.4	2.2L
		FINAL	02JUL2003	12:50	57	6.2	61.8	3.83	4.3	0.27	0.2	30.9	2.8L
	E0041004	BSLN	27JAN2003	10:15	-3	6.0	50.8	3.05	2.9	0.17	0.5	40.0	5.8
		FINAL	31MAR2003	12:00	61	8.0	62.6	5.01	2.1	0.17	0.2	29.7	5.4
	E0041009	BSLN	22APR2003	15:15	-9	5.7	59.1	3.37	1.9	0.11	0.6	29.4	9.0
		FINAL	16JUN2003	13:00	47	7.4	76.7	5.68	0.3	0.02	0.2	19.2	3.6L
	E0042002	BSLN	02JUL2003	12:10	-7	5.4	48.0	2.59	1.8	0.10	0.4	38.3	11.5H
		FINAL	02SEP2003	10:25	56	5.6	61.5	3.44	1.9	0.11	0.5	23.2	12.9H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN	23JUN2003	10:00	-18	6.1	68.4	4.17	3.5	0.21	0.1	17.5	10.5H
		FINAL	25JUL2003	9:00	15	6.5	56.1	3.65	5.7	0.37	0.3	28.3	9.6H
	E0003002	BSLN	22OCT2002	11:05	-7	7.6	67.4	5.12	2.2	0.17	0.3	21.0	9.1
		FINAL	14JAN2003	12:15	78	7.2	58.2	4.19	5.1	0.37	0.5	30.1	6.1
	E0005031	BSLN	26MAR2003	12:30	-7	9.2	65.9	6.06	1.4	0.13	0.2	27.1	5.4
	E0005033	BSLN	08APR2003	14:00	-8	6.9	65.7	4.53	2.4	0.17	0.2	24.7	7.0
		FINAL	06MAY2003	11:20	21	5.0	62.2	3.11	2.3	0.12	0.5	27.9	7.1
	E0005038	BSLN	05MAY2003	11:40	-9	7.3	55.7	4.07	2.2	0.16	0.2	38.1	3.8L
		FINAL	05JUN2003	13:00	23	6.9	55.5	3.83	4.0	0.28	0.5	34.4	5.6
	E0007009	BSLN	14APR2003	7:48	-3	6.2	50.8	3.15	1.7	0.11	0.2	41.4	5.9
	E0009010	BSLN	27FEB2003	16:55	-14	10.2	77.1H	7.86H	1.5	0.15	0.0	18.1	3.3L
	E0009011	BSLN	28APR2003	14:17	-8	7.6	65.3	4.96	1.6	0.12	0.3	27.4	5.4
		FINAL	03JUL2003	15:40	59	5.2	61.6	3.20	3.5	0.18	0.4	30.5	4.0
	E0010005	BSLN	11DEC2002	10:15	-7	11.0	51.1	5.62	6.6H	0.73H	0.2	35.2	6.9
	E0011016	BSLN	14APR2003	10:00	-7	6.7	55.7	3.73	1.7	0.11	0.3	36.4	5.9
		FINAL	16JUN2003	9:45	57	5.9	48.6	2.87	2.3	0.14	0.3	41.4	7.4
	E0011020	BSLN	01MAY2003	9:20	-7	4.7	39.1L	1.84L	1.1	0.05	0.5	52.3H	7.0
		FINAL	15MAY2003	17:00	8	7.0	52.7	3.69	0.3	0.02	0.2	41.6	5.2
	E0018002	BSLN	15NOV2002	15:35	-14	5.8	54.9	3.18	5.0	0.29	0.6	30.9	8.6
		FINAL	22JAN2003	16:20	55	5.9	58.7	3.46	5.8	0.34	0.2	29.7	5.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	BSLN		19NOV2002	13:05	-7	9.4	68.5	6.44	1.5	0.14	0.2	25.9	3.9L
		FINAL		10DEC2002	11:00	15	6.9	74.8	5.16	0.7	0.05	0.1	22.6	1.8L
	E0018013	BSLN		17JAN2003	14:15	-7	4.9	61.3	3.00	3.4	0.17	0.1	28.8	6.4
		FINAL		06FEB2003	16:10	14	5.8	61.3	3.56	4.8	0.28	0.2	27.7	6.0
	E0019002	BSLN		29OCT2002	10:45	-14	6.6	73.0	4.82	1.3	0.09	0.1	20.1	5.5
	E0019008	BSLN	*	06NOV2002	12:35	-15	9.1	49.8	4.53	12.3H	1.12H#	0.4	34.3	3.2L
		BSLN		13NOV2002	10:30	-8	5.6	60.7	3.40	7.2H	0.40H	0.0	25.5	6.6
	E0019009	BSLN		06NOV2002	13:35	-8	7.8	68.4	5.34	5.8	0.45	0.3	22.5	3.0L
	E0019016	BSLN		30DEC2002	16:55	-7	8.9	60.8	5.41	1.6	0.14	0.1	33.6	3.9L
		FINAL		03MAR2003	16:00	57	8.3	70.8	5.88	0.7	0.06	0.3	27.8	0.4L
	E0019020	BSLN		16JAN2003	10:10	-7	5.1	46.3	2.36	3.3	0.17	0.2	43.5	6.7
		FINAL		27MAR2003	10:50	64	8.2	76.1	6.24	0.7	0.06	0.4	18.7	4.1
	E0019021	BSLN		16JAN2003	11:45	-14	5.5	61.1	3.36	3.2	0.18	0.3	28.8	6.6
		FINAL		03MAR2003	13:18	33	5.2	60.5	3.15	2.9	0.15	0.2	31.2	5.2
	E0019024	BSLN		24JAN2003	16:00	-6	5.8	46.3	2.69	4.4	0.26	0.4	38.5	10.4H
		FINAL		06FEB2003	12:33	8	6.2	54.5	3.38	4.1	0.25	0.4	31.1	9.9H
	E0019031	BSLN		06MAR2003	11:35	-7	4.9	54.1	2.65	2.6	0.13	0.3	34.0	9.0
		FINAL		25MAR2003	10:08	13	5.0	62.5	3.13	2.9	0.15	0.2	25.2	9.2
	E0019035	BSLN		11MAR2003	9:28	-7	9.5	57.8	5.49	2.8	0.27	0.2	36.2	3.0L
		FINAL		17APR2003	14:30	31	7.8	52.7	4.11	2.4	0.19	0.4	40.0	4.5
	E0019040	BSLN		08MAY2003	15:25	-12	7.0	57.2	4.00	2.3	0.16	0.5	31.4	8.6

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	FINAL		17JUL2003	9:50	59	4.9	47.4	2.32	2.6	0.13	0.7	38.1	11.2H
	E0019042	BSLN		29MAY2003	8:50	-6	6.4	63.4	4.06	1.4	0.09	0.2	28.3	6.7
		FINAL		20JUN2003	8:20	17	5.7	59.4	3.39	1.5	0.09	0.3	32.9	5.9
	E0019045	BSLN		19JUN2003	14:54	-7	6.1	61.4	3.75	1.5	0.09	0.4	27.7	9.0
		FINAL		16JUL2003	10:15	21	4.6	57.7	2.65	1.9	0.09	0.3	31.1	9.0
	E0020024	BSLN		12JUN2003	15:40	-11	8.8	66.0	5.81	0.6	0.05	0.3	26.3	6.8
		FINAL		25AUG2003	14:20	64	7.6	52.0	3.95	2.0	0.15	0.3	36.0	9.7H
	E0022044	BSLN		12MAR2003	9:50	-6	9.7	70.5	6.84	0.5	0.05	0.2	25.3	3.5L
		FINAL		12MAY2003	9:55	56	7.8	58.8	4.59	1.5	0.12	0.2	33.6	5.9
	E0023007	BSLN		07JAN2003	14:30	-7	6.6	59.2	3.91	2.3	0.15	0.2	30.9	7.4
		FINAL		13MAR2003	15:00	59	8.3	64.7	5.37	1.3	0.11	0.3	28.0	5.7
	E0023011	BSLN		28JAN2003	11:45	-7	8.3	64.7	5.37	2.3	0.19	0.1	25.5	7.4
		FINAL		01APR2003	12:00	57	6.0	50.6	3.04	2.0	0.12	0.1	41.1	6.2
	E0023014	BSLN	*	14FEB2003	15:00	-7	8.5	64.6	5.49	2.1	0.18	0.4	24.6	8.3
		BSLN		19FEB2003	11:30	-2	6.4	54.4	3.48	2.3	0.15	0.4	34.7	8.2
		FINAL		25APR2003	14:00	64	6.9	38.5L	2.66L	2.6	0.18	0.4	49.2H	9.3
	E0023019	BSLN		21MAR2003	14:00	-17	11.9	67.8	8.07	0.7	0.08	1.3	21.3	8.9
		FINAL		03JUN2003	13:30	58	6.0	51.2	3.07	3.3	0.20	0.3	40.0	5.2
	E0023022	BSLN		10APR2003	16:00	-8	6.8	53.0	3.60	3.3	0.22	0.4	37.4	5.9
		FINAL		12JUN2003	15:40	56	5.3	42.2	2.24	5.1	0.27	0.6	43.0	9.1
	E0023023	BSLN		17APR2003	10:00	-8	6.8	72.6	4.94	1.4	0.10	0.4	20.7	4.9
		FINAL		01MAY2003	14:00	7	6.4	68.8	4.40	0.9	0.06	0.3	25.0	5.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0023029	BSLN		16MAY2003	14:00	-7	8.3	70.6	5.86	0.2	0.02	0.2	25.1	3.9L
	E0023031	BSLN	*	22MAY2003	12:00	-33	6.1	52.5	3.20	4.0	0.24	0.8	36.1	6.6
		BSLN		24JUN2003	12:00	1	5.2	42.2	2.19	5.2	0.27	0.4	42.6	9.6H
		FINAL		19AUG2003	11:00	57	4.2	41.5	1.74	4.6	0.19	0.6	45.0	8.3
	E0023041	BSLN		03JUL2003	11:00	-6	6.9	59.3	4.09	4.6	0.32	0.4	30.3	5.4
		FINAL		05SEP2003	13:00	59	6.5	64.0	4.16	2.0	0.13	0.4	28.6	5.0
	E0023043	BSLN		11JUL2003	9:00	-3	10.7	79.4H	8.50H	0.3	0.03	0.1	15.4L	4.8
		FINAL		09SEP2003	10:30	58	5.6	69.5	3.89	1.2	0.07	0.4	21.7	7.2
	E0026003	BSLN	*	25NOV2002	12:20	-9	17.3H#	86.9H	15.03H#	0.4	0.07	0.0	7.6L	5.1
		BSLN		02DEC2002	9:25	-2	10.4	90.2H	9.38H	0.2	0.02	0.0	9.0L	0.6L
		FINAL		03FEB2003	10:50	62	8.1	66.8	5.41	3.8	0.31	0.2	24.0	5.2
	E0026005	BSLN		23DEC2002	12:40	-7	4.0L	61.6	2.46	0.5	0.02	0.4	31.1	6.4
		FINAL		06JAN2003	15:25	8	5.3	61.9	3.28	1.2	0.06	0.2	30.2	6.5
	E0026009	BSLN		10JAN2003	10:20	-5	6.2	59.6	3.70	1.8	0.11	0.3	32.5	5.8
	E0026015	BSLN		20FEB2003	11:30	-7	5.8	63.3	3.67	1.7	0.10	1.9	26.4	6.7
		FINAL		25APR2003	9:50	58	5.4	76.8	4.15	0.5	0.03	0.2	18.3	4.2
	E0026023	BSLN		23APR2003	10:50	-7	5.8	54.3	3.15	5.8	0.34	0.3	35.3	4.3
		FINAL		27JUN2003	12:25	59	5.1	45.8	2.34	1.7	0.09	0.4	46.4	5.7
	E0027016	BSLN	*	19MAR2003	11:55	-21	9.0	66.2	5.96	1.6	0.14	0.1	25.3	6.8
		BSLN		04APR2003	9:50	-5	7.5	60.4	4.53	2.5	0.19	0.6	32.1	4.4
		FINAL		03JUN2003	10:18	56	6.3	56.2	3.54	1.6	0.10	0.5	35.8	5.9
	E0027018	BSLN		21MAR2003	11:30	-4	5.2	66.4	3.45	3.1	0.16	0.4	24.0	6.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0027018	FINAL	22MAY2003	10:05	59	5.4	65.3	3.53	4.4	0.24	0.3	23.5	6.5
	E0028032	BSLN	13MAR2003	13:58	-12	4.6	62.9	2.89	2.2	0.10	0.3	28.9	5.7
		FINAL	06JUN2003	11:38	74	5.6	61.0	3.42	2.7	0.15	0.3	29.5	6.5
	E0029003	BSLN	28OCT2002	12:30	-7	8.0	59.4	4.75	2.8	0.22	0.3	32.8	4.7
		FINAL	30DEC2002	9:45	57	6.8	59.5	4.05	3.1	0.21	0.3	33.7	3.4L
	E0029020	BSLN	25FEB2003	10:12	-8	9.1	58.4	5.31	1.8	0.16	0.4	33.7	5.7
	E0031005	BSLN	13DEC2002	16:00	-7	6.2	61.2	3.79	4.4	0.27	0.3	27.0	7.1
		FINAL	14FEB2003	12:10	57	4.2	59.4	2.49	4.4	0.18	0.1	29.7	6.4
	E0031006	BSLN	31JAN2003	11:25	-18	14.7H	61.5	9.04	2.5	0.37	0.4	28.6	7.0
		FINAL	15APR2003	9:25	57	15.4H	66.8	10.29 #	3.9	0.60	0.5	23.6	5.2
	E0031010	BSLN	12FEB2003	14:50	-7	4.7	45.6	2.14	2.7	0.13	0.3	44.2	7.2
		FINAL	06MAR2003	12:50	16	4.5	49.7	2.24	3.1	0.14	0.1	39.5	7.6
	E0031011	BSLN	18FEB2003	11:50	-9	6.4	52.2	3.34	2.5	0.16	0.1	33.9	11.3H
		FINAL	24APR2003	9:25	57	6.4	48.7	3.12	3.3	0.21	0.4	36.2	11.4H
	E0031015	BSLN	14MAR2003	8:40	-12	8.8	60.3	5.31	5.3	0.47	0.1	29.2	5.1
		FINAL	01APR2003	11:55	7	8.4	58.1	4.88	5.0	0.42	0.3	31.2	5.4
	E0031031	BSLN	01JUL2003	10:30	-7	9.0	64.0	5.76	0.9	0.08	0.5	29.6	5.0
		FINAL	28AUG2003	10:35	52	6.0	49.1	2.95	2.2	0.13	0.3	43.9	4.5
	E0033009	BSLN	22JAN2003	13:40	-21	10.9	65.4	7.13	10.8H	1.18H#	0.7	18.9	4.2
	E0034009	BSLN	10JUN2003	13:00	-9	10.1	68.9	6.96	1.7	0.17	0.7	22.0	6.7
		FINAL	18AUG2003	17:25	61	7.0	50.5	3.54	2.8	0.20	0.4	33.4	12.9H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0037007	BSLN	04APR2003	11:30	-7	13.2H	72.5	9.57	0.4	0.05	0.4	22.0	4.7
	E0037012	BSLN	11JUL2003	13:00	-5	5.7	54.4	3.10	3.7	0.21	0.4	33.9	7.6
		FINAL	08SEP2003	13:20	55	6.0	52.0	3.12	3.7	0.22	0.4	35.5	8.4
	E0039019	BSLN	20JAN2003	14:50	-17	5.4	41.7	2.25	1.3	0.07	1.0	50.2H	5.8
		FINAL	03APR2003	11:05	57	4.2	47.7	2.00	1.4	0.06	0.4	43.3	7.2
	E0039043	BSLN	28APR2003	10:15	-10	6.9	51.3	3.54	3.4	0.23	0.2	38.3	6.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0002001	BSLN		21DEC2002	9:45	-9	4.9	60.2	2.95	0.3	0.01	0.5	35.5	3.5L
		FINAL		26FEB2003	8:45	59	4.7	55.6	2.61	0.5	0.02	0.2	37.6	6.1
	E0002003	BSLN	*	03JAN2003	11:50	-19	4.3	55.4	2.38	1.9	0.08	0.1	39.6	3.0L
		BSLN		10JAN2003	12:30	-12	5.8	68.9	4.00	1.4	0.08	0.1	25.2	4.4
		FINAL		19MAR2003	13:45	57	6.2	63.2	3.92	0.9	0.06	0.5	30.5	4.9
	E0002004	BSLN		14JAN2003	8:15	-11	9.9	69.1	6.84	3.0	0.30	0.1	25.1	2.7L
	E0002008	BSLN		14FEB2003	16:00	-11	6.4	66.7	4.27	2.3	0.15	0.3	25.6	5.1
		FINAL		23APR2003	14:25	58	5.9	71.0	4.19	1.1	0.06	0.4	23.0	4.5
	E0002016	BSLN		14JUL2003	11:00	-10	5.1	56.9	2.90	3.5	0.18	0.1	32.4	7.1
		FINAL		17SEP2003	11:15	56	4.5	57.3	2.58	3.9	0.18	0.6	30.4	7.8
	E0003008	BSLN		21JAN2003	12:45	-7	6.2	57.2	3.55	4.9	0.30	0.1	32.9	4.9
	E0004003	BSLN		02OCT2002	11:00	-8	7.5	61.5	4.61	1.9	0.14	0.5	28.9	7.2
	E0004006	BSLN		28OCT2002	9:55	-7	8.1	66.1	5.35	1.5	0.12	0.3	27.2	4.9
		FINAL		06JAN2003	10:55	64	7.3	71.3	5.20	1.2	0.09	0.4	22.0	5.1
	E0004016	BSLN		12FEB2003	15:10	-7	8.9	74.1	6.59	1.0	0.09	0.2	20.9	3.8L
		FINAL		17APR2003	17:10	58	10.0	69.1	6.91	0.4	0.04	0.4	25.6	4.5
	E0004024	BSLN		25JUN2003	16:00	-8	10.2	67.3	6.86	0.6	0.06	0.5	27.9	3.7L
		FINAL		28AUG2003	9:50	57	9.3	67.0	6.23	1.7	0.16	0.3	25.7	5.3
	E0005006	BSLN		24SEP2002	15:30	-9	7.9	65.6	5.18	1.8	0.14	0.4	27.3	4.9
	E0005017	BSLN	*	11DEC2002	10:30	-19	6.7	72.3	4.84	1.7	0.11	0.3	23.1	2.6L
		BSLN		23DEC2002	12:30	-7	6.8	72.7	4.94	1.7	0.12	0.3	22.1	3.2L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0005017	FINAL	04MAR2003	13:00	65	7.4	60.8	4.50	1.6	0.12	0.3	30.6	6.7
	E0005019	BSLN	19DEC2002	14:00	-27	7.5	74.5	5.59	1.3	0.10	0.3	19.7	4.2
		FINAL	23JAN2003	15:45	9	7.6	72.7	5.53	1.4	0.11	0.2	21.2	4.5
	E0005026	BSLN	28FEB2003	10:15	-6	5.9	62.9	3.71	1.9	0.11	0.5	30.0	4.7
		FINAL	02APR2003	9:40	28	5.4	57.6	3.11	2.5	0.14	0.4	34.8	4.7
	E0005039	BSLN	15MAY2003	9:00	-7	7.1	60.9	4.32	1.7	0.12	0.9	32.0	4.5
		FINAL	16JUL2003	8:40	56	7.5	60.9	4.57	3.1	0.23	0.1	31.3	4.6
	E0005043	BSLN	02JUL2003	8:30	-7	7.2	60.1	4.33	2.0	0.14	0.4	31.1	6.4
		FINAL	03SEP2003	9:45	57	5.9	59.9	3.53	2.5	0.15	0.5	31.6	5.5
	E0006020	BSLN	02MAY2003	13:30	-11	5.9	64.5	3.81	2.5	0.15	0.3	25.8	6.9
		FINAL	08JUL2003	14:45	57	1.2L#	86.4H	1.04H	2.0	0.02	0.0	11.6L	0.0L
		FINAL *	10JUL2003	16:30	59	6.1	69.2	4.22	1.6	0.10	0.3	21.4	7.5
	E0007001	BSLN	16DEC2002	9:25	-15	7.5	61.5	4.61	1.3	0.10	0.1	32.8	4.3
		FINAL	24FEB2003	8:43	56	6.7	65.5	4.39	1.4	0.09	0.3	27.3	5.5
	E0007003	BSLN	13JAN2003	10:30	-17	8.2	61.2	5.02	6.5H	0.53H	0.2	23.2	8.9
		FINAL	01APR2003	13:30	62	11.5	72.6	8.35	1.9	0.22	0.2	17.1	8.2
	E0007006	BSLN	24FEB2003	11:00	-9	4.7	49.7	2.34	1.6	0.08	0.2	37.4	11.1H
		FINAL	27MAR2003	10:50	23	4.9	52.3	2.56	4.0	0.20	0.6	35.4	7.7
	E0009004	BSLN	19NOV2002	12:30	-7	10.2	64.3	6.56	1.8	0.18	0.3	24.8	8.8
		FINAL	18DEC2002	14:50	23	11.1	73.6	8.17	0.9	0.10	0.2	18.0	7.3
	E0009012	BSLN	16JUN2003	14:45	-9	7.2	62.1	4.47	1.8	0.13	0.2	30.3	5.6
		FINAL	03JUL2003	17:45	9	8.4	66.5	5.59	1.9	0.16	0.4	25.5	5.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0010008	BSLN		11DEC2002	9:15	-7	4.3	48.2	2.07	11.8H	0.51H	0.3	33.9	5.8
	E0010018	BSLN		26FEB2003	8:51	-21	6.7	77.4H	5.19H	0.7	0.05	0.3	16.9	4.7
		FINAL		14MAY2003	10:45	57	5.3	76.9	4.08	0.6	0.03	0.1	18.4	4.0
	E0010028	BSLN		09JUN2003	8:46	-7	6.4	70.3	4.50	1.7	0.11	0.1	23.6	4.3
		FINAL		15JUL2003	13:50	30	5.3	57.7	3.06	1.4	0.07	0.4	35.1	5.4
	E0011008	BSLN	*	17DEC2002	12:30	-44	11.0	66.4	7.30	5.5	0.61	0.4	23.8	3.9L
		BSLN		23JAN2003	9:20	-7	10.8	60.5	6.53	8.0H	0.86H	0.3	24.8	6.4
		FINAL		13FEB2003	12:30	15	7.4	60.0	4.44	4.8	0.36	0.3	27.6	7.3
	E0011009	BSLN		23DEC2002	14:30	-4	10.4	53.0	5.51	10.1H	1.05H#	0.8	28.8	7.3
		FINAL		20FEB2003	9:00	56	10.4	65.4	6.80	4.1	0.43	0.2	26.6	3.7L
	E0011010	BSLN		03FEB2003	10:00	-7	3.7L	54.3	2.01	3.8	0.14	0.3	34.4	7.2
		FINAL		19MAR2003	8:45	38	3.2L	49.4	1.58	4.4	0.14	0.3	38.9	7.0
	E0013001	BSLN		07NOV2002	9:10	-7	8.5	65.2	5.54	4.0	0.34	0.3	19.9	10.6H
		FINAL		10JAN2003	10:45	58	7.4	62.5	4.63	2.1	0.16	0.2	23.6	11.6H
	E0013003	BSLN		07NOV2002	9:25	-5	6.4	65.4	4.19	3.8	0.24	0.5	26.2	4.1
		FINAL		06JAN2003	13:17	56	7.0	68.5	4.80	3.0	0.21	0.2	23.6	4.7
	E0013005	BSLN		13FEB2003	11:42	-5	5.1	62.3	3.18	2.1	0.11	0.2	26.0	9.4
		FINAL		15APR2003	12:16	57	3.6L	41.6	1.50	3.7	0.13	0.4	43.4	10.9H
	E0013013	BSLN		01MAY2003	10:14	-5	6.9	61.7	4.26	2.1	0.14	0.3	29.9	6.0
		FINAL		30MAY2003	9:55	25	10.4	57.9	6.02	2.0	0.21	0.2	34.0	5.9
	E0014002	BSLN		19FEB2003	16:35	-7	7.4	52.0	3.85	4.7	0.35	0.6	34.9	7.8
		FINAL		10APR2003	13:05	44	6.9	61.8	4.26	3.6	0.25	0.3	27.4	6.9

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0014004	BSLN		04MAR2003	11:40	-8	10.9	43.4	4.73	2.3	0.25	0.2	48.8H	5.3
		FINAL		15APR2003	11:40	35	10.4	60.0	6.24	2.0	0.21	0.4	30.0	7.6
	E0014009	BSLN	*	15APR2003	14:45	-8	9.9	63.5	6.29	1.6	0.16	0.5	29.0	5.4
		BSLN		17APR2003	12:30	-6	8.4	61.0	5.12	1.1	0.09	0.3	31.3	6.3
	E0014015	BSLN		11JUN2003	10:15	-7	4.9	52.4	2.57	4.0	0.20	0.2	37.2	6.2
	E0014017	BSLN		17JUN2003	17:00	-10	6.8	70.4	4.79	1.0	0.07	0.1	23.5	5.0
		FINAL		19AUG2003	17:05	54	5.8	64.2	3.72	0.7	0.04	0.4	28.6	6.1
	E0014018	BSLN		24JUN2003	16:35	-7	6.0	55.6	3.34	5.4	0.32	0.3	30.5	8.2
		FINAL		27AUG2003	16:00	58	6.2	65.0	4.03	4.2	0.26	0.6	23.8	6.4
	E0015005	BSLN		25NOV2002	13:15	-7	8.6	64.7	5.56	1.1	0.09	0.3	27.4	6.5
		FINAL		18DEC2002	9:30	17	6.8	59.2	4.03	1.8	0.12	0.7	31.1	7.2
	E0017002	BSLN		08MAY2003	17:00	-26	6.9	43.9	3.03	1.8	0.12	0.1	47.9H	6.3
		FINAL		13JUN2003	16:00	11	5.2	35.5L	1.85L	1.4	0.07	0.4	54.0H	8.7
	E0018009	BSLN		17DEC2002	10:45	-20	6.7	61.1	4.09	1.5	0.10	0.3	30.1	7.0
		FINAL		14JAN2003	13:15	9	7.5	60.5	4.54	0.7	0.05	0.2	28.4	10.2H
	E0018010	BSLN		09JAN2003	9:30	-7	4.8	67.0	3.22	1.9	0.09	0.6	22.7	7.8
		FINAL		13MAR2003	9:20	57	4.1	70.7	2.90	1.5	0.06	0.3	21.2	6.3
	E0018015	BSLN		24JAN2003	10:40	-4	4.8	63.2	3.03	1.5	0.07	0.1	28.2	7.0
		FINAL		27MAR2003	10:50	59	3.8L	56.0	2.13	1.7	0.06	0.2	34.1	8.0
	E0020015	BSLN		18MAR2003	13:30	-9	9.6	56.6	5.43	4.2	0.40	0.3	30.2	8.7
		FINAL		23MAY2003	13:40	58	8.6	51.7	4.45	4.1	0.35	0.4	32.9	10.9H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0020017	BSLN		27MAR2003	12:00	-7	5.7	69.9	3.98	2.3	0.13	0.2	22.3	5.3
		FINAL		03JUN2003	17:40	62	7.1	71.3	5.06	3.0	0.21	0.3	18.5	6.9
	E0020020	BSLN		07MAY2003	15:00	-5	3.8L	56.4	2.14	4.5	0.17	0.5	30.0	8.6
		FINAL		23MAY2003	14:00	12	3.9L	62.8	2.45	3.0	0.12	0.2	25.2	8.8
	E0020022	BSLN		09JUN2003	13:05	-7	6.2	50.0	3.10	1.7	0.11	0.5	39.9	7.9
		FINAL		11AUG2003	9:30	57	6.2	51.4	3.19	2.3	0.14	0.6	41.2	4.5
	E0022001	BSLN		09OCT2002	14:20	-19	4.2	53.5	2.25	1.7	0.07	0.5	35.7	8.6
		FINAL		26DEC2002	17:55	60	5.4	49.3	2.66	3.7	0.20	0.5	38.3	8.2
	E0022004	BSLN	*	17OCT2002	8:48	-11	5.0	45.0	2.25	1.9	0.10	0.4	43.3	9.4
		BSLN		28OCT2002	9:47	1	5.1	49.9	2.54	2.6	0.13	0.3	39.5	7.7
		FINAL		23DEC2002	10:15	57	6.1	58.4	3.56	3.4	0.21	0.3	31.1	6.8
	E0022005	BSLN		18OCT2002	7:40	-21	10.7	61.9	6.62	2.5	0.27	0.4	31.8	3.4L
		FINAL		03JAN2003	9:20	57	11.7	65.4	7.65	3.7	0.43	0.1	27.1	3.7L
	E0022011	BSLN		21NOV2002	9:25	-8	7.2	62.2	4.48	2.2	0.16	0.2	29.2	6.2
	E0022015	BSLN	*	29NOV2002	13:50	-11	6.1	64.3	3.92	2.7	0.16	0.3	21.1	11.6H
		BSLN	*	03DEC2002	10:10	-7	11.4	82.7H	9.43H	1.6	0.18	0.2	12.4L	3.1L
		BSLN		10DEC2002	16:10	1	9.3	76.7	7.13	0.8	0.07	0.1	19.5	2.9L
		FINAL		06FEB2003	9:50	59	6.1	61.7	3.76	2.6	0.16	0.3	24.6	10.8H
	E0022016	BSLN		03DEC2002	12:10	-14	5.9	65.3	3.85	3.2	0.19	0.3	21.8	9.4
		FINAL		11FEB2003	11:05	57	5.6	57.1	3.20	3.3	0.18	0.5	28.9	10.2H
	E0022020	BSLN		05DEC2002	12:21	-7	6.3	55.8	3.52	1.8	0.11	0.3	37.7	4.4
		FINAL		23JAN2003	16:20	43	9.1	70.0	6.37	1.6	0.15	0.1	25.0	3.3L
		FINAL	*	28JAN2003	10:35	48	8.3	70.3	5.83	1.2	0.10	0.2	23.7	4.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0022023	BSLN	20DEC2002	14:28	-5	4.7	36.8L	1.73L	7.3H	0.34H	0.3	48.9H	6.7
		FINAL	20FEB2003	10:05	58	6.3	41.0	2.58	9.5H	0.60H	0.4	41.3	7.8
	E0022029	BSLN	10FEB2003	12:30	-9	5.9	54.3	3.20	2.1	0.12	0.2	35.2	8.2
		FINAL	14APR2003	9:45	55	5.4	47.4	2.56	1.7	0.09	0.2	43.2	7.5
	E0022041	BSLN	11MAR2003	9:53	-7	6.6	59.8	3.95	4.1	0.27	0.4	31.5	4.2
		FINAL	13MAY2003	9:18	57	7.2	58.9	4.24	3.5	0.25	0.4	33.7	3.5L
	E0022042	BSLN	05MAR2003	9:50	-7	6.7	58.9	3.95	6.6H	0.44H	0.2	25.4	8.9
		FINAL	12MAY2003	9:35	62	8.1	57.0	4.62	6.1H	0.49	0.2	29.0	7.7
	E0022043	BSLN	11MAR2003	13:50	-9	7.8	60.9	4.75	2.1	0.16	0.4	29.0	7.6
		FINAL	12MAY2003	8:05	54	6.1	61.2	3.73	2.2	0.13	0.3	28.9	7.4
	E0022054	BSLN	07APR2003	11:25	-4	7.3	64.0	4.67	3.4	0.25	0.6	25.6	6.4
	E0022059	BSLN	23APR2003	15:30	-13	3.7L	48.5	1.79	5.1	0.19	0.6	37.6	8.2
		FINAL	08JUL2003	16:30	64	4.8	63.3	3.04	2.0	0.10	0.0	27.4	7.3
	E0022065	BSLN	01MAY2003	9:30	-6	15.0H	71.0	10.65 #	2.0	0.30	0.0	12.0L	6.0
		FINAL	02JUL2003	8:50	57	10.1	69.5	7.02	1.0	0.10	0.5	22.7	6.3
	E0022070	BSLN	05JUN2003	11:40	-7	9.6	59.9	5.75	10.8H	1.04H#	0.3	24.2	4.8
		FINAL	18JUN2003	15:15	7	9.1	60.8	5.53	4.9	0.45	0.7	29.5	4.1
	E0023001	BSLN	13NOV2002	13:30	-2	12.2	65.8	8.03	1.5	0.18	0.4	28.3	4.0
	E0023009	BSLN	24JAN2003	11:30	-18	9.2	75.6	6.96	0.7	0.06	0.5	19.2	4.0
		FINAL	08APR2003	11:15	57	10.5	72.2	7.58	1.3	0.14	0.5	21.7	4.3
	E0023028	BSLN	16MAY2003	12:15	-13	5.3	63.8	3.38	1.8	0.10	0.6	28.8	5.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0023028	FINAL	21JUL2003	11:00	54	11.2	68.9	7.72	3.4	0.38	0.3	27.3	0.1L
	E0023033	BSLN	30MAY2003	12:10	-6	5.9	60.9	3.59	0.8	0.05	0.2	31.2	6.9
		FINAL	12JUN2003	13:15	8	5.5	61.0	3.36	1.3	0.07	0.4	31.2	6.1
	E0023047	BSLN	11JUL2003	15:00	-7	7.2	64.1	4.62	1.5	0.11	0.3	30.1	4.0
		FINAL	16SEP2003	13:00	61	5.9	59.0	3.48	0.9	0.05	0.5	29.7	9.9H
	E0025001	BSLN	25MAR2003	16:00	-7	6.4	68.0	4.35	2.8	0.18	0.3	26.4	2.5L
		FINAL	23APR2003	10:30	23	6.6	63.1	4.16	2.4	0.16	0.3	30.1	4.1
	E0026012	BSLN	05FEB2003	11:00	-15	5.7	67.7	3.86	2.9	0.17	0.2	21.8	7.4
		FINAL	17APR2003	9:10	57	4.5	61.8	2.78	2.4	0.11	0.3	28.9	6.6
	E0026020	BSLN	28MAR2003	10:50	-4	6.4	53.6	3.43	0.6	0.04	0.4	41.0	4.4
		FINAL	22APR2003	14:05	22	5.4	46.9	2.53	2.0	0.11	0.3	44.9	5.9
	E0026024	BSLN	25APR2003	12:30	-7	7.7	57.8	4.45	4.7	0.36	0.3	32.8	4.4
	E0026028	BSLN	06JUN2003	10:20	-14	9.0	65.1	5.86	3.8	0.34	0.3	24.4	6.4
		FINAL	23JUL2003	10:00	34	11.0	69.9	7.69	1.9	0.21	0.5	21.6	6.1
	E0028001	BSLN	07OCT2002	14:00	-3	15.6H	70.2	10.95 #	3.1	0.48	0.3	22.1	4.3
		FINAL	03DEC2002	9:50	55	8.5	68.6	5.83	4.6	0.39	0.2	21.7	4.9
	E0028003	BSLN	23SEP2002	9:10	-7	9.8	70.1	6.87	0.6	0.06	0.2	23.6	5.5
		FINAL	26NOV2002	9:20	58	5.3	55.1	2.92	0.9	0.05	0.1	37.8	6.1
	E0028005	BSLN	30SEP2002	11:00	-3	4.7	64.5	3.03	2.9	0.14	0.2	26.0	6.4
		FINAL	31OCT2002	12:15	29	5.0	61.9	3.10	3.1	0.16	0.3	29.6	5.1
	E0028010	BSLN	* 15OCT2002	11:00	-21	4.3							

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0028010	BSLN		25OCT2002	9:00	-11	4.9	56.1	2.75	4.2	0.21	0.7	30.4	8.6
		FINAL	*	19NOV2002	12:40	15	6.6	68.4	4.51	1.3	0.09	0.2	24.9	5.2
		FINAL		31DEC2002	9:20	57	3.9L	55.3	2.16	9.5H	0.37H	0.4	26.3	8.5
	E0028011	BSLN	*	16OCT2002	15:10	-50	9.6	74.5	7.15	5.9	0.57	0.0	14.2L	5.4
		BSLN		03DEC2002	9:30	-2	6.8	69.0	4.69	2.5	0.17	0.2	20.4	7.9
		FINAL		30JAN2003	12:35	57	6.7	75.9	5.09	1.8	0.12	0.4	14.5L	7.4
	E0028030	BSLN		26FEB2003	11:30	-6	7.0	68.2	4.77	3.8	0.27	0.5	20.3	7.2
		FINAL		30APR2003	12:35	58	5.9	68.6	4.05	3.2	0.19	0.2	18.1	9.9H
	E0028031	BSLN		06MAR2003	9:00	-5	9.4	70.6	6.64	1.5	0.14	0.3	20.0	7.6
		FINAL		17APR2003	13:30	38	13.9H	71.2	9.90	1.6	0.22	0.3	18.4	8.5
	E0028047	BSLN		09JUL2003	10:40	-5	4.4	44.0	1.94	1.0	0.04	0.4	47.9H	6.7
		FINAL		09SEP2003	10:24	58	4.3	50.7	2.18	1.1	0.05	0.3	42.5	5.4
	E0029001	BSLN		25SEP2002	8:45	-6	21.0H#	72.0	15.12 #	1.0	0.21	0.0	16.0	6.0
	E0029014	BSLN		28JAN2003	9:35	-7	11.2	75.7	8.48	1.3	0.15	0.1	17.6	5.3
		FINAL		01APR2003	11:20	57	11.5	76.5	8.80	1.4	0.16	0.4	18.0	3.7L
	E0029023	BSLN		01APR2003	8:47	-7	11.6	54.3	6.30	1.7	0.20	0.1	38.9	5.0
		FINAL		10JUN2003	11:10	64	8.4	51.3	4.31	1.8	0.15	0.2	41.7	5.0
	E0029032	BSLN		22MAY2003	12:45	-19	5.9	58.6	3.46	2.3	0.14	0.7	33.9	4.5
		FINAL		01JUL2003	12:00	22	4.6	59.8	2.75	2.7	0.12	0.1	32.6	4.8
	E0029033	BSLN		27MAY2003	12:50	-6	7.2	60.3	4.34	2.4	0.17	0.3	31.1	5.9
	E0029039	BSLN		10JUL2003	13:02	-5	4.7	46.1	2.17	2.0	0.09	0.3	45.5	6.1
		FINAL		28JUL2003	15:30	14	5.3	49.8	2.64	3.5	0.19	0.6	37.9	8.2

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0030003	BSLN	10DEC2002	9:00	-6	3.2L	32.9L	1.05L	4.2	0.13	0.2	55.6H	7.1
		FINAL	21MAR2003	9:50	96	3.8L	50.4	1.92	2.2	0.08	1.3	40.2	5.9
	E0030009	BSLN	14JAN2003	9:55	-9	6.3	57.8	3.64	3.0	0.19	0.3	33.9	5.0
		FINAL	19MAR2003	10:35	56	4.9	60.1	2.94	2.5	0.12	0.5	29.2	7.7
	E0030016	BSLN	21FEB2003	11:50	-10	9.3	79.4H	7.38H	0.1	0.01	0.2	12.2L	8.1
		FINAL	22APR2003	18:55	51	7.8	59.2	4.62	2.0	0.16	0.0	26.4	12.4H
	E0030021	BSLN	13MAY2003	17:25	-7	8.2	64.4	5.28	1.8	0.15	0.5	26.3	7.0
	E0031001	BSLN	14NOV2002	11:48	-7	5.0	57.7	2.89	3.2	0.16	0.2	34.4	4.5
	E0031017	BSLN	25MAR2003	16:15	-7	8.8	58.2	5.12	2.5	0.22	0.2	30.3	8.8
		FINAL	29APR2003	10:30	29	6.2	58.8	3.65	2.9	0.18	0.3	29.9	8.1
	E0031018	BSLN	01APR2003	14:45	-9	9.5	61.7	5.86	3.5	0.33	0.3	28.6	5.9
	E0031023	BSLN	22APR2003	14:03	-7	10.5	70.6	7.41	2.1	0.22	0.3	22.4	4.6
		FINAL	24JUN2003	11:48	57	11.8	75.4	8.90	1.2	0.14	0.3	19.3	3.8L
	E0033001	BSLN	23DEC2002	12:50	-17	6.3	45.6	2.87	4.9	0.31	0.3	42.1	7.1
		FINAL	30JAN2003	13:25	22	5.6	49.6	2.78	5.1	0.29	0.2	37.6	7.5
	E0033004	BSLN	09JAN2003	13:10	-8	7.8	55.6	4.34	4.3	0.34	0.3	30.3	9.5H
		FINAL	14MAR2003	11:40	57	7.4	64.6	4.78	3.6	0.27	0.0	24.3	7.5
	E0033010	BSLN	22JAN2003	16:20	-13	6.7	63.2	4.23	1.4	0.09	0.3	27.9	7.2
		FINAL	26MAR2003	16:00	51	6.0	62.4	3.74	2.2	0.13	0.2	25.4	9.8H
	E0033014	BSLN	12MAR2003	17:25	-7	10.4	70.5	7.33	0.9	0.09	0.2	23.3	5.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA101.SAS
GENERATED: 12JUL2005 17:43:32 iceadmn3

Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0035002	BSLN		14NOV2002	10:50	-7	8.4	35.6L	2.99L	1.3	0.11	0.5	50.8H	11.8H
	E0035007	BSLN		13DEC2002	12:40	-6	8.5	33.1L	2.81L	2.7	0.23	0.1	58.3H	5.8
		FINAL		11FEB2003	10:10	55	6.7	51.0	3.42	2.6	0.17	0.3	42.3	3.8L
	E0035011	BSLN		13JAN2003	8:35	-22	12.1	51.7	6.26	1.4	0.17	0.2	46.0	0.7L
		FINAL		01APR2003	9:00	57	8.7	46.4	4.04	1.6	0.14	0.4	48.2H	3.4L
	E0035020	BSLN		15APR2003	8:15	-3	6.4	53.4	3.42	0.8	0.05	0.3	38.1	7.4
	E0037003	BSLN		28JAN2003	11:40	-2	7.4	73.5	5.44	2.5	0.19	0.6	15.7	7.7
		FINAL		20FEB2003	15:32	22	5.9	67.0	3.95	4.0	0.24	0.0	10.0L	13.0H
	E0037004	BSLN		06FEB2003	12:35	-7	5.9	62.6	3.69	2.5	0.15	0.4	29.6	4.9
		FINAL		10APR2003	13:00	57	5.5	52.6	2.89	1.9	0.10	0.4	38.2	6.9
	E0039007	BSLN		25NOV2002	13:20	-9	8.5	80.0H	6.80H	0.8	0.07	0.6	15.5	3.1L
		FINAL		29JAN2003	14:15	57	6.8	70.7	4.81	0.8	0.05	0.3	22.4	5.8
	E0039022	BSLN		06FEB2003	9:50	-19	4.3	58.4	2.51	1.7	0.07	0.7	31.4	7.8
		FINAL		24APR2003	12:10	59	4.0L	53.0	2.12	0.9	0.04	0.5	38.0	7.6
	E0039023	BSLN	*	05FEB2003	10:37	-19	3.7L	18.8L	0.70L	12.7H	0.47H	0.6	55.0H	12.9H
		BSLN		14FEB2003	9:30	-10	6.7	43.6	2.92	5.9	0.40	0.3	42.7	7.5
	E0039030	BSLN		12MAR2003	8:55	-12	3.6L	60.4	2.17	4.3	0.15	0.4	28.1	6.8
		FINAL		19MAY2003	9:15	57	3.8L	66.9	2.54	3.1	0.12	0.0	22.7	7.3
	E0039031	BSLN		05MAR2003	19:15	-19	6.2	56.6	3.51	3.2	0.20	0.2	34.6	5.4
		FINAL		20MAY2003	12:50	58	5.8	55.9	3.24	3.6	0.21	0.2	32.6	7.7
	E0039037	BSLN		26MAR2003	18:30	-21	5.6	46.2	2.59	4.3	0.24	0.3	44.7	4.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:32 iceadmn3

Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR I)	E0039037	FINAL	12JUN2003	11:30	58	7.5	73.0	5.48	1.8	0.14	0.3	21.5	3.4L
	E0039038	BSLN	27MAR2003	10:10	-27	8.0	50.7	4.06	0.5	0.04	0.3	44.7	3.8L
		FINAL	20JUN2003	11:15	59	8.1	51.9	4.20	0.3	0.02	0.4	44.0	3.4L
	E0039047	BSLN	13MAY2003	9:20	-6	9.8	72.3	7.09	3.4	0.33	0.2	20.3	3.8L
	E0039059	BSLN	07JUL2003	11:10	-4	5.6	47.5	2.66	1.3	0.07	0.1	46.8H	4.3
		FINAL	05SEP2003	11:10	57	5.8	40.3L	2.34L	0.4	0.02	0.6	54.4H	4.3
	E0041007	BSLN	05MAR2003	13:45	-8	4.6	40.0L	1.84L	3.9	0.18	0.4	47.9H	7.8
		FINAL	08MAY2003	13:45	57	5.5	56.5	3.11	1.3	0.07	0.2	35.6	6.4
	E0041010	BSLN	23APR2003	14:45	-7	10.9	60.5	6.59	3.3	0.36	0.4	29.2	6.6
		FINAL	11JUN2003	15:30	43	9.0	62.9	5.66	3.4	0.31	0.4	27.1	6.2
	E0041011	BSLN	15MAY2003	16:00	-7	5.5	43.9	2.41	1.0	0.06	0.9	43.8	10.4H
		FINAL	17JUL2003	14:30	57	4.9	38.4L	1.88L	1.1	0.05	1.0	51.8H	7.7
	E0041012	BSLN	05JUN2003	12:28	-14	9.3	55.3	5.14	2.4	0.22	0.2	37.8	4.3
		FINAL	14AUG2003	11:45	57	8.7	66.2	5.76	1.9	0.17	0.3	28.6	3.0L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR II)	E0001004	BSLN		23APR2003	11:00	-8	12.1	76.0	9.20	1.5	0.18	0.1	19.6	2.8L
		FINAL		27JUN2003	12:45	58	7.6	60.7	4.61	1.8	0.14	0.3	33.2	4.0
	E0005023	BSLN		29JAN2003	7:30	-7	5.6	61.0	3.42	0.9	0.05	0.2	32.9	5.0
		FINAL		01APR2003	16:30	56	8.9	63.2	5.62	1.0	0.09	0.2	30.5	5.1
	E0005034	BSLN		09APR2003	9:30	-6	5.6	49.7	2.78	2.5	0.14	0.3	39.7	7.8
		FINAL		09JUN2003	13:00	56	7.5	67.0	5.03	0.8	0.06	0.3	26.1	5.8
	E0005041	BSLN		17JUN2003	11:55	-7	3.5L	52.3	1.83	1.7	0.06	0.5	33.0	12.5H
		FINAL		18AUG2003	10:10	56	3.5L	50.6	1.77	2.0	0.07	0.4	35.2	11.8H
	E0007004	BSLN		28JAN2003	8:05	-2	12.3	63.8	7.85	1.5	0.18	0.5	30.4	3.8L
		FINAL		13FEB2003	8:30	15	10.2	61.9	6.31	1.0	0.10	0.4	33.8	2.9L
	E0007010	BSLN		14APR2003	8:10	-4	6.7	64.2	4.30	3.6	0.24	0.3	24.7	7.2
		FINAL		13JUN2003	7:40	57	6.9	66.2	4.57	3.5	0.24	0.5	23.7	6.1
		FINAL	*	16JUN2003	7:50	60	7.5	70.0	5.25	2.5	0.19	0.5	19.7	7.3
	E0007012	BSLN		12MAY2003	8:50	-4	7.0	59.8	4.19	4.2	0.29	0.4	30.4	5.2
		FINAL		02JUL2003	11:35	48	6.8	62.7	4.26	3.6	0.24	0.3	29.1	4.3
	E0009007	BSLN		27JAN2003	15:25	-7	7.0	67.5	4.73	1.4	0.10	0.4	25.4	5.3
		FINAL		03MAR2003	15:40	29	5.7	58.7	3.35	2.2	0.13	1.2	30.5	7.4
	E0009008	BSLN		04FEB2003	13:37	-8	6.5	60.8	3.95	3.0	0.20	0.4	31.7	4.1
		FINAL		15APR2003	12:30	63	6.5	58.2	3.78	3.3	0.21	0.2	33.6	4.7
	E0011001	BSLN		25OCT2002	16:00	-7	5.8	59.3	3.44	3.9	0.23	0.4	30.9	5.5
		FINAL		26DEC2002	8:30	56	4.4	53.0	2.33	7.8H	0.34H	0.4	32.1	6.7
	E0011011	BSLN		12FEB2003	12:00	-8	5.7	54.6	3.11	1.6	0.09	0.4	38.8	4.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR II)	E0011011	FINAL		16APR2003	8:30	56	4.3	49.3	2.12	1.2	0.05	0.2	42.8	6.5
	E0011013	BSLN		25MAR2003	9:45	-23	8.1	71.7	5.81	3.7	0.30	0.0	24.0	0.6L
		FINAL		12JUN2003	8:45	57	7.9	64.4	5.09	6.0	0.47	0.3	25.0	4.3
	E0011014	BSLN		02APR2003	8:20	-5	4.7	39.0L	1.83L	2.0	0.09	0.0	50.0H	9.0
		FINAL		08MAY2003	15:30	32	6.3	63.2	3.98	0.8	0.05	0.4	29.0	6.6
	E0011021	BSLN		15MAY2003	10:00	-7	5.2	64.9	3.37	1.2	0.06	0.3	26.5	7.1
		FINAL		21JUL2003	10:00	61	4.6	64.1	2.95	1.1	0.05	0.4	28.9	5.5
	E0013008	BSLN		19MAR2003	16:20	-7	11.5	64.1	7.37	0.9	0.10	0.1	28.6	6.3
		FINAL		19MAY2003	11:25	55	10.4	69.7	7.25	0.9	0.09	0.3	24.7	4.4
	E0014001	BSLN	*	18FEB2003	15:45	-8	6.0	40.3L	2.42L	1.4	0.08	0.1	53.8H	4.4
		BSLN	*	25FEB2003	9:58	-1	4.2	42.8L	1.58L	1.2	0.04	0.7	51.6H	3.7
		BSLN		25FEB2003	10:15	-1	3.7L	41.9	1.55	0.9	0.03	0.4	50.9H	5.9
		FINAL		08APR2003	11:10	42	4.0L	55.0	2.20	3.4	0.14	0.4	34.6	6.6
		FINAL	*	16APR2003	10:40	50	3.3L	48.9	1.61	4.2	0.14	0.2	39.8	6.9
	E0014013	BSLN		20MAY2003	14:50	-7	6.9	52.5	3.62	1.2	0.08	0.2	42.1	4.0
		FINAL		23JUL2003	15:00	58	6.8	48.7	3.31	1.1	0.07	0.2	46.0	4.0
	E0014014	BSLN		03JUN2003	16:35	-7	5.4	61.3	3.31	5.0	0.27	0.4	28.2	5.1
		FINAL		06AUG2003	10:50	58	6.4	62.8	4.02	4.2	0.27	0.5	25.3	7.2
	E0015004	BSLN		25NOV2002	8:50	-7	7.9	65.1	5.14	1.9	0.15	0.2	27.6	5.2
		FINAL		29JAN2003	8:45	59	7.8	63.7	4.97	2.2	0.17	0.3	27.9	5.9
	E0018005	BSLN		10DEC2002	16:00	-10	5.8	68.0	3.94	0.8	0.05	0.2	24.7	6.3
		FINAL		17FEB2003	11:05	60	3.8L	51.0	1.94	2.9	0.11	1.1	33.9	11.1H

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Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR II)	E0018012	BSLN		17JAN2003	10:30	-7	5.9	67.2	3.96	2.3	0.14	0.5	24.5	5.5
		FINAL		26FEB2003	19:20	34	6.9	65.5	4.52	3.7	0.26	0.3	26.2	4.3
	E0019019	BSLN		14JAN2003	10:30	-9	10.1	59.9	6.05	3.4	0.34	0.3	32.3	4.1
	E0019033	BSLN		10MAR2003	16:05	-8	7.1	67.9	4.82	1.3	0.09	0.3	21.7	8.8
	E0019038	BSLN	*	10APR2003	12:30	-14	6.0	57.7	3.46	0.6	0.04	0.4	36.0	5.3
		BSLN		17APR2003	11:05	-7	5.8	55.4	3.21	0.8	0.05	0.3	35.9	7.6
		FINAL		19JUN2003	9:40	57	4.7	55.7	2.62	0.5	0.02	0.4	36.3	7.1
	E0019046	BSLN		19JUN2003	15:00	-7	5.6	54.3	3.04	3.9	0.22	0.6	36.0	5.2
		FINAL		21AUG2003	9:12	57	4.0L	54.3	2.17	1.5	0.06	0.7	38.5	5.0
	E0019047	BSLN		26JUN2003	12:30	-12	6.6	58.7	3.87	2.7	0.18	0.3	32.5	5.8
		FINAL		04SEP2003	8:40	59	8.4	64.8	5.44	3.1	0.26	0.0	26.1	6.0
	E0019048	BSLN		03JUL2003	11:05	-7	3.8L	57.1	2.17	2.3	0.09	0.9	33.6	6.1
		FINAL		03SEP2003	16:12	56	6.0	68.0	4.08	0.2	0.01	0.2	24.9	6.7
	E0022006	BSLN		22OCT2002	10:10	-21	10.9	53.7	5.85	5.4	0.59	0.6	31.2	9.1
		FINAL		07JAN2003	7:40	57	7.5	33.0L	2.48L	1.0	0.08	0.0	51.0H	13.0H
	E0022047	BSLN		21MAR2003	8:10	-7	6.8	69.1	4.70	2.5	0.17	0.2	23.4	4.8
		FINAL		23MAY2003	9:45	57	7.4	59.9	4.43	2.5	0.19	0.1	31.6	5.9
	E0022075	BSLN		27JUN2003	7:45	-11	4.8	49.6	2.38	0.7	0.03	0.4	39.9	9.4
		FINAL		03SEP2003	9:15	58	4.7	51.2	2.41	0.5	0.02	0.5	43.1	4.7
	E0023012	BSLN		31JAN2003	15:30	-6	9.0	70.0	6.30	0.7	0.06	0.4	21.9	7.0
		FINAL		04APR2003	12:15	58	8.9	73.2	6.51	0.2	0.02	0.4	21.7	4.5

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PLACEBO (BIPOLAR II)	E0023016	BSLN		15MAY2003	13:30	-7	7.0	50.9	3.56	2.7	0.19	0.7	41.0	4.7
		FINAL		17JUL2003	11:10	57	5.6	43.7	2.45	3.2	0.18	0.9	42.9	9.3
	E0023018	BSLN		18MAR2003	13:30	-9	11.2	58.6	6.56	1.2	0.13	0.3	32.8	7.1
		FINAL		22MAY2003	10:15	57	5.9	59.3	3.50	2.4	0.14	0.3	32.8	5.2
	E0023036	BSLN		10JUN2003	12:00	-10	6.5	47.4	3.08	0.3	0.02	0.3	48.6H	3.4L
		FINAL		13AUG2003	17:00	55	10.0	42.5	4.25	1.2	0.12	0.3	53.7H	2.3L
	E0023046	BSLN		11JUL2003	10:00	-12	4.8	70.8	3.40	1.4	0.07	0.2	22.4	5.2
		FINAL		16SEP2003	14:00	56	4.6	53.6	2.47	4.3	0.20	0.5	34.4	7.2
	E0026006	BSLN		06JAN2003	9:00	-2	5.8	67.5	3.92	1.5	0.09	0.4	23.8	6.8
	E0026021	BSLN		14APR2003	15:45	-9	6.9	62.2	4.29	1.2	0.08	0.6	29.4	6.6
	E0026027	BSLN		05JUN2003	13:10	-14	10.8	67.6	7.30	1.8	0.19	0.3	25.1	5.2
	E0029002		*	05NOV2002	9:30		10.0	67.6	6.76	1.8	0.18	0.3	25.7	4.6
	E0029004	BSLN		13NOV2002	14:50	-6	7.4	63.4	4.69	9.0H	0.67H	0.3	22.6	4.7
		FINAL		17JAN2003	8:25	60	3.3L	48.4	1.60	6.5H	0.21H	0.3	38.6	6.2
	E0029013	BSLN		10FEB2003	8:55	-9	11.2	69.6	7.80	1.5	0.17	0.4	25.7	2.8L
	E0029019	BSLN		24FEB2003	9:30	-7	5.4	56.3	3.04	3.8	0.21	0.2	33.6	6.1
		FINAL		17MAR2003	9:50	15	5.4	60.0	3.24	1.6	0.09	0.3	32.9	5.2
	E0029024	BSLN		11MAR2003	12:10	-6	10.2	67.8	6.92	0.6	0.06	0.3	27.0	4.3
		FINAL		20MAY2003	14:45	65	9.1	65.9	6.00	0.8	0.07	0.2	28.4	4.7
	E0029038	BSLN		30JUN2003	9:25	-7	10.1	73.6	7.43	2.5	0.25	0.2	20.2	3.5L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/HEMA101.SAS
GENERATED: 12JUL2005 17:43:32 iceadmn3

Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR II)	E0031004	BSLN	12DEC2002	13:59	-7	9.2	67.5	6.21	2.1	0.19	0.2	25.1	5.1
		FINAL	14FEB2003	10:50	58	8.5	69.5	5.91	1.8	0.15	0.3	23.1	5.3
	E0031013	BSLN	06MAR2003	10:35	-7	8.9	52.9	4.71	1.5	0.13	2.0	38.2	5.4
		FINAL	08MAY2003	11:05	57	8.7	54.5	4.74	2.7	0.23	0.2	38.5	4.1
	E0031016	BSLN	17MAR2003	10:45	-7	5.2	50.8	2.64	5.5	0.29	0.1	33.8	9.8H
		FINAL	15APR2003	10:03	23	4.8	47.7	2.29	6.5H	0.31H	0.2	35.3	10.3H
	E0031019	BSLN	03APR2003	11:25	-8	5.3	47.7	2.53	6.1H	0.32	1.3	37.0	7.9
		FINAL	12MAY2003	16:40	32	6.4	64.1	4.10	3.5	0.22	0.8	25.9	5.7
	E0031022	BSLN	21APR2003	12:40	-7	7.5	64.9	4.87	1.4	0.11	0.5	28.1	5.1
	E0033007	BSLN	22JAN2003	16:00	-6	8.6	55.5	4.77	1.4	0.12	0.2	40.4	2.5L
		FINAL	27MAR2003	15:35	59	8.2	66.9	5.49	0.9	0.07	0.2	27.9	4.1
	E0033013	BSLN	06FEB2003	11:45	-13	6.4	65.9	4.22	0.8	0.05	0.5	30.4	2.4L
		FINAL	16APR2003	11:45	57	5.8	54.5	3.16	0.3	0.02	0.4	40.8	4.0
	E0033016	BSLN	17APR2003	12:00	-21	5.4	51.5	2.78	1.9	0.10	0.2	42.6	3.8L
		FINAL	02JUL2003	13:00	56	6.1	58.3	3.56	0.2	0.01	0.4	36.3	4.8
	E0033022	BSLN	09JUL2003	11:00	-5	8.1	69.7	5.65	0.6	0.05	0.1	21.8	7.8
		FINAL	11SEP2003	12:00	60	7.9	72.1	5.70	0.2	0.02	0.2	22.2	5.3
	E0034007	BSLN	07MAY2003	14:05	-9	9.4	69.4	6.52	2.4	0.23	0.5	19.5	8.2
		FINAL	14JUL2003	11:15	60	7.8	73.3	5.72	2.5	0.20	0.5	16.5	7.2
	E0035004	BSLN	22NOV2002	11:45	-5	8.3	50.6	4.20	3.9	0.32	0.8	37.7	7.0
	E0035009	BSLN	23DEC2002	14:50	-4	2.7L#	41.4	1.12	0.9	0.02	0.5	45.4	11.8H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:43:32 iceadmn3

Listing 12.2.8.1.2 Hematology Data - White Cells

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10 **9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS (CALC) (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (CALC) (X10 **9/L)	BASO-PHILS (%)	LYMPHO-CYTES (%)	MONO-CYTES (%)
PLACEBO (BIPOLAR II)	E0035009	FINAL	19FEB2003	8:55	55	3.2L	39.6L	1.27L	2.7	0.09	0.8	49.3H	7.6
	E0035010	BSLN	07JAN2003	7:45	-3	5.6	55.7	3.12	3.2	0.18	0.2	33.8	7.1
		FINAL	06MAR2003	9:00	56	5.5	66.7	3.67	1.8	0.10	0.1	25.4	6.0
	E0035022	BSLN	01MAY2003	9:45	-8	4.6	64.7	2.98	2.3	0.11	0.3	24.8	7.9
		FINAL	07JUL2003	8:55	60	3.7L	56.6	2.09	2.1	0.08	0.7	32.1	8.5
	E0039003	BSLN	12NOV2002	11:19	-13	4.5	63.2	2.84	8.4H	0.38H	0.5	16.5	11.4H
		FINAL	02JAN2003	14:06	39	5.7	65.8	3.75	5.7	0.32	0.2	16.9	11.4H
	E0040001	BSLN	18JUN2003	14:30	-9	7.2	74.8	5.39	0.6	0.04	0.2	19.4	5.0
		FINAL	22AUG2003	9:00	57	4.4	58.1	2.56	1.4	0.06	0.3	34.8	5.4
	E0040004	BSLN	11JUL2003	13:00	-7	6.5	58.6	3.81	0.7	0.05	0.2	34.4	6.1
	E0041002	BSLN	13JAN2003	14:35	-8	6.1	58.4	3.56	3.7	0.23	0.4	29.1	8.4
		FINAL	11MAR2003	10:35	50	8.7	71.1	6.19	1.7	0.15	0.2	20.8	6.2
	E0041005	BSLN	28FEB2003	12:31	-5	8.5	62.2	5.29	0.8	0.07	0.3	31.7	5.0
		FINAL	30APR2003	14:08	57	11.8	63.3	7.47	2.3	0.27	0.5	27.6	6.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		22JAN2003	14:00	-13	24	27	85.0	0.2
		FINAL		02APR2003	10:10	58	19	20	93.0	0.2
	E0002010	BSLN		28MAR2003	10:00	-7	49H	88H	88.0	0.3
	E0002012	BSLN		16APR2003	10:10	-5	21	19	57.0	1.0
		FINAL		16JUN2003	11:30	57	26	29	58.0	0.6
	E0002015	BSLN		22MAY2003	10:15	-13	35	60H	86.0	0.4
	E0002018	BSLN		16JUL2003	13:25	-8	20	24	104.0	0.5
		FINAL		04AUG2003	9:40	12	27	30	94.0	0.4
	E0003004	BSLN	*	03DEC2002	11:48	-14	24	32	116.0	0.4
		BSLN		17DEC2002	9:20	1	26	39	107.0	0.2
		FINAL		07JAN2003	15:40	22	22	25	95.0	0.4
	E0003005	BSLN		16DEC2002	15:00	-7	16	12	66.0	0.5
		FINAL		18FEB2003	8:55	58	23	21	75.0	0.3
	E0003007	BSLN		19DEC2002	10:15	-14	17	14	39.0	0.4
		FINAL		27FEB2003	8:50	57	16	11	41.0	0.4
	E0003015	BSLN		29APR2003	11:30	-6	21	18	57.0	0.6
		FINAL		02JUL2003	14:45	59	15	13	74.0	0.3
	E0004002	BSLN		24SEP2002	10:40	-7	21	14	60.0	0.5
		FINAL		26NOV2002	11:00	57	29	30	67.0	0.3
	E0004013	BSLN		08JAN2003	10:00	-6	17	13	108.0	0.3
		FINAL		19FEB2003	8:20	37	23	28	119.0	0.3
	E0004018	BSLN		12MAR2003	10:50	-7	21	18	87.0	0.7
		FINAL		13MAY2003	13:45	56	21	20	75.0	0.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	BSLN	07MAY2003	15:55	-7	34	37	99.0		0.3
		FINAL	09JUL2003	14:10	57	27	31	92.0		0.4
	E0005002	BSLN	23SEP2002	10:00	-10	29	28	95.0		0.4
		FINAL	25NOV2002	8:30	54	31	58H	107.0		0.2
	E0005004	BSLN	24SEP2002	12:00	-7	18	16	79.0		0.6
	E0005013	BSLN	30OCT2002	8:00	-8	16	15	41.0		0.4
	E0005024	BSLN	05FEB2003	15:00	-5	17	19	66.0		0.5
		FINAL	10APR2003	11:30	60	19	20	72.0		0.4
	E0005027	BSLN	04MAR2003	7:45	-7	21	29	80.0		0.8
		FINAL	03APR2003	8:15	24	23	26	87.0		0.5
	E0005037	BSLN	30APR2003	12:00	-7	17	21	123.0	H	0.3
		FINAL	02JUL2003	12:15	57	14	15	126.0	H	0.2
	E0005042	BSLN	19JUN2003	11:30	-5	20	23	87.0		0.4
		FINAL	18AUG2003	16:25	56	14	25	87.0		0.4
	E0006005	BSLN	25NOV2002	12:15	-10	19	28	72.0		0.4
		FINAL	30JAN2003	16:10	57	17	23	74.0		0.3
	E0006018	BSLN	07MAR2003	12:40	-6	23	28	74.0		1.1
		FINAL	24MAR2003	10:45	12	25	34	76.0		0.7
	E0007013	BSLN	10JUN2003	9:25	-3	15	15	82.0		0.4
		FINAL	07AUG2003	9:20	56	17	12	97.0		0.2
	E0010004	BSLN	05DEC2002	11:10	-6	19	18	75.0		0.3
		FINAL	06FEB2003	12:40	58	18	17	69.0		0.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	BSLN	30DEC2002	9:48	-8	18	18	63.0		0.1	L
		FINAL	05MAR2003	13:59	58	20	16	65.0		0.1	L
	E0010024	BSLN	23APR2003	8:45	-12	21	23	96.0		0.8	
		FINAL	02JUL2003	10:30	59	16	19	139.0	H	0.7	
	E0010032	BSLN	03JUL2003	11:30	-7	16	14	86.0		0.4	
		FINAL	17JUL2003	11:38	8	15	12	81.0		0.5	
	E0011025	BSLN	20JUN2003	14:30	-6	24	20	69.0		0.2	
		FINAL	22AUG2003	10:00	58	20	13	74.0		0.4	
	E0013007	BSLN	14MAR2003	8:48	-6	23	41	93.0		0.9	
		FINAL	07APR2003	17:15	19	22	33	108.0		0.7	
	E0013009	BSLN	26MAR2003	9:09	-7	14	15	51.0		0.5	
		FINAL	29MAY2003	17:50	58	21	20	71.0		0.3	
	E0014006	BSLN	14MAR2003	11:30	-11	16	13	197.0	H	0.5	
		FINAL	21MAY2003	16:20	58	17	13	218.0	H	0.2	
	E0014010	BSLN	15APR2003	17:20	-7	17	23	85.0		0.2	
		FINAL	17JUN2003	18:10	57	13	18	78.0		0.2	
	E0016001	BSLN	02JAN2003	8:50	-20	18	13	103.0		0.2	
		FINAL	19MAR2003	12:00	57	26	28	87.0		0.6	
	E0016004	BSLN	27JAN2003	9:30	-7	19	32	79.0		0.5	
	E0018001	BSLN	22OCT2002	16:15	-7	20	27	75.0		0.2	
		FINAL	24DEC2002	9:55	57	25	33	66.0		0.3	
	E0018006	BSLN	10DEC2002	17:15	-7	32	49H	75.0		0.4	
		FINAL	27FEB2003	12:10	73	19	24	82.0		0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	BSLN		30OCT2002	8:40	-8	19	14	79.0	0.2	
		FINAL		19DEC2002	12:55	43	22	14	71.0	0.1	L
	E0019011	BSLN		12NOV2002	12:05	-9	16	14	84.0	0.4	
		FINAL		16JAN2003	14:20	57	16	19	90.0	0.5	
	E0019025	BSLN		30JAN2003	14:40	-7	45H	45H	73.0	0.9	
		FINAL		03APR2003	13:30	57	30	20	61.0	1.0	
	E0019026	BSLN		17FEB2003	12:40	-7	17	16	85.0	0.3	
	E0019043	BSLN		21MAY2003	11:04	-13	20	21	91.0	0.7	
		FINAL	*	17JUN2003	12:10	15	21	28	91.0	0.4	
		FINAL		29JUL2003	11:38	57	24	31	104.0	0.4	
	E0020001	BSLN		15OCT2002	20:00	-14	25	25	69.0	0.9	
		FINAL		20DEC2002	12:30	53	21	20	73.0	0.5	
	E0020006	BSLN		26NOV2002	18:00	-20	28	25	99.0	0.2	
		FINAL		08JAN2003	10:00	24	20	22	83.0	0.4	
	E0020007	BSLN		10JAN2003	12:00	-5	23	23	82.0	0.3	
		FINAL		25MAR2003	18:50	70	23	18	84.0	0.3	
	E0020011	BSLN		19FEB2003	13:45	-7	26	32	75.0	0.3	
		FINAL		23APR2003	14:30	57	19	24	80.0	0.2	
		FINAL	*	07MAY2003	12:00	71	15	20	67.0	0.2	
	E0020013	BSLN		26FEB2003	14:15	-7	21	62H	103.0	0.5	
		FINAL		25MAR2003	12:00	21	27	78H	91.0	0.2	
	E0022008	BSLN		05NOV2002	10:00	-7	21	30	76.0	0.4	
		FINAL		07JAN2003	9:45	57	45	40	100.0	0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	BSLN	05DEC2002	12:35	-14	19	22	91.0	0.5
		FINAL	07MAR2003	9:47	79	21	22	95.0	0.4
	E0022018	BSLN	04DEC2002	10:15	-8	54H	99H	70.0	0.7
		FINAL	11FEB2003	8:40	62	49H	92H	74.0	0.6
	E0022022	BSLN	16DEC2002	13:15	-14	18	12	80.0	0.3
		FINAL	27FEB2003	11:35	60	18	20	85.0	0.4
	E0022027	BSLN	24JAN2003	7:40	-13	23	26	72.0	0.5
		FINAL	03APR2003	9:00	57	17	21	75.0	0.3
	E0022030	BSLN	10FEB2003	7:40	-4	29	60H	81.0	0.3
	E0022031	BSLN	11FEB2003	10:25	-7	27	50H	75.0	0.4
		FINAL	15APR2003	9:30	57	25	37	81.0	0.3
	E0022032	BSLN	12FEB2003	8:05	-6	17	12	47.0	0.2
		FINAL	18APR2003	10:30	60	18	9	62.0	0.5
	E0022035	BSLN	13FEB2003	13:50	-6	23	12	99.0	0.5
		FINAL	13MAR2003	17:55	23	21	17	84.0	0.4
	E0022036	BSLN	14FEB2003	8:55	-11	13	13	75.0	0.4
		FINAL	22APR2003	7:36	57	15	11	87.0	0.2
	E0022056	BSLN	11APR2003	8:07	-6	18	15	73.0	0.3
	E0022060	BSLN	24APR2003	12:05	-6	21	13	57.0	0.4
		FINAL	24JUN2003	9:25	56	18	13	60.0	0.3
	E0022063	BSLN	29APR2003	10:10	-8	53H	66H	100.0	0.7
	E0023008	BSLN	23JAN2003	10:00	-7	15	6	46.0	0.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	FINAL		24MAR2003	15:40	54	15	10	65.0		0.3	
	E0023013	BSLN		13FEB2003	11:00	-14	22	34	78.0		0.3	
		FINAL		06MAR2003	11:00	8	20	32	74.0		0.4	
	E0023015	BSLN		04MAR2003	11:00	-7	16	14	41.0		0.5	
		FINAL		06MAY2003	10:00	57	21	14	61.0		0.5	
	E0023034	BSLN		03JUN2003	14:00	-6	15	17	68.0		0.5	
		FINAL		05AUG2003	16:00	58	18	13	76.0		0.2	
	E0023037	BSLN		11JUN2003	16:30	-7	22	16	62.0		0.4	
		FINAL	*	24JUN2003	16:30	7	21	16	55.0		0.4	
		FINAL		15AUG2003	9:30	59	28	21	76.0		0.4	
	E0023038	BSLN		20JUN2003	12:45	-10	25	26	64.0		0.3	
		FINAL		16SEP2003	18:30	79	21	19	72.0		0.2	
	E0023044	BSLN		08JUL2003	14:00	-8	20	19	130.0	H	0.2	
		FINAL		12AUG2003	12:00	28	19	19	143.0	H	0.2	
	E0023045	BSLN		10JUL2003	11:40	-7	18	18	71.0		0.8	
		FINAL		15SEP2003	11:00	61	16	9	80.0		0.5	
	E0025002	BSLN		27MAR2003	11:05	-7	26	37	67.0		0.4	
		FINAL		29MAY2003	11:40	57	28	73H	103.0		0.4	
	E0026010	BSLN		15JAN2003	14:00	-7	24	24	54.0		1.7	H
		FINAL		30JAN2003	16:30	9	19	23	55.0		0.8	
	E0026017	BSLN		26FEB2003	11:50	-8	96H	128H	109.0		0.5	
		FINAL		21MAR2003	11:10	16	28	35	105.0		0.5	
	E0026018	BSLN		06MAR2003	16:30	-14	33	56H	84.0		0.1	L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	FINAL	15MAY2003	14:15	57	49H	70H	81.0		0.3
	E0026025	BSLN	01MAY2003	11:40	-8	14	15	55.0		0.3
		FINAL	03JUL2003	9:30	56	34	26	76.0		0.4
	E0026029	BSLN	02JUL2003	11:10	-7	17	16	80.0		0.9
		FINAL	28JUL2003	13:30	20	21	16	74.0		0.9
	E0026030	BSLN	02JUL2003	11:50	-7	47H	55H	79.0		0.6
		FINAL	03SEP2003	17:10	57	56H	79H	103.0		0.3
	E0026031	BSLN	10JUL2003	14:00	-11	21	18	78.0		0.6
		FINAL	15SEP2003	11:15	57	14	12	59.0		0.4
	E0027003	BSLN	08JAN2003	14:40	-20	26	37	220.0	H	0.2
		FINAL	25MAR2003	11:55	57	23	26	218.0	H	0.2
	E0028004	BSLN	27SEP2002	9:45	-3	17	13	87.0		1.2
		FINAL	09OCT2002	14:30	10	18	15	82.0		0.7
	E0028006	BSLN	01OCT2002	10:00	-3	27	21	61.0		0.6
		FINAL	04DEC2002	10:15	62	23	18	58.0		0.7
	E0028008	BSLN	08OCT2002	12:45	-7	41	50H	95.0		0.3
		FINAL	10DEC2002	12:30	57	20	27	93.0		0.3
	E0028009	BSLN	10OCT2002	10:45	-5	25	26	64.0		0.4
		FINAL	12DEC2002	13:50	59	37H	61H	79.0		0.3
	E0028016	BSLN	07NOV2002	10:15	-7	20	16	50.0		0.4
		FINAL	09JAN2003	11:50	57	14	17	54.0		0.3
	E0028017	*	12NOV2002	9:45		65H	76H	94.0		0.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	BSLN		14JAN2003	10:15	-7	15	13	90.0		0.4	
	E0028029	BSLN		28JAN2003	10:00	-7	24	25	57.0		0.6	
		FINAL		04APR2003	10:55	60	29	33	68.0		0.6	
	E0028034	BSLN		20MAR2003	9:40	-12	25	47	93.0		0.4	
		FINAL		02JUN2003	12:54	63	24	38	87.0		0.6	
	E0028038	BSLN		18APR2003	10:20	-7	23	36	80.0		0.3	
		FINAL		18JUN2003	13:45	55	33	68H	88.0		0.5	
	E0028043	BSLN		29MAY2003	11:55	-7	26	43	66.0		2.0	H#
		FINAL	*	12JUN2003	8:50	8					2.0	H#
		FINAL		29JUL2003	8:25	55	22	35	68.0		2.3	H#
	E0028045	BSLN		09JUN2003	13:00	-9	23	21	101.0		0.4	
		FINAL		11SEP2003	12:50	86	24	28	124.0	H	0.3	
	E0029005	BSLN	*	14NOV2002	13:00	-13	17	13	103.0		0.3	
		BSLN		21NOV2002	10:30	-6	10	12	92.0		0.2	
		FINAL		21JAN2003	12:50	56	16	18	121.0		0.3	
	E0030001	BSLN		12NOV2002	15:15	-7	40H	30	27.0	L	0.5	
		FINAL		16JAN2003	12:07	59	22	21	33.0		0.8	
	E0030008	BSLN		07JAN2003	14:33	-7	22	25	79.0		0.4	
		FINAL		18MAR2003	10:42	64	24	37	106.0		0.8	
	E0030011	BSLN		16JAN2003	16:10	-11	30	61H	53.0		0.2	
		FINAL		24MAR2003	14:35	57	35	68H	52.0		0.3	
	E0030015	BSLN		13FEB2003	12:05	-8	20	16	74.0		0.9	
		FINAL		22APR2003	12:10	61	18	12	69.0		1.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	BSLN	10JUN2003	11:15	-6	27	42	61.0	0.5	
		FINAL	14AUG2003	15:30	60	20	23	64.0	0.4	
	E0031002	BSLN	20NOV2002	17:05	-7	20	13	52.0	0.1	L
		FINAL	23JAN2003	12:55	58	22	10	77.0	0.3	
	E0031003	BSLN	03DEC2002	16:07	-7	22	16	78.0	0.3	
		FINAL	04FEB2003	16:20	57	22	24	75.0	0.7	
	E0033015	BSLN	03APR2003	17:05	-7	18	15	40.0	0.4	
		FINAL	04JUN2003	11:00	56	35	44H	36.0	0.5	
	E0034002	BSLN	18MAR2003	9:25	-7	25	34	91.0	0.9	
		FINAL	16APR2003	14:40	23	22	34	115.0	0.7	
	E0034003	BSLN	11APR2003	10:10	-13	26	21	94.0	0.3	
		FINAL	19JUN2003	15:50	57	19	18	85.0	0.3	
	E0034006	BSLN	25APR2003	11:33	-21	17	13	89.0	0.2	
		FINAL	10JUL2003	9:54	56	22	17	84.0	0.3	
	E0034008	BSLN	16MAY2003	13:26	-8	16	15	88.0	0.5	
		FINAL	21JUL2003	10:07	59	17	15	80.0	0.3	
	E0035003	BSLN	15NOV2002	10:30	-7	52H	111H	64.0	0.8	
	E0035005	BSLN	26NOV2002	10:00	-7	22	15	50.0	0.3	
	E0035014	BSLN	28JAN2003	11:10	-6	18	12	63.0	0.5	
		FINAL	31MAR2003	9:20	57	19	12	54.0	0.2	
	E0035024	BSLN	15MAY2003	11:30	-8	20	15	68.0	0.1	L
		FINAL	18JUL2003	9:00	57	13	10	54.0	0.2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	BSLN		24JUN2003	10:45	-7	16	13	118.0		0.4
		FINAL		27AUG2003	12:45	58	15	12	105.0		0.4
	E0037002	BSLN		18DEC2002	12:10	-8	20	17	71.0		0.3
		FINAL		20FEB2003	13:25	57	28	28	84.0		0.2
	E0037005	BSLN		27FEB2003	15:00	-7	25	20	68.0		0.3
		FINAL		01MAY2003	14:15	57	45H	41H	70.0		0.3
	E0037006	BSLN		07MAR2003	12:00	-7	22	18	45.0		0.7
		FINAL		09MAY2003	12:18	57	23	17	56.0		0.7
	E0039006	BSLN	*	11NOV2002	10:05	-49	9L	12	71.0		0.2
		BSLN	*	22NOV2002	9:20	-38	12	10	71.0		0.2
		BSLN		10DEC2002	11:35	-20	12	11	70.0		0.2
		FINAL		24FEB2003	10:58	57	11	14	77.0		0.2
	E0039015	BSLN		02JAN2003	10:20	-21	18	20	95.0		0.4
		FINAL		20MAR2003	9:30	57	26	32	91.0		0.3
	E0039024	BSLN		14FEB2003	8:50	-13	25	39H	86.0		0.5
		FINAL		25APR2003	16:05	58	29	47H	89.0		0.3
	E0039025	BSLN		26FEB2003	11:00	-20	16	17	130.0	H	0.3
		FINAL		27MAY2003	10:00	71	19	27	118.0		0.2
	E0039041	BSLN		08APR2003	9:40	-7	31	34	51.0		0.5
		FINAL		11JUN2003	11:25	58	29	17	63.0		0.7
	E0039044	BSLN		06MAY2003	10:30	-16	17	30	104.0		0.3
		FINAL		23JUL2003	18:20	63	19	25	95.0		0.3
	E0039046		*	06MAY2003	11:46		22	24	94.0		0.2
			*	03JUN2003	10:25		18	18	105.0		0.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	BSLN	23MAY2003	9:30	-24	19	25	106.0		0.2
		FINAL	12AUG2003	14:45	58	18	18	105.0		0.4
	E0039053	BSLN	16JUN2003	13:25	-25	33	28	111.0		0.4
		FINAL	08SEP2003	12:45	60	27	24	123.0	H	0.6
	E0039057	BSLN	02JUL2003	19:50	-12	30	22	90.0		0.4
		FINAL	09SEP2003	9:25	58	25	19	80.0		0.3
	E0041003	BSLN	16JAN2003	17:30	-12	18	15	77.0		0.2
		FINAL	25MAR2003	9:55	57	17	21	86.0		0.4
	E0041008	BSLN	26MAR2003	15:35	-12	17	19	94.0		0.4
		FINAL	02JUN2003	15:30	57	22	17	85.0		0.2
	E0042001	BSLN	17JUN2003	9:45	-15	18	19	104.0		0.5
		FINAL	26AUG2003	10:50	56	17	17	115.0		0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN		26FEB2003	14:25	-14	29	35	50.0		0.4	
		FINAL		07MAY2003	13:45	57	29	31	67.0		0.4	
	E0003018	BSLN		06MAY2003	16:22	-7	18	9	52.0		0.5	
		FINAL		08JUL2003	14:18	57	18	7	50.0		0.4	
	E0005011	BSLN	*	17OCT2002	15:00	-7	23	28	90.0		2.2	H#
		BSLN		22OCT2002	16:30	-2	21	29	86.0		1.0	
	E0005030	BSLN		18MAR2003	14:00	-8	16	7	75.0		0.4	
	E0005036	BSLN		28APR2003	13:30	-8	18	17	56.0		0.5	
		FINAL		27MAY2003	10:00	22	16	14	60.0		0.4	
	E0006015	BSLN		07FEB2003	9:30	-4	15	9	55.0		0.4	
		FINAL		08APR2003	12:00	57	18	19	60.0		0.2	
	E0006016	BSLN		07FEB2003	12:55	-10	23	27	64.0		0.6	
		FINAL		18APR2003	12:15	61	23	17	63.0		0.6	
	E0007008	BSLN		08APR2003	9:55	-10	17	17	49.0		0.4	
		FINAL		02JUL2003	14:00	76	16	20	48.0		0.2	
		FINAL	*	12AUG2003	11:30	117	17	22	46.0		0.3	
	E0009002	BSLN		30OCT2002	11:45	-20	19	43	99.0		1.8	H#
		FINAL		15JAN2003	13:47	58	20	35	91.0		1.3	H
	E0009006	BSLN		23JAN2003	17:50	-5	76H	33	86.0		0.3	
		FINAL		25MAR2003	16:20	57	36	63H	85.0		0.2	
	E0009009	BSLN		27FEB2003	15:00	-13	17	25	100.0		0.4	
		FINAL		24MAR2003	13:40	13	19	25	108.0		0.2	
	E0010015	BSLN		30JAN2003	10:35	-21	31	55H	134.0	H	0.6	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	FINAL		15APR2003	13:29	55	27	47	134.0	H	0.7
	E0011004	BSLN		17DEC2002	11:00	-7	18	20	93.0		0.3
		FINAL		18FEB2003	9:00	57	19	15	89.0		0.5
	E0011007	BSLN		12DEC2002	10:43	-7	21	29	114.0		0.3
		FINAL		13FEB2003	8:00	57	29	45H	122.0	H	0.2
	E0011018	BSLN		15MAY2003	12:30	-7	30	35	107.0		0.4
		FINAL		17JUL2003	17:30	57	14	17	87.0		0.3
	E0011024	BSLN		17JUN2003	12:10	-7	19	13	80.0		0.6
		FINAL		21AUG2003	13:00	59	18	13	83.0		0.4
	E0015003	BSLN		13NOV2002	12:20	-12	25	27	112.0		0.4
		FINAL		02DEC2002	10:55	8	38H	52H	114.0		0.2
	E0019003	BSLN		30OCT2002	9:10	-22	22	22	90.0		0.4
		FINAL		16JAN2003	11:25	57	21	22	89.0		0.6
	E0019007	BSLN		06NOV2002	10:32	-7	36	33	90.0		0.5
		FINAL		07JAN2003	8:30	56	36	42H	91.0		0.4
	E0019014	BSLN	*	17DEC2002	11:02	-23	21	22	120.0		0.6
		BSLN		26DEC2002	10:25	-14	17	16	111.0		0.4
		FINAL		22JAN2003	9:00	14	21	14	117.0		0.4
	E0019018	BSLN	*	14JAN2003	10:45	-16		70H			
		BSLN		14JAN2003	10:45	-16	34		98.0		0.6
		BSLN		23JAN2003	9:10	-7		56H			
		FINAL		27MAR2003	9:30	57	29	61H	101.0		0.6
	E0019022	BSLN		23JAN2003	12:00	-7	52H	77H	120.0		0.4
		FINAL		27MAR2003	15:10	57	31	48H	128.0	H	0.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	BSLN		20FEB2003	10:50	-7	14	13	102.0		0.3
	E0019032	BSLN		06MAR2003	14:50	-26	59H	30	39.0		0.2
		FINAL		28MAY2003	11:00	58	25	17	77.0		0.3
	E0019034	BSLN		10MAR2003	16:55	-8	16	13	72.0		0.2
	E0019036	BSLN		18MAR2003	9:15	-7	22	28	77.0		0.3
	E0019039	BSLN		22APR2003	11:00	-9	26	26	70.0		0.7
		FINAL		08MAY2003	15:30	8	30	31	62.0		0.6
	E0019041	BSLN		14MAY2003	10:50	-7	23	18	56.0		0.7
		FINAL		16JUL2003	11:10	57	16	14	57.0		0.4
	E0019049	BSLN		03JUL2003	13:40	-7	27	19	105.0		0.8
		FINAL		08SEP2003	12:10	61	24	22	111.0		0.5
	E0022052	BSLN		01APR2003	10:50	-9	22	19	96.0		0.6
		FINAL		05JUN2003	9:32	57	21	26	91.0		0.6
	E0022064	BSLN		01MAY2003	10:40	-5	22	24	110.0		1.0
		FINAL		01JUL2003	12:30	57	20	24	97.0		0.5
	E0022073	BSLN		20JUN2003	14:10	-6	16	13	51.0		0.7
		FINAL		21AUG2003	9:45	57	22	19	63.0		0.4
	E0023002	BSLN		25OCT2002	16:00	-11	20	13	44.0		0.4
	E0023017	BSLN		20MAR2003	11:00	-5	16	18	102.0		0.6
		FINAL		22MAY2003	12:30	59	21	13	128.0	H	0.5
	E0023021	BSLN	*	10APR2003	10:20	-13	57H	78H	187.0	H	0.4
		BSLN		16APR2003	15:00	-7	32	55H	183.0	H	0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	FINAL		17JUN2003	16:00	56	31	53H	183.0	H	0.4	
	E0023027	BSLN		07MAY2003	13:30	-9	23	24	76.0		0.3	
		FINAL		09JUL2003	13:00	55	24	30	70.0		0.4	
	E0023030	BSLN		21MAY2003	10:00	-13	15	21	56.0		0.5	
		FINAL		30JUL2003	15:30	58	19	25	63.0		0.4	
	E0023040	BSLN		25JUN2003	15:00	-8	21	25	61.0		0.4	
		FINAL		05SEP2003	10:00	65	22	15	75.0		0.2	
	E0026014	BSLN		12FEB2003	11:40	-7	32	42	114.0		0.6	
		FINAL		19MAR2003	10:35	29	31	40	109.0		0.3	
	E0026019	BSLN		10MAR2003	11:45	-7	15	17	71.0		0.3	
		FINAL		12MAY2003	9:10	57	21	19	83.0		0.3	
	E0027005	BSLN		19DEC2002	14:50	-7	22	14	121.0		0.3	
		FINAL		20FEB2003	11:28	57	22	26	148.0	H	0.4	
	E0029009	BSLN		13JAN2003	12:50	-7	20	22	56.0		0.4	
		FINAL		18MAR2003	9:05	58	16	17	61.0		0.4	
	E0029021	BSLN	*	03MAR2003	10:40	-15	36	85H	101.0		1.0	
		BSLN		18MAR2003	9:50	1	27	45H	85.0		1.4	H
		FINAL		15MAY2003	12:30	59	46H	87H	130.0	H	0.6	
		FINAL	*	27MAY2003	8:40	71	30	63H	108.0		1.3	H
	E0029026	BSLN		07APR2003	9:10	-7	18	19	64.0		0.5	
		FINAL		10JUN2003	15:00	58	20	18	68.0		0.7	
	E0029030	BSLN	*	13MAY2003	11:20	-14	90H	119H	69.0		0.5	
		BSLN		20MAY2003	12:55	-7	72H	97H	71.0		0.4	
		FINAL		23JUL2003	17:25	58	81H	101H	75.0		0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0031008	BSLN		05FEB2003	11:40	-23	16	23	86.0		0.2	
		FINAL		24APR2003	13:17	56	18	13	69.0		0.3	
	E0031020	BSLN		14APR2003	10:35	-7	16	24	118.0		0.5	
		FINAL		13MAY2003	10:50	23	20	28	124.0	H	0.5	
	E0031021	BSLN		18APR2003	10:40	-7	26	17	116.0		0.4	
		FINAL		19JUN2003	10:40	56	32	23	106.0		0.1	L
	E0031029	BSLN		05JUN2003	10:45	-13	26	26	64.0		0.4	
	E0033002	BSLN		23DEC2002	12:15	-18	30	28	65.0		0.4	
		FINAL		07MAR2003	11:25	57	26	35	72.0		0.5	
	E0033006	BSLN		15JAN2003	10:25	-8	20	19	63.0		0.5	
		FINAL		12FEB2003	12:30	21	17	18	70.0		0.3	
	E0033021	BSLN		25JUN2003	14:40	-7	25	17	64.0		0.8	
		FINAL		18AUG2003	16:20	48	25	17	64.0		0.6	
	E0035013	BSLN		27JAN2003	10:30	-8	20	18	99.0		0.1	L
		FINAL		10FEB2003	11:05	7	18	19	96.0		0.3	
	E0035015	BSLN		03FEB2003	10:30	-8	70H	85H	107.0		0.4	
		FINAL		18FEB2003	11:20	8	32	37	105.0		0.4	
	E0035016	BSLN		10MAR2003	11:00	-25	21	24	121.0		0.4	
	E0035023	BSLN		06MAY2003	10:30	-7	16	11	70.0		0.7	
	E0039052	BSLN	*	29MAY2003	10:25	-22	30	24	96.0		0.4	
		BSLN		13JUN2003	12:10	-7	23	22	87.0		0.4	
	E0039056	BSLN		01JUL2003	12:50	-14	20	18	95.0		0.6	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	BSLN	09JUL2003	14:00	-10	15	14	76.0	0.3
		FINAL	12SEP2003	11:00	56	17	15	100.0	0.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	18	18	140.0	H	0.5	
		FINAL	02MAY2003	10:30	61	20	18	131.0	H	0.4	
	E0002011	BSLN	16APR2003	11:30	-13	45H	32	52.0		0.3	
		FINAL	25JUN2003	11:20	58	27	25	83.0		0.4	
	E0003010	BSLN	28JAN2003	9:10	-6	28	19	84.0		0.5	
		FINAL	31MAR2003	16:20	57	38H	32	132.0	H	0.4	
	E0003011	BSLN	28JAN2003	11:47	-7	17	19	59.0		0.4	
	E0003016	BSLN	01MAY2003	11:40	-21	25	26	54.0		0.3	
		FINAL	13JUN2003	8:45	23	21	20	48.0		0.4	
	E0003019	BSLN	19JUN2003	11:30	-8	24	22	59.0		0.7	
		FINAL	21AUG2003	8:50	56	28	25	87.0		0.4	
	E0003020	BSLN	27JUN2003	8:55	-26	26	30	64.0		0.6	
		FINAL	17SEP2003	15:00	57	24	19	84.0		0.6	
	E0004001	BSLN	23SEP2002	11:00	-7	14	8	54.0		1.2	
		FINAL	05NOV2002	13:30	37	14	9	56.0		2.1	H#
	E0004009	BSLN	17DEC2002	10:10	-9	16	13	74.0		0.2	
		FINAL	19FEB2003	16:00	56	18	14	102.0		0.3	
	E0004012	BSLN	07JAN2003	12:45	-7	25	18	78.0		0.6	
		FINAL	11MAR2003	11:35	57	25	13	90.0		1.1	
	E0004015	BSLN	06FEB2003	10:05	-14	26	44	158.0	H	0.7	
		FINAL	15APR2003	9:10	55	26	37	157.0	H	0.5	
	E0005003	BSLN	23SEP2002	15:00	-9	17	18	43.0		0.4	
		FINAL	26NOV2002	13:25	56	29	32	47.0		0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	BSLN		24SEP2002	15:20	-6	17	18	88.0	0.5	
	E0005007	BSLN		02OCT2002	12:40	-7	64H	88H	81.0	0.6	
		FINAL		04DEC2002	14:20	57	84H	136H#	76.0	0.2	
		FINAL	*	14JAN2003	10:50	98	54H	75H			
	E0005008	BSLN		08OCT2002	18:00	-7	22	28	82.0	0.5	
		FINAL		11DEC2002	16:00	58	26	32	92.0	0.5	
	E0005009	BSLN	*	09OCT2002	10:00	-20	49H	119H	75.0		
		BSLN		09OCT2002	10:00	-20				0.5	
		BSLN		22OCT2002	9:30	-7	23	60H	84.0		
	E0005010	BSLN		14OCT2002	13:00	-7	20	19	95.0	0.2	
		FINAL		17DEC2002	14:25	58	15	17	101.0	0.2	
		FINAL	*	23DEC2002	16:00	64	10	13	102.0	0.2	
	E0005012	BSLN		24OCT2002	7:00	-21	25	40	76.0	0.3	
		FINAL		07JAN2003	11:00	55	20	22	119.0	0.3	
	E0005014	BSLN		05NOV2002	16:30	-8	19	19	99.0	1.5	H
		FINAL		06JAN2003	10:00	55	25	24	91.0	0.8	
	E0005022	BSLN		27JAN2003	10:30	-2	20	28	70.0	0.9	
		FINAL		11MAR2003	10:10	42	33	25	72.0	1.1	
	E0005025	BSLN		20FEB2003	13:20	-7	21	37	67.0	0.5	
		FINAL		03APR2003	11:30	36	24	34	68.0	0.6	
	E0006019	BSLN		26MAR2003	11:35	-12	20	15	88.0	0.4	
		FINAL		03JUN2003	12:00	58	20	15	81.0	0.6	
	E0007005	BSLN		27JAN2003	14:30	-4	21	16	66.0	0.4	
		FINAL		28MAR2003	13:30	57	21	17	86.0	0.3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	FINAL	*	11APR2003	11:00	71	15	13	82.0		0.4	
	E0007015	BSLN		10JUL2003	7:35	-6	24	17	84.0		0.6	
		FINAL		10SEP2003	7:40	57	24	20	76.0		0.3	
	E0009001	BSLN		29OCT2002	15:30	-14	22	28	43.0		0.2	
	E0010002	BSLN		14NOV2002	10:36	-11	18	22	81.0		0.4	
		FINAL		02DEC2002	9:05	8	18	24	89.0		0.3	
	E0010009	BSLN		18DEC2002	9:42	-8	30	22	88.0		0.2	
		FINAL		19FEB2003	13:59	56	34	44H	97.0		0.2	
	E0010010	BSLN		20DEC2002	8:45	-10	17	12	69.0		0.6	
		FINAL		13JAN2003	10:28	15	18	18	75.0		0.5	
	E0010014	BSLN		14JAN2003	9:05	-14	18	15	65.0		0.6	
		FINAL		25MAR2003	11:05	57	24	20	60.0		0.3	
	E0010017	BSLN		05FEB2003	8:51	-20	18	14	48.0		0.5	
		FINAL		22APR2003	10:20	57	20	14	60.0		0.7	
	E0010023	BSLN		10APR2003	9:22	-7	22	22	63.0		0.6	
		FINAL		01MAY2003	10:19	15	26	20	64.0		0.3	
	E0010027	BSLN		05JUN2003	9:10	-11	54H	88H	109.0		0.7	
		FINAL		01JUL2003	13:00	16	58H	70H	125.0	H	0.9	
	E0010029	BSLN		10JUN2003	9:25	-9	21	39	65.0		0.3	
	E0011022	BSLN		02JUN2003	11:00	-7	17	23	92.0		0.5	
		FINAL		05AUG2003	10:30	58	12	22	86.0		0.1	L
	E0013006	BSLN		06MAR2003	10:15	-7	20	25	108.0		0.6	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	FINAL	24MAR2003	12:42	12	25	32	114.0		0.4	
	E0013012	BSLN	29APR2003	9:48	-8	28	31	111.0		0.5	
		FINAL	02JUL2003	10:05	57	29	37	141.0	H	0.4	
	E0013014	BSLN	08MAY2003	11:15	-26	19	19	57.0		1.1	
		FINAL	30JUN2003	12:21	28	24	25	66.0		0.7	
	E0014005	BSLN	04MAR2003	17:20	-7	17	14	80.0		0.3	
		FINAL	06MAY2003	12:20	57	19	21	83.0		0.4	
	E0014007	BSLN	25MAR2003	17:50	-7	19	14	91.0		0.4	
		FINAL	22APR2003	13:50	22	20	12	83.0		0.5	
	E0014011	BSLN	06MAY2003	16:45	-7	19	25	67.0		0.4	
		FINAL	08JUL2003	15:50	57	17	22	69.0		0.7	
	E0014012	BSLN	19MAY2003	10:05	-8	21	21	73.0		0.4	
		FINAL	24JUN2003	18:40	29	20	21	95.0		0.1	L
	E0015001	BSLN	11NOV2002	9:10	-18	21	48	85.0		0.3	
		FINAL	20JAN2003	7:30	53	19	28	105.0		0.3	
	E0015008	BSLN	13DEC2002	9:30	-6	22	23	111.0		0.4	
	E0016003	BSLN	10JAN2003	9:30	-14	16	17	98.0		0.3	
	E0016005	BSLN	21FEB2003	8:45	-4	17	24	60.0		0.5	
		FINAL	22APR2003	8:30	57	25	24	62.0		0.3	
	E0018007	BSLN	16DEC2002	10:15	-11	16	13	82.0		0.3	
		FINAL	10JAN2003	14:15	15	27	30	97.0		0.2	
	E0019005	BSLN	30OCT2002	11:50	-6	26	21	92.0		0.7	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	FINAL	02JAN2003	14:00	59	21	17	107.0	0.4
	E0019015	BSLN	19DEC2002	10:49	-14	19	14	117.0	0.5
		FINAL	27FEB2003	11:23	57	18	24	120.0	0.4
	E0020004	BSLN	21NOV2002	15:20	-18	25	26	93.0	0.5
		FINAL	22JAN2003	16:15	45	15	18	75.0	0.4
		FINAL *	24FEB2003	11:50	78	18	22	73.0	0.5
	E0020010	BSLN	31JAN2003	9:15	-5	24	16	49.0	0.5
		FINAL	02APR2003	10:30	57	36	22	57.0	0.3
	E0020014	BSLN	11MAR2003	10:00	-7	22	13	97.0	0.6
		FINAL	12MAY2003	11:15	56	21	12	107.0	0.4
	E0020021	BSLN	13MAY2003	9:45	-6	34	37	69.0	0.4
		FINAL	14JUL2003	13:25	57	31	30	86.0	0.2
	E0020023	BSLN	09JUN2003	19:05	-8	25	25	87.0	0.2
		FINAL	11AUG2003	11:40	56	18	18	100.0	0.4
	E0022007	BSLN	01NOV2002	10:23	-6	14	10	67.0	0.2
	E0022010	BSLN	15NOV2002	10:40	-6	27	29	87.0	0.5
		FINAL	16JAN2003	18:00	57	30	29	94.0	0.3
	E0022012	BSLN	29NOV2002	15:40	-6	21	28	71.0	1.2
		FINAL	30JAN2003	12:00	57	22	31	68.0	0.8
	E0022019	BSLN	06DEC2002	10:10	-5	23	32	69.0	0.9
		FINAL	06FEB2003	11:20	58	20	25	66.0	0.6
	E0022025	BSLN	08JAN2003	10:10	-20	21	17	60.0	0.3
		FINAL	04FEB2003	11:30	8	23	29	68.0	0.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	BSLN	12FEB2003	10:05	-6	15	14	43.0		0.4	
		FINAL	15APR2003	12:10	57	23	18	47.0		0.3	
	E0022034	BSLN	12FEB2003	12:40	-6	56H	102H	97.0		0.5	
		FINAL	15APR2003	14:00	57	49H	94H	100.0		0.5	
	E0022038	BSLN	21FEB2003	11:05	-7	23	17	48.0		0.8	
		FINAL	14APR2003	9:40	46	29	21	48.0		0.6	
	E0022039	BSLN	27FEB2003	11:15	-7	16	17	86.0		0.3	
		FINAL	01MAY2003	12:50	57	25	31	101.0		0.3	
	E0022046	BSLN	14MAR2003	8:00	-6	30	35	127.0	H	0.5	
		FINAL	16MAY2003	8:05	58	21	24	144.0	H	0.2	
	E0022048	BSLN	26MAR2003	9:58	-6	21	7	59.0		0.2	
	E0022051	BSLN	01APR2003	10:15	-6	18	16	69.0		0.4	
		FINAL	02JUN2003	10:45	57	22	20	71.0		0.3	
	E0022053	BSLN	04APR2003	12:50	-7	15	13	85.0		0.4	
	E0022058	BSLN	14APR2003	10:25	-7	16	20	50.0		0.4	
		FINAL	22MAY2003	14:00	32	42	67H	51.0		0.3	
	E0022061	BSLN	25APR2003	9:37	-5	29	34	78.0		0.3	
		FINAL	26JUN2003	12:30	58	25	43H	93.0		0.4	
	E0022062	BSLN	28APR2003	7:43	-7	18	30	69.0		0.7	
		FINAL	23MAY2003	7:40	19	23	33	84.0		0.6	
	E0022068	BSLN	14MAY2003	10:23	-9	16	18	43.0		1.9	H#
	E0022069	BSLN	04JUN2003	7:40	-6	20	13	75.0		0.6	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	FINAL		05AUG2003	9:45	57	14	13	77.0		0.1	L
	E0022071	BSLN		16JUN2003	11:40	-14	33	45	110.0		1.9	H#
		FINAL		26AUG2003	9:33	58	26	44	100.0		1.1	
	E0023003	BSLN	*	08NOV2002	16:00	-39	20	22	84.0		0.6	
		BSLN		12DEC2002	10:00	-5	18	16	71.0		0.4	
		FINAL		11FEB2003	14:00	57	18	17	81.0		0.3	
	E0023006	BSLN		10DEC2002	10:30	-7	24	31	80.0		0.4	
		FINAL		11FEB2003	11:50	57	24	35	75.0		0.6	
	E0023010	BSLN		28JAN2003	9:30	-7	22	27	117.0		0.5	
		FINAL		31MAR2003	10:00	56	24	29	143.0	H	0.3	
	E0023025	BSLN		01MAY2003	15:00	-14	27	18	127.0	H	0.6	
		FINAL		10JUL2003	13:30	57	23	20	97.0		0.8	
	E0023039	BSLN		24JUN2003	13:30	-7	21	13	60.0		0.5	
		FINAL		26AUG2003	13:30	57	33	42H	84.0		0.2	
	E0026002	BSLN		05NOV2002	10:15	-7	16	17	113.0		0.3	
		FINAL		09JAN2003	9:25	59	13	12	113.0		0.4	
	E0026007	BSLN		06JAN2003	10:30	-10	16	17	45.0		0.3	
		FINAL		12MAR2003	14:25	56	25	44H	45.0		0.4	
	E0026013	BSLN		05FEB2003	12:20	-8	21	16	109.0		0.3	
		FINAL		14APR2003	10:00	61	15	23	89.0		0.1	L
	E0028007	BSLN		01OCT2002	10:30	-3	15	14	73.0		0.4	
		FINAL		14NOV2002	12:45	42	13	9	48.0		0.2	
	E0028023	BSLN		15JAN2003	10:00	-6	23	14	86.0		0.2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	FINAL		27JUN2003	15:00	158	30	23	88.0		0.2
	E0028025	BSLN		08JAN2003	12:07	-5	52H	42	61.0		0.5
		FINAL		27JAN2003	9:25	15	18	20	76.0		0.6
	E0028033	BSLN		18MAR2003	10:50	-9	14	12	49.0		0.5
		FINAL		22MAY2003	10:50	57	23	29	81.0		0.4
	E0028035	BSLN		27MAR2003	12:00	-7	22	38	67.0		0.3
		FINAL		29MAY2003	15:40	57	23	41	66.0		0.5
	E0028037	BSLN	*	18APR2003	8:30	-56	20	24	108.0		0.5
		BSLN	*	24APR2003	7:50	-50	22	21	120.0		0.5
		BSLN		04JUN2003	8:33	-9	33	34	77.0		0.4
		FINAL		08AUG2003	15:30	57	55H	44	64.0		0.5
	E0028039	BSLN		05MAY2003	7:10	-4	16	13	122.0	H	0.9
		FINAL		05JUN2003	12:30	28	21	15	121.0		0.3
	E0028046	BSLN		17JUN2003	13:45	-8	19	12	61.0		0.3
	E0028048	BSLN		11JUL2003	14:00	-6	21	17	74.0		0.5
	E0029008	BSLN		09DEC2002	11:40	-7	23	20	53.0		0.2
	E0029011	BSLN		14JAN2003	11:20	-8	18	26	81.0		0.6
	E0029012	BSLN		04FEB2003	10:05	-7	20	20	82.0		0.6
		FINAL		27MAR2003	8:45	45	15	12	79.0		0.3
	E0029015	BSLN		11FEB2003	10:05	-13	20	14	89.0		0.3
		FINAL		14MAR2003	10:30	19	16	14	86.0		0.2
	E0029018	BSLN	*	26FEB2003	16:25	-8	23	18	95.0		0.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0029018	BSLN		06MAR2003	16:05	1	18	21	95.0	0.3	
	E0030014	BSLN		14FEB2003	10:35	-7	35	23	39.0	0.7	
		FINAL		22APR2003	12:50	61	35	29	45.0	0.7	
	E0030020	BSLN		13MAY2003	15:30	-16	36	56H	87.0	0.7	
	E0030024	BSLN		17JUN2003	15:35	-24	17	14	92.0	0.6	
		FINAL		18JUL2003	15:35	8	29	41H	116.0	0.6	
	E0030025	BSLN	*	24JUN2003	16:35	-17	25	15	98.0	0.3	
		BSLN		07JUL2003	10:20	-4	21	14	87.0	0.4	
		FINAL		19AUG2003	16:45	40	22	8	85.0	0.3	
	E0031027	BSLN		28MAY2003	9:10	-6	19	17	47.0	0.7	
		FINAL		29JUL2003	14:40	57	17	17	56.0	1.4	H
	E0031030	BSLN		17JUN2003	10:46	-7	21	12	53.0	0.3	
		FINAL		21AUG2003	11:10	59	22	18	52.0	0.3	
	E0033012	BSLN		05FEB2003	15:26	-5	15	14	101.0	0.2	
	E0034001	BSLN		17MAR2003	10:03	-3	23	17	79.0	0.5	
		FINAL		15MAY2003	9:55	57	21	15	79.0	0.3	
	E0034004	BSLN		11APR2003	11:15	-10	23	35	87.0	0.3	
		FINAL		16JUN2003	12:03	57	41	83H	83.0	0.4	
	E0035001	BSLN		12NOV2002	11:40	-8	16	11	64.0	0.3	
		FINAL		14JAN2003	9:05	56	15	12	100.0	0.4	
	E0035006	BSLN		03DEC2002	10:45	-9	47H	40H	62.0	0.7	
		FINAL		06FEB2003	9:30	57	44H	35	70.0	0.3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	BSLN	18APR2003	10:45	-7	17	21	75.0	0.3	
		FINAL	20JUN2003	8:15	57	14	13	65.0	0.5	
	E0036002	BSLN	10JUN2003	13:45	-7	14	14	59.0	0.5	
		FINAL	15JUL2003	10:05	29	13	13	64.0	0.3	
	E0036006	BSLN	24JUN2003	16:45	-9	20	28	109.0	0.3	
		FINAL	28AUG2003	9:50	57	36	49H	102.0	0.4	
	E0036007	BSLN	27JUN2003	10:00	-6	15	15	89.0	0.2	
		FINAL	18JUL2003	9:15	16	21	17	84.0	0.6	
	E0037009	BSLN	12MAY2003	9:15	-4	16	8	77.0	0.1	L
		FINAL	10JUL2003	16:05	56	38H	38H	86.0	0.6	
	E0039011	BSLN	16DEC2002	17:40	-17	16	19	61.0	0.4	
	E0039018	BSLN	15JAN2003	9:10	-8	21	32	77.0	0.4	
	E0039026	BSLN	03MAR2003	9:05	-4	23	19	59.0	0.3	
		FINAL	02MAY2003	9:20	57	27	29	84.0	0.3	
	E0039028	BSLN	03MAR2003	14:15	-21	17	27	59.0	0.4	
		FINAL	16MAY2003	12:25	54	23	27	81.0	0.4	
	E0039032	BSLN	07MAR2003	13:45	-7	17	17	78.0	0.2	
		FINAL	04APR2003	11:45	22	19	15	84.0	0.3	
	E0039034	BSLN	12MAR2003	20:05	-7	19	11	91.0	0.6	
		FINAL	14MAY2003	15:00	57	20	25	108.0	0.5	
	E0039042	BSLN	25APR2003	10:15	-12	26	18	70.0	0.4	
		FINAL	02JUL2003	12:50	57	20	31	88.0	0.3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	BSLN	27JAN2003	10:15	-3	32	39	82.0	1.0
		FINAL	31MAR2003	12:00	61	21	32	76.0	0.5
	E0041009	BSLN	22APR2003	15:15	-9	20	11	70.0	0.8
		FINAL	16JUN2003	13:00	47	11	8	78.0	0.6
	E0042002	BSLN	02JUL2003	12:10	-7	23	40	94.0	0.4
		FINAL	02SEP2003	10:25	56	32	65H	94.0	0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN		23JUN2003	10:00	-18	20	23	58.0	0.9
		FINAL		25JUL2003	9:00	15	26	30	69.0	0.6
	E0003002	BSLN		22OCT2002	11:05	-7	18	14	111.0	0.5
		FINAL		23DEC2002	15:35	56	23	12	100.0	0.3
	E0005031	BSLN		26MAR2003	12:30	-7	16	11	57.0	0.3
	E0005033	BSLN		08APR2003	14:00	-8	55H	85H	62.0	0.6
		FINAL		06MAY2003	11:20	21	49H	72H	62.0	0.3
		FINAL	*	28MAY2003	11:30	43	39H	58H		
	E0005038	BSLN		05MAY2003	11:40	-9	34	54H	72.0	0.4
		FINAL		05JUN2003	13:00	23	59H	84H	75.0	0.3
	E0007009	BSLN		14APR2003	7:48	-3	22	9	73.0	0.3
	E0009010	BSLN		27FEB2003	16:55	-14	20	12	101.0	0.7
	E0009011	BSLN		28APR2003	14:17	-8	29	40	81.0	0.3
		FINAL		03JUL2003	15:40	59	27	28	109.0	0.3
	E0010005	BSLN		11DEC2002	10:15	-7	34	56H	91.0	0.4
	E0011016	BSLN		14APR2003	10:00	-7	25	38	104.0	0.5
		FINAL		16JUN2003	9:45	57	32	57H	120.0	0.4
	E0011020	BSLN		01MAY2003	9:20	-7	37	51H	109.0	1.2
		FINAL		15MAY2003	17:00	8	41	57H	89.0	1.0
	E0018002	BSLN		15NOV2002	15:35	-14	28	28	59.0	0.6
		FINAL		22JAN2003	16:20	55	18	18	73.0	0.5
	E0018003	BSLN		19NOV2002	13:05	-7	17	20	101.0	0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	FINAL		10DEC2002	11:00	15	19	20	112.0		0.7
	E0018013	BSLN		17JAN2003	14:15	-7	19	26	83.0		0.5
		FINAL		06FEB2003	16:10	14	20	20	82.0		0.7
	E0019002	BSLN		29OCT2002	10:45	-14	13	13	80.0		0.4
	E0019008	BSLN	*	06NOV2002	12:35	-15	20	34	111.0		0.3
		BSLN		13NOV2002	10:30	-8	25	39H	117.0		0.3
	E0019009	BSLN		06NOV2002	13:35	-8	21	13	65.0		0.6
	E0019016	BSLN		30DEC2002	16:55	-7	21	22	71.0		0.5
		FINAL		03MAR2003	16:00	57	21	32	81.0		0.4
	E0019020	BSLN		16JAN2003	10:10	-7	15	8	70.0		0.7
		FINAL		27MAR2003	10:50	64	16	5L	66.0		0.3
	E0019021	BSLN		16JAN2003	11:45	-14	37	66H	65.0		0.3
		FINAL		03MAR2003	13:18	33	26	46	72.0		0.6
	E0019024	BSLN		24JAN2003	16:00	-6	20	23	98.0		0.9
		FINAL		06FEB2003	12:33	8	23	20	94.0		0.8
	E0019031	BSLN		06MAR2003	11:35	-7	30	47	82.0		0.9
		FINAL		25MAR2003	10:08	13	23	23	87.0		1.0
	E0019035	BSLN		11MAR2003	9:28	-7	13	20	132.0	H	0.4
		FINAL		17APR2003	14:30	31	37H	56H	135.0	H	0.3
	E0019040	BSLN		08MAY2003	15:25	-12	25	29	98.0		0.6
		FINAL		17JUL2003	9:50	59	26	36	77.0		0.3
	E0019042	BSLN		29MAY2003	8:50	-6	14	16	83.0		0.5

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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	FINAL		20JUN2003	8:20	17	16	17	85.0		0.4	
	E0019045	BSLN		19JUN2003	14:54	-7	20	20	58.0		0.5	
		FINAL		16JUL2003	10:15	21	16	17	65.0		0.4	
	E0020024	BSLN		12JUN2003	15:40	-11	17	19	149.0	H	0.8	
		FINAL		20AUG2003	18:45	59	46H	78H	144.0	H	0.5	
		FINAL	*	25AUG2003	14:20	64	51H	100H	149.0	H		
	E0022044	BSLN		12MAR2003	9:50	-6	15	18	84.0		0.7	
		FINAL		12MAY2003	9:55	56	23	20	89.0		0.5	
	E0023007	BSLN		07JAN2003	14:30	-7	24	17	103.0		0.4	
		FINAL		13MAR2003	15:00	59	24	16	92.0		0.3	
	E0023011	BSLN		28JAN2003	11:45	-7	12	21	77.0		0.3	
		FINAL		01APR2003	12:00	57	44H	53H	87.0		0.4	
	E0023014	BSLN		14FEB2003	15:00	-7	20	18	52.0		0.5	
		FINAL		25APR2003	14:00	64	21	16	87.0		1.5	H
	E0023019	BSLN		21MAR2003	14:00	-17	22	17	56.0		0.4	
		FINAL		03JUN2003	13:30	58	22	43	83.0		0.4	
	E0023022	BSLN		10APR2003	16:00	-8	23	23	66.0		0.5	
		FINAL		12JUN2003	15:40	56	32	23	58.0		0.4	
	E0023023	BSLN		17APR2003	10:00	-8	23	14	67.0		0.7	
		FINAL		01MAY2003	14:00	7	23	12	61.0		0.5	
	E0023029	BSLN		16MAY2003	14:00	-7	9L	13	52.0		0.4	
	E0023031	BSLN	*	22MAY2003	12:00	-33	105H	148H#	95.0		0.4	
		BSLN		19JUN2003	10:00	-5	70H	110H	81.0		0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	FINAL		19AUG2003	11:00	57	58H	89H	82.0	0.6
	E0023041	BSLN		03JUL2003	11:00	-6	46H	105H	106.0	0.3
		FINAL		05SEP2003	13:00	59	27	36	101.0	0.3
	E0023043	BSLN		07JUL2003	15:00	-7	20	24	70.0	0.4
		FINAL		09SEP2003	10:30	58	15	13	64.0	0.6
	E0026003	BSLN	*	25NOV2002	12:20	-9	11	24	68.0	0.4
		BSLN		02DEC2002	9:25	-2	14	51H	73.0	0.6
		FINAL		03FEB2003	10:50	62	15	48	90.0	0.7
	E0026005	BSLN		23DEC2002	12:40	-7	28	15	69.0	0.7
		FINAL		06JAN2003	15:25	8	24	19	72.0	0.3
	E0026009	BSLN		10JAN2003	10:20	-5	14	8	70.0	0.2
		FINAL		21JAN2003	9:50	7	8L	5L	71.0	0.2
	E0026015	BSLN		20FEB2003	11:30	-7	74H	85H	89.0	0.2
		FINAL		25APR2003	9:50	58	65H	56H	100.0	0.2
	E0026023	BSLN		23APR2003	10:50	-7	18	11	87.0	0.8
		FINAL		27JUN2003	12:25	59	21	16	68.0	0.6
	E0027016	BSLN	*	19MAR2003	11:55	-21	15	15	71.0	0.2
		BSLN		04APR2003	9:50	-5	17	14	75.0	0.3
		FINAL		03JUN2003	10:18	56	16	20	69.0	0.2
	E0027018	BSLN		21MAR2003	11:30	-4	14	11	84.0	0.3
		FINAL		22MAY2003	10:05	59	19	8	87.0	0.3
	E0028032	BSLN		13MAR2003	13:58	-12	21	23	60.0	0.8
		FINAL		06JUN2003	11:38	74	16	29	62.0	0.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	BSLN	28OCT2002	12:30	-7	54H	109H	102.0	0.8
		FINAL	30DEC2002	9:45	57	21	20	85.0	0.6
	E0029020	BSLN	25FEB2003	10:12	-8	38	38	100.0	0.5
	E0031005	BSLN	13DEC2002	16:00	-7	24	42H	77.0	0.4
		FINAL	14FEB2003	12:10	57	26	32	58.0	0.6
	E0031006	BSLN	31JAN2003	11:25	-18	40	38	114.0	1.2
		FINAL	15APR2003	9:25	57	31	24	113.0	0.6
	E0031010	BSLN	12FEB2003	14:50	-7	23	13	51.0	0.5
		FINAL	06MAR2003	12:50	16	20	14	54.0	0.3
	E0031011	BSLN	18FEB2003	11:50	-9	25	31	61.0	0.6
		FINAL	24APR2003	9:25	57	27	37	69.0	0.8
	E0031015	BSLN	14MAR2003	8:40	-12	21	24	80.0	0.4
		FINAL	01APR2003	11:55	7	26	28	106.0	0.5
	E0031031	BSLN	01JUL2003	10:30	-7	20	16	96.0	0.4
		FINAL	28AUG2003	10:35	52	16	14	94.0	0.4
	E0033009	BSLN	22JAN2003	13:40	-21	31	33	47.0	0.4
	E0034009	BSLN	10JUN2003	13:00	-9	19	11	68.0	0.3
		FINAL	18AUG2003	17:25	61	20	15	66.0	0.5
	E0037007	BSLN	04APR2003	11:30	-7	17	16	85.0	0.5
	E0037012	BSLN	11JUL2003	13:00	-5	13	12	102.0	0.6
		FINAL	08SEP2003	13:20	55	18	13	84.0	0.2
	E0039019	BSLN	20JAN2003	14:50	-17	21	9	91.0	0.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	FINAL	03APR2003	11:05	57	16	10	97.0	0.2
	E0039043	BSLN	28APR2003	10:15	-10	21	21	96.0	0.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	17	20	68.0	0.5
		FINAL		26FEB2003	8:45	59	17	22	47.0	0.3
	E0002003	BSLN		03JAN2003	11:50	-19	19	13	87.0	0.4
		FINAL		18MAR2003	12:10	56	20	15	77.0	0.2
	E0002004	BSLN		14JAN2003	8:15	-11	16	18	90.0	0.4
	E0002008	BSLN		14FEB2003	16:00	-11	31	37	87.0	0.2
		FINAL		23APR2003	14:25	58	21	27	65.0	0.6
	E0002016	BSLN		14JUL2003	11:00	-10	27	19	67.0	0.3
		FINAL		17SEP2003	11:15	56	22	15	71.0	0.2
	E0003008	BSLN		21JAN2003	12:45	-7	17	8	55.0	0.5
	E0004003	BSLN		02OCT2002	11:00	-8	35	59H	110.0	0.6
	E0004006	BSLN		28OCT2002	9:55	-7	18	17	85.0	0.2
		FINAL		06JAN2003	10:55	64	16	15	71.0	0.2
	E0004016	BSLN		12FEB2003	15:10	-7	20	13	69.0	0.8
		FINAL		17APR2003	17:10	58	73H	28	85.0	0.3
	E0004024	BSLN		25JUN2003	16:00	-8	18	19	84.0	0.4
		FINAL		28AUG2003	9:50	57	16	18	86.0	0.6
	E0005006	BSLN	*	24SEP2002	15:30	-9	19	18	56.0	0.4
		BSLN		03OCT2002	8:30	1	19	19	56.0	0.4
	E0005017	BSLN	*	11DEC2002	10:30	-19	23	20	52.0	0.6
		BSLN		23DEC2002	12:30	-7	17	12	42.0	0.2
		FINAL		04MAR2003	13:00	65	19	20	40.0	0.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0005019	BSLN		19DEC2002	14:00	-27	25	22	62.0	0.3	
		FINAL		23JAN2003	15:45	9	21	20	55.0	0.1	L
	E0005026	BSLN		28FEB2003	10:15	-6	20	14	51.0	0.7	
		FINAL		02APR2003	9:40	28	19	15	42.0	0.5	
	E0005039	BSLN		15MAY2003	9:00	-7	25	38H	92.0	0.4	
		FINAL		16JUL2003	8:40	56	29	41H	87.0	0.3	
	E0005043	BSLN		02JUL2003	8:30	-7	18	23	68.0	0.4	
		FINAL		03SEP2003	9:45	57	22	24	68.0	0.5	
	E0006020	BSLN		02MAY2003	13:30	-11	25	23	75.0	0.5	
		FINAL		08JUL2003	14:45	57	23	20	70.0	0.4	
		FINAL	*	10JUL2003	16:30	59	23	20	72.0	0.4	
	E0007001	BSLN	*	16DEC2002	9:25	-15	25	22	94.0	0.5	
		BSLN		26DEC2002	9:25	-5	30	29	95.0	0.4	
		FINAL		24FEB2003	8:43	56	22	28	86.0	0.5	
		FINAL	*	10MAR2003	8:54	70	25	24	91.0	0.5	
	E0007003	BSLN		13JAN2003	10:30	-17	26	23	86.0	0.2	
		FINAL		01APR2003	13:30	62	16	12	97.0	0.3	
	E0007006	BSLN		24FEB2003	11:00	-9	38	28	79.0	0.3	
		FINAL		27MAR2003	10:50	23	34	31	81.0	0.3	
	E0009004	BSLN	*	19NOV2002	12:30	-7	49H	63H	98.0	0.3	
		BSLN		25NOV2002	12:55	-1	48H	51H	95.0	0.6	
		FINAL		18DEC2002	14:50	23	52H	77H	108.0	0.4	
	E0009012	BSLN		16JUN2003	14:45	-9	18	26	72.0	0.5	
		FINAL		03JUL2003	17:45	9	24	26	88.0	0.7	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
PLACEBO (BIPOLAR I)	E0010008	BSLN		11DEC2002	9:15	-7	19	10	49.0		0.2
	E0010018	BSLN		26FEB2003	8:51	-21	9L	8	75.0		0.3
		FINAL		14MAY2003	10:45	57	13	6	60.0		0.6
	E0010028	BSLN		09JUN2003	8:46	-7	18	14	48.0		0.3
		FINAL		15JUL2003	13:50	30	20	16	49.0		0.5
	E0011008	BSLN	*	17DEC2002	12:30	-44	18	14	114.0		0.2
		BSLN		23JAN2003	9:20	-7	25	17	121.0		0.5
		FINAL		13FEB2003	12:30	15	16	8	114.0		0.4
	E0011009	BSLN		19DEC2002	10:15	-8	26	33	124.0	H	0.8
		FINAL		20FEB2003	9:00	56	25	34	131.0	H	0.3
	E0011010	BSLN		03FEB2003	10:00	-7	25	19	95.0		0.4
		FINAL		19MAR2003	8:45	38	16	19	82.0		0.4
	E0013001	BSLN		01NOV2002	8:50	-13	19	32	85.0		0.4
		FINAL		10JAN2003	10:45	58	19	24	76.0		0.6
	E0013003	BSLN		07NOV2002	9:25	-5	17	18	111.0		0.2
		FINAL		06JAN2003	13:17	56	21	24	107.0		0.5
	E0013005	BSLN		13FEB2003	11:42	-5	38	17	65.0		0.4
		FINAL		15APR2003	12:16	57	25	23	70.0		0.4
	E0013013	BSLN		01MAY2003	10:14	-5	20	10	60.0		0.2
		FINAL		30MAY2003	9:55	25	15	17	54.0		0.4
	E0014002	BSLN		19FEB2003	16:35	-7	23	18	45.0		0.3
		FINAL		10APR2003	13:05	44	26	24	47.0		0.3
	E0014004	BSLN		04MAR2003	11:40	-8	17	17	134.0	H	0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
PLACEBO (BIPOLAR I)	E0014004	FINAL		15APR2003	11:40	35	15	13	143.0	H	0.4
	E0014009	BSLN	*	15APR2003	14:45	-8	27	22	78.0		0.2
		BSLN		17APR2003	12:30	-6	20	26	77.0		0.3
		FINAL		16MAY2003	8:55	24	16	18	67.0		0.6
	E0014015	BSLN		11JUN2003	10:15	-7	14	19	83.0		0.3
	E0014017	BSLN		17JUN2003	17:00	-10	19	9	58.0		0.4
		FINAL		19AUG2003	17:05	54	17	13	64.0		0.3
	E0014018	BSLN		24JUN2003	16:35	-7	22	13	84.0		0.8
		FINAL		27AUG2003	16:00	58	145H#	67H	84.0		0.5
		FINAL	*	24SEP2003	16:45	86	15	13	74.0		0.6
	E0015005	BSLN		25NOV2002	13:15	-7	23	26	87.0		0.3
		FINAL		18DEC2002	9:30	17	21	25	84.0		0.2
	E0017002	BSLN		08MAY2003	17:00	-26	37H	30	87.0		0.2
		FINAL		13JUN2003	16:00	11	22	18	60.0		0.5
	E0018009	BSLN		17DEC2002	10:45	-20	26	30	117.0		0.6
		FINAL		14JAN2003	13:15	9	27	37	111.0		0.4
	E0018010	BSLN		09JAN2003	9:30	-7	19	14	93.0		0.7
		FINAL		13MAR2003	9:20	57	19	11	101.0		0.6
	E0018015	BSLN		21JAN2003	11:20	-7	18	32	117.0		0.3
		FINAL		27MAR2003	10:50	59	31	46	120.0		0.4
	E0020015	BSLN		18MAR2003	13:30	-9	28	42	100.0		0.5
		FINAL		23MAY2003	13:40	58	26	29	89.0		0.6
	E0020017	BSLN		27MAR2003	12:00	-7	20	16	69.0		1.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0020017	FINAL		03JUN2003	17:40	62	22	20	69.0	1.5	H
	E0020020	BSLN		07MAY2003	15:00	-5	35	28	34.0	0.4	
		FINAL		23MAY2003	14:00	12	32	28	35.0	0.3	
	E0020022	BSLN		09JUN2003	13:05	-7	34	41H	91.0	0.7	
		FINAL		11AUG2003	9:30	57	25	32	87.0	0.6	
	E0022001	BSLN		09OCT2002	14:20	-19	27	31	52.0	1.0	
		FINAL		26DEC2002	17:55	60	32	25	53.0	0.8	
	E0022004	BSLN	*	17OCT2002	8:48	-11	52H	89H	64.0	0.7	
		BSLN		28OCT2002	9:47	1	50H	85H	65.0	0.5	
		FINAL		23DEC2002	10:15	57	23	37	57.0	0.3	
	E0022005	BSLN		18OCT2002	7:40	-21	26	41H	88.0	0.3	
		FINAL		03JAN2003	9:20	57	24	42H	89.0	0.4	
	E0022011	BSLN		21NOV2002	9:25	-8	20	14	68.0	0.7	
	E0022015	BSLN	*	29NOV2002	13:50	-11	19	10	115.0	0.9	
		BSLN	*	03DEC2002	10:10	-7	19	12	120.0	0.5	
		BSLN		10DEC2002	16:10	1	15	12	99.0	0.5	
		FINAL		06FEB2003	9:50	59	15	15	108.0	0.7	
	E0022016	BSLN		03DEC2002	12:10	-14	22	33	58.0	0.8	
		FINAL		11FEB2003	11:05	57	22	35	57.0	0.4	
	E0022020	BSLN		05DEC2002	12:21	-7	14	12	83.0	0.4	
		FINAL		23JAN2003	16:20	43	14	13	66.0	0.3	
		FINAL	*	28JAN2003	10:35	48	13	11	62.0	0.4	
	E0022023	BSLN		20DEC2002	14:28	-5	20	18	70.0	0.6	
		FINAL		20FEB2003	10:05	58	23	18	77.0	0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
PLACEBO (BIPOLAR I)	E0022029	BSLN	10FEB2003	12:30	-9	78H	96H	59.0		0.7
		FINAL	14APR2003	9:45	55	45	87H	56.0		0.3
	E0022041	BSLN	11MAR2003	9:53	-7	17	9	58.0		0.4
		FINAL	13MAY2003	9:18	57	23	10	61.0		0.3
	E0022042	BSLN	05MAR2003	9:50	-7	19	24	88.0		0.4
		FINAL	12MAY2003	9:35	62	24	29	84.0		0.5
	E0022043	BSLN	11MAR2003	13:50	-9	20	16	88.0		0.4
		FINAL	12MAY2003	8:05	54	19	19	98.0		0.3
	E0022054	BSLN	07APR2003	11:25	-4	13	27	128.0	H	0.6
	E0022059	BSLN	23APR2003	15:30	-13	27	21	51.0		0.5
		FINAL	08JUL2003	16:30	64	25	23	45.0		0.6
	E0022065	BSLN	01MAY2003	9:30	-6	23	19	81.0		0.5
		FINAL	02JUL2003	8:50	57	21	21	83.0		0.3
	E0022070	BSLN	05JUN2003	11:40	-7	23	37	109.0		0.3
		FINAL	18JUN2003	15:15	7	20	19	114.0		0.3
	E0023001	BSLN	24OCT2002	13:30	-22	20	13	69.0		0.4
		FINAL	14JAN2003	13:30	61	26	13	80.0		0.4
	E0023009	BSLN	24JAN2003	11:30	-18	17	14	112.0		0.2
		FINAL	08APR2003	11:15	57	18	18	134.0	H	0.2
	E0023028	BSLN	16MAY2003	12:15	-13	20	20	56.0		0.5
		FINAL	21JUL2003	11:00	54	33	23	78.0		0.4
	E0023033	BSLN	30MAY2003	12:10	-6	25	29	105.0		0.6
		FINAL	12JUN2003	13:15	8	26	26	104.0		0.4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0023047	BSLN		11JUL2003	15:00	-7	26	21	65.0		0.7	
		FINAL		16SEP2003	13:00	61	21	26	88.0		0.7	
	E0025001	BSLN		25MAR2003	16:00	-7	13	24	58.0		0.1	L
		FINAL		23APR2003	10:30	23	18	32	55.0		0.3	
	E0026012	BSLN		05FEB2003	11:00	-15	30	52H	92.0		0.5	
		FINAL		17APR2003	9:10	57	30	47	88.0		0.4	
	E0026020	BSLN		28MAR2003	10:50	-4	17	13	93.0		0.2	
		FINAL		22APR2003	14:05	22	23	19	103.0		0.2	
	E0026024	BSLN		25APR2003	12:30	-7	11	14	125.0	H	0.3	
	E0026028	BSLN		06JUN2003	10:20	-14	25	31	93.0		0.4	
		FINAL		23JUL2003	10:00	34	26	33	102.0		0.4	
	E0028001	BSLN		07OCT2002	14:00	-3	23	26	76.0		0.4	
		FINAL		03DEC2002	9:50	55	21	25	90.0		0.3	
	E0028003	BSLN		23SEP2002	9:10	-7	20	27	73.0		0.5	
		FINAL		26NOV2002	9:20	58	22	21	85.0		0.4	
	E0028005	BSLN		30SEP2002	11:00	-3	15	12	47.0		0.3	
		FINAL		31OCT2002	12:15	29	20	14	50.0		0.5	
	E0028010	BSLN		15OCT2002	11:00	-21	30	25	45.0		0.5	
		FINAL	*	19NOV2002	12:40	15	27	22	48.0		0.3	
		FINAL		31DEC2002	9:20	57	25	24	40.0		0.3	
	E0028011	BSLN	*	22OCT2002	8:30	-44	17	18	167.0	H	0.5	
		BSLN		25NOV2002	9:00	-10	33	18	173.0	H	0.5	
		FINAL		30JAN2003	12:35	57	20	13	145.0	H	0.3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
PLACEBO (BIPOLAR I)	E0028030	BSLN	26FEB2003	11:30	-6	22	21	80.0		0.7
		FINAL	30APR2003	12:35	58	25	27	82.0		0.6
	E0028031	BSLN	06MAR2003	9:00	-5	53H	45	100.0		0.6
		FINAL	17APR2003	13:30	38	27	31	86.0		0.5
	E0028047	BSLN	09JUL2003	10:40	-5	23	20	107.0		0.5
		FINAL	09SEP2003	10:24	58	26	23	113.0		0.4
	E0029001	BSLN	25SEP2002	8:45	-6	18	14	107.0		0.8
	E0029014	BSLN	28JAN2003	9:35	-7	15	15	68.0		0.5
		FINAL	01APR2003	11:20	57	18	15	74.0		0.5
	E0029023	BSLN	01APR2003	8:47	-7	13	13	60.0		0.5
		FINAL	10JUN2003	11:10	64	18	19	62.0		1.0
	E0029032	BSLN	22MAY2003	12:45	-19	35	41	69.0		0.5
		FINAL	01JUL2003	12:00	22	20	28	63.0		0.5
	E0029033	BSLN	27MAY2003	12:50	-6	64H	107H	134.0	H	0.3
	E0029039	BSLN	10JUL2003	13:02	-5	10	7	61.0		0.3
		FINAL	28JUL2003	15:30	14	11	11	53.0		0.4
	E0030003	BSLN	03DEC2002	14:25	-13	13	10	103.0		0.2
		FINAL	21MAR2003	9:50	96	10	10	98.0		0.3
	E0030009	BSLN	14JAN2003	9:55	-9	30	17	98.0		0.4
		FINAL	19MAR2003	10:35	56	23	18	94.0		0.4
	E0030016	BSLN	21FEB2003	11:50	-10	22	54H	65.0		0.5
		FINAL	22APR2003	18:55	51	21	15	62.0		0.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0030021	BSLN	13MAY2003	17:25	-7	47H	70H	84.0	1.3	H
	E0031001	BSLN	14NOV2002	11:48	-7	20	17	37.0	0.2	
	E0031017	BSLN	25MAR2003	16:15	-7	24	26	70.0	1.0	
		FINAL	29APR2003	10:30	29	24	33	67.0	0.8	
	E0031018	BSLN	01APR2003	14:45	-9	15	19	111.0	0.3	
	E0031023	BSLN	22APR2003	14:03	-7	29	37	110.0	0.5	
		FINAL	24JUN2003	11:48	57	19	35	96.0	0.5	
	E0033001	BSLN	23DEC2002	12:50	-17	26	18	73.0	0.6	
		FINAL	30JAN2003	13:25	22	20	15	67.0	0.4	
	E0033004	BSLN	09JAN2003	13:10	-8	21	19	68.0	0.4	
		FINAL	14MAR2003	11:40	57	17	17	64.0	0.5	
	E0033010	BSLN	22JAN2003	16:20	-13	12	12	48.0	0.4	
		FINAL	26MAR2003	16:00	51	14	18	58.0	0.3	
	E0033014	BSLN	12MAR2003	17:25	-7	19	21	95.0	0.3	
	E0035002	BSLN	14NOV2002	10:50	-7	48H	85H	91.0	0.5	
	E0035007	BSLN	13DEC2002	12:40	-6	16	20	90.0	0.5	
		FINAL	11FEB2003	10:10	55	24	23	91.0	0.5	
	E0035011	BSLN	13JAN2003	8:35	-22	18	28	95.0	0.2	
		FINAL	01APR2003	9:00	57	13	17	86.0	0.2	
	E0035020	BSLN	15APR2003	8:15	-3	18	7	58.0	0.5	
	E0037003	BSLN	23JAN2003	11:40	-7	34	18	75.0	0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0037003	FINAL		20FEB2003	15:32	22	63H	80H	111.0		0.2	
	E0037004	BSLN		06FEB2003	12:35	-7	15	11	95.0		0.4	
		FINAL		10APR2003	13:00	57	9L	12	93.0		0.4	
	E0039007	BSLN		25NOV2002	13:20	-9	18	12	69.0		0.4	
		FINAL		29JAN2003	14:15	57	16	14	63.0		0.6	
	E0039022	BSLN		06FEB2003	9:50	-19	22	12	85.0		0.6	
		FINAL		24APR2003	12:10	59	21	13	80.0		0.4	
	E0039023	BSLN		05FEB2003	10:37	-19	36	43	115.0		0.2	
	E0039030	BSLN		12MAR2003	8:55	-12	65H	44H	134.0	H	0.8	
		FINAL		19MAY2003	9:15	57	116H#	88H	152.0	H	1.2	
		FINAL	*	30MAY2003	9:50	68	139H#	99H	152.0	H	1.4	H
	E0039031	BSLN		05MAR2003	19:15	-19	20	19	55.0		0.4	
		FINAL		20MAY2003	12:50	58	16	16	53.0		0.7	
	E0039037	BSLN		26MAR2003	18:30	-21	18	13	63.0		0.3	
		FINAL		12JUN2003	11:30	58	15	8	64.0		0.5	
	E0039038	BSLN	*	27MAR2003	10:10	-27	25	31	106.0		0.3	
		BSLN		21APR2003	10:16	-2	25	35	95.0		0.3	
		FINAL		20JUN2003	11:15	59	18	28	101.0		0.3	
	E0039047	BSLN		13MAY2003	9:20	-6	12	11	117.0		0.3	
	E0039059	BSLN		07JUL2003	11:10	-4	37H	29	118.0		0.4	
		FINAL		05SEP2003	11:10	57	39H	35	121.0		0.4	
	E0041007	BSLN		05MAR2003	13:45	-8	23	26	66.0		0.4	
		FINAL		08MAY2003	13:45	57	28	18	76.0		0.3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0041010	BSLN	23APR2003	14:45	-7	20	13	109.0		0.2	
		FINAL	11JUN2003	15:30	43	19	12	126.0	H	0.3	
	E0041011	BSLN	15MAY2003	16:00	-7	30	20	69.0		0.3	
		FINAL	17JUL2003	14:30	57	20	25	80.0		0.3	
	E0041012	BSLN	05JUN2003	12:28	-14	13	14	93.0		0.3	
		FINAL	14AUG2003	11:45	57	16	17	88.0		0.1	L

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Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
PLACEBO (BIPOLAR II)	E0001004	BSLN		23APR2003	11:00	-8	15	12	87.0		0.6
		FINAL		27JUN2003	12:45	58	13	12	89.0		1.0
	E0005023	BSLN		29JAN2003	7:30	-7	15	14	51.0		0.5
		FINAL		01APR2003	16:30	56	20	16	68.0		1.0
	E0005034	BSLN		09APR2003	9:30	-6	53H	54H	125.0	H	0.5
		FINAL		09JUN2003	13:00	56	24	32	111.0		0.6
	E0005041	BSLN		17JUN2003	11:55	-7	35	41H	83.0		0.7
		FINAL		18AUG2003	10:10	56	30	30	89.0		0.8
	E0007004	BSLN		28JAN2003	8:05	-2	18	15	81.0		0.2
		FINAL		13FEB2003	8:30	15	18	21	77.0		0.3
	E0007010	BSLN		14APR2003	8:10	-4	33	47H	90.0		0.4
		FINAL	*	21APR2003	8:30	4	25	44H	87.0		0.6
		FINAL		13JUN2003	7:40	57	26	35	91.0		0.4
		FINAL	*	16JUN2003	7:50	60	22	31	90.0		0.5
	E0007012	BSLN		12MAY2003	8:50	-4	21	28	65.0		0.4
		FINAL		02JUL2003	11:35	48	19	20	57.0		0.4
	E0009007	BSLN		27JAN2003	15:25	-7	21	35	71.0		0.6
		FINAL		03MAR2003	15:40	29	28	45	71.0		0.5
	E0009008	BSLN		04FEB2003	13:37	-8	20	27	90.0		0.7
		FINAL		08APR2003	12:35	56	27	28	91.0		0.6
	E0011001	BSLN		25OCT2002	16:00	-7	24	12	116.0		0.5
		FINAL		26DEC2002	8:30	56	24	13	113.0		0.4
	E0011011	BSLN		12FEB2003	12:00	-8	17	12	42.0		0.7
		FINAL		16APR2003	8:30	56	16	9	42.0		0.5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR II)	E0011013	BSLN		25MAR2003	9:45	-23	20	18	162.0	H	0.3	
		FINAL		12JUN2003	8:45	57	22	21	171.0	H	0.3	
	E0011014	BSLN		02APR2003	8:20	-5	23	25	70.0		0.2	
		FINAL		08MAY2003	15:30	32	17	15	70.0		0.3	
	E0011021	BSLN		15MAY2003	10:00	-7	26	14	60.0		0.4	
		FINAL		21JUL2003	10:00	61	20	12	51.0		0.5	
	E0013008	BSLN		19MAR2003	16:20	-7	16	23	109.0		0.3	
		FINAL		19MAY2003	11:25	55	20	20	113.0		0.3	
	E0014001	BSLN		18FEB2003	15:45	-8	27	29	151.0	H	0.2	
		FINAL		08APR2003	11:10	42	13	13	310.0	H	0.1	L
		FINAL	*	16APR2003	10:40	50	21	17	242.0	H	0.2	
	E0014013	BSLN		20MAY2003	14:50	-7	18	10	71.0		0.2	
		FINAL		23JUL2003	15:00	58	18	12	77.0		0.2	
	E0014014	BSLN		03JUN2003	16:35	-7	32	17	103.0		0.4	
		FINAL		06AUG2003	10:50	58	25	15	124.0	H	0.3	
	E0015004	BSLN		25NOV2002	8:50	-7	18	21	70.0		0.4	
		FINAL		29JAN2003	8:45	59	13	10	69.0		0.5	
	E0018005	BSLN		10DEC2002	16:00	-10	19	17	61.0		0.9	
		FINAL		17FEB2003	11:05	60	20	20	64.0		1.1	
	E0018012	BSLN		17JAN2003	10:30	-7	15	13	62.0		0.7	
		FINAL		26FEB2003	19:20	34	13	11	56.0		0.3	
	E0019019	BSLN		14JAN2003	10:30	-9	16	10	69.0		0.3	
	E0019033	BSLN		10MAR2003	16:05	-8	18	15	97.0		0.9	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR II)	E0019033	FINAL		16MAY2003	8:30	60	18	14	76.0		0.9	
	E0019038	BSLN	*	10APR2003	12:30	-14	27	30	123.0	H	1.7	H
		BSLN		17APR2003	11:05	-7	24	13	108.0		1.3	H
		FINAL		19JUN2003	9:40	57	21	17	97.0		0.1	L
	E0019046	BSLN		19JUN2003	15:00	-7	21	11	50.0		0.1	L
		FINAL		21AUG2003	9:12	57	16	13	46.0		0.7	
	E0019047	BSLN		26JUN2003	12:30	-12	17	15	80.0		0.4	
		FINAL		04SEP2003	8:40	59	15	14	83.0		0.2	
	E0019048	BSLN		03JUL2003	11:05	-7	17	12	56.0		0.4	
		FINAL		03SEP2003	16:12	56	15	12	54.0		0.4	
	E0022006	BSLN		22OCT2002	10:10	-21	19	21	77.0		0.3	
		FINAL		07JAN2003	7:40	57	16	16	77.0		0.2	
	E0022047	BSLN		21MAR2003	8:10	-7	16	26	120.0		0.7	
		FINAL		23MAY2003	9:45	57	25	35	109.0		0.7	
	E0022075	BSLN		27JUN2003	7:45	-11	51H	51H	64.0		0.8	
		FINAL		03SEP2003	9:15	58	27	22	53.0		0.7	
	E0023012	BSLN		31JAN2003	15:30	-6	19	14	110.0		0.3	
		FINAL		04APR2003	12:15	58	21	19	111.0		0.2	
	E0023016	BSLN		15MAY2003	13:30	-7	22	15	53.0		0.3	
		FINAL		17JUL2003	11:10	57	14	10	60.0		0.3	
	E0023018	BSLN		18MAR2003	13:30	-9	20	14	52.0		0.4	
		FINAL		22MAY2003	10:15	57	20	34	111.0		0.7	
	E0023036	BSLN		10JUN2003	12:00	-10	15	12	79.0		0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR II)	E0023036	FINAL		13AUG2003	17:00	55	13	12	91.0		0.1	L
	E0023046	BSLN	*	11JUL2003	10:00	-12			184.0	H		
		BSLN		11JUL2003	10:00	-12	23	18			0.4	
		BSLN		18JUL2003	9:00	-5			178.0	H		
		FINAL		16SEP2003	14:00	56	25	21	182.0	H	0.3	
	E0026006	BSLN		31DEC2002	10:35	-8	19	14	167.0	H	0.5	
	E0026021	BSLN		14APR2003	15:45	-9	18	16	64.0		0.3	
	E0026027	BSLN		05JUN2003	13:10	-14	37H	46H	59.0		0.2	
	E0029002		*	07NOV2002	8:10		16	13	98.0		0.1	L
	E0029004	BSLN		13NOV2002	14:50	-6	18	16	89.0		0.5	
		FINAL		17JAN2003	8:25	60	15	12	97.0		0.4	
	E0029013	BSLN		10FEB2003	8:55	-9	20	25	92.0		0.3	
	E0029019	BSLN		24FEB2003	9:30	-7	17	30	65.0		0.6	
		FINAL		17MAR2003	9:50	15	23	44	57.0		0.9	
	E0029024	BSLN		11MAR2003	12:10	-6	23	19	59.0		0.5	
		FINAL		20MAY2003	14:45	65	22	15	58.0		0.6	
	E0029038	BSLN		30JUN2003	9:25	-7	13	18	64.0		2.3	H#
	E0031004	BSLN		12DEC2002	13:59	-7	28	19	52.0		0.6	
		FINAL		14FEB2003	10:50	58	19	18	49.0		0.2	
	E0031013	BSLN		06MAR2003	10:35	-7	18	28	88.0		0.4	
		FINAL		08MAY2003	11:05	57	20	24	82.0		0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR II)	E0031016	BSLN		17MAR2003	10:45	-7	21	17	78.0		0.3	
		FINAL		15APR2003	10:03	23	21	15	84.0		0.5	
	E0031019	BSLN		03APR2003	11:25	-8	23	24	93.0		0.3	
		FINAL		12MAY2003	16:40	32	18	17	91.0		0.4	
	E0031022	BSLN		21APR2003	12:40	-7	26	32	86.0		0.3	
	E0033007	BSLN		15JAN2003	15:20	-13	18	12	50.0		0.3	
		FINAL		27MAR2003	15:35	59	15	11	60.0		0.6	
	E0033013	BSLN		06FEB2003	11:45	-13	16	19	64.0		0.6	
		FINAL		16APR2003	11:45	57	16	13	56.0		0.9	
	E0033016	BSLN		17APR2003	12:00	-21	21	17	41.0		0.2	
		FINAL		02JUL2003	13:00	56	17	14	45.0		0.2	
	E0033022	BSLN		09JUL2003	11:00	-5	20	23	77.0		0.3	
		FINAL		11SEP2003	12:00	60	21	21	67.0		0.2	
	E0034007	BSLN		07MAY2003	14:05	-9	40H	39H	50.0		1.2	
		FINAL		14JUL2003	11:15	60	121H#	128H#	73.0		2.2	H#
		FINAL	*	28JUL2003	11:48	74	121H#	134H#	68.0		1.2	
	E0035004	BSLN		22NOV2002	11:45	-5	136H#	126H	100.0		0.8	
	E0035009	BSLN		20DEC2002	11:12	-7	20	19	84.0		0.5	
		FINAL		19FEB2003	8:55	55	23	24	72.0		0.5	
	E0035010	BSLN		07JAN2003	7:45	-3	15	13	135.0	H	0.3	
		FINAL		06MAR2003	9:00	56	17	13	137.0	H	0.4	
	E0035022	BSLN		01MAY2003	9:45	-8	23	16	72.0		0.7	
		FINAL		07JUL2003	8:55	60	18	12	63.0		0.7	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM100.SAS
GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.1 Chemistry Data - Liver Function Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)
PLACEBO (BIPOLAR II)	E0039003	BSLN	12NOV2002	11:19	-13	20	17	61.0		0.2
		FINAL	02JAN2003	14:06	39	17	15	55.0		0.3
	E0040001	BSLN	18JUN2003	14:30	-9	13	9	51.0		0.5
		FINAL	22AUG2003	9:00	57	16	16	49.0		0.6
	E0040004	BSLN	11JUL2003	13:00	-7	24	20	131.0	H	1.1
	E0041002	BSLN	13JAN2003	14:35	-8	24	34	76.0		0.3
		FINAL	11MAR2003	10:35	50	29	27	92.0		0.3
	E0041005	BSLN	28FEB2003	12:31	-5	16	21	66.0		0.8
		FINAL	30APR2003	14:08	57	21	33	65.0		0.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:17 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		22JAN2003	14:00	-13	0.5
		FINAL		02APR2003	10:10	58	0.6
	E0002010	BSLN		28MAR2003	10:00	-7	1.0
	E0002012	BSLN		16APR2003	10:10	-5	1.0
		FINAL		16JUN2003	11:30	57	0.9
	E0002015	BSLN		22MAY2003	10:15	-13	1.0
	E0002018	BSLN		16JUL2003	13:25	-8	1.1
		FINAL		04AUG2003	9:40	12	1.1
	E0003004	BSLN	*	03DEC2002	11:48	-14	1.1
		BSLN		17DEC2002	9:20	1	1.0
		FINAL		07JAN2003	15:40	22	1.1
	E0003005	BSLN		16DEC2002	15:00	-7	0.8
		FINAL		18FEB2003	8:55	58	0.7
	E0003007	BSLN		19DEC2002	10:15	-14	0.8
		FINAL		27FEB2003	8:50	57	0.7
	E0003015	BSLN		29APR2003	11:30	-6	0.6
		FINAL		02JUL2003	14:45	59	0.5
	E0004002	BSLN		24SEP2002	10:40	-7	0.6
		FINAL		26NOV2002	11:00	57	0.6
	E0004013	BSLN		08JAN2003	10:00	-6	0.6
		FINAL		19FEB2003	8:20	37	0.6
	E0004018	BSLN		12MAR2003	10:50	-7	0.9
		FINAL		13MAY2003	13:45	56	1.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	BSLN	07MAY2003	15:55	-7	0.9
		FINAL	09JUL2003	14:10	57	1.1
	E0005002	BSLN	23SEP2002	10:00	-10	1.0
		FINAL	25NOV2002	8:30	54	0.8
	E0005004	BSLN	24SEP2002	12:00	-7	0.7
	E0005013	BSLN	30OCT2002	8:00	-8	0.9
	E0005024	BSLN	05FEB2003	15:00	-5	0.6
		FINAL	10APR2003	11:30	60	0.7
	E0005027	BSLN	04MAR2003	7:45	-7	0.9
		FINAL	03APR2003	8:15	24	0.9
	E0005037	BSLN	30APR2003	12:00	-7	0.7
		FINAL	02JUL2003	12:15	57	0.8
	E0005042	BSLN	19JUN2003	11:30	-5	0.8
		FINAL	18AUG2003	16:25	56	0.9
	E0006005	BSLN	25NOV2002	12:15	-10	0.6
		FINAL	30JAN2003	16:10	57	0.5
	E0006018	BSLN	07MAR2003	12:40	-6	0.9
		FINAL	24MAR2003	10:45	12	0.9
	E0007013	BSLN	10JUN2003	9:25	-3	0.6
		FINAL	07AUG2003	9:20	56	0.8
	E0010004	BSLN	05DEC2002	11:10	-6	0.7
		FINAL	06FEB2003	12:40	58	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	BSLN	30DEC2002	9:48	-8	0.7
		FINAL	05MAR2003	13:59	58	0.9
	E0010024	BSLN	23APR2003	8:45	-12	1.0
		FINAL	02JUL2003	10:30	59	0.8
	E0010032	BSLN	03JUL2003	11:30	-7	0.7
		FINAL	17JUL2003	11:38	8	0.8
	E0011025	BSLN	20JUN2003	14:30	-6	0.5
		FINAL	22AUG2003	10:00	58	0.7
	E0013007	BSLN	14MAR2003	8:48	-6	0.8
		FINAL	07APR2003	17:15	19	0.9
	E0013009	BSLN	26MAR2003	9:09	-7	0.9
		FINAL	29MAY2003	17:50	58	0.9
	E0014006	BSLN	14MAR2003	11:30	-11	0.7
		FINAL	21MAY2003	16:20	58	0.7
	E0014010	BSLN	15APR2003	17:20	-7	0.7
		FINAL	17JUN2003	18:10	57	0.9
	E0016001	BSLN	02JAN2003	8:50	-20	0.7
		FINAL	19MAR2003	12:00	57	0.8
	E0016004	BSLN	27JAN2003	9:30	-7	0.9
	E0018001	BSLN	22OCT2002	16:15	-7	0.8
		FINAL	24DEC2002	9:55	57	0.8
	E0018006	BSLN	10DEC2002	17:15	-7	0.9
		FINAL	27FEB2003	12:10	73	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	BSLN		30OCT2002	8:40	-8	0.7
		FINAL		19DEC2002	12:55	43	0.8
	E0019011	BSLN		12NOV2002	12:05	-9	0.6
		FINAL		16JAN2003	14:20	57	0.6
	E0019025	BSLN		30JAN2003	14:40	-7	0.8
		FINAL		03APR2003	13:30	57	0.9
	E0019026	BSLN		17FEB2003	12:40	-7	0.6
	E0019043	BSLN		21MAY2003	11:04	-13	0.8
		FINAL	*	17JUN2003	12:10	15	0.8
		FINAL		29JUL2003	11:38	57	0.8
	E0020001	BSLN		15OCT2002	20:00	-14	0.8
		FINAL		20DEC2002	12:30	53	0.8
	E0020006	BSLN		26NOV2002	18:00	-20	0.9
		FINAL		08JAN2003	10:00	24	1.0
	E0020007	BSLN		10JAN2003	12:00	-5	0.5
		FINAL		25MAR2003	18:50	70	0.5
	E0020011	BSLN		19FEB2003	13:45	-7	0.9
		FINAL		23APR2003	14:30	57	0.7
		FINAL	*	07MAY2003	12:00	71	0.7
	E0020013	BSLN		26FEB2003	14:15	-7	1.0
		FINAL		25MAR2003	12:00	21	0.9
	E0022008	BSLN		05NOV2002	10:00	-7	1.0
		FINAL		07JAN2003	9:45	57	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	BSLN	05DEC2002	12:35	-14	1.0
		FINAL	07MAR2003	9:47	79	1.1
	E0022018	BSLN	04DEC2002	10:15	-8	1.0
		FINAL	11FEB2003	8:40	62	1.0
	E0022022	BSLN	16DEC2002	13:15	-14	0.8
		FINAL	27FEB2003	11:35	60	0.6
	E0022027	BSLN	24JAN2003	7:40	-13	0.9
		FINAL	03APR2003	9:00	57	0.9
	E0022030	BSLN	10FEB2003	7:40	-4	0.9
	E0022031	BSLN	11FEB2003	10:25	-7	1.0
		FINAL	15APR2003	9:30	57	1.0
	E0022032	BSLN	12FEB2003	8:05	-6	0.8
		FINAL	18APR2003	10:30	60	0.8
	E0022035	BSLN	13FEB2003	13:50	-6	0.8
		FINAL	13MAR2003	17:55	23	0.8
	E0022036	BSLN	14FEB2003	8:55	-11	0.9
		FINAL	22APR2003	7:36	57	0.9
	E0022056	BSLN	11APR2003	8:07	-6	0.8
	E0022060	BSLN	24APR2003	12:05	-6	1.1
		FINAL	24JUN2003	9:25	56	1.1
	E0022063	BSLN	29APR2003	10:10	-8	0.7
	E0023008	BSLN	23JAN2003	10:00	-7	0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	FINAL		24MAR2003	15:40	54	0.7
	E0023013	BSLN		13FEB2003	11:00	-14	0.7
		FINAL		06MAR2003	11:00	8	0.7
	E0023015	BSLN		04MAR2003	11:00	-7	0.7
		FINAL		06MAY2003	10:00	57	0.7
	E0023034	BSLN		03JUN2003	14:00	-6	0.6
		FINAL		05AUG2003	16:00	58	0.5
	E0023037	BSLN		11JUN2003	16:30	-7	1.1
		FINAL	*	24JUN2003	16:30	7	1.3
		FINAL		15AUG2003	9:30	59	1.2
	E0023038	BSLN		20JUN2003	12:45	-10	1.0
		FINAL		16SEP2003	18:30	79	1.0
	E0023044	BSLN		08JUL2003	14:00	-8	0.7
		FINAL		12AUG2003	12:00	28	0.6
	E0023045	BSLN		10JUL2003	11:40	-7	0.9
		FINAL		15SEP2003	11:00	61	0.9
	E0025002	BSLN		27MAR2003	11:05	-7	0.8
		FINAL		29MAY2003	11:40	57	0.7
	E0026010	BSLN		15JAN2003	14:00	-7	0.8
		FINAL		30JAN2003	16:30	9	0.9
	E0026017	BSLN		26FEB2003	11:50	-8	0.8
		FINAL		21MAR2003	11:10	16	0.9
	E0026018	BSLN		06MAR2003	16:30	-14	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	FINAL	15MAY2003	14:15	57	0.6
	E0026025	BSLN	01MAY2003	11:40	-8	0.7
		FINAL	03JUL2003	9:30	56	0.6
	E0026029	BSLN	02JUL2003	11:10	-7	0.9
		FINAL	28JUL2003	13:30	20	0.9
	E0026030	BSLN	02JUL2003	11:50	-7	1.1
		FINAL	03SEP2003	17:10	57	1.1
	E0026031	BSLN	10JUL2003	14:00	-11	1.0
		FINAL	15SEP2003	11:15	57	1.0
	E0027003	BSLN	08JAN2003	14:40	-20	0.8
		FINAL	25MAR2003	11:55	57	0.7
	E0028004	BSLN	27SEP2002	9:45	-3	0.8
		FINAL	09OCT2002	14:30	10	0.8
	E0028006	BSLN	01OCT2002	10:00	-3	0.7
		FINAL	04DEC2002	10:15	62	0.9
	E0028008	BSLN	08OCT2002	12:45	-7	0.9
		FINAL	10DEC2002	12:30	57	0.8
	E0028009	BSLN	10OCT2002	10:45	-5	0.7
		FINAL	12DEC2002	13:50	59	0.7
	E0028016	BSLN	07NOV2002	10:15	-7	1.1
		FINAL	09JAN2003	11:50	57	1.1
	E0028017	*	12NOV2002	9:45		0.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	BSLN		14JAN2003	10:15	-7	1.0
	E0028029	BSLN		28JAN2003	10:00	-7	1.0
		FINAL		04APR2003	10:55	60	1.1
	E0028034	BSLN		20MAR2003	9:40	-12	0.9
		FINAL		02JUN2003	12:54	63	1.1
	E0028038	BSLN		18APR2003	10:20	-7	0.9
		FINAL		18JUN2003	13:45	55	1.0
	E0028043	BSLN		29MAY2003	11:55	-7	1.1
		FINAL		29JUL2003	8:25	55	1.3
	E0028045	BSLN		09JUN2003	13:00	-9	1.2
		FINAL		11SEP2003	12:50	86	0.9
	E0029005	BSLN	*	14NOV2002	13:00	-13	0.8
		BSLN		21NOV2002	10:30	-6	0.9
		FINAL		21JAN2003	12:50	56	0.8
	E0030001	BSLN		12NOV2002	15:15	-7	0.8
		FINAL		16JAN2003	12:07	59	0.9
	E0030008	BSLN		07JAN2003	14:33	-7	0.8
		FINAL		18MAR2003	10:42	64	1.0
	E0030011	BSLN		16JAN2003	16:10	-11	0.7
		FINAL		24MAR2003	14:35	57	0.8
	E0030015	BSLN		13FEB2003	12:05	-8	1.2
		FINAL		22APR2003	12:10	61	1.1
	E0030022	BSLN		10JUN2003	11:15	-6	1.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	FINAL	14AUG2003	15:30	60	1.1
	E0031002	BSLN	20NOV2002	17:05	-7	0.6
		FINAL	23JAN2003	12:55	58	0.7
	E0031003	BSLN	03DEC2002	16:07	-7	1.1
		FINAL	04FEB2003	16:20	57	1.0
	E0033015	BSLN	03APR2003	17:05	-7	0.7
		FINAL	04JUN2003	11:00	56	0.8
	E0034002	BSLN	18MAR2003	9:25	-7	0.9
		FINAL	16APR2003	14:40	23	1.0
	E0034003	BSLN	11APR2003	10:10	-13	0.9
		FINAL	19JUN2003	15:50	57	0.8
	E0034006	BSLN	25APR2003	11:33	-21	0.9
		FINAL	10JUL2003	9:54	56	0.7
	E0034008	BSLN	16MAY2003	13:26	-8	1.1
		FINAL	21JUL2003	10:07	59	1.1
	E0035003	BSLN	15NOV2002	10:30	-7	1.2
	E0035005	BSLN	26NOV2002	10:00	-7	0.8
	E0035014	BSLN	28JAN2003	11:10	-6	0.5
		FINAL	31MAR2003	9:20	57	0.6
	E0035024	BSLN	15MAY2003	11:30	-8	0.8
		FINAL	18JUL2003	9:00	57	0.9
	E0036005	BSLN	24JUN2003	10:45	-7	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	FINAL		27AUG2003	12:45	58	0.7
	E0037002	BSLN		18DEC2002	12:10	-8	0.5
		FINAL		20FEB2003	13:25	57	0.7
	E0037005	BSLN		27FEB2003	15:00	-7	0.8
		FINAL		01MAY2003	14:15	57	0.8
	E0037006	BSLN		07MAR2003	12:00	-7	0.7
		FINAL		09MAY2003	12:18	57	0.7
	E0039006	BSLN	*	11NOV2002	10:05	-49	0.8
		BSLN	*	22NOV2002	9:20	-38	0.7
		BSLN		10DEC2002	11:35	-20	0.6
		FINAL		24FEB2003	10:58	57	0.6
	E0039015	BSLN		02JAN2003	10:20	-21	1.1
		FINAL		20MAR2003	9:30	57	1.1
	E0039024	BSLN		14FEB2003	8:50	-13	0.7
		FINAL		25APR2003	16:05	58	0.7
	E0039025	BSLN		26FEB2003	11:00	-20	0.8
		FINAL		27MAY2003	10:00	71	0.7
	E0039041	BSLN		08APR2003	9:40	-7	0.9
		FINAL		11JUN2003	11:25	58	0.9
	E0039044	BSLN		06MAY2003	10:30	-16	0.8
		FINAL		23JUL2003	18:20	63	0.7
	E0039046		*	06MAY2003	11:46		0.6
			*	03JUN2003	10:25		0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	BSLN	23MAY2003	9:30	-24	0.7
		FINAL	12AUG2003	14:45	58	0.9
	E0039053	BSLN	16JUN2003	13:25	-25	1.2
		FINAL	08SEP2003	12:45	60	1.2
	E0039057	BSLN	02JUL2003	19:50	-12	1.0
		FINAL	09SEP2003	9:25	58	0.7
	E0041003	BSLN	16JAN2003	17:30	-12	0.8
		FINAL	25MAR2003	9:55	57	0.8
	E0041008	BSLN	26MAR2003	15:35	-12	0.9
		FINAL	02JUN2003	15:30	57	0.7
	E0042001	BSLN	17JUN2003	9:45	-15	1.1
		FINAL	26AUG2003	10:50	56	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN		26FEB2003	14:25	-14	0.6
		FINAL		07MAY2003	13:45	57	0.7
	E0003018	BSLN		06MAY2003	16:22	-7	0.8
		FINAL		08JUL2003	14:18	57	0.9
	E0005011	BSLN		17OCT2002	15:00	-7	0.8
	E0005030	BSLN		18MAR2003	14:00	-8	0.7
	E0005036	BSLN		28APR2003	13:30	-8	0.7
		FINAL		27MAY2003	10:00	22	0.7
	E0006015	BSLN		07FEB2003	9:30	-4	0.7
		FINAL		08APR2003	12:00	57	0.6
	E0006016	BSLN		07FEB2003	12:55	-10	1.0
		FINAL		18APR2003	12:15	61	1.1
	E0007008	BSLN		08APR2003	9:55	-10	0.9
		FINAL		02JUL2003	14:00	76	0.9
		FINAL	*	12AUG2003	11:30	117	0.7
	E0009002	BSLN		30OCT2002	11:45	-20	1.0
		FINAL		15JAN2003	13:47	58	1.0
	E0009006	BSLN		23JAN2003	17:50	-5	0.8
		FINAL		25MAR2003	16:20	57	0.8
	E0009009	BSLN		27FEB2003	15:00	-13	0.9
		FINAL		24MAR2003	13:40	13	0.8
	E0010015	BSLN		30JAN2003	10:35	-21	1.0
		FINAL		15APR2003	13:29	55	1.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	BSLN		17DEC2002	11:00	-7	0.8
		FINAL		18FEB2003	9:00	57	1.0
	E0011007	BSLN		12DEC2002	10:43	-7	0.5
		FINAL		13FEB2003	8:00	57	0.5
	E0011018	BSLN		15MAY2003	12:30	-7	0.9
		FINAL		17JUL2003	17:30	57	0.9
	E0011024	BSLN		17JUN2003	12:10	-7	0.8
		FINAL		21AUG2003	13:00	59	0.8
	E0015003	BSLN		13NOV2002	12:20	-12	0.9
		FINAL		02DEC2002	10:55	8	0.7
	E0019003	BSLN		30OCT2002	9:10	-22	0.7
		FINAL		16JAN2003	11:25	57	0.7
	E0019007	BSLN		06NOV2002	10:32	-7	0.6
		FINAL		07JAN2003	8:30	56	0.8
	E0019014	BSLN	*	17DEC2002	11:02	-23	1.0
		BSLN		26DEC2002	10:25	-14	1.0
		FINAL		22JAN2003	9:00	14	1.0
	E0019018	BSLN		14JAN2003	10:45	-16	1.1
		FINAL		27MAR2003	9:30	57	1.0
	E0019022	BSLN		23JAN2003	12:00	-7	0.7
		FINAL		27MAR2003	15:10	57	1.0
	E0019027	BSLN		20FEB2003	10:50	-7	0.7
	E0019032	BSLN		06MAR2003	14:50	-26	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	FINAL		28MAY2003	11:00	58	0.8
	E0019034	BSLN		10MAR2003	16:55	-8	0.7
	E0019036	BSLN		18MAR2003	9:15	-7	0.9
	E0019039	BSLN		22APR2003	11:00	-9	1.1
		FINAL		08MAY2003	15:30	8	1.1
	E0019041	BSLN		14MAY2003	10:50	-7	0.6
		FINAL		16JUL2003	11:10	57	0.6
	E0019049	BSLN		03JUL2003	13:40	-7	0.6
		FINAL		08SEP2003	12:10	61	0.7
	E0022052	BSLN		01APR2003	10:50	-9	0.6
		FINAL		05JUN2003	9:32	57	0.6
	E0022064	BSLN		01MAY2003	10:40	-5	1.1
		FINAL		01JUL2003	12:30	57	1.2
	E0022073	BSLN		20JUN2003	14:10	-6	0.8
		FINAL		21AUG2003	9:45	57	0.7
	E0023002	BSLN		25OCT2002	16:00	-11	0.9
	E0023017	BSLN		20MAR2003	11:00	-5	1.0
		FINAL		22MAY2003	12:30	59	0.9
	E0023021	BSLN	*	10APR2003	10:20	-13	1.0
		BSLN		16APR2003	15:00	-7	0.9
		FINAL		17JUN2003	16:00	56	1.0
	E0023027	BSLN		07MAY2003	13:30	-9	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	FINAL		09JUL2003	13:00	55	0.7	
	E0023030	BSLN		21MAY2003	10:00	-13	0.7	
		FINAL		30JUL2003	15:30	58	0.8	
	E0023040	BSLN		25JUN2003	15:00	-8	0.8	
		FINAL		05SEP2003	10:00	65	0.9	
	E0026014	BSLN		12FEB2003	11:40	-7	0.9	
		FINAL		19MAR2003	10:35	29	0.7	
	E0026019	BSLN		10MAR2003	11:45	-7	0.8	
		FINAL		12MAY2003	9:10	57	0.8	
	E0027005	BSLN		19DEC2002	14:50	-7	1.1	
		FINAL		20FEB2003	11:28	57	1.0	
	E0029009	BSLN		13JAN2003	12:50	-7	1.5	H
		FINAL		18MAR2003	9:05	58	1.1	
	E0029021	BSLN	*	03MAR2003	10:40	-15	0.7	
		BSLN		18MAR2003	9:50	1	0.7	
		FINAL		15MAY2003	12:30	59	0.7	
		FINAL	*	27MAY2003	8:40	71	0.7	
	E0029026	BSLN		07APR2003	9:10	-7	0.9	
		FINAL		10JUN2003	15:00	58	1.2	
	E0029030	BSLN	*	13MAY2003	11:20	-14	0.9	
		BSLN		20MAY2003	12:55	-7	0.9	
		FINAL		23JUL2003	17:25	58	1.0	
	E0031008	BSLN		05FEB2003	11:40	-23	0.7	
		FINAL		24APR2003	13:17	56	0.7	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	BSLN		14APR2003	10:35	-7	1.1
		FINAL		13MAY2003	10:50	23	1.1
	E0031021	BSLN		18APR2003	10:40	-7	1.0
		FINAL		19JUN2003	10:40	56	1.0
	E0031029	BSLN		05JUN2003	10:45	-13	1.1
	E0033002	BSLN		23DEC2002	12:15	-18	0.9
		FINAL		07MAR2003	11:25	57	0.9
	E0033006	BSLN		15JAN2003	10:25	-8	0.9
		FINAL		12FEB2003	12:30	21	1.0
	E0033021	BSLN		25JUN2003	14:40	-7	0.8
		FINAL		18AUG2003	16:20	48	0.8
	E0035013	BSLN		27JAN2003	10:30	-8	0.5
		FINAL		10FEB2003	11:05	7	0.6
	E0035015	BSLN		03FEB2003	10:30	-8	0.8
		FINAL		18FEB2003	11:20	8	0.7
	E0035016	BSLN		10MAR2003	11:00	-25	0.7
	E0035023	BSLN		06MAY2003	10:30	-7	0.9
	E0039052	BSLN	*	29MAY2003	10:25	-22	0.7
		BSLN		13JUN2003	12:10	-7	0.7
	E0039056	BSLN		01JUL2003	12:50	-14	0.8
	E0040003	BSLN		09JUL2003	14:00	-10	0.8
		FINAL		12SEP2003	11:00	56	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	0.8
		FINAL	02MAY2003	10:30	61	0.7
	E0002011	BSLN	16APR2003	11:30	-13	0.9
		FINAL	25JUN2003	11:20	58	0.9
	E0003010	BSLN	28JAN2003	9:10	-6	0.8
		FINAL	31MAR2003	16:20	57	0.7
	E0003011	BSLN	28JAN2003	11:47	-7	0.8
	E0003016	BSLN	01MAY2003	11:40	-21	0.5
		FINAL	13JUN2003	8:45	23	0.6
	E0003019	BSLN	19JUN2003	11:30	-8	1.1
		FINAL	21AUG2003	8:50	56	1.2
	E0003020	BSLN	27JUN2003	8:55	-26	1.0
		FINAL	17SEP2003	15:00	57	1.0
	E0004001	BSLN	23SEP2002	11:00	-7	0.7
		FINAL	05NOV2002	13:30	37	0.7
	E0004009	BSLN	17DEC2002	10:10	-9	0.7
		FINAL	19FEB2003	16:00	56	0.6
	E0004012	BSLN	07JAN2003	12:45	-7	0.6
		FINAL	11MAR2003	11:35	57	0.7
	E0004015	BSLN	06FEB2003	10:05	-14	0.9
		FINAL	15APR2003	9:10	55	1.2
	E0005003	BSLN	23SEP2002	15:00	-9	1.1
		FINAL	26NOV2002	13:25	56	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	BSLN		24SEP2002	15:20	-6	0.9
	E0005007	BSLN		02OCT2002	12:40	-7	0.6
		FINAL		04DEC2002	14:20	57	0.6
	E0005008	BSLN		08OCT2002	18:00	-7	0.9
		FINAL		11DEC2002	16:00	58	0.9
	E0005009	BSLN		09OCT2002	10:00	-20	0.9
	E0005010	BSLN		14OCT2002	13:00	-7	0.8
		FINAL		17DEC2002	14:25	58	0.8
		FINAL	*	23DEC2002	16:00	64	0.9
	E0005012	BSLN		24OCT2002	7:00	-21	1.0
		FINAL		07JAN2003	11:00	55	0.9
	E0005014	BSLN		05NOV2002	16:30	-8	1.0
		FINAL		06JAN2003	10:00	55	1.0
	E0005022	BSLN		27JAN2003	10:30	-2	0.9
		FINAL		11MAR2003	10:10	42	0.9
	E0005025	BSLN		20FEB2003	13:20	-7	0.8
		FINAL		03APR2003	11:30	36	0.7
	E0006019	BSLN		26MAR2003	11:35	-12	0.9
		FINAL		03JUN2003	12:00	58	1.1
	E0007005	BSLN		27JAN2003	14:30	-4	0.7
		FINAL		28MAR2003	13:30	57	0.8
		FINAL	*	11APR2003	11:00	71	0.8
	E0007015	BSLN		10JUL2003	7:35	-6	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	FINAL	10SEP2003	7:40	57	0.9
	E0009001	BSLN	29OCT2002	15:30	-14	0.7
	E0010002	BSLN	14NOV2002	10:36	-11	0.8
		FINAL	02DEC2002	9:05	8	1.0
	E0010009	BSLN	18DEC2002	9:42	-8	0.8
		FINAL	19FEB2003	13:59	56	0.8
	E0010010	BSLN	20DEC2002	8:45	-10	0.7
		FINAL	13JAN2003	10:28	15	0.7
	E0010014	BSLN	14JAN2003	9:05	-14	0.5
		FINAL	25MAR2003	11:05	57	0.6
	E0010017	BSLN	05FEB2003	8:51	-20	0.9
		FINAL	22APR2003	10:20	57	0.9
	E0010023	BSLN	10APR2003	9:22	-7	0.6
		FINAL	01MAY2003	10:19	15	0.7
	E0010027	BSLN	05JUN2003	9:10	-11	0.9
		FINAL	01JUL2003	13:00	16	0.8
	E0010029	BSLN	10JUN2003	9:25	-9	1.1
	E0011022	BSLN	02JUN2003	11:00	-7	0.8
		FINAL	05AUG2003	10:30	58	0.7
	E0013006	BSLN	06MAR2003	10:15	-7	0.7
		FINAL	24MAR2003	12:42	12	0.7
	E0013012	BSLN	29APR2003	9:48	-8	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	FINAL	02JUL2003	10:05	57	0.8
	E0013014	BSLN	08MAY2003	11:15	-26	1.1
		FINAL	30JUN2003	12:21	28	0.9
	E0014005	BSLN	04MAR2003	17:20	-7	0.8
		FINAL	06MAY2003	12:20	57	0.8
	E0014007	BSLN	25MAR2003	17:50	-7	0.7
		FINAL	22APR2003	13:50	22	0.7
	E0014011	BSLN	06MAY2003	16:45	-7	1.2
		FINAL	08JUL2003	15:50	57	1.2
	E0014012	BSLN	19MAY2003	10:05	-8	0.8
		FINAL	24JUN2003	18:40	29	0.7
	E0015001	BSLN	11NOV2002	9:10	-18	1.0
		FINAL	20JAN2003	7:30	53	1.0
	E0015008	BSLN	13DEC2002	9:30	-6	0.8
	E0016003	BSLN	10JAN2003	9:30	-14	0.8
	E0016005	BSLN	21FEB2003	8:45	-4	0.9
		FINAL	22APR2003	8:30	57	1.0
	E0018007	BSLN	16DEC2002	10:15	-11	0.7
		FINAL	10JAN2003	14:15	15	0.5
	E0019005	BSLN	30OCT2002	11:50	-6	0.8
		FINAL	02JAN2003	14:00	59	0.8
	E0019015	BSLN	19DEC2002	10:49	-14	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	FINAL		27FEB2003	11:23	57	0.7
	E0020004	BSLN		21NOV2002	15:20	-18	0.9
		FINAL		22JAN2003	16:15	45	1.2
		FINAL	*	24FEB2003	11:50	78	1.0
	E0020010	BSLN		31JAN2003	9:15	-5	0.7
		FINAL		02APR2003	10:30	57	0.8
	E0020014	BSLN		11MAR2003	10:00	-7	0.7
		FINAL		12MAY2003	11:15	56	0.7
	E0020021	BSLN		13MAY2003	9:45	-6	0.9
		FINAL		14JUL2003	13:25	57	0.8
	E0020023	BSLN		09JUN2003	19:05	-8	0.9
		FINAL		11AUG2003	11:40	56	0.9
	E0022007	BSLN		01NOV2002	10:23	-6	0.6
	E0022010	BSLN		15NOV2002	10:40	-6	0.8
		FINAL		16JAN2003	18:00	57	0.7
	E0022012	BSLN		29NOV2002	15:40	-6	0.7
		FINAL		30JAN2003	12:00	57	0.6
	E0022019	BSLN		06DEC2002	10:10	-5	0.9
		FINAL		06FEB2003	11:20	58	1.2
	E0022025	BSLN		08JAN2003	10:10	-20	0.8
		FINAL		04FEB2003	11:30	8	0.9
	E0022033	BSLN		12FEB2003	10:05	-6	0.7
		FINAL		15APR2003	12:10	57	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	BSLN	12FEB2003	12:40	-6	1.0
		FINAL	15APR2003	14:00	57	1.0
	E0022038	BSLN	21FEB2003	11:05	-7	0.8
		FINAL	14APR2003	9:40	46	0.8
	E0022039	BSLN	27FEB2003	11:15	-7	0.9
		FINAL	01MAY2003	12:50	57	0.9
	E0022046	BSLN	14MAR2003	8:00	-6	1.1
		FINAL	16MAY2003	8:05	58	1.0
	E0022048	BSLN	26MAR2003	9:58	-6	0.7
	E0022051	BSLN	01APR2003	10:15	-6	0.8
		FINAL	02JUN2003	10:45	57	0.8
	E0022053	BSLN	04APR2003	12:50	-7	0.8
	E0022058	BSLN	14APR2003	10:25	-7	1.1
		FINAL	22MAY2003	14:00	32	1.0
	E0022061	BSLN	25APR2003	9:37	-5	0.8
		FINAL	26JUN2003	12:30	58	0.8
	E0022062	BSLN	28APR2003	7:43	-7	1.0
		FINAL	23MAY2003	7:40	19	1.0
	E0022068	BSLN	14MAY2003	10:23	-9	0.7
	E0022069	BSLN	04JUN2003	7:40	-6	0.9
		FINAL	05AUG2003	9:45	57	1.0
	E0022071	BSLN	16JUN2003	11:40	-14	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	FINAL		26AUG2003	9:33	58	0.9
	E0023003	BSLN	*	08NOV2002	16:00	-39	1.0
		BSLN		12DEC2002	10:00	-5	0.9
		FINAL		11FEB2003	14:00	57	0.9
	E0023006	BSLN		10DEC2002	10:30	-7	0.8
		FINAL		11FEB2003	11:50	57	0.7
	E0023010	BSLN		28JAN2003	9:30	-7	0.9
		FINAL		31MAR2003	10:00	56	0.9
	E0023025	BSLN		01MAY2003	15:00	-14	0.9
		FINAL		10JUL2003	13:30	57	0.8
	E0023039	BSLN		24JUN2003	13:30	-7	0.6
		FINAL		26AUG2003	13:30	57	0.8
	E0026002	BSLN		05NOV2002	10:15	-7	0.7
		FINAL		09JAN2003	9:25	59	0.7
	E0026007	BSLN		06JAN2003	10:30	-10	0.8
		FINAL		12MAR2003	14:25	56	1.0
	E0026013	BSLN		05FEB2003	12:20	-8	0.8
		FINAL		14APR2003	10:00	61	0.8
	E0028007	BSLN		01OCT2002	10:30	-3	0.6
		FINAL		14NOV2002	12:45	42	0.4
	E0028023	BSLN		15JAN2003	10:00	-6	1.0
		FINAL		27JUN2003	15:00	158	1.1
	E0028025	BSLN		08JAN2003	12:07	-5	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	FINAL		27JAN2003	9:25	15	1.0
	E0028033	BSLN		18MAR2003	10:50	-9	0.7
		FINAL		22MAY2003	10:50	57	0.8
	E0028035	BSLN		27MAR2003	12:00	-7	0.8
		FINAL		29MAY2003	15:40	57	1.0
	E0028037	BSLN	*	18APR2003	8:30	-56	0.8
		BSLN	*	24APR2003	7:50	-50	0.8
		BSLN		04JUN2003	8:33	-9	0.9
		FINAL		08AUG2003	15:30	57	0.8
	E0028039	BSLN		05MAY2003	7:10	-4	1.1
		FINAL		05JUN2003	12:30	28	1.1
	E0028046	BSLN		17JUN2003	13:45	-8	0.7
	E0028048	BSLN		11JUL2003	14:00	-6	0.7
	E0029008	BSLN		09DEC2002	11:40	-7	0.8
	E0029011	BSLN		14JAN2003	11:20	-8	0.9
	E0029012	BSLN		04FEB2003	10:05	-7	0.8
		FINAL		27MAR2003	8:45	45	0.8
	E0029015	BSLN		11FEB2003	10:05	-13	0.5
		FINAL		14MAR2003	10:30	19	0.5
	E0029018	BSLN	*	26FEB2003	16:25	-8	1.1
		BSLN		06MAR2003	16:05	1	1.1
	E0030014	BSLN		14FEB2003	10:35	-7	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	FINAL		22APR2003	12:50	61	0.9
	E0030020	BSLN		13MAY2003	15:30	-16	0.8
	E0030024	BSLN		17JUN2003	15:35	-24	0.6
		FINAL		18JUL2003	15:35	8	0.7
	E0030025	BSLN	*	24JUN2003	16:35	-17	0.9
		BSLN		07JUL2003	10:20	-4	0.8
		FINAL		19AUG2003	16:45	40	0.9
	E0031027	BSLN		28MAY2003	9:10	-6	0.9
		FINAL		29JUL2003	14:40	57	1.1
	E0031030	BSLN		17JUN2003	10:46	-7	0.9
		FINAL		21AUG2003	11:10	59	0.9
	E0033012	BSLN		05FEB2003	15:26	-5	0.8
	E0034001	BSLN		17MAR2003	10:03	-3	0.8
		FINAL		15MAY2003	9:55	57	0.8
	E0034004	BSLN		11APR2003	11:15	-10	1.1
		FINAL		16JUN2003	12:03	57	1.1
	E0035001	BSLN		12NOV2002	11:40	-8	0.8
		FINAL		14JAN2003	9:05	56	0.7
	E0035006	BSLN		03DEC2002	10:45	-9	0.7
		FINAL		06FEB2003	9:30	57	0.6
	E0035021	BSLN		18APR2003	10:45	-7	0.6
		FINAL		20JUN2003	8:15	57	0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	BSLN	10JUN2003	13:45	-7	0.8
		FINAL	15JUL2003	10:05	29	0.7
	E0036006	BSLN	24JUN2003	16:45	-9	0.9
		FINAL	28AUG2003	9:50	57	0.9
	E0036007	BSLN	27JUN2003	10:00	-6	0.8
		FINAL	18JUL2003	9:15	16	0.7
	E0037009	BSLN	12MAY2003	9:15	-4	0.6
		FINAL	10JUL2003	16:05	56	0.8
	E0039011	BSLN	16DEC2002	17:40	-17	0.6
	E0039018	BSLN	15JAN2003	9:10	-8	0.7
	E0039026	BSLN	03MAR2003	9:05	-4	0.8
		FINAL	02MAY2003	9:20	57	0.8
	E0039028	BSLN	03MAR2003	14:15	-21	0.9
		FINAL	16MAY2003	12:25	54	1.1
	E0039032	BSLN	07MAR2003	13:45	-7	0.8
		FINAL	04APR2003	11:45	22	0.8
	E0039034	BSLN	12MAR2003	20:05	-7	0.6
		FINAL	14MAY2003	15:00	57	0.6
	E0039042	BSLN	25APR2003	10:15	-12	0.9
		FINAL	02JUL2003	12:50	57	0.9
	E0041004	BSLN	27JAN2003	10:15	-3	1.2
		FINAL	31MAR2003	12:00	61	1.3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	BSLN	22APR2003	15:15	-9	0.7
		FINAL	16JUN2003	13:00	47	0.5
	E0042002	BSLN	02JUL2003	12:10	-7	1.1
		FINAL	02SEP2003	10:25	56	1.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN	23JUN2003	10:00	-18	1.0
		FINAL	25JUL2003	9:00	15	1.0
	E0003002	BSLN	22OCT2002	11:05	-7	0.9
		FINAL	23DEC2002	15:35	56	0.9
	E0005031	BSLN	26MAR2003	12:30	-7	0.8
	E0005033	BSLN	08APR2003	14:00	-8	0.8
		FINAL	06MAY2003	11:20	21	0.8
	E0005038	BSLN	05MAY2003	11:40	-9	0.7
		FINAL	05JUN2003	13:00	23	0.7
	E0007009	BSLN	14APR2003	7:48	-3	0.6
	E0009010	BSLN	27FEB2003	16:55	-14	0.9
	E0009011	BSLN	28APR2003	14:17	-8	0.7
		FINAL	03JUL2003	15:40	59	0.8
	E0010005	BSLN	11DEC2002	10:15	-7	0.9
	E0011016	BSLN	14APR2003	10:00	-7	1.1
		FINAL	16JUN2003	9:45	57	1.1
	E0011020	BSLN	01MAY2003	9:20	-7	0.8
		FINAL	15MAY2003	17:00	8	0.8
	E0018002	BSLN	15NOV2002	15:35	-14	0.8
		FINAL	22JAN2003	16:20	55	0.8
	E0018003	BSLN	19NOV2002	13:05	-7	0.9
		FINAL	10DEC2002	11:00	15	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	BSLN		17JAN2003	14:15	-7	1.0
		FINAL		06FEB2003	16:10	14	1.1
	E0019002	BSLN		29OCT2002	10:45	-14	0.8
	E0019008	BSLN	*	06NOV2002	12:35	-15	0.6
		BSLN		13NOV2002	10:30	-8	0.7
	E0019009	BSLN		06NOV2002	13:35	-8	0.7
	E0019016	BSLN		30DEC2002	16:55	-7	0.8
		FINAL		03MAR2003	16:00	57	0.9
	E0019020	BSLN		16JAN2003	10:10	-7	0.7
		FINAL		27MAR2003	10:50	64	0.6
	E0019021	BSLN		16JAN2003	11:45	-14	1.0
		FINAL		03MAR2003	13:18	33	0.9
	E0019024	BSLN		24JAN2003	16:00	-6	0.9
		FINAL		06FEB2003	12:33	8	0.9
	E0019031	BSLN		06MAR2003	11:35	-7	1.1
		FINAL		25MAR2003	10:08	13	1.0
	E0019035	BSLN		11MAR2003	9:28	-7	0.6
		FINAL		17APR2003	14:30	31	0.5
	E0019040	BSLN		08MAY2003	15:25	-12	1.1
		FINAL		17JUL2003	9:50	59	1.1
	E0019042	BSLN		29MAY2003	8:50	-6	0.9
		FINAL		20JUN2003	8:20	17	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	BSLN		19JUN2003	14:54	-7	0.7
		FINAL		16JUL2003	10:15	21	0.7
	E0020024	BSLN		12JUN2003	15:40	-11	0.8
		FINAL		20AUG2003	18:45	59	0.9
	E0022044	BSLN		12MAR2003	9:50	-6	0.5
		FINAL		12MAY2003	9:55	56	0.5
	E0023007	BSLN		07JAN2003	14:30	-7	0.8
		FINAL		13MAR2003	15:00	59	0.7
	E0023011	BSLN		28JAN2003	11:45	-7	0.8
		FINAL		01APR2003	12:00	57	0.9
	E0023014	BSLN		14FEB2003	15:00	-7	0.6
		FINAL		25APR2003	14:00	64	1.2
	E0023019	BSLN		21MAR2003	14:00	-17	0.7
		FINAL		03JUN2003	13:30	58	1.0
	E0023022	BSLN		10APR2003	16:00	-8	0.9
		FINAL		12JUN2003	15:40	56	0.9
	E0023023	BSLN		17APR2003	10:00	-8	0.6
		FINAL		01MAY2003	14:00	7	0.8
	E0023029	BSLN		16MAY2003	14:00	-7	0.7
	E0023031	BSLN	*	22MAY2003	12:00	-33	0.7
		BSLN		19JUN2003	10:00	-5	0.6
		FINAL		19AUG2003	11:00	57	0.7
	E0023041	BSLN		03JUL2003	11:00	-6	0.6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	FINAL		05SEP2003	13:00	59	0.8
	E0023043	BSLN		07JUL2003	15:00	-7	1.0
		FINAL		09SEP2003	10:30	58	0.9
	E0026003	BSLN	*	25NOV2002	12:20	-9	1.3
		BSLN		02DEC2002	9:25	-2	0.9
		FINAL		03FEB2003	10:50	62	1.0
	E0026005	BSLN		23DEC2002	12:40	-7	0.6
		FINAL		06JAN2003	15:25	8	0.6
	E0026009	BSLN		10JAN2003	10:20	-5	0.6
		FINAL		21JAN2003	9:50	7	0.6
	E0026015	BSLN		20FEB2003	11:30	-7	0.6
		FINAL		25APR2003	9:50	58	0.7
	E0026023	BSLN		23APR2003	10:50	-7	1.0
		FINAL		27JUN2003	12:25	59	0.9
	E0027016	BSLN	*	19MAR2003	11:55	-21	0.8
		BSLN		04APR2003	9:50	-5	0.9
		FINAL		03JUN2003	10:18	56	0.9
	E0027018	BSLN		21MAR2003	11:30	-4	0.8
		FINAL		22MAY2003	10:05	59	0.8
	E0028032	BSLN		13MAR2003	13:58	-12	0.8
		FINAL		06JUN2003	11:38	74	1.0
	E0029003	BSLN		28OCT2002	12:30	-7	0.9
		FINAL		30DEC2002	9:45	57	1.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0029020	BSLN	25FEB2003	10:12	-8	0.9
	E0031005	BSLN	13DEC2002	16:00	-7	0.6
		FINAL	14FEB2003	12:10	57	0.6
	E0031006	BSLN	31JAN2003	11:25	-18	0.7
		FINAL	15APR2003	9:25	57	0.8
	E0031010	BSLN	12FEB2003	14:50	-7	0.6
		FINAL	06MAR2003	12:50	16	0.7
	E0031011	BSLN	18FEB2003	11:50	-9	1.2
		FINAL	24APR2003	9:25	57	1.2
	E0031015	BSLN	14MAR2003	8:40	-12	0.7
		FINAL	01APR2003	11:55	7	0.8
	E0031031	BSLN	01JUL2003	10:30	-7	0.7
		FINAL	28AUG2003	10:35	52	0.6
	E0033009	BSLN	22JAN2003	13:40	-21	0.6
	E0034009	BSLN	10JUN2003	13:00	-9	0.8
		FINAL	18AUG2003	17:25	61	1.0
	E0037007	BSLN	04APR2003	11:30	-7	0.9
	E0037012	BSLN	11JUL2003	13:00	-5	0.9
		FINAL	08SEP2003	13:20	55	1.0
	E0039019	BSLN	20JAN2003	14:50	-17	0.7
		FINAL	03APR2003	11:05	57	0.7
	E0039043	BSLN	28APR2003	10:15	-10	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	0.7
		FINAL		26FEB2003	8:45	59	0.8
	E0002003	BSLN		03JAN2003	11:50	-19	0.7
		FINAL		18MAR2003	12:10	56	0.7
	E0002004	BSLN		14JAN2003	8:15	-11	0.7
	E0002008	BSLN		14FEB2003	16:00	-11	1.0
		FINAL		23APR2003	14:25	58	0.9
	E0002016	BSLN		14JUL2003	11:00	-10	0.8
		FINAL		17SEP2003	11:15	56	0.9
	E0003008	BSLN		21JAN2003	12:45	-7	0.6
	E0004003	BSLN		02OCT2002	11:00	-8	1.0
	E0004006	BSLN		28OCT2002	9:55	-7	0.7
		FINAL		06JAN2003	10:55	64	0.6
	E0004016	BSLN		12FEB2003	15:10	-7	0.8
		FINAL		17APR2003	17:10	58	0.8
	E0004024	BSLN		25JUN2003	16:00	-8	0.7
		FINAL		28AUG2003	9:50	57	0.8
	E0005006	BSLN	*	24SEP2002	15:30	-9	0.9
		BSLN		03OCT2002	8:30	1	0.8
	E0005017	BSLN	*	11DEC2002	10:30	-19	0.8
		BSLN		23DEC2002	12:30	-7	0.8
		FINAL		04MAR2003	13:00	65	0.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0005019	BSLN		19DEC2002	14:00	-27	0.6
		FINAL		23JAN2003	15:45	9	0.6
	E0005026	BSLN		28FEB2003	10:15	-6	0.7
		FINAL		02APR2003	9:40	28	0.9
	E0005039	BSLN		15MAY2003	9:00	-7	0.6
		FINAL		16JUL2003	8:40	56	0.6
	E0005043	BSLN		02JUL2003	8:30	-7	0.8
		FINAL		03SEP2003	9:45	57	0.9
	E0006020	BSLN		02MAY2003	13:30	-11	0.8
		FINAL		08JUL2003	14:45	57	0.9
		FINAL	*	10JUL2003	16:30	59	0.9
	E0007001	BSLN	*	16DEC2002	9:25	-15	1.2
		BSLN		26DEC2002	9:25	-5	1.0
		FINAL		24FEB2003	8:43	56	1.1
		FINAL	*	10MAR2003	8:54	70	1.1
	E0007003	BSLN		13JAN2003	10:30	-17	0.7
		FINAL		01APR2003	13:30	62	0.7
	E0007006	BSLN		24FEB2003	11:00	-9	1.1
		FINAL		27MAR2003	10:50	23	1.1
	E0009004	BSLN	*	19NOV2002	12:30	-7	0.8
		BSLN		25NOV2002	12:55	-1	0.8
		FINAL		18DEC2002	14:50	23	0.8
	E0009012	BSLN		16JUN2003	14:45	-9	0.9
		FINAL		03JUL2003	17:45	9	0.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0010008	BSLN		11DEC2002	9:15	-7	0.6
	E0010018	BSLN		26FEB2003	8:51	-21	0.8
		FINAL		14MAY2003	10:45	57	0.7
	E0010028	BSLN		09JUN2003	8:46	-7	0.7
		FINAL		15JUL2003	13:50	30	0.6
	E0011008	BSLN	*	17DEC2002	12:30	-44	1.0
		BSLN		23JAN2003	9:20	-7	1.0
		FINAL		13FEB2003	12:30	15	0.8
	E0011009	BSLN		19DEC2002	10:15	-8	0.8
		FINAL		20FEB2003	9:00	56	0.8
	E0011010	BSLN		03FEB2003	10:00	-7	0.7
		FINAL		19MAR2003	8:45	38	0.7
	E0013001	BSLN		01NOV2002	8:50	-13	1.0
		FINAL		10JAN2003	10:45	58	0.9
	E0013003	BSLN		07NOV2002	9:25	-5	0.8
		FINAL		06JAN2003	13:17	56	0.8
	E0013005	BSLN		13FEB2003	11:42	-5	0.9
		FINAL		15APR2003	12:16	57	1.0
	E0013013	BSLN		01MAY2003	10:14	-5	0.6
		FINAL		30MAY2003	9:55	25	0.7
	E0014002	BSLN		19FEB2003	16:35	-7	0.8
		FINAL		10APR2003	13:05	44	0.9
	E0014004	BSLN		04MAR2003	11:40	-8	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0014004	FINAL		15APR2003	11:40	35	0.8
	E0014009	BSLN	*	15APR2003	14:45	-8	0.8
		BSLN		17APR2003	12:30	-6	0.6
		FINAL		16MAY2003	8:55	24	0.6
	E0014015	BSLN		11JUN2003	10:15	-7	1.0
	E0014017	BSLN		17JUN2003	17:00	-10	0.9
		FINAL		19AUG2003	17:05	54	0.6
	E0014018	BSLN		24JUN2003	16:35	-7	0.9
		FINAL		27AUG2003	16:00	58	0.9
		FINAL	*	24SEP2003	16:45	86	0.9
	E0015005	BSLN		25NOV2002	13:15	-7	0.8
		FINAL		18DEC2002	9:30	17	0.9
	E0017002	BSLN		08MAY2003	17:00	-26	0.8
		FINAL		13JUN2003	16:00	11	0.9
	E0018009	BSLN		17DEC2002	10:45	-20	1.2
		FINAL		14JAN2003	13:15	9	0.9
	E0018010	BSLN		09JAN2003	9:30	-7	0.9
		FINAL		13MAR2003	9:20	57	1.0
	E0018015	BSLN		21JAN2003	11:20	-7	1.3
		FINAL		27MAR2003	10:50	59	1.1
	E0020015	BSLN		18MAR2003	13:30	-9	1.0
		FINAL		23MAY2003	13:40	58	1.1
	E0020017	BSLN		27MAR2003	12:00	-7	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0020017	FINAL		03JUN2003	17:40	62	0.8
	E0020020	BSLN		07MAY2003	15:00	-5	0.6
		FINAL		23MAY2003	14:00	12	0.7
	E0020022	BSLN		09JUN2003	13:05	-7	0.7
		FINAL		11AUG2003	9:30	57	0.8
	E0022001	BSLN		09OCT2002	14:20	-19	1.0
		FINAL		26DEC2002	17:55	60	0.9
	E0022004	BSLN	*	17OCT2002	8:48	-11	1.0
		BSLN		28OCT2002	9:47	1	0.9
		FINAL		23DEC2002	10:15	57	0.9
	E0022005	BSLN		18OCT2002	7:40	-21	0.9
		FINAL		03JAN2003	9:20	57	0.7
	E0022011	BSLN		21NOV2002	9:25	-8	1.1
	E0022015	BSLN	*	29NOV2002	13:50	-11	0.7
		BSLN	*	03DEC2002	10:10	-7	0.7
		BSLN		10DEC2002	16:10	1	0.6
		FINAL		06FEB2003	9:50	59	0.7
	E0022016	BSLN		03DEC2002	12:10	-14	0.6
		FINAL		11FEB2003	11:05	57	0.7
	E0022020	BSLN		05DEC2002	12:21	-7	0.7
		FINAL		23JAN2003	16:20	43	0.6
		FINAL	*	28JAN2003	10:35	48	0.6
	E0022023	BSLN		20DEC2002	14:28	-5	1.0
		FINAL		20FEB2003	10:05	58	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0022029	BSLN	10FEB2003	12:30	-9	0.9
		FINAL	14APR2003	9:45	55	0.8
	E0022041	BSLN	11MAR2003	9:53	-7	0.5
		FINAL	13MAY2003	9:18	57	0.6
	E0022042	BSLN	05MAR2003	9:50	-7	1.2
		FINAL	12MAY2003	9:35	62	1.4 H
	E0022043	BSLN	11MAR2003	13:50	-9	0.6
		FINAL	12MAY2003	8:05	54	0.5
	E0022054	BSLN	07APR2003	11:25	-4	1.0
	E0022059	BSLN	23APR2003	15:30	-13	0.8
		FINAL	08JUL2003	16:30	64	0.7
	E0022065	BSLN	01MAY2003	9:30	-6	0.8
		FINAL	02JUL2003	8:50	57	0.7
	E0022070	BSLN	05JUN2003	11:40	-7	1.1
		FINAL	18JUN2003	15:15	7	1.1
	E0023001	BSLN	24OCT2002	13:30	-22	0.5
		FINAL	14JAN2003	13:30	61	0.6
	E0023009	BSLN	24JAN2003	11:30	-18	0.6
		FINAL	08APR2003	11:15	57	0.7
	E0023028	BSLN	16MAY2003	12:15	-13	0.7
		FINAL	21JUL2003	11:00	54	0.6
	E0023033	BSLN	30MAY2003	12:10	-6	1.1
		FINAL	12JUN2003	13:15	8	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0023047	BSLN		11JUL2003	15:00	-7	0.6
		FINAL		16SEP2003	13:00	61	0.9
	E0025001	BSLN		25MAR2003	16:00	-7	0.6
		FINAL		23APR2003	10:30	23	0.6
	E0026012	BSLN		05FEB2003	11:00	-15	1.2
		FINAL		17APR2003	9:10	57	1.1
	E0026020	BSLN		28MAR2003	10:50	-4	0.8
		FINAL		22APR2003	14:05	22	0.7
	E0026024	BSLN		25APR2003	12:30	-7	0.7
	E0026028	BSLN		06JUN2003	10:20	-14	0.8
		FINAL		23JUL2003	10:00	34	0.9
	E0028001	BSLN		07OCT2002	14:00	-3	0.8
		FINAL		03DEC2002	9:50	55	0.8
	E0028003	BSLN		23SEP2002	9:10	-7	0.6
		FINAL		26NOV2002	9:20	58	0.6
	E0028005	BSLN		30SEP2002	11:00	-3	0.7
		FINAL		31OCT2002	12:15	29	0.7
	E0028010	BSLN		15OCT2002	11:00	-21	0.6
		FINAL	*	19NOV2002	12:40	15	0.8
		FINAL		31DEC2002	9:20	57	0.7
	E0028011	BSLN	*	22OCT2002	8:30	-44	0.7
		BSLN		25NOV2002	9:00	-10	0.7
		FINAL		30JAN2003	12:35	57	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0028030	BSLN	26FEB2003	11:30	-6	0.7
		FINAL	30APR2003	12:35	58	0.9
	E0028031	BSLN	06MAR2003	9:00	-5	1.1
		FINAL	17APR2003	13:30	38	0.9
	E0028047	BSLN	09JUL2003	10:40	-5	0.8
		FINAL	09SEP2003	10:24	58	0.8
	E0029001	BSLN	25SEP2002	8:45	-6	0.8
	E0029014	BSLN	28JAN2003	9:35	-7	0.7
		FINAL	01APR2003	11:20	57	0.7
	E0029023	BSLN	01APR2003	8:47	-7	0.9
		FINAL	10JUN2003	11:10	64	0.9
	E0029032	BSLN	22MAY2003	12:45	-19	1.0
		FINAL	01JUL2003	12:00	22	1.0
	E0029033	BSLN	27MAY2003	12:50	-6	0.9
	E0029039	BSLN	10JUL2003	13:02	-5	0.6
		FINAL	28JUL2003	15:30	14	0.6
	E0030003	BSLN	03DEC2002	14:25	-13	0.5
		FINAL	21MAR2003	9:50	96	0.4
	E0030009	BSLN	14JAN2003	9:55	-9	1.1
		FINAL	19MAR2003	10:35	56	1.1
	E0030016	BSLN	21FEB2003	11:50	-10	0.9
		FINAL	22APR2003	18:55	51	0.9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0030021	BSLN	13MAY2003	17:25	-7	1.1
	E0031001	BSLN	14NOV2002	11:48	-7	0.7
	E0031017	BSLN	25MAR2003	16:15	-7	1.3
		FINAL	29APR2003	10:30	29	0.8
	E0031018	BSLN	01APR2003	14:45	-9	0.7
	E0031023	BSLN	22APR2003	14:03	-7	0.7
		FINAL	24JUN2003	11:48	57	0.9
	E0033001	BSLN	23DEC2002	12:50	-17	1.0
		FINAL	30JAN2003	13:25	22	1.0
	E0033004	BSLN	09JAN2003	13:10	-8	0.8
		FINAL	14MAR2003	11:40	57	0.8
	E0033010	BSLN	22JAN2003	16:20	-13	0.7
		FINAL	26MAR2003	16:00	51	0.7
	E0033014	BSLN	12MAR2003	17:25	-7	1.2
	E0035002	BSLN	14NOV2002	10:50	-7	0.9
	E0035007	BSLN	13DEC2002	12:40	-6	0.6
		FINAL	11FEB2003	10:10	55	0.6
	E0035011	BSLN	13JAN2003	8:35	-22	0.7
		FINAL	01APR2003	9:00	57	0.7
	E0035020	BSLN	15APR2003	8:15	-3	0.8
	E0037003	BSLN	23JAN2003	11:40	-7	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0037003	FINAL		20FEB2003	15:32	22	1.1
	E0037004	BSLN		06FEB2003	12:35	-7	0.5
		FINAL		10APR2003	13:00	57	0.5
	E0039007	BSLN		25NOV2002	13:20	-9	1.0
		FINAL		29JAN2003	14:15	57	0.9
	E0039022	BSLN		06FEB2003	9:50	-19	0.7
		FINAL		24APR2003	12:10	59	0.6
	E0039023	BSLN		05FEB2003	10:37	-19	1.1
	E0039030	BSLN		12MAR2003	8:55	-12	0.5
		FINAL		19MAY2003	9:15	57	0.5
		FINAL	*	30MAY2003	9:50	68	0.5
	E0039031	BSLN		05MAR2003	19:15	-19	0.7
		FINAL		20MAY2003	12:50	58	0.7
	E0039037	BSLN		26MAR2003	18:30	-21	0.6
		FINAL		12JUN2003	11:30	58	0.5
	E0039038	BSLN	*	27MAR2003	10:10	-27	0.9
		BSLN		21APR2003	10:16	-2	0.8
		FINAL		20JUN2003	11:15	59	1.0
	E0039047	BSLN		13MAY2003	9:20	-6	0.6
	E0039059	BSLN		07JUL2003	11:10	-4	0.7
		FINAL		05SEP2003	11:10	57	0.8
	E0041007	BSLN		05MAR2003	13:45	-8	0.9
		FINAL		08MAY2003	13:45	57	1.2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR I)	E0041010	BSLN	23APR2003	14:45	-7	0.8
		FINAL	11JUN2003	15:30	43	0.8
	E0041011	BSLN	15MAY2003	16:00	-7	0.7
		FINAL	17JUL2003	14:30	57	0.8
	E0041012	BSLN	05JUN2003	12:28	-14	0.7
		FINAL	14AUG2003	11:45	57	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR II)	E0001004	BSLN		23APR2003	11:00	-8	0.7
		FINAL		27JUN2003	12:45	58	0.8
	E0005023	BSLN		29JAN2003	7:30	-7	0.7
		FINAL		01APR2003	16:30	56	0.9
	E0005034	BSLN		09APR2003	9:30	-6	0.7
		FINAL		09JUN2003	13:00	56	0.6
	E0005041	BSLN		17JUN2003	11:55	-7	0.8
		FINAL		18AUG2003	10:10	56	0.9
	E0007004	BSLN		28JAN2003	8:05	-2	0.5
		FINAL		13FEB2003	8:30	15	0.6
	E0007010	BSLN		14APR2003	8:10	-4	0.7
		FINAL	*	21APR2003	8:30	4	0.7
		FINAL		13JUN2003	7:40	57	0.7
		FINAL	*	16JUN2003	7:50	60	0.8
	E0007012	BSLN		12MAY2003	8:50	-4	1.0
		FINAL		02JUL2003	11:35	48	0.9
	E0009007	BSLN		27JAN2003	15:25	-7	0.9
		FINAL		03MAR2003	15:40	29	1.0
	E0009008	BSLN		04FEB2003	13:37	-8	1.1
		FINAL		08APR2003	12:35	56	1.2
	E0011001	BSLN		25OCT2002	16:00	-7	0.8
		FINAL		26DEC2002	8:30	56	0.9
	E0011011	BSLN		12FEB2003	12:00	-8	0.6
		FINAL		16APR2003	8:30	56	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR II)	E0011013	BSLN		25MAR2003	9:45	-23	0.8
		FINAL		12JUN2003	8:45	57	0.7
	E0011014	BSLN		02APR2003	8:20	-5	0.8
		FINAL		08MAY2003	15:30	32	0.9
	E0011021	BSLN		15MAY2003	10:00	-7	0.7
		FINAL		21JUL2003	10:00	61	0.9
	E0013008	BSLN		19MAR2003	16:20	-7	0.7
		FINAL		19MAY2003	11:25	55	0.7
	E0014001	BSLN		18FEB2003	15:45	-8	0.9
		FINAL		08APR2003	11:10	42	0.7
		FINAL	*	16APR2003	10:40	50	0.7
	E0014013	BSLN		20MAY2003	14:50	-7	0.7
		FINAL		23JUL2003	15:00	58	0.7
	E0014014	BSLN		03JUN2003	16:35	-7	1.2
		FINAL		06AUG2003	10:50	58	1.1
	E0015004	BSLN		25NOV2002	8:50	-7	0.8
		FINAL		29JAN2003	8:45	59	0.8
	E0018005	BSLN		10DEC2002	16:00	-10	0.8
		FINAL		17FEB2003	11:05	60	0.9
	E0018012	BSLN		17JAN2003	10:30	-7	0.8
		FINAL		26FEB2003	19:20	34	0.7
	E0019019	BSLN		14JAN2003	10:30	-9	0.7
	E0019033	BSLN		10MAR2003	16:05	-8	0.8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR II)	E0019033	FINAL		16MAY2003	8:30	60	0.9
	E0019038	BSLN	*	10APR2003	12:30	-14	1.0
		BSLN		17APR2003	11:05	-7	1.1
		FINAL		19JUN2003	9:40	57	1.0
	E0019046	BSLN		19JUN2003	15:00	-7	0.8
		FINAL		21AUG2003	9:12	57	0.8
	E0019047	BSLN		26JUN2003	12:30	-12	0.9
		FINAL		04SEP2003	8:40	59	0.8
	E0019048	BSLN		03JUL2003	11:05	-7	0.6
		FINAL		03SEP2003	16:12	56	0.6
	E0022006	BSLN		22OCT2002	10:10	-21	0.7
		FINAL		07JAN2003	7:40	57	0.6
	E0022047	BSLN		21MAR2003	8:10	-7	1.0
		FINAL		23MAY2003	9:45	57	0.9
	E0022075	BSLN		27JUN2003	7:45	-11	0.8
		FINAL		03SEP2003	9:15	58	0.8
	E0023012	BSLN		31JAN2003	15:30	-6	0.7
		FINAL		04APR2003	12:15	58	0.9
	E0023016	BSLN		15MAY2003	13:30	-7	0.6
		FINAL		17JUL2003	11:10	57	0.7
	E0023018	BSLN		18MAR2003	13:30	-9	0.7
		FINAL		22MAY2003	10:15	57	0.9
	E0023036	BSLN		10JUN2003	12:00	-10	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR II)	E0023036	FINAL		13AUG2003	17:00	55	0.6
	E0023046	BSLN		11JUL2003	10:00	-12	0.7
		FINAL		16SEP2003	14:00	56	0.7
	E0026006	BSLN		31DEC2002	10:35	-8	0.8
	E0026021	BSLN		14APR2003	15:45	-9	0.8
	E0026027	BSLN		05JUN2003	13:10	-14	0.5
	E0029002		*	07NOV2002	8:10		0.8
	E0029004	BSLN		13NOV2002	14:50	-6	0.7
		FINAL		17JAN2003	8:25	60	0.7
	E0029013	BSLN		10FEB2003	8:55	-9	0.9
	E0029019	BSLN		24FEB2003	9:30	-7	0.9
		FINAL		17MAR2003	9:50	15	1.0
	E0029024	BSLN		11MAR2003	12:10	-6	0.8
		FINAL		20MAY2003	14:45	65	0.8
	E0029038	BSLN		30JUN2003	9:25	-7	1.0
	E0031004	BSLN		12DEC2002	13:59	-7	0.8
		FINAL		14FEB2003	10:50	58	0.8
	E0031013	BSLN		06MAR2003	10:35	-7	0.6
		FINAL		08MAY2003	11:05	57	0.5
	E0031016	BSLN		17MAR2003	10:45	-7	0.9
		FINAL		15APR2003	10:03	23	1.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR II)	E0031019	BSLN		03APR2003	11:25	-8	0.9
		FINAL		12MAY2003	16:40	32	0.9
	E0031022	BSLN		21APR2003	12:40	-7	0.7
	E0033007	BSLN		15JAN2003	15:20	-13	0.8
		FINAL		27MAR2003	15:35	59	0.7
	E0033013	BSLN		06FEB2003	11:45	-13	0.7
		FINAL		16APR2003	11:45	57	0.6
	E0033016	BSLN		17APR2003	12:00	-21	0.7
		FINAL		02JUL2003	13:00	56	0.6
	E0033022	BSLN		09JUL2003	11:00	-5	0.7
		FINAL		11SEP2003	12:00	60	0.6
	E0034007	BSLN		07MAY2003	14:05	-9	0.7
		FINAL		14JUL2003	11:15	60	0.6
		FINAL	*	28JUL2003	11:48	74	0.7
	E0035004	BSLN		22NOV2002	11:45	-5	0.9
	E0035009	BSLN		20DEC2002	11:12	-7	0.9
		FINAL		19FEB2003	8:55	55	1.1
	E0035010	BSLN		07JAN2003	7:45	-3	0.8
		FINAL		06MAR2003	9:00	56	0.8
	E0035022	BSLN		01MAY2003	9:45	-8	0.8
		FINAL		07JUL2003	8:55	60	0.6
	E0039003	BSLN		12NOV2002	11:19	-13	0.8
		FINAL		02JAN2003	14:06	39	0.7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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H: Higher than upper limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.2 Chemistry Data - Renal Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	CREATININE (MG/DL)
PLACEBO (BIPOLAR II)	E0040001	BSLN	18JUN2003	14:30	-9	0.6
		FINAL	22AUG2003	9:00	57	0.6
	E0040004	BSLN	11JUL2003	13:00	-7	0.9
	E0041002	BSLN	13JAN2003	14:35	-8	1.2
		FINAL	11MAR2003	10:35	50	1.2
	E0041005	BSLN	28FEB2003	12:31	-5	0.8
		FINAL	30APR2003	14:08	57	1.1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM101.SAS
GENERATED: 12JUL2005 17:40:20 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		22JAN2003	14:00	-13	82.0	55.6	8
		FINAL		02APR2003	10:10	58	91.0	41.7	6
	E0002010	BSLN		28MAR2003	10:00	-7	88.0	243.1 H	35 H
	E0002012	BSLN		16APR2003	10:10	-5	103.0	319.5 H	46 H
		FINAL		16JUN2003	11:30	57	85.0	27.8	4
	E0002015	BSLN		22MAY2003	10:15	-13	110.0	138.9 H	20 H
	E0002018	BSLN		16JUL2003	13:25	-8	91.0	111.1	16
		FINAL		04AUG2003	9:40	12	115.0	125.0 H	18 H
	E0003004	BSLN	*	03DEC2002	11:48	-14	76.0	138.9 H	20 H
		BSLN		17DEC2002	9:20	1	80.0	222.2 H	32 H
		FINAL		07JAN2003	15:40	22	74.0	104.2	15
	E0003005	BSLN		16DEC2002	15:00	-7	79.0	76.4	11
		FINAL		18FEB2003	8:55	58	94.0	194.5 H	28 H
		FINAL	*	04MAR2003	9:55	72		104.2	15
	E0003007	BSLN		19DEC2002	10:15	-14	79.0	76.4	11
		FINAL		27FEB2003	8:50	57	75.0	62.5	9
	E0003015	BSLN		29APR2003	11:30	-6	76.0	55.6	8
		FINAL		02JUL2003	14:45	59	80.0	48.6	7
	E0004002	BSLN		24SEP2002	10:40	-7	82.0	76.4	11
		FINAL		26NOV2002	11:00	57	95.0	201.4 H	29 H
		FINAL	*	17DEC2002	12:00	78		90.3	13
	E0004013	BSLN		08JAN2003	10:00	-6	89.0	125.0 H	18 H
		FINAL		19FEB2003	8:20	37	94.0	118.1 H	17 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	BSLN		12MAR2003	10:50	-7	85.0	48.6	7
		FINAL		13MAY2003	13:45	56	81.0	13.9 L	2 L
	E0004021	BSLN		07MAY2003	15:55	-7	75.0	83.3	12
		FINAL		09JUL2003	14:10	57	87.0	152.8 H	22 H
	E0005002	BSLN		23SEP2002	10:00	-10	98.0	55.6	8
		FINAL		25NOV2002	8:30	54	86.0	180.6 H	26 H
	E0005004	BSLN		24SEP2002	12:00	-7	94.0	76.4	11
	E0005013	BSLN		30OCT2002	8:00	-8	85.0	20.8	3
	E0005024	BSLN		05FEB2003	15:00	-5	75.0	138.9 H	20 H
		FINAL		10APR2003	11:30	60	86.0	250.0 H	36 H
		FINAL	*	22JUL2003	16:05	163		90.3	13
	E0005027	BSLN		04MAR2003	7:45	-7	94.0	97.2	14
		FINAL		03APR2003	8:15	24	90.0	69.5	10
	E0005037	BSLN		30APR2003	12:00	-7	93.0	69.5	10
		FINAL		02JUL2003	12:15	57	102.0	138.9 H	20 H
		FINAL	*	16JUL2003	11:00	71		138.9 H	20 H
	E0005042	BSLN		19JUN2003	11:30	-5	90.0	132.0 H	19 H
		FINAL		18AUG2003	16:25	56	85.0	152.8 H	22 H
	E0006005	BSLN		25NOV2002	12:15	-10	75.0	111.1	16
		FINAL		30JAN2003	16:10	57	84.0	132.0 H	19 H
	E0006018	BSLN		07MAR2003	12:40	-6	88.0	97.2	14
		FINAL		24MAR2003	10:45	12	82.0	159.7 H	23 H
	E0007013	BSLN		10JUN2003	9:25	-3	93.0	34.7	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0007013	FINAL		07AUG2003	9:20	56	97.0	27.8	4
	E0010004	BSLN		05DEC2002	11:10	-6	81.0	34.7	5
		FINAL		06FEB2003	12:40	58	92.0	34.7	5
	E0010012	BSLN		30DEC2002	9:48	-8	107.0	236.1 H	34 H
		FINAL		05MAR2003	13:59	58	108.0	243.1 H	35 H
	E0010024	BSLN		23APR2003	8:45	-12	136.0H#	111.1	16
		FINAL		02JUL2003	10:30	59	156.0H#	111.1	16
	E0010032	BSLN		03JUL2003	11:30	-7	79.0	90.3	13
		FINAL		17JUL2003	11:38	8	89.0	69.5	10
	E0011025	BSLN		20JUN2003	14:30	-6	82.0	34.7	5
		FINAL		22AUG2003	10:00	58	81.0	34.7	5
	E0013007	BSLN		14MAR2003	8:48	-6	174.0H#	69.5	10
		FINAL		07APR2003	17:15	19	142.0H#	76.4	11
	E0013009	BSLN		26MAR2003	9:09	-7	95.0	55.6	8
		FINAL		29MAY2003	17:50	58	90.0	48.6	7
	E0014006	BSLN	*	14MAR2003	11:30	-11		277.8 H	40 H
		BSLN		14MAR2003	11:30	-11	58.0L		
		BSLN		19MAR2003	10:40	-6		62.5	9
		FINAL		21MAY2003	16:20	58	86.0	562.5 H	81 H
	E0014010	BSLN		15APR2003	17:20	-7	83.0	444.5 H	64 H
		FINAL		17JUN2003	18:10	57	93.0	395.9 H	57 H
	E0016001	BSLN		02JAN2003	8:50	-20	95.0	180.6 H	26 H
		FINAL		19MAR2003	12:00	57	80.0	34.7	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0016004	BSLN		27JAN2003	9:30	-7	73.0	55.6	8
	E0018001	BSLN		22OCT2002	16:15	-7	80.0	263.9 H	38 H
		FINAL		24DEC2002	9:55	57	137.0H#	1562.6 H	225 H
	E0018006	BSLN		10DEC2002	17:15	-7	92.0	55.6	8
		FINAL		27FEB2003	12:10	73	90.0	41.7	6
	E0019004	BSLN		30OCT2002	8:40	-8	79.0	27.8	4
		FINAL		19DEC2002	12:55	43	83.0	90.3	13
	E0019011	BSLN		12NOV2002	12:05	-9	87.0	48.6	7
		FINAL		16JAN2003	14:20	57	95.0	69.5	10
	E0019025	BSLN		30JAN2003	14:40	-7	78.0	41.7	6
		FINAL		03APR2003	13:30	57	79.0	41.7	6
	E0019026	BSLN		11FEB2003	11:10	-13		118.1 H	17 H
		BSLN		17FEB2003	12:40	-7	91.0		
	E0019043	BSLN		21MAY2003	11:04	-13	93.0	27.8	4
		FINAL	*	17JUN2003	12:10	15	61.0L		
		FINAL		29JUL2003	11:38	57	83.0	34.7	5
	E0020001	BSLN		15OCT2002	20:00	-14	76.0	41.7	6
		FINAL		20DEC2002	12:30	53	81.0	76.4	11
	E0020006	BSLN	*	26NOV2002	18:00	-20		145.8 H	21 H
		BSLN		26NOV2002	18:00	-20	73.0		
		BSLN		10DEC2002	16:00	-6		180.6 H	26 H
		FINAL	*	20DEC2002	8:45	5		361.1 H	52 H
		FINAL		08JAN2003	10:00	24	90.0	208.4 H	30 H
	E0020007	BSLN		10JAN2003	12:00	-5	81.0	104.2	15

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0020007	FINAL		25MAR2003	18:50	70	93.0	138.9 H	20 H
	E0020011	BSLN		19FEB2003	13:45	-7	87.0	402.8 H	58 H
		FINAL		23APR2003	14:30	57	98.0	1284.8 H	185 H
		FINAL	*	07MAY2003	12:00	71	87.0	437.5 H	63 H
	E0020013	BSLN		26FEB2003	14:15	-7	74.0	20.8	3
		FINAL		25MAR2003	12:00	21	75.0	104.2	15
	E0022008	BSLN		05NOV2002	10:00	-7	72.0	41.7	6
		FINAL		07JAN2003	9:45	57	97.0	34.7	5
	E0022017	BSLN	*	05DEC2002	12:35	-14		312.5 H	45 H
		BSLN		05DEC2002	12:35	-14	86.0		
		BSLN		11DEC2002	12:35	-8		41.7	6
		FINAL		07MAR2003	9:47	79	94.0	187.5 H	27 H
	E0022018	BSLN		04DEC2002	10:15	-8	93.0	104.2	15
		FINAL		11FEB2003	8:40	62	91.0	118.1 H	17 H
	E0022022	BSLN		16DEC2002	13:15	-14	79.0	69.5	10
		FINAL		27FEB2003	11:35	60	74.0	132.0 H	19 H
	E0022027	BSLN		24JAN2003	7:40	-13	88.0	41.7	6
		FINAL		03APR2003	9:00	57	96.0	55.6	8
	E0022030	BSLN		10FEB2003	7:40	-4	98.0	173.6 H	25 H
	E0022031	BSLN		11FEB2003	10:25	-7	106.0	62.5	9
		FINAL		15APR2003	9:30	57	93.0	104.2	15
	E0022032	BSLN		12FEB2003	8:05	-6	102.0	159.7 H	23 H
		FINAL		18APR2003	10:30	60	92.0	55.6	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0022035	BSLN		13FEB2003	13:50	-6	74.0	41.7	6
		FINAL		13MAR2003	17:55	23	81.0	62.5	9
	E0022036	BSLN		14FEB2003	8:55	-11	91.0	41.7	6
		FINAL		22APR2003	7:36	57	84.0	34.7	5
	E0022056	BSLN		11APR2003	8:07	-6	91.0	41.7	6
	E0022060	BSLN		24APR2003	12:05	-6	94.0	27.8	4
		FINAL		24JUN2003	9:25	56	80.0	27.8	4
	E0022063	BSLN		29APR2003	10:10	-8	88.0	69.5	10
	E0023008	BSLN		23JAN2003	10:00	-7	78.0	41.7	6
		FINAL		24MAR2003	15:40	54	93.0	76.4	11
	E0023013	BSLN		13FEB2003	11:00	-14	87.0	69.5	10
		FINAL		06MAR2003	11:00	8	90.0	41.7	6
	E0023015	BSLN		04MAR2003	11:00	-7	91.0	34.7	5
		FINAL		06MAY2003	10:00	57	83.0	27.8	4
	E0023034	BSLN		03JUN2003	14:00	-6	82.0	104.2	15
		FINAL		05AUG2003	16:00	58	84.0	111.1	16
	E0023037	BSLN		11JUN2003	16:30	-7	87.0	48.6	7
		FINAL	*	24JUN2003	16:30	7	91.0		
		FINAL		15AUG2003	9:30	59	87.0	34.7	5
	E0023038	BSLN		20JUN2003	12:45	-10	91.0	76.4	11
		FINAL		16SEP2003	18:30	79	84.0	152.8 H	22 H
	E0023044	BSLN		08JUL2003	14:00	-8	94.0	90.3	13
		FINAL		12AUG2003	12:00	28	93.0	138.9 H	20 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	BSLN		10JUL2003	11:40	-7	82.0	13.9 L	2 L
		FINAL		15SEP2003	11:00	61	62.0L	104.2	15
	E0025002	BSLN		27MAR2003	11:05	-7	90.0	48.6	7
		FINAL		29MAY2003	11:40	57	100.0	152.8 H	22 H
	E0026010	BSLN		15JAN2003	14:00	-7	92.0	48.6	7
		FINAL		30JAN2003	16:30	9	100.0	34.7	5
	E0026017	BSLN		26FEB2003	11:50	-8	84.0	62.5	9
		FINAL		21MAR2003	11:10	16	72.0	104.2	15
	E0026018	BSLN	*	06MAR2003	16:30	-14		333.4 H	48 H
		BSLN		06MAR2003	16:30	-14	84.0		
		BSLN	*	11MAR2003	10:15	-9		1034.8 H	149 H
		BSLN		14MAR2003	9:30	-6		104.2	15
		FINAL		15MAY2003	14:15	57	81.0	104.2	15
	E0026025	BSLN		01MAY2003	11:40	-8	92.0	27.8	4
		FINAL		03JUL2003	9:30	56	75.0	20.8	3
	E0026029	BSLN		02JUL2003	11:10	-7	86.0	83.3	12
		FINAL		28JUL2003	13:30	20	97.0	90.3	13
	E0026030	BSLN		02JUL2003	11:50	-7	80.0	20.8	3
		FINAL		03SEP2003	17:10	57	87.0	90.3	13
	E0026031	BSLN		10JUL2003	14:00	-11	71.0	6.9 L	1 L
		FINAL		15SEP2003	11:15	57	75.0	34.7	5
	E0027003	BSLN		08JAN2003	14:40	-20	96.0	138.9 H	20 H
		FINAL		25MAR2003	11:55	57	68.0	76.4	11
	E0028004	BSLN		27SEP2002	9:45	-3	89.0	48.6	7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0028004	FINAL		09OCT2002	14:30	10	83.0	34.7	5
	E0028006	BSLN		01OCT2002	10:00	-3	80.0	27.8	4
		FINAL		04DEC2002	10:15	62	77.0	20.8	3
	E0028008	BSLN	*	08OCT2002	12:45	-7		680.6 H	98 H
		BSLN		08OCT2002	12:45	-7	76.0		
		BSLN		11OCT2002	10:00	-4		382.0 H	55 H
		FINAL		10DEC2002	12:30	57	84.0	236.1 H	34 H
	E0028009	BSLN		10OCT2002	10:45	-5	81.0	76.4	11
		FINAL		12DEC2002	13:50	59	83.0	90.3	13
	E0028016	BSLN		07NOV2002	10:15	-7	82.0	55.6	8
		FINAL		09JAN2003	11:50	57	68.0	55.6	8
	E0028017		*	12NOV2002	9:45		76.0	125.0 H	18 H
	E0028027	BSLN		14JAN2003	10:15	-7	92.0	111.1	16
	E0028029	BSLN		28JAN2003	10:00	-7	91.0	69.5	10
		FINAL		04APR2003	10:55	60	83.0	83.3	12
	E0028034	BSLN		20MAR2003	9:40	-12	76.0	69.5	10
		FINAL		02JUN2003	12:54	63	76.0	69.5	10
	E0028038	BSLN		18APR2003	10:20	-7	97.0	132.0 H	19 H
		FINAL		18JUN2003	13:45	55	103.0	166.7 H	24 H
	E0028043	BSLN		29MAY2003	11:55	-7	77.0	159.7 H	23 H
		FINAL		29JUL2003	8:25	55	114.0	152.8 H	22 H
	E0028045	BSLN		09JUN2003	13:00	-9	78.0	55.6	8
		FINAL		11SEP2003	12:50	86	71.0	48.6	7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	BSLN	*	14NOV2002	13:00	-13	82.0	194.5 H	28 H
		BSLN		21NOV2002	10:30	-6	82.0	90.3	13
		FINAL		21JAN2003	12:50	56	80.0	97.2	14
	E0030001	BSLN		12NOV2002	15:15	-7	93.0	20.8	3
		FINAL		16JAN2003	12:07	59	96.0	41.7	6
	E0030008	BSLN		07JAN2003	14:33	-7	80.0	34.7	5
		FINAL		18MAR2003	10:42	64	108.0	48.6	7
	E0030011	BSLN		16JAN2003	16:10	-11	71.0	243.1 H	35 H
		FINAL		24MAR2003	14:35	57	88.0	159.7 H	23 H
	E0030015	BSLN		13FEB2003	12:05	-8	78.0	48.6	7
		FINAL		22APR2003	12:10	61	91.0	55.6	8
	E0030022	BSLN		10JUN2003	11:15	-6	91.0	83.3	12
		FINAL		14AUG2003	15:30	60	68.0	312.5 H	45 H
	E0031002	BSLN		20NOV2002	17:05	-7	86.0	34.7	5
		FINAL		23JAN2003	12:55	58	83.0	41.7	6
	E0031003	BSLN		03DEC2002	16:07	-7	73.0	20.8	3
		FINAL		04FEB2003	16:20	57	81.0	13.9 L	2 L
	E0033015	BSLN		03APR2003	17:05	-7	75.0	27.8	4
		FINAL		04JUN2003	11:00	56	69.0	27.8	4
	E0034002	BSLN		18MAR2003	9:25	-7	121.0H	194.5 H	28 H
		FINAL		16APR2003	14:40	23	132.0H#	625.1 H	90 H
	E0034003	BSLN		11APR2003	10:10	-13	87.0	48.6	7
		FINAL		19JUN2003	15:50	57	90.0	41.7	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	BSLN		25APR2003	11:33	-21	102.0	1020.9 H	147 H
		FINAL		10JUL2003	9:54	56	78.0	257.0 H	37 H
	E0034008	BSLN		16MAY2003	13:26	-8	86.0	180.6 H	26 H
		FINAL		21JUL2003	10:07	59	92.0	132.0 H	19 H
	E0035003	BSLN		15NOV2002	10:30	-7	82.0	104.2	15
	E0035005	BSLN		26NOV2002	10:00	-7	80.0	118.1 H	17 H
	E0035014	BSLN		28JAN2003	11:10	-6	76.0	34.7	5
		FINAL		31MAR2003	9:20	57	81.0	55.6	8
	E0035024	BSLN		15MAY2003	11:30	-8	86.0	104.2	15
		FINAL		18JUL2003	9:00	57	85.0	69.5	10
	E0036005	BSLN		24JUN2003	10:45	-7	83.0	76.4	11
		FINAL		27AUG2003	12:45	58	78.0	69.5	10
	E0037002	BSLN		18DEC2002	12:10	-8	86.0	111.1	16
		FINAL		20FEB2003	13:25	57	89.0	62.5	9
	E0037005	BSLN		27FEB2003	15:00	-7	75.0	111.1	16
		FINAL		01MAY2003	14:15	57	80.0	76.4	11
	E0037006	BSLN		07MAR2003	12:00	-7	85.0	13.9 L	2 L
		FINAL		09MAY2003	12:18	57	76.0	6.9 L	1 L
	E0039006	BSLN	*	11NOV2002	10:05	-49	76.0	104.2	15
		BSLN	*	22NOV2002	9:20	-38	82.0		
		BSLN		10DEC2002	11:35	-20	77.0	48.6	7
		FINAL		24FEB2003	10:58	57	72.0	97.2	14
	E0039015	BSLN		02JAN2003	10:20	-21	83.0	20.8	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR I)	E0039015	FINAL		20MAR2003	9:30	57	88.0	27.8	4
	E0039024	BSLN		14FEB2003	8:50	-13	92.0	83.3	12
		FINAL		25APR2003	16:05	58	80.0	76.4	11
	E0039025	BSLN		26FEB2003	11:00	-20	81.0	41.7	6
		FINAL		27MAY2003	10:00	71	97.0	90.3	13
	E0039041	BSLN		08APR2003	9:40	-7	83.0	27.8	4
		FINAL		11JUN2003	11:25	58	83.0	41.7	6
	E0039044	BSLN		06MAY2003	10:30	-16	98.0	55.6	8
		FINAL		23JUL2003	18:20	63	100.0	90.3	13
	E0039046		*	06MAY2003	11:46		92.0	583.4 H	84 H
			*	03JUN2003	10:25		91.0	562.5 H	81 H
	E0039051	BSLN		23MAY2003	9:30	-24	83.0	125.0 H	18 H
		FINAL		12AUG2003	14:45	58	84.0	243.1 H	35 H
	E0039053	BSLN		16JUN2003	13:25	-25	89.0	76.4	11
		FINAL		08SEP2003	12:45	60	93.0	48.6	7
	E0039057	BSLN		02JUL2003	19:50	-12	69.0	27.8	4
		FINAL		09SEP2003	9:25	58	134.0H#	423.6 H	61 H
	E0041003	BSLN		16JAN2003	17:30	-12	96.0	777.8 H	112 H
		FINAL		25MAR2003	9:55	57	95.0	159.7 H	23 H
	E0041008	BSLN		26MAR2003	15:35	-12	105.0	229.2 H	33 H
		FINAL		02JUN2003	15:30	57	86.0	83.3	12
	E0042001	BSLN		17JUN2003	9:45	-15	93.0	62.5	9
		FINAL		26AUG2003	10:50	56	85.0	62.5	9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN		26FEB2003	14:25	-14	76.0	111.1	16
		FINAL		07MAY2003	13:45	57	89.0	138.9 H	20 H
	E0003018	BSLN		06MAY2003	16:22	-7	87.0	34.7	5
		FINAL		08JUL2003	14:18	57	82.0	62.5	9
	E0005011	BSLN		17OCT2002	15:00	-7	79.0	20.8	3
	E0005030	BSLN		18MAR2003	14:00	-8	77.0	41.7	6
	E0005036	BSLN		28APR2003	13:30	-8	83.0	76.4	11
		FINAL		27MAY2003	10:00	22	79.0	69.5	10
	E0006015	BSLN		07FEB2003	9:30	-4	87.0	125.0 H	18 H
		FINAL		08APR2003	12:00	57	89.0	166.7 H	24 H
	E0006016	BSLN		07FEB2003	12:55	-10	87.0	34.7	5
		FINAL		18APR2003	12:15	61	99.0	48.6	7
	E0007008	BSLN		08APR2003	9:55	-10	110.0	159.7 H	23 H
		FINAL		02JUL2003	14:00	76	108.0	472.3 H	68 H
		FINAL	*	12AUG2003	11:30	117	103.0	152.8 H	22 H
	E0009002	BSLN		30OCT2002	11:45	-20	85.0	173.6 H	25 H
		FINAL		15JAN2003	13:47	58	84.0	118.1 H	17 H
	E0009006	BSLN		23JAN2003	17:50	-5	64.0L	41.7	6
		FINAL		25MAR2003	16:20	57	67.0L	34.7	5
	E0009009	BSLN		27FEB2003	15:00	-13	80.0	90.3	13
		FINAL		24MAR2003	13:40	13	90.0	152.8 H	22 H
	E0010015	BSLN		30JAN2003	10:35	-21	107.0	270.9 H	39 H
		FINAL		15APR2003	13:29	55	106.0	701.4 H	101 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	BSLN		17DEC2002	11:00	-7	91.0	69.5	10
		FINAL		18FEB2003	9:00	57	81.0	69.5	10
	E0011007	BSLN		12DEC2002	10:43	-7	101.0	97.2	14
		FINAL		13FEB2003	8:00	57	127.0H#	111.1	16
	E0011018	BSLN		15MAY2003	12:30	-7	74.0	27.8	4
		FINAL		17JUL2003	17:30	57	95.0	298.6 H	43 H
	E0011024	BSLN		17JUN2003	12:10	-7	76.0	76.4	11
		FINAL		21AUG2003	13:00	59	84.0	111.1	16
	E0015003	BSLN		13NOV2002	12:20	-12	94.0	104.2	15
		FINAL		02DEC2002	10:55	8	95.0	132.0 H	19 H
	E0019003	BSLN	*	30OCT2002	9:10	-22		423.6 H	61 H
		BSLN		30OCT2002	9:10	-22	99.0		
		BSLN		05NOV2002	11:15	-16		187.5 H	27 H
		FINAL		16JAN2003	11:25	57	85.0	187.5 H	27 H
	E0019007	BSLN		06NOV2002	10:32	-7	99.0	62.5	9
		FINAL		07JAN2003	8:30	56	88.0	20.8	3
	E0019014	BSLN	*	17DEC2002	11:02	-23	80.0		
		BSLN		17DEC2002	11:02	-23		34.7	5
		BSLN		26DEC2002	10:25	-14	66.0L		
		FINAL		22JAN2003	9:00	14	67.0L	48.6	7
	E0019018	BSLN		14JAN2003	10:45	-16	83.0	125.0 H	18 H
		FINAL		27MAR2003	9:30	57	85.0	104.2	15
	E0019022	BSLN		23JAN2003	12:00	-7	84.0	83.3	12
		FINAL		27MAR2003	15:10	57	88.0	291.7 H	42 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	BSLN	20FEB2003	10:50	-7	206.0H#	291.7 H	42 H
		FINAL	06MAR2003	9:14	8		243.1 H	35 H
	E0019032	BSLN	06MAR2003	14:50	-26	99.0		
		FINAL	28MAY2003	11:00	58	105.0	83.3	12
	E0019034	BSLN	10MAR2003	16:55	-8	87.0	76.4	11
	E0019036	BSLN	18MAR2003	9:15	-7	86.0	20.8	3
	E0019039	BSLN	22APR2003	11:00	-9	86.0	62.5	9
		FINAL	08MAY2003	15:30	8	99.0	118.1 H	17 H
	E0019041	BSLN	14MAY2003	10:50	-7	62.0L	20.8	3
		FINAL	16JUL2003	11:10	57	78.0	90.3	13
	E0019049	BSLN	03JUL2003	13:40	-7	81.0	48.6	7
		FINAL	08SEP2003	12:10	61	94.0	62.5	9
	E0022052	BSLN	01APR2003	10:50	-9	98.0	104.2	15
		FINAL	05JUN2003	9:32	57	99.0	138.9 H	20 H
	E0022064	BSLN	01MAY2003	10:40	-5	85.0	41.7	6
		FINAL	01JUL2003	12:30	57	81.0	20.8	3
	E0022073	BSLN	20JUN2003	14:10	-6	81.0	41.7	6
		FINAL	21AUG2003	9:45	57	88.0	62.5	9
	E0023002	BSLN	25OCT2002	16:00	-11	87.0	69.5	10
	E0023017	BSLN	14MAR2003	13:00	-11		41.7	6
		BSLN	20MAR2003	11:00	-5	68.0		
		FINAL	22MAY2003	12:30	59	106.0	354.2 H	51 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	BSLN	*	10APR2003	10:20	-13	94.0	291.7 H	42 H
		BSLN		16APR2003	15:00	-7	86.0	90.3	13
		FINAL		17JUN2003	16:00	56	106.0	409.8 H	59 H
	E0023027	BSLN	*	07MAY2003	13:30	-9		402.8 H	58 H
		BSLN		07MAY2003	13:30	-9	82.0		
		BSLN		13MAY2003	14:10	-3		118.1 H	17 H
		FINAL		09JUL2003	13:00	55	70.0	222.2 H	32 H
	E0023030	BSLN		21MAY2003	10:00	-13	101.0	62.5	9
		FINAL		30JUL2003	15:30	58	111.0	55.6	8
	E0023040	BSLN		25JUN2003	15:00	-8	79.0	27.8	4
		FINAL		05SEP2003	10:00	65	68.0	13.9 L	2 L
	E0026014	BSLN		12FEB2003	11:40	-7	97.0	83.3	12
		FINAL		19MAR2003	10:35	29	105.0	83.3	12
	E0026019	BSLN		10MAR2003	11:45	-7	82.0	62.5	9
		FINAL		12MAY2003	9:10	57	87.0	451.4 H	65 H
	E0027005	BSLN		19DEC2002	14:50	-7	87.0	55.6	8
		FINAL		20FEB2003	11:28	57	86.0	125.0 H	18 H
	E0029009	BSLN		13JAN2003	12:50	-7	77.0	48.6	7
		FINAL		18MAR2003	9:05	58	92.0	41.7	6
	E0029021	BSLN	*	03MAR2003	10:40	-15		48.6	7
		BSLN		03MAR2003	10:40	-15	87.0		
		BSLN		18MAR2003	9:50	1		41.7	6
		FINAL		15MAY2003	12:30	59	86.0	166.7 H	24 H
		FINAL	*	27MAY2003	8:40	71	91.0	69.5	10
	E0029026	BSLN		07APR2003	9:10	-7	97.0	97.2	14

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	FINAL		10JUN2003	15:00	58	86.0	41.7	6
	E0029030	BSLN	*	13MAY2003	11:20	-14	86.0		
		BSLN		13MAY2003	11:20	-14		41.7	6
		BSLN		20MAY2003	12:55	-7	80.0		
		FINAL		23JUL2003	17:25	58	94.0	55.6	8
	E0031008	BSLN		05FEB2003	11:40	-23	86.0	69.5	10
		FINAL		24APR2003	13:17	56	91.0	55.6	8
	E0031020	BSLN		14APR2003	10:35	-7	105.0	132.0 H	19 H
		FINAL		13MAY2003	10:50	23	95.0	69.5	10
	E0031021	BSLN		18APR2003	10:40	-7	84.0	69.5	10
		FINAL		19JUN2003	10:40	56	108.0	263.9 H	38 H
	E0031029	BSLN		05JUN2003	10:45	-13	81.0	62.5	9
	E0033002	BSLN		23DEC2002	12:15	-18	91.0	48.6	7
		FINAL		07MAR2003	11:25	57	97.0	48.6	7
	E0033006	BSLN		15JAN2003	10:25	-8	85.0	27.8	4
		FINAL		12FEB2003	12:30	21	81.0	48.6	7
	E0033021	BSLN		25JUN2003	14:40	-7	81.0	20.8	3
		FINAL		18AUG2003	16:20	48	100.0	132.0 H	19 H
	E0035013	BSLN		27JAN2003	10:30	-8	79.0	48.6	7
		FINAL		10FEB2003	11:05	7	92.0	104.2	15
	E0035015	BSLN		03FEB2003	10:30	-8	103.0	375.0 H	54 H
		FINAL		18FEB2003	11:20	8	124.0H	1194.5 H	172 H
	E0035016	BSLN		10MAR2003	11:00	-25	80.0	118.1 H	17 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 300 MG (BIPOLAR II)	E0035023	BSLN		06MAY2003	10:30	-7	91.0	41.7	6
	E0039052	BSLN	*	29MAY2003	10:25	-22	145.0H#		
		BSLN		29MAY2003	10:25	-22		159.7 H	23 H
		BSLN		13JUN2003	12:10	-7	92.0		
	E0039056	BSLN		01JUL2003	12:50	-14	78.0	41.7	6
	E0040003	BSLN		09JUL2003	14:00	-10	80.0	90.3	13
		FINAL		12SEP2003	11:00	56	82.0	83.3	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN		14FEB2003	10:30	-17	86.0	55.6	8
		FINAL		02MAY2003	10:30	61	94.0	55.6	8
	E0002011	BSLN		16APR2003	11:30	-13	79.0	48.6	7
		FINAL		25JUN2003	11:20	58	89.0	62.5	9
	E0003010	BSLN		28JAN2003	9:10	-6	89.0	34.7	5
		FINAL		31MAR2003	16:20	57	81.0	20.8	3
	E0003011	BSLN		28JAN2003	11:47	-7	86.0	118.1 H	17 H
	E0003016	BSLN		01MAY2003	11:40	-21	82.0	48.6	7
		FINAL		13JUN2003	8:45	23	79.0	138.9 H	20 H
	E0003019	BSLN		19JUN2003	11:30	-8	91.0	41.7	6
		FINAL		21AUG2003	8:50	56	104.0	132.0 H	19 H
	E0003020	BSLN		27JUN2003	8:55	-26	64.0L	62.5	9
		FINAL		17SEP2003	15:00	57	82.0	62.5	9
	E0004001	BSLN		23SEP2002	11:00	-7	84.0	20.8	3
		FINAL		05NOV2002	13:30	37	107.0	166.7 H	24 H
	E0004009	BSLN		17DEC2002	10:10	-9	86.0	83.3	12
		FINAL		19FEB2003	16:00	56	96.0	312.5 H	45 H
		FINAL	*	13MAR2003	8:55	78		90.3	13
	E0004012	BSLN		07JAN2003	12:45	-7	83.0	48.6	7
		FINAL		11MAR2003	11:35	57	87.0	48.6	7
	E0004015	BSLN		06FEB2003	10:05	-14	94.0	111.1	16
		FINAL		15APR2003	9:10	55	94.0	125.0 H	18 H
	E0005003	BSLN		23SEP2002	15:00	-9	94.0	111.1	16

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	FINAL		26NOV2002	13:25	56	106.0	236.1 H	34 H
		FINAL	*	20DEC2002	9:50	80	155.0H#	1041.8 H	150 H
		FINAL	*	02JAN2003	10:10	93	139.0H#	354.2 H	51 H
	E0005005	BSLN		24SEP2002	15:20	-6	92.0	55.6	8
	E0005007	BSLN		02OCT2002	12:40	-7	76.0	69.5	10
		FINAL		04DEC2002	14:20	57	107.0	520.9 H	75 H
		FINAL	*	23DEC2002	10:00	76	82.0	159.7 H	23 H
		FINAL	*	14JAN2003	10:50	98	85.0	118.1 H	17 H
	E0005008	BSLN		08OCT2002	18:00	-7	100.0	1145.9 H	165 H
		FINAL		11DEC2002	16:00	58	172.0H#	2722.4 H	392 H
		FINAL	*	06JAN2003	9:30	84		618.1 H	89 H
		FINAL	*	24FEB2003	10:30	133	116.0	423.6 H	61 H
		FINAL	*	12MAR2003	16:30	149	92.0	194.5 H	28 H
	E0005009	BSLN		09OCT2002	10:00	-20	99.0	62.5	9
	E0005010	BSLN		14OCT2002	13:00	-7	86.0	270.9 H	39 H
		FINAL		17DEC2002	14:25	58	85.0	687.6 H	99 H
		FINAL	*	23DEC2002	16:00	64	103.0	611.2 H	88 H
	E0005012	BSLN		24OCT2002	7:00	-21	79.0	76.4	11
		FINAL		07JAN2003	11:00	55	88.0	62.5	9
	E0005014	BSLN		05NOV2002	16:30	-8	85.0	34.7	5
		FINAL		06JAN2003	10:00	55	80.0	69.5	10
	E0005022	BSLN		27JAN2003	10:30	-2	82.0	83.3	12
		FINAL		11MAR2003	10:10	42	70.0	34.7	5
	E0005025	BSLN		20FEB2003	13:20	-7	84.0	69.5	10
		FINAL		03APR2003	11:30	36	87.0	83.3	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	BSLN		26MAR2003	11:35	-12	90.0	48.6	7
		FINAL		03JUN2003	12:00	58	85.0	48.6	7
	E0007005	BSLN		27JAN2003	14:30	-4	82.0	41.7	6
		FINAL		28MAR2003	13:30	57	89.0	76.4	11
		FINAL	*	11APR2003	11:00	71	96.0		
	E0007015	BSLN		10JUL2003	7:35	-6	99.0	55.6	8
		FINAL		10SEP2003	7:40	57	97.0	55.6	8
	E0009001	BSLN		29OCT2002	15:30	-14	81.0	62.5	9
	E0010002	BSLN		14NOV2002	10:36	-11	82.0	55.6	8
		FINAL		02DEC2002	9:05	8	118.0	562.5 H	81 H
	E0010009	BSLN		18DEC2002	9:42	-8	88.0	69.5	10
		FINAL		19FEB2003	13:59	56	88.0	27.8	4
	E0010010	BSLN		20DEC2002	8:45	-10	88.0	48.6	7
		FINAL		13JAN2003	10:28	15	84.0	48.6	7
	E0010014	BSLN		14JAN2003	9:05	-14	81.0	34.7	5
		FINAL		25MAR2003	11:05	57	76.0	6.9 L	1 L
	E0010017	BSLN		05FEB2003	8:51	-20	82.0	55.6	8
		FINAL		22APR2003	10:20	57	64.0L	27.8	4
	E0010023	BSLN		10APR2003	9:22	-7	80.0	34.7	5
		FINAL		01MAY2003	10:19	15	106.0	173.6 H	25 H
	E0010027	BSLN		05JUN2003	9:10	-11	109.0	152.8 H	22 H
		FINAL		01JUL2003	13:00	16	95.0		
	E0010029	BSLN		10JUN2003	9:25	-9	145.0H#	222.2 H	32 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0011022	BSLN	02JUN2003	11:00	-7	69.0	132.0 H	19 H
		FINAL	05AUG2003	10:30	58	88.0	2430.8 H	350 H
	E0013006	BSLN	06MAR2003	10:15	-7	75.0	125.0 H	18 H
		FINAL	24MAR2003	12:42	12	105.0	812.6 H	117 H
	E0013012	BSLN	29APR2003	9:48	-8	95.0	69.5	10
		FINAL	02JUL2003	10:05	57	89.0	215.3 H	31 H
	E0013014	BSLN	08MAY2003	11:15	-26	88.0	34.7	5
		FINAL	30JUN2003	12:21	28	83.0	76.4	11
	E0014005	BSLN	04MAR2003	17:20	-7	80.0	34.7	5
		FINAL	06MAY2003	12:20	57	95.0	34.7	5
	E0014007	BSLN	25MAR2003	17:50	-7	76.0	41.7	6
		FINAL	22APR2003	13:50	22	76.0	34.7	5
	E0014011	BSLN	06MAY2003	16:45	-7	57.0L	83.3	12
		FINAL	08JUL2003	15:50	57	77.0	132.0 H	19 H
	E0014012	BSLN	19MAY2003	10:05	-8	84.0	34.7	5
		FINAL	24JUN2003	18:40	29	97.0	55.6	8
	E0015001	BSLN	11NOV2002	9:10	-18	112.0	277.8 H	40 H
		FINAL	20JAN2003	7:30	53	175.0H#	729.2 H	105 H
	E0015008	BSLN	13DEC2002	9:30	-6	56.0L	111.1	16
	E0016003	BSLN	10JAN2003	9:30	-14	80.0	83.3	12
	E0016005	BSLN	21FEB2003	8:45	-4	85.0	48.6	7
		FINAL	22APR2003	8:30	57	94.0	125.0 H	18 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0018007	BSLN		16DEC2002	10:15	-11	80.0	76.4	11
		FINAL		10JAN2003	14:15	15	111.0	388.9 H	56 H
	E0019005	BSLN		30OCT2002	11:50	-6	78.0	27.8	4
		FINAL		02JAN2003	14:00	59	76.0	6.9 L	1 L
	E0019015	BSLN		19DEC2002	10:49	-14	85.0	132.0 H	19 H
		FINAL		27FEB2003	11:23	57	86.0	208.4 H	30 H
	E0020004	BSLN		21NOV2002	15:20	-18	91.0	48.6	7
		FINAL		22JAN2003	16:15	45	155.0H#	145.8 H	21 H
		FINAL	*	24FEB2003	11:50	78	107.0	48.6	7
	E0020010	BSLN		31JAN2003	9:15	-5	73.0	13.9 L	2 L
		FINAL		02APR2003	10:30	57	74.0	27.8	4
	E0020014	BSLN		11MAR2003	10:00	-7	74.0	20.8	3
		FINAL		12MAY2003	11:15	56	63.0L	83.3	12
	E0020021	BSLN		13MAY2003	9:45	-6	88.0	166.7 H	24 H
		FINAL		14JUL2003	13:25	57	94.0	507.0 H	73 H
	E0020023	BSLN		09JUN2003	19:05	-8	84.0	48.6	7
		FINAL		11AUG2003	11:40	56	78.0		
		FINAL		02SEP2003	9:45	78		76.4	11
	E0022007	BSLN		01NOV2002	10:23	-6	85.0	41.7	6
	E0022010	BSLN		15NOV2002	10:40	-6	96.0	62.5	9
		FINAL		16JAN2003	18:00	57	86.0	118.1 H	17 H
	E0022012	BSLN		29NOV2002	15:40	-6	85.0	97.2	14
		FINAL		30JAN2003	12:00	57	85.0	76.4	11

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0022019	BSLN	06DEC2002	10:10	-5	87.0	62.5	9
		FINAL	06FEB2003	11:20	58	82.0	48.6	7
	E0022025	BSLN	08JAN2003	10:10	-20	88.0	55.6	8
		FINAL	04FEB2003	11:30	8	82.0	55.6	8
	E0022033	BSLN	12FEB2003	10:05	-6	90.0	48.6	7
		FINAL	15APR2003	12:10	57	86.0	69.5	10
	E0022034	BSLN	12FEB2003	12:40	-6	94.0	111.1	16
		FINAL	15APR2003	14:00	57	93.0	145.8 H	21 H
	E0022038	BSLN	21FEB2003	11:05	-7	78.0	13.9 L	2 L
		FINAL	14APR2003	9:40	46	96.0	27.8	4
	E0022039	BSLN	27FEB2003	11:15	-7	80.0	83.3	12
		FINAL	01MAY2003	12:50	57	100.0	132.0 H	19 H
	E0022046	BSLN	14MAR2003	8:00	-6	130.0H#	83.3	12
		FINAL	16MAY2003	8:05	58	107.0	69.5	10
	E0022048	BSLN	26MAR2003	9:58	-6	65.0L	55.6	8
	E0022051	BSLN	01APR2003	10:15	-6	105.0	83.3	12
		FINAL	02JUN2003	10:45	57	94.0	69.5	10
	E0022053	BSLN	04APR2003	12:50	-7	86.0	83.3	12
	E0022058	BSLN	14APR2003	10:25	-7	90.0	20.8	3
		FINAL	22MAY2003	14:00	32	122.0H	173.6 H	25 H
	E0022061	BSLN	25APR2003	9:37	-5	52.0L	90.3	13
		FINAL	26JUN2003	12:30	58	73.0	83.3	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	BSLN		28APR2003	7:43	-7	91.0	76.4	11
		FINAL		23MAY2003	7:40	19	100.0	104.2	15
	E0022068	BSLN		14MAY2003	10:23	-9	94.0	62.5	9
	E0022069	BSLN		04JUN2003	7:40	-6	78.0	41.7	6
		FINAL		05AUG2003	9:45	57	83.0	41.7	6
	E0022071	BSLN		16JUN2003	11:40	-14	93.0	41.7	6
		FINAL		26AUG2003	9:33	58	99.0	55.6	8
	E0023003	BSLN	*	08NOV2002	16:00	-39	79.0	55.6	8
		BSLN		12DEC2002	10:00	-5	85.0	55.6	8
		FINAL		11FEB2003	14:00	57	85.0	62.5	9
	E0023006	BSLN		10DEC2002	10:30	-7	60.0L	41.7	6
		FINAL		11FEB2003	11:50	57	87.0	145.8 H	21 H
	E0023010	BSLN		28JAN2003	9:30	-7	84.0	27.8	4
		FINAL		31MAR2003	10:00	56	91.0	104.2	15
	E0023025	BSLN	*	01MAY2003	15:00	-14	98.0	312.5 H	45 H
		BSLN		08MAY2003	14:15	-7	87.0	62.5	9
		FINAL		10JUL2003	13:30	57	102.0	166.7 H	24 H
	E0023039	BSLN		24JUN2003	13:30	-7	79.0	20.8	3
		FINAL		26AUG2003	13:30	57	71.0	90.3	13
	E0026002	BSLN		05NOV2002	10:15	-7	91.0	34.7	5
		FINAL		09JAN2003	9:25	59	94.0	48.6	7
	E0026007	BSLN		06JAN2003	10:30	-10	102.0	159.7 H	23 H
		FINAL		12MAR2003	14:25	56	129.0H#	611.2 H	88 H
		FINAL	*	13MAR2003	13:05	57		1034.8 H	149 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	BSLN		05FEB2003	12:20	-8	71.0	83.3	12
		FINAL		14APR2003	10:00	61	96.0	507.0 H	73 H
	E0028007	BSLN		01OCT2002	10:30	-3	106.0	145.8 H	21 H
		FINAL		14NOV2002	12:45	42	66.0L	138.9 H	20 H
	E0028023	BSLN		15JAN2003	10:00	-6	105.0	104.2	15
		FINAL		27JUN2003	15:00	158	99.0		
	E0028025	BSLN		08JAN2003	12:07	-5	87.0	48.6	7
		FINAL		27JAN2003	9:25	15	86.0	97.2	14
	E0028033	BSLN		18MAR2003	10:50	-9	80.0	48.6	7
		FINAL		22MAY2003	10:50	57	83.0	83.3	12
	E0028035	BSLN		27MAR2003	12:00	-7	89.0	159.7 H	23 H
		FINAL		29MAY2003	15:40	57	104.0	173.6 H	25 H
	E0028037	BSLN	*	18APR2003	8:30	-56	301.0H#	62.5	9
		BSLN	*	24APR2003	7:50	-50	370.0H#		
		BSLN		04JUN2003	8:33	-9	113.0	76.4	11
		FINAL		08AUG2003	15:30	57	86.0	20.8	3
	E0028039	BSLN		05MAY2003	7:10	-4	92.0	48.6	7
		FINAL		05JUN2003	12:30	28	74.0	20.8	3
	E0028046	BSLN		17JUN2003	13:45	-8	99.0	132.0 H	19 H
	E0028048	BSLN		11JUL2003	14:00	-6	104.0	194.5 H	28 H
	E0029008	BSLN		09DEC2002	11:40	-7	77.0	34.7	5
	E0029011	BSLN		14JAN2003	11:20	-8	80.0	55.6	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0029012	BSLN		04FEB2003	10:05	-7	71.0	76.4	11
		FINAL		27MAR2003	8:45	45	95.0	111.1	16
	E0029015	BSLN		11FEB2003	10:05	-13	95.0	48.6	7
		FINAL		14MAR2003	10:30	19	95.0	41.7	6
	E0029018	BSLN	*	26FEB2003	16:25	-8	85.0	41.7	6
		BSLN		06MAR2003	16:05	1	105.0	305.6 H	44 H
	E0030014	BSLN		14FEB2003	10:35	-7	79.0	48.6	7
		FINAL		22APR2003	12:50	61	86.0	34.7	5
	E0030020	BSLN		13MAY2003	15:30	-16	80.0	111.1	16
	E0030024	BSLN		17JUN2003	15:35	-24	68.0	34.7	5
		FINAL		18JUL2003	15:35	8	67.0L	125.0 H	18 H
	E0030025	BSLN	*	24JUN2003	16:35	-17	91.0		
		BSLN		24JUN2003	16:35	-17		76.4	11
		BSLN		07JUL2003	10:20	-4	84.0		
		FINAL		19AUG2003	16:45	40	101.0	111.1	16
	E0031027	BSLN		28MAY2003	9:10	-6	80.0	27.8	4
		FINAL		29JUL2003	14:40	57	85.0	41.7	6
	E0031030	BSLN		17JUN2003	10:46	-7	85.0	69.5	10
		FINAL		21AUG2003	11:10	59	74.0	20.8	3
	E0033012	BSLN		05FEB2003	15:26	-5	91.0	48.6	7
	E0034001	BSLN		17MAR2003	10:03	-3	86.0	20.8	3
		FINAL		15MAY2003	9:55	57	91.0	34.7	5
	E0034004	BSLN		11APR2003	11:15	-10	83.0	90.3	13

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0034004	FINAL	16JUN2003	12:03	57	82.0	138.9 H	20 H
	E0035001	BSLN	12NOV2002	11:40	-8	86.0	62.5	9
		FINAL	14JAN2003	9:05	56	82.0		
	E0035006	BSLN	03DEC2002	10:45	-9	75.0	27.8	4
		FINAL	06FEB2003	9:30	57	78.0	118.1 H	17 H
	E0035021	BSLN	18APR2003	10:45	-7	85.0	69.5	10
		FINAL	20JUN2003	8:15	57	89.0	83.3	12
	E0036002	BSLN	10JUN2003	13:45	-7	93.0	48.6	7
		FINAL	15JUL2003	10:05	29	101.0	97.2	14
	E0036006	BSLN	24JUN2003	16:45	-9	82.0	111.1	16
		FINAL	28AUG2003	9:50	57	83.0	152.8 H	22 H
	E0036007	BSLN	27JUN2003	10:00	-6	69.0	69.5	10
		FINAL	18JUL2003	9:15	16	112.0	250.0 H	36 H
	E0037009	BSLN	12MAY2003	9:15	-4	88.0	62.5	9
		FINAL	10JUL2003	16:05	56	120.0H	458.4 H	66 H
	E0039011	BSLN	16DEC2002	17:40	-17	111.0	34.7	5
	E0039018	BSLN	15JAN2003	9:10	-8	67.0L	41.7	6
	E0039026	BSLN	03MAR2003	9:05	-4	91.0	34.7	5
		FINAL	02MAY2003	9:20	57	98.0	62.5	9
	E0039028	BSLN	03MAR2003	14:15	-21	84.0	55.6	8
		FINAL	16MAY2003	12:25	54	85.0	76.4	11
	E0039032	BSLN	07MAR2003	13:45	-7	81.0	145.8 H	21 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR I)	E0039032	FINAL	04APR2003	11:45	22	90.0	173.6 H	25 H
	E0039034	BSLN	12MAR2003	20:05	-7	85.0	69.5	10
		FINAL	14MAY2003	15:00	57	69.0	97.2	14
	E0039042	BSLN	25APR2003	10:15	-12	79.0	55.6	8
		FINAL	02JUL2003	12:50	57	94.0	83.3	12
	E0041004	BSLN	27JAN2003	10:15	-3	73.0	55.6	8
		FINAL	31MAR2003	12:00	61	69.0	111.1	16
	E0041009	BSLN	22APR2003	15:15	-9	90.0	159.7 H	23 H
		FINAL	16JUN2003	13:00	47	106.0	201.4 H	29 H
	E0042002	BSLN	02JUL2003	12:10	-7	68.0	145.8 H	21 H
		FINAL	02SEP2003	10:25	56	81.0	229.2 H	33 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN		23JUN2003	10:00	-18	81.0	34.7	5
		FINAL		25JUL2003	9:00	15	83.0	20.8	3
	E0003002	BSLN		22OCT2002	11:05	-7	84.0	48.6	7
		FINAL		23DEC2002	15:35	56	85.0	20.8	3
	E0005031	BSLN		26MAR2003	12:30	-7	77.0	48.6	7
	E0005033	BSLN		08APR2003	14:00	-8	70.0	13.9 L	2 L
		FINAL		06MAY2003	11:20	21	75.0	27.8	4
	E0005038	BSLN		05MAY2003	11:40	-9	81.0	76.4	11
		FINAL		05JUN2003	13:00	23	82.0	118.1 H	17 H
	E0007009	BSLN		14APR2003	7:48	-3	87.0	41.7	6
	E0009010	BSLN		27FEB2003	16:55	-14	107.0	125.0 H	18 H
	E0009011	BSLN		28APR2003	14:17	-8	85.0	41.7	6
		FINAL		03JUL2003	15:40	59	91.0		
		FINAL		09JUL2003	14:30	65		138.9 H	20 H
	E0010005	BSLN		11DEC2002	10:15	-7	87.0	257.0 H	37 H
	E0011016	BSLN		14APR2003	10:00	-7	83.0	159.7 H	23 H
		FINAL		16JUN2003	9:45	57	89.0	257.0 H	37 H
	E0011020	BSLN		01MAY2003	9:20	-7	76.0	20.8	3
		FINAL		15MAY2003	17:00	8	71.0	34.7	5
	E0018002	BSLN		15NOV2002	15:35	-14	83.0		
		FINAL	*	18DEC2002	10:45	20		62.5	9
		FINAL		22JAN2003	16:20	55	80.0	27.8	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	BSLN		19NOV2002	13:05	-7	96.0	375.0 H	54 H
		FINAL		10DEC2002	11:00	15	89.0	201.4 H	29 H
	E0018013	BSLN		17JAN2003	14:15	-7	76.0	83.3	12
		FINAL		06FEB2003	16:10	14	76.0	166.7 H	24 H
	E0019002	BSLN		29OCT2002	10:45	-14	78.0	118.1 H	17 H
	E0019008	BSLN	*	06NOV2002	12:35	-15	78.0		
		BSLN		06NOV2002	12:35	-15		69.5	10
		BSLN		13NOV2002	10:30	-8	115.0		
	E0019009	BSLN		06NOV2002	13:35	-8	73.0	34.7	5
	E0019016	BSLN		30DEC2002	16:55	-7	85.0	152.8 H	22 H
		FINAL		03MAR2003	16:00	57	85.0	270.9 H	39 H
	E0019020	BSLN		16JAN2003	10:10	-7	72.0	27.8	4
		FINAL		27MAR2003	10:50	64	90.0	55.6	8
	E0019021	BSLN		16JAN2003	11:45	-14	89.0	104.2	15
		FINAL		03MAR2003	13:18	33	86.0	111.1	16
	E0019024	BSLN		24JAN2003	16:00	-6	84.0	69.5	10
		FINAL		06FEB2003	12:33	8	74.0	48.6	7
	E0019031	BSLN		06MAR2003	11:35	-7	94.0	76.4	11
		FINAL		25MAR2003	10:08	13	98.0	284.7 H	41 H
	E0019035	BSLN		11MAR2003	9:28	-7	129.0H#	118.1 H	17 H
		FINAL		17APR2003	14:30	31	177.0H#	257.0 H	37 H
	E0019040	BSLN		08MAY2003	15:25	-12	90.0	173.6 H	25 H
		FINAL	*	03JUL2003	9:40	45		326.4 H	47 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	FINAL		17JUL2003	9:50	59	100.0	520.9 H	75 H
	E0019042	BSLN		29MAY2003	8:50	-6	91.0	69.5	10
		FINAL		20JUN2003	8:20	17	89.0	69.5	10
	E0019045	BSLN		19JUN2003	14:54	-7	108.0	55.6	8
		FINAL		16JUL2003	10:15	21	81.0	41.7	6
	E0020024	BSLN		12JUN2003	15:40	-11	84.0	48.6	7
		FINAL		20AUG2003	18:45	59	94.0	208.4 H	30 H
	E0022044	BSLN		12MAR2003	9:50	-6	78.0	27.8	4
		FINAL		12MAY2003	9:55	56	74.0	55.6	8
	E0023007	BSLN		07JAN2003	14:30	-7	83.0	20.8	3
		FINAL		13MAR2003	15:00	59	98.0	90.3	13
	E0023011	BSLN	*	28JAN2003	11:45	-7		298.6 H	43 H
		BSLN		28JAN2003	11:45	-7	104.0		
		BSLN		31JAN2003	10:00	-4		145.8 H	21 H
		FINAL		01APR2003	12:00	57	101.0	125.0 H	18 H
	E0023014	BSLN		14FEB2003	15:00	-7	85.0	34.7	5
		FINAL		25APR2003	14:00	64	89.0	41.7	6
	E0023019	BSLN		21MAR2003	14:00	-17	91.0		
		BSLN		25MAR2003	14:00	-13		27.8	4
		FINAL		03JUN2003	13:30	58	80.0	41.7	6
	E0023022	BSLN		10APR2003	16:00	-8	76.0	41.7	6
		FINAL		12JUN2003	15:40	56	77.0	69.5	10
	E0023023	BSLN		17APR2003	10:00	-8	96.0	41.7	6
		FINAL		01MAY2003	14:00	7	121.0H	118.1 H	17 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR II)	E0023029	BSLN		16MAY2003	14:00	-7	78.0	41.7	6
	E0023031	BSLN	*	22MAY2003	12:00	-33	94.0	437.5 H	63 H
		BSLN		19JUN2003	10:00	-5	86.0	257.0 H	37 H
		FINAL		19AUG2003	11:00	57	113.0	382.0 H	55 H
	E0023041	BSLN		03JUL2003	11:00	-6	78.0	27.8	4
		FINAL		05SEP2003	13:00	59	77.0	90.3	13
	E0023043	BSLN		07JUL2003	15:00	-7	95.0	76.4	11
		FINAL		09SEP2003	10:30	58	78.0	20.8	3
	E0026003	BSLN	*	25NOV2002	12:20	-9	128.0H#	312.5 H	45 H
		BSLN		02DEC2002	9:25	-2	104.0	97.2	14
		FINAL		03FEB2003	10:50	62	139.0H#	451.4 H	65 H
	E0026005	BSLN		23DEC2002	12:40	-7	97.0	20.8	3
		FINAL		06JAN2003	15:25	8	95.0	34.7	5
	E0026009	BSLN		10JAN2003	10:20	-5	87.0	41.7	6
		FINAL		21JAN2003	9:50	7	79.0	48.6	7
	E0026015	BSLN		20FEB2003	11:30	-7	81.0	69.5	10
		FINAL		25APR2003	9:50	58	138.0H#	291.7 H	42 H
	E0026023	BSLN		23APR2003	10:50	-7	80.0	27.8	4
		FINAL		27JUN2003	12:25	59	110.0	118.1 H	17 H
	E0027016	BSLN	*	19MAR2003	11:55	-21	69.0	513.9 H	74 H
		BSLN		04APR2003	9:50	-5	87.0	180.6 H	26 H
		FINAL		03JUN2003	10:18	56	80.0	222.2 H	32 H
	E0027018	BSLN		21MAR2003	11:30	-4	73.0	55.6	8
		FINAL		22MAY2003	10:05	59	82.0	55.6	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	BSLN	13MAR2003	13:58	-12	86.0	55.6	8
		FINAL	06JUN2003	11:38	74	89.0	97.2	14
	E0029003	BSLN	28OCT2002	12:30	-7	75.0	48.6	7
		FINAL	30DEC2002	9:45	57	88.0	97.2	14
	E0029020	BSLN	25FEB2003	10:12	-8	86.0	48.6	7
	E0031005	BSLN	13DEC2002	16:00	-7	104.0	55.6	8
		FINAL	14FEB2003	12:10	57	97.0	48.6	7
	E0031006	BSLN	31JAN2003	11:25	-18	122.0H	125.0 H	18 H
		FINAL	15APR2003	9:25	57	100.0	83.3	12
	E0031010	BSLN	12FEB2003	14:50	-7	82.0	41.7	6
		FINAL	06MAR2003	12:50	16	82.0	62.5	9
	E0031011	BSLN	18FEB2003	11:50	-9	105.0	76.4	11
		FINAL	24APR2003	9:25	57	90.0	76.4	11
	E0031015	BSLN	14MAR2003	8:40	-12	89.0	69.5	10
		FINAL	01APR2003	11:55	7	89.0		
	E0031031	BSLN	01JUL2003	10:30	-7	82.0	76.4	11
		FINAL	28AUG2003	10:35	52	74.0	48.6	7
	E0033009	BSLN	22JAN2003	13:40	-21	77.0		
		BSLN	04FEB2003	11:20	-8		62.5	9
	E0034009	BSLN	10JUN2003	13:00	-9	77.0	34.7	5
		FINAL	18AUG2003	17:25	61	82.0	145.8 H	21 H
	E0037007	BSLN	04APR2003	11:30	-7	77.0	62.5	9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	BSLN	11JUL2003	13:00	-5	84.0	48.6	7
		FINAL	08SEP2003	13:20	55	92.0	55.6	8
	E0039019	BSLN	20JAN2003	14:50	-17	82.0	152.8 H	22 H
		FINAL	03APR2003	11:05	57	80.0	97.2	14
	E0039043	BSLN	28APR2003	10:15	-10	94.0	76.4	11

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	76.0	41.7	6
		FINAL		26FEB2003	8:45	59	142.0H#	132.0 H	19 H
	E0002003	BSLN		03JAN2003	11:50	-19	76.0	104.2	15
		FINAL		18MAR2003	12:10	56	81.0	138.9 H	20 H
	E0002004	BSLN		14JAN2003	8:15	-11	81.0	145.8 H	21 H
	E0002008	BSLN		14FEB2003	16:00	-11	96.0	104.2	15
		FINAL		23APR2003	14:25	58	89.0	69.5	10
	E0002016	BSLN		14JUL2003	11:00	-10	98.0	90.3	13
		FINAL		17SEP2003	11:15	56	87.0	118.1 H	17 H
	E0003008	BSLN		21JAN2003	12:45	-7	86.0	27.8	4
	E0004003	BSLN		02OCT2002	11:00	-8	81.0	180.6 H	26 H
	E0004006	BSLN		28OCT2002	9:55	-7	113.0	305.6 H	44 H
		FINAL		06JAN2003	10:55	64	147.0H#	791.7 H	114 H
		FINAL	*	15JAN2003	8:30	73	118.0	104.2	15
	E0004016	BSLN		12FEB2003	15:10	-7	64.0L	13.9 L	2 L
		FINAL		17APR2003	17:10	58	58.0L	97.2	14
	E0004024	BSLN		25JUN2003	16:00	-8	74.0	55.6	8
		FINAL		28AUG2003	9:50	57	97.0	83.3	12
	E0005006	BSLN	*	24SEP2002	15:30	-9	89.0	291.7 H	42 H
		BSLN		03OCT2002	8:30	1	73.0	222.2 H	32 H
	E0005017	BSLN	*	11DEC2002	10:30	-19	85.0	27.8	4
		BSLN		23DEC2002	12:30	-7	83.0	41.7	6
		FINAL		04MAR2003	13:00	65	61.0L	55.6	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0005019	BSLN		19DEC2002	14:00	-27	69.0	76.4	11
		FINAL		23JAN2003	15:45	9	80.0	83.3	12
	E0005026	BSLN		28FEB2003	10:15	-6	75.0	27.8	4
		FINAL		02APR2003	9:40	28	77.0	27.8	4
	E0005039	BSLN		15MAY2003	9:00	-7	91.0	243.1 H	35 H
		FINAL		16JUL2003	8:40	56	78.0	180.6 H	26 H
	E0005043	BSLN		02JUL2003	8:30	-7	92.0	97.2	14
		FINAL		03SEP2003	9:45	57	87.0	76.4	11
	E0006020	BSLN		02MAY2003	13:30	-11	88.0	34.7	5
		FINAL		08JUL2003	14:45	57	87.0	48.6	7
		FINAL	*	10JUL2003	16:30	59	86.0		
	E0007001	BSLN	*	16DEC2002	9:25	-15	112.0	201.4 H	29 H
		BSLN		26DEC2002	9:25	-5	95.0	111.1	16
		FINAL		24FEB2003	8:43	56	100.0	90.3	13
		FINAL	*	10MAR2003	8:54	70	98.0		
	E0007003	BSLN		13JAN2003	10:30	-17	89.0	20.8	3
		FINAL		01APR2003	13:30	62	99.0	27.8	4
	E0007006	BSLN		24FEB2003	11:00	-9	78.0	76.4	11
		FINAL		27MAR2003	10:50	23	86.0	62.5	9
	E0009004	BSLN	*	19NOV2002	12:30	-7	75.0		
		BSLN		19NOV2002	12:30	-7		55.6	8
		BSLN		25NOV2002	12:55	-1	103.0		
		FINAL		18DEC2002	14:50	23	86.0	111.1	16
	E0009012	BSLN		16JUN2003	14:45	-9	81.0	55.6	8
		FINAL		03JUL2003	17:45	9	86.0		

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0009012	FINAL		22JUL2003	18:00	28		243.1 H	35 H
	E0010008	BSLN		11DEC2002	9:15	-7	96.0	27.8	4
	E0010018	BSLN		26FEB2003	8:51	-21	96.0	76.4	11
		FINAL		14MAY2003	10:45	57	99.0	97.2	14
	E0010028	BSLN		09JUN2003	8:46	-7	77.0	55.6	8
		FINAL		15JUL2003	13:50	30	80.0	132.0 H	19 H
	E0011008	BSLN	*	17DEC2002	12:30	-44	82.0	41.7	6
		BSLN		23JAN2003	9:20	-7	72.0	69.5	10
		FINAL		13FEB2003	12:30	15	81.0	69.5	10
	E0011009	BSLN		19DEC2002	10:15	-8	82.0	62.5	9
		FINAL		20FEB2003	9:00	56	96.0	76.4	11
	E0011010	BSLN		03FEB2003	10:00	-7	83.0	27.8	4
		FINAL		19MAR2003	8:45	38	80.0	69.5	10
	E0013001	BSLN		01NOV2002	8:50	-13	90.0	104.2	15
		FINAL		10JAN2003	10:45	58	83.0	83.3	12
	E0013003	BSLN		07NOV2002	9:25	-5	97.0	333.4 H	48 H
		FINAL		06JAN2003	13:17	56	82.0	166.7 H	24 H
	E0013005	BSLN		13FEB2003	11:42	-5	78.0	27.8	4
		FINAL		15APR2003	12:16	57	79.0	69.5	10
	E0013013	BSLN		01MAY2003	10:14	-5	85.0	83.3	12
		FINAL		30MAY2003	9:55	25	75.0	62.5	9
	E0014002	BSLN		19FEB2003	16:35	-7	92.0	83.3	12
		FINAL		10APR2003	13:05	44	87.0	97.2	14

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0014004	BSLN		04MAR2003	11:40	-8	70.0	27.8	4
		FINAL		15APR2003	11:40	35	78.0	90.3	13
	E0014009	BSLN	*	15APR2003	14:45	-8	75.0	132.0 H	19 H
		BSLN		17APR2003	12:30	-6	77.0	291.7 H	42 H
		FINAL		16MAY2003	8:55	24	82.0	55.6	8
	E0014015	BSLN		11JUN2003	10:15	-7	82.0	62.5	9
	E0014017	BSLN		17JUN2003	17:00	-10	79.0	34.7	5
		FINAL		19AUG2003	17:05	54	81.0	48.6	7
	E0014018	BSLN		24JUN2003	16:35	-7	69.0	13.9 L	2 L
		FINAL		27AUG2003	16:00	58	94.0	444.5 H	64 H
		FINAL	*	24SEP2003	16:45	86	74.0		
		FINAL	*	08OCT2003	16:35	100		34.7	5
	E0015005	BSLN		25NOV2002	13:15	-7	90.0	27.8	4
		FINAL		18DEC2002	9:30	17	100.0	34.7	5
	E0017002	BSLN		08MAY2003	17:00	-26	96.0	673.7 H	97 H
		FINAL		13JUN2003	16:00	11	80.0	76.4	11
	E0018009	BSLN		17DEC2002	10:45	-20	82.0	48.6	7
		FINAL		14JAN2003	13:15	9	84.0	69.5	10
	E0018010	BSLN		09JAN2003	9:30	-7	81.0	34.7	5
		FINAL		13MAR2003	9:20	57	84.0	41.7	6
	E0018015	BSLN		21JAN2003	11:20	-7	88.0	69.5	10
		FINAL		27MAR2003	10:50	59	96.0	62.5	9
	E0020015	BSLN		18MAR2003	13:30	-9	92.0	41.7	6
		FINAL		23MAY2003	13:40	58	87.0	48.6	7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0020017	BSLN		27MAR2003	12:00	-7	81.0	27.8	4
		FINAL		03JUN2003	17:40	62	75.0	13.9 L	2 L
	E0020020	BSLN		07MAY2003	15:00	-5	81.0	55.6	8
		FINAL		23MAY2003	14:00	12	70.0	48.6	7
	E0020022	BSLN		09JUN2003	13:05	-7	102.0	159.7 H	23 H
		FINAL		11AUG2003	9:30	57	103.0		
		FINAL		21AUG2003	8:54	67		236.1 H	34 H
	E0022001	BSLN		09OCT2002	14:20	-19	78.0	34.7	5
		FINAL		26DEC2002	17:55	60	85.0	41.7	6
	E0022004	BSLN	*	17OCT2002	8:48	-11	86.0	97.2	14
		BSLN		28OCT2002	9:47	1	91.0	97.2	14
		FINAL		23DEC2002	10:15	57	89.0	180.6 H	26 H
	E0022005	BSLN		18OCT2002	7:40	-21	83.0	159.7 H	23 H
		FINAL		03JAN2003	9:20	57	97.0	298.6 H	43 H
	E0022011	BSLN		21NOV2002	9:25	-8	84.0	27.8	4
	E0022015	BSLN	*	29NOV2002	13:50	-11	74.0	55.6	8
		BSLN	*	03DEC2002	10:10	-7	84.0	90.3	13
		BSLN		10DEC2002	16:10	1	88.0	257.0 H	37 H
		FINAL	*	26DEC2002	12:15	17		97.2	14
		FINAL		06FEB2003	9:50	59	83.0	62.5	9
	E0022016	BSLN		03DEC2002	12:10	-14	85.0	48.6	7
		FINAL		11FEB2003	11:05	57	71.0	118.1 H	17 H
	E0022020	BSLN		05DEC2002	12:21	-7	77.0	34.7	5
		FINAL		23JAN2003	16:20	43	73.0	27.8	4
		FINAL	*	28JAN2003	10:35	48	79.0	55.6	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0022023	BSLN	20DEC2002	14:28	-5	81.0	69.5	10
		FINAL	20FEB2003	10:05	58	77.0	125.0 H	18 H
	E0022029	BSLN	10FEB2003	12:30	-9	95.0	152.8 H	22 H
		FINAL	14APR2003	9:45	55	87.0	166.7 H	24 H
	E0022041	BSLN	11MAR2003	9:53	-7	85.0	83.3	12
		FINAL	13MAY2003	9:18	57	92.0	173.6 H	25 H
	E0022042	BSLN	05MAR2003	9:50	-7	95.0	34.7	5
		FINAL	12MAY2003	9:35	62	100.0	62.5	9
	E0022043	BSLN	11MAR2003	13:50	-9	95.0	34.7	5
		FINAL	12MAY2003	8:05	54	88.0	62.5	9
	E0022054	BSLN	07APR2003	11:25	-4	89.0	48.6	7
	E0022059	BSLN	23APR2003	15:30	-13	79.0	48.6	7
		FINAL	08JUL2003	16:30	64	69.0	20.8	3
	E0022065	BSLN	01MAY2003	9:30	-6	77.0	41.7	6
		FINAL	02JUL2003	8:50	57	88.0	90.3	13
	E0022070	BSLN	05JUN2003	11:40	-7	103.0	69.5	10
		FINAL	18JUN2003	15:15	7	103.0	104.2	15
	E0023001	BSLN	24OCT2002	13:30	-22	71.0	69.5	10
		FINAL	14JAN2003	13:30	61	84.0	215.3 H	31 H
	E0023009	BSLN	24JAN2003	11:30	-18	89.0	41.7	6
		FINAL	08APR2003	11:15	57	105.0	104.2	15
	E0023028	BSLN	16MAY2003	12:15	-13	93.0	55.6	8
		FINAL	21JUL2003	11:00	54	80.0	41.7	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0023033	BSLN		30MAY2003	12:10	-6	91.0	48.6	7
		FINAL		12JUN2003	13:15	8	99.0	208.4 H	30 H
	E0023047	BSLN		11JUL2003	15:00	-7	71.0	13.9 L	2 L
		FINAL		16SEP2003	13:00	61	94.0	62.5	9
	E0025001	BSLN		25MAR2003	16:00	-7	192.0H#	1951.5 H	281 H
		FINAL		23APR2003	10:30	23	93.0	152.8 H	22 H
	E0026012	BSLN		05FEB2003	11:00	-15	74.0	41.7	6
		FINAL		17APR2003	9:10	57	84.0	27.8	4
	E0026020	BSLN		28MAR2003	10:50	-4	102.0	62.5	9
		FINAL		22APR2003	14:05	22	93.0	48.6	7
	E0026024	BSLN		25APR2003	12:30	-7	79.0	41.7	6
	E0026028	BSLN		06JUN2003	10:20	-14	105.0	187.5 H	27 H
		FINAL		23JUL2003	10:00	34	100.0	111.1	16
	E0028001	BSLN		07OCT2002	14:00	-3	116.0	145.8 H	21 H
		FINAL		03DEC2002	9:50	55	172.0H#	118.1 H	17 H
	E0028003	BSLN		23SEP2002	9:10	-7	91.0	69.5	10
		FINAL		26NOV2002	9:20	58	83.0	27.8	4
	E0028005	BSLN		30SEP2002	11:00	-3	73.0	13.9 L	2 L
		FINAL		31OCT2002	12:15	29	81.0	34.7	5
	E0028010	BSLN		15OCT2002	11:00	-21	75.0	27.8	4
		FINAL	*	19NOV2002	12:40	15	104.0		
		FINAL		31DEC2002	9:20	57	72.0	34.7	5
	E0028011	BSLN	*	16OCT2002	15:10	-50		444.5 H	64 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0028011	BSLN	*	22OCT2002	8:30	-44	81.0		
		BSLN		25NOV2002	9:00	-10	78.0	13.9 L	2 L
		FINAL		30JAN2003	12:35	57	80.0	166.7 H	24 H
	E0028030	BSLN		26FEB2003	11:30	-6	89.0	41.7	6
		FINAL		30APR2003	12:35	58	86.0	48.6	7
	E0028031	BSLN		06MAR2003	9:00	-5	92.0	111.1	16
		FINAL		17APR2003	13:30	38	90.0	194.5 H	28 H
	E0028047	BSLN		09JUL2003	10:40	-5	95.0	62.5	9
		FINAL		09SEP2003	10:24	58	91.0	111.1	16
	E0029001	BSLN		25SEP2002	8:45	-6	78.0	76.4	11
	E0029014	BSLN		28JAN2003	9:35	-7	102.0	48.6	7
		FINAL		01APR2003	11:20	57	88.0	20.8	3
	E0029023	BSLN		01APR2003	8:47	-7	91.0	159.7 H	23 H
		FINAL		10JUN2003	11:10	64	90.0	90.3	13
	E0029032	BSLN		22MAY2003	12:45	-19	97.0	55.6	8
		FINAL		01JUL2003	12:00	22	134.0H#	201.4 H	29 H
	E0029033	BSLN		27MAY2003	12:50	-6	95.0	180.6 H	26 H
	E0029039	BSLN		10JUL2003	13:02	-5	80.0	27.8	4
		FINAL		28JUL2003	15:30	14	81.0	20.8	3
	E0030003	BSLN		03DEC2002	14:25	-13	83.0	118.1 H	17 H
		FINAL		21MAR2003	9:50	96	123.0H	409.8 H	59 H
	E0030009	BSLN		14JAN2003	9:55	-9	88.0	41.7	6
		FINAL		19MAR2003	10:35	56	88.0	20.8	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0030016	BSLN		21FEB2003	11:50	-10	89.0	55.6	8
		FINAL		22APR2003	18:55	51	68.0	83.3	12
	E0030021	BSLN		13MAY2003	17:25	-7	88.0	20.8	3
	E0031001	BSLN		14NOV2002	11:48	-7	88.0	83.3	12
	E0031017	BSLN		25MAR2003	16:15	-7	86.0	48.6	7
		FINAL		29APR2003	10:30	29	83.0	69.5	10
	E0031018	BSLN		01APR2003	14:45	-9	90.0	111.1	16
	E0031023	BSLN		22APR2003	14:03	-7	80.0	333.4 H	48 H
		FINAL		24JUN2003	11:48	57	96.0	493.1 H	71 H
	E0033001	BSLN		23DEC2002	12:50	-17	84.0	48.6	7
		FINAL		30JAN2003	13:25	22	79.0	34.7	5
	E0033004	BSLN		09JAN2003	13:10	-8	76.0	90.3	13
		FINAL		14MAR2003	11:40	57	78.0	27.8	4
	E0033010	BSLN		22JAN2003	16:20	-13	72.0	257.0 H	37 H
		FINAL		26MAR2003	16:00	51	88.0	62.5	9
	E0033014	BSLN		12MAR2003	17:25	-7	91.0	55.6	8
	E0035002	BSLN		14NOV2002	10:50	-7	85.0	83.3	12
	E0035007	BSLN		13DEC2002	12:40	-6	81.0	62.5	9
		FINAL		11FEB2003	10:10	55	95.0	83.3	12
	E0035011	BSLN	*	13JAN2003	8:35	-22		284.7 H	41 H
		BSLN		13JAN2003	8:35	-22	100.0		
		BSLN		30JAN2003	8:30	-5		194.5 H	28 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0035011	FINAL		01APR2003	9:00	57	90.0	215.3 H	31 H
	E0035020	BSLN		15APR2003	8:15	-3	75.0	34.7	5
	E0037003	BSLN		23JAN2003	11:40	-7	79.0	48.6	7
		FINAL		20FEB2003	15:32	22	79.0	97.2	14
	E0037004	BSLN		06FEB2003	12:35	-7	81.0	20.8	3
		FINAL		10APR2003	13:00	57	83.0	34.7	5
	E0039007	BSLN		25NOV2002	13:20	-9	93.0	145.8 H	21 H
		FINAL		29JAN2003	14:15	57	87.0	27.8	4
	E0039022	BSLN		06FEB2003	9:50	-19	85.0	20.8	3
		FINAL		24APR2003	12:10	59	76.0	27.8	4
	E0039023	BSLN		05FEB2003	10:37	-19	101.0	166.7 H	24 H
	E0039030	BSLN		12MAR2003	8:55	-12	95.0	159.7 H	23 H
		FINAL		19MAY2003	9:15	57	101.0	236.1 H	34 H
		FINAL	*	30MAY2003	9:50	68	91.0		
	E0039031	BSLN		05MAR2003	19:15	-19	78.0	27.8	4
		FINAL		20MAY2003	12:50	58	81.0	48.6	7
	E0039037	BSLN		26MAR2003	18:30	-21	79.0	6.9 L	1 L
		FINAL		12JUN2003	11:30	58	87.0	41.7	6
	E0039038	BSLN	*	27MAR2003	10:10	-27	291.0H#	493.1 H	71 H
		BSLN		21APR2003	10:16	-2	163.0H#	590.3 H	85 H
		FINAL		20JUN2003	11:15	59	410.0H#		
	E0039047	BSLN		13MAY2003	9:20	-6	93.0	159.7 H	23 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR I)	E0039059	BSLN	07JUL2003	11:10	-4	101.0	180.6 H	26 H
		FINAL	05SEP2003	11:10	57	94.0	111.1	16
	E0041007	BSLN	05MAR2003	13:45	-8	80.0	118.1 H	17 H
		FINAL	08MAY2003	13:45	57	70.0	48.6	7
	E0041010	BSLN	23APR2003	14:45	-7	82.0	62.5	9
		FINAL	11JUN2003	15:30	43	104.0	159.7 H	23 H
	E0041011	BSLN	15MAY2003	16:00	-7	97.0	138.9 H	20 H
		FINAL	17JUL2003	14:30	57	119.0H	257.0 H	37 H
	E0041012	BSLN	05JUN2003	12:28	-14	77.0	55.6	8
		FINAL	14AUG2003	11:45	57	77.0	104.2	15

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR II)	E0001004	BSLN		23APR2003	11:00	-8	80.0	83.3	12
		FINAL		27JUN2003	12:45	58	81.0	97.2	14
	E0005023	BSLN		29JAN2003	7:30	-7	89.0	118.1 H	17 H
		FINAL		01APR2003	16:30	56	96.0	305.6 H	44 H
	E0005034	BSLN		09APR2003	9:30	-6	80.0	347.3 H	50 H
		FINAL		09JUN2003	13:00	56	76.0	180.6 H	26 H
	E0005041	BSLN		17JUN2003	11:55	-7	94.0	257.0 H	37 H
		FINAL		18AUG2003	10:10	56	93.0	166.7 H	24 H
	E0007004	BSLN		28JAN2003	8:05	-2	84.0	215.3 H	31 H
		FINAL		13FEB2003	8:30	15	83.0	187.5 H	27 H
	E0007010	BSLN		14APR2003	8:10	-4	137.0H#	132.0 H	19 H
		FINAL	*	21APR2003	8:30	4	136.0H#		
		FINAL		13JUN2003	7:40	57	127.0H#	166.7 H	24 H
		FINAL	*	16JUN2003	7:50	60	136.0H#		
	E0007012	BSLN		12MAY2003	8:50	-4	89.0	62.5	9
		FINAL		02JUL2003	11:35	48	87.0	34.7	5
	E0009007	BSLN		27JAN2003	15:25	-7	84.0	76.4	11
		FINAL		03MAR2003	15:40	29	83.0	55.6	8
	E0009008	BSLN		04FEB2003	13:37	-8	90.0	41.7	6
		FINAL		08APR2003	12:35	56	89.0	104.2	15
	E0011001	BSLN		25OCT2002	16:00	-7	75.0	27.8	4
		FINAL		26DEC2002	8:30	56	83.0	41.7	6
	E0011011	BSLN		12FEB2003	12:00	-8	81.0	69.5	10
		FINAL		16APR2003	8:30	56	75.0	48.6	7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR II)	E0011013	BSLN		25MAR2003	9:45	-23	87.0	48.6	7
		FINAL		12JUN2003	8:45	57	77.0	55.6	8
	E0011014	BSLN		02APR2003	8:20	-5	79.0	62.5	9
		FINAL		08MAY2003	15:30	32	87.0	236.1 H	34 H
	E0011021	BSLN		15MAY2003	10:00	-7	76.0	55.6	8
		FINAL		21JUL2003	10:00	61	87.0	34.7	5
	E0013008	BSLN		19MAR2003	16:20	-7	77.0	104.2	15
		FINAL		19MAY2003	11:25	55	83.0	97.2	14
	E0014001	BSLN		18FEB2003	15:45	-8	101.0	132.0 H	19 H
		FINAL		08APR2003	11:10	42	77.0		
		FINAL	*	16APR2003	10:40	50	64.0L		
		FINAL		16APR2003	10:40	50		20.8	3
	E0014013	BSLN		20MAY2003	14:50	-7	60.0L	34.7	5
		FINAL		23JUL2003	15:00	58	81.0	55.6	8
	E0014014	BSLN		03JUN2003	16:35	-7	84.0	34.7	5
		FINAL		06AUG2003	10:50	58	70.0	125.0 H	18 H
	E0015004	BSLN		25NOV2002	8:50	-7	95.0	243.1 H	35 H
		FINAL		29JAN2003	8:45	59	93.0	76.4	11
	E0018005	BSLN		10DEC2002	16:00	-10	83.0	27.8	4
		FINAL		17FEB2003	11:05	60	93.0	27.8	4
	E0018012	BSLN		17JAN2003	10:30	-7	83.0	62.5	9
		FINAL		26FEB2003	19:20	34	100.0	312.5 H	45 H
	E0019019	BSLN		14JAN2003	10:30	-9	85.0	104.2	15

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR II)	E0019033	BSLN		10MAR2003	16:05	-8	86.0	20.8	3
		FINAL		16MAY2003	8:30	60	85.0	27.8	4
	E0019038	BSLN	*	10APR2003	12:30	-14	75.0		
		BSLN		10APR2003	12:30	-14		27.8	4
		BSLN		17APR2003	11:05	-7	86.0		
		FINAL		19JUN2003	9:40	57	90.0	41.7	6
	E0019046	BSLN		19JUN2003	15:00	-7	80.0	20.8	3
		FINAL		21AUG2003	9:12	57	86.0	41.7	6
	E0019047	BSLN		26JUN2003	12:30	-12	81.0	55.6	8
		FINAL		04SEP2003	8:40	59	82.0	118.1 H	17 H
	E0019048	BSLN		03JUL2003	11:05	-7	86.0	76.4	11
		FINAL		03SEP2003	16:12	56	82.0	48.6	7
	E0022006	BSLN		22OCT2002	10:10	-21	85.0	132.0 H	19 H
		FINAL		07JAN2003	7:40	57	93.0	125.0 H	18 H
	E0022047	BSLN		21MAR2003	8:10	-7	97.0	111.1	16
		FINAL		23MAY2003	9:45	57	83.0	138.9 H	20 H
	E0022075	BSLN		27JUN2003	7:45	-11	82.0	20.8	3
		FINAL		03SEP2003	9:15	58	77.0	27.8	4
	E0023012	BSLN		31JAN2003	15:30	-6	63.0L	111.1	16
		FINAL		04APR2003	12:15	58	93.0	187.5 H	27 H
	E0023016	BSLN		15MAY2003	13:30	-7	70.0	6.9 L	1 L
		FINAL		17JUL2003	11:10	57	95.0	41.7	6
	E0023018	BSLN		18MAR2003	13:30	-9	75.0	20.8	3
		FINAL		22MAY2003	10:15	57	74.0	152.8 H	22 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM102.SAS
GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR II)	E0023036	BSLN		10JUN2003	12:00	-10	82.0	41.7	6
		FINAL		13AUG2003	17:00	55	95.0	97.2	14
	E0023046	BSLN	*	11JUL2003	10:00	-12		201.4 H	29 H
		BSLN		11JUL2003	10:00	-12	86.0		
		BSLN		18JUL2003	9:00	-5		187.5 H	27 H
		FINAL		16SEP2003	14:00	56	74.0	166.7 H	24 H
	E0026006	BSLN		31DEC2002	10:35	-8	86.0	41.7	6
	E0026021	BSLN		14APR2003	15:45	-9	83.0	13.9 L	2 L
	E0026027	BSLN		05JUN2003	13:10	-14	85.0	20.8	3
	E0029002		*	07NOV2002	8:10		77.0	55.6	8
	E0029004	BSLN		13NOV2002	14:50	-6	71.0	76.4	11
		FINAL		17JAN2003	8:25	60	81.0	111.1	16
	E0029013	BSLN		10FEB2003	8:55	-9	112.0		
		BSLN		14FEB2003	9:20	-5		48.6	7
	E0029019	BSLN		24FEB2003	9:30	-7	91.0	90.3	13
		FINAL		17MAR2003	9:50	15	91.0	83.3	12
	E0029024	BSLN		11MAR2003	12:10	-6	92.0	20.8	3
		FINAL		20MAY2003	14:45	65	156.0H#	125.0 H	18 H
	E0029038	BSLN		30JUN2003	9:25	-7	106.0	55.6	8
	E0031004	BSLN		12DEC2002	13:59	-7	85.0	48.6	7
		FINAL		14FEB2003	10:50	58	85.0	48.6	7
	E0031013	BSLN		06MAR2003	10:35	-7	86.0	125.0 H	18 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR II)	E0031013	FINAL		08MAY2003	11:05	57	85.0	104.2	15
	E0031016	BSLN		17MAR2003	10:45	-7	86.0	34.7	5
		FINAL		15APR2003	10:03	23	81.0	41.7	6
	E0031019	BSLN		03APR2003	11:25	-8	96.0	55.6	8
		FINAL		12MAY2003	16:40	32	92.0	20.8	3
	E0031022	BSLN		21APR2003	12:40	-7	79.0	111.1	16
	E0033007	BSLN		15JAN2003	15:20	-13	83.0	20.8	3
		FINAL		27MAR2003	15:35	59	86.0	34.7	5
	E0033013	BSLN		06FEB2003	11:45	-13	84.0	83.3	12
		FINAL		16APR2003	11:45	57	79.0	62.5	9
	E0033016	BSLN		17APR2003	12:00	-21	76.0	34.7	5
		FINAL		02JUL2003	13:00	56	87.0	187.5 H	27 H
	E0033022	BSLN		09JUL2003	11:00	-5	65.0L	104.2	15
		FINAL		11SEP2003	12:00	60	66.0L	76.4	11
	E0034007	BSLN		07MAY2003	14:05	-9	104.0	55.6	8
		FINAL		14JUL2003	11:15	60	97.0	34.7	5
		FINAL	*	28JUL2003	11:48	74	95.0		
	E0035004	BSLN		22NOV2002	11:45	-5	105.0	194.5 H	28 H
	E0035009	BSLN		20DEC2002	11:12	-7	91.0	41.7	6
		FINAL		19FEB2003	8:55	55	98.0	90.3	13
	E0035010	BSLN		07JAN2003	7:45	-3	92.0	125.0 H	18 H
		FINAL		06MAR2003	9:00	56	94.0	97.2	14

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.3 Chemistry Data - Diabetic Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)
PLACEBO (BIPOLAR II)	E0035022	BSLN	01MAY2003	9:45	-8	84.0	13.9 L	2 L
		FINAL	07JUL2003	8:55	60	94.0	20.8	3
	E0039003	BSLN	12NOV2002	11:19	-13	84.0	76.4	11
		FINAL	02JAN2003	14:06	39	68.0	284.7 H	41 H
	E0040001	BSLN	18JUN2003	14:30	-9	84.0	34.7	5
		FINAL	22AUG2003	9:00	57	86.0	34.7	5
	E0040004	BSLN	11JUL2003	13:00	-7	78.0	20.8	3
	E0041002	BSLN	13JAN2003	14:35	-8	83.0	76.4	11
		FINAL	11MAR2003	10:35	50	88.0	138.9 H	20 H
	E0041005	BSLN	28FEB2003	12:31	-5	82.0	55.6	8
		FINAL	30APR2003	14:08	57	86.0	437.5 H	63 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 13JUL2005 12:51:56 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		22JAN2003	14:00	-13	141	4.0	103.0	23.0	
		FINAL		02APR2003	10:10	58	143	4.4	109.0	24.0	
	E0002010	BSLN		28MAR2003	10:00	-7	143	4.9	104.0	28.0	
	E0002012	BSLN		16APR2003	10:10	-5	142	3.8	105.0	24.0	
		FINAL		16JUN2003	11:30	57	145	4.4	111.0	25.0	
	E0002015	BSLN		22MAY2003	10:15	-13	140	4.5	105.0	26.0	
	E0002018	BSLN		16JUL2003	13:25	-8	140	4.2	105.0	24.0	
		FINAL		04AUG2003	9:40	12	134	4.1	102.0	18.0	L#
	E0003004	BSLN	*	03DEC2002	11:48	-14	142	4.7	102.0	26.0	
		BSLN		17DEC2002	9:20	1	142	4.6	103.0	26.0	
		FINAL		07JAN2003	15:40	22	141	4.8	100.0	27.0	
	E0003005	BSLN		16DEC2002	15:00	-7	141	3.7	100.0	27.0	
		FINAL		18FEB2003	8:55	58	151H	5.2	110.0	28.0	
	E0003007	BSLN		19DEC2002	10:15	-14	147	4.6	110.0	28.0	
		FINAL		27FEB2003	8:50	57	145	4.1	106.0	27.0	
	E0003015	BSLN		29APR2003	11:30	-6	135	4.4	98.0	19.0	L
		FINAL		02JUL2003	14:45	59	139	4.2	104.0	26.0	
	E0004002	BSLN		24SEP2002	10:40	-7	140	3.9	103.0	28.0	
		FINAL		26NOV2002	11:00	57	142	4.4	108.0	26.0	
	E0004013	BSLN		08JAN2003	10:00	-6	142	4.1	106.0	24.0	
		FINAL		19FEB2003	8:20	37	144	4.0	104.0	24.0	
	E0004018	BSLN		12MAR2003	10:50	-7	142	4.7	105.0	28.0	
		FINAL		13MAY2003	13:45	56	141	4.5	107.0	28.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	BSLN	07MAY2003	15:55	-7	141	4.7	104.0	27.0
		FINAL	09JUL2003	14:10	57	141	4.3	105.0	24.0
	E0005002	BSLN	23SEP2002	10:00	-10	141	4.7	103.0	28.0
		FINAL	25NOV2002	8:30	54	138	4.1	104.0	22.0
	E0005004	BSLN	24SEP2002	12:00	-7	140	4.1	105.0	23.0
	E0005013	BSLN	30OCT2002	8:00	-8	141	4.7	107.0	22.0
	E0005024	BSLN	05FEB2003	15:00	-5	148H	3.6	110.0	23.0
		FINAL	10APR2003	11:30	60	142	4.4	112.0 H	20.0 L
	E0005027	BSLN	04MAR2003	7:45	-7	142	4.6	103.0	29.0
		FINAL	03APR2003	8:15	24	142	5.1	104.0	26.0
	E0005037	BSLN	30APR2003	12:00	-7	144	4.4	103.0	31.0 #
		FINAL	02JUL2003	12:15	57	142	4.4	106.0	25.0
	E0005042	BSLN	19JUN2003	11:30	-5	141	4.8	108.0	20.0 L
		FINAL	18AUG2003	16:25	56	140	4.3	107.0	25.0
	E0006005	BSLN	25NOV2002	12:15	-10	139	4.2	106.0	21.0
		FINAL	30JAN2003	16:10	57	144	4.5	109.0	22.0
	E0006018	BSLN	07MAR2003	12:40	-6	141	4.3	106.0	26.0
		FINAL	24MAR2003	10:45	12	142	4.3	107.0	23.0
	E0007013	BSLN	10JUN2003	9:25	-3	140	4.8	107.0	25.0
		FINAL	07AUG2003	9:20	56	139	5.2	106.0	24.0
	E0010004	BSLN	05DEC2002	11:10	-6	140	4.4	106.0	26.0
		FINAL	06FEB2003	12:40	58	148H	5.1	107.0	28.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	BSLN	30DEC2002	9:48	-8	145		4.9	109.0	31.0	#
		FINAL	05MAR2003	13:59	58	143		4.0	105.0	25.0	
	E0010024	BSLN	23APR2003	8:45	-12	144		4.6	109.0	31.0	#
		FINAL	02JUL2003	10:30	59	142		4.8	108.0	27.0	
	E0010032	BSLN	03JUL2003	11:30	-7	140		4.3	108.0	21.0	
		FINAL	17JUL2003	11:38	8	140		4.0	106.0	24.0	
	E0011025	BSLN	20JUN2003	14:30	-6	142		4.3	106.0	26.0	
		FINAL	22AUG2003	10:00	58	140		4.5	106.0	26.0	
	E0013007	BSLN	14MAR2003	8:48	-6	141		4.4	104.0	24.0	
		FINAL	07APR2003	17:15	19	138		4.4	103.0	26.0	
	E0013009	BSLN	26MAR2003	9:09	-7	143		5.5	# 107.0	28.0	
		FINAL	29MAY2003	17:50	58	143		5.3	106.0	25.0	
	E0014006	BSLN	14MAR2003	11:30	-11	143		3.9	108.0	24.0	
		FINAL	21MAY2003	16:20	58	146		3.9	110.0	26.0	
	E0014010	BSLN	15APR2003	17:20	-7	141		4.5	106.0	25.0	
		FINAL	17JUN2003	18:10	57	145		4.5	108.0	21.0	
	E0016001	BSLN	02JAN2003	8:50	-20	140		4.7	105.0	24.0	
		FINAL	19MAR2003	12:00	57	141		4.7	104.0	23.0	
	E0016004	BSLN	27JAN2003	9:30	-7	145		4.5	105.0	26.0	
	E0018001	BSLN	22OCT2002	16:15	-7	141		4.7	103.0	28.0	
		FINAL	24DEC2002	9:55	57	139		3.8	104.0	20.0	L
	E0018006	BSLN	10DEC2002	17:15	-7	146		5.0	105.0	27.0	
		FINAL	27FEB2003	12:10	73	147		4.8	102.0	28.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	BSLN		30OCT2002	8:40	-8	145	4.6	108.0	24.0	
		FINAL		19DEC2002	12:55	43	143	4.4	108.0	27.0	
	E0019011	BSLN		12NOV2002	12:05	-9	139	4.7	104.0	23.0	
		FINAL		16JAN2003	14:20	57	143	4.7	110.0	22.0	
	E0019025	BSLN		30JAN2003	14:40	-7	142	5.7 H#	104.0	25.0	
		FINAL		03APR2003	13:30	57	144	4.6	107.0	26.0	
	E0019026	BSLN		17FEB2003	12:40	-7	141	4.3	105.0	26.0	
	E0019043	BSLN		21MAY2003	11:04	-13	141	5.8 H#	103.0	27.0	
		FINAL	*	17JUN2003	12:10	15	140	4.3	106.0	24.0	
		FINAL		29JUL2003	11:38	57	135	4.2	101.0	22.0	
	E0020001	BSLN		15OCT2002	20:00	-14	137	3.9	100.0	23.0	
		FINAL		20DEC2002	12:30	53	141	3.9	105.0	23.0	
	E0020006	BSLN		26NOV2002	18:00	-20	144	4.2	101.0	26.0	
		FINAL		08JAN2003	10:00	24	143	4.2	103.0	26.0	
	E0020007	BSLN		10JAN2003	12:00	-5	143	3.7	108.0	17.0	L#
		FINAL		25MAR2003	18:50	70	144	4.2	111.0	21.0	
	E0020011	BSLN		19FEB2003	13:45	-7	140	4.7	100.0	23.0	
		FINAL		23APR2003	14:30	57	141	4.6	108.0	19.0	L
		FINAL	*	07MAY2003	12:00	71	143	4.6	108.0	26.0	
	E0020013	BSLN		26FEB2003	14:15	-7	146	4.8	104.0	27.0	
		FINAL		25MAR2003	12:00	21	142	4.6	107.0	21.0	
	E0022008	BSLN		05NOV2002	10:00	-7	142	4.5	104.0	26.0	
		FINAL		07JAN2003	9:45	57	140	4.3	105.0	27.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	BSLN	05DEC2002	12:35	-14	144	5.0	107.0	20.0	L
		FINAL	07MAR2003	9:47	79	145	5.4	109.0	25.0	
	E0022018	BSLN	04DEC2002	10:15	-8	144	4.9	105.0	30.0	#
		FINAL	11FEB2003	8:40	62	146	4.8	106.0	28.0	
	E0022022	BSLN	16DEC2002	13:15	-14	139	4.6	104.0	28.0	
		FINAL	27FEB2003	11:35	60	140	4.4	103.0	25.0	
	E0022027	BSLN	24JAN2003	7:40	-13	141	4.4	103.0	25.0	
		FINAL	03APR2003	9:00	57	144	4.9	109.0	28.0	
	E0022030	BSLN	10FEB2003	7:40	-4	143	4.5	104.0	26.0	
	E0022031	BSLN	11FEB2003	10:25	-7	143	4.4	103.0	28.0	
		FINAL	15APR2003	9:30	57	145	4.1	107.0	28.0	
	E0022032	BSLN	12FEB2003	8:05	-6	142	4.5	108.0	26.0	
		FINAL	18APR2003	10:30	60	141	4.4	108.0	26.0	
	E0022035	BSLN	13FEB2003	13:50	-6	145	4.1	105.0	26.0	
		FINAL	13MAR2003	17:55	23	142	3.9	106.0	25.0	
	E0022036	BSLN	14FEB2003	8:55	-11	145	4.6	105.0	29.0	
		FINAL	22APR2003	7:36	57	146	4.0	110.0	29.0	
	E0022056	BSLN	11APR2003	8:07	-6	143	4.8	109.0	24.0	
	E0022060	BSLN	24APR2003	12:05	-6	143	4.5	103.0	29.0	
		FINAL	24JUN2003	9:25	56	142	4.4	107.0	25.0	
	E0022063	BSLN	29APR2003	10:10	-8	138	3.8	104.0	22.0	
	E0023008	BSLN	23JAN2003	10:00	-7	141	4.1	104.0	26.0	

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	FINAL		24MAR2003	15:40	54	140	3.7	106.0	19.0	L
	E0023013	BSLN		13FEB2003	11:00	-14	141	4.3	104.0	26.0	
		FINAL		06MAR2003	11:00	8	140	3.9	105.0	25.0	
	E0023015	BSLN		04MAR2003	11:00	-7	144	4.7	108.0	29.0	
		FINAL		06MAY2003	10:00	57	140	4.6	106.0	25.0	
	E0023034	BSLN		03JUN2003	14:00	-6	138	4.3	105.0	24.0	
		FINAL		05AUG2003	16:00	58	142	4.2	107.0	25.0	
	E0023037	BSLN		11JUN2003	16:30	-7	137	4.1	100.0	26.0	
		FINAL	*	24JUN2003	16:30	7	141	5.0	103.0	27.0	
		FINAL		15AUG2003	9:30	59	137	4.8	102.0	28.0	
	E0023038	BSLN		20JUN2003	12:45	-10	140	4.2	107.0	23.0	
		FINAL		16SEP2003	18:30	79	145	5.0	108.0	24.0	
	E0023044	BSLN		08JUL2003	14:00	-8	142	4.3	103.0	24.0	
		FINAL		12AUG2003	12:00	28	143	4.3	107.0	23.0	
	E0023045	BSLN		10JUL2003	11:40	-7	139	4.3	105.0	25.0	
		FINAL		15SEP2003	11:00	61	144	4.0	108.0	27.0	
	E0025002	BSLN		27MAR2003	11:05	-7	142	4.2	104.0	30.0	#
		FINAL		29MAY2003	11:40	57	139	4.0	106.0	25.0	
	E0026010	BSLN		15JAN2003	14:00	-7	142	4.4	106.0	28.0	
		FINAL		30JAN2003	16:30	9	143	4.2	103.0	28.0	
	E0026017	BSLN		26FEB2003	11:50	-8	146	4.3	104.0	26.0	
		FINAL		21MAR2003	11:10	16	142	4.1	105.0	29.0	
	E0026018	BSLN		06MAR2003	16:30	-14	141	4.3	109.0	25.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	FINAL	15MAY2003	14:15	57	140	4.3	105.0	24.0	
	E0026025	BSLN	01MAY2003	11:40	-8	142	4.0	108.0	23.0	
		FINAL	03JUL2003	9:30	56	140	3.9	101.0	20.0	L
	E0026029	BSLN	02JUL2003	11:10	-7	141	5.4	109.0	25.0	
		FINAL	28JUL2003	13:30	20	144	4.6	106.0	24.0	
	E0026030	BSLN	02JUL2003	11:50	-7	138	4.2	104.0	26.0	
		FINAL	03SEP2003	17:10	57	136	4.2	104.0	23.0	
	E0026031	BSLN	10JUL2003	14:00	-11	143	4.1	105.0	22.0	
		FINAL	15SEP2003	11:15	57	143	4.1	107.0	24.0	
	E0027003	BSLN	08JAN2003	14:40	-20	140	4.0	101.0	21.0	
		FINAL	25MAR2003	11:55	57	141	4.5	104.0	25.0	
	E0028004	BSLN	27SEP2002	9:45	-3	143	5.2	105.0	26.0	
		FINAL	09OCT2002	14:30	10	143	4.6	107.0	27.0	
	E0028006	BSLN	01OCT2002	10:00	-3	139	4.4	100.0	25.0	
		FINAL	04DEC2002	10:15	62	142	4.3	106.0	23.0	
	E0028008	BSLN	08OCT2002	12:45	-7	143	3.6	105.0	30.0	#
		FINAL	10DEC2002	12:30	57	144	3.5	105.0	25.0	
	E0028009	BSLN	10OCT2002	10:45	-5	144	4.1	107.0	23.0	
		FINAL	12DEC2002	13:50	59	140	4.3	102.0	33.0	#
	E0028016	BSLN	07NOV2002	10:15	-7	141	4.2	104.0	25.0	
		FINAL	09JAN2003	11:50	57	140	4.3	104.0	22.0	
	E0028017	*	12NOV2002	9:45		141	4.0	102.0	22.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
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Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	BSLN		14JAN2003	10:15	-7	139	4.7	106.0	25.0	
	E0028029	BSLN		28JAN2003	10:00	-7	142	4.3	106.0	21.0	
		FINAL		04APR2003	10:55	60	143	4.2	104.0	21.0	
	E0028034	BSLN		20MAR2003	9:40	-12	142	4.9	103.0	29.0	
		FINAL		02JUN2003	12:54	63	142	4.3	106.0	28.0	
	E0028038	BSLN		18APR2003	10:20	-7	141	4.7	109.0	23.0	
		FINAL		18JUN2003	13:45	55	142	4.8	109.0	22.0	
	E0028043	BSLN		29MAY2003	11:55	-7	141	4.1	106.0	25.0	
		FINAL		29JUL2003	8:25	55	145	4.5	108.0	27.0	
	E0028045	BSLN		09JUN2003	13:00	-9	146	4.5	116.0 H	23.0	
		FINAL		11SEP2003	12:50	86	144	4.5	109.0	26.0	
	E0029005	BSLN	*	14NOV2002	13:00	-13	134	4.4	100.0	26.0	
		BSLN		21NOV2002	10:30	-6	143	4.0	108.0	26.0	
		FINAL		21JAN2003	12:50	56	143	4.1	106.0	29.0	
	E0030001	BSLN		12NOV2002	15:15	-7	140	4.5	100.0	21.0	
		FINAL		16JAN2003	12:07	59	145	5.6 H#	105.0	25.0	
	E0030008	BSLN		07JAN2003	14:33	-7	143	4.3	106.0	22.0	
		FINAL		18MAR2003	10:42	64	144	4.3	109.0	24.0	
	E0030011	BSLN		16JAN2003	16:10	-11	141	4.6	107.0	28.0	
		FINAL		24MAR2003	14:35	57	145	4.5	108.0	27.0	
	E0030015	BSLN		13FEB2003	12:05	-8	146	5.2	105.0	33.0	#
		FINAL		22APR2003	12:10	61	144	4.4	106.0	33.0	#
	E0030022	BSLN		10JUN2003	11:15	-6	140	5.1	104.0	28.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	FINAL	14AUG2003	15:30	60	143	5.0	105.0	26.0	
	E0031002	BSLN	20NOV2002	17:05	-7	137	3.5	104.0	23.0	
		FINAL	23JAN2003	12:55	58	145	4.1	103.0	29.0	
	E0031003	BSLN	03DEC2002	16:07	-7	145	4.8	107.0	20.0	L
		FINAL	04FEB2003	16:20	57	144	5.7 H#	105.0	27.0	
	E0033015	BSLN	03APR2003	17:05	-7	140	4.5	105.0	21.0	
		FINAL	04JUN2003	11:00	56	141	4.6	107.0	23.0	
	E0034002	BSLN	18MAR2003	9:25	-7	144	4.5	109.0	26.0	
		FINAL	16APR2003	14:40	23	142	4.4	104.0	24.0	
	E0034003	BSLN	11APR2003	10:10	-13	140	4.4	105.0	23.0	
		FINAL	19JUN2003	15:50	57	138	4.6	102.0	23.0	
	E0034006	BSLN	25APR2003	11:33	-21	143	3.8	107.0	22.0	
		FINAL	10JUL2003	9:54	56	143	4.5	106.0	29.0	
	E0034008	BSLN	16MAY2003	13:26	-8	141	4.4	107.0	22.0	
		FINAL	21JUL2003	10:07	59	144	4.2	106.0	27.0	
	E0035003	BSLN	15NOV2002	10:30	-7	141	4.3	103.0	24.0	
	E0035005	BSLN	26NOV2002	10:00	-7	145	4.0	106.0	23.0	
	E0035014	BSLN	28JAN2003	11:10	-6	141	4.2	105.0	20.0	L
		FINAL	31MAR2003	9:20	57	145	4.2	111.0	27.0	
	E0035024	BSLN	15MAY2003	11:30	-8	138	4.3	103.0	23.0	
		FINAL	18JUL2003	9:00	57	139	4.3	104.0	25.0	
	E0036005	BSLN	24JUN2003	10:45	-7	142	4.2	107.0	22.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	FINAL		27AUG2003	12:45	58	142		4.2		108.0		24.0	
	E0037002	BSLN		18DEC2002	12:10	-8	147		4.1		111.0		23.0	
		FINAL		20FEB2003	13:25	57	146		4.3		110.0		27.0	
	E0037005	BSLN		27FEB2003	15:00	-7	143		3.9		107.0		24.0	
		FINAL		01MAY2003	14:15	57	143		4.6		108.0		28.0	
	E0037006	BSLN		07MAR2003	12:00	-7	140		3.9		106.0		25.0	
		FINAL		09MAY2003	12:18	57	142		3.7		106.0		21.0	
	E0039006	BSLN	*	11NOV2002	10:05	-49	125L#		3.6		90.0	L#	17.0	L#
		BSLN	*	22NOV2002	9:20	-38	144		4.4		107.0		22.0	
		BSLN		10DEC2002	11:35	-20	145		4.2		107.0		25.0	
		FINAL		24FEB2003	10:58	57	144		4.1		108.0		21.0	
	E0039015	BSLN		02JAN2003	10:20	-21	147		4.4		107.0		29.0	
		FINAL		20MAR2003	9:30	57	143		4.4		106.0		25.0	
	E0039024	BSLN		14FEB2003	8:50	-13	139		3.9		105.0		23.0	
		FINAL		25APR2003	16:05	58	139		4.2		105.0		19.0	L
	E0039025	BSLN		26FEB2003	11:00	-20	143		4.2		103.0		26.0	
		FINAL		27MAY2003	10:00	71	143		4.1		108.0		22.0	
	E0039041	BSLN		08APR2003	9:40	-7	142		4.3		106.0		30.0	#
		FINAL		11JUN2003	11:25	58	140		4.6		102.0		28.0	
	E0039044	BSLN		06MAY2003	10:30	-16	141		4.5		107.0		24.0	
		FINAL		23JUL2003	18:20	63	139		4.0		106.0		23.0	
	E0039046		*	06MAY2003	11:46		141		4.1		108.0		24.0	
			*	03JUN2003	10:25		138		4.0		105.0		23.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	BSLN	23MAY2003	9:30	-24	138	4.8	103.0	24.0	
		FINAL	12AUG2003	14:45	58	142	4.5	106.0	23.0	
	E0039053	BSLN	16JUN2003	13:25	-25	144	4.1	110.0	24.0	
		FINAL	08SEP2003	12:45	60	140	4.8	105.0	24.0	
	E0039057	BSLN	02JUL2003	19:50	-12	140	4.0	106.0	24.0	
		FINAL	09SEP2003	9:25	58	142	3.6	111.0	23.0	
	E0041003	BSLN	16JAN2003	17:30	-12	142	4.3	106.0	24.0	
		FINAL	25MAR2003	9:55	57	142	4.1	108.0	19.0	L
	E0041008	BSLN	26MAR2003	15:35	-12	143	4.9	101.0	31.0	#
		FINAL	02JUN2003	15:30	57	142	4.2	103.0	29.0	
	E0042001	BSLN	17JUN2003	9:45	-15	139	3.8	99.0	31.0	#
		FINAL	26AUG2003	10:50	56	143	4.3	106.0	25.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN		26FEB2003	14:25	-14	141	4.3	102.0	24.0
		FINAL		07MAY2003	13:45	57	142	4.2	105.0	29.0
	E0003018	BSLN		06MAY2003	16:22	-7	145	4.5	110.0	26.0
		FINAL		08JUL2003	14:18	57	139	4.3	106.0	27.0
	E0005011	BSLN		17OCT2002	15:00	-7	136	4.5	100.0	28.0
	E0005030	BSLN		18MAR2003	14:00	-8	141	3.7	105.0	25.0
	E0005036	BSLN		28APR2003	13:30	-8	141	3.9	106.0	25.0
		FINAL		27MAY2003	10:00	22	141	3.8	108.0	22.0
	E0006015	BSLN		07FEB2003	9:30	-4	141	4.7	101.0	27.0
		FINAL		08APR2003	12:00	57	144	4.2	109.0	28.0
	E0006016	BSLN		07FEB2003	12:55	-10	142	5.0	101.0	28.0
		FINAL		18APR2003	12:15	61	142	4.8	107.0	26.0
	E0007008	BSLN		08APR2003	9:55	-10	141	4.8	106.0	27.0
		FINAL		02JUL2003	14:00	76	138	4.4	104.0	27.0
		FINAL	*	12AUG2003	11:30	117	140	4.4	107.0	24.0
	E0009002	BSLN		30OCT2002	11:45	-20	143	4.3	106.0	25.0
		FINAL		15JAN2003	13:47	58	146	4.9	108.0	29.0
	E0009006	BSLN		23JAN2003	17:50	-5	140	3.7	101.0	25.0
		FINAL		25MAR2003	16:20	57	143	4.5	109.0	28.0
	E0009009	BSLN		27FEB2003	15:00	-13	144	4.0	106.0	26.0
		FINAL		24MAR2003	13:40	13	143	3.9	110.0	21.0
	E0010015	BSLN		30JAN2003	10:35	-21	148H	4.4	108.0	27.0
		FINAL		15APR2003	13:29	55	143	3.7	109.0	26.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	BSLN		17DEC2002	11:00	-7	143	4.4	106.0	27.0	
		FINAL		18FEB2003	9:00	57	147	4.5	106.0	27.0	
	E0011007	BSLN		12DEC2002	10:43	-7	142	4.8	104.0	24.0	
		FINAL		13FEB2003	8:00	57	142	5.2	102.0	29.0	
	E0011018	BSLN		15MAY2003	12:30	-7	141	4.7	102.0	31.0	#
		FINAL		17JUL2003	17:30	57	142	4.3	106.0	25.0	
	E0011024	BSLN		17JUN2003	12:10	-7	137	3.9	106.0	27.0	
		FINAL		21AUG2003	13:00	59	139	4.2	106.0	25.0	
	E0015003	BSLN		13NOV2002	12:20	-12	139	5.1	103.0	24.0	
		FINAL		02DEC2002	10:55	8	137	4.0	101.0	17.0	L#
	E0019003	BSLN		30OCT2002	9:10	-22	141	5.2	106.0	22.0	
		FINAL		16JAN2003	11:25	57	144	5.4	111.0	24.0	
	E0019007	BSLN		06NOV2002	10:32	-7	144	5.3	103.0	27.0	
		FINAL		07JAN2003	8:30	56	148H	5.7 H#	105.0	29.0	
	E0019014	BSLN	*	17DEC2002	11:02	-23	148H	5.0	111.0	27.0	
		BSLN		26DEC2002	10:25	-14	143	4.5	106.0	29.0	
		FINAL		22JAN2003	9:00	14	144	4.9	106.0	28.0	
	E0019018	BSLN		14JAN2003	10:45	-16	146	5.2	106.0	26.0	
		FINAL		27MAR2003	9:30	57	143	4.9	107.0	26.0	
	E0019022	BSLN		23JAN2003	12:00	-7	143	4.6	104.0	25.0	
		FINAL		27MAR2003	15:10	57	142	4.1	109.0	22.0	
	E0019027	BSLN		20FEB2003	10:50	-7	140	3.9	98.0	25.0	
	E0019032	BSLN		06MAR2003	14:50	-26	141	4.0	105.0	29.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	FINAL		28MAY2003	11:00	58	132	#	4.6		97.0	23.0	
	E0019034	BSLN		10MAR2003	16:55	-8	149H		4.5		108.0	25.0	
	E0019036	BSLN		18MAR2003	9:15	-7	144		4.8		108.0	26.0	
	E0019039	BSLN		22APR2003	11:00	-9	144		4.2		104.0	27.0	
		FINAL		08MAY2003	15:30	8	145		4.6		105.0	29.0	
	E0019041	BSLN		14MAY2003	10:50	-7	139		4.4		105.0	23.0	
		FINAL		16JUL2003	11:10	57	141		4.9		104.0	26.0	
	E0019049	BSLN		03JUL2003	13:40	-7	142		4.6		106.0	24.0	
		FINAL		08SEP2003	12:10	61	143		5.1		107.0	25.0	
	E0022052	BSLN		01APR2003	10:50	-9	141		4.5		106.0	25.0	
		FINAL		05JUN2003	9:32	57	141		4.5		106.0	26.0	
	E0022064	BSLN		01MAY2003	10:40	-5	145		5.5	#	107.0	30.0	#
		FINAL		01JUL2003	12:30	57	145		4.2		110.0	26.0	
	E0022073	BSLN		20JUN2003	14:10	-6	142		4.7		106.0	26.0	
		FINAL		21AUG2003	9:45	57	140		4.0		109.0	23.0	
	E0023002	BSLN		25OCT2002	16:00	-11	141		3.8		102.0	25.0	
	E0023017	BSLN		20MAR2003	11:00	-5	144		4.0		104.0	30.0	#
		FINAL		22MAY2003	12:30	59	143		4.0		106.0	29.0	
	E0023021	BSLN	*	10APR2003	10:20	-13	142		4.1		108.0	22.0	
		BSLN		16APR2003	15:00	-7	145		3.9		110.0	21.0	
		FINAL		17JUN2003	16:00	56	144		4.2		109.0	23.0	
	E0023027	BSLN		07MAY2003	13:30	-9	141		4.2		106.0	29.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	FINAL		09JUL2003	13:00	55	139		3.7		105.0		22.0	
	E0023030	BSLN		21MAY2003	10:00	-13	139		4.1		104.0		25.0	
		FINAL		30JUL2003	15:30	58	139		4.3		104.0		22.0	
	E0023040	BSLN		25JUN2003	15:00	-8	140		4.3		109.0		24.0	
		FINAL		05SEP2003	10:00	65	143		4.4		111.0		24.0	
	E0026014	BSLN		12FEB2003	11:40	-7	142		4.6		104.0		28.0	
		FINAL		19MAR2003	10:35	29	143		4.5		103.0		25.0	
	E0026019	BSLN		10MAR2003	11:45	-7	145		4.1		107.0		26.0	
		FINAL		12MAY2003	9:10	57	143		3.9		108.0		26.0	
	E0027005	BSLN		19DEC2002	14:50	-7	146		4.1		111.0		25.0	
		FINAL		20FEB2003	11:28	57	143		5.1		105.0		22.0	
	E0029009	BSLN		13JAN2003	12:50	-7	143		4.0		108.0		24.0	
		FINAL		18MAR2003	9:05	58	145		4.0		111.0		27.0	
	E0029021	BSLN	*	03MAR2003	10:40	-15	144		4.4		107.0		28.0	
		BSLN		18MAR2003	9:50	1	143		4.2		107.0		25.0	
		FINAL		15MAY2003	12:30	59	142		4.5		108.0		27.0	
		FINAL	*	27MAY2003	8:40	71	146		4.7		110.0		26.0	
	E0029026	BSLN		07APR2003	9:10	-7	139		4.2		105.0		25.0	
		FINAL		10JUN2003	15:00	58	144		4.0		109.0		28.0	
	E0029030	BSLN	*	13MAY2003	11:20	-14	141		4.4		108.0		28.0	
		BSLN		20MAY2003	12:55	-7	140		4.2		108.0		30.0	#
		FINAL		23JUL2003	17:25	58	142		4.2		109.0		23.0	
	E0031008	BSLN		05FEB2003	11:40	-23	144		5.4		104.0		26.0	
		FINAL		24APR2003	13:17	56	142		5.5	#	108.0		24.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	BSLN		14APR2003	10:35	-7	142	4.9	105.0	27.0	
		FINAL		13MAY2003	10:50	23	145	5.2	110.0	25.0	
	E0031021	BSLN		18APR2003	10:40	-7	142	4.7	106.0	28.0	
		FINAL		19JUN2003	10:40	56	142	4.6	106.0	23.0	
	E0031029	BSLN		05JUN2003	10:45	-13	143	5.0	106.0	29.0	
	E0033002	BSLN		23DEC2002	12:15	-18	142	4.9	104.0	28.0	
		FINAL		07MAR2003	11:25	57	142	4.5	105.0	25.0	
	E0033006	BSLN		15JAN2003	10:25	-8	140	4.5	105.0	27.0	
		FINAL		12FEB2003	12:30	21	144	4.6	107.0	27.0	
	E0033021	BSLN		25JUN2003	14:40	-7	142	4.2	106.0	24.0	
		FINAL		18AUG2003	16:20	48	143	4.1	108.0	28.0	
	E0035013	BSLN		27JAN2003	10:30	-8	143	4.7	105.0	26.0	
		FINAL		10FEB2003	11:05	7	140	4.3	104.0	22.0	
	E0035015	BSLN		03FEB2003	10:30	-8	143	4.0	103.0	26.0	
		FINAL		18FEB2003	11:20	8	145	4.4	105.0	28.0	
	E0035016	BSLN		10MAR2003	11:00	-25	142	4.6	108.0	22.0	
	E0035023	BSLN		06MAY2003	10:30	-7	143	4.9	110.0	25.0	
	E0039052	BSLN	*	29MAY2003	10:25	-22	143	4.3	106.0	23.0	
		BSLN		13JUN2003	12:10	-7	138	4.2	103.0	25.0	
	E0039056	BSLN		01JUL2003	12:50	-14	142	4.0	105.0	25.0	
	E0040003	BSLN		09JUL2003	14:00	-10	143	4.3	105.0	31.0	#
		FINAL		12SEP2003	11:00	56	138	4.2	104.0	27.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	144	4.1	106.0	27.0	
		FINAL	02MAY2003	10:30	61	142	4.1	107.0	26.0	
	E0002011	BSLN	16APR2003	11:30	-13	142	4.2	105.0	26.0	
		FINAL	25JUN2003	11:20	58	143	4.7	107.0	25.0	
	E0003010	BSLN	28JAN2003	9:10	-6	143	5.5 #	105.0	22.0	
		FINAL	31MAR2003	16:20	57	140	3.9	105.0	26.0	
	E0003011	BSLN	28JAN2003	11:47	-7	143	5.0	106.0	20.0	L
	E0003016	BSLN	01MAY2003	11:40	-21	142	4.1	108.0	28.0	
		FINAL	13JUN2003	8:45	23	144	4.4	109.0	25.0	
	E0003019	BSLN	19JUN2003	11:30	-8	142	4.3	106.0	21.0	
		FINAL	21AUG2003	8:50	56	141	4.3	107.0	26.0	
	E0003020	BSLN	27JUN2003	8:55	-26	141	4.1	107.0	23.0	
		FINAL	17SEP2003	15:00	57	143	5.0	107.0	28.0	
	E0004001	BSLN	23SEP2002	11:00	-7	145	5.0	106.0	27.0	
		FINAL	05NOV2002	13:30	37	144	4.6	104.0	25.0	
	E0004009	BSLN	17DEC2002	10:10	-9	146	4.9	106.0	26.0	
		FINAL	19FEB2003	16:00	56	146	4.3	105.0	24.0	
	E0004012	BSLN	07JAN2003	12:45	-7	140	4.8	104.0	25.0	
		FINAL	11MAR2003	11:35	57	142	4.7	108.0	24.0	
	E0004015	BSLN	06FEB2003	10:05	-14	149H	5.0	108.0	25.0	
		FINAL	15APR2003	9:10	55	145	4.5	109.0	28.0	
	E0005003	BSLN	23SEP2002	15:00	-9	143	4.4	105.0	26.0	
		FINAL	26NOV2002	13:25	56	146	3.6	104.0	22.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	BSLN		24SEP2002	15:20	-6	143	4.4	105.0	25.0	
	E0005007	BSLN		02OCT2002	12:40	-7	137	3.8	102.0	22.0	
		FINAL		04DEC2002	14:20	57	142	3.7	107.0	22.0	
	E0005008	BSLN		08OCT2002	18:00	-7	144	4.6	102.0	30.0	#
		FINAL		11DEC2002	16:00	58	141	4.4	100.0	26.0	
	E0005009	BSLN		09OCT2002	10:00	-20	144	4.4	105.0	22.0	
	E0005010	BSLN		14OCT2002	13:00	-7	140	4.0	104.0	23.0	
		FINAL		17DEC2002	14:25	58	141	3.9	102.0	26.0	
		FINAL	*	23DEC2002	16:00	64	145	3.9	110.0	26.0	
	E0005012	BSLN		24OCT2002	7:00	-21	139	4.3	99.0	28.0	
		FINAL		07JAN2003	11:00	55	139	4.2	101.0	25.0	
	E0005014	BSLN		05NOV2002	16:30	-8	142	4.8	102.0	26.0	
		FINAL		06JAN2003	10:00	55	145	4.3	106.0	24.0	
	E0005022	BSLN		27JAN2003	10:30	-2	143	4.2	105.0	28.0	
		FINAL		11MAR2003	10:10	42	145	4.3	108.0	30.0	#
	E0005025	BSLN		20FEB2003	13:20	-7	142	4.3	102.0	23.0	
		FINAL		03APR2003	11:30	36	140	4.2	105.0	24.0	
	E0006019	BSLN		26MAR2003	11:35	-12	145	4.5	109.0	25.0	
		FINAL		03JUN2003	12:00	58	143	4.0	106.0	28.0	
	E0007005	BSLN		27JAN2003	14:30	-4	143	4.6	105.0	25.0	
		FINAL		28MAR2003	13:30	57	142	4.9	108.0	22.0	
		FINAL	*	11APR2003	11:00	71	142	4.1	107.0	23.0	
	E0007015	BSLN		10JUL2003	7:35	-6	143	5.4	107.0	27.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	FINAL	10SEP2003	7:40	57	142	4.2	110.0	24.0	
	E0009001	BSLN	29OCT2002	15:30	-14	138	3.9	102.0	21.0	
	E0010002	BSLN	14NOV2002	10:36	-11	139	4.7	103.0	28.0	
		FINAL	02DEC2002	9:05	8	141	4.9	105.0	24.0	
	E0010009	BSLN	18DEC2002	9:42	-8	147	4.3	109.0	25.0	
		FINAL	19FEB2003	13:59	56	144	4.3	106.0	24.0	
	E0010010	BSLN	20DEC2002	8:45	-10	140	4.3	107.0	20.0	L
		FINAL	13JAN2003	10:28	15	144	4.8	107.0	25.0	
	E0010014	BSLN	14JAN2003	9:05	-14	140	4.7	102.0	31.0	#
		FINAL	25MAR2003	11:05	57	144	4.2	106.0	26.0	
	E0010017	BSLN	05FEB2003	8:51	-20	142	4.1	105.0	29.0	
		FINAL	22APR2003	10:20	57	142	4.1	108.0	28.0	
	E0010023	BSLN	10APR2003	9:22	-7	144	4.0	106.0	29.0	
		FINAL	01MAY2003	10:19	15	143	4.4	106.0	28.0	
	E0010027	BSLN	05JUN2003	9:10	-11	140	4.1	106.0	28.0	
		FINAL	01JUL2003	13:00	16	139	4.3	107.0	21.0	
	E0010029	BSLN	10JUN2003	9:25	-9	141	4.6	103.0	27.0	
	E0011022	BSLN	02JUN2003	11:00	-7	144	3.9	105.0	29.0	
		FINAL	05AUG2003	10:30	58	139	3.9	99.0	25.0	
	E0013006	BSLN	06MAR2003	10:15	-7	140	4.5	104.0	28.0	
		FINAL	24MAR2003	12:42	12	141	3.9	105.0	24.0	
	E0013012	BSLN	29APR2003	9:48	-8	144	4.7	105.0	22.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	FINAL	02JUL2003	10:05	57	144	4.5	106.0	27.0	
	E0013014	BSLN	08MAY2003	11:15	-26	144	4.8	107.0	29.0	
		FINAL	30JUN2003	12:21	28	142	5.0	105.0	31.0	#
	E0014005	BSLN	04MAR2003	17:20	-7	146	4.5	107.0	26.0	
		FINAL	06MAY2003	12:20	57	140	4.3	108.0	24.0	
	E0014007	BSLN	25MAR2003	17:50	-7	142	4.1	107.0	23.0	
		FINAL	22APR2003	13:50	22	144	4.0	109.0	21.0	
	E0014011	BSLN	06MAY2003	16:45	-7	142	4.0	105.0	29.0	
		FINAL	08JUL2003	15:50	57	142	4.2	108.0	24.0	
	E0014012	BSLN	19MAY2003	10:05	-8	143	4.1	106.0	26.0	
		FINAL	24JUN2003	18:40	29	143	5.0	106.0	26.0	
	E0015001	BSLN	11NOV2002	9:10	-18	141	4.2	103.0	22.0	
		FINAL	20JAN2003	7:30	53	142	3.8	107.0	25.0	
	E0015008	BSLN	13DEC2002	9:30	-6	142	4.4	104.0	25.0	
	E0016003	BSLN	10JAN2003	9:30	-14	140	4.1	106.0	21.0	
	E0016005	BSLN	21FEB2003	8:45	-4	143	4.7	107.0	24.0	
		FINAL	22APR2003	8:30	57	144	4.3	107.0	23.0	
	E0018007	BSLN	16DEC2002	10:15	-11	142	4.7	103.0	26.0	
		FINAL	10JAN2003	14:15	15	141	4.2	103.0	22.0	
	E0019005	BSLN	30OCT2002	11:50	-6	140	4.7	102.0	26.0	
		FINAL	02JAN2003	14:00	59	142	4.6	103.0	24.0	
	E0019015	BSLN	19DEC2002	10:49	-14	142	4.4	106.0	28.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	FINAL		27FEB2003	11:23	57	144	4.3	104.0	29.0	
	E0020004	BSLN		21NOV2002	15:20	-18	140	3.5	105.0	25.0	
		FINAL		22JAN2003	16:15	45	141	3.9	104.0	25.0	
		FINAL	*	24FEB2003	11:50	78	144	4.6	103.0	28.0	
	E0020010	BSLN		31JAN2003	9:15	-5	142	4.8	102.0	24.0	
		FINAL		02APR2003	10:30	57	140	4.0	101.0	26.0	
	E0020014	BSLN		11MAR2003	10:00	-7	142	4.0	109.0	25.0	
		FINAL		12MAY2003	11:15	56	141	3.4	108.0	25.0	
	E0020021	BSLN		13MAY2003	9:45	-6	144	4.4	107.0	27.0	
		FINAL		14JUL2003	13:25	57	143	4.1	101.0	32.0	#
	E0020023	BSLN		09JUN2003	19:05	-8	141	4.6	106.0	28.0	
		FINAL		11AUG2003	11:40	56	139	4.6	107.0	23.0	
	E0022007	BSLN		01NOV2002	10:23	-6	144	4.3	109.0	28.0	
	E0022010	BSLN		15NOV2002	10:40	-6	143	4.7	103.0	26.0	
		FINAL		16JAN2003	18:00	57	141	4.0	108.0	27.0	
	E0022012	BSLN		29NOV2002	15:40	-6	140	4.4	103.0	25.0	
		FINAL		30JAN2003	12:00	57	142	4.1	106.0	25.0	
	E0022019	BSLN		06DEC2002	10:10	-5	141	4.9	105.0	28.0	
		FINAL		06FEB2003	11:20	58	144	4.5	105.0	28.0	
	E0022025	BSLN		08JAN2003	10:10	-20	139	4.1	102.0	25.0	
		FINAL		04FEB2003	11:30	8	142	4.6	101.0	29.0	
	E0022033	BSLN		12FEB2003	10:05	-6	140	4.5	102.0	29.0	
		FINAL		15APR2003	12:10	57	140	4.2	105.0	24.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	BSLN	12FEB2003	12:40	-6	144	4.6	108.0	26.0	
		FINAL	15APR2003	14:00	57	142	4.4	108.0	23.0	
	E0022038	BSLN	21FEB2003	11:05	-7	143	4.5	109.0	22.0	
		FINAL	14APR2003	9:40	46	142	4.5	106.0	29.0	
	E0022039	BSLN	27FEB2003	11:15	-7	143	4.4	104.0	27.0	
		FINAL	01MAY2003	12:50	57	140	4.3	106.0	27.0	
	E0022046	BSLN	14MAR2003	8:00	-6	143	4.2	103.0	27.0	
		FINAL	16MAY2003	8:05	58	144	5.1	106.0	23.0	
	E0022048	BSLN	26MAR2003	9:58	-6	138	4.3	107.0	21.0	
	E0022051	BSLN	01APR2003	10:15	-6	141	4.0	105.0	26.0	
		FINAL	02JUN2003	10:45	57	141	4.3	109.0	24.0	
	E0022053	BSLN	04APR2003	12:50	-7	139	4.4	106.0	25.0	
	E0022058	BSLN	14APR2003	10:25	-7	140	4.5	105.0	30.0	#
		FINAL	22MAY2003	14:00	32	140	5.0	105.0	26.0	
	E0022061	BSLN	25APR2003	9:37	-5	142	4.2	106.0	22.0	
		FINAL	26JUN2003	12:30	58	142	4.8	106.0	27.0	
	E0022062	BSLN	28APR2003	7:43	-7	146	3.8	111.0	29.0	
		FINAL	23MAY2003	7:40	19	140	3.5	104.0	26.0	
	E0022068	BSLN	14MAY2003	10:23	-9	141	4.7	105.0	23.0	
	E0022069	BSLN	04JUN2003	7:40	-6	142	4.9	109.0	25.0	
		FINAL	05AUG2003	9:45	57	143	4.7	107.0	27.0	
	E0022071	BSLN	16JUN2003	11:40	-14	144	4.1	105.0	28.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	FINAL		26AUG2003	9:33	58	142	4.6	106.0	26.0	
	E0023003	BSLN	*	08NOV2002	16:00	-39	140	4.9	100.0	30.0	#
		BSLN		12DEC2002	10:00	-5	139	4.6	102.0	21.0	
		FINAL		11FEB2003	14:00	57	140	4.4	100.0	26.0	
	E0023006	BSLN		10DEC2002	10:30	-7	148H	4.3	110.0	28.0	
		FINAL		11FEB2003	11:50	57	143	3.8	106.0	27.0	
	E0023010	BSLN		28JAN2003	9:30	-7	141	4.8	100.0	22.0	
		FINAL		31MAR2003	10:00	56	139	4.3	101.0	29.0	
	E0023025	BSLN		01MAY2003	15:00	-14	142	4.1	107.0	27.0	
		FINAL		10JUL2003	13:30	57	138	4.1	105.0	24.0	
	E0023039	BSLN		24JUN2003	13:30	-7	142	4.5	106.0	23.0	
		FINAL		26AUG2003	13:30	57	141	4.7	106.0	24.0	
	E0026002	BSLN		05NOV2002	10:15	-7	147	5.6 H#	108.0	23.0	
		FINAL		09JAN2003	9:25	59	146	5.0	109.0	23.0	
	E0026007	BSLN		06JAN2003	10:30	-10	145	4.9	105.0	27.0	
		FINAL		12MAR2003	14:25	56	146	4.1	107.0	26.0	
	E0026013	BSLN		05FEB2003	12:20	-8	141	4.0	101.0	32.0	#
		FINAL		14APR2003	10:00	61	140	3.8	103.0	30.0	#
	E0028007	BSLN		01OCT2002	10:30	-3	143	4.1	105.0	21.0	
		FINAL		14NOV2002	12:45	42	132 #	3.6	99.0	26.0	
	E0028023	BSLN		15JAN2003	10:00	-6	140	4.0	108.0	23.0	
		FINAL		27JUN2003	15:00	158	143	4.4	108.0	26.0	
	E0028025	BSLN		08JAN2003	12:07	-5	143	4.9	105.0	27.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	FINAL		27JAN2003	9:25	15	141	4.7	102.0	24.0	
	E0028033	BSLN		18MAR2003	10:50	-9	141	4.1	107.0	27.0	
		FINAL		22MAY2003	10:50	57	139	3.8	104.0	24.0	
	E0028035	BSLN		27MAR2003	12:00	-7	142	4.4	105.0	27.0	
		FINAL		29MAY2003	15:40	57	143	4.4	108.0	25.0	
	E0028037	BSLN	*	18APR2003	8:30	-56	137	4.7	98.0	27.0	
		BSLN	*	24APR2003	7:50	-50	137	4.5	98.0	29.0	
		BSLN		04JUN2003	8:33	-9	138	4.7	104.0	24.0	
		FINAL		08AUG2003	15:30	57	140	4.4	105.0	25.0	
	E0028039	BSLN		05MAY2003	7:10	-4	142	4.9	106.0	28.0	
		FINAL		05JUN2003	12:30	28	140	3.8	104.0	28.0	
	E0028046	BSLN		17JUN2003	13:45	-8	140	3.8	106.0	24.0	
	E0028048	BSLN		11JUL2003	14:00	-6	140	4.3	105.0	26.0	
	E0029008	BSLN		09DEC2002	11:40	-7	143	4.3	107.0	24.0	
	E0029011	BSLN		14JAN2003	11:20	-8	140	4.4	103.0	24.0	
	E0029012	BSLN		04FEB2003	10:05	-7	142	4.4	104.0	29.0	
		FINAL		27MAR2003	8:45	45	142	4.2	110.0	23.0	
	E0029015	BSLN		11FEB2003	10:05	-13	140	3.9	104.0	24.0	
		FINAL		14MAR2003	10:30	19	141	4.2	108.0	25.0	
	E0029018	BSLN	*	26FEB2003	16:25	-8	143	4.9	104.0	27.0	
		BSLN		06MAR2003	16:05	1	144	4.9	105.0	26.0	
	E0030014	BSLN		14FEB2003	10:35	-7	140	4.3	109.0	20.0	L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	FINAL		22APR2003	12:50	61	141	4.8	112.0 H	26.0
	E0030020	BSLN		13MAY2003	15:30	-16	143	4.1	106.0	23.0
	E0030024	BSLN		17JUN2003	15:35	-24	142	4.9	107.0	22.0
		FINAL		18JUL2003	15:35	8	139	4.8	106.0	21.0
	E0030025	BSLN	*	24JUN2003	16:35	-17	160H#	5.1	119.0 H	25.0
		BSLN		07JUL2003	10:20	-4	143	4.2	108.0	24.0
		FINAL		19AUG2003	16:45	40				21.0
	E0031027	BSLN		28MAY2003	9:10	-6	142	5.2	107.0	26.0
		FINAL		29JUL2003	14:40	57	143	5.9 H#	108.0	25.0
	E0031030	BSLN		17JUN2003	10:46	-7	137	4.8	107.0	27.0
		FINAL		21AUG2003	11:10	59	135	4.2	104.0	26.0
	E0033012	BSLN		05FEB2003	15:26	-5	146	5.0	104.0	28.0
	E0034001	BSLN		17MAR2003	10:03	-3	144	4.4	109.0	27.0
		FINAL		15MAY2003	9:55	57	141	4.1	106.0	27.0
	E0034004	BSLN		11APR2003	11:15	-10	143	4.8	108.0	23.0
		FINAL		16JUN2003	12:03	57	144	4.6	111.0	24.0
	E0035001	BSLN		12NOV2002	11:40	-8	141	4.7	100.0	29.0
		FINAL		14JAN2003	9:05	56	141	4.4	107.0	28.0
	E0035006	BSLN		03DEC2002	10:45	-9	142	4.6	107.0	24.0
		FINAL		06FEB2003	9:30	57	141	5.0	104.0	25.0
	E0035021	BSLN		18APR2003	10:45	-7	139	4.2	107.0	24.0
		FINAL		20JUN2003	8:15	57	141	4.0	108.0	20.0 L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	BSLN	10JUN2003	13:45	-7	145	4.2	112.0	H	26.0	
		FINAL	15JUL2003	10:05	29	140	4.3	108.0		20.0	L
	E0036006	BSLN	24JUN2003	16:45	-9	141	4.4	105.0		22.0	
		FINAL	28AUG2003	9:50	57	141	4.0	107.0		27.0	
	E0036007	BSLN	27JUN2003	10:00	-6	140	4.3	103.0		26.0	
		FINAL	18JUL2003	9:15	16	137	4.5	103.0		22.0	
	E0037009	BSLN	12MAY2003	9:15	-4	139	4.3	104.0		23.0	
		FINAL	10JUL2003	16:05	56	139	3.5	105.0		17.0	L#
	E0039011	BSLN	16DEC2002	17:40	-17	141	4.1	103.0		24.0	
	E0039018	BSLN	15JAN2003	9:10	-8	140	4.3	104.0		23.0	
	E0039026	BSLN	03MAR2003	9:05	-4	140	4.1	105.0		27.0	
		FINAL	02MAY2003	9:20	57	137	3.9	105.0		20.0	L
	E0039028	BSLN	03MAR2003	14:15	-21	142	3.9	106.0		27.0	
		FINAL	16MAY2003	12:25	54	145	4.6	106.0		30.0	#
	E0039032	BSLN	07MAR2003	13:45	-7	141	4.3	108.0		26.0	
		FINAL	04APR2003	11:45	22	140	4.1	107.0		24.0	
	E0039034	BSLN	12MAR2003	20:05	-7	143	4.3	108.0		20.0	L
		FINAL	14MAY2003	15:00	57	141	4.3	104.0		25.0	
	E0039042	BSLN	25APR2003	10:15	-12	142	4.2	104.0		26.0	
		FINAL	02JUL2003	12:50	57	138	4.8	105.0		26.0	
	E0041004	BSLN	27JAN2003	10:15	-3	144	4.0	102.0		25.0	
		FINAL	31MAR2003	12:00	61	144	4.2	109.0		20.0	L

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	BSLN	22APR2003	15:15	-9	138	4.6	105.0	24.0
		FINAL	16JUN2003	13:00	47	138	4.4	106.0	25.0
	E0042002	BSLN	02JUL2003	12:10	-7	140	4.6	103.0	29.0
		FINAL	02SEP2003	10:25	56	138	4.8	103.0	24.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN	23JUN2003	10:00	-18	143	4.0	107.0	25.0
		FINAL	25JUL2003	9:00	15	139	4.3	105.0	24.0
	E0003002	BSLN	22OCT2002	11:05	-7	144	4.4	101.0	26.0
		FINAL	23DEC2002	15:35	56	139	4.2	102.0	27.0
	E0005031	BSLN	26MAR2003	12:30	-7	144	4.1	111.0	26.0
	E0005033	BSLN	08APR2003	14:00	-8	141	4.3	105.0	26.0
		FINAL	06MAY2003	11:20	21	143	4.5	106.0	27.0
	E0005038	BSLN	05MAY2003	11:40	-9	142	3.6	108.0	25.0
		FINAL	05JUN2003	13:00	23	141	4.0	107.0	29.0
	E0007009	BSLN	14APR2003	7:48	-3	142	5.1	107.0	28.0
	E0009010	BSLN	27FEB2003	16:55	-14	139	4.2	100.0	25.0
	E0009011	BSLN	28APR2003	14:17	-8	147	4.3	110.0	25.0
		FINAL	03JUL2003	15:40	59	144	5.2	109.0	26.0
	E0010005	BSLN	11DEC2002	10:15	-7	144	3.5	105.0	26.0
	E0011016	BSLN	14APR2003	10:00	-7	143	4.7	104.0	27.0
		FINAL	16JUN2003	9:45	57	143	4.4	107.0	26.0
	E0011020	BSLN	01MAY2003	9:20	-7	143	4.6	106.0	28.0
		FINAL	15MAY2003	17:00	8	139	4.2	103.0	28.0
	E0018002	BSLN	15NOV2002	15:35	-14	145	4.9	108.0	28.0
		FINAL	22JAN2003	16:20	55	144	4.5	109.0	26.0
	E0018003	BSLN	19NOV2002	13:05	-7	138	4.6	101.0	27.0
		FINAL	10DEC2002	11:00	15	143	4.7	107.0	25.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	BSLN		17JAN2003	14:15	-7	146	4.8	110.0	28.0	
		FINAL		06FEB2003	16:10	14	145	4.3	105.0	26.0	
	E0019002	BSLN		29OCT2002	10:45	-14	141	4.6	107.0	17.0	L#
	E0019008	BSLN	*	06NOV2002	12:35	-15	139	4.4	104.0	23.0	
		BSLN		13NOV2002	10:30	-8	142	4.7	104.0	22.0	
	E0019009	BSLN		06NOV2002	13:35	-8	137	4.1	102.0	25.0	
	E0019016	BSLN		30DEC2002	16:55	-7	144	4.3	104.0	24.0	
		FINAL		03MAR2003	16:00	57	143	4.6	104.0	28.0	
	E0019020	BSLN		16JAN2003	10:10	-7	144	4.7	107.0	24.0	
		FINAL		27MAR2003	10:50	64	142	4.6	108.0	25.0	
	E0019021	BSLN		16JAN2003	11:45	-14	144	5.2	105.0	26.0	
		FINAL		03MAR2003	13:18	33	142	4.5	100.0	28.0	
	E0019024	BSLN		24JAN2003	16:00	-6	142	4.0	100.0	24.0	
		FINAL		06FEB2003	12:33	8	141	4.1	102.0	27.0	
	E0019031	BSLN		06MAR2003	11:35	-7	141	4.3	102.0	32.0	#
		FINAL		25MAR2003	10:08	13	143	4.0	106.0	29.0	
	E0019035	BSLN		11MAR2003	9:28	-7	140	5.0	105.0	24.0	
		FINAL		17APR2003	14:30	31	142	4.3	105.0	24.0	
	E0019040	BSLN		08MAY2003	15:25	-12	147	4.5	107.0	28.0	
		FINAL		17JUL2003	9:50	59	145	4.7	109.0	26.0	
	E0019042	BSLN		29MAY2003	8:50	-6	145	4.8	110.0	26.0	
		FINAL		20JUN2003	8:20	17	145	5.4	109.0	22.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	BSLN		19JUN2003	14:54	-7	141	5.2	105.0	23.0	
		FINAL		16JUL2003	10:15	21	145	5.1	108.0	25.0	
	E0020024	BSLN		12JUN2003	15:40	-11	145	4.3	105.0	25.0	
		FINAL		20AUG2003	18:45	59	142	4.9	105.0	25.0	
	E0022044	BSLN		12MAR2003	9:50	-6	142	4.1	110.0	24.0	
		FINAL		12MAY2003	9:55	56	139	4.0	104.0	27.0	
	E0023007	BSLN		07JAN2003	14:30	-7	139	4.2	101.0	28.0	
		FINAL		13MAR2003	15:00	59	143	4.0	110.0	23.0	
	E0023011	BSLN		28JAN2003	11:45	-7	138	4.2	101.0	24.0	
		FINAL		01APR2003	12:00	57	142	4.4	106.0	24.0	
	E0023014	BSLN		14FEB2003	15:00	-7	143	4.1	106.0	23.0	
		FINAL		25APR2003	14:00	64	140	4.1	105.0	21.0	
	E0023019	BSLN		21MAR2003	14:00	-17	142	4.3	106.0	26.0	
		FINAL		03JUN2003	13:30	58	143	4.4	105.0	30.0	#
	E0023022	BSLN		10APR2003	16:00	-8	140	4.5	103.0	26.0	
		FINAL		12JUN2003	15:40	56	140	4.3	105.0	27.0	
	E0023023	BSLN		17APR2003	10:00	-8	144	4.0	107.0	24.0	
		FINAL		01MAY2003	14:00	7	142	3.9	108.0	27.0	
	E0023029	BSLN		16MAY2003	14:00	-7	143	4.2	111.0	27.0	
	E0023031	BSLN	*	22MAY2003	12:00	-33	141	4.0	105.0	22.0	
		BSLN		19JUN2003	10:00	-5	142	4.5	106.0	21.0	
		FINAL		19AUG2003	11:00	57	142	4.8	107.0	23.0	
	E0023041	BSLN		03JUL2003	11:00	-6	138	3.9	104.0	24.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	FINAL		05SEP2003	13:00	59	140	4.5	106.0	19.0	L
	E0023043	BSLN		07JUL2003	15:00	-7	138	4.1	102.0	25.0	
		FINAL		09SEP2003	10:30	58	139	4.7	103.0	28.0	
	E0026003	BSLN	*	25NOV2002	12:20	-9	140	4.4	105.0	21.0	
		BSLN		02DEC2002	9:25	-2	142	3.7	106.0	25.0	
		FINAL		03FEB2003	10:50	62	144	3.7	105.0	27.0	
	E0026005	BSLN		23DEC2002	12:40	-7	144	4.9	107.0	25.0	
		FINAL		06JAN2003	15:25	8	140	4.1	102.0	26.0	
	E0026009	BSLN		10JAN2003	10:20	-5	142	4.2	108.0	26.0	
		FINAL		21JAN2003	9:50	7	140	4.3	111.0	20.0	L
	E0026015	BSLN		20FEB2003	11:30	-7	139	4.7	103.0	22.0	
		FINAL		25APR2003	9:50	58	138	4.2	106.0	21.0	
	E0026023	BSLN		23APR2003	10:50	-7	143	4.1	110.0	22.0	
		FINAL		27JUN2003	12:25	59	143	3.5	109.0	24.0	
	E0027016	BSLN	*	19MAR2003	11:55	-21	140	4.0	105.0	26.0	
		BSLN		04APR2003	9:50	-5	142	5.0	106.0	26.0	
		FINAL		03JUN2003	10:18	56	142	4.0	107.0	26.0	
	E0027018	BSLN		21MAR2003	11:30	-4	141	4.2	107.0	24.0	
		FINAL		22MAY2003	10:05	59	139	4.3	105.0	23.0	
	E0028032	BSLN		13MAR2003	13:58	-12	144	4.3	105.0	25.0	
		FINAL		06JUN2003	11:38	74	143	4.2	106.0	28.0	
	E0029003	BSLN		28OCT2002	12:30	-7	140	4.1	101.0	22.0	
		FINAL		30DEC2002	9:45	57	144	4.7	105.0	24.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0029020	BSLN	25FEB2003	10:12	-8	142	3.7	102.0	27.0
	E0031005	BSLN	13DEC2002	16:00	-7	148H	4.4	113.0 H	23.0
		FINAL	14FEB2003	12:10	57	141	4.2	105.0	22.0
	E0031006	BSLN	31JAN2003	11:25	-18	141	4.8	101.0	26.0
		FINAL	15APR2003	9:25	57	144	5.0	104.0	28.0
	E0031010	BSLN	12FEB2003	14:50	-7	144	5.0	109.0	24.0
		FINAL	06MAR2003	12:50	16	143	4.1	108.0	26.0
	E0031011	BSLN	18FEB2003	11:50	-9	143	5.2	105.0	26.0
		FINAL	24APR2003	9:25	57	140	4.5	105.0	28.0
	E0031015	BSLN	14MAR2003	8:40	-12	144	4.9	109.0	27.0
		FINAL	01APR2003	11:55	7	142	4.9	104.0	26.0
	E0031031	BSLN	01JUL2003	10:30	-7	141	5.1	106.0	25.0
		FINAL	28AUG2003	10:35	52	142	4.4	107.0	23.0
	E0033009	BSLN	22JAN2003	13:40	-21	138	4.2	103.0	25.0
	E0034009	BSLN	10JUN2003	13:00	-9	144	4.7	107.0	26.0
		FINAL	18AUG2003	17:25	61	142	3.8	106.0	24.0
	E0037007	BSLN	04APR2003	11:30	-7	140	4.1	103.0	23.0
	E0037012	BSLN	11JUL2003	13:00	-5	140	4.1	105.0	24.0
		FINAL	08SEP2003	13:20	55	146	3.9	110.0	26.0
	E0039019	BSLN	20JAN2003	14:50	-17	142	4.0	103.0	28.0
		FINAL	03APR2003	11:05	57	141	4.2	108.0	23.0
	E0039043	BSLN	28APR2003	10:15	-10	144	4.0	107.0	27.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	144		4.4		105.0		27.0	
		FINAL		26FEB2003	8:45	59	139		4.5		103.0		26.0	
	E0002003	BSLN		03JAN2003	11:50	-19	139		5.0		102.0		21.0	
		FINAL		18MAR2003	12:10	56	141		4.8		107.0		24.0	
	E0002004	BSLN		14JAN2003	8:15	-11	139		3.7		105.0		26.0	
	E0002008	BSLN		14FEB2003	16:00	-11	137		4.3		103.0		25.0	
		FINAL		23APR2003	14:25	58	136		4.5		104.0		30.0	#
	E0002016	BSLN		14JUL2003	11:00	-10	142		4.1		104.0		30.0	#
		FINAL		17SEP2003	11:15	56	146		5.0		112.0	H	26.0	
	E0003008	BSLN		21JAN2003	12:45	-7	142		5.5	#	107.0		29.0	
	E0004003	BSLN		02OCT2002	11:00	-8	141		4.8		100.0		30.0	#
	E0004006	BSLN		28OCT2002	9:55	-7	137		4.8		101.0		19.0	L
		FINAL		06JAN2003	10:55	64	142		4.3		106.0		21.0	
	E0004016	BSLN		12FEB2003	15:10	-7	142		4.8		104.0		25.0	
		FINAL		17APR2003	17:10	58	147		4.2		108.0		24.0	
	E0004024	BSLN		25JUN2003	16:00	-8	144		3.7		106.0		24.0	
		FINAL		28AUG2003	9:50	57	139		4.8		103.0		27.0	
	E0005006	BSLN	*	24SEP2002	15:30	-9	142		4.2		104.0		22.0	
		BSLN		03OCT2002	8:30	1	139		4.3		102.0		28.0	
	E0005017	BSLN	*	11DEC2002	10:30	-19	145		4.8		107.0		25.0	
		BSLN		23DEC2002	12:30	-7	140		5.0		107.0		26.0	
		FINAL		04MAR2003	13:00	65	142		4.3		104.0		30.0	#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0005019	BSLN		19DEC2002	14:00	-27	142		4.0	107.0	23.0	
		FINAL		23JAN2003	15:45	9	139		4.2	104.0	23.0	
	E0005026	BSLN		28FEB2003	10:15	-6	138		4.2	101.0	24.0	
		FINAL		02APR2003	9:40	28	141		3.6	104.0	28.0	
	E0005039	BSLN		15MAY2003	9:00	-7	138		4.4	104.0	24.0	
		FINAL		16JUL2003	8:40	56	140		4.2	106.0	21.0	
	E0005043	BSLN		02JUL2003	8:30	-7	141		4.3	110.0	25.0	
		FINAL		03SEP2003	9:45	57	143		4.4	109.0	26.0	
	E0006020	BSLN		02MAY2003	13:30	-11	142		4.2	105.0	26.0	
		FINAL		08JUL2003	14:45	57	139		4.6	104.0	27.0	
		FINAL	*	10JUL2003	16:30	59	142		4.0	104.0	30.0	#
	E0007001	BSLN	*	16DEC2002	9:25	-15	141		4.2	100.0	25.0	
		BSLN		26DEC2002	9:25	-5	138		4.0	100.0	27.0	
		FINAL		24FEB2003	8:43	56	144		4.6	107.0	23.0	
		FINAL	*	10MAR2003	8:54	70	144		4.9	106.0	25.0	
	E0007003	BSLN		13JAN2003	10:30	-17	143		5.4	104.0	26.0	
		FINAL		01APR2003	13:30	62	132	#	4.5	95.0	27.0	
	E0007006	BSLN		24FEB2003	11:00	-9	135		4.9	98.0	26.0	
		FINAL		27MAR2003	10:50	23	140		4.5	105.0	25.0	
	E0009004	BSLN	*	19NOV2002	12:30	-7	141		4.5	101.0	26.0	
		BSLN		25NOV2002	12:55	-1	142		4.0	105.0	22.0	
		FINAL		18DEC2002	14:50	23	141		4.3	101.0	28.0	
	E0009012	BSLN		16JUN2003	14:45	-9	144		4.8	108.0	27.0	
		FINAL		03JUL2003	17:45	9	136		4.3	105.0	23.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0010008	BSLN		11DEC2002	9:15	-7	144	5.0	109.0	22.0	
	E0010018	BSLN		26FEB2003	8:51	-21	140	4.3	104.0	28.0	
		FINAL		14MAY2003	10:45	57	140	4.1	106.0	25.0	
	E0010028	BSLN		09JUN2003	8:46	-7	141	4.0	111.0	21.0	
		FINAL		15JUL2003	13:50	30	142	4.2	108.0	27.0	
	E0011008	BSLN	*	17DEC2002	12:30	-44	143	4.2	110.0	24.0	
		BSLN		23JAN2003	9:20	-7	141	4.0	102.0	27.0	
		FINAL		13FEB2003	12:30	15	140	4.2	103.0	25.0	
	E0011009	BSLN		19DEC2002	10:15	-8	140	4.3	100.0	26.0	
		FINAL		20FEB2003	9:00	56	143	4.5	102.0	18.0	L#
	E0011010	BSLN		03FEB2003	10:00	-7	144	4.1	106.0	26.0	
		FINAL		19MAR2003	8:45	38	143	3.9	108.0	24.0	
	E0013001	BSLN		01NOV2002	8:50	-13	142	5.1	103.0	28.0	
		FINAL		10JAN2003	10:45	58	141	4.6	104.0	22.0	
	E0013003	BSLN		07NOV2002	9:25	-5	144	5.2	106.0	24.0	
		FINAL		06JAN2003	13:17	56	144	4.7	105.0	21.0	
	E0013005	BSLN		13FEB2003	11:42	-5	140	3.9	100.0	28.0	
		FINAL		15APR2003	12:16	57	142	4.5	103.0	27.0	
	E0013013	BSLN		01MAY2003	10:14	-5	141	5.4	106.0	29.0	
		FINAL		30MAY2003	9:55	25	141	4.6	104.0	27.0	
	E0014002	BSLN		19FEB2003	16:35	-7	143	4.5	108.0	25.0	
		FINAL		10APR2003	13:05	44	141	4.5	110.0	22.0	
	E0014004	BSLN		04MAR2003	11:40	-8	144	4.3	105.0	26.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0014004	FINAL		15APR2003	11:40	35	142	4.2	106.0	26.0	
	E0014009	BSLN	*	15APR2003	14:45	-8	143	4.4	108.0	26.0	
		BSLN		17APR2003	12:30	-6	146	4.5	111.0	23.0	
		FINAL		16MAY2003	8:55	24	141	4.5	108.0	21.0	
	E0014015	BSLN		11JUN2003	10:15	-7	140	4.9	105.0	31.0	#
	E0014017	BSLN		17JUN2003	17:00	-10	144	4.5	110.0	25.0	
		FINAL		19AUG2003	17:05	54	140	4.2	106.0	24.0	
	E0014018	BSLN		24JUN2003	16:35	-7	143	4.4	105.0	27.0	
		FINAL		27AUG2003	16:00	58	142	4.5	104.0	27.0	
		FINAL	*	24SEP2003	16:45	86	141	4.0	106.0	27.0	
	E0015005	BSLN		25NOV2002	13:15	-7	141	4.7	108.0	23.0	
		FINAL		18DEC2002	9:30	17	144	4.9	108.0	28.0	
	E0017002	BSLN		08MAY2003	17:00	-26	142	4.1	108.0	21.0	
		FINAL		13JUN2003	16:00	11	140	4.1	108.0	24.0	
	E0018009	BSLN		17DEC2002	10:45	-20	139	4.6	103.0	25.0	
		FINAL		14JAN2003	13:15	9	140	4.7	103.0	26.0	
	E0018010	BSLN		09JAN2003	9:30	-7	141	4.0	103.0	23.0	
		FINAL		13MAR2003	9:20	57	142	4.2	106.0	23.0	
	E0018015	BSLN		21JAN2003	11:20	-7	142	5.0	104.0	31.0	#
		FINAL		27MAR2003	10:50	59	144	5.0	107.0	27.0	
	E0020015	BSLN		18MAR2003	13:30	-9	143	4.5	106.0	25.0	
		FINAL		23MAY2003	13:40	58	143	4.7	107.0	25.0	
	E0020017	BSLN		27MAR2003	12:00	-7	140	3.9	105.0	26.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0020017	FINAL		03JUN2003	17:40	62	139	3.6	103.0	27.0	
	E0020020	BSLN		07MAY2003	15:00	-5	135	4.2	99.0	27.0	
		FINAL		23MAY2003	14:00	12	136	3.6	98.0	29.0	
	E0020022	BSLN		09JUN2003	13:05	-7	142	4.1	108.0	24.0	
		FINAL		11AUG2003	9:30	57	144	5.1	108.0	23.0	
	E0022001	BSLN		09OCT2002	14:20	-19	144	4.3	103.0	28.0	
		FINAL		26DEC2002	17:55	60	141	3.6	99.0	28.0	
	E0022004	BSLN	*	17OCT2002	8:48	-11	143	4.8	102.0	30.0	#
		BSLN		28OCT2002	9:47	1	146	5.3	105.0	28.0	
		FINAL		23DEC2002	10:15	57	146	5.3	110.0	29.0	
	E0022005	BSLN		18OCT2002	7:40	-21	146	4.7	107.0	21.0	
		FINAL		03JAN2003	9:20	57	140	4.1	104.0	23.0	
	E0022011	BSLN		21NOV2002	9:25	-8	142	4.5	108.0	25.0	
	E0022015	BSLN	*	29NOV2002	13:50	-11	143	4.4	103.0	27.0	
		BSLN	*	03DEC2002	10:10	-7	146	4.5	108.0	26.0	
		BSLN		10DEC2002	16:10	1	145	4.3	109.0	27.0	
		FINAL		06FEB2003	9:50	59	147	4.5	107.0	27.0	
	E0022016	BSLN		03DEC2002	12:10	-14	143	4.5	106.0	26.0	
		FINAL		11FEB2003	11:05	57	143	4.7	106.0	28.0	
	E0022020	BSLN		05DEC2002	12:21	-7	141	4.7	105.0	25.0	
		FINAL		23JAN2003	16:20	43	136	3.8	100.0	22.0	
		FINAL	*	28JAN2003	10:35	48	138	4.1	102.0	20.0	L
	E0022023	BSLN		20DEC2002	14:28	-5	141	4.5	104.0	24.0	
		FINAL		20FEB2003	10:05	58	145	4.5	105.0	24.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0022029	BSLN	10FEB2003	12:30	-9	143	4.5	102.0	25.0	
		FINAL	14APR2003	9:45	55	141	4.5	105.0	27.0	
	E0022041	BSLN	11MAR2003	9:53	-7	143	4.2	109.0	24.0	
		FINAL	13MAY2003	9:18	57	142	4.4	108.0	27.0	
	E0022042	BSLN	05MAR2003	9:50	-7	147	4.5	107.0	30.0	#
		FINAL	12MAY2003	9:35	62	142	4.8	105.0	27.0	
	E0022043	BSLN	11MAR2003	13:50	-9	140	4.4	105.0	25.0	
		FINAL	12MAY2003	8:05	54	139	4.5	104.0	29.0	
	E0022054	BSLN	07APR2003	11:25	-4	142	4.5	105.0	29.0	
	E0022059	BSLN	23APR2003	15:30	-13	142	4.1	106.0	26.0	
		FINAL	08JUL2003	16:30	64	141	4.4	104.0	25.0	
	E0022065	BSLN	01MAY2003	9:30	-6	142	4.2	106.0	29.0	
		FINAL	02JUL2003	8:50	57	143	4.5	107.0	26.0	
	E0022070	BSLN	05JUN2003	11:40	-7	143	4.3	108.0	27.0	
		FINAL	18JUN2003	15:15	7	146	4.4	108.0	27.0	
	E0023001	BSLN	24OCT2002	13:30	-22	140	4.5	101.0	31.0	#
		FINAL	14JAN2003	13:30	61	138	4.8	103.0	28.0	
	E0023009	BSLN	24JAN2003	11:30	-18	139	4.6	101.0	24.0	
		FINAL	08APR2003	11:15	57	142	4.6	108.0	29.0	
	E0023028	BSLN	16MAY2003	12:15	-13	141	4.7	107.0	23.0	
		FINAL	21JUL2003	11:00	54	142	4.7	104.0	23.0	
	E0023033	BSLN	30MAY2003	12:10	-6	141	4.8	106.0	27.0	
		FINAL	12JUN2003	13:15	8	138	3.8	105.0	23.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0023047	BSLN		11JUL2003	15:00	-7	136	4.1	103.0	23.0	
		FINAL		16SEP2003	13:00	61	147	4.4	110.0	26.0	
	E0025001	BSLN		25MAR2003	16:00	-7	140	4.1	108.0	23.0	
		FINAL		23APR2003	10:30	23	143	4.7	109.0	20.0	L
	E0026012	BSLN		05FEB2003	11:00	-15	143	4.6	104.0	28.0	
		FINAL		17APR2003	9:10	57	146	4.3	110.0	22.0	
	E0026020	BSLN		28MAR2003	10:50	-4	147	4.7	110.0	28.0	
		FINAL		22APR2003	14:05	22	143	4.4	109.0	26.0	
	E0026024	BSLN		25APR2003	12:30	-7	141	4.1	110.0	13.0	L#
	E0026028	BSLN		06JUN2003	10:20	-14	143	4.6	105.0	28.0	
		FINAL		23JUL2003	10:00	34	144	4.9	108.0	23.0	
	E0028001	BSLN		07OCT2002	14:00	-3	144	4.9	103.0	25.0	
		FINAL		03DEC2002	9:50	55	139	4.8	101.0	26.0	
	E0028003	BSLN		23SEP2002	9:10	-7	146	4.3	107.0	26.0	
		FINAL		26NOV2002	9:20	58	152H#	4.9	110.0	22.0	
	E0028005	BSLN		30SEP2002	11:00	-3	143	4.6	109.0	27.0	
		FINAL		31OCT2002	12:15	29	146	4.2	107.0	23.0	
	E0028010	BSLN		15OCT2002	11:00	-21	139	4.5	101.0	30.0	#
		FINAL	*	19NOV2002	12:40	15	141	4.9	102.0	26.0	
		FINAL		31DEC2002	9:20	57	141	3.9	104.0	24.0	
	E0028011	BSLN	*	22OCT2002	8:30	-44	142	4.1	103.0	29.0	
		BSLN		25NOV2002	9:00	-10	146	4.7	107.0	23.0	
		FINAL		30JAN2003	12:35	57	142	4.1	104.0	30.0	#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0028030	BSLN	26FEB2003	11:30	-6	139	4.2	97.0	26.0	
		FINAL	30APR2003	12:35	58	140	4.1	101.0	26.0	
	E0028031	BSLN	06MAR2003	9:00	-5	145	4.8	106.0	27.0	
		FINAL	17APR2003	13:30	38	147	4.6	106.0	26.0	
	E0028047	BSLN	09JUL2003	10:40	-5	142	4.0	105.0	25.0	
		FINAL	09SEP2003	10:24	58	143	4.2	106.0	24.0	
	E0029001	BSLN	25SEP2002	8:45	-6	139	4.0	102.0	30.0	#
	E0029014	BSLN	28JAN2003	9:35	-7	140	4.8	101.0	22.0	
		FINAL	01APR2003	11:20	57	144	4.8	106.0	27.0	
	E0029023	BSLN	01APR2003	8:47	-7	139	4.6	105.0	21.0	
		FINAL	10JUN2003	11:10	64	143	4.0	108.0	21.0	
	E0029032	BSLN	22MAY2003	12:45	-19	143	4.2	106.0	28.0	
		FINAL	01JUL2003	12:00	22	140	4.3	105.0	24.0	
	E0029033	BSLN	27MAY2003	12:50	-6	140	4.5	106.0	26.0	
	E0029039	BSLN	10JUL2003	13:02	-5	140	4.4	107.0	25.0	
		FINAL	28JUL2003	15:30	14	139	4.1	108.0	22.0	
	E0030003	BSLN	03DEC2002	14:25	-13	138	4.0	104.0	23.0	
		FINAL	21MAR2003	9:50	96	143	4.6	111.0	22.0	
	E0030009	BSLN	14JAN2003	9:55	-9	141	4.7	105.0	29.0	
		FINAL	19MAR2003	10:35	56	142	5.2	104.0	26.0	
	E0030016	BSLN	21FEB2003	11:50	-10	142	4.3	103.0	26.0	
		FINAL	22APR2003	18:55	51	142	4.6	104.0	26.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0030021	BSLN	13MAY2003	17:25	-7	142	4.3	105.0	24.0	
	E0031001	BSLN	14NOV2002	11:48	-7	146	4.8	108.0	24.0	
	E0031017	BSLN	25MAR2003	16:15	-7	145	4.7	106.0	24.0	
		FINAL	29APR2003	10:30	29	141	4.6	106.0	23.0	
	E0031018	BSLN	01APR2003	14:45	-9	145	4.8	106.0	26.0	
	E0031023	BSLN	22APR2003	14:03	-7	140	4.4	107.0	25.0	
		FINAL	24JUN2003	11:48	57	141	4.5	107.0	21.0	
	E0033001	BSLN	23DEC2002	12:50	-17	142	4.5	101.0	29.0	
		FINAL	30JAN2003	13:25	22	142	4.1	101.0	28.0	
	E0033004	BSLN	09JAN2003	13:10	-8	142	5.1	106.0	20.0	L
		FINAL	14MAR2003	11:40	57	142	4.9	108.0	26.0	
	E0033010	BSLN	22JAN2003	16:20	-13	138	3.6	104.0	26.0	
		FINAL	26MAR2003	16:00	51	142	4.3	108.0	26.0	
	E0033014	BSLN	12MAR2003	17:25	-7	142	4.6	106.0	26.0	
	E0035002	BSLN	14NOV2002	10:50	-7	143	4.2	100.0	23.0	
	E0035007	BSLN	13DEC2002	12:40	-6	141	4.1	103.0	30.0	#
		FINAL	11FEB2003	10:10	55	141	4.3	98.0	28.0	
	E0035011	BSLN	13JAN2003	8:35	-22	138	4.1	104.0	25.0	
		FINAL	01APR2003	9:00	57	147	4.4	111.0	26.0	
	E0035020	BSLN	15APR2003	8:15	-3	145	4.0	108.0	30.0	#
	E0037003	BSLN	23JAN2003	11:40	-7	140	3.8	103.0	27.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0037003	FINAL		20FEB2003	15:32	22	143	4.7	105.0	25.0	
	E0037004	BSLN		06FEB2003	12:35	-7	144	4.0	108.0	26.0	
		FINAL		10APR2003	13:00	57	143	4.5	110.0	27.0	
	E0039007	BSLN		25NOV2002	13:20	-9	148H	4.4	108.0	32.0	#
		FINAL		29JAN2003	14:15	57	146	4.4	105.0	27.0	
	E0039022	BSLN		06FEB2003	9:50	-19	145	4.2	106.0	23.0	
		FINAL		24APR2003	12:10	59	141	4.0	109.0	26.0	
	E0039023	BSLN		05FEB2003	10:37	-19	147	4.7	110.0	25.0	
	E0039030	BSLN		12MAR2003	8:55	-12	141	3.9	109.0	28.0	
		FINAL		19MAY2003	9:15	57	143	4.1	110.0	25.0	
		FINAL	*	30MAY2003	9:50	68	141	4.0	110.0	21.0	
	E0039031	BSLN		05MAR2003	19:15	-19	141	4.4	105.0	27.0	
		FINAL		20MAY2003	12:50	58	140	4.2	106.0	29.0	
	E0039037	BSLN		26MAR2003	18:30	-21	139	3.9	105.0	25.0	
		FINAL		12JUN2003	11:30	58	140	4.0	106.0	24.0	
	E0039038	BSLN	*	27MAR2003	10:10	-27	136	4.5	101.0	25.0	
		BSLN		21APR2003	10:16	-2	140	4.3	106.0	24.0	
		FINAL		20JUN2003	11:15	59	136	4.8	101.0	22.0	
	E0039047	BSLN		13MAY2003	9:20	-6	142	4.5	108.0	27.0	
	E0039059	BSLN		07JUL2003	11:10	-4	138	4.5	105.0	24.0	
		FINAL		05SEP2003	11:10	57	144	4.6	107.0	22.0	
	E0041007	BSLN		05MAR2003	13:45	-8	146	4.0	108.0	26.0	
		FINAL		08MAY2003	13:45	57	147	4.5	107.0	26.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
PLACEBO (BIPOLAR I)	E0041010	BSLN	23APR2003	14:45	-7	140	4.5	106.0	26.0
		FINAL	11JUN2003	15:30	43	140	4.1	106.0	23.0
	E0041011	BSLN	15MAY2003	16:00	-7	138	3.8	104.0	22.0
		FINAL	17JUL2003	14:30	57	140	4.3	106.0	24.0
	E0041012	BSLN	05JUN2003	12:28	-14	140	3.9	104.0	27.0
		FINAL	14AUG2003	11:45	57	145	3.8	107.0	25.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
PLACEBO (BIPOLAR II)	E0001004	BSLN		23APR2003	11:00	-8	141	4.8	105.0	28.0
		FINAL		27JUN2003	12:45	58	140	4.0	104.0	22.0
	E0005023	BSLN		29JAN2003	7:30	-7	140	3.9	103.0	23.0
		FINAL		01APR2003	16:30	56	141	3.5	105.0	25.0
	E0005034	BSLN		09APR2003	9:30	-6	144	4.8	109.0	29.0
		FINAL		09JUN2003	13:00	56	141	3.8	108.0	27.0
	E0005041	BSLN		17JUN2003	11:55	-7	142	3.9	106.0	25.0
		FINAL		18AUG2003	10:10	56	144	3.9	107.0	26.0
	E0007004	BSLN		28JAN2003	8:05	-2	138	4.7	101.0	25.0
		FINAL		13FEB2003	8:30	15	138	4.6	102.0	25.0
	E0007010	BSLN		14APR2003	8:10	-4	144	4.9	108.0	25.0
		FINAL	*	21APR2003	8:30	4	146	5.0	110.0	27.0
		FINAL		13JUN2003	7:40	57	142	4.2	107.0	27.0
		FINAL	*	16JUN2003	7:50	60	143	4.5	108.0	26.0
	E0007012	BSLN		12MAY2003	8:50	-4	141	4.2	103.0	28.0
		FINAL		02JUL2003	11:35	48	144	4.7	107.0	28.0
	E0009007	BSLN		27JAN2003	15:25	-7	145	4.2	106.0	24.0
		FINAL		03MAR2003	15:40	29	141	4.3	107.0	26.0
	E0009008	BSLN		04FEB2003	13:37	-8	147	4.3	108.0	29.0
		FINAL		08APR2003	12:35	56	147	4.4	110.0	26.0
	E0011001	BSLN		25OCT2002	16:00	-7	143	3.8	104.0	23.0
		FINAL		26DEC2002	8:30	56	142	3.8	104.0	28.0
	E0011011	BSLN		12FEB2003	12:00	-8	144	3.9	107.0	27.0
		FINAL		16APR2003	8:30	56	142	3.8	107.0	23.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR II)	E0011013	BSLN		25MAR2003	9:45	-23	142	4.7	106.0		27.0	
		FINAL		12JUN2003	8:45	57	139	3.9	102.0		29.0	
	E0011014	BSLN		02APR2003	8:20	-5	140	4.6	106.0		24.0	
		FINAL		08MAY2003	15:30	32	141	4.1	104.0		27.0	
	E0011021	BSLN		15MAY2003	10:00	-7	138	4.1	102.0		27.0	
		FINAL		21JUL2003	10:00	61	143	4.3	110.0		25.0	
	E0013008	BSLN		19MAR2003	16:20	-7	142	4.7	107.0		21.0	
		FINAL		19MAY2003	11:25	55	143	4.7	106.0		26.0	
	E0014001	BSLN		18FEB2003	15:45	-8	141	3.3	101.0		26.0	
		FINAL		08APR2003	11:10	42	143	4.2	113.0	H	27.0	
		FINAL	*	16APR2003	10:40	50	141	4.4	109.0		25.0	
	E0014013	BSLN		20MAY2003	14:50	-7	145	3.9	106.0		28.0	
		FINAL		23JUL2003	15:00	58	142	4.1	107.0		25.0	
	E0014014	BSLN		03JUN2003	16:35	-7	146	4.5	110.0		25.0	
		FINAL		06AUG2003	10:50	58	145	4.5	106.0		30.0	#
	E0015004	BSLN		25NOV2002	8:50	-7	144	4.8	108.0		23.0	
		FINAL		29JAN2003	8:45	59	142	4.3	104.0		22.0	
	E0018005	BSLN		10DEC2002	16:00	-10	144	4.1	109.0		24.0	
		FINAL		17FEB2003	11:05	60	144	4.7	105.0		26.0	
	E0018012	BSLN		17JAN2003	10:30	-7	141	4.3	106.0		27.0	
		FINAL		26FEB2003	19:20	34	143	4.4	107.0		25.0	
	E0019019	BSLN		14JAN2003	10:30	-9	141	4.5	105.0		25.0	
	E0019033	BSLN		10MAR2003	16:05	-8	146	4.3	104.0		26.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)		POTASSIUM (MEQ/L)		CHLORIDE (MEQ/L)		BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR II)	E0019033	FINAL		16MAY2003	8:30	60	145		5.5	#	107.0		30.0	#
	E0019038	BSLN	*	10APR2003	12:30	-14	143		4.7		104.0		28.0	
		BSLN		17APR2003	11:05	-7	145		4.4		108.0		25.0	
		FINAL		19JUN2003	9:40	57	140		4.1		105.0		23.0	
	E0019046	BSLN		19JUN2003	15:00	-7	141		3.6		104.0		23.0	
		FINAL		21AUG2003	9:12	57	143		4.6		106.0		26.0	
	E0019047	BSLN		26JUN2003	12:30	-12	141		4.5		104.0		22.0	
		FINAL		04SEP2003	8:40	59	148H		5.0		108.0		26.0	
	E0019048	BSLN		03JUL2003	11:05	-7	139		4.4		100.0		26.0	
		FINAL		03SEP2003	16:12	56	135		4.7		100.0		25.0	
	E0022006	BSLN		22OCT2002	10:10	-21	141		4.6		101.0		26.0	
		FINAL		07JAN2003	7:40	57	136		4.0		101.0		27.0	
	E0022047	BSLN		21MAR2003	8:10	-7	141		4.6		105.0		27.0	
		FINAL		23MAY2003	9:45	57	140		3.8		102.0		27.0	
	E0022075	BSLN		27JUN2003	7:45	-11	144		4.5		103.0		31.0	#
		FINAL		03SEP2003	9:15	58	141		4.1		104.0		28.0	
	E0023012	BSLN		31JAN2003	15:30	-6	142		3.6		103.0		24.0	
		FINAL		04APR2003	12:15	58	142		4.3		109.0		23.0	
	E0023016	BSLN		15MAY2003	13:30	-7	142		3.7		107.0		28.0	
		FINAL		17JUL2003	11:10	57	143		4.1		109.0		21.0	
	E0023018	BSLN		18MAR2003	13:30	-9	143		4.5		108.0		27.0	
		FINAL		22MAY2003	10:15	57	138		4.2		104.0		26.0	
	E0023036	BSLN		10JUN2003	12:00	-10	141		4.7		107.0		28.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR II)	E0023036	FINAL		13AUG2003	17:00	55	139	4.4	107.0	24.0	
	E0023046	BSLN		11JUL2003	10:00	-12	139	3.2 L	102.0	25.0	
		FINAL		16SEP2003	14:00	56	141	3.8	105.0	26.0	
	E0026006	BSLN		31DEC2002	10:35	-8	144	3.9	102.0	27.0	
	E0026021	BSLN		14APR2003	15:45	-9	140	3.9	107.0	25.0	
	E0026027	BSLN		05JUN2003	13:10	-14	139	3.9	107.0	25.0	
	E0029002		*	07NOV2002	8:10		140	4.5	102.0	24.0	
	E0029004	BSLN		13NOV2002	14:50	-6	142	4.6	102.0	23.0	
		FINAL		17JAN2003	8:25	60	142	4.0	108.0	29.0	
	E0029013	BSLN		10FEB2003	8:55	-9	140	4.7	104.0	25.0	
	E0029019	BSLN		24FEB2003	9:30	-7	145	4.3	108.0	24.0	
		FINAL		17MAR2003	9:50	15	145	4.1	108.0	30.0	#
	E0029024	BSLN		11MAR2003	12:10	-6	142	5.2	104.0	29.0	
		FINAL		20MAY2003	14:45	65	142	4.6	104.0	27.0	
	E0029038	BSLN		30JUN2003	9:25	-7	143	4.3	105.0	27.0	
	E0031004	BSLN		12DEC2002	13:59	-7	140	4.3	104.0	24.0	
		FINAL		14FEB2003	10:50	58	141	5.1	107.0	24.0	
	E0031013	BSLN		06MAR2003	10:35	-7	146	5.2	106.0	29.0	
		FINAL		08MAY2003	11:05	57	145	4.9	108.0	26.0	
	E0031016	BSLN		17MAR2003	10:45	-7	139	4.4	103.0	28.0	
		FINAL		15APR2003	10:03	23	141	4.4	103.0	26.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM103.SAS
GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR II)	E0031019	BSLN		03APR2003	11:25	-8	145	4.7	106.0	27.0	
		FINAL		12MAY2003	16:40	32	143	4.9	106.0	27.0	
	E0031022	BSLN		21APR2003	12:40	-7	142	4.7	107.0	24.0	
	E0033007	BSLN		15JAN2003	15:20	-13	142	5.0	104.0	32.0	#
		FINAL		27MAR2003	15:35	59	143	4.7	107.0	26.0	
	E0033013	BSLN		06FEB2003	11:45	-13	144	4.8	106.0	26.0	
		FINAL		16APR2003	11:45	57	144	4.7	110.0	23.0	
	E0033016	BSLN		17APR2003	12:00	-21	138	4.4	107.0	27.0	
		FINAL		02JUL2003	13:00	56	140	4.1	106.0	26.0	
	E0033022	BSLN		09JUL2003	11:00	-5	140	4.6	105.0	25.0	
		FINAL		11SEP2003	12:00	60	141	4.6	107.0	24.0	
	E0034007	BSLN		07MAY2003	14:05	-9	137	3.7	101.0	24.0	
		FINAL		14JUL2003	11:15	60	143	4.0	100.0	27.0	
		FINAL	*	28JUL2003	11:48	74	145	4.0	104.0	26.0	
	E0035004	BSLN		22NOV2002	11:45	-5	140	4.4	101.0	25.0	
	E0035009	BSLN		20DEC2002	11:12	-7	144	4.3	105.0	25.0	
		FINAL		19FEB2003	8:55	55	145	4.2	104.0	29.0	
	E0035010	BSLN		07JAN2003	7:45	-3	147	4.4	106.0	26.0	
		FINAL		06MAR2003	9:00	56	145	4.5	107.0	29.0	
	E0035022	BSLN		01MAY2003	9:45	-8	145	4.6	110.0	29.0	
		FINAL		07JUL2003	8:55	60	143	4.0	110.0	24.0	
	E0039003	BSLN		12NOV2002	11:19	-13	143	4.6	105.0	27.0	
		FINAL		02JAN2003	14:06	39	143	4.2	109.0	24.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.4 Chemistry Data - Electrolytes

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)
PLACEBO (BIPOLAR II)	E0040001	BSLN	18JUN2003	14:30	-9	144	3.8	109.0	25.0
		FINAL	22AUG2003	9:00	57	142	4.0	108.0	25.0
	E0040004	BSLN	11JUL2003	13:00	-7	140	4.1	102.0	24.0
	E0041002	BSLN	13JAN2003	14:35	-8	144	4.0	107.0	24.0
		FINAL	11MAR2003	10:35	50	140	3.5	104.0	26.0
	E0041005	BSLN	28FEB2003	12:31	-5	143	4.7	104.0	22.0
		FINAL	30APR2003	14:08	57	144	3.7	108.0	27.0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:26 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		22JAN2003	14:00	-13	172		207	H	41		132	H
		FINAL		02APR2003	10:10	58	142		198		41		129	
	E0002010	BSLN		28MAR2003	10:00	-7	427H#		222	H	28	L#	128	
	E0002012	BSLN		16APR2003	10:10	-5	93		150		43		88	
		FINAL		16JUN2003	11:30	57	77		188		57		116	
	E0002015	BSLN		22MAY2003	10:15	-13	278H#		248	H#	50		142	H
	E0002018	BSLN		16JUL2003	13:25	-8	464H#		241	H#	27	L#	130	
		FINAL		04AUG2003	9:40	12	273H#		215	H	31	L#	129	
	E0003004	BSLN	*	03DEC2002	11:48	-14	160		178		42		104	
		BSLN		17DEC2002	9:20	1	128		187		44		117	
		FINAL		07JAN2003	15:40	22	153		154		34	L#	89	
	E0003005	BSLN		16DEC2002	15:00	-7	260H#		238	H	31	L#	155	H
		FINAL		18FEB2003	8:55	58	460H#		241	H#	32	L#	117	
	E0003007	BSLN		19DEC2002	10:15	-14	85		158		52		89	
		FINAL		27FEB2003	8:50	57	106		167		44		102	
	E0003015	BSLN		29APR2003	11:30	-6	162		204	H	67		105	
		FINAL		02JUL2003	14:45	59	148		249	H#	68		151	H
	E0004002	BSLN		24SEP2002	10:40	-7	104		144		43		80	
		FINAL		26NOV2002	11:00	57	111		147		42		83	
	E0004013	BSLN		08JAN2003	10:00	-6	161		191		33	L#	126	
		FINAL		19FEB2003	8:20	37	215	#	202	H	33	L#	126	
	E0004018	BSLN		12MAR2003	10:50	-7	152		167		46		91	
		FINAL		13MAY2003	13:45	56	80		149		37	L#	96	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	BSLN		07MAY2003	15:55	-7	264	H#	215	H	41		121	
		FINAL		09JUL2003	14:10	57	524	H#	205	H	29	L#	96	
	E0005002	BSLN		23SEP2002	10:00	-10	540	H#	223	H	38	L#	102	
		FINAL		25NOV2002	8:30	54	877	H#	252	H#	29	L#	97	
	E0005004	BSLN		24SEP2002	12:00	-7	184		222	H	59		126	
	E0005013	BSLN		30OCT2002	8:00	-8	101		188		78		90	
	E0005024	BSLN		05FEB2003	15:00	-5	63		138		49		76	
		FINAL		10APR2003	11:30	60	86		157		52		88	
		FINAL	*	22JUL2003	16:05	163	117							
	E0005027	BSLN		04MAR2003	7:45	-7	504	H#	191		34	L#	68	
		FINAL		03APR2003	8:15	24	709	H#	185		28	L#	56	
	E0005037	BSLN		30APR2003	12:00	-7	272	H#	264	H#	37	L#	173	H#
		FINAL		02JUL2003	12:15	57	359	H#	210	H	29	L#	109	
		FINAL	*	16JUL2003	11:00	71	280	H#	259	H#	36	L#	167	H#
	E0005042	BSLN		19JUN2003	11:30	-5	191		215	H	45		132	H
		FINAL		18AUG2003	16:25	56	162		199		32	L#	135	H
	E0006005	BSLN		25NOV2002	12:15	-10	158		162		31	L#	99	
		FINAL		30JAN2003	16:10	57	166		169		44		92	
	E0006018	BSLN		07MAR2003	12:40	-6	94		148		31	L#	98	
		FINAL		24MAR2003	10:45	12	77		138		34	L#	89	
	E0007013	BSLN		10JUN2003	9:25	-3	248	#	233	H	70		113	
		FINAL		07AUG2003	9:20	56	200	#	256	H#	81	H	135	H
	E0010004	BSLN		05DEC2002	11:10	-6	282	H#	287	H#	56		175	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	FINAL	06FEB2003	12:40	58	283H#		269	H#	47		165	H#
	E0010012	BSLN	30DEC2002	9:48	-8	211 #		220	H	50		128	
		FINAL	05MAR2003	13:59	58	477H#		235	H	41		153	H
	E0010024	BSLN	23APR2003	8:45	-12	311H#		203	H	34	L#	107	
		FINAL	02JUL2003	10:30	59	376H#		221	H	39	L#	107	
	E0010032	BSLN	03JUL2003	11:30	-7	109		149		42		85	
		FINAL	17JUL2003	11:38	8	166		164		35	L#	96	
	E0011025	BSLN	20JUN2003	14:30	-6	136		291	H#	65		199	H#
		FINAL	22AUG2003	10:00	58	145		259	H#	57		173	H#
	E0013007	BSLN	14MAR2003	8:48	-6	189		225	H	56		131	H
		FINAL	07APR2003	17:15	19	465H#		227	H	53		123	
	E0013009	BSLN	26MAR2003	9:09	-7	132		231	H	52		153	H
		FINAL	29MAY2003	17:50	58	171		245	H#	60		151	H
	E0014006	BSLN	14MAR2003	11:30	-11	106		153		47		85	
		FINAL	21MAY2003	16:20	58	169		187		70		83	
	E0014010	BSLN	15APR2003	17:20	-7	211 #		142		29	L#	71	
		FINAL	17JUN2003	18:10	57	289H#		161		26	L#	77	
	E0016001	BSLN	02JAN2003	8:50	-20	142		231	H	66		137	H
		FINAL	19MAR2003	12:00	57	159		246	H#	52		162	H#
	E0016004	BSLN	27JAN2003	9:30	-7	304H#		177		33	L#	83	
	E0018001	BSLN	22OCT2002	16:15	-7	306H#		135		23	L#	51	
		FINAL	24DEC2002	9:55	57	292H#		161		37	L#	66	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	BSLN	10DEC2002	17:15	-7	172	176	40 #	102
		FINAL	27FEB2003	12:10	73	177	174	38 L#	101
	E0019004	BSLN	30OCT2002	8:40	-8	263H#	181	46	82
		FINAL	19DEC2002	12:55	43	116	179	57	99
	E0019011	BSLN	12NOV2002	12:05	-9	158	219 H	53	134 H
		FINAL	16JAN2003	14:20	57	120	214 H	46	144 H
	E0019025	BSLN	30JAN2003	14:40	-7	118	202 H	65	113
		FINAL	03APR2003	13:30	57	130	175	61	88
	E0019026	BSLN	17FEB2003	12:40	-7	102	148	50	78
	E0019043	BSLN	21MAY2003	11:04	-13	203 #	174	63	70
		FINAL *	17JUN2003	12:10	15	227 #	192	64	83
		FINAL	29JUL2003	11:38	57	363H#	212 H	54	85
	E0020001	BSLN	15OCT2002	20:00	-14	64	219 H	88 H	118
		FINAL	20DEC2002	12:30	53	85	224 H	66	141 H
	E0020006	BSLN	26NOV2002	18:00	-20	239 #	217 H	42	127
		FINAL	08JAN2003	10:00	24	165	202 H	51	118
	E0020007	BSLN	10JAN2003	12:00	-5	74	145	34 L#	96
		FINAL	25MAR2003	18:50	70	106	159	47	91
	E0020011	BSLN	19FEB2003	13:45	-7	450H#	287 H#	31 L#	180 H#
		FINAL	23APR2003	14:30	57	803H#	264 H#	25 L#	143 H
		FINAL *	07MAY2003	12:00	71	620H#	258 H#	26 L#	134 H
	E0020013	BSLN	26FEB2003	14:15	-7	103	159	44	94
		FINAL	25MAR2003	12:00	21	242 #	172	38 L#	86

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	BSLN	05NOV2002	10:00	-7	115	147	47	77
		FINAL	07JAN2003	9:45	57	69	128 L	59	55
	E0022017	BSLN	05DEC2002	12:35	-14	240 #	235 H	28 L#	159 H
		FINAL	07MAR2003	9:47	79	197	226 H	29 L#	158 H
	E0022018	BSLN	04DEC2002	10:15	-8	183	221 H	47	137 H
		FINAL	11FEB2003	8:40	62	142	200	48	124
	E0022022	BSLN	16DEC2002	13:15	-14	38L	100 L	59	33
		FINAL	27FEB2003	11:35	60	82	126 L	57	53
	E0022027	BSLN	24JAN2003	7:40	-13	137	208 H	35 L#	146 H
		FINAL	03APR2003	9:00	57	126	159	34 L#	100
	E0022030	BSLN	10FEB2003	7:40	-4	159	137	34 L#	71
	E0022031	BSLN	11FEB2003	10:25	-7	202 #	264 H#	47	177 H#
		FINAL	15APR2003	9:30	57	258H#	216 H	35 L#	129
	E0022032	BSLN	12FEB2003	8:05	-6	213 #	206 H	35 L#	128
		FINAL	18APR2003	10:30	60	171	230 H	46	150 H
	E0022035	BSLN	13FEB2003	13:50	-6	63	145	59	73
		FINAL	13MAR2003	17:55	23	67	153	58	82
	E0022036	BSLN	14FEB2003	8:55	-11	105	153	41	91
		FINAL	22APR2003	7:36	57	87	135	39 L#	79
	E0022056	BSLN	11APR2003	8:07	-6	116	160	63	74
	E0022060	BSLN	24APR2003	12:05	-6	71	160	62	84
		FINAL	24JUN2003	9:25	56	81	148	58	74

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	BSLN		29APR2003	10:10	-8	150		177		72		75	
	E0023008	BSLN		23JAN2003	10:00	-7	58		114	L	56		46	
		FINAL		24MAR2003	15:40	54	57		140		58		71	
	E0023013	BSLN		13FEB2003	11:00	-14	161		232	H	47		153	H
		FINAL		06MAR2003	11:00	8	135		130		39	L#	64	
	E0023015	BSLN		04MAR2003	11:00	-7	79		180		59		105	
		FINAL		06MAY2003	10:00	57	73		151		65		71	
	E0023034	BSLN		03JUN2003	14:00	-6	93		148		40	#	89	
		FINAL		05AUG2003	16:00	58	204	#	138		28	L#	69	
	E0023037	BSLN		11JUN2003	16:30	-7	67		161		86	H	62	
		FINAL	*	24JUN2003	16:30	7	54		167		87	H	69	
		FINAL		15AUG2003	9:30	59	68		176		101	H	61	
	E0023038	BSLN		20JUN2003	12:45	-10	318H	#	192		35	L#	93	
		FINAL		16SEP2003	18:30	79	298H	#	208	H	36	L#	112	
	E0023044	BSLN		08JUL2003	14:00	-8	146		176		69		78	
		FINAL		12AUG2003	12:00	28	188		180		63		79	
	E0023045	BSLN		10JUL2003	11:40	-7	83		154		46		91	
		FINAL		15SEP2003	11:00	61	94		147		48		80	
	E0025002	BSLN		27MAR2003	11:05	-7	139		297	H#	84	H	185	H#
		FINAL		29MAY2003	11:40	57	175		292	H#	90	H	167	H#
	E0026010	BSLN		15JAN2003	14:00	-7	90		171		45		108	
		FINAL		30JAN2003	16:30	9	102		174		47		107	
	E0026017	BSLN		26FEB2003	11:50	-8	217	#	289	H#	33	L#	213	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0026017	FINAL	21MAR2003	11:10	16	309	H#	258	H#	29	L#	167	H#
	E0026018	BSLN	06MAR2003	16:30	-14	127		125	L	26	L#	74	
		FINAL	15MAY2003	14:15	57	128		130		26	L#	78	
	E0026025	BSLN	01MAY2003	11:40	-8	242	#	221	H	30	L#	143	H
		FINAL	03JUL2003	9:30	56	263	H#	256	H#	47		156	H
	E0026029	BSLN	02JUL2003	11:10	-7	48		130		56		64	
		FINAL	28JUL2003	13:30	20	72		120	L	51		55	
	E0026030	BSLN	02JUL2003	11:50	-7	80		167		64		87	
		FINAL	03SEP2003	17:10	57	136		164		62		75	
	E0026031	BSLN	10JUL2003	14:00	-11	74		176		42		119	
		FINAL	15SEP2003	11:15	57	95		161		46		96	
	E0027003	BSLN	08JAN2003	14:40	-20	293	H#	251	H#	35	L#	157	H
		FINAL	25MAR2003	11:55	57	270	H#	254	H#	46		154	H
	E0028004	BSLN	27SEP2002	9:45	-3	85		164		30	L#	117	
		FINAL	09OCT2002	14:30	10	67		194		42		139	H
	E0028006	BSLN	01OCT2002	10:00	-3	66		199		59		127	
		FINAL	04DEC2002	10:15	62	67		188		51		124	
	E0028008	BSLN	08OCT2002	12:45	-7	335	H#	174		32	L#	75	
		FINAL	10DEC2002	12:30	57	132		159		31	L#	102	
	E0028009	BSLN	10OCT2002	10:45	-5	121		205	H	46		135	H
		FINAL	12DEC2002	13:50	59	153		248	H#	49		168	H#
	E0028016	BSLN	07NOV2002	10:15	-7	87		175		50		108	
		FINAL	09JAN2003	11:50	57	223	#	182		38	L#	99	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0028017		*	12NOV2002	9:45		123		144		37	L#	82	
	E0028027	BSLN		14JAN2003	10:15	-7	96		244	H#	44		181	H#
	E0028029	BSLN		28JAN2003	10:00	-7	162	#	275	H#	50		193	H#
		FINAL		04APR2003	10:55	60	200	#	241	H#	45		156	H
	E0028034	BSLN		20MAR2003	9:40	-12	214	#	195		35	L#	117	
		FINAL		02JUN2003	12:54	63	418	H#	211	H	32	L#	111	
	E0028038	BSLN		18APR2003	10:20	-7	223	#	239	H	57		137	H
		FINAL		18JUN2003	13:45	55	181		186		56		94	
	E0028043	BSLN		29MAY2003	11:55	-7	219	#	203	H	39	L#	120	
		FINAL		29JUL2003	8:25	55	273	H#	186		35	L#	96	
	E0028045	BSLN		09JUN2003	13:00	-9	59		162		50		100	
		FINAL		11SEP2003	12:50	86	85		177		61		99	
	E0029005	BSLN	*	14NOV2002	13:00	-13	111		181		52		107	
		BSLN		21NOV2002	10:30	-6	89		162		38	L#	106	
		FINAL		21JAN2003	12:50	56	103		173		56		96	
	E0030001	BSLN		12NOV2002	15:15	-7	183		270	H#	124	H	109	
		FINAL		16JAN2003	12:07	59	83		255	H#	115	H	123	
	E0030008	BSLN		07JAN2003	14:33	-7	153		233	H	55		147	H
		FINAL		18MAR2003	10:42	64	130		240	H#	56		158	H
	E0030011	BSLN		16JAN2003	16:10	-11	78		136		43		77	
		FINAL		24MAR2003	14:35	57	169		168		39	L#	95	
	E0030015	BSLN		13FEB2003	12:05	-8	79		188		54		118	
		FINAL		22APR2003	12:10	61	108		182		60		100	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	BSLN	10JUN2003	11:15	-6	126		248	H#	52		171	H#
		FINAL	14AUG2003	15:30	60	161		229	H	47		150	H
	E0031002	BSLN	20NOV2002	17:05	-7	63		193		85	H	95	
		FINAL	23JAN2003	12:55	58	71		214	H	95	H	105	
	E0031003	BSLN	03DEC2002	16:07	-7	118		213	H	47		142	H
		FINAL	04FEB2003	16:20	57	93		178		49		110	
	E0033015	BSLN	03APR2003	17:05	-7	92		191		81	H	92	
		FINAL	04JUN2003	11:00	56	78		188		86	H	86	
	E0034002	BSLN	18MAR2003	9:25	-7	374H#		186		36	L#	75	
		FINAL	16APR2003	14:40	23	312H#		156		32	L#	62	
	E0034003	BSLN	11APR2003	10:10	-13	101		219	H	53		146	H
		FINAL	19JUN2003	15:50	57	288H#		218	H	44		116	
	E0034006	BSLN	25APR2003	11:33	-21	223 #		219	H	31	L#	143	H
		FINAL	10JUL2003	9:54	56	382H#		235	H	28	L#	131	H
	E0034008	BSLN	16MAY2003	13:26	-8	109		174		49		103	
		FINAL	21JUL2003	10:07	59	92		157		47		92	
	E0035003	BSLN	15NOV2002	10:30	-7	108		177		44		111	
	E0035005	BSLN	26NOV2002	10:00	-7	156		257	H#	56		170	H#
	E0035014	BSLN	28JAN2003	11:10	-6	73		240	H#	79		146	H
		FINAL	31MAR2003	9:20	57	60		205	H	76		117	
	E0035024	BSLN	15MAY2003	11:30	-8	153		232	H	87	H	114	
		FINAL	18JUL2003	9:00	57	113		200		91	H	86	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0036005	BSLN		24JUN2003	10:45	-7	78		185		52		117	
		FINAL		27AUG2003	12:45	58	92		170		44		108	
	E0037002	BSLN		18DEC2002	12:10	-8	60		138		36	L#	90	
		FINAL		20FEB2003	13:25	57	53		157		44		102	
	E0037005	BSLN		27FEB2003	15:00	-7	120		205	H	57		124	
		FINAL		01MAY2003	14:15	57	112		240	H#	61		157	H
	E0037006	BSLN		07MAR2003	12:00	-7	56		174		89	H	74	
		FINAL		09MAY2003	12:18	57	66		197		98	H	86	
	E0039006	BSLN	*	11NOV2002	10:05	-49	105		272	H#	34	L#	217	H#
		BSLN	*	22NOV2002	9:20	-38	86		217	H	30	L#	170	H#
		BSLN		10DEC2002	11:35	-20	104		204	H	36	L#	147	H
		FINAL		24FEB2003	10:58	57	72		225	H	37	L#	174	H#
	E0039015	BSLN		02JAN2003	10:20	-21	80		200		48		136	H
		FINAL		20MAR2003	9:30	57	82		202	H	55		131	H
	E0039024	BSLN		14FEB2003	8:50	-13	143		202	H	43		130	
		FINAL		25APR2003	16:05	58	209	#	191		44		105	
	E0039025	BSLN		26FEB2003	11:00	-20	120		153		44		85	
		FINAL		27MAY2003	10:00	71	163		158		55		70	
	E0039041	BSLN		08APR2003	9:40	-7	41L		148		59		81	
		FINAL		11JUN2003	11:25	58	76		167		88	H	64	
	E0039044	BSLN		06MAY2003	10:30	-16	167		231	H	43		155	H
		FINAL		23JUL2003	18:20	63	527H#		201	H	30	L#	94	
	E0039046		*	06MAY2003	11:46		164		168		30	L#	105	
			*	03JUN2003	10:25		207	#	163		33	L#	89	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0039051	BSLN	23MAY2003	9:30	-24	67	212 H	55	144 H
		FINAL	12AUG2003	14:45	58	272H#	192	36 L#	102
	E0039053	BSLN	16JUN2003	13:25	-25	100	150	38 L#	92
		FINAL	08SEP2003	12:45	60	206 #	175	43	91
	E0039057	BSLN	02JUL2003	19:50	-12	86	186	77	92
		FINAL	09SEP2003	9:25	58	104	138	53	64
	E0041003	BSLN	16JAN2003	17:30	-12	218 #	187	46	97
		FINAL	25MAR2003	9:55	57	109	197	50	125
	E0041008	BSLN	26MAR2003	15:35	-12	183	251 H#	54	160 H#
		FINAL	02JUN2003	15:30	57	143	161	59	73
	E0042001	BSLN	17JUN2003	9:45	-15	113	209 H	52	134 H
		FINAL	26AUG2003	10:50	56	87	266 H#	60	189 H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN		26FEB2003	14:25	-14	107		212	H	53		138	H
		FINAL		07MAY2003	13:45	57	185		229	H	58		134	H
	E0003018	BSLN		06MAY2003	16:22	-7	48		189		56		123	
		FINAL		08JUL2003	14:18	57	61		209	H	54		143	H
	E0005011	BSLN		17OCT2002	15:00	-7	60		177		55		110	
	E0005030	BSLN		18MAR2003	14:00	-8	117		167		49		95	
	E0005036	BSLN		28APR2003	13:30	-8	112		222	H	53		147	H
		FINAL		27MAY2003	10:00	22	144		214	H	46		139	H
	E0006015	BSLN		07FEB2003	9:30	-4	167		205	H	46		126	
		FINAL		08APR2003	12:00	57	133		208	H	48		133	H
	E0006016	BSLN		07FEB2003	12:55	-10	126		181		66		90	
		FINAL		18APR2003	12:15	61	99		191		66		105	
	E0007008	BSLN		08APR2003	9:55	-10	248	#	216	H	36	L#	130	
		FINAL		02JUL2003	14:00	76	489	H#	214	H	35	L#	112	
		FINAL	*	12AUG2003	11:30	117	192		215	H	34	L#	143	H
	E0009002	BSLN		30OCT2002	11:45	-20	105		164		44		99	
		FINAL		15JAN2003	13:47	58	184		151		32	L#	82	
	E0009006	BSLN		23JAN2003	17:50	-5	117		176		38	L#	115	
		FINAL		25MAR2003	16:20	57	110		239	H	50		167	H#
	E0009009	BSLN		27FEB2003	15:00	-13	204	#	183		40	#	102	
		FINAL		24MAR2003	13:40	13	148		176		47		99	
	E0010015	BSLN		30JAN2003	10:35	-21	117		208	H	37	L#	148	H
		FINAL		15APR2003	13:29	55	334	H#	199		30	L#	102	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	BSLN		17DEC2002	11:00	-7	169		131		24	L#	73	
		FINAL		18FEB2003	9:00	57	272H#		158		26	L#	78	
	E0011007	BSLN		12DEC2002	10:43	-7	175		247	H#	55		157	H
		FINAL		13FEB2003	8:00	57	254H#		265	H#	51		163	H#
	E0011018	BSLN		15MAY2003	12:30	-7	161		153		41		80	
		FINAL		17JUL2003	17:30	57	184		150		40	#	73	
	E0011024	BSLN		17JUN2003	12:10	-7	77		210	H	57		138	H
		FINAL		21AUG2003	13:00	59	88		258	H#	57		183	H#
	E0015003	BSLN		13NOV2002	12:20	-12	234 #		298	H#	50		201	H#
		FINAL		02DEC2002	10:55	8	612H#		348	H#	51		212	H#
	E0019003	BSLN		30OCT2002	9:10	-22	208 #		197		48		107	
		FINAL		16JAN2003	11:25	57	180		189		41		112	
	E0019007	BSLN		06NOV2002	10:32	-7	115		226	H	86	H	117	
		FINAL		07JAN2003	8:30	56	75		219	H	89	H	115	
	E0019014	BSLN	*	17DEC2002	11:02	-23	84		116	L	39	L#	60	
		BSLN		26DEC2002	10:25	-14	122		114	L	35	L#	55	
		FINAL		22JAN2003	9:00	14	115		104	L	32	L#	49	
	E0019018	BSLN		14JAN2003	10:45	-16	85		190		40	#	133	H
		FINAL		27MAR2003	9:30	57	102		206	H	39	L#	147	H
	E0019022	BSLN		23JAN2003	12:00	-7	106		164		31	L#	112	
		FINAL		27MAR2003	15:10	57	168		170		31	L#	105	
	E0019027	BSLN		20FEB2003	10:50	-7	109		185		47		116	
	E0019032	BSLN		06MAR2003	14:50	-26	65		259	H#	59		187	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	FINAL		28MAY2003	11:00	58	104		368	H#	77		270	H#
	E0019034	BSLN		10MAR2003	16:55	-8	60		169		47		110	
	E0019036	BSLN		18MAR2003	9:15	-7	112		173		42		109	
	E0019039	BSLN		22APR2003	11:00	-9	144		230	H	55		146	H
		FINAL		08MAY2003	15:30	8	186		186		46		103	
	E0019041	BSLN		14MAY2003	10:50	-7	46		150		68		73	
		FINAL		16JUL2003	11:10	57	92		166		65		83	
	E0019049	BSLN		03JUL2003	13:40	-7	67		172		47		112	
		FINAL		08SEP2003	12:10	61	147		199		60		110	
	E0022052	BSLN		01APR2003	10:50	-9	75		186		61		110	
		FINAL		05JUN2003	9:32	57	155		188		60		97	
	E0022064	BSLN		01MAY2003	10:40	-5	88		171		49		104	
		FINAL		01JUL2003	12:30	57	56		160		48		101	
	E0022073	BSLN		20JUN2003	14:10	-6	103		197		54		122	
		FINAL		21AUG2003	9:45	57	85		180		59		104	
	E0023002	BSLN		25OCT2002	16:00	-11	173		179		28	L#	116	
	E0023017	BSLN		20MAR2003	11:00	-5	167		130		36	L#	61	
		FINAL		22MAY2003	12:30	59	203	#	133		43		49	
	E0023021	BSLN	*	10APR2003	10:20	-13	216	#	237	H	44		150	H
		BSLN		16APR2003	15:00	-7	134		240	H#	43		170	H#
		FINAL		17JUN2003	16:00	56	267	H#	244	H#	39	L#	152	H
	E0023027	BSLN		07MAY2003	13:30	-9	428	H#	233	H	30	L#	151	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	FINAL		09JUL2003	13:00	55	270	H#	208	H	30	L#	124	
	E0023030	BSLN		21MAY2003	10:00	-13	161		262	H#	73		157	H
		FINAL		30JUL2003	15:30	58	410	H#	279	H#	57		168	H#
	E0023040	BSLN		25JUN2003	15:00	-8	34	L	171		105	H	59	
		FINAL		05SEP2003	10:00	65	68		203	H	119	H	70	
	E0026014	BSLN		12FEB2003	11:40	-7	168		213	H	41		138	H
		FINAL		19MAR2003	10:35	29	76		174		54		105	
	E0026019	BSLN		10MAR2003	11:45	-7	61		223	H	121	H	90	
		FINAL		12MAY2003	9:10	57	61		233	H	131	H	90	
	E0027005	BSLN		19DEC2002	14:50	-7	197		233	H	62		132	H
		FINAL		20FEB2003	11:28	57	530	H#	288	H#	46		173	H#
	E0029009	BSLN		13JAN2003	12:50	-7	100		139		52		67	
		FINAL		18MAR2003	9:05	58	68		200		64		122	
	E0029021	BSLN	*	03MAR2003	10:40	-15	68		184		61		109	
		BSLN		18MAR2003	9:50	1	84		172		55		100	
		FINAL		15MAY2003	12:30	59	151		183		58		95	
		FINAL	*	27MAY2003	8:40	71	61		169		55		102	
	E0029026	BSLN		07APR2003	9:10	-7	173		197		42		120	
		FINAL		10JUN2003	15:00	58	99		175		34	L#	121	
	E0029030	BSLN	*	13MAY2003	11:20	-14	73		149		44		90	
		BSLN		20MAY2003	12:55	-7	86		141		39	L#	85	
		FINAL		23JUL2003	17:25	58	94		157		55		83	
	E0031008	BSLN		05FEB2003	11:40	-23	144		235	H	49		157	H
		FINAL		24APR2003	13:17	56	114		235	H	51		161	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	BSLN		14APR2003	10:35	-7	230	#	243	H#	44		153	H
		FINAL		13MAY2003	10:50	23	187		225	H	39	L#	149	H
	E0031021	BSLN		18APR2003	10:40	-7	77		204	H	45		144	H
		FINAL		19JUN2003	10:40	56	79		214	H	48		150	H
	E0031029	BSLN		05JUN2003	10:45	-13	243	#	210	H	52		109	
	E0033002	BSLN		23DEC2002	12:15	-18	242	#	218	H	35	L#	135	H
		FINAL		07MAR2003	11:25	57	170		232	H	39	L#	159	H
	E0033006	BSLN		15JAN2003	10:25	-8	71		208	H	56		138	H
		FINAL		12FEB2003	12:30	21	156		182		42		109	
	E0033021	BSLN		25JUN2003	14:40	-7	93		222	H	63		140	H
		FINAL		18AUG2003	16:20	48	103		222	H	75		126	
	E0035013	BSLN		27JAN2003	10:30	-8	84		212	H	51		144	H
		FINAL		10FEB2003	11:05	7	119		220	H	46		150	H
	E0035015	BSLN		03FEB2003	10:30	-8	198		243	H#	43		160	H#
		FINAL		18FEB2003	11:20	8	258	H#	266	H#	43		171	H#
	E0035016	BSLN		10MAR2003	11:00	-25	172		166		43		89	
	E0035023	BSLN		06MAY2003	10:30	-7	97		198		33	L#	146	H
	E0039052	BSLN	*	29MAY2003	10:25	-22	136		171		47		97	
		BSLN		13JUN2003	12:10	-7	169		177		52		91	
	E0039056	BSLN		01JUL2003	12:50	-14	118		232	H	33	L#	175	H#
	E0040003	BSLN		09JUL2003	14:00	-10	101		213	H	67		126	
		FINAL		12SEP2003	11:00	56	176		218	H	56		127	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	104	196	35 L#	140 H
		FINAL	02MAY2003	10:30	61	140	197	35 L#	134 H
	E0002011	BSLN	16APR2003	11:30	-13	124	184	46	113
		FINAL	25JUN2003	11:20	58	221 #	192	45	103
	E0003010	BSLN	28JAN2003	9:10	-6	113	264 H#	84 H	157 H
		FINAL	31MAR2003	16:20	57	127	254 H#	83 H	146 H
	E0003011	BSLN	28JAN2003	11:47	-7	131	145	37 L#	82
	E0003016	BSLN	01MAY2003	11:40	-21	97	195	55	121
		FINAL	13JUN2003	8:45	23	126	169	41	103
	E0003019	BSLN	19JUN2003	11:30	-8	53	179	41	127
		FINAL	21AUG2003	8:50	56	153	216 H	44	141 H
	E0003020	BSLN	27JUN2003	8:55	-26	56	205 H	45	149 H
		FINAL	17SEP2003	15:00	57	98	239 H	60	159 H
	E0004001	BSLN	23SEP2002	11:00	-7	90	137	42	77
		FINAL	05NOV2002	13:30	37	70	155	47	94
	E0004009	BSLN	17DEC2002	10:10	-9	133	196	46	123
		FINAL	19FEB2003	16:00	56	193	249 H#	64	146 H
	E0004012	BSLN	07JAN2003	12:45	-7	96	111 L	46	46
		FINAL	11MAR2003	11:35	57	93	137	53	65
	E0004015	BSLN	06FEB2003	10:05	-14	121	234 H	40 #	170 H#
		FINAL	15APR2003	9:10	55	156	252 H#	38 L#	183 H#
	E0005003	BSLN	23SEP2002	15:00	-9	444H#	211 H	33 L#	113
		FINAL	26NOV2002	13:25	56	474H#	199	30 L#	87

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	FINAL	*	20DEC2002	9:50	80	314	H#	197					
	E0005005	BSLN		24SEP2002	15:20	-6	89		157		39	L#	100	
	E0005007	BSLN		02OCT2002	12:40	-7	105		214	H	34	L#	159	H
		FINAL		04DEC2002	14:20	57	120		196		35	L#	137	H
		FINAL	*	23DEC2002	10:00	76			209	H				
	E0005008	BSLN		08OCT2002	18:00	-7	308	H#	241	H#	64		115	
		FINAL		11DEC2002	16:00	58	475	H#	237	H	52		145	H
		FINAL	*	24FEB2003	10:30	133	274	H#	256	H#	53		148	H
		FINAL	*	12MAR2003	16:30	149	163		196		54		109	
	E0005009	BSLN		09OCT2002	10:00	-20	109		193		45		126	
	E0005010	BSLN		14OCT2002	13:00	-7	135		132		27	L#	78	
		FINAL		17DEC2002	14:25	58	212	#	155		28	L#	85	
		FINAL	*	23DEC2002	16:00	64	235	#	136		24	L#	65	
	E0005012	BSLN		24OCT2002	7:00	-21	158		237	H	38	L#	167	H#
		FINAL		07JAN2003	11:00	55	106		232	H	41		170	H#
	E0005014	BSLN		05NOV2002	16:30	-8	102		170		59		91	
		FINAL		06JAN2003	10:00	55	192		168		52		78	
	E0005022	BSLN		27JAN2003	10:30	-2	64		143		43		87	
		FINAL		11MAR2003	10:10	42	56		122	L	32	L#	79	
	E0005025	BSLN		20FEB2003	13:20	-7	200	#	353	H#	43		270	H#
		FINAL		03APR2003	11:30	36	180		334	H#	40	#	258	H#
	E0006019	BSLN		26MAR2003	11:35	-12	172		187		42		111	
		FINAL		03JUN2003	12:00	58	92		194		44		132	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	BSLN		27JAN2003	14:30	-4	381H#		232	H	37	L#	119	
		FINAL		28MAR2003	13:30	57	528H#		220	H	33	L#	112	
		FINAL	*	11APR2003	11:00	71	221 #		197		36	L#	117	
	E0007015	BSLN		10JUL2003	7:35	-6	91		154		59		77	
		FINAL		10SEP2003	7:40	57	85		160		66		77	
	E0009001	BSLN		29OCT2002	15:30	-14	94		207	H	49		139	H
	E0010002	BSLN		14NOV2002	10:36	-11	123		140		33	L#	82	
		FINAL		02DEC2002	9:05	8	232 #		163		38	L#	79	
	E0010009	BSLN		18DEC2002	9:42	-8	160		187		70		85	
		FINAL		19FEB2003	13:59	56	157		218	H	80		107	
	E0010010	BSLN		20DEC2002	8:45	-10	37L		156		49		100	
		FINAL		13JAN2003	10:28	15	54		181		55		115	
	E0010014	BSLN		14JAN2003	9:05	-14	40L		180		70		102	
		FINAL		25MAR2003	11:05	57	35L		166		66		93	
	E0010017	BSLN		05FEB2003	8:51	-20	119		217	H	43		150	H
		FINAL		22APR2003	10:20	57	96		215	H	53		143	H
	E0010023	BSLN		10APR2003	9:22	-7	49		153		72		71	
		FINAL		01MAY2003	10:19	15	80		162		68		78	
	E0010027	BSLN		05JUN2003	9:10	-11	103		163		56		86	
		FINAL		01JUL2003	13:00	16	83		149		46		86	
	E0010029	BSLN		10JUN2003	9:25	-9	252H#		218	H	47		121	
	E0011022	BSLN		02JUN2003	11:00	-7	215 #		210	H	41		126	
		FINAL		05AUG2003	10:30	58	399H#		235	H	43		112	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	BSLN	06MAR2003	10:15	-7	147	141	30 L#	82
		FINAL	24MAR2003	12:42	12	179	154	30 L#	88
	E0013012	BSLN	29APR2003	9:48	-8	78	185	58	111
		FINAL	02JUL2003	10:05	57	135	175	53	95
	E0013014	BSLN	08MAY2003	11:15	-26	76	223 H	49	159 H
		FINAL	30JUN2003	12:21	28	135	216 H	43	146 H
	E0014005	BSLN	04MAR2003	17:20	-7	434H#	284 H#	36 L#	172 H#
		FINAL	06MAY2003	12:20	57	208 #	199	39 L#	118
	E0014007	BSLN	25MAR2003	17:50	-7	131	156	38 L#	92
		FINAL	22APR2003	13:50	22	82	133	42	75
	E0014011	BSLN	06MAY2003	16:45	-7	275H#	193	38 L#	100
		FINAL	08JUL2003	15:50	57	249 #	221 H	37 L#	134 H
	E0014012	BSLN	19MAY2003	10:05	-8	140	221 H	60	133 H
		FINAL	24JUN2003	18:40	29	190	237 H	57	142 H
	E0015001	BSLN	11NOV2002	9:10	-18	175	184	40 #	109
		FINAL	20JAN2003	7:30	53	249 #	188	43	95
	E0015008	BSLN	13DEC2002	9:30	-6	119	157	44	89
	E0016003	BSLN	10JAN2003	9:30	-14	97	189	36 L#	134 H
	E0016005	BSLN	21FEB2003	8:45	-4	99	247 H#	47	180 H#
		FINAL	22APR2003	8:30	57	142	230 H	44	158 H
	E0018007	BSLN	16DEC2002	10:15	-11	387H#	226 H	40 #	109
		FINAL	10JAN2003	14:15	15	270H#	223 H	30 L#	139 H

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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	BSLN		30OCT2002	11:50	-6	79		182		92	H	74	
		FINAL		02JAN2003	14:00	59	59		170		97	H	61	
	E0019015	BSLN		19DEC2002	10:49	-14	90		193		44		131	H
		FINAL		27FEB2003	11:23	57	191		197		38	L#	121	
	E0020004	BSLN		21NOV2002	15:20	-18	120		145		41		80	
		FINAL		22JAN2003	16:15	45	212	#	209	H	42		125	
		FINAL	*	24FEB2003	11:50	78	214	#	260	H#	50		167	H#
	E0020010	BSLN		31JAN2003	9:15	-5	126		161		69		67	
		FINAL		02APR2003	10:30	57	159		203	H	67		104	
	E0020014	BSLN		11MAR2003	10:00	-7	71		150		42		94	
		FINAL		12MAY2003	11:15	56	44L		144		50		85	
	E0020021	BSLN		13MAY2003	9:45	-6	112		256	H#	57		177	H#
		FINAL		14JUL2003	13:25	57	131		241	H#	62		153	H
	E0020023	BSLN		09JUN2003	19:05	-8	113		210	H	50		137	H
		FINAL		11AUG2003	11:40	56	87		255	H#	54		184	H#
	E0022007	BSLN		01NOV2002	10:23	-6	50		146		40	#	96	
	E0022010	BSLN		15NOV2002	10:40	-6	159		186		55		99	
		FINAL		16JAN2003	18:00	57	98		173		76		77	
	E0022012	BSLN		29NOV2002	15:40	-6	109		173		43		108	
		FINAL		30JAN2003	12:00	57	48		164		43		111	
	E0022019	BSLN		06DEC2002	10:10	-5	137		195		34	L#	134	H
		FINAL		06FEB2003	11:20	58	102		224	H	40	#	164	H#
	E0022025	BSLN		08JAN2003	10:10	-20	173		161		35	L#	91	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	FINAL	04FEB2003	11:30	8	186		191		36	L#	118	
	E0022033	BSLN	12FEB2003	10:05	-6	63		190		92	H	85	
		FINAL	15APR2003	12:10	57	83		190		68		105	
	E0022034	BSLN	12FEB2003	12:40	-6	203 #		270	H#	39	L#	190	H#
		FINAL	15APR2003	14:00	57	215 #		271	H#	35	L#	193	H#
	E0022038	BSLN	21FEB2003	11:05	-7	50		134		51		73	
		FINAL	14APR2003	9:40	46	46		156		60		87	
	E0022039	BSLN	27FEB2003	11:15	-7	99		211	H	34	L#	157	H
		FINAL	01MAY2003	12:50	57	136		230	H	35	L#	168	H#
	E0022046	BSLN	14MAR2003	8:00	-6	575H#		317	H#	36	L#	185	H#
		FINAL	16MAY2003	8:05	58	526H#		313	H#	42		177	H#
	E0022048	BSLN	26MAR2003	9:58	-6	91		112	L	32	L#	62	
	E0022051	BSLN	01APR2003	10:15	-6	82		163		55		92	
		FINAL	02JUN2003	10:45	57	147		192		56		107	
	E0022053	BSLN	04APR2003	12:50	-7	99		235	H	48		167	H#
	E0022058	BSLN	14APR2003	10:25	-7	99		162		43		99	
		FINAL	22MAY2003	14:00	32	137		149		48		74	
	E0022061	BSLN	25APR2003	9:37	-5	81		194		72		106	
		FINAL	26JUN2003	12:30	58	92		204	H	54		132	H
	E0022062	BSLN	28APR2003	7:43	-7	132		172		39	L#	107	
		FINAL	23MAY2003	7:40	19	125		156		42		89	
	E0022068	BSLN	14MAY2003	10:23	-9	56		192		59		122	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	BSLN		04JUN2003	7:40	-6	81		165		48		101	
		FINAL		05AUG2003	9:45	57	76		145		47		83	
	E0022071	BSLN		16JUN2003	11:40	-14	211 #		346	H#	73		231	H#
		FINAL		26AUG2003	9:33	58	181		271	H#	61		174	H#
	E0023003	BSLN	*	08NOV2002	16:00	-39	53		198		48		139	H
		BSLN		12DEC2002	10:00	-5	79		175		54		105	
		FINAL		11FEB2003	14:00	57	102		171		43		108	
	E0023006	BSLN		10DEC2002	10:30	-7	264H#		178		35	L#	90	
		FINAL		11FEB2003	11:50	57	115		186		38	L#	125	
	E0023010	BSLN		28JAN2003	9:30	-7	345H#		302	H#	55		178	H#
		FINAL		31MAR2003	10:00	56	524H#		336	H#	45		115	
	E0023025	BSLN		01MAY2003	15:00	-14	66		149		42		94	
		FINAL		10JUL2003	13:30	57	80		161		47		98	
	E0023039	BSLN		24JUN2003	13:30	-7	104		162		65		76	
		FINAL		26AUG2003	13:30	57	113		150		42		85	
	E0026002	BSLN		05NOV2002	10:15	-7	78		181		61		104	
		FINAL		09JAN2003	9:25	59	54		165		49		105	
	E0026007	BSLN		06JAN2003	10:30	-10	215 #		261	H#	32	L#	186	H#
		FINAL		12MAR2003	14:25	56	145		183		37	L#	117	
	E0026013	BSLN		05FEB2003	12:20	-8	100		164		45		99	
		FINAL		14APR2003	10:00	61	186		167		42		88	
	E0028007	BSLN		01OCT2002	10:30	-3	37L		167		61		99	
		FINAL		14NOV2002	12:45	42	54		108	L	36	L#	61	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	BSLN		15JAN2003	10:00	-6	203	#	160		50		69	
		FINAL		27JUN2003	15:00	158	249	#	229	H	39	L#	140	H
	E0028025	BSLN		08JAN2003	12:07	-5	95		114	L	40	#	55	
		FINAL		27JAN2003	9:25	15	118		134		40	#	70	
	E0028033	BSLN		18MAR2003	10:50	-9	265	H#	273	H#	43		177	H#
		FINAL		22MAY2003	10:50	57	303	H#	273	H#	34	L#	178	H#
	E0028035	BSLN		27MAR2003	12:00	-7	128		267	H#	35	L#	206	H#
		FINAL		29MAY2003	15:40	57	211	#	253	H#	40	#	171	H#
	E0028037	BSLN	*	18APR2003	8:30	-56	610	H#	292	H#	42		171	H#
		BSLN	*	24APR2003	7:50	-50	1190	H#	336	H#	38	L#	143	H
		BSLN		04JUN2003	8:33	-9	215	#	189		48		98	
		FINAL		08AUG2003	15:30	57	68		164		69		81	
	E0028039	BSLN		05MAY2003	7:10	-4	149		178		32	L#	116	
		FINAL		05JUN2003	12:30	28	142		175		25	L#	122	
	E0028046	BSLN		17JUN2003	13:45	-8	54		144		68		65	
	E0028048	BSLN		11JUL2003	14:00	-6	87		132		53		62	
	E0029008	BSLN		09DEC2002	11:40	-7	73		190		71		104	
	E0029011	BSLN		14JAN2003	11:20	-8	163		199		38	L#	128	
	E0029012	BSLN		04FEB2003	10:05	-7	159		223	H	43		148	H
		FINAL		27MAR2003	8:45	45	154		197		41		125	
	E0029015	BSLN		11FEB2003	10:05	-13	57		154		61		82	
		FINAL		14MAR2003	10:30	19	71		194		62		118	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0029018	BSLN	*	26FEB2003	16:25	-8	389	H#	180		29	L#	73	
		BSLN		06MAR2003	16:05	1	500	H#	205	H	27	L#	66	
	E0030014	BSLN		14FEB2003	10:35	-7	73		146		70		61	
		FINAL		22APR2003	12:50	61	70		139		68		57	
	E0030020	BSLN		13MAY2003	15:30	-16	103		179		41		117	
	E0030024	BSLN		17JUN2003	15:35	-24	299	H#	275	H#	59		156	H
		FINAL		18JUL2003	15:35	8	222	#	296	H#	41		211	H#
	E0030025	BSLN	*	24JUN2003	16:35	-17	80		214	H	81	H	117	
		BSLN		07JUL2003	10:20	-4	94		202	H	68		115	
		FINAL		19AUG2003	16:45	40	78		162		58		88	
	E0031027	BSLN		28MAY2003	9:10	-6	86		179		52		110	
		FINAL		29JUL2003	14:40	57	53		147		59		77	
	E0031030	BSLN		17JUN2003	10:46	-7	66		220	H	64		143	H
		FINAL		21AUG2003	11:10	59	97		208	H	55		134	H
	E0033012	BSLN		05FEB2003	15:26	-5	93		178		39	L#	120	
	E0034001	BSLN		17MAR2003	10:03	-3	86		242	H#	56		169	H#
		FINAL		15MAY2003	9:55	57	122		231	H	56		151	H
	E0034004	BSLN		11APR2003	11:15	-10	240	#	199		35	L#	116	
		FINAL		16JUN2003	12:03	57	282	H#	186		32	L#	98	
	E0035001	BSLN		12NOV2002	11:40	-8	152		160		57		73	
		FINAL		14JAN2003	9:05	56	108		155		74		59	
	E0035006	BSLN		03DEC2002	10:45	-9	64		202	H	72		117	
		FINAL		06FEB2003	9:30	57	137		170		66		77	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	BSLN		18APR2003	10:45	-7	77	145	41	89
		FINAL		20JUN2003	8:15	57	82	146	39 L#	91
	E0036002	BSLN		10JUN2003	13:45	-7	130	196	39 L#	131 H
		FINAL		15JUL2003	10:05	29	106	183	44	118
	E0036006	BSLN	*	24JUN2003	16:45	-9	267H#	268 H#	40 #	175 H#
		BSLN		01JUL2003	10:58	-2	304H#	269 H#	36 L#	172 H#
		FINAL		28AUG2003	9:50	57	316H#	272 H#	35 L#	174 H#
	E0036007	BSLN		27JUN2003	10:00	-6	116	195	42	130
		FINAL		18JUL2003	9:15	16	188	250 H#	47	165 H#
	E0037009	BSLN		12MAY2003	9:15	-4	207 #	222 H	59	122
		FINAL		10JUL2003	16:05	56	461H#	243 H#	41	147 H
	E0039011	BSLN		16DEC2002	17:40	-17	318H#	285 H#	44	177 H#
	E0039018	BSLN		15JAN2003	9:10	-8	71	195	63	118
	E0039026	BSLN		03MAR2003	9:05	-4	109	190	56	112
		FINAL		02MAY2003	9:20	57	149	218 H	67	121
	E0039028	BSLN		03MAR2003	14:15	-21	125	126 L	39 L#	62
		FINAL		16MAY2003	12:25	54	125	138	48	65
	E0039032	BSLN		07MAR2003	13:45	-7	92	173	39 L#	116
		FINAL		04APR2003	11:45	22	59	178	44	122
	E0039034	BSLN		12MAR2003	20:05	-7	70	150	45	91
		FINAL		14MAY2003	15:00	57	78	182	51	115
	E0039042	BSLN		25APR2003	10:15	-12	66	208 H	96 H	99
		FINAL		02JUL2003	12:50	57	211 #	204 H	40 #	122

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	BSLN	27JAN2003	10:15	-3	116	206 H	43	140 H
		FINAL	31MAR2003	12:00	61	129	183	36 L#	121
	E0041009	BSLN	22APR2003	15:15	-9	77	177	55	107
		FINAL	16JUN2003	13:00	47	87	197	60	120
	E0042002	BSLN	02JUL2003	12:10	-7	174	149	31 L#	83
		FINAL	02SEP2003	10:25	56	343H#	155	30 L#	56

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN	23JUN2003	10:00	-18	103		108	L	43		44	
		FINAL	25JUL2003	9:00	15	118		121	L	34	L#	63	
	E0003002	BSLN	22OCT2002	11:05	-7	123		216	H	58		133	H
		FINAL	23DEC2002	15:35	56	99		207	H	61		126	
	E0005031	BSLN	26MAR2003	12:30	-7	109		159		41		96	
	E0005033	BSLN	08APR2003	14:00	-8	51		225	H	50		165	H#
		FINAL	06MAY2003	11:20	21	41L		208	H	45		155	H
	E0005038	BSLN	05MAY2003	11:40	-9	80		148		36	L#	96	
		FINAL	05JUN2003	13:00	23	144		163		32	L#	102	
	E0007009	BSLN	14APR2003	7:48	-3	61		104	L	46		46	
	E0009010	BSLN	27FEB2003	16:55	-14	260H#		188		28	L#	108	
	E0009011	BSLN	28APR2003	14:17	-8	315H#		137		41		33	
		FINAL	03JUL2003	15:40	59	305H#		124	L	29	L#	34	
	E0010005	BSLN	11DEC2002	10:15	-7	203 #		202	H	38	L#	123	
	E0011016	BSLN	14APR2003	10:00	-7	275H#		240	H#	36	L#	149	H
		FINAL	16JUN2003	9:45	57	412H#		237	H	32	L#	154	H
	E0011020	BSLN	01MAY2003	9:20	-7	70		165		42		109	
		FINAL	15MAY2003	17:00	8	108		153		42		89	
	E0018002	BSLN	15NOV2002	15:35	-14	139		218	H	45		145	H
		FINAL	22JAN2003	16:20	55	166		199		38	L#	128	
	E0018003	BSLN	19NOV2002	13:05	-7	515H#		125	L	21	L#	44	
		FINAL	10DEC2002	11:00	15	247 #		121	L	21	L#	51	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	BSLN		17JAN2003	14:15	-7	182		198		30	L#	132	H
		FINAL		06FEB2003	16:10	14	190		186		27	L#	121	
	E0019002	BSLN		29OCT2002	10:45	-14	73		118	L	44		59	
	E0019008	BSLN	*	06NOV2002	12:35	-15	119		190		35	L#	131	H
		BSLN		13NOV2002	10:30	-8	74		157		32	L#	110	
	E0019009	BSLN		06NOV2002	13:35	-8	66		132		74		45	
	E0019016	BSLN		30DEC2002	16:55	-7	198		159		37	L#	82	
		FINAL		03MAR2003	16:00	57	235	#	186		36	L#	103	
	E0019020	BSLN		16JAN2003	10:10	-7	112		197		51		124	
		FINAL		27MAR2003	10:50	64	98		192		52		120	
	E0019021	BSLN		16JAN2003	11:45	-14	385H	#	268	H#	39	L#	152	H
		FINAL		03MAR2003	13:18	33	388H	#	246	H#	34	L#	134	H
	E0019024	BSLN		24JAN2003	16:00	-6	142		217	H	42		147	H
		FINAL		06FEB2003	12:33	8	158		217	H	43		142	H
	E0019031	BSLN		06MAR2003	11:35	-7	650H	#	323	H#	35	L#	160	H#
		FINAL		25MAR2003	10:08	13	1000H	#	333	H#	32	L#	125	
	E0019035	BSLN		11MAR2003	9:28	-7	426H	#	247	H#	29	L#	154	H
		FINAL		17APR2003	14:30	31	418H	#	215	H	30	L#	126	
	E0019040	BSLN		08MAY2003	15:25	-12	220	#	198		34	L#	120	
		FINAL		17JUL2003	9:50	59	150		202	H	34	L#	138	H
	E0019042	BSLN		29MAY2003	8:50	-6	118		166		47		95	
		FINAL		20JUN2003	8:20	17	94		197		48		130	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	BSLN		19JUN2003	14:54	-7	78		156		74		66	
		FINAL		16JUL2003	10:15	21	61		146		68		66	
	E0020024	BSLN		12JUN2003	15:40	-11	100		167		46		101	
		FINAL		20AUG2003	18:45	59	241	#	163		41		74	
	E0022044	BSLN		12MAR2003	9:50	-6	106		191		49		121	
		FINAL		12MAY2003	9:55	56	107		241	H#	80		140	H
	E0023007	BSLN		07JAN2003	14:30	-7	34L		186		64		115	
		FINAL		13MAR2003	15:00	59	45		173		65		99	
	E0023011	BSLN		28JAN2003	11:45	-7	557H	#	211	H	36	L#	124	
		FINAL		01APR2003	12:00	57	573H	#	283	H#	40	#	153	H
	E0023014	BSLN		14FEB2003	15:00	-7	96		135		55		61	
		FINAL		25APR2003	14:00	64	213	#	234	H	63		128	
	E0023019	BSLN		21MAR2003	14:00	-17	122		163		71		68	
		FINAL		03JUN2003	13:30	58	119		233	H	45		164	H#
	E0023022	BSLN		10APR2003	16:00	-8	95		243	H#	63		161	H#
		FINAL		12JUN2003	15:40	56	96		202	H	72		111	
	E0023023	BSLN		17APR2003	10:00	-8	79		155		66		73	
		FINAL		01MAY2003	14:00	7	63		128	L	56		59	
	E0023029	BSLN		16MAY2003	14:00	-7	101		196		59		117	
	E0023031	BSLN	*	22MAY2003	12:00	-33	390H	#	353	H#	48		227	H#
		BSLN		19JUN2003	10:00	-5	150		293	H#	39	L#	224	H#
		FINAL		19AUG2003	11:00	57	267H	#	319	H#	44		222	H#
	E0023041	BSLN		03JUL2003	11:00	-6	97		268	H#	71		178	H#

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	FINAL		05SEP2003	13:00	59	130		294	H#	59		209	H#
	E0023043	BSLN		07JUL2003	15:00	-7	133		160		51		82	
		FINAL		09SEP2003	10:30	58	139		134		47		59	
	E0026003	BSLN	*	25NOV2002	12:20	-9	323H#		161		30	L#	66	
		BSLN	*	02DEC2002	9:25	-2							137	H
		BSLN		02DEC2002	9:25	-2	164		216	H	46		159	H
		FINAL		03FEB2003	10:50	62	284H#		183		24	L#	102	
	E0026005	BSLN		23DEC2002	12:40	-7	87		221	H	106	H	98	
		FINAL		06JAN2003	15:25	8	94		263	H#	95	H	149	H
	E0026009	BSLN		10JAN2003	10:20	-5	103		220	H	38	L#	161	H#
		FINAL		21JAN2003	9:50	7	115		193		44		126	
	E0026015	BSLN		20FEB2003	11:30	-7	126		192		57		110	
		FINAL		25APR2003	9:50	58	96		195		65		111	
	E0026023	BSLN		23APR2003	10:50	-7	72		142		37	L#	91	
		FINAL		27JUN2003	12:25	59	57		122	L	36	L#	75	
	E0027016	BSLN	*	19MAR2003	11:55	-21	113		156		33	L#	100	
		BSLN		04APR2003	9:50	-5	113		180		34	L#	123	
		FINAL		03JUN2003	10:18	56	113		171		31	L#	117	
	E0027018	BSLN		21MAR2003	11:30	-4	54		180		58		111	
		FINAL		22MAY2003	10:05	59	40L		191		70		113	
	E0028032	BSLN		13MAR2003	13:58	-12	191		318	H#	44		236	H#
		FINAL		06JUN2003	11:38	74	499H#		267	H#	32	L#	161	H#
	E0029003	BSLN		28OCT2002	12:30	-7	97		211	H	45		147	H
		FINAL		30DEC2002	9:45	57	156		186		36	L#	119	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0029020	BSLN	25FEB2003	10:12	-8	145		205	H	58		118	
	E0031005	BSLN	13DEC2002	16:00	-7	154		200		55		114	
		FINAL	14FEB2003	12:10	57	137		212	H	53		132	H
	E0031006	BSLN	31JAN2003	11:25	-18	112		221	H	72		127	
		FINAL	15APR2003	9:25	57	86		202	H	54		131	H
	E0031010	BSLN	12FEB2003	14:50	-7	74		164		41		108	
		FINAL	06MAR2003	12:50	16	77		161		42		104	
	E0031011	BSLN	18FEB2003	11:50	-9	150		254	H#	47		177	H#
		FINAL	24APR2003	9:25	57	165		256	H#	47		176	H#
	E0031015	BSLN	14MAR2003	8:40	-12	97		167		52		96	
		FINAL	01APR2003	11:55	7	124		214	H	68		121	
	E0031031	BSLN	01JUL2003	10:30	-7	161		185		39	L#	114	
		FINAL	28AUG2003	10:35	52	88		166		38	L#	110	
	E0033009	BSLN	22JAN2003	13:40	-21	45		209	H	70		130	
	E0034009	BSLN	10JUN2003	13:00	-9	129		192		43		123	
		FINAL	18AUG2003	17:25	61	253	H#	200		42		107	
	E0037007	BSLN	04APR2003	11:30	-7	148		229	H	39	L#	160	H#
	E0037012	BSLN	11JUL2003	13:00	-5	57		170		38	L#	121	
		FINAL	08SEP2003	13:20	55	240	#	174		34	L#	92	
	E0039019	BSLN	20JAN2003	14:50	-17	97		234	H	62		153	H
		FINAL	03APR2003	11:05	57	89		214	H	59		137	H
	E0039043	BSLN	28APR2003	10:15	-10	111		185		44		119	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	72		212	H	53		145	H
		FINAL		26FEB2003	8:45	59	51		200		54		136	H
	E0002003	BSLN		03JAN2003	11:50	-19	305H#		246	H#	51		134	H
		FINAL		18MAR2003	12:10	56	380H#		216	H	43		97	
	E0002004	BSLN		14JAN2003	8:15	-11	223 #		154		40	#	69	
	E0002008	BSLN		14FEB2003	16:00	-11	1240H#		320	H#	30	L#	83	
		FINAL		23APR2003	14:25	58	190		214	H	38	L#	138	H
	E0002016	BSLN		14JUL2003	11:00	-10	233 #		207	H	59		101	
		FINAL		17SEP2003	11:15	56	468H#		318	H#	50		175	H#
	E0003008	BSLN		21JAN2003	12:45	-7	46		162		60		93	
	E0004003	BSLN		02OCT2002	11:00	-8	369H#		228	H	44		110	
	E0004006	BSLN		28OCT2002	9:55	-7	110		176		40	#	114	
		FINAL		06JAN2003	10:55	64	96		176		41		116	
	E0004016	BSLN		12FEB2003	15:10	-7	47		158		58		91	
		FINAL		17APR2003	17:10	58	75		156		66		75	
	E0004024	BSLN		25JUN2003	16:00	-8	121		203	H	61		118	
		FINAL		28AUG2003	9:50	57	106		214	H	65		128	
	E0005006	BSLN	*	24SEP2002	15:30	-9	392H#		158		37	L#	43	
		BSLN		03OCT2002	8:30	1	254H#		170		31	L#	88	
	E0005017	BSLN	*	11DEC2002	10:30	-19	170		239	H	70		135	H
		BSLN		23DEC2002	12:30	-7	98		179		64		95	
		FINAL		04MAR2003	13:00	65	143		198		56		113	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0005019	BSLN	19DEC2002	14:00	-27	105	147	44	82
		FINAL	23JAN2003	15:45	9	122	142	34 L#	84
	E0005026	BSLN	28FEB2003	10:15	-6	60	179	69	98
		FINAL	02APR2003	9:40	28	40L	156	55	93
	E0005039	BSLN	15MAY2003	9:00	-7	187	232 H	36 L#	159 H
		FINAL	16JUL2003	8:40	56	180	217 H	34 L#	147 H
	E0005043	BSLN	02JUL2003	8:30	-7	107	176	48	107
		FINAL	03SEP2003	9:45	57	74	172	52	105
	E0006020	BSLN	02MAY2003	13:30	-11	118	237 H	47	166 H#
		FINAL	08JUL2003	14:45	57	114	229 H	39 L#	167 H#
		FINAL *	10JUL2003	16:30	59	204 #	239 H	37 L#	161 H#
	E0007001	BSLN *	16DEC2002	9:25	-15	224 #	287 H#	45	197 H#
		BSLN	26DEC2002	9:25	-5	206 #	264 H#	43	180 H#
		FINAL	24FEB2003	8:43	56	276H#	285 H#	42	188 H#
		FINAL *	10MAR2003	8:54	70	193	270 H#	44	187 H#
	E0007003	BSLN	13JAN2003	10:30	-17	120	189	56	109
		FINAL	01APR2003	13:30	62	114	102 L	48	31
	E0007006	BSLN	24FEB2003	11:00	-9	75	131	37 L#	79
		FINAL	27MAR2003	10:50	23	143	159	39 L#	91
	E0009004	BSLN *	19NOV2002	12:30	-7	784H#	332 H#	51	126
		BSLN	25NOV2002	12:55	-1	243 #	263 H#	52	162 H#
		FINAL	18DEC2002	14:50	23	719H#	315 H#	64	138 H
	E0009012	BSLN	16JUN2003	14:45	-9	226 #	215 H	37 L#	133 H
		FINAL	03JUL2003	17:45	9	113	209 H	47	139 H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0010008	BSLN		11DEC2002	9:15	-7	67		174		58		103	
	E0010018	BSLN		26FEB2003	8:51	-21	81		173		50		107	
		FINAL		14MAY2003	10:45	57	92		187		47		122	
	E0010028	BSLN		09JUN2003	8:46	-7	55		167		56		100	
		FINAL		15JUL2003	13:50	30	83		157		59		81	
	E0011008	BSLN	*	17DEC2002	12:30	-44	85		130		24	L#	89	
		BSLN		23JAN2003	9:20	-7	67		130		42		75	
		FINAL		13FEB2003	12:30	15	93		135		30	L#	86	
	E0011009	BSLN		19DEC2002	10:15	-8	264	H#	233	H	45		135	H
		FINAL		20FEB2003	9:00	56	338	H#	243	H#	45		130	
	E0011010	BSLN		03FEB2003	10:00	-7	85		260	H#	65		178	H#
		FINAL		19MAR2003	8:45	38	122		198		55		119	
	E0013001	BSLN		01NOV2002	8:50	-13	266	H#	234	H	37	L#	144	H
		FINAL		10JAN2003	10:45	58	222	#	222	H	28	L#	150	H
	E0013003	BSLN		07NOV2002	9:25	-5	143		193		45		119	
		FINAL		06JAN2003	13:17	56	129		208	H	53		129	
	E0013005	BSLN		13FEB2003	11:42	-5	95		175		45		111	
		FINAL		15APR2003	12:16	57	240	#	191		31	L#	112	
	E0013013	BSLN		01MAY2003	10:14	-5	61		146		50		84	
		FINAL		30MAY2003	9:55	25	68		160		55		91	
	E0014002	BSLN		19FEB2003	16:35	-7	134		173		53		93	
		FINAL		10APR2003	13:05	44	80		162		58		88	
	E0014004	BSLN		04MAR2003	11:40	-8	167		217	H	44		140	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0014004	FINAL		15APR2003	11:40	35	265	H#	208	H	36	L#	119	
	E0014009	BSLN	*	15APR2003	14:45	-8	389	H#	211	H	41		92	
		BSLN		17APR2003	12:30	-6	185		204	H	47		120	
		FINAL		16MAY2003	8:55	24	112		210	H	40	#	148	H
	E0014015	BSLN		11JUN2003	10:15	-7	196		155		46		70	
	E0014017	BSLN		17JUN2003	17:00	-10	114		169		47		99	
		FINAL		19AUG2003	17:05	54	91		190		53		119	
	E0014018	BSLN		24JUN2003	16:35	-7	47		149		44		96	
		FINAL		27AUG2003	16:00	58	61		137		38	L#	87	
		FINAL	*	24SEP2003	16:45	86	57		132		40	#	81	
	E0015005	BSLN		25NOV2002	13:15	-7	83		249	H#	58		174	H#
		FINAL		18DEC2002	9:30	17	85		236	H	62		157	H
	E0017002	BSLN		08MAY2003	17:00	-26	327	H#	213	H	49		99	
		FINAL		13JUN2003	16:00	11	86		242	H#	49		176	H#
	E0018009	BSLN		17DEC2002	10:45	-20	187		209	H	34	L#	138	H
		FINAL		14JAN2003	13:15	9	101		201	H	41		140	H
	E0018010	BSLN		09JAN2003	9:30	-7	142		221	H	41		152	H
		FINAL		13MAR2003	9:20	57	113		224	H	46		155	H
	E0018015	BSLN		21JAN2003	11:20	-7	188		216	H	40	#	138	H
		FINAL		27MAR2003	10:50	59	92		231	H	43		170	H#
	E0020015	BSLN		18MAR2003	13:30	-9	174		222	H	36	L#	151	H
		FINAL		23MAY2003	13:40	58	172		192		28	L#	130	
	E0020017	BSLN		27MAR2003	12:00	-7	65		183		73		97	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0020017	FINAL		03JUN2003	17:40	62	53		167		75		81	
	E0020020	BSLN		07MAY2003	15:00	-5	62		158		69		77	
		FINAL		23MAY2003	14:00	12	68		159		73		72	
	E0020022	BSLN		09JUN2003	13:05	-7	190		245	H#	55		152	H
		FINAL		11AUG2003	9:30	57	152		227	H	51		146	H
	E0022001	BSLN		09OCT2002	14:20	-19	76		168		67		86	
		FINAL		26DEC2002	17:55	60	142		209	H	67		114	
	E0022004	BSLN	*	17OCT2002	8:48	-11	172		228	H	35	L#	159	H
		BSLN		28OCT2002	9:47	1	183		218	H	41		140	H
		FINAL		23DEC2002	10:15	57	125		238	H	46		167	H#
	E0022005	BSLN		18OCT2002	7:40	-21	190		216	H	35	L#	143	H
		FINAL		03JAN2003	9:20	57	172		243	H#	42		167	H#
	E0022011	BSLN		21NOV2002	9:25	-8	56		195		53		131	H
	E0022015	BSLN	*	29NOV2002	13:50	-11	85		125	L	50		58	
		BSLN	*	03DEC2002	10:10	-7	70		115	L	52		49	
		BSLN		10DEC2002	16:10	1	204	#	124	L	52		31	
		FINAL		06FEB2003	9:50	59	74		120	L	51		54	
	E0022016	BSLN		03DEC2002	12:10	-14	78		159		58		85	
		FINAL		11FEB2003	11:05	57	31L		144		45		93	
	E0022020	BSLN		05DEC2002	12:21	-7	75		162		34	L#	113	
		FINAL		23JAN2003	16:20	43	65		126	L	33	L#	80	
		FINAL	*	28JAN2003	10:35	48	72		121	L	37	L#	70	
	E0022023	BSLN		20DEC2002	14:28	-5	285H	#	213	H	36	L#	120	
		FINAL		20FEB2003	10:05	58	527H	#	244	H#	34	L#	106	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0022029	BSLN	10FEB2003	12:30	-9	387	H#	283	H#	32	L#	174	H#
		FINAL	14APR2003	9:45	55	199		221	H	30	L#	151	H
	E0022041	BSLN	11MAR2003	9:53	-7	180		192		47		109	
		FINAL	13MAY2003	9:18	57	242	#	219	H	63		108	
	E0022042	BSLN	05MAR2003	9:50	-7	263	H#	205	H	44		108	
		FINAL	12MAY2003	9:35	62	362	H#	222	H	47		103	
	E0022043	BSLN	11MAR2003	13:50	-9	122		182		45		113	
		FINAL	12MAY2003	8:05	54	129		190		48		116	
	E0022054	BSLN	07APR2003	11:25	-4	115		163		27	L#	113	
	E0022059	BSLN	23APR2003	15:30	-13	61		158		61		85	
		FINAL	08JUL2003	16:30	64	76		147		60		72	
	E0022065	BSLN	01MAY2003	9:30	-6	137		204	H	50		127	
		FINAL	02JUL2003	8:50	57	110		199		47		130	
	E0022070	BSLN	05JUN2003	11:40	-7	255	H#	231	H	36	L#	144	H
		FINAL	18JUN2003	15:15	7	474	H#	259	H#	34	L#	152	H
	E0023001	BSLN	24OCT2002	13:30	-22	98		238	H	53		165	H#
		FINAL	14JAN2003	13:30	61	160		226	H	51		143	H
	E0023009	BSLN	24JAN2003	11:30	-18	103		250	H#	40	#	189	H#
		FINAL	08APR2003	11:15	57	133		289	H#	47		215	H#
	E0023028	BSLN	16MAY2003	12:15	-13	93		249	H#	78		152	H
		FINAL	21JUL2003	11:00	54	66		185		92	H	80	
	E0023033	BSLN	30MAY2003	12:10	-6	348	H#	193		33	L#	90	
		FINAL	12JUN2003	13:15	8	292	H#	182		30	L#	94	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0023047	BSLN		11JUL2003	15:00	-7	80	169	78	75
		FINAL		16SEP2003	13:00	61	113	133	39 L#	71
	E0025001	BSLN		25MAR2003	16:00	-7	320H#	191	23 L#	104
		FINAL		23APR2003	10:30	23	136	160	27 L#	106
	E0026012	BSLN		05FEB2003	11:00	-15	108	224 H	51	151 H
		FINAL		17APR2003	9:10	57	150	208 H	54	124
	E0026020	BSLN		28MAR2003	10:50	-4	80	165	42	107
		FINAL		22APR2003	14:05	22	86	166	51	98
	E0026024	BSLN		25APR2003	12:30	-7	112	210 H	62	126
	E0026028	BSLN		06JUN2003	10:20	-14	155	218 H	46	141 H
		FINAL		23JUL2003	10:00	34	161	227 H	47	148 H
	E0028001	BSLN		07OCT2002	14:00	-3	510H#	253 H#	30 L#	162 H#
		FINAL		03DEC2002	9:50	55	461H#	354 H#	24 L#	235 H#
	E0028003	BSLN		23SEP2002	9:10	-7	100	183	61	102
		FINAL		26NOV2002	9:20	58	120	188	66	98
	E0028005	BSLN		30SEP2002	11:00	-3	62	193	64	117
		FINAL		31OCT2002	12:15	29	79	215 H	60	139 H
	E0028010	BSLN		15OCT2002	11:00	-21	102	165	59	86
		FINAL	*	19NOV2002	12:40	15	98	158	58	80
		FINAL		31DEC2002	9:20	57	133	144	59	58
	E0028011	BSLN	*	22OCT2002	8:30	-44	204 #	197	31 L#	125
		BSLN		25NOV2002	9:00	-10	176	190	32 L#	123
		FINAL		30JAN2003	12:35	57	299H#	183	29 L#	94

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0028030	BSLN	26FEB2003	11:30	-6	124		176		40	#	111	
		FINAL	30APR2003	12:35	58	99		213	H	44		149	H
	E0028031	BSLN	06MAR2003	9:00	-5	188		237	H	36	L#	163	H#
		FINAL	17APR2003	13:30	38	155		209	H	46		132	H
	E0028047	BSLN	09JUL2003	10:40	-5	153		197		42		124	
		FINAL	09SEP2003	10:24	58	162		178		38	L#	108	
	E0029001	BSLN	25SEP2002	8:45	-6	126		164		36	L#	103	
	E0029014	BSLN	28JAN2003	9:35	-7	118		245	H#	85	H	136	H
		FINAL	01APR2003	11:20	57	184		235	H	83	H	115	
	E0029023	BSLN	01APR2003	8:47	-7	291H#		234	H	52		124	
		FINAL	10JUN2003	11:10	64	167		230	H	51		146	H
	E0029032	BSLN	22MAY2003	12:45	-19	109		180		36	L#	122	
		FINAL	01JUL2003	12:00	22	113		162		32	L#	107	
	E0029033	BSLN	27MAY2003	12:50	-6	116		124	L	45		56	
	E0029039	BSLN	10JUL2003	13:02	-5	68		194		40	#	140	H
		FINAL	28JUL2003	15:30	14	60		162		47		103	
	E0030003	BSLN	03DEC2002	14:25	-13	148		119	L	45		44	
		FINAL	21MAR2003	9:50	96	125		129	L	61		43	
	E0030009	BSLN	14JAN2003	9:55	-9	345H#		288	H#	53		166	H#
		FINAL	19MAR2003	10:35	56	283H#		274	H#	50		167	H#
	E0030016	BSLN	21FEB2003	11:50	-10	90		192		38	L#	136	H
		FINAL	22APR2003	18:55	51	333H#		168		36	L#	65	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0030021	BSLN	13MAY2003	17:25	-7	84	172	39 L#	116
	E0031001	BSLN	14NOV2002	11:48	-7	231 #	204 H	36 L#	122
	E0031017	BSLN	25MAR2003	16:15	-7	133	183	43	113
		FINAL	29APR2003	10:30	29	131	180	44	110
	E0031018	BSLN	01APR2003	14:45	-9	107	175	41	113
	E0031023	BSLN	22APR2003	14:03	-7	416H#	153	24 L#	88
		FINAL	24JUN2003	11:48	57	280H#	194	27 L#	111
	E0033001	BSLN	23DEC2002	12:50	-17	48	195	61	124
		FINAL	30JAN2003	13:25	22	58	193	54	127
	E0033004	BSLN	09JAN2003	13:10	-8	93	144	46	79
		FINAL	14MAR2003	11:40	57	67	144	51	80
	E0033010	BSLN	22JAN2003	16:20	-13	105	193	50	122
		FINAL	26MAR2003	16:00	51	62	199	44	143 H
	E0033014	BSLN	12MAR2003	17:25	-7	255H#	226 H	36 L#	139 H
	E0035002	BSLN	14NOV2002	10:50	-7	154	193	40 #	122
	E0035007	BSLN	13DEC2002	12:40	-6	151	191	43	118
		FINAL	11FEB2003	10:10	55	206 #	214 H	53	120
	E0035011	BSLN	13JAN2003	8:35	-22	283H#	240 H#	35 L#	148 H
		FINAL	01APR2003	9:00	57	288H#	196	34 L#	104
	E0035020	BSLN	15APR2003	8:15	-3	78	235 H	65	154 H
	E0037003	BSLN	23JAN2003	11:40	-7	132	233 H	69	138 H

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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0037003	FINAL		20FEB2003	15:32	22	169		231	H	62		135	H
	E0037004	BSLN		06FEB2003	12:35	-7	61		158		49		97	
		FINAL		10APR2003	13:00	57	60		160		53		95	
	E0039007	BSLN		25NOV2002	13:20	-9	94		178		46		113	
		FINAL		29JAN2003	14:15	57	69		186		47		125	
	E0039022	BSLN		06FEB2003	9:50	-19	43	L	144		59		76	
		FINAL		24APR2003	12:10	59	35	L	145		56		82	
	E0039023	BSLN		05FEB2003	10:37	-19	109		150		40	#	88	
	E0039030	BSLN		12MAR2003	8:55	-12	91		130		46		66	
		FINAL		19MAY2003	9:15	57	74		143		63		65	
		FINAL	*	30MAY2003	9:50	68	71		153		57		82	
	E0039031	BSLN		05MAR2003	19:15	-19	103		210	H	44		145	H
		FINAL		20MAY2003	12:50	58	97		194		47		128	
	E0039037	BSLN		26MAR2003	18:30	-21	100		206	H	56		130	
		FINAL		12JUN2003	11:30	58	164		163		52		78	
	E0039038	BSLN	*	27MAR2003	10:10	-27	104		241	H#	80		140	H
		BSLN		21APR2003	10:16	-2	89		231	H	81	H	132	H
		FINAL		20JUN2003	11:15	59	159		242	H#	88	H	122	
	E0039047	BSLN		13MAY2003	9:20	-6	128		217	H	41		150	H
	E0039059	BSLN		07JUL2003	11:10	-4	242	#	243	H#	35	L#	160	H#
		FINAL		05SEP2003	11:10	57	205	#	239	H	37	L#	161	H#
	E0041007	BSLN		05MAR2003	13:45	-8	60		112	L	49		51	
		FINAL		08MAY2003	13:45	57	84		150		60		73	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0041010	BSLN	23APR2003	14:45	-7	502H#	272 H#	34 L#	168 H#
		FINAL	11JUN2003	15:30	43	350H#	244 H#	39 L#	135 H
	E0041011	BSLN	15MAY2003	16:00	-7	215 #	143	39 L#	61
		FINAL	17JUL2003	14:30	57	210 #	146	39 L#	65
	E0041012	BSLN	05JUN2003	12:28	-14	262H#	208 H	42	114
		FINAL	14AUG2003	11:45	57	405H#	218 H	41	125

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR II)	E0001004	BSLN	23APR2003	11:00	-8	89	171	34 L#	119
		FINAL	27JUN2003	12:45	58	111	195	35 L#	138 H
	E0005023	BSLN	29JAN2003	7:30	-7	54	159	62	86
		FINAL	01APR2003	16:30	56	43L	167	70	88
	E0005034	BSLN	09APR2003	9:30	-6	179	225 H	40 #	149 H
		FINAL	09JUN2003	13:00	56	110	153	35 L#	96
	E0005041	BSLN	17JUN2003	11:55	-7	198	212 H	39 L#	133 H
		FINAL	18AUG2003	10:10	56	153	221 H	37 L#	153 H
	E0007004	BSLN	28JAN2003	8:05	-2	1030H#	272 H#	41	98
		FINAL	13FEB2003	8:30	15	1930H#	466 H#	39 L#	80
	E0007010	BSLN	14APR2003	8:10	-4	180	191	37 L#	118
		FINAL *	21APR2003	8:30	4	234 #	183	31 L#	105
		FINAL	13JUN2003	7:40	57	192	165	32 L#	95
		FINAL *	16JUN2003	7:50	60	142	173	33 L#	112
	E0007012	BSLN	12MAY2003	8:50	-4	272H#	199	29 L#	116
		FINAL	02JUL2003	11:35	48	155	205 H	34 L#	140 H
	E0009007	BSLN	27JAN2003	15:25	-7	163	212 H	31 L#	148 H
		FINAL	03MAR2003	15:40	29	158	232 H	35 L#	165 H#
	E0009008	BSLN	04FEB2003	13:37	-8	94	173	40 #	114
		FINAL	08APR2003	12:35	56	123	213 H	47	141 H
	E0011001	BSLN	25OCT2002	16:00	-7	70	242 H#	73	155 H
		FINAL	26DEC2002	8:30	56	72	224 H	67	143 H
	E0011011	BSLN	12FEB2003	12:00	-8	61	194	59	123
		FINAL	16APR2003	8:30	56	66	192	63	116

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR II)	E0011013	BSLN		25MAR2003	9:45	-23	181		207	H	34	L#	137	H
		FINAL		12JUN2003	8:45	57	260H#		200		34	L#	114	
	E0011014	BSLN		02APR2003	8:20	-5	53		150		51		88	
		FINAL		08MAY2003	15:30	32	165		182		55		94	
	E0011021	BSLN		15MAY2003	10:00	-7	117		157		47		87	
		FINAL		21JUL2003	10:00	61	82		163		55		92	
	E0013008	BSLN		19MAR2003	16:20	-7	86		158		45		96	
		FINAL		19MAY2003	11:25	55	112		179		43		114	
	E0014001	BSLN		18FEB2003	15:45	-8	139		112	L	47		37	
		FINAL		08APR2003	11:10	42	121		91	L	33	L#	34	
		FINAL	*	16APR2003	10:40	50	188		125	L	42		45	
	E0014013	BSLN		20MAY2003	14:50	-7	119		150		42		84	
		FINAL		23JUL2003	15:00	58	193		171		47		85	
	E0014014	BSLN		03JUN2003	16:35	-7	108		180		49		109	
		FINAL		06AUG2003	10:50	58	130		195		51		118	
	E0015004	BSLN		25NOV2002	8:50	-7	90		111	L	36	L#	57	
		FINAL		29JAN2003	8:45	59	52		113	L	43		60	
	E0018005	BSLN		10DEC2002	16:00	-10	38L		122	L	49		65	
		FINAL		17FEB2003	11:05	60	69		153		57		82	
	E0018012	BSLN		17JAN2003	10:30	-7	62		148		56		80	
		FINAL		26FEB2003	19:20	34	159		147		50		65	
	E0019019	BSLN		14JAN2003	10:30	-9	83		110	L	41		52	
	E0019033	BSLN		10MAR2003	16:05	-8	52		214	H	68		136	H

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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR II)	E0019033	FINAL		16MAY2003	8:30	60	62		194		57		125	
	E0019038	BSLN	*	10APR2003	12:30	-14	52		134		39	L#	85	
		BSLN		17APR2003	11:05	-7	47		101	L	38	L#	54	
		FINAL		19JUN2003	9:40	57	69		106	L	36	L#	56	
	E0019046	BSLN		19JUN2003	15:00	-7	48		194		94	H	90	
		FINAL		21AUG2003	9:12	57	64		208	H	75		120	
	E0019047	BSLN		26JUN2003	12:30	-12	55		152		52		89	
		FINAL		04SEP2003	8:40	59	53		142		52		79	
	E0019048	BSLN		03JUL2003	11:05	-7	67		202	H	67		122	
		FINAL		03SEP2003	16:12	56	90		169		65		86	
	E0022006	BSLN		22OCT2002	10:10	-21	308H#		185		36	L#	87	
		FINAL		07JAN2003	7:40	57	234 #		159		35	L#	77	
	E0022047	BSLN		21MAR2003	8:10	-7	660H#		317	H#	30	L#	70	
		FINAL		23MAY2003	9:45	57	537H#		341	H#	36	L#	77	
	E0022075	BSLN		27JUN2003	7:45	-11	75		233	H	79		139	H
		FINAL		03SEP2003	9:15	58	96		236	H	71		146	H
	E0023012	BSLN		31JAN2003	15:30	-6	214 #		167		40	#	84	
		FINAL		04APR2003	12:15	58	193		144		31	L#	74	
	E0023016	BSLN		15MAY2003	13:30	-7	73		159		63		81	
		FINAL		17JUL2003	11:10	57	61		143		56		75	
	E0023018	BSLN		18MAR2003	13:30	-9	85		175		79		79	
		FINAL		22MAY2003	10:15	57	123		176		40	#	111	
	E0023036	BSLN		10JUN2003	12:00	-10	93		164		35	L#	110	

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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR II)	E0023036	FINAL	13AUG2003	17:00	55	89		146		43		85	
	E0023046	BSLN	11JUL2003	10:00	-12	160		167		38	L#	97	
		FINAL	16SEP2003	14:00	56	120		187		41		122	
	E0026006	BSLN	31DEC2002	10:35	-8	201	#	204	H	37	L#	127	
	E0026021	BSLN	14APR2003	15:45	-9	71		176		68		94	
	E0026027	BSLN	05JUN2003	13:10	-14	149		163		51		82	
	E0029002	*	07NOV2002	8:10		319H	#	276	H#	64		148	H
	E0029004	BSLN	13NOV2002	14:50	-6	81		158		43		99	
		FINAL	17JAN2003	8:25	60	84		143		40	#	86	
	E0029013	BSLN	10FEB2003	8:55	-9	174		219	H	55		129	
	E0029019	BSLN	24FEB2003	9:30	-7	360H	#	261	H#	36	L#	153	H
		FINAL	17MAR2003	9:50	15	168		198		36	L#	128	
	E0029024	BSLN	11MAR2003	12:10	-6	61		189		88	H	89	
		FINAL	20MAY2003	14:45	65	52		169		81	H	78	
	E0029038	BSLN	30JUN2003	9:25	-7	143		185		40	#	116	
	E0031004	BSLN	12DEC2002	13:59	-7	168		232	H	53		145	H
		FINAL	14FEB2003	10:50	58	434H	#	243	H#	43		137	H
	E0031013	BSLN	06MAR2003	10:35	-7	179		217	H	42		139	H
		FINAL	08MAY2003	11:05	57	177		177		45		97	
	E0031016	BSLN	17MAR2003	10:45	-7	93		154		47		88	
		FINAL	15APR2003	10:03	23	105		166		48		97	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR II)	E0031019	BSLN		03APR2003	11:25	-8	165		238	H	36	L#	169	H#
		FINAL		12MAY2003	16:40	32	184		202	H	30	L#	135	H
	E0031022	BSLN		21APR2003	12:40	-7	356	H#	235	H	46		118	
	E0033007	BSLN		15JAN2003	15:20	-13	65		224	H	56		155	H
		FINAL		27MAR2003	15:35	59	160		239	H	61		146	H
	E0033013	BSLN		06FEB2003	11:45	-13	124		224	H	46		153	H
		FINAL		16APR2003	11:45	57	97		208	H	44		145	H
	E0033016	BSLN		17APR2003	12:00	-21	103		188		55		112	
		FINAL		02JUL2003	13:00	56	110		175		55		98	
	E0033022	BSLN		09JUL2003	11:00	-5	107		170		48		101	
		FINAL		11SEP2003	12:00	60	91		193		53		122	
	E0034007	BSLN		07MAY2003	14:05	-9	94		255	H#	65		171	H#
		FINAL		14JUL2003	11:15	60	73		249	H#	88	H	146	H
		FINAL	*	28JUL2003	11:48	74	187		305	H#	90	H	178	H#
	E0035004	BSLN		22NOV2002	11:45	-5	337	H#	282	H#	53		162	H#
	E0035009	BSLN		20DEC2002	11:12	-7	43	L	133		41		83	
		FINAL		19FEB2003	8:55	55	68		135		44		77	
	E0035010	BSLN		07JAN2003	7:45	-3	96		141		55		67	
		FINAL		06MAR2003	9:00	56	108		159		65		72	
	E0035022	BSLN		01MAY2003	9:45	-8	66		157		48		96	
		FINAL		07JUL2003	8:55	60	49		153		47		96	
	E0039003	BSLN		12NOV2002	11:19	-13	149		181		55		96	
		FINAL		02JAN2003	14:06	39	226	#	143		44		54	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM104.SAS
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Listing 12.2.8.2.5 Chemistry Data - Lipids

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR II)	E0040001	BSLN	18JUN2003	14:30	-9	49	186	61	115
		FINAL	22AUG2003	9:00	57	40L	181	56	117
	E0040004	BSLN	11JUL2003	13:00	-7	110	211 H	72	117
	E0041002	BSLN	13JAN2003	14:35	-8	80	214 H	42	156 H
		FINAL	11MAR2003	10:35	50	70	192	37 L#	141 H
	E0041005	BSLN	28FEB2003	12:31	-5	84	209 H	31 L#	161 H#
		FINAL	30APR2003	14:08	57	177	185	43	107

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:30 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BSLN		22JAN2003	14:00	-13	1		111		33	
		FINAL		02APR2003	10:10	58	1		95		27	
	E0002010	BSLN		28MAR2003	10:00	-7	5		90		29	
	E0002012	BSLN		16APR2003	10:10	-5	2		81		39	
		FINAL		16JUN2003	11:30	57	3		88		37	
	E0002015	BSLN		22MAY2003	10:15	-13	3		100		30	
	E0002018	BSLN		16JUL2003	13:25	-8	4		77		31	
		FINAL		07AUG2003	8:10	15	5	#	108		30	
	E0003004	BSLN	*	03DEC2002	11:48	-14	2		106		33	
		BSLN		17DEC2002	9:20	1	3		94		33	
		FINAL		07JAN2003	15:40	22	2		108		36	
	E0003005	BSLN		16DEC2002	15:00	-7	1		138		34	
		FINAL		18FEB2003	8:55	58	1		106		34	
	E0003007	BSLN		19DEC2002	10:15	-14	1		115		37	
		FINAL		27FEB2003	8:50	57	1		81		36	
	E0003015	BSLN		29APR2003	11:30	-6	2		187	H#	27	
		FINAL		02JUL2003	14:45	59	1		145		28	
	E0004002	BSLN		24SEP2002	10:40	-7	1		118		30	
		FINAL		26NOV2002	11:00	57	1		84		35	
	E0004013	BSLN		08JAN2003	10:00	-6	2		111		31	
		FINAL		19FEB2003	8:20	37	1		93		37	
	E0004018	BSLN		12MAR2003	10:50	-7	2		88		35	
		FINAL		13MAY2003	13:45	56	2		80		41	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	BSLN	07MAY2003	15:55	-7	2	71	36
		FINAL	09JUL2003	14:10	57	2	76	36
	E0005002	BSLN	23SEP2002	10:00	-10	1	113	36
		FINAL	25NOV2002	8:30	54	2	73	33
	E0005004	BSLN	24SEP2002	12:00	-7	1	107	25
	E0005013	BSLN	30OCT2002	8:00	-8	2	126	29
	E0005024	BSLN	05FEB2003	15:00	-5	2	89	30
		FINAL	10APR2003	11:30	60	2	95	32
	E0005027	BSLN	04MAR2003	7:45	-7	2	93	35
		FINAL	03APR2003	8:15	24	2	88	32
	E0005037	BSLN	30APR2003	12:00	-7	3	112	34
		FINAL	02JUL2003	12:15	57	2	102	35
	E0005042	BSLN	19JUN2003	11:30	-5	1	120	32
		FINAL	18AUG2003	16:25	56	1	85	32
	E0006005	BSLN	25NOV2002	12:15	-10	3	143	24
		FINAL	30JAN2003	16:10	57	3	117	24
	E0006018	BSLN	07MAR2003	12:40	-6	1	99	32
		FINAL	24MAR2003	10:45	12	1	99	31
	E0007013	BSLN	10JUN2003	9:25	-3	1	97	29
		FINAL	07AUG2003	9:20	56	1	89	29
	E0010004	BSLN	05DEC2002	11:10	-6	2	84	32
		FINAL	06FEB2003	12:40	58	3	94	35

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	BSLN	30DEC2002	9:48	-8	4	76	34
		FINAL	05MAR2003	13:59	58	3	68	29
	E0010024	BSLN	23APR2003	8:45	-12	3	106	34
		FINAL	02JUL2003	10:30	59	2	77	34
	E0010032	BSLN	03JUL2003	11:30	-7	1	85	35
		FINAL	17JUL2003	11:38	8	2	88	32
	E0011025	BSLN	20JUN2003	14:30	-6	2	109	29
		FINAL	22AUG2003	10:00	58	2	73	34
	E0013007	BSLN	14MAR2003	8:48	-6	4	89	35
		FINAL	07APR2003	17:15	19	4	85	38
	E0013009	BSLN	26MAR2003	9:09	-7	5	108	33
		FINAL	29MAY2003	17:50	58	3	98	33
	E0014006	BSLN	14MAR2003	11:30	-11	1	136	31
		FINAL	21MAY2003	16:20	58	1	126	31
	E0014010	BSLN	15APR2003	17:20	-7	2	127	24
		FINAL	17JUN2003	18:10	57	2	122	25
	E0016001	BSLN	02JAN2003	8:50	-20	2	90	34
		FINAL	19MAR2003	12:00	57	1	102	30
	E0016004	BSLN	27JAN2003	9:30	-7	2	100	35
	E0018001	BSLN	22OCT2002	16:15	-7	1	125	33
		FINAL	24DEC2002	9:55	57	2	73	40
	E0018006	BSLN	10DEC2002	17:15	-7	2	124	32
		FINAL	27FEB2003	12:10	73	2	113	36

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	BSLN		30OCT2002	8:40	-8	3		112	37	
		FINAL		19DEC2002	12:55	43	2		88	32	
	E0019011	BSLN		12NOV2002	12:05	-9	2		115	31	
		FINAL		16JAN2003	14:20	57	1		121	32	
	E0019025	BSLN		30JAN2003	14:40	-7	1		126	31	
		FINAL		03APR2003	13:30	57	2		134	35	
	E0019026	BSLN		11FEB2003	11:10	-13	4		93	36	
	E0019043	BSLN		21MAY2003	11:04	-13	1		82	32	
		FINAL		29JUL2003	11:38	57	0		81	31	
	E0020001	BSLN		15OCT2002	20:00	-14	2		72	38	
		FINAL		20DEC2002	12:30	53	2		72	36	
	E0020006	BSLN		26NOV2002	18:00	-20	2		106	31	
		FINAL		08JAN2003	10:00	24	1		109	28	
	E0020007	BSLN		10JAN2003	12:00	-5	3		122	30	
		FINAL		25MAR2003	18:50	70	5		104	30	
	E0020011	BSLN		19FEB2003	13:45	-7	2		107	30	
		FINAL		23APR2003	14:30	57	2		82	36	
		FINAL	*	07MAY2003	12:00	71	2		77	36	
	E0020013	BSLN		26FEB2003	14:15	-7	1		94	35	
		FINAL		25MAR2003	12:00	21	1		82	33	
	E0022008	BSLN		05NOV2002	10:00	-7	5	#	69	39	
		FINAL		07JAN2003	9:45	57	2		69	42	H
	E0022017	BSLN		05DEC2002	12:35	-14	1		100	41	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	FINAL	07MAR2003	9:47	79	1	90	36	
	E0022018	BSLN	04DEC2002	10:15	-8	5 #	99	30	
		FINAL	11FEB2003	8:40	62	4	104	34	
	E0022022	BSLN	16DEC2002	13:15	-14	1	151	34	
		FINAL	27FEB2003	11:35	60	2	134	34	
	E0022027	BSLN	24JAN2003	7:40	-13	1	84	39	
		FINAL	03APR2003	9:00	57	1	97	36	
	E0022030	BSLN	10FEB2003	7:40	-4	4	124	31	
	E0022031	BSLN	11FEB2003	10:25	-7	1	115	35	
		FINAL	15APR2003	9:30	57	3	120	31	
	E0022032	BSLN	12FEB2003	8:05	-6	1	143	30	
		FINAL	18APR2003	10:30	60	0	133	34	
	E0022035	BSLN	13FEB2003	13:50	-6	2	125	32	
		FINAL	13MAR2003	17:55	23	3	111	30	
	E0022036	BSLN	14FEB2003	8:55	-11	1	75	39	
		FINAL	22APR2003	7:36	57	1	73	43	H
	E0022056	BSLN	11APR2003	8:07	-6	6H#	88	37	
	E0022060	BSLN	24APR2003	12:05	-6	1	103	29	
		FINAL	24JUN2003	9:25	56	3	102	37	
	E0022063	BSLN	29APR2003	10:10	-8	2	121	33	
	E0023008	BSLN	23JAN2003	10:00	-7	1	113	33	
		FINAL	24MAR2003	15:40	54	1	115	31	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0023013	BSLN		13FEB2003	11:00	-14	3		149		30	
		FINAL		06MAR2003	11:00	8	2		130		29	
	E0023015	BSLN		04MAR2003	11:00	-7	2		75		40	
		FINAL		06MAY2003	10:00	57	4		133		30	
	E0023034	BSLN		03JUN2003	14:00	-6	1		91		31	
		FINAL		05AUG2003	16:00	58	1		98		31	
	E0023037	BSLN		11JUN2003	16:30	-7	3		95		31	
		FINAL	*	24JUN2003	16:30	7	2		85		34	
		FINAL		15AUG2003	9:30	59	5		66		35	
	E0023038	BSLN		20JUN2003	12:45	-10	2		108		33	
		FINAL		16SEP2003	18:30	79	2		90		36	
	E0023044	BSLN		08JUL2003	14:00	-8	4		156	H	20	L
		FINAL		12AUG2003	12:00	28	3		116		27	
	E0023045	BSLN		10JUL2003	11:40	-7	1		100		33	
		FINAL		15SEP2003	11:00	61	1		81		45	H
	E0025002	BSLN		27MAR2003	11:05	-7	2		118		29	
		FINAL		29MAY2003	11:40	57	2		84		32	
	E0026010	BSLN		15JAN2003	14:00	-7	2		112		34	
		FINAL		30JAN2003	16:30	9	2		80		35	
	E0026017	BSLN		26FEB2003	11:50	-8	2		89		32	
		FINAL		21MAR2003	11:10	16	3		104		32	
	E0026018	BSLN		06MAR2003	16:30	-14	1		138		27	
		FINAL		15MAY2003	14:15	57	1		129		28	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	BSLN	01MAY2003	11:40	-8	1	113	28
		FINAL	03JUL2003	9:30	56	2	90	38
	E0026029	BSLN	02JUL2003	11:10	-7	2	126	31
		FINAL	28JUL2003	13:30	20	2	125	31
	E0026030	BSLN	02JUL2003	11:50	-7	1	113	32
		FINAL	03SEP2003	17:10	57	1	140	35
	E0026031	BSLN	10JUL2003	14:00	-11	1	122	38
		FINAL	15SEP2003	11:15	57	1	118	39
	E0027003	BSLN	08JAN2003	14:40	-20	2	94	32
		FINAL	25MAR2003	11:55	57	1	72	32
	E0028004	BSLN	27SEP2002	9:45	-3	2	125	30
		FINAL	09OCT2002	14:30	10	3	115	31
	E0028006	BSLN	01OCT2002	10:00	-3	2	90	35
		FINAL	04DEC2002	10:15	62	1	104	38
	E0028008	BSLN	08OCT2002	12:45	-7	2	104	31
		FINAL	10DEC2002	12:30	57	1	144	32
	E0028009	BSLN	10OCT2002	10:45	-5	3	91	28
		FINAL	12DEC2002	13:50	59	1	97	27
	E0028016	BSLN	07NOV2002	10:15	-7	2	97	37
		FINAL	09JAN2003	11:50	57	2	116	34
	E0028017	*	12NOV2002	9:45		2	136	28
	E0028027	BSLN	14JAN2003	10:15	-7	2	121	35

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	BSLN		28JAN2003	10:00	-7	3		103		36	
		FINAL		04APR2003	10:55	60	3		93		29	
	E0028034	BSLN		20MAR2003	9:40	-12	2		109		34	
		FINAL		02JUN2003	12:54	63	2		95		32	
	E0028038	BSLN		18APR2003	10:20	-7	1		64		36	
		FINAL		18JUN2003	13:45	55	1		91		33	
	E0028043	BSLN		29MAY2003	11:55	-7	3		98		32	
		FINAL		29JUL2003	8:25	55	4		102		32	
	E0028045	BSLN		09JUN2003	13:00	-9	1		156	H	24	
		FINAL		11SEP2003	12:50	86	3		129		24	
	E0029005	BSLN	*	14NOV2002	13:00	-13	2		113		31	
		BSLN		21NOV2002	10:30	-6	1		100		33	
		FINAL		21JAN2003	12:50	56	1		80		30	
	E0030001	BSLN		12NOV2002	15:15	-7	3		108		27	
		FINAL		16JAN2003	12:07	59	5	#	89		28	
	E0030008	BSLN		07JAN2003	14:33	-7	2		89		30	
		FINAL		18MAR2003	10:42	64	2		88		37	
	E0030011	BSLN		16JAN2003	16:10	-11	1		106		34	
		FINAL		24MAR2003	14:35	57	1		82		32	
	E0030015	BSLN		13FEB2003	12:05	-8	1		100		39	
		FINAL		22APR2003	12:10	61	1		97		36	
	E0030022	BSLN		10JUN2003	11:15	-6	3		75		38	
		FINAL		14AUG2003	15:30	60	3		79		41	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	BSLN	20NOV2002	17:05	-7	1L	143	28	
		FINAL	23JAN2003	12:55	58	1	143	25	
	E0031003	BSLN	03DEC2002	16:07	-7	2	125	33	
		FINAL	04FEB2003	16:20	57	2	99	36	
	E0033015	BSLN	03APR2003	17:05	-7	0L	86	33	
		FINAL	04JUN2003	11:00	56	1	93	33	
	E0034002	BSLN	18MAR2003	9:25	-7	1	106	33	
		FINAL	16APR2003	14:40	23	1	130	35	
	E0034003	BSLN	11APR2003	10:10	-13	1	112	32	
		FINAL	19JUN2003	15:50	57	1	100	32	
	E0034006	BSLN	25APR2003	11:33	-21	2	113	31	
		FINAL	10JUL2003	9:54	56	5	115	28	
	E0034008	BSLN	16MAY2003	13:26	-8	1	94	32	
		FINAL	21JUL2003	10:07	59	1	77	36	
	E0035003	BSLN	15NOV2002	10:30	-7	1	125	35	
	E0035005	BSLN	26NOV2002	10:00	-7	1	72	26	
	E0035014	BSLN	28JAN2003	11:10	-6	1	109	33	
		FINAL	31MAR2003	9:20	57	1	115	30	
	E0035024	BSLN	15MAY2003	11:30	-8	2	100	27	
		FINAL	18JUL2003	9:00	57	2	88	28	
	E0036005	BSLN	24JUN2003	10:45	-7	2	131	40	
		FINAL	27AUG2003	12:45	58	1	112	41	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0037002	BSLN		18DEC2002	12:10	-8	2		104		33
		FINAL		20FEB2003	13:25	57	1		76		36
	E0037005	BSLN		27FEB2003	15:00	-7	4		91		26
		FINAL		01MAY2003	14:15	57	3		84		24
	E0037006	BSLN		07MAR2003	12:00	-7	2		75		36
		FINAL		09MAY2003	12:18	57	2		69		35
	E0039006	BSLN	*	11NOV2002	10:05	-49	1		122		32
		BSLN		10DEC2002	11:35	-20	0L		117		37
		FINAL		24FEB2003	10:58	57	1		76		31
	E0039015	BSLN		02JAN2003	10:20	-21	2		91		38
		FINAL		20MAR2003	9:30	57	3		73		38
	E0039024	BSLN		14FEB2003	8:50	-13	1		108		31
		FINAL		25APR2003	16:05	58	2		118		32
	E0039025	BSLN		26FEB2003	11:00	-20	2		116		35
		FINAL		27MAY2003	10:00	71	1		107		34
	E0039041	BSLN		08APR2003	9:40	-7	3		81		36
		FINAL		11JUN2003	11:25	58	2		80		36
	E0039044	BSLN		06MAY2003	10:30	-16	1		157	H	32
		FINAL		23JUL2003	18:20	63	1		106		35
	E0039046		*	06MAY2003	11:46		2		136		31
			*	03JUN2003	10:25		2		109		32
	E0039051	BSLN		23MAY2003	9:30	-24	2		85		32
		FINAL		12AUG2003	14:45	58	1		80		37

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0039053	BSLN	16JUN2003	13:25	-25	1	76	36	
		FINAL	08SEP2003	12:45	60	1	100	38	
	E0039057	BSLN	02JUL2003	19:50	-12	1	86	36	
		FINAL	09SEP2003	9:25	58	2	84	44	H
	E0041003	BSLN	16JAN2003	17:30	-12	1	95	37	
		FINAL	25MAR2003	9:55	57	2	89	34	
	E0041008	BSLN	26MAR2003	15:35	-12	0	102	33	
		FINAL	02JUN2003	15:30	57	0L	99	39	
	E0042001	BSLN	17JUN2003	9:45	-15	2	129	31	
		FINAL	26AUG2003	10:50	56	1	71	31	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BSLN		26FEB2003	14:25	-14	1	104	30
		FINAL		07MAY2003	13:45	57	1	88	26
	E0003018	BSLN		06MAY2003	16:22	-7	2	103	31
		FINAL		08JUL2003	14:18	57	1	76	31
	E0005011	BSLN		17OCT2002	15:00	-7	1	112	38
	E0005030	BSLN		18MAR2003	14:00	-8	1	107	29
	E0005036	BSLN		28APR2003	13:30	-8	3	111	37
		FINAL		27MAY2003	10:00	22	4	102	32
	E0006015	BSLN		07FEB2003	9:30	-4	1	90	36
		FINAL		08APR2003	12:00	57	1	62	34
	E0006016	BSLN		07FEB2003	12:55	-10	3	107	32
		FINAL		18APR2003	12:15	61	2	117	31
	E0007008	BSLN		08APR2003	9:55	-10	3	91	31
		FINAL		02JUL2003	14:00	76	3	107	32
	E0009002	BSLN		30OCT2002	11:45	-20	4	131	35
		FINAL		15JAN2003	13:47	58	7H#	93	35
		FINAL	*	21JAN2003	12:20	64	15H#		
	E0009006	BSLN		23JAN2003	17:50	-5	3	89	34
		FINAL		25MAR2003	16:20	57	1	73	35
	E0009009	BSLN		27FEB2003	15:00	-13	3	95	35
		FINAL		24MAR2003	13:40	13	2	79	34
	E0010015	BSLN	*	30JAN2003	10:35	-21	7H#		
		BSLN		30JAN2003	10:35	-21		84	32

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	BSLN	17FEB2003	13:50	-3	5				
		FINAL	15APR2003	13:29	55	4		53	L	31
	E0011004	BSLN	17DEC2002	11:00	-7	2		86		34
		FINAL	18FEB2003	9:00	57	3		62		39
	E0011007	BSLN	12DEC2002	10:43	-7	1		108		30
		FINAL	13FEB2003	8:00	57	2		97		32
	E0011018	BSLN	15MAY2003	12:30	-7	2		122		34
		FINAL	17JUL2003	17:30	57	0		109		36
	E0011024	BSLN	17JUN2003	12:10	-7	1		91		39
		FINAL	21AUG2003	13:00	59	2		97		36
	E0015003	BSLN	13NOV2002	12:20	-12	4		91		27
		FINAL	02DEC2002	10:55	8	4		57	L	27
	E0019003	BSLN	30OCT2002	9:10	-22	6H#		99		28
		FINAL	16JAN2003	11:25	57	2		94		34
	E0019007	BSLN	06NOV2002	10:32	-7	1		77		38
		FINAL	07JAN2003	8:30	56	2		97		39
	E0019014	BSLN	17DEC2002	11:02	-23	1		91		37
		FINAL	22JAN2003	9:00	14	2		91		36
	E0019018	BSLN	14JAN2003	10:45	-16	1		113		32
		FINAL	27MAR2003	9:30	57	2		109		30
	E0019022	BSLN	23JAN2003	12:00	-7	2		90		30
		FINAL	27MAR2003	15:10	57	2		97		31
	E0019027	BSLN	20FEB2003	10:50	-7	1		117		40

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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	BSLN		06MAR2003	14:50	-26	1	86	26
		FINAL		28MAY2003	11:00	58	3	84	27
	E0019034	BSLN		10MAR2003	16:55	-8	1	102	30
	E0019036	BSLN		18MAR2003	9:15	-7	1	59	40
	E0019039	BSLN		22APR2003	11:00	-9	2	93	35
		FINAL		08MAY2003	15:30	8	1	75	39
	E0019041	BSLN		14MAY2003	10:50	-7	1	98	29
		FINAL		16JUL2003	11:10	57	1	80	33
	E0019049	BSLN		03JUL2003	13:40	-7	0	104	34
		FINAL		08SEP2003	12:10	61	1	109	35
	E0022052	BSLN		01APR2003	10:50	-9	2	98	33
		FINAL		05JUN2003	9:32	57	4	82	30
	E0022064	BSLN		01MAY2003	10:40	-5	1	109	31
		FINAL		01JUL2003	12:30	57	1	102	37
	E0022073	BSLN		20JUN2003	14:10	-6	1	133	33
		FINAL		21AUG2003	9:45	57	6H#	102	37
	E0023002	BSLN		25OCT2002	16:00	-11	2	120	34
	E0023017	BSLN		14MAR2003	13:00	-11	2	126	30
		FINAL		22MAY2003	12:30	59	2	106	31
	E0023021	BSLN	*	10APR2003	10:20	-13	3	127	31
		BSLN		16APR2003	15:00	-7	3	124	30
		FINAL		17JUN2003	16:00	56	1	129	31

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	BSLN		07MAY2003	13:30	-9	2	117		31
		FINAL		09JUL2003	13:00	55	2	109		32
	E0023030	BSLN		21MAY2003	10:00	-13	1	98		31
		FINAL		30JUL2003	15:30	58	1	82		32
	E0023040	BSLN		25JUN2003	15:00	-8	1	102		35
		FINAL		05SEP2003	10:00	65	1	104		38
	E0026014	BSLN		12FEB2003	11:40	-7	1	176	H	30
		FINAL		19MAR2003	10:35	29	1	134		29
	E0026019	BSLN		10MAR2003	11:45	-7	1	97		29
		FINAL		12MAY2003	9:10	57	1	85		38
	E0027005	BSLN		19DEC2002	14:50	-7	4	126		32
		FINAL		20FEB2003	11:28	57	2	82		32
	E0029009	BSLN		13JAN2003	12:50	-7	1	103		38
		FINAL		18MAR2003	9:05	58	1	69		34
	E0029021	BSLN	*	03MAR2003	10:40	-15	2	97		31
		BSLN		18MAR2003	9:50	1	2	93		31
		FINAL		15MAY2003	12:30	59	2	71		30
		FINAL	*	27MAY2003	8:40	71	2	104		33
	E0029026	BSLN		07APR2003	9:10	-7	1	121		33
		FINAL		10JUN2003	15:00	58	1	106		35
	E0029030	BSLN		13MAY2003	11:20	-14	1	129		27
		FINAL		23JUL2003	17:25	58	1	89		26
	E0031008	BSLN		05FEB2003	11:40	-23	1	82		29
		FINAL		24APR2003	13:17	56	1	66		30

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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	BSLN		14APR2003	10:35	-7	2	127	31	
		FINAL		13MAY2003	10:50	23	3	113	32	
	E0031021	BSLN		18APR2003	10:40	-7	1	118	29	
		FINAL		19JUN2003	10:40	56	4	99	32	
	E0031029	BSLN		05JUN2003	10:45	-13	3	102	32	
	E0033002	BSLN		23DEC2002	12:15	-18	2	111	33	
		FINAL		07MAR2003	11:25	57	2	117	30	
	E0033006	BSLN		15JAN2003	10:25	-8	2	135	33	
		FINAL		12FEB2003	12:30	21	1	124	39	
	E0033021	BSLN		25JUN2003	14:40	-7	1	125	31	
		FINAL		18AUG2003	16:20	48	5	111	28	
	E0035013	BSLN		27JAN2003	10:30	-8	2	89	29	
		FINAL		10FEB2003	11:05	7	1	99	30	
	E0035015	BSLN		03FEB2003	10:30	-8	3	120	32	
		FINAL		18FEB2003	11:20	8	2	131	33	
	E0035016	BSLN		10MAR2003	11:00	-25	1	91	25	
	E0035023	BSLN		06MAY2003	10:30	-7	1	126	32	
	E0039052	BSLN		29MAY2003	10:25	-22	2	113	31	
	E0039056	BSLN		01JUL2003	12:50	-14	1	118	32	
	E0040003	BSLN		09JUL2003	14:00	-10	3	91	33	
		FINAL		12SEP2003	11:00	56	6H#	75	41	H
		FINAL	*	25SEP2003	11:30	69	2	66	38	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BSLN	14FEB2003	10:30	-17	2		126		28	
		FINAL	02MAY2003	10:30	61	3		86		30	
	E0002011	BSLN	16APR2003	11:30	-13	2		79		38	
		FINAL	25JUN2003	11:20	58	2		58		39	
	E0003010	BSLN	28JAN2003	9:10	-6	2		94		28	
		FINAL	31MAR2003	16:20	57	1		75		29	
	E0003011	BSLN	28JAN2003	11:47	-7	1		88		30	
	E0003016	BSLN	01MAY2003	11:40	-21	2		94		28	
		FINAL	13JUN2003	8:45	23	3		106		36	
	E0003019	BSLN	19JUN2003	11:30	-8	1		95		37	
		FINAL	21AUG2003	8:50	56	3		82		41	H
	E0003020	BSLN	27JUN2003	8:55	-26	1		163	H	35	
		FINAL	17SEP2003	15:00	57	1		98		36	
	E0004001	BSLN	23SEP2002	11:00	-7	1		117		35	
		FINAL	05NOV2002	13:30	37	1		122		32	
	E0004009	BSLN	17DEC2002	10:10	-9	1		171	H	26	
		FINAL	19FEB2003	16:00	56	1		85		28	
	E0004012	BSLN	07JAN2003	12:45	-7	1		116		36	
		FINAL	11MAR2003	11:35	57	1		67	L	33	
	E0004015	BSLN	06FEB2003	10:05	-14	2		135		34	
		FINAL	15APR2003	9:10	55	2		73		33	
	E0005003	BSLN	23SEP2002	15:00	-9	2		77		35	
		FINAL	26NOV2002	13:25	56	1		53	L	33	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0005005	BSLN		24SEP2002	15:20	-6	1		82		31
	E0005007	BSLN		02OCT2002	12:40	-7	2		109		25
		FINAL		04DEC2002	14:20	57	2		77		28
	E0005008	BSLN		08OCT2002	18:00	-7	2		94		35
		FINAL		11DEC2002	16:00	58	1		71		29
	E0005009	BSLN		09OCT2002	10:00	-20	1		84		36
	E0005010	BSLN		14OCT2002	13:00	-7	2		124		33
		FINAL		17DEC2002	14:25	58	1		72	L	34
		FINAL	*	23DEC2002	16:00	64	2		84		37
	E0005012	BSLN		24OCT2002	7:00	-21	4		107		29
		FINAL		07JAN2003	11:00	55	1		93		35
	E0005014	BSLN		05NOV2002	16:30	-8	2		103		33
		FINAL		06JAN2003	10:00	55	6H#		68		37
	E0005022	BSLN		27JAN2003	10:30	-2	1		88		39
		FINAL		11MAR2003	10:10	42	1		90		38
	E0005025	BSLN		20FEB2003	13:20	-7	1		109		34
		FINAL		03APR2003	11:30	36	1		104		34
	E0006019	BSLN		26MAR2003	11:35	-12			113		35
		FINAL		03JUN2003	12:00	58	1		86		32
	E0007005	BSLN		27JAN2003	14:30	-4	1		145		24
		FINAL		28MAR2003	13:30	57	2		79		32
	E0007015	BSLN		10JUL2003	7:35	-6	2		136		29
		FINAL		10SEP2003	7:40	57	2		67		37

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0009001	BSLN	29OCT2002	15:30	-14	1	81		33
	E0010002	BSLN	22NOV2002	9:35	-3	2	135		34
		FINAL	02DEC2002	9:05	8	2	111		31
	E0010009	BSLN	18DEC2002	9:42	-8	1	102		36
		FINAL	19FEB2003	13:59	56	1	64		39
	E0010010	BSLN	20DEC2002	8:45	-10	2	89		38
		FINAL	13JAN2003	10:28	15	2	75		38
	E0010014	BSLN	14JAN2003	9:05	-14	2	99		32
		FINAL	25MAR2003	11:05	57	2	81		33
	E0010017	BSLN	05FEB2003	8:51	-20	1	104		35
		FINAL	22APR2003	10:20	57	1	95		34
	E0010023	BSLN	10APR2003	9:22	-7	2	115		33
		FINAL	01MAY2003	10:19	15	1	93		31
	E0010027	BSLN	05JUN2003	9:10	-11		109		27
		BSLN	12JUN2003	10:15	-4	1			
		FINAL	01JUL2003	13:00	16	1	111		28
	E0010029	BSLN	10JUN2003	9:25	-9	1	143		31
	E0011022	BSLN	02JUN2003	11:00	-7	1	153		30
		FINAL	05AUG2003	10:30	58	1	120		27
	E0013006	BSLN	06MAR2003	10:15	-7	1	108		30
		FINAL	24MAR2003	12:42	12	1	104		32
	E0013012	BSLN	29APR2003	9:48	-8	0	158	H	35
		FINAL	02JUL2003	10:05	57	0L	84		36

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0013014	BSLN	08MAY2003	11:15	-26	1	94		34
		FINAL	30JUN2003	12:21	28	2	107		37
	E0014005	BSLN	04MAR2003	17:20	-7	0	117		27
		FINAL	06MAY2003	12:20	57	0L	104		31
	E0014007	BSLN	25MAR2003	17:50	-7	2	108		29
		FINAL	22APR2003	13:50	22	2	118		33
	E0014011	BSLN	06MAY2003	16:45	-7	2	113		32
		FINAL	08JUL2003	15:50	57	2	117		33
	E0014012	BSLN	19MAY2003	10:05	-8	1	108		27
		FINAL	24JUN2003	18:40	29	1	93		33
	E0015001	BSLN	11NOV2002	9:10	-18	3	116		37
		FINAL	20JAN2003	7:30	53	1	109		37
	E0015008	BSLN	13DEC2002	9:30	-6	1	94		33
	E0016003	BSLN	10JAN2003	9:30	-14	2	84		34
	E0016005	BSLN	21FEB2003	8:45	-4	3	112		34
		FINAL	22APR2003	8:30	57	2	73		36
	E0018007	BSLN	16DEC2002	10:15	-11	2	171	H	23
		FINAL	10JAN2003	14:15	15	3	171	H	27
	E0019005	BSLN	30OCT2002	11:50	-6		127		34
		FINAL	02JAN2003	14:00	59	0L	72		36
	E0019015	BSLN	19DEC2002	10:49	-14	1	93		33
		FINAL	27FEB2003	11:23	57	1	76		34

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	BSLN		21NOV2002	15:20	-18	1		104		35
		FINAL		22JAN2003	16:15	45	0		58		40
		FINAL	*	24FEB2003	11:50	78	1		85		38
	E0020010	BSLN		31JAN2003	9:15	-5	1		62		33
		FINAL		02APR2003	10:30	57	1		54	L	29
	E0020014	BSLN		11MAR2003	10:00	-7	1		93		29
		FINAL		12MAY2003	11:15	56	1		93		34
	E0020021	BSLN		13MAY2003	9:45	-6	1		99		28
		FINAL		14JUL2003	13:25	57	1		63		32
	E0020023	BSLN		09JUN2003	19:05	-8	1		125		31
		FINAL		11AUG2003	11:40	56	0L		84		32
	E0022007	BSLN		01NOV2002	10:23	-6	2		107		36
	E0022010	BSLN		15NOV2002	10:40	-6	3		86		29
		FINAL		16JAN2003	18:00	57	2		71		39
	E0022012	BSLN		29NOV2002	15:40	-6	2		93		34
		FINAL		30JAN2003	12:00	57	1		72		34
	E0022019	BSLN		06DEC2002	10:10	-5	1		122		39
		FINAL		06FEB2003	11:20	58	1		90		40
	E0022025	BSLN		08JAN2003	10:10	-20	1		97		33
		FINAL		04FEB2003	11:30	8	1		69		35
	E0022033	BSLN		12FEB2003	10:05	-6	1		122		32
		FINAL		15APR2003	12:10	57	1		72		27
	E0022034	BSLN		12FEB2003	12:40	-6	2		109		34

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR I)	E0022034	FINAL	15APR2003	14:00	57	2		72		31	
	E0022038	BSLN	21FEB2003	11:05	-7	1		72		42	H
		FINAL	14APR2003	9:40	46	2		77		36	
	E0022039	BSLN	27FEB2003	11:15	-7	1		67		39	
		FINAL	01MAY2003	12:50	57	1		54	L	37	
	E0022046	BSLN	14MAR2003	8:00	-6	2		120		28	
		FINAL	16MAY2003	8:05	58	3		76		28	
	E0022048	BSLN	26MAR2003	9:58	-6	2		122		36	
	E0022051	BSLN	01APR2003	10:15	-6	1		178	H	24	
		FINAL	02JUN2003	10:45	57	1		118		25	
	E0022053	BSLN	04APR2003	12:50	-7	1		94		31	
	E0022058	BSLN	14APR2003	10:25	-7	2		99		36	
		FINAL	22MAY2003	14:00	32	1		85		36	
	E0022061	BSLN	25APR2003	9:37	-5	1		93		35	
		FINAL	26JUN2003	12:30	58	1		94		37	
	E0022062	BSLN	28APR2003	7:43	-7	2		117		31	
		FINAL	23MAY2003	7:40	19	2		109		34	
	E0022068	BSLN	14MAY2003	10:23	-9	5		109		28	
	E0022069	BSLN	04JUN2003	7:40	-6	1		108		33	
		FINAL	05AUG2003	9:45	57	1		125		35	
	E0022071	BSLN	16JUN2003	11:40	-14	2		98		34	
		FINAL	26AUG2003	9:33	58	1		51	L	39	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	BSLN	*	08NOV2002	16:00	-39	1L	125	32	
		BSLN		12DEC2002	10:00	-5	1	106	31	
		FINAL		11FEB2003	14:00	57	0L	98	38	
	E0023006	BSLN		10DEC2002	10:30	-7	2	86	31	
		FINAL		11FEB2003	11:50	57	2	88	33	
	E0023010	BSLN		28JAN2003	9:30	-7	2	67	40	
		FINAL		31MAR2003	10:00	56	2	89	36	
	E0023025	BSLN		01MAY2003	15:00	-14	2	86	34	
		FINAL		10JUL2003	13:30	57	2	85	31	
	E0023039	BSLN		24JUN2003	13:30	-7	3	117	30	
		FINAL		26AUG2003	13:30	57	0	129	35	
	E0026002	BSLN		05NOV2002	10:15	-7		117	33	
		FINAL		09JAN2003	9:25	59		134	31	
	E0026007	BSLN		06JAN2003	10:30	-10	4	81	27	
		FINAL		12MAR2003	14:25	56	2	62	33	
	E0026013	BSLN		05FEB2003	12:20	-8	3	98	32	
		FINAL		14APR2003	10:00	61	2	120	24	
	E0028007	BSLN		01OCT2002	10:30	-3	2	90	33	
		FINAL		14NOV2002	12:45	42	1	82	41	H
	E0028023	BSLN		15JAN2003	10:00	-6	3	112	34	
		FINAL		27JUN2003	15:00	158	2	93	33	
	E0028025	BSLN		08JAN2003	12:07	-5	3	93	34	
		FINAL		27JAN2003	9:25	15	4	72	38	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	BSLN		18MAR2003	10:50	-9	2	99		31	
		FINAL		22MAY2003	10:50	57	1	89		33	
	E0028035	BSLN		27MAR2003	12:00	-7	2	136		30	
		FINAL		29MAY2003	15:40	57	2	90		33	
	E0028037	BSLN	*	18APR2003	8:30	-56	2	108		32	
		BSLN		04JUN2003	8:33	-9	2	117		29	
		FINAL		08AUG2003	15:30	57	1	84		34	
	E0028039	BSLN		05MAY2003	7:10	-4	1	112		31	
		FINAL		05JUN2003	12:30	28	1	67		32	
	E0028046	BSLN		17JUN2003	13:45	-8	1	97		44	H
	E0028048	BSLN		11JUL2003	14:00	-6	1L	88		38	
	E0029008	BSLN		09DEC2002	11:40	-7	1	121		20	L
	E0029011	BSLN		14JAN2003	11:20	-8	3	95		37	
	E0029012	BSLN		04FEB2003	10:05	-7	2	104		30	
		FINAL		27MAR2003	8:45	45	1	138		27	
	E0029015	BSLN		11FEB2003	10:05	-13		154		42	H
		FINAL		14MAR2003	10:30	19	0L	212	H#	36	
	E0029018	BSLN	*	26FEB2003	16:25	-8	2	85		33	
		BSLN		06MAR2003	16:05	1	1	81		31	
	E0030014	BSLN		14FEB2003	10:35	-7	1	79		32	
		FINAL		22APR2003	12:50	61	1	69		37	
	E0030020	BSLN		13MAY2003	15:30	-16	4	97		29	

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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR I)	E0030024	BSLN	*	17JUN2003	15:35	-24	2		138		21	L
		BSLN		27JUN2003	11:20	-14	2		140		25	
		FINAL		18JUL2003	15:35	8	2		108		29	
	E0030025	BSLN		24JUN2003	16:35	-17	4		116		33	
		FINAL		19AUG2003	16:45	40			103		37	
	E0031027	BSLN		28MAY2003	9:10	-6	4		111		33	
		FINAL		29JUL2003	14:40	57	2		116		32	
	E0031030	BSLN		17JUN2003	10:46	-7	1		171	H	44	H
		FINAL		21AUG2003	11:10	59	1		109		38	
	E0033012	BSLN		05FEB2003	15:26	-5	1		113		31	
	E0034001	BSLN		17MAR2003	10:03	-3	1		127		29	
		FINAL		15MAY2003	9:55	57	2		153		30	
	E0034004	BSLN		11APR2003	11:15	-10	4		76		31	
		FINAL		16JUN2003	12:03	57	3		54	L	36	
	E0035001	BSLN		12NOV2002	11:40	-8	2		98		35	
		FINAL		14JAN2003	9:05	56	1		88		39	
	E0035006	BSLN		03DEC2002	10:45	-9	1		121		26	
		FINAL		06FEB2003	9:30	57	1		107		30	
	E0035021	BSLN		18APR2003	10:45	-7	1		111		35	
		FINAL		20JUN2003	8:15	57	2		120		36	
	E0036002	BSLN		10JUN2003	13:45	-7	1		134		32	
		FINAL		15JUL2003	10:05	29	1		140		30	
	E0036006	BSLN		24JUN2003	16:45	-9	1		95		41	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	FINAL	28AUG2003	9:50	57	2	81		43	H
	E0036007	BSLN	27JUN2003	10:00	-6	1	109		34	
		FINAL	18JUL2003	9:15	16	1	72		31	
	E0037009	BSLN	12MAY2003	9:15	-4	4	161	H	22	
		FINAL	10JUL2003	16:05	56	1	121		29	
	E0039011	BSLN	16DEC2002	17:40	-17	1	98		34	
	E0039018	BSLN	15JAN2003	9:10	-8	2	89		36	
	E0039026	BSLN	03MAR2003	9:05	-4	2	79		36	
		FINAL	02MAY2003	9:20	57	2	59		34	
	E0039028	BSLN	03MAR2003	14:15	-21	1	84		41	H
		FINAL	16MAY2003	12:25	54	2	86		35	
	E0039032	BSLN	07MAR2003	13:45	-7	1	112		31	
		FINAL	04APR2003	11:45	22	1	100		32	
	E0039034	BSLN	12MAR2003	20:05	-7	1	133		30	
		FINAL	14MAY2003	15:00	57	1	99		32	
	E0039042	BSLN	25APR2003	10:15	-12	2	97		34	
		FINAL	02JUL2003	12:50	57	1	118		28	
	E0041004	BSLN	27JAN2003	10:15	-3	2	107		33	
		FINAL	31MAR2003	12:00	61	1	106		33	
	E0041009	BSLN	22APR2003	15:15	-9		126		35	
		FINAL	16JUN2003	13:00	47		97		35	
	E0042002	BSLN	02JUL2003	12:10	-7	2	107		39	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	FINAL	02SEP2003	10:25	56	2	68	40

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BSLN	23JUN2003	10:00	-18	2		88		41	H
		FINAL	25JUL2003	9:00	15	2		80		34	
	E0003002	BSLN	22OCT2002	11:05	-7	2		100		38	
		FINAL	23DEC2002	15:35	56	1		62		41	H
	E0005031	BSLN	26MAR2003	12:30	-7	2		183	H	26	
	E0005033	BSLN	08APR2003	14:00	-8	1		63		33	
		FINAL	06MAY2003	11:20	21	1		68		37	
	E0005038	BSLN	05MAY2003	11:40	-9	1		130		31	
		FINAL	05JUN2003	13:00	23	1		103		30	
	E0007009	BSLN	14APR2003	7:48	-3	1		99		33	
	E0009010	BSLN	27FEB2003	16:55	-14	2		98		36	
	E0009011	BSLN	28APR2003	14:17	-8			133		47	H
		FINAL	09JUL2003	14:30	65			156	H	42	H
	E0010005	BSLN	11DEC2002	10:15	-7	5		108		35	
	E0011016	BSLN	14APR2003	10:00	-7	2		133		34	
		FINAL	16JUN2003	9:45	57	1		90		35	
	E0011020	BSLN	01MAY2003	9:20	-7	1		91		34	
		FINAL	15MAY2003	17:00	8	1		100		33	
	E0018002	BSLN	15NOV2002	15:35	-14	1		88		37	
		FINAL	22JAN2003	16:20	55	2		80		33	
	E0018003	BSLN	19NOV2002	13:05	-7	4		112		36	
		FINAL	10DEC2002	11:00	15	3		115		33	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	BSLN		17JAN2003	14:15	-7	1	120	31
		FINAL		06FEB2003	16:10	14	1	122	34
	E0019002	BSLN		29OCT2002	10:45	-14	1	103	33
	E0019008	BSLN	*	06NOV2002	12:35	-15	7H#	122	28
		BSLN		13NOV2002	10:30	-8	6H#	153	30
	E0019009	BSLN		06NOV2002	13:35	-8	1	91	31
	E0019016	BSLN		30DEC2002	16:55	-7	2	125	33
		FINAL		03MAR2003	16:00	57	2	86	31
	E0019020	BSLN		16JAN2003	10:10	-7	2	81	34
		FINAL		27MAR2003	10:50	64	1	72	30
	E0019021	BSLN		16JAN2003	11:45	-14	2	85	38
		FINAL		03MAR2003	13:18	33	2	76	38
	E0019024	BSLN		24JAN2003	16:00	-6	1	85	30
		FINAL		06FEB2003	12:33	8	1	90	31
	E0019031	BSLN		06MAR2003	11:35	-7	1	99	29
		FINAL		25MAR2003	10:08	13	1	85	31
	E0019035	BSLN		11MAR2003	9:28	-7	1	95	33
		FINAL		17APR2003	14:30	31	1	82	33
	E0019040	BSLN		08MAY2003	15:25	-12	1	77	34
		FINAL		17JUL2003	9:50	59	2	67	31
	E0019042	BSLN		29MAY2003	8:50	-6	1	103	37
		FINAL		20JUN2003	8:20	17	3	99	38

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	BSLN		19JUN2003	14:54	-7	1		99		38
		FINAL		16JUL2003	10:15	21	1		106		38
	E0020024	BSLN		12JUN2003	15:40	-11	1		89		33
		FINAL		20AUG2003	18:45	59	1L		82		37
	E0022044	BSLN		12MAR2003	9:50	-6	1		157	H	23
		FINAL		12MAY2003	9:55	56	0		95		27
	E0023007	BSLN		07JAN2003	14:30	-7	2		100		39
		FINAL		13MAR2003	15:00	59	1		79		31
	E0023011	BSLN		28JAN2003	11:45	-7	0L		116		33
		FINAL		01APR2003	12:00	57	2		66		30
	E0023014	BSLN		14FEB2003	15:00	-7	0L		121		38
		FINAL		25APR2003	14:00	64	1		80		39
	E0023019	BSLN		21MAR2003	14:00	-17	0L		162	H	33
		FINAL		03JUN2003	13:30	58	2		81		32
	E0023022	BSLN		10APR2003	16:00	-8	4		81		35
		FINAL		12JUN2003	15:40	56	2		76		39
	E0023023	BSLN		17APR2003	10:00	-8	1		102		33
		FINAL		01MAY2003	14:00	7	2		93		35
	E0023029	BSLN		16MAY2003	14:00	-7	4		135		28
	E0023031	BSLN	*	22MAY2003	12:00	-33	7H#		88		30
		BSLN		19JUN2003	10:00	-5	3		154		33
		FINAL		19AUG2003	11:00	57	3		77		32
	E0023041	BSLN		03JUL2003	11:00	-6	3		88		29

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	FINAL		05SEP2003	13:00	59	2		77		38	
	E0023043	BSLN		07JUL2003	15:00	-7	1		84		32	
		FINAL		09SEP2003	10:30	58	1		63		44	H
	E0026003	BSLN	*	25NOV2002	12:20	-9	2		75		35	
		BSLN		02DEC2002	9:25	-2	1		103		31	
		FINAL		03FEB2003	10:50	62	0		111		32	
	E0026005	BSLN		23DEC2002	12:40	-7	2		55	L	41	H
		FINAL		06JAN2003	15:25	8	1		63		40	
	E0026009	BSLN		10JAN2003	10:20	-5	1		93		30	
		FINAL		21JAN2003	9:50	7	1		79		36	
	E0026015	BSLN		20FEB2003	11:30	-7	2		98		29	
		FINAL		25APR2003	9:50	58	1		59		29	
	E0026023	BSLN		23APR2003	10:50	-7	2		130		35	
		FINAL		27JUN2003	12:25	59	3		111		36	
	E0027016	BSLN	*	19MAR2003	11:55	-21	1		77		29	
		BSLN		04APR2003	9:50	-5	1		88		27	
		FINAL		03JUN2003	10:18	56	1		88		32	
	E0027018	BSLN		21MAR2003	11:30	-4	1		84		34	
		FINAL		22MAY2003	10:05	59	2		90		35	
	E0028032	BSLN		20MAR2003	13:00	-5	2		80		36	
		FINAL		06JUN2003	11:38	74	2		68		34	
	E0029003	BSLN		28OCT2002	12:30	-7	1		80		32	
		FINAL		30DEC2002	9:45	57	2		68		36	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0029020	BSLN	25FEB2003	10:12	-8	1	95	37
	E0031005	BSLN	13DEC2002	16:00	-7	2	104	27
		FINAL	14FEB2003	12:10	57	2	93	34
	E0031006	BSLN	31JAN2003	11:25	-18	2	82	40
		FINAL	15APR2003	9:25	57	3	59	36
	E0031010	BSLN	12FEB2003	14:50	-7	2	116	37
		FINAL	06MAR2003	12:50	16	4	72	30
	E0031011	BSLN	18FEB2003	11:50	-9	1	91	33
		FINAL	24APR2003	9:25	57	1	82	31
	E0031015	BSLN	14MAR2003	8:40	-12	1	81	35
		FINAL	01APR2003	11:55	7	1	73	32
	E0031031	BSLN	01JUL2003	10:30	-7	1	112	30
		FINAL	28AUG2003	10:35	52	1	124	33
	E0033009	BSLN	22JAN2003	13:40	-21	2	68	34
	E0034009	BSLN	10JUN2003	13:00	-9	1	80	35
		FINAL	18AUG2003	17:25	61	1	76	37
	E0037007	BSLN	04APR2003	11:30	-7	2	95	29
	E0037012	BSLN	11JUL2003	13:00	-5	1	111	30
		FINAL	08SEP2003	13:20	55	1	85	36
	E0039019	BSLN	20JAN2003	14:50	-17	1	115	31
		FINAL	03APR2003	11:05	57	1	76	33
	E0039043	BSLN	28APR2003	10:15	-10	2	102	33

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0002001	BSLN		17DEC2002	15:10	-13	4	120		35
		FINAL		26FEB2003	8:45	59	13H#	116		32
	E0002003	BSLN		03JAN2003	11:50	-19	4	113		31
		FINAL		18MAR2003	12:10	56	1	125		27
	E0002004	BSLN		14JAN2003	8:15	-11	3	79		38
	E0002008	BSLN		14FEB2003	16:00	-11	3	76		33
		FINAL		23APR2003	14:25	58	3	93		39
	E0002016	BSLN		14JUL2003	11:00	-10	2	131		25
		FINAL		17SEP2003	11:15	56	1	133		26
	E0003008	BSLN		21JAN2003	12:45	-7	1	68		33
	E0004003	BSLN		02OCT2002	11:00	-8	2	64		33
	E0004006	BSLN		28OCT2002	9:55	-7	2	118		32
		FINAL		06JAN2003	10:55	64	2	120		35
	E0004016	BSLN		12FEB2003	15:10	-7	0L	147		32
		FINAL		17APR2003	17:10	58	1L	72	L	34
	E0004024	BSLN		25JUN2003	16:00	-8	1	125		31
		FINAL		28AUG2003	9:50	57	1	139		33
	E0005006	BSLN		24SEP2002	15:30	-9	2	103		27
	E0005017	BSLN	*	11DEC2002	10:30	-19	1	126		28
		BSLN		23DEC2002	12:30	-7	2	134		24
		FINAL		04MAR2003	13:00	65	2	102		30
	E0005019	BSLN		19DEC2002	14:00	-27		145		25

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
PLACEBO (BIPOLAR I)	E0005019	BSLN		08JAN2003	11:55	-7	1			
		FINAL		23JAN2003	15:45	9	1	126	22	
	E0005026	BSLN		28FEB2003	10:15	-6	2	77	34	
		FINAL		02APR2003	9:40	28	3	84	34	
	E0005039	BSLN		15MAY2003	9:00	-7	2	111	27	
		FINAL		16JUL2003	8:40	56	3	108	26	
	E0005043	BSLN		02JUL2003	8:30	-7	3	106	35	
		FINAL		03SEP2003	9:45	57	1	103	40	
	E0006020	BSLN		02MAY2003	13:30	-11	3	93	32	
		FINAL		08JUL2003	14:45	57	4	104	31	
		FINAL	*	10JUL2003	16:30	59	3	103	35	
	E0007001	BSLN		16DEC2002	9:25	-15	1	89	31	
		FINAL		24FEB2003	8:43	56	1	80	33	
	E0007003	BSLN		13JAN2003	10:30	-17	1	79	34	
		FINAL		01APR2003	13:30	62	1	112	37	
	E0007006	BSLN		24FEB2003	11:00	-9	2	100	35	
		FINAL		27MAR2003	10:50	23	1	104	34	
	E0009004	BSLN		19NOV2002	12:30	-7	1	89	32	
		FINAL		18DEC2002	14:50	23	1	67	35	
	E0009012	BSLN		16JUN2003	14:45	-9	2	130	37	
		FINAL		03JUL2003	17:45	9	1	102	35	
	E0010008	BSLN		11DEC2002	9:15	-7	2	85	35	
	E0010018	BSLN		26FEB2003	8:51	-21	1	90	42	H

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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0010018	FINAL		14MAY2003	10:45	57	0	72	39
	E0010028	BSLN		09JUN2003	8:46	-7	2	100	37
		FINAL		15JUL2003	13:50	30	1	116	33
	E0011008	BSLN	*	17DEC2002	12:30	-44	1	104	39
		BSLN		23JAN2003	9:20	-7	2	95	38
		FINAL		13FEB2003	12:30	15	1	103	40
	E0011009	BSLN		19DEC2002	10:15	-8	1	102	32
		FINAL		20FEB2003	9:00	56	1	89	37
	E0011010	BSLN		03FEB2003	10:00	-7	2	79	34
		FINAL		19MAR2003	8:45	38	2	89	35
	E0013001	BSLN		01NOV2002	8:50	-13	1	144	38
		FINAL		10JAN2003	10:45	58	2	126	37
	E0013003	BSLN		07NOV2002	9:25	-5	1	109	39
		FINAL		06JAN2003	13:17	56	1	120	34
	E0013005	BSLN		13FEB2003	11:42	-5	2	108	35
		FINAL		15APR2003	12:16	57	2	99	32
	E0013013	BSLN		01MAY2003	10:14	-5	2	75	31
		FINAL		30MAY2003	9:55	25	5	86	33
	E0014002	BSLN		19FEB2003	16:35	-7	1	97	34
		FINAL		10APR2003	13:05	44	2	112	32
	E0014004	BSLN		04MAR2003	11:40	-8	1	120	29
		FINAL		15APR2003	11:40	35	2	111	27
	E0014009	BSLN	*	15APR2003	14:45	-8	2	104	31

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0014009	BSLN	17APR2003	12:30	-6	2	102	30
		FINAL	16MAY2003	8:55	24	2	95	29
	E0014015	BSLN	11JUN2003	10:15	-7	3	117	30
	E0014017	BSLN	17JUN2003	17:00	-10	3	126	32
		FINAL	19AUG2003	17:05	54	2	120	37
	E0014018	BSLN	24JUN2003	16:35	-7	2	81	38
		FINAL	27AUG2003	16:00	58	2	100	40
	E0015005	BSLN	25NOV2002	13:15	-7	3	60	32
		FINAL	18DEC2002	9:30	17	4	72	36
	E0017002	BSLN	08MAY2003	17:00	-26	1	106	33
		FINAL	13JUN2003	16:00	11	0L	127	33
	E0018009	BSLN	17DEC2002	10:45	-20	1	97	34
		FINAL	14JAN2003	13:15	9	2	103	35
	E0018010	BSLN	09JAN2003	9:30	-7	1	111	31
		FINAL	13MAR2003	9:20	57	1	117	30
	E0018015	BSLN	21JAN2003	11:20	-7	5	89	30
		FINAL	27MAR2003	10:50	59	6H#	113	30
	E0020015	BSLN	18MAR2003	13:30	-9	2	134	29
		FINAL	23MAY2003	13:40	58	2	133	34
	E0020017	BSLN	27MAR2003	12:00	-7	1	122	31
		FINAL	03JUN2003	17:40	62	1	104	35
	E0020020	BSLN	07MAY2003	15:00	-5	3	67	33
		FINAL	23MAY2003	14:00	12	2	77	30

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
PLACEBO (BIPOLAR I)	E0020022	BSLN		09JUN2003	13:05	-7	2	120	29	
		FINAL		11AUG2003	9:30	57	3	126	30	
	E0022001	BSLN		09OCT2002	14:20	-19	2	76	39	
		FINAL		26DEC2002	17:55	60	2	79	33	
	E0022004	BSLN	*	17OCT2002	8:48	-11	1	102	41	H
		BSLN		28OCT2002	9:47	1	1	76	38	
		FINAL		23DEC2002	10:15	57	1	81	38	
	E0022005	BSLN	*	18OCT2002	7:40	-21	19H#			
		BSLN		18OCT2002	7:40	-21		76	29	
		BSLN		01NOV2002	11:15	-7	5			
		FINAL		03JAN2003	9:20	57	10H#	80	30	
	E0022011	BSLN		21NOV2002	9:25	-8	5 #	100	37	
	E0022015	BSLN	*	29NOV2002	13:50	-11	2	95	35	
		BSLN		10DEC2002	16:10	1	0L	91	35	
		FINAL	*	26DEC2002	12:15	17	1	106	40	
		FINAL		06FEB2003	9:50	59	3	103	35	
	E0022016	BSLN		03DEC2002	12:10	-14	1	95	34	
		FINAL		11FEB2003	11:05	57	1	94	38	
	E0022020	BSLN		05DEC2002	12:21	-7	2	108	32	
		FINAL		23JAN2003	16:20	43	1	95	31	
		FINAL	*	28JAN2003	10:35	48	2	107	29	
	E0022023	BSLN		20DEC2002	14:28	-5	2	91	32	
		FINAL		20FEB2003	10:05	58	3	82	34	
	E0022029	BSLN		10FEB2003	12:30	-9	2	94	31	
		FINAL		14APR2003	9:45	55	1	124	33	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0022041	BSLN		11MAR2003	9:53	-7	2	125	26
		FINAL		13MAY2003	9:18	57	2	117	29
	E0022042	BSLN		05MAR2003	9:50	-7	2	89	35
		FINAL		12MAY2003	9:35	62	3	86	34
	E0022043	BSLN		11MAR2003	13:50	-9	3	108	29
		FINAL		12MAY2003	8:05	54	2	94	32
	E0022054	BSLN		07APR2003	11:25	-4	1	115	34
	E0022059	BSLN		23APR2003	15:30	-13	1	84	34
		FINAL		08JUL2003	16:30	64	1	115	34
	E0022065	BSLN		01MAY2003	9:30	-6	1	126	24
		FINAL		02JUL2003	8:50	57	2	124	31
	E0022070	BSLN		05JUN2003	11:40	-7	2	88	32
		FINAL		18JUN2003	15:15	7	1	103	34
	E0023001	BSLN	*	24OCT2002	13:30	-22	10H#	99	34
		BSLN		13NOV2002	13:30	-2	2	134	34
		FINAL		14JAN2003	13:30	61	2	121	35
	E0023009	BSLN		24JAN2003	11:30	-18	2	94	33
		FINAL		08APR2003	11:15	57	1	94	29
	E0023028	BSLN		16MAY2003	12:15	-13	3	115	29
		FINAL		21JUL2003	11:00	54	3	111	30
	E0023033	BSLN		30MAY2003	12:10	-6	2	108	32
		FINAL		12JUN2003	13:15	8	2	95	37
	E0023047	BSLN		11JUL2003	15:00	-7	4	113	29

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
PLACEBO (BIPOLAR I)	E0023047	FINAL		16SEP2003	13:00	61	1	117	34	
	E0025001	BSLN		25MAR2003	16:00	-7	2	133	29	
		FINAL		23APR2003	10:30	23	2	130	30	
	E0026012	BSLN		05FEB2003	11:00	-15	2	84	35	
		FINAL		17APR2003	9:10	57	2	71	35	
	E0026020	BSLN		28MAR2003	10:50	-4	1	112	30	
		FINAL		22APR2003	14:05	22	1	113	33	
	E0026024	BSLN		25APR2003	12:30	-7	1	106	39	
	E0026028	BSLN		06JUN2003	10:20	-14	2	73	41	H
		FINAL		23JUL2003	10:00	34	2	75	42	H
	E0028001	BSLN		07OCT2002	14:00	-3	2	88	31	
		FINAL		03DEC2002	9:50	55	1	108	29	
	E0028003	BSLN		23SEP2002	9:10	-7	2	104	31	
		FINAL		26NOV2002	9:20	58	3	107	33	
	E0028005	BSLN		30SEP2002	11:00	-3	1	99	33	
		FINAL		31OCT2002	12:15	29	1	109	31	
	E0028010	BSLN		15OCT2002	11:00	-21	1	112	29	
		FINAL		31DEC2002	9:20	57	2	115	27	
	E0028011	BSLN	*	16OCT2002	15:10	-50	2	97	36	
		BSLN	*	22OCT2002	8:30	-44	2	89	39	
		BSLN		25NOV2002	9:00	-10	1	102	35	
		FINAL		30JAN2003	12:35	57	1	93	37	
	E0028030	BSLN		26FEB2003	11:30	-6	3	118	38	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0028030	FINAL	30APR2003	12:35	58	2	117		33
	E0028031	BSLN	06MAR2003	9:00	-5	2	89		38
		FINAL	17APR2003	13:30	38	3	73		37
	E0028047	BSLN	09JUL2003	10:40	-5	1	176	H	26
		FINAL	09SEP2003	10:24	58	2	162	H	29
	E0029001	BSLN	25SEP2002	8:45	-6	1	89		30
	E0029014	BSLN	28JAN2003	9:35	-7	1	89		33
		FINAL	01APR2003	11:20	57	1	89		31
	E0029023	BSLN	01APR2003	8:47	-7	5	99		31
		FINAL	10JUN2003	11:10	64	2	120		33
	E0029032	BSLN	22MAY2003	12:45	-19	2	129		31
		FINAL	01JUL2003	12:00	22	2	112		33
	E0029033	BSLN	27MAY2003	12:50	-6	2	178	H	23
	E0029039	BSLN	10JUL2003	13:02	-5	1	107		33
		FINAL	28JUL2003	15:30	14	1	93		35
	E0030003	BSLN	03DEC2002	14:25	-13	2	102		35
		FINAL	21MAR2003	9:50	96	1	108		32
	E0030009	BSLN	14JAN2003	9:55	-9	2	94		31
		FINAL	19MAR2003	10:35	56	1	85		32
	E0030016	BSLN	21FEB2003	11:50	-10	1	121		37
		FINAL	22APR2003	18:55	51	1	106		38
	E0030021	BSLN	13MAY2003	17:25	-7	1	107		26

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0031001	BSLN	14NOV2002	11:48	-7	3	93	26
	E0031017	BSLN	25MAR2003	16:15	-7	3	106	32
		FINAL	29APR2003	10:30	29	2	104	36
	E0031018	BSLN	01APR2003	14:45	-9	4	115	29
	E0031023	BSLN	22APR2003	14:03	-7	3	90	36
		FINAL	24JUN2003	11:48	57	2	97	35
	E0033001	BSLN	23DEC2002	12:50	-17	2	79	33
		FINAL	30JAN2003	13:25	22	4	82	34
	E0033004	BSLN	09JAN2003	13:10	-8	1	126	31
		FINAL	14MAR2003	11:40	57	2	147	32
	E0033010	BSLN	22JAN2003	16:20	-13	0	91	36
		FINAL	26MAR2003	16:00	51	0	138	39
	E0033014	BSLN	12MAR2003	17:25	-7	3	102	30
	E0035002	BSLN	14NOV2002	10:50	-7	2	138	35
	E0035007	BSLN	13DEC2002	12:40	-6	2	94	36
		FINAL	11FEB2003	10:10	55	2	100	38
	E0035011	BSLN	13JAN2003	8:35	-22	5	104	27
		FINAL	01APR2003	9:00	57	6H#	94	28
	E0035020	BSLN	15APR2003	8:15	-3	1	129	33
	E0037003	BSLN	23JAN2003	11:40	-7	4	108	30
		FINAL	20FEB2003	15:32	22	4	85	35

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0037004	BSLN	06FEB2003	12:35	-7	2	77	38
		FINAL	10APR2003	13:00	57	1	98	40
	E0039007	BSLN	25NOV2002	13:20	-9	1	90	31
		FINAL	29JAN2003	14:15	57	1	98	39
	E0039022	BSLN	06FEB2003	9:50	-19	0L	97	38
		FINAL	24APR2003	12:10	59	0L	72	39
	E0039023	BSLN	05FEB2003	10:37	-19	1	86	36
	E0039030	BSLN	12MAR2003	8:55	-12	2	111	29
		FINAL	19MAY2003	9:15	57	2	126	24
	E0039031	BSLN	05MAR2003	19:15	-19	1	99	27
		FINAL	20MAY2003	12:50	58	1	111	30
	E0039037	BSLN	26MAR2003	18:30	-21	2	138	23
		FINAL	12JUN2003	11:30	58	1	109	29
	E0039038	BSLN	27MAR2003	10:10	-27	5 #	176 H	22
		FINAL	20JUN2003	11:15	59	3	167 H	26
	E0039047	BSLN	13MAY2003	9:20	-6	1	124	37
	E0039059	BSLN	07JUL2003	11:10	-4	2	98	25
		FINAL	05SEP2003	11:10	57	1	122	32
	E0041007	BSLN	05MAR2003	13:45	-8	1	76	43 H
		FINAL	08MAY2003	13:45	57	3	85	37
	E0041010	BSLN	23APR2003	14:45	-7	1	115	31
		FINAL	11JUN2003	15:30	43	1	120	31

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
PLACEBO (BIPOLAR I)	E0041011	BSLN	15MAY2003	16:00	-7	2	67	33
		FINAL	17JUL2003	14:30	57	1	79	35
	E0041012	BSLN	05JUN2003	12:28	-14	1	134	28
		FINAL	14AUG2003	11:45	57	2	115	33

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
PLACEBO (BIPOLAR II)	E0001004	BSLN		23APR2003	11:00	-8	1		115		39
		FINAL		27JUN2003	12:45	58	1		130		37
	E0005023	BSLN		29JAN2003	7:30	-7	2		113		24
		FINAL		01APR2003	16:30	56	1		100		24
	E0005034	BSLN		09APR2003	9:30	-6	3		73		29
		FINAL		09JUN2003	13:00	56	0L		95		37
	E0005041	BSLN		17JUN2003	11:55	-7	4		106		34
		FINAL		18AUG2003	10:10	56	3		90		34
	E0007004	BSLN		28JAN2003	8:05	-2	1		144		26
		FINAL		13FEB2003	8:30	15	1		176	H	26
	E0007010	BSLN		14APR2003	8:10	-4	1		138		31
		FINAL		13JUN2003	7:40	57	1		148		31
		FINAL	*	16JUN2003	7:50	60	2		152		31
	E0007012	BSLN		12MAY2003	8:50	-4	4		100		34
		FINAL		02JUL2003	11:35	48	3		103		36
	E0009007	BSLN		27JAN2003	15:25	-7	1		124		30
		FINAL		03MAR2003	15:40	29	1		118		31
	E0009008	BSLN		04FEB2003	13:37	-8	2		81		33
		FINAL		08APR2003	12:35	56	3		88		31
	E0011001	BSLN		25OCT2002	16:00	-7	2		104		31
		FINAL		26DEC2002	8:30	56	2		95		31
	E0011011	BSLN		12FEB2003	12:00	-8	1		102		39
		FINAL		16APR2003	8:30	56	2		104		34

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
PLACEBO (BIPOLAR II)	E0011013	BSLN	*	25MAR2003	9:45	-23	15H#					
		BSLN		25MAR2003	9:45	-23			93		30	
		BSLN		15APR2003	9:00	-2	2					
		FINAL		12JUN2003	8:45	57	4		109		35	
	E0011014	BSLN		02APR2003	8:20	-5	2		103		29	
		FINAL		08MAY2003	15:30	32	1		112		29	
	E0011021	BSLN		15MAY2003	10:00	-7	4		86		31	
		FINAL		21JUL2003	10:00	61	2		81		39	
	E0013008	BSLN		19MAR2003	16:20	-7	1		99		32	
		FINAL		19MAY2003	11:25	55	2		122		31	
	E0014001	BSLN		18FEB2003	15:45	-8	1		33	L#	49	H
		FINAL		08APR2003	11:10	42	1		51	L	46	H
	E0014013	BSLN		20MAY2003	14:50	-7	1		125		34	
		FINAL		23JUL2003	15:00	58	1		91		33	
	E0014014	BSLN		03JUN2003	16:35	-7	2		68		36	
		FINAL		06AUG2003	10:50	58	3		88		38	
	E0015004	BSLN		25NOV2002	8:50	-7	1		107		34	
		FINAL		29JAN2003	8:45	59	1		111		37	
	E0018005	BSLN		10DEC2002	16:00	-10	0		97		38	
		FINAL		17FEB2003	11:05	60	1		67		37	
	E0018012	BSLN		17JAN2003	10:30	-7	2		93		36	
		FINAL		26FEB2003	19:20	34	2		88		37	
	E0019019	BSLN		14JAN2003	10:30	-9	1		122		33	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)
PLACEBO (BIPOLAR II)	E0019033	BSLN		10MAR2003	16:05	-8	2	113		28
		FINAL		16MAY2003	8:30	60	2	100		34
	E0019038	BSLN	*	10APR2003	12:30	-14	2	145	H	33
		BSLN		17APR2003	11:05	-7	1	106		32
		FINAL		19JUN2003	9:40	57	2	109		34
	E0019046	BSLN		19JUN2003	15:00	-7	1	103		31
		FINAL		21AUG2003	9:12	57	1	125		35
	E0019047	BSLN		26JUN2003	12:30	-12	3	118		35
		FINAL		04SEP2003	8:40	59	3	134		37
	E0019048	BSLN		03JUL2003	11:05	-7	1	165	H	28
		FINAL		03SEP2003	16:12	56	1	147		30
	E0022006	BSLN		22OCT2002	10:10	-21	2	97		31
		FINAL		07JAN2003	7:40	57	2	111		31
	E0022047	BSLN		21MAR2003	8:10	-7	1	91		32
		FINAL		23MAY2003	9:45	57	3	85		34
	E0022075	BSLN		27JUN2003	7:45	-11	1	113		30
		FINAL		03SEP2003	9:15	58	1	109		35
	E0023012	BSLN		31JAN2003	15:30	-6	2	109		34
		FINAL		04APR2003	12:15	58	3	117		31
	E0023016	BSLN		15MAY2003	13:30	-7	4	112		30
		FINAL		17JUL2003	11:10	57	3	104		30
	E0023018	BSLN		18MAR2003	13:30	-9	0L	162	H	33
		FINAL		22MAY2003	10:15	57	2	84		37

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)
PLACEBO (BIPOLAR II)	E0023036	BSLN	10JUN2003	12:00	-10	1	120	34
		FINAL	13AUG2003	17:00	55	1	100	31
	E0023046	BSLN	11JUL2003	10:00	-12	1	151	25
		FINAL	16SEP2003	14:00	56	1	135	32
	E0026006	BSLN	31DEC2002	10:35	-8	2	91	34
	E0026021	BSLN	14APR2003	15:45	-9	2	85	36
	E0026027	BSLN	05JUN2003	13:10	-14	2	76	36
	E0029002	*	07NOV2002	8:10		20H#	108	30
	E0029004	BSLN	13NOV2002	14:50	-6	1	125	28
		FINAL	17JAN2003	8:25	60	1	120	33
	E0029013	BSLN	10FEB2003	8:55	-9	2	118	33
	E0029019	BSLN	24FEB2003	9:30	-7	3	98	39
		FINAL	17MAR2003	9:50	15	3	104	32
	E0029024	BSLN	11MAR2003	12:10	-6	0	72	31
		FINAL	20MAY2003	14:45	65	1	80	31
	E0029038	BSLN	30JUN2003	9:25	-7	2	103	31
	E0031004	BSLN	12DEC2002	13:59	-7	3	88	34
		FINAL	14FEB2003	10:50	58	2	93	27
	E0031013	BSLN	06MAR2003	10:35	-7	1	106	26
		FINAL	08MAY2003	11:05	57	1	100	32
	E0031016	BSLN	17MAR2003	10:45	-7	1	88	34

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)		T3-UPTAKE (%)	
PLACEBO (BIPOLAR II)	E0031016	FINAL	15APR2003	10:03	23	1	80		35	
	E0031019	BSLN	03APR2003	11:25	-8	1	112		29	
		FINAL	12MAY2003	16:40	32	2	124		32	
	E0031022	BSLN	21APR2003	12:40	-7	2	98		29	
	E0033007	BSLN	15JAN2003	15:20	-13	2	93		40	
		FINAL	27MAR2003	15:35	59	2	97		34	
	E0033013	BSLN	06FEB2003	11:45	-13	2	122		32	
		FINAL	16APR2003	11:45	57	2	117		34	
	E0033016	BSLN	17APR2003	12:00	-21	1	122		23	
		FINAL	02JUL2003	13:00	56	1	151		21	L
	E0033022	BSLN	09JUL2003	11:00	-5	1L	145		24	
		FINAL	11SEP2003	12:00	60	0L	147		27	
	E0034007	BSLN	07MAY2003	14:05	-9	1	108		37	
		FINAL	14JUL2003	11:15	60	1	88		36	
	E0035004	BSLN	22NOV2002	11:45	-5	4	134		25	
	E0035009	BSLN	20DEC2002	11:12	-7	1	143		30	
		FINAL	19FEB2003	8:55	55	2	107		36	
	E0035010	BSLN	07JAN2003	7:45	-3	1	122		36	
		FINAL	06MAR2003	9:00	56	1	115		29	
	E0035022	BSLN	01MAY2003	9:45	-8	1	172	H	24	
		FINAL	07JUL2003	8:55	60	1	153		32	
	E0039003	BSLN	12NOV2002	11:19	-13	4	131		32	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
GENERATED: 12JUL2005 17:40:33 iceadmn3

Listing 12.2.8.2.6 Chemistry Data - Thyroid Tests

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	THYROXINE (T4) (NMOL/L)	T3-UPTAKE (%)	
PLACEBO (BIPOLAR II)	E0039003	FINAL	02JAN2003	14:06	39	2	103	39	
	E0040001	BSLN	18JUN2003	14:30	-9	1	102	34	
		FINAL	22AUG2003	9:00	57	1	73	38	
	E0040004	BSLN	11JUL2003	13:00	-7	1	94	32	
	E0041002	BSLN	13JAN2003	14:35	-8	3	97	36	
		FINAL	11MAR2003	10:35	50	2	108	38	
	E0041005	BSLN	28FEB2003	12:31	-5	1	140	41	H
		FINAL	30APR2003	14:08	57	1	98	41	H

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/CHEM105.SAS
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AstraZeneca

Clinical Study Report: Appendix 12.2.9

Drug Substance	Quetiapine
Study Code	5077US0049

Appendix 12.2.9
Listing of vital signs

Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	SCREEN	14JAN2003	-21	64	130	90	70	132	80	6	2	-10
		DAY 1	04FEB2003	1	64	132	90	76	132	80	12	0	-10
		BASELINE			64	132	90	76	132	80	12	0	-10
		DAY 8	12FEB2003	9	76	140	78	84	138	74	8	-2	-4
		DAY 15	19FEB2003	16	72	118	72	80	120	76	8	2	4
		DAY 22	26FEB2003	23	76	116	76	80	118	72	4	2	-4
		DAY 29	05MAR2003	30	76	122	82	80	128	84	4	6	2
		DAY 36	11MAR2003	36	84	120	80	88	132	84	4	12	4
		DAY 43	18MAR2003	43	80	130	80	84	142	82	4	12	2
		DAY 50	25MAR2003	50	80	108	66	80	112	76	0	4	10
		DAY 57	02APR2003	58	78	124	76	80	112	68	2	-12	-8
		FINAL		58	78	124	76	80	112	68	2	-12	-8
	E0002010	SCREEN	25MAR2003	-10	80	124	80	78	122	80	-2	-2	0
		DAY 1	04APR2003	1	82	142	100	80	152	106	-2	10	6
		BASELINE			82	142	100	80	152	106	-2	10	6
		DAY 8	10APR2003	7	84	120	94	80	120	88	-4	0	-6
		FINAL		7	84	120	94	80	120	88	-4	0	-6
	E0002012	SCREEN	16APR2003	-5	60	102	58	72	104	60	12	2	2
		DAY 1	21APR2003	1	64	102	66	72	108	68	8	6	2
		BASELINE			64	102	66	72	108	68	8	6	2
		DAY 8	29APR2003	9	64	102	68	68	108	70	4	6	2
		DAY 15	06MAY2003	16	64	104	68	72	110	82	8	6	14
		DAY 22	15MAY2003	25	56	100	64	60	108	68	4	8	4
		DAY 29	21MAY2003	31	60	110	70	60	108	72	0	-2	2
		DAY 36	28MAY2003	38	64	102	58	64	114	66	0	12	8
		DAY 43	04JUN2003	45	60	100	70	62	104	70	2	4	0
		DAY 50	11JUN2003	52	56	102	70	56	112	74	0	10	4
		DAY 57	16JUN2003	57	56	100	62	60	102	68	4	2	6
		FINAL		57	56	100	62	60	102	68	4	2	6
	E0002015	SCREEN	22MAY2003	-13	74	120	86	76	118	92	2	-2	6
		DAY 1	04JUN2003	1	80	120	78	78	124	80	-2	4	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)		BASELINE				80	120	78	78	124	80	-2	4	2
	E0002018	SCREEN		16JUL2003	-8	88	138	82	76	148	80	-12	10	-2
		DAY 1		24JUL2003	1	80	140	96	78	138	90	-2	-2	-6
		BASELINE				80	140	96	78	138	90	-2	-2	-6
		DAY 8	*	30JUL2003	7	82	140	96	86	132	96	4	-8	0
		DAY 8		01AUG2003	9	80	132	92	80	136	96	0	4	4
		FINAL			9	80	132	92	80	136	96	0	4	4
	E0003004	SCREEN		03DEC2002	-14	64	128	90	76	120	80	12	-8	-10
		DAY 1		17DEC2002	1	72	112	82	80	90	70	8	-22	-12
		BASELINE				72	112	82	80	90	70	8	-22	-12
		DAY 22		07JAN2003	22	74	132	70	88	134	82	14	2	12
		FINAL			22	74	132	70	88	134	82	14	2	12
	E0003005	SCREEN		16DEC2002	-7	72	130	84	80	120	88	8	-10	4
		DAY 1		23DEC2002	1	74	124	82	78	122	78	4	-2	-4
		BASELINE				74	124	82	78	122	78	4	-2	-4
		DAY 8		30DEC2002	8	64	128	90	72	135	82	8	7	-8
		DAY 15		06JAN2003	15	68	124	84	72	120	86	4	-4	2
		DAY 22		14JAN2003	23	80	112	82	88	120	86	8	8	4
		DAY 29		21JAN2003	30	74	122	80	84	128	84	10	6	4
		DAY 36		28JAN2003	37	76	132	90	82	140	94	6	8	4
		DAY 43		04FEB2003	44	72	122	82	86	128	92	14	6	10
		DAY 50		11FEB2003	51	66	120	70	64	128	84	-2	8	14
		DAY 57		18FEB2003	58	74	120	68	80	124	74	6	4	6
		FINAL			58	74	120	68	80	124	74	6	4	6
	E0003007	SCREEN		19DEC2002	-14	84	110	78	80	120	70	-4	10	-8
		DAY 1		02JAN2003	1	72	130	78	88	125	82	16	-5	4
		BASELINE				72	130	78	88	125	82	16	-5	4
		DAY 8		09JAN2003	8	72	110	68	80	110	70	8	0	2
		DAY 15		16JAN2003	15	84	120	75	92	124	72	8	4	-3
		DAY 22		23JAN2003	22	82	120	64	100	126	80	18	6	16

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
GENERATED: 12JUL2005 17:46:40 iceadmn3

Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	DAY 29	30JAN2003	29	70	118	84	76	118	86	6	0	2
		DAY 36	07FEB2003	37	70	118	78	76	122	80	6	4	2
		DAY 43	13FEB2003	43	70	126	74	72	122	80	2	-4	6
		DAY 50	20FEB2003	50	88	118	68	106	110	76	18	-8	8
		DAY 57	27FEB2003	57	92	106	70	76	106	72	-16	0	2
		FINAL		57	92	106	70	76	106	72	-16	0	2
	E0003015	SCREEN	29APR2003	-6	60	118	74	64	110	84	4	-8	10
		DAY 1	05MAY2003	1	60	112	70	68	100	72	8	-12	2
		BASELINE			60	112	70	68	100	72	8	-12	2
		DAY 8	13MAY2003	9	62	108	70	74	110	74	12	2	4
		DAY 15	19MAY2003	15	56	100	70	60	110	74	4	10	4
		DAY 22	27MAY2003	23	52	120	70	60	110	80	8	-10	10
		DAY 29	04JUN2003	31	68	100	70	68	110	70	0	10	0
		DAY 36	10JUN2003	37	60	104	70	68	106	78	8	2	8
		DAY 43	17JUN2003	44	66	100	72	78	118	80	12	18	8
		DAY 50	24JUN2003	51	74	110	78	86	106	80	12	-4	2
		DAY 57	02JUL2003	59	74	100	68	68	96	64	-6	-4	-4
		FINAL		59	74	100	68	68	96	64	-6	-4	-4
	E0004002	SCREEN	24SEP2002	-7	68	114	70	70	112	68	2	-2	-2
		DAY 1	01OCT2002	1	70	110	64	72	112	60	2	2	-4
		BASELINE			70	110	64	72	112	60	2	2	-4
		DAY 8	10OCT2002	10	76	108	62	88	120	66	12	12	4
		DAY 15	17OCT2002	17	84	108	62	90	110	70	6	2	8
		DAY 22	22OCT2002	22	88	110	72	86	104	70	-2	-6	-2
		DAY 29	29OCT2002	29	84	110	62	80	104	64	-4	-6	2
		DAY 36	05NOV2002	36	96	122	60	100	108	76	4	-14	16
		DAY 43	12NOV2002	43	96	108	74	88	102	70	-8	-6	-4
		DAY 50	19NOV2002	50	90	110	60	96	108	74	6	-2	14
		DAY 57	26NOV2002	57	88	120	68	96	114	76	8	-6	8
		FINAL		57	88	120	68	96	114	76	8	-6	8
	E0004013	SCREEN	08JAN2003	-6	80	114	72	84	112	76	4	-2	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
GENERATED: 12JUL2005 17:46:40 iceadmn3

Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	DAY 1	14JAN2003	1	84	110	78	88	112	72	4	2	-6
		BASELINE			84	110	78	88	112	72	4	2	-6
		DAY 8	21JAN2003	8	80	108	80	88	102	78	8	-6	-2
		DAY 15	30JAN2003	17	84	104	72	88	102	76	4	-2	4
		DAY 22	05FEB2003	23	84	118	78	92	116	80	8	-2	2
		FINAL		23	84	118	78	92	116	80	8	-2	2
	E0004018	SCREEN	12MAR2003	-7	60	118	74	64	120	78	4	2	4
		DAY 1	19MAR2003	1	64	112	70	72	118	78	8	6	8
		BASELINE			64	112	70	72	118	78	8	6	8
		DAY 8	26MAR2003	8	88	126	72	92	130	80	4	4	8
		DAY 15	02APR2003	15	88	122	70	96	124	84	8	2	14
		DAY 22	09APR2003	22	76	128	82	88	130	88	12	2	6
		DAY 29	16APR2003	29	80	128	80	90	124	88	10	-4	8
		DAY 36	23APR2003	36	88	122	80	94	120	86	6	-2	6
		DAY 43	30APR2003	43	80	124	80	88	120	82	8	-4	2
		DAY 50	06MAY2003	49	80	108	70	100	100	68	20	-8	-2
		DAY 57	13MAY2003	56	76	110	78	84	112	82	8	2	4
		FINAL		56	76	110	78	84	112	82	8	2	4
	E0004021	SCREEN	07MAY2003	-7	72	120	80	68	128	90	-4	8	10
		DAY 1	14MAY2003	1	74	120	80	80	130	90	6	10	10
		BASELINE			74	120	80	80	130	90	6	10	10
		DAY 8	21MAY2003	8	76	114	88	88	118	84	12	4	-4
		DAY 15	28MAY2003	15	84	122	90	88	124	92	4	2	2
		DAY 22	04JUN2003	22	76	122	90	84	120	84	8	-2	-6
		DAY 29	11JUN2003	29	80	136	88	88	138	94	8	2	6
		DAY 36	18JUN2003	36	78	130	90	88	132	92	10	2	2
		DAY 43	25JUN2003	43	72	130	88	84	122	90	12	-8	2
		DAY 50	02JUL2003	50	80	124	92	84	130	90	4	6	-2
		DAY 57	09JUL2003	57	80	128	90	76	120	88	-4	-8	-2
		FINAL		57	80	128	90	76	120	88	-4	-8	-2
	E0005002	SCREEN	23SEP2002	-10	74	118	62	76	112	60	2	-6	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

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GENERATED: 12JUL2005 17:46:40 iceadmn3

Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0005002	DAY 1		03OCT2002	1	84	110	70	84	110	70	0	0	0
		BASELINE				84	110	70	84	110	70	0	0	0
		DAY 8		08OCT2002	6	88	106	70	88	116	70	0	10	0
		DAY 8	*	14OCT2002	12	84	120	78	88	112	78	4	-8	0
		DAY 15		21OCT2002	19	92	114	70	92	108	70	0	-6	0
		DAY 22		28OCT2002	26	96	108	68	96	100	68	0	-8	0
		DAY 29		04NOV2002	33	90	114	80	90	110	80	0	-4	0
		DAY 43		13NOV2002	42	90	110	70	90	110	70	0	0	0
		DAY 43	*	18NOV2002	47	90	110	70	90	110	70	0	0	0
		DAY 50		25NOV2002	54	92	124	80	88	120	80	-4	-4	0
		FINAL			54	92	124	80	88	120	80	-4	-4	0
	E0005004	SCREEN		24SEP2002	-7	68	112	70	66	108	64	-2	-4	-6
		DAY 1		01OCT2002	1	60	100	60	60	96	58	0	-4	-2
		BASELINE				60	100	60	60	96	58	0	-4	-2
		DAY 8		10OCT2002	10	80	116	70	80	110	70	0	-6	0
		DAY 15		15OCT2002	15	84	126	68	84	118	66	0	-8	-2
		FINAL			15	84	126	68	84	118	66	0	-8	-2
	E0005013	SCREEN		30OCT2002	-8	72	110	70	72	100	70	0	-10	0
		DAY 1		07NOV2002	1	64	110	80	64	110	74	0	0	-6
		BASELINE				64	110	80	64	110	74	0	0	-6
		DAY 43		19DEC2002	43	80	120	80	80	120	80	0	0	0
		FINAL			43	80	120	80	80	120	80	0	0	0
	E0005024	SCREEN		05FEB2003	-5	68	120	84	68	120	78	0	0	-6
		DAY 1		10FEB2003	1	60	124	80	60	120	80	0	-4	0
		BASELINE				60	124	80	60	120	80	0	-4	0
		DAY 8		18FEB2003	9	64	120	74	64	110	70	0	-10	-4
		DAY 15		26FEB2003	17	80	110	70	80	100	70	0	-10	0
		DAY 22		06MAR2003	25	80	110	80	80	100	70	0	-10	-10
		DAY 29		13MAR2003	32	68	110	80	68	100	74	0	-10	-6
		DAY 36		20MAR2003	39	72	110	74	72	110	70	0	0	-4
		DAY 43		25MAR2003	44	68	110	70	68	100	60	0	-10	-10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	DAY 50	02APR2003	52	88	120	80	84	110	70	-4	-10	-10
		DAY 57	09APR2003	59	64	110	70	64	100	68	0	-10	-2
		FINAL		59	64	110	70	64	100	68	0	-10	-2
	E0005027	SCREEN	03MAR2003	-8	60	130	80	60	124	80	0	-6	0
		DAY 1	11MAR2003	1	60	112	80	60	110	75	0	-2	-5
		BASELINE			60	112	80	60	110	75	0	-2	-5
		DAY 8	19MAR2003	9	84	120	80	80	120	80	-4	0	0
		DAY 15	26MAR2003	16	68	120	78	68	120	80	0	0	2
		DAY 22	03APR2003	24	60	120	80	60	110	80	0	-10	0
		FINAL		24	60	120	80	60	110	80	0	-10	0
	E0005037	SCREEN	30APR2003	-7	60	130	80	60	130	70	0	0	-10
		DAY 1	07MAY2003	1	96	140	86	96	130	86	0	-10	0
		BASELINE			96	140	86	96	130	86	0	-10	0
		DAY 8	15MAY2003	9	86	140	88	86	140	86	0	0	-2
		DAY 15	22MAY2003	16	86	140	86	86	140	84	0	0	-2
		DAY 22	27MAY2003	21	80	140	90	80	130	88	0	-10	-2
		DAY 29	05JUN2003	30	80	138	90	80	134	88	0	-4	-2
		DAY 36	12JUN2003	37	80	130	84	80	126	80	0	-4	-4
		DAY 50	25JUN2003	50	80	126	82	80	130	86	0	4	4
		DAY 57	02JUL2003	57	80	134	78	80	134	82	0	0	4
		FINAL		57	80	134	78	80	134	82	0	0	4
	E0005042	SCREEN	19JUN2003	-5	64	126	84	64	124	84	0	-2	0
		DAY 1	24JUN2003	1	84	124	80	84	122	80	0	-2	0
		BASELINE			84	124	80	84	122	80	0	-2	0
		DAY 8	02JUL2003	9	60	118	84	64	118	82	4	0	-2
		DAY 15	09JUL2003	16	80	120	80	80	116	80	0	-4	0
		DAY 22	16JUL2003	23	88	138	82	92	140	80	4	2	-2
		DAY 29	23JUL2003	30	84	130	80	84	124	80	0	-6	0
		DAY 36	30JUL2003	37	76	136	84	76	120	84	0	-16	0
		DAY 43	06AUG2003	44	82	126	82	82	120	80	0	-6	-2
		DAY 50	12AUG2003	50	68	126	82	72	120	80	4	-6	-2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	DAY 57	18AUG2003	56	80	128	84	88	128	80	8	0	-4
		FINAL		56	80	128	84	88	128	80	8	0	-4
	E0006005	SCREEN	25NOV2002	-10	64	100	72	75	104	78	11	4	6
		DAY 1	05DEC2002	1	74	146	82	88	142	92	14	-4	10
		BASELINE			74	146	82	88	142	92	14	-4	10
		DAY 8	12DEC2002	8	76	102	70	96	100	68	20	-2	-2
		DAY 15	20DEC2002	16	89	127	76	106	132	87	17	5	11
		DAY 22	30DEC2002	26	81	123	69	107	127	76	26	4	7
		DAY 29	03JAN2003	30	86	119	67	100	126	72	14	7	5
		DAY 36	09JAN2003	36	83	134	86	84	117	87	1	-17	1
		DAY 43	16JAN2003	43	78	118	78	90	135	85	12	17	7
		DAY 50	23JAN2003	50	76	140	80	78	96	46	2	-44	-34
		DAY 57	30JAN2003	57	76	115	65	98	123	70	22	8	5
		FINAL		57	76	115	65	98	123	70	22	8	5
	E0006018	SCREEN	06MAR2003	-7	68	138	78	69	138	74	1	0	-4
		DAY 1	13MAR2003	1	68	138	76	70	136	72	2	-2	-4
		BASELINE			68	138	76	70	136	72	2	-2	-4
		DAY 8	24MAR2003	12	70	130	80	82	124	84	12	-6	4
		FINAL		12	70	130	80	82	124	84	12	-6	4
	E0007013	SCREEN	06JUN2003	-7	64	108	64	68	104	60	4	-4	-4
		DAY 1	13JUN2003	1	70	94	62	72	100	66	2	6	4
		BASELINE			70	94	62	72	100	66	2	6	4
		DAY 8	20JUN2003	8	72	114	68	76	116	72	4	2	4
		DAY 15	26JUN2003	14	70	110	70	72	108	72	2	-2	2
		DAY 22	03JUL2003	21	70	116	70	72	120	70	2	4	0
		DAY 29	10JUL2003	28	72	120	70	76	126	72	4	6	2
		DAY 36	17JUL2003	35	70	114	70	72	116	74	2	2	4
		DAY 43	24JUL2003	42	70	122	74	76	116	70	6	-6	-4
		DAY 50	01AUG2003	50	76	136	76	80	134	80	4	-2	4
		DAY 57	07AUG2003	56	72	126	80	76	122	80	4	-4	0
		FINAL		56	72	126	80	76	122	80	4	-4	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	SCREEN	05DEC2002	-6	64	90	60	70	96	68	6	6	8
		DAY 1	11DEC2002	1	60	110	84	64	100	78	4	-10	-6
		BASELINE			60	110	84	64	100	78	4	-10	-6
		DAY 8	18DEC2002	8	68	104	68	84	98	62	16	-6	-6
		DAY 15	26DEC2002	16	61	130	80	71	110	82	10	-20	2
		DAY 22	02JAN2003	23	66	126	80	68	120	72	2	-6	-8
		DAY 36	13JAN2003	34	67	116	76	81	110	70	14	-6	-6
		DAY 43	21JAN2003	42	61	126	88	74	118	82	13	-8	-6
		DAY 50	31JAN2003	52	66	112	74	86	98	68	20	-14	-6
		DAY 57	06FEB2003	58	60	120	80	72	110	70	12	-10	-10
		FINAL		58	60	120	80	72	110	70	12	-10	-10
	E0010012	SCREEN	30DEC2002	-8	65	132	90	66	130	90	1	-2	0
		DAY 1	07JAN2003	1	94	128	78	90	144	88	-4	16	10
		BASELINE			94	128	78	90	144	88	-4	16	10
		DAY 8	14JAN2003	8	84	118	76	79	130	80	-5	12	4
		DAY 15	21JAN2003	15	84	130	80	82	142	92	-2	12	12
		DAY 22	28JAN2003	22	84	130	84	74	136	94	-10	6	10
		DAY 29	04FEB2003	29	88	142	86	91	126	90	3	-16	4
		DAY 36	11FEB2003	36	80	118	90	80	110	84	0	-8	-6
		DAY 43	18FEB2003	43	86	144	90	88	140	90	2	-4	0
		DAY 50	25FEB2003	50	88	138	88	82	130	86	-6	-8	-2
		DAY 57	05MAR2003	58	80	126	84	78	132	88	-2	6	4
		FINAL		58	80	126	84	78	132	88	-2	6	4
	E0010024	SCREEN	23APR2003	-12	62	114	78	78	132	96	16	18	18
		DAY 1	05MAY2003	1	50	124	80	56	132	88	6	8	8
		BASELINE			50	124	80	56	132	88	6	8	8
		DAY 8	12MAY2003	8	62	110	70	88	124	88	26	14	18
		DAY 15	19MAY2003	15	78	130	78	84	124	80	6	-6	2
		DAY 22	27MAY2003	23	88	140	90	86	140	90	-2	0	0
		DAY 29	04JUN2003	31	74	140	94	76	140	100	2	0	6
		DAY 36	11JUN2003	38	98	130	86	104	144	96	6	14	10
		DAY 43	18JUN2003	45	76	140	88	72	140	72	-4	0	-16

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0010024	DAY 50	25JUN2003	52	86	130	88	98	134	90	12	4	2
		DAY 57	02JUL2003	59	84	130	78	84	130	80	0	0	2
		FINAL		59	84	130	78	84	130	80	0	0	2
	E0010032	SCREEN	03JUL2003	-7	92	122	80	84	110	72	-8	-12	-8
		DAY 1	10JUL2003	1	76	110	80	76	110	82	0	0	2
		BASELINE			76	110	80	76	110	82	0	0	2
		DAY 8	17JUL2003	8	72	120	70	80	120	80	8	0	10
		FINAL		8	72	120	70	80	120	80	8	0	10
	E0011025	SCREEN	20JUN2003	-6	68	118	74	70	120	74	2	2	0
		DAY 1	26JUN2003	1	84	100	80	88	100	75	4	0	-5
		BASELINE			84	100	80	88	100	75	4	0	-5
		DAY 8	02JUL2003	7	90	100	70	88	100	72	-2	0	2
		DAY 15	10JUL2003	15	84	102	80	88	100	82	4	-2	2
		DAY 22	17JUL2003	22	92	120	80	90	118	80	-2	-2	0
		DAY 29	22JUL2003	27	84	90	68	82	90	60	-2	0	-8
		DAY 36	30JUL2003	35	88	100	60	84	100	62	-4	0	2
		DAY 43	07AUG2003	43	84	100	70	86	102	70	2	2	0
		DAY 50	14AUG2003	50	82	102	70	84	100	72	2	-2	2
		DAY 57	22AUG2003	58	80	100	70	82	100	72	2	0	2
		FINAL		58	80	100	70	82	100	72	2	0	2
	E0013007	SCREEN	14MAR2003	-6	72	132	90	72	130	90	0	-2	0
		DAY 1	20MAR2003	1	72	128	88	80	130	88	8	2	0
		BASELINE			72	128	88	80	130	88	8	2	0
		DAY 8	27MAR2003	8	66	128	82	72	128	80	6	0	-2
		DAY 15	07APR2003	19	72	124	88	66	126	88	-6	2	0
		FINAL		19	72	124	88	66	126	88	-6	2	0
	E0013009	SCREEN	26MAR2003	-7	72	128	80	66	126	80	-6	-2	0
		DAY 1	02APR2003	1	66	112	80	66	112	80	0	0	0
		BASELINE			66	112	80	66	112	80	0	0	0
		DAY 8	09APR2003	8	66	128	86	66	120	86	0	-8	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	DAY 15	16APR2003	15	72	124	82	72	120	80	0	-4	-2
		DAY 22	24APR2003	23	72	120	70	64	120	70	-8	0	0
		DAY 29	01MAY2003	30	84	120	70	70	120	70	-14	0	0
		DAY 36	07MAY2003	36	60	124	80	64	120	80	4	-4	0
		DAY 43	16MAY2003	45	72	120	62	64	120	70	-8	0	8
		DAY 50	21MAY2003	50	88	120	78	80	120	80	-8	0	2
		DAY 57	29MAY2003	58	60	120	80	68	120	80	8	0	0
		FINAL		58	60	120	80	68	120	80	8	0	0
	E0014006	SCREEN	11MAR2003	-14	84	118	88	92	110	84	8	-8	-4
		DAY 1	25MAR2003	1	80	124	84	92	110	80	12	-14	-4
		BASELINE			80	124	84	92	110	80	12	-14	-4
		DAY 8	02APR2003	9	84	120	82	96	124	78	12	4	-4
		DAY 15	09APR2003	16	80	122	90	92	120	88	12	-2	-2
		DAY 22	16APR2003	23	88	120	90	96	112	88	8	-8	-2
		DAY 29	23APR2003	30	100	130	78	108	120	84	8	-10	6
		DAY 36	30APR2003	37	84	130	80	96	130	84	12	0	4
		DAY 43	07MAY2003	44	88	126	84	96	110	80	8	-16	-4
		DAY 50	14MAY2003	51	88	120	80	92	124	88	4	4	8
		DAY 57	21MAY2003	58	100	124	74	120	110	80	20	-14	6
		FINAL		58	100	124	74	120	110	80	20	-14	6
	E0014010	SCREEN	15APR2003	-7	76	140	84	103	140	80	27	0	-4
		DAY 1	22APR2003	1	80	134	86	88	124	88	8	-10	2
		BASELINE			80	134	86	88	124	88	8	-10	2
		DAY 8	30APR2003	9	86	132	90	92	118	80	6	-14	-10
		DAY 15	07MAY2003	16	88	138	88	96	122	74	8	-16	-14
		DAY 22	14MAY2003	23	78	138	88	84	126	88	6	-12	0
		DAY 29	21MAY2003	30	84	118	78	88	112	76	4	-6	-2
		DAY 36	28MAY2003	37	82	130	88	86	126	90	4	-4	2
		DAY 43	03JUN2003	43	76	116	84	80	112	84	4	-4	0
		DAY 50	11JUN2003	51	76	118	82	78	114	80	2	-4	-2
		DAY 57	17JUN2003	57	80	124	84	82	120	82	2	-4	-2
		FINAL		57	80	124	84	82	120	82	2	-4	-2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	SCREEN	02JAN2003	-20				86	141	88			
		DAY 1	22JAN2003	1				89	122	68			
		BASELINE						89	122	68			
		DAY 8	29JAN2003	8	80	126	72	86	134	82	6	8	10
		DAY 15	05FEB2003	15	69	118	74	72	124	84	3	6	10
		DAY 22	12FEB2003	22	76	128	84	98	142	94	22	14	10
		DAY 29	19FEB2003	29	78	129	83	87	141	94	9	12	11
		DAY 36	26FEB2003	36	84	128	84	96	142	92	12	14	8
		DAY 43	05MAR2003	43	76	124	86	88	136	92	12	12	6
		DAY 50	12MAR2003	50	80	121	79	87	128	84	7	7	5
		DAY 57	19MAR2003	57	89	124	80	96	131	85	7	7	5
		FINAL		57	89	124	80	96	131	85	7	7	5
	E0016004	SCREEN	27JAN2003	-7	81	118	86	86	128	92	5	10	6
		DAY 1	03FEB2003	1	78	119	91	88	128	82	10	9	-9
		BASELINE			78	119	91	88	128	82	10	9	-9
		DAY 8	10FEB2003	8	78	115	78	86	128	81	8	13	3
		FINAL		8	78	115	78	86	128	81	8	13	3
	E0018001	SCREEN	22OCT2002	-7	64	122	70	60	120	72	-4	-2	2
		DAY 1	29OCT2002	1	64	122	78						
		BASELINE			64	122	70	60	120	72	-4	-2	2
		DAY 8	05NOV2002	8	84	126	80	76	122	80	-8	-4	0
		DAY 15	13NOV2002	16	76	116	66	76	116	68	0	0	2
		DAY 22	20NOV2002	23	78	112	72	82	112	74	4	0	2
		DAY 29	27NOV2002	30	80	110	68	80	112	68	0	2	0
		DAY 36	04DEC2002	37	72	114	72	73	116	73	1	2	1
		DAY 43	11DEC2002	44	84	128	78	84	130	78	0	2	0
		DAY 50	18DEC2002	51	84	130	82	84	130	82	0	0	0
		DAY 57	24DEC2002	57	86	126	82	88	126	84	2	0	2
		FINAL		57	86	126	82	88	126	84	2	0	2
	E0018006	SCREEN	10DEC2002	-7	64	112	72	68	112	76	4	0	4
		DAY 1	17DEC2002	1	68	122	74	72	124	74	4	2	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0018006	BASELINE			68	122	74	72	124	74	4	2	0
		DAY 8	23DEC2002	7	80	128	90	84	126	88	4	-2	-2
		DAY 15	31DEC2002	15	68	132	86	72	124	86	4	-8	0
		DAY 22	07JAN2003	22	72	124	82	76	118	84	4	-6	2
		DAY 29	14JAN2003	29	80	116	82	84	120	84	4	4	2
		DAY 36	21JAN2003	36	84	118	84	80	124	84	-4	6	0
		DAY 43	28JAN2003	43	64	128	88	72	132	92	8	4	4
		DAY 50	06FEB2003	52	84	118	80	80	124	78	-4	6	-2
		DAY 57	13FEB2003	59	68	128	78	72	126	82	4	-2	4
		FINAL		59	68	128	78	72	126	82	4	-2	4
	E0019004	SCREEN	30OCT2002	-8	64	120	90	70	120	80	6	0	-10
		DAY 1	07NOV2002	1	68	120	75	68	123	80	0	3	5
		BASELINE			68	120	75	68	123	80	0	3	5
		DAY 8	14NOV2002	8	72	110	80	72	110	80	0	0	0
		DAY 15	21NOV2002	15	68	115	75	68	120	80	0	5	5
		DAY 22	26NOV2002	20	72	125	80	76	120	75	4	-5	-5
		DAY 29	05DEC2002	29	60	110	80	60	115	80	0	5	0
		DAY 36	12DEC2002	36	70	140	84	80	146	98	10	6	14
		DAY 43	19DEC2002	43	72	135	82	76	135	80	4	0	-2
		FINAL		43	72	135	82	76	135	80	4	0	-2
	E0019011	SCREEN	12NOV2002	-9	76	120	80	80	140	84	4	20	4
		DAY 1	21NOV2002	1	80	120	70	84	125	65	4	5	-5
		BASELINE			80	120	70	84	125	65	4	5	-5
		DAY 8	27NOV2002	7	84	130	70	88	130	75	4	0	5
		DAY 15	05DEC2002	15	80	130	80	84	132	75	4	2	-5
		DAY 22	12DEC2002	22	66	132	88	90	116	62	24	-16	-26
		DAY 29	19DEC2002	29	84	108	68	88	120	74	4	12	6
		DAY 43	02JAN2003	43	88	120	80	92	118	85	4	-2	5
		DAY 50	09JAN2003	50	60	110	70	64	120	80	4	10	10
		DAY 57	16JAN2003	57	84	112	78	96	112	80	12	0	2
		FINAL		57	84	112	78	96	112	80	12	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0019025	SCREEN	30JAN2003	-7	68	120	75	68	120	80	0	0	5
		DAY 1	06FEB2003	1	60	110	70	64	110	75	4	0	5
		BASELINE			60	110	70	64	110	75	4	0	5
		DAY 8	13FEB2003	8	80	112	70	88	110	75	8	-2	5
		DAY 15	20FEB2003	15	80	108	72	88	100	68	8	-8	-4
		DAY 22	27FEB2003	22	80	110	76	88	104	80	8	-6	4
		DAY 29	06MAR2003	29	80	110	70	88	100	74	8	-10	4
		DAY 36	13MAR2003	36	80	110	72	84	108	80	4	-2	8
		DAY 43	20MAR2003	43	78	102	68	82	100	74	4	-2	6
		DAY 50	27MAR2003	50	80	118	80	88	115	75	8	-3	-5
		DAY 57	03APR2003	57	80	102	60	88	90	60	8	-12	0
		FINAL		57	80	102	60	88	90	60	8	-12	0
	E0019026	SCREEN	10FEB2003	-14	68	110	70	72	120	90	4	10	20
		DAY 1	24FEB2003	1	76	120	78		105	65		-15	-13
		BASELINE			68	110	70	72	120	90	4	10	20
	E0019043	SCREEN	21MAY2003	-13	64	110	84	68	132	82	4	22	-2
		DAY 1	03JUN2003	1	72	120	78	80	122	84	8	2	6
		BASELINE			72	120	78	80	122	84	8	2	6
		DAY 8	10JUN2003	8	92	122	74	80	128	88	-12	6	14
		DAY 15	17JUN2003	15	88	115	75	84	118	80	-4	3	5
		DAY 22	24JUN2003	22	84	130	82	92	130	80	8	0	-2
		DAY 29	01JUL2003	29	88	116	78	84	112	78	-4	-4	0
		DAY 36	08JUL2003	36	76	134	86	80	130	88	4	-4	2
		DAY 43	15JUL2003	43	76	138	84	82	134	86	6	-4	2
		DAY 50	22JUL2003	50	80	120	70	80	120	78	0	0	8
		DAY 57	29JUL2003	57	76	112	78	92	116	80	16	4	2
		FINAL		57	76	112	78	92	116	80	16	4	2
	E0020001	SCREEN	15OCT2002	-14	60	122	90	62	120	88	2	-2	-2
		DAY 1	29OCT2002	1	62	110	78	60	114	74	-2	4	-4
		BASELINE			62	110	78	60	114	74	-2	4	-4
		DAY 8	05NOV2002	8	78	148	78	82	158	82	4	10	4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	DAY 15		12NOV2002	15	72	120	82	78	118	82	6	-2	0
		DAY 22		19NOV2002	22	80	128	78	80	124	76	0	-4	-2
		DAY 29		26NOV2002	29	78	140	80	82	138	80	4	-2	0
		DAY 36		03DEC2002	36	78	126	78	80	128	78	2	2	0
		DAY 43		10DEC2002	43	80	124	76	82	126	78	2	2	2
		DAY 50		16DEC2002	49	70	130	88	68	120	86	-2	-10	-2
		DAY 50	*	20DEC2002	53	76	120	78	80	118	78	4	-2	0
		FINAL			53	76	120	78	80	118	78	4	-2	0
	E0020006	SCREEN		26NOV2002	-20	78	124	72	74	120	70	-4	-4	-2
		DAY 1		16DEC2002	1	72	128	80	76	134	82	4	6	2
		BASELINE				72	128	80	76	134	82	4	6	2
		DAY 8		20DEC2002	5	88	122	70	84	122	64	-4	0	-6
		DAY 22		08JAN2003	24	76	150	80	70	148	80	-6	-2	0
		FINAL			24	76	150	80	70	148	80	-6	-2	0
	E0020007	SCREEN		19DEC2002	-27	78	102	62	82	98	60	4	-4	-2
		DAY 1		15JAN2003	1	70	108	70	72	104	68	2	-4	-2
		BASELINE				70	108	70	72	104	68	2	-4	-2
		DAY 8		22JAN2003	8	60	92	60	64	94	60	4	2	0
		DAY 57		25MAR2003	70	70	90	58	74	100	60	4	10	2
		FINAL			70	70	90	58	74	100	60	4	10	2
	E0020011	SCREEN		19FEB2003	-7	78	118	72	80	120	72	2	2	0
		DAY 1		26FEB2003	1	68	120	76	70	118	74	2	-2	-2
		BASELINE				68	120	76	70	118	74	2	-2	-2
		DAY 8		05MAR2003	8	78	124	78	80	118	78	2	-6	0
		DAY 15		12MAR2003	15	72	108	72	80	106	74	8	-2	2
		DAY 22		20MAR2003	23	70	118	70	76	112	70	6	-6	0
		DAY 29		26MAR2003	29	72	100	60	74	98	58	2	-2	-2
		DAY 36		02APR2003	36	60	100	60	58	98	60	-2	-2	0
		DAY 43		09APR2003	43	64	118	76	62	116	76	-2	-2	0
		DAY 50		16APR2003	50	60	110	68	62	110	70	2	0	2
		DAY 57		23APR2003	57	74	120	88	72	118	88	-2	-2	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	FINAL		57	74	120	88	72	118	88	-2	-2	0
	E0020013	SCREEN	25FEB2003	-8	78	138	80	80	132	78	2	-6	-2
		DAY 1	05MAR2003	1	76	118	70	78	122	72	2	4	2
		BASELINE			76	118	70	78	122	72	2	4	2
		DAY 8	12MAR2003	8	72	124	80	88	124	84	16	0	4
		DAY 22	25MAR2003	21	68	120	72	76	114	74	8	-6	2
		FINAL		21	68	120	72	76	114	74	8	-6	2
	E0022008	SCREEN	05NOV2002	-7	64	120	72	68	110	68	4	-10	-4
		DAY 1	12NOV2002	1	62	112	44	82	131	66	20	19	22
		BASELINE			62	112	44	82	131	66	20	19	22
		DAY 8	19NOV2002	8	80	120	62	84	115	72	4	-5	10
		DAY 15	26NOV2002	15	70	120	70	64	110	68	-6	-10	-2
		DAY 22	03DEC2002	22	78	120	68	66	100	62	-12	-20	-6
		DAY 29	12DEC2002	31	66	122	70	75	116	74	9	-6	4
		DAY 36	17DEC2002	36	64	120	70	70	115	72	6	-5	2
		DAY 43	24DEC2002	43	62	125	74	66	110	70	4	-15	-4
		DAY 50	31DEC2002	50	68	120	68	70	126	70	2	6	2
		DAY 57	07JAN2003	57	68	120	66	78	132	74	10	12	8
		FINAL		57	68	120	66	78	132	74	10	12	8
	E0022017	SCREEN	03DEC2002	-16	64	110	80	76	100	78	12	-10	-2
		DAY 1	19DEC2002	1	60	120	82	96	116	82	36	-4	0
		BASELINE			60	120	82	96	116	82	36	-4	0
		DAY 8	26DEC2002	8	72	134	94	92	110	96	20	-24	2
		DAY 15	03JAN2003	16	76	126	86	104	116	92	28	-10	6
		DAY 22	09JAN2003	22	80	122	76	108	128	98	28	6	22
		DAY 29	17JAN2003	30	64	116	76	96	128	98	32	12	22
		DAY 36	22JAN2003	35	80	116	72	92	122	94	12	6	22
		DAY 43	31JAN2003	44	76	114	76	104	122	98	28	8	22
		DAY 50	06FEB2003	50	72	122	78	104	126	90	32	4	12
		DAY 57	13FEB2003	57	88	138	86	96	132	100	8	-6	14
		FINAL		57	88	138	86	96	132	100	8	-6	14

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	SCREEN	04DEC2002	-8	72	128	78	76	118	80	4	-10	2
		DAY 1	12DEC2002	1	88	130	90	88	126	80	0	-4	-10
		BASELINE			88	130	90	88	126	80	0	-4	-10
		DAY 8	19DEC2002	8	80	128	78	100	120	76	20	-8	-2
		DAY 15	26DEC2002	15	76	126	72	84	112	76	8	-14	4
		DAY 22	02JAN2003	22	84	118	76	80	114	76	-4	-4	0
		DAY 29	09JAN2003	29	84	126	76	100	116	68	16	-10	-8
		DAY 36	16JAN2003	36	76	124	80	88	118	76	12	-6	-4
		DAY 43	23JAN2003	43	84	118	76	96	114	74	12	-4	-2
		DAY 50	30JAN2003	50	88	116	72	100	108	82	12	-8	10
		DAY 57	06FEB2003	57	80	110	74	88	108	76	8	-2	2
		FINAL		57	80	110	74	88	108	76	8	-2	2
	E0022022	SCREEN	16DEC2002	-14	76	102	62	88	102	74	12	0	12
		DAY 1	30DEC2002	1	80	110	70	78	114	72	-2	4	2
		BASELINE			80	110	70	78	114	72	-2	4	2
		DAY 8	06JAN2003	8	76	108	64	88	108	68	12	0	4
		DAY 15	14JAN2003	16	88	98	54	84	96	60	-4	-2	6
		DAY 22	21JAN2003	23	88	100	78	88	112	68	0	12	-10
		DAY 29	28JAN2003	30	68	104	60	92	96	66	24	-8	6
		DAY 36	04FEB2003	37	64	112	68	88	98	70	24	-14	2
		DAY 57	27FEB2003	60									
		FINAL		60	64	112	68	88	98	70	24	-14	2
	E0022027	SCREEN	23JAN2003	-14	60	108	74	64	128	88	4	20	14
		DAY 1	06FEB2003	1	58	116	80	64	122	78	6	6	-2
		BASELINE			58	116	80	64	122	78	6	6	-2
		DAY 8	13FEB2003	8	70	116	72	72	108	70	2	-8	-2
		DAY 15	20FEB2003	15	64	104	70	72	112	70	8	8	0
		DAY 22	27FEB2003	22	64	108	64	68	106	74	4	-2	10
		DAY 29	06MAR2003	29	56	114	70	64	114	84	8	0	14
		DAY 36	13MAR2003	36	60	110	70	76	106	68	16	-4	-2
		DAY 43	20MAR2003	43	64	114	74	72	110	72	8	-4	-2
		DAY 50	27MAR2003	50	74	120	76	76	118	78	2	-2	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	DAY 57	03APR2003	57	60	108	70	66	110	74	6	2	4
		FINAL		57	60	108	70	66	110	74	6	2	4
	E0022030	SCREEN	07FEB2003	-7	88	128	82	84	138	88	-4	10	6
		DAY 1	14FEB2003	1	88	108	82	96	110	80	8	2	-2
		BASELINE			88	108	82	96	110	80	8	2	-2
		DAY 8	20FEB2003	7	80	122	72	96	128	88	16	6	16
		DAY 15	28FEB2003	15	88	108	72	80	118	84	-8	10	12
		DAY 22	07MAR2003	22	88	126	68	96	128	72	8	2	4
		FINAL		22	88	126	68	96	128	72	8	2	4
	E0022031	SCREEN	10FEB2003	-8	64	102	70	60	102	80	-4	0	10
		DAY 1	18FEB2003	1	60	110	78	64	118	74	4	8	-4
		BASELINE			60	110	78	64	118	74	4	8	-4
		DAY 8	25FEB2003	8	76	126	80	84	110	74	8	-16	-6
		DAY 15	04MAR2003	15	80	118	84	88	122	88	8	4	4
		DAY 22	11MAR2003	22	84	122	72	88	124	74	4	2	2
		DAY 29	18MAR2003	29	80	124	72	88	112	86	8	-12	14
		DAY 36	25MAR2003	36	80	124	80	88	120	80	8	-4	0
		DAY 43	01APR2003	43	80	118	80	84	122	90	4	4	10
		DAY 50	08APR2003	50	84	110	68	78	112	78	-6	2	10
		DAY 57	15APR2003	57	78	110	76	84	122	84	6	12	8
		FINAL		57	78	110	76	84	122	84	6	12	8
	E0022032	SCREEN	11FEB2003	-7	86	116	78	92	108	78	6	-8	0
		DAY 1	18FEB2003	1	82	124	76	96	108	74	14	-16	-2
		BASELINE			82	124	76	96	108	74	14	-16	-2
		DAY 8	28FEB2003	11	78	104	72	74	108	76	-4	4	4
		DAY 15	04MAR2003	15	84	114	78	84	108	76	0	-6	-2
		DAY 22	11MAR2003	22	76	120	76	84	114	76	8	-6	0
		DAY 29	21MAR2003	32	78	108	62	82	116	70	4	8	8
		DAY 36	27MAR2003	38	88	100	56	92	98	70	4	-2	14
		DAY 43	03APR2003	45	80	108	64	88	106	70	8	-2	6
		DAY 50	10APR2003	52	74	136	94	96	122	96	22	-14	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	DAY 57	18APR2003	60	76	108	62	74	106	66	-2	-2	4
		FINAL		60	76	108	62	74	106	66	-2	-2	4
	E0022035	SCREEN	11FEB2003	-8	72	108	72	84	102	74	12	-6	2
		DAY 1	19FEB2003	1	86	122	86	94	140	88	8	18	2
		BASELINE			86	122	86	94	140	88	8	18	2
		DAY 8	26FEB2003	8	78	116	80	87	122	84	9	6	4
		FINAL		8	78	116	80	87	122	84	9	6	4
	E0022036	SCREEN	13FEB2003	-12	72	122	74	80	114	84	8	-8	10
		DAY 1	25FEB2003	1	72	120	68	96	108	96	24	-12	28
		BASELINE			72	120	68	96	108	96	24	-12	28
		DAY 8	03MAR2003	7	78	110	64	98	102	80	20	-8	16
		DAY 15	10MAR2003	14	88	122	82	96	124	86	8	2	4
		DAY 22	18MAR2003	22	80	110	68	88	102	80	8	-8	12
		DAY 29	25MAR2003	29	80	110	74	88	102	82	8	-8	8
		DAY 36	01APR2003	36	84	112	68	88	110	82	4	-2	14
		DAY 43	08APR2003	43	78	122	74	96	118	88	18	-4	14
		DAY 50	15APR2003	50	78	100	72	88	102	72	10	2	0
		DAY 57	22APR2003	57	64	102	58	80	104	72	16	2	14
		FINAL		57	64	102	58	80	104	72	16	2	14
	E0022056	SCREEN	09APR2003	-8	84	128	82	88	142	88	4	14	6
		DAY 1	17APR2003	1	78	112	68	84	114	78	6	2	10
		BASELINE			78	112	68	84	114	78	6	2	10
		DAY 8	24APR2003	8	88	110	70	96	102	72	8	-8	2
		DAY 15	01MAY2003	15	88	108	70	96	112	76	8	4	6
		DAY 22	08MAY2003	22	100	106	68	104	110	80	4	4	12
		FINAL		22	100	106	68	104	110	80	4	4	12
	E0022060	SCREEN	23APR2003	-7	48	124	74	63	132	90	15	8	16
		DAY 1	30APR2003	1	48	116	78	60	124	88	12	8	10
		BASELINE			48	116	78	60	124	88	12	8	10
		DAY 8	05MAY2003	6	53	126	72	75	126	80	22	0	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	DAY 15		12MAY2003	13	60	104	68	66	122	72	6	18	4
		DAY 22		19MAY2003	20	57	124	74	57	124	80	0	0	6
		DAY 29		28MAY2003	29	60	116	62	66	118	74	6	2	12
		DAY 36		02JUN2003	34	63	114	70	69	122	72	6	8	2
		DAY 43		10JUN2003	42	60	112	60	63	120	76	3	8	16
		DAY 50		17JUN2003	49	63	124	70	72	118	68	9	-6	-2
		DAY 57		24JUN2003	56	52	110	70	60	116	74	8	6	4
		FINAL			56	52	110	70	60	116	74	8	6	4
	E0022063	SCREEN		30APR2003	-7	69	108	78	81	110	86	12	2	8
		DAY 1		07MAY2003	1	78	112	84	81	98	86	3	-14	2
		BASELINE				78	112	84	81	98	86	3	-14	2
		DAY 8		12MAY2003	6	69	110	74	72	110	80	3	0	6
		DAY 15		21MAY2003	15	81	108	76	84	110	82	3	2	6
		DAY 22		28MAY2003	22	69	108	80	75	112	82	6	4	2
		DAY 29		04JUN2003	29	72	108	70	75	104	66	3	-4	-4
		DAY 36		11JUN2003	36	78	102	64	78	112	70	0	10	6
		FINAL			36	78	102	64	78	112	70	0	10	6
	E0023008	SCREEN		23JAN2003	-7	68	110	67	70	108	66	2	-2	-1
		DAY 1		30JAN2003	1	76	108	68	72	108	66	-4	0	-2
		BASELINE				76	108	68	72	108	66	-4	0	-2
		DAY 8		06FEB2003	8	79	99	71	81	102	72	2	3	1
		DAY 15		13FEB2003	15	97	125	85	91	131	85	-6	6	0
		DAY 22		20FEB2003	22	80	102	74	80	100	70	0	-2	-4
		DAY 29		25FEB2003	27	90	108	76	88	110	76	-2	2	0
		DAY 36		06MAR2003	36	76	112	74	80	100	70	4	-12	-4
		DAY 43		11MAR2003	41	76	103	63	92	125	72	16	22	9
		DAY 50		18MAR2003	48	76	124	76	81	110	77	5	-14	1
		DAY 50	*	24MAR2003	54	78	114	74	78	114	76	0	0	2
		FINAL			54	78	114	74	78	114	76	0	0	2
	E0023013	SCREEN		13FEB2003	-14	79	119	77	84	124	76	5	5	-1
		DAY 1		27FEB2003	1	80	120	76	86	118	76	6	-2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023013	BASELINE			80	120	76	86	118	76	6	-2	0
		DAY 8	06MAR2003	8	78	120	70	76	128	78	-2	8	8
		FINAL		8	78	120	70	76	128	78	-2	8	8
	E0023015	SCREEN	04MAR2003	-7	82	120	84	86	128	86	4	8	2
		DAY 1	11MAR2003	1	70	120	68	76	120	70	6	0	2
		BASELINE			70	120	68	76	120	70	6	0	2
		DAY 8	18MAR2003	8	63	127	86	68	120	80	5	-7	-6
		DAY 15	25MAR2003	15	81	105	67	105	135	91	24	30	24
		DAY 22	01APR2003	22	75	90	60	81	93	56	6	3	-4
		DAY 29	08APR2003	29	79	116	75	105	100	73	26	-16	-2
		DAY 36	15APR2003	36	86	108	73	109	118	71	23	10	-2
		DAY 43	22APR2003	43	82	95	55	86	110	88	4	15	33
		DAY 50	29APR2003	50	72	128	70	98	128	72	26	0	2
		DAY 57	06MAY2003	57	87	99	71	97	103	69	10	4	-2
		FINAL		57	87	99	71	97	103	69	10	4	-2
	E0023034	SCREEN	03JUN2003	-6	86	99	62		109	70		10	8
		DAY 1	09JUN2003	1	88	104	64	109	105	64	21	1	0
		BASELINE			88	104	64	109	105	64	21	1	0
		DAY 8	16JUN2003	8	96	130	83	99	113	68	3	-17	-15
		DAY 15	23JUN2003	15	88	121	80	88	120	80	0	-1	0
		DAY 22	30JUN2003	22	100	113	66	121	131	78	21	18	12
		DAY 29	07JUL2003	29	97	114	72	126	116	74	29	2	2
		DAY 36	14JUL2003	36	126	121	69	142	109	56	16	-12	-13
		DAY 43	22JUL2003	44	107	136	80	111	122	80	4	-14	0
		DAY 57	05AUG2003	58	100	130	80	101	126	84	1	-4	4
		FINAL		58	100	130	80	101	126	84	1	-4	4
	E0023037	SCREEN	11JUN2003	-7	68	128	88	70	128	88	2	0	0
		DAY 1	18JUN2003	1	59	154	98	67	157	100	8	3	2
		BASELINE			59	154	98	67	157	100	8	3	2
		DAY 8	24JUN2003	7	86	148	92	90	150	90	4	2	-2
		DAY 15	01JUL2003	14	76	159	109	89	162	116	13	3	7

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023037	DAY 29	*	14JUL2003	27	65	158	103	78	148	106	13	-10	3
		DAY 29		18JUL2003	31	71	155	100	76	163	110	5	8	10
		DAY 36		25JUL2003	38	77	143	101	96	105	69	19	-38	-32
		DAY 43		01AUG2003	45	74	140	98	79	128	86	5	-12	-12
		DAY 50		08AUG2003	52	97	137	84	98	130	80	1	-7	-4
		DAY 57		15AUG2003	59	94	139	86	86	132	84	-8	-7	-2
		FINAL			59	94	139	86	86	132	84	-8	-7	-2
	E0023038	SCREEN		20JUN2003	-10	78	150	98	88	150	96	10	0	-2
		DAY 1		30JUN2003	1	79	149	89	92	157	94	13	8	5
		BASELINE				79	149	89	92	157	94	13	8	5
		DAY 8		09JUL2003	10	91	149	82	100	154	86	9	5	4
		DAY 15		15JUL2003	16	82	144	88	88	134	86	6	-10	-2
		DAY 22		21JUL2003	22	87	153	89	96	144	84	9	-9	-5
		DAY 29		28JUL2003	29	86	155	82	90	135	80	4	-20	-2
		DAY 36		07AUG2003	39	74	124	79	78	120	77	4	-4	-2
		DAY 43		13AUG2003	45	93	138	83	87	125	87	-6	-13	4
		DAY 50		21AUG2003	53	84	139	95	78	155	98	-6	16	3
		DAY 57		27AUG2003	59	84	136	91	99	109	72	15	-27	-19
		FINAL			59	84	136	91	99	109	72	15	-27	-19
	E0023044	SCREEN		08JUL2003	-8	78	130	90	84	134	90	6	4	0
		DAY 1		16JUL2003	1	81	118	81	85	120	80	4	2	-1
		BASELINE				81	118	81	85	120	80	4	2	-1
		DAY 8		22JUL2003	7	93	108	74	109	127	87	16	19	13
		DAY 15		29JUL2003	14	79	115	77	84	110	76	5	-5	-1
		DAY 22		05AUG2003	21	84	121	80	88	120	78	4	-1	-2
		DAY 29		12AUG2003	28	72	114	81	82	146	102	10	32	21
		FINAL			28	72	114	81	82	146	102	10	32	21
	E0023045	SCREEN		10JUL2003	-7	80	115	78	84	99	69	4	-16	-9
		DAY 1		17JUL2003	1	66	110	66	68	110	60	2	0	-6
		BASELINE				66	110	66	68	110	60	2	0	-6
		DAY 8		24JUL2003	8	74	94	61	80	98	64	6	4	3

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023045	DAY 15	31JUL2003	15	74	100	70	76	98	68	2	-2	-2
		DAY 22	07AUG2003	22	70	100	70	72	100	72	2	0	2
		DAY 29	14AUG2003	29	88	110	76	80	113	74	-8	3	-2
		DAY 36	21AUG2003	36	82	124	71	86	120	70	4	-4	-1
		DAY 43	28AUG2003	43	84	120	76	88	118	70	4	-2	-6
		DAY 50	04SEP2003	50	94	118	80	90	120	84	-4	2	4
		DAY 57	11SEP2003	57	86	118	80	80	134	71	-6	16	-9
		FINAL		57	86	118	80	80	134	71	-6	16	-9
	E0025002	SCREEN	27MAR2003	-7	84	130	90	76	120	82	-8	-10	-8
		DAY 1	03APR2003	1	64	120	72	72	116	70	8	-4	-2
		BASELINE			64	120	72	72	116	70	8	-4	-2
		DAY 8	10APR2003	8	60	120	88	72	130	90	12	10	2
		DAY 15	17APR2003	15	64	120	80	72	116	70	8	-4	-10
		DAY 22	24APR2003	22	64	120	70	64	116	80	0	-4	10
		DAY 29	01MAY2003	29	72	130	82	72	120	78	0	-10	-4
		DAY 36	08MAY2003	36	72	120	82	72	120	80	0	0	-2
		DAY 43	15MAY2003	43	84	130	80	88	120	88	4	-10	8
		DAY 50	22MAY2003	50	80	120	70	88	130	80	8	10	10
		DAY 57	29MAY2003	57	68	120	88	80	120	80	12	0	-8
		FINAL		57	68	120	88	80	120	80	12	0	-8
	E0026010	SCREEN	15JAN2003	-7	68	138	62	80	145	74	12	7	12
		DAY 1	22JAN2003	1	61	129	70	66	142	71	5	13	1
		BASELINE			61	129	70	66	142	71	5	13	1
		DAY 8	30JAN2003	9	78	121	60	86	138	68	8	17	8
		FINAL		9	78	121	60	86	138	68	8	17	8
	E0026017	SCREEN	26FEB2003	-8	60	156	74	64	158	82	4	2	8
		DAY 1	06MAR2003	1	62	144	62	69	148	73	7	4	11
		BASELINE			62	144	62	69	148	73	7	4	11
		DAY 15	21MAR2003	16	59	142	58	62	146	66	3	4	8
		FINAL		16	59	142	58	62	146	66	3	4	8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	SCREEN	06MAR2003	-14	73	138	67	86	139	72	13	1	5
		DAY 1	20MAR2003	1	88	113	72	94	132	75	6	19	3
		BASELINE			88	113	72	94	132	75	6	19	3
		DAY 8	27MAR2003	8	82	136	76	90	134	73	8	-2	-3
		DAY 15	03APR2003	15	87	142	65	91	123	79	4	-19	14
		DAY 22	10APR2003	22	84	145	81	89	116	77	5	-29	-4
		DAY 29	17APR2003	29	70	121	70	88	139	79	18	18	9
		DAY 36	24APR2003	36	94	133	80	98	145	79	4	12	-1
		DAY 43	01MAY2003	43	80	115	73	96	117	68	16	2	-5
		DAY 50	08MAY2003	50	79	121	72	88	105	69	9	-16	-3
		DAY 57	15MAY2003	57	71	126	63	80	127	84	9	1	21
		FINAL		57	71	126	63	80	127	84	9	1	21
	E0026025	SCREEN	01MAY2003	-8	75	136	82	78	123	88	3	-13	6
		DAY 1	09MAY2003	1	98	127	82	102	133	86	4	6	4
		BASELINE			98	127	82	102	133	86	4	6	4
		DAY 8	15MAY2003	7	78	134	88	97	131	96	19	-3	8
		DAY 15	22MAY2003	14	76	115	88	80	130	76	4	15	-12
		DAY 22	29MAY2003	21	80	132	90	84	141	96	4	9	6
		DAY 29	05JUN2003	28	92	153	87	90	148	95	-2	-5	8
		DAY 36	13JUN2003	36	80	150	90	96	191	102	16	41	12
		DAY 43	20JUN2003	43	90	150	90	89	148	102	-1	-2	12
		DAY 50	27JUN2003	50	75	138	88	77	132	87	2	-6	-1
		DAY 57	03JUL2003	56	90	130	87	85	145	56	-5	15	-31
		FINAL		56	90	130	87	85	145	56	-5	15	-31
	E0026029	SCREEN	02JUL2003	-7	63	100	60	72	103	65	9	3	5
		DAY 1	09JUL2003	1	86	103	64	80	105	70	-6	2	6
		BASELINE			86	103	64	80	105	70	-6	2	6
		DAY 8	16JUL2003	8	92	126	69	94	135	73	2	9	4
		DAY 22	28JUL2003	20	100	130	72	100	120	68	0	-10	-4
		FINAL		20	100	130	72	100	120	68	0	-10	-4
	E0026030	SCREEN	02JUL2003	-7	66	123	69	66	121	70	0	-2	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	DAY 1	09JUL2003	1	90	126	66	84	133	69	-6	7	3
		BASELINE			90	126	66	84	133	69	-6	7	3
		DAY 8	16JUL2003	8	72	147	72	80	142	68	8	-5	-4
		DAY 15	23JUL2003	15	72	123	66	82	130	74	10	7	8
		DAY 22	30JUL2003	22	86	139	78	90	131	83	4	-8	5
		DAY 29	04AUG2003	27	77	114	62	89	126	77	12	12	15
		DAY 36	12AUG2003	35	73	110	85	73	120	85	0	10	0
		DAY 43	19AUG2003	42	67	115	68	74	116	72	7	1	4
		DAY 50	26AUG2003	49	75	105	63	80	110	70	5	5	7
		DAY 57	03SEP2003	57	65	126	73	72	130	80	7	4	7
		FINAL		57	65	126	73	72	130	80	7	4	7
	E0026031	SCREEN	10JUL2003	-11	80	140	83	92	139	84	12	-1	1
		DAY 1	21JUL2003	1	90	120	70	89	130	72	-1	10	2
		BASELINE			90	120	70	89	130	72	-1	10	2
		DAY 8	28JUL2003	8	72	137	72	70	140	68	-2	3	-4
		DAY 15	04AUG2003	15	86	132	72	82	140	66	-4	8	-6
		DAY 22	11AUG2003	22	73	147	83	85	144	87	12	-3	4
		DAY 29	18AUG2003	29	83	136	82	90	150	80	7	14	-2
		DAY 36	25AUG2003	36	82	140	80	84	142	76	2	2	-4
		DAY 43	02SEP2003	44	86	121	80	90	123	90	4	2	10
		DAY 50	08SEP2003	50	72	126	80	80	130	76	8	4	-4
		DAY 57	15SEP2003	57	72	110	80	78	122	76	6	12	-4
		FINAL		57	72	110	80	78	122	76	6	12	-4
	E0027003	SCREEN *	08JAN2003	-20				86	142	84			
		SCREEN	23JAN2003	-5				78	126	82			
		BASELINE						78	126	82			
		DAY 8	06FEB2003	10	80	130	90	96	120	92	16	-10	2
		DAY 15	13FEB2003	17	104	142	90	104	132	88	0	-10	-2
		DAY 22	19FEB2003	23	92	130	90	104	126	88	12	-4	-2
		DAY 29	27FEB2003	31	96	130	94	100	134	96	4	4	2
		DAY 36	06MAR2003	38	96	120	92	100	114	92	4	-6	0
		DAY 43	13MAR2003	45	88	124	86	88	134	90	0	10	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0027003	DAY 50		20MAR2003	52	98	138	98	104	130	92	6	-8	-6
		DAY 57		25MAR2003	57	92	152	86	94	148	84	2	-4	-2
		FINAL			57	92	152	86	94	148	84	2	-4	-2
	E0028004	SCREEN		27SEP2002	-3	48	100	70	52	110	70	4	10	0
		DAY 1		30SEP2002	1	74	92	68	74	100	82	0	8	14
		BASELINE				74	92	68	74	100	82	0	8	14
		DAY 8		07OCT2002	8	63	100	80	62	100	70	-1	0	-10
		DAY 8	*	09OCT2002	10	64	108	80	76	110	80	12	2	0
		FINAL			10	64	108	80	76	110	80	12	2	0
	E0028006	SCREEN		01OCT2002	-3	60	100	70	56	100	70	-4	0	0
		DAY 1		04OCT2002	1	68	102	60	68	98	70	0	-4	10
		BASELINE				68	102	60	68	98	70	0	-4	10
		DAY 8		11OCT2002	8	68	130	80	70	128	70	2	-2	-10
		DAY 15		16OCT2002	13	60	122	70	62	120	70	2	-2	0
		DAY 22		23OCT2002	20	76	118	82	78	124	90	2	6	8
		DAY 29		31OCT2002	28	68	115	70	62	122	70	-6	7	0
		DAY 36		07NOV2002	35	70	112	80	84	114	76	14	2	-4
		DAY 43		14NOV2002	42	68	118	82	78	118	84	10	0	2
		DAY 50		21NOV2002	49	68	130	84	74	118	92	6	-12	8
		DAY 57		04DEC2002	62	64	110	76	64	108	80	0	-2	4
		FINAL			62	64	110	76	64	108	80	0	-2	4
	E0028008	SCREEN		08OCT2002	-7	68	130	78	68	118	76	0	-12	-2
		DAY 1		15OCT2002	1	70	100	60	68	120	60	-2	20	0
		BASELINE				70	100	60	68	120	60	-2	20	0
		DAY 8		22OCT2002	8	68	121	68	68	116	72	0	-5	4
		DAY 15		29OCT2002	15	76	112	70	76	105	78	0	-7	8
		DAY 22		07NOV2002	24	68	138	70	68	130	72	0	-8	2
		DAY 29		14NOV2002	31	68	128	76	68	126	78	0	-2	2
		DAY 36		21NOV2002	38	64	110	70	64	122	70	0	12	0
		DAY 43		26NOV2002	43	62	110	68	66	110	78	4	0	10
		DAY 50		03DEC2002	50	56	118	78	56	114	56	0	-4	-22

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028008	DAY 57	10DEC2002	57	68	110	70	68	110	74	0	0	4
		FINAL		57	68	110	70	68	110	74	0	0	4
	E0028009	SCREEN	10OCT2002	-5	54	115	70	56	115	70	2	0	0
		DAY 1	15OCT2002	1	56	118	60	60	115	60	4	-3	0
		BASELINE			56	118	60	60	115	60	4	-3	0
		DAY 8	23OCT2002	9	54	100	70	56	110	70	2	10	0
		DAY 15	31OCT2002	17	64	116	80	82	116	82	18	0	2
		DAY 22	07NOV2002	24	60	102	80	82	100	80	22	-2	0
		DAY 29	14NOV2002	31	56	114	76	72	98	82	16	-16	6
		DAY 36	19NOV2002	36	66	114	78	88	110	90	22	-4	12
		DAY 43	26NOV2002	43	60	118	82	64	118	90	4	0	8
		DAY 50	03DEC2002	50	60	102	78	60	108	78	0	6	0
		DAY 57	12DEC2002	59	68	118	70	72	112	64	4	-6	-6
		FINAL		59	68	118	70	72	112	64	4	-6	-6
	E0028016	SCREEN	07NOV2002	-7	68	130	72	68	118	80	0	-12	8
		DAY 1	14NOV2002	1	64	118	88	64	110	80	0	-8	-8
		BASELINE			64	118	88	64	110	80	0	-8	-8
		DAY 8	21NOV2002	8	68	120	82	68	116	80	0	-4	-2
		DAY 15	26NOV2002	13	76	126	82	88	124	90	12	-2	8
		DAY 22	05DEC2002	22	76	130	88	76	119	90	0	-11	2
		DAY 29	12DEC2002	29	76	140	86	76	118	90	0	-22	4
		DAY 36	19DEC2002	36	64	120	78	64	120	82	0	0	4
		DAY 43	26DEC2002	43	80	112	80	80	120	78	0	8	-2
		DAY 50	02JAN2003	50	76	128	72	80	124	70	4	-4	-2
		DAY 57	09JAN2003	57	80	126	80	88	122	88	8	-4	8
		FINAL		57	80	126	80	88	122	88	8	-4	8
	E0028017		12NOV2002		64	120	80	64	118	80	0	-2	0
			19NOV2002		68	118	90	68	118	88	0	0	-2
	E0028027	SCREEN	14JAN2003	-7	60	110	92	62	110	88	2	0	-4
		DAY 1	21JAN2003	1	66	110	88	66	110	90	0	0	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028027	BASELINE			66	110	88	66	110	90	0	0	2
		DAY 8	28JAN2003	8	64	140	98	68	134	92	4	-6	-6
		DAY 15	04FEB2003	15	80	110	90	76	108	90	-4	-2	0
		DAY 22	11FEB2003	22	70	114	92	70	120	92	0	6	0
		DAY 29	20FEB2003	31	62	120	80	79	112	74	17	-8	-6
		DAY 36	28FEB2003	39	72	88	70	76	90	68	4	2	-2
		FINAL		39	72	88	70	76	90	68	4	2	-2
	E0028029	SCREEN	28JAN2003	-7	56	110	80	62	112	88	6	2	8
		DAY 1	04FEB2003	1	72	118	74	76	118	92	4	0	18
		BASELINE			72	118	74	76	118	92	4	0	18
		DAY 8	11FEB2003	8	72	124	64	76	120	58	4	-4	-6
		DAY 15	17FEB2003	14	88	114	84	88	108	92	0	-6	8
		DAY 22	27FEB2003	24	80	130	78	84	132	76	4	2	-2
		DAY 29	06MAR2003	31	72	122	70	90	110	62	18	-12	-8
		DAY 36	13MAR2003	38	78	120	74	84	114	80	6	-6	6
		DAY 43	20MAR2003	45	72	120	80	76	118	84	4	-2	4
		DAY 50	27MAR2003	52	78	122	90	76	110	84	-2	-12	-6
		DAY 57	04APR2003	60	68	122	90	68	118	84	0	-4	-6
		FINAL		60	68	122	90	68	118	84	0	-4	-6
	E0028034	SCREEN	20MAR2003	-12	64	122	82	68	114	76	4	-8	-6
		DAY 1	01APR2003	1	76	122	70	92	110	66	16	-12	-4
		BASELINE			76	122	70	92	110	66	16	-12	-4
		DAY 8	08APR2003	8	68	114	84	80	116	84	12	2	0
		DAY 15	15APR2003	15	84	122	84	92	100	76	8	-22	-8
		DAY 22	22APR2003	22	80	122	70	88	116	66	8	-6	-4
		DAY 29	01MAY2003	31	92	126	80	100	122	78	8	-4	-2
		DAY 36	06MAY2003	36	88	120	80	100	120	76	12	0	-4
		DAY 43	13MAY2003	43	88	128	64	100	118	66	12	-10	2
		DAY 50	21MAY2003	51	88	124	76	96	122	74	8	-2	-2
		DAY 57	02JUN2003	63	80	116	88	88	104	84	8	-12	-4
		FINAL		63	80	116	88	88	104	84	8	-12	-4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	SCREEN	18APR2003	-7	72	140	88	84	124	82	12	-16	-6
		DAY 1	25APR2003	1	74	142	84	80	126	82	6	-16	-2
		BASELINE			74	142	84	80	126	82	6	-16	-2
		DAY 8	02MAY2003	8	76	136	88	88	134	84	12	-2	-4
		DAY 15	08MAY2003	14	77	130	88	70	130	88	-7	0	0
		DAY 29	22MAY2003	28	80	136	80	92	130	84	12	-6	4
		DAY 36	30MAY2003	36	88	152	98	92	138	88	4	-14	-10
		DAY 43	05JUN2003	42		138	90		110	80		-28	-10
		DAY 50	12JUN2003	49	88	145	92	80	140	90	-8	-5	-2
		DAY 57	18JUN2003	55	72	140	80	78	130	82	6	-10	2
		FINAL		55	72	140	80	78	130	82	6	-10	2
	E0028043	SCREEN	29MAY2003	-7	60	146	92	64	144	88	4	-2	-4
		DAY 1	05JUN2003	1	70	154	98	74	150	94	4	-4	-4
		BASELINE			70	154	98	74	150	94	4	-4	-4
		DAY 8	12JUN2003	8	80	155	105	100	150	110	20	-5	5
		DAY 15	19JUN2003	15	74	140	100	64	138	104	-10	-2	4
		DAY 22	26JUN2003	22	78	130	80	80	130	86	2	0	6
		DAY 29	01JUL2003	27	100	140	100	98	130	98	-2	-10	-2
		DAY 36	08JUL2003	34	60	130	86	64	130	90	4	0	4
		DAY 43	15JUL2003	41	80	140	100	80	140	102	0	0	2
		DAY 50	22JUL2003	48	76	142	92	76	128	94	0	-14	2
		DAY 57	29JUL2003	55	60	130	80	80	140	88	20	10	8
		FINAL		55	60	130	80	80	140	88	20	10	8
	E0028045	SCREEN	09JUN2003	-9	74	140	82	80	120	70	6	-20	-12
		DAY 1	18JUN2003	1	72	126	84	84	132	88	12	6	4
		BASELINE			72	126	84	84	132	88	12	6	4
		DAY 8	25JUN2003	8	80	112	74	78	115	86	-2	3	12
		DAY 15	30JUN2003	13	106	120	78	110	115	86	4	-5	8
		DAY 57	11SEP2003	86	76	115	78	76	100	80	0	-15	2
		FINAL		86	76	115	78	76	100	80	0	-15	2
	E0029005	SCREEN	14NOV2002	-13	78	102	74	80	108	68	2	6	-6

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0029005	DAY 1		27NOV2002	1	56	118	82	80	110	82	24	-8	0
		BASELINE				56	118	82	80	110	82	24	-8	0
		DAY 8		03DEC2002	7	72	120	84	96	110	82	24	-10	-2
		DAY 15		09DEC2002	13	84	134	92	92	134	90	8	0	-2
		DAY 22		16DEC2002	20	96	108	70	112	104	80	16	-4	10
		DAY 29		23DEC2002	27	80	118	76	112	126	80	32	8	4
		DAY 36		30DEC2002	34	92	110	76	92	110	82	0	0	6
		DAY 43		07JAN2003	42	76	110	80	104	110	82	28	0	2
		DAY 50		14JAN2003	49	80	90	64	100	106	80	20	16	16
		DAY 57		21JAN2003	56	80	110	80	92	110	82	12	0	2
		FINAL			56	80	110	80	92	110	82	12	0	2
	E0030001	SCREEN		12NOV2002	-7	80	120	78	88	126	84	8	6	6
		DAY 1		19NOV2002	1	68	120	84	80	124	84	12	4	0
		BASELINE				68	120	84	80	124	84	12	4	0
		DAY 8		26NOV2002	8	80	110	66	84	110	68	4	0	2
		DAY 15		03DEC2002	15	80	138	88	84	134	86	4	-4	-2
		DAY 22		10DEC2002	22	84	110	74	88	112	74	4	2	0
		DAY 29		17DEC2002	29	92	120	76	92	120	80	0	0	4
		DAY 43		02JAN2003	45	72	110	72	84	108	78	12	-2	6
		DAY 50		09JAN2003	52	88	114	76	88	126	80	0	12	4
		DAY 57		16JAN2003	59	80	120	80	80	120	82	0	0	2
		FINAL			59	80	120	80	80	120	82	0	0	2
	E0030008	SCREEN		07JAN2003	-7	62	110	70	63	106	72	1	-4	2
		DAY 1		14JAN2003	1	60	112	70	60	108	76	0	-4	6
		BASELINE				60	112	70	60	108	76	0	-4	6
		DAY 8		23JAN2003	10	72	110	80	80	118	86	8	8	6
		DAY 15		30JAN2003	17	80	118	84	80	112	84	0	-6	0
		DAY 22		07FEB2003	25	64	108	70	80	104	76	16	-4	6
		DAY 29		14FEB2003	32	80	110	70	88	104	70	8	-6	0
		DAY 36		21FEB2003	39	68	112	76	76	108	78	8	-4	2
		DAY 50		03MAR2003	49	64	118	74	72	110	80	8	-8	6
		DAY 57	*	11MAR2003	57	60	110	70	64	104	80	4	-6	10

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030008	DAY 57		18MAR2003	64	80	108	86	72	110	76	-8	2	-10
		FINAL			64	80	108	86	72	110	76	-8	2	-10
	E0030011	SCREEN		16JAN2003	-11	72	130	80	88	136	78	16	6	-2
		DAY 1		27JAN2003	1	84	136	76	88	138	84	4	2	8
		BASELINE				84	136	76	88	138	84	4	2	8
		DAY 8		03FEB2003	8	80	138	86	84	134	88	4	-4	2
		DAY 15		10FEB2003	15	84	134	80	84	138	82	0	4	2
		DAY 22		18FEB2003	23	80	128	66	86	134	72	6	6	6
		DAY 29		24FEB2003	29	80	124	68	88	130	66	8	6	-2
		DAY 36		03MAR2003	36	88	122	78	88	130	90	0	8	12
		DAY 43		10MAR2003	43	88	138	82	96	132	84	8	-6	2
		DAY 50		17MAR2003	50	84	140	70	96	130	94	12	-10	24
		DAY 57		24MAR2003	57	80	130	80	88	140	90	8	10	10
		FINAL			57	80	130	80	88	140	90	8	10	10
	E0030015	SCREEN		13FEB2003	-8	52	122	86	56	132	92	4	10	6
		DAY 1		21FEB2003	1	68	118	74	74	116	82	6	-2	8
		BASELINE				68	118	74	74	116	82	6	-2	8
		DAY 8		03MAR2003	11	60	126	74	68	120	70	8	-6	-4
		DAY 15		11MAR2003	19	60	130	74	88	136	80	28	6	6
		DAY 29		19MAR2003	27	56	114	64	80	120	80	24	6	16
		DAY 36		26MAR2003	34	56	130	80	72	124	84	16	-6	4
		DAY 43		02APR2003	41	52	112	82	80	110	84	28	-2	2
		DAY 50		09APR2003	48	52	110	80	72	112	78	20	2	-2
		DAY 57	*	17APR2003	56	52	130	80	68	110	84	16	-20	4
		DAY 57		22APR2003	61	60	120	84	72	124	90	12	4	6
		FINAL			61	60	120	84	72	124	90	12	4	6
	E0030022	SCREEN		06JUN2003	-10	64	124	92	62	122	91	-2	-2	-1
		DAY 1		16JUN2003	1	72	122	80	88	124	84	16	2	4
		BASELINE				72	122	80	88	124	84	16	2	4
		DAY 8		20JUN2003	5	68	118	90	78	120	90	10	2	0
		DAY 15		30JUN2003	15	68	112	84	80	118	88	12	6	4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	DAY 22		07JUL2003	22	68	134	90	80	134	90	12	0	0
		DAY 29		14JUL2003	29	60	124	90	90	126	90	30	2	0
		DAY 36		21JUL2003	36	60	128	88	64	124	88	4	-4	0
		DAY 43		29JUL2003	44	60	124	88	64	120	90	4	-4	2
		DAY 50		05AUG2003	51	68	128	92	68	122	96	0	-6	4
		DAY 57		14AUG2003	60	72	124	88	76	128	90	4	4	2
		FINAL			60	72	124	88	76	128	90	4	4	2
	E0031002	SCREEN		20NOV2002	-7	74	120	88	76	118	82	2	-2	-6
		DAY 1		27NOV2002	1	60	122	62	74	118	72	14	-4	10
		BASELINE				60	122	62	74	118	72	14	-4	10
		DAY 8		06DEC2002	10	80	90	70	84	105	75	4	15	5
		DAY 15		12DEC2002	16	68	112	80	72	110	80	4	-2	0
		DAY 22		19DEC2002	23	70	118	64	64	120	68	-6	2	4
		DAY 29		27DEC2002	31	60	110	68	64	118	72	4	8	4
		DAY 36		02JAN2003	37	58	108	58	67	110	64	9	2	6
		DAY 50	*	13JAN2003	48	66	118	62	60	124	68	-6	6	6
		DAY 50		17JAN2003	52	68	110	64	72	114	70	4	4	6
		DAY 57		22JAN2003	57	66	104	60	70	116	70	4	12	10
		FINAL			57	66	104	60	70	116	70	4	12	10
	E0031003	SCREEN		03DEC2002	-7	72	110	78	78	118	82	6	8	4
		DAY 1		10DEC2002	1	78	116	80	90	112	80	12	-4	0
		BASELINE				78	116	80	90	112	80	12	-4	0
		DAY 8		17DEC2002	8	92	128	84	96	124	81	4	-4	-3
		DAY 15		23DEC2002	14	90	110	72	94	114	74	4	4	2
		DAY 22		31DEC2002	22	74	119	76	80	120	80	6	1	4
		DAY 29		07JAN2003	29	80	122	68	88	124	68	8	2	0
		DAY 36		15JAN2003	37	64	112	74	75	114	76	11	2	2
		DAY 43		21JAN2003	43	90	120	78	90	124	84	0	4	6
		DAY 50		30JAN2003	52	78	124	76	86	130	80	8	6	4
		DAY 57		04FEB2003	57	74	124	76	90	130	82	16	6	6
		FINAL			57	74	124	76	90	130	82	16	6	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	SCREEN		03APR2003	-7	52	100	70	60	100	72	8	0	2
		DAY 1		10APR2003	1	60	98	68	64	100	70	4	2	2
		BASELINE				60	98	68	64	100	70	4	2	2
		DAY 8		17APR2003	8	56	90	70	64	100	70	8	10	0
		DAY 15		22APR2003	13	56	98	62	64	100	66	8	2	4
		DAY 15	*	28APR2003	19	52	110	70	68	110	70	16	0	0
		DAY 29		06MAY2003	27	60	100	60	84	100	64	24	0	4
		DAY 36		13MAY2003	34	48	90	70	60	96	70	12	6	0
		DAY 43		20MAY2003	41	56	100	70	64	100	70	8	0	0
		DAY 50		27MAY2003	48	56	100	70	72	110	70	16	10	0
		DAY 57		04JUN2003	56	64	100	70	68	100	70	4	0	0
		FINAL			56	64	100	70	68	100	70	4	0	0
	E0034002	SCREEN		14MAR2003	-11	72	145	100	88	130	95	16	-15	-5
		DAY 1		25MAR2003	1	68	150	100	80	145	105	12	-5	5
		BASELINE				68	150	100	80	145	105	12	-5	5
		DAY 8		01APR2003	8	84	140	88	96	132	86	12	-8	-2
		DAY 15		08APR2003	15	72	128	88	92	130	94	20	2	6
		DAY 22		15APR2003	22	76	132	85	80	138	90	4	6	5
		FINAL			22	76	132	85	80	138	90	4	6	5
	E0034003	SCREEN		11APR2003	-13	68	120	80	84	115	70	16	-5	-10
		DAY 1		24APR2003	1	68	116	74	84	118	78	16	2	4
		BASELINE				68	116	74	84	118	78	16	2	4
		DAY 8		01MAY2003	8	72	114	80	92	118	82	20	4	2
		DAY 15		08MAY2003	15	84	126	82	102	128	88	18	2	6
		DAY 22		15MAY2003	22	88	110	80	96	118	85	8	8	5
		DAY 29		22MAY2003	29	68	120	85	84	125	80	16	5	-5
		DAY 36		29MAY2003	36	68	115	70	96	120	85	28	5	15
		DAY 43		05JUN2003	43	84	120	80	100	118	76	16	-2	-4
		DAY 50		12JUN2003	50	76	125	75	92	130	90	16	5	15
		DAY 57		19JUN2003	57	68	115	85	80	125	90	12	10	5
		FINAL			57	68	115	85	80	125	90	12	10	5

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0034006	SCREEN	25APR2003	-21	56	120	65	72	130	80	16	10	15
		DAY 1	16MAY2003	1	76	125	70	80	130	90	4	5	20
		BASELINE			76	125	70	80	130	90	4	5	20
		DAY 8	23MAY2003	8	68	130	80	92	120	85	24	-10	5
		DAY 15	02JUN2003	18	80	124	86	88	122	82	8	-2	-4
		DAY 22	09JUN2003	25	76	125	80	86	110	70	10	-15	-10
		DAY 29	13JUN2003	29	80	108	74	84	110	72	4	2	-2
		DAY 36	20JUN2003	36	74	125	90	88	110	85	14	-15	-5
		DAY 43	27JUN2003	43	86	135	85	84	139	90	-2	4	5
		DAY 50	03JUL2003	49	68	130	95	80	140	100	12	10	5
		DAY 57	10JUL2003	56	68	125	85	80	130	90	12	5	5
		FINAL		56	68	125	85	80	130	90	12	5	5
	E0034008	SCREEN	15MAY2003	-9	72	116	78	84	118	82	12	2	4
		DAY 1	23MAY2003	-1	64	130	70	76	110	85	12	-20	15
		BASELINE			64	130	70	76	110	85	12	-20	15
		DAY 8	02JUN2003	10	92	125	90	104	120	85	12	-5	-5
		DAY 15	06JUN2003	14	64	122	85	76	110	80	12	-12	-5
		DAY 22	13JUN2003	21	74	102	70	78	106	70	4	4	0
		DAY 29	20JUN2003	28	68	114	80	72	108	76	4	-6	-4
		DAY 36	27JUN2003	35	64	120	80	72	130	85	8	10	5
		DAY 43	07JUL2003	45	68	120	85	88	125	95	20	5	10
		DAY 50	14JUL2003	52	64	110	70	88	110	80	24	0	10
		DAY 57	21JUL2003	59	68	125	80	88	120	85	20	-5	5
		FINAL		59	68	125	80	88	120	85	20	-5	5
	E0035003	SCREEN	15NOV2002	-7	76	124	80	82	126	84	6	2	4
		DAY 1	22NOV2002	1	78	126	80	84	126	86	6	0	6
		BASELINE			78	126	80	84	126	86	6	0	6
		DAY 8	27NOV2002	6	74	118	82	80	122	76	6	4	-6
		DAY 15	04DEC2002	13	78	120	74	82	122	76	4	2	2
		DAY 22	13DEC2002	22	80	122	70	82	124	74	2	2	4
		DAY 29	20DEC2002	29	80	122	70	84	122	76	4	0	6
		DAY 36	27DEC2002	36	82	124	76	88	126	80	6	2	4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	DAY 43	03JAN2003	43	80	126	72	84	128	72	4	2	0
		DAY 50	10JAN2003	50	78	122	66	80	124	70	2	2	4
		FINAL		50	78	122	66	80	124	70	2	2	4
	E0035005	SCREEN	26NOV2002	-7	96	114	80	104	118	84	8	4	4
		DAY 1	03DEC2002	1	90	114	80	96	118	82	6	4	2
		BASELINE			90	114	80	96	118	82	6	4	2
		DAY 8	12DEC2002	10	90	116	68	94	118	72	4	2	4
		DAY 15	17DEC2002	15	88	118	68	90	118	76	2	0	8
		DAY 22	24DEC2002	22	82	114	72	88	116	78	6	2	6
		DAY 29	31DEC2002	29	82	112	70	84	114	74	2	2	4
		DAY 36	07JAN2003	36	82	114	70	88	114	76	6	0	6
		DAY 43	14JAN2003	43	84	114	72	86	114	78	2	0	6
		DAY 50	21JAN2003	50	66	124	64	68	126	68	2	2	4
		FINAL		50	66	124	64	68	126	68	2	2	4
	E0035014	SCREEN	28JAN2003	-6	64	110	74	70	112	78	6	2	4
		DAY 1	03FEB2003	1	64	110	72	68	110	76	4	0	4
		BASELINE			64	110	72	68	110	76	4	0	4
		DAY 8	10FEB2003	8	64	108	62	68	110	70	4	2	8
		DAY 15	17FEB2003	15	66	108	72	70	112	72	4	4	0
		DAY 22	24FEB2003	22	68	106	70	72	110	72	4	4	2
		DAY 29	03MAR2003	29	68	108	64	74	110	70	6	2	6
		DAY 36	10MAR2003	36	64	110	68	72	112	74	8	2	6
		DAY 43	17MAR2003	43	66	108	68	70	108	74	4	0	6
		DAY 50	24MAR2003	50	68	108	68	74	110	72	6	2	4
		DAY 57	31MAR2003	57	70	106	70	74	108	78	4	2	8
		FINAL		57	70	106	70	74	108	78	4	2	8
	E0035024	SCREEN	15MAY2003	-8	78	116	70	82	118	74	4	2	4
		DAY 1	22MAY2003	-1	80	114	72	84	118	70	4	4	-2
		BASELINE			80	114	72	84	118	70	4	4	-2
		DAY 8	29MAY2003	7	84	120	76	88	122	80	4	2	4
		DAY 15	05JUN2003	14	78	120	80	82	124	76	4	4	-4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	DAY 22	13JUN2003	22	84	122	80	88	124	82	4	2	2
		DAY 29	19JUN2003	28	80	122	84	84	124	84	4	2	0
		DAY 36	27JUN2003	36	84	132	86	88	136	84	4	4	-2
		DAY 43	03JUL2003	42	82	132	86	88	134	86	6	2	0
		DAY 50	10JUL2003	49	80	130	80	84	132	86	4	2	6
		DAY 57	18JUL2003	57	80	130	80	88	132	88	8	2	8
		FINAL		57	80	130	80	88	132	88	8	2	8
	E0036005	SCREEN	24JUN2003	-7	93	109	68	94	107	71	1	-2	3
		DAY 1	01JUL2003	1	61	103	66	71	100	66	10	-3	0
		BASELINE			61	103	66	71	100	66	10	-3	0
		DAY 8	08JUL2003	8	75	106	65	89	103	66	14	-3	1
		DAY 15	15JUL2003	15	86	122	65	95	119	76	9	-3	11
		DAY 22	23JUL2003	23	78	109	72	96	119	73	18	10	1
		DAY 29	29JUL2003	29	91	113	78	96	119	79	5	6	1
		DAY 36	05AUG2003	36	90	118	78	84	123	73	-6	5	-5
		DAY 43	12AUG2003	43	66	120	69	72	120	73	6	0	4
		DAY 50	19AUG2003	50	105	120	73	115	110	74	10	-10	1
		DAY 57	27AUG2003	58	77	111	67	109	116	81	32	5	14
		FINAL		58	77	111	67	109	116	81	32	5	14
	E0037002	SCREEN	18DEC2002	-8	68	102	78	64	102	80	-4	0	2
		DAY 1	26DEC2002	1	68	106	70	68	108	70	0	2	0
		BASELINE			68	106	70	68	108	70	0	2	0
		DAY 8	03JAN2003	9	64	112	78	60	110	80	-4	-2	2
		DAY 15	09JAN2003	15	76	119	70	76	117	70	0	-2	0
		DAY 22	17JAN2003	23	80	110	70	80	100	70	0	-10	0
		DAY 29	24JAN2003	30	72	108	70	68	108	70	-4	0	0
		DAY 36	31JAN2003	37	72	110	70	72	106	70	0	-4	0
		DAY 43	07FEB2003	44	68	116	70	68	114	70	0	-2	0
		DAY 50	13FEB2003	50	68	100	70	76	98	70	8	-2	0
		DAY 57	20FEB2003	57	68	102	70	68	106	74	0	4	4
		FINAL		57	68	102	70	68	106	74	0	4	4

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					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	SCREEN	26FEB2003	-8	72	118	70	68	114	70	-4	-4	0
		DAY 1	06MAR2003	1	72	114	70	72	110	70	0	-4	0
		BASELINE			72	114	70	72	110	70	0	-4	0
		DAY 8	13MAR2003	8	80	121	80	80	115	80	0	-6	0
		DAY 15	20MAR2003	15	60	115	80	80	115	70	20	0	-10
		DAY 22	27MAR2003	22	60	114	78	60	116	80	0	2	2
		DAY 29	03APR2003	29	72	118	70	72	118	72	0	0	2
		DAY 36	10APR2003	36	84	130	80	84	130	80	0	0	0
		DAY 43	17APR2003	43	80	132	80	84	128	80	4	-4	0
		DAY 50	24APR2003	50	80	130	90	80	130	90	0	0	0
		DAY 57	01MAY2003	57	68	130	98	72	120	70	4	-10	-28
		FINAL		57	68	130	98	72	120	70	4	-10	-28
	E0037006	SCREEN	06MAR2003	-8	76	134	85	80	121	88	4	-13	3
		DAY 1	14MAR2003	1	80	118	82	76	118	80	-4	0	-2
		BASELINE			80	118	82	76	118	80	-4	0	-2
		DAY 8	21MAR2003	8	80	110	80	80	110	70	0	0	-10
		DAY 15	28MAR2003	15	68	114	78	68	116	80	0	2	2
		DAY 22	04APR2003	22	68	106	72	68	105	70	0	-1	-2
		DAY 29	11APR2003	29	80	120	90	72	120	92	-8	0	2
		DAY 36	18APR2003	36	80	110	70	80	110	68	0	0	-2
		DAY 43	25APR2003	43	84	120	90	88	120	90	4	0	0
		DAY 50	01MAY2003	49	80	120	72	80	108	90	0	-12	18
		DAY 57	09MAY2003	57	72	115	80	64	115	80	-8	0	0
		FINAL		57	72	115	80	64	115	80	-8	0	0
	E0039006	SCREEN	10DEC2002	-20	88	134	86	94	138	94	6	4	8
		DAY 1	30DEC2002	1	68	124	90	80	116	86	12	-8	-4
		BASELINE			68	124	90	80	116	86	12	-8	-4
		DAY 8	06JAN2003	8	88	108	78	65	102	80	-23	-6	2
		DAY 15	13JAN2003	15	64	156	108	68	132	100	4	-24	-8
		DAY 22	20JAN2003	22	77	140	98	97	128	102	20	-12	4
		DAY 29	28JAN2003	30	84	140	96	72	128	90	-12	-12	-6
		DAY 36	04FEB2003	37	76	112	74	88	116	78	12	4	4

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	DAY 43	10FEB2003	43	60	126	94	72	118	96	12	-8	2
		DAY 50	18FEB2003	51	88	130	96	89	112	90	1	-18	-6
		DAY 57	24FEB2003	57	76	116	82	84	114	86	8	-2	4
		FINAL		57	76	116	82	84	114	86	8	-2	4
	E0039015	SCREEN	02JAN2003	-21	50	126	80	56	118	82	6	-8	2
		DAY 1	23JAN2003	1	54	136	86	63	140	92	9	4	6
		BASELINE			54	136	86	63	140	92	9	4	6
		DAY 8	30JAN2003	8	56	142	92	64	136	98	8	-6	6
		DAY 15	06FEB2003	15	60	136	96	72	142	98	12	6	2
		DAY 22	14FEB2003	23	62	130	78	70	126	96	8	-4	18
		DAY 29	20FEB2003	29	58	116	76	60	120	86	2	4	10
		DAY 36	27FEB2003	36	58	140	86	64	138	94	6	-2	8
		DAY 43	06MAR2003	43	56	132	92	58	126	94	2	-6	2
		DAY 50	14MAR2003	51	56	118	80	64	128	88	8	10	8
		DAY 57	20MAR2003	57	56	128	96	60	132	94	4	4	-2
		FINAL		57	56	128	96	60	132	94	4	4	-2
	E0039024	SCREEN	05FEB2003	-22	74	110	76	84	112	80	10	2	4
		DAY 1	27FEB2003	1	88	112	82	80	118	88	-8	6	6
		BASELINE			88	112	82	80	118	88	-8	6	6
		DAY 8	05MAR2003	7	70	98	68	70	100	68	0	2	0
		DAY 15	11MAR2003	13	60	106	78	64	110	82	4	4	4
		DAY 22	20MAR2003	22	84	100	70	86	108	60	2	8	-10
		DAY 29	27MAR2003	29	88	110	76	92	120	90	4	10	14
		DAY 36	03APR2003	36	72	102	64	88	108	86	16	6	22
		DAY 43	10APR2003	43	68	116	82	76	120	90	8	4	8
		DAY 50	17APR2003	50	74	104	76	78	114	90	4	10	14
		DAY 57	24APR2003	57	64	100	66	68	110	80	4	10	14
		FINAL		57	64	100	66	68	110	80	4	10	14
	E0039025	SCREEN	26FEB2003	-20	60	134	96	64	130	100	4	-4	4
		DAY 1	18MAR2003	1	68	134	86	69	126	96	1	-8	10
		BASELINE			68	134	86	69	126	96	1	-8	10

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039025	DAY 8	25MAR2003	8	80	114	80	84	116	86	4	2	6
		DAY 15	01APR2003	15	88	126	98	84	126	100	-4	0	2
		DAY 22	10APR2003	24	68	136	94	76	134	104	8	-2	10
		DAY 29	15APR2003	29	70	122	96	72	130	98	2	8	2
		DAY 36	22APR2003	36	60	130	94	68	128	98	8	-2	4
		DAY 43	29APR2003	43	70	120	92	78	122	96	8	2	4
		DAY 50	06MAY2003	50	84	126	88	88	120	84	4	-6	-4
		DAY 57	27MAY2003	71	80	138	96	88	134	98	8	-4	2
		FINAL		71	80	138	96	88	134	98	8	-4	2
	E0039041	SCREEN	07APR2003	-8	60	122	80	64	116	78	4	-6	-2
		DAY 1	15APR2003	1	64	120	82	68	124	84	4	4	2
		BASELINE			64	120	82	68	124	84	4	4	2
		DAY 8	22APR2003	8	68	132	86	88	120	88	20	-12	2
		DAY 15	29APR2003	15	88	140	92	86	132	86	-2	-8	-6
		DAY 22	06MAY2003	22	62	124	86	66	128	84	4	4	-2
		DAY 29	13MAY2003	29	64	118	86	76	124	88	12	6	2
		DAY 36	20MAY2003	36	66	134	80	78	130	86	12	-4	6
		DAY 43	27MAY2003	43	64	132	88	70	122	100	6	-10	12
		DAY 50	03JUN2003	50	60	128	78	78	132	86	18	4	8
		DAY 57	11JUN2003	58	58	126	86	68	122	84	10	-4	-2
		FINAL		58	58	126	86	68	122	84	10	-4	-2
	E0039044	SCREEN	05MAY2003	-17	72	102	80	78	108	82	6	6	2
		DAY 1	22MAY2003	1	64	108	76	80	104	78	16	-4	2
		BASELINE			64	108	76	80	104	78	16	-4	2
		DAY 8	29MAY2003	8	77	118	80	80	116	86	3	-2	6
		DAY 15	04JUN2003	14	100	120	86	80	106	80	-20	-14	-6
		DAY 22	11JUN2003	21	92	114	76	100	120	88	8	6	12
		DAY 29	18JUN2003	28	98	112	84	100	118	90	2	6	6
		DAY 36	26JUN2003	36	84	106	84	92	110	90	8	4	6
		DAY 43	02JUL2003	42	100	130	88	102	120	84	2	-10	-4
		DAY 50	09JUL2003	49	77	126	80	88	128	88	11	2	8
		FINAL		49	77	126	80	88	128	88	11	2	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039046		06MAY2003		72	128	80	76	134	90	4	6	10
			21MAY2003		74	136	96	88	126	88	14	-10	-8
			30MAY2003		76	114	84	72	120	84	-4	6	0
	E0039051	SCREEN	22MAY2003	-25	92	128	76	106	136	80	14	8	4
		DAY 1	16JUN2003	1	78	126	88	80	136	84	2	10	-4
		BASELINE			78	126	88	80	136	84	2	10	-4
		DAY 8	23JUN2003	8	66	124	90	72	130	92	6	6	2
		DAY 15	30JUN2003	15	66	134	84	72	124	80	6	-10	-4
		DAY 22	07JUL2003	22	80	136	86	78	138	92	-2	2	6
		DAY 29	14JUL2003	29	86	136	96	88	120	90	2	-16	-6
		DAY 36	22JUL2003	37	88	140	88	97	130	96	9	-10	8
		DAY 43	28JUL2003	43	90	146	98	88	128	92	-2	-18	-6
		DAY 50	04AUG2003	50	80	132	96	76	126	90	-4	-6	-6
		DAY 57	12AUG2003	58	90	124	80	93	112	80	3	-12	0
		FINAL		58	90	124	80	93	112	80	3	-12	0
	E0039053	SCREEN	16JUN2003	-25	64	156	96	74	140	92	10	-16	-4
		DAY 1	11JUL2003	1	84	140	86	88	150	96	4	10	10
		BASELINE			84	140	86	88	150	96	4	10	10
		DAY 8	18JUL2003	8	84	152	80	88	142	90	4	-10	10
		DAY 15	25JUL2003	15	76	148	80	84	142	82	8	-6	2
		DAY 22	01AUG2003	22	80	130	80	88	126	86	8	-4	6
		DAY 29	07AUG2003	28	68	144	88	76	142	84	8	-2	-4
		DAY 36	14AUG2003	35	74	140	74	82	126	80	8	-14	6
		DAY 43	21AUG2003	42	85	134	80	100	126	88	15	-8	8
		DAY 50	29AUG2003	50	84	126	72	100	118	86	16	-8	14
		DAY 57	08SEP2003	60	80	136	90	84	124	88	4	-12	-2
		FINAL		60	80	136	90	84	124	88	4	-12	-2
	E0039057	SCREEN	02JUL2003	-12	60	118	82	68	128	100	8	10	18
		DAY 1	14JUL2003	1	60	124	78	76	118	90	16	-6	12
		BASELINE			60	124	78	76	118	90	16	-6	12
		DAY 8	22JUL2003	9	60	118	74	76	114	86	16	-4	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039057	DAY 15	28JUL2003	15	60	122	80	68	124	90	8	2	10
		DAY 22	04AUG2003	22	60	110	68	77	110	80	17	0	12
		DAY 29	12AUG2003	30	62	126	80	80	112	90	18	-14	10
		DAY 36	18AUG2003	36	66	118	70	77	128	88	11	10	18
		DAY 43	26AUG2003	44	60	118	80	64	114	80	4	-4	0
		DAY 50	02SEP2003	51	72	138	68	92	110	78	20	-28	10
		DAY 57	09SEP2003	58	64	124	70	72	110	80	8	-14	10
		FINAL		58	64	124	70	72	110	80	8	-14	10
	E0041003	SCREEN	16JAN2003	-12	80	110	72	84	112	76	4	2	4
		DAY 1	28JAN2003	1	72	108	66	72	114	70	0	6	4
		BASELINE			72	108	66	72	114	70	0	6	4
		DAY 8	04FEB2003	8	68	108	80	76	120	88	8	12	8
		DAY 15	11FEB2003	15	76	132	82	80	140	84	4	8	2
		DAY 22	18FEB2003	22	76	136	78	76	134	82	0	-2	4
		DAY 29	25FEB2003	29	72	148	86	76	136	80	4	-12	-6
		DAY 36	04MAR2003	36	84	146	80	86	142	84	2	-4	4
		DAY 43	11MAR2003	43	80	126	80	80	130	84	0	4	4
		DAY 50	18MAR2003	50	64	126	80	72	126	82	8	0	2
		DAY 57	25MAR2003	57	80	118	82	88	120	88	8	2	6
		FINAL		57	80	118	82	88	120	88	8	2	6
	E0041008	SCREEN	26MAR2003	-12	84	122	80	88	126	82	4	4	2
		DAY 1	07APR2003	1	77	120	80	84	122	80	7	2	0
		BASELINE			77	120	80	84	122	80	7	2	0
		DAY 8	14APR2003	8	60	110	80	66	110	76	6	0	-4
		DAY 15	22APR2003	16	66	118	80	72	110	72	6	-8	-8
		DAY 22	28APR2003	22	66	120	70	66	118	70	0	-2	0
		DAY 29	05MAY2003	29	82	110	80	80	110	76	-2	0	-4
		DAY 36	12MAY2003	36	80	112	80	84	108	78	4	-4	-2
		DAY 43	21MAY2003	45	76	116	82	78	112	78	2	-4	-4
		DAY 50	27MAY2003	51	72	118	80	70	116	78	-2	-2	-2
		DAY 57	02JUN2003	57	76	118	78	84	114	80	8	-4	2
		FINAL		57	76	118	78	84	114	80	8	-4	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0042001	SCREEN	17JUN2003	-15	76	110	80	80	110	80	4	0	0
		DAY 1	02JUL2003	1	80	110	80	84	120	90	4	10	10
		BASELINE			80	110	80	84	120	90	4	10	10
		DAY 8	09JUL2003	8	84	120	80	80	130	88	-4	10	8
		DAY 15	15JUL2003	14	76	120	80	88	120	90	12	0	10
		DAY 22	22JUL2003	21	76	122	80	80	110	80	4	-12	0
		DAY 29	29JUL2003	28	80	120	80	92	124	80	12	4	0
		DAY 36	05AUG2003	35	76	120	84	80	120	90	4	0	6
		DAY 43	12AUG2003	42	88	120	88	80	130	80	-8	10	-8
		DAY 50	19AUG2003	49	76	110	78	84	120	80	8	10	2
		DAY 57	26AUG2003	56	84	110	78	80	110	80	-4	0	2
		FINAL		56	84	110	78	80	110	80	-4	0	2
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	SCREEN	26FEB2003	-14	72	120	80	72	120	80	0	0	0
		DAY 1	12MAR2003	1	70	120	75	70	130	80	0	10	5
		BASELINE			70	120	75	70	130	80	0	10	5
		DAY 8	19MAR2003	8	64	120	70	68	120	70	4	0	0
		DAY 15	26MAR2003	15	68	130	70	70	130	70	2	0	0
		DAY 22	02APR2003	22	80	150	90	82	152	82	2	2	-8
		DAY 29	09APR2003	29	64	120	80	64	120	80	0	0	0
		DAY 36	16APR2003	36	72	140	80	72	140	80	0	0	0
		DAY 43	23APR2003	43	65	130	75	68	135	80	3	5	5
		DAY 50	30APR2003	50	63	125	80	65	130	85	2	5	5
		DAY 57	07MAY2003	57	74	120	75	74	120	75	0	0	0
		FINAL		57	74	120	75	74	120	75	0	0	0
	E0003018	SCREEN	06MAY2003	-7	54	124	90	62	128	84	8	4	-6
		DAY 1	13MAY2003	1	62	118	78	68	116	84	6	-2	6
		BASELINE			62	118	78	68	116	84	6	-2	6
		DAY 8	20MAY2003	8	70	138	88	76	128	88	6	-10	0
		DAY 15	27MAY2003	15	70	130	88	88	124	88	18	-6	0
		DAY 22	03JUN2003	22	66	118	90	70	112	88	4	-6	-2
		DAY 29	10JUN2003	29	68	112	82	72	108	80	4	-4	-2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0003018	DAY 36	17JUN2003	36	70	120	86	72	118	84	2	-2	-2
		DAY 43	24JUN2003	43	66	126	90	70	120	88	4	-6	-2
		DAY 50	02JUL2003	51	72	126	94	82	132	98	10	6	4
		DAY 57	08JUL2003	57	72	110	80	64	106	72	-8	-4	-8
		FINAL		57	72	110	80	64	106	72	-8	-4	-8
	E0005011	SCREEN	16OCT2002	-8	76	120	74	76	118	70	0	-2	-4
		DAY 1	24OCT2002	1	68	120	74	68	110	70	0	-10	-4
		BASELINE			68	120	74	68	110	70	0	-10	-4
		DAY 8	31OCT2002	8	72	120	80	72	110	80	0	-10	0
		DAY 15	07NOV2002	15	80	120	84	80	120	80	0	0	-4
		DAY 22	14NOV2002	22	72	118	80	72	110	70	0	-8	-10
		DAY 29	21NOV2002	29	72	112	70	72	108	80	0	-4	10
		DAY 36	26NOV2002	34	76	124	80	76	120	80	0	-4	0
		DAY 43	03DEC2002	41	80	126	80	80	124	80	0	-2	0
		DAY 50	12DEC2002	50	76	110	70	76	100	70	0	-10	0
		FINAL		50	76	110	70	76	100	70	0	-10	0
	E0005030	SCREEN	18MAR2003	-8	76	96	60	80	90	60	4	-6	0
		DAY 1	26MAR2003	1	80	98	64	84	96	60	4	-2	-4
		BASELINE			80	98	64	84	96	60	4	-2	-4
		DAY 8	02APR2003	8	76	98	60	72	104	60	-4	6	0
		DAY 15	09APR2003	15	84	108	66	100	110	70	16	2	4
		DAY 22	16APR2003	22	84	100	60	88	110	68	4	10	8
		FINAL		22	84	100	60	88	110	68	4	10	8
	E0005036	SCREEN	28APR2003	-8	76	110	74	76	128	78	0	18	4
		DAY 1	06MAY2003	1	64	110	70	64	110	70	0	0	0
		BASELINE			64	110	70	64	110	70	0	0	0
		DAY 8	12MAY2003	7	68	104	60	68	100	60	0	-4	0
		DAY 22	27MAY2003	22	76	110	78	76	110	78	0	0	0
		FINAL		22	76	110	78	76	110	78	0	0	0
	E0006015	SCREEN	06FEB2003	-5	64	120	62	76	114	60	12	-6	-2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	DAY 1	11FEB2003	1	72	116	64	70	135	85	-2	19	21
		BASELINE			72	116	64	70	135	85	-2	19	21
		DAY 8	18FEB2003	8	92	129	76	88	131	90	-4	2	14
		DAY 15	25FEB2003	15	88	128	76	90	127	83	2	-1	7
		DAY 22	04MAR2003	22	87	126	83	86	131	79	-1	5	-4
		DAY 29	11MAR2003	29	74	126	83	72	128	93	-2	2	10
		DAY 36	18MAR2003	36	75	128	77	101	122	80	26	-6	3
		DAY 43	25MAR2003	43	78	129	78	88	123	88	10	-6	10
		DAY 50	01APR2003	50	84	110	78	84	108	78	0	-2	0
		DAY 57	08APR2003	57	84	127	77	80	128	83	-4	1	6
		FINAL		57	84	127	77	80	128	83	-4	1	6
	E0006016	SCREEN	07FEB2003	-10	56	121	67	68	121	72	12	0	5
		DAY 1	17FEB2003	1	57	118	57	73	116	82	16	-2	25
		BASELINE			57	118	57	73	116	82	16	-2	25
		DAY 8	24FEB2003	8	58	133	75	60	120	70	2	-13	-5
		DAY 15	03MAR2003	15	68	120	71	72	133	81	4	13	10
		DAY 22	10MAR2003	22	58	130	71	72	127	91	14	-3	20
		DAY 29	17MAR2003	29	61	113	64	61	133	73	0	20	9
		DAY 36	27MAR2003	39	61	127	62	75	119	74	14	-8	12
		DAY 43	03APR2003	46	64	116	78	72	120	80	8	4	2
		DAY 50	10APR2003	53	64	124	73	66	134	92	2	10	19
		DAY 57	18APR2003	61	58	135	76	75	129	81	17	-6	5
		FINAL		61	58	135	76	75	129	81	17	-6	5
	E0007008	SCREEN	07APR2003	-11	70	118	70	78	124	74	8	6	4
		DAY 1	18APR2003	1	70	98	60	70	106	68	0	8	8
		BASELINE			70	98	60	70	106	68	0	8	8
		DAY 8	25APR2003	8	70	118	80	74	124	80	4	6	0
		FINAL		8	70	118	80	74	124	80	4	6	0
	E0009002	SCREEN	29OCT2002	-21	78	104	78	80	102	80	2	-2	2
		DAY 1	19NOV2002	1	64	132	84	84	136	90	20	4	6
		BASELINE			64	132	84	84	136	90	20	4	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0009002	DAY 8	26NOV2002	8	84	118	80	80	116	82	-4	-2	2
		DAY 15	03DEC2002	15	80	120	78	78	118	82	-2	-2	4
		DAY 22	10DEC2002	22	84	126	84	86	124	82	2	-2	-2
		DAY 29	18DEC2002	30	60	110	84	88	120	90	28	10	6
		DAY 36	23DEC2002	35	68	132	80	68	134	86	0	2	6
		DAY 43	30DEC2002	42	80	122	82	84	118	80	4	-4	-2
		DAY 50	07JAN2003	50	60	134	90	68	134	94	8	0	4
		DAY 57	15JAN2003	58	68	130	80	70	132	84	2	2	4
		FINAL		58	68	130	80	70	132	84	2	2	4
	E0009006	SCREEN	22JAN2003	-6	78	110	60	74	110	70	-4	0	10
		DAY 1	28JAN2003	1	76	100	64	82	100	70	6	0	6
		BASELINE			76	100	64	82	100	70	6	0	6
		DAY 8	04FEB2003	8	60	128	70	80	134	84	20	6	14
		DAY 15	11FEB2003	15	82	120	70	84	120	80	2	0	10
		DAY 22	18FEB2003	22	80	140	80	78	138	78	-2	-2	-2
		DAY 29	25FEB2003	29	82	110	60	82	110	68	0	0	8
		DAY 36	04MAR2003	36	80	118	70	80	116	68	0	-2	-2
		DAY 43	11MAR2003	43	86	124	62	78	120	60	-8	-4	-2
		DAY 50	18MAR2003	50	82	110	70	80	110	70	-2	0	0
		DAY 57	25MAR2003	57	84	110	84	80	120	86	-4	10	2
		FINAL		57	84	110	84	80	120	86	-4	10	2
	E0009009	SCREEN	27FEB2003	-13	60	100	70	80	120	80	20	20	10
		DAY 1	12MAR2003	1	78	110	62	80	120	76	2	10	14
		BASELINE			78	110	62	80	120	76	2	10	14
		DAY 8	19MAR2003	8	88	124	60	86	110	70	-2	-14	10
		DAY 15	24MAR2003	13	60	130	60	68	120	70	8	-10	10
		FINAL		13	60	130	60	68	120	70	8	-10	10
	E0010015	SCREEN	29JAN2003	-22	72	140	96	76	150	100	4	10	4
		DAY 1	20FEB2003	1	86	138	88	88	146	90	2	8	2
		BASELINE			86	138	88	88	146	90	2	8	2
		DAY 8	27FEB2003	8	92	142	94	94	136	92	2	-6	-2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	DAY 15	06MAR2003	15	76	130	90	84	120	88	8	-10	-2
		DAY 22	13MAR2003	22	78	156	90	78	140	90	0	-16	0
		DAY 29	20MAR2003	29	68	138	88	80	136	90	12	-2	2
		DAY 36	26MAR2003	35	84	142	90	80	140	90	-4	-2	0
		DAY 43	02APR2003	42	73	138	90	85	134	94	12	-4	4
		DAY 50	09APR2003	49	80	138	88	88	130	80	8	-8	-8
		DAY 57	15APR2003	55	76	130	90	82	136	94	6	6	4
		FINAL		55	76	130	90	82	136	94	6	6	4
	E0011004	SCREEN	17DEC2002	-7	68	124	68	78	122	66	10	-2	-2
		DAY 1	24DEC2002	1	62	118	76	69	120	80	7	2	4
		BASELINE			62	118	76	69	120	80	7	2	4
		DAY 8	31DEC2002	8	60	112	80	64	114	82	4	2	2
		DAY 15	07JAN2003	15	54	124	74	77	119	86	23	-5	12
		DAY 22	14JAN2003	22	72	124	86	80	118	84	8	-6	-2
		DAY 29	21JAN2003	29	68	124	76	78	128	78	10	4	2
		DAY 36	28JAN2003	36	64	118	78	72	114	78	8	-4	0
		DAY 43	04FEB2003	43	68	120	78	76	118	82	8	-2	4
		DAY 50	11FEB2003	50	60	124	82	72	126	82	12	2	0
		DAY 57	18FEB2003	57	64	120	82	76	114	82	12	-6	0
		FINAL		57	64	120	82	76	114	82	12	-6	0
	E0011007	SCREEN	12DEC2002	-7	88	118	72	92	126	82	4	8	10
		DAY 1	19DEC2002	1	97	113	84	93	121	92	-4	8	8
		BASELINE			97	113	84	93	121	92	-4	8	8
		DAY 8	26DEC2002	8	98	117	91	78	117	89	-20	0	-2
		DAY 15	02JAN2003	15	86	127	90	90	130	90	4	3	0
		DAY 22	09JAN2003	22	88	130	86	92	128	84	4	-2	-2
		DAY 29	17JAN2003	30	76	128	88	88	130	82	12	2	-6
		DAY 36	23JAN2003	36	84	132	90	86	138	88	2	6	-2
		DAY 43	30JAN2003	43	78	130	86	82	132	90	4	2	4
		DAY 50	06FEB2003	50	76	132	80	80	128	82	4	-4	2
		DAY 57	13FEB2003	57	84	124	86	96	118	84	12	-6	-2
		FINAL		57	84	124	86	96	118	84	12	-6	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	SCREEN		15MAY2003	-7	80	120	78	84	118	76	4	-2	-2
		DAY 1		22MAY2003	1	72	118	68	84	116	68	12	-2	0
		BASELINE				72	118	68	84	116	68	12	-2	0
		DAY 8		30MAY2003	9	76	122	72	84	118	68	8	-4	-4
		DAY 22	*	10JUN2003	20	78	106	70	80	118	70	2	12	0
		DAY 22		13JUN2003	23	84	114	66	84	118	64	0	4	-2
		DAY 29		20JUN2003	30	82	114	78	84	116	82	2	2	4
		DAY 36		28JUN2003	38	85	118	68	84	110	68	-1	-8	0
		DAY 43		03JUL2003	43	84	114	82	88	114	86	4	0	4
		DAY 50		10JUL2003	50	86	114	74	86	110	78	0	-4	4
		DAY 57		17JUL2003	57	86	114	78	84	110	76	-2	-4	-2
		FINAL			57	86	114	78	84	110	76	-2	-4	-2
	E0011024	SCREEN		17JUN2003	-7	74	108	78	72	112	80	-2	4	2
		DAY 1		24JUN2003	1	64	108	78	65	110	78	1	2	0
		BASELINE				64	108	78	65	110	78	1	2	0
		DAY 8		01JUL2003	8	85	118	76	80	122	80	-5	4	4
		DAY 15		08JUL2003	15	84	115	80	82	110	80	-2	-5	0
		DAY 22		15JUL2003	22	60	120	80	62	118	80	2	-2	0
		DAY 29		22JUL2003	29	64	128	80	62	128	80	-2	0	0
		DAY 36		30JUL2003	37	72	110	70	70	112	70	-2	2	0
		DAY 43		05AUG2003	43	72	110	72	70	112	70	-2	2	-2
		DAY 50		12AUG2003	50	82	120	78	84	118	76	2	-2	-2
		DAY 57		21AUG2003	59	86	120	76	88	122	78	2	2	2
		FINAL			59	86	120	76	88	122	78	2	2	2
	E0015003	SCREEN		13NOV2002	-12	74	106	68	72	110	70	-2	4	2
		DAY 1		25NOV2002	1	64	112	72	62	110	70	-2	-2	-2
		BASELINE				64	112	72	62	110	70	-2	-2	-2
		DAY 8		02DEC2002	8	70	102	62	68	104	60	-2	2	-2
		FINAL			8	70	102	62	68	104	60	-2	2	-2
	E0019003	SCREEN		29OCT2002	-23	68	122	78	68	110	78	0	-12	0
		DAY 1		21NOV2002	1	68	125	80	68	122	80	0	-3	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	BASELINE				68	125	80	68	122	80	0	-3	0
		DAY 8		27NOV2002	7	68	110	80	72	115	80	4	5	0
		DAY 15		09DEC2002	19	72	120	60	84	118	70	12	-2	10
		DAY 22		16DEC2002	26	72	120	70	88	118	70	16	-2	0
		DAY 36		24DEC2002	34	72	118	70	76	122	80	4	4	10
		DAY 36	*	30DEC2002	40	64	118	78	80	122	82	16	4	4
		DAY 43		06JAN2003	47	68	110	64	72	114	70	4	4	6
		DAY 57	*	14JAN2003	55	64	130	90	76	124	88	12	-6	-2
		DAY 57		16JAN2003	57	68	122	82	84	118	74	16	-4	-8
		FINAL			57	68	122	82	84	118	74	16	-4	-8
	E0019007	SCREEN		06NOV2002	-7	84	105	60	84	105	65	0	0	5
		DAY 1		13NOV2002	1	68	105	70	80	105	70	12	0	0
		BASELINE				68	105	70	80	105	70	12	0	0
		DAY 8		21NOV2002	9	64	90	70	72	100	72	8	10	2
		DAY 15		27NOV2002	15	76	98	66	80	104	78	4	6	12
		DAY 22		05DEC2002	23	68	100	65	72	100	65	4	0	0
		DAY 29		12DEC2002	30	64	90	68	70	90	72	6	0	4
		DAY 36		17DEC2002	35	64	92	65	68	90	68	4	-2	3
		DAY 43		24DEC2002	42	68	95	65	72	98	68	4	3	3
		DAY 50		30DEC2002	48	68	112	72	76	116	80	8	4	8
		DAY 57		07JAN2003	56	68	110	78	68	118	80	0	8	2
		FINAL			56	68	110	78	68	118	80	0	8	2
	E0019014	SCREEN		17DEC2002	-23	56	85	60	56	90	60	0	5	0
		DAY 1		09JAN2003	1	60	85	58	60	95	65	0	10	7
		BASELINE				60	85	58	60	95	65	0	10	7
		DAY 8		20JAN2003	12	60	95	65	64	100	65	4	5	0
		FINAL			12	60	95	65	64	100	65	4	5	0
	E0019018	SCREEN		14JAN2003	-16	72	120	70	76	120	75	4	0	5
		DAY 1		30JAN2003	1	72	120	80	72	125	80	0	5	0
		BASELINE				72	120	80	72	125	80	0	5	0
		DAY 8		06FEB2003	8	60	125	90	68	128	95	8	3	5

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019018	DAY 15	13FEB2003	15	64	110	75	72	120	80	8	10	5
		DAY 22	20FEB2003	22	60	120	75	64	130	80	4	10	5
		DAY 29	27FEB2003	29	60	110	80	68	120	85	8	10	5
		DAY 36	06MAR2003	36	72	122	80	72	122	82	0	0	2
		DAY 43	13MAR2003	43	68	128	70	80	122	80	12	-6	10
		DAY 50	20MAR2003	50	64	110	78	76	112	80	12	2	2
		DAY 57	27MAR2003	57	74	112	82	80	126	74	6	14	-8
		FINAL		57	74	112	82	80	126	74	6	14	-8
	E0019022	SCREEN	23JAN2003	-7	76	118	78	100	118	80	24	0	2
		DAY 1	30JAN2003	1	88	125	74	92	120	75	4	-5	1
		BASELINE			88	125	74	92	120	75	4	-5	1
		DAY 8	06FEB2003	8	84	130	85	88	130	85	4	0	0
		DAY 15	13FEB2003	15	90	110	80	90	115	85	0	5	5
		DAY 22	20FEB2003	22	84	120	75	90	122	80	6	2	5
		DAY 29	27FEB2003	29	76	125	75	90	125	80	14	0	5
		DAY 36	06MAR2003	36	68	118	80	80	122	84	12	4	4
		DAY 43	13MAR2003	43	104	120	84	104	120	88	0	0	4
		DAY 50	20MAR2003	50	92	130	80	100	130	85	8	0	5
		DAY 57	27MAR2003	57	84	128	80	88	130	85	4	2	5
		FINAL		57	84	128	80	88	130	85	4	2	5
	E0019027	SCREEN	20FEB2003	-7	72	126	80	68	118	80	-4	-8	0
		DAY 1	27FEB2003	1	76	120	80	80	114	80	4	-6	0
		BASELINE			76	120	80	80	114	80	4	-6	0
		DAY 8	06MAR2003	8	64	130	78	64	125	80	0	-5	2
		FINAL		8	64	130	78	64	125	80	0	-5	2
	E0019032	SCREEN	06MAR2003	-26	72	92	62	76	94	60	4	2	-2
		DAY 1	01APR2003	1	64	110	70	80	110	75	16	0	5
		BASELINE			64	110	70	80	110	75	16	0	5
		DAY 8	08APR2003	8	80	110	60	92	110	70	12	0	10
		DAY 15	15APR2003	15	84	105	60	88	100	70	4	-5	10
		DAY 22	21APR2003	21	100	120	86	120	110	82	20	-10	-4

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	DAY 29	29APR2003	29	96	118	70	108	115	80	12	-3	10
		DAY 36	07MAY2003	37	76	102	78	96	102	82	20	0	4
		DAY 43	14MAY2003	44	80	110	78	88	110	75	8	0	-3
		DAY 50	21MAY2003	51	68	105	70	72	110	70	4	5	0
		DAY 57	27MAY2003	57	64	100	78	64	98	80	0	-2	2
		FINAL		57	64	100	78	64	98	80	0	-2	2
	E0019034	SCREEN	10MAR2003	-8	68	100	80	72	110	85	4	10	5
		DAY 1	18MAR2003	1	84	110	80	88	120	82	4	10	2
		BASELINE			84	110	80	88	120	82	4	10	2
		DAY 8	25MAR2003	8	80	120	70	92	118	80	12	-2	10
		DAY 15	01APR2003	15	76	120	75	84	120	78	8	0	3
		FINAL		15	76	120	75	84	120	78	8	0	3
	E0019036	SCREEN	18MAR2003	-7	74	118	72	80	140	68	6	22	-4
		DAY 1	25MAR2003	1	60	125	65	80	130	70	20	5	5
		BASELINE			60	125	65	80	130	70	20	5	5
		DAY 8	31MAR2003	7	80	130	70	88	125	70	8	-5	0
		DAY 15	10APR2003	17	76	130	70	88	110	70	12	-20	0
		DAY 22	15APR2003	22	68	120	70	84	120	80	16	0	10
		DAY 29	22APR2003	29	60	120	70	68	130	75	8	10	5
		DAY 36	29APR2003	36	60	130	70	80	128	78	20	-2	8
		FINAL		36	60	130	70	80	128	78	20	-2	8
	E0019039	SCREEN	22APR2003	-9	80	142	90	84	132	92	4	-10	2
		DAY 1	01MAY2003	1	72	140	90	80	138	88	8	-2	-2
		BASELINE			72	140	90	80	138	88	8	-2	-2
		DAY 8	08MAY2003	8	88	140	80	96	140	82	8	0	2
		FINAL		8	88	140	80	96	140	82	8	0	2
	E0019041	SCREEN	14MAY2003	-7	76	102	80	68	108	70	-8	6	-10
		DAY 1	21MAY2003	1	72	100	60	68	95	60	-4	-5	0
		BASELINE			72	100	60	68	95	60	-4	-5	0
		DAY 8	28MAY2003	8	68	100	65	74	95	60	6	-5	-5

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	DAY 15	04JUN2003	15	64	100	52	68	90	48	4	-10	-4
		DAY 22	12JUN2003	23	66	100	70	70	100	65	4	0	-5
		DAY 29	18JUN2003	29	80	108	60	84	100	60	4	-8	0
		DAY 36	25JUN2003	36	56	102	64	84	104	58	28	2	-6
		DAY 43	02JUL2003	43	64	108	72	76	90	58	12	-18	-14
		DAY 50	09JUL2003	50	64	104	66	72	102	64	8	-2	-2
		DAY 57	16JUL2003	57	64	110	70	76	115	75	12	5	5
		FINAL		57	64	110	70	76	115	75	12	5	5
	E0019049	SCREEN	03JUL2003	-7	72	118	68	84	112	78	12	-6	10
		DAY 1	10JUL2003	1	62	118	64	70	116	68	8	-2	4
		BASELINE			62	118	64	70	116	68	8	-2	4
		DAY 8	17JUL2003	8	88	120	75	92	105	80	4	-15	5
		DAY 15	24JUL2003	15	84	108	70	96	106	78	12	-2	8
		DAY 22	31JUL2003	22	76	122	76	96	118	78	20	-4	2
		DAY 29	07AUG2003	29	76	120	80	92	122	76	16	2	-4
		DAY 36	14AUG2003	36	84	125	78	84	120	75	0	-5	-3
		DAY 50	26AUG2003	48	84	120	80	88	115	75	4	-5	-5
		DAY 57	08SEP2003	61	76	126	80	76	116	84	0	-10	4
		FINAL		61	76	126	80	76	116	84	0	-10	4
	E0022052	SCREEN	01APR2003	-9	76	120	82	80	118	80	4	-2	-2
		DAY 1	10APR2003	1	81	126	78	81	124	86	0	-2	8
		BASELINE			81	126	78	81	124	86	0	-2	8
		DAY 8	17APR2003	8	69	130	78	90	122	76	21	-8	-2
		DAY 15	24APR2003	15	87	128	74	96	118	86	9	-10	12
		DAY 22	01MAY2003	22	96	128	70	102	132	84	6	4	14
		DAY 29	08MAY2003	29	63	120	74	90	124	78	27	4	4
		DAY 36	15MAY2003	36	64	124	76	64	112	70	0	-12	-6
		DAY 43	22MAY2003	43	87	124	72	90	114	74	3	-10	2
		DAY 50	29MAY2003	50	69	124	78	87	122	82	18	-2	4
		DAY 57	05JUN2003	57	88	124	82	88	126	84	0	2	2
		FINAL		57	88	124	82	88	126	84	0	2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	SCREEN	29APR2003	-7	72	118	82	75	124	88	3	6	6
		DAY 1	06MAY2003	1	60	118	70	75	132	92	15	14	22
		BASELINE			60	118	70	75	132	92	15	14	22
		DAY 8	12MAY2003	7	69	122	74	75	120	80	6	-2	6
		DAY 15	20MAY2003	15	75	114	66	90	122	78	15	8	12
		DAY 22	27MAY2003	22	72	122	78	90	130	84	18	8	6
		DAY 29	03JUN2003	29	86	120	70	90	126	78	4	6	8
		DAY 36	10JUN2003	36	72	126	72	80	132	78	8	6	6
		DAY 43	17JUN2003	43	84	124	72	90	126	76	6	2	4
		DAY 50	24JUN2003	50	78	122	70	81	124	78	3	2	8
		DAY 57	01JUL2003	57	72	124	76	75	128	80	3	4	4
		FINAL		57	72	124	76	75	128	80	3	4	4
	E0022073	SCREEN	19JUN2003	-7	66	106	64	75	102	62	9	-4	-2
		DAY 1	26JUN2003	1	72	102	70	81	100	74	9	-2	4
		BASELINE			72	102	70	81	100	74	9	-2	4
		DAY 8	03JUL2003	8	80	100	62	84	96	74	4	-4	12
		DAY 15	10JUL2003	15	66	102	68	80	92	70	14	-10	2
		DAY 22	17JUL2003	22	80	106	58	100	102	60	20	-4	2
		DAY 29	24JUL2003	29	81	112	64	105	104	64	24	-8	0
		DAY 36	31JUL2003	36	75	98	62	79	100	68	4	2	6
		DAY 43	07AUG2003	43	64	106	68	76	110	74	12	4	6
		DAY 50	14AUG2003	50	68	106	62	72	108	66	4	2	4
		DAY 57	21AUG2003	57	82	116	70	90	104	74	8	-12	4
		FINAL		57	82	116	70	90	104	74	8	-12	4
	E0023002	SCREEN	25OCT2002	-11	70	116	64	72	114	72	2	-2	8
		DAY 1	05NOV2002	1	60	98	70	72	108	80	12	10	10
		BASELINE			60	98	70	72	108	80	12	10	10
		DAY 8	12NOV2002	8	68	110	76	76	118	82	8	8	6
		DAY 15	19NOV2002	15	80	108	75	84	115	80	4	7	5
		DAY 22	25NOV2002	21	72	120	76	88	120	70	16	0	-6
		DAY 29	03DEC2002	29	79	115	73	107	131	66	28	16	-7
		DAY 36	10DEC2002	36	72	120	80	60	126	74	-12	6	-6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	FINAL		36	72	120	80	60	126	74	-12	6	-6
	E0023017	SCREEN	14MAR2003	-11	78	127	86	78	149	97	0	22	11
		DAY 1	25MAR2003	1	76	128	80	78	140	80	2	12	0
		BASELINE			76	128	80	78	140	80	2	12	0
		DAY 8	03APR2003	10	77	104	63	85	110	70	8	6	7
		DAY 15	10APR2003	17	69	115	71	71	114	70	2	-1	-1
		DAY 22	18APR2003	25	68	100	70	80	110	74	12	10	4
		DAY 29	24APR2003	31	78	128	80	80	130	80	2	2	0
		DAY 36	01MAY2003	38	90	128	84	94	124	80	4	-4	-4
		DAY 43	08MAY2003	45	75	110	71	78	108	70	3	-2	-1
		DAY 50	15MAY2003	52	78	155	90	100	121	75	22	-34	-15
		DAY 57	22MAY2003	59	78	132	71	84	130	70	6	-2	-1
		FINAL		59	78	132	71	84	130	70	6	-2	-1
	E0023021	SCREEN	10APR2003	-13	90	141	98	94	139	96	4	-2	-2
		DAY 1	23APR2003	1	88	118	86	88	122	92	0	4	6
		BASELINE			88	118	86	88	122	92	0	4	6
		DAY 8	29APR2003	7	86	110	80	94	115	86	8	5	6
		DAY 15	06MAY2003	14	74	113	64	88	118	70	14	5	6
		DAY 22	13MAY2003	21	78	116	81	100	132	95	22	16	14
		DAY 29	20MAY2003	28	79	114	71	97	104	76	18	-10	5
		DAY 36	29MAY2003	37	85	118	76	109	121	83	24	3	7
		DAY 43	03JUN2003	42	92	120	77	96	124	80	4	4	3
		DAY 50	10JUN2003	49	77	109	71	84	112	82	7	3	11
		DAY 57	17JUN2003	56	111	122	66	100	141	98	-11	19	32
		FINAL		56	111	122	66	100	141	98	-11	19	32
	E0023027	SCREEN	07MAY2003	-9	64	93	65	68	93	63	4	0	-2
		DAY 1	16MAY2003	1	79	124	80	99	129	86	20	5	6
		BASELINE			79	124	80	99	129	86	20	5	6
		DAY 8	21MAY2003	6	63	136	96	68	140	98	5	4	2
		DAY 15	30MAY2003	15	123	159	102	126	152	105	3	-7	3
		DAY 22	05JUN2003	21	88	148	99	107	163	105	19	15	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	DAY 29		11JUN2003	27	76	134	96	80	136	96	4	2	0
		DAY 36		18JUN2003	34	88	136	100	88	130	90	0	-6	-10
		DAY 43		27JUN2003	43	76	138	104	80	130	98	4	-8	-6
		DAY 50		02JUL2003	48	105	134	88	123	137	82	18	3	-6
		DAY 57		09JUL2003	55	85	143	85	90	140	86	5	-3	1
		FINAL			55	85	143	85	90	140	86	5	-3	1
	E0023030	SCREEN		16MAY2003	-18	84	125	86	80	120	84	-4	-5	-2
		DAY 1		03JUN2003	1	89	115	81	102	131	94	13	16	13
		BASELINE				89	115	81	102	131	94	13	16	13
		DAY 8		10JUN2003	8	100	107	78	104	148	87	4	41	9
		DAY 15		17JUN2003	15	99	131	91	109	132	91	10	1	0
		DAY 22		24JUN2003	22	87	110	73	96	121	80	9	11	7
		DAY 29		01JUL2003	29	79	127	85	89	130	90	10	3	5
		DAY 36		08JUL2003	36	91	127	88	99	152	99	8	25	11
		DAY 43		15JUL2003	43	92	125	86	97	86	82	5	-39	-4
		DAY 50		21JUL2003	49	100	142	100	104	141	98	4	-1	-2
		DAY 57		30JUL2003	58	86	135	93	97	148	98	11	13	5
		FINAL			58	86	135	93	97	148	98	11	13	5
	E0023040	SCREEN		25JUN2003	-8	80	120	76	76	117	80	-4	-3	4
		DAY 1		03JUL2003	1	81	117	82	80	117	80	-1	0	-2
		BASELINE				81	117	82	80	117	80	-1	0	-2
		DAY 8		12JUL2003	10	82	121	82	86	123	84	4	2	2
		DAY 15		17JUL2003	15	77	114	81	81	126	88	4	12	7
		DAY 22		25JUL2003	23	86	132	89	84	108	71	-2	-24	-18
		DAY 36	*	05AUG2003	34	76	127	86	75	133	73	-1	6	-13
		DAY 36		08AUG2003	37	88	93	67	93	101	69	5	8	2
		DAY 43		18AUG2003	47	77	127	84	80	117	90	3	-10	6
		DAY 57	*	28AUG2003	57	68	125	85	84	132	88	16	7	3
		DAY 57		05SEP2003	65	63	117	86	63	126	84	0	9	-2
		FINAL			65	63	117	86	63	126	84	0	9	-2
	E0026014	SCREEN		12FEB2003	-7	68	168	97	71	137	97	3	-31	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	DAY 1	19FEB2003	1	68	148	99	74	142	102	6	-6	3
		BASELINE			68	148	99	74	142	102	6	-6	3
		DAY 8	26FEB2003	8	86	140	99	87	138	95	1	-2	-4
		DAY 15	05MAR2003	15	75	126	91	76	123	88	1	-3	-3
		DAY 22	12MAR2003	22	85	142	90	86	138	95	1	-4	5
		DAY 29	19MAR2003	29	90	140	90	74	129	94	-16	-11	4
		FINAL		29	90	140	90	74	129	94	-16	-11	4
	E0026019	SCREEN	10MAR2003	-7	72	136	81	75	147	91	3	11	10
		DAY 1	17MAR2003	1	73	138	84	83	148	85	10	10	1
		BASELINE			73	138	84	83	148	85	10	10	1
		DAY 8	24MAR2003	8	85	161	89	88	157	88	3	-4	-1
		DAY 15	31MAR2003	15	98	170	95	96	173	96	-2	3	1
		DAY 22	07APR2003	22	82	157	83	88	138	89	6	-19	6
		DAY 29	14APR2003	29	83	148	87	88	154	85	5	6	-2
		DAY 36	21APR2003	36	74	140	76	76	146	82	2	6	6
		DAY 43	28APR2003	43	70	136	77	71	157	80	1	21	3
		DAY 50	05MAY2003	50	88	108	75	92	127	79	4	19	4
		DAY 57	12MAY2003	57	78	151	54	89	148	60	11	-3	6
		FINAL		57	78	151	54	89	148	60	11	-3	6
	E0027005	SCREEN	19DEC2002	-7									
		DAY 1	26DEC2002	1	80	130	84	84	128	80	4	-2	-4
		BASELINE			80	130	84	84	128	80	4	-2	-4
		DAY 8	02JAN2003	8	96	130	85	92	120	80	-4	-10	-5
		DAY 15	09JAN2003	15	100	120	90	84	120	88	-16	0	-2
		DAY 22	16JAN2003	22	72	140	94	76	130	90	4	-10	-4
		DAY 29	23JAN2003	29	88	122	84	92	110	70	4	-12	-14
		DAY 36	30JAN2003	36	84	130	86	90	120	76	6	-10	-10
		DAY 43	06FEB2003	43	88	160	100	96	130	90	8	-30	-10
		DAY 50	12FEB2003	49	75	136	84	90	138	88	15	2	4
		DAY 57	20FEB2003	57	84	130	90	84	120	90	0	-10	0
		FINAL		57	84	130	90	84	120	90	0	-10	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0029009	SCREEN	13JAN2003	-7	60	100	70	68	110	80	8	10	10
		DAY 1	20JAN2003	1	56	108	68	60	110	78	4	2	10
		BASELINE			56	108	68	60	110	78	4	2	10
		DAY 8	27JAN2003	8	60	110	70	64	110	80	4	0	10
		DAY 15	03FEB2003	15	64	120	84	72	114	90	8	-6	6
		DAY 22	11FEB2003	23	60	120	84	64	120	90	4	0	6
		DAY 29	17FEB2003	29	72	100	72	80	98	80	8	-2	8
		DAY 36	24FEB2003	36	64	118	80	68	118	90	4	0	10
		DAY 43	03MAR2003	43	60	130	80	76	130	84	16	0	4
		DAY 50	11MAR2003	51	68	104	72	76	110	80	8	6	8
		DAY 57	18MAR2003	58	64	118	80	68	104	68	4	-14	-12
		FINAL		58	64	118	80	68	104	68	4	-14	-12
	E0029021	SCREEN	03MAR2003	-15	64	110	80	80	110	80	16	0	0
		DAY 1	18MAR2003	1	64	100	62	60	102	62	-4	2	0
		BASELINE			64	100	62	60	102	62	-4	2	0
		DAY 8	25MAR2003	8	68	112	72	60	112	70	-8	0	-2
		DAY 15	01APR2003	15	72	102	70	68	100	68	-4	-2	-2
		DAY 22	07APR2003	21	60	102	62	60	100	64	0	-2	2
		DAY 29	15APR2003	29	72	100	60	68	108	64	-4	8	4
		DAY 36	22APR2003	36	64	102	68	60	100	68	-4	-2	0
		DAY 43	29APR2003	43	92	102	68	104	90	68	12	-12	0
		DAY 50	06MAY2003	50	80	98	60	80	102	64	0	4	4
		DAY 57	15MAY2003	59	88	104	76	100	98	64	12	-6	-12
		FINAL		59	88	104	76	100	98	64	12	-6	-12
	E0029026	SCREEN	07APR2003	-7	76	122	80	92	114	78	16	-8	-2
		DAY 1	14APR2003	1	72	118	82	80	100	70	8	-18	-12
		BASELINE			72	118	82	80	100	70	8	-18	-12
		DAY 8	21APR2003	8	84	98	74	96	100	76	12	2	2
		DAY 15	28APR2003	15	84	108	84	96	120	80	12	12	-4
		DAY 22	05MAY2003	22	88	124	82	100	110	84	12	-14	2
		DAY 29	12MAY2003	29	80	120	80	100	114	78	20	-6	-2
		DAY 36	19MAY2003	36	80	108	76	100	110	70	20	2	-6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	DAY 43	28MAY2003	45	88	114	74	100	90	70	12	-24	-4
		DAY 50	02JUN2003	50	84	118	80	88	112	84	4	-6	4
		DAY 57	10JUN2003	58	76	110	70	92	110	76	16	0	6
		FINAL		58	76	110	70	92	110	76	16	0	6
	E0029030	SCREEN	13MAY2003	-14	56	110	80	60	110	80	4	0	0
		DAY 1	27MAY2003	1	56	100	64	60	98	66	4	-2	2
		BASELINE			56	100	64	60	98	66	4	-2	2
		DAY 8	03JUN2003	8	68	130	88	68	114	80	0	-16	-8
		DAY 15	10JUN2003	15	68	112	80	72	118	80	4	6	0
		DAY 22	17JUN2003	22	72	110	84	72	124	82	0	14	-2
		DAY 29	26JUN2003	31	80	130	80	88	120	70	8	-10	-10
		DAY 36	02JUL2003	37	80	120	76	80	118	70	0	-2	-6
		DAY 43	09JUL2003	44	76	110	70	92	120	80	16	10	10
		DAY 50	16JUL2003	51	80	132	70	96	134	80	16	2	10
		DAY 57	23JUL2003	58	64	120	78	72	124	84	8	4	6
		FINAL		58	64	120	78	72	124	84	8	4	6
	E0031008	SCREEN	05FEB2003	-23	64	128	80	68	134	88	4	6	8
		DAY 1	28FEB2003	1	60	136	80	68	138	84	8	2	4
		BASELINE			60	136	80	68	138	84	8	2	4
		DAY 8	07MAR2003	8	72	114	76	78	122	80	6	8	4
		DAY 15	13MAR2003	14	70	142	84	68	138	84	-2	-4	0
		DAY 22	21MAR2003	22	80	136	74	84	140	76	4	4	2
		DAY 29	28MAR2003	29	66	114	76	72	118	68	6	4	-8
		DAY 36	04APR2003	36	68	120	68	74	120	72	6	0	4
		DAY 43	10APR2003	42	78	118	74	86	120	80	8	2	6
		DAY 50	17APR2003	49	80	138	82	82	136	84	2	-2	2
		DAY 57	24APR2003	56	68	126	80	72	130	84	4	4	4
		FINAL		56	68	126	80	72	130	84	4	4	4
	E0031020	SCREEN	14APR2003	-7	62	114	68	66	122	70	4	8	2
		DAY 1	21APR2003	1	60	116	74	64	118	70	4	2	-4
		BASELINE			60	116	74	64	118	70	4	2	-4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0031020	DAY 8		28APR2003	8	66	122	78	70	130	80	4	8	2
		DAY 15		05MAY2003	15	70	120	76	74	124	82	4	4	6
		DAY 22		13MAY2003	23	60	118	70	64	124	68	4	6	-2
		FINAL			23	60	118	70	64	124	68	4	6	-2
	E0031021	SCREEN		18APR2003	-7	60	118	66	64	122	70	4	4	4
		DAY 1		25APR2003	1	60	112	68	66	116	72	6	4	4
		BASELINE				60	112	68	66	116	72	6	4	4
		DAY 8		02MAY2003	8	62	124	70	66	130	74	4	6	4
		DAY 15		09MAY2003	15	64	122	68	68	128	72	4	6	4
		DAY 22		16MAY2003	22	76	125	80	84	120	78	8	-5	-2
		DAY 29		23MAY2003	29	62	116	68	70	124	78	8	8	10
		DAY 36		29MAY2003	35	70	116	78	76	120	80	6	4	2
		DAY 43		06JUN2003	43	64	124	88	68	130	90	4	6	2
		DAY 43	*	10JUN2003	47	72	124	86	76	132	88	4	8	2
		DAY 57		19JUN2003	56	70	118	68	76	120	70	6	2	2
		FINAL			56	70	118	68	76	120	70	6	2	2
	E0031029	SCREEN		05JUN2003	-13	58	110	68	64	118	76	6	8	8
		DAY 1		18JUN2003	1	58	118	68	64	124	76	6	6	8
		BASELINE				58	118	68	64	124	76	6	6	8
		DAY 8		23JUN2003	6	60	118	80	64	130	84	4	12	4
		DAY 22		08JUL2003	21	64	116	62	70	124	70	6	8	8
		FINAL			21	64	116	62	70	124	70	6	8	8
	E0033002	SCREEN		23DEC2002	-18	68	120	78	76	110	78	8	-10	0
		DAY 1		10JAN2003	1	76	150	84	80	138	88	4	-12	4
		BASELINE				76	150	84	80	138	88	4	-12	4
		DAY 8		16JAN2003	7	92	130	80	100	128	80	8	-2	0
		DAY 15		24JAN2003	15	92	132	88	84	132	84	-8	0	-4
		DAY 22		30JAN2003	21	68	108	70	76	114	76	8	6	6
		DAY 29		06FEB2003	28	80	104	70	80	112	76	0	8	6
		DAY 36		13FEB2003	35	72	120	78	80	130	84	8	10	6
		DAY 43		24FEB2003	46	72	122	80	76	126	86	4	4	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0033002	DAY 50		28FEB2003	50	76	120	80	84	130	80	8	10	0
		DAY 57		07MAR2003	57	76	118	78	80	120	82	4	2	4
		FINAL			57	76	118	78	80	120	82	4	2	4
	E0033006	SCREEN		15JAN2003	-8	64	110	80	76	118	86	12	8	6
		DAY 1		23JAN2003	1	64	100	70	72	106	80	8	6	10
		BASELINE				64	100	70	72	106	80	8	6	10
		DAY 8		30JAN2003	8	60	120	84	76	126	88	16	6	4
		DAY 22		12FEB2003	21	68	120	80	72	120	86	4	0	6
		FINAL			21	68	120	80	72	120	86	4	0	6
	E0033021	SCREEN		25JUN2003	-7	60	90	62	76	80	64	16	-10	2
		DAY 1		02JUL2003	1	56	90	70	72	90	74	16	0	4
		BASELINE				56	90	70	72	90	74	16	0	4
		DAY 8		11JUL2003	10	58	90	67	74	90	70	16	0	3
		DAY 22	*	21JUL2003	20	60	100	60	76	98	66	16	-2	6
		DAY 22		25JUL2003	24	72	90	68	80	100	70	8	10	2
		DAY 29		01AUG2003	31	76	90	64	80	96	66	4	6	2
		DAY 36		06AUG2003	36	72	112	74	68	110	70	-4	-2	-4
		DAY 50		18AUG2003	48	76	96	70	76	96	72	0	0	2
		FINAL			48	76	96	70	76	96	72	0	0	2
	E0035013	SCREEN		27JAN2003	-8	72	112	70	76	112	74	4	0	4
		DAY 1		04FEB2003	1	68	112	70	74	114	74	6	2	4
		BASELINE				68	112	70	74	114	74	6	2	4
		DAY 8		10FEB2003	7	66	112	72	70	114	76	4	2	4
		FINAL			7	66	112	72	70	114	76	4	2	4
	E0035015	SCREEN		03FEB2003	-8	76	116	70	78	118	72	2	2	2
		DAY 1		11FEB2003	1	82	128	76	88	130	80	6	2	4
		BASELINE				82	128	76	88	130	80	6	2	4
		DAY 8		18FEB2003	8	74	118	76	80	122	74	6	4	-2
		FINAL			8	74	118	76	80	122	74	6	4	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0035016	SCREEN	10MAR2003	-25	76	110	78	80	112	82	4	2	4
		DAY 1	04APR2003	1	80	110	72	88	112	80	8	2	8
		BASELINE			80	110	72	88	112	80	8	2	8
	E0035023	SCREEN	06MAY2003	-7	82	108	78	88	110	82	6	2	4
		DAY 1	13MAY2003	1	60	114	72	62	116	80	2	2	8
		BASELINE			60	114	72	62	116	80	2	2	8
		DAY 8	20MAY2003	8	68	112	78	72	114	82	4	2	4
		DAY 15	29MAY2003	17	70	112	76	74	114	80	4	2	4
		DAY 22	03JUN2003	22	74	112	76	76	114	76	2	2	0
		DAY 29	10JUN2003	29	76	112	74	80	114	78	4	2	4
		FINAL		29	76	112	74	80	114	78	4	2	4
	E0039052	SCREEN	29MAY2003	-22	84	126	88	88	118	92	4	-8	4
		DAY 1	20JUN2003	1	88	118	88	92	120	90	4	2	2
		BASELINE			88	118	88	92	120	90	4	2	2
		DAY 8	27JUN2003	8	64	126	96	68	120	92	4	-6	-4
		DAY 15	03JUL2003	14	74	134	92	78	122	94	4	-12	2
		FINAL		14	74	134	92	78	122	94	4	-12	2
	E0039056	SCREEN	01JUL2003	-14	64	124	84	72	130	90	8	6	6
		DAY 1	14JUL2003	-1	84	136	84	92	140	92	8	4	8
		BASELINE			84	136	84	92	140	92	8	4	8
		DAY 8	23JUL2003	9	72	132	90	86	122	96	14	-10	6
		FINAL		9	72	132	90	86	122	96	14	-10	6
	E0040003	SCREEN	09JUL2003	-10	70	125	80	74	120	70	4	-5	-10
		DAY 1	18JUL2003	-1	68	120	82	71	115	80	3	-5	-2
		BASELINE			68	120	82	71	115	80	3	-5	-2
		DAY 8	25JUL2003	7	70	110	70	74	108	68	4	-2	-2
		DAY 15	01AUG2003	14	74	116	79	76	120	78	2	4	-1
		DAY 22	08AUG2003	21	72	118	78	74	120	80	2	2	2
		DAY 29	15AUG2003	28	74	120	81	76	122	78	2	2	-3
		DAY 36	22AUG2003	35	70	122	80	72	120	78	2	-2	-2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	DAY 43	29AUG2003	42	72	124	80	74	122	78	2	-2	-2
		DAY 50	05SEP2003	49	70	120	82	76	118	79	6	-2	-3
		DAY 57	12SEP2003	56	68	122	80	72	120	77	4	-2	-3
		FINAL		56	68	122	80	72	120	77	4	-2	-3
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	SCREEN	19FEB2003	-12	64	112	70	68	110	68	4	-2	-2
		DAY 1	03MAR2003	1	64	102	74	64	110	80	0	8	6
		BASELINE			64	102	74	64	110	80	0	8	6
		DAY 8	11MAR2003	9	72	108	68	80	122	84	8	14	16
		DAY 15	18MAR2003	16	78	106	64	78	114	68	0	8	4
		DAY 22	25MAR2003	23	70	110	68	72	110	70	2	0	2
		DAY 29	01APR2003	30	72	106	66	72	110	72	0	4	6
		DAY 36	08APR2003	37	78	98	60	82	110	76	4	12	16
		DAY 43	15APR2003	44	76	106	72	80	110	72	4	4	0
		DAY 50	24APR2003	53	76	108	68	78	118	76	2	10	8
		DAY 57	02MAY2003	61	72	104	72	68	110	80	-4	6	8
		FINAL		61	72	104	72	68	110	80	-4	6	8
	E0002011	SCREEN	16APR2003	-13	104	126	80	88	128	80	-16	2	0
		DAY 1	29APR2003	1	84	120	78	86	118	72	2	-2	-6
		BASELINE			84	120	78	86	118	72	2	-2	-6
		DAY 8	08MAY2003	10	84	120	72	86	126	74	2	6	2
		DAY 15	15MAY2003	17	88	120	78	86	120	74	-2	0	-4
		DAY 22	22MAY2003	24	84	124	68	88	118	70	4	-6	2
		DAY 29	29MAY2003	31	92	120	74	92	124	82	0	4	8
		DAY 36	05JUN2003	38	88	120	72	88	122	78	0	2	6
		DAY 43	12JUN2003	45	88	118	68	88	124	68	0	6	0
		DAY 50	19JUN2003	52	88	116	66	88	122	76	0	6	10
		DAY 57	25JUN2003	58	80	126	80	80	122	80	0	-4	0
		FINAL		58	80	126	80	80	122	80	0	-4	0
	E0003010	SCREEN	27JAN2003	-7	70	118	70	72	120	72	2	2	2
		DAY 1	03FEB2003	1	70	118	72	76	124	80	6	6	8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0003010	BASELINE				70	118	72	76	124	80	6	6	8
		DAY 8		10FEB2003	8	70	130	90	88	126	90	18	-4	0
		DAY 15		19FEB2003	17	82	124	82	84	120	80	2	-4	-2
		DAY 22		27FEB2003	25	88	108	74	96	98	60	8	-10	-14
		DAY 29		03MAR2003	29	84	138	88	90	120	88	6	-18	0
		DAY 36		14MAR2003	40	90	140	88	92	140	90	2	0	2
		DAY 43		20MAR2003	46	100	128	86	90	138	92	-10	10	6
		DAY 50		25MAR2003	51	84	140	84	90	126	92	6	-14	8
		DAY 57		31MAR2003	57	79	128	86	90	136	98	11	8	12
		FINAL			57	79	128	86	90	136	98	11	8	12
	E0003011	SCREEN		28JAN2003	-7	92	118	70	100	124	72	8	6	2
		DAY 1		04FEB2003	1	92	110	72	98	120	70	6	10	-2
		BASELINE				92	110	72	98	120	70	6	10	-2
		DAY 8		11FEB2003	8	84	118	72	110	130	80	26	12	8
		DAY 15		18FEB2003	15	88	110	72	94	114	78	6	4	6
		FINAL			15	88	110	72	94	114	78	6	4	6
	E0003016	SCREEN		01MAY2003	-21	68	110	78	84	114	80	16	4	2
		DAY 1		22MAY2003	1	70	110	84	68	108	84	-2	-2	0
		BASELINE				70	110	84	68	108	84	-2	-2	0
		DAY 8		29MAY2003	8	92	130	80	104	124	84	12	-6	4
		DAY 15		05JUN2003	15	84	122	88	96	118	86	12	-4	-2
		DAY 22		12JUN2003	22	86	108	80	90	116	72	4	8	-8
		FINAL			22	86	108	80	90	116	72	4	8	-8
	E0003019	SCREEN		19JUN2003	-8	58	112	76	60	112	82	2	0	6
		DAY 1		27JUN2003	1	56	116	94	58	118	90	2	2	-4
		BASELINE				56	116	94	58	118	90	2	2	-4
		DAY 8		03JUL2003	7	64	120	84	62	114	86	-2	-6	2
		DAY 15		10JUL2003	14	60	120	82	66	112	82	6	-8	0
		DAY 15	*	15JUL2003	19	62	110	68	64	114	76	2	4	8
		DAY 29		29JUL2003	33	72	134	86	78	138	90	6	4	4
		DAY 43		07AUG2003	42	70	126	88	66	124	88	-4	-2	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	DAY 50	14AUG2003	49	66	124	82	72	122	82	6	-2	0
		DAY 57	21AUG2003	56	68	140	92	70	132	90	2	-8	-2
		FINAL		56	68	140	92	70	132	90	2	-8	-2
	E0003020	SCREEN	24JUN2003	-29	62	126	82	80	112	76	18	-14	-6
		DAY 1	23JUL2003	1	64	110	50	70	118	70	6	8	20
		BASELINE			64	110	50	70	118	70	6	8	20
		DAY 8	29JUL2003	7	66	130	84	86	124	76	20	-6	-8
		DAY 15	06AUG2003	15	62	118	76	84	132	80	22	14	4
		DAY 22	13AUG2003	22	84	108	70	88	118	78	4	10	8
		DAY 29	20AUG2003	29	76	130	76	80	132	80	4	2	4
		DAY 36	27AUG2003	36	76	126	88	82	124	88	6	-2	0
		DAY 43	03SEP2003	43	72	134	90	78	130	88	6	-4	-2
		DAY 50	10SEP2003	50	80	120	80	76	110	70	-4	-10	-10
		DAY 57	17SEP2003	57	72	110	80	72	114	80	0	4	0
		FINAL		57	72	110	80	72	114	80	0	4	0
	E0004001	SCREEN	23SEP2002	-7	54	100	60	56	98	58	2	-2	-2
		DAY 1	30SEP2002	1	64	98	62	60	96	58	-4	-2	-4
		BASELINE			64	98	62	60	96	58	-4	-2	-4
		DAY 8	07OCT2002	8	64	98	60	68	92	62	4	-6	2
		DAY 22	21OCT2002	22	64	98	62	72	100	68	8	2	6
		DAY 29	28OCT2002	29	80	94	60	84	86	60	4	-8	0
		DAY 36	05NOV2002	37	76	100	62	84	92	60	8	-8	-2
		FINAL		37	76	100	62	84	92	60	8	-8	-2
	E0004009	SCREEN	17DEC2002	-9	64	108	70	72	104	64	8	-4	-6
		DAY 1	26DEC2002	1	76	100	58	88	102	64	12	2	6
		BASELINE			76	100	58	88	102	64	12	2	6
		DAY 8	02JAN2003	8	88	100	62	88	102	60	0	2	-2
		DAY 15	08JAN2003	14	96	102	66	100	108	64	4	6	-2
		DAY 22	15JAN2003	21	88	100	60	100	104	70	12	4	10
		DAY 29	22JAN2003	28	96	116	64	104	100	70	8	-16	6
		DAY 36	29JAN2003	35	80	110	62	88	98	62	8	-12	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
GENERATED: 12JUL2005 17:46:40 iceadmn3

Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0004009	DAY 43	05FEB2003	42	96	100	60	100	104	64	4	4	4
		DAY 50	12FEB2003	49	84	100	70	100	92	68	16	-8	-2
		DAY 57	19FEB2003	56	90	100	68	104	102	72	14	2	4
		FINAL		56	90	100	68	104	102	72	14	2	4
	E0004012	SCREEN	07JAN2003	-7	56	114	62	62	100	60	6	-14	-2
		DAY 1	14JAN2003	1	56	104	72	68	100	70	12	-4	-2
		BASELINE			56	104	72	68	100	70	12	-4	-2
		DAY 8	21JAN2003	8	76	90	62	88	106	64	12	16	2
		DAY 15	28JAN2003	15	64	104	60	72	108	68	8	4	8
		DAY 22	04FEB2003	22	80	94	58	88	90	56	8	-4	-2
		DAY 29	11FEB2003	29	84	100	70	88	102	72	4	2	2
		DAY 36	18FEB2003	36	92	94	68	100	100	74	8	6	6
		DAY 43	25FEB2003	43	68	92	62	72	100	70	4	8	8
		DAY 50	04MAR2003	50	72	100	60	90	98	64	18	-2	4
		DAY 57	11MAR2003	57	84	98	70	92	100	72	8	2	2
		FINAL		57	84	98	70	92	100	72	8	2	2
	E0004015	SCREEN	06FEB2003	-14	60	120	88	76	118	86	16	-2	-2
		DAY 1	20FEB2003	1	64	120	82	72	118	90	8	-2	8
		BASELINE			64	120	82	72	118	90	8	-2	8
		DAY 8	25FEB2003	6	88	130	84	96	122	90	8	-8	6
		DAY 15	04MAR2003	13	80	124	80	92	112	82	12	-12	2
		DAY 22	11MAR2003	20	88	120	90	96	128	92	8	8	2
		DAY 29	18MAR2003	27	80	138	82	88	132	88	8	-6	6
		DAY 36	25MAR2003	34	80	128	90	90	124	92	10	-4	2
		DAY 43	01APR2003	41	88	142	84	92	136	88	4	-6	4
		DAY 50	08APR2003	48	84	130	90	86	122	90	2	-8	0
		DAY 57	15APR2003	55	84	122	90	88	118	88	4	-4	-2
		FINAL		55	84	122	90	88	118	88	4	-4	-2
	E0005003	SCREEN	23SEP2002	-9				80	134	86			
		DAY 1	02OCT2002	1	68	128	80	72	134	86	4	6	6
		BASELINE			68	128	80	72	134	86	4	6	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	DAY 8	09OCT2002	8	72	134	86	84	134	84	12	0	-2
		DAY 15	16OCT2002	15	76	132	80	82	130	76	6	-2	-4
		DAY 22	23OCT2002	22	92	116	70	92	116	76	0	0	6
		DAY 29	30OCT2002	29	80	140	78	88	136	78	8	-4	0
		DAY 36	06NOV2002	36	88	134	82	92	136	90	4	2	8
		DAY 43	14NOV2002	44	88	140	90	96	136	90	8	-4	0
		DAY 50	21NOV2002	51	84	128	86	88	130	90	4	2	4
		DAY 57	26NOV2002	56	92	128	78	88	130	86	-4	2	8
		FINAL		56	92	128	78	88	130	86	-4	2	8
	E0005005	SCREEN	24SEP2002	-6	84	126	76	76	124	78	-8	-2	2
		DAY 1	30SEP2002	1	72	110	70	84	124	80	12	14	10
		BASELINE			72	110	70	84	124	80	12	14	10
	E0005007	SCREEN	02OCT2002	-7									
		DAY 1	09OCT2002	1	60	98	64	68	96	64	8	-2	0
		BASELINE			60	98	64	68	96	64	8	-2	0
		DAY 8	16OCT2002	8	72	124	78	68	112	70	-4	-12	-8
		DAY 15	23OCT2002	15	80	118	78	76	110	64	-4	-8	-14
		DAY 22	30OCT2002	22	84	104	76	80	100	70	-4	-4	-6
		DAY 29	06NOV2002	29	80	112	72	88	110	74	8	-2	2
		DAY 36	14NOV2002	37	84	116	72	88	110	70	4	-6	-2
		DAY 43	20NOV2002	43	72	106	64	80	100	64	8	-6	0
		DAY 50	26NOV2002	49	84	118	68	88	120	74	4	2	6
		DAY 57	04DEC2002	57	84	116	78	88	118	76	4	2	-2
		FINAL		57	84	116	78	88	118	76	4	2	-2
	E0005008	SCREEN	08OCT2002	-7	80	150	82	80	148	80	0	-2	-2
		DAY 1	15OCT2002	1	92	126	68	92	126	64	0	0	-4
		BASELINE			92	126	68	92	126	64	0	0	-4
		DAY 8	22OCT2002	8	96	130	84	96	134	80	0	4	-4
		DAY 15	29OCT2002	15	92	138	84	92	138	82	0	0	-2
		DAY 22	06NOV2002	23	100	148	88	92	140	86	-8	-8	-2
		DAY 29	13NOV2002	30	92	146	88	92	140	86	0	-6	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	DAY 36		18NOV2002	35	84	145	80	84	138	80	0	-7	0
		DAY 43		25NOV2002	42	88	140	86	88	140	88	0	0	2
		DAY 50		02DEC2002	49	88	134	82	88	136	82	0	2	0
		DAY 57		11DEC2002	58	88	130	84	88	134	80	0	4	-4
		FINAL			58	88	130	84	88	134	80	0	4	-4
	E0005009	SCREEN		09OCT2002	-20	60	120	76	60	126	82	0	6	6
		DAY 1		29OCT2002	1	64	110	74	64	110	70	0	0	-4
		BASELINE				64	110	74	64	110	70	0	0	-4
	E0005010	SCREEN		14OCT2002	-7	68	120	80	68	110	70	0	-10	-10
		DAY 1		21OCT2002	1	64	120	70	64	110	64	0	-10	-6
		BASELINE				64	120	70	64	110	64	0	-10	-6
		DAY 8		28OCT2002	8	64	110	70	64	110	68	0	0	-2
		DAY 15		04NOV2002	15	80	110	68	80	100	64	0	-10	-4
		DAY 22		13NOV2002	24	80	110	70	80	100	60	0	-10	-10
		DAY 29		19NOV2002	30	88	120	80	88	120	76	0	0	-4
		DAY 36		26NOV2002	37	76	124	70	76	110	60	0	-14	-10
		DAY 43		03DEC2002	44	80	114	74	80	104	68	0	-10	-6
		DAY 50		09DEC2002	50	80	116	74	80	110	70	0	-6	-4
		DAY 57		17DEC2002	58	80	128	74	80	124	74	0	-4	0
		FINAL			58	80	128	74	80	124	74	0	-4	0
	E0005012	SCREEN		24OCT2002	-21	68	104	70	68	100	72	0	-4	2
		DAY 1		14NOV2002	1	64	140	88	64	138	88	0	-2	0
		BASELINE				64	140	88	64	138	88	0	-2	0
		DAY 8		20NOV2002	7	80	130	80	80	130	80	0	0	0
		DAY 15		26NOV2002	13	68	124	80	68	124	80	0	0	0
		DAY 22		06DEC2002	23	80	124	82	80	120	78	0	-4	-4
		DAY 29		10DEC2002	27	80	120	80	80	120	76	0	0	-4
		DAY 36		18DEC2002	35	80	120	80	80	120	80	0	0	0
		DAY 36	*	23DEC2002	40	64	120	80	64	124	80	0	4	0
		DAY 50		02JAN2003	50	80	120	74	80	122	80	0	2	6
		DAY 57		07JAN2003	55	80	126	80	80	124	82	0	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005012	FINAL		55	80	126	80	80	124	82	0	-2	2
	E0005014	SCREEN	05NOV2002	-8	60	100	70	60	100	70	0	0	0
		DAY 1	13NOV2002	1	60	106	66	60	100	70	0	-6	4
		BASELINE			60	106	66	60	100	70	0	-6	4
		DAY 8	20NOV2002	8	60	110	64	60	110	66	0	0	2
		DAY 15	27NOV2002	15	60	110	70	60	100	64	0	-10	-6
		DAY 22	03DEC2002	21	80	110	74	80	100	70	0	-10	-4
		DAY 29	11DEC2002	29	80	110	70	80	110	70	0	0	0
		DAY 36	17DEC2002	35	80	110	70	80	110	68	0	0	-2
		DAY 43	23DEC2002	41	80	112	80	80	110	80	0	-2	0
		DAY 50	30DEC2002	48	80	120	76	80	110	74	0	-10	-2
		DAY 57	06JAN2003	55	80	114	80	80	110	74	0	-4	-6
		FINAL		55	80	114	80	80	110	74	0	-4	-6
	E0005022	SCREEN	23JAN2003	-6	64	120	80	64	120	80	0	0	0
		DAY 1	29JAN2003	1	72	110	70	72	120	80	0	10	10
		BASELINE			72	110	70	72	120	80	0	10	10
		DAY 8	04FEB2003	7	72	110	80	72	110	80	0	0	0
		DAY 15	11FEB2003	14	64	114	74	64	104	74	0	-10	0
		DAY 22	21FEB2003	24	64	110	70	64	100	70	0	-10	0
		DAY 29	26FEB2003	29	64	120	70	64	118	70	0	-2	0
		DAY 36	06MAR2003	37	60	110	80	60	100	80	0	-10	0
		FINAL		37	60	110	80	60	100	80	0	-10	0
	E0005025	SCREEN	20FEB2003	-7	80	116	68	84	110	64	4	-6	-4
		DAY 1	27FEB2003	1	80	110	60	80	106	60	0	-4	0
		BASELINE			80	110	60	80	106	60	0	-4	0
		DAY 8	06MAR2003	8	88	110	60	100	100	56	12	-10	-4
		DAY 15	14MAR2003	16	88	90	60	88	94	60	0	4	0
		DAY 22	20MAR2003	22	88	106	64	88	100	60	0	-6	-4
		DAY 29	27MAR2003	29	68	100	58	80	90	54	12	-10	-4
		DAY 36	03APR2003	36	80	100	64	88	104	66	8	4	2
		FINAL		36	80	100	64	88	104	66	8	4	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	SCREEN	26MAR2003	-12	78	127	72	82	131	78	4	4	6
		DAY 1	07APR2003	1	58	118	72	75	116	84	17	-2	12
		BASELINE			58	118	72	75	116	84	17	-2	12
		DAY 8	14APR2003	8	70	129	90	86	129	79	16	0	-11
		DAY 15	21APR2003	15	83	119	85	88	112	88	5	-7	3
		DAY 22	28APR2003	22	66	122	87	82	131	90	16	9	3
		DAY 29	05MAY2003	29	70	119	71	93	113	84	23	-6	13
		DAY 36	12MAY2003	36	68	117	72	90	129	84	22	12	12
		DAY 43	19MAY2003	43	66	112	64	70	116	78	4	4	14
		DAY 50	27MAY2003	51	71	104	72	93	115	76	22	11	4
		DAY 57	03JUN2003	58	70	120	80	77	122	82	7	2	2
		FINAL		58	70	120	80	77	122	82	7	2	2
	E0007005	SCREEN	27JAN2003	-4	80	114	70	82	110	72	2	-4	2
		DAY 1	31JAN2003	1	70	110	68	72	104	70	2	-6	2
		BASELINE			70	110	68	72	104	70	2	-6	2
		DAY 8	07FEB2003	8	70	108	76	74	112	78	4	4	2
		DAY 15	14FEB2003	15	70	100	70	78	108	70	8	8	0
		DAY 22	22FEB2003	23	72	98	72	78	104	70	6	6	-2
		DAY 29	03MAR2003	32	78	100	70	82	102	70	4	2	0
		DAY 36	10MAR2003	39	76	104	70	84	100	72	8	-4	2
		DAY 43	14MAR2003	43	70	96	70	76	100	72	6	4	2
		DAY 50	21MAR2003	50	82	90	60	88	96	64	6	6	4
		DAY 57	28MAR2003	57	72	94	62	78	98	60	6	4	-2
		FINAL		57	72	94	62	78	98	60	6	4	-2
	E0007015	SCREEN	09JUL2003	-7	70	136	76	74	138	82	4	2	6
		DAY 1	16JUL2003	1	72	124	70	74	120	74	2	-4	4
		BASELINE			72	124	70	74	120	74	2	-4	4
		DAY 8	23JUL2003	8	70	120	80	76	126	76	6	6	-4
		DAY 15	01AUG2003	17	72	120	74	76	124	74	4	4	0
		DAY 22	06AUG2003	22	70	122	78	78	126	80	8	4	2
		DAY 29	13AUG2003	29	74	124	74	80	118	78	6	-6	4
		DAY 36	20AUG2003	36	70	130	70	76	126	74	6	-4	4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	DAY 43	27AUG2003	43	70	130	76	78	130	80	8	0	4
		DAY 50	03SEP2003	50	74	124	74	78	130	76	4	6	2
		DAY 57	10SEP2003	57	70	124	76	72	128	80	2	4	4
		FINAL		57	70	124	76	72	128	80	2	4	4
	E0009001	SCREEN	29OCT2002	-14	70	134	96	74	128	94	4	-6	-2
		DAY 1	12NOV2002	1	88	130	94	86	128	92	-2	-2	-2
		BASELINE			88	130	94	86	128	92	-2	-2	-2
		DAY 8	21NOV2002	10	88	140	86	92	136	94	4	-4	8
		DAY 15	26NOV2002	15	80	126	70	82	110	74	2	-16	4
		DAY 22	04DEC2002	23	74	130	88	80	128	90	6	-2	2
		DAY 29	10DEC2002	29	60	136	84	76	140	90	16	4	6
		DAY 36	17DEC2002	36	80	128	78	82	130	80	2	2	2
		DAY 43	23DEC2002	42	78	120	78	82	120	76	4	0	-2
		DAY 50	30DEC2002	49	76	120	68	80	110	72	4	-10	4
		FINAL		49	76	120	68	80	110	72	4	-10	4
	E0010002	SCREEN	14NOV2002	-11	68	102	78	70	115	80	2	13	2
		DAY 1	25NOV2002	1	106	110	60	122	102	72	16	-8	12
		BASELINE			106	110	60	122	102	72	16	-8	12
		DAY 8	02DEC2002	8	72	110	74	82	114	80	10	4	6
		FINAL		8	72	110	74	82	114	80	10	4	6
	E0010009	SCREEN	18DEC2002	-8	56	130	70	65	130	64	9	0	-6
		DAY 1	26DEC2002	1	56	138	88	60	136	88	4	-2	0
		BASELINE			56	138	88	60	136	88	4	-2	0
		DAY 8	02JAN2003	8	66	120	76	76	110	76	10	-10	0
		DAY 15	09JAN2003	15	74	140	82	89	120	80	15	-20	-2
		DAY 22	17JAN2003	23	72	110	78	84	108	78	12	-2	0
		DAY 29	22JAN2003	28	68	128	76	76	104	80	8	-24	4
		DAY 36	30JAN2003	36	82	138	66	90	146	86	8	8	20
		DAY 43	05FEB2003	42	84	124	82	90	108	76	6	-16	-6
		DAY 50	13FEB2003	50	68	126	62	86	118	72	18	-8	10
		DAY 57	19FEB2003	56	74	126	80	89	126	82	15	0	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	FINAL		56	74	126	80	89	126	82	15	0	2
	E0010010	SCREEN	20DEC2002	-10	55	110	68	67	108	70	12	-2	2
		DAY 1	30DEC2002	1	62	100	62	78	100	62	16	0	0
		BASELINE			62	100	62	78	100	62	16	0	0
		DAY 8	06JAN2003	8	64	110	68	74	108	68	10	-2	0
		DAY 15	13JAN2003	15	68	114	76	81	100	70	13	-14	-6
		FINAL		15	68	114	76	81	100	70	13	-14	-6
	E0010014	SCREEN	14JAN2003	-14	52	120	70	68	124	70	16	4	0
		DAY 1	28JAN2003	1	49	126	66	65	114	66	16	-12	0
		BASELINE			49	126	66	65	114	66	16	-12	0
		DAY 8	04FEB2003	8	58	112	68	70	102	66	12	-10	-2
		DAY 15	11FEB2003	15	58	104	62	77	106	64	19	2	2
		DAY 22	18FEB2003	22	52	118	70	66	120	76	14	2	6
		DAY 29	25FEB2003	29	58	108	68	76	110	70	18	2	2
		DAY 36	04MAR2003	36	54	120	70	74	110	78	20	-10	8
		DAY 43	11MAR2003	43	52	112	70	70	112	70	18	0	0
		DAY 50	18MAR2003	50	52	110	74	66	110	70	14	0	-4
		DAY 57	25MAR2003	57	51	118	78	58	110	80	7	-8	2
		FINAL		57	51	118	78	58	110	80	7	-8	2
	E0010017	SCREEN	05FEB2003	-20	61	114	62	79	110	80	18	-4	18
		DAY 1	25FEB2003	1	68	124	66	72	128	80	4	4	14
		BASELINE			68	124	66	72	128	80	4	4	14
		DAY 8	03MAR2003	7	60	110	70	76	100	60	16	-10	-10
		DAY 15	10MAR2003	14	84	112	68	100	120	70	16	8	2
		DAY 22	18MAR2003	22	64	120	72	86	126	86	22	6	14
		DAY 29	25MAR2003	29	80	110	68	86	112	76	6	2	8
		DAY 36	01APR2003	36	84	110	76	92	116	80	8	6	4
		DAY 43	08APR2003	43	84	120	78	94	112	80	10	-8	2
		DAY 50	15APR2003	50	72	126	76	88	128	80	16	2	4
		DAY 57	22APR2003	57	69	110	66	78	112	76	9	2	10
		FINAL		57	69	110	66	78	112	76	9	2	10

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010023	SCREEN	10APR2003	-7	72	108	70	78	94	74	6	-14	4
		DAY 1	17APR2003	1	72	110	60	92	108	68	20	-2	8
		BASELINE			72	110	60	92	108	68	20	-2	8
		DAY 8	24APR2003	8	72	98	68	88	104	70	16	6	2
		DAY 15	01MAY2003	15	72	100	64	98	96	70	26	-4	6
		FINAL		15	72	100	64	98	96	70	26	-4	6
	E0010027	SCREEN	05JUN2003	-11	66	118	70	82	112	70	16	-6	0
		DAY 1	16JUN2003	1	80	110	90	80	110	82	0	0	-8
		BASELINE			80	110	90	80	110	82	0	0	-8
		DAY 8	23JUN2003	8	78	120	74	110	118	78	32	-2	4
		DAY 15	01JUL2003	16	76	110	80	80	120	82	4	10	2
		FINAL		16	76	110	80	80	120	82	4	10	2
	E0010029	SCREEN	10JUN2003	-9	75	120	84	96	134	90	21	14	6
		DAY 1	19JUN2003	1	88	120	80	88	120	89	0	0	9
		BASELINE			88	120	80	88	120	89	0	0	9
		DAY 8	25JUN2003	7	92	138	94	104	134	94	12	-4	0
		FINAL		7	92	138	94	104	134	94	12	-4	0
	E0011022	SCREEN	02JUN2003	-7	70	130	80	72	136	78	2	6	-2
		DAY 1	09JUN2003	1	68	130	86	72	132	86	4	2	0
		BASELINE			68	130	86	72	132	86	4	2	0
		DAY 8	16JUN2003	8	88	126	80	96	128	76	8	2	-4
		DAY 15	24JUN2003	16	90	122	82	88	118	78	-2	-4	-4
		DAY 22	01JUL2003	23	82	110	68	86	114	70	4	4	2
		DAY 29	08JUL2003	30	88	110	74	84	102	68	-4	-8	-6
		DAY 36	15JUL2003	37	90	124	82	90	120	80	0	-4	-2
		DAY 43	24JUL2003	46	82	124	82	82	120	80	0	-4	-2
		DAY 50	31JUL2003	53	78	124	82	82	120	78	4	-4	-4
		DAY 57	05AUG2003	58	82	120	84	86	116	80	4	-4	-4
		FINAL		58	82	120	84	86	116	80	4	-4	-4
	E0013006	SCREEN	06MAR2003	-7	72	124	80	72	118	80	0	-6	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	DAY 1	13MAR2003	1	66	124	72	66	120	78	0	-4	6
		BASELINE			66	124	72	66	120	78	0	-4	6
		DAY 8	24MAR2003	12	72	118	74	66	122	66	-6	4	-8
		FINAL		12	72	118	74	66	122	66	-6	4	-8
	E0013012	SCREEN	29APR2003	-8	72	114	80	72	118	80	0	4	0
		DAY 1	07MAY2003	1	72	128	82	72	128	80	0	0	-2
		BASELINE			72	128	82	72	128	80	0	0	-2
		DAY 8	16MAY2003	10	72	140	80	64	140	80	-8	0	0
		DAY 15	22MAY2003	16	76	120	78	72	122	78	-4	2	0
		DAY 22	30MAY2003	24	60	120	62	64	120	70	4	0	8
		DAY 29	05JUN2003	30	68	122	76	68	122	80	0	0	4
		DAY 36	12JUN2003	37	64	120	74	68	120	80	4	0	6
		DAY 43	19JUN2003	44	68	120	68	68	120	70	0	0	2
		DAY 50	25JUN2003	50	68	120	78	72	126	80	4	6	2
		DAY 57	02JUL2003	57	72	140	88	72	138	90	0	-2	2
		FINAL		57	72	140	88	72	138	90	0	-2	2
	E0013014	SCREEN	08MAY2003	-26	62	120	80	64	120	80	2	0	0
		DAY 1	03JUN2003	1	60	126	84	64	120	84	4	-6	0
		BASELINE			60	126	84	64	120	84	4	-6	0
		DAY 8	10JUN2003	8	64	120	82	64	120	80	0	0	-2
		DAY 15	19JUN2003	17	84	118	80	80	120	82	-4	2	2
		DAY 29	30JUN2003	28	68	122	80	68	120	80	0	-2	0
		FINAL		28	68	122	80	68	120	80	0	-2	0
	E0014005	SCREEN	04MAR2003	-7	82	140	95	80	138	95	-2	-2	0
		DAY 1	11MAR2003	1	88	124	86	98	118	86	10	-6	0
		BASELINE			88	124	86	98	118	86	10	-6	0
		DAY 8	18MAR2003	8	98	140	98	100	135	98	2	-5	0
		DAY 15	25MAR2003	15	95	125	93	100	125	98	5	0	5
		DAY 22	01APR2003	22	94	135	95	100	125	95	6	-10	0
		DAY 29	08APR2003	29	100	120	90	102	125	90	2	5	0
		DAY 36	16APR2003	37	100	116	78	116	116	86	16	0	8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	DAY 43	23APR2003	44	105	128	82	116	124	88	11	-4	6
		DAY 50	29APR2003	50	102	130	95	102	140	95	0	10	0
		DAY 57	06MAY2003	57	100	125	92	92	130	93	-8	5	1
		FINAL		57	100	125	92	92	130	93	-8	5	1
	E0014007	SCREEN	25MAR2003	-7	62	128	88	68	128	87	6	0	-1
		DAY 1	01APR2003	1	92	120	87	93	120	87	1	0	0
		BASELINE			92	120	87	93	120	87	1	0	0
		DAY 8	08APR2003	8	79	98	75	80	110	80	1	12	5
		DAY 15	15APR2003	15	90	110	82	93	120	90	3	10	8
		DAY 22	22APR2003	22	80	128	82	84	134	82	4	6	0
		FINAL		22	80	128	82	84	134	82	4	6	0
	E0014011	SCREEN	06MAY2003	-7	92	130	70	96	118	70	4	-12	0
		DAY 1	13MAY2003	1	88	124	70	92	118	68	4	-6	-2
		BASELINE			88	124	70	92	118	68	4	-6	-2
		DAY 8	20MAY2003	8	96	130	94	97	125	96	1	-5	2
		DAY 15	27MAY2003	15	84	130	78	88	128	78	4	-2	0
		DAY 22	04JUN2003	23	78	122	76	86	116	72	8	-6	-4
		DAY 29	10JUN2003	29	80	120	80	84	118	84	4	-2	4
		DAY 36	17JUN2003	36	84	126	80	84	122	80	0	-4	0
		DAY 43	26JUN2003	45	82	110	87	83	120	94	1	10	7
		DAY 50	02JUL2003	51	76	120	78	80	122	82	4	2	4
		DAY 57	08JUL2003	57	78	126	78	82	124	78	4	-2	0
		FINAL		57	78	126	78	82	124	78	4	-2	0
	E0014012	SCREEN	19MAY2003	-8	84	107	90	90	120	90	6	13	0
		DAY 1	27MAY2003	1	80	124	88	84	116	86	4	-8	-2
		BASELINE			80	124	88	84	116	86	4	-8	-2
		DAY 8	03JUN2003	8	80	128	88	82	122	86	2	-6	-2
		DAY 15	10JUN2003	15	86	134	86	84	126	80	-2	-8	-6
		DAY 22	17JUN2003	22	74	110	72	78	108	72	4	-2	0
		DAY 29	24JUN2003	29	80	128	86	82	120	84	2	-8	-2
		FINAL		29	80	128	86	82	120	84	2	-8	-2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	SCREEN	08NOV2002	-21	60	106	62	58	102	68	-2	-4	6
		DAY 1	29NOV2002	1	58	108	62	58	104	60	0	-4	-2
		BASELINE			58	108	62	58	104	60	0	-4	-2
		DAY 8	06DEC2002	8	54	106	62	58	110	64	4	4	2
		DAY 15	13DEC2002	15	60	110	62	62	112	64	2	2	2
		DAY 22	19DEC2002	21	68	116	82	70	116	78	2	0	-4
		DAY 29	27DEC2002	29	62	108	78	64	116	72	2	8	-6
		DAY 36	03JAN2003	36	60	106	78	68	112	70	8	6	-8
		DAY 43	09JAN2003	42	64	110	74	64	106	70	0	-4	-4
		DAY 50	20JAN2003	53	60	112	72	58	108	68	-2	-4	-4
		FINAL		53	60	112	72	58	108	68	-2	-4	-4
	E0015008	SCREEN	13DEC2002	-6	62	110	72	64	108	68	2	-2	-4
		DAY 1	19DEC2002	1	68	112	74	64	108	70	-4	-4	-4
		BASELINE			68	112	74	64	108	70	-4	-4	-4
		DAY 8	27DEC2002	9	64	108	68	68	112	68	4	4	0
		DAY 15	03JAN2003	16	62	110	62	64	102	60	2	-8	-2
		DAY 22	10JAN2003	23	60	120	64	64	110	68	4	-10	4
		DAY 29	16JAN2003	29	68	118	78	64	110	72	-4	-8	-6
		DAY 36	23JAN2003	36	76	122	76	74	112	72	-2	-10	-4
		FINAL		36	76	122	76	74	112	72	-2	-10	-4
	E0016003	SCREEN	10JAN2003	-14	74	128	88	80	132	90	6	4	2
		DAY 1	24JAN2003	1	72	126	79	82	138	88	10	12	9
		BASELINE			72	126	79	82	138	88	10	12	9
		DAY 8	31JAN2003	8	90	128	80	86	132	84	-4	4	4
		DAY 15	07FEB2003	15	82	126	84	89	138	92	7	12	8
		DAY 22	14FEB2003	22	86	128	92	94	132	84	8	4	-8
		DAY 29	21FEB2003	29	89	121	78	98	132	89	9	11	11
		DAY 36	27FEB2003	35	86	121	81	92	132	86	6	11	5
		DAY 43	07MAR2003	43	89	136	94	96	142	98	7	6	4
		FINAL		43	89	136	94	96	142	98	7	6	4
	E0016005	SCREEN	20FEB2003	-5	64	118	78	86	108	84	22	-10	6

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	DAY 1		25FEB2003	1	81	118	72	96	126	84	15	8	12
		BASELINE				81	118	72	96	126	84	15	8	12
		DAY 8		04MAR2003	8	88	122	79	95	128	85	7	6	6
		DAY 15		11MAR2003	15	81	111	69	91	132	86	10	21	17
		DAY 22		18MAR2003	22	78	115	76	83	126	81	5	11	5
		DAY 29		25MAR2003	29	76	116	82	84	126	76	8	10	-6
		DAY 36		01APR2003	36	74	118	69	86	132	81	12	14	12
		DAY 43		08APR2003	43	82	140	81	87	150	88	5	10	7
		DAY 57		22APR2003	57	91	105	73	98	117	76	7	12	3
		FINAL			57	91	105	73	98	117	76	7	12	3
	E0018007	SCREEN		16DEC2002	-11	70	138	78	74	132	78	4	-6	0
		DAY 1		27DEC2002	1	88	124	84	88	122	86	0	-2	2
		BASELINE				88	124	84	88	122	86	0	-2	2
		DAY 8		31DEC2002	5	80	128	86	84	126	82	4	-2	-4
		DAY 15		10JAN2003	15	76	120	76	80	120	82	4	0	6
		FINAL			15	76	120	76	80	120	82	4	0	6
	E0019005	SCREEN		30OCT2002	-6	60	140	86	62	140	88	2	0	2
		DAY 1		05NOV2002	1	64	130	70	72	125	70	8	-5	0
		BASELINE				64	130	70	72	125	70	8	-5	0
		DAY 8		12NOV2002	8	54	110	60	62	110	65	8	0	5
		DAY 15		19NOV2002	15	72	120	80	64	128	78	-8	8	-2
		DAY 22		26NOV2002	22	68	135	80	76	125	70	8	-10	-10
		DAY 29		05DEC2002	31	60	120	82	80	124	78	20	4	-4
		DAY 36		12DEC2002	38	70	118	70	68	115	70	-2	-3	0
		DAY 43		19DEC2002	45	68	112	80	72	115	80	4	3	0
		DAY 57	*	30DEC2002	56	80	130	74	88	136	78	8	6	4
		DAY 57		02JAN2003	59	88	120	72	94	120	78	6	0	6
		FINAL			59	88	120	72	94	120	78	6	0	6
	E0019015	SCREEN		19DEC2002	-14	56	110	84	76	100	82	20	-10	-2
		DAY 1		02JAN2003	1	60	110	90	80	120	90	20	10	0
		BASELINE				60	110	90	80	120	90	20	10	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	DAY 8		09JAN2003	8	72	112	92	76	110	90	4	-2	-2
		DAY 15		16JAN2003	15	72	128	80	80	126	82	8	-2	2
		DAY 22		23JAN2003	22	60	117	75	62	118	80	2	1	5
		DAY 29		30JAN2003	29	80	130	85	84	135	85	4	5	0
		DAY 36		06FEB2003	36	84	135	80	76	140	90	-8	5	10
		DAY 43		13FEB2003	43	80	130	80	88	135	80	8	5	0
		DAY 50		20FEB2003	50	90	125	85	90	130	90	0	5	5
		DAY 57		27FEB2003	57	50	120	104	96	124	100	46	4	-4
		FINAL			57	50	120	104	96	124	100	46	4	-4
	E0020004	SCREEN		21NOV2002	-18	78	160	80	82	162	84	4	2	4
		DAY 1		09DEC2002	1	84	140	80	80	144	82	-4	4	2
		BASELINE				84	140	80	80	144	82	-4	4	2
		DAY 8		16DEC2002	8	82	138	80	80	140	82	-2	2	2
		DAY 8	*	20DEC2002	12	80	178	100	86	180	104	6	2	4
		DAY 22		31DEC2002	23	74	122	78	76	120	78	2	-2	0
		DAY 29		07JAN2003	30	76	170	92	80	168	90	4	-2	-2
		DAY 36		14JAN2003	37	76	152	82	70	148	80	-6	-4	-2
		DAY 43		22JAN2003	45	80	138	80	84	138	82	4	0	2
		FINAL			45	80	138	80	84	138	82	4	0	2
	E0020010	SCREEN		28JAN2003	-8	70	104	70	76	110	68	6	6	-2
		DAY 1		05FEB2003	1	66	102	80	64	106	80	-2	4	0
		BASELINE				66	102	80	64	106	80	-2	4	0
		DAY 8		12FEB2003	8	80	110	70	76	112	72	-4	2	2
		DAY 15		19FEB2003	15	80	120	88	78	118	90	-2	-2	2
		DAY 22		26FEB2003	22	78	120	86	76	118	88	-2	-2	2
		DAY 29		05MAR2003	29	84	120	72	80	124	74	-4	4	2
		DAY 36		10MAR2003	34	80	120	78	82	120	80	2	0	2
		DAY 43		17MAR2003	41	64	122	70	64	118	70	0	-4	0
		DAY 50		25MAR2003	49	74	120	74	76	122	72	2	2	-2
		DAY 57		02APR2003	57	80	144	82	84	130	84	4	-14	2
		FINAL			57	80	144	82	84	130	84	4	-14	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	SCREEN	11MAR2003	-7	64	118	76	68	112	74	4	-6	-2
		DAY 1	18MAR2003	1	76	112	72	72	120	74	-4	8	2
		BASELINE			76	112	72	72	120	74	-4	8	2
		DAY 8	25MAR2003	8	78	122	76	84	124	74	6	2	-2
		DAY 15	01APR2003	15	82	140	88	80	160	90	-2	20	2
		DAY 22	08APR2003	22	76	148	90	74	152	90	-2	4	0
		DAY 29	15APR2003	29	78	124	80	80	128	84	2	4	4
		DAY 36	22APR2003	36	80	140	70	82	138	72	2	-2	2
		DAY 43	29APR2003	43	64	124	82	70	126	84	6	2	2
		DAY 50	06MAY2003	50	80	126	76	78	120	76	-2	-6	0
		DAY 57	12MAY2003	56	62	132	72	68	130	74	6	-2	2
		FINAL		56	62	132	72	68	130	74	6	-2	2
	E0020021	SCREEN	13MAY2003	-6	70	134	82	76	140	84	6	6	2
		DAY 1	19MAY2003	1	72	130	80	70	128	82	-2	-2	2
		BASELINE			72	130	80	70	128	82	-2	-2	2
		DAY 8	23MAY2003	5	62	128	86	64	130	86	2	2	0
		DAY 15	02JUN2003	15	76	142	82	80	148	84	4	6	2
		DAY 22	10JUN2003	23	78	140	82	80	144	80	2	4	-2
		DAY 29	16JUN2003	29	92	140	80	88	140	90	-4	0	10
		DAY 36	23JUN2003	36	80	140	76	88	138	76	8	-2	0
		DAY 43	30JUN2003	43	88	130	78	88	130	80	0	0	2
		DAY 50	07JUL2003	50	94	166	98	90	160	98	-4	-6	0
		DAY 57	14JUL2003	57	88	174	106	80	160	108	-8	-14	2
		FINAL		57	88	174	106	80	160	108	-8	-14	2
	E0020023	SCREEN	09JUN2003	-8	62	118	80	60	120	80	-2	2	0
		DAY 1	16JUN2003	-1	54	110	80	60	120	88	6	10	8
		BASELINE			54	110	80	60	120	88	6	10	8
		DAY 8	24JUN2003	8	64	110	80	64	118	80	0	8	0
		DAY 15	30JUN2003	14	76	112	88	80	116	90	4	4	2
		DAY 22	07JUL2003	21	60	102	72	62	106	72	2	4	0
		DAY 29	14JUL2003	28	78	110	80	82	108	80	4	-2	0
		DAY 36	21JUL2003	35	72	94	58	78	92	70	6	-2	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	DAY 43		28JUL2003	42	80	128	78	78	120	78	-2	-8	0
		DAY 50		04AUG2003	49	74	106	86	80	108	86	6	2	0
		DAY 57		11AUG2003	56	60	110	88	58	100	88	-2	-10	0
		FINAL			56	60	110	88	58	100	88	-2	-10	0
	E0022007	SCREEN		01NOV2002	-6	52	112	69	64	120	73	12	8	4
		DAY 1		07NOV2002	1	64	108	68	68	112	72	4	4	4
		BASELINE				64	108	68	68	112	72	4	4	4
		DAY 8		14NOV2002	8	72	124	62	100	114	76	28	-10	14
		DAY 15		22NOV2002	16	84	104	62	88	102	64	4	-2	2
		DAY 22		02DEC2002	26	72	112	58	88	100	68	16	-12	10
		DAY 29		09DEC2002	33	74	112	70	78	104	72	4	-8	2
		FINAL			33	74	112	70	78	104	72	4	-8	2
	E0022010	SCREEN		14NOV2002	-7	59	135	69	75	133	70	16	-2	1
		DAY 1		21NOV2002	1	68	124	68	72	118	68	4	-6	0
		BASELINE				68	124	68	72	118	68	4	-6	0
		DAY 8		29NOV2002	9	84	122	64	80	120	70	-4	-2	6
		DAY 15		06DEC2002	16	84	142	78	88	142	106	4	0	28
		DAY 22		12DEC2002	22	72	130	68	80	136	72	8	6	4
		DAY 36		26DEC2002	36	78	142	64	78	144	68	0	2	4
		DAY 43		02JAN2003	43	84	146	70	88	142	86	4	-4	16
		DAY 50		09JAN2003	50	80	134	72	100	132	96	20	-2	24
		DAY 57		16JAN2003	57	76	134	70	72	132	76	-4	-2	6
		FINAL			57	76	134	70	72	132	76	-4	-2	6
	E0022012	SCREEN		21NOV2002	-14	64	126	60	68	118	72	4	-8	12
		DAY 1		05DEC2002	1	60	122	62	64	122	68	4	0	6
		BASELINE				60	122	62	64	122	68	4	0	6
		DAY 8		12DEC2002	8	64	122	72	68	110	68	4	-12	-4
		DAY 15		19DEC2002	15	76	116	68	90	116	74	14	0	6
		DAY 15	*	23DEC2002	19	76	110	68	84	108	74	8	-2	6
		DAY 29		02JAN2003	29	78	108	68	78	120	80	0	12	12
		DAY 36		09JAN2003	36	90	126	64	90	110	78	0	-16	14

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022012	DAY 43	16JAN2003	43	88	124	64	100	128	72	12	4	8
		DAY 50	23JAN2003	50	81	122	68	84	122	80	3	0	12
		DAY 57	30JAN2003	57	84	112	68	84	128	70	0	16	2
		FINAL		57	84	112	68	84	128	70	0	16	2
	E0022019	SCREEN	04DEC2002	-7	68	122	64	84	130	88	16	8	24
		DAY 1	11DEC2002	1	60	120	76	80	126	90	20	6	14
		BASELINE			60	120	76	80	126	90	20	6	14
		DAY 8	19DEC2002	9	80	146	78	88	118	90	8	-28	12
		DAY 15	26DEC2002	16	88	144	84	96	132	88	8	-12	4
		DAY 22	03JAN2003	24	96	134	96	112	142	100	16	8	4
		DAY 29	09JAN2003	30	96	126	82	108	136	98	12	10	16
		DAY 36	17JAN2003	38	92	132	96	100	138	92	8	6	-4
		DAY 43	24JAN2003	45	80	140	94	92	124	94	12	-16	0
		DAY 50	30JAN2003	51	100	134	92	112	132	104	12	-2	12
		DAY 57	06FEB2003	58	76	124	80	92	118	92	16	-6	12
		FINAL		58	76	124	80	92	118	92	16	-6	12
	E0022025	SCREEN	08JAN2003	-20	52	132	72	60	114	72	8	-18	0
		DAY 1	28JAN2003	1	54	124	62	57	120	70	3	-4	8
		BASELINE			54	124	62	57	120	70	3	-4	8
		DAY 8	04FEB2003	8	60	132	72	60	116	78	0	-16	6
		FINAL		8	60	132	72	60	116	78	0	-16	6
	E0022033	SCREEN	11FEB2003	-7	64	112	78	60	120	72	-4	8	-6
		DAY 1	18FEB2003	1	76	104	64	72	100	66	-4	-4	2
		BASELINE			76	104	64	72	100	66	-4	-4	2
		DAY 8	25FEB2003	8	60	130	76	76	132	84	16	2	8
		DAY 15	04MAR2003	15	74	128	80	88	128	88	14	0	8
		DAY 22	11MAR2003	22	80	128	80	88	128	82	8	0	2
		DAY 29	18MAR2003	29	64	130	76	78	106	82	14	-24	6
		DAY 36	27MAR2003	38	68	128	80	68	110	82	0	-18	2
		DAY 43	01APR2003	43	68	118	72	78	118	80	10	0	8
		DAY 50	08APR2003	50	72	120	70	80	118	78	8	-2	8

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	DAY 57	15APR2003	57	60	120	70	72	128	82	12	8	12
		FINAL		57	60	120	70	72	128	82	12	8	12
	E0022034	SCREEN	11FEB2003	-7	64	136	84	70	138	86	6	2	2
		DAY 1	18FEB2003	1	66	128	78	76	142	78	10	14	0
		BASELINE			66	128	78	76	142	78	10	14	0
		DAY 8	25FEB2003	8	60	128	74	75	138	82	15	10	8
		DAY 15	04MAR2003	15	60	126	74	69	114	80	9	-12	6
		DAY 22	11MAR2003	22	75	124	80	78	120	82	3	-4	2
		DAY 29	18MAR2003	29	68	116	78	75	128	84	7	12	6
		DAY 36	25MAR2003	36	87	140	78	75	138	86	-12	-2	8
		DAY 43	01APR2003	43	78	118	74	90	130	84	12	12	10
		DAY 50	07APR2003	49	96	132	80	92	126	86	-4	-6	6
		DAY 57	15APR2003	57	81	120	76	84	118	80	3	-2	4
		FINAL		57	81	120	76	84	118	80	3	-2	4
	E0022038	SCREEN	20FEB2003	-8	56	128	84	64	142	88	8	14	4
		DAY 1	28FEB2003	1	60	118	74	78	118	80	18	0	6
		BASELINE			60	118	74	78	118	80	18	0	6
		DAY 8	07MAR2003	8	60	128	72	72	122	88	12	-6	16
		DAY 15	14MAR2003	15	80	130	78	88	120	70	8	-10	-8
		DAY 22	21MAR2003	22	78	140	82	88	130	80	10	-10	-2
		DAY 29	28MAR2003	29	76	128	68	88	130	80	12	2	12
		DAY 36	04APR2003	36	84	134	60	96	124	72	12	-10	12
		DAY 43	11APR2003	43	56	130	72	64	130	78	8	0	6
		FINAL		43	56	130	72	64	130	78	8	0	6
	E0022039	SCREEN	27FEB2003	-7	64	90	58	68	116	70	4	26	12
		DAY 1	06MAR2003	1	74	110	84	78	120	82	4	10	-2
		BASELINE			74	110	84	78	120	82	4	10	-2
		DAY 8	13MAR2003	8	88	118	70	96	122	78	8	4	8
		DAY 15	20MAR2003	15	84	122	82	88	118	90	4	-4	8
		DAY 22	27MAR2003	22	72	120	82	78	108	84	6	-12	2
		DAY 29	04APR2003	30	88	118	78	98	108	72	10	-10	-6

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	DAY 36	10APR2003	36	84	124	78	80	118	84	-4	-6	6
		DAY 43	18APR2003	44	78	118	82	80	112	80	2	-6	-2
		DAY 50	24APR2003	50	78	112	78	84	122	78	6	10	0
		DAY 57	01MAY2003	57	84	108	76	116	106	74	32	-2	-2
		FINAL		57	84	108	76	116	106	74	32	-2	-2
	E0022046	SCREEN	13MAR2003	-7	88	132	74	97	138	72	9	6	-2
		DAY 1	20MAR2003	1	68	128	64	70	124	70	2	-4	6
		BASELINE			68	128	64	70	124	70	2	-4	6
		DAY 8	27MAR2003	8	68	146	84	70	140	74	2	-6	-10
		DAY 15	04APR2003	16	100	150	68	108	146	70	8	-4	2
		DAY 22	11APR2003	23	96	146	80	116	132	66	20	-14	-14
		DAY 29	18APR2003	30	88	144	74	108	130	70	20	-14	-4
		DAY 36	24APR2003	36	96	136	90	96	128	78	0	-8	-12
		DAY 43	02MAY2003	44	112	142	70	120	138	74	8	-4	4
		DAY 50	12MAY2003	54	92	128	72	110	124	68	18	-4	-4
		DAY 57	16MAY2003	58	104	130	72	116	128	78	12	-2	6
		FINAL		58	104	130	72	116	128	78	12	-2	6
	E0022048	SCREEN	25MAR2003	-7	54	104	64	72	98	62	18	-6	-2
		DAY 1	01APR2003	1	64	98	58	72	98	64	8	0	6
		BASELINE			64	98	58	72	98	64	8	0	6
		DAY 8	08APR2003	8	80	104	60	80	100	64	0	-4	4
		DAY 15	15APR2003	15	74	118	62	74	110	62	0	-8	0
		DAY 22	24APR2003	24	68	102	64	80	100	70	12	-2	6
		DAY 29	02MAY2003	32	78	110	66	84	102	72	6	-8	6
		DAY 36	06MAY2003	36	72	110	64	60	108	70	-12	-2	6
		DAY 43	13MAY2003	43	64	104	64	72	110	68	8	6	4
		DAY 50	23MAY2003	53	78	104	70	80	102	72	2	-2	2
		FINAL		53	78	104	70	80	102	72	2	-2	2
	E0022051	SCREEN	31MAR2003	-7	68	110	66	96	114	68	28	4	2
		DAY 1	07APR2003	1	72	124	66	76	110	72	4	-14	6
		BASELINE			72	124	66	76	110	72	4	-14	6

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022051	DAY 8		14APR2003	8	60	112	74	64	102	72	4	-10	-2
		DAY 15		21APR2003	15	68	108	74	88	114	68	20	6	-6
		DAY 22		28APR2003	22	84	118	64	96	110	72	12	-8	8
		DAY 29		05MAY2003	29	100	130	80	88	116	82	-12	-14	2
		DAY 36		12MAY2003	36	80	138	74	80	112	68	0	-26	-6
		DAY 43		19MAY2003	43	76	120	80	72	112	68	-4	-8	-12
		DAY 50		28MAY2003	52	84	120	74	88	110	78	4	-10	4
		DAY 57		02JUN2003	57	88	120	72	88	116	76	0	-4	4
		FINAL			57	88	120	72	88	116	76	0	-4	4
	E0022053	SCREEN		04APR2003	-7	56	106	60	76	126	84	20	20	24
		DAY 1		11APR2003	1	60	110	60	66	118	70	6	8	10
		BASELINE				60	110	60	66	118	70	6	8	10
	E0022058	SCREEN		11APR2003	-10	64	110	80	84	126	88	20	16	8
		DAY 1		21APR2003	1	80	122	76	88	118	72	8	-4	-4
		BASELINE				80	122	76	88	118	72	8	-4	-4
		DAY 8		28APR2003	8	75	130	74	87	114	80	12	-16	6
		DAY 15		05MAY2003	15	80	132	86	100	110	80	20	-22	-6
		DAY 22		12MAY2003	22	88	126	74	88	112	80	0	-14	6
		DAY 29		19MAY2003	29	88	110	68	84	126	78	-4	16	10
		DAY 29	*	22MAY2003	32	78	120	78	80	118	80	2	-2	2
		FINAL			32	78	120	78	80	118	80	2	-2	2
	E0022061	SCREEN		24APR2003	-6	72	118	74	68	118	80	-4	0	6
		DAY 1		30APR2003	1	76	120	68	84	114	62	8	-6	-6
		BASELINE				76	120	68	84	114	62	8	-6	-6
		DAY 8		07MAY2003	8	84	122	56	68	118	70	-16	-4	14
		DAY 15		14MAY2003	15	80	114	54	104	110	54	24	-4	0
		DAY 22		22MAY2003	23	88	112	62	76	102	70	-12	-10	8
		DAY 29		28MAY2003	29	80	114	54	96	114	60	16	0	6
		DAY 36		04JUN2003	36	80	122	60	76	110	70	-4	-12	10
		DAY 50		18JUN2003	50	88	118	60	96	110	66	8	-8	6
		DAY 57		26JUN2003	58	84	114	64	108	104	68	24	-10	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	FINAL			58	84	114	64	108	104	68	24	-10	4
	E0022062	SCREEN		25APR2003	-10	78	156	86	96	144	88	18	-12	2
		DAY 1		05MAY2003	1	80	152	88	78	156	94	-2	4	6
		BASELINE				80	152	88	78	156	94	-2	4	6
		DAY 8		12MAY2003	8	100	164	78	100	138	90	0	-26	12
		DAY 15		19MAY2003	15	84	162	102	92	148	98	8	-14	-4
		DAY 15	*	23MAY2003	19	88	162	110	84	162	108	-4	0	-2
		FINAL			19	88	162	110	84	162	108	-4	0	-2
	E0022068	SCREEN		14MAY2003	-9	72	112	70	68	114	78	-4	2	8
		DAY 1		22MAY2003	-1	60	96	56	68	92	60	8	-4	4
		BASELINE				60	96	56	68	92	60	8	-4	4
		DAY 8		29MAY2003	7	80	98	62	76	98	64	-4	0	2
		DAY 15		05JUN2003	14	84	110	70	80	102	68	-4	-8	-2
		FINAL			14	84	110	70	80	102	68	-4	-8	-2
	E0022069	SCREEN		03JUN2003	-7	57	96	68	72	106	74	15	10	6
		DAY 1		10JUN2003	1	66	108	70	72	118	74	6	10	4
		BASELINE				66	108	70	72	118	74	6	10	4
		DAY 8		17JUN2003	8	76	124	66	88	126	82	12	2	16
		DAY 15		24JUN2003	15	72	112	74	84	122	82	12	10	8
		DAY 22		01JUL2003	22	68	122	62	68	116	82	0	-6	20
		DAY 29		08JUL2003	29	60	118	80	64	112	78	4	-6	-2
		DAY 36		15JUL2003	36	69	112	64	75	122	80	6	10	16
		DAY 43		22JUL2003	43	56	104	68	72	106	80	16	2	12
		DAY 50		29JUL2003	50	66	110	66	66	116	64	0	6	-2
		DAY 57		05AUG2003	57	72	114	72	80	106	68	8	-8	-4
		FINAL			57	72	114	72	80	106	68	8	-8	-4
	E0022071	SCREEN		16JUN2003	-14	72	138	88	86	146	94	14	8	6
		DAY 1		30JUN2003	1	60	132	78	78	136	92	18	4	14
		BASELINE				60	132	78	78	136	92	18	4	14
		DAY 8		07JUL2003	8	90	124	78	88	136	82	-2	12	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:46:40 iceadmn3

Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 15	14JUL2003	15	78	128	76	80	130	72	2	2	-4
		DAY 22	21JUL2003	22	72	124	78	90	124	88	18	0	10
		DAY 29	28JUL2003	29	82	138	88	102	126	94	20	-12	6
		DAY 36	04AUG2003	36	84	140	86	104	132	96	20	-8	10
		DAY 43	11AUG2003	43	84	136	86	102	142	90	18	6	4
		DAY 50	18AUG2003	50	74	132	84	84	124	92	10	-8	8
		DAY 57	25AUG2003	57	82	138	92	88	128	90	6	-10	-2
		FINAL		57	82	138	92	88	128	90	6	-10	-2
	E0023003	SCREEN	12DEC2002	-5	79	148	86	74	129	80	-5	-19	-6
		DAY 1	17DEC2002	1	72	104	80	76	110	84	4	6	4
		BASELINE			72	104	80	76	110	84	4	6	4
		DAY 8	23DEC2002	7	68	134	89	72	125	84	4	-9	-5
		DAY 15	30DEC2002	14	88	118	64	80	124	70	-8	6	6
		DAY 22	07JAN2003	22	86	104	78	80	100	78	-6	-4	0
		DAY 29	16JAN2003	31	86	117	70	88	114	68	2	-3	-2
		DAY 36	21JAN2003	36	88	124	84	88	120	80	0	-4	-4
		DAY 43	28JAN2003	43	90	98	65	92	100	67	2	2	2
		DAY 50	06FEB2003	52	68	108	68	72	110	70	4	2	2
		DAY 57	11FEB2003	57	82	127	88	110	107	74	28	-20	-14
		FINAL		57	82	127	88	110	107	74	28	-20	-14
	E0023006	SCREEN	10DEC2002	-7	65	116	74	66	120	70	1	4	-4
		DAY 1	17DEC2002	1	60	114	70	70	120	70	10	6	0
		BASELINE			60	114	70	70	120	70	10	6	0
		DAY 8	23DEC2002	7	86	143	78	89	130	75	3	-13	-3
		DAY 15	02JAN2003	17	75	120	80	75	114	76	0	-6	-4
		DAY 22	07JAN2003	22	80	98	60	88	110	70	8	12	10
		DAY 29	16JAN2003	31	72	143	82	76	130	76	4	-13	-6
		DAY 36	21JAN2003	36	72	104	70	80	104	70	8	0	0
		DAY 43	28JAN2003	43	72	102	70	74	110	80	2	8	10
		DAY 50	04FEB2003	50	66	120	57	78	121	71	12	1	14
		DAY 57	11FEB2003	57	63	119	58	78	133	67	15	14	9
		FINAL		57	63	119	58	78	133	67	15	14	9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	SCREEN	28JAN2003	-7	72	118	72	70	118	72	-2	0	0
		DAY 1	04FEB2003	1	78	127	79	76	130	89	-2	3	10
		BASELINE			78	127	79	76	130	89	-2	3	10
		DAY 8	11FEB2003	8	78	121	71	76	110	58	-2	-11	-13
		DAY 15	18FEB2003	15	76	112	84	80	108	80	4	-4	-4
		DAY 22	25FEB2003	22	89	111	73	96	130	85	7	19	12
		DAY 29	04MAR2003	29	85	142	98	95	148	99	10	6	1
		DAY 36	11MAR2003	36	70	120	70	76	130	78	6	10	8
		DAY 43	18MAR2003	43	75	137	96	87	133	93	12	-4	-3
		DAY 50	25MAR2003	50	88	126	80	91	135	88	3	9	8
		DAY 57	31MAR2003	56	84	134	80	85	130	76	1	-4	-4
		FINAL		56	84	134	80	85	130	76	1	-4	-4
	E0023025	SCREEN	01MAY2003	-14	100	126	65	96	120	57	-4	-6	-8
		DAY 1	15MAY2003	1	72	115	60	76	114	64	4	-1	4
		BASELINE			72	115	60	76	114	64	4	-1	4
		DAY 8	22MAY2003	8	80	126	73	88	120	70	8	-6	-3
		DAY 15	29MAY2003	15	85	132	79	105	146	93	20	14	14
		DAY 22	05JUN2003	22	92	117	58	119	140	92	27	23	34
		DAY 29	12JUN2003	29	92	120	60	90	124	70	-2	4	10
		DAY 36	19JUN2003	36	97	119	79	90	118	76	-7	-1	-3
		DAY 43	27JUN2003	44	96	116	72	96	110	72	0	-6	0
		DAY 50	03JUL2003	50	80	110	82	84	120	80	4	10	-2
		DAY 57	10JUL2003	57	72	103	68	76	100	65	4	-3	-3
		FINAL		57	72	103	68	76	100	65	4	-3	-3
	E0023039	SCREEN	24JUN2003	-7	88	121	80	94	136	87	6	15	7
		DAY 1	01JUL2003	1	60	120	79	81	108	73	21	-12	-6
		BASELINE			60	120	79	81	108	73	21	-12	-6
		DAY 8	08JUL2003	8	85	126	74	102	102	71	17	-24	-3
		DAY 15	15JUL2003	15	72	110	73	80	108	73	8	-2	0
		DAY 22	22JUL2003	22	86	100	72	96	103	67	10	3	-5
		DAY 29	29JUL2003	29	86	115	79	100	112	79	14	-3	0
		DAY 36	05AUG2003	36	93	109	76	131	111	74	38	2	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0023039	DAY 43	12AUG2003	43	77	101	70	109	109	71	32	8	1
		DAY 50	19AUG2003	50	104	90	65	139	120	82	35	30	17
		DAY 57	26AUG2003	57	89	115	82	117	114	75	28	-1	-7
		FINAL		57	89	115	82	117	114	75	28	-1	-7
	E0026002	SCREEN	05NOV2002	-7	77	116	73	70	129	84	-7	13	11
		DAY 1	12NOV2002	1	70	105	70	82	111	84	12	6	14
		BASELINE			70	105	70	82	111	84	12	6	14
		DAY 8	19NOV2002	8	86	131	81	93	132	80	7	1	-1
		DAY 15	26NOV2002	15	75	99	83	79	101	76	4	2	-7
		DAY 22	03DEC2002	22	85	143	87	89	123	77	4	-20	-10
		DAY 29	11DEC2002	30	75	146	93	78	129	85	3	-17	-8
		DAY 36	18DEC2002	37	75	132	85	75	121	76	0	-11	-9
		DAY 43	26DEC2002	45	74	154	89	75	111	81	1	-43	-8
		DAY 50	02JAN2003	52	75	135	86	74	100	67	-1	-35	-19
		DAY 57	09JAN2003	59	70	126	75	70	113	77	0	-13	2
		FINAL		59	70	126	75	70	113	77	0	-13	2
	E0026007	SCREEN	06JAN2003	-10	70	131	69	72	129	66	2	-2	-3
		DAY 1	16JAN2003	1	72	140	76	80	130	72	8	-10	-4
		BASELINE			72	140	76	80	130	72	8	-10	-4
		DAY 8	23JAN2003	8	82	114	66	90	112	60	8	-2	-6
		DAY 15	30JAN2003	15	77	127	79	92	104	64	15	-23	-15
		DAY 22	06FEB2003	22	90	154	83	96	115	68	6	-39	-15
		DAY 29	13FEB2003	29	80	132	73	86	126	94	6	-6	21
		DAY 36	19FEB2003	35	77	113	67	83	108	67	6	-5	0
		DAY 43	26FEB2003	42	90	117	74	96	115	68	6	-2	-6
		DAY 50	05MAR2003	49	81	135	63	97	143	76	16	8	13
		DAY 57	12MAR2003	56	92	116	70	91	123	67	-1	7	-3
		FINAL		56	92	116	70	91	123	67	-1	7	-3
	E0026013	SCREEN	05FEB2003	-8	80	139	73	80	134	74	0	-5	1
		DAY 1	13FEB2003	1	70	140	70	68	142	72	-2	2	2
		BASELINE			70	140	70	68	142	72	-2	2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	DAY 8	20FEB2003	8	88	129	71	91	132	80	3	3	9
		DAY 15	27FEB2003	15	94	136	75	104	132	79	10	-4	4
		DAY 22	06MAR2003	22	87	149	79	89	134	78	2	-15	-1
		DAY 29	13MAR2003	29	89	116	74	85	135	73	-4	19	-1
		DAY 36	20MAR2003	36	88	116	72	86	122	78	-2	6	6
		DAY 43	27MAR2003	43	98	126	80	98	132	71	0	6	-9
		DAY 50	03APR2003	50	80	130	70	82	136	72	2	6	2
		DAY 57	14APR2003	61	83	104	67	86	132	74	3	28	7
		FINAL		61	83	104	67	86	132	74	3	28	7
	E0028007	SCREEN	01OCT2002	-3	60	100	70	68	100	70	8	0	0
		DAY 1	04OCT2002	1	60	110	70	62	108	70	2	-2	0
		BASELINE			60	110	70	62	108	70	2	-2	0
		DAY 8	11OCT2002	8	64	110	60	68	110	60	4	0	0
		DAY 15	16OCT2002	13	52	90	50	58	98	58	6	8	8
		DAY 22	23OCT2002	20	70	98	60	70	102	60	0	4	0
		DAY 29	31OCT2002	28	80	90	54	88	94	58	8	4	4
		DAY 36	07NOV2002	35	56	128	78	58	114	68	2	-14	-10
		DAY 43	14NOV2002	42	56	104	58	60	104	56	4	0	-2
		FINAL		42	56	104	58	60	104	56	4	0	-2
	E0028023	SCREEN	14JAN2003	-7	72	114	78	74	106	90	2	-8	12
		DAY 1	21JAN2003	1	64	150	92	68	144	102	4	-6	10
		BASELINE			64	150	92	68	144	102	4	-6	10
		DAY 8	30JAN2003	10	52	188	128	56	188	112	4	0	-16
		DAY 15	04FEB2003	15	70	122	92	78	140	94	8	18	2
		DAY 22	11FEB2003	22	76	118	84	80	102	80	4	-16	-4
		DAY 29	17FEB2003	28	74	90	70	78	84	70	4	-6	0
		DAY 36	27FEB2003	38	68	112	70	70	104	62	2	-8	-8
		DAY 43	04MAR2003	43	72	100	60	76	72	62	4	-28	2
		DAY 57	27JUN2003	158									
		FINAL		158	72	100	60	76	72	62	4	-28	2
	E0028025	SCREEN	08JAN2003	-5	62	114	76	74	108	70	12	-6	-6

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	DAY 1	13JAN2003	1	60	106	78	72	94	72	12	-12	-6
		BASELINE			60	106	78	72	94	72	12	-12	-6
		DAY 8	17JAN2003	5	76	114	70	80	110	70	4	-4	0
		DAY 15	27JAN2003	15	56	120	86	76	124	90	20	4	4
		FINAL		15	56	120	86	76	124	90	20	4	4
	E0028033	SCREEN	18MAR2003	-9	66	108	72	76	102	68	10	-6	-4
		DAY 1	27MAR2003	1	76	106	62	84	102	60	8	-4	-2
		BASELINE			76	106	62	84	102	60	8	-4	-2
		DAY 8	03APR2003	8	78	112	72	104	108	78	26	-4	6
		DAY 15	10APR2003	15	98	118	68	146	98	68	48	-20	0
		DAY 22	17APR2003	22	80	114	78	100	110	72	20	-4	-6
		DAY 29	24APR2003	29	88	96	62	108	100	66	20	4	4
		DAY 36	01MAY2003	36	60	94	68	88	90	74	28	-4	6
		DAY 43	08MAY2003	43	84	120	70	100	116	68	16	-4	-2
		DAY 50	15MAY2003	50	84	108	68	108	104	62	24	-4	-6
		DAY 57	22MAY2003	57	76	112	72	100	108	74	24	-4	2
		FINAL		57	76	112	72	100	108	74	24	-4	2
	E0028035	SCREEN	27MAR2003	-7	60	118	82	68	110	80	8	-8	-2
		DAY 1	03APR2003	1	60	136	82	64	126	76	4	-10	-6
		BASELINE			60	136	82	64	126	76	4	-10	-6
		DAY 8	10APR2003	8	60	124	76	64	110	70	4	-14	-6
		DAY 15	17APR2003	15	68	134	88	84	120	82	16	-14	-6
		DAY 22	24APR2003	22	72	130	82	76	122	72	4	-8	-10
		DAY 29	01MAY2003	29	80	134	86	72	136	84	-8	2	-2
		DAY 36	08MAY2003	36	68	138	94	76	120	90	8	-18	-4
		DAY 50	22MAY2003	50	72	134	78	80	124	84	8	-10	6
		DAY 57	29MAY2003	57	76	144	86	80	136	82	4	-8	-4
		FINAL		57	76	144	86	80	136	82	4	-8	-4
	E0028037	SCREEN	04JUN2003	-9	68	130	70	72	130	82	4	0	12
		DAY 1	12JUN2003	-1	68	140	80	66	140	82	-2	0	2
		BASELINE			68	140	80	66	140	82	-2	0	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028037	DAY 8		20JUN2003	8	76	122	84	80	122	86	4	0	2
		DAY 15		25JUN2003	13	74	132	86	86	110	80	12	-22	-6
		DAY 15	*	01JUL2003	19	80	130	82	78	115	70	-2	-15	-12
		DAY 22		08JUL2003	26	74	136	86	80	132	86	6	-4	0
		DAY 36		16JUL2003	34	80	130	78	80	116	72	0	-14	-6
		DAY 43		23JUL2003	41	78	118	80	80	116	82	2	-2	2
		DAY 50		30JUL2003	48	84	118	86	84	122	86	0	4	0
		DAY 57		08AUG2003	57	80	120	80	78	120	70	-2	0	-10
		FINAL			57	80	120	80	78	120	70	-2	0	-10
	E0028039	SCREEN		02MAY2003	-7	72	120	82	92	118	76	20	-2	-6
		DAY 1		08MAY2003	-1	72	110	70	92	104	66	20	-6	-4
		BASELINE				72	110	70	92	104	66	20	-6	-4
		DAY 8		16MAY2003	8	88	118	72	100	120	74	12	2	2
		DAY 15		22MAY2003	14	84	108	72	100	104	70	16	-4	-2
		DAY 22		29MAY2003	21	92	110	76	106	104	76	14	-6	0
		DAY 29		05JUN2003	28	88	110	70	96	112	70	8	2	0
		FINAL			28	88	110	70	96	112	70	8	2	0
	E0028046	SCREEN		17JUN2003	-8	78	120	78	82	115	74	4	-5	-4
		DAY 1		25JUN2003	1	62	100	78	86	100	78	24	0	0
		BASELINE				62	100	78	86	100	78	24	0	0
	E0028048	SCREEN		11JUL2003	-6	64	98	60	66	98	70	2	0	10
		DAY 1		17JUL2003	1	64	96	58	76	92	62	12	-4	4
		BASELINE				64	96	58	76	92	62	12	-4	4
		DAY 8		24JUL2003	8	68	98	64	78	98	76	10	0	12
		DAY 15		31JUL2003	15	70	100	70	76	98	70	6	-2	0
		DAY 22		06AUG2003	21	68	90	58	80	90	64	12	0	6
		DAY 29		14AUG2003	29	58	86	58	72	94	58	14	8	0
		DAY 36		21AUG2003	36	64	92	64	84	98	78	20	6	14
		DAY 43		29AUG2003	44	68	115	60	88	110	62	20	-5	2
		DAY 57		09SEP2003	55	72	80	40	88	84	64	16	4	24
		FINAL			55	72	80	40	88	84	64	16	4	24

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0029008	SCREEN	09DEC2002	-7	64	96	56	80	98	56	16	2	0
		DAY 1	16DEC2002	1	68	96	58	72	92	60	4	-4	2
		BASELINE			68	96	58	72	92	60	4	-4	2
		DAY 8	23DEC2002	8	72	94	56	76	90	50	4	-4	-6
		FINAL		8	72	94	56	76	90	50	4	-4	-6
	E0029011	SCREEN	14JAN2003	-8	68	104	68	76	110	70	8	6	2
		DAY 1	21JAN2003	-1	80	120	70	76	126	76	-4	6	6
		BASELINE			80	120	70	76	126	76	-4	6	6
		DAY 8	28JAN2003	7	72	132	74	92	130	70	20	-2	-4
		DAY 15	04FEB2003	14	84	140	70	112	140	82	28	0	12
		DAY 22	13FEB2003	23	72	138	90	100	120	90	28	-18	0
		FINAL		23	72	138	90	100	120	90	28	-18	0
	E0029012	SCREEN	04FEB2003	-7	56	110	70	56	104	68	0	-6	-2
		DAY 1	11FEB2003	1	78	132	82	78	130	80	0	-2	-2
		BASELINE			78	132	82	78	130	80	0	-2	-2
		DAY 8	19FEB2003	9	64	128	80	72	122	70	8	-6	-10
		DAY 15	26FEB2003	16	72	126	72	78	122	70	6	-4	-2
		DAY 22	03MAR2003	21	84	126	90	88	124	80	4	-2	-10
		DAY 29	11MAR2003	29	80	112	68	80	118	74	0	6	6
		DAY 36	18MAR2003	36	80	126	64	88	122	72	8	-4	8
		FINAL		36	80	126	64	88	122	72	8	-4	8
	E0029015	SCREEN	11FEB2003	-13	80	116	68	88	112	64	8	-4	-4
		DAY 1	24FEB2003	1	100	140	80	96	132	80	-4	-8	0
		BASELINE			100	140	80	96	132	80	-4	-8	0
		DAY 8	03MAR2003	8	84	114	78	88	122	84	4	8	6
		DAY 15	11MAR2003	16	60	108	60	76	104	58	16	-4	-2
		FINAL		16	60	108	60	76	104	58	16	-4	-2
	E0029018	SCREEN	26FEB2003	-8	72	134	82	88	128	78	16	-6	-4
		DAY 1	06MAR2003	1	64	132	66	68	128	58	4	-4	-8
		BASELINE			64	132	66	68	128	58	4	-4	-8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	SCREEN	12FEB2003	-9	60	88	60	80	88	60	20	0	0
		DAY 1	21FEB2003	1	60	102	68	64	98	64	4	-4	-4
		BASELINE			60	102	68	64	98	64	4	-4	-4
		DAY 8	28FEB2003	8	60	106	68	68	100	66	8	-6	-2
		DAY 15	07MAR2003	15	60	104	72	72	100	68	12	-4	-4
		DAY 22	14MAR2003	22	68	108	70	80	108	70	12	0	0
		DAY 29	21MAR2003	29	72	108	70	80	104	78	8	-4	8
		DAY 36	27MAR2003	35	60	100	64	88	104	74	28	4	10
		DAY 43	04APR2003	43	60	100	62	72	100	64	12	0	2
		DAY 50	11APR2003	50	60	102	70	72	106	70	12	4	0
		DAY 57	22APR2003	61	60	100	74	84	104	70	24	4	-4
		FINAL		61	60	100	74	84	104	70	24	4	-4
	E0030020	SCREEN	13MAY2003	-16	68	134	62	80	128	78	12	-6	16
		DAY 1	29MAY2003	1	60	120	66	80	126	74	20	6	8
		BASELINE			60	120	66	80	126	74	20	6	8
		DAY 8	05JUN2003	8	72	130	70	88	130	76	16	0	6
		DAY 15	12JUN2003	15	80	120	76	88	120	80	8	0	4
		DAY 22	17JUN2003	20	60	128	90	80	124	90	20	-4	0
		DAY 29	24JUN2003	27	68	130	60	88	126	66	20	-4	6
		FINAL		27	68	130	60	88	126	66	20	-4	6
	E0030024	SCREEN	17JUN2003	-24	80	120	74	88	114	80	8	-6	6
		DAY 1	11JUL2003	1	60	112	74	78	108	74	18	-4	0
		BASELINE			60	112	74	78	108	74	18	-4	0
		DAY 8	18JUL2003	8	60	114	84	68	114	82	8	0	-2
		FINAL		8	60	114	84	68	114	82	8	0	-2
	E0030025	SCREEN	24JUN2003	-17	60	130	70	60	130	70	0	0	0
		DAY 1	11JUL2003	1	48	118	74	64	120	80	16	2	6
		BASELINE			48	118	74	64	120	80	16	2	6
		DAY 8	18JUL2003	8	60	118	80	64	120	84	4	2	4
		DAY 15	25JUL2003	15	56	112	84	64	118	84	8	6	0
		DAY 22	31JUL2003	21	60	114	78	64	110	80	4	-4	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030025	DAY 29	11AUG2003	32	68	118	86	72	112	88	4	-6	2
		DAY 36	19AUG2003	40	68	112	80	72	114	84	4	2	4
		FINAL		40	68	112	80	72	114	84	4	2	4
	E0031027	SCREEN	27MAY2003	-7	60	118	60	68	124	66	8	6	6
		DAY 1	03JUN2003	1	60	105	70	68	108	80	8	3	10
		BASELINE			60	105	70	68	108	80	8	3	10
		DAY 8	11JUN2003	9	74	118	70	76	118	72	2	0	2
		DAY 15	17JUN2003	15	64	108	70	70	114	72	6	6	2
		DAY 22	24JUN2003	22	76	128	62	80	130	64	4	2	2
		DAY 29	01JUL2003	29	70	120	62	66	128	70	-4	8	8
		DAY 36	09JUL2003	37	64	118	64	74	124	70	10	6	6
		DAY 43	15JUL2003	43	58	114	60	64	116	68	6	2	8
		DAY 50	22JUL2003	50	70	108	62	76	120	70	6	12	8
		DAY 57	29JUL2003	57	62	106	74	70	110	70	8	4	-4
		FINAL		57	62	106	74	70	110	70	8	4	-4
	E0031030	SCREEN	17JUN2003	-7	62	108	76	74	110	82	12	2	6
		DAY 1	24JUN2003	1	68	112	80	76	116	84	8	4	4
		BASELINE			68	112	80	76	116	84	8	4	4
		DAY 8	01JUL2003	8	68	126	78	76	120	84	8	-6	6
		DAY 15	08JUL2003	15	88	126	74	86	130	76	-2	4	2
		DAY 22	16JUL2003	23	60	112	82	70	120	84	10	8	2
		DAY 29	23JUL2003	30	68	119	76	76	120	80	8	1	4
		DAY 36	31JUL2003	38	66	112	80	74	124	86	8	12	6
		DAY 43	08AUG2003	46	64	114	76	74	118	82	10	4	6
		DAY 50	14AUG2003	52	60	111	72	64	114	76	4	3	4
		DAY 57	21AUG2003	59	64	114	72	70	120	74	6	6	2
		FINAL		59	64	114	72	70	120	74	6	6	2
	E0033012	SCREEN	05FEB2003	-5	68	122	80	76	118	80	8	-4	0
		DAY 1	10FEB2003	1	72	112	86	76	112	84	4	0	-2
		BASELINE			72	112	86	76	112	84	4	0	-2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	SCREEN		17MAR2003	-3	62	110	72	64	104	70	2	-6	-2
		DAY 1		20MAR2003	1	56	100	55	72	95	68	16	-5	13
		BASELINE				56	100	55	72	95	68	16	-5	13
		DAY 8		27MAR2003	8	64	110	65	76	126	80	12	16	15
		DAY 15		03APR2003	15	64	118	78	72	112	80	8	-6	2
		DAY 22		10APR2003	22	60	110	70	72	105	80	12	-5	10
		DAY 29		17APR2003	29	56	105	70	68	100	80	12	-5	10
		DAY 36		24APR2003	36	60	110	70	72	105	80	12	-5	10
		DAY 43		01MAY2003	43	60	110	70	76	100	80	16	-10	10
		DAY 50		08MAY2003	50	56	114	74	64	112	78	8	-2	4
		DAY 57		15MAY2003	57	64	120	75	72	110	80	8	-10	5
		FINAL			57	64	120	75	72	110	80	8	-10	5
	E0034004	SCREEN		11APR2003	-10	64	118	86	62	110	78	-2	-8	-8
		DAY 1		21APR2003	1	76	145	95	80	130	100	4	-15	5
		BASELINE				76	145	95	80	130	100	4	-15	5
		DAY 8		30APR2003	10	76	135	90	88	110	80	12	-25	-10
		DAY 15		05MAY2003	15	76	122	82	88	126	80	12	4	-2
		DAY 22		13MAY2003	23	92	128	88	96	124	82	4	-4	-6
		DAY 29		19MAY2003	29	96	128	86	100	122	78	4	-6	-8
		DAY 29	*	23MAY2003	33	92	135	75	108	130	80	16	-5	5
		DAY 43		02JUN2003	43	92	122	84	92	126	86	0	4	2
		DAY 50		09JUN2003	50	88	135	90	100	120	80	12	-15	-10
		DAY 57		16JUN2003	57	80	110	70	66	105	75	-14	-5	5
		FINAL			57	80	110	70	66	105	75	-14	-5	5
	E0035001	SCREEN		12NOV2002	-8	84	130	80	88	134	78	4	4	-2
		DAY 1		20NOV2002	1	88	128	76	76	134	80	-12	6	4
		BASELINE				88	128	76	76	134	80	-12	6	4
		DAY 8		27NOV2002	8	84	126	80	84	130	76	0	4	-4
		DAY 15		03DEC2002	14	82	122	76	88	126	84	6	4	8
		DAY 22		12DEC2002	23	82	120	80	86	122	80	4	2	0
		DAY 29		18DEC2002	29	82	122	80	88	128	86	6	6	6
		DAY 36		23DEC2002	34	80	122	82	84	124	84	4	2	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0035001	DAY 43	30DEC2002	41	78	130	84	82	132	88	4	2	4
		DAY 50	07JAN2003	49	80	130	90	88	132	90	8	2	0
		DAY 57	14JAN2003	56	86	128	74	89	132	80	3	4	6
		FINAL		56	86	128	74	89	132	80	3	4	6
	E0035006	SCREEN	03DEC2002	-9	82	108	70	88	110	74	6	2	4
		DAY 1	12DEC2002	1	80	110	72	84	110	78	4	0	6
		BASELINE			80	110	72	84	110	78	4	0	6
		DAY 8	19DEC2002	8	66	116	84	74	118	88	8	2	4
		DAY 15	26DEC2002	15	72	114	78	78	116	82	6	2	4
		DAY 22	02JAN2003	22	70	112	72	78	116	76	8	4	4
		DAY 29	09JAN2003	29	76	112	74	80	114	70	4	2	-4
		DAY 36	16JAN2003	36	80	112	62	82	112	76	2	0	14
		DAY 43	24JAN2003	44	84	112	70	88	114	74	4	2	4
		DAY 50	30JAN2003	50	80	112	70	88	112	78	8	0	8
		DAY 57	06FEB2003	57	80	112	70	82	114	76	2	2	6
		FINAL		57	80	112	70	82	114	76	2	2	6
	E0035021	SCREEN	18APR2003	-7	70	98	62	76	100	68	6	2	6
		DAY 1	25APR2003	1	76	100	68	82	102	72	6	2	4
		BASELINE			76	100	68	82	102	72	6	2	4
		DAY 8	01MAY2003	7	80	100	66	84	104	68	4	4	2
		DAY 15	09MAY2003	15	78	100	68	82	102	72	4	2	4
		DAY 22	15MAY2003	21	76	100	62	80	100	70	4	0	8
		DAY 29	23MAY2003	29	80	102	66	84	104	70	4	2	4
		DAY 36	30MAY2003	36	82	104	68	88	108	74	6	4	6
		DAY 43	09JUN2003	46	82	106	72	86	110	74	4	4	2
		DAY 50	13JUN2003	50	80	110	74	88	112	72	8	2	-2
		DAY 57	20JUN2003	57	74	100	82	76	102	80	2	2	-2
		FINAL		57	74	100	82	76	102	80	2	2	-2
	E0036002	SCREEN	10JUN2003	-7	64	102	64	69	111	69	5	9	5
		DAY 1	17JUN2003	1	71	100	66	92	127	74	21	27	8
		BASELINE			71	100	66	92	127	74	21	27	8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	DAY 8	24JUN2003	8	68	114	75	93	104	77	25	-10	2
		DAY 15	30JUN2003	14	92	115	76	108	115	74	16	0	-2
		DAY 22	08JUL2003	22	90	108	69	105	113	75	15	5	6
		DAY 29	14JUL2003	28	96	121	74	105	110	70	9	-11	-4
		FINAL		28	96	121	74	105	110	70	9	-11	-4
	E0036006	SCREEN	24JUN2003	-9	89	127	79	103	128	91	14	1	12
		DAY 1	03JUL2003	1	104	124	80	121	133	88	17	9	8
		BASELINE			104	124	80	121	133	88	17	9	8
		DAY 8	10JUL2003	8	91	128	80	98	139	93	7	11	13
		DAY 15	18JUL2003	16	120	135	84	104	136	88	-16	1	4
		DAY 22	25JUL2003	23	112	135	92	125	137	97	13	2	5
		DAY 29	31JUL2003	29	113	131	86	128	131	87	15	0	1
		DAY 36	07AUG2003	36	98	131	84	120	129	90	22	-2	6
		DAY 43	13AUG2003	42	96	139	89	107	132	94	11	-7	5
		DAY 50	20AUG2003	49	111	138	83	128	139	85	17	1	2
		DAY 57	27AUG2003	56	96	129	86	116	131	87	20	2	1
		FINAL		56	96	129	86	116	131	87	20	2	1
	E0036007	SCREEN	26JUN2003	-7	88	122	86	89	126	89	1	4	3
		DAY 1	03JUL2003	1	78	127	86	93	116	82	15	-11	-4
		BASELINE			78	127	86	93	116	82	15	-11	-4
		DAY 8	08JUL2003	6	109	130	86	113	132	82	4	2	-4
		DAY 15	18JUL2003	16	79	123	82	90	123	88	11	0	6
		FINAL		16	79	123	82	90	123	88	11	0	6
	E0037009	SCREEN	09MAY2003	-7	72	120	80	72	120	80	0	0	0
		DAY 1	16MAY2003	1	84	122	82	86	122	80	2	0	-2
		BASELINE			84	122	82	86	122	80	2	0	-2
		DAY 8	23MAY2003	8	80	130	80	80	130	80	0	0	0
		DAY 15	29MAY2003	14	72	126	82	74	124	84	2	-2	2
		DAY 22	05JUN2003	21	78	124	84	76	120	82	-2	-4	-2
		DAY 29	12JUN2003	28	78	118	84	80	122	82	2	4	-2
		DAY 36	19JUN2003	35	76	122	68	76	120	70	0	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0037009	DAY 43	26JUN2003	42	78	128	86	78	120	90	0	-8	4
		DAY 50	03JUL2003	49	82	130	86	80	130	84	-2	0	-2
		DAY 57	10JUL2003	56	88	130	86	88	130	85	0	0	-1
		FINAL		56	88	130	86	88	130	85	0	0	-1
	E0039011	SCREEN	16DEC2002	-17	80	142	94	84	144	96	4	2	2
		DAY 1	02JAN2003	1	72	144	88	72	138	100	0	-6	12
		BASELINE			72	144	88	72	138	100	0	-6	12
		DAY 8	09JAN2003	8	64	146	96	72	142	100	8	-4	4
		DAY 15	16JAN2003	15	64	136	86	67	140	100	3	4	14
		DAY 22	23JAN2003	22	78	124	90	79	122	86	1	-2	-4
		DAY 29	03FEB2003	33	80	134	86	80	132	88	0	-2	2
		DAY 36	06FEB2003	36	76	136	86	80	122	92	4	-14	6
		DAY 43	13FEB2003	43	84	120	88	82	132	92	-2	12	4
		DAY 50	19FEB2003	49	84	128	80	86	128	88	2	0	8
		FINAL		49	84	128	80	86	128	88	2	0	8
	E0039018	SCREEN	14JAN2003	-9	76	128	76	80	124	82	4	-4	6
		DAY 1	23JAN2003	1	64	124	76	72	126	84	8	2	8
		BASELINE			64	124	76	72	126	84	8	2	8
		DAY 8	30JAN2003	8	72	136	82	76	122	76	4	-14	-6
		DAY 15	06FEB2003	15	70	120	80	72	130	90	2	10	10
		DAY 22	13FEB2003	22	78	114	76	74	126	88	-4	12	12
		DAY 29	20FEB2003	29	79	122	76	75	126	80	-4	4	4
		FINAL		29	79	122	76	75	126	80	-4	4	4
	E0039026	SCREEN	26FEB2003	-9	72	118	84	70	112	80	-2	-6	-4
		DAY 1	07MAR2003	1	72	104	70	73	102	80	1	-2	10
		BASELINE			72	104	70	73	102	80	1	-2	10
		DAY 8	14MAR2003	8	72	114	76	76	118	86	4	4	10
		DAY 15	19MAR2003	13	64	116	70	80	108	80	16	-8	10
		DAY 22	28MAR2003	22	86	114	78	82	118	80	-4	4	2
		DAY 29	04APR2003	29	64	102	64	60	108	80	-4	6	16
		DAY 36	11APR2003	36	82	98	70	78	92	70	-4	-6	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	DAY 43	18APR2003	43	72	116	78	68	118	82	-4	2	4
		DAY 50	25APR2003	50	60	116	86	64	120	90	4	4	4
		DAY 57	01MAY2003	56	60	102	76	60	108	80	0	6	4
		FINAL		56	60	102	76	60	108	80	0	6	4
	E0039028	SCREEN	03MAR2003	-21	70	140	90	78	142	92	8	2	2
		DAY 1	24MAR2003	1	76	134	98	80	150	100	4	16	2
		BASELINE			76	134	98	80	150	100	4	16	2
		DAY 8	31MAR2003	8	86	144	96	100	148	100	14	4	4
		DAY 15	07APR2003	15	80	134	96	96	148	98	16	14	2
		DAY 22	14APR2003	22	84	138	100	92	150	104	8	12	4
		DAY 29	21APR2003	29	80	130	90	92	140	98	12	10	8
		DAY 36	28APR2003	36	80	130	88	72	148	102	-8	18	14
		DAY 43	05MAY2003	43	80	142	100	80	138	102	0	-4	2
		DAY 50	16MAY2003	54	96	136	104	92	144	118	-4	8	14
		FINAL		54	96	136	104	92	144	118	-4	8	14
	E0039032	SCREEN	07MAR2003	-7	60	116	70	76	118	80	16	2	10
		DAY 1	14MAR2003	1	85	136	70	88	130	80	3	-6	10
		BASELINE			85	136	70	88	130	80	3	-6	10
		DAY 8	19MAR2003	6	73	118	80	75	110	90	2	-8	10
		DAY 15	28MAR2003	15	74	128	90	80	134	90	6	6	0
		FINAL		15	74	128	90	80	134	90	6	6	0
	E0039034	SCREEN	12MAR2003	-7	76	120	82	76	122	82	0	2	0
		DAY 1	19MAR2003	1	76	118	76	88	104	70	12	-14	-6
		BASELINE			76	118	76	88	104	70	12	-14	-6
		DAY 8	26MAR2003	8	68	122	82	70	118	78	2	-4	-4
		DAY 15	02APR2003	15	70	128	74	70	126	72	0	-2	-2
		DAY 22	09APR2003	22	68	122	78	72	118	80	4	-4	2
		DAY 29	16APR2003	29	82	116	68	92	118	80	10	2	12
		DAY 36	24APR2003	37	70	106	70	76	110	72	6	4	2
		DAY 43	30APR2003	43	80	126	76	76	124	84	-4	-2	8
		DAY 50	09MAY2003	52	80	120	78	88	120	82	8	0	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	DAY 57	14MAY2003	57	88	128	84	80	116	72	-8	-12	-12
		FINAL		57	88	128	84	80	116	72	-8	-12	-12
	E0039042	SCREEN	24APR2003	-13	60	132	80	64	138	86	4	6	6
		DAY 1	07MAY2003	1	66	124	84	64	126	90	-2	2	6
		BASELINE			66	124	84	64	126	90	-2	2	6
		DAY 8	14MAY2003	8	76	136	88	84	130	90	8	-6	2
		DAY 15	21MAY2003	15	80	108	70	84	116	76	4	8	6
		DAY 22	28MAY2003	22	68	120	84	73	132	90	5	12	6
		DAY 29	05JUN2003	30	84	126	86	84	132	80	0	6	-6
		DAY 36	11JUN2003	36	82	130	90	80	128	96	-2	-2	6
		DAY 43	18JUN2003	43	88	120	80	92	130	90	4	10	10
		DAY 50	25JUN2003	50	84	124	78	88	120	90	4	-4	12
		DAY 57	02JUL2003	57	75	112	60	76	108	70	1	-4	10
		FINAL		57	75	112	60	76	108	70	1	-4	10
	E0041004	SCREEN	22JAN2003	-8	64	118	88	80	114	86	16	-4	-2
		DAY 1	30JAN2003	1	78	110	80	80	108	84	2	-2	4
		BASELINE			78	110	80	80	108	84	2	-2	4
		DAY 8	10FEB2003	12	76	138	92	88	120	90	12	-18	-2
		DAY 15	14FEB2003	16	80	110	78	88	108	78	8	-2	0
		DAY 22	20FEB2003	22	100	136	90	100	130	90	0	-6	0
		DAY 29	27FEB2003	29	92	100	78	92	110	70	0	10	-8
		DAY 36	07MAR2003	37	80	108	68	80	100	60	0	-8	-8
		DAY 43	14MAR2003	44	72	120	82	78	130	88	6	10	6
		DAY 50	21MAR2003	51	78	100	68	76	110	80	-2	10	12
		DAY 57	31MAR2003	61	76	110	68	84	110	70	8	0	2
		FINAL		61	76	110	68	84	110	70	8	0	2
	E0041009	SCREEN	22APR2003	-9	62	110	58	74	112	80	12	2	22
		DAY 1	01MAY2003	1	66	112	70	70	112	76	4	0	6
		BASELINE			66	112	70	70	112	76	4	0	6
		DAY 8	08MAY2003	8	78	120	80	80	122	78	2	2	-2
		DAY 15	15MAY2003	15	84	122	84	80	124	80	-4	2	-4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0041009	DAY 22	22MAY2003	22	74	122	82	76	120	80	2	-2	-2
		DAY 36	03JUN2003	34	72	124	82	74	122	80	2	-2	-2
		DAY 43	16JUN2003	47	80	110	80	90	122	74	10	12	-6
		FINAL		47	80	110	80	90	122	74	10	12	-6
	E0042002	SCREEN	02JUL2003	-7	64	130	90	64	120	90	0	-10	0
		DAY 1	09JUL2003	1	76	110	80	72	120	80	-4	10	0
		BASELINE			76	110	80	72	120	80	-4	10	0
		DAY 8	15JUL2003	7	68	100	70	64	102	70	-4	2	0
		DAY 15	22JUL2003	14	76	110	80	80	100	80	4	-10	0
		DAY 22	29JUL2003	21	80	110	80	84	100	78	4	-10	-2
		DAY 29	05AUG2003	28	76	110	70	76	110	80	0	0	10
		DAY 36	12AUG2003	35	76	120	70	84	110	80	8	-10	10
		DAY 43	19AUG2003	42	76	120	80	88	110	90	12	-10	10
		DAY 50	26AUG2003	49	76	110	70	76	102	70	0	-8	0
		DAY 57	02SEP2003	56	72	100	70	80	102	80	8	2	10
		FINAL		56	72	100	70	80	102	80	8	2	10
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	SCREEN	23JUN2003	-18	60	130	80	60	130	80	0	0	0
		DAY 1	11JUL2003	1	60	120	70	62	125	75	2	5	5
		BASELINE			60	120	70	62	125	75	2	5	5
		DAY 8	18JUL2003	8	62	104	78	62	104	80	0	0	2
		FINAL		8	62	104	78	62	104	80	0	0	2
	E0003002	SCREEN	22OCT2002	-7	60	130	90	68	142	80	8	12	-10
		DAY 1	29OCT2002	1	88	120	90	88	120	90	0	0	0
		BASELINE			88	120	90	88	120	90	0	0	0
		DAY 15	14NOV2002	17	84	130	80	88	140	90	4	10	10
		DAY 22	19NOV2002	22	96	130	90	94	130	88	-2	0	-2
		DAY 29	26NOV2002	29	80	140	84	84	130	82	4	-10	-2
		DAY 36	03DEC2002	36	84	120	80	88	124	84	4	4	4
		DAY 43	10DEC2002	43	84	130	80	96	122	90	12	-8	10
		DAY 50	17DEC2002	50	76	114	84	88	94	64	12	-20	-20

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 57	23DEC2002	56	74	118	70	70	120	78	-4	2	8
		FINAL		56	74	118	70	70	120	78	-4	2	8
	E0005031	SCREEN	26MAR2003	-7	64	100	60	64	98	60	0	-2	0
		DAY 1	02APR2003	1	84	98	62	84	100	64	0	2	2
		BASELINE			84	98	62	84	100	64	0	2	2
		DAY 8	09APR2003	8	84	100	60	84	98	60	0	-2	0
		DAY 15	16APR2003	15	76	96	68	80	94	68	4	-2	0
		DAY 22	24APR2003	23	76	110	70	76	100	70	0	-10	0
		DAY 29	01MAY2003	30	66	110	66	68	115	68	2	5	2
		DAY 36	07MAY2003	36	68	100	60	72	104	66	4	4	6
		DAY 43	14MAY2003	43	80	98	60	80	110	68	0	12	8
		FINAL		43	80	98	60	80	110	68	0	12	8
	E0005033	SCREEN	08APR2003	-8	64	108	64	76	100	60	12	-8	-4
		DAY 1	15APR2003	-1	68	108	70	68	108	70	0	0	0
		BASELINE			68	108	70	68	108	70	0	0	0
		DAY 8	22APR2003	7	72	108	68	76	112	74	4	4	6
		DAY 15	30APR2003	15	68	116	70	72	114	74	4	-2	4
		DAY 22	06MAY2003	21	64	96	64	68	98	66	4	2	2
		FINAL		21	64	96	64	68	98	66	4	2	2
	E0005038	SCREEN	05MAY2003	-9	84	116	76	80	114	76	-4	-2	0
		DAY 1	14MAY2003	1	76	126	80	72	120	80	-4	-6	0
		BASELINE			76	126	80	72	120	80	-4	-6	0
		DAY 8	22MAY2003	9	80	110	70	88	118	80	8	8	10
		DAY 15	28MAY2003	15	88	106	70	92	96	64	4	-10	-6
		DAY 22	05JUN2003	23	72	120	80	88	120	78	16	0	-2
		FINAL		23	72	120	80	88	120	78	16	0	-2
	E0007009	SCREEN	09APR2003	-8	70	120	70	74	116	66	4	-4	-4
		DAY 1	17APR2003	1	72	118	64	74	114	68	2	-4	4
		BASELINE			72	118	64	74	114	68	2	-4	4
		DAY 8	24APR2003	8	72	118	70	76	122	70	4	4	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0007009	DAY 8	*	28APR2003	12	76	120	70	72	118	66	-4	-2	-4
		FINAL			12	76	120	70	72	118	66	-4	-2	-4
	E0009010	SCREEN		27FEB2003	-14	60	120	70	90	130	100	30	10	30
		DAY 1		13MAR2003	1	74	120	78	78	120	82	4	0	4
		BASELINE				74	120	78	78	120	82	4	0	4
		DAY 8		20MAR2003	8	80	130	92	82	130	90	2	0	-2
		DAY 15		26MAR2003	14	100	122	70	88	118	72	-12	-4	2
		DAY 22		02APR2003	21	88	120	74	86	122	76	-2	2	2
		FINAL			21	88	120	74	86	122	76	-2	2	2
	E0009011	SCREEN		28APR2003	-8	80	130	76	80	120	82	0	-10	6
		DAY 1		06MAY2003	1	74	110	60	76	116	64	2	6	4
		BASELINE				74	110	60	76	116	64	2	6	4
		DAY 8		12MAY2003	7	88	130	70	90	126	70	2	-4	0
		DAY 15		19MAY2003	14	86	110	70	90	110	74	4	0	4
		DAY 22		27MAY2003	22	100	120	68	98	118	70	-2	-2	2
		DAY 29		03JUN2003	29	76	100	60	76	100	60	0	0	0
		DAY 36		10JUN2003	36	86	100	60	90	90	60	4	-10	0
		DAY 43		17JUN2003	43	80	104	62	78	102	64	-2	-2	2
		DAY 50		24JUN2003	50	60	104	66	60	102	64	0	-2	-2
		DAY 57		03JUL2003	59	60	90	60	62	98	64	2	8	4
		FINAL			59	60	90	60	62	98	64	2	8	4
	E0010005	SCREEN		10DEC2002	-8	94	140	86	100	132	90	6	-8	4
		DAY 1		18DEC2002	1	100	174	86	101	160	100	1	-14	14
		BASELINE				100	174	86	101	160	100	1	-14	14
	E0011016	SCREEN		14APR2003	-7	72	132	88	84	128	86	12	-4	-2
		DAY 1		21APR2003	1	72	138	88	88	136	80	16	-2	-8
		BASELINE				72	138	88	88	136	80	16	-2	-8
		DAY 8		28APR2003	8	84	132	86	98	128	88	14	-4	2
		DAY 15		05MAY2003	15	92	138	88	92	136	88	0	-2	0
		DAY 22		12MAY2003	22	92	124	88	92	120	86	0	-4	-2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	DAY 29		19MAY2003	29	92	130	88	98	128	86	6	-2	-2
		DAY 36		27MAY2003	37	90	128	84	94	130	88	4	2	4
		DAY 43		02JUN2003	43	88	140	88	92	134	88	4	-6	0
		DAY 50		09JUN2003	50	92	136	88	96	138	88	4	2	0
		DAY 57		16JUN2003	57	92	132	88	96	130	86	4	-2	-2
		FINAL			57	92	132	88	96	130	86	4	-2	-2
	E0011020	SCREEN		01MAY2003	-7	64	128	84	72	126	86	8	-2	2
		DAY 1		08MAY2003	1	76	128	82	84	120	84	8	-8	2
		BASELINE				76	128	82	84	120	84	8	-8	2
		DAY 8		15MAY2003	8	78	128	84	84	130	84	6	2	0
		FINAL			8	78	128	84	84	130	84	6	2	0
	E0018002	SCREEN		15NOV2002	-14	84	128	88	80	126	84	-4	-2	-4
		DAY 1		29NOV2002	1	80	126	84	84	124	82	4	-2	-2
		BASELINE				80	126	84	84	124	82	4	-2	-2
		DAY 8		04DEC2002	6	72	122	72	78	124	74	6	2	2
		DAY 15		11DEC2002	13	76	124	80	78	124	82	2	0	2
		DAY 22		18DEC2002	20	74	136	82	76	134	82	2	-2	0
		DAY 22	*	24DEC2002	26	72	126	82	74	128	82	2	2	0
		DAY 29		30DEC2002	32	76	134	78	76	136	78	0	2	0
		DAY 43		08JAN2003	41	82	124	82	78	128	80	-4	4	-2
		DAY 50		15JAN2003	48	74	136	80	78	138	82	4	2	2
		DAY 57		22JAN2003	55	72	140	86	76	136	84	4	-4	-2
		FINAL			55	72	140	86	76	136	84	4	-4	-2
	E0018003	SCREEN		19NOV2002	-7	72	112	80	80	116	80	8	4	0
		DAY 1		26NOV2002	1	80	118	70	84	122	74	4	4	4
		BASELINE				80	118	70	84	122	74	4	4	4
		DAY 8		03DEC2002	8	64	124	78	76	126	80	12	2	2
		DAY 15		10DEC2002	15	72	128	76	74	130	80	2	2	4
		FINAL			15	72	128	76	74	130	80	2	2	4
	E0018013	SCREEN		17JAN2003	-7	64	122	72	68	122	74	4	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	DAY 1	24JAN2003	1	76	124	74	88	126	76	12	2	2
		BASELINE			76	124	74	88	126	76	12	2	2
		DAY 8	31JAN2003	8	64	130	70	72	134	72	8	4	2
		FINAL		8	64	130	70	72	134	72	8	4	2
	E0019002	SCREEN	29OCT2002	-14	68	122	70	72	126	86	4	4	16
		DAY 1	12NOV2002	1	76	110	75	80	110	75	4	0	0
		BASELINE			76	110	75	80	110	75	4	0	0
		DAY 8	19NOV2002	8	84	125	65	80	120	60	-4	-5	-5
		FINAL		8	84	125	65	80	120	60	-4	-5	-5
	E0019008	SCREEN	06NOV2002	-15	56	100	70	84	110	72	28	10	2
		DAY 1	21NOV2002	1	72	110	82	76	98	72	4	-12	-10
		BASELINE			72	110	82	76	98	72	4	-12	-10
		DAY 8	27NOV2002	7	92	110	85	100	125	80	8	15	-5
		DAY 15	05DEC2002	15	76	110	75	84	112	80	8	2	5
		DAY 22	12DEC2002	22	84	112	80	100	102	68	16	-10	-12
		DAY 29	19DEC2002	29	72	102	68	96	100	78	24	-2	10
		FINAL		29	72	102	68	96	100	78	24	-2	10
	E0019009	SCREEN	06NOV2002	-8	72	105	65	72	110	70	0	5	5
		DAY 1	14NOV2002	1	80	110	68	72	110	62	-8	0	-6
		BASELINE			80	110	68	72	110	62	-8	0	-6
		DAY 8	21NOV2002	8	80	98	68	78	98	60	-2	0	-8
		DAY 15	27NOV2002	14	80	110	76	82	112	82	2	2	6
		DAY 22	05DEC2002	22	72	108	70	78	108	70	6	0	0
		DAY 29	10DEC2002	27	90	102	62	96	100	64	6	-2	2
		FINAL		27	90	102	62	96	100	64	6	-2	2
	E0019016	SCREEN	30DEC2002	-7	84	120	84	86	110	90	2	-10	6
		DAY 1	06JAN2003	1	92	124	80	88	120	80	-4	-4	0
		BASELINE			92	124	80	88	120	80	-4	-4	0
		DAY 8	13JAN2003	8	88	120	78	96	118	80	8	-2	2
		DAY 15	20JAN2003	15	84	110	75	80	110	78	-4	0	3

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	DAY 22	27JAN2003	22	84	115	80	80	120	80	-4	5	0
		DAY 29	03FEB2003	29	88	120	78	92	124	80	4	4	2
		DAY 36	10FEB2003	36	96	115	70	100	118	70	4	3	0
		DAY 43	17FEB2003	43	84	120	85	86	120	80	2	0	-5
		DAY 50	27FEB2003	53	96	120	82	104	120	86	8	0	4
		DAY 57	03MAR2003	57	96	118	80	96	120	80	0	2	0
		FINAL		57	96	118	80	96	120	80	0	2	0
	E0019020	SCREEN	16JAN2003	-7	80	108	72	88	106	68	8	-2	-4
		DAY 1	23JAN2003	1	80	110	70	80	105	65	0	-5	-5
		BASELINE			80	110	70	80	105	65	0	-5	-5
		DAY 8	30JAN2003	8	88	120	78	92	122	82	4	2	4
		DAY 15	06FEB2003	15	68	122	80	76	122	85	8	0	5
		DAY 22	13FEB2003	22	76	120	75	88	125	80	12	5	5
		DAY 29	20FEB2003	29	76	108	70	88	115	80	12	7	10
		DAY 36	27FEB2003	36	84	110	70	92	115	70	8	5	0
		DAY 43	06MAR2003	43	80	100	76	96	110	78	16	10	2
		DAY 50	13MAR2003	50	92	108	60	96	100	72	4	-8	12
		DAY 57	27MAR2003	64	86	112	68	84	120	70	-2	8	2
		FINAL		64	86	112	68	84	120	70	-2	8	2
	E0019021	SCREEN	16JAN2003	-14	68	125	80	72	120	80	4	-5	0
		DAY 1	30JAN2003	1	72	130	85	76	130	88	4	0	3
		BASELINE			72	130	85	76	130	88	4	0	3
		DAY 8	06FEB2003	8	68	130	85	72	130	85	4	0	0
		DAY 29	03MAR2003	33	76	126	86	76	124	82	0	-2	-4
		FINAL		33	76	126	86	76	124	82	0	-2	-4
	E0019024	SCREEN	23JAN2003	-7	80	120	80	76	120	78	-4	0	-2
		DAY 1	30JAN2003	1	80	120	82	88	115	75	8	-5	-7
		BASELINE			80	120	82	88	115	75	8	-5	-7
		DAY 8	06FEB2003	8	80	130	75	88	125	80	8	-5	5
		FINAL		8	80	130	75	88	125	80	8	-5	5

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0019031	SCREEN	06MAR2003	-7	56	100	80	68	94	76	12	-6	-4
		DAY 1	13MAR2003	1	60	118	80	76	110	88	16	-8	8
		BASELINE			60	118	80	76	110	88	16	-8	8
		DAY 15	25MAR2003	13	66	120	68	74	118	76	8	-2	8
		FINAL		13	66	120	68	74	118	76	8	-2	8
	E0019035	SCREEN	11MAR2003	-7	80	126	86	88	122	80	8	-4	-6
		DAY 1	18MAR2003	1	82	134	80	86	126	78	4	-8	-2
		BASELINE			82	134	80	86	126	78	4	-8	-2
		DAY 8	27MAR2003	10	78	140	74	80	130	74	2	-10	0
		DAY 15	03APR2003	17	84	130	70	104	130	75	20	0	5
		DAY 22	10APR2003	24	88	130	90	92	130	80	4	0	-10
		DAY 29	17APR2003	31	88	135	85	96	135	90	8	0	5
		FINAL		31	88	135	85	96	135	90	8	0	5
	E0019040	SCREEN	08MAY2003	-12	92	130	82	94	150	90	2	20	8
		DAY 1	20MAY2003	1	96	130	90	100	140	90	4	10	0
		BASELINE			96	130	90	100	140	90	4	10	0
		DAY 8	29MAY2003	10	96	122	88	100	130	88	4	8	0
		DAY 15	05JUN2003	17	116	124	80	116	130	88	0	6	8
		DAY 22	12JUN2003	24	96	128	90	112	118	82	16	-10	-8
		DAY 29	18JUN2003	30	98	142	82	104	124	88	6	-18	6
		DAY 36	26JUN2003	38	100	122	82	104	124	90	4	2	8
		DAY 43	03JUL2003	45	96	138	92	104	136	94	8	-2	2
		DAY 50	10JUL2003	52	100	132	88	108	130	90	8	-2	2
		DAY 57	17JUL2003	59	92	122	80	98	128	85	6	6	5
		FINAL		59	92	122	80	98	128	85	6	6	5
	E0019042	SCREEN	28MAY2003	-7	72	118	70	80	130	80	8	12	10
		DAY 1	04JUN2003	1	66	124	76	92	118	82	26	-6	6
		BASELINE			66	124	76	92	118	82	26	-6	6
		DAY 8	12JUN2003	9	76	122	62	96	120	62	20	-2	0
		DAY 15	19JUN2003	16	66	118	62	80	122	74	14	4	12
		FINAL		16	66	118	62	80	122	74	14	4	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0019045	SCREEN	19JUN2003	-7	64	108	64	64	110	72	0	2	8
		DAY 1	26JUN2003	1	72	106	66	80	112	78	8	6	12
		BASELINE			72	106	66	80	112	78	8	6	12
		DAY 8	03JUL2003	8	66	110	70	76	122	82	10	12	12
		DAY 22	16JUL2003	21	66	115	80	70	110	80	4	-5	0
		FINAL		21	66	115	80	70	110	80	4	-5	0
	E0020024	SCREEN	12JUN2003	-11	76	118	64	80	110	68	4	-8	4
		DAY 1	23JUN2003	1	52	110	70	54	110	70	2	0	0
		BASELINE			52	110	70	54	110	70	2	0	0
		DAY 8	30JUN2003	8	90	110	72	98	108	72	8	-2	0
		DAY 15	07JUL2003	15	74	112	70	88	104	78	14	-8	8
		DAY 22	15JUL2003	23	98	112	62	104	106	64	6	-6	2
		DAY 29	21JUL2003	29	92	110	80	90	112	80	-2	2	0
		DAY 36	28JUL2003	36	102	118	66	98	100	70	-4	-18	4
		DAY 43	04AUG2003	43	108	112	68	116	116	68	8	4	0
		DAY 50	12AUG2003	51	86	106	70	86	120	78	0	14	8
		DAY 57	20AUG2003	59	80	118	76	88	120	74	8	2	-2
		FINAL		59	80	118	76	88	120	74	8	2	-2
	E0022044	SCREEN	11MAR2003	-7	74	116	82	76	110	72	2	-6	-10
		DAY 1	18MAR2003	1	80	102	70	84	104	76	4	2	6
		BASELINE			80	102	70	84	104	76	4	2	6
		DAY 8	25MAR2003	8	84	100	68	96	98	70	12	-2	2
		DAY 15	01APR2003	15	92	110	80	100	112	90	8	2	10
		DAY 22	08APR2003	22	88	108	64	100	118	70	12	10	6
		DAY 29	15APR2003	29	88	112	74	96	116	84	8	4	10
		DAY 36	22APR2003	36	100	122	88	120	112	88	20	-10	0
		DAY 43	29APR2003	43	104	122	78	116	102	82	12	-20	4
		DAY 50	06MAY2003	50	96	126	80	104	120	84	8	-6	4
		DAY 57	12MAY2003	56	88	130	92	84	132	94	-4	2	2
		FINAL		56	88	130	92	84	132	94	-4	2	2
	E0023007	SCREEN	07JAN2003	-7	68	110	76	80	112	78	12	2	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023007	DAY 1	14JAN2003	1	74	116	80	80	110	90	6	-6	10
		BASELINE			74	116	80	80	110	90	6	-6	10
		DAY 8	21JAN2003	8	80	110	82	80	112	80	0	2	-2
		DAY 15	28JAN2003	15	97	136	88	88	128	86	-9	-8	-2
		DAY 22	07FEB2003	25	97	140	95	88	130	86	-9	-10	-9
		DAY 29	11FEB2003	29	97	119	77	126	136	93	29	17	16
		DAY 36	18FEB2003	36	80	132	92	82	124	78	2	-8	-14
		DAY 43	25FEB2003	43	80	130	85	80	129	85	0	-1	0
		DAY 50	04MAR2003	50	76	133	94	76	145	83	0	12	-11
		DAY 57	11MAR2003	57	52	100	70	60	104	76	8	4	6
		FINAL		57	52	100	70	60	104	76	8	4	6
	E0023011	SCREEN	28JAN2003	-7	68	110	67	72	108	70	4	-2	3
		DAY 1	04FEB2003	1	58	118	72	58	120	70	0	2	-2
		BASELINE			58	118	72	58	120	70	0	2	-2
		DAY 8	11FEB2003	8	88	112	78	88	108	80	0	-4	2
		DAY 15	21FEB2003	18	80	104	78	80	108	82	0	4	4
		DAY 22	25FEB2003	22	77	127	80	87	148	101	10	21	21
		DAY 29	04MAR2003	29	70	126	78	80	140	80	10	14	2
		DAY 36	11MAR2003	36	64	124	74	84	128	70	20	4	-4
		DAY 43	18MAR2003	43	76	120	70	80	120	76	4	0	6
		DAY 50	27MAR2003	52	78	141	94	78	136	90	0	-5	-4
		DAY 57	01APR2003	57	89	114	76	90	121	79	1	7	3
		FINAL		57	89	114	76	90	121	79	1	7	3
	E0023014	SCREEN	14FEB2003	-7	109	138	93	96	136	92	-13	-2	-1
		DAY 1	21FEB2003	1	80	118	76	84	100	70	4	-18	-6
		BASELINE			80	118	76	84	100	70	4	-18	-6
		DAY 8	02MAR2003	10	84	116	74	88	100	74	4	-16	0
		DAY 15	06MAR2003	14	84	120	80	86	112	76	2	-8	-4
		DAY 22	18MAR2003	26	88	128	88	94	132	90	6	4	2
		DAY 29	25MAR2003	33	102	133	78	102	128	78	0	-5	0
		DAY 36	01APR2003	40	87	121	79	80	120	80	-7	-1	1
		DAY 50	09APR2003	48	92	109	72	92	112	70	0	3	-2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023014	DAY 50	*	15APR2003	54	92	118	71	92	118	71	0	0	0
		DAY 57		25APR2003	64	92	122	84	90	124	84	-2	2	0
		FINAL			64	92	122	84	90	124	84	-2	2	0
	E0023019	SCREEN		21MAR2003	-17	78	145	77	80	138	76	2	-7	-1
		DAY 1		07APR2003	1	100	127	87	123	141	98	23	14	11
		BASELINE				100	127	87	123	141	98	23	14	11
		DAY 8		15APR2003	9	95	134	78	123	154	89	28	20	11
		DAY 15		22APR2003	16	104	140	88	155	151	79	51	11	-9
		DAY 22		02MAY2003	26	72	117	79	99	144	90	27	27	11
		DAY 29		06MAY2003	30	95	126	88	117	130	80	22	4	-8
		DAY 36		13MAY2003	37	86	129	88	95	137	86	9	8	-2
		DAY 43		20MAY2003	44	84	132	86	107	137	88	23	5	2
		DAY 50		29MAY2003	53	97	121	79	113	147	79	16	26	0
		DAY 57		03JUN2003	58	93	129	90	95	131	92	2	2	2
		FINAL			58	93	129	90	95	131	92	2	2	2
	E0023022	SCREEN		10APR2003	-8	80	115	71	84	110	70	4	-5	-1
		DAY 1		18APR2003	1	64	114	67	119	120	80	55	6	13
		BASELINE				64	114	67	119	120	80	55	6	13
		DAY 8		25APR2003	8	88	108	80	92	106	76	4	-2	-4
		DAY 15		01MAY2003	14	100	126	65	93	105	57	-7	-21	-8
		DAY 22		08MAY2003	21	100	131	70	155	141	88	55	10	18
		DAY 29		15MAY2003	28	103	108	73	96	112	72	-7	4	-1
		DAY 36		22MAY2003	35	73	126	76	115	108	71	42	-18	-5
		DAY 43		30MAY2003	43	77	108	65	109	108	69	32	0	4
		DAY 50		06JUN2003	50	104	112	63	123	124	65	19	12	2
		DAY 57		12JUN2003	56	72	122	84	76	118	80	4	-4	-4
		FINAL			56	72	122	84	76	118	80	4	-4	-4
	E0023023	SCREEN		17APR2003	-8	84	89	65	88	91	67	4	2	2
		DAY 1		25APR2003	1	80	108	80	86	110	82	6	2	2
		BASELINE				80	108	80	86	110	82	6	2	2
		DAY 8		01MAY2003	7	89	110	68	86	104	53	-3	-6	-15

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	FINAL		7	89	110	68	86	104	53	-3	-6	-15
	E0023029	SCREEN	16MAY2003	-7	63	122	68	66	120	64	3	-2	-4
		DAY 1	23MAY2003	1	72	132	72	88	121	82	16	-11	10
		BASELINE			72	132	72	88	121	82	16	-11	10
	E0023031	SCREEN	22MAY2003	-33	85	148	95	104	159	103	19	11	8
		DAY 1	24JUN2003	1	90	136	87	94	140	93	4	4	6
		BASELINE			90	136	87	94	140	93	4	4	6
		DAY 8	01JUL2003	8	85	104	73	88	103	76	3	-1	3
		DAY 15	08JUL2003	15	90	148	94	98	140	90	8	-8	-4
		DAY 22	15JUL2003	22	74	111	75	86	132	87	12	21	12
		DAY 29	22JUL2003	29	85	131	88	88	130	86	3	-1	-2
		DAY 36	29JUL2003	36	89	140	90	94	148	92	5	8	2
		DAY 43	05AUG2003	43	99	150	90	96	156	99	-3	6	9
		DAY 50	12AUG2003	50	109	132	90	108	131	90	-1	-1	0
		DAY 57	19AUG2003	57	93	136	95	96	138	95	3	2	0
		FINAL		57	93	136	95	96	138	95	3	2	0
	E0023041	SCREEN	02JUL2003	-7	72	106	70	82	119	82	10	13	12
		DAY 1	09JUL2003	1	80	121	82	79	115	78	-1	-6	-4
		BASELINE			80	121	82	79	115	78	-1	-6	-4
		DAY 8	16JUL2003	8	79	124	79	84	127	86	5	3	7
		DAY 15	24JUL2003	16	80	120	80	84	116	76	4	-4	-4
		DAY 22	30JUL2003	22	96	125	87	109	124	87	13	-1	0
		DAY 29	06AUG2003	29	92	119	77	98	118	74	6	-1	-3
		DAY 36	13AUG2003	36	117	105	80	107	114	69	-10	9	-11
		DAY 43	20AUG2003	43	97	107	74	100	118	80	3	11	6
		DAY 50	27AUG2003	50	105	110	71	119	104	72	14	-6	1
		DAY 57	05SEP2003	59	99	124	79	96	111	78	-3	-13	-1
		FINAL		59	99	124	79	96	111	78	-3	-13	-1
	E0023043	SCREEN	07JUL2003	-7	100	138	91	96	143	97	-4	5	6
		DAY 1	14JUL2003	1	102	104	57	98	97	57	-4	-7	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023043	BASELINE			102	104	57	98	97	57	-4	-7	0
		DAY 8	23JUL2003	10	100	105	53	111	98	48	11	-7	-5
		DAY 15	28JUL2003	15	100	97	62	98	96	60	-2	-1	-2
		DAY 22	05AUG2003	23	111	98	67	113	83	56	2	-15	-11
		DAY 29	12AUG2003	30	105	125	89	105	101	62	0	-24	-27
		DAY 36	19AUG2003	37	102	130	81	115	130	81	13	0	0
		DAY 43	26AUG2003	44	96	112	70	90	110	74	-6	-2	4
		DAY 50	02SEP2003	51	113	113	66	119	93	59	6	-20	-7
		DAY 57	09SEP2003	58	102	100	68	100	98	70	-2	-2	2
		FINAL		58	102	100	68	100	98	70	-2	-2	2
	E0026003	SCREEN	25NOV2002	-9	51	131	72	77	122	80	26	-9	8
		DAY 1	04DEC2002	1	91	129	92	108	122	85	17	-7	-7
		BASELINE			91	129	92	108	122	85	17	-7	-7
		DAY 8	12DEC2002	9	119	122	94	120	123	98	1	1	4
		DAY 15	19DEC2002	16	100	129	98	107	135	84	7	6	-14
		DAY 22	26DEC2002	23	100	119	79	100	116	86	0	-3	7
		DAY 29	02JAN2003	30	98	106	79	100	128	83	2	22	4
		DAY 36	09JAN2003	37	78	138	91	80	134	96	2	-4	5
		DAY 43	16JAN2003	44	110	123	87	110	114	79	0	-9	-8
		DAY 50	23JAN2003	51	110	107	78	111	94	64	1	-13	-14
		DAY 57	03FEB2003	62	98	129	95	101	132	99	3	3	4
		FINAL		62	98	129	95	101	132	99	3	3	4
	E0026005	SCREEN	23DEC2002	-7	82	168	80	70	146	76	-12	-22	-4
		DAY 1	30DEC2002	1	60	150	100	60	152	100	0	2	0
		BASELINE			60	150	100	60	152	100	0	2	0
		DAY 8	06JAN2003	8	68	144	98	68	137	100	0	-7	2
		FINAL		8	68	144	98	68	137	100	0	-7	2
	E0026009	SCREEN	10JAN2003	-5	63	113	66	68	114	73	5	1	7
		DAY 1	15JAN2003	1	119	131	87	118	114	88	-1	-17	1
		BASELINE			119	131	87	118	114	88	-1	-17	1
		DAY 8	21JAN2003	7	70	97	57	90	107	63	20	10	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0026009	FINAL		7	70	97	57	90	107	63	20	10	6
	E0026015	SCREEN	20FEB2003	-7	78	120	85	85	131	87	7	11	2
		DAY 1	27FEB2003	1	88	113	73	98	107	65	10	-6	-8
		BASELINE			88	113	73	98	107	65	10	-6	-8
		DAY 8	07MAR2003	9	98	109	69	100	91	61	2	-18	-8
		DAY 15	13MAR2003	15	86	127	86	88	130	72	2	3	-14
		DAY 22	20MAR2003	22	89	128	78	92	120	88	3	-8	10
		DAY 29	27MAR2003	29	76	130	72	72	128	68	-4	-2	-4
		DAY 36	03APR2003	36	90	140	80	100	138	97	10	-2	17
		DAY 43	10APR2003	43	89	120	80	100	110	80	11	-10	0
		DAY 50	17APR2003	50	93	126	83	94	117	81	1	-9	-2
		DAY 57	25APR2003	58	88	133	77	92	140	78	4	7	1
		FINAL		58	88	133	77	92	140	78	4	7	1
	E0026023	SCREEN	23APR2003	-7	52	117	57	61	109	70	9	-8	13
		DAY 1	30APR2003	1	86	106	59	96	112	61	10	6	2
		BASELINE			86	106	59	96	112	61	10	6	2
		DAY 8	07MAY2003	8	66	101	63	76	107	62	10	6	-1
		DAY 15	14MAY2003	15	76	110	60	78	112	61	2	2	1
		DAY 22	21MAY2003	22	88	116	68	90	109	65	2	-7	-3
		DAY 29	28MAY2003	29	78	100	58	96	104	65	18	4	7
		DAY 36	04JUN2003	36	66	108	59	62	115	68	-4	7	9
		DAY 43	11JUN2003	43	65	104	63	70	125	65	5	21	2
		DAY 50	18JUN2003	50	70	110	58	87	116	68	17	6	10
		DAY 57	27JUN2003	59	77	104	55	65	103	58	-12	-1	3
		FINAL		59	77	104	55	65	103	58	-12	-1	3
	E0027016	SCREEN	19MAR2003	-21	72	110	70	80	110	75	8	0	5
		DAY 1	09APR2003	1	68	130	90	80	124	90	12	-6	0
		BASELINE			68	130	90	80	124	90	12	-6	0
		DAY 8	14APR2003	6	84	122	80	74	124	78	-10	2	-2
		DAY 15	22APR2003	14	84	140	60	100	140	70	16	0	10
		DAY 22	29APR2003	21	84	120	68	88	122	70	4	2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	DAY 29	05MAY2003	27	94	120	70	96	122	68	2	2	-2
		DAY 36	14MAY2003	36	64	126	72	80	122	72	16	-4	0
		DAY 43	19MAY2003	41	68	128	76	80	124	70	12	-4	-6
		DAY 50	27MAY2003	49	76	120	70	92	116	72	16	-4	2
		DAY 57	03JUN2003	56	72	105	75	76	105	75	4	0	0
		FINAL		56	72	105	75	76	105	75	4	0	0
	E0027018	SCREEN	21MAR2003	-4	80	120	82	84	116	80	4	-4	-2
		DAY 1	25MAR2003	1	80	122	80	96	114	78	16	-8	-2
		BASELINE			80	122	80	96	114	78	16	-8	-2
		DAY 8	02APR2003	9	88	130	84	92	130	78	4	0	-6
		DAY 15	08APR2003	15	98	124	82	88	120	80	-10	-4	-2
		DAY 22	15APR2003	22	98	130	90	88	130	92	-10	0	2
		DAY 29	22APR2003	29	92	120	92	84	130	92	-8	10	0
		DAY 36	29APR2003	36	84	124	80	92	120	80	8	-4	0
		DAY 43	05MAY2003	42	80	128	90	84	124	92	4	-4	2
		DAY 50	13MAY2003	50	72	134	92	88	130	94	16	-4	2
		DAY 57	22MAY2003	59	86	124	82	88	122	80	2	-2	-2
		FINAL		59	86	124	82	88	122	80	2	-2	-2
	E0028032	SCREEN	13MAR2003	-12	66	122	82	72	118	78	6	-4	-4
		DAY 1	25MAR2003	1	56	100	76	80	94	82	24	-6	6
		BASELINE			56	100	76	80	94	82	24	-6	6
		DAY 8	01APR2003	8	68	122	70	76	118	74	8	-4	4
		DAY 15	08APR2003	15	68	112	78	84	120	86	16	8	8
		DAY 22	15APR2003	22	64	100	78	78	104	90	14	4	12
		DAY 29	22APR2003	29	64	120	82	76	118	84	12	-2	2
		DAY 36	30APR2003	37	70	108	72	70	100	80	0	-8	8
		DAY 43	06MAY2003	43	64	110	70	76	112	70	12	2	0
		DAY 50	13MAY2003	50	76	134	86	88	128	84	12	-6	-2
		DAY 57	06JUN2003	74	80	120	78	76	122	80	-4	2	2
		FINAL		74	80	120	78	76	122	80	-4	2	2
	E0029003	SCREEN	28OCT2002	-7	72	92	60	76	90	64	4	-2	4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 1	04NOV2002	1	80	100	60	92	110	64	12	10	4
		BASELINE			80	100	60	92	110	64	12	10	4
		DAY 8	11NOV2002	8	68	90	54	80	104	70	12	14	16
		DAY 15	18NOV2002	15	80	110	60	84	90	60	4	-20	0
		DAY 22	25NOV2002	22	84	110	60	92	110	70	8	0	10
		DAY 29	02DEC2002	29	84	114	74	92	120	78	8	6	4
		DAY 36	09DEC2002	36	80	120	76	92	124	76	12	4	0
		DAY 43	16DEC2002	43	84	114	70	92	110	90	8	-4	20
		DAY 50	23DEC2002	50	80	112	80	80	118	76	0	6	-4
		DAY 57	30DEC2002	57	68	100	60	88	98	80	20	-2	20
		FINAL		57	68	100	60	88	98	80	20	-2	20
	E0029020	SCREEN	25FEB2003	-8	60	130	76	60	124	98	0	-6	22
		DAY 1	04MAR2003	-1	60	122	84	68	130	88	8	8	4
		BASELINE			60	122	84	68	130	88	8	8	4
		DAY 8	11MAR2003	7	60	118	76	72	130	86	12	12	10
		FINAL		7	60	118	76	72	130	86	12	12	10
	E0031005	SCREEN	13DEC2002	-7	80	110	70	88	118	80	8	8	10
		DAY 1	20DEC2002	1	68	120	80	80	120	84	12	0	4
		BASELINE			68	120	80	80	120	84	12	0	4
		DAY 8	27DEC2002	8	72	128	84	86	124	86	14	-4	2
		DAY 15	03JAN2003	15	66	124	80	72	128	84	6	4	4
		DAY 22	10JAN2003	22	75	130	78	82	128	80	7	-2	2
		DAY 29	17JAN2003	29	78	130	74	88	132	80	10	2	6
		DAY 36	24JAN2003	36	66	128	84	70	128	86	4	0	2
		DAY 43	30JAN2003	42	80	130	82	88	134	84	8	4	2
		DAY 50	07FEB2003	50	76	132	86	70	140	88	-6	8	2
		DAY 57	14FEB2003	57	80	138	86	82	140	88	2	2	2
		FINAL		57	80	138	86	82	140	88	2	2	2
	E0031006	SCREEN	31JAN2003	-18	77	156	80	90	166	82	13	10	2
		DAY 1	18FEB2003	1	75	164	76	90	172	80	15	8	4
		BASELINE			75	164	76	90	172	80	15	8	4

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0031006	DAY 8	26FEB2003	9	88	142	72	100	138	70	12	-4	-2
		DAY 15	05MAR2003	16	92	160	86	98	174	86	6	14	0
		DAY 22	11MAR2003	22	74	158	80	78	160	76	4	2	-4
		DAY 29	18MAR2003	29	70	142	72	80	148	76	10	6	4
		DAY 36	25MAR2003	36	88	148	82	94	150	84	6	2	2
		DAY 43	02APR2003	44	88	146	82	92	150	80	4	4	-2
		DAY 50	07APR2003	49	96	162	88	104	170	94	8	8	6
		DAY 57	15APR2003	57	76	148	82	88	150	88	12	2	6
		FINAL		57	76	148	82	88	150	88	12	2	6
	E0031010	SCREEN	12FEB2003	-7	80	132	78	78	134	80	-2	2	2
		DAY 1	19FEB2003	1	88	140	80	90	140	82	2	0	2
		BASELINE			88	140	80	90	140	82	2	0	2
		DAY 8	26FEB2003	8	74	132	72	78	136	76	4	4	4
		DAY 15	05MAR2003	15	78	124	78	86	124	84	8	0	6
		FINAL		15	78	124	78	86	124	84	8	0	6
	E0031011	SCREEN	18FEB2003	-9	68	129	74	74	138	80	6	9	6
		DAY 1	27FEB2003	1	82	144	76	86	148	82	4	4	6
		BASELINE			82	144	76	86	148	82	4	4	6
		DAY 8	06MAR2003	8	78	138	80	78	140	78	0	2	-2
		DAY 15	13MAR2003	15	68	136	82	86	138	84	18	2	2
		DAY 22	20MAR2003	22	98	144	88	104	152	94	6	8	6
		DAY 29	27MAR2003	29	84	130	76	86	132	74	2	2	-2
		DAY 36	03APR2003	36	88	136	80	86	138	78	-2	2	-2
		DAY 43	11APR2003	44	76	126	74	84	128	76	8	2	2
		DAY 50	17APR2003	50	66	130	78	68	128	76	2	-2	-2
		DAY 57	24APR2003	57	70	120	80	74	126	82	4	6	2
		FINAL		57	70	120	80	74	126	82	4	6	2
	E0031015	SCREEN	14MAR2003	-12	76	110	72	80	112	74	4	2	2
		DAY 1	26MAR2003	1	64	124	72	72	128	74	8	4	2
		BASELINE			64	124	72	72	128	74	8	4	2
		DAY 8	01APR2003	7	92	130	76	88	134	82	-4	4	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	FINAL		7	92	130	76	88	134	82	-4	4	6
	E0031031	SCREEN	01JUL2003	-7	72	111	72	62	114	80	-10	3	8
		DAY 1	08JUL2003	1	68	111	74	74	118	76	6	7	2
		BASELINE			68	111	74	74	118	76	6	7	2
		DAY 8	15JUL2003	8	76	116	80	78	114	82	2	-2	2
		DAY 15	22JUL2003	15	70	116	84	78	122	82	8	6	-2
		DAY 22	29JUL2003	22	70	118	78	72	116	82	2	-2	4
		DAY 50	28AUG2003	52	68	118	78	74	118	76	6	0	-2
		FINAL		52	68	118	78	74	118	76	6	0	-2
	E0033009	SCREEN	22JAN2003	-21	68	110	70	68	112	70	0	2	0
		DAY 1	12FEB2003	1	72	110	76	76	110	74	4	0	-2
		BASELINE			72	110	76	76	110	74	4	0	-2
	E0034009	SCREEN	10JUN2003	-9	52	130	80	72	120	75	20	-10	-5
		DAY 1	19JUN2003	1	64	130	90	72	120	85	8	-10	-5
		BASELINE			64	130	90	72	120	85	8	-10	-5
		DAY 8	27JUN2003	9	80	115	90	88	120	80	8	5	-10
		DAY 15	03JUL2003	15	80	135	85	96	130	90	16	-5	5
		DAY 22	10JUL2003	22	80	130	90	96	135	95	16	5	5
		DAY 29	18JUL2003	30	68	140	85	76	150	100	8	10	15
		DAY 36	25JUL2003	37	72	150	100	88	145	95	16	-5	-5
		DAY 43	31JUL2003	43	64	150	100	81	145	95	17	-5	-5
		DAY 50	07AUG2003	50	68	130	70	88	125	85	20	-5	15
		DAY 57	18AUG2003	61	76	135	80	88	142	90	12	7	10
		FINAL		61	76	135	80	88	142	90	12	7	10
	E0037007	SCREEN	04APR2003	-7	68	100	70	84	105	70	16	5	0
		DAY 1	11APR2003	1	56	90	70	56	90	70	0	0	0
		BASELINE			56	90	70	56	90	70	0	0	0
		DAY 8	17APR2003	7	80	92	70	80	90	70	0	-2	0
		FINAL		7	80	92	70	80	90	70	0	-2	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	SCREEN	11JUL2003	-5	60	100	80	60	100	80	0	0	0
		DAY 1	16JUL2003	1	60	106	68	60	106	70	0	0	2
		BASELINE			60	106	68	60	106	70	0	0	2
		DAY 8	24JUL2003	9	64	110	70	64	112	68	0	2	-2
		DAY 15	01AUG2003	17	76	116	68	76	114	64	0	-2	-4
		DAY 22	08AUG2003	24	84	118	65	86	124	70	2	6	5
		DAY 29	15AUG2003	31	86	124	68	90	124	70	4	0	2
		DAY 36	22AUG2003	38	70	114	72	75	118	82	5	4	10
		DAY 43	29AUG2003	45	68	110	68	68	114	70	0	4	2
		DAY 50	05SEP2003	52	70	122	82	70	120	90	0	-2	8
		DAY 57	08SEP2003	55	60	108	60	60	108	62	0	0	2
		FINAL		55	60	108	60	60	108	62	0	0	2
	E0039019	SCREEN	20JAN2003	-17	72	132	96	80	124	88	8	-8	-8
		DAY 1	06FEB2003	1	88	126	92	96	124	96	8	-2	4
		BASELINE			88	126	92	96	124	96	8	-2	4
		DAY 8	13FEB2003	8	66	134	92	62	124	94	-4	-10	2
		DAY 15	20FEB2003	15	83	118	90	96	114	86	13	-4	-4
		DAY 22	27FEB2003	22	88	102	78	96	106	78	8	4	0
		DAY 29	07MAR2003	30	84	98	50	88	100	60	4	2	10
		DAY 36	13MAR2003	36	96	116	90	100	110	88	4	-6	-2
		DAY 43	20MAR2003	43	80	110	84	88	108	86	8	-2	2
		DAY 50	27MAR2003	50	90	110	80	78	108	84	-12	-2	4
		DAY 57	03APR2003	57	90	118	88	94	112	90	4	-6	2
		FINAL		57	90	118	88	94	112	90	4	-6	2
	E0039043	SCREEN	25APR2003	-13	62	120	74	70	118	70	8	-2	-4
		DAY 1	08MAY2003	1	78	134	76	95	118	86	17	-16	10
		BASELINE			78	134	76	95	118	86	17	-16	10
		DAY 8	15MAY2003	8	66	120	80	90	108	82	24	-12	2
		DAY 15	23MAY2003	16	85	128	88	96	118	88	11	-10	0
		DAY 22	29MAY2003	22	74	122	76	92	106	60	18	-16	-16
		DAY 29	05JUN2003	29	80	124	78	88	120	86	8	-4	8
		DAY 36	13JUN2003	37	80	144	84	88	126	90	8	-18	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0039043	FINAL		37	80	144	84	88	126	90	8	-18	6
PLACEBO (BIPOLAR I)	E0002001	SCREEN	17DEC2002	-13	68	107	70	64	100	68	-4	-7	-2
		DAY 1	30DEC2002	1	72	106	66	76	108	66	4	2	0
		BASELINE			72	106	66	76	108	66	4	2	0
		DAY 8	06JAN2003	8	72	104	74	76	110	68	4	6	-6
		DAY 15	14JAN2003	16	68	118	74	68	110	70	0	-8	-4
		DAY 22	21JAN2003	23	64	108	64	68	108	62	4	0	-2
		DAY 29	29JAN2003	31	62	102	60	66	100	62	4	-2	2
		DAY 36	05FEB2003	38	64	102	74	64	100	68	0	-2	-6
		DAY 43	12FEB2003	45	66	106	62	70	110	68	4	4	6
		DAY 50	19FEB2003	52	64	116	70	64	116	72	0	0	2
		DAY 57	26FEB2003	59	72	118	58	76	110	74	4	-8	16
		FINAL		59	72	118	58	76	110	74	4	-8	16
	E0002003	SCREEN	03JAN2003	-19	80	120	78	76	116	72	-4	-4	-6
		DAY 1	22JAN2003	1	68	100	80	72	100	80	4	0	0
		BASELINE			68	100	80	72	100	80	4	0	0
		DAY 8	29JAN2003	8	64	102	72	72	98	60	8	-4	-12
		DAY 15	05FEB2003	15	76	110	60	80	102	62	4	-8	2
		DAY 22	12FEB2003	22	64	102	62	76	104	66	12	2	4
		DAY 29	19FEB2003	29	80	112	60	78	100	64	-2	-12	4
		DAY 36	26FEB2003	36	64	112	66	66	112	72	2	0	6
		DAY 43	05MAR2003	43	78	112	66	76	110	68	-2	-2	2
		DAY 50	11MAR2003	49	76	108	68	74	106	66	-2	-2	-2
		DAY 57	18MAR2003	56	64	120	68	76	110	68	12	-10	0
		FINAL		56	64	120	68	76	110	68	12	-10	0
	E0002004	SCREEN	14JAN2003	-11	66	132	68	72	124	80	6	-8	12
		DAY 1	25JAN2003	1	64	130	84	68	130	86	4	0	2
		BASELINE			64	130	84	68	130	86	4	0	2
	E0002008	SCREEN	05FEB2003	-20	64	122	70	64	120	70	0	-2	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0002008	DAY 1	25FEB2003	1	72	128	74	68	126	82	-4	-2	8
		BASELINE			72	128	74	68	126	82	-4	-2	8
		DAY 8	05MAR2003	9	74	120	82	78	128	88	4	8	6
		DAY 15	13MAR2003	17	80	122	80	78	128	82	-2	6	2
		DAY 22	20MAR2003	24	70	118	76	78	120	82	8	2	6
		DAY 29	27MAR2003	31	76	110	72	72	116	84	-4	6	12
		DAY 36	03APR2003	38	70	110	60	80	120	82	10	10	22
		DAY 43	11APR2003	46	76	126	82	72	118	72	-4	-8	-10
		DAY 50	16APR2003	51	78	116	86	84	126	88	6	10	2
		DAY 57	23APR2003	58	74	108	68	80	118	70	6	10	2
		FINAL		58	74	108	68	80	118	70	6	10	2
	E0002016	SCREEN	14JUL2003	-10	62	130	82	64	118	72	2	-12	-10
		DAY 1	24JUL2003	1	64	136	72	66	138	70	2	2	-2
		BASELINE			64	136	72	66	138	70	2	2	-2
		DAY 8	30JUL2003	7	68	128	78	68	130	82	0	2	4
		DAY 15	06AUG2003	14	68	128	70	68	132	68	0	4	-2
		DAY 22	13AUG2003	21	68	126	68	68	118	68	0	-8	0
		DAY 29	21AUG2003	29	68	130	74	68	128	76	0	-2	2
		DAY 36	27AUG2003	35	64	130	70	68	120	74	4	-10	4
		DAY 43	03SEP2003	42	64	126	70	68	112	68	4	-14	-2
		DAY 50	11SEP2003	50	64	122	72	66	116	70	2	-6	-2
		DAY 57	17SEP2003	56	66	138	82	66	138	86	0	0	4
		FINAL		56	66	138	82	66	138	86	0	0	4
	E0003008	SCREEN	21JAN2003	-7	80	118	80	92	128	88	12	10	8
		DAY 1	28JAN2003	1	78	122	78	82	124	80	4	2	2
		BASELINE			78	122	78	82	124	80	4	2	2
		DAY 8	04FEB2003	8	70	120	78	88	120	70	18	0	-8
		DAY 15	11FEB2003	15	78	126	70	82	110	64	4	-16	-6
		DAY 22	18FEB2003	22	82	108	64	78	102	60	-4	-6	-4
		FINAL		22	82	108	64	78	102	60	-4	-6	-4
	E0004003	SCREEN	02OCT2002	-8	76	112	72	80	110	74	4	-2	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0004003	DAY 1	10OCT2002	1	80	110	72	84	108	70	4	-2	-2
		BASELINE			80	110	72	84	108	70	4	-2	-2
		DAY 8	17OCT2002	8	72	104	68	80	110	78	8	6	10
		FINAL		8	72	104	68	80	110	78	8	6	10
	E0004006	SCREEN	28OCT2002	-7	68	104	76	72	108	80	4	4	4
		DAY 1	04NOV2002	1	68	110	80	72	108	82	4	-2	2
		BASELINE			68	110	80	72	108	82	4	-2	2
		DAY 8	11NOV2002	8	80	104	84	84	102	80	4	-2	-4
		DAY 15	18NOV2002	15	68	108	78	80	110	76	12	2	-2
		DAY 22	25NOV2002	22	80	124	80	76	120	78	-4	-4	-2
		DAY 29	02DEC2002	29	76	120	80	80	118	78	4	-2	-2
		DAY 36	09DEC2002	36	74	106	80	72	102	76	-2	-4	-4
		DAY 43	16DEC2002	43	72	102	70	68	100	76	-4	-2	6
		DAY 57	06JAN2003	64	68	116	78	72	120	80	4	4	2
		FINAL		64	68	116	78	72	120	80	4	4	2
	E0004016	SCREEN	12FEB2003	-7	64	110	62	68	102	68	4	-8	6
		DAY 1	19FEB2003	1	68	100	60	68	96	62	0	-4	2
		BASELINE			68	100	60	68	96	62	0	-4	2
		DAY 8	26FEB2003	8	64	108	64	68	118	70	4	10	6
		DAY 15	05MAR2003	15	60	104	70	64	110	74	4	6	4
		DAY 22	13MAR2003	23	64	110	80	60	102	76	-4	-8	-4
		DAY 36	26MAR2003	36	60	104	68	60	100	64	0	-4	-4
		DAY 43	03APR2003	44	82	104	64	86	110	70	4	6	6
		DAY 50	10APR2003	51	64	100	70	60	108	74	-4	8	4
		DAY 57	17APR2003	58	60	94	62	64	100	60	4	6	-2
		FINAL		58	60	94	62	64	100	60	4	6	-2
	E0004024	SCREEN	25JUN2003	-8	80	138	90	88	138	94	8	0	4
		DAY 1	03JUL2003	1	84	134	90	80	128	86	-4	-6	-4
		BASELINE			84	134	90	80	128	86	-4	-6	-4
		DAY 8	10JUL2003	8	88	130	90	80	134	86	-8	4	-4
		DAY 15	17JUL2003	15	76	130	88	80	126	84	4	-4	-4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0004024	DAY 22	24JUL2003	22	84	124	84	80	138	92	-4	14	8
		DAY 29	31JUL2003	29	84	138	90	88	128	86	4	-10	-4
		DAY 36	07AUG2003	36	84	128	88	88	120	82	4	-8	-6
		DAY 43	14AUG2003	43	88	130	90	88	134	92	0	4	2
		DAY 50	21AUG2003	50	80	140	90	76	132	92	-4	-8	2
		DAY 57	28AUG2003	57	80	130	90	84	142	98	4	12	8
		FINAL		57	80	130	90	84	142	98	4	12	8
	E0005006	SCREEN	24SEP2002	-9	64	110	68	64	100	60	0	-10	-8
		DAY 1	03OCT2002	1	62	110	68	62	100	62	0	-10	-6
		BASELINE			62	110	68	62	100	62	0	-10	-6
		DAY 8	14OCT2002	12	76	110	70	82	112	72	6	2	2
		FINAL		12	76	110	70	82	112	72	6	2	2
	E0005017	SCREEN	11DEC2002	-19	80	130	96	80	124	94	0	-6	-2
		DAY 1	30DEC2002	1	80	130	94	80	124	94	0	-6	0
		BASELINE			80	130	94	80	124	94	0	-6	0
		DAY 8	06JAN2003	8	68	124	94	68	120	70	0	-4	-24
		DAY 15	14JAN2003	16	64	120	90	68	120	90	4	0	0
		DAY 22	22JAN2003	24	72	130	94	72	126	90	0	-4	-4
		DAY 29	30JAN2003	32	76	130	94	76	130	90	0	0	-4
		DAY 36	04FEB2003	37	60	124	84	60	122	82	0	-2	-2
		DAY 43	13FEB2003	46	60	130	86	60	120	86	0	-10	0
		DAY 50	20FEB2003	53	60	120	76	60	116	70	0	-4	-6
		DAY 57	04MAR2003	65	60	120	80	60	120	78	0	0	-2
		FINAL		65	60	120	80	60	120	78	0	0	-2
	E0005019	SCREEN	19DEC2002	-27	88	112	74	88	110	74	0	-2	0
		DAY 1	15JAN2003	1	96	108	70	92	110	76	-4	2	6
		BASELINE			96	108	70	92	110	76	-4	2	6
		DAY 8	23JAN2003	9	60	118	78	64	114	80	4	-4	2
		FINAL		9	60	118	78	64	114	80	4	-4	2
	E0005026	SCREEN	26FEB2003	-8	72	96	60	68	96	60	-4	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0005026	DAY 1	06MAR2003	1	64	94	60	60	96	66	-4	2	6
		BASELINE			64	94	60	60	96	66	-4	2	6
		DAY 8	13MAR2003	8	76	96	64	80	90	60	4	-6	-4
		DAY 15	20MAR2003	15	76	84	60	80	84	60	4	0	0
		DAY 22	25MAR2003	20	80	90	58	80	88	58	0	-2	0
		FINAL		20	80	90	58	80	88	58	0	-2	0
	E0005039	SCREEN	15MAY2003	-7	68	130	80	72	124	78	4	-6	-2
		DAY 1	22MAY2003	1	64	130	80	64	126	80	0	-4	0
		BASELINE			64	130	80	64	126	80	0	-4	0
		DAY 8	28MAY2003	7	76	138	86	76	136	86	0	-2	0
		DAY 15	05JUN2003	15	64	130	82	64	130	84	0	0	2
		DAY 22	12JUN2003	22	80	134	84	80	130	84	0	-4	0
		DAY 29	18JUN2003	28	64	130	84	64	124	84	0	-6	0
		DAY 36	24JUN2003	34	60	130	80	60	126	80	0	-4	0
		DAY 43	03JUL2003	43	60	130	84	60	130	84	0	0	0
		DAY 50	10JUL2003	50	64	130	84	64	134	84	0	4	0
		DAY 57	16JUL2003	56	68	134	78	64	136	86	-4	2	8
		FINAL		56	68	134	78	64	136	86	-4	2	8
	E0005043	SCREEN	01JUL2003	-8	60	110	72	60	110	72	0	0	0
		DAY 1	09JUL2003	1	60	120	70	60	110	70	0	-10	0
		BASELINE			60	120	70	60	110	70	0	-10	0
		DAY 8	17JUL2003	9	64	120	62	66	118	64	2	-2	2
		DAY 15	24JUL2003	16	60	110	76	60	110	70	0	0	-6
		DAY 22	31JUL2003	23	60	110	70	60	110	70	0	0	0
		DAY 29	07AUG2003	30	60	110	70	60	110	70	0	0	0
		DAY 36	13AUG2003	36	60	100	70	60	100	70	0	0	0
		DAY 43	20AUG2003	43	64	118	70	60	110	70	-4	-8	0
		DAY 50	27AUG2003	50	64	116	68	72	110	64	8	-6	-4
		DAY 57	03SEP2003	57	60	126	76	68	124	70	8	-2	-6
		FINAL		57	60	126	76	68	124	70	8	-2	-6
	E0006020	SCREEN	02MAY2003	-11	58	100	72	60	120	80	2	20	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0006020	DAY 1	13MAY2003	1	72	133	90	70	132	89	-2	-1	-1
		BASELINE			72	133	90	70	132	89	-2	-1	-1
		DAY 8	20MAY2003	8	72	133	81	74	134	85	2	1	4
		DAY 15	27MAY2003	15	88	132	77	90	132	99	2	0	22
		DAY 22	03JUN2003	22	86	130	76	88	132	85	2	2	9
		DAY 29	10JUN2003	29	76	129	77	78	136	82	2	7	5
		DAY 36	17JUN2003	36	66	134	83	68	138	87	2	4	4
		DAY 43	24JUN2003	43	68	138	84	70	138	84	2	0	0
		DAY 50	01JUL2003	50	78	132	86	82	150	90	4	18	4
		DAY 57	08JUL2003	57	68	131	87	72	132	95	4	1	8
		FINAL		57	68	131	87	72	132	95	4	1	8
	E0007001	SCREEN	10DEC2002	-21	74	130	78	71	124	80	-3	-6	2
		DAY 1	31DEC2002	1	70	110	70	74	118	76	4	8	6
		BASELINE			70	110	70	74	118	76	4	8	6
		DAY 8	07JAN2003	8	68	112	70	76	116	74	8	4	4
		DAY 15	14JAN2003	15	70	108	70	72	110	74	2	2	4
		DAY 22	21JAN2003	22	72	110	70	76	108	70	4	-2	0
		DAY 29	28JAN2003	29	70	102	72	78	110	78	8	8	6
		DAY 36	04FEB2003	36	72	104	70	76	110	76	4	6	6
		DAY 43	11FEB2003	43	70	100	70	74	94	70	4	-6	0
		DAY 50	18FEB2003	50	66	104	70	70	108	76	4	4	6
		DAY 50 *	22FEB2003	54	70	110	72	78	116	78	8	6	6
		FINAL		54	70	110	72	78	116	78	8	6	6
	E0007003	SCREEN	03JAN2003	-27	74	138	88	78	136		4	-2	
		DAY 1	30JAN2003	1	70	136	80	78	138	84	8	2	4
		BASELINE			70	136	80	78	138	84	8	2	4
		DAY 8	06FEB2003	8	72	136	84	78	138	80	6	2	-4
		DAY 15	14FEB2003	16	64	138	78	70	136	76	6	-2	-2
		DAY 22	22FEB2003	24	70	134	76	74	130	80	4	-4	4
		DAY 36	10MAR2003	40	72	126	70	78	120	72	6	-6	2
		FINAL		40	72	126	70	78	120	72	6	-6	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0007006	SCREEN		21FEB2003	-12	70	112	70	74	116	74	4	4	4
		DAY 1		05MAR2003	1	74	118	80	76	120	82	2	2	2
		BASELINE				74	118	80	76	120	82	2	2	2
		DAY 8		12MAR2003	8	70	124	80	74	126	80	4	2	0
		DAY 15		19MAR2003	15	70	128	70	78	120	76	8	-8	6
		DAY 22	*	25MAR2003	21	74	120	74	80	128	76	6	8	2
		DAY 22		26MAR2003	22	78	124	70	84	120	72	6	-4	2
		FINAL			22	78	124	70	84	120	72	6	-4	2
	E0009004	SCREEN		19NOV2002	-7	84	142	94	86	138	88	2	-4	-6
		DAY 1		26NOV2002	1	72	140	84	80	136	84	8	-4	0
		BASELINE				72	140	84	80	136	84	8	-4	0
		DAY 8		04DEC2002	9	70	140	90	74	138	88	4	-2	-2
		DAY 15		11DEC2002	16	80	150	98	78	148	90	-2	-2	-8
		DAY 22		18DEC2002	23	104	130	94	102	132	96	-2	2	2
		FINAL			23	104	130	94	102	132	96	-2	2	2
	E0009012	SCREEN		16JUN2003	-9	76	110	74	80	110	80	4	0	6
		DAY 1		25JUN2003	1	80	122	80	80	124	82	0	2	2
		BASELINE				80	122	80	80	124	82	0	2	2
		DAY 8		03JUL2003	9	72	100	70	72	108	74	0	8	4
		FINAL			9	72	100	70	72	108	74	0	8	4
	E0010008	SCREEN		11DEC2002	-7	84	110	68	86	100	64	2	-10	-4
		DAY 1		18DEC2002	1	95	110	66	105	100	70	10	-10	4
		BASELINE				95	110	66	105	100	70	10	-10	4
		DAY 8		26DEC2002	9	72	102	56	80	100	60	8	-2	4
		DAY 15		02JAN2003	16	94	118	70	97	120	70	3	2	0
		DAY 22		08JAN2003	22	80	108	60	89	106	56	9	-2	-4
		DAY 29		15JAN2003	29	88	122	60	102	102	66	14	-20	6
		FINAL			29	88	122	60	102	102	66	14	-20	6
	E0010018	SCREEN		26FEB2003	-21	68	108	74	80	110	80	12	2	6
		DAY 1		19MAR2003	1	68	118	80	85	110	80	17	-8	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0010018	BASELINE			68	118	80	85	110	80	17	-8	0
		DAY 8	26MAR2003	8	56	100	68	60	100	70	4	0	2
		DAY 15	02APR2003	15	74	110	70	84	124	80	10	14	10
		DAY 22	09APR2003	22	76	104	70	88	108	76	12	4	6
		DAY 29	16APR2003	29	72	104	64	80	104	68	8	0	4
		DAY 36	23APR2003	36	66	106	70	90	110	72	24	4	2
		DAY 43	01MAY2003	44	80	112	80	86	108	74	6	-4	-6
		DAY 57	14MAY2003	57	78	100	70	84	108	70	6	8	0
		FINAL		57	78	100	70	84	108	70	6	8	0
	E0010028	SCREEN	09JUN2003	-7	66	124	74	70	118	82	4	-6	8
		DAY 1	16JUN2003	1	80	120	60	80	120	72	0	0	12
		BASELINE			80	120	60	80	120	72	0	0	12
		DAY 8	24JUN2003	9	86	118	70	92	120	70	6	2	0
		DAY 15	01JUL2003	16	84	110	70	84	118	72	0	8	2
		DAY 22	08JUL2003	23	80	110	60	80	110	70	0	0	10
		DAY 29	15JUL2003	30	66	110	60	70	120	70	4	10	10
		FINAL		30	66	110	60	70	120	70	4	10	10
	E0011008	SCREEN	23JAN2003	-7	56	112	64	72	112	70	16	0	6
		DAY 1	30JAN2003	1	62	118	70	68	112	78	6	-6	8
		BASELINE			62	118	70	68	112	78	6	-6	8
		DAY 8	06FEB2003	8	70	110	68	74	100	70	4	-10	2
		DAY 15	13FEB2003	15	68	122	72	80	118	78	12	-4	6
		FINAL		15	68	122	72	80	118	78	12	-4	6
	E0011009	SCREEN	19DEC2002	-8	75	138	89	79	143	89	4	5	0
		DAY 1	26DEC2002	-1	74	140	89	76	140	82	2	0	-7
		BASELINE			74	140	89	76	140	82	2	0	-7
		DAY 8	02JAN2003	7	74	140	88	76	140	90	2	0	2
		DAY 15	09JAN2003	14	72	132	86	80	134	84	8	2	-2
		DAY 22	16JAN2003	21	68	140	86	76	138	84	8	-2	-2
		DAY 29	23JAN2003	28	71	132	88	80	140	86	9	8	-2
		DAY 36	30JAN2003	35	64	130	80	68	128	84	4	-2	4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0011009	DAY 43		06FEB2003	42	68	140	80	72	134	88	4	-6	8
		DAY 50		13FEB2003	49	82	140	84	80	138	84	-2	-2	0
		DAY 57		20FEB2003	56	72	130	84	88	124	80	16	-6	-4
		FINAL			56	72	130	84	88	124	80	16	-6	-4
	E0011010	SCREEN		03FEB2003	-7	64	112	74	72	110	76	8	-2	2
		DAY 1		10FEB2003	1	64	110	72	72	108	74	8	-2	2
		BASELINE				64	110	72	72	108	74	8	-2	2
		DAY 8		17FEB2003	8	64	110	72	72	107	78	8	-3	6
		DAY 15		24FEB2003	15	72	110	70	84	104	72	12	-6	2
		DAY 22		03MAR2003	22	68	112	78	76	110	80	8	-2	2
		DAY 29		10MAR2003	29	58	103	68	52	100	70	-6	-3	2
		DAY 36		17MAR2003	36	72	108	72	88	104	72	16	-4	0
		DAY 36	*	19MAR2003	38	72	104	74	80	104	76	8	0	2
		FINAL			38	72	104	74	80	104	76	8	0	2
	E0013001	SCREEN		01NOV2002	-13	72	118	80	66	118	76	-6	0	-4
		DAY 1		14NOV2002	1	72	120	88	72	120	86	0	0	-2
		BASELINE				72	120	88	72	120	86	0	0	-2
		DAY 8		21NOV2002	8	72	120	80	72	122	80	0	2	0
		DAY 15		27NOV2002	14	80	124	86	72	120	84	-8	-4	-2
		DAY 22		06DEC2002	23	80	120	88	72	120	84	-8	0	-4
		DAY 29		11DEC2002	28	72	120	80	72	116	80	0	-4	0
		DAY 36		18DEC2002	35	66	124	86	66	120	80	0	-4	-6
		DAY 43		27DEC2002	44	72	120	84	72	120	82	0	0	-2
		DAY 50		02JAN2003	50	78	120	80	72	118	80	-6	-2	0
		DAY 57		10JAN2003	58	80	122	84	80	122	86	0	0	2
		FINAL			58	80	122	84	80	122	86	0	0	2
	E0013003	SCREEN		06NOV2002	-6	66	140	90	72	140	92	6	0	2
		DAY 1		12NOV2002	1	72	144	90	72	138	90	0	-6	0
		BASELINE				72	144	90	72	138	90	0	-6	0
		DAY 8		19NOV2002	8	72	160	90	72	160	96	0	0	6
		DAY 15		26NOV2002	15	66	140	90	66	150	90	0	10	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0013003	DAY 22	03DEC2002	22	72	140	90	72	146	94	0	6	4
		DAY 29	11DEC2002	30	66	162	94	66	164	98	0	2	4
		DAY 36	18DEC2002	37	82	162	98	78	164	98	-4	2	0
		DAY 43	23DEC2002	42	86	156	92	84	150	90	-2	-6	-2
		DAY 50	30DEC2002	49	72	140	90	66	144	90	-6	4	0
		DAY 57	06JAN2003	56	60	136	90	60	142	90	0	6	0
		FINAL		56	60	136	90	60	142	90	0	6	0
	E0013005	SCREEN	13FEB2003	-5	72	120	80	72	120	80	0	0	0
		DAY 1	18FEB2003	1	66	120	74	72	120	78	6	0	4
		BASELINE			66	120	74	72	120	78	6	0	4
		DAY 8	25FEB2003	8	60	115	68	60	115	76	0	0	8
		DAY 15	04MAR2003	15	60	120	80	66	120	80	6	0	0
		DAY 22	11MAR2003	22	72	115	70	66	118	76	-6	3	6
		DAY 29	19MAR2003	30	72	124	80	72	120	80	0	-4	0
		DAY 36	25MAR2003	36	66	100	80	66	110	80	0	10	0
		DAY 43	02APR2003	44	72	118	70	66	116	70	-6	-2	0
		DAY 50	08APR2003	50	64	120	80	64	120	78	0	0	-2
		DAY 57	15APR2003	57	66	132	80	66	132	80	0	0	0
		FINAL		57	66	132	80	66	132	80	0	0	0
	E0013013	SCREEN	01MAY2003	-5	60	114	78	64	114	80	4	0	2
		DAY 1	06MAY2003	1	80	112	60	68	112	64	-12	0	4
		BASELINE			80	112	60	68	112	64	-12	0	4
		DAY 8	12MAY2003	7	68	118	70	68	118	68	0	0	-2
		DAY 15	19MAY2003	14	60	120	80	68	114	76	8	-6	-4
		DAY 22	27MAY2003	22	60	120	80	60	124	80	0	4	0
		DAY 22 *	30MAY2003	25	64	112	78	68	110	80	4	-2	2
		FINAL		25	64	112	78	68	110	80	4	-2	2
	E0014002	SCREEN	19FEB2003	-7	60	120	74	68	110	72	8	-10	-2
		DAY 1	26FEB2003	1	64	135	78	80	120	80	16	-15	2
		BASELINE			64	135	78	80	120	80	16	-15	2
		DAY 8	04MAR2003	7	64	124	70	80	110	70	16	-14	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0014002	DAY 15	12MAR2003	15	74	110	78	88	110	80	14	0	2
		DAY 22	20MAR2003	23	76	110	80	86	110	74	10	0	-6
		DAY 29	27MAR2003	30	48	112	88	52	108	85	4	-4	-3
		DAY 43	10APR2003	44	60	110	70	63	120	78	3	10	8
		FINAL		44	60	110	70	63	120	78	3	10	8
	E0014004	SCREEN	04MAR2003	-8	65	113	77	67	107	77	2	-6	0
		DAY 1	12MAR2003	1	74	110	78	72	106	82	-2	-4	4
		BASELINE			74	110	78	72	106	82	-2	-4	4
		DAY 8	20MAR2003	9	64	110	75	68	110	70	4	0	-5
		DAY 15	25MAR2003	14	73	102	80	74	107	80	1	5	0
		DAY 22	01APR2003	21	68	95	75	72	110	80	4	15	5
		DAY 36	15APR2003	35	76	105	82	78	102	75	2	-3	-7
		FINAL		35	76	105	82	78	102	75	2	-3	-7
	E0014009	SCREEN	15APR2003	-8	92	130	82	95	125	82	3	-5	0
		DAY 1	23APR2003	1	100	140	80	100	140	78	0	0	-2
		BASELINE			100	140	80	100	140	78	0	0	-2
		DAY 8	30APR2003	8	104	140	100	100	130	88	-4	-10	-12
		FINAL		8	104	140	100	100	130	88	-4	-10	-12
	E0014015	SCREEN	11JUN2003	-7	80	120	90	84	120	80	4	0	-10
		DAY 1	18JUN2003	1	80	120	80	82	123	80	2	3	0
		BASELINE			80	120	80	82	123	80	2	3	0
		DAY 8	26JUN2003	9	80	100	75	85	110	85	5	10	10
		FINAL		9	80	100	75	85	110	85	5	10	10
	E0014017	SCREEN	17JUN2003	-10	72	110	70	80	112	70	8	2	0
		DAY 1	27JUN2003	1	80	124	70	88	118	76	8	-6	6
		BASELINE			80	124	70	88	118	76	8	-6	6
		DAY 8	02JUL2003	6	84	116	80	84	116	86	0	0	6
		DAY 15	09JUL2003	13	80	126	80	84	120	84	4	-6	4
		DAY 22	16JUL2003	20	76	130	82	88	102	80	12	-28	-2
		DAY 29	23JUL2003	27	76	132	86	98	124	88	22	-8	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0014017	DAY 29	*	29JUL2003	33	72	120	70	80	120	80	8	0	10
		DAY 36		05AUG2003	40	88	114	70	88	112	80	0	-2	10
		DAY 43		12AUG2003	47	80	122	80	84	110	80	4	-12	0
		DAY 50		19AUG2003	54	84	122	76	84	112	82	0	-10	6
		FINAL			54	84	122	76	84	112	82	0	-10	6
	E0014018	SCREEN		24JUN2003	-7	70	118	76	68	120	72	-2	2	-4
		DAY 1		01JUL2003	1	68	117	75	66	112	80	-2	-5	5
		BASELINE				68	117	75	66	112	80	-2	-5	5
		DAY 8		09JUL2003	9	92	120	78	96	110	76	4	-10	-2
		DAY 15		16JUL2003	16	92	115	75	94	110	78	2	-5	3
		DAY 22		22JUL2003	22	64	110	70	68	110	80	4	0	10
		DAY 29		29JUL2003	29	80	100	60	78	110	80	-2	10	20
		DAY 36		05AUG2003	36	80	110	78	83	116	77	3	6	-1
		DAY 43		12AUG2003	43	82	115	78	80	114	75	-2	-1	-3
		DAY 50		19AUG2003	50	76	115	82	76	117	80	0	2	-2
		DAY 57		27AUG2003	58	64	125	76	66	120	82	2	-5	6
		FINAL			58	64	125	76	66	120	82	2	-5	6
	E0015005	SCREEN		25NOV2002	-7	70	130	84	68	130	80	-2	0	-4
		DAY 1		02DEC2002	1	72	128	78	68	132	76	-4	4	-2
		BASELINE				72	128	78	68	132	76	-4	4	-2
		DAY 8		11DEC2002	10	72	132	82	74	130	80	2	-2	-2
		DAY 15		18DEC2002	17	72	128	78	74	132	82	2	4	4
		FINAL			17	72	128	78	74	132	82	2	4	4
	E0017002	SCREEN		08MAY2003	-26	68	112	70	68	110	70	0	-2	0
		BASELINE				68	112	70	68	110	70	0	-2	0
		DAY 8		13JUN2003	11	56	105	80	56	103	80	0	-2	0
		FINAL			11	56	105	80	56	103	80	0	-2	0
	E0018009	SCREEN		17DEC2002	-20	76	122	76	80	126	80	4	4	4
		DAY 1		06JAN2003	1	68	124	72	76	128	80	8	4	8
		BASELINE				68	124	72	76	128	80	8	4	8

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0018009	DAY 8		13JAN2003	8	80	120	70	84	122	70	4	2	0
		DAY 8	*	14JAN2003	9	80	108	80	84	110	80	4	2	0
		FINAL			9	80	108	80	84	110	80	4	2	0
	E0018010	SCREEN		09JAN2003	-7	60	112	68	64	114	70	4	2	2
		DAY 1		16JAN2003	1	64	114	70	68	116	70	4	2	0
		BASELINE				64	114	70	68	116	70	4	2	0
		DAY 8		23JAN2003	8	64	112	70	76	112	68	12	0	-2
		DAY 15		30JAN2003	15	68	104	72	72	106	70	4	2	-2
		DAY 22		06FEB2003	22	60	110	68	64	108	70	4	-2	2
		DAY 29		13FEB2003	29	72	104	68	76	108	68	4	4	0
		DAY 36		20FEB2003	36	68	108	68	72	112	72	4	4	4
		DAY 43		26FEB2003	42	72	112	70	76	118	72	4	6	2
		DAY 50		06MAR2003	50	68	126	70	76	128	74	8	2	4
		DAY 57		13MAR2003	57	64	118	70	68	120	70	4	2	0
		FINAL			57	64	118	70	68	120	70	4	2	0
	E0018015	SCREEN		21JAN2003	-7	68	110	68	80	110	70	12	0	2
		DAY 1		28JAN2003	1	68	102	68	72	104	68	4	2	0
		BASELINE				68	102	68	72	104	68	4	2	0
		DAY 8		04FEB2003	8	64	108	72	72	106	72	8	-2	0
		DAY 15		13FEB2003	17	88	118	78	96	122	78	8	4	0
		DAY 22		20FEB2003	24	76	118	68	88	116	68	12	-2	0
		DAY 29		26FEB2003	30	64	112	64	64	118	70	0	6	6
		DAY 36		06MAR2003	38	72	120	70	76	122	72	4	2	2
		DAY 43		13MAR2003	45	64	104	62	72	104	68	8	0	6
		DAY 50		20MAR2003	52	72	104	66	76	106	68	4	2	2
		DAY 57		27MAR2003	59	60	110	68	64	112	70	4	2	2
		FINAL			59	60	110	68	64	112	70	4	2	2
	E0020015	SCREEN		18MAR2003	-9	76	128	72	80	112	74	4	-16	2
		DAY 1		27MAR2003	1	78	114	72	80	116	70	2	2	-2
		BASELINE				78	114	72	80	116	70	2	2	-2
		DAY 8		03APR2003	8	80	116	70	76	122	72	-4	6	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0020015	DAY 15		10APR2003	15	98	114	90	99	116	90	1	2	0
		DAY 22		16APR2003	21	80	124	78	82	118	74	2	-6	-4
		DAY 29		23APR2003	28	88	130	80	90	130	82	2	0	2
		DAY 36		30APR2003	35	78	136	72	80	140	80	2	4	8
		DAY 43		08MAY2003	43	82	112	62	80	114	70	-2	2	8
		DAY 50		15MAY2003	50	78	112	74	80	110	74	2	-2	0
		DAY 57		23MAY2003	58	72	100	80	74	98	78	2	-2	-2
		FINAL			58	72	100	80	74	98	78	2	-2	-2
	E0020017	SCREEN		27MAR2003	-7	76	104	68	72	106	70	-4	2	2
		DAY 1		03APR2003	1	64	100	60	62	102	62	-2	2	2
		BASELINE				64	100	60	62	102	62	-2	2	2
		DAY 8		10APR2003	8	74	116	70	72	114	72	-2	-2	2
		DAY 15		17APR2003	15	88	106	78	86	102	80	-2	-4	2
		DAY 22		22APR2003	20	74	116	74	80	120	76	6	4	2
		DAY 29		29APR2003	27	74	122	74	72	116	74	-2	-6	0
		DAY 29	*	05MAY2003	33	76	118	72	70	112	72	-6	-6	0
		DAY 36		12MAY2003	40	80	100	60	86	104	66	6	4	6
		DAY 50		20MAY2003	48	78	118	74	80	108	70	2	-10	-4
		DAY 57		03JUN2003	62	78	120	74	80	118	74	2	-2	0
		FINAL			62	78	120	74	80	118	74	2	-2	0
	E0020020	SCREEN		07MAY2003	-5	80	102	60	82	104	62	2	2	2
		DAY 1		12MAY2003	1	78	102	64	80	100	66	2	-2	2
		BASELINE				78	102	64	80	100	66	2	-2	2
		DAY 8		19MAY2003	8	84	104	62	80	102	62	-4	-2	0
		DAY 8	*	23MAY2003	12	82	100	60	84	102	60	2	2	0
		FINAL			12	82	100	60	84	102	60	2	2	0
	E0020022	SCREEN		09JUN2003	-7	80	126	76	78	128	78	-2	2	2
		DAY 1		16JUN2003	1	64	112	84	66	120	88	2	8	4
		BASELINE				64	112	84	66	120	88	2	8	4
		DAY 8		23JUN2003	8	58	132	76	60	124	70	2	-8	-6
		DAY 15		30JUN2003	15	58	112	84	60	114	86	2	2	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0020022	DAY 22	07JUL2003	22	58	114	80	68	120	94	10	6	14
		DAY 29	14JUL2003	29	68	100	80	70	112	82	2	12	2
		DAY 36	21JUL2003	36	78	108	74	76	116	78	-2	8	4
		DAY 43	28JUL2003	43	68	104	72	70	110	74	2	6	2
		DAY 50	04AUG2003	50	68	110	80	70	108	80	2	-2	0
		DAY 57	11AUG2003	57	64	112	70	60	104	80	-4	-8	10
		FINAL		57	64	112	70	60	104	80	-4	-8	10
	E0022001	SCREEN	07OCT2002	-21	62	136	96		142	97		6	1
		DAY 1	28OCT2002	1	64	132	98	64	132	92	0	0	-6
		BASELINE			64	132	98	64	132	92	0	0	-6
		DAY 8	04NOV2002	8	68	128	90	80	126	88	12	-2	-2
		DAY 15	11NOV2002	15	72	136	92	72	124	94	0	-12	2
		DAY 22	18NOV2002	22	80	138	88	88	132	86	8	-6	-2
		DAY 29	26NOV2002	30	68	158	90	76	160	94	8	2	4
		DAY 36	02DEC2002	36	68	142	90	72	144	84	4	2	-6
		DAY 43	09DEC2002	43	68	132	86	72	124	90	4	-8	4
		DAY 50	16DEC2002	50	72	136	80	76	130	88	4	-6	8
		DAY 57	26DEC2002	60	64	146	82	68	138	90	4	-8	8
		FINAL		60	64	146	82	68	138	90	4	-8	8
	E0022004	SCREEN	17OCT2002	-11	72	120	82	84	100	70	12	-20	-12
		DAY 1	28OCT2002	1	68	110	78	74	115	72	6	5	-6
		BASELINE			68	110	78	74	115	72	6	5	-6
		DAY 8	04NOV2002	8	70	110	68	78	100	74	8	-10	6
		DAY 15	11NOV2002	15	72	120	80	74	116	72	2	-4	-8
		DAY 22	19NOV2002	23	70	110	78	76	115	78	6	5	0
		DAY 29	26NOV2002	30	74	100	68	72	98	65	-2	-2	-3
		DAY 36	02DEC2002	36	68	110	70	74	115	78	6	5	8
		DAY 43	10DEC2002	44	74	110	66	80	116	68	6	6	2
		DAY 50	16DEC2002	50	76	110	60	78	110	58	2	0	-2
		DAY 57	23DEC2002	57	80	100	60	86	110	72	6	10	12
		FINAL		57	80	100	60	86	110	72	6	10	12

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022005	SCREEN	17OCT2002	-22	76	122	82	80	128	106	4	6	24
		DAY 1	08NOV2002	1	68	130	80	80	126	94	12	-4	14
		BASELINE			68	130	80	80	126	94	12	-4	14
		DAY 8	15NOV2002	8	66	120	68	78	115	70	12	-5	2
		DAY 15	22NOV2002	15	58	125	70	69	110	69	11	-15	-1
		DAY 22	29NOV2002	22	62	120	70	72	115	78	10	-5	8
		DAY 29	06DEC2002	29	74	115	76	80	110	70	6	-5	-6
		DAY 36	13DEC2002	36	78	120	78	82	110	72	4	-10	-6
		DAY 43	20DEC2002	43	68	120	80	74	110	70	6	-10	-10
		DAY 50	27DEC2002	50	70	115	70	74	110	64	4	-5	-6
		DAY 57	03JAN2003	57	72	100	66	76	90	72	4	-10	6
		FINAL		57	72	100	66	76	90	72	4	-10	6
	E0022011	SCREEN	20NOV2002	-9	60	120	78	68	134	82	8	14	4
		DAY 1	29NOV2002	1	60	126	64	72	124	72	12	-2	8
		BASELINE			60	126	64	72	124	72	12	-2	8
	E0022015	SCREEN	29NOV2002	-11	86	112	62		116	76		4	14
		DAY 1	10DEC2002	1	76	120	58	88	126	68	12	6	10
		BASELINE			76	120	58	88	126	68	12	6	10
		DAY 8	17DEC2002	8	64	112	66	68	122	76	4	10	10
		DAY 15	26DEC2002	17	64	108	68	68	106	72	4	-2	4
		DAY 22	02JAN2003	24	68	114	60	84	108	78	16	-6	18
		DAY 29	09JAN2003	31	76	112	66	76	110	60	0	-2	-6
		DAY 36	16JAN2003	38	72	106	60	72	118	70	0	12	10
		DAY 43	23JAN2003	45	80	104	56	92	110	66	12	6	10
		DAY 50	30JAN2003	52	76	114	58	88	116	56	12	2	-2
		DAY 57	06FEB2003	59	72	110	66	92	120	78	20	10	12
		FINAL		59	72	110	66	92	120	78	20	10	12
	E0022016	SCREEN	03DEC2002	-14	76	118	62	72	120	70	-4	2	8
		DAY 1	17DEC2002	1	68	130	70	72	114	78	4	-16	8
		BASELINE			68	130	70	72	114	78	4	-16	8
		DAY 8	26DEC2002	10	72	128	68	80	118	80	8	-10	12

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022016	DAY 15	30DEC2002	14	78	120	66	78	122	72	0	2	6
		DAY 22	06JAN2003	21	66	114	56	78	116	64	12	2	8
		DAY 29	13JAN2003	28	84	128	66	88	118	68	4	-10	2
		DAY 36	21JAN2003	36	64	98	58	62	94	60	-2	-4	2
		DAY 43	30JAN2003	45	78	120	62	84	116	72	6	-4	10
		DAY 50	06FEB2003	52	84	126	70	94	116	76	10	-10	6
		DAY 57	11FEB2003	57	68	120	70	64	118	74	-4	-2	4
		FINAL		57	68	120	70	64	118	74	-4	-2	4
	E0022020	SCREEN	05DEC2002	-7	60	110	58	86	106	80	26	-4	22
		DAY 1	12DEC2002	1	56	102	58	58	98	68	2	-4	10
		BASELINE			56	102	58	58	98	68	2	-4	10
		DAY 8	19DEC2002	8	64	110	70	82	110	64	18	0	-6
		DAY 15	26DEC2002	15	64	110	60	78	112	70	14	2	10
		DAY 22	02JAN2003	22	72	112	64	88	108	68	16	-4	4
		DAY 29	10JAN2003	30	60	94	58	64	102	60	4	8	2
		DAY 36	16JAN2003	36	76	106	48	100	104	66	24	-2	18
		DAY 43	23JAN2003	43	76	94	48	76	102	64	0	8	16
		FINAL		43	76	94	48	76	102	64	0	8	16
	E0022023	SCREEN	19DEC2002	-6	80	118	72	84	118	76	4	0	4
		DAY 1	24DEC2002	-1	78	122	70	88	120	72	10	-2	2
		BASELINE			78	122	70	88	120	72	10	-2	2
		DAY 8	02JAN2003	9	72	116	70	84	118	84	12	2	14
		DAY 15	09JAN2003	16	72	128	72	80	120	82	8	-8	10
		DAY 22	16JAN2003	23	60	102	68	80	108	70	20	6	2
		DAY 29	23JAN2003	30	68	104	68	88	128	74	20	24	6
		DAY 36	30JAN2003	37	64	102	64	72	104	62	8	2	-2
		DAY 43	06FEB2003	44	72	112	60	76	118	58	4	6	-2
		DAY 50	13FEB2003	51	76	102	62	92	118	80	16	16	18
		DAY 57	20FEB2003	58	72	112	78	88	128	72	16	16	-6
		FINAL		58	72	112	78	88	128	72	16	16	-6
	E0022029	SCREEN	05FEB2003	-14	72	128	66	104	116	70	32	-12	4

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022029	DAY 1	19FEB2003	1	75	134	72	84	118	74	9	-16	2
		BASELINE			75	134	72	84	118	74	9	-16	2
		DAY 8	26FEB2003	8	72	116	64	84	122	74	12	6	10
		DAY 15	03MAR2003	13	69	120	66	90	126	74	21	6	8
		DAY 22	12MAR2003	22	72	110	72	84	126	74	12	16	2
		DAY 29	18MAR2003	28	78	116	64	78	126	70	0	10	6
		DAY 36	26MAR2003	36	63	108	70	90	118	78	27	10	8
		DAY 43	02APR2003	43	66	104	72	84	98	74	18	-6	2
		DAY 50	07APR2003	48	68	126	72	80	124	80	12	-2	8
		DAY 57	14APR2003	55	78	132	78	84	118	82	6	-14	4
		FINAL		55	78	132	78	84	118	82	6	-14	4
	E0022041	SCREEN	04MAR2003	-14	64	104	62	70	116	72	6	12	10
		DAY 1	18MAR2003	1	64	124	76	70	120	70	6	-4	-6
		BASELINE			64	124	76	70	120	70	6	-4	-6
		DAY 8	25MAR2003	8	66	126	80	74	116	72	8	-10	-8
		DAY 15	01APR2003	15	64	120	68	60	124	70	-4	4	2
		DAY 22	08APR2003	22	60	124	76	68	128	80	8	4	4
		DAY 29	15APR2003	29	68	116	66	80	124	70	12	8	4
		DAY 36	21APR2003	35	66	120	74	69	128	80	3	8	6
		DAY 43	29APR2003	43	68	126	68	74	132	72	6	6	4
		DAY 50	06MAY2003	50	69	118	76	75	124	78	6	6	2
		DAY 57	13MAY2003	57	70	116	64	68	122	74	-2	6	10
		FINAL		57	70	116	64	68	122	74	-2	6	10
	E0022042	SCREEN	05MAR2003	-7	63	136	90	72	124	88	9	-12	-2
		DAY 1	12MAR2003	1	75	130	86	84	126	92	9	-4	6
		BASELINE			75	130	86	84	126	92	9	-4	6
		DAY 8	19MAR2003	8	69	124	86	84	128	90	15	4	4
		DAY 15	27MAR2003	16	68	120	74	70	120	86	2	0	12
		DAY 22	02APR2003	22	68	130	84	70	120	82	2	-10	-2
		DAY 29	10APR2003	30	78	136	84	84	130	86	6	-6	2
		DAY 36	17APR2003	37	69	134	80	75	140	92	6	6	12
		DAY 43	24APR2003	44	78	134	86	90	128	90	12	-6	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0022042	DAY 50		01MAY2003	51	63	132	80	75	122	88	12	-10	8
		DAY 57		12MAY2003	62	69	134	86	78	124	90	9	-10	4
		FINAL			62	69	134	86	78	124	90	9	-10	4
	E0022043	SCREEN		10MAR2003	-10	66	106	80	72	102	80	6	-4	0
		DAY 1		20MAR2003	1	63	116	80	66	108	78	3	-8	-2
		BASELINE				63	116	80	66	108	78	3	-8	-2
		DAY 8		26MAR2003	7	63	106	70	81	110	82	18	4	12
		DAY 15		03APR2003	15	69	114	76	81	112	80	12	-2	4
		DAY 22		10APR2003	22	60	118	72	66	116	78	6	-2	6
		DAY 29		17APR2003	29	66	124	76	75	120	88	9	-4	12
		DAY 36		24APR2003	36	69	118	74	75	112	80	6	-6	6
		DAY 43		01MAY2003	43	66	116	70	72	120	88	6	4	18
		DAY 50		08MAY2003	50	66	118	72	84	114	84	18	-4	12
		DAY 50	*	12MAY2003	54	63	112	70	66	120	86	3	8	16
		FINAL			54	63	112	70	66	120	86	3	8	16
	E0022054	SCREEN		04APR2003	-7	88	144	68	80	132	86	-8	-12	18
		DAY 1		11APR2003	1	78	116	70	86	110	66	8	-6	-4
		BASELINE				78	116	70	86	110	66	8	-6	-4
		DAY 8		18APR2003	8	80	124	70	88	122	74	8	-2	4
		DAY 15		28APR2003	18	82	124	68	88	120	78	6	-4	10
		DAY 22		02MAY2003	22	96	126	62	100	118	66	4	-8	4
		DAY 29		12MAY2003	32	84	134	76	88	126	82	4	-8	6
		DAY 36		16MAY2003	36	86	116	74	80	122	78	-6	6	4
		FINAL			36	86	116	74	80	122	78	-6	6	4
	E0022059	SCREEN		22APR2003	-14	64	130	70	68	126	80	4	-4	10
		DAY 1		06MAY2003	1	72	108	66	80	104	72	8	-4	6
		BASELINE				72	108	66	80	104	72	8	-4	6
		DAY 8		13MAY2003	8	72	100	68	80	112	78	8	12	10
		DAY 15		20MAY2003	15	80	102	60	78	102	68	-2	0	8
		DAY 22		27MAY2003	22	64	102	70	60	102	72	-4	0	2
		DAY 29		03JUN2003	29	78	106	64	83	120	76	5	14	12

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0022059	DAY 36		10JUN2003	36	64	98	68	80	104	70	16	6	2
		DAY 43		17JUN2003	43	76	98	56	72	100	66	-4	2	10
		DAY 43	*	20JUN2003	46	76	104	52	76	106	64	0	2	12
		DAY 57		08JUL2003	64	64	102	70	64	102	68	0	0	-2
		FINAL			64	64	102	70	64	102	68	0	0	-2
	E0022065	SCREEN		30APR2003	-7	64	100	68	68	112	78	4	12	10
		DAY 1		07MAY2003	1	72	94	62	87	96	70	15	2	8
		BASELINE				72	94	62	87	96	70	15	2	8
		DAY 8		14MAY2003	8	76	106	62	92	94	70	16	-12	8
		DAY 15		21MAY2003	15	64	96	62	80	92	64	16	-4	2
		DAY 22		28MAY2003	22	72	92	60	84	94	62	12	2	2
		DAY 29		04JUN2003	29	75	92	60	90	88	56	15	-4	-4
		DAY 36		11JUN2003	36	64	104	72	64	92	62	0	-12	-10
		DAY 43		18JUN2003	43	81	104	60	90	98	62	9	-6	2
		DAY 50		25JUN2003	50	69	98	58	78	106	64	9	8	6
		DAY 57		02JUL2003	57	64	110	62	68	108	60	4	-2	-2
		FINAL			57	64	110	62	68	108	60	4	-2	-2
	E0022070	SCREEN		05JUN2003	-7	68	120	64	76	120	70	8	0	6
		DAY 1		12JUN2003	1	84	116	68	88	114	70	4	-2	2
		BASELINE				84	116	68	88	114	70	4	-2	2
		DAY 8		18JUN2003	7	76	130	84	72	124	78	-4	-6	-6
		FINAL			7	76	130	84	72	124	78	-4	-6	-6
	E0023001	SCREEN		24OCT2002	-22	60	120	76	60	118	78	0	-2	2
		DAY 1		15NOV2002	1	60	128	76	64	130	80	4	2	4
		BASELINE				60	128	76	64	130	80	4	2	4
		DAY 8		22NOV2002	8	60	124	70	68	104	76	8	-20	6
		DAY 15		29NOV2002	15	120	102	66	100	109	67	-20	7	1
		DAY 22		06DEC2002	22	64	128	84	88	112	84	24	-16	0
		DAY 29		16DEC2002	32	72	110	74	66	104	76	-6	-6	2
		DAY 36		23DEC2002	39	65	124	64	71	138	93	6	14	29
		DAY 43		30DEC2002	46	75	131	81	74			-1		

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0023001	DAY 50		07JAN2003	54	64	130	84	72	122	76	8	-8	-8
		DAY 57		14JAN2003	61	70	120	84	72	116	80	2	-4	-4
		FINAL			61	70	120	84	72	116	80	2	-4	-4
	E0023009	SCREEN		24JAN2003	-18	82	118	76	80	120	78	-2	2	2
		DAY 1		11FEB2003	1	86	134	76	96	127	80	10	-7	4
		BASELINE				86	134	76	96	127	80	10	-7	4
		DAY 8		18FEB2003	8	80	128	78	80	132	76	0	4	-2
		DAY 15		27FEB2003	17	76	134	76	80	134	74	4	0	-2
		DAY 22		04MAR2003	22	85	109	72	92	129	81	7	20	9
		DAY 29		11MAR2003	29	80	128	74	76	120	70	-4	-8	-4
		DAY 36		18MAR2003	36	80	119	70	93	129	81	13	10	11
		DAY 43		25MAR2003	43	87	105	73	102	133	78	15	28	5
		DAY 50		03APR2003	52	86	118	68	93	119	81	7	1	13
		DAY 57		08APR2003	57	92	109	72	90	107	70	-2	-2	-2
		FINAL			57	92	109	72	90	107	70	-2	-2	-2
	E0023028	SCREEN		16MAY2003	-13	99	129	86	79	124	80	-20	-5	-6
		DAY 1		29MAY2003	1	68	122	85	77	116	79	9	-6	-6
		BASELINE				68	122	85	77	116	79	9	-6	-6
		DAY 8		05JUN2003	8	75	136	85	86	95	70	11	-41	-15
		DAY 15		12JUN2003	15	65	118	77	69	104	70	4	-14	-7
		DAY 22		19JUN2003	22	71	115	76	70	108	71	-1	-7	-5
		DAY 29		25JUN2003	28	96	121	80	82	115	79	-14	-6	-1
		DAY 43		09JUL2003	42	84	114	76	82	110	74	-2	-4	-2
		DAY 50		16JUL2003	49	85	115	71	83	112	76	-2	-3	5
		DAY 50	*	21JUL2003	54	80	141	93	74	130	89	-6	-11	-4
		FINAL			54	80	141	93	74	130	89	-6	-11	-4
	E0023033	SCREEN		30MAY2003	-6	75	133	93	78	135	96	3	2	3
		DAY 1		05JUN2003	1	82	146	95	92	136	94	10	-10	-1
		BASELINE				82	146	95	92	136	94	10	-10	-1
		DAY 8		12JUN2003	8	90	160	98	85	162	108	-5	2	10
		FINAL			8	90	160	98	85	162	108	-5	2	10

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0023047	SCREEN	11JUL2003	-7	73	117	75	126	115	77	53	-2	2
		DAY 1	18JUL2003	1	61	130	61	89	120	84	28	-10	23
		BASELINE			61	130	61	89	120	84	28	-10	23
		DAY 8	25JUL2003	8	67	119	68	76	143	69	9	24	1
		DAY 15	31JUL2003	14	61	117	71	76	125	81	15	8	10
		DAY 22	08AUG2003	22	85	139	95	87	151	95	2	12	0
		DAY 29	15AUG2003	29	69	143	82	72	148	86	3	5	4
		DAY 36	21AUG2003	35	78	131	85	97	142	80	19	11	-5
		DAY 43	29AUG2003	43	123	123	78	104	121	72	-19	-2	-6
		DAY 50	05SEP2003	50	85	129	82	92	121	77	7	-8	-5
		DAY 57	12SEP2003	57	80	138	83	120	118	81	40	-20	-2
		FINAL		57	80	138	83	120	118	81	40	-20	-2
	E0025001	SCREEN	25MAR2003	-7	68	130	72	84	126	78	16	-4	6
		DAY 1	01APR2003	1	80	136	88	76	130	90	-4	-6	2
		BASELINE			80	136	88	76	130	90	-4	-6	2
		DAY 8	10APR2003	10	64	135	80	80	130	80	16	-5	0
		DAY 15	16APR2003	16	72	110	62	76	112	70	4	2	8
		DAY 22	23APR2003	23	76	130	78	80	120	70	4	-10	-8
		FINAL		23	76	130	78	80	120	70	4	-10	-8
	E0026012	SCREEN	05FEB2003	-15	57	134	86	53	145	90	-4	11	4
		DAY 1	20FEB2003	1	63	133	86	65	146	82	2	13	-4
		BASELINE			63	133	86	65	146	82	2	13	-4
		DAY 8	27FEB2003	8	71	123	74	73	134	87	2	11	13
		DAY 15	06MAR2003	15	59	123	71	53	136	92	-6	13	21
		DAY 22	13MAR2003	22	68	146	80	74	154	86	6	8	6
		DAY 29	20MAR2003	29	68	123	79	75	134	93	7	11	14
		DAY 36	27MAR2003	36	72	126	83	72	133	89	0	7	6
		DAY 43	03APR2003	43	72	140	72	74	138	72	2	-2	0
		DAY 50	10APR2003	50	69	128	80	77	122	84	8	-6	4
		DAY 57	17APR2003	57	68	116	71	67	121	84	-1	5	13
		FINAL		57	68	116	71	67	121	84	-1	5	13

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0026020	SCREEN		28MAR2003	-4	82	161	84	85	155	67	3	-6	-17
		DAY 1		01APR2003	1	74	116	76	72	131	63	-2	15	-13
		BASELINE				74	116	76	72	131	63	-2	15	-13
		DAY 8		08APR2003	8	87	115	67	90	131	61	3	16	-6
		DAY 15		15APR2003	15	73	137	74	72	146	63	-1	9	-11
		DAY 22		22APR2003	22	70	160	71	78	110	74	8	-50	3
		FINAL			22	70	160	71	78	110	74	8	-50	3
	E0026024	SCREEN		25APR2003	-7	82	104	61	85	98	58	3	-6	-3
		DAY 1		02MAY2003	1	89	108	74	92	108	71	3	0	-3
		BASELINE				89	108	74	92	108	71	3	0	-3
		DAY 8		09MAY2003	8	77	111	70	85	107	71	8	-4	1
		DAY 15		16MAY2003	15	76	112	68	82	116	70	6	4	2
		DAY 22		23MAY2003	22	75	99	67	83	116	76	8	17	9
		DAY 29		30MAY2003	29	78	100	72	89	97	77	11	-3	5
		FINAL			29	78	100	72	89	97	77	11	-3	5
	E0026028	SCREEN		06JUN2003	-14	73	172	60	80	160	80	7	-12	20
		DAY 1		20JUN2003	1	86	154	82	90	160	90	4	6	8
		BASELINE				86	154	82	90	160	90	4	6	8
		DAY 8		27JUN2003	8	90	156	78	100	166	81	10	10	3
		DAY 15		02JUL2003	13	72	150	72	80	160	80	8	10	8
		DAY 15	*	08JUL2003	19	90	137	85	96	161	90	6	24	5
		DAY 36		23JUL2003	34	91	161	88	87	156	92	-4	-5	4
		FINAL			34	91	161	88	87	156	92	-4	-5	4
	E0028001	SCREEN		07OCT2002	-3	72	110	80	72	118	80	0	8	0
		DAY 1		10OCT2002	1	74	128	88	73	122	82	-1	-6	-6
		BASELINE				74	128	88	73	122	82	-1	-6	-6
		DAY 8		16OCT2002	7	70	130	90	72	130	90	2	0	0
		DAY 15		23OCT2002	14	72	136	90	82	140	90	10	4	0
		DAY 22		29OCT2002	20	70	128	80	72	122	90	2	-6	10
		DAY 29		05NOV2002	27	74	130	102	88	140	110	14	10	8
		DAY 36		12NOV2002	34	70	122	88	78	126	88	8	4	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028001	DAY 43	19NOV2002	41	78	134	94	84	150	104	6	16	10
		DAY 50	26NOV2002	48	82	120	92	92	118	98	10	-2	6
		DAY 57	03DEC2002	55	90	138	98	94	116	96	4	-22	-2
		FINAL		55	90	138	98	94	116	96	4	-22	-2
	E0028003	SCREEN	23SEP2002	-7	58	112	88	70	116	90	12	4	2
		DAY 1	30SEP2002	1	60	122	80	64	120	80	4	-2	0
		BASELINE			60	122	80	64	120	80	4	-2	0
		DAY 8	07OCT2002	8	73	122	80	76	118	80	3	-4	0
		DAY 15	16OCT2002	17	72	130	90	71	132	90	-1	2	0
		DAY 22	22OCT2002	23	66	130	90	78	120	80	12	-10	-10
		DAY 29	29OCT2002	30	60	134	78	72	138	78	12	4	0
		DAY 36	07NOV2002	39	64	142	86	74	142	88	10	0	2
		DAY 43	12NOV2002	44	66	130	80	68	128	80	2	-2	0
		DAY 50	19NOV2002	51	66	130	92	76	112	84	10	-18	-8
		DAY 57	26NOV2002	58	72	132	82	72	134	76	0	2	-6
		FINAL		58	72	132	82	72	134	76	0	2	-6
	E0028005	SCREEN	30SEP2002	-3	60	90	70	60	90	70	0	0	0
		DAY 1	03OCT2002	1	68	90	60	68	98	70	0	8	10
		BASELINE			68	90	60	68	98	70	0	8	10
		DAY 8	11OCT2002	9	61	98	70	68	100	70	7	2	0
		DAY 29	31OCT2002	29	58	98	62	62	96	68	4	-2	6
		FINAL		29	58	98	62	62	96	68	4	-2	6
	E0028010	SCREEN	15OCT2002	-21	60	118	78	62	118	80	2	0	2
		DAY 1	05NOV2002	1	70	104	60	70	118	68	0	14	8
		BASELINE			70	104	60	70	118	68	0	14	8
		DAY 8	12NOV2002	8	60	102	70	62	110	70	2	8	0
		DAY 15	19NOV2002	15	74	112	68	78	98	70	4	-14	2
		DAY 22	25NOV2002	21	70	104	58	80	112	84	10	8	26
		DAY 29	03DEC2002	29	68	114	68	80	128	68	12	14	0
		DAY 36	10DEC2002	36	64	110	64	76	104	68	12	-6	4
		DAY 43	17DEC2002	43	74	114	60	72	128	72	-2	14	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028010	DAY 50	23DEC2002	49	76	98	60	84	102	70	8	4	10
		DAY 57	31DEC2002	57	60	118	68	64	112	66	4	-6	-2
		FINAL		57	60	118	68	64	112	66	4	-6	-2
	E0028011	SCREEN	25NOV2002	-10	76	130	82	80	130	70	4	0	-12
		DAY 1	05DEC2002	1	72	136	78	88	128	80	16	-8	2
		BASELINE			72	136	78	88	128	80	16	-8	2
		DAY 8	12DEC2002	8	74	136	86	86	122	90	12	-14	4
		DAY 15	19DEC2002	15	68	110	70	76	118	80	8	8	10
		DAY 22	26DEC2002	22	70	122	88	78	118	90	8	-4	2
		DAY 29	02JAN2003	29	72	128	82	80	118	78	8	-10	-4
		DAY 36	09JAN2003	36	78	116	88	84	112	90	6	-4	2
		DAY 43	16JAN2003	43	66	130	80	86	120	90	20	-10	10
		DAY 50	23JAN2003	50	76	118	86	94	124	98	18	6	12
		DAY 57	30JAN2003	57	82	132	76	98	128	84	16	-4	8
		FINAL		57	82	132	76	98	128	84	16	-4	8
	E0028030	SCREEN	26FEB2003	-6	60	122	82	84	120	80	24	-2	-2
		DAY 1	04MAR2003	1	56	118	86	76	114	92	20	-4	6
		BASELINE			56	118	86	76	114	92	20	-4	6
		DAY 8	11MAR2003	8	74	100	78	70	106	94	-4	6	16
		DAY 15	18MAR2003	15	80	118	76	88	112	78	8	-6	2
		DAY 22	25MAR2003	22	84	116	80	80	112	78	-4	-4	-2
		DAY 29	01APR2003	29	68	112	72	92	106	74	24	-6	2
		DAY 36	08APR2003	36	64	120	76	80	106	72	16	-14	-4
		DAY 43	17APR2003	45	72	122	72	88	100	72	16	-22	0
		DAY 50	22APR2003	50	60	120	64	84	110	68	24	-10	4
		DAY 57	30APR2003	58	70	110	78	70	110	86	0	0	8
		FINAL		58	70	110	78	70	110	86	0	0	8
	E0028031	SCREEN	06MAR2003	-5	92	126	84	84	124	86	-8	-2	2
		DAY 1	11MAR2003	1	84	122	74	88	108	74	4	-14	0
		BASELINE			84	122	74	88	108	74	4	-14	0
		DAY 8	18MAR2003	8	88	118	84	96	108	76	8	-10	-8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028031	DAY 15	25MAR2003	15	92	130	82	96	132	86	4	2	4
		DAY 36	17APR2003	38	96	130	76	100	124	74	4	-6	-2
		FINAL		38	96	130	76	100	124	74	4	-6	-2
	E0028047	SCREEN	08JUL2003	-6	78	170	120	74	160	120	-4	-10	0
		DAY 1	14JUL2003	1	64	130	100	60	130	100	-4	0	0
		BASELINE			64	130	100	60	130	100	-4	0	0
		DAY 8	21JUL2003	8	68	140	100	72	140	115	4	0	15
		DAY 15	29JUL2003	16	66	148	100	78	160	108	12	12	8
		DAY 22	05AUG2003	23	62	140	94	62	162	110	0	22	16
		DAY 29	12AUG2003	30	61	168	101	60	168	112	-1	0	11
		DAY 36	19AUG2003	37	62	160	110	78	160	110	16	0	0
		DAY 43	26AUG2003	44	60	140	100	60	140	100	0	0	0
		DAY 50	02SEP2003	51	62	150	110	62	148	110	0	-2	0
		DAY 57	09SEP2003	58	70	162	108	66	144	100	-4	-18	-8
		FINAL		58	70	162	108	66	144	100	-4	-18	-8
	E0029001	SCREEN	24SEP2002	-7	76	120	60	88	120	66	12	0	6
		DAY 1	01OCT2002	1	76	108	72	74	112	76	-2	4	4
		BASELINE			76	108	72	74	112	76	-2	4	4
		DAY 8	09OCT2002	9	72	124	80	80	130	84	8	6	4
		FINAL		9	72	124	80	80	130	84	8	6	4
	E0029014	SCREEN	28JAN2003	-7	60	102	60	84	106	62	24	4	2
		DAY 1	04FEB2003	1	60	90	60	72	100	50	12	10	-10
		BASELINE			60	90	60	72	100	50	12	10	-10
		DAY 8	11FEB2003	8	60	114	80	72	100	76	12	-14	-4
		DAY 15	18FEB2003	15	64	104	64	68	94	62	4	-10	-2
		DAY 22	25FEB2003	22	68	118	64	64	118	64	-4	0	0
		DAY 29	06MAR2003	31	76	96	58	76	104	64	0	8	6
		DAY 36	11MAR2003	36	68	126	76	76	134	84	8	8	8
		DAY 43	20MAR2003	45	72	138	76	84	122	74	12	-16	-2
		DAY 50	27MAR2003	52	72	120	68	80	110	70	8	-10	2
		DAY 57	01APR2003	57	56	114	70	60	108	64	4	-6	-6

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0029014	FINAL		57	56	114	70	60	108	64	4	-6	-6
	E0029023	SCREEN	11MAR2003	-28	80	112	72	80	110	72	0	-2	0
		DAY 1	08APR2003	1	76	112	72	76	108	70	0	-4	-2
		BASELINE			76	112	72	76	108	70	0	-4	-2
		DAY 8	15APR2003	8	64	118	72	68	118	76	4	0	4
		DAY 15	22APR2003	15	64	112	70	64	112	68	0	0	-2
		DAY 22	01MAY2003	24	72	118	76	72	116	78	0	-2	2
		DAY 36	12MAY2003	35	72	112	70	72	112	68	0	0	-2
		DAY 43	20MAY2003	43	76	120	80	76	116	80	0	-4	0
		DAY 50	29MAY2003	52	72	116	78	72	118	74	0	2	-4
		DAY 57	10JUN2003	64	68	110	74	68	110	72	0	0	-2
		FINAL		64	68	110	74	68	110	72	0	0	-2
	E0029032	SCREEN	22MAY2003	-19	60	102	78	72	118	80	12	16	2
		DAY 1	10JUN2003	1	64	110	80	68	108	80	4	-2	0
		BASELINE			64	110	80	68	108	80	4	-2	0
		DAY 8	17JUN2003	8	64	110	80	68	120	80	4	10	0
		DAY 22	01JUL2003	22	68	110	80	76	105	80	8	-5	0
		FINAL		22	68	110	80	76	105	80	8	-5	0
	E0029033	SCREEN	27MAY2003	-6	60	110	70	64	100	80	4	-10	10
		DAY 1	02JUN2003	1	60	104	70	72	118	80	12	14	10
		BASELINE			60	104	70	72	118	80	12	14	10
		DAY 8	09JUN2003	8	64	114	68	76	144	78	12	30	10
		DAY 15	16JUN2003	15	60	118	70	76	114	76	16	-4	6
		DAY 22	23JUN2003	22	64	104	68	76	110	80	12	6	12
		DAY 29	30JUN2003	29	64	118	70	68	136	80	4	18	10
		FINAL		29	64	118	70	68	136	80	4	18	10
	E0029039	SCREEN	10JUL2003	-5	60	100	70	60	90	70	0	-10	0
		DAY 1	15JUL2003	1	56	100	64	64	90	60	8	-10	-4
		BASELINE			56	100	64	64	90	60	8	-10	-4
		DAY 8	23JUL2003	9	64	100	70	64	90	70	0	-10	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0029039	DAY 15		28JUL2003	14	88	98	60	84	92	58	-4	-6	-2
		FINAL			14	88	98	60	84	92	58	-4	-6	-2
	E0030003	SCREEN		03DEC2002	-13	72	122	84	80	110	80	8	-12	-4
		DAY 1		16DEC2002	1	68	130	78	80	118	70	12	-12	-8
		BASELINE				68	130	78	80	118	70	12	-12	-8
		DAY 8		23DEC2002	8	60	130	70	60	126	70	0	-4	0
		DAY 8	*	24DEC2002	9	60	120	70	72	122	74	12	2	4
		FINAL			9	60	120	70	72	122	74	12	2	4
	E0030009	SCREEN		10JAN2003	-13	72	136	86	80	134	90	8	-2	4
		DAY 1		23JAN2003	1	64	144	90	64	128	94	0	-16	4
		BASELINE				64	144	90	64	128	94	0	-16	4
		DAY 8		29JAN2003	7	60	126	78	72	130	80	12	4	2
		DAY 15		07FEB2003	16	56	126	72	60	122	76	4	-4	4
		DAY 36		27FEB2003	36	64	122	74	64	120	80	0	-2	6
		DAY 43		06MAR2003	43	68	126	80	76	128	80	8	2	0
		DAY 50		12MAR2003	49	68	134	80	76	126	80	8	-8	0
		DAY 57		19MAR2003	56	64	140	80	72	116	80	8	-24	0
		FINAL			56	64	140	80	72	116	80	8	-24	0
	E0030016	SCREEN		21FEB2003	-10	68	120	62	80	114	70	12	-6	8
		DAY 1		03MAR2003	1	76	126	78	76	112	76	0	-14	-2
		BASELINE				76	126	78	76	112	76	0	-14	-2
		DAY 8		10MAR2003	8	84	124	80	88	118	84	4	-6	4
		DAY 15		17MAR2003	15	84	130	80	88	116	80	4	-14	0
		DAY 22		25MAR2003	23	80	124	78	96	120	76	16	-4	-2
		DAY 29		02APR2003	31	88	138	80	88	120	80	0	-18	0
		DAY 36		09APR2003	38	92	120	80	96	112	82	4	-8	2
		DAY 50		22APR2003	51	84	128	76	88	120	80	4	-8	4
		FINAL			51	84	128	76	88	120	80	4	-8	4
	E0030021	SCREEN		13MAY2003	-7	60	100	60	80	100	70	20	0	10
		DAY 1		20MAY2003	1	68	100	64	80	102	70	12	2	6

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0030021	BASELINE			68	100	64	80	102	70	12	2	6
		DAY 8	27MAY2003	8	68	98	68	80	100	72	12	2	4
		DAY 15	03JUN2003	15	60	132	74	80	124	70	20	-8	-4
		DAY 22	10JUN2003	22	68	131	70	70	128	71	2	-3	1
		DAY 29	17JUN2003	29	60	111	70	80	108	70	20	-3	0
		FINAL		29	60	111	70	80	108	70	20	-3	0
	E0031001	SCREEN	14NOV2002	-7	78	126	88	82	122	86	4	-4	-2
		DAY 1	21NOV2002	1	68	124	80	76	126	84	8	2	4
		BASELINE			68	124	80	76	126	84	8	2	4
		DAY 8	27NOV2002	7	58	124	68	64	124	74	6	0	6
		DAY 15	05DEC2002	15	64	126	74	76	128	74	12	2	0
		DAY 22	11DEC2002	21	66	126	80	60	128	82	-6	2	2
		DAY 29	20DEC2002	30	62	118	64	66	114	66	4	-4	2
		FINAL		30	62	118	64	66	114	66	4	-4	2
	E0031017	SCREEN	25MAR2003	-7	60	112	68	66	118	74	6	6	6
		DAY 1	01APR2003	1	69	124	72	76	128	74	7	4	2
		BASELINE			69	124	72	76	128	74	7	4	2
		DAY 8	07APR2003	7	70	126	72	66	130	74	-4	4	2
		DAY 15	15APR2003	15	88	129	68	84	132	74	-4	3	6
		DAY 22	22APR2003	22	70	120	70	66	126	74	-4	6	4
		DAY 29	29APR2003	29	70	126	72	72	128	76	2	2	4
		FINAL		29	70	126	72	72	128	76	2	2	4
	E0031018	SCREEN	01APR2003	-9	90	114	72	80	116	74	-10	2	2
		DAY 1	10APR2003	1	76	118	70	84	116	74	8	-2	4
		BASELINE			76	118	70	84	116	74	8	-2	4
		DAY 8	17APR2003	8	68	120	68	76	118	72	8	-2	4
		DAY 15	24APR2003	15	76	128	76	74	126	68	-2	-2	-8
		FINAL		15	76	128	76	74	126	68	-2	-2	-8
	E0031023	SCREEN	21APR2003	-8	72	136	84	76	140	86	4	4	2
		DAY 1	29APR2003	1	74	140	82	78	142	84	4	2	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0031023	BASELINE			74	140	82	78	142	84	4	2	2
		DAY 8	07MAY2003	9	80	140	80	78	144	82	-2	4	2
		DAY 15	13MAY2003	15	84	142	82	88	146	86	4	4	4
		DAY 22	20MAY2003	22	86	144	80	88	146	84	2	2	4
		DAY 29	27MAY2003	29	80	142	84	86	148	88	6	6	4
		DAY 36	04JUN2003	37	96	130	90	100	140	90	4	10	0
		DAY 43	10JUN2003	43	72	134	84	86	140	90	14	6	6
		DAY 50	17JUN2003	50	74	136	84	76	140	90	2	4	6
		DAY 57	24JUN2003	57	78	140	78	86	144	88	8	4	10
		FINAL		57	78	140	78	86	144	88	8	4	10
	E0033001	SCREEN	23DEC2002	-17	68	120	80	80	120	88	12	0	8
		DAY 1	09JAN2003	1	80	120	72	86	120	76	6	0	4
		BASELINE			80	120	72	86	120	76	6	0	4
		DAY 8	16JAN2003	8	64	104	70	76	108	84	12	4	14
		DAY 15	23JAN2003	15	68	120	78	76	116	86	8	-4	8
		DAY 22	30JAN2003	22	64	110	80	76	120	82	12	10	2
		FINAL		22	64	110	80	76	120	82	12	10	2
	E0033004	SCREEN	09JAN2003	-8	76	110	76	80	108	76	4	-2	0
		DAY 1	17JAN2003	1	76	100	70	80	104	70	4	4	0
		BASELINE			76	100	70	80	104	70	4	4	0
		DAY 8	24JAN2003	8	80	110	76	76	100	72	-4	-10	-4
		DAY 15	31JAN2003	15	88	110	74	84	114	72	-4	4	-2
		DAY 22	07FEB2003	22	76	102	62	84	110	76	8	8	14
		DAY 29	14FEB2003	29	64	100	70	76	100	76	12	0	6
		DAY 36	21FEB2003	36	72	114	76	68	110	80	-4	-4	4
		DAY 43	28FEB2003	43	72	100	70	84	92	70	12	-8	0
		DAY 50	07MAR2003	50	84	100	70	92	110	80	8	10	10
		DAY 57	14MAR2003	57	76	102	70	80	110	78	4	8	8
		FINAL		57	76	102	70	80	110	78	4	8	8
	E0033010	SCREEN	22JAN2003	-13	72	110	70	84	110	72	12	0	2
		DAY 1	04FEB2003	1	76	110	68	80	96	62	4	-14	-6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0033010	BASELINE			76	110	68	80	96	62	4	-14	-6
		DAY 8	11FEB2003	8	76	112	80	84	110	76	8	-2	-4
		DAY 15	20FEB2003	17	76	104	70	88	100	70	12	-4	0
		DAY 22	27FEB2003	24	68	100	68	72	90	68	4	-10	0
		DAY 29	04MAR2003	29	64	110	74	76	100	76	12	-10	2
		DAY 36	14MAR2003	39	76	102	68	76	108	70	0	6	2
		DAY 50	26MAR2003	51	60	100	60	76	90	68	16	-10	8
		FINAL		51	60	100	60	76	90	68	16	-10	8
	E0033014	SCREEN	12MAR2003	-7	76	102	78	80	110	80	4	8	2
		DAY 1	19MAR2003	1	84	110	86	84	100	82	0	-10	-4
		BASELINE			84	110	86	84	100	82	0	-10	-4
		DAY 8	26MAR2003	8	80	100	76	92	90	76	12	-10	0
		DAY 15	03APR2003	16	84	90	72	92	100	80	8	10	8
		DAY 22	11APR2003	24	88	110	82	92	98	78	4	-12	-4
		DAY 29	16APR2003	29	72	104	82	84	100	86	12	-4	4
		DAY 36	21APR2003	34	72	90	74	76	100	80	4	10	6
		FINAL		34	72	90	74	76	100	80	4	10	6
	E0035002	SCREEN	14NOV2002	-7	80	106	76	84	108	78	4	2	2
		DAY 1	21NOV2002	1	62	110	86	74	112	80	12	2	-6
		BASELINE			62	110	86	74	112	80	12	2	-6
		DAY 8	27NOV2002	7	80	106	72	86	106	78	6	0	6
		DAY 15	05DEC2002	15	60	102	70	70	110	70	10	8	0
		DAY 22	12DEC2002	22	68	108	64	72	110	72	4	2	8
		FINAL		22	68	108	64	72	110	72	4	2	8
	E0035007	SCREEN	13DEC2002	-6	72	112	76	78	118	72	6	6	-4
		DAY 1	19DEC2002	1	72	118	72	78	120	76	6	2	4
		BASELINE			72	118	72	78	120	76	6	2	4
		DAY 8	26DEC2002	8	76	112	72	80	116	76	4	4	4
		DAY 15	02JAN2003	15	72	110	74	76	112	76	4	2	2
		DAY 22	09JAN2003	22	74	112	70	78	114	66	4	2	-4
		DAY 29	17JAN2003	30	74	114	72	80	114	68	6	0	-4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0035007	DAY 36	23JAN2003	36	78	112	74	80	116	80	2	4	6
		DAY 43	30JAN2003	43	64	112	68	76	116	74	12	4	6
		DAY 50	06FEB2003	50	72	112	70	76	114	72	4	2	2
		DAY 57	11FEB2003	55	78	112	72	82	116	78	4	4	6
		FINAL		55	78	112	72	82	116	78	4	4	6
	E0035011	SCREEN	09JAN2003	-26	80	122	74	88	124	80	8	2	6
		DAY 1	04FEB2003	1	82	124	88	88	126	86	6	2	-2
		BASELINE			82	124	88	88	126	86	6	2	-2
		DAY 8	11FEB2003	8	82	124	84	88	126	84	6	2	0
		DAY 15	18FEB2003	15	80	124	78	88	128	82	8	4	4
		DAY 22	25FEB2003	22	82	120	82	88	122	80	6	2	-2
		DAY 29	04MAR2003	29	80	118	76	88	122	80	8	4	4
		DAY 36	11MAR2003	36	68	132	80	72	136	84	4	4	4
		DAY 43	18MAR2003	43	76	132	78	78	134	80	2	2	2
		DAY 50	25MAR2003	50	76	124	74	80	128	78	4	4	4
		DAY 57	01APR2003	57	80	128	78	82	130	82	2	2	4
		FINAL		57	80	128	78	82	130	82	2	2	4
	E0035020	SCREEN	11APR2003	-7	68	100	72	72	102	78	4	2	6
		DAY 1	18APR2003	1	64	102	72	68	104	76	4	2	4
		BASELINE			64	102	72	68	104	76	4	2	4
		DAY 8	25APR2003	8	72	98	62	78	102	68	6	4	6
		DAY 15	01MAY2003	14	76	100	64	84	106	68	8	6	4
		DAY 22	09MAY2003	22	78	102	70	80	104	78	2	2	8
		DAY 29	15MAY2003	28	78	102	64	82	102	78	4	0	14
		DAY 36	23MAY2003	36	76	100	68	84	104	72	8	4	4
		DAY 43	30MAY2003	43	80	100	74	88	102	76	8	2	2
		DAY 50	06JUN2003	50	76	104	70	80	108	74	4	4	4
		DAY 57	13JUN2003	57	70	102	76	74	104	80	4	2	4
		FINAL		57	70	102	76	74	104	80	4	2	4
	E0037003	SCREEN	22JAN2003	-8	72	112	70	72	116	70	0	4	0
		DAY 1	30JAN2003	1	80	122	84	80	120	80	0	-2	-4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0037003	BASELINE			80	122	84	80	120	80	0	-2	-4
		DAY 8	06FEB2003	8	80	124	80	80	124	84	0	0	4
		DAY 15	13FEB2003	15	78	128	84	78	126	80	0	-2	-4
		DAY 22	20FEB2003	22	76	126	84	76	128	82	0	2	-2
		FINAL		22	76	126	84	76	128	82	0	2	-2
	E0037004	SCREEN	06FEB2003	-7	72	130	100	72	130	96	0	0	-4
		DAY 1	13FEB2003	1	72	128	74	68	128	76	-4	0	2
		BASELINE			72	128	74	68	128	76	-4	0	2
		DAY 8	21FEB2003	9	64	127	83	76	119	90	12	-8	7
		DAY 15	27FEB2003	15	80	103	80	76	120	85	-4	17	5
		DAY 22	06MAR2003	22	76	112	68	76	112	70	0	0	2
		DAY 29	13MAR2003	29	70	118	80	78	120	90	8	2	10
		DAY 36	20MAR2003	36	76	120	80	96	120	70	20	0	-10
		DAY 43	28MAR2003	44	64	120	78	80	120	80	16	0	2
		DAY 50	04APR2003	51	68	120	80	80	117	80	12	-3	0
		DAY 57	10APR2003	57	72	120	90	72	120	90	0	0	0
		FINAL		57	72	120	90	72	120	90	0	0	0
	E0039007	SCREEN	25NOV2002	-9	68	118	76	70	120	72	2	2	-4
		DAY 1	04DEC2002	1	76	126	88	88	128	86	12	2	-2
		BASELINE			76	126	88	88	128	86	12	2	-2
		DAY 8	11DEC2002	8	80	132	88	96	124	94	16	-8	6
		DAY 15	18DEC2002	15	92	118	80	88	112	88	-4	-6	8
		DAY 22	23DEC2002	20	80	122	88	96	118	90	16	-4	2
		DAY 29	30DEC2002	27	72	114	86	76	118	90	4	4	4
		DAY 36	08JAN2003	36	80	116	84	80	126	96	0	10	12
		DAY 43	15JAN2003	43	80	110	80	88	120	88	8	10	8
		DAY 50	22JAN2003	50	80	108	80	86	110	86	6	2	6
		DAY 57	29JAN2003	57	72	116	82	84	124	90	12	8	8
		FINAL		57	72	116	82	84	124	90	12	8	8
	E0039022	SCREEN	04FEB2003	-21	88	130	68	85	132	80	-3	2	12
		DAY 1	25FEB2003	1	64	128	80	68	132	86	4	4	6

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0039022	BASELINE			64	128	80	68	132	86	4	4	6
		DAY 8	06MAR2003	10	72	112	70	74	102	78	2	-10	8
		DAY 15	11MAR2003	15	76	118	78	80	116	86	4	-2	8
		DAY 22	18MAR2003	22	80	126	78	82	124	88	2	-2	10
		DAY 29	25MAR2003	29	84	110	60	80	116	80	-4	6	20
		DAY 36	01APR2003	36	76	120	68	74	122	88	-2	2	20
		DAY 43	07APR2003	42	68	114	76	63	116	86	-5	2	10
		DAY 50	15APR2003	50	68	102	68	68	108	70	0	6	2
		DAY 57	24APR2003	59	60	106	66	64	102	70	4	-4	4
		FINAL		59	60	106	66	64	102	70	4	-4	4
	E0039023	SCREEN	05FEB2003	-19	63	122	80	68	128	92	5	6	12
		DAY 1	24FEB2003	1	74	110	66	80	108	80	6	-2	14
		BASELINE			74	110	66	80	108	80	6	-2	14
		DAY 8	03MAR2003	8	73	108	70	80	110	80	7	2	10
		FINAL		8	73	108	70	80	110	80	7	2	10
	E0039030	SCREEN	12MAR2003	-12	68	132	84	64	126	86	-4	-6	2
		DAY 1	24MAR2003	1	66	136	76	69	130	82	3	-6	6
		BASELINE			66	136	76	69	130	82	3	-6	6
		DAY 8	31MAR2003	8	68	130	82	78	138	84	10	8	2
		DAY 15	07APR2003	15	68	128	60	72	132	80	4	4	20
		DAY 22	14APR2003	22	70	132	86	78	140	96	8	8	10
		DAY 29	21APR2003	29	66	124	74	70	116	80	4	-8	6
		DAY 36	28APR2003	36	72	136	92	70	132	88	-2	-4	-4
		DAY 43	05MAY2003	43	64	140	90	64	142	92	0	2	2
		DAY 50	13MAY2003	51	68	140	78	78	136	86	10	-4	8
		DAY 57	19MAY2003	57	64	150	82	74	142	86	10	-8	4
		FINAL		57	64	150	82	74	142	86	10	-8	4
	E0039031	SCREEN	05MAR2003	-19	82	100	70	80	98	74	-2	-2	4
		DAY 1	24MAR2003	1	74	98	70	76	94	64	2	-4	-6
		BASELINE			74	98	70	76	94	64	2	-4	-6
		DAY 8	31MAR2003	8	88	104	70	100	94	72	12	-10	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039031	DAY 15	07APR2003	15	92	100	60	90	98	60	-2	-2	0
		DAY 22	15APR2003	23	82	102	60	84	112	80	2	10	20
		DAY 29	21APR2003	29	82	104	70	84	106	80	2	2	10
		DAY 36	28APR2003	36	92	104	74	84	108	80	-8	4	6
		DAY 43	05MAY2003	43	90	104	70	96	108	80	6	4	10
		DAY 50	13MAY2003	51	88	110	70	92	114	78	4	4	8
		DAY 57	20MAY2003	58	72	106	66	80	108	74	8	2	8
		FINAL		58	72	106	66	80	108	74	8	2	8
	E0039037	SCREEN	26MAR2003	-21	76	124	74	92	122	88	16	-2	14
		DAY 1	16APR2003	1	84	126	78	80	122	78	-4	-4	0
		BASELINE			84	126	78	80	122	78	-4	-4	0
		DAY 8	23APR2003	8	88	132	72	96	136	80	8	4	8
		DAY 15	01MAY2003	16	84	128	76	96	124	88	12	-4	12
		DAY 22	07MAY2003	22	72	104	78	72	102	76	0	-2	-2
		DAY 29	15MAY2003	30	88	122	88	96	116	90	8	-6	2
		DAY 36	21MAY2003	36	80	128	80	88	130	88	8	2	8
		DAY 43	28MAY2003	43	72	120	76	74	120	74	2	0	-2
		DAY 50	05JUN2003	51	96	126	70	96	124	78	0	-2	8
		DAY 57	12JUN2003	58	76	128	88	82	132	92	6	4	4
		FINAL		58	76	128	88	82	132	92	6	4	4
	E0039038	SCREEN	26MAR2003	-28	80	126	90	82	132	86	2	6	-4
		DAY 1	23APR2003	1	60	116	82	64	120	84	4	4	2
		BASELINE			60	116	82	64	120	84	4	4	2
		DAY 8	30APR2003	8	72	116	88	78	120	92	6	4	4
		DAY 22	15MAY2003	23	72	106	74	76	110	70	4	4	-4
		DAY 29	21MAY2003	29	76	110	70	80	116	80	4	6	10
		DAY 36	29MAY2003	37	76	136	98	88	118	90	12	-18	-8
		DAY 57	20JUN2003	59	68	110	78	76	116	82	8	6	4
		FINAL		59	68	110	78	76	116	82	8	6	4
	E0039047	SCREEN	12MAY2003	-7	84	134	86	92	120	82	8	-14	-4
		DAY 1	19MAY2003	1	70	134	88	84	128	90	14	-6	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0039047	BASELINE			70	134	88	84	128	90	14	-6	2
		DAY 8	27MAY2003	9	76	148	86	88	130	80	12	-18	-6
		DAY 15	03JUN2003	16	63	142	96	76	128	98	13	-14	2
		DAY 22	09JUN2003	22	64	144	90	80	130	92	16	-14	2
		DAY 29	16JUN2003	29	80	126	60	78	130	88	-2	4	28
		DAY 36	23JUN2003	36	62	124	86	72	130	90	10	6	4
		DAY 43	30JUN2003	43	64	130	86	74	116	84	10	-14	-2
		DAY 50	07JUL2003	50	65	134	88	80	128	96	15	-6	8
		DAY 57	14JUL2003	57	76	142	86	68	126	90	-8	-16	4
		FINAL		57	76	142	86	68	126	90	-8	-16	4
	E0039059	SCREEN	03JUL2003	-8	68	122	70	68	134	72	0	12	2
		DAY 1	11JUL2003	1	60	114	68	68	124	78	8	10	10
		BASELINE			60	114	68	68	124	78	8	10	10
		DAY 8	18JUL2003	8	76	120	68	80	126	70	4	6	2
		DAY 15	25JUL2003	15	73	116	70	74	116	80	1	0	10
		DAY 22	01AUG2003	22	60	118	90	70	106	80	10	-12	-10
		DAY 29	07AUG2003	28	60	106	60	68	110	70	8	4	10
		DAY 36	15AUG2003	36	60	120	78	69	108	80	9	-12	2
		DAY 43	21AUG2003	42	64	122	80	64	122	78	0	0	-2
		DAY 50	29AUG2003	50	60	114	60	72	120	60	12	6	0
		DAY 57	05SEP2003	57	56	110	70	60	118	74	4	8	4
		FINAL		57	56	110	70	60	118	74	4	8	4
	E0041007	SCREEN	05MAR2003	-8	60	110	68	78	124	88	18	14	20
		DAY 1	13MAR2003	1	80	130	60	88	140	78	8	10	18
		BASELINE			80	130	60	88	140	78	8	10	18
		DAY 8	20MAR2003	8	79	120	60	80	140	70	1	20	10
		DAY 15	27MAR2003	15	82	130	70	88	140	80	6	10	10
		DAY 22	03APR2003	22	70	110	60	72	120	70	2	10	10
		DAY 29	10APR2003	29	62	112	70	66	110	70	4	-2	0
		DAY 36	17APR2003	36	68	120	82	80	116	84	12	-4	2
		DAY 43	25APR2003	44	76	110	78	80	112	78	4	2	0
		DAY 50	01MAY2003	50	66	117	76	70	118	80	4	1	4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0041007	DAY 57	08MAY2003	57	72	114	76	80	120	78	8	6	2
		FINAL		57	72	114	76	80	120	78	8	6	2
	E0041010	SCREEN	23APR2003	-7	72	118	78	76	116	72	4	-2	-6
		DAY 1	30APR2003	1	90	120	80	86	122	80	-4	2	0
		BASELINE			90	120	80	86	122	80	-4	2	0
		DAY 8	08MAY2003	9	90	122	82	88	120	80	-2	-2	-2
		DAY 15	14MAY2003	15	90	122	82	84	120	80	-6	-2	-2
		DAY 22	21MAY2003	22	90	122	82	86	120	82	-4	-2	0
		DAY 29	28MAY2003	29	88	124	88	88	130	84	0	6	-4
		DAY 36	04JUN2003	36	86	132	90	86	128	86	0	-4	-4
		DAY 43	11JUN2003	43	82	130	84	84	130	82	2	0	-2
		FINAL		43	82	130	84	84	130	82	2	0	-2
	E0041011	SCREEN	15MAY2003	-7	74	130	78	82	140	88	8	10	10
		DAY 1	22MAY2003	1	76	128	78	80	132	82	4	4	4
		BASELINE			76	128	78	80	132	82	4	4	4
		DAY 8	02JUN2003	12	76	130	78	80	130	80	4	0	2
		DAY 15	06JUN2003	16	78	132	82	76	130	80	-2	-2	-2
		DAY 22	16JUN2003	26	76	130	80	76	130	78	0	0	-2
		DAY 29	20JUN2003	30	78	126	82	78	126	80	0	0	-2
		DAY 36	26JUN2003	36	76	126	80	78	126	82	2	0	2
		DAY 43	03JUL2003	43	72	124	82	74	126	80	2	2	-2
		DAY 50	10JUL2003	50	76	126	84	78	126	86	2	0	2
		DAY 57	17JUL2003	57	88	120	78	92	122	74	4	2	-4
		FINAL		57	88	120	78	92	122	74	4	2	-4
	E0041012	SCREEN	05JUN2003	-14	82	126	92	80	130	96	-2	4	4
		DAY 1	19JUN2003	1	82	150	90	86	156	110	4	6	20
		BASELINE			82	150	90	86	156	110	4	6	20
		DAY 8	26JUN2003	8	88	148	88	90	148	90	2	0	2
		DAY 15	03JUL2003	15	86	148	86	86	148	88	0	0	2
		DAY 22	10JUL2003	22	80	140	80	84	142	78	4	2	-2
		DAY 29	17JUL2003	29	82	138	80	84	136	80	2	-2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0041012	DAY 36	24JUL2003	36	84	132	92	84	130	86	0	-2	-6
		DAY 43	31JUL2003	43	88	134	88	86	132	84	-2	-2	-4
		DAY 50	07AUG2003	50	78	152	94	76	150	90	-2	-2	-4
		DAY 57	14AUG2003	57	76	160	110	78	150	112	2	-10	2
		FINAL		57	76	160	110	78	150	112	2	-10	2
PLACEBO (BIPOLAR II)	E0001004	SCREEN	23APR2003	-8	60	90	60	60	90	60	0	0	0
		DAY 1	01MAY2003	1	60	95	70	65	100	70	5	5	0
		BASELINE			60	95	70	65	100	70	5	5	0
		DAY 8	09MAY2003	9	60	120	70	62	120	75	2	0	5
		DAY 15	16MAY2003	16	62	120	70	65	125	75	3	5	5
		DAY 22	23MAY2003	23	60	110	65	62	110	70	2	0	5
		DAY 29	29MAY2003	29	62	120	75	63	120	80	1	0	5
		DAY 36	06JUN2003	37	62	110	70	63	115	75	1	5	5
		DAY 43	12JUN2003	43	80	110	70	80	100	70	0	-10	0
		DAY 50	20JUN2003	51	62	110	80	64	115	80	2	5	0
		DAY 57	02JUL2003	63	82	98	70	82	98	70	0	0	0
		FINAL		63	82	98	70	82	98	70	0	0	0
	E0005023	SCREEN	28JAN2003	-8	76	106	68	80	108	70	4	2	2
		DAY 1	05FEB2003	1	72	100	70	72	104	74	0	4	4
		BASELINE			72	100	70	72	104	74	0	4	4
		DAY 8	13FEB2003	9	80	100	64	80	100	60	0	0	-4
		DAY 15	20FEB2003	16	96	104	64	100	100	62	4	-4	-2
		DAY 22	27FEB2003	23	72	100	70	72	100	64	0	0	-6
		DAY 29	06MAR2003	30	72	100	70	72	100	70	0	0	0
		DAY 36	13MAR2003	37	80	100	70	80	96	68	0	-4	-2
		DAY 43	18MAR2003	42	80	100	60	80	100	60	0	0	0
		DAY 50	26MAR2003	50	80	100	60	80	90	60	0	-10	0
		DAY 57	01APR2003	56	80	90	60	80	90	60	0	0	0
		FINAL		56	80	90	60	80	90	60	0	0	0
	E0005034	SCREEN	08APR2003	-7	60	95	60	60	107	63	0	12	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0005034	DAY 1	15APR2003	1	68	100	60	68	100	60	0	0	0
		BASELINE			68	100	60	68	100	60	0	0	0
		DAY 8	23APR2003	9	68	100	70	68	90	60	0	-10	-10
		DAY 15	01MAY2003	17	76	118	70	68	122	80	-8	4	10
		DAY 22	06MAY2003	22	68	110	70	68	100	60	0	-10	-10
		DAY 29	13MAY2003	29	64	108	64	64	100	60	0	-8	-4
		DAY 36	22MAY2003	38	60	120	80	60	110	70	0	-10	-10
		DAY 43	28MAY2003	44	60	120	70	60	110	70	0	-10	0
		DAY 50	05JUN2003	52	80	110	70	80	110	70	0	0	0
		DAY 57	09JUN2003	56	80	110	70	74	110	70	-6	0	0
		FINAL		56	80	110	70	74	110	70	-6	0	0
	E0005041	SCREEN	17JUN2003	-7	76	130	80	72	132	80	-4	2	0
		DAY 1	24JUN2003	1	76	102	72	68	110	68	-8	8	-4
		BASELINE			76	102	72	68	110	68	-8	8	-4
		DAY 8	01JUL2003	8	76	114	76	76	114	78	0	0	2
		DAY 15	08JUL2003	15	64	110	62	64	110	64	0	0	2
		DAY 22	16JUL2003	23	68	130	82	64	128	84	-4	-2	2
		DAY 29	22JUL2003	29	64	118	76	68	122	80	4	4	4
		DAY 36	28JUL2003	35	68	124	74	72	120	76	4	-4	2
		DAY 43	04AUG2003	42	76	116	68	72	120	74	-4	4	6
		DAY 50	11AUG2003	49	76	120	78	80	116	76	4	-4	-2
		DAY 57	18AUG2003	56	68	112	70	64	108	70	-4	-4	0
		FINAL		56	68	112	70	64	108	70	-4	-4	0
	E0007004	SCREEN	24JAN2003	-6	70	118	70	78	116	70	8	-2	0
		DAY 1	30JAN2003	1	72	116	70	76	112	74	4	-4	4
		BASELINE			72	116	70	76	112	74	4	-4	4
		DAY 8	07FEB2003	9	74	110	70	78	116	76	4	6	6
		DAY 15	12FEB2003	14	78	112	64	84	118	70	6	6	6
		FINAL		14	78	112	64	84	118	70	6	6	6
	E0007010	SCREEN	11APR2003	-7	70	122	78	78	130	80	8	8	2
		DAY 1	18APR2003	1	72	118	70	76	124	76	4	6	6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0007010	BASELINE				72	118	70	76	124	76	4	6	6
		DAY 8		25APR2003	8	70	120	70	76	124	68	6	4	-2
		DAY 15		02MAY2003	15	70	120	70	78	128	84	8	8	14
		DAY 22		09MAY2003	22	70	110	70	74	118	72	4	8	2
		DAY 29		16MAY2003	29	70	108	66	76	114	74	6	6	8
		DAY 36		23MAY2003	36	70	120	72	74	126	80	4	6	8
		DAY 43		29MAY2003	42	78	124	80	82	128	76	4	4	-4
		DAY 50		06JUN2003	50	72	126	82	76	132	84	4	6	2
		DAY 57		16JUN2003	60	76	116	66	84	110	70	8	-6	4
		FINAL			60	76	116	66	84	110	70	8	-6	4
	E0007012	SCREEN		02MAY2003	-14	70	110	70	74	104	68	4	-6	-2
		DAY 1		16MAY2003	1	72	104	60	76	108	66	4	4	6
		BASELINE				72	104	60	76	108	66	4	4	6
		DAY 8		23MAY2003	8	70	94	64	74	100	68	4	6	4
		DAY 15		29MAY2003	14	72	90	60	76	96	64	4	6	4
		DAY 22		06JUN2003	22	72	92	60	78	94	64	6	2	4
		DAY 29		13JUN2003	29	68	92	64	72	96	66	4	4	2
		DAY 36		20JUN2003	36	72	106	70	76	110	74	4	4	4
		DAY 43		25JUN2003	41	74	94	68	74	98	64	0	4	-4
		DAY 43	*	01JUL2003	47	70	100	70	74	106	74	4	6	4
		FINAL			47	70	100	70	74	106	74	4	6	4
	E0009007	SCREEN		27JAN2003	-7	80	138	88	80	130	88	0	-8	0
		DAY 1		03FEB2003	1	92	130	80	80	120	88	-12	-10	8
		BASELINE				92	130	80	80	120	88	-12	-10	8
		DAY 8		10FEB2003	8	70	130	84	80	134	88	10	4	4
		DAY 15		17FEB2003	15	64	130	80	80	134	84	16	4	4
		DAY 22		25FEB2003	23	78	130	72	80	130	80	2	0	8
		DAY 29		03MAR2003	29	80	120	84	86	120	90	6	0	6
		FINAL			29	80	120	84	86	120	90	6	0	6
	E0009008	SCREEN		04FEB2003	-8	66	118	80	70	120	80	4	2	0
		DAY 1		12FEB2003	1	72	130	84	76	128	86	4	-2	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0009008	BASELINE			72	130	84	76	128	86	4	-2	2
		DAY 8	19FEB2003	8	68	100	60	72	106	72	4	6	12
		DAY 15	25FEB2003	14	78	100	70	80	110	70	2	10	0
		DAY 22	04MAR2003	21	60	120	70	70	120	80	10	0	10
		DAY 29	11MAR2003	28	80	120	84	78	120	80	-2	0	-4
		DAY 36	18MAR2003	35	60	100	64	80	110	80	20	10	16
		DAY 43	26MAR2003	43	66	100	60	68	110	76	2	10	16
		DAY 50	03APR2003	51	72	100	70	76	106	74	4	6	4
		DAY 57	08APR2003	56	68	100	60	74	100	70	6	0	10
		FINAL		56	68	100	60	74	100	70	6	0	10
	E0011001	SCREEN	25OCT2002	-7	68	118	78	72	118	80	4	0	2
		DAY 1	01NOV2002	1	72	118	78	76	116	78	4	-2	0
		BASELINE			72	118	78	76	116	78	4	-2	0
		DAY 8	07NOV2002	7	84	120	68	72	112	78	-12	-8	10
		DAY 15	14NOV2002	14	72	118	72	80	122	74	8	4	2
		DAY 22	21NOV2002	21	78	122	70	72	118	70	-6	-4	0
		DAY 29	27NOV2002	27	88	116	68	84	118	70	-4	2	2
		DAY 36	05DEC2002	35	76	118	72	80	112	72	4	-6	0
		DAY 43	12DEC2002	42	84	108	72	92	110	74	8	2	2
		DAY 50	19DEC2002	49	77	118	74	88	129	74	11	11	0
		DAY 57	26DEC2002	56	68	104	71	66	103	75	-2	-1	4
		FINAL		56	68	104	71	66	103	75	-2	-1	4
	E0011011	SCREEN	12FEB2003	-8	68	98	74	70	98	74	2	0	0
		DAY 1	20FEB2003	1	72	110	70	80	108	72	8	-2	2
		BASELINE			72	110	70	80	108	72	8	-2	2
		DAY 8	26FEB2003	7	68	110	74	72	106	72	4	-4	-2
		DAY 15	05MAR2003	14	80	112	72	82	110	74	2	-2	2
		DAY 22	12MAR2003	21	68	108	70	80	106	72	12	-2	2
		DAY 29	19MAR2003	28	68	100	66	72	102	68	4	2	2
		DAY 36	26MAR2003	35	80	108	72	80	106	72	0	-2	0
		DAY 43	02APR2003	42	76	106	74	88	104	74	12	-2	0
		DAY 50	09APR2003	49	76	108	74	76	104	72	0	-4	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0011011	DAY 57	16APR2003	56	72	110	72	80	108	72	8	-2	0
		FINAL		56	72	110	72	80	108	72	8	-2	0
	E0011013	SCREEN	25MAR2003	-23	80	138	98	68	140	88	-12	2	-10
		DAY 1	17APR2003	1	64	132	84	76	132	86	12	0	2
		BASELINE			64	132	84	76	132	86	12	0	2
		DAY 8	24APR2003	8	68	126	84	76	126	88	8	0	4
		DAY 15	01MAY2003	15	64	120	84	68	120	86	4	0	2
		DAY 22	08MAY2003	22	68	112	80	72	114	82	4	2	2
		DAY 29	15MAY2003	29	72	122	80	76	124	82	4	2	2
		DAY 36	22MAY2003	36	80	130	88	84	128	90	4	-2	2
		DAY 43	29MAY2003	43	76	128	84	80	126	88	4	-2	4
		DAY 50	05JUN2003	50	72	126	82	76	124	82	4	-2	0
		DAY 57	12JUN2003	57	68	130	86	72	130	88	4	0	2
		FINAL		57	68	130	86	72	130	88	4	0	2
	E0011014	SCREEN	31MAR2003	-7	80	118	78	82	114	76	2	-4	-2
		DAY 1	07APR2003	1	68	126	74	76	118	78	8	-8	4
		BASELINE			68	126	74	76	118	78	8	-8	4
		DAY 8	14APR2003	8	76	114	78	88	122	82	12	8	4
		DAY 29	08MAY2003	32	72	122	70	88	120	70	16	-2	0
		FINAL		32	72	122	70	88	120	70	16	-2	0
	E0011021	SCREEN	15MAY2003	-7	64	112	68	68	114	70	4	2	2
		DAY 1	22MAY2003	1	64	110	60	78	110	64	14	0	4
		BASELINE			64	110	60	78	110	64	14	0	4
		DAY 8	29MAY2003	8	64	108	64	76	110	66	12	2	2
		DAY 15	05JUN2003	15	64	112	64	76	110	62	12	-2	-2
		DAY 22	12JUN2003	22	72	110	64	80	110	62	8	0	-2
		DAY 29	20JUN2003	30	72	100	62	76	98	62	4	-2	0
		DAY 36	27JUN2003	37	72	112	68	76	110	68	4	-2	0
		DAY 43	02JUL2003	42	72	114	68	72	112	62	0	-2	-6
		DAY 50	10JUL2003	50	74	114	62	72	110	60	-2	-4	-2
		DAY 57	21JUL2003	61	64	110	68	64	106	62	0	-4	-6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0011021	FINAL		61	64	110	68	64	106	62	0	-4	-6
	E0013008	SCREEN	19MAR2003	-7	72	120	80	72	120	80	0	0	0
		DAY 1	26MAR2003	1	66	120	80	72	120	80	6	0	0
		BASELINE			66	120	80	72	120	80	6	0	0
		DAY 8	02APR2003	8	60	115	80	66	118	80	6	3	0
		DAY 15	09APR2003	15	66	120	60	60	118	62	-6	-2	2
		DAY 22	17APR2003	23	76	122	68	74	120	70	-2	-2	2
		DAY 29	23APR2003	29	72	120	80	66	120	80	-6	0	0
		DAY 36	30APR2003	36	80	124	80	80	124	78	0	0	-2
		DAY 43	07MAY2003	43	68	120	76	64	120	76	-4	0	0
		DAY 50	12MAY2003	48	68	120	64	60	120	68	-8	0	4
		DAY 57	19MAY2003	55	68	112	80	64	116	78	-4	4	-2
		FINAL		55	68	112	80	64	116	78	-4	4	-2
	E0014001	SCREEN	18FEB2003	-8	72	95	63	75	92	65	3	-3	2
		DAY 1	26FEB2003	1	68	100	68	69	97	72	1	-3	4
		BASELINE			68	100	68	69	97	72	1	-3	4
		DAY 8	05MAR2003	8	72	90	65	75	100	67	3	10	2
		DAY 15	12MAR2003	15	96	96	60	100	94	62	4	-2	2
		DAY 22	19MAR2003	22	84	100	66	92	90	66	8	-10	0
		DAY 29	25MAR2003	28	84	105	70	88	95	63	4	-10	-7
		DAY 36	01APR2003	35	80	100	70	82	105	68	2	5	-2
		FINAL		35	80	100	70	82	105	68	2	5	-2
	E0014013	SCREEN	20MAY2003	-7	90	98	67	92	107	67	2	9	0
		DAY 1	27MAY2003	1	74	110	70	78	116	68	4	6	-2
		BASELINE			74	110	70	78	116	68	4	6	-2
		DAY 8	04JUN2003	9	78	110	76	82	100	68	4	-10	-8
		DAY 15	13JUN2003	18	74	104	68	78	98	66	4	-6	-2
		DAY 22	18JUN2003	23	74	114	66	82	102	64	8	-12	-2
		DAY 29	25JUN2003	30	80	102	78	82	102	76	2	0	-2
		DAY 36	02JUL2003	37	82	112	70	88	110	72	6	-2	2
		DAY 43	10JUL2003	45	88	102	70	90	100	70	2	-2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0014013	DAY 50		16JUL2003	51	90	114	68	96	104	70	6	-10	2
		DAY 57		23JUL2003	58	84	102	64	96	100	64	12	-2	0
		FINAL			58	84	102	64	96	100	64	12	-2	0
	E0014014	SCREEN		03JUN2003	-7	60	115	76	62	110	70	2	-5	-6
		DAY 1		10JUN2003	1	54	110	74	56	114	74	2	4	0
		BASELINE				54	110	74	56	114	74	2	4	0
		DAY 8		18JUN2003	9	56	115	78	60	120	76	4	5	-2
		DAY 15		24JUN2003	15	52	112	68	56	108	68	4	-4	0
		DAY 22		03JUL2003	24	48	128	90	50	126	87	2	-2	-3
		DAY 29		10JUL2003	31	60	120	77	63	123	78	3	3	1
		DAY 36		18JUL2003	39	52	112	68	56	110	70	4	-2	2
		DAY 50		30JUL2003	51	64	122	72	66	120	72	2	-2	0
		DAY 57		06AUG2003	58	60	126	74	64	124	72	4	-2	-2
		FINAL			58	60	126	74	64	124	72	4	-2	-2
	E0015004	SCREEN		25NOV2002	-7	70	120	78	68	120	70	-2	0	-8
		DAY 1		02DEC2002	1	74	118	72	70	116	74	-4	-2	2
		BASELINE				74	118	72	70	116	74	-4	-2	2
		DAY 8		11DEC2002	10	68	116	70	72	118	72	4	2	2
		DAY 15		18DEC2002	17	64	112	72	70	116	68	6	4	-4
		DAY 22		27DEC2002	26	68	110	72	70	118	70	2	8	-2
		DAY 36		06JAN2003	36	62	112	68	72	118	70	10	6	2
		DAY 36	*	09JAN2003	39	60	120	68	68	116	72	8	-4	4
		DAY 43		17JAN2003	47	64	118	72	64	120	78	0	2	6
		DAY 57		29JAN2003	59	68	116	72	74	120	68	6	4	-4
		FINAL			59	68	116	72	74	120	68	6	4	-4
	E0018005	SCREEN		10DEC2002	-10	60	118	76	64	122	78	4	4	2
		DAY 1		20DEC2002	1	76	122	70	76	124	72	0	2	2
		BASELINE				76	122	70	76	124	72	0	2	2
		DAY 8		27DEC2002	8	76	128	78	80	128	76	4	0	-2
		DAY 8	*	31DEC2002	12	76	120	72	80	120	74	4	0	2
		DAY 22		10JAN2003	22	64	118	78	72	124	78	8	6	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0018005	DAY 29	17JAN2003	29	64	124	76	68	122	76	4	-2	0
		DAY 36	24JAN2003	36	76	128	72	80	130	76	4	2	4
		DAY 43	31JAN2003	43	64	112	68	68	114	68	4	2	0
		DAY 50	07FEB2003	50	72	120	70	76	126	72	4	6	2
		DAY 57	14FEB2003	57	60	120	70	64	122	70	4	2	0
		FINAL		57	60	120	70	64	122	70	4	2	0
	E0018012	SCREEN	17JAN2003	-7	70	120	76	80	120	78	10	0	2
		DAY 1	24JAN2003	1	76	108	70	88	110	72	12	2	2
		BASELINE			76	108	70	88	110	72	12	2	2
		DAY 8	30JAN2003	7	72	112	72	80	114	74	8	2	2
		DAY 15	07FEB2003	15	72	126	70	88	128	70	16	2	0
		DAY 22	14FEB2003	22	64	120	70	76	122	70	12	2	0
		DAY 29	21FEB2003	29	76	120	68	88	124	70	12	4	2
		DAY 36	26FEB2003	34	76	126	70	88	128	72	12	2	2
		FINAL		34	76	126	70	88	128	72	12	2	2
	E0019019	SCREEN	14JAN2003	-9	72	115	75	80	120	70	8	5	-5
		DAY 1	23JAN2003	1	60	105	68	64	105	75	4	0	7
		BASELINE			60	105	68	64	105	75	4	0	7
		DAY 8	30JAN2003	8	72	118	80	76	122	85	4	4	5
		DAY 15	06FEB2003	15	76	115	70	84	125	80	8	10	10
		FINAL		15	76	115	70	84	125	80	8	10	10
	E0019033	SCREEN	10MAR2003	-8	64	120	80	72	120	70	8	0	-10
		DAY 1	18MAR2003	1	70	110	70	74	120	80	4	10	10
		BASELINE			70	110	70	74	120	80	4	10	10
		DAY 8	27MAR2003	10	68	110	60	76	110	75	8	0	15
		DAY 15	03APR2003	17	68	110	60	80	100	60	12	-10	0
		DAY 22	10APR2003	24	64	110	60	72	110	62	8	0	2
		DAY 29	14APR2003	28	64	110	70	68	100	70	4	-10	0
		DAY 36	22APR2003	36	68	120	74	76	110	70	8	-10	-4
		DAY 43	01MAY2003	45	72	110	59	76	110	70	4	0	11
		DAY 50	08MAY2003	52	74	122	72	72	116	68	-2	-6	-4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0019033	DAY 57	15MAY2003	59	72	104	62	80	102	60	8	-2	-2
		FINAL		59	72	104	62	80	102	60	8	-2	-2
	E0019038	SCREEN	10APR2003	-14	60	105	60	64	110	65	4	5	5
		DAY 1	24APR2003	1	60	105	65	66	108	65	6	3	0
		BASELINE			60	105	65	66	108	65	6	3	0
		DAY 8	01MAY2003	8	56	120	70	76	118	78	20	-2	8
		DAY 15	07MAY2003	14	60	110	60	66	105	60	6	-5	0
		DAY 22	14MAY2003	21	62	112	58	72	108	70	10	-4	12
		DAY 29	21MAY2003	28	60	110	65	64	115	70	4	5	5
		DAY 36	28MAY2003	35	64	105	65	64	110	70	0	5	5
		DAY 43	04JUN2003	42	62	118	50	68	82	60	6	-36	10
		DAY 50	11JUN2003	49	60	110	65	64	120	70	4	10	5
		DAY 57	18JUN2003	56	60	104	60	72	110	68	12	6	8
		FINAL		56	60	104	60	72	110	68	12	6	8
	E0019046	SCREEN	19JUN2003	-7	60	110	70	68	110	70	8	0	0
		DAY 1	26JUN2003	1	64	102	70	60	104	78	-4	2	8
		BASELINE			64	102	70	60	104	78	-4	2	8
		DAY 8	03JUL2003	8	68	98	68	60	100	80	-8	2	12
		DAY 15	10JUL2003	15	60	102	94	80	100	82	20	-2	-12
		DAY 22	17JUL2003	22	60	100	75	68	95	70	8	-5	-5
		DAY 29	24JUL2003	29	64	94	76	80	94	76	16	0	0
		DAY 36	30JUL2003	35	64	100	70	70	95	70	6	-5	0
		DAY 50	14AUG2003	50	64	105	75	70	95	75	6	-10	0
		DAY 57	21AUG2003	57	68	112	76	64	100	74	-4	-12	-2
		FINAL		57	68	112	76	64	100	74	-4	-12	-2
	E0019047	SCREEN	26JUN2003	-12	72	112	72	76	116	76	4	4	4
		DAY 1	08JUL2003	1	68	118	64	84	116	82	16	-2	18
		BASELINE			68	118	64	84	116	82	16	-2	18
		DAY 8	17JUL2003	10	68	120	70	82	118	75	14	-2	5
		DAY 15	24JUL2003	17	80	122	68	100	118	82	20	-4	14
		DAY 22	31JUL2003	24	76	118	64	100	116	76	24	-2	12

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0019047	DAY 29	07AUG2003	31	88	118	74	100	124	76	12	6	2
		DAY 36	14AUG2003	38	76	116	60	84	122	78	8	6	18
		DAY 43	21AUG2003	45	80	112	60	88	110	60	8	-2	0
		DAY 50	28AUG2003	52	80	115	70	84	105	70	4	-10	0
		DAY 57	04SEP2003	59	80	122	74	84	118	74	4	-4	0
		FINAL		59	80	122	74	84	118	74	4	-4	0
	E0019048	SCREEN	03JUL2003	-7	68	126	76	80	126	86	12	0	10
		DAY 1	10JUL2003	1	72	122	80	84	130	82	12	8	2
		BASELINE			72	122	80	84	130	82	12	8	2
		DAY 8	17JUL2003	8	72	120	75	76	120	80	4	0	5
		DAY 15	22JUL2003	13	76	122	80	76	126	85	0	4	5
		DAY 22	31JUL2003	22	80	120	80	76	118	78	-4	-2	-2
		DAY 29	07AUG2003	29	80	122	78	84	120	76	4	-2	-2
		DAY 36	14AUG2003	36	80	110	70	72	104	78	-8	-6	8
		DAY 43	21AUG2003	43	76	112	75	82	110	75	6	-2	0
		DAY 50	28AUG2003	50	76	124	82	72	110	80	-4	-14	-2
		DAY 57	03SEP2003	56	68	116	84	72	114	80	4	-2	-4
		FINAL		56	68	116	84	72	114	80	4	-2	-4
	E0022006	SCREEN	21OCT2002	-22	93	121	83	101	115	80	8	-6	-3
		DAY 1	12NOV2002	1	64	120	68	68	108	70	4	-12	2
		BASELINE			64	120	68	68	108	70	4	-12	2
		DAY 8	19NOV2002	8	84	112	64	84	98	68	0	-14	4
		DAY 15	26NOV2002	15	76	102	68	92	100	72	16	-2	4
		DAY 22	03DEC2002	22	72	104	54	72	102	60	0	-2	6
		DAY 29	10DEC2002	29	68	108	68	72	98	72	4	-10	4
		DAY 36	17DEC2002	36	68	100	58	78	100	62	10	0	4
		DAY 43	24DEC2002	43	84	100	52	78	98	54	-6	-2	2
		DAY 50	31DEC2002	50	66	94	56	75	100	62	9	6	6
		DAY 57	07JAN2003	57	90	110	56	84	98	66	-6	-12	10
		FINAL		57	90	110	56	84	98	66	-6	-12	10
	E0022047	SCREEN	21MAR2003	-7	72	118	80	76	120	82	4	2	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0022047	DAY 1	28MAR2003	1	64	110	82	68	108	80	4	-2	-2
		BASELINE			64	110	82	68	108	80	4	-2	-2
		DAY 8	04APR2003	8	68	118	74	80	102	80	12	-16	6
		DAY 15	11APR2003	15	78	118	82	72	104	80	-6	-14	-2
		DAY 22	17APR2003	21	64	132	82	80	110	80	16	-22	-2
		DAY 29	25APR2003	29	64	118	76	78	110	80	14	-8	4
		DAY 36	02MAY2003	36	68	120	76	72	118	82	4	-2	6
		DAY 43	09MAY2003	43	72	122	82	76	126	80	4	4	-2
		DAY 50	16MAY2003	50	64	132	76	88	124	82	24	-8	6
		DAY 57	23MAY2003	57	72	122	80	84	130	102	12	8	22
		FINAL		57	72	122	80	84	130	102	12	8	22
	E0022075	SCREEN	25JUN2003	-13	66	112	76	78	108	80	12	-4	4
		DAY 1	08JUL2003	1	57	110	68	66	122	74	9	12	6
		BASELINE			57	110	68	66	122	74	9	12	6
		DAY 8	15JUL2003	8	60	114	74	72	106	72	12	-8	-2
		DAY 15	22JUL2003	15	66	104	68	75	106	78	9	2	10
		DAY 22	29JUL2003	22	60	106	74	63	102	80	3	-4	6
		DAY 29	05AUG2003	29	68	102	64	80	100	66	12	-2	2
		DAY 36	12AUG2003	36	62	106	60	76	116	68	14	10	8
		DAY 43	19AUG2003	43	64	106	64	76	110	68	12	4	4
		DAY 50	26AUG2003	50	64	104	60	84	108	64	20	4	4
		DAY 57	03SEP2003	58	72	104	58	76	120	72	4	16	14
		FINAL		58	72	104	58	76	120	72	4	16	14
	E0023012	SCREEN	31JAN2003	-6	88	136	88	86	140	80	-2	4	-8
		DAY 1	06FEB2003	1	88	116	62	97	144	83	9	28	21
		BASELINE			88	116	62	97	144	83	9	28	21
		DAY 8	17FEB2003	12	76	118	76	80	116	74	4	-2	-2
		DAY 15	20FEB2003	15	76	110	76	80	120	74	4	10	-2
		DAY 22	28FEB2003	23	80	126	70	80	120	70	0	-6	0
		DAY 29	07MAR2003	30	82	126	72	85	147	81	3	21	9
		DAY 36	14MAR2003	37	75	110	80	91	142	75	16	32	-5
		DAY 43	21MAR2003	44	74	118	68	78	145	77	4	27	9

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0023012	DAY 50	28MAR2003	51	85	129	60	80	126	64	-5	-3	4
		DAY 57	04APR2003	58	68	120	70	70	124	68	2	4	-2
		FINAL		58	68	120	70	70	124	68	2	4	-2
	E0023016	SCREEN	15MAY2003	-7	82	120	75	84	120	75	2	0	0
		DAY 1	22MAY2003	1	79	117	83	78	106	74	-1	-11	-9
		BASELINE			79	117	83	78	106	74	-1	-11	-9
		DAY 8	29MAY2003	8	78	94	64	97	105	74	19	11	10
		DAY 15	05JUN2003	15	76	103	69	84	108	70	8	5	1
		DAY 22	12JUN2003	22	69	103	70	95	101	61	26	-2	-9
		DAY 29	19JUN2003	29	63	101	67	70	108	71	7	7	4
		DAY 36	26JUN2003	36	74	85	58	78	98	64	4	13	6
		DAY 43	01JUL2003	41	70	91	63	85	104	73	15	13	10
		DAY 50	14JUL2003	54	72	94	64	84	100	68	12	6	4
		DAY 57	17JUL2003	57	80	96	74	84	102	70	4	6	-4
		FINAL		57	80	96	74	84	102	70	4	6	-4
	E0023018	SCREEN	18MAR2003	-9	66	140	94	71	129	84	5	-11	-10
		DAY 1	27MAR2003	1	60	113	75	66	110	74	6	-3	-1
		BASELINE			60	113	75	66	110	74	6	-3	-1
		DAY 8	03APR2003	8	70	120	76	74	120	70	4	0	-6
		DAY 15	10APR2003	15	69	115	71	70	110	70	1	-5	-1
		DAY 22	16APR2003	21	86	120	80	91	116	76	5	-4	-4
		DAY 29	24APR2003	29	84	120	80	88	114	72	4	-6	-8
		DAY 36	02MAY2003	37	66	110	79	68	108	76	2	-2	-3
		DAY 43	12MAY2003	47	67	133	91	68	130	90	1	-3	-1
		DAY 50	15MAY2003	50	64	136	95	70	125	84	6	-11	-11
		DAY 57	22MAY2003	57	71	128	82	80	126	80	9	-2	-2
		FINAL		57	71	128	82	80	126	80	9	-2	-2
	E0023036	SCREEN	10JUN2003	-10	86	121	73	85	120	70	-1	-1	-3
		DAY 1	20JUN2003	1	88	119	71	90	120	74	2	1	3
		BASELINE			88	119	71	90	120	74	2	1	3
		DAY 8	26JUN2003	7	99	110	63	104	104	55	5	-6	-8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0023036	DAY 15		02JUL2003	13	88	124	81	90	120	80	2	-4	-1
		DAY 22		09JUL2003	20	99	100	61	99	104	64	0	4	3
		DAY 29		16JUL2003	27	95	105	75	95	100	61	0	-5	-14
		DAY 29	*	22JUL2003	33	90	104	64	90	100	60	0	-4	-4
		DAY 36		29JUL2003	40	80	116	67	90	104	60	10	-12	-7
		DAY 43		05AUG2003	47	99	110	82	101	110	80	2	0	-2
		DAY 57		13AUG2003	55	102	110	63	111	121	75	9	11	12
		FINAL			55	102	110	63	111	121	75	9	11	12
	E0023046	SCREEN		11JUL2003	-12	84	126	88	97	122	84	13	-4	-4
		DAY 1		23JUL2003	1	69	136	85	86	146	92	17	10	7
		BASELINE				69	136	85	86	146	92	17	10	7
		DAY 8		01AUG2003	10	72	170	90	86	179	94	14	9	4
		DAY 15		08AUG2003	17	74	111	70	91	104	68	17	-7	-2
		DAY 22		14AUG2003	23	69	115	60	72	111	61	3	-4	1
		DAY 29		22AUG2003	31	75	133	69	85	127	75	10	-6	6
		DAY 36		28AUG2003	37	73	109	69	76	112	72	3	3	3
		DAY 43		04SEP2003	44	79	115	65	104	119	65	25	4	0
		DAY 50		11SEP2003	51	72	121	64	84	127	80	12	6	16
		DAY 57		16SEP2003	56	81	127	73	91	124	79	10	-3	6
		FINAL			56	81	127	73	91	124	79	10	-3	6
	E0026006	SCREEN		31DEC2002	-8	73	128	66	78	129	77	5	1	11
		DAY 1		08JAN2003	1	65	133	75	71	139	81	6	6	6
		BASELINE				65	133	75	71	139	81	6	6	6
		DAY 8		15JAN2003	8	94	167	83	94	136	81	0	-31	-2
		DAY 15		22JAN2003	15	90	144	80	101	146	91	11	2	11
		DAY 22		29JAN2003	22	87	128	77	94	131	83	7	3	6
		DAY 29		05FEB2003	29	82	152	77	96	127	73	14	-25	-4
		DAY 36		12FEB2003	36	87	132	74	93	122	71	6	-10	-3
		DAY 43		19FEB2003	43	72	140	76	80	142	80	8	2	4
		FINAL			43	72	140	76	80	142	80	8	2	4
	E0026021	SCREEN		14APR2003	-9	62	128	84	65	133	86	3	5	2

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0026021	DAY 1	23APR2003	1	72	128	73	66	139	86	-6	11	13
		BASELINE			72	128	73	66	139	86	-6	11	13
		DAY 8	29APR2003	7	67	129	89	70	142	90	3	13	1
		DAY 15	08MAY2003	16	65	127	94	65	127	90	0	0	-4
		FINAL		16	65	127	94	65	127	90	0	0	-4
	E0026027	SCREEN	05JUN2003	-14	64	143	79	72	103	74	8	-40	-5
		DAY 1	19JUN2003	1	83	146	81	85	132	79	2	-14	-2
		BASELINE			83	146	81	85	132	79	2	-14	-2
	E0029002		12NOV2002		76	102	70	80	104	78	4	2	8
			12NOV2002		76	102	70	80	104	78	4	2	8
	E0029004	SCREEN	13NOV2002	-6	80	98	62	84	100	72	4	2	10
		DAY 1	19NOV2002	1	80	100	70	92	96	70	12	-4	0
		BASELINE			80	100	70	92	96	70	12	-4	0
		DAY 8	26NOV2002	8	64	116	76	84	116	80	20	0	4
		DAY 15	04DEC2002	16	80	112	78	82	110	76	2	-2	-2
		DAY 22	12DEC2002	24	72	106	74	84	122	78	12	16	4
		DAY 36	26DEC2002	38	84	100	60	96	108	82	12	8	22
		DAY 43	02JAN2003	45	84	98	60	72	98	70	-12	0	10
		DAY 50	09JAN2003	52	80	104	72	76	110	78	-4	6	6
		DAY 57	16JAN2003	59	76	100	72	84	90	68	8	-10	-4
		FINAL		59	76	100	72	84	90	68	8	-10	-4
	E0029013	SCREEN	10FEB2003	-9	84	118	80	88	120	78	4	2	-2
		DAY 1	19FEB2003	1	84	120	84	84	120	80	0	0	-4
		BASELINE			84	120	84	84	120	80	0	0	-4
		DAY 8	25FEB2003	7	88	118	82	88	120	80	0	2	-2
		DAY 15	04MAR2003	14	84	115	70	88	120	80	4	5	10
		DAY 22	13MAR2003	23	80	138	88	76	134	84	-4	-4	-4
		DAY 29	20MAR2003	30	72	130	80	76	128	78	4	-2	-2
		DAY 36	25MAR2003	35	72	120	76	72	120	76	0	0	0
		DAY 43	31MAR2003	41	72	118	80	72	118	76	0	0	-4

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0029013	DAY 50		10APR2003	51	88	128	80	84	126	80	-4	-2	0
		FINAL			51	88	128	80	84	126	80	-4	-2	0
	E0029019	SCREEN		24FEB2003	-7	60	110	76	64	92	70	4	-18	-6
		DAY 1		03MAR2003	1	60	110	80	68	110	78	8	0	-2
		BASELINE				60	110	80	68	110	78	8	0	-2
		DAY 8		10MAR2003	8	56	130	88	68	110	90	12	-20	2
		DAY 15		17MAR2003	15	60	112	78	60	108	76	0	-4	-2
		FINAL			15	60	112	78	60	108	76	0	-4	-2
	E0029024	SCREEN		11MAR2003	-6	48	114	84	52	130	80	4	16	-4
		DAY 1		17MAR2003	1	52	102	78	52	102	68	0	0	-10
		BASELINE				52	102	78	52	102	68	0	0	-10
		DAY 8		25MAR2003	9	56	100	78	56	102	70	0	2	-8
		DAY 15		02APR2003	17	56	92	64	56	96	64	0	4	0
		DAY 22		09APR2003	24	52	118	68	66	108	64	14	-10	-4
		DAY 29		17APR2003	32	60	102	62	60	98	62	0	-4	0
		DAY 36		24APR2003	39	60	96	60	60	96	60	0	0	0
		DAY 50		05MAY2003	50	72	100	60	64	98	60	-8	-2	0
		DAY 57	*	12MAY2003	57	54	90	62	54	92	60	0	2	-2
		DAY 57		20MAY2003	65	58	110	60	58	108	60	0	-2	0
		FINAL			65	58	110	60	58	108	60	0	-2	0
	E0029038	SCREEN		30JUN2003	-7	68	132	78	72	136	78	4	4	0
		DAY 1		07JUL2003	1	64	128	76	68	128	76	4	0	0
		BASELINE				64	128	76	68	128	76	4	0	0
	E0031004	SCREEN		12DEC2002	-7	80	120	64	80	110	70	0	-10	6
		DAY 1		19DEC2002	1	75	124	66	68	126	80	-7	2	14
		BASELINE				75	124	66	68	126	80	-7	2	14
		DAY 8		27DEC2002	9	82	122	68	90	132	80	8	10	12
		DAY 15		03JAN2003	16	86	122	64	88	129	72	2	7	8
		DAY 22		09JAN2003	22	86	129	78	74	122	74	-12	-7	-4
		DAY 29		16JAN2003	29	72	129	68	70	130	70	-2	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0031004	DAY 36	23JAN2003	36	78	124	72	76	124	74	-2	0	2
		DAY 43	30JAN2003	43	68	124	78	74	136	86	6	12	8
		DAY 50	06FEB2003	50	78	124	74	76	126	76	-2	2	2
		DAY 57	13FEB2003	57	74	116	72	88	122	80	14	6	8
		FINAL		57	74	116	72	88	122	80	14	6	8
	E0031013	SCREEN	06MAR2003	-7	68	130	86	100	128	88	32	-2	2
		DAY 1	13MAR2003	1	86	138	80	82	142	84	-4	4	4
		BASELINE			86	138	80	82	142	84	-4	4	4
		DAY 8	20MAR2003	8	78	140	82	74	148	90	-4	8	8
		DAY 15	27MAR2003	15	66	138	78	69	142	86	3	4	8
		DAY 22	04APR2003	23	74	134	82	86	138	86	12	4	4
		DAY 29	11APR2003	30	88	130	78	86	132	86	-2	2	8
		DAY 36	17APR2003	36	96	140	86	99	142	90	3	2	4
		DAY 43	24APR2003	43	78	140	88	82	146	94	4	6	6
		DAY 50	01MAY2003	50	80	140	88	88	142	90	8	2	2
		DAY 57	08MAY2003	57	68	138	90	66	142	90	-2	4	0
		FINAL		57	68	138	90	66	142	90	-2	4	0
	E0031016	SCREEN	17MAR2003	-7	62	130	62	66	128	62	4	-2	0
		DAY 1	24MAR2003	1	56	110	58	72	112	64	16	2	6
		BASELINE			56	110	58	72	112	64	16	2	6
		DAY 8	31MAR2003	8	78	114	58	88	120	62	10	6	4
		DAY 15	07APR2003	15	62	116	60	70	120	62	8	4	2
		DAY 22	14APR2003	22	64	118	60	72	122	64	8	4	4
		FINAL		22	64	118	60	72	122	64	8	4	4
	E0031019	SCREEN	03APR2003	-8	62	114	62	70	120	68	8	6	6
		DAY 1	11APR2003	1	66	126	76	64	130	80	-2	4	4
		BASELINE			66	126	76	64	130	80	-2	4	4
		DAY 8	18APR2003	8	76	124	76	78	128	80	2	4	4
		DAY 15	25APR2003	15	72	132	80	76	132	82	4	0	2
		DAY 22	02MAY2003	22	70	122	80	72	124	80	2	2	0
		DAY 29	09MAY2003	29	68	120	70	68	124	70	0	4	0

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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0031019	DAY 29	*	12MAY2003	32	68	128	66	78	130	70	10	2	4
		FINAL			32	68	128	66	78	130	70	10	2	4
	E0031022	SCREEN		21APR2003	-7	62	108	66	66	114	74	4	6	8
		DAY 1		28APR2003	1	60	110	66	70	110	70	10	0	4
		BASELINE				60	110	66	70	110	70	10	0	4
		DAY 8		06MAY2003	9	64	120	74	66	124	80	2	4	6
		DAY 15		13MAY2003	16	62	118	72	66	124	78	4	6	6
		DAY 22		20MAY2003	23	70	130	70	68	140	76	-2	10	6
		DAY 29		27MAY2003	30	66	124	70	74	128	72	8	4	2
		FINAL			30	66	124	70	74	128	72	8	4	2
	E0033007	SCREEN		15JAN2003	-13	80	122	86	80	128	84	0	6	-2
		DAY 1		28JAN2003	1	76	126	80	84	128	88	8	2	8
		BASELINE				76	126	80	84	128	88	8	2	8
		DAY 8		04FEB2003	8	72	128	80	76	122	84	4	-6	4
		DAY 15		12FEB2003	16	76	140	80	80	130	86	4	-10	6
		DAY 22		20FEB2003	24	80	122	80	84	124	88	4	2	8
		DAY 29		25FEB2003	29	80	128	84	86	138	92	6	10	8
		DAY 36		04MAR2003	36	84	138	88	88	130	86	4	-8	-2
		DAY 43		13MAR2003	45	80	120	80	84	130	90	4	10	10
		DAY 50		18MAR2003	50	80	120	86	88	126	88	8	6	2
		DAY 57		27MAR2003	59	80	100	80	80	120	80	0	20	0
		FINAL			59	80	100	80	80	120	80	0	20	0
	E0033013	SCREEN		06FEB2003	-13	64	100	70	76	90	70	12	-10	0
		DAY 1		19FEB2003	1	68	108	72	72	110	76	4	2	4
		BASELINE				68	108	72	72	110	76	4	2	4
		DAY 8		26FEB2003	8	60	100	70	72	100	80	12	0	10
		DAY 15		05MAR2003	15	64	100	70	80	110	74	16	10	4
		DAY 22		13MAR2003	23	60	110	90	72	100	86	12	-10	-4
		DAY 29		19MAR2003	29	68	98	70	72	100	74	4	2	4
		DAY 36		27MAR2003	37	68	88	60	76	90	64	8	2	4
		DAY 43		01APR2003	42	60	80	60	76	90	70	16	10	10

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0033013	DAY 50		10APR2003	51	56	80	60	68	80	68	12	0	8
		DAY 57		16APR2003	57	64	80	60	76	90	78	12	10	18
		FINAL			57	64	80	60	76	90	78	12	10	18
	E0033016	SCREEN		17APR2003	-21	60	100	70	76	100	72	16	0	2
		DAY 1		08MAY2003	1	68	106	60	76	100	66	8	-6	6
		BASELINE				68	106	60	76	100	66	8	-6	6
		DAY 8		13MAY2003	6	80	110	64	88	106	72	8	-4	8
		DAY 15		20MAY2003	13	60	90	70	72	100	80	12	10	10
		DAY 22		28MAY2003	21	68	110	70	76	108	70	8	-2	0
		DAY 29		09JUN2003	33	60	100	70	76	100	70	16	0	0
		DAY 43		17JUN2003	41	68	118	74	76	110	70	8	-8	-4
		DAY 43	*	23JUN2003	47	68	110	80	80	94	76	12	-16	-4
		DAY 50		27JUN2003	51	68	100	62	72	100	60	4	0	-2
		DAY 57		02JUL2003	56	60	90	64	64	90	68	4	0	4
		FINAL			56	60	90	64	64	90	68	4	0	4
	E0033022	SCREEN		09JUL2003	-5	76	100	76	80	98	70	4	-2	-6
		DAY 1		14JUL2003	1	80	100	78	84	100	70	4	0	-8
		BASELINE				80	100	78	84	100	70	4	0	-8
		DAY 8		23JUL2003	10	64	90	62	80	90	60	16	0	-2
		DAY 15		30JUL2003	17	68	100	70	80	90	70	12	-10	0
		DAY 22		06AUG2003	24	64	100	68	68	110	70	4	10	2
		DAY 29		11AUG2003	29	70	120	74	80	124	80	10	4	6
		DAY 36		18AUG2003	36	60	110	72	68	100	70	8	-10	-2
		DAY 43		26AUG2003	44	64	110	70	68	110	72	4	0	2
		DAY 50		04SEP2003	53	64	100	70	68	100	72	4	0	2
		DAY 57		11SEP2003	60	64	110	70	68	110	72	4	0	2
		FINAL			60	64	110	70	68	110	72	4	0	2
	E0034007	SCREEN		07MAY2003	-9	76	110	90	80	120	85	4	10	-5
		DAY 1		16MAY2003	1	62	122	82	68	138	88	6	16	6
		BASELINE				62	122	82	68	138	88	6	16	6
		DAY 8		24MAY2003	9	68	130	90	72	125	85	4	-5	-5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0034007	DAY 15		02JUN2003	18	62	128	84	72	128	88	10	0	4
		DAY 22		09JUN2003	25	72	128	88	68	126	94	-4	-2	6
		DAY 29		16JUN2003	32	72	140	90	80	130	85	8	-10	-5
		DAY 36		20JUN2003	36	64	125	85	68	130	80	4	5	-5
		DAY 43		30JUN2003	46	74	160	100	68	140	95	-6	-20	-5
		DAY 50		07JUL2003	53	80	140	95	88	135	100	8	-5	5
		DAY 57		14JUL2003	60	68	160	105	64	158	108	-4	-2	3
		FINAL			60	68	160	105	64	158	108	-4	-2	3
	E0035004	SCREEN		22NOV2002	-5	78	120	82	82	126	88	4	6	6
		DAY 1		27NOV2002	1	80	120	72	86	124	76	6	4	4
		BASELINE				80	120	72	86	124	76	6	4	4
		DAY 8		04DEC2002	8	78	118	76	84	120	74	6	2	-2
		FINAL			8	78	118	76	84	120	74	6	2	-2
	E0035009	SCREEN		20DEC2002	-7	88	102	76	90	104	80	2	2	4
		DAY 1		27DEC2002	1	88	102	70	92	104	76	4	2	6
		BASELINE				88	102	70	92	104	76	4	2	6
		DAY 8		31DEC2002	5	80	114	64	84	120	60	4	6	-4
		DAY 15		08JAN2003	13	82	122	60	88	124	64	6	2	4
		DAY 22		15JAN2003	20	80	120	64	86	122	60	6	2	-4
		DAY 29		22JAN2003	27	78	120	64	84	120	66	6	0	2
		DAY 36		29JAN2003	34	70	118	70	74	120	72	4	2	2
		DAY 43		05FEB2003	41	74	122	62	82	120	68	8	-2	6
		DAY 43	*	11FEB2003	47	60	116	70	66	120	72	6	4	2
		DAY 57		19FEB2003	55	80	116	64	84	118	72	4	2	8
		FINAL			55	80	116	64	84	118	72	4	2	8
	E0035010	SCREEN		06JAN2003	-4	82	140	92	88	142	96	6	2	4
		DAY 1		10JAN2003	1	82	126	90	88	130	92	6	4	2
		BASELINE				82	126	90	88	130	92	6	4	2
		DAY 8		17JAN2003	8	82	122	80	86	124	76	4	2	-4
		DAY 15		24JAN2003	15	78	128	80	80	130	82	2	2	2
		DAY 22		31JAN2003	22	68	132	80	74	132	88	6	0	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT100.SAS
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Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0035010	DAY 29	07FEB2003	29	68	138	82	70	144	88	2	6	6
		DAY 36	14FEB2003	36	82	132	88	86	134	86	4	2	-2
		DAY 43	24FEB2003	46	82	130	86	88	132	84	6	2	-2
		DAY 50	28FEB2003	50	82	132	78	86	134	82	4	2	4
		DAY 57	06MAR2003	56	84	132	78	88	132	86	4	0	8
		FINAL		56	84	132	78	88	132	86	4	0	8
	E0035022	SCREEN	01MAY2003	-8	78	110	64	86	114	70	8	4	6
		DAY 1	09MAY2003	1	78	112	68	86	114	78	8	2	10
		BASELINE			78	112	68	86	114	78	8	2	10
		DAY 8	15MAY2003	7	80	112	68	82	114	72	2	2	4
		DAY 15	23MAY2003	15	78	110	70	88	112	74	10	2	4
		DAY 22	30MAY2003	22	80	112	74	84	114	72	4	2	-2
		DAY 29	06JUN2003	29	82	114	78	86	116	80	4	2	2
		DAY 36	13JUN2003	36	78	116	76	80	116	82	2	0	6
		DAY 43	20JUN2003	43	80	112	74	88	114	80	8	2	6
		DAY 50	27JUN2003	50	90	100	68	88	110	72	-2	10	4
		DAY 57	07JUL2003	60	82	102	70	88	106	72	6	4	2
		FINAL		60	82	102	70	88	106	72	6	4	2
	E0039003	SCREEN	06NOV2002	-19	60	108	80	64	102	76	4	-6	-4
		DAY 1	25NOV2002	1	72	122	78	76	114	88	4	-8	10
		BASELINE			72	122	78	76	114	88	4	-8	10
		DAY 8	02DEC2002	8	78	132	78	76	130	76	-2	-2	-2
		DAY 15	09DEC2002	15	76	122	68	84	128	80	8	6	12
		DAY 36	02JAN2003	39	68	118	74	76	116	70	8	-2	-4
		FINAL		39	68	118	74	76	116	70	8	-2	-4
	E0040001	SCREEN	18JUN2003	-9	68	120	70	71	120	68	3	0	-2
		DAY 1	27JUN2003	1	62	110	65	66	104	60	4	-6	-5
		BASELINE			62	110	65	66	104	60	4	-6	-5
		DAY 8	03JUL2003	7	64	115	70	69	110	68	5	-5	-2
		DAY 15	11JUL2003	15	68	120	78	70	115	76	2	-5	-2
		DAY 22	18JUL2003	22	74	105	70	76	105	68	2	0	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:46:40 iceadmn3

Listing 12.2.9.1 Vital Signs

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0040001	DAY 29	25JUL2003	29	69	120	80	72	118	79	3	-2	-1
		DAY 36	01AUG2003	36	70	122	80	74	118	76	4	-4	-4
		DAY 43	08AUG2003	43	72	125	78	75	122	80	3	-3	2
		DAY 50	15AUG2003	50	72	118	78	76	120	80	4	2	2
		DAY 57	22AUG2003	57	72	122	80	76	118	78	4	-4	-2
		FINAL		57	72	122	80	76	118	78	4	-4	-2
	E0040004	SCREEN	11JUL2003	-7	68	100	65	70	110	70	2	10	5
		DAY 1	18JUL2003	1	70	105	70	72	110	72	2	5	2
		BASELINE			70	105	70	72	110	72	2	5	2
	E0041002	SCREEN	13JAN2003	-8	76	142	94	80	148	90	4	6	-4
		DAY 1	21JAN2003	1	80	146	92	84	148	96	4	2	4
		BASELINE			80	146	92	84	148	96	4	2	4
		DAY 8	28JAN2003	8	88	142	84	84	150	90	-4	8	6
		DAY 15	04FEB2003	15	84	148	92	80	132	90	-4	-16	-2
		DAY 22	11FEB2003	22	86	148	84	84	148	88	-2	0	4
		DAY 29	18FEB2003	29	76	136	84	80	142	82	4	6	-2
		DAY 36	25FEB2003	36	80	144	86	76	146	86	-4	2	0
		DAY 50	11MAR2003	50	86	148	86	86	152	94	0	4	8
		FINAL		50	86	148	86	86	152	94	0	4	8
	E0041005	SCREEN	24FEB2003	-9	72	150	100	76	148	92	4	-2	-8
		DAY 1	05MAR2003	1	76	140	92	78	148	92	2	8	0
		BASELINE			76	140	92	78	148	92	2	8	0
		DAY 8	11MAR2003	7	74	140	98	74	148	90	0	8	-8
		DAY 15	19MAR2003	15	82	138	90	92	150	96	10	12	6
		DAY 22	26MAR2003	22	80	140	90	80	142	100	0	2	10
		DAY 29	02APR2003	29	80	110	90	88	130	96	8	20	6
		DAY 36	09APR2003	36	60	110	80	66	120	76	6	10	-4
		DAY 43	16APR2003	43	80	132	100	84	150	108	4	18	8
		DAY 50	23APR2003	50	60	150	98	80	150	100	20	0	2
		DAY 57	30APR2003	57	88	138	86	88	140	84	0	2	-2
		FINAL		57	88	138	86	88	140	84	0	2	-2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 8		12FEB2003	9	12	8	-12	8	6	-6	-4	-2	6
		DAY 15		19FEB2003	16	8	-14	-18	4	-12	-4	-4	2	14
		DAY 22		26FEB2003	23	12	-16	-14	4	-14	-8	-8	2	6
		DAY 29		05MAR2003	30	12	-10	-8	4	-4	4	-8	6	12
		DAY 36		11MAR2003	36	20	-12	-10	12	0	4	-8	12	14
		DAY 43		18MAR2003	43	16	-2	-10	8	10	2	-8	12	12
		DAY 50		25MAR2003	50	16	-24	-24	4	-20	-4	-12	4	20
		DAY 57		02APR2003	58	14	-8	-14	4	-20	-12	-10	-12	2
		FINAL			58	14	-8	-14	4	-20	-12	-10	-12	2
	E0002010	DAY 8		10APR2003	7	2	-22	-6	0	-32	-18	-2	-10	-12
		FINAL			7	2	-22	-6	0	-32	-18	-2	-10	-12
	E0002012	DAY 8		29APR2003	9	0	0	2	-4	0	2	-4	0	0
		DAY 15		06MAY2003	16	0	2	2	0	2	14	0	0	12
		DAY 22		15MAY2003	25	-8	-2	-2	-12	0	0	-4	2	2
		DAY 29		21MAY2003	31	-4	8	4	-12	0	4	-8	-8	0
		DAY 36		28MAY2003	38	0	0	-8	-8	6	-2	-8	6	6
		DAY 43		04JUN2003	45	-4	-2	4	-10	-4	2	-6	-2	-2
		DAY 50		11JUN2003	52	-8	0	4	-16	4	6	-8	4	2
		DAY 57		16JUN2003	57	-8	-2	-4	-12	-6	0	-4	-4	4
		FINAL			57	-8	-2	-4	-12	-6	0	-4	-4	4
	E0002018	DAY 8	*	30JUL2003	7	2	0	0	8	-6	6	6	-6	6
		DAY 8		01AUG2003	9	0	-8	-4	2	-2	6	2	6	10
		FINAL			9	0	-8	-4	2	-2	6	2	6	10
	E0003004	DAY 22		07JAN2003	22	2	20	-12	8	44	12	6	24	24
		FINAL			22	2	20	-12	8	44	12	6	24	24
	E0003005	DAY 8		30DEC2002	8	-10	4	8	-6	13	4	4	9	-4
		DAY 15		06JAN2003	15	-6	0	2	-6	-2	8	0	-2	6
		DAY 22		14JAN2003	23	6	-12	0	10	-2	8	4	10	8
		DAY 29		21JAN2003	30	0	-2	-2	6	6	6	6	8	8
		DAY 36		28JAN2003	37	2	8	8	4	18	16	2	10	8

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0003005	DAY 43	04FEB2003	44	-2	-2	0	8	6	14	10	8	14
		DAY 50	11FEB2003	51	-8	-4	-12	-14	6	6	-6	10	18
		DAY 57	18FEB2003	58	0	-4	-14	2	2	-4	2	6	10
		FINAL		58	0	-4	-14	2	2	-4	2	6	10
	E0003007	DAY 8	09JAN2003	8	0	-20	-10	-8	-15	-12	-8	5	-2
		DAY 15	16JAN2003	15	12	-10	-3	4	-1	-10	-8	9	-7
		DAY 22	23JAN2003	22	10	-10	-14	12	1	-2	2	11	12
		DAY 29	30JAN2003	29	-2	-12	6	-12	-7	4	-10	5	-2
		DAY 36	07FEB2003	37	-2	-12	0	-12	-3	-2	-10	9	-2
		DAY 43	13FEB2003	43	-2	-4	-4	-16	-3	-2	-14	1	2
		DAY 50	20FEB2003	50	16	-12	-10	18	-15	-6	2	-3	4
		DAY 57	27FEB2003	57	20	-24	-8	-12	-19	-10	-32	5	-2
		FINAL		57	20	-24	-8	-12	-19	-10	-32	5	-2
	E0003015	DAY 8	13MAY2003	9	2	-4	0	6	10	2	4	14	2
		DAY 15	19MAY2003	15	-4	-12	0	-8	10	2	-4	22	2
		DAY 22	27MAY2003	23	-8	8	0	-8	10	8	0	2	8
		DAY 29	04JUN2003	31	8	-12	0	0	10	-2	-8	22	-2
		DAY 36	10JUN2003	37	0	-8	0	0	6	6	0	14	6
		DAY 43	17JUN2003	44	6	-12	2	10	18	8	4	30	6
		DAY 50	24JUN2003	51	14	-2	8	18	6	8	4	8	0
		DAY 57	02JUL2003	59	14	-12	-2	0	-4	-8	-14	8	-6
		FINAL		59	14	-12	-2	0	-4	-8	-14	8	-6
	E0004002	DAY 8	10OCT2002	10	6	-2	-2	16	8	6	10	10	8
		DAY 15	17OCT2002	17	14	-2	-2	18	-2	10	4	0	12
		DAY 22	22OCT2002	22	18	0	8	14	-8	10	-4	-8	2
		DAY 29	29OCT2002	29	14	0	-2	8	-8	4	-6	-8	6
		DAY 36	05NOV2002	36	26	12	-4	28	-4	16	2	-16	20
		DAY 43	12NOV2002	43	26	-2	10	16	-10	10	-10	-8	0
		DAY 50	19NOV2002	50	20	0	-4	24	-4	14	4	-4	18
		DAY 57	26NOV2002	57	18	10	4	24	2	16	6	-8	12
		FINAL		57	18	10	4	24	2	16	6	-8	12

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	DAY 8		21JAN2003	8	-4	-2	2	0	-10	6	4	-8	4
		DAY 15		30JAN2003	17	0	-6	-6	0	-10	4	0	-4	10
		DAY 22		05FEB2003	23	0	8	0	4	4	8	4	-4	8
		FINAL			23	0	8	0	4	4	8	4	-4	8
	E0004018	DAY 8		26MAR2003	8	24	14	2	20	12	2	-4	-2	0
		DAY 15		02APR2003	15	24	10	0	24	6	6	0	-4	6
		DAY 22		09APR2003	22	12	16	12	16	12	10	4	-4	-2
		DAY 29		16APR2003	29	16	16	10	18	6	10	2	-10	0
		DAY 36		23APR2003	36	24	10	10	22	2	8	-2	-8	-2
		DAY 43		30APR2003	43	16	12	10	16	2	4	0	-10	-6
		DAY 50		06MAY2003	49	16	-4	0	28	-18	-10	12	-14	-10
		DAY 57		13MAY2003	56	12	-2	8	12	-6	4	0	-4	-4
		FINAL			56	12	-2	8	12	-6	4	0	-4	-4
	E0004021	DAY 8		21MAY2003	8	2	-6	8	8	-12	-6	6	-6	-14
		DAY 15		28MAY2003	15	10	2	10	8	-6	2	-2	-8	-8
		DAY 22		04JUN2003	22	2	2	10	4	-10	-6	2	-12	-16
		DAY 29		11JUN2003	29	6	16	8	8	8	4	2	-8	-4
		DAY 36		18JUN2003	36	4	10	10	8	2	2	4	-8	-8
		DAY 43		25JUN2003	43	-2	10	8	4	-8	0	6	-18	-8
		DAY 50		02JUL2003	50	6	4	12	4	0	0	-2	-4	-12
		DAY 57		09JUL2003	57	6	8	10	-4	-10	-2	-10	-18	-12
		FINAL			57	6	8	10	-4	-10	-2	-10	-18	-12
	E0005002	DAY 8		08OCT2002	6	4	-4	0	4	6	0	0	10	0
		DAY 8	*	14OCT2002	12	0	10	8	4	2	8	4	-8	0
		DAY 15		21OCT2002	19	8	4	0	8	-2	0	0	-6	0
		DAY 22		28OCT2002	26	12	-2	-2	12	-10	-2	0	-8	0
		DAY 29		04NOV2002	33	6	4	10	6	0	10	0	-4	0
		DAY 43		13NOV2002	42	6	0	0	6	0	0	0	0	0
		DAY 43	*	18NOV2002	47	6	0	0	6	0	0	0	0	0
		DAY 50		25NOV2002	54	8	14	10	4	10	10	-4	-4	0
		FINAL			54	8	14	10	4	10	10	-4	-4	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0005004	DAY 8	10OCT2002	10	20	16	10	20	14	12	0	-2	2
		DAY 15	15OCT2002	15	24	26	8	24	22	8	0	-4	0
		FINAL		15	24	26	8	24	22	8	0	-4	0
	E0005013	DAY 43	19DEC2002	43	16	10	0	16	10	6	0	0	6
		FINAL		43	16	10	0	16	10	6	0	0	6
	E0005024	DAY 8	18FEB2003	9	4	-4	-6	4	-10	-10	0	-6	-4
		DAY 15	26FEB2003	17	20	-14	-10	20	-20	-10	0	-6	0
		DAY 22	06MAR2003	25	20	-14	0	20	-20	-10	0	-6	-10
		DAY 29	13MAR2003	32	8	-14	0	8	-20	-6	0	-6	-6
		DAY 36	20MAR2003	39	12	-14	-6	12	-10	-10	0	4	-4
		DAY 43	25MAR2003	44	8	-14	-10	8	-20	-20	0	-6	-10
		DAY 50	02APR2003	52	28	-4	0	24	-10	-10	-4	-6	-10
		DAY 57	09APR2003	59	4	-14	-10	4	-20	-12	0	-6	-2
		FINAL		59	4	-14	-10	4	-20	-12	0	-6	-2
	E0005027	DAY 8	19MAR2003	9	24	8	0	20	10	5	-4	2	5
		DAY 15	26MAR2003	16	8	8	-2	8	10	5	0	2	7
		DAY 22	03APR2003	24	0	8	0	0	0	5	0	-8	5
		FINAL		24	0	8	0	0	0	5	0	-8	5
	E0005037	DAY 8	15MAY2003	9	-10	0	2	-10	10	0	0	10	-2
		DAY 15	22MAY2003	16	-10	0	0	-10	10	-2	0	10	-2
		DAY 22	27MAY2003	21	-16	0	4	-16	0	2	0	0	-2
		DAY 29	05JUN2003	30	-16	-2	4	-16	4	2	0	6	-2
		DAY 36	12JUN2003	37	-16	-10	-2	-16	-4	-6	0	6	-4
		DAY 50	25JUN2003	50	-16	-14	-4	-16	0	0	0	14	4
		DAY 57	02JUL2003	57	-16	-6	-8	-16	4	-4	0	10	4
		FINAL		57	-16	-6	-8	-16	4	-4	0	10	4
	E0005042	DAY 8	02JUL2003	9	-24	-6	4	-20	-4	2	4	2	-2
		DAY 15	09JUL2003	16	-4	-4	0	-4	-6	0	0	-2	0
		DAY 22	16JUL2003	23	4	14	2	8	18	0	4	4	-2
		DAY 29	23JUL2003	30	0	6	0	0	2	0	0	-4	0

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0005042	DAY 36	30JUL2003	37	-8	12	4	-8	-2	4	0	-14	0
		DAY 43	06AUG2003	44	-2	2	2	-2	-2	0	0	-4	-2
		DAY 50	12AUG2003	50	-16	2	2	-12	-2	0	4	-4	-2
		DAY 57	18AUG2003	56	-4	4	4	4	6	0	8	2	-4
		FINAL		56	-4	4	4	4	6	0	8	2	-4
	E0006005	DAY 8	12DEC2002	8	2	-44	-12	8	-42	-24	6	2	-12
		DAY 15	20DEC2002	16	15	-19	-6	18	-10	-5	3	9	1
		DAY 22	30DEC2002	26	7	-23	-13	19	-15	-16	12	8	-3
		DAY 29	03JAN2003	30	12	-27	-15	12	-16	-20	0	11	-5
		DAY 36	09JAN2003	36	9	-12	4	-4	-25	-5	-13	-13	-9
		DAY 43	16JAN2003	43	4	-28	-4	2	-7	-7	-2	21	-3
		DAY 50	23JAN2003	50	2	-6	-2	-10	-46	-46	-12	-40	-44
		DAY 57	30JAN2003	57	2	-31	-17	10	-19	-22	8	12	-5
		FINAL		57	2	-31	-17	10	-19	-22	8	12	-5
	E0006018	DAY 8	24MAR2003	12	2	-8	4	12	-12	12	10	-4	8
		FINAL		12	2	-8	4	12	-12	12	10	-4	8
	E0007013	DAY 8	20JUN2003	8	2	20	6	4	16	6	2	-4	0
		DAY 15	26JUN2003	14	0	16	8	0	8	6	0	-8	-2
		DAY 22	03JUL2003	21	0	22	8	0	20	4	0	-2	-4
		DAY 29	10JUL2003	28	2	26	8	4	26	6	2	0	-2
		DAY 36	17JUL2003	35	0	20	8	0	16	8	0	-4	0
		DAY 43	24JUL2003	42	0	28	12	4	16	4	4	-12	-8
		DAY 50	01AUG2003	50	6	42	14	8	34	14	2	-8	0
		DAY 57	07AUG2003	56	2	32	18	4	22	14	2	-10	-4
		FINAL		56	2	32	18	4	22	14	2	-10	-4
	E0010004	DAY 8	18DEC2002	8	8	-6	-16	20	-2	-16	12	4	0
		DAY 15	26DEC2002	16	1	20	-4	7	10	4	6	-10	8
		DAY 22	02JAN2003	23	6	16	-4	4	20	-6	-2	4	-2
		DAY 36	13JAN2003	34	7	6	-8	17	10	-8	10	4	0
		DAY 43	21JAN2003	42	1	16	4	10	18	4	9	2	0
		DAY 50	31JAN2003	52	6	2	-10	22	-2	-10	16	-4	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	DAY 57	06FEB2003	58	0	10	-4	8	10	-8	8	0	-4
		FINAL		58	0	10	-4	8	10	-8	8	0	-4
	E0010012	DAY 8	14JAN2003	8	-10	-10	-2	-11	-14	-8	-1	-4	-6
		DAY 15	21JAN2003	15	-10	2	2	-8	-2	4	2	-4	2
		DAY 22	28JAN2003	22	-10	2	6	-16	-8	6	-6	-10	0
		DAY 29	04FEB2003	29	-6	14	8	1	-18	2	7	-32	-6
		DAY 36	11FEB2003	36	-14	-10	12	-10	-34	-4	4	-24	-16
		DAY 43	18FEB2003	43	-8	16	12	-2	-4	2	6	-20	-10
		DAY 50	25FEB2003	50	-6	10	10	-8	-14	-2	-2	-24	-12
		DAY 57	05MAR2003	58	-14	-2	6	-12	-12	0	2	-10	-6
		FINAL		58	-14	-2	6	-12	-12	0	2	-10	-6
	E0010024	DAY 8	12MAY2003	8	12	-14	-10	32	-8	0	20	6	10
		DAY 15	19MAY2003	15	28	6	-2	28	-8	-8	0	-14	-6
		DAY 22	27MAY2003	23	38	16	10	30	8	2	-8	-8	-8
		DAY 29	04JUN2003	31	24	16	14	20	8	12	-4	-8	-2
		DAY 36	11JUN2003	38	48	6	6	48	12	8	0	6	2
		DAY 43	18JUN2003	45	26	16	8	16	8	-16	-10	-8	-24
		DAY 50	25JUN2003	52	36	6	8	42	2	2	6	-4	-6
		DAY 57	02JUL2003	59	34	6	-2	28	-2	-8	-6	-8	-6
		FINAL		59	34	6	-2	28	-2	-8	-6	-8	-6
	E0010032	DAY 8	17JUL2003	8	-4	10	-10	4	10	-2	8	0	8
		FINAL		8	-4	10	-10	4	10	-2	8	0	8
	E0011025	DAY 8	02JUL2003	7	6	0	-10	0	0	-3	-6	0	7
		DAY 15	10JUL2003	15	0	2	0	0	0	7	0	-2	7
		DAY 22	17JUL2003	22	8	20	0	2	18	5	-6	-2	5
		DAY 29	22JUL2003	27	0	-10	-12	-6	-10	-15	-6	0	-3
		DAY 36	30JUL2003	35	4	0	-20	-4	0	-13	-8	0	7
		DAY 43	07AUG2003	43	0	0	-10	-2	2	-5	-2	2	5
		DAY 50	14AUG2003	50	-2	2	-10	-4	0	-3	-2	-2	7
		DAY 57	22AUG2003	58	-4	0	-10	-6	0	-3	-2	0	7
		FINAL		58	-4	0	-10	-6	0	-3	-2	0	7

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0013007	DAY 8	27MAR2003	8	-6	0	-6	-8	-2	-8	-2	-2	-2
		DAY 15	07APR2003	19	0	-4	0	-14	-4	0	-14	0	0
		FINAL		19	0	-4	0	-14	-4	0	-14	0	0
	E0013009	DAY 8	09APR2003	8	0	16	6	0	8	6	0	-8	0
		DAY 15	16APR2003	15	6	12	2	6	8	0	0	-4	-2
		DAY 22	24APR2003	23	6	8	-10	-2	8	-10	-8	0	0
		DAY 29	01MAY2003	30	18	8	-10	4	8	-10	-14	0	0
		DAY 36	07MAY2003	36	-6	12	0	-2	8	0	4	-4	0
		DAY 43	16MAY2003	45	6	8	-18	-2	8	-10	-8	0	8
		DAY 50	21MAY2003	50	22	8	-2	14	8	0	-8	0	2
		DAY 57	29MAY2003	58	-6	8	0	2	8	0	8	0	0
		FINAL		58	-6	8	0	2	8	0	8	0	0
	E0014006	DAY 8	02APR2003	9	4	-4	-2	4	14	-2	0	18	0
		DAY 15	09APR2003	16	0	-2	6	0	10	8	0	12	2
		DAY 22	16APR2003	23	8	-4	6	4	2	8	-4	6	2
		DAY 29	23APR2003	30	20	6	-6	16	10	4	-4	4	10
		DAY 36	30APR2003	37	4	6	-4	4	20	4	0	14	8
		DAY 43	07MAY2003	44	8	2	0	4	0	0	-4	-2	0
		DAY 50	14MAY2003	51	8	-4	-4	0	14	8	-8	18	12
		DAY 57	21MAY2003	58	20	0	-10	28	0	0	8	0	10
		FINAL		58	20	0	-10	28	0	0	8	0	10
	E0014010	DAY 8	30APR2003	9	6	-2	4	4	-6	-8	-2	-4	-12
		DAY 15	07MAY2003	16	8	4	2	8	-2	-14	0	-6	-16
		DAY 22	14MAY2003	23	-2	4	2	-4	2	0	-2	-2	-2
		DAY 29	21MAY2003	30	4	-16	-8	0	-12	-12	-4	4	-4
		DAY 36	28MAY2003	37	2	-4	2	-2	2	2	-4	6	0
		DAY 43	03JUN2003	43	-4	-18	-2	-8	-12	-4	-4	6	-2
		DAY 50	11JUN2003	51	-4	-16	-4	-10	-10	-8	-6	6	-4
		DAY 57	17JUN2003	57	0	-10	-2	-6	-4	-6	-6	6	-4
		FINAL		57	0	-10	-2	-6	-4	-6	-6	6	-4
	E0016001	DAY 8	29JAN2003	8				-3	12	14			

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	DAY 15	05FEB2003	15				-17	2	16			
		DAY 22	12FEB2003	22				9	20	26			
		DAY 29	19FEB2003	29				-2	19	26			
		DAY 36	26FEB2003	36				7	20	24			
		DAY 43	05MAR2003	43				-1	14	24			
		DAY 50	12MAR2003	50				-2	6	16			
		DAY 57	19MAR2003	57				7	9	17			
		FINAL		57				7	9	17			
	E0016004	DAY 8	10FEB2003	8	0	-4	-13	-2	0	-1	-2	4	12
		FINAL		8	0	-4	-13	-2	0	-1	-2	4	12
	E0018001	DAY 8	05NOV2002	8	20	4	10	16	2	8	-4	-2	-2
		DAY 15	13NOV2002	16	12	-6	-4	16	-4	-4	4	2	0
		DAY 22	20NOV2002	23	14	-10	2	22	-8	2	8	2	0
		DAY 29	27NOV2002	30	16	-12	-2	20	-8	-4	4	4	-2
		DAY 36	04DEC2002	37	8	-8	2	13	-4	1	5	4	-1
		DAY 43	11DEC2002	44	20	6	8	24	10	6	4	4	-2
		DAY 50	18DEC2002	51	20	8	12	24	10	10	4	2	-2
		DAY 57	24DEC2002	57	22	4	12	28	6	12	6	2	0
		FINAL		57	22	4	12	28	6	12	6	2	0
	E0018006	DAY 8	23DEC2002	7	12	6	16	12	2	14	0	-4	-2
		DAY 15	31DEC2002	15	0	10	12	0	0	12	0	-10	0
		DAY 22	07JAN2003	22	4	2	8	4	-6	10	0	-8	2
		DAY 29	14JAN2003	29	12	-6	8	12	-4	10	0	2	2
		DAY 36	21JAN2003	36	16	-4	10	8	0	10	-8	4	0
		DAY 43	28JAN2003	43	-4	6	14	0	8	18	4	2	4
		DAY 50	06FEB2003	52	16	-4	6	8	0	4	-8	4	-2
		DAY 57	13FEB2003	59	0	6	4	0	2	8	0	-4	4
		FINAL		59	0	6	4	0	2	8	0	-4	4
	E0019004	DAY 8	14NOV2002	8	4	-10	5	4	-13	0	0	-3	-5
		DAY 15	21NOV2002	15	0	-5	0	0	-3	0	0	2	0
		DAY 22	26NOV2002	20	4	5	5	8	-3	-5	4	-8	-10

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	DAY 29	05DEC2002	29	-8	-10	5	-8	-8	0	0	2	-5
		DAY 36	12DEC2002	36	2	20	9	12	23	18	10	3	9
		DAY 43	19DEC2002	43	4	15	7	8	12	0	4	-3	-7
		FINAL		43	4	15	7	8	12	0	4	-3	-7
	E0019011	DAY 8	27NOV2002	7	4	10	0	4	5	10	0	-5	10
		DAY 15	05DEC2002	15	0	10	10	0	7	10	0	-3	0
		DAY 22	12DEC2002	22	-14	12	18	6	-9	-3	20	-21	-21
		DAY 29	19DEC2002	29	4	-12	-2	4	-5	9	0	7	11
		DAY 43	02JAN2003	43	8	0	10	8	-7	20	0	-7	10
		DAY 50	09JAN2003	50	-20	-10	0	-20	-5	15	0	5	15
		DAY 57	16JAN2003	57	4	-8	8	12	-13	15	8	-5	7
		FINAL		57	4	-8	8	12	-13	15	8	-5	7
	E0019025	DAY 8	13FEB2003	8	20	2	0	24	0	0	4	-2	0
		DAY 15	20FEB2003	15	20	-2	2	24	-10	-7	4	-8	-9
		DAY 22	27FEB2003	22	20	0	6	24	-6	5	4	-6	-1
		DAY 29	06MAR2003	29	20	0	0	24	-10	-1	4	-10	-1
		DAY 36	13MAR2003	36	20	0	2	20	-2	5	0	-2	3
		DAY 43	20MAR2003	43	18	-8	-2	18	-10	-1	0	-2	1
		DAY 50	27MAR2003	50	20	8	10	24	5	0	4	-3	-10
		DAY 57	03APR2003	57	20	-8	-10	24	-20	-15	4	-12	-5
		FINAL		57	20	-8	-10	24	-20	-15	4	-12	-5
	E0019043	DAY 8	10JUN2003	8	20	2	-4	0	6	4	-20	4	8
		DAY 15	17JUN2003	15	16	-5	-3	4	-4	-4	-12	1	-1
		DAY 22	24JUN2003	22	12	10	4	12	8	-4	0	-2	-8
		DAY 29	01JUL2003	29	16	-4	0	4	-10	-6	-12	-6	-6
		DAY 36	08JUL2003	36	4	14	8	0	8	4	-4	-6	-4
		DAY 43	15JUL2003	43	4	18	6	2	12	2	-2	-6	-4
		DAY 50	22JUL2003	50	8	0	-8	0	-2	-6	-8	-2	2
		DAY 57	29JUL2003	57	4	-8	0	12	-6	-4	8	2	-4
		FINAL		57	4	-8	0	12	-6	-4	8	2	-4
	E0020001	DAY 8	05NOV2002	8	16	38	0	22	44	8	6	6	8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0020001	DAY 15		12NOV2002	15	10	10	4	18	4	8	8	-6	4
		DAY 22		19NOV2002	22	18	18	0	20	10	2	2	-8	2
		DAY 29		26NOV2002	29	16	30	2	22	24	6	6	-6	4
		DAY 36		03DEC2002	36	16	16	0	20	14	4	4	-2	4
		DAY 43		10DEC2002	43	18	14	-2	22	12	4	4	-2	6
		DAY 50		16DEC2002	49	8	20	10	8	6	12	0	-14	2
		DAY 50	*	20DEC2002	53	14	10	0	20	4	4	6	-6	4
		FINAL			53	14	10	0	20	4	4	6	-6	4
	E0020006	DAY 8		20DEC2002	5	16	-6	-10	8	-12	-18	-8	-6	-8
		DAY 22		08JAN2003	24	4	22	0	-6	14	-2	-10	-8	-2
		FINAL			24	4	22	0	-6	14	-2	-10	-8	-2
	E0020007	DAY 8		22JAN2003	8	-10	-16	-10	-8	-10	-8	2	6	2
		DAY 57		25MAR2003	70	0	-18	-12	2	-4	-8	2	14	4
		FINAL			70	0	-18	-12	2	-4	-8	2	14	4
	E0020011	DAY 8		05MAR2003	8	10	4	2	10	0	4	0	-4	2
		DAY 15		12MAR2003	15	4	-12	-4	10	-12	0	6	0	4
		DAY 22		20MAR2003	23	2	-2	-6	6	-6	-4	4	-4	2
		DAY 29		26MAR2003	29	4	-20	-16	4	-20	-16	0	0	0
		DAY 36		02APR2003	36	-8	-20	-16	-12	-20	-14	-4	0	2
		DAY 43		09APR2003	43	-4	-2	0	-8	-2	2	-4	0	2
		DAY 50		16APR2003	50	-8	-10	-8	-8	-8	-4	0	2	4
		DAY 57		23APR2003	57	6	0	12	2	0	14	-4	0	2
		FINAL			57	6	0	12	2	0	14	-4	0	2
	E0020013	DAY 8		12MAR2003	8	-4	6	10	10	2	12	14	-4	2
		DAY 22		25MAR2003	21	-8	2	2	-2	-8	2	6	-10	0
		FINAL			21	-8	2	2	-2	-8	2	6	-10	0
	E0022008	DAY 8		19NOV2002	8	18	8	18	2	-16	6	-16	-24	-12
		DAY 15		26NOV2002	15	8	8	26	-18	-21	2	-26	-29	-24
		DAY 22		03DEC2002	22	16	8	24	-16	-31	-4	-32	-39	-28
		DAY 29		12DEC2002	31	4	10	26	-7	-15	8	-11	-25	-18

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 36	17DEC2002	36	2	8	26	-12	-16	6	-14	-24	-20
		DAY 43	24DEC2002	43	0	13	30	-16	-21	4	-16	-34	-26
		DAY 50	31DEC2002	50	6	8	24	-12	-5	4	-18	-13	-20
		DAY 57	07JAN2003	57	6	8	22	-4	1	8	-10	-7	-14
		FINAL		57	6	8	22	-4	1	8	-10	-7	-14
	E0022017	DAY 8	26DEC2002	8	12	14	12	-4	-6	14	-16	-20	2
		DAY 15	03JAN2003	16	16	6	4	8	0	10	-8	-6	6
		DAY 22	09JAN2003	22	20	2	-6	12	12	16	-8	10	22
		DAY 29	17JAN2003	30	4	-4	-6	0	12	16	-4	16	22
		DAY 36	22JAN2003	35	20	-4	-10	-4	6	12	-24	10	22
		DAY 43	31JAN2003	44	16	-6	-6	8	6	16	-8	12	22
		DAY 50	06FEB2003	50	12	2	-4	8	10	8	-4	8	12
		DAY 57	13FEB2003	57	28	18	4	0	16	18	-28	-2	14
		FINAL		57	28	18	4	0	16	18	-28	-2	14
	E0022018	DAY 8	19DEC2002	8	-8	-2	-12	12	-6	-4	20	-4	8
		DAY 15	26DEC2002	15	-12	-4	-18	-4	-14	-4	8	-10	14
		DAY 22	02JAN2003	22	-4	-12	-14	-8	-12	-4	-4	0	10
		DAY 29	09JAN2003	29	-4	-4	-14	12	-10	-12	16	-6	2
		DAY 36	16JAN2003	36	-12	-6	-10	0	-8	-4	12	-2	6
		DAY 43	23JAN2003	43	-4	-12	-14	8	-12	-6	12	0	8
		DAY 50	30JAN2003	50	0	-14	-18	12	-18	2	12	-4	20
		DAY 57	06FEB2003	57	-8	-20	-16	0	-18	-4	8	2	12
		FINAL		57	-8	-20	-16	0	-18	-4	8	2	12
	E0022022	DAY 8	06JAN2003	8	-4	-2	-6	10	-6	-4	14	-4	2
		DAY 15	14JAN2003	16	8	-12	-16	6	-18	-12	-2	-6	4
		DAY 22	21JAN2003	23	8	-10	8	10	-2	-4	2	8	-12
		DAY 29	28JAN2003	30	-12	-6	-10	14	-18	-6	26	-12	4
		DAY 36	04FEB2003	37	-16	2	-2	10	-16	-2	26	-18	0
		DAY 57	27FEB2003	60									
		FINAL		60	-16	2	-2	10	-16	-2	26	-18	0
	E0022027	DAY 8	13FEB2003	8	12	0	-8	8	-14	-8	-4	-14	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022027	DAY 15	20FEB2003	15	6	-12	-10	8	-10	-8	2	2	2
		DAY 22	27FEB2003	22	6	-8	-16	4	-16	-4	-2	-8	12
		DAY 29	06MAR2003	29	-2	-2	-10	0	-8	6	2	-6	16
		DAY 36	13MAR2003	36	2	-6	-10	12	-16	-10	10	-10	0
		DAY 43	20MAR2003	43	6	-2	-6	8	-12	-6	2	-10	0
		DAY 50	27MAR2003	50	16	4	-4	12	-4	0	-4	-8	4
		DAY 57	03APR2003	57	2	-8	-10	2	-12	-4	0	-4	6
		FINAL		57	2	-8	-10	2	-12	-4	0	-4	6
	E0022030	DAY 8	20FEB2003	7	-8	14	-10	0	18	8	8	4	18
		DAY 15	28FEB2003	15	0	0	-10	-16	8	4	-16	8	14
		DAY 22	07MAR2003	22	0	18	-14	0	18	-8	0	0	6
		FINAL		22	0	18	-14	0	18	-8	0	0	6
	E0022031	DAY 8	25FEB2003	8	16	16	2	20	-8	0	4	-24	-2
		DAY 15	04MAR2003	15	20	8	6	24	4	14	4	-4	8
		DAY 22	11MAR2003	22	24	12	-6	24	6	0	0	-6	6
		DAY 29	18MAR2003	29	20	14	-6	24	-6	12	4	-20	18
		DAY 36	25MAR2003	36	20	14	2	24	2	6	4	-12	4
		DAY 43	01APR2003	43	20	8	2	20	4	16	0	-4	14
		DAY 50	08APR2003	50	24	0	-10	14	-6	4	-10	-6	14
		DAY 57	15APR2003	57	18	0	-2	20	4	10	2	4	12
		FINAL		57	18	0	-2	20	4	10	2	4	12
	E0022032	DAY 8	28FEB2003	11	-4	-20	-4	-22	0	2	-18	20	6
		DAY 15	04MAR2003	15	2	-10	2	-12	0	2	-14	10	0
		DAY 22	11MAR2003	22	-6	-4	0	-12	6	2	-6	10	2
		DAY 29	21MAR2003	32	-4	-16	-14	-14	8	-4	-10	24	10
		DAY 36	27MAR2003	38	6	-24	-20	-4	-10	-4	-10	14	16
		DAY 43	03APR2003	45	-2	-16	-12	-8	-2	-4	-6	14	8
		DAY 50	10APR2003	52	-8	12	18	0	14	22	8	2	4
		DAY 57	18APR2003	60	-6	-16	-14	-22	-2	-8	-16	14	6
		FINAL		60	-6	-16	-14	-22	-2	-8	-16	14	6
	E0022035	DAY 8	26FEB2003	8	-8	-6	-6	-7	-18	-4	1	-12	2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0022035	FINAL		8	-8	-6	-6	-7	-18	-4	1	-12	2
	E0022036	DAY 8	03MAR2003	7	6	-10	-4	2	-6	-16	-4	4	-12
		DAY 15	10MAR2003	14	16	2	14	0	16	-10	-16	14	-24
		DAY 22	18MAR2003	22	8	-10	0	-8	-6	-16	-16	4	-16
		DAY 29	25MAR2003	29	8	-10	6	-8	-6	-14	-16	4	-20
		DAY 36	01APR2003	36	12	-8	0	-8	2	-14	-20	10	-14
		DAY 43	08APR2003	43	6	2	6	0	10	-8	-6	8	-14
		DAY 50	15APR2003	50	6	-20	4	-8	-6	-24	-14	14	-28
		DAY 57	22APR2003	57	-8	-18	-10	-16	-4	-24	-8	14	-14
		FINAL		57	-8	-18	-10	-16	-4	-24	-8	14	-14
	E0022056	DAY 8	24APR2003	8	10	-2	2	12	-12	-6	2	-10	-8
		DAY 15	01MAY2003	15	10	-4	2	12	-2	-2	2	2	-4
		DAY 22	08MAY2003	22	22	-6	0	20	-4	2	-2	2	2
		FINAL		22	22	-6	0	20	-4	2	-2	2	2
	E0022060	DAY 8	05MAY2003	6	5	10	-6	15	2	-8	10	-8	-2
		DAY 15	12MAY2003	13	12	-12	-10	6	-2	-16	-6	10	-6
		DAY 22	19MAY2003	20	9	8	-4	-3	0	-8	-12	-8	-4
		DAY 29	28MAY2003	29	12	0	-16	6	-6	-14	-6	-6	2
		DAY 36	02JUN2003	34	15	-2	-8	9	-2	-16	-6	0	-8
		DAY 43	10JUN2003	42	12	-4	-18	3	-4	-12	-9	0	6
		DAY 50	17JUN2003	49	15	8	-8	12	-6	-20	-3	-14	-12
		DAY 57	24JUN2003	56	4	-6	-8	0	-8	-14	-4	-2	-6
		FINAL		56	4	-6	-8	0	-8	-14	-4	-2	-6
	E0022063	DAY 8	12MAY2003	6	-9	-2	-10	-9	12	-6	0	14	4
		DAY 15	21MAY2003	15	3	-4	-8	3	12	-4	0	16	4
		DAY 22	28MAY2003	22	-9	-4	-4	-6	14	-4	3	18	0
		DAY 29	04JUN2003	29	-6	-4	-14	-6	6	-20	0	10	-6
		DAY 36	11JUN2003	36	0	-10	-20	-3	14	-16	-3	24	4
		FINAL		36	0	-10	-20	-3	14	-16	-3	24	4
	E0023008	DAY 8	06FEB2003	8	3	-9	3	9	-6	6	6	3	3

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	DAY 15		13FEB2003	15	21	17	17	19	23	19	-2	6	2
		DAY 22		20FEB2003	22	4	-6	6	8	-8	4	4	-2	-2
		DAY 29		25FEB2003	27	14	0	8	16	2	10	2	2	2
		DAY 36		06MAR2003	36	0	4	6	8	-8	4	8	-12	-2
		DAY 43		11MAR2003	41	0	-5	-5	20	17	6	20	22	11
		DAY 50		18MAR2003	48	0	16	8	9	2	11	9	-14	3
		DAY 50	*	24MAR2003	54	2	6	6	6	6	10	4	0	4
		FINAL			54	2	6	6	6	6	10	4	0	4
	E0023013	DAY 8		06MAR2003	8	-2	0	-6	-10	10	2	-8	10	8
		FINAL			8	-2	0	-6	-10	10	2	-8	10	8
	E0023015	DAY 8		18MAR2003	8	-7	7	18	-8	0	10	-1	-7	-8
		DAY 15		25MAR2003	15	11	-15	-1	29	15	21	18	30	22
		DAY 22		01APR2003	22	5	-30	-8	5	-27	-14	0	3	-6
		DAY 29		08APR2003	29	9	-4	7	29	-20	3	20	-16	-4
		DAY 36		15APR2003	36	16	-12	5	33	-2	1	17	10	-4
		DAY 43		22APR2003	43	12	-25	-13	10	-10	18	-2	15	31
		DAY 50		29APR2003	50	2	8	2	22	8	2	20	0	0
		DAY 57		06MAY2003	57	17	-21	3	21	-17	-1	4	4	-4
		FINAL			57	17	-21	3	21	-17	-1	4	4	-4
	E0023034	DAY 8		16JUN2003	8	8	26	19	-10	8	4	-18	-18	-15
		DAY 15		23JUN2003	15	0	17	16	-21	15	16	-21	-2	0
		DAY 22		30JUN2003	22	12	9	2	12	26	14	0	17	12
		DAY 29		07JUL2003	29	9	10	8	17	11	10	8	1	2
		DAY 36		14JUL2003	36	38	17	5	33	4	-8	-5	-13	-13
		DAY 43		22JUL2003	44	19	32	16	2	17	16	-17	-15	0
		DAY 57		05AUG2003	58	12	26	16	-8	21	20	-20	-5	4
		FINAL			58	12	26	16	-8	21	20	-20	-5	4
	E0023037	DAY 8		24JUN2003	7	27	-6	-6	23	-7	-10	-4	-1	-4
		DAY 15		01JUL2003	14	17	5	11	22	5	16	5	0	5
		DAY 29	*	14JUL2003	27	6	4	5	11	-9	6	5	-13	1
		DAY 29		18JUL2003	31	12	1	2	9	6	10	-3	5	8

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0023037	DAY 36	25JUL2003	38	18	-11	3	29	-52	-31	11	-41	-34
		DAY 43	01AUG2003	45	15	-14	0	12	-29	-14	-3	-15	-14
		DAY 50	08AUG2003	52	38	-17	-14	31	-27	-20	-7	-10	-6
		DAY 57	15AUG2003	59	35	-15	-12	19	-25	-16	-16	-10	-4
		FINAL		59	35	-15	-12	19	-25	-16	-16	-10	-4
	E0023038	DAY 8	09JUL2003	10	12	0	-7	8	-3	-8	-4	-3	-1
		DAY 15	15JUL2003	16	3	-5	-1	-4	-23	-8	-7	-18	-7
		DAY 22	21JUL2003	22	8	4	0	4	-13	-10	-4	-17	-10
		DAY 29	28JUL2003	29	7	6	-7	-2	-22	-14	-9	-28	-7
		DAY 36	07AUG2003	39	-5	-25	-10	-14	-37	-17	-9	-12	-7
		DAY 43	13AUG2003	45	14	-11	-6	-5	-32	-7	-19	-21	-1
		DAY 50	21AUG2003	53	5	-10	6	-14	-2	4	-19	8	-2
		DAY 57	27AUG2003	59	5	-13	2	7	-48	-22	2	-35	-24
		FINAL		59	5	-13	2	7	-48	-22	2	-35	-24
	E0023044	DAY 8	22JUL2003	7	12	-10	-7	24	7	7	12	17	14
		DAY 15	29JUL2003	14	-2	-3	-4	-1	-10	-4	1	-7	0
		DAY 22	05AUG2003	21	3	3	-1	3	0	-2	0	-3	-1
		DAY 29	12AUG2003	28	-9	-4	0	-3	26	22	6	30	22
		FINAL		28	-9	-4	0	-3	26	22	6	30	22
	E0023045	DAY 8	24JUL2003	8	8	-16	-5	12	-12	4	4	4	9
		DAY 15	31JUL2003	15	8	-10	4	8	-12	8	0	-2	4
		DAY 22	07AUG2003	22	4	-10	4	4	-10	12	0	0	8
		DAY 29	14AUG2003	29	22	0	10	12	3	14	-10	3	4
		DAY 36	21AUG2003	36	16	14	5	18	10	10	2	-4	5
		DAY 43	28AUG2003	43	18	10	10	20	8	10	2	-2	0
		DAY 50	04SEP2003	50	28	8	14	22	10	24	-6	2	10
		DAY 57	11SEP2003	57	20	8	14	12	24	11	-8	16	-3
		FINAL		57	20	8	14	12	24	11	-8	16	-3
	E0025002	DAY 8	10APR2003	8	-4	0	16	0	14	20	4	14	4
		DAY 15	17APR2003	15	0	0	8	0	0	0	0	0	-8
		DAY 22	24APR2003	22	0	0	-2	-8	0	10	-8	0	12

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0025002	DAY 29	01MAY2003	29	8	10	10	0	4	8	-8	-6	-2
		DAY 36	08MAY2003	36	8	0	10	0	4	10	-8	4	0
		DAY 43	15MAY2003	43	20	10	8	16	4	18	-4	-6	10
		DAY 50	22MAY2003	50	16	0	-2	16	14	10	0	14	12
		DAY 57	29MAY2003	57	4	0	16	8	4	10	4	4	-6
		FINAL		57	4	0	16	8	4	10	4	4	-6
	E0026010	DAY 8	30JAN2003	9	17	-8	-10	20	-4	-3	3	4	7
		FINAL		9	17	-8	-10	20	-4	-3	3	4	7
	E0026017	DAY 15	21MAR2003	16	-3	-2	-4	-7	-2	-7	-4	0	-3
		FINAL		16	-3	-2	-4	-7	-2	-7	-4	0	-3
	E0026018	DAY 8	27MAR2003	8	-6	23	4	-4	2	-2	2	-21	-6
		DAY 15	03APR2003	15	-1	29	-7	-3	-9	4	-2	-38	11
		DAY 22	10APR2003	22	-4	32	9	-5	-16	2	-1	-48	-7
		DAY 29	17APR2003	29	-18	8	-2	-6	7	4	12	-1	6
		DAY 36	24APR2003	36	6	20	8	4	13	4	-2	-7	-4
		DAY 43	01MAY2003	43	-8	2	1	2	-15	-7	10	-17	-8
		DAY 50	08MAY2003	50	-9	8	0	-6	-27	-6	3	-35	-6
		DAY 57	15MAY2003	57	-17	13	-9	-14	-5	9	3	-18	18
		FINAL		57	-17	13	-9	-14	-5	9	3	-18	18
	E0026025	DAY 8	15MAY2003	7	-20	7	6	-5	-2	10	15	-9	4
		DAY 15	22MAY2003	14	-22	-12	6	-22	-3	-10	0	9	-16
		DAY 22	29MAY2003	21	-18	5	8	-18	8	10	0	3	2
		DAY 29	05JUN2003	28	-6	26	5	-12	15	9	-6	-11	4
		DAY 36	13JUN2003	36	-18	23	8	-6	58	16	12	35	8
		DAY 43	20JUN2003	43	-8	23	8	-13	15	16	-5	-8	8
		DAY 50	27JUN2003	50	-23	11	6	-25	-1	1	-2	-12	-5
		DAY 57	03JUL2003	56	-8	3	5	-17	12	-30	-9	9	-35
		FINAL		56	-8	3	5	-17	12	-30	-9	9	-35
	E0026029	DAY 8	16JUL2003	8	6	23	5	14	30	3	8	7	-2
		DAY 22	28JUL2003	20	14	27	8	20	15	-2	6	-12	-10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0026029	FINAL			20	14	27	8	20	15	-2	6	-12	-10
	E0026030	DAY 8		16JUL2003	8	-18	21	6	-4	9	-1	14	-12	-7
		DAY 15		23JUL2003	15	-18	-3	0	-2	-3	5	16	0	5
		DAY 22		30JUL2003	22	-4	13	12	6	-2	14	10	-15	2
		DAY 29		04AUG2003	27	-13	-12	-4	5	-7	8	18	5	12
		DAY 36		12AUG2003	35	-17	-16	19	-11	-13	16	6	3	-3
		DAY 43		19AUG2003	42	-23	-11	2	-10	-17	3	13	-6	1
		DAY 50		26AUG2003	49	-15	-21	-3	-4	-23	1	11	-2	4
		DAY 57		03SEP2003	57	-25	0	7	-12	-3	11	13	-3	4
		FINAL			57	-25	0	7	-12	-3	11	13	-3	4
	E0026031	DAY 8		28JUL2003	8	-18	17	2	-19	10	-4	-1	-7	-6
		DAY 15		04AUG2003	15	-4	12	2	-7	10	-6	-3	-2	-8
		DAY 22		11AUG2003	22	-17	27	13	-4	14	15	13	-13	2
		DAY 29		18AUG2003	29	-7	16	12	1	20	8	8	4	-4
		DAY 36		25AUG2003	36	-8	20	10	-5	12	4	3	-8	-6
		DAY 43		02SEP2003	44	-4	1	10	1	-7	18	5	-8	8
		DAY 50		08SEP2003	50	-18	6	10	-9	0	4	9	-6	-6
		DAY 57		15SEP2003	57	-18	-10	10	-11	-8	4	7	2	-6
		FINAL			57	-18	-10	10	-11	-8	4	7	2	-6
	E0027003	DAY 8		06FEB2003	10				18	-6	10			
		DAY 15		13FEB2003	17				26	6	6			
		DAY 22		19FEB2003	23				26	0	6			
		DAY 29		27FEB2003	31				22	8	14			
		DAY 36		06MAR2003	38				22	-12	10			
		DAY 43		13MAR2003	45				10	8	8			
		DAY 50		20MAR2003	52				26	4	10			
		DAY 57		25MAR2003	57				16	22	2			
		FINAL			57				16	22	2			
	E0028004	DAY 8		07OCT2002	8	-11	8	12	-12	0	-12	-1	-8	-24
		DAY 8	*	09OCT2002	10	-10	16	12	2	10	-2	12	-6	-14
		FINAL			10	-10	16	12	2	10	-2	12	-6	-14

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028006	DAY 8	11OCT2002	8	0	28	20	2	30	0	2	2	-20
		DAY 15	16OCT2002	13	-8	20	10	-6	22	0	2	2	-10
		DAY 22	23OCT2002	20	8	16	22	10	26	20	2	10	-2
		DAY 29	31OCT2002	28	0	13	10	-6	24	0	-6	11	-10
		DAY 36	07NOV2002	35	2	10	20	16	16	6	14	6	-14
		DAY 43	14NOV2002	42	0	16	22	10	20	14	10	4	-8
		DAY 50	21NOV2002	49	0	28	24	6	20	22	6	-8	-2
		DAY 57	04DEC2002	62	-4	8	16	-4	10	10	0	2	-6
		FINAL		62	-4	8	16	-4	10	10	0	2	-6
	E0028008	DAY 8	22OCT2002	8	-2	21	8	0	-4	12	2	-25	4
		DAY 15	29OCT2002	15	6	12	10	8	-15	18	2	-27	8
		DAY 22	07NOV2002	24	-2	38	10	0	10	12	2	-28	2
		DAY 29	14NOV2002	31	-2	28	16	0	6	18	2	-22	2
		DAY 36	21NOV2002	38	-6	10	10	-4	2	10	2	-8	0
		DAY 43	26NOV2002	43	-8	10	8	-2	-10	18	6	-20	10
		DAY 50	03DEC2002	50	-14	18	18	-12	-6	-4	2	-24	-22
		DAY 57	10DEC2002	57	-2	10	10	0	-10	14	2	-20	4
		FINAL		57	-2	10	10	0	-10	14	2	-20	4
	E0028009	DAY 8	23OCT2002	9	-2	-18	10	-4	-5	10	-2	13	0
		DAY 15	31OCT2002	17	8	-2	20	22	1	22	14	3	2
		DAY 22	07NOV2002	24	4	-16	20	22	-15	20	18	1	0
		DAY 29	14NOV2002	31	0	-4	16	12	-17	22	12	-13	6
		DAY 36	19NOV2002	36	10	-4	18	28	-5	30	18	-1	12
		DAY 43	26NOV2002	43	4	0	22	4	3	30	0	3	8
		DAY 50	03DEC2002	50	4	-16	18	0	-7	18	-4	9	0
		DAY 57	12DEC2002	59	12	0	10	12	-3	4	0	-3	-6
		FINAL		59	12	0	10	12	-3	4	0	-3	-6
	E0028016	DAY 8	21NOV2002	8	4	2	-6	4	6	0	0	4	6
		DAY 15	26NOV2002	13	12	8	-6	24	14	10	12	6	16
		DAY 22	05DEC2002	22	12	12	0	12	9	10	0	-3	10
		DAY 29	12DEC2002	29	12	22	-2	12	8	10	0	-14	12
		DAY 36	19DEC2002	36	0	2	-10	0	10	2	0	8	12

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	DAY 43	26DEC2002	43	16	-6	-8	16	10	-2	0	16	6
		DAY 50	02JAN2003	50	12	10	-16	16	14	-10	4	4	6
		DAY 57	09JAN2003	57	16	8	-8	24	12	8	8	4	16
		FINAL		57	16	8	-8	24	12	8	8	4	16
	E0028027	DAY 8	28JAN2003	8	-2	30	10	2	24	2	4	-6	-8
		DAY 15	04FEB2003	15	14	0	2	10	-2	0	-4	-2	-2
		DAY 22	11FEB2003	22	4	4	4	4	10	2	0	6	-2
		DAY 29	20FEB2003	31	-4	10	-8	13	2	-16	17	-8	-8
		DAY 36	28FEB2003	39	6	-22	-18	10	-20	-22	4	2	-4
		FINAL		39	6	-22	-18	10	-20	-22	4	2	-4
	E0028029	DAY 8	11FEB2003	8	0	6	-10	0	2	-34	0	-4	-24
		DAY 15	17FEB2003	14	16	-4	10	12	-10	0	-4	-6	-10
		DAY 22	27FEB2003	24	8	12	4	8	14	-16	0	2	-20
		DAY 29	06MAR2003	31	0	4	-4	14	-8	-30	14	-12	-26
		DAY 36	13MAR2003	38	6	2	0	8	-4	-12	2	-6	-12
		DAY 43	20MAR2003	45	0	2	6	0	0	-8	0	-2	-14
		DAY 50	27MAR2003	52	6	4	16	0	-8	-8	-6	-12	-24
		DAY 57	04APR2003	60	-4	4	16	-8	0	-8	-4	-4	-24
		FINAL		60	-4	4	16	-8	0	-8	-4	-4	-24
	E0028034	DAY 8	08APR2003	8	-8	-8	14	-12	6	18	-4	14	4
		DAY 15	15APR2003	15	8	0	14	0	-10	10	-8	-10	-4
		DAY 22	22APR2003	22	4	0	0	-4	6	0	-8	6	0
		DAY 29	01MAY2003	31	16	4	10	8	12	12	-8	8	2
		DAY 36	06MAY2003	36	12	-2	10	8	10	10	-4	12	0
		DAY 43	13MAY2003	43	12	6	-6	8	8	0	-4	2	6
		DAY 50	21MAY2003	51	12	2	6	4	12	8	-8	10	2
		DAY 57	02JUN2003	63	4	-6	18	-4	-6	18	-8	0	0
		FINAL		63	4	-6	18	-4	-6	18	-8	0	0
	E0028038	DAY 8	02MAY2003	8	2	-6	4	8	8	2	6	14	-2
		DAY 15	08MAY2003	14	3	-12	4	-10	4	6	-13	16	2
		DAY 29	22MAY2003	28	6	-6	-4	12	4	2	6	10	6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028038	DAY 36	30MAY2003	36	14	10	14	12	12	6	-2	2	-8
		DAY 43	05JUN2003	42		-4	6		-16	-2		-12	-8
		DAY 50	12JUN2003	49	14	3	8	0	14	8	-14	11	0
		DAY 57	18JUN2003	55	-2	-2	-4	-2	4	0	0	6	4
		FINAL		55	-2	-2	-4	-2	4	0	0	6	4
	E0028043	DAY 8	12JUN2003	8	10	1	7	26	0	16	16	-1	9
		DAY 15	19JUN2003	15	4	-14	2	-10	-12	10	-14	2	8
		DAY 22	26JUN2003	22	8	-24	-18	6	-20	-8	-2	4	10
		DAY 29	01JUL2003	27	30	-14	2	24	-20	4	-6	-6	2
		DAY 36	08JUL2003	34	-10	-24	-12	-10	-20	-4	0	4	8
		DAY 43	15JUL2003	41	10	-14	2	6	-10	8	-4	4	6
		DAY 50	22JUL2003	48	6	-12	-6	2	-22	0	-4	-10	6
		DAY 57	29JUL2003	55	-10	-24	-18	6	-10	-6	16	14	12
		FINAL		55	-10	-24	-18	6	-10	-6	16	14	12
	E0028045	DAY 8	25JUN2003	8	8	-14	-10	-6	-17	-2	-14	-3	8
		DAY 15	30JUN2003	13	34	-6	-6	26	-17	-2	-8	-11	4
		DAY 57	11SEP2003	86	4	-11	-6	-8	-32	-8	-12	-21	-2
		FINAL		86	4	-11	-6	-8	-32	-8	-12	-21	-2
	E0029005	DAY 8	03DEC2002	7	16	2	2	16	0	0	0	-2	-2
		DAY 15	09DEC2002	13	28	16	10	12	24	8	-16	8	-2
		DAY 22	16DEC2002	20	40	-10	-12	32	-6	-2	-8	4	10
		DAY 29	23DEC2002	27	24	0	-6	32	16	-2	8	16	4
		DAY 36	30DEC2002	34	36	-8	-6	12	0	0	-24	8	6
		DAY 43	07JAN2003	42	20	-8	-2	24	0	0	4	8	2
		DAY 50	14JAN2003	49	24	-28	-18	20	-4	-2	-4	24	16
		DAY 57	21JAN2003	56	24	-8	-2	12	0	0	-12	8	2
		FINAL		56	24	-8	-2	12	0	0	-12	8	2
	E0030001	DAY 8	26NOV2002	8	12	-10	-18	4	-14	-16	-8	-4	2
		DAY 15	03DEC2002	15	12	18	4	4	10	2	-8	-8	-2
		DAY 22	10DEC2002	22	16	-10	-10	8	-12	-10	-8	-2	0
		DAY 29	17DEC2002	29	24	0	-8	12	-4	-4	-12	-4	4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	DAY 43		02JAN2003	45	4	-10	-12	4	-16	-6	0	-6	6
		DAY 50		09JAN2003	52	20	-6	-8	8	2	-4	-12	8	4
		DAY 57		16JAN2003	59	12	0	-4	0	-4	-2	-12	-4	2
		FINAL			59	12	0	-4	0	-4	-2	-12	-4	2
	E0030008	DAY 8		23JAN2003	10	12	-2	10	20	10	10	8	12	0
		DAY 15		30JAN2003	17	20	6	14	20	4	8	0	-2	-6
		DAY 22		07FEB2003	25	4	-4	0	20	-4	0	16	0	0
		DAY 29		14FEB2003	32	20	-2	0	28	-4	-6	8	-2	-6
		DAY 36		21FEB2003	39	8	0	6	16	0	2	8	0	-4
		DAY 50		03MAR2003	49	4	6	4	12	2	4	8	-4	0
		DAY 57	*	11MAR2003	57	0	-2	0	4	-4	4	4	-2	4
		DAY 57		18MAR2003	64	20	-4	16	12	2	0	-8	6	-16
		FINAL			64	20	-4	16	12	2	0	-8	6	-16
	E0030011	DAY 8		03FEB2003	8	-4	2	10	-4	-4	4	0	-6	-6
		DAY 15		10FEB2003	15	0	-2	4	-4	0	-2	-4	2	-6
		DAY 22		18FEB2003	23	-4	-8	-10	-2	-4	-12	2	4	-2
		DAY 29		24FEB2003	29	-4	-12	-8	0	-8	-18	4	4	-10
		DAY 36		03MAR2003	36	4	-14	2	0	-8	6	-4	6	4
		DAY 43		10MAR2003	43	4	2	6	8	-6	0	4	-8	-6
		DAY 50		17MAR2003	50	0	4	-6	8	-8	10	8	-12	16
		DAY 57		24MAR2003	57	-4	-6	4	0	2	6	4	8	2
		FINAL			57	-4	-6	4	0	2	6	4	8	2
	E0030015	DAY 8		03MAR2003	11	-8	8	0	-6	4	-12	2	-4	-12
		DAY 15		11MAR2003	19	-8	12	0	14	20	-2	22	8	-2
		DAY 29		19MAR2003	27	-12	-4	-10	6	4	-2	18	8	8
		DAY 36		26MAR2003	34	-12	12	6	-2	8	2	10	-4	-4
		DAY 43		02APR2003	41	-16	-6	8	6	-6	2	22	0	-6
		DAY 50		09APR2003	48	-16	-8	6	-2	-4	-4	14	4	-10
		DAY 57	*	17APR2003	56	-16	12	6	-6	-6	2	10	-18	-4
		DAY 57		22APR2003	61	-8	2	10	-2	8	8	6	6	-2
		FINAL			61	-8	2	10	-2	8	8	6	6	-2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	DAY 8		20JUN2003	5	-4	-4	10	-10	-4	6	-6	0	-4
		DAY 15		30JUN2003	15	-4	-10	4	-8	-6	4	-4	4	0
		DAY 22		07JUL2003	22	-4	12	10	-8	10	6	-4	-2	-4
		DAY 29		14JUL2003	29	-12	2	10	2	2	6	14	0	-4
		DAY 36		21JUL2003	36	-12	6	8	-24	0	4	-12	-6	-4
		DAY 43		29JUL2003	44	-12	2	8	-24	-4	6	-12	-6	-2
		DAY 50		05AUG2003	51	-4	6	12	-20	-2	12	-16	-8	0
		DAY 57		14AUG2003	60	0	2	8	-12	4	6	-12	2	-2
		FINAL			60	0	2	8	-12	4	6	-12	2	-2
	E0031002	DAY 8		06DEC2002	10	20	-32	8	10	-13	3	-10	19	-5
		DAY 15		12DEC2002	16	8	-10	18	-2	-8	8	-10	2	-10
		DAY 22		19DEC2002	23	10	-4	2	-10	2	-4	-20	6	-6
		DAY 29		27DEC2002	31	0	-12	6	-10	0	0	-10	12	-6
		DAY 36		02JAN2003	37	-2	-14	-4	-7	-8	-8	-5	6	-4
		DAY 50	*	13JAN2003	48	6	-4	0	-14	6	-4	-20	10	-4
		DAY 50		17JAN2003	52	8	-12	2	-2	-4	-2	-10	8	-4
		DAY 57		22JAN2003	57	6	-18	-2	-4	-2	-2	-10	16	0
		FINAL			57	6	-18	-2	-4	-2	-2	-10	16	0
	E0031003	DAY 8		17DEC2002	8	14	12	4	6	12	1	-8	0	-3
		DAY 15		23DEC2002	14	12	-6	-8	4	2	-6	-8	8	2
		DAY 22		31DEC2002	22	-4	3	-4	-10	8	0	-6	5	4
		DAY 29		07JAN2003	29	2	6	-12	-2	12	-12	-4	6	0
		DAY 36		15JAN2003	37	-14	-4	-6	-15	2	-4	-1	6	2
		DAY 43		21JAN2003	43	12	4	-2	0	12	4	-12	8	6
		DAY 50		30JAN2003	52	0	8	-4	-4	18	0	-4	10	4
		DAY 57		04FEB2003	57	-4	8	-4	0	18	2	4	10	6
		FINAL			57	-4	8	-4	0	18	2	4	10	6
	E0033015	DAY 8		17APR2003	8	-4	-8	2	0	0	0	4	8	-2
		DAY 15		22APR2003	13	-4	0	-6	0	0	-4	4	0	2
		DAY 15	*	28APR2003	19	-8	12	2	4	10	0	12	-2	-2
		DAY 29		06MAY2003	27	0	2	-8	20	0	-6	20	-2	2
		DAY 36		13MAY2003	34	-12	-8	2	-4	-4	0	8	4	-2

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0033015	DAY 43	20MAY2003	41	-4	2	2	0	0	0	4	-2	-2
		DAY 50	27MAY2003	48	-4	2	2	8	10	0	12	8	-2
		DAY 57	04JUN2003	56	4	2	2	4	0	0	0	-2	-2
		FINAL		56	4	2	2	4	0	0	0	-2	-2
	E0034002	DAY 8	01APR2003	8	16	-10	-12	16	-13	-19	0	-3	-7
		DAY 15	08APR2003	15	4	-22	-12	12	-15	-11	8	7	1
		DAY 22	15APR2003	22	8	-18	-15	0	-7	-15	-8	11	0
		FINAL		22	8	-18	-15	0	-7	-15	-8	11	0
	E0034003	DAY 8	01MAY2003	8	4	-2	6	8	0	4	4	2	-2
		DAY 15	08MAY2003	15	16	10	8	18	10	10	2	0	2
		DAY 22	15MAY2003	22	20	-6	6	12	0	7	-8	6	1
		DAY 29	22MAY2003	29	0	4	11	0	7	2	0	3	-9
		DAY 36	29MAY2003	36	0	-1	-4	12	2	7	12	3	11
		DAY 43	05JUN2003	43	16	4	6	16	0	-2	0	-4	-8
		DAY 50	12JUN2003	50	8	9	1	8	12	12	0	3	11
		DAY 57	19JUN2003	57	0	-1	11	-4	7	12	-4	8	1
		FINAL		57	0	-1	11	-4	7	12	-4	8	1
	E0034006	DAY 8	23MAY2003	8	-8	5	10	12	-10	-5	20	-15	-15
		DAY 15	02JUN2003	18	4	-1	16	8	-8	-8	4	-7	-24
		DAY 22	09JUN2003	25	0	0	10	6	-20	-20	6	-20	-30
		DAY 29	13JUN2003	29	4	-17	4	4	-20	-18	0	-3	-22
		DAY 36	20JUN2003	36	-2	0	20	8	-20	-5	10	-20	-25
		DAY 43	27JUN2003	43	10	10	15	4	9	0	-6	-1	-15
		DAY 50	03JUL2003	49	-8	5	25	0	10	10	8	5	-15
		DAY 57	10JUL2003	56	-8	0	15	0	0	0	8	0	-15
		FINAL		56	-8	0	15	0	0	0	8	0	-15
	E0034008	DAY 8	02JUN2003	10	28	-5	20	28	10	0	0	15	-20
		DAY 15	06JUN2003	14	0	-8	15	0	0	-5	0	8	-20
		DAY 22	13JUN2003	21	10	-28	0	2	-4	-15	-8	24	-15
		DAY 29	20JUN2003	28	4	-16	10	-4	-2	-9	-8	14	-19
		DAY 36	27JUN2003	35	0	-10	10	-4	20	0	-4	30	-10

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0034008	DAY 43	07JUL2003	45	4	-10	15	12	15	10	8	25	-5
		DAY 50	14JUL2003	52	0	-20	0	12	0	-5	12	20	-5
		DAY 57	21JUL2003	59	4	-5	10	12	10	0	8	15	-10
		FINAL		59	4	-5	10	12	10	0	8	15	-10
	E0035003	DAY 8	27NOV2002	6	-4	-8	2	-4	-4	-10	0	4	-12
		DAY 15	04DEC2002	13	0	-6	-6	-2	-4	-10	-2	2	-4
		DAY 22	13DEC2002	22	2	-4	-10	-2	-2	-12	-4	2	-2
		DAY 29	20DEC2002	29	2	-4	-10	0	-4	-10	-2	0	0
		DAY 36	27DEC2002	36	4	-2	-4	4	0	-6	0	2	-2
		DAY 43	03JAN2003	43	2	0	-8	0	2	-14	-2	2	-6
		DAY 50	10JAN2003	50	0	-4	-14	-4	-2	-16	-4	2	-2
		FINAL		50	0	-4	-14	-4	-2	-16	-4	2	-2
	E0035005	DAY 8	12DEC2002	10	0	2	-12	-2	0	-10	-2	-2	2
		DAY 15	17DEC2002	15	-2	4	-12	-6	0	-6	-4	-4	6
		DAY 22	24DEC2002	22	-8	0	-8	-8	-2	-4	0	-2	4
		DAY 29	31DEC2002	29	-8	-2	-10	-12	-4	-8	-4	-2	2
		DAY 36	07JAN2003	36	-8	0	-10	-8	-4	-6	0	-4	4
		DAY 43	14JAN2003	43	-6	0	-8	-10	-4	-4	-4	-4	4
		DAY 50	21JAN2003	50	-24	10	-16	-28	8	-14	-4	-2	2
		FINAL		50	-24	10	-16	-28	8	-14	-4	-2	2
	E0035014	DAY 8	10FEB2003	8	0	-2	-10	0	0	-6	0	2	4
		DAY 15	17FEB2003	15	2	-2	0	2	2	-4	0	4	-4
		DAY 22	24FEB2003	22	4	-4	-2	4	0	-4	0	4	-2
		DAY 29	03MAR2003	29	4	-2	-8	6	0	-6	2	2	2
		DAY 36	10MAR2003	36	0	0	-4	4	2	-2	4	2	2
		DAY 43	17MAR2003	43	2	-2	-4	2	-2	-2	0	0	2
		DAY 50	24MAR2003	50	4	-2	-4	6	0	-4	2	2	0
		DAY 57	31MAR2003	57	6	-4	-2	6	-2	2	0	2	4
		FINAL		57	6	-4	-2	6	-2	2	0	2	4
	E0035024	DAY 8	29MAY2003	7	4	6	4	4	4	10	0	-2	6
		DAY 15	05JUN2003	14	-2	6	8	-2	6	6	0	0	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	DAY 22	13JUN2003	22	4	8	8	4	6	12	0	-2	4
		DAY 29	19JUN2003	28	0	8	12	0	6	14	0	-2	2
		DAY 36	27JUN2003	36	4	18	14	4	18	14	0	0	0
		DAY 43	03JUL2003	42	2	18	14	4	16	16	2	-2	2
		DAY 50	10JUL2003	49	0	16	8	0	14	16	0	-2	8
		DAY 57	18JUL2003	57	0	16	8	4	14	18	4	-2	10
		FINAL		57	0	16	8	4	14	18	4	-2	10
	E0036005	DAY 8	08JUL2003	8	14	3	-1	18	3	0	4	0	1
		DAY 15	15JUL2003	15	25	19	-1	24	19	10	-1	0	11
		DAY 22	23JUL2003	23	17	6	6	25	19	7	8	13	1
		DAY 29	29JUL2003	29	30	10	12	25	19	13	-5	9	1
		DAY 36	05AUG2003	36	29	15	12	13	23	7	-16	8	-5
		DAY 43	12AUG2003	43	5	17	3	1	20	7	-4	3	4
		DAY 50	19AUG2003	50	44	17	7	44	10	8	0	-7	1
		DAY 57	27AUG2003	58	16	8	1	38	16	15	22	8	14
		FINAL		58	16	8	1	38	16	15	22	8	14
	E0037002	DAY 8	03JAN2003	9	-4	6	8	-8	2	10	-4	-4	2
		DAY 15	09JAN2003	15	8	13	0	8	9	0	0	-4	0
		DAY 22	17JAN2003	23	12	4	0	12	-8	0	0	-12	0
		DAY 29	24JAN2003	30	4	2	0	0	0	0	-4	-2	0
		DAY 36	31JAN2003	37	4	4	0	4	-2	0	0	-6	0
		DAY 43	07FEB2003	44	0	10	0	0	6	0	0	-4	0
		DAY 50	13FEB2003	50	0	-6	0	8	-10	0	8	-4	0
		DAY 57	20FEB2003	57	0	-4	0	0	-2	4	0	2	4
		FINAL		57	0	-4	0	0	-2	4	0	2	4
	E0037005	DAY 8	13MAR2003	8	8	7	10	8	5	10	0	-2	0
		DAY 15	20MAR2003	15	-12	1	10	8	5	0	20	4	-10
		DAY 22	27MAR2003	22	-12	0	8	-12	6	10	0	6	2
		DAY 29	03APR2003	29	0	4	0	0	8	2	0	4	2
		DAY 36	10APR2003	36	12	16	10	12	20	10	0	4	0
		DAY 43	17APR2003	43	8	18	10	12	18	10	4	0	0
		DAY 50	24APR2003	50	8	16	20	8	20	20	0	4	0

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GENERATED: 12JUL2005 17:46:43 iceadmn3

Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	DAY 57	01MAY2003	57	-4	16	28	0	10	0	4	-6	-28
		FINAL		57	-4	16	28	0	10	0	4	-6	-28
	E0037006	DAY 8	21MAR2003	8	0	-8	-2	4	-8	-10	4	0	-8
		DAY 15	28MAR2003	15	-12	-4	-4	-8	-2	0	4	2	4
		DAY 22	04APR2003	22	-12	-12	-10	-8	-13	-10	4	-1	0
		DAY 29	11APR2003	29	0	2	8	-4	2	12	-4	0	4
		DAY 36	18APR2003	36	0	-8	-12	4	-8	-12	4	0	0
		DAY 43	25APR2003	43	4	2	8	12	2	10	8	0	2
		DAY 50	01MAY2003	49	0	2	-10	4	-10	10	4	-12	20
		DAY 57	09MAY2003	57	-8	-3	-2	-12	-3	0	-4	0	2
		FINAL		57	-8	-3	-2	-12	-3	0	-4	0	2
	E0039006	DAY 8	06JAN2003	8	20	-16	-12	-15	-14	-6	-35	2	6
		DAY 15	13JAN2003	15	-4	32	18	-12	16	14	-8	-16	-4
		DAY 22	20JAN2003	22	9	16	8	17	12	16	8	-4	8
		DAY 29	28JAN2003	30	16	16	6	-8	12	4	-24	-4	-2
		DAY 36	04FEB2003	37	8	-12	-16	8	0	-8	0	12	8
		DAY 43	10FEB2003	43	-8	2	4	-8	2	10	0	0	6
		DAY 50	18FEB2003	51	20	6	6	9	-4	4	-11	-10	-2
		DAY 57	24FEB2003	57	8	-8	-8	4	-2	0	-4	6	8
		FINAL		57	8	-8	-8	4	-2	0	-4	6	8
	E0039015	DAY 8	30JAN2003	8	2	6	6	1	-4	6	-1	-10	0
		DAY 15	06FEB2003	15	6	0	10	9	2	6	3	2	-4
		DAY 22	14FEB2003	23	8	-6	-8	7	-14	4	-1	-8	12
		DAY 29	20FEB2003	29	4	-20	-10	-3	-20	-6	-7	0	4
		DAY 36	27FEB2003	36	4	4	0	1	-2	2	-3	-6	2
		DAY 43	06MAR2003	43	2	-4	6	-5	-14	2	-7	-10	-4
		DAY 50	14MAR2003	51	2	-18	-6	1	-12	-4	-1	6	2
		DAY 57	20MAR2003	57	2	-8	10	-3	-8	2	-5	0	-8
		FINAL		57	2	-8	10	-3	-8	2	-5	0	-8
	E0039024	DAY 8	05MAR2003	7	-18	-14	-14	-10	-18	-20	8	-4	-6
		DAY 15	11MAR2003	13	-28	-6	-4	-16	-8	-6	12	-2	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039024	DAY 22	20MAR2003	22	-4	-12	-12	6	-10	-28	10	2	-16
		DAY 29	27MAR2003	29	0	-2	-6	12	2	2	12	4	8
		DAY 36	03APR2003	36	-16	-10	-18	8	-10	-2	24	0	16
		DAY 43	10APR2003	43	-20	4	0	-4	2	2	16	-2	2
		DAY 50	17APR2003	50	-14	-8	-6	-2	-4	2	12	4	8
		DAY 57	24APR2003	57	-24	-12	-16	-12	-8	-8	12	4	8
		FINAL		57	-24	-12	-16	-12	-8	-8	12	4	8
	E0039025	DAY 8	25MAR2003	8	12	-20	-6	15	-10	-10	3	10	-4
		DAY 15	01APR2003	15	20	-8	12	15	0	4	-5	8	-8
		DAY 22	10APR2003	24	0	2	8	7	8	8	7	6	0
		DAY 29	15APR2003	29	2	-12	10	3	4	2	1	16	-8
		DAY 36	22APR2003	36	-8	-4	8	-1	2	2	7	6	-6
		DAY 43	29APR2003	43	2	-14	6	9	-4	0	7	10	-6
		DAY 50	06MAY2003	50	16	-8	2	19	-6	-12	3	2	-14
		DAY 57	27MAY2003	71	12	4	10	19	8	2	7	4	-8
		FINAL		71	12	4	10	19	8	2	7	4	-8
	E0039041	DAY 8	22APR2003	8	4	12	4	20	-4	4	16	-16	0
		DAY 15	29APR2003	15	24	20	10	18	8	2	-6	-12	-8
		DAY 22	06MAY2003	22	-2	4	4	-2	4	0	0	0	-4
		DAY 29	13MAY2003	29	0	-2	4	8	0	4	8	2	0
		DAY 36	20MAY2003	36	2	14	-2	10	6	2	8	-8	4
		DAY 43	27MAY2003	43	0	12	6	2	-2	16	2	-14	10
		DAY 50	03JUN2003	50	-4	8	-4	10	8	2	14	0	6
		DAY 57	11JUN2003	58	-6	6	4	0	-2	0	6	-8	-4
		FINAL		58	-6	6	4	0	-2	0	6	-8	-4
	E0039044	DAY 8	29MAY2003	8	13	10	4	0	12	8	-13	2	4
		DAY 15	04JUN2003	14	36	12	10	0	2	2	-36	-10	-8
		DAY 22	11JUN2003	21	28	6	0	20	16	10	-8	10	10
		DAY 29	18JUN2003	28	34	4	8	20	14	12	-14	10	4
		DAY 36	26JUN2003	36	20	-2	8	12	6	12	-8	8	4
		DAY 43	02JUL2003	42	36	22	12	22	16	6	-14	-6	-6
		DAY 50	09JUL2003	49	13	18	4	8	24	10	-5	6	6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	FINAL		49	13	18	4	8	24	10	-5	6	6
	E0039051	DAY 8	23JUN2003	8	-12	-2	2	-8	-6	8	4	-4	6
		DAY 15	30JUN2003	15	-12	8	-4	-8	-12	-4	4	-20	0
		DAY 22	07JUL2003	22	2	10	-2	-2	2	8	-4	-8	10
		DAY 29	14JUL2003	29	8	10	8	8	-16	6	0	-26	-2
		DAY 36	22JUL2003	37	10	14	0	17	-6	12	7	-20	12
		DAY 43	28JUL2003	43	12	20	10	8	-8	8	-4	-28	-2
		DAY 50	04AUG2003	50	2	6	8	-4	-10	6	-6	-16	-2
		DAY 57	12AUG2003	58	12	-2	-8	13	-24	-4	1	-22	4
		FINAL		58	12	-2	-8	13	-24	-4	1	-22	4
	E0039053	DAY 8	18JUL2003	8	0	12	-6	0	-8	-6	0	-20	0
		DAY 15	25JUL2003	15	-8	8	-6	-4	-8	-14	4	-16	-8
		DAY 22	01AUG2003	22	-4	-10	-6	0	-24	-10	4	-14	-4
		DAY 29	07AUG2003	28	-16	4	2	-12	-8	-12	4	-12	-14
		DAY 36	14AUG2003	35	-10	0	-12	-6	-24	-16	4	-24	-4
		DAY 43	21AUG2003	42	1	-6	-6	12	-24	-8	11	-18	-2
		DAY 50	29AUG2003	50	0	-14	-14	12	-32	-10	12	-18	4
		DAY 57	08SEP2003	60	-4	-4	4	-4	-26	-8	0	-22	-12
		FINAL		60	-4	-4	4	-4	-26	-8	0	-22	-12
	E0039057	DAY 8	22JUL2003	9	0	-6	-4	0	-4	-4	0	2	0
		DAY 15	28JUL2003	15	0	-2	2	-8	6	0	-8	8	-2
		DAY 22	04AUG2003	22	0	-14	-10	1	-8	-10	1	6	0
		DAY 29	12AUG2003	30	2	2	2	4	-6	0	2	-8	-2
		DAY 36	18AUG2003	36	6	-6	-8	1	10	-2	-5	16	6
		DAY 43	26AUG2003	44	0	-6	2	-12	-4	-10	-12	2	-12
		DAY 50	02SEP2003	51	12	14	-10	16	-8	-12	4	-22	-2
		DAY 57	09SEP2003	58	4	0	-8	-4	-8	-10	-8	-8	-2
		FINAL		58	4	0	-8	-4	-8	-10	-8	-8	-2
	E0041003	DAY 8	04FEB2003	8	-4	0	14	4	6	18	8	6	4
		DAY 15	11FEB2003	15	4	24	16	8	26	14	4	2	-2
		DAY 22	18FEB2003	22	4	28	12	4	20	12	0	-8	0

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	DAY 29	25FEB2003	29	0	40	20	4	22	10	4	-18	-10
		DAY 36	04MAR2003	36	12	38	14	14	28	14	2	-10	0
		DAY 43	11MAR2003	43	8	18	14	8	16	14	0	-2	0
		DAY 50	18MAR2003	50	-8	18	14	0	12	12	8	-6	-2
		DAY 57	25MAR2003	57	8	10	16	16	6	18	8	-4	2
		FINAL		57	8	10	16	16	6	18	8	-4	2
	E0041008	DAY 8	14APR2003	8	-17	-10	0	-18	-12	-4	-1	-2	-4
		DAY 15	22APR2003	16	-11	-2	0	-12	-12	-8	-1	-10	-8
		DAY 22	28APR2003	22	-11	0	-10	-18	-4	-10	-7	-4	0
		DAY 29	05MAY2003	29	5	-10	0	-4	-12	-4	-9	-2	-4
		DAY 36	12MAY2003	36	3	-8	0	0	-14	-2	-3	-6	-2
		DAY 43	21MAY2003	45	-1	-4	2	-6	-10	-2	-5	-6	-4
		DAY 50	27MAY2003	51	-5	-2	0	-14	-6	-2	-9	-4	-2
		DAY 57	02JUN2003	57	-1	-2	-2	0	-8	0	1	-6	2
		FINAL		57	-1	-2	-2	0	-8	0	1	-6	2
	E0042001	DAY 8	09JUL2003	8	4	10	0	-4	10	-2	-8	0	-2
		DAY 15	15JUL2003	14	-4	10	0	4	0	0	8	-10	0
		DAY 22	22JUL2003	21	-4	12	0	-4	-10	-10	0	-22	-10
		DAY 29	29JUL2003	28	0	10	0	8	4	-10	8	-6	-10
		DAY 36	05AUG2003	35	-4	10	4	-4	0	0	0	-10	-4
		DAY 43	12AUG2003	42	8	10	8	-4	10	-10	-12	0	-18
		DAY 50	19AUG2003	49	-4	0	-2	0	0	-10	4	0	-8
		DAY 57	26AUG2003	56	4	0	-2	-4	-10	-10	-8	-10	-8
		FINAL		56	4	0	-2	-4	-10	-10	-8	-10	-8
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 8	19MAR2003	8	-6	0	-5	-2	-10	-10	4	-10	-5
		DAY 15	26MAR2003	15	-2	10	-5	0	0	-10	2	-10	-5
		DAY 22	02APR2003	22	10	30	15	12	22	2	2	-8	-13
		DAY 29	09APR2003	29	-6	0	5	-6	-10	0	0	-10	-5
		DAY 36	16APR2003	36	2	20	5	2	10	0	0	-10	-5
		DAY 43	23APR2003	43	-5	10	0	-2	5	0	3	-5	0
		DAY 50	30APR2003	50	-7	5	5	-5	0	5	2	-5	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 57	07MAY2003	57	4	0	0	4	-10	-5	0	-10	-5
		FINAL		57	4	0	0	4	-10	-5	0	-10	-5
	E0003018	DAY 8	20MAY2003	8	8	20	10	8	12	4	0	-8	-6
		DAY 15	27MAY2003	15	8	12	10	20	8	4	12	-4	-6
		DAY 22	03JUN2003	22	4	0	12	2	-4	4	-2	-4	-8
		DAY 29	10JUN2003	29	6	-6	4	4	-8	-4	-2	-2	-8
		DAY 36	17JUN2003	36	8	2	8	4	2	0	-4	0	-8
		DAY 43	24JUN2003	43	4	8	12	2	4	4	-2	-4	-8
		DAY 50	02JUL2003	51	10	8	16	14	16	14	4	8	-2
		DAY 57	08JUL2003	57	10	-8	2	-4	-10	-12	-14	-2	-14
		FINAL		57	10	-8	2	-4	-10	-12	-14	-2	-14
	E0005011	DAY 8	31OCT2002	8	4	0	6	4	0	10	0	0	4
		DAY 15	07NOV2002	15	12	0	10	12	10	10	0	10	0
		DAY 22	14NOV2002	22	4	-2	6	4	0	0	0	2	-6
		DAY 29	21NOV2002	29	4	-8	-4	4	-2	10	0	6	14
		DAY 36	26NOV2002	34	8	4	6	8	10	10	0	6	4
		DAY 43	03DEC2002	41	12	6	6	12	14	10	0	8	4
		DAY 50	12DEC2002	50	8	-10	-4	8	-10	0	0	0	4
		FINAL		50	8	-10	-4	8	-10	0	0	0	4
	E0005030	DAY 8	02APR2003	8	-4	0	-4	-12	8	0	-8	8	4
		DAY 15	09APR2003	15	4	10	2	16	14	10	12	4	8
		DAY 22	16APR2003	22	4	2	-4	4	14	8	0	12	12
		FINAL		22	4	2	-4	4	14	8	0	12	12
	E0005036	DAY 8	12MAY2003	7	4	-6	-10	4	-10	-10	0	-4	0
		DAY 22	27MAY2003	22	12	0	8	12	0	8	0	0	0
		FINAL		22	12	0	8	12	0	8	0	0	0
	E0006015	DAY 8	18FEB2003	8	20	13	12	18	-4	5	-2	-17	-7
		DAY 15	25FEB2003	15	16	12	12	20	-8	-2	4	-20	-14
		DAY 22	04MAR2003	22	15	10	19	16	-4	-6	1	-14	-25
		DAY 29	11MAR2003	29	2	10	19	2	-7	8	0	-17	-11

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	DAY 36	18MAR2003	36	3	12	13	31	-13	-5	28	-25	-18
		DAY 43	25MAR2003	43	6	13	14	18	-12	3	12	-25	-11
		DAY 50	01APR2003	50	12	-6	14	14	-27	-7	2	-21	-21
		DAY 57	08APR2003	57	12	11	13	10	-7	-2	-2	-18	-15
		FINAL		57	12	11	13	10	-7	-2	-2	-18	-15
	E0006016	DAY 8	24FEB2003	8	1	15	18	-13	4	-12	-14	-11	-30
		DAY 15	03MAR2003	15	11	2	14	-1	17	-1	-12	15	-15
		DAY 22	10MAR2003	22	1	12	14	-1	11	9	-2	-1	-5
		DAY 29	17MAR2003	29	4	-5	7	-12	17	-9	-16	22	-16
		DAY 36	27MAR2003	39	4	9	5	2	3	-8	-2	-6	-13
		DAY 43	03APR2003	46	7	-2	21	-1	4	-2	-8	6	-23
		DAY 50	10APR2003	53	7	6	16	-7	18	10	-14	12	-6
		DAY 57	18APR2003	61	1	17	19	2	13	-1	1	-4	-20
		FINAL		61	1	17	19	2	13	-1	1	-4	-20
	E0007008	DAY 8	25APR2003	8	0	20	20	4	18	12	4	-2	-8
		FINAL		8	0	20	20	4	18	12	4	-2	-8
	E0009002	DAY 8	26NOV2002	8	20	-14	-4	-4	-20	-8	-24	-6	-4
		DAY 15	03DEC2002	15	16	-12	-6	-6	-18	-8	-22	-6	-2
		DAY 22	10DEC2002	22	20	-6	0	2	-12	-8	-18	-6	-8
		DAY 29	18DEC2002	30	-4	-22	0	4	-16	0	8	6	0
		DAY 36	23DEC2002	35	4	0	-4	-16	-2	-4	-20	-2	0
		DAY 43	30DEC2002	42	16	-10	-2	0	-18	-10	-16	-8	-8
		DAY 50	07JAN2003	50	-4	2	6	-16	-2	4	-12	-4	-2
		DAY 57	15JAN2003	58	4	-2	-4	-14	-4	-6	-18	-2	-2
		FINAL		58	4	-2	-4	-14	-4	-6	-18	-2	-2
	E0009006	DAY 8	04FEB2003	8	-16	28	6	-2	34	14	14	6	8
		DAY 15	11FEB2003	15	6	20	6	2	20	10	-4	0	4
		DAY 22	18FEB2003	22	4	40	16	-4	38	8	-8	-2	-8
		DAY 29	25FEB2003	29	6	10	-4	0	10	-2	-6	0	2
		DAY 36	04MAR2003	36	4	18	6	-2	16	-2	-6	-2	-8
		DAY 43	11MAR2003	43	10	24	-2	-4	20	-10	-14	-4	-8

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	DAY 50	18MAR2003	50	6	10	6	-2	10	0	-8	0	-6
		DAY 57	25MAR2003	57	8	10	20	-2	20	16	-10	10	-4
		FINAL		57	8	10	20	-2	20	16	-10	10	-4
	E0009009	DAY 8	19MAR2003	8	10	14	-2	6	-10	-6	-4	-24	-4
		DAY 15	24MAR2003	13	-18	20	-2	-12	0	-6	6	-20	-4
		FINAL		13	-18	20	-2	-12	0	-6	6	-20	-4
	E0010015	DAY 8	27FEB2003	8	6	4	6	6	-10	2	0	-14	-4
		DAY 15	06MAR2003	15	-10	-8	2	-4	-26	-2	6	-18	-4
		DAY 22	13MAR2003	22	-8	18	2	-10	-6	0	-2	-24	-2
		DAY 29	20MAR2003	29	-18	0	0	-8	-10	0	10	-10	0
		DAY 36	26MAR2003	35	-2	4	2	-8	-6	0	-6	-10	-2
		DAY 43	02APR2003	42	-13	0	2	-3	-12	4	10	-12	2
		DAY 50	09APR2003	49	-6	0	0	0	-16	-10	6	-16	-10
		DAY 57	15APR2003	55	-10	-8	2	-6	-10	4	4	-2	2
		FINAL		55	-10	-8	2	-6	-10	4	4	-2	2
	E0011004	DAY 8	31DEC2002	8	-2	-6	4	-5	-6	2	-3	0	-2
		DAY 15	07JAN2003	15	-8	6	-2	8	-1	6	16	-7	8
		DAY 22	14JAN2003	22	10	6	10	11	-2	4	1	-8	-6
		DAY 29	21JAN2003	29	6	6	0	9	8	-2	3	2	-2
		DAY 36	28JAN2003	36	2	0	2	3	-6	-2	1	-6	-4
		DAY 43	04FEB2003	43	6	2	2	7	-2	2	1	-4	0
		DAY 50	11FEB2003	50	-2	6	6	3	6	2	5	0	-4
		DAY 57	18FEB2003	57	2	2	6	7	-6	2	5	-8	-4
		FINAL		57	2	2	6	7	-6	2	5	-8	-4
	E0011007	DAY 8	26DEC2002	8	1	4	7	-15	-4	-3	-16	-8	-10
		DAY 15	02JAN2003	15	-11	14	6	-3	9	-2	8	-5	-8
		DAY 22	09JAN2003	22	-9	17	2	-1	7	-8	8	-10	-10
		DAY 29	17JAN2003	30	-21	15	4	-5	9	-10	16	-6	-14
		DAY 36	23JAN2003	36	-13	19	6	-7	17	-4	6	-2	-10
		DAY 43	30JAN2003	43	-19	17	2	-11	11	-2	8	-6	-4
		DAY 50	06FEB2003	50	-21	19	-4	-13	7	-10	8	-12	-6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0011007	DAY 57		13FEB2003	57	-13	11	2	3	-3	-8	16	-14	-10
		FINAL			57	-13	11	2	3	-3	-8	16	-14	-10
	E0011018	DAY 8		30MAY2003	9	4	4	4	0	2	0	-4	-2	-4
		DAY 22	*	10JUN2003	20	6	-12	2	-4	2	2	-10	14	0
		DAY 22		13JUN2003	23	12	-4	-2	0	2	-4	-12	6	-2
		DAY 29		20JUN2003	30	10	-4	10	0	0	14	-10	4	4
		DAY 36		28JUN2003	38	13	0	0	0	-6	0	-13	-6	0
		DAY 43		03JUL2003	43	12	-4	14	4	-2	18	-8	2	4
		DAY 50		10JUL2003	50	14	-4	6	2	-6	10	-12	-2	4
		DAY 57		17JUL2003	57	14	-4	10	0	-6	8	-14	-2	-2
		FINAL			57	14	-4	10	0	-6	8	-14	-2	-2
	E0011024	DAY 8		01JUL2003	8	21	10	-2	15	12	2	-6	2	4
		DAY 15		08JUL2003	15	20	7	2	17	0	2	-3	-7	0
		DAY 22		15JUL2003	22	-4	12	2	-3	8	2	1	-4	0
		DAY 29		22JUL2003	29	0	20	2	-3	18	2	-3	-2	0
		DAY 36		30JUL2003	37	8	2	-8	5	2	-8	-3	0	0
		DAY 43		05AUG2003	43	8	2	-6	5	2	-8	-3	0	-2
		DAY 50		12AUG2003	50	18	12	0	19	8	-2	1	-4	-2
		DAY 57		21AUG2003	59	22	12	-2	23	12	0	1	0	2
		FINAL			59	22	12	-2	23	12	0	1	0	2
	E0015003	DAY 8		02DEC2002	8	6	-10	-10	6	-6	-10	0	4	0
		FINAL			8	6	-10	-10	6	-6	-10	0	4	0
	E0019003	DAY 8		27NOV2002	7	0	-15	0	4	-7	0	4	8	0
		DAY 15		09DEC2002	19	4	-5	-20	16	-4	-10	12	1	10
		DAY 22		16DEC2002	26	4	-5	-10	20	-4	-10	16	1	0
		DAY 36		24DEC2002	34	4	-7	-10	8	0	0	4	7	10
		DAY 36	*	30DEC2002	40	-4	-7	-2	12	0	2	16	7	4
		DAY 43		06JAN2003	47	0	-15	-16	4	-8	-10	4	7	6
		DAY 57	*	14JAN2003	55	-4	5	10	8	2	8	12	-3	-2
		DAY 57		16JAN2003	57	0	-3	2	16	-4	-6	16	-1	-8
		FINAL			57	0	-3	2	16	-4	-6	16	-1	-8

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019007	DAY 8	21NOV2002	9	-4	-15	0	-8	-5	2	-4	10	2
		DAY 15	27NOV2002	15	8	-7	-4	0	-1	8	-8	6	12
		DAY 22	05DEC2002	23	0	-5	-5	-8	-5	-5	-8	0	0
		DAY 29	12DEC2002	30	-4	-15	-2	-10	-15	2	-6	0	4
		DAY 36	17DEC2002	35	-4	-13	-5	-12	-15	-2	-8	-2	3
		DAY 43	24DEC2002	42	0	-10	-5	-8	-7	-2	-8	3	3
		DAY 50	30DEC2002	48	0	7	2	-4	11	10	-4	4	8
		DAY 57	07JAN2003	56	0	5	8	-12	13	10	-12	8	2
		FINAL		56	0	5	8	-12	13	10	-12	8	2
	E0019014	DAY 8	20JAN2003	12	0	10	7	4	5	0	4	-5	-7
		FINAL		12	0	10	7	4	5	0	4	-5	-7
	E0019018	DAY 8	06FEB2003	8	-12	5	10	-4	3	15	8	-2	5
		DAY 15	13FEB2003	15	-8	-10	-5	0	-5	0	8	5	5
		DAY 22	20FEB2003	22	-12	0	-5	-8	5	0	4	5	5
		DAY 29	27FEB2003	29	-12	-10	0	-4	-5	5	8	5	5
		DAY 36	06MAR2003	36	0	2	0	0	-3	2	0	-5	2
		DAY 43	13MAR2003	43	-4	8	-10	8	-3	0	12	-11	10
		DAY 50	20MAR2003	50	-8	-10	-2	4	-13	0	12	-3	2
		DAY 57	27MAR2003	57	2	-8	2	8	1	-6	6	9	-8
		FINAL		57	2	-8	2	8	1	-6	6	9	-8
	E0019022	DAY 8	06FEB2003	8	-4	5	11	-4	10	10	0	5	-1
		DAY 15	13FEB2003	15	2	-15	6	-2	-5	10	-4	10	4
		DAY 22	20FEB2003	22	-4	-5	1	-2	2	5	2	7	4
		DAY 29	27FEB2003	29	-12	0	1	-2	5	5	10	5	4
		DAY 36	06MAR2003	36	-20	-7	6	-12	2	9	8	9	3
		DAY 43	13MAR2003	43	16	-5	10	12	0	13	-4	5	3
		DAY 50	20MAR2003	50	4	5	6	8	10	10	4	5	4
		DAY 57	27MAR2003	57	-4	3	6	-4	10	10	0	7	4
		FINAL		57	-4	3	6	-4	10	10	0	7	4
	E0019027	DAY 8	06MAR2003	8	-12	10	-2	-16	11	0	-4	1	2
		FINAL		8	-12	10	-2	-16	11	0	-4	1	2

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019032	DAY 8	08APR2003	8	16	0	-10	12	0	-5	-4	0	5
		DAY 15	15APR2003	15	20	-5	-10	8	-10	-5	-12	-5	5
		DAY 22	21APR2003	21	36	10	16	40	0	7	4	-10	-9
		DAY 29	29APR2003	29	32	8	0	28	5	5	-4	-3	5
		DAY 36	07MAY2003	37	12	-8	8	16	-8	7	4	0	-1
		DAY 43	14MAY2003	44	16	0	8	8	0	0	-8	0	-8
		DAY 50	21MAY2003	51	4	-5	0	-8	0	-5	-12	5	-5
		DAY 57	27MAY2003	57	0	-10	8	-16	-12	5	-16	-2	-3
		FINAL		57	0	-10	8	-16	-12	5	-16	-2	-3
	E0019034	DAY 8	25MAR2003	8	-4	10	-10	4	-2	-2	8	-12	8
		DAY 15	01APR2003	15	-8	10	-5	-4	0	-4	4	-10	1
		FINAL		15	-8	10	-5	-4	0	-4	4	-10	1
	E0019036	DAY 8	31MAR2003	7	20	5	5	8	-5	0	-12	-10	-5
		DAY 15	10APR2003	17	16	5	5	8	-20	0	-8	-25	-5
		DAY 22	15APR2003	22	8	-5	5	4	-10	10	-4	-5	5
		DAY 29	22APR2003	29	0	-5	5	-12	0	5	-12	5	0
		DAY 36	29APR2003	36	0	5	5	0	-2	8	0	-7	3
		FINAL		36	0	5	5	0	-2	8	0	-7	3
	E0019039	DAY 8	08MAY2003	8	16	0	-10	16	2	-6	0	2	4
		FINAL		8	16	0	-10	16	2	-6	0	2	4
	E0019041	DAY 8	28MAY2003	8	-4	0	5	6	0	0	10	0	-5
		DAY 15	04JUN2003	15	-8	0	-8	0	-5	-12	8	-5	-4
		DAY 22	12JUN2003	23	-6	0	10	2	5	5	8	5	-5
		DAY 29	18JUN2003	29	8	8	0	16	5	0	8	-3	0
		DAY 36	25JUN2003	36	-16	2	4	16	9	-2	32	7	-6
		DAY 43	02JUL2003	43	-8	8	12	8	-5	-2	16	-13	-14
		DAY 50	09JUL2003	50	-8	4	6	4	7	4	12	3	-2
		DAY 57	16JUL2003	57	-8	10	10	8	20	15	16	10	5
		FINAL		57	-8	10	10	8	20	15	16	10	5
	E0019049	DAY 8	17JUL2003	8	26	2	11	22	-11	12	-4	-13	1

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019049	DAY 15	24JUL2003	15	22	-10	6	26	-10	10	4	0	4
		DAY 22	31JUL2003	22	14	4	12	26	2	10	12	-2	-2
		DAY 29	07AUG2003	29	14	2	16	22	6	8	8	4	-8
		DAY 36	14AUG2003	36	22	7	14	14	4	7	-8	-3	-7
		DAY 50	26AUG2003	48	22	2	16	18	-1	7	-4	-3	-9
		DAY 57	08SEP2003	61	14	8	16	6	0	16	-8	-8	0
		FINAL		61	14	8	16	6	0	16	-8	-8	0
	E0022052	DAY 8	17APR2003	8	-12	4	0	9	-2	-10	21	-6	-10
		DAY 15	24APR2003	15	6	2	-4	15	-6	0	9	-8	4
		DAY 22	01MAY2003	22	15	2	-8	21	8	-2	6	6	6
		DAY 29	08MAY2003	29	-18	-6	-4	9	0	-8	27	6	-4
		DAY 36	15MAY2003	36	-17	-2	-2	-17	-12	-16	0	-10	-14
		DAY 43	22MAY2003	43	6	-2	-6	9	-10	-12	3	-8	-6
		DAY 50	29MAY2003	50	-12	-2	0	6	-2	-4	18	0	-4
		DAY 57	05JUN2003	57	7	-2	4	7	2	-2	0	4	-6
		FINAL		57	7	-2	4	7	2	-2	0	4	-6
	E0022064	DAY 8	12MAY2003	7	9	4	4	0	-12	-12	-9	-16	-16
		DAY 15	20MAY2003	15	15	-4	-4	15	-10	-14	0	-6	-10
		DAY 22	27MAY2003	22	12	4	8	15	-2	-8	3	-6	-16
		DAY 29	03JUN2003	29	26	2	0	15	-6	-14	-11	-8	-14
		DAY 36	10JUN2003	36	12	8	2	5	0	-14	-7	-8	-16
		DAY 43	17JUN2003	43	24	6	2	15	-6	-16	-9	-12	-18
		DAY 50	24JUN2003	50	18	4	0	6	-8	-14	-12	-12	-14
		DAY 57	01JUL2003	57	12	6	6	0	-4	-12	-12	-10	-18
		FINAL		57	12	6	6	0	-4	-12	-12	-10	-18
	E0022073	DAY 8	03JUL2003	8	8	-2	-8	3	-4	0	-5	-2	8
		DAY 15	10JUL2003	15	-6	0	-2	-1	-8	-4	5	-8	-2
		DAY 22	17JUL2003	22	8	4	-12	19	2	-14	11	-2	-2
		DAY 29	24JUL2003	29	9	10	-6	24	4	-10	15	-6	-4
		DAY 36	31JUL2003	36	3	-4	-8	-2	0	-6	-5	4	2
		DAY 43	07AUG2003	43	-8	4	-2	-5	10	0	3	6	2
		DAY 50	14AUG2003	50	-4	4	-8	-9	8	-8	-5	4	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0022073	DAY 57	21AUG2003	57	10	14	0	9	4	0	-1	-10	0
		FINAL		57	10	14	0	9	4	0	-1	-10	0
	E0023002	DAY 8	12NOV2002	8	8	12	6	4	10	2	-4	-2	-4
		DAY 15	19NOV2002	15	20	10	5	12	7	0	-8	-3	-5
		DAY 22	25NOV2002	21	12	22	6	16	12	-10	4	-10	-16
		DAY 29	03DEC2002	29	19	17	3	35	23	-14	16	6	-17
		DAY 36	10DEC2002	36	12	22	10	-12	18	-6	-24	-4	-16
		FINAL		36	12	22	10	-12	18	-6	-24	-4	-16
	E0023017	DAY 8	03APR2003	10	1	-24	-17	7	-30	-10	6	-6	7
		DAY 15	10APR2003	17	-7	-13	-9	-7	-26	-10	0	-13	-1
		DAY 22	18APR2003	25	-8	-28	-10	2	-30	-6	10	-2	4
		DAY 29	24APR2003	31	2	0	0	2	-10	0	0	-10	0
		DAY 36	01MAY2003	38	14	0	4	16	-16	0	2	-16	-4
		DAY 43	08MAY2003	45	-1	-18	-9	0	-32	-10	1	-14	-1
		DAY 50	15MAY2003	52	2	27	10	22	-19	-5	20	-46	-15
		DAY 57	22MAY2003	59	2	4	-9	6	-10	-10	4	-14	-1
		FINAL		59	2	4	-9	6	-10	-10	4	-14	-1
	E0023021	DAY 8	29APR2003	7	-2	-8	-6	6	-7	-6	8	1	0
		DAY 15	06MAY2003	14	-14	-5	-22	0	-4	-22	14	1	0
		DAY 22	13MAY2003	21	-10	-2	-5	12	10	3	22	12	8
		DAY 29	20MAY2003	28	-9	-4	-15	9	-18	-16	18	-14	-1
		DAY 36	29MAY2003	37	-3	0	-10	21	-1	-9	24	-1	1
		DAY 43	03JUN2003	42	4	2	-9	8	2	-12	4	0	-3
		DAY 50	10JUN2003	49	-11	-9	-15	-4	-10	-10	7	-1	5
		DAY 57	17JUN2003	56	23	4	-20	12	19	6	-11	15	26
		FINAL		56	23	4	-20	12	19	6	-11	15	26
	E0023027	DAY 8	21MAY2003	6	-16	12	16	-31	11	12	-15	-1	-4
		DAY 15	30MAY2003	15	44	35	22	27	23	19	-17	-12	-3
		DAY 22	05JUN2003	21	9	24	19	8	34	19	-1	10	0
		DAY 29	11JUN2003	27	-3	10	16	-19	7	10	-16	-3	-6
		DAY 36	18JUN2003	34	9	12	20	-11	1	4	-20	-11	-16

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0023027	DAY 43		27JUN2003	43	-3	14	24	-19	1	12	-16	-13	-12
		DAY 50		02JUL2003	48	26	10	8	24	8	-4	-2	-2	-12
		DAY 57		09JUL2003	55	6	19	5	-9	11	0	-15	-8	-5
		FINAL			55	6	19	5	-9	11	0	-15	-8	-5
	E0023030	DAY 8		10JUN2003	8	11	-8	-3	2	17	-7	-9	25	-4
		DAY 15		17JUN2003	15	10	16	10	7	1	-3	-3	-15	-13
		DAY 22		24JUN2003	22	-2	-5	-8	-6	-10	-14	-4	-5	-6
		DAY 29		01JUL2003	29	-10	12	4	-13	-1	-4	-3	-13	-8
		DAY 36		08JUL2003	36	2	12	7	-3	21	5	-5	9	-2
		DAY 43		15JUL2003	43	3	10	5	-5	-45	-12	-8	-55	-17
		DAY 50		21JUL2003	49	11	27	19	2	10	4	-9	-17	-15
		DAY 57		30JUL2003	58	-3	20	12	-5	17	4	-2	-3	-8
		FINAL			58	-3	20	12	-5	17	4	-2	-3	-8
	E0023040	DAY 8		12JUL2003	10	1	4	0	6	6	4	5	2	4
		DAY 15		17JUL2003	15	-4	-3	-1	1	9	8	5	12	9
		DAY 22		25JUL2003	23	5	15	7	4	-9	-9	-1	-24	-16
		DAY 36	*	05AUG2003	34	-5	10	4	-5	16	-7	0	6	-11
		DAY 36		08AUG2003	37	7	-24	-15	13	-16	-11	6	8	4
		DAY 43		18AUG2003	47	-4	10	2	0	0	10	4	-10	8
		DAY 57	*	28AUG2003	57	-13	8	3	4	15	8	17	7	5
		DAY 57		05SEP2003	65	-18	0	4	-17	9	4	1	9	0
		FINAL			65	-18	0	4	-17	9	4	1	9	0
	E0026014	DAY 8		26FEB2003	8	18	-8	0	13	-4	-7	-5	4	-7
		DAY 15		05MAR2003	15	7	-22	-8	2	-19	-14	-5	3	-6
		DAY 22		12MAR2003	22	17	-6	-9	12	-4	-7	-5	2	2
		DAY 29		19MAR2003	29	22	-8	-9	0	-13	-8	-22	-5	1
		FINAL			29	22	-8	-9	0	-13	-8	-22	-5	1
	E0026019	DAY 8		24MAR2003	8	12	23	5	5	9	3	-7	-14	-2
		DAY 15		31MAR2003	15	25	32	11	13	25	11	-12	-7	0
		DAY 22		07APR2003	22	9	19	-1	5	-10	4	-4	-29	5
		DAY 29		14APR2003	29	10	10	3	5	6	0	-5	-4	-3

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0026019	DAY 36	21APR2003	36	1	2	-8	-7	-2	-3	-8	-4	5
		DAY 43	28APR2003	43	-3	-2	-7	-12	9	-5	-9	11	2
		DAY 50	05MAY2003	50	15	-30	-9	9	-21	-6	-6	9	3
		DAY 57	12MAY2003	57	5	13	-30	6	0	-25	1	-13	5
		FINAL		57	5	13	-30	6	0	-25	1	-13	5
	E0027005	DAY 8	02JAN2003	8	16	0	1	8	-8	0	-8	-8	-1
		DAY 15	09JAN2003	15	20	-10	6	0	-8	8	-20	2	2
		DAY 22	16JAN2003	22	-8	10	10	-8	2	10	0	-8	0
		DAY 29	23JAN2003	29	8	-8	0	8	-18	-10	0	-10	-10
		DAY 36	30JAN2003	36	4	0	2	6	-8	-4	2	-8	-6
		DAY 43	06FEB2003	43	8	30	16	12	2	10	4	-28	-6
		DAY 50	12FEB2003	49	-5	6	0	6	10	8	11	4	8
		DAY 57	20FEB2003	57	4	0	6	0	-8	10	-4	-8	4
		FINAL		57	4	0	6	0	-8	10	-4	-8	4
	E0029009	DAY 8	27JAN2003	8	4	2	2	4	0	2	0	-2	0
		DAY 15	03FEB2003	15	8	12	16	12	4	12	4	-8	-4
		DAY 22	11FEB2003	23	4	12	16	4	10	12	0	-2	-4
		DAY 29	17FEB2003	29	16	-8	4	20	-12	2	4	-4	-2
		DAY 36	24FEB2003	36	8	10	12	8	8	12	0	-2	0
		DAY 43	03MAR2003	43	4	22	12	16	20	6	12	-2	-6
		DAY 50	11MAR2003	51	12	-4	4	16	0	2	4	4	-2
		DAY 57	18MAR2003	58	8	10	12	8	-6	-10	0	-16	-22
		FINAL		58	8	10	12	8	-6	-10	0	-16	-22
	E0029021	DAY 8	25MAR2003	8	4	12	10	0	10	8	-4	-2	-2
		DAY 15	01APR2003	15	8	2	8	8	-2	6	0	-4	-2
		DAY 22	07APR2003	21	-4	2	0	0	-2	2	4	-4	2
		DAY 29	15APR2003	29	8	0	-2	8	6	2	0	6	4
		DAY 36	22APR2003	36	0	2	6	0	-2	6	0	-4	0
		DAY 43	29APR2003	43	28	2	6	44	-12	6	16	-14	0
		DAY 50	06MAY2003	50	16	-2	-2	20	0	2	4	2	4
		DAY 57	15MAY2003	59	24	4	14	40	-4	2	16	-8	-12
		FINAL		59	24	4	14	40	-4	2	16	-8	-12

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	DAY 8	21APR2003	8	12	-20	-8	16	0	6	4	20	14
		DAY 15	28APR2003	15	12	-10	2	16	20	10	4	30	8
		DAY 22	05MAY2003	22	16	6	0	20	10	14	4	4	14
		DAY 29	12MAY2003	29	8	2	-2	20	14	8	12	12	10
		DAY 36	19MAY2003	36	8	-10	-6	20	10	0	12	20	6
		DAY 43	28MAY2003	45	16	-4	-8	20	-10	0	4	-6	8
		DAY 50	02JUN2003	50	12	0	-2	8	12	14	-4	12	16
		DAY 57	10JUN2003	58	4	-8	-12	12	10	6	8	18	18
		FINAL		58	4	-8	-12	12	10	6	8	18	18
	E0029030	DAY 8	03JUN2003	8	12	30	24	8	16	14	-4	-14	-10
		DAY 15	10JUN2003	15	12	12	16	12	20	14	0	8	-2
		DAY 22	17JUN2003	22	16	10	20	12	26	16	-4	16	-4
		DAY 29	26JUN2003	31	24	30	16	28	22	4	4	-8	-12
		DAY 36	02JUL2003	37	24	20	12	20	20	4	-4	0	-8
		DAY 43	09JUL2003	44	20	10	6	32	22	14	12	12	8
		DAY 50	16JUL2003	51	24	32	6	36	36	14	12	4	8
		DAY 57	23JUL2003	58	8	20	14	12	26	18	4	6	4
		FINAL		58	8	20	14	12	26	18	4	6	4
	E0031008	DAY 8	07MAR2003	8	12	-22	-4	10	-16	-4	-2	6	0
		DAY 15	13MAR2003	14	10	6	4	0	0	0	-10	-6	-4
		DAY 22	21MAR2003	22	20	0	-6	16	2	-8	-4	2	-2
		DAY 29	28MAR2003	29	6	-22	-4	4	-20	-16	-2	2	-12
		DAY 36	04APR2003	36	8	-16	-12	6	-18	-12	-2	-2	0
		DAY 43	10APR2003	42	18	-18	-6	18	-18	-4	0	0	2
		DAY 50	17APR2003	49	20	2	2	14	-2	0	-6	-4	-2
		DAY 57	24APR2003	56	8	-10	0	4	-8	0	-4	2	0
		FINAL		56	8	-10	0	4	-8	0	-4	2	0
	E0031020	DAY 8	28APR2003	8	6	6	4	6	12	10	0	6	6
		DAY 15	05MAY2003	15	10	4	2	10	6	12	0	2	10
		DAY 22	13MAY2003	23	0	2	-4	0	6	-2	0	4	2
		FINAL		23	0	2	-4	0	6	-2	0	4	2

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0031021	DAY 8		02MAY2003	8	2	12	2	0	14	2	-2	2	0
		DAY 15		09MAY2003	15	4	10	0	2	12	0	-2	2	0
		DAY 22		16MAY2003	22	16	13	12	18	4	6	2	-9	-6
		DAY 29		23MAY2003	29	2	4	0	4	8	6	2	4	6
		DAY 36		29MAY2003	35	10	4	10	10	4	8	0	0	-2
		DAY 43		06JUN2003	43	4	12	20	2	14	18	-2	2	-2
		DAY 43	*	10JUN2003	47	12	12	18	10	16	16	-2	4	-2
		DAY 57		19JUN2003	56	10	6	0	10	4	-2	0	-2	-2
		FINAL			56	10	6	0	10	4	-2	0	-2	-2
	E0031029	DAY 8		23JUN2003	6	2	0	12	0	6	8	-2	6	-4
		DAY 22		08JUL2003	21	6	-2	-6	6	0	-6	0	2	0
		FINAL			21	6	-2	-6	6	0	-6	0	2	0
	E0033002	DAY 8		16JAN2003	7	16	-20	-4	20	-10	-8	4	10	-4
		DAY 15		24JAN2003	15	16	-18	4	4	-6	-4	-12	12	-8
		DAY 22		30JAN2003	21	-8	-42	-14	-4	-24	-12	4	18	2
		DAY 29		06FEB2003	28	4	-46	-14	0	-26	-12	-4	20	2
		DAY 36		13FEB2003	35	-4	-30	-6	0	-8	-4	4	22	2
		DAY 43		24FEB2003	46	-4	-28	-4	-4	-12	-2	0	16	2
		DAY 50		28FEB2003	50	0	-30	-4	4	-8	-8	4	22	-4
		DAY 57		07MAR2003	57	0	-32	-6	0	-18	-6	0	14	0
		FINAL			57	0	-32	-6	0	-18	-6	0	14	0
	E0033006	DAY 8		30JAN2003	8	-4	20	14	4	20	8	8	0	-6
		DAY 22		12FEB2003	21	4	20	10	0	14	6	-4	-6	-4
		FINAL			21	4	20	10	0	14	6	-4	-6	-4
	E0033021	DAY 8		11JUL2003	10	2	0	-3	2	0	-4	0	0	-1
		DAY 22	*	21JUL2003	20	4	10	-10	4	8	-8	0	-2	2
		DAY 22		25JUL2003	24	16	0	-2	8	10	-4	-8	10	-2
		DAY 29		01AUG2003	31	20	0	-6	8	6	-8	-12	6	-2
		DAY 36		06AUG2003	36	16	22	4	-4	20	-4	-20	-2	-8
		DAY 50		18AUG2003	48	20	6	0	4	6	-2	-16	0	-2
		FINAL			48	20	6	0	4	6	-2	-16	0	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0035013	DAY 8	10FEB2003	7	-2	0	2	-4	0	2	-2	0	0
		FINAL		7	-2	0	2	-4	0	2	-2	0	0
	E0035015	DAY 8	18FEB2003	8	-8	-10	0	-8	-8	-6	0	2	-6
		FINAL		8	-8	-10	0	-8	-8	-6	0	2	-6
	E0035023	DAY 8	20MAY2003	8	8	-2	6	10	-2	2	2	0	-4
		DAY 15	29MAY2003	17	10	-2	4	12	-2	0	2	0	-4
		DAY 22	03JUN2003	22	14	-2	4	14	-2	-4	0	0	-8
		DAY 29	10JUN2003	29	16	-2	2	18	-2	-2	2	0	-4
		FINAL		29	16	-2	2	18	-2	-2	2	0	-4
	E0039052	DAY 8	27JUN2003	8	-24	8	8	-24	0	2	0	-8	-6
		DAY 15	03JUL2003	14	-14	16	4	-14	2	4	0	-14	0
		FINAL		14	-14	16	4	-14	2	4	0	-14	0
	E0039056	DAY 8	23JUL2003	9	-12	-4	6	-6	-18	4	6	-14	-2
		FINAL		9	-12	-4	6	-6	-18	4	6	-14	-2
	E0040003	DAY 8	25JUL2003	7	2	-10	-12	3	-7	-12	1	3	0
		DAY 15	01AUG2003	14	6	-4	-3	5	5	-2	-1	9	1
		DAY 22	08AUG2003	21	4	-2	-4	3	5	0	-1	7	4
		DAY 29	15AUG2003	28	6	0	-1	5	7	-2	-1	7	-1
		DAY 36	22AUG2003	35	2	2	-2	1	5	-2	-1	3	0
		DAY 43	29AUG2003	42	4	4	-2	3	7	-2	-1	3	0
		DAY 50	05SEP2003	49	2	0	0	5	3	-1	3	3	-1
		DAY 57	12SEP2003	56	0	2	-2	1	5	-3	1	3	-1
		FINAL		56	0	2	-2	1	5	-3	1	3	-1
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 8	11MAR2003	9	8	6	-6	16	12	4	8	6	10
		DAY 15	18MAR2003	16	14	4	-10	14	4	-12	0	0	-2
		DAY 22	25MAR2003	23	6	8	-6	8	0	-10	2	-8	-4
		DAY 29	01APR2003	30	8	4	-8	8	0	-8	0	-4	0
		DAY 36	08APR2003	37	14	-4	-14	18	0	-4	4	4	10

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 43	15APR2003	44	12	4	-2	16	0	-8	4	-4	-6
		DAY 50	24APR2003	53	12	6	-6	14	8	-4	2	2	2
		DAY 57	02MAY2003	61	8	2	-2	4	0	0	-4	-2	2
		FINAL		61	8	2	-2	4	0	0	-4	-2	2
	E0002011	DAY 8	08MAY2003	10	0	0	-6	0	8	2	0	8	8
		DAY 15	15MAY2003	17	4	0	0	0	2	2	-4	2	2
		DAY 22	22MAY2003	24	0	4	-10	2	0	-2	2	-4	8
		DAY 29	29MAY2003	31	8	0	-4	6	6	10	-2	6	14
		DAY 36	05JUN2003	38	4	0	-6	2	4	6	-2	4	12
		DAY 43	12JUN2003	45	4	-2	-10	2	6	-4	-2	8	6
		DAY 50	19JUN2003	52	4	-4	-12	2	4	4	-2	8	16
		DAY 57	25JUN2003	58	-4	6	2	-6	4	8	-2	-2	6
		FINAL		58	-4	6	2	-6	4	8	-2	-2	6
	E0003010	DAY 8	10FEB2003	8	0	12	18	12	2	10	12	-10	-8
		DAY 15	19FEB2003	17	12	6	10	8	-4	0	-4	-10	-10
		DAY 22	27FEB2003	25	18	-10	2	20	-26	-20	2	-16	-22
		DAY 29	03MAR2003	29	14	20	16	14	-4	8	0	-24	-8
		DAY 36	14MAR2003	40	20	22	16	16	16	10	-4	-6	-6
		DAY 43	20MAR2003	46	30	10	14	14	14	12	-16	4	-2
		DAY 50	25MAR2003	51	14	22	12	14	2	12	0	-20	0
		DAY 57	31MAR2003	57	9	10	14	14	12	18	5	2	4
		FINAL		57	9	10	14	14	12	18	5	2	4
	E0003011	DAY 8	11FEB2003	8	-8	8	0	12	10	10	20	2	10
		DAY 15	18FEB2003	15	-4	0	0	-4	-6	8	0	-6	8
		FINAL		15	-4	0	0	-4	-6	8	0	-6	8
	E0003016	DAY 8	29MAY2003	8	22	20	-4	36	16	0	14	-4	4
		DAY 15	05JUN2003	15	14	12	4	28	10	2	14	-2	-2
		DAY 22	12JUN2003	22	16	-2	-4	22	8	-12	6	10	-8
		FINAL		22	16	-2	-4	22	8	-12	6	10	-8
	E0003019	DAY 8	03JUL2003	7	8	4	-10	4	-4	-4	-4	-8	6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0003019	DAY 15		10JUL2003	14	4	4	-12	8	-6	-8	4	-10	4
		DAY 15	*	15JUL2003	19	6	-6	-26	6	-4	-14	0	2	12
		DAY 29		29JUL2003	33	16	18	-8	20	20	0	4	2	8
		DAY 43		07AUG2003	42	14	10	-6	8	6	-2	-6	-4	4
		DAY 50		14AUG2003	49	10	8	-12	14	4	-8	4	-4	4
		DAY 57		21AUG2003	56	12	24	-2	12	14	0	0	-10	2
		FINAL			56	12	24	-2	12	14	0	0	-10	2
	E0003020	DAY 8		29JUL2003	7	2	20	34	16	6	6	14	-14	-28
		DAY 15		06AUG2003	15	-2	8	26	14	14	10	16	6	-16
		DAY 22		13AUG2003	22	20	-2	20	18	0	8	-2	2	-12
		DAY 29		20AUG2003	29	12	20	26	10	14	10	-2	-6	-16
		DAY 36		27AUG2003	36	12	16	38	12	6	18	0	-10	-20
		DAY 43		03SEP2003	43	8	24	40	8	12	18	0	-12	-22
		DAY 50		10SEP2003	50	16	10	30	6	-8	0	-10	-18	-30
		DAY 57		17SEP2003	57	8	0	30	2	-4	10	-6	-4	-20
		FINAL			57	8	0	30	2	-4	10	-6	-4	-20
	E0004001	DAY 8		07OCT2002	8	0	0	-2	8	-4	4	8	-4	6
		DAY 22		21OCT2002	22	0	0	0	12	4	10	12	4	10
		DAY 29		28OCT2002	29	16	-4	-2	24	-10	2	8	-6	4
		DAY 36		05NOV2002	37	12	2	0	24	-4	2	12	-6	2
		FINAL			37	12	2	0	24	-4	2	12	-6	2
	E0004009	DAY 8		02JAN2003	8	12	0	4	0	0	-4	-12	0	-8
		DAY 15		08JAN2003	14	20	2	8	12	6	0	-8	4	-8
		DAY 22		15JAN2003	21	12	0	2	12	2	6	0	2	4
		DAY 29		22JAN2003	28	20	16	6	16	-2	6	-4	-18	0
		DAY 36		29JAN2003	35	4	10	4	0	-4	-2	-4	-14	-6
		DAY 43		05FEB2003	42	20	0	2	12	2	0	-8	2	-2
		DAY 50		12FEB2003	49	8	0	12	12	-10	4	4	-10	-8
		DAY 57		19FEB2003	56	14	0	10	16	0	8	2	0	-2
		FINAL			56	14	0	10	16	0	8	2	0	-2
	E0004012	DAY 8		21JAN2003	8	20	-14	-10	20	6	-6	0	20	4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	DAY 15	28JAN2003	15	8	0	-12	4	8	-2	-4	8	10
		DAY 22	04FEB2003	22	24	-10	-14	20	-10	-14	-4	0	0
		DAY 29	11FEB2003	29	28	-4	-2	20	2	2	-8	6	4
		DAY 36	18FEB2003	36	36	-10	-4	32	0	4	-4	10	8
		DAY 43	25FEB2003	43	12	-12	-10	4	0	0	-8	12	10
		DAY 50	04MAR2003	50	16	-4	-12	22	-2	-6	6	2	6
		DAY 57	11MAR2003	57	28	-6	-2	24	0	2	-4	6	4
		FINAL		57	28	-6	-2	24	0	2	-4	6	4
	E0004015	DAY 8	25FEB2003	6	24	10	2	24	4	0	0	-6	-2
		DAY 15	04MAR2003	13	16	4	-2	20	-6	-8	4	-10	-6
		DAY 22	11MAR2003	20	24	0	8	24	10	2	0	10	-6
		DAY 29	18MAR2003	27	16	18	0	16	14	-2	0	-4	-2
		DAY 36	25MAR2003	34	16	8	8	18	6	2	2	-2	-6
		DAY 43	01APR2003	41	24	22	2	20	18	-2	-4	-4	-4
		DAY 50	08APR2003	48	20	10	8	14	4	0	-6	-6	-8
		DAY 57	15APR2003	55	20	2	8	16	0	-2	-4	-2	-10
		FINAL		55	20	2	8	16	0	-2	-4	-2	-10
	E0005003	DAY 8	09OCT2002	8	4	6	6	12	0	-2	8	-6	-8
		DAY 15	16OCT2002	15	8	4	0	10	-4	-10	2	-8	-10
		DAY 22	23OCT2002	22	24	-12	-10	20	-18	-10	-4	-6	0
		DAY 29	30OCT2002	29	12	12	-2	16	2	-8	4	-10	-6
		DAY 36	06NOV2002	36	20	6	2	20	2	4	0	-4	2
		DAY 43	14NOV2002	44	20	12	10	24	2	4	4	-10	-6
		DAY 50	21NOV2002	51	16	0	6	16	-4	4	0	-4	-2
		DAY 57	26NOV2002	56	24	0	-2	16	-4	0	-8	-4	2
		FINAL		56	24	0	-2	16	-4	0	-8	-4	2
	E0005007	DAY 8	16OCT2002	8	12	26	14	0	16	6	-12	-10	-8
		DAY 15	23OCT2002	15	20	20	14	8	14	0	-12	-6	-14
		DAY 22	30OCT2002	22	24	6	12	12	4	6	-12	-2	-6
		DAY 29	06NOV2002	29	20	14	8	20	14	10	0	0	2
		DAY 36	14NOV2002	37	24	18	8	20	14	6	-4	-4	-2
		DAY 43	20NOV2002	43	12	8	0	12	4	0	0	-4	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005007	DAY 50		26NOV2002	49	24	20	4	20	24	10	-4	4	6
		DAY 57		04DEC2002	57	24	18	14	20	22	12	-4	4	-2
		FINAL			57	24	18	14	20	22	12	-4	4	-2
	E0005008	DAY 8		22OCT2002	8	4	4	16	4	8	16	0	4	0
		DAY 15		29OCT2002	15	0	12	16	0	12	18	0	0	2
		DAY 22		06NOV2002	23	8	22	20	0	14	22	-8	-8	2
		DAY 29		13NOV2002	30	0	20	20	0	14	22	0	-6	2
		DAY 36		18NOV2002	35	-8	19	12	-8	12	16	0	-7	4
		DAY 43		25NOV2002	42	-4	14	18	-4	14	24	0	0	6
		DAY 50		02DEC2002	49	-4	8	14	-4	10	18	0	2	4
		DAY 57		11DEC2002	58	-4	4	16	-4	8	16	0	4	0
		FINAL			58	-4	4	16	-4	8	16	0	4	0
	E0005010	DAY 8		28OCT2002	8	0	-10	0	0	0	4	0	10	4
		DAY 15		04NOV2002	15	16	-10	-2	16	-10	0	0	0	2
		DAY 22		13NOV2002	24	16	-10	0	16	-10	-4	0	0	-4
		DAY 29		19NOV2002	30	24	0	10	24	10	12	0	10	2
		DAY 36		26NOV2002	37	12	4	0	12	0	-4	0	-4	-4
		DAY 43		03DEC2002	44	16	-6	4	16	-6	4	0	0	0
		DAY 50		09DEC2002	50	16	-4	4	16	0	6	0	4	2
		DAY 57		17DEC2002	58	16	8	4	16	14	10	0	6	6
		FINAL			58	16	8	4	16	14	10	0	6	6
	E0005012	DAY 8		20NOV2002	7	16	-10	-8	16	-8	-8	0	2	0
		DAY 15		26NOV2002	13	4	-16	-8	4	-14	-8	0	2	0
		DAY 22		06DEC2002	23	16	-16	-6	16	-18	-10	0	-2	-4
		DAY 29		10DEC2002	27	16	-20	-8	16	-18	-12	0	2	-4
		DAY 36		18DEC2002	35	16	-20	-8	16	-18	-8	0	2	0
		DAY 36	*	23DEC2002	40	0	-20	-8	0	-14	-8	0	6	0
		DAY 50		02JAN2003	50	16	-20	-14	16	-16	-8	0	4	6
		DAY 57		07JAN2003	55	16	-14	-8	16	-14	-6	0	0	2
		FINAL			55	16	-14	-8	16	-14	-6	0	0	2
	E0005014	DAY 8		20NOV2002	8	0	4	-2	0	10	-4	0	6	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	DAY 15	27NOV2002	15	0	4	4	0	0	-6	0	-4	-10
		DAY 22	03DEC2002	21	20	4	8	20	0	0	0	-4	-8
		DAY 29	11DEC2002	29	20	4	4	20	10	0	0	6	-4
		DAY 36	17DEC2002	35	20	4	4	20	10	-2	0	6	-6
		DAY 43	23DEC2002	41	20	6	14	20	10	10	0	4	-4
		DAY 50	30DEC2002	48	20	14	10	20	10	4	0	-4	-6
		DAY 57	06JAN2003	55	20	8	14	20	10	4	0	2	-10
		FINAL		55	20	8	14	20	10	4	0	2	-10
	E0005022	DAY 8	04FEB2003	7	0	0	10	0	-10	0	0	-10	-10
		DAY 15	11FEB2003	14	-8	4	4	-8	-16	-6	0	-20	-10
		DAY 22	21FEB2003	24	-8	0	0	-8	-20	-10	0	-20	-10
		DAY 29	26FEB2003	29	-8	10	0	-8	-2	-10	0	-12	-10
		DAY 36	06MAR2003	37	-12	0	10	-12	-20	0	0	-20	-10
		FINAL		37	-12	0	10	-12	-20	0	0	-20	-10
	E0005025	DAY 8	06MAR2003	8	8	0	0	20	-6	-4	12	-6	-4
		DAY 15	14MAR2003	16	8	-20	0	8	-12	0	0	8	0
		DAY 22	20MAR2003	22	8	-4	4	8	-6	0	0	-2	-4
		DAY 29	27MAR2003	29	-12	-10	-2	0	-16	-6	12	-6	-4
		DAY 36	03APR2003	36	0	-10	4	8	-2	6	8	8	2
		FINAL		36	0	-10	4	8	-2	6	8	8	2
	E0006019	DAY 8	14APR2003	8	12	11	18	11	13	-5	-1	2	-23
		DAY 15	21APR2003	15	25	1	13	13	-4	4	-12	-5	-9
		DAY 22	28APR2003	22	8	4	15	7	15	6	-1	11	-9
		DAY 29	05MAY2003	29	12	1	-1	18	-3	0	6	-4	1
		DAY 36	12MAY2003	36	10	-1	0	15	13	0	5	14	0
		DAY 43	19MAY2003	43	8	-6	-8	-5	0	-6	-13	6	2
		DAY 50	27MAY2003	51	13	-14	0	18	-1	-8	5	13	-8
		DAY 57	03JUN2003	58	12	2	8	2	6	-2	-10	4	-10
		FINAL		58	12	2	8	2	6	-2	-10	4	-10
	E0007005	DAY 8	07FEB2003	8	0	-2	8	2	8	8	2	10	0
		DAY 15	14FEB2003	15	0	-10	2	6	4	0	6	14	-2

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	DAY 22	22FEB2003	23	2	-12	4	6	0	0	4	12	-4
		DAY 29	03MAR2003	32	8	-10	2	10	-2	0	2	8	-2
		DAY 36	10MAR2003	39	6	-6	2	12	-4	2	6	2	0
		DAY 43	14MAR2003	43	0	-14	2	4	-4	2	4	10	0
		DAY 50	21MAR2003	50	12	-20	-8	16	-8	-6	4	12	2
		DAY 57	28MAR2003	57	2	-16	-6	6	-6	-10	4	10	-4
		FINAL		57	2	-16	-6	6	-6	-10	4	10	-4
	E0007015	DAY 8	23JUL2003	8	-2	-4	10	2	6	2	4	10	-8
		DAY 15	01AUG2003	17	0	-4	4	2	4	0	2	8	-4
		DAY 22	06AUG2003	22	-2	-2	8	4	6	6	6	8	-2
		DAY 29	13AUG2003	29	2	0	4	6	-2	4	4	-2	0
		DAY 36	20AUG2003	36	-2	6	0	2	6	0	4	0	0
		DAY 43	27AUG2003	43	-2	6	6	4	10	6	6	4	0
		DAY 50	03SEP2003	50	2	0	4	4	10	2	2	10	-2
		DAY 57	10SEP2003	57	-2	0	6	-2	8	6	0	8	0
		FINAL		57	-2	0	6	-2	8	6	0	8	0
	E0009001	DAY 8	21NOV2002	10	0	10	-8	6	8	2	6	-2	10
		DAY 15	26NOV2002	15	-8	-4	-24	-4	-18	-18	4	-14	6
		DAY 22	04DEC2002	23	-14	0	-6	-6	0	-2	8	0	4
		DAY 29	10DEC2002	29	-28	6	-10	-10	12	-2	18	6	8
		DAY 36	17DEC2002	36	-8	-2	-16	-4	2	-12	4	4	4
		DAY 43	23DEC2002	42	-10	-10	-16	-4	-8	-16	6	2	0
		DAY 50	30DEC2002	49	-12	-10	-26	-6	-18	-20	6	-8	6
		FINAL		49	-12	-10	-26	-6	-18	-20	6	-8	6
	E0010002	DAY 8	02DEC2002	8	-34	0	14	-40	12	8	-6	12	-6
		FINAL		8	-34	0	14	-40	12	8	-6	12	-6
	E0010009	DAY 8	02JAN2003	8	10	-18	-12	16	-26	-12	6	-8	0
		DAY 15	09JAN2003	15	18	2	-6	29	-16	-8	11	-18	-2
		DAY 22	17JAN2003	23	16	-28	-10	24	-28	-10	8	0	0
		DAY 29	22JAN2003	28	12	-10	-12	16	-32	-8	4	-22	4
		DAY 36	30JAN2003	36	26	0	-22	30	10	-2	4	10	20

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010009	DAY 43	05FEB2003	42	28	-14	-6	30	-28	-12	2	-14	-6
		DAY 50	13FEB2003	50	12	-12	-26	26	-18	-16	14	-6	10
		DAY 57	19FEB2003	56	18	-12	-8	29	-10	-6	11	2	2
		FINAL		56	18	-12	-8	29	-10	-6	11	2	2
	E0010010	DAY 8	06JAN2003	8	2	10	6	-4	8	6	-6	-2	0
		DAY 15	13JAN2003	15	6	14	14	3	0	8	-3	-14	-6
		FINAL		15	6	14	14	3	0	8	-3	-14	-6
	E0010014	DAY 8	04FEB2003	8	9	-14	2	5	-12	0	-4	2	-2
		DAY 15	11FEB2003	15	9	-22	-4	12	-8	-2	3	14	2
		DAY 22	18FEB2003	22	3	-8	4	1	6	10	-2	14	6
		DAY 29	25FEB2003	29	9	-18	2	11	-4	4	2	14	2
		DAY 36	04MAR2003	36	5	-6	4	9	-4	12	4	2	8
		DAY 43	11MAR2003	43	3	-14	4	5	-2	4	2	12	0
		DAY 50	18MAR2003	50	3	-16	8	1	-4	4	-2	12	-4
		DAY 57	25MAR2003	57	2	-8	12	-7	-4	14	-9	4	2
		FINAL		57	2	-8	12	-7	-4	14	-9	4	2
	E0010017	DAY 8	03MAR2003	7	-8	-14	4	4	-28	-20	12	-14	-24
		DAY 15	10MAR2003	14	16	-12	2	28	-8	-10	12	4	-12
		DAY 22	18MAR2003	22	-4	-4	6	14	-2	6	18	2	0
		DAY 29	25MAR2003	29	12	-14	2	14	-16	-4	2	-2	-6
		DAY 36	01APR2003	36	16	-14	10	20	-12	0	4	2	-10
		DAY 43	08APR2003	43	16	-4	12	22	-16	0	6	-12	-12
		DAY 50	15APR2003	50	4	2	10	16	0	0	12	-2	-10
		DAY 57	22APR2003	57	1	-14	0	6	-16	-4	5	-2	-4
		FINAL		57	1	-14	0	6	-16	-4	5	-2	-4
	E0010023	DAY 8	24APR2003	8	0	-12	8	-4	-4	2	-4	8	-6
		DAY 15	01MAY2003	15	0	-10	4	6	-12	2	6	-2	-2
		FINAL		15	0	-10	4	6	-12	2	6	-2	-2
	E0010027	DAY 8	23JUN2003	8	-2	10	-16	30	8	-4	32	-2	12
		DAY 15	01JUL2003	16	-4	0	-10	0	10	0	4	10	10

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0010027	FINAL		16	-4	0	-10	0	10	0	4	10	10
	E0010029	DAY 8	25JUN2003	7	4	18	14	16	14	5	12	-4	-9
		FINAL		7	4	18	14	16	14	5	12	-4	-9
	E0011022	DAY 8	16JUN2003	8	20	-4	-6	24	-4	-10	4	0	-4
		DAY 15	24JUN2003	16	22	-8	-4	16	-14	-8	-6	-6	-4
		DAY 22	01JUL2003	23	14	-20	-18	14	-18	-16	0	2	2
		DAY 29	08JUL2003	30	20	-20	-12	12	-30	-18	-8	-10	-6
		DAY 36	15JUL2003	37	22	-6	-4	18	-12	-6	-4	-6	-2
		DAY 43	24JUL2003	46	14	-6	-4	10	-12	-6	-4	-6	-2
		DAY 50	31JUL2003	53	10	-6	-4	10	-12	-8	0	-6	-4
		DAY 57	05AUG2003	58	14	-10	-2	14	-16	-6	0	-6	-4
		FINAL		58	14	-10	-2	14	-16	-6	0	-6	-4
	E0013006	DAY 8	24MAR2003	12	6	-6	2	0	2	-12	-6	8	-14
		FINAL		12	6	-6	2	0	2	-12	-6	8	-14
	E0013012	DAY 8	16MAY2003	10	0	12	-2	-8	12	0	-8	0	2
		DAY 15	22MAY2003	16	4	-8	-4	0	-6	-2	-4	2	2
		DAY 22	30MAY2003	24	-12	-8	-20	-8	-8	-10	4	0	10
		DAY 29	05JUN2003	30	-4	-6	-6	-4	-6	0	0	0	6
		DAY 36	12JUN2003	37	-8	-8	-8	-4	-8	0	4	0	8
		DAY 43	19JUN2003	44	-4	-8	-14	-4	-8	-10	0	0	4
		DAY 50	25JUN2003	50	-4	-8	-4	0	-2	0	4	6	4
		DAY 57	02JUL2003	57	0	12	6	0	10	10	0	-2	4
		FINAL		57	0	12	6	0	10	10	0	-2	4
	E0013014	DAY 8	10JUN2003	8	4	-6	-2	0	0	-4	-4	6	-2
		DAY 15	19JUN2003	17	24	-8	-4	16	0	-2	-8	8	2
		DAY 29	30JUN2003	28	8	-4	-4	4	0	-4	-4	4	0
		FINAL		28	8	-4	-4	4	0	-4	-4	4	0
	E0014005	DAY 8	18MAR2003	8	10	16	12	2	17	12	-8	1	0
		DAY 15	25MAR2003	15	7	1	7	2	7	12	-5	6	5

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0014005	DAY 22	01APR2003	22	6	11	9	2	7	9	-4	-4	0
		DAY 29	08APR2003	29	12	-4	4	4	7	4	-8	11	0
		DAY 36	16APR2003	37	12	-8	-8	18	-2	0	6	6	8
		DAY 43	23APR2003	44	17	4	-4	18	6	2	1	2	6
		DAY 50	29APR2003	50	14	6	9	4	22	9	-10	16	0
		DAY 57	06MAY2003	57	12	1	6	-6	12	7	-18	11	1
		FINAL		57	12	1	6	-6	12	7	-18	11	1
	E0014007	DAY 8	08APR2003	8	-13	-22	-12	-13	-10	-7	0	12	5
		DAY 15	15APR2003	15	-2	-10	-5	0	0	3	2	10	8
		DAY 22	22APR2003	22	-12	8	-5	-9	14	-5	3	6	0
		FINAL		22	-12	8	-5	-9	14	-5	3	6	0
	E0014011	DAY 8	20MAY2003	8	8	6	24	5	7	28	-3	1	4
		DAY 15	27MAY2003	15	-4	6	8	-4	10	10	0	4	2
		DAY 22	04JUN2003	23	-10	-2	6	-6	-2	4	4	0	-2
		DAY 29	10JUN2003	29	-8	-4	10	-8	0	16	0	4	6
		DAY 36	17JUN2003	36	-4	2	10	-8	4	12	-4	2	2
		DAY 43	26JUN2003	45	-6	-14	17	-9	2	26	-3	16	9
		DAY 50	02JUL2003	51	-12	-4	8	-12	4	14	0	8	6
		DAY 57	08JUL2003	57	-10	2	8	-10	6	10	0	4	2
		FINAL		57	-10	2	8	-10	6	10	0	4	2
	E0014012	DAY 8	03JUN2003	8	0	4	0	-2	6	0	-2	2	0
		DAY 15	10JUN2003	15	6	10	-2	0	10	-6	-6	0	-4
		DAY 22	17JUN2003	22	-6	-14	-16	-6	-8	-14	0	6	2
		DAY 29	24JUN2003	29	0	4	-2	-2	4	-2	-2	0	0
		FINAL		29	0	4	-2	-2	4	-2	-2	0	0
	E0015001	DAY 8	06DEC2002	8	-4	-2	0	0	6	4	4	8	4
		DAY 15	13DEC2002	15	2	2	0	4	8	4	2	6	4
		DAY 22	19DEC2002	21	10	8	20	12	12	18	2	4	-2
		DAY 29	27DEC2002	29	4	0	16	6	12	12	2	12	-4
		DAY 36	03JAN2003	36	2	-2	16	10	8	10	8	10	-6
		DAY 43	09JAN2003	42	6	2	12	6	2	10	0	0	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	DAY 50	20JAN2003	53	2	4	10	0	4	8	-2	0	-2
		FINAL		53	2	4	10	0	4	8	-2	0	-2
	E0015008	DAY 8	27DEC2002	9	-4	-4	-6	4	4	-2	8	8	4
		DAY 15	03JAN2003	16	-6	-2	-12	0	-6	-10	6	-4	2
		DAY 22	10JAN2003	23	-8	8	-10	0	2	-2	8	-6	8
		DAY 29	16JAN2003	29	0	6	4	0	2	2	0	-4	-2
		DAY 36	23JAN2003	36	8	10	2	10	4	2	2	-6	0
		FINAL		36	8	10	2	10	4	2	2	-6	0
	E0016003	DAY 8	31JAN2003	8	18	2	1	4	-6	-4	-14	-8	-5
		DAY 15	07FEB2003	15	10	0	5	7	0	4	-3	0	-1
		DAY 22	14FEB2003	22	14	2	13	12	-6	-4	-2	-8	-17
		DAY 29	21FEB2003	29	17	-5	-1	16	-6	1	-1	-1	2
		DAY 36	27FEB2003	35	14	-5	2	10	-6	-2	-4	-1	-4
		DAY 43	07MAR2003	43	17	10	15	14	4	10	-3	-6	-5
		FINAL		43	17	10	15	14	4	10	-3	-6	-5
	E0016005	DAY 8	04MAR2003	8	7	4	7	-1	2	1	-8	-2	-6
		DAY 15	11MAR2003	15	0	-7	-3	-5	6	2	-5	13	5
		DAY 22	18MAR2003	22	-3	-3	4	-13	0	-3	-10	3	-7
		DAY 29	25MAR2003	29	-5	-2	10	-12	0	-8	-7	2	-18
		DAY 36	01APR2003	36	-7	0	-3	-10	6	-3	-3	6	0
		DAY 43	08APR2003	43	1	22	9	-9	24	4	-10	2	-5
		DAY 57	22APR2003	57	10	-13	1	2	-9	-8	-8	4	-9
		FINAL		57	10	-13	1	2	-9	-8	-8	4	-9
	E0018007	DAY 8	31DEC2002	5	-8	4	2	-4	4	-4	4	0	-6
		DAY 15	10JAN2003	15	-12	-4	-8	-8	-2	-4	4	2	4
		FINAL		15	-12	-4	-8	-8	-2	-4	4	2	4
	E0019005	DAY 8	12NOV2002	8	-10	-20	-10	-10	-15	-5	0	5	5
		DAY 15	19NOV2002	15	8	-10	10	-8	3	8	-16	13	-2
		DAY 22	26NOV2002	22	4	5	10	4	0	0	0	-5	-10
		DAY 29	05DEC2002	31	-4	-10	12	8	-1	8	12	9	-4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	DAY 36		12DEC2002	38	6	-12	0	-4	-10	0	-10	2	0
		DAY 43		19DEC2002	45	4	-18	10	0	-10	10	-4	8	0
		DAY 57	*	30DEC2002	56	16	0	4	16	11	8	0	11	4
		DAY 57		02JAN2003	59	24	-10	2	22	-5	8	-2	5	6
		FINAL			59	24	-10	2	22	-5	8	-2	5	6
	E0019015	DAY 8		09JAN2003	8	12	2	2	-4	-10	0	-16	-12	-2
		DAY 15		16JAN2003	15	12	18	-10	0	6	-8	-12	-12	2
		DAY 22		23JAN2003	22	0	7	-15	-18	-2	-10	-18	-9	5
		DAY 29		30JAN2003	29	20	20	-5	4	15	-5	-16	-5	0
		DAY 36		06FEB2003	36	24	25	-10	-4	20	0	-28	-5	10
		DAY 43		13FEB2003	43	20	20	-10	8	15	-10	-12	-5	0
		DAY 50		20FEB2003	50	30	15	-5	10	10	0	-20	-5	5
		DAY 57		27FEB2003	57	-10	10	14	16	4	10	26	-6	-4
		FINAL			57	-10	10	14	16	4	10	26	-6	-4
	E0020004	DAY 8		16DEC2002	8	-2	-2	0	0	-4	0	2	-2	0
		DAY 8	*	20DEC2002	12	-4	38	20	6	36	22	10	-2	2
		DAY 22		31DEC2002	23	-10	-18	-2	-4	-24	-4	6	-6	-2
		DAY 29		07JAN2003	30	-8	30	12	0	24	8	8	-6	-4
		DAY 36		14JAN2003	37	-8	12	2	-10	4	-2	-2	-8	-4
		DAY 43		22JAN2003	45	-4	-2	0	4	-6	0	8	-4	0
		FINAL			45	-4	-2	0	4	-6	0	8	-4	0
	E0020010	DAY 8		12FEB2003	8	14	8	-10	12	6	-8	-2	-2	2
		DAY 15		19FEB2003	15	14	18	8	14	12	10	0	-6	2
		DAY 22		26FEB2003	22	12	18	6	12	12	8	0	-6	2
		DAY 29		05MAR2003	29	18	18	-8	16	18	-6	-2	0	2
		DAY 36		10MAR2003	34	14	18	-2	18	14	0	4	-4	2
		DAY 43		17MAR2003	41	-2	20	-10	0	12	-10	2	-8	0
		DAY 50		25MAR2003	49	8	18	-6	12	16	-8	4	-2	-2
		DAY 57		02APR2003	57	14	42	2	20	24	4	6	-18	2
		FINAL			57	14	42	2	20	24	4	6	-18	2
	E0020014	DAY 8		25MAR2003	8	2	10	4	12	4	0	10	-6	-4

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020014	DAY 15	01APR2003	15	6	28	16	8	40	16	2	12	0
		DAY 22	08APR2003	22	0	36	18	2	32	16	2	-4	-2
		DAY 29	15APR2003	29	2	12	8	8	8	10	6	-4	2
		DAY 36	22APR2003	36	4	28	-2	10	18	-2	6	-10	0
		DAY 43	29APR2003	43	-12	12	10	-2	6	10	10	-6	0
		DAY 50	06MAY2003	50	4	14	4	6	0	2	2	-14	-2
		DAY 57	12MAY2003	56	-14	20	0	-4	10	0	10	-10	0
		FINAL		56	-14	20	0	-4	10	0	10	-10	0
	E0020021	DAY 8	23MAY2003	5	-10	-2	6	-6	2	4	4	4	-2
		DAY 15	02JUN2003	15	4	12	2	10	20	2	6	8	0
		DAY 22	10JUN2003	23	6	10	2	10	16	-2	4	6	-4
		DAY 29	16JUN2003	29	20	10	0	18	12	8	-2	2	8
		DAY 36	23JUN2003	36	8	10	-4	18	10	-6	10	0	-2
		DAY 43	30JUN2003	43	16	0	-2	18	2	-2	2	2	0
		DAY 50	07JUL2003	50	22	36	18	20	32	16	-2	-4	-2
		DAY 57	14JUL2003	57	16	44	26	10	32	26	-6	-12	0
		FINAL		57	16	44	26	10	32	26	-6	-12	0
	E0020023	DAY 8	24JUN2003	8	10	0	0	4	-2	-8	-6	-2	-8
		DAY 15	30JUN2003	14	22	2	8	20	-4	2	-2	-6	-6
		DAY 22	07JUL2003	21	6	-8	-8	2	-14	-16	-4	-6	-8
		DAY 29	14JUL2003	28	24	0	0	22	-12	-8	-2	-12	-8
		DAY 36	21JUL2003	35	18	-16	-22	18	-28	-18	0	-12	4
		DAY 43	28JUL2003	42	26	18	-2	18	0	-10	-8	-18	-8
		DAY 50	04AUG2003	49	20	-4	6	20	-12	-2	0	-8	-8
		DAY 57	11AUG2003	56	6	0	8	-2	-20	0	-8	-20	-8
		FINAL		56	6	0	8	-2	-20	0	-8	-20	-8
	E0022007	DAY 8	14NOV2002	8	8	16	-6	32	2	4	24	-14	10
		DAY 15	22NOV2002	16	20	-4	-6	20	-10	-8	0	-6	-2
		DAY 22	02DEC2002	26	8	4	-10	20	-12	-4	12	-16	6
		DAY 29	09DEC2002	33	10	4	2	10	-8	0	0	-12	-2
		FINAL		33	10	4	2	10	-8	0	0	-12	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022010	DAY 8		29NOV2002	9	16	-2	-4	8	2	2	-8	4	6
		DAY 15		06DEC2002	16	16	18	10	16	24	38	0	6	28
		DAY 22		12DEC2002	22	4	6	0	8	18	4	4	12	4
		DAY 36		26DEC2002	36	10	18	-4	6	26	0	-4	8	4
		DAY 43		02JAN2003	43	16	22	2	16	24	18	0	2	16
		DAY 50		09JAN2003	50	12	10	4	28	14	28	16	4	24
		DAY 57		16JAN2003	57	8	10	2	0	14	8	-8	4	6
		FINAL			57	8	10	2	0	14	8	-8	4	6
	E0022012	DAY 8		12DEC2002	8	4	0	10	4	-12	0	0	-12	-10
		DAY 15		19DEC2002	15	16	-6	6	26	-6	6	10	0	0
		DAY 15	*	23DEC2002	19	16	-12	6	20	-14	6	4	-2	0
		DAY 29		02JAN2003	29	18	-14	6	14	-2	12	-4	12	6
		DAY 36		09JAN2003	36	30	4	2	26	-12	10	-4	-16	8
		DAY 43		16JAN2003	43	28	2	2	36	6	4	8	4	2
		DAY 50		23JAN2003	50	21	0	6	20	0	12	-1	0	6
		DAY 57		30JAN2003	57	24	-10	6	20	6	2	-4	16	-4
		FINAL			57	24	-10	6	20	6	2	-4	16	-4
	E0022019	DAY 8		19DEC2002	9	20	26	2	8	-8	0	-12	-34	-2
		DAY 15		26DEC2002	16	28	24	8	16	6	-2	-12	-18	-10
		DAY 22		03JAN2003	24	36	14	20	32	16	10	-4	2	-10
		DAY 29		09JAN2003	30	36	6	6	28	10	8	-8	4	2
		DAY 36		17JAN2003	38	32	12	20	20	12	2	-12	0	-18
		DAY 43		24JAN2003	45	20	20	18	12	-2	4	-8	-22	-14
		DAY 50		30JAN2003	51	40	14	16	32	6	14	-8	-8	-2
		DAY 57		06FEB2003	58	16	4	4	12	-8	2	-4	-12	-2
		FINAL			58	16	4	4	12	-8	2	-4	-12	-2
	E0022025	DAY 8		04FEB2003	8	6	8	10	3	-4	8	-3	-12	-2
		FINAL			8	6	8	10	3	-4	8	-3	-12	-2
	E0022033	DAY 8		25FEB2003	8	-16	26	12	4	32	18	20	6	6
		DAY 15		04MAR2003	15	-2	24	16	16	28	22	18	4	6
		DAY 22		11MAR2003	22	4	24	16	16	28	16	12	4	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	DAY 29	18MAR2003	29	-12	26	12	6	6	16	18	-20	4
		DAY 36	27MAR2003	38	-8	24	16	-4	10	16	4	-14	0
		DAY 43	01APR2003	43	-8	14	8	6	18	14	14	4	6
		DAY 50	08APR2003	50	-4	16	6	8	18	12	12	2	6
		DAY 57	15APR2003	57	-16	16	6	0	28	16	16	12	10
		FINAL		57	-16	16	6	0	28	16	16	12	10
	E0022034	DAY 8	25FEB2003	8	-6	0	-4	-1	-4	4	5	-4	8
		DAY 15	04MAR2003	15	-6	-2	-4	-7	-28	2	-1	-26	6
		DAY 22	11MAR2003	22	9	-4	2	2	-22	4	-7	-18	2
		DAY 29	18MAR2003	29	2	-12	0	-1	-14	6	-3	-2	6
		DAY 36	25MAR2003	36	21	12	0	-1	-4	8	-22	-16	8
		DAY 43	01APR2003	43	12	-10	-4	14	-12	6	2	-2	10
		DAY 50	07APR2003	49	30	4	2	16	-16	8	-14	-20	6
		DAY 57	15APR2003	57	15	-8	-2	8	-24	2	-7	-16	4
		FINAL		57	15	-8	-2	8	-24	2	-7	-16	4
	E0022038	DAY 8	07MAR2003	8	0	10	-2	-6	4	8	-6	-6	10
		DAY 15	14MAR2003	15	20	12	4	10	2	-10	-10	-10	-14
		DAY 22	21MAR2003	22	18	22	8	10	12	0	-8	-10	-8
		DAY 29	28MAR2003	29	16	10	-6	10	12	0	-6	2	6
		DAY 36	04APR2003	36	24	16	-14	18	6	-8	-6	-10	6
		DAY 43	11APR2003	43	-4	12	-2	-14	12	-2	-10	0	0
		FINAL		43	-4	12	-2	-14	12	-2	-10	0	0
	E0022039	DAY 8	13MAR2003	8	14	8	-14	18	2	-4	4	-6	10
		DAY 15	20MAR2003	15	10	12	-2	10	-2	8	0	-14	10
		DAY 22	27MAR2003	22	-2	10	-2	0	-12	2	2	-22	4
		DAY 29	04APR2003	30	14	8	-6	20	-12	-10	6	-20	-4
		DAY 36	10APR2003	36	10	14	-6	2	-2	2	-8	-16	8
		DAY 43	18APR2003	44	4	8	-2	2	-8	-2	-2	-16	0
		DAY 50	24APR2003	50	4	2	-6	6	2	-4	2	0	2
		DAY 57	01MAY2003	57	10	-2	-8	38	-14	-8	28	-12	0
		FINAL		57	10	-2	-8	38	-14	-8	28	-12	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	DAY 8		27MAR2003	8	0	18	20	0	16	4	0	-2	-16
		DAY 15		04APR2003	16	32	22	4	38	22	0	6	0	-4
		DAY 22		11APR2003	23	28	18	16	46	8	-4	18	-10	-20
		DAY 29		18APR2003	30	20	16	10	38	6	0	18	-10	-10
		DAY 36		24APR2003	36	28	8	26	26	4	8	-2	-4	-18
		DAY 43		02MAY2003	44	44	14	6	50	14	4	6	0	-2
		DAY 50		12MAY2003	54	24	0	8	40	0	-2	16	0	-10
		DAY 57		16MAY2003	58	36	2	8	46	4	8	10	2	0
		FINAL			58	36	2	8	46	4	8	10	2	0
	E0022048	DAY 8		08APR2003	8	16	6	2	8	2	0	-8	-4	-2
		DAY 15		15APR2003	15	10	20	4	2	12	-2	-8	-8	-6
		DAY 22		24APR2003	24	4	4	6	8	2	6	4	-2	0
		DAY 29		02MAY2003	32	14	12	8	12	4	8	-2	-8	0
		DAY 36		06MAY2003	36	8	12	6	-12	10	6	-20	-2	0
		DAY 43		13MAY2003	43	0	6	6	0	12	4	0	6	-2
		DAY 50		23MAY2003	53	14	6	12	8	4	8	-6	-2	-4
		FINAL			53	14	6	12	8	4	8	-6	-2	-4
	E0022051	DAY 8		14APR2003	8	-12	-12	8	-12	-8	0	0	4	-8
		DAY 15		21APR2003	15	-4	-16	8	12	4	-4	16	20	-12
		DAY 22		28APR2003	22	12	-6	-2	20	0	0	8	6	2
		DAY 29		05MAY2003	29	28	6	14	12	6	10	-16	0	-4
		DAY 36		12MAY2003	36	8	14	8	4	2	-4	-4	-12	-12
		DAY 43		19MAY2003	43	4	-4	14	-4	2	-4	-8	6	-18
		DAY 50		28MAY2003	52	12	-4	8	12	0	6	0	4	-2
		DAY 57		02JUN2003	57	16	-4	6	12	6	4	-4	10	-2
		FINAL			57	16	-4	6	12	6	4	-4	10	-2
	E0022058	DAY 8		28APR2003	8	-5	8	-2	-1	-4	8	4	-12	10
		DAY 15		05MAY2003	15	0	10	10	12	-8	8	12	-18	-2
		DAY 22		12MAY2003	22	8	4	-2	0	-6	8	-8	-10	10
		DAY 29		19MAY2003	29	8	-12	-8	-4	8	6	-12	20	14
		DAY 29	*	22MAY2003	32	-2	-2	2	-8	0	8	-6	2	6
		FINAL			32	-2	-2	2	-8	0	8	-6	2	6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022061	DAY 8		07MAY2003	8	8	2	-12	-16	4	8	-24	2	20
		DAY 15		14MAY2003	15	4	-6	-14	20	-4	-8	16	2	6
		DAY 22		22MAY2003	23	12	-8	-6	-8	-12	8	-20	-4	14
		DAY 29		28MAY2003	29	4	-6	-14	12	0	-2	8	6	12
		DAY 36		04JUN2003	36	4	2	-8	-8	-4	8	-12	-6	16
		DAY 50		18JUN2003	50	12	-2	-8	12	-4	4	0	-2	12
		DAY 57		26JUN2003	58	8	-6	-4	24	-10	6	16	-4	10
		FINAL			58	8	-6	-4	24	-10	6	16	-4	10
	E0022062	DAY 8		12MAY2003	8	20	12	-10	22	-18	-4	2	-30	6
		DAY 15		19MAY2003	15	4	10	14	14	-8	4	10	-18	-10
		DAY 15	*	23MAY2003	19	8	10	22	6	6	14	-2	-4	-8
		FINAL			19	8	10	22	6	6	14	-2	-4	-8
	E0022068	DAY 8		29MAY2003	7	20	2	6	8	6	4	-12	4	-2
		DAY 15		05JUN2003	14	24	14	14	12	10	8	-12	-4	-6
		FINAL			14	24	14	14	12	10	8	-12	-4	-6
	E0022069	DAY 8		17JUN2003	8	10	16	-4	16	8	8	6	-8	12
		DAY 15		24JUN2003	15	6	4	4	12	4	8	6	0	4
		DAY 22		01JUL2003	22	2	14	-8	-4	-2	8	-6	-16	16
		DAY 29		08JUL2003	29	-6	10	10	-8	-6	4	-2	-16	-6
		DAY 36		15JUL2003	36	3	4	-6	3	4	6	0	0	12
		DAY 43		22JUL2003	43	-10	-4	-2	0	-12	6	10	-8	8
		DAY 50		29JUL2003	50	0	2	-4	-6	-2	-10	-6	-4	-6
		DAY 57		05AUG2003	57	6	6	2	8	-12	-6	2	-18	-8
		FINAL			57	6	6	2	8	-12	-6	2	-18	-8
	E0022071	DAY 8		07JUL2003	8	30	-8	0	10	0	-10	-20	8	-10
		DAY 15		14JUL2003	15	18	-4	-2	2	-6	-20	-16	-2	-18
		DAY 22		21JUL2003	22	12	-8	0	12	-12	-4	0	-4	-4
		DAY 29		28JUL2003	29	22	6	10	24	-10	2	2	-16	-8
		DAY 36		04AUG2003	36	24	8	8	26	-4	4	2	-12	-4
		DAY 43		11AUG2003	43	24	4	8	24	6	-2	0	2	-10
		DAY 50		18AUG2003	50	14	0	6	6	-12	0	-8	-12	-6

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	DAY 57	25AUG2003	57	22	6	14	10	-8	-2	-12	-14	-16
		FINAL		57	22	6	14	10	-8	-2	-12	-14	-16
	E0023003	DAY 8	23DEC2002	7	-4	30	9	-4	15	0	0	-15	-9
		DAY 15	30DEC2002	14	16	14	-16	4	14	-14	-12	0	2
		DAY 22	07JAN2003	22	14	0	-2	4	-10	-6	-10	-10	-4
		DAY 29	16JAN2003	31	14	13	-10	12	4	-16	-2	-9	-6
		DAY 36	21JAN2003	36	16	20	4	12	10	-4	-4	-10	-8
		DAY 43	28JAN2003	43	18	-6	-15	16	-10	-17	-2	-4	-2
		DAY 50	06FEB2003	52	-4	4	-12	-4	0	-14	0	-4	-2
		DAY 57	11FEB2003	57	10	23	8	34	-3	-10	24	-26	-18
		FINAL		57	10	23	8	34	-3	-10	24	-26	-18
	E0023006	DAY 8	23DEC2002	7	26	29	8	19	10	5	-7	-19	-3
		DAY 15	02JAN2003	17	15	6	10	5	-6	6	-10	-12	-4
		DAY 22	07JAN2003	22	20	-16	-10	18	-10	0	-2	6	10
		DAY 29	16JAN2003	31	12	29	12	6	10	6	-6	-19	-6
		DAY 36	21JAN2003	36	12	-10	0	10	-16	0	-2	-6	0
		DAY 43	28JAN2003	43	12	-12	0	4	-10	10	-8	2	10
		DAY 50	04FEB2003	50	6	6	-13	8	1	1	2	-5	14
		DAY 57	11FEB2003	57	3	5	-12	8	13	-3	5	8	9
		FINAL		57	3	5	-12	8	13	-3	5	8	9
	E0023010	DAY 8	11FEB2003	8	0	-6	-8	0	-20	-31	0	-14	-23
		DAY 15	18FEB2003	15	-2	-15	5	4	-22	-9	6	-7	-14
		DAY 22	25FEB2003	22	11	-16	-6	20	0	-4	9	16	2
		DAY 29	04MAR2003	29	7	15	19	19	18	10	12	3	-9
		DAY 36	11MAR2003	36	-8	-7	-9	0	0	-11	8	7	-2
		DAY 43	18MAR2003	43	-3	10	17	11	3	4	14	-7	-13
		DAY 50	25MAR2003	50	10	-1	1	15	5	-1	5	6	-2
		DAY 57	31MAR2003	56	6	7	1	9	0	-13	3	-7	-14
		FINAL		56	6	7	1	9	0	-13	3	-7	-14
	E0023025	DAY 8	22MAY2003	8	8	11	13	12	6	6	4	-5	-7
		DAY 15	29MAY2003	15	13	17	19	29	32	29	16	15	10

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0023025	DAY 22	05JUN2003	22	20	2	-2	43	26	28	23	24	30
		DAY 29	12JUN2003	29	20	5	0	14	10	6	-6	5	6
		DAY 36	19JUN2003	36	25	4	19	14	4	12	-11	0	-7
		DAY 43	27JUN2003	44	24	1	12	20	-4	8	-4	-5	-4
		DAY 50	03JUL2003	50	8	-5	22	8	6	16	0	11	-6
		DAY 57	10JUL2003	57	0	-12	8	0	-14	1	0	-2	-7
		FINAL		57	0	-12	8	0	-14	1	0	-2	-7
	E0023039	DAY 8	08JUL2003	8	25	6	-5	21	-6	-2	-4	-12	3
		DAY 15	15JUL2003	15	12	-10	-6	-1	0	0	-13	10	6
		DAY 22	22JUL2003	22	26	-20	-7	15	-5	-6	-11	15	1
		DAY 29	29JUL2003	29	26	-5	0	19	4	6	-7	9	6
		DAY 36	05AUG2003	36	33	-11	-3	50	3	1	17	14	4
		DAY 43	12AUG2003	43	17	-19	-9	28	1	-2	11	20	7
		DAY 50	19AUG2003	50	44	-30	-14	58	12	9	14	42	23
		DAY 57	26AUG2003	57	29	-5	3	36	6	2	7	11	-1
		FINAL		57	29	-5	3	36	6	2	7	11	-1
	E0026002	DAY 8	19NOV2002	8	16	26	11	11	21	-4	-5	-5	-15
		DAY 15	26NOV2002	15	5	-6	13	-3	-10	-8	-8	-4	-21
		DAY 22	03DEC2002	22	15	38	17	7	12	-7	-8	-26	-24
		DAY 29	11DEC2002	30	5	41	23	-4	18	1	-9	-23	-22
		DAY 36	18DEC2002	37	5	27	15	-7	10	-8	-12	-17	-23
		DAY 43	26DEC2002	45	4	49	19	-7	0	-3	-11	-49	-22
		DAY 50	02JAN2003	52	5	30	16	-8	-11	-17	-13	-41	-33
		DAY 57	09JAN2003	59	0	21	5	-12	2	-7	-12	-19	-12
		FINAL		59	0	21	5	-12	2	-7	-12	-19	-12
	E0026007	DAY 8	23JAN2003	8	10	-26	-10	10	-18	-12	0	8	-2
		DAY 15	30JAN2003	15	5	-13	3	12	-26	-8	7	-13	-11
		DAY 22	06FEB2003	22	18	14	7	16	-15	-4	-2	-29	-11
		DAY 29	13FEB2003	29	8	-8	-3	6	-4	22	-2	4	25
		DAY 36	19FEB2003	35	5	-27	-9	3	-22	-5	-2	5	4
		DAY 43	26FEB2003	42	18	-23	-2	16	-15	-4	-2	8	-2
		DAY 50	05MAR2003	49	9	-5	-13	17	13	4	8	18	17

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0026007	DAY 57	12MAR2003	56	20	-24	-6	11	-7	-5	-9	17	1
		FINAL		56	20	-24	-6	11	-7	-5	-9	17	1
	E0026013	DAY 8	20FEB2003	8	18	-11	1	23	-10	8	5	1	7
		DAY 15	27FEB2003	15	24	-4	5	36	-10	7	12	-6	2
		DAY 22	06MAR2003	22	17	9	9	21	-8	6	4	-17	-3
		DAY 29	13MAR2003	29	19	-24	4	17	-7	1	-2	17	-3
		DAY 36	20MAR2003	36	18	-24	2	18	-20	6	0	4	4
		DAY 43	27MAR2003	43	28	-14	10	30	-10	-1	2	4	-11
		DAY 50	03APR2003	50	10	-10	0	14	-6	0	4	4	0
		DAY 57	14APR2003	61	13	-36	-3	18	-10	2	5	26	5
		FINAL		61	13	-36	-3	18	-10	2	5	26	5
	E0028007	DAY 8	11OCT2002	8	4	0	-10	6	2	-10	2	2	0
		DAY 15	16OCT2002	13	-8	-20	-20	-4	-10	-12	4	10	8
		DAY 22	23OCT2002	20	10	-12	-10	8	-6	-10	-2	6	0
		DAY 29	31OCT2002	28	20	-20	-16	26	-14	-12	6	6	4
		DAY 36	07NOV2002	35	-4	18	8	-4	6	-2	0	-12	-10
		DAY 43	14NOV2002	42	-4	-6	-12	-2	-4	-14	2	2	-2
		FINAL		42	-4	-6	-12	-2	-4	-14	2	2	-2
	E0028023	DAY 8	30JAN2003	10	-12	38	36	-12	44	10	0	6	-26
		DAY 15	04FEB2003	15	6	-28	0	10	-4	-8	4	24	-8
		DAY 22	11FEB2003	22	12	-32	-8	12	-42	-22	0	-10	-14
		DAY 29	17FEB2003	28	10	-60	-22	10	-60	-32	0	0	-10
		DAY 36	27FEB2003	38	4	-38	-22	2	-40	-40	-2	-2	-18
		DAY 43	04MAR2003	43	8	-50	-32	8	-72	-40	0	-22	-8
		DAY 57	27JUN2003	158									
		FINAL		158	8	-50	-32	8	-72	-40	0	-22	-8
	E0028025	DAY 8	17JAN2003	5	16	8	-8	8	16	-2	-8	8	6
		DAY 15	27JAN2003	15	-4	14	8	4	30	18	8	16	10
		FINAL		15	-4	14	8	4	30	18	8	16	10
	E0028033	DAY 8	03APR2003	8	2	6	10	20	6	18	18	0	8

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028033	DAY 15		10APR2003	15	22	12	6	62	-4	8	40	-16	2
		DAY 22		17APR2003	22	4	8	16	16	8	12	12	0	-4
		DAY 29		24APR2003	29	12	-10	0	24	-2	6	12	8	6
		DAY 36		01MAY2003	36	-16	-12	6	4	-12	14	20	0	8
		DAY 43		08MAY2003	43	8	14	8	16	14	8	8	0	0
		DAY 50		15MAY2003	50	8	2	6	24	2	2	16	0	-4
		DAY 57		22MAY2003	57	0	6	10	16	6	14	16	0	4
		FINAL			57	0	6	10	16	6	14	16	0	4
	E0028035	DAY 8		10APR2003	8	0	-12	-6	0	-16	-6	0	-4	0
		DAY 15		17APR2003	15	8	-2	6	20	-6	6	12	-4	0
		DAY 22		24APR2003	22	12	-6	0	12	-4	-4	0	2	-4
		DAY 29		01MAY2003	29	20	-2	4	8	10	8	-12	12	4
		DAY 36		08MAY2003	36	8	2	12	12	-6	14	4	-8	2
		DAY 50		22MAY2003	50	12	-2	-4	16	-2	8	4	0	12
		DAY 57		29MAY2003	57	16	8	4	16	10	6	0	2	2
		FINAL			57	16	8	4	16	10	6	0	2	2
	E0028037	DAY 8		20JUN2003	8	8	-18	4	14	-18	4	6	0	0
		DAY 15		25JUN2003	13	6	-8	6	20	-30	-2	14	-22	-8
		DAY 15	*	01JUL2003	19	12	-10	2	12	-25	-12	0	-15	-14
		DAY 22		08JUL2003	26	6	-4	6	14	-8	4	8	-4	-2
		DAY 36		16JUL2003	34	12	-10	-2	14	-24	-10	2	-14	-8
		DAY 43		23JUL2003	41	10	-22	0	14	-24	0	4	-2	0
		DAY 50		30JUL2003	48	16	-22	6	18	-18	4	2	4	-2
		DAY 57		08AUG2003	57	12	-20	0	12	-20	-12	0	0	-12
		FINAL			57	12	-20	0	12	-20	-12	0	0	-12
	E0028039	DAY 8		16MAY2003	8	16	8	2	8	16	8	-8	8	6
		DAY 15		22MAY2003	14	12	-2	2	8	0	4	-4	2	2
		DAY 22		29MAY2003	21	20	0	6	14	0	10	-6	0	4
		DAY 29		05JUN2003	28	16	0	0	4	8	4	-12	8	4
		FINAL			28	16	0	0	4	8	4	-12	8	4
	E0028048	DAY 8		24JUL2003	8	4	2	6	2	6	14	-2	4	8

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028048	DAY 15	31JUL2003	15	6	4	12	0	6	8	-6	2	-4
		DAY 22	06AUG2003	21	4	-6	0	4	-2	2	0	4	2
		DAY 29	14AUG2003	29	-6	-10	0	-4	2	-4	2	12	-4
		DAY 36	21AUG2003	36	0	-4	6	8	6	16	8	10	10
		DAY 43	29AUG2003	44	4	19	2	12	18	0	8	-1	-2
		DAY 57	09SEP2003	55	8	-16	-18	12	-8	2	4	8	20
		FINAL		55	8	-16	-18	12	-8	2	4	8	20
	E0029008	DAY 8	23DEC2002	8	4	-2	-2	4	-2	-10	0	0	-8
		FINAL		8	4	-2	-2	4	-2	-10	0	0	-8
	E0029011	DAY 8	28JAN2003	7	-8	12	4	16	4	-6	24	-8	-10
		DAY 15	04FEB2003	14	4	20	0	36	14	6	32	-6	6
		DAY 22	13FEB2003	23	-8	18	20	24	-6	14	32	-24	-6
		FINAL		23	-8	18	20	24	-6	14	32	-24	-6
	E0029012	DAY 8	19FEB2003	9	-14	-4	-2	-6	-8	-10	8	-4	-8
		DAY 15	26FEB2003	16	-6	-6	-10	0	-8	-10	6	-2	0
		DAY 22	03MAR2003	21	6	-6	8	10	-6	0	4	0	-8
		DAY 29	11MAR2003	29	2	-20	-14	2	-12	-6	0	8	8
		DAY 36	18MAR2003	36	2	-6	-18	10	-8	-8	8	-2	10
		FINAL		36	2	-6	-18	10	-8	-8	8	-2	10
	E0029015	DAY 8	03MAR2003	8	-16	-26	-2	-8	-10	4	8	16	6
		DAY 15	11MAR2003	16	-40	-32	-20	-20	-28	-22	20	4	-2
		FINAL		16	-40	-32	-20	-20	-28	-22	20	4	-2
	E0030014	DAY 8	28FEB2003	8	0	4	0	4	2	2	4	-2	2
		DAY 15	07MAR2003	15	0	2	4	8	2	4	8	0	0
		DAY 22	14MAR2003	22	8	6	2	16	10	6	8	4	4
		DAY 29	21MAR2003	29	12	6	2	16	6	14	4	0	12
		DAY 36	27MAR2003	35	0	-2	-4	24	6	10	24	8	14
		DAY 43	04APR2003	43	0	-2	-6	8	2	0	8	4	6
		DAY 50	11APR2003	50	0	0	2	8	8	6	8	8	4
		DAY 57	22APR2003	61	0	-2	6	20	6	6	20	8	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	FINAL		61	0	-2	6	20	6	6	20	8	0
	E0030020	DAY 8	05JUN2003	8	12	10	4	8	4	2	-4	-6	-2
		DAY 15	12JUN2003	15	20	0	10	8	-6	6	-12	-6	-4
		DAY 22	17JUN2003	20	0	8	24	0	-2	16	0	-10	-8
		DAY 29	24JUN2003	27	8	10	-6	8	0	-8	0	-10	-2
		FINAL		27	8	10	-6	8	0	-8	0	-10	-2
	E0030024	DAY 8	18JUL2003	8	0	2	10	-10	6	8	-10	4	-2
		FINAL		8	0	2	10	-10	6	8	-10	4	-2
	E0030025	DAY 8	18JUL2003	8	12	0	6	0	0	4	-12	0	-2
		DAY 15	25JUL2003	15	8	-6	10	0	-2	4	-8	4	-6
		DAY 22	31JUL2003	21	12	-4	4	0	-10	0	-12	-6	-4
		DAY 29	11AUG2003	32	20	0	12	8	-8	8	-12	-8	-4
		DAY 36	19AUG2003	40	20	-6	6	8	-6	4	-12	0	-2
		FINAL		40	20	-6	6	8	-6	4	-12	0	-2
	E0031027	DAY 8	11JUN2003	9	14	13	0	8	10	-8	-6	-3	-8
		DAY 15	17JUN2003	15	4	3	0	2	6	-8	-2	3	-8
		DAY 22	24JUN2003	22	16	23	-8	12	22	-16	-4	-1	-8
		DAY 29	01JUL2003	29	10	15	-8	-2	20	-10	-12	5	-2
		DAY 36	09JUL2003	37	4	13	-6	6	16	-10	2	3	-4
		DAY 43	15JUL2003	43	-2	9	-10	-4	8	-12	-2	-1	-2
		DAY 50	22JUL2003	50	10	3	-8	8	12	-10	-2	9	-2
		DAY 57	29JUL2003	57	2	1	4	2	2	-10	0	1	-14
		FINAL		57	2	1	4	2	2	-10	0	1	-14
	E0031030	DAY 8	01JUL2003	8	0	14	-2	0	4	0	0	-10	2
		DAY 15	08JUL2003	15	20	14	-6	10	14	-8	-10	0	-2
		DAY 22	16JUL2003	23	-8	0	2	-6	4	0	2	4	-2
		DAY 29	23JUL2003	30	0	7	-4	0	4	-4	0	-3	0
		DAY 36	31JUL2003	38	-2	0	0	-2	8	2	0	8	2
		DAY 43	08AUG2003	46	-4	2	-4	-2	2	-2	2	0	2
		DAY 50	14AUG2003	52	-8	-1	-8	-12	-2	-8	-4	-1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0031030	DAY 57		21AUG2003	59	-4	2	-8	-6	4	-10	-2	2	-2
		FINAL			59	-4	2	-8	-6	4	-10	-2	2	-2
	E0034001	DAY 8		27MAR2003	8	8	10	10	4	31	12	-4	21	2
		DAY 15		03APR2003	15	8	18	23	0	17	12	-8	-1	-11
		DAY 22		10APR2003	22	4	10	15	0	10	12	-4	0	-3
		DAY 29		17APR2003	29	0	5	15	-4	5	12	-4	0	-3
		DAY 36		24APR2003	36	4	10	15	0	10	12	-4	0	-3
		DAY 43		01MAY2003	43	4	10	15	4	5	12	0	-5	-3
		DAY 50		08MAY2003	50	0	14	19	-8	17	10	-8	3	-9
		DAY 57		15MAY2003	57	8	20	20	0	15	12	-8	-5	-8
		FINAL			57	8	20	20	0	15	12	-8	-5	-8
	E0034004	DAY 8		30APR2003	10	0	-10	-5	8	-20	-20	8	-10	-15
		DAY 15		05MAY2003	15	0	-23	-13	8	-4	-20	8	19	-7
		DAY 22		13MAY2003	23	16	-17	-7	16	-6	-18	0	11	-11
		DAY 29		19MAY2003	29	20	-17	-9	20	-8	-22	0	9	-13
		DAY 29	*	23MAY2003	33	16	-10	-20	28	0	-20	12	10	0
		DAY 43		02JUN2003	43	16	-23	-11	12	-4	-14	-4	19	-3
		DAY 50		09JUN2003	50	12	-10	-5	20	-10	-20	8	0	-15
		DAY 57		16JUN2003	57	4	-35	-25	-14	-25	-25	-18	10	0
		FINAL			57	4	-35	-25	-14	-25	-25	-18	10	0
	E0035001	DAY 8		27NOV2002	8	-4	-2	4	8	-4	-4	12	-2	-8
		DAY 15		03DEC2002	14	-6	-6	0	12	-8	4	18	-2	4
		DAY 22		12DEC2002	23	-6	-8	4	10	-12	0	16	-4	-4
		DAY 29		18DEC2002	29	-6	-6	4	12	-6	6	18	0	2
		DAY 36		23DEC2002	34	-8	-6	6	8	-10	4	16	-4	-2
		DAY 43		30DEC2002	41	-10	2	8	6	-2	8	16	-4	0
		DAY 50		07JAN2003	49	-8	2	14	12	-2	10	20	-4	-4
		DAY 57		14JAN2003	56	-2	0	-2	13	-2	0	15	-2	2
		FINAL			56	-2	0	-2	13	-2	0	15	-2	2
	E0035006	DAY 8		19DEC2002	8	-14	6	12	-10	8	10	4	2	-2
		DAY 15		26DEC2002	15	-8	4	6	-6	6	4	2	2	-2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 22	02JAN2003	22	-10	2	0	-6	6	-2	4	4	-2
		DAY 29	09JAN2003	29	-4	2	2	-4	4	-8	0	2	-10
		DAY 36	16JAN2003	36	0	2	-10	-2	2	-2	-2	0	8
		DAY 43	24JAN2003	44	4	2	-2	4	4	-4	0	2	-2
		DAY 50	30JAN2003	50	0	2	-2	4	2	0	4	0	2
		DAY 57	06FEB2003	57	0	2	-2	-2	4	-2	-2	2	0
		FINAL		57	0	2	-2	-2	4	-2	-2	2	0
	E0035021	DAY 8	01MAY2003	7	4	0	-2	2	2	-4	-2	2	-2
		DAY 15	09MAY2003	15	2	0	0	0	0	0	-2	0	0
		DAY 22	15MAY2003	21	0	0	-6	-2	-2	-2	-2	-2	4
		DAY 29	23MAY2003	29	4	2	-2	2	2	-2	-2	0	0
		DAY 36	30MAY2003	36	6	4	0	6	6	2	0	2	2
		DAY 43	09JUN2003	46	6	6	4	4	8	2	-2	2	-2
		DAY 50	13JUN2003	50	4	10	6	6	10	0	2	0	-6
		DAY 57	20JUN2003	57	-2	0	14	-6	0	8	-4	0	-6
		FINAL		57	-2	0	14	-6	0	8	-4	0	-6
	E0036002	DAY 8	24JUN2003	8	-3	14	9	1	-23	3	4	-37	-6
		DAY 15	30JUN2003	14	21	15	10	16	-12	0	-5	-27	-10
		DAY 22	08JUL2003	22	19	8	3	13	-14	1	-6	-22	-2
		DAY 29	14JUL2003	28	25	21	8	13	-17	-4	-12	-38	-12
		FINAL		28	25	21	8	13	-17	-4	-12	-38	-12
	E0036006	DAY 8	10JUL2003	8	-13	4	0	-23	6	5	-10	2	5
		DAY 15	18JUL2003	16	16	11	4	-17	3	0	-33	-8	-4
		DAY 22	25JUL2003	23	8	11	12	4	4	9	-4	-7	-3
		DAY 29	31JUL2003	29	9	7	6	7	-2	-1	-2	-9	-7
		DAY 36	07AUG2003	36	-6	7	4	-1	-4	2	5	-11	-2
		DAY 43	13AUG2003	42	-8	15	9	-14	-1	6	-6	-16	-3
		DAY 50	20AUG2003	49	7	14	3	7	6	-3	0	-8	-6
		DAY 57	27AUG2003	56	-8	5	6	-5	-2	-1	3	-7	-7
		FINAL		56	-8	5	6	-5	-2	-1	3	-7	-7
	E0036007	DAY 8	08JUL2003	6	31	3	0	20	16	0	-11	13	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0036007	DAY 15	18JUL2003	16	1	-4	-4	-3	7	6	-4	11	10
		FINAL		16	1	-4	-4	-3	7	6	-4	11	10
	E0037009	DAY 8	23MAY2003	8	-4	8	-2	-6	8	0	-2	0	2
		DAY 15	29MAY2003	14	-12	4	0	-12	2	4	0	-2	4
		DAY 22	05JUN2003	21	-6	2	2	-10	-2	2	-4	-4	0
		DAY 29	12JUN2003	28	-6	-4	2	-6	0	2	0	4	0
		DAY 36	19JUN2003	35	-8	0	-14	-10	-2	-10	-2	-2	4
		DAY 43	26JUN2003	42	-6	6	4	-8	-2	10	-2	-8	6
		DAY 50	03JUL2003	49	-2	8	4	-6	8	4	-4	0	0
		DAY 57	10JUL2003	56	4	8	4	2	8	5	-2	0	1
		FINAL		56	4	8	4	2	8	5	-2	0	1
	E0039011	DAY 8	09JAN2003	8	-8	2	8	0	4	0	8	2	-8
		DAY 15	16JAN2003	15	-8	-8	-2	-5	2	0	3	10	2
		DAY 22	23JAN2003	22	6	-20	2	7	-16	-14	1	4	-16
		DAY 29	03FEB2003	33	8	-10	-2	8	-6	-12	0	4	-10
		DAY 36	06FEB2003	36	4	-8	-2	8	-16	-8	4	-8	-6
		DAY 43	13FEB2003	43	12	-24	0	10	-6	-8	-2	18	-8
		DAY 50	19FEB2003	49	12	-16	-8	14	-10	-12	2	6	-4
		FINAL		49	12	-16	-8	14	-10	-12	2	6	-4
	E0039018	DAY 8	30JAN2003	8	8	12	6	4	-4	-8	-4	-16	-14
		DAY 15	06FEB2003	15	6	-4	4	0	4	6	-6	8	2
		DAY 22	13FEB2003	22	14	-10	0	2	0	4	-12	10	4
		DAY 29	20FEB2003	29	15	-2	0	3	0	-4	-12	2	-4
		FINAL		29	15	-2	0	3	0	-4	-12	2	-4
	E0039026	DAY 8	14MAR2003	8	0	10	6	3	16	6	3	6	0
		DAY 15	19MAR2003	13	-8	12	0	7	6	0	15	-6	0
		DAY 22	28MAR2003	22	14	10	8	9	16	0	-5	6	-8
		DAY 29	04APR2003	29	-8	-2	-6	-13	6	0	-5	8	6
		DAY 36	11APR2003	36	10	-6	0	5	-10	-10	-5	-4	-10
		DAY 43	18APR2003	43	0	12	8	-5	16	2	-5	4	-6
		DAY 50	25APR2003	50	-12	12	16	-9	18	10	3	6	-6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039026	DAY 57	01MAY2003	56	-12	-2	6	-13	6	0	-1	8	-6
		FINAL		56	-12	-2	6	-13	6	0	-1	8	-6
	E0039028	DAY 8	31MAR2003	8	10	10	-2	20	-2	0	10	-12	2
		DAY 15	07APR2003	15	4	0	-2	16	-2	-2	12	-2	0
		DAY 22	14APR2003	22	8	4	2	12	0	4	4	-4	2
		DAY 29	21APR2003	29	4	-4	-8	12	-10	-2	8	-6	6
		DAY 36	28APR2003	36	4	-4	-10	-8	-2	2	-12	2	12
		DAY 43	05MAY2003	43	4	8	2	0	-12	2	-4	-20	0
		DAY 50	16MAY2003	54	20	2	6	12	-6	18	-8	-8	12
		FINAL		54	20	2	6	12	-6	18	-8	-8	12
	E0039032	DAY 8	19MAR2003	6	-12	-18	10	-13	-20	10	-1	-2	0
		DAY 15	28MAR2003	15	-11	-8	20	-8	4	10	3	12	-10
		FINAL		15	-11	-8	20	-8	4	10	3	12	-10
	E0039034	DAY 8	26MAR2003	8	-8	4	6	-18	14	8	-10	10	2
		DAY 15	02APR2003	15	-6	10	-2	-18	22	2	-12	12	4
		DAY 22	09APR2003	22	-8	4	2	-16	14	10	-8	10	8
		DAY 29	16APR2003	29	6	-2	-8	4	14	10	-2	16	18
		DAY 36	24APR2003	37	-6	-12	-6	-12	6	2	-6	18	8
		DAY 43	30APR2003	43	4	8	0	-12	20	14	-16	12	14
		DAY 50	09MAY2003	52	4	2	2	0	16	12	-4	14	10
		DAY 57	14MAY2003	57	12	10	8	-8	12	2	-20	2	-6
		FINAL		57	12	10	8	-8	12	2	-20	2	-6
	E0039042	DAY 8	14MAY2003	8	10	12	4	20	4	0	10	-8	-4
		DAY 15	21MAY2003	15	14	-16	-14	20	-10	-14	6	6	0
		DAY 22	28MAY2003	22	2	-4	0	9	6	0	7	10	0
		DAY 29	05JUN2003	30	18	2	2	20	6	-10	2	4	-12
		DAY 36	11JUN2003	36	16	6	6	16	2	6	0	-4	0
		DAY 43	18JUN2003	43	22	-4	-4	28	4	0	6	8	4
		DAY 50	25JUN2003	50	18	0	-6	24	-6	0	6	-6	6
		DAY 57	02JUL2003	57	9	-12	-24	12	-18	-20	3	-6	4
		FINAL		57	9	-12	-24	12	-18	-20	3	-6	4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	DAY 8	10FEB2003	12	-2	28	12	8	12	6	10	-16	-6
		DAY 15	14FEB2003	16	2	0	-2	8	0	-6	6	0	-4
		DAY 22	20FEB2003	22	22	26	10	20	22	6	-2	-4	-4
		DAY 29	27FEB2003	29	14	-10	-2	12	2	-14	-2	12	-12
		DAY 36	07MAR2003	37	2	-2	-12	0	-8	-24	-2	-6	-12
		DAY 43	14MAR2003	44	-6	10	2	-2	22	4	4	12	2
		DAY 50	21MAR2003	51	0	-10	-12	-4	2	-4	-4	12	8
		DAY 57	31MAR2003	61	-2	0	-12	4	2	-14	6	2	-2
		FINAL		61	-2	0	-12	4	2	-14	6	2	-2
	E0041009	DAY 8	08MAY2003	8	12	8	10	10	10	2	-2	2	-8
		DAY 15	15MAY2003	15	18	10	14	10	12	4	-8	2	-10
		DAY 22	22MAY2003	22	8	10	12	6	8	4	-2	-2	-8
		DAY 36	03JUN2003	34	6	12	12	4	10	4	-2	-2	-8
		DAY 43	16JUN2003	47	14	-2	10	20	10	-2	6	12	-12
		FINAL		47	14	-2	10	20	10	-2	6	12	-12
	E0042002	DAY 8	15JUL2003	7	-8	-10	-10	-8	-18	-10	0	-8	0
		DAY 15	22JUL2003	14	0	0	0	8	-20	0	8	-20	0
		DAY 22	29JUL2003	21	4	0	0	12	-20	-2	8	-20	-2
		DAY 29	05AUG2003	28	0	0	-10	4	-10	0	4	-10	10
		DAY 36	12AUG2003	35	0	10	-10	12	-10	0	12	-20	10
		DAY 43	19AUG2003	42	0	10	0	16	-10	10	16	-20	10
		DAY 50	26AUG2003	49	0	0	-10	4	-18	-10	4	-18	0
		DAY 57	02SEP2003	56	-4	-10	-10	8	-18	0	12	-8	10
		FINAL		56	-4	-10	-10	8	-18	0	12	-8	10
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 8	18JUL2003	8	2	-16	8	0	-21	5	-2	-5	-3
		FINAL		8	2	-16	8	0	-21	5	-2	-5	-3
	E0003002	DAY 15	14NOV2002	17	-4	10	-10	0	20	0	4	10	10
		DAY 22	19NOV2002	22	8	10	0	6	10	-2	-2	0	-2
		DAY 29	26NOV2002	29	-8	20	-6	-4	10	-8	4	-10	-2
		DAY 36	03DEC2002	36	-4	0	-10	0	4	-6	4	4	4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0003002	DAY 43		10DEC2002	43	-4	10	-10	8	2	0	12	-8	10
		DAY 50		17DEC2002	50	-12	-6	-6	0	-26	-26	12	-20	-20
		DAY 57		23DEC2002	56	-14	-2	-20	-18	0	-12	-4	2	8
		FINAL			56	-14	-2	-20	-18	0	-12	-4	2	8
	E0005031	DAY 8		09APR2003	8	0	2	-2	0	-2	-4	0	-4	-2
		DAY 15		16APR2003	15	-8	-2	6	-4	-6	4	4	-4	-2
		DAY 22		24APR2003	23	-8	12	8	-8	0	6	0	-12	-2
		DAY 29		01MAY2003	30	-18	12	4	-16	15	4	2	3	0
		DAY 36		07MAY2003	36	-16	2	-2	-12	4	2	4	2	4
		DAY 43		14MAY2003	43	-4	0	-2	-4	10	4	0	10	6
		FINAL			43	-4	0	-2	-4	10	4	0	10	6
	E0005033	DAY 8		22APR2003	7	4	0	-2	8	4	4	4	4	6
		DAY 15		30APR2003	15	0	8	0	4	6	4	4	-2	4
		DAY 22		06MAY2003	21	-4	-12	-6	0	-10	-4	4	2	2
		FINAL			21	-4	-12	-6	0	-10	-4	4	2	2
	E0005038	DAY 8		22MAY2003	9	4	-16	-10	16	-2	0	12	14	10
		DAY 15		28MAY2003	15	12	-20	-10	20	-24	-16	8	-4	-6
		DAY 22		05JUN2003	23	-4	-6	0	16	0	-2	20	6	-2
		FINAL			23	-4	-6	0	16	0	-2	20	6	-2
	E0007009	DAY 8		24APR2003	8	0	0	6	2	8	2	2	8	-4
		DAY 8	*	28APR2003	12	4	2	6	-2	4	-2	-6	2	-8
		FINAL			12	4	2	6	-2	4	-2	-6	2	-8
	E0009010	DAY 8		20MAR2003	8	6	10	14	4	10	8	-2	0	-6
		DAY 15		26MAR2003	14	26	2	-8	10	-2	-10	-16	-4	-2
		DAY 22		02APR2003	21	14	0	-4	8	2	-6	-6	2	-2
		FINAL			21	14	0	-4	8	2	-6	-6	2	-2
	E0009011	DAY 8		12MAY2003	7	14	20	10	14	10	6	0	-10	-4
		DAY 15		19MAY2003	14	12	0	10	14	-6	10	2	-6	0
		DAY 22		27MAY2003	22	26	10	8	22	2	6	-4	-8	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0009011	DAY 29		03JUN2003	29	2	-10	0	0	-16	-4	-2	-6	-4
		DAY 36		10JUN2003	36	12	-10	0	14	-26	-4	2	-16	-4
		DAY 43		17JUN2003	43	6	-6	2	2	-14	0	-4	-8	-2
		DAY 50		24JUN2003	50	-14	-6	6	-16	-14	0	-2	-8	-6
		DAY 57		03JUL2003	59	-14	-20	0	-14	-18	0	0	2	0
		FINAL			59	-14	-20	0	-14	-18	0	0	2	0
	E0011016	DAY 8		28APR2003	8	12	-6	-2	10	-8	8	-2	-2	10
		DAY 15		05MAY2003	15	20	0	0	4	0	8	-16	0	8
		DAY 22		12MAY2003	22	20	-14	0	4	-16	6	-16	-2	6
		DAY 29		19MAY2003	29	20	-8	0	10	-8	6	-10	0	6
		DAY 36		27MAY2003	37	18	-10	-4	6	-6	8	-12	4	12
		DAY 43		02JUN2003	43	16	2	0	4	-2	8	-12	-4	8
		DAY 50		09JUN2003	50	20	-2	0	8	2	8	-12	4	8
		DAY 57		16JUN2003	57	20	-6	0	8	-6	6	-12	0	6
		FINAL			57	20	-6	0	8	-6	6	-12	0	6
	E0011020	DAY 8		15MAY2003	8	2	0	2	0	10	0	-2	10	-2
		FINAL			8	2	0	2	0	10	0	-2	10	-2
	E0018002	DAY 8		04DEC2002	6	-8	-4	-12	-6	0	-8	2	4	4
		DAY 15		11DEC2002	13	-4	-2	-4	-6	0	0	-2	2	4
		DAY 22		18DEC2002	20	-6	10	-2	-8	10	0	-2	0	2
		DAY 22	*	24DEC2002	26	-8	0	-2	-10	4	0	-2	4	2
		DAY 29		30DEC2002	32	-4	8	-6	-8	12	-4	-4	4	2
		DAY 43		08JAN2003	41	2	-2	-2	-6	4	-2	-8	6	0
		DAY 50		15JAN2003	48	-6	10	-4	-6	14	0	0	4	4
		DAY 57		22JAN2003	55	-8	14	2	-8	12	2	0	-2	0
		FINAL			55	-8	14	2	-8	12	2	0	-2	0
	E0018003	DAY 8		03DEC2002	8	-16	6	8	-8	4	6	8	-2	-2
		DAY 15		10DEC2002	15	-8	10	6	-10	8	6	-2	-2	0
		FINAL			15	-8	10	6	-10	8	6	-2	-2	0
	E0018013	DAY 8		31JAN2003	8	-12	6	-4	-16	8	-4	-4	2	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0018013	FINAL		8	-12	6	-4	-16	8	-4	-4	2	0
	E0019002	DAY 8	19NOV2002	8	8	15	-10	0	10	-15	-8	-5	-5
		FINAL		8	8	15	-10	0	10	-15	-8	-5	-5
	E0019008	DAY 8	27NOV2002	7	20	0	3	24	27	8	4	27	5
		DAY 15	05DEC2002	15	4	0	-7	8	14	8	4	14	15
		DAY 22	12DEC2002	22	12	2	-2	24	4	-4	12	2	-2
		DAY 29	19DEC2002	29	0	-8	-14	20	2	6	20	10	20
		FINAL		29	0	-8	-14	20	2	6	20	10	20
	E0019009	DAY 8	21NOV2002	8	0	-12	0	6	-12	-2	6	0	-2
		DAY 15	27NOV2002	14	0	0	8	10	2	20	10	2	12
		DAY 22	05DEC2002	22	-8	-2	2	6	-2	8	14	0	6
		DAY 29	10DEC2002	27	10	-8	-6	24	-10	2	14	-2	8
		FINAL		27	10	-8	-6	24	-10	2	14	-2	8
	E0019016	DAY 8	13JAN2003	8	-4	-4	-2	8	-2	0	12	2	2
		DAY 15	20JAN2003	15	-8	-14	-5	-8	-10	-2	0	4	3
		DAY 22	27JAN2003	22	-8	-9	0	-8	0	0	0	9	0
		DAY 29	03FEB2003	29	-4	-4	-2	4	4	0	8	8	2
		DAY 36	10FEB2003	36	4	-9	-10	12	-2	-10	8	7	0
		DAY 43	17FEB2003	43	-8	-4	5	-2	0	0	6	4	-5
		DAY 50	27FEB2003	53	4	-4	2	16	0	6	12	4	4
		DAY 57	03MAR2003	57	4	-6	0	8	0	0	4	6	0
		FINAL		57	4	-6	0	8	0	0	4	6	0
	E0019020	DAY 8	30JAN2003	8	8	10	8	12	17	17	4	7	9
		DAY 15	06FEB2003	15	-12	12	10	-4	17	20	8	5	10
		DAY 22	13FEB2003	22	-4	10	5	8	20	15	12	10	10
		DAY 29	20FEB2003	29	-4	-2	0	8	10	15	12	12	15
		DAY 36	27FEB2003	36	4	0	0	12	10	5	8	10	5
		DAY 43	06MAR2003	43	0	-10	6	16	5	13	16	15	7
		DAY 50	13MAR2003	50	12	-2	-10	16	-5	7	4	-3	17
		DAY 57	27MAR2003	64	6	2	-2	4	15	5	-2	13	7

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	FINAL		64	6	2	-2	4	15	5	-2	13	7
	E0019021	DAY 8	06FEB2003	8	-4	0	0	-4	0	-3	0	0	-3
		DAY 29	03MAR2003	33	4	-4	1	0	-6	-6	-4	-2	-7
		FINAL		33	4	-4	1	0	-6	-6	-4	-2	-7
	E0019024	DAY 8	06FEB2003	8	0	10	-7	0	10	5	0	0	12
		FINAL		8	0	10	-7	0	10	5	0	0	12
	E0019031	DAY 15	25MAR2003	13	6	2	-12	-2	8	-12	-8	6	0
		FINAL		13	6	2	-12	-2	8	-12	-8	6	0
	E0019035	DAY 8	27MAR2003	10	-4	6	-6	-6	4	-4	-2	-2	2
		DAY 15	03APR2003	17	2	-4	-10	18	4	-3	16	8	7
		DAY 22	10APR2003	24	6	-4	10	6	4	2	0	8	-8
		DAY 29	17APR2003	31	6	1	5	10	9	12	4	8	7
		FINAL		31	6	1	5	10	9	12	4	8	7
	E0019040	DAY 8	29MAY2003	10	0	-8	-2	0	-10	-2	0	-2	0
		DAY 15	05JUN2003	17	20	-6	-10	16	-10	-2	-4	-4	8
		DAY 22	12JUN2003	24	0	-2	0	12	-22	-8	12	-20	-8
		DAY 29	18JUN2003	30	2	12	-8	4	-16	-2	2	-28	6
		DAY 36	26JUN2003	38	4	-8	-8	4	-16	0	0	-8	8
		DAY 43	03JUL2003	45	0	8	2	4	-4	4	4	-12	2
		DAY 50	10JUL2003	52	4	2	-2	8	-10	0	4	-12	2
		DAY 57	17JUL2003	59	-4	-8	-10	-2	-12	-5	2	-4	5
		FINAL		59	-4	-8	-10	-2	-12	-5	2	-4	5
	E0019042	DAY 8	12JUN2003	9	10	-2	-14	4	2	-20	-6	4	-6
		DAY 15	19JUN2003	16	0	-6	-14	-12	4	-8	-12	10	6
		FINAL		16	0	-6	-14	-12	4	-8	-12	10	6
	E0019045	DAY 8	03JUL2003	8	-6	4	4	-4	10	4	2	6	0
		DAY 22	16JUL2003	21	-6	9	14	-10	-2	2	-4	-11	-12
		FINAL		21	-6	9	14	-10	-2	2	-4	-11	-12

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0020024	DAY 8	30JUN2003	8	38	0	2	44	-2	2	6	-2	0
		DAY 15	07JUL2003	15	22	2	0	34	-6	8	12	-8	8
		DAY 22	15JUL2003	23	46	2	-8	50	-4	-6	4	-6	2
		DAY 29	21JUL2003	29	40	0	10	36	2	10	-4	2	0
		DAY 36	28JUL2003	36	50	8	-4	44	-10	0	-6	-18	4
		DAY 43	04AUG2003	43	56	2	-2	62	6	-2	6	4	0
		DAY 50	12AUG2003	51	34	-4	0	32	10	8	-2	14	8
		DAY 57	20AUG2003	59	28	8	6	34	10	4	6	2	-2
		FINAL		59	28	8	6	34	10	4	6	2	-2
	E0022044	DAY 8	25MAR2003	8	4	-2	-2	12	-6	-6	8	-4	-4
		DAY 15	01APR2003	15	12	8	10	16	8	14	4	0	4
		DAY 22	08APR2003	22	8	6	-6	16	14	-6	8	8	0
		DAY 29	15APR2003	29	8	10	4	12	12	8	4	2	4
		DAY 36	22APR2003	36	20	20	18	36	8	12	16	-12	-6
		DAY 43	29APR2003	43	24	20	8	32	-2	6	8	-22	-2
		DAY 50	06MAY2003	50	16	24	10	20	16	8	4	-8	-2
		DAY 57	12MAY2003	56	8	28	22	0	28	18	-8	0	-4
		FINAL		56	8	28	22	0	28	18	-8	0	-4
	E0023007	DAY 8	21JAN2003	8	6	-6	2	0	2	-10	-6	8	-12
		DAY 15	28JAN2003	15	23	20	8	8	18	-4	-15	-2	-12
		DAY 22	07FEB2003	25	23	24	15	8	20	-4	-15	-4	-19
		DAY 29	11FEB2003	29	23	3	-3	46	26	3	23	23	6
		DAY 36	18FEB2003	36	6	16	12	2	14	-12	-4	-2	-24
		DAY 43	25FEB2003	43	6	14	5	0	19	-5	-6	5	-10
		DAY 50	04MAR2003	50	2	17	14	-4	35	-7	-6	18	-21
		DAY 57	11MAR2003	57	-22	-16	-10	-20	-6	-14	2	10	-4
		FINAL		57	-22	-16	-10	-20	-6	-14	2	10	-4
	E0023011	DAY 8	11FEB2003	8	30	-6	6	30	-12	10	0	-6	4
		DAY 15	21FEB2003	18	22	-14	6	22	-12	12	0	2	6
		DAY 22	25FEB2003	22	19	9	8	29	28	31	10	19	23
		DAY 29	04MAR2003	29	12	8	6	22	20	10	10	12	4
		DAY 36	11MAR2003	36	6	6	2	26	8	0	20	2	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	DAY 43		18MAR2003	43	18	2	-2	22	0	6	4	-2	8
		DAY 50		27MAR2003	52	20	23	22	20	16	20	0	-7	-2
		DAY 57		01APR2003	57	31	-4	4	32	1	9	1	5	5
		FINAL			57	31	-4	4	32	1	9	1	5	5
	E0023014	DAY 8		02MAR2003	10	4	-2	-2	4	0	4	0	2	6
		DAY 15		06MAR2003	14	4	2	4	2	12	6	-2	10	2
		DAY 22		18MAR2003	26	8	10	12	10	32	20	2	22	8
		DAY 29		25MAR2003	33	22	15	2	18	28	8	-4	13	6
		DAY 36		01APR2003	40	7	3	3	-4	20	10	-11	17	7
		DAY 50		09APR2003	48	12	-9	-4	8	12	0	-4	21	4
		DAY 50	*	15APR2003	54	12	0	-5	8	18	1	-4	18	6
		DAY 57		25APR2003	64	12	4	8	6	24	14	-6	20	6
		FINAL			64	12	4	8	6	24	14	-6	20	6
	E0023019	DAY 8		15APR2003	9	-5	7	-9	0	13	-9	5	6	0
		DAY 15		22APR2003	16	4	13	1	32	10	-19	28	-3	-20
		DAY 22		02MAY2003	26	-28	-10	-8	-24	3	-8	4	13	0
		DAY 29		06MAY2003	30	-5	-1	1	-6	-11	-18	-1	-10	-19
		DAY 36		13MAY2003	37	-14	2	1	-28	-4	-12	-14	-6	-13
		DAY 43		20MAY2003	44	-16	5	-1	-16	-4	-10	0	-9	-9
		DAY 50		29MAY2003	53	-3	-6	-8	-10	6	-19	-7	12	-11
		DAY 57		03JUN2003	58	-7	2	3	-28	-10	-6	-21	-12	-9
		FINAL			58	-7	2	3	-28	-10	-6	-21	-12	-9
	E0023022	DAY 8		25APR2003	8	24	-6	13	-27	-14	-4	-51	-8	-17
		DAY 15		01MAY2003	14	36	12	-2	-26	-15	-23	-62	-27	-21
		DAY 22		08MAY2003	21	36	17	3	36	21	8	0	4	5
		DAY 29		15MAY2003	28	39	-6	6	-23	-8	-8	-62	-2	-14
		DAY 36		22MAY2003	35	9	12	9	-4	-12	-9	-13	-24	-18
		DAY 43		30MAY2003	43	13	-6	-2	-10	-12	-11	-23	-6	-9
		DAY 50		06JUN2003	50	40	-2	-4	4	4	-15	-36	6	-11
		DAY 57		12JUN2003	56	8	8	17	-43	-2	0	-51	-10	-17
		FINAL			56	8	8	17	-43	-2	0	-51	-10	-17

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0023023	DAY 8	01MAY2003	7	9	2	-12	0	-6	-29	-9	-8	-17
		FINAL		7	9	2	-12	0	-6	-29	-9	-8	-17
	E0023031	DAY 8	01JUL2003	8	-5	-32	-14	-6	-37	-17	-1	-5	-3
		DAY 15	08JUL2003	15	0	12	7	4	0	-3	4	-12	-10
		DAY 22	15JUL2003	22	-16	-25	-12	-8	-8	-6	8	17	6
		DAY 29	22JUL2003	29	-5	-5	1	-6	-10	-7	-1	-5	-8
		DAY 36	29JUL2003	36	-1	4	3	0	8	-1	1	4	-4
		DAY 43	05AUG2003	43	9	14	3	2	16	6	-7	2	3
		DAY 50	12AUG2003	50	19	-4	3	14	-9	-3	-5	-5	-6
		DAY 57	19AUG2003	57	3	0	8	2	-2	2	-1	-2	-6
		FINAL		57	3	0	8	2	-2	2	-1	-2	-6
	E0023041	DAY 8	16JUL2003	8	-1	3	-3	5	12	8	6	9	11
		DAY 15	24JUL2003	16	0	-1	-2	5	1	-2	5	2	0
		DAY 22	30JUL2003	22	16	4	5	30	9	9	14	5	4
		DAY 29	06AUG2003	29	12	-2	-5	19	3	-4	7	5	1
		DAY 36	13AUG2003	36	37	-16	-2	28	-1	-9	-9	15	-7
		DAY 43	20AUG2003	43	17	-14	-8	21	3	2	4	17	10
		DAY 50	27AUG2003	50	25	-11	-11	40	-11	-6	15	0	5
		DAY 57	05SEP2003	59	19	3	-3	17	-4	0	-2	-7	3
		FINAL		59	19	3	-3	17	-4	0	-2	-7	3
	E0023043	DAY 8	23JUL2003	10	-2	1	-4	13	1	-9	15	0	-5
		DAY 15	28JUL2003	15	-2	-7	5	0	-1	3	2	6	-2
		DAY 22	05AUG2003	23	9	-6	10	15	-14	-1	6	-8	-11
		DAY 29	12AUG2003	30	3	21	32	7	4	5	4	-17	-27
		DAY 36	19AUG2003	37	0	26	24	17	33	24	17	7	0
		DAY 43	26AUG2003	44	-6	8	13	-8	13	17	-2	5	4
		DAY 50	02SEP2003	51	11	9	9	21	-4	2	10	-13	-7
		DAY 57	09SEP2003	58	0	-4	11	2	1	13	2	5	2
		FINAL		58	0	-4	11	2	1	13	2	5	2
	E0026003	DAY 8	12DEC2002	9	28	-7	2	12	1	13	-16	8	11
		DAY 15	19DEC2002	16	9	0	6	-1	13	-1	-10	13	-7

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	DAY 22	26DEC2002	23	9	-10	-13	-8	-6	1	-17	4	14
		DAY 29	02JAN2003	30	7	-23	-13	-8	6	-2	-15	29	11
		DAY 36	09JAN2003	37	-13	9	-1	-28	12	11	-15	3	12
		DAY 43	16JAN2003	44	19	-6	-5	2	-8	-6	-17	-2	-1
		DAY 50	23JAN2003	51	19	-22	-14	3	-28	-21	-16	-6	-7
		DAY 57	03FEB2003	62	7	0	3	-7	10	14	-14	10	11
		FINAL		62	7	0	3	-7	10	14	-14	10	11
	E0026005	DAY 8	06JAN2003	8	8	-6	-2	8	-15	0	0	-9	2
		FINAL		8	8	-6	-2	8	-15	0	0	-9	2
	E0026009	DAY 8	21JAN2003	7	-49	-34	-30	-28	-7	-25	21	27	5
		FINAL		7	-49	-34	-30	-28	-7	-25	21	27	5
	E0026015	DAY 8	07MAR2003	9	10	-4	-4	2	-16	-4	-8	-12	0
		DAY 15	13MAR2003	15	-2	14	13	-10	23	7	-8	9	-6
		DAY 22	20MAR2003	22	1	15	5	-6	13	23	-7	-2	18
		DAY 29	27MAR2003	29	-12	17	-1	-26	21	3	-14	4	4
		DAY 36	03APR2003	36	2	27	7	2	31	32	0	4	25
		DAY 43	10APR2003	43	1	7	7	2	3	15	1	-4	8
		DAY 50	17APR2003	50	5	13	10	-4	10	16	-9	-3	6
		DAY 57	25APR2003	58	0	20	4	-6	33	13	-6	13	9
		FINAL		58	0	20	4	-6	33	13	-6	13	9
	E0026023	DAY 8	07MAY2003	8	-20	-5	4	-20	-5	1	0	0	-3
		DAY 15	14MAY2003	15	-10	4	1	-18	0	0	-8	-4	-1
		DAY 22	21MAY2003	22	2	10	9	-6	-3	4	-8	-13	-5
		DAY 29	28MAY2003	29	-8	-6	-1	0	-8	4	8	-2	5
		DAY 36	04JUN2003	36	-20	2	0	-34	3	7	-14	1	7
		DAY 43	11JUN2003	43	-21	-2	4	-26	13	4	-5	15	0
		DAY 50	18JUN2003	50	-16	4	-1	-9	4	7	7	0	8
		DAY 57	27JUN2003	59	-9	-2	-4	-31	-9	-3	-22	-7	1
		FINAL		59	-9	-2	-4	-31	-9	-3	-22	-7	1
	E0027016	DAY 8	14APR2003	6	16	-8	-10	-6	0	-12	-22	8	-2

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	DAY 15	22APR2003	14	16	10	-30	20	16	-20	4	6	10
		DAY 22	29APR2003	21	16	-10	-22	8	-2	-20	-8	8	2
		DAY 29	05MAY2003	27	26	-10	-20	16	-2	-22	-10	8	-2
		DAY 36	14MAY2003	36	-4	-4	-18	0	-2	-18	4	2	0
		DAY 43	19MAY2003	41	0	-2	-14	0	0	-20	0	2	-6
		DAY 50	27MAY2003	49	8	-10	-20	12	-8	-18	4	2	2
		DAY 57	03JUN2003	56	4	-25	-15	-4	-19	-15	-8	6	0
		FINAL		56	4	-25	-15	-4	-19	-15	-8	6	0
	E0027018	DAY 8	02APR2003	9	8	8	4	-4	16	0	-12	8	-4
		DAY 15	08APR2003	15	18	2	2	-8	6	2	-26	4	0
		DAY 22	15APR2003	22	18	8	10	-8	16	14	-26	8	4
		DAY 29	22APR2003	29	12	-2	12	-12	16	14	-24	18	2
		DAY 36	29APR2003	36	4	2	0	-4	6	2	-8	4	2
		DAY 43	05MAY2003	42	0	6	10	-12	10	14	-12	4	4
		DAY 50	13MAY2003	50	-8	12	12	-8	16	16	0	4	4
		DAY 57	22MAY2003	59	6	2	2	-8	8	2	-14	6	0
		FINAL		59	6	2	2	-8	8	2	-14	6	0
	E0028032	DAY 8	01APR2003	8	12	22	-6	-4	24	-8	-16	2	-2
		DAY 15	08APR2003	15	12	12	2	4	26	4	-8	14	2
		DAY 22	15APR2003	22	8	0	2	-2	10	8	-10	10	6
		DAY 29	22APR2003	29	8	20	6	-4	24	2	-12	4	-4
		DAY 36	30APR2003	37	14	8	-4	-10	6	-2	-24	-2	2
		DAY 43	06MAY2003	43	8	10	-6	-4	18	-12	-12	8	-6
		DAY 50	13MAY2003	50	20	34	10	8	34	2	-12	0	-8
		DAY 57	06JUN2003	74	24	20	2	-4	28	-2	-28	8	-4
		FINAL		74	24	20	2	-4	28	-2	-28	8	-4
	E0029003	DAY 8	11NOV2002	8	-12	-10	-6	-12	-6	6	0	4	12
		DAY 15	18NOV2002	15	0	10	0	-8	-20	-4	-8	-30	-4
		DAY 22	25NOV2002	22	4	10	0	0	0	6	-4	-10	6
		DAY 29	02DEC2002	29	4	14	14	0	10	14	-4	-4	0
		DAY 36	09DEC2002	36	0	20	16	0	14	12	0	-6	-4
		DAY 43	16DEC2002	43	4	14	10	0	0	26	-4	-14	16

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 50	23DEC2002	50	0	12	20	-12	8	12	-12	-4	-8
		DAY 57	30DEC2002	57	-12	0	0	-4	-12	16	8	-12	16
		FINAL		57	-12	0	0	-4	-12	16	8	-12	16
	E0029020	DAY 8	11MAR2003	7	0	-4	-8	4	0	-2	4	4	6
		FINAL		7	0	-4	-8	4	0	-2	4	4	6
	E0031005	DAY 8	27DEC2002	8	4	8	4	6	4	2	2	-4	-2
		DAY 15	03JAN2003	15	-2	4	0	-8	8	0	-6	4	0
		DAY 22	10JAN2003	22	7	10	-2	2	8	-4	-5	-2	-2
		DAY 29	17JAN2003	29	10	10	-6	8	12	-4	-2	2	2
		DAY 36	24JAN2003	36	-2	8	4	-10	8	2	-8	0	-2
		DAY 43	30JAN2003	42	12	10	2	8	14	0	-4	4	-2
		DAY 50	07FEB2003	50	8	12	6	-10	20	4	-18	8	-2
		DAY 57	14FEB2003	57	12	18	6	2	20	4	-10	2	-2
		FINAL		57	12	18	6	2	20	4	-10	2	-2
	E0031006	DAY 8	26FEB2003	9	13	-22	-4	10	-34	-10	-3	-12	-6
		DAY 15	05MAR2003	16	17	-4	10	8	2	6	-9	6	-4
		DAY 22	11MAR2003	22	-1	-6	4	-12	-12	-4	-11	-6	-8
		DAY 29	18MAR2003	29	-5	-22	-4	-10	-24	-4	-5	-2	0
		DAY 36	25MAR2003	36	13	-16	6	4	-22	4	-9	-6	-2
		DAY 43	02APR2003	44	13	-18	6	2	-22	0	-11	-4	-6
		DAY 50	07APR2003	49	21	-2	12	14	-2	14	-7	0	2
		DAY 57	15APR2003	57	1	-16	6	-2	-22	8	-3	-6	2
		FINAL		57	1	-16	6	-2	-22	8	-3	-6	2
	E0031010	DAY 8	26FEB2003	8	-14	-8	-8	-12	-4	-6	2	4	2
		DAY 15	05MAR2003	15	-10	-16	-2	-4	-16	2	6	0	4
		FINAL		15	-10	-16	-2	-4	-16	2	6	0	4
	E0031011	DAY 8	06MAR2003	8	-4	-6	4	-8	-8	-4	-4	-2	-8
		DAY 15	13MAR2003	15	-14	-8	6	0	-10	2	14	-2	-4
		DAY 22	20MAR2003	22	16	0	12	18	4	12	2	4	0
		DAY 29	27MAR2003	29	2	-14	0	0	-16	-8	-2	-2	-8

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0031011	DAY 36	03APR2003	36	6	-8	4	0	-10	-4	-6	-2	-8
		DAY 43	11APR2003	44	-6	-18	-2	-2	-20	-6	4	-2	-4
		DAY 50	17APR2003	50	-16	-14	2	-18	-20	-6	-2	-6	-8
		DAY 57	24APR2003	57	-12	-24	4	-12	-22	0	0	2	-4
		FINAL		57	-12	-24	4	-12	-22	0	0	2	-4
	E0031015	DAY 8	01APR2003	7	28	6	4	16	6	8	-12	0	4
		FINAL		7	28	6	4	16	6	8	-12	0	4
	E0031031	DAY 8	15JUL2003	8	8	5	6	4	-4	6	-4	-9	0
		DAY 15	22JUL2003	15	2	5	10	4	4	6	2	-1	-4
		DAY 22	29JUL2003	22	2	7	4	-2	-2	6	-4	-9	2
		DAY 50	28AUG2003	52	0	7	4	0	0	0	0	-7	-4
		FINAL		52	0	7	4	0	0	0	0	-7	-4
	E0034009	DAY 8	27JUN2003	9	16	-15	0	16	0	-5	0	15	-5
		DAY 15	03JUL2003	15	16	5	-5	24	10	5	8	5	10
		DAY 22	10JUL2003	22	16	0	0	24	15	10	8	15	10
		DAY 29	18JUL2003	30	4	10	-5	4	30	15	0	20	20
		DAY 36	25JUL2003	37	8	20	10	16	25	10	8	5	0
		DAY 43	31JUL2003	43	0	20	10	9	25	10	9	5	0
		DAY 50	07AUG2003	50	4	0	-20	16	5	0	12	5	20
		DAY 57	18AUG2003	61	12	5	-10	16	22	5	4	17	15
		FINAL		61	12	5	-10	16	22	5	4	17	15
	E0037007	DAY 8	17APR2003	7	24	2	0	24	0	0	0	-2	0
		FINAL		7	24	2	0	24	0	0	0	-2	0
	E0037012	DAY 8	24JUL2003	9	4	4	2	4	6	-2	0	2	-4
		DAY 15	01AUG2003	17	16	10	0	16	8	-6	0	-2	-6
		DAY 22	08AUG2003	24	24	12	-3	26	18	0	2	6	3
		DAY 29	15AUG2003	31	26	18	0	30	18	0	4	0	0
		DAY 36	22AUG2003	38	10	8	4	15	12	12	5	4	8
		DAY 43	29AUG2003	45	8	4	0	8	8	0	0	4	0
		DAY 50	05SEP2003	52	10	16	14	10	14	20	0	-2	6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0037012	DAY 57	08SEP2003	55	0	2	-8	0	2	-8	0	0	0
		FINAL		55	0	2	-8	0	2	-8	0	0	0
	E0039019	DAY 8	13FEB2003	8	-22	8	0	-34	0	-2	-12	-8	-2
		DAY 15	20FEB2003	15	-5	-8	-2	0	-10	-10	5	-2	-8
		DAY 22	27FEB2003	22	0	-24	-14	0	-18	-18	0	6	-4
		DAY 29	07MAR2003	30	-4	-28	-42	-8	-24	-36	-4	4	6
		DAY 36	13MAR2003	36	8	-10	-2	4	-14	-8	-4	-4	-6
		DAY 43	20MAR2003	43	-8	-16	-8	-8	-16	-10	0	0	-2
		DAY 50	27MAR2003	50	2	-16	-12	-18	-16	-12	-20	0	0
		DAY 57	03APR2003	57	2	-8	-4	-2	-12	-6	-4	-4	-2
		FINAL		57	2	-8	-4	-2	-12	-6	-4	-4	-2
	E0039043	DAY 8	15MAY2003	8	-12	-14	4	-5	-10	-4	7	4	-8
		DAY 15	23MAY2003	16	7	-6	12	1	0	2	-6	6	-10
		DAY 22	29MAY2003	22	-4	-12	0	-3	-12	-26	1	0	-26
		DAY 29	05JUN2003	29	2	-10	2	-7	2	0	-9	12	-2
		DAY 36	13JUN2003	37	2	10	8	-7	8	4	-9	-2	-4
		FINAL		37	2	10	8	-7	8	4	-9	-2	-4
PLACEBO (BIPOLAR I)	E0002001	DAY 8	06JAN2003	8	0	-2	8	0	2	2	0	4	-6
		DAY 15	14JAN2003	16	-4	12	8	-8	2	4	-4	-10	-4
		DAY 22	21JAN2003	23	-8	2	-2	-8	0	-4	0	-2	-2
		DAY 29	29JAN2003	31	-10	-4	-6	-10	-8	-4	0	-4	2
		DAY 36	05FEB2003	38	-8	-4	8	-12	-8	2	-4	-4	-6
		DAY 43	12FEB2003	45	-6	0	-4	-6	2	2	0	2	6
		DAY 50	19FEB2003	52	-8	10	4	-12	8	6	-4	-2	2
		DAY 57	26FEB2003	59	0	12	-8	0	2	8	0	-10	16
		FINAL		59	0	12	-8	0	2	8	0	-10	16
	E0002003	DAY 8	29JAN2003	8	-4	2	-8	0	-2	-20	4	-4	-12
		DAY 15	05FEB2003	15	8	10	-20	8	2	-18	0	-8	2
		DAY 22	12FEB2003	22	-4	2	-18	4	4	-14	8	2	4
		DAY 29	19FEB2003	29	12	12	-20	6	0	-16	-6	-12	4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0002003	DAY 36	26FEB2003	36	-4	12	-14	-6	12	-8	-2	0	6
		DAY 43	05MAR2003	43	10	12	-14	4	10	-12	-6	-2	2
		DAY 50	11MAR2003	49	8	8	-12	2	6	-14	-6	-2	-2
		DAY 57	18MAR2003	56	-4	20	-12	4	10	-12	8	-10	0
		FINAL		56	-4	20	-12	4	10	-12	8	-10	0
	E0002008	DAY 8	05MAR2003	9	2	-8	8	10	2	6	8	10	-2
		DAY 15	13MAR2003	17	8	-6	6	10	2	0	2	8	-6
		DAY 22	20MAR2003	24	-2	-10	2	10	-6	0	12	4	-2
		DAY 29	27MAR2003	31	4	-18	-2	4	-10	2	0	8	4
		DAY 36	03APR2003	38	-2	-18	-14	12	-6	0	14	12	14
		DAY 43	11APR2003	46	4	-2	8	4	-8	-10	0	-6	-18
		DAY 50	16APR2003	51	6	-12	12	16	0	6	10	12	-6
		DAY 57	23APR2003	58	2	-20	-6	12	-8	-12	10	12	-6
		FINAL		58	2	-20	-6	12	-8	-12	10	12	-6
	E0002016	DAY 8	30JUL2003	7	4	-8	6	2	-8	12	-2	0	6
		DAY 15	06AUG2003	14	4	-8	-2	2	-6	-2	-2	2	0
		DAY 22	13AUG2003	21	4	-10	-4	2	-20	-2	-2	-10	2
		DAY 29	21AUG2003	29	4	-6	2	2	-10	6	-2	-4	4
		DAY 36	27AUG2003	35	0	-6	-2	2	-18	4	2	-12	6
		DAY 43	03SEP2003	42	0	-10	-2	2	-26	-2	2	-16	0
		DAY 50	11SEP2003	50	0	-14	0	0	-22	0	0	-8	0
		DAY 57	17SEP2003	56	2	2	10	0	0	16	-2	-2	6
		FINAL		56	2	2	10	0	0	16	-2	-2	6
	E0003008	DAY 8	04FEB2003	8	-8	-2	0	6	-4	-10	14	-2	-10
		DAY 15	11FEB2003	15	0	4	-8	0	-14	-16	0	-18	-8
		DAY 22	18FEB2003	22	4	-14	-14	-4	-22	-20	-8	-8	-6
		FINAL		22	4	-14	-14	-4	-22	-20	-8	-8	-6
	E0004003	DAY 8	17OCT2002	8	-8	-6	-4	-4	2	8	4	8	12
		FINAL		8	-8	-6	-4	-4	2	8	4	8	12
	E0004006	DAY 8	11NOV2002	8	12	-6	4	12	-6	-2	0	0	-6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0004006	DAY 15	18NOV2002	15	0	-2	-2	8	2	-6	8	4	-4
		DAY 22	25NOV2002	22	12	14	0	4	12	-4	-8	-2	-4
		DAY 29	02DEC2002	29	8	10	0	8	10	-4	0	0	-4
		DAY 36	09DEC2002	36	6	-4	0	0	-6	-6	-6	-2	-6
		DAY 43	16DEC2002	43	4	-8	-10	-4	-8	-6	-8	0	4
		DAY 57	06JAN2003	64	0	6	-2	0	12	-2	0	6	0
		FINAL		64	0	6	-2	0	12	-2	0	6	0
	E0004016	DAY 8	26FEB2003	8	-4	8	4	0	22	8	4	14	4
		DAY 15	05MAR2003	15	-8	4	10	-4	14	12	4	10	2
		DAY 22	13MAR2003	23	-4	10	20	-8	6	14	-4	-4	-6
		DAY 36	26MAR2003	36	-8	4	8	-8	4	2	0	0	-6
		DAY 43	03APR2003	44	14	4	4	18	14	8	4	10	4
		DAY 50	10APR2003	51	-4	0	10	-8	12	12	-4	12	2
		DAY 57	17APR2003	58	-8	-6	2	-4	4	-2	4	10	-4
		FINAL		58	-8	-6	2	-4	4	-2	4	10	-4
	E0004024	DAY 8	10JUL2003	8	4	-4	0	0	6	0	-4	10	0
		DAY 15	17JUL2003	15	-8	-4	-2	0	-2	-2	8	2	0
		DAY 22	24JUL2003	22	0	-10	-6	0	10	6	0	20	12
		DAY 29	31JUL2003	29	0	4	0	8	0	0	8	-4	0
		DAY 36	07AUG2003	36	0	-6	-2	8	-8	-4	8	-2	-2
		DAY 43	14AUG2003	43	4	-4	0	8	6	6	4	10	6
		DAY 50	21AUG2003	50	-4	6	0	-4	4	6	0	-2	6
		DAY 57	28AUG2003	57	-4	-4	0	4	14	12	8	18	12
		FINAL		57	-4	-4	0	4	14	12	8	18	12
	E0005006	DAY 8	14OCT2002	12	14	0	2	20	12	10	6	12	8
		FINAL		12	14	0	2	20	12	10	6	12	8
	E0005017	DAY 8	06JAN2003	8	-12	-6	0	-12	-4	-24	0	2	-24
		DAY 15	14JAN2003	16	-16	-10	-4	-12	-4	-4	4	6	0
		DAY 22	22JAN2003	24	-8	0	0	-8	2	-4	0	2	-4
		DAY 29	30JAN2003	32	-4	0	0	-4	6	-4	0	6	-4
		DAY 36	04FEB2003	37	-20	-6	-10	-20	-2	-12	0	4	-2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0005017	DAY 43	13FEB2003	46	-20	0	-8	-20	-4	-8	0	-4	0
		DAY 50	20FEB2003	53	-20	-10	-18	-20	-8	-24	0	2	-6
		DAY 57	04MAR2003	65	-20	-10	-14	-20	-4	-16	0	6	-2
		FINAL		65	-20	-10	-14	-20	-4	-16	0	6	-2
	E0005019	DAY 8	23JAN2003	9	-36	10	8	-28	4	4	8	-6	-4
		FINAL		9	-36	10	8	-28	4	4	8	-6	-4
	E0005026	DAY 8	13MAR2003	8	12	2	4	20	-6	-6	8	-8	-10
		DAY 15	20MAR2003	15	12	-10	0	20	-12	-6	8	-2	-6
		DAY 22	25MAR2003	20	16	-4	-2	20	-8	-8	4	-4	-6
		FINAL		20	16	-4	-2	20	-8	-8	4	-4	-6
	E0005039	DAY 8	28MAY2003	7	12	8	6	12	10	6	0	2	0
		DAY 15	05JUN2003	15	0	0	2	0	4	4	0	4	2
		DAY 22	12JUN2003	22	16	4	4	16	4	4	0	0	0
		DAY 29	18JUN2003	28	0	0	4	0	-2	4	0	-2	0
		DAY 36	24JUN2003	34	-4	0	0	-4	0	0	0	0	0
		DAY 43	03JUL2003	43	-4	0	4	-4	4	4	0	4	0
		DAY 50	10JUL2003	50	0	0	4	0	8	4	0	8	0
		DAY 57	16JUL2003	56	4	4	-2	0	10	6	-4	6	8
		FINAL		56	4	4	-2	0	10	6	-4	6	8
	E0005043	DAY 8	17JUL2003	9	4	0	-8	6	8	-6	2	8	2
		DAY 15	24JUL2003	16	0	-10	6	0	0	0	0	10	-6
		DAY 22	31JUL2003	23	0	-10	0	0	0	0	0	10	0
		DAY 29	07AUG2003	30	0	-10	0	0	0	0	0	10	0
		DAY 36	13AUG2003	36	0	-20	0	0	-10	0	0	10	0
		DAY 43	20AUG2003	43	4	-2	0	0	0	0	-4	2	0
		DAY 50	27AUG2003	50	4	-4	-2	12	0	-6	8	4	-4
		DAY 57	03SEP2003	57	0	6	6	8	14	0	8	8	-6
		FINAL		57	0	6	6	8	14	0	8	8	-6
	E0006020	DAY 8	20MAY2003	8	0	0	-9	4	2	-4	4	2	5
		DAY 15	27MAY2003	15	16	-1	-13	20	0	10	4	1	23

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0006020	DAY 22		03JUN2003	22	14	-3	-14	18	0	-4	4	3	10
		DAY 29		10JUN2003	29	4	-4	-13	8	4	-7	4	8	6
		DAY 36		17JUN2003	36	-6	1	-7	-2	6	-2	4	5	5
		DAY 43		24JUN2003	43	-4	5	-6	0	6	-5	4	1	1
		DAY 50		01JUL2003	50	6	-1	-4	12	18	1	6	19	5
		DAY 57		08JUL2003	57	-4	-2	-3	2	0	6	6	2	9
		FINAL			57	-4	-2	-3	2	0	6	6	2	9
	E0007001	DAY 8		07JAN2003	8	-2	2	0	2	-2	-2	4	-4	-2
		DAY 15		14JAN2003	15	0	-2	0	-2	-8	-2	-2	-6	-2
		DAY 22		21JAN2003	22	2	0	0	2	-10	-6	0	-10	-6
		DAY 29		28JAN2003	29	0	-8	2	4	-8	2	4	0	0
		DAY 36		04FEB2003	36	2	-6	0	2	-8	0	0	-2	0
		DAY 43		11FEB2003	43	0	-10	0	0	-24	-6	0	-14	-6
		DAY 50		18FEB2003	50	-4	-6	0	-4	-10	0	0	-4	0
		DAY 50	*	22FEB2003	54	0	0	2	4	-2	2	4	-2	0
		FINAL			54	0	0	2	4	-2	2	4	-2	0
	E0007003	DAY 8		06FEB2003	8	2	0	4	0	0	-4	-2	0	-8
		DAY 15		14FEB2003	16	-6	2	-2	-8	-2	-8	-2	-4	-6
		DAY 22		22FEB2003	24	0	-2	-4	-4	-8	-4	-4	-6	0
		DAY 36		10MAR2003	40	2	-10	-10	0	-18	-12	-2	-8	-2
		FINAL			40	2	-10	-10	0	-18	-12	-2	-8	-2
	E0007006	DAY 8		12MAR2003	8	-4	6	0	-2	6	-2	2	0	-2
		DAY 15		19MAR2003	15	-4	10	-10	2	0	-6	6	-10	4
		DAY 22	*	25MAR2003	21	0	2	-6	4	8	-6	4	6	0
		DAY 22		26MAR2003	22	4	6	-10	8	0	-10	4	-6	0
		FINAL			22	4	6	-10	8	0	-10	4	-6	0
	E0009004	DAY 8		04DEC2002	9	-2	0	6	-6	2	4	-4	2	-2
		DAY 15		11DEC2002	16	8	10	14	-2	12	6	-10	2	-8
		DAY 22		18DEC2002	23	32	-10	10	22	-4	12	-10	6	2
		FINAL			23	32	-10	10	22	-4	12	-10	6	2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0009012	DAY 8	03JUL2003	9	-8	-22	-10	-8	-16	-8	0	6	2
		FINAL		9	-8	-22	-10	-8	-16	-8	0	6	2
	E0010008	DAY 8	26DEC2002	9	-23	-8	-10	-25	0	-10	-2	8	0
		DAY 15	02JAN2003	16	-1	8	4	-8	20	0	-7	12	-4
		DAY 22	08JAN2003	22	-15	-2	-6	-16	6	-14	-1	8	-8
		DAY 29	15JAN2003	29	-7	12	-6	-3	2	-4	4	-10	2
		FINAL		29	-7	12	-6	-3	2	-4	4	-10	2
	E0010018	DAY 8	26MAR2003	8	-12	-18	-12	-25	-10	-10	-13	8	2
		DAY 15	02APR2003	15	6	-8	-10	-1	14	0	-7	22	10
		DAY 22	09APR2003	22	8	-14	-10	3	-2	-4	-5	12	6
		DAY 29	16APR2003	29	4	-14	-16	-5	-6	-12	-9	8	4
		DAY 36	23APR2003	36	-2	-12	-10	5	0	-8	7	12	2
		DAY 43	01MAY2003	44	12	-6	0	1	-2	-6	-11	4	-6
		DAY 57	14MAY2003	57	10	-18	-10	-1	-2	-10	-11	16	0
		FINAL		57	10	-18	-10	-1	-2	-10	-11	16	0
	E0010028	DAY 8	24JUN2003	9	6	-2	10	12	0	-2	6	2	-12
		DAY 15	01JUL2003	16	4	-10	10	4	-2	0	0	8	-10
		DAY 22	08JUL2003	23	0	-10	0	0	-10	-2	0	0	-2
		DAY 29	15JUL2003	30	-14	-10	0	-10	0	-2	4	10	-2
		FINAL		30	-14	-10	0	-10	0	-2	4	10	-2
	E0011008	DAY 8	06FEB2003	8	8	-8	-2	6	-12	-8	-2	-4	-6
		DAY 15	13FEB2003	15	6	4	2	12	6	0	6	2	-2
		FINAL		15	6	4	2	12	6	0	6	2	-2
	E0011009	DAY 8	02JAN2003	7	0	0	-1	0	0	8	0	0	9
		DAY 15	09JAN2003	14	-2	-8	-3	4	-6	2	6	2	5
		DAY 22	16JAN2003	21	-6	0	-3	0	-2	2	6	-2	5
		DAY 29	23JAN2003	28	-3	-8	-1	4	0	4	7	8	5
		DAY 36	30JAN2003	35	-10	-10	-9	-8	-12	2	2	-2	11
		DAY 43	06FEB2003	42	-6	0	-9	-4	-6	6	2	-6	15
		DAY 50	13FEB2003	49	8	0	-5	4	-2	2	-4	-2	7

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0011009	DAY 57		20FEB2003	56	-2	-10	-5	12	-16	-2	14	-6	3
		FINAL			56	-2	-10	-5	12	-16	-2	14	-6	3
	E0011010	DAY 8		17FEB2003	8	0	0	0	0	-1	4	0	-1	4
		DAY 15		24FEB2003	15	8	0	-2	12	-4	-2	4	-4	0
		DAY 22		03MAR2003	22	4	2	6	4	2	6	0	0	0
		DAY 29		10MAR2003	29	-6	-7	-4	-20	-8	-4	-14	-1	0
		DAY 36		17MAR2003	36	8	-2	0	16	-4	-2	8	-2	-2
		DAY 36	*	19MAR2003	38	8	-6	2	8	-4	2	0	2	0
		FINAL			38	8	-6	2	8	-4	2	0	2	0
	E0013001	DAY 8		21NOV2002	8	0	0	-8	0	2	-6	0	2	2
		DAY 15		27NOV2002	14	8	4	-2	0	0	-2	-8	-4	0
		DAY 22		06DEC2002	23	8	0	0	0	0	-2	-8	0	-2
		DAY 29		11DEC2002	28	0	0	-8	0	-4	-6	0	-4	2
		DAY 36		18DEC2002	35	-6	4	-2	-6	0	-6	0	-4	-4
		DAY 43		27DEC2002	44	0	0	-4	0	0	-4	0	0	0
		DAY 50		02JAN2003	50	6	0	-8	0	-2	-6	-6	-2	2
		DAY 57		10JAN2003	58	8	2	-4	8	2	0	0	0	4
		FINAL			58	8	2	-4	8	2	0	0	0	4
	E0013003	DAY 8		19NOV2002	8	0	16	0	0	22	6	0	6	6
		DAY 15		26NOV2002	15	-6	-4	0	-6	12	0	0	16	0
		DAY 22		03DEC2002	22	0	-4	0	0	8	4	0	12	4
		DAY 29		11DEC2002	30	-6	18	4	-6	26	8	0	8	4
		DAY 36		18DEC2002	37	10	18	8	6	26	8	-4	8	0
		DAY 43		23DEC2002	42	14	12	2	12	12	0	-2	0	-2
		DAY 50		30DEC2002	49	0	-4	0	-6	6	0	-6	10	0
		DAY 57		06JAN2003	56	-12	-8	0	-12	4	0	0	12	0
		FINAL			56	-12	-8	0	-12	4	0	0	12	0
	E0013005	DAY 8		25FEB2003	8	-6	-5	-6	-12	-5	-2	-6	0	4
		DAY 15		04MAR2003	15	-6	0	6	-6	0	2	0	0	-4
		DAY 22		11MAR2003	22	6	-5	-4	-6	-2	-2	-12	3	2
		DAY 29		19MAR2003	30	6	4	6	0	0	2	-6	-4	-4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0013005	DAY 36		25MAR2003	36	0	-20	6	-6	-10	2	-6	10	-4
		DAY 43		02APR2003	44	6	-2	-4	-6	-4	-8	-12	-2	-4
		DAY 50		08APR2003	50	-2	0	6	-8	0	0	-6	0	-6
		DAY 57		15APR2003	57	0	12	6	-6	12	2	-6	0	-4
		FINAL			57	0	12	6	-6	12	2	-6	0	-4
	E0013013	DAY 8		12MAY2003	7	-12	6	10	0	6	4	12	0	-6
		DAY 15		19MAY2003	14	-20	8	20	0	2	12	20	-6	-8
		DAY 22		27MAY2003	22	-20	8	20	-8	12	16	12	4	-4
		DAY 22	*	30MAY2003	25	-16	0	18	0	-2	16	16	-2	-2
		FINAL			25	-16	0	18	0	-2	16	16	-2	-2
	E0014002	DAY 8		04MAR2003	7	0	-11	-8	0	-10	-10	0	1	-2
		DAY 15		12MAR2003	15	10	-25	0	8	-10	0	-2	15	0
		DAY 22		20MAR2003	23	12	-25	2	6	-10	-6	-6	15	-8
		DAY 29		27MAR2003	30	-16	-23	10	-28	-12	5	-12	11	-5
		DAY 43		10APR2003	44	-4	-25	-8	-17	0	-2	-13	25	6
		FINAL			44	-4	-25	-8	-17	0	-2	-13	25	6
	E0014004	DAY 8		20MAR2003	9	-10	0	-3	-4	4	-12	6	4	-9
		DAY 15		25MAR2003	14	-1	-8	2	2	1	-2	3	9	-4
		DAY 22		01APR2003	21	-6	-15	-3	0	4	-2	6	19	1
		DAY 36		15APR2003	35	2	-5	4	6	-4	-7	4	1	-11
		FINAL			35	2	-5	4	6	-4	-7	4	1	-11
	E0014009	DAY 8		30APR2003	8	4	0	20	0	-10	10	-4	-10	-10
		FINAL			8	4	0	20	0	-10	10	-4	-10	-10
	E0014015	DAY 8		26JUN2003	9	0	-20	-5	3	-13	5	3	7	10
		FINAL			9	0	-20	-5	3	-13	5	3	7	10
	E0014017	DAY 8		02JUL2003	6	4	-8	10	-4	-2	10	-8	6	0
		DAY 15		09JUL2003	13	0	2	10	-4	2	8	-4	0	-2
		DAY 22		16JUL2003	20	-4	6	12	0	-16	4	4	-22	-8
		DAY 29		23JUL2003	27	-4	8	16	10	6	12	14	-2	-4

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0014017	DAY 29	*	29JUL2003	33	-8	-4	0	-8	2	4	0	6	4
		DAY 36		05AUG2003	40	8	-10	0	0	-6	4	-8	4	4
		DAY 43		12AUG2003	47	0	-2	10	-4	-8	4	-4	-6	-6
		DAY 50		19AUG2003	54	4	-2	6	-4	-6	6	-8	-4	0
		FINAL			54	4	-2	6	-4	-6	6	-8	-4	0
	E0014018	DAY 8		09JUL2003	9	24	3	3	30	-2	-4	6	-5	-7
		DAY 15		16JUL2003	16	24	-2	0	28	-2	-2	4	0	-2
		DAY 22		22JUL2003	22	-4	-7	-5	2	-2	0	6	5	5
		DAY 29		29JUL2003	29	12	-17	-15	12	-2	0	0	15	15
		DAY 36		05AUG2003	36	12	-7	3	17	4	-3	5	11	-6
		DAY 43		12AUG2003	43	14	-2	3	14	2	-5	0	4	-8
		DAY 50		19AUG2003	50	8	-2	7	10	5	0	2	7	-7
		DAY 57		27AUG2003	58	-4	8	1	0	8	2	4	0	1
		FINAL			58	-4	8	1	0	8	2	4	0	1
	E0015005	DAY 8		11DEC2002	10	0	4	4	6	-2	4	6	-6	0
		DAY 15		18DEC2002	17	0	0	0	6	0	6	6	0	6
		FINAL			17	0	0	0	6	0	6	6	0	6
	E0017002	DAY 8		13JUN2003	11	-12	-7	10	-12	-7	10	0	0	0
		FINAL			11	-12	-7	10	-12	-7	10	0	0	0
	E0018009	DAY 8		13JAN2003	8	12	-4	-2	8	-6	-10	-4	-2	-8
		DAY 8	*	14JAN2003	9	12	-16	8	8	-18	0	-4	-2	-8
		FINAL			9	12	-16	8	8	-18	0	-4	-2	-8
	E0018010	DAY 8		23JAN2003	8	0	-2	0	8	-4	-2	8	-2	-2
		DAY 15		30JAN2003	15	4	-10	2	4	-10	0	0	0	-2
		DAY 22		06FEB2003	22	-4	-4	-2	-4	-8	0	0	-4	2
		DAY 29		13FEB2003	29	8	-10	-2	8	-8	-2	0	2	0
		DAY 36		20FEB2003	36	4	-6	-2	4	-4	2	0	2	4
		DAY 43		26FEB2003	42	8	-2	0	8	2	2	0	4	2
		DAY 50		06MAR2003	50	4	12	0	8	12	4	4	0	4
		DAY 57		13MAR2003	57	0	4	0	0	4	0	0	0	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0018010	FINAL			57	0	4	0	0	4	0	0	0	0
	E0018015	DAY 8		04FEB2003	8	-4	6	4	0	2	4	4	-4	0
		DAY 15		13FEB2003	17	20	16	10	24	18	10	4	2	0
		DAY 22		20FEB2003	24	8	16	0	16	12	0	8	-4	0
		DAY 29		26FEB2003	30	-4	10	-4	-8	14	2	-4	4	6
		DAY 36		06MAR2003	38	4	18	2	4	18	4	0	0	2
		DAY 43		13MAR2003	45	-4	2	-6	0	0	0	4	-2	6
		DAY 50		20MAR2003	52	4	2	-2	4	2	0	0	0	2
		DAY 57		27MAR2003	59	-8	8	0	-8	8	2	0	0	2
		FINAL			59	-8	8	0	-8	8	2	0	0	2
	E0020015	DAY 8		03APR2003	8	2	2	-2	-4	6	2	-6	4	4
		DAY 15		10APR2003	15	20	0	18	19	0	20	-1	0	2
		DAY 22		16APR2003	21	2	10	6	2	2	4	0	-8	-2
		DAY 29		23APR2003	28	10	16	8	10	14	12	0	-2	4
		DAY 36		30APR2003	35	0	22	0	0	24	10	0	2	10
		DAY 43		08MAY2003	43	4	-2	-10	0	-2	0	-4	0	10
		DAY 50		15MAY2003	50	0	-2	2	0	-6	4	0	-4	2
		DAY 57		23MAY2003	58	-6	-14	8	-6	-18	8	0	-4	0
		FINAL			58	-6	-14	8	-6	-18	8	0	-4	0
	E0020017	DAY 8		10APR2003	8	10	16	10	10	12	10	0	-4	0
		DAY 15		17APR2003	15	24	6	18	24	0	18	0	-6	0
		DAY 22		22APR2003	20	10	16	14	18	18	14	8	2	0
		DAY 29		29APR2003	27	10	22	14	10	14	12	0	-8	-2
		DAY 29	*	05MAY2003	33	12	18	12	8	10	10	-4	-8	-2
		DAY 36		12MAY2003	40	16	0	0	24	2	4	8	2	4
		DAY 50		20MAY2003	48	14	18	14	18	6	8	4	-12	-6
		DAY 57		03JUN2003	62	14	20	14	18	16	12	4	-4	-2
		FINAL			62	14	20	14	18	16	12	4	-4	-2
	E0020020	DAY 8		19MAY2003	8	6	2	-2	0	2	-4	-6	0	-2
		DAY 8	*	23MAY2003	12	4	-2	-4	4	2	-6	0	4	-2
		FINAL			12	4	-2	-4	4	2	-6	0	4	-2

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0020022	DAY 8	23JUN2003	8	-6	20	-8	-6	4	-18	0	-16	-10
		DAY 15	30JUN2003	15	-6	0	0	-6	-6	-2	0	-6	-2
		DAY 22	07JUL2003	22	-6	2	-4	2	0	6	8	-2	10
		DAY 29	14JUL2003	29	4	-12	-4	4	-8	-6	0	4	-2
		DAY 36	21JUL2003	36	14	-4	-10	10	-4	-10	-4	0	0
		DAY 43	28JUL2003	43	4	-8	-12	4	-10	-14	0	-2	-2
		DAY 50	04AUG2003	50	4	-2	-4	4	-12	-8	0	-10	-4
		DAY 57	11AUG2003	57	0	0	-14	-6	-16	-8	-6	-16	6
		FINAL		57	0	0	-14	-6	-16	-8	-6	-16	6
	E0022001	DAY 8	04NOV2002	8	4	-4	-8	16	-6	-4	12	-2	4
		DAY 15	11NOV2002	15	8	4	-6	8	-8	2	0	-12	8
		DAY 22	18NOV2002	22	16	6	-10	24	0	-6	8	-6	4
		DAY 29	26NOV2002	30	4	26	-8	12	28	2	8	2	10
		DAY 36	02DEC2002	36	4	10	-8	8	12	-8	4	2	0
		DAY 43	09DEC2002	43	4	0	-12	8	-8	-2	4	-8	10
		DAY 50	16DEC2002	50	8	4	-18	12	-2	-4	4	-6	14
		DAY 57	26DEC2002	60	0	14	-16	4	6	-2	4	-8	14
		FINAL		60	0	14	-16	4	6	-2	4	-8	14
	E0022004	DAY 8	04NOV2002	8	2	0	-10	4	-15	2	2	-15	12
		DAY 15	11NOV2002	15	4	10	2	0	1	0	-4	-9	-2
		DAY 22	19NOV2002	23	2	0	0	2	0	6	0	0	6
		DAY 29	26NOV2002	30	6	-10	-10	-2	-17	-7	-8	-7	3
		DAY 36	02DEC2002	36	0	0	-8	0	0	6	0	0	14
		DAY 43	10DEC2002	44	6	0	-12	6	1	-4	0	1	8
		DAY 50	16DEC2002	50	8	0	-18	4	-5	-14	-4	-5	4
		DAY 57	23DEC2002	57	12	-10	-18	12	-5	0	0	5	18
		FINAL		57	12	-10	-18	12	-5	0	0	5	18
	E0022005	DAY 8	15NOV2002	8	-2	-10	-12	-2	-11	-24	0	-1	-12
		DAY 15	22NOV2002	15	-10	-5	-10	-11	-16	-25	-1	-11	-15
		DAY 22	29NOV2002	22	-6	-10	-10	-8	-11	-16	-2	-1	-6
		DAY 29	06DEC2002	29	6	-15	-4	0	-16	-24	-6	-1	-20
		DAY 36	13DEC2002	36	10	-10	-2	2	-16	-22	-8	-6	-20

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022005	DAY 43	20DEC2002	43	0	-10	0	-6	-16	-24	-6	-6	-24
		DAY 50	27DEC2002	50	2	-15	-10	-6	-16	-30	-8	-1	-20
		DAY 57	03JAN2003	57	4	-30	-14	-4	-36	-22	-8	-6	-8
		FINAL		57	4	-30	-14	-4	-36	-22	-8	-6	-8
	E0022015	DAY 8	17DEC2002	8	-12	-8	8	-20	-4	8	-8	4	0
		DAY 15	26DEC2002	17	-12	-12	10	-20	-20	4	-8	-8	-6
		DAY 22	02JAN2003	24	-8	-6	2	-4	-18	10	4	-12	8
		DAY 29	09JAN2003	31	0	-8	8	-12	-16	-8	-12	-8	-16
		DAY 36	16JAN2003	38	-4	-14	2	-16	-8	2	-12	6	0
		DAY 43	23JAN2003	45	4	-16	-2	4	-16	-2	0	0	0
		DAY 50	30JAN2003	52	0	-6	0	0	-10	-12	0	-4	-12
		DAY 57	06FEB2003	59	-4	-10	8	4	-6	10	8	4	2
		FINAL		59	-4	-10	8	4	-6	10	8	4	2
	E0022016	DAY 8	26DEC2002	10	4	-2	-2	8	4	2	4	6	4
		DAY 15	30DEC2002	14	10	-10	-4	6	8	-6	-4	18	-2
		DAY 22	06JAN2003	21	-2	-16	-14	6	2	-14	8	18	0
		DAY 29	13JAN2003	28	16	-2	-4	16	4	-10	0	6	-6
		DAY 36	21JAN2003	36	-4	-32	-12	-10	-20	-18	-6	12	-6
		DAY 43	30JAN2003	45	10	-10	-8	12	2	-6	2	12	2
		DAY 50	06FEB2003	52	16	-4	0	22	2	-2	6	6	-2
		DAY 57	11FEB2003	57	0	-10	0	-8	4	-4	-8	14	-4
		FINAL		57	0	-10	0	-8	4	-4	-8	14	-4
	E0022020	DAY 8	19DEC2002	8	8	8	12	24	12	-4	16	4	-16
		DAY 15	26DEC2002	15	8	8	2	20	14	2	12	6	0
		DAY 22	02JAN2003	22	16	10	6	30	10	0	14	0	-6
		DAY 29	10JAN2003	30	4	-8	0	6	4	-8	2	12	-8
		DAY 36	16JAN2003	36	20	4	-10	42	6	-2	22	2	8
		DAY 43	23JAN2003	43	20	-8	-10	18	4	-4	-2	12	6
		FINAL		43	20	-8	-10	18	4	-4	-2	12	6
	E0022023	DAY 8	02JAN2003	9	-6	-6	0	-4	-2	12	2	4	12
		DAY 15	09JAN2003	16	-6	6	2	-8	0	10	-2	-6	8

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0022023	DAY 22	16JAN2003	23	-18	-20	-2	-8	-12	-2	10	8	0
		DAY 29	23JAN2003	30	-10	-18	-2	0	8	2	10	26	4
		DAY 36	30JAN2003	37	-14	-20	-6	-16	-16	-10	-2	4	-4
		DAY 43	06FEB2003	44	-6	-10	-10	-12	-2	-14	-6	8	-4
		DAY 50	13FEB2003	51	-2	-20	-8	4	-2	8	6	18	16
		DAY 57	20FEB2003	58	-6	-10	8	0	8	0	6	18	-8
		FINAL		58	-6	-10	8	0	8	0	6	18	-8
	E0022029	DAY 8	26FEB2003	8	-3	-18	-8	0	4	0	3	22	8
		DAY 15	03MAR2003	13	-6	-14	-6	6	8	0	12	22	6
		DAY 22	12MAR2003	22	-3	-24	0	0	8	0	3	32	0
		DAY 29	18MAR2003	28	3	-18	-8	-6	8	-4	-9	26	4
		DAY 36	26MAR2003	36	-12	-26	-2	6	0	4	18	26	6
		DAY 43	02APR2003	43	-9	-30	0	0	-20	0	9	10	0
		DAY 50	07APR2003	48	-7	-8	0	-4	6	6	3	14	6
		DAY 57	14APR2003	55	3	-2	6	0	0	8	-3	2	2
		FINAL		55	3	-2	6	0	0	8	-3	2	2
	E0022041	DAY 8	25MAR2003	8	2	2	4	4	-4	2	2	-6	-2
		DAY 15	01APR2003	15	0	-4	-8	-10	4	0	-10	8	8
		DAY 22	08APR2003	22	-4	0	0	-2	8	10	2	8	10
		DAY 29	15APR2003	29	4	-8	-10	10	4	0	6	12	10
		DAY 36	21APR2003	35	2	-4	-2	-1	8	10	-3	12	12
		DAY 43	29APR2003	43	4	2	-8	4	12	2	0	10	10
		DAY 50	06MAY2003	50	5	-6	0	5	4	8	0	10	8
		DAY 57	13MAY2003	57	6	-8	-12	-2	2	4	-8	10	16
		FINAL		57	6	-8	-12	-2	2	4	-8	10	16
	E0022042	DAY 8	19MAR2003	8	-6	-6	0	0	2	-2	6	8	-2
		DAY 15	27MAR2003	16	-7	-10	-12	-14	-6	-6	-7	4	6
		DAY 22	02APR2003	22	-7	0	-2	-14	-6	-10	-7	-6	-8
		DAY 29	10APR2003	30	3	6	-2	0	4	-6	-3	-2	-4
		DAY 36	17APR2003	37	-6	4	-6	-9	14	0	-3	10	6
		DAY 43	24APR2003	44	3	4	0	6	2	-2	3	-2	-2
		DAY 50	01MAY2003	51	-12	2	-6	-9	-4	-4	3	-6	2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0022042	DAY 57		12MAY2003	62	-6	4	0	-6	-2	-2	0	-6	-2
		FINAL			62	-6	4	0	-6	-2	-2	0	-6	-2
	E0022043	DAY 8		26MAR2003	7	0	-10	-10	15	2	4	15	12	14
		DAY 15		03APR2003	15	6	-2	-4	15	4	2	9	6	6
		DAY 22		10APR2003	22	-3	2	-8	0	8	0	3	6	8
		DAY 29		17APR2003	29	3	8	-4	9	12	10	6	4	14
		DAY 36		24APR2003	36	6	2	-6	9	4	2	3	2	8
		DAY 43		01MAY2003	43	3	0	-10	6	12	10	3	12	20
		DAY 50		08MAY2003	50	3	2	-8	18	6	6	15	4	14
		DAY 50	*	12MAY2003	54	0	-4	-10	0	12	8	0	16	18
		FINAL			54	0	-4	-10	0	12	8	0	16	18
	E0022054	DAY 8		18APR2003	8	2	8	0	2	12	8	0	4	8
		DAY 15		28APR2003	18	4	8	-2	2	10	12	-2	2	14
		DAY 22		02MAY2003	22	18	10	-8	14	8	0	-4	-2	8
		DAY 29		12MAY2003	32	6	18	6	2	16	16	-4	-2	10
		DAY 36		16MAY2003	36	8	0	4	-6	12	12	-14	12	8
		FINAL			36	8	0	4	-6	12	12	-14	12	8
	E0022059	DAY 8		13MAY2003	8	0	-8	2	0	8	6	0	16	4
		DAY 15		20MAY2003	15	8	-6	-6	-2	-2	-4	-10	4	2
		DAY 22		27MAY2003	22	-8	-6	4	-20	-2	0	-12	4	-4
		DAY 29		03JUN2003	29	6	-2	-2	3	16	4	-3	18	6
		DAY 36		10JUN2003	36	-8	-10	2	0	0	-2	8	10	-4
		DAY 43		17JUN2003	43	4	-10	-10	-8	-4	-6	-12	6	4
		DAY 43	*	20JUN2003	46	4	-4	-14	-4	2	-8	-8	6	6
		DAY 57		08JUL2003	64	-8	-6	4	-16	-2	-4	-8	4	-8
		FINAL			64	-8	-6	4	-16	-2	-4	-8	4	-8
	E0022065	DAY 8		14MAY2003	8	4	12	0	5	-2	0	1	-14	0
		DAY 15		21MAY2003	15	-8	2	0	-7	-4	-6	1	-6	-6
		DAY 22		28MAY2003	22	0	-2	-2	-3	-2	-8	-3	0	-6
		DAY 29		04JUN2003	29	3	-2	-2	3	-8	-14	0	-6	-12
		DAY 36		11JUN2003	36	-8	10	10	-23	-4	-8	-15	-14	-18

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0022065	DAY 43		18JUN2003	43	9	10	-2	3	2	-8	-6	-8	-6
		DAY 50		25JUN2003	50	-3	4	-4	-9	10	-6	-6	6	-2
		DAY 57		02JUL2003	57	-8	16	0	-19	12	-10	-11	-4	-10
		FINAL			57	-8	16	0	-19	12	-10	-11	-4	-10
	E0022070	DAY 8		18JUN2003	7	-8	14	16	-16	10	8	-8	-4	-8
		FINAL			7	-8	14	16	-16	10	8	-8	-4	-8
	E0023001	DAY 8		22NOV2002	8	0	-4	-6	4	-26	-4	4	-22	2
		DAY 15		29NOV2002	15	60	-26	-10	36	-21	-13	-24	5	-3
		DAY 22		06DEC2002	22	4	0	8	24	-18	4	20	-18	-4
		DAY 29		16DEC2002	32	12	-18	-2	2	-26	-4	-10	-8	-2
		DAY 36		23DEC2002	39	5	-4	-12	7	8	13	2	12	25
		DAY 43		30DEC2002	46	15	3	5	10			-5		
		DAY 50		07JAN2003	54	4	2	8	8	-8	-4	4	-10	-12
		DAY 57		14JAN2003	61	10	-8	8	8	-14	0	-2	-6	-8
		FINAL			61	10	-8	8	8	-14	0	-2	-6	-8
	E0023009	DAY 8		18FEB2003	8	-6	-6	2	-16	5	-4	-10	11	-6
		DAY 15		27FEB2003	17	-10	0	0	-16	7	-6	-6	7	-6
		DAY 22		04MAR2003	22	-1	-25	-4	-4	2	1	-3	27	5
		DAY 29		11MAR2003	29	-6	-6	-2	-20	-7	-10	-14	-1	-8
		DAY 36		18MAR2003	36	-6	-15	-6	-3	2	1	3	17	7
		DAY 43		25MAR2003	43	1	-29	-3	6	6	-2	5	35	1
		DAY 50		03APR2003	52	0	-16	-8	-3	-8	1	-3	8	9
		DAY 57		08APR2003	57	6	-25	-4	-6	-20	-10	-12	5	-6
		FINAL			57	6	-25	-4	-6	-20	-10	-12	5	-6
	E0023028	DAY 8		05JUN2003	8	7	14	0	9	-21	-9	2	-35	-9
		DAY 15		12JUN2003	15	-3	-4	-8	-8	-12	-9	-5	-8	-1
		DAY 22		19JUN2003	22	3	-7	-9	-7	-8	-8	-10	-1	1
		DAY 29		25JUN2003	28	28	-1	-5	5	-1	0	-23	0	5
		DAY 43		09JUL2003	42	16	-8	-9	5	-6	-5	-11	2	4
		DAY 50		16JUL2003	49	17	-7	-14	6	-4	-3	-11	3	11
		DAY 50	*	21JUL2003	54	12	19	8	-3	14	10	-15	-5	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0023028	FINAL		54	12	19	8	-3	14	10	-15	-5	2
	E0023033	DAY 8	12JUN2003	8	8	14	3	-7	26	14	-15	12	11
		FINAL		8	8	14	3	-7	26	14	-15	12	11
	E0023047	DAY 8	25JUL2003	8	6	-11	7	-13	23	-15	-19	34	-22
		DAY 15	31JUL2003	14	0	-13	10	-13	5	-3	-13	18	-13
		DAY 22	08AUG2003	22	24	9	34	-2	31	11	-26	22	-23
		DAY 29	15AUG2003	29	8	13	21	-17	28	2	-25	15	-19
		DAY 36	21AUG2003	35	17	1	24	8	22	-4	-9	21	-28
		DAY 43	29AUG2003	43	62	-7	17	15	1	-12	-47	8	-29
		DAY 50	05SEP2003	50	24	-1	21	3	1	-7	-21	2	-28
		DAY 57	12SEP2003	57	19	8	22	31	-2	-3	12	-10	-25
		FINAL		57	19	8	22	31	-2	-3	12	-10	-25
	E0025001	DAY 8	10APR2003	10	-16	-1	-8	4	0	-10	20	1	-2
		DAY 15	16APR2003	16	-8	-26	-26	0	-18	-20	8	8	6
		DAY 22	23APR2003	23	-4	-6	-10	4	-10	-20	8	-4	-10
		FINAL		23	-4	-6	-10	4	-10	-20	8	-4	-10
	E0026012	DAY 8	27FEB2003	8	8	-10	-12	8	-12	5	0	-2	17
		DAY 15	06MAR2003	15	-4	-10	-15	-12	-10	10	-8	0	25
		DAY 22	13MAR2003	22	5	13	-6	9	8	4	4	-5	10
		DAY 29	20MAR2003	29	5	-10	-7	10	-12	11	5	-2	18
		DAY 36	27MAR2003	36	9	-7	-3	7	-13	7	-2	-6	10
		DAY 43	03APR2003	43	9	7	-14	9	-8	-10	0	-15	4
		DAY 50	10APR2003	50	6	-5	-6	12	-24	2	6	-19	8
		DAY 57	17APR2003	57	5	-17	-15	2	-25	2	-3	-8	17
		FINAL		57	5	-17	-15	2	-25	2	-3	-8	17
	E0026020	DAY 8	08APR2003	8	13	-1	-9	18	0	-2	5	1	7
		DAY 15	15APR2003	15	-1	21	-2	0	15	0	1	-6	2
		DAY 22	22APR2003	22	-4	44	-5	6	-21	11	10	-65	16
		FINAL		22	-4	44	-5	6	-21	11	10	-65	16

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0026024	DAY 8		09MAY2003	8	-12	3	-4	-7	-1	0	5	-4	4
		DAY 15		16MAY2003	15	-13	4	-6	-10	8	-1	3	4	5
		DAY 22		23MAY2003	22	-14	-9	-7	-9	8	5	5	17	12
		DAY 29		30MAY2003	29	-11	-8	-2	-3	-11	6	8	-3	8
		FINAL			29	-11	-8	-2	-3	-11	6	8	-3	8
	E0026028	DAY 8		27JUN2003	8	4	2	-4	10	6	-9	6	4	-5
		DAY 15		02JUL2003	13	-14	-4	-10	-10	0	-10	4	4	0
		DAY 15	*	08JUL2003	19	4	-17	3	6	1	0	2	18	-3
		DAY 36		23JUL2003	34	5	7	6	-3	-4	2	-8	-11	-4
		FINAL			34	5	7	6	-3	-4	2	-8	-11	-4
	E0028001	DAY 8		16OCT2002	7	-4	2	2	-1	8	8	3	6	6
		DAY 15		23OCT2002	14	-2	8	2	9	18	8	11	10	6
		DAY 22		29OCT2002	20	-4	0	-8	-1	0	8	3	0	16
		DAY 29		05NOV2002	27	0	2	14	15	18	28	15	16	14
		DAY 36		12NOV2002	34	-4	-6	0	5	4	6	9	10	6
		DAY 43		19NOV2002	41	4	6	6	11	28	22	7	22	16
		DAY 50		26NOV2002	48	8	-8	4	19	-4	16	11	4	12
		DAY 57		03DEC2002	55	16	10	10	21	-6	14	5	-16	4
		FINAL			55	16	10	10	21	-6	14	5	-16	4
	E0028003	DAY 8		07OCT2002	8	13	0	0	12	-2	0	-1	-2	0
		DAY 15		16OCT2002	17	12	8	10	7	12	10	-5	4	0
		DAY 22		22OCT2002	23	6	8	10	14	0	0	8	-8	-10
		DAY 29		29OCT2002	30	0	12	-2	8	18	-2	8	6	0
		DAY 36		07NOV2002	39	4	20	6	10	22	8	6	2	2
		DAY 43		12NOV2002	44	6	8	0	4	8	0	-2	0	0
		DAY 50		19NOV2002	51	6	8	12	12	-8	4	6	-16	-8
		DAY 57		26NOV2002	58	12	10	2	8	14	-4	-4	4	-6
		FINAL			58	12	10	2	8	14	-4	-4	4	-6
	E0028005	DAY 8		11OCT2002	9	-7	8	10	0	2	0	7	-6	-10
		DAY 29		31OCT2002	29	-10	8	2	-6	-2	-2	4	-10	-4
		FINAL			29	-10	8	2	-6	-2	-2	4	-10	-4

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028010	DAY 8	12NOV2002	8	-10	-2	10	-8	-8	2	2	-6	-8
		DAY 15	19NOV2002	15	4	8	8	8	-20	2	4	-28	-6
		DAY 22	25NOV2002	21	0	0	-2	10	-6	16	10	-6	18
		DAY 29	03DEC2002	29	-2	10	8	10	10	0	12	0	-8
		DAY 36	10DEC2002	36	-6	6	4	6	-14	0	12	-20	-4
		DAY 43	17DEC2002	43	4	10	0	2	10	4	-2	0	4
		DAY 50	23DEC2002	49	6	-6	0	14	-16	2	8	-10	2
		DAY 57	31DEC2002	57	-10	14	8	-6	-6	-2	4	-20	-10
		FINAL		57	-10	14	8	-6	-6	-2	4	-20	-10
	E0028011	DAY 8	12DEC2002	8	2	0	8	-2	-6	10	-4	-6	2
		DAY 15	19DEC2002	15	-4	-26	-8	-12	-10	0	-8	16	8
		DAY 22	26DEC2002	22	-2	-14	10	-10	-10	10	-8	4	0
		DAY 29	02JAN2003	29	0	-8	4	-8	-10	-2	-8	-2	-6
		DAY 36	09JAN2003	36	6	-20	10	-4	-16	10	-10	4	0
		DAY 43	16JAN2003	43	-6	-6	2	-2	-8	10	4	-2	8
		DAY 50	23JAN2003	50	4	-18	8	6	-4	18	2	14	10
		DAY 57	30JAN2003	57	10	-4	-2	10	0	4	0	4	6
		FINAL		57	10	-4	-2	10	0	4	0	4	6
	E0028030	DAY 8	11MAR2003	8	18	-18	-8	-6	-8	2	-24	10	10
		DAY 15	18MAR2003	15	24	0	-10	12	-2	-14	-12	-2	-4
		DAY 22	25MAR2003	22	28	-2	-6	4	-2	-14	-24	0	-8
		DAY 29	01APR2003	29	12	-6	-14	16	-8	-18	4	-2	-4
		DAY 36	08APR2003	36	8	2	-10	4	-8	-20	-4	-10	-10
		DAY 43	17APR2003	45	16	4	-14	12	-14	-20	-4	-18	-6
		DAY 50	22APR2003	50	4	2	-22	8	-4	-24	4	-6	-2
		DAY 57	30APR2003	58	14	-8	-8	-6	-4	-6	-20	4	2
		FINAL		58	14	-8	-8	-6	-4	-6	-20	4	2
	E0028031	DAY 8	18MAR2003	8	4	-4	10	8	0	2	4	4	-8
		DAY 15	25MAR2003	15	8	8	8	8	24	12	0	16	4
		DAY 36	17APR2003	38	12	8	2	12	16	0	0	8	-2
		FINAL		38	12	8	2	12	16	0	0	8	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028047	DAY 8	21JUL2003	8	4	10	0	12	10	15	8	0	15
		DAY 15	29JUL2003	16	2	18	0	18	30	8	16	12	8
		DAY 22	05AUG2003	23	-2	10	-6	2	32	10	4	22	16
		DAY 29	12AUG2003	30	-3	38	1	0	38	12	3	0	11
		DAY 36	19AUG2003	37	-2	30	10	18	30	10	20	0	0
		DAY 43	26AUG2003	44	-4	10	0	0	10	0	4	0	0
		DAY 50	02SEP2003	51	-2	20	10	2	18	10	4	-2	0
		DAY 57	09SEP2003	58	6	32	8	6	14	0	0	-18	-8
		FINAL		58	6	32	8	6	14	0	0	-18	-8
	E0029001	DAY 8	09OCT2002	9	-4	16	8	6	18	8	10	2	0
		FINAL		9	-4	16	8	6	18	8	10	2	0
	E0029014	DAY 8	11FEB2003	8	0	24	20	0	0	26	0	-24	6
		DAY 15	18FEB2003	15	4	14	4	-4	-6	12	-8	-20	8
		DAY 22	25FEB2003	22	8	28	4	-8	18	14	-16	-10	10
		DAY 29	06MAR2003	31	16	6	-2	4	4	14	-12	-2	16
		DAY 36	11MAR2003	36	8	36	16	4	34	34	-4	-2	18
		DAY 43	20MAR2003	45	12	48	16	12	22	24	0	-26	8
		DAY 50	27MAR2003	52	12	30	8	8	10	20	-4	-20	12
		DAY 57	01APR2003	57	-4	24	10	-12	8	14	-8	-16	4
		FINAL		57	-4	24	10	-12	8	14	-8	-16	4
	E0029023	DAY 8	15APR2003	8	-12	6	0	-8	10	6	4	4	6
		DAY 15	22APR2003	15	-12	0	-2	-12	4	-2	0	4	0
		DAY 22	01MAY2003	24	-4	6	4	-4	8	8	0	2	4
		DAY 36	12MAY2003	35	-4	0	-2	-4	4	-2	0	4	0
		DAY 43	20MAY2003	43	0	8	8	0	8	10	0	0	2
		DAY 50	29MAY2003	52	-4	4	6	-4	10	4	0	6	-2
		DAY 57	10JUN2003	64	-8	-2	2	-8	2	2	0	4	0
		FINAL		64	-8	-2	2	-8	2	2	0	4	0
	E0029032	DAY 8	17JUN2003	8	0	0	0	0	12	0	0	12	0
		DAY 22	01JUL2003	22	4	0	0	8	-3	0	4	-3	0
		FINAL		22	4	0	0	8	-3	0	4	-3	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0029033	DAY 8		09JUN2003	8	4	10	-2	4	26	-2	0	16	0
		DAY 15		16JUN2003	15	0	14	0	4	-4	-4	4	-18	-4
		DAY 22		23JUN2003	22	4	0	-2	4	-8	0	0	-8	2
		DAY 29		30JUN2003	29	4	14	0	-4	18	0	-8	4	0
		FINAL			29	4	14	0	-4	18	0	-8	4	0
	E0029039	DAY 8		23JUL2003	9	8	0	6	0	0	10	-8	0	4
		DAY 15		28JUL2003	14	32	-2	-4	20	2	-2	-12	4	2
		FINAL			14	32	-2	-4	20	2	-2	-12	4	2
	E0030003	DAY 8		23DEC2002	8	-8	0	-8	-20	8	0	-12	8	8
		DAY 8	*	24DEC2002	9	-8	-10	-8	-8	4	4	0	14	12
		FINAL			9	-8	-10	-8	-8	4	4	0	14	12
	E0030009	DAY 8		29JAN2003	7	-4	-18	-12	8	2	-14	12	20	-2
		DAY 15		07FEB2003	16	-8	-18	-18	-4	-6	-18	4	12	0
		DAY 36		27FEB2003	36	0	-22	-16	0	-8	-14	0	14	2
		DAY 43		06MAR2003	43	4	-18	-10	12	0	-14	8	18	-4
		DAY 50		12MAR2003	49	4	-10	-10	12	-2	-14	8	8	-4
		DAY 57		19MAR2003	56	0	-4	-10	8	-12	-14	8	-8	-4
		FINAL			56	0	-4	-10	8	-12	-14	8	-8	-4
	E0030016	DAY 8		10MAR2003	8	8	-2	2	12	6	8	4	8	6
		DAY 15		17MAR2003	15	8	4	2	12	4	4	4	0	2
		DAY 22		25MAR2003	23	4	-2	0	20	8	0	16	10	0
		DAY 29		02APR2003	31	12	12	2	12	8	4	0	-4	2
		DAY 36		09APR2003	38	16	-6	2	20	0	6	4	6	4
		DAY 50		22APR2003	51	8	2	-2	12	8	4	4	6	6
		FINAL			51	8	2	-2	12	8	4	4	6	6
	E0030021	DAY 8		27MAY2003	8	0	-2	4	0	-2	2	0	0	-2
		DAY 15		03JUN2003	15	-8	32	10	0	22	0	8	-10	-10
		DAY 22		10JUN2003	22	0	31	6	-10	26	1	-10	-5	-5
		DAY 29		17JUN2003	29	-8	11	6	0	6	0	8	-5	-6
		FINAL			29	-8	11	6	0	6	0	8	-5	-6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0031001	DAY 8	27NOV2002	7	-10	0	-12	-12	-2	-10	-2	-2	2
		DAY 15	05DEC2002	15	-4	2	-6	0	2	-10	4	0	-4
		DAY 22	11DEC2002	21	-2	2	0	-16	2	-2	-14	0	-2
		DAY 29	20DEC2002	30	-6	-6	-16	-10	-12	-18	-4	-6	-2
		FINAL		30	-6	-6	-16	-10	-12	-18	-4	-6	-2
	E0031017	DAY 8	07APR2003	7	1	2	0	-10	2	0	-11	0	0
		DAY 15	15APR2003	15	19	5	-4	8	4	0	-11	-1	4
		DAY 22	22APR2003	22	1	-4	-2	-10	-2	0	-11	2	2
		DAY 29	29APR2003	29	1	2	0	-4	0	2	-5	-2	2
		FINAL		29	1	2	0	-4	0	2	-5	-2	2
	E0031018	DAY 8	17APR2003	8	-8	2	-2	-8	2	-2	0	0	0
		DAY 15	24APR2003	15	0	10	6	-10	10	-6	-10	0	-12
		FINAL		15	0	10	6	-10	10	-6	-10	0	-12
	E0031023	DAY 8	07MAY2003	9	6	0	-2	0	2	-2	-6	2	0
		DAY 15	13MAY2003	15	10	2	0	10	4	2	0	2	2
		DAY 22	20MAY2003	22	12	4	-2	10	4	0	-2	0	2
		DAY 29	27MAY2003	29	6	2	2	8	6	4	2	4	2
		DAY 36	04JUN2003	37	22	-10	8	22	-2	6	0	8	-2
		DAY 43	10JUN2003	43	-2	-6	2	8	-2	6	10	4	4
		DAY 50	17JUN2003	50	0	-4	2	-2	-2	6	-2	2	4
		DAY 57	24JUN2003	57	4	0	-4	8	2	4	4	2	8
		FINAL		57	4	0	-4	8	2	4	4	2	8
	E0033001	DAY 8	16JAN2003	8	-16	-16	-2	-10	-12	8	6	4	10
		DAY 15	23JAN2003	15	-12	0	6	-10	-4	10	2	-4	4
		DAY 22	30JAN2003	22	-16	-10	8	-10	0	6	6	10	-2
		FINAL		22	-16	-10	8	-10	0	6	6	10	-2
	E0033004	DAY 8	24JAN2003	8	4	10	6	-4	-4	2	-8	-14	-4
		DAY 15	31JAN2003	15	12	10	4	4	10	2	-8	0	-2
		DAY 22	07FEB2003	22	0	2	-8	4	6	6	4	4	14
		DAY 29	14FEB2003	29	-12	0	0	-4	-4	6	8	-4	6

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0033004	DAY 36	21FEB2003	36	-4	14	6	-12	6	10	-8	-8	4
		DAY 43	28FEB2003	43	-4	0	0	4	-12	0	8	-12	0
		DAY 50	07MAR2003	50	8	0	0	12	6	10	4	6	10
		DAY 57	14MAR2003	57	0	2	0	0	6	8	0	4	8
		FINAL		57	0	2	0	0	6	8	0	4	8
	E0033010	DAY 8	11FEB2003	8	0	2	12	4	14	14	4	12	2
		DAY 15	20FEB2003	17	0	-6	2	8	4	8	8	10	6
		DAY 22	27FEB2003	24	-8	-10	0	-8	-6	6	0	4	6
		DAY 29	04MAR2003	29	-12	0	6	-4	4	14	8	4	8
		DAY 36	14MAR2003	39	0	-8	0	-4	12	8	-4	20	8
		DAY 50	26MAR2003	51	-16	-10	-8	-4	-6	6	12	4	14
		FINAL		51	-16	-10	-8	-4	-6	6	12	4	14
	E0033014	DAY 8	26MAR2003	8	-4	-10	-10	8	-10	-6	12	0	4
		DAY 15	03APR2003	16	0	-20	-14	8	0	-2	8	20	12
		DAY 22	11APR2003	24	4	0	-4	8	-2	-4	4	-2	0
		DAY 29	16APR2003	29	-12	-6	-4	0	0	4	12	6	8
		DAY 36	21APR2003	34	-12	-20	-12	-8	0	-2	4	20	10
		FINAL		34	-12	-20	-12	-8	0	-2	4	20	10
	E0035002	DAY 8	27NOV2002	7	18	-4	-14	12	-6	-2	-6	-2	12
		DAY 15	05DEC2002	15	-2	-8	-16	-4	-2	-10	-2	6	6
		DAY 22	12DEC2002	22	6	-2	-22	-2	-2	-8	-8	0	14
		FINAL		22	6	-2	-22	-2	-2	-8	-8	0	14
	E0035007	DAY 8	26DEC2002	8	4	-6	0	2	-4	0	-2	2	0
		DAY 15	02JAN2003	15	0	-8	2	-2	-8	0	-2	0	-2
		DAY 22	09JAN2003	22	2	-6	-2	0	-6	-10	-2	0	-8
		DAY 29	17JAN2003	30	2	-4	0	2	-6	-8	0	-2	-8
		DAY 36	23JAN2003	36	6	-6	2	2	-4	4	-4	2	2
		DAY 43	30JAN2003	43	-8	-6	-4	-2	-4	-2	6	2	2
		DAY 50	06FEB2003	50	0	-6	-2	-2	-6	-4	-2	0	-2
		DAY 57	11FEB2003	55	6	-6	0	4	-4	2	-2	2	2
		FINAL		55	6	-6	0	4	-4	2	-2	2	2

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0035011	DAY 8	11FEB2003	8	0	0	-4	0	0	-2	0	0	2
		DAY 15	18FEB2003	15	-2	0	-10	0	2	-4	2	2	6
		DAY 22	25FEB2003	22	0	-4	-6	0	-4	-6	0	0	0
		DAY 29	04MAR2003	29	-2	-6	-12	0	-4	-6	2	2	6
		DAY 36	11MAR2003	36	-14	8	-8	-16	10	-2	-2	2	6
		DAY 43	18MAR2003	43	-6	8	-10	-10	8	-6	-4	0	4
		DAY 50	25MAR2003	50	-6	0	-14	-8	2	-8	-2	2	6
		DAY 57	01APR2003	57	-2	4	-10	-6	4	-4	-4	0	6
		FINAL		57	-2	4	-10	-6	4	-4	-4	0	6
	E0035020	DAY 8	25APR2003	8	8	-4	-10	10	-2	-8	2	2	2
		DAY 15	01MAY2003	14	12	-2	-8	16	2	-8	4	4	0
		DAY 22	09MAY2003	22	14	0	-2	12	0	2	-2	0	4
		DAY 29	15MAY2003	28	14	0	-8	14	-2	2	0	-2	10
		DAY 36	23MAY2003	36	12	-2	-4	16	0	-4	4	2	0
		DAY 43	30MAY2003	43	16	-2	2	20	-2	0	4	0	-2
		DAY 50	06JUN2003	50	12	2	-2	12	4	-2	0	2	0
		DAY 57	13JUN2003	57	6	0	4	6	0	4	0	0	0
		FINAL		57	6	0	4	6	0	4	0	0	0
	E0037003	DAY 8	06FEB2003	8	0	2	-4	0	4	4	0	2	8
		DAY 15	13FEB2003	15	-2	6	0	-2	6	0	0	0	0
		DAY 22	20FEB2003	22	-4	4	0	-4	8	2	0	4	2
		FINAL		22	-4	4	0	-4	8	2	0	4	2
	E0037004	DAY 8	21FEB2003	9	-8	-1	9	8	-9	14	16	-8	5
		DAY 15	27FEB2003	15	8	-25	6	8	-8	9	0	17	3
		DAY 22	06MAR2003	22	4	-16	-6	8	-16	-6	4	0	0
		DAY 29	13MAR2003	29	-2	-10	6	10	-8	14	12	2	8
		DAY 36	20MAR2003	36	4	-8	6	28	-8	-6	24	0	-12
		DAY 43	28MAR2003	44	-8	-8	4	12	-8	4	20	0	0
		DAY 50	04APR2003	51	-4	-8	6	12	-11	4	16	-3	-2
		DAY 57	10APR2003	57	0	-8	16	4	-8	14	4	0	-2
		FINAL		57	0	-8	16	4	-8	14	4	0	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039007	DAY 8	11DEC2002	8	4	6	0	8	-4	8	4	-10	8
		DAY 15	18DEC2002	15	16	-8	-8	0	-16	2	-16	-8	10
		DAY 22	23DEC2002	20	4	-4	0	8	-10	4	4	-6	4
		DAY 29	30DEC2002	27	-4	-12	-2	-12	-10	4	-8	2	6
		DAY 36	08JAN2003	36	4	-10	-4	-8	-2	10	-12	8	14
		DAY 43	15JAN2003	43	4	-16	-8	0	-8	2	-4	8	10
		DAY 50	22JAN2003	50	4	-18	-8	-2	-18	0	-6	0	8
		DAY 57	29JAN2003	57	-4	-10	-6	-4	-4	4	0	6	10
		FINAL		57	-4	-10	-6	-4	-4	4	0	6	10
	E0039022	DAY 8	06MAR2003	10	8	-16	-10	6	-30	-8	-2	-14	2
		DAY 15	11MAR2003	15	12	-10	-2	12	-16	0	0	-6	2
		DAY 22	18MAR2003	22	16	-2	-2	14	-8	2	-2	-6	4
		DAY 29	25MAR2003	29	20	-18	-20	12	-16	-6	-8	2	14
		DAY 36	01APR2003	36	12	-8	-12	6	-10	2	-6	-2	14
		DAY 43	07APR2003	42	4	-14	-4	-5	-16	0	-9	-2	4
		DAY 50	15APR2003	50	4	-26	-12	0	-24	-16	-4	2	-4
		DAY 57	24APR2003	59	-4	-22	-14	-4	-30	-16	0	-8	-2
		FINAL		59	-4	-22	-14	-4	-30	-16	0	-8	-2
	E0039023	DAY 8	03MAR2003	8	-1	-2	4	0	2	0	1	4	-4
		FINAL		8	-1	-2	4	0	2	0	1	4	-4
	E0039030	DAY 8	31MAR2003	8	2	-6	6	9	8	2	7	14	-4
		DAY 15	07APR2003	15	2	-8	-16	3	2	-2	1	10	14
		DAY 22	14APR2003	22	4	-4	10	9	10	14	5	14	4
		DAY 29	21APR2003	29	0	-12	-2	1	-14	-2	1	-2	0
		DAY 36	28APR2003	36	6	0	16	1	2	6	-5	2	-10
		DAY 43	05MAY2003	43	-2	4	14	-5	12	10	-3	8	-4
		DAY 50	13MAY2003	51	2	4	2	9	6	4	7	2	2
		DAY 57	19MAY2003	57	-2	14	6	5	12	4	7	-2	-2
		FINAL		57	-2	14	6	5	12	4	7	-2	-2
	E0039031	DAY 8	31MAR2003	8	14	6	0	24	0	8	10	-6	8
		DAY 15	07APR2003	15	18	2	-10	14	4	-4	-4	2	6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039031	DAY 22	15APR2003	23	8	4	-10	8	18	16	0	14	26
		DAY 29	21APR2003	29	8	6	0	8	12	16	0	6	16
		DAY 36	28APR2003	36	18	6	4	8	14	16	-10	8	12
		DAY 43	05MAY2003	43	16	6	0	20	14	16	4	8	16
		DAY 50	13MAY2003	51	14	12	0	16	20	14	2	8	14
		DAY 57	20MAY2003	58	-2	8	-4	4	14	10	6	6	14
		FINAL		58	-2	8	-4	4	14	10	6	6	14
	E0039037	DAY 8	23APR2003	8	4	6	-6	16	14	2	12	8	8
		DAY 15	01MAY2003	16	0	2	-2	16	2	10	16	0	12
		DAY 22	07MAY2003	22	-12	-22	0	-8	-20	-2	4	2	-2
		DAY 29	15MAY2003	30	4	-4	10	16	-6	12	12	-2	2
		DAY 36	21MAY2003	36	-4	2	2	8	8	10	12	6	8
		DAY 43	28MAY2003	43	-12	-6	-2	-6	-2	-4	6	4	-2
		DAY 50	05JUN2003	51	12	0	-8	16	2	0	4	2	8
		DAY 57	12JUN2003	58	-8	2	10	2	10	14	10	8	4
		FINAL		58	-8	2	10	2	10	14	10	8	4
	E0039038	DAY 8	30APR2003	8	12	0	6	14	0	8	2	0	2
		DAY 22	15MAY2003	23	12	-10	-8	12	-10	-14	0	0	-6
		DAY 29	21MAY2003	29	16	-6	-12	16	-4	-4	0	2	8
		DAY 36	29MAY2003	37	16	20	16	24	-2	6	8	-22	-10
		DAY 57	20JUN2003	59	8	-6	-4	12	-4	-2	4	2	2
		FINAL		59	8	-6	-4	12	-4	-2	4	2	2
	E0039047	DAY 8	27MAY2003	9	6	14	-2	4	2	-10	-2	-12	-8
		DAY 15	03JUN2003	16	-7	8	8	-8	0	8	-1	-8	0
		DAY 22	09JUN2003	22	-6	10	2	-4	2	2	2	-8	0
		DAY 29	16JUN2003	29	10	-8	-28	-6	2	-2	-16	10	26
		DAY 36	23JUN2003	36	-8	-10	-2	-12	2	0	-4	12	2
		DAY 43	30JUN2003	43	-6	-4	-2	-10	-12	-6	-4	-8	-4
		DAY 50	07JUL2003	50	-5	0	0	-4	0	6	1	0	6
		DAY 57	14JUL2003	57	6	8	-2	-16	-2	0	-22	-10	2
		FINAL		57	6	8	-2	-16	-2	0	-22	-10	2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039059	DAY 8	18JUL2003	8	16	6	0	12	2	-8	-4	-4	-8
		DAY 15	25JUL2003	15	13	2	2	6	-8	2	-7	-10	0
		DAY 22	01AUG2003	22	0	4	22	2	-18	2	2	-22	-20
		DAY 29	07AUG2003	28	0	-8	-8	0	-14	-8	0	-6	0
		DAY 36	15AUG2003	36	0	6	10	1	-16	2	1	-22	-8
		DAY 43	21AUG2003	42	4	8	12	-4	-2	0	-8	-10	-12
		DAY 50	29AUG2003	50	0	0	-8	4	-4	-18	4	-4	-10
		DAY 57	05SEP2003	57	-4	-4	2	-8	-6	-4	-4	-2	-6
		FINAL		57	-4	-4	2	-8	-6	-4	-4	-2	-6
	E0041007	DAY 8	20MAR2003	8	-1	-10	0	-8	0	-8	-7	10	-8
		DAY 15	27MAR2003	15	2	0	10	0	0	2	-2	0	-8
		DAY 22	03APR2003	22	-10	-20	0	-16	-20	-8	-6	0	-8
		DAY 29	10APR2003	29	-18	-18	10	-22	-30	-8	-4	-12	-18
		DAY 36	17APR2003	36	-12	-10	22	-8	-24	6	4	-14	-16
		DAY 43	25APR2003	44	-4	-20	18	-8	-28	0	-4	-8	-18
		DAY 50	01MAY2003	50	-14	-13	16	-18	-22	2	-4	-9	-14
		DAY 57	08MAY2003	57	-8	-16	16	-8	-20	0	0	-4	-16
		FINAL		57	-8	-16	16	-8	-20	0	0	-4	-16
	E0041010	DAY 8	08MAY2003	9	0	2	2	2	-2	0	2	-4	-2
		DAY 15	14MAY2003	15	0	2	2	-2	-2	0	-2	-4	-2
		DAY 22	21MAY2003	22	0	2	2	0	-2	2	0	-4	0
		DAY 29	28MAY2003	29	-2	4	8	2	8	4	4	4	-4
		DAY 36	04JUN2003	36	-4	12	10	0	6	6	4	-6	-4
		DAY 43	11JUN2003	43	-8	10	4	-2	8	2	6	-2	-2
		FINAL		43	-8	10	4	-2	8	2	6	-2	-2
	E0041011	DAY 8	02JUN2003	12	0	2	0	0	-2	-2	0	-4	-2
		DAY 15	06JUN2003	16	2	4	4	-4	-2	-2	-6	-6	-6
		DAY 22	16JUN2003	26	0	2	2	-4	-2	-4	-4	-4	-6
		DAY 29	20JUN2003	30	2	-2	4	-2	-6	-2	-4	-4	-6
		DAY 36	26JUN2003	36	0	-2	2	-2	-6	0	-2	-4	-2
		DAY 43	03JUL2003	43	-4	-4	4	-6	-6	-2	-2	-2	-6
		DAY 50	10JUL2003	50	0	-2	6	-2	-6	4	-2	-4	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0041011	DAY 57	17JUL2003	57	12	-8	0	12	-10	-8	0	-2	-8
		FINAL		57	12	-8	0	12	-10	-8	0	-2	-8
	E0041012	DAY 8	26JUN2003	8	6	-2	-2	4	-8	-20	-2	-6	-18
		DAY 15	03JUL2003	15	4	-2	-4	0	-8	-22	-4	-6	-18
		DAY 22	10JUL2003	22	-2	-10	-10	-2	-14	-32	0	-4	-22
		DAY 29	17JUL2003	29	0	-12	-10	-2	-20	-30	-2	-8	-20
		DAY 36	24JUL2003	36	2	-18	2	-2	-26	-24	-4	-8	-26
		DAY 43	31JUL2003	43	6	-16	-2	0	-24	-26	-6	-8	-24
		DAY 50	07AUG2003	50	-4	2	4	-10	-6	-20	-6	-8	-24
		DAY 57	14AUG2003	57	-6	10	20	-8	-6	2	-2	-16	-18
		FINAL		57	-6	10	20	-8	-6	2	-2	-16	-18
PLACEBO (BIPOLAR II)	E0001004	DAY 8	09MAY2003	9	0	25	0	-3	20	5	-3	-5	5
		DAY 15	16MAY2003	16	2	25	0	0	25	5	-2	0	5
		DAY 22	23MAY2003	23	0	15	-5	-3	10	0	-3	-5	5
		DAY 29	29MAY2003	29	2	25	5	-2	20	10	-4	-5	5
		DAY 36	06JUN2003	37	2	15	0	-2	15	5	-4	0	5
		DAY 43	12JUN2003	43	20	15	0	15	0	0	-5	-15	0
		DAY 50	20JUN2003	51	2	15	10	-1	15	10	-3	0	0
		DAY 57	02JUL2003	63	22	3	0	17	-2	0	-5	-5	0
		FINAL		63	22	3	0	17	-2	0	-5	-5	0
	E0005023	DAY 8	13FEB2003	9	8	0	-6	8	-4	-14	0	-4	-8
		DAY 15	20FEB2003	16	24	4	-6	28	-4	-12	4	-8	-6
		DAY 22	27FEB2003	23	0	0	0	0	-4	-10	0	-4	-10
		DAY 29	06MAR2003	30	0	0	0	0	-4	-4	0	-4	-4
		DAY 36	13MAR2003	37	8	0	0	8	-8	-6	0	-8	-6
		DAY 43	18MAR2003	42	8	0	-10	8	-4	-14	0	-4	-4
		DAY 50	26MAR2003	50	8	0	-10	8	-14	-14	0	-14	-4
		DAY 57	01APR2003	56	8	-10	-10	8	-14	-14	0	-4	-4
		FINAL		56	8	-10	-10	8	-14	-14	0	-4	-4
	E0005034	DAY 8	23APR2003	9	0	0	10	0	-10	0	0	-10	-10

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0005034	DAY 15	01MAY2003	17	8	18	10	0	22	20	-8	4	10
		DAY 22	06MAY2003	22	0	10	10	0	0	0	0	-10	-10
		DAY 29	13MAY2003	29	-4	8	4	-4	0	0	0	-8	-4
		DAY 36	22MAY2003	38	-8	20	20	-8	10	10	0	-10	-10
		DAY 43	28MAY2003	44	-8	20	10	-8	10	10	0	-10	0
		DAY 50	05JUN2003	52	12	10	10	12	10	10	0	0	0
		DAY 57	09JUN2003	56	12	10	10	6	10	10	-6	0	0
		FINAL		56	12	10	10	6	10	10	-6	0	0
	E0005041	DAY 8	01JUL2003	8	0	12	4	8	4	10	8	-8	6
		DAY 15	08JUL2003	15	-12	8	-10	-4	0	-4	8	-8	6
		DAY 22	16JUL2003	23	-8	28	10	-4	18	16	4	-10	6
		DAY 29	22JUL2003	29	-12	16	4	0	12	12	12	-4	8
		DAY 36	28JUL2003	35	-8	22	2	4	10	8	12	-12	6
		DAY 43	04AUG2003	42	0	14	-4	4	10	6	4	-4	10
		DAY 50	11AUG2003	49	0	18	6	12	6	8	12	-12	2
		DAY 57	18AUG2003	56	-8	10	-2	-4	-2	2	4	-12	4
		FINAL		56	-8	10	-2	-4	-2	2	4	-12	4
	E0007004	DAY 8	07FEB2003	9	2	-6	0	2	4	2	0	10	2
		DAY 15	12FEB2003	14	6	-4	-6	8	6	-4	2	10	2
		FINAL		14	6	-4	-6	8	6	-4	2	10	2
	E0007010	DAY 8	25APR2003	8	-2	2	0	0	0	-8	2	-2	-8
		DAY 15	02MAY2003	15	-2	2	0	2	4	8	4	2	8
		DAY 22	09MAY2003	22	-2	-8	0	-2	-6	-4	0	2	-4
		DAY 29	16MAY2003	29	-2	-10	-4	0	-10	-2	2	0	2
		DAY 36	23MAY2003	36	-2	2	2	-2	2	4	0	0	2
		DAY 43	29MAY2003	42	6	6	10	6	4	0	0	-2	-10
		DAY 50	06JUN2003	50	0	8	12	0	8	8	0	0	-4
		DAY 57	16JUN2003	60	4	-2	-4	8	-14	-6	4	-12	-2
		FINAL		60	4	-2	-4	8	-14	-6	4	-12	-2
	E0007012	DAY 8	23MAY2003	8	-2	-10	4	-2	-8	2	0	2	-2
		DAY 15	29MAY2003	14	0	-14	0	0	-12	-2	0	2	-2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0007012	DAY 22		06JUN2003	22	0	-12	0	2	-14	-2	2	-2	-2
		DAY 29		13JUN2003	29	-4	-12	4	-4	-12	0	0	0	-4
		DAY 36		20JUN2003	36	0	2	10	0	2	8	0	0	-2
		DAY 43		25JUN2003	41	2	-10	8	-2	-10	-2	-4	0	-10
		DAY 43	*	01JUL2003	47	-2	-4	10	-2	-2	8	0	2	-2
		FINAL			47	-2	-4	10	-2	-2	8	0	2	-2
	E0009007	DAY 8		10FEB2003	8	-22	0	4	0	14	0	22	14	-4
		DAY 15		17FEB2003	15	-28	0	0	0	14	-4	28	14	-4
		DAY 22		25FEB2003	23	-14	0	-8	0	10	-8	14	10	0
		DAY 29		03MAR2003	29	-12	-10	4	6	0	2	18	10	-2
		FINAL			29	-12	-10	4	6	0	2	18	10	-2
	E0009008	DAY 8		19FEB2003	8	-4	-30	-24	-4	-22	-14	0	8	10
		DAY 15		25FEB2003	14	6	-30	-14	4	-18	-16	-2	12	-2
		DAY 22		04MAR2003	21	-12	-10	-14	-6	-8	-6	6	2	8
		DAY 29		11MAR2003	28	8	-10	0	2	-8	-6	-6	2	-6
		DAY 36		18MAR2003	35	-12	-30	-20	4	-18	-6	16	12	14
		DAY 43		26MAR2003	43	-6	-30	-24	-8	-18	-10	-2	12	14
		DAY 50		03APR2003	51	0	-30	-14	0	-22	-12	0	8	2
		DAY 57		08APR2003	56	-4	-30	-24	-2	-28	-16	2	2	8
		FINAL			56	-4	-30	-24	-2	-28	-16	2	2	8
	E0011001	DAY 8		07NOV2002	7	12	2	-10	-4	-4	0	-16	-6	10
		DAY 15		14NOV2002	14	0	0	-6	4	6	-4	4	6	2
		DAY 22		21NOV2002	21	6	4	-8	-4	2	-8	-10	-2	0
		DAY 29		27NOV2002	27	16	-2	-10	8	2	-8	-8	4	2
		DAY 36		05DEC2002	35	4	0	-6	4	-4	-6	0	-4	0
		DAY 43		12DEC2002	42	12	-10	-6	16	-6	-4	4	4	2
		DAY 50		19DEC2002	49	5	0	-4	12	13	-4	7	13	0
		DAY 57		26DEC2002	56	-4	-14	-7	-10	-13	-3	-6	1	4
		FINAL			56	-4	-14	-7	-10	-13	-3	-6	1	4
	E0011011	DAY 8		26FEB2003	7	-4	0	4	-8	-2	0	-4	-2	-4
		DAY 15		05MAR2003	14	8	2	2	2	2	2	-6	0	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0011011	DAY 22	12MAR2003	21	-4	-2	0	0	-2	0	4	0	0
		DAY 29	19MAR2003	28	-4	-10	-4	-8	-6	-4	-4	4	0
		DAY 36	26MAR2003	35	8	-2	2	0	-2	0	-8	0	-2
		DAY 43	02APR2003	42	4	-4	4	8	-4	2	4	0	-2
		DAY 50	09APR2003	49	4	-2	4	-4	-4	0	-8	-2	-4
		DAY 57	16APR2003	56	0	0	2	0	0	0	0	0	-2
		FINAL		56	0	0	2	0	0	0	0	0	-2
	E0011013	DAY 8	24APR2003	8	4	-6	0	0	-6	2	-4	0	2
		DAY 15	01MAY2003	15	0	-12	0	-8	-12	0	-8	0	0
		DAY 22	08MAY2003	22	4	-20	-4	-4	-18	-4	-8	2	0
		DAY 29	15MAY2003	29	8	-10	-4	0	-8	-4	-8	2	0
		DAY 36	22MAY2003	36	16	-2	4	8	-4	4	-8	-2	0
		DAY 43	29MAY2003	43	12	-4	0	4	-6	2	-8	-2	2
		DAY 50	05JUN2003	50	8	-6	-2	0	-8	-4	-8	-2	-2
		DAY 57	12JUN2003	57	4	-2	2	-4	-2	2	-8	0	0
		FINAL		57	4	-2	2	-4	-2	2	-8	0	0
	E0011014	DAY 8	14APR2003	8	8	-12	4	12	4	4	4	16	0
		DAY 29	08MAY2003	32	4	-4	-4	12	2	-8	8	6	-4
		FINAL		32	4	-4	-4	12	2	-8	8	6	-4
	E0011021	DAY 8	29MAY2003	8	0	-2	4	-2	0	2	-2	2	-2
		DAY 15	05JUN2003	15	0	2	4	-2	0	-2	-2	-2	-6
		DAY 22	12JUN2003	22	8	0	4	2	0	-2	-6	0	-6
		DAY 29	20JUN2003	30	8	-10	2	-2	-12	-2	-10	-2	-4
		DAY 36	27JUN2003	37	8	2	8	-2	0	4	-10	-2	-4
		DAY 43	02JUL2003	42	8	4	8	-6	2	-2	-14	-2	-10
		DAY 50	10JUL2003	50	10	4	2	-6	0	-4	-16	-4	-6
		DAY 57	21JUL2003	61	0	0	8	-14	-4	-2	-14	-4	-10
		FINAL		61	0	0	8	-14	-4	-2	-14	-4	-10
	E0013008	DAY 8	02APR2003	8	-6	-5	0	-6	-2	0	0	3	0
		DAY 15	09APR2003	15	0	0	-20	-12	-2	-18	-12	-2	2
		DAY 22	17APR2003	23	10	2	-12	2	0	-10	-8	-2	2

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0013008	DAY 29	23APR2003	29	6	0	0	-6	0	0	-12	0	0
		DAY 36	30APR2003	36	14	4	0	8	4	-2	-6	0	-2
		DAY 43	07MAY2003	43	2	0	-4	-8	0	-4	-10	0	0
		DAY 50	12MAY2003	48	2	0	-16	-12	0	-12	-14	0	4
		DAY 57	19MAY2003	55	2	-8	0	-8	-4	-2	-10	4	-2
		FINAL		55	2	-8	0	-8	-4	-2	-10	4	-2
	E0014001	DAY 8	05MAR2003	8	4	-10	-3	6	3	-5	2	13	-2
		DAY 15	12MAR2003	15	28	-4	-8	31	-3	-10	3	1	-2
		DAY 22	19MAR2003	22	16	0	-2	23	-7	-6	7	-7	-4
		DAY 29	25MAR2003	28	16	5	2	19	-2	-9	3	-7	-11
		DAY 36	01APR2003	35	12	0	2	13	8	-4	1	8	-6
		FINAL		35	12	0	2	13	8	-4	1	8	-6
	E0014013	DAY 8	04JUN2003	9	4	0	6	4	-16	0	0	-16	-6
		DAY 15	13JUN2003	18	0	-6	-2	0	-18	-2	0	-12	0
		DAY 22	18JUN2003	23	0	4	-4	4	-14	-4	4	-18	0
		DAY 29	25JUN2003	30	6	-8	8	4	-14	8	-2	-6	0
		DAY 36	02JUL2003	37	8	2	0	10	-6	4	2	-8	4
		DAY 43	10JUL2003	45	14	-8	0	12	-16	2	-2	-8	2
		DAY 50	16JUL2003	51	16	4	-2	18	-12	2	2	-16	4
		DAY 57	23JUL2003	58	10	-8	-6	18	-16	-4	8	-8	2
		FINAL		58	10	-8	-6	18	-16	-4	8	-8	2
	E0014014	DAY 8	18JUN2003	9	2	5	4	4	6	2	2	1	-2
		DAY 15	24JUN2003	15	-2	2	-6	0	-6	-6	2	-8	0
		DAY 22	03JUL2003	24	-6	18	16	-6	12	13	0	-6	-3
		DAY 29	10JUL2003	31	6	10	3	7	9	4	1	-1	1
		DAY 36	18JUL2003	39	-2	2	-6	0	-4	-4	2	-6	2
		DAY 50	30JUL2003	51	10	12	-2	10	6	-2	0	-6	0
		DAY 57	06AUG2003	58	6	16	0	8	10	-2	2	-6	-2
		FINAL		58	6	16	0	8	10	-2	2	-6	-2
	E0015004	DAY 8	11DEC2002	10	-6	-2	-2	2	2	-2	8	4	0
		DAY 15	18DEC2002	17	-10	-6	0	0	0	-6	10	6	-6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0015004	DAY 22		27DEC2002	26	-6	-8	0	0	2	-4	6	10	-4
		DAY 36		06JAN2003	36	-12	-6	-4	2	2	-4	14	8	0
		DAY 36	*	09JAN2003	39	-14	2	-4	-2	0	-2	12	-2	2
		DAY 43		17JAN2003	47	-10	0	0	-6	4	4	4	4	4
		DAY 57		29JAN2003	59	-6	-2	0	4	4	-6	10	6	-6
		FINAL			59	-6	-2	0	4	4	-6	10	6	-6
	E0018005	DAY 8		27DEC2002	8	0	6	8	4	4	4	4	-2	-4
		DAY 8	*	31DEC2002	12	0	-2	2	4	-4	2	4	-2	0
		DAY 22		10JAN2003	22	-12	-4	8	-4	0	6	8	4	-2
		DAY 29		17JAN2003	29	-12	2	6	-8	-2	4	4	-4	-2
		DAY 36		24JAN2003	36	0	6	2	4	6	4	4	0	2
		DAY 43		31JAN2003	43	-12	-10	-2	-8	-10	-4	4	0	-2
		DAY 50		07FEB2003	50	-4	-2	0	0	2	0	4	4	0
		DAY 57		14FEB2003	57	-16	-2	0	-12	-2	-2	4	0	-2
		FINAL			57	-16	-2	0	-12	-2	-2	4	0	-2
	E0018012	DAY 8		30JAN2003	7	-4	4	2	-8	4	2	-4	0	0
		DAY 15		07FEB2003	15	-4	18	0	0	18	-2	4	0	-2
		DAY 22		14FEB2003	22	-12	12	0	-12	12	-2	0	0	-2
		DAY 29		21FEB2003	29	0	12	-2	0	14	-2	0	2	0
		DAY 36		26FEB2003	34	0	18	0	0	18	0	0	0	0
		FINAL			34	0	18	0	0	18	0	0	0	0
	E0019019	DAY 8		30JAN2003	8	12	13	12	12	17	10	0	4	-2
		DAY 15		06FEB2003	15	16	10	2	20	20	5	4	10	3
		FINAL			15	16	10	2	20	20	5	4	10	3
	E0019033	DAY 8		27MAR2003	10	-2	0	-10	2	-10	-5	4	-10	5
		DAY 15		03APR2003	17	-2	0	-10	6	-20	-20	8	-20	-10
		DAY 22		10APR2003	24	-6	0	-10	-2	-10	-18	4	-10	-8
		DAY 29		14APR2003	28	-6	0	0	-6	-20	-10	0	-20	-10
		DAY 36		22APR2003	36	-2	10	4	2	-10	-10	4	-20	-14
		DAY 43		01MAY2003	45	2	0	-11	2	-10	-10	0	-10	1
		DAY 50		08MAY2003	52	4	12	2	-2	-4	-12	-6	-16	-14

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0019033	DAY 57	15MAY2003	59	2	-6	-8	6	-18	-20	4	-12	-12
		FINAL		59	2	-6	-8	6	-18	-20	4	-12	-12
	E0019038	DAY 8	01MAY2003	8	-4	15	5	10	10	13	14	-5	8
		DAY 15	07MAY2003	14	0	5	-5	0	-3	-5	0	-8	0
		DAY 22	14MAY2003	21	2	7	-7	6	0	5	4	-7	12
		DAY 29	21MAY2003	28	0	5	0	-2	7	5	-2	2	5
		DAY 36	28MAY2003	35	4	0	0	-2	2	5	-6	2	5
		DAY 43	04JUN2003	42	2	13	-15	2	-26	-5	0	-39	10
		DAY 50	11JUN2003	49	0	5	0	-2	12	5	-2	7	5
		DAY 57	18JUN2003	56	0	-1	-5	6	2	3	6	3	8
		FINAL		56	0	-1	-5	6	2	3	6	3	8
	E0019046	DAY 8	03JUL2003	8	4	-4	-2	0	-4	2	-4	0	4
		DAY 15	10JUL2003	15	-4	0	24	20	-4	4	24	-4	-20
		DAY 22	17JUL2003	22	-4	-2	5	8	-9	-8	12	-7	-13
		DAY 29	24JUL2003	29	0	-8	6	20	-10	-2	20	-2	-8
		DAY 36	30JUL2003	35	0	-2	0	10	-9	-8	10	-7	-8
		DAY 50	14AUG2003	50	0	3	5	10	-9	-3	10	-12	-8
		DAY 57	21AUG2003	57	4	10	6	4	-4	-4	0	-14	-10
		FINAL		57	4	10	6	4	-4	-4	0	-14	-10
	E0019047	DAY 8	17JUL2003	10	0	2	6	-2	2	-7	-2	0	-13
		DAY 15	24JUL2003	17	12	4	4	16	2	0	4	-2	-4
		DAY 22	31JUL2003	24	8	0	0	16	0	-6	8	0	-6
		DAY 29	07AUG2003	31	20	0	10	16	8	-6	-4	8	-16
		DAY 36	14AUG2003	38	8	-2	-4	0	6	-4	-8	8	0
		DAY 43	21AUG2003	45	12	-6	-4	4	-6	-22	-8	0	-18
		DAY 50	28AUG2003	52	12	-3	6	0	-11	-12	-12	-8	-18
		DAY 57	04SEP2003	59	12	4	10	0	2	-8	-12	-2	-18
		FINAL		59	12	4	10	0	2	-8	-12	-2	-18
	E0019048	DAY 8	17JUL2003	8	0	-2	-5	-8	-10	-2	-8	-8	3
		DAY 15	22JUL2003	13	4	0	0	-8	-4	3	-12	-4	3
		DAY 22	31JUL2003	22	8	-2	0	-8	-12	-4	-16	-10	-4

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0019048	DAY 29	07AUG2003	29	8	0	-2	0	-10	-6	-8	-10	-4
		DAY 36	14AUG2003	36	8	-12	-10	-12	-26	-4	-20	-14	6
		DAY 43	21AUG2003	43	4	-10	-5	-2	-20	-7	-6	-10	-2
		DAY 50	28AUG2003	50	4	2	2	-12	-20	-2	-16	-22	-4
		DAY 57	03SEP2003	56	-4	-6	4	-12	-16	-2	-8	-10	-6
		FINAL		56	-4	-6	4	-12	-16	-2	-8	-10	-6
	E0022006	DAY 8	19NOV2002	8	20	-8	-4	16	-10	-2	-4	-2	2
		DAY 15	26NOV2002	15	12	-18	0	24	-8	2	12	10	2
		DAY 22	03DEC2002	22	8	-16	-14	4	-6	-10	-4	10	4
		DAY 29	10DEC2002	29	4	-12	0	4	-10	2	0	2	2
		DAY 36	17DEC2002	36	4	-20	-10	10	-8	-8	6	12	2
		DAY 43	24DEC2002	43	20	-20	-16	10	-10	-16	-10	10	0
		DAY 50	31DEC2002	50	2	-26	-12	7	-8	-8	5	18	4
		DAY 57	07JAN2003	57	26	-10	-12	16	-10	-4	-10	0	8
		FINAL		57	26	-10	-12	16	-10	-4	-10	0	8
	E0022047	DAY 8	04APR2003	8	4	8	-8	12	-6	0	8	-14	8
		DAY 15	11APR2003	15	14	8	0	4	-4	0	-10	-12	0
		DAY 22	17APR2003	21	0	22	0	12	2	0	12	-20	0
		DAY 29	25APR2003	29	0	8	-6	10	2	0	10	-6	6
		DAY 36	02MAY2003	36	4	10	-6	4	10	2	0	0	8
		DAY 43	09MAY2003	43	8	12	0	8	18	0	0	6	0
		DAY 50	16MAY2003	50	0	22	-6	20	16	2	20	-6	8
		DAY 57	23MAY2003	57	8	12	-2	16	22	22	8	10	24
		FINAL		57	8	12	-2	16	22	22	8	10	24
	E0022075	DAY 8	15JUL2003	8	3	4	6	6	-16	-2	3	-20	-8
		DAY 15	22JUL2003	15	9	-6	0	9	-16	4	0	-10	4
		DAY 22	29JUL2003	22	3	-4	6	-3	-20	6	-6	-16	0
		DAY 29	05AUG2003	29	11	-8	-4	14	-22	-8	3	-14	-4
		DAY 36	12AUG2003	36	5	-4	-8	10	-6	-6	5	-2	2
		DAY 43	19AUG2003	43	7	-4	-4	10	-12	-6	3	-8	-2
		DAY 50	26AUG2003	50	7	-6	-8	18	-14	-10	11	-8	-2
		DAY 57	03SEP2003	58	15	-6	-10	10	-2	-2	-5	4	8

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0022075	FINAL		58	15	-6	-10	10	-2	-2	-5	4	8
	E0023012	DAY 8	17FEB2003	12	-12	2	14	-17	-28	-9	-5	-30	-23
		DAY 15	20FEB2003	15	-12	-6	14	-17	-24	-9	-5	-18	-23
		DAY 22	28FEB2003	23	-8	10	8	-17	-24	-13	-9	-34	-21
		DAY 29	07MAR2003	30	-6	10	10	-12	3	-2	-6	-7	-12
		DAY 36	14MAR2003	37	-13	-6	18	-6	-2	-8	7	4	-26
		DAY 43	21MAR2003	44	-14	2	6	-19	1	-6	-5	-1	-12
		DAY 50	28MAR2003	51	-3	13	-2	-17	-18	-19	-14	-31	-17
		DAY 57	04APR2003	58	-20	4	8	-27	-20	-15	-7	-24	-23
		FINAL		58	-20	4	8	-27	-20	-15	-7	-24	-23
	E0023016	DAY 8	29MAY2003	8	-1	-23	-19	19	-1	0	20	22	19
		DAY 15	05JUN2003	15	-3	-14	-14	6	2	-4	9	16	10
		DAY 22	12JUN2003	22	-10	-14	-13	17	-5	-13	27	9	0
		DAY 29	19JUN2003	29	-16	-16	-16	-8	2	-3	8	18	13
		DAY 36	26JUN2003	36	-5	-32	-25	0	-8	-10	5	24	15
		DAY 43	01JUL2003	41	-9	-26	-20	7	-2	-1	16	24	19
		DAY 50	14JUL2003	54	-7	-23	-19	6	-6	-6	13	17	13
		DAY 57	17JUL2003	57	1	-21	-9	6	-4	-4	5	17	5
		FINAL		57	1	-21	-9	6	-4	-4	5	17	5
	E0023018	DAY 8	03APR2003	8	10	7	1	8	10	-4	-2	3	-5
		DAY 15	10APR2003	15	9	2	-4	4	0	-4	-5	-2	0
		DAY 22	16APR2003	21	26	7	5	25	6	2	-1	-1	-3
		DAY 29	24APR2003	29	24	7	5	22	4	-2	-2	-3	-7
		DAY 36	02MAY2003	37	6	-3	4	2	-2	2	-4	1	-2
		DAY 43	12MAY2003	47	7	20	16	2	20	16	-5	0	0
		DAY 50	15MAY2003	50	4	23	20	4	15	10	0	-8	-10
		DAY 57	22MAY2003	57	11	15	7	14	16	6	3	1	-1
		FINAL		57	11	15	7	14	16	6	3	1	-1
	E0023036	DAY 8	26JUN2003	7	11	-9	-8	14	-16	-19	3	-7	-11
		DAY 15	02JUL2003	13	0	5	10	0	0	6	0	-5	-4
		DAY 22	09JUL2003	20	11	-19	-10	9	-16	-10	-2	3	0

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0023036	DAY 29		16JUL2003	27	7	-14	4	5	-20	-13	-2	-6	-17
		DAY 29	*	22JUL2003	33	2	-15	-7	0	-20	-14	-2	-5	-7
		DAY 36		29JUL2003	40	-8	-3	-4	0	-16	-14	8	-13	-10
		DAY 43		05AUG2003	47	11	-9	11	11	-10	6	0	-1	-5
		DAY 57		13AUG2003	55	14	-9	-8	21	1	1	7	10	9
		FINAL			55	14	-9	-8	21	1	1	7	10	9
	E0023046	DAY 8		01AUG2003	10	3	34	5	0	33	2	-3	-1	-3
		DAY 15		08AUG2003	17	5	-25	-15	5	-42	-24	0	-17	-9
		DAY 22		14AUG2003	23	0	-21	-25	-14	-35	-31	-14	-14	-6
		DAY 29		22AUG2003	31	6	-3	-16	-1	-19	-17	-7	-16	-1
		DAY 36		28AUG2003	37	4	-27	-16	-10	-34	-20	-14	-7	-4
		DAY 43		04SEP2003	44	10	-21	-20	18	-27	-27	8	-6	-7
		DAY 50		11SEP2003	51	3	-15	-21	-2	-19	-12	-5	-4	9
		DAY 57		16SEP2003	56	12	-9	-12	5	-22	-13	-7	-13	-1
		FINAL			56	12	-9	-12	5	-22	-13	-7	-13	-1
	E0026006	DAY 8		15JAN2003	8	29	34	8	23	-3	0	-6	-37	-8
		DAY 15		22JAN2003	15	25	11	5	30	7	10	5	-4	5
		DAY 22		29JAN2003	22	22	-5	2	23	-8	2	1	-3	0
		DAY 29		05FEB2003	29	17	19	2	25	-12	-8	8	-31	-10
		DAY 36		12FEB2003	36	22	-1	-1	22	-17	-10	0	-16	-9
		DAY 43		19FEB2003	43	7	7	1	9	3	-1	2	-4	-2
		FINAL			43	7	7	1	9	3	-1	2	-4	-2
	E0026021	DAY 8		29APR2003	7	-5	1	16	4	3	4	9	2	-12
		DAY 15		08MAY2003	16	-7	-1	21	-1	-12	4	6	-11	-17
		FINAL			16	-7	-1	21	-1	-12	4	6	-11	-17
	E0029004	DAY 8		26NOV2002	8	-16	16	6	-8	20	10	8	4	4
		DAY 15		04DEC2002	16	0	12	8	-10	14	6	-10	2	-2
		DAY 22		12DEC2002	24	-8	6	4	-8	26	8	0	20	4
		DAY 36		26DEC2002	38	4	0	-10	4	12	12	0	12	22
		DAY 43		02JAN2003	45	4	-2	-10	-20	2	0	-24	4	10
		DAY 50		09JAN2003	52	0	4	2	-16	14	8	-16	10	6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0029004	DAY 57		16JAN2003	59	-4	0	2	-8	-6	-2	-4	-6	-4
		FINAL			59	-4	0	2	-8	-6	-2	-4	-6	-4
	E0029013	DAY 8		25FEB2003	7	4	-2	-2	4	0	0	0	2	2
		DAY 15		04MAR2003	14	0	-5	-14	4	0	0	4	5	14
		DAY 22		13MAR2003	23	-4	18	4	-8	14	4	-4	-4	0
		DAY 29		20MAR2003	30	-12	10	-4	-8	8	-2	4	-2	2
		DAY 36		25MAR2003	35	-12	0	-8	-12	0	-4	0	0	4
		DAY 43		31MAR2003	41	-12	-2	-4	-12	-2	-4	0	0	0
		DAY 50		10APR2003	51	4	8	-4	0	6	0	-4	-2	4
		FINAL			51	4	8	-4	0	6	0	-4	-2	4
	E0029019	DAY 8		10MAR2003	8	-4	20	8	0	0	12	4	-20	4
		DAY 15		17MAR2003	15	0	2	-2	-8	-2	-2	-8	-4	0
		FINAL			15	0	2	-2	-8	-2	-2	-8	-4	0
	E0029024	DAY 8		25MAR2003	9	4	-2	0	4	0	2	0	2	2
		DAY 15		02APR2003	17	4	-10	-14	4	-6	-4	0	4	10
		DAY 22		09APR2003	24	0	16	-10	14	6	-4	14	-10	6
		DAY 29		17APR2003	32	8	0	-16	8	-4	-6	0	-4	10
		DAY 36		24APR2003	39	8	-6	-18	8	-6	-8	0	0	10
		DAY 50		05MAY2003	50	20	-2	-18	12	-4	-8	-8	-2	10
		DAY 57	*	12MAY2003	57	2	-12	-16	2	-10	-8	0	2	8
		DAY 57		20MAY2003	65	6	8	-18	6	6	-8	0	-2	10
		FINAL			65	6	8	-18	6	6	-8	0	-2	10
	E0031004	DAY 8		27DEC2002	9	7	-2	2	22	6	0	15	8	-2
		DAY 15		03JAN2003	16	11	-2	-2	20	3	-8	9	5	-6
		DAY 22		09JAN2003	22	11	5	12	6	-4	-6	-5	-9	-18
		DAY 29		16JAN2003	29	-3	5	2	2	4	-10	5	-1	-12
		DAY 36		23JAN2003	36	3	0	6	8	-2	-6	5	-2	-12
		DAY 43		30JAN2003	43	-7	0	12	6	10	6	13	10	-6
		DAY 50		06FEB2003	50	3	0	8	8	0	-4	5	0	-12
		DAY 57		13FEB2003	57	-1	-8	6	20	-4	0	21	4	-6
		FINAL			57	-1	-8	6	20	-4	0	21	4	-6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0031013	DAY 8		20MAR2003	8	-8	2	2	-8	6	6	0	4	4
		DAY 15		27MAR2003	15	-20	0	-2	-13	0	2	7	0	4
		DAY 22		04APR2003	23	-12	-4	2	4	-4	2	16	0	0
		DAY 29		11APR2003	30	2	-8	-2	4	-10	2	2	-2	4
		DAY 36		17APR2003	36	10	2	6	17	0	6	7	-2	0
		DAY 43		24APR2003	43	-8	2	8	0	4	10	8	2	2
		DAY 50		01MAY2003	50	-6	2	8	6	0	6	12	-2	-2
		DAY 57		08MAY2003	57	-18	0	10	-16	0	6	2	0	-4
		FINAL			57	-18	0	10	-16	0	6	2	0	-4
	E0031016	DAY 8		31MAR2003	8	22	4	0	16	8	-2	-6	4	-2
		DAY 15		07APR2003	15	6	6	2	-2	8	-2	-8	2	-4
		DAY 22		14APR2003	22	8	8	2	0	10	0	-8	2	-2
		FINAL			22	8	8	2	0	10	0	-8	2	-2
	E0031019	DAY 8		18APR2003	8	10	-2	0	14	-2	0	4	0	0
		DAY 15		25APR2003	15	6	6	4	12	2	2	6	-4	-2
		DAY 22		02MAY2003	22	4	-4	4	8	-6	0	4	-2	-4
		DAY 29		09MAY2003	29	2	-6	-6	4	-6	-10	2	0	-4
		DAY 29	*	12MAY2003	32	2	2	-10	14	0	-10	12	-2	0
		FINAL			32	2	2	-10	14	0	-10	12	-2	0
	E0031022	DAY 8		06MAY2003	9	4	10	8	-4	14	10	-8	4	2
		DAY 15		13MAY2003	16	2	8	6	-4	14	8	-6	6	2
		DAY 22		20MAY2003	23	10	20	4	-2	30	6	-12	10	2
		DAY 29		27MAY2003	30	6	14	4	4	18	2	-2	4	-2
		FINAL			30	6	14	4	4	18	2	-2	4	-2
	E0033007	DAY 8		04FEB2003	8	-4	2	0	-8	-6	-4	-4	-8	-4
		DAY 15		12FEB2003	16	0	14	0	-4	2	-2	-4	-12	-2
		DAY 22		20FEB2003	24	4	-4	0	0	-4	0	-4	0	0
		DAY 29		25FEB2003	29	4	2	4	2	10	4	-2	8	0
		DAY 36		04MAR2003	36	8	12	8	4	2	-2	-4	-10	-10
		DAY 43		13MAR2003	45	4	-6	0	0	2	2	-4	8	2
		DAY 50		18MAR2003	50	4	-6	6	4	-2	0	0	4	-6

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0033007	DAY 57		27MAR2003	59	4	-26	0	-4	-8	-8	-8	18	-8
		FINAL			59	4	-26	0	-4	-8	-8	-8	18	-8
	E0033013	DAY 8		26FEB2003	8	-8	-8	-2	0	-10	4	8	-2	6
		DAY 15		05MAR2003	15	-4	-8	-2	8	0	-2	12	8	0
		DAY 22		13MAR2003	23	-8	2	18	0	-10	10	8	-12	-8
		DAY 29		19MAR2003	29	0	-10	-2	0	-10	-2	0	0	0
		DAY 36		27MAR2003	37	0	-20	-12	4	-20	-12	4	0	0
		DAY 43		01APR2003	42	-8	-28	-12	4	-20	-6	12	8	6
		DAY 50		10APR2003	51	-12	-28	-12	-4	-30	-8	8	-2	4
		DAY 57		16APR2003	57	-4	-28	-12	4	-20	2	8	8	14
		FINAL			57	-4	-28	-12	4	-20	2	8	8	14
	E0033016	DAY 8		13MAY2003	6	12	4	4	12	6	6	0	2	2
		DAY 15		20MAY2003	13	-8	-16	10	-4	0	14	4	16	4
		DAY 22		28MAY2003	21	0	4	10	0	8	4	0	4	-6
		DAY 29		09JUN2003	33	-8	-6	10	0	0	4	8	6	-6
		DAY 43		17JUN2003	41	0	12	14	0	10	4	0	-2	-10
		DAY 43	*	23JUN2003	47	0	4	20	4	-6	10	4	-10	-10
		DAY 50		27JUN2003	51	0	-6	2	-4	0	-6	-4	6	-8
		DAY 57		02JUL2003	56	-8	-16	4	-12	-10	2	-4	6	-2
		FINAL			56	-8	-16	4	-12	-10	2	-4	6	-2
	E0033022	DAY 8		23JUL2003	10	-16	-10	-16	-4	-10	-10	12	0	6
		DAY 15		30JUL2003	17	-12	0	-8	-4	-10	0	8	-10	8
		DAY 22		06AUG2003	24	-16	0	-10	-16	10	0	0	10	10
		DAY 29		11AUG2003	29	-10	20	-4	-4	24	10	6	4	14
		DAY 36		18AUG2003	36	-20	10	-6	-16	0	0	4	-10	6
		DAY 43		26AUG2003	44	-16	10	-8	-16	10	2	0	0	10
		DAY 50		04SEP2003	53	-16	0	-8	-16	0	2	0	0	10
		DAY 57		11SEP2003	60	-16	10	-8	-16	10	2	0	0	10
		FINAL			60	-16	10	-8	-16	10	2	0	0	10
	E0034007	DAY 8		24MAY2003	9	6	8	8	4	-13	-3	-2	-21	-11
		DAY 15		02JUN2003	18	0	6	2	4	-10	0	4	-16	-2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0034007	DAY 22		09JUN2003	25	10	6	6	0	-12	6	-10	-18	0
		DAY 29		16JUN2003	32	10	18	8	12	-8	-3	2	-26	-11
		DAY 36		20JUN2003	36	2	3	3	0	-8	-8	-2	-11	-11
		DAY 43		30JUN2003	46	12	38	18	0	2	7	-12	-36	-11
		DAY 50		07JUL2003	53	18	18	13	20	-3	12	2	-21	-1
		DAY 57		14JUL2003	60	6	38	23	-4	20	20	-10	-18	-3
		FINAL			60	6	38	23	-4	20	20	-10	-18	-3
	E0035004	DAY 8		04DEC2002	8	-2	-2	4	-2	-4	-2	0	-2	-6
		FINAL			8	-2	-2	4	-2	-4	-2	0	-2	-6
	E0035009	DAY 8		31DEC2002	5	-8	12	-6	-8	16	-16	0	4	-10
		DAY 15		08JAN2003	13	-6	20	-10	-4	20	-12	2	0	-2
		DAY 22		15JAN2003	20	-8	18	-6	-6	18	-16	2	0	-10
		DAY 29		22JAN2003	27	-10	18	-6	-8	16	-10	2	-2	-4
		DAY 36		29JAN2003	34	-18	16	0	-18	16	-4	0	0	-4
		DAY 43		05FEB2003	41	-14	20	-8	-10	16	-8	4	-4	0
		DAY 43	*	11FEB2003	47	-28	14	0	-26	16	-4	2	2	-4
		DAY 57		19FEB2003	55	-8	14	-6	-8	14	-4	0	0	2
		FINAL			55	-8	14	-6	-8	14	-4	0	0	2
	E0035010	DAY 8		17JAN2003	8	0	-4	-10	-2	-6	-16	-2	-2	-6
		DAY 15		24JAN2003	15	-4	2	-10	-8	0	-10	-4	-2	0
		DAY 22		31JAN2003	22	-14	6	-10	-14	2	-4	0	-4	6
		DAY 29		07FEB2003	29	-14	12	-8	-18	14	-4	-4	2	4
		DAY 36		14FEB2003	36	0	6	-2	-2	4	-6	-2	-2	-4
		DAY 43		24FEB2003	46	0	4	-4	0	2	-8	0	-2	-4
		DAY 50		28FEB2003	50	0	6	-12	-2	4	-10	-2	-2	2
		DAY 57		06MAR2003	56	2	6	-12	0	2	-6	-2	-4	6
		FINAL			56	2	6	-12	0	2	-6	-2	-4	6
	E0035022	DAY 8		15MAY2003	7	2	0	0	-4	0	-6	-6	0	-6
		DAY 15		23MAY2003	15	0	-2	2	2	-2	-4	2	0	-6
		DAY 22		30MAY2003	22	2	0	6	-2	0	-6	-4	0	-12
		DAY 29		06JUN2003	29	4	2	10	0	2	2	-4	0	-8

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0035022	DAY 36	13JUN2003	36	0	4	8	-6	2	4	-6	-2	-4
		DAY 43	20JUN2003	43	2	0	6	2	0	2	0	0	-4
		DAY 50	27JUN2003	50	12	-12	0	2	-4	-6	-10	8	-6
		DAY 57	07JUL2003	60	4	-10	2	2	-8	-6	-2	2	-8
		FINAL		60	4	-10	2	2	-8	-6	-2	2	-8
	E0039003	DAY 8	02DEC2002	8	6	10	0	0	16	-12	-6	6	-12
		DAY 15	09DEC2002	15	4	0	-10	8	14	-8	4	14	2
		DAY 36	02JAN2003	39	-4	-4	-4	0	2	-18	4	6	-14
		FINAL		39	-4	-4	-4	0	2	-18	4	6	-14
	E0040001	DAY 8	03JUL2003	7	2	5	5	3	6	8	1	1	3
		DAY 15	11JUL2003	15	6	10	13	4	11	16	-2	1	3
		DAY 22	18JUL2003	22	12	-5	5	10	1	8	-2	6	3
		DAY 29	25JUL2003	29	7	10	15	6	14	19	-1	4	4
		DAY 36	01AUG2003	36	8	12	15	8	14	16	0	2	1
		DAY 43	08AUG2003	43	10	15	13	9	18	20	-1	3	7
		DAY 50	15AUG2003	50	10	8	13	10	16	20	0	8	7
		DAY 57	22AUG2003	57	10	12	15	10	14	18	0	2	3
		FINAL		57	10	12	15	10	14	18	0	2	3
	E0041002	DAY 8	28JAN2003	8	8	-4	-8	0	2	-6	-8	6	2
		DAY 15	04FEB2003	15	4	2	0	-4	-16	-6	-8	-18	-6
		DAY 22	11FEB2003	22	6	2	-8	0	0	-8	-6	-2	0
		DAY 29	18FEB2003	29	-4	-10	-8	-4	-6	-14	0	4	-6
		DAY 36	25FEB2003	36	0	-2	-6	-8	-2	-10	-8	0	-4
		DAY 50	11MAR2003	50	6	2	-6	2	4	-2	-4	2	4
		FINAL		50	6	2	-6	2	4	-2	-4	2	4
	E0041005	DAY 8	11MAR2003	7	-2	0	6	-4	0	-2	-2	0	-8
		DAY 15	19MAR2003	15	6	-2	-2	14	2	4	8	4	6
		DAY 22	26MAR2003	22	4	0	-2	2	-6	8	-2	-6	10
		DAY 29	02APR2003	29	4	-30	-2	10	-18	4	6	12	6
		DAY 36	09APR2003	36	-16	-30	-12	-12	-28	-16	4	2	-4
		DAY 43	16APR2003	43	4	-8	8	6	2	16	2	10	8

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UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

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Listing 12.2.9.2 Vital Signs - Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0041005	DAY 50	23APR2003	50	-16	10	6	2	2	8	18	-8	2
		DAY 57	30APR2003	57	12	-2	-6	10	-8	-8	-2	-6	-2
		FINAL		57	12	-2	-6	10	-8	-8	-2	-6	-2

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KEY: SYS=SYSTOLIC BLOOD PRESSURE DIA=DIASTOLIC BLOOD PRESSURE.
UNITS: SYSTOLIC BP (SYS)=MMHG, DIASTOLIC BP (DIA)=MMHG, PULSE=BPM.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT101.SAS
GENERATED: 12JUL2005 17:46:43 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	SCREEN	14JAN2003	-21	170.0	89.0	30.8			
		DAY 57	02APR2003	58		89.0	30.8	0.0	0.0	
	E0002010	SCREEN	25MAR2003	-10	183.0	159.0	47.5			
	E0002012	SCREEN	16APR2003	-5	183.0	70.0	20.9			
		DAY 57	16JUN2003	57		64.0	19.1	-6.0	-1.8	D
	E0002015	SCREEN	22MAY2003	-13	166.0	64.0	23.2			
	E0002018	SCREEN	16JUL2003	-8	188.0	148.0	41.9			
		DAY 8	01AUG2003	9		148.0	41.9	0.0	0.0	
	E0003004	SCREEN	03DEC2002	-14	175.0	103.0	33.6			
		DAY 22	07JAN2003	22		106.0	34.6	3.0	1.0	
	E0003005	SCREEN	16DEC2002	-7	160.0	79.0	30.9			
		DAY 57	18FEB2003	58		81.0	31.6	2.0	0.7	
	E0003007	SCREEN	19DEC2002	-14	170.0	81.0	28.0			
		DAY 57	27FEB2003	57		81.0	28.0	0.0	0.0	
	E0003015	SCREEN	29APR2003	-6	158.0	57.0	22.8			
		DAY 57	02JUL2003	59		61.0	24.4	4.0	1.6	I
	E0004002	SCREEN	24SEP2002	-7	156.0	65.0	26.7			
		DAY 57	26NOV2002	57		61.0	25.1	-4.0	-1.6	
	E0004013	SCREEN	08JAN2003	-6	157.0	84.0	34.1			
		DAY 22	05FEB2003	23		87.0	35.3	3.0	1.2	
	E0004018	SCREEN	12MAR2003	-7	178.0	65.0	20.5			
		DAY 57	13MAY2003	56		65.0	20.5	0.0	0.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
GENERATED: 12JUL2005 17:46:50 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	SCREEN	07MAY2003	-7	173.0	89.0	29.7			
		DAY 57	09JUL2003	57		88.0	29.4	-1.0	-0.3	
	E0005002	SCREEN	23SEP2002	-10	173.0	60.0	20.0			
		DAY 50	25NOV2002	54		66.0	22.1	6.0	2.1	I
	E0005004	SCREEN	24SEP2002	-7	165.0	73.0	26.8			
	E0005013	SCREEN	30OCT2002	-8	168.0	71.0	25.2			
		DAY 43	19DEC2002	43		70.0	24.8	-1.0	-0.4	
	E0005024	SCREEN	05FEB2003	-5	170.0	105.0	36.3			
		DAY 57	09APR2003	59		103.0	35.6	-2.0	-0.7	
	E0005027	SCREEN	03MAR2003	-8	180.0	90.0	27.8			
		DAY 22	03APR2003	24		89.0	27.5	-1.0	-0.3	
	E0005037	SCREEN	30APR2003	-7	165.0	138.0	50.7			
		DAY 57	02JUL2003	57		144.0	52.9	6.0	2.2	
	E0005042	SCREEN	19JUN2003	-5	188.0	118.0	33.4			
		DAY 57	18AUG2003	56		119.0	33.7	1.0	0.3	
	E0006005	SCREEN	25NOV2002	-10	158.0	101.0	40.5			
	E0006018	SCREEN	06MAR2003	-7	180.0	95.0	29.3			
	E0007013	SCREEN	06JUN2003	-7	152.0	53.0	22.9			
		DAY 57	07AUG2003	56		54.0	23.4	1.0	0.5	
	E0010004	SCREEN	05DEC2002	-6	158.0	68.0	27.2			
		DAY 57	06FEB2003	58		68.0	27.2	0.0	0.0	
	E0010012	SCREEN	30DEC2002	-8	173.0	122.0	40.8			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	DAY 57	05MAR2003	58		123.0	41.1	1.0	0.3	
	E0010024	SCREEN	23APR2003	-12	170.0	98.0	33.9			
		DAY 57	02JUL2003	59		100.0	34.6	2.0	0.7	
	E0010032	SCREEN	03JUL2003	-7	171.0	87.0	29.8			
		DAY 8	17JUL2003	8		87.0	29.8	0.0	0.0	
	E0011025	SCREEN	20JUN2003	-6	152.0	54.0	23.4			
		DAY 57	22AUG2003	58		56.0	24.2	2.0	0.8	
	E0013007	SCREEN	14MAR2003	-6	180.0	90.0	27.8			
		DAY 15	07APR2003	19		90.0	27.8	0.0	0.0	
	E0013009	SCREEN	26MAR2003	-7	173.0	104.0	34.7			
		DAY 57	29MAY2003	58		108.0	36.1	4.0	1.4	
	E0014006	SCREEN	11MAR2003	-14	158.0	101.0	40.5			
		DAY 57	21MAY2003	58		106.0	42.5	5.0	2.0	
	E0014010	SCREEN	15APR2003	-7	170.0	103.0	35.6			
		DAY 57	17JUN2003	57		104.0	36.0	1.0	0.4	
	E0016001	SCREEN	02JAN2003	-20	161.0	69.0	26.6			
		DAY 57	19MAR2003	57		73.0	28.2	4.0	1.6	
	E0016004	SCREEN	27JAN2003	-7	173.0	91.0	30.4			
	E0018001	SCREEN	22OCT2002	-7	168.0	93.0	33.0			
		DAY 57	24DEC2002	57		94.0	33.3	1.0	0.3	
	E0018006	SCREEN	10DEC2002	-7	180.0	94.0	29.0			
		DAY 57	13FEB2003	59		94.0	29.0	0.0	0.0	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	SCREEN	30OCT2002	-8	163.0	62.0	23.3			
	E0019011	SCREEN	12NOV2002	-9	151.0	93.0	40.8			
		DAY 57	16JAN2003	57		94.0	41.2	1.0	0.4	
	E0019025	SCREEN	30JAN2003	-7	165.0	62.0	22.8			
		DAY 57	03APR2003	57		60.0	22.0	-2.0	-0.8	
	E0019026	SCREEN	10FEB2003	-14	158.0	100.0	40.1			
	E0019043	SCREEN	21MAY2003	-13	170.0	67.0	23.2			
		DAY 57	29JUL2003	57		68.0	23.5	1.0	0.3	
	E0020001	SCREEN	15OCT2002	-14	168.0	79.0	28.0			
		DAY 50	20DEC2002	53		84.0	29.8	5.0	1.8	
	E0020006	SCREEN	26NOV2002	-20	166.0	114.0	41.4			
		DAY 22	08JAN2003	24		104.0	37.7	-10.0	-3.7	D
	E0020007	SCREEN	19DEC2002	-27	155.0	47.0	19.6			
		DAY 57	25MAR2003	70		47.0	19.6	0.0	0.0	
	E0020011	SCREEN	19FEB2003	-7	170.0	99.0	34.3			
		DAY 57	23APR2003	57		100.0	34.6	1.0	0.3	
	E0020013	SCREEN	25FEB2003	-8	173.0	81.0	27.1			
		DAY 22	25MAR2003	21		83.0	27.7	2.0	0.6	
	E0022008	SCREEN	05NOV2002	-7	175.0	84.0	27.4			
		DAY 57	07JAN2003	57		83.0	27.1	-1.0	-0.3	
	E0022017	SCREEN	03DEC2002	-16	193.0	96.0	25.8			
		DAY 57	13FEB2003	57		97.0	26.0	1.0	0.2	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	SCREEN	04DEC2002	-8	188.0	123.0	34.8			
		DAY 57	06FEB2003	57		126.0	35.6	3.0	0.8	
	E0022022	SCREEN	16DEC2002	-14	159.0	50.0	19.8			
		DAY 57	27FEB2003	60		50.0	19.8	0.0	0.0	
	E0022027	SCREEN	23JAN2003	-14	186.0	121.0	35.0			
		DAY 57	03APR2003	57		118.0	34.1	-3.0	-0.9	
	E0022030	SCREEN	07FEB2003	-7	173.0	140.0	46.8			
	E0022031	SCREEN	10FEB2003	-8	177.0	86.0	27.5			
		DAY 57	15APR2003	57		90.0	28.7	4.0	1.2	
	E0022032	SCREEN	11FEB2003	-7	170.0	66.0	22.8			
		DAY 57	18APR2003	60		66.0	22.8	0.0	0.0	
	E0022035	SCREEN	11FEB2003	-8	157.0	73.0	29.6			
		DAY 8	26FEB2003	8		75.0	30.4	2.0	0.8	
	E0022036	SCREEN	13FEB2003	-12	183.0	74.0	22.1			
		DAY 57	22APR2003	57		78.0	23.3	4.0	1.2	
	E0022056	SCREEN	09APR2003	-8	163.0	78.0	29.4			
	E0022060	SCREEN	23APR2003	-7	182.0	76.0	22.9			
		DAY 57	24JUN2003	56		75.0	22.6	-1.0	-0.3	
	E0022063	SCREEN	30APR2003	-7	177.0	85.0	27.1			
	E0023008	SCREEN	23JAN2003	-7	170.0	64.0	22.1			
		DAY 50	24MAR2003	54		68.0	23.5	4.0	1.4	
	E0023013	SCREEN	13FEB2003	-14	163.0	66.0	24.8			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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I: Potentially Clinically Important increase.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0023013	DAY 8	06MAR2003	8		66.0	24.8	0.0	0.0	
	E0023015	SCREEN	04MAR2003	-7	173.0	64.0	21.4			
		DAY 57	06MAY2003	57		65.0	21.7	1.0	0.3	
	E0023034	SCREEN	03JUN2003	-6	163.0	60.0	22.6			
		DAY 57	05AUG2003	58		60.0	22.6	0.0	0.0	
	E0023037	SCREEN	11JUN2003	-7	188.0	86.0	24.3			
		DAY 57	15AUG2003	59		91.0	25.7	5.0	1.4	
	E0023038	SCREEN	20JUN2003	-10	170.0	100.0	34.6			
		DAY 57	27AUG2003	59		94.0	32.5	-6.0	-2.1	
	E0023044	SCREEN	08JUL2003	-8	168.0	115.0	40.7			
		DAY 29	12AUG2003	28		116.0	41.1	1.0	0.4	
	E0023045	SCREEN	10JUL2003	-7	178.0	64.0	20.2			
		DAY 57	11SEP2003	57		70.0	22.1	6.0	1.9	I
	E0025002	SCREEN	27MAR2003	-7	168.0	100.0	35.4			
		DAY 57	29MAY2003	57		105.0	37.2	5.0	1.8	
	E0026010	SCREEN	15JAN2003	-7	180.0	94.0	29.0			
		DAY 8	30JAN2003	9		96.0	29.6	2.0	0.6	
	E0026017	SCREEN	26FEB2003	-8	173.0	85.0	28.4			
		DAY 15	21MAR2003	16		86.0	28.7	1.0	0.3	
	E0026018	SCREEN	06MAR2003	-14	168.0	109.0	38.6			
		DAY 57	15MAY2003	57		109.0	38.6	0.0	0.0	
	E0026025	SCREEN	01MAY2003	-8	173.0	74.0	24.7			
		DAY 57	03JUL2003	56		80.0	26.7	6.0	2.0	I

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
GENERATED: 12JUL2005 17:46:50 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0026029	SCREEN	02JUL2003	-7	157.0	158.0	64.1			
		DAY 22	28JUL2003	20		59.0	23.9	-99.0	-40.2	D
	E0026030	SCREEN	02JUL2003	-7	185.0	89.0	26.0			
		DAY 57	03SEP2003	57		90.0	26.3	1.0	0.3	
	E0026031	SCREEN	10JUL2003	-11	188.0	86.0	24.3			
		DAY 57	15SEP2003	57		74.0	20.9	-12.0	-3.4	D
	E0027003	SCREEN	08JAN2003	-20	163.0	76.0	28.6			
		DAY 57	25MAR2003	57		84.0	31.6	8.0	3.0	I
	E0028004	SCREEN	27SEP2002	-3	198.0	82.0	20.9			
		DAY 8	09OCT2002	10		83.0	21.2	1.0	0.3	
	E0028006	SCREEN	01OCT2002	-3	163.0	64.0	24.1			
		DAY 57	04DEC2002	62		63.0	23.7	-1.0	-0.4	
	E0028008	SCREEN	08OCT2002	-7	183.0	112.0	33.4			
		DAY 57	10DEC2002	57		105.0	31.4	-7.0	-2.0	
	E0028009	SCREEN	10OCT2002	-5	168.0	90.0	31.9			
		DAY 57	12DEC2002	59		95.0	33.7	5.0	1.8	
	E0028016	SCREEN	07NOV2002	-7	183.0	95.0	28.4			
		DAY 57	09JAN2003	57		93.0	27.8	-2.0	-0.6	
	E0028017		12NOV2002		165.0	91.0	33.4			
	E0028027	SCREEN	14JAN2003	-7	178.0	89.0	28.1			
	E0028029	SCREEN	28JAN2003	-7	181.0	96.0	29.3			
		DAY 57	04APR2003	60		99.0	30.2	3.0	0.9	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0028034	SCREEN	20MAR2003	-12	168.0	86.0	30.5			
		DAY 57	02JUN2003	63		86.0	30.5	0.0	0.0	
	E0028038	SCREEN	18APR2003	-7	173.0	138.0	46.1			
		DAY 57	18JUN2003	55		136.0	45.4	-2.0	-0.7	
	E0028043	SCREEN	29MAY2003	-7	168.0	86.0	30.5			
		DAY 57	29JUL2003	55		87.0	30.8	1.0	0.3	
	E0028045	SCREEN	09JUN2003	-9	183.0	72.0	21.5			
		DAY 57	11SEP2003	86		73.0	21.8	1.0	0.3	
	E0029005	SCREEN	14NOV2002	-13	168.0	96.0	34.0			
		DAY 57	21JAN2003	56		107.0	37.9	11.0	3.9	I
	E0030001	SCREEN	12NOV2002	-7	172.0	63.0	21.3			
		DAY 57	16JAN2003	59		65.0	22.0	2.0	0.7	
	E0030008	SCREEN	07JAN2003	-7	183.0	90.0	26.9			
		DAY 57	18MAR2003	64		85.0	25.4	-5.0	-1.5	
	E0030011	SCREEN	16JAN2003	-11	170.0	108.0	37.4			
		DAY 57	24MAR2003	57		111.0	38.4	3.0	1.0	
	E0030015	SCREEN	13FEB2003	-8	185.0	91.0	26.6			
		DAY 57	22APR2003	61		87.0	25.4	-4.0	-1.2	
	E0030022	SCREEN	06JUN2003	-10	155.0	92.0	38.3			
		DAY 57	14AUG2003	60		90.0	37.5	-2.0	-0.8	
	E0031002	SCREEN	20NOV2002	-7	166.0	59.0	21.4			
		DAY 57	22JAN2003	57		57.0	20.7	-2.0	-0.7	
	E0031003	SCREEN	03DEC2002	-7	176.0	72.0	23.2			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0031003	DAY 57	04FEB2003	57		73.0	23.6	1.0	0.4	
	E0033015	SCREEN	03APR2003	-7	168.0	60.0	21.3			
		DAY 57	04JUN2003	56		62.0	22.0	2.0	0.7	
	E0034002	SCREEN	14MAR2003	-11	170.0	98.0	33.9			
		DAY 22	15APR2003	22		100.0	34.6	2.0	0.7	
	E0034003	SCREEN	11APR2003	-13	173.0	77.0	25.7			
		DAY 57	19JUN2003	57		77.0	25.7	0.0	0.0	
	E0034006	SCREEN	25APR2003	-21	173.0	150.0	50.1			
		DAY 57	10JUL2003	56		153.0	51.1	3.0	1.0	
	E0034008	SCREEN	15MAY2003	-9	175.0	85.0	27.8			
		DAY 57	21JUL2003	59		85.0	27.8	0.0	0.0	
	E0035003	SCREEN	15NOV2002	-7	188.0	108.0	30.6			
	E0035005	SCREEN	26NOV2002	-7	170.0	81.0	28.0			
	E0035014	SCREEN	28JAN2003	-6	155.0	66.0	27.5			
		DAY 57	31MAR2003	57		64.0	26.6	-2.0	-0.9	
	E0035024	SCREEN	15MAY2003	-8	165.0	114.0	41.9			
		DAY 57	18JUL2003	57		115.0	42.2	1.0	0.3	
	E0036005	SCREEN	24JUN2003	-7	152.0	97.0	42.0			
		DAY 57	27AUG2003	58		95.0	41.1	-2.0	-0.9	
	E0037002	SCREEN	18DEC2002	-8	168.0	77.0	27.3			
		DAY 57	20FEB2003	57		81.0	28.7	4.0	1.4	
	E0037005	SCREEN	26FEB2003	-8	165.0	95.0	34.9			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0037005	DAY 57	01MAY2003	57		98.0	36.0	3.0	1.1	
	E0037006	SCREEN	06MAR2003	-8	156.0	57.0	23.4			
		DAY 57	09MAY2003	57		61.0	25.1	4.0	1.7	I
	E0039006	SCREEN	10DEC2002	-20	152.0	65.0	28.1			
		DAY 57	24FEB2003	57		66.0	28.6	1.0	0.5	
	E0039015	SCREEN	02JAN2003	-21	183.0	79.0	23.6			
		DAY 57	20MAR2003	57		81.0	24.2	2.0	0.6	
	E0039024	SCREEN	05FEB2003	-22	173.0	98.0	32.7			
		DAY 57	24APR2003	57		100.0	33.4	2.0	0.7	
	E0039025	SCREEN	26FEB2003	-20	179.0	96.0	30.0			
		DAY 57	27MAY2003	71		96.0	30.0	0.0	0.0	
	E0039041	SCREEN	07APR2003	-8	178.0	75.0	23.7			
		DAY 57	11JUN2003	58		74.0	23.4	-1.0	-0.3	
	E0039044	SCREEN	05MAY2003	-17	173.0	82.0	27.4			
		DAY 50	09JUL2003	49		80.0	26.7	-2.0	-0.7	
	E0039046		06MAY2003		152.0	101.0	43.7			
			30MAY2003			102.0	44.1			
	E0039051	SCREEN	22MAY2003	-25	165.0	82.0	30.1			
		DAY 57	12AUG2003	58		81.0	29.8	-1.0	-0.3	
	E0039053	SCREEN	16JUN2003	-25	183.0	87.0	26.0			
		DAY 57	08SEP2003	60		87.0	26.0	0.0	0.0	
	E0039057	SCREEN	02JUL2003	-12	178.0	97.0	30.6			
		DAY 57	09SEP2003	58		99.0	31.2	2.0	0.6	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR I)	E0041003	SCREEN	16JAN2003	-12	163.0	96.0	36.1			
		DAY 57	25MAR2003	57		98.0	36.9	2.0	0.8	
	E0041008	SCREEN	26MAR2003	-12	167.0	70.0	25.1			
		DAY 57	02JUN2003	57		67.0	24.0	-3.0	-1.1	
	E0042001	SCREEN	17JUN2003	-15	168.0	87.0	30.8			
		DAY 57	26AUG2003	56		87.0	30.8	0.0	0.0	
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	SCREEN	26FEB2003	-14	158.0	68.0	27.2			
		DAY 57	07MAY2003	57		69.0	27.6	1.0	0.4	
	E0003018	SCREEN	06MAY2003	-7	166.0	56.0	20.3			
		DAY 57	08JUL2003	57		61.0	22.1	5.0	1.8	I
	E0005011	SCREEN	16OCT2002	-8	178.0	83.0	26.2			
	E0005030	SCREEN	18MAR2003	-8	167.0	59.0	21.2			
	E0005036	SCREEN	28APR2003	-8	142.0	90.0	44.6			
		DAY 22	27MAY2003	22		90.0	44.6	0.0	0.0	
	E0006015	SCREEN	06FEB2003	-5	163.0	76.0	28.6			
		DAY 57	08APR2003	57		81.0	30.5	5.0	1.9	
	E0006016	SCREEN	07FEB2003	-10	180.0	87.0	26.9			
		DAY 57	18APR2003	61		86.0	26.5	-1.0	-0.4	
	E0007008	SCREEN	07APR2003	-11	168.0	125.0	44.3			
		DAY 8	25APR2003	8		127.0	45.0	2.0	0.7	
	E0009002	SCREEN	29OCT2002	-21	182.0	103.0	31.1			
		DAY 57	15JAN2003	58		104.0	31.4	1.0	0.3	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR II)	E0009006	SCREEN	22JAN2003	-6	185.0	78.0	22.8			
		DAY 57	25MAR2003	57		86.0	25.1	8.0	2.3	I
	E0009009	SCREEN	27FEB2003	-13	177.0	85.0	27.1			
		DAY 15	24MAR2003	13		88.0	28.1	3.0	1.0	
	E0010015	SCREEN	29JAN2003	-22	178.0	112.0	35.3			
		DAY 57	15APR2003	55		116.0	36.6	4.0	1.3	
	E0011004	SCREEN	17DEC2002	-7	178.0	91.0	28.7			
		DAY 57	18FEB2003	57		93.0	29.4	2.0	0.7	
	E0011007	SCREEN	12DEC2002	-7	161.0	95.0	36.6			
		DAY 57	13FEB2003	57		95.0	36.6	0.0	0.0	
	E0011018	SCREEN	15MAY2003	-7	170.0	76.0	26.3			
		DAY 57	17JUL2003	57		72.0	24.9	-4.0	-1.4	
	E0011024	SCREEN	17JUN2003	-7	165.0	96.0	35.3			
		DAY 57	21AUG2003	59		99.0	36.4	3.0	1.1	
	E0015003	SCREEN	13NOV2002	-12	152.0	64.0	27.7			
		DAY 8	02DEC2002	8		64.0	27.7	0.0	0.0	
	E0019003	SCREEN	29OCT2002	-23	161.0	78.0	30.1			
		DAY 57	16JAN2003	57		81.0	31.2	3.0	1.1	
	E0019007	SCREEN	06NOV2002	-7	171.0	64.0	21.9			
		DAY 57	07JAN2003	56		64.0	21.9	0.0	0.0	
	E0019014	SCREEN	17DEC2002	-23	178.0	63.0	19.9			
		DAY 8	20JAN2003	12		63.0	19.9	0.0	0.0	
	E0019018	SCREEN	14JAN2003	-16	173.0	104.0	34.7			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR II)	E0019018	DAY 57	27MAR2003	57		108.0	36.1	4.0	1.4	
	E0019022	SCREEN	23JAN2003	-7	163.0	97.0	36.5			
		DAY 57	27MAR2003	57		96.0	36.1	-1.0	-0.4	
	E0019027	SCREEN	20FEB2003	-7	163.0	96.0	36.1			
		DAY 8	06MAR2003	8		99.0	37.3	3.0	1.2	
	E0019032	SCREEN	06MAR2003	-26	166.0	66.0	24.0			
		DAY 57	27MAY2003	57		71.0	25.8	5.0	1.8	I
	E0019034	SCREEN	10MAR2003	-8	161.0	95.0	36.6			
	E0019036	SCREEN	18MAR2003	-7	173.0	74.0	24.7			
	E0019039	SCREEN	22APR2003	-9	181.0	70.0	21.4			
	E0019041	SCREEN	14MAY2003	-7	165.0	68.0	25.0			
		DAY 57	16JUL2003	57		69.0	25.3	1.0	0.3	
	E0019049	SCREEN	03JUL2003	-7	170.0	83.0	28.7			
		DAY 57	08SEP2003	61		80.0	27.7	-3.0	-1.0	
	E0022052	SCREEN	01APR2003	-9	173.0	92.0	30.7			
		DAY 57	05JUN2003	57		93.0	31.1	1.0	0.4	
	E0022064	SCREEN	29APR2003	-7	190.0	70.0	19.4			
		DAY 57	01JUL2003	57		69.0	19.1	-1.0	-0.3	
	E0022073	SCREEN	19JUN2003	-7	157.0	61.0	24.7			
		DAY 57	21AUG2003	57		66.0	26.8	5.0	2.1	I
	E0023002	SCREEN	25OCT2002	-11	170.0	82.0	28.4			
		DAY 36	10DEC2002	36		82.0	28.4	0.0	0.0	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	SCREEN	14MAR2003	-11	178.0	63.0	19.9			
		DAY 57	22MAY2003	59		68.0	21.5	5.0	1.6	I
	E0023021	SCREEN	10APR2003	-13	185.0	135.0	39.4			
		DAY 57	17JUN2003	56		131.0	38.3	-4.0	-1.1	
	E0023027	SCREEN	07MAY2003	-9	173.0	113.0	37.8			
		DAY 57	09JUL2003	55		118.0	39.4	5.0	1.6	
	E0023030	SCREEN	16MAY2003	-18	160.0	87.0	34.0			
		DAY 57	30JUL2003	58		90.0	35.2	3.0	1.2	
	E0023040	SCREEN	25JUN2003	-8	170.0	94.0	32.5			
		DAY 57	05SEP2003	65		97.0	33.6	3.0	1.1	
	E0026014	SCREEN	12FEB2003	-7	175.0	78.0	25.5			
		DAY 29	19MAR2003	29		78.0	25.5	0.0	0.0	
	E0026019	SCREEN	10MAR2003	-7	168.0	77.0	27.3			
		DAY 57	12MAY2003	57		78.0	27.6	1.0	0.3	
	E0027005	SCREEN	19DEC2002	-7	170.0	75.0	26.0			
		DAY 57	20FEB2003	57		81.0	28.0	6.0	2.0	I
	E0029009	SCREEN	13JAN2003	-7	183.0	103.0	30.8			
		DAY 57	18MAR2003	58		105.0	31.4	2.0	0.6	
	E0029021	SCREEN	03MAR2003	-15	164.0	80.0	29.7			
		DAY 57	15MAY2003	59		82.0	30.5	2.0	0.8	
	E0029026	SCREEN	07APR2003	-7	183.0	100.0	29.9			
		DAY 57	10JUN2003	58		100.0	29.9	0.0	0.0	
	E0029030	SCREEN	13MAY2003	-14	160.0	63.0	24.6			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	DAY 57	23JUL2003	58		68.0	26.6	5.0	2.0	I
	E0031008	SCREEN	05FEB2003	-23	157.0	70.0	28.4			
		DAY 57	24APR2003	56		70.0	28.4	0.0	0.0	
	E0031020	SCREEN	14APR2003	-7	178.0	87.0	27.5			
		DAY 22	13MAY2003	23		87.0	27.5	0.0	0.0	
	E0031021	SCREEN	18APR2003	-7	185.0	90.0	26.3			
		DAY 57	19JUN2003	56		90.0	26.3	0.0	0.0	
	E0031029	SCREEN	05JUN2003	-13	183.0	81.0	24.2			
		DAY 22	08JUL2003	21		81.0	24.2	0.0	0.0	
	E0033002	SCREEN	23DEC2002	-18	168.0	86.0	30.5			
		DAY 57	07MAR2003	57		87.0	30.8	1.0	0.3	
	E0033006	SCREEN	15JAN2003	-8	175.0	76.0	24.8			
		DAY 22	12FEB2003	21		76.0	24.8	0.0	0.0	
	E0033021	SCREEN	25JUN2003	-7	163.0	62.0	23.3			
		DAY 50	18AUG2003	48		68.0	25.6	6.0	2.3	I
	E0035013	SCREEN	27JAN2003	-8	158.0	86.0	34.4			
		DAY 8	10FEB2003	7		158.0	63.3	72.0	28.9	I
	E0035015	SCREEN	03FEB2003	-8	162.0	132.0	50.3			
		DAY 8	18FEB2003	8		132.0	50.3	0.0	0.0	
	E0035016	SCREEN	10MAR2003	-25	168.0	117.0	41.5			
	E0035023	SCREEN	06MAY2003	-7	180.0	88.0	27.2			
	E0039052	SCREEN	29MAY2003	-22	188.0	136.0	38.5			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
GENERATED: 12JUL2005 17:46:50 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 300 MG (BIPOLAR II)	E0039052	DAY 15	03JUL2003	14		133.0	37.6	-3.0	-0.9	
	E0039056	SCREEN	01JUL2003	-14	183.0	95.0	28.4			
	E0040003	SCREEN	09JUL2003	-10	165.0	65.0	23.9			
		DAY 57	12SEP2003	56		69.0	25.3	4.0	1.4	
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	SCREEN	19FEB2003	-12	152.0	81.0	35.1			
		DAY 57	02MAY2003	61		81.0	35.1	0.0	0.0	
	E0002011	SCREEN	16APR2003	-13	173.0	74.0	24.7			
		DAY 57	25JUN2003	58		80.0	26.7	6.0	2.0	I
	E0003010	SCREEN	27JAN2003	-7	163.0	60.0	22.6			
		DAY 57	31MAR2003	57		66.0	24.8	6.0	2.2	I
	E0003011	SCREEN	28JAN2003	-7	165.0	109.0	40.0			
	E0003016	SCREEN	01MAY2003	-21	168.0	74.0	26.2			
		DAY 22	12JUN2003	22		75.0	26.6	1.0	0.4	
	E0003019	SCREEN	19JUN2003	-8	184.0	88.0	26.0			
		DAY 57	21AUG2003	56		94.0	27.8	6.0	1.8	
	E0003020	SCREEN	24JUN2003	-29	175.0	108.0	35.3			
		DAY 57	17SEP2003	57		109.0	35.6	1.0	0.3	
	E0004001	SCREEN	23SEP2002	-7	160.0	44.0	17.2			
		DAY 36	05NOV2002	37		43.0	16.8	-1.0	-0.4	
	E0004009	SCREEN	17DEC2002	-9	155.0	64.0	26.6			
		DAY 57	19FEB2003	56		65.0	27.1	1.0	0.5	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	SCREEN	07JAN2003	-7	157.0	50.0	20.3			
		DAY 57	11MAR2003	57		53.0	21.5	3.0	1.2	
	E0004015	SCREEN	06FEB2003	-14	188.0	117.0	33.1			
		DAY 57	15APR2003	55		122.0	34.5	5.0	1.4	
	E0005003	SCREEN	23SEP2002	-9	185.0	101.0	29.5			
		DAY 57	26NOV2002	56		104.0	30.4	3.0	0.9	
	E0005007	SCREEN	02OCT2002	-7	163.0	80.0	30.1			
		DAY 57	04DEC2002	57		82.0	30.9	2.0	0.8	
	E0005008	SCREEN	08OCT2002	-7	170.0	124.0	42.9			
		DAY 57	11DEC2002	58		130.0	45.0	6.0	2.1	
	E0005009	SCREEN	09OCT2002	-20	183.0	87.0	26.0			
	E0005010	SCREEN	14OCT2002	-7	183.0	156.0	46.6			
		DAY 57	17DEC2002	58		153.0	45.7	-3.0	-0.9	
	E0005012	SCREEN	24OCT2002	-21	180.0	86.0	26.5			
		DAY 57	07JAN2003	55		91.0	28.1	5.0	1.6	
	E0005014	SCREEN	05NOV2002	-8	188.0	85.0	24.0			
		DAY 57	06JAN2003	55		94.0	26.6	9.0	2.6	I
	E0005022	SCREEN	23JAN2003	-6	183.0	93.0	27.8			
		DAY 36	06MAR2003	37		92.0	27.5	-1.0	-0.3	
	E0005025	SCREEN	20FEB2003	-7	158.0	72.0	28.8			
		DAY 36	03APR2003	36		78.0	31.2	6.0	2.4	I
	E0006019	SCREEN	26MAR2003	-12	183.0	83.0	24.8			
		DAY 57	03JUN2003	58		86.0	25.7	3.0	0.9	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0007005	SCREEN	27JAN2003	-4	167.0	80.0	28.7			
		DAY 57	28MAR2003	57		82.0	29.4	2.0	0.7	
	E0007015	SCREEN	09JUL2003	-7	160.0	65.0	25.4			
		DAY 57	10SEP2003	57		69.0	27.0	4.0	1.6	
	E0009001	SCREEN	29OCT2002	-14	160.0	93.0	36.3			
	E0010002	SCREEN	14NOV2002	-11	173.0	81.0	27.1			
		DAY 8	02DEC2002	8		82.0	27.4	1.0	0.3	
	E0010009	SCREEN	18DEC2002	-8	171.0	79.0	27.0			
		DAY 57	19FEB2003	56		81.0	27.7	2.0	0.7	
	E0010010	SCREEN	20DEC2002	-10	155.0	53.0	22.1			
		DAY 15	13JAN2003	15		55.0	22.9	2.0	0.8	
	E0010014	SCREEN	14JAN2003	-14	173.0	87.0	29.1			
		DAY 57	25MAR2003	57		82.0	27.4	-5.0	-1.7	
	E0010017	SCREEN	05FEB2003	-20	183.0	95.0	28.4			
		DAY 57	22APR2003	57		94.0	28.1	-1.0	-0.3	
	E0010023	SCREEN	10APR2003	-7	165.0	73.0	26.8			
		DAY 15	01MAY2003	15		78.0	28.7	5.0	1.9	
	E0010027	SCREEN	05JUN2003	-11	173.0	76.0	25.4			
		DAY 15	01JUL2003	16		76.0	25.4	0.0	0.0	
	E0010029	SCREEN	10JUN2003	-9	170.0	129.0	44.6			
	E0011022	SCREEN	02JUN2003	-7	161.0	87.0	33.6			
		DAY 57	05AUG2003	58		67.0	25.8	-20.0	-7.8	D

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	SCREEN	06MAR2003	-7	183.0	126.0	37.6			
		DAY 8	24MAR2003	12		128.0	38.2	2.0	0.6	
	E0013012	SCREEN	29APR2003	-8	160.0	95.0	37.1			
		DAY 57	02JUL2003	57		100.0	39.1	5.0	2.0	
	E0013014	SCREEN	08MAY2003	-26	183.0	72.0	21.5			
		DAY 29	30JUN2003	28		75.0	22.4	3.0	0.9	
	E0014005	SCREEN	04MAR2003	-7	160.0	69.0	27.0			
		DAY 57	06MAY2003	57		72.0	28.1	3.0	1.1	
	E0014007	SCREEN	25MAR2003	-7	155.0	60.0	25.0			
		DAY 22	22APR2003	22		60.0	25.0	0.0	0.0	
	E0014011	SCREEN	06MAY2003	-7	183.0	89.0	26.6			
		DAY 57	08JUL2003	57		90.0	26.9	1.0	0.3	
	E0014012	SCREEN	19MAY2003	-8	165.0	72.0	26.4			
		DAY 29	24JUN2003	29		72.0	26.4	0.0	0.0	
	E0015001	SCREEN	08NOV2002	-21	187.0	106.0	30.3			
		DAY 50	20JAN2003	53		107.0	30.6	1.0	0.3	
	E0015008	SCREEN	13DEC2002	-6	183.0	73.0	21.8			
	E0016003	SCREEN	10JAN2003	-14	165.0	127.0	46.6			
	E0016005	SCREEN	20FEB2003	-5	168.0	75.0	26.6			
		DAY 57	22APR2003	57		76.0	26.9	1.0	0.3	
	E0018007	SCREEN	16DEC2002	-11	165.0	85.0	31.2			
		DAY 15	10JAN2003	15		83.0	30.5	-2.0	-0.7	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	SCREEN	30OCT2002	-6	163.0	66.0	24.8			
		DAY 57	02JAN2003	59		66.0	24.8	0.0	0.0	
	E0019015	SCREEN	19DEC2002	-14	173.0	81.0	27.1			
		DAY 57	27FEB2003	57		80.0	26.7	-1.0	-0.4	
	E0020004	SCREEN	21NOV2002	-18	170.0	91.0	31.5			
		DAY 43	22JAN2003	45		91.0	31.5	0.0	0.0	
	E0020010	SCREEN	28JAN2003	-8	160.0	64.0	25.0			
		DAY 57	02APR2003	57		66.0	25.8	2.0	0.8	
	E0020014	SCREEN	11MAR2003	-7	165.0	54.0	19.8			
		DAY 57	12MAY2003	56		54.0	19.8	0.0	0.0	
	E0020021	SCREEN	13MAY2003	-6	173.0	143.0	47.8			
		DAY 57	14JUL2003	57		152.0	50.8	9.0	3.0	
	E0020023	SCREEN	09JUN2003	-8	173.0	99.0	33.1			
		DAY 57	11AUG2003	56		99.0	33.1	0.0	0.0	
	E0022007	SCREEN	01NOV2002	-6	158.0	82.0	32.8			
	E0022010	SCREEN	14NOV2002	-7	184.0	80.0	23.6			
		DAY 57	16JAN2003	57		81.0	23.9	1.0	0.3	
	E0022012	SCREEN	21NOV2002	-14	177.0	108.0	34.5			
		DAY 57	30JAN2003	57		112.0	35.7	4.0	1.2	
	E0022019	SCREEN	04DEC2002	-7	181.0	102.0	31.1			
		DAY 57	06FEB2003	58		104.0	31.7	2.0	0.6	
	E0022025	SCREEN	08JAN2003	-20	160.0	72.0	28.1			
		DAY 8	04FEB2003	8		72.0	28.1	0.0	0.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	SCREEN	11FEB2003	-7	162.0	74.0	28.2			
		DAY 57	15APR2003	57		77.0	29.3	3.0	1.1	
	E0022034	SCREEN	11FEB2003	-7	178.0	104.0	32.8			
		DAY 57	15APR2003	57		104.0	32.8	0.0	0.0	
	E0022038	SCREEN	20FEB2003	-8	188.0	101.0	28.6			
		DAY 43	11APR2003	43		103.0	29.1	2.0	0.5	
	E0022039	SCREEN	27FEB2003	-7	168.0	134.0	47.5			
		DAY 57	01MAY2003	57		135.0	47.8	1.0	0.3	
	E0022046	SCREEN	13MAR2003	-7	158.0	75.0	30.0			
		DAY 57	16MAY2003	58		78.0	31.2	3.0	1.2	
	E0022048	SCREEN	25MAR2003	-7	157.0	55.0	22.3			
	E0022051	SCREEN	31MAR2003	-7	164.0	80.0	29.7			
		DAY 57	02JUN2003	57		86.0	32.0	6.0	2.3	I
	E0022053	SCREEN	04APR2003	-7	160.0	86.0	33.6			
	E0022058	SCREEN	11APR2003	-10	179.0	82.0	25.6			
		DAY 29	22MAY2003	32		84.0	26.2	2.0	0.6	
	E0022061	SCREEN	24APR2003	-6	167.0	73.0	26.2			
		DAY 57	26JUN2003	58		77.0	27.6	4.0	1.4	
	E0022062	SCREEN	25APR2003	-10	180.0	110.0	34.0			
		DAY 15	23MAY2003	19		109.0	33.6	-1.0	-0.4	
	E0022068	SCREEN	14MAY2003	-9	169.0	89.0	31.2			
	E0022069	SCREEN	03JUN2003	-7	175.0	68.0	22.2			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0022069	DAY 57	05AUG2003	57		66.0	21.6	-2.0	-0.6	
	E0022071	SCREEN	16JUN2003	-14	180.0	76.0	23.5			
		DAY 57	25AUG2003	57		77.0	23.8	1.0	0.3	
	E0023003	SCREEN	12DEC2002	-5	185.0	87.0	25.4			
		DAY 57	11FEB2003	57		87.0	25.4	0.0	0.0	
	E0023006	SCREEN	10DEC2002	-7	175.0	69.0	22.5			
		DAY 57	11FEB2003	57		70.0	22.9	1.0	0.4	
	E0023010	SCREEN	28JAN2003	-7	185.0	102.0	29.8			
		DAY 57	31MAR2003	56		114.0	33.3	12.0	3.5	I
	E0023025	SCREEN	01MAY2003	-14	188.0	77.0	21.8			
		DAY 57	10JUL2003	57		77.0	21.8	0.0	0.0	
	E0023039	SCREEN	24JUN2003	-7	163.0	79.0	29.7			
		DAY 57	26AUG2003	57		81.0	30.5	2.0	0.8	
	E0026002	SCREEN	05NOV2002	-7	175.0	84.0	27.4			
		DAY 57	09JAN2003	59		86.0	28.1	2.0	0.7	
	E0026007	SCREEN	06JAN2003	-10	168.0	103.0	36.5			
		DAY 57	12MAR2003	56		107.0	37.9	4.0	1.4	
	E0026013	SCREEN	05FEB2003	-8	170.0	81.0	28.0			
		DAY 57	14APR2003	61		76.0	26.3	-5.0	-1.7	
	E0028007	SCREEN	01OCT2002	-3	155.0	41.0	17.1			
		DAY 43	14NOV2002	42		43.0	17.9	2.0	0.8	
	E0028023	SCREEN	14JAN2003	-7	170.0	72.0	24.9			
		DAY 57	27JUN2003	158		73.0	25.3	1.0	0.4	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	SCREEN	08JAN2003	-5	178.0	75.0	23.7			
		DAY 15	27JAN2003	15		75.0	23.7	0.0	0.0	
	E0028033	SCREEN	18MAR2003	-9	170.0	83.0	28.7			
		DAY 57	22MAY2003	57		83.0	28.7	0.0	0.0	
	E0028035	SCREEN	27MAR2003	-7	180.0	106.0	32.7			
		DAY 57	29MAY2003	57		114.0	35.2	8.0	2.5	I
	E0028037	SCREEN	04JUN2003	-9	180.0	95.0	29.3			
		DAY 57	08AUG2003	57		85.0	26.2	-10.0	-3.1	D
	E0028039	SCREEN	02MAY2003	-7	178.0	71.0	22.4			
		DAY 29	05JUN2003	28		70.0	22.1	-1.0	-0.3	
	E0028046	SCREEN	17JUN2003	-8	170.0	93.0	32.2			
	E0028048	SCREEN	11JUL2003	-6	158.0	67.0	26.8			
	E0029008	SCREEN	09DEC2002	-7	141.0	57.0	28.7			
		DAY 8	23DEC2002	8		58.0	29.2	1.0	0.5	
	E0029011	SCREEN	14JAN2003	-8	193.0	122.0	32.8			
	E0029012	SCREEN	04FEB2003	-7	170.0	99.0	34.3			
		DAY 36	18MAR2003	36		103.0	35.6	4.0	1.3	
	E0029015	SCREEN	11FEB2003	-13	168.0	64.0	22.7			
		DAY 15	11MAR2003	16		65.0	23.0	1.0	0.3	
	E0029018	SCREEN	26FEB2003	-8	173.0	81.0	27.1			
	E0030014	SCREEN	12FEB2003	-9	168.0	60.0	21.3			
		DAY 57	22APR2003	61		64.0	22.7	4.0	1.4	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0030020	SCREEN	13MAY2003	-16	191.0	120.0	32.9			
	E0030024	SCREEN	17JUN2003	-24	158.0	61.0	24.4			
		DAY 8	18JUL2003	8		62.0	24.8	1.0	0.4	
	E0030025	SCREEN	24JUN2003	-17	168.0	82.0	29.1			
		DAY 36	19AUG2003	40		81.0	28.7	-1.0	-0.4	
	E0031027	SCREEN	27MAY2003	-7	173.0	64.0	21.4			
		DAY 57	29JUL2003	57		64.0	21.4	0.0	0.0	
	E0031030	SCREEN	17JUN2003	-7	164.0	70.0	26.0			
		DAY 57	21AUG2003	59		66.0	24.5	-4.0	-1.5	
	E0033012	SCREEN	05FEB2003	-5	175.0	76.0	24.8			
	E0034001	SCREEN	17MAR2003	-3	165.0	73.0	26.8			
		DAY 57	15MAY2003	57		74.0	27.2	1.0	0.4	
	E0034004	SCREEN	11APR2003	-10	183.0	97.0	29.0			
		DAY 57	16JUN2003	57		98.0	29.3	1.0	0.3	
	E0035001	SCREEN	12NOV2002	-8	168.0	132.0	46.8			
		DAY 57	14JAN2003	56		132.0	46.8	0.0	0.0	
	E0035006	SCREEN	03DEC2002	-9	168.0	66.0	23.4			
		DAY 57	06FEB2003	57		65.0	23.0	-1.0	-0.4	
	E0035021	SCREEN	18APR2003	-7	160.0	82.0	32.0			
		DAY 57	20JUN2003	57		75.0	29.3	-7.0	-2.7	D
	E0036002	SCREEN	10JUN2003	-7	175.0	79.0	25.8			
		DAY 29	14JUL2003	28		80.0	26.1	1.0	0.3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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I: Potentially Clinically Important increase.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
GENERATED: 12JUL2005 17:46:50 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0036006	SCREEN	24JUN2003	-9	173.0	101.0	33.7			
		DAY 57	27AUG2003	56		106.0	35.4	5.0	1.7	
	E0036007	SCREEN	26JUN2003	-7	163.0	64.0	24.1			
		DAY 15	18JUL2003	16		65.0	24.5	1.0	0.4	
	E0037009	SCREEN	09MAY2003	-7	163.0	77.0	29.0			
		DAY 57	10JUL2003	56		80.0	30.1	3.0	1.1	
	E0039011	SCREEN	16DEC2002	-17	180.0	97.0	29.9			
	E0039018	SCREEN	14JAN2003	-9	150.0	62.0	27.6			
	E0039026	SCREEN	26FEB2003	-9	160.0	66.0	25.8			
		DAY 57	01MAY2003	56		77.0	30.1	11.0	4.3	I
	E0039028	SCREEN	03MAR2003	-21	185.0	158.0	46.2			
		DAY 50	16MAY2003	54		158.0	46.2	0.0	0.0	
	E0039032	SCREEN	07MAR2003	-7	160.0	127.0	49.6			
		DAY 15	28MAR2003	15		129.0	50.4	2.0	0.8	
	E0039034	SCREEN	12MAR2003	-7	163.0	94.0	35.4			
		DAY 57	14MAY2003	57		94.0	35.4	0.0	0.0	
	E0039042	SCREEN	24APR2003	-13	152.0	67.0	29.0			
	E0041004	SCREEN	22JAN2003	-8	183.0	101.0	30.2			
		DAY 57	31MAR2003	61		104.0	31.1	3.0	0.9	
	E0041009	SCREEN	22APR2003	-9	163.0	36.0	13.5			
		DAY 43	16JUN2003	47		83.0	31.2	47.0	17.7	I
	E0042002	SCREEN	02JUL2003	-7	168.0	97.0	34.4			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR I)	E0042002	DAY 57	02SEP2003	56		102.0	36.1	5.0	1.7	
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	SCREEN	23JUN2003	-18	180.0	95.0	29.3			
		DAY 8	18JUL2003	8		95.0	29.3	0.0	0.0	
	E0003002	SCREEN	22OCT2002	-7	180.0	67.0	20.7			
		DAY 57	23DEC2002	56		73.0	22.5	6.0	1.8	I
	E0005031	SCREEN	26MAR2003	-7	157.0	60.0	24.3			
	E0005033	SCREEN	08APR2003	-8	165.0	64.0	23.5			
		DAY 22	06MAY2003	21		65.0	23.9	1.0	0.4	
	E0005038	SCREEN	05MAY2003	-9	163.0	103.0	38.8			
		DAY 22	05JUN2003	23		108.0	40.6	5.0	1.8	
	E0007009	SCREEN	09APR2003	-8	165.0	65.0	23.9			
		DAY 8	28APR2003	12		64.0	23.5	-1.0	-0.4	
	E0009010	SCREEN	27FEB2003	-14	185.0	79.0	23.1			
	E0009011	SCREEN	28APR2003	-8	188.0	88.0	24.9			
		DAY 57	03JUL2003	59		87.0	24.6	-1.0	-0.3	
	E0010005	SCREEN	10DEC2002	-8	191.0	159.0	43.6			
	E0011016	SCREEN	14APR2003	-7	181.0	97.0	29.6			
		DAY 57	16JUN2003	57		97.0	29.6	0.0	0.0	
	E0011020	SCREEN	01MAY2003	-7	182.0	71.0	21.4			
		DAY 8	15MAY2003	8		72.0	21.7	1.0	0.3	
	E0018002	SCREEN	15NOV2002	-14	175.0	95.0	31.0			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	DAY 57	22JAN2003	55		96.0	31.3	1.0	0.3	
	E0018003	SCREEN	19NOV2002	-7	163.0	127.0	47.8			
		DAY 15	10DEC2002	15		126.0	47.4	-1.0	-0.4	
	E0018013	SCREEN	17JAN2003	-7	178.0	110.0	34.7			
		DAY 8	31JAN2003	8		110.0	34.7	0.0	0.0	
	E0019002	SCREEN	29OCT2002	-14	174.0	77.0	25.4			
	E0019008	SCREEN	06NOV2002	-15	155.0	86.0	35.8			
	E0019009	SCREEN	06NOV2002	-8	153.0	50.0	21.4			
	E0019016	SCREEN	30DEC2002	-7	152.0	100.0	43.3			
		DAY 57	03MAR2003	57		106.0	45.9	6.0	2.6	
	E0019020	SCREEN	16JAN2003	-7	159.0	56.0	22.2			
		DAY 57	27MAR2003	64		128.0	50.6	72.0	28.4	I
	E0019021	SCREEN	16JAN2003	-14	173.0	81.0	27.1			
		DAY 29	03MAR2003	33		82.0	27.4	1.0	0.3	
	E0019024	SCREEN	23JAN2003	-7	172.0	101.0	34.1			
		DAY 8	06FEB2003	8		104.0	35.2	3.0	1.1	
	E0019031	SCREEN	06MAR2003	-7	188.0					
		DAY 15	25MAR2003	13		86.0	24.3			
	E0019035	SCREEN	11MAR2003	-7	155.0	104.0	43.3			
	E0019040	SCREEN	08MAY2003	-12	180.0	123.0	38.0			
		DAY 57	17JUL2003	59		132.0	40.7	9.0	2.7	I

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	SCREEN	28MAY2003	-7	173.0	75.0	25.1			
	E0019045	SCREEN	19JUN2003	-7	161.0	61.0	23.5			
		DAY 22	16JUL2003	21		64.0	24.7	3.0	1.2	
	E0020024	SCREEN	12JUN2003	-11	176.0	73.0	23.6			
		DAY 57	20AUG2003	59		79.0	25.5	6.0	1.9	I
	E0022044	SCREEN	11MAR2003	-7	173.0	61.0	20.4			
		DAY 57	12MAY2003	56		72.0	24.1	11.0	3.7	I
	E0023007	SCREEN	07JAN2003	-7	170.0	72.0	24.9			
		DAY 57	11MAR2003	57		72.0	24.9	0.0	0.0	
	E0023011	SCREEN	28JAN2003	-7	163.0	75.0	28.2			
		DAY 57	01APR2003	57		81.0	30.5	6.0	2.3	I
	E0023014	SCREEN	14FEB2003	-7	175.0	93.0	30.4			
		DAY 57	25APR2003	64		95.0	31.0	2.0	0.6	
	E0023019	SCREEN	21MAR2003	-17	177.0	72.0	23.0			
		DAY 57	03JUN2003	58		78.0	24.9	6.0	1.9	I
	E0023022	SCREEN	10APR2003	-8	180.0	73.0	22.5			
		DAY 57	12JUN2003	56		75.0	23.1	2.0	0.6	
	E0023023	SCREEN	17APR2003	-8	160.0	54.0	21.1			
		DAY 8	01MAY2003	7		54.0	21.1	0.0	0.0	
	E0023029	SCREEN	16MAY2003	-7	163.0	60.0	22.6			
	E0023031	SCREEN	22MAY2003	-33	163.0	107.0	40.3			
		DAY 57	19AUG2003	57		104.0	39.1	-3.0	-1.2	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR II)	E0023041	SCREEN	02JUL2003	-7	161.0	80.0	30.9			
		DAY 57	05SEP2003	59		85.0	32.8	5.0	1.9	
	E0023043	SCREEN	07JUL2003	-7	185.0	64.0	18.7			
	E0026003	SCREEN	25NOV2002	-9	175.0	81.0	26.4			
		DAY 57	03FEB2003	62		73.0	23.8	-8.0	-2.6	D
	E0026005	SCREEN	23DEC2002	-7	168.0	63.0	22.3			
		DAY 8	06JAN2003	8		62.0	22.0	-1.0	-0.3	
	E0026009	SCREEN	10JAN2003	-5	152.0	56.0	24.2			
		DAY 8	21JAN2003	7		56.0	24.2	0.0	0.0	
	E0026015	SCREEN	20FEB2003	-7	163.0	57.0	21.5			
		DAY 57	25APR2003	58		57.0	21.5	0.0	0.0	
	E0026023	SCREEN	23APR2003	-7	185.0	96.0	28.0			
		DAY 57	27JUN2003	59		95.0	27.8	-1.0	-0.2	
	E0027016	SCREEN	19MAR2003	-21	150.0	87.0	38.7			
		DAY 57	03JUN2003	56		88.0	39.1	1.0	0.4	
	E0027018	SCREEN	21MAR2003	-4	163.0	79.0	29.7			
		DAY 57	22MAY2003	59		85.0	32.0	6.0	2.3	I
	E0028032	SCREEN	13MAR2003	-12	180.0	78.0	24.1			
		DAY 57	06JUN2003	74		77.0	23.8	-1.0	-0.3	
	E0029003	SCREEN	28OCT2002	-7	191.0	134.0	36.7			
		DAY 57	30DEC2002	57		135.0	37.0	1.0	0.3	
	E0029020	SCREEN	25FEB2003	-8	183.0	91.0	27.2			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	SCREEN	13DEC2002	-7	178.0	92.0	29.0			
		DAY 57	14FEB2003	57		95.0	30.0	3.0	1.0	
	E0031006	SCREEN	31JAN2003	-18	201.0	119.0	29.5			
		DAY 57	15APR2003	57		130.0	32.2	11.0	2.7	I
	E0031010	SCREEN	12FEB2003	-7	167.0	75.0	26.9			
		DAY 15	05MAR2003	15		76.0	27.3	1.0	0.4	
	E0031011	SCREEN	18FEB2003	-9	173.0	79.0	26.4			
		DAY 57	24APR2003	57		81.0	27.1	2.0	0.7	
	E0031015	SCREEN	14MAR2003	-12	163.0	74.0	27.9			
		DAY 8	01APR2003	7		73.0	27.5	-1.0	-0.4	
	E0031031	SCREEN	01JUL2003	-7	168.0	87.0	30.8			
		DAY 50	28AUG2003	52		89.0	31.5	2.0	0.7	
	E0033009	SCREEN	22JAN2003	-21	163.0	62.0	23.3			
	E0034009	SCREEN	10JUN2003	-9	189.0	93.0	26.0			
		DAY 57	18AUG2003	61		99.0	27.7	6.0	1.7	
	E0037007	SCREEN	04APR2003	-7	170.0	67.0	23.2			
	E0037012	SCREEN	11JUL2003	-5	163.0	54.0	20.3			
		DAY 57	08SEP2003	55		57.0	21.5	3.0	1.2	
	E0039019	SCREEN	20JAN2003	-17	150.0	100.0	44.4			
		DAY 57	03APR2003	57		96.0	42.7	-4.0	-1.7	
	E0039043	SCREEN	25APR2003	-13	178.0	74.0	23.4			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0002001	SCREEN	17DEC2002	-13	140.0	53.0	27.0			
		DAY 57	26FEB2003	59		59.0	30.1	6.0	3.1	I
	E0002003	SCREEN	03JAN2003	-19	155.0	60.0	25.0			
		DAY 57	18MAR2003	56		60.0	25.0	0.0	0.0	
	E0002004	SCREEN	14JAN2003	-11	165.0	98.0	36.0			
	E0002008	SCREEN	05FEB2003	-20	178.0	90.0	28.4			
		DAY 57	23APR2003	58		88.0	27.8	-2.0	-0.6	
	E0002016	SCREEN	14JUL2003	-10	163.0	78.0	29.4			
		DAY 57	17SEP2003	56		78.0	29.4	0.0	0.0	
	E0003008	SCREEN	21JAN2003	-7	168.0	64.0	22.7			
	E0004003	SCREEN	02OCT2002	-8	168.0	86.0	30.5			
	E0004006	SCREEN	28OCT2002	-7	165.0	91.0	33.4			
		DAY 57	06JAN2003	64		93.0	34.2	2.0	0.8	
	E0004016	SCREEN	12FEB2003	-7	160.0	55.0	21.5			
		DAY 57	17APR2003	58		54.0	21.1	-1.0	-0.4	
	E0004024	SCREEN	25JUN2003	-8	155.0	85.0	35.4			
		DAY 57	28AUG2003	57		85.0	35.4	0.0	0.0	
	E0005006	SCREEN	24SEP2002	-9	180.0	77.0	23.8			
	E0005017	SCREEN	11DEC2002	-19	168.0	76.0	26.9			
		DAY 57	04MAR2003	65		78.0	27.6	2.0	0.7	
	E0005019	SCREEN	19DEC2002	-27	170.0	77.0	26.6			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0005026	SCREEN	26FEB2003	-8	168.0	52.0	18.4			
		DAY 22	25MAR2003	20		50.0	17.7	-2.0	-0.7	
	E0005039	SCREEN	15MAY2003	-7	170.0	142.0	49.1			
		DAY 57	16JUL2003	56		146.0	50.5	4.0	1.4	
	E0005043	SCREEN	01JUL2003	-8	191.0	135.0	37.0			
		DAY 57	03SEP2003	57		138.0	37.8	3.0	0.8	
	E0006020	SCREEN	02MAY2003	-11	183.0	86.0	25.7			
		DAY 57	08JUL2003	57		86.0	25.7	0.0	0.0	
	E0007001	SCREEN	10DEC2002	-21	180.0	89.0	27.5			
		DAY 50	22FEB2003	54		85.0	26.2	-4.0	-1.3	
	E0007003	SCREEN	03JAN2003	-27	173.0	63.0	21.0			
		DAY 36	10MAR2003	40		63.0	21.0	0.0	0.0	
	E0007006	SCREEN	21FEB2003	-12	183.0	113.0	33.7			
		DAY 22	26MAR2003	22		113.0	33.7	0.0	0.0	
	E0009004	SCREEN	19NOV2002	-7	175.0	85.0	27.8			
		DAY 22	18DEC2002	23		87.0	28.4	2.0	0.6	
	E0009012	SCREEN	16JUN2003	-9	177.0	84.0	26.8			
		DAY 8	03JUL2003	9		82.0	26.2	-2.0	-0.6	
	E0010008	SCREEN	11DEC2002	-7	163.0	56.0	21.1			
	E0010018	SCREEN	26FEB2003	-21	155.0	49.0	20.4			
		DAY 57	14MAY2003	57		49.0	20.4	0.0	0.0	
	E0010028	SCREEN	09JUN2003	-7	163.0	66.0	24.8			
		DAY 29	15JUL2003	30		67.0	25.2	1.0	0.4	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0011008	SCREEN	23JAN2003	-7	177.0	61.0	19.5			
		DAY 15	13FEB2003	15		60.0	19.2	-1.0	-0.3	
	E0011009	SCREEN	19DEC2002	-8	180.0	95.0	29.3			
		DAY 57	20FEB2003	56		92.0	28.4	-3.0	-0.9	
	E0011010	SCREEN	03FEB2003	-7	168.0	83.0	29.4			
		DAY 36	19MAR2003	38		87.0	30.8	4.0	1.4	
	E0013001	SCREEN	01NOV2002	-13	183.0	107.0	32.0			
		DAY 57	10JAN2003	58		109.0	32.5	2.0	0.5	
	E0013003	SCREEN	06NOV2002	-6	165.0	130.0	47.8			
		DAY 57	06JAN2003	56		138.0	50.7	8.0	2.9	
	E0013005	SCREEN	13FEB2003	-5	175.0	68.0	22.2			
		DAY 57	15APR2003	57		68.0	22.2	0.0	0.0	
	E0013013	SCREEN	01MAY2003	-5	175.0	70.0	22.9			
		DAY 22	30MAY2003	25		69.0	22.5	-1.0	-0.4	
	E0014002	SCREEN	19FEB2003	-7	163.0	67.0	25.2			
		DAY 43	10APR2003	44		70.0	26.3	3.0	1.1	
	E0014004	SCREEN	04MAR2003	-8	173.0	75.0	25.1			
		DAY 36	15APR2003	35		74.0	24.7	-1.0	-0.4	
	E0014009	SCREEN	15APR2003	-8	155.0	95.0	39.5			
		DAY 8	30APR2003	8		95.0	39.5	0.0	0.0	
	E0014015	SCREEN	11JUN2003	-7	173.0	74.0	24.7			
	E0014017	SCREEN	17JUN2003	-10	166.0	75.0	27.2			
		DAY 50	19AUG2003	54		77.0	27.9	2.0	0.7	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0014018	SCREEN	24JUN2003	-7	178.0	73.0	23.0			
		DAY 57	27AUG2003	58		72.0	22.7	-1.0	-0.3	
	E0015005	SCREEN	25NOV2002	-7	185.0	70.0	20.5			
		DAY 15	18DEC2002	17		70.0	20.5	0.0	0.0	
	E0017002	SCREEN	08MAY2003	-26	156.0	80.0	32.9			
		DAY 8	13JUN2003	11		74.0	30.4	-6.0	-2.5	D
	E0018009	SCREEN	17DEC2002	-20	180.0	85.0	26.2			
		DAY 8	14JAN2003	9		85.0	26.2	0.0	0.0	
	E0018010	SCREEN	09JAN2003	-7	178.0	88.0	27.8			
		DAY 57	13MAR2003	57		87.0	27.5	-1.0	-0.3	
	E0018015	SCREEN	21JAN2003	-7	178.0	80.0	25.2			
		DAY 57	27MAR2003	59		82.0	25.9	2.0	0.7	
	E0020015	SCREEN	18MAR2003	-9	173.0	78.0	26.1			
		DAY 57	23MAY2003	58		79.0	26.4	1.0	0.3	
	E0020017	SCREEN	27MAR2003	-7	165.0	58.0	21.3			
		DAY 57	03JUN2003	62		58.0	21.3	0.0	0.0	
	E0020020	SCREEN	07MAY2003	-5	163.0	50.0	18.8			
		DAY 8	23MAY2003	12		50.0	18.8	0.0	0.0	
	E0020022	SCREEN	09JUN2003	-7	152.0	84.0	36.4			
		DAY 57	11AUG2003	57		84.0	36.4	0.0	0.0	
	E0022001	SCREEN	07OCT2002	-21	175.0	74.0	24.2			
		DAY 57	26DEC2002	60		75.0	24.5	1.0	0.3	
	E0022004	SCREEN	17OCT2002	-11	172.0	95.0	32.1			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0022004	DAY 57	23DEC2002	57		93.0	31.4	-2.0	-0.7	
	E0022005	SCREEN	17OCT2002	-22	167.0	110.0	39.4			
		DAY 57	03JAN2003	57		110.0	39.4	0.0	0.0	
	E0022011	SCREEN	20NOV2002	-9	179.0	90.0	28.1			
	E0022015	SCREEN	29NOV2002	-11	165.0	71.0	26.1			
		DAY 57	06FEB2003	59		71.0	26.1	0.0	0.0	
	E0022016	SCREEN	03DEC2002	-14	140.0	81.0	41.3			
		DAY 57	11FEB2003	57		82.0	41.8	1.0	0.5	
	E0022020	SCREEN	05DEC2002	-7	158.0	44.0	17.6			
		DAY 43	23JAN2003	43		46.0	18.4	2.0	0.8	
	E0022023	SCREEN	19DEC2002	-6	167.0	79.0	28.3			
		DAY 57	20FEB2003	58		82.0	29.4	3.0	1.1	
	E0022029	SCREEN	05FEB2003	-14	179.0	146.0	45.6			
		DAY 57	14APR2003	55		149.0	46.5	3.0	0.9	
	E0022041	SCREEN	04MAR2003	-14	152.0	81.0	35.1			
		DAY 57	13MAY2003	57		81.0	35.1	0.0	0.0	
	E0022042	SCREEN	05MAR2003	-7	197.0	109.0	28.1			
		DAY 57	12MAY2003	62		111.0	28.6	2.0	0.5	
	E0022043	SCREEN	10MAR2003	-10	167.0	79.0	28.3			
		DAY 50	12MAY2003	54		80.0	28.7	1.0	0.4	
	E0022054	SCREEN	04APR2003	-7	178.0	92.0	29.0			
	E0022059	SCREEN	22APR2003	-14	167.0	79.0	28.3			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0022059	DAY 57	08JUL2003	64		79.0	28.3	0.0	0.0	
	E0022065	SCREEN	30APR2003	-7	168.0	100.0	35.4			
		DAY 57	02JUL2003	57		101.0	35.8	1.0	0.4	
	E0022070	SCREEN	05JUN2003	-7	178.0	96.0	30.3			
		DAY 8	18JUN2003	7		93.0	29.4	-3.0	-0.9	
	E0023001	SCREEN	24OCT2002	-22	168.0	104.0	36.8			
		DAY 57	14JAN2003	61		104.0	36.8	0.0	0.0	
	E0023009	SCREEN	24JAN2003	-18	158.0	60.0	24.0			
		DAY 57	08APR2003	57		62.0	24.8	2.0	0.8	
	E0023028	SCREEN	16MAY2003	-13	158.0	64.0	25.6			
		DAY 50	21JUL2003	54		60.0	24.0	-4.0	-1.6	
	E0023033	SCREEN	30MAY2003	-6	172.0	90.0	30.4			
		DAY 8	12JUN2003	8		90.0	30.4	0.0	0.0	
	E0023047	SCREEN	11JUL2003	-7	191.0	111.0	30.4			
		DAY 57	12SEP2003	57		103.0	28.2	-8.0	-2.2	D
	E0025001	SCREEN	25MAR2003	-7	165.0	149.0	54.7			
		DAY 22	23APR2003	23		144.0	52.9	-5.0	-1.8	
	E0026012	SCREEN	05FEB2003	-15	173.0	80.0	26.7			
		DAY 57	17APR2003	57		80.0	26.7	0.0	0.0	
	E0026020	SCREEN	28MAR2003	-4	175.0	80.0	26.1			
		DAY 22	22APR2003	22		81.0	26.4	1.0	0.3	
	E0026024	SCREEN	25APR2003	-7	165.0	71.0	26.1			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0026028	SCREEN	06JUN2003	-14	173.0	112.0	37.4			
		DAY 36	23JUL2003	34		109.0	36.4	-3.0	-1.0	
	E0028001	SCREEN	07OCT2002	-3	188.0	130.0	36.8			
		DAY 57	03DEC2002	55		130.0	36.8	0.0	0.0	
	E0028003	SCREEN	23SEP2002	-7	165.0	105.0	38.6			
		DAY 57	26NOV2002	58		104.0	38.2	-1.0	-0.4	
	E0028005	SCREEN	30SEP2002	-3	175.0	63.0	20.6			
		DAY 29	31OCT2002	29		63.0	20.6	0.0	0.0	
	E0028010	SCREEN	15OCT2002	-21	170.0	54.0	18.7			
		DAY 57	31DEC2002	57		52.0	18.0	-2.0	-0.7	
	E0028011	SCREEN	25NOV2002	-10	173.0	63.0	21.0			
		DAY 57	30JAN2003	57		62.0	20.7	-1.0	-0.3	
	E0028030	SCREEN	26FEB2003	-6	175.0	76.0	24.8			
		DAY 57	30APR2003	58		74.0	24.2	-2.0	-0.6	
	E0028031	SCREEN	06MAR2003	-5	173.0	118.0	39.4			
		DAY 36	17APR2003	38		121.0	40.4	3.0	1.0	
	E0028047	SCREEN	08JUL2003	-6	178.0	114.0	36.0			
		DAY 57	09SEP2003	58		114.0	36.0	0.0	0.0	
	E0029001	SCREEN	24SEP2002	-7	183.0	86.0	25.7			
	E0029014	SCREEN	28JAN2003	-7	163.0	75.0	28.2			
		DAY 57	01APR2003	57		75.0	28.2	0.0	0.0	
	E0029023	SCREEN	11MAR2003	-28	157.0	79.0	32.0			
		DAY 57	10JUN2003	64		86.0	34.9	7.0	2.9	I

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0029032	SCREEN	22MAY2003	-19	170.0	91.0	31.5			
		DAY 22	01JUL2003	22		91.0	31.5	0.0	0.0	
	E0029033	SCREEN	27MAY2003	-6	179.0	98.0	30.6			
	E0029039	SCREEN	10JUL2003	-5	157.0	47.0	19.1			
		DAY 15	28JUL2003	14		47.0	19.1	0.0	0.0	
	E0030003	SCREEN	03DEC2002	-13	165.0	84.0	30.9			
		DAY 8	24DEC2002	9		84.0	30.9	0.0	0.0	
	E0030009	SCREEN	10JAN2003	-13	178.0	69.0	21.8			
		DAY 57	19MAR2003	56		67.0	21.1	-2.0	-0.7	
	E0030016	SCREEN	21FEB2003	-10	180.0	93.0	28.7			
		DAY 50	22APR2003	51		92.0	28.4	-1.0	-0.3	
	E0030021	SCREEN	13MAY2003	-7	168.0	55.0	19.5			
	E0031001	SCREEN	14NOV2002	-7	171.0	125.0	42.7			
	E0031017	SCREEN	25MAR2003	-7	186.0	104.0	30.1			
		DAY 29	29APR2003	29		107.0	30.9	3.0	0.8	
	E0031018	SCREEN	01APR2003	-9	150.0	110.0	48.9			
	E0031023	SCREEN	21APR2003	-8	168.0	145.0	51.4			
		DAY 57	24JUN2003	57		146.0	51.7	1.0	0.3	
	E0033001	SCREEN	23DEC2002	-17	188.0	95.0	26.9			
		DAY 22	30JAN2003	22		97.0	27.4	2.0	0.5	
	E0033004	SCREEN	09JAN2003	-8	160.0	68.0	26.6			
		DAY 57	14MAR2003	57		70.0	27.3	2.0	0.7	

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0033010	SCREEN	22JAN2003	-13	173.0	74.0	24.7			
		DAY 50	26MAR2003	51		70.0	23.4	-4.0	-1.3	
	E0033014	SCREEN	12MAR2003	-7	183.0	95.0	28.4			
	E0035002	SCREEN	14NOV2002	-7	180.0	92.0	28.4			
	E0035007	SCREEN	13DEC2002	-6	188.0	99.0	28.0			
		DAY 57	11FEB2003	55		99.0	28.0	0.0	0.0	
	E0035011	SCREEN	09JAN2003	-26	168.0	146.0	51.7			
		DAY 57	01APR2003	57		146.0	51.7	0.0	0.0	
	E0035020	SCREEN	11APR2003	-7	152.0	81.0	35.1			
		DAY 57	13JUN2003	57		81.0	35.1	0.0	0.0	
	E0037003	SCREEN	22JAN2003	-8	168.0	70.0	24.8			
		DAY 22	20FEB2003	22		73.0	25.9	3.0	1.1	
	E0037004	SCREEN	06FEB2003	-7	163.0	110.0	41.4			
		DAY 57	10APR2003	57		110.0	41.4	0.0	0.0	
	E0039007	SCREEN	25NOV2002	-9	175.0	65.0	21.2			
		DAY 57	29JAN2003	57		65.0	21.2	0.0	0.0	
	E0039022	SCREEN	04FEB2003	-21	170.0	70.0	24.2			
		DAY 57	24APR2003	59		69.0	23.9	-1.0	-0.3	
	E0039023	SCREEN	05FEB2003	-19	178.0	77.0	24.3			
	E0039030	SCREEN	12MAR2003	-12	152.0	122.0	52.8			
		DAY 57	19MAY2003	57		127.0	55.0	5.0	2.2	
	E0039031	SCREEN	05MAR2003	-19	170.0	68.0	23.5			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR I)	E0039031	DAY 57	20MAY2003	58		67.0	23.2	-1.0	-0.3	
	E0039037	SCREEN	26MAR2003	-21	165.0	58.0	21.3			
		DAY 57	12JUN2003	58		57.0	20.9	-1.0	-0.4	
	E0039038	SCREEN	26MAR2003	-28	157.0	93.0	37.7			
		DAY 57	20JUN2003	59		92.0	37.3	-1.0	-0.4	
	E0039047	SCREEN	12MAY2003	-7	160.0	96.0	37.5			
		DAY 57	14JUL2003	57		96.0	37.5	0.0	0.0	
	E0039059	SCREEN	03JUL2003	-8	163.0	93.0	35.0			
		DAY 57	05SEP2003	57		92.0	34.6	-1.0	-0.4	
	E0041007	SCREEN	05MAR2003	-8	188.0	73.0	20.7			
		DAY 57	08MAY2003	57		67.0	19.0	-6.0	-1.7	D
	E0041010	SCREEN	23APR2003	-7	175.0	86.0	28.1			
		DAY 43	11JUN2003	43		86.0	28.1	0.0	0.0	
	E0041011	SCREEN	15MAY2003	-7	163.0	115.0	43.3			
		DAY 57	17JUL2003	57		116.0	43.7	1.0	0.4	
	E0041012	SCREEN	05JUN2003	-14	168.0	117.0	41.5			
		DAY 57	14AUG2003	57		122.0	43.2	5.0	1.7	
PLACEBO (BIPOLAR II)	E0001004	SCREEN	23APR2003	-8	158.0	67.0	26.8			
		DAY 57	02JUL2003	63		66.0	26.4	-1.0	-0.4	
	E0005023	SCREEN	28JAN2003	-8	168.0	69.0	24.4			
		DAY 57	01APR2003	56		66.0	23.4	-3.0	-1.0	
	E0005034	SCREEN	08APR2003	-7	165.0	92.0	33.8			

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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR II)	E0005034	DAY 57	09JUN2003	56		92.0	33.8	0.0	0.0	
	E0005041	SCREEN	17JUN2003	-7	155.0	73.0	30.4			
		DAY 57	18AUG2003	56		75.0	31.2	2.0	0.8	
	E0007004	SCREEN	24JAN2003	-6	156.0	94.0	38.6			
		DAY 15	12FEB2003	14		95.0	39.0	1.0	0.4	
	E0007010	SCREEN	11APR2003	-7	178.0	113.0	35.7			
		DAY 57	16JUN2003	60		111.0	35.0	-2.0	-0.7	
	E0007012	SCREEN	02MAY2003	-14	163.0	65.0	24.5			
		DAY 43	01JUL2003	47		68.0	25.6	3.0	1.1	
	E0009007	SCREEN	27JAN2003	-7	188.0	93.0	26.3			
		DAY 29	03MAR2003	29		95.0	26.9	2.0	0.6	
	E0009008	SCREEN	04FEB2003	-8	188.0	93.0	26.3			
		DAY 57	08APR2003	56		92.0	26.0	-1.0	-0.3	
	E0011001	SCREEN	25OCT2002	-7	159.0	64.0	25.3			
		DAY 57	26DEC2002	56		62.0	24.5	-2.0	-0.8	
	E0011011	SCREEN	12FEB2003	-8	163.0	52.0	19.6			
		DAY 57	16APR2003	56		51.0	19.2	-1.0	-0.4	
	E0011013	SCREEN	25MAR2003	-23	164.0	86.0	32.0			
		DAY 57	12JUN2003	57		84.0	31.2	-2.0	-0.8	
	E0011014	SCREEN	31MAR2003	-7	163.0	93.0	35.0			
		DAY 29	08MAY2003	32		94.0	35.4	1.0	0.4	
	E0011021	SCREEN	15MAY2003	-7	173.0	68.0	22.7			
		DAY 57	21JUL2003	61		68.0	22.7	0.0	0.0	

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* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
GENERATED: 12JUL2005 17:46:50 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR II)	E0013008	SCREEN	19MAR2003	-7	165.0	118.0	43.3			
		DAY 57	19MAY2003	55		119.0	43.7	1.0	0.4	
	E0014001	SCREEN	18FEB2003	-8	165.0	61.0	22.4			
		DAY 36	01APR2003	35		63.0	23.1	2.0	0.7	
	E0014013	SCREEN	20MAY2003	-7	165.0	55.0	20.2			
		DAY 57	23JUL2003	58		56.0	20.6	1.0	0.4	
	E0014014	SCREEN	03JUN2003	-7	183.0	92.0	27.5			
		DAY 57	06AUG2003	58		90.0	26.9	-2.0	-0.6	
	E0015004	SCREEN	25NOV2002	-7	170.0	102.0	35.3			
		DAY 57	29JAN2003	59		102.0	35.3	0.0	0.0	
	E0018005	SCREEN	10DEC2002	-10	183.0	68.0	20.3			
		DAY 57	14FEB2003	57		67.0	20.0	-1.0	-0.3	
	E0018012	SCREEN	17JAN2003	-7	173.0	85.0	28.4			
		DAY 36	26FEB2003	34		85.0	28.4	0.0	0.0	
	E0019019	SCREEN	14JAN2003	-9	168.0	116.0	41.1			
	E0019033	SCREEN	10MAR2003	-8	176.0	70.0	22.6			
		DAY 57	15MAY2003	59		69.0	22.3	-1.0	-0.3	
	E0019038	SCREEN	10APR2003	-14	185.0	79.0	23.1			
		DAY 57	18JUN2003	56		79.0	23.1	0.0	0.0	
	E0019046	SCREEN	19JUN2003	-7	175.0	66.0	21.6			
		DAY 57	21AUG2003	57		68.0	22.2	2.0	0.6	
	E0019047	SCREEN	26JUN2003	-12	174.0	77.0	25.4			
		DAY 57	04SEP2003	59		76.0	25.1	-1.0	-0.3	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
GENERATED: 12JUL2005 17:46:50 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR II)	E0019048	SCREEN	03JUL2003	-7	161.0	57.0	22.0			
		DAY 57	03SEP2003	56		55.0	21.2	-2.0	-0.8	
	E0022006	SCREEN	21OCT2002	-22	156.0	71.0	29.2			
		DAY 57	07JAN2003	57		70.0	28.8	-1.0	-0.4	
	E0022047	SCREEN	21MAR2003	-7	180.0	87.0	26.9			
		DAY 57	23MAY2003	57		89.0	27.5	2.0	0.6	
	E0022075	SCREEN	25JUN2003	-13	157.0	53.0	21.5			
		DAY 57	03SEP2003	58		50.0	20.3	-3.0	-1.2	
	E0023012	SCREEN	31JAN2003	-6	170.0	102.0	35.3			
		DAY 57	04APR2003	58		104.0	36.0	2.0	0.7	
	E0023016	SCREEN	15MAY2003	-7	175.0	60.0	19.6			
		DAY 57	17JUL2003	57		66.0	21.6	6.0	2.0	I
	E0023018	SCREEN	18MAR2003	-9	173.0	92.0	30.7			
		DAY 57	22MAY2003	57		91.0	30.4	-1.0	-0.3	
	E0023036	SCREEN	10JUN2003	-10	173.0	73.0	24.4			
		DAY 57	13AUG2003	55		73.0	24.4	0.0	0.0	
	E0023046	SCREEN	11JUL2003	-12	165.0	98.0	36.0			
		DAY 57	16SEP2003	56		99.0	36.4	1.0	0.4	
	E0026006	SCREEN	31DEC2002	-8	173.0	60.0	20.0			
	E0026021	SCREEN	14APR2003	-9	163.0	53.0	19.9			
	E0026027	SCREEN	05JUN2003	-14	160.0	59.0	23.0			
	E0029002		12NOV2002		160.0	55.0	21.5			

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
GENERATED: 12JUL2005 17:46:50 iceadmn3

Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR II)	E0029002		12NOV2002		160.0	55.0	21.5			
	E0029004	SCREEN	13NOV2002	-6	168.0	82.0	29.1			
		DAY 57	16JAN2003	59		82.0	29.1	0.0	0.0	
	E0029013	SCREEN	10FEB2003	-9	180.0	113.0	34.9			
	E0029019	SCREEN	24FEB2003	-7	170.0	91.0	31.5			
		DAY 15	17MAR2003	15		90.0	31.1	-1.0	-0.4	
	E0029024	SCREEN	11MAR2003	-6	160.0	51.0	19.9			
		DAY 57	20MAY2003	65		52.0	20.3	1.0	0.4	
	E0029038	SCREEN	30JUN2003	-7	172.0	86.0	29.1			
	E0031004	SCREEN	12DEC2002	-7	155.0	67.0	27.9			
		DAY 57	13FEB2003	57		70.0	29.1	3.0	1.2	
	E0031013	SCREEN	06MAR2003	-7	152.0	109.0	47.2			
		DAY 57	08MAY2003	57		112.0	48.5	3.0	1.3	
	E0031016	SCREEN	17MAR2003	-7	178.0	74.0	23.4			
		DAY 22	14APR2003	22		77.0	24.3	3.0	0.9	
	E0031019	SCREEN	03APR2003	-8	170.0	71.0	24.6			
		DAY 29	12MAY2003	32		70.0	24.2	-1.0	-0.4	
	E0031022	SCREEN	21APR2003	-7	165.0	96.0	35.3			
	E0033007	SCREEN	15JAN2003	-13	160.0	69.0	27.0			
		DAY 57	27MAR2003	59		67.0	26.2	-2.0	-0.8	
	E0033013	SCREEN	06FEB2003	-13	152.0	59.0	25.5			
		DAY 57	16APR2003	57		58.0	25.1	-1.0	-0.4	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
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Listing 12.2.9.3 Height, Weight and BMI

TREATMENT	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	HEIGHT (cm)	WEIGHT (kg)	BMI	CHANGE FROM BASELINE WEIGHT	CHANGE FROM BASELINE BMI	POTENTIALLY CLINICALLY IMPORTANT
PLACEBO (BIPOLAR II)	E0033016	SCREEN	17APR2003	-21	160.0	60.0	23.4			
		DAY 57	02JUL2003	56		61.0	23.8	1.0	0.4	
	E0033022	SCREEN	09JUL2003	-5	160.0	95.0	37.1			
		DAY 57	11SEP2003	60		93.0	36.3	-2.0	-0.8	
	E0034007	SCREEN	07MAY2003	-9	155.0	50.0	20.8			
		DAY 57	14JUL2003	60		49.0	20.4	-1.0	-0.4	
	E0035004	SCREEN	22NOV2002	-5	183.0	103.0	30.8			
	E0035009	SCREEN	20DEC2002	-7	188.0	71.0	20.1			
		DAY 57	19FEB2003	55		71.0	20.1	0.0	0.0	
	E0035010	SCREEN	06JAN2003	-4	158.0	96.0	38.5			
		DAY 57	06MAR2003	56		98.0	39.3	2.0	0.8	
	E0035022	SCREEN	01MAY2003	-8	155.0	56.0	23.3			
		DAY 57	07JUL2003	60		54.0	22.5	-2.0	-0.8	
	E0039003	SCREEN	06NOV2002	-19	170.0	95.0	32.9			
		DAY 36	02JAN2003	39		97.0	33.6	2.0	0.7	
	E0040001	SCREEN	18JUN2003	-9	163.0	65.0	24.5			
		DAY 57	22AUG2003	57		62.0	23.3	-3.0	-1.2	
	E0040004	SCREEN	11JUL2003	-7	178.0	56.0	17.7			
	E0041002	SCREEN	13JAN2003	-8	173.0	90.0	30.1			
		DAY 50	11MAR2003	50		92.0	30.7	2.0	0.6	
	E0041005	SCREEN	24FEB2003	-9	180.0	98.0	30.2			
		DAY 57	30APR2003	57		98.0	30.2	0.0	0.0	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/VIT104.SAS
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AstraZeneca

Clinical Study Report: Appendix 12.2.10

Drug Substance	Quetiapine
Study Code	507US0049

Appendix 12.2.10
Listing of other safety data

Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BASELINE	22JAN2003/14:20	-13	82	82	174	94	373	414						
		FINAL	02APR2003/11:50	58	83	83	190	96	376	420	1	1	16	2	3	6
	E0002010	BASELINE	28MAR2003/9:28	-7	82	82	139	79	369	410						
	E0002012	BASELINE	16APR2003/10:50	-5	67	67	167	92	356	369						
		FINAL	16JUN2003/11:50	57	57	57	159	87	391	383	-10	-10	-8	-5	35	14
	E0002015	BASELINE	22MAY2003/10:40	-13	70	71	140	80	344	363						
	E0002018	BASELINE	16JUL2003/14:30	-8	77	78	171	85	346	377						
		FINAL	04AUG2003/10:30	12	77	77	151	92	344	375	0	-1	-20	7	-2	-2
	E0003004	BASELINE *	03DEC2002/11:35	-14	64	63	165	91	354	362						
		BASELINE	17DEC2002/9:25	1	66	66	160	90	351	362						
		FINAL	07JAN2003/15:20	22	65	65	161	97	350	360	-1	-1	1	7	-1	-2
	E0003005	BASELINE	16DEC2002/16:30	-7	62	60	137	94	416	417						
		FINAL	18FEB2003/10:56	58	66	66	130	95	394	407	4	6	-7	1	-22	-10
	E0003007	BASELINE	19DEC2002/11:05	-14	81	81	144	92	349	386						
		FINAL	27FEB2003/9:20	57	56	56	156	89	401	392	-25	-25	12	-3	52	6
	E0003015	BASELINE	29APR2003/11:25	-6	56	56	123	87	382	373						
		FINAL	02JUL2003/14:30	59	69	69	132	81	384	403	13	13	9	-6	2	30
	E0004002	BASELINE	24SEP2002/11:00	-7	68	68	136	83	367	383						
		FINAL	26NOV2002/11:15	57	83	84	140	92	383	428	15	16	4	9	16	45
	E0004013	BASELINE	08JAN2003/10:40	-6	76	76	152	89	368	399						
		FINAL	05FEB2003/13:25	23	92	92	141	92	330	380	16	16	-11	3	-38	-19
	E0004018	BASELINE	12MAR2003/10:35	-7	57	57	136	91	369	362						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
GENERATED: 12JUL2005 17:42:24 iceadmn3

Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	FINAL	13MAY2003/13:55	56	60	59	111	94	350	350	3	2	-25	3	-19	-12
	E0004021	BASELINE	07MAY2003/15:30	-7	65	65	146	96	368	382						
		FINAL	09JUL2003/13:50	57	71	72	157	92	350	371	6	7	11	-4	-18	-11
	E0005002	BASELINE	23SEP2002/10:00	-10	81	81	131	83	353	390						
		FINAL	25NOV2002/8:45	54	100	101	122	83	307	365	19	20	-9	0	-46	-25
	E0005004	BASELINE	24SEP2002/12:00	-7	60	60	144	103	359	359						
	E0005013	BASELINE	30OCT2002/7:30	-8	69	68	160	94	374	391						
	E0005024	BASELINE	05FEB2003/9:20	-5	64	64	132	95	379	387						
		FINAL	09APR2003/15:00	59	71	71	152	96	355	376	7	7	20	1	-24	-11
	E0005027	BASELINE	03MAR2003/16:00	-8	59	59	158	92	356	354						
		FINAL	03APR2003/8:00	24	61	62	154	82	384	387	2	3	-4	-10	28	33
	E0005037	BASELINE	30APR2003/12:05	-7	85	84	170	87	380	426						
		FINAL	02JUL2003/11:50	57	89	89	202	87	356	405	4	5	32	0	-24	-21
	E0005042	BASELINE	19JUN2003/12:50	-5	58	58	149	83	410	406						
		FINAL	18AUG2003/16:40	56	74	75	191	93	363	390	16	17	42	10	-47	-16
	E0006005	BASELINE	25NOV2002/12:45	-10	65	66	179	115	386	397						
		FINAL	30JAN2003/11:20	57	84	84	176	101	347	388	19	18	-3	-14	-39	-9
	E0006018	BASELINE	06MAR2003/12:04	-7	66	66	201	88	364	376						
		FINAL	24MAR2003/10:50	12	70	71	215	81	367	387	4	5	14	-7	3	11
	E0007013	BASELINE	06JUN2003/15:50	-7	54	54	165	95	416	402						
		FINAL	07AUG2003/10:10	56	75	76	169	100	367	396	21	22	4	5	-49	-6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
GENERATED: 12JUL2005 17:42:24 iceadmn3

Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	BASELINE		05DEC2002/10:45	-6	62	62	135	84	409	414						
		FINAL		06FEB2003/12:25	58	52	52	146	88	424	405	-10	-10	11	4	15	-9
	E0010012	BASELINE		30DEC2002/9:32	-8	63	63	159	84	392	398						
		FINAL		05MAR2003/13:40	58	80	80	157	92	375	412	17	17	-2	8	-17	14
	E0010024	BASELINE		23APR2003/10:26	-12	52	52	138	85	383	365						
		FINAL		02JUL2003/10:25	59	73	73	166	87	363	388	21	21	28	2	-20	23
	E0010032	BASELINE		03JUL2003/11:40	-7	67	68	152	95	370	385						
		FINAL		17JUL2003/11:26	8	69	70	168	84	376	394	2	2	16	-11	6	9
	E0011025	BASELINE		20JUN2003/14:15	-6	72	72	174	96	371	395						
		FINAL		22AUG2003/10:50	58	76	75	163	94	353	382	4	3	-11	-2	-18	-13
	E0013007	BASELINE		14MAR2003/9:20	-6	70	70	162	85	365	384						
		FINAL		07APR2003/17:20	19	80	81	149	93	355	391	10	11	-13	8	-10	7
	E0013009	BASELINE		26MAR2003/9:23	-7	71	72	149	95	355	375						
		FINAL		29MAY2003/18:00	58	71	71	161	97	368	389	0	-1	12	2	13	14
		FINAL	*	30MAY2003/10:05	59	84	85	158	89	345	386	13	13	9	-6	-10	11
	E0014006	BASELINE		11MAR2003/16:10	-14	51	51	139	108	439	416						
		FINAL		28MAY2003/15:15	65	68	69	157	100	394	411	17	18	18	-8	-45	-5
	E0014010	BASELINE		15APR2003/17:09	-7	68	67	156	98	409	427						
		FINAL		17JUN2003/16:55	57	96	97	125	90	336	394	28	30	-31	-8	-73	-33
	E0016001	BASELINE		02JAN2003/9:45	-20	65	65	177	89	311	319						
		FINAL		19MAR2003/12:15	57	78	78	171	82	342	373	13	13	-6	-7	31	54
	E0016004	BASELINE		27JAN2003/10:00	-7	67	67	174	86	365	378						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
GENERATED: 12JUL2005 17:42:24 iceadmn3

Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	BASELINE	22OCT2002/16:00	-7	57	57	131	83	379	371						
		FINAL	24DEC2002/10:15	57	71	71	151	95	364	384	14	14	20	12	-15	13
	E0018006	BASELINE	10DEC2002/16:40	-7	70	70	187	94	335	352						
		FINAL	27FEB2003/12:00	73	81	81	157	89	335	371	11	11	-30	-5	0	19
	E0019004	BASELINE	30OCT2002/10:25	-8	66	66	159	97	381	393						
		FINAL	19DEC2002/12:31	43	77	77	174	97	409	444	11	11	15	0	28	51
	E0019011	BASELINE	12NOV2002/12:30	-9	66	66	149	76	424	439						
		FINAL	16JAN2003/13:55	57	77	77	131	87	328	357	11	11	-18	11	-96	-82
	E0019025	BASELINE	30JAN2003/15:52	-7	63	63	153	88	351	357						
		FINAL	03APR2003/14:10	57	60	60	143	84	394	393	-3	-3	-10	-4	43	36
	E0019026	BASELINE	10FEB2003/15:15	-14	78	78	130	85	368	400						
	E0019043	BASELINE	21MAY2003/12:07	-13	58	58	158	89	364	359						
		FINAL	29JUL2003/11:24	57	76	76	159	85	342	369	18	18	1	-4	-22	10
	E0020001	BASELINE	15OCT2002/19:40	-14	63	63	166	80	400	406						
		FINAL	20DEC2002/12:41	53	71	71	121	101	348	368	8	8	-45	21	-52	-38
	E0020006	BASELINE *	26NOV2002/17:35	-20	72	72	196	110	385	409						
		BASELINE	10DEC2002/16:20	-6	82	82	184	100	355	394						
		FINAL	08JAN2003/9:45	24	72	72	174	100	359	381	-10	-10	-10	0	4	-13
	E0020007	BASELINE	19DEC2002/18:30	-27	71	71	122	90	358	378						
		FINAL	25MAR2003/19:00	70	65	64	123	87	371	379	-6	-7	1	-3	13	1
	E0020011	BASELINE	19FEB2003/16:20	-7	65	65	153	91	388	398						
		FINAL	23APR2003/15:15	57	66	66	158	89	369	381	1	1	5	-2	-19	-17

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
GENERATED: 12JUL2005 17:42:24 iceadmn3

Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0020013	BASELINE	26FEB2003/14:25	-7	62	61	160	101	343	346						
		FINAL	25MAR2003/12:30	21	69	69	143	88	357	373	7	8	-17	-13	14	27
	E0022008	BASELINE	05NOV2002/11:00	-7	61	62	151	87	350	353						
		FINAL	07JAN2003/10:18	57	60	60	174	97	386	386	-1	-2	23	10	36	33
	E0022017	BASELINE	03DEC2002/15:20	-16	62	62	150	107	373	377						
		FINAL	13FEB2003/15:10	57	72	72	124	103	337	358	10	10	-26	-4	-36	-19
	E0022018	BASELINE	04DEC2002/12:00	-8	71	71	123	111	355	375						
		FINAL	06FEB2003/11:13	57	69	69	181	90	354	371	-2	-2	58	-21	-1	-4
	E0022022	BASELINE	16DEC2002/12:32	-14	65	65	153	82	359	369						
	E0022027	BASELINE	23JAN2003/16:30	-14	53	53	174	91	405	388						
		FINAL	03APR2003/9:08	57	51	51	175	85	421	399	-2	-2	1	-6	16	11
	E0022030	BASELINE	07FEB2003/14:40	-7	75	76	130	82	311	336						
	E0022031	BASELINE	10FEB2003/15:35	-8	59	59	150	94	380	377						
		FINAL	15APR2003/10:10	57	67	67	156	96	373	387	8	8	6	2	-7	10
	E0022032	BASELINE	11FEB2003/9:20	-7	68	68	156	87	387	402						
		FINAL	18APR2003/10:45	60	67	67	167	87	368	381	-1	-1	11	0	-19	-21
	E0022035	BASELINE	11FEB2003/16:21	-8	74	74	135	89	362	388						
		FINAL	26FEB2003/11:35	8	74	74	151	90	345	369	0	0	16	1	-17	-19
	E0022036	BASELINE	13FEB2003/12:20	-12	68	68	137	92	339	353						
		FINAL	22APR2003/8:55	57	57	57	136	89	388	381	-11	-11	-1	-3	49	28
	E0022056	BASELINE	09APR2003/15:10	-8	81	81	126	80	341	377						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0022060	BASELINE	23APR2003/15:25	-7	42	42	121	88	394	349						
		FINAL	24JUN2003/9:30	56	40	40	151	83	429	373	-2	-2	30	-5	35	24
	E0022063	BASELINE	30APR2003/10:35	-7	65	65	133	101	350	360						
	E0023008	BASELINE	23JAN2003/10:15	-7	64	64	135	81	377	386						
		FINAL	24MAR2003/16:00	54	73	73	123	89	369	394	9	9	-12	8	-8	8
	E0023013	BASELINE	13FEB2003/11:00	-14	62	61	123	88	426	430						
		FINAL	06MAR2003/11:15	8	83	82	137	86	335	372	21	21	14	-2	-91	-58
	E0023015	BASELINE	04MAR2003/11:00	-7	57	57	180	91	389	382						
		FINAL	06MAY2003/10:20	57	77	76	131	90	337	366	20	19	-49	-1	-52	-16
	E0023034	BASELINE	03JUN2003/14:00	-6	64	65	139	83	375	384						
		FINAL	05AUG2003/15:45	58	64	64	154	94	375	384	0	-1	15	11	0	0
	E0023037	BASELINE	11JUN2003/16:00	-7	65	65	136	99	392	402						
		FINAL	15AUG2003/9:15	59	57	57	159	94	402	396	-8	-8	23	-5	10	-6
	E0023038	BASELINE	20JUN2003/13:00	-10	71	72	178	100	386	409						
	E0023044	BASELINE	08JUL2003/13:30	-8	79	79	161	94	376	412						
		FINAL	12AUG2003/11:45	28	87	88	201	93	315	357	8	9	40	-1	-61	-55
	E0023045	BASELINE	10JUL2003/11:45	-7	68	68	139	92	361	376						
		FINAL	11SEP2003/10:45	57	80	80	139	95	347	382	12	12	0	3	-14	6
	E0025002	BASELINE	27MAR2003/10:50	-7	61	62	187	95	358	360						
		FINAL	29MAY2003/11:30	57	69	70	189	93	356	374	8	8	2	-2	-2	14
	E0026010	BASELINE	15JAN2003/14:10	-7	58	57	152	100	380	374						
		FINAL	30JAN2003/14:50	9	62	62	146	102	343	346	4	5	-6	2	-37	-28

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0026017	BASELINE	26FEB2003/12:05	-8	51	51	124	93	425	402						
		FINAL	21MAR2003/11:20	16	46	46	150	92	404	369	-5	-5	26	-1	-21	-33
	E0026018	BASELINE	06MAR2003/16:35	-14	69	69	134	84	378	397						
		FINAL	15MAY2003/14:00	57	56	56	135	88	406	396	-13	-13	1	4	28	-1
	E0026025	BASELINE	01MAY2003/11:40	-8	68	68	178	95	387	404						
		FINAL	03JUL2003/10:05	56	84	83	157	97	360	402	16	15	-21	2	-27	-2
	E0026029	BASELINE	02JUL2003/11:25	-7	52	52	149	86	412	392						
		FINAL	28JUL2003/13:40	20	92	92	146	88	328	379	40	40	-3	2	-84	-13
	E0026030	BASELINE	02JUL2003/11:58	-7	58	58	165	93	406	402						
		FINAL	03SEP2003/17:10	57	59	60	146	93	387	386	1	2	-19	0	-19	-16
	E0026031	BASELINE	10JUL2003/14:05	-11	69	69	131	99	381	399						
		FINAL	15SEP2003/11:40	57	55	56	138	87	383	373	-14	-13	7	-12	2	-26
	E0027003	BASELINE	08JAN2003/14:40	-20	99	99	141	91	334	395						
		FINAL	25MAR2003/11:45	57	94	94	132	89	338	394	-5	-5	-9	-2	4	-1
	E0028004	BASELINE	27SEP2002/9:25	-3	48	48	173	91	446	413						
		FINAL	09OCT2002/14:00	10	61	61	178	94	384	387	13	13	5	3	-62	-26
	E0028006	BASELINE	01OCT2002/9:50	-3	59	59	129	90	432	430						
		FINAL	04DEC2002/10:00	62	50	50	118	90	410	386	-9	-9	-11	0	-22	-44
	E0028008	BASELINE	08OCT2002/12:40	-7	65	64	162	94	378	387						
		FINAL	10DEC2002/12:15	57	60	59	136	88	372	369	-5	-5	-26	-6	-6	-18
	E0028009	BASELINE	10OCT2002/10:30	-5	51	50	150	90	399	377						
		FINAL	12DEC2002/13:00	59	59	59	153	94	384	382	8	9	3	4	-15	5

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	BASELINE		07NOV2002/10:10	-7	70	70	222	87	376	396						
		FINAL		09JAN2003/11:59	57	71	71	266	92	363	384	1	1	44	5	-13	-12
	E0028017		*	12NOV2002/9:35		66	66	177	88	388	400						
	E0028027	BASELINE		14JAN2003/10:30	-7	58	58	158	87	379	374						
	E0028029	BASELINE		28JAN2003/10:00	-7	65	65	114	103	413	422						
		FINAL		03APR2003/11:37	59	73	73	139	96	377	398	8	8	25	-7	-36	-24
	E0028034	BASELINE		20MAR2003/9:22	-12	77	77	186	77	346	376						
		FINAL		02JUN2003/13:15	63	77	77	171	78	341	371	0	0	-15	1	-5	-5
	E0028038	BASELINE		18APR2003/10:10	-7	78	78	146	80	353	384						
		FINAL		18JUN2003/13:07	55	79	79	148	90	355	389	1	1	2	10	2	5
	E0028043	BASELINE		29MAY2003/11:50	-7	54	54	142	87	386	374						
		FINAL		29JUL2003/8:30	55	54	54	162	87	373	361	0	0	20	0	-13	-13
	E0028045	BASELINE		09JUN2003/12:45	-9	70	70	162	81	360	379						
		FINAL		11SEP2003/12:45	86	68	67	156	81	363	378	-2	-3	-6	0	3	-1
	E0029005	BASELINE	*	14NOV2002/12:30	-13	76	76	122	95	344	372						
		BASELINE		27NOV2002/12:20	1	62	61	142	92	383	386						
		FINAL		21JAN2003/12:35	56	80	81	143	89	355	391	18	20	1	-3	-28	5
	E0030001	BASELINE		12NOV2002/15:05	-7	76	76	143	84	365	396						
		FINAL		16JAN2003/11:53	59	81	82	138	91	345	382	5	6	-5	7	-20	-14
	E0030008	BASELINE		07JAN2003/14:15	-7	59	60	164	110	382	381						
		FINAL		18MAR2003/11:35	64	75	75	176	114	381	411	16	15	12	4	-1	30
	E0030011	BASELINE		16JAN2003/17:04	-11	71	71	127	90	335	354						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0030011	FINAL	24MAR2003/14:25	57	79	78	124	90	342	374	8	7	-3	0	7	20
	E0030015	BASELINE	13FEB2003/12:15	-8	48	48	134	94	396	368						
		FINAL	22APR2003/12:00	61	49	49	136	89	377	351	1	1	2	-5	-19	-17
	E0030022	BASELINE	10JUN2003/11:30	-6	65	65	137	89	359	370						
		FINAL	14AUG2003/16:00	60	82	82	128	97	334	370	17	17	-9	8	-25	0
	E0031002	BASELINE	20NOV2002/16:56	-7	56	56	125	96	391	383						
		FINAL	22JAN2003/16:15	57	62	62	134	92	390	394	6	6	9	-4	-1	11
	E0031003	BASELINE	03DEC2002/15:58	-7	61	61	124	94	352	354						
		FINAL	04FEB2003/16:25	57	58	58	138	89	371	367	-3	-3	14	-5	19	13
	E0033015	BASELINE	03APR2003/16:50	-7	52	52	139	91	425	404						
		FINAL	04JUN2003/13:43	56	64	65	131	79	402	412	12	13	-8	-12	-23	8
	E0034002	BASELINE	14MAR2003/14:45	-11	80	81	142	91	353	388						
		FINAL	16APR2003/15:05	23	87	87	157	86	341	385	7	6	15	-5	-12	-3
	E0034003	BASELINE	11APR2003/11:10	-13	65	66	133	87	358	369						
		FINAL	19JUN2003/16:25	57	62	63	154	82	371	376	-3	-3	21	-5	13	7
	E0034006	BASELINE	25APR2003/11:18	-21	59	59	153	92	405	402						
		FINAL	10JUL2003/9:18	56	68	67	181	96	381	397	9	8	28	4	-24	-5
	E0034008	BASELINE	15MAY2003/15:48	-9	71	71	158	88	357	377						
		FINAL	21JUL2003/9:55	59	69	68	179	88	358	374	-2	-3	21	0	1	-3
	E0035003	BASELINE	15NOV2002/12:40	-7	83	84	187	97	361	403						
	E0035005	BASELINE	26NOV2002/12:20	-7	98	98	166	88	350	411						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	BASELINE	28JAN2003/10:55	-6	67	67	147	93	395	410						
		FINAL	31MAR2003/9:40	57	71	71	145	91	386	407	4	4	-2	-2	-9	-3
	E0035024	BASELINE	15MAY2003/11:12	-8	66	66	158	86	361	373						
		FINAL	18JUL2003/9:00	57	81	81	150	82	347	384	15	15	-8	-4	-14	11
	E0036005	BASELINE	24JUN2003/15:30	-7	71	71	161	86	340	359						
		FINAL	27AUG2003/11:46	58	65	65	149	90	333	342	-6	-6	-12	4	-7	-17
	E0037002	BASELINE	18DEC2002/12:35	-8	55	55	147	83	387	377						
		FINAL	20FEB2003/14:05	57	61	60	147	85	396	398	6	5	0	2	9	21
	E0037005	BASELINE	26FEB2003/12:38	-8	50	50	174	98	378	356						
		FINAL	01MAY2003/14:25	57	63	63	162	89	359	366	13	13	-12	-9	-19	10
	E0037006	BASELINE	06MAR2003/13:00	-8	70	70	162	83	370	389						
		FINAL	09MAY2003/12:35	57	73	73	153	81	364	389	3	3	-9	-2	-6	0
	E0039006	BASELINE *	08NOV2002/16:35	-52	81	81	145	80	354	392						
		BASELINE	10DEC2002/11:50	-20	82	81	127	83	364	403						
		FINAL	24FEB2003/11:05	57	81	81	133	91	355	392	-1	0	6	8	-9	-11
	E0039015	BASELINE	02JAN2003/10:25	-21	43	43	142	92	448	402						
		FINAL	20MAR2003/9:40	57	55	56	145	96	396	385	12	13	3	4	-52	-17
	E0039024	BASELINE	05FEB2003/20:50	-22	72	71	146	106	433	460						
		FINAL	24APR2003/15:55	57	71	72	148	101	398	421	-1	1	2	-5	-35	-39
	E0039025	BASELINE	26FEB2003/11:07	-20	58	57	147	105	400	395						
		FINAL	27MAY2003/10:05	71	84	84	137	97	350	392	26	27	-10	-8	-50	-3
	E0039041	BASELINE	07APR2003/15:20	-8	58	58	173	90	357	353						
		FINAL	11JUN2003/11:35	58	53	53	146	92	393	375	-5	-5	-27	2	36	22

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	BASELINE	05MAY2003/13:40	-17	66	67	159	92	342	354						
		FINAL	09JUL2003/19:40	49	80	80	166	100	335	369	14	13	7	8	-7	15
	E0039046		* 06MAY2003/12:00		75	75	163	88	358	384						
			* 30MAY2003/9:20		67	68	169	92	352	358						
	E0039051	BASELINE	22MAY2003/15:40	-25	97	98	155	87	314	369						
		FINAL	12AUG2003/14:55	58	80	80	177	84	344	379	-17	-18	22	-3	30	10
	E0039053	BASELINE	16JUN2003/13:30	-25	65	65	181	97	374	384						
		FINAL	08SEP2003/12:30	60	74	74	161	90	343	367	9	9	-20	-7	-31	-17
	E0039057	BASELINE	02JUL2003/17:45	-12	56	55	157	91	411	400						
		FINAL	09SEP2003/9:40	58	61	60	141	88	375	376	5	5	-16	-3	-36	-24
	E0041003	BASELINE	16JAN2003/8:16	-12	72	72	148	88	360	382						
		FINAL	25MAR2003/11:20	57	75	76	157	76	354	381	3	4	9	-12	-6	-1
	E0041008	BASELINE	26MAR2003/16:00	-12	91	91	155	87	355	409						
		FINAL	02JUN2003/15:45	57	63	64	152	90	399	406	-28	-27	-3	3	44	-3
	E0042001	BASELINE	17JUN2003/12:00	-15	76	76	182	91	384	417						
		FINAL	26AUG2003/11:05	56	86	86	159	96	349	393	10	10	-23	5	-35	-24

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BASELINE	26FEB2003/13:00	-14	73	73	129	89	368	393						
		FINAL	07MAY2003/14:15	57	76	75	132	96	321	347	3	2	3	7	-47	-46
	E0003018	BASELINE	08MAY2003/9:30	-5	61	61	164	89	416	418						
		FINAL	08JUL2003/14:40	57	67	67	157	92	389	404	6	6	-7	3	-27	-14
	E0005011	BASELINE	17OCT2002/15:00	-7	57	57	152	98	371	365						
	E0005030	BASELINE	18MAR2003/14:20	-8	75	75	139	85	373	401						
	E0005036	BASELINE	28APR2003/13:30	-8	74	74	189	93	390	417						
		FINAL	27MAY2003/9:50	22	78	78	198	91	368	402	4	4	9	-2	-22	-15
	E0006015	BASELINE	06FEB2003/12:25	-5	60	59	143	99	353	352						
		FINAL	08APR2003/11:48	57	75	75	160	94	342	368	15	16	17	-5	-11	16
	E0006016	BASELINE	07FEB2003/13:14	-10	51	51	231	96	396	374						
		FINAL	18APR2003/12:30	61	57	57	219	91	391	383	6	6	-12	-5	-5	9
	E0007008	BASELINE	07APR2003/13:00	-11	72	72	166	86	367	391						
		FINAL	25APR2003/11:55	8	70	70	169	87	335	353	-2	-2	3	1	-32	-38
	E0009002	BASELINE *	29OCT2002/16:21	-21	65	65	145	97	386	396						
		BASELINE	06NOV2002/11:20	-13	53	53	168	97	416	399						
		FINAL	15JAN2003/13:35	58	63	63	158	107	381	388	10	10	-10	10	-35	-11
	E0009006	BASELINE	22JAN2003/17:05	-6	73	74	159	100	355	379						
		FINAL	25MAR2003/16:15	57	70	71	152	83	333	351	-3	-3	-7	-17	-22	-28
	E0009009	BASELINE	27FEB2003/14:50	-13	77	77	170	92	384	418						
		FINAL	24MAR2003/13:25	13	82	82	141	96	331	367	5	5	-29	4	-53	-51
	E0010015	BASELINE	29JAN2003/16:19	-22	68	67	136	95	352	366						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	FINAL	15APR2003/13:15	55	69	69	157	100	355	373	1	2	21	5	3	7
	E0011004	BASELINE	17DEC2002/10:50	-7	49	49	161	90	410	385						
		FINAL	18FEB2003/9:30	57	58	58	158	93	389	385	9	9	-3	3	-21	0
	E0011007	BASELINE	12DEC2002/10:43	-7	88	87	153	85	336	381						
		FINAL	13FEB2003/8:45	57	93	93	138	89	332	384	5	6	-15	4	-4	3
	E0011018	BASELINE	15MAY2003/12:50	-7	57	57	192	97	378	371						
		FINAL	17JUL2003/17:45	57	74	74	168	89	364	391	17	17	-24	-8	-14	20
	E0011024	BASELINE	17JUN2003/12:40	-7	52	52	178	94	415	395						
		FINAL	21AUG2003/13:45	59	70	71	165	95	367	388	18	19	-13	1	-48	-7
	E0015003	BASELINE	13NOV2002/12:02	-12	70	69	156	88	400	420						
		FINAL	02DEC2002/10:45	8	79	79	150	78	377	414	9	10	-6	-10	-23	-6
	E0019003	BASELINE	29OCT2002/10:44	-23	60	60	133	87	390	390						
		FINAL	16JAN2003/11:33	57	62	62	144	88	372	376	2	2	11	1	-18	-14
	E0019007	BASELINE	06NOV2002/10:50	-7	64	64	124	81	404	412						
		FINAL	07JAN2003/9:45	56	75	74	122	89	380	409	11	10	-2	8	-24	-3
	E0019014	BASELINE	17DEC2002/10:50	-23	54	54	137	84	404	390						
		FINAL	20JAN2003/13:31	12	52	52	126	86	368	351	-2	-2	-11	2	-36	-39
	E0019018	BASELINE	14JAN2003/10:33	-16	72	72	194	92	365	388						
		FINAL	27MAR2003/10:00	57	63	64	173	85	353	359	-9	-8	-21	-7	-12	-29
	E0019022	BASELINE	23JAN2003/11:40	-7	54	54	137	95	362	349						
		FINAL	27MAR2003/15:45	57	92	92	132	84	339	391	38	38	-5	-11	-23	42
	E0019027	BASELINE	20FEB2003/10:20	-7	63	62	133	96	386	391						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	FINAL	06MAR2003/8:35	8	97	96	138	88	319	375	34	34	5	-8	-67	-16
	E0019032	BASELINE	06MAR2003/15:20	-26	65	65	126	81	366	377						
		FINAL	27MAY2003/12:15	57	61	61	144	89	353	355	-4	-4	18	8	-13	-22
	E0019034	BASELINE	10MAR2003/17:05	-8	78	78	136	90	347	379						
	E0019036	BASELINE	18MAR2003/10:10	-7	50	50	176	91	374	352						
	E0019039	BASELINE	22APR2003/10:30	-9	67	67	170	93	364	378						
		FINAL	08MAY2003/16:00	8	86	86	151	91	356	402	19	19	-19	-2	-8	24
	E0019041	BASELINE	14MAY2003/10:30	-7	62	62	174	91	360	363						
		FINAL	16JUL2003/10:55	57	56	56	158	88	360	353	-6	-6	-16	-3	0	-10
	E0019049	BASELINE	03JUL2003/15:30	-7	61	61	169	95	420	423						
		FINAL	08SEP2003/12:00	61	68	68	151	93	382	399	7	7	-18	-2	-38	-24
	E0022052	BASELINE	01APR2003/10:55	-9	71	71	134	85	385	408						
		FINAL	05JUN2003/9:45	57	88	88	133	85	350	398	17	17	-1	0	-35	-10
	E0022064	BASELINE	29APR2003/13:30	-7	64	64	116	90	382	390						
		FINAL	01JUL2003/12:55	57	60	61	134	80	377	378	-4	-3	18	-10	-5	-12
	E0022073	BASELINE	19JUN2003/12:45	-7	63	63	153	81	362	368						
		FINAL	21AUG2003/10:35	57	87	88	150	93	322	365	24	25	-3	12	-40	-3
	E0023002	BASELINE	25OCT2002/16:00	-11	62	62	132	84	377	374						
	E0023017	BASELINE	14MAR2003/13:30	-11	53	53	132	88	384	368						
		FINAL	22MAY2003/12:40	59	66	66	128	94	356	367	13	13	-4	6	-28	-1
	E0023021	BASELINE	10APR2003/10:40	-13	53	53	176	88	421	403						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR II)	E0023021	FINAL	17JUN2003/16:00	56	89	89	170	83	339	387	36	36	-6	-5	-82	-16
	E0023027	BASELINE	07MAY2003/13:00	-9	63	63	142	95	398	404						
		FINAL	09JUL2003/13:45	55	77	78	140	80	371	404	14	15	-2	-15	-27	0
	E0023030	BASELINE	21MAY2003/10:30	-13	62	62	152	93	386	390						
		FINAL	30JUL2003/16:30	58	86	86	150	100	352	396	24	24	-2	7	-34	6
	E0023040	BASELINE	25JUN2003/15:15	-8	59	59	129	79	398	396						
		FINAL	05SEP2003/10:55	65	67	67	136	85	387	401	8	8	7	6	-11	5
	E0026014	BASELINE	12FEB2003/12:00	-7	66	66	151	94	376	389						
		FINAL	19MAR2003/10:15	29	91	92	143	91	359	412	25	26	-8	-3	-17	23
	E0026019	BASELINE	10MAR2003/12:10	-7	71	72	136	96	383	405						
		FINAL	12MAY2003/9:15	57	70	70	146	88	357	376	-1	-2	10	-8	-26	-29
	E0027005	BASELINE	19DEC2002/14:50	-7	88	88	151	98	326	371						
		FINAL	20FEB2003/11:20	57	98	99	141	98	307	362	10	11	-10	0	-19	-9
	E0029009	BASELINE	13JAN2003/13:43	-7	51	51	177	98	402	382						
		FINAL	18MAR2003/10:00	58	57	57	167	98	400	394	6	6	-10	0	-2	12
	E0029021	BASELINE *	03MAR2003/10:23	-15	69	69	144	93	371	389						
		BASELINE	18MAR2003/9:30	1	67	68	165	84	358	372						
		FINAL	15MAY2003/13:20	59	92	92	152	85	314	362	25	24	-13	1	-44	-10
	E0029026	BASELINE	07APR2003/9:35	-7	69	69	204	82	329	345						
		FINAL	10JUN2003/10:02	58	77	76	186	90	333	362	8	7	-18	8	4	17
	E0029030	BASELINE	13MAY2003/11:25	-14	55	55	165	97	375	364						
		FINAL	23JUL2003/17:55	58	61	62	150	87	366	368	6	7	-15	-10	-9	4

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR II)	E0031008	BASELINE	05FEB2003/11:45	-23	62	62	179	84	382	386						
		FINAL	24APR2003/13:05	56	73	73	163	85	360	384	11	11	-16	1	-22	-2
	E0031020	BASELINE	14APR2003/10:38	-7	59	59	160	90	385	383						
		FINAL	13MAY2003/10:55	23	59	59	164	86	376	375	0	0	4	-4	-9	-8
	E0031021	BASELINE	18APR2003/10:45	-7	57	57	193	91	378	372						
		FINAL	19JUN2003/10:35	56	60	60	208	94	362	361	3	3	15	3	-16	-11
	E0031029	BASELINE	05JUN2003/10:48	-13	51	51	141	91	389	369						
	E0033002	BASELINE	23DEC2002/12:05	-18	77	77	181	80	337	366						
		FINAL	07MAR2003/11:15	57	82	82	166	88	321	357	5	5	-15	8	-16	-9
	E0033006	BASELINE	15JAN2003/10:20	-8	64	64	158	86	380	389						
		FINAL	12FEB2003/12:25	21	66	67	153	83	340	350	2	3	-5	-3	-40	-39
	E0033021	BASELINE	25JUN2003/14:30	-7	54	53	121	78	384	370						
		FINAL	18AUG2003/16:30	48	63	63	140	80	375	381	9	10	19	2	-9	11
	E0035013	BASELINE	27JAN2003/10:50	-8	74	73	137	91	338	361						
	E0035015	BASELINE	03FEB2003/11:20	-8	90	89	183	87	327	375						
		FINAL	18FEB2003/11:33	8	102	102	178	87	323	386	12	13	-5	0	-4	11
	E0035016	BASELINE	10MAR2003/16:54	-25	90	90	144	85	338	387						
	E0035023	BASELINE	06MAY2003/10:41	-7	47	47	167	87	384	353						
	E0039052	BASELINE	29MAY2003/10:30	-22	79	79	189	89	360	394						
		FINAL	04JUL2003/11:35	15	71	70	189	95	395	416	-8	-9	0	6	35	22
	E0039056	BASELINE	01JUL2003/13:00	-14	56	56	156	95	371	363						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS						CHANGE FROM BASELINE					
					VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	BASELINE	09JUL2003/13:40	-10	77	76	133	90	387	419						
		FINAL	12SEP2003/11:25	56	90	90	125	82	359	411	13	14	-8	-8	-28	-8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BASELINE	14FEB2003/10:50	-17	70	70	138	91	397	418						
		FINAL	02MAY2003/10:30	61	67	66	143	97	413	428	-3	-4	5	6	16	10
	E0002011	BASELINE	16APR2003/12:00	-13	104	103	159	91	319	383						
		FINAL	25JUN2003/11:56	58	104	105	157	98	301	362	0	2	-2	7	-18	-21
	E0003010	BASELINE	27JAN2003/17:45	-7	68	68	141	83	354	368						
		FINAL	31MAR2003/16:05	57	76	76	142	82	374	404	8	8	1	-1	20	36
	E0003011	BASELINE	28JAN2003/12:05	-7	85	86	132	80	335	377						
	E0003016	BASELINE	01MAY2003/11:30	-21	77	78	149	87	370	402						
		FINAL	13JUN2003/8:55	23	84	84	143	87	334	374	7	6	-6	0	-36	-28
	E0003019	BASELINE	19JUN2003/11:20	-8	53	53	159	101	400	384						
		FINAL	21AUG2003/9:00	56	78	77	150	89	357	389	25	24	-9	-12	-43	5
	E0003020	BASELINE	27JUN2003/8:30	-26	59	59	142	97	408	406						
		FINAL	17SEP2003/0:00	57	70	70	131	103	382	401	11	11	-11	6	-26	-5
	E0004001	BASELINE	23SEP2002/11:40	-7	47	47	180	96	379	349						
		FINAL	05NOV2002/13:25	37	81	81	173	81	319	354	34	34	-7	-15	-60	5
	E0004009	BASELINE	17DEC2002/9:45	-9	60	61	131	99	396	397						
		FINAL	19FEB2003/16:10	56	103	104	147	84	327	391	43	43	16	-15	-69	-6
	E0004012	BASELINE	07JAN2003/12:30	-7	48	48	125	74	452	420						
		FINAL	11MAR2003/11:25	57	70	70	121	87	377	397	22	22	-4	13	-75	-23
	E0004015	BASELINE	06FEB2003/9:40	-14	57	57	139	90	383	376						
		FINAL	15APR2003/9:20	55	75	75	170	90	363	391	18	18	31	0	-20	15
	E0005003	BASELINE	23SEP2002/15:10	-9	60	60	145	100	368	368						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	FINAL		26NOV2002/13:30	56	90	90	148	96	307	351	30	30	3	-4	-61	-17
	E0005005	BASELINE		24SEP2002/15:15	-6	72	72	139	87	349	371						
	E0005007	BASELINE		02OCT2002/13:15	-7	66	66	156	84	405	417						
		FINAL		04DEC2002/14:10	57	86	87	135	90	357	403	20	21	-21	6	-48	-14
	E0005008	BASELINE		08OCT2002/18:00	-7	80	79	171	89	350	384						
		FINAL		11DEC2002/16:00	58	100	100	179	86	307	365	20	21	8	-3	-43	-19
		FINAL	*	30DEC2002/16:45	77	89	90	170	85	344	392	9	11	-1	-4	-6	8
	E0005009	BASELINE		09OCT2002/10:30	-20	49	49	154	90	384	359						
	E0005010	FINAL		17DEC2002/14:15	58	94	94	188	80	331	384						
	E0005012	BASELINE		24OCT2002/7:00	-21	59	59	167	81	402	401						
	E0005014	BASELINE		05NOV2002/16:30	-8	58	57	150	100	393	387						
		FINAL	*	06JAN2003/9:45	55	73	73	154	97	368	393	15	16	4	-3	-25	6
		FINAL		06JAN2003/11:45	55	83	83	152	97	361	402	25	26	2	-3	-32	15
	E0005022	BASELINE		23JAN2003/11:20	-6	58	59	204	95	383	379						
		FINAL		06FEB2003/10:50	9	56	56	188	102	362	354	-2	-3	-16	7	-21	-25
	E0005025	BASELINE		20FEB2003/13:20	-7	66	66	163	84	363	375						
		FINAL		03APR2003/11:40	36	68	69	167	90	361	377	2	3	4	6	-2	2
	E0006019	BASELINE		26MAR2003/11:40	-12	63	63	165	85	366	373						
		FINAL		03JUN2003/12:10	58	76	76	163	93	359	388	13	13	-2	8	-7	15
	E0007005	BASELINE		27JAN2003/13:30	-4	63	62	149	89	371	377						
		FINAL		28MAR2003/12:30	57	79	80	156	86	350	384	16	18	7	-3	-21	7

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	BASELINE	09JUL2003/19:35	-7	58	58	131	100	387	382						
		FINAL	10SEP2003/17:20	57	80	80	150	95	358	395	22	22	19	-5	-29	13
	E0009001	BASELINE	29OCT2002/15:03	-14	66	66	195	90	356	368						
	E0010002	BASELINE	14NOV2002/14:45	-11	63	62	164	92	400	405						
		FINAL	02DEC2002/9:00	8	88	89	140	91	344	391	25	27	-24	-1	-56	-14
	E0010009	BASELINE	18DEC2002/11:33	-8	55	55	153	94	431	419						
		FINAL	19FEB2003/13:40	56	71	71	142	90	366	388	16	16	-11	-4	-65	-31
	E0010010	BASELINE	20DEC2002/8:52	-10	42	42	144	84	430	381						
		FINAL	13JAN2003/10:15	15	58	58	139	87	388	383	16	16	-5	3	-42	2
	E0010014	BASELINE	14JAN2003/8:51	-14	57	58	135	103	404	398						
		FINAL	25MAR2003/10:50	57	47	47	148	106	384	354	-10	-11	13	3	-20	-44
	E0010017	BASELINE	05FEB2003/10:46	-20	58	58	161	91	378	373						
		FINAL	22APR2003/10:03	57	78	78	146	91	343	374	20	20	-15	0	-35	1
	E0010023	BASELINE	10APR2003/11:18	-7	67	67	174	95	396	410						
		FINAL	01MAY2003/10:03	15	67	67	153	98	391	406	0	0	-21	3	-5	-4
	E0010027	BASELINE	05JUN2003/10:46	-11	56	56	135	87	342	335						
		FINAL	01JUL2003/12:30	16	62	62	186	87	389	392	6	6	51	0	47	57
	E0010029	BASELINE	10JUN2003/9:13	-9	80	80	135	80	344	379						
	E0011022	BASELINE	02JUN2003/11:15	-7	89	90	128	92	360	412						
		FINAL	05AUG2003/10:35	58	104	104	125	86	333	400	15	14	-3	-6	-27	-12
	E0013006	BASELINE	06MAR2003/10:22	-7	70	70	162	104	380	400						
		FINAL	24MAR2003/12:45	12	85	85	159	87	341	383	15	15	-3	-17	-39	-17

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	BASELINE	29APR2003/10:40	-8	72	72	161	88	400	425						
		FINAL	02JUL2003/10:10	57	87	87	200	93	326	369	15	15	39	5	-74	-56
	E0013014	BASELINE	08MAY2003/11:23	-26	53	53	233	86	398	383						
		FINAL	30JUN2003/12:27	28	54	54	217	87	380	368	1	1	-16	1	-18	-15
	E0014005	BASELINE	04MAR2003/16:47	-7	72	72	148	94	360	382						
		FINAL	06MAY2003/11:43	57	86	86	142	84	336	379	14	14	-6	-10	-24	-3
	E0014007	BASELINE	25MAR2003/16:30	-7	65	65	164	97	402	412						
		FINAL	22APR2003/13:20	22	69	69	159	95	393	412	4	4	-5	-2	-9	0
	E0014011	BASELINE	06MAY2003/16:25	-7	71	72	134	96	371	394						
		FINAL	08JUL2003/15:25	57	80	80	142	94	349	385	9	8	8	-2	-22	-9
	E0014012	BASELINE	19MAY2003/9:40	-8	70	69	130	91	351	369						
		FINAL	24JUN2003/16:05	29	76	76	116	96	361	391	6	7	-14	5	10	22
	E0015001	BASELINE	08NOV2002/10:35	-21	51	51	163	92	404	383						
		FINAL	20JAN2003/7:45	53	68	69	160	102	387	404	17	18	-3	10	-17	21
	E0015008	BASELINE	13DEC2002/9:40	-6	55	55	134	89	436	423						
	E0016003	BASELINE	10JAN2003/10:50	-14	66			83	371	384						
	E0016005	BASELINE	20FEB2003/13:40	-5	59	59	147	90	410	408						
		FINAL	22APR2003/8:05	57	80	80	144	86	375	414	21	21	-3	-4	-35	6
	E0018007	BASELINE	16DEC2002/9:10	-11	70	70	182	90	348	367						
		FINAL	10JAN2003/14:40	15	82	83	156	88	315	349	12	13	-26	-2	-33	-18
	E0019005	BASELINE	30OCT2002/12:43	-6	56	55	135	91	399	390						
		FINAL	02JAN2003/13:50	59	63	63	157	83	355	361	7	8	22	-8	-44	-29

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0019015	BASELINE	19DEC2002/10:05	-14	56	57	190	93	415	407						
		FINAL	27FEB2003/11:10	57	76	76	157	91	368	399	20	19	-33	-2	-47	-8
	E0020004	BASELINE	21NOV2002/16:10	-18	75	75	170	94	393	424						
		FINAL	22JAN2003/16:18	45	71	72	176	80	366	388	-4	-3	6	-14	-27	-36
	E0020010	BASELINE	31JAN2003/9:30	-5	66	67	164	96	384	396						
		FINAL	02APR2003/10:55	57	73	72	155	96	363	387	7	5	-9	0	-21	-9
	E0020014	BASELINE	11MAR2003/10:17	-7	68	68	149	87	388	403						
		FINAL	12MAY2003/11:30	56	63	63	141	85	392	398	-5	-5	-8	-2	4	-5
	E0020021	BASELINE	13MAY2003/10:00	-6	63	63	159	93	362	367						
		FINAL	14JUL2003/9:55	57	84	85	142	97	299	335	21	22	-17	4	-63	-32
	E0020023	BASELINE	09JUN2003/19:20	-8	51	51	161	85	407	386						
		FINAL	11AUG2003/11:45	56	56	56	191	95	385	376	5	5	30	10	-22	-10
	E0022007	BASELINE	01NOV2002/11:35	-6	47	47	152	93	402	370						
	E0022010	BASELINE	14NOV2002/16:05	-7	59	59	135	95	391	389						
		FINAL	16JAN2003/18:23	57	72	72	158	103	354	376	13	13	23	8	-37	-13
	E0022012	BASELINE	21NOV2002/12:15	-14	57	57	113	95	394	386						
		FINAL	30JAN2003/12:35	57	73	73	135	97	352	376	16	16	22	2	-42	-10
	E0022019	BASELINE	04DEC2002/13:00	-7	58	58	160	101	345	340						
		FINAL	06FEB2003/11:30	58	71	70	151	92	336	355	13	12	-9	-9	-9	15
	E0022025	BASELINE	08JAN2003/10:20	-20	49	49	189	98	424	396						
		FINAL	04FEB2003/11:40	8	57	57	178	93	410	403	8	8	-11	-5	-14	7
	E0022033	BASELINE	11FEB2003/12:00	-7	53	53	147	88	400	385						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	FINAL	15APR2003/11:20	57	58	59	148	87	391	387	5	6	1	-1	-9	2
	E0022034	BASELINE	11FEB2003/14:00	-7	74	74	153	99	341	365						
		FINAL	15APR2003/14:05	57	75	74	155	100	345	371	1	0	2	1	4	6
	E0022038	BASELINE	20FEB2003/15:40	-8	48	48	182	96	406	376						
		FINAL	10APR2003/13:05	42	56	57	194	94	386	379	8	9	12	-2	-20	3
	E0022039	BASELINE	27FEB2003/11:30	-7	52	52	198	97	401	383						
		FINAL	01MAY2003/13:05	57	92	91	182	91	357	412	40	39	-16	-6	-44	29
	E0022046	BASELINE	13MAR2003/11:25	-7	91	92	143	91	348	400						
		FINAL	16MAY2003/8:10	58	95	95	168	92	339	395	4	3	25	1	-9	-5
	E0022048	BASELINE	25MAR2003/11:45	-7	56	55	163	90	397	387						
	E0022051	BASELINE	31MAR2003/11:35	-7	63	63	167	78	381	387						
		FINAL	02JUN2003/11:00	57	80	80	151	81	350	385	17	17	-16	3	-31	-2
	E0022053	BASELINE	04APR2003/13:52	-7	49	49	154	88	408	381						
	E0022058	BASELINE	11APR2003/13:20	-10	60	60	165	103	371	370						
		FINAL	22MAY2003/15:15	32	73	74	132	98	335	357	13	14	-33	-5	-36	-13
	E0022061	BASELINE	24APR2003/10:05	-6	67	68	141	94	375	389						
		FINAL	26JUN2003/12:43	58	84	84	162	96	332	371	17	16	21	2	-43	-18
	E0022062	BASELINE	25APR2003/12:50	-10	77	77	176	94	356	387						
	E0022068	BASELINE	14MAY2003/10:30	-9	53	53	153	82	390	375						
	E0022069	BASELINE	03JUN2003/10:55	-7	53	53	146	90	415	398						
		FINAL	05AUG2003/10:05	57	67	67	124	89	393	407	14	14	-22	-1	-22	9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0022071	BASELINE	16JUN2003/11:50	-14	63	63	164	87	423	430						
		FINAL	25AUG2003/9:55	57	77	76	179	90	351	381	14	13	15	3	-72	-49
	E0023003	BASELINE *	08NOV2002/16:05	-39	90	91	120	108	355	406						
		BASELINE	12DEC2002/10:00	-5	66	66	156	105	389	401						
		FINAL	11FEB2003/14:00	57	62	62	140	113	384	388	-4	-4	-16	8	-5	-13
	E0023006	BASELINE	10DEC2002/11:20	-7	63	63	172	103	361	367						
		FINAL	11FEB2003/12:00	57	65	65	174	104	378	388	2	2	2	1	17	21
	E0023010	BASELINE	28JAN2003/9:30	-7	64	64	164	97	382	390						
		FINAL	31MAR2003/10:15	56	77	77	163	93	359	390	13	13	-1	-4	-23	0
	E0023025	BASELINE	01MAY2003/15:30	-14	65	64	148	101	341	350						
		FINAL	10JUL2003/14:00	57	72	72	123	94	341	362	7	8	-25	-7	0	12
	E0023039	BASELINE	24JUN2003/13:45	-7	68	68	167	82	386	402						
		FINAL	26AUG2003/13:00	57	86	86	148	86	351	395	18	18	-19	4	-35	-7
	E0026002	BASELINE	05NOV2002/10:30	-7	61	61	170	89	352	354						
		FINAL	09JAN2003/9:30	59	68	68	184	91	362	377	7	7	14	2	10	23
	E0026007	BASELINE	06JAN2003/10:35	-10	65	65	158	85	406	418						
		FINAL	12MAR2003/14:30	56	89	90	167	83	351	400	24	25	9	-2	-55	-18
	E0026013	BASELINE	05FEB2003/12:25	-8	69	70	152	91	363	380						
		FINAL	14APR2003/10:05	61	79	79	145	87	340	373	10	9	-7	-4	-23	-7
	E0028007	BASELINE	01OCT2002/10:15	-3	65	65	171	93	353	362						
		FINAL	14NOV2002/12:50	42	73	73	182	95	330	353	8	8	11	2	-23	-9
	E0028023	BASELINE *	17DEC2002/9:45	-35	64	65	122	97	407	415						
		BASELINE	14JAN2003/9:40	-7	63	63	136	97	416	423						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	FINAL	27JUN2003/15:15	158	72	72	134	91	386	410	9	9	-2	-6	-30	-13
	E0028025	BASELINE	08JAN2003/11:17	-5	52	52	135	91	378	361						
		FINAL	27JAN2003/9:30	15	60	60	133	83	345	345	8	8	-2	-8	-33	-16
	E0028033	BASELINE	18MAR2003/10:36	-9	73	73	124	92	348	371						
		FINAL	22MAY2003/11:03	57	72	72	135	83	359	381	-1	-1	11	-9	11	10
	E0028035	BASELINE	27MAR2003/12:15	-7	58	58	151	93	375	372						
		FINAL	29MAY2003/15:33	57	66	66	136	101	362	374	8	8	-15	8	-13	2
	E0028037	BASELINE *	18APR2003/8:05	-56	86	85	136	83	374	421						
		BASELINE	04JUN2003/9:00	-9	57	57	146	95	394	388						
		FINAL	08AUG2003/14:30	57	79	78	143	94	360	395	22	21	-3	-1	-34	7
	E0028039	BASELINE	02MAY2003/12:55	-7	69	69	143	95	350	366						
		FINAL	05JUN2003/11:30	28	80	81	136	92	325	357	11	12	-7	-3	-25	-9
	E0028046	BASELINE	17JUN2003/13:20	-8	74	74	171	85	382	410						
	E0028048	BASELINE	11JUL2003/13:25	-6	56	56	143	91	384	376						
	E0029008	BASELINE	09DEC2002/12:53	-7	66	65	109	81	345	356						
		FINAL	23DEC2002/12:30	8	64	63	122	93	363	370	-2	-2	13	12	18	14
	E0029011	BASELINE	14JAN2003/10:05	-8	70	70	163	95	353	371						
	E0029012	BASELINE	04FEB2003/9:30	-7	46	47	130	93	430	394						
		FINAL	27MAR2003/9:00	45	55	55	156	95	397	385	9	8	26	2	-33	-9
	E0029015	BASELINE	11FEB2003/10:22	-13	88	88	144	85	331	376						
		FINAL	11MAR2003/13:50	16	76	76	149	94	354	384	-12	-12	5	9	23	8

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0029018	BASELINE	26FEB2003/17:23	-8	76	76	121	89	366	396						
	E0030014	BASELINE	14FEB2003/10:30	-7	52	52	167	84	415	394						
		FINAL	22APR2003/12:40	61	65	65	166	89	383	393	13	13	-1	5	-32	-1
	E0030020	BASELINE	13MAY2003/15:15	-16	64	64	136	91	334	341						
	E0030024	BASELINE	17JUN2003/15:15	-24	82	81	147	89	375	416						
		FINAL	18JUL2003/16:15	8	78	77	155	95	381	415	-4	-4	8	6	6	-1
	E0030025	BASELINE	24JUN2003/16:43	-17	61	62	137	88	424	427						
		FINAL	19AUG2003/16:15	40	66	66	134	95	370	382	5	4	-3	7	-54	-45
	E0031027	BASELINE	28MAY2003/9:15	-6	58	58	174	93	373	369						
		FINAL	29JUL2003/14:30	57	62	62	178	99	379	383	4	4	4	6	6	14
	E0031030	BASELINE	17JUN2003/10:45	-7	60	60	126	93	404	404						
		FINAL	21AUG2003/11:15	59	63	63	147	103	385	393	3	3	21	10	-19	-11
	E0033012	BASELINE	05FEB2003/13:20	-5	76	76	150	94	339	367						
	E0034001	BASELINE	17MAR2003/9:40	-3	58	58	183	75	410	405						
		FINAL	15MAY2003/11:40	57	65	65	152	84	388	399	7	7	-31	9	-22	-6
	E0034004	BASELINE	11APR2003/11:22	-10	62	63	142	95	354	357						
		FINAL	16JUN2003/12:22	57	85	86	146	83	333	374	23	23	4	-12	-21	17
	E0035001	BASELINE	12NOV2002/12:50	-8	57	57	181	89	392	385						
		FINAL	14JAN2003/9:30	56	60	60	186	92	405	405	3	3	5	3	13	20
	E0035006	BASELINE	03DEC2002/13:32	-9	72	72	119	84	358	380						
		FINAL	06FEB2003/9:35	57	64	64	123	89	382	391	-8	-8	4	5	24	11

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	BASELINE	18APR2003/10:26	-7	57	57	151	87	367	361						
		FINAL	20JUN2003/8:23	57	74	74	139	87	359	385	17	17	-12	0	-8	24
	E0036002	BASELINE	10JUN2003/12:12	-7	59	59	140	89	412	410						
		FINAL	14JUL2003/14:05	28	83	83	139	84	342	381	24	24	-1	-5	-70	-29
	E0036006	BASELINE	24JUN2003/14:30	-9	87	88	131	92	340	385						
		FINAL	27AUG2003/13:56	56	91		130	83	336	385	4		-1	-9	-4	0
	E0036007	BASELINE	26JUN2003/10:54	-7	76	77	141	93	358	388						
		FINAL	18JUL2003/9:48	16	80	81	136	86	372	411	4	4	-5	-7	14	23
	E0037009	BASELINE	09MAY2003/14:45	-7	78	78	142	81	359	392						
		FINAL	10JUL2003/17:45	56	81	81	146	88	358	395	3	3	4	7	-1	3
	E0039011	BASELINE	16DEC2002/15:00	-17	75	75	144	88	391	421						
	E0039018	BASELINE	14JAN2003/11:35	-9	62	62	156	96	388	393						
		FINAL	06FEB2003/11:37	15	65	65	161	92	357	367	3	3	5	-4	-31	-26
	E0039026	BASELINE	26FEB2003/13:55	-9	75	75	147	90	363	391						
		FINAL	01MAY2003/11:20	56	88	88	142	79	333	379	13	13	-5	-11	-30	-12
	E0039028	BASELINE	03MAR2003/14:25	-21	76	77	171	83	370	401						
		FINAL	16MAY2003/12:20	54	88	89	139	92	341	388	12	12	-32	9	-29	-13
	E0039032	BASELINE	07MAR2003/13:55	-7	63	63	142	90	388	394						
		FINAL	28MAR2003/16:38	15	77	77	148	99	354	385	14	14	6	9	-34	-9
	E0039034	BASELINE	12MAR2003/20:20	-7	69	69	158	87	343	360						
		FINAL	14MAY2003/15:10	57	80	80	158	94	340	375	11	11	0	7	-3	15
	E0039042	BASELINE	24APR2003/15:15	-13	57	57	165	96	389	381						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	FINAL	02JUL2003/13:00	57	86	86	162	89	371	417	29	29	-3	-7	-18	36
	E0041004	BASELINE	22JAN2003/16:00	-8	56	56	167	90	376	367						
		FINAL	31MAR2003/12:40	61	76	76	168	90	339	367	20	20	1	0	-37	0
	E0041009	BASELINE	22APR2003/15:30	-9	56	57	134	96	379	372						
	E0042002	BASELINE	02JUL2003/14:15	-7	63	63	202	95	367	373						
		FINAL	02SEP2003/10:30	56	64	64	185	84	365	373	1	1	-17	-11	-2	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BASELINE	23JUN2003/12:20	-18	56	57	159	86	388	378						
		FINAL	25JUL2003/9:59	15	48	48	166	87	411	381	-8	-9	7	1	23	3
	E0003002	BASELINE	22OCT2002/10:40	-7	59	58	200	81	406	402						
		FINAL	23DEC2002/15:45	56	74	75	169	87	373	402	15	17	-31	6	-33	0
	E0005031	BASELINE	27MAR2003/13:15	-6	62	62	142	94	382	385						
	E0005033	BASELINE	15APR2003/9:50	-1	66	66	138	86	354	365						
		FINAL	06MAY2003/11:35	21	68	68	182	82	374	389	2	2	44	-4	20	24
	E0005038	BASELINE	05MAY2003/11:45	-9	67	66	170	93	392	406						
		FINAL	05JUN2003/12:40	23	72	72	161	86	392	417	5	6	-9	-7	0	11
	E0007009	BASELINE	09APR2003/18:55	-8	61	61	145	101	385	386						
		FINAL	28APR2003/17:45	12	87	87	155	95	350	396	26	26	10	-6	-35	10
	E0009010	BASELINE	27FEB2003/17:05	-14	59	60	137	107	368	368						
	E0009011	BASELINE	28APR2003/14:10	-8	82	82	204	91	342	379						
		FINAL	03JUL2003/15:45	59	55	55	201	93	388	378	-27	-27	-3	2	46	-1
	E0010005	BASELINE	10DEC2002/11:30	-8	103	104	184	103	318	380						
	E0011016	BASELINE	14APR2003/10:15	-7	65	65	162	92	363	373						
		FINAL	16JUN2003/10:30	57	86	87	165	84	332	375	21	22	3	-8	-31	2
	E0011020	BASELINE	01MAY2003/9:45	-7	58	58	195	88	399	395						
		FINAL	15MAY2003/17:00	8	63	64	178	80	357	363	5	6	-17	-8	-42	-32
	E0018002	BASELINE	15NOV2002/15:35	-14	60	60	152	89	371	370						
		FINAL	22JAN2003/16:10	55	60	60	152	91	393	393	0	0	0	2	22	23

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	BASELINE	19NOV2002/13:00	-7	87	87	164	97	352	399						
		FINAL	10DEC2002/11:15	15	86	85	162	96	340	383	-1	-2	-2	-1	-12	-16
	E0018013	BASELINE	17JAN2003/15:20	-7	46	46	187	89	444	405						
		FINAL	31JAN2003/16:50	8	53	53	191	83	392	378	7	7	4	-6	-52	-27
	E0019002	BASELINE	29OCT2002/11:00	-14	69	68	133	91	336	352						
	E0019008	BASELINE	06NOV2002/12:25	-15	54	54	139	86	406	392						
	E0019009	BASELINE	06NOV2002/13:49	-8	67	66	121	85	371	384						
	E0019016	BASELINE	30DEC2002/17:15	-7	78	78	155	91	322	351						
		FINAL	03MAR2003/16:16	57	96	96	151	90	321	375	18	18	-4	-1	-1	24
	E0019020	BASELINE	16JAN2003/9:50	-7	77	77	153	92	356	387						
		FINAL	27MAR2003/11:05	64	71	72	156	82	386	409	-6	-5	3	-10	30	22
	E0019021	BASELINE	16JAN2003/12:03	-14	58	59	145	92	361	357						
		FINAL	03MAR2003/14:05	33	53	53	143	96	369	355	-5	-6	-2	4	8	-2
	E0019024	BASELINE	23JAN2003/16:43	-7	68	68	147	96	366	381						
		FINAL	06FEB2003/14:00	8	84	84	158	103	344	385	16	16	11	7	-22	4
	E0019031	BASELINE	06MAR2003/11:54	-7	48	48	185	96	384	355						
		FINAL	25MAR2003/10:50	13	68	69	184	93	356	372	20	21	-1	-3	-28	17
	E0019035	BASELINE	11MAR2003/11:10	-7	71	71	169	87	379	402						
	E0019040	BASELINE	08MAY2003/15:10	-12	98	98	137	81	324	381						
		FINAL	17JUL2003/10:43	59	103	104	135	86	342	410	5	6	-2	5	18	29
	E0019042	BASELINE	28MAY2003/10:20	-7	61	61	139	86	370	372						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	FINAL	19JUN2003/14:25	16	61	61	145	85	366	369	0	0	6	-1	-4	-3
	E0019045	BASELINE	19JUN2003/14:35	-7	66	66	144	90	377	390						
		FINAL	16JUL2003/9:45	21	71	71	147	91	368	389	5	5	3	1	-9	-1
	E0020024	BASELINE	12JUN2003/13:55	-11	76	76	154	92	327	353						
		FINAL	20AUG2003/18:55	59	85	85	136	92	322	362	9	9	-18	0	-5	9
	E0022044	BASELINE	11MAR2003/11:45	-7	85	85	144	99	345	388						
		FINAL	12MAY2003/10:25	56	86	86	153	89	374	422	1	1	9	-10	29	34
	E0023007	BASELINE	07JAN2003/14:40	-7	62	62	148	80	395	399						
		FINAL	13MAR2003/15:15	59	68	68	156	85	371	388	6	6	8	5	-24	-11
	E0023011	BASELINE	28JAN2003/12:30	-7	80	80	171	83	339	373						
		FINAL	01APR2003/12:15	57	73	73	156	89	362	386	-7	-7	-15	6	23	13
	E0023014	BASELINE	14FEB2003/14:00	-7	85	84	125	94	347	389						
		FINAL	25APR2003/14:30	64	82	82	126	87	341	378	-3	-2	1	-7	-6	-11
	E0023019	BASELINE	21MAR2003/14:00	-17	63	63	155	94	380	387						
		FINAL	03JUN2003/13:30	58	75	76	160	89	347	375	12	13	5	-5	-33	-12
	E0023022	BASELINE	10APR2003/15:40	-8	51	51	158	86	376	357						
		FINAL	12JUN2003/15:45	56	70	70	152	88	332	350	19	19	-6	2	-44	-7
	E0023023	BASELINE	17APR2003/11:40	-8	92	93	175	105	363	420						
		FINAL	01MAY2003/14:45	7	91	91	159	99	349	402	-1	-2	-16	-6	-14	-18
	E0023029	BASELINE	16MAY2003/14:20	-7	74	74	154	92	357	384						
	E0023031	BASELINE *	22MAY2003/13:50	-33	97	97	127	87	352	413						
		BASELINE	24JUN2003/12:20	1	91	91	145	89	359	412						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	FINAL	19AUG2003/11:00	57	90	90	130	89	339	390	-1	-1	-15	0	-20	-22
	E0023041	BASELINE	02JUL2003/12:00	-7	73	73	165	82	351	375						
		FINAL	05SEP2003/12:00	59	87	87	142	82	313	355	14	14	-23	0	-38	-20
	E0023043	BASELINE	07JUL2003/15:15	-7	78	78	158	93	378	413						
		FINAL	09SEP2003/10:40	58	85	84	110	92	338	379	7	6	-48	-1	-40	-34
	E0026003	BASELINE	25NOV2002/12:25	-9	54	55	143	85	401	388						
		FINAL	03FEB2003/11:05	62	95	95	158	82	331	386	41	40	15	-3	-70	-2
	E0026005	BASELINE	23DEC2002/12:30	-7	52	53	162	96	427	406						
		FINAL	06JAN2003/15:25	8	59	59	178	91	378	376	7	6	16	-5	-49	-30
	E0026009	BASELINE	10JAN2003/10:10	-5	58	58	161	86	417	412						
		FINAL	21JAN2003/9:30	7	70	70	178	90	379	400	12	12	17	4	-38	-12
	E0026015	BASELINE	20FEB2003/11:35	-7	62	63	158	90	370	375						
		FINAL	25APR2003/10:10	58	85	85	143	90	307	345	23	22	-15	0	-63	-30
	E0026023	BASELINE	23APR2003/10:55	-7	51	51	149	107	367	347						
		FINAL	27JUN2003/12:30	59	76	77	164	101	345	374	25	26	15	-6	-22	27
	E0027016	BASELINE	19MAR2003/11:45	-21	81	81	178	80	338	374						
		FINAL	03JUN2003/10:15	56	73	73	192	82	371	395	-8	-8	14	2	33	21
	E0027018	BASELINE	21MAR2003/11:20	-4	72	72	124	90	345	367						
		FINAL	22MAY2003/10:00	59	74	75	116	84	347	373	2	3	-8	-6	2	6
	E0028032	BASELINE	13MAR2003/14:08	-12	60	60	144	86	346	346						
		FINAL	06JUN2003/11:25	74	66	66	144	87	329	340	6	6	0	1	-17	-6
	E0029003	BASELINE	28OCT2002/13:50	-7	68	68	175	80	352	368						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	FINAL	30DEC2002/10:38	57	68	68	167	95	347	361	0	0	-8	15	-5	-7
	E0029020	BASELINE	25FEB2003/10:50	-8	58	58	140	90	393	388						
	E0031005	BASELINE	13DEC2002/16:10	-7	70	69	127	89	397	417						
		FINAL	14FEB2003/12:15	57	75	76	155	97	381	410	5	7	28	8	-16	-7
	E0031006	BASELINE	31JAN2003/11:35	-18	80	80	180	89	339	373						
		FINAL	15APR2003/9:30	57	79	78	164	90	356	389	-1	-2	-16	1	17	16
	E0031010	BASELINE	12FEB2003/14:55	-7	72	72	162	85	376	399						
		FINAL	06MAR2003/13:00	16	82	83	157	88	373	414	10	11	-5	3	-3	15
	E0031011	BASELINE	18FEB2003/11:55	-9	67	67	125	93	371	385						
		FINAL	24APR2003/9:28	57	65	65	162	94	372	382	-2	-2	37	1	1	-3
	E0031015	BASELINE	14MAR2003/8:45	-12	67	67	175	84	343	356						
		FINAL	01APR2003/12:00	7	79	79	154	84	387	424	12	12	-21	0	44	68
	E0031031	BASELINE	01JUL2003/10:35	-7	52	52	150	91	413	394						
		FINAL	28AUG2003/10:35	52	50	50	157	91	431	405	-2	-2	7	0	18	11
	E0033009	BASELINE	22JAN2003/13:30	-21	63	63	135	89	376	382						
	E0034009	BASELINE	10JUN2003/12:40	-9	53	54	170	92	427	410						
		FINAL	18AUG2003/17:10	61	78	78	165	85	364	397	25	24	-5	-7	-63	-13
	E0037007	BASELINE	04APR2003/12:00	-7	74	74	170	93	403	431						
	E0037012	BASELINE	11JUL2003/13:25	-5	54	54	132	93	350	338						
		FINAL	08SEP2003/13:45	55	81	81	138	92	326	361	27	27	6	-1	-24	23
	E0039019	BASELINE	20JAN2003/15:20	-17	79	78	153	89	351	383						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS						CHANGE FROM BASELINE					
					VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC	VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	FINAL	03APR2003/11:00	57	86	86	175	89	323	365	7	8	22	0	-28	-18
	E0039043	BASELINE	25APR2003/13:25	-13	57	57	146	93	370	363						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR I)	E0002001	BASELINE	18DEC2002/15:30	-12	66	66	134	91	400	413						
		FINAL	26FEB2003/9:35	59	63	63	137	78	401	408	-3	-3	3	-13	1	-5
	E0002003	BASELINE	03JAN2003/12:20	-19	64	64	128	82	387	395						
		FINAL	18MAR2003/12:55	56	70	71	137	76	375	395	6	7	9	-6	-12	0
	E0002004	BASELINE	14JAN2003/8:15	-11	66	66	145	88	366	379						
	E0002008	BASELINE	05FEB2003/14:20	-20	61	61	190	90	382	384						
		FINAL	23APR2003/14:35	58	60	61	207	98	389	389	-1	0	17	8	7	5
	E0002016	BASELINE	14JUL2003/11:25	-10	60	60	151	95	424	424						
		FINAL	17SEP2003/11:45	56	57	57	155	95	410	404	-3	-3	4	0	-14	-20
	E0003008	BASELINE	21JAN2003/12:24	-7	68	68	144	90	362	377						
	E0004003	BASELINE	02OCT2002/11:15	-8	73	73	168	92	327	350						
	E0004006	BASELINE	28OCT2002/10:10	-7	73	72	143	91	370	395						
		FINAL	06JAN2003/10:35	64	69	68	167	94	374	391	-4	-4	24	3	4	-4
	E0004016	BASELINE	14FEB2003/11:10	-5	69	68	133	90	405	423						
		FINAL	17APR2003/17:18	58	61	61	143	84	429	431	-8	-7	10	-6	24	8
	E0004024	BASELINE	25JUN2003/16:45	-8	82	82	129	91	356	395						
		FINAL	28AUG2003/8:35	57	73	73	121	90	371	396	-9	-9	-8	-1	15	1
	E0005006	BASELINE	24SEP2002/14:50	-9	57	57	120	103	402	394						
	E0005017	BASELINE	11DEC2002/10:05	-19	54	55	154	92	395	382						
		FINAL	04MAR2003/13:10	65	59	59	154	94	400	397	5	4	0	2	5	15
	E0005019	BASELINE	19DEC2002/13:50	-27	76	76	143	97	385	416						
		FINAL	24JAN2003/10:00	10	74	74	139	88	387	415	-2	-2	-4	-9	2	-1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR I)	E0005026	BASELINE	26FEB2003/13:50	-8	63	63	181	93	372	377						
		FINAL	02APR2003/9:45	28	55	56	165	87	360	351	-8	-7	-16	-6	-12	-26
	E0005039	BASELINE	15MAY2003/9:15	-7	61	61	166	91	385	386						
		FINAL	16JUL2003/8:30	56	60	60	177	94	386	386	-1	-1	11	3	1	0
	E0005043	BASELINE	01JUL2003/16:30	-8	53	53	167	87	399	382						
		FINAL	03SEP2003/9:55	57	55	55	164	95	390	378	2	2	-3	8	-9	-4
	E0006020	BASELINE	02MAY2003/13:35	-11	56	56	125	105	383	373						
		FINAL	08JUL2003/14:55	57	63	63	140	104	364	368	7	7	15	-1	-19	-5
	E0007001	BASELINE	10DEC2002/17:49	-21	59	59	175	94	376	374						
		FINAL	22FEB2003/10:05	54	64	64	141	94	354	362	5	5	-34	0	-22	-12
	E0007003	BASELINE	03JAN2003/4:30	-27	82	82	159	96	382	424						
		FINAL	10MAR2003/12:45	40	109	108	127	91	339	413	27	26	-32	-5	-43	-11
	E0007006	BASELINE	21FEB2003/18:25	-12	71	71	173	94	370	391						
		FINAL	26MAR2003/12:10	22	63	63	190	94	346	352	-8	-8	17	0	-24	-39
	E0009004	BASELINE	19NOV2002/12:20	-7	81	81	158	78	364	402						
		FINAL	18DEC2002/14:35	23	97	97	154	85	325	381	16	16	-4	7	-39	-21
	E0009012	BASELINE	16JUN2003/14:38	-9	73	73	135	93	347	371						
		FINAL	03JUL2003/18:00	9	62	62	145	93	383	389	-11	-11	10	0	36	18
	E0010008	BASELINE	11DEC2002/9:20	-7	68	68	139	83	336	350						
	E0010018	BASELINE	26FEB2003/10:30	-21	65	65	171	89	429	441						
		FINAL	14MAY2003/10:35	57	71	71	158	88	408	431	6	6	-13	-1	-21	-10
	E0010028	BASELINE	09JUN2003/11:03	-7	63	63	128	86	407	413						
		FINAL	15JUL2003/13:30	30	76	75	143	83	369	398	13	12	15	-3	-38	-15

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR I)	E0011008	BASELINE *	17DEC2002/12:10	-44	43	43	139	89	436	390						
		BASELINE	23JAN2003/9:40	-7	57	57	153	95	395	388						
		FINAL	13FEB2003/13:30	15	47	47	145	90	384	353	-10	-10	-8	-5	-11	-35
	E0011009	BASELINE	19DEC2002/10:00	-8	77	78	161	91	377	410						
		FINAL	20FEB2003/9:30	56	72	72	163	97	393	417	-5	-6	2	6	16	7
	E0011010	BASELINE	03FEB2003/10:15	-7	52	52	165	87	458	436						
		FINAL	19MAR2003/9:15	38	56	57	162	84	411	403	4	5	-3	-3	-47	-33
	E0013001	BASELINE	01NOV2002/9:05	-13	88	90	147	95	322	366						
		FINAL	10JAN2003/10:52	58	64	64	191	92	379	387	-24	-26	44	-3	57	21
	E0013003	BASELINE	07NOV2002/10:44	-5	71	71	164	93	408	431						
		FINAL	06JAN2003/13:50	56	73	73	161	90	382	408	2	2	-3	-3	-26	-23
	E0013005	BASELINE	13FEB2003/11:54	-5	56	56	152	84	384	374						
		FINAL	15APR2003/12:24	57	66	67	152	79	366	380	10	11	0	-5	-18	6
	E0013013	BASELINE	01MAY2003/10:30	-5	76	76	162	90	326	353						
	E0014002	BASELINE	19FEB2003/16:00	-7	45	45	144	93	446	404						
		FINAL	10APR2003/13:17	44	51	51	152	84	403	383	6	6	8	-9	-43	-21
	E0014004	BASELINE	04MAR2003/11:15	-8	53	53	164	97	424	407						
		FINAL	15APR2003/11:25	35	67	68	190	99	391	406	14	15	26	2	-33	-1
	E0014009	BASELINE	15APR2003/14:22	-8	93	93	142	92	342	397						
		FINAL	16MAY2003/8:20	24	86	86	136	88	369	415	-7	-7	-6	-4	27	18
	E0014015	BASELINE	16JUN2003/11:09	-2	69	68	140	101	378	395						
	E0014017	BASELINE	17JUN2003/16:37	-10	60	60	177	83	354	355						
		FINAL	19AUG2003/15:55	54	76	76	137	86	372	402	16	16	-40	3	18	47

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
PLACEBO (BIPOLAR I)	E0014018	BASELINE	24JUN2003/16:25	-7	64	64	157	88	373	380						
		FINAL	27AUG2003/15:05	58	68	69	144	91	381	398	4	5	-13	3	8	18
	E0015005	BASELINE	25NOV2002/13:30	-7	55	55	174	96	402	391						
		FINAL	18DEC2002/9:10	17	48	48	197	86	429	398	-7	-7	23	-10	27	7
	E0017002	BASELINE	08MAY2003/17:15	-26	67	66	123	82	356	367						
		FINAL	13JUN2003/15:25	11	57	56	122	89	399	391	-10	-10	-1	7	43	24
	E0018009	BASELINE	17DEC2002/11:00	-20	63	64	123	91	353	360						
		FINAL	14JAN2003/13:10	9	81	81	137	93	339	374	18	17	14	2	-14	14
	E0018010	BASELINE	09JAN2003/9:15	-7	55	55	174	90	398	386						
		FINAL	13MAR2003/9:05	57	52	52	161	90	378	359	-3	-3	-13	0	-20	-27
	E0018015	BASELINE	21JAN2003/11:00	-7	58	58	153	95	353	350						
		FINAL	27MAR2003/10:55	59	62	62	153	91	366	370	4	4	0	-4	13	20
	E0020015	BASELINE	18MAR2003/14:25	-9	69	69	130	98	328	344						
		FINAL	23MAY2003/13:55	58	70	70	150	100	312	329	1	1	20	2	-16	-15
	E0020017	BASELINE	27MAR2003/14:15	-7	82	82	140	89	370	410						
		FINAL	03JUN2003/17:55	62	70	70	155	93	373	392	-12	-12	15	4	3	-18
	E0020020	BASELINE	07MAY2003/15:00	-5	74	73	170	89	356	381						
		FINAL	23MAY2003/16:20	12	58	57	191	84	351	346	-16	-16	21	-5	-5	-35
	E0020022	BASELINE	09JUN2003/11:55	-7	61	61	142	90	388	390						
		FINAL	11AUG2003/9:19	57	64	64	160	96	389	398	3	3	18	6	1	8
	E0022001	BASELINE	07OCT2002/16:02	-21	61	62	132	81	394	397						
		FINAL	26DEC2002/18:30	60	65	65	130	86	392	403	4	3	-2	5	-2	6
	E0022004	BASELINE *	17OCT2002/10:30	-11	56	56	141	92	365	357						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR I)	E0022004	BASELINE	28OCT2002/10:10	1	58	58	150	85	392	387						
		FINAL	23DEC2002/10:50	57	64	65	144	87	380	389	6	7	-6	2	-12	2
	E0022005	BASELINE *	17OCT2002/11:25	-22	74	74	117	87	341	366						
		BASELINE	17OCT2002/12:05	-22	73	73	138	94	352	376						
		FINAL	03JAN2003/10:00	57	80	80	132	81	362	398	7	7	-6	-13	10	22
	E0022011	BASELINE	20NOV2002/8:55	-9	52	53	163	89	386	368						
	E0022015	BASELINE *	29NOV2002/14:25	-11	65	65	136	95	387	397						
		BASELINE	10DEC2002/15:10	1	75	74	136	90	351	378						
		FINAL	06FEB2003/10:20	59	64	64	115	82	364	372	-11	-10	-21	-8	13	-6
	E0022016	BASELINE	03DEC2002/12:25	-14	57	57	140	95	380	374						
		FINAL	11FEB2003/11:10	57	72	73	170	80	358	381	15	16	30	-15	-22	7
	E0022020	BASELINE	05DEC2002/12:06	-7	62	62	179	84	390	394						
		FINAL	23JAN2003/16:45	43	65	65	168	87	374	385	3	3	-11	3	-16	-9
	E0022023	BASELINE	19DEC2002/17:50	-6	61	60	159	88	389	391						
		FINAL	20FEB2003/10:20	58	50	50	166	91	416	390	-11	-10	7	3	27	-1
	E0022029	BASELINE	05FEB2003/11:25	-14	67	66	123	88	353	365						
		FINAL	14APR2003/9:50	55	64	64	130	86	382	390	-3	-2	7	-2	29	25
	E0022041	BASELINE	04MAR2003/14:15	-14	52	52	177	99	465	444						
		FINAL	13MAY2003/9:23	57	57	57	166	91	415	407	5	5	-11	-8	-50	-37
	E0022042	BASELINE	05MAR2003/9:30	-7	65	65	168	95	396	406						
		FINAL	12MAY2003/9:45	62	76	74	145	85	383	413	11	9	-23	-10	-13	7
	E0022043	BASELINE	10MAR2003/11:05	-10	62	62	162	90	386	390						
		FINAL	12MAY2003/8:40	54	59	59	179	93	386	384	-3	-3	17	3	0	-6

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
PLACEBO (BIPOLAR I)	E0022054	BASELINE	04APR2003/15:44	-7	73	73	141	90	340	363						
	E0022059	BASELINE	22APR2003/18:27	-14	68	68	166	84	354	369						
		FINAL	08JUL2003/18:00	64	60	59	186	93	396	396	-8	-9	20	9	42	27
	E0022065	BASELINE	30APR2003/12:15	-7	53	53	161	91	375	360						
		FINAL	02JUL2003/9:20	57	66	66	150	100	391	403	13	13	-11	9	16	43
	E0022070	BASELINE	05JUN2003/11:55	-7	66	66	169	97	376	389						
		FINAL	18JUN2003/15:30	7	81	81	169	111	372	411	15	15	0	14	-4	22
	E0023001	BASELINE	24OCT2002/11:45	-22	56	57	166	90	404	394						
		FINAL	14JAN2003/13:15	61	59	59	163	94	383	381	3	2	-3	4	-21	-13
	E0023009	BASELINE	24JAN2003/11:50	-18	69	69	128	78	393	411						
		FINAL	08APR2003/11:30	57	85	84	125	95	351	394	16	15	-3	17	-42	-17
	E0023028	BASELINE	16MAY2003/12:30	-13	55	56	132	94	409	399						
		FINAL	21JUL2003/10:15	54	72	72	128	85	369	392	17	16	-4	-9	-40	-7
	E0023033	BASELINE	30MAY2003/12:10	-6	76	76	163	91	383	415						
		FINAL	12JUN2003/13:15	8	81	81	153	87	352	389	5	5	-10	-4	-31	-26
	E0023047	BASELINE	11JUL2003/14:15	-7	61	61	142	91	377	379						
		FINAL	16SEP2003/13:00	61	63	64	162	93	350	356	2	3	20	2	-27	-23
	E0025001	BASELINE	25MAR2003/15:20	-7	77	78	154	92	367	399						
		FINAL	23APR2003/11:00	23	76	76	182	94	357	386	-1	-2	28	2	-10	-13
	E0026012	BASELINE	05FEB2003/11:05	-15	49	49	194	92	372	347						
		FINAL	17APR2003/9:20	57	56	56	193	92	384	375	7	7	-1	0	12	28
	E0026020	BASELINE	28MAR2003/11:00	-4	73	72	138	96	381	406						
		FINAL	22APR2003/14:10	22	74	74	137	89	368	395	1	2	-1	-7	-13	-11

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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR I)	E0026024	BASELINE	25APR2003/12:35	-7	71	71	156	86	365	385						
	E0026028	BASELINE	06JUN2003/10:25	-14	88	89	186	98	343	390						
		FINAL	23JUL2003/10:10	34	93	93	175	96	357	414	5	4	-11	-2	14	24
	E0028001	BASELINE	20SEP2002/12:55	-20	84	85	142	87	355	396						
		FINAL	03DEC2002/10:00	55	69	69	167	84	343	360	-15	-16	25	-3	-12	-36
	E0028003	BASELINE	23SEP2002/9:15	-7	62	62	129	89	395	399						
		FINAL	26NOV2002/9:40	58	53	53	123	91	405	390	-9	-9	-6	2	10	-9
	E0028005	BASELINE	30SEP2002/10:35	-3	53	53	170	91	411	393						
		FINAL	31OCT2002/12:20	29	57	57	178	93	397	390	4	4	8	2	-14	-3
	E0028010	BASELINE	15OCT2002/11:10	-21	55	55	140	100	438	426						
		FINAL	31DEC2002/9:30	57	57	57	144	101	398	391	2	2	4	1	-40	-35
	E0028011	BASELINE *	16OCT2002/15:25	-50	77	77	156	91	359	391						
		BASELINE	25NOV2002/10:30	-10	66	66	159	100	366	377						
		FINAL	30JAN2003/12:45	57	74	74	146	97	351	376	8	8	-13	-3	-15	-1
	E0028030	BASELINE	26FEB2003/11:57	-6	61	60	162	105	378	379						
		FINAL	30APR2003/12:48	58	64	65	135	88	348	356	3	5	-27	-17	-30	-23
	E0028031	BASELINE	06MAR2003/9:15	-5	85	85	180	90	330	370						
		FINAL	17APR2003/13:20	38	104	104	191	92	324	389	19	19	11	2	-6	19
	E0028047	BASELINE	08JUL2003/11:35	-6	66	66	155	107	384	396						
		FINAL	09SEP2003/10:30	58	63	61	172	91	387	397	-3	-5	17	-16	3	1
	E0029001	BASELINE	24SEP2002/12:10	-7	72	72	119	91	324	344						
	E0029014	BASELINE	28JAN2003/10:50	-7	64	64	136	94	388	401						
		FINAL	01APR2003/11:04	57	62	62	144	97	378	382	-2	-2	8	3	-10	-19

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR I)	E0029023	BASELINE	01APR2003/8:30	-7	70	69	128	76	370	389						
		FINAL	10JUN2003/11:50	64	69	69	132	82	376	394	-1	0	4	6	6	5
	E0029032	BASELINE	22MAY2003/12:30	-19	62	62	186	90	385	390						
		FINAL	01JUL2003/12:45	22	71	71	156	92	350	369	9	9	-30	2	-35	-21
	E0029033	BASELINE	27MAY2003/12:35	-6	55	55	181	84	386	374						
		FINAL	30JUN2003/8:57	29	55	56	178	87	370	361	0	1	-3	3	-16	-13
	E0029039	BASELINE	10JUL2003/15:00	-5	48	48	134	95	396	367						
		FINAL	28JUL2003/15:20	14	55	55	148	91	382	370	7	7	14	-4	-14	3
	E0030003	BASELINE	03DEC2002/14:10	-13	77	77	200	83	368	401						
		FINAL	24DEC2002/9:40	9	64	64	187	82	415	423	-13	-13	-13	-1	47	22
	E0030009	BASELINE	10JAN2003/15:16	-13	67	67	145	94	359	371						
		FINAL	19MAR2003/10:26	56	66	66	135	88	380	392	-1	-1	-10	-6	21	21
	E0030016	BASELINE	21FEB2003/11:55	-10	69	69	154	90	371	389						
		FINAL	22APR2003/18:50	51	88	87	154	86	341	387	19	18	0	-4	-30	-2
	E0030021	BASELINE	13MAY2003/17:10	-7	70	70	133	87	361	379						
	E0031001	BASELINE	14NOV2002/11:27	-7	51	51	196	99	429	406						
	E0031017	BASELINE	25MAR2003/16:20	-7	58	58	170	79	427	423						
		FINAL	29APR2003/10:30	29	66	65	192	91	416	428	8	7	22	12	-11	5
	E0031018	BASELINE	01APR2003/14:55	-9	64	64	148	94	400	407						
	E0031023	BASELINE	22APR2003/14:00	-7	75	75	144	87	365	393						
		FINAL	24JUN2003/11:50	57	66	66	121	95	388	401	-9	-9	-23	8	23	8
	E0033001	BASELINE	23DEC2002/13:40	-17	75	75	164	83	327	352						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR I)	E0033001	FINAL	30JAN2003/13:15	22	67	67	158	92	341	353	-8	-8	-6	9	14	1
	E0033004	BASELINE	09JAN2003/12:50	-8	86	85	160	82	345	389						
		FINAL	14MAR2003/11:30	57	81	81	169	81	335	370	-5	-4	9	-1	-10	-19
	E0033010	BASELINE	22JAN2003/16:40	-13	68	68	178	85	344	360						
		FINAL	26MAR2003/16:10	51	62	63	155	89	364	369	-6	-5	-23	4	20	9
	E0033014	BASELINE	12MAR2003/17:10	-7	83	83	133	79	323	359						
	E0035002	BASELINE	14NOV2002/12:20	-7	51	51	193	101	409	387						
	E0035007	BASELINE	13DEC2002/13:30	-6	58	57	133	92	410	404						
		FINAL	11FEB2003/10:20	55	56	56	140	89	435	426	-2	-1	7	-3	25	22
	E0035011	BASELINE	09JAN2003/11:55	-26	58	58	185	86	404	400						
		FINAL	01APR2003/9:10	57	60	60	163	82	405	404	2	2	-22	-4	1	4
	E0035020	BASELINE	11APR2003/11:15	-7	79	80	166	89	382	420						
		FINAL	13JUN2003/8:20	57	50	50	157	92	422	397	-29	-30	-9	3	40	-23
	E0037003	BASELINE	22JAN2003/13:55	-8	80	80	133	88	334	367						
		FINAL	20FEB2003/16:45	22	101	100	140	94	318	378	21	20	7	6	-16	11
	E0037004	BASELINE	06FEB2003/12:50	-7	73	73	150	80	355	380						
		FINAL	10APR2003/12:15	57	73	73	142	94	363	389	0	0	-8	14	8	9
	E0039007	BASELINE	25NOV2002/13:50	-9	79	79	131	88	332	363						
		FINAL	29JAN2003/14:58	57	74	73	133	85	349	374	-5	-6	2	-3	17	11
	E0039022	BASELINE	04FEB2003/14:21	-21	81	81	137	93	354	390						
		FINAL	24APR2003/12:15	59	57	57	127	87	422	414	-24	-24	-10	-6	68	24
	E0039023	BASELINE	05FEB2003/10:51	-19	67	67	132	90	379	394						

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
GENERATED: 12JUL2005 17:42:24 iceadmn3

Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
PLACEBO (BIPOLAR I)	E0039030	BASELINE	12MAR2003/9:05	-12	62	61	180	95	422	425						
		FINAL	19MAY2003/9:40	57	71	71	135	87	416	440	9	10	-45	-8	-6	15
	E0039031	BASELINE	05MAR2003/17:50	-19	84	84	194	91	353	395						
		FINAL	20MAY2003/13:00	58	88	87	189	83	353	400	4	3	-5	-8	0	5
	E0039037	BASELINE	26MAR2003/18:40	-21	66	65	144	99	381	392						
		FINAL	12JUN2003/11:45	58	82	82	141	91	331	368	16	17	-3	-8	-50	-24
	E0039038	BASELINE	27MAR2003/10:15	-27	78	77	145	92	388	423						
		FINAL	20JUN2003/11:40	59	81	81	131	85	369	406	3	4	-14	-7	-19	-17
	E0039047	BASELINE	12MAY2003/14:05	-7	65	65	148	98	391	401						
		FINAL	14JUL2003/11:15	57	54	54	163	81	415	400	-11	-11	15	-17	24	-1
	E0039059	BASELINE	03JUL2003/16:10	-8	68	68	152	92	389	406						
		FINAL	05SEP2003/11:20	57	50	51	150	83	418	394	-18	-17	-2	-9	29	-12
	E0041007	BASELINE	05MAR2003/14:00	-8	56	56	229	91	363	355						
		FINAL	08MAY2003/13:40	57	73	73	203	81	353	377	17	17	-26	-10	-10	22
	E0041010	BASELINE	23APR2003/15:00	-7	73	73	171	94	337	360						
		FINAL	11JUN2003/16:00	43	83	83	147	100	351	392	10	10	-24	6	14	32
	E0041011	BASELINE	15MAY2003/16:05	-7	90	91	142	84	367	421						
		FINAL	17JUL2003/15:00	57	89	89	144	84	351	401	-1	-2	2	0	-16	-20
	E0041012	BASELINE	05JUN2003/12:38	-14	79	80	164	98	380	416						
		FINAL	14AUG2003/11:15	57	81	81	152	95	360	398	2	1	-12	-3	-20	-18

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR II)	E0001004	BASELINE	28APR2003/15:00	-3	70	70	156	86	355	374						
		FINAL	02JUL2003/13:30	63	70	70	164	82	370	388	0	0	8	-4	15	14
	E0005023	BASELINE	28JAN2003/18:00	-8	68	68	139	92	385	401						
	E0005034	BASELINE	08APR2003/16:30	-7	76	76	165	86	391	423						
		FINAL	09JUN2003/12:55	56	67	67	171	89	365	379	-9	-9	6	3	-26	-44
	E0005041	BASELINE	17JUN2003/11:50	-7	60	59	145	92	410	408						
		FINAL	18AUG2003/10:45	56	61	61	160	94	428	430	1	2	15	2	18	22
	E0007004	BASELINE	24JAN2003/7:50	-6	61	61	163	85	410	411						
		FINAL	12FEB2003/18:35	14	101	102	178	85	304	362	40	41	15	0	-106	-49
	E0007010	BASELINE	11APR2003/12:00	-7	76	76	170	91	388	420						
		FINAL *	25APR2003/13:20	8	83	84	174	97	374	418	7	8	4	6	-14	-2
		FINAL *	02MAY2003/16:50	15	81	81	171	93	391	431	5	5	1	2	3	11
		FINAL	16JUN2003/14:25	60	89	89	157	87	356	406	13	13	-13	-4	-32	-14
	E0007012	BASELINE	02MAY2003/17:45	-14	58	59	147	90	376	372						
		FINAL	03JUL2003/10:45	49	66	66	148	92	383	397	8	7	1	2	7	25
	E0009007	BASELINE	27JAN2003/15:17	-7	75	75	131	89	334	362						
		FINAL	03MAR2003/15:30	29	72	73	139	94	341	363	-3	-2	8	5	7	1
	E0009008	BASELINE	04FEB2003/13:25	-8	58	58	161	90	378	374						
		FINAL	08APR2003/12:50	56	65	66	164	85	337	347	7	8	3	-5	-41	-27
	E0011001	BASELINE	25OCT2002/15:50	-7	61	61	129	92	390	392						
		FINAL	26DEC2002/8:55	56	64	64	146	84	369	376	3	3	17	-8	-21	-16
	E0011011	BASELINE	12FEB2003/12:06	-8	61	61	163	99	367	369						
		FINAL	16APR2003/9:10	56	65	66	171	90	359	370	4	5	8	-9	-8	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR II)	E0011013	BASELINE	25MAR2003/10:10	-23	82	82	122	91	380	422						
		FINAL	12JUN2003/9:15	57	62	63	152	88	433	434	-20	-19	30	-3	53	12
	E0011014	BASELINE	31MAR2003/10:30	-7	56	57	179	92	458	448						
		FINAL	08MAY2003/15:50	32	69	69	153	89	387	405	13	12	-26	-3	-71	-43
	E0011021	BASELINE	15MAY2003/10:10	-7	46	47	138	90	412	378						
		FINAL	21JUL2003/10:44	61	52	52	131	84	417	397	6	5	-7	-6	5	19
	E0013008	BASELINE	19MAR2003/15:30	-7	69	69	149	78	379	397						
		FINAL	19MAY2003/11:41	55	73	73	134	84	348	372	4	4	-15	6	-31	-25
	E0014001	BASELINE	18FEB2003/15:50	-8	68	67	188	90	433	450						
		FINAL	08APR2003/10:44	42	70	70	178	78	390	410	2	3	-10	-12	-43	-40
	E0014013	BASELINE	20MAY2003/16:30	-7	82	82	145	87	353	392						
		FINAL	23JUL2003/16:10	58	88	88	137	90	349	396	6	6	-8	3	-4	4
	E0014014	BASELINE	03JUN2003/16:30	-7	41	41	123	86	431	380						
		FINAL	06AUG2003/10:20	58	54	54	128	89	403	389	13	13	5	3	-28	9
	E0015004	BASELINE	25NOV2002/9:30	-7	71	70	161	80	345	364						
	E0018005	BASELINE	10DEC2002/15:30	-10	50	50	142	87	358	336						
		FINAL	14FEB2003/16:45	57	47	47	136	93	374	345	-3	-3	-6	6	16	9
	E0018012	BASELINE	17JAN2003/10:20	-7	49	49	164	101	400	374						
		FINAL	26FEB2003/19:20	34	52	52	183	97	396	378	3	3	19	-4	-4	4
	E0019019	BASELINE	14JAN2003/11:53	-9	70	70	164	97	371	390						
	E0019033	BASELINE	11MAR2003/13:19	-7	68	68	142	92	381	398						
		FINAL	15MAY2003/12:25	59	65	65	148	93	360	370	-3	-3	6	1	-21	-28

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRI-CULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDER-ICIA QTC	CHANGE FROM BASELINE VENTRI-CULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDER-ICIA QTC
PLACEBO (BIPOLAR II)	E0019038	BASELINE	10APR2003/12:43	-14	49	49	174	87	379	354						
		FINAL	18JUN2003/9:45	56	54	54	184	91	365	351	5	5	10	4	-14	-3
	E0019046	BASELINE	19JUN2003/16:15	-7	71	71	138	86	369	390						
		FINAL	21AUG2003/9:20	57	59	59	139	89	363	361	-12	-12	1	3	-6	-29
	E0019047	BASELINE	26JUN2003/12:00	-12	58	58	154	95	338	335						
		FINAL	04SEP2003/8:45	59	69	70	155	89	334	351	11	12	1	-6	-4	16
	E0019048	BASELINE	03JUL2003/11:27	-7	68	69	150	98	371	387						
		FINAL	03SEP2003/16:25	56	76	76	172	100	368	398	8	7	22	2	-3	11
	E0022006	BASELINE	21OCT2002/15:10	-22	83	84	120	77	341	380						
		FINAL	07JAN2003/8:10	57	78	78	130	87	383	418	-5	-6	10	10	42	38
	E0022047	BASELINE	21MAR2003/9:59	-7	54	54	150	75	395	382						
		FINAL	23MAY2003/10:00	57	61	61	166	82	360	362	7	7	16	7	-35	-20
	E0022075	BASELINE	25JUN2003/12:45	-13	59	58	108	88	378	376						
		FINAL	03SEP2003/9:25	58	50	50	154	90	399	376	-9	-8	46	2	21	0
	E0023012	BASELINE	31JAN2003/16:00	-6	52	52	143	94	404	385						
		FINAL	04APR2003/12:30	58	64	64	130	90	381	390	12	12	-13	-4	-23	5
	E0023016	BASELINE	15MAY2003/14:00	-7	63	63	173	98	413	420						
	E0023018	BASELINE	18MAR2003/13:30	-9	61	61	168	97	362	364						
		FINAL	22MAY2003/11:00	57	60	60	168	90	362	362	-1	-1	0	-7	0	-2
	E0023036	BASELINE	10JUN2003/12:00	-10	74	73	226	93	342	366						
	E0023046	BASELINE	11JUL2003/10:00	-12	81	81	152	96	387	429						
		FINAL	16SEP2003/14:00	56	69	69	171	92	389	408	-12	-12	19	-4	2	-21

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR II)	E0026006	BASELINE		31DEC2002/10:45	-8	71	71	146	89	380	402						
	E0026021	BASELINE		14APR2003/15:50	-9	57	57	128	112	408	400						
	E0026027	BASELINE		05JUN2003/13:15	-14	54	53	151	99	417	401						
	E0029002		*	05NOV2002/10:44		60	61	186	83	381	382						
	E0029004	BASELINE		13NOV2002/14:43	-6	73	73	182	88	364	387						
		FINAL		16JAN2003/10:05	59	74	74	185	91	366	393	1	1	3	3	2	6
	E0029013	BASELINE		10FEB2003/9:05	-9	71	71	154	82	371	392						
	E0029019	BASELINE		24FEB2003/9:17	-7	60	59	134	91	397	396						
		FINAL		17MAR2003/9:40	15	51	51	143	83	370	350	-9	-8	9	-8	-27	-46
	E0029024	BASELINE	*	11MAR2003/12:41	-6	51	51	148	90	410	390						
		BASELINE		17MAR2003/15:00	1	53	53	133	84	399	384						
		FINAL		20MAY2003/15:15	65	51	51	128	81	402	381	-2	-2	-5	-3	3	-3
	E0029038	BASELINE		30JUN2003/9:55	-7	62	63	179	87	355	360						
	E0031004	BASELINE		12DEC2002/14:18	-7	73	73	137	85	381	407						
		FINAL		14FEB2003/10:55	58	75	75	141	82	390	420	2	2	4	-3	9	13
	E0031013	BASELINE		06MAR2003/10:40	-7	75	75	166	85	374	402						
		FINAL		08MAY2003/11:05	57	69	69	157	89	375	393	-6	-6	-9	4	1	-9
	E0031016	BASELINE		17MAR2003/10:50	-7	59	59	157	111	383	382						
		FINAL		15APR2003/10:05	23	70	70	140	114	372	391	11	11	-17	3	-11	9
	E0031019	BASELINE		03APR2003/11:40	-8	58	58	136	91	394	389						
		FINAL		12MAY2003/16:48	32	70	70	139	85	389	410	12	12	3	-6	-5	21

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR II)	E0031022	BASELINE	21APR2003/12:43	-7	60	60	136	91	388	388						
	E0033007	BASELINE	15JAN2003/15:15	-13	75	75	137	83	357	384						
		FINAL	27MAR2003/15:15	59	80	80	152	81	348	382	5	5	15	-2	-9	-2
	E0033013	BASELINE	06FEB2003/11:55	-13	73	73	132	81	378	404						
		FINAL	16APR2003/11:35	57	61	62	124	95	385	387	-12	-11	-8	14	7	-17
	E0033016	BASELINE	17APR2003/11:58	-21	57	57	162	82	394	388						
		FINAL	02JUL2003/12:40	56	69	69	156	80	386	403	12	12	-6	-2	-8	15
	E0033022	BASELINE	09JUL2003/11:45	-5	70	70	174	98	372	392						
		FINAL	11SEP2003/11:13	60	71	71	148	92	385	408	1	1	-26	-6	13	16
	E0034007	BASELINE	06MAY2003/14:12	-10	68	68	106	86	388	405						
		FINAL	14JUL2003/11:37	60	65	66	117	83	398	410	-3	-2	11	-3	10	5
	E0035004	BASELINE	22NOV2002/11:58	-5	69	69	160	92	373	391						
	E0035009	BASELINE	20DEC2002/11:35	-7	57	57	152	93	379	373						
		FINAL	19FEB2003/9:05	55	54	55	155	89	389	377	-3	-2	3	-4	10	4
	E0035010	BASELINE	06JAN2003/12:27	-4	55	55	183	90	383	373						
		FINAL	06MAR2003/9:23	56	63	62	181	90	359	364	8	7	-2	0	-24	-9
	E0035022	BASELINE	01MAY2003/10:20	-8	68	68	162	78	388	404						
		FINAL	07JUL2003/9:04	60	55	55	131	82	415	403	-13	-13	-31	4	27	-1
	E0039003	BASELINE	06NOV2002/16:00	-19	63	62	159	97	372	377						
		FINAL	02JAN2003/14:10	39	73	72	159	96	378	402	10	10	0	-1	6	25
	E0040001	BASELINE	18JUN2003/14:45	-9	59	59	144	95	410	407						
		FINAL	22AUG2003/9:15	57	61	61	158	95	396	398	2	2	14	0	-14	-9

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 12JUL2005 17:42:24 iceadmn3

Listing 12.2.10.1 ECG Rates and Intervals

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	VENTRICULAR RATE	ATRIAL RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE VENTRICULAR RATE	ATRIAL RATE	PR	QRS	QT	FRIDERICIA QTC
PLACEBO (BIPOLAR II)	E0040004	BASELINE	11JUL2003/15:21	-7	66	66	126	85	367	378						
	E0041002	BASELINE	13JAN2003/14:55	-8	67	67	143	84	350	364						
		FINAL	11MAR2003/10:40	50	79	78	148	86	339	370	12	11	5	2	-11	6
	E0041005	BASELINE	24FEB2003/11:20	-9	62	62	154	101	379	383						
		FINAL	30APR2003/14:15	57	82	83	167	99	327	364	20	21	13	-2	-52	-19

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG100.SAS
GENERATED: 12JUL2005 17:42:24 iceadmn3

Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BASELINE	22JAN2003 14:20	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02APR2003 11:50	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002010	BASELINE	28MAR2003 9:28	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002012	BASELINE	16APR2003 10:50	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JUN2003 11:50	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002015	BASELINE	22MAY2003 10:40	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002018	BASELINE	16JUL2003 14:30	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04AUG2003 10:30	12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003004	BASELINE*	03DEC2002 11:35	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	17DEC2002 9:25	1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG102.SAS
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0003004	FINAL	07JAN2003 15:20	22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003005	BASELINE	16DEC2002 16:30	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	18FEB2003 10:56	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003007	BASELINE	19DEC2002 11:05	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27FEB2003 9:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003015	BASELINE	29APR2003 11:25	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUL2003 14:30	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004002	BASELINE	24SEP2002 11:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26NOV2002 11:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004013	BASELINE	08JAN2003 10:40	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	FINAL	05FEB2003 13:25	23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004018	BASELINE	12MAR2003 10:35	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13MAY2003 13:55	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004021	BASELINE	07MAY2003 15:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09JUL2003 13:50	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005002	BASELINE	23SEP2002 10:00	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25NOV2002 8:45	54	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005004	BASELINE	24SEP2002 12:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005013	BASELINE	30OCT2002 7:30	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005024	BASELINE	05FEB2003 9:20	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	FINAL	09APR2003 15:00	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005027	BASELINE	03MAR2003 16:00	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03APR2003 8:00	24	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005037	BASELINE	30APR2003 12:05	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUL2003 11:50	57	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005042	BASELINE	19JUN2003 12:50	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18AUG2003 16:40	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0006005	BASELINE	25NOV2002 12:45	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JAN2003 11:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0006018	BASELINE	06MAR2003 12:04	-7	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0006018	FINAL	24MAR2003 10:50	12	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007013	BASELINE	06JUN2003 15:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	07AUG2003 10:10	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010004	BASELINE	05DEC2002 10:45	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 12:25	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010012	BASELINE	30DEC2002 9:32	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05MAR2003 13:40	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010024	BASELINE	23APR2003 10:26	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUL2003 10:25	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010032	BASELINE	03JUL2003 11:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0010032	FINAL	17JUL2003 11:26	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011025	BASELINE	20JUN2003 14:15	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22AUG2003 10:50	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0013007	BASELINE	14MAR2003 9:20	-6	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	07APR2003 17:20	19	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0013009	BASELINE	26MAR2003 9:23	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	29MAY2003 18:00	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL *	30MAY2003 10:05	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014006	BASELINE	11MAR2003 16:10	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28MAY2003 15:15	65	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	BASELINE	15APR2003 17:09	-7	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17JUN2003 16:55	57	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0016001	BASELINE	02JAN2003 9:45	-20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19MAR2003 12:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0016004	BASELINE	27JAN2003 10:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018001	BASELINE	22OCT2002 16:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24DEC2002 10:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018006	BASELINE	10DEC2002 16:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27FEB2003 12:00	73	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019004	BASELINE	30OCT2002 10:25	-8	ABNORMAL	ECTOPIC ATRIAL RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	FINAL	19DEC2002 12:31	43	ABNORMAL	ECTOPIC ATRIAL RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019011	BASELINE	12NOV2002 12:30	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JAN2003 13:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019025	BASELINE	30JAN2003 15:52	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03APR2003 14:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019026	BASELINE	10FEB2003 15:15	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019043	BASELINE	21MAY2003 12:07	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	29JUL2003 11:24	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020001	BASELINE	15OCT2002 19:40	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20DEC2002 12:41	53	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0020006	BASELINE*	26NOV2002 17:35	-20									EXCESSIVE ARTIFACTS
		BASELINE	10DEC2002 16:20	-6	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	DEPRESSED	NORMAL	NORMAL	
		FINAL	08JAN2003 9:45	24	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020007	BASELINE	19DEC2002 18:30	-27	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25MAR2003 19:00	70	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020011	BASELINE	19FEB2003 16:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23APR2003 15:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020013	BASELINE	26FEB2003 14:25	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25MAR2003 12:30	21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022008	BASELINE	05NOV2002 11:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	07JAN2003 10:18	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022017	BASELINE	03DEC2002 15:20	-16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13FEB2003 15:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022018	BASELINE	04DEC2002 12:00	-8	ABNORMAL	NORMAL SINUS RHYTHM	IVCD	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 11:13	57	ABNORMAL	NORMAL SINUS RHYTHM	IVCD	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022022	BASELINE	16DEC2002 12:32	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022027	BASELINE	23JAN2003 16:30	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03APR2003 9:08	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022030	BASELINE	07FEB2003 14:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022031	BASELINE	10FEB2003 15:35	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 10:10	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	BASELINE	11FEB2003 9:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18APR2003 10:45	60	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022035	BASELINE	11FEB2003 16:21	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26FEB2003 11:35	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022036	BASELINE	13FEB2003 12:20	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22APR2003 8:55	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0022056	BASELINE	09APR2003 15:10	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022060	BASELINE	23APR2003 15:25	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24JUN2003 9:30	56	ABNORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022063	BASELINE	30APR2003 10:35	-7	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0023008	BASELINE	23JAN2003 10:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	FINAL	24MAR2003 16:00	54	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023013	BASELINE	13FEB2003 11:00	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06MAR2003 11:15	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023015	BASELINE	04MAR2003 11:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06MAY2003 10:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023034	BASELINE	03JUN2003 14:00	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05AUG2003 15:45	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023037	BASELINE	11JUN2003 16:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15AUG2003 9:15	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023038	BASELINE	20JUN2003 13:00	-10	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0023044	BASELINE	08JUL2003 13:30	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12AUG2003 11:45	28	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023045	BASELINE	10JUL2003 11:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11SEP2003 10:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0025002	BASELINE	27MAR2003 10:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	29MAY2003 11:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026010	BASELINE	15JAN2003 14:10	-7	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JAN2003 14:50	9	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026017	BASELINE	26FEB2003 12:05	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21MAR2003 11:20	16	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026018	BASELINE	06MAR2003 16:35	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0026018	FINAL	15MAY2003 14:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026025	BASELINE	01MAY2003 11:40	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03JUL2003 10:05	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026029	BASELINE	02JUL2003 11:25	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28JUL2003 13:40	20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026030	BASELINE	02JUL2003 11:58	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03SEP2003 17:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026031	BASELINE	10JUL2003 14:05	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15SEP2003 11:40	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0027003	BASELINE	08JAN2003 14:40	-20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0027003	FINAL	25MAR2003 11:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028004	BASELINE	27SEP2002 9:25	-3	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09OCT2002 14:00	10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028006	BASELINE	01OCT2002 9:50	-3	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04DEC2002 10:00	62	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028008	BASELINE	08OCT2002 12:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10DEC2002 12:15	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	LOW VOLTAGE	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028009	BASELINE	10OCT2002 10:30	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12DEC2002 13:00	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028016	BASELINE	07NOV2002 10:10	-7	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09JAN2003 11:59	57	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028017	*	12NOV2002 9:35		NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028027	BASELINE	14JAN2003 10:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028029	BASELINE	28JAN2003 10:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03APR2003 11:37	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028034	BASELINE	20MAR2003 9:22	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUN2003 13:15	63	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028038	BASELINE	18APR2003 10:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18JUN2003 13:07	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028043	BASELINE	29MAY2003 11:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	29JUL2003 8:30	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028045	BASELINE	09JUN2003 12:45	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11SEP2003 12:45	86	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029005	BASELINE*	14NOV2002 12:30	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	27NOV2002 12:20	1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21JAN2003 12:35	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030001	BASELINE	12NOV2002 15:05	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JAN2003 11:53	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030008	BASELINE	07JAN2003 14:15	-7	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18MAR2003 11:35	64	ABNORMAL	NORMAL SINUS RHYTHM|VPC	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030011	BASELINE	16JAN2003 17:04	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24MAR2003 14:25	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	BASELINE	13FEB2003 12:15	-8	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22APR2003 12:00	61	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030022	BASELINE	10JUN2003 11:30	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14AUG2003 16:00	60	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031002	BASELINE	20NOV2002 16:56	-7	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22JAN2003 16:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031003	BASELINE	03DEC2002 15:58	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04FEB2003 16:25	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033015	BASELINE	03APR2003 16:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04JUN2003 13:43	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034002	BASELINE	14MAR2003 14:45	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0034002	FINAL	16APR2003 15:05	23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034003	BASELINE	11APR2003 11:10	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19JUN2003 16:25	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034006	BASELINE	25APR2003 11:18	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10JUL2003 9:18	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034008	BASELINE	15MAY2003 15:48	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21JUL2003 9:55	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035003	BASELINE	15NOV2002 12:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035005	BASELINE	26NOV2002 12:20	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0035014	BASELINE	28JAN2003 10:55	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	FINAL	31MAR2003 9:40	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035024	BASELINE	15MAY2003 11:12	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18JUL2003 9:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0036005	BASELINE	24JUN2003 15:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27AUG2003 11:46	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0037002	BASELINE	18DEC2002 12:35	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20FEB2003 14:05	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0037005	BASELINE	26FEB2003 12:38	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01MAY2003 14:25	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0037006	BASELINE	06MAR2003 13:00	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0037006	FINAL	09MAY2003 12:35	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039006	BASELINE*	08NOV2002 16:35	-52	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		BASELINE	10DEC2002 11:50	-20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	LIMB LEAD REVERSAL
		FINAL	24FEB2003 11:05	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039015	BASELINE	02JAN2003 10:25	-21	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20MAR2003 9:40	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039024	BASELINE	05FEB2003 20:50	-22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24APR2003 15:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039025	BASELINE	26FEB2003 11:07	-20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27MAY2003 10:05	71	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039041	BASELINE	07APR2003 15:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 300 MG (BIPOLAR I)	E0039041	FINAL	11JUN2003 11:35	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039044	BASELINE	05MAY2003 13:40	-17	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09JUL2003 19:40	49	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039046	*	06MAY2003 12:00		NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		*	30MAY2003 9:20		ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0039051	BASELINE	22MAY2003 15:40	-25	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12AUG2003 14:55	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039053	BASELINE	16JUN2003 13:30	-25	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08SEP2003 12:30	60	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039057	BASELINE	02JUL2003 17:45	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 300 MG (BIPOLAR I)	E0039057	FINAL	09SEP2003 9:40	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0041003	BASELINE	16JAN2003 8:16	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25MAR2003 11:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0041008	BASELINE	26MAR2003 16:00	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUN2003 15:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0042001	BASELINE	17JUN2003 12:00	-15	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	26AUG2003 11:05	56	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BASELINE	26FEB2003 13:00	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	07MAY2003 14:15	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0003018	BASELINE	08MAY2003 9:30	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08JUL2003 14:40	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005011	BASELINE	17OCT2002 15:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005030	BASELINE	18MAR2003 14:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005036	BASELINE	28APR2003 13:30	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27MAY2003 9:50	22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0006015	BASELINE	06FEB2003 12:25	-5	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08APR2003 11:48	57	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0006016	BASELINE	07FEB2003 13:14	-10	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	INVERTED	NORMAL	
		FINAL	18APR2003 12:30	61	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	INVERTED	NORMAL	
	E0007008	BASELINE	07APR2003 13:00	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25APR2003 11:55	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0009002	BASELINE*	29OCT2002 16:21	-21	ABNORMAL	NORMAL SINUS RHYTHM	LAH|IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	06NOV2002 11:20	-13	ABNORMAL	NORMAL SINUS RHYTHM	LAH|IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15JAN2003 13:35	58	ABNORMAL	NORMAL SINUS RHYTHM	LAH|IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0009006	BASELINE	22JAN2003 17:05	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25MAR2003 16:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0009009	BASELINE	27FEB2003 14:50	-13	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	24MAR2003 13:25	13	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	BASELINE	29JAN2003 16:19	-22	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	15APR2003 13:15	55	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0011004	BASELINE	17DEC2002 10:50	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18FEB2003 9:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011007	BASELINE	12DEC2002 10:43	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13FEB2003 8:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011018	BASELINE	15MAY2003 12:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17JUL2003 17:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011024	BASELINE	17JUN2003 12:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21AUG2003 13:45	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0015003	BASELINE	13NOV2002 12:02	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0015003	FINAL	02DEC2002 10:45	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019003	BASELINE	29OCT2002 10:44	-23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JAN2003 11:33	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019007	BASELINE	06NOV2002 10:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	07JAN2003 9:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019014	BASELINE	17DEC2002 10:50	-23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20JAN2003 13:31	12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019018	BASELINE	14JAN2003 10:33	-16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27MAR2003 10:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019022	BASELINE	23JAN2003 11:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	FINAL	27MAR2003 15:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019027	BASELINE	20FEB2003 10:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06MAR2003 8:35	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019032	BASELINE	06MAR2003 15:20	-26	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27MAY2003 12:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019034	BASELINE	10MAR2003 17:05	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019036	BASELINE	18MAR2003 10:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019039	BASELINE	22APR2003 10:30	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08MAY2003 16:00	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019041	BASELINE	14MAY2003 10:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019041	FINAL	16JUL2003 10:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019049	BASELINE	03JUL2003 15:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08SEP2003 12:00	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022052	BASELINE	01APR2003 10:55	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05JUN2003 9:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022064	BASELINE	29APR2003 13:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01JUL2003 12:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022073	BASELINE	19JUN2003 12:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21AUG2003 10:35	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0023002	BASELINE	25OCT2002 16:00	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	BASELINE	14MAR2003 13:30	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22MAY2003 12:40	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023021	BASELINE	10APR2003 10:40	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17JUN2003 16:00	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023027	BASELINE	07MAY2003 13:00	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09JUL2003 13:45	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023030	BASELINE	21MAY2003 10:30	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JUL2003 16:30	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023040	BASELINE	25JUN2003 15:15	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05SEP2003 10:55	65	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	BASELINE	12FEB2003 12:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19MAR2003 10:15	29	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026019	BASELINE	10MAR2003 12:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12MAY2003 9:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0027005	BASELINE	19DEC2002 14:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20FEB2003 11:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029009	BASELINE	13JAN2003 13:43	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18MAR2003 10:00	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029021	BASELINE*	03MAR2003 10:23	-15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	18MAR2003 9:30	1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15MAY2003 13:20	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	BASELINE	07APR2003 9:35	-7	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10JUN2003 10:02	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029030	BASELINE	13MAY2003 11:25	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23JUL2003 17:55	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031008	BASELINE	05FEB2003 11:45	-23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24APR2003 13:05	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031020	BASELINE	14APR2003 10:38	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13MAY2003 10:55	23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031021	BASELINE	18APR2003 10:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19JUN2003 10:35	56	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0031029	BASELINE	05JUN2003 10:48	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033002	BASELINE	23DEC2002 12:05	-18	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	07MAR2003 11:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033006	BASELINE	15JAN2003 10:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12FEB2003 12:25	21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033021	BASELINE	25JUN2003 14:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18AUG2003 16:30	48	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035013	BASELINE	27JAN2003 10:50	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035015	BASELINE	03FEB2003 11:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18FEB2003 11:33	8	NORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0035016	BASELINE	10MAR2003 16:54	-25	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035023	BASELINE	06MAY2003 10:41	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039052	BASELINE	29MAY2003 10:30	-22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04JUL2003 11:35	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039056	BASELINE	01JUL2003 13:00	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0040003	BASELINE	09JUL2003 13:40	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12SEP2003 11:25	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BASELINE	14FEB2003 10:50	-17	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02MAY2003 10:30	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002011	BASELINE	16APR2003 12:00	-13	ABNORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	25JUN2003 11:56	58	NORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003010	BASELINE	27JAN2003 17:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	31MAR2003 16:05	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003011	BASELINE	28JAN2003 12:05	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003016	BASELINE	01MAY2003 11:30	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13JUN2003 8:55	23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003019	BASELINE	19JUN2003 11:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21AUG2003 9:00	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0003020	BASELINE	27JUN2003 8:30	-26	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17SEP2003 0:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004001	BASELINE	23SEP2002 11:40	-7	ABNORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	05NOV2002 13:25	37	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004009	BASELINE	17DEC2002 9:45	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19FEB2003 16:10	56	NORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004012	BASELINE	07JAN2003 12:30	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11MAR2003 11:25	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004015	BASELINE	06FEB2003 9:40	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 9:20	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005003	BASELINE	23SEP2002 15:10	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0005003	FINAL	26NOV2002 13:30	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005005	BASELINE	24SEP2002 15:15	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005007	BASELINE	02OCT2002 13:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04DEC2002 14:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005008	BASELINE	08OCT2002 18:00	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	11DEC2002 16:00	58	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	DEPRESSED	NORMAL	NORMAL	LIMB LEAD REVERSAL
		FINAL *	30DEC2002 16:45	77	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	DEPRESSED	INVERTED	NORMAL	
	E0005009	BASELINE	09OCT2002 10:30	-20	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005010	FINAL	17DEC2002 14:15	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005012	BASELINE	24OCT2002 7:00	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0005014	BASELINE	05NOV2002 16:30	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL *	06JAN2003 9:45	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06JAN2003 11:45	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005022	BASELINE	23JAN2003 11:20	-6	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 10:50	9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005025	BASELINE	20FEB2003 13:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03APR2003 11:40	36	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0006019	BASELINE	26MAR2003 11:40	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03JUN2003 12:10	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007005	BASELINE	27JAN2003 13:30	-4	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28MAR2003 12:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0007015	BASELINE	09JUL2003 19:35	-7	NORMAL	NORMAL SINUS RHYTHM|APC	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10SEP2003 17:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0009001	BASELINE	29OCT2002 15:03	-14	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0010002	BASELINE	14NOV2002 14:45	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02DEC2002 9:00	8	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0010009	BASELINE	18DEC2002 11:33	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19FEB2003 13:40	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010010	BASELINE	20DEC2002 8:52	-10	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13JAN2003 10:15	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010014	BASELINE	14JAN2003 8:51	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25MAR2003 10:50	57	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 600 MG (BIPOLAR I)	E0010017	BASELINE	05FEB2003 10:46	-20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22APR2003 10:03	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010023	BASELINE	10APR2003 11:18	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01MAY2003 10:03	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010027	BASELINE	05JUN2003 10:46	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01JUL2003 12:30	16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010029	BASELINE	10JUN2003 9:13	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011022	BASELINE	02JUN2003 11:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05AUG2003 10:35	58	ABNORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0013006	BASELINE	06MAR2003 10:22	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24MAR2003 12:45	12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0013012	BASELINE	29APR2003 10:40	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUL2003 10:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0013014	BASELINE	08MAY2003 11:23	-26	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JUN2003 12:27	28	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014005	BASELINE	04MAR2003 16:47	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06MAY2003 11:43	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014007	BASELINE	25MAR2003 16:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22APR2003 13:20	22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014011	BASELINE	06MAY2003 16:25	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08JUL2003 15:25	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 600 MG (BIPOLAR I)	E0014012	BASELINE	19MAY2003 9:40	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24JUN2003 16:05	29	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0015001	BASELINE	08NOV2002 10:35	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20JAN2003 7:45	53	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0015008	BASELINE	13DEC2002 9:40	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0016003	BASELINE	10JAN2003 10:50	-14	ABNORMAL	JUNCTIONAL	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0016005	BASELINE	20FEB2003 13:40	-5	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22APR2003 8:05	57	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0018007	BASELINE	16DEC2002 9:10	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10JAN2003 14:40	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 600 MG (BIPOLAR I)	E0019005	BASELINE	30OCT2002 12:43	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JAN2003 13:50	59	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	BIPHASIC	NORMAL	
	E0019015	BASELINE	19DEC2002 10:05	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27FEB2003 11:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020004	BASELINE	21NOV2002 16:10	-18	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	DEPRESSED	INVERTED	NORMAL	
		FINAL	22JAN2003 16:18	45	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	INVERTED	NORMAL	
	E0020010	BASELINE	31JAN2003 9:30	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02APR2003 10:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020014	BASELINE	11MAR2003 10:17	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12MAY2003 11:30	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 600 MG (BIPOLAR I)	E0020021	BASELINE	13MAY2003 10:00	-6	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	14JUL2003 9:55	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0020023	BASELINE	09JUN2003 19:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11AUG2003 11:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022007	BASELINE	01NOV2002 11:35	-6	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022010	BASELINE	14NOV2002 16:05	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JAN2003 18:23	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022012	BASELINE	21NOV2002 12:15	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JAN2003 12:35	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022019	BASELINE	04DEC2002 13:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 11:30	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	BASELINE	08JAN2003 10:20	-20	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04FEB2003 11:40	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022033	BASELINE	11FEB2003 12:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 11:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022034	BASELINE	11FEB2003 14:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 14:05	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022038	BASELINE	20FEB2003 15:40	-8	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10APR2003 13:05	42	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022039	BASELINE	27FEB2003 11:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01MAY2003 13:05	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022046	BASELINE	13MAR2003 11:25	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022046	FINAL	16MAY2003 8:10	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022048	BASELINE	25MAR2003 11:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022051	BASELINE	31MAR2003 11:35	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUN2003 11:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022053	BASELINE	04APR2003 13:52	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022058	BASELINE	11APR2003 13:20	-10	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22MAY2003 15:15	32	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022061	BASELINE	24APR2003 10:05	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26JUN2003 12:43	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022062	BASELINE	25APR2003 12:50	-10	ABNORMAL	NORMAL SINUS RHYTHM	LAH	LVH	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022068	BASELINE	14MAY2003 10:30	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022069	BASELINE	03JUN2003 10:55	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05AUG2003 10:05	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022071	BASELINE	16JUN2003 11:50	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25AUG2003 9:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023003	BASELINE*	08NOV2002 16:05	-39	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	12DEC2002 10:00	-5	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11FEB2003 14:00	57	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023006	BASELINE	10DEC2002 11:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11FEB2003 12:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0023010	BASELINE	28JAN2003 9:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	31MAR2003 10:15	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023025	BASELINE	01MAY2003 15:30	-14	ABNORMAL	ECTOPIC ATRIAL RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10JUL2003 14:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023039	BASELINE	24JUN2003 13:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26AUG2003 13:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026002	BASELINE	05NOV2002 10:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09JAN2003 9:30	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026007	BASELINE	06JAN2003 10:35	-10	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12MAR2003 14:30	56	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0026013	BASELINE	05FEB2003 12:25	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14APR2003 10:05	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028007	BASELINE	01OCT2002 10:15	-3	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14NOV2002 12:50	42	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028023	BASELINE*	17DEC2002 9:45	-35	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	INVERTED	NORMAL	
		BASELINE	14JAN2003 9:40	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	INVERTED	NORMAL	
		FINAL	27JUN2003 15:15	158	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0028025	BASELINE	08JAN2003 11:17	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27JAN2003 9:30	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028033	BASELINE	18MAR2003 10:36	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22MAY2003 11:03	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	BASELINE	27MAR2003 12:15	-7	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	29MAY2003 15:33	57	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028037	BASELINE*	18APR2003 8:05	-56	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		BASELINE	04JUN2003 9:00	-9	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	08AUG2003 14:30	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0028039	BASELINE	02MAY2003 12:55	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05JUN2003 11:30	28	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028046	BASELINE	17JUN2003 13:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028048	BASELINE	11JUL2003 13:25	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029008	BASELINE	09DEC2002 12:53	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0029008	FINAL	23DEC2002 12:30	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029011	BASELINE	14JAN2003 10:05	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029012	BASELINE	04FEB2003 9:30	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27MAR2003 9:00	45	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029015	BASELINE	11FEB2003 10:22	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11MAR2003 13:50	16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029018	BASELINE	26FEB2003 17:23	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030014	BASELINE	14FEB2003 10:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22APR2003 12:40	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030020	BASELINE	13MAY2003 15:15	-16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0030024	BASELINE	17JUN2003 15:15	-24	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18JUL2003 16:15	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030025	BASELINE	24JUN2003 16:43	-17	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19AUG2003 16:15	40	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0031027	BASELINE	28MAY2003 9:15	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	29JUL2003 14:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031030	BASELINE	17JUN2003 10:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21AUG2003 11:15	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033012	BASELINE	05FEB2003 13:20	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034001	BASELINE	17MAR2003 9:40	-3	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0034001	FINAL	15MAY2003 11:40	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034004	BASELINE	11APR2003 11:22	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JUN2003 12:22	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035001	BASELINE	12NOV2002 12:50	-8	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	14JAN2003 9:30	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035006	BASELINE	03DEC2002 13:32	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 9:35	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035021	BASELINE	18APR2003 10:26	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20JUN2003 8:23	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0036002	BASELINE	10JUN2003 12:12	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	FINAL	14JUL2003 14:05	28	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0036006	BASELINE	24JUN2003 14:30	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27AUG2003 13:56	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0036007	BASELINE	26JUN2003 10:54	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18JUL2003 9:48	16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0037009	BASELINE	09MAY2003 14:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10JUL2003 17:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039011	BASELINE	16DEC2002 15:00	-17	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039018	BASELINE	14JAN2003 11:35	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 11:37	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 600 MG (BIPOLAR I)	E0039026	BASELINE	26FEB2003 13:55	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01MAY2003 11:20	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039028	BASELINE	03MAR2003 14:25	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16MAY2003 12:20	54	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039032	BASELINE	07MAR2003 13:55	-7	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28MAR2003 16:38	15	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0039034	BASELINE	12MAR2003 20:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14MAY2003 15:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039042	BASELINE	24APR2003 15:15	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUL2003 13:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0041004	BASELINE	22JAN2003 16:00	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	31MAR2003 12:40	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0041009	BASELINE	22APR2003 15:30	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0042002	BASELINE	02JUL2003 14:15	-7	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02SEP2003 10:30	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BASELINE	23JUN2003 12:20	-18	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25JUL2003 9:59	15	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003002	BASELINE	22OCT2002 10:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23DEC2002 15:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005031	BASELINE	27MAR2003 13:15	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005033	BASELINE	15APR2003 9:50	-1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06MAY2003 11:35	21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005038	BASELINE	05MAY2003 11:45	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05JUN2003 12:40	23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007009	BASELINE	09APR2003 18:55	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28APR2003 17:45	12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0009010	BASELINE	27FEB2003 17:05	-14	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0009011	BASELINE	28APR2003 14:10	-8	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03JUL2003 15:45	59	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010005	BASELINE	10DEC2002 11:30	-8	ABNORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0011016	BASELINE	14APR2003 10:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JUN2003 10:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011020	BASELINE	01MAY2003 9:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15MAY2003 17:00	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018002	BASELINE	15NOV2002 15:35	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22JAN2003 16:10	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	BASELINE	19NOV2002 13:00	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	10DEC2002 11:15	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018013	BASELINE	17JAN2003 15:20	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	31JAN2003 16:50	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019002	BASELINE	29OCT2002 11:00	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019008	BASELINE	06NOV2002 12:25	-15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019009	BASELINE	06NOV2002 13:49	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019016	BASELINE	30DEC2002 17:15	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	03MAR2003 16:16	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019020	BASELINE	16JAN2003 9:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019020	FINAL	27MAR2003 11:05	64	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019021	BASELINE	16JAN2003 12:03	-14	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03MAR2003 14:05	33	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019024	BASELINE	23JAN2003 16:43	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 14:00	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019031	BASELINE	06MAR2003 11:54	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25MAR2003 10:50	13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019035	BASELINE	11MAR2003 11:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019040	BASELINE	08MAY2003 15:10	-12	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	17JUL2003 10:43	59	ABNORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0019042	BASELINE	28MAY2003 10:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	FINAL	19JUN2003 14:25	16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019045	BASELINE	19JUN2003 14:35	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JUL2003 9:45	21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020024	BASELINE	12JUN2003 13:55	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20AUG2003 18:55	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022044	BASELINE	11MAR2003 11:45	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12MAY2003 10:25	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023007	BASELINE	07JAN2003 14:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13MAR2003 15:15	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023011	BASELINE	28JAN2003 12:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	FINAL	01APR2003 12:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023014	BASELINE	14FEB2003 14:00	-7	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25APR2003 14:30	64	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023019	BASELINE	21MAR2003 14:00	-17	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03JUN2003 13:30	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023022	BASELINE	10APR2003 15:40	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12JUN2003 15:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023023	BASELINE	17APR2003 11:40	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01MAY2003 14:45	7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023029	BASELINE	16MAY2003 14:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	BASELINE*	22MAY2003 13:50	-33	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	24JUN2003 12:20	1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19AUG2003 11:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023041	BASELINE	02JUL2003 12:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05SEP2003 12:00	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023043	BASELINE	07JUL2003 15:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09SEP2003 10:40	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026003	BASELINE	25NOV2002 12:25	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03FEB2003 11:05	62	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026005	BASELINE	23DEC2002 12:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06JAN2003 15:25	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 600 MG (BIPOLAR II)	E0026009	BASELINE	10JAN2003 10:10	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21JAN2003 9:30	7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026015	BASELINE	20FEB2003 11:35	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	25APR2003 10:10	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026023	BASELINE	23APR2003 10:55	-7	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27JUN2003 12:30	59	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0027016	BASELINE	19MAR2003 11:45	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03JUN2003 10:15	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0027018	BASELINE	21MAR2003 11:20	-4	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22MAY2003 10:00	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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QUETIAPINE 600 MG (BIPOLAR II)	E0028032	BASELINE	13MAR2003 14:08	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06JUN2003 11:25	74	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029003	BASELINE	28OCT2002 13:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30DEC2002 10:38	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029020	BASELINE	25FEB2003 10:50	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031005	BASELINE	13DEC2002 16:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14FEB2003 12:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031006	BASELINE	31JAN2003 11:35	-18	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 9:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031010	BASELINE	12FEB2003 14:55	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0031010	FINAL	06MAR2003 13:00	16	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031011	BASELINE	18FEB2003 11:55	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24APR2003 9:28	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031015	BASELINE	14MAR2003 8:45	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01APR2003 12:00	7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031031	BASELINE	01JUL2003 10:35	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28AUG2003 10:35	52	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033009	BASELINE	22JAN2003 13:30	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034009	BASELINE	10JUN2003 12:40	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18AUG2003 17:10	61	ABNORMAL	NORMAL SINUS RHYTHM|APC	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0037007	BASELINE	04APR2003 12:00	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0037012	BASELINE	11JUL2003 13:25	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08SEP2003 13:45	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039019	BASELINE	20JAN2003 15:20	-17	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03APR2003 11:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039043	BASELINE	25APR2003 13:25	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0002001	BASELINE	18DEC2002 15:30	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26FEB2003 9:35	59	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0002003	BASELINE	03JAN2003 12:20	-19	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18MAR2003 12:55	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002004	BASELINE	14JAN2003 8:15	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002008	BASELINE	05FEB2003 14:20	-20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23APR2003 14:35	58	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0002016	BASELINE	14JUL2003 11:25	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17SEP2003 11:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0003008	BASELINE	21JAN2003 12:24	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0004003	BASELINE	02OCT2002 11:15	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004006	BASELINE	28OCT2002 10:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06JAN2003 10:35	64	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004016	BASELINE	14FEB2003 11:10	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17APR2003 17:18	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0004024	BASELINE	25JUN2003 16:45	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28AUG2003 8:35	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005006	BASELINE	24SEP2002 14:50	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005017	BASELINE	11DEC2002 10:05	-19	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04MAR2003 13:10	65	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0005019	BASELINE	19DEC2002 13:50	-27	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24JAN2003 10:00	10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005026	BASELINE	26FEB2003 13:50	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02APR2003 9:45	28	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005039	BASELINE	15MAY2003 9:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JUL2003 8:30	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005043	BASELINE	01JUL2003 16:30	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03SEP2003 9:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0006020	BASELINE	02MAY2003 13:35	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08JUL2003 14:55	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0007001	BASELINE	10DEC2002 17:49	-21	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22FEB2003 10:05	54	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007003	BASELINE	03JAN2003 4:30	-27	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10MAR2003 12:45	40	NORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007006	BASELINE	21FEB2003 18:25	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26MAR2003 12:10	22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0009004	BASELINE	19NOV2002 12:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18DEC2002 14:35	23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0009012	BASELINE	16JUN2003 14:38	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03JUL2003 18:00	9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010008	BASELINE	11DEC2002 9:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0010018	BASELINE	26FEB2003 10:30	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14MAY2003 10:35	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0010028	BASELINE	09JUN2003 11:03	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15JUL2003 13:30	30	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011008	BASELINE*	17DEC2002 12:10	-44	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	23JAN2003 9:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13FEB2003 13:30	15	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011009	BASELINE	19DEC2002 10:00	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20FEB2003 9:30	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011010	BASELINE	03FEB2003 10:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19MAR2003 9:15	38	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0013001	BASELINE	01NOV2002 9:05	-13	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	10JAN2003 10:52	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0013003	BASELINE	07NOV2002 10:44	-5	ABNORMAL	NORMAL SINUS RHYTHM|VPC	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	06JAN2003 13:50	56	ABNORMAL	NORMAL SINUS RHYTHM|VPC	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0013005	BASELINE	13FEB2003 11:54	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 12:24	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	LIMB LEAD REVERSAL
	E0013013	BASELINE	01MAY2003 10:30	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014002	BASELINE	19FEB2003 16:00	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10APR2003 13:17	44	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014004	BASELINE	04MAR2003 11:15	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 11:25	35	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0014009	BASELINE	15APR2003 14:22	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16MAY2003 8:20	24	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014015	BASELINE	16JUN2003 11:09	-2	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014017	BASELINE	17JUN2003 16:37	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19AUG2003 15:55	54	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014018	BASELINE	24JUN2003 16:25	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27AUG2003 15:05	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0015005	BASELINE	25NOV2002 13:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18DEC2002 9:10	17	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0017002	BASELINE	08MAY2003 17:15	-26	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13JUN2003 15:25	11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0018009	BASELINE	17DEC2002 11:00	-20	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14JAN2003 13:10	9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018010	BASELINE	09JAN2003 9:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13MAR2003 9:05	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018015	BASELINE	21JAN2003 11:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27MAR2003 10:55	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020015	BASELINE	18MAR2003 14:25	-9	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	23MAY2003 13:55	58	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0020017	BASELINE	27MAR2003 14:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03JUN2003 17:55	62	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0020020	BASELINE	07MAY2003 15:00	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23MAY2003 16:20	12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0020022	BASELINE	09JUN2003 11:55	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11AUG2003 9:19	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022001	BASELINE	07OCT2002 16:02	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26DEC2002 18:30	60	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022004	BASELINE*	17OCT2002 10:30	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	28OCT2002 10:10	1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23DEC2002 10:50	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022005	BASELINE*	17OCT2002 11:25	-22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	17OCT2002 12:05	-22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0022005	FINAL	03JAN2003 10:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022011	BASELINE	20NOV2002 8:55	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022015	BASELINE*	29NOV2002 14:25	-11	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	10DEC2002 15:10	1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06FEB2003 10:20	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022016	BASELINE	03DEC2002 12:25	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11FEB2003 11:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022020	BASELINE	05DEC2002 12:06	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23JAN2003 16:45	43	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022023	BASELINE	19DEC2002 17:50	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0022023	FINAL	20FEB2003 10:20	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022029	BASELINE	05FEB2003 11:25	-14	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	INVERTED	NORMAL	
		FINAL	14APR2003 9:50	55	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	INVERTED	NORMAL	
	E0022041	BASELINE	04MAR2003 14:15	-14	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	13MAY2003 9:23	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0022042	BASELINE	05MAR2003 9:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12MAY2003 9:45	62	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022043	BASELINE	10MAR2003 11:05	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12MAY2003 8:40	54	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022054	BASELINE	04APR2003 15:44	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0022059	BASELINE	22APR2003 18:27	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08JUL2003 18:00	64	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022065	BASELINE	30APR2003 12:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUL2003 9:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022070	BASELINE	05JUN2003 11:55	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	18JUN2003 15:30	7	ABNORMAL	NORMAL SINUS RHYTHM	ILBBB	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0023001	BASELINE	24OCT2002 11:45	-22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14JAN2003 13:15	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023009	BASELINE	24JAN2003 11:50	-18	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08APR2003 11:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0023028	BASELINE	16MAY2003 12:30	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21JUL2003 10:15	54	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023033	BASELINE	30MAY2003 12:10	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12JUN2003 13:15	8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023047	BASELINE	11JUL2003 14:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16SEP2003 13:00	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0025001	BASELINE	25MAR2003 15:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23APR2003 11:00	23	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026012	BASELINE	05FEB2003 11:05	-15	ABNORMAL	SINUS BRADYCARDIA	LAH	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	17APR2003 9:20	57	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0026020	BASELINE	28MAR2003 11:00	-4	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0026020	FINAL	22APR2003 14:10	22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026024	BASELINE	25APR2003 12:35	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026028	BASELINE	06JUN2003 10:25	-14	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23JUL2003 10:10	34	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028001	BASELINE	20SEP2002 12:55	-20	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03DEC2002 10:00	55	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028003	BASELINE	23SEP2002 9:15	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	26NOV2002 9:40	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028005	BASELINE	30SEP2002 10:35	-3	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	31OCT2002 12:20	29	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0028010	BASELINE	15OCT2002 11:10	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	31DEC2002 9:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028011	BASELINE*	16OCT2002 15:25	-50	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	25NOV2002 10:30	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JAN2003 12:45	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028030	BASELINE	26FEB2003 11:57	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30APR2003 12:48	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028031	BASELINE	06MAR2003 9:15	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17APR2003 13:20	38	NORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0028047	BASELINE	08JUL2003 11:35	-6	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	09SEP2003 10:30	58	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0029001	BASELINE	24SEP2002 12:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029014	BASELINE	28JAN2003 10:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	LIMB LEAD REVERSAL
		FINAL	01APR2003 11:04	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029023	BASELINE	01APR2003 8:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10JUN2003 11:50	64	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029032	BASELINE	22MAY2003 12:30	-19	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01JUL2003 12:45	22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029033	BASELINE	27MAY2003 12:35	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JUN2003 8:57	29	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029039	BASELINE	10JUL2003 15:00	-5	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	28JUL2003 15:20	14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0030003	BASELINE	03DEC2002 14:10	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24DEC2002 9:40	9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030009	BASELINE	10JAN2003 15:16	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19MAR2003 10:26	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030016	BASELINE	21FEB2003 11:55	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22APR2003 18:50	51	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0030021	BASELINE	13MAY2003 17:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031001	BASELINE	14NOV2002 11:27	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0031017	BASELINE	25MAR2003 16:20	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	DEPRESSED	FLAT	NORMAL	
		FINAL	29APR2003 10:30	29	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	DEPRESSED	FLAT	NORMAL	

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PLACEBO (BIPOLAR I)	E0031018	BASELINE	01APR2003 14:55	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031023	BASELINE	22APR2003 14:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24JUN2003 11:50	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033001	BASELINE	23DEC2002 13:40	-17	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	30JAN2003 13:15	22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	LIMB LEAD REVERSAL
	E0033004	BASELINE	09JAN2003 12:50	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14MAR2003 11:30	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033010	BASELINE	22JAN2003 16:40	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26MAR2003 16:10	51	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033014	BASELINE	12MAR2003 17:10	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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PLACEBO (BIPOLAR I)	E0035002	BASELINE	14NOV2002 12:20	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035007	BASELINE	13DEC2002 13:30	-6	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	DEPRESSED	FLAT	NORMAL	
		FINAL	11FEB2003 10:20	55	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0035011	BASELINE	09JAN2003 11:55	-26	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	01APR2003 9:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035020	BASELINE	11APR2003 11:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	13JUN2003 8:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0037003	BASELINE	22JAN2003 13:55	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20FEB2003 16:45	22	NORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0037004	BASELINE	06FEB2003 12:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	10APR2003 12:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0039007	BASELINE	25NOV2002 13:50	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	29JAN2003 14:58	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039022	BASELINE	04FEB2003 14:21	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	24APR2003 12:15	59	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	BIPHASIC	NORMAL	
	E0039023	BASELINE	05FEB2003 10:51	-19	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039030	BASELINE	12MAR2003 9:05	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19MAY2003 9:40	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039031	BASELINE	05MAR2003 17:50	-19	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20MAY2003 13:00	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039037	BASELINE	26MAR2003 18:40	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0039037	FINAL	12JUN2003 11:45	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039038	BASELINE	27MAR2003 10:15	-27	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20JUN2003 11:40	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039047	BASELINE	12MAY2003 14:05	-7	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	BIPHASIC	NORMAL	
		FINAL	14JUL2003 11:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039059	BASELINE	03JUL2003 16:10	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	05SEP2003 11:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0041007	BASELINE	05MAR2003 14:00	-8	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08MAY2003 13:40	57	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0041010	BASELINE	23APR2003 15:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR I)	E0041010	FINAL	11JUN2003 16:00	43	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0041011	BASELINE	15MAY2003 16:05	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17JUL2003 15:00	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0041012	BASELINE	05JUN2003 12:38	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14AUG2003 11:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0001004	BASELINE	28APR2003 15:00	-3	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JUL2003 13:30	63	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005023	BASELINE	28JAN2003 18:00	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005034	BASELINE	08APR2003 16:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	09JUN2003 12:55	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0005041	BASELINE	17JUN2003 11:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18AUG2003 10:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007004	BASELINE	24JAN2003 7:50	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12FEB2003 18:35	14	NORMAL	SINUS TACHYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007010	BASELINE	11APR2003 12:00	-7	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL *	25APR2003 13:20	8	ABNORMAL	NORMAL SINUS RHYTHM|VPC	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0007010	FINAL	*	02MAY2003 16:50	15	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL		16JUN2003 14:25	60	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0007012	BASELINE		02MAY2003 17:45	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL		03JUL2003 10:45	49	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0009007	BASELINE		27JAN2003 15:17	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	LIMB LEAD REVERSAL
		FINAL		03MAR2003 15:30	29	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
	E0009008	BASELINE		04FEB2003 13:25	-8	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL		08APR2003 12:50	56	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011001	BASELINE		25OCT2002 15:50	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL		26DEC2002 8:55	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0011011	BASELINE	12FEB2003 12:06	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16APR2003 9:10	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011013	BASELINE	25MAR2003 10:10	-23	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	
		FINAL	12JUN2003 9:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011014	BASELINE	31MAR2003 10:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08MAY2003 15:50	32	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0011021	BASELINE	15MAY2003 10:10	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21JUL2003 10:44	61	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0013008	BASELINE	19MAR2003 15:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19MAY2003 11:41	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014001	BASELINE	18FEB2003 15:50	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0014001	FINAL	08APR2003 10:44	42	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014013	BASELINE	20MAY2003 16:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23JUL2003 16:10	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0014014	BASELINE	03JUN2003 16:30	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06AUG2003 10:20	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0015004	BASELINE	25NOV2002 9:30	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018005	BASELINE	10DEC2002 15:30	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14FEB2003 16:45	57	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0018012	BASELINE	17JAN2003 10:20	-7	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	26FEB2003 19:20	34	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019019	BASELINE	14JAN2003 11:53	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0019033	BASELINE	11MAR2003 13:19	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15MAY2003 12:25	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019038	BASELINE	10APR2003 12:43	-14	NORMAL	SINUS BRADYCARDIA	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	18JUN2003 9:45	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019046	BASELINE	19JUN2003 16:15	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	21AUG2003 9:20	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019047	BASELINE	26JUN2003 12:00	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04SEP2003 8:45	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0019048	BASELINE	03JUL2003 11:27	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03SEP2003 16:25	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022006	BASELINE	21OCT2002 15:10	-22	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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PLACEBO (BIPOLAR II)	E0022006	FINAL	07JAN2003 8:10	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022047	BASELINE	21MAR2003 9:59	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	23MAY2003 10:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0022075	BASELINE	25JUN2003 12:45	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	03SEP2003 9:25	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023012	BASELINE	31JAN2003 16:00	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	04APR2003 12:30	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023016	BASELINE	15MAY2003 14:00	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023018	BASELINE	18MAR2003 13:30	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22MAY2003 11:00	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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PLACEBO (BIPOLAR II)	E0023036	BASELINE	10JUN2003 12:00	-10	ABNORMAL	NORMAL SINUS RHYTHM	FIRST DEGREE BLOCK	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0023046	BASELINE	11JUL2003 10:00	-12	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16SEP2003 14:00	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026006	BASELINE	31DEC2002 10:45	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026021	BASELINE	14APR2003 15:50	-9	ABNORMAL	NORMAL SINUS RHYTHM	LAH|IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0026027	BASELINE	05JUN2003 13:15	-14	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029002	*	05NOV2002 10:44		NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029004	BASELINE	13NOV2002 14:43	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16JAN2003 10:05	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029013	BASELINE	10FEB2003 9:05	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

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PLACEBO (BIPOLAR II)	E0029019	BASELINE	24FEB2003 9:17	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	17MAR2003 9:40	15	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029024	BASELINE*	11MAR2003 12:41	-6	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		BASELINE	17MAR2003 15:00	1	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	20MAY2003 15:15	65	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0029038	BASELINE	30JUN2003 9:55	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031004	BASELINE	12DEC2002 14:18	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14FEB2003 10:55	58	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031013	BASELINE	06MAR2003 10:40	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	08MAY2003 11:05	57	ABNORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	FLAT	NORMAL	

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PLACEBO (BIPOLAR II)	E0031016	BASELINE	17MAR2003 10:50	-7	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	15APR2003 10:05	23	ABNORMAL	NORMAL SINUS RHYTHM	IRBBB	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031019	BASELINE	03APR2003 11:40	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	12MAY2003 16:48	32	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0031022	BASELINE	21APR2003 12:43	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033007	BASELINE	15JAN2003 15:15	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	27MAR2003 15:15	59	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033013	BASELINE	06FEB2003 11:55	-13	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	16APR2003 11:35	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033016	BASELINE	17APR2003 11:58	-21	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG102.SAS
GENERATED: 12JUL2005 17:42:28 iceadmn3

Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCT ION	MORPHO LOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0033016	FINAL	02JUL2003 12:40	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0033022	BASELINE	09JUL2003 11:45	-5	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11SEP2003 11:13	60	ABNORMAL	ECTOPIC ATRIAL RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0034007	BASELINE	06MAY2003 14:12	-10	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	14JUL2003 11:37	60	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035004	BASELINE	22NOV2002 11:58	-5	ABNORMAL	NORMAL SINUS RHYTHM	LAH	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035009	BASELINE	20DEC2002 11:35	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	19FEB2003 9:05	55	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0035010	BASELINE	06JAN2003 12:27	-4	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	06MAR2003 9:23	56	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG102.SAS
GENERATED: 12JUL2005 17:42:28 iceadmn3

Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0035022	BASELINE	01MAY2003 10:20	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	07JUL2003 9:04	60	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0039003	BASELINE	06NOV2002 16:00	-19	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	02JAN2003 14:10	39	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0040001	BASELINE	18JUN2003 14:45	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	22AUG2003 9:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0040004	BASELINE	11JUL2003 15:21	-7	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0041002	BASELINE	13JAN2003 14:55	-8	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
		FINAL	11MAR2003 10:40	50	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	
	E0041005	BASELINE	24FEB2003 11:20	-9	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG102.SAS
GENERATED: 12JUL2005 17:42:28 iceadmn3

Listing 12.2.10.2 ECG Interpretation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE TIME	DAY	INTERPR-ETATION	RHYTHM	CONDUCTION	MORPHOLOGY	MYO-CARDIAL INFARCT	ST SEGMENT	T WAVE	U WAVE	COMMENT
PLACEBO (BIPOLAR II)	E0041005	FINAL	30APR2003 14:15	57	NORMAL	NORMAL SINUS RHYTHM	NORMAL	NORMAL	ABSENT	NORMAL	NORMAL	NORMAL	

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/ECG102.SAS
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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	BASELINE	30.8 #	131	90 #	172 #	FEMALE	41 #	82	82
		FINAL	30.8 #	116	71	142	FEMALE	41 #	91	91
	E0002012	BASELINE	20.9	102	62	93	MALE	43	103	103
		FINAL	19.1	101	66	77	MALE	57	85	85
	E0002018	BASELINE	41.9 #	139	89 #	464 #	MALE	27 #	91	91
		FINAL	41.9 #	136	94 #	273 #	MALE	31 #	115 #	115
	E0003004	BASELINE	33.6 #	120	86 #	128	MALE	44	80	80
		FINAL	34.6 #	132	70 #	153 #	MALE	34 #	74	74
	E0003005	BASELINE	30.9 #	127	83	260 #	FEMALE	31 #	79	79
		FINAL	31.6 #	120	69	460 #	FEMALE	32 #	94	94
	E0003007	BASELINE	28.0	120	78	85	FEMALE	52	79	79
		FINAL	28.0	112	69	106	FEMALE	44 #	75	75
	E0003015	BASELINE	22.8	115	72	162 #	FEMALE	67	76	76
		FINAL	24.4	105	73	148	FEMALE	68	80	80
	E0004002	BASELINE	26.7	112	67	104	FEMALE	43 #	82	82
		FINAL	25.1	115	64	111	FEMALE	42 #	95	95
	E0004013	BASELINE	34.1 #	112	75	161 #	FEMALE	33 #	89	89
		FINAL	35.3 #	111	75	215 #	FEMALE	33 #	94	94
	E0004018	BASELINE	20.5	115	72	152 #	MALE	46	85	85
		FINAL	20.5	109	74	80	MALE	37 #	81	81
	E0004021	BASELINE	29.7	120	80	264 #	MALE	41	75	75
		FINAL	29.4	126	91 #	524 #	MALE	29 #	87	87
	E0005002	BASELINE	20.0	114	66	540 #	MALE	38 #	98	98
		FINAL	22.1	117	75	877 #	MALE	29 #	86	86
	E0005024	BASELINE	36.3 #	122	82	63	FEMALE	49 #	75	75

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND100.SAS
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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0005024	FINAL	35.6 #	115	75	86	FEMALE	52	86	86
	E0005027	BASELINE	27.8	121	80	504 #	MALE	34 #	94	94
		FINAL	27.5	120	79	709 #	MALE	28 #	90	90
	E0005037	BASELINE	50.7 #	135	83 #	272 #	FEMALE	37 #	93	93
		FINAL	52.9 #	130	80 #	359 #	FEMALE	29 #	102	102
	E0005042	BASELINE	33.4 #	125	82	191 #	MALE	45	90	90
		FINAL	33.7 #	127	83	162 #	MALE	32 #	85	85
	E0006005	BASELINE	40.5 #	123	77	158 #	FEMALE	31 #	75	75
		FINAL		128	73	166 #	FEMALE	44 #	84	84
	E0006018	BASELINE	29.3	138	77 #	94	MALE	31 #	88	88
		FINAL		130	80 #	77	MALE	34 #	82	82
	E0007013	BASELINE	22.9	101	63 #	248 #	FEMALE	70	93	93
		FINAL	23.4	131	78 #	200 #	FEMALE	81	97	97
	E0010004	BASELINE	27.2	100	72	282 #	FEMALE	56	81	81
		FINAL	27.2	116	77	283 #	FEMALE	47 #	92	92
	E0010012	BASELINE	40.8 #	130	84 #	211 #	FEMALE	50	107	107
		FINAL	41.1 #	132	86 #	477 #	FEMALE	41 #	108	108
	E0010024	BASELINE	33.9 #	119	79 #	311 #	MALE	34 #	136 #	136 #
		FINAL	34.6 #	130	83 #	376 #	MALE	39 #	156 #	156 #
	E0010032	BASELINE	29.8	116	80	109	FEMALE	42 #	79	79
		FINAL	29.8	120	70	166 #	FEMALE	35 #	89	89
	E0011025	BASELINE	23.4	109	77	136	FEMALE	65	82	82
		FINAL	24.2	101	70	145	FEMALE	57	81	81
	E0013007	BASELINE	27.8	130	89 #	189 #	MALE	56 #	174 #	174 #
		FINAL	27.8	126	85 #	465 #	MALE	53 #	142 #	142 #

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	BASELINE	34.7 #	120	80	132	FEMALE	52	95	95
		FINAL	36.1 #	120	79	171 #	FEMALE	60	90	90
	E0014006	BASELINE	40.5 #	121	86 #	106	FEMALE	47 #	58	58
		FINAL	42.5 #	122	77	169 #	FEMALE	70	86	86
	E0014010	BASELINE	35.6 #	137	85 #	211 #	FEMALE	29 #	83 #	83 #
		FINAL	36.0 #	121	83	289 #	FEMALE	26 #	93 #	93 #
	E0016001	BASELINE	26.6			142	MALE	66	95	95
		FINAL	28.2	123	80	159 #	MALE	52	80	80
	E0018001	BASELINE	33.0 #	122	74	306 #	FEMALE	23 #	80	80
		FINAL	33.3 #	128	82	292 #	FEMALE	37 #	137 #	137
	E0018006	BASELINE	29.0	117	73	172 #	MALE	40	92	92
		FINAL	29.0	123	79	177 #	MALE	38 #	90	90
	E0019004	BASELINE	23.3	120	83	263 #	FEMALE	46 #	79	79
		FINAL		138	83 #	116	FEMALE	57	83	83
	E0019011	BASELINE	40.8 #	120	75	158 #	FEMALE	53	87 #	87 #
		FINAL	41.2 #	111	74	120	FEMALE	46 #	95 #	95 #
	E0019025	BASELINE	22.8	115	73	118	FEMALE	65	78	78
		FINAL	22.0	110	70	130	FEMALE	61	79	79
	E0019043	BASELINE	23.2	115	81	203 #	MALE	63	93	93
		FINAL	23.5	116	74	363 #	MALE	54	83	83
	E0020001	BASELINE	28.0	116	84	64	FEMALE	88	76	76
		FINAL	29.8	125	83	85	FEMALE	66	81	81
	E0020006	BASELINE	41.4 #	126	76 #	239 #	FEMALE	42 #	73	73
		FINAL	37.7 #	136	75 #	165 #	FEMALE	51	90	90
	E0020007	BASELINE	19.6	105	66	74	FEMALE	34 #	81	81

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0020007	FINAL	19.6	91	59	106	FEMALE	47 #	93	93
	E0020011	BASELINE	34.3 #	119	74	450 #	FEMALE	31 #	87	87
		FINAL	34.6 #	115	78	803 #	FEMALE	25 #	98	98
	E0020013	BASELINE	27.1	128	75	103	MALE	44	74	74
		FINAL	27.7	122	76	242 #	MALE	38 #	75	75
	E0022008	BASELINE	27.4	116	58	115	MALE	47	72	72
		FINAL	27.1	120	67	69	MALE	59	97	97
	E0022017	BASELINE	25.8	115	81	240 #	MALE	28 #	86	86
		FINAL	26.0	130	82 #	197 #	MALE	29 #	94	94
	E0022018	BASELINE	34.8 #	129	84	183 #	MALE	47	93	93
		FINAL	35.6 #	113	73	142	MALE	48	91	91
	E0022022	BASELINE	19.8	106	66	38	FEMALE	59	79	79
		FINAL	19.8	112	68	82	FEMALE	57	74	74
	E0022027	BASELINE	35.0 #	112	77	137	MALE	35 #	88	88
		FINAL	34.1 #	114	73	126	MALE	34 #	96	96
	E0022031	BASELINE	27.5	106	74	202 #	MALE	47	106	106
		FINAL	28.7	110	72	258 #	MALE	35 #	93	93
	E0022032	BASELINE	22.8	120	77	213 #	FEMALE	35 #	102	102
		FINAL	22.8	122	78	171 #	FEMALE	46 #	92	92
	E0022035	BASELINE	29.6	115	79	63	FEMALE	59	74	74
		FINAL	30.4 #	116	80	67	FEMALE	58	81	81
	E0022036	BASELINE	22.1	121	71	105	MALE	41	91	91
		FINAL	23.3	101	65	87	MALE	39 #	84	84
	E0022060	BASELINE	22.9	120	76	71	MALE	62	94	94
		FINAL	22.6	117	70	81	MALE	58	80	80

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GENERATED: 12JUL2005 17:46:23 iceadmn3

Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0023008	BASELINE	22.1	109	68	58	FEMALE	56	78	78
		FINAL	23.5	119	75	57	FEMALE	58	93	93
	E0023013	BASELINE	24.8	120	77	161 #	FEMALE	47 #	87	87
		FINAL	24.8	120	70	135	FEMALE	39 #	90	90
	E0023015	BASELINE	21.4	120	76	79	FEMALE	59	91	91
		FINAL	21.7	114	71	73	FEMALE	65	83	83
	E0023034	BASELINE	22.6	102	63	93	FEMALE	40 #	82	82
		FINAL	22.6	133	80 #	204 #	FEMALE	28 #	84	84
	E0023037	BASELINE	24.3	141	93 #	67	MALE	86	87	87
		FINAL	25.7	138	85 #	68	MALE	101	87	87
	E0023038	BASELINE	34.6 #	150	94 #	318 #	MALE	35 #	91	91
		FINAL	32.5 #	138	93 #	298 #	MALE	36 #	84	84
	E0023044	BASELINE	40.7 #	124	86 #	146	FEMALE	69	94	94
		FINAL	41.1 #	118	81	188 #	FEMALE	63	93	93
	E0023045	BASELINE	20.2	113	72	83	MALE	46	82	82
		FINAL	22.1	118	80	94	MALE	48	62	62
	E0025002	BASELINE	35.4 #	125	81	139	FEMALE	84	90	90
		FINAL	37.2 #	120	79	175 #	FEMALE	90	100	100
	E0026010	BASELINE	29.0	134	66 #	90	MALE	45	92	92
		FINAL	29.6	121	60	102	MALE	47	100	100
	E0026017	BASELINE	28.4	150	68 #	217 #	MALE	33 #	84	84
		FINAL	28.7	142	58 #	309 #	MALE	29 #	72	72
	E0026018	BASELINE	38.6 #	126	70	127	FEMALE	26 #	84	84
		FINAL	38.6 #	124	68	128	FEMALE	26 #	81	81
	E0026025	BASELINE	24.7	132	82 #	242 #	MALE	30 #	92	92

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0026025	FINAL	26.7	134	88 #	263 #	MALE	47	75	75
	E0026029	BASELINE	64.1 #	102	62	48	FEMALE	56	86	86
		FINAL	23.9	128	71	72	FEMALE	51	97	97
	E0026030	BASELINE	26.0	125	68	80	MALE	64	80	80
		FINAL	26.3	116	68	136	MALE	62	87	87
	E0026031	BASELINE	24.3	130	77 #	74	MALE	42	71	71
		FINAL	20.9	118	80 #	95	MALE	46	75	75
	E0027003	BASELINE	28.6			293 #	FEMALE	35 #	96	96
		FINAL	31.6 #	145	92 #	270 #	FEMALE	46 #	68	68
	E0028004	BASELINE	20.9	96	69	85	MALE	30 #	89	89
		FINAL	21.2	104	80	67	MALE	42	83	83
	E0028006	BASELINE	24.1	101	65	66	FEMALE	59	80	80
		FINAL	23.7	120	80	67	FEMALE	51	77	77
	E0028008	BASELINE	33.4 #	115	69	335 #	MALE	32 #	76	76
		FINAL	31.4 #	114	74	132	MALE	31 #	84	84
	E0028009	BASELINE	31.9 #	117	65	121	FEMALE	46 #	81	81
		FINAL	33.7 #	110	74	153 #	FEMALE	49 #	83	83
	E0028016	BASELINE	28.4	124	80	87	MALE	50	82	82
		FINAL	27.8	127	76	223 #	MALE	38 #	68	68
	E0028029	BASELINE	29.3	114	77	162 #	MALE	50	91	91
		FINAL	30.2 #	122	90 #	200 #	MALE	45	83	83
	E0028034	BASELINE	30.5 #	122	76	214 #	MALE	35 #	76	76
		FINAL	30.5 #	120	82	418 #	MALE	32 #	76	76
	E0028038	BASELINE	46.1 #	141	86 #	223 #	MALE	57	97	97
		FINAL	45.4 #	143	86 #	181 #	MALE	56	103	103

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0028043	BASELINE	30.5 #	150	95 #	219 #	MALE	39 #	77	77
		FINAL	30.8 #	136	86 #	273 #	MALE	35 #	114 #	114
	E0028045	BASELINE	21.5	133	83 #	59	MALE	50	78 #	78 #
		FINAL	21.8	118	78	85	MALE	61	71 #	71 #
	E0029005	BASELINE	34.0 #	110	78	89	FEMALE	38 #	82	82
		FINAL	37.9 #	100	72	103	FEMALE	56	80	80
	E0030001	BASELINE	21.3	120	81	183 #	FEMALE	124	93	93
		FINAL	22.0	117	78	83	FEMALE	115	96	96
	E0030008	BASELINE	26.9	111	70	153 #	MALE	55	80	80
		FINAL	25.4	109	78	130	MALE	56	108	108
	E0030011	BASELINE	37.4 #	133	78 #	78	MALE	43	71 #	71 #
		FINAL	38.4 #	135	75 #	169 #	MALE	39 #	88 #	88 #
	E0030015	BASELINE	26.6	120	80	79	MALE	54	78	78
		FINAL	25.4	125	82	108	MALE	60	91	91
	E0030022	BASELINE	38.3 #	123	86 #	126	MALE	52 #	91	91
		FINAL	37.5 #	126	90 #	161 #	MALE	47 #	68	68
	E0031002	BASELINE	21.4	121	75	63	FEMALE	85	86	86
		FINAL	20.7	107	62	71	FEMALE	95	83	83
	E0031003	BASELINE	23.2	113	79	118	MALE	47	73	73
		FINAL	23.6	124	76	93	MALE	49	81	81
	E0033015	BASELINE	21.3	99	69	92	FEMALE	81	75	75
		FINAL	22.0	100	70	78	FEMALE	86	69	69
	E0034002	BASELINE	33.9 #	148	100 #	374 #	MALE	36 #	121 #	121
		FINAL	34.6 #	130	87 #	312 #	MALE	32 #	132 #	132
	E0034003	BASELINE	25.7	118	77	101	MALE	53	87	87

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND100.SAS
GENERATED: 12JUL2005 17:46:23 iceadmn3

Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	FINAL	25.7	120	80	288 #	MALE	44	90	90
	E0034006	BASELINE	50.1 #	123	68	223 #	FEMALE	31 #	102	102
		FINAL	51.1 #	128	90 #	382 #	FEMALE	28 #	78	78
	E0034008	BASELINE	27.8	123	74	109	MALE	49	86	86
		FINAL	27.8	118	75	92	MALE	47	92	92
	E0035014	BASELINE	27.5	110	73	73	FEMALE	79	76	76
		FINAL	26.6	107	69	60	FEMALE	76	81	81
	E0035024	BASELINE	41.9 #	115	71	153 #	FEMALE	87	86	86
		FINAL	42.2 #	130	80 #	113	FEMALE	91	85	85
	E0036005	BASELINE	42.0 #	106	67	78	FEMALE	52	83	83
		FINAL	41.1 #	116	70	92	FEMALE	44 #	78	78
	E0037002	BASELINE	27.3	104	74	60	FEMALE	36 #	86	86
		FINAL	28.7	101	70	53	FEMALE	44 #	89	89
	E0037005	BASELINE	34.9 #	116	70	120	FEMALE	57	75	75
		FINAL	36.0 #	130	94 #	112	FEMALE	61	80	80
	E0037006	BASELINE	23.4	126	84	56	FEMALE	89	85	85
		FINAL	25.1	118	76	66	FEMALE	98	76	76
	E0039006	BASELINE	28.1	129	88 #	104	FEMALE	36 #	77	77
		FINAL	28.6	123	89 #	72	FEMALE	37 #	72	72
	E0039015	BASELINE	23.6	131	83 #	80	MALE	48	83	83
		FINAL	24.2	123	88 #	82	MALE	55	88	88
	E0039024	BASELINE	32.7 #	111	79	143	FEMALE	43 #	92	92
		FINAL	33.4 #	102	71	209 #	FEMALE	44 #	80	80
	E0039025	BASELINE	30.0 #	134	91 #	120	MALE	44	81	81
		FINAL	30.0 #	132	92 #	163 #	MALE	55	97	97

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	BASELINE	23.7	121	81	41	MALE	59	83	83
		FINAL	23.4	127	82	76	MALE	88	83	83
	E0039044	BASELINE	27.4	105	78	167 #	MALE	43	98	98
		FINAL	26.7	128	84	527 #	MALE	30 #	100	100
	E0039051	BASELINE	30.1 #	127	82	67	FEMALE	55	83	83
		FINAL	29.8	128	88 #	272 #	FEMALE	36 #	84	84
	E0039053	BASELINE	26.0	148	91 #	100	MALE	38 #	89	89
		FINAL	26.0	131	81 #	206 #	MALE	43	93	93
	E0039057	BASELINE	30.6 #	121	80	86	MALE	77	69	69
		FINAL	31.2 #	131	69 #	104	MALE	53	134 #	134
	E0041003	BASELINE	36.1 #	109	69 #	218 #	FEMALE	46 #	96	96
		FINAL	36.9 #	122	81 #	109	FEMALE	50	95	95
	E0041008	BASELINE	25.1	121	80	183 #	FEMALE	54	105	105
		FINAL	24.0	118	79	143	FEMALE	59	86	86
	E0042001	BASELINE	30.8 #	110	80 #	113	FEMALE	52	93	93
		FINAL	30.8 #	110	78 #	87	FEMALE	60	85	85

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	BASELINE	27.2	120	78 #	107	FEMALE	53	76	76
		FINAL	27.6	123	78 #	185 #	FEMALE	58	89	89
	E0003018	BASELINE	20.3	121	84	48	FEMALE	56	87	87
		FINAL	22.1	118	87 #	61	FEMALE	54	82	82
	E0005036	BASELINE	44.6 #	110	72	112	FEMALE	53 #	83	83
		FINAL	44.6 #	107	69	144	FEMALE	46 #	79	79
	E0006015	BASELINE	28.6	118	63	167 #	FEMALE	46 #	87	87
		FINAL	30.5 #	119	78	133 #	FEMALE	48 #	89	89
	E0006016	BASELINE	26.9	120	62	126	MALE	66	87	87
		FINAL	26.5	130	75	99	MALE	66	99	99
	E0007008	BASELINE	44.3 #	108	65	248 #	FEMALE	36 #	110 #	110
		FINAL	45.0 #	118	80	489 #	FEMALE	35 #	108	108
	E0009002	BASELINE	31.1 #	118	81	105	MALE	44 #	85	85
		FINAL	31.4 #	132	85 #	184 #	MALE	32 #	84	84
	E0009006	BASELINE	22.8	105	62	117	MALE	38 #	64	64
		FINAL	25.1	110	77	110	MALE	50	67	67
	E0009009	BASELINE	27.1	105	66	204 #	FEMALE	40 #	80	80
		FINAL	28.1	127	60	148	FEMALE	47 #	90	90
	E0010015	BASELINE	35.3 #	139	92 #	117	MALE	37 #	107	107
		FINAL	36.6 #	134	89 #	334 #	MALE	30 #	106	106
	E0011004	BASELINE	28.7	121	72	169 #	MALE	24 #	91	91
		FINAL	29.4	122	82	272 #	MALE	26 #	81	81
	E0011007	BASELINE	36.6 #	116	78	175 #	FEMALE	55	101	101
		FINAL	36.6 #	128	83	254 #	FEMALE	51	127 #	127
	E0011018	BASELINE	26.3	119	73	161 #	MALE	41	74	74

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0011018	FINAL	24.9	114	76	184 #	MALE	40	95	95
	E0011024	BASELINE	35.3 #	108	78	77	FEMALE	57	76	76
		FINAL	36.4 #	120	77	88	FEMALE	57	84	84
	E0015003	BASELINE	27.7	109	70	234 #	FEMALE	50	94	94
		FINAL	27.7	102	62	612 #	FEMALE	51	95	95
	E0019003	BASELINE	30.1 #	124	79	208 #	FEMALE	48 #	99	99
		FINAL	31.2 #	126	86 #	180 #	FEMALE	41 #	85	85
	E0019007	BASELINE	21.9	105	65	115	FEMALE	86	99	99
		FINAL	21.9	111	75	75	FEMALE	89	88	88
	E0019014	BASELINE	19.9	85	59	122	MALE	35 #	66	66
		FINAL	19.9	95	65	115	MALE	32 #	67	67
	E0019018	BASELINE	34.7 #	120	75	85	MALE	40	83	83
		FINAL	36.1 #	111	80	102	MALE	39 #	85	85
	E0019022	BASELINE	36.5 #	122	76	106	FEMALE	31 #	84	84
		FINAL	36.1 #	129	80	168 #	FEMALE	31 #	88	88
	E0019032	BASELINE	24.0	101	66	65	FEMALE	59	99	99
		FINAL	25.8	103	74	104	FEMALE	77	105	105
	E0019039	BASELINE	21.4	141	90 #	144	MALE	55	86	86
		FINAL		140	80 #	186 #	MALE	46	99	99
	E0019041	BASELINE	25.0	101	70	46	FEMALE	68	62	62
		FINAL	25.3	107	68	92	FEMALE	65	78	78
	E0019049	BASELINE	28.7	118	66	67	FEMALE	47 #	81	81
		FINAL	27.7	123	80	147	FEMALE	60	94	94
	E0022052	BASELINE	30.7 #	123	80	75	FEMALE	61	98	98
		FINAL	31.1 #	124	80	155 #	FEMALE	60	99	99

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	BASELINE	19.4	118	76	88	MALE	49	85	85
		FINAL	19.1	123	73	56	MALE	48	81	81
	E0022073	BASELINE	24.7	104	67	103	FEMALE	54	81	81
		FINAL	26.8	111	66	85	FEMALE	59	88	88
	E0023017	BASELINE	19.9	128	83	167 #	MALE	36 #	68	68
		FINAL	21.5	144	81 #	203 #	MALE	43	106	106
	E0023021	BASELINE	39.4 #	130	92 #	134	MALE	43	86	86
		FINAL	38.3 #	116	69	267 #	MALE	39 #	106	106
	E0023027	BASELINE	37.8 #	109	73 #	428 #	FEMALE	30 #	82	82
		FINAL	39.4 #	139	87 #	270 #	FEMALE	30 #	70	70
	E0023030	BASELINE	34.0 #	120	84	161 #	FEMALE	73	101	101
		FINAL	35.2 #	139	97 #	410 #	FEMALE	57	111 #	111
	E0023040	BASELINE	32.5 #	119	79	34	FEMALE	105	79	79
		FINAL	33.6 #	121	86 #	68	FEMALE	119	68	68
	E0026014	BASELINE	25.5	158	98 #	168 #	MALE	41	97	97
		FINAL	25.5	141	90 #	76	MALE	54	105	105
	E0026019	BASELINE	27.3	137	83 #	61 #	FEMALE	121	82	82
		FINAL	27.6	130	65	61 #	FEMALE	131	87	87
	E0027005	BASELINE	26.0	130	84 #	197 #	FEMALE	62 #	87	87
		FINAL	28.0	133	87 #	530 #	FEMALE	46 #	86	86
	E0029009	BASELINE	30.8 #	104	69	100	MALE	52	77	77
		FINAL	31.4 #	111	76	68	MALE	64	92	92
	E0029021	BASELINE	29.7	105	71	84	FEMALE	55	87	87
		FINAL	30.5 #	101	68	151 #	FEMALE	58	86	86
	E0029026	BASELINE	29.9	120	81	173 #	MALE	42	97	97

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 300 MG (BIPOLAR II)	E0029026	FINAL	29.9	114	75	99	MALE	34 #	86	86
	E0029030	BASELINE	24.6	105	72	86	MALE	39 #	80	80
		FINAL	26.6	126	74	94	MALE	55	94	94
	E0031008	BASELINE	28.4	132	80 #	144	FEMALE	49 #	86	86
		FINAL	28.4	132	81 #	114	FEMALE	51	91	91
	E0031020	BASELINE	27.5	115	71	230 #	MALE	44	105	105
		FINAL	27.5	119	73	187 #	MALE	39 #	95	95
	E0031021	BASELINE	26.3	115	67	77	MALE	45	84	84
		FINAL	26.3	121	77	79	MALE	48	108	108
	E0033002	BASELINE	30.5 #	135	81 #	242 #	MALE	35 #	91	91
		FINAL	30.8 #	119	79	170 #	MALE	39 #	97	97
	E0033006	BASELINE	24.8	105	75	71	MALE	56	85	85
		FINAL	24.8	120	82	156 #	MALE	42	81	81
	E0033021	BASELINE	23.3	90	66	93	FEMALE	63	81	81
		FINAL	25.6	104	72	103	FEMALE	75	100	100
	E0035013	BASELINE	34.4 #	112	70	84	FEMALE	51 #	79	79
		FINAL	63.3 #	112	72	119	FEMALE	46 #	92	92
	E0035015	BASELINE	50.3 #	122	73	198 #	FEMALE	43 #	103	103
		FINAL	50.3 #	118	76	258 #	FEMALE	43 #	124 #	124
	E0040003	BASELINE	23.9	123	81	101	FEMALE	67	80	80
		FINAL	25.3	121	81	176 #	FEMALE	56	82	82

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	BASELINE	35.1 #	107	72	104	FEMALE	35 #	86	86
		FINAL	35.1 #	106	70	140	FEMALE	35 #	94	94
	E0002011	BASELINE	24.7	123	79	124	FEMALE	46 #	79	79
		FINAL	26.7	121	73	221 #	FEMALE	45 #	89	89
	E0003010	BASELINE	22.6	118	71	113	FEMALE	84	89	89
		FINAL	24.8	134	85 #	127	FEMALE	83	81	81
	E0003016	BASELINE	26.2	110	81	97	FEMALE	55	82	82
		FINAL	26.6	115	84	126	FEMALE	41 #	79	79
	E0003019	BASELINE	26.0	114	85 #	53	MALE	41	91	91
		FINAL	27.8	132	87 #	153 #	MALE	44	104	104
	E0003020	BASELINE	35.3 #	118	66	56	MALE	45	64	64
		FINAL	35.6 #	115	80	98	MALE	60	82	82
	E0004001	BASELINE	17.2	99	61	90	FEMALE	42 #	84	84
		FINAL	16.8	97	61	70	FEMALE	47 #	107	107
	E0004009	BASELINE	26.6	104	64	133	FEMALE	46 #	86	86
		FINAL	27.1	100	69	193 #	FEMALE	64	96	96
	E0004012	BASELINE	20.3	109	67	96	FEMALE	46 #	83	83
		FINAL	21.5	99	65	93	FEMALE	53	87	87
	E0004015	BASELINE	33.1 #	120	85 #	121	MALE	40	94	94
		FINAL	34.5 #	126	90 #	156 #	MALE	38 #	94	94
	E0005003	BASELINE	29.5	128	80 #	444 #	MALE	33 #	94	94
		FINAL	30.4 #	128	82 #	474 #	MALE	30 #	106	106
	E0005007	BASELINE	30.1 #	98	64	105	FEMALE	34 #	76	76
		FINAL	30.9 #	117	73	120	FEMALE	35 #	107	107
	E0005008	BASELINE	42.9 #	138	75 #	308 #	MALE	64	100	100

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0005008	FINAL	45.0 #	132	83 #	475 #	MALE	52	172 #	172 #
	E0005010	BASELINE	46.6 #	120	75	135	FEMALE	27 #	86	86
		FINAL	45.7 #	122	74	212 #	FEMALE	28 #	85	85
	E0005012	BASELINE	26.5	122	79	158 #	MALE	38 #	79	79
		FINAL	28.1	123	77	106	MALE	41	88	88
	E0005014	BASELINE	24.0	103	68	102	MALE	59	85	85
		FINAL	26.6	117	78	192 #	MALE	52	80	80
	E0005022	BASELINE	27.8	115	75	64	MALE	43	82	82
		FINAL	27.5	115	75	56	MALE	32 #	70	70
	E0005025	BASELINE	28.8	113	64	200 #	FEMALE	43 #	84	84
		FINAL	31.2 #	100	61	180 #	FEMALE	40 #	87	87
	E0006019	BASELINE	24.8	123	72	172 #	MALE	42	90	90
		FINAL	25.7	112	76	92	MALE	44	85	85
	E0007005	BASELINE	28.7	112	69	381 #	FEMALE	37 #	82	82
		FINAL	29.4	92	61	528 #	FEMALE	33 #	89	89
	E0007015	BASELINE	25.4	130	73 #	91 #	FEMALE	59	99	99
		FINAL	27.0	124	75	85 #	FEMALE	66	97	97
	E0010002	BASELINE	27.1	106	69	123	MALE	33 #	82	82
		FINAL	27.4	110	74	232 #	MALE	38 #	118 #	118
	E0010009	BASELINE	27.0	134	79 #	160 #	FEMALE	70 #	88	88
		FINAL	27.7	126	71	157 #	FEMALE	80 #	88	88
	E0010010	BASELINE	22.1	105	65	37	FEMALE	49 #	88	88
		FINAL	22.9	112	72	54	FEMALE	55	84	84
	E0010014	BASELINE	29.1 #	123	68 #	40	FEMALE	70	81 #	81 #
		FINAL	27.4 #	114	76 #	35	FEMALE	66	76 #	76 #

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0010017	BASELINE	28.4	119	64	119	MALE	43	82	82
		FINAL	28.1	118	71	96	MALE	53	64	64
	E0010023	BASELINE	26.8	109	65	49	FEMALE	72	80	80
		FINAL	28.7	99	66	80	FEMALE	68	106	106
	E0010027	BASELINE	25.4	114	80	103	MALE	56	109	109
		FINAL	25.4	115	77	83	MALE	46	95	95
	E0011022	BASELINE	33.6 #	130	83 #	215 #	FEMALE	41 #	69	69
		FINAL	25.8	122	83 #	399 #	FEMALE	43 #	88	88
	E0013006	BASELINE	37.6 #	124	76	147	FEMALE	30 #	75	75
		FINAL	38.2 #	118	74	179 #	FEMALE	30 #	105	105
	E0013012	BASELINE	37.1 #	121	81	78 #	FEMALE	58	95	95
		FINAL	39.1 #	130	83 #	135 #	FEMALE	53	89	89
	E0013014	BASELINE	21.5	123	82	76	MALE	49	88	88
		FINAL	22.4	120	80	135	MALE	43	83	83
	E0014005	BASELINE	27.0	132	91 #	434 #	FEMALE	36 #	80	80
		FINAL	28.1	128	94 #	208 #	FEMALE	39 #	95	95
	E0014007	BASELINE	25.0	124	88 #	131	FEMALE	38 #	76	76
		FINAL	25.0	119	82	82	FEMALE	42 #	76	76
	E0014011	BASELINE	26.6	127	70	275 #	MALE	38 #	57	57
		FINAL	26.9	123	78	249 #	MALE	37 #	77	77
	E0014012	BASELINE	26.4	116	89 #	140	FEMALE	60	84	84
		FINAL	26.4	119	79	190 #	FEMALE	57	97	97
	E0015001	BASELINE	30.3 #	107	62	175 #	MALE	40	112 #	112
		FINAL	30.6 #	111	73	249 #	MALE	43	175 #	175 #
	E0016005	BASELINE	26.6	118	75	99	FEMALE	47 #	85	85

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND100.SAS
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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0016005	FINAL	26.9	123	77	142	FEMALE	44 #	94	94
	E0018007	BASELINE	31.2 #	131	81 #	387 #	FEMALE	40 #	80	80
		FINAL	30.5 #	124	81	270 #	FEMALE	30 #	111 #	111
	E0019005	BASELINE	24.8	135	78 #	79	FEMALE	92	78	78
		FINAL	24.8	125	73	59	FEMALE	97	76	76
	E0019015	BASELINE	27.1	110	87 #	90	FEMALE	44 #	85	85
		FINAL	26.7	123	95 #	191 #	FEMALE	38 #	86	86
	E0020004	BASELINE	31.5 #	150	80 #	120	MALE	41 #	91 #	91 #
		FINAL	31.5 #	145	81 #	212 #	MALE	42 #	155 #	155 #
	E0020010	BASELINE	25.0	103	75	126	FEMALE	69	73	73
		FINAL	25.8	132	78 #	159 #	FEMALE	67	74	74
	E0020014	BASELINE	19.8	115	74	71	FEMALE	42 #	74	74
		FINAL	19.8	129	74	44	FEMALE	50	63	63
	E0020021	BASELINE	47.8 #	132	81 #	112	MALE	57	88	88
		FINAL	50.8 #	170	102 #	131	MALE	62	94	94
	E0020023	BASELINE	33.1 #	114	80 #	113	MALE	50 #	84	84
		FINAL	33.1 #	108	87 #	87	MALE	54 #	78	78
	E0022010	BASELINE	23.6	130	69	159 #	MALE	55	96	96
		FINAL	23.9	134	71 #	98	MALE	76	86	86
	E0022012	BASELINE	34.5 #	124	61	109	FEMALE	43 #	85	85
		FINAL	35.7 #	117	68	48	FEMALE	43 #	85	85
	E0022019	BASELINE	31.1 #	121	70	137	MALE	34 #	87	87
		FINAL	31.7 #	129	86 #	102	MALE	40	82	82
	E0022025	BASELINE	28.1	128	67 #	173 #	FEMALE	35 #	88	88
		FINAL	28.1	132	72 #	186 #	FEMALE	36 #	82	82

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0022033	BASELINE	28.2	108	71	63	FEMALE	92	90	90
		FINAL	29.3	120	70	83	FEMALE	68	86	86
	E0022034	BASELINE	32.8 #	132	81 #	203 #	MALE	39 #	94	94
		FINAL	32.8 #	126	78	215 #	MALE	35 #	93	93
	E0022038	BASELINE	28.6	123	79	50	MALE	51	78	78
		FINAL	29.1	132	66 #	46	MALE	60	96	96
	E0022039	BASELINE	47.5 #	100	71	99	FEMALE	34 #	80	80
		FINAL	47.8 #	110	77	136	FEMALE	35 #	100	100
	E0022046	BASELINE	30.0 #	130	69 #	575 #	FEMALE	36 #	130 #	130
		FINAL	31.2 #	129	72	526 #	FEMALE	42 #	107	107
	E0022051	BASELINE	29.7	117	66	82	FEMALE	55	105	105
		FINAL	32.0 #	120	73	147	FEMALE	56	94	94
	E0022058	BASELINE	25.6	116	78	99	MALE	43	90	90
		FINAL	26.2	115	73	137	MALE	48	122 #	122
	E0022061	BASELINE	26.2	119	71	81	FEMALE	72	52	52
		FINAL	27.6	116	62	92	FEMALE	54	73	73
	E0022062	BASELINE	34.0 #	154	87 #	132	MALE	39 #	91	91
		FINAL	33.6 #	162	106 #	125	MALE	42	100	100
	E0022069	BASELINE	22.2	102	69	81	FEMALE	48 #	78	78
		FINAL	21.6	112	69	76	FEMALE	47 #	83	83
	E0022071	BASELINE	23.5	135	83 #	211 #	MALE	73 #	93	93
		FINAL	23.8	135	88 #	181 #	MALE	61 #	99	99
	E0023003	BASELINE	25.4	126	83	79	MALE	54	85	85
		FINAL	25.4	118	78	102	MALE	43	85	85
	E0023006	BASELINE	22.5	115	72	264 #	MALE	35 #	60	60

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0023006	FINAL	22.9	120	58	115	MALE	38 #	87	87
	E0023010	BASELINE	29.8	123	76	345 #	MALE	55	84	84
		FINAL	33.3 #	130	80 #	524 #	MALE	45	91	91
	E0023025	BASELINE	21.8	121	63	66	MALE	42	87	87
		FINAL	21.8	107	75	80	MALE	47	102	102
	E0023039	BASELINE	29.7	121	80	104	FEMALE	65	79	79
		FINAL	30.5 #	103	74	113	FEMALE	42 #	71	71
	E0026002	BASELINE	27.4	111	72	78	MALE	61	91	91
		FINAL	28.1	131	81 #	54	MALE	49	94	94
	E0026007	BASELINE	36.5 #	136	73 #	215 #	FEMALE	32 #	102	102
		FINAL	37.9 #	126	67 #	145	FEMALE	37 #	129 #	129
	E0026013	BASELINE	28.0	140	72 #	100	FEMALE	45 #	71	71
		FINAL	26.3	117	69	186 #	FEMALE	42 #	96	96
	E0028007	BASELINE	17.1	105	70	37	FEMALE	61	106	106
		FINAL	17.9	116	68	54	FEMALE	36 #	66	66
	E0028023	BASELINE	24.9	132	85 #	203 #	MALE	50	105	105
		FINAL	25.3	100	60 #	249 #	MALE	39 #	99	99
	E0028025	BASELINE	23.7	110	77	95	MALE	40	87	87
		FINAL	23.7	117	78	118	MALE	40	86	86
	E0028033	BASELINE	28.7 #	107	67	265 #	FEMALE	43 #	80	80
		FINAL	28.7 #	110	70	303 #	FEMALE	34 #	83	83
	E0028035	BASELINE	32.7 #	127	82	128	MALE	35 #	89	89
		FINAL	35.2 #	139	82 #	211 #	MALE	40	104	104
	E0028037	BASELINE	29.3 #	135	75 #	215 #	MALE	48	113 #	113 #
		FINAL	26.2 #	119	83	68 #	MALE	69	86 #	86 #

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0028039	BASELINE	22.4	115	76	149	MALE	32 #	92	92
		FINAL	22.1	110	73	142	MALE	25 #	74	74
	E0029012	BASELINE	34.3 #	121	76	159 #	FEMALE	43 #	71	71
		FINAL	35.6 #	119	66	154 #	FEMALE	41 #	95	95
	E0029015	BASELINE	22.7	128	74	57	FEMALE	61	95	95
		FINAL	23.0	111	69	71	FEMALE	62	95	95
	E0030014	BASELINE	21.3	95	64	73	FEMALE	70	79	79
		FINAL	22.7	101	72	70	FEMALE	68	86	86
	E0030024	BASELINE	24.4	116	74	299 #	FEMALE	59	68	68
		FINAL	24.8	114	84	222 #	FEMALE	41 #	67	67
	E0030025	BASELINE	29.1	124	72	94	FEMALE	68	84	84
		FINAL	28.7	115	83	78	FEMALE	58	101	101
	E0031027	BASELINE	21.4	112	65 #	86	MALE	52	80	80
		FINAL	21.4	107	68 #	53	MALE	59	85	85
	E0031030	BASELINE	26.0	110	78	66	FEMALE	64 #	85	85
		FINAL	24.5	113	72	97	FEMALE	55 #	74	74
	E0034001	BASELINE	26.8	105	64	86	FEMALE	56	86	86
		FINAL	27.2	117	75	122	FEMALE	56	91	91
	E0034004	BASELINE	29.0	132	91 #	240 #	MALE	35 #	83	83
		FINAL	29.3	123	80	282 #	MALE	32 #	82	82
	E0035001	BASELINE	46.8 #	129	78 #	152 #	FEMALE	57	86	86
		FINAL	46.8 #	129	82 #	108	FEMALE	74	82	82
	E0035006	BASELINE	23.4	109	71	64	FEMALE	72	75	75
		FINAL	23.0	112	70	137	FEMALE	66	78	78
	E0035021	BASELINE	32.0 #	99	65	77	FEMALE	41 #	85	85

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR I)	E0035021	FINAL	29.3	105	78	82	FEMALE	39 #	89	89
	E0036002	BASELINE	25.8	101	65	130	FEMALE	39 #	93	93
		FINAL	26.1	115	72	106	FEMALE	44 #	101	101
	E0036006	BASELINE	33.7 #	126	80	304 #	MALE	36 #	82	82
		FINAL	35.4 #	134	85 #	316 #	MALE	35 #	83	83
	E0036007	BASELINE	24.1	125	86 #	116	FEMALE	42 #	69	69
		FINAL	24.5	127	84	188 #	FEMALE	47 #	112 #	112
	E0037009	BASELINE	29.0	121	81	207 #	FEMALE	59	88	88
		FINAL	30.1 #	130	86 #	461 #	FEMALE	41 #	120 #	120
	E0039026	BASELINE	25.8	111	77	109	FEMALE	56	91	91
		FINAL	30.1 #	109	81	149	FEMALE	67	98	98
	E0039028	BASELINE	46.2 #	137	94 #	125	MALE	39 #	84	84
		FINAL	46.2 #	139	102 #	125	MALE	48	85	85
	E0039032	BASELINE	49.6 #	126	70	92	FEMALE	39 #	81	81
		FINAL	50.4 #	123	85 #	59	FEMALE	44 #	90	90
	E0039034	BASELINE	35.4 #	119	79	70	FEMALE	45 #	85	85
		FINAL	35.4 #	124	81	78	FEMALE	51	69	69
	E0039042	BASELINE	29.0	128	82	66	FEMALE	96	79	79
		FINAL		118	69	211 #	FEMALE	40 #	94	94
	E0041004	BASELINE	30.2 #	114	84	116	MALE	43	73	73
		FINAL	31.1 #	105	68	129	MALE	36 #	69	69
	E0041009	BASELINE	13.5	111	64	77	FEMALE	55	90	90
		FINAL	31.2 #	117	81	87	FEMALE	60	106	106
	E0042002	BASELINE	34.4 #	120	85 #	174 #	MALE	31 #	68	68
		FINAL	36.1 #	105	70 #	343 #	MALE	30 #	81	81

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	BASELINE	29.3	125	75	103	MALE	43	81	81
		FINAL	29.3	104	78	118	MALE	34 #	83	83
	E0003002	BASELINE	20.7	125	90 #	123	MALE	58	84	84
		FINAL	22.5	116	77	99	MALE	61	85	85
	E0005033	BASELINE	23.5	108	67	51	FEMALE	50	70	70
		FINAL	23.9	106	67	41	FEMALE	45 #	75	75
	E0005038	BASELINE	38.8 #	121	78	80	FEMALE	36 #	81	81
		FINAL	40.6 #	113	75	144	FEMALE	32 #	82	82
	E0009011	BASELINE	24.9	120	68	315 #	MALE	41	85	85
		FINAL	24.6	97	63	305 #	MALE	29 #	91	91
	E0011016	BASELINE	29.6	135	88 #	275 #	MALE	36 #	83	83
		FINAL	29.6	134	88 #	412 #	MALE	32 #	89	89
	E0011020	BASELINE	21.4	128	83	70	MALE	42	76	76
		FINAL	21.7	128	84	108	MALE	42	71	71
	E0018002	BASELINE	31.0 #	127	86 #	139	MALE	45	83	83
		FINAL	31.3 #	138	83 #	166 #	MALE	38 #	80	80
	E0018003	BASELINE	47.8 #	115	75	515 #	FEMALE	21 #	96	96
		FINAL	47.4 #	126	77	247 #	FEMALE	21 #	89	89
	E0018013	BASELINE	34.7 #	123	73	182 #	MALE	30 #	76	76
		FINAL	34.7 #	130	70 #	190 #	MALE	27 #	76	76
	E0019016	BASELINE	43.3 #	122	82	198 #	FEMALE	37 #	85	85
		FINAL	45.9 #	119	81	235 #	FEMALE	36 #	85	85
	E0019020	BASELINE	22.2	109	71	112	FEMALE	51	72	72
		FINAL	50.6 #	110	64	98	FEMALE	52	90	90
	E0019021	BASELINE	27.1	128	83	385 #	MALE	39 #	89	89

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0019021	FINAL	27.4	128	86 #	388 #	MALE	34 #	86	86
	E0019024	BASELINE	34.1 #	120	81	142	MALE	42	84	84
		FINAL	35.2 #	130	75 #	158 #	MALE	43	74	74
	E0019031	BASELINE		109	80	650 #	MALE	35 #	94	94
		FINAL	24.3	120	68	1000 #	MALE	32 #	98	98
	E0019035	BASELINE	43.3 #	130	83 #	426 #	FEMALE	29 #	129 #	129
		FINAL		133	88 #	418 #	FEMALE	30 #	177 #	177 #
	E0019040	BASELINE	38.0 #	130	86 #	220 #	MALE	34 #	90	90
		FINAL	40.7 #	127	84	150 #	MALE	34 #	100	100
	E0019042	BASELINE	25.1	121	73	118	FEMALE	47 #	91	91
		FINAL		120	62	94	FEMALE	48 #	89	89
	E0019045	BASELINE	23.5	107	65	78	FEMALE	74	108	108
		FINAL	24.7	113	75	61	FEMALE	68	81	81
	E0020024	BASELINE	23.6	114	67	100	MALE	46	84	84
		FINAL	25.5	112	73	241 #	MALE	41	94	94
	E0022044	BASELINE	20.4	109	76	106	FEMALE	49 #	78	78
		FINAL	24.1	128	86 #	107	FEMALE	80	74	74
	E0023007	BASELINE	24.9	113	78	34	FEMALE	64	83	83
		FINAL	24.9	117	82	45	FEMALE	65	98	98
	E0023011	BASELINE	28.2	114	70	557 #	FEMALE	36 #	104	104
		FINAL	30.5 #	128	85 #	573 #	FEMALE	40 #	101	101
	E0023014	BASELINE	30.4 #	128	85	96	MALE	55	85	85
		FINAL	31.0 #	120	78	213 #	MALE	63	89	89
	E0023019	BASELINE	23.0	136	82 #	122	MALE	71	91	91
		FINAL	24.9	125	85	119	MALE	45	80	80

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0023022	BASELINE	22.5	115	69	95	MALE	63	76	76
		FINAL	23.1	117	74	96	MALE	72	77	77
	E0023023	BASELINE	21.1	99	73	79	FEMALE	66	96	96
		FINAL	21.1	110	68	63	FEMALE	56	121 #	121
	E0023031	BASELINE	40.3 #	142	91 #	150 #	FEMALE	39 #	86	86
		FINAL	39.1 #	134	93 #	267 #	FEMALE	44 #	113 #	113
	E0023041	BASELINE	30.9 #	114	76	97	FEMALE	71	78	78
		FINAL	32.8 #	117	75	130	FEMALE	59	77	77
	E0023043	BASELINE	18.7	121	74	133	MALE	51	95	95
		FINAL		107	67	139	MALE	47	78	78
	E0026003	BASELINE	26.4	130	82 #	164 #	MALE	46	104	104
		FINAL	23.8	118	87 #	284 #	MALE	24 #	139 #	139
	E0026005	BASELINE	22.3	159	90 #	87	FEMALE	106	97	97
		FINAL	22.0	144	98 #	94	FEMALE	95	95	95
	E0026009	BASELINE	24.2	122	77	103	FEMALE	38 #	87	87
		FINAL	24.2	97	57	115	FEMALE	44 #	79	79
	E0026015	BASELINE	21.5	117	79	126	FEMALE	57	81	81
		FINAL	21.5	130	80	96	FEMALE	65	138 #	138
	E0026023	BASELINE	28.0	112	58	72	MALE	37 #	80	80
		FINAL	27.8	107	57	57	MALE	36 #	110 #	110
	E0027016	BASELINE	38.7 #	120	80	113	FEMALE	34 #	87	87
		FINAL	39.1 #	113	73	113	FEMALE	31 #	80	80
	E0027018	BASELINE	29.7	121	81	54	FEMALE	58	73	73
		FINAL	32.0 #	129	87 #	40	FEMALE	70	82	82
	E0028032	BASELINE	24.1	111	79	191 #	MALE	44	86	86

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0028032	FINAL	23.8	127	82	499 #	MALE	32 #	89	89
	E0029003	BASELINE	36.7 #	96	60	97	MALE	45	75	75
		FINAL	37.0 #	106	70	156 #	MALE	36 #	88	88
	E0031005	BASELINE	29.0	115	75	154 #	FEMALE	55 #	104	104
		FINAL	30.0 #	135	86 #	137	FEMALE	53 #	97	97
	E0031006	BASELINE	29.5 #	160	78 #	112	MALE	72	122 #	122 #
		FINAL	32.2 #	155	85 #	86	MALE	54	100 #	100 #
	E0031010	BASELINE	26.9	136	79 #	74	FEMALE	41 #	82	82
		FINAL	27.3	128	75	77	FEMALE	42 #	82	82
	E0031011	BASELINE	26.4	137	75 #	150 #	MALE	47	105	105
		FINAL	27.1	125	79	165 #	MALE	47	90	90
	E0031015	BASELINE	27.9	117	72	97	FEMALE	52	89	89
		FINAL	27.5	130	76 #	124	FEMALE	68	89	89
	E0031031	BASELINE	30.8 #	111	73	161 #	FEMALE	39 #	82	82
		FINAL	31.5 #	118	78	88	FEMALE	38 #	74	74
	E0034009	BASELINE	26.0	130	85 #	129	MALE	43	77	77
		FINAL	27.7	133	75 #	253 #	MALE	42	82	82
	E0037012	BASELINE	20.3	103	74	57	MALE	38 #	84	84
		FINAL	21.5	115	71	240 #	MALE	34 #	92	92
	E0039019	BASELINE	44.4 #	129	94 #	97	FEMALE	62	82 #	82 #
		FINAL	42.7 #	114	84 #	89	FEMALE	59	80 #	80 #

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0002001	BASELINE	27.0	107	68	72	FEMALE	53	76	76
		FINAL	30.1 #	117	64	51	FEMALE	54	142 #	142 #
	E0002003	BASELINE	25.0	110	79	305 #	FEMALE	51	76	76
		FINAL	25.0	114	68	380 #	FEMALE	43 #	81	81
	E0002008	BASELINE	28.4	125	72	1240 #	MALE	30 #	96	96
		FINAL	27.8	112	77	190 #	MALE	38 #	89	89
	E0002016	BASELINE	29.4	133	77 #	233 #	FEMALE	59 #	98	98
		FINAL	29.4	130	77 #	468 #	FEMALE	50 #	87	87
	E0004006	BASELINE	33.4 #	107	78	110	FEMALE	40 #	113 #	113
		FINAL	34.2 #	109	74	96	FEMALE	41 #	147 #	147 #
	E0004016	BASELINE	21.5	105	61	47	FEMALE	58	64	64
		FINAL	21.1	97	66	75	FEMALE	66	58	58
	E0004024	BASELINE	35.4 #	136	90 #	121	FEMALE	61	74	74
		FINAL	35.4 #	135	90 #	106	FEMALE	65	97	97
	E0005017	BASELINE	26.9	130	95 #	98	FEMALE	64	83	83
		FINAL	27.6	120	78 #	143	FEMALE	56	61	61
	E0005019	BASELINE	26.6	110	72	105	FEMALE	44 #	69	69
		FINAL		118	78	122	FEMALE	34 #	80	80
	E0005026	BASELINE	18.4	95	60	60	FEMALE	69	75	75
		FINAL	17.7	87	59	40	FEMALE	55	77	77
	E0005039	BASELINE	49.1 #	130	80 #	187 #	FEMALE	36 #	91	91
		FINAL	50.5 #	132	81 #	180 #	FEMALE	34 #	78	78
	E0005043	BASELINE	37.0 #	115	71	107	MALE	48	92	92
		FINAL	37.8 #	121	72	74	MALE	52	87	87
	E0006020	BASELINE	25.7	117	81	118	MALE	47	88	88

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0006020	FINAL	25.7	132	87 #	114	MALE	39 #	87	87
	E0007001	BASELINE	27.5	120	74	206 #	MALE	43	95	95
		FINAL	26.2	107	71	276 #	MALE	42	100	100
	E0007003	BASELINE	21.0	137	84 #	120 #	MALE	56	89	89
		FINAL	21.0	130	73 #	114 #	MALE	48	99	99
	E0007006	BASELINE	33.7 #	115	75	75	MALE	37 #	78	78
		FINAL	33.7 #	122	72	143	MALE	39 #	86	86
	E0009004	BASELINE	27.8	141	89 #	243 #	MALE	52	103	103
		FINAL	28.4	140	96 #	719 #	MALE	64	86	86
	E0009012	BASELINE	26.8	116	77	226 #	MALE	37 #	81	81
		FINAL	26.2	100	70	113	MALE	47	86	86
	E0010018	BASELINE	20.4	113	77	81	FEMALE	50	96	96
		FINAL	20.4	106	75	92	FEMALE	47 #	99	99
	E0010028	BASELINE	24.8	122	67	55	FEMALE	56	77	77
		FINAL	25.2	110	60	83	FEMALE	59	80	80
	E0011008	BASELINE	19.5	115	67	67	MALE	42	72	72
		FINAL	19.2	116	70	93	MALE	30 #	81	81
	E0011009	BASELINE	29.3	139	89 #	264 #	MALE	45	82	82
		FINAL	28.4	135	84 #	338 #	MALE	45	96	96
	E0011010	BASELINE	29.4	111	73	85	FEMALE	65	83	83
		FINAL	30.8 #	106	73	122	FEMALE	55	80	80
	E0013001	BASELINE	32.0 #	119	84	266 #	MALE	37 #	90	90
		FINAL	32.5 #	121	82	222 #	MALE	28 #	83	83
	E0013003	BASELINE	47.8 #	142	90 #	143	FEMALE	45 #	97	97
		FINAL	50.7 #	138	90 #	129	FEMALE	53	82	82

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0013005	BASELINE	22.2	120	77	95	MALE	45	78	78
		FINAL	22.2	126	80	240 #	MALE	31 #	79	79
	E0013013	BASELINE	22.9	113	69	61	FEMALE	50	85	85
		FINAL	22.5	116	79	68	FEMALE	55	75	75
	E0014002	BASELINE	25.2	128	76	134	FEMALE	53	92	92
		FINAL	26.3	111	79	80	FEMALE	58	87	87
	E0014004	BASELINE	25.1	112	78	167 #	FEMALE	44 #	70	70
		FINAL	24.7	100	79	265 #	FEMALE	36 #	78	78
	E0014009	BASELINE	39.5 #	135	81 #	185 #	FEMALE	47 #	77	77
		FINAL	39.5 #	140	100 #	112	FEMALE	40 #	82	82
	E0014017	BASELINE	27.2	117	70	114	FEMALE	47 #	79	79
		FINAL	27.9	122	78	91	FEMALE	53	81	81
	E0014018	BASELINE	23.0	118	76	47	MALE	44	69	69
		FINAL	22.7	120	79	61	MALE	38 #	94	94
	E0015005	BASELINE	20.5	129	81	83	MALE	58	90	90
		FINAL	20.5	130	80 #	85	MALE	62	100	100
	E0017002	BASELINE	32.9 #	112	70	327 #	FEMALE	49 #	96	96
		FINAL	30.4 #	105	80	86	FEMALE	49 #	80	80
	E0018009	BASELINE	26.2	123	74	187 #	MALE	34 #	82	82
		FINAL	26.2	114	75	101	MALE	41	84	84
	E0018010	BASELINE	27.8	113	69	142	MALE	41	81	81
		FINAL	27.5	122	70	113	MALE	46	84	84
	E0018015	BASELINE	25.2	106	68	188 #	MALE	40	88	88
		FINAL	25.9	107	67	92	MALE	43	96	96
	E0020015	BASELINE	26.1	121	72	174 #	MALE	36 #	92	92

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0020015	FINAL	26.4	106	77	172 #	MALE	28 #	87	87
	E0020017	BASELINE	21.3	102	64	65	FEMALE	73	81	81
		FINAL	21.3	119	74	53	FEMALE	75	75	75
	E0020020	BASELINE	18.8	102	62	62	FEMALE	69	81	81
		FINAL	18.8	102	61	68	FEMALE	73	70	70
	E0020022	BASELINE	36.4 #	119	80	190 #	FEMALE	55	102	102
		FINAL	36.4 #	111	75	152 #	FEMALE	51	103	103
	E0022001	BASELINE	24.2	134	97 #	76	MALE	67	78	78
		FINAL	24.5	141	81 #	142	MALE	67	85	85
	E0022004	BASELINE	32.1 #	115	80	183 #	FEMALE	41 #	91	91
		FINAL	31.4 #	105	60	125	FEMALE	46 #	89	89
	E0022005	BASELINE	39.4 #	126	81	190 #	FEMALE	35 #	83	83
		FINAL	39.4 #	108	68	172 #	FEMALE	42 #	97	97
	E0022015	BASELINE	26.1	116	60	204 #	FEMALE	52	88	88
		FINAL	26.1	112	62	74	FEMALE	51	83	83
	E0022016	BASELINE	41.3 #	124	66	78	FEMALE	58	85	85
		FINAL	41.8 #	123	70	31	FEMALE	45 #	71	71
	E0022020	BASELINE	17.6	106	58	75	FEMALE	34 #	77	77
		FINAL	18.4	100	48	65	FEMALE	33 #	73	73
	E0022023	BASELINE	28.3	120	71	285 #	MALE	36 #	81	81
		FINAL	29.4	107	70	527 #	MALE	34 #	77	77
	E0022029	BASELINE	45.6 #	131	69 #	387 #	MALE	32 #	95	95
		FINAL	46.5 #	129	75	199 #	MALE	30 #	87	87
	E0022041	BASELINE	35.1 #	114	69	180 #	FEMALE	47 #	85	85
		FINAL	35.1 #	117	70	242 #	FEMALE	63	92	92

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0022042	BASELINE	28.1	133	88 #	263 #	MALE	44	95	95
		FINAL	28.6	133	83 #	362 #	MALE	47	100	100
	E0022043	BASELINE	28.3	111	80	122	FEMALE	45 #	95	95
		FINAL	28.7	115	71	129	FEMALE	48 #	88	88
	E0022059	BASELINE	28.3	119	68	61	FEMALE	61	79	79
		FINAL	28.3	103	61	76	FEMALE	60	69	69
	E0022065	BASELINE	35.4 #	97	65	137	FEMALE	50	77	77
		FINAL	35.8 #	104	60	110	FEMALE	47 #	88	88
	E0022070	BASELINE	30.3 #	118	66 #	255 #	MALE	36 #	103	103
		FINAL	29.4	130	84 #	474 #	MALE	34 #	103	103
	E0023001	BASELINE	36.8 #	124	76	98	FEMALE	53	71	71
		FINAL	36.8 #	125	84	160 #	FEMALE	51	84	84
	E0023009	BASELINE	24.0	126	76	103	FEMALE	40 #	89	89
		FINAL	24.8	114	70	133	FEMALE	47 #	105	105
	E0023028	BASELINE	25.6	126	86 #	93	FEMALE	78	93	93
		FINAL	24.0	128	82	66	FEMALE	92	80	80
	E0023033	BASELINE	30.4 #	140	94 #	348 #	MALE	33 #	91	91
		FINAL	30.4 #	160	98 #	292 #	MALE	30 #	99	99
	E0023047	BASELINE	30.4 #	124	68	80	MALE	78	71	71
		FINAL	28.2	134	83 #	113	MALE	39 #	94	94
	E0025001	BASELINE	54.7 #	133	80 #	320 #	FEMALE	23 #	192 #	192 #
		FINAL	52.9 #	120	70	136	FEMALE	27 #	93 #	93 #
	E0026012	BASELINE	26.7	134	86 #	108	MALE	51	74	74
		FINAL	26.7	122	76	150 #	MALE	54	84	84
	E0026020	BASELINE	26.1	139	80 #	80	MALE	42	102	102

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0026020	FINAL	26.4	149	73 #	86	MALE	51	93	93
	E0026028	BASELINE	37.4 #	163	71 #	155 #	MALE	46 #	105	105
		FINAL	36.4 #	149	87 #	161 #	MALE	47 #	100	100
	E0028001	BASELINE	36.8 #	119	84 #	510 #	MALE	30 #	116 #	116 #
		FINAL	36.8 #	129	95 #	461 #	MALE	24 #	172 #	172 #
	E0028003	BASELINE	38.6 #	117	84	100 #	FEMALE	61	91 #	91 #
		FINAL	38.2 #	131	87 #	120 #	FEMALE	66	83 #	83 #
	E0028005	BASELINE	20.6	90	65	62	FEMALE	64	73	73
		FINAL	20.6	98	66	79	FEMALE	60	81	81
	E0028010	BASELINE	18.7	111	69	102	FEMALE	59	75	75
		FINAL	18.0	108	64	133	FEMALE	59	72	72
	E0028011	BASELINE	21.0	133	80 #	176 #	MALE	32 #	78	78
		FINAL	20.7	125	81	299 #	MALE	29 #	80	80
	E0028030	BASELINE	24.8	120	84	124	MALE	40	89	89
		FINAL	24.2	115	71	99	MALE	44	86	86
	E0028031	BASELINE	39.4 #	124	79	188 #	MALE	36 #	92	92
		FINAL	40.4 #	130	79 #	155 #	MALE	46	90	90
	E0028047	BASELINE	36.0 #	150	110 #	153 #	FEMALE	42 #	95 #	95 #
		FINAL	36.0 #	156	109 #	162 #	FEMALE	38 #	91 #	91 #
	E0029014	BASELINE	28.2	96	60	118	FEMALE	85	102	102
		FINAL	28.2	117	69	184 #	FEMALE	83	88	88
	E0029023	BASELINE	32.0 #	112	72	291 #	FEMALE	52	91	91
		FINAL	34.9 #	113	76	167 #	FEMALE	51	90	90
	E0029032	BASELINE	31.5 #	106	79	109	MALE	36 #	97	97
		FINAL	31.5 #	110	80	113	MALE	32 #	134 #	134

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0029039	BASELINE	19.1	100	67	68	FEMALE	40 #	80	80
		FINAL	19.1	99	65	60	FEMALE	47 #	81	81
	E0030003	BASELINE	30.9 #	126	81	148	FEMALE	45 #	83	83
		FINAL	30.9 #	125	70	125	FEMALE	61	123 #	123
	E0030009	BASELINE	21.8	140	88 #	345 #	MALE	53	88	88
		FINAL	21.1	137	80 #	283 #	MALE	50	88	88
	E0030016	BASELINE	28.7	123	70	90	MALE	38 #	89	89
		FINAL	28.4	124	78	333 #	MALE	36 #	68	68
	E0031017	BASELINE	30.1 #	118	70 #	133	MALE	43 #	86	86
		FINAL	30.9 #	123	71 #	131	MALE	44 #	83	83
	E0031023	BASELINE	51.4 #	138	83 #	416 #	FEMALE	24 #	80	80
		FINAL	51.7 #	138	81 #	280 #	FEMALE	27 #	96	96
	E0033001	BASELINE	26.9	120	76	48	MALE	61	84	84
		FINAL	27.4	115	79	58	MALE	54	79	79
	E0033004	BASELINE	26.6	105	73	93	FEMALE	46 #	76	76
		FINAL	27.3	101	70	67	FEMALE	51	78	78
	E0033010	BASELINE	24.7	110	69	105	FEMALE	50	72	72
		FINAL	23.4	101	64	62	FEMALE	44 #	88	88
	E0035007	BASELINE	28.0	115	74	151 #	FEMALE	43 #	81	81
		FINAL	28.0	112	71	206 #	FEMALE	53	95	95
	E0035011	BASELINE	51.7 #	123	81	283 #	FEMALE	35 #	100 #	100 #
		FINAL	51.7 #	126	76	288 #	FEMALE	34 #	90 #	90 #
	E0037003	BASELINE	24.8	117	77	132	FEMALE	69	79	79
		FINAL	25.9	127	84	169 #	FEMALE	62	79	79
	E0037004	BASELINE	41.4 #	129	87 #	61	FEMALE	49 #	81	81

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR I)	E0037004	FINAL	41.4 #	120	85 #	60	FEMALE	53	83	83
	E0039007	BASELINE	21.2	122	82	94	MALE	46	93	93
		FINAL	21.2	112	81	69	MALE	47	87	87
	E0039022	BASELINE	24.2	129	74	43	FEMALE	59	85	85
		FINAL	23.9	104	67	35	FEMALE	56	76	76
	E0039030	BASELINE	52.8 #	134	80 #	91	FEMALE	46 #	95	95
		FINAL	55.0 #	145	80 #	74	FEMALE	63	101	101
	E0039031	BASELINE	23.5	99	70	103	FEMALE	44 #	78	78
		FINAL	23.2	108	68	97	FEMALE	47 #	81	81
	E0039037	BASELINE	21.3	125	76	100	FEMALE	56	79	79
		FINAL	20.9	127	79	164 #	FEMALE	52	87	87
	E0039038	BASELINE	37.7 #	121	86 #	89	FEMALE	81	163 #	163 #
		FINAL	37.3 #	123	88 #	159 #	FEMALE	88	410 #	410 #
	E0039059	BASELINE	35.0 #	118	69	242 #	FEMALE	35 #	101	101
		FINAL	34.6 #	112	65	205 #	FEMALE	37 #	94	94
	E0041007	BASELINE	20.7	120	64	60	MALE	49	80	80
		FINAL	19.0	116	76	84	MALE	60	70	70
	E0041010	BASELINE	28.1	119	79	502 #	MALE	34 #	82	82
		FINAL	28.1	131	87 #	350 #	MALE	39 #	104	104
	E0041011	BASELINE	43.3 #	129	78	215 #	FEMALE	39 #	97	97
		FINAL	43.7 #	123	81	210 #	FEMALE	39 #	119 #	119
	E0041012	BASELINE	41.5 #	138	91 #	262 #	FEMALE	42 #	77	77
		FINAL	43.2 #	156	102 #	405 #	FEMALE	41 #	77	77

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR II)	E0001004	BASELINE	26.8	93	65	89	FEMALE	34 #	80	80
		FINAL	26.4	104	75	111	FEMALE	35 #	81	81
	E0005023	BASELINE	24.4	103	69	54	FEMALE	62	89	89
		FINAL	23.4	95	60	43	FEMALE	70	96	96
	E0005034	BASELINE	33.8 #	98	60	179 #	FEMALE	40 #	80	80
		FINAL	33.8 #	110	70	110	FEMALE	35 #	76	76
	E0005041	BASELINE	30.4 #	116	76	198 #	FEMALE	39 #	94	94
		FINAL	31.2 #	116	74	153 #	FEMALE	37 #	93	93
	E0007004	BASELINE	38.6 #	117	70	1030 #	FEMALE	41 #	84	84
		FINAL	39.0 #	111	67	1930 #	FEMALE	39 #	83	83
	E0007010	BASELINE	35.7 #	120	74	180 #	FEMALE	37 #	137 #	137
		FINAL	35.0 #	121	74	192 #	FEMALE	32 #	127 #	127
	E0007012	BASELINE	24.5	107	65	272 #	MALE	29 #	89	89
		FINAL	25.6	97	69	155 #	MALE	34 #	87	87
	E0009007	BASELINE	26.3	134	84 #	163 #	MALE	31 #	84	84
		FINAL	26.9	125	78	158 #	MALE	35 #	83	83
	E0009008	BASELINE	26.3	124	82	94	MALE	40	90	90
		FINAL	26.0	100	65	123	MALE	47	89	89
	E0011001	BASELINE	25.3	118	78	70	FEMALE	73	75	75
		FINAL	24.5	111	73	72	FEMALE	67	83	83
	E0011011	BASELINE	19.6	104	72	61	FEMALE	59	81	81
		FINAL	19.2	109	73	66	FEMALE	63	75	75
	E0011013	BASELINE	32.0 #	135	91 #	181 #	FEMALE	34 #	87	87
		FINAL	31.2 #	128	84 #	260 #	FEMALE	34 #	77	77
	E0011014	BASELINE	35.0 #	122	76	53	FEMALE	51	79	79

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND100.SAS
GENERATED: 12JUL2005 17:46:23 iceadmn3

Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR II)	E0011014	FINAL	35.4 #	118	74	165 #	FEMALE	55	87	87
	E0011021	BASELINE	22.7	111	64	117	FEMALE	47 #	76	76
		FINAL	22.7	112	65	82	FEMALE	55	87	87
	E0013008	BASELINE	43.3 #	120	80	86	FEMALE	45 #	77	77
		FINAL	43.7 #	116	72	112	FEMALE	43 #	83	83
	E0014001	BASELINE	22.4	98	66	139	FEMALE	47 #	101	101
		FINAL	23.1	103	70	121	FEMALE	33 #	77	77
	E0014013	BASELINE	20.2	104	69	119	FEMALE	42 #	60	60
		FINAL	20.6	108	66	193 #	FEMALE	47 #	81	81
	E0014014	BASELINE	27.5	113	75	108	MALE	49	84	84
		FINAL	26.9	124	73	130	MALE	51	70	70
	E0015004	BASELINE	35.3 #	119	75	90	FEMALE	36 #	95	95
		FINAL	35.3 #	117	72	52	FEMALE	43 #	93	93
	E0018005	BASELINE	20.3	120	73	38	MALE	49	83	83
		FINAL	20.0	120	70	69	MALE	57	93	93
	E0018012	BASELINE	28.4	114	73	62 #	FEMALE	56	83	83
		FINAL	28.4	123	69	159 #	FEMALE	50	100	100
	E0019033	BASELINE	22.6	115	75	52	MALE	68	86	86
		FINAL	22.3	113	67	62	MALE	57	85	85
	E0019038	BASELINE	23.1	105	63	47	MALE	38 #	86	86
		FINAL	23.1	107	63	69	MALE	36 #	90	90
	E0019046	BASELINE	21.6	106	70	48	FEMALE	94	80	80
		FINAL	22.2	109	76	64	FEMALE	75	86	86
	E0019047	BASELINE	25.4	115	68	55	MALE	52	81	81
		FINAL	25.1	119	72	53	MALE	52	82	82

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
#: potentially clinically important.

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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR II)	E0019048	BASELINE	22.0	124	78	67	FEMALE	67	86	86
		FINAL	21.2	120	83	90	FEMALE	65	82	82
	E0022006	BASELINE	29.2	121	76	308 #	FEMALE	36 #	85	85
		FINAL	28.8	102	56	234 #	FEMALE	35 #	93	93
	E0022047	BASELINE	26.9	114	81	660 #	MALE	30 #	97	97
		FINAL	27.5	127	78	537 #	MALE	36 #	83	83
	E0022075	BASELINE	21.5	111	72	75	FEMALE	79	82	82
		FINAL	20.3	104	59	96	FEMALE	71	77	77
	E0023012	BASELINE	35.3 #	126	75	214 #	FEMALE	40 #	63	63
		FINAL	36.0 #	125	65	193 #	FEMALE	31 #	93	93
	E0023016	BASELINE	19.6	119	79	73	FEMALE	63	70	70
		FINAL	21.6	95	69	61	FEMALE	56	95	95
	E0023018	BASELINE	30.7 #	127	85	85	MALE	79	75	75
		FINAL	30.4 #	132	89 #	123	MALE	40	74	74
	E0023036	BASELINE	24.4	120	72	93	FEMALE	35 #	82	82
		FINAL	24.4	110	73	89	FEMALE	43 #	95	95
	E0023046	BASELINE	36.0 #	131	87 #	160 #	FEMALE	38 #	86	86
		FINAL	36.4 #	124	69 #	120	FEMALE	41 #	74	74
	E0029004	BASELINE	29.1	99	66	81	FEMALE	43 #	71	71
		FINAL	29.1	102	72	84	FEMALE	40 #	81	81
	E0029019	BASELINE	31.5 #	110	78	360 #	MALE	36 #	91	91
		FINAL	31.1 #	121	83	168 #	MALE	36 #	91	91
	E0029024	BASELINE	19.9	108	81	61	FEMALE	88	92	92
		FINAL	20.3	100	61	52	FEMALE	81	156 #	156 #
	E0031004	BASELINE	27.9	122	65	168 #	FEMALE	53 #	85	85

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND100.SAS
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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR II)	E0031004	FINAL	29.1	120	73	434 #	FEMALE	43 #	85	85
	E0031013	BASELINE	47.2 #	134	83 #	179 #	FEMALE	42 #	86	86
		FINAL	48.5 #	139	89 #	177 #	FEMALE	45 #	85	85
	E0031016	BASELINE	23.4	120	60	93	MALE	47	86	86
		FINAL	24.3	117	60	105	MALE	48	81	81
	E0031019	BASELINE	24.6	120	69	165 #	MALE	36 #	96	96
		FINAL	24.2	124	68	184 #	MALE	30 #	92	92
	E0033007	BASELINE	27.0	124	83	65	FEMALE	56	83	83
		FINAL	26.2	110	83	160 #	FEMALE	61	86	86
	E0033013	BASELINE	25.5	104	71	124	FEMALE	46 #	84	84
		FINAL	25.1	80	60	97	FEMALE	44 #	79	79
	E0033016	BASELINE	23.4	103	65	103	FEMALE	55	76	76
		FINAL	23.8	95	63	110	FEMALE	55	87	87
	E0033022	BASELINE	37.1 #	100	77	107	FEMALE	48 #	65	65
		FINAL	36.3 #	105	70	91	FEMALE	53	66	66
	E0034007	BASELINE	20.8	116	86 #	94	FEMALE	65	104	104
		FINAL	20.4	150	100 #	73	FEMALE	88	97	97
	E0035009	BASELINE	20.1	102	73	43	MALE	41	91	91
		FINAL	20.1	116	67	68	MALE	44	98	98
	E0035010	BASELINE	38.5 #	133	91 #	96	FEMALE	55	92	92
		FINAL	39.3 #	132	78 #	108	FEMALE	65	94	94
	E0035022	BASELINE	23.3	111	66	66	FEMALE	48 #	84	84
		FINAL	22.5	101	69	49	FEMALE	47 #	94	94
	E0039003	BASELINE	32.9 #	115	79	149	FEMALE	55	84	84
		FINAL	33.6 #	120	71	226 #	FEMALE	44 #	68	68

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND100.SAS
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Listing 12.2.10.3 Metabolic Syndrome

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	BODY MASS INDEX	MEAN SUPINE SYS	MEAN SUPINE DIA	TRIGLY-CERIDE (MG/DL)	SEX	DIRECT HDL (MG/DL)	FASTING GLUCOSE (MG/DL)	RANDOM GLUCOSE (MG/DL)
PLACEBO (BIPOLAR II)	E0040001	BASELINE	24.5	115	68	49	FEMALE	61	84	84
		FINAL	23.3	120	79	40	FEMALE	56	86	86
	E0041002	BASELINE	30.1 #	144	93 #	80	MALE	42	83	83
		FINAL	30.7 #	146	86 #	70	MALE	37 #	88	88
	E0041005	BASELINE	30.2 #	145	96 #	84	MALE	31 #	82	82
		FINAL	30.2 #	144	92 #	177 #	MALE	43	86	86

SYS: Systolic blood pressure DIA: Diastolic blood pressure.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SYND100.SAS
GENERATED: 12JUL2005 17:46:23 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1	04FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02APR2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0002010	DAY 1	04APR2003	1	2		0	0	0	0	1	1	0	0	0	0
	E0002012	DAY 1	21APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JUN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0002015	DAY 1	04JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0002018	DAY 1	24JUL2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	01AUG2003	9	1	0	0	0	0	0	0	0	0	0	0	1
	E0003004	DAY 1	17DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0003005	DAY 1	23DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18FEB2003	58	1	1	0	0	0	1	0	0	0	0	0	0
	E0003007	DAY 1	02JAN2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	27FEB2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0003015	DAY 1	05MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	59	3	3	0	0	0	0	0	0	0	0	0	3
	E0004002	DAY 1	01OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26NOV2002	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0004013	DAY 1	14JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05FEB2003	23	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0004018	DAY 1	19MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13MAY2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0004021	DAY 1	14MAY2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	09JUL2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0005002	DAY 1	03OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	25NOV2002	54	0	-1	0	0	0	0	0	0	0	0	0	0
	E0005004	DAY 1	01OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0005013	DAY 1	07NOV2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0005024	DAY 1	10FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09APR2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0005027	DAY 1	11MAR2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	03APR2003	24	1	0	0	0	0	0	0	0	0	0	0	1
	E0005037	DAY 1	07MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0005042	DAY 1	24JUN2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	18AUG2003	56	0	-1	0	0	0	0	0	0	0	0	0	0
	E0006005	DAY 1	05DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30JAN2003	57	1	1	0	0	0	0	0	0	0	0	0	1
	E0006018	DAY 1	13MAR2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0006018	DAY 57	24MAR2003	12	0	0	0	0	0	0	0	0	0	0	0	0
	E0007013	DAY 1	13JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	07AUG2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0010004	DAY 1	11DEC2002	1	2		0	1	0	0	0	0	0	0	0	1
	E0010012	DAY 1	07JAN2003	1	6		0	1	1	1	1	0	0	1	0	1
		DAY 57	05MAR2003	58	0	-6	0	0	0	0	0	0	0	0	0	0
	E0010024	DAY 1	05MAY2003	1	2		0	0	0	0	0	1	0	0	0	1
		DAY 57	02JUL2003	59	1	-1	0	0	0	0	0	0	0	0	0	1
	E0010032	DAY 1	10JUL2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	17JUL2003	8	0	-1	0	0	0	0	0	0	0	0	0	0
	E0011025	DAY 1	26JUN2003	1	2		0	1	0	0	0	0	0	0	0	1
		DAY 57	22AUG2003	58	0	-2	0	0	0	0	0	0	0	0	0	0
	E0013007	DAY 1	20MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	07APR2003	19	0	0	0	0	0	0	0	0	0	0	0	0
	E0013009	DAY 1	02APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29MAY2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0014006	DAY 1	25MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21MAY2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0014010	DAY 1	22APR2003	1	1		0	0	0	0	0	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	DAY 57	17JUN2003	57	1	0	0	0	0	0	0	0	0	0	0	1
	E0016001	DAY 1	22JAN2003	1	5		0	1	0	3	1	0	0	0	0	0
		DAY 57	19MAR2003	57	0	-5	0	0	0	0	0	0	0	0	0	0
	E0016004	DAY 1	03FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0018001	DAY 1	29OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	24DEC2002	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0018006	DAY 1	17DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13FEB2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0019004	DAY 1	07NOV2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	19DEC2002	43	0	-1	0	0	0	0	0	0	0	0	0	0
	E0019011	DAY 1	21NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019025	DAY 1	06FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019026	DAY 1	24FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0019043	DAY 1	03JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0020001	DAY 1	29OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20DEC2002	53	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0020006	DAY 1	16DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0020007	DAY 1	15JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0020011	DAY 1	26FEB2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	23APR2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0020013	DAY 1	05MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0022008	DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022017	DAY 1	19DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13FEB2003	57	1	1	0	0	0	0	0	0	0	1	0	0
	E0022018	DAY 1	12DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022022	DAY 1	30DEC2002	1	2		0	0	0	0	0	0	0	0	0	2
		DAY 57	27FEB2003	60			9	9	0	9	0	0	0	1	0	1
	E0022027	DAY 1	06FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022030	DAY 1	14FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0022031	DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0022032	DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18APR2003	60	0	0	0	0	0	0	0	0	0	0	0	0
	E0022035	DAY 1	19FEB2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	26FEB2003	8	1	0	0	0	0	0	0	0	0	1	0	0
	E0022036	DAY 1	25FEB2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	22APR2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0022056	DAY 1	17APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0022060	DAY 1	30APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	24JUN2003	56	2	2	0	0	1	0	0	0	0	1	0	0
	E0022063	DAY 1	07MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0023008	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	24MAR2003	54	0	0	0	0	0	0	0	0	0	0	0	0
	E0023013	DAY 1	27FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06MAR2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0023015	DAY 1	11MAR2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	06MAY2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0023034	DAY 1	09JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05AUG2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0023037	DAY 1	18JUN2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0023037	DAY 57	15AUG2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0023038	DAY 1	30JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27AUG2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0023044	DAY 1	16JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12AUG2003	28	0	0	0	0	0	0	0	0	0	0	0	0
	E0023045	DAY 1	17JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11SEP2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0025002	DAY 1	03APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0026010	DAY 1	22JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30JAN2003	9	0	0	0	0	0	0	0	0	0	0	0	0
	E0026017	DAY 1	06MAR2003	1	1		0	1	0	0	0	0	0	0	0	0
		DAY 57	21MAR2003	16	0	-1	0	0	0	0	0	0	0	0	0	0
	E0026018	DAY 1	20MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0026025	DAY 1	09MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03JUL2003	56	1	1	0	0	0	0	0	0	0	1	0	0
	E0026029	DAY 1	09JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	28JUL2003	20	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0026030	DAY 1	09JUL2003	1	1		0	0	0	0	0	0	0	0	1	0
		DAY 57	03SEP2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0026031	DAY 1	21JUL2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	15SEP2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0027003	DAY 1	23JAN2003	-5	5		1	0	1	1	0	1	0	1	0	0
		DAY 57	25MAR2003	57	1	-4	0	0	0	0	0	0	0	1	0	0
	E0028004	DAY 1	30SEP2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09OCT2002	10	1	1	0	0	0	0	0	0	0	0	0	1
	E0028006	DAY 1	04OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	04DEC2002	62	0	0	0	0	0	0	0	0	0	0	0	0
	E0028008	DAY 1	15OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10DEC2002	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0028009	DAY 1	15OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12DEC2002	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0028016	DAY 1	14NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0028017	*	19NOV2002		0		0	0	0	0	0	0	0	0	0	0
	E0028027	DAY 1	21JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0028029	DAY 1	04FEB2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0028029	DAY 57	03APR2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0028034	DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUN2003	63	0	0	0	0	0	0	0	0	0	0	0	0
	E0028038	DAY 1	25APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18JUN2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0028043	DAY 1	05JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29JUL2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0028045	DAY 1	18JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0029005	DAY 1	27NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21JAN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0030001	DAY 1	19NOV2002	1	6		0	0	0	0	0	0	0	3	0	3
		DAY 57	16JAN2003	59	4	-2	0	0	1	0	0	1	0	1	0	1
	E0030008	DAY 1	14JAN2003	1	3		1	1	0	0	0	0	0	0	0	1
		DAY 57	18MAR2003	64	0	-3	0	0	0	0	0	0	0	0	0	0
	E0030011	DAY 1	27JAN2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	24MAR2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0030015	DAY 1	21FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0030022	DAY 1	16JUN2003	1	1		0	0	0	0	0	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	DAY 57	14AUG2003	60	0	-1	0	0	0	0	0	0	0	0	0	0
	E0031002	DAY 1	27NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0031003	DAY 1	10DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	04FEB2003	57	1	1	0	0	0	1	0	0	0	0	0	0
	E0033015	DAY 1	10APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	04JUN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0034002	DAY 1	25MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	22	0	0	0	0	0	0	0	0	0	0	0	0
	E0034003	DAY 1	24APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19JUN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0034006	DAY 1	16MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10JUL2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0034008	DAY 1	23MAY2003	-1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21JUL2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0035003	DAY 1	22NOV2002	1	3		0	0	0	0	0	1	0	1	0	1
	E0035005	DAY 1	03DEC2002	1	4		0	0	1	1	1	1	0	0	0	0
	E0035014	DAY 1	03FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	31MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0035024	DAY 1	22MAY2003	-1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0036005	DAY 1	01JUL2003	1	3		1	0	0	0	0	1	0	0	0	1
		DAY 57	27AUG2003	58	4	1	1	0	0	0	0	1	0	1	0	1
	E0037002	DAY 1	26DEC2002	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	20FEB2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0037005	DAY 1	06MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0037006	DAY 1	14MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039006	DAY 1	30DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	24FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039015	DAY 1	23JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039024	DAY 1	27FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	24APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039025	DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27MAY2003	71	0	0	0	0	0	0	0	0	0	0	0	0
	E0039041	DAY 1	15APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11JUN2003	58	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	DAY 1		22MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57		09JUL2003	49	0	0	0	0	0	0	0	0	0	0	0	0
	E0039046		*	21MAY2003		0		0	0	0	0	0	0	0	0	0	0
			*	30MAY2003		0		0	0	0	0	0	0	0	0	0	0
	E0039051	DAY 1		16JUN2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57		12AUG2003	58	0	-1	0	0	0	0	0	0	0	0	0	0
	E0039053	DAY 1		11JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57		08SEP2003	60	0	0	0	0	0	0	0	0	0	0	0	0
	E0039057	DAY 1		14JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57		09SEP2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0041003	DAY 1		28JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57		25MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0041008	DAY 1		07APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57		02JUN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0042001	DAY 1		02JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57		26AUG2003	56	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	07MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0003018	DAY 1	13MAY2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	08JUL2003	57	1	0	0	0	0	1	0	0	0	0	0	0
	E0005011	DAY 1	24OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0005030	DAY 1	26MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0005036	DAY 1	06MAY2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	27MAY2003	22	0	-1	0	0	0	0	0	0	0	0	0	0
	E0006015	DAY 1	11FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0006016	DAY 1	17FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18APR2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0007008	DAY 1	18APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	25APR2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0009002	DAY 1	19NOV2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	15JAN2003	58	0	-1	0	0	0	0	0	0	0	0	0	0
	E0009006	DAY 1	28JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	25MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0009009	DAY 1	12MAR2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0009009	DAY 57	24MAR2003	13	0	0	0	0	0	0	0	0	0	0	0	0
	E0010015	DAY 1	20FEB2003	1	2		0	1	0	0	0	0	0	0	0	1
		DAY 57	15APR2003	55	1	-1	0	0	0	0	0	0	0	0	0	1
	E0011004	DAY 1	24DEC2002	1	1		0	0	0	0	0	1	0	0	0	0
		DAY 57	18FEB2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0011007	DAY 1	19DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0011018	DAY 1	22MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17JUL2003	57	4	4	0	0	1	1	0	1	0	0	0	1
	E0011024	DAY 1	24JUN2003	1	2		0	2	0	0	0	0	0	0	0	0
		DAY 57	21AUG2003	59	2	0	0	1	0	0	0	0	0	0	0	1
	E0015003	DAY 1	25NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02DEC2002	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0019003	DAY 1	21NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019007	DAY 1	13NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0019014	DAY 1	09JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20JAN2003	12	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0019018	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019022	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019027	DAY 1	27FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06MAR2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0019032	DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019034	DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0019036	DAY 1	25MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0019039	DAY 1	01MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08MAY2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0019041	DAY 1	21MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019049	DAY 1	10JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08SEP2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0022052	DAY 1	10APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05JUN2003	57	1	1	0	0	0	0	0	0	0	1	0	0
	E0022064	DAY 1	06MAY2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0022064	DAY 57	01JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022073	DAY 1	26JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023002	DAY 1	05NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10DEC2002	36	0	0	0	0	0	0	0	0	0	0	0	0
	E0023017	DAY 1	25MAR2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	22MAY2003	59	0	-1	0	0	0	0	0	0	0	0	0	0
	E0023021	DAY 1	23APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17JUN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0023027	DAY 1	16MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09JUL2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0023030	DAY 1	03JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30JUL2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0023040	DAY 1	03JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05SEP2003	65	0	0	0	0	0	0	0	0	0	0	0	0
	E0026014	DAY 1	19FEB2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	19MAR2003	29	1	0	0	0	0	0	0	0	0	1	0	0
	E0026019	DAY 1	17MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0027005	DAY 1	26DEC2002	1	2		0	1	0	0	0	1	0	0	0	0
		DAY 57	20FEB2003	57	2	0	0	1	0	0	1	0	0	0	0	0
	E0029009	DAY 1	20JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18MAR2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0029021	DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15MAY2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0029026	DAY 1	14APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10JUN2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0029030	DAY 1	27MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	23JUL2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0031008	DAY 1	28FEB2003	1	4		1	0	0	1	0	0	0	1	0	1
		DAY 57	24APR2003	56	0	-4	0	0	0	0	0	0	0	0	0	0
	E0031020	DAY 1	21APR2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	13MAY2003	23	0	-1	0	0	0	0	0	0	0	0	0	0
	E0031021	DAY 1	25APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19JUN2003	56	1	1	0	0	0	0	0	0	0	0	0	1
	E0031029	DAY 1	18JUN2003	1	2		1	0	0	0	0	0	0	1	0	0
	E0033002	DAY 1	10JAN2003	1	4		0	1	1	0	0	1	0	1	0	0
		DAY 57	07MAR2003	57	2	-2	0	1	0	0	0	0	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 300 MG (BIPOLAR II)	E0033006	DAY 1	23JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0033021	DAY 1	02JUL2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	18AUG2003	48	0	-1	0	0	0	0	0	0	0	0	0	0
	E0035013	DAY 1	04FEB2003	1	2		0	0	1	0	0	1	0	0	0	0
		DAY 57	10FEB2003	7	1	-1	0	0	1	0	0	0	0	0	0	0
	E0035015	DAY 1	11FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18FEB2003	8	1	1	0	0	0	0	0	1	0	0	0	0
	E0035016	DAY 1	04APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0035023	DAY 1	13MAY2003	1	2		0	0	0	0	0	1	0	1	0	0
	E0039052	DAY 1	20JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03JUL2003	14	0	0	0	0	0	0	0	0	0	0	0	0
	E0039056	DAY 1	14JUL2003	-1	0		0	0	0	0	0	0	0	0	0	0
	E0040003	DAY 1	18JUL2003	-1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12SEP2003	56	2	2	1	1	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02MAY2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0002011	DAY 1	29APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	25JUN2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0003010	DAY 1	03FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	31MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0003011	DAY 1	04FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0003016	DAY 1	22MAY2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	12JUN2003	22	3	2	0	0	0	1	1	0	0	0	0	1
	E0003019	DAY 1	27JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21AUG2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0003020	DAY 1	23JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17SEP2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0004001	DAY 1	30SEP2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0004009	DAY 1	26DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19FEB2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0004012	DAY 1	14JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0004015	DAY 1	20FEB2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0004015	DAY 57	15APR2003	55	1	1	1	0	0	0	0	0	0	0	0	0
	E0005003	DAY 1	02OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	26NOV2002	56	0	-1	0	0	0	0	0	0	0	0	0	0
	E0005005	DAY 1	30SEP2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0005007	DAY 1	09OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	04DEC2002	57	1	0	0	0	0	0	0	0	0	0	0	1
	E0005008	DAY 1	15OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11DEC2002	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0005009	DAY 1	29OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0005010	DAY 1	21OCT2002	1	3		0	0	0	0	0	0	0	0	0	3
		DAY 57	17DEC2002	58	0	-3	0	0	0	0	0	0	0	0	0	0
	E0005012	DAY 1	14NOV2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	07JAN2003	55	0	-1	0	0	0	0	0	0	0	0	0	0
	E0005014	DAY 1	13NOV2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	06JAN2003	55	1	0	0	0	0	0	0	0	0	0	0	1
	E0005022	DAY 1	29JAN2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	06MAR2003	37	1	0	0	0	0	0	0	0	0	0	0	1
	E0005025	DAY 1	27FEB2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	03APR2003	36	0	-1	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0006019	DAY 1	07APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03JUN2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0007005	DAY 1	31JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	28MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0007015	DAY 1	16JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10SEP2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0009001	DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0010002	DAY 1	25NOV2002	1	2		0	0	0	0	0	0	0	1	0	1
		DAY 57	02DEC2002	8	3	1	0	1	0	0	0	0	0	1	0	1
	E0010009	DAY 1	26DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19FEB2003	56	1	1	0	0	0	0	0	0	0	0	0	1
	E0010010	DAY 1	30DEC2002	1	4		1	0	0	0	0	0	1	1	0	1
		DAY 57	13JAN2003	15	3	-1	0	1	0	0	0	1	0	0	0	1
	E0010014	DAY 1	28JAN2003	1	3		0	1	1	0	0	0	0	0	0	1
		DAY 57	25MAR2003	57	0	-3	0	0	0	0	0	0	0	0	0	0
	E0010017	DAY 1	25FEB2003	1	3		0	0	1	0	0	1	0	0	0	1
		DAY 57	22APR2003	57	2	-1	0	0	1	0	0	1	0	0	0	0
	E0010023	DAY 1	17APR2003	1	1		0	0	1	0	0	0	0	0	0	0
		DAY 57	01MAY2003	15	4	3	0	0	2	0	0	1	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0010027	DAY 1	16JUN2003	1	4		0	0	1	0	0	1	0	0	0	2
		DAY 57	01JUL2003	16	2	-2	0	0	0	0	0	0	0	0	0	2
	E0010029	DAY 1	19JUN2003	1	2		0	0	0	0	0	1	0	0	0	1
	E0011022	DAY 1	09JUN2003	1	4		0	0	1	0	0	0	0	1	0	2
		DAY 57	05AUG2003	58	1	-3	0	0	0	0	0	0	0	0	0	1
	E0013006	DAY 1	13MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	24MAR2003	12	0	0	0	0	0	0	0	0	0	0	0	0
	E0013012	DAY 1	07MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0013014	DAY 1	03JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30JUN2003	28	0	0	0	0	0	0	0	0	0	0	0	0
	E0014005	DAY 1	11MAR2003	1	4		0	0	0	0	0	1	1	0	1	1
		DAY 57	06MAY2003	57	0	-4	0	0	0	0	0	0	0	0	0	0
	E0014007	DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	22	0	0	0	0	0	0	0	0	0	0	0	0
	E0014011	DAY 1	13MAY2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	08JUL2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0014012	DAY 1	27MAY2003	1	5		0	1	0	1	0	1	0	1	0	1
		DAY 57	24JUN2003	29	2	-3	0	0	0	0	0	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0015001	DAY 1	29NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20JAN2003	53	0	0	0	0	0	0	0	0	0	0	0	0
	E0015008	DAY 1	19DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0016003	DAY 1	24JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0016005	DAY 1	25FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0018007	DAY 1	27DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10JAN2003	15	0	0	0	0	0	0	0	0	0	0	0	0
	E0019005	DAY 1	05NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JAN2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0019015	DAY 1	02JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0020004	DAY 1	09DEC2002	1	7		3	1	1	1	0	1	0	0	0	0
		DAY 57	22JAN2003	45	7	0	0	1	0	1	0	1	4	0	0	0
	E0020010	DAY 1	05FEB2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	02APR2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0020014	DAY 1	18MAR2003	1	4		1	1	0	0	0	2	0	0	0	0
		DAY 57	12MAY2003	56	3	-1	1	1	0	0	0	1	0	0	0	0
	E0020021	DAY 1	19MAY2003	1	1		1	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0020021	DAY 57	14JUL2003	57	2	1	1	0	0	0	0	1	0	0	0	0
	E0020023	DAY 1	16JUN2003	-1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	11AUG2003	56	2	1	0	0	0	0	0	0	0	2	0	0
	E0022007	DAY 1	07NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0022010	DAY 1	21NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JAN2003	57	1	1	0	0	0	0	0	0	0	1	0	0
	E0022012	DAY 1	05DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022019	DAY 1	11DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06FEB2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0022025	DAY 1	28JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	04FEB2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0022033	DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022034	DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022038	DAY 1	28FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11APR2003	43	2	2	0	0	0	0	1	0	0	1	0	0
	E0022039	DAY 1	06MAR2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0022039	DAY 57	01MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022046	DAY 1	20MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16MAY2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0022048	DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0022051	DAY 1	07APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022053	DAY 1	11APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0022058	DAY 1	21APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	32	1	1	0	0	0	0	0	0	0	1	0	0
	E0022061	DAY 1	30APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26JUN2003	58	1	1	0	0	0	0	0	0	0	1	0	0
	E0022062	DAY 1	05MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	23MAY2003	19	0	0	0	0	0	0	0	0	0	0	0	0
	E0022068	DAY 1	22MAY2003	-1	0		0	0	0	0	0	0	0	0	0	0
	E0022069	DAY 1	10JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022071	DAY 1	30JUN2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	25AUG2003	57	0	-1	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0023003	DAY 1	17DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023006	DAY 1	17DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023010	DAY 1	04FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	31MAR2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0023025	DAY 1	15MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023039	DAY 1	01JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0026002	DAY 1	12NOV2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	09JAN2003	59	0	-1	0	0	0	0	0	0	0	0	0	0
	E0026007	DAY 1	16JAN2003	1	4		2	0	0	0	0	1	0	0	0	1
		DAY 57	12MAR2003	56	0	-4	0	0	0	0	0	0	0	0	0	0
	E0026013	DAY 1	13FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0028007	DAY 1	04OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14NOV2002	42	0	0	0	0	0	0	0	0	0	0	0	0
	E0028023	DAY 1	21JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0028025	DAY 1	13JAN2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0028025	DAY 57	27JAN2003	15	0	0	0	0	0	0	0	0	0	0	0	0
	E0028033	DAY 1	27MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0028035	DAY 1	03APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0028037	DAY 1	12JUN2003	-1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0028039	DAY 1	08MAY2003	-1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05JUN2003	28	0	0	0	0	0	0	0	0	0	0	0	0
	E0028046	DAY 1	25JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0028048	DAY 1	17JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0029008	DAY 1	16DEC2002	1	2		0	0	0	0	0	0	0	0	0	2
		DAY 57	23DEC2002	8	0	-2	0	0	0	0	0	0	0	0	0	0
	E0029011	DAY 1	21JAN2003	-1	0		0	0	0	0	0	0	0	0	0	0
	E0029012	DAY 1	11FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18MAR2003	36	0	0	0	0	0	0	0	0	0	0	0	0
	E0029015	DAY 1	24FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11MAR2003	16	10	10	1	1	1	1	1	1	0	1	0	3

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0029018	DAY 1	06MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0030014	DAY 1	21FEB2003	1			0	0	0				0	1	0	1
		DAY 57	22APR2003	61	0		0	0	0	0	0	0	0	0	0	0
	E0030020	DAY 1	29MAY2003	1	1		0	0	0	0	0	0	0	0	0	1
	E0030024	DAY 1	11JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18JUL2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0030025	DAY 1	11JUL2003	1	1		1	0	0	0	0	0	0	0	0	0
		DAY 57	19AUG2003	40	1	0	0	0	0	0	0	0	0	0	0	1
	E0031027	DAY 1	03JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0031030	DAY 1	24JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21AUG2003	59	1	1	0	0	0	0	0	0	0	0	0	1
	E0033012	DAY 1	10FEB2003	1	1		0	0	0	0	0	0	0	1	0	0
	E0034001	DAY 1	20MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0034004	DAY 1	21APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JUN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0035001	DAY 1	20NOV2002	1	2		0	0	0	0	0	0	0	1	1	0
		DAY 57	14JAN2003	56	0	-2	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 1	12DEC2002	1	2		0	0	1	0	0	1	0	0	0	0
		DAY 57	06FEB2003	57	2	0	0	0	1	0	0	1	0	0	0	0
	E0035021	DAY 1	25APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20JUN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0036002	DAY 1	17JUN2003	1	2		0	0	0	0	0	0	0	0	0	2
		DAY 57	14JUL2003	28	3	1	0	0	0	0	0	0	0	0	0	3
	E0036006	DAY 1	03JUL2003	1	2		0	0	0	0	0	0	0	0	0	2
		DAY 57	27AUG2003	56	2	0	0	0	0	0	0	1	0	1	0	0
	E0036007	DAY 1	03JUL2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	18JUL2003	16	2	1	0	0	0	0	0	0	0	1	0	1
	E0037009	DAY 1	16MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10JUL2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0039011	DAY 1	02JAN2003	1	2		0	0	0	0	0	0	0	0	0	2
	E0039018	DAY 1	23JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0039026	DAY 1	07MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01MAY2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0039028	DAY 1	24MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0039032	DAY 1	14MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	28MAR2003	15	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL		ITEM SCORES									
					SCORE	CHG FROM BSLN	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR I)	E0039034	DAY 1	19MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039042	DAY 1	07MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0041004	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	31MAR2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0041009	DAY 1	01MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0042002	DAY 1	09JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02SEP2003	56	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	3		0	0	1	0	0	1	0	0	0	1
		DAY 57	18JUL2003	8	2	-1	0	0	1	0	0	1	0	0	0	0
	E0003002	DAY 1	29OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	23DEC2002	56	0	-1	0	0	0	0	0	0	0	0	0	0
	E0005031	DAY 1	02APR2003	1	1		0	0	0	0	0	0	0	0	0	1
	E0005033	DAY 1	15APR2003	-1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06MAY2003	21	0	0	0	0	0	0	0	0	0	0	0	0
	E0005038	DAY 1	14MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05JUN2003	23	1	1	0	0	0	0	0	0	0	0	0	1
	E0007009	DAY 1	17APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	28APR2003	12	0	0	0	0	0	0	0	0	0	0	0	0
	E0009010	DAY 1	13MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0009011	DAY 1	06MAY2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	03JUL2003	59	1	0	0	0	0	0	1	0	0	0	0	0
	E0010005	DAY 1	18DEC2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0011016	DAY 1	21APR2003	1	4		0	0	0	0	0	1	0	1	1	1
		DAY 57	16JUN2003	57	2	-2	0	0	0	0	0	0	0	1	0	1
	E0011020	DAY 1	08MAY2003	1	2		0	0	0	0	0	0	0	1	0	1
		DAY 57	15MAY2003	8	0	-2	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0018002	DAY 1	29NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22JAN2003	55	1	1	0	0	0	0	0	0	0	0	0	1
	E0018003	DAY 1	26NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10DEC2002	15	0	0	0	0	0	0	0	0	0	0	0	0
	E0018013	DAY 1	24JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	31JAN2003	8	1	1	0	0	0	0	0	0	0	0	0	1
	E0019002	DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0019008	DAY 1	21NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0019009	DAY 1	14NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0019016	DAY 1	06JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019020	DAY 1	23JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27MAR2003	64	0	0	0	0	0	0	0	0	0	0	0	0
	E0019021	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03MAR2003	33	0	0	0	0	0	0	0	0	0	0	0	0
	E0019024	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06FEB2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0019031	DAY 1	13MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	25MAR2003	13	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0019035	DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17APR2003	31	0	0	0	0	0	0	0	0	0	0	0	0
	E0019040	DAY 1	20MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17JUL2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0019042	DAY 1	04JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19JUN2003	16	0	0	0	0	0	0	0	0	0	0	0	0
	E0019045	DAY 1	26JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JUL2003	21	0	0	0	0	0	0	0	0	0	0	0	0
	E0020024	DAY 1	23JUN2003	1	4		1	1	1	0	0	1	0	0	0	0
		DAY 57	20AUG2003	59	0	-4	0	0	0	0	0	0	0	0	0	0
	E0022044	DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12MAY2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0023007	DAY 1	14JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023011	DAY 1	04FEB2003	1	2		0	0	0	0	0	0	0	1	0	1
		DAY 57	01APR2003	57	0	-2	0	0	0	0	0	0	0	0	0	0
	E0023014	DAY 1	21FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	25APR2003	64	0	0	0	0	0	0	0	0	0	0	0	0
	E0023019	DAY 1	07APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03JUN2003	58	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0023022	DAY 1	18APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12JUN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0023023	DAY 1	25APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01MAY2003	7	0	0	0	0	0	0	0	0	0	0	0	0
	E0023029	DAY 1	23MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0023031	DAY 1	24JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023041	DAY 1	09JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05SEP2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0023043	DAY 1	14JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09SEP2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0026003	DAY 1	04DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03FEB2003	62	0	0	0	0	0	0	0	0	0	0	0	0
	E0026005	DAY 1	30DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06JAN2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0026009	DAY 1	15JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21JAN2003	7	1	1	0	0	0	0	0	0	0	0	0	1
	E0026015	DAY 1	27FEB2003	1	3		0	0	0	0	0	0	0	0	0	3
		DAY 57	25APR2003	58	2	-1	0	0	0	0	0	0	0	0	0	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0026023	DAY 1	30APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0027016	DAY 1	09APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03JUN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0027018	DAY 1	25MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	59	1	1	0	0	0	0	0	0	0	1	0	0
	E0028032	DAY 1	25MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06JUN2003	74	0	0	0	0	0	0	0	0	0	0	0	0
	E0029003	DAY 1	04NOV2002	1	2		0	0	0	0	0	0	0	1	0	1
		DAY 57	30DEC2002	57	1	-1	0	0	0	0	0	0	0	0	0	1
	E0029020	DAY 1	04MAR2003	-1	0		0	0	0	0	0	0	0	0	0	0
	E0031005	DAY 1	20DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0031006	DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	3	3	1	0	0	1	1	0	0	0	0	0
	E0031010	DAY 1	19FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05MAR2003	15	0	0	0	0	0	0	0	0	0	0	0	0
	E0031011	DAY 1	27FEB2003	1	2		1	0	0	0	0	0	0	0	0	1
		DAY 57	24APR2003	57	1	-1	0	0	0	0	0	0	1	0	0	0
	E0031015	DAY 1	26MAR2003	1	2		0	0	0	0	0	0	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
QUETIAPINE 600 MG (BIPOLAR II)	E0031015	DAY 57	01APR2003	7	1	-1	0	0	0	0	0	0	0	1	0	0
	E0031031	DAY 1	08JUL2003	1	1		0	0	0	1	0	0	0	0	0	0
		DAY 57	28AUG2003	52	2	1	0	0	0	0	0	0	0	0	0	2
	E0033009	DAY 1	12FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0034009	DAY 1	19JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18AUG2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0037007	DAY 1	11APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0037012	DAY 1	16JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08SEP2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0039019	DAY 1	06FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039043	DAY 1	08MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13JUN2003	37	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	6		1	0	1	1	1	1	0	0	0	1
		DAY 57	26FEB2003	59	0	-6	0	0	0	0	0	0	0	0	0	0
	E0002003	DAY 1	22JAN2003	1	1		0	0	0	0	0	1	0	0	0	0
		DAY 57	18MAR2003	56	1	0	0	0	0	0	0	1	0	0	0	0
	E0002004	DAY 1	25JAN2003	1	1		0	0	0	0	0	1	0	0	0	0
	E0002008	DAY 1	25FEB2003	1	1		0	0	0	0	0	1	0	0	0	0
		DAY 57	23APR2003	58	0	-1	0	0	0	0	0	0	0	0	0	0
	E0002016	DAY 1	24JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17SEP2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0003008	DAY 1	28JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0004003	DAY 1	10OCT2002	1	2		0	0	0	0	0	0	0	0	0	2
	E0004006	DAY 1	04NOV2002	1	2		0	0	0	1	0	0	0	1	0	0
		DAY 57	06JAN2003	64	3	1	0	0	0	1	1	0	0	1	0	0
	E0004016	DAY 1	19FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17APR2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0004024	DAY 1	03JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	28AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0005006	DAY 1	03OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0005017	DAY 1	30DEC2002	1	1		0	0	0	0	0	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0005017	DAY 57	04MAR2003	65	1	0	0	0	0	0	0	0	0	0	0	1
	E0005019	DAY 1	15JAN2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	23JAN2003	9	0	-1	0	0	0	0	0	0	0	0	0	0
	E0005026	DAY 1	06MAR2003	1	1		0	1	0	0	0	0	0	0	0	0
		DAY 57	25MAR2003	20	0	-1	0	0	0	0	0	0	0	0	0	0
	E0005039	DAY 1	22MAY2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	16JUL2003	56	1	0	0	0	0	0	0	0	0	0	0	1
	E0005043	DAY 1	09JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03SEP2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0006020	DAY 1	13MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0007001	DAY 1	31DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22FEB2003	54	0	0	0	0	0	0	0	0	0	0	0	0
	E0007003	DAY 1	30JAN2003	1	2		0	0	0	0	0	0	0	1	0	1
		DAY 57	10MAR2003	40	0	-2	0	0	0	0	0	0	0	0	0	0
	E0007006	DAY 1	05MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26MAR2003	22	0	0	0	0	0	0	0	0	0	0	0	0
	E0009004	DAY 1	26NOV2002	1	2		0	0	0	0	0	0	0	0	0	2
		DAY 57	18DEC2002	23	1	-1	0	0	0	0	0	0	0	0	0	1
	E0009012	DAY 1	25JUN2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
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GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0009012	DAY 57	03JUL2003	9	0	0	0	0	0	0	0	0	0	0	0	0
	E0010008	DAY 1	18DEC2002	1	4		0	1	0	0	0	0	0	1	0	2
	E0010018	DAY 1	19MAR2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	14MAY2003	57	0	-1	0	0	0	0	0	0	0	0	0	0
	E0010028	DAY 1	16JUN2003	1	1		0	0	0	0	0	0	0	0	0	1
	E0011008	DAY 1	30JAN2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	13FEB2003	15	0	-1	0	0	0	0	0	0	0	0	0	0
	E0011009	DAY 1	26DEC2002	-1	2		0	0	0	1	0	0	0	1	0	0
		DAY 57	20FEB2003	56	1	-1	0	0	0	0	0	1	0	0	0	0
	E0011010	DAY 1	10FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAR2003	38	0	0	0	0	0	0	0	0	0	0	0	0
	E0013001	DAY 1	14NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10JAN2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0013003	DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06JAN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0013005	DAY 1	18FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0013013	DAY 1	06MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30MAY2003	25	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0014002	DAY 1	26FEB2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	10APR2003	44	0	-1	0	0	0	0	0	0	0	0	0	0
	E0014004	DAY 1	12MAR2003	1	1		0	0	0	0	0	1	0	0	0	0
		DAY 57	15APR2003	35	0	-1	0	0	0	0	0	0	0	0	0	0
	E0014009	DAY 1	23APR2003	1	1		0	0	1	0	0	0	0	0	0	0
		DAY 57	16MAY2003	24	0	-1	0	0	0	0	0	0	0	0	0	0
	E0014015	DAY 1	18JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0014017	DAY 1	27JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19AUG2003	54	2	2	0	1	1	0	0	0	0	0	0	0
	E0014018	DAY 1	01JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27AUG2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0015005	DAY 1	02DEC2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	18DEC2002	17	0	-1	0	0	0	0	0	0	0	0	0	0
	E0017002	DAY 57	13JUN2003	11	1		0	0	0	0	0	0	1	0	0	0
	E0018009	DAY 1	06JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14JAN2003	9	0	0	0	0	0	0	0	0	0	0	0	0
	E0018010	DAY 1	16JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13MAR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0018015	DAY 1	28JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27MAR2003	59	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0020015	DAY 1	27MAR2003	1	2		1	0	0	0	0	1	0	0	0	0
		DAY 57	23MAY2003	58	1	-1	0	0	0	0	0	1	0	0	0	0
	E0020017	DAY 1	03APR2003	1	1		0	1	0	0	0	0	0	0	0	0
	E0020020	DAY 1	12MAY2003	1	2		1	0	1	0	0	0	0	0	0	0
		DAY 57	23MAY2003	12	1	-1	0	0	0	0	0	0	0	0	0	1
	E0020022	DAY 1	16JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022001	DAY 1	28OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26DEC2002	60	0	0	0	0	0	0	0	0	0	0	0	0
	E0022004	DAY 1	28OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	23DEC2002	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022005	DAY 1	08NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022011	DAY 1	29NOV2002	1	1		0	0	0	0	0	0	0	1	0	0
	E0022015	DAY 1	10DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06FEB2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0022016	DAY 1	17DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022020	DAY 1	12DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	23JAN2003	43	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0022023	DAY 1	24DEC2002	-1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20FEB2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0022029	DAY 1	19FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14APR2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0022041	DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022042	DAY 1	12MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12MAY2003	62	0	0	0	0	0	0	0	0	0	0	0	0
	E0022043	DAY 1	20MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12MAY2003	54	1	1	0	0	0	0	0	1	0	0	0	0
	E0022054	DAY 1	11APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0022059	DAY 1	06MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08JUL2003	64	0	0	0	0	0	0	0	0	0	0	0	0
	E0022065	DAY 1	07MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	02JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022070	DAY 1	12JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18JUN2003	7	0	0	0	0	0	0	0	0	0	0	0	0
	E0023001	DAY 1	15NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14JAN2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0023009	DAY 1	11FEB2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0023009	DAY 57	08APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023028	DAY 1	29MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21JUL2003	54	0	0	0	0	0	0	0	0	0	0	0	0
	E0023033	DAY 1	05JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12JUN2003	8	0	0	0	0	0	0	0	0	0	0	0	0
	E0023047	DAY 1	18JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12SEP2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0025001	DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	23APR2003	23	0	0	0	0	0	0	0	0	0	0	0	0
	E0026012	DAY 1	20FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0026020	DAY 1	01APR2003	1	1		1	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	22	0	-1	0	0	0	0	0	0	0	0	0	0
	E0026024	DAY 1	02MAY2003	1	2		0	0	0	0	0	0	0	1	0	1
	E0026028	DAY 1	20JUN2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	23JUL2003	34	0	-1	0	0	0	0	0	0	0	0	0	0
	E0028001	DAY 1	10OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03DEC2002	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0028003	DAY 1	30SEP2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26NOV2002	58	1	1	0	0	0	0	0	0	1	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0028005	DAY 1	03OCT2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	31OCT2002	29	0	0	0	0	0	0	0	0	0	0	0	0
	E0028010	DAY 1	05NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	31DEC2002	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0028011	DAY 1	05DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0028030	DAY 1	04MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30APR2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0028031	DAY 1	11MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0028047	DAY 1	14JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09SEP2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0029001	DAY 1	01OCT2002	1	1		0	0	0	0	0	0	0	0	0	1
	E0029014	DAY 1	04FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0029023	DAY 1	08APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10JUN2003	64	0	0	0	0	0	0	0	0	0	0	0	0
	E0029032	DAY 1	10JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01JUL2003	22	1	1	0	0	0	0	0	0	1	0	0	0
	E0029033	DAY 1	02JUN2003	1	2		0	0	0	0	0	1	0	0	0	1
		DAY 57	30JUN2003	29	2	0	0	0	0	0	0	1	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0029039	DAY 1	15JUL2003	1	1		0	0	1	0	0	0	0	0	0	0
		DAY 57	28JUL2003	14	0	-1	0	0	0	0	0	0	0	0	0	0
	E0030003	DAY 1	16DEC2002	1	4		1	2	0	0	0	0	0	0	0	1
		DAY 57	24DEC2002	9	3	-1	1	2	0	0	0	0	0	0	0	0
	E0030009	DAY 1	23JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAR2003	56	1	1	0	0	0	0	0	0	0	0	0	1
	E0030016	DAY 1	03MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22APR2003	51	0	0	0	0	0	0	0	0	0	0	0	0
	E0030021	DAY 1	20MAY2003	1	3		0	0	0	0	0	0	0	1	1	1
	E0031001	DAY 1	21NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0031017	DAY 1	01APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29APR2003	29	0	0	0	0	0	0	0	0	0	0	0	0
	E0031018	DAY 1	10APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0031023	DAY 1	29APR2003	1	2		1	1	0	0	0	0	0	0	0	0
		DAY 57	24JUN2003	57	0	-2	0	0	0	0	0	0	0	0	0	0
	E0033001	DAY 1	09JAN2003	1	1		1	0	0	0	0	0	0	0	0	0
		DAY 57	30JAN2003	22	2	1	1	0	1	0	0	0	0	0	0	0
	E0033004	DAY 1	17JAN2003	1	1		0	0	0	0	0	0	0	1	0	0
		DAY 57	14MAR2003	57	1	0	0	0	0	0	0	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0033010	DAY 1	04FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26MAR2003	51	0	0	0	0	0	0	0	0	0	0	0	0
	E0033014	DAY 1	19MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0035002	DAY 1	21NOV2002	1	4		0	0	1	1	0	1	0	1	0	0
	E0035007	DAY 1	19DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11FEB2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0035011	DAY 1	04FEB2003	1	2		0	0	1	0	0	1	0	0	0	0
		DAY 57	01APR2003	57	1	-1	0	0	0	0	0	0	0	1	0	0
	E0035020	DAY 1	18APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13JUN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0037003	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20FEB2003	22	0	0	0	0	0	0	0	0	0	0	0	0
	E0037004	DAY 1	13FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	10APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039007	DAY 1	04DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	29JAN2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039022	DAY 1	25FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	24APR2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0039023	DAY 1	24FEB2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR I)	E0039030	DAY 1	24MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039031	DAY 1	24MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20MAY2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0039037	DAY 1	16APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12JUN2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0039038	DAY 1	23APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	20JUN2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0039047	DAY 1	19MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0039059	DAY 1	11JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	05SEP2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0041007	DAY 1	13MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0041010	DAY 1	30APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	11JUN2003	43	0	0	0	0	0	0	0	0	0	0	0	0
	E0041011	DAY 1	22MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0041012	DAY 1	19JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0001004	DAY 1	01MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	27JUN2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0005023	DAY 1	05FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01APR2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0005034	DAY 1	15APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	09JUN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0005041	DAY 1	24JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18AUG2003	56	1	1	0	0	0	0	0	0	0	0	0	1
	E0007004	DAY 1	30JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12FEB2003	14	0	0	0	0	0	0	0	0	0	0	0	0
	E0007010	DAY 1	18APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16JUN2003	60	0	0	0	0	0	0	0	0	0	0	0	0
	E0007012	DAY 1	16MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01JUL2003	47	0	0	0	0	0	0	0	0	0	0	0	0
	E0009007	DAY 1	03FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03MAR2003	29	0	0	0	0	0	0	0	0	0	0	0	0
	E0009008	DAY 1	12FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	08APR2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0011001	DAY 1	01NOV2002	1	4		1	1	0	0	0	0	0	0	0	2
		DAY 57	26DEC2002	56	0	-4	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0011011	DAY 1	20FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16APR2003	56	1	1	0	0	0	0	0	0	0	0	0	1
	E0011013	DAY 1	17APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	12JUN2003	57	1	1	0	0	0	0	0	1	0	0	0	0
	E0011014	DAY 1	07APR2003	1	2		0	0	0	0	0	0	0	1	0	1
		DAY 57	08MAY2003	32	0	-2	0	0	0	0	0	0	0	0	0	0
	E0011021	DAY 1	22MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21JUL2003	61	0	0	0	0	0	0	0	0	0	0	0	0
	E0013008	DAY 1	26MAR2003	1	1		0	1	0	0	0	0	0	0	0	0
		DAY 57	19MAY2003	55	0	-1	0	0	0	0	0	0	0	0	0	0
	E0014001	DAY 1	26FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	01APR2003	35	0	0	0	0	0	0	0	0	0	0	0	0
	E0014013	DAY 1	27MAY2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	23JUL2003	58	0	-1	0	0	0	0	0	0	0	0	0	0
	E0014014	DAY 1	10JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	06AUG2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0015004	DAY 1	02DEC2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	29JAN2003	59	0	-1	0	0	0	0	0	0	0	0	0	0
	E0018005	DAY 1	20DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0018012	DAY 1	24JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	26FEB2003	34	0	0	0	0	0	0	0	0	0	0	0	0
	E0019019	DAY 1	23JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0019033	DAY 1	18MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	15MAY2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0019038	DAY 1	24APR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	18JUN2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0019046	DAY 1	26JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	21AUG2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0019047	DAY 1	08JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	04SEP2003	59	0	0	0	0	0	0	0	0	0	0	0	0
	E0019048	DAY 1	10JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03SEP2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0022006	DAY 1	12NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	07JAN2003	57	1	1	0	0	0	1	0	0	0	0	0	0
	E0022047	DAY 1	28MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	23MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0022075	DAY 1	08JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	03SEP2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0023012	DAY 1	06FEB2003	1	0		0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0023012	DAY 57	04APR2003	58	0	0	0	0	0	0	0	0	0	0	0	0
	E0023016	DAY 1	22MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17JUL2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023018	DAY 1	27MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	22MAY2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0023036	DAY 1	20JUN2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13AUG2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0023046	DAY 1	23JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16SEP2003	56	0	0	0	0	0	0	0	0	0	0	0	0
	E0026006	DAY 1	08JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0026021	DAY 1	23APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0026027	DAY 1	19JUN2003	1	2		0	0	0	0	0	0	0	1	0	1
	E0029002	*	12NOV2002		0		0	0	0	0	0	0	0	0	0	0
	E0029004	DAY 1	19NOV2002	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	16JAN2003	59	0	-1	0	0	0	0	0	0	0	0	0	0
	E0029013	DAY 1	19FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0029019	DAY 1	03MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	17MAR2003	15	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0029024	DAY 1	17MAR2003	1	2		0	0	0	0	0	1	1	0	0	0
		DAY 57	20MAY2003	65	0	-2	0	0	0	0	0	0	0	0	0	0
	E0029038	DAY 1	07JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0031004	DAY 1	19DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	13FEB2003	57	0	0	0	0	0	0	0	0	0	0	0	0
	E0031013	DAY 1	13MAR2003	1	4		1	2	0	0	0	0	0	1	0	0
		DAY 57	08MAY2003	57	1	-3	0	0	0	0	0	0	0	0	0	1
	E0031016	DAY 1	24MAR2003	1	3		1	1	0	1	0	0	0	0	0	0
		DAY 57	14APR2003	22	3	0	1	1	0	1	0	0	0	0	0	0
	E0031019	DAY 1	11APR2003	1	2		0	0	0	0	0	1	0	0	0	1
		DAY 57	12MAY2003	32	0	-2	0	0	0	0	0	0	0	0	0	0
	E0031022	DAY 1	28APR2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0033007	DAY 1	28JAN2003	1	2		0	0	1	0	0	1	0	0	0	0
		DAY 57	25MAR2003	57	3	1	0	0	1	0	1	1	0	0	0	0
	E0033013	DAY 1	19FEB2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	16APR2003	57	2	2	0	0	1	0	0	1	0	0	0	0
	E0033016	DAY 1	08MAY2003	1	1		0	0	0	0	1	0	0	0	0	0
		DAY 57	02JUL2003	56	0	-1	0	0	0	0	0	0	0	0	0	0
	E0033022	DAY 1	14JUL2003	1	1		0	0	0	0	0	0	0	0	0	1
		DAY 57	11SEP2003	60	1	0	0	0	0	0	0	0	0	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
GENERATED: 12JUL2005 17:46:16 iceadmn3

Listing 12.2.10.4 Modified Simpson-Angus Scale (SAS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	TOTAL SCORE	TOTAL CHG FROM BSLN	ITEM SCORES 1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
PLACEBO (BIPOLAR II)	E0034007	DAY 1	16MAY2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	14JUL2003	60	0	0	0	0	0	0	0	0	0	0	0	0
	E0035004	DAY 1	27NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0035009	DAY 1	27DEC2002	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	19FEB2003	55	0	0	0	0	0	0	0	0	0	0	0	0
	E0035010	DAY 1	10JAN2003	1	9		3	2	2	0	0	2	0	0	0	0
		DAY 57	06MAR2003	56	0	-9	0	0	0	0	0	0	0	0	0	0
	E0035022	DAY 1	09MAY2003	1	2		0	0	1	0	1	0	0	0	0	0
		DAY 57	07JUL2003	60	0	-2	0	0	0	0	0	0	0	0	0	0
	E0039003	DAY 1	25NOV2002	1	0		0	0	0	0	0	0	0	0	0	0
	E0040001	DAY 1	27JUN2003	1	2		1	1	0	0	0	0	0	0	0	0
		DAY 57	22AUG2003	57	1	-1	1	0	0	0	0	0	0	0	0	0
	E0040004	DAY 1	18JUL2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0041002	DAY 1	21JAN2003	1	0		0	0	0	0	0	0	0	0	0	0
	E0041005	DAY 1	05MAR2003	1	0		0	0	0	0	0	0	0	0	0	0
		DAY 57	30APR2003	57	0	0	0	0	0	0	0	0	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
Item Scores: 1=Gait, 2=Arm Dropping, 3=Shoulder Shaking, 4=Elbow Rigidity, 5=Wrist Rigidity, 6=Head Rotation, 7=Glabellar Tap, 8=Tremor, 9=Salivation, 10=Akathisia.
SCORES: 0=NORMAL, 1=MILD, 2=MODERATE, 3=MARKED, 4=EXTREME, 9=NOT RATABLE.
GLABELLAR TAP: 0=0-5 BLINKS, 1=6-10 BLINKS, 2=11-15 BLINKS, 3=16-20 BLINKS, 4=21+ BLINKS, 9=NOT RATABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/SAS100.SAS
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0002006	DAY 1	04FEB2003	1	0	0	0	0
		DAY 57	02APR2003	58	0	0	0	0
	E0002010	DAY 1	04APR2003	1	0	1	1	1
	E0002012	DAY 1	21APR2003	1	0	0	0	0
		DAY 57	16JUN2003	57	0	0	0	0
	E0002015	DAY 1	04JUN2003	1	0	1	0	0
	E0002018	DAY 1	24JUL2003	1	0	0	0	0
		DAY 57	01AUG2003	9	0	0	0	1
	E0003004	DAY 1	17DEC2002	1	0	0	0	0
	E0003005	DAY 1	23DEC2002	1	0	0	0	0
		DAY 57	18FEB2003	58	0	0	0	0
	E0003007	DAY 1	02JAN2003	1	0	2	0	2
		DAY 57	27FEB2003	57	2	2	0	2
	E0003015	DAY 1	05MAY2003	1	0	0	0	0
		DAY 57	02JUL2003	59	3	2	1	2
	E0004002	DAY 1	01OCT2002	1	0	0	0	0
		DAY 57	26NOV2002	57	0	0	0	0
	E0004013	DAY 1	14JAN2003	1	0	1	2	1
		DAY 57	05FEB2003	23	0	0	0	0
	E0004018	DAY 1	19MAR2003	1	0	1	1	0
		DAY 57	13MAY2003	56	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
OBJECTIVE RATING: 0=NORMAL, 1=[RESTLESS MOVEMENTS] LESS THAN HALF THE TIME, 2=AT LEAST HALF THE TIME, 3=CONSTANT.
SUBJECTIVE AWARENESS: 0=ABSENT, 1=NONSPECIFIC, 2=AWARE OF RESTLESSNESS, 3=AWARE OF INTENSE COMPULSION TO MOVE.
SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/BARS100.SAS
GENERATED: 12JUL2005 17:39:38 iceadmn3

Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	DAY 1	14MAY2003	1	0	1	0	1
		DAY 57	09JUL2003	57	0	0	0	0
	E0005002	DAY 1	03OCT2002	1	1	1	1	1
		DAY 57	25NOV2002	54	0	0	0	0
	E0005004	DAY 1	01OCT2002	1	0	1	1	1
	E0005013	DAY 1	07NOV2002	1	1	1	1	1
	E0005024	DAY 1	10FEB2003	1	1	1	1	1
		DAY 57	09APR2003	59	0	0	0	0
	E0005027	DAY 1	11MAR2003	1	1	1	1	1
		DAY 57	03APR2003	24	1	1	1	1
	E0005037	DAY 1	07MAY2003	1	0	1	0	1
		DAY 57	02JUL2003	57	0	0	0	0
	E0005042	DAY 1	24JUN2003	1	1	1	1	1
		DAY 57	18AUG2003	56	0	0	0	0
	E0006005	DAY 1	05DEC2002	1	0	0	0	0
		DAY 57	30JAN2003	57	0	1	0	1
	E0006018	DAY 1	13MAR2003	1	0	0	0	0
		DAY 57	24MAR2003	12	0	0	0	0
	E0007013	DAY 1	13JUN2003	1	0	0	0	0
		DAY 57	07AUG2003	56	0	0	0	0
	E0010004	DAY 1	11DEC2002	1	0	2	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
OBJECTIVE RATING: 0=NORMAL, 1=[RESTLESS MOVEMENTS] LESS THAN HALF THE TIME, 2=AT LEAST HALF THE TIME, 3=CONSTANT.
SUBJECTIVE AWARENESS: 0=ABSENT, 1=NONSPECIFIC, 2=AWARE OF RESTLESSNESS, 3=AWARE OF INTENSE COMPULSION TO MOVE.
SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/BARS100.SAS
GENERATED: 12JUL2005 17:39:38 iceadmn3

Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0010004	DAY 57	06FEB2003	58	0	0	0	0
	E0010012	DAY 1	07JAN2003	1	0	1	1	2
		DAY 57	05MAR2003	58	0	0	0	0
	E0010024	DAY 1	05MAY2003	1	1	2	0	1
		DAY 57	02JUL2003	59	1	2	0	2
	E0010032	DAY 1	10JUL2003	1	0	1	0	1
		DAY 57	17JUL2003	8	1	2	1	2
	E0011025	DAY 1	26JUN2003	1	0	1	1	2
		DAY 57	22AUG2003	58	1	1	0	0
	E0013007	DAY 1	20MAR2003	1	0	0	0	0
		DAY 57	07APR2003	19	0	0	0	0
	E0013009	DAY 1	02APR2003	1	0	1	0	1
		DAY 57	29MAY2003	58	0	0	0	0
	E0014006	DAY 1	25MAR2003	1	0	0	0	0
		DAY 57	21MAY2003	58	0	0	0	0
	E0014010	DAY 1	22APR2003	1	0	1	0	0
		DAY 57	17JUN2003	57	1	1	1	1
	E0016001	DAY 1	22JAN2003	1	0	0	0	0
		DAY 57	19MAR2003	57	0	0	0	0
	E0016004	DAY 1	03FEB2003	1	0	0	0	0
	E0018001	DAY 1	29OCT2002	1	0	1	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
OBJECTIVE RATING: 0=NORMAL, 1=[RESTLESS MOVEMENTS] LESS THAN HALF THE TIME, 2=AT LEAST HALF THE TIME, 3=CONSTANT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0018001	DAY 57	24DEC2002	57	0	0	0	0
	E0018006	DAY 1	17DEC2002	1	0	0	0	0
		DAY 57	13FEB2003	59	0	0	0	0
	E0019004	DAY 1	07NOV2002	1	0	1	0	0
		DAY 57	19DEC2002	43	0	1	0	0
	E0019011	DAY 1	21NOV2002	1	0	0	0	0
		DAY 57	16JAN2003	57	0	0	0	0
	E0019025	DAY 1	06FEB2003	1	0	0	0	0
		DAY 57	03APR2003	57	0	0	0	0
	E0019026	DAY 1	24FEB2003	1	0	0	0	0
	E0019043	DAY 1	03JUN2003	1	0	0	0	0
		DAY 57	29JUL2003	57	0	0	0	0
	E0020001	DAY 1	29OCT2002	1	0	0	0	0
		DAY 57	20DEC2002	53	0	0	0	0
	E0020006	DAY 1	16DEC2002	1	0	0	0	0
	E0020007	DAY 1	15JAN2003	1	0	0	0	0
	E0020011	DAY 1	26FEB2003	1	0	0	0	0
		DAY 57	23APR2003	57	0	0	0	0
	E0020013	DAY 1	05MAR2003	1	0	0	0	0
	E0022008	DAY 1	12NOV2002	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022008	DAY 57	07JAN2003	57	0	0	0	0
	E0022017	DAY 1	19DEC2002	1	0	0	0	0
		DAY 57	13FEB2003	57	0	0	0	0
	E0022018	DAY 1	12DEC2002	1	0	0	0	0
		DAY 57	06FEB2003	57	0	0	0	0
	E0022022	DAY 1	30DEC2002	1	2	1	1	2
		DAY 57	27FEB2003	60	0	1	0	1
	E0022027	DAY 1	06FEB2003	1	0	0	0	0
		DAY 57	03APR2003	57	0	0	0	0
	E0022030	DAY 1	14FEB2003	1	0	0	0	0
	E0022031	DAY 1	18FEB2003	1	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0
	E0022032	DAY 1	18FEB2003	1	0	0	0	0
		DAY 57	18APR2003	60	0	0	0	0
	E0022035	DAY 1	19FEB2003	1	0	0	0	0
		DAY 57	26FEB2003	8	0	0	0	0
	E0022036	DAY 1	25FEB2003	1	0	0	0	0
		DAY 57	22APR2003	57	0	0	0	0
	E0022056	DAY 1	17APR2003	1	0	0	0	0
	E0022060	DAY 1	30APR2003	1	0	0	0	0
		DAY 57	24JUN2003	56	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	DAY 1	07MAY2003	1	0	0	0	0
	E0023008	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	24MAR2003	54	0	0	0	0
	E0023013	DAY 1	27FEB2003	1	0	0	0	0
		DAY 57	06MAR2003	8	0	0	0	0
	E0023015	DAY 1	11MAR2003	1	0	0	0	0
		DAY 57	06MAY2003	57	0	0	0	0
	E0023034	DAY 1	09JUN2003	1	0	0	0	0
		DAY 57	05AUG2003	58	0	0	0	0
	E0023037	DAY 1	18JUN2003	1	0	0	0	0
		DAY 57	15AUG2003	59	0	0	0	0
	E0023038	DAY 1	30JUN2003	1	0	0	0	0
		DAY 57	27AUG2003	59	0	0	0	0
	E0023044	DAY 1	16JUL2003	1	0	1	0	1
		DAY 57	12AUG2003	28	1	2	2	2
	E0023045	DAY 1	17JUL2003	1	0	0	0	0
		DAY 57	11SEP2003	57	0	0	0	0
	E0025002	DAY 1	03APR2003	1	0	0	0	0
		DAY 57	29MAY2003	57	0	0	0	0
	E0026010	DAY 1	22JAN2003	1	0	0	0	0
		DAY 57	30JAN2003	9	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0026017	DAY 1	06MAR2003	1	0	0	0	0
		DAY 57	21MAR2003	16	0	0	0	0
	E0026018	DAY 1	20MAR2003	1	0	1	1	1
		DAY 57	15MAY2003	57	0	0	0	0
	E0026025	DAY 1	09MAY2003	1	0	0	0	0
		DAY 57	03JUL2003	56	0	0	0	0
	E0026029	DAY 1	09JUL2003	1	0	0	0	0
		DAY 57	28JUL2003	20	0	0	0	0
	E0026030	DAY 1	09JUL2003	1	0	0	0	0
		DAY 57	03SEP2003	57	0	0	0	0
	E0026031	DAY 1	21JUL2003	1	1	0	0	0
		DAY 57	15SEP2003	57	0	0	0	0
	E0027003	DAY 1	28JAN2003	1	0	0	0	0
		DAY 57	25MAR2003	57	0	1	0	1
	E0028004	DAY 1	30SEP2002	1	0	0	0	0
		DAY 57	09OCT2002	10	1	1	1	1
	E0028006	DAY 1	04OCT2002	1	0	0	0	0
		DAY 57	04DEC2002	62	0	0	0	0
	E0028008	DAY 1	15OCT2002	1	0	0	0	0
		DAY 57	10DEC2002	57	0	0	0	0
	E0028009	DAY 1	15OCT2002	1	0	0	0	0
		DAY 57	12DEC2002	59	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0028016	DAY 1		14NOV2002	1	0	0	0	0
		DAY 57		09JAN2003	57	0	0	0	0
	E0028017		*	19NOV2002		0	0	0	0
	E0028027	DAY 1		21JAN2003	1	0	0	0	0
	E0028029	DAY 1		04FEB2003	1	0	0	0	0
		DAY 57		03APR2003	59	0	0	0	0
	E0028034	DAY 1		01APR2003	1	0	0	0	0
		DAY 57		02JUN2003	63	0	0	0	0
	E0028038	DAY 1		25APR2003	1	0	1	2	1
		DAY 57		18JUN2003	55	0	0	0	0
	E0028043	DAY 1		05JUN2003	1	0	0	0	0
		DAY 57		29JUL2003	55	0	0	0	0
	E0028045	DAY 1		18JUN2003	1	0	0	0	0
	E0029005	DAY 1		27NOV2002	1	0	0	0	0
		DAY 57		21JAN2003	56	0	0	0	0
	E0030001	DAY 1		19NOV2002	1	2	2	1	2
		DAY 57		16JAN2003	59	1	1	0	1
	E0030008	DAY 1		14JAN2003	1	0	0	0	0
		DAY 57		18MAR2003	64	1	0	0	0
	E0030011	DAY 1		27JAN2003	1	0	1	0	1
		DAY 57		24MAR2003	57	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0030015	DAY 1	21FEB2003	1	0	1	0	0
		DAY 57	22APR2003	61	0	0	0	0
	E0030022	DAY 1	16JUN2003	1	0	1	1	1
		DAY 57	14AUG2003	60	0	0	0	0
	E0031002	DAY 1	27NOV2002	1	0	0	0	0
		DAY 57	22JAN2003	57	0	0	0	0
	E0031003	DAY 1	10DEC2002	1	0	0	0	0
		DAY 57	04FEB2003	57	0	0	0	0
	E0033015	DAY 1	10APR2003	1	0	0	0	0
		DAY 57	04JUN2003	56	0	0	0	1
	E0034002	DAY 1	25MAR2003	1	0	0	0	0
		DAY 57	15APR2003	22	0	0	0	0
	E0034003	DAY 1	24APR2003	1	0	0	0	0
		DAY 57	19JUN2003	57	0	0	0	0
	E0034006	DAY 1	16MAY2003	1	0	0	0	0
		DAY 57	10JUL2003	56	0	0	0	0
	E0034008	DAY 1	23MAY2003	-1	0	0	0	0
		DAY 57	21JUL2003	59	0	0	0	0
	E0035003	DAY 1	22NOV2002	1	0	1	1	1
	E0035005	DAY 1	03DEC2002	1	0	0	0	0
	E0035014	DAY 1	03FEB2003	1	0	0	0	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0035014	DAY 57	31MAR2003	57	0	0	0	0
	E0035024	DAY 1	22MAY2003	-1	0	1	1	1
		DAY 57	18JUL2003	57	0	0	0	0
	E0036005	DAY 1	01JUL2003	1	1	1	0	1
		DAY 57	27AUG2003	58	1	0	0	1
	E0037002	DAY 1	26DEC2002	1	0	0	0	0
		DAY 57	20FEB2003	57	0	0	0	0
	E0037005	DAY 1	06MAR2003	1	0	0	0	0
		DAY 57	01MAY2003	57	0	0	0	0
	E0037006	DAY 1	14MAR2003	1	0	0	0	0
		DAY 57	09MAY2003	57	0	0	0	0
	E0039006	DAY 1	30DEC2002	1	0	0	0	0
		DAY 57	24FEB2003	57	0	0	0	0
	E0039015	DAY 1	23JAN2003	1	0	0	0	0
		DAY 57	20MAR2003	57	0	0	0	0
	E0039024	DAY 1	27FEB2003	1	0	0	0	0
		DAY 57	24APR2003	57	0	0	0	0
	E0039025	DAY 1	18MAR2003	1	0	0	0	0
		DAY 57	27MAY2003	71	0	0	0	0
	E0039041	DAY 1	15APR2003	1	0	0	0	0
		DAY 57	11JUN2003	58	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR I)	E0039044	DAY 1		22MAY2003	1	0	0	0	0
		DAY 57		09JUL2003	49	0	0	0	0
	E0039046		*	30MAY2003		0	0	0	0
			*	21MAY2003		0	0	0	0
	E0039051	DAY 1		16JUN2003	1	0	2	2	2
		DAY 57		12AUG2003	58	0	0	0	0
	E0039053	DAY 1		11JUL2003	1	0	0	0	0
		DAY 57		08SEP2003	60	0	0	0	0
	E0039057	DAY 1		14JUL2003	1	0	0	0	0
		DAY 57		09SEP2003	58	0	0	0	0
	E0041003	DAY 1		28JAN2003	1	0	0	0	0
		DAY 57		25MAR2003	57	0	0	0	0
	E0041008	DAY 1		07APR2003	1	0	0	0	0
		DAY 57		02JUN2003	57	0	0	0	0
	E0042001	DAY 1		02JUL2003	1	0	0	0	0
		DAY 57		26AUG2003	56	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	DAY 1	12MAR2003	1	0	1	0	0
		DAY 57	07MAY2003	57	0	0	0	0
	E0003018	DAY 1	13MAY2003	1	1	1	1	1
		DAY 57	08JUL2003	57	0	1	1	1
	E0005011	DAY 1	24OCT2002	1	1	0	0	1
	E0005030	DAY 1	26MAR2003	1	0	0	0	0
	E0005036	DAY 1	06MAY2003	1	0	1	0	1
		DAY 57	27MAY2003	22	0	1	0	1
	E0006015	DAY 1	11FEB2003	1	0	0	0	0
		DAY 57	08APR2003	57	0	0	0	0
	E0006016	DAY 1	17FEB2003	1	0	1	0	1
		DAY 57	18APR2003	61	0	0	0	0
	E0007008	DAY 1	18APR2003	1	0	1	0	0
		DAY 57	25APR2003	8	0	0	0	0
	E0009002	DAY 1	19NOV2002	1	0	0	0	1
		DAY 57	15JAN2003	58	0	0	0	0
	E0009006	DAY 1	28JAN2003	1	0	0	0	0
		DAY 57	25MAR2003	57	0	0	0	0
	E0009009	DAY 1	12MAR2003	1	0	0	0	0
		DAY 57	24MAR2003	13	0	0	0	0
	E0010015	DAY 1	20FEB2003	1	0	1	1	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0010015	DAY 57	15APR2003	55	1	1	0	2
	E0011004	DAY 1	24DEC2002	1	0	0	0	0
		DAY 57	18FEB2003	57	0	0	0	0
	E0011007	DAY 1	19DEC2002	1	0	0	0	0
		DAY 57	13FEB2003	57	0	0	0	0
	E0011018	DAY 1	22MAY2003	1	0	0	0	0
		DAY 57	17JUL2003	57	1	1	1	2
	E0011024	DAY 1	24JUN2003	1	0	1	1	2
		DAY 57	21AUG2003	59	0	1	0	1
	E0015003	DAY 1	25NOV2002	1	0	0	0	0
		DAY 57	02DEC2002	8	0	0	0	0
	E0019003	DAY 1	21NOV2002	1	1	1	0	0
		DAY 57	16JAN2003	57	0	0	0	0
	E0019007	DAY 1	13NOV2002	1	0	1	0	0
		DAY 57	07JAN2003	56	0	0	0	0
	E0019014	DAY 1	09JAN2003	1	0	0	0	0
		DAY 57	20JAN2003	12	0	0	0	0
	E0019018	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	27MAR2003	57	0	0	0	0
	E0019022	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	27MAR2003	57	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	DAY 1	27FEB2003	1	0	1	0	0
		DAY 57	06MAR2003	8	0	0	0	0
	E0019032	DAY 1	01APR2003	1	0	0	0	0
		DAY 57	27MAY2003	57	0	0	0	0
	E0019034	DAY 1	18MAR2003	1	0	0	0	0
	E0019036	DAY 1	25MAR2003	1	0	1	0	0
	E0019039	DAY 1	01MAY2003	1	0	0	0	0
		DAY 57	08MAY2003	8	0	2	3	3
	E0019041	DAY 1	21MAY2003	1	0	0	0	0
		DAY 57	16JUL2003	57	0	0	0	0
	E0019049	DAY 1	10JUL2003	1	0	0	0	0
		DAY 57	08SEP2003	61	0	0	0	0
	E0022052	DAY 1	10APR2003	1	0	0	0	0
		DAY 57	05JUN2003	57	0	0	0	0
	E0022064	DAY 1	06MAY2003	1	0	0	0	0
		DAY 57	01JUL2003	57	0	0	0	0
	E0022073	DAY 1	26JUN2003	1	0	0	0	0
		DAY 57	21AUG2003	57	0	0	0	0
	E0023002	DAY 1	05NOV2002	1	0	0	0	0
		DAY 57	10DEC2002	36	0	0	0	0
	E0023017	DAY 1	25MAR2003	1	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0023017	DAY 57	22MAY2003	59	0	0	0	0
	E0023021	DAY 1	23APR2003	1	0	0	0	0
		DAY 57	17JUN2003	56	0	0	0	0
	E0023027	DAY 1	16MAY2003	1	0	0	0	0
		DAY 57	09JUL2003	55	0	1	1	0
	E0023030	DAY 1	03JUN2003	1	0	0	0	0
		DAY 57	30JUL2003	58	0	0	0	0
	E0023040	DAY 1	03JUL2003	1	0	0	0	0
		DAY 57	05SEP2003	65	0	0	0	0
	E0026014	DAY 1	19FEB2003	1	0	0	0	0
		DAY 57	19MAR2003	29	0	0	0	0
	E0026019	DAY 1	17MAR2003	1	0	0	0	0
		DAY 57	12MAY2003	57	0	0	0	0
	E0027005	DAY 1	26DEC2002	1	0	1	2	1
		DAY 57	20FEB2003	57	0	1	1	1
	E0029009	DAY 1	20JAN2003	1	0	0	0	0
		DAY 57	18MAR2003	58	0	0	0	0
	E0029021	DAY 1	18MAR2003	1	0	0	0	0
		DAY 57	15MAY2003	59	0	0	0	0
	E0029026	DAY 1	14APR2003	1	0	0	0	0
		DAY 57	10JUN2003	58	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0029030	DAY 1	27MAY2003	1	0	0	0	0
		DAY 57	23JUL2003	58	0	0	0	0
	E0031008	DAY 1	28FEB2003	1	0	1	1	1
		DAY 57	24APR2003	56	0	0	0	0
	E0031020	DAY 1	21APR2003	1	0	1	0	1
		DAY 57	13MAY2003	23	0	0	0	0
	E0031021	DAY 1	25APR2003	1	0	1	0	0
		DAY 57	19JUN2003	56	0	1	1	1
	E0031029	DAY 1	18JUN2003	1	0	0	0	0
	E0033002	DAY 1	10JAN2003	1	0	0	0	0
		DAY 57	07MAR2003	57	0	0	0	0
	E0033006	DAY 1	23JAN2003	1	0	1	1	1
	E0033021	DAY 1	02JUL2003	1	1	0	0	0
		DAY 57	18AUG2003	48	0	0	0	0
	E0035013	DAY 1	04FEB2003	1	0	0	0	0
		DAY 57	10FEB2003	7	0	0	0	0
	E0035015	DAY 1	11FEB2003	1	0	0	0	0
		DAY 57	18FEB2003	8	0	0	0	0
	E0035016	DAY 1	04APR2003	1	0	0	0	1
	E0035023	DAY 1	13MAY2003	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 300 MG (BIPOLAR II)	E0039052	DAY 1	20JUN2003	1	0	0	0	0
		DAY 57	03JUL2003	14	0	0	0	0
	E0039056	DAY 1	14JUL2003	-1	0	0	0	0
	E0040003	DAY 1	18JUL2003	-1	0	0	0	0
		DAY 57	12SEP2003	56	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	DAY 1	03MAR2003	1	1	1	1	1
		DAY 57	02MAY2003	61	0	0	0	0
	E0002011	DAY 1	29APR2003	1	0	0	0	0
		DAY 57	25JUN2003	58	0	0	0	1
	E0003010	DAY 1	03FEB2003	1	0	0	0	0
		DAY 57	31MAR2003	57	0	0	0	0
	E0003011	DAY 1	04FEB2003	1	0	0	0	0
	E0003016	DAY 1	22MAY2003	1	0	2	1	1
		DAY 57	12JUN2003	22	1	2	2	2
	E0003019	DAY 1	27JUN2003	1	1	1	1	0
		DAY 57	21AUG2003	56	0	0	0	0
	E0003020	DAY 1	23JUL2003	1	0	0	0	0
		DAY 57	17SEP2003	57	0	0	0	0
	E0004001	DAY 1	30SEP2002	1	1	1	0	1
	E0004009	DAY 1	26DEC2002	1	0	0	0	0
		DAY 57	19FEB2003	56	0	0	0	0
	E0004012	DAY 1	14JAN2003	1	0	0	0	0
		DAY 57	11MAR2003	57	0	0	0	0
	E0004015	DAY 1	20FEB2003	1	0	0	0	0
		DAY 57	15APR2003	55	0	0	0	0
	E0005003	DAY 1	02OCT2002	1	1	1	0	1

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QUETIAPINE 600 MG (BIPOLAR I)	E0005003	DAY 57	26NOV2002	56	0	0	0	0
	E0005005	DAY 1	30SEP2002	1	1	1	0	1
	E0005007	DAY 1	09OCT2002	1	0	1	1	1
		DAY 57	04DEC2002	57	1	1	1	1
	E0005008	DAY 1	15OCT2002	1	0	0	0	0
		DAY 57	11DEC2002	58	0	0	0	0
	E0005009	DAY 1	29OCT2002	1	1	1	1	1
	E0005010	DAY 1	21OCT2002	1	2	1	1	2
		DAY 57	17DEC2002	58	0	0	0	0
	E0005012	DAY 1	14NOV2002	1	1	1	1	1
		DAY 57	07JAN2003	55	0	0	0	0
	E0005014	DAY 1	13NOV2002	1	2	1	1	1
		DAY 57	06JAN2003	55	1	1	1	1
	E0005022	DAY 1	29JAN2003	1	1	1	1	1
		DAY 57	06MAR2003	37	1	0	0	0
	E0005025	DAY 1	27FEB2003	1	1	1	1	1
		DAY 57	03APR2003	36	0	0	0	0
	E0006019	DAY 1	07APR2003	1	0	0	0	0
		DAY 57	03JUN2003	58	0	0	0	0
	E0007005	DAY 1	31JAN2003	1	0	0	0	0
		DAY 57	28MAR2003	57	0	0	0	0

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QUETIAPINE 600 MG (BIPOLAR I)	E0007015	DAY 1	16JUL2003	1	0	0	0	0
		DAY 57	10SEP2003	57	0	0	0	0
	E0009001	DAY 1	12NOV2002	1	0	0	0	0
	E0010002	DAY 1	25NOV2002	1	0	1	1	1
		DAY 57	02DEC2002	8	0	1	1	2
	E0010009	DAY 1	26DEC2002	1	0	0	0	0
		DAY 57	19FEB2003	56	0	0	0	1
	E0010010	DAY 1	30DEC2002	1	1	1	0	1
		DAY 57	13JAN2003	15	0	1	0	1
	E0010014	DAY 1	28JAN2003	1	0	1	1	1
		DAY 57	25MAR2003	57	0	0	0	0
	E0010017	DAY 1	25FEB2003	1	0	1	1	1
		DAY 57	22APR2003	57	0	0	0	0
	E0010023	DAY 1	17APR2003	1	0	1	2	2
		DAY 57	01MAY2003	15	1	1	1	1
	E0010027	DAY 1	16JUN2003	1	0	1	2	3
		DAY 57	01JUL2003	16	0	1	1	1
	E0010029	DAY 1	19JUN2003	1	0	1	0	1
	E0011022	DAY 1	09JUN2003	1	1	1	1	2
		DAY 57	05AUG2003	58	1	1	1	1
	E0013006	DAY 1	13MAR2003	1	0	1	1	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0013006	DAY 57	24MAR2003	12	0	0	0	0
	E0013012	DAY 1	07MAY2003	1	0	0	0	0
		DAY 57	02JUL2003	57	0	0	0	0
	E0013014	DAY 1	03JUN2003	1	0	0	0	0
		DAY 57	30JUN2003	28	0	0	0	0
	E0014005	DAY 1	11MAR2003	1	1	1	0	1
		DAY 57	06MAY2003	57	0	0	0	0
	E0014007	DAY 1	01APR2003	1	0	0	0	0
		DAY 57	22APR2003	22	0	0	0	0
	E0014011	DAY 1	13MAY2003	1	0	1	1	1
		DAY 57	08JUL2003	57	0	0	0	0
	E0014012	DAY 1	27MAY2003	1	1	1	1	1
		DAY 57	24JUN2003	29	1	2	2	3
	E0015001	DAY 1	29NOV2002	1	0	0	0	0
		DAY 57	20JAN2003	53	0	0	0	0
	E0015008	DAY 1	19DEC2002	1	0	0	0	0
	E0016003	DAY 1	24JAN2003	1	0	0	0	0
	E0016005	DAY 1	25FEB2003	1	0	0	0	0
		DAY 57	22APR2003	57	0	0	0	0
	E0018007	DAY 1	27DEC2002	1	0	0	0	0
		DAY 57	10JAN2003	15	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0019005	DAY 1	05NOV2002	1	0	0	0	0
		DAY 57	02JAN2003	59	0	0	0	0
	E0019015	DAY 1	02JAN2003	1	0	0	0	0
		DAY 57	27FEB2003	57	0	0	0	0
	E0020004	DAY 1	09DEC2002	1	0	0	0	0
		DAY 57	22JAN2003	45	0	0	0	0
	E0020010	DAY 1	05FEB2003	1	0	1	0	0
		DAY 57	02APR2003	57	0	0	0	0
	E0020014	DAY 1	18MAR2003	1	0	0	0	0
		DAY 57	12MAY2003	56	0	0	0	0
	E0020021	DAY 1	19MAY2003	1	0	0	0	0
		DAY 57	14JUL2003	57	0	0	0	0
	E0020023	DAY 1	16JUN2003	-1	0	0	0	0
		DAY 57	11AUG2003	56	0	0	0	0
	E0022007	DAY 1	07NOV2002	1	0	0	0	0
	E0022010	DAY 1	21NOV2002	1	0	1	0	1
		DAY 57	16JAN2003	57	0	0	0	0
	E0022012	DAY 1	05DEC2002	1	0	0	0	0
		DAY 57	30JAN2003	57	0	0	0	0
	E0022019	DAY 1	11DEC2002	1	0	0	0	0
		DAY 57	06FEB2003	58	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
OBJECTIVE RATING: 0=NORMAL, 1=[RESTLESS MOVEMENTS] LESS THAN HALF THE TIME, 2=AT LEAST HALF THE TIME, 3=CONSTANT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022025	DAY 1	28JAN2003	1	0	0	0	0
		DAY 57	04FEB2003	8	1	2	2	3
	E0022033	DAY 1	18FEB2003	1	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0
	E0022034	DAY 1	18FEB2003	1	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0
	E0022038	DAY 1	28FEB2003	1	0	0	0	0
		DAY 57	11APR2003	43	0	0	0	0
	E0022039	DAY 1	06MAR2003	1	0	0	0	0
		DAY 57	01MAY2003	57	0	0	0	0
	E0022046	DAY 1	20MAR2003	1	0	0	0	0
		DAY 57	16MAY2003	58	0	0	0	0
	E0022048	DAY 1	01APR2003	1	0	0	0	0
	E0022051	DAY 1	07APR2003	1	0	0	0	0
		DAY 57	02JUN2003	57	0	0	0	0
	E0022053	DAY 1	11APR2003	1	0	0	0	0
	E0022058	DAY 1	21APR2003	1	0	0	0	0
		DAY 57	22MAY2003	32	0	0	0	0
	E0022061	DAY 1	30APR2003	1	0	0	0	0
		DAY 57	26JUN2003	58	0	0	0	0
	E0022062	DAY 1	05MAY2003	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0022062	DAY 57	23MAY2003	19	0	0	0	0
	E0022068	DAY 1	22MAY2003	-1	0	0	0	0
	E0022069	DAY 1	10JUN2003	1	0	0	0	0
		DAY 57	05AUG2003	57	0	0	0	0
	E0022071	DAY 1	30JUN2003	1	0	0	0	0
		DAY 57	25AUG2003	57	0	0	0	0
	E0023003	DAY 1	17DEC2002	1	0	0	0	0
		DAY 57	11FEB2003	57	0	0	0	0
	E0023006	DAY 1	17DEC2002	1	0	0	0	0
		DAY 57	11FEB2003	57	0	0	0	0
	E0023010	DAY 1	04FEB2003	1	0	0	0	0
		DAY 57	31MAR2003	56	0	0	0	0
	E0023025	DAY 1	15MAY2003	1	0	0	0	0
		DAY 57	10JUL2003	57	0	0	0	0
	E0023039	DAY 1	01JUL2003	1	0	0	0	0
		DAY 57	26AUG2003	57	0	0	0	0
	E0026002	DAY 1	12NOV2002	1	0	1	1	1
		DAY 57	09JAN2003	59	0	0	0	0
	E0026007	DAY 1	16JAN2003	1	0	1	0	1
		DAY 57	12MAR2003	56	0	0	0	0
	E0026013	DAY 1	13FEB2003	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	DAY 1	04OCT2002	1	0	0	0	0
		DAY 57	14NOV2002	42	0	0	0	0
	E0028023	DAY 1	21JAN2003	1	0	0	0	0
	E0028025	DAY 1	13JAN2003	1	0	0	0	0
		DAY 57	27JAN2003	15	0	0	0	0
	E0028033	DAY 1	27MAR2003	1	0	0	0	0
		DAY 57	22MAY2003	57	0	0	0	0
	E0028035	DAY 1	03APR2003	1	0	0	0	0
		DAY 57	29MAY2003	57	0	0	0	0
	E0028037	DAY 1	12JUN2003	-1	0	0	0	0
		DAY 57	08AUG2003	57	0	0	0	0
	E0028039	DAY 1	08MAY2003	-1	0	0	0	0
		DAY 57	05JUN2003	28	0	0	0	0
	E0028046	DAY 1	25JUN2003	1	0	0	0	0
	E0028048	DAY 1	17JUL2003	1	0	0	0	0
	E0029008	DAY 1	16DEC2002	1	1	2	1	2
		DAY 57	23DEC2002	8	0	0	0	0
	E0029011	DAY 1	21JAN2003	-1	0	0	0	0
	E0029012	DAY 1	11FEB2003	1	0	0	0	0
		DAY 57	18MAR2003	36	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0029015	DAY 1	24FEB2003	1	3	2	2	2
		DAY 57	11MAR2003	16	3	2	2	4
	E0029018	DAY 1	06MAR2003	1	0	0	0	0
	E0030014	DAY 1	21FEB2003	1	0	1	2	1
		DAY 57	22APR2003	61	0	1	0	0
	E0030020	DAY 1	29MAY2003	1	1	1	2	1
	E0030024	DAY 1	11JUL2003	1	0	1	1	0
		DAY 57	18JUL2003	8	0	1	1	1
	E0030025	DAY 1	11JUL2003	1	0	1	2	0
		DAY 57	19AUG2003	40	0	0	0	0
	E0031027	DAY 1	03JUN2003	1	0	0	0	0
		DAY 57	29JUL2003	57	0	0	0	0
	E0031030	DAY 1	24JUN2003	1	0	0	0	0
		DAY 57	21AUG2003	59	0	2	2	2
	E0033012	DAY 1	10FEB2003	1	0	0	0	0
	E0034001	DAY 1	20MAR2003	1	0	0	0	0
		DAY 57	15MAY2003	57	0	0	0	0
	E0034004	DAY 1	21APR2003	1	0	0	0	0
		DAY 57	16JUN2003	57	0	0	0	0
	E0035001	DAY 1	20NOV2002	1	0	0	0	0
		DAY 57	14JAN2003	56	1	0	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0035006	DAY 1	12DEC2002	1	0	0	0	0
		DAY 57	06FEB2003	57	0	0	0	0
	E0035021	DAY 1	25APR2003	1	0	0	0	0
		DAY 57	20JUN2003	57	0	0	0	0
	E0036002	DAY 1	17JUN2003	1	1	2	0	2
		DAY 57	14JUL2003	28	2	3	3	4
	E0036006	DAY 1	03JUL2003	1	1	2	2	3
		DAY 57	27AUG2003	56	0	0	0	0
	E0036007	DAY 1	03JUL2003	1	0	1	0	1
		DAY 57	18JUL2003	16	1	0	0	1
	E0037009	DAY 1	16MAY2003	1	0	0	0	0
		DAY 57	10JUL2003	56	0	0	0	0
	E0039011	DAY 1	02JAN2003	1	2	2	2	3
	E0039018	DAY 1	23JAN2003	1	0	0	0	0
	E0039026	DAY 1	07MAR2003	1	0	0	0	0
		DAY 57	01MAY2003	56	0	0	0	0
	E0039028	DAY 1	24MAR2003	1	0	0	0	0
	E0039032	DAY 1	14MAR2003	1	0	0	0	0
		DAY 57	28MAR2003	15	0	0	0	0
	E0039034	DAY 1	19MAR2003	1	0	0	0	0
		DAY 57	14MAY2003	57	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR I)	E0039042	DAY 1	07MAY2003	1	0	0	0	0
		DAY 57	02JUL2003	57	0	0	0	0
	E0041004	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	31MAR2003	61	0	0	0	0
	E0041009	DAY 1	01MAY2003	1	0	0	0	0
	E0042002	DAY 1	09JUL2003	1	0	0	0	0
		DAY 57	02SEP2003	56	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0001006	DAY 1	11JUL2003	1	0	1	1	1
		DAY 57	18JUL2003	8	0	1	0	0
	E0003002	DAY 1	29OCT2002	1	0	1	0	1
		DAY 57	23DEC2002	56	0	0	0	0
	E0005031	DAY 1	02APR2003	1	1	1	0	1
	E0005033	DAY 1	15APR2003	-1	0	0	0	0
		DAY 57	06MAY2003	21	0	0	0	0
	E0005038	DAY 1	14MAY2003	1	0	0	0	0
		DAY 57	05JUN2003	23	3	2	3	3
	E0007009	DAY 1	17APR2003	1	0	1	0	0
		DAY 57	28APR2003	12	0	0	0	0
	E0009010	DAY 1	13MAR2003	1	0	0	0	0
	E0009011	DAY 1	06MAY2003	1	0	1	0	1
		DAY 57	03JUL2003	59	0	0	0	0
	E0010005	DAY 1	18DEC2002	1	0	0	0	1
	E0011016	DAY 1	21APR2003	1	0	1	0	0
		DAY 57	16JUN2003	57	0	1	1	1
	E0011020	DAY 1	08MAY2003	1	0	1	1	1
		DAY 57	15MAY2003	8	0	0	0	0
	E0018002	DAY 1	29NOV2002	1	0	1	0	0
		DAY 57	22JAN2003	55	0	1	1	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0018003	DAY 1	26NOV2002	1	0	0	0	0
		DAY 57	10DEC2002	15	0	1	0	0
	E0018013	DAY 1	24JAN2003	1	0	1	0	1
		DAY 57	31JAN2003	8	1	2	2	2
	E0019002	DAY 1	12NOV2002	1	0	0	0	0
	E0019008	DAY 1	21NOV2002	1	0	0	0	0
	E0019009	DAY 1	14NOV2002	1	0	0	0	0
	E0019016	DAY 1	06JAN2003	1	0	0	0	0
		DAY 57	03MAR2003	57	0	0	0	0
	E0019020	DAY 1	23JAN2003	1	0	0	0	0
		DAY 57	27MAR2003	64	0	0	0	0
	E0019021	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	03MAR2003	33	0	0	0	0
	E0019024	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	06FEB2003	8	0	0	0	0
	E0019031	DAY 1	13MAR2003	1	0	0	0	0
		DAY 57	25MAR2003	13	0	0	0	0
	E0019035	DAY 1	18MAR2003	1	0	0	0	0
		DAY 57	17APR2003	31	0	0	0	0
	E0019040	DAY 1	20MAY2003	1	0	0	0	0
		DAY 57	17JUL2003	59	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0019042	DAY 1	04JUN2003	1	0	0	0	0
		DAY 57	19JUN2003	16	0	0	0	0
	E0019045	DAY 1	26JUN2003	1	0	0	0	0
		DAY 57	16JUL2003	21	0	0	0	0
	E0020024	DAY 1	23JUN2003	1	0	0	0	0
		DAY 57	20AUG2003	59	0	0	0	0
	E0022044	DAY 1	18MAR2003	1	0	0	0	0
		DAY 57	12MAY2003	56	0	0	0	0
	E0023007	DAY 1	14JAN2003	1	0	0	0	0
		DAY 57	11MAR2003	57	0	0	0	0
	E0023011	DAY 1	04FEB2003	1	0	1	1	1
		DAY 57	01APR2003	57	0	0	0	0
	E0023014	DAY 1	21FEB2003	1	0	0	0	0
		DAY 57	25APR2003	64	0	0	0	0
	E0023019	DAY 1	07APR2003	1	0	0	0	0
		DAY 57	03JUN2003	58	0	0	0	0
	E0023022	DAY 1	18APR2003	1	0	0	0	0
		DAY 57	12JUN2003	56	0	0	0	0
	E0023023	DAY 1	25APR2003	1	0	0	0	0
		DAY 57	01MAY2003	7	0	0	0	0
	E0023029	DAY 1	23MAY2003	1	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0023031	DAY 1	24JUN2003	1	0	0	0	0
		DAY 57	19AUG2003	57	0	0	0	0
	E0023041	DAY 1	09JUL2003	1	1	1	0	0
		DAY 57	05SEP2003	59	0	0	0	0
	E0023043	DAY 1	14JUL2003	1	0	0	0	0
		DAY 57	09SEP2003	58	0	0	0	0
	E0026003	DAY 1	04DEC2002	1	0	0	0	0
		DAY 57	03FEB2003	62	0	0	0	0
	E0026005	DAY 1	30DEC2002	1	0	0	0	0
		DAY 57	06JAN2003	8	0	0	0	0
	E0026009	DAY 1	15JAN2003	1	0	1	0	0
		DAY 57	21JAN2003	7	0	0	0	1
	E0026015	DAY 1	27FEB2003	1	3	0	0	0
		DAY 57	25APR2003	58	2	2	2	3
	E0026023	DAY 1	30APR2003	1	0	0	0	0
	E0027016	DAY 1	09APR2003	1	0	1	1	0
		DAY 57	03JUN2003	56	0	1	1	1
	E0027018	DAY 1	25MAR2003	1	0	0	0	0
		DAY 57	22MAY2003	59	0	0	0	0
	E0028032	DAY 1	25MAR2003	1	0	0	0	0
		DAY 57	06JUN2003	74	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0029003	DAY 1	04NOV2002	1	1	2	1	2
		DAY 57	30DEC2002	57	1	1	1	2
	E0029020	DAY 1	04MAR2003	-1	0	0	0	0
	E0031005	DAY 1	20DEC2002	1	0	0	0	0
		DAY 57	14FEB2003	57	0	0	0	0
	E0031006	DAY 1	18FEB2003	1	0	0	0	0
		DAY 57	15APR2003	57	0	0	0	0
	E0031010	DAY 1	19FEB2003	1	0	0	0	0
		DAY 57	05MAR2003	15	0	0	0	0
	E0031011	DAY 1	27FEB2003	1	1	1	0	1
		DAY 57	24APR2003	57	0	0	0	0
	E0031015	DAY 1	26MAR2003	1	0	1	1	1
		DAY 57	01APR2003	7	0	1	0	0
	E0031031	DAY 1	08JUL2003	1	0	1	0	0
		DAY 57	28AUG2003	52	1	2	1	2
	E0033009	DAY 1	12FEB2003	1	0	0	0	0
	E0034009	DAY 1	19JUN2003	1	0	0	0	0
		DAY 57	18AUG2003	61	0	0	0	0
	E0037007	DAY 1	11APR2003	1	0	0	0	0
	E0037012	DAY 1	16JUL2003	1	0	0	0	0
		DAY 57	08SEP2003	55	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	DAY 1	06FEB2003	1	0	0	0	0
		DAY 57	03APR2003	57	0	0	0	0
	E0039043	DAY 1	08MAY2003	1	0	0	0	0
		DAY 57	13JUN2003	37	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0002001	DAY 1	30DEC2002	1	0	1	2	1
		DAY 57	26FEB2003	59	0	0	0	0
	E0002003	DAY 1	22JAN2003	1	0	0	0	0
		DAY 57	18MAR2003	56	0	0	0	0
	E0002004	DAY 1	25JAN2003	1	0	1	1	0
	E0002008	DAY 1	25FEB2003	1	0	0	0	0
		DAY 57	23APR2003	58	0	0	0	0
	E0002016	DAY 1	24JUL2003	1	0	0	0	0
		DAY 57	17SEP2003	56	0	0	0	0
	E0003008	DAY 1	28JAN2003	1	0	0	0	0
	E0004003	DAY 1	10OCT2002	1	2	2	0	2
	E0004006	DAY 1	04NOV2002	1	0	0	0	0
		DAY 57	06JAN2003	64	0	0	0	0
	E0004016	DAY 1	19FEB2003	1	0	0	0	0
		DAY 57	17APR2003	58	0	0	0	0
	E0004024	DAY 1	03JUL2003	1	0	0	0	0
		DAY 57	28AUG2003	57	0	0	0	0
	E0005006	DAY 1	03OCT2002	1	1	1	0	1
	E0005017	DAY 1	30DEC2002	1	1	1	1	1
		DAY 57	04MAR2003	65	1	1	1	1

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0005019	DAY 1	15JAN2003	1	0	0	0	0
		DAY 57	23JAN2003	9	0	0	0	0
	E0005026	DAY 1	06MAR2003	1	0	0	0	0
		DAY 57	25MAR2003	20	0	1	0	1
	E0005039	DAY 1	22MAY2003	1	1	1	1	1
		DAY 57	16JUL2003	56	1	1	1	1
	E0005043	DAY 1	09JUL2003	1	0	0	0	0
		DAY 57	03SEP2003	57	0	0	0	0
	E0006020	DAY 1	13MAY2003	1	0	0	0	0
		DAY 57	08JUL2003	57	0	0	0	0
	E0007001	DAY 1	31DEC2002	1	0	0	0	0
		DAY 57	22FEB2003	54	0	0	0	0
	E0007003	DAY 1	30JAN2003	1	1	1	0	1
		DAY 57	10MAR2003	40	0	0	0	0
	E0007006	DAY 1	05MAR2003	1	0	1	0	1
		DAY 57	26MAR2003	22	0	0	0	0
	E0009004	DAY 1	26NOV2002	1	2	2	2	3
		DAY 57	18DEC2002	23	1	1	1	2
	E0009012	DAY 1	25JUN2003	1	0	1	0	1
		DAY 57	03JUL2003	9	0	0	0	0
	E0010008	DAY 1	18DEC2002	1	1	2	2	3

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SUBJECTIVE AWARENESS: 0=ABSENT, 1=NONSPECIFIC, 2=AWARE OF RESTLESSNESS, 3=AWARE OF INTENSE COMPULSION TO MOVE.
SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0010018	DAY 1	19MAR2003	1	0	1	0	1
		DAY 57	14MAY2003	57	0	0	0	0
	E0010028	DAY 1	16JUN2003	1	1	1	3	3
	E0011008	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	13FEB2003	15	0	0	0	0
	E0011009	DAY 1	26DEC2002	-1	0	1	1	1
		DAY 57	20FEB2003	56	0	1	0	1
	E0011010	DAY 1	10FEB2003	1	0	0	0	0
		DAY 57	19MAR2003	38	0	0	0	0
	E0013001	DAY 1	14NOV2002	1	0	1	0	0
		DAY 57	10JAN2003	58	0	0	0	0
	E0013003	DAY 1	12NOV2002	1	0	0	0	0
		DAY 57	06JAN2003	56	0	0	0	0
	E0013005	DAY 1	18FEB2003	1	0	1	0	0
		DAY 57	15APR2003	57	0	0	0	0
	E0013013	DAY 1	06MAY2003	1	0	0	0	0
		DAY 57	30MAY2003	25	0	0	0	0
	E0014002	DAY 1	26FEB2003	1	1	1	0	1
		DAY 57	10APR2003	44	0	0	0	0
	E0014004	DAY 1	12MAR2003	1	0	0	0	0
		DAY 57	15APR2003	35	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0014009	DAY 1	23APR2003	1	0	0	0	0
		DAY 57	16MAY2003	24	0	0	0	0
	E0014015	DAY 1	18JUN2003	1	0	0	0	0
	E0014017	DAY 1	27JUN2003	1	0	1	0	0
		DAY 57	19AUG2003	54	0	1	1	1
	E0014018	DAY 1	01JUL2003	1	0	0	0	0
		DAY 57	27AUG2003	58	0	0	0	0
	E0015005	DAY 1	02DEC2002	1	0	0	0	0
		DAY 57	18DEC2002	17	0	1	1	0
	E0017002	DAY 57	13JUN2003	11	0	0	0	0
	E0018009	DAY 1	06JAN2003	1	0	0	0	0
		DAY 57	14JAN2003	9	0	0	0	0
	E0018010	DAY 1	16JAN2003	1	0	0	0	0
		DAY 57	13MAR2003	57	0	0	0	0
	E0018015	DAY 1	28JAN2003	1	0	0	0	0
		DAY 57	27MAR2003	59	0	0	0	0
	E0020015	DAY 1	27MAR2003	1	0	0	0	0
		DAY 57	23MAY2003	58	0	0	0	0
	E0020017	DAY 1	03APR2003	1	0	0	0	0
	E0020020	DAY 1	12MAY2003	1	0	0	0	0
		DAY 57	23MAY2003	12	0	1	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0020022	DAY 1	16JUN2003	1	0	0	0	0
		DAY 57	11AUG2003	57	0	0	0	0
	E0022001	DAY 1	28OCT2002	1	0	0	0	0
		DAY 57	26DEC2002	60	0	0	0	0
	E0022004	DAY 1	28OCT2002	1	0	0	0	0
		DAY 57	23DEC2002	57	0	0	0	0
	E0022005	DAY 1	08NOV2002	1	0	1	1	1
		DAY 57	03JAN2003	57	0	0	0	0
	E0022011	DAY 1	29NOV2002	1	0	0	0	0
	E0022015	DAY 1	10DEC2002	1	0	0	0	0
		DAY 57	06FEB2003	59	0	0	0	0
	E0022016	DAY 1	17DEC2002	1	0	0	0	0
		DAY 57	11FEB2003	57	0	0	0	0
	E0022020	DAY 1	12DEC2002	1	0	0	0	0
		DAY 57	23JAN2003	43	0	0	0	0
	E0022023	DAY 1	24DEC2002	-1	0	0	0	0
		DAY 57	20FEB2003	58	0	0	0	0
	E0022029	DAY 1	19FEB2003	1	0	0	0	0
		DAY 57	14APR2003	55	0	0	0	0
	E0022041	DAY 1	18MAR2003	1	0	0	0	0
		DAY 57	13MAY2003	57	0	0	0	0

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0022042	DAY 1	12MAR2003	1	0	0	0	0
		DAY 57	12MAY2003	62	0	0	0	0
	E0022043	DAY 1	20MAR2003	1	0	0	0	0
		DAY 57	12MAY2003	54	0	0	0	0
	E0022054	DAY 1	11APR2003	1	0	0	0	0
	E0022059	DAY 1	06MAY2003	1	0	0	0	0
		DAY 57	08JUL2003	64	0	0	0	0
	E0022065	DAY 1	07MAY2003	1	0	0	0	0
		DAY 57	02JUL2003	57	0	1	0	0
	E0022070	DAY 1	12JUN2003	1	0	0	0	0
		DAY 57	18JUN2003	7	0	0	0	0
	E0023001	DAY 1	15NOV2002	1	0	0	0	0
		DAY 57	14JAN2003	61	0	0	0	0
	E0023009	DAY 1	11FEB2003	1	0	0	0	0
		DAY 57	08APR2003	57	0	0	0	0
	E0023028	DAY 1	29MAY2003	1	0	0	0	0
		DAY 57	21JUL2003	54	0	0	0	0
	E0023033	DAY 1	05JUN2003	1	0	0	0	0
		DAY 57	12JUN2003	8	0	0	0	0
	E0023047	DAY 1	18JUL2003	1	0	0	0	0
		DAY 57	12SEP2003	57	0	0	0	0

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PLACEBO (BIPOLAR I)	E0025001	DAY 1	01APR2003	1	0	0	0	0
		DAY 57	23APR2003	23	0	0	0	0
	E0026012	DAY 1	20FEB2003	1	0	0	0	0
		DAY 57	17APR2003	57	0	0	0	0
	E0026020	DAY 1	01APR2003	1	0	1	1	1
		DAY 57	22APR2003	22	0	0	0	0
	E0026024	DAY 1	02MAY2003	1	2	1	0	2
	E0026028	DAY 1	20JUN2003	1	0	0	0	0
		DAY 57	23JUL2003	34	0	0	0	0
	E0028001	DAY 1	10OCT2002	1	0	0	0	0
		DAY 57	03DEC2002	55	0	0	0	0
	E0028003	DAY 1	30SEP2002	1	0	0	0	0
		DAY 57	26NOV2002	58	0	0	0	0
	E0028005	DAY 1	03OCT2002	1	0	1	1	0
		DAY 57	31OCT2002	29	0	0	0	0
	E0028010	DAY 1	05NOV2002	1	0	0	0	0
		DAY 57	31DEC2002	57	0	0	0	0
	E0028011	DAY 1	05DEC2002	1	0	0	0	0
		DAY 57	30JAN2003	57	0	0	0	0
	E0028030	DAY 1	04MAR2003	1	0	0	0	0
		DAY 57	30APR2003	58	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0028031	DAY 1	11MAR2003	1	0	0	0	0
	E0028047	DAY 1	14JUL2003	1	0	0	0	0
		DAY 57	09SEP2003	58	0	0	0	0
	E0029001	DAY 1	01OCT2002	1	0	2	1	0
	E0029014	DAY 1	04FEB2003	1	0	1	0	1
		DAY 57	01APR2003	57	0	0	0	0
	E0029023	DAY 1	08APR2003	1	0	0	0	0
		DAY 57	10JUN2003	64	0	0	0	0
	E0029032	DAY 1	10JUN2003	1	0	0	0	0
		DAY 57	01JUL2003	22	0	2	2	1
	E0029033	DAY 1	02JUN2003	1	1	0	0	1
		DAY 57	30JUN2003	29	1	1	2	2
	E0029039	DAY 1	15JUL2003	1	0	0	0	0
		DAY 57	28JUL2003	14	0	1	1	1
	E0030003	DAY 1	16DEC2002	1	0	1	1	1
		DAY 57	24DEC2002	9	0	0	0	0
	E0030009	DAY 1	23JAN2003	1	1	2	1	2
		DAY 57	19MAR2003	56	0	1	1	0
	E0030016	DAY 1	03MAR2003	1	0	0	0	0
		DAY 57	22APR2003	51	0	0	0	0
	E0030021	DAY 1	20MAY2003	1	2	2	1	2

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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OBJECTIVE RATING: 0=NORMAL, 1=[RESTLESS MOVEMENTS] LESS THAN HALF THE TIME, 2=AT LEAST HALF THE TIME, 3=CONSTANT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0031001	DAY 1	21NOV2002	1	0	0	0	0
	E0031017	DAY 1	01APR2003	1	0	0	0	0
		DAY 57	29APR2003	29	0	0	0	0
	E0031018	DAY 1	10APR2003	1	0	0	0	0
	E0031023	DAY 1	29APR2003	1	0	1	1	1
		DAY 57	24JUN2003	57	0	0	0	0
	E0033001	DAY 1	09JAN2003	1	0	0	0	0
		DAY 57	30JAN2003	22	0	0	0	0
	E0033004	DAY 1	17JAN2003	1	0	0	0	0
		DAY 57	14MAR2003	57	0	0	0	1
	E0033010	DAY 1	04FEB2003	1	0	0	0	0
		DAY 57	26MAR2003	51	0	0	0	0
	E0033014	DAY 1	19MAR2003	1	0	0	0	0
	E0035002	DAY 1	21NOV2002	1	0	0	0	1
	E0035007	DAY 1	19DEC2002	1	0	0	0	0
		DAY 57	11FEB2003	55	0	0	0	0
	E0035011	DAY 1	04FEB2003	1	0	0	0	0
		DAY 57	01APR2003	57	0	0	0	0
	E0035020	DAY 1	18APR2003	1	0	0	0	0
		DAY 57	13JUN2003	57	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SUBJECTIVE DISTRESS: 0=NONE, 1=MILD, 2=MODERATE, 3=SEVERE.
GLOBAL CLINICAL ASSESSMENT: 0=ABSENT, 1=QUESTIONABLE, 2=MILD, 3=MODERATE, 4=MARKED, 5=SEVERE.

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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0037003	DAY 1	30JAN2003	1	0	0	0	0
		DAY 57	20FEB2003	22	0	0	0	0
	E0037004	DAY 1	13FEB2003	1	0	0	0	0
		DAY 57	10APR2003	57	0	0	0	0
	E0039007	DAY 1	04DEC2002	1	0	0	0	0
		DAY 57	29JAN2003	57	0	0	0	0
	E0039022	DAY 1	25FEB2003	1	0	0	0	0
		DAY 57	24APR2003	59	0	0	0	0
	E0039023	DAY 1	24FEB2003	1	0	0	0	0
	E0039030	DAY 1	24MAR2003	1	0	0	0	0
		DAY 57	19MAY2003	57	0	0	0	0
	E0039031	DAY 1	24MAR2003	1	0	0	0	0
		DAY 57	20MAY2003	58	0	0	0	0
	E0039037	DAY 1	16APR2003	1	0	0	0	0
		DAY 57	12JUN2003	58	0	0	0	0
	E0039038	DAY 1	23APR2003	1	0	0	0	0
		DAY 57	20JUN2003	59	0	0	0	0
	E0039047	DAY 1	19MAY2003	1	0	0	0	0
		DAY 57	14JUL2003	57	0	0	0	0
	E0039059	DAY 1	11JUL2003	1	0	0	0	0
		DAY 57	05SEP2003	57	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR I)	E0041007	DAY 1	13MAR2003	1	0	0	0	0
		DAY 57	08MAY2003	57	0	0	0	0
	E0041010	DAY 1	30APR2003	1	0	0	0	0
		DAY 57	11JUN2003	43	0	0	0	0
	E0041011	DAY 1	22MAY2003	1	0	0	0	0
		DAY 57	17JUL2003	57	0	0	0	0
	E0041012	DAY 1	19JUN2003	1	0	0	0	0
		DAY 57	14AUG2003	57	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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OBJECTIVE RATING: 0=NORMAL, 1=[RESTLESS MOVEMENTS] LESS THAN HALF THE TIME, 2=AT LEAST HALF THE TIME, 3=CONSTANT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR II)	E0001004	DAY 1	01MAY2003	1	0	1	0	1
		DAY 57	27JUN2003	58	0	0	0	0
	E0005023	DAY 1	05FEB2003	1	1	0	0	1
		DAY 57	01APR2003	56	1	0	0	1
	E0005034	DAY 1	15APR2003	1	0	0	0	0
		DAY 57	09JUN2003	56	0	0	0	0
	E0005041	DAY 1	24JUN2003	1	0	0	0	0
		DAY 57	18AUG2003	56	1	1	1	1
	E0007004	DAY 1	30JAN2003	1	0	1	0	1
		DAY 57	12FEB2003	14	0	0	0	0
	E0007010	DAY 1	18APR2003	1	0	1	0	0
		DAY 57	16JUN2003	60	0	0	0	0
	E0007012	DAY 1	16MAY2003	1	0	0	0	0
		DAY 57	01JUL2003	47	0	0	0	1
	E0009007	DAY 1	03FEB2003	1	0	0	0	0
		DAY 57	03MAR2003	29	0	0	0	0
	E0009008	DAY 1	12FEB2003	1	0	0	0	0
		DAY 57	08APR2003	56	0	0	0	0
	E0011001	DAY 1	01NOV2002	1	1	1	1	2
		DAY 57	26DEC2002	56	0	0	0	0
	E0011011	DAY 1	20FEB2003	1	0	0	0	0
		DAY 57	16APR2003	56	0	1	0	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR II)	E0011013	DAY 1	17APR2003	1	0	0	0	0
		DAY 57	12JUN2003	57	0	1	1	1
	E0011014	DAY 1	07APR2003	1	0	1	0	1
		DAY 57	08MAY2003	32	0	0	0	0
	E0011021	DAY 1	22MAY2003	1	0	1	1	1
		DAY 57	21JUL2003	61	0	0	0	0
	E0013008	DAY 1	26MAR2003	1	0	1	0	0
		DAY 57	19MAY2003	55	0	0	0	0
	E0014001	DAY 1	26FEB2003	1	0	0	0	0
		DAY 57	01APR2003	35	0	0	0	0
	E0014013	DAY 1	27MAY2003	1	1	2	1	2
		DAY 57	23JUL2003	58	0	1	0	0
	E0014014	DAY 1	10JUN2003	1	0	1	0	1
		DAY 57	06AUG2003	58	0	0	0	0
	E0015004	DAY 1	02DEC2002	1	1	1	0	1
		DAY 57	29JAN2003	59	0	1	1	1
	E0018005	DAY 1	20DEC2002	1	0	0	0	0
		DAY 57	14FEB2003	57	0	0	0	0
	E0018012	DAY 1	24JAN2003	1	0	0	0	0
		DAY 57	26FEB2003	34	0	0	0	0
	E0019019	DAY 1	23JAN2003	1	0	0	0	0

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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR II)	E0019033	DAY 1	18MAR2003	1	0	0	0	0
		DAY 57	15MAY2003	59	0	0	0	0
	E0019038	DAY 1	24APR2003	1	0	0	0	0
		DAY 57	18JUN2003	56	0	0	0	0
	E0019046	DAY 1	26JUN2003	1	0	0	0	0
		DAY 57	21AUG2003	57	0	0	0	0
	E0019047	DAY 1	08JUL2003	1	0	0	0	0
		DAY 57	04SEP2003	59	0	0	0	0
	E0019048	DAY 1	10JUL2003	1	0	0	0	0
		DAY 57	03SEP2003	56	0	0	0	0
	E0022006	DAY 1	12NOV2002	1	0	0	0	0
		DAY 57	07JAN2003	57	0	0	0	0
	E0022047	DAY 1	28MAR2003	1	0	0	0	0
		DAY 57	23MAY2003	57	0	0	0	0
	E0022075	DAY 1	08JUL2003	1	0	0	0	0
		DAY 57	03SEP2003	58	0	0	0	0
	E0023012	DAY 1	06FEB2003	1	0	0	0	0
		DAY 57	04APR2003	58	0	0	0	0
	E0023016	DAY 1	22MAY2003	1	0	0	0	0
		DAY 57	17JUL2003	57	0	1	1	0
	E0023018	DAY 1	27MAR2003	1	0	0	0	0
		DAY 57	22MAY2003	57	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR II)	E0023036	DAY 1		20JUN2003	1	0	0	0	0
		DAY 57		13AUG2003	55	0	0	0	0
	E0023046	DAY 1		23JUL2003	1	0	0	0	0
		DAY 57		16SEP2003	56	0	0	0	0
	E0026006	DAY 1		08JAN2003	1	0	0	0	0
	E0026021	DAY 1		23APR2003	1	0	0	0	0
	E0026027	DAY 1		19JUN2003	1	0	2	1	1
	E0029002		*	12NOV2002		0	0	0	0
	E0029004	DAY 1		19NOV2002	1	0	1	0	1
		DAY 57		16JAN2003	59	0	0	0	0
	E0029013	DAY 1		19FEB2003	1	0	0	0	0
	E0029019	DAY 1		03MAR2003	1	0	0	0	0
		DAY 57		17MAR2003	15	0	0	0	0
	E0029024	DAY 1		17MAR2003	1	0	1	0	0
		DAY 57		20MAY2003	65	0	0	0	0
	E0029038	DAY 1		07JUL2003	1	0	0	0	0
	E0031004	DAY 1		19DEC2002	1	0	0	0	0
		DAY 57		13FEB2003	57	0	0	0	0
	E0031013	DAY 1		13MAR2003	1	0	0	0	0
		DAY 57		08MAY2003	57	0	1	2	1

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR II)	E0031016	DAY 1	24MAR2003	1	0	0	0	0
		DAY 57	14APR2003	22	0	0	0	0
	E0031019	DAY 1	11APR2003	1	0	1	1	1
		DAY 57	12MAY2003	32	0	0	0	0
	E0031022	DAY 1	28APR2003	1	0	0	0	0
	E0033007	DAY 1	28JAN2003	1	0	0	0	0
		DAY 57	25MAR2003	57	0	1	1	1
	E0033013	DAY 1	19FEB2003	1	0	0	0	0
		DAY 57	16APR2003	57	0	1	1	1
	E0033016	DAY 1	08MAY2003	1	0	1	1	1
		DAY 57	02JUL2003	56	0	0	0	0
	E0033022	DAY 1	14JUL2003	1	1	0	0	1
		DAY 57	11SEP2003	60	0	0	0	0
	E0034007	DAY 1	16MAY2003	1	0	0	0	0
		DAY 57	14JUL2003	60	0	0	0	0
	E0035004	DAY 1	27NOV2002	1	0	0	0	1
	E0035009	DAY 1	27DEC2002	1	0	0	0	0
		DAY 57	19FEB2003	55	0	0	0	0
	E0035010	DAY 1	10JAN2003	1	0	0	0	0
		DAY 57	06MAR2003	56	0	0	0	0
	E0035022	DAY 1	09MAY2003	1	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.5 Barnes Akathisia Rating Scale (BARS)

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	OBJECTIVE RATING	SUBJECTIVE AWARENESS	SUBJECTIVE DISTRESS	GLOBAL CLINICAL ASSESSMENT
PLACEBO (BIPOLAR II)	E0035022	DAY 57	07JUL2003	60	0	0	0	0
	E0039003	DAY 1	25NOV2002	1	0	0	0	0
	E0040001	DAY 1	27JUN2003	1	0	1	0	0
		DAY 57	22AUG2003	57	0	0	0	0
	E0040004	DAY 1	18JUL2003	1	0	0	0	0
	E0041002	DAY 1	21JAN2003	1	0	0	0	0
	E0041005	DAY 1	05MAR2003	1	0	0	0	0
		DAY 57	30APR2003	57	0	0	0	0

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/BARS100.SAS
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	01JUL1993-25MAR2003	3564	NO	LITHIUM [NERVOUS SYSTEM]	1200 MG	BIPOLAR DEPRESSION
		01JUL1995-26MAR2003	2834	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	PSYCHOSIS
		01JUL1996-25MAR2003	2468	NO	LORAZEPAM [NERVOUS SYSTEM]	6.00 MG	ANXIETY DUE TO DEPRESSION
		01JUL1998-25MAR2003	1738	NO	AMITRIPTYLINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR DEPRESSION
		15FEB2003-25MAR2003	48	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DEPRESSION
		26MAR2003-26MAR2003	9	NO	AMITRIPTYLINE HYDROCHLORIDE [NERVOUS SYSTEM]	0.50 MG	BIPOLAR DEPRESSION
			9	NO	LORAZEPAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY DUE TO DEPRESSION
	E0003004	01DEC2002-03DEC2002	16	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	2.00 TABLETS	INSOMNIA
	E0003005	15OCT1996-CONTINUE	2260	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MG	HYPOTHYROID
	E0003007	19DEC2002-CONTINUE	14	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE
	E0003015	01MAR2001-CONTINUE	795	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES, PRN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* Number of Days prior to study treatment.

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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0003015	01MAR2001-CONTINUE	795	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	MIGRAINE HEADACHE, PRN
		15MAR2002-CONTINUE	416	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	PREGNANCY PREVENTION
		01JAN2003-CONTINUE	124	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MENSTRUAL CRAMPS, PRN
	E0004002	01APR2002-CONTINUE	183	YES	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	ACID REFLUX
			183	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	ACID REFLUX
	E0004013	15DEC1990-CONTINUE	4413	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	PRN FOR ASTHMA
	E0004018	01JAN2002-CONTINUE	442	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
		01MAR2003-CONTINUE	18	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	500.0 MG	SUPPLEMENT
	E0004021	15JAN1995-CONTINUE	3041	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
		01JUL2002-CONTINUE	317	YES	TILACTASE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	LACTOSE INTOLERENCE
		09MAY2003-CONTINUE	5	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	SINUS HEADACHE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 300 MG (BIPOLAR I)	E0004021	09MAY2003-25MAY2003	5	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	SINUS HEADACHE
	E0005002	07FEB2001-13OCT2002	603	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	SLEEPLESSNESS SECONDARY TO BIPOLAR DEPRESSION
		15OCT2001-22SEP2002	353	NO	LAMOTRIGINE [NERVOUS SYSTEM]	250.0 MG	BIPOLAR DISORDER
		08JUL2002-17NOV2002	87	YES	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	15.00 MG	HEARTBURN/ACID REFLUX
		22SEP2002-23SEP2002	11	NO	LAMOTRIGINE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR DEPRESSION
		23SEP2002-24SEP2002	10	NO	LAMOTRIGINE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DEPRESSION
		24SEP2002-25SEP2002	9	NO	LAMOTRIGINE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR DEPRESSION
	E0005013	UNK-CONTINUE		YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	RHINITIS/SINUS ITIS
		01JUL1985-30OCT2002	6338	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	INSOMNIA - PRN
		01JUL1992-14OCT2002	3781	NO	METHOCARBAMOL [MUSCULO-SKELETAL SYSTEM]	500.0 MG	NECK PAIN
		15APR1993-23OCT2002	3493	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.50 MG	INSOMNIA - PRN

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QUETIAPINE 300 MG (BIPOLAR I)	E0005013	01JUL1995-CONTINUE	2686	YES	MOMETASONE FUROATE [RESPIRATORY SYSTEM]	1.00 SPRAY	RHINITIS/SINUSITIS
		01JUL1996-CONTINUE	2320	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHE - PRN
		01MAY2001-CONTINUE	555	YES	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	INDIGESTION
		01JUL2001-01OCT2002	494	NO	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	INDIGESTION - PRN
		15JUN2002-CONTINUE	145	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		30OCT2002-CONTINUE	8	YES	PHOSPHORIC ACID [ALIMENTARY TRACT AND METABOLISM]	2.00 TBLSPNS	NAUSEA - PRN
			8	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	20.00 MG	INSOMNIA - PRN
	E0005024	01JAN2003-CONTINUE	40	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL STATUS
			40	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFF	ASTHMA
	E0005027	01JAN2003-CONTINUE	69	YES	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	INDIGESTION
			69	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	INDIGESTION
		01MAY2000-CONTINUE	1044	YES	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES

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QUETIAPINE 300 MG (BIPOLAR I)	E0005027	01DEC2002-01MAR2003	100	NO	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	DEPRESSION
	E0005037	01MAR2003-CONTINUE	67	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	BACK PAIN SECONDARY TO ARTHRITIS
		01JAN1999-CONTINUE	1587	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES
		01JAN2000-CONTINUE	1222	YES	BENAZEPRIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION
	E0005042	03JUN2003-CONTINUE	21	YES	CALCIPOTRIOL [DERMATOLOGICALS]	1.00 APPLICATION	PSORISIS
		13JUN2003-CONTINUE	11	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 PILLS	PAIN PRN
	E0006005	15JUN2002-CONTINUE	173	YES	DESLORATADINE [RESPIRATORY SYSTEM]	1.00 TABLET	SEASONAL ALLERGIES
			173	YES	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	SEASONAL ALLERGIES
		15OCT2001-CONTINUE	416	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	HEADACHES
		01AUG2002-27NOV2002	126	NO	LAMOTRIGINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DISORDER
		01OCT2002-27NOV2002	65	NO	TIAGABINE HYDROCHLORIDE [NERVOUS SYSTEM]	4.00 MG	INSOMNIA

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QUETIAPINE 300 MG (BIPOLAR I)	E0006005	03NOV2002-CONTINUE	32	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TABLET	BIRTH CONTROL
			32	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	1.00 TABLET	MENSTRAL CRAMPS
	E0006018	01JAN2002-CONTINUE	436	YES	CHONDROITIN SULFATE [MUSCULO-SKELETAL SYSTEM]	2.00 TABLETS	BACK PAIN
		01JUL2002-CONTINUE	255	YES	LINSEED OIL [VARIOUS]	1.00 CAPSULE	PROPHYLAXIS
		01JAN2000-CONTINUE	1167	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TABLET	ELEVATED BLOOD PRESSURE
		01FEB2002-CONTINUE	405	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	2.00 TABLETS	ELEVATED CHOLESTEROL
	E0007013	01JUL2002-CONTINUE	347	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTROESOPHAGEAL REFLUX
		01JUL1990-CONTINUE	4730	YES	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	6.25 MG	HORMONE REPLACEMENT
		01JUL1998-CONTINUE	1808	YES	LOSARTAN POTASSIUM [CARDIOVASCULAR SYSTEM]	50.00 MG	HYPERTENSION
	E0010004	01JAN2000-CONTINUE	1075	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	MG	NUTRITIONAL SUPPLEMENT
			1075	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	MG	NUTRITIONAL SUPPLEMENT
			1075	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	MG	NUTRITIONAL SUPPLEMENT

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QUETIAPINE 300 MG (BIPOLAR I)	E0010004	01JAN2002-04DEC2002	344	NO	DOXYLAMINE SUCCINATE [RESPIRATORY SYSTEM]	MG	PRN INSOMNIA
		04DEC2002-03JAN2003	7	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA (PRN)
	E0010012	01JAN1996-16DEC2002	2563	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
			2563	NO	MIRTAZAPINE [NERVOUS SYSTEM]	60.00 MG	DEPRESSION
			2563	NO	TOPIRAMATE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR
			2563	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	2000 MG	BIPOLAR
	E0010024	01JUL2002-CONTINUE	308	YES	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	DIABETES MELLITUS TYPE II
		01JAN2000-23APR2003	1220	NO	MIRTAZAPINE [NERVOUS SYSTEM]	15.00 MG	INSOMNIA
		01JUL2002-16MAY2003	308	YES	FOSINOPRIL SODIUM [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		01MAR2003-23APR2003	65	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR DISORDER
		23APR2003-26APR2003	12	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
		23APR2003-05MAY2003	12	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA

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QUETIAPINE 300 MG (BIPOLAR I)	E0013007	01JUL2000-CONTINUE	992	YES	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	DIABETES
		01DEC2002-CONTINUE	109	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HIGH CHOLESTEROL
	E0013009	01JUL1993-CONTINUE	3562	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	ARTHRITIC PAIN
		01JUL2002-12MAR2003	275	NO	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	UNK	ARTHRITIC PAIN
		15JAN2003-10MAR2003	77	NO	HERBAL PREPARATION [VARIOUS]	2.00 TABS	ENERGY
	E0014006	01MAR2003-10MAR2003	24	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1.00 CAP	INSOMNIA
	E0014010	15JUN1980-CONTINUE	8346	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	HEADACHES
		01JUN1988-CONTINUE	5438	YES	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	MUSCULO - SKELETAL PAIN
		15FEB2003-CONTINUE	66	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	MUSCULO - SKELETAL PAIN
		14MAR2003-14APR2003	39	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA
	E0016001	19NOV2002-25DEC2002	64	NO	OLANZAPINE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA

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QUETIAPINE 300 MG (BIPOLAR I)	E0016001	28NOV2002-01JAN2003	55	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
		26DEC2002-01JAN2003	27	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR
		18JAN2003-22JAN2003	4	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	HEADACHE
		18JAN2003-29JAN2003	4	YES	PARACETAMOL [NERVOUS SYSTEM]	800.0 MG	HEADACHE
	E0016004	15JUN2001-15JAN2003	598	NO	VALPROIC ACID [NERVOUS SYSTEM]	1000 MG	BIPOLAR DISORDER
		15SEP2002-15JAN2003	141	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	DEPRESSION
	E0018001	01JUN1998-CONTINUE	1611	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	GERD
		14OCT2002-CONTINUE	15	YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	UNK	BIRTH CONTROL
	E0019004	01JAN1975-CONTINUE	10172	YES	PARACETAMOL [NERVOUS SYSTEM]	UNK	GENERAL ACHES
		30OCT2002-06NOV2002	8	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA
	E0019011	09NOV2001-13NOV2002	377	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR DISORDER

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QUETIAPINE 300 MG (BIPOLAR I)	E0019011	21DEC2001-CONTINUE	335	YES	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	HYPERGLYCEMIA.
	E0019025	UNK-CONTINUE		YES	NORETHISTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL.
		01JAN1994-16JAN2003	3323	NO	LITHIUM [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DX
		01JAN2001-16JAN2003	766	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	250.0 MG	DEPRESSION
		01NOV2002-CONTINUE	97	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	DIETARY SUPPLEMENT
	E0019026	UNK-CONTINUE		YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
	E0019043	01JAN1992-01MAY2003	4171	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	DEPRESSION
		01JAN1992-21MAY2003	4171	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR DISORDER
		01JAN1993-07JUN2003	3805	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR DISORDER
		22MAY2003-24MAY2003	12	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	400.0 MG	BIPOLAR
		25MAY2003-27MAY2003	9	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR

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QUETIAPINE 300 MG (BIPOLAR I)	E0020006	01JAN1998-09DEC2002	1810	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	BIPOLAR DISORDER
			1810	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
		01JAN2001-CONTINUE	714	YES	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	GASTRIC ESOPHAGEAL REFLUX DISORDER
		01AUG2002-CONTINUE	137	YES	METOPROLOL SUCCINATE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
		11NOV2002-09DEC2002	35	NO	CLONAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY SYMPTOMS
	E0020007	05JAN2003-05JAN2003	10	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		06JAN2003-06JAN2003	9	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	COMMON COLD SYMPTOMS
		09JAN2003-09JAN2003	6	NO	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	PNEUMONIA
		10JAN2003-13JAN2003	5	NO	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	PNEUMONIA
	E0022008	03NOV2002-05NOV2002	9	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	FLUE LIKE SYMPTOMS
		05NOV2002-05NOV2002	7	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE

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QUETIAPINE 300 MG (BIPOLAR I)	E0022017	01JAN1980-CONTINUE	8388	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		01JAN1985-CONTINUE	6561	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	CHRONIC BACK PAIN
		01SEP2000-CONTINUE	839	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
	E0022018	01JAN2002-CONTINUE	345	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		01JAN2000-CONTINUE	1076	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
			1076	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHE
			1076	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
		01JAN1990-CONTINUE	4728	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		01JAN1995-CONTINUE	2902	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHE
		01JAN1997-CONTINUE	2171	YES	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	524.0 MG	GASTRO - ESOPHAGEAL REFLUX
		15NOV2002-CONTINUE	27	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	4.00 PUFFS	ASTHMA
	E0022022	01JAN1999-CONTINUE	1459	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	GASTRIC REFLUX

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QUETIAPINE 300 MG (BIPOLAR I)	E0022022	01JAN1999-CONTINUE	1459	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01JAN1998-CONTINUE	1824	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01OCT2002-CONTINUE	90	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TRANSDERMALPATCH	CONTRACEPTIVE
		13DEC2002-CONTINUE	17	YES	ENEMAS [ALIMENTARY TRACT AND METABOLISM]	1.00 BOTTLE	CONSTIPATION
			17	YES	FIBRE, DIETARY [ALIMENTARY TRACT AND METABOLISM]	1.00 TBSP	CONSTIPATION
			17	YES	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TBSP	CONSTIPATION
		23DEC2002-CONTINUE	7	YES	MACROGOL [ALIMENTARY TRACT AND METABOLISM]	17.00 GRAMS	CONSTIPATION
		24DEC2002-24DEC2002	6	NO	DICYCLOVERINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	UNK	CONSTIPATION
	E0022027	01JAN1999-CONTINUE	1497	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MUSCULOSKELETAL PAIN
		01JAN1998-CONTINUE	1862	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		01JAN2002-22JAN2003	401	NO	FLUOXETINE [NERVOUS SYSTEM]	60.00 MG	DEPRESSION
		03FEB2003-14MAR2003	3	YES	GLUCOSE MONOHYDRATE [ALIMENTARY TRACT AND METABOLISM]	3.00 TABS	CONSTIPATION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022030	01JAN1998-CONTINUE	1870	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
	E0022031	01JAN1998-08FEB2003	1874	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DEPRESSION
		01AUG2001-CONTINUE	566	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
	E0022032	01FEB2000-CONTINUE	1113	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES PRN
		21JAN2003-CONTINUE	28	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL
		27JAN2003-06FEB2003	22	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR DISORDER
	E0022035	01JAN1998-CONTINUE	1875	YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	NA	CONTRACEPTION
	E0022036	15FEB2003-CONTINUE	10	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		01JAN1995-CONTINUE	2977	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
	E0022056	01APR2002-CONTINUE	381	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN/REFLUX

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	01JAN2001-CONTINUE	856	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	GE REFLUX
		01JUL2002-29APR2003	310	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
		07APR2003-CONTINUE	30	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	81.00 MG	HEADACHES
	E0023008	08JAN2003-23JAN2003	22	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.25 MG	ANXIETY
			22	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	DEPRESSION
		24JAN2003-27JAN2003	6	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION
	E0023015	15JUL1999-03MAR2003	1335	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	600.0 MG	MOOD STABILIZATION
			1335	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSIVE EPISODE
			1335	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	MOOD STABILIZATION
		04MAR2003-05MAR2003	7	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	DEPRESSIVE EPISODE
			7	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	MOOD STABILIZATION
		04MAR2003-06MAR2003	7	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	300.0 MG	MOOD STABILIZATION
		06MAR2003-06MAR2003	5	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	DEPRESSIVE EPISODE

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QUETIAPINE 300 MG (BIPOLAR I)	E0023015	06MAR2003-06MAR2003	5	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	250.0 MG	MOOD STABILIZATION
		07MAR2003-09MAR2003	4	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSIVE EPISODE
	E0023038	27JAN2002-23JUN2003	519	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR - DEPRESSION
		29DEC2002-20JUN2003	183	NO	RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
		15MAR2003-01MAY2003	107	NO	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	20.00 MG	HIGH CHOLESTEROL
	E0023044	01JUL1996-CONTINUE	2571	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01JUL2000-CONTINUE	1110	YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	SEASONAL ALLERGIES
		24JAN2001-10JUL2003	903	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR DEPRESSION
		15DEC2001-CONTINUE	578	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		15SEP2002-10JUL2003	304	NO	LAMOTRIGINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DEPRESSION
	E0023045	01MAY2003-09JUL2003	77	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	DEPRESSION

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QUETIAPINE 300 MG (BIPOLAR I)	E0023045	10JUL2003-10JUL2003	7	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	30.00 MG	DEPRESSION
		11JUL2003-11JUL2003	6	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
		12JUL2003-12JUL2003	5	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	DEPRESSION
	E0025002	01JUL2000-CONTINUE	1006	YES	HYOSCYAMINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	0.13 MG	ESOPHAGEAL SPASMS PRN
	E0026017	15MAY2002-25FEB2003	295	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	900.0 MG	BIPOLAR CONDITION
		15JUN2002-25FEB2003	264	NO	TRAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	MG	BIPOLAR CONDITION
		15DEC2002-25FEB2003	81	NO	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	BIPOLAR CONDITION
		15FEB2003-25FEB2003	19	NO	OLANZAPINE [NERVOUS SYSTEM]	MG	BIPOLAR CONDITION
			19	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR CONDITION
	E0026018	01JUL1970-CONTINUE	11950	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		01JUL2001-CONTINUE	627	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	8.00 TAB	HEARTBURN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 300 MG (BIPOLAR I)	E0026030	01JUL1994-02JUL2003	3295	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	400.0 MG	BIPOLAR CONDITION
	E0026031	25MAY2003-CONTINUE	57	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
	E0027003	21JAN2002-CONTINUE	372	YES	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	12.00 PUFFS	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
			372	YES	PANCRELIPASE [ALIMENTARY TRACT AND METABOLISM]	8.00 CAPS	PANCREATITIS, CHRONIC
			372	YES	RIZATRIPTAN BENZOATE [NERVOUS SYSTEM]	20.00 MG	MIGRAINES
		21JAN2002-11DEC2002	372	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	1200 MG	BIPOLAR DISORDER
		28MAY2002-CONTINUE	245	YES	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTRO ESOPHAGEL REFLUX
			245	YES	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
		14JUN2002-11DEC2002	228	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION
			228	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	450.0 MG	DEPRESSION
			228	NO	ZIPRASIDONE HYDROCHLORIDE [NERVOUS SYSTEM]	80.00 MG	BIPOLAR DISORDER

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QUETIAPINE 300 MG (BIPOLAR I)	E0027003	26JUN2002-CONTINUE	216	YES	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	ARTHRITIS
		10DEC2002-CONTINUE	49	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
			49	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	20.00 MG	INSOMNIA
	E0028006	01SEP1992-CONTINUE	3685	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01SEP1999-CONTINUE	1129	YES	GLUCOSAMINE [MUSCULO-SKELETAL SYSTEM]	3.00 TAB	ARTHRITIS
	E0028008	01JUN2000-CONTINUE	866	YES	ATROPINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	2.50 MG	PRN FOR DIARRHEA
			866	YES	BIMATOPROST [SENSORY ORGANS]	5.00 ML	GLAUCOMA
			866	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTRO ESOPHAGEAL REFLUX DISEASE
			866	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	PRN FOR MIGRAINE
			866	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	4.00 PUFFS	PRN FOR ASTHMA
		01JUL2002-08OCT2002	106	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	ANTI - PSYCHOTIC
		20SEP2002-08OCT2002	25	NO	MIRTAZAPINE [NERVOUS SYSTEM]	30.00 MG	ANTI - DEPRESSANT
			25	NO	TRAZODONE [NERVOUS SYSTEM]	50.00 MG	ANTI - DEPRESSANT

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QUETIAPINE 300 MG (BIPOLAR I)	E0028009	01JUL2002-25OCT2002	106	YES	FISH OIL [CARDIOVASCULAR SYSTEM]	4000 MG	PROPHYLAXIS
			106	YES	LECITHIN [BLOOD AND BLOOD FORMING ORGANS]	4800 MG	PROPHYLAXIS
	E0028016	01JUL1980-CONTINUE	8171	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT
		15JUL2002-13NOV2002	122	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	4.00 PILLS	INSOMNIA
	E0028017	01NOV2002-CONTINUE			CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	5.00 TABS	GI DISTRESS
		01JAN1982-CONTINUE			PARACETAMOL [NERVOUS SYSTEM]	100.0 MG	TENSION HEADACHES
		01SEP2002-CONTINUE			IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	KNEE PAIN
		05NOV2002-CONTINUE			GABAPENTIN [NERVOUS SYSTEM]	800.0 MG	BIPOLAR
					LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
					ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA (SECONDARY TO BIPOLAR)
	E0028027	01DEC2000-13JAN2003	781	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA PRN

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QUETIAPINE 300 MG (BIPOLAR I)	E0028038	01MAR2003-CONTINUE	55	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	UNK	GASTRIC REFLUX DISEASE
		01MAY2001-CONTINUE	724	YES	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	40.00 MG	HYPERLIPIDEMA
		01JUN1998-17APR2003	1789	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR
		01JUN1999-17APR2003	1424	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		01JUN2001-CONTINUE	693	YES	DOXAZOSIN MESILATE [CARDIOVASCULAR SYSTEM]	4.00 MG	PROSTATIC HYPERTROPHY (SIC)
		01OCT2002-11APR2003	206	NO	PARACETAMOL [NERVOUS SYSTEM]	UNK	EAR INFECTION
		01APR2003-CONTINUE	24	YES	LORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGIES
	E0028043	01JUL2000-CONTINUE	1069	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		01JUL1993-CONTINUE	3626	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		01JUL2001-CONTINUE	704	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	BACK PAIN PRN
	E0028045	UNK-CONTINUE		YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	UNK	HYPOTHYROIDISM

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 300 MG (BIPOLAR I)	E0028045	01JAN1987-08JUN2003	6012	NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
		01JAN2000-08JUN2003	1264	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
		01JAN2000-11JUN2003	1264	NO	TOPIRAMATE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
		15MAY2003-CONTINUE	34	YES	ARIPIPRAZOLE [NERVOUS SYSTEM]	UNK	BIPOLAR
		11JUN2003-CONTINUE	7	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
	E0029005	01JUN2000-CONTINUE	909	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	17.00 G	PRN ASTHMA
		01JUN2000-15AUG2002	909	NO	GABAPENTIN [NERVOUS SYSTEM]	1200 MG	BIPOLAR I
			909	NO	OLANZAPINE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR I
	E0030001	01JUL2001-CONTINUE	506	YES	CORTISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	1.00 Q4WK	PROPHYLAXIS
		01JUL1987-CONTINUE	5620	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
	E0030015	15JAN2003-28JAN2003	37	NO	ST. JOHN'S WORT [VARIOUS]	UNKN	DEPRESSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 300 MG (BIPOLAR I)	E0030022	01JAN2003-CONTINUE	166	YES	LINSEED OIL [VARIOUS]	1.00 TAB	PROPHYLAXIS
			166	YES	OMEGA-3 MARINE TRIGLYCERIDES [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
			166	YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JUL2000-CONTINUE	1080	YES	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TBLSPN	GASTRO ESOPHAGEAL REFLUX DISEASE
			1080	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	GASTRO ESOPHAGEAL REFLUX DISEASE
		01JUL2001-CONTINUE	715	YES	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION
		15MAY2003-CONTINUE	32	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	1.00 TAB	HIGH CHOLESTEROL
		01JUL1983-CONTINUE	7290	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN2003-CONTINUE	152	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION
	E0031002	15JUN2002-CONTINUE	165	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15NOV2001-CONTINUE	377	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	ORAL CONTRACEPTIVE
		23OCT2002-02NOV2002	35	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 300 MG (BIPOLAR I)	E0031003	03DEC2002-05DEC2002	7	NO	DOXEPIN [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA
	E0034002	01JAN1995-CONTINUE	3005	YES	FIBRE, DIETARY [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS AS NEEDED
		01JAN1997-CONTINUE	2274	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	5.00 MG	SEASONAL ALLERGIES
		01JAN1993-CONTINUE	3735	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	AS NEED FOR GENERAL HEALTH
		01FEB2001-17MAR2003	782	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR DISORDER
			782	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR DISORDER
		21MAR2003-23MAR2003	4	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHE
	E0034003	01JAN1984-CONTINUE	7053	YES	ANTACIDS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GASTRO - ESOPHOGEAL REFLUX DISEASE
		15JAN1995-11APR2003	3021	NO	ST. JOHN'S WORT [VARIOUS]	3.00 TABS	ANTI - DEPRESSANT
		15JAN1999-01FEB2003	1560	NO	KAVA-KAVA RHIZOMA [VARIOUS]	2.00 TABS	ANTI - DEPRESSANT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	01JAN2000-05MAY2003	1209	YES	PRASTERONE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GENERAL HEALTH/DIETARY SUPPLEMENT
		01FEB2003-CONTINUE	82	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	PRN FOR HEADACHES
	E0034006	01JAN1999-CONTINUE	1596	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX DISEASE
		01JAN2003-14APR2003	135	NO	ANTIDEPRESSANTS [NERVOUS SYSTEM]	25.00 MG	FOR IMPROVEMENT OF CONCENTRATION
			135	NO	ARIPIPRAZOLE [NERVOUS SYSTEM]	15.00 MG	MOOD STABILIZER
			135	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DISORDER MOOD STABILIZER
			135	NO	ESCITALOPRAM [NERVOUS SYSTEM]	40.00 MG	BIPOLAR DISORDER
			135	NO	MODAFINIL [NERVOUS SYSTEM]	100.0 MG	DROWSINESS
			135	NO	TOPIRAMATE [NERVOUS SYSTEM]	400.0 MG	MOOD STABILIZER
		20APR2003-20APR2003	26	NO	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	PRN FOR BACK PAIN
	E0035003	01JUL1995-CONTINUE	2701	YES	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	100.0 MG	ENVIRONMENTAL ALLERGIES
		01JUL1995-14NOV2002	2701	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	MOOD STABILIZER

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	01JUL1997-14NOV2002	1970	NO	OLANZAPINE [NERVOUS SYSTEM]	10.00 MG	PSYCHOSIS
		15SEP2002-CONTINUE	68	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	CHOLESTEROL
	E0035005	01JUL1999-25NOV2002	1251	NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	MOOD STABILIZER
		15AUG2002-25NOV2002	110	NO	BUSPIRONE HYDROCHLORIDE [NERVOUS SYSTEM]	45.00 MG	ANXIETY
			110	NO	CLONAZEPAM [NERVOUS SYSTEM]	1.50 MG	ANXIETY
			110	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	100.0 MG	INSOMNIA
			110	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	PSYCHOSIS
	E0035024	01MAR2003-14MAY2003	83	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	DEPRESSION
	E0036005	30JUN2003-11JUL2003	1	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL - WEEKLY
	E0037002	01JAN2000-CONTINUE	1090	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	MIGRAINE HEADACHES
	E0037005	01JAN2000-CONTINUE	1160	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL

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QUETIAPINE 300 MG (BIPOLAR I)	E0037005	01JAN2001-CONTINUE	794	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	WRIST PAIN
	E0037006	01JAN2003-05MAR2003	72	NO	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA (SECONDARY TO DEPRESSION)
	E0039006	01JUL2001-18DEC2002	547	NO	MIRTAZAPINE [NERVOUS SYSTEM]	30.00 MG	BIPOLAR
			547	NO	OLANZAPINE [NERVOUS SYSTEM]	15.00 MG	BIPOLAR
			547	NO	TRAZODONE [NERVOUS SYSTEM]	50.00 MG	INSOMNIA
			547	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	BIPOLAR
		06NOV2002-07NOV2002	54	NO	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	HEADACHES
	E0039024	01JUL2001-CONTINUE	606	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	GASTRIC ULCERS
		28JAN2003-06FEB2003	30	NO	CLIDINIUM [ALIMENTARY TRACT AND METABOLISM]	3.00 CAPSULES	BOWEL IRRITATION
	E0039041	15FEB1983-30APR2003	7364	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1000 MG	PROPHYLAXIS
			7364	YES	LACTOBACILLUS ACIDOPHILUS [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	PROPHYLAXIS
			7364	YES	MULTIVITAMINS WITH MINERALS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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QUETIAPINE 300 MG (BIPOLAR I)	E0039041	15FEB1983-30APR2003	7364	YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	PROPHYLAXIS
			7364	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1000 IV	PROPHYLAXIS
			7364	YES	VITAMINS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			7364	YES	ZINC [ALIMENTARY TRACT AND METABOLISM]	50.00 MG	PROPHYLAXIS
		01JUL2002-05APR2003	288	NO	TRYPTOPHAN, L- [NERVOUS SYSTEM]	50.00 MG	PROPHYLAXIS
	E0039044	15JUN2002-06MAY2003	341	NO	GABAPENTIN [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
			341	NO	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	BIPOLAR
		15JUN2002-10MAY2003	341	NO	OLANZAPINE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR
		07MAY2003-09MAY2003	15	NO	GABAPENTIN [NERVOUS SYSTEM]	600.0 MG	BIPOLAR
			15	NO	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	BIPOLAR
		10MAY2003-12MAY2003	12	NO	GABAPENTIN [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
			12	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
	E0039046	UNK-CONTINUE			ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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QUETIAPINE 300 MG (BIPOLAR I)	E0039046	01JUL2000-CONTINUE			IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	HERNIATED DISC PRN
		01JUL1996-02MAY2003			RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
		06MAY2003-15MAY2003			RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
		21MAY2003-21MAY2003			PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	NASAL CONGESTION
		24MAY2003-CONTINUE			AMPICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	200.0 MG	FEVER
		24MAY2003-24MAY2003			CHARCOAL, ACTIVATED [ALIMENTARY TRACT AND METABOLISM]	UNK	VOMITING
		24MAY2003-29MAY2003			PARACETAMOL [NERVOUS SYSTEM]	1000 MG	FEVER PRN
		29MAY2003-CONTINUE			RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
	E0039051	29APR2003-19MAY2003	48	NO	OLANZAPINE [NERVOUS SYSTEM]	7.50 MG	BIPOLAR DISORDER
		29APR2003-27MAY2003	48	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR DISORDER
		28MAY2003-03JUN2003	19	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	BIPOLAR DISORDER
		04JUN2003-10JUN2003	12	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	37.50 MG	BIPOLAR DISORDER

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QUETIAPINE 300 MG (BIPOLAR I)	E0039051	14JUN2003-14JUN2003	2	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	EARACHE
	E0039057	15MAR2003-23JUN2003	121	NO	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	4.00 TABS	PROPHYLAXIS
		15MAR2003-25JUN2003	121	NO	SMILAX ARISTOLOCHIIFOLIA ROOT [DERMATOLOGICALS]	1.00 TAB	PROPHYLAXIS
	E0041003	01JUL2002-15JAN2003	211	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR
			211	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA
		01NOV2002-01MAR2003	88	YES	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION
		23DEC2002-14JAN2003	36	NO	CYCLOBENZAPRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	10.00 MG	FIBROMYLASIA
		21JAN2003-08MAR2003	7	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	UPPER RESPIRATORY SYMPTOMS
	E0041008	01JUL1997-CONTINUE	2106	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	HYPOTHYROIDISM
		27NOV2002-26MAR2003	131	NO	ESCITALOPRAM [NERVOUS SYSTEM]	20.00 MG	BIPOLAR DISORDER
		28JAN2003-26MAR2003	69	NO	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR DISORDER

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QUETIAPINE 300 MG (BIPOLAR I)	E0042001	01JUL1997-CONTINUE	2192	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			2192	YES	POTASSIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	8.00 MEQ	HYPERTENSION
		01JUL1999-CONTINUE	1462	YES	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	250.0 MG	CONSTIPATION
			1462	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	SEASONAL RHINITIS
			1462	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	GASTRO ESOPHAGEAL REFLUX
			1462	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	100.0 IU	PROPHYLAXIS
		01JUL2000-19JUN2003	1096	NO	DIAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY DUE TO BIPOLAR DEPRESSION

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QUETIAPINE 300 MG (BIPOLAR II)	E0001002	15FEB2002-CONTINUE	390	YES	ATENOLOL [CARDIOVASCULAR SYSTEM]	50.00 MG	HIGH BLOOD PRESSURE
		15OCT2002-25FEB2003	148	NO	GABAPENTIN [NERVOUS SYSTEM]	900.0 MG	BIPOLAR DISORDER
		15DEC2002-CONTINUE	87	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			87	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN2003-24APR2003	56	YES	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	12.50 MG	ARTHRITIS IN RIGHT ANKLE PRN
		26FEB2003-26FEB2003	14	NO	GABAPENTIN [NERVOUS SYSTEM]	600.0 MG	BIPOLAR DISORDER
		27FEB2003-27FEB2003	13	NO	GABAPENTIN [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
	E0003018	01JAN2003-CONTINUE	132	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 POWDER	HEADACHE, PRN
			132	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABLETS	HEADACHE, PRN
			132	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE, PRN
		01MAY2002-CONTINUE	377	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	120.0 MG	SINUS HEADACHE, PRN
		01DEC2002-04MAY2003	163	NO	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABLETS	DIFFICULTY SLEEPING, PRN

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QUETIAPINE 300 MG (BIPOLAR II)	E0005030	15JAN2000-CONTINUE	1166	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT
	E0005036	15FEB2003-CONTINUE	80	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	CHOLESTEROL - ELEVATED
			80	YES	CARNITINE [CARDIOVASCULAR SYSTEM]	1.00 TAB	CHOLESTEROL - ELEVATED
			80	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	CHOLESTEROL - ELEVATED
			80	YES	FISH OIL [CARDIOVASCULAR SYSTEM]	400.0 MG	CHOLESTEROL - ELEVATED
			80	YES	NICOTINIC ACID [CARDIOVASCULAR SYSTEM]	1.00 TAB	CHOLESTEROL - ELEVATED
			80	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	CHOLESTEROL - ELEVATED
	E0006015	01JUL2002-CONTINUE	225	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TABLET	UNKNOWN
		01JUL2001-CONTINUE	590	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TABLET	MIGRAINE
		15FEB2001-CONTINUE	726	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	UNKNOWN
			726	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	PROPHYLAXIS
		17JAN2003-24JAN2003	25	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR DEPRESSION
	E0006016	01JUL2001-CONTINUE	596	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	PROPHYLAXIS

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QUETIAPINE 300 MG (BIPOLAR II)	E0006016	01JUL1999-CONTINUE	1327	YES	VALACICLOVIR HYDROCHLORIDE [ANTIINFECTIVES FOR SYSTEMIC USE]	2.00 GRAM	GENITAL HERPES PRN
		27DEC2002-09JAN2003	52	NO	INDOMETACIN [MUSCULO-SKELETAL SYSTEM]	50.00 MG	UNKNOWN
	E0007008	01JAN2003-CONTINUE	107	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	37.50 MG	(LEFT) VESTIBULAR INBALANCE
			107	YES	LIOTHYRONINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	15.00 MCG	HYPOTHYROID
		01JAN1997-CONTINUE	2298	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	200.0 MCG	HYPOTHYROID
		02AUG2002-10APR2003	259	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	350.0 MG	DEPRESSION
	E0009002	01JUL1998-CONTINUE	1602	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	80.00 MG	CARDIOVASCULAR PROPHYLAXIS
		01JUL2001-CONTINUE	506	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HIGH CHOLESTERAL
		15AUG1999-CONTINUE	1192	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	88.00 MCG	GRAVES DISEASE
		15FEB2001-12DEC2002	642	YES	TESTOSTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	50.00 MG	LOW TESTOSTERONE

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QUETIAPINE 300 MG (BIPOLAR II)	E0009006	01JUL1984-CONTINUE	6785	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
	E0009009	01JUL2002-CONTINUE	254	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	TOOTHACHE
		25FEB2003-25FEB2003	15	NO	PARACETAMOL [NERVOUS SYSTEM]	UNK	TOOTHACHE
	E0010015	01JAN1999-29JAN2003	1511	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
			1511	NO	TEMAZEPAM [NERVOUS SYSTEM]	30.00 MG	INSOMNIA
		01JAN2002-29JAN2003	415	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION
		29JAN2003-13MAR2003	22	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
			22	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	PRN - INSOMNIA
	E0011004	15JUN2002-CONTINUE	192	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	6.00 PUFFS	ASTHMA
		15SEP2000-CONTINUE	830	YES	KETOPROFEN [MUSCULO-SKELETAL SYSTEM]	100.0 MG	BACKACHE
		07DEC2002-11DEC2002	17	NO	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	TOOTH PAIN DUE TO TOOTH ABSCESS

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QUETIAPINE 300 MG (BIPOLAR II)	E0011004	07DEC2002-13DEC2002	17	NO	BENZYLPENICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	TOOTH ABSCESS
	E0011007	01JUL2000-CONTINUE	901	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	SINUS INFECTION
		01JUL1993-CONTINUE	3458	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	750.0 MG	HEADACHES BACKACHES
	E0011018	01JUL1995-CONTINUE	2882	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES PRN
	E0015003	15JAN2002-CONTINUE	314	YES	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	CONSTIPATION
	E0019007	01FEB2001-CONTINUE	650	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			650	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1500 MG	PROPHYLAXIS
		01NOV2001-CONTINUE	377	YES	RALOXIFENE HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 CAP	PROPHYLAXIS
	E0019014	06JAN2003-CONTINUE	3	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	UNK	HEADACHE
	E0019027	UNK-21FEB2003		NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	DEPRESSION.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0019027	27MAR1987-CONTINUE	5816	YES	INSULIN [ALIMENTARY TRACT AND METABOLISM]	CC	DIABETES .4 - 1
		26FEB2003-CONTINUE	1	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	UNK	SINUS HEADACHE
			1	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNK	SINUS HEADACHE
	E0019032	01JAN1993-CONTINUE	3742	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		01JUN2002-27FEB2003	304	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
	E0019041	01JAN2001-CONTINUE	870	YES	ECHINACEA EXTRACT [VARIOUS]	1.00 TAB	HEALTH SUPPLEMENT
		01APR2003-16APR2003	50	NO	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	ALLERGIES
	E0019049	19JUN2003-01JUL2003	21	NO	CODEINE PHOSPHATE [NERVOUS SYSTEM]	4.00 TABS	RIGHT LEG PAIN
	E0022052	01JAN1999-CONTINUE	1560	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01JAN1997-CONTINUE	2290	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MUSCULOSKELETAL PAIN
			2290	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	01SEP2002-CONTINUE	221	YES	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 MG	DIARRHEA
	E0022064	05MAY2003-CONTINUE	1	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0022073	01MAR2003-CONTINUE	117	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	ALLERGIC RHINITIS
		01JAN1995-CONTINUE	3098	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	DYSMENORRHEA
			3098	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		01JAN1996-CONTINUE	2733	YES	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	GASTROESOPHAGEAL REFLUX
	E0023027	01SEP2002-CONTINUE	257	YES	RABEPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	ESOPHOGEAL REFLUX
		01DEC1997-CONTINUE	1992	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.10 MG	HYPOTHYROID
		01FEB2001-07MAY2003	834	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	BIPOLAR
		10FEB2003-07MAY2003	95	NO	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	40.00 MG	DEPRESSION (BIPOLAR)
		11FEB2003-19MAY2003	94	YES	PROPRANOLOL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION (CONTROLLED)

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0026014	01JUL1978-CONTINUE	8999	YES	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	120.0 MG	HYPERTENSION
		01JUL1991-11FEB2003	4251	NO	TRAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA
		15OCT2002-11FEB2003	127	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR CONDITION
			127	NO	GABAPENTIN [NERVOUS SYSTEM]	MG	BIPOLAR CONDITION
			127	NO	OLANZAPINE [NERVOUS SYSTEM]	MG	BIPOLAR CONDITION
			127	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR CONDITION
	E0027005	01JUL2000-12DEC2002	908	NO	ALPRAZOLAM [NERVOUS SYSTEM]	1.50 MG	BIPOLAR
			908	NO	TRAZODONE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR
			908	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR
		01JUL2001-12DEC2002	543	NO	LITHIUM [NERVOUS SYSTEM]	1200 MG	BIPOLAR
		12DEC2002-CONTINUE	14	YES	LORAZEPAM [NERVOUS SYSTEM]	4.00 MG	ANXIETY
			14	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0029021	01JAN1999-CONTINUE	1537	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHES - PRN.

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QUETIAPINE 300 MG (BIPOLAR II)	E0029021	01JAN1995-CONTINUE	2998	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TAB	HEADACHES - PRN.
		01JUL2001-03MAR2003	625	NO	HERBAL PREPARATION [VARIOUS]	1.00 CAP	NUTRITIONAL SUPPLEMENT
	E0029026	01JAN2001-CONTINUE	833	YES	SERENOA REPENS [GENITO URINARY SYSTEM AND SEX HORMONES]	600.0 MG	DIETARY SUPPLEMENT
		01JAN1993-14APR2003	3755	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		02APR2002-28MAY2003	377	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	KNEE ARTHRITIS
	E0029030	UNK-CONTINUE		YES	HERBAL PREPARATION [VARIOUS]	400.0 MG	DIETARY SUPPLEMENT
				YES	POTASSIUM [ALIMENTARY TRACT AND METABOLISM]	MG	DIETARY SUPPLEMENT
		01MAY2003-CONTINUE	26	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1000 MG	DIETARY SUPPLEMENT
		01MAY2003-11MAY2003	26	NO	ECHINACEA EXTRACT [VARIOUS]	500.0 MG	DIETARY SUPPLEMENT
		06MAY2003-06MAY2003	21	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1000 MG	HEADACHE
		06MAY2003-08MAY2003	21	NO	PSEUDOEPHEDRINE [RESPIRATORY SYSTEM]	60.00 MG	ALLERGIC RHINITIS

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QUETIAPINE 300 MG (BIPOLAR II)	E0031008	01DEC2002-CONTINUE	89	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	FIBROMYALGIA
		01NOV2002-CONTINUE	119	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	ORAL CONTRACEPTIVE
		06JAN2003-06JAN2003	53	NO	ZIPRASIDONE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	DEPRESSION
		01JAN1987-CONTINUE	5902	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	FIBROMYALGIA
		23DEC2002-05FEB2003	67	NO	TIAGABINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	MOOD STABILIZER
		16JAN2003-05FEB2003	43	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	400.0 MG	MOOD STABILIZER
		16FEB2003-04MAR2003	12	YES	LORAZEPAM [NERVOUS SYSTEM]	1.50 MG	ANXIETY
		24FEB2003-CONTINUE	4	YES	ACICLOVIR [ANTIINFECTIVES FOR SYSTEMIC USE]	800.0 MG	GENITAL HERPES
	E0031020	01JAN2000-CONTINUE	1206	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 SPRAY	ASTHMA
		01JAN2001-CONTINUE	840	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SPRAY	SEASONAL ALLERGIES
	E0031029	01JUL1993-CONTINUE	3639	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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QUETIAPINE 300 MG (BIPOLAR II)	E0031029	01JUL1981-CONTINUE	8022	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	MIGRAINES
			8022	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	MIGRAINES
			8022	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	MIGRAINES
	E0033002	01JAN2002-01JAN2003	374	NO	CYCLOBENZAPRINE [NERVOUS SYSTEM]	10.00 MG	NECK PAIN
		06JAN2003-24JAN2003	4	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	AGITATION (SYMPTOM OF BIPOLAR DEPRESSION)
			4	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0033021	01JUL1993-22JUN2003	3653	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DEPRESSION
		01JUN2002-CONTINUE	396	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	0.25 MG	BIRTH CONTROL
		25JUN2003-15JUL2003	7	YES	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	INSOMNIA ASSOCIATED WITH DEPRESSION
	E0035013	01OCT2002-CONTINUE	126	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	CHOLESTEROL
		01JAN2002-23JAN2003	399	NO	CARBAMAZEPINE [NERVOUS SYSTEM]	500.0 MG	MOOD STABILIZER

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QUETIAPINE 300 MG (BIPOLAR II)	E0035013	01JAN2002-01FEB2003	399	NO	RISPERIDONE [NERVOUS SYSTEM]	4.00 MG	PSYCHOSIS
		08JAN2002-26JAN2003	392	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	INSOMNIA
	E0035016	09MAR2003-09MAR2003	26	NO	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	SEVERE MENSTRAL CRAMPS
	E0035023	15FEB2003-03MAY2003	87	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	200.0 MG	DEPRESSION
		15FEB2003-04MAY2003	87	NO	HYDROXYZINE [NERVOUS SYSTEM]	50.00 MG	INSOMNIA DUE TO DEPRESSION
	E0039052	UNK-CONTINUE		YES	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	UNK	PROPHYLAXIS
				YES	FOLIC ACID [BLOOD AND BLOOD FORMING ORGANS]	UNK	PROPHYLAXIS
				YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLAXIS
		01JUL1993-CONTINUE	3641	YES	TRIAMCINOLONE [DERMATOLOGICALS]	2.00 APPLICATIONS	ECZEMA
		01JUL1978-CONTINUE	9120	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA (AS NEEDED)
		01JUL1999-19MAY2003	1450	NO	RISPERIDONE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR DISORDER

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QUETIAPINE 300 MG (BIPOLAR II)	E0039052	01JUL2000-19MAY2003	1084	NO	MIRTAZAPINE [NERVOUS SYSTEM]	30.00 MG	BIPOLAR DISORDER
		01JUL2002-19MAY2003	354	NO	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	120.0 MG	SEASONAL ALLERGIES
			354	NO	GABAPENTIN [NERVOUS SYSTEM]	500.0 MG	BIPOLAR DISORDER
		04JUN2003-CONTINUE	16	YES	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	500.0 MG	NON INSULIN DEPENDENT DIABETES
		16JUN2003-16JUN2003	4	NO	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	NON INSULIN DEPENDENT DIABETES
		18JUN2003-18JUN2003	2	NO	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	NON INSULIN DEPENDENT DIABETES
	E0039056	15FEB2003-CONTINUE	150	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			150	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0040003	01JUL1998-CONTINUE	1844	YES	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	ASTHMA
		03MAR2003-09JUL2003	138	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	MOOD STABILIZER
			138	NO	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	INSOMNIA
			138	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	DEPRESSION

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QUETIAPINE 300 MG (BIPOLAR II)	E0040003	18JUL2003-29JUL2003	1	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA

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QUETIAPINE 600 MG (BIPOLAR I)	E0002009	15FEB1990-CONTINUE	4764	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	25.00 MG	ASTHMA PRN
			4764	YES	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	25.00 MG	ASTHMA PRN
		15APR1997-CONTINUE	2148	YES	OMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	HIATEL HERNIA
		15FEB1998-CONTINUE	1842	YES	SALMETEROL XINAFOATE [RESPIRATORY SYSTEM]	21.00 MCG	ASTHMA PRN
		15MAY2000-17FEB2003	1022	NO	LAMOTRIGINE [NERVOUS SYSTEM]	275.0 MG	BIPOLAR DISORDER
		15MAY2000-23FEB2003	1022	NO	MIRTAZAPINE [NERVOUS SYSTEM]	45.00 MG	ANTIDEPRESSANT
		18FEB2003-20FEB2003	13	NO	LAMOTRIGINE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR DISORDER
		21FEB2003-22FEB2003	10	NO	LAMOTRIGINE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR DISORDER
	E0002011	17APR2002-18APR2003	377	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	BIPOLAR DISORDER
		15SEP2002-15APR2003	226	NO	CLONAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY DUE TO DEPRESSION
			226	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR DISORDER
		15DEC2002-16APR2003	135	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	450.0 MG	BIPOLAR DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR I)	E0002011	16APR2003-16APR2003	13	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	750.0 MG	BIPOLAR DISORDER
		16APR2003-20APR2003	13	NO	CLONAZEPAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY DUE TO DEPRESSION
		17APR2003-18APR2003	12	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DEPRESSION
		19APR2003-20APR2003	10	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR DEPRESSION
			10	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	250.0 MG	BIPOLAR DISORDER
	E0003010	29JAN2003-29JAN2003	5	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		02FEB2003-02FEB2003	1	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0003016	15FEB2003-CONTINUE	96	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15NOV1991-CONTINUE	4206	YES	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEARTBURN, PRN
		25APR2003-28APR2003	27	NO	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TSP	COUGH
			27	NO	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TABS	CONGESTION
	E0003019	01JUL2001-CONTINUE	726	YES	FISH OIL [CARDIOVASCULAR SYSTEM]	1200 MG	PROPHYLAXIS

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QUETIAPINE 600 MG (BIPOLAR I)	E0003019	01JAN2001-15JUN2003	907	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	250.0 MG	INSOMNIA PRN
		01JAN2003-18JUN2003	177	NO	MIRTAZAPINE [NERVOUS SYSTEM]	15.00 MG	INSOMNIA PRN
		01JUN2003-18JUN2003	26	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA PRN
		25JUN2003-25JUN2003	2	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0003020	01JAN2001-CONTINUE	933	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HIP PAIN DUE TO VASCULAR NECROSIS
	E0004001	01JAN1999-CONTINUE	1368	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	220.0 MG	HEADACHE
	E0004009	01AUG2001-CONTINUE	512	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
			512	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
	E0005003	15FEB2000-01SEP2002	960	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
		01JUL2000-24OCT2002	823	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 PILL	HYPERTENSION
		23SEP2002-CONTINUE	9	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	3.00 PILLS	JOINT PAIN

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QUETIAPINE 600 MG (BIPOLAR I)	E0005003	23SEP2002-30SEP2002	9	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	AGITATION SECONDARY TO BIPOLAR
		30SEP2002-24OCT2002	2	YES	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	JOINT PAIN
	E0005005	17SEP2002-25SEP2002	13	NO	TETRACYCLINE [ALIMENTARY TRACT AND METABOLISM]	1.00 PO	ACNE
	E0005007	01JUL2002-CONTINUE	100	YES	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	ARTHRITIS PRN
		03OCT2002-08OCT2002	6	NO	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	AGITATION - PRN
	E0005008	01JAN1998-CONTINUE	1748	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
			1748	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 PILL	BACK PAIN
	E0005009	01JUN2002-CONTINUE	150	YES	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	UNKN	HEARTBURN
			150	YES	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN - PRN
		01JUN2002-04OCT2002	150	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNKN	SINUSES - PRN
			150	NO	PARACETAMOL [NERVOUS SYSTEM]	UNKN	SINUSES - PRN
		01JUN2002-16OCT2002	150	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 PILLS	MIGRAINE HA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0005009	01JUN2002-16OCT2002	150	NO	OXYMETAZOLINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 SPRAY/NOSTRIL	SINUSES - PRN
		09OCT2002-CONTINUE	20	YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	ALLERGIES/SINUSITIS
		16OCT2002-CONTINUE	13	YES	BUDESONIDE [RESPIRATORY SYSTEM]	2.00 SPRAYSEACH NOSTRIL	SINUSITIS
			13	YES	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	SINUSITIS - PRN
		16OCT2002-22OCT2002	13	NO	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHES
	E0005012	UNK-CONTINUE		YES	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TBLSPNS	HEARTBURN
				YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		15JAN1980-03NOV2002	8339	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	450.0 MG	BIPOLAR DEPRESSION
		15JAN1997-29OCT2002	2129	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	900.0 MG	BIPOLAR DISORDER
		15OCT2001-29OCT2002	395	NO	NEFAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	400.0 MG	BIPOLAR DEPRESSION
		30OCT2002-03NOV2002	15	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	450.0 MG	BIPOLAR DEPRESSION
			15	NO	NEFAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DISORDER

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QUETIAPINE 600 MG (BIPOLAR I)	E0005012	03NOV2002-20NOV2002	11	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	SLEEPLESNESS SECONDARY TO BIPOLAR DISORDER
	E0005014	12NOV2002-12NOV2002	1	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	UPPER RESPIRATORY INFECTION
	E0005022	15OCT2002-CONTINUE	106	YES	ASCORBIC ACID [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	CARTILIDGE REPAIR/JOINT PAIN
	E0005025	01JUL1991-21MAR2003	4259	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	75.00 MCG	HYPOTHYROID
	E0006019	10NOV1999-CONTINUE	1244	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.15 MG	HYPOTHYROIDISM
		15DEC1999-CONTINUE	1209	YES	ALENDRONATE SODIUM [MUSCULO-SKELETAL SYSTEM]	70.00 MG	OSTEOPEROSIS ONCE PER WEEK
		15JUN2001-CONTINUE	661	YES	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	220.0 MCG	SEASONAL ALLERGIES
		15JUL2002-CONTINUE	266	YES	PSEUDOEPHEDRINE SULFATE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGIES PRN
		14OCT2002-31MAR2003	175	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	1200 MG	BIPOLAR DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR I)	E0006019	11FEB2003-31MAR2003	55	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	BIPOLAR DEPRESSION
		27MAR2003-30MAR2003	11	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR DEPRESSION
			11	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	37.50 MG	BIPOLAR DEPRESSION
	E0007005	25NOV2002-01JAN2003	67	NO	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	BIPOLAR
			67	NO	LAMOTRIGINE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR
	E0007015	01JUL1996-CONTINUE	2571	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1500 MG	OSTEOPENIA
			2571	YES	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	0.30 MG	HORMONE REPLACEMENT
			2571	YES	PROGESTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	2.50 MG	HORMONE REPLACEMENT
		01JUL1993-CONTINUE	3667	YES	ACICLOVIR [ANTIINFECTIVES FOR SYSTEMIC USE]	400.0 MG	HERPES GENITALIA
			3667	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SELF PRESCRIBED GENERAL HEALTH
		24JAN2003-CONTINUE	173	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERLIPIDEMIA
	E0009001	20AUG2001-CONTINUE	449	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	HEADACHES
			449	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINES

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QUETIAPINE 600 MG (BIPOLAR I)	E0009001	20AUG2001-CONTINUE	449	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	HEADACHES
	E0010002	01JUL2002-14NOV2002	147	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	PRN - INSOMNIA
		05OCT2002-18OCT2002	51	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	BIPOLAR
		18OCT2002-19OCT2002	38	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR
		21OCT2002-25OCT2002	35	NO	OLANZAPINE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR
		25OCT2002-14NOV2002	31	NO	OLANZAPINE [NERVOUS SYSTEM]	2.50 MG	BIPOLAR
		14NOV2002-CONTINUE	11	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
	E0010009	01JAN2001-CONTINUE	724	YES	FLUVASTATIN SODIUM [CARDIOVASCULAR SYSTEM]	40.00 MG	ELEVATED CHOLESTEROL
		01AUG1992-CONTINUE	3799	YES	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	20.00 MG	LESION ON THE AORTA
			3799	YES	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	15.00 MG	LESION ON THE AORTA
		01JUN1999-18DEC2002	1304	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	DEPRESSION
		01SEP2002-18DEC2002	116	NO	RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	BIPOLAR DISORDER

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QUETIAPINE 600 MG (BIPOLAR I)	E0010010	UNK-CONTINUE		YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLAXIS
		20NOV2002-20NOV2002	40	NO	BOTULINUM TOXIN TYPE A [MUSCULO-SKELETAL SYSTEM]	INJECTION	SPASMODIC DYSPHONIA
	E0010014	01JUL1991-16FEB2003	4229	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TABLET	HYPERTENSION
		01DEC2002-14JAN2003	58	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]		INSOMNIA - PRN
	E0010017	05FEB2003-10MAR2003	20	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0010023	01JUL2002-CONTINUE	290	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	MG	PROPHYLAXIS
		01JAN2003-28MAR2003	106	NO	DEXAMFETAMINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	15.00 MG	DEPRESSION USED PRN
			106	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
	E0010027	05JUN2003-CONTINUE	11	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	SLEEP
		12JUN2003-CONTINUE	4	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	SEVERE ANXIETY

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QUETIAPINE 600 MG (BIPOLAR I)	E0010029	12MAY2003-CONTINUE	38	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	12.50 MG	DIABETES MELLITUS TYPE II
			38	YES	MOEXIPRIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	7.50 MG	DIABETES MELLITUS TYPE II
			38	YES	ROSIGLITAZONE MALEATE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	HYPERTENSION
		10JUN2003-CONTINUE	9	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	SLEEP
	E0011022	01JAN2003-CONTINUE	159	YES	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	INDIGESTION PRN
		15MAY2003-CONTINUE	25	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES PRN
			25	YES	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
		01JUL1987-CONTINUE	5822	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES PRN
		01JUL1973-CONTINUE	10935	YES	PARACETAMOL [NERVOUS SYSTEM]	3000 MG	HEADACHES PRN
		15MAR2003-CONTINUE	86	YES	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	PROPHYLAXIS
		15MAY2003-02JUN2003	25	NO	ARIPIPRAZOLE [NERVOUS SYSTEM]	15.00 MG	BIPOLAR AFFECTIVE DISORDER
			25	NO	BUTORPHANOL TARTRATE [NERVOUS SYSTEM]	1.00 SPRAYPERNOSTRIL	MIGRAINES PRN

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QUETIAPINE 600 MG (BIPOLAR I)	E0011022	15MAY2003-02JUN2003	25	NO	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	100.0 MG	MIGRAINES PRN
			25	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	DEPRESSION, DUE TO BIPOLAR DISORDER
			25	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	DEPRESSION DUE TO BIPOLAR PRN AFFECTIVE DISORDER/INSOMNIA
		15MAY2003-09JUN2003	25	YES	HYDROXYZINE EMBONATE [NERVOUS SYSTEM]	200.0 MG	INSOMNIA PRN
			25	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	ANXIETY PRN DUE TO DEPRESSION
		15MAY2003-08JUL2003	25	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	12.50 MG	HYPERTENSION
	E0013006	01JUN1985-CONTINUE	6494	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
	E0013012	01MAR2001-CONTINUE	797	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERLIPIDEMIA
			797	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
			797	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MG	HYPOTHYROIDISM

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QUETIAPINE 600 MG (BIPOLAR I)	E0013014	01JUL1995-03JUN2003	2894	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
		15JAN2001-27MAY2003	869	NO	CLONAZEPAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY
		15AUG2001-20APR2003	657	NO	GABAPENTIN [NERVOUS SYSTEM]	300.0 MG	ANXIETY
		15AUG2001-02JUN2003	657	NO	ZALEPLON [NERVOUS SYSTEM]	25.00 MG	INSOMNIA
		15DEC2002-08MAY2003	170	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	DEPRESSION
	E0014005	14FEB2003-14MAR2003	25	YES	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	MUSCLE SPASMS - PAIN NECK/PRN
		07MAR2003-CONTINUE	4	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	DYSLIPIDEMIA
	E0014007	01JAN2003-CONTINUE	90	YES	PARACETAMOL [NERVOUS SYSTEM]	750.0 MG	ACHES
	E0014011	01JUL1983-CONTINUE	7256	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	ACID REFLUX (PRN)
			7256	YES	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	HEADACHES (PRN)
	E0014012	01JUL1998-CONTINUE	1791	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	MIGRAINE

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QUETIAPINE 600 MG (BIPOLAR I)	E0014012	01JUL2001-CONTINUE	695	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
			695	YES	MINERAL SUPPLEMENTS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
			695	YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
			695	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
		01JUL1972-CONTINUE	11287	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MUSCLE PAIN
			11287	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		01JUL1998-06MAY2003	1791	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	MUSCLE PAIN
		16APR2003-06MAY2003	41	NO	CLONAZEPAM [NERVOUS SYSTEM]	1.00 MG	SLEEP
	E0015001	01JUL1988-CONTINUE	5264	YES	LEVOTHYROXINE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	HYPOTHYROID
	E0015008	UNK-CONTINUE		YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLAXIS
	E0016003	15APR2002-10JAN2003	284	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	DEPRESSION
		15OCT2002-10JAN2003	101	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	1350 MG	BIPOLAR

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QUETIAPINE 600 MG (BIPOLAR I)	E0018007	01JUN1979-CONTINUE	8610	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	ARTHRITIS
		01JUN1992-CONTINUE	3861	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	180.0 MCG	ASTHMA
		01APR1995-31DEC2002	2827	YES	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	1.25 MG	HORMONE REPLACEMENT THERAPY
		26NOV2002-26NOV2002	31	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	MG	DEPRESSION
		26NOV2002-07DEC2002	31	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	DEPRESSION
		17DEC2002-CONTINUE	10	YES	ASCORBIC ACID [MUSCULO-SKELETAL SYSTEM]	3.00 TABS	ARTHRITIS
			10	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	LEFT LEG PAIN
	E0019005	01JAN1993-CONTINUE	3595	YES	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	2.00 MG	HORMONE REPLACEMENT THERAPY
			3595	YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	2.50 MG	HORMONE REPLACEMENT THERAPY
		01JAN1991-CONTINUE	4326	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	SECONDARY HYPOTHROIDISM
	E0019015	30DEC2002-CONTINUE	3	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	TABS	HEADACHES

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QUETIAPINE 600 MG (BIPOLAR I)	E0020004	01JAN2000-CONTINUE	1073	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERCHOLESTEROLEMIA
		01JAN1997-CONTINUE	2168	YES	METOPROLOL [CARDIOVASCULAR SYSTEM]	100.0 MG	HYPERTENSION
		26OCT2002-30NOV2002	44	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	600.0 MG	DEPRESSION
			44	NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
	E0020010	01JAN1990-CONTINUE	4783	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 PUFF	ASTHMA
		02FEB2003-03FEB2003	3	NO	PARACETAMOL [NERVOUS SYSTEM]	400.0 MG	HEADACHE
	E0020014	01JAN1996-CONTINUE	2633	YES	OXYBUTYNIN HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	5.00 MG	OVERACTIVE BLADDER
			2633	YES	TOLTERODINE L-TARTRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	2.00 MG	OVERACTIVE BLADDER
		21FEB2003-10MAR2003	25	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION
		08MAR2003-12MAR2003	10	NO	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 CAP	UPPER RESPIRATORY INFECTION
	E0020023	01JAN1998-CONTINUE	1993	YES	OMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	10.00 MG	REFLUX (PRN)

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0020023	01JAN1973-CONTINUE	11124	YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
			11124	YES	VERAPAMIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	240.0 MG	HYPERTENSION
	E0022012	01JAN1999-CONTINUE	1434	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	HEARTBURN
		01JAN1992-CONTINUE	3991	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
			3991	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
	E0022019	01JAN1981-CONTINUE	8014	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
	E0022025	01JAN2001-CONTINUE	757	YES	ATENOLOL [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			757	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			757	YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		10JAN2003-13JAN2003	18	NO	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	BIPOLAR
		01JAN1980-CONTINUE	8428	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		01JAN1990-CONTINUE	4775	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	MENSTRUAL CRAMPS

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QUETIAPINE 600 MG (BIPOLAR I)	E0022025	01JAN1998-CONTINUE	1853	YES	LOPERAMIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 MG	IRRITABLE BOWEL SYNDROME
		01APR2002-08JAN2003	302	NO	CLONAZEPAM [NERVOUS SYSTEM]	3.00 MG	BIPOLAR
		08JAN2003-09JAN2003	20	NO	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	BIPOLAR
		14JAN2003-17JAN2003	14	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
	E0022033	01JAN1997-CONTINUE	2239	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
		01JAN1993-11FEB2003	3700	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA
		11FEB2003-15FEB2003	7	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0022034	01NOV2002-11FEB2003	109	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	1200 MG	BIPOLAR I
	E0022038	01FEB2002-CONTINUE	392	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	RIGHT KNEE PAIN
			392	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	LUMBAR DISC DISEASE
	E0022039	01JAN1999-CONTINUE	1525	YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	120.0 MG	ALLERGIC RHINITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 600 MG (BIPOLAR I)	E0022039	01JAN1999-CONTINUE	1525	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SPRAY	ALLERGIC RHINITIS
		01JAN2000-CONTINUE	1160	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
			1160	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	CHEST WALL PAIN
		01NOV2002-CONTINUE	125	YES	MECLOZINE [RESPIRATORY SYSTEM]	25.00 MG	VERTIGO
		01JAN1998-CONTINUE	1890	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01APR2001-24FEB2003	704	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR
		01APR2001-26FEB2003	704	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	250.0 MG	BIPOLAR
		25FEB2003-26FEB2003	9	NO	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR
	E0022046	01JAN1988-CONTINUE	5557	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		13MAR2003-19MAR2003	7	NO	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY - SECONDARY TO DEPRESSION
	E0022048	01MAY2002-CONTINUE	335	YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	FOOD ALLERGIES

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QUETIAPINE 600 MG (BIPOLAR I)	E0022048	01MAR1997-CONTINUE	2222	YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	150.0 MG	CONTRACEPTION IM Q 3 MONTHS
	E0022051	01JAN1990-CONTINUE	4844	YES	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	0.63 MG	POST MENOPAUSAL STATUS
		01JAN1998-CONTINUE	1922	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	HEARTBURN
		01JAN1979-CONTINUE	8862	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		01AUG1988-11MAR2003	5362	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	450.0 MG	DEPRESSION
			5362	NO	TRAZODONE [NERVOUS SYSTEM]	200.0 MG	INSOMNIA
		12MAR2003-15MAR2003	26	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
			26	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA
	E0022053	01JUL1991-CONTINUE	4302	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
	E0022058	01JUL1990-CONTINUE	4677	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		01JUL1985-CONTINUE	6503	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE

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QUETIAPINE 600 MG (BIPOLAR I)	E0022058	11MAR2003-11APR2003	41	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
	E0022061	01JAN1996-CONTINUE	2676	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	975.0 MG	HEADACHES
		15APR2003-CONTINUE	15	YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	150.0 MG	CONTRACEPTION
	E0022062	01MAR2003-CONTINUE	65	YES	SILDENAFIL CITRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	50.00 MG	ERECTILE DYSFUNCTION
		01JAN2001-CONTINUE	854	YES	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	ALLERGIC RHINITIS
		01JAN1993-CONTINUE	3776	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
		UNK-24APR2003		NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
		UNK-25APR2003		NO	CLONAZEPAM [NERVOUS SYSTEM]	MG	BIPOLAR
				NO	MODAFINIL [NERVOUS SYSTEM]	MG	BIPOLAR
				NO	NEFAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	MG	BIPOLAR
		01JAN1983-CONTINUE	7429	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
		03FEB2003-04FEB2003	91	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR

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QUETIAPINE 600 MG (BIPOLAR I)	E0022062	05FEB2003-25APR2003	89	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
		25APR2003-26APR2003	10	NO	LITHIUM [NERVOUS SYSTEM]	600.0 MG	BIPOLAR
		27APR2003-28APR2003	8	NO	LITHIUM [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
		28APR2003-07MAY2003	7	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
	E0022068	01DEC2002-CONTINUE	173	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHES
		15FEB2003-13MAY2003	97	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	DEPRESSION
		10MAY2003-11MAY2003	13	NO	AMITRIPTYLINE [NERVOUS SYSTEM]	10.00 MG	DEPRESSION
	E0022069	01MAY2001-CONTINUE	770	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	INDIGESTION
		04JUN2003-10JUN2003	6	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	BIPOLAR
		01JAN1991-CONTINUE	4543	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	HEADACHES
			4543	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	DYSMENORRHEA

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QUETIAPINE 600 MG (BIPOLAR I)	E0022071	01JUL2001-15JUN2003	729	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
		15MAR2003-15JUN2003	107	NO	BUSPIRONE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
			107	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	DEPRESSION
		16JUN2003-17JUN2003	14	NO	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY SECONDARY TO DEPRESSED EPISODE
		18JUN2003-30JUN2003	12	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY SECONDARY TO DEPRESSED EPISODE
	E0023003	01JAN2001-CONTINUE	715	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			715	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		14DEC2001-15DEC2002	368	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
	E0023006	24JUN2002-09DEC2002	176	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR DEPRESSION
		29OCT2002-09DEC2002	49	NO	LAMOTRIGINE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DEPRESSION
		10DEC2002-11DEC2002	7	NO	LAMOTRIGINE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR

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QUETIAPINE 600 MG (BIPOLAR I)	E0023006	10DEC2002-11DEC2002	7	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR DEPRESSION
		11DEC2002-13DEC2002	6	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	12.50 MG	BIPOLAR DEPRESSION
		12DEC2002-14DEC2002	5	NO	LAMOTRIGINE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR
	E0023010	01NOV2002-01JAN2003	95	NO	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	BIPOLAR
			95	NO	LAMOTRIGINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR
		01NOV2002-01FEB2003	95	NO	CLONAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
	E0023025	01SEP2002-22APR2003	256	NO	GABAPENTIN [NERVOUS SYSTEM]	1800 MG	BIPOLAR DISORDER
	E0026002	01JUL1984-CONTINUE	6708	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]		HEADACHES (PRN)
	E0026007	15JUN2002-CONTINUE	215	YES	ATENOLOL [CARDIOVASCULAR SYSTEM]	50.00 MG	HYPERTENSION
		15JAN2003-CONTINUE	1	YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		01JUL1987-15DEC2002	5678	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR I)	E0026007	15OCT2002-02JAN2003	93	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR I
	E0026013	01JUL1999-CONTINUE	1323	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]		BIRTH CONTROL
			1323	YES	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
	E0028023	17DEC2002-CONTINUE	35	YES	LABETALOL [CARDIOVASCULAR SYSTEM]	200.0 MG	HYPERTENSION
		UNK-UNK		YES	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	UNK	BACK PAIN
				YES	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	UNK
		17DEC2002-05FEB2003	35	YES	CLONIDINE [CARDIOVASCULAR SYSTEM]	0.30 MG	HYPERTENSION
		17DEC2002-21FEB2003	35	YES	MINOXIDIL [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERTENSION
	E0028025	01JAN1991-CONTINUE	4395	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JAN2000-29DEC2002	1108	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR
		01JUN2000-12JAN2003	956	NO	MELATONIN [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	2.00 MG	INSOMNIA

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QUETIAPINE 600 MG (BIPOLAR I)	E0028033	01JUL2002-CONTINUE	269	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFF	ASTHMA
			269	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 SPRAY	ALLERGIES
		01DEC2002-18MAR2003	116	NO	NEFAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEP/ANXIETY SYMPTOMS
		01DEC2002-20MAR2003	116	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR ILLNESS
	E0028035	01JAN2000-CONTINUE	1188	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	OCCASIONAL HEARTBURN
		27MAR2003-CONTINUE	7	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	CARDIAC PROPHYLAXIS
	E0028037	01JAN2003-CONTINUE	163	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JAN2000-CONTINUE	1259	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINE HEADACHES
		05MAY2003-CONTINUE	39	YES	ROSIGLITAZONE MALEATE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	DIABETES
		01JAN2000-16APR2003	1259	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION
		01JAN2000-06JUN2003	1259	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	BIPOLAR

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QUETIAPINE 600 MG (BIPOLAR I)	E0028039	05MAY2003-07MAY2003	4	NO	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	3.00 TAB	COLD SYMPTOMS
		08MAY2003-09MAY2003	1	YES	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	HEAD INJURY
	E0029008	01SEP2002-CONTINUE	106	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
			106	YES	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	10.00 MG	ABDOMINAL PAIN
	E0029011	01JAN2000-CONTINUE	1117	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE PRN
		01JAN2001-CONTINUE	751	YES	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	3.00 TABS	PROPHYLAXIS PRN
	E0029012	15JAN2002-CONTINUE	392	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	PRN. FOR HEADACHES
		15SEP2002-14JAN2003	149	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	1500 MG	MOOD STABITIZATION
		15SEP2002-21JAN2003	149	NO	LAMOTRIGINE [NERVOUS SYSTEM]	50.00 MG	MOOD STABILIZATION
		15SEP2002-24JAN2003	149	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	DEPRESSION
		15OCT2002-21JAN2003	119	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR I)	E0029012	28JAN2003-17FEB2003	14	YES	NICOTINE [NERVOUS SYSTEM]	7.00 MG	PRN. FOR SMOKING CESSATION
	E0029015	01FEB2002-CONTINUE	388	YES	OXYBUTYNIN [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	OVER - ACTIVE BLADDER
		01JAN1993-CONTINUE	3706	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	LOWER BACK PAIN
		01NOV2002-11FEB2003	115	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DISORDER
			115	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR DISORDER
		01JAN1994-CONTINUE	3341	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.20 MG	HYPOTHYROIDISM
		01NOV2002-18FEB2003	115	NO	ZALEPLON [NERVOUS SYSTEM]	1.00 CAP	INSOMNIA
		18FEB2003-CONTINUE	6	YES	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY - BIPOLAR DISORDER
			6	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA - BIPOLAR DISORDER
	E0029018	15APR2002-17FEB2003	325	NO	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	RIGHT HIP PAIN
		05MAR2003-05MAR2003	1	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	RIGHT HIP PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0030014	01JUL2002-CONTINUE	235	YES	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	PROPHYLAXIS
			235	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			235	YES	OMEGA-3 MARINE TRIGLYCERIDES [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
			235	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			235	YES	UBIDECARENONE [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
		01JUL1984-CONTINUE	6809	YES	ACETAZOLAMIDE [NERVOUS SYSTEM]	500.0 MG	MYOTOMIC DYSTROPHY
	E0030020	01JUL1992-CONTINUE	3984	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
		12APR2003-05MAY2003	47	NO	LORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIES
		05MAY2003-05MAY2003	24	NO	TRAZODONE [NERVOUS SYSTEM]	0.50 TAB	SLEEP
		11MAY2003-11MAY2003	18	NO	TRAZODONE [NERVOUS SYSTEM]	1.00 TAB	SLEEP
		12MAY2003-12MAY2003	17	NO	TRAZODONE [NERVOUS SYSTEM]	0.50 TAB	SLEEP
	E0030024	01JUL1992-CONTINUE	4027	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
		15MAR2003-30JUN2003	118	NO	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

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QUETIAPINE 600 MG (BIPOLAR I)	E0030024	01JUN2003-01JUN2003	40	NO	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TAB	SINUS INFECTION
		07JUL2003-CONTINUE	4	YES	BENZYLPENICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	GUM INFECTION
	E0030025	15FEB2003-CONTINUE	146	YES	ALENDRONATE SODIUM [MUSCULO-SKELETAL SYSTEM]	35.00 MG	PREVENTION OF OSTEOPOROSIS
	E0031027	15MAY2002-26MAY2003	384	NO	RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
			384	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR
		01JUN2003-CONTINUE	2	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	EMPHYSEMA
	E0034001	01JAN1993-CONTINUE	3730	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES (PRN)
	E0034004	01JAN2001-CONTINUE	840	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	PRN FOR HEADACHES
		01JAN1980-CONTINUE	8511	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	PRN FOR STIFF JOINTS
			8511	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GENERAL HEALTH
	E0035001	01JUL1999-CONTINUE	1238	YES	METOPROLOL [CARDIOVASCULAR SYSTEM]	100.0 MG	HYPERTENSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 600 MG (BIPOLAR I)	E0035001	01JUL2000-12NOV2002	872	NO	RISPERIDONE [NERVOUS SYSTEM]	6.00 MG	PSYCHOSIS
			872	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	MOOD STABILIZER
	E0035021	15FEB2003-12APR2003	69	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	MOOD STABILIZER
		15APR2003-17APR2003	10	NO	CODEINE PHOSPHATE [NERVOUS SYSTEM]	1000 MG	MENSTRUAL CRAMPS
	E0036002	01JAN1997-CONTINUE	2358	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	2.00 CAPS	PROPHYLAXIS
			2358	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0036006	01JAN1993-CONTINUE	3835	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA, PRN
		01FEB2002-10JUN2003	517	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
		11MAY2003-CONTINUE	53	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTROESOPHAGEAL REFLUX DISEASE
	E0036007	01JUN2001-CONTINUE	762	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TAB	SEASONAL ALLERGIES, - PRN
		01APR2003-25JUN2003	93	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR DEPRESSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 600 MG (BIPOLAR I)	E0037009	01JAN2000-CONTINUE	1231	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
			1231	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		15APR2002-08MAY2003	396	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	DEPRESSION
		09MAY2003-15MAY2003	7	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0039026	01JUL2000-CONTINUE	979	YES	HERBAL PREPARATION [VARIOUS]	4.00 TABS	CONSTIPATION (AS NEEDED)
		25FEB2003-25FEB2003	10	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
		01JUL1975-CONTINUE	10111	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	2000 MG	PROPHYLAXIS
			10111	YES	HERBAL PREPARATION [VARIOUS]	600.0 MG	PROPHYLAXIS
			10111	YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	PROPHYLAXIS
			10111	YES	RETINOL [ALIMENTARY TRACT AND METABOLISM]	25000 IU	PROPHYLAXIS
			10111	YES	SELENIUM [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	PROPHYLAXIS
			10111	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	400.0 IU	PROPHYLAXIS
		15JAN2003-26FEB2003	51	NO	MINERAL SUPPLEMENTS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	APPETITE SUPPSESSANT

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 600 MG (BIPOLAR I)	E0039028	23JAN2003-24FEB2003	60	NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR DISORDER
			60	NO	RISPERIDONE [NERVOUS SYSTEM]	3.00 MG	BIPOLAR DISORDER
		05MAR2003-CONTINUE	19	YES	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX
		05MAR2003-15MAY2003	19	YES	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR DISORDER
			19	YES	RISPERIDONE [NERVOUS SYSTEM]	3.00 MG	BIPOLAR DISORDER
	E0039034	10MAR2003-11MAR2003	9	NO	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	TOOTHEXTRACTION
		12MAR2003-CONTINUE	7	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	TOOTH EXTRACTION (AS NEEDED)
		14MAR2003-15MAR2003	5	NO	BENZYLPENICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	2.00 TABS	ORAL INFECTION
	E0039042	01JUL2000-CONTINUE	1040	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFF	ASTHMA
		06MAY2003-06MAY2003	1	NO	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 APP	BURN ON BACK OF NECK
		15MAR2003-CONTINUE	53	YES	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	CONSTIPATION
		05MAY2003-05MAY2003	2	NO	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 600 MG (BIPOLAR I)	E0041004	01JAN2001-CONTINUE	759	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0041009	15FEB2003-21APR2003	75	NO	ZIPRASIDONE HYDROCHLORIDE [NERVOUS SYSTEM]	60.00 MG	BIPOLAR DISORDER
	E0042002	01JUL1999-CONTINUE	1469	YES	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	180.0 MG	HYPERTENSION
		23OCT2002-CONTINUE	259	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	1.10 GM	TENDONITIS KNEES
		15NOV2002-11JUN2003	236	NO	AMITRIPTYLINE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR II)	E0001006	01JUL2000-CONTINUE	1105	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIES PRN
			1105	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SNIFF	ALLERGIES PRN
		15DEC2002-CONTINUE	208	YES	GINGER [VARIOUS]	3.00 TABS	WEIGHT LOSS
	E0003002	15JAN2002-CONTINUE	287	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	250.0 MG	OCCASIONAL BODY ACHES AND PAINS
	E0005031	01APR2001-CONTINUE	731	YES	NORETHISTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
	E0005033	01JUL2002-CONTINUE	289	YES	CEFALEXIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	FOLICULITIS
		01JUL2001-CONTINUE	654	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	2000 MG	NUTRITIONAL SUPPLEMENT
		01JUL2001-14APR2003	654	NO	ETHANOL [NERVOUS SYSTEM]	2.00 TBSP	INSOMNIA
	E0005038	UNK-CONTINUE		YES	EPINEPHRINE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA - SMOKING INDUCED PRN
		01MAY2003-01MAY2003	13	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE

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QUETIAPINE 600 MG (BIPOLAR II)	E0005038	02MAY2003-02MAY2003	12	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	200.0 MG	MENSTRAL CRAMPING
	E0009010	15NOV2002-26FEB2003	118	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	BI - POLAR DISODER
			118	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	BI - POLAR DISORDER
		15NOV2002-06MAR2003	118	NO	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	INDEGESTION
	E0009011	01JUL2001-CONTINUE	674	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01APR2003-CONTINUE	35	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	PROPHYLAXIS
	E0010005	04DEC2002-CONTINUE	14	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA
	E0011016	UNK-CONTINUE		YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	HEADACHE; PAIN PRN DUE TO BACK STRAIN
				YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE PRN
	E0011020	01JAN2003-CONTINUE	127	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	MIGRAINE PRN
		01JUL1983-CONTINUE	7251	YES	PARACETAMOL [NERVOUS SYSTEM]	1500 MG	HEADACHES PRN

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QUETIAPINE 600 MG (BIPOLAR II)	E0018002	01JUN1998-CONTINUE	1642	YES	NABUMETONE [MUSCULO-SKELETAL SYSTEM]	600.0 MG	ARTHRITIS
			1642	YES	OXAPROZIN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	ARTHRITIS
		01JUN1995-CONTINUE	2738	YES	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES
		01JUN1996-CONTINUE	2372	YES	TAMSULOSIN HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	0.40 MG	SEASONAL ALLERGIES
		01JUN1999-14NOV2002	1277	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	30.00 MG	DEPRESSION
	E0018003	01JUN1988-CONTINUE	5291	YES	LEVONORGESTREL [GENITO URINARY SYSTEM AND SEX HORMONES]	36.00 MG	BIRTH CONTROL
		22NOV2002-23NOV2002	4	NO	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	275.0 MG	MIGRAINE
			4	NO	SUMATRIPTAN SUCCINATE [NERVOUS SYSTEM]	50.00 MG	MIGRAINE
	E0018013	01JUL1990-CONTINUE	4590	YES	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA
	E0019002	01NOV2001-CONTINUE	376	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TAB	SEASONAL ALLERGIES
		01JAN2000-19NOV2002	1046	YES	HERBAL PREPARATION [VARIOUS]	1.00 TAB	ENERGY
		01MAY2002-28OCT2002	195	NO	AMITRIPTYLINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	MIGRAINE HEADACHES

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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QUETIAPINE 600 MG (BIPOLAR II)	E0019002	01MAY2002-29OCT2002	195	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSIVE SYMPTOMS
	E0019008	01JAN1987-CONTINUE	5803	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MENSTRAL CRAMPS
		01DEC2001-CONTINUE	355	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.09 MG	HYPOTHYROIDISM
		13NOV2002-CONTINUE	8	YES	CAMPHOR [RESPIRATORY SYSTEM]	TOPICAL	CHEST CONGESTION
	E0019009	06NOV2002-CONTINUE	8	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 CAP	BIRTH CONTROL
	E0019016	04JAN2003-CONTINUE	2	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	UNK	HEADACHE
	E0019020	15JAN2003-15JAN2003	8	NO	HYDROXYZINE EMBONATE [NERVOUS SYSTEM]	UNK	INSOMNIA (SECONDARY TO BIPOLAR DEPRESSION)
	E0019021	01JAN2002-CONTINUE	394	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	SUPPLEMENT
		01JAN1998-01JAN2003	1855	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	26JAN2003-CONTINUE	4	YES	ALLERGY MEDICATION [RESPIRATORY SYSTEM]	2.00 CAPS	SINUS ALLERGIES (PRN)
	E0019031	01FEB2000-CONTINUE	1136	YES	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	PROPHYLAXIS
	E0019040	10MAY2003-11MAY2003	10	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	37.50 MG	DEPRESSION
		08MAY2003-09MAY2003	12	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	DEPRESSION
		01NOV2002-07MAY2003	200	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
		01NOV2002-03JUN2003	200	YES	RABEPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	ACID REFLUX
		19MAY2003-26MAY2003	1	YES	BENZONATATE [RESPIRATORY SYSTEM]	600.0 MG	UPPER RESPIRATORY INFECTION
		19MAY2003-08JUN2003	1	YES	BENZONATATE [RESPIRATORY SYSTEM]	200.0 MG	COUGH PRN
			1	YES	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TABS	UPPER RESPIRATORY INFECTION
		19MAY2003-10JUN2003	1	YES	BUDESONIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	UPPER RESPIRATORY INFECTION

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QUETIAPINE 600 MG (BIPOLAR II)	E0019042	01SEP2002-25MAY2003	276	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	2.00 CAPS	INSOMNIA.
		01DEC2002-20MAY2003	185	NO	HERBAL PREPARATION [VARIOUS]	6.00 CAPS	WEIGHT LOSS
		28FEB2003-CONTINUE	96	YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 INJECTION	CONTRACEPTION
	E0019045	01OCT2002-08JUN2003	268	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR
		01OCT2002-17JUN2003	268	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
	E0020024	01JAN2002-15MAY2003	538	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	250.0 MG	DEPRESSION
			538	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	DEPRESSION
		01JAN2002-13JUN2003	538	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	1200 MG	BIPOLAR
		11JUN2003-21JUN2003	12	NO	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
	E0022044	01JAN2000-CONTINUE	1172	YES	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	INDIGESTION
			1172	YES	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	DIARRHEA
			1172	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0022044	01JAN1985-CONTINUE	6650	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 MCG	ASTHMA
	E0023007	01JAN2002-01DEC2002	378	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
		01SEP2002-12JAN2003	135	NO	LAMOTRIGINE [NERVOUS SYSTEM]	300.0 MG	BI - POLAR
		10JAN2003-CONTINUE	4	YES	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	1200 MG	HEARTBURN
	E0023011	15JUL2002-CONTINUE	204	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.75 MG	HYPOTHYROIDISM
		15APR1999-CONTINUE	1391	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ALLERGIES
		15MAR2002-27JAN2003	326	NO	GABAPENTIN [NERVOUS SYSTEM]	1200 MG	BIPOLAR
			326	NO	LAMOTRIGINE [NERVOUS SYSTEM]	400.0 MG	BIPOLAR
			326	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	30.00 MG	BIPOLAR - DEPRESSION
		15APR2002-27JAN2003	295	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA
		15JUL2002-27JAN2003	204	NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
		28JAN2003-29JAN2003	7	NO	GABAPENTIN [NERVOUS SYSTEM]	600.0 MG	BIPOLAR

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0023011	28JAN2003-29JAN2003	7	NO	LAMOTRIGINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR
			7	NO	LITHIUM [NERVOUS SYSTEM]	600.0 MG	BIPOLAR
		29JAN2003-30JAN2003	6	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR - DEPRESSION
		30JAN2003-31JAN2003	5	NO	GABAPENTIN [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
			5	NO	LAMOTRIGINE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR
			5	NO	LITHIUM [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
		31JAN2003-31JAN2003	4	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR DEPRESSION
	E0023014	06FEB2002-13FEB2003	380	NO	CODEINE PHOSPHATE [NERVOUS SYSTEM]	30.00 MG	SHOULDER PAIN
		15JAN2003-14FEB2003	37	NO	OLANZAPINE [NERVOUS SYSTEM]	2.50 MG	BIPOLAR DISORDER
			37	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
		15FEB2003-16FEB2003	6	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	100.0 MG	DEPRESSION
		17FEB2003-19FEB2003	4	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	DEPRESSION
	E0023019	01DEC2002-19MAR2003	127	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR II)	E0023019	14MAR2003-20MAR2003	24	NO	ALPRAZOLAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
	E0023023	01JAN2003-14APR2003	114	NO	AMITRIPTYLINE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION
		01JUN1997-CONTINUE	2154	YES	HYOSCYAMINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	0.75 MG	BIPOLAR
		06DEC2000-15APR2003	870	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY
		29JAN2002-17APR2003	451	NO	NEFAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
		18APR2003-19APR2003	7	NO	NEFAZODONE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
	E0023031	01DEC2000-08MAY2003	935	NO	LORAZEPAM [NERVOUS SYSTEM]	4.00 MG	ANXIETY
		01JUN2002-15APR2003	388	NO	LAMOTRIGINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR
		01AUG2002-22MAY2003	327	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR
		15APR2003-22MAY2003	70	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR II)	E0023043	01APR2003-06JUL2003	104	NO	ALPRAZOLAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY ASSOCIATED WITH EPISODE OF DEPRESSION.
	E0026003	UNK-CONTINUE		YES	AMITRIPTYLINE HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	BIPOLAR II
				YES	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	BIPOLAR II
				YES	CLONIDINE [CARDIOVASCULAR SYSTEM]	UNK	HYPERTENSION
				YES	GABAPENTIN [NERVOUS SYSTEM]	UNK	UNK
				YES	LEVETIRACETAM [NERVOUS SYSTEM]	UNK	UNK
				YES	POTASSIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	UNK	HYPOKALEMIA
				YES	RITONAVIR [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	H. I. V.
				YES	TAMSULOSIN HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	UNK	UNK
				YES	TOPIRAMATE [NERVOUS SYSTEM]	UNK	UNK
				YES	ZIDOVUDINE [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	H. I. V.
		01JUL1978-24NOV2002	8922	NO	LITHIUM [NERVOUS SYSTEM]	600.0 MG	BIPOLAR II
		01JUL1990-24NOV2002	4539	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	BIPOLAR II
		24JAN2002-24NOV2002	314	NO	DIAZEPAM [NERVOUS SYSTEM]	10.00 MG	INSOMNIA

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QUETIAPINE 600 MG (BIPOLAR II)	E0026003	14NOV2002-24NOV2002	20	NO	PARACETAMOL [NERVOUS SYSTEM]		PINCHED NERVE
	E0026005	15JUL2002-CONTINUE	168	YES	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	HEARTBURN
		01JUL1995-22DEC2002	2739	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
		23DEC2002-25DEC2002	7	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	DEPRESSION
	E0026009	01JUL2001-06JAN2003	563	NO	TOPIRAMATE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR II
	E0026015	04FEB2003-04FEB2003	23	NO	CODEINE PHOSPHATE [NERVOUS SYSTEM]	4.00 CAPS	MIGRAINES
	E0026023	01JUL1995-CONTINUE	2860	YES	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	10.00 MG	SCOLIOSIS
		27APR2003-CONTINUE	3	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	200.0 MCG	ACUTE BRONCHITIS
		27APR2003-03MAY2003	3	YES	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	ACUTE BRONCHITIS
	E0027016	12MAR2003-CONTINUE	28	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHES (PRN)

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QUETIAPINE 600 MG (BIPOLAR II)	E0027016	15JAN2002-18MAR2003	449	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	60.00 MG	BIPOLAR DEPRESSION
		15MAY2002-18MAR2003	329	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	1200 MG	BIPOLAR
		19MAR2003-27MAR2003	21	NO	DOXYCYCLINE [ALIMENTARY TRACT AND METABOLISM]	200.0 MG	CHLAMYDIA
	E0027018	15JAN2003-CONTINUE	69	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	UNK	ASTHMA
		15JAN2003-15FEB2003	69	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	BIPOLAR DEPRESSION
	E0029003	20SEP2002-CONTINUE	45	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE
		20SEP2002-11NOV2002	45	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
		01OCT2002-15OCT2002	34	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
		17OCT2002-27OCT2002	18	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	DEPRESSION
	E0031005	01NOV2002-CONTINUE	49	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			49	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			49	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT

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QUETIAPINE 600 MG (BIPOLAR II)	E0031005	01NOV2002-CONTINUE	49	YES	GINKGO BILOBA [NERVOUS SYSTEM]	1.00 TAB	VITAMIN SUPPLEMENT
			49	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	BURSITIS IN SHOULDERS
			49	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	HIP PAIN
			49	YES	OMEGA-3 MARINE TRIGLYCERIDES [CARDIOVASCULAR SYSTEM]	1.00 TAB	VITAMIN SUPPLEMENT
			49	YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			49	YES	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERCHOLESTEROLEMIA
			49	YES	UBIDECARENONE [CARDIOVASCULAR SYSTEM]	1.00 TAB	VITAMIN SUPPLEMENT
			49	YES	ZINC [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
		01JUL1997-CONTINUE	1998	YES	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	0.15 MG	REFLUX
		01JUL1999-CONTINUE	1268	YES	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	ENVIRONMENTAL ALLERGIES
		15FEB2000-06DEC2002	1039	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	900.0 MG	DEPRESSION
		15JUL2002-06DEC2002	158	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	1800 MG	DEPRESSION
			158	NO	ZIPRASIDONE HYDROCHLORIDE [NERVOUS SYSTEM]	160.0 MG	DEPRESSION
		07DEC2002-09DEC2002	13	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	600.0 MG	DEPRESSION
		07DEC2002-12DEC2002	13	NO	OXCARBAZEPINE [NERVOUS SYSTEM]	MG	DEPRESSION

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QUETIAPINE 600 MG (BIPOLAR II)	E0031005	10DEC2002-12DEC2002	10	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
	E0031006	01NOV2001-05FEB2003	474	NO	FUROSEMIDE [CARDIOVASCULAR SYSTEM]	80.00 MG	HYPERTENSION
		01DEC2001-05FEB2003	444	NO	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		08DEC2002-15JAN2003	72	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
		31JAN2003-04FEB2003	18	NO	ZALEPLON [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		10FEB2003-CONTINUE	8	YES	FUROSEMIDE [CARDIOVASCULAR SYSTEM]	80.00 MG	HYPERTENSION
			8	YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERTENSION
		10FEB2003-18FEB2003	8	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0031010	01JAN1996-CONTINUE	2606	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	STOMACH ACHES
		31JAN2003-CONTINUE	19	YES	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	25.00 MG	SHOULDER PAIN
	E0031011	01JAN2002-CONTINUE	422	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES

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QUETIAPINE 600 MG (BIPOLAR II)	E0031011	01JAN2001-CONTINUE	787	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	HIATAL HERNIA
	E0031015	UNK-CONTINUE		YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	450.0 MG	LEG CRAMPS
		01JUL1995-CONTINUE	2825	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		15OCT2002-CONTINUE	162	YES	EQUISETUM ARVENSE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	NUTRITIONAL SUPPLEMENT
			162	YES	HERBAL PREPARATION [VARIOUS]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		19MAR2003-26MAR2003	7	YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	SORE THROAT
	E0031031	15DEC2002-CONTINUE	205	YES	VALACICLOVIR HYDROCHLORIDE [ANTIINFECTIVES FOR SYSTEMIC USE]	1.00 G	GENITAL HERPES
		30JUN2003-CONTINUE	8	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	SINUS HEADACHES
	E0034009	01JAN1998-CONTINUE	1995	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	SHOULDER PAIN
		17JUN2003-17JUN2003	2	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	SHOULDER PAIN
	E0037007	01JAN2001-CONTINUE	830	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE

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QUETIAPINE 600 MG (BIPOLAR II)	E0037007	01JAN2001-CONTINUE	830	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		15FEB2002-23MAR2003	420	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
	E0037012	01JAN2002-CONTINUE	561	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	BACK
			561	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	SHIN PAIN
		01JAN2000-CONTINUE	1292	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE PAIN
	E0039019	01JAN2002-CONTINUE	401	YES	LATANOPROST [SENSORY ORGANS]	1.00 DROP	GLAUCOMA
		01DEC2001-CONTINUE	432	YES	FERROUS SULFATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01DEC2001-23JAN2003	432	NO	MIRTAZAPINE [NERVOUS SYSTEM]	60.00 MG	BIPOLAR
		01DEC2001-25JAN2003	432	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	100.0 MG	INSOMNIA
		01DEC2001-26JAN2003	432	NO	RISPERIDONE [NERVOUS SYSTEM]	2.00 MG	BIPOLAR
		24JAN2003-26JAN2003	13	NO	MIRTAZAPINE [NERVOUS SYSTEM]	30.00 MG	BIPOLAR

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QUETIAPINE 600 MG (BIPOLAR II)	E0039043	01JUL2000-CONTINUE	1041	YES	ANTIHISTAMINES FOR SYSTEMIC USE [RESPIRATORY SYSTEM]	4.00 TABS	SEASONAL ALLERGIES
		01MAR2003-30MAR2003	68	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	MG	MANIA SYMPTOMS
			68	NO	TRAZODONE [NERVOUS SYSTEM]	400.0 MG	INSOMNIA
		21APR2003-03MAY2003	17	NO	GINGER [VARIOUS]	1.00 TAB	PROPHYLAXIS

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PLACEBO (BIPOLAR I)	E0002001	15FEB2002-CONTINUE	318	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	ELEVATED CHOLESTEROL
		15SEP1993-CONTINUE	3393	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	50.00 UG	HYPOTHYROIDISM
		01NOV2002-13DEC2002	59	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION BIPOLAR DISORDER
			59	NO	RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	MOOD SWINGS
		25DEC2002-CONTINUE	5	YES	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 MG	HORMONE REPLACEMENT THERAPY
	E0002003	03JAN2003-CONTINUE	19	YES	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	SEVERE JUVENILE ARTHRITIS
			19	YES	ETANERCEPT [ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS]	25.00 MG	ARTHRITIS/2 TIMES A WEEK
	E0002004	24JAN2003-CONTINUE	1	YES	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	150.0 MG	PRURITIS
		15JUL2001-17JAN2003	559	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR DISORDER
		15NOV2002-20JAN2003	71	NO	CLONAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
		17JAN2003-CONTINUE	8	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY

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PLACEBO (BIPOLAR I)	E0002004	17JAN2003-CONTINUE	8	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		17JAN2003-22JAN2003	8	NO	CLARITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	BRONCHITIS/SINUS INFECTION
			8	NO	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	1000 MG	BRONCHITIS, SINUS INFECTION
	E0002008	22MAR2000-10FEB2003	1070	NO	TRAZODONE [NERVOUS SYSTEM]	50.00 MG	INSOMNIA DUE TO BIPOLAR DEPRESSION
		14FEB2001-10FEB2003	741	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	60.00 MG	BIPOLAR DEPRESSION
	E0002016	15MAY2003-CONTINUE	70	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	80.00 MG	HYPERTENSION
		15DEC2002-CONTINUE	221	YES	BISACODYL [ALIMENTARY TRACT AND METABOLISM]	5.00 MG	IRREGULARITY
			221	YES	BISACODYL [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	IRREGULARETY
		15SEP2000-CONTINUE	1042	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	500.0 MG	PROPHYLAXIS
			1042	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1200 MG	NUTRITION
			1042	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITION
			1042	YES	TETRACYCLINE [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	ADULT ACNE
		15JUN1996-CONTINUE	2595	YES	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	0.63 MG	HORMONAL THERAPY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0002016	15SEP1996-13JUL2003	2503	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	30.00 MG	DEPRESSION
		15JAN2001-CONTINUE	920	YES	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	40.00 MG	HIGH CHOLESTEROL
		15APR2002-CONTINUE	465	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	8.00 PUFFS	EMPHYSEMA
			465	YES	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	EMPHYSEMA
		14JUL2003-15JUL2003	10	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	15.00 MG	DEPRESSION
	E0003008	01JUL2002-CONTINUE	211	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 INHALATIONS	ASTHMA PRN
		01JAN2001-17JAN2003	757	NO	DEXAMFETAMINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	50.00 MG	ATTENTION PROBLEMS
	E0004003	15AUG2002-CONTINUE	56	YES	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0004016	15JAN2001-CONTINUE	765	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	600.0 MG	SUPPLEMENT
			765	YES	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
		15DEC2001-07FEB2003	431	NO	DEXAMFETAMINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	ADHD

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PLACEBO (BIPOLAR I)	E0004024	15JAN1997-CONTINUE	2360	YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN1997-05JUL2003	2360	YES	VITAMINS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0005006	01AUG2001-CONTINUE	428	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PILL	CARDIAC PROPHYLACTIC
			428	YES	ATENOLOL [CARDIOVASCULAR SYSTEM]	20.00 MG	VASODILATION
			428	YES	GEMFIBROZIL [CARDIOVASCULAR SYSTEM]	1200 MG	HYPERLIPIDEMIA /HYPERTRIGLYCERIDEMIA
			428	YES	PRAVASTATIN SODIUM [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERLIPIDEMIA /HYPERCHOLESTEROLEMIA
			428	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 PILLS	REFLUX (PRN)
		02OCT2002-CONTINUE	1	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 PILLS	HEADACHE (PRN)
	E0005017	01JAN2002-CONTINUE	363	YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGY
			363	YES	MOMETASONE FUROATE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGY
		01JAN1985-CONTINUE	6572	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
			6572	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEARTBURN
		01JAN1985-11DEC2002	6572	NO	ALPRAZOLAM [NERVOUS SYSTEM]	1.00 TAB	ANXIETY - SECONDARY TO BPD

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PLACEBO (BIPOLAR I)	E0005017	06DEC2002-CONTINUE	24	YES	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	120.0 MG	BORDERLINE HYPERTENSION
		06DEC2002-06DEC2002	24	NO	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	HEADACHES
		06DEC2002-08DEC2002	24	NO	HYDROCODONE [RESPIRATORY SYSTEM]	2.00 TAB	HEADACHES
		11DEC2002-06JAN2003	19	YES	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	HEADACHES
		11DEC2002-14JAN2003	19	YES	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY - SECONDARY TO BPD
	E0005019	01JUL1998-07JAN2003	1659	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	2.00 TABS	PRN INSOMNIA SECONDARY TO BPD
		20DEC2002-CONTINUE	26	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL
	E0005026	UNK-CONTINUE		YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	PRN FOR HEADACHES/BACK PAIN
		28FEB2003-05MAR2003	6	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
	E0005039	01JAN2003-CONTINUE	141	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEARTBURN

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PLACEBO (BIPOLAR I)	E0005039	01APR2002-CONTINUE	416	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	SEASONAL ALLERGIES
		11MAY2003-CONTINUE	11	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHES/MUSCLE ACHES
		UNK-13MAY2003		NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
	E0006020	15APR1996-CONTINUE	2584	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SPRAY	SEASONAL ALLERGIES PRN
			2584	YES	PSEUDOEPHEDRINE SULFATE [RESPIRATORY SYSTEM]	1.00 TABLET	SEASONAL ALLERGIES PRN
	E0007001	28MAR2002-23DEC2002	278	NO	LAMOTRIGINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DISORDER
		01OCT2002-22JAN2003	91	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	TENDONITIS LEFT ELBOW
	E0007003	UNK-CONTINUE		YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	20.00 MG	(HTN) HYPERTENSION
		01JUL2002-19JAN2003	213	NO	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	20.00 MGM	BIPOLAR
			213	NO	DIAZEPAM [NERVOUS SYSTEM]	5.00 MGM	BIPOLAR
			213	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MGM	BIPOLAR
			213	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR
		02JUL2002-CONTINUE	212	YES	FELODIPINE [CARDIOVASCULAR SYSTEM]	5.00 MG	(HTN) HYPERTENSION

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PLACEBO (BIPOLAR I)	E0009004	15SEP2002-16NOV2002	72	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	375.0 MG	BIPOLAR
		20SEP2002-28OCT2002	67	NO	METHYSERGIDE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR
		19NOV2002-13DEC2002	7	YES	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY
	E0009012	01JUL1999-09JUN2003	1455	NO	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	TAB	HEADACHES
	E0010008	01FEB2002-27NOV2002	320	NO	SEROTONIN ANTAGONISTS [CARDIOVASCULAR SYSTEM]	MG	PRN INSOMNIA
		01FEB2002-04DEC2002	320	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	MG	PRN INSOMNIA
	E0010018	15FEB2003-26FEB2003	32	NO	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS [MUSCULO-SKELETAL SYSTEM]	MG	BACK PAIN PRN
			32	NO	MUSCLE RELAXANTS [MUSCULO-SKELETAL SYSTEM]	MG	BACK PAIN PRN
		26FEB2003-09APR2003	21	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
	E0010028	UNK-CONTINUE		YES	VALACICLOVIR HYDROCHLORIDE [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	GENITAL HERPES
		09JUN2003-08JUL2003	7	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA

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PLACEBO (BIPOLAR I)	E0011009	UNK-CONTINUE		YES	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1500 MG	HEADACHES
	E0011010	UNK-CONTINUE		YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES PRN
	E0013003	01JAN1998-CONTINUE	1776	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0013005	06JAN2003-11FEB2003	43	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	MANIC/DEPRESSION
			43	NO	RISPERIDONE [NERVOUS SYSTEM]	3.00 MG	BIPOLAR
			43	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	625.0 MG	BIPOLAR
		20JAN2003-11FEB2003	29	NO	LORAZEPAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY
	E0013013	01JUL1998-CONTINUE	1770	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DYSPEPSIA
		01JUL2000-CONTINUE	1039	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TABS	NUTRITIONAL SUPPLEMENT
			1039	YES	IRON [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		15MAR2003-CONTINUE	52	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHES
		20APR2003-27APR2003	16	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	BIPOLAR DISORDER

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PLACEBO (BIPOLAR I)	E0014002	23FEB2003-23FEB2003	3	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	HAYFEVER
	E0014004	20DEC2002-CONTINUE	82	YES	HOMEOPATIC PREPARATION [VARIOUS]	2.00 CAPS	HOT FLASHES
	E0014009	07MAR2003-CONTINUE	47	YES	FUROSEMIDE [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERTENSION
		18APR2003-22APR2003	5	NO	TRAMADOL [NERVOUS SYSTEM]	50.00 MG	KNEE PAIN
	E0014015	01JUL2002-10JUN2003	352	NO	LITHIUM [NERVOUS SYSTEM]	1200 MG	BIPOLAR DISORDER
	E0014017	15FEB2003-CONTINUE	132	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 PUFF	MILD ASTHMA (PRN)
		18JUN2003-18JUN2003	9	NO	LITHIUM [NERVOUS SYSTEM]	600.0 MG	MANIA
		15AUG2002-17JUN2003	316	NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	MANIA
		19JUN2003-19JUN2003	8	NO	LITHIUM [NERVOUS SYSTEM]	300.0 MG	MANIA
	E0014018	01MAR2003-CONTINUE	122	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES (PRN)
		01FEB2003-CONTINUE	150	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	SINUSITIS

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PLACEBO (BIPOLAR I)	E0014018	07MAY2003-07JUN2003	55	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR DISORDER
	E0015005	01JAN2002-14NOV2002	335	NO	GABAPENTIN [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DISORDER
			335	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
	E0017002	20SEP2002-08MAY2003	256	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	BIPOLAR DISORDER
	E0018009	01SEP2002-16DEC2002	127	NO	LITHIUM [NERVOUS SYSTEM]	1800 MG	BIPOLAR DEPRESSION
			127	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DEPRESSION
		31OCT2002-16DEC2002	67	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DEPRESSION
		27DEC2002-02JAN2003	10	NO	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	UPPER RESPIRATORY INFECTION
			10	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	UPPER RESPIRATORY INFECTION
			10	NO	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	220.0 MG	UPPER RESPIRATORY INFECTION
	E0018010	01JUN1990-CONTINUE	4612	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINES

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PLACEBO (BIPOLAR I)	E0018010	01JUN1999-23DEC2002	1325	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.50 MG	INSOMNIA
	E0020017	01JAN2003-CONTINUE	92	YES	HERBAL PREPARATION [VARIOUS]	2.00 TAB	VITAMIN SUPPLEMENT
			92	YES	OTHER NUTRIENTS [VARIOUS]	3.00 CAP	VITAMIN SUPPLEMENT
			92	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			92	YES	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
		01JAN2002-CONTINUE	457	YES	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	GASTRIC ESOPHAGEAL REFLUX DISORDER
		12MAR2003-CONTINUE	22	YES	HOMEOPATIC PREPARATION [VARIOUS]	4.00 SPRAYS	SEASONAL ALLERGIES
		24MAR2003-CONTINUE	10	YES	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES
		01APR2003-02APR2003	2	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 CAP	MENSTRUAL CRAMPS
	E0020020	01APR2003-04MAY2003	41	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	DEPRESSION
	E0020022	01JAN1993-CONTINUE	3818	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1200 MG	VITAMIN SUPPLEMENT
			3818	YES	FERROUS FUMARATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT

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PLACEBO (BIPOLAR I)	E0022001	01OCT2000-23NOV2002	757	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
	E0022004	01JAN1993-CONTINUE	3587	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHE
	E0022005	01JUL1998-CONTINUE	1591	YES	BUDESONIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			1591	YES	CALCIUM CITRATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			1591	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHES
			1591	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
			1591	YES	PIRBUTEROL ACETATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			1591	YES	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	ASTHMA
			1591	YES	ZOLMITRIPTAN [NERVOUS SYSTEM]	2.50 MG	MIGRAINE
		01JUL1999-CONTINUE	1226	YES	MECLOZINE [RESPIRATORY SYSTEM]	25.00 MG	VERTIGO
			1226	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIC RHINITIS
		01JUN2002-CONTINUE	160	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MCG	HYPOTHYRODISM
			160	YES	LIOTHYRONINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	12.50 MCG	HYPOTHYRODISM
		01JUL1992-CONTINUE	3782	YES	IRON [BLOOD AND BLOOD FORMING ORGANS]	20.00 MG	PROPHYLAXIS

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PLACEBO (BIPOLAR I)	E0022005	01JUL1992-CONTINUE	3782	YES	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			3782	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			3782	YES	ZINC [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	PROPHYLAXIS VISION
		01SEP2002-17OCT2002	68	NO	LITHIUM [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
	E0022011	01JAN1990-CONTINUE	4715	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHE
		01MAR2002-18NOV2002	273	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
		20NOV2002-21NOV2002	9	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
	E0022015	01JAN1999-CONTINUE	1439	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	CHRONIC BACK PAIN
			1439	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
			1439	YES	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		01JUL1999-CONTINUE	1258	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	SHOULDER PAIN
			1258	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
	E0022016	01JAN2000-CONTINUE	1081	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0022016	01JAN1990-CONTINUE	4733	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		01JAN1998-CONTINUE	1811	YES	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	220.0 MG	CHRONIC BACK PAIN
	E0022020	01JAN2000-CONTINUE	1076	YES	HERBAL EXTRACTS NOS [VARIOUS]	1.00 TAB	MIGRAINE HEADACHES
		01JUL2000-CONTINUE	894	YES	SUMATRIPTAN SUCCINATE [NERVOUS SYSTEM]	6.00 MG	MIGRAINE HEADACHES
		01JAN1997-CONTINUE	2171	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
	E0022023	01JAN1970-CONTINUE	12046	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		01JAN2001-18DEC2002	723	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA
		19DEC2002-23DEC2002	6	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		24DEC2002-CONTINUE	1	YES	PARACETAMOL [NERVOUS SYSTEM]	3000 MG	HEADACHES
		24DEC2002-01JAN2003	1	YES	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	INSOMNIA
	E0022029	01JAN1995-CONTINUE	2971	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES

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PLACEBO (BIPOLAR I)	E0022041	01JAN1973-CONTINUE	11033	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		15MAR2003-16MAR2003	3	NO	PSEUDOEPHEDRINE [RESPIRATORY SYSTEM]	30.00 MG	UPPER RESPIRATORY INFECTION
		15MAR2003-17MAR2003	3	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0022043	01JAN2003-CONTINUE	78	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	GASTROESOPHAGEAL REFLUX
		01JAN1999-CONTINUE	1539	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHE
		01JAN1990-CONTINUE	4826	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		01DEC2002-10MAR2003	109	NO	LITHIUM [NERVOUS SYSTEM]	600.0 MG	BIPOLAR
		11MAR2003-12MAR2003	9	NO	LITHIUM [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
	E0022054	01JAN2000-CONTINUE	1196	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	HEARTBURN
		01JAN1997-CONTINUE	2291	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
			2291	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	NECK PAIN

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PLACEBO (BIPOLAR I)	E0022059	01JAN1998-CONTINUE	1951	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
			1951	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	CHRONIC BACK PAIN
		01DEC2001-22APR2003	521	NO	VENLAFAXINE [NERVOUS SYSTEM]	150.0 MG	STUDY CONDITION/BIPOLAR DEPRESSION
		22APR2003-24APR2003	14	NO	CITALOPRAM [NERVOUS SYSTEM]	20.00 MG	STUDY CONDITION/BIPOLAR DEPRESSION TAPER OFF EFFEXOR/VENLAFAXINE
	E0022065	01JAN1995-CONTINUE	3048	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHES
		01FEB2003-CONTINUE	95	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	GASTROESOPHAGEAL REFLUX
			95	YES	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	GASTROESOPHAGEAL REFLUX
		01JAN1988-CONTINUE	5605	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
	E0022070	15NOV2001-CONTINUE	574	YES	METOPROLOL [CARDIOVASCULAR SYSTEM]	200.0 MG	HYPERTENSION
		15DEC2002-CONTINUE	179	YES	COLCHICINE [MUSCULO-SKELETAL SYSTEM]	1.20 MG	GOUT

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PLACEBO (BIPOLAR I)	E0022070	15SEP2001-CONTINUE	635	YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	40.00 MG	HYPERTENSION
			635	YES	MINOXIDIL [CARDIOVASCULAR SYSTEM]	2.50 MG	HYPERTENSION
			635	YES	NIFEDIPINE [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
			635	YES	TRIAMTERENE [CARDIOVASCULAR SYSTEM]	37.50 MG	HYPERTENSION
		15DEC2001-03JUN2003	544	NO	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	40.00 MG	DEPRESSION - BIPOLAR I
		15APR2002-03JUN2003	423	NO	GABAPENTIN [NERVOUS SYSTEM]	800.0 MG	BIPOLAR I
		05MAY2003-12MAY2003	38	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.25 MG	DEPRESSION
	E0023001	01JAN2001-CONTINUE	683	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.15 MG	HYPOTHYROID
	E0023009	15NOV2002-26JAN2003	88	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	BIPOLAR DISORDER
		27JAN2003-29JAN2003	15	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR DISORDER
	E0023028	01OCT2002-15MAY2003	240	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	DEPRESSION
	E0023033	01AUG2002-25MAY2003	308	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR DEPRESSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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PLACEBO (BIPOLAR I)	E0023047	UNK-11JUL2003		NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA SECONDARY TO DEPRESSIVE EPISODE.
		15DEC2001-11JUL2003	580	NO	OLANZAPINE [NERVOUS SYSTEM]	7.50 MG	DEPRESSION
		12JUL2003-13JUL2003	6	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	DEPRESSION
	E0025001	01JUN2002-CONTINUE	304	YES	GLIMEPIRIDE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	NON INSULIN DEPENDENT DIABETES MELLITUS
		01SEP2001-26MAR2003	577	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR I
			577	NO	OLANZAPINE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR I
			577	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	BIPOLAR I
		08MAR2003-29MAR2003	24	NO	NITROFURANTOIN [ANTIINFECTIVES FOR SYSTEMIC USE]	200.0 MG	URINARY TRACT INFECTION
		28MAR2003-16APR2003	4	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0026012	05JAN2003-05JAN2003	46	NO	CARISOPRODOL [MUSCULO-SKELETAL SYSTEM]	350.0 MG	RIGHT SHOULDER PAIN
		01JUL1979-CONTINUE	8635	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES

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PLACEBO (BIPOLAR I)	E0026012	01JUL2002-01FEB2003	234	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	INSOMNIA
		15JAN2003-05FEB2003	36	NO	PARACETAMOL [NERVOUS SYSTEM]	350.0 MG	RIGHT SHOULDER PAIN
	E0026024	01JUL1999-CONTINUE	1401	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MCG	HYPOTHYROID
			1401	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	MCG	ASTHMA
		01JUL1999-23APR2003	1401	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA
		01JUL1999-25APR2003	1401	NO	ZALEPLON [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
			1401	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	MG	INSOMNIA
		01JUL2001-25APR2003	670	NO	TOPIRAMATE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR
			670	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR
	E0026028	01JUL1998-11JUL2003	1815	YES	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTRO - REFLUX
	E0028001	01JUL1999-CONTINUE	1197	YES	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	0.50 TAB	HYPERCHOLESTEROLEMA
		01JUL1992-01OCT2002	3753	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	3500 MG	BIPOLAR DEPRESSION

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PLACEBO (BIPOLAR I)	E0028001	15SEP1998-CONTINUE	1486	YES	METFORMIN [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DIABETES
		22AUG2002-20SEP2002	49	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	1.00 TAB	DEPRESSION
	E0028003	01SEP1991-22SEP2002	4047	NO	BUMETANIDE [CARDIOVASCULAR SYSTEM]	3.00 MG	WATER RETENTION
			4047	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
			4047	NO	POTASSIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	20.00 MEQ	POTASSIUM SUPPLEMENT
		15AUG2002-11SEP2002	46	NO	TOPIRAMATE [NERVOUS SYSTEM]	UNK	BIPOLAR
		25SEP2002-25SEP2002	5	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	4.00 TABS	DEGENERATIVE ARTHRITIS
		28SEP2002-19OCT2002	2	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	3000 MG	COLD SYMPTOMS
			2	YES	ECHINACEA EXTRACT [VARIOUS]	4.00 TABS	COLD SYMPTOMS
	E0028010	01JAN2001-CONTINUE	673	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHES
		01SEP2002-CONTINUE	65	YES	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNK	ALLERGIES
		01OCT1996-CONTINUE	2226	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		08OCT2002-09OCT2002	28	NO	AMITRIPTYLINE [NERVOUS SYSTEM]	10.00 MG	BREAST TENDERNESS

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PLACEBO (BIPOLAR I)	E0028031	01JUN1998-CONTINUE	1744	YES	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	ACID REFLUX
		01JUN2001-CONTINUE	648	YES	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX
	E0028047	01JUL2001-CONTINUE	743	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	ARTHRITIS
			743	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	HEADACHES
		01JUL1997-20JUL2003	2204	YES	ATENOLOL [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
		11SEP2001-CONTINUE	671	YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
			671	YES	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	DIABETES
	E0029001	01JUN1998-CONTINUE	1583	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
	E0029023	01JUL2000-CONTINUE	1011	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	NUTRITIONAL SUPPLEMENT
			1011	YES	HERBAL PREPARATION [VARIOUS]	1.00 PKG	PROPHYLAXIS FOR CONSTIPATION
			1011	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	MENSTRUAL CRAMPS (PRN)
		01JUL2000-01MAR2003	1011	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	INSOMNIA (PRN)

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PLACEBO (BIPOLAR I)	E0029023	01MAR2003-01APR2003	38	NO	PHENTERMINE [ALIMENTARY TRACT AND METABOLISM]	UNKNOWN	WEIGHT LOSS
		05APR2003-05APR2003	3	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	2.00 CAPS	INSOMNIA
		06APR2003-07APR2003	2	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	INSOMNIA
	E0029032	01JUL1998-CONTINUE	1805	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	TENSION HEADACHE PRN
		01JUL2000-CONTINUE	1074	YES	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	STOMACH PAIN PRN
		23MAY2003-07JUN2003	18	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	FLU PRN
		25MAY2003-25MAY2003	16	NO	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TSP	FLU PRN
		26MAY2003-28MAY2003	15	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	FLU PRN
		29MAY2003-01JUN2003	12	NO	PARACETAMOL [NERVOUS SYSTEM]	2.00 TAB	FLU PRN
	E0029033	01JAN2003-CONTINUE	152	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	HERNIATED CERVICAL DISKS
		15APR2003-26MAY2003	48	NO	CARISOPRODOL [MUSCULO-SKELETAL SYSTEM]	350.0 MG	HERNIATED CERVICAL DISKS

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PLACEBO (BIPOLAR I)	E0029039	01JUL2003-CONTINUE	14	YES	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	MIGRAINE HEADACHE
	E0030003	01JUL1992-CONTINUE	3820	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JUL1997-27NOV2002	1994	NO	CODEINE [RESPIRATORY SYSTEM]	150.0 MG	BACK PAIN
		01JUL2000-02DEC2002	898	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	ALLERGIES
	E0030016	21FEB2003-20APR2003	10	YES	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	INDIGESTION
			10	YES	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	INDIGESTION
	E0031001	01NOV2001-CONTINUE	385	YES	CLONAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY
		15JUN1991-CONTINUE	4177	YES	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	2.00 MG	HORMONE REPLACEMENT
	E0031017	01JAN2001-CONTINUE	820	YES	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	SEASONAL ALLERGIES
		01JAN1996-CONTINUE	2647	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	STROKE RISK REDUCTION
		17MAR2003-24MAR2003	15	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	DEPRESSION
			15	NO	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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PLACEBO (BIPOLAR I)	E0031017	17MAR2003-24MAR2003	15	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	MOOD STABILZER
		18MAR2003-CONTINUE	14	YES	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION
			14	YES	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	40.00 MG	HYPERCHOLESTEROLEMIA
			14	YES	CLOPIDOGREL SULFATE [BLOOD AND BLOOD FORMING ORGANS]	75.00 MG	STROKE RISK REDUCTION
			14	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	12.50 MG	HYPERTENSON
			14	YES	ISOSORBIDE MONONITRATE [CARDIOVASCULAR SYSTEM]	30.00 MG	HYPERTENSION
			14	YES	METOPROLOL [CARDIOVASCULAR SYSTEM]	100.0 MG	HYPERTENSION
			14	YES	NICOTINIC ACID [CARDIOVASCULAR SYSTEM]	1000 MG	STROKE RISK REDUCTION
			14	YES	OMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	GASTROESOPHOGEAL REFLUX DISEASE
	E0031018	26MAR2003-26MAR2003	15	NO	BUTALBITAL [NERVOUS SYSTEM]	6.00 CAPS	MIGRAINES
		01JAN1990-CONTINUE	4847	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MIGRAINES
		13DEC2002-10MAR2003	118	NO	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
			118	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DISORDER
			118	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR DISORDER

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0031023	15MAR2003-CONTINUE	45	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	300.0 MG	GASTROESOPHAGEAL REFLUX DISEASE
		15APR2003-CONTINUE	14	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PHOPHYLAXIS
		01MAR2002-CONTINUE	424	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	20.00 MG	SEASONAL ALLERGIES
		23MAR2003-CONTINUE	37	YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	150.0 MG	CONTRACEPTION
	E0033004	01FEB2000-CONTINUE	1081	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MCG	HYPOTHYROIDISM
	E0033010	30JAN2003-CONTINUE	5	YES	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	HEADACHES
	E0033014	01MAR2003-13MAR2003	18	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNK	SINUS ALLERGIES
		14MAR2003-26MAR2003	5	YES	LORATADINE [RESPIRATORY SYSTEM]	UNK	SINUS ALLERGIES
	E0035002	01JUL1999-12NOV2002	1239	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	MOOD STABILIZER
		13NOV2002-13NOV2002	8	NO	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0035011	10JAN2003-CONTINUE	25	YES	ROSIGLITAZONE MALEATE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	DIABETES
		01SEP2001-CONTINUE	521	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MG	HYPOTHYROID
	E0035020	05APR1990-10APR2003	4761	NO	RISPERIDONE [NERVOUS SYSTEM]	2.00 MG	PSYCHOSIS
			4761	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	MOOD STABILIZER
	E0037003	01NOV2002-CONTINUE	90	YES	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	400.0 MG	ARTHRITIS PAIN
		01JAN2001-15JAN2003	759	NO	TRAZODONE [NERVOUS SYSTEM]	100.0 MG	INSOMNIA
	E0037004	01AUG2002-CONTINUE	196	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	GENERAL HEALTH
		12FEB2003-CONTINUE	1	YES	TETRYZOLINE HYDROCHLORIDE [SENSORY ORGANS]	DROPS	ITCHY, SWOLLEN EYES
	E0039022	15JAN2003-CONTINUE	41	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		23FEB2003-23FEB2003	2	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	SORE THROAT
		15JAN2003-06FEB2003	41	NO	AMOXICILLIN TRIHYDRATE [ANTIINFECTIVES FOR SYSTEMIC USE]	1500 MG	BILATERAL EAR INFECTION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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PLACEBO (BIPOLAR I)	E0039023	11FEB2003-14FEB2003	13	NO	BENZYLPENICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	SORE THROAT
	E0039030	01JUL1996-22FEB2003	2457	NO	FLUOXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR DEPRESSION
		01JUL2002-26FEB2003	266	NO	TEMAZEPAM [NERVOUS SYSTEM]	15.00 MG	INSOMNIA
	E0039031	01JUL2000-CONTINUE	996	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JUL2002-09MAR2003	266	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	BIPOLAR DEPRESSION
		01JUL2002-14MAY2003	266	YES	DOXYCYCLINE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	ACNE
		10MAR2003-16MAR2003	14	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR DEPRESSION (EVERY OTHER DAY)
		11MAR2003-15MAR2003	13	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	40.00 MG	BIPOLAR DEPRESSION (EVERY OTHER DAY)
		16MAR2003-16MAR2003	8	NO	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	INSOMNIA
		17MAR2003-19MAR2003	7	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES

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PLACEBO (BIPOLAR I)	E0039031	20MAR2003-21MAR2003	4	NO	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	DIARRHEA
	E0039037	01JUL2002-CONTINUE	289	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	ORAL CONTRACEPTION
		01JUL1992-31MAR2003	3941	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
		01APR2003-04APR2003	15	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1800 MG	HEADACHES
			15	NO	NICOTINE [NERVOUS SYSTEM]	1.00 PATCH	SMOKING CESSATION
		01APR2003-06APR2003	15	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	DEPRESSION
	E0039038	26MAR2003-26MAR2003	28	NO	ZALEPLON [NERVOUS SYSTEM]	20.00 MG	INSOMNIA
		05APR2003-CONTINUE	18	YES	GLIPIZIDE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	DIABETES MELLITUS
		21APR2003-28APR2003	2	YES	MICONAZOLE NITRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 APPLICATION	VAGINAL ITCHING
	E0039047	15DEC1981-CONTINUE	7825	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA (AS NEEDED)
	E0039059	15MAR2003-30JUN2003	118	NO	PRASTERONE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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PLACEBO (BIPOLAR I)	E0039059	01JUL1999-30JUN2003	1471	NO	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			1471	NO	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			1471	NO	IRON [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	PROPHYLAXIS
			1471	NO	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15MAY2003-30JUN2003	57	NO	CHONDROITIN SULFATE [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	PROPHYLAXIS
	E0041010	20APR2003-20APR2003	10	NO	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	MIGRAINE
		06MAR2003-22APR2003	55	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	BIPOLAR DISORDER
		19APR2003-22APR2003	11	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
	E0041011	15JAN2003-15MAY2003	127	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR DISORDER
			127	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	BIPOLAR DISORDER
	E0041012	01JUL1993-CONTINUE	3640	YES	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	300.0 MG	ACID REFLUX
		01JUL1989-07JUL2003	5101	YES	CLONIDINE [CARDIOVASCULAR SYSTEM]	0.10 MG	HYPERTENSION
			5101	YES	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	12.50 MG	CLOT PROPHYLAXIS

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PLACEBO (BIPOLAR I)	E0041012	01JUL1994-CONTINUE	3275	YES	PRAVASTATIN SODIUM [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERLIPIDEMIA
		01JUL1995-07JUL2003	2910	YES	TRIAMTERENE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION

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PLACEBO (BIPOLAR II)	E0001004	UNK-CONTINUE		YES	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 SHOT	BIRTH CONTROL EVERY 3 MONTHS
		27APR2003-30APR2003	4	NO	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	MENSTRUAL CRAMPS PRN
	E0005023	01JAN2000-CONTINUE	1131	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	HEADACHES
		01JUN2002-CONTINUE	249	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PILL	BIRTH CONTROL
		01JAN2000-27JAN2003	1131	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	SLEEPLESSNESS
	E0005034	01DEC1999-CONTINUE	1231	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	HYPOTHYROIDISM
		01MAR2003-07APR2003	45	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR DISORDER
	E0005041	15APR2002-CONTINUE	435	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	2.00 PILLS	NUTRITIONAL SUPPLEMENT
			435	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT
			435	YES	LINSEED OIL [VARIOUS]	1.00 PILL	NUTRITIONAL SUPPLEMENT
			435	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT

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PLACEBO (BIPOLAR II)	E0007004	01JUN2000-CONTINUE	973	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.05 MG	HYPOTHYROIDISM
		02JAN2000-CONTINUE	1124	YES	NORETHISTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PILL	BIRTH CONTROL
		14JAN2003-23JAN2003	16	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MGM	DEPRESSION
		24JAN2003-24JAN2003	6	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MGM	DEPRESSION
	E0007012	01JUL2000-CONTINUE	1049	YES	LORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIC RHINITIS
	E0009007	01JUL1995-CONTINUE	2774	YES	BUTORPHANOL TARTRATE [NERVOUS SYSTEM]	ML	MIGRAINES
			2774	YES	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	MG	BACK PAIN
	E0009008	01JUL1985-CONTINUE	6435	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	MG	PROPHYLAXIS
			6435	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	MG	PROPHYLAXIS
			6435	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	MG	HEADACHES
		01JUL2000-03FEB2003	956	NO	DIPHENHYDRAMINE [RESPIRATORY SYSTEM]	MG	INSOMNIA
	E0011001	UNK-25OCT2002		NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	2.00 TABLETS	INSOMNIA

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PLACEBO (BIPOLAR II)	E0011001	UNK-25OCT2002		NO	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABLETS	SINUS INFECTION
		10OCT2002-CONTINUE	22	YES	RETINOL [ALIMENTARY TRACT AND METABOLISM]	12500 IU	PROPHYLAXIS
			22	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	200.0 IU	PROPHYLAXIS
		10OCT2002-25OCT2002	22	NO	MULTIVITAMINS, PLAIN [ALIMENTARY TRACT AND METABOLISM]	1.00 CAPSULES	PROPHYLAXIS
			22	NO	VITAMINS [ALIMENTARY TRACT AND METABOLISM]	1.00 CAPSULES	PROPHYLAXIS
		25OCT2002-CONTINUE	7	YES	SELENIUM [ALIMENTARY TRACT AND METABOLISM]	25.00 MCG	PROPHYLAXIS
	E0011011	01JUL2000-CONTINUE	964	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES PRN
		01JUL2000-08APR2003	964	YES	FERROUS SULFATE [BLOOD AND BLOOD FORMING ORGANS]	500.0 MG	IRON DEFICIENCY ANEMIA
	E0011013	05MAR2003-CONTINUE	43	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION
		01JUL2000-28MAR2003	1020	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1300 MG	HEADACHE PRN
		15JUN2002-28MAR2003	306	NO	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	ARTHRITIS PRN

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PLACEBO (BIPOLAR II)	E0011013	01JUL2002-18MAR2003	290	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY ANXIETY IS SECONDARY TO DEPRESSION
			290	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
		28MAR2003-CONTINUE	20	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 CAP	ARTHRITIS PAIN HEADACHE
			20	YES	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.10 MG	HYPOTHYROIDISM
	E0011021	01JUL2002-CONTINUE	325	YES	NITROFURANTOIN [ANTIINFECTIVES FOR SYSTEMIC USE]	100.0 MG	URINARY TRACT INFECTION PROPHYLAXIS
		01JUL1998-CONTINUE	1786	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
		01JUL1999-CONTINUE	1421	YES	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN2003-16APR2003	127	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	200.0 MG	DEPRESSION
	E0013008	04AUG1987-CONTINUE	5713	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	215.0 MG	ASTHMA
		02FEB1992-CONTINUE	4070	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACK	HEADACHE
			4070	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE

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PLACEBO (BIPOLAR II)	E0014001	01DEC2002-CONTINUE	87	YES	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	HORMONE REPLACEMENT
		18FEB2001-18FEB2003	738	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION
	E0014013	01JUL1998-CONTINUE	1791	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
	E0018012	01JUN1974-CONTINUE	10464	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 PUFF	REACTIVE AIRWAY DISEASE
			10464	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 PUFF	REACTIVE AIRWAY DISEASE
			10464	YES	SALMETEROL XINAFOATE [RESPIRATORY SYSTEM]	1.00 PUFF	REACTIVE AIRWAY DISEASE
	E0019033	01OCT2002-CONTINUE	168	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	2.00 CAPS	DIETARY SUPPLEMENT
	E0019038	01JUN2002-10MAR2003	327	NO	PARACETAMOL [NERVOUS SYSTEM]	5.00 MG	BACK PAIN
		01OCT2002-25MAR2003	205	NO	DIAZEPAM [NERVOUS SYSTEM]	5.00 MG	BACK PAIN
	E0019046	01JAN2000-CONTINUE	1272	YES	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	HORMONE REPLACEMENT THERAPY ESTRODIAL 1MG NORGESTIMATE .09MG

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PLACEBO (BIPOLAR II)	E0019047	01JAN2003-CONTINUE	188	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIES PRN
		01JAN2002-CONTINUE	553	YES	ECHINACEA EXTRACT [VARIOUS]	1.00 TAB	PROPHYLAXIS [HEALTH] PRN
	E0019048	01JAN2002-CONTINUE	555	YES	METAXALONE [MUSCULO-SKELETAL SYSTEM]	1200 MG	INFLAMATION OF JOINTS LOWER BACK PAIN
		01APR2003-CONTINUE	100	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	0.10 MG	BIRTH CONTROL
		01JAN2002-17JUL2003	555	YES	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0022006	01SEP2002-CONTINUE	72	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	ALLERGIC RHINITIS
			72	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01NOV2001-CONTINUE	376	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TABLET	BIRTH CONTROL
		01SEP2001-CONTINUE	437	YES	SPIRONOLACTONE [CARDIOVASCULAR SYSTEM]	50.00 MG	ACNE
		01OCT1995-CONTINUE	2599	YES	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01JAN1999-21OCT2002	1411	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1500 MG	BIPOLAR
			1411	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	225.0 MG	BIPOLAR

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PLACEBO (BIPOLAR II)	E0022006	22OCT2002-28OCT2002	21	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR
			21	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR
		29OCT2002-03NOV2002	14	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	BIPOLAR
			14	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	BIPOLAR
		04NOV2002-04NOV2002	8	NO	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	20.00 MG	SEROTONIN WITHDRAWAL SYNDROME (TEARFUL & IRRITABLE)
		07NOV2002-07NOV2002	5	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA
	E0022047	01JAN2000-CONTINUE	1182	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		03APR2002-CONTINUE	359	YES	DESLORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIC RHINITIS
			359	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
	E0022075	01JAN2000-CONTINUE	1284	YES	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1500 MG	OSTEOPOROSIS
			1284	YES	CHONDROITIN SULFATE [MUSCULO-SKELETAL SYSTEM]	3.00 TABS	HIP PAIN
			1284	YES	CHONDROITIN SULFATE [MUSCULO-SKELETAL SYSTEM]	3.00 TABS	KNEE PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* Number of Days prior to study treatment.

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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0022075	01APR2003-CONTINUE	98	YES	ACTONEL [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	35.00 MG	OSTEOPOROSIS
		11JUN2003-CONTINUE	27	YES	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	ESOPHAGEAL REFLUX
		01MAY2003-CONTINUE	68	YES	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	HIP PAIN
			68	YES	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	KNEE PAIN
		01JUN2002-CONTINUE	402	YES	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	5.00 MG	ALLERGIC RHINITIS
		01JAN1988-CONTINUE	5667	YES	BECLOMETASONE DIPROPIONATE [RESPIRATORY SYSTEM]	4.00 SPRAYS	ALLERGIC RHINITIS
			5667	YES	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	400.0 MG	DRY SKIN
		01OCT2002-24JUN2003	280	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.50 MG	BIPOLAR
		01OCT2002-25JUN2003	280	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR
		01JUL2003-25JUL2003	7	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	DENTAL PAIN
		02JUL2003-25JUL2003	6	YES	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	12.50 MG	DENTAL PAIN
		07JUL2003-25JUL2003	1	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	DENTAL PAIN

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0023012	UNK-04FEB2003		NO	GABAPENTIN [NERVOUS SYSTEM]		ANXIETY RELATED TO BIPOLAR DISORDER
		15JUN1999-31JAN2003	1332	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR
		15OCT2002-04FEB2003	114	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	75.00 MG	BIPOLAR
		01FEB2003-04FEB2003	5	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	250.0 MG	BIPOLAR
	E0023016	01DEC2000-CONTINUE	902	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	NECK PAIN
			902	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	SHOULDER PAIN
		01DEC2002-08MAY2003	172	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.25 MG	ANXIETY
		10JAN2003-15APR2003	132	NO	PARACETAMOL [NERVOUS SYSTEM]	5.00 MG	NECK PAIN
			132	NO	PARACETAMOL [NERVOUS SYSTEM]	5.00 MG	SHOULDER PAIN
		24APR2003-28APR2003	28	NO	PROMETHAZINE [RESPIRATORY SYSTEM]	5.00 MLS	COUGH
	E0023018	01FEB2003-20MAR2003	54	NO	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0023046	01JUL2000-CONTINUE	1117	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			1117	YES	VERAPAMIL [CARDIOVASCULAR SYSTEM]	240.0 MG	HYPERTENSION
		01JUL2001-CONTINUE	752	YES	METHOTREXATE [ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS]	2.50 MG	RHEUMATOID ARTHRITIS
	E0026027	01JAN2003-04JUN2003	169	NO	DIPHENHYDRAMINE [NERVOUS SYSTEM]	2.00 TABS	INSOMNIA
		01APR2003-02JUN2003	79	NO	DIAZEPAM [NERVOUS SYSTEM]	10.00 MG	ANXIETY
		15APR2003-05JUN2003	65	NO	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	MCG	MILD BRONCHITIS
	E0029002	15JUN2002-CONTINUE			ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DIETARY SUPPLEMENT
		01JUL1998-CONTINUE			PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		06NOV2002-CONTINUE			AMOXICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	2.00 TABS	EAR INFECTION
		01JUL1976-CONTINUE			LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MCG	HYPOTHYRIODISM
		01JUL1989-31OCT2002			ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	0.65 MG	HORMONE REPLACEMENT THERAPY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0029002	15MAY2002-01OCT2002			SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	MG	DEPRESSION
		01OCT2002-01NOV2002			PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	JAW PAIN
	E0029004	01JAN1999-CONTINUE	1418	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		01JAN1985-CONTINUE	6531	YES	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		01OCT2002-CONTINUE	49	YES	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TABS	SEASONAL ALLERGIES
		01MAY2002-CONTINUE	202	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINES
		15OCT2002-CONTINUE	35	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DIETARY SUPPLEMENT
		13NOV2002-CONTINUE	6	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		31OCT2002-CONTINUE	19	YES	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	GERD
		11NOV2002-11NOV2002	8	NO	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 PACKS	HEADACHE
	E0029013	01JUL2001-CONTINUE	598	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0029024	01MAR2001-CONTINUE	746	YES	THYROID [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	60.00 MG	HYPOTHYROIDISM
		01MAR1991-CONTINUE	4399	YES	BORAGE OIL [VARIOUS]	1.00 CAP	DIETARY SUPPLEMENT
			4399	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DIETARY SUPPLEMENT
			4399	YES	FISH OIL [CARDIOVASCULAR SYSTEM]	1.00 CAP	DIETARY SUPPLEMENT
	E0029038	13JUN2003-19JUN2003	24	NO	ST. JOHN'S WORT [VARIOUS]	3.00 CAPS	DEPRESSION
	E0031004	01APR2002-CONTINUE	262	YES	ZALEPLON [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		01JAN2002-CONTINUE	352	YES	LEVODOPA [NERVOUS SYSTEM]	2050 MG	RESTLESS LEG SYNDROME
			352	YES	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTROESOPHAGEAL REFLUX DISEASE
		01MAY2000-CONTINUE	962	YES	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 SPRAYS	ENVIRONMENTAL ALLERGIES
		01MAY2002-31JAN2003	232	YES	DESLORATADINE [RESPIRATORY SYSTEM]	5.00 MG	ENVIRONMENTAL ALLERGIES
		01SEP2002-31JAN2003	109	YES	MONTELUKAST SODIUM [RESPIRATORY SYSTEM]	10.00 MG	MILD ASTHMA
		16DEC2002-16DEC2002	3	NO	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	PRE - MENSTRUAL CRAMPS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0031013	01MAR2002-CONTINUE	377	YES	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX
		01JAN1999-13FEB2003	1532	NO	LITHIUM [NERVOUS SYSTEM]	1200 MG	BIPOLAR
		01NOV2002-13FEB2003	132	NO	LAMOTRIGINE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR
			132	NO	TOPIRAMATE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR
		16DEC2002-CONTINUE	87	YES	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		03MAR2003-21MAR2003	10	YES	BENZONATATE [RESPIRATORY SYSTEM]	200.0 MG	CHRONIC BRONCHITIS
	E0031016	01FEB2003-16MAR2003	51	NO	GABAPENTIN [NERVOUS SYSTEM]	1800 MG	MOOD STABILIZER
			51	NO	VENLAFAXINE HYDROCHLORIDE [NERVOUS SYSTEM]	225.0 MG	DEPRESSION
	E0031019	01JAN1994-CONTINUE	3387	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	SHOULDER PAIN
			3387	YES	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	LOWER BACK PAIN
	E0031022	15MAR2003-CONTINUE	44	YES	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	INTERMITTENT HEADACHES
	E0033007	15JUL2001-17FEB2003	562	YES	CARISOPRODOL [MUSCULO-SKELETAL SYSTEM]	350.0 MG	ARTHRITIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0033007	15JUL2001-17FEB2003	562	YES	PARACETAMOL [NERVOUS SYSTEM]	1.00 TABLET	ARTHRITIS
		15JUL2001-19FEB2003	562	YES	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	25.00 MG	ARTHRITIS
	E0033013	15APR2001-CONTINUE	675	YES	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0033016	15JAN2002-CONTINUE	478	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL (WEEKLY)
		15MAR1998-08MAY2003	1880	YES	CALCIUM ASCORBATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			1880	YES	FISH OIL [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
		15JAN2000-08MAY2003	1209	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			1209	YES	IRON [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	ANEMIA
		15JAN2002-08MAY2003	478	YES	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	PROPHYLAXIS
		15JUN2002-05MAY2003	327	NO	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0033022	01JUN2002-CONTINUE	408	YES	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	0.03 MG	BIRTH CONTROL
		01JAN2002-25JUN2003	559	NO	LITHIUM [NERVOUS SYSTEM]	1200 MG	BIPOLAR DISORDER

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0033022	01JAN2002-25JUN2003	559	NO	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR DISORDER
	E0034007	01JUL2000-CONTINUE	1049	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GENERAL HEALTH
		01JUL1980-CONTINUE	8354	YES	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TAB	PRN FOR HEADACHES
		26MAR2003-CONTINUE	51	YES	ATENOLOL [CARDIOVASCULAR SYSTEM]	50.00 MG	HYPERTENSION
			51	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
		15APR2003-07MAY2003	31	NO	TRAZODONE [NERVOUS SYSTEM]	50.00 MG	INSOMNIA
			31	NO	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	500.0 MG	MOOD STABILIZER
	E0035010	01DEC2000-CONTINUE	770	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	DIURETIC
			770	YES	POTASSIUM [ALIMENTARY TRACT AND METABOLISM]	600.0 MG	NUTRITIONAL SUPPLEMENT
			770	YES	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	50.00 MG	ARTHIRITIS INFLAMMATION
			770	YES	VERAPAMIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	240.0 MG	HYPERTENSION
	E0035022	15MAY2002-30APR2003	359	NO	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
			359	NO	OLANZAPINE [NERVOUS SYSTEM]	20.00 MG	PSYCHOSIS

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0039003	01JAN2002-CONTINUE	328	YES	FERROUS SULFATE [BLOOD AND BLOOD FORMING ORGANS]	325.0 MG	ANEMIA
		01OCT2002-14NOV2002	55	NO	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
		10OCT2002-14NOV2002	46	NO	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	BIPOLAR
	E0040001	20DEC2002-15JUN2003	189	NO	OLANZAPINE [NERVOUS SYSTEM]	7.50 MG	BIPOLAR DEPRESSION
		15JUN2003-18JUN2003	12	NO	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR DEPRESSION
	E0041002	01OCT2002-CONTINUE	112	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JAN2001-13FEB2003	750	YES	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
	E0041005	01JAN1984-CONTINUE	7003	YES	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15FEB2001-12FEB2003	748	NO	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	NECK PAIN
		15JUL2001-12FEB2003	598	NO	METHOCARBAMOL [MUSCULO-SKELETAL SYSTEM]	500.0 MG	NECK PAIN
			598	NO	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	NECK PAIN
		15APR2002-06FEB2003	324	NO	ALPRAZOLAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* Number of Days prior to study treatment.

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Listing 12.2.10.6 Prior Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS PRIOR*	MED CON-CURRENT	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0041005	15NOV2002-09FEB2003	110	NO	HYDROCODONE [RESPIRATORY SYSTEM]	1.00 TAB	BACK PAIN
		15DEC2002-05FEB2003	80	NO	BUSPIRONE HYDROCHLORIDE [NERVOUS SYSTEM]	30.00 MG	BIPOLAR
		15DEC2002-12FEB2003	80	NO	LITHIUM CARBONATE [NERVOUS SYSTEM]	900.0 MG	BIPOLAR
		01MAR2003-03MAR2003	4	NO	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA

SUBJECTS E0028017, E0029002 AND E0039046 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0002010	04APR2003-CONTINUE	1	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY DUE TO DEPRESSION
		04APR2003-15APR2003	1	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	FOR INSOMNIA
	E0002012	29APR2003-03MAY2003	9	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	UNKNOWN	COLD SYMPTOMS
	E0003005	15OCT1996-CONTINUE	-2260	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MG	HYPOTHYROID
		23DEC2002-CONTINUE	1	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	BACK PAIN
		31DEC2002-01JAN2003	9	CONCOMITANT	HYDROCODONE [RESPIRATORY SYSTEM]	1.00 TAB	BACK PAIN
		07JAN2003-07JAN2003	16	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2000 MG	BODY PAIN
		13JAN2003-13JAN2003	22	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	BODY PAIN
		16JAN2003-16JAN2003	25	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	BODY PAIN
		21JAN2003-23JAN2003	30	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	BODY PAIN
	E0003007	19DEC2002-CONTINUE	-14	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0003007	08JAN2003-08JAN2003	7	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MENSTRUAL CRAMPS
		30JAN2003-30JAN2003	29	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	400.0 MG	SORE THROAT
		20FEB2003-20FEB2003	50	CONCOMITANT	FLUCONAZOLE [ANTIINFECTIVES FOR SYSTEMIC USE]	150.0 MG	YEAST INFECTION
	E0003015	01MAR2001-CONTINUE	-795	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	MIGRAINE HEADACHE, PRN
			-795	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES, PRN
		15MAR2002-CONTINUE	-416	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	PREGNANCY PREVENTION
		01JAN2003-CONTINUE	-124	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MENSTRUAL CRAMPS, PRN
		20JUN2003-24JUN2003	47	CONCOMITANT	SIMETICONE [ALIMENTARY TRACT AND METABOLISM]	4.00 TABS	ABDOMINAL GAS
	E0004002	01APR2002-CONTINUE	-183	PRIOR/CONCOM	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	ACID REFLUX
			-183	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	ACID REFLUX
		06NOV2002-09NOV2002	37	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	1.00 CAP	SINUS CONGESTION
		10NOV2002-10NOV2002	41	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 CAP	SINUS CONGESTION

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0004013	15DEC1990-CONTINUE	-4413	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	PRN FOR ASTHMA
		15JAN2003-16JAN2003	2	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	PRN FOR CYST LEFT BREAST
		15JAN2003-01FEB2003	2	CONCOMITANT	ANTIBIOTICS [ANTIINFECTIVES FOR SYSTEMIC USE]	2.00 TABS	CYST LEFT BREAST
		30JAN2003-01FEB2003	17	CONCOMITANT	HYDROCODONE BITARTRATE [NERVOUS SYSTEM]	1.00 TAB	PRN FOR CYST LEFT BREAST
		01FEB2003-01FEB2003	19	CONCOMITANT	MORPHINE SULFATE [NERVOUS SYSTEM]	20.00 MG	CYST LEFT BREAST
		02FEB2003-CONTINUE	20	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	PRN FOR CYST LEFT BREAST
			20	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	200.0 MG	PRN FOR CYST LEFT BREAST
	E0004018	01JAN2002-CONTINUE	-442	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
		01MAR2003-CONTINUE	-18	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	500.0 MG	SUPPLEMENT
	E0004021	15JAN1995-CONTINUE	-3041	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
		01JUL2002-CONTINUE	-317	PRIOR/CONCOM	TILACTASE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	LACTOSE INTOLERENCE
		09MAY2003-CONTINUE	-5	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	SINUS HEADACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0004021	09MAY2003-25MAY2003	-5	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	SINUS HEADACHE
	E0005002	07FEB2001-13OCT2002	-603	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	SLEEPLESSNESS SECONDARY TO BIPOLAR DEPRESSION
		08JUL2002-17NOV2002	-87	PRIOR/CONCOM	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	15.00 MG	HEARTBURN/ACID REFLUX
		17NOV2002-CONTINUE	46	CONCOMITANT	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	HEARTBURN/ACID REFLUX
		25NOV2002-CONTINUE	54	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DEPRESSION
	E0005013	UNK-CONTINUE		PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	RHINITIS/SINUS ITIS
		01JUL1995-CONTINUE	-2686	PRIOR/CONCOM	MOMETASONE FUROATE [RESPIRATORY SYSTEM]	1.00 SPRAY	RHINITIS/SINUS ITIS
		01JUL1996-CONTINUE	-2320	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHE - PRN
		01MAY2001-CONTINUE	-555	PRIOR/CONCOM	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	INDIGESTION
		15JUN2002-CONTINUE	-145	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		30OCT2002-CONTINUE	-8	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	20.00 MG	INSOMNIA - PRN

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0005013	30OCT2002-CONTINUE	-8	PRIOR/CONCOM	PHOSPHORIC ACID [ALIMENTARY TRACT AND METABOLISM]	2.00 TBLSPNS	NAUSEA - PRN
		11NOV2002-23NOV2002	5	POST	ANTIBIOTICS [ANTIINFECTIVES FOR SYSTEMIC USE]		UPPER RESPIRATORY INFECTION
	E0005024	01JAN2003-CONTINUE	-40	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFF	ASTHMA
			-40	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL STATUS
		09APR2003-CONTINUE	59	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
	E0005027	01JAN2003-CONTINUE	-69	PRIOR/CONCOM	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	INDIGESTION
			-69	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	INDIGESTION
		01MAY2000-CONTINUE	-1044	PRIOR/CONCOM	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES
	E0005037	01MAR2003-CONTINUE	-67	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	BACK PAIN SECONDARY TO ARTHRITIS
		01JAN1999-CONTINUE	-1587	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES
		01JAN2000-CONTINUE	-1222	PRIOR/CONCOM	BENAZEPRIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0005037	02JUL2003-CONTINUE	57	POST	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MG	BIPOLAR DISORDER
	E0005042	03JUN2003-CONTINUE	-21	PRIOR/CONCOM	CALCIPOTRIOL [DERMATOLOGICALS]	1.00 APPLICATION	PSORISIS
		13JUN2003-CONTINUE	-11	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 PILLS	PAIN PRN
	E0006005	15JUN2002-CONTINUE	-173	PRIOR/CONCOM	DESLORATADINE [RESPIRATORY SYSTEM]	1.00 TABLET	SEASONAL ALLERGIES
			-173	PRIOR/CONCOM	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	SEASONAL ALLERGIES
		15OCT2001-CONTINUE	-416	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	HEADACHES
		03NOV2002-CONTINUE	-32	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	1.00 TABLET	MENSTRAL CRAMPS
			-32	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TABLET	BIRTH CONTROL
		02JAN2003-02JAN2003	29	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	COLD SYMPTOMS
	E0006018	01JAN2002-CONTINUE	-436	PRIOR/CONCOM	CHONDROITIN SULFATE [MUSCULO-SKELETAL SYSTEM]	2.00 TABLETS	BACK PAIN
		01JUL2002-CONTINUE	-255	PRIOR/CONCOM	LINSEED OIL [VARIOUS]	1.00 CAPSULE	PROPHYLAXIS
		01JAN2000-CONTINUE	-1167	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TABLET	ELEVATED BLOOD PRESSURE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0006018	01FEB2002-CONTINUE	-405	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	2.00 TABLETS	ELEVATED CHOLESTEROL
	E0007013	01JUL2002-CONTINUE	-347	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTROESOPHAGEAL REFLUX
		01JUL1990-CONTINUE	-4730	PRIOR/CONCOM	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	6.25 MG	HORMONE REPLACEMENT
		01JUL1998-CONTINUE	-1808	PRIOR/CONCOM	LOSARTAN POTASSIUM [CARDIOVASCULAR SYSTEM]	50.00 MG	HYPERTENSION
		24JUN2003-24JUN2003	12	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	MIGRAINE HEADACHE
		25JUN2003-CONTINUE	13	CONCOMITANT	SENNA [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	CONSTIPATION
		15JUL2003-17JUL2003	33	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	4000 MGM	HEADACHE PRN
		18JUL2003-19JUL2003	36	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	HEADACHE
	E0010004	01JAN2000-CONTINUE	-1075	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	MG	NUTRITIONAL SUPPLEMENT
			-1075	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	MG	NUTRITIONAL SUPPLEMENT
			-1075	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	MG	NUTRITIONAL SUPPLEMENT
		04DEC2002-03JAN2003	-7	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA (PRN)

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0010012	07JAN2003-28JAN2003	1	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY/SLEEP
		11FEB2003-18FEB2003	36	CONCOMITANT	AMOXICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1500 MG	EAR INFECTION
		18FEB2003-24FEB2003	43	CONCOMITANT	HYDROCORTISONE [SENSORY ORGANS]	15.00 DROPS	EAR INFECTION
	E0010024	01JUL2002-CONTINUE	-308	PRIOR/CONCOM	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	DIABETES MELLITUS TYPE II
		01JUL2002-16MAY2003	-308	PRIOR/CONCOM	FOSINOPRIL SODIUM [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		23APR2003-05MAY2003	-12	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA
		05MAY2003-19MAY2003	1	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	INSOMNIA
		27MAY2003-CONTINUE	23	CONCOMITANT	FOSINOPRIL SODIUM [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		21JUN2003-01JUL2003	48	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	MG	COUGH
			48	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	MG	NASAL CONGESTION
	E0013007	01JUL2000-CONTINUE	-992	PRIOR/CONCOM	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	DIABETES
		01DEC2002-CONTINUE	-109	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HIGH CHOLESTEROL

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	01JUL1993-CONTINUE	-3562	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	ARTHRITIC PAIN
	E0014006	23MAY2003-CONTINUE	60	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	100.0 MG	MOOD - BIPOLAR
	E0014010	15JUN1980-CONTINUE	-8346	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	HEADACHES
		01JUN1988-CONTINUE	-5438	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	MUSCULO - SKELETAL PAIN
		15FEB2003-CONTINUE	-66	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	MUSCULO - SKELETAL PAIN
		21MAY2003-CONTINUE	30	CONCOMITANT	PIOGLITAZONE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	15.00 MG	HYPERINSULINEMIA
	E0016001	18JAN2003-22JAN2003	-4	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	HEADACHE
		18JAN2003-29JAN2003	-4	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	800.0 MG	HEADACHE
	E0018001	01JUN1998-CONTINUE	-1611	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	GERD
		14OCT2002-CONTINUE	-15	PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	UNK	BIRTH CONTROL
		23DEC2002-23DEC2002	56	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	5.00 ML	COUGH.

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0019004	01JAN1975-CONTINUE	-10172	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	UNK	GENERAL ACHES
		25NOV2002-25NOV2002	19	CONCOMITANT	TROPICAMIDE [SENSORY ORGANS]	1.00 DROP	DIALATE PUPILS
		03DEC2002-CONTINUE	27	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	UNK	INDIGESTION
	E0019011	21DEC2001-CONTINUE	-335	PRIOR/CONCOM	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	HYPERGLYCEMIA.
		11DEC2002-CONTINUE	21	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	MG	HEADACHE
	E0019025	UNK-CONTINUE		PRIOR/CONCOM	NORETHISTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL.
		01NOV2002-CONTINUE	-97	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	DIETARY SUPPLEMENT
		06MAR2003-CONTINUE	29	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	TENSION HEADACHE
	E0019026	UNK-CONTINUE		PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
	E0019043	01JAN1993-07JUN2003	-3805	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR DISORDER
		08JUN2003-17JUN2003	6	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	0.50 MG	BIPOLAR DISORDER

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QUETIAPINE 300 MG (BIPOLAR I)	E0019043	08JUL2003-CONTINUE	36	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	FLU
		21JUL2003-CONTINUE	49	CONCOMITANT	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	SINUS/FLU
	E0020001	17NOV2002-CONTINUE	20	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	5.00 TAB	PROPHYLAXIS
		05DEC2002-05DEC2002	38	CONCOMITANT	ENEMAS [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	CONSTIPATION
		08DEC2002-09DEC2002	41	CONCOMITANT	ENEMAS [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	CONSTIPATION
		14DEC2002-14DEC2002	47	CONCOMITANT	ENEMAS [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	CONSTIPATION
		18DEC2002-18DEC2002	51	CONCOMITANT	ENEMAS [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	CONSTIPATION
		19DEC2002-19DEC2002	52	CONCOMITANT	LAXATIVES [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	CONSTIPATION
	E0020006	18DEC2002-18DEC2002	3	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		01JAN2001-CONTINUE	-714	PRIOR/CONCOM	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	GASTRIC ESOPHAGEAL REFLUX DISORDER
		01AUG2002-CONTINUE	-137	PRIOR/CONCOM	METOPROLOL SUCCINATE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0020011	23MAR2003-23MAR2003	26	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	SEASONAL ALLERGIES
		25MAR2003-25MAR2003	28	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	SEASONAL ALLERGIES
		27MAR2003-27MAR2003	30	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TAB	SEASONAL ALLERGIES
	E0020013	17MAR2003-17MAR2003	13	POST	CHARCOAL, ACTIVATED [ALIMENTARY TRACT AND METABOLISM]	50.00 GM	OVERDOSE
			13	POST	NALOXONE HYDROCHLORIDE [VARIOUS]	0.40 MG	NARCOTIC ANTAGONIST
			13	POST	OXYGEN [RESPIRATORY SYSTEM]	2.00 L	OVERDOSE
			13	POST	PARACETAMOL [NERVOUS SYSTEM]	MG	SUICIDE ATTEMPT
			13	POST	SODIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	5.00 CC	OVERDOSE
			13	POST	SODIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 CC	HYDRATION
			13	POST	DIPHENHYDRAMINE [NERVOUS SYSTEM]	MG	SUICIDE ATTEMPT
			13	POST	CODEINE PHOSPHATE [NERVOUS SYSTEM]	MG	SUICIDE ATTEMPT
	E0022008	16NOV2002-16NOV2002	5	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
	E0022017	13JAN2003-13JAN2003	26	CONCOMITANT	SILDENAFIL CITRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	50.00 MG	ERECTILE DYSFUNCTION
		01JAN1980-CONTINUE	-8388	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES

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QUETIAPINE 300 MG (BIPOLAR I)	E0022017	01JAN1985-CONTINUE	-6561	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	CHRONIC BACK PAIN
		01SEP2000-CONTINUE	-839	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		19DEC2002-20DEC2002	1	CONCOMITANT	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA
		27DEC2002-31DEC2002	9	CONCOMITANT	ETHANOL [NERVOUS SYSTEM]	2.00 TABS	UPPER RESPIRATORY INFECTION
		15JAN2003-15JAN2003	28	CONCOMITANT	SILDENAFIL CITRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	50.00 MG	ERECTILE DYSFUNCTION
		19JAN2003-19JAN2003	32	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	1.00 TBSP	UPPER RESPIRATORY INFECTION
		19JAN2003-20JAN2003	32	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	975.0 MG	UPPER RESPIRATORY INFECTION
	E0022018	01JAN2002-CONTINUE	-345	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		01JAN2000-CONTINUE	-1076	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHE
			-1076	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
			-1076	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
		01JAN1990-CONTINUE	-4728	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022018	01JAN1995-CONTINUE	-2902	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHE
		01JAN1997-CONTINUE	-2171	PRIOR/CONCOM	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	524.0 MG	GASTRO - ESOPHAGEAL REFLUX
		15NOV2002-CONTINUE	-27	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	4.00 PUFFS	ASTHMA
		17JAN2003-CONTINUE	37	CONCOMITANT	ANTACIDS [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	GASTRIC REFLUX
	E0022022	23DEC2002-CONTINUE	-7	PRIOR/CONCOM	MACROGOL [ALIMENTARY TRACT AND METABOLISM]	17.00 GRAMS	CONSTIPATION
		01JAN1999-CONTINUE	-1459	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			-1459	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	GASTRIC REFLUX
		01JAN1998-CONTINUE	-1824	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01OCT2002-CONTINUE	-90	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TRANSDERMALPATCH	CONTRACEPTIVE
		13DEC2002-CONTINUE	-17	PRIOR/CONCOM	ENEMAS [ALIMENTARY TRACT AND METABOLISM]	1.00 BOTTLE	CONSTIPATION
			-17	PRIOR/CONCOM	FIBRE, DIETARY [ALIMENTARY TRACT AND METABOLISM]	1.00 TBSP	CONSTIPATION
			-17	PRIOR/CONCOM	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TBSP	CONSTIPATION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022022	30DEC2002-18MAR2003	1	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	UNK	BACK PAIN
		06JAN2003-19JAN2003	8	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	AKATHISIA
		20JAN2003-20JAN2003	22	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	DENTAL CARIES
		03FEB2003-18MAR2003	36	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	UNK	BACK PAIN
		13FEB2003-14FEB2003	46	POST	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	MG	NAUSEA
		24FEB2003-24FEB2003	57	POST	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	25.00 MG	BACK PAIN
	E0022027	01JAN1999-CONTINUE	-1497	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MUSCULOSKELETAL PAIN
		01JAN1998-CONTINUE	-1862	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		03FEB2003-14MAR2003	-3	PRIOR/CONCOM	GLUCOSE MONOHYDRATE [ALIMENTARY TRACT AND METABOLISM]	3.00 TABS	CONSTIPATION
		26MAR2003-26MAR2003	49	CONCOMITANT	GARLIC [RESPIRATORY SYSTEM]	1.00 TAB	UPPER RESPIRATORY INFECTION
	E0022030	01JAN1998-CONTINUE	-1870	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022031	01AUG2001-CONTINUE	-566	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
	E0022032	01FEB2000-CONTINUE	-1113	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES PRN
		21JAN2003-CONTINUE	-28	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL
		21MAR2003-CONTINUE	32	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2000 MG	HEADACHES
		24MAR2003-01APR2003	35	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	VIRAL SYNDROME
		14APR2003-18APR2003	56	POST	HYDROCORTISONE [DERMATOLOGICALS]	2.00 APPLIC.	HEMORRHOIDS
			56	POST	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEMORRHOIDS
	E0022035	01JAN1998-CONTINUE	-1875	PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	NA	CONTRACEPTION
		24FEB2003-CONTINUE	6	POST	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	SINUSITIS
	E0022036	15FEB2003-CONTINUE	-10	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		01JAN1995-CONTINUE	-2977	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		06APR2003-CONTINUE	41	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	TOOTHACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	12MAY2003-CONTINUE	77	POST	LITHIUM CARBONATE [NERVOUS SYSTEM]	1200 MG	PRIMARY STUDY CONDITION
		13MAY2003-CONTINUE	78	POST	FLUOXETINE [NERVOUS SYSTEM]	20.00 MG	PRIMARY STUDY CONDITION
		13MAY2003-13MAY2003	78	POST	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
			78	POST	KETOROLAC TROMETHAMINE [SENSORY ORGANS]	10.00 MG	HEADACHES
		14MAY2003-CONTINUE	79	POST	MICONAZOLE [DERMATOLOGICALS]	4.00 APPLICATION	TINEA VERSICOLOR
		14MAY2003-14MAY2003	79	POST	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	DIARRHEA
			79	POST	KAOLIN [ALIMENTARY TRACT AND METABOLISM]	30.00 CC	DIARRHEA
			79	POST	KETOROLAC TROMETHAMINE [SENSORY ORGANS]	20.00 MG	HEADACHES
		15MAY2003-15MAY2003	80	POST	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 MG	DIARRHEA
			80	POST	KETOROLAC TROMETHAMINE [SENSORY ORGANS]	10.00 MG	HEADACHES
		15MAY2003-16MAY2003	80	POST	ETHANOL [RESPIRATORY SYSTEM]	10.00 CC	COUGH
		15MAY2003-17MAY2003	80	POST	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		17MAY2003-CONTINUE	82	POST	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	EPIGASTRIC PAIN

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	18MAY2003-18MAY2003	83	POST	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	COUGH
		19MAY2003-19MAY2003	84	POST	DIFLUNISAL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		20MAY2003-20MAY2003	85	POST	SUMATRIPTAN SUCCINATE [NERVOUS SYSTEM]	50.00 MG	HEADACHES
		22MAY2003-23MAY2003	87	POST	DIFLUNISAL [NERVOUS SYSTEM]	MG	HEADACHES
		23MAY2003-23MAY2003	88	POST	ETHANOL [RESPIRATORY SYSTEM]	10.00 CC	COUGH
		24MAY2003-24MAY2003	89	POST	TEMAZEPAM [NERVOUS SYSTEM]	30.00 MG	PRIMARY CONDITION
		26MAY2003-26MAY2003	91	POST	DIFLUNISAL [NERVOUS SYSTEM]	MG	HEADACHES
			91	POST	TEMAZEPAM [NERVOUS SYSTEM]	30.00 MG	PRIMARY CONDITION
		27MAY2003-27MAY2003	92	POST	DIFLUNISAL [NERVOUS SYSTEM]	MG	HEADACHES
		28MAY2003-29MAY2003	93	POST	DIFLUNISAL [NERVOUS SYSTEM]	MG	HEADACHES
		28MAY2003-30MAY2003	93	POST	UREA HYDROGEN PEROXIDE [SENSORY ORGANS]	8.00 GTTS	IMPACTED CERUMEN
		29MAY2003-29MAY2003	94	POST	PARACETAMOL [NERVOUS SYSTEM]	1300 MG	OTITIS
			94	POST	TEMAZEPAM [NERVOUS SYSTEM]	30.00 MG	PRIMARY CONDITION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022036	30MAY2003-30MAY2003	95	POST	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	COUGH
			95	POST	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	OTITIS
			95	POST	KAOLIN [ALIMENTARY TRACT AND METABOLISM]	30.00 CC	DIARRHEA
		30MAY2003-02JUN2003	95	POST	BENZOCAINE [SENSORY ORGANS]	6.00 DROPS	OTITIS
		31MAY2003-01JUN2003	96	POST	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1800 MG	OTITIS
		01JUN2003-01JUN2003	97	POST	PARACETAMOL [NERVOUS SYSTEM]	1300 MG	OTITIS
			97	POST	TEMAZEPAM [NERVOUS SYSTEM]	30.00 MG	PRIMARY CONDITION
		02JUN2003-CONTINUE	98	POST	HYDROCORTISONE [SENSORY ORGANS]	4.00 DROPS	OTITIS
			98	POST	PARACETAMOL [NERVOUS SYSTEM]	4.00 TABS	OTITIS
		03JUN2003-03JUN2003	99	POST	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	OTITIS
	E0022056	01APR2002-CONTINUE	-381	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN/REFLUX
	E0022060	09JUN2003-09JUN2003	41	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	220.0 MG	HEADACHE
		19JUN2003-19JUN2003	51	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0022063	01JAN2001-CONTINUE	-856	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	GE REFLUX
		07APR2003-CONTINUE	-30	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	81.00 MG	HEADACHES
		22MAY2003-CONTINUE	16	CONCOMITANT	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	4.00 TABLE-SPOON	GASTROESOPHAGEAL REFLUX.
	E0023034	25JUN2003-27JUN2003	17	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MENSTRUAL CRAMPS
	E0023037	11JUL2003-14JUL2003	24	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	UPPER RESPIRATORY INFECTION
	E0023044	01JUL1996-CONTINUE	-2571	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01JUL2000-CONTINUE	-1110	PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	SEASONAL ALLERGIES
		15DEC2001-CONTINUE	-578	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
	E0025002	01JUL2000-CONTINUE	-1006	PRIOR/CONCOM	HYOSCYAMINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	0.13 MG	ESOPHAGEAL SPASMS PRN
	E0026017	13MAR2003-CONTINUE	8	CONCOMITANT	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	BIPOLAR CONDITION

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0026017	13MAR2003-CONTINUE	8	CONCOMITANT	LITHIUM CARBONATE [NERVOUS SYSTEM]	900.0 MG	BIPOLAR CONDITION
	E0026018	01JUL1970-CONTINUE	-11950	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		01JUL2001-CONTINUE	-627	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	8.00 TAB	HEARTBURN
		17APR2003-18APR2003	29	CONCOMITANT	PERMETHRIN [ANTIPARASITIC PRODUCTS,INSECTICIDES AND REPELLENTS]	5.00 %	SCABIES
	E0026029	19JUL2003-19JUL2003	11	CONCOMITANT	CYCLOBENZAPRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	10.00 MG	LOWER BACK PAIN
	E0026030	15AUG2003-17AUG2003	38	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	LEFT FOOT INJURY
	E0026031	25MAY2003-CONTINUE	-57	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
	E0027003	21JAN2002-CONTINUE	-372	PRIOR/CONCOM	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	12.00 PUFFS	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
			-372	PRIOR/CONCOM	RIZATRIPTAN BENZOATE [NERVOUS SYSTEM]	20.00 MG	MIGRAINES
			-372	PRIOR/CONCOM	PANCRELIPASE [ALIMENTARY TRACT AND METABOLISM]	8.00 CAPS	PANCREATITIS, CHRONIC

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0027003	28MAY2002-CONTINUE	-245	PRIOR/CONCOM	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
			-245	PRIOR/CONCOM	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTRO ESOPHAGEL REFLUX
		26JUN2002-CONTINUE	-216	PRIOR/CONCOM	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	ARTHRITIS
		10DEC2002-CONTINUE	-49	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	20.00 MG	INSOMNIA
			-49	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
	E0028006	01SEP1992-CONTINUE	-3685	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01SEP1999-CONTINUE	-1129	PRIOR/CONCOM	GLUCOSAMINE [MUSCULO-SKELETAL SYSTEM]	3.00 TAB	ARTHRITIS
		11OCT2002-12OCT2002	8	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
		31OCT2002-07NOV2002	28	CONCOMITANT	CLINDAMYCIN [GENITO URINARY SYSTEM AND SEX HORMONES]	2.00 TABS	SINUS INFECTION
		21NOV2002-21NOV2002	49	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	SEASONAL ALLERGIES
	E0028008	01JUN2000-CONTINUE	-866	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	4.00 PUFFS	PRN FOR ASTHMA
			-866	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	PRN FOR MIGRAINE

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QUETIAPINE 300 MG (BIPOLAR I)	E0028008	01JUN2000-CONTINUE	-866	PRIOR/CONCOM	ATROPINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	2.50 MG	PRN FOR DIARRHEA
			-866	PRIOR/CONCOM	BIMATOPROST [SENSORY ORGANS]	5.00 ML	GLAUCOMA
			-866	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTRO ESOPHAGEAL REFLUX DISEASE
	E0028009	01JUL2002-25OCT2002	-106	PRIOR/CONCOM	FISH OIL [CARDIOVASCULAR SYSTEM]	4000 MG	PROPHYLAXIS
			-106	PRIOR/CONCOM	LECITHIN [BLOOD AND BLOOD FORMING ORGANS]	4800 MG	PROPHYLAXIS
	E0028016	01JUL1980-CONTINUE	-8171	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT
		05JAN2003-07JAN2003	53	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	COLD SYMPTOMS
	E0028034	01APR2003-04APR2003	1	CONCOMITANT	ECHINACEA EXTRACT [VARIOUS]	9.00 TABS	COLD SYMPTOMS
	E0028038	01MAR2003-CONTINUE	-55	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	UNK	GASTRIC REFLUX DISEASE
		01MAY2001-CONTINUE	-724	PRIOR/CONCOM	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	40.00 MG	HYPERLIPIDEMA
		01JUN2001-CONTINUE	-693	PRIOR/CONCOM	DOXAZOSIN MESILATE [CARDIOVASCULAR SYSTEM]	4.00 MG	PROSTATIC HYPERTROPHY (SIC)

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QUETIAPINE 300 MG (BIPOLAR I)	E0028038	01APR2003-CONTINUE	-24	PRIOR/CONCOM	LORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGIES
	E0028043	01JUL2000-CONTINUE	-1069	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		01JUL1993-CONTINUE	-3626	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		01JUL2001-CONTINUE	-704	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	BACK PAIN PRN
	E0028045	UNK-CONTINUE		PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	UNK	HYPOTHYROIDISM
		15MAY2003-CONTINUE	-34	PRIOR/CONCOM	ARIPIPRAZOLE [NERVOUS SYSTEM]	UNK	BIPOLAR
		11JUN2003-CONTINUE	-7	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
		22JUN2003-22JUN2003	5	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	4.00 TABS	HEADACHE
		15JUL2003-CONTINUE	28	POST	ARIPIPRAZOLE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR DISORDER
			28	POST	ARIPIPRAZOLE [NERVOUS SYSTEM]	60.00 MG	BIPOLAR
			28	POST	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	100.0 MG	BIPOLAR
			28	POST	HALOPERIDOL [NERVOUS SYSTEM]	UNK	EXTREME RESTLESSNESS
			28	POST	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR DISORDER

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0028045	15JUL2003-CONTINUE	28	POST	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR DISORDER
			28	POST	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	10.00 MG	BIPOLAR
			28	POST	METHOCARBAMOL [MUSCULO-SKELETAL SYSTEM]	UNK	MUSCLE SPASMS
			28	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	UNK	BIPOLAR
			28	POST	TOPIRAMATE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
			28	POST	TOPIRAMATE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR
			28	POST	TOPIRAMATE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR
			28	POST	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
			28	POST	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR
		15AUG2003-CONTINUE	59	POST	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
	E0029005	13JAN2003-13JAN2003	48	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	SINUS HEADACHE
		01JUN2000-CONTINUE	-909	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	17.00 G	PRN ASTHMA
		01DEC2002-07DEC2002	5	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	LOWER BACK PAIN PRN
		21DEC2002-22DEC2002	25	CONCOMITANT	ETHANOL [RESPIRATORY SYSTEM]	2.00 TSP	COMMON COLD PRN

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0030001	01JUL2001-CONTINUE	-506	PRIOR/CONCOM	CORTISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	1.00 Q4WK	PROPHYLAXIS
		01JUL1987-CONTINUE	-5620	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		04DEC2002-04DEC2002	16	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	MENSTRUAL CRAMPS
		10DEC2002-11DEC2002	22	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	MENSTRUAL CRAMPS
		26DEC2002-26DEC2002	38	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	BLOATING
		29DEC2002-01JAN2003	41	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	BLOATING
			41	CONCOMITANT	HERBAL PREPARATION [VARIOUS]	6.00 TABS	PROPHYLAXIS
		06JAN2003-08JAN2003	49	CONCOMITANT	HERBAL PREPARATION [VARIOUS]	6.00 TABS	PROPHYLAXIS
			49	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
	E0030008	18JAN2003-CONTINUE	5	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			5	CONCOMITANT	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	PROPHYLAXIS
		14MAR2003-17MAR2003	60	CONCOMITANT	BENZYLPENICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	2.00 TAB	TOOTH INFECTION
	E0030022	01JAN2003-CONTINUE	-166	PRIOR/CONCOM	LINSEED OIL [VARIOUS]	1.00 TAB	PROPHYLAXIS

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0030022	01JAN2003-CONTINUE	-166	PRIOR/CONCOM	OMEGA-3 MARINE TRIGLYCERIDES [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
			-166	PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JUL2000-CONTINUE	-1080	PRIOR/CONCOM	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TBLSPN	GASTRO ESOPHAGEAL REFLUX DISEASE
			-1080	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	GASTRO ESOPHAGEAL REFLUX DISEASE
		01JUL2001-CONTINUE	-715	PRIOR/CONCOM	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION
		15MAY2003-CONTINUE	-32	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	1.00 TAB	HIGH CHOLESTEROL
		01JUL1983-CONTINUE	-7290	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN2003-CONTINUE	-152	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION
		26JUL2003-29JUL2003	41	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	ALLERGIES
			41	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIES
			41	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	ALLERGIES
		29JUL2003-03AUG2003	44	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1.00 TAB	COLD SYMPTOMS
	E0031002	15JUN2002-CONTINUE	-165	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0031002	20JAN2003-20JAN2003	55	CONCOMITANT	DIPHENHYDRAMINE [RESPIRATORY SYSTEM]	2.00 TABS	CONGESTION
		15NOV2001-CONTINUE	-377	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	ORAL CONTRACEPTIVE
	E0033015	20MAY2003-20MAY2003	41	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	500.0 MG	HEADACHE
	E0034002	01JAN1995-CONTINUE	-3005	PRIOR/CONCOM	FIBRE, DIETARY [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS AS NEEDED
		01JAN1997-CONTINUE	-2274	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	5.00 MG	SEASONAL ALLERGIES
		07APR2003-CONTINUE	14	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	325.0 MG	FLU SYMPTOMS
		01JAN1993-CONTINUE	-3735	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	AS NEED FOR GENERAL HEALTH
		29MAR2003-29MAR2003	5	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHE
		07APR2003-10APR2003	14	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TSPS	FLU SYMPTOMS
		10APR2003-CONTINUE	17	CONCOMITANT	CLAVULANATE POTASSIUM [ANTIINFECTIVES FOR SYSTEMIC USE]	325.0 MG	BRONCHITIS
			17	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	200.0 MG	BRONCHITIS
	E0034003	03JUN2003-03JUN2003	41	CONCOMITANT	OTHER COLD COMBINATION PREPARATIONS [RESPIRATORY SYSTEM]	2.00 CAPS	NASAL CONGESTION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0034003	01JAN1984-CONTINUE	-7053	PRIOR/CONCOM	ANTACIDS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GASTRO - ESOPHOGEAL REFLUX DISEASE
		01JAN2000-05MAY2003	-1209	PRIOR/CONCOM	PRASTERONE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GENERAL HEALTH/DIETARY SUPPLEMENT
		01FEB2003-CONTINUE	-82	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	PRN FOR HEADACHES
		20MAY2003-21MAY2003	27	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	BACK PAIN
		16JUN2003-16JUN2003	54	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	975.0 MG	HEADACHE
	E0034006	01JAN1999-CONTINUE	-1596	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX DISEASE
		16MAY2003-16MAY2003	1	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
	E0034008	18JUN2003-18JUN2003	26	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	325.0 MG	HEADACHE
		15JUL2003-15JUL2003	53	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		18JUL2003-18JUL2003	56	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0035003	01JUL1995-CONTINUE	-2701	PRIOR/CONCOM	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	100.0 MG	ENVIRONMENTAL ALLERGIES
		15SEP2002-CONTINUE	-68	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	CHOLESTEROL
	E0035005	16DEC2002-16DEC2002	14	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	220.0 MG	HEADACHE
		20JAN2003-21JAN2003	49	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	DENTAL PAIN
	E0036005	30JUN2003-11JUL2003	-1	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL - WEEKLY
		09JUL2003-09JUL2003	9	CONCOMITANT	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	4.00 TABS	INDIGESTION
		12JUL2003-12JUL2003	12	CONCOMITANT	KETOROLAC TROMETHAMINE [SENSORY ORGANS]	30.00 MG	CHEST WALL PAIN "NOT CARDIAC RELATED"
	E0037002	01JAN2000-CONTINUE	-1090	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	MIGRAINE HEADACHES
	E0037005	01JAN2000-CONTINUE	-1160	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		01JAN2001-CONTINUE	-794	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	WRIST PAIN

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0039006	13JAN2003-13JAN2003	15	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		02JAN2003-02JAN2003	4	CONCOMITANT	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA
	E0039015	23JAN2003-23JAN2003	1	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		13FEB2003-13FEB2003	22	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HIP PAIN
	E0039024	01JUL2001-CONTINUE	-606	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	GASTRIC ULCERS
		05MAR2003-17MAR2003	7	CONCOMITANT	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGIES
		19MAR2003-19MAR2003	21	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	NASAL CONGESTION
			21	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	ITCHING EARS
		12APR2003-17APR2003	45	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	RIGHT ANKLE PAIN
		22APR2003-22APR2003	55	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	SEASONAL ALLERGIES
	E0039041	15FEB1983-30APR2003	-7364	PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	PROPHYLAXIS
			-7364	PRIOR/CONCOM	LACTOBACILLUS ACIDOPHILUS [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	PROPHYLAXIS

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0039041	15FEB1983-30APR2003	-7364	PRIOR/CONCOM	MULTIVITAMINS WITH MINERALS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-7364	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1000 MG	PROPHYLAXIS
			-7364	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1000 IV	PROPHYLAXIS
			-7364	PRIOR/CONCOM	VITAMINS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-7364	PRIOR/CONCOM	ZINC [ALIMENTARY TRACT AND METABOLISM]	50.00 MG	PROPHYLAXIS
	E0039044	28JUN2003-CONTINUE	38	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	PALPITATIONS (POST DOSE)
	E0039051	10AUG2003-10AUG2003	56	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	TONGUE PAIN
	E0039057	02SEP2003-02SEP2003	51	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHE
		07SEP2003-07SEP2003	56	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	LEFT LEG PAIN DUE TO BASKETBALL INJURY
		08SEP2003-08SEP2003	57	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	LEFT LEG PAIN DUE TO BASKETBALL INJURY
	E0041003	01NOV2002-01MAR2003	-88	PRIOR/CONCOM	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION

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QUETIAPINE 300 MG (BIPOLAR I)	E0041003	21JAN2003-08MAR2003	-7	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	UPPER RESPIRATORY SYMPTOMS
	E0041008	29APR2003-03MAY2003	23	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	INTERMITTENT HEADACHE
		23MAY2003-23MAY2003	47	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	INTERMITTENT HEADACHE
		22APR2003-22APR2003	16	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INTERMITTENT INSOMNIA
			16	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	INTERMITTENT HEADACHE
		01JUL1997-CONTINUE	-2106	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	HYPOTHYROIDISM
		09APR2003-10APR2003	3	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INTERMITTENT INSOMNIA
		24APR2003-26APR2003	18	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INTERMITTENT INSOMNIA
		02JUN2003-02JUN2003	57	POST	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	INTERMITTENT HEADACHE
	E0042001	01JUL1997-CONTINUE	-2192	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			-2192	PRIOR/CONCOM	POTASSIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	8.00 MEQ	HYPERTENSION
		01JUL1999-CONTINUE	-1462	PRIOR/CONCOM	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	250.0 MG	CONSTIPATION

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR I)	E0042001	01JUL1999-CONTINUE	-1462	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	SEASONAL RHINITIS
			-1462	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	100.0 IU	PROPHYLAXIS
			-1462	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	GASTRO ESOPHAGEAL REFLUX

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0001002	15FEB2002-CONTINUE	-390	PRIOR/CONCOM	ATENOLOL [CARDIOVASCULAR SYSTEM]	50.00 MG	HIGH BLOOD PRESSURE
		15DEC2002-CONTINUE	-87	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-87	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN2003-24APR2003	-56	PRIOR/CONCOM	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	12.50 MG	ARTHRITIS IN RIGHT ANKLE PRN
		16APR2003-CONTINUE	36	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0003018	01JAN2003-CONTINUE	-132	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 POWDER	HEADACHE, PRN
			-132	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABLETS	HEADACHE, PRN
			-132	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE, PRN
		01MAY2002-CONTINUE	-377	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	120.0 MG	SINUS HEADACHE, PRN
		11JUN2003-11JUN2003	30	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	SINUS DRAINAGE
		01JUL2003-02JUL2003	50	CONCOMITANT	CAMPHOR [RESPIRATORY SYSTEM]	1.00 APPLICATION	SINUS DRAINAGE
	E0005030	15JAN2000-CONTINUE	-1166	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0005030	27MAR2003-28MAR2003	2	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 PILL	PAINFUL MENSES
		02APR2003-02APR2003	8	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY SECONDARY TO BIPOLAR
		03APR2003-03APR2003	9	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY SECONDARY TO BIPOLAR
		05APR2003-07APR2003	11	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY SECONDARY TO BIPOLAR
		15APR2003-15APR2003	21	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1300 MG	MIGRAINE
	E0005036	15FEB2003-CONTINUE	-80	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	CHOLESTEROL - ELEVATED
			-80	PRIOR/CONCOM	CARNITINE [CARDIOVASCULAR SYSTEM]	1.00 TAB	CHOLESTEROL - ELEVATED
			-80	PRIOR/CONCOM	FISH OIL [CARDIOVASCULAR SYSTEM]	400.0 MG	CHOLESTEROL - ELEVATED
			-80	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	CHOLESTEROL - ELEVATED
			-80	PRIOR/CONCOM	NICOTINIC ACID [CARDIOVASCULAR SYSTEM]	1.00 TAB	CHOLESTEROL - ELEVATED
			-80	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	CHOLESTEROL - ELEVATED
		10MAY2003-CONTINUE	5	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHES - PRN
		12MAY2003-12MAY2003	7	CONCOMITANT	BENZATROPINE MESILATE [NERVOUS SYSTEM]	1.00 MG	RESTLESS LEGS

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0006015	01JUL2002-CONTINUE	-225	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TABLET	UNKNOWN
		01JUL2001-CONTINUE	-590	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TABLET	MIGRAINE
		15FEB2001-CONTINUE	-726	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	PROPHYLAXIS
			-726	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	UNKNOWN
		19MAR2003-CONTINUE	37	CONCOMITANT	FISH OIL [CARDIOVASCULAR SYSTEM]	1.00 TABLET	MEMORY IMPROVEMENT
	E0006016	01JUL2001-CONTINUE	-596	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	PROPHYLAXIS
		01JUL1999-CONTINUE	-1327	PRIOR/CONCOM	VALACICLOVIR HYDROCHLORIDE [ANTIINFECTIVES FOR SYSTEMIC USE]	2.00 GRAM	GENITAL HERPES PRN
	E0007008	01JAN2003-CONTINUE	-107	PRIOR/CONCOM	LIOTHYRONINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	15.00 MCG	HYPOTHYROID
			-107	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	37.50 MG	(LEFT) VESTIBULAR INBALANCE
		01JAN1997-CONTINUE	-2298	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	200.0 MCG	HYPOTHYROID
	E0009002	01JUL1998-CONTINUE	-1602	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	80.00 MG	CARDIOVASCULAR PROPHYLAXIS

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0009002	13DEC2002-CONTINUE	25	CONCOMITANT	TESTOSTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	100.0 MG	LOW TESTOSTERONE PRODUCTION
		01JUL2001-CONTINUE	-506	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HIGH CHOLESTERAL
		15AUG1999-CONTINUE	-1192	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	88.00 MCG	GRAVES DISEASE
		15FEB2001-12DEC2002	-642	PRIOR/CONCOM	TESTOSTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	50.00 MG	LOW TESTOSTERONE
	E0009006	01JUL1984-CONTINUE	-6785	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		08MAR2003-CONTINUE	40	CONCOMITANT	NICOTINE [NERVOUS SYSTEM]	1.00 PATCH	SMOKING CESSATION
	E0009009	01JUL2002-CONTINUE	-254	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	TOOTHACHE
	E0010015	29JAN2003-13MAR2003	-22	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
			-22	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	PRN - INSOMNIA
	E0011004	15JUN2002-CONTINUE	-192	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	6.00 PUFFS	ASTHMA
		20JAN2003-20JAN2003	28	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	50.00 MG	VIRAL SYNDROME

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0011004	15SEP2000-CONTINUE	-830	PRIOR/CONCOM	KETOPROFEN [MUSCULO-SKELETAL SYSTEM]	100.0 MG	BACKACHE
		21JAN2003-21JAN2003	29	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	100.0 MG	VIRAL SYNDROME.
		21JAN2003-25JAN2003	29	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	25.00 MG	VIRAL SYNDROME
		26JAN2003-26JAN2003	34	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	BACK PAIN
		10FEB2003-10FEB2003	49	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	BACK PAIN
	E0011007	01JUL2000-CONTINUE	-901	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	SINUS INFECTION
		01JUL1993-CONTINUE	-3458	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	750.0 MG	HEADACHES BACKACHES
		01JAN2003-29JAN2003	14	CONCOMITANT	BISACODYL [ALIMENTARY TRACT AND METABOLISM]	5.00 MG	CONSTIPATION
	E0011018	01JUL1995-CONTINUE	-2882	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES PRN
	E0015003	15JAN2002-CONTINUE	-314	PRIOR/CONCOM	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	CONSTIPATION
	E0019003	25NOV2002-CONTINUE	5	CONCOMITANT	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	GSTROESOPHAGED REFLUX DISEASE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0019003	01DEC2002-CONTINUE	11	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2000 MG	TENSION HEADACHES
	E0019007	07JAN2003-07JAN2003	56	POST	DIMENHYDRINATE [RESPIRATORY SYSTEM]	2.00 TABS	MIGRAINE
			56	POST	CAFFEINE [NERVOUS SYSTEM]	2.00 CAPS	MIGRAINE
		01FEB2001-CONTINUE	-650	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1500 MG	PROPHYLAXIS
			-650	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01NOV2001-CONTINUE	-377	PRIOR/CONCOM	RALOXIFENE HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 CAP	PROPHYLAXIS
	E0019014	06JAN2003-CONTINUE	-3	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	UNK	HEADACHE
	E0019018	11MAR2003-11MAR2003	41	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	324.0 MG	TOOTHACHE
		14MAR2003-14MAR2003	44	CONCOMITANT	PROCAINE HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	TOOTH EXTRACTION
			44	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2000 MG	GUM PAIN
	E0019022	04FEB2003-CONTINUE	6	CONCOMITANT	TIZANIDINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	4.00 MG	LOWER BACK PAIN
		10FEB2003-CONTINUE	12	CONCOMITANT	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	UNK	DIARRHEA

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0019022	27FEB2003-CONTINUE	29	CONCOMITANT	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	INDISGESTION
	E0019027	27MAR1987-CONTINUE	-5816	PRIOR/CONCOM	INSULIN [ALIMENTARY TRACT AND METABOLISM]	CC	DIABETES .4 - 1
		26FEB2003-CONTINUE	-1	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	UNK	SINUS HEADACHE
			-1	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNK	SINUS HEADACHE
		05MAR2003-05MAR2003	7	POST	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNK	INSOMNIA
	E0019032	01JAN1993-CONTINUE	-3742	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		20APR2003-20APR2003	20	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	UPPER RESPIRATORY INFECTION
	E0019036	26MAR2003-26MAR2003	2	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE
		31MAR2003-11APR2003	7	CONCOMITANT	CEFALEXIN MONOHYDRATE [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	SPIDER BITE
	E0019041	01JAN2001-CONTINUE	-870	PRIOR/CONCOM	ECHINACEA EXTRACT [VARIOUS]	1.00 TAB	HEALTH SUPPLEMENT
	E0019049	02AUG2003-04AUG2003	24	CONCOMITANT	DOCUSATE CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 CAPSULE	CONSTIPATION

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0022052	01JAN1999-CONTINUE	-1560	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		01JAN1997-CONTINUE	-2290	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MUSCULOSKELETAL PAIN
			-2290	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		03JUN2003-03JUN2003	55	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	MUSCULOSKELETAL PAIN
		01SEP2002-CONTINUE	-221	PRIOR/CONCOM	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 MG	DIARRHEA
	E0022064	05MAY2003-CONTINUE	-1	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0022073	01MAR2003-CONTINUE	-117	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	ALLERGIC RHINITIS
		01JAN1995-CONTINUE	-3098	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	DYSMENORRHEA
			-3098	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		01JAN1996-CONTINUE	-2733	PRIOR/CONCOM	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	GASTROESOPHAGEAL REFLUX
		21JUL2003-23JUL2003	26	CONCOMITANT	PHENAZOPYRIDINE HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	300.0 MG	URINARY TRACT INFECTION
			26	CONCOMITANT	SULFAMETHOXAZOLE [ANTIINFECTIVES FOR SYSTEMIC USE]	1.00 TAB	URINARY TRACT INFECTION

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0023002	29NOV2002-29NOV2002	25	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
	E0023021	12JUN2003-12JUN2003	51	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
	E0023027	01SEP2002-CONTINUE	-257	PRIOR/CONCOM	RABEPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	ESOPHOGEAL REFLUX
		01DEC1997-CONTINUE	-1992	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.10 MG	HYPOTHYROID
		11FEB2003-19MAY2003	-94	PRIOR/CONCOM	PROPRANOLOL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION (CONTROLLED)
	E0026014	01JUL1978-CONTINUE	-8999	PRIOR/CONCOM	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	120.0 MG	HYPERTENSION
	E0027005	12DEC2002-CONTINUE	-14	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
			-14	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	4.00 MG	ANXIETY
	E0029021	01JAN1999-CONTINUE	-1537	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHES - PRN.
		01JAN1995-CONTINUE	-2998	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TAB	HEADACHES - PRN.

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QUETIAPINE 300 MG (BIPOLAR II)	E0029026	01JAN2001-CONTINUE	-833	PRIOR/CONCOM	SERENOA REPENS [GENITO URINARY SYSTEM AND SEX HORMONES]	600.0 MG	DIETARY SUPPLEMENT
		10MAY2003-CONTINUE	27	CONCOMITANT	HERBAL PREPARATION [VARIOUS]	1.00 TBSP	CONSTIPATION
		01JAN1993-14APR2003	-3755	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		02APR2002-28MAY2003	-377	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	KNEE ARTHRITIS
		14APR2003-15APR2003	1	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA SECONDARY TO DEPRESSION
		28MAY2003-CONTINUE	45	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	KNEE ARTHRITIS
	E0029030	UNK-CONTINUE		PRIOR/CONCOM	HERBAL PREPARATION [VARIOUS]	400.0 MG	DIETARY SUPPLEMENT
				PRIOR/CONCOM	POTASSIUM [ALIMENTARY TRACT AND METABOLISM]	MG	DIETARY SUPPLEMENT
		01MAY2003-CONTINUE	-26	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1000 MG	DIETARY SUPPLEMENT
		02JUN2003-18JUL2003	7	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHE
		20JUL2003-20JUL2003	55	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1000 MG	TOOTHACHE
	E0031008	01DEC2002-CONTINUE	-89	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	FIBROMYALGIA

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QUETIAPINE 300 MG (BIPOLAR II)	E0031008	01NOV2002-CONTINUE	-119	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	ORAL CONTRACEPTIVE
		24FEB2003-CONTINUE	-4	PRIOR/CONCOM	ACICLOVIR [ANTIINFECTIVES FOR SYSTEMIC USE]	800.0 MG	GENITAL HERPES
		01JAN1987-CONTINUE	-5902	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	FIBROMYALGIA
		16FEB2003-04MAR2003	-12	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.50 MG	ANXIETY
	E0031020	01JAN2000-CONTINUE	-1206	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 SPRAY	ASTHMA
		01JAN2001-CONTINUE	-840	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SPRAY	SEASONAL ALLERGIES
		29APR2003-12MAY2003	9	CONCOMITANT	PETROLATUM [DERMATOLOGICALS]	1.00 TSPN	POISON IVY
	E0031021	30MAY2003-30MAY2003	36	CONCOMITANT	I.V. SOLUTIONS [BLOOD AND BLOOD FORMING ORGANS]	UNK	STAB WOUNDS
			36	CONCOMITANT	LACTATED RINGER'S INJECTION [BLOOD AND BLOOD FORMING ORGANS]	250.0 CC	STAB WOUNDS
	E0031029	01JUL1993-CONTINUE	-3639	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JUL1981-CONTINUE	-8022	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	MIGRAINES
			-8022	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	MIGRAINES

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QUETIAPINE 300 MG (BIPOLAR II)	E0031029	01JUL1981-CONTINUE	-8022	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	MIGRAINES
	E0033002	06JAN2003-24JAN2003	-4	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
			-4	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	AGITATION (SYMPTOM OF BIPOLAR DEPRESSION)
		19JAN2003-30JAN2003	10	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE
	E0033021	01JUN2002-CONTINUE	-396	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	0.25 MG	BIRTH CONTROL
		25JUN2003-15JUL2003	-7	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	INSOMNIA ASSOCIATED WITH DEPRESSION
		22JUL2003-22JUL2003	21	CONCOMITANT	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	50.00 MCG	SEASONAL ALLERGIES
		25JUL2003-25JUL2003	24	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	250.0 MG	HEADACHE
		18AUG2003-18AUG2003	48	POST	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	5.00 ML	DIARRHEA
	E0035013	01OCT2002-CONTINUE	-126	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	CHOLESTEROL

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QUETIAPINE 300 MG (BIPOLAR II)	E0035013	07FEB2003-CONTINUE	4	POST	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	INSOMNIA
			4	POST	RISPERIDONE [NERVOUS SYSTEM]	4.00 MG	PSYCHOSIS
			4	POST	CARBAMAZEPINE [NERVOUS SYSTEM]	500.0 MG	MOOD STABILIZER
	E0039052	UNK-CONTINUE		PRIOR/CONCOM	FOLIC ACID [BLOOD AND BLOOD FORMING ORGANS]	UNK	PROPHYLAXIS
				PRIOR/CONCOM	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	UNK	PROPHYLAXIS
				PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLAXIS
		01JUL1993-CONTINUE	-3641	PRIOR/CONCOM	TRIAMCINOLONE [DERMATOLOGICALS]	2.00 APPLICATIONS	ECZEMA
		01JUL1978-CONTINUE	-9120	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA (AS NEEDED)
		04JUN2003-CONTINUE	-16	PRIOR/CONCOM	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	500.0 MG	NON INSULIN DEPENDENT DIABETES
		26JUN2003-26JUN2003	7	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		01JUL2003-01JUL2003	12	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	HEADACHE
	E0039056	15FEB2003-CONTINUE	-150	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-150	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 300 MG (BIPOLAR II)	E0040003	01JUL1998-CONTINUE	-1844	PRIOR/CONCOM	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	ASTHMA
		18JUL2003-29JUL2003	-1	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		21JUL2003-04AUG2003	3	CONCOMITANT	BENZATROPINE MESILATE [NERVOUS SYSTEM]	2.00 MG	AKATHISIA
		19AUG2003-29AUG2003	32	CONCOMITANT	CLAVULANATE POTASSIUM [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	BRONCHITIS

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0002009	15FEB1990-CONTINUE	-4764	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	25.00 MG	ASTHMA PRN
			-4764	PRIOR/CONCOM	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	25.00 MG	ASTHMA PRN
		15APR1997-CONTINUE	-2148	PRIOR/CONCOM	OMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	HIATEL HERNIA
		15FEB1998-CONTINUE	-1842	PRIOR/CONCOM	SALMETEROL XINAFOATE [RESPIRATORY SYSTEM]	21.00 MCG	ASTHMA PRN
	E0002011	29APR2003-CONTINUE	1	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	ACHES BODY AND MUSCLE
			1	CONCOMITANT	LAXATIVES [ALIMENTARY TRACT AND METABOLISM]	UNKNOWN	CONSTIPATION
	E0003010	14MAR2003-14MAR2003	40	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA
			40	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	6.00 TABS	INDIGESTION
		13FEB2003-15FEB2003	11	CONCOMITANT	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	6.00 TABS	INDIGESTION
		25FEB2003-25FEB2003	23	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	MIGRAINE
			23	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	INDIGESTION
		08MAR2003-08MAR2003	34	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	INDIGESTION
		14MAR2003-CONTINUE	40	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	INDIGESTION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0003016	15FEB2003-CONTINUE	-96	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		24MAY2003-24MAY2003	3	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MENSTRUAL CRAMPS
		15NOV1991-CONTINUE	-4206	PRIOR/CONCOM	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEARTBURN, PRN
	E0003019	01JUL2001-CONTINUE	-726	PRIOR/CONCOM	FISH OIL [CARDIOVASCULAR SYSTEM]	1200 MG	PROPHYLAXIS
		03JUL2003-15JUL2003	7	CONCOMITANT	HYDROCORTISONE [DERMATOLOGICALS]	3.00 APPLICATIONS	POISON IVY RASH
			7	CONCOMITANT	NEOMYCIN SULFATE [DERMATOLOGICALS]	3.00 APPLICATIONS	POISON IVY RASH
		05AUG2003-07AUG2003	40	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	4.00 TABS	SINUS CONGESTION
	E0003020	01JAN2001-CONTINUE	-933	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HIP PAIN DUE TO VASCULAR NECROSIS
	E0004001	01JAN1999-CONTINUE	-1368	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	220.0 MG	HEADACHE
		03OCT2002-CONTINUE	4	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		31OCT2002-CONTINUE	32	POST	CIPROFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	KIDNEY INFECTION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0004001	31OCT2002-CONTINUE	32	POST	DICYCLOVERINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	10.00 MG	DIARRHEA
			32	POST	HYDROCODONE [RESPIRATORY SYSTEM]	500.0 MG	BACK PAIN
			32	POST	PHENAZOPYRIDINE HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	200.0 MG	BLOOD IN URINE
	E0004009	27DEC2002-31DEC2002	2	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	LEG CRAMPS
		01AUG2001-CONTINUE	-512	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
			-512	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
		02JAN2003-CONTINUE	8	CONCOMITANT	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1600 MG	LEG CRAMPS
			8	CONCOMITANT	MAGNESIUM [ALIMENTARY TRACT AND METABOLISM]	600.0 MG	LEG CRAMPS
	E0005003	15NOV2002-CONTINUE	45	CONCOMITANT	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 PILL	HYPERTENSION
		01JUL2000-24OCT2002	-823	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 PILL	HYPERTENSION
		23SEP2002-CONTINUE	-9	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	3.00 PILLS	JOINT PAIN
		30SEP2002-24OCT2002	-2	PRIOR/CONCOM	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	JOINT PAIN
		09OCT2002-14OCT2002	8	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA

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Listing 12.2.10.7 Concomitant Medications

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QUETIAPINE 600 MG (BIPOLAR I)	E0005007	01JUL2002-CONTINUE	-100	PRIOR/CONCOM	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	ARTHRITIS PRN
		09OCT2002-15OCT2002	1	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA - PRN
		16OCT2002-28OCT2002	8	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		17OCT2002-CONTINUE	9	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 PILLS	HEARTBURN
		20NOV2002-30NOV2002	43	CONCOMITANT	BENZATROPINE MESILATE [NERVOUS SYSTEM]	2.00 MG	AKIATHISIA/MUSCLE TENSION
		01DEC2002-04DEC2002	54	CONCOMITANT	BENZATROPINE MESILATE [NERVOUS SYSTEM]	4.00 MG	AKATHISIA/MUSCLE TENSION
		04DEC2002-CONTINUE	57	POST	BENZATROPINE MESILATE [NERVOUS SYSTEM]	6.00 MG	AKATHISIA/MUSCLE TENSION
			57	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR
		07JAN2003-09JAN2003	91	POST	GUAIFENESIN [RESPIRATORY SYSTEM]	TBSP	UPPER RESPIRATORY INFECTION
	E0005008	01JAN1998-CONTINUE	-1748	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 PILL	BACK PAIN
			-1748	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
		14NOV2002-CONTINUE	31	CONCOMITANT	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	BACK PAIN

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Listing 12.2.10.7 Concomitant Medications

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QUETIAPINE 600 MG (BIPOLAR I)	E0005009	01JUN2002-CONTINUE	-150	PRIOR/CONCOM	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN - PRN
			-150	PRIOR/CONCOM	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	UNKN	HEARTBURN
		09OCT2002-CONTINUE	-20	PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	ALLERGIES/SINUSITIS
		16OCT2002-CONTINUE	-13	PRIOR/CONCOM	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	SINUSITIS - PRN
			-13	PRIOR/CONCOM	BUDESONIDE [RESPIRATORY SYSTEM]	2.00 SPRAYSEACH NOSTRIL	SINUSITIS
	E0005012	UNK-CONTINUE		PRIOR/CONCOM	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TBLSPNS	HEARTBURN
				PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		05DEC2002-05DEC2002	22	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	0.50 MG	SLEEPLESSNESS SECONDARY TO BIPOLAR DISORDER
		19DEC2002-19DEC2002	36	CONCOMITANT	BARIUM [VARIOUS]	UNK	COLONOSCOPY PREP
		03NOV2002-20NOV2002	-11	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	SLEEPLESNESS SECONDARY TO BIPOLAR DISORDER
		20NOV2002-CONTINUE	7	CONCOMITANT	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	JOINT PAIN

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QUETIAPINE 600 MG (BIPOLAR I)	E0005012	02DEC2002-CONTINUE	19	CONCOMITANT	CARISOPRODOL [MUSCULO-SKELETAL SYSTEM]	350.0 MG	JOINT/MUSCLE PAIN
	E0005022	15OCT2002-CONTINUE	-106	PRIOR/CONCOM	ASCORBIC ACID [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	CARTILIDGE REPAIR/JOINT PAIN
	E0005025	01JUL1991-21MAR2003	-4259	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	75.00 MCG	HYPOTHYROID
		27MAR2003-CONTINUE	29	CONCOMITANT	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	75.00 MCG	HYPOTHYROID
	E0006019	10NOV1999-CONTINUE	-1244	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.15 MG	HYPOTHYROIDISM
		15DEC1999-CONTINUE	-1209	PRIOR/CONCOM	ALENDRONATE SODIUM [MUSCULO-SKELETAL SYSTEM]	70.00 MG	OSTEOPEROSIS ONCE PER WEEK
		15JUN2001-CONTINUE	-661	PRIOR/CONCOM	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	220.0 MCG	SEASONAL ALLERGIES
		15JUL2002-CONTINUE	-266	PRIOR/CONCOM	PSEUDOEPHEDRINE SULFATE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGIES PRN
	E0007015	01JUL1996-CONTINUE	-2571	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1500 MG	OSTEOPENIA
			-2571	PRIOR/CONCOM	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	0.30 MG	HORMONE REPLACEMENT

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QUETIAPINE 600 MG (BIPOLAR I)	E0007015	01JUL1996-CONTINUE	-2571	PRIOR/CONCOM	PROGESTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	2.50 MG	HORMONE REPLACEMENT
		01JUL1993-CONTINUE	-3667	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SELF PRESCRIBED GENERAL HEALTH
			-3667	PRIOR/CONCOM	ACICLOVIR [ANTIINFECTIVES FOR SYSTEMIC USE]	400.0 MG	HERPES GENITALIA
		24JAN2003-CONTINUE	-173	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERLIPIDEMIA
		29JUL2003-15AUG2003	14	CONCOMITANT	CLOBETASOL PROPIONATE [DERMATOLOGICALS]	2.00 APPLICATIONS	CONTACT DERMATITUS
	E0009001	20AUG2001-CONTINUE	-449	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	HEADACHES
			-449	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINES
			-449	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	HEADACHES
		29DEC2002-CONTINUE	48	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		30DEC2002-CONTINUE	49	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TAB	NASAL CONGESTION
	E0010002	14NOV2002-CONTINUE	-11	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
	E0010009	01JAN2001-CONTINUE	-724	PRIOR/CONCOM	FLUVASTATIN SODIUM [CARDIOVASCULAR SYSTEM]	40.00 MG	ELEVATED CHOLESTEROL

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QUETIAPINE 600 MG (BIPOLAR I)	E0010009	01AUG1992-CONTINUE	-3799	PRIOR/CONCOM	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	20.00 MG	LESION ON THE AORTA
			-3799	PRIOR/CONCOM	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	15.00 MG	LESION ON THE AORTA
	E0010010	UNK-CONTINUE		PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLAXIS
	E0010014	01JUL1991-16FEB2003	-4229	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TABLET	HYPERTENSION
		17FEB2003-CONTINUE	21	CONCOMITANT	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TABLET	HYPERTENSION
	E0010017	05FEB2003-10MAR2003	-20	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		26FEB2003-02MAR2003	2	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	4.00 TABLETS	HEADACHE
		24MAR2003-06APR2003	28	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 TABLETS	PULLED BACK MUSCLE
	E0010023	01JUL2002-CONTINUE	-290	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	MG	PROPHYLAXIS
	E0010027	05JUN2003-CONTINUE	-11	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	SLEEP
		12JUN2003-CONTINUE	-4	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	SEVERE ANXIETY

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QUETIAPINE 600 MG (BIPOLAR I)	E0010029	12MAY2003-CONTINUE	-38	PRIOR/CONCOM	ROSIGLITAZONE MALEATE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	HYPERTENSION
			-38	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	12.50 MG	DIABETES MELLITUS TYPE II
			-38	PRIOR/CONCOM	MOEXIPRIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	7.50 MG	DIABETES MELLITUS TYPE II
		10JUN2003-CONTINUE	-9	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	SLEEP
	E0011022	01JAN2003-CONTINUE	-159	PRIOR/CONCOM	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	INDIGESTION PRN
		15MAY2003-CONTINUE	-25	PRIOR/CONCOM	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
			-25	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES PRN
		01JUL1987-CONTINUE	-5822	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES PRN
		01JUL1973-CONTINUE	-10935	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	3000 MG	HEADACHES PRN
		15MAR2003-CONTINUE	-86	PRIOR/CONCOM	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	PROPHYLAXIS
		15MAY2003-09JUN2003	-25	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	ANXIETY PRN DUE TO DEPRESSION
			-25	PRIOR/CONCOM	HYDROXYZINE EMBONATE [NERVOUS SYSTEM]	200.0 MG	INSOMNIA PRN

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QUETIAPINE 600 MG (BIPOLAR I)	E0011022	15MAY2003-08JUL2003	-25	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	12.50 MG	HYPERTENSION
		09JUL2003-CONTINUE	31	CONCOMITANT	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
	E0013006	01JUN1985-CONTINUE	-6494	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
	E0013012	01MAR2001-CONTINUE	-797	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERLIPIDEMIA
			-797	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
			-797	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MG	HYPOTHYROIDISM
	E0013014	01JUL1995-03JUN2003	-2894	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
	E0014005	14FEB2003-14MAR2003	-25	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	MUSCLE SPASMS - PAIN NECK/PRN
		07MAR2003-CONTINUE	-4	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	DYSLIPIDEMIA
	E0014007	01JAN2003-CONTINUE	-90	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	750.0 MG	ACHES

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	01JUL1983-CONTINUE	-7256	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	ACID REFLUX (PRN)
			-7256	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	HEADACHES (PRN)
		12JUN2003-CONTINUE	31	CONCOMITANT	LORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	HAY FEVER
	E0014012	01JUL1998-CONTINUE	-1791	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	MIGRAINE
		01JUL2001-CONTINUE	-695	PRIOR/CONCOM	MINERAL SUPPLEMENTS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
			-695	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
			-695	PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
			-695	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
		10JUN2003-CONTINUE	15	CONCOMITANT	PROPRANOLOL [CARDIOVASCULAR SYSTEM]	40.00 MG	AKATHISIA
		01JUL1972-CONTINUE	-11287	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MUSCLE PAIN
			-11287	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		14JUN2003-15JUN2003	19	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	AKATHISIA
	E0015001	01JUL1988-CONTINUE	-5264	PRIOR/CONCOM	LEVOTHYROXINE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	HYPOTHYROID

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QUETIAPINE 600 MG (BIPOLAR I)	E0015008	UNK-CONTINUE		PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLAXIS
	E0018007	06JAN2003-08JAN2003	11	POST	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	7.50 MG	DEEP VEIN THROMBOSIS
		01JUN1979-CONTINUE	-8610	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	ARTHRITIS
		01JUN1992-CONTINUE	-3861	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	180.0 MCG	ASTHMA
		01APR1995-31DEC2002	-2827	PRIOR/CONCOM	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	1.25 MG	HORMONE REPLACEMENT THERAPY
		17DEC2002-CONTINUE	-10	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	LEFT LEG PAIN
			-10	PRIOR/CONCOM	ASCORBIC ACID [MUSCULO-SKELETAL SYSTEM]	3.00 TABS	ARTHRITIS
		31DEC2002-31DEC2002	5	POST	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	10.00 MG	DEEP VEIN THROMBOSIS
		01JAN2003-02JAN2003	6	POST	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	5.00 MG	DEEP VEIN THROMBOSIS
		01JAN2003-07JAN2003	6	POST	HEPARIN-FRACTION, SODIUM SALT [BLOOD AND BLOOD FORMING ORGANS]	130.0 MG	DEEP VEIN THROMBOSIS
		02JAN2003-07JAN2003	7	POST	HYDROMORPHONE HYDROCHLORIDE [NERVOUS SYSTEM]	6.00 MG	LEFT LEG PAIN
		03JAN2003-04JAN2003	8	POST	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	7.50 MG	DEEP VEIN THROMBOSIS

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QUETIAPINE 600 MG (BIPOLAR I)	E0018007	05JAN2003-05JAN2003	10	POST	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	10.00 MG	DEEP VEIN THROMBOSIS
		07JAN2003-CONTINUE	12	POST	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	20.00 MG	BIPOLAR DEPRESSION
		07JAN2003-17JAN2003	12	POST	MORPHINE [NERVOUS SYSTEM]	4.00 MG	LEFT LEG PAIN
		09JAN2003-CONTINUE	14	POST	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	MG	RECURRENT DEEP VEIN THROMBOSIS
		17JAN2003-06FEB2003	22	POST	MORPHINE [NERVOUS SYSTEM]	90.00 MG	LEFT LEG PAIN
	E0019005	01JAN1993-CONTINUE	-3595	PRIOR/CONCOM	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	2.00 MG	HORMONE REPLACEMENT THERAPY
			-3595	PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	2.50 MG	HORMONE REPLACEMENT THERAPY
		01JAN1991-CONTINUE	-4326	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	SECONDARY HYPOTHROIDISM
		11NOV2002-11NOV2002	7	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	HEADACHE
	E0019015	30DEC2002-CONTINUE	-3	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	TABS	HEADACHES
		14JAN2003-14JAN2003	13	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	TABS	GI DISCOMFORT

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0020004	01JAN2000-CONTINUE	-1073	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERCHOLESTEROLEMIA
		01JAN1997-CONTINUE	-2168	PRIOR/CONCOM	METOPROLOL [CARDIOVASCULAR SYSTEM]	100.0 MG	HYPERTENSION
		01JAN2003-07JAN2003	24	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	ABDOMINAL PAIN
			24	CONCOMITANT	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	ABDOMINAL PAIN
		11DEC2002-11DEC2002	3	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 CAP	HEADACHE
		24DEC2002-24DEC2002	16	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	ABDOMINAL PAIN
	E0020010	01JAN1990-CONTINUE	-4783	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 PUFF	ASTHMA
		05FEB2003-10FEB2003	1	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	PRN SLEEP DISTURBANCE
		15FEB2003-18FEB2003	11	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABLETS	INTERMITTENT HEARTBURN
		22FEB2003-23FEB2003	18	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	ENTIRE BODYACHES
	E0020014	01JAN1996-CONTINUE	-2633	PRIOR/CONCOM	TOLTERODINE L-TARTRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	2.00 MG	OVERACTIVE BLADDER
			-2633	PRIOR/CONCOM	OXYBUTYNIN HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	5.00 MG	OVERACTIVE BLADDER

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QUETIAPINE 600 MG (BIPOLAR I)	E0020021	05JUL2003-07JUL2003	48	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 CAPS	INTERMITTANT LEG ACHES
	E0020023	01JAN1998-CONTINUE	-1993	PRIOR/CONCOM	OMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	10.00 MG	REFLUX (PRN)
		01JAN1973-CONTINUE	-11124	PRIOR/CONCOM	VERAPAMIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	240.0 MG	HYPERTENSION
			-11124	PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		07JUL2003-14JUL2003	21	CONCOMITANT	AMANTADINE [NERVOUS SYSTEM]	200.0 MG	BRADYKINESIA DUE TO EPS
		14JUL2003-CONTINUE	28	CONCOMITANT	AMANTADINE [NERVOUS SYSTEM]	300.0 MG	BRADYKINESIA DUE TO EPS
	E0022012	01JAN1999-CONTINUE	-1434	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	HEARTBURN
		01JAN1992-CONTINUE	-3991	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
			-3991	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
	E0022019	01JAN1981-CONTINUE	-8014	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
	E0022025	01JAN2001-CONTINUE	-757	PRIOR/CONCOM	ATENOLOL [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			-757	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION

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QUETIAPINE 600 MG (BIPOLAR I)	E0022025	01JAN2001-CONTINUE	-757	PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		01JAN1980-CONTINUE	-8428	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		01JAN1990-CONTINUE	-4775	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	MENSTRUAL CRAMPS
		01JAN1998-CONTINUE	-1853	PRIOR/CONCOM	LOPERAMIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 MG	IRRITABLE BOWEL SYNDROME
		28JAN2003-04FEB2003	1	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	BIPOLAR
	E0022033	01JAN1997-CONTINUE	-2239	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
		15MAR2003-23MAR2003	26	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	UPPER RESPIRATORY INFECTION
			26	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	UPPER RESPIRATORY INFECTION
	E0022038	01FEB2002-CONTINUE	-392	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	RIGHT KNEE PAIN
			-392	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	LUMBAR DISC DISEASE
	E0022039	01JAN1999-CONTINUE	-1525	PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	120.0 MG	ALLERGIC RHINITIS
			-1525	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SPRAY	ALLERGIC RHINITIS

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QUETIAPINE 600 MG (BIPOLAR I)	E0022039	01JAN2000-CONTINUE	-1160	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
			-1160	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	CHEST WALL PAIN
		01NOV2002-CONTINUE	-125	PRIOR/CONCOM	MECLOZINE [RESPIRATORY SYSTEM]	25.00 MG	VERTIGO
		01JAN1998-CONTINUE	-1890	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
	E0022046	01JAN1988-CONTINUE	-5557	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
	E0022048	01MAY2002-CONTINUE	-335	PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	FOOD ALLERGIES
		01MAR1997-CONTINUE	-2222	PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	150.0 MG	CONTRACEPTION IM Q 3 MONTHS
		14APR2003-14APR2003	14	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MUSCULOSKELETAL PAIN
		21APR2003-23APR2003	21	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	VIRAL SYNDROME WITH MYALGIA
	E0022051	01JAN1990-CONTINUE	-4844	PRIOR/CONCOM	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	0.63 MG	POST MENOPAUSAL STATUS
		01JAN1998-CONTINUE	-1922	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	HEARTBURN

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QUETIAPINE 600 MG (BIPOLAR I)	E0022051	01JAN1979-CONTINUE	-8862	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
	E0022053	01JUL1991-CONTINUE	-4302	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
	E0022058	01JUL1990-CONTINUE	-4677	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		01JUL1985-CONTINUE	-6503	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE
	E0022061	12MAY2003-12MAY2003	13	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	TOOTHACHE
		01JAN1996-CONTINUE	-2676	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	975.0 MG	HEADACHES
		15APR2003-CONTINUE	-15	PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	150.0 MG	CONTRACEPTION
	E0022062	01MAR2003-CONTINUE	-65	PRIOR/CONCOM	SILDENAFIL CITRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	50.00 MG	ERECTILE DYSFUNCTION
		01JAN2001-CONTINUE	-854	PRIOR/CONCOM	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	ALLERGIC RHINITIS
		15MAY2003-CONTINUE	11	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	SLEEP APNEA
			11	CONCOMITANT	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	GASTRIC REFLUX

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QUETIAPINE 600 MG (BIPOLAR I)	E0022062	01JAN1993-CONTINUE	-3776	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
		01JAN1983-CONTINUE	-7429	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
		28APR2003-07MAY2003	-7	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
		08MAY2003-14MAY2003	4	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	BIPOLAR
		13MAY2003-14MAY2003	9	CONCOMITANT	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	SLEEP APNEA
		15MAY2003-19MAY2003	11	CONCOMITANT	OXYMETAZOLINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	4.00 SPRAYS	SLEEP APNEA
	E0022068	01DEC2002-CONTINUE	-173	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHES
	E0022069	01MAY2001-CONTINUE	-770	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	INDIGESTION
		01JAN1991-CONTINUE	-4543	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	HEADACHES
			-4543	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	DYSMENORRHEA
		04JUN2003-10JUN2003	-6	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	BIPOLAR
		11JUN2003-22JUN2003	2	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	BIPOLAR

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QUETIAPINE 600 MG (BIPOLAR I)	E0022069	23JUN2003-30JUN2003	14	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
	E0022071	18JUN2003-30JUN2003	-12	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY SECONDARY TO DEPRESSED EPISODE
		02JUL2003-02JUL2003	3	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY SECONDARY TO DEPRESSED EPISODE
		06JUL2003-06JUL2003	7	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY SECONDARY TO DEPRESSED EPISODE
		14AUG2003-14AUG2003	46	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY SECONDARY TO DEPRESSED EPISODE
	E0023003	01JAN2001-CONTINUE	-715	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-715	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		03JAN2003-03JAN2003	18	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
	E0023006	23DEC2002-CONTINUE	7	CONCOMITANT	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA

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QUETIAPINE 600 MG (BIPOLAR I)	E0023010	26FEB2003-27MAR2003	23	CONCOMITANT	AMOXICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1750 MG	UPPER RESPIRATORY INFECTION
	E0026002	01JUL1984-CONTINUE	-6708	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]		HEADACHES (PRN)
	E0026007	15JUN2002-CONTINUE	-215	PRIOR/CONCOM	ATENOLOL [CARDIOVASCULAR SYSTEM]	50.00 MG	HYPERTENSION
		15JAN2003-CONTINUE	-1	PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
	E0026013	01JUL1999-CONTINUE	-1323	PRIOR/CONCOM	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			-1323	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]		BIRTH CONTROL
	E0028007	11NOV2002-11NOV2002	39	CONCOMITANT	CHARCOAL, ACTIVATED [ALIMENTARY TRACT AND METABOLISM]	50.00 GRAMS	STUDY MEDICATION OVERDOSE
			39	CONCOMITANT	POTASSIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	20.00 MEQ	STUDY MEDICATION OVERDOSE
		21OCT2002-21OCT2002	18	CONCOMITANT	ANAESTHETICS, LOCAL [NERVOUS SYSTEM]	UNK	TOOTHACHE
		30OCT2002-30OCT2002	27	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	HEADACHE
		05NOV2002-06NOV2002	33	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	4.00 TABS	CRAMPS - MENSTRAUL

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0028007	06NOV2002-10NOV2002	34	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	COLD SYMPTOMS
	E0028023	21MAR2003-CONTINUE	60	POST	PHENYTOIN SODIUM [NERVOUS SYSTEM]	900.0 MG	SEIZURES
			60	POST	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	UNK	HYPOTHYROIDISM
		11MAR2003-11MAR2003	50	POST	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	SEIZURE
		15MAR2003-CONTINUE	54	POST	CLONIDINE [CARDIOVASCULAR SYSTEM]	UNK	HYPERTENSION
			54	POST	MINOXIDIL [CARDIOVASCULAR SYSTEM]	UNK	HYPERTENSION
		17DEC2002-CONTINUE	-35	PRIOR/CONCOM	LABETALOL [CARDIOVASCULAR SYSTEM]	200.0 MG	HYPERTENSION
		UNK-UNK		PRIOR/CONCOM	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	UNK	BACK PAIN
				PRIOR/CONCOM	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	UNK
		17DEC2002-05FEB2003	-35	PRIOR/CONCOM	CLONIDINE [CARDIOVASCULAR SYSTEM]	0.30 MG	HYPERTENSION
		17DEC2002-21FEB2003	-35	PRIOR/CONCOM	MINOXIDIL [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERTENSION
		09MAR2003-CONTINUE	48	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	UNK	CARDIAR PROPHYLAXIS
			48	CONCOMITANT	FENTANYL [NERVOUS SYSTEM]	UNK	SUICIDE ATTEMPT

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0028023	09MAR2003-CONTINUE	48	CONCOMITANT	FENTANYL [NERVOUS SYSTEM]	UNK	SUICIDE ATTEMPT
			48	CONCOMITANT	FUROSEMIDE [CARDIOVASCULAR SYSTEM]	UNK	CORONARY ARTERY DISEASE
			48	CONCOMITANT	OXYCODONE HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	BACK PAIN
			48	CONCOMITANT	POTASSIUM [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHLYAXIS
			48	CONCOMITANT	VALSARTAN [CARDIOVASCULAR SYSTEM]	150.0 MG	HYPERTENSION
			48	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	UNK	BACK PAIN
			48	CONCOMITANT	SERTRALINE HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	DEPRESSION
		09MAR2003-09MAR2003	48	CONCOMITANT	NALOXONE HYDROCHLORIDE [VARIOUS]	UNK	PROPHYLAXIS
	E0028025	26JAN2003-26JAN2003	14	POST	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1000 MG	HEADACHE
		01JAN1991-CONTINUE	-4395	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		27JAN2003-27JAN2003	15	POST	MELATONIN [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	1.00 MG	INSOMNIA
	E0028033	01JUL2002-CONTINUE	-269	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFF	ASTHMA
			-269	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 SPRAY	ALLERGIES
		09MAY2003-12MAY2003	44	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	MG	SINUS PAIN

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0028035	01JAN2000-CONTINUE	-1188	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	OCCASIONAL HEARTBURN
		12MAY2003-12MAY2003	40	CONCOMITANT	VALERIANA OFFICINALIS ROOT [NERVOUS SYSTEM]	2.00 TABS	INSOMNIA
		27MAR2003-CONTINUE	-7	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	CARDIAC PROPHYLAXIS
	E0028037	01JAN2003-CONTINUE	-163	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JAN2000-CONTINUE	-1259	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINE HEADACHES
		05MAY2003-CONTINUE	-39	PRIOR/CONCOM	ROSIGLITAZONE MALEATE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	DIABETES
	E0028039	08MAY2003-09MAY2003	-1	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	HEAD INJURY
		09MAY2003-09MAY2003	1	CONCOMITANT	ONDANSETRON HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	16.00 MG	NAUSEA
	E0028048	28AUG2003-28AUG2003	43	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHE
	E0029008	01SEP2002-CONTINUE	-106	PRIOR/CONCOM	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	10.00 MG	ABDOMINAL PAIN
			-106	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0029011	01JAN2000-CONTINUE	-1117	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE PRN
		01JAN2001-CONTINUE	-751	PRIOR/CONCOM	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	3.00 TABS	PROPHYLAXIS PRN
	E0029012	15JAN2002-CONTINUE	-392	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	PRN. FOR HEADACHES
		28JAN2003-17FEB2003	-14	PRIOR/CONCOM	NICOTINE [NERVOUS SYSTEM]	7.00 MG	PRN. FOR SMOKING CESSATION
		14FEB2003-24FEB2003	4	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
		16FEB2003-CONTINUE	6	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	ACID REFLUX (PRN.)
		22FEB2003-CONTINUE	12	CONCOMITANT	RABEPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	ACID REFLUX
	E0029015	01FEB2002-CONTINUE	-388	PRIOR/CONCOM	OXYBUTYNIN [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	OVER - ACTIVE BLADDER
		24FEB2003-CONTINUE	1	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	JOINT PAIN (PRN)
		01JAN1993-CONTINUE	-3706	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	LOWER BACK PAIN
		01JAN1994-CONTINUE	-3341	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.20 MG	HYPOTHYROIDISM

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QUETIAPINE 600 MG (BIPOLAR I)	E0029015	18FEB2003-CONTINUE	-6	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA - BIPOLAR DISORDER
			-6	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY - BIPOLAR DISORDER
	E0030014	01JUL2002-CONTINUE	-235	PRIOR/CONCOM	UBIDECARENONE [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
			-235	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-235	PRIOR/CONCOM	OMEGA-3 MARINE TRIGLYCERIDES [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
			-235	PRIOR/CONCOM	CYANOCOBALAMIN [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	PROPHYLAXIS
			-235	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01JUL1984-CONTINUE	-6809	PRIOR/CONCOM	ACETAZOLAMIDE [NERVOUS SYSTEM]	500.0 MG	MYOTOMIC DYSTROPHY
	E0030020	01JUL1992-CONTINUE	-3984	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
	E0030024	01JUL1992-CONTINUE	-4027	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
		07JUL2003-CONTINUE	-4	PRIOR/CONCOM	BENZYLPENICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	GUM INFECTION
	E0030025	15FEB2003-CONTINUE	-146	PRIOR/CONCOM	ALENDRONATE SODIUM [MUSCULO-SKELETAL SYSTEM]	35.00 MG	PREVENTION OF OSTEOPOROSIS

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QUETIAPINE 600 MG (BIPOLAR I)	E0030025	11AUG2003-11AUG2003	32	CONCOMITANT	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	DIARRHEA
	E0031027	01JUN2003-CONTINUE	-2	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	EMPHYSEMA
	E0034001	01JAN1993-CONTINUE	-3730	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES (PRN)
		27MAR2003-28MAR2003	8	CONCOMITANT	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	3.00 TABS	CONSTIPATION
	E0034004	01JAN2001-CONTINUE	-840	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	PRN FOR HEADACHES
		01JAN1980-CONTINUE	-8511	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	PRN FOR STIFF JOINTS
			-8511	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GENERAL HEALTH
		08JUN2003-09JUN2003	49	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	1.00 TBSP	FLU - LIKE SYMPTOMS
	E0035001	01JUL1999-CONTINUE	-1238	PRIOR/CONCOM	METOPROLOL [CARDIOVASCULAR SYSTEM]	100.0 MG	HYPERTENSION
	E0036002	01JAN1997-CONTINUE	-2358	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	2.00 CAPS	PROPHYLAXIS
			-2358	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR I)	E0036002	01JUL2003-02JUL2003	15	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TAB	MIGRAINE HEADACHE
	E0036006	01JAN1993-CONTINUE	-3835	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA, PRN
		11MAY2003-CONTINUE	-53	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTROESOPHAGEAL REFLUX DISEASE
		27AUG2003-CONTINUE	56	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR DISORDER
	E0036007	01JUN2001-CONTINUE	-762	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TAB	SEASONAL ALLERGIES, -PRN
		06JUL2003-06JUL2003	4	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 CAPLETS	SEASONAL ALLERGIES
		16JUL2003-16JUL2003	14	POST	SENNA [ALIMENTARY TRACT AND METABOLISM]	2.00 CAPLETS	CONSTIPATION
	E0037009	01JAN2000-CONTINUE	-1231	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
			-1231	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0039011	16JAN2003-16JAN2003	15	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
		08JAN2003-08JAN2003	7	CONCOMITANT	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1.00 TAB	TOOTHACHE

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QUETIAPINE 600 MG (BIPOLAR I)	E0039011	20JAN2003-20JAN2003	19	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	SORE BUTTOCKS (DUE TO FALL)
		02JAN2003-02FEB2003	1	CONCOMITANT	OTHER COLD COMBINATION PREPARATIONS [RESPIRATORY SYSTEM]	1.00 TAB	NASAL CONGESTION
	E0039018	13FEB2003-13FEB2003	22	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MENSTRUAL CRAMPS
		28JAN2003-28JAN2003	6	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	BACK PAIN
		19FEB2003-19FEB2003	28	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	BACK PAIN
	E0039026	01JUL2000-CONTINUE	-979	PRIOR/CONCOM	HERBAL PREPARATION [VARIOUS]	4.00 TABS	CONSTIPATION (AS NEEDED)
		01JUL1975-CONTINUE	-10111	PRIOR/CONCOM	HERBAL PREPARATION [VARIOUS]	600.0 MG	PROPHYLAXIS
			-10111	PRIOR/CONCOM	SELENIUM [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	PROPHYLAXIS
			-10111	PRIOR/CONCOM	RETINOL [ALIMENTARY TRACT AND METABOLISM]	25000 IU	PROPHYLAXIS
			-10111	PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	PROPHYLAXIS
			-10111	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	2000 MG	PROPHYLAXIS
			-10111	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	400.0 IU	PROPHYLAXIS
		10APR2003-10APR2003	35	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	BODY ACHES

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QUETIAPINE 600 MG (BIPOLAR I)	E0039026	16APR2003-16APR2003	41	CONCOMITANT	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			41	CONCOMITANT	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		02MAY2003-CONTINUE	57	POST	FUROSEMIDE [CARDIOVASCULAR SYSTEM]	40.00 MG	PERIPHERAL EDEMA
	E0039028	15APR2003-CONTINUE	23	CONCOMITANT	METOPROLOL [CARDIOVASCULAR SYSTEM]	100.0 MG	INCREASE IN BLOOD PRESSURE
		10APR2003-10APR2003	18	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	PAIN IN LEFT FOREARM
		05MAR2003-CONTINUE	-19	PRIOR/CONCOM	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX
		05MAR2003-15MAY2003	-19	PRIOR/CONCOM	LITHIUM [NERVOUS SYSTEM]	900.0 MG	BIPOLAR DISORDER
			-19	PRIOR/CONCOM	RISPERIDONE [NERVOUS SYSTEM]	3.00 MG	BIPOLAR DISORDER
		08APR2003-08APR2003	16	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	LEFT FOREARM PAIN
		06MAY2003-CONTINUE	44	CONCOMITANT	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	INCREASE IN BLOOD PRESSURE
		15MAY2003-31MAY2003	53	POST	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	UNKNOWN
			53	POST	TRAZODONE [NERVOUS SYSTEM]	50.00 MG	INSOMNIA RELATED TO DEPRESSION
		16MAY2003-19MAY2003	54	POST	LITHIUM [NERVOUS SYSTEM]	600.0 MG	BIPOLAR DISORDER

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QUETIAPINE 600 MG (BIPOLAR I)	E0039028	16MAY2003-19MAY2003	54	POST	RISPERIDONE [NERVOUS SYSTEM]	1.00 MG	BIPOLAR DISORDER
	E0039034	14APR2003-14APR2003	27	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		12MAR2003-CONTINUE	-7	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	TOOTH EXTRACTION (AS NEEDED)
		07APR2003-09APR2003	20	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	RIGHT ARM PAIN (AS NEEDED)
		18APR2003-20APR2003	31	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	RIGHT ARM PAIN PRN
		21APR2003-21APR2003	34	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	STREP THROAT
		24APR2003-24APR2003	37	CONCOMITANT	PARACETAMOL [RESPIRATORY SYSTEM]	2.00 TABS	NASAL CONGESTION
		25APR2003-CONTINUE	38	CONCOMITANT	AMOXICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1650 MG	STREP THROAT
		25APR2003-28APR2003	38	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	NASAL CONGESTION
		07MAY2003-09MAY2003	50	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	RIGHT ARM PAIN
	E0039042	01JUL2000-CONTINUE	-1040	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFF	ASTHMA

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QUETIAPINE 600 MG (BIPOLAR I)	E0039042	15MAR2003-CONTINUE	-53	PRIOR/CONCOM	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	CONSTIPATION
		02JUL2003-02JUL2003	57	POST	MAGNESIUM CITRATE [ALIMENTARY TRACT AND METABOLISM]	5.00 OZ	INCREASED CONSTIPATION
		08MAY2003-09JUN2003	2	CONCOMITANT	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
	E0041004	01JAN2001-CONTINUE	-759	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		19FEB2003-19FEB2003	21	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	HEADACHE
		21FEB2003-23FEB2003	23	CONCOMITANT	CHLORPHENAMINE MALEATE [RESPIRATORY SYSTEM]	8.00 MG	UPPER RESPIRATORY INFECTION
		31MAR2003-CONTINUE	61	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR
	E0042002	01JUL1999-CONTINUE	-1469	PRIOR/CONCOM	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	180.0 MG	HYPERTENSION
		23OCT2002-CONTINUE	-259	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	1.10 GM	TENDONITIS KNEES

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QUETIAPINE 600 MG (BIPOLAR II)	E0001006	01JUL2000-CONTINUE	-1105	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SNIFF	ALLERGIES PRN
			-1105	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIES PRN
		15DEC2002-CONTINUE	-208	PRIOR/CONCOM	GINGER [VARIOUS]	3.00 TABS	WEIGHT LOSS
	E0003002	15JAN2002-CONTINUE	-287	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	250.0 MG	OCCASIONAL BODY ACHES AND PAINS
		12NOV2002-12NOV2002	15	CONCOMITANT	SODIUM BICARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABLETS	INDIGESTION
	E0005031	01APR2001-CONTINUE	-731	PRIOR/CONCOM	NORETHISTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		03APR2003-13APR2003	2	CONCOMITANT	OMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	2.00 PILLS	HEARTBURN
		06APR2003-13APR2003	5	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	4.00 PILLS	HEARTBURN
		30APR2003-CONTINUE	29	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	HEARTBURN
	E0005033	01JUL2002-CONTINUE	-289	PRIOR/CONCOM	CEFALEXIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	FOLICULITIS
		01JUL2001-CONTINUE	-654	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	2000 MG	NUTRITIONAL SUPPLEMENT

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0005033	15MAY2003-CONTINUE	30	POST	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		26APR2003-26APR2003	11	CONCOMITANT	MEPYRAMINE MALEATE [RESPIRATORY SYSTEM]	2.00 SPRAYS	NASAL CONGESTION
			11	CONCOMITANT	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 PILL	NASAL CONGESTION
		27APR2003-27APR2003	12	CONCOMITANT	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 PILL	NASAL CONGESTION
			12	CONCOMITANT	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 SPRAYS	NASAL CONGESTION
		28APR2003-28APR2003	13	CONCOMITANT	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	NASAL CONGESTION
			13	CONCOMITANT	PHENYLEPHRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 SPRAYS	NASAL CONGESTION
		30APR2003-05MAY2003	15	CONCOMITANT	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 PILL	NASAL CONGESTION
			15	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	120.0 MG	NASAL CONGESTION
		07MAY2003-14MAY2003	22	POST	ETHANOL [NERVOUS SYSTEM]	2.00 TBSP	INSOMNIA
	E0005038	UNK-CONTINUE		PRIOR/CONCOM	EPINEPHRINE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA - SMOKING INDUCED PRN
		26MAY2003-26MAY2003	13	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	MENSTRAL CRAMPS
	E0007009	25APR2003-CONTINUE	9	POST	KETOCONAZOLE [DERMATOLOGICALS]	2.00 APP	LESION ON NECK

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0009010	13MAR2003-CONTINUE	1	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	INDIGESTION
		19MAR2003-CONTINUE	7	CONCOMITANT	OXYMETAZOLINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	4.00 SPRAY	NASAL CONGESTION
	E0009011	08JUL2003-CONTINUE	64	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DISORDER
		01JUL2001-CONTINUE	-674	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		01APR2003-CONTINUE	-35	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	PROPHYLAXIS
		05JUL2003-07JUL2003	61	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DISORDER
		03JUL2003-04JUL2003	59	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	50.00 MG	BIPOLAR DISORDER
	E0010005	04DEC2002-CONTINUE	-14	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA
	E0011016	UNK-CONTINUE		PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	HEADACHE; PAIN PRN DUE TO BACK STRAIN
				PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE PRN
		14JUN2003-15JUN2003	55	CONCOMITANT	HYDROCORTISONE [DERMATOLOGICALS]	2.00 TOPICALAPPLICATION	POISON IVY - ITCHING

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0011016	03JUN2003-14JUN2003	44	CONCOMITANT	GLYCEROL [DERMATOLOGICALS]	3.00 TOPICALAPPLICATION	POISON IVY - PRN ITCHING
	E0011020	01JAN2003-CONTINUE	-127	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	MIGRAINE PRN
		01JUL1983-CONTINUE	-7251	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1500 MG	HEADACHES PRN
	E0018002	01JUN1998-CONTINUE	-1642	PRIOR/CONCOM	OXAPROZIN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	ARTHRITIS
			-1642	PRIOR/CONCOM	NABUMETONE [MUSCULO-SKELETAL SYSTEM]	600.0 MG	ARTHRITIS
		01JUN1995-CONTINUE	-2738	PRIOR/CONCOM	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES
		01JUN1996-CONTINUE	-2372	PRIOR/CONCOM	TAMSULOSIN HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	0.40 MG	SEASONAL ALLERGIES
		24DEC2002-CONTINUE	26	CONCOMITANT	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	110.0 MCG	SEASONAL ALLERGIES
	E0018003	01JUN1988-CONTINUE	-5291	PRIOR/CONCOM	LEVONORGESTREL [GENITO URINARY SYSTEM AND SEX HORMONES]	36.00 MG	BIRTH CONTROL
	E0018013	01JUL1990-CONTINUE	-4590	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	INSOMNIA
		29JAN2003-30JAN2003	6	POST	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 TAB	INCREASED INTENSITY HEADACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0019002	01NOV2001-CONTINUE	-376	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TAB	SEASONAL ALLERGIES
		01JAN2000-19NOV2002	-1046	PRIOR/CONCOM	HERBAL PREPARATION [VARIOUS]	1.00 TAB	ENERGY
		18NOV2002-CONTINUE	7	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	975.0 MG	TENSION HEADACHE
	E0019008	10DEC2002-CONTINUE	20	CONCOMITANT	CHLORPHENAMINE MALEATE [RESPIRATORY SYSTEM]	TAB	SINUS CONGESTION
			20	CONCOMITANT	CHLORPHENAMINE MALEATE [RESPIRATORY SYSTEM]	TAB	HEADACHE
		01JAN1987-CONTINUE	-5803	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MENSTRAL CRAMPS
		01DEC2001-CONTINUE	-355	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.09 MG	HYPOTHYROIDISM
		13NOV2002-CONTINUE	-8	PRIOR/CONCOM	CAMPHOR [RESPIRATORY SYSTEM]	TOPICAL	CHEST CONGESTION
		27NOV2002-CONTINUE	7	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	TAB	INDIGESTION
	E0019009	06NOV2002-CONTINUE	-8	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 CAP	BIRTH CONTROL
		20NOV2002-20NOV2002	7	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0019016	04JAN2003-CONTINUE	-2	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	UNK	HEADACHE
		31JAN2003-CONTINUE	26	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	TAB	HEARTBURN
	E0019020	27JAN2003-CONTINUE	5	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	4.00 TABS	TENSION HEADACHE
		12MAR2003-12MAR2003	49	CONCOMITANT	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNK	MIGRAINE HEADACHE
			49	CONCOMITANT	KETOROLAC TROMETHAMINE [SENSORY ORGANS]	UNK	MIGRAINE HEADACHE
	E0019021	01JAN2002-CONTINUE	-394	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	SUPPLEMENT
		30JAN2003-11FEB2003	1	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		28FEB2003-CONTINUE	30	POST	PAROXETINE HYDROCHLORIDE [NERVOUS SYSTEM]	25.00 MG	DEPRESSION/ANXIETY
		02MAR2003-02MAR2003	32	POST	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0019024	26JAN2003-CONTINUE	-4	PRIOR/CONCOM	ALLERGY MEDICATION [RESPIRATORY SYSTEM]	2.00 CAPS	SINUS ALLERGIES (PRN)
		02FEB2003-02FEB2003	4	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	325.0 MG.	HEADACHE (PRN)

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QUETIAPINE 600 MG (BIPOLAR II)	E0019024	05FEB2003-05FEB2003	7	CONCOMITANT	CODEINE PHOSPHATE [RESPIRATORY SYSTEM]	1.00 TBSP.	CHRONIC COUGH (PRN)
	E0019031	01FEB2000-CONTINUE	-1136	PRIOR/CONCOM	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	PROPHYLAXIS
	E0019035	25MAR2003-CONTINUE	8	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	TENSION HEADACHE
		31MAR2003-03APR2003	14	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	FLU
			14	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	1.00 TBSP	FLU
		04APR2003-08APR2003	18	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1.00 TAB	FLU
	E0019040	01NOV2002-03JUN2003	-200	PRIOR/CONCOM	RABEPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	ACID REFLUX
		19MAY2003-26MAY2003	-1	PRIOR/CONCOM	BENZONATATE [RESPIRATORY SYSTEM]	600.0 MG	UPPER RESPIRATORY INFECTION
		19MAY2003-08JUN2003	-1	PRIOR/CONCOM	BENZONATATE [RESPIRATORY SYSTEM]	200.0 MG	COUGH PRN
			-1	PRIOR/CONCOM	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TABS	UPPER RESPIRATORY INFECTION
		19MAY2003-10JUN2003	-1	PRIOR/CONCOM	BUDESONIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	UPPER RESPIRATORY INFECTION

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0019040	04JUN2003-08JUN2003	16	CONCOMITANT	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	200.0 MG	ACID REFLUX
	E0019042	28FEB2003-CONTINUE	-96	PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 INJECTION	CONTRACEPTION
	E0019045	07JUL2003-08JUL2003	12	CONCOMITANT	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	MG	DEPRESSION
	E0020024	03AUG2003-03AUG2003	42	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0022044	01JAN2000-CONTINUE	-1172	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
			-1172	PRIOR/CONCOM	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	INDIGESTION
			-1172	PRIOR/CONCOM	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	DIARRHEA
		01JAN1985-CONTINUE	-6650	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 MCG	ASTHMA
		06MAY2003-08MAY2003	50	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	TOOTHACHE
	E0023007	10JAN2003-CONTINUE	-4	PRIOR/CONCOM	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	1200 MG	HEARTBURN
	E0023011	15JUL2002-CONTINUE	-204	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.75 MG	HYPOTHYROIDISM

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QUETIAPINE 600 MG (BIPOLAR II)	E0023011	15APR1999-CONTINUE	-1391	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ALLERGIES
	E0023014	25MAR2003-CONTINUE	33	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	100.0 MG	JOINT PAIN
	E0023019	20MAY2003-20MAY2003	44	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
	E0023023	01JUN1997-CONTINUE	-2154	PRIOR/CONCOM	HYOSCYAMINE SULFATE [ALIMENTARY TRACT AND METABOLISM]	0.75 MG	BIPOLAR
	E0026003	UNK-CONTINUE		PRIOR/CONCOM	CLONIDINE [CARDIOVASCULAR SYSTEM]	UNK	HYPERTENSION
				PRIOR/CONCOM	ZIDOVUDINE [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	H. I. V.
				PRIOR/CONCOM	AMITRIPTYLINE HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	BIPOLAR II
				PRIOR/CONCOM	TAMSULOSIN HYDROCHLORIDE [GENITO URINARY SYSTEM AND SEX HORMONES]	UNK	UNK
				PRIOR/CONCOM	POTASSIUM CHLORIDE [ALIMENTARY TRACT AND METABOLISM]	UNK	HYPOKALEMIA
				PRIOR/CONCOM	RITONAVIR [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	H. I. V.
				PRIOR/CONCOM	LEVETIRACETAM [NERVOUS SYSTEM]	UNK	UNK
				PRIOR/CONCOM	GABAPENTIN [NERVOUS SYSTEM]	UNK	UNK
				PRIOR/CONCOM	TOPIRAMATE [NERVOUS SYSTEM]	UNK	UNK
				PRIOR/CONCOM	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	BIPOLAR II

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0026003	29JAN2003-CONTINUE	57	CONCOMITANT	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	MG	HEART - BURN
		29JAN2003-29JAN2003	57	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	UNK	ACUTE PROSTATITIS
			57	CONCOMITANT	MORPHINE HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	ACUTE PROSTATITIS
		29JAN2003-01FEB2003	57	CONCOMITANT	CEFTRIAXONE SODIUM [ANTIINFECTIVES FOR SYSTEMIC USE]	4.00 MG	ACUTE PROSTATITIS
		01FEB2003-01MAR2003	60	POST	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	ACUTE PROSTATITIS
	E0026005	15JUL2002-CONTINUE	-168	PRIOR/CONCOM	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	HEARTBURN
	E0026009	19JAN2003-CONTINUE	5	POST	TOPIRAMATE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR II
	E0026023	01JUL1995-CONTINUE	-2860	PRIOR/CONCOM	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	10.00 MG	SCOLIOSIS
		27APR2003-CONTINUE	-3	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	200.0 MCG	ACUTE BRONCHITIS
		27APR2003-03MAY2003	-3	PRIOR/CONCOM	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	ACUTE BRONCHITIS
	E0027016	12MAR2003-CONTINUE	-28	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHES (PRN)

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0027016	03MAY2003-CONTINUE	25	CONCOMITANT	SALBUTAMOL [RESPIRATORY SYSTEM]	17.00 G	BRONCHITIS
		03MAY2003-08MAY2003	25	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	BRONCHITIS
	E0027018	15JAN2003-CONTINUE	-69	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	UNK	ASTHMA
	E0028032	23MAY2003-CONTINUE	60	POST	TOPIRAMATE [NERVOUS SYSTEM]	25.00 MG	BIPOLAR MIXED EPISODE
			60	POST	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR MIXED EPISODE
		10MAY2003-10MAY2003	47	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	HEADACHE
		18MAY2003-CONTINUE	55	CONCOMITANT	DOXEPIN HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	INSOMNIA
		20MAY2003-CONTINUE	57	POST	BUPROPION HYDROCHLORIDE [NERVOUS SYSTEM]	150.0 MG	BIPOLAR MIXED EPISODE
		21MAY2003-22MAY2003	58	POST	RISPERIDONE [NERVOUS SYSTEM]	3.00 MG	BIPOLAR MIXED EPISODE
	E0029003	30DEC2002-CONTINUE	57	POST	RANITIDINE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	HEARTBURN
		27NOV2002-CONTINUE	24	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
		20SEP2002-CONTINUE	-45	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE

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QUETIAPINE 600 MG (BIPOLAR II)	E0029003	20SEP2002-11NOV2002	-45	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
		06NOV2002-07NOV2002	3	CONCOMITANT	CIMETIDINE [ALIMENTARY TRACT AND METABOLISM]	200.0 MG	HEARTBURN
		12NOV2002-19NOV2002	9	CONCOMITANT	RANITIDINE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	HEARTBURN
		20NOV2002-24NOV2002	17	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	COUGH, NASAL CONGESTION
		27NOV2002-28NOV2002	24	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	COUGH
		21DEC2002-21DEC2002	48	CONCOMITANT	KETOROLAC TROMETHAMINE [SENSORY ORGANS]	30.00 MG	BACK STRAIN
		22DEC2002-27DEC2002	49	CONCOMITANT	ORPHENADRINE CITRATE [MUSCULO-SKELETAL SYSTEM]	100.0 MG	BACK STRAIN
			49	CONCOMITANT	KETOROLAC TROMETHAMINE [SENSORY ORGANS]	10.00 MG	BACK STRAIN
	E0031005	01NOV2002-CONTINUE	-49	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			-49	PRIOR/CONCOM	GINKGO BILOBA [NERVOUS SYSTEM]	1.00 TAB	VITAMIN SUPPLEMENT
			-49	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			-49	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	BURSITIS IN SHOULDERS
			-49	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	HIP PAIN
			-49	PRIOR/CONCOM	OMEGA-3 MARINE TRIGLYCERIDES [CARDIOVASCULAR SYSTEM]	1.00 TAB	VITAMIN SUPPLEMENT

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0031005	01NOV2002-CONTINUE	-49	PRIOR/CONCOM	UBIDECARENONE [CARDIOVASCULAR SYSTEM]	1.00 TAB	VITAMIN SUPPLEMENT
			-49	PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			-49	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			-49	PRIOR/CONCOM	ZINC [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			-49	PRIOR/CONCOM	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERCHOLESTEROLEMIA
		15JAN2003-15JAN2003	27	CONCOMITANT	CORTISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	UNK	ADHESIVE CAPSULITIS
		01JUL1997-CONTINUE	-1998	PRIOR/CONCOM	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	0.15 MG	REFLUX
		01JUL1999-CONTINUE	-1268	PRIOR/CONCOM	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	ENVIRONMENTAL ALLERGIES
	E0031006	23MAR2003-23MAR2003	34	CONCOMITANT	ANTI-ASTHMATICS [RESPIRATORY SYSTEM]	3.00 PUFFS	ASTHMA INDUCED BY CHEST COLD
			34	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	6.00 MG	ASTHMA INDUCED BY CHEST COLD
		10FEB2003-CONTINUE	-8	PRIOR/CONCOM	FUROSEMIDE [CARDIOVASCULAR SYSTEM]	80.00 MG	HYPERTENSION
			-8	PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERTENSION
		10FEB2003-18FEB2003	-8	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA

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Listing 12.2.10.7 Concomitant Medications

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QUETIAPINE 600 MG (BIPOLAR II)	E0031006	08MAR2003-05APR2003	19	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	350.0 MG	BLOOD THINNING
	E0031010	01JAN1996-CONTINUE	-2606	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	STOMACH ACHES
		31JAN2003-CONTINUE	-19	PRIOR/CONCOM	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	25.00 MG	SHOULDER PAIN
	E0031011	01JAN2002-CONTINUE	-422	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		01JAN2001-CONTINUE	-787	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	HIATAL HERNIA
	E0031015	UNK-CONTINUE		PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	450.0 MG	LEG CRAMPS
		01JUL1995-CONTINUE	-2825	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		15OCT2002-CONTINUE	-162	PRIOR/CONCOM	EQUISETUM ARVENSE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	NUTRITIONAL SUPPLEMENT
			-162	PRIOR/CONCOM	HERBAL PREPARATION [VARIOUS]	1.00 TAB	NUTRITIONAL SUPPLEMENT
		19MAR2003-26MAR2003	-7	PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	SORE THROAT
	E0031031	15DEC2002-CONTINUE	-205	PRIOR/CONCOM	VALACICLOVIR HYDROCHLORIDE [ANTIINFECTIVES FOR SYSTEMIC USE]	1.00 G	GENITAL HERPES

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0031031	30JUN2003-CONTINUE	-8	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	SINUS HEADACHES
		11JUL2003-13JUL2003	4	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	SINUSITIS
		12JUL2003-14JUL2003	5	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	SINUSITIS
		17JUL2003-25JUL2003	10	CONCOMITANT	CLAVULANATE POTASSIUM [ANTIINFECTIVES FOR SYSTEMIC USE]	1750 MG	SINUSITIS
	E0033009	12FEB2003-18FEB2003	1	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA
	E0034009	01JAN1998-CONTINUE	-1995	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	SHOULDER PAIN
		25JUN2003-26JUN2003	7	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	SHOULDER PAIN
	E0037007	01JAN2001-CONTINUE	-830	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
			-830	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0037012	01JAN2002-CONTINUE	-561	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	BACK
			-561	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	SHIN PAIN
		01JAN2000-CONTINUE	-1292	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHE PAIN

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
QUETIAPINE 600 MG (BIPOLAR II)	E0039019	01JAN2002-CONTINUE	-401	PRIOR/CONCOM	LATANOPROST [SENSORY ORGANS]	1.00 DROP	GLAUCOMA
		01DEC2001-CONTINUE	-432	PRIOR/CONCOM	FERROUS SULFATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0039043	01JUL2000-CONTINUE	-1041	PRIOR/CONCOM	ANTIHISTAMINES FOR SYSTEMIC USE [RESPIRATORY SYSTEM]	4.00 TABS	SEASONAL ALLERGIES
		22MAY2003-22MAY2003	15	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	3.00 TABS	MIGRAINE

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Listing 12.2.10.7 Concomitant Medications

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PLACEBO (BIPOLAR I)	E0002001	15FEB2002-CONTINUE	-318	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	10.00 MG	ELEVATED CHOLESTEROL
		15SEP1993-CONTINUE	-3393	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	50.00 UG	HYPOTHYROIDISM
		25DEC2002-CONTINUE	-5	PRIOR/CONCOM	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 MG	HORMONE REPLACEMENT THERAPY
	E0002003	03JAN2003-CONTINUE	-19	PRIOR/CONCOM	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	SEVERE JUVENILE ARTHRITIS
			-19	PRIOR/CONCOM	ETANERCEPT [ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS]	25.00 MG	ARTHRITIS/2 TIMES A WEEK
	E0002004	17JAN2003-CONTINUE	-8	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
			-8	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
		24JAN2003-CONTINUE	-1	PRIOR/CONCOM	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	150.0 MG	PRURITIS
	E0002016	15MAY2003-CONTINUE	-70	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	80.00 MG	HYPERTENSION
		15AUG2003-CONTINUE	23	CONCOMITANT	CLOPIDOGREL SULFATE [BLOOD AND BLOOD FORMING ORGANS]	75.00 MG	PROPHYLAXIS
			23	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	INTERMITTENT HEADACHES
		15DEC2002-CONTINUE	-221	PRIOR/CONCOM	BISACODYL [ALIMENTARY TRACT AND METABOLISM]	5.00 MG	IRREGULARITY

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PLACEBO (BIPOLAR I)	E0002016	15DEC2002-CONTINUE	-221	PRIOR/CONCOM	BISACODYL [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	IRREGULARETY
		15SEP2000-CONTINUE	-1042	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	500.0 MG	PROPHYLAXIS
			-1042	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1200 MG	NUTRITION
			-1042	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITION
			-1042	PRIOR/CONCOM	TETRACYCLINE [ALIMENTARY TRACT AND METABOLISM]	100.0 MG	ADULT ACNE
		15JUN1996-CONTINUE	-2595	PRIOR/CONCOM	ESTROGENS CONJUGATED [GENITO URINARY SYSTEM AND SEX HORMONES]	0.63 MG	HORMONAL THERAPY
		15JAN2001-CONTINUE	-920	PRIOR/CONCOM	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	40.00 MG	HIGH CHOLESTEROL
		15APR2002-CONTINUE	-465	PRIOR/CONCOM	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	EMPHYSEMA
			-465	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	8.00 PUFFS	EMPHYSEMA
		16AUG2003-16AUG2003	24	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	UNK	TO CALM
		20AUG2003-CONTINUE	28	CONCOMITANT	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	EMPHYSEMA
			28	CONCOMITANT	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	4.00 PUFFS	EMPHYSEMA
			28	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	HEARTBURN
	E0003008	01JUL2002-CONTINUE	-211	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 INHALATIONS	ASTHMA PRN

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PLACEBO (BIPOLAR I)	E0003008	09FEB2003-11FEB2003	13	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	100.0 MG	FLU SYMPTOMS
		13FEB2003-CONTINUE	17	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 INHALATIONS	UPPER RESPIRATORY INFECTION PRN
			17	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	UPPER RESPIRATORY INFECTION
	E0004003	15AUG2002-CONTINUE	-56	PRIOR/CONCOM	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		12OCT2002-12OCT2002	3	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0004006	13NOV2002-03DEC2002	10	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		19JAN2003-23JAN2003	77	POST	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	HYPERSENSITIVITY REACTION TO LAMICTAL
			77	POST	VANCOMYCIN [ALIMENTARY TRACT AND METABOLISM]	UNK	HYPERSENSITIVITY REACTION TO LAMICTAL
	E0004016	15JAN2001-CONTINUE	-765	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	600.0 MG	SUPPLEMENT
			-765	PRIOR/CONCOM	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	SUPPLEMENT
		03MAR2003-CONTINUE	13	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	200.0 MG	PRN FOR HEADACHE

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PLACEBO (BIPOLAR I)	E0004024	15JAN1997-CONTINUE	-2360	PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN1997-05JUL2003	-2360	PRIOR/CONCOM	VITAMINS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		06JUL2003-CONTINUE	4	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		25JUL2003-CONTINUE	23	CONCOMITANT	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	5.00 MG	BORDERLINE HYPERTENSION
	E0005006	01AUG2001-CONTINUE	-428	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PILL	CARDIAC PROPHYLACTIC
			-428	PRIOR/CONCOM	ATENOLOL [CARDIOVASCULAR SYSTEM]	20.00 MG	VASODILATION
			-428	PRIOR/CONCOM	GEMFIBROZIL [CARDIOVASCULAR SYSTEM]	1200 MG	HYPERLIPIDEMIA /HYPERTRIGLYCERIDEMIA
			-428	PRIOR/CONCOM	PRAVASTATIN SODIUM [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERLIPIDEMIA /HYPERCHOLESTEROLEMIA
			-428	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 PILLS	REFLUX (PRN)
		03OCT2002-CONTINUE	1	CONCOMITANT	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 PILLS	REFLUX
		02OCT2002-CONTINUE	-1	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 PILLS	HEADACHE (PRN)
	E0005017	01JAN2002-CONTINUE	-363	PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGY
			-363	PRIOR/CONCOM	MOMETASONE FUROATE [RESPIRATORY SYSTEM]	1.00 TAB	SEASONAL ALLERGY

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PLACEBO (BIPOLAR I)	E0005017	01JAN1985-CONTINUE	-6572	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
			-6572	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEARTBURN
		06JAN2003-CONTINUE	8	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	5.00 TABS	HEADACHES
		06DEC2002-CONTINUE	-24	PRIOR/CONCOM	PROPRANOLOL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	120.0 MG	BORDERLINE HYPERTENSION
		11DEC2002-06JAN2003	-19	PRIOR/CONCOM	VALDECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	HEADACHES
		11DEC2002-14JAN2003	-19	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY - SECONDARY TO BPD
		30DEC2002-06JAN2003	1	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	20.00 MG	HEADACHES
		30JAN2003-CONTINUE	32	CONCOMITANT	SUMATRIPTAN SUCCINATE [NERVOUS SYSTEM]	100.0 MG	MIGRANES HEADACHES
		26FEB2003-28FEB2003	59	CONCOMITANT	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	8.00 TBSP	GI - FLU
	E0005019	20DEC2002-CONTINUE	-26	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL
	E0005026	UNK-CONTINUE		PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	PRN FOR HEADACHES/BACK PAIN
		11MAR2003-11MAR2003	6	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE

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PLACEBO (BIPOLAR I)	E0005026	09MAR2003-CONTINUE	4	CONCOMITANT	OXYMETAZOLINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	URI
		08MAR2003-10MAR2003	3	CONCOMITANT	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	URI
		10MAR2003-11MAR2003	5	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TSP	URI
		13MAR2003-13MAR2003	8	CONCOMITANT	BISMUTH SUBSALICYLATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TBLSPN	SECONDARY TO BPD - UPSET STOMACH
		20MAR2003-25MAR2003	15	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY SECONDARY TO BPD
	E0005039	01JAN2003-CONTINUE	-141	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEARTBURN
		01APR2002-CONTINUE	-416	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	SEASONAL ALLERGIES
		11MAY2003-CONTINUE	-11	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHES/MUSCLE ACHES
	E0006020	15APR1996-CONTINUE	-2584	PRIOR/CONCOM	PSEUDOEPHEDRINE SULFATE [RESPIRATORY SYSTEM]	1.00 TABLET	SEASONAL ALLERGIES PRN
			-2584	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 SPRAY	SEASONAL ALLERGIES PRN
	E0007001	01OCT2002-22JAN2003	-91	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	TENDONITIS LEFT ELBOW

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PLACEBO (BIPOLAR I)	E0007001	03FEB2003-20FEB2003	35	CONCOMITANT	OXYMETAZOLINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	NASAL CONGESTION
	E0007003	UNK-CONTINUE		PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	20.00 MG	(HTN) HYPERTENSION
		26FEB2003-CONTINUE	28	POST	AMOXICILLIN TRIHYDRATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	BLEEDING ULCER
			28	POST	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	DUODENAL ULCER
		03MAR2003-CONTINUE	33	POST	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	20.00 MGM	BIPOLAR
			33	POST	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	1000 MGM	BIPOLAR
			33	POST	OLANZAPINE [NERVOUS SYSTEM]	5.00 MGM	BIPOLAR
		02JUL2002-CONTINUE	-212	PRIOR/CONCOM	FELODIPINE [CARDIOVASCULAR SYSTEM]	5.00 MG	(HTN) HYPERTENSION
		02FEB2003-04FEB2003	4	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	PAIN RIGHT HIP
		06FEB2003-CONTINUE	8	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	5.00 MG	BACK PAIN
			8	CONCOMITANT	METAXALONE [MUSCULO-SKELETAL SYSTEM]	400.0 MG	BACK PAIN
		23FEB2003-24FEB2003	25	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2925 MGM	PAIN RIGHT HIP
		26FEB2003-26FEB2003	28	POST	PETHIDINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	BLEEDING ULCER SURGERY
			28	POST	MIDAZOLAM HYDROCHLORIDE [NERVOUS SYSTEM]	3.00 MG	BLEEDING ULCER SURGERY

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0009004	19NOV2002-13DEC2002	-7	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY
	E0009012	04JUL2003-CONTINUE	10	POST	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	BIPOLAR DEPRESSION
	E0010008	09JAN2003-CONTINUE	23	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	MG	HEADACHES
		02JAN2003-08JAN2003	16	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY
	E0010018	26FEB2003-09APR2003	-21	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
		01APR2003-28APR2003	14	CONCOMITANT	ANALGESICS [NERVOUS SYSTEM]	MG	HEADACHE
	E0010028	UNK-CONTINUE		PRIOR/CONCOM	VALACICLOVIR HYDROCHLORIDE [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	GENITAL HERPES
		09JUN2003-08JUL2003	-7	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		01JUL2003-08JUL2003	16	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	AGITATION
	E0011009	UNK-CONTINUE		PRIOR/CONCOM	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1500 MG	HEADACHES
		06JAN2003-12JAN2003	11	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	4.00 TBLSP	VIRAL SYNDROME/COUGH .

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0011010	UNK-CONTINUE		PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES PRN
		13FEB2003-13FEB2003	4	CONCOMITANT	ALPRAZOLAM [NERVOUS SYSTEM]	0.50 MG	ANXIETY SYMPTOMS DUE TO DEPRESSION
		14FEB2003-16FEB2003	5	CONCOMITANT	DEXBROMPHENIRAMINE MALEATE [RESPIRATORY SYSTEM]	120.0 MG	VIRAL SYNDROME
		17FEB2003-21FEB2003	8	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	VIRAL SYNDROME
	E0013003	01JAN1998-CONTINUE	-1776	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0013005	18MAR2003-23MAR2003	29	CONCOMITANT	NYSTATIN [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	SORE THROAT
	E0013013	01JUL1998-CONTINUE	-1770	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DYSPEPSIA
		01JUL2000-CONTINUE	-1039	PRIOR/CONCOM	IRON [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	NUTRITIONAL SUPPLEMENT
			-1039	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TABS	NUTRITIONAL SUPPLEMENT
		15MAR2003-CONTINUE	-52	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHES
	E0014002	10APR2003-CONTINUE	44	POST	ANTIDEPRESSANTS [NERVOUS SYSTEM]	40.00 MG	DEPRESSION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0014002	09MAR2003-10MAR2003	12	CONCOMITANT	PHENYLPROPANOLAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TABS	HAYFEVER
		11MAR2003-12MAR2003	14	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	HAYFEVER
	E0014004	20DEC2002-CONTINUE	-82	PRIOR/CONCOM	HOMEOPATIC PREPARATION [VARIOUS]	2.00 CAPS	HOT FLASHES
		16MAR2003-29MAR2003	5	CONCOMITANT	CLAVULANATE POTASSIUM [ANTIINFECTIVES FOR SYSTEMIC USE]	1600 MG	URINAIRY HESITANCY
	E0014009	13MAY2003-CONTINUE	21	POST	OLANZAPINE [NERVOUS SYSTEM]	5.00 MG	BIPOLAR
		07MAR2003-CONTINUE	-47	PRIOR/CONCOM	FUROSEMIDE [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERTENSION
		23APR2003-CONTINUE	1	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	KNEE PAIN
		29APR2003-04MAY2003	7	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA
		30APR2003-12MAY2003	8	POST	OLANZAPINE [NERVOUS SYSTEM]	2.50 MG	BIPOLAR
	E0014017	15FEB2003-CONTINUE	-132	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 PUFF	MILD ASTHMA (PRN)
		04AUG2003-04AUG2003	39	CONCOMITANT	MEPYRAMINE MALEATE [NERVOUS SYSTEM]	4.00 TABS	PAINFUL MENSES
		12AUG2003-CONTINUE	47	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0014018	01MAR2003-CONTINUE	-122	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES (PRN)
		01FEB2003-CONTINUE	-150	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	SINUSITIS
	E0018010	01JUN1990-CONTINUE	-4612	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINES
	E0020017	01JAN2003-CONTINUE	-92	PRIOR/CONCOM	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
			-92	PRIOR/CONCOM	HERBAL PREPARATION [VARIOUS]	2.00 TAB	VITAMIN SUPPLEMENT
			-92	PRIOR/CONCOM	OTHER NUTRIENTS [VARIOUS]	3.00 CAP	VITAMIN SUPPLEMENT
			-92	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
		01JAN2002-CONTINUE	-457	PRIOR/CONCOM	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	GASTRIC ESOPHAGEAL REFLUX DISORDER
		12MAR2003-CONTINUE	-22	PRIOR/CONCOM	HOMEOPATIC PREPARATION [VARIOUS]	4.00 SPRAYS	SEASONAL ALLERGIES
		07APR2003-09APR2003	5	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		24MAR2003-CONTINUE	-10	PRIOR/CONCOM	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	SEASONAL ALLERGIES
		10APR2003-15APR2003	8	CONCOMITANT	AMANTADINE [NERVOUS SYSTEM]	200.0 MG	LEFT ELBOW RIGIDITY DUE TO EPS

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Listing 12.2.10.7 Concomitant Medications

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PLACEBO (BIPOLAR I)	E0020017	17APR2003-21APR2003	15	CONCOMITANT	AMANTADINE [NERVOUS SYSTEM]	100.0 MG	RIGHT CERVICAL AREA ACHE (NECK) DUE TO EPS
		22APR2003-04MAY2003	20	CONCOMITANT	AMANTADINE [NERVOUS SYSTEM]	300.0 MG	RIGHT CERVICAL AREA ACHE (NECK) DUE TO EPS
		05MAY2003-30MAY2003	33	CONCOMITANT	AMANTADINE [NERVOUS SYSTEM]	100.0 MG	RIGHT CERVICAL AREA ACHE (NECK) DUE TO EPS
	E0020020	17MAY2003-17MAY2003	6	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	SLEEP DISTURBANCE
	E0020022	01JAN1993-CONTINUE	-3818	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1200 MG	VITAMIN SUPPLEMENT
			-3818	PRIOR/CONCOM	FERROUS FUMARATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	VITAMIN SUPPLEMENT
		02JUL2003-09JUL2003	17	CONCOMITANT	HYDROCORTISONE [SENSORY ORGANS]	16.00 DROPS	OTITIS MEDIA
		09JUL2003-19JUL2003	24	CONCOMITANT	CLAVULANATE POTASSIUM [ANTIINFECTIVES FOR SYSTEMIC USE]	2.00 TAB	OTITIS MEDIA
		05AUG2003-11AUG2003	51	CONCOMITANT	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	INFECTED SALIVARY GLAND
	E0022001	01OCT2000-23NOV2002	-757	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION

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PLACEBO (BIPOLAR I)	E0022001	11NOV2002-CONTINUE	15	CONCOMITANT	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTRIC REFLUX
		23NOV2002-23NOV2002	27	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
		30NOV2002-CONTINUE	34	CONCOMITANT	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
		25DEC2002-25DEC2002	59	POST	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
	E0022004	01JAN1993-CONTINUE	-3587	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHE
		20DEC2002-23DEC2002	54	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	VIRAL SYMPTOMS
	E0022005	01JUL1998-CONTINUE	-1591	PRIOR/CONCOM	TRIAMCINOLONE ACETONIDE [RESPIRATORY SYSTEM]	4.00 PUFFS	ASTHMA
			-1591	PRIOR/CONCOM	CALCIUM CITRATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-1591	PRIOR/CONCOM	PIRBUTEROL ACETATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			-1591	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHES
			-1591	PRIOR/CONCOM	BUDESONIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			-1591	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
			-1591	PRIOR/CONCOM	ZOLMITRIPTAN [NERVOUS SYSTEM]	2.50 MG	MIGRAINE
		01JUL1999-CONTINUE	-1226	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIC RHINITIS

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PLACEBO (BIPOLAR I)	E0022005	01JUL1999-CONTINUE	-1226	PRIOR/CONCOM	MECLOZINE [RESPIRATORY SYSTEM]	25.00 MG	VERTIGO
		01JUN2002-CONTINUE	-160	PRIOR/CONCOM	LIOTHYRONINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	12.50 MCG	HYPOTHYRODISM
			-160	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MCG	HYPOTHYRODISM
		01JUL1992-CONTINUE	-3782	PRIOR/CONCOM	IRON [BLOOD AND BLOOD FORMING ORGANS]	20.00 MG	PROPHYLAXIS
			-3782	PRIOR/CONCOM	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-3782	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-3782	PRIOR/CONCOM	ZINC [ALIMENTARY TRACT AND METABOLISM]	1.00 TABLET	PROPHYLAXIS VISION
		22NOV2002-CONTINUE	15	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
	E0022011	01JAN1990-CONTINUE	-4715	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHE
		29NOV2002-CONTINUE	1	CONCOMITANT	DOCUSATE SODIUM [ALIMENTARY TRACT AND METABOLISM]	500.0 MG	CONSTIPATION PROPHYLAXIS
			1	CONCOMITANT	MORPHINE SULFATE [NERVOUS SYSTEM]	30.00 MG	PAIN MANAGEMENT
			1	CONCOMITANT	MORPHINE SULFATE [NERVOUS SYSTEM]	120.0 MG	PAIN MANAGEMENT
		30NOV2002-30NOV2002	2	CONCOMITANT	PETHIDINE HYDROCHLORIDE [NERVOUS SYSTEM]	50.00 MG	PAIN MANAGEMENT
			2	CONCOMITANT	HYDROMORPHONE HYDROCHLORIDE [NERVOUS SYSTEM]	0.50 MG	PAIN MANAGEMENT

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PLACEBO (BIPOLAR I)	E0022011	30NOV2002-30NOV2002	2	CONCOMITANT	LACTATED RINGER'S INJECTION [BLOOD AND BLOOD FORMING ORGANS]	800.0 CC	HYDRATION MAINTENANCE
			2	CONCOMITANT	MORPHINE SULFATE [NERVOUS SYSTEM]	20.00 MG	PAIN MANAGEMENT
			2	CONCOMITANT	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	PAIN MANAGEMENT
			2	CONCOMITANT	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	12.00 MG	UNKNOWN
			2	CONCOMITANT	METOCLOPRAMIDE [ALIMENTARY TRACT AND METABOLISM]	10.00 MG	UNKNOWN
			2	CONCOMITANT	DIAZEPAM [NERVOUS SYSTEM]	5.00 MG	PAIN MANAGEMENT
			2	CONCOMITANT	MIDAZOLAM HYDROCHLORIDE [NERVOUS SYSTEM]	5.00 MG	PAIN MANAGEMENT
		04DEC2002-20MAY2003	6	CONCOMITANT	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	5.00 MG	DEEP VEIN THROMBOSIS LEFT LEG
			6	CONCOMITANT	HEPARIN-FRACTION, SODIUM SALT [BLOOD AND BLOOD FORMING ORGANS]	180.0 MG	DEEP VEIN THROMBOSIS LEFT LEG
	E0022015	01JAN1999-CONTINUE	-1439	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	CHRONIC BACK PAIN
			-1439	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
			-1439	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		01JUL1999-CONTINUE	-1258	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	SHOULDER PAIN
			-1258	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
		05FEB2003-05FEB2003	58	CONCOMITANT	PARACETAMOL [RESPIRATORY SYSTEM]	2.00 CAPS	UPPER RESPITORY INFECTION

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PLACEBO (BIPOLAR I)	E0022015	05FEB2003-05FEB2003	58	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	DYSMENORHEA
		06JAN2003-12JAN2003	28	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	6.00 TABS	TOOTH ACHE
		16DEC2002-29DEC2002	7	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	ADOMINAL PAIN
		06JAN2003-10JAN2003	28	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	TOOTH ACHE
		13JAN2003-16JAN2003	35	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	TOOTH ACHE
	E0022016	01JAN2000-CONTINUE	-1081	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
		01JAN1990-CONTINUE	-4733	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		01JAN1998-CONTINUE	-1811	PRIOR/CONCOM	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	220.0 MG	CHRONIC BACK PAIN
		09JAN2003-11JAN2003	24	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	HEADACHES
	E0022020	01JAN2000-CONTINUE	-1076	PRIOR/CONCOM	HERBAL EXTRACTS NOS [VARIOUS]	1.00 TAB	MIGRAINE HEADACHES
		01JUL2000-CONTINUE	-894	PRIOR/CONCOM	SUMATRIPTAN SUCCINATE [NERVOUS SYSTEM]	6.00 MG	MIGRAINE HEADACHES
		01JAN1997-CONTINUE	-2171	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA

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PLACEBO (BIPOLAR I)	E0022020	20JAN2003-CONTINUE	40	POST	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0022023	02JAN2003-CONTINUE	9	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2400 MG	HEADACHES
		24DEC2002-CONTINUE	-1	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	3000 MG	HEADACHES
		01JAN1970-CONTINUE	-12046	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		24DEC2002-01JAN2003	-1	PRIOR/CONCOM	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	INSOMNIA
		02JAN2003-16JAN2003	9	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		17JAN2003-23JAN2003	24	CONCOMITANT	ETHANOL [NERVOUS SYSTEM]	2.00 TSP	INSOMNIA
	E0022029	01JAN1995-CONTINUE	-2971	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		08APR2003-11APR2003	49	CONCOMITANT	PARACETAMOL [RESPIRATORY SYSTEM]	2.00 TABS	UPPER RESPIRATORY INFECTION
	E0022041	01JAN1973-CONTINUE	-11033	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		18MAR2003-18MAR2003	1	CONCOMITANT	PSEUDOEPHEDRINE [RESPIRATORY SYSTEM]	30.00 MG	UPPER RESPIRATORY INFECTION

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PLACEBO (BIPOLAR I)	E0022041	07APR2003-08APR2003	21	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	INGROWN TOENAIL
		07APR2003-12APR2003	21	CONCOMITANT	CEFALEXIN [ANTIINFECTIVES FOR SYSTEMIC USE]	2000 MG	INGROWN TOENAIL
	E0022042	25MAR2003-07APR2003	14	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	UPPER RESPIRATORY INFECTION
	E0022043	01JAN2003-CONTINUE	-78	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	GASTROESOPHAGEAL REFLUX
		01JAN1999-CONTINUE	-1539	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHE
		01JAN1990-CONTINUE	-4826	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		03APR2003-03APR2003	15	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	ALLERGIC RHINITIS
		25APR2003-CONTINUE	37	CONCOMITANT	TEGASEROD [ALIMENTARY TRACT AND METABOLISM]	12.00 MG	IRRITABLE BOWEL SYNDROME
		23APR2003-CONTINUE	35	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	IRRITABLE BOWEL
		29MAR2003-30MAR2003	10	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	ALLERGIC RHINITIS
		11APR2003-12APR2003	23	CONCOMITANT	HYOSCYAMINE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	IRRITABLE BOWEL
		12APR2003-13APR2003	24	CONCOMITANT	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	IRRITABLE BOWEL

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0022043	13APR2003-17APR2003	25	CONCOMITANT	LEVOFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	IRRITABLE BOWEL
		13APR2003-26APR2003	25	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	IRRITABLE BOWEL
		21APR2003-22APR2003	33	CONCOMITANT	HYOSCYAMINE [ALIMENTARY TRACT AND METABOLISM]	250.0 MG	IRRITABLE BOWEL
	E0022054	01JAN2000-CONTINUE	-1196	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TAB	HEARTBURN
		01JAN1997-CONTINUE	-2291	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
			-2291	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	NECK PAIN
		24APR2003-24APR2003	14	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		29APR2003-30APR2003	19	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	4.00 TABS	UPPER RESPIRATORY INFECTION
	E0022059	01JAN1998-CONTINUE	-1951	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
			-1951	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	CHRONIC BACK PAIN
		11MAY2003-11MAY2003	6	CONCOMITANT	DIPHENHYDRAMINE [NERVOUS SYSTEM]	1.00 TAB	STUDY CONDITION - INSOMNIA
		08JUN2003-11JUN2003	34	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	SINUSITIS

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0022059	20JUN2003-CONTINUE	46	CONCOMITANT	SALBUTAMOL [RESPIRATORY SYSTEM]	8.00 PUFFS	ASTHMA
		28JUN2003-08JUL2003	54	CONCOMITANT	AMOXICILLIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1500 MG	SINUSITIS
		05JUL2003-05JUL2003	61	POST	FLUCONAZOLE [ANTIINFECTIVES FOR SYSTEMIC USE]	150.0 MG	CANDIDAL VAGINITIS
	E0022065	01JAN1995-CONTINUE	-3048	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	HEADACHES
		01FEB2003-CONTINUE	-95	PRIOR/CONCOM	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	GASTROESOPHAGEAL REFLUX
			-95	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	GASTROESOPHAGEAL REFLUX
		01JAN1988-CONTINUE	-5605	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES
		06JUN2003-CONTINUE	31	CONCOMITANT	OXYMETAZOLINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	ALLERGIC RHINITIS
		11JUN2003-19JUN2003	36	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	DENTAL PAIN
	E0022070	15NOV2001-CONTINUE	-574	PRIOR/CONCOM	METOPROLOL [CARDIOVASCULAR SYSTEM]	200.0 MG	HYPERTENSION
		15DEC2002-CONTINUE	-179	PRIOR/CONCOM	COLCHICINE [MUSCULO-SKELETAL SYSTEM]	1.20 MG	GOUT
		15SEP2001-CONTINUE	-635	PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	40.00 MG	HYPERTENSION
			-635	PRIOR/CONCOM	MINOXIDIL [CARDIOVASCULAR SYSTEM]	2.50 MG	HYPERTENSION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0022070	15SEP2001-CONTINUE	-635	PRIOR/CONCOM	NIFEDIPINE [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
			-635	PRIOR/CONCOM	TRIAMTERENE [CARDIOVASCULAR SYSTEM]	37.50 MG	HYPERTENSION
		18JUN2003-CONTINUE	7	POST	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	BIPOLAR I
	E0023001	01JAN2001-CONTINUE	-683	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.15 MG	HYPOTHYROID
	E0023047	24JUL2003-24JUL2003	7	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	250.0 MG	SHOULDER PAIN
	E0025001	10APR2003-CONTINUE	10	CONCOMITANT	PIOGLITAZONE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	NON INSULIN DEPENDENT DIABETES MELLITUS
		01JUN2002-CONTINUE	-304	PRIOR/CONCOM	GLIMEPIRIDE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	NON INSULIN DEPENDENT DIABETES MELLITUS
		28MAR2003-16APR2003	-4	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		10APR2003-16APR2003	10	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	3.00 MG	ANXIETY
	E0026012	01JUL1979-CONTINUE	-8635	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHES

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0026024	01JUL1999-CONTINUE	-1401	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	MCG	ASTHMA
			-1401	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MCG	HYPOTHYROID
	E0026028	11JUL2003-13JUL2003	22	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
		01JUL1998-11JUL2003	-1815	PRIOR/CONCOM	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTRO - REFLUX
		11JUL2003-CONTINUE	22	CONCOMITANT	ESCITALOPRAM [NERVOUS SYSTEM]	10.00 MG	BIPOLAR CONDITION
			22	CONCOMITANT	GABAPENTIN [NERVOUS SYSTEM]	1800 MG	BIPOLAR CONDITION
			22	CONCOMITANT	RISPERIDONE [NERVOUS SYSTEM]	2.00 MG	BIPOLAR CONDITION
			22	CONCOMITANT	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR CONDITION
		11JUL2003-11JUL2003	22	CONCOMITANT	CLONAZEPAM [NERVOUS SYSTEM]	1.00 MG	AGITATION
			22	CONCOMITANT	OXCARBAZEPINE [NERVOUS SYSTEM]	300.0 MG	BIPOLAR CONDITION
		11JUL2003-12JUL2003	22	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		12JUL2003-CONTINUE	23	CONCOMITANT	RAMIPRIL [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION
			23	CONCOMITANT	CLONAZEPAM [NERVOUS SYSTEM]	3.00 MG	AGITATION
			23	CONCOMITANT	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	80.00 MG	GASTRO - REFLUX
			23	CONCOMITANT	OXCARBAZEPINE [NERVOUS SYSTEM]	600.0 MG	BIPOLAR CONDITION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0026028	13JUL2003-CONTINUE	24	CONCOMITANT	ATENOLOL [CARDIOVASCULAR SYSTEM]	50.00 MG	HYPERTENSION
		13JUL2003-13JUL2003	24	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA
	E0028001	01JUL1999-CONTINUE	-1197	PRIOR/CONCOM	SIMVASTATIN [CARDIOVASCULAR SYSTEM]	0.50 TAB	HYPERCHOLESTEROLEMA
		15SEP1998-CONTINUE	-1486	PRIOR/CONCOM	METFORMIN [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DIABETES
		14OCT2002-14OCT2002	5	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
		23OCT2002-28OCT2002	14	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
		29OCT2002-29OCT2002	20	CONCOMITANT	INFLUENZA VIRUS VACCINE POLYVALENT [ANTIINFECTIVES FOR SYSTEMIC USE]	UNK	PROPHYLAXIS
	E0028003	05NOV2002-06NOV2002	37	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	UNK	SURGERY PAIN
		22NOV2002-CONTINUE	54	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	8.00 TABS	SPRAINED C 6
		28SEP2002-19OCT2002	-2	PRIOR/CONCOM	ECHINACEA EXTRACT [VARIOUS]	4.00 TABS	COLD SYMPTOMS
			-2	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	3000 MG	COLD SYMPTOMS
		01OCT2002-02OCT2002	2	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	DEPRESSIVE ANXIETY

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PLACEBO (BIPOLAR I)	E0028003	06OCT2002-14OCT2002	7	CONCOMITANT	PROTEIN SUPPLEMENTS [VARIOUS]	9.00 TABS	COLD SYMPTOMS
		14OCT2002-15OCT2002	15	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	EXACERBATION OF CHOLECYSTITIS
		17OCT2002-21OCT2002	18	CONCOMITANT	HERBAL PREPARATION [VARIOUS]	1.00 GALLON	PROPHYLAXIS
		04NOV2002-04NOV2002	36	CONCOMITANT	ANAESTHETICS, GENERAL [NERVOUS SYSTEM]	UNK	GALL BLADDER SURGERY
			36	CONCOMITANT	PETHIDINE HYDROCHLORIDE [NERVOUS SYSTEM]	UNK	SURGERY PAIN
	E0028005	13OCT2002-CONTINUE	11	POST	OXCARBAZEPINE [NERVOUS SYSTEM]	150.0 MG	DEPRESSION
	E0028010	01JAN2001-CONTINUE	-673	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	2.00 TABS	HEADACHES
		01SEP2002-CONTINUE	-65	PRIOR/CONCOM	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	UNK	ALLERGIES
		12NOV2002-19NOV2002	8	CONCOMITANT	ECHINACEA EXTRACT [VARIOUS]	4.00 TABS	PROPHYLAXIS
		01OCT1996-CONTINUE	-2226	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	BIRTH CONTROL
		13NOV2002-13NOV2002	9	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA
		15NOV2002-15NOV2002	11	CONCOMITANT	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	PROPHYLAXIS

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0028011	13JAN2003-23JAN2003	40	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	HEADACHE
	E0028030	08MAR2003-08MAR2003	5	CONCOMITANT	PHENYLEPHRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	SINUSITIS
		30MAR2003-30MAR2003	27	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TAB	SINUS HEADACHE DUE TO SINUSITIS
	E0028031	01JUN1998-CONTINUE	-1744	PRIOR/CONCOM	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	ACID REFLUX
		01JUN2001-CONTINUE	-648	PRIOR/CONCOM	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX
		30MAR2003-CONTINUE	20	CONCOMITANT	BENZATROPINE MESILATE [NERVOUS SYSTEM]	0.50 MG	BIPOLAR
			20	CONCOMITANT	CLONAZEPAM [NERVOUS SYSTEM]	1.00 MG	BIPOLAR
			20	CONCOMITANT	LITHIUM [NERVOUS SYSTEM]	1200 MG	BIPOLAR
			20	CONCOMITANT	GABAPENTIN [NERVOUS SYSTEM]	1800 MG	BIPOLAR
			20	CONCOMITANT	RISPERIDONE [NERVOUS SYSTEM]	2.00 MG	BIPOLAR
	E0028047	21JUL2003-CONTINUE	8	CONCOMITANT	ATENOLOL [CARDIOVASCULAR SYSTEM]	120.0 MG	HYPERTENSION
		01JUL2001-CONTINUE	-743	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	ARTHRITIS
			-743	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	HEADACHES

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PLACEBO (BIPOLAR I)	E0028047	01JUL1997-20JUL2003	-2204	PRIOR/CONCOM	ATENOLOL [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
		11SEP2001-CONTINUE	-671	PRIOR/CONCOM	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1000 MG	DIABETES
			-671	PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	60.00 MG	HYPERTENSION
		05SEP2003-07SEP2003	54	CONCOMITANT	VERAPAMIL [CARDIOVASCULAR SYSTEM]	240.0 MG	HYPERTENSION
	E0029001	01JUN1998-CONTINUE	-1583	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	NUTRITIONAL SUPPLEMENT
	E0029014	13FEB2003-14FEB2003	10	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA SECONDARY TO DEPRESSION
		11FEB2003-CONTINUE	8	CONCOMITANT	LORATADINE [RESPIRATORY SYSTEM]	10.00 MG	ALLERGIC RHINITIS
		12FEB2003-12FEB2003	9	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	5.00 MG	INSOMNIA SECONDARY TO DEPRESSION
		22FEB2003-22FEB2003	19	CONCOMITANT	CODEINE PHOSPHATE [NERVOUS SYSTEM]	1.00 PACK	HEAD COLD
		10MAR2003-10MAR2003	35	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MENSTRUAL CRAMPS
	E0029023	01JUL2000-CONTINUE	-1011	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	MENSTRUAL CRAMPS (PRN)

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PLACEBO (BIPOLAR I)	E0029023	01JUL2000-CONTINUE	-1011	PRIOR/CONCOM	HERBAL PREPARATION [VARIOUS]	1.00 PKG	PROPHYLAXIS FOR CONSTIPATION
			-1011	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 CAP	NUTRITIONAL SUPPLEMENT
		15APR2003-CONTINUE	8	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	HEARTBURN
		15APR2003-23APR2003	8	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA PRN
		25APR2003-26APR2003	18	CONCOMITANT	ETHANOL [NERVOUS SYSTEM]	30.00 CC	INSOMNIA
		06MAY2003-09MAY2003	29	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	FLU SYMPTOMS
			29	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	FLU SYMPTOMS
	E0029032	01JUL1998-CONTINUE	-1805	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	TENSION HEADACHE PRN
		01JUL2000-CONTINUE	-1074	PRIOR/CONCOM	MAGNESIUM HYDROXIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 TSP	STOMACH PAIN PRN
		13JUN2003-14JUN2003	4	CONCOMITANT	CODEINE PHOSPHATE [NERVOUS SYSTEM]	1.00 PACKET	COLD
		18JUN2003-22JUN2003	9	CONCOMITANT	CEFALEXIN MONOHYDRATE [ANTIINFECTIVES FOR SYSTEMIC USE]	1500 MG	COLD
	E0029033	01JAN2003-CONTINUE	-152	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	HERNIATED CERVICAL DISKS

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0029033	09JUN2003-21JUN2003	8	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA PRN
		17JUN2003-CONTINUE	16	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	MIGRAINE HEADACHES PRN
	E0029039	01JUL2003-CONTINUE	-14	PRIOR/CONCOM	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	440.0 MG	MIGRAINE HEADACHE
		25JUL2003-27JUL2003	11	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	WORSENING OF INSOMNIA PRN
	E0030003	19DEC2002-20DEC2002	4	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	2.00 TAB	URI
			4	CONCOMITANT	ETHANOL [NERVOUS SYSTEM]	1.00 TAB	URI
		01JUL1992-CONTINUE	-3820	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0030009	13MAR2003-13MAR2003	50	CONCOMITANT	GENTAMICIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1.00 INJECTION	PROSTATE INFECTION
		07MAR2003-14MAR2003	44	CONCOMITANT	GATIFLOXACIN [ANTIINFECTIVES FOR SYSTEMIC USE]	400.0 MG	PROSTATE INFECTION
	E0030016	21FEB2003-20APR2003	-10	PRIOR/CONCOM	DIHYDROXYALUMINUM SODIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	INDIGESTION
			-10	PRIOR/CONCOM	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	INDIGESTION
	E0031001	04DEC2002-04DEC2002	14	CONCOMITANT	LORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	INFLUENZA

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PLACEBO (BIPOLAR I)	E0031001	04DEC2002-04DEC2002	14	CONCOMITANT	CLONAZEPAM [NERVOUS SYSTEM]	2.00 MG	INSOMNIA
		01NOV2001-CONTINUE	-385	PRIOR/CONCOM	CLONAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY
		15JUN1991-CONTINUE	-4177	PRIOR/CONCOM	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	2.00 MG	HORMONE REPLACEMENT
		02DEC2002-09DEC2002	12	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	INFLUENZA
		02DEC2002-14DEC2002	12	CONCOMITANT	OXYMETAZOLINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	CONGESTION
		04DEC2002-06DEC2002	14	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	FEVER
	E0031017	01JAN2001-CONTINUE	-820	PRIOR/CONCOM	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	SEASONAL ALLERGIES
		01JAN1996-CONTINUE	-2647	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	STROKE RISK REDUCTION
		18MAR2003-CONTINUE	-14	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	12.50 MG	HYPERTENSON
			-14	PRIOR/CONCOM	ISOSORBIDE MONONITRATE [CARDIOVASCULAR SYSTEM]	30.00 MG	HYPERTENSION
			-14	PRIOR/CONCOM	ATORVASTATIN [CARDIOVASCULAR SYSTEM]	40.00 MG	HYPERCHOLESTEROLEMIA
			-14	PRIOR/CONCOM	METOPROLOL [CARDIOVASCULAR SYSTEM]	100.0 MG	HYPERTENSION
			-14	PRIOR/CONCOM	NICOTINIC ACID [CARDIOVASCULAR SYSTEM]	1000 MG	STROKE RISK REDUCTION
			-14	PRIOR/CONCOM	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0031017	18MAR2003-CONTINUE	-14	PRIOR/CONCOM	CLOPIDOGREL SULFATE [BLOOD AND BLOOD FORMING ORGANS]	75.00 MG	STROKE RISK REDUCTION
			-14	PRIOR/CONCOM	OMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	GASTROESOPHOGEAL REFLUX DISEASE
		09APR2003-09APR2003	9	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0031018	01JAN1990-CONTINUE	-4847	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	MIGRAINES
		16APR2003-16APR2003	7	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0031023	15MAR2003-CONTINUE	-45	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	300.0 MG	GASTROESOPHAGEAL REFLUX DISEASE
		15APR2003-CONTINUE	-14	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PHOPHYLAXIS
		01MAR2002-CONTINUE	-424	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	20.00 MG	SEASONAL ALLERGIES
		23MAR2003-CONTINUE	-37	PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	150.0 MG	CONTRACEPTION
		06MAY2003-13MAY2003	8	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	500.0 MG	INTERMITTENT HEADACHES
	E0033001	13JAN2003-24JAN2003	5	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	UPPER RESPIRATORY INFECTION

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0033001	25JAN2003-CONTINUE	17	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	240.0 MG	ALLERGIES
	E0033004	01FEB2000-CONTINUE	-1081	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MCG	HYPOTHYROIDISM
		25FEB2003-25FEB2003	40	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	LEFT ANKLE PAIN (DUE TO SPRAIN)
	E0033010	24FEB2003-24FEB2003	21	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	220.0 MG	HEADACHE
		19MAR2003-19MAR2003	44	CONCOMITANT	ANAESTHETICS, GENERAL [NERVOUS SYSTEM]	UNK	SURGICAL REMOVAL OF TUBAL PREGNANCY
		30JAN2003-CONTINUE	-5	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	HEADACHES
		08FEB2003-10FEB2003	5	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	INFLUENZA
	E0033014	10APR2003-10APR2003	23	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	UNKNOWN	HEADACHE
		14MAR2003-26MAR2003	-5	PRIOR/CONCOM	LORATADINE [RESPIRATORY SYSTEM]	UNK	SINUS ALLERGIES
		26MAR2003-CONTINUE	8	CONCOMITANT	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	50.00 MCG	SINUS ALLERGIES
			8	CONCOMITANT	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	SINUS ALLERGIES

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Listing 12.2.10.7 Concomitant Medications

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PLACEBO (BIPOLAR I)	E0033014	21APR2003-CONTINUE	34	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	HEADACHE
			34	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	200.0 MG	BACK (SPINAL DISC HERNIA) PAIN
	E0035011	10JAN2003-CONTINUE	-25	PRIOR/CONCOM	ROSIGLITAZONE MALEATE [ALIMENTARY TRACT AND METABOLISM]	4.00 MG	DIABETES
		01SEP2001-CONTINUE	-521	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	100.0 MG	HYPOTHYROID
	E0035020	19APR2003-19APR2003	2	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
	E0037003	01NOV2002-CONTINUE	-90	PRIOR/CONCOM	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	400.0 MG	ARTHRITIS PAIN
		06FEB2003-19FEB2003	8	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
			8	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	ANXIETY
	E0037004	01AUG2002-CONTINUE	-196	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	GENERAL HEALTH
		12FEB2003-CONTINUE	-1	PRIOR/CONCOM	TETRYZOLINE HYDROCHLORIDE [SENSORY ORGANS]	DROPS	ITCHY, SWOLLEN EYES
	E0039007	07JAN2003-07JAN2003	35	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	HEADACHE

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0039007	05DEC2002-05DEC2002	2	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	HEADACHE
		09JAN2003-CONTINUE	37	CONCOMITANT	NEOMYCIN SULFATE [DERMATOLOGICALS]	1.00 APPLICATION	PRURITIC GROIN
		26DEC2002-04JAN2003	23	CONCOMITANT	COLECALCIFEROL [DERMATOLOGICALS]	1.00 APPLICATION	REDNESS ON BILATERAL CHEEKS
		13JAN2003-14JAN2003	41	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	HEADACHE
	E0039022	15JAN2003-CONTINUE	-41	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		31MAR2003-31MAR2003	35	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	TOOTHACHE
	E0039030	07APR2003-07APR2003	15	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1000 MG	BILATERAL KNEE PAIN
	E0039031	01JUL2000-CONTINUE	-996	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		19MAY2003-19MAY2003	57	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
		15MAY2003-CONTINUE	53	CONCOMITANT	DOXYCYCLINE [ALIMENTARY TRACT AND METABOLISM]	75.00 MG	ACNE
		07APR2003-10APR2003	15	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TSP	NON PRODUCTIVE COUGH

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0039031	16MAY2003-16MAY2003	54	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	NASAL CONGESTION
		14APR2003-14APR2003	22	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TSP	NON PRODUCTIVE COUGH
		16APR2003-16APR2003	24	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	HEADACHES
		26APR2003-26APR2003	34	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	MIGRAINE
		01JUL2002-14MAY2003	-266	PRIOR/CONCOM	DOXYCYCLINE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	ACNE
		04APR2003-04APR2003	12	CONCOMITANT	COUGH AND COLD PREPARATIONS [RESPIRATORY SYSTEM]	3.00 DROPS	NON PRODUCTIVE COUGH
		01MAY2003-01MAY2003	39	CONCOMITANT	THYROID [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.50 MG	ACCIDENTAL OVERDOSE
		04MAY2003-04MAY2003	42	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
		08MAY2003-10MAY2003	46	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1200 MG	SORE THROAT
			46	CONCOMITANT	SODIUM CHLORIDE [RESPIRATORY SYSTEM]	3.00 SPRAYS	NASAL CONGESTION
			46	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	180.0 MG	NASAL CONGESTION
	E0039037	01JUL2002-CONTINUE	-289	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	ORAL CONTRACEPTION

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PLACEBO (BIPOLAR I)	E0039037	05MAY2003-CONTINUE	20	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES
		04MAY2003-04MAY2003	19	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	1600 MG	HEADACHES
		24APR2003-30APR2003	9	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
	E0039038	21MAY2003-CONTINUE	29	CONCOMITANT	DISULFIRAM [NERVOUS SYSTEM]	MG	ALCOHOL WITHDRAWAL
		10MAY2003-CONTINUE	18	CONCOMITANT	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA (AS NEEDED)
			18	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	ASTHMA
			18	CONCOMITANT	CITALOPRAM HYDROBROMIDE [NERVOUS SYSTEM]	20.00 MG	DEPRESSION
			18	CONCOMITANT	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	440.0 MCG	ASTHMA
			18	CONCOMITANT	METFORMIN HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	500.0 MG	DIABETES MELLITUS
			18	CONCOMITANT	NPH INSULIN [ALIMENTARY TRACT AND METABOLISM]	20.00 UNITS	DIABETES MELLITUS
		09MAY2003-09MAY2003	17	CONCOMITANT	CORTISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	UNK	ASTHMA
		07MAY2003-09MAY2003	15	CONCOMITANT	HEPARIN [BLOOD AND BLOOD FORMING ORGANS]		PROPHYLACTIC
		18JUN2003-CONTINUE	57	POST	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR I)	E0039038	06MAY2003-09MAY2003	14	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	MG	ASTHMA
		05APR2003-CONTINUE	-18	PRIOR/CONCOM	GLIPIZIDE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	DIABETES MELLITUS
		21APR2003-28APR2003	-2	PRIOR/CONCOM	MICONAZOLE NITRATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 APPLICATION	VAGINAL ITCHING
		05MAY2003-05MAY2003	13	CONCOMITANT	LORAZEPAM [NERVOUS SYSTEM]	2.00 MG	ANXIETY
			13	CONCOMITANT	IPRATROPIUM BROMIDE [CARDIOVASCULAR SYSTEM]	UNK	ASTHMA
			13	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	ALLERGY
			13	CONCOMITANT	MAGNESIUM SULFATE [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLACTIC
			13	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLACTIC
			13	CONCOMITANT	POTASSIUM [ALIMENTARY TRACT AND METABOLISM]	MG	PROPHYLAXIS
			13	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	MG	ASTHMA
		05MAY2003-07MAY2003	13	CONCOMITANT	DIAZEPAM [NERVOUS SYSTEM]	5.00 MG	ANXIETY
		05MAY2003-09MAY2003	13	CONCOMITANT	SALBUTAMOL [RESPIRATORY SYSTEM]	4.00 PUFFS	ASTHMA
			13	CONCOMITANT	DEXAMETHASONE [ALIMENTARY TRACT AND METABOLISM]	12.00 MG	ASTHMA
			13	CONCOMITANT	FOLIC ACID [BLOOD AND BLOOD FORMING ORGANS]	UNK	PROPHYLACTIC
			13	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	TSP	ASTHMA

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PLACEBO (BIPOLAR I)	E0039038	05MAY2003-09MAY2003	13	CONCOMITANT	THIAMINE [ALIMENTARY TRACT AND METABOLISM]	UNK	PROPHYLACTIC
		10MAY2003-12MAY2003	18	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	40.00 MG	ASTHMA
		13MAY2003-15MAY2003	21	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	30.00 MG	ASTHMA
		16MAY2003-18MAY2003	24	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	20.00 MG	ASTHMA
		19MAY2003-21MAY2003	27	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	10.00 MG	ASTHMA
	E0039047	09JUN2003-09JUN2003	22	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	BILATERAL LEG PAIN
			22	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	PRODUCTIVE COUGH
		02JUN2003-02JUN2003	15	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
		11JUN2003-11JUN2003	24	CONCOMITANT	METHYLPREDNISOLONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	40.00 MG	PRODUCTIVE COUGH
		18JUN2003-CONTINUE	31	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	ABDOMINAL CRAMPING SECONDARY TO HYSTEROSALPINGOGRAM

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PLACEBO (BIPOLAR I)	E0039047	15DEC1981-CONTINUE	-7825	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA (AS NEEDED)
		20MAY2003-28MAY2003	2	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
		08JUN2003-08JUN2003	21	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	FEVER
		09JUN2003-10JUN2003	22	CONCOMITANT	METHYLPREDNISOLONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	48.00 MG	PRODUCTIVE COUGH
		09JUN2003-14JUN2003	22	CONCOMITANT	DEXTROMETHORPHAN HYDROBROMIDE [RESPIRATORY SYSTEM]	2.00 TBSP	PRODUCTIVE COUGH (AS NEEDED)
		10JUN2003-13JUN2003	23	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	250.0 MG	PRODUCTIVE COUGH
		17JUN2003-17JUN2003	30	CONCOMITANT	DIAGNOSTIC RADIOPHARMACEUTICALS [VARIOUS]	UNK	HYSTEROSALPINGOGRAM
			30	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	ABDOMINAL PAIN SECONDARY TO HYSTEROSALPINGOGRAM
	E0039059	17JUL2003-17JUL2003	7	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	120.0 MG	NASAL CONGESTION
		18JUL2003-21JUL2003	8	CONCOMITANT	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	NASAL CONGESTION
		21AUG2003-CONTINUE	42	CONCOMITANT	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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PLACEBO (BIPOLAR I)	E0039059	21AUG2003-CONTINUE	42	CONCOMITANT	FERROUS SULFATE [BLOOD AND BLOOD FORMING ORGANS]	27.00 MG	PROPHYLAXIS
			42	CONCOMITANT	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			42	CONCOMITANT	PYRIDOXINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0041010	11JUN2003-11JUN2003	43	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	100.0 MG	BIPOLAR DISORDER (MANIC EPISODE)
		12JUN2003-12JUN2003	44	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	200.0 MG	BIPOLAR DISORDER (MANIC EPISODE)
		09MAY2003-12MAY2003	10	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	INTERMITTENT HEADACHE (INCREASE IN FREQUENCY)
		02MAY2003-02MAY2003	3	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	INTERMITTENT HEADACHE (INCREASE IN FREQUENCY)
		17MAY2003-20MAY2003	18	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	INTERMITTENT HEADACHE (INCREASE IN FREQUENCY)
		28MAY2003-02JUN2003	29	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	INTERMITTENT HEADACHE (INCREASE IN FREQUENCY)

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PLACEBO (BIPOLAR I)	E0041010	11JUN2003-12JUN2003	43	POST	LORAZEPAM [NERVOUS SYSTEM]	1.00 MG	INSOMNIA
		11JUN2003-13JUN2003	43	POST	VALPROATE SEMISODIUM [NERVOUS SYSTEM]	750.0 MG	BIPOLAR DISORDER (MANIC EPISODE)
	E0041012	01JUL1993-CONTINUE	-3640	PRIOR/CONCOM	RANITIDINE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	300.0 MG	ACID REFLUX
		08JUL2003-CONTINUE	20	CONCOMITANT	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	5.00 MG	CLOT PROPHALAXIS
			20	CONCOMITANT	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			20	CONCOMITANT	AMLODIPINE BESILATE [CARDIOVASCULAR SYSTEM]	5.00 MG	HYPERTENSION
		01JUL1989-07JUL2003	-5101	PRIOR/CONCOM	CLONIDINE [CARDIOVASCULAR SYSTEM]	0.10 MG	HYPERTENSION
			-5101	PRIOR/CONCOM	WARFARIN SODIUM [BLOOD AND BLOOD FORMING ORGANS]	12.50 MG	CLOT PROPHYLAXIS
		01JUL1994-CONTINUE	-3275	PRIOR/CONCOM	PRAVASTATIN SODIUM [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERLIPIDEMIA
		01JUL1995-07JUL2003	-2910	PRIOR/CONCOM	TRIAMTERENE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION
		08JUL2003-18JUL2003	20	CONCOMITANT	CLARITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	1000 MG	BRONCHITIS

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0001004	UNK-CONTINUE		PRIOR/CONCOM	MEDROXYPROGESTERONE ACETATE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 SHOT	BIRTH CONTROL EVERY 3 MONTHS
		27MAY2003-05JUN2003	27	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TAB	COLD PRN
		29MAY2003-10JUN2003	29	CONCOMITANT	TERPIN HYDRATE [RESPIRATORY SYSTEM]	2.00 TSP	COLD PRN
		05JUN2003-10JUN2003	36	CONCOMITANT	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	300.0 MG	BRONCHITIS
			36	CONCOMITANT	ANTIBIOTICS [ANTIINFECTIVES FOR SYSTEMIC USE]		BRONCHITIS
	E0005023	01JAN2000-CONTINUE	-1131	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACKET	HEADACHES
		01JUN2002-CONTINUE	-249	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PILL	BIRTH CONTROL
	E0005034	05JUN2003-CONTINUE	52	CONCOMITANT	MECLOZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	75.00 MG	VIRAL EAR INFECTION
		01DEC1999-CONTINUE	-1231	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	150.0 MCG	HYPOTHYROIDISM
	E0005041	15APR2002-CONTINUE	-435	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	2.00 PILLS	NUTRITIONAL SUPPLEMENT
			-435	PRIOR/CONCOM	LINSEED OIL [VARIOUS]	1.00 PILL	NUTRITIONAL SUPPLEMENT
			-435	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT
			-435	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 PILL	NUTRITIONAL SUPPLEMENT

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0007004	01JUN2000-CONTINUE	-973	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.05 MG	HYPOTHYROIDISM
		02JAN2000-CONTINUE	-1124	PRIOR/CONCOM	NORETHISTERONE [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PILL	BIRTH CONTROL
	E0007010	26APR2003-01MAY2003	9	CONCOMITANT	COUGH AND COLD PREPARATIONS [RESPIRATORY SYSTEM]	1.50 TAB	UPPER RESPIRATORY INFECTION
		21MAY2003-27MAY2003	34	CONCOMITANT	NAPROXEN SODIUM [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	SPRAIN RIGHT FOOT
		27MAY2003-10JUN2003	40	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	4000 MG	SPRAIN RIGHT FOOT
	E0007012	01JUL2000-CONTINUE	-1049	PRIOR/CONCOM	LORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIC RHINITIS
	E0009007	01JUL1995-CONTINUE	-2774	PRIOR/CONCOM	BUTORPHANOL TARTRATE [NERVOUS SYSTEM]	ML	MIGRAINES
			-2774	PRIOR/CONCOM	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	MG	BACK PAIN
	E0009008	01JUL1985-CONTINUE	-6435	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	MG	PROPHYLAXIS
			-6435	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	MG	HEADACHES
			-6435	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	MG	PROPHYLAXIS
		08APR2003-CONTINUE	56	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	300.0 MG	BI - POLAR DISORDER

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Listing 12.2.10.7 Concomitant Medications

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PLACEBO (BIPOLAR II)	E0011001	10OCT2002-CONTINUE	-22	PRIOR/CONCOM	RETINOL [ALIMENTARY TRACT AND METABOLISM]	12500 IU	PROPHYLAXIS
			-22	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	200.0 IU	PROPHYLAXIS
		25OCT2002-CONTINUE	-7	PRIOR/CONCOM	SELENIUM [ALIMENTARY TRACT AND METABOLISM]	25.00 MCG	PROPHYLAXIS
		04DEC2002-10DEC2002	34	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 CAPSULES	SINUS PAIN
	E0011011	01JUL2000-CONTINUE	-964	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	HEADACHES PRN
		01JUL2000-08APR2003	-964	PRIOR/CONCOM	FERROUS SULFATE [BLOOD AND BLOOD FORMING ORGANS]	500.0 MG	IRON DEFICIENCY ANEMIA
	E0011013	04JUN2003-CONTINUE	49	CONCOMITANT	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			49	CONCOMITANT	MONTELUKAST SODIUM [RESPIRATORY SYSTEM]	10.00 MG	ASTHMA
		05MAR2003-CONTINUE	-43	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	1.00 TAB	HYPERTENSION
		28MAR2003-CONTINUE	-20	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 CAP	ARTHRITIS PAIN HEADACHE
			-20	PRIOR/CONCOM	LEVOTHYROXINE SODIUM [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	0.10 MG	HYPOTHYROIDISM
		04JUN2003-04JUN2003	49	CONCOMITANT	DEXAMETHASONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	1.00 MG	ACUTE ASTHMATIC ATTACK

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Listing 12.2.10.7 Concomitant Medications

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PLACEBO (BIPOLAR II)	E0011021	01JUL2002-CONTINUE	-325	PRIOR/CONCOM	NITROFURANTOIN [ANTIINFECTIVES FOR SYSTEMIC USE]	100.0 MG	URINARY TRACT INFECTION PROPHYLAXIS
		01JUL1998-CONTINUE	-1786	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHES
		01JUL1999-CONTINUE	-1421	PRIOR/CONCOM	ASCORBIC ACID [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		11JUN2003-14JUN2003	21	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TSP	UPPER RESPIRATORY TRACT INFECTION
	E0013008	04AUG1987-CONTINUE	-5713	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	215.0 MG	ASTHMA
		02FEB1992-CONTINUE	-4070	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHE
			-4070	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	1.00 PACK	HEADACHE
	E0014001	01DEC2002-CONTINUE	-87	PRIOR/CONCOM	NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	HORMONE REPLACEMENT
		27MAR2003-27MAR2003	30	CONCOMITANT	HYDROMORPHONE HYDROCHLORIDE [NERVOUS SYSTEM]	0.40 MG	PAIN - PRN
			30	CONCOMITANT	HEPARIN-FRACTION, SODIUM SALT [BLOOD AND BLOOD FORMING ORGANS]	40.00 MG	HYPERCOAGULAVITY - PRN
			30	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	HEARTBURN
		26MAR2003-26MAR2003	29	CONCOMITANT	DOLASETRON MESILATE [ALIMENTARY TRACT AND METABOLISM]	12.50 MG	NAUSEA - PRN

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PLACEBO (BIPOLAR II)	E0014001	26MAR2003-26MAR2003	29	CONCOMITANT	HYDROMORPHONE HYDROCHLORIDE [NERVOUS SYSTEM]	0.60 MG	PAIN - PRN
			29	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	HEARTBURN
			29	CONCOMITANT	HEPARIN [BLOOD AND BLOOD FORMING ORGANS]	3000 ML	HYPERCOAGULAVITY - PRN
			29	CONCOMITANT	HEPARIN [BLOOD AND BLOOD FORMING ORGANS]	1000 ML	HYPERCOAGULAVITY - PRN
			29	CONCOMITANT	PROMETHAZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	50.00 MG	NAUSEA - PRN
		13MAR2003-CONTINUE	16	CONCOMITANT	FEXOFENADINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	60.00 MG	SINUSITIS
		01APR2003-CONTINUE	35	POST	QUETIAPINE FUMARATE [NERVOUS SYSTEM]	175.0 MG	BIPOLAR
		29MAR2003-29MAR2003	32	CONCOMITANT	HEPARIN-FRACTION, SODIUM SALT [BLOOD AND BLOOD FORMING ORGANS]	40.00 MG	HYPERCOAGULAVITY - PRN
			32	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TAB	PAIN - PRN
		19MAR2003-22MAR2003	22	CONCOMITANT	AZITHROMYCIN [ANTIINFECTIVES FOR SYSTEMIC USE]	200.0 MG	SINUSITIS
		28MAR2003-28MAR2003	31	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	5.00 TAB	PAIN - PRN
		28MAR2003-29MAR2003	31	CONCOMITANT	RANITIDINE [ALIMENTARY TRACT AND METABOLISM]	150.0 MG	HEART BURN
	E0014013	01JUL1998-CONTINUE	-1791	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	HEALTH
	E0018005	21DEC2002-23DEC2002	2	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES

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PLACEBO (BIPOLAR II)	E0018012	12FEB2003-12FEB2003	20	CONCOMITANT	PREDNISONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	20.00 MG	REACTIVE AIRWAY DISEASE
		01JUN1974-CONTINUE	-10464	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	1.00 PUFF	REACTIVE AIRWAY DISEASE
			-10464	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	1.00 PUFF	REACTIVE AIRWAY DISEASE
			-10464	PRIOR/CONCOM	SALMETEROL XINAFOATE [RESPIRATORY SYSTEM]	1.00 PUFF	REACTIVE AIRWAY DISEASE
	E0019019	30JAN2003-CONTINUE	8	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	UNK	LOW BACK PAIN
			8	CONCOMITANT	TIZANIDINE HYDROCHLORIDE [MUSCULO-SKELETAL SYSTEM]	1.00 MG	LOW BACK PAIN
	E0019033	01OCT2002-CONTINUE	-168	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	2.00 CAPS	DIETARY SUPPLEMENT
	E0019038	13MAY2003-11JUN2003	20	CONCOMITANT	DIPHENHYDRAMINE [NERVOUS SYSTEM]	2.00 CAPS	INSOMNIA PRN
		31MAY2003-31MAY2003	38	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	5.00 MG	BACK PAIN
	E0019046	01JAN2000-CONTINUE	-1272	PRIOR/CONCOM	ESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TAB	HORMONE REPLACEMENT THERAPY ESTRODIAL 1MG NORGESTIMATE .09MG

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PLACEBO (BIPOLAR II)	E0019047	01JAN2003-CONTINUE	-188	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIES PRN
		01JAN2002-CONTINUE	-553	PRIOR/CONCOM	ECHINACEA EXTRACT [VARIOUS]	1.00 TAB	PROPHYLAXIS [HEALTH] PRN
		20AUG2003-20AUG2003	44	CONCOMITANT	ETHANOL [NERVOUS SYSTEM]	1.00 TBS	CHEST CONGESTION
	E0019048	01JAN2002-CONTINUE	-555	PRIOR/CONCOM	METAXALONE [MUSCULO-SKELETAL SYSTEM]	1200 MG	INFLAMATION OF JOINTS LOWER BACK PAIN
		01APR2003-CONTINUE	-100	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	0.10 MG	BIRTH CONTROL
		01JAN2002-17JUL2003	-555	PRIOR/CONCOM	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		14AUG2003-15AUG2003	36	CONCOMITANT	HYDROCODONE [RESPIRATORY SYSTEM]	500.0 MG	ORAL SURGERY DENTAL (PAIN)
	E0022006	01NOV2001-CONTINUE	-376	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 TABLET	BIRTH CONTROL
		01SEP2002-CONTINUE	-72	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			-72	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	10.00 MG	ALLERGIC RHINITIS
		29NOV2002-29NOV2002	18	CONCOMITANT	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 MG	DIARRHEA
		13NOV2002-13NOV2002	2	CONCOMITANT	FAMOTIDINE [ALIMENTARY TRACT AND METABOLISM]	20.00 MG	VIRAL ILLNESS

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PLACEBO (BIPOLAR II)	E0022006	01SEP2001-CONTINUE	-437	PRIOR/CONCOM	SPIRONOLACTONE [CARDIOVASCULAR SYSTEM]	50.00 MG	ACNE
		01OCT1995-CONTINUE	-2599	PRIOR/CONCOM	SALBUTAMOL [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
		12NOV2002-15NOV2002	1	CONCOMITANT	LOPERAMIDE HYDROCHLORIDE [ALIMENTARY TRACT AND METABOLISM]	2.00 MG	VIRAL ILLNESS
		15NOV2002-16NOV2002	4	CONCOMITANT	CODEINE PHOSPHATE [RESPIRATORY SYSTEM]	2.00 TSP	VIRAL ILLNESS
		28DEC2002-29DEC2002	47	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	LARYNGITIS
	E0022047	01JAN2000-CONTINUE	-1182	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		03APR2002-CONTINUE	-359	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 PUFFS	ASTHMA
			-359	PRIOR/CONCOM	DESLORATADINE [RESPIRATORY SYSTEM]	1.00 TAB	ALLERGIC RHINITIS
	E0022075	01JAN2000-CONTINUE	-1284	PRIOR/CONCOM	CALCIUM [ALIMENTARY TRACT AND METABOLISM]	1500 MG	OSTEOPOROSIS
			-1284	PRIOR/CONCOM	CHONDROITIN SULFATE [MUSCULO-SKELETAL SYSTEM]	3.00 TABS	HIP PAIN
			-1284	PRIOR/CONCOM	CHONDROITIN SULFATE [MUSCULO-SKELETAL SYSTEM]	3.00 TABS	KNEE PAIN
		01APR2003-CONTINUE	-98	PRIOR/CONCOM	ACTONEL [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	35.00 MG	OSTEOPOROSIS
		11JUN2003-CONTINUE	-27	PRIOR/CONCOM	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	ESOPHAGEAL REFLUX

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PLACEBO (BIPOLAR II)	E0022075	01MAY2003-CONTINUE	-68	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	HIP PAIN
			-68	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	500.0 MG	KNEE PAIN
		01JUN2002-CONTINUE	-402	PRIOR/CONCOM	CETIRIZINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	5.00 MG	ALLERGIC RHINITIS
		01JAN1988-CONTINUE	-5667	PRIOR/CONCOM	BECLOMETASONE DIPROPIONATE [RESPIRATORY SYSTEM]	4.00 SPRAYS	ALLERGIC RHINITIS
			-5667	PRIOR/CONCOM	TOCOPHEROL [ALIMENTARY TRACT AND METABOLISM]	400.0 MG	DRY SKIN
		01JUL2003-25JUL2003	-7	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	DENTAL PAIN
		02JUL2003-25JUL2003	-6	PRIOR/CONCOM	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	12.50 MG	DENTAL PAIN
		07JUL2003-25JUL2003	-1	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	DENTAL PAIN
		21JUL2003-03AUG2003	14	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HIP PAIN
		04AUG2003-05AUG2003	28	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HIP PAIN
		06AUG2003-19AUG2003	30	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1300 MG	HIP PAIN
		06AUG2003-02SEP2003	30	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	HEADACHE
	E0023016	01DEC2000-CONTINUE	-902	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	NECK PAIN

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PLACEBO (BIPOLAR II)	E0023016	01DEC2000-CONTINUE	-902	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	SHOULDER PAIN
	E0023046	01JUL2000-CONTINUE	-1117	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
			-1117	PRIOR/CONCOM	VERAPAMIL [CARDIOVASCULAR SYSTEM]	240.0 MG	HYPERTENSION
		01JUL2001-CONTINUE	-752	PRIOR/CONCOM	METHOTREXATE [ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS]	2.50 MG	RHEUMATOID ARTHRITIS
	E0026027	19JUN2003-CONTINUE	1	CONCOMITANT	PHENYTOIN SODIUM [NERVOUS SYSTEM]	300.0 MG	SEIZURES
	E0029004	01JAN1999-CONTINUE	-1418	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		01JAN1985-CONTINUE	-6531	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1000 MG	HEADACHES
		01OCT2002-CONTINUE	-49	PRIOR/CONCOM	PSEUDOEPHEDRINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	2.00 TABS	SEASONAL ALLERGIES
		01MAY2002-CONTINUE	-202	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	MIGRAINES
		31OCT2002-CONTINUE	-19	PRIOR/CONCOM	LANSOPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	30.00 MG	GERD
		01DEC2002-04DEC2002	13	CONCOMITANT	FLUCONAZOLE [ANTIINFECTIVES FOR SYSTEMIC USE]	400.0 MG	BRONCHITIS
		15OCT2002-CONTINUE	-35	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DIETARY SUPPLEMENT

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PLACEBO (BIPOLAR II)	E0029004	13NOV2002-CONTINUE	-6	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	HEADACHES
		09JAN2003-11JAN2003	52	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	25.00 MG	SEASONAL ALLERGIES
		04DEC2002-10DEC2002	16	CONCOMITANT	ETHANOL [RESPIRATORY SYSTEM]	2.00 TB	BRONCHITIS
		02DEC2002-02DEC2002	14	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		09DEC2002-08JAN2003	21	CONCOMITANT	SULFAMETHOXAZOLE [ANTIINFECTIVES FOR SYSTEMIC USE]	800.0 MG	BRONCHITIS PRN
	E0029013	24FEB2003-24FEB2003	6	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	2.00 TABS	INDIGESTION
		01JUL2001-CONTINUE	-598	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	HEADACHE
		26FEB2003-17MAR2003	8	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	3.00 TABS	HEARTBURN
	E0029019	03MAR2003-CONTINUE	1	CONCOMITANT	LOVASTATIN [CARDIOVASCULAR SYSTEM]	20.00 MG	HYPERCHOLESTEROLEMIA
	E0029024	01MAR2001-CONTINUE	-746	PRIOR/CONCOM	THYROID [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	60.00 MG	HYPOTHYROIDISM
		01MAR1991-CONTINUE	-4399	PRIOR/CONCOM	BORAGE OIL [VARIOUS]	1.00 CAP	DIETARY SUPPLEMENT
			-4399	PRIOR/CONCOM	FISH OIL [CARDIOVASCULAR SYSTEM]	1.00 CAP	DIETARY SUPPLEMENT

* Number of days on study treatment at time of concomitant medication.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/0049/SP/PROG/TLF/MEDS101.SAS
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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0029024	01MAR1991-CONTINUE	-4399	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	DIETARY SUPPLEMENT
		21MAR2003-21MAR2003	5	CONCOMITANT	BISACODYL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	CONSTIPATION
		10APR2003-14APR2003	25	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	6.00 TABS	FLU SYMPTOMS
			25	CONCOMITANT	ECHINACEA EXTRACT [VARIOUS]	2.00 CAPS	FLU SYMPTOMS
	E0031004	01APR2002-CONTINUE	-262	PRIOR/CONCOM	ZALEPLON [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
		01JAN2002-CONTINUE	-352	PRIOR/CONCOM	PANTOPRAZOLE SODIUM [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	GASTROESOPHAGEAL REFLUX DISEASE
			-352	PRIOR/CONCOM	LEVODOPA [NERVOUS SYSTEM]	2050 MG	RESTLESS LEG SYNDROME
		01MAY2000-CONTINUE	-962	PRIOR/CONCOM	FLUTICASONE PROPIONATE [RESPIRATORY SYSTEM]	2.00 SPRAYS	ENVIRONMENTAL ALLERGIES
		04FEB2003-CONTINUE	48	CONCOMITANT	CLAVULANATE POTASSIUM [ANTIINFECTIVES FOR SYSTEMIC USE]	500.0 MG	SINUSITIS
		29DEC2002-CONTINUE	11	CONCOMITANT	NAPROXEN [MUSCULO-SKELETAL SYSTEM]	500.0 MG	LOWER BACK PAIN
		27JAN2003-27JAN2003	40	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	HEADACHE
		31JAN2003-CONTINUE	44	CONCOMITANT	IPRATROPIUM BROMIDE [RESPIRATORY SYSTEM]	2.00 PUFFS	SINUSITIS
			44	CONCOMITANT	NASAL DECONGESTANTS FOR SYSTEMIC USE [RESPIRATORY SYSTEM]	0.50 TAB	SINUSITIS

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0031004	25DEC2002-25DEC2002	7	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	SORE THROAT
		01MAY2002-31JAN2003	-232	PRIOR/CONCOM	DESLORATADINE [RESPIRATORY SYSTEM]	5.00 MG	ENVIRONMENTAL ALLERGIES
		01SEP2002-31JAN2003	-109	PRIOR/CONCOM	MONTELUKAST SODIUM [RESPIRATORY SYSTEM]	10.00 MG	MILD ASTHMA
		21DEC2002-CONTINUE	3	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	LOWER BACK PAIN
		22DEC2002-CONTINUE	4	CONCOMITANT	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	CONTRACEPTIVE THERAPY
		27DEC2002-03JAN2003	9	CONCOMITANT	GUAIFENESIN [RESPIRATORY SYSTEM]	2.00 TBS	UPPER RESPIRATORY INFECTION
		03JAN2003-29JAN2003	16	CONCOMITANT	AZELASTINE HYDROCHLORIDE [RESPIRATORY SYSTEM]	1.00 SPRAY	CONGESTION
		04JAN2003-29JAN2003	17	CONCOMITANT	BENZONATATE [RESPIRATORY SYSTEM]	200.0 MG	UPPER RESPIRATORY INFECTION
		29JAN2003-03FEB2003	42	CONCOMITANT	METHYLPREDNISOLONE [SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS]	6.00 MG	SINUSITIS
		05FEB2003-12FEB2003	49	CONCOMITANT	DEXTROMETHORPHAN HYDROBROMIDE [RESPIRATORY SYSTEM]	10.00 MG	SINUSITIS
	E0031013	01MAR2002-CONTINUE	-377	PRIOR/CONCOM	ESOMEPRAZOLE [ALIMENTARY TRACT AND METABOLISM]	40.00 MG	ACID REFLUX

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0031013	26MAR2003-CONTINUE	14	CONCOMITANT	CALCIUM CARBONATE [ALIMENTARY TRACT AND METABOLISM]	1050 MG	ACID REFLUX
		16DEC2002-CONTINUE	-87	PRIOR/CONCOM	LISINOPRIL [CARDIOVASCULAR SYSTEM]	10.00 MG	HYPERTENSION
		03MAR2003-21MAR2003	-10	PRIOR/CONCOM	BENZONATATE [RESPIRATORY SYSTEM]	200.0 MG	CHRONIC BRONCHITIS
		16MAR2003-CONTINUE	4	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	HEADACHE
	E0031019	01JAN1994-CONTINUE	-3387	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	800.0 MG	SHOULDER PAIN
			-3387	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	650.0 MG	LOWER BACK PAIN
		18APR2003-25APR2003	8	CONCOMITANT	ZOLPIDEM TARTRATE [NERVOUS SYSTEM]	10.00 MG	INSOMNIA
	E0031022	15MAR2003-CONTINUE	-44	PRIOR/CONCOM	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	INTERMITTENT HEADACHES
	E0033007	15JUL2001-17FEB2003	-562	PRIOR/CONCOM	CARISOPRODOL [MUSCULO-SKELETAL SYSTEM]	350.0 MG	ARTHRITIS
			-562	PRIOR/CONCOM	PARACETAMOL [NERVOUS SYSTEM]	1.00 TABLET	ARTHRITIS
		15JUL2001-19FEB2003	-562	PRIOR/CONCOM	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	25.00 MG	ARTHRITIS
		20FEB2003-CONTINUE	24	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	400.0 MG	ARTHRITIS

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0033007	03MAR2003-05MAR2003	35	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	1.00 TABLET	ARTHRITIS
	E0033013	15APR2001-CONTINUE	-675	PRIOR/CONCOM	VITAMINS NOS [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
	E0033016	15JAN2002-CONTINUE	-478	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	1.00 PATCH	BIRTH CONTROL (WEEKLY)
		15MAR1998-08MAY2003	-1880	PRIOR/CONCOM	CALCIUM ASCORBATE [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
			-1880	PRIOR/CONCOM	FISH OIL [CARDIOVASCULAR SYSTEM]	1.00 TAB	PROPHYLAXIS
		15JAN2000-08MAY2003	-1209	PRIOR/CONCOM	IRON [BLOOD AND BLOOD FORMING ORGANS]	1.00 TAB	ANEMIA
			-1209	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		15JAN2002-08MAY2003	-478	PRIOR/CONCOM	ANTIINFLAMMATORY/ANTIRHEUMATIC NON-STEROIDS [MUSCULO-SKELETAL SYSTEM]	1.00 TAB	PROPHYLAXIS
	E0033022	01JUN2002-CONTINUE	-408	PRIOR/CONCOM	ETHINYLESTRADIOL [GENITO URINARY SYSTEM AND SEX HORMONES]	0.03 MG	BIRTH CONTROL
		08AUG2003-14AUG2003	26	CONCOMITANT	CELECOXIB [MUSCULO-SKELETAL SYSTEM]	200.0 MG	KNEE PAIN
	E0034007	01JUL2000-CONTINUE	-1049	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PRN FOR GENERAL HEALTH
		24MAY2003-24MAY2003	9	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	SEASONAL ALLERGIES

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0034007	01JUL1980-CONTINUE	-8354	PRIOR/CONCOM	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TAB	PRN FOR HEADACHES
		20MAY2003-21MAY2003	5	CONCOMITANT	ETHANOL [NERVOUS SYSTEM]	2.00 TBSPS	FLU LIKE SYMPTOMS
		26MAR2003-CONTINUE	-51	PRIOR/CONCOM	ATENOLOL [CARDIOVASCULAR SYSTEM]	50.00 MG	HYPERTENSION
			-51	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
		21MAY2003-24MAY2003	6	CONCOMITANT	PARACETAMOL [NERVOUS SYSTEM]	2.00 TABS	ALLERGIES
		20JUN2003-20JUN2003	36	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	2.00 TABS	SPRAINED NECK MUSCLE
	E0035010	24JAN2003-CONTINUE	15	CONCOMITANT	DIPHENHYDRAMINE HYDROCHLORIDE [DERMATOLOGICALS]	1.00 SPRAY	RASH
		01DEC2000-CONTINUE	-770	PRIOR/CONCOM	VERAPAMIL HYDROCHLORIDE [CARDIOVASCULAR SYSTEM]	240.0 MG	HYPERTENSION
			-770	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	DIURETIC
			-770	PRIOR/CONCOM	POTASSIUM [ALIMENTARY TRACT AND METABOLISM]	600.0 MG	NUTRITIONAL SUPPLEMENT
			-770	PRIOR/CONCOM	ROFECOXIB [MUSCULO-SKELETAL SYSTEM]	50.00 MG	ARTHIRITIS INFLAMMATION
	E0039003	01JAN2002-CONTINUE	-328	PRIOR/CONCOM	FERROUS SULFATE [BLOOD AND BLOOD FORMING ORGANS]	325.0 MG	ANEMIA
		02DEC2002-02DEC2002	8	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	400.0 MG	TOOTHACHE

* Number of days on study treatment at time of concomitant medication.

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Listing 12.2.10.7 Concomitant Medications

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	START DATE-STOP DATE	DAYS*	MED TYPE	MEDICATION GENERIC TERM [MEDICATION CLASSIFICATION]	DOSE	INDICATION
PLACEBO (BIPOLAR II)	E0039003	03DEC2002-03DEC2002	9	CONCOMITANT	IBUPROFEN [MUSCULO-SKELETAL SYSTEM]	600.0 MG	TOOTHACHE
	E0041002	01OCT2002-CONTINUE	-112	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS
		21JAN2003-21JAN2003	1	CONCOMITANT	ACETYLSALICYLIC ACID [NERVOUS SYSTEM]	325.0 MG	HEADACHE
		01JAN2001-13FEB2003	-750	PRIOR/CONCOM	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	25.00 MG	HYPERTENSION
		14FEB2003-CONTINUE	25	CONCOMITANT	HYDROCHLOROTHIAZIDE [CARDIOVASCULAR SYSTEM]	16.00 MG	HYPERTENSION
	E0041005	01JAN1984-CONTINUE	-7003	PRIOR/CONCOM	ERGOCALCIFEROL [ALIMENTARY TRACT AND METABOLISM]	1.00 TAB	PROPHYLAXIS

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Clinical Study Report: Appendix 12.3

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.3
Case report forms

If required by the authority, Appendix 12.3 will be included in the appropriate section of the application

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Clinical Study Report: Appendix 12.4

Drug Substance	Quetiapine fumarate
Study Code	D1447L00001

Appendix 12.4
Individual subject data (US archival listings)

If required by the authority, Appendix 12.4 will be included in the appropriate section of the application.